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INFORMATION DISCLOSURE	First Named Inventor Mohan		mmed N. ISLAM	
STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Art Unit			
(Not for Submission under or of it 1.50)	Examiner Name			
	Attorney Docket Number		OMNI 0101 PUSA5	

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Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

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Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-08
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#### **CERTIFICATION STATEMENT**

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imes None

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-08
Name/Print	David S. Bir	Registration Number	38383

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.** 

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#### **CERTIFICATION STATEMENT**

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

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That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

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Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-08
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	33	International Search Report and Written Opinion for International Application No. PCT/US2013/075700 dated April 24, 2014							
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Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-08
Name/Print	David S. Bir	Registration Number	38383

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	2	2005013843	wo	A2	2005-02-17	The Regents of the University of California								
	3	2007061772	wo	A2	2007-05-31	OMNI SCIENCES, INC.								
	4	2009130464	wo	A1	2009-10-29	UNIVERSITY OF MANCHESTER								
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	2	Schulz, I., J. Putzge Danilov, S. Giglberg model for dental pul	er, M. Hirmer, S	.D. Ganichev	, G. Monkman,	Knorzer, K.A. Hiller, S. Loffle 'PPG signal acquisition and a 2012).	er, G. Schmalz, S.N. analysis on in vitro tooth	ו						
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PTO/SB/08a (01-10)
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Mation Disclosure Statement (IDS) Filed
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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	Application Number		
INFORMATION DIGGLOOUSE	Filing Date		
INFORMATION DISCLOSURE	First Named Inventor Mohar		mmed N. ISLAM
STATEMENT BY APPLICANT ( Not for submission under 37 CFR 1.99)	Art Unit		
(Not for submission under or of K 1.55)	Examiner Name		
	Attorney Docket Number	er	OMNI 0101 PUSA5

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) Filing Date First Named Art Unit

Application Number		
Filing Date		
First Named Inventor	Moha	mmed N. ISLAM
Art Unit		
Examiner Name		
Attorney Docket Number	ər	OMNI 0101 PUSA5

Examiner Initials*	Cite No	(book	nclude name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), ublisher, city and/or country where published.									
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First Named Inventor	Moha	mmed N. ISLAM
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Examiner Name		
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Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-08
Name/Print	David S. Bir	Registration Number	38383

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	Application Number			
	Filing Date			
INFORMATION DISCLOSURE	First Named Inventor	Mohai	mmed N. ISLAM	
STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Art Unit			
(Not for submission under or of K 1.55)	Examiner Name			
	Attorney Docket Number	er	OMNI 0101 PUSA5	

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	3		20130327966	A1	2013-12	-12	Fidler et al.					
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	INFORMATION DISCLOSURE				Filing Date							
STATEMENT BY APPLICANT				First N	Named I	nventor	Moh	ammed N. ISLAM				
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Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-08
Name/Print	David S. Bir	Registration Number	38383

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Mation Disclosure Statement (IDS) Filed

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INFORMATION DISCLOSURE	Application Number		
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	First Named Inventor Mohar		ammed N. ISLAM
STATEMENT BY APPLICANT ( Not for submission under 37 CFR 1.99)	Art Unit		
(Not for Submission under or OTK 1.53)	Examiner Name		
	Attorney Docket Number	er	OMNI 0101 PUSA5

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		Application Number				
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INFORMATION DISCLOSURE	First Named Inventor	First Named Inventor Mohammed N. ISLAN				
STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		Art Unit				
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	Attorney Docket Number	er	OMNI 0101 PUSA5	

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	2	2012135952	wo		A1	2012-10-11	The Governing Cour The University Of To				

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Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-08
Name/Print	David S. Bir	Registration Number	38383

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Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-08
Name/Print	David S. Bir	Registration Number	38383

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	3	7648463	В1	2010-01-19	Elhag et al.			
	4	8172761	B1	2012-05-08	Rulkov et al.			
	5	8315682	B2	2012-11-20	Such et al.			
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	2	H. HARRY ASADA ET AL.; Mobile Monitoring With Wearable Photoplethysmographic Biosensors; IEEE Engineering In Medicine And Biology Magazine, June 2003; 13 pps									
	3	UNITED STATES DISTRICT COURT EASTERN DISTRICT OF TEXAS MARSHALL DIVISION; Defendant And Counter Claimant Apple Inc.'s Amended Answer, Affirmative Defenses, And Counterclaims To Complaint Of Plaintiff And Counter Defendant Omni Medsci, Inc.; Document 38; July 19, 2018; 32 pps									
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	3	5795300	Α	1998-08-18	Bryars	
	4	5919134	Α	1999-07-06	Diab	
	5	6031603	Α	2000-02-29	Fine et al	
	6	6325978	B1	2001-12-04	Labuda et al.	
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	8	6708048	B1	2004-03-16	Chance	

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11	7184148	B2	2007-02-27	Alphonse	
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13	7468036	B1	2008-12-23	Rulkov et al.	
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22	8945017	B2	2015-02-03	Venkatraman et al.	
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24	9142117	B2	2015-09-22	Muhsin et al.	
25	9179876	B2	2015-11-10	Ochs et al.	
26	9192329	B2	2015-11-24	Al-Ali	
27	9241676	B2	2016-01-26	Lisogurski et al.	
28	9596990	B2	2017-03-21	Park et al.	
29	9651533	B2	2017-05-16	Islam	
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	31	9757040	B2	2017-09-12	Islam			
	32	9820658	B2	2017-11-21	Tran			
	33	9861286	B1	2018-01-09	Islam			
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	35	RE44875	E	2014-04-29	Kiani et al.			
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	1	20050049468	A1	2005-03-03	Carlson et al.			
	2	20050209516	A1	2005-09-22	Fraden			
	3	20110237911	A1	2011-09-29	Lamego et al.			_
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	5		20120310062	A1	2012-12	2-06	Li et al.					
	6		20130303921	A1	2013-11	-14	CHU et al.					
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	1	200	2005 <b>270</b> 544 JP		A	2005-10-06	Seiko Instruments I	nc.				
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	1		OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit A), 66 pps									
	2		OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit B), 73 pps									
	3		OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit C), 85 pps									
	4		NI MEDSCI, INC. V. / just 28, 2018 (Exhibit			e No. 2:	18-cv-134-RWS	(E.D. Tex.); Defenda	ant's Inv	alidity Cont	entions,	
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5	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit E), 120 pps	
6	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit F), 40 pps	
7	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit G), 66 pps	
8	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit H), 74 pps	
9	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit I), 102 pps	
10	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit J), 64 pps	
11	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit K), 77 pps	
12	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit L), 64 pps	
13	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit M), 119 pps	
14	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit N), 50 pps	
15	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit O), 63 pps	

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16	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit P), 78 pps	
17	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit Q), 69 pps	
18	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit R), 61 pps	
19	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit S), 50 pps	
20	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit T), 174 pps	
21	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit U), 334 pps	
22	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit V), 137 pps	
23	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit W), 384 pps	
24	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit X), 291 pps	
25	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit Y), 120 pps	
26	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit Z), 53 pps	

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27		OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit AA), 75 pps	
28		OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit BB), 65 pps	
29		OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit CC), 320 pps	
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See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

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## **SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-08
Name/Print	David S. Bir	Registration Number	38383

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Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-08
Name/Print	David S. Bir	Registration Number	38383

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- 7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
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STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Art Unit			
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	1	5746206	A	1998-05-05	Mannheimer				
	2	6505133	B1	2003-01-07	Hanna et al.				
	3	8172761	B1	2012-05-08	Rulkov et al.				
	4	9241676	B2	2016-01-26	Lisogurski et al.				
	5	9596990	B2	2017-03-21	Park et al.				
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	1	20050049468	A1	2005-03-03	Carlson et al.				

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	2	20100217099	A1	2010-08	3-26	LeBoeuf et al.				
	3	20120197093	A1	2012-08	3-02	LeBoeuf et al.				
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	2		Inter Partes Review No. IPR2019-00911; Petition for Inter Partes Review of U.S. Patent No. 9,861,286; Apple Inc. v. OMNI MEDSCI, INC.; pps. 1-83; dated April 10, 2019							
	3		Inter Partes Review No. IPR2019-00912; Petition for Inter Partes Review of U.S. Patent No. 9,885,698; Apple Inc. v. OMNI MEDSCI, INC.; pps. 1-94; dated April 10, 2019							
	4	nter Partes Review No. IPR2019-00913; Petition for Inter Partes Review of U.S. Patent No. 9,651,533; Apple Inc. v. DMNI MEDSCI, INC.; pps. 1-96; dated April 10, 2019								

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	5	Inter Partes Review No. IPR2019-00914; Petition for Inter Partes Review of U.S. Patent No. 9,861,286; Apple Inc. v. OMNI MEDSCI, INC.; pps. 1-90; dated April 10, 2019					
	6	Inter Partes Review No. IPR2019-00915; Petition for Inter Partes Review of U.S. Patent No. 9,885,698; Apple Inc. v. OMNI MEDSCI, INC.; pps. 1-91; dated April 10, 2019					
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	8	Inter Partes Review No. IPR2019-00917; Petition for Inter Partes Review of U.S. Patent No. 9,757,040; Apple Inc. v. OMNI MEDSCI, INC.; pps. 1-93; dated April 10, 2019					
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Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

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See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

X A certification statement is not submitted herewith.

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Name/Print	David S. Bir	Registration Number	38383

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	1	5084880		1992-01-28	Esterowitz, et al.	
	2	5180378		1993-01-19	Kung, et al.	
	3	5400165		1995-03-21	Gnauck, et al.	
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	5	5617871		1997-04-08	Burrows	
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First Named Inventor Moha		mmed N. ISLAM
Art Unit		
Examiner Name		
Attorney Docket Number		OMNI 0101 PUSA5

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10	5718234	1998-02-17	Warden, et al.	
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Application Number		
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First Named Inventor	Moha	mmed N. ISLAM
Art Unit		
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Attorney Docket Number		OMNI 0101 PUSA5

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32	6659947	2003-12-09	Carter, et al.	
33	6802811	2004-10-12	Slepian	
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Application Number		
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Attorney Docket Number		OMNI 0101 PUSA5

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51	8472108	2013-06-25	Islam					
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	1	200189362	WO	wo		2001-11-29	West Kenneth G et	al.			

Application Number		
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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.							
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Application Number		
Filing Date		
First Named Inventor	Moha	mmed N. ISLAM
Art Unit		
Examiner Name		
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after making reasonable inquiry, no item of information contained in the information disclosure statement was known to
any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure
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See attached certification statement.

Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

✓ None

### **SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-08
Name/Print	David S. Bir	Registration Number	38383

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INFORMATION DIGGLOOUSE	Filing Date		
INFORMATION DISCLOSURE	First Named Inventor	Mohar	mmed N. ISLAM
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	Attorney Docket Number	er	OMNI 0101 PUSA5

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Application Number		
Filing Date		
First Named Inventor	Moha	mmed N. ISLAM
Art Unit		
Examiner Name		
Attorney Docket Number		OMNI 0101 PUSA5

	1	NELLCOR; Charts 1-3: NELLCOR-533; U.S. Patent No. 9,651,533 vs. Nellcor; Omni MedSci, Inc. v. Apple Inc., pps. 1-155; May 22, 2019									
	2	LISOGURSKI; Charts 1-3: LISOGURSKI-533; U.S. Patent No. 9,651,533 vs. Lisogurski; Omni MedSci, Inc. v. Apple Inc., pps. 1-84; May 22, 2019									
		ASADA; Charts 1-3: ASADA-533; U.S. Patent No. 9,651,533 vs. Asada; Omni MedSci, Inc. v. Apple Inc., pps. 1-188; May 22, 2019									
		PARK; Charts 1-3: Park-533; U.S. Patent No. 9,651,533 vs. Park; Omni MedSci, Inc. v. Apple Inc., pps. 1-171; May 22, 2019									
		VALENCELL; Charts 1-3: Valencell-533; U.S. Patent No. 9,651,533 vs. Valencell; Omni MedSci, Inc. v. Apple Inc., pps. 1-122; May 22, 2019									
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INFORMATION DIGGLOOUSE	Filing Date			
INFORMATION DISCLOSURE	First Named Inventor Mohan		ammed N. ISLAM	
STATEMENT BY APPLICANT ( Not for submission under 37 CFR 1.99)	Art Unit			
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	Attorney Docket Number	er	OMNI 0101 PUSA5	

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Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4972331		1990-11-20	Chance	
	2	5774213	Α	1998-06-30	Trebino et al.	
	3	5855550	А	1999-01-05	Lai et al.	
	4	6044283	А	2000-03-28	Fein et al.	
	5	6898451	B2	2005-05-24	Wuori	
	6	7278966	B2	2007-10-09	Hjelt et al.	
	7	9651533	B2	2017-05-16	Islam	
	8	9757040	B2	2017-09-12	Islam	

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) 9 9861286 Application Number Filing Date First Named Inventor Mohammed N. ISLAM Art Unit Examiner Name Attorney Docket Number OMNI 0101 PUSA5

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		Declaration of Brian W. Anthony, PhD regarding USPN 9,651,533 filed in IPR2019-00913 & IPR2019-00916 (April 10, 2019)										
	2		Declaration of Brian W. Anthony, PhD regarding USPN 9,757,040 filed in IPR2019-00910 & IPR2019-00917 (April 10, 2019)									

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3	Declaration of Brian W. Anthony, PhD regarding USPN 9,861,286 filed in IPR2019-00911 & IPR2019-00914 (April 10, 2019)	
4	Declaration of Brian W. Anthony, PhD regarding USPN 9,885,698 filed in IPR2019-00912 & IPR2019-00915 (April 10, 2019)	
5	Proof of Service of Summons in Omni MedSci, Inc. v. Apple Inc., No. 2:18-cv-134 (E.D. Tex.) (Dkt. #12) (April 13, 2018)	
6	J.S. Provisional Application No. 61/747,487 filed December 31, 2012	
7	J.S. Provisional Application No. 61/747,472 filed December 31, 2012	
8	J.S. Provisional Application No. 61/747,477 filed December 31, 2012	
9	J.S. Provisional Application No. 61/754,698 filed January 21, 2013	
10	JOSEPH D. BRONZINO; "The Biomedical Engineering Handbook", (1995)	
11	M. KRANTZ, ET AL., The mobile fitness coach: Towards individualized skill assessment using personalized mobile devices, Pervasive and Mobile Computing (June 2012)	
12	S. PATEL, ET AL., A review of wearable sensors and systems with application rehabilitation, Journal of Neuroengineering & Rehabilitation 2012 9:21	
13	ScienceDirect Report on M. KRANTZ, ET AL., The mobile fitness coach: Towards individualized skill assessment using personalized mobile devices, Pervasive and Mobile Computing (2012), available at https://www.sciencedirect.com/science/article/pii/S1574119212000673?via%3Dihub (2018 Elsevier B.V.)	

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15	A. OMRE, Bluetooth Low Energy: Wireless Connectivity for Medical Monitoring, Journal of Diabetes Science & Technology , Vol. 4, Issue 2 (March 2010)	
16	'Absorption Coefficient and Penetration Depth," The Science of Solar, available at https://photon.libretexts.org/ The_Science_of_Solar/Solar_Basics/CSemiconductors_and_Solar_Interactions/IIIAbsorption_of_Light_and_Generation/1Absorption_Coefficient_and_Penetration_Depth (Last Updated Nov. 3, 2018)	
17	F. BUTTUSSI, ET AL., MOPET: A context-aware and user-adaptive wearable system for fitness training, Artificial Intelligence in Medicine (2008) 42, 153-163	
18	P. BAUM ET AL., Strategic Intelligence Monitor on Personal Health Systems, Phase 2: Market Developments - Remote Patient Monitoring and Treatment, Telecare, Fitness/Wellness and mHealth, JRC Scientific and Policy Reports of European Commission (2013)	
19	'Compendium of Chemical Terminology Gold Book," International Union of Pure and Applied Chemistry, Version 2.3.3 (2014-02-24)	
20	M. SWAN, Sensor Mania! The Internet of Things, Wearable Computing, Objective Metrics, and the Quantified Self 2.0, Journal of Sensor and Actuator Networks (2012)	
21	Excerpts from Merriam-Webster's Collegiate Dictionary Eleventh Edition (2011)	
22	T. LISTER ET AL., Optical properties of human skin, Journal of Biomedical Optics (Sept. 2012)	
23	A. BASHKATOV ET AL., Optical properties of human skin, subcutaneous and mucous tissues in the wavelength range from 400 to 2000 nm, Journal of Physics D: Applied Physics 38 (2005) 2543-2555	
24	E.F. SCHUBERT, Light-Emitting Diodes (Cambridge Univ. Press, 2nd ed. Reprinted 2014)	

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25	BAROLET, DANIEL, Light-Emitting Diodes (LEDs) in Dermatology, Seminars in Cutaneous Medicine and Surgery 27:227-238 (2008)	
26	Omni MedSci Inc.'s Opening Claim Construction Brief filed in Case No. 2:18-cv-134-RWS (Dkt. #85) (Dec. 20, 2018)	
27	Apple Inc.'s Preliminary Claim Constructions and Extrinsic Evidence Pursuant to Patent Local Rule 4-2 served in Case No. 2:18-cv-134-RWS (Nov. 1, 2018)	
28	Excerpts from the American Heritage Dictionary, 5th Edition (July 2012)	
29	Curriculum Vitae of Brian W. Anthony, PhD (Nov. 18, 2018)	
30	Amended Joint Claim Construction and Prehearing Statement filed in Case No. 2:18-cv-134-RWS (Dkt. #102) (Jan. 11, 2019)	
31	Excerpt from Claim Construction Markman Hearing Transcript filed in Case No. 2:18-cv-134-RWS (Feb. 6, 2019) Vol. 1, pgs. 1, 2, 21, 22	
32	Dr. MOHAMMED ISLAM, Faculty Profile, University of Michigan, College of Engineering (available at https://islam. engin.umich.edu) (2019 The Regents of the University of Michigan)	
33	Technology Transfer Policy, Office of Technology Transfer - University of Michigan (available at https://techtransfer. umich.edu/for-inventors/policies/technology-transfer-policy/) (revision effective June 1, 2009)	
34	The Bylaws of the University of Michigan Board of Regents, (available at http://www.regents.umich.edu/bylaws/ bylawsrevised_09-18.pdf) (last updated Sept. 20, 2018)	
35	District Court Preliminary Claim Constructions in Case No. 2:18-cv-134-RWS (received February 6, 2019) from Court at Markman hearing	

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) Application Number Filing Date First Named Inventor Mohammed N. ISLAM Art Unit Examiner Name Attorney Docket Number OMNI 0101 PUSA5

	36	File History for U.S. Patent No. 9,651,533 issued May 16, 2017								
	37	File Hi	File History for U.S. Patent No. 9,757,040 issued September 12, 2017							
	38	File History for U.S. Patent No. 9,861,286 issued January 9, 2018								
	39	File History for U.S. Patent No. 9,885,698 issued February 6, 2018								
If you wisl	h to ad	d addi	itional non-patent literature document citation information p	lease click the Add b	utton Add					
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Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-08
Name/Print	David S. Bir	Registration Number	38383

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See attached certification statement.

Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

× None

#### **SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-08
Name/Print	David S. Bir	Registration Number	38383

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;	U.S. Appln. Serial No. 12/206432, "System and Method for Voice Control of Medical Devices," by Mohammed N. Islam, pending (074036.0154) Date filed: September 8, 2008
;	U.S. Patent and Trademark Office, Office Action for USSN 12/206,432, filed 09/08/2008, Mohammed N, Islam, Attorney Docket No. 074036.0154, Date filed: March 12, 2009
;	U.S. Patent and Trademark Office, Notice of Allowance and Fee(s) Due for USSN 12/206,432, filed 09/08/2008, Mohammed N. Islam, Attorney Docket No. 074036.0154, Date filed: August 28, 2009
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Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-08
Name/Print	David S. Bir	Registration Number	38383

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- 7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
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Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-08
Name/Print	David S. Bir	Registration Number	38383

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	1	20070021670	A1	2007-01	-25	Mandelis et al.				
	2	20110282167	A1	2011-11	-17	Ridder et al.				
	3	20120239013	A1	2012-09	-20	Islam				
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Examiner Initial*		Foreign Document Number <sup>3</sup>	Country Code <sup>2</sup> i	′	Kind Code <sup>4</sup>	Publication Date	Name of Patentee Applicant of cited Document	e or V	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	

		Application Number							
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		TON DISCLOSURE	First Named Inventor	Moha	mmed N. ISLAM				
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	1	International Search Report and W 2014	∕ritten Opinion for Internatio	nal Ap <sub>l</sub>	plication No. PCT/US2013	3/075736	dated	April 7,	
	2	International Preliminary Report or 2015	n Patentability for Internatio	nal App	olication No. PCT/US2013	/075736	dated	July 9,	
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<sup>1</sup> See Kind Codes of USPTO Patent Documents at <u>www.USPTO.GOV</u> or MPEP 901.04. <sup>2</sup> Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>3</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark here if English language translation is attached.

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Application Number		
Filing Date		
First Named Inventor	Moha	mmed N. ISLAM
Art Unit		
Examiner Name		
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Name/Print	David S. Bir	Registration Number	38383

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- 9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Doc code: IDS Doc description: Information Disclosure Statement (IDS) Filed

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INFORMATION DIOCE COURT	Filing Date			
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STATEMENT BY APPLICANT ( Not for submission under 37 CFR 1.99)	Art Unit			
(Not for submission under or of K 1.33)	Examiner Name			
	Attorney Docket Number		OMNI 0101 PUSA5	

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Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	Name of Patentee or Applicant of cited Document	Releva	Columns,Lines where nt Passages or Relevant s Appear
	1	7318909	B2	2008-01-15	Lehmann et al.		
	2	8180422	B2	2012-05-15	Rebec		
	3	9207121	B2	2015-12-08	Adler		
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	1	20030107739	A1	2003-06-12	Lehmann et al.		
	2	20030109055	A1	2003-06-12	Lehmann et al.		
	3	20030152307	A1	2003-08-14	Drasek et al.		

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) Application Number Filing Date First Named Inventor Mohammed N. ISLAM Art Unit Examiner Name Attorney Docket Number OMNI 0101 PUSA5

		1	<u> </u>		ı		ir .					
	4		20050133691	A1	2005-06	5-23	Doppke et al.					
	5		20060283931	A1	2006-12	2-21	Polli et al.					
	6 20110267688 A1 2011-11-03 KI		Kleppe et al.									
	7		20130327966	A1	2013-12	2-12	Fidler et al.					
	8		20140078510	A1	2014-03	3-20	Rubio Guivern	au et al.				
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	1	200	5013843	wo		A2	2005-02-17	The Regents of the University of California				
	2	200	7061772	wo		A2	2007-05-31	OMNI SCIENCES,	INC.			
	3	200	2009130464 WO		wo		2009-10-29	UNIVERSITY OF MANCHESTER				
	4	102	010012987	DE		A1	2010-10-07	FRAUNHOFER GE FORSCHUNG	S			
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	1		ROBERT S. JONES ET AL.; Near-Infrared Transillumination At 1310-nm For The Imaging Of Early Dental Decay; Volume 11, No. 18; Optics Express 2259; September 8, 2003							
	2	Extend	Extended European Search Report for European Application No. 13867892.5 dated July 22, 2016							
	3	Extend	Extended European Search Report for European Application No. 13867874.3 dated July 15, 2016							
	4	VINAY V. ALEXANDER ET AL.; Modulation Instability High Power All-Fiber Supercontinuum Lasers And Their Applications; Optical Fiber Technology 18; 2012; pages 349-374								
	5	Final (	Office Action dated October 21, 2016 for U.S. Application No. 14/875,709							
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Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-08
Name/Print	David S. Bir	Registration Number	38383

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INFORMATION DISCLOSURE	First Named Inventor Mohamme		mmed N. ISLAM
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Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	of sited Decument		Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	
	1	5795300	A	1998-08-18	Bryars			
	2	6731967	B1	2004-05-04	Turcott			
	3	7648463	В1	2010-01-19	Elhag et al.			
	4	8172761	B1	2012-05-08	Rulkov et al.			
	5	8315682	B2	2012-11-20	Such et al.			
	6	8954135	B2	2015-02-10	Yuen et al.			
	7	9241676	B2	2016-01-26	Lisogurski et al.			
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	1		20050049468	A1	2005-03	i- <b>0</b> 3	Carlson et al.						
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	1	J.G. WEBSTER; Design Of Pulse Oximeters; Medical Science Series; Taylor & Francis Group; CRC Press; October 23, 1997; 260 pps											
	2	H. HARRY ASADA ET AL.; Mobile Monitoring With Wearable Photoplethysmographic Biosensors; IEEE Engineering In Medicine And Biology Magazine, June 2003; 13 pps											
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- 7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
- 8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
- 9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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	First Named Inventor Moham		mmed N. ISLAM
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Application Number					
Filing Date					
First Named Inventor	Inventor Mohammed N. ISLAM				
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Attorney Docket Number		OMNI 0101 PUSA5			

	1	LI et al, A Wireless Reflective Pulse Oximeter with Digital Baseline Control for Unfiltered Photoplethysmograms, (June 2012) IEEE Transactions on Biomedical Circuits and Systems, Vol. 6, No. 3, 10 pages.										:			
	2	HUMPHREYS et al., Noncontact Simultaneous Dual Wavelength Photoplethysmography: A Further Step Toward Noncontact Pulse Oximetry, (2007) Review of Scientific Instruments 78, 044304, American Institute of Physics, 6 pages.													
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	4	UNITED STATES DISTRICT COURT EASTERN DISTRICT OF TEXAS MARSHALL DIVISION; Omni Medsci, Inc. vs. Apple Inc.; Civil Action No. 2:18-cv-00134 Jury Trial Demanded; Defendant's Invalidity Contentions; August 28, 2018; 33 pps													
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#### **CERTIFICATION STATEMENT**

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

#### OR

That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

X A certification statement is not submitted herewith.

#### **SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-08
Name/Print	David S. Bir	Registration Number	38383

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.** 

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The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

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- 3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
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- 5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
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STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Art Unit		
(Not lot submission under of office 1.50)	Examiner Name		
	Attorney Docket Number	er	OMNI 0101 PUSA5

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Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5368224	Α	1994-11-29	Richardson et al.	
	2	5746206	Α	1998-05-05	Mannheimer	
	3	5795300	Α	1998-08-18	Bryars	
	4	5919134	Α	1999-07-06	Diab	
	5	6031603	Α	2000-02-29	Fine et al	
	6	6325978	B1	2001-12-04	Labuda et al.	
	7	6701170	B2	2004-03-02	Stetson	
	8	6708048	B1	2004-03-16	Chance	

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Attorney Docket Number		OMNI 0101 PUSA5

9	6731967	B1	2004-05-04	Turcott	
10	6916096	B2	2005-07-12	Eberl et al.	
11	7184148	B2	2007-02-27	Alphonse	
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14	7648463	B1	2010-01-19	Elhag et al.	
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16	8180591	B2	2012-05-15	Yuen et al.	
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Attorney Docket Number		OMNI 0101 PUSA5

20	8475367	B1	2013-07-02	Yuen et al.	
21	8755871	B2	2014-06-17	Weng et al.	
22	8945017	B2	2015-02-03	Venkatraman et al.	
23	8954135	B2	2015-02-10	Yuen et al.	
24	9142117	B2	2015-09-22	Muhsin et al.	
25	9179876	B2	2015-11-10	Ochs et al.	
26	9192329	B2	2015-11-24	Al-Ali	
27	9241676	B2	2016-01-26	Lisogurski et al.	
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29	9651533	B2	2017-05-16	Islam	
30	9675250	B2	2017-06-13	Tverskoy	

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	31	9757040	B2	2017-09-12	Islam			
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	33	9861286	B1	2018-01-09	Islam			
	34	9885698		2018-02-06	Islam			
	35 RE44875		E	2014-04-29	Kiani et al.			
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	1	20050049468	A1	2005-03-03	Carlson et al.			
	2	20050209516	A1	2005-09-22	Fraden			
	3	20110237911	A1	2011-09-29	Lamego et al.			
	4	20120203077	A1	2012-08-09	He et al.			

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	5		20120310062	A1	2012-12	?- <b>0</b> 6	Li et al.					
	6		20130303921	A1	2013-11	-14	CHU et al.					
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	1	2005	5270544	JP		Α	2005-10-06	Seiko Instruments I	nc.			
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	1		NI MEDSCI, INC. V. A ust 28, 2018 (Exhibit			e No. 2:	18-cv-134-RWS	(E.D. Tex.); Defenda	ant's Inv	alidity Conto	entions,	
	2	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit B), 73 pps										
	3	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit C), 85 pps										
	4		OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit D), 38 pps									
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Application Number		
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First Named Inventor Mohar		mmed N. ISLAM
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5	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit E), 120 pps	
6	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit F), 40 pps	
7	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit G), 66 pps	
8	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit H), 74 pps	
9	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit I), 102 pps	
10	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit J), 64 pps	
11	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit K), 77 pps	
12	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit L), 64 pps	
13	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit M), 119 pps	
14	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit N), 50 pps	
15	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit O), 63 pps	

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Filing Date		
First Named Inventor Mohai		mmed N. ISLAM
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16	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit P), 78 pps	
17	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit Q), 69 pps	
18	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit R), 61 pps	
19	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit S), 50 pps	
20	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit T), 174 pps	
21	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit U), 334 pps	
22	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit V), 137 pps	
23	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit W), 384 pps	
24	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit X), 291 pps	
25	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit Y), 120 pps	
26	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit Z), 53 pps	

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First Named Inventor Moha		mmed N. ISLAM
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27	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit AA), 75 pps	
28	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit BB), 65 pps	
29	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit CC), 320 pps	
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First Named Inventor	Moha	mmed N. ISLAM
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Standard S <sup>-1</sup> Kind of do	T.3). <sup>3</sup> F cument l	or Japa by the a	TO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. <sup>2</sup> Enter office that issued the document, by the two-letter code (WIF panese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark him is attached.	ment.					

( Not for submission under 37 CFR 1.99)

Application Number		
Filing Date		
First Named Inventor	Moha	mmed N. ISLAM
Art Unit		
Examiner Name		
Attorney Docket Number		OMNI 0101 PUSA5

#### **CERTIFICATION STATEMENT**

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

#### OR

That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

X A certification statement is not submitted herewith.

#### **SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-08
Name/Print	David S. Bir	Registration Number	38383

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.** 

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- 2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
- 3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
- 4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
- 5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
- 6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
- 7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
- 8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
- 9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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INFORMATION DISCLOSURE	First Named Inventor	Mohar	mmed N. ISLAM
STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Art Unit		
(Notion Submission under or or N 1.00)	Examiner Name		
	Attorney Docket Number		OMNI 0101 PUSA5

	U.S.PATENTS Remove							
Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear		
	1	4972331		1990-11-20	Chance			
	2	5774213	Α	1998-06-30	Trebino et al.			
	3	5855550	Α	1999-01-05	Lai et al.			
	4	6044283	Α	2000-03-28	Fein et al.			
	5	6898451	B2	2005-05-24	Wuori			
	6	7278966	B2	2007-10-09	Hjelt et al.			
	7	9651533	B2	2017-05-16	Islam			
	8	9757040	B2	2017-09-12	Islam			

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	9	9861286	B1	2018-01	-09	Islam					
	10	9885698	B2	2018-02	!- <b>0</b> 6	Islam					
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	1	20120041767	A1	2012-02	!-16	Hoffman et al.					
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		Declaration of Brian W. Anthony, PhD regarding USPN 9,651,533 filed in IPR2019-00913 & IPR2019-00916 (April 10, 2019)									
		Declaration of Brian W. A 2019)	nthony, I	PhD rega	arding U	SPN 9,757,040	filed in IPR2019-009	10 & IPF	R2019-0091	7 (April 10,	

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3	Declaration of Brian W. Anthony, PhD regarding USPN 9,861,286 filed in IPR2019-00911 & IPR2019-00914 (April 10, 2019)	
4	Declaration of Brian W. Anthony, PhD regarding USPN 9,885,698 filed in IPR2019-00912 & IPR2019-00915 (April 10, 2019)	
5	Proof of Service of Summons in Omni MedSci, Inc. v. Apple Inc., No. 2:18-cv-134 (E.D. Tex.) (Dkt. #12) (April 13, 2018)	
6	U.S. Provisional Application No. 61/747,487 filed December 31, 2012	
7	U.S. Provisional Application No. 61/747,472 filed December 31, 2012	
8	J.S. Provisional Application No. 61/747,477 filed December 31, 2012	
9	J.S. Provisional Application No. 61/754,698 filed January 21, 2013	
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13	ScienceDirect Report on M. KRANTZ, ET AL., The mobile fitness coach: Towards individualized skill assessment using personalized mobile devices, Pervasive and Mobile Computing (2012), available at https://www.sciencedirect.com/science/article/pii/S1574119212000673?via%3Dihub (2018 Elsevier B.V.)	

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15	A. OMRE, Bluetooth Low Energy: Wireless Connectivity for Medical Monitoring, Journal of Diabetes Science & Technology , Vol. 4, Issue 2 (March 2010)	
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23	A. BASHKATOV ET AL., Optical properties of human skin, subcutaneous and mucous tissues in the wavelength range from 400 to 2000 nm, Journal of Physics D: Applied Physics 38 (2005) 2543-2555	
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26	Omni MedSci Inc.'s Opening Claim Construction Brief filed in Case No. 2:18-cv-134-RWS (Dkt. #85) (Dec. 20, 2018)	
27	Apple Inc.'s Preliminary Claim Constructions and Extrinsic Evidence Pursuant to Patent Local Rule 4-2 served in Case No. 2:18-cv-134-RWS (Nov. 1, 2018)	
28	Excerpts from the American Heritage Dictionary, 5th Edition (July 2012)	
29	Curriculum Vitae of Brian W. Anthony, PhD (Nov. 18, 2018)	
30	Amended Joint Claim Construction and Prehearing Statement filed in Case No. 2:18-cv-134-RWS (Dkt. #102) (Jan. 11, 2019)	
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33	Technology Transfer Policy, Office of Technology Transfer - University of Michigan (available at https://techtransfer. umich.edu/for-inventors/policies/technology-transfer-policy/) (revision effective June 1, 2009)	
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35	District Court Preliminary Claim Constructions in Case No. 2:18-cv-134-RWS (received February 6, 2019) from Court at Markman hearing	

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) Application Number Filing Date First Named Inventor Mohammed N. ISLAM Art Unit Examiner Name Attorney Docket Number OMNI 0101 PUSA5

	36	File Hi	e History for U.S. Patent No. 9,651,533 issued May 16, 2017						
	37	File Hi	y for U.S. Patent No. 9,757,040 issued September 12, 2017						
	38 File History for U.S. Patent No. 9,861,286 issued January 9, 2018								
	39	File Hi	e History for U.S. Patent No. 9,885,698 issued February 6, 2018						
If you wish	n to ad	d addi	itional non-patent literature document citation information p	lease click the Add b	utton Add				
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#### **CERTIFICATION STATEMENT**

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See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

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#### **SIGNATURE**

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Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-08
Name/Print	David S. Bir	Registration Number	38383

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Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	of cited Document Relevan			ines where es or Relevant	
	1	5746206	A	1998-05-05	Mannheimer				
	2	6505133	B1	2003-01-07	Hanna et al.				
	3	8172761	B1	2012-05-08	Rulkov et al.				
	4	9241676	B2	2016-01-26	Lisogurski et al.				
	5	9596990	B2	2017-03-21	Park et al.				
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	1	20050049468	A1	2005-03-03	Carlson et al.				

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	2	20100217099	A1	2010-08	3-26	LeBoeuf et al.					
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	1		Inter Partes Review No. IPR2019-00910; Petition for Inter Partes Review of U.S. Patent No. 9,757,040; Apple Inc. v. OMNI MEDSCI, INC.; pps. 1-96; dated April 10, 2019								
	2	Inter Partes Review No. IPR2019-00911; Petition for Inter Partes Review of U.S. Patent No. 9,861,286; Apple Inc. v. OMNI MEDSCI, INC.; pps. 1-83; dated April 10, 2019									
	3	Inter Partes Review No. IPR2019-00912; Petition for Inter Partes Review of U.S. Patent No. 9,885,698; Apple Inc. v. OMNI MEDSCI, INC.; pps. 1-94; dated April 10, 2019									
	4	Inter Partes Review No. IPR2019-00913; Petition for Inter Partes Review of U.S. Patent No. 9,651,533; Apple Inc. v. OMNI MEDSCI, INC.; pps. 1-96; dated April 10, 2019									

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Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

#### OR

That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

X A certification statement is not submitted herewith.

#### **SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-08
Name/Print	David S. Bir	Registration Number	38383

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See attached certification statement.

Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

✓ None

## **SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-08
Name/Print	David S. Bir	Registration Number	38383

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See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

X A certification statement is not submitted herewith.

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Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-08
Name/Print	David S. Bir	Registration Number	38383

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Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-08
Name/Print	David S. Bir	Registration Number	38383

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	Application Number		
	Filing Date		
INFORMATION DISCLOSURE	First Named Inventor	Mohai	mmed N. ISLAM
STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Art Unit		
(Not for submission under or of K 1.55)	Examiner Name		
	Attorney Docket Number	er	OMNI 0101 PUSA5

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	1	8198589	B2	2012-06	i-12	Tolton, et al.			
	2	6509566	B1	2003-01	-21	Wamsley, et al.	-		
	3	8472108		2013-06	-25	Islam			
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	1	20130274569		2013-10	)-17	Islam			
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	1	CA 2 458 123	CA			2012-05-15	Tolton, et al.		

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	1	WATARI, M., H. MIGASHIYAMA, N. MITSUI, M. TOMO, Y. OZAKI, "On-line monitoring of the density of linear low-density polyethylene in a real plant by near-infrared spectroscopy and chemometrics," Applied Spectroscopy, vol. 58, no. 2, pp. 248-255 (2004)					
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That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

X A certification statement is not submitted herewith.

#### **SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-08
Name/Print	David S. Bir	Registration Number	38383

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- 3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
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- 6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
- 7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
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- 9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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	1	7318909	B2	2008-01-15	Lehmann et al.		
	2	8180422	B2	2012-05-15	Rebec		
Initial* No Patent Number Code1 Issue Date of cited Document  1 7318909 B2 2008-01-15 Lehmann et al.  2 8180422 B2 2012-05-15 Rebec  3 9207121 B2 2015-12-08 Adler  If you wish to add additional U.S. Patent citation information please click the Add button.  U.S.PATENT APPLICATION PUBLICATIONS  Examiner Initial* Cite No Number Kind Code1 Date Name of Patentee or Application of cited Document  1 20030107739 A1 2003-06-12 Lehmann et al.  2 20030109055 A1 2003-06-12 Lehmann et al.  If you wish to add additional U.S. Published Application citation information please click the		Adler					
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	1	102010012987	DE	A1	2010-10-07	FRAUNHOFER GES FORSCHUNG				
	2	2005013843	wo	A2	2005-02-17	The Regents of the University of California				
	3	2007061772	wo	A2	2007-05-31	OMNI SCIENCES, INC.				
	4	2009130464	wo	A1	2009-10-29	UNIVERSITY OF MANCHESTER				
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Application Number		
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First Named Inventor	Moha	mmed N. ISLAM
Art Unit		
Examiner Name		
Attorney Docket Numb	er	OMNI 0101 PUSA5

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See attached certification statement.

Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

imes None

#### **SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-08
Name/Print	David S. Bir	Registration Number	38383

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- 7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
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Name/Print	David S. Bir	Registration Number	38383

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	2	6281471	B1	2001-08-28	SMART			
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	1	STEPANIAN, ROBERT H., "The Comparative Performance of Mobile Telemedical Systems based on the IS-54 and GSM Cellular Telephone Standards"; Journal of Telemedicine and Telecare 1999; pp 97-104											
	ARIS, ISHAK BIN, "An Internet-Based Blood Pressure Monitoring System for Patients"; Journal of Telemedicine and Telecare 2001; pp 51-53.												
If you wis	h to ac	d additional no	n-paten	t literatur	e docui	ment cit	ation inform	atior	n please click the	Add b	utton Ad	d	
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<sup>1</sup> See Kind Codes of USPTO Patent Documents at <u>www.USPTO.GOV</u> or MPEP 901.04. <sup>2</sup> Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>3</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark here if

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English language translation is attached.

( Not for submission under 37 CFR 1.99)

Application Number		
Filing Date		
First Named Inventor	Moha	mmed N. ISLAM
Art Unit		
Examiner Name		
Attorney Docket Number		OMNI 0101 PUSA5

#### **CERTIFICATION STATEMENT**

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

#### OR

That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

X A certification statement is not submitted herewith.

#### **SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-08
Name/Print	David S. Bir	Registration Number	38383

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.** 

#### **Privacy Act Statement**

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The information provided by you in this form will be subject to the following routine uses:

- 1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.
- 2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
- 3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
- 4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
- 5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
- 6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
- 7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
- 8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
- 9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Doc code: IDS Doc description: Information Disclosure Statement (IDS) Filed PTO/SB/08a (01-10)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		
	Filing Date		
	First Named Inventor Mohammed		mmed N. ISLAM
	Art Unit		
	Examiner Name		
	Attorney Docket Number	er	OMNI 0101 PUSA5

				U.S.	PATENTS	Remove
Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5084880		1992-01-28	Esterowitz, et al.	
	2	5180378		1993-01-19	Kung, et al.	
	3	5400165		1995-03-21	Gnauck, et al.	
	4	5458122		1995-10-17	Hethuin	
	5	5617871		1997-04-08	Burrows	
	6	5631758		1997-05-20	Knox, et al.	
	7	5687734		1997-11-18	Dempsey, et al.	
	8	5696778		1997-12-09	MacPherson	

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Filing Date		
First Named Inventor	Moha	mmed N. ISLAM
Art Unit		
Examiner Name		
Attorney Docket Number		OMNI 0101 PUSA5

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9	5704351	1998-01-06	Mortara, et al.	
10	5718234	1998-02-17	Warden, et al.	
11	5748103	1998-05-05	Flach, et al.	
12	5855550	1999-01-05	Lai, et al.	
13	5862803	1999-01-26	Besson, et al.	
14	5867305	1999-02-02	Waarts, et al.	
15	5912749	1999-06-15	Harstead, et al.	
16	5944659	1999-08-31	Flach, et al.	
17	5957854	1999-09-28	Besson, et al.	
18	6014249	2000-01-11	Fermann, et al.	
19	6043927	2000-03-28	Islam	

Application Number		
Filing Date		
First Named Inventor	Moha	mmed N. ISLAM
Art Unit		
Examiner Name		
Attorney Docket Number		OMNI 0101 PUSA5

20	6289238	2001-09-11	Besson, et al.	
21	6333803	2001-12-25	Kurotori, et al.	
22	6364834	2002-04-02	Reuss, et al.	
23	6381391	2002-04-30	Islam, et al.	
24	6402691	2002-06-11	Peddicord, et al.	
25	6407853	2002-06-18	Samson, et al.	
26	6441747	2002-08-27	Khair, et al.	
27	6443890	2002-09-03	Schulze, et al.	
28	6454705	2002-09-24	Cosentino, et al.	
29	6480656	2002-11-12	Islam, et al.	
30	6549702	2003-04-15	Islam, et al.	

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) Application Number Filing Date First Named Inventor Mohammed N. ISLAM Art Unit Examiner Name Attorney Docket Number OMNI 0101 PUSA5

			_				
	31	6603910		2003-08-05	Islam, et al.		
	32	6659947		2003-12-09	Carter, et al.		
	33	6802811		2004-10-12	Slepian		
	34	7167300		2007-01-23	Fermann, et al.		
	35	7209657		2007-04-24	Islam		
	36	7263288		2007-08-28	Islam		
	37	7519253		2009-04-14	Islam		
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Examiner Initial*	Cite No	Publication Number	Kind Code <sup>1</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Releva	Columns,Lines where nt Passages or Relevant Appear
	1	20020013518		2002-01-31	West, Kenneth G. ; et al.		
	2	20020019584		2002-02-14	Schulze, Arthur E. ; et al.		

Application Number		
Filing Date		
First Named Inventor Moha		mmed N. ISLAM
Art Unit		
Examiner Name		
Attorney Docket Number		OMNI 0101 PUSA5

3	20020032468	2002-03-14	Hill, Michael R.S. ; et al.	
4	20020082612	2002-06-27	Moll, Frederic H. ; et al.	
5	20020109621	2002-08-15	Khair, Mohammad ; et al.	
6	20020115914	2002-08-22	Russ, Tomas	
7	20020178003	2002-11-28	Gehrke, James K. ; et al.	
8	20040174914	2004-09-09	Fukatsu, Susumu	
9	20040240037	2004-12-02	Harter, Donald J.	
10	20050111500	2005-05-26	Harter, Donald J. ; et al.	
11	20060245461	2006-11-02	Islam; Mohammed N.	
12	20060268393	2006-11-30	Islam; Mohammed N.	
13	20070078348	2007-04-05	Holman; Hoi-Ying N.	

INFORMATION DISCLOSURE			Filing Date											
					First N	lamed I	nventor	Moh	amm	ed N. ISLAM				
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	14	2	0090028193	,		2009-01-29		slam; Mohammed N.						
	15	2	0090204110		2009-08-13		Islam; Mohammed N.							
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	1	20018	89362	wo			2001-11-29	9	West	t Kenneth G et	al.			
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	3	20022	28123	wo			2002-04-04	4	Whitt	tington Charles	s Lynn			
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**Application Number** 

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Filing Date		
First Named Inventor Moha		mmed N. ISLAM
Art Unit		
Examiner Name		
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( Not for submission under 37 CFR 1.99)

Application Number		
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First Named Inventor	Moha	mmed N. ISLAM
Art Unit		
Examiner Name		
Attorney Docket Number		OMNI 0101 PUSA5

#### **CERTIFICATION STATEMENT**

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statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

✓ None

#### **SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-08
Name/Print	David S. Bir	Registration Number	38383

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.** 

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Doc code: IDS Doc description: Information Disclosure Statement (IDS) Filed PTO/SB/08a (01-10)
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	Application Number			
	Filing Date			
INFORMATION DISCLOSURE	First Named Inventor Mohan		ammed N. ISLAM	
STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Art Unit			
(Notion Submission under or or N 1.00)	Examiner Name			
	Attorney Docket Number	er	OMNI 0101 PUSA5	

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Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4063106		1977-12-13	Ashkin, et al.	
	2	4158750		1979-06-19	Sakoe, et al.	
	3	4221997		1980-09-09	Flemming	
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	5	4374618		1983-02-22	Howard	
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Application Number		
Filing Date		
First Named Inventor Moha		mmed N. ISLAM
Art Unit		
Examiner Name		
Attorney Docket Number	er	OMNI 0101 PUSA5

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9	4523884	1985-06-18	Clement, et al.	
10	4605080	1986-08-12	Lemelson	
11	4641292	1987-02-03	Tunnell, et al.	
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13	4728974	1988-03-01	Nio, et al.	
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15	4776016	1988-10-04	Hansen	
16	4958910	1990-09-25	Taylor, et al.	
17	4989253	1991-01-29	Liang, et al.	
18	5078140	1992-01-07	Kwoh	
19	5084880	1992-01-28	Esterowitz, et al.	

Application Number		
Filing Date		
First Named Inventor	Moha	mmed N. ISLAM
Art Unit		
Examiner Name		
Attorney Docket Number		OMNI 0101 PUSA5

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21	5134620	1992-07-28	Huber	
22	5142930	1992-09-01	Allen, et al.	
23	5180378	1993-01-19	Kung, et al.	
24	5191628	1993-03-02	Byron	
25	5218655	1993-06-08	Mizrahi	
26	5230023	1993-07-20	Nakano	
27	5267256	1993-11-30	Saruwatari, et al.	
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Application Number		
Filing Date		
First Named Inventor	Moha	mmed N. ISLAM
Art Unit		
Examiner Name		
Attorney Docket Number		OMNI 0101 PUSA5

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32	5313306	1994-05-17	Kuban, et al.	
33	5323404	1994-06-21	Grubb	
34	5345538	1994-09-06	Narayannan, et al.	
35	5408409	1995-04-18	Glassman, et al.	
36	5544654	1996-08-13	Murphy, et al.	
37	5572999	1996-11-12	Funda, et al.	
38	5695493	1997-12-09	Nakajima, et al.	
39	5696778	1997-12-09	MacPherson	
40	5792204	1998-08-11	Snell	
41	5812978	1998-09-22	Nolan	

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Filing Date		
First Named Inventor	Moha	mmed N. ISLAM
Art Unit		
Examiner Name		
Attorney Docket Number		OMNI 0101 PUSA5

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42	5950629	1999-09-14	Taylor, et al.	
43	5970457	1999-10-19	Brant, et al.	
44	6014249	2000-01-11	Fermann, et al.	
45	6185535	2001-02-06	Hedin, et al.	
46	6200309	2001-03-13	Rice, et al.	
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49	6273858	2001-08-14	Fox, et al.	
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First Named Inventor	Moha	mmed N. ISLAM
Art Unit		
Examiner Name		
Attorney Docket Numb	er	OMNI 0101 PUSA5

53	6340806	2002-01-22	Smart, et al.	
54	6350261	2002-02-26	Domankevitz, et al.	
55	6374006	2002-04-16	Islam, et al.	
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57	6436107	2002-08-20	Wang, et al.	
58	6442430	2002-08-27	Ferek-Petric	
59	6450172	2002-09-17	Hartlaub, et al.	
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61	6458120	2002-10-01	Shen, et al.	
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Art Unit		
Examiner Name		
Attorney Docket Number		OMNI 0101 PUSA5

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64	6567431	2003-05-20	Tabirian, et al.	
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69	6760148	2004-07-06	Islam	
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73	7027467	2006-04-11	Baev, et al.	
74	7060061	2006-06-13	Altshuler, et al.	

#### **Application Number** Filing Date INFORMATION DISCLOSURE First Named Inventor Mohammed N. ISLAM STATEMENT BY APPLICANT Art Unit ( Not for submission under 37 CFR 1.99) **Examiner Name** Attorney Docket Number **OMNI 0101 PUSA5** 2007-01-23 75 7167300 ermann, et al. 76 2007-08-21 7259906 Islam 77 7433116 2008-10-07 Islam Add If you wish to add additional U.S. Patent citation information please click the Add button. Remove **U.S.PATENT APPLICATION PUBLICATIONS** Pages, Columns, Lines where Publication Kind Publication Name of Patentee or Applicant Examiner Cite No Relevant Passages or Relevant Initial\* Number Code<sup>1</sup> Date of cited Document Figures Appear 1 20020032468 2002-03-14 Hill, Michael R.S.; et al. 2 2002-06-27 20020082612 Moll, Frederic H.; et al. 3 2002-09-12 Miller, Steven C. 20020128846 20020178003 2002-11-28 4 Gehrke, James K.; et al. 5 20040174914 2004-09-09 Fukatsu, Susumu

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	1	EP114	18666	EP		2001-10-24	Gran	nt Andrew R et al.		
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	3	WO09	715240	wo		1997-05-01	BRA	NT		
	4	WO97	049340	wo		1997-12-31	WAN	lG		
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See attached certification statement.

Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

× None

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-08
Name/Print	David S. Bir	Registration Number	38383

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	2	7800818	B2	2010-09	-21	MATTSSON					
	3	8000574	B2	2011-08	<b>-16</b>	BUCHTER	BUCHTER				
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Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-08
Name/Print	David S. Bir	Registration Number	38383

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Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.** 

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Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-08
Name/Print	David S. Bir	Registration Number	38383

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Name/Print	David S. Bir	Registration Number	38383

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First Named Inventor	Moha	mmed N. ISLAM
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9	6587702	B1	2003-07-01	RUCHTI	
10	6864978	B1	2005-03-08	HAZEN	
11	6990364		2006-01-24	Ruchti	
12	7010336	B2	2006-03-07	LORENZ	
13	7133710	B2	2006-11-07	Acosta	
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	22	8145286		2012-03-27	Arai			
	23	6773922		2004-08-10	JENG			
	24	7807718	B2	2010-10-05	HASHIM			
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	1	20100331637	A1	2010-12-30	Ting			
	2	20110143364	A1	2011-06-16	KIM			
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See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

X A certification statement is not submitted herewith.

#### **SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-08
Name/Print	David S. Bir	Registration Number	38383

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.** 

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#### **SIGNATURE**

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Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-08
Name/Print	David S. Bir	Registration Number	38383

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	1	8157730	B2	2012-04-17	LeBoeuf, et al.		
	2	8430310	B1	2013-04-30	Ho, et al.		
	3	8509882	B2	2013-08-13	Albert, et al.		
	4	8788002	B2	2014-07-22	LeBoeuf, et al.		
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	1	20080086318	A1	2008-04-10	Gilley, et al.		

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	5 20150011851		A1	2015-01-08		Mehta, et al.						
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	1	wo	2013012938			A1	2013-01-24	Raskin, et al.				
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Name/Print	David S. Bir	Registration Number	38383

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	1	6212310	B1	2001-04-03 Waarts, et al.					
	2	7890158	B2	2011-02-15 Rowe, et al.					
	3	8213007	B2	2012-07-03	2-07-03 Wang, et al.				
	4	7848605	B2	2010-12-07	Ridder, et al.				
	5	8158493	B2	2012-04-17 Shah, et al.					
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	1	20060198397	A1	2006-09-07	Korolev, et al.				

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## ABSTRACT

A wearable device includes a measurement device to measure a physiological parameter adapted to be placed on a wrist or an ear of a user. A plurality of semiconductor light sources such as light emitting diodes generate corresponding output light having an initial light intensity. A receiver includes spatially separated detectors receiving reflected light from the output lights and coupled to analog to digital converters. The receiver is configured to synchronize to the semiconductor source(s). The measurement device improves signal-to-noise ratio of the output signal by increasing light intensity relative to the initial light intensity and by increasing a pulse rate. Further improvement in signal-to-noise ratio is achieved by using change detection, where the receiver compares the signals with light on and with light off.

#### WHAT IS CLAIMED IS:

1. A system for measuring one or more physiological parameters and for use with a smart phone or tablet, the system comprising:

a wearable device adapted to be placed on a wrist or an ear of a user, including a light source comprising a plurality of semiconductor sources that are light emitting diodes, each of the light emitting diodes configured to generate an output optical light having one or more optical wavelengths;

the wearable device comprising one or more lenses configured to receive a portion of at least one of the output optical lights and to direct a lens output light to tissue;

the wearable device further comprising a detection system configured to receive at least a portion of the lens output light reflected from the tissue and to generate an output signal having a signal-to-noise ratio, wherein the detection system is configured to be synchronized to the light source;

wherein the detection system comprises a plurality of spatially separated detectors, and wherein at least one analog to digital converter is coupled to at least one of the spatially separated detectors:

wherein a detector output from the at least one of the plurality of spatially separated detectors is coupled to an amplifier having a gain configured to improve detection sensitivity;

the smart phone or tablet comprising a wireless receiver, a wireless transmitter, a display, a speaker, a voice input module, one or more buttons or knobs, a microprocessor and a touch screen, the smart phone or tablet configured to receive and process at least a portion of the output signal, wherein the smart phone or tablet is configured to store and display the processed output signal, and wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link;

a cloud configured to receive over the wireless transmission link an output status comprising the at least a portion of the processed output signal, to process the received output status to generate processed data, and to store the processed data;

wherein the output signal is indicative of one or more of the physiological parameters, and the cloud is configured to store a history of at least a portion of the one or more physiological parameters over a specified period of time;

the wearable device configured to increase the signal-to-noise ratio by increasing light intensity of at least one of the plurality of semiconductor sources from an initial light intensity and by

increasing a pulse rate of at least one of the plurality of semiconductor sources from an initial pulse rate; and

the detection system further configured to:

generate a first signal responsive to light received while the light emitting diodes are off,

generate a second signal responsive to light received while at least one of the light emitting diodes is on, and

increase the signal-to-noise ratio by comparing the first signal and the second signal.

- 2. The system of Claim 1, wherein the wearable device is configured to use artificial intelligence in making decisions associated with at least a portion of the output signal.
- 3. The system of Claim 2, wherein the wearable device is at least in part configured to identify an object, and to compare a property of at least some of the output signal to a threshold.
- 4. The system of Claim 3, wherein the wearable device is configured to perform pattern identification or classification based on at least a part of the output signal.
- 5. The system of Claim 4, wherein at least one of the spatially separated detectors is located at a first distance from at least one of the light emitting diodes and at least another of the spatially separated detectors is located at a second distance from the at least one of the light emitting diodes, and the at least one of the spatially separated detectors is configured to generate a third signal responsive to light from the at least one light emitting diode and the at least another of the spatially separated detectors is configured to generate a fourth signal responsive to the light from the at least one of the light emitting diodes; and

wherein at least one of the spatially separated detectors is located at a third distance from a first one of the light emitting diodes and at a fourth distance from a second one of the light emitting diodes, and is configured to generate a fifth signal responsive to light from the first light emitting diode and a sixth signal responsive to light from the second light emitting diode, and wherein the first

distance is different from the second distance, and the third distance is different from the fourth distance.

- 6. The system of Claim 5, wherein the wearable device further comprises a reflective surface positioned to reflect at least a portion of the lens output light reflected from the tissue.
- 7. A system for measuring one or more physiological parameters and for use with a smart phone or tablet, the system comprising:

a wearable device adapted to be placed on a wrist or an ear of a user, and including a light source comprising a plurality of semiconductor sources, each of the semiconductor sources configured to generate an output light having one or more optical wavelengths;

the wearable device comprising one or more lenses configured to receive a portion of at least one of the output lights and to deliver a lens output light to tissue;

the wearable device further comprising a detection system configured to receive at least a portion of the lens output light reflected from the tissue and to generate an output signal having a signal-to-noise ratio, wherein the detection system is configured to be synchronized to the light source;

wherein the detection system comprises a plurality of spatially separated detectors, and wherein at least one analog to digital converter is coupled to at least one of the spatially separated detectors;

the smart phone or tablet comprising a wireless receiver, a wireless transmitter, a display, a speaker, a voice input module, one or more buttons or knobs, a microprocessor and a touch screen, the smart phone or tablet configured to receive and process at least a portion of the output signal, wherein the smart phone or tablet is configured to store and display the processed output signal, and wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link;

a cloud configured to receive over the wireless transmission link an output status comprising the at least a portion of the processed output signal, to process the received output status to generate processed data, and to store the processed data;

wherein the output signal is indicative of one or more of the physiological parameters;

the wearable device configured to increase the signal-to-noise ratio by increasing light intensity of at least one of the semiconductor sources from an initial light intensity and by increasing a pulse rate of at least one of the semiconductor sources from an initial pulse rate; and

the detection system further configured to:

generate a first signal responsive to light received while the semiconductor sources are off,

generate a second signal responsive to light received while at least one of the semiconductor sources is on, and

increase the signal-to-noise ratio by comparing the first signal and the second signal.

- 8. The system of Claim 7, wherein the wearable device is at least in part configured to identify an object, and a property of at least some of the output signal is compared by at least one of the wearable device, the smart phone or tablet to a threshold.
- 9. The system of Claim 8, wherein a detector output from at least one of the plurality of spatially separated detectors is coupled to an amplifier having a gain configured to improve detection sensitivity.
- 10. The system of Claim 9, wherein the wearable device is configured to use artificial intelligence to process at least a portion of the output signal.
- 11. The system of Claim 10, wherein the artificial intelligence comprises pattern identification or classification.
- 12. The system of Claim 10, wherein the wearable device is configured to perform pattern identification or classification based on at least a part of the output signal.
- 13. The system of Claim 12, wherein at least one of the spatially separated detectors is located at a first distance from at least one of the light emitting diodes and at least another of the spatially separated detectors is located at a second distance from the at least one of the light emitting diodes, and the at least one of the spatially separated detectors is configured to generate a third signal

responsive to light from the at least one light emitting diode and the at least another of the spatially separated detectors is configured to generate a fourth signal responsive to the light from the at least one of the light emitting diodes; and

wherein at least one of the spatially separated detectors is located at a third distance from a first one of the light emitting diodes and at a fourth distance from a second one of the light emitting diodes, and is configured to generate a fifth signal responsive to light from the first light emitting diode and a sixth signal responsive to light from the second light emitting diode, and wherein the first distance is different from the second distance, and the third distance is different from the fourth distance.

- 14. The system of Claim 13, wherein the wearable device further comprises a reflective surface positioned to reflect at least a portion of the lens output light reflected from the tissue.
- 15. A system for measuring one or more physiological parameters and for use with a smart phone or tablet, the system comprising:

a wearable device adapted to be placed on a wrist or an ear of a user, including a light source comprising a plurality of semiconductor sources that are light emitting diodes, each of the light emitting diodes configured to generate an output optical light having one or more optical wavelengths;

the wearable device comprising one or more lenses configured to receive a portion of at least some of the output optical light and to deliver a lens output light to tissue;

the wearable device further comprising a detection system configured to receive at least a portion of the lens output light reflected from the tissue and to generate an output signal having a signal-to-noise ratio, wherein the detection system is configured to be synchronized to the light source;

wherein the detection system comprises a plurality of spatially separated detectors, and wherein at least one analog to digital converter is coupled to at least one of the spatially separated detectors;

the smart phone or tablet comprising a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor and a touch screen, the smart phone or tablet configured to receive and process at least a portion of the output signal, wherein the smart phone or tablet is configured to store and display the processed output signal, and

wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link;

a cloud configured to receive over the wireless transmission link an output status comprising the at least a portion of the processed output signal, to process the received output status to generate processed data, and to store the processed data;

wherein the output signal is indicative of one or more of the physiological parameters; the wearable device configured to increase the signal-to-noise ratio by increasing light intensity of at least one of the plurality of semiconductor sources from an initial light intensity; and the detection system further configured to:

generate a first signal responsive to light received while the light emitting diodes are off.

generate a second signal responsive to light received while at least one of the light emitting diodes is on, and

increase the signal-to-noise ratio by comparing the first signal and the second signal.

- 16. The system of Claim 15, wherein the wearable device is at least in part configured to detect an object, and a property of at least some of the output signal is compared to a threshold.
- 17. The system of Claim 15, wherein a detector output from at least one of the plurality of spatially separated detectors is coupled to an amplifier having a gain configured to be adjusted to improve detection sensitivity.
- 18. The system of Claim 15, wherein the wearable device is configured to use artificial intelligence in making decisions associated with at least a portion of the output signal.
- 19. The system of claim 18 wherein the artificial intelligence comprises a pattern matching algorithm.
- 20. The system of claim 18 wherein the artificial intelligence comprises spectral fingerprinting.

- 21. The system of Claim 15, wherein the wearable device is configured to perform pattern identification or classification based on at least a part of the output signal.
- 22. The system of Claim 21, wherein the pattern identification or classification comprises a pattern matching algorithm or spectral fingerprinting.
- 23. The system of Claim 15, wherein the wearable device further comprises a reflective surface positioned to reflect at least a portion of light reflected from the tissue.

# SEMICONDUCTOR DIODES-BASED PHYSIOLOGICAL MEASUREMENT DEVICE WITH IMPROVED SIGNAL-TO-NOISE RATIO

#### CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. application Serial No. 16/272,069 filed February, 11, 2019, which is a continuation of U.S. application Serial No. 16/029,611 filed July 8, 2018 (now U.S. Patent No. 10,201,283), which is a continuation of U.S. application Serial No. 15/888,052 filed February 4, 2018 (now U.S. Patent No. 10,136,819), which is a continuation of U.S. application Serial No. 15/212,549 filed July 18, 2016 (now U.S. Patent No. 9,885,698), which is a continuation of U.S. application Serial No. 14/650,897 filed June 10, 2015 (now U.S. Patent No. 9,494,567), which is a U.S. National Phase of PCT/US2013/075700 filed December 17, 2013, which claims the benefit of U.S. provisional application Serial No. 61/747,472 filed December 31, 2012, the disclosures of all of which are hereby incorporated in their entirety by reference herein.

This application is also a continuation of U.S. application Serial No. 16/004,359 filed June 9, 2018, which is a continuation of U.S. application Serial No. 14/109,007 filed December 17, 2013 (now U.S. Patent No. 9,993,159), which claims the benefit of U.S. provisional application Serial No. 61/747,553 filed December 31, 2012, the disclosures of all of which are hereby incorporated in their entirety by reference herein.

[0003] This application is also a continuation of U.S. application Serial No.16/188,194 filed November 12, 2018, which is a continuation of U.S. Application No. 16/004,154 filed June 8, 2018 (now U.S. Patent No. 10,126,283), which is a continuation of U.S. Application No. 15/855,201 filed December 27, 2017 (now U.S. Patent No. 9,995,722), which is a continuation of U.S. Application No. 15/711,907 filed September 21, 2017 (now U.S. Patent No. 9,897,584), which is a divisional of U.S. Application No. 15/357,225 filed November 21, 2016 (now U.S. Patent No. 9,797,876), which is a continuation of U.S. Application No. 14/650,981 filed June 10, 2015 (now U.S. Patent No. 9,500,634), which is the U.S. national phase of PCT Application No. PCT/US2013/075767 filed December 17, 2013, which claims the benefit of U.S. provisional

application Ser. No. 61/747,485 filed Dec. 31, 2012, the disclosures of all of which are hereby incorporated by reference in their entirety.

This application is also a continuation of U.S. application Serial No. 16/241,628 filed January 7, 2019, which is a continuation of U.S. Serial No. 16/015,737 filed June 22, 2018 (now U.S. Patent No. 10,172,523), which is a continuation of U.S. Serial No. 15/594,053 filed May 12, 2017 (now U.S. Patent No. 10,188,299), which is a continuation of U.S. application Serial No. 14/875,709 filed October 6, 2015 (now U.S. Patent No. 9,651,533), which is a continuation of U.S. application Serial No. 14/108,986 filed December 17, 2013 (now U.S. Patent No. 9,164,032), which claims the benefit of U.S. provisional application Serial No. 61/747,487 filed December 31, 2012, the disclosures of all of which are hereby incorporated in their entirety by reference herein.

This application is also a continuation of U.S. Application Ser. No. 16/284,514 filed February 25, 2019, which is a continuation of U.S. Application Ser. No. 16/016,649 filed June 24, 2018 (now U.S. Patent No. 10,213,113), which is a continuation of U.S. Application Ser. No. 15/860,065 filed January 2, 2018 (now U.S. Patent No. 10,098,546), which is a Continuation of U.S. Application Ser. No. 15/686,198 filed August 25, 2017 (now U.S. Patent No. 9,861,286), which is a continuation of U.S. Application Ser. No. 15/357,136 filed November 21, 2016 (now U.S. Patent. No. 9,757,040), which is a continuation of U.S. Application Ser. No. 14/651,367 filed June 11, 2015 (now U.S. Patent No. 9,500,635), which is the U.S. national phase of PCT Application No. PCT/US2013/075736 filed December 17, 2013, which claims the benefit of U.S. provisional application Ser. No. 61/747,477 filed Dec. 31, 2012 and U.S. provisional application Ser. No. 61/754,698 filed Jan. 21, 2013, the disclosures of all of which are hereby incorporated by reference in their entirety.

[0006] This application is related to U.S. provisional application Serial Nos. 61/747,477 filed Dec. 31, 2012; Ser. No. 61/747,481 filed Dec. 31, 2012; Ser. No. 61/747,485 filed Dec. 31, 2012; Ser. No. 61/747,487 filed Dec. 31, 2012; Ser. No. 61/747,492 filed Dec. 31, 2012; Ser. No. 61/747,553 filed Dec. 31, 2012; and Ser. No. 61/754,698 filed Jan. 21, 2013, the disclosures of all of which are hereby incorporated in their entirety by reference herein.

This application is also related to International Application PCT/US2013/075736 entitled Short-Wave Infrared Super-Continuum Lasers For Early Detection Of Dental Caries; U.S. Application 14/108,995 filed December 17, 2013 entitled Focused Near-Infrared Lasers For Non-Invasive Vasectomy And Other Thermal Coagulation Or Occlusion Procedures (U.S. Pat. App. Pub. No. US2014/0188092A1); International Application PCT/US2013/075767 entitled Short-Wave Infrared Super-Continuum Lasers For Natural Gas Leak Detection, Exploration, And Other Active Remote Sensing Applications; U.S. Application 14/108,986 filed December 17, 2013 entitled Short-Wave Infrared Super-Continuum Lasers For Detecting Counterfeit Or Illicit Drugs And Pharmaceutical Process Control (now U.S. Patent No. 9,164,032); U.S. Application 14/108,974 filed December 17, 2013 entitled Non-Invasive Treatment Of Varicose Veins (U.S. Pat. App. Pub. No. US2014/018894A1); and U.S. Application 14/109,007 filed December 17, 2013 entitled Near-Infrared Super-Continuum Lasers For Early Detection Of Breast And Other Cancers (now U.S. Patent No. 9,993,159), the disclosures of all of which are hereby incorporated in their entirety by reference herein.

#### BACKGROUND

[0008] With the growing obesity epidemic, the number of individuals with diabetes is also increasing dramatically. For example, there are over 200 million people who have diabetes. Diabetes control requires monitoring of the glucose level, and most glucose measuring systems available commercially require drawing of blood. Depending on the severity of the diabetes, a patient may have to draw blood and measure glucose four to six times a day. This may be extremely painful and inconvenient for many people. In addition, for some groups, such as soldiers in the battlefield, it may be dangerous to have to measure periodically their glucose level with finger pricks.

Thus, there is an unmet need for non-invasive glucose monitoring (e.g., monitoring glucose without drawing blood). The challenge has been that a non-invasive system requires adequate sensitivity and selectivity, along with repeatability of the results. Yet, this is a very large market, with an estimated annual market of over \$10B in 2011 for self-monitoring of glucose levels.

One approach to non-invasive monitoring of blood constituents or blood analytes is to use near-infrared spectroscopy, such as absorption spectroscopy or near-infrared diffuse reflection or transmission spectroscopy. Some attempts have been made to use broadband light sources, such as tungsten lamps, to perform the spectroscopy. However, several challenges have arisen in these efforts. First, many other constituents in the blood also have signatures in the near-infrared, so spectroscopy and pattern matching, often called spectral fingerprinting, is required to distinguish the glucose with sufficient confidence. Second, the non-invasive procedures have often transmitted or reflected light through the skin, but skin has many spectral artifacts in the near-infrared that may mask the glucose signatures. Moreover, the skin may have significant water and blood content. These difficulties become particularly complicated when a weak light source is used, such as a lamp. More light intensity can help to increase the signal levels, and, hence, the signal-to-noise ratio.

As described in this disclosure, by using brighter light sources, such as fiber-based supercontinuum lasers, super-luminescent laser diodes, light-emitting diodes or a number of laser diodes, the near-infrared signal level from blood constituents may be increased. By shining light through the teeth, which have fewer spectral artifacts than skin in the near-infrared, the blood constituents may be measured with less interfering artifacts. Also, by using pattern matching in spectral fingerprinting and various software techniques, the signatures from different constituents in the blood may be identified. Moreover, value-add services may be provided by wirelessly communicating the monitored data to a handheld device such as a smart phone, and then wirelessly communicating the processed data to the cloud for storing, processing, and transmitting to several locations.

#### SUMMARY OF EXAMPLE EMBODIMENTS

[0012] In one embodiment, a smart phone or tablet comprises one or more laser diodes configured to be pulsed and to generate light having one or more optical wavelengths, wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers. A first one or more lenses is configured to receive a portion of the light from the one or more laser diodes and to direct at least some portion of the received light

to tissue. An array of laser diodes is configured to be pulsed and to generate light having one or more optical wavelengths, wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers. A second one or more lenses is configured to receive a portion of the light from the array of laser diodes, the array of laser diodes and the second one or more lenses configured to form the light into a plurality of spots and to direct at least some of the spots to tissue. An infrared camera is configured to be synchronized to the at least one of the one or more laser diodes to receive at least a portion of light reflected from the tissue from at least one of the one or more laser diodes, wherein the infrared camera generates data based at least in part on the received light. The infrared camera is further configured to be synchronized to the array of laser diodes to receive light from at least a portion of the plurality of spots reflected from the tissue, and wherein the infrared camera generates additional data based at least in part on the received light. The infrared camera is further configured to: receive light while the one or more laser diodes and the array of laser diodes are off and convert the received light into a first signal; and receive light while at least some of the one or more laser diodes or some of the array of laser diodes are on, and convert the received light into a second signal, the received light including at least a part of the portion of the light from the at least one of the one or more laser diodes reflected from the tissue, or at least a part of the portion of the light from the array of laser diodes reflected from the tissue. The smart phone or tablet is configured to generate a two-dimensional or three-dimensional image using a difference between the first signal and the second signal, and using at least part of the data or at least part of the additional data from the infrared camera. The smart phone or tablet further comprises a wireless receiver, a wireless transmitter, a display, a voice input module, and a speaker.

[0013] Embodiments may include a smart phone or tablet comprising one or more laser diodes configured to be pulsed and to generate light having one or more optical wavelengths, wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers. A first one or more lenses is configured to receive a portion of the light from the one or more laser diodes and to direct at least some portion of the received light to tissue. An array of laser diodes is configured to be pulsed and to generate light having one or more optical wavelengths, wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers. A

second one or more lenses is configured to receive a portion of the light from the array of laser diodes, the array of laser diodes and the second one or more lenses configured to form the light into a plurality of spots and to direct at least some of the spots to tissue. An infrared camera is configured to be synchronized to the at least one of the one or more laser diodes to receive at least a portion of light reflected from the tissue from at least one of the one or more laser diodes, and wherein the infrared camera generates data based at least in part on the received light. The infrared camera is further configured to be synchronized to the array of laser diodes to receive light from at least a portion of the plurality of spots reflected from the tissue, wherein the infrared camera generates additional data based at least in part on the received light. The smart phone or tablet is configured to generate a two-dimensional or three-dimensional image using at least part of the data or part of the additional data from the infrared camera. The smart phone or tablet further comprises a wireless receiver, a wireless transmitter, a display, a voice input module, and a speaker.

[0014] In one embodiment, a smart phone or tablet comprises one or more laser diodes configured to be pulsed and to generate light having one or more optical wavelengths, wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers. A first one or more lenses is configured to receive a portion of the light from the one or more laser diodes and to direct at least some portion of the received light to tissue. An array of laser diodes is configured to be pulsed and to generate light having one or more optical wavelengths, wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers. A second one or more lenses is configured to receive a portion of the light from the array of laser diodes, the array of laser diodes and the second one or more lenses configured to form the light into a plurality of spots and to direct at least some of the spots to tissue, wherein the plurality of spots are also formed at least in part by using an assembly in front of the array of laser diodes. An infrared camera is configured to be synchronized to the at least one of the one or more laser diodes to receive at least a portion of light reflected from the tissue from at least one of the one or more laser diodes, wherein the infrared camera generates data based at least in part on the received light. The infrared camera is further configured to be synchronized to the array of laser diodes to receive light from at least a portion of the plurality of spots reflected from the tissue, wherein the infrared camera generates additional data based at least in part on the received light. The smart phone or tablet is configured to generate a two-dimensional or three-dimensional image using at least part of the data or part of the additional data from the infrared camera. The smart phone or tablet further comprises a wireless receiver, a wireless transmitter, a display, a voice input module, and a speaker.

## BRIEF DESCRIPTION OF THE DRAWINGS

[0015] For a more complete understanding of the present disclosure, and for further features and advantages thereof, reference is now made to the following description taken in conjunction with the accompanying drawings, in which:

[0016] FIG. 1 plots the transmittance versus wavenumber for glucose in the mid-wave and long-wave infrared wavelengths between approximately 2.7 to 12 microns.

[0017] FIG. 2 illustrates measurements of the absorbance of different blood constituents, such as glucose, hemoglobin, and hemoglobin A1c. The measurements are done using an FTIR spectrometer in samples with a 1 mm path length.

[0018] FIG. 3A shows the normalized absorbance of water and glucose (not drawn to scale). Water shows transmission windows between about 1500-1850 nm and 2050-2500 nm.

[0019] FIG. 3B illustrates the absorbance of hemoglobin and oxygenated hemoglobin overlapped with water.

[0020] FIG. 4A shows measured absorbance in different concentrations of glucose solution over the wavelength range of about 2000 to 2400 nm. This data is collected using a SWIR super-continuum laser with the sample path length of about 1.1 mm.

[0021] FIG. 4B illustrates measured absorbance in different concentrations of glucose solution over the wavelength range of about 1550 to 1800 nm. The data is collected using a SWIR super-continuum laser with a sample path length of about 10 mm.

[0022] FIG. 5 illustrates the spectrum for different blood constituents in the wavelength range of about 2 to 2.45 microns (2000 to 2450 nm).

[0023] FIG. 6 shows the transmittance versus wavelength in microns for the ketone 3-hydroxybutyrate. The wavelength range is approximately 2 to 16 microns.

[0024] FIG. 7 illustrates the optical absorbance for ketones as well as some other blood constituents in the wavelength range of about 2100 to 2400 nm.

[0025] FIG. 8A shows the first derivative spectra of ketone and protein at concentrations of 10 g/L (left). In addition, the first derivative spectra of urea, creatinine, and glucose are shown on the right at concentrations of 10 g/L.

[0026] FIG. 8B illustrates the near infrared absorbance for triglyceride.

[10027] FIG. 8C shows the near-infrared reflectance spectrum for cholesterol.

[0028] FIG. 8D illustrates the near-infrared reflectance versus wavelength for various blood constituents, including cholesterol, glucose, albumin, uric acid, and urea.

[0029] FIG. 9 shows a schematic of the human skin. In particular, the dermis may comprise significant amounts of collagen, elastin, lipids, and water.

[0030] FIG. 10 illustrates the absorption coefficients for water (including scattering), adipose, collagen, and elastin.

[0031] FIG. 11 shows the dorsal of the hand, where a differential measurement may be made to at least partially compensate for or subtract out the skin interference.

[0032] FIG. 12 shows the dorsal of the foot, where a differential measurement may be made to at least partially compensate for or subtract out the skin interference.

[0033] FIG. 13A shows an embodiment that may comprise multiple collimated or focused light beams.

[0034] FIG. 13B illustrates a typical human nail tissue structure and the capillary vessels below it.

[0035] FIG. 14 shows the attenuation coefficient for seven nail samples that are allowed to stand in an environment with a humidity level of 14%. These coefficients are measured using an FTIR spectrometer over the near-infrared wavelength range of approximately 1 to 2.5 microns. Below is also included the spectrum of glucose.

[0036] FIG. 15 illustrates the structure of a tooth.

[0037] FIG. 16A shows the attenuation coefficient for dental enamel and water versus wavelength from approximately 600nm to 2600nm.

[0038] FIG. 16B illustrates the absorption spectrum of intact enamel and dentine in the wavelength range of approximately 1.2 to 2.4 microns.

[0039] FIG. 17 shows the near infrared spectral reflectance over the wavelength range of approximately 800nm to 2500nm from an occlusal tooth surface. The black diamonds correspond to the reflectance from a sound, intact tooth section. The asterisks correspond to a tooth section with an enamel lesion. The circles correspond to a tooth section with a dentine lesion.

[0040] FIG. 18A illustrates a clamp design of a human interface to cap over one or more teeth and perform a non-invasive measurement of blood constituents.

[0041] FIG. 18B shows a mouth guard design of a human interface to perform a non-invasive measurement of blood constituents.

[0042] FIG. 19 illustrates a block diagram or building blocks for constructing high power laser diode assemblies.

[0043] FIG. 20 shows a platform architecture for different wavelength ranges for an all-fiber-integrated, high powered, super-continuum light source.

[0044] FIG. 21 illustrates one embodiment of a short-wave infrared (SWIR) supercontinuum (SC) light source. [0045] FIG. 22 shows the output spectrum from the SWIR SC laser of FIG. 21 when about 10m length of fiber for SC generation is used. This fiber is a single-mode, non-dispersion shifted fiber that is optimized for operation near 1550 nm.

[0046] FIG. 23 illustrates high power SWIR-SC lasers that may generate light between approximately 1.4-1.8 microns (top) or approximately 2-2.5 microns (bottom).

[0047] FIG. 24 schematically shows that the medical measurement device can be part of a personal or body area network that communicates with another device (e.g., smart phone or tablet) that communicates with the cloud. The cloud may in turn communicate information with the user, healthcare providers, or other designated recipients.

[0048] FIGURE 25 shows the experimental set-up for a reflection-spectroscopy based stand-off detection system.

[0049] FIGURE 26 shows what might be an eventual flow-chart of a smart manufacturing process.

#### DETAILED DESCRIPTION

[0050] As required, detailed embodiments of the present disclosure are disclosed herein; however, it is to be understood that the disclosed embodiments are merely exemplary of the disclosure that may be embodied in various and alternative forms. The figures are not necessarily to scale; some features may be exaggerated or minimized to show details of particular components. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a representative basis for teaching one skilled in the art to variously employ the present disclosure.

[0051] Various ailments or diseases may require measurement of the concentration of one or more blood constituents. For example, diabetes may require measurement of the blood glucose and HbA1c levels. On the other hand, diseases or disorders characterized by impaired glucose metabolism may require the measurement of ketone bodies in the blood. Examples of impaired glucose metabolism diseases include Alzheimer's, Parkinson's, Huntington's, and Lou Gehrig's or

amyotrophic lateral sclerosis (ALS). Techniques related to near-infrared spectroscopy or hyperspectral imaging may be particularly advantageous for non-invasive monitoring of some of these blood constituents.

[0052] Hyper-spectral images may provide spectral information to identify and distinguish between spectrally similar materials, providing the ability to make proper distinctions among materials with only subtle signature differences. In the SWIR wavelength range, numerous gases, liquids and solids have unique chemical signatures, particularly materials comprising hydro-carbon bonds, O-H bonds, N-H bonds, etc. Therefore, spectroscopy in the SWIR may be attractive for stand-off or remote sensing of materials based on their chemical signature, which may complement other imaging information.

One embodiment of remote sensing that is used to identify and classify various materials is so-called "hyper-spectral imaging." Hyper-spectral sensors may collect information as a set of images, where each image represents a range of wavelengths over a spectral band. Hyper-spectral imaging may deal with imaging narrow spectral bands over an approximately continuous spectral range. As an example, in hyper-spectral imaging the sun may be used as the illumination source, and the daytime illumination may comprise direct solar illumination as well as scattered solar (skylight), which is caused by the presence of the atmosphere. However, the sun illumination changes with time of day, clouds or inclement weather may block the sun light, and the sun light is not accessible in the night time. Therefore, it would be advantageous to have a broadband light source covering the SWIR that may be used in place of the sun to identify or classify materials in remote sensing or stand-off detection applications.

[0054] In one embodiment, a SWIR camera or infrared camera system may be used to capture the images. The camera may include one or more lenses on the input, which may be adjustable. The focal plane assemblies may be made from mercury cadmium telluride material (HgCdTe), and the detectors may also include thermo-electric coolers. Alternately, the image sensors may be made from indium gallium arsenide (InGaAs), and CMOS transistors may be connected to each pixel of the InGaAs photodiode array. The camera may interface wirelessly or with a cable (e.g., USB, Ethernet cable, or fiber optics cable) to a computer or tablet or smart phone, where the images may be captured and processed. These are a few examples of infrared

cameras, but other SWIR or infrared cameras may be used and are intended to be covered by this disclosure.

100551 Described herein are just some examples of the beneficial use of near-infrared or SWIR lasers for active remote sensing or hyper-spectral imaging. However, many other spectroscopy and identification procedures can use the near-infrared or SWIR light consistent with this disclosure and are intended to be covered by the disclosure. As one example, the fiberbased super-continuum lasers may have a pulsed output with pulse durations of approximately 0.5-2nsec and pulse repetition rates of several Megahertz. Therefore, the active remote sensing or hyper-spectral imaging applications may also be combined with LIDAR-type applications. Namely, the distance or time axis can be added to the information based on time-of-flight measurements. For this type of information to be used, the detection system would also have to be time-gated to be able to measure the time difference between the pulses sent and the pulses received. By calculating the round-trip time for the signal, the distance of the object may be judged. In another embodiment, GPS (global positioning system) information may be added, so the active remote sensing or hyper-spectral imagery would also have a location tag on the data. Moreover, the active remote sensing or hyper-spectral imaging information could also be combined with two-dimensional or three-dimensional images to provide a physical picture as well as a chemical composition identification of the materials. These are just some modifications of the active remote sensing or hyper-spectral imaging system described in this disclosure, but other techniques may also be added or combinations of these techniques may be added, and these are also intended to be covered by this disclosure.

[0056] Described herein are just some examples of the beneficial use of near-infrared or SWIR lasers for active remote sensing or hyper-spectral imaging. However, many other spectroscopy and identification procedures can use the near-infrared or SWIR light consistent with this disclosure and are intended to be covered by the disclosure. As one example, the fiber-based super-continuum lasers may have a pulsed output with pulse durations of approximately 0.5-2nsec and pulse repetition rates of several Megahertz. Therefore, the active remote sensing or hyper-spectral imaging applications may also be combined with LIDAR-type applications. Namely, the distance or time axis can be added to the information based on time-of-flight measurements. For this type of information to be used, the detection system would also have to

be time-gated to be able to measure the time difference between the pulses sent and the pulses received. By calculating the round-trip time for the signal, the distance of the object may be judged. In another embodiment, GPS (global positioning system) information may be added, so the active remote sensing or hyper-spectral imagery would also have a location tag on the data. Moreover, the active remote sensing or hyper-spectral imaging information could also be combined with two-dimensional or three-dimensional images to provide a physical picture as well as a chemical composition identification of the materials. These are just some modifications of the active remote sensing or hyper-spectral imaging system described in this disclosure, but other techniques may also be added or combinations of these techniques may be added, and these are also intended to be covered by this disclosure.

100571 In some instances, it may be desirable to create multiple locations of focused light on the varicose vein. For example, the speed of the treatment may be increased by causing thermal coagulation or occlusion at multiple locations. Multiple collimated or focused light beams may be created in one assembly. In this embodiment, optionally a surface cooling apparatus may be used, where a cooling fluid may be flowed either touching or in close proximity to the skin. Also, in this particular embodiment a cylindrical assembly may optionally be used, where the cylindrical length may be several millimeters in length and defined by a clamp or mount placed on or near the leg. In one embodiment, a window and/or lenslet array is also shown on the cylindrical surface for permitting the light to be incident on the skin and varicose vein at multiple spots. The lenslet array may comprise circular, spherical or cylindrical lenses, depending on the type of spots desired. As before, one advantage of placing the lenslet array in close proximity to the skin and varicose vein may be that a high NA, lens may be used. Also, the input from the lens and/or mirror assembly to the lenslet array may be single large beam, or a plurality of smaller beams. In one embodiment, a plurality of spots may be created by the lenslet array to cause a plurality of locations of thermal coagulation in the varicose vein. Any number of spots may be used and are intended to be covered by this disclosure.

[0058] In a non-limiting example, a plurality of spots may be used, or what might be called a fractionated beam. The fractionated laser beam may be added to the laser delivery assembly or delivery head in a number of ways. In one embodiment, a screen-like spatial filter may be placed in the pathway of the beam to be delivered to the biological tissue. The screen-

like spatial filter can have opaque regions to block the light and holes or transparent regions, through which the laser beam may pass to the tissue sample. The ratio of opaque to transparent regions may be varied, depending on the application of the laser. In another embodiment, a lenslet array can be used at or near the output interface where the light emerges. In yet another embodiment, at least a part of the delivery fiber from the infrared laser system to the delivery head may be a bundle of fibers, which may comprise a plurality of fiber cores surrounded by cladding regions. The fiber cores can then correspond to the exposed regions, and the cladding areas can approximate the opaque areas not to be exposed to the laser light. As an example, a bundle of fibers may be excited by at least a part of the laser system output, and then the fiber bundle can be fused together and perhaps pulled down to a desired diameter to expose to the tissue sample near the delivery head. In yet another embodiment, a photonic crystal fiber may be used to create the fractionated laser beam. In one non-limiting example, the photonic crystal fiber can be coupled to at least a part of the laser system output at one end, and the other end can be coupled to the delivery head. In a further example, the fractionated laser beam may be generated by a heavily multi-mode fiber, where the speckle pattern at the output may create the high intensity and low intensity spatial pattern at the output. Although several exemplary techniques are provided for creating a fractionated laser beam, other techniques that can be compatible with optical fibers are also intended to be included by this disclosure.

Although the output from a fiber laser may be from a single or multi-mode fiber, different spatial spot sizes or spatial profiles may be beneficial for different applications. For example, in some instances it may be desirable to have a series of spots or a fractionated beam with a grid of spots. In one embodiment, a bundle of fibers or a light pipe with a plurality of guiding cores may be used. In another embodiment, one or more fiber cores may be followed by a lenslet array to create a plurality of collimated or focused beams. In yet another embodiment, a delivery light pipe may be followed by a grid-like structure to divide up the beam into a plurality of spots. These are specific examples of beam shaping, and other apparatuses and methods may also be used and are consistent with this disclosure.

[0060] As used throughout this document, the term "couple" and or "coupled" refers to any direct or indirect communication between two or more elements, whether or not those elements are physically connected to one another. As used throughout this disclosure, the term

"spectroscopy" means that a tissue or sample is inspected by comparing different features, such as wavelength (or frequency), spatial location, transmission, absorption, reflectivity, scattering, refractive index, or opacity. In one embodiment, "spectroscopy" may mean that the wavelength of the light source is varied, and the transmission, absorption or reflectivity of the tissue or sample is measured as a function of wavelength. In another embodiment, "spectroscopy" may mean that the wavelength dependence of the transmission, absorption or reflectivity is compared between different spatial locations on a tissue or sample. As an illustration, the "spectroscopy" may be performed by varying the wavelength of the light source, or by using a broadband light source and analyzing the signal using a spectrometer, wavemeter, or optical spectrum analyzer.

As used throughout this document, the term "fiber laser" refers to a laser or oscillator that has as an output light or an optical beam, wherein at least a part of the laser comprises an optical fiber. For instance, the fiber in the "fiber laser" may comprise one of or a combination of a single mode fiber, a multi-mode fiber, a mid-infrared fiber, a photonic crystal fiber, a doped fiber, a gain fiber, or, more generally, an approximately cylindrically shaped waveguide or light-pipe. In one embodiment, the gain fiber may be doped with rare earth material, such as ytterbium, erbium, and/or thulium. In another embodiment, the mid-infrared fiber may comprise one or a combination of fluoride fiber, ZBLAN fiber, chalcogenide fiber, tellurite fiber, or germanium doped fiber. In yet another embodiment, the single mode fiber may include standard single-mode fiber, dispersion shifted fiber, non-zero dispersion shifted fiber, high-nonlinearity fiber, and small core size fibers.

As used throughout this disclosure, the term "pump laser" refers to a laser or oscillator that has as an output light or an optical beam, wherein the output light or optical beam is coupled to a gain medium to excite the gain medium, which in turn may amplify another input optical signal or beam. In one particular example, the gain medium may be a doped fiber, such as a fiber doped with ytterbium, erbium or thulium. In one embodiment, the "pump laser" may be a fiber laser, a solid state laser, a laser involving a nonlinear crystal, an optical parametric oscillator, a semiconductor laser, or a plurality of semiconductor lasers that may be multiplexed together. In another embodiment, the "pump laser" may be coupled to the gain medium by using a fiber coupler, a dichroic mirror, a multiplexer, a wavelength division multiplexer, a grating, or a fused fiber coupler.

[0063] As used throughout this document, the term "super-continuum" and or "supercontinuum" and or "SC" refers to a broadband light beam or output that comprises a plurality of wavelengths. In a particular example, the plurality of wavelengths may be adjacent to one-another, so that the spectrum of the light beam or output appears as a continuous band when measured with a spectrometer. In one embodiment, the broadband light beam may have a bandwidth of at least 10 nm. In another embodiment, the "super-continuum" may be generated through nonlinear optical interactions in a medium, such as an optical fiber or nonlinear crystal. For example, the "super-continuum" may be generated through one or a combination of nonlinear activities such as four-wave mixing, the Raman effect, modulational instability, and self-phase modulation.

As used throughout this disclosure, the terms "optical light" and or "optical beam" and or "light beam" refer to photons or light transmitted to a particular location in space. The "optical light" and or "optical beam" and or "light beam" may be modulated or unmodulated. In one embodiment, the "optical light" and or "optical beam" and or "light beam" may originate from a fiber, a fiber laser, a laser, a light emitting diode, a lamp, a pump laser, or a light source. In general, the "near-infrared (NIR)" region of the electromagnetic spectrum covers between approximately 0.7 microns (700 nm) to about 2.5 microns (2500nm). However, it may also be advantageous to use just the short-wave infrared between approximately 1.4 microns (1400 nm) and about 2.5 microns (2500 nm). One reason for preferring the SWIR over the entire NIR may be to operate in the so-called "eye-safe" window, which corresponds to wavelengths longer than about 1400 nm. Therefore, for the remainder of the disclosure the SWIR will be used for illustrative purposes. However, it should be clear that the discussion that follows could also apply to using the NIR wavelength range, or other wavelength bands.

# Spectrum for Glucose

[0065] One molecule of interest is glucose. The glucose molecule has the chemical formula C<sub>6</sub>H<sub>12</sub>O<sub>6</sub>, so it has a number of hydro-carbon bonds. An example of the infrared transmittance of glucose 100 is illustrated in FIG. 1. The vibrational spectroscopy shows that the strongest lines for bending and stretching modes of C-H and O-H bonds lie in the wavelength range of approximately 6-12 microns. However, light sources and detectors are more difficult in

the mid-wave infrared and long-wave infrared, and there is also strongly increasing water absorption in the human body beyond about 2.5 microns. Although weaker, there are also non-linear combinations of stretching and bending modes between about 2 to 2.5 microns, and first overtone of C--H stretching modes between approximately 1.5-1.8 microns. These signatures may fall in valleys of water absorption, permitting non-invasive detection through the body. In addition, there are yet weaker features from the second overtones and higher-order combinations between about 0.8-1.2 microns; in addition to being weaker, these features may also be masked by absorption in the hemoglobin. Hence, the short-wave infrared (SWIR) wavelength range of approximately 1.4 to 2.5 microns may be an attractive window for near-infrared spectroscopy of blood constituents.

[0066] As an example, measurements of the optical absorbance 200 of hemoglobin, glucose and HbA1c have been performed using a Fourier-Transform Infrared Spectrometer-FTIR. As FIG. 2 shows, in the SWIR wavelength range hemoglobin is nearly flat in spectrum 201 (the noise at the edges is due to the weaker light signal in the measurements). On the other hand, the glucose absorbance 202 has at least five distinct peaks near 1587 nm, 1750 nm, 2120 nm, 2270 nm and 2320 nm.

FIG. 3A overlaps 300 the normalized absorbance of glucose 301 with the absorbance of water 302 (not drawn to scale). It may be seen that water has an absorbance feature between approximately 1850 nm and 2050 nm, but water 302 also has a nice transmission window between approximately 1500-1850 nm and 2050 to 2500 nm. For wavelengths less than about 1100 nm, the absorption of hemoglobin 351 and oxygenated hemoglobin 352 in FIG. 3B has a number of features 350, which may make it more difficult to measure blood constituents. Also, beyond 2500 nm the water absorption becomes considerably stronger over a wide wavelength range. Therefore, an advantageous window for measuring glucose and other blood constituents may be in the SWIR between 1500 and 1850 nm and 2050 to 2500 nm. These are exemplary wavelength ranges, and other ranges can be used that would still fall within the scope of this disclosure.

[0068] One further consideration in choosing the laser wavelength is known as the "eye safe" window for wavelengths longer than about 1400 nm. In particular, wavelengths in the eye

safe window may not transmit down to the retina of the eye, and therefore, these wavelengths may be less likely to create permanent eye damage. The near-infrared wavelengths have the potential to be dangerous, because the eye cannot see the wavelengths (as it can in the visible), yet they can penetrate and cause damage to the eye. Even if a practitioner is not looking directly at the laser beam, the practitioner's eyes may receive stray light from a reflection or scattering from some surface. Hence, it can always be a good practice to use eye protection when working around lasers. Since wavelengths longer than about 1400 nm are substantially not transmitted to the retina or substantially absorbed in the retina, this wavelength range is known as the eye safe window. For wavelengths longer than 1400 nm, in general only the cornea of the eye may receive or absorb the light radiation.

Beyond measuring blood constituents such as glucose using FTIR spectrometers, measurements have also been conducted in another embodiment using super-continuum lasers, which will be described later in this disclosure. In this particular embodiment, some of the exemplary preliminary data for glucose absorbance are illustrated in FIGS. 4A and 4B. The optical spectra 401 in FIG. 4A for different levels of glucose concentration in the wavelength range between 2000 and 2400 nm show the three absorption peaks near 2120 nm (2.12 μm), 2270 nm (2.27 μm) and 2320 nm (2.32 μm). Moreover, the optical spectra 402 in FIG. 4B for different levels of glucose concentration in the wavelength range between 1500 and 1800 nm show the two broader absorption peaks near 1587 nm and 1750 nm. It should be appreciated that although data measured with FTIR spectrometers or super-continuum lasers have been illustrated, other light sources can also be used to obtain the data, such as super-luminescent laser diodes, light emitting diodes, a plurality of laser diodes, or even bright lamp sources that generate adequate light in the SWIR.

[0070] Although glucose has a distinctive signature in the SWIR wavelength range, one problem of non-invasive glucose monitoring is that many other blood constituents also have hydro-carbon bonds. Consequently, there can be interfering signals from other constituents in the blood. As an example, FIG. 5 illustrates the spectrum 500 for different blood constituents in the wavelength range of 2 to 2.45 microns. The glucose absorption spectrum 501 can be unique with its three peaks in this wavelength range. However, other blood constituents such as triacetin 502, ascorbate 503, lactate 504, alanine 505, urea 506, and BSA 507 also have spectral features in this

wavelength range. To distinguish the glucose 501 from these overlapping spectra, it may be advantageous to have information at multiple wavelengths. In addition, it may be advantageous to use pattern matching algorithms and other software and mathematical methods to identify the blood constituents of interest. In one embodiment, the spectrum may be correlated with a library of known spectra to determine the overlap integrals, and a threshold function may be used to quantify the concentration of different constituents. This is just one way to perform the signal processing, and many other techniques, algorithms, and software may be used and would fall within the scope of this disclosure.

# Ketone Bodies Monitoring

[0071] Beyond glucose, there are many other blood constituents that may also be of interest for health or disease monitoring. In another embodiment, it may be desirous to monitor the level of ketone bodies in the blood stream. Ketone bodies are three water-soluble compounds that are produced as by-products when fatty acids are broken down for energy in the liver. Two of the three are used as a source of energy in the heart and brain, while the third is a waste product excreted from the body. In particular, the three endogenous ketone bodies are acetone, acetoacetic acid, and beta-hydroxybutyrate or 3-hydroxybutyrate, and the waste product ketone body is acetone.

[0072] Ketone bodies may be used for energy, where they are transported from the liver to other tissues. The brain may utilize ketone bodies when sufficient glucose is not available for energy. For instance, this may occur during fasting, strenuous exercise, low carbohydrate, ketogenic diet and in neonates. Unlike most other tissues that have additional energy sources such as fatty acids during periods of low blood glucose, the brain cannot break down fatty acids and relies instead on ketones. In one embodiment, these ketone bodies are detected.

[0073] Ketone bodies may also be used for reducing or eliminating symptoms of diseases or disorders characterized by impaired glucose metabolism. For example, diseases associated with reduced neuronal metabolism of glucose include Parkinson's disease, Alzheimer's disease, amyotrophic lateral sclerosis (ALS, also called Lou Gehrig's disease), Huntington's disease and epilepsy. In one embodiment, monitoring of alternate sources of ketone bodies that may be

administered orally as a dietary supplement or in a nutritional composition to counteract some of the glucose metabolism impairments is performed. However, if ketone bodies supplements are provided, there is also a need to monitor the ketone level in the blood stream. For instance, if elevated levels of ketone bodies are present in the body, this may lead to ketosis; hyperketonemia is also an elevated level of ketone bodies in the blood. In addition, both acetoacetic acid and beta-hydroxybutyric acid are acidic, and, if levels of these ketone bodies are too high, the pH of the blood may drop, resulting in ketoacidosis.

The general formula for ketones is  $C_nH_{2n0}$ . In organic chemistry, a ketone is an organic compound with the structure RC(==0)R', where R and R' can be a variety of carbon-containing substituents. It features a carbonyl group (C==0) bonded to two other carbon atoms. Because the ketones contain the hydrocarbon bonds, there might be expected to be features in the SWIR, similar in structure to those found for glucose.

[0075] The infrared spectrum 600 for the ketone 3-hydroxybutyrate is illustrated in FIG. 6. Just as in glucose, there are significant features in the mid- and long-wave infrared between 6 to 12 microns, but these may be difficult to observe non-invasively. On the other hand, there are some features in the SWIR that may be weaker, but they could potentially be observed non-invasively, perhaps through blood and water.

[0076] The optical spectra 700 for ketones as well as some other blood constituents are exemplified in FIG. 7 in the wavelength range of 2100 nm to 2400 nm. In this embodiment, the absorbance for ketones is 701, while the absorbance for glucose is 702. However, there are also features in this wavelength range for other blood constituents, such as urea 703, albumin or blood protein 704, creatinine 705, and nitrite 706. In this wavelength range of 2100 to 2400 nm, the features for ketone 701 seem more spectrally pronounced than even glucose.

[0077] Different signal processing techniques can be used to enhance the spectral differences between different constituents. In one embodiment, the first or second derivatives of the spectra may enable better discrimination between substances. The first derivative may help remove any flat offset or background, while the second derivative may help to remove any sloped offset or background. In some instances, the first or second derivative may be applied after curve

fitting or smoothing the reflectance, transmittance, or absorbance. For example, FIG. 8A illustrates the derivative spectra for ketone 801 and glucose 802, which can be distinguished from the derivative spectra for protein 803, urea 804 and creatinine 805. Based on FIG. 8A, it appears that ketones 801 may have a more pronounced difference than even glucose 802 in the wavelength range between 2100 and 2400 nm. Therefore, ketone bodies should also be capable of being monitored using a non-invasive optical technique in the SWIR, and a different pattern matching library could be used for glucose and ketones.

# Hemoglobin A1c Monitoring

[0078] Another blood constituent that may be of interest for monitoring of health or diseases is hemoglobin AIc, also known as HbAIc or glycated hemoglobin (glycol-hemoglobin or glycosylated hemoglobin). HbAIc is a form of hemoglobin that is measured primarily to identify the average plasma glucose concentration over prolonged periods of time. Thus, HbAIc may serve as a marker for average blood glucose levels over the previous months prior to the measurements.

In one embodiment, when a physician suspects that a patient may be diabetic, the measurement of HbA1c may be one of the first tests that are conducted. An HbA1c level less than approximately 6% may be considered normal. On the other hand, an HbA1c level greater than approximately 6.5% may be considered to be diabetic. In diabetes mellitus, higher amounts of HbA1c indicate poorer control of blood glucose levels. Thus, monitoring the HbA1c in diabetic patients may improve treatment. Current techniques for measuring HbA1c require drawing blood, which may be inconvenient and painful. The point-of-care devices use immunoassay or boronate affinity chromatography, as an example. Thus, there is also an unmet need for non-invasive monitoring of HbA1c.

[0080] FIG. 2 illustrates the FTIR measurements of HbA1c absorbance 203 over the wavelength range between 1500 and 2400 nm for a concentration of approximately 1 mg/ml. Whereas the absorbance of hemoglobin 201 over this wavelength range is approximately flat, the HbA1c absorbance 203 shows broad features and distinct curvature. Although the HbA1c absorbance 203 does not appear to exhibit as pronounced features as glucose 202, the non-

invasive SWIR measurement should be able to detect HbA1c with appropriate pattern matching algorithms. Moreover, the spectrum for HbA1c may be further enhanced by using first or second derivative data, as seen for ketones in FIG. 8A. Beyond absorption, reflectance, or transmission spectroscopy, it may also be possible to detect blood constituents such as HbA1c using Raman spectroscopy or surface-enhanced Raman spectroscopy. In general, Raman spectroscopy may require higher optical power levels.

[0081] As an illustration, non-invasive measurement of blood constituents such as glucose, ketone bodies, and HbA1c has been discussed thus far. However, other blood constituents can also be measured using similar techniques, and these are also intended to be covered by this disclosure. In other embodiments, blood constituents such as proteins, albumin, urea, creatinine or nitrites could also be measured. For instance, the same type of SWIR optical techniques might be used, but the pattern matching algorithms and software could use different library features or functions for the different constituents.

100821 In yet another embodiment, the optical techniques described in this disclosure could also be used to measure levels of triglycerides. Triglycerides are bundles of fats that may be found in the blood stream, particularly after ingesting meals. The body manufactures triglycerides from carbohydrates and fatty foods that are eaten. In other words, triglycerides are the body's storage form of fat. Triglycerides are comprised of three fatty acids attached to a glycerol molecule, and measuring the level of triglycerides may be important for diabetics. The triglyceride levels or concentrations in blood may be rated as follows: desirable or normal may be less than 150 mg/dl; borderline high may be 150-199 mg/dl; high may be 200-499 mg/dl; and very high may be 500 mg/dl or greater. FIG. 8B illustrates one example of the near-infrared absorbance 825 for triglycerides. There are distinct absorbance peaks in the spectrum that should be measurable. The characteristic absorption bands may be assigned as follows: (a) the first overtones of C--H stretching vibrations (1600-1900 nm); (b) the region of second overtones of C--H stretching vibrations (1100-1250 nm); and, (c) two regions (2000-2200 nm and 1350-1500 nm) that comprise bands due to combinations of C-H stretching vibrations and other vibrational modes.

[0083] A further example of blood compositions that can be detected or measured using near-infrared light includes cholesterol monitoring. For example, FIG. 8C shows the near-infrared reflectance spectrum for cholesterol 850 with wavelength in microns (μm). Distinct absorption peaks are observable near 1210 nm (1.21 μm), 1720 nm (1.72 μm), and between 2300-2500 nm (2.3-2.5 μm). Also, there are other features near 1450 nm (1.45 μm) and 2050 nm (2.05 μm). In FIG. 8D the near-infrared reflectances 875 are displayed versus wavelength (nm) for various blood constituents. The spectrum for cholesterol 876 is overlaid with glucose 877, albumin 878, uric acid 879, and urea 880. As may be noted from FIG. 8D, at about 1720 nm and 2300 nm, cholesterol 876 reaches approximate reflectance peaks, while some of the other analytes are in a more gradual mode. Various signal processing methods may be used to identify and quantify the concentration of cholesterol 876 and/or glucose 877, or some of the other blood constituents.

As illustrated by FIGS. 5 and 7, one of the issues in measuring a particular blood [0084] constituent is the interfering and overlapping signal from other blood constituents. The selection of the constituent of interest may be improved using a number of techniques. For example, a higher light level or intensity may improve the signal-to-noise ratio for the measurement. Second, mathematical modeling and signal processing methodologies may help to reduce the interference, such as multivariate techniques, multiple linear regression, and factor-based algorithms, for example. For instance, a number of mathematical approaches include multiple linear regression, partial least squares, and principal component regression (PCR). Also, as illustrated in FIG. 8A, various mathematical derivatives, including the first and second derivatives, may help to accentuate differences between spectra. In addition, by using a wider wavelength range and using more sampling wavelengths may improve the ability to discriminate one signal from another. Moreover, it may be advantageous to pulse the light source with a particular pulse width and pulse repetition rate, and then the detection system can measure the pulsed light returned from or transmitted through the tissue. Using a lock-in type technique (e.g., detecting at the same frequency as the pulsed light source and also possibly phase locked to the same signal), the detection system may be able to reject background or spurious signals and increase the signal-tonoise ratio of the measurement. In one particular embodiment, high signal-to-noise ratio may be achieved using a fiber-based super-continuum (SC) light source (described further herein). Other light sources may also be used, including a plurality of laser diodes, super-luminescent laser

diodes, or fiber lasers. In one embodiment, an all-fiber-integrated, high-powered SC light source may be elegant for its simplicity. The light may be first generated from a seed laser diode (LD). For example, the seed LD may be a distributed feedback (DFB) laser diode with a wavelength near 1542nm or 1550nm, with approximately 0.5–2.0ns pulsed output, and with a pulse repetition rate between one kilohertz and about 100MHz or more.

Beyond having a pulse width, the laser output can also have a preferred repetition rate. For pulse repetition rates above around 10MHz, where multiple pulses fall within a thermal diffusion time, the tissue response may be more related to the energy deposited or the fluence of the laser beam. The separation between pulses or a sub-group of pulses may also be selected so that the tissue sample can reach thermal equilibrium between pulses. Also, the pulse pattern may or may not be periodic. In one embodiment, there may be several pulses used per spot, where the pulse pattern is selected to obtain a desired thermal profile. The laser beam may then be moved to a new spot and then another pulse train delivered to that spot. In one embodiment, there can be several seconds of pre-cooling, the laser can be exposed on the tissue for several seconds, and then there may also be post-cooling. Although particular examples of laser duration and repetition rate are described, other values may also be used consistent with this disclosure. For example, depending on the application and mechanisms, the pulse rate could range all the way from continuous wave to 100°s of Megahertz.

[0086] The above are just examples of some of the methods of improving the ability to discriminate between different constituents, but other techniques may also be used and are intended to be covered by this disclosure.

[0087] In one embodiment, a SWIR camera or infrared camera system may be used to capture the images. The camera may include one or more lenses on the input, which may be adjustable. The focal plane assemblies may be made from mercury cadmium telluride material (HgCdTe), and the detectors may also include thermo-electric coolers. Alternately, the image sensors may be made from indium gallium arsenide (InGaAs), and CMOS transistors may be connected to each pixel of the InGaAs photodiode array. The camera may interface wirelessly or with a cable (e.g., USB, Ethernet cable, or fiber optics cable) to a computer or tablet or smart phone, where the images may be captured and processed. These are a few examples of infrared

cameras, but other SWIR or infrared cameras may be used and are intended to be covered by this disclosure.

By use of an active illuminator, a number of advantages may be achieved. First, the variations due to sunlight and time-of-day may be factored out. The effects of the weather, such as clouds and rain, might also be reduced. Also, higher signal-to-noise ratios may be achieved. For example, one way to improve the signal-to-noise ratio would be to use modulation and lock-in techniques. In one embodiment, the light source may be modulated, and then the detection system would be synchronized with the light source. In a particular embodiment, the techniques from lock-in detection may be used, where narrow band filtering around the modulation frequency may be used to reject noise outside the modulation frequency. In an alternate embodiment, change detection schemes may be used, where the detection system captures the signal with the light source on and with the light source off. Again, for this system the light source may be modulated. Then, the signal with and without the light source is differenced. This may enable the sun light changes to be subtracted out. In addition, change detection may help to identify objects that change in the field of view. In the following some exemplary detection systems are described.

# Interference from Skin

[0089] Several proposed non-invasive glucose monitoring techniques rely on transmission, absorption, and/or diffuse reflection through the skin to measure blood constituents or blood analytes in veins, arteries, capillaries or in the tissue itself. However, on top of the interference from other blood constituents or analytes, the skin also introduces significant interference. For example, chemical, structural, and physiological variations occur that may produce relatively large and nonlinear changes in the optical properties of the tissue sample. In one embodiment, the near-infrared reflectance or absorbance spectrum may be a complex combination of the tissue scattering properties that result from the concentration and characteristics of a multiplicity of tissue components including water, fat, protein, collagen, elastin, and/or glucose. Moreover, the optical properties of the skin may also change with environmental factors such as humidity, temperature and pressure. Physiological variation may also cause changes in the tissue measurement over time and may vary based on lifestyle, health,

aging, etc. The structure and composition of skin may also vary widely among individuals, between different sites within an individual, and over time on the same individual. Thus, the skin introduces a dynamic interference signal that may have a wide variation due to a number of parameters.

[0090] FIG. 9 shows a schematic cross-section of human skin 900, 901. The top layer of the skin is epidermis 902, followed by a layer of dermis 903 and then subcutaneous fat 904 below the dermis. The epidermis 902, with a thickness of approximately 10-150 microns, may provide a barrier to infection and loss of moisture and other body constituents. The dermis 903 ranges in thickness from approximately 0.5 mm to 4 mm (averages approximately 1.2 mm over most of the body) and may provide the mechanical strength and elasticity of skin.

In the dermis 903, water may account for approximately 70% of the volume. The next most abundant constituent in the dermis 903 may be collagen 905, a fibrous protein comprising 70-75% of the dry weight of the dermis 903. Elastin fibers 906, also a protein, may also be plentiful in the dermis 903, although they constitute a smaller portion of the bulk. In addition, the dermis 903 may contain a variety of structures (e.g., sweat glands, hair follieles with adipose rich sebaceous glands 907 near their roots, and blood vessels) and other cellular constituents.

Below the dermis 903 lies the subcutaneous layer 904 comprising mostly adipose tissue. The subcutaneous layer 904 may be by volume approximately 10% water and may be comprised primarily of cells rich in triglycerides or fat. With this complicated structure of the skin 900, 901, the concentration of glucose may vary in each layer according to a variety of factors including the water content, the relative sizes of the fluid compartments, the distribution of capillaries, the perfusion of blood, the glucose uptake of cells, the concentration of glucose in blood, and the driving forces (e.g., osmotic pressure) behind diffusion.

[0093] To better understand the interference that the skin introduces when attempting to measure glucose, the absorption coefficient for the various skin constituents should be examined. For example, FIG. 10 illustrates 1000 the absorption coefficients for water (including scattering) 1001, adipose 1002, collagen 1003 and elastin 1004. Note that the absorption curves for water

1001 and adipose 1002 are calibrated, whereas the absorption curves for collagen 1003 and elastin 1004 are in arbitrary units. Also shown are vertical lines demarcating the wavelengths near 1210 nm 1005 and 1720 nm 1006. In general, the water absorption increases with increasing wavelength. With the increasing absorption beyond about 2000 nm, it may be difficult to achieve deeper penetration into biological tissue in the infrared wavelengths beyond approximately 2500 nm.

Although the absorption coefficient may be useful for determining the material in which light of a certain infrared wavelength will be absorbed, to determine the penetration depth of the light of a certain wavelength may also require the addition of scattering loss to the curves. For example, the water curve 1001 includes the scattering loss curve in addition to the water absorption. In particular, the scattering loss can be significantly higher at shorter wavelengths. In one embodiment, near the wavelength of 1720 nm (vertical line 1006 shown in FIG. 10), the adipose absorption 1002 can still be higher than the water plus scattering loss 1001. For tissue that contains adipose, collagen and elastin, such as the dermis of the skin, the total absorption can exceed the light energy lost to water absorption and light scattering at 1720 nm. On the other hand, at 1210 nm the adipose absorption 1002 can be considerably lower than the water plus scattering loss 1001, particularly since the scattering loss can be dominant at these shorter wavelengths.

The interference for glucose lines observed through skin may be illustrated by overlaying the glucose lines over the absorption curves 1000 for the skin constituents. For example, FIG. 2 illustrated that the glucose absorption 202 included features centered around 1587 nm, 1750 nm, 2120 nm, 2270 nm and 2320 nm. On FIG. 10 vertical lines have been drawn at the glucose line wavelengths of 1587 nm 1007, 1750 nm 1008, 2120 nm 1009, 2270 nm 1010 and 2320 nm 1011. In one embodiment, it may be difficult to detect the glucose lines near 1750 nm 1008, 2270 nm 1010 and 2320 nm 1011 due to significant spectral interference from other skin constituents. On the other hand, the glucose line near 1587m 1007 may be more easily detected because it peaks while most of the other skin constituents are sloped downward toward an absorption valley. Moreover, the glucose line near 2120 nm 1009 may also be detectable for similar reasons, although adipose may have conflicting behavior due to local absorption minimum and maximum nearby in wavelength.

Thus, beyond the problem of other blood constituents or analytes having overlapping spectral features (e.g., FIG. 5), it may be difficult to observe glucose spectral signatures through the skin and its constituents of water, adipose, collagen and elastin. One approach to overcoming this difficulty may be to try to measure the blood constituents in veins that are located at relatively shallow distances below the skin. Veins may be more beneficial for the measurement than arteries, since arteries tend to be located at deeper levels below the skin. Also, in one embodiment it may be advantageous to use a differential measurement to subtract out some of the interfering absorption lines from the skin. For example, an instrument head may be designed to place one probe above a region of skin over a blood vein, while a second probe may be placed at a region of the skin without a noticeable blood vein below it. Then, by differencing the signals from the two probes, at least part of the skin interference may be cancelled out.

100971 Two representative embodiments for performing such a differential measurement are illustrated in FIG. 11 and FIG. 12. In one embodiment shown in FIG. 11, the dorsal of the hand 1100 may be used for measuring blood constituents or analytes. The dorsal of the hand 1100 may have regions that have distinct veins 1101 as well as regions where the veins are not as shallow or pronounced 1102. By stretching the hand and leaning it backwards, the veins 1101 may be accentuated in some cases. A near-infrared diffuse reflectance measurement may be performed by placing one probe 1103 above the vein-rich region 1101. To turn this into a differential measurement, a second probe 1104 may be placed above a region without distinct veins 1102. Then, the outputs from the two probes may be subtracted 1105 to at least partially cancel out the features from the skin. The subtraction may be done preferably in the electrical domain, although it can also be performed in the optical domain or digitally/mathematically using sampled data based on the electrical and/or optical signals. Although one example of using the dorsal of the hand 1100 is shown, many other parts of the hand can be used within the scope of this disclosure. For example, alternate methods may use transmission through the webbing between the thumb and the fingers 1106, or transmission or diffuse reflection through the tips of the fingers 1107.

[0098] In another embodiment, the dorsal of the foot 1200 may be used instead of the hand. One advantage of such a configuration may be that for self-testing by a user, the foot may

be easier to position the instrument using both hands. One probe 1203 may be placed over regions where there are more distinct veins 1201, and a near-infrared diffuse reflectance measurement may be made. For a differential measurement, a second probe 1204 may be placed over a region with less prominent veins 1202, and then the two probe signals may be subtracted, either electronically or optically, or may be digitized/sampled and processed mathematically depending on the particular application and implementation. As with the hand, the differential measurements may be intended to compensate for or subtract out (at least in part) the interference from the skin. Since two regions are used in close proximity on the same body part, this may also aid in removing some variability in the skin from environmental effects such as temperature, humidity, or pressure. In addition, it may be advantageous to first treat the skin before the measurement, by perhaps wiping with a cloth or treated cotton ball, applying some sort of cream, or placing an ice cube or chilled bag over the region of interest.

[0099] Although two embodiments have been described, many other locations on the body may be used using a single or differential probe within the scope of this disclosure. In yet another embodiment, the wrist may be advantageously used, particularly where a pulse rate is typically monitored. Since the pulse may be easily felt on the wrist, there is underlying the region a distinct blood flow. Other embodiments may use other parts of the body, such as the ear lobes, the tongue, the inner lip, the nails, the eye, or the teeth. Some of these embodiments will be further described below. The ear lobes or the tip of the tongue may be advantageous because they are thinner skin regions, thus permitting transmission rather than diffuse reflection. However, the interference from the skin is still a problem in these embodiments. Other regions such as the inner lip or the bottom of the tongue may be contemplated because distinct veins are observable, but still the interference from the skin may be problematic in these embodiments. The eye may seem as a viable alternative because it is more transparent than skin. However, there are still issues with scattering in the eye. For example, the anterior chamber of the eye (the space between the cornea and the iris) comprises a fluid known as aqueous humor. However, the glucose level in the eye chamber may have a significant temporal lag on changes in the glucose level compared to the blood glucose level.

[0100] In some instances, it may be desirable to create multiple locations of focused light. One way to accomplish this may be to slide the assemblies and/or the light source. In yet another

embodiment shown in FIGURE 13A, multiple collimated or focused light beams may be created in one assembly 1320. In this embodiment, optionally a surface cooling apparatus 1324 may be used, where a cooling fluid may be flowed either touching or in close proximity to the skin 1321. Also, in this particular embodiment a cylindrical assembly may optionally be used, where the cylindrical length may be several millimeters in length and defined by a clamp or mount 1323 placed on or near the leg. The light input 1327 may be received from a light source, which may use a fiber or fiber bundles to couple the light to the lens/mirror assembly 1326. A lens and/or mirror assembly 1326 may be used to couple the light input 1327 to the lenslet array or window 1325, either directly or indirectly. The lens and/or mirror assembly 1326 may also be coupled to the clamp or mount assembly 1323.

In the embodiment of FIGURE 13A, a window and/or lenslet array 1325 is also shown on the cylindrical surface for permitting the light to be incident on the skin 1321 and varicose vein 1322 at multiple spots. The lenslet array 1325 may comprise circular, spherical or cylindrical lenses, depending on the type of spots desired. As before, one advantage of placing the lenslet array 1325 in close proximity to the skin 1321 may be that a high NA lens may be used. Also, the input from the lens and/or mirror assembly to the lenslet array 1325 may be a single large beam, or a plurality of smaller beams. In one embodiment, a plurality of spots may be created by the lenslet array 1325. Although four spots are shown in FIGURE 13A, any number of spots may be used and are intended to be covered by this disclosure.

[0102] Different combinations of these techniques may be employed, and other techniques may also be used and are intended to be covered by this disclosure. For example, in some instances only focused light may be used, in other instances only surface cooling or cryogenic sprays may be used, and in yet other embodiments a combination of the two may be used. Moreover, the clamps, mounts and holders are shown in simple design for illustrative purposes, but human factors engineering may be used to make these more user friendly or ergonomic design. These and other variations are also intended to be covered by this disclosure.

[0103] The lens and/or mirror assemblies may comprise one or more lenses, microscope objectives, curved or flat mirrors, lens tipped fibers, or some combination of these elements. As an example, the optics such as used in a camera may be employed in this arrangement, provided

that the optics are substantially transparent at the light wavelengths being used. Moreover, reflections and losses through the optics may be reduced by applying anti-reflection coatings, and chromatic dispersion may be reduced by using reflective optics rather than refractive optics. Although a particular method of focusing the light has been described, other methods may also be used and are intended to be covered by this disclosure.

Because of the complexity of the interference from skin in non-invasive glucose monitoring (e.g., FIG. 10), other parts of the body without skin above blood vessels or capitlaries may be alternative candidates for measuring blood constituents. One embodiment may involve transmission or reflection through human nails. As an example, FIG. 13B illustrates a typical human nail tissue structure 1300 and the capillary vessels below it. The fingernail 1301 is approximately 1 mm thick, and below this resides a layer of epidermis 1302 with a thickness of approximately 1 mm. The dermis 1304 is also shown, and within particularly the top about 0.5 mm of dermis are a significant number of capillary vessels. To measure the blood constituents, the light exposed on the top of the fingernail must penetrate about 2-2.5 mm or more, and the reflected light (round trip passage) should be sufficiently strong to measure. In one embodiment, the distance required to penetrate could be reduced by drilling a hole in the fingernail 1301.

In this alternative embodiment using the fingernail, there may still be interference from the nail's spectral features. For example, FIG. 14 illustrates the attenuation coefficient 1400 for seven nail samples that are allowed to stand in an environment with a humidity level of 14%. These coefficients are measured using an FTIR spectrometer over the near-infrared wavelength range of approximately 1 to 2.5 microns. These spectra are believed to correspond to the spectra of keratin contained in the nail plate. The base lines for the different samples are believed to differ because of the influence of scattering. Several of the absorption peaks observed correspond to peaks of keratin absorption, while other features may appear from the underlying epidermis and dermis. It should also be noted that the attenuation coefficients 1400 also vary considerably depending on humidity level or water content as well as temperature and other environmental factors. Moreover, the attenuation coefficient may also change in the presence of nail polish of various sorts.

[0106] Similar to skin, the large variations in attenuation coefficient for fingernails also may interfere with the absorption peaks of glucose. As an example, in FIG. 14 below the fingernail spectrum is also shown the glucose spectrum 1401 for two different glucose concentrations. The vertical lines 1402, 1403, 1404, 1405 and 1406 are drawn to illustrate the glucose absorption peaks and where they lie on the fingernail spectra 1400. As is apparent, the nail has interfering features that may be similar to skin, particularly since both have spectra that vary not only in wavelength but also with environmental factors. In one embodiment, it may be possible to see the glucose peaks 1402 and 1404 through the fingernail, but it may be much more difficult to observe the glucose peaks near 1403, 1405 and 1406.

# Transmission or Reflection Through Teeth

Yet another embodiment may observe the transmittance or reflectance through teeth to measure blood constituents or analytes. FIG. 15 illustrates an exemplary structure of a tooth 1500. The tooth 1500 has a top layer called the crown 1501 and below that a root 1502 that reaches well into the gum 1506 and bone 1508 of the mouth. The exterior of the crown 1501 is an enamel layer 1503, and below the enamel is a layer of dentine 1504 that sits atop a layer of cementum 1507. Below the dentine 1504 is a pulp region 1505, which comprises within it blood vessels 1509 and nerves 1510. If the light can penetrate the enamel 1503 and dentine 1504, then the blood flow and blood constituents can be measured through the blood vessels in the dental pulp 1505. While it may be true that the amount of blood flow in the dental pulp 1505 may be less since it comprises capillaries, the smaller blood flow could still be advantageous if there is less interfering spectral features from the tooth.

[0108] The transmission, absorption and reflection from teeth has been studied in the near infrared, and, although there are some features, the enamel and dentine appear to be fairly transparent in the near infrared (particularly wavelengths between 1500 and 2500 nm). For example, the absorption or extinction ratio for light transmission has been studied. FIG. 16A illustrates the attenuation coefficient 1600 for dental enamel 1601 (filled circles) and the absorption coefficient of water 1602 (open circles) versus wavelength. Near-infrared light may penetrate much further without scattering through all the tooth enamel, due to the reduced scattering coefficient in normal enamel. Scattering in enamel may be fairly strong in the visible,

but decreases as approximately 1/wavelength<sup>3</sup> (i.e., inverse of the wavelength cubed) with increasing wavelength to a value of only 2-3 cm<sup>-1</sup> at 1310 nm and 1550 nm in the near infrared. Therefore, enamel may be virtually transparent in the near infrared with optical attenuation 1-2 orders of magnitude less than in the visible range.

As another example, FIG. 16B illustrates the absorption spectrum 1650 of intact enamel 1651 (dashed line) and dentine 1652 (solid line) in the wavelength range of approximately 1.2 to 2.4 microns. In the near infrared there are two absorption bands around 1.5 and 2 microns. The band with a peak around 1.57 microns may be attributed to the overtone of valent vibration of water present in both enamel and dentine. In this band, the absorption is greater for dentine than for enamel, which may be related to the large water content in this tissue. In the region of 2 microns, dentine may have two absorption bands, and enamel one. The band with a maximum near 2.1 microns may belong to the overtone of vibration of PO hydroxyapatite groups, which is the main substance of both enamel and dentine. Moreover, the band with a peak near 1.96 microns in dentine may correspond to water absorption (dentine may contain substantially higher water than enamel).

[0110] In addition to the absorption coefficient, the reflectance from intact teeth and teeth with dental caries (e.g., cavities) has been studied. In one embodiment, FIG. 17 shows the near infrared spectral reflectance 1700 over the wavelength range of approximately 800 nm to 2500 nm from an occlusal (e.g., top/bottom) tooth surface 1704. The curve with black diamonds 1701 corresponds to the reflectance from a sound, intact tooth section. The curve with asterisks \* 1702 corresponds to a tooth section with an enamel lesion. The curve with circles 1703 corresponds to a tooth section with a dentine lesion. Thus, when there is a lesion, more scattering occurs and there may be an increase in the reflected light.

[0111] For wavelengths shorter than approximately 1400 nm, the shapes of the spectra remain similar, but the amplitude of the reflection changes with lesions. Between approximately 1400 nm and 2500 nm, an intact tooth 1701 has low reflectance (e.g., high transmission), and the reflectance appears to be more or less independent of wavelength. On the other hand, in the presence of lesions 1702 and 1703, there is increased scattering, and the scattering loss may be wavelength dependent. For example, the scattering loss may decrease as 1/(wavelength)<sup>3</sup>--so, the

scattering loss decreases with longer wavelengths. When there is a lesion in the dentine 1703, more water can accumulate in the area, so there is also increased water absorption. For example, the dips near 1450 nm and 1900 nm correspond to water absorption, and the reflectance dips are particularly pronounced in the dentine lesion 1703. One other benefit of the absorption, transmission or reflectance in the near infrared may be that stains and non-calcified plaque are not visible in this wavelength range, enabling better discrimination of defects, cracks, and demineralized areas.

[0112] Compared with the interference from skin 1000 in FIG. 10 or fingernails 1400 in FIG. 14, the teeth appear to introduce much less interference for non-invasive monitoring of blood constituents. The few features in FIG. 16B or 17 may be calibrated out of the measurement. Also, using an intact tooth 1701 may further minimize any interfering signals. Furthermore, since the tooth comprises relatively hard tissue, higher power from the light sources in the near infrared may be used without damaging the tissue, such as with skin.

## Human Interface for Measurement System

A number of different types of measurements may be used to sample the blood in the dental pulp. The basic feature of the measurements should be that the optical properties are measured as a function of wavelength at a plurality of wavelengths. As further described below, the light source may output a plurality of wavelengths, or a continuous spectrum over a range of wavelengths. In a preferred embodiment, the light source may cover some or all of the wavelength range between approximately 1400 nm and 2500 nm. The signal may be received at a receiver, which may also comprise a spectrometer or filters to discriminate between different wavelengths. The signal may also be received at a camera, which may also comprise filters or a spectrometer. In an alternate embodiment, the spectral discrimination using filters or a spectrometer may be placed after the light source rather than at the receiver. The receiver usually comprises one or more detectors (optical-to-electrical conversion element) and electrical circuitry. The receiver may also be coupled to analog to digital converters, particularly if the signal is to be fed to a digital device.

[0114] Referring to FIG. 15, one or more light sources 1511 may be used for illumination. In one embodiment, a transmission measurement may be performed by directing the light source output 1511 to the region near the interface between the gum 1506 and dentine 1504. In one embodiment, the light may be directed using a light guide or a fiber optic. The light may then propagate through the dental pulp 1505 to the other side, where the light may be incident on one or more detectors or another light guide to transport the signal to a spectrometer, receiver or camera 1512. In another embodiment, the light source may be directed to one or more locations near the interface between the gum 1506 and dentine 1504 (in one example, could be from the two sides of the tooth). The transmitted light may then be detected in the occlusal surface above the tooth using a spectrometer, receiver, or camera 1512. In yet another embodiment, a reflectance measurement may be conducted by directing the light source output 1511 to, for example, the occlusal surface of the tooth, and then detecting the reflectance at a spectrometer, receiver or camera 1513. Although a few embodiments for measuring the blood constituents through a tooth are described, other embodiments and techniques may also be used and are intended to be covered by this disclosure.

[0115] The human interface for the non-invasive measurement of blood constituents may be of various forms. In one embodiment, a "clamp" design 1800 may be used cap over one or more teeth, as illustrated in FIG. 18A. The clamp design may be different for different types of teeth, or it may be flexible enough to fit over different types of teeth. For example, different types of teeth include the molars (toward the back of the mouth), the premolars, the canine, and the incisors (toward the front of the mouth). One embodiment of the clamp-type design is illustrated in FIG. 18A for a molar tooth 1808. The C-clamp 1801 may be made of a plastic or rubber material, and it may comprise a light source input 1802 and a detector output 1803 on the front or back of the tooth.

[0116] The light source input 1802 may comprise a light source directly, or it may have light guided to it from an external light source. Also, the light source input 1802 may comprise a lens system to collimate or focus the light across the tooth. The detector output 1803 may comprise a detector directly, or it may have a light guide to transport the signal to an external detector element. The light source input 1802 may be coupled electrically or optically through 1804 to a light input 1806. For example, if the light source is external in 1806, then the coupling

element 1804 may be a light guide, such as a fiber optic. Alternately, if the light source is contained in 1802, then the coupling element 1804 may be electrical wires connecting to a power supply in 1806. Similarly, the detector output 1803 may be coupled to a detector output unit 1807 with a coupling element 1805, which may be one or more electrical wires or a light guide, such as a fiber optic. This is just one example of a clamp over one or more teeth, but other embodiments may also be used and are intended to be covered by this disclosure.

[0117] In yet another embodiment, one or more light source ports and sensor ports may be used in a mouth-guard type design. For example, one embodiment of a dental mouth guard 1850 is illustrated in FIG. 18B. The structure of the mouth guard 1851 may be similar to mouth guards used in sports (e.g., when playing football or boxing) or in dental trays used for applying fluoride treatment, and the mouth guard may be made from plastic or rubber materials, for example. As an example, the mouth guard may have one or more light source input ports 1852, 1853 and one or more detector output ports 1854, 1855. Although six input and output ports are illustrated, any number of ports may be used.

[0118] Similar to the clamp design described above, the light inputs 1852, 1853 may comprise one or more light sources directly, or they may have light guided to them from an external light source. Also, the light source inputs 1852, 1853 may comprise lens systems to collimate or focus the light across the teeth. The detector outputs 1854, 1855 may comprise one or more detectors directly, or they may have one or more light guides to transport the signals to an external detector element. The light source inputs 1852, 1853 may be coupled electrically or optically through 1856 to a light input 1857. For example, if the light source is external in 1857, then the one or more coupling elements 1856 may be one or more light guides. such as a fiber optic. Alternately, if the light sources are contained in 1852, 1853, then the coupling element 1856 may be one or more electrical wires connecting to a power supply in 1857. Similarly, the detector outputs 1854, 1855 may be coupled to a detector output unit 1859 with one or more coupling elements 1858, which may be one or more electrical wires or one or more light guides, such as a liber optic. This is just one example of a mouth guard design covering a plurality of teeth, but other embodiments may also be used and are intended to be covered by this disclosure. For instance, the position of the light source inputs and detector output ports could be exchanged, or some mixture of locations of light source inputs and detector output ports could be used.

Also, if reflectance from the teeth is to be measured, then the light sources and detectors may be on the same side of the tooth. Moreover, it may be advantageous to pulse the light source with a particular pulse width and pulse repetition rate, and then the detection system can measure the pulsed light returned from or transmitted through the tooth. Using a lock-in type technique (e.g., detecting at the same frequency as the pulsed light source and also possibly phase locked to the same signal), the detection system may be able to reject background or spurious signals and increase the signal-to-noise ratio of the measurement.

Other elements may be added to the human interface designs of FIG. 18 and are also intended to be covered by this disclosure. For instance, in one embodiment it may be desirable to have replaceable inserts that may be disposable. Particularly in a doctor's office or hospital setting, the same instrument may be used with a plurality of patients. Rather than disinfecting the human interface after each use, it may be preferable to have disposable inserts that can be thrown away after each use. In one embodiment, a thin plastic coating material may enclose the clamp design of FIG. 18A or mouth guard design of FIG. 18B. The coating material may be inserted before each use, and then after the measurement is exercised the coating material may be peeled off and replaced. Such a design may save the physician or user considerable time, while at the same time provide the business venture with a recurring cost revenue source. Any coating material or other disposable device may be constructed of a material having suitable optical properties that may be considered during processing of the signals used to detect any anomalies in the teeth.

## Light Sources for Near Infrared

[0121] In general, the near-infrared (NIR) region of the electromagnetic spectrum covers between approximately 0.7 microns (700 nm) to about 2.5 microns (2500nm). However, it may also be advantageous to use just the short-wave infrared between approximately 1.4 microns (1400 nm) and about 2.5 microns (2500 nm). One reason for preferring the SWIR over the entire NIR may be to operate in the so-called "eye-safe" window, which corresponds to wavelengths

longer than about 1400 nm. While the SWIR is used for illustrative purposes, it should be clear that the discussion that follows could also apply to using the NIR wavelength range, or other wavelength bands. There are a number of light sources that may be used in the near infrared. To be more specific, the discussion below will consider light sources operating in the so-called short wave infrared (SWIR), which may cover the wavelength range of approximately 1400 nm to 2500 nm. Other wavelength ranges may also be used for the applications described in this disclosure, so the discussion below is merely provided for exemplary types of light sources. The SWIR wavelength range may be valuable for a number of reasons. First, the SWIR corresponds to a transmission window through water and the atmosphere. For example, 302 in FIG. 3A and 1602 in FIG. 16A illustrate the water transmission windows. Also, through the atmosphere, wavelengths in the SWIR have similar transmission windows due to water vapor in the atmosphere. Second, the so-called "eye-safe" wavelengths are wavelengths longer than approximately 1400 nm. Third, the SWIR covers the wavelength range for nonlinear combinations of stretching and bending modes as well as the first overtone of C--H stretching modes. Thus, for example, glucose and ketones among other substances may have unique signatures in the SWIR. Moreover, many solids have distinct spectral signatures in the SWIR, so particular solids may be identified using stand-off detection or remote sensing. For instance, many explosives have unique signatures in the SWIR.

Different light sources may be selected for the SWIR based on the needs of the application. Some of the features for selecting a particular light source include power or intensity, wavelength range or bandwidth, spatial or temporal coherence, spatial beam quality for focusing or transmission over long distance, and pulse width or pulse repetition rate. Depending on the application, lamps, light emitting diodes (LEDs), laser diodes (LD's), tunable LD's, super-luminescent laser diodes (SLDs), fiber lasers or super-continuum sources (SC) may be advantageously used. Also, different fibers may be used for transporting the light, such as fused silica fibers, plastic fibers, mid-infrared fibers (e.g., tellurite, chalcogenides, fluorides, ZBLAN, etc), or a hybrid of these fibers.

[0123] Lamps may be used if low power or intensity of light is required in the SWIR, and if an incoherent beam is suitable. In one embodiment, in the SWIR an incandescent lamp that can be used is based on tungsten and halogen, which have an emission wavelength between

approximately 500 nm to 2500 nm. For low intensity applications, it may also be possible to use thermal sources, where the SWIR radiation is based on the black body radiation from the hot object. Although the thermal and lamp based sources are broadband and have low intensity fluctuations, it may be difficult to achieve a high signal-to-noise ratio in a non-invasive blood constituent measurement due to the low power levels. Also, the lamp based sources tend to be energy inefficient.

In another embodiment, LED's can be used that have a higher power level in the SWIR wavelength range. LED's also produce an incoherent beam, but the power level can be higher than a lamp and with higher energy efficiency. Also, the LED output may more easily be modulated, and the LED provides the option of continuous wave or pulsed mode of operation. LED's are solid state components that emit a wavelength band that is of moderate width, typically between about 20 nm to 40 nm. There are also so-called super-luminescent LEDs that may even emit over a much wider wavelength range. In another embodiment, a wide band light source may be constructed by combining different LEDs that emit in different wavelength bands, some of which could preferably overlap in spectrum. One advantage of LEDs as well as other solid state components is the compact size that they may be packaged into.

In yet another embodiment, various types of laser diodes may be used in the SWIR wavelength range. Just as LEDs may be higher in power but narrower in wavelength emission than lamps and thermal sources, the LDs may be yet higher in power but yet narrower in wavelength emission than LEDs. Different kinds of LDs may be used, including Fabry-Perot LDs, distributed feedback (DFB) LDs, distributed Bragg reflector (DBR) LDs. Since the LDs have relatively narrow wavelength range (typically under 10 nm), in one embodiment a plurality of LDs may be used that are at different wavelengths in the SWIR. For example, in a preferred embodiment for non-invasive glucose monitoring, it may be advantageous to use LDs having emission spectra near some or all of the glucose spectral peaks (e.g., near 1587 nm, 1750 nm, 2120 nm, 2270 nm, and 2320 nm). The various LDs may be spatially multiplexed, polarization multiplexed, wavelength multiplexed, or a combination of these multiplexing methods. Also, the LDs may be fiber pig-tailed or have one or more lenses on the output to collimate or focus the light. Another advantage of LDs is that they may be packaged compactly and may have a spatially coherent beam output. Moreover, tunable LDs that can tune over a range of wavelengths are also

available. The tuning may be done by varying the temperature, or electrical current may be used in particular structures, such as distributed Bragg reflector LDs. In another embodiment, external cavity LDs may be used that have a tuning element, such as a fiber grating or a bulk grating, in the external cavity.

In another embodiment, super-luminescent laser diodes may provide higher power as well as broad bandwidth. An SLD is typically an edge emitting semiconductor light source based on super-luminescence (e.g., this could be amplified spontaneous emission). SLDs combine the higher power and brightness of LDs with the low coherence of conventional LEDs, and the emission band for SLD's may be 5 to 100 nm wide, preferably in the 60 to 100 nm range. Although currently SLDs are commercially available in the wavelength range of approximately 400 nm to 1700 nm, SLDs could and may in the future be made to cover a broader region of the SWIR.

[0127] In yet another embodiment, high power LDs for either direct excitation or to pump fiber lasers and SC light sources may be constructed using one or more laser diode bar stacks. As an example, FIG. 19 shows an example of the block diagram 1900 or building blocks for constructing the high power LDs. In this embodiment, one or more diode bar stacks 1901 may be used, where the diode bar stack may be an array of several single emitter LDs. Since the fast axis (e.g., vertical direction) may be nearly diffraction limited while the slow-axis (e.g., horizontal axis) may be far from diffraction limited, different collimators 1902 may be used for the two axes.

Then, the brightness may be increased by spatially combining the beams from multiple stacks 1903. The combiner may include spatial interleaving, it may include wavelength multiplexing, or it may involve a combination of the two. Different spatial interleaving schemes may be used, such as using an array of prisms or mirrors with spacers to bend one array of beams into the beam path of the other. In another embodiment, segmented mirrors with alternate high-reflection and anti-reflection coatings may be used. Moreover, the brightness may be increased by polarization beam combining 1904 the two orthogonal polarizations, such as by using a polarization beam splitter. In one embodiment, the output may then be focused or coupled into a large diameter core fiber. As an example, typical dimensions for the large diameter core fiber range from approximately 100 microns in diameter to 400 microns or more. Alternatively or in addition, a custom beam shaping module 1905 may be used, depending on the particular

application. For example, the output of the high power LD may be used directly 1906, or it may be fiber coupled 1907 to combine, integrate, or transport the high power LD energy. These high power LDs may grow in importance because the LD powers can rapidly scale up. For example, instead of the power being limited by the power available from a single emitter, the power may increase in multiples depending on the number of diodes multiplexed and the size of the large diameter fiber. Although FIG. 19 is shown as one embodiment, some or all of the elements may be used in a high power LD, or additional elements may also be used.

### SWIR Super-Continuum Lasers

Each of the light sources described above have particular strengths, but they also may have limitations. For example, there is typically a trade-off between wavelength range and power output. Also, sources such as lamps, thermal sources, and LEDs produce incoherent beams that may be difficult to focus to a small area and may have difficulty propagating for long distances. An alternative source that may overcome some of these limitations is an SC light source. Some of the advantages of the SC source may include high power and intensity, wide bandwidth, spatially coherent beam that can propagate nearly transform limited over long distances, and easy compatibility with fiber delivery.

[0130] Supercontinuum lasers may combine the broadband attributes of lamps with the spatial coherence and high brightness of lasers. By exploiting a modulational instability initiated supercontinuum (SC) mechanism, an all-fiber-integrated SC laser with no moving parts may be built using commercial-off-the-shelf (COTS) components. Moreover, the fiber laser architecture may be a platform where SC in the visible, near-infrared/SWIR, or mid-IR can be generated by appropriate selection of the amplifier technology and the SC generation fiber. But until now, SC lasers were used primarily in laboratory settings since typically large, table-top, mode-locked lasers were used to pump nonlinear media such as optical fibers to generate SC light. However, those large pump lasers may now be replaced with diode lasers and fiber amplifiers that gained maturity in the telecommunications industry.

[0131] In one embodiment, an all-fiber-integrated, high-powered SC light source 2000 may be elegant for its simplicity (FIG. 20). The light may be first generated from a seed laser

diode 2001. For example, the seed LD 2001 may be a distributed feedback laser diode with a wavelength near 1542 or 1550 nm, with approximately 0.5-2.0 ns pulsed output, and with a pulse repetition rate between a kilohertz to about 100 MHz or more. The output from the seed laser diode may then be amplified in a multiple-stage fiber amplifier 2002 comprising one or more gain fiber segments. In one embodiment, the first stage pre-amplifier 2003 may be designed for optimal noise performance. For example, the pre-amplifier 2003 may be a standard erbium-doped fiber amplifier or an erbium/ytterbium doped cladding pumped fiber amplifier. Between amplifier stages 2003 and 2006, it may be advantageous to use band-pass filters 2004 to block amplified spontaneous emission and isolators 2005 to prevent spurious reflections. Then, the power amplifier stage 2006 may use a cladding-pumped fiber amplifier that may be optimized to minimize nonlinear distortion. The power amplifier fiber 2006 may also be an erbium-doped fiber amplifier, if only low or moderate power levels are to be generated.

[0132] The SC generation 2007 may occur in the relatively short lengths of fiber that follow the pump laser. In one exemplary embodiment, the SC fiber length may range from a few millimeters to 100m or more. In one embodiment, the SC generation may occur in a first fiber 2008 where the modulational-instability initiated pulse break-up primarily occurs, followed by a second fiber 2009 where the SC generation and spectral broadening primarily occurs.

In one embodiment, one or two meters of standard single-mode fiber (SMF) after the power amplifier stage may be followed by several meters of SC generation fiber. For this example, in the SMF the peak power may be several kilowatts and the pump light may fall in the anomalous group-velocity dispersion regime--often called the soliton regime. For high peak powers in the dispersion regime, the nanosecond pulses may be unstable due to a phenomenon known as modulational instability, which is basically parametric amplification in which the fiber nonlinearity helps to phase match the pulses. As a consequence, the nanosecond pump pulses may be broken into many shorter pulses as the modulational instability tries to form soliton pulses from the quasi-continuous-wave background. Although the laser diode and amplification process starts with approximately nanosecond-long pulses, modulational instability in the short length of SMF fiber may form approximately 0.5 ps to several-picosecond-long pulses with high intensity. Thus, the few meters of SMF fiber may result in an output similar to that produced by mode-locked lasers, except in a much simpler and cost-effective manner.

The short pulses created through modulational instability may then be coupled into a nonlinear fiber for SC generation. The nonlinear mechanisms leading to broadband SC may include four-wave mixing or self-phase modulation along with the optical Raman effect. Since the Raman effect is self-phase-matched and shifts light to longer wavelengths by emission of optical photons, the SC may spread to longer wavelengths very efficiently. The short-wavelength edge may arise from four-wave mixing, and often times the short wavelength edge may be limited by increasing group-velocity dispersion in the fiber. In many instances, if the particular fiber used has sufficient peak power and SC fiber length, the SC generation process may fill the long-wavelength edge up to the transmission window.

Mature fiber amplifiers for the power amplifier stage 2006 include ytterbium-doped fibers (near 1060 nm), erbium-doped fibers (near 1550 nm), erbium/ytterbium-doped fibers (near 1550 nm), or thulium-doped fibers (near 2000 nm). In various embodiments, candidates for SC fiber 2009 include fused silica fibers (for generating SC between 0.8-2.7  $\mu$ m), mid-IR fibers such as fluorides, chalcogenides, or tellurites (for generating SC out to 4.5  $\mu$ m or longer), photonic crystal fibers (for generating SC between 0.4 and 1.7  $\mu$ m), or combinations of these fibers. Therefore, by selecting the appropriate fiber-amplifier doping for 2006 and nonlinear fiber 2009, SC may be generated in the visible, near-IR/SWIR, or mid-IR wavelength region.

[0136] The configuration 2000 of FIG. 20 is just one particular example, and other configurations can be used and are intended to be covered by this disclosure. For example, further gain stages may be used, and different types of lossy elements or fiber taps may be used between the amplifier stages. In another embodiment, the SC generation may occur partially in the amplifier fiber and in the pig-tails from the pump combiner or other elements. In yet another embodiment, polarization maintaining fibers may be used, and a polarizer may also be used to enhance the polarization contrast between amplifier stages. Also, not discussed in detail are many accessories that may accompany this set-up, such as driver electronics, pump laser diodes, safety shut-offs, and thermal management and packaging.

[0137] One example of an SC laser that operates in the SWIR used in one embodiment is illustrated in FIG. 21. This SWIR SC source 2100 produces an output of up to approximately 5W over a spectral range of about 1.5 to 2.4 microns, and this particular laser is made out of

polarization maintaining components. The seed laser 2101 is a distributed feedback (DFB) laser operating near 1542 nm producing approximately 0.5 nanosecond (ns) pulses at an about 8 MHz repetition rate. The pre-amplifier 2102 is forward pumped and uses about 2 m length of erbium/ytterbium cladding pumped fiber 2103 (often also called dual-core fiber) with an inner core diameter of 12 microns and outer core diameter of 130 microns. The pre-amplifier gain fiber 2103 is pumped using a 10 W 940 nm laser diode 2105 that is coupled in using a fiber combiner 2104.

In this particular 5W unit, the mid-stage between amplifier stages 2102 and 2106 comprises an isolator 2107, a band-pass filter 2108, a polarizer 2109 and a fiber tap 2110. The power amplifier 2106 uses a 4 m length of the 12/130 micron erbium/ytterbium doped fiber 2111 that is counter-propagating pumped using one or more 30 W 940 nm laser diodes 2112 coupled in through a combiner 2113. An approximately 1-2 meter length of the combiner pig-tail helps to initiate the SC process, and then a length of PM-1550 fiber 2115 (polarization maintaining, single-mode, fused silica fiber optimized for 1550 nm) is spliced 2114 to the combiner output.

If an output fiber of about 10 m in length is used, then the resulting output spectrum 2200 is shown in FIG. 22. The details of the output spectrum 2200 depend on the peak power into the fiber, the fiber length, and properties of the fiber such as length and core size, as well as the zero dispersion wavelength and the dispersion properties. For example, if a shorter length of fiber is used, then the spectrum actually reaches to longer wavelengths (e.g., a 2m length of SC fiber broadens the spectrum to -2500 nm). Also, if extra-dry fibers are used with less O--H content, then the wavelength edge may also reach to a longer wavelength. To generate more spectrum toward the shorter wavelengths, the pump wavelength (in this case about 1542 nm) should be close to the zero dispersion wavelength in the fiber. For example, by using a dispersion shifted fiber or so-called non-zero dispersion shifted fiber, the short wavelength edge may shift to shorter wavelengths.

[0140] Although one particular example of a 5 W SWIR-SC has been described, different components, different fibers, and different configurations may also be used consistent with this disclosure. For instance, another embodiment of the similar configuration 2100 in FIG. 21 may be used to generate high powered SC between approximately 1060 and 1800 nm. For this

embodiment, the seed laser 2101 may be a 1064 nm distributed feedback (DFB) laser diode, the pre-amplifier gain fiber 2103 may be a ytterbium-doped fiber amplifier with 10/125 microns dimensions, and the pump laser 2105 may be a 10 W 915 nm laser diode. In the mid-stage, a mode field adapter may be included in addition to the isolator 2107, band pass filter 2108, polarizer 2109 and tap 2110. The gain fiber 2111 in the power amplifier may be a 20 m length of ytterbium-doped fiber with 25/400 microns dimension for example. The pump 2112 for the power amplifier may be up to six pump diodes providing 30 W each near 915 nm, for example. For this much pump power, the output power in the SC may be as high as 50 W or more.

In another embodiment, it may be desirous to generate high power SWIR SC over 1.4-1.8 microns and separately 2-2.5 microns (the window between 1.8 and 2 microns may be less important due to the strong water and atmospheric absorption). For example, the top SC source of FIG. 23 can lead to bandwidths ranging from about 1400 nm to 1800 nm or broader, while the lower SC source of FIG. 23 can lead to bandwidths ranging from about 1900 nm to 2500 nm or broader. Since these wavelength ranges are shorter than about 2500 nm, the SC fiber can be based on fused silica fiber. Exemplary SC fibers include standard single-mode fiber SMF, high-nonlinearity fiber, high-NA fiber, dispersion shifted fiber, dispersion compensating fiber, and photonic crystal fibers. Non-fused-silica fibers can also be used for SC generation, including chalcogenides, fluorides, ZBLAN, tellurites, and germanium oxide fibers.

In one embodiment, the top of FIG. 23 illustrates a block diagram for an SC source 2300 capable of generating light between approximately 1400 and 1800 nm or broader. As an example, a pump fiber laser similar to FIG. 21 can be used as the input to a SC fiber 2309. The seed laser diode 2301 can comprise a DFB laser that generates, for example, several milliwatts of power around 1542 or 1553 nm. The fiber pre-amplifier 2302 can comprise an erbium-doped fiber amplifier or an erbium/ytterbium doped double clad fiber. In this example a mid-stage amplifier 2303 can be used, which can comprise an erbium/ytterbium doped double-clad fiber. A bandpass filter 2305 and isolator 2306 may be used between the pre-amplifier 2302 and mid-stage amplifier 2303. The power amplifier stage 2304 can comprise a larger core size erbium/ytterbium doped double-clad fiber, and another bandpass filter 2307 and isolator 2308 can be used before the power amplifier 2304. The output of the power amplifier can be coupled to the SC fiber 2309 to generate

the SC output 2310. This is just one exemplary configuration for an SC source, and other configurations or elements may be used consistent with this disclosure.

[0143] In yet another embodiment, the bottom of FIG. 23 illustrates a block diagram for an SC source 2350 capable of generating light between approximately 1900 and 2500 nm or broader. As an example, the seed laser diode 2351 can comprise a DFB or DBR laser that generates, for example, several milliwatts of power around 1542 or 1553 nm. The fiber preamplifier 2352 can comprise an erbium-doped fiber amplifier or an erbium/ytterbium doped double-clad fiber. In this example a mid-stage amplifier 2353 can be used, which can comprise an erbium/ytterbium doped double-clad fiber. A bandpass filter 2355 and isolator 2356 may be used between the pre-amplifier 2352 and mid-stage amplifier 2353. The power amplifier stage 2354 can comprise a thulium doped double-clad fiber, and another isolator 2357 can be used before the power amplifier 2354. Note that the output of the mid-stage amplifier 2353 can be approximately near 1550 nm, while the thulium-doped fiber amplifier 2354 can amplify wavelengths longer than approximately 1900 nm and out to about 2100 nm. Therefore, for this configuration wavelength shifting may be required between 2353 and 2354. In one embodiment, the wavelength shifting can be accomplished using a length of standard single-mode fiber 2358, which can have a length between approximately 5 and 50 meters, for example. The output of the power amplifier 2354 can be coupled to the SC fiber 2359 to generate the SC output 2360. This is just one exemplary configuration for an SC source, and other configurations or elements can be used consistent with this disclosure. For example, the various amplifier stages can comprise different amplifier types, such as erbium doped fibers, ytterbium doped fibers, erbium/ytterbium co-doped fibers and thulium doped fibers. One advantage of the SC lasers illustrated in FIGS, 20-23 are that they may use all-fiber components, so that the SC laser can be all-fiber, monolithically integrated with no moving parts. The all-integrated configuration can consequently be robust and reliable.

[0144] FIGS. 20-23 are examples of SC light sources that may be advantageously used for SWIR light generation in various medical diagnostic and therapeutic applications. However, many other versions of the SC light sources may also be made that are intended to also be covered by this disclosure. For example, the SC generation fiber could be pumped by a mode-locked laser, a gain-switched semiconductor laser, an optically pumped semiconductor laser, a solid state laser,

other fiber lasers, or a combination of these types of lasers. Also, rather than using a fiber for SC generation, either a liquid or a gas cell might be used as the nonlinear medium in which the spectrum is to be broadened.

[0145] Even within the all-fiber versions illustrated such as in FIG. 21, different configurations could be used consistent with the disclosure. In an alternate embodiment, it may be desirous to have a lower cost version of the SWIR SC laser of FIG. 21. One way to lower the cost could be to use a single stage of optical amplification, rather than two stages, which may be feasible if lower output power is required or the gain fiber is optimized. For example, the preamplifier stage 2102 might be removed, along with at least some of the mid-stage elements. In yet another embodiment, the gain fiber could be double passed to emulate a two stage amplifier. In this example, the pre-amplifier stage 2102 might be removed, and perhaps also some of the mid-stage elements. A mirror or fiber grating reflector could be placed after the power amplifier stage 2106 that may preferentially reflect light near the wavelength of the seed laser 2101. If the mirror or fiber grating reflector can transmit the pump light near 940 nm, then this could also be used instead of the pump combiner 2113 to bring in the pump light 2112. The SC fiber 2115 could be placed between the seed laser 2101 and the power amplifier stage 2106 (SC is only generated after the second pass through the amplifier, since the power level may be sufficiently high at that time). In addition, an output coupler may be placed between the seed laser diode 2101 and the SC fiber, which now may be in front of the power amplifier 2106. In a particular embodiment, the output coupler could be a power coupler or divider, a dichroic coupler (e.g., passing seed laser wavelength but outputting the SC wavelengths), or a wavelength division multiplexer coupler. This is just one further example, but a myriad of other combinations of components and architectures could also be used for SC light sources to generate SWIR light that are intended to be covered by this disclosure.

#### Wireless Link to the Cloud

[0146] The non-invasive blood constituent or analytes measurement device may also benefit from communicating the data output to the "cloud" (e.g., data servers and processors in the web remotely connected) via wired and/or wireless communication strategies. The non-invasive devices may be part of a series of biosensors applied to the patient, and collectively these

devices form what might be called a body area network or a personal area network. The biosensors and non-invasive devices may communicate to a smart phone, tablet, personal data assistant, computer, and/or other microprocessor-based device, which may in turn wirelessly or over wire and/or fiber optically transmit some or all of the signal or processed data to the internet or cloud. The cloud or internet may in turn send the data to doctors or health care providers as well as the patients themselves. Thus, it may be possible to have a panoramic, high-definition, relatively comprehensive view of a patient that doctors can use to assess and manage disease, and that patients can use to help maintain their health and direct their own care.

In a particular embodiment 2400, the physiological measurement device or non-invasive blood constituent measurement device 2401 may comprise a transmitter 2403 to communicate over a first communication link 2404 in the body area network or personal area network to a receiver in a smart phone, tablet cell phone, PDA, or computer 2405. For the measurement device 2401, it may also be advantageous to have a processor 2402 to process some of the physiological data, since with processing the amount of data to transmit may be less (hence, more energy efficient). The first communication link 2404 may operate through the use of one of many wireless technologies such as Bluetooth, Zigbee, WiFi, IrDA (infrared data association), wireless USB, or Z-wave, to name a few. Alternatively, the communication link 2404 may occur in the wireless medical band between 2360 and 2390 MHz, which the FCC allocated for medical body area network devices, or in other designated medical device or WMTS bands. These are examples of devices that can be used in the body area network and surroundings, but other devices could also be used and are included in the scope of this disclosure.

The personal device 2405 may store, process, display, and transmit some of the data from the measurement device 2401. The device 2405 may comprise a receiver, transmitter, display, voice control and speakers, and one or more control buttons or knobs and a touch screen. Examples of the device 2405 include smart phones such as the Apple iPhones.RTM, or phones operating on the Android or Microsoft systems. In one embodiment, the device 2405 may have an application, software program, or firmware to receive and process the data from the measurement device 2401. The device 2405 may then transmit some or all of the data or the processed data over a second communication link 2406 to the internet or "cloud" 2407. The second communication link 2406 may advantageously comprise at least one segment of a wireless

transmission link, which may operate using WiFi or the cellular network. The second communication link 2406 may additionally comprise lengths of fiber optic and/or communication over copper wires or cables.

The internet or cloud 2407 may add value to the measurement device 2401 by providing services that augment the physiological data collected. In a particular embodiment, some of the functions performed by the cloud include: (a) receive at least a fraction of the data from the device 2405; (b) buffer or store the data received; (c) process the data using software stored on the cloud; (d) store the resulting processed data; and (e) transmit some or all of the data either upon request or based on an alarm. As an example, the data or processed data may be transmitted 2408 back to the originator (e.g., patient or user), it may be transmitted 2409 to a health care provider or doctor, or it may be transmitted 2410 to other designated recipients.

[0150] The cloud 2407 may provide a number of value-add services. For example, the cloud application may store and process the physiological data for future reference or during a visit with the healthcare provider. If a patient has some sort of medical mishap or emergency, the physician can obtain the history of the physiological parameters over a specified period of time. In another embodiment, if the physiological parameters fall out of acceptable range, alarms may be delivered to the user 2408, the healthcare provider 2409, or other designated recipients 2410. These are just some of the features that may be offered, but many others may be possible and are intended to be covered by this disclosure. As an example, the device 2405 may also have a GPS sensor, so the cloud 2407 may be able to provide time, data and position along with the physiological parameters. Thus, if there is a medical emergency, the cloud 2407 could provide the location of the patient to the healthcare provider 2409 or other designated recipients 2410. Moreover, the digitized data in the cloud 2407 may help to move toward what is often called "personalized medicine." Based on the physiological parameter data history, medication or medical therapies may be prescribed that are customized to the particular patient.

[0151] Beyond the above benefits, the cloud application 2407 and application on the device 2405 may also have financial value for companies developing measurement devices 2401 such as a non-invasive blood constituent monitor. In the case of glucose monitors, the companies make the majority of their revenue on the measurement strips. However, with a non-invasive

monitor, there is no need for strips, so there is less of an opportunity for recurring costs (e.g., the razor/razor blade model does not work for non-invasive devices). On the other hand, people may be willing to pay a periodic fee for the value-add services provided on the cloud 2407. Diabetic patients, for example, would probably be willing to pay a periodic fee for monitoring their glucose levels, storing the history of the glucose levels, and having alarm warnings when the glucose level falls out of range. Similarly, patients taking ketone bodies supplement for treatment of disorders characterized by impaired glucose metabolism (e.g., Alzheimer's, Parkinson's, Huntington's or ALS) may need to monitor their ketone bodies level. These patients would also probably be willing to pay a periodic fee for the value-add services provided on the cloud 2407. Thus, by leveraging the advances in wireless connectivity and the widespread use of handheld devices such as smart phones that can wirelessly connect to the cloud, businesses can build a recurring cost business model even using non-invasive measurement devices.

[0152] In addition, it may be advantageous to use pattern matching algorithms and other software and mathematical methods to identify the blood constituents of interest. In one embodiment, the spectrum may be correlated with a library of known spectra to determine the overlap integrals, and a threshold function may be used to quantify the concentration of different constituents. This is just one way to perform the signal processing, and many other techniques, algorithms, and software may be used and would fall within the scope of this disclosure.

[0153] Described herein are just some examples of the beneficial use of near-infrared or SWIR lasers for non-invasive monitoring of glucose, ketones, HbA1 c and other blood constituents. However, many other medical procedures can use the near-infrared or SWIR light consistent with this disclosure and are intended to be covered by the disclosure.

[0154] In another specific embodiment, experiments have been performed for stand-off detection of solid targets with diffuse reflection spectroscopy using a fiber-based supercontinuum source (further described herein). In particular, the diffuse reflection spectrum of solid samples such as explosives (TNT, RDX, PETN), fertilizers (ammonium nitrate, urea), and paints (automotive and military grade) have been measured at stand-off distances of 5m. Although the measurements were done at 5m, calculations show that the distance could be anywhere from a few meters to over 150m. These are specific samples that have been tested, but more generally

other materials (particularly comprising hydro-carbons) could also be tested and identified using similar methods. The experimental set-up 2500 for the reflection-spectroscopy-based stand-off detection system is shown in FIGURE 25, while details of the SC source 2501 are described in this disclosure in FIGURES 20,21, and 23. First, the diverging SC output is collimated to a 1 cm diameter beam using a 25 mm focal length, 90 degrees off-axis, gold coated, parabolic mirror 2502. To reduce the effects of chromatic aberration, refractive optics are avoided in the setup. All focusing and collimation is done using metallic mirrors that have almost constant reflectivity and focal length over the entire SC output spectrum. The sample 2504 is kept at a distance of 5m from the collimating mirror 2502, which corresponds to a total round trip path length of 10m before reaching the collection optics 2505. A 12cm diameter silver coated concave mirror 2505 with a 75cm focal length is kept 20cm to the side of the collimation mirror 2502. The mirror 2505 is used to collect a fraction of the diffusely reflected light from the sample, and focus it into the input slit of a monochromator 2506. Thus, the beam is incident normally on the sample 2504, but detected at a reflection angle of tan-1(0.2/5) or about 2.3 degrees. Appropriate long wavelength pass filters mounted in a motorized rotating filter wheel are placed in the beam path before the input slit 2506 to avoid contribution from higher wavelength orders from the grating (300 grooves/mm, 2 µm blaze). The output slit width is set to 2mm corresponding to a spectral resolution of 10.8nm, and the light is detected by a 2mm x 2mm liquid nitrogen cooled (77K) indium antimonide (InSb) detector 2507. The detected output is amplified using a transimpedance pre-amplifier 2507 with a gain of about 105V/A and connected to a lock-in amplifier 2508 setup for high sensitivity detection. The chopper frequency is 400Hz, and the lock-in time constant is set to 100ms corresponding to a noise bandwidth of about 1Hz. These are exemplary elements and parameter values, but other or different optical elements may be used consistent with this disclosure.

### PROCESS ANALYTICAL TECHNOLOGY (PAT)

[0155] One definition of process analytical technology, PAT, is "a system for designing, analyzing and controlling manufacturing through timely evaluations (i.e., during processing) of significant quality and performance attributes of raw and in-process materials and processes, with the goal of ensuring final product quality." Near-infrared or SWIR spectroscopy may have applications in the PAT of the pharmaceutical industry by providing, for example, quantitative

analysis of multiple components in a sample and in pack quantification of drugs in formulation, as well as quality of a drug and quality control of complex excipients used in formulation. The PAT process may benefit from near-infrared or SWIR spectroscopy for some steps, such as: raw material identification, active pharmaceutical ingredient applications, drying, granulation, blend uniformity and content uniformity. Some of the strengths of near-infrared or SWIR spectroscopy include: radiation has good penetration properties, and, thus, minimal sample preparation may be required; measurement results may be obtained rapidly, and simultaneous measurements may be obtained for several parameters; non-destructive methods with little or no chemical waste; and organic chemicals that comprise most pharmaceutical products have unique spectra in the near-infrared and SWIR ranges, for example.

One goal of the manufacturing process and PAT may be the concept of a "smart" manufacturing process, which may be a system or manufacturing operation responding to analytical data generated in real-time. Such a system may also have an in-built "artificial intelligence" as decisions may be made whether to continue a manufacturing operation. For example, with respect to the raw materials, integration of the quality measurement into smart manufacturing processes could be used to improve manufacturing operations by ensuring that the correct materials of the appropriate quality are used in the manufacture. Similarly, a smart blender would be under software control and would respond to the real-time spectral data collected.

[0157] FIGURE 26 illustrates what might be an eventual flow-chart 2600 of a smart manufacturing process. The manufacturing process 2601 may have as input the process feed 2602 and result in a process output 2603. A process controller 2604 may at least partially control the manufacturing process 2601, and the controller 2604 may receive inputs from the closed loop control (process parameters) 2605 as well as the on-line monitoring of process parameters 2606. The feedback loops in the process could refine the manufacturing process 2601 and improve the quality of the process output 2603. These are particular embodiments of the use of near-infrared or SWIR spectroscopy in the PAT of the pharmaceutical industry, but other variations, combinations, and methods may also be used and are intended to be covered by this disclosure.

[0158] The discussion thus far has included use of near-infrared or SWIR spectroscopy in applications such as identification of counterfeit drugs, detection of illicit drugs, and

pharmaceutical process control. Although drugs and pharmaceuticals are one example, many other fields and applications may also benefit from the use of near infrared or SWIR spectroscopy, and these may also be implemented without departing from the scope of this disclosure. As just another example, near-infrared or SWIR spectroscopy may also be used as an analytic tool for food quality and safety control. Applications in food safety and quality assessment include contaminant detection, defect identification, constituent analysis, and quality evaluation. The techniques described in this disclosure are particularly valuable when non-destructive testing is desired at stand-off or remote distances.

[0159] Although the present disclosure has been described in several embodiments, a myriad of changes, variations, alterations, transformations, and modifications may be suggested to one skilled in the art, and it is intended that the present disclosure encompass such changes, variations, alterations, transformations, and modifications as falling within the spirit and scope of the appended claims.

While exemplary embodiments are described above, it is not intended that these embodiments describe all possible forms of the disclosure. Rather, the words used in the specification are words of description rather than limitation, and it is understood that various changes may be made without departing from the spirit and scope of the disclosure. Additionally, the features of various implementing embodiments may be combined to form further embodiments of the disclosure. While various embodiments may have been described as providing advantages or being preferred over other embodiments with respect to one or more desired characteristics, as one skilled in the art is aware, one or more characteristics may be compromised to achieve desired system attributes, which depend on the specific application and implementation. These attributes include, but are not limited to: cost, strength, durability, life cycle cost, marketability, appearance, packaging, size, serviceability, weight, manufacturability, ease of assembly, etc. The embodiments described herein that are described as less desirable than other embodiments or prior art implementations with respect to one or more characteristics are not outside the scope of the disclosure and may be desirable for particular applications.

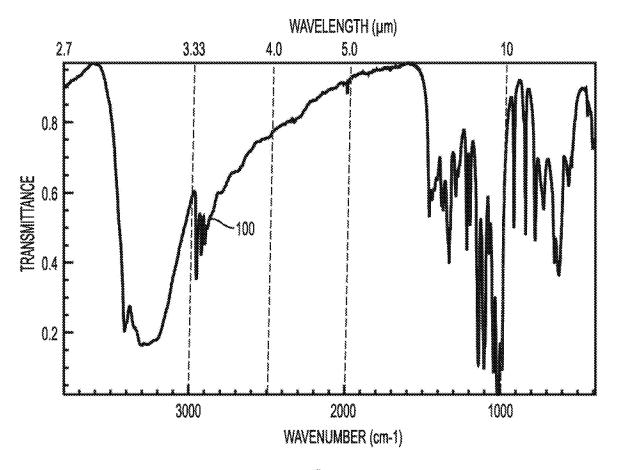
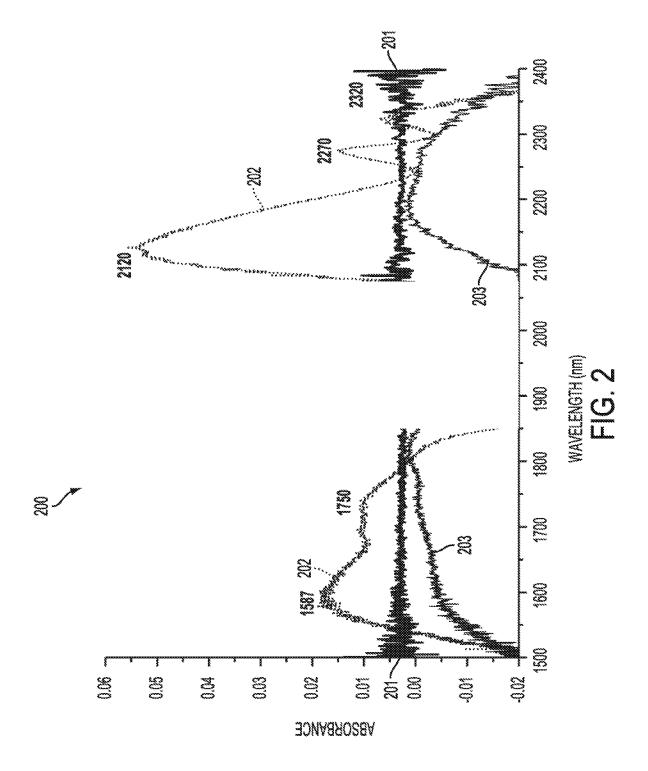
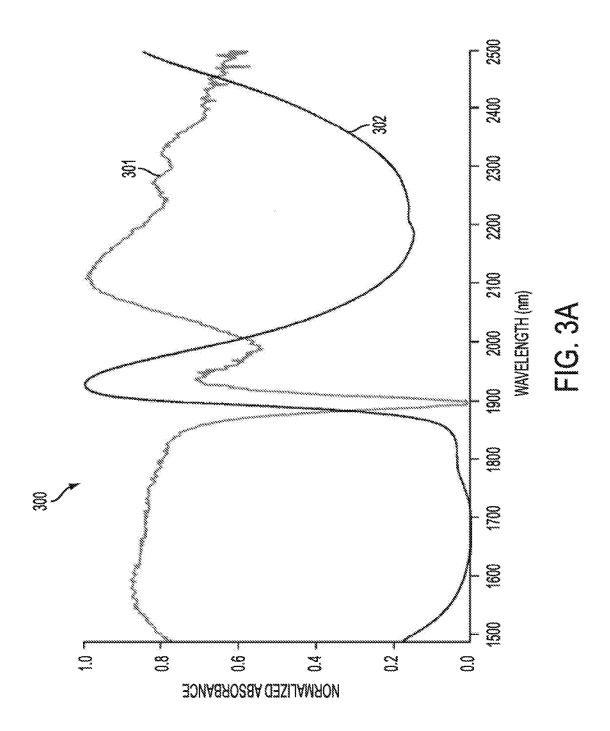


FIG. 1





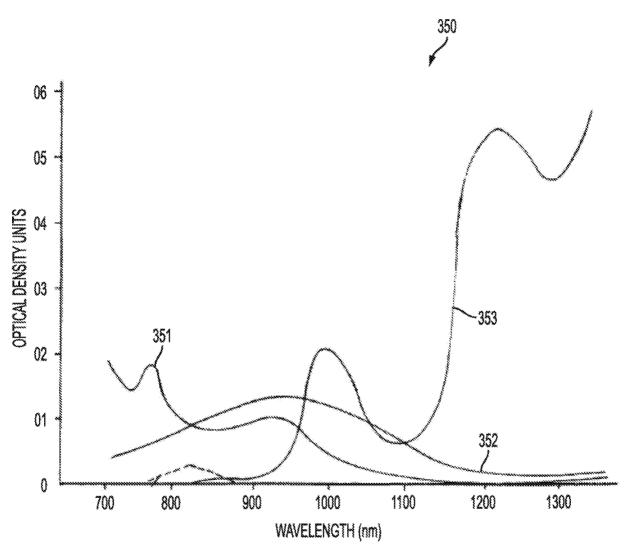
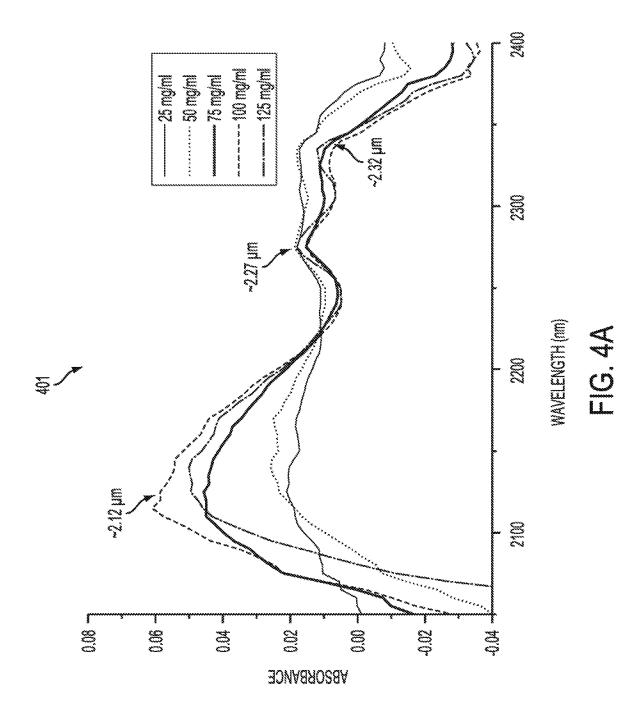
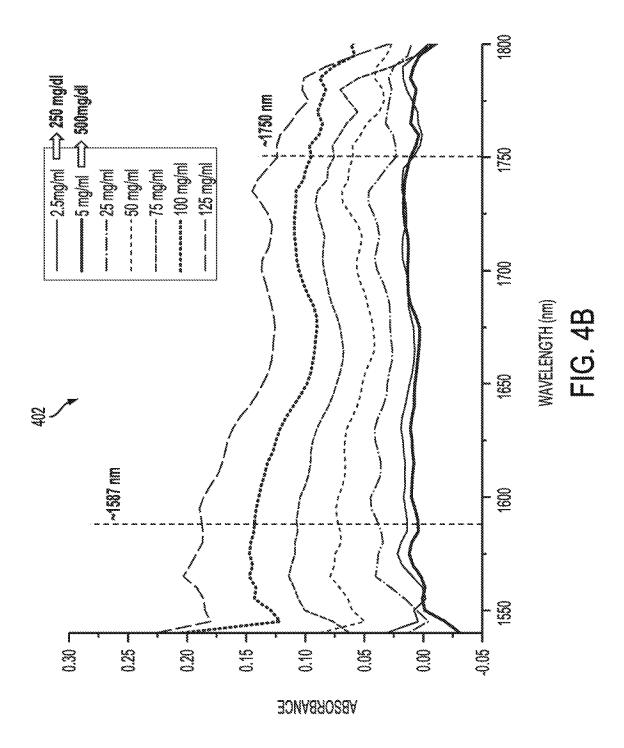
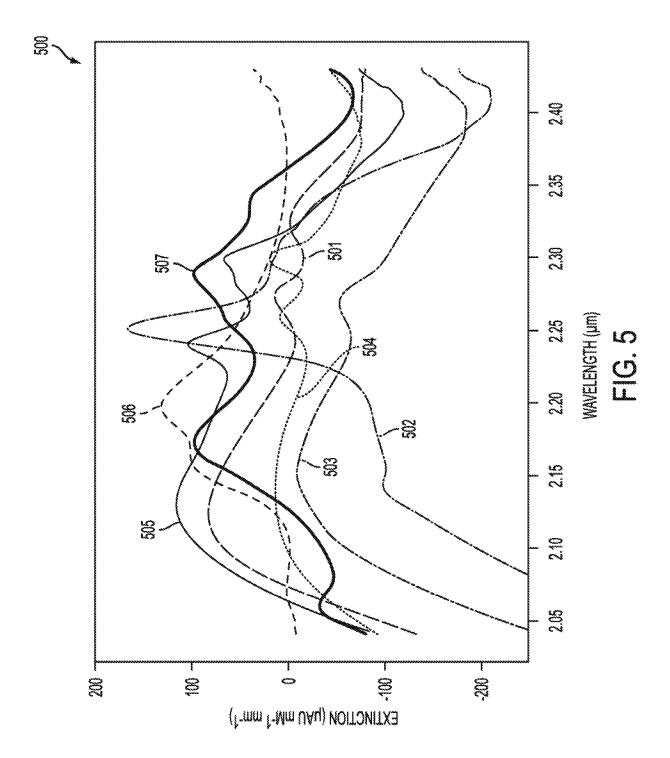
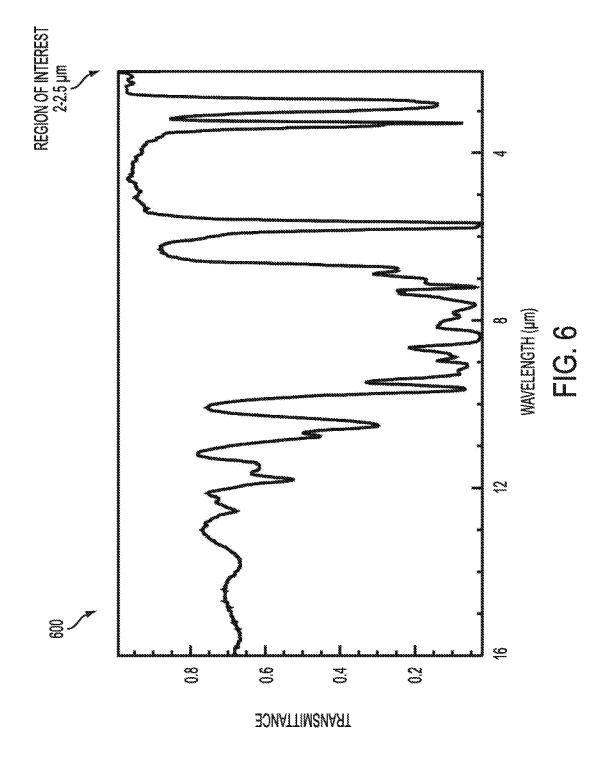


FIG. 3B

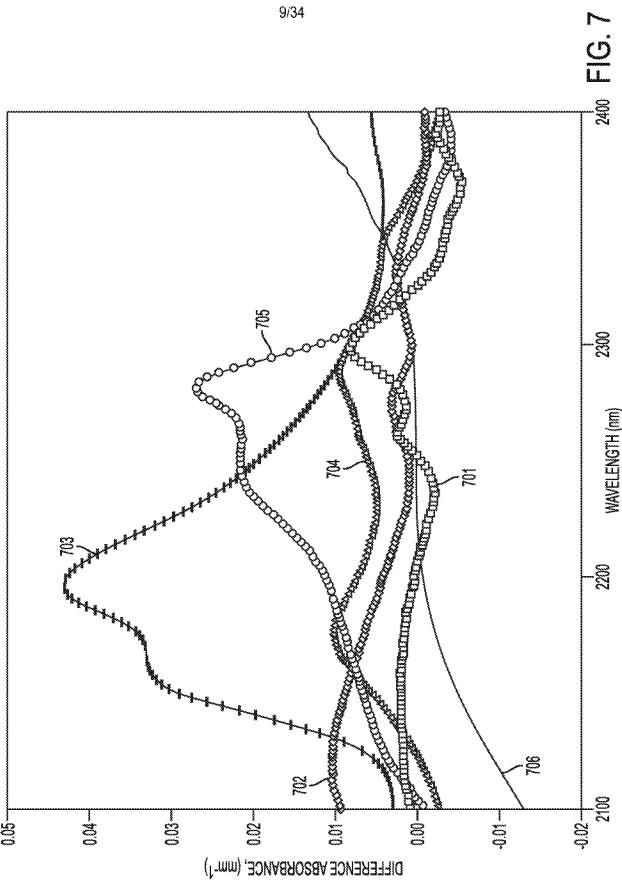




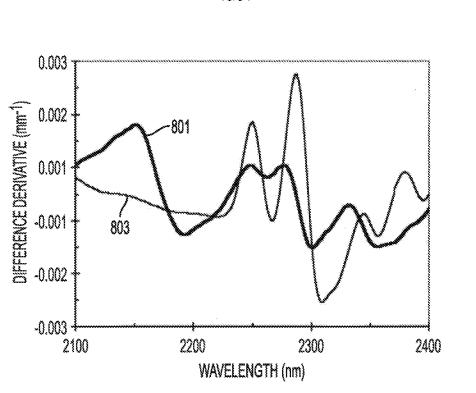












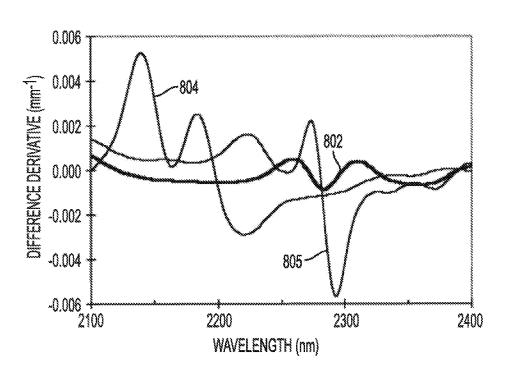
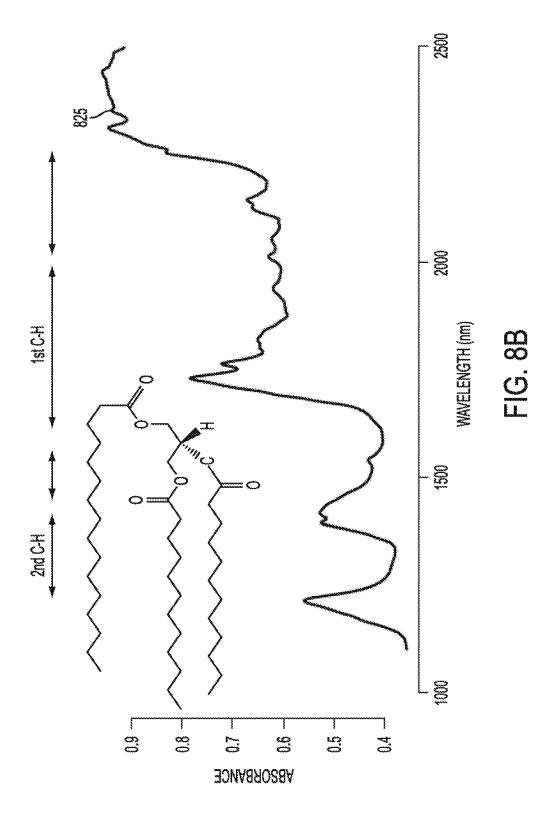
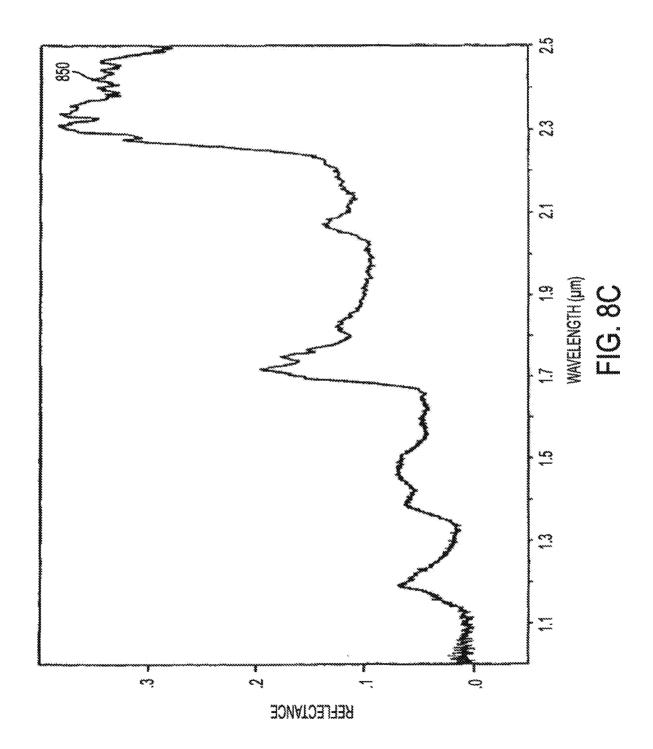
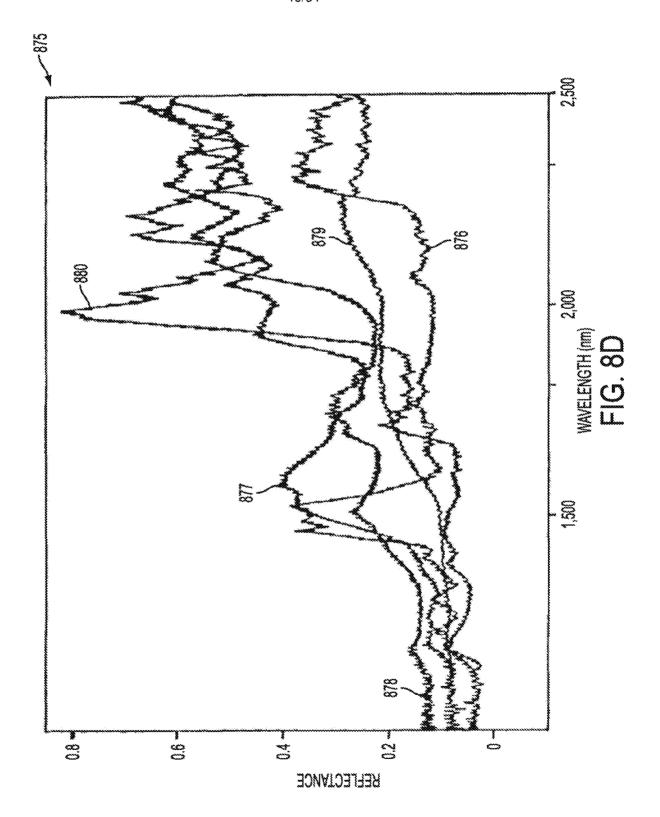


FIG. 8A

800







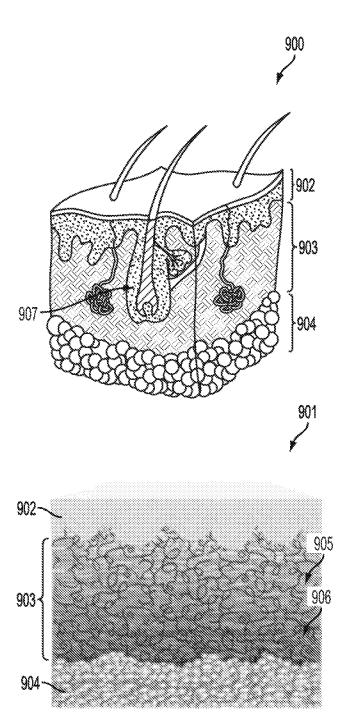
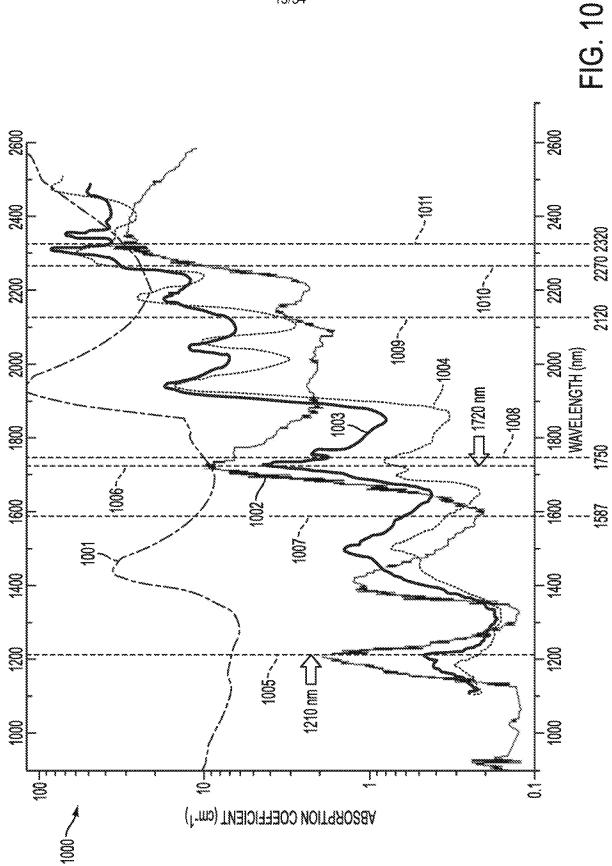


FIG. 9





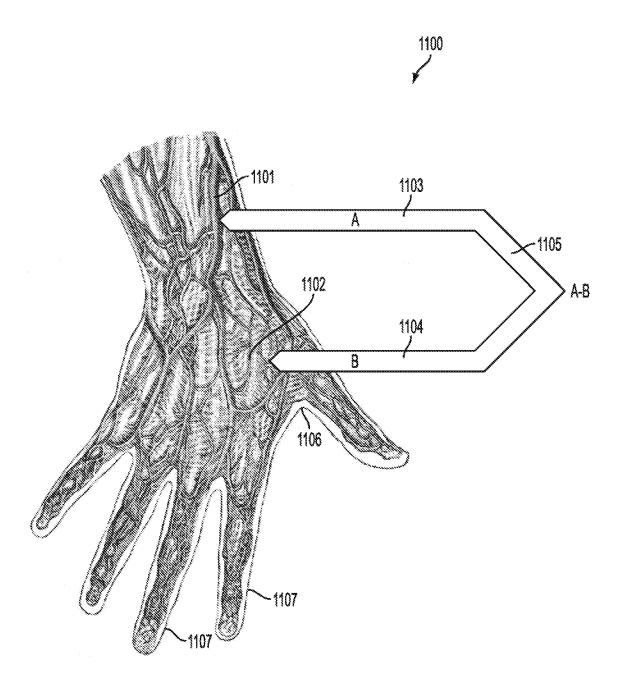


FIG. 11

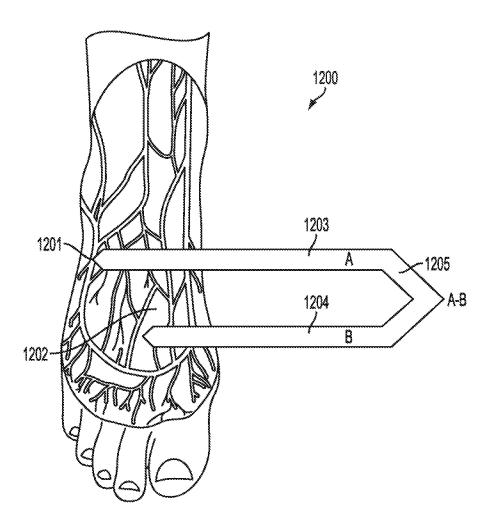


FIG. 12

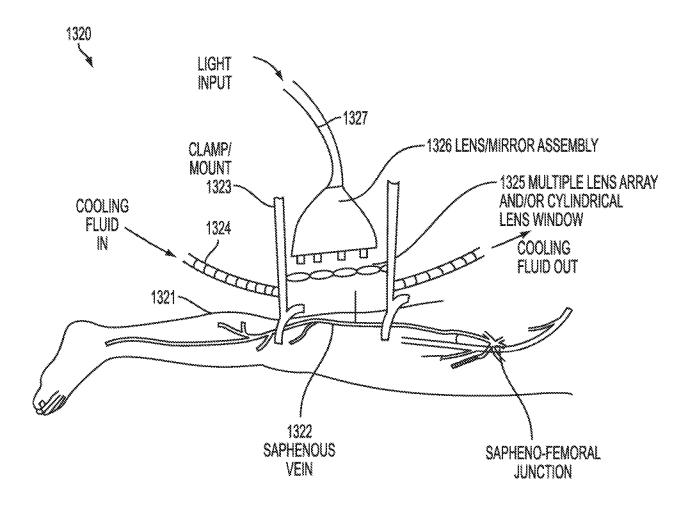


FIG. 13A

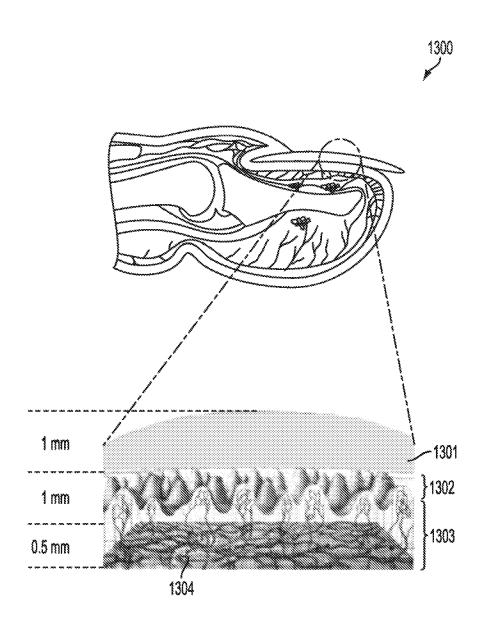


FIG. 13B

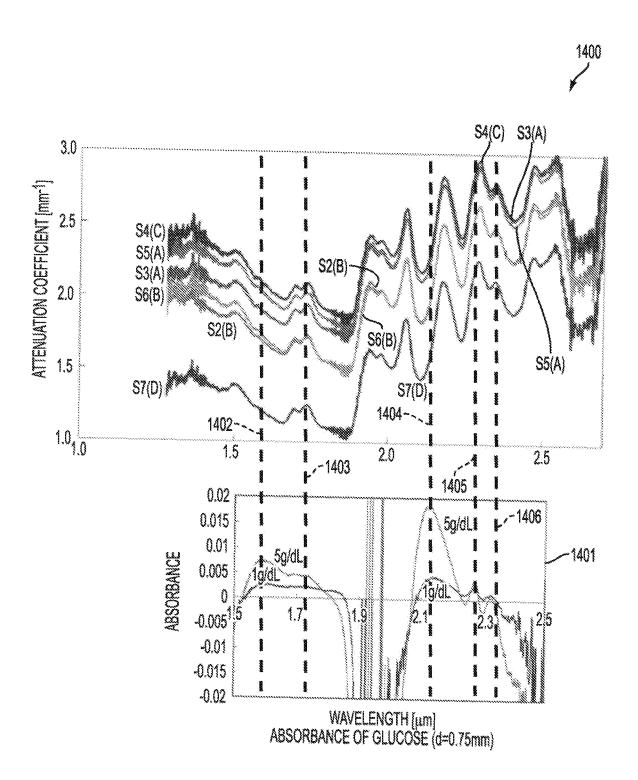
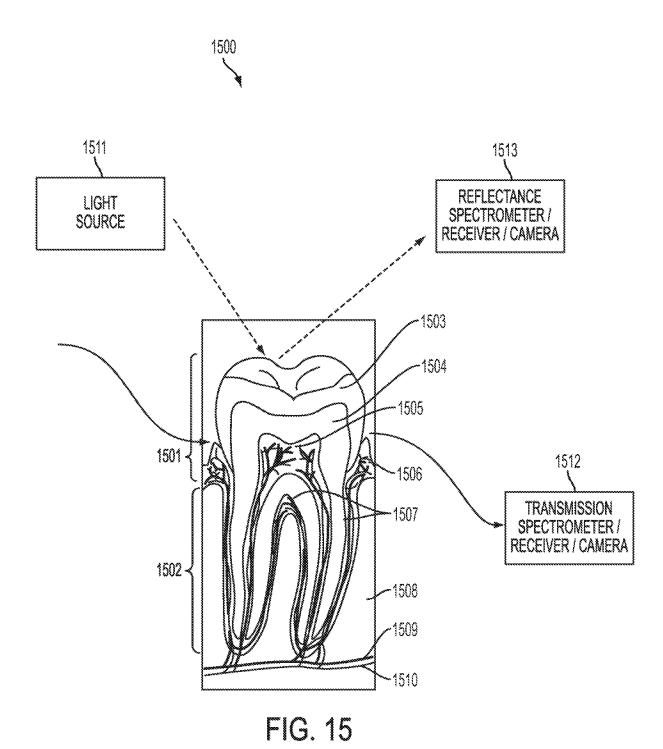


FIG. 14





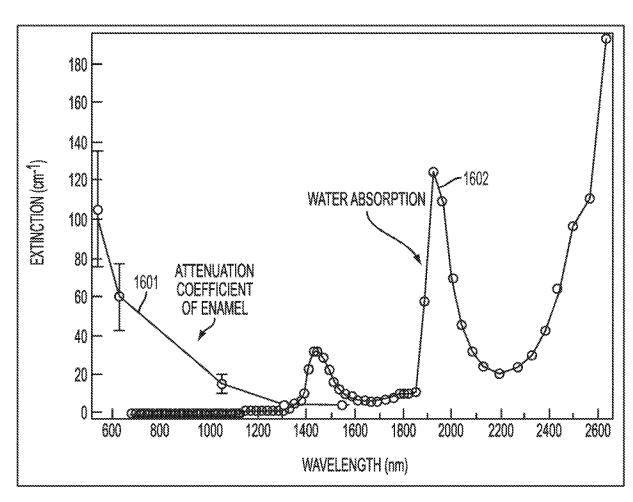


FIG. 16A

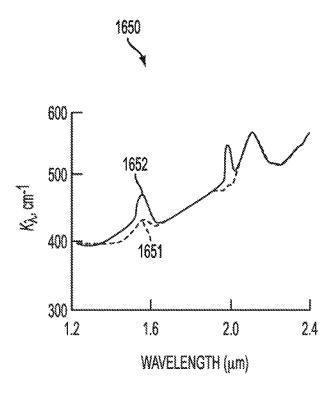
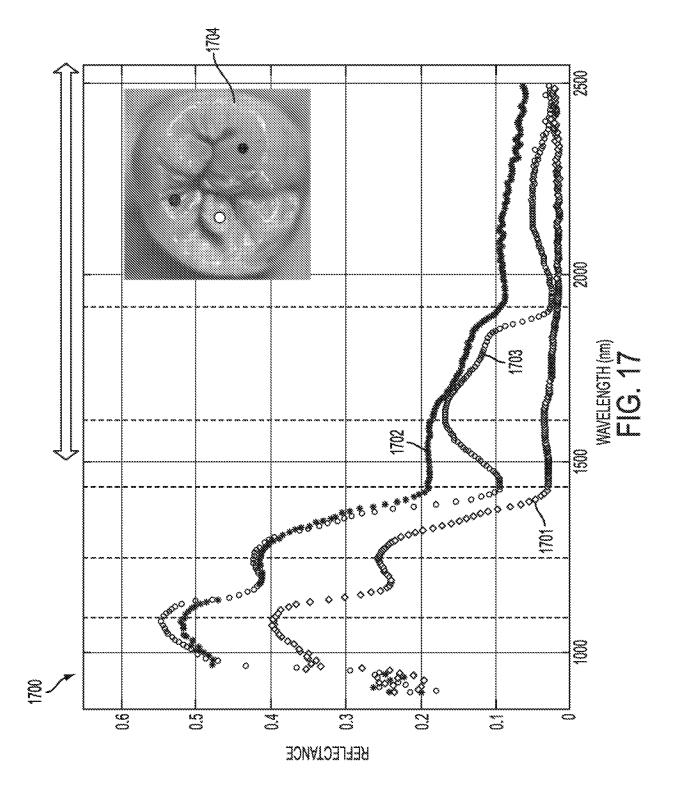


FIG. 16B



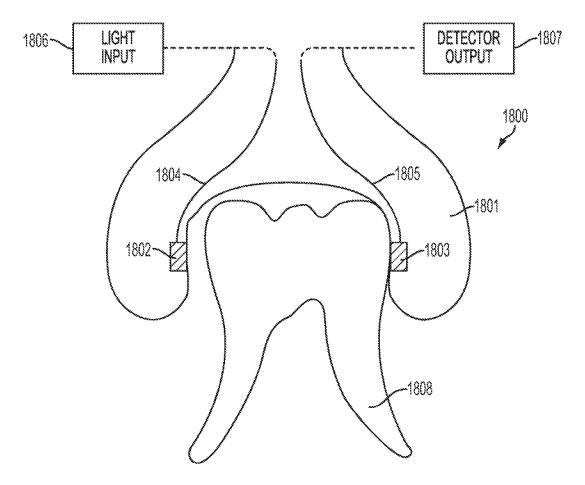


FIG. 18A

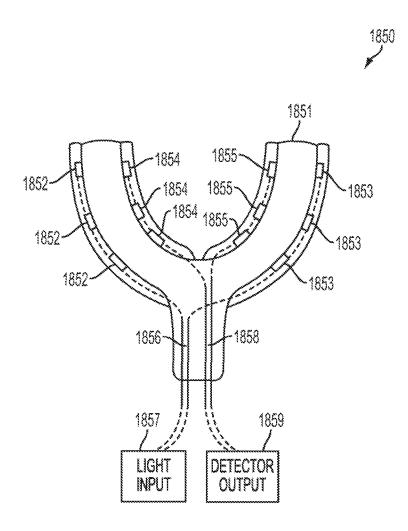
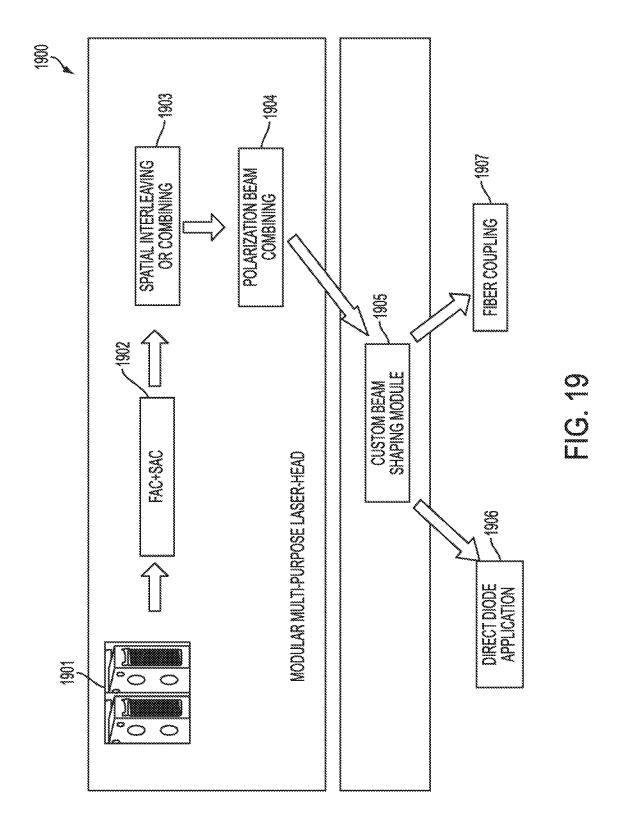
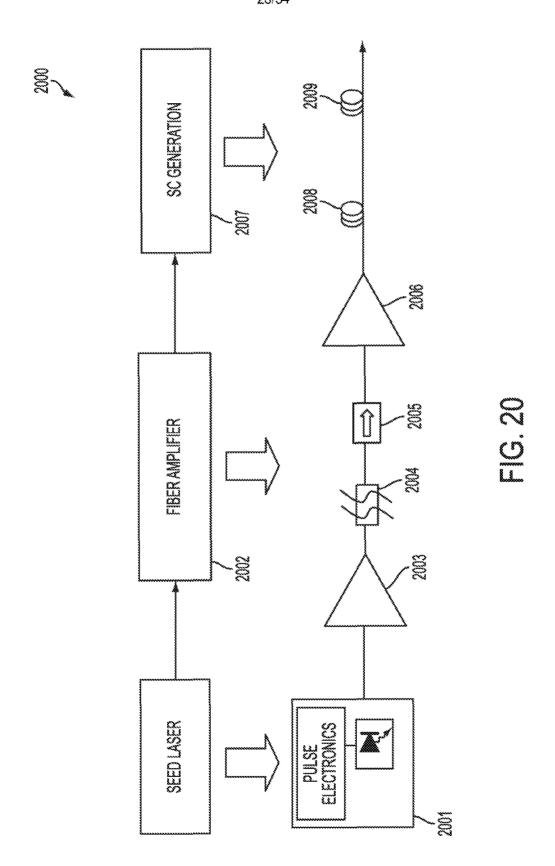
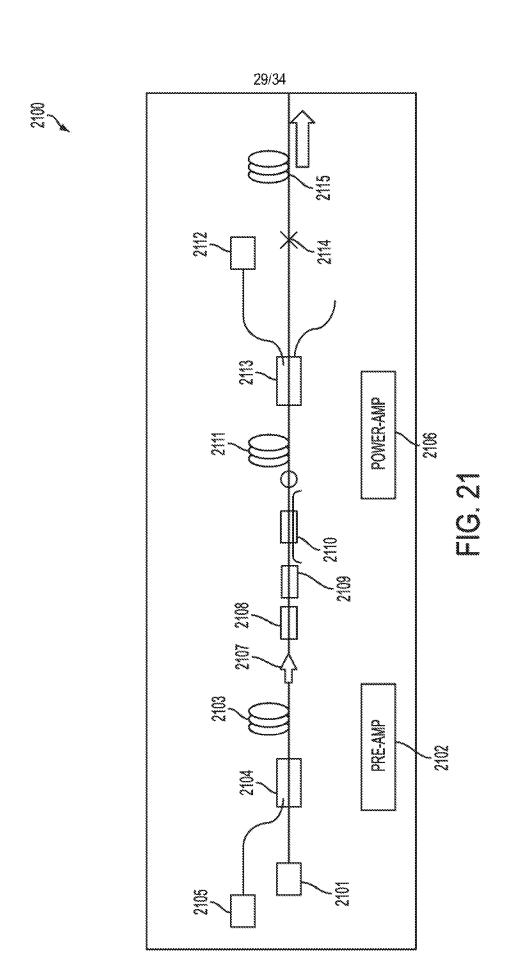
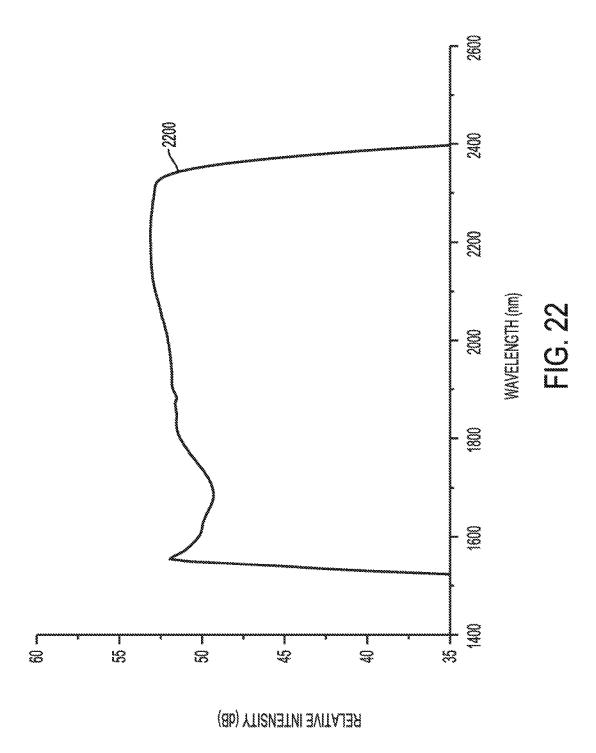


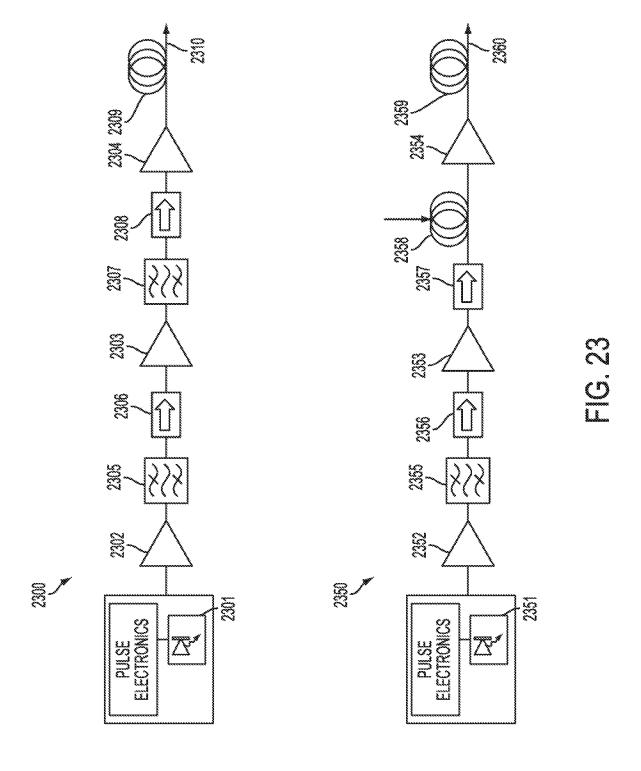
FIG. 18B

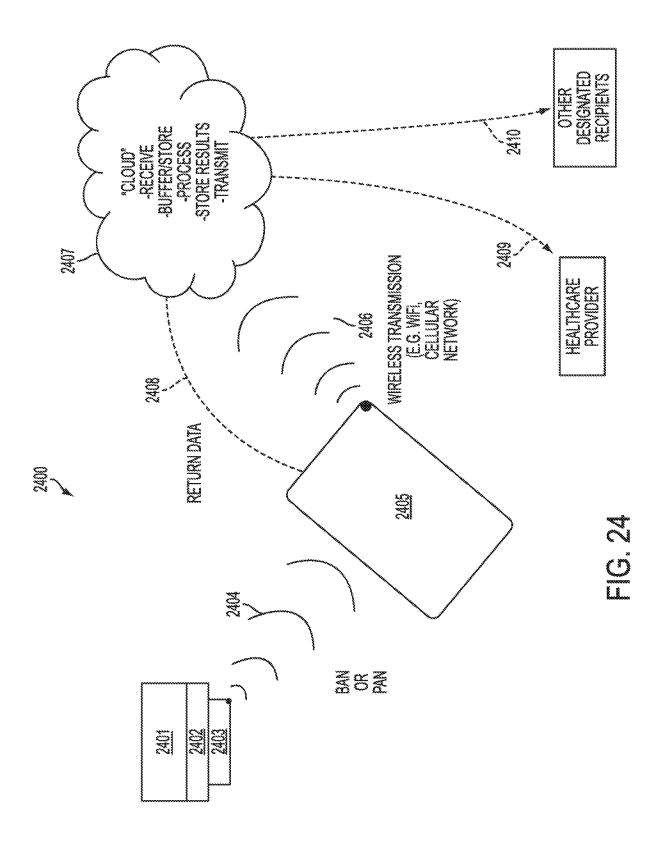












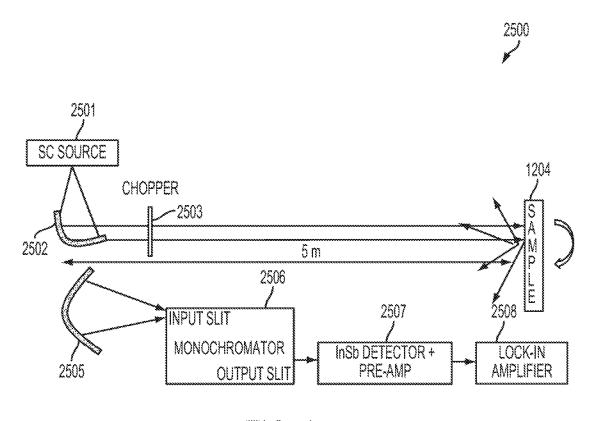
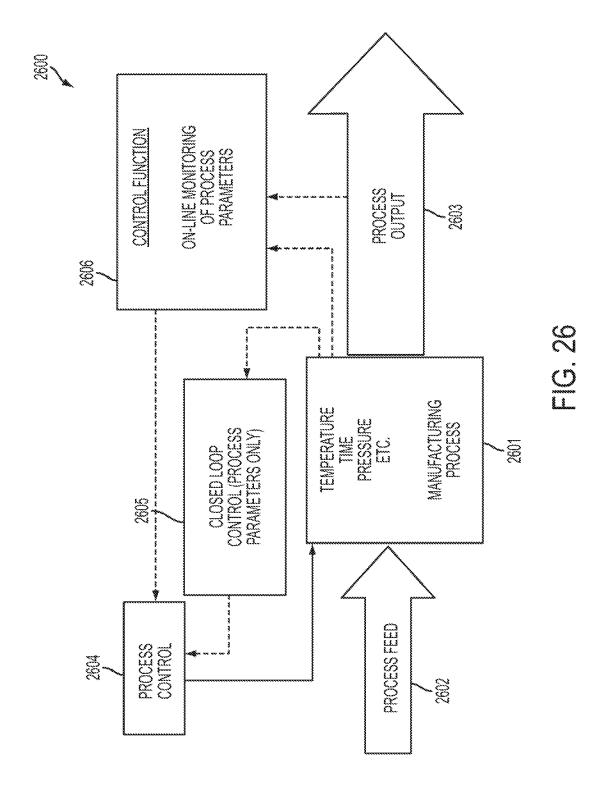


FIG. 25



#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

ľη	re	app]	lication	of:
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Group Art Unit:

Mohammed N. ISLAM

Examiner:

Serial No.:

Filed:

For: SEMICONDUCTOR DIODES-BASED PHYSIOLOGICAL

MEASUREMENT DEVICE WITH IMPROVED SIGNAL-TO-NOISE

RATIO

Attorney Docket No.: OMNI 0101 PUSA5

## INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)(1)

Commissioner for Patents P.O. Box 1450 Alexandría, VA 22313-1450

Commissioner:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56 and §§ 1.97-1.98, the references listed and identified on the attached Form PTO/SB/08a are being submitted herewith for consideration by the Examiner. This Statement is being filed in accordance with 37 C.F.R. § 1.97(b)(1).

While this Statement is being filed in compliance with the duty of disclosure, citation of the listed references is not to be construed as an admission that any of the references are "material" as defined under 37 C.F.R. § 1.56(b).

In accordance with 37 C.F.R. § 1.98(d), copies of the listed references are not being provided since the references were previously cited by or submitted to the Patent and Trademark Serial No.

Office in prior applications Serial No. 16/272,069, filed February 11, 2019 (pending), Serial No. 16/004,359 filed June 9, 2018 (pending), Serial No. 16/188,194 filed November 12, 2018 (pending), Serial No. 16/241,628 filed January 7, 2019 (pending), and Serial No. 16/284,514 filed February 25, 2019 (pending), of which the present application is a continuation.

Please charge any fees or credit any overpayments as a result of the filing of this paper to our Deposit Account No. 02-3978.

Respectfully submitted,

#### Mohammed N. ISLAM

By: /David S. Bir/
David S. Bir
Reg. No. 38,383
Attorney/Agent for Applicant

Date: July 8, 2019

#### BROOKS KUSHMAN P.C.

1000 Town Center, 22nd Floor Southfield, MI 48075-1238

Phone: 248-358-4400 Fax: 248-358-3351

# TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B or equivalent) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5. If the Power of Attorney by Applicant form is not accompanied by this transmittal form or an equivalent, the Power of Attorney will not be recognized in the application. Application Number Filing Date First Named Inventor Mohammed N. ISLAM Title SEMICONDUCTOR DIODES-BASED PHYSIOLOGICAL MEASUREMENT DEVICE WITH IMPROVED SIGNAL-TO-NOISE RATIO Art Unit **Examiner Name** Attorney Docket Number OMNI 0101 PUSA5 SIGNATURE of Applicant or Patent Practitioner Signature /David S. Bir/ Date (Optional) 2018-07-08 Registration David S. Bir 38,383 Name Number Title (if Applicant is a juristic entity) Applicant Name (if Applicant is a juristic entity) NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. If more than one applicant, use multiple forms.  $\boxtimes$ \* Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.** 

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## POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in the attached transmittal letter.										
transact all bus	I hereby appoint Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A or equivalent):									
OR	OR 109543									
United States F	I hereby appoint Practitioner(s) named below as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A or equivalent):									
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Telephone I am the Applicant:			) [ [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]	***************************************	OCCOCCOCCOCCOCCOCCOCCOCCOCCOCCOCCOCCOCC	anadriininnnnnnni TTTTTTTTTTTTTTTTTTTTTTTTTT				
Inventor or Joi	int Inventor									
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,	erson to Whom the Invent			Assian						
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	application or is concurre					(10)(10) 0000				
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Signature	III Sugar	116111		Date	October 10, 201	2				
Name _	Mokemmed N. Islam			Telephone	734-647-6941					
Title and Company	President - OMNI MEDSCI, INC.	30000000000000000000000000000000000000	***************************************	Physpodadaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaa	000000000000000000000000000000000000000	WWW.Webooooooooooooooooooooooooooooooooo				
	NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. Submit multiple forms for more than one signature, see below *.									
Total of 1	forms are submitted.	nganan 997, katiku 1990 000 000 katiku 1990 1991 1991	aaaaaaankannanannak49	**************************************	accondition accompandation and	<u>ópriorionograposas as allego que que de del de de</u>				

This collection of information is required by 37 CFR 1.31, 1.32 and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will very depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Application Data She	at 37 CFD 1 7	Attorney	Docket Number	OMNI 0101 PUSA5		
Application Data Sile	CIN I.	Application	on Number			
I ITID OT INVONTION I	ONDUCTOR DIOE L-TO-NOISE RATI		YSIOLOGICAL M	EASUREMENT DEVIC	E WITH IMPROVEI	D
The application data sheet is part bibliographic data arranged in a for This document may be complete document may be printed and inc	ormat specified by the ed electronically and	e United States Pa submitted to the	atent and Trademark	Office as outlined in 37 C	FR 1.76.	
Secrecy Order 37 (	CFR 5.2:					
Portions or all of the app 37 CFR 5.2 (Paper file						suant to
Inventor Informatio	n:					
Inventor 1				Rer	move	
Legal Name	_			_		
Prefix Given Name		Middle Nam	е	Family Name		Suffix
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Residence Information (	Select One) •	US Residency	Non US F	Residency Active	US Military Service	)
City Ann Arbor	Sta	ate/Province	MI Coun	try of Residence	US	
Mailing Address of Invento	or:					
Address 1	1718 Newport Cre	eek				
Address 2						
City Ann Arbor			State/Pr	ovince MI		
Postal Code	48103		Countryi	us		
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Enter either Customer Nu For further information se			spondence Info	rmation section bel	ow.	
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Customer Number	109543					
Email Address				Add Er	nail Remove	Email
Application Inform	ation:					
Title of the Invention	SEMICONDUCT IMPROVED SIG			GICAL MEASUREMEN	IT DEVICE WITH	
Attorney Docket Number				ntity Status Claimed	d 🖂	
Application Type	Nonprovisional		<u> </u>			<b>~</b>
Subject Matter	Utility					▼
Total Number of Drawing	Sheets (if anv)	34	Sugge	sted Figure for Publ	ication (if any)	24

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Application Dat	ta Sheet 37 CF	R 1 76	Attorney Docket Number	OMNI 0101 PUSA5					
Application But		1.70	Application Number						
Title of Invention SEMICONDUCTOR DIODES-BASED PHYSIOLOGICAL MEASUREMENT DEVICE WITH IMPROVED SIGNAL-TO-NOISE RATIO									
Filing By Refe	rence:								
application papers include provided in the appropri For the purposes of a filit	ding a specification an ate section(s) below (i ng date under 37 CFR	d any draw .e., "Domes 1.53(b), the	ings are being filed. Any domestic tic Benefit/National Stage Informa description and any drawings of t	nd 37 CFR 1.57(a). Do not complete this section in the benefit or foreign priority information must be ation" and "Foreign Priority Information").  The present application are replaced by this					
reference to the previous  Application number of filed application			nditions and requirements of 37 C te (YYYY-MM-DD)	CFR 1.57(a).  Intellectual Property Authority or Count					
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Publication I	nformation:								
Request Early	Publication (Fee re	equired at	time of Request 37 CFR 1.2	219)					
subject of an a	pplication filed in a eighteen months af	nother co ter filing.		ed application has not and will not be the all international agreement, that requires					
Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32). Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.									
Please Select One:	Custome	er Number	US Patent Practitione	er					
Customer Number	109543								
Domestic Benefit/National Stage Information:  This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.  When referring to the current application, please leave the "Application Number" field blank.									

2019-02-11

**Prior Application Number** 

16/272069

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Filing or 371(c) Date

(YYYY-MM-DD)

**Prior Application Status** 

**Application Number** 

Pending

Continuation of

**Continuity Type** 

Application Da	ita Sheet 37 CED 1 76	Attorney Docket Number	OMNI 0101 PUSA5
Application Data Sheet 37 CFR 1.76		Application Number	
Title of Invention	SEMICONDUCTOR DIODES- SIGNAL-TO-NOISE RATIO	BASED PHYSIOLOGICAL MEA	ASUREMENT DEVICE WITH IMPROVED

Prior Application	on Status	Patented		Ţ			Remo	ove
Application Number	Cont	inuity Type	Prior Applicati Number	on	Filing Date (YYYY-MM-DD)	Pat	ent Number	Issue Date (YYYY-MM-DD)
16/272069	Continuat	ion of	16/029611		2018-07-08	10201	283	2019-02-12
Prior Application	on Status	Patented		T			Remo	ove
Application Number	Cont	inuity Type	Prior Applicati Number	ion	Filing Date (YYYY-MM-DD)	Pat	ent Number	Issue Date (YYYY-MM-DD)
16/029611	Continuat	ion of ▼	15/888052		2018-02-04	10136	819	2018-11-27
Prior Application	on Status	Patented		•			Remo	ove
Application Number	Cont	inuity Type	Prior Applicati Number	ion	Filing Date (YYYY-MM-DD)	Pat	ent Number	Issue Date (YYYY-MM-DD)
15/888052	Continuat	ion of 🔻	15/212549		2016-07-18	98856	698	2018-02-06
Prior Application	on Status	Patented		•			Remo	ove
Application Number	Cont	inuity Type	Prior Applicati Number	ion	Filing Date (YYYY-MM-DD)	Pat	ent Number	Issue Date (YYYY-MM-DD)
15/212549	Continuat	ion of 🔻	14/650897		2015-06-10	94945	567	2016-11-15
Prior Application	on Status	Expired		¥			Remo	ove
Application N	umber	Cont	inuity Type		Prior Application N	umber	_	· 371(c) Date Y-MM-DD)
14/650897		a 371 of interr	national	-	PCT/US2013/075700		2013-12-17	
Prior Application	on Status	Expired		7			Remo	ove
Application N	umber	Cont	inuity Type		Prior Application N	umber		· 371(c) Date Y-MM-DD)
PCT/2013/075700		Claims benefi	t of provisional	7	61/747472		2012-12-31	
Prior Application	on Status	Pending		~	,		Remo	ove
Application N	umber	Cont	inuity Type		Prior Application N	umber	_	· 371(c) Date Y-MM-DD)
Continuation (		of	•	16/004359		2018-06-09	2018-06-09	
Prior Application Status Patented			▼			Remo	ove	
Application Number	Cont	inuity Type	Prior Applicati Number	ion	Filing Date (YYYY-MM-DD)	Pat	ent Number	Issue Date (YYYY-MM-DD)
16/004359	Continuat	ion of 🔻	14/109007		2013-12-17	99931	59	2018-06-12
Prior Application	on Status	Expired		•			Remo	ove
Application N	umber	Cont	inuity Type				· 371(c) Date Y-MM-DD)	
14/109007		Claims benefi	t of provisional	•	61/747553 2012-12-31			

Application Da	ata Shoot 37 CED 1 76	Attorney Docket Number	OMNI 0101 PUSA5
Application Data Sheet 37 CFR 1.76		Application Number	
Title of Invention	SEMICONDUCTOR DIODES- SIGNAL-TO-NOISE RATIO	BASED PHYSIOLOGICAL MEA	ASUREMENT DEVICE WITH IMPROVED

Prior Applicati	ion Status	Pending	▼			Remo	ove
Application N	lumber	Cont	inuity Type	Prior Application Number Filing or 371(c) Do (YYYY-MM-DD)			` '
		Continuation	of -	16/188194		2018-11-12	
Prior Applicati	ion Status	Patented	▼			Remo	ove
Application Number	Conti	inuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Pat	ent Number	Issue Date (YYYY-MM-DD)
16/188194	Continuat	ion of 🔻	16/004154	2018-06-08	10126	5283	2018-11-13
Prior Applicati	ion Status	Patented	▼		1	Remo	ove
Application Number	Conti	inuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Pat	ent Number	Issue Date (YYYY-MM-DD
16/004154	Continuat	ion of 🔻	15/855201	2017-12-27	99957	722	2018-06-12
Prior Applicati	ion Status	Patented	▼			Remo	ove
Application Number	Conti	inuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Pat	ent Number	Issue Date (YYYY-MM-DD)
15/855201	Continuat	ion of	15/711907	2017-09-21	98975	584	2018-02-20
Prior Applicati	ion Status	Patented	▼		•	Remo	ove
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15/711907	Division o	f 🔻	15/357225	2016-11-21	97978	376	2017-10-24
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Application Number	Conti	inuity Type	Prior Application Number	Filing Date (YYYY-MM-DD) Patent Number		ent Number	Issue Date (YYYY-MM-DD
15/357225	Continuat	ion of	14/650981	2015-06-10	95006	334	2016-11-22
Prior Applicati	ion Status	Expired	▼			Remo	ove
Application N	lumber	Cont	inuity Type				· 371(c) Date Y-MM-DD)
14/650981		a 371 of interr	national -	PCT/US2013/075767 2013-12		2013-12-17	
Prior Applicati	ion Status	Expired	▼			Remo	ove
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PCT/US2013/075	767	Claims benefi	t of provisional 🔻	61/747485		2012-12-31	
Prior Applicati	ion Status	Pending	▼			Remo	ove
Application Number Cont		inuity Type	Prior Application Number			Filing or 371(c) Date (YYYY-MM-DD)	
		Continuation	of -	16/241628		2019-01-07	
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Application Number	Conti	inuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)		Patent Number   Issue Date (YYYY-MM-I	
16/241628 Continuation of		16/015737	2018-06-22	10172	2500	2019-01-08	

Application Da	ita Sheet 37 CED 1 76	Attorney Docket Number	OMNI 0101 PUSA5
Application Data Sheet 37 CFR 1.76		Application Number	
Title of Invention	SEMICONDUCTOR DIODES- SIGNAL-TO-NOISE RATIO	BASED PHYSIOLOGICAL MEA	ASUREMENT DEVICE WITH IMPROVED

Prior Applicat	ion Status	Patented	▼		Rem	ove	
Application Number	Cont	inuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD	
16/015737	Continuat	tion of	15/594053	2017-05-12	10188299	2019-01-29	
Prior Applicat	ion Status	Patented	-		Rem	ove	
Application Number	Cont	inuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD	
15/594053	Continuat	tion of	14/875709	2015-10-06	9651533	2017-05-16	
Prior Applicat	ion Status	Patented	▼		Rem	ove	
Application Number	Cont	inuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DE	
14/875709	Continuat	tion of	14/108986	2013-12-17	9164032	2015-10-20	
Prior Applicat	ion Status	Expired	▼		Rem	ove	
Application N	lumber	Cont	inuity Type	Prior Application N		r 371(c) Date Y-MM-DD)	
14/108986		Claims benefi	t of provisional 🔻	61/747487	2012-12-31		
Prior Applicat	ion Status	Pending	-			Remove	
Application N	lumber	Cont	inuity Type	Prior Application N		r 371(c) Date Y-MM-DD)	
		Continuation of	of v	16/284514	2019-02-25		
Prior Applicat	ion Status	Patented	▼		Rem	ove	
Application Number	Cont	inuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DE	
16/284514	Continuat	tion of	16/016649	2018-06-24	10213113	2019-02-26	
Prior Applicat	ion Status	Patented	▼		Rem	ove	
Application Number	Cont	inuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DE	
16/016649	Continuat	tion of	15/860065	2018-01-02	10098546	2018-10-16	
Prior Applicat	ion Status	Patented	•		Rem	ove	
Application Number	Cont	inuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DE	
15/860065	Continuat	tion of	15/686198	2017-08-25	9861286	2018-01-09	
Prior Applicat	ion Status	Patented	•		Rem	ove	
Application Number	Cont	inuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DE	
15/686198	Continuat	tion of	15/357136	2016-11-21	9757040	2017-09-12	
Prior Applicat	ion Status	Patented	<b>-</b>		Rem	ove	
Application Number	Cont	inuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DE	
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Application Da	ata Shoot 37 CED 1 76	Attorney Docket Number	OMNI 0101 PUSA5
Application Data Sheet 37 CFR 1.76		Application Number	
Title of Invention	SEMICONDUCTOR DIODES SIGNAL-TO-NOISE RATIO	-BASED PHYSIOLOGICAL MEA	ASUREMENT DEVICE WITH IMPROVED

Prior Application Status	Expired	•		Remove
Application Number	Continuity Type		Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
14/651367	a 371 of international	•	PCT/US2013/075736	2013-12-17
Prior Application Status	Expired	•		Remove
Application Number	Continuity Type		Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
PCT/US2013/075736	Claims benefit of provisional	•	61/747477	2012-12-31
Prior Application Status	Expired	•		Remove
Application Number	Continuity Type		Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
PCT/US2013/075736	Claims benefit of provisional	~	61/754698	2013-01-21
Additional Domestic Benefi by selecting the <b>Add</b> buttor	t/National Stage Data may be n.	e ge	enerated within this form	Add

### **Foreign Priority Information:**

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)<sup>i</sup> the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

				Remove
	Application Number	Country <sup>i</sup>	Filing Date (YYYY-MM-DD)	Access Code <sup>i</sup> (if applicable)
Additional Foreign Priority Data may be generated within this form by selecting the <b>Add</b> button.				Add

# Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.

NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

Application Da	ta Shoot 37 CED 1 76	Attorney Docket Number	OMNI 0101 PUSA5
Application Data Sheet 37 CFR 1.76		Application Number	
Title of Invention	SEMICONDUCTOR DIODES- SIGNAL-TO-NOISE RATIO	ES-BASED PHYSIOLOGICAL MEASUREMENT DEVICE WITH IMPROV	

#### **Authorization or Opt-Out of Authorization to Permit Access:**

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant <u>must opt-out</u> of the authorization by checking the corresponding box A or B or both in subsection 2 below.

**NOTE**: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

- 1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)
- A. <u>Priority Document Exchange (PDX)</u> Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby <u>grants the USPTO authority</u> to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h) (1).
- B. <u>Search Results from U.S. Application to EPO</u> Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby <u>grants the USPTO authority</u> to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2.	Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)
	A. Applicant <b>DOES NOT</b> authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.
	B. Applicant <u>DOES NOT</u> authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.
ı	OTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the plication in accordance with 37 CFR 1.14.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	OMNI 0101 PUSA5	
		Application Number		
Title of Invention	SEMICONDUCTOR DIODES- SIGNAL-TO-NOISE RATIO	CTOR DIODES-BASED PHYSIOLOGICAL MEASUREMENT DEVICE WITH IMPROVIOISE RATIO		

### **Applicant Information:**

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.					
Applicant 1 Remove			Remove		
If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.					
<ul><li>Assignee</li></ul>	Legal Representative ur	nder 35 U.S.C. 117	Joint Inventor		
Person to whom the inventor is obligated to assign.  Person who shows sufficient proprietary			s sufficient proprietary interest		
If applicant is the legal representa	tive, indicate the authority to	file the patent application	on, the inventor is:		
			▼		
Name of the Deceased or Legally	Incapacitated Inventor:				
If the Applicant is an Organization check here.					
Organization Name Omni Me	dsci, Inc.				
Mailing Address Information For Applicant:					
Address 1 1718	Newport Creek Drive				
Address 2		_			
City Ann	Arbor	State/Province	МІ		
Country US		Postal Code	48103		
Phone Number		Fax Number			
Email Address					
Additional Applicant Data may be generated within this form by selecting the Add button.					

## **Assignee Information including Non-Applicant Assignee Information:**

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number OMNI 0101 I		01 PUSA5					
		Application N	lumber						
Title of Inven			JCTOR DIODES- NOISE RATIO	BASED PHYSIC	OLOGICAL M	IEASUREMEI	NT DEVICE W	/ITH I	MPROVED
Assignee	1								
application publ	ication. An a n applicant.	ssignee-	ormation, including applicant identifie ssignee-applicant,	d in the "Applica	ant Informatio	n" section will	appear on the as an assigne	e pate e is a	ent application also desired on the
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if the Assigne	ee or Non-/	Applican	t Assignee is an	Organization	cneck nere.		1		
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Address 1									
Address 2									
City					State/Prov	vince			
Country i					Postal Cod	de			
Phone Numb	er				Fax Numb	er			
Email Addres	ss					•			
Additional Ass selecting the			icant Assignee l	Data may be g	enerated wi	thin this forn	n by	Ad	d
Signature	:							Rem	ove
NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). However, if this Application Data Sheet is submitted with the INITIAL filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).  This Application Data Sheet must be signed by a patent practitioner if one or more of the applicants is a juristic entity (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, all joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of all joint inventor-applicants.  See 37 CFR 1.4(d) for the manner of making signatures and certifications.									
Signature	/David S. Bi	r/				Date (Y	YYY-MM-DI	D) 2	2019-07-09
First Name	David S.		Last Name	Bir		Registra	tion Number	-   3	38383
Additional Si	gnature ma	y be ge	nerated within th	nis form by sel	ecting the A	dd button.		Add	

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	OMNI 0101 PUSA5
		Application Number	
Title of Invention	SEMICONDUCTOR DIODES SIGNAL-TO-NOISE RATIO	-BASED PHYSIOLOGICAL MEA	ASUREMENT DEVICE WITH IMPROVED

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.** 

### **Privacy Act Statement**

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

- 1 The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
- 2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
- 3 A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
- 4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
- 5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent CooperationTreaty.
- 6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
- 7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
- 8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
- A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent P	ւրբ	ilcation ree	: ITAIISIII	ıttaı	
Application Number:					
Filing Date:					
Title of Invention:	SEMICONDUCTOR DIODES-BASED PHYSIOLOGICAL MEASUREMENT DEVI WITH IMPROVED SIGNAL-TO-NOISE RATIO				
First Named Inventor/Applicant Name:	Mohammed N. ISLAM				
Filer: David S. Bir					
Attorney Docket Number:	OMNI 0101 PUSA5				
Filed as Small Entity					
Filing Fees for Utility under 35 USC 111(a)					
Description		Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:					
UTILITY FILING FEE (ELECTRONIC FILING)		4011	1	75	75
UTILITY SEARCH FEE		2111	1	330	330
UTILITY EXAMINATION FEE		2311	1	380	380
Pages:					
Claims:					
CLAIMS IN EXCESS OF 20		2202	3	50	150
Miscellaneous-Filing:					
LATE FILING FEE FOR OATH OR DECLARATION		2051	1	80	80

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
	Tot	al in USD	(\$)	1015

Electronic Acl	knowledgement Receipt
EFS ID:	36479783
Application Number:	16506885
International Application Number:	
Confirmation Number:	7781
Title of Invention:	SEMICONDUCTOR DIODES-BASED PHYSIOLOGICAL MEASUREMENT DEVICE WITH IMPROVED SIGNAL-TO-NOISE RATIO
First Named Inventor/Applicant Name:	Mohammed N. ISLAM
Customer Number:	109543
Filer:	David S. Bir
Filer Authorized By:	
Attorney Docket Number:	OMNI 0101 PUSA5
Receipt Date:	09-JUL-2019
Filing Date:	
Time Stamp:	19:37:40
Application Type:	Utility under 35 USC 111(a)

### **Payment information:**

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	\$1015
RAM confirmation Number	071019INTEFSW00006002023978
Deposit Account	023978
Authorized User	David Bir

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

37 CFR 1.16 (National application filing, search, and examination fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

File Listin	g:				
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl
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15	Information Disclosure Statement (IDS) Form (SB08)	OMNI0101PUSA5_updated_IDS _15.PDF	471d0aec9c2f2771206da40268d6f8fd139a 5a80	no	5
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	Application Number		16506885		
	Filing Date		2019-07-09		
INFORMATION DISCLOSURE	First Named Inventor	First Named Inventor Mohammed N. ISLAM			
STATEMENT BY APPLICANT ( Not for submission under 37 CFR 1.99)	Art Unit		1636		
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	1	5747806		1998-05-05	Khalil	
	2	6115673		2000-09-05	Malin	
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Application Number		16506885		
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First Named Inventor Moha		mmed N. ISLAM		
Art Unit		1636		
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Attorney Docket Number		OMNI 0101 PUSA5		

	20	7697966 B2 2010-0		2010-04-13	MONFRE			
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Application Number		16506885		
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	2		MALIN, S.F., T.L. Ruchti, T.B. Blank, S.N. Thennadil, S.L. Monfre, "Noninvasive prediction of glucose by near-infrared diffuse reflectance spectroscopy," Clinical Chemistry, vol. 45, no. 9, pp. 1651-1658 (1999).								
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Application Number		16506885			
Filing Date		2019-07-09			
First Named Inventor Mohar		mmed N. ISLAM			
Art Unit		1636			
Examiner Name					
Attorney Docket Number		OMNI 0101 PUSA5			

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Application Number		16506885		
Filing Date		2019-07-09		
First Named Inventor Mohai		mmed N. ISLAM		
Art Unit		1636		
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Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-10
Name/Print	David S. Bir	Registration Number	38383

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INFORMATION DISCLOSURE	First Named Inventor Mohan		mmed N. ISLAM		
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	3	9326712	B1	2016-05-03	Kiani				
	4	5267152	A	1993-11-30	Yang et al.				
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	1	20100217102	A1	2010-08-26	LeBoeuf, et al.	
	2	20120310062	A1	2012-12-06	Li, et al.	
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	6	20160045118	A1	2016-02-18	Kiani	
	7	20110208015	A1	2011-08-25	Welch, et al.	
	8	20110040197	A1	2011-02-17	Welch et al.	
	9	20070021670	A1	2007-01-25	Mandelis et al.	
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	4		Ooi ET, Zhang XQ, Chen JH, Soh PH, Ng K, Yeo JH, "Non-invasive glucose measurement using multiple laser diodes," Optical Diagnostic and Sensing VII, edited by Gerard L. Cote, Alexander V. Priezzhev, Proc. of SPIE Vol. 6445, 64450K, (2007).									
	5	Schulz, I., J. Putzger, A. Niklas, M. Brandt, A. Jager, A. Hardt, S. Knorzer, K.A. Hiller, S. Loffler, G. Schmalz, S.N. Danilov, S. Giglberger, M. Hirmer, S.D. Ganichev, G. Monkman, "PPG signal acquisition and analysis on in vitro tooth model for dental pulp vitality assessment," ARC Submission 16, (2012).										

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	8		, J.H. Baek, S.Y. Ryu, C. Lee, B.H. Lee, "Tomographic imaging of igraphy and comparison with various modalities," Optical Review, v							
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	6	Redlich, B., Schulz, I., Monkman, G., Ganichev, S. "Infrared spectroscopy for clinical diagnosis of dental pulp vitality." Infrared, Millimeter, and Terahertz Waves (IRMMW-THz), 2012 37th International Conference on. IEEE (2012).								

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-10
Name/Print	David S. Bir	Registration Number	38383

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PTO/SB/08a (01-10) Approved for use through 07/31/2012. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Doc code: IDS Doc description: Information Disclosure Statement (IDS) Filed

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	Application Number		16506885	
	Filing Date		2019-07-09	
INFORMATION DISCLOSURE	First Named Inventor	amed Inventor Mohammed N. ISLAM		
STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Art Unit		1636	
(Not for Submission under or or N 1.00)	Examiner Name			
	Attorney Docket Number	er	OMNI 0101 PUSA5	

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	1	20050133691	A1	2005-06-23	Doppke et al.			
	2	20090244288	A1	2009-10-01	FUJIMOTO et al.			
	3	20110267688	A1	2011-11-03	Kleppe et al.			
	4	20130327966	A1	2013-12-12	Fidler et al.			
	5	20140078510	A1	2014-03-20	Rubio Guivernau et al.			

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	1	102010012987	DE	A1	2010-10-07	FRAUNHOFER GES FORSCHUNG	
	2	2005013843	wo	A2	2005-02-17	The Regents of the University of Californi	ia
	3	2007061772	wo	A2	2007-05-31	OMNI SCIENCES, IN	IC.
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	1	VINAY V. ALEXANDER ET AL.; Modulation Instability High Power All-Fiber Supercontinuum Lasers And Their Applications; Optical Fiber Technology 18; 2012; pages 349-374.					
	2	ROBERT S. JONES E Volume 11, No. 18; Op				310-nm For The Imagin	g Of Early Dental Decay;

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	3	Extend	tended European Search Report for European Application No. 13867874.3 dated July 15, 2016					
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<sup>1</sup> See Kind Codes of USPTO Patent Documents at <a href="https://www.USPTO.GOV">www.USPTO.GOV</a> or MPEP 901.04. <sup>2</sup> Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>3</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark here it English language translation is attached.								

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Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date			Columns,Lines where nt Passages or Relevant Appear	
	1	8158175	B2	2012-04-17	Bourg, Jr.			
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	1	20180231373	A1	2018-08-16	Pesach et al.			
	2	20080240502	A1	2008-10-02	Freedman et al.			
	3	20090185274	A1	2009-07-23	Shpunt			
	4	20100284082	A1	2010-11-11	Shpunt et al.			
	5	20110188054	A1	2011-08-04	Petronius et al.			

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	6	20100118123	A1	2010-05	5-13	Freedman et al.					
	7	20100007717	A1	2010-01	-14	Spektor et al.					
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	1		Segtnan, Vegard H., et al. "Screening of acrylamide contents in potato crisps using process variable settings and near-infrared spectroscopy." Molecular nutrition & food research 50.9 (2006): 811-817.								
	2		Shiroma, Cecilia, and Luis Rodriguez-Saona. "Application of NIR and MIR spectroscopy in quality control of potato chips." Journal of Food Composition and Analysis 22.6 (2009): 596-605.								
	3		Pedreschi, F., V. H. Segtnan, and S. H. Knutsen. "On-line monitoring of fat, dry matter and acrylamide contents in potato chips using near infrared interactance and visual reflectance imaging." Food Chemistry 121.2 (2010): 616-620.								
	4		Kays, Sandra E., William R. Windham, and Franklin E. Barton. "Prediction of total dietary fiber in cereal products using lear-infrared reflectance spectroscopy." Journal of Agricultural and food chemistry 44.8 (1996): 2266-2271.								

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5	Williams, Phil. "Near-Infrared Spectroscopy of Cereals." Handbook of vibrational spectroscopy (2006).	
6	Ng, Choo Lum, Randy L. Wehling, and Susan L. Cuppett. "Method for determining frying oil degradation by near-infrared spectroscopy." Journal of agricultural and food chemistry 55.3 (2007): 593-597.	
7	'Analysis of Edible Oils Using FT-NIR Spectroscopy." Bruker Optics, www.azom.com/article.aspx?ArticleID=5981, Mar 10, 2012.	
8	Shiroma, Cecilia. "Rapid quality control of potato chips using near and mid-infrared spectroscopy." (2007).	
9	Shiroma, Cecilia, and Luis Rodriguez-Saona. "Application of NIR and MIR spectroscopy in quality control of potato chips." Journal of Food Composition and Analysis 22.6 (2009): 596-605.	
10	Ni, Yongnian, Minghua Mei, and Serge Kokot. "Analysis of complex, processed substances with the use of NIR spectroscopy and chemometrics: Classification and prediction of properties—The potato crisps example." Chemometrics and Intelligent Laboratory Systems 105.2 (2011): 147-156.	
11	Hartmann, R., and H. Büning-Pfaue. "NIR determination of potato constituents." Potato research 41.4 (1998): 327-334.	
12	Thybo, Anette Kistrup, et al. "Prediction of sensory texture of cooked potatoes using uniaxial compression, near infrared spectroscopy and low field1H NMR spectroscopy." LWT-Food Science and Technology 33.2 (2000): 103-111.	
13	Büning-Pfaue, Hans. "Analysis of water in food by near infrared spectroscopy." Food Chemistry 82.1 (2003): 107-115.	
14	Haase, Norbert U. "Prediction of potato processing quality by near infrared reflectance spectroscopy of ground raw tubers." Journal of Near Infrared Spectroscopy 19.1 (2011): 37-45.	
15	September, Danwille Jacqwin Franco. Detection and quantification of spice adulteration by near infrared hyperspectral maging. Diss. Stellenbosch: University of Stellenbosch, 2011.	

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	16		Galvis-Sánchez, Andrea C., et al. "Fourier transform near-infrared spectroscopy application for sea salt quality evaluation." Journal of agricultural and food chemistry 59.20 (2011): 11109-11116.						
	17		ein, Alan, and Luis Rodriguez-Saona. "Measurement of Acrylamide in Potato Chips by Portable FTIR nalyzers." (2013)						
		Ayvaz, Huseyin, et al. "Application of infrared microspectroscopy and chemometric analysis for screening the acrylamide content in potato chips." Analytical Methods 5.8 (2013): 2020-2027.							
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	Application Number		16506885	
	Filing Date		2019-07-09	
INFORMATION DISCLOSURE	First Named Inventor Mohan		mmed N. ISLAM	
STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Art Unit		1636	
(Not for Submission under or of K 1.00)	Examiner Name			
	Attorney Docket Number	er	OMNI 0101 PUSA5	

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	2	6505133	B1	2003-01-07	Hanna et al.		
	3	8172761	B1	2012-05-08	Rulkov et al.		
	4	9241676	B2	2016-01-26	Lisogurski et al.		
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	1 20050049468 A1 2005-03-03		Carlson et al.				

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	2		20100217099	A1	2010-08	3-26	LeBoeuf et al.				
	3		20120197093	A1	2012-08	3-02	LeBoeuf et al.				
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	2		Inter Partes Review No. IPR2019-00911; Petition for Inter Partes Review of U.S. Patent No. 9,861,286; Apple Inc. v. OMNI MEDSCI, INC.; pps. 1-83; dated April 10, 2019								
	3		Inter Partes Review No. IPR2019-00912; Petition for Inter Partes Review of U.S. Patent No. 9,885,698; Apple Inc. v. OMNI MEDSCI, INC.; pps. 1-94; dated April 10, 2019								
	4		nter Partes Review No. IPR2019-00913; Petition for Inter Partes Review of U.S. Patent No. 9,651,533; Apple Inc. v. DMNI MEDSCI, INC.; pps. 1-96; dated April 10, 2019								

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	5	Inter Partes Review No. IPR2019-00914; Petition for Inter Partes Review of U.S. Patent No. 9,861,286; Apple Inc. v. OMNI MEDSCI, INC.; pps. 1-90; dated April 10, 2019										
	6	Inter Partes Review No. IPR2019-00915; Petition for Inter Partes Review of U.S. Patent No. 9,885,698; Apple Inc. v. DMNI MEDSCI, INC.; pps. 1-91; dated April 10, 2019										
	7 Inter Partes Review No. IPR2019-00916; Petition for Inter Partes Review of U.S. Patent No. 9,651,533; Apple Inc. v. OMNI MEDSCI, INC.; pps. 1-90; dated April 10, 2019											
	8	Inter Partes Review No. IPR2019-00917; Petition for Inter Partes Review of U.S. Patent No. 9,757,040; Apple Inc. v. OMNI MEDSCI, INC.; pps. 1-93; dated April 10, 2019										
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#### **CERTIFICATION STATEMENT**

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

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See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

X A certification statement is not submitted herewith.

#### **SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-10
Name/Print	David S. Bir	Registration Number	38383

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.** 

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- 6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
- 7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
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INFORMATION DISCLOSURE	First Named Inventor	Named Inventor Mohammed N. ISLAM	
STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Art Unit		1636
(Not for Submission under or of K 1.00)	Examiner Name		
	Attorney Docket Number	er	OMNI 0101 PUSA5

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	1	4972331		1990-11-20	Chance	
	2	5774213	Α	1998-06-30	Trebino et al.	
	3	5855550	Α	1999-01-05	Lai et al.	
	4	6044283	Α	2000-03-28	Fein et al.	
	5	6898451	B2	2005-05-24	Wuori	
	6	7278966	B2	2007-10-09	Hjelt et al.	
	7	9651533	B2	2017-05-16	Islam	
	8	9757040	B2	2017-09-12	Islam	

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Art Unit		1636			
Examiner Name					
Attorney Docket Numb	er	OMNI 0101 PUSA5			

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	9	9861286	B1	2018-01	-09	Islam					
	10	9885698	B2	2018-02	-06	Islam					
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		Declaration of Brian W. Anthony, PhD regarding USPN 9,651,533 filed in IPR2019-00913 & IPR2019-00916 (April 10, 2019)									
		Declaration of Brian W. A 2019)	anthony, I	PhD rega	arding U	SPN 9,757,040	filed in IPR2019-009	10 & IPR	2019-0091	7 (April 10,	

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3	Declaration of Brian W. Anthony, PhD regarding USPN 9,861,286 filed in IPR2019-00911 & IPR2019-00914 (April 10, 2019)
4	Declaration of Brian W. Anthony, PhD regarding USPN 9,885,698 filed in IPR2019-00912 & IPR2019-00915 (April 10, 2019)
5	Proof of Service of Summons in Omni MedSci, Inc. v. Apple Inc., No. 2:18-cv-134 (E.D. Tex.) (Dkt. #12) (April 13, 2018)
6	J.S. Provisional Application No. 61/747,487 filed December 31, 2012
7	J.S. Provisional Application No. 61/747,472 filed December 31, 2012
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13	ScienceDirect Report on M. KRANTZ, ET AL., The mobile fitness coach: Towards individualized skill assessment using personalized mobile devices, Pervasive and Mobile Computing (2012), available at https://www.sciencedirect.com/science/article/pii/S1574119212000673?via%3Dihub (2018 Elsevier B.V.)

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14	RAUF ADIL, "The Usage of Tablets in the HealthCare Industry," available at https://www.healthcareitnews.com/blog/ usage-tablets-healthcare-industry (Aug. 2, 2012)
15	A. OMRE, Bluetooth Low Energy: Wireless Connectivity for Medical Monitoring, Journal of Diabetes Science & Technology, Vol. 4, Issue 2 (March 2010)
16	'Absorption Coefficient and Penetration Depth," The Science of Solar, available at https://photon.libretexts.org/ The_Science_of_Solar/Solar_Basics/CSemiconductors_and_Solar_Interactions/IIIAbsorption_of_Light_and_Generation/1Absorption_Coefficient_and_Penetration_Depth (Last Updated Nov. 3, 2018)
17	F. BUTTUSSI, ET AL., MOPET: A context-aware and user-adaptive wearable system for fitness training, Artificial Intelligence in Medicine (2008) 42, 153-163
18	P. BAUM ET AL., Strategic Intelligence Monitor on Personal Health Systems, Phase 2: Market Developments - Remote Patient Monitoring and Treatment, Telecare, Fitness/Wellness and mHealth, JRC Scientific and Policy Reports of European Commission (2013)
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20	M. SWAN, Sensor Mania! The Internet of Things, Wearable Computing, Objective Metrics, and the Quantified Self 2.0, Journal of Sensor and Actuator Networks (2012)
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22	T. LISTER ET AL., Optical properties of human skin, Journal of Biomedical Optics (Sept. 2012)
23	A. BASHKATOV ET AL., Optical properties of human skin, subcutaneous and mucous tissues in the wavelength range from 400 to 2000 nm, Journal of Physics D: Applied Physics 38 (2005) 2543-2555
24	E.F. SCHUBERT, Light-Emitting Diodes (Cambridge Univ. Press, 2nd ed. Reprinted 2014)

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25	BAROLET, DANIEL, Light-Emitting Diodes (LEDs) in Dermatology, Seminars in Cutaneous Medicine and Surgery 27:227-238 (2008)
26	Omni MedSci Inc.'s Opening Claim Construction Brief filed in Case No. 2:18-cv-134-RWS (Dkt. #85) (Dec. 20, 2018)
27	Apple Inc.'s Preliminary Claim Constructions and Extrinsic Evidence Pursuant to Patent Local Rule 4-2 served in Case No. 2:18-cv-134-RWS (Nov. 1, 2018)
28	Excerpts from the American Heritage Dictionary, 5th Edition (July 2012)
29	Curriculum Vitae of Brian W. Anthony, PhD (Nov. 18, 2018)
30	Amended Joint Claim Construction and Prehearing Statement filed in Case No. 2:18-cv-134-RWS (Dkt. #102) (Jan. 11, 2019)
31	Excerpt from Claim Construction Markman Hearing Transcript filed in Case No. 2:18-cv-134-RWS (Feb. 6, 2019) Vol. 1, pgs. 1, 2, 21, 22
32	Dr. MOHAMMED ISLAM, Faculty Profile, University of Michigan, College of Engineering (available at https://islam.engin.umich.edu) (2019 The Regents of the University of Michigan)
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34	The Bylaws of the University of Michigan Board of Regents, (available at http://www.regents.umich.edu/bylaws/bylawsrevised_09-18.pdf) (last updated Sept. 20, 2018)
35	District Court Preliminary Claim Constructions in Case No. 2:18-cv-134-RWS (received February 6, 2019) from Court at Markman hearing

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	36	File History for U.S. Patent No. 9,651,533 issued May 16, 2017									
	37	File H	File History for U.S. Patent No. 9,757,040 issued September 12, 2017								
	38	File H	File History for U.S. Patent No. 9,861,286 issued January 9, 2018								
	39	File History for U.S. Patent No. 9,885,698 issued February 6, 2018									
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Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-10
Name/Print	David S. Bir	Registration Number	38383

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INFORMATION DIGGLOOUSE	Filing Date		2019-07-09
INFORMATION DISCLOSURE	First Named Inventor	Mohammed N. ISLAM	
STATEMENT BY APPLICANT ( Not for submission under 37 CFR 1.99)	Art Unit		1636
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	1	NELLCOR; Charts 1-3: NELLCOR-533; U.S. Patent No. 9,651,533 vs. Nellcor; Omni MedSci, Inc. v. Apple Inc., pps. 1-155; May 22, 2019									
	2		OGURSKI; Charts 1-3: LISOGURSKI-533; U.S. Patent No. 9,651,533 vs. Lisogurski; Omni MedSci, Inc. v. Apple ., pps. 1-84; May 22, 2019								
	3		ASADA; Charts 1-3: ASADA-533; U.S. Patent No. 9,651,533 vs. Asada; Omni MedSci, Inc. v. Apple Inc., pps. 1-188; May 22, 2019								
	4	PARK; Charts 1-3: Park-533; U.S. Patent No. 9,651,533 vs. Park; Omni MedSci, Inc. v. Apple Inc., pps. 1-171; May 22, 2019									
		VALENCELL; Charts 1-3: Valencell-533; U.S. Patent No. 9,651,533 vs. Valencell; Omni MedSci, Inc. v. Apple Inc., pps. 1-122; May 22, 2019									
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See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

X A certification statement is not submitted herewith.

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-10
Name/Print	David S. Bir	Registration Number	63108

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.** 

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- 7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
- 8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
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Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-10
Name/Print	David S. Bir	Registration Number	38383

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	2		20080105665	A1	2008-05	i-08	KONDO						
	3	2	20090156932	A1	2009-06	i-18	Zharov						
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				NON	-PATEN	NT LITE	RATURE DO	CUI	MENTS		Remove		
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.											
	1	ISTEPANIAN, ROBERT H., "The Comparative Performance of Mobile Telemedical Systems based on the IS-54 and GSM Cellular Telephone Standards"; Journal of Telemedicine and Telecare 1999; pp 97-104.											
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WANG, Lohong V., Multiscale photoacoustic microscopy and computed tomography, Sept. 2009, Nature Photonics, Vol. 3, pp. 503-509.													
If you wisl	h to ac	ld ad	ditional non-paten	t literatur	e docur	ment cit	ation informati	ion	please click the	Add bu	ıtton Ad	ld	
EXAMINER SIGNATURE													
Examiner	Signa	ture							Date Consider	red			
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Application Number		16506885		
Filing Date		2019-07-09		
First Named Inventor Moha		nmed N. ISLAM		
Art Unit		1636		
Examiner Name				
Attorney Docket Number		OMNI 0101 PUSA5		

<sup>&</sup>lt;sup>1</sup> See Kind Codes of USPTO Patent Documents at <u>www.USPTO.GOV</u> or MPEP 901.04. <sup>2</sup> Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>3</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark here if English language translation is attached.

( Not for submission under 37 CFR 1.99)

Application Number		16506885		
Filing Date		2019-07-09		
First Named Inventor Moha		nmed N. ISLAM		
Art Unit		1636		
Examiner Name				
Attorney Docket Number		OMNI 0101 PUSA5		

#### **CERTIFICATION STATEMENT**

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

#### OR

That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

X A certification statement is not submitted herewith.

#### **SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-10
Name/Print	David S. Bir	Registration Number	38383

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.** 

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The information provided by you in this form will be subject to the following routine uses:

- 1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.
- 2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
- 3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
- 4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
- 5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
- 6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
- 7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
- 8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
- 9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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	Application Number		16506885	
	Filing Date		2019-07-09	
INFORMATION DISCLOSURE	First Named Inventor Mohan		ammed N. ISLAM	
STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Art Unit		1636	
(Not for Submission under or of K 1.00)	Examiner Name			
	Attorney Docket Number		OMNI 0101 PUSA5	

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Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5084880		1992-01-28	Esterowitz, et al.	
	2	5180378		1993-01-19	Kung, et al.	
	3	5400165		1995-03-21	Gnauck, et al.	
	4	5458122		1995-10-17	Hethuin	
	5	5617871		1997-04-08	Burrows	
	6	5631758		1997-05-20	Knox, et al.	
	7	5687734		1997-11-18	Dempsey, et al.	
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Application Number		16506885		
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First Named Inventor Moha		mmed N. ISLAM		
Art Unit		1636		
Examiner Name				
Attorney Docket Number		OMNI 0101 PUSA5		

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10	5718234	1998-02-17	Warden, et al.	
11	5748103	1998-05-05	Flach, et al.	
12	5855550	1999-01-05	Lai, et al.	
13	5862803	1999-01-26	Besson, et al.	
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19	6043927	2000-03-28	Islam	

Application Number		16506885		
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First Named Inventor Moha		mmed N. ISLAM		
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20	6289238	2001-09-11	Besson, et al.	
21	6333803	2001-12-25	Kurotori, et al.	
22	6364834	2002-04-02	Reuss, et al.	
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Application Number		16506885		
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First Named Inventor	Moha	mmed N. ISLAM		
Art Unit		1636		
Examiner Name				
Attorney Docket Number		OMNI 0101 PUSA5		

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	31	6603910		2003-08-05	Islam, et al.	
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	35	7209657		2007-04-24	Islam	
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	37	7519253		2009-04-14	Islam	
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	1	20020013518		2002-01-31	West, Kenneth G. ; et al.	
	2	20020019584		2002-02-14	Schulze, Arthur E. ; et al.	
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Application Number		16506885		
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First Named Inventor Moha		mmed N. ISLAM		
Art Unit		1636		
Examiner Name				
Attorney Docket Numb	er	OMNI 0101 PUSA5		

3	20020032468	2002-03-14	Hill, Michael R.S. ; et al.	
4	20020082612	2002-06-27	Moll, Frederic H. ; et al.	
5	20020109621	2002-08-15	Khair, Mohammad ; et al.	
6	20020115914	2002-08-22	Russ, Tomas	
7	20020178003	2002-11-28	Gehrke, James K. ; et al.	
8	20040174914	2004-09-09	Fukatsu, Susumu	
9	20040240037	2004-12-02	Harter, Donald J.	
10	20050111500	2005-05-26	Harter, Donald J. ; et al.	
11	20060245461	2006-11-02	Islam; Mohammed N.	
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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) Application Number 16506885 Filing Date 2019-07-09 First Named Inventor Mohammed N. ISLAM Art Unit 1636 Examiner Name Attorney Docket Number OMNI 0101 PUSA5

	14		20090028193	2009-01-		-29	Islam; Mohammed N.						
	15		20090204110	2009-08-		i-13	Islam; Mohammed N.						
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	1	200	189362	wo			2001-11-29	Wes	West Kenneth G et al.				
	2	200	227640	wo			2002-04-04	Whi et a	hittington Charles Lynn al.				
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Application Number		16506885		
Filing Date		2019-07-09		
First Named Inventor	Moha	mmed N. ISLAM		
Art Unit		1636		
Examiner Name				
Attorney Docket Number		OMNI 0101 PUSA5		

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Application Number		16506885		
Filing Date		2019-07-09		
First Named Inventor	Moha	mmed N. ISLAM		
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statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

× None

#### **SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-10
Name/Print	David S. Bir	Registration Number	38383

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Doc code: IDS Doc description: Information Disclosure Statement (IDS) Filed

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	Application Number		16506885	
	Filing Date		2019-07-09	
INFORMATION DISCLOSURE	First Named Inventor Moham		mmed N. ISLAM	
STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Art Unit		1636	
(Not for Submission under or of K 1.00)	Examiner Name			
	Attorney Docket Number	er	OMNI 0101 PUSA5	

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Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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	2	4158750		1979-06-19	Sakoe, et al.	
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	5	4374618		1983-02-22	Howard	
	6	4403605		1983-09-13	Tanikawa	
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Application Number		16506885		
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First Named Inventor	Moha	mmed N. ISLAM		
Art Unit		1636		
Examiner Name				
Attorney Docket Numb	er	OMNI 0101 PUSA5		

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13	4728974	1988-03-01	Nio, et al.	
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15	4776016	1988-10-04	Hansen	
16	4958910	1990-09-25	Taylor, et al.	
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Application Number		16506885	
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First Named Inventor Moha		mmed N. ISLAM	
Art Unit		1636	
Examiner Name			
Attorney Docket Number		OMNI 0101 PUSA5	

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21	5134620	1992-07-28	Huber	
22	5142930	1992-09-01	Allen, et al.	
23	5180378	1993-01-19	Kung, et al.	
24	5191628	1993-03-02	Byron	
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26	5230023	1993-07-20	Nakano	
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First Named Inventor	Moha	mmed N. ISLAM	
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Examiner Name			
Attorney Docket Number		OMNI 0101 PUSA5	

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31	5305427	1994-04-19	Nagata	
32	5313306	1994-05-17	Kuban, et al.	
33	5323404	1994-06-21	Grubb	
34	5345538	1994-09-06	Narayannan, et al.	
35	5408409	1995-04-18	Glassman, et al.	
36	5544654	1996-08-13	Murphy, et al.	
37	5572999	1996-11-12	Funda, et al.	
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39	5696778	1997-12-09	MacPherson	
40	5792204	1998-08-11	Snell	
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Art Unit		1636	
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Attorney Docket Number		OMNI 0101 PUSA5	

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42	5950629	1999-09-14	Taylor, et al.	
43	5970457	1999-10-19	Brant, et al.	
44	6014249	2000-01-11	Fermann, et al.	
45	6185535	2001-02-06	Hedin, et al.	
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Application Number		16506885	
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First Named Inventor Moha		mmed N. ISLAM	
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65	6605080	2003-08-12	Altshuler, et al.	
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Examiner Initial*	I CITO NO I		Kind Code <sup>1</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Releva		ines where es or Relevant
	1	20020032468		2002-03-14	Hill, Michael R.S. ; et al.			
	2	20020082612		2002-06-27	Moll, Frederic H. ; et al.			
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	4	20020178003		2002-11-28	Gehrke, James K. ; et al.			
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Examiner Initial*	Cite No	Foreign Document Number <sup>3</sup>	Country Code <sup>2</sup> i	Kind Code <sup>4</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T5
	1	EP1148666	EP		2001-10-24	Grant Andrew R et al.		
	2	WO01150959	wo		2001-07-19	SUHM		
	3	WO09715240	wo		1997-05-01	BRANT		
	4	WO97049340	wo		1997-12-31	WANG		
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Standard ST.3). <sup>3</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark here if

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See attached certification statement.

Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

imes None

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-10
Name/Print	David S. Bir	Registration Number	38383

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- 2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
- 3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
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- 6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
- 7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
- 8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
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	Application Number		16506885	
	Filing Date		2019-07-09	
INFORMATION DISCLOSURE	First Named Inventor Moham		mmed N. ISLAM	
STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Art Unit		1636	
(Not for Submission ander or of N 1.00)	Examiner Name			
	Attorney Docket Number	er	OMNI 0101 PUSA5	

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	1	7787503	B2	2010-08	<b>⊹31</b>	WADSWORTH			
	2	7800818	B2	2010-09	-21	MATTSSON			
	3	8000574	B2	2011-08	÷16	BUCHTER			
	4	6611643	B2	2003-08	-26	BIRK			
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	1	SUN, Y., C.F. Booker, S. Kumari, R.N. Day, M. Davidson, A. Periasamy, "Characterization of an orange acceptor fluorescent protein for sensitized spectral fluorescence resonant energy transfer microscopy using a white-light laser," Journal of Biomedical Optics, Vol. 14, no. 5, paper 054009 (2009).							
	2	BORLINGHAUS, R., "Colours Count: how the challenge of fluorescence was solved in confocal microscopy," in Modern Research and Educational Topics in Microscopy, A. Mendez-Vilas and J. Diaz, eds, pp. 890-899, Formatex (2007)							
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If you wis	h to ad	additional non-patent literature document citation information please click the Add button Add							
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See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

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Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-10
Name/Print	David S. Bir	Registration Number	38383

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INFORMATION DISCLOSURE	Application Number		16506885		
	Filing Date		2019-07-09		
	First Named Inventor Moham		ammed N. ISLAM		
STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Art Unit		1636		
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	Attorney Docket Number	er	OMNI 0101 PUSA5		

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	1	6246896	B1	2001-06	i-12	DUMOULIN			
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First Named Inventor	Moha	mmed N. ISLAM		
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Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-10
Name/Print	David S. Bir	Registration Number	38383

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INFORMATION DISCLOSURE	Application Number		16506885	
	Filing Date		2019-07-09	
	First Named Inventor Mohan		ammed N. ISLAM	
STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Art Unit		1636	
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Name/Print	David S. Bir	Registration Number	38383

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	Filing Date		2019-07-09	
	First Named Inventor	Mohammed N. ISLAM		
	Art Unit		1636	
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The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

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Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-10
Name/Print	David S. Bir	Registration Number	38383

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- 6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
- 7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
- 8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
- 9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt				
EFS ID:	36540738			
Application Number:	16506885			
International Application Number:				
Confirmation Number:	7781			
Title of Invention:	SEMICONDUCTOR DIODES-BASED PHYSIOLOGICAL MEASUREMENT DEVICE WITH IMPROVED SIGNAL-TO-NOISE RATIO			
First Named Inventor/Applicant Name:	Mohammed N. ISLAM			
Customer Number:	109543			
Filer:	David S. Bir/Pamela Demos			
Filer Authorized By:	David S. Bir			
Attorney Docket Number:	OMNI 0101 PUSA5			
Receipt Date:	12-JUL-2019			
Filing Date:				
Time Stamp:	09:33:55			
Application Type:	Utility under 35 USC 111(a)			
Payment information:				

### **Payment information:**

Submitted with Payment	no
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### File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	OMNI017PUSP1_updated_IDS_ 9.PDF	710696 117a1dcba5dc070e9720ba1d35c1c30c746 551a3	no	9
Warnings:			'	•	

Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	OMNI0104PUSA5_IDS_1.PDF	702013 ae3a92f8c8852c2f79ae1e63d72a8c4e0ce3 945f	no	4
Warnings:					
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3	Information Disclosure Statement (IDS) Form (SB08)	OMNI0105PUSP4_IDS_13.PDF	4dcd9a58dcf57308047d34f3ccd7e48e1fe7 7936	no	6
Warnings:					
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	Information Disclosure Statement (IDS)		679121		
4	Form (SB08)	OMNI0105PUSP4_IDS_14.PDF	a10e61e227016e4650f798e129a6c94af63f ca7f	no	5
Warnings:					
Information:	:				
			1212242		
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Warnings:	-				
Information:					
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7	Information Disclosure Statement (IDS) Form (SB08)	OMNI0105PUSP4_updated_IDS _17.PDF	4329a02f7fbbba9822cadad3dc5405da34af 1adc		8
Warnings:					
Information:					
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8	Information Disclosure Statement (IDS) Form (SB08)	OMNI0105PUSP4_updated_IDS _18.PDF		no	4
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9	Information Disclosure Statement (IDS) Form (SB08)	OMNI0107PUSP1updated_ID S_8.PDF	685920	no	7
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10	Information Disclosure Statement (IDS) Form (SB08)	OMNI0107PUSP1_updated_IDS _1.PDF	61354a712b73b91ef79934ba19d51311c7c 39eed	no	5
Warnings:					
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Warnings:					
Information:					
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Warnings:					
Information:					
12	Information Disclosure Statement (IDS)	OMNI0107PUSP1_updated_IDS	662703		5
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Warnings:					
Information:					

	Information Disclosure Statement (IDS)	CAMANIO107DUSD1 updated IDS	698779		
15	Form (SB08)	OMNI0107PUSP1_updated_IDS _6.PDF	cb17059fb53d634416eb957f10f6eb053b4f 2201	no	8
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Information:					
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16	Information Disclosure Statement (IDS) Form (SB08)	OMNI0107PUSP1_updated_IDS _7.PDF		no	8
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17 Information Disclosure Statement (IDS) Form (SB08)		OMNI0107PUSP1_Updated_ID S10.PDF	d820f362588e35d5e260151163059b38491 Sdb3e	no	5
Warnings:					
Information:					
		Total Files Size (in bytes):	136	599651	
This Acknow	ledgement Receipt evidences receip	t on the noted date by the U!	SPTO of the indicated	document	s,

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

#### New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.



#### United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

1	APPLICATION	FILING or	GRP ART				
	NUMBER	371(c) DATE	UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
•	16/506,885	07/09/2019	1636	1015	OMNI 0101 PUSA5	23	3

109543 Brooks, Kushman P.C./Cheetah Omni MedSci 1000 Town Center Twenty Second Floor Southfield, MI 48075 CONFIRMATION NO. 7781 FILING RECEIPT



Date Mailed: 07/24/2019

Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please submit a written request for a corrected Filing Receipt, including a properly marked-up ADS showing the changes with strike-through for deletions and underlining for additions. If you received a "Notice to File Missing Parts" or other Notice requiring a response for this application, please submit any request for correction to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections provided that the request is grantable.

Inventor(s)

Mohammed N. ISLAM, Ann Arbor, MI;

Applicant(s)

Omni Medsci, Inc., Ann Arbor, MI;

Power of Attorney: The patent practitioners associated with Customer Number 109543

#### Domestic Priority data as claimed by applicant

This application is a CON of 16/272,069 02/11/2019 which is a CON of 16/029.611 07/08/2018 PAT 10201283 which is a CON of 15/888,052 02/04/2018 PAT 10136819 which is a CON of 15/212.549 07/18/2016 PAT 9885698 which is a CON of 14/650.897 06/10/2015 PAT 9494567 which is a 371 of PCT/US2013/075700 12/17/2013 which claims benefit of 61/747,472 12/31/2012 This application 16/506,885 is a CON of 16/004,359 06/09/2018 which is a CON of 14/109.007 12/17/2013 PAT 9993159 which claims benefit of 61/747.553 12/31/2012 This application 16/506,885 is a CON of 16/188,194 11/12/2018 which is a CON of 16/004,154 06/08/2018 PAT 10126283 which is a CON of 15/855.201 12/27/2017 PAT 9995722 which is a CON of 15/711,907 09/21/2017 PAT 9897584

page 1 of 4

which is a DIV of 15/357,225 11/21/2016 PAT 9797876 which is a CON of 14/650.981 06/10/2015 PAT 9500634 which is a 371 of PCT/US2013/075767 12/17/2013 which claims benefit of 61/747,485 12/31/2012 This application 16/506.885 is a CON of 16/241,628 01/07/2019 which is a CON of 16/015.737 06/22/2018 PAT 10172523 which is a CON of 15/594,053 05/12/2017 PAT 10188299 which is a CON of 14/875,709 10/06/2015 PAT 9651533 which is a CON of 14/108.986 12/17/2013 PAT 9164032 which claims benefit of 61/747,487 12/31/2012 This application 16/506.885 is a CON of 16/284,514 02/25/2019 which is a CON of 16/016.649 06/24/2018 PAT 10213113 which is a CON of 15/860,065 01/02/2018 PAT 10098546 which is a CON of 15/686.198 08/25/2017 PAT 9861286 which is a CON of 15/357.136 11/21/2016 PAT 9757040 which is a CON of 14/651.367 06/11/2015 PAT 9500635 which is a 371 of PCT/US2013/075736 12/17/2013 which claims benefit of 61/747,477 12/31/2012 and claims benefit of 61/754,698 01/21/2013

**Foreign Applications** for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see <a href="http://www.uspto.gov">http://www.uspto.gov</a> for more information.) - None. Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

#### Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

#### If Required, Foreign Filing License Granted: 07/23/2019

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 16/506.885** 

Projected Publication Date: 10/31/2019

Non-Publication Request: No Early Publication Request: No

\*\* SMALL ENTITY \*\*

Title

SEMICONDUCTOR DIODES-BASED PHYSIOLOGICAL MEASUREMENT DEVICE WITH IMPROVED SIGNAL-TO-NOISE RATIO

#### **Preliminary Class**

435

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: Yes page 2 of 4

#### PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

#### LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

#### **GRANTED**

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

#### **NOT GRANTED**

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

#### SelectUSA

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop technology, manufacture products, deliver services, and grow your business, visit <a href="http://www.SelectUSA.gov">http://www.SelectUSA.gov</a> or call +1-202-482-6800.



### UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandra, Virginia 22313-1450 www.uspio.gov

APPLICATION NUMBER FILING OR 371(C) DATE FIRST NAMED APPLICANT ATTY. DOCKET NO./TITLE

16/506,885 07/09/2019 Mohammed N. ISLAM

OMNI 0101 PUSA5
CONFIRMATION NO. 7781

**INFORMAL NOTICE** 

109543 Brooks, Kushman P.C./Cheetah Omni MedSci 1000 Town Center Twenty Second Floor Southfield, MI 48075

Date Mailed: 07/24/2019

#### INFORMATIONAL NOTICE TO APPLICANT

Applicant is notified that the above-identified application contains the deficiencies noted below. No period for reply is set forth in this notice for correction of these deficiencies. However, if a deficiency relates to the inventor's oath or declaration, the applicant must file an oath or declaration in compliance with 37 CFR 1.63, or a substitute statement in compliance with 37 CFR 1.64, executed by or with respect to each actual inventor no later than the expiration of the time period set in the "Notice of Allowability" to avoid abandonment. See 37 CFR 1.53(f).

The item(s) indicated below are also required and should be submitted with any reply to this notice to avoid further processing delays.

• A properly executed inventor's oath or declaration has not been received for the following inventor(s):

Mohammed N. ISLAM

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at (571) 272-4000 or (571) 272-4200 or 1-888-786-0101.

/ldvan/		

	PATE	ENT APPLI		ON FEE DE		TON RECOR	RD		Applica 16/50	tion or Docket Num 6,885	ber
	APPL	ICATION A			umn 2)	SMAL	L EN	NTITY	OR	OTHER SMALL	
FOR NUMBER FILED NUMBER EXTRA					R EXTRA	RATE(\$)		FEE(\$)		RATE(\$)	FEE(\$)
BASIC FEE (37 CFR 1.16(a), (b), or (c)) N/A N				I/A	N/A		75	1	N/A		
	RCH FEE FR 1.16(k), (i), or (m))	N	/A	١	N/A			330	1	N/A	
	MINATION FEE FR 1.16(o), (p), or (q))	N	/A	١	I/A	N/A		380	1	N/A	
TOT	AL CLAIMS FR 1.16(i))	23	minus :	20= *	3	× 50	-	150	OR		
INDE	PENDENT CLAIM FR 1.16(h))	<sup>1S</sup> 3	minus :	3 = *		× 230	=	0.00	1		
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MUL	TIPLE DEPENDE	NT CLAIM PRE	SENT (37	7 CFR 1.16(j))				0.00	1		
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#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Group Art Unit: 2886

MOHAMMED N. ISLAM

Examiner: RAHMAN, MD M

Serial No.: 16/506885

Filed: 7/9/2019

For: SEMICONDUCTOR DIODES-BASED PHYSIOLOGICAL

MEASUREMENT DEVICE WITH IMPROVED SIGNAL-TO-

**NOISE RATIO** 

Attorney Docket No.: OMNI0101PUSA5

### PRELIMINARY AMENDMENT UNDER 37 C.F.R. § 1.115

Commissioner for Patents U.S. Patent & Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450

Commissioner:

Please amend the above-identified application as follows:

### **Amendments to the Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Currently Amended) A system for measuring one or more physiological parameters and for use with a smart phone or tablet, the system comprising:

a wearable device adapted to be placed on a wrist or an ear of a user, including a light source comprising a plurality of semiconductor sources that are light emitting diodes, each of the light emitting diodes configured to generate an output optical light having one or more optical wavelengths;

the wearable device <del>comprising one or more lenses</del>-configured to receive a portion of at least one of the output optical lights and to direct <u>an output a lens output light</u> to tissue;

the wearable device further comprising a detection system configured to receive at least a portion of the lens output light-output reflected from the tissue and to generate an output signal having a signal-to-noise ratio, wherein the detection system is configured to be synchronized to the light source;

wherein the detection system comprises a plurality of spatially separated detectors, and wherein at least one analog to digital converter is coupled to at least one of the spatially separated detectors;

wherein a detector output from the at least one of the plurality of spatially separated detectors is coupled to an amplifier having a gain configured to improve detection sensitivity;

the smart phone or tablet comprising a wireless receiver, a wireless transmitter, a display, a speaker, a voice input module, one or more buttons or knobs, a microprocessor and a touch screen, the smart phone or tablet configured to receive and process at least a portion of the output signal, wherein the smart phone or tablet is configured to store and display the processed output signal, and wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link;

a cloud configured to receive over the wireless transmission link an output status comprising the at least a portion of the processed output signal, to process the received output status to generate processed data, and to store the processed data;

wherein the output signal is indicative of one or more of the physiological parameters, and the cloud is configured to store a history of at least a portion of the one or more physiological parameters over a specified period of time;

the wearable device configured to increase the signal-to-noise ratio by increasing light intensity of at least one of the plurality of semiconductor sources from an initial light intensity and by increasing a pulse rate of at least one of the plurality of semiconductor sources from an initial pulse rate; and

the detection system further configured to:

generate a first signal responsive to light received while the light emitting diodes are off, generate a second signal responsive to light received while at least one of the light emitting diodes is on, and

increase the signal-to-noise ratio by comparing the first signal and the second signal.

- 2. (Original) The system of Claim 1, wherein the wearable device is configured to use artificial intelligence in making decisions associated with at least a portion of the output signal.
- 3. (Original) The system of Claim 2, wherein the wearable device is at least in part configured to identify an object, and to compare a property of at least some of the output signal to a threshold.
- 4. (Currently Amended) The system of Claim 3, wherein the wearable device is configured to perform pattern identification or classification based on at least a part of the output signal, or the wearable device is configured to apply regression signal processing methodologies to at least a part of the output signal.
- 5. (Original) The system of Claim 4, wherein at least one of the spatially separated detectors is located at a first distance from at least one of the light emitting diodes and at least another of the spatially separated detectors is located at a second distance from the at least one of the light emitting diodes, and the at least one of the spatially separated detectors is configured to generate a third signal responsive to light from the at least one light emitting diode and the at least another of the spatially separated detectors is configured to generate a fourth signal responsive to the light from the at least one of the light emitting diodes; and

wherein at least one of the spatially separated detectors is located at a third distance from a first one of the light emitting diodes and at a fourth distance from a second one of the light emitting diodes, and is configured to generate a fifth signal responsive to light from the first light emitting diode and a sixth signal responsive to light from the second light emitting diode, and wherein the first distance is different from the second distance, and the third distance is different from the fourth distance.

- 6. (Currently Amended) The system of Claim 5, wherein the wearable device further comprises a reflective surface positioned to reflect at least a portion of the lens output light output reflected from the tissue.
- 7. (Currently Amended) A system for measuring one or more physiological parameters and for use with a smart phone or tablet, the system comprising:

a wearable device adapted to be placed on a wrist or an ear of a user, and including a light source comprising a plurality of semiconductor sources, each of the semiconductor sources configured to generate an output light having one or more optical wavelengths;

the wearable device <del>comprising one or more lenses</del> configured to receive a portion of at least one of the output lights and to deliver <del>a lens output light an output to tissue;</del>

the wearable device further comprising a detection system configured to receive at least a portion of the lens output light output reflected from the tissue and to generate an output signal having a signal-to-noise ratio, wherein the detection system is configured to be synchronized to the light source;

wherein the detection system comprises a plurality of spatially separated detectors, and wherein at least one analog to digital converter is coupled to at least one of the spatially separated detectors;

the smart phone or tablet comprising a wireless receiver, a wireless transmitter, a display, a speaker, a voice input module, one or more buttons or knobs, a microprocessor and a touch screen, the smart phone or tablet configured to receive and process at least a portion of the output signal, wherein the smart phone or tablet is configured to store and display the processed output signal, and wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link;

a cloud configured to receive over the wireless transmission link an output status comprising the at least a portion of the processed output signal, to process the received output status to generate processed data, and to store the processed data;

wherein the output signal is indicative of one or more of the physiological parameters;

the wearable device configured to increase the signal-to-noise ratio by increasing light intensity of at least one of the semiconductor sources from an initial light intensity and by increasing a pulse rate of at least one of the semiconductor sources from an initial pulse rate; and the detection system further configured to:

generate a first signal responsive to light received while the semiconductor sources are off, generate a second signal responsive to light received while at least one of the semiconductor sources is on, and

increase the signal-to-noise ratio by comparing the first signal and the second signal.

- 8. (Original) The system of Claim 7, wherein the wearable device is at least in part configured to identify an object, and a property of at least some of the output signal is compared by at least one of the wearable device, the smart phone or tablet to a threshold.
- 9. (Original) The system of Claim 8, wherein a detector output from at least one of the plurality of spatially separated detectors is coupled to an amplifier having a gain configured to improve detection sensitivity.
- 10. (Original) The system of Claim 9, wherein the wearable device is configured to use artificial intelligence to process at least a portion of the output signal.
- 11. (Currently Amended) The system of Claim 10, wherein the artificial intelligence comprises pattern identification or classification or regression signal processing methodologies.
- 12. (Currently Amended) The system of Claim 10, wherein the wearable device is configured to perform pattern identification or classification based on at least a part of the output signal, or the wearable device is configured to apply regression signal processing methodologies to at least a part of the output signal.

detectors is located at a first distance from at least one of the light emitting diodes and at least another of the spatially separated detectors is located at a second distance from the at least one of the light emitting diodes, and the at least one of the spatially separated detectors is configured to generate a third signal responsive to light from the at least one light emitting diode and the at least another of the spatially separated detectors is configured to generate a fourth signal responsive to the light from the at least one of the light emitting diodes; and

wherein at least one of the spatially separated detectors is located at a third distance from a first one of the light emitting diodes and at a fourth distance from a second one of the light emitting diodes, and is configured to generate a fifth signal responsive to light from the first light emitting diode and a sixth signal responsive to light from the second light emitting diode, and wherein the first distance is different from the second distance, and the third distance is different from the fourth distance.

- 14. (Currently Amended) The system of Claim 13, wherein the wearable device further comprises a reflective surface positioned to reflect at least a portion of the lens output light output reflected from the tissue.
- 15. (Currently Amended) A system for measuring one or more physiological parameters and for use with a smart phone or tablet, the system comprising:

a wearable device adapted to be placed on a wrist or an ear of a user, including a light source comprising a plurality of semiconductor sources that are light emitting diodes, each of the light emitting diodes configured to generate an output optical light having one or more optical wavelengths;

the wearable device <del>comprising one or more lenses</del>-configured to receive a portion of at least some of the output optical light and to deliver <del>a lens output light an output</del> to tissue;

the wearable device further comprising a detection system configured to receive at least a portion of the lens output light output reflected from the tissue and to generate an output signal having a signal-to-noise ratio, wherein the detection system is configured to be synchronized to the light source;

wherein the detection system comprises a plurality of spatially separated detectors, and wherein at least one analog to digital converter is coupled to at least one of the spatially separated detectors;

the smart phone or tablet comprising a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor and a touch screen, the smart phone or tablet configured to receive and process at least a portion of the output signal, wherein the smart phone or tablet is configured to store and display the processed output signal, and wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link;

a cloud configured to receive over the wireless transmission link an output status comprising the at least a portion of the processed output signal, to process the received output status to generate processed data, and to store the processed data;

wherein the output signal is indicative of one or more of the physiological parameters;

the wearable device configured to increase the signal-to-noise ratio by increasing light intensity of at least one of the plurality of semiconductor sources from an initial light intensity; and

the detection system further configured to:

generate a first signal responsive to light received while the light emitting diodes are off, generate a second signal responsive to light received while at least one of the light emitting diodes is on, and

increase the signal-to-noise ratio by comparing the first signal and the second signal.

- 16. (Original) The system of Claim 15, wherein the wearable device is at least in part configured to detect an object, and a property of at least some of the output signal is compared to a threshold.
- 17. (Original) The system of Claim 15, wherein a detector output from at least one of the plurality of spatially separated detectors is coupled to an amplifier having a gain configured to be adjusted to improve detection sensitivity.
- 18. (Original) The system of Claim 15, wherein the wearable device is configured to use artificial intelligence in making decisions associated with at least a portion of the output signal.

- 19. (Original) The system of claim 18 wherein the artificial intelligence comprises a pattern matching algorithm.
- 20. (Original) The system of claim 18 wherein the artificial intelligence comprises spectral fingerprinting.
- 21. (Currently Amended) The system of Claim 15, wherein the wearable device is configured to perform pattern identification or classification based on at least a part of the output signal, or the wearable device is configured to apply regression signal processing methodologies to at least a part of the output signal.
- 22. (Original) The system of Claim 21, wherein the pattern identification or classification comprises a pattern matching algorithm or spectral fingerprinting.
- 23. (Currently Amended) The system of Claim 15, wherein the wearable device further comprises a reflective surface positioned to reflect at least a portion of <u>light-the output</u> reflected from the tissue.

### **Remarks**

Applicant has amended various claims to more particularly point out the claimed subject matter. Applicant respectfully requests entry of this amendment prior to substantive examination.

No additional fee is believed to be due. However, please charge any fees or credit any overpayments as a result of the filing of this paper to our Deposit Account No. 02-3978.

Respectfully submitted,

#### MOHAMMED N. ISLAM

By: /Andrew B. Turner/
Andrew B. Turner
Reg. No. 63,121
Attorney for Applicant

Date: August 6, 2019

#### **BROOKS KUSHMAN P.C.**

1000 Town Center, 22nd Floor Southfield, MI 48075-1238

Phone: 248-358-4400 Fax: 248-358-3351

Electronic Ac	knowledgement Receipt
EFS ID:	36798714
Application Number:	16506885
International Application Number:	
Confirmation Number:	7781
Title of Invention:	SEMICONDUCTOR DIODES-BASED PHYSIOLOGICAL MEASUREMENT DEVICE WITH IMPROVED SIGNAL-TO-NOISE RATIO
First Named Inventor/Applicant Name:	Mohammed N. ISLAM
Customer Number:	109543
Filer:	Andrew B. Turner/Amy Tanner
Filer Authorized By:	Andrew B. Turner
Attorney Docket Number:	OMNI 0101 PUSA5
Receipt Date:	06-AUG-2019
Filing Date:	09-JUL-2019
Time Stamp:	16:43:07
Application Type:	Utility under 35 USC 111(a)
Payment information:	

## **Payment information:**

Submitted with Payment	no
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# File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
			54185		
1		OMNI0101PUSA5_preliminary_ amendment.pdf	22b081825aa6bf47e81fc1427383d4be649 b1da1	yes	9

	Multipart Description/PDF files in .	zip description	
	Document Description	Start	End
	Preliminary Amendment	1	1
	Claims	2	8
	Applicant Arguments/Remarks Made in an Amendment	9	9
Warnings:			
Information:			
	Total Files Size (in bytes)	5	4185

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#### New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

#### National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office If a new international application is being filed and the international application

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Attorney Docket Number

OMNI0101PUSA5

# ASSIGNMENT AND DECLARATION (37 C.F.R. 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 C.F.R. 1.76)

Title of Invention	SEMICONDUCTOR DIODES-BASED PHYSIOLOGICAL					
	MEASUREMENT DEVICE WITH IMPROVED SIGNAL-TO-NOISE RATIO					
As a balayy named inventor. I have						
As a below named inventor, I hereby declare that:						
This declaration is directed to:						
The attached ap	oplication, or					
	pplication or PCT international application number filed on (I hereby authorize the application filing date and number when they become known.)					
The above-identified application	was made or authorized to be made by me.					
I believe that I am the original inv	ventor or an original joint inventor of a claimed invention in the application.					
I hereby state that I have reviewed	d and understand the contents of the above-identified specification, including the claims.					
I am aware of the duty to disclose as defined in 37 C.F.R. § 1.56.	e to the U.S. Patent and Trademark Office all information known to me to be material to patentability					
over to Omni Medsci, Inc., a corp of business at 1718 Newport Cr assigns or other legal representation in the above-identified application applications and to receive Letter names, or in my name, at its or the legal representatives, all rights of	and valuable consideration, receipt of which is hereby acknowledged, I do hereby assign, sell and set poration organized and existing under the laws of the state or country of Michigan, and having a place seek Drive, Ann Arbor, Michigan 48103, hereinafter referred to as the ASSIGNEE, its successors, lives, my entire right, title and interest, domestic and foreign, in and to the inventions and discoveries in including the right of said ASSIGNEE, its successors, assigns or other legal representatives to make as Patent for said inventions and discoveries in any and all foreign countries in its or their own name or their election, and I hereby assign, sell and set over to said ASSIGNEE, its successors, assigns or other of priority, including any provisional applications, in and to said inventions and discoveries in all ions claiming benefit of the filing date hereof, continuations, continuations-in-part, divisionals, rations.					
applications for Letters Patent of	my heirs, successors, assigns or other legal representatives to execute any and all papers, including any and all kinds and in any and all countries and to perform any and all acts which said ASSIGNEE, gal representatives may deem necessary to secure thereto the rights herein assigned, sold and set over.					
And I hereby represent and warra	nt that I have not granted any rights inconsistent with the rights granted herein.					
I hereby acknowledge that any imprisonment of not more than fi	willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or we (5) years or both.					
LEGAL NAME OF INVENTOR	August 1, 2019					
Inventor: Mohammed N. IS	LAM Date:					
Signature:/Mishamof	1/11 Juliu					
Page 1 (Supplemental Sheet with	Additional Joint Inventors is attached if necessary)					
Note: An Application Data Sheet (P	TO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form.					

Electronic Acl	knowledgement Receipt
EFS ID:	36799654
Application Number:	16506885
International Application Number:	
Confirmation Number:	7781
Title of Invention:	SEMICONDUCTOR DIODES-BASED PHYSIOLOGICAL MEASUREMENT DEVICE WITH IMPROVED SIGNAL-TO-NOISE RATIO
First Named Inventor/Applicant Name:	Mohammed N. ISLAM
Customer Number:	109543
Filer:	Andrew B. Turner/Amy Tanner
Filer Authorized By:	Andrew B. Turner
Attorney Docket Number:	OMNI 0101 PUSA5
Receipt Date:	06-AUG-2019
Filing Date:	09-JUL-2019
Time Stamp:	16:54:42
Application Type:	Utility under 35 USC 111(a)

# **Payment information:**

Submitted with Payment	no
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# File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
			264646		
1	Oath or Declaration filed	OMNI0101PUSA5_Signed_Decl aration_Assignment.pdf	97d96363ac9113d68914ea2be3aeb7dd42f 57834	no	1
Warnings:				•	

Information:	
Total Files Size (in bytes):	264646

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#### New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

#### National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875  Applica					n or Docket Number 16/506,885	Filing Date 07/09/2019	To be Mailed		
							ENTITY:	LARGE 🗹 SM	IALL MICRO
				APPLIC	CATION AS FIL	ED - PAI	RT I		
	FOR		(Column <sup>-</sup> UMBER FI		(Column 2) NUMBER EXTRA		RATE (\$)		FEE (\$)
	BASIC FEE	<del>-    </del>	N/A		N/A		N/A	†	1 LL (Ψ)
┝┯	(37 CFR 1.16(a), (b), c	or (c))						1	
	(37 CFR 1.16(k), (i), or		N/A		N/A		N/A		
	EXAMINATION FEE (37 CFR 1.16(o), (p), c		N/A		N/A		N/A		
TOTAL CLAIMS (37 CFR 1.16(i)) minus 20 = *					x \$50 =				
IND	EPENDENT CLAIM	S	m	inus 3 = *			x \$230 =		
	(37 CFR 1.16(h))  If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).					(\$155 or			
	MULTIPLE DEPENI	DENT CLAIM PF	ESENT (37	' CFR 1.16(j))					
* If th	ne difference in co	olumn 1 is less	than zero	enter "0" in coli	umn 2.		TOTAL		
					TION AS AMEI		ART II		
$\vdash$		(Column 1) CLAIMS		(Column 2) HIGHEST	(Column 3	)		<del>]</del>	
AMENDMENT	08/06/2019	REMAINING AFTER AMENDMENT		NUMBER PREVIOUSLY PAID FOR	PRESENT EX	TRA	RATE (\$)	ADDIT	IONAL FEE (\$)
	Total (37 CFR 1.16(i))	* 23	Minus	** 23	= 0		x \$50 =		0
	Independent (37 CFR 1.16(h))	* 3	Minus	*** 3	= 0		x \$230 =		0
₽		Size Fee (37 C	R 1.16(s	))					
	│	SENTATION C	F MULTIF	LE DEPENDEN	NT CLAIM (37 CF	R			
H	1.10(j))						TOTAL ADD'L FE	E	0
		(Column 1)		(Column 2)	(Column 3	)			
ΔŢ		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EX	TRA	RATE (\$)	ADDIT	IONAL FEE (\$)
AMENDMEN	Total (37 CFR 1.16(i))	*	Minus	**	=		x \$0 =		
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x \$0 =		
ME		Size Fee (37 C	R 1.16(s	))					
<b>d</b>	☐ FIRST PRES 1.16(j))	SENTATION C	F MULTIF	LE DEPENDEN	NT CLAIM (37 CF	R			
							TOTAL ADD'L FE	E	
* If t	he entry in column 1	I is less than the	entry in col	umn 2, write "0" in	column 3.		LIE		
	the "Highest Number						/VERONICA E	:VERETTE/	
	f the "Highest Number R					found in the	appropriate box in colu	mn 1	

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS

ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Doc Code: DIST.E.FILE Document Description: Electroni	c Terminal Disclaimer - Filed	PTO/SB/25 PTO/SB/26 U.S. Patent and Trademark Office Department of Commerce				
Electronic Petition Request	REJECTION OVER A PENDING	BVIATE A PROVISIONAL DOUBLE PATENTING 'REFERENCE" APPLICATION TO OBVIATE A DOUBLE PATENTING REJECTION OVER A				
Application Number	16506885					
Filing Date	09-Jul-2019	09-Jul-2019				
First Named Inventor	Mohammed ISLAM	Mohammed ISLAM				
Attorney Docket Number	OMNI 0101 PUSA5	USA5				
Title of Invention		SEMICONDUCTOR DIODES-BASED PHYSIOLOGICAL MEASUREMENT DEVICE WITH IMPROVED SIGNAL-TO-NOISE RATIO				
Filing of terminal disclaimer does not obviate requiremer  Office Action		ponse under 37 CFR 1.111 to outstanding				
This electronic Terminal Discl	aimer is not being used for a Joint Re	esearch Agreement.				
Owner	P	ercent Interest				
OMNI MEDSCI, INC.		00 %				
The owner(s) of percent interest lis	ted above in the instant application	hereby disclaims, except as provided below, the terminal				

The owner(s) of percent interest listed above in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of any patent granted on pending reference Application Number(s)

16272069 filed on 02/11/2019

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In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term of any patent granted on said reference application, "as the term of any patent granted on said reference application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending reference application," in the event that any such patent granted on the pending reference application: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims canceled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as shortened by any terminal disclaimer filed prior to its grant.

The owner(s) with percent interest listed above in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of prior patent number(s)

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as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.
In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer," in the event that said prior patent later: - expires for failure to pay a maintenance fee; - is held unenforceable;
<ul> <li>is found invalid by a court of competent jurisdiction;</li> <li>is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;</li> <li>has all claims canceled by a reexamination certificate;</li> </ul>
- is reissued; or
- is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.
Terminal disclaimer fee under 37 CFR 1.20(d) is included with Electronic Terminal Disclaimer request.
O I certify, in accordance with 37 CFR 1.4(d)(4), that the terminal disclaimer fee under 37 CFR 1.20(d) required for this terminal disclaimer has already been paid in the above-identified application.
Applicants claims the following fee status:
Small Entity
Micro Entity
○ Regular Undiscounted
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.
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I certify, in accordance with 37 CFR 1.4(d)(4) that I am:
reertily, in accordance with 37 CFK 1.4(d)(4) that Fam.
An attorney or agent registered to practice before the Patent and Trademark Office who is of record in this application
An attorney or agent registered to practice before the Patent and Trademark Office who is of record in
An attorney or agent registered to practice before the Patent and Trademark Office who is of record in this application
An attorney or agent registered to practice before the Patent and Trademark Office who is of record in this application  Registration Number 63121

Signature	/Andrew B. Turner/
Name	Andrew B. Turner

<sup>\*</sup>Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner). Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

Electronic Patent Application Fee Transmittal					
Application Number:	165	506885			
Filing Date:	09-Jul-2019				
Title of Invention:	SEMICONDUCTOR DIODES-BASED PHYSIOLOGICAL MEASUREMENT DEVIC WITH IMPROVED SIGNAL-TO-NOISE RATIO				SUREMENT DEVICE
First Named Inventor/Applicant Name:	Mohammed N. ISLAM				
Filer:	Andrew B. Turner/Amy Tanner				
Attorney Docket Number:	OMNI 0101 PUSA5				
Filed as Small Entity					
Filing Fees for Utility under 35 USC 111(a)					
Description		Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:					
STATUTORY OR TERMINAL DISCLAIMER		2814	1	160	160
Pages:					
Claims:					
Miscellaneous-Filing:					
Petition:					
Patent-Appeals-and-Interference:					
Post-Allowance-and-Post-Issuance:					

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Miscellaneous:				
	Tot	al in USD	(\$)	160

Doc Code: DISQ.E.FILE Document Description: Electronic Terminal Disclaimer – Approved
Application No.: 16506885
Filing Date: 09-Jul-2019
Applicant/Patent under Reexamination: ISLAM
Electronic Terminal Disclaimer filed on August 12, 2019
This patent is subject to a terminal disclaimer
DISAPPROVED
Approved/Disapproved by: Electronic Terminal Disclaimer automatically approved by EFS-Web
U.S. Patent and Trademark Office

Electronic Acknowledgement Receipt				
EFS ID:	36831701			
Application Number:	16506885			
International Application Number:				
Confirmation Number:	7781			
Title of Invention:	SEMICONDUCTOR DIODES-BASED PHYSIOLOGICAL MEASUREMENT DEVICE WITH IMPROVED SIGNAL-TO-NOISE RATIO			
First Named Inventor/Applicant Name:	Mohammed N. ISLAM			
Customer Number:	109543			
Filer:	Andrew B. Turner/Amy Tanner			
Filer Authorized By:	Andrew B. Turner			
Attorney Docket Number:	OMNI 0101 PUSA5			
Receipt Date:	12-AUG-2019			
Filing Date:	09-JUL-2019			
Time Stamp:	13:42:59			
Application Type:	Utility under 35 USC 111(a)			
Payment information:	•			

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	\$160
RAM confirmation Number	E20198BD42315924
Deposit Account	
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

File Listing:								
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)			
			37271					
1	Terminal Disclaimer-Filed (Electronic)	e Terminal-Disclaimer.pdf	no ea42f653525a058fe82b6bb4592fceacee1e 1b91		3			
Warnings:			1	·				
Information:								
			30548					
2	Fee Worksheet (SB06)	fee-info.pdf	f724ab344ed54cc59396354a213ca7ee125 3fedf	no	2			
Warnings:	+		<u> </u>	1				
Information:								

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

Total Files Size (in bytes):

#### **New Applications Under 35 U.S.C. 111**

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

#### National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

#### New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

67819

#### United States Patent and Trademark Office



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#### NOTICE OF ALLOWANCE AND FEE(S) DUE

Brooks, Kushman P.C./Cheetah Omni MedSci 1000 Town Center Twenty Second Floor Southfield, MI 48075

**EXAMINER** RAHMAN, MD M ART UNIT PAPER NUMBER 2886

DATE MAILED: 08/19/2019

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/506,885	07/09/2019	Mohammed N. ISLAM	OMNI 0101 PUSA5	7781

TITLE OF INVENTION: SEMICONDUCTOR DIODES-BASED PHYSIOLOGICAL MEASUREMENT DEVICE WITH IMPROVED SIGNAL-TO-NOISE RATIO

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$500	\$0.00	\$0.00	\$500	11/19/2019

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

#### HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

		PART 1	B - FEE(S) TRANS	SMITTAL				
Complete and send t	his form, together v	vith applicable fee(s	), by mail or fax, or	via EFS-Web.				
By mail, send to:	Mail Stop ISSUE I Commissioner for P.O. Box 1450 Alexandria, Virgin	Patents				By fax, send to	o: (571	1)-273-2885
INSTRUCTIONS: This further correspondence in below or directed otherw	cluding the Patent, advar	nce orders and notificatio	n of maintenance fees wi dence address; and/or (b	ill be mailed to the cu ) indicating a separa ote: A certificate of	irrent cor te "FEE . f mailing	respondence address as ADDRESS" for mainted can only be used for	indicated u nance fee no domestic n	inless corrected otifications. nailings of the
109543 Brooks, Kushm	7590 08/19/ nan P.C./Cheetah (	72019	p h I S	apers. Each addition ave its own certifical Co hereby certify that t tates Postal Service	ial paper, te of mai ertificate his Fee(s with sufi	icate cannot be used for such as an assignment ling or transmission. of Mailing or Transmiss Transmittal is being ficient postage for first	t or formal  nission deposited w class mail	drawing, mus
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Southfield, MI 4							(Турс	ed or printed name
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APPLICATION NO.	FILING DATE		FIRST NAMED INVENT	OR	ATTO	RNEY DOCKET NO.	CONFIRM	IATION NO.
16/506,885	07/09/2019		Mohammed N. ISLAN	А	OM	INI 0101 PUSA5	77	781
TITLE OF INVENTION:	SEMICONDUCTOR D	OIODES-BASED PHYSI	OLOGICAL MEASURI	EMENT DEVICE W	TTH IMI	PROVED SIGNAL-TO	-NOISE	
APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DU	JE PREV. PAID ISS	UE FEE	TOTAL FEE(S) DUE	DA	TE DUE
nonprovisional	SMALL	\$500	\$0.00	\$0.00		\$500	11/	19/2019
EXAM	INER	ART UNIT	CLASS-SUBCLASS					
RAHMAN	N, MD M	2886	250-341800	_				
Address form PTO/SB  "Fee Address" indi	ondence address (or Char	nge of Correspondence	2. For printing on th  (1) The names of up or agents OR, altern  (2) The name of a si registered attorney of 2 registered patent a listed, no name will	o to 3 registered pate atively, ngle firm (having as or agent) and the nar ttorneys or agents. I	a members a members of up	1 er a p to 2		
3. ASSIGNEE NAME AT	ND RESIDENCE DATA	TO BE PRINTED ON	THE PATENT (print or	type)				
	ecordation, as set forth in	ed below, no assignee dat a 37 CFR 3.11 and 37 CF		of this form is NOT	a substit	ute for filing an assign		een previously
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Date \_

Registration No.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature \_

Typed or printed name

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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 07/09/2019 OMNI 0101 PUSA5 7781 16/506,885 Mohammed N. ISLAM **EXAMINER** 08/19/2019 Brooks, Kushman P.C./Cheetah Omni MedSci RAHMAN, MD M 1000 Town Center ART UNIT PAPER NUMBER Twenty Second Floor Southfield, MI 48075 2886 DATE MAILED: 08/19/2019

#### Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

#### OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

#### **Privacy Act Statement**

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b) (2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

- The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
- 2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
- 3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
- 4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
- 5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
- 6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
- 7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
- 8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
- 9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential characteristic properties of the properties of the USPTO becomes aware of a violation or potential characteristics.

	Application No. 16/506,885		Applicant(s) ISLAM, Mohammed N.			
Notice of Allowability	Examiner MD M RAHMAN	Art Unit 2886	AIA (FITF) Status Yes			
The MAILING DATE of this communication appearance All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RION of the Office or upon petition by the applicant. See 37 CFR 1.313	(OR REMAINS) CLOSED in or other appropriate commur GHTS. This application is sul	this application. If no nication will be maile	ot included d in due course. <b>THIS</b>			
<ul> <li>1.</li></ul>	/were filed on					
2. An election was made by the applicant in response to a res restriction requirement and election have been incorporated		during the interview	on; the			
3. The allowed claim(s) is/are 1-23. As a result of the allowed Highway program at a participating intellectual property off http://www.uspto.gov/patents/init_events/pph/index.jsp	ice for the corresponding app	lication. For more in	formation, please see			
4. Acknowledgment is made of a claim for foreign priority under	er 35 U.S.C. § 119(a)-(d) or (	f).				
Certified copies:						
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International Bureau (PCT Rule 17.2(a)).	ocuments have been received	ı iii tilis Hationai Staç	је аррисацоп пош ше			
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Applicant has THREE MONTHS FROM THE "MAILING DATE' noted below. Failure to timely comply will result in ABANDONN THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.		a reply complying v	vith the requirements			
5. CORRECTED DRAWINGS (as "replacement sheets") must	t be submitted.					
including changes required by the attached Examiner's Paper No./Mail Date	s Amendment / Comment or i	n the Office action o	f			
Identifying indicia such as the application number (see 37 CFR 1 sheet. Replacement sheet(s) should be labeled as such in the he			nt (not the back) of each			
6. DEPOSIT OF and/or INFORMATION about the deposit of E attached Examiner's comment regarding REQUIREMENT F						
Attachment(s)	_					
1. Notice of References Cited (PTO-892)		Amendment/Comm				
.☑ Information Disclosure Statements (PTO/SB/08), 6. ☑ Examiner's Statement of Reasons for Allowance Paper No./Mail Date						
3. Examiner's Comment Regarding Requirement for Deposit 7. Other  of Biological Material						
4. Interview Summary (PTO-413), Paper No./Mail Date						
/MD M RAHMAN/						
Primary Examiner, Art Unit 2886						

U.S. Patent and Trademark Office PTOL-37 (Rev. 08-13)

Notice of Allowability

Part of Paper No./Mail Date 20190813

Application/Control Number: 16/506,885

Art Unit: 2886

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined

under the first inventor to file provisions of the AIA.

**Information Disclosure Statement** 

Acknowledgment is made of Applicant's Information Disclosure Statement (IDS)

form PTO 1449. These IDS has been considered.

**Terminal Disclaimer** 

The terminal disclaimer filed on 8/12/19 disclaiming the terminal portion of any

patent granted on this application which would extend beyond the expiration date of (US

application no 16272069) and US patent (9494567, 9885698, 10136819 and 10201283)

has been reviewed and is accepted. The terminal disclaimer has been recorded.

Allowable Subject Matter

Claims 1-23 are allowed.

The following is an examiner's statement of reasons for allowance:

As to claim 1, 7 and 15, the prior arts alone or in combination fail to disclose the

claimed limitations such as, "the wearable device further comprising a detection system

configured to receive at least a portion of the lens output light output reflected from the

tissue and to generate an output signal having a signal-to-noise ratio, wherein the

detection system is configured to be synchronized to the light source;

Page 2

Application/Control Number: 16/506,885

Art Unit: 2886

a cloud configured to receive over the wireless transmission link an output status comprising the at least a portion of the processed output signal, to process the received output status to generate processed data, and to store the processed data;

wherein the output signal is indicative of one or more of the physiological parameters, and the cloud is configured to store a history of at least a portion of the one or more physiological parameters over a specified period of time;

the wearable device configured to increase the signal-to-noise ratio by increasing light intensity of at least one of the plurality of semiconductor sources from an initial light intensity and by increasing a pulse rate of at least one of the plurality of semiconductor sources from an initial pulse rate; and

the detection system further configured to:

generate a first signal responsive to light received while the light emitting diodes are off, generate a second signal responsive to light received while at least one of the light emitting diodes is on, and increase the signal-to-noise ratio by comparing the first signal and the second signal" along with all other limitations of the claim.

Claims 2-6, 8-14 and 16-23 are allowable due to their dependencies.

The closest references, Islam (US PG Pub 2009/0204110) (cited in the IDS filed by the applicant), Islam et al. (US 6381391) (cited in the IDS filed by the applicant), Holman (US PG Pub 2007/0078348) (cited in the IDS filed by the applicant) and Waarts et al. (US 6212310 B1) (cited in the IDS filed by the applicant) alone or in combination disclose some features of the claimed invention but do not disclose the claimed invention.

Page 3

Application/Control Number: 16/506,885 Page 4

Art Unit: 2886

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MD M RAHMAN whose telephone number is (571)272-9175. The examiner can normally be reached on Mon-Thur.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, TARIFUR CHOWDHURY can be reached on 571-272-2287. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MD M RAHMAN/ Primary Examiner, Art Unit 2886

	Application/Control No.	Applicant(s)/Patent Under Reexamination
Index of Claims	16/506,885	ISLAM, Mohammed N.
	Examiner	Art Unit
	MD M RAHMAN	2886

1	Rejected	-	Cancelled	N	Non-Elected	Α	Appeal
=	Allowed	÷	Restricted	I	Interference	0	Objected

	CLAIMS									
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CL	CLAIM			DATE						
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U.S. Patent and Trademark Office Part of Paper No.: 20190813

# Search Notes

Application/Control No.	Applicant(s)/Patent Under Reexamination
16/506,885	ISLAM, Mohammed N.
Examiner	Art Unit
MD M RAHMAN	2886

CPC - Searched*		
Symbol	Date	Examiner
G 01N 21/3581 G 01N 21/3563 G 01N 21/35 , G 01N 21/4738, G 01N 21/55	08/13/2019	MR
G01J3/02 G01J3/28 G01J3/42, G01N21/31, G01N21/552	08/13/2019	MR

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classificat	US Classification - Searched*					
Class	Subclass	Date	Examiner			
356	300	08/13/2019	MR			

<sup>\*</sup> See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
INVENTOR SEARCH, US PG PUB AND PAT	08/13/2019	MR

Interference Search					
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner		
G 01N 21/3581	G 01N 21/3563 G 01N 21/35 , G 01N 21/4738, G 01N 21/55	08/13/2019	MR		

/MD M RAHMAN/ Primary Examiner, Art Unit 2886	

Issue Classific	cation

Application/Control No.	Applicant(s)/Patent Under Reexamination
16/506,885	ISLAM, Mohammed N.
Examiner	Art Unit
MD M BAHMAN	2886

CPC						
Symbol			Туре	Version		
A61B		5	7	0088	F	2013-01-01
G01N		21	/	3563	ı	2013-01-01
G01N		33	7	025	1	2013-01-01
G01N		33		15	1	2013-01-01
G01N		33	7	442	ı	2013-01-01
G01N		33	1	49	ı	2013-01-01
A61B		5	7	14532	ı	2013-01-01
A61B		5	7	1455	ı	2013-01-01
A61B		5	/	742	ı	2013-01-01
G01J		3	7	0218	ı	2013-01-01
G01J		3	7	108	ı	2013-01-01
G01J		3	7	14	ı	2013-01-01
G01J		3	7	28	ı	2013-01-01
G01J		3		2823	ı	2013-01-01
G01J		3	7	42	ı	2013-01-01
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G01N		21	7	359	ı	2013-01-01
G01N		21	/	39	ı	2013-01-01
G01N		21	7	88	1	2013-01-01
A61B		5		0013	1	2013-01-01
A61B		5	/	0075	1	2013-01-01
A61B		5	7	7405	ı	2013-01-01
A61B		5	7	7257	ı	2013-01-01
A61B		5	7	6801	ı	2013-01-01
<b>4</b> 61B		5	7	4547	ı	2013-01-01
A61B		5		14546	1	2013-01-01
<b>4</b> 61 <b>B</b>		5	7	0086	I	2013-01-01
A61B		5	1	0022	1	2013-01-01
A61B		2562		146	Α	2013-01-01

NONE	ONE Total Claims Allowe					
(Assistant Examiner)	Examiner) (Date) 23					
/MD M RAHMAN/ Primary Examiner, Art Unit 2886	13 August 2019	O.G. Print Claim(s)	O.G. Print Figure			
(Primary Examiner)	21					

Part of Paper No.: 20190813

Issue Classification

Application/Control No.	Applicant(s)/Patent Under Reexamination
16/506,885	ISLAM, Mohammed N.
Examiner	Art Unit
MD M RAHMAN	2886

CPC						
Symbol					Туре	Version
G01N		21	1	85	Α	2013-01-01
H01S		3	7	06758	А	2013-01-01
G01N		21	1	9508	А	2013-01-01
G01N		2021	7	3595	A	2013-01-01
G01N		2021	1	399	Α	2013-01-01
G01N		2201		061	A	2013-01-01
G01N		2201	1	06113	А	2013-01-01
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G01J	7	2003	7	104	А	2013-01-01
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NONE	Total Claims Allowed					
(Assistant Examiner)	(Date) 23					
/MD M RAHMAN/ Primary Examiner, Art Unit 2886	13 August 2019	O.G. Print Claim(s)	O.G. Print Figure			
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Application/Control No.	Applicant(s)/Patent Under Reexamination
16/506,885	ISLAM, Mohammed N.
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	Claims renumbered in the same order as presented by applicant 🔲 CPA 📝 T.D. 📋 R.1.47														
CLAIM	CLAIMS														
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(Primary Examiner)	(Date)	1	21		

Part of Paper No.: 20190813

16/506,885 - GAU: 2886

Doc code: IDS Doc description: Information Disclosure Statement (IDS) Filed PTO/SB/08a (01-10)
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	Application Number		16/506,885 - GAU: 2886		
INFORMATION BIOOLOGUES	Filing Date				
INFORMATION DISCLOSURE	First Named Inventor Mohammed		ned N. ISLAM		
STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Art Unit				
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1	7771320	B2	2010-08-10	Riley, et al.			
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	Application Number		16/506,885 - GAU: 2886		
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INFORMATION DISCLOSURE	First Named Inventor Mohan		mmed N. ISLAM		
STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Art Unit				
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	1	7,969,558	B2	2011-06	-28	Hall				
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Application Number

Filing Date

First Named Inventor Mohammed N. ISLAM

Art Unit

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The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

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  request involving an individual, to whom the record pertains, when the individual has requested assistance from the
  Member with respect to the subject matter of the record.
- 4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
- 5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
- 6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
- 7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
- 8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
- 9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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PTO/SB/08a (01-10)

Doc code: IDS Doc description: Information Disclosure Statement (IDS) Filed

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	16506885		
	Filing Date	2019-07-09		
	First Named Inventor Mo	mmed N. ISLAM		
	Art Unit	1636		
( Not for Submission under or or it not)	Examiner Name	MD M RAHMAN/		
	Attorney Docket Number	OMNI 0101 PUSA5		

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Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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		mmed N. ISLAM		
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Application Number Filing Date		16506885	. ,				
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Examiner Name							
Attorney Docket Number		OMNI 0101 PUSA5					

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		2019-07-09				
First Named Inventor	Moha	mmed N. ISLAM				
Examiner Name		1636				
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Attorney Docket Number

**OMNI 0101 PUSA5** 

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Examiner Name	
Attorney Docket Number	OMNI 0101 PUSA5

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Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

#### OR

That no item of information contained in the information disclosure statement was cited in a communication from a
foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification
after making reasonable inquiry, no item of information contained in the information disclosure statement was known to
any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure
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See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

X A certification statement is not submitted herewith.

#### **SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-10
Name/Print	David S. Bir	Registration Number	38383

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.** 

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	Filing Date				
	First Named Inventor Moha		mmed N. ISLAM		
STATEMENT BY APPLICANT ( Not for submission under 37 CFR 1.99)	Art Unit				
(Not for Submission under or STR 1.55)	Examiner Name				
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Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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	First Named Inventor	Moha	mmed N. ISLAM					
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	JNITED STATES DISTRICT COURT EASTERN DISTRICT OF TEXAS MARSHALL DIVISION; Defendant And Counter Claimant Apple Inc.'s Amended Answer, Affirmative Defenses, And Counterclaims To Complaint Of Plaintiff And Counter Defendant Omni Medsci, Inc.; Document 38; July 19, 2018; 32 pps													
If you wisl	h to ac	ld add	ditional non-patent	literatur	e docur	ment cit	ation infor	matio	n please click the	Add b	utton Ad	d	-	
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Examiner	Signa	ture	/MD M	RAHMA	N/				Date Conside	red	08/13	/2019		
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.														

Application Number

Receipt date: 07/09/2019

16/506,885 - GAU: 2886

Rece	sipt date: 07/09/2019				16/506,885	- GAU:	288
	•	Application Number			,		
<u></u> .		Filing Date					
	FORMATION DISCLOSURE	First Named Inventor	Moha	ammed N. ISLAM			
STATEMENT BY APPLICAN  ( Not for submission under 27 CER 1 99	ot for submission under 37 CFR 1.99)	Art Unit	•				
'"	ot for submission under or or it 1.55,	Examiner Name					
	Attorney Docket Numb	er	OMNI 0101 PUSA5				

<sup>&</sup>lt;sup>1</sup> See Kind Codes of USPTO Patent Documents at <u>www.USPTO.GOV</u> or MPEP 901.04. <sup>2</sup> Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>3</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark here if English language translation is attached.

			Application Number				
			Filing Date				
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)			First Named Inventor	Moha	mmed N. ISLAI	M	
			Art Unit				
( 144	ot for submission	i under 37 CFR 1.33)	Examiner Name		1		
			Attorney Docket Nur	nber	OMNI 0101 PUSA5		
			CERTIFICATION ST	ATEME	NT		
Plea	ase see 37 CFR 1	1.97 and 1.98 to make the a	appropriate selection(s	<b>)</b> :			
		nor and more than the		<i>)</i> -			
	from a foreign p		oart foreign application			first cited in any communication months prior to the filing of the	
OF	2						
	foreign patent o after making rea any individual d	ffice in a counterpart forei asonable inquiry, no item o	ign application, and, to	the kn	owledge of the information dis	cited in a communication from a e person signing the certification sclosure statement was known to ling of the information disclosure	
	See attached ce	rtification statement.					
		in 37 CFR 1.17 (p) has be	en submitted herewith				
×	A certification st	atement is not submitted h	erewith.				
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_	n of the signature.		required in accordant	e with C	FK 1.33, 10.1	8. Please see CFR 1.4(d) for the	
Sigi	nature	/David S. Bir/	Da	te (YYY	Y-MM-DD)	2019-07-08	
Nar	me/Print	David S. Bir	Re	Registration Nun		38383	
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This	s collection of info	rmation is required by 37 (	CFR 1.97 and 1.98. Th	e inform	ation is requir	ed to obtain or retain a benefit by th	

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.** 

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- A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
- A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a
  request involving an individual, to whom the record pertains, when the individual has requested assistance from the
  Member with respect to the subject matter of the record.
- 4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
- 5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
- 6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
- 7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
- 8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
- 9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

16/506,885 - GAU: 2886

Doc code: IDS Doc description: Information Disclosure Statement (IDS) Filed PTO/SB/08a (01-10)
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	Application Number		16506885
INFORMATION BIOOLOGUES	Filing Date		2019-07-09
INFORMATION DISCLOSURE	First Named Inventor	Mohar	mmed N. ISLAM
STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Art Unit		1636
(Not lot submission under or of it 1.00)	Examiner Name		
	Attorney Docket Number	er	OMNI 0101 PUSA5

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Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5084880		1992-01-28	Esterowitz, et al.	
	2	5180378		1993-01-19	Kung, et al.	
	3	5400165		1995-03-21	Gnauck, et al.	
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			16/506.885	-	GAU:	2886
Application Number		16506885	,			
Filing Date		2019-07-09				
First Named Inventor	Moha	mmed N. ISLAM				
Art Unit		1636				
Examiner Name						
Attorney Docket Number	er	OMNI 0101 PUSA5				

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19	6043927	2000-03-28	Islam	

			16/506.885	-	GAU:	2886
Application Number		16506885	,			
Filing Date		2019-07-09				
First Named Inventor	Moha	mmed N. ISLAM				
Art Unit		1636				
Examiner Name						
Attorney Docket Number	er	OMNI 0101 PUSA5				

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			<u> 16/506.885</u>	-	GAU:	2886
Application Number		16506885				
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First Named Inventor	Moha	mmed N. ISLAM				
Art Unit		1636				
Examiner Name						
Attorney Docket Numb	er	OMNI 0101 PUSA5				

	31	6603910		2003-08-05	Islam, et al.			
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	35	7209657		2007-04-24	Islam			
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	37	7519253		2009-04-14	Islam			
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Examiner Initial*	Cite No	Publication Number	Kind Code <sup>1</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Releva	Columns, nt Passag Appear	_ines where es or Relevant
	1	20020013518		2002-01-31	West, Kenneth G. ; et al.			_
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			16/506.885	-	GAU:	2886
Application Number		16506885	,			
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First Named Inventor	Moha	mmed N. ISLAM				
Art Unit		1636				
Examiner Name						
Attorney Docket Number	er	OMNI 0101 PUSA5				

3	20020032468	2002-03-14	Hill, Michael R.S. ; et al.	
4	20020082612	2002-06-27	Moll, Frederic H. ; et al.	
5	20020109621	2002-08-15	Khair, Mohammad ; et al.	
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12	20060268393	2006-11-30	Islam; Mohammed N.	
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Receipt date: 07/12/2019 <u> 16/506,885 - GAU: 2886</u> Application Number 16506885 Filing Date 2019-07-09 INFORMATION DISCLOSURE First Named Inventor Mohammed N. ISLAM STATEMENT BY APPLICANT Art Unit 1636 ( Not for submission under 37 CFR 1.99) **Examiner Name** Attorney Docket Number OMNI 0101 PUSA5 2009-01-29 14 20090028193 Islam; Mohammed N. 2009-08-13 15 20090204110 slam; Mohammed N. Add If you wish to add additional U.S. Published Application citation information please click the Add button. Remove **FOREIGN PATENT DOCUMENTS** Pages, Columns, Lines Name of Patentee or Cite Foreign Document Country Kind Publication where Relevant Examiner Applicant of cited T5 Number<sup>3</sup> Code2i Passages or Relevant Initial\* No Code<sup>4</sup> Date Document Figures Appear wo 200189362 West Kenneth G et al. 1 2001-11-29 Whittington Charles Lynn 2 200227640 wo 2002-04-04 et al. 3 wo 200228123 2002-04-04 Whittington Charles Lynn Add If you wish to add additional Foreign Patent Document citation information please click the Add button Remove **NON-PATENT LITERATURE DOCUMENTS** Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item Examiner Cite (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), T5 Initials\* No publisher, city and/or country where published. 1 Add If you wish to add additional non-patent literature document citation information please click the Add button **EXAMINER SIGNATURE** /MD M RAHMAN/ Date Considered **Examiner Signature** 08/13/2019

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Receipt date: 07/12/2019 16/506,885 - GAU: 2886

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

			15/305,553	-	GAU	2000
Application Number		16506885	,			
Filing Date		2019-07-09				
First Named Inventor	Moha	mmed N. ISLAM				
Art Unit		1636				
Examiner Name						
Attorney Docket Numb	er	OMNI 0101 PUSA5				

<sup>&</sup>lt;sup>1</sup> See Kind Codes of USPTO Patent Documents at <u>www.USPTO.GOV</u> or MPEP 901.04. <sup>2</sup> Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>3</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark here if English language translation is attached.

CEDTI	ATION	CTA	TEMENT

**OMNI 0101 PUSA5** 

Attorney Docket Number

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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That no item of information contained in the information disclosure statement was cited in a communication from a
foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification
after making reasonable inquiry, no item of information contained in the information disclosure statement was known to
any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure
statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

X None

#### **SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-10
Name/Print	David S. Bir	Registration Number	38383

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.** 

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16/506,885 - GAU: 2886

Doc code: IDS Doc description: Information Disclosure Statement (IDS) Filed PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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	Application Number		16506885	
	Filing Date		2019-07-09	
INFORMATION DISCLOSURE	First Named Inventor Moham		ammed N. ISLAM	
STATEMENT BY APPLICANT ( Not for submission under 37 CFR 1.99)	Art Unit		1636	
(Not for Submission under or of K 1.00)	Examiner Name			
	Attorney Docket Number	er	OMNI 0101 PUSA5	

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Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	Name of Patentee or Applicant of cited Document	Releva	Columns,Lines where nt Passages or Relevant Appear	
	1	7771320	B2	2010-08-10	Riley, et al.			
	2	6619835	B2	2003-09-16	Kita			
	3	9326712	B1	2016-05-03	Kiani			
	4	5267152	A	1993-11-30	Yang et al.			
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	6	5246004		1993-09-21	Clarke, et al.			
	7	8472108		2013-06-25	Islam			
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			16/506,885	-	GAU:	2886
Application Number		16506885	,			
Filing Date		2019-07-09				
First Named Inventor	Moha	mmed N. ISLAM				
Art Unit		1636				
Examiner Name						
Attorney Docket Number		OMNI 0101 PUSA5				

Examiner Initial*	Cite No	Publication Number	Kind Code <sup>1</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20100217102	A1	2010-08-26	LeBoeuf, et al.	
	2	20120310062	A1	2012-12-06	Li, et al.	
	3	20120316455	A1	2012-12-13	Rahman, et al.	
	4	20140275854	A1	2014-09-18	Venkatraman, et al.	
	5	20140275852	A1	2014-09-18	Hong, et al.	
	6	20160045118	A1	2016-02-18	Kiani	
	7	20110208015	A1	2011-08-25	Welch, et al.	
	8	20110040197	A1	2011-02-17	Welch et al.	
	9	20070021670	A1	2007-01-25	Mandelis et al.	
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Receipt date: 07/12/2019 16/506,885 - GAU: 288
Application Number 16506885

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

			16/506.885	-	GAU:	288
Application Number		16506885	,			
Filing Date		2019-07-09				
First Named Inventor	mmed N. ISLAM					
Art Unit		1636				
Examiner Name						
Attorney Docket Number		OMNI 0101 PUSA5				

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	11	20130274569	2013-10	)-17	Islam							
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	1	J.S. Provisional Application No. 61/350,673; titled: OPTICOUSTIC SENSOR; Inventor: Massi Joe E. Kiani; filed on June 2, 2010.										
	2	International Search Report and Written Opinion for International Application No. PCT/US2013/075700 dated April 24, 2014										
	3	International Preliminary Report on Patentability for International Application No. PCT/US2013/075700 dated July 9, 2015										
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Receipt date: 07/12/2019 16/506,885 - GAU: 2886 Application Number 16506885 Filing Date 2019-07-09 INFORMATION DISCLOSURE First Named Inventor Mohammed N. ISLAM STATEMENT BY APPLICANT Art Unit 1636 (Not for submission under 37 CFR 1.99) **Examiner Name** Attorney Docket Number **OMNI 0101 PUSA5** 

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

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Name/Print	David S. Bir	Registration Number	38383

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- 7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
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16/506,885 - GAU: 2886

Doc code: IDS Doc description: Information Disclosure Statement (IDS) Filed PTO/SB/08a (01-10)
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16/506,885 - GAU: 2886

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	Application Number		16/506,885 - GAU: 2886	
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INFORMATION DISCLOSURE	First Named Inventor Mohar		mmed N. ISLAM	
STATEMENT BY APPLICANT ( Not for submission under 37 CFR 1.99)	Art Unit			
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16/506,885 - GAU: 2886

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- A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a
  request involving an individual, to whom the record pertains, when the individual has requested assistance from the
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- 7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
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	Application Number		16/506,885 - GAU: 2886
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INFORMATION DISCLOSURE	First Named Inventor Mohamr		mmed N. ISLAM
STATEMENT BY APPLICANT ( Not for submission under 37 CFR 1.99)	Art Unit		
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	1	4972331		1990-11-20	Chance	
	2	5774213	А	1998-06-30	Trebino et al.	
	3	5855550	А	1999-01-05	Lai et al.	
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4	Declaration of Brian W. Anthony, PhD regarding USPN 9,885,698 filed in IPR2019-00912 & IPR2019-00915 (April 10, 2019)	
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2	28	Excerpts from the American Heritage Dictionary, 5th Edition (July 2012)	
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3		Amended Joint Claim Construction and Prehearing Statement filed in Case No. 2:18-cv-134-RWS (Dkt. #102) (Jan. 11, 2019)	
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<u> 16/506,885 - GAU: 2886</u>

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Examiner Initial*	Cite No	Publication Number	Kind Code <sup>1</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Releva	Columns,Lines where nt Passages or Relevant s Appear
	1	20030107739	A1	2003-06-12	Lehmann et al.		
	2 20030109055		A1	2003-06-12	Lehmann et al.		
	3	20030152307	A1	2003-08-14	Drasek et al.		

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			N DISCLOS		First N	Named	Inventor M	loha	mmed N. ISLAM				
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					Attorn	ney Doc	ket Number		OMNI 0101 PUSA	45			
	4		20050133691	A1	2005-06	6-23	Doppke et al.	-					
	5		20060283931	A1	2006-12	2-21	Polli et al.						
	6		20110267688	A1	2011-11	1-03	Kleppe et al.						
	7110207000												
	7		20130327966	A1	2013-12	2-12	Fidler et al.						
	8		20140078510	A1	2014-03	3-20	Rubio Guiver	nau	et al.				
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	1	200	95013843	WO		A2	2005-02-17		The Regents of the University of Califor	nia			
	2	200	7061772	wo		A2	2007-05-31		DMNI SCIENCES,	INC.			
	3	200	9130464	wo		A1	2009-10-29		JNIVERSITY OF MANCHESTER				

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<u>.</u>			Application Number			•			
			Filing Date						
		TION DISCLOSURE	First Named Inventor	Moh	ammed N. ISLAM				
		NT BY APPLICANT	Art Unit						
( NOT TOP :	subm	ission under 37 CFR 1.99)	Examiner Name		1				
			Attorney Docket Numb	per	OMNI 0101 PUSA5				
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	1	ROBERT S. JONES ET AL.; Nea Volume 11, No. 18; Optics Expres			0-nm For The Imaging Of I	Early Dental Decay;			
	2	Extended European Search Report for European Application No. 13867892.5 dated July 22, 2016							
	3	Extended European Search Report for European Application No. 13867874.3 dated July 15, 2016							
	4	VINAY V. ALEXANDER ET AL.; I Applications; Optical Fiber Techn			All-Fiber Supercontinuum L	asers And Their			
	5	Final Office Action dated October	<sup>-</sup> 21, 2016 for U.S. Applicatio	on No.	14/875,709				
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Examiner	Signa	ature /MD M RAHMAN	<u></u>		Date Considered	08/14/2019			
		nitial if reference considered, who conformance and not considered					a		
<sup>1</sup> See Kind 0	Codes o	of USPTO Patent Documents at <u>www.U</u>	ISPTO.GOV or MPEP 901.04.	<sup>2</sup> Enter	office that issued the docume	nt, by the two-letter code	(WIPO		

Standard ST.3). <sup>3</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark here if

English language translation is attached.

			Application Hamber									
			Filing Date									
		DISCLOSURE	First Named Inventor	Moha	mmed N. ISLAI	M						
		BY APPLICANT  1 under 37 CFR 1.99)	Art Unit									
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			Attorney Docket Num	ber	OMNI 0101 P	USA5						
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	That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).											
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	foreign patent o after making rea any individual d	ffice in a counterpart forei sonable inquiry, no item o	gn application, and, to finformation contained	the kno in the i	owledge of the nformation dis	cited in a communication from a see person signing the certification sclosure statement was known to ling of the information disclosure						
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		in 37 CFR 1.17 (p) has be	en submitted herewith.									
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Sign	nature	/David S. Bir/	Dat	YYY)	/-MM-DD)	2019-07-08						
Nar	ne/Print	David S. Bir	Reg	Registration Number		38383						
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Application Number

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.** 

Receipt date: 07/09/2019

16/506,885 - GAU: 2886

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- 1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.
- A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
- A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a
  request involving an individual, to whom the record pertains, when the individual has requested assistance from the
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- 4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
- 5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
- 6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
- 7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
- 8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
- 9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

16/506,885 - GAU: 2886

Doc code: IDS Doc description: Information Disclosure Statement (IDS) Filed PTO/SB/08a (02-18)
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	Application Number	16506885
	Filing Date	2019-07-09
INFORMATION DISCLOSURE	First Named Inventor	Mohammed N. ISLAM
( Not for submission under 37 CFR 1.99)	Art Unit	1636
(Not lot Submission under of of N 1.00)	Examiner Name	
	Attorney Docket Numbe	or OMNI 0101 PUSA5

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Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5746206	Α	1998-05-05	Mannheimer	
	2 6505133		B1	2003-01-07	Hanna et al.	
	3 8172761		B1	2012-05-08	Rulkov et al.	
	4	9241676	B2	2016-01-26	Lisogurski et al.	
	5	9596990	B2	2017-03-21	Park et al.	
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Examiner Initial*	Cite No	Publication Number	Kind Code <sup>1</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20050049468	A1	2005-03-03	Carlson et al.	

Receipt date: 07/12/2019 16/506,885 - GAU: 2886
Application Number 16506885

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

			16/506.885	-	GAU:	2886
Application Number		16506885	. ,			
Filing Date		2019-07-09				
First Named Inventor	Moha	mmed N. ISLAM				
Art Unit		1636				
Examiner Name						
Attorney Docket Number	er	OMNI 0101 PUSA5				

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	2		20100217099	A1	2010-08	3-26	LeBoeuf et al.					
	3		20120197093	A1	2012-08	3-02	LeBoeuf et al.					
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	1		r Partes Review No. I NI MEDSCI, INC.; pp					Review of U.S. Paten	t No. 9,7	′57,040; Ap	ple Inc. v.	
	Inter Partes Review No. IPR2019-00911; Petition for Inter Partes Review of U.S. Patent No. 9,861,286; Apple Inc. v. OMNI MEDSCI, INC.; pps. 1-83; dated April 10, 2019											
	Inter Partes Review No. IPR2019-00912; Petition for Inter Partes Review of U.S. Patent No. 9,885,698; Apple Inc. v. OMNI MEDSCI, INC.; pps. 1-94; dated April 10, 2019											
	4	Inter Partes Review No. IPR2019-00913; Petition for Inter Partes Review of U.S. Patent No. 9,651,533; Apple Inc. v. OMNI MEDSCI, INC.; pps. 1-96; dated April 10, 2019										

Receipt date: 07/12/2019 16/506,885 - GAU: 2880 Application Number 16506885

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( Not for submission under 37 CFR 1.99)

			16/306.883	-	GAU	200
Application Number		16506885	•			
Filing Date		2019-07-09				
First Named Inventor	Moha	mmed N. ISLAM				
Art Unit		1636				
Examiner Name						
Attorney Docket Numb	er	OMNI 0101 PUSA5				

			nter Partes Review No. IPR2019-00914; Petition for Inter Partes Review of U.S. Patent No. 9,861,286; Apple Inc. v. DMNI MEDSCI, INC.; pps. 1-90; dated April 10, 2019							
	ın ı		er Partes Review No. IPR2019-00915; Petition for Inter Partes Review of U.S. Patent No. 9,885,698; Apple Inc. v. //INI MEDSCI, INC.; pps. 1-91; dated April 10, 2019							
		Inter Partes Review No. IPR2019-00916; Petition for Inter Partes Review of U.S. Patent No. 9,651,533; Apple Inc. v. OMNI MEDSCI, INC.; pps. 1-90; dated April 10, 2019								
	Inter Partes Review No. IPR2019-00917; Petition for Inter Partes Review of U.S. Patent No. 9,757,040; Apple Inc. v. OMNI MEDSCI, INC.; pps. 1-93; dated April 10, 2019									
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Examiner Signature /MD M RAHMAN/ Date Considered 08/13/2019										

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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a

citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

**Examiner Name** 

( Not for submission under 37 CFR 1.99)

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**OMNI 0101 PUSA5** 

Attorney Docket Number

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That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

#### OR

That no item of information contained in the information disclosure statement was cited in a communication from a
foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification
after making reasonable inquiry, no item of information contained in the information disclosure statement was known to
any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure
 statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

X A certification statement is not submitted herewith.

#### **SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-10
Name/Print	David S. Bir	Registration Number	38383

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Receipt date: 07/12/2019 16/506,885 - GAU: 2886

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- A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
- A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a
  request involving an individual, to whom the record pertains, when the individual has requested assistance from the
  Member with respect to the subject matter of the record.
- 4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
- A record related to an International Application filed under the Patent Cooperation Treaty in this system of records
  may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant
  to the Patent Cooperation Treaty.
- 6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
- 7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
- 8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
- 9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

16/506,885 - GAU: 2886

Doc code: IDS Doc description: Information Disclosure Statement (IDS) Filed PTO/SB/08a (02-18)
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	Application Number		16/506,885 - GAU: 2886				
INFORMATION BIOOLOGUES	Filing Date						
INFORMATION DISCLOSURE	First Named Inventor	Moha	nmed N. ISLAM				
STATEMENT BY APPLICANT ( Not for submission under 37 CFR 1.99)	Art Unit						
(Not lot submission under or of it 1.55)	Examiner Name						
	Attorney Docket Number	er	OMNI 0101 PUSA5				

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Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	
	1	5746206	A	1998-05-05	Mannheimer		
	2	6505133	B1	2003-01-07	Hanna et al.		
	3	B172761	B1	2012-05-08	Rulkov et al.		
	4	9241676	B2	2016-01-26	Lisogurski et al.		
	5	9596990	B2	2017-03-21	Park et al.		
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	1	20050049468	A1	2005-03-03	Carlson et al.		

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		BY APPLICANT	Art Unit					
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			Attorney Docket Number OMNI 0101 PUSA5					
5	OMNI	I MEDSCI, INC.; pps. 1-90;					1	
6		Inter Partes Review No. IPR2019-00915; Petition for Inter Partes Review of U.S. Patent No. 9,885,698; Apple Inc. v. OMNI MEDSCI, INC.; pps. 1-91; dated April 10, 2019						
7	Inter Partes Review No. IPR2019-00916; Petition for Inter Partes Review of U.S. Patent No. 9,651,533; Apple Inc. v. OMNI MEDSCI, INC.; pps. 1-90; dated April 10, 2019							
8		Partes Review No. IPR2019 I MEDSCI, INC.; pps. 1-93;	9-00917; Petition for Inter Pa dated April 10, 2019	rtes Re	eview of U.S. Patent No. 9,	757,040; Apple Inc. v.		
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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.** 

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16/506,885 - GAU: 2886

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16/506,885 - GAU: 2886

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	Application Number		16506885	
	Filing Date		2019-07-09	
INFORMATION DISCLOSURE	First Named Inventor Moham		ammed N. ISLAM	
STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Art Unit		1636	
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	Attorney Docket Number	er	OMNI 0101 PUSA5	

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			16/506.885	-	GAU:	2886
Application Number		16506885	,			
Filing Date		2019-07-09				
First Named Inventor	Moha	mmed N. ISLAM				
Art Unit		1636				
Examiner Name						
Attorney Docket Numb	er	OMNI 0101 PUSA5				

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Application Number		16506885	, ,			
Filing Date		2019-07-09				
First Named Inventor Moha		mmed N. ISLAM				
Art Unit		1636				
Examiner Name						
Attorney Docket Numb	er	OMNI 0101 PUSA5				

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Receipt date: 07/12/2019

### INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

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Application Number			16506885	,			
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	Art Unit		1636				
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#### **EXAMINER SIGNATURE**

/MD M RAHMAN/ 08/13/2019 **Examiner Signature Date Considered** 

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STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)

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First Named Inventor Moha		mmed N. ISLAM
Art Unit		1636
Examiner Name		
Attorney Docket Numb	er	OMNI 0101 PUSA5

#### **CERTIFICATION STATEMENT**

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-10
Name/Print	David S. Bir	Registration Number	38383

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- 1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.
- A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
- A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a
  request involving an individual, to whom the record pertains, when the individual has requested assistance from the
  Member with respect to the subject matter of the record.
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- 6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
- 7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
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- 9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Doc code: IDS Doc description: Information Disclosure Statement (IDS) Filed PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

	Application Number		16/506,885 - GAU: 2886	
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT	First Named Inventor	Mohammed N. ISLAM		
( Not for submission under 37 CFR 1.99)	Art Unit			
(Not for submission under 37 OFK 1.33)	Examiner Name			
	Attorney Docket Number		OMNI 0101 PUSA5	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date						
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	(Not for Submission under or or K 1.33)	Examiner Name					
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			Filing Date						
			First Named Inventor	Moha	mmed N. ISLAI	M			
			Art Unit						
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16/506,885 - GAU: 2886

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	Application Number		16/506,885 - GAU: 2886		
	Filing Date				
INFORMATION DISCLOSURE	First Named Inventor	med Inventor Mohammed N. ISLAM			
STATEMENT BY APPLICANT ( Not for submission under 37 CFR 1.99)	Art Unit				
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Application Number			. ,			
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First Named Inventor Mohammed N. ISLAM						
Art Unit						
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Application Number			,				
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First Named Inventor	Moha	Mohammed N. ISLAM					
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Application Number			,			
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First Named Inventor	Moha	mmed N. ISLAM				
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First Named Inventor	Moha	mmed N. ISLAM					
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16/506,885 - GAU: 2886

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Doc code: IDS Doc description: Information Disclosure Statement (IDS) Filed PTO/SB/08a (01-10)
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	Application Number		16/506,885 - GAU: 2886				
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INFORMATION DISCLOSURE	First Named Inventor Mohan		mmed N. ISLAM				
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		07/09/2019	Application Number			6/506,885		
			Filing Date					
		TION DISCLOSURE	First Named Inventor	Moha	ammed N. ISLAM			
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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.M.R/

			Application Number				
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		N DISCLOSURE	First Named Inventor	Moha	mmed N. ISLAN	VI	
		BY APPLICANT n under 37 CFR 1.99)	Art Unit				
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			Attorney Docket Num	per	OMNI 0101 PUSA5		
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Nan	ne/Print	David S. Bir	Reg	istration	n Number	38383	
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16/506,885 - GAU: 2886

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- A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
- A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a
  request involving an individual, to whom the record pertains, when the individual has requested assistance from the
  Member with respect to the subject matter of the record.
- 4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
- A record related to an International Application filed under the Patent Cooperation Treaty in this system of records
  may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant
  to the Patent Cooperation Treaty.
- 6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
- 7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
- 8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
- 9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Doc code: IDS Doc description: Information Disclosure Statement (IDS) Filed PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

	Application Number		16506885	
INFORMATION PIGGI COURT	Filing Date		2019-07-09	
INFORMATION DISCLOSURE	First Named Inventor Moham		mmed N. ISLAM	
STATEMENT BY APPLICANT ( Not for submission under 37 CFR 1.99)	Art Unit		1636	
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	2	6285897	B1	2001-09	)-04	KILCOYNE		KILCOYNE		KILCOYNE		KILCOYNE		KILCOYNE		KILCOYNE					
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Receipt date: 07/12/2019			16/506,885 - GAU: 2886
	Application Number		16506885
	Filing Date		2019-07-09
INFORMATION DISCLOSURE	First Named Inventor	Moha	ammed N. ISLAM
STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Art Unit		1636
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Receipt date: 07/12/2019 16/506,885 - GAU: 2886 Application Number 16506885 Filing Date 2019-07-09 INFORMATION DISCLOSURE First Named Inventor Mohammed N. ISLAM STATEMENT BY APPLICANT Art Unit 1636

**Examiner Name** 

( Not for submission under 37 CFR 1.99)

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**OMNI 0101 PUSA5** 

Attorney Docket Number

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

That no item of information contained in the information disclosure statement was cited in a communication from a
foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification
after making reasonable inquiry, no item of information contained in the information disclosure statement was known to
any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure
statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

X A certification statement is not submitted herewith.

#### **SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-10
Name/Print	David S. Bir	Registration Number	38383

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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- 9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Doc code: IDS Doc description: Information Disclosure Statement (IDS) Filed PTO/SB/08a (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

	Application Number		16/506,885 - GAU: 2886		
INCORMATION BLOOK COURS	Filing Date				
INFORMATION DISCLOSURE	First Named Inventor Moham		mmed N. ISLAM		
STATEMENT BY APPLICANT ( Not for submission under 37 CFR 1.99)	Art Unit				
(Not 101 Submission under 01 Of N 1.00)	Examiner Name				
	Attorney Docket Number	er	OMNI 0101 PUSA5		

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Application Number							
Filing Date							
First Named Inventor	First Named Inventor Moha						
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Examiner Name							
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First Named Inventor	Moha	mmed N. ISLAM			
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Examiner Name		
Attorney Docket Numb	er	OMNI 0101 PUSA5

5	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit E), 120 pps	
6	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit F), 40 pps	
7	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit G), 66 pps	
8	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit H), 74 pps	
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10	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit J), 64 pps	
11	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit K), 77 pps	
12	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit L), 64 pps	
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14	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit N), 50 pps	
15	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit O), 63 pps	

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16	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit P), 78 pps	
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20	OMNI MEDSCI, INC. V. APPLE INC.; Case No. 2:18-cv-134-RWS (E.D. Tex.); Defendant's Invalidity Contentions, August 28, 2018 (Exhibit T), 174 pps	
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	Application Number		16506885	
	Filing Date		2019-07-09	
INFORMATION DISCLOSURE	First Named Inventor Mohammed N.		mmed N. ISLAM	
STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Art Unit		1636	
(Not lot submission under or of it 1.00)	Examiner Name			
	Attorney Docket Number		OMNI 0101 PUSA5	

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<sup>1</sup> See Kind Codes of USPTO Patent Documents at <u>www.USPTO.GOV</u> or MPEP 901.04. <sup>2</sup> Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>3</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark here if English language translation is attached.

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**OMNI 0101 PUSA5** 

Attorney Docket Number

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OR

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after making reasonable inquiry, no item of information contained in the information disclosure statement was known to
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See attached certification statement.

Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

X None

#### **SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-10
Name/Print	David S. Bir	Registration Number	38383

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Receipt date: 07/12/2019 16/506,885 - GAU: 2886

### **Privacy Act Statement**

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16/506,885 - GAU: 2886

Doc code: IDS Doc description: Information Disclosure Statement (IDS) Filed PTO/SB/08a (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

	Application Number		16506885	
	Filing Date		2019-07-09	
INFORMATION DISCLOSURE	First Named Inventor Moham		ammed N. ISLAM	
STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Art Unit		1636	
(Not for Submission under or of K 1.55)	Examiner Name			
	Attorney Docket Number	er	OMNI 0101 PUSA5	

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Receipt date: 07/12/2019 16/506,885 - GAU: 288

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

			16/506.885	-	GAU:	288
Application Number		16506885	,			
Filing Date		2019-07-09				
First Named Inventor	Moha	mmed N. ISLAM				
Art Unit		1636				
Examiner Name						
Attorney Docket Number		OMNI 0101 PUSA5				

	1	NELLCOR; Charts 1-3: NELLCOR-533; U.S. Patent No. 9,651,533 vs. Nellcor; Omni MedSci, Inc. v. Apple Inc., pps. I-155; May 22, 2019								
	2	SOGURSKI; Charts 1-3: LISOGURSKI-533; U.S. Patent No. 9,651,533 vs. Lisogurski; Omni MedSci, Inc. v. Apple c., pps. 1-84; May 22, 2019								
	3	SADA; Charts 1-3: ASADA-533; U.S. Patent No. 9,651,533 vs. Asada; Omni MedSci, Inc. v. Apple Inc., pps. 1-188; lay 22, 2019								
	4	PARK; Charts 1-3: Park-533; U.S. Patent No. 9,651,533 vs. Park; Omni MedSci, Inc. v. Apple Inc., pps. 1-171; May 22, 2019								
	VALENCELL; Charts 1-3: Valencell-533; U.S. Patent No. 9,651,533 vs. Valencell; Omni MedSci, Inc. v. Apple Inc., pps. 1-122; May 22, 2019									
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Examiner	Signat	Signature Date Considered 08/13/2019								
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X A certification statement is not submitted herewith.

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Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-10
Name/Print	David S. Bir	Registration Number	63108

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16/506,885 - GAU: 2886

Doc code: IDS Doc description: Information Disclosure Statement (IDS) Filed PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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	Application Number		16506885		
	Filing Date		2019-07-09		
INFORMATION DISCLOSURE	First Named Inventor Moham		ammed N. ISLAM		
STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Art Unit		1636		
(Not lot submission under or of it 1.00)	Examiner Name				
	Attorney Docket Number	er	OMNI 0101 PUSA5		

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	1 20050133691		A1	2005-06-23	Doppke et al.		
	2 20090244288			2009-10-01	FUJIMOTO et al.		
	3 20110267688 A		A1	2011-11-03	Kleppe et al.		
	4	20130327966	A1	2013-12-12	Fidler et al.		
	5	20140078510	A1	2014-03-20	Rubio Guivernau et al.		

Receipt date: 07/12/2019 16/506,885 - GAU: 2

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

				16/506,885	-	GAU:	2886
Арр	lication Number		16506885				
Filin	g Date		2019-07-09				
Firs	t Named Inventor	Moha	mmed N. ISLAM				
Art	Unit		1636				
Examiner Name							
Attorney Docket Number			OMNI 0101 PUSA5				

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	6	20140249427	A1	2014-09	-04	Liu					
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Examiner Initial*	Cite No	Foreign Document Country Number <sup>3</sup> Code <sup>2</sup> i		,	Kind Code <sup>4</sup>	Publication Date	Name of Patentee Applicant of cited Document	e Or	Pages,Columns,Line where Relevant Passages or Relevar Figures Appear	T5	
	1	102010012 <del>9</del> 87	DE		A1	2010-10-07	FRAUNHOFER GE FORSCHUNG	s			
	2	2005013843	wo		A2	2005-02-17	The Regents of the University of Califor	nia			
	3	2007061772	wo		A2	2007-05-31	OMNI SCIENCES, I	INC.			
	4	2009130464	wo		A1	2009-10-29	UNIVERSITY OF MANCHESTER				
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	1		/INAY V. ALEXANDER ET AL.; Modulation Instability High Power All-Fiber Supercontinuum Lasers And Their Applications; Optical Fiber Technology 18; 2012; pages 349-374.								
	2	ROBERT S. JONES ET Volume 11, No. 18; Opti					10-nm For The Imagi	ing Of E	Early Dental Decay;		

Receipt date: 07/12/2019 16/506,885 - GAU: 2886 Application Number 16506885 Filing Date 2019-07-09 INFORMATION DISCLOSURE First Named Inventor Mohammed N. ISLAM STATEMENT BY APPLICANT Art Unit 1636 ( Not for submission under 37 CFR 1.99) **Examiner Name** Attorney Docket Number OMNI 0101 PUSA5 3 Extended European Search Report for European Application No. 13867874.3 dated July 15, 2016 4 Extended European Search Report for European Application No. 13867892.5 dated July 22, 2016 Add If you wish to add additional non-patent literature document citation information please click the Add button **EXAMINER SIGNATURE Examiner Signature** Date Considered <u>/MD M RAHMAN/</u> \*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant. See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. 2 Enter office that issued the document, by the two-letter code (WIPO)

<sup>&</sup>lt;sup>1</sup> See Kind Codes of USPTO Patent Documents at <u>www.USPTO.GOV</u> or MPEP 901.04. <sup>2</sup> Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>3</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark here if English language translation is attached.

**Examiner Name** 

( Not for submission under 37 CFR 1.99)

CERT	IEIC	ATIO	м ст/	TEMI	CNIT

**OMNI 0101 PUSA5** 

Attorney Docket Number

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16/506,885 - GAU: 2886

Doc code: IDS Doc description: Information Disclosure Statement (IDS) Filed PTO/SB/08a (01-10)
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	Application Number		16506885		
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INFORMATION DISCLOSURE	First Named Inventor Moham		mmed N. ISLAM		
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	Attorney Docket Number	er	OMNI 0101 PUSA5		

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Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue D	)ate	of cited Document		es,Columns,Lines where vant Passages or Relevan es Appear				
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			16/506.885	 GAU:	2886
Application Number		16506885	. ,		
Filing Date		2019-07-09			
First Named Inventor	Moha	mmed N. ISLAM			
Art Unit		1636			
Examiner Name					
Attorney Docket Numb	er	OMNI 0101 PUSA5			

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Application Number		16506885	. ,
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Filing Date		2019-07-09					
First Named Inventor	mmed N. ISLAM						
Art Unit		1636					
Examiner Name							
Attorney Docket Number		OMNI 0101 PUSA5					

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( Not for submission under 37 CFR 1.99)

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**OMNI 0101 PUSA5** 

Attorney Docket Number

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any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure
statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

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#### **SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-10
Name/Print	David S. Bir	Registration Number	38383

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  request involving an individual, to whom the record pertains, when the individual has requested assistance from the
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- 7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
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16/506,885 - GAU: 2886

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	Application Number		16506885		
	Filing Date		2019-07-09		
INFORMATION DISCLOSURE	First Named Inventor	Mohar	nmed N. ISLAM		
STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Art Unit		1636		
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			Filing Date	2019-07-09	2019-07-09				
			First Named Inventor	Mohammed N. ISLAM					
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Receipt date: 07/12/2019 16/506,885 - GAU: 2886 Application Number 16506885 Filing Date 2019-07-09 INFORMATION DISCLOSURE First Named Inventor Mohammed N. ISLAM STATEMENT BY APPLICANT Art Unit 1636

**Examiner Name** 

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Signature	/David S. Bir/	Date (YYYY-MM-DD)	2019-07-10
Name/Print	David S. Bir	Registration Number	38383

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16/506,885 - GAU: 2886

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INFORMATION DISCLOSURE	First Named Inventor	First Named Inventor Mohammed N. ISLAM		
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