EXHIBIT 1002:

U.S. PAT. NO. 7,250,105 TO DAVIES. ("THE '105 PATENT")

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Davies et al.

(10) **Patent No.: US 7,250,105 B1**
(45) **Date of Patent: *Jul. 31, 2007**

(54) **MEASUREMENT OF SUBSTANCES IN LIQUIDS**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 369 days.

This patent is subject to a terminal disclaimer.

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(22) Filed: **May 7, 2003**

Related U.S. Application Data

(63) Continuation of application No. 09/521,163, filed on Mar. 8, 2000, now Pat. No. 6,733,655.

(51) **Int. Cl.**
G01N 27/327 (2006.01)
G01N 27/333 (2006.01)

(52) **U.S. Cl.** **205/777.5**; 205/789

(58) **Field of Classification Search** 204/403.01–403.14, 416–418; 205/777.5, 205/778, 792
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,004,998	A		4/1991	Horii
5,120,420	A	*	6/1992	Nankai et al. 204/403.11
5,234,813	A		8/1993	McGeehan et al.
5,582,697	A		12/1996	Ikeda et al.
5,628,890	A		5/1997	Carter et al.
5,650,062	A		7/1997	Ikeda et al.
5,672,256	A		9/1997	Yee
5,786,584	A		7/1998	Button et al.
5,791,344	A		8/1998	Schulman et al.
5,820,551	A		10/1998	Hill et al.
5,837,546	A		11/1998	Allen et al.
6,004,441	A	*	12/1999	Fujiwara et al. 204/403.14
6,287,451	B1	*	9/2001	Winarta et al. 205/777.5
6,733,655	B1	*	5/2004	Davies et al. 205/775

FOREIGN PATENT DOCUMENTS

EP	0537761 A2	4/1993
EP	0942278 A2	9/1999
WO	WO 97/02487 A1	1/1997
WO	WO 9730344 A1	8/1997
WO	WO 9958709 A1	11/1999

OTHER PUBLICATIONS

V.A. Bodner "Aviation Devices", The Machine Building Publishing House, Moscow, Russia, 1969, p. 158.
Official Action Issued by the Patent Office of the Russian Federation, mailed on or about Dec. 6, 2004, re Russuan Application No. 2002126814.

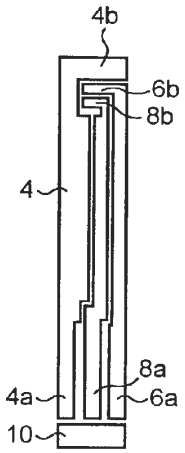
* cited by examiner

Primary Examiner—Alex Noguerola

(57) **ABSTRACT**

In accordance with the present invention a measuring device compares the current generated by two working sensor parts and gives an error indication if they are too dissimilar, i.e., the current at one sensor part differs too greatly from what would be expected from considering the current at the other. Not only can this method detect when one of the sensor parts has not been properly covered with sample liquid, but it can also detect if there is a manufacturing defect in either sensor part or if either has been damaged after manufacture, since even with complete coverage of the working sensor parts, an anomalous current will be generated at the affected sensor part under such circumstances.

3 Claims, 2 Drawing Sheets



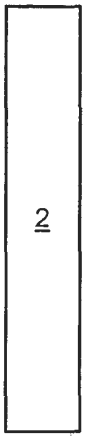


FIG. 1

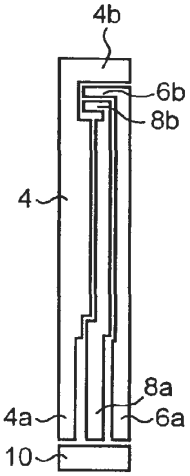


FIG. 2

FIG. 3

FIG. 4

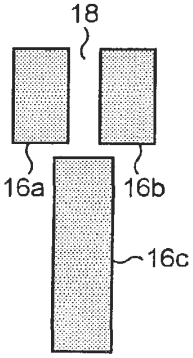


FIG. 5

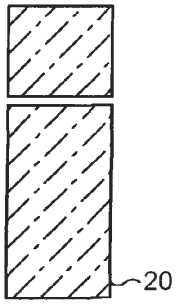


FIG. 6

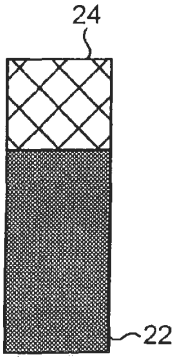


FIG. 7

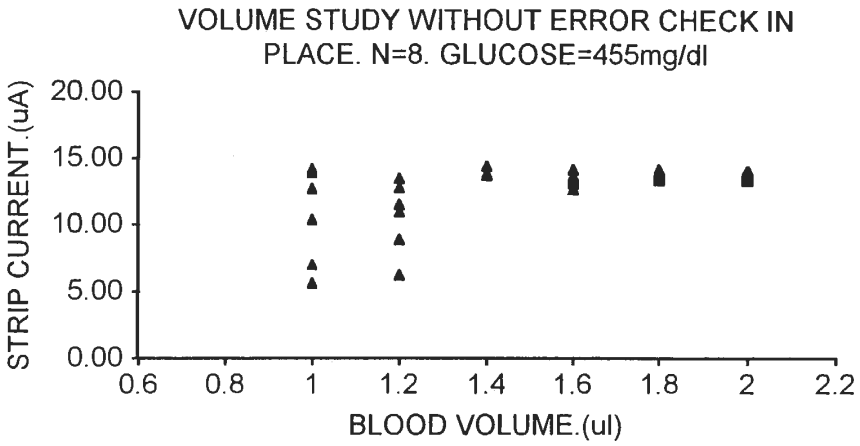


FIG. 8

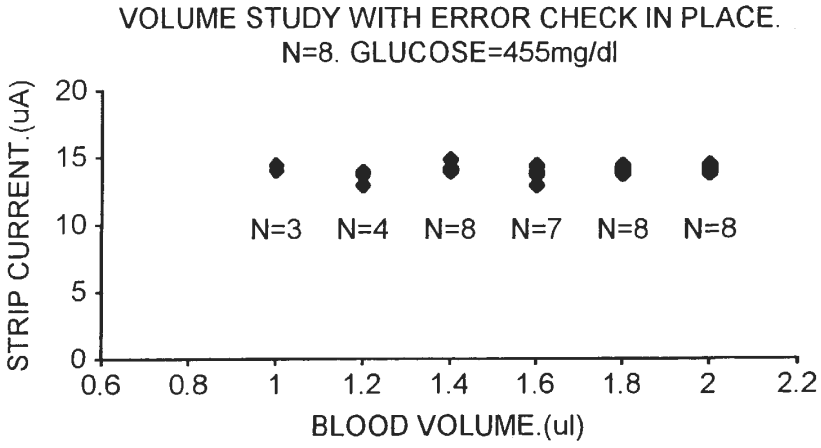


FIG. 9

MEASUREMENT OF SUBSTANCES IN LIQUIDS

This application is a Continuation application of Ser. No. 09/521,163 filed Mar. 8, 2000, now U.S. Pat. No. 6,733,655, which is incorporated herein by reference in its entirety.

This invention relates to apparatus for measuring the concentration of a substance in a liquid and particularly, but not exclusively, to apparatus for measuring the concentration of glucose in blood.

Devices for measuring blood glucose levels are invaluable for diabetics, especially devices that may be used by the sufferers themselves since they may then monitor their own glucose levels and take an appropriate dose of insulin. Correspondingly therefore the accuracy of such devices is very important since an inaccurate reading could lead to the wrong level of insulin being administered which could be very harmful.

It is also the case that in all practical blood glucose measuring systems at least part of the device, i.e. that part which comes into contact with the sample blood, is disposable. This means that it is particularly important that the cost particularly of any disposable parts can be minimised as a user will generally need large numbers of them regularly.

Known glucose measuring devices now favour an electrochemical measurement method over old colorimetric methods. The general principle is that an electric current is measured between two sensor parts called the working and reference sensor parts respectively. The working sensor part comprises a layer of enzyme reagent, the current being generated by the transfer of electrons from the enzyme substrate, via the enzyme and an electron mediator compound to the surface of a conductive electrode. The current generated is proportional to both the area of the sensor part and also the concentration of glucose in the test sample. Since the area of the working sensor part is supposedly known, the electric current should be proportional to the glucose concentration.

It has been recognised in the art that inaccurate results are obtained if the working sensor part is not fully covered with blood since then its effective area is reduced. Various ways of dealing with this problem have been proposed, two of which are disclosed in U.S. Pat. No. 5,628,890 and U.S. Pat. No. 5,582,697 Both of these methods rely on a unidirectional flow of blood across the surface of the test strip and both initiate the test measurement by detecting the presence of the sample liquid at an electrode or sensor part located downstream of the working sensor part.

The problem of insufficient sample liquid being present and thus the working sensor part not being completely covered may of course be reduced by reducing the size of the working sensor part. However a small area for the working sensor part tends to give a greater variability in calibrated results.

The present inventors have realised that as well as incomplete coverage of the working sensor part, inaccurate results can also arise from occasional defects in the production of the test strips for such devices, in the area and/or the thickness of the working sensor part and also from accidental damage to the working sensor part e.g by a user. As far as the inventors are aware, the only practical way to deal with this problem so far has been to ensure that the printing process used to produce the test strips is as accurate as possible and to rely on adequate quality control.

It is an object of the present invention at least partially to alleviate the above-mentioned disadvantages and when viewed from a first aspect the invention provides a method

of measuring the concentration of a substance in a sample liquid comprising the steps of:

providing a measuring device having a first working sensor part comprising a working layer which generates an electric current proportional to the concentration of said substance in the sample liquid, a reference sensor part and a second working sensor part comprising a working layer which also generates an electric current proportional to the concentration of said substance in the sample liquid;

applying the sample liquid to said measuring device;

comparing the electric current generated at each of the working sensor parts to establish a difference parameter; and

giving an indication of an error if said difference, parameter is greater than a predetermined threshold.

Furthermore the measuring device used in this method is novel and inventive in its own right and thus from a second aspect the present invention provides a device for measuring the concentration of a substance in a sample liquid, said device comprising:

a reference sensor part,

a first working sensor part, comprising a working layer for generating an electric current proportional to the concentration of said substance in the sample liquid; and

a second working sensor part comprising a working layer also for generating an electric current proportional to the concentration of said substance in the sample liquid.

Thus it will be seen that in accordance with the invention the measuring device compares the current generated by two working sensor parts and gives an error indication if they are too dissimilar—i.e. the current at one sensor part differs too greatly from what would be expected from considering the current at the other. Not only can this method detect when one of the sensor parts has not been properly covered with sample liquid, but it can also detect if there is a manufacturing defect in either sensor part or if either has been damaged after manufacture, since even with complete coverage of the working sensor parts, an anomalous current will be generated at the affected sensor part such circumstances.

In accordance with the invention the only type of defect or damage which would not necessarily be recognised is one which affected both of the working sensor parts to the same degree. However, this is logically less likely than a defect affecting a single working sensor part and is thus an improvement over the prior art. In practice such a likelihood is considered to be negligible. In any event the invention is not limited to providing just two working sensor parts and the skilled person could therefore choose to provide three or more working sensor parts to further reduce the probability that they are all affected by an identical defect.

Looking at the invention another way, it provides an arrangement whereby for a given total area of working sensor part and thus a given minimum sample volume, detection of inadequate fill and of defects in the working sensor part provided by separating the area of the working sensor part into two.

Some or all of the sensor parts may be provided as part of an integrated device. Preferably however at least the working sensor parts are provided on a removable test member. Thus when viewed from a further aspect the present invention provides a test member for measuring the concentration of a substance in a sample liquid comprising:

a substrate; and

two working sensor parts provided on the substrate, each working sensor part comprising a working layer for generating an electric current proportional to the concentration of said substance in the sample liquid.

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