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Attorneys for Plaintiffs
LIFESCAN, INC. and
LIFESCAN SCOTLAND, LTD.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE

LIFESCAN, INC. and
LIFESCAN SCOTLAND, LTD.,

Plaintiffs,

v.

SHASTA TECHNOLOGIES, LLC,
DECISION DIAGNOSTICS CORP.,
PHARMATECH SOLUTIONS, INC., and
CONDUCTIVE TECHNOLOGIES, INC.,

Defendants.

Case No. CV11-04494-EJD (PSG)

CORRECTED DECLARATION OF PETER MENZIUSO IN SUPPORT OF PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION (FED. R. CIV. P. 65)

Date: March 13, 2013
Time: 9:00 a.m.
Place: 5th Floor, Courtroom 4
Judge: Hon. Edward J. Davila

DECLARATION OF PETER MENZIUSO

1. I am Vice President of U.S. Sales & Market Development for the Diabetes Care Franchise at LifeScan, Inc. ("LifeScan"), in Milpitas, California. As part of my responsibilities, I am in charge of sales for LifeScan's OneTouch® Ultra® blood glucose monitoring systems, including OneTouch Ultra meters and OneTouch Ultra test strips. I am fully familiar with the facts and circumstances set forth below.

2. I submit this declaration in support of the motion by LifeScan and LifeScan Scotland, Ltd. for a preliminary injunction barring Defendants from selling the Shasta Genstrip or offering it for sale.

3. If the court does not issue a preliminary injunction, the sale of the Shasta Genstrip would have a devastating impact on LifeScan's business, causing harm that a later award of money damages could not remedy.

LifeScan's OneTouch Ultra Blood Glucose Monitoring System

4. Persons with diabetes use blood glucose monitoring systems to self-monitor their blood glucose levels. This self-monitoring is one of the most important things diabetic patients can do to manage their disease and prevent long term complications. Using these systems, a person with diabetes can determine if his or her blood glucose is abnormally low or abnormally high, requiring management.

5. LifeScan sells a glucose monitoring system known as the OneTouch Ultra system. To use LifeScan's OneTouch Ultra system, a person inserts a disposable OneTouch Ultra test strip in the port of a OneTouch Ultra meter. The person then pricks his or her finger or forearm with a lancet to obtain a small blood sample and places a drop of blood on the test strip. The meter determines the blood glucose level in the sample by measuring the flow of electrical current. Within seconds, the meter displays the person's blood glucose level as a number on a digital display. Based on this reading, the person may determine if his or her blood glucose level is within a satisfactory range or if some intervention or treatment is required to raise or lower the blood glucose level.

6. LifeScan and its affiliates and predecessor companies are pioneers in the field of developing blood glucose monitoring systems. They have been developing new and improved glucose monitoring systems since the mid-1990s. Their products, including the OneTouch Ultra family of meters and test strips, allow for fast and accurate testing of blood samples, while requiring little blood.

7. LifeScan's OneTouch Ultra systems are the market-leading blood glucose monitoring systems in the United States. Other major companies sell test strips, including Abbott Diabetes Care, Bayer Diabetes Care and Roche Diagnostics. Each of these companies distributes its own glucose meters and test strips that work with that particular company's meters. Their test strips are not compatible with OneTouch Ultra meters and cannot be used with them. Similarly, LifeScan's OneTouch Ultra test strips are not compatible with those companies' blood glucose meters.

LifeScan's DoubleSure™ Technology

8. An important feature of the OneTouch Ultra system is that it checks each blood sample twice to promote accuracy in blood glucose measurements. LifeScan refers to this feature in promotional materials and on its website as its "DoubleSure™ Technology." This feature represents a key advantage of LifeScan's OneTouch Ultra system over competitors' glucose monitoring systems.

9. LifeScan emphasizes its DoubleSure Technology in its promotional literature. For example, LifeScan tells customers on its website that its "DoubleSure™ Technology automatically checks each blood sample twice." Ex. A. It tells customers: "Don't just be sure. Be DoubleSure™." *Id.* The example shown below appears on LifeScan's website, *id.*:

10. LifeScan has invested heavily in print, electronic, and television advertising to promote DoubleSure Technology as an advantage over competing systems. Examples of print and electronic materials promoting LifeScan's DoubleSure Technology are attached to this declaration as Exhibits B through K; storyboards of television advertisements promoting DoubleSure are attached as Exhibits L and M.

LifeScan's Practice of Providing Meters Free of Charge or at Discount

11. Over the years, LifeScan has had a policy and practice of providing blood glucose test meters to patients and doctors either free of charge or at sharply discounted prices.

12. LifeScan does not realize a profit on its U.S. sales of its meters. More than half of the meters that LifeScan distributes are given to patients and doctors free of charge. This comes to more than one million meters per year. The remainder are sold at sharply discounted prices.

13. LifeScan makes this investment in the expectation and intent that customers will use its OneTouch Ultra meters with LifeScan's OneTouch Ultra test strips, from which LifeScan does derive a profit, in their ongoing course of therapy.

The Notice on LifeScan's Packaging

14. LifeScan's glucose monitors are packaged in boxes that feature the following notice:

> "Use of the monitoring device included here is protected under one or more of the following U.S. patents: 7,250,105, 6,413,410, 6,733,655, 6,468,125. Purchase of this device does not act to grant a use license under these patents. Such a license is granted only when the device is used with [LifeScan's] OneTouch® Ultra® Test Strips. No test strip supplier other than LifeScan is authorized to grant such a license.
>
> "The accuracy of results generated with LifeScan meters using test strips manufactured by anyone other than LifeScan has not been evaluated by LifeScan…."

Exhibit N to this declaration is a copy of the front and bottom panels of the package for the OneTouch UltraMini, with this notice.

15. The User Guide for OneTouch Ultra meters, which is included in the package, features the same notice. *See* Ex. O.

16. The User Guide for OneTouch Ultra test strips, a copy of which is attached to this declaration as Exhibit P, has a similar notice:

> "Use of these test strips and associated monitoring device is protected under the following U.S. patents: 6,413,410, 5,733,655, 7,250,105. Purchase of the associated monitoring device does not act to grant a use license under these patents. Such a license is granted only when the associated monitoring device is used with [LifeScan's] OneTouch® Ultra® Blue Test Strips. No test strip supplier other than LifeScan is authorized to grant such a license. The accuracy of results generated with LifeScan meters using test strips manufactured by anyone other than LifeScan has not been evaluated by LifeScan."

The Introduction of Defendants' Shasta GenStrip Product

17. On November 30, 2012, the U.S. Food & Drug Administration ("FDA") cleared Defendants' Shasta GenStrip product for sale in the United States for certain uses in connection with glucose meters sold by LifeScan before July 2010. A copy of the FDA clearance letter, from the website of Defendant Decision Diagnostics Corp. ("DDC," formerly known as Instacare Corp.), is attached to this declaration as Exhibit Q.

18. The "Indications for Use" document that accompanies the FDA's November 30 letter states: "GenStrip™ Test Strips with calibration codes 4, 10, and 13 are for use with [LifeScan's] OneTouch® Ultra®, Ultra®2 and UltraMini® Meters purchased before July 2010." *Id.*

19. As of December 13, 2012, Defendant DDC stated on its website:

> **Introducing Genstrip**
>
> **Blood Glucose Test Strip**
>
> **For use with Lifescan One Touch® Ultra®, Ultra 2®, Ultra Smart® and Ultra Mini® meters**

Exhibit R hereto. DDC's website also states that the GenStrip "will be comparable to the existing consumable provided by the platform manufacturer [LifeScan], but priced significantly (50%) lower." *Id.* The website of Defendant PharmaTech Solutions, Inc. ("PharmaTech"), which is linked to DDC's website, has the same text. Ex. S at 1.

20. The packaging for the GenStrip shown on the websites of Defendants PharmaTech and Shasta show the GenStrip being used with a LifeScan OneTouch UltraMini meter:

See id. at 2; Ex. T at 1-2 (Shasta website).

21. There is no suggestion that the Shasta GenStrip could be used with meters supplied by any company other than LifeScan, and the FDA has not cleared the GenStrip for use with other companies' meters.

The GenStrip's Impact on LifeScan's OneTouch Ultra Sales

22. Defendant DDC has made clear that it expects to achieve substantial sales of the Shasta GenStrip. According to a May 24, 2011 memorandum published on DDC's website in 2011, DDC projects sales of $173.5 million in the United States in the GenStrip's first full year on the market, with sales increasing sharply afterward. *See* Ex. U at 2 (total sales minus international sales); *see also* D.E. 1 ¶ 32.

23. This estimate is not unrealistic. Competition in the market for glucose test strips is intense, and the market is increasingly sensitive to price considerations. A test strip that can be used as a substitute for LifeScan's OneTouch Ultra test strips for half the price would substantially reduce LifeScan's sales. It would have a devastating and catastrophic effect on LifeScan's business.

24. Because Defendants plan to sell the GenStrip at half the price of LifeScan's OneTouch Ultra test strips, it is safe to conclude that LifeScan's lost sales would be significantly greater than the sales made by Defendants.

25. This loss of sales would destroy LifeScan's position as the market leader, jeopardizing or destroying brand equity that LifeScan has worked hard for many years to create and maintain.

Doubts as to Defendants' Ability to Pay a Damage Award

26. If this court does not issue an injunction, Defendants likely would be unable to compensate LifeScan for its lost profits. DDC stated in its most recent 10-K Report, filed with the Securities and Exchange Commission ("S.E.C."), that it had suffered a net loss of more than $2 million in 2011. Ex. V at F-6. For the period ending September 30, 2012, DDC reported to the SEC that it was operating at a net loss and had just over $7,000 in

net cash. *See* Ex. W at 5. I understand that Defendant PharmaTech Solutions, Inc. is a wholly owned subsidiary of DDC, formerly known as InstaCare. Ex. V at F-7.

Customers Could Blame LifeScan for Problems with the Shasta GenStrip

27. LifeScan's OneTouch Ultra test strips have been on the market for years and have a proven track record for safety and reliability. A study summarizing nine years of accuracy data with OneTouch Ultra test strips is attached to this declaration as Exhibit X.

28. In contrast, the Shasta GenStrip has no track record in the marketplace. If there were defects or problems with Shasta GenStrip test strips, then inserting those strips into LifeScan OneTouch meters could result in inaccurate readings of patients' blood glucose levels. The consequences for patients could be serious, and customers are likely to blame LifeScan for any problems, harming its good will. This is particularly so since the packaging of the Shasta GenStrip prominently features a picture of a LifeScan One Touch meter, implying that LifeScan has endorsed and licensed the Shasta GenStrip.

29. If there were defects or other problems related to the Shasta GenStrip, it is likely, if not inevitable, that customers would contact LifeScan to complain and to seek information, refunds and assurances – which LifeScan would not be able to provide. This would further injure the good will that LifeScan has worked hard to develop.

30. These concerns are heightened because the FDA has cleared the Shasta GenStrip only for limited purposes. As discussed above, the Shasta GenStrip is cleared only with three calibration codes – "calibration codes 4, 10, and 13" – out of 49 possible codes. Ex. Q at 4. Moreover, the GenStrip is cleared only "for use with [LifeScan's] OneTouch® Ultra®, Ultra®2 and UltraMini® Meters purchased before July 2010." *Id.*

31. But the test strips LifeScan has sold in the United States since 2009 have a calibration code – calibration code 25 – that is different from the calibration code for which the GenStrip is cleared. Moreover, for the past three years all of the OneTouch Ultra

meters distributed by LifeScan have been pre-set to calibration code 25 to get accurate results.

32. If a customer uses strips with a calibration code other than calibration code 25 (for example, the calibration codes for which the GenStrip has received clearance) without resetting his or her OneTouch Ultra meter to the strips' calibration code, there would be a mismatch between calibration codes for the meter and the strips.

33. Because customers have become accustomed to a single, preset calibration code and to the ease and convenience of not having to reset it, they would have to be trained and reminded to calibrate when using the Shasta GenStrip. If they were not trained to do so, they could blame LifeScan for any resulting problems, further injuring the good will associated with LifeScan's products.

34. Closely related to these issues, sale of the GenStrip is likely to cause customer confusion. LifeScan would have to devote considerable resources to helping consumers understand the respective roles of LifeScan and the Defendants. This would distract LifeScan from its core business and be costly to implement, diverting precious and limited resources from LifeScan's other competitive selling activities.

35. Any such consumer education effort, coupled with the confusion and inconvenience resulting from the GenStrip and its calibration code, could cause customers to perceive LifeScan's products as difficult to use and undesirable to buy. They could abandon LifeScan's meters entirely and switch to those made by LifeScan's current competitors, particularly Roche, Bayer, and Abbot, most of which require no calibration at all. This loss of customers is further evidence of the irreparable harm that LifeScan would suffer from the entry of the GenStrip.

Sale of the Shasta GenStrip Would Cause Price Erosion and Related Harms

36. In addition, LifeScan would have to dramatically lower its prices to compete with a supposedly "comparable" test strip that is sold at a much lower price. As

indicated above, DDC's website states that the GenStrip will be "priced significantly (50%) lower" than LifeScan's OneTouch Ultra test strips.

37. Once LifeScan lowered its price to compete with the GenStrip, it would be difficult or impossible to raise the price to earlier levels, even if the GenStrip eventually is removed from the market. Trying to raise prices to earlier levels would cause consumer anger and resentment. Thus, any reduction in price to meet competition from the GenStrip would cause a long-lasting drop in prices for OneTouch Ultra strips.

38. Sales of a compatible test strip for a much lower price also would undermine the goodwill with consumers that LifeScan has worked hard to develop. The harm to LifeScan would be difficult or impossible to quantify. This harm would occur even if LifeScan reduces the price of OneTouch Ultra strips in response to the introduction of the Shasta GenStrip.

39. These factors would harm LifeScan's good will with customers. It would be difficult or impossible to effectively communicate to customers that LifeScan needs to maintain higher prices because it invests heavily in research & development and generates no profit from its OneTouch Ultra blood glucose meters. As discussed above, LifeScan distributes its meters to customers free of charge or at sharply reduced or rebated prices in the expectation that customers will use the meters with LifeScan's OneTouch Ultra test strips – an expectation that would be frustrated by the sale of the GenStrip.

Denying an Injunction Would Undermine the Incentives for Innovation

40. LifeScan and other Johnson & Johnson companies sell some of the world's most advanced medical devices and pharmaceutical products. LifeScan and these other Johnson & Johnson companies follow a business model that is based on efforts to develop innovative medical/diagnostic products that can make a significant contribution to patient care.

41. Developing such products is an expensive, time-consuming and risky endeavor. Developing a new medical device or pharmaceutical product can take many years

and cost hundreds of millions of dollars. For every project that succeeds, there are many that never result in a commercially available product.

42. LifeScan and other Johnson & Johnson companies invest time and money in developing innovative medical products with the expectation that, when these efforts succeed, courts will protect their patented technology by enjoining the sale of products that infringe their patents. If other companies can effectively ride on an innovator's coattails by selling an infringing product and merely paying a reasonable royalty on infringing sales, there would be less incentive to spend time and money on the risky venture of trying to develop new medical products. The result would be that technology-based companies such as LifeScan and other Johnson & Johnson companies would have less of an incentive to engage in the risky and expensive endeavor of trying to develop new medical products, and their ability to carry on their core business and attract investors would be seriously impaired.

43. In 2011, LifeScan's ultimate parent company, Johnson & Johnson, invested approximately $7 billion in research and development. LifeScan and its affiliates also have a history of making large investments in research and development.

44. The risks and expense associated with trying to develop new medical technologies make it important for innovator companies to have some assurance that their patents will be fully protected when their investment leads to a new product. Any other result will reduce the incentive to engage in the risky and expensive process of developing new medical technologies.

45. It would be unfair to allow Defendants to use LifeScan's and LifeScan Scotland's patented technology to compete against us. If sales of the Shasta GenStrip are not enjoined, Defendants would, in effect, be riding on our coattails and using our patented technology to do so.

Sale of the Shasta GenStrip Would Deprive LifeScan of Funds for R&D

46. To the extent the Shasta GenStrip takes sales that otherwise would have gone to LifeScan, then LifeScan will be deprived of revenues it otherwise could invest in research and development ("R&D").

47. The resulting harm to LifeScan – and to the public in general – is impossible to quantify. No one ever will know what life-saving products could have been developed if LifeScan and affiliated companies had additional funds available to invest in research and development.

48. Moreover, investment in R&D means investment in people – scientists, physicians, engineers and technical assistants. A reduction in R&D spending would necessary mean a reduction in LifeScan's R&D staff. Once these personnel are discharged, institutional knowledge and company-specific know-how are irretrievably lost, and LifeScan's ability to compete in the marketplace would be significantly impaired.

Reduced Sales Could Force LifeScan to Lay Off Employees

49. Sales of the Shasta GenStrip could harm LifeScan's employees, as well as the company itself. Those sales might force LifeScan to lay off sales, marketing and R&D personnel, with many people losing their jobs, particularly in the Northern District of California.

50. These dangers are not speculative. Because of recent changes in the way the U.S. Government reimburses diabetes testing supplies used by Medicare patients, and the resulting decline in the amount that LifeScan will be able to charge its biggest customer for OneTouch Ultra products (*i.e.*, the U.S. Government), LifeScan recently reduced its workforce by several hundred positions, separate and apart from the introduction of the GenStrip.

51. A reduction in sales and prices resulting from the introduction of the GenStrip will necessitate further layoffs. And as with R&D personnel, a company's ability to compete effectively depends on the experience, depth, and strength of its sales and marketing teams. If the GenStrip is introduced and garners substantial sales at LifeScan's expense,

there is no doubt that LifeScan would be forced to lay off sales and marketing personnel, as well as R&D personnel. The impact on LifeScan cannot be overstated. Simply put, it will threaten LifeScan's viability as an ongoing concern. Clearly, damages flowing from such an event would be difficult to calculate and impossible to compensate through an award of money damages.

Reduced Contributions to Diabetes Education and Advocacy

52. To the extent the Shasta GenStrip takes sales that otherwise would have gone to LifeScan, LifeScan also will be deprived of revenues that it could devote to diabetes education and to other charitable and advocacy efforts aimed at helping diabetics. That injury would be felt by other organizations and by the broader community of persons with diabetes.

53. LifeScan participates extensively in non-commercial, humanitarian efforts to improve the quality of life for persons with diabetes. In this regard, LifeScan provides assistance to the diabetes community in four areas: (i) legislative advocacy; (ii) professional associations; (iii) corporate philanthropy; and (iv) local community efforts. Relevant portions of LifeScan's website discussing these activities are attached to this Declaration as Exhibit Y. *See Being a Responsible Corporate Citizen,* LifeScan, http://www.lifescan.com/responsibility/giving (last visited Dec. 13, 2012).

54. With respect to legislative advocacy, LifeScan works with the Diabetes Access to Care Coalition to assist diabetes organizations in the passage of laws that increase insurance coverage and medical rights for people with diabetes.

55. To further the goal of diabetes education, LifeScan also supports diabetes organizations and awards that focus on educating health care professionals in diabetes-related field to provide the highest quality of care for people with diabetes. Support for these organizations provides a wide range of support for the diabetes community.

56. As part of these efforts, LifeScan has partnerships with leading organizations in the diabetes field, including the American Diabetes Association ("ADA"),

the American Association of Diabetes Educators ("AADE"), the Diabetes Exercise and Sports Association ("DESA"), the National Diabetes Education Program, the American Association of Clinical Endocrinologists, the American Diabetes Association, the European Association for the Study of Diabetes, the Federation of European Nurses for Diabetes, the International Diabetes Federation, the International Society for Pediatric and Adolescent Diabetes, and the Juvenile Diabetes Research Foundation ("JDRF").

57. In addition, LifeScan sponsors awards, including: (a) an annual award given by the AADE to the Diabetes Educator of the Year, an individual who has made a special contribution to diabetes education through dedication and innovation in the practice of patient care; (b) an annual award given by the Canadian Diabetes Association to the Canadian Educator of the Year; (c) the DESA LifeScan Prize for Athletic Achievement; and (d) the American Diabetic Association's Distinguished Service Award in Diabetes Care and Education. LifeScan also is a sponsor of the Diabetes Education and Camping Association, which provides leadership and education for diabetes camps that serve children affected with diabetes.

58. As part of its philanthropic efforts, LifeScan also donates testing supplies to camp programs nationwide so that thousands of children with diabetes can experience the camaraderie of summer camps. In addition, LifeScan sponsors educational programs for patients and health care professionals. It also provides sponsorship for diabetes fundraising events such as ADA's Tour to Cure and JDRF's Walk to Cure Diabetes.

59. In addition, LifeScan contributes to the Johnson & Johnson Diabetes Institute LLC, which provides healthcare professionals with education, training and a space for collaboration with the aim of enhancing the understanding of diabetes and helping to improve patient outcomes. The Institute aims to ensure that diabetes specialists are able to receive skills training and education customized to reflect the needed of patients and providers in the region, as well as supporting proven guideline implementation and an efficient use of resources within diabetes care. Relevant pages from the Institute's website

are attached to this Declaration as Exhibit Z. *See also* Johnson & Johnson Diabetes Institute, LLC, http://www.jjdi.com/ (last visited Dec. 13, 2012).

60. To the extent the Shasta GenStrip takes sales that otherwise would have gone to LifeScan, LifeScan would have substantially less funds available to devote to these philanthropic and humanitarian causes.

Conclusion

61. As discussed above, the introduction of the Shasta Genstrip would irreparably harm LifeScan in ways that could not be remedied through an award of money damages.

I declare under penalty of perjury that the foregoing is true and correct.

Executed: December 19, 2012

By: Peter Menziuso
Peter Menziuso

EXHIBIT A

Life First. ONETOUCH

Register Your Meter | Sign In | Forgot Password?

Healthcare Professionals ▸

Submit

Home | Our Products | Understanding Diabetes | Support

Buy OneTouch®

Share & Print

Features

DoubleSure™ Technology automatically checks each blood sample twice.

Stands behind eight years of proven accuracy.

Eliminates falsely elevated results from other sugars. Why is this important?

OneTouch® Ultra® Blue Test Strips

OneTouch® Verio™ Gold Test Strips

Compatible with:

- OneTouch® Ultra®2 Blood Glucose Monitoring System
- OneTouch® UltraSmart® Blood Glucose Monitoring System
- OneTouch® UltraMini® Blood Glucose Monitoring System
- OneTouch® Ultra® Blood Glucose Monitoring System
- OneTouch® UltraLink™ Blood Glucose Monitoring System
- OneTouch® Ping™ Glucose Management System

FAQs

- How do I get test strips?
- Can I use expired test strips?
- How do I insert the test strip into the meter?
- How do I apply blood to the test strip?
- How do I get control solution?

Need testing support

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This information is for general background purposes and is not a substitute for medical advice or treatment for specific conditions. Seek prompt medical attention for health care questions you have. Consult your physician before making changes to your medication, diet, fitness program or blood glucose testing schedules.

This site was last updated on November 12, 2012.

AW 3060236A

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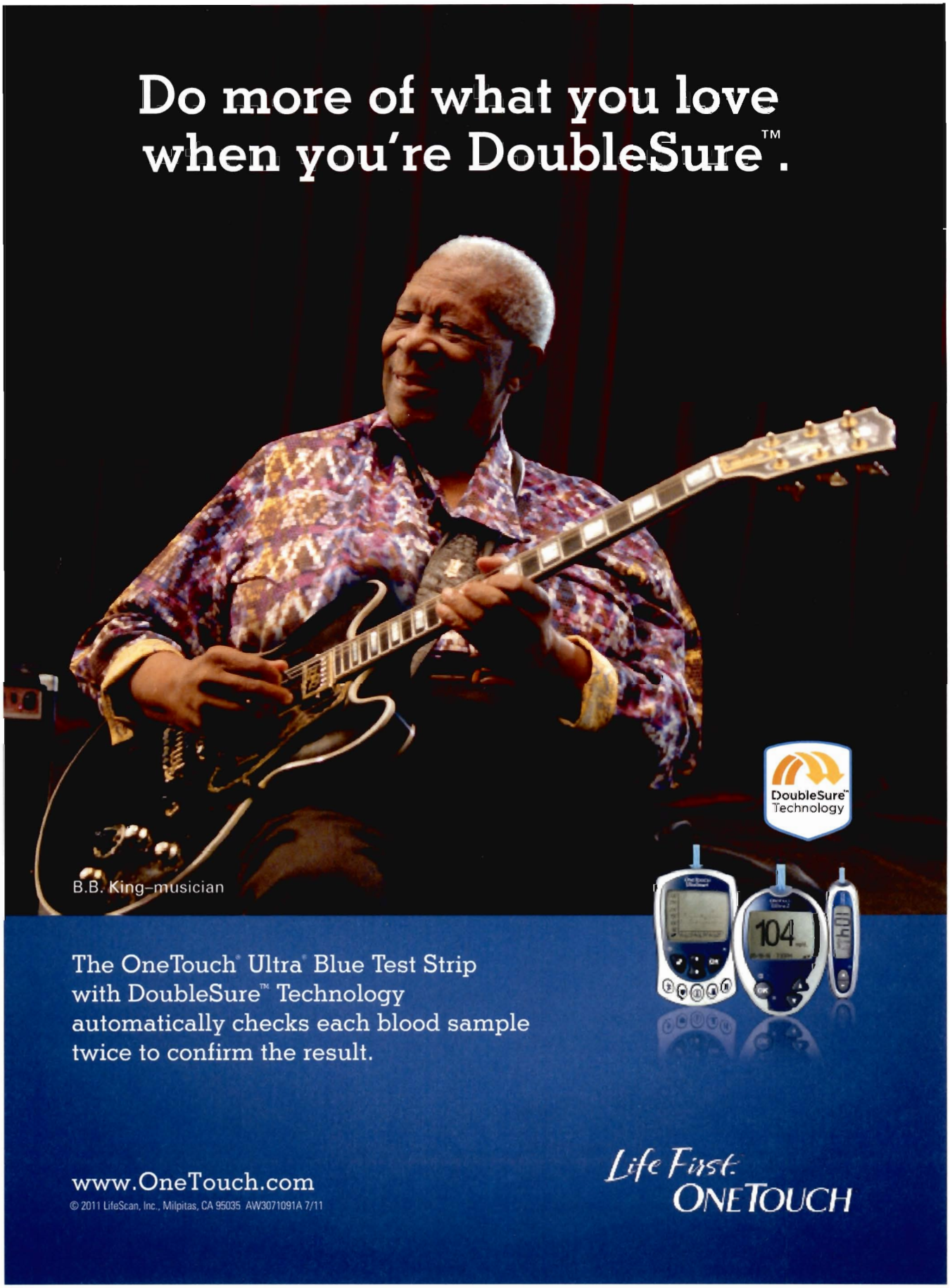
EXHIBIT B


Do more of what you love when you're DoubleSure™.
B.B. King–musician
DoubleSure™ Technology
104
The OneTouch® Ultra® Blue Test Strip with DoubleSure™ Technology automatically checks each blood sample twice to confirm the result.
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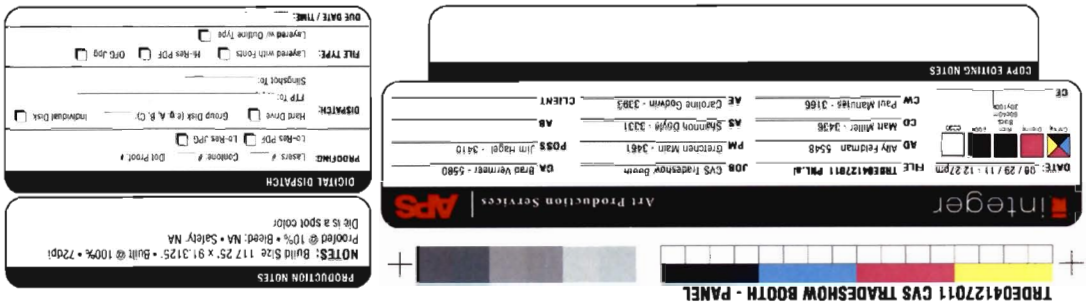
ONETOUCH

EXHIBIT C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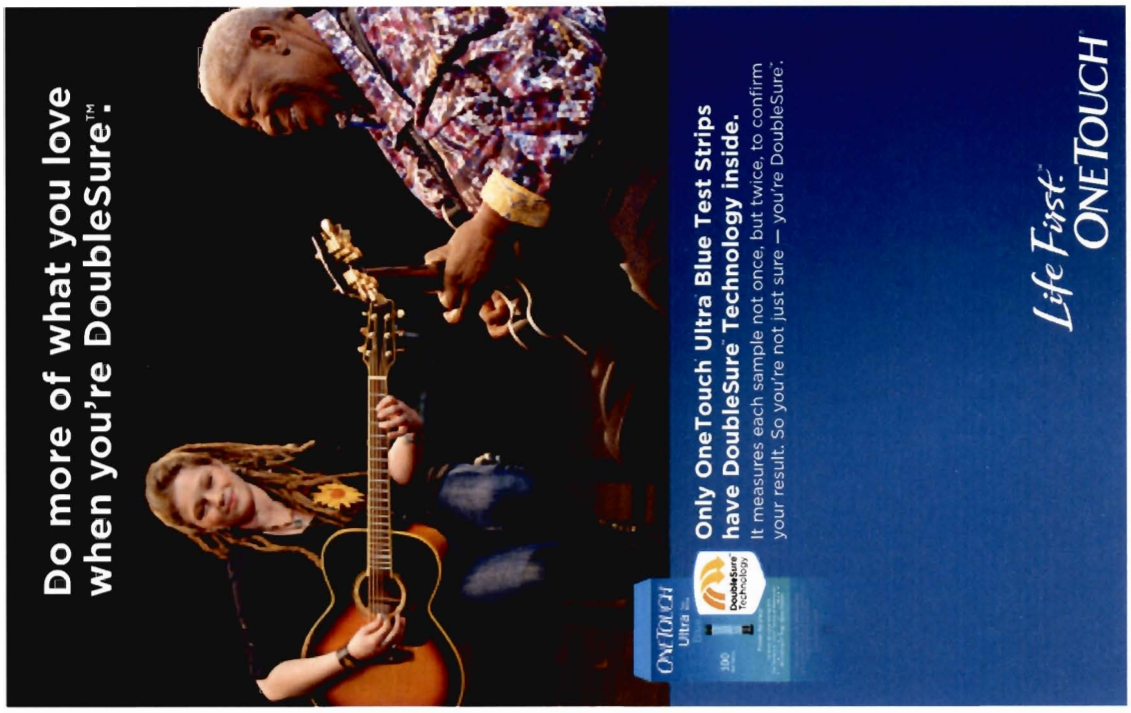
Do more of what you love when you're DoubleSure™.
Only OneTouch Ultra Blue Test Strips have DoubleSure Technology inside.
It measures each sample not once, but twice, to confirm your result. So you're not just sure — you're DoubleSure.
Life First.™ ONETOUCH

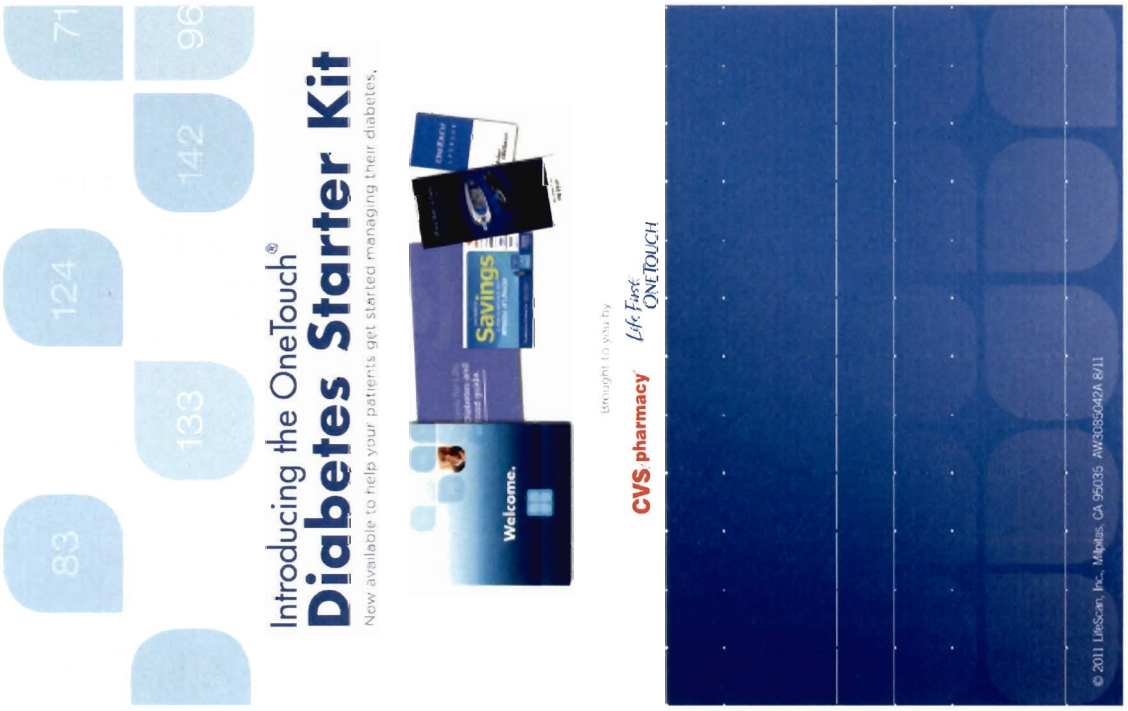
Introducing the OneTouch®
Diabetes Starter Kit
New available to help your patients get started managing their diabetes.
Welcome.
Savings
Brought to you by
Life First ONETOUCH
CVS pharmacy
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EXHIBIT D

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Find

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Buy OneTouch®

Getting started with OneTouch®

New to testing?
New to OneTouch®?
Learn how to use your meter, step-by-step.

1 2 3

DoubleSure™ Test Strip Technology. Don't be just sure. Be DoubleSure™

Measures every blood sample, not once but twice.

OneTouch® Delica™ Lancing System for More Comfortable Testing*

Less motion. More control.
And our thinnest needle ever.

Download the OneTouch® Logbook

Keeping track is as simple as clicking print.

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This site was last updated on December 13, 2010.

AW 3060227B

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*Response from study subjects when asked to compare OneTouch® Delica™ to their current lancing device.

EXHIBIT E


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ONETOUCH
Ultra Test Strips
Blue
50 Test Strips
DoubleSure™ Technology
Proven Accuracy
DoubleSure™ Technology automatically checks each sample twice to confirm the result.
Life First. ONETOUCH
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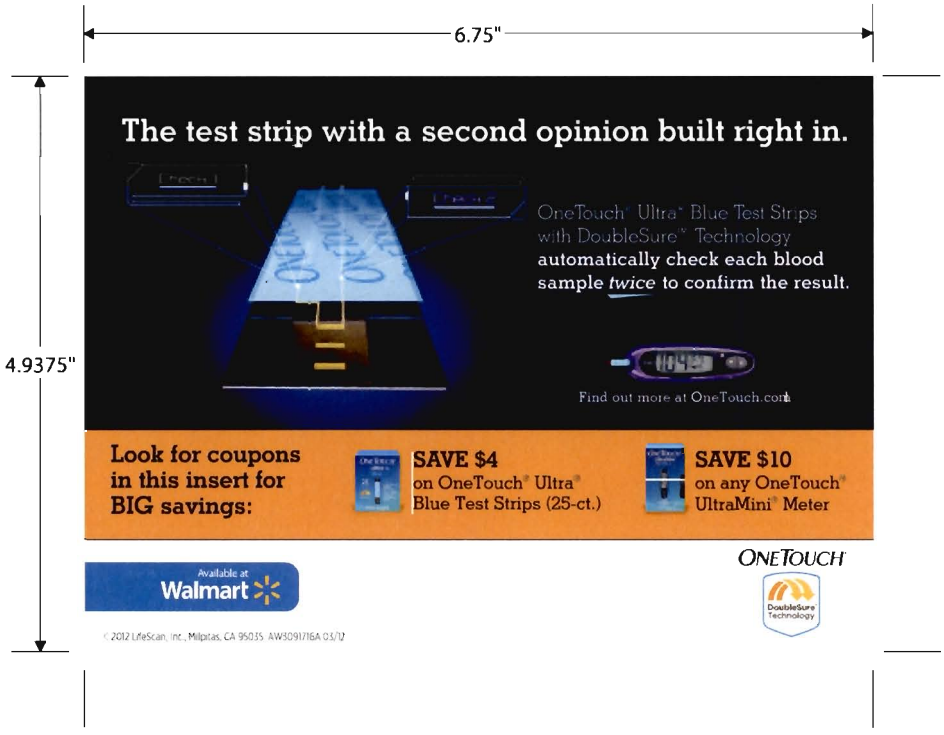
On Sale Now!
OneTouch® UltraMini®

EXHIBIT F



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CW: Paul Manutes - 3166
AE: Caroline Godwin - 3393
CLIENT:
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PRODUCTION NOTES

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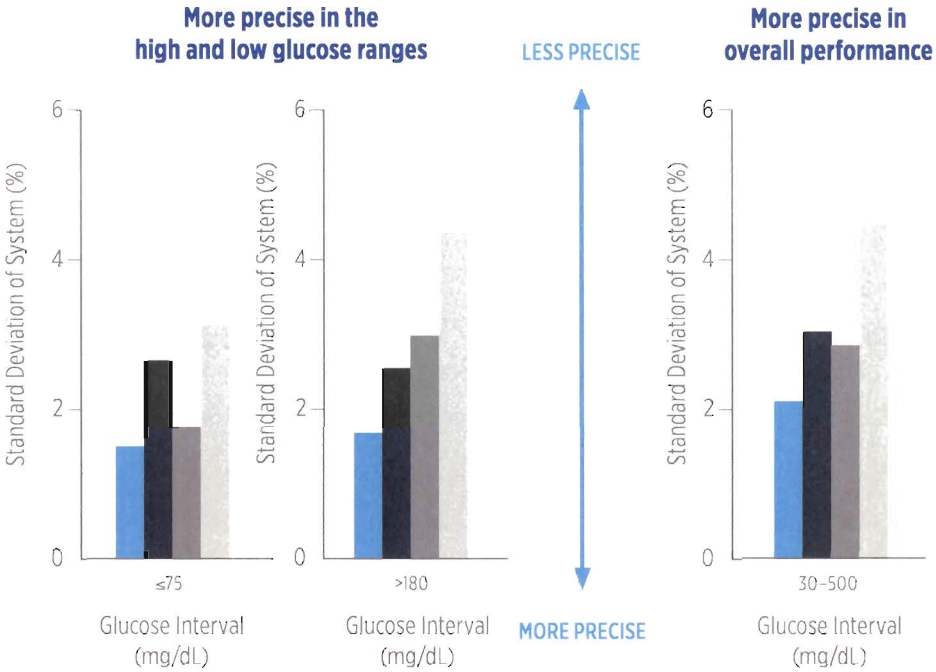
FTP To: ___
Slingshot To: ___
FILE TYPE: Layered with Fonts ☐ Hi-Res PDF ☐ OPI Jpg ☐
Layered w/ Outline Type ☐
DUE DATE / TIME: ___

EXHIBIT G


Unsurpassed precision in the high and low ranges compared with leading brands.[1]
ONETOUCH UltraMini
ONETOUCH UltraMini
ONETOUCH UltraMini
ONETOUCH UltraMini
Life First.
ONETOUCH

OneTouch®. Precise. Proven. And #1 recommended.

Unsurpassed precision versus leading brands.[1]



The OneTouch® Ultra® System demonstrated:

- Up to twice the precision of Abbott FreeStyle Lite®[2,3]
- 30% greater precision than ACCU-CHEK® Aviva[2,3]
- 20% greater precision than Bayer Contour®[2,3]

OneTouch® Ultra®
ACCU-CHEK® Aviva
Bayer Contour®
FreeStyle Lite®

Precision is a measure of test result reproducibility. Precision comparison includes meter, strip, and strip lot variability. Data normalized to remove patient-to-patient variation. Three thousand tests were produced from three test strip lots and venous blood samples from 100 patients.[2]

All test strips in this study meet ISO standards for accuracy.[1]

Accuracy that's proven.

Proven accuracy: Study over 8 years running in over 70,000 strips from over 800 strip lots using capillary samples.

OneTouch®: the brand that's #1 recommended.

#1 recommended by endocrinologists.
#1 recommended by primary care physicians.
Lowest co-pay on the most health plans.*
Covered by Medicare Part B.†

Some health plans may have more than one test strip covered at the lowest co-pay. Co-insurance or co-payment and deductibles apply.

Products powered by DoubleSure™ Technology.

The OneTouch® Ultra® Blue Test Strip

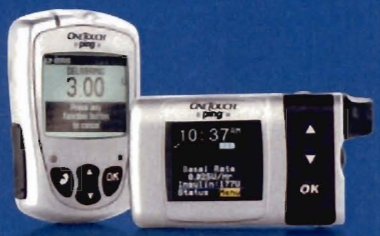
Unsurpassed precision versus other leading brands.[1]

- Checks each blood sample twice to confirm the result

The OneTouch® UltraMini® Meter

Sleek design. Precise results.

- Simple to teach, easy to use
- Convenient size that's easy to transport
- Available in 6 colors



The OneTouch® Ping® Insulin Pump and Meter-Remote

Designed to help your patients perform at their best.

- The only pump that can deliver basal insulin in 0.025 U/hr increments across all available basal rates (0.025 U/hr–25 U/hr)[4]
- Carb values can be accessed anytime from the meter-remote's 500-item CalorieKing™ food database

The OneTouch® Ultra®2 Meter

Essential for people focused on better food decisions.

- See the impact of food
- Flag results as before or after meal

LOWEST CO-PAY
*on the most health plans**

*Some health plans may have more than one test strip covered at the lowest co-pay.

OneTouch®. Precise. Proven. And #1 recommended.

- The OneTouch® Ultra® Blue Test Strip demonstrated unsurpassed precision versus other leading brands[1]
- Proven accurate in over 70,000 separate measures
- OneTouch® is the brand most recommended by endocrinologists and primary care physicians

OneTouch® and Animas®: working together to create a world without limits for people with diabetes.

LifeScan, maker of OneTouch® Meters, and Animas®, maker of insulin pumps, have combined forces in order to bring your practice and patients a whole new level of responsiveness and performance.

- Better, faster innovations
- Integrated solutions to streamline the steps to control
- Outstanding support for healthcare professionals and patients

LIFESCAN Animas® CORPORATION

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

1. Leading brands include OneTouch® Ultra® Test Strips, Roche ACCU-CHEK® Aviva Test Strips, Abbott FreeStyle Lite® Test Strips, and Bayer Contour® Test Strips. OneTouch® Ultra® Test Strips, Abbott FreeStyle Lite® Test Strips, Bayer Contour® Test Strips, and Roche ACCU-CHEK® Aviva Test Strips meet ISO standards for accuracy (ISO 15197:2003).
2. Study conducted using OneTouch® Ultra®2 Meter versus Roche ACCU-CHEK® Aviva Meter, Abbott FreeStyle Lite® Meter, and Bayer Contour® Meter in 27 [illegible] given individual. Data on file. LifeScan, Inc.
3. The standard deviation ratio compared to the OneTouch® Ultra® System: Roche ACCU-CHEK® Aviva System was 1.32, Bayer Contour® System was 1.21, and Abbott FreeStyle Lite® System was 2.06.
4. OneTouch® Pring® Owner's Booklet, p. 102. 410106000C.

All product names and trademarks are the property of their respective owners.
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EXHIBIT H

LIFESCAN
a Johnson & Johnson company

With the OneTouch® UltraMini® Meter, a small change can make a big difference.

Fast, simple, accurate blood glucose monitoring comes in a small, sleek size.

Compact enough to fit in a pocket or purse

- Simplified design, so it's easy to use and handle
- Large, easy-to-read display
- Small, portable testing kit

Fast, accurate, streamlined blood sugar testing

- Simple three-step testing process
- Gives results in just 5 seconds, helping save time
- Two-way scrolling button for simplified operation
- 500-test memory helps you track results

Uses OneTouch® Ultra® Blue Test Strips

- The only test strip with DoubleSure™ Technology that automatically checks each blood sample twice to confirm the results
- The #1 selling test strip
- 8 years of proven accuracy
- Just one CalCode

More power to you.™
ONETOUCH®

EXHIBIT I

OneTouch

http://www.facebook.com/OneTouch?ref=ts

Apple Yahoo! Google Maps YouTube Wikipedia News (127) Popular

facebook Search Home Profile Account

OneTouch

Like

Health/Beauty

Life First. ONETOUCH

- Wall
- Info
- Life First
- Products and Offers
- Video

About

Welcome to the OneTouch® Facebook page. OneTouch® believes diabetes shouldn...

More

Take a moment to explore our line of OneTouch® products. You'll find what you need to help manage your diabetes and never miss out on a minute of living.

See if you qualify for a OneTouch® Meter at no charge.

Blood Glucose Meters

OneTouch® Ultra 2
A fast, gentle* and simple way to see the effect of food on your blood sugar results.
Learn more >

OneTouch® UltraMini
A simple way to check your blood sugar on the go.
Learn more >

OneTouch® UltraSmart
The meter that automatically collects and organizes blood sugar results into useful charts and graphs.
Learn more >

Test Strips

OneTouch® Ultra® Blue Test Strips
Measures every sample, not once but twice. So you can be DoubleSure.**
Learn more >

OneTouch® Delica™ Lancing System

OneTouch® Delica™ Lancing System for more Comfortable Testing™*
Advanced Glide™ Control System and our thinnest needle offer less motion and gentle, more precise lancing.
Learn more >

Management Tools

OneTouch® Diabetes Management Software Kit
Download data from your OneTouch® Meter to your computer and identify trends in your blood sugar levels.
Learn more >

ADDITIONAL LINKS:
- Check Your Coverage
- Buy OneTouch®
- Find Support

See if you qualify for a OneTouch® Meter at no charge.

EXHIBIT J

The OneTouch® UltraMini® Meter works with DoubleSure™ Technology, automatically checking each sample twice to confirm the result. To take advantage of this offer, please fill in your information below.

1 Do you have diabetes? * ○ Yes ○ No

2 Your contact information

Title
First name *
Last name *
Suffix
Address 1 *
Address 2
City *
State * Select...
Zipcode *
Phone *
Example: xxx-xxx-xxxx
Date of birth * Month Day Year
E-mail *
*Your email will be used to send you important offer details.

3 Your diabetes information

If you do not have diabetes yourself, but care about someone who does, answer with this person in mind.

When were you diagnosed with diabetes? *
Year Select

What is the name of the blood glucose Meter that you use most often to check your blood glucose levels? *
Select your meter

How long have you had your Meter? *
Less than 1 yr 1 yr 2 yrs 3+ yrs

How often do you test your blood glucose? *
Select a number

What methods do you use to manage your diabetes? *
Diet
Exercise
Other
Insulin pump
Insulin shots
Pills/Oral medication
Shots other than insulin

Yes, I would like to receive diabetes-related information and promotional offers from LifeScan, Inc. I agree that my information will be available to LifeScan, its affiliates and companies that work with LifeScan and that LifeScan may contact me for my opinions related to its business. (You can request that your information be removed from LifeScan's contact list by emailing CustomerService@LifeScan.com.)

Note: The information you submit will be governed by our site's Privacy Policy. Unless you choose to receive additional information from us by checking the box below, it will be used only to determine whether you qualify for this offer.

For more information about OneTouch® Products, visit www.OneTouchDiabetes.com/Monitoring.

Submit Clear

EXHIBIT K

Pumper Email #1

To: Sample

From: OneTouch@xxxxxx.com

Subject: Packing List for Pumpers

Follow Us

Life First. ONETOUCH

Have pump, will travel.

And bring along the only strip with DoubleSure™ Technology.

Learn More >

Take off on your trip—without taking off your pump.

Increased airport security is a concern for everyone. Especially if you use an insulin pump. So it's important to know, that by law, you are permitted to wear your insulin pump on the plane. That is, when you actually get on the plane.

The inevitable delay can challenge anyone's daily routine. As a pumper, things like time zone changes, or even the time of day of your trip, can affect your insulin dosing. With so much uncertainty, it's even more important that you test as advised by your doctor. And when you do test, make sure you can be confident in the results.

Baggage Claim

OneTouch® Ultra® Blue Test Strips have DoubleSure™ Technology. It measures every blood sample not once, but twice—so you can be DoubleSure™. Even when your travel plans are up in the air.

Learn more about DoubleSure™ Technology >

Packing for Pumpers.

There's a lot to remember when packing for a trip. Consider bringing an extra insulin pump, especially if traveling abroad. Ask your pump company about getting a loaner. Here are a few of the other things you should be packing.

- Reservoir cartridges
- Infusion sets
- Additional batteries
- Skin site prep supplies
- Back-up meter
- Lancets and lancing device
- Plenty of test strips

If you can't bring an extra pump, then bring insulin, syringes, and dosing instructions. Visit the TSA web site for the most up to date information.

www.tsa.gov >

It's time to switch to OneTouch® Ping.™
When your existing pump warranty is up, it's a great time to look at your options.

6 good reasons to switch >

Save $10

Buy any OneTouch® Meter and Save $10 on OneTouch® test strips, lancets, or lancing device.

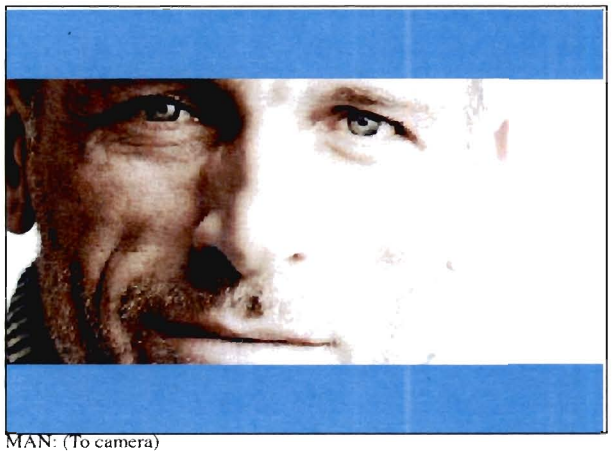
Check Sunday's paper for our coupon >

Home | Our Products | Understanding Diabetes | Support

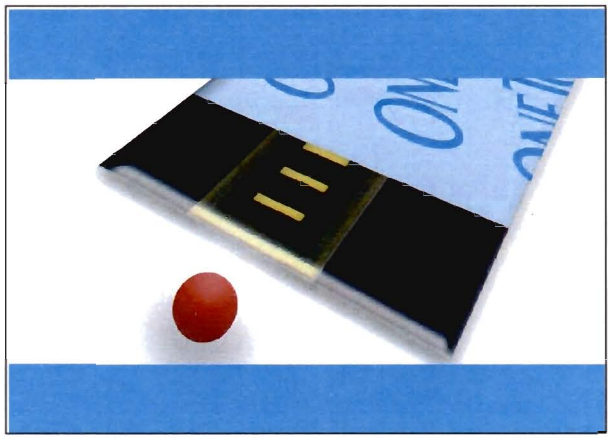
EXHIBIT L

What's Inside. Technology Launch

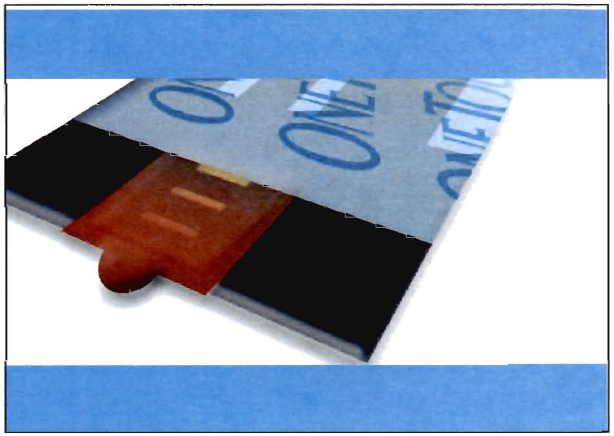
:30 Storyboard



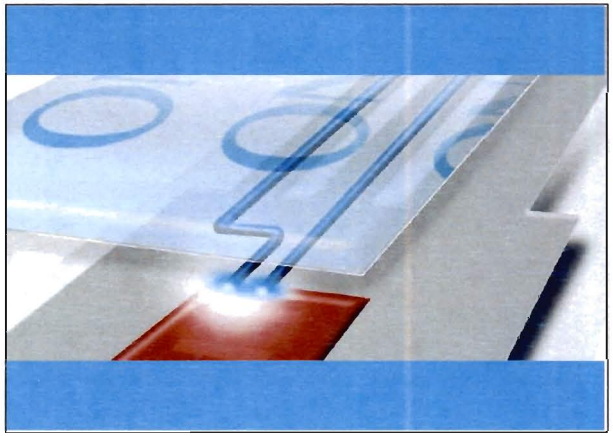
MAN: (To camera)
When you have diabetes, you're never really sure what's happening inside you.



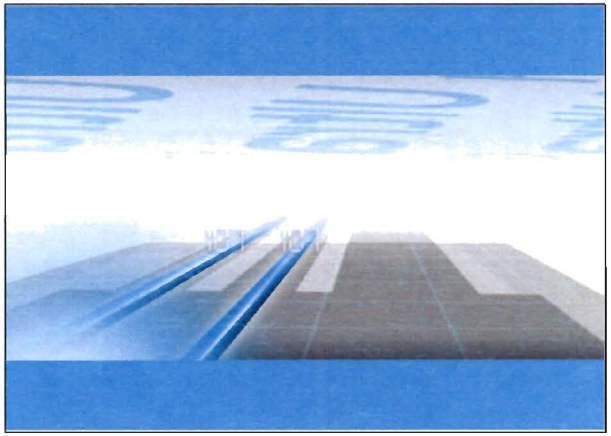
Well, that's about to change.



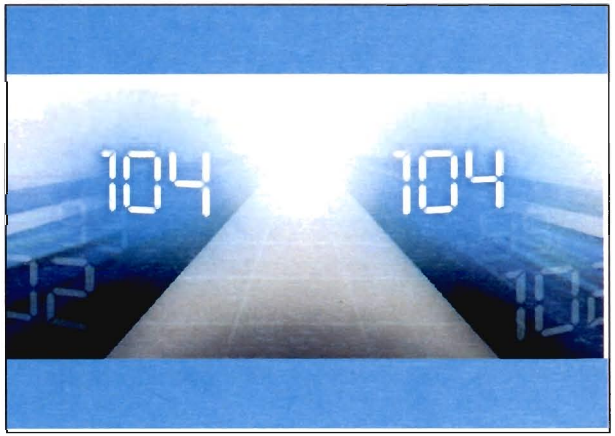
Because inside every OneTouch® Ultra™ Blue Test Strip...



is DoubleSure™ Technology.



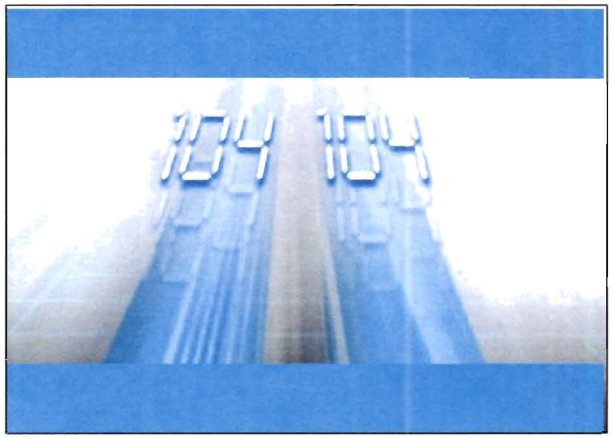
It measures each blood sample...

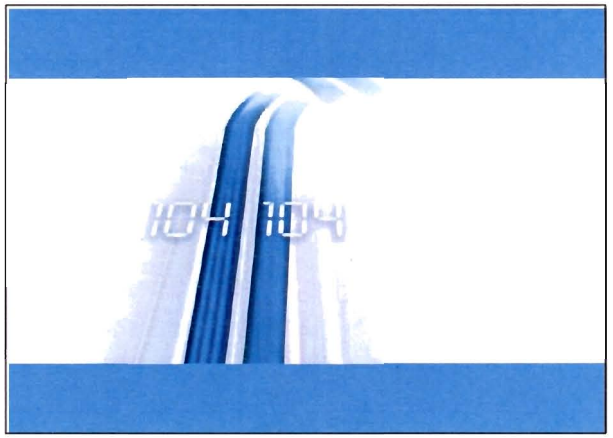


not once, but twice.

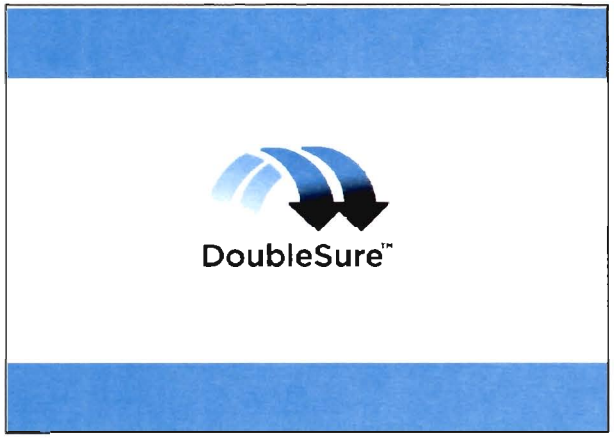
What's Inside. Technology Launch

:30 Storyboard

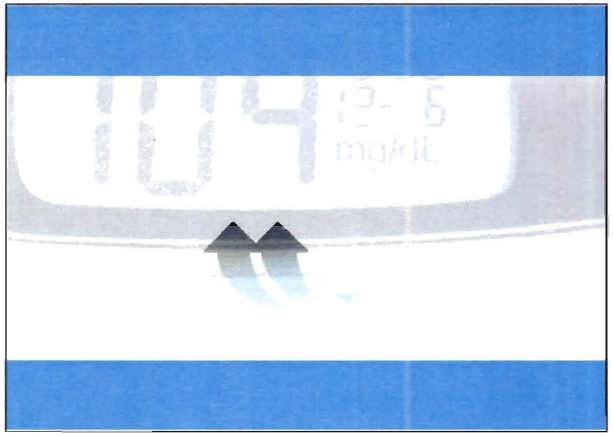




So you're not just sure



you're double sure.



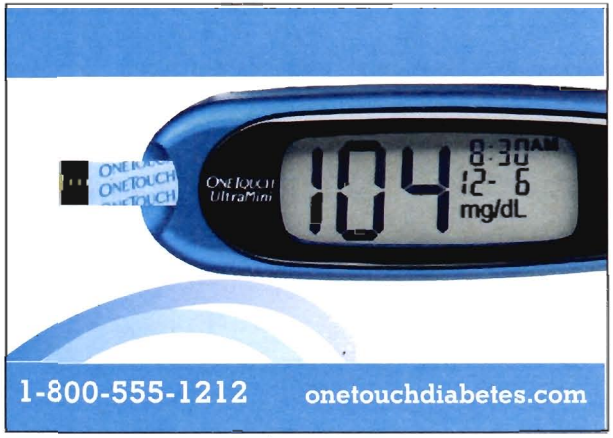
Experience it for yourself.

What's Inside. Technology Launch

:30 Storyboard

Get a DoubleSure™ starter kit at no charge.

including a OneTouch® UltraMini™ Meter



and ten test strips.

Call 1-800-555-1212 now to see if you qualify.

What's Inside. Technology Launch
:30 Script

MAN: (To camera.)
When you have diabetes, you're never really sure what's happening inside you.

Well, that's about to change.

Because inside every OneTouch® Ultra™ Blue Test Strip...is DoubleSure™ Technology.

It measures each blood sample not once, but twice.

So you're not just sure ...you're double sure.

Experience it for yourself.

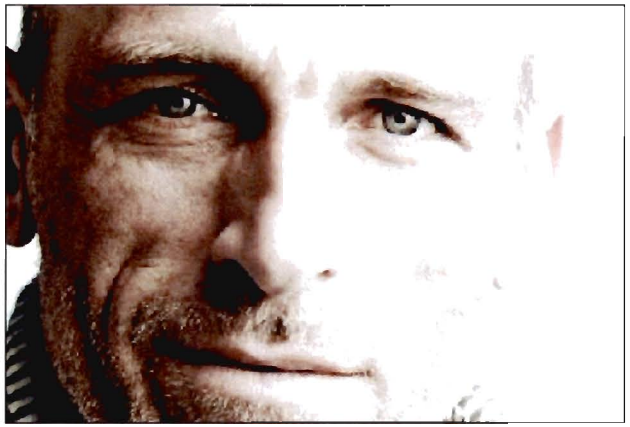
Get a DoubleSure™ starter kit at no charge, including a OneTouch® UltraMini™ Meter and ten test strips.

Call 1-800-555-1212 now to see if you qualify.

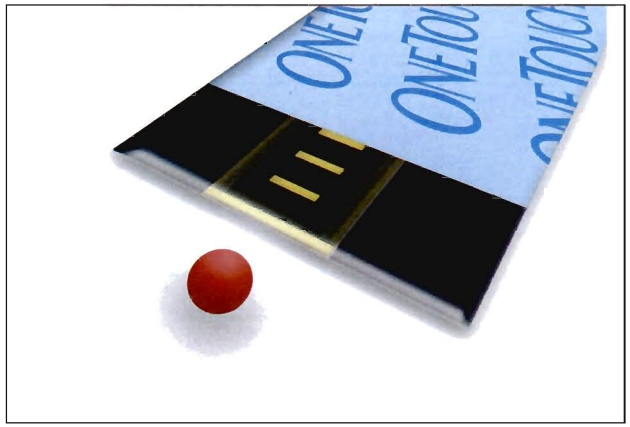
EXHIBIT M

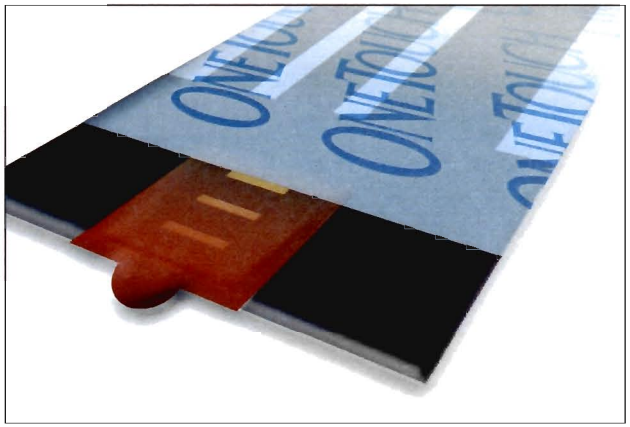
What's Inside. Technology Launch

:15 Storyboard

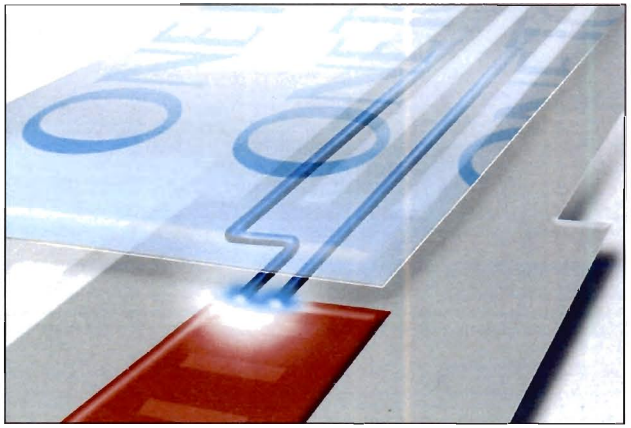


ANNCR VO: When you have diabetes, you're never really sure what's happening inside you.

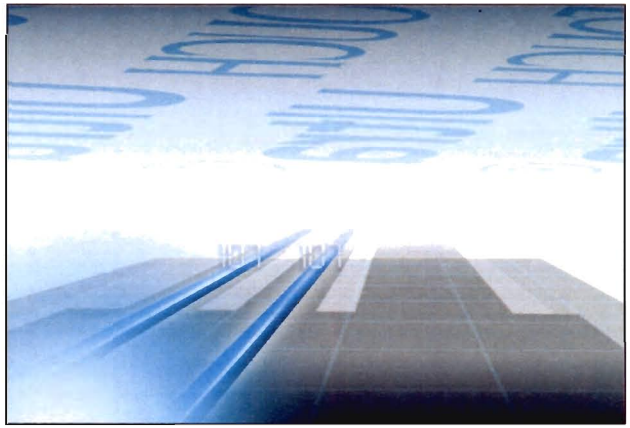


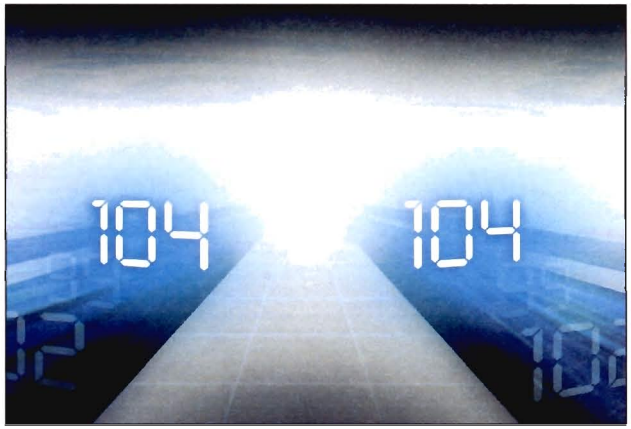


Well, that's about to change.



Because inside every new OneTouch® Ultra® Blue Test Strip … is DoubleSure™ Technology.

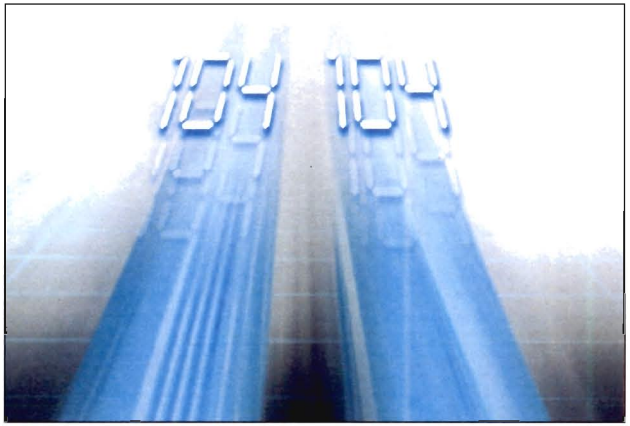




It automatically measures every blood sample, not once but twice.

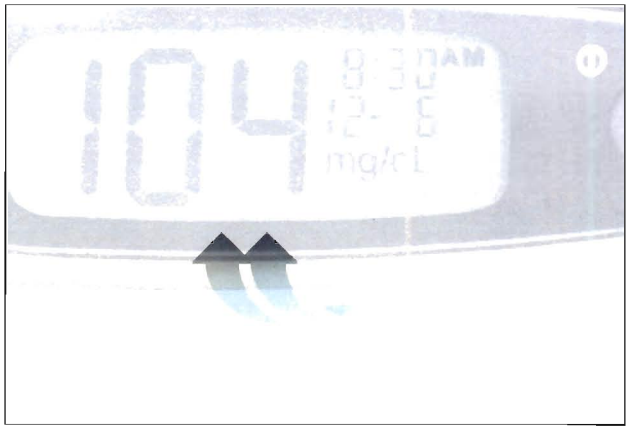
What's Inside. Technology Launch

:15 Storyboard



DoubleSure™

ANNCR VO: So you're not just sure about what's going on inside you … you're double sure.



More power to you.

ONETOUCH

What's Inside. Technology Launch

:15 Script

AUDIO:

ANNCR VO: When you have diabetes, you're never really sure what's happening inside you.

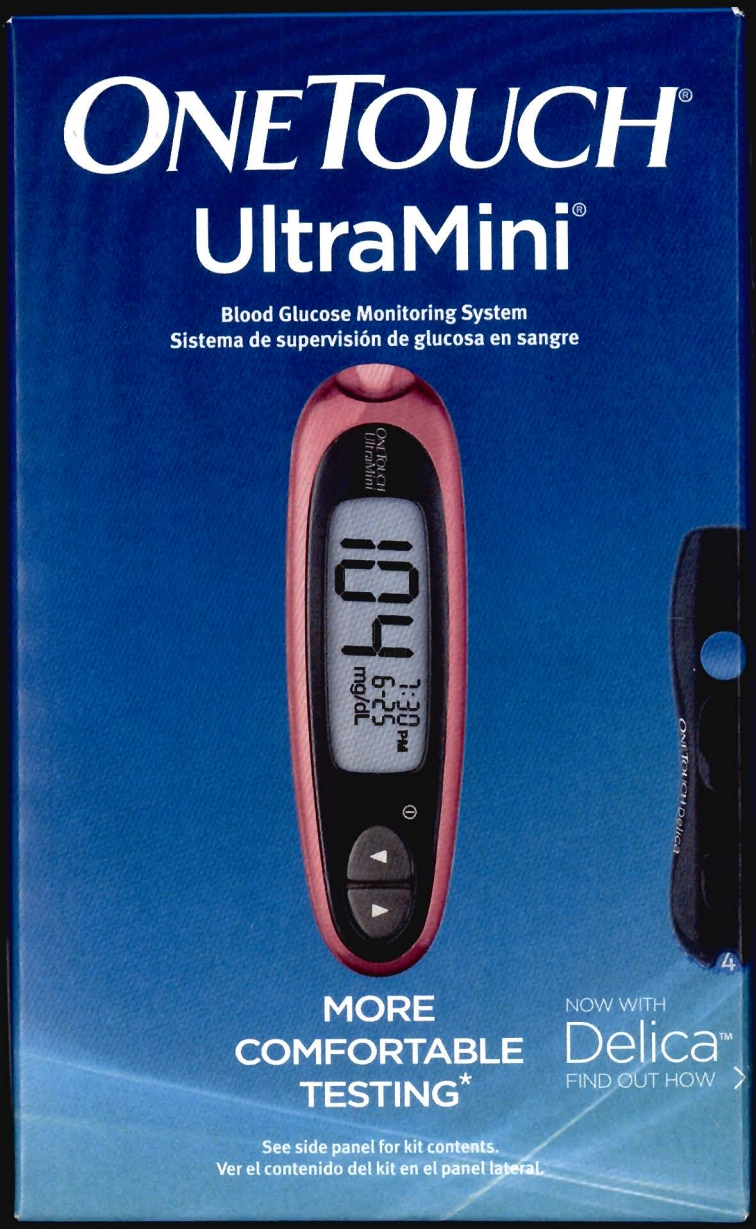
Well, that's about to change.

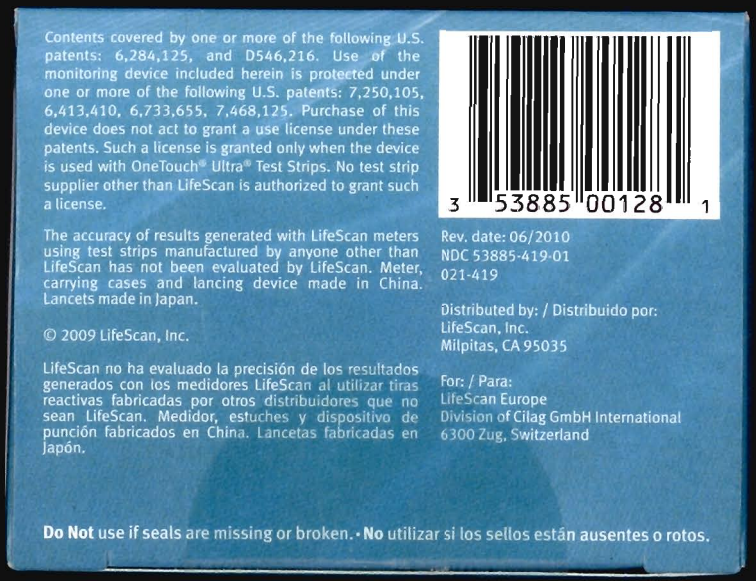
Because inside every new OneTouch® Ultra® Blue Test Strip … is DoubleSure™ Technology.

It automatically measures every blood sample, not once but twice.

So you're not just sure about what's going on inside you … you're double sure.

EXHIBIT N


ONETOUCH®
UltraMini®
Blood Glucose Monitoring System
Sistema de supervisión de glucosa en sangre
104
1:30 PM
6-25
mg/dL
MORE COMFORTABLE TESTING*
NOW WITH
Delica™
FIND OUT HOW
See side panel for kit contents.
Ver el contenido del kit en el panel lateral.



Contents covered by one or more of the following U.S. patents: 6,284,125, and D546,216. Use of the monitoring device included herein is protected under one or more of the following U.S. patents: 7,250,105, 6,413,410, 6,733,655, 7,468,125. Purchase of this device does not act to grant a use license under these patents. Such a license is granted only when the device is used with OneTouch® Ultra® Test Strips. No test strip supplier other than LifeScan is authorized to grant such a license.

The accuracy of results generated with LifeScan meters using test strips manufactured by anyone other than LifeScan has not been evaluated by LifeScan. Meter, carrying cases and lancing device made in China. Lancets made in Japan.

LifeScan no ha evaluado la precisión de los resultados generados con los medidores LifeScan al utilizar tiras reactivas fabricadas por otros distribuidores que no sean LifeScan. Medidor, estuches y dispositivo de punción fabricados en China. Lancetas fabricadas en Japón.

3 53885 00128 1

Rev. date: 06/2010
NDC 53885-419-01
021-419

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LifeScan, Inc.
Milpitas, CA 95035

For: / Para:
LifeScan Europe
Division of Cilag GmbH International
6300 Zug, Switzerland

Do Not use if seals are missing or broken. • **No** utilizar si los sellos están ausentes o rotos.

EXHIBIT O

ONETOUCH®

UltraMini®

Blood Glucose Monitoring System

USER GUIDE

AW 06629001B
Rev. date: 07/2009

Before you begin

Before using this product to test your blood glucose, carefully read this User Guide and the inserts that come with the OneTouch® Ultra® Test Strips and OneTouch® Ultra® Control Solution. Take note of warnings and cautions throughout this User Guide, which are identified with ⚠. Many people find it helpful to practice the test with control solution before testing with blood for the first time. See Section 5, Control solution testing.

Intended use

The OneTouch® UltraMini® Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood. The OneTouch® UltraMini® System is intended for self-testing outside the body (*in vitro* diagnostic use) by people with diabetes at home and by healthcare professionals in a clinical setting as an aid to monitor the effectiveness of diabetes control. It should not be used for the diagnosis of diabetes or for testing newborns.

Test principle

Glucose in the blood sample mixes with special chemicals in the test strip and a small electric current is produced. The strength of this current changes with the amount of glucose in the blood sample. Your meter measures the current, calculates your blood glucose level, displays the result, and stores it in its memory.

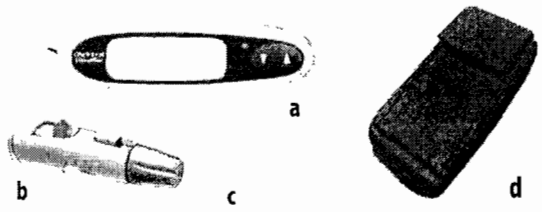
Contents:

1 Getting to know your system

The OneTouch® UltraMini® Blood Glucose Monitoring System

Included with your kit:

a. OneTouch® UltraMini® Meter (battery included)
b. Lancing Device
c. Lancet(s)
d. Carrying Case

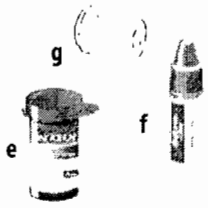


If any of these items are missing from your kit, call LifeScan Customer Service at 1 800 227-8862 (available 24 hours a day, seven days a week).

Available separately:

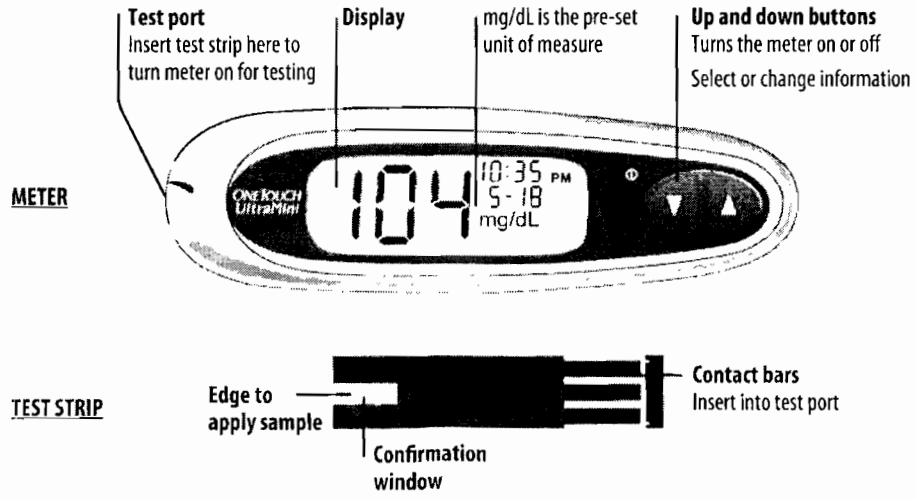
e. OneTouch® Ultra® Test Strips
f. OneTouch® Ultra® Control Solution
g. Clear Cap for AST testing

For availability of control solution, ask for control solution where you obtain your test strips.



⚠ WARNING: Keep the meter and testing supplies away from young children. Small items such as the battery door, battery, test strips, lancets, protective disks on the lancets and control solution vial cap are choking hazards.

Getting to know your system



Patent information

The system described herein is covered by one or more of the following U.S. patents: 5,708,247, 5,951,836, 6,241,862, 6,284,125, 7,112,265, and D546,216. Use of the monitoring device included herein is protected under one or more of the following U.S. patents: 6,413,410, 6,733,655, 7,250,105, 7,468,125. Purchase of this device does not act to grant a use license under these patents. Such a license is granted only when the device is used with OneTouch® Ultra® Test Strips. No test strip supplier other than LifeScan is authorized to grant such a license. The accuracy of results generated with LifeScan meters using test strips manufactured by anyone other than LifeScan has not been evaluated by LifeScan.

As your partner in diabetes care, we welcome you to contact us anytime.
1 800 227-8862 (English)
www.OneTouchDiabetes.com

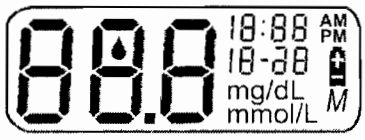
If you cannot reach Customer Service, contact your healthcare professional for advice.

LIFESCAN
a Johnson & Johnson company

Manufactured for:
LifeScan, Inc.
Milpitas, CA USA 95035

Turning your meter on

To perform a test, insert a test strip as far as it will go. The display will turn on and the meter will briefly perform system checks. ***Or***, to change the time and date, start with the meter off, then press and hold ▼ for five seconds until the start-up test screen appears. After the start-up test screen, the pre-set time and date will appear on the display. ***Or***, if you want to turn the meter on to review past results, start with the meter off, then press and release ▼.



Start-up Test Screen

Every time you turn your meter on, a start-up test screen will appear for two seconds. All segments of the display should appear briefly on the start-up test screen to tell you that the meter is working properly. To check that all display segments are working, as soon as the start up test screen appears, press and hold ▲ to keep the start-up test screen display on. Release ▲ to proceed to the next step. If the meter does not power on, try changing the meter battery. See *Replacing the battery* in Section 6.

Turning your meter off

There are several ways to turn your meter off:

- Press and hold ▼ for two seconds, when reviewing past results.
- Your meter will turn off by itself if left alone for two minutes.
- Before or after completing a test, remove the test strip.

⚠ **CAUTION:** If any information is missing from the start-up test screen, there may be a problem with the meter. Call LifeScan Customer Service at 1 800 227-8862 (available 24 hours a day, seven days a week).

2 Setting the time and date, and coding your meter

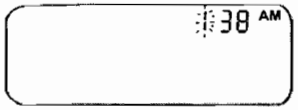
Setting the time and date

Your OneTouch® UltraMini® Meter comes with the time, date and unit of measure pre-set. Before using your meter for the first time or if you change the meter battery, you should check and update the time and date. Make sure you complete steps 1 to 7 below to ensure your desired settings are saved.

⚠ WARNING: If your display shows mmol/L rather than mg/dL, contact LifeScan Customer Service at 1 800 227-8862 (available 24 hours a day, seven days a week). You cannot change the unit of measure. Use of the wrong unit of measure may cause you to misinterpret your blood glucose level, and may lead to incorrect treatment.

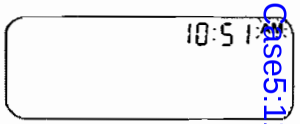
❶ Turn the meter on
Press and hold ▼ for five seconds until the start-up test screen appears. After the test screen, the pre-set time and date will appear on the display for five seconds. The hour will now start flashing.

NOTE: If a setting does not need to be updated, simply wait five seconds. The meter display will automatically advance to the next setting.

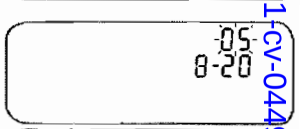


❷ Set the hour
With the hour flashing on the display, press and release ▲ or ▼ to go forward or backward one hour. To move faster, hold the ▲ or ▼ buttons down.

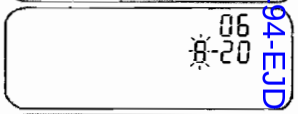
❹ Set AM or PM
"AM" or "PM" will be displayed next to the minutes. Press ▲ or ▼ to set AM or PM, then wait five seconds to move to the next setting. The year (last two digits only), month and day appear on the display and the year flashes.



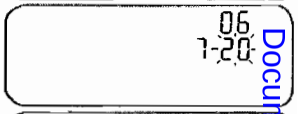
❺ Set the year
Press ▲ or ▼ to change the year. When you have the correct year on the display, wait five seconds to move to the next setting. The month will now start flashing.



❻ Set the month
Press ▲ or ▼ to change the month. When you have the correct month on the display, wait five seconds to move to the next setting. The day will now start flashing.



❼ Set the day
Press ▲ or ▼ to change the day. When you have the correct day on the display, wait five seconds to move to the next screen.



Your time and date settings will be displayed for five seconds. After the five seconds, the settings will be saved and the meter will then turn off. If you want to adjust your settings, press ▲ or ▼ while the time and date are still on the display. You will be returned to the first set-up screen where you can begin with the hour.

Coding your meter

Have these things ready when you test your blood glucose level:

- OneTouch® UltraMini® Meter
- OneTouch® Ultra® Test Strips
- Lancing device
- Sterile lancets with protective disks
- OneTouch® Ultra® Control Solution

NOTE:

- Use only OneTouch® Ultra® Test Strips with your OneTouch® UltraMini® Meter.
- Make sure your meter and test strips are about the same temperature before you test.
- Testing must be done within the operating temperature range (43–111°F). For the most accurate results, try to test as close to room temperature (68–77°F) as you can.

⚠ **CAUTION:** If you cannot test due to a problem with your testing supplies, contact your healthcare professional or LifeScan Customer Service at 1 800 227-8862 (available 24 hours a day, seven days a week). Failure to test could delay treatment decisions and lead to a serious medical condition

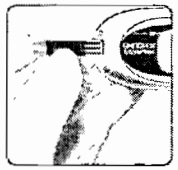
❶ Check the code on the test strip vial before inserting the test strip

Code numbers are used to calibrate your meter with the test strips you are using to obtain accurate test results. You must code the meter before using it for the first time and then every time you change to another vial of test strips.

⚠ **CAUTION:** The test strip vial contains drying agents that are harmful if inhaled or swallowed and may cause skin or eye irritation.

❷ Insert a test strip to turn on the meter

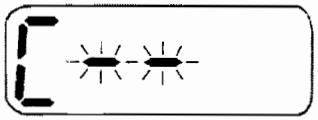
Start with the meter off. If you have turned the meter on to change settings or review past results, turn it off. Remove a test strip from its vial. With clean, dry hands, you may touch the test strip anywhere on its surface. **Do Not** bend, cut or modify the test strips in any way. Use each test strip immediately after removing it from the vial.



Hold the meter as shown and insert the test strip into the test port. Make sure the three contact bars are facing you. Push the test strip in as far as it will go. **Do Not** bend the test strip.

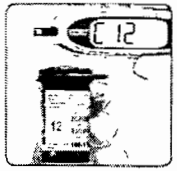
⚠ **CAUTION:** OneTouch® Ultra® Test Strips are for single use only. Never re-use a test strip that had either blood or control solution applied to it.

After the start-up test screen appears, the meter will display the code from your last test. If a constant C and a flashing "---" appear instead of a code number, such as when you are first using the meter, follow the instructions in step 3 to change to a numerical code.



❸ Match the code on the meter with the code on the test strip vial

If the code on the meter does not match the code on the test strip vial, press ▲ or ▼ to match the code number on the test strip vial. The new code number will flash on the display for three seconds, and then stay constant for three seconds. The display will advance to the screen with the flashing blood drop icon.



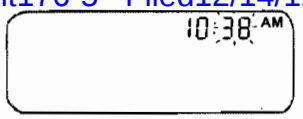
If the codes already match, wait three seconds. The display will advance to the screen with the flashing blood drop icon. The meter is now ready to perform a blood glucose test.

NOTE:

- If the screen with the flashing blood drop icon appears before you are sure the codes match, remove the test strip, wait until the meter turns off, then re-start from step 1 in *Coding your meter*.
- If you press ▲ by mistake so that the control solution test symbol **CtL** appears on the display, press ▲ again to change it back to the screen with the flashing blood drop icon.

⚠ **CAUTION:** Matching the code on the meter and the code on the test strip vial is essential to obtain accurate results. Each time you test, check to make sure the code numbers match.

When the correct hour appears on the display, wait five seconds. Your entry will be saved and you will move to the next setting. The minutes will now start flashing.

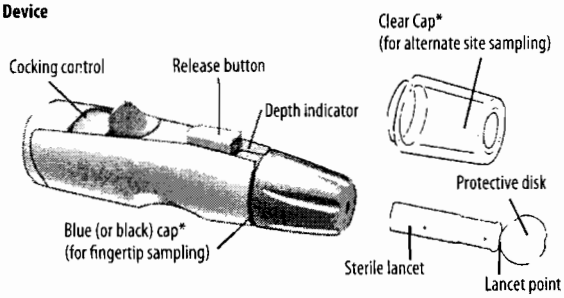


❸ Set the minutes
Press ▲ or ▼ to change the minutes. When you have the correct minutes on the display, wait five seconds to move to the next setting. AM or PM will now start flashing.

❸ Testing your blood glucose

Getting a blood sample

Overview of the Lancing Device

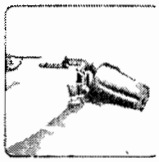


*The blue (or black) cap and clear cap are also used for depth adjustment

NOTE: If you do not have a lancing device, please refer to the instructions that came with your lancing device.

⚠ **CAUTION:** To reduce the chance of infection:
- Make sure to wash the puncture site with soap and water before sampling.
- Never share a lancet or a lancing device with anyone.
- Always use a new, sterile lancet—lancets are for single use only.
- Keep your meter and lancing device clean. See *Caring for your system* in Section 6.

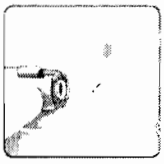
Preparing your sample site
Before you test your blood glucose, wash your hands and forearm (if applicable) thoroughly with warm, soapy water. Rinse and dry.



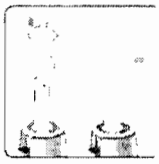
Lancing and sampling from your fingertip

❶ Remove the blue (or black) cap by snapping it off

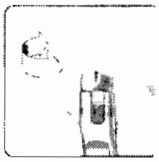
❷ Insert a sterile lancet into the lancing device
Insert the lancet into the holder and push in firmly. Twist the protective disk until it separates from the lancet and save the disk for later use.
Do Not twist the lancet.



❸ Replace the blue (or black) cap by snapping it back on

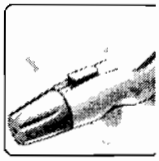


❹ Adjust the depth setting
The lancing device has nine puncture depth settings, numbered 1 through 9. The smaller numbers are for a shallower puncture, and the larger numbers are for a deeper puncture. Shallower punctures work for children and most adults. Deeper punctures work well for people with thick or callused skin. Twist the blue (or black) cap until the correct setting appears.

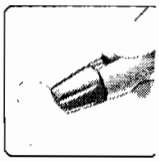


NOTE: A shallower puncture may be less painful. Try a shallower setting first and increase the depth until you find the one deep enough to get a large enough drop of blood (● approximate size).

❺ Cock the lancing device
Slide the cocking control back until it clicks. If it does not click, it may have been cocked when you inserted the lancet.



❻ Puncture your finger
Hold the lancing device firmly against the side of your finger. Press the release button. Remove the lancing device from your finger.



❼ Get a round drop of blood
Gently squeeze and/or massage your fingertip until a round drop of blood **(● approximate size)** forms on your fingertip. If the blood smears or runs, **Do Not** use that sample. Wipe the area and gently squeeze another drop of blood or puncture a new site.

Choosing the right sampling site at the right time

The OneTouch® UltraMini® Meter allows you to sample blood from your fingertip, forearm or palm. Forearm and palm sampling is also referred to as "alternate site testing" (AST). At times, results obtained at the forearm or palm may be different from a fingertip measurement. Talk to your healthcare professional before you begin using your forearm or palm for sampling.

If you are testing:	Use blood sample from your:
Routinely before meals Prior to or more than two hours after: • a meal • a rapid-acting insulin injection or insulin pump bolus • exercise	Fingertip, forearm, or palm
When your blood glucose is changing rapidly, such as: • within two hours after a meal • within two hours after a rapid-acting insulin injection or insulin pump bolus, or • during or within two hours after exercise When you are concerned about the possibility of hypoglycemia (low blood sugar)	Fingertip

⚠ **CAUTION: Do Not** test on your forearm or palm when:

- You think your blood glucose is rapidly falling, such as within two hours of exercise or a rapid-acting insulin injection or insulin pump bolus. Testing with a fingertip sample may identify hypoglycemia or an insulin reaction sooner than testing with a forearm or palm sample.
- It has been less than two hours after a meal, a rapid-acting insulin injection or insulin pump bolus, physical exercise, or you think your glucose level is changing rapidly.
- You are concerned about the possibility of hypoglycemia or an insulin reaction, such as when driving a car. This is especially important if you suffer from hypoglycemia unawareness (lack of symptoms to indicate an insulin reaction).

Remember: Consult with your healthcare professional before using your forearm or palm for testing.

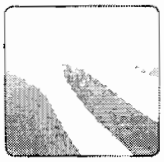
Choose a different puncture site each time you test. Repeated punctures in the same spot may cause soreness and calluses. If bruising occurs at an alternate site or you have difficulty getting a sample, consider sampling from a fingertip instead. You may want to review the choice of sites with your healthcare professional.

Lancing and sampling from an alternate site

Sampling from your palm or forearm allows you to use your fingertips less often. You may find that obtaining a blood sample from an alternate site is less painful than using a fingertip. Getting a blood sample from your forearm or palm is different than getting a sample from your fingertips.

Forearm sampling

Choose a fleshy area of the forearm away from bone, visible veins and hair. Sometimes there is less blood flow to the forearm than to the fingertips. To help you get a large enough drop of blood, you may gently massage or apply warmth to the site to increase blood flow.



Forearm

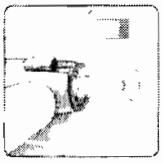
Palm

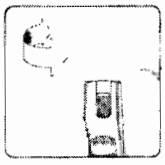
Palm sampling

Choose a fleshy area on the palm below your thumb or little pinky finger. Select a spot with no visible veins and away from deep lines, which may cause your blood sample to smear.

The clear cap is used for forearm and palm sampling only. Replace the blue (or black) cap with the clear cap.

❶ Insert a sterile lancet and snap on the clear cap





❷ Adjust the depth setting

You may have to adjust the lancing device to a deeper setting to get a large enough drop of blood from your forearm or palm. Twist the clear cap toward the larger numbers to increase the depth.

Be sure to cock the lancing device.

❸ Puncture your forearm or palm

Firmly press and hold the lancing device against your forearm or palm for a few seconds. **Wait until the skin surface under the clear cap changes color (as blood collects beneath the skin). This tells you there is enough blood flow for a good sample.** Then press the release button while continuing to apply pressure. Keep holding the lancing device against your skin until a round drop of blood forms under the cap.

Forearm

Palm

Start with the meter off. If you have turned the meter off to change settings or review past results, turn it on.
Remove a test strip from its vial. With clean, dry hands, you may touch the test strip on the front or its surface. **Do Not** bend, cut or modify the test strips in any way. Use each test strip immediately after removing it from the vial.

Hold the meter as shown and insert the test strip into the test port. Make sure the three contact bars are facing you. Push the test strip in as far as it will go. **Do Not** bend the test strip.

When sampling blood from your forearm or palm, make sure the drop of blood is large enough (● **approximate size**) before you release pressure and remove the lancing device.

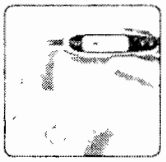
❹ Remove the lancing device
Carefully lift the lancing device away from your skin. **Do Not** smear the blood sample.

NOTE:
- You may need to wait a little longer to get a large enough drop of blood from the forearm or palm. **Do Not** squeeze the site excessively.
- If the sample drop of blood runs or spreads due to contact with hair or with a line in your palm, **Do Not** use that sample. Try puncturing again in a smoother area.
- Remember: You may have to adjust the lancing device to a deeper setting to get a large enough drop of blood (● approximate size).

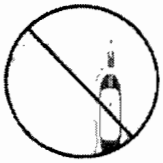
Applying blood and reading results

Once you have a blood sample and your meter shows the screen with the flashing blood drop icon , *you are ready to obtain a blood glucose result. If your meter does not show the screen with the flashing blood drop icon* , *remove the unused test strip and re-start the test process. See Getting a blood sample in Section 3.*

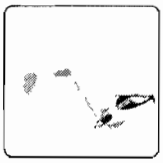
❶ Prepare to apply the sample
Keeping your finger extended and steady, move the meter and test strip toward the blood drop.


Fingertip


Do Not apply blood on the top of the test strip.

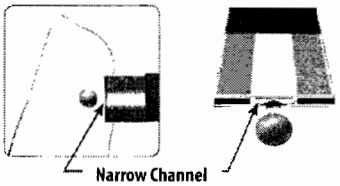

Do Not hold the meter and test strip underneath the blood drop. This may cause blood to run into the test port and damage the meter.

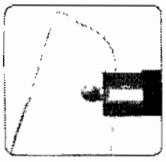
When applying a drop of blood from your forearm or palm, keep your palm or forearm steady and bring the top edge of the test strip to the drop of blood with your other hand.

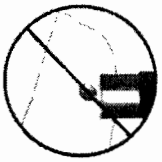

Forearm


Palm

❷ Apply the sample
Line up the test strip with the blood drop so that the narrow channel on the edge of the test strip is almost touching the edge of the blood drop.


Narrow Channel





Gently touch the channel to the edge of the blood drop.

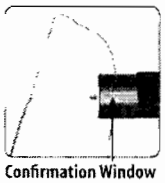
Be careful not to push the test strip against your fingertip or the test strip may not fill completely.

NOTE:
- **Do Not** smear or scrape the drop of blood with the test strip.
- **Do Not** apply more blood to the test strip after you have moved the drop of blood away.
- **Do Not** move the test strip in the meter during a test.

> ⚠ **CAUTION:** You may get an **Er 5** message or an inaccurate result if the blood sample does not fill the confirmation window completely. See *Understanding error and other messages* in Section 7. Discard the test strip and re-start the test process.

❸ Wait for the confirmation window to fill completely
The blood drop will be drawn into the narrow channel and the confirmation window should fill completely.

When the confirmation window is full, this means you have applied enough blood. Now you can move the test strip away from the blood drop and wait for the meter to count down from 5 to 1.


Confirmation Window


Full

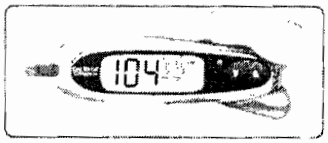

Not Full

• If you press ▲ by mistake so that the control solution test symbol **Ctl** appears on the display, press ▲ again to change it back to the screen with the flashing blood drop icon.

⚠ **CAUTION:** Matching the code on the meter and the code on the test strip vial is essential to obtain accurate results. Each time you test, check to make sure the code numbers match.

❹ Read your result on the meter

Your blood glucose level appears on the display, along with the unit of measure, and the date and time of the test. Blood glucose results are automatically stored in the meter's memory.



(Example)

⚠ **CAUTION:** If you test at the low end of the operating range (43–111°F) and your glucose is high (over 180 mg/dL), the reading on your meter may be lower than your actual glucose. In this situation, repeat the test in a warmer environment with a new test strip as soon as possible.

⚠ **WARNING: If mg/dL does not appear with the test result, call LifeScan Customer Service at 1 800 227-8862 (available 24 hours a day, seven days a week). Use of the wrong unit of measure may cause you to misinterpret your blood glucose level, and may lead to incorrect treatment.**

Error messages

If you get an **Er** message on your screen rather than a result, see *Understanding error and other messages* in Section 7.

Unexpected test results

Refer to these cautions ⚠ whenever your results are lower than, higher than, or otherwise not what you expect.

⚠ **CAUTION: Dehydration and low glucose results**

Severe dehydration resulting from excessive water loss may cause false low results. If you think you are suffering from severe dehydration, contact your healthcare professional immediately.

⚠ **CAUTION: Low glucose results**

If your test result is lower than 70 mg/dL or is shown as LO, it may mean hypoglycemia (low blood glucose). This may require immediate treatment according to your healthcare professional's recommendations. Although this result could be due to a test error, it is safer to treat first, then do another test.

⚠ **CAUTION: High glucose results**

If your test result is higher than 180 mg/dL, it may mean hyperglycemia (high blood glucose). If you are uncertain about this test result, consider re-testing. Your healthcare professional can work with you to determine what actions, if any, you should take if your results are higher than 180 mg/dL.

If your meter displays HI, you may have a very high blood glucose level (severe hyperglycemia) exceeding 600 mg/dL. Re-check your glucose level. If the result is HI again, this may indicate a severe problem with your blood glucose control and it is important you obtain and follow instructions from your healthcare professional without delay.

⚠ **CAUTION: Repeated unexpected glucose results**

If you continue to get unexpected results, check your system with control solution. See Section 5, Control solution testing. If you are experiencing symptoms that are not consistent with your blood glucose results and you have followed all instructions in this User Guide, call your healthcare professional. Never ignore symptoms or make significant changes to your diabetes control program without speaking to your healthcare professional.

⚠ **CAUTION: Unusual red blood cell count**

A hematocrit (percentage of your blood that is red blood cells) that is either very high (above 55%) or very low (below 30%) can cause false results.

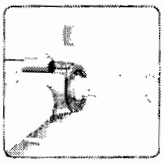
After getting a result

Once you have read your result, you may:

- Review your meter memory by pressing ▼ to enter memory mode, see Section 4, Reviewing past results, *or*
- Turn the meter off by removing the test strip.

Removing the used lancet

Remove the lancing device cap by snapping it off. **Cover the exposed lancet tip before removing the lancet.** Place the lancet protective disk on a hard surface. Push the lancet tip into the disk. Remove the lancet and place it in a container for sharp objects. Replace the cap.



Disposing of the used lancet and test strip

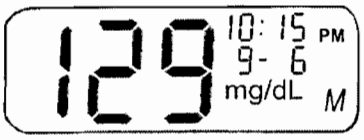
It is important to discard the used lancet carefully after each use to avoid unintended lancet stick injuries. Used test strips and lancets may be considered biohazardous waste in your area. Be sure to follow your local regulations or your healthcare professional's recommendations for proper disposal.

4 Reviewing past results

Reviewing past results

The meter stores a maximum of 500 blood glucose test results. When the meter memory is full, the oldest result is dropped as the newest is added. Results are stored automatically when you test, along with the time, date and unit of measure. You can review the results stored in the meter memory, starting with the most recent.

If your meter is off, press and release ▼ to turn it on. After the start up test screen, your most recent test result will appear on the display. "*M*" also appears to indicate memory mode.



If you have just completed a test, leave the test strip in the meter and press ▼ to enter the memory mode. Your most recent blood glucose test result appears along with "*M*".

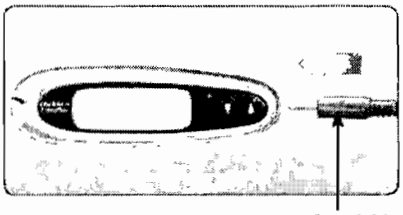
Press ▼ to move to the previous result stored in the meter. Then, press ▲ or ▼ to move forward or backward through all of your results. When you're finished reviewing past results, press and hold ▼ for two seconds until the meter turns off.

NOTE: If no results are currently stored in the meter, "---" will appear on the display.

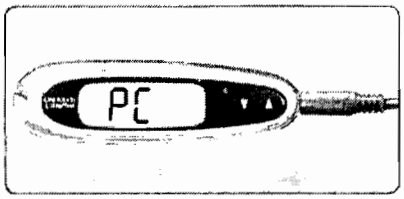
Downloading results to a computer

You can use your meter with OneTouch® Diabetes Management Software (DMS) for storing your records and to help you spot patterns for planning meals, exercise, and medication. OneTouch® DMS puts information downloaded from the meter into charts and graphs. If you are a current OneTouch® DMS user, additional software updates may be required for use with the OneTouch® UltraMini® Meter. Please visit www.OneTouchDiabetesSoftware.com.

❶ Obtain the required software and cable
For order information and to learn more about OneTouch® Diabetes Management Software visit www.OneTouchDiabetesSoftware.com.



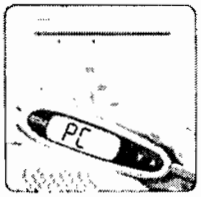
❷ Install the software on a computer
Follow the installation instructions provided with the Software. If using a OneTouch® Interface Cable (USB format), install the software driver.



⚠ WARNING: To avoid a possible shock, Do Not insert a test strip when the meter is connected to a computer with the OneTouch® Interface Cable.

❸ Get ready to transfer readings
Connect the OneTouch® Interface Cable to the COM or USB port on your computer. Make sure the meter is turned off. If you insert the cable while the meter is already on, the meter will not respond to computer commands. Then connect the other end of the OneTouch® Interface Cable to the meter data port.

❹ Transfer data
Follow the instructions provided with OneTouch® DMS to download the results from the meter. Once the command to start the download is sent from the computer to the meter, the meter display will show "PC" indicating that the meter is in communication mode. You will not be able to perform a test when the meter is in communication mode.



5 Control solution testing

When to test with control solution

OneTouch® Ultra® Control Solution contains a known amount of glucose and is used to check that the meter and the test strips are working properly.

Do a control solution test:
- to practice the test process instead of using blood,
- once a week,
- whenever you open a new vial of test strips,
- if you suspect the meter or test strips are not working properly,
- if you have had repeated unexpected blood glucose results as described in *Applying blood and reading results* in Section 3, or
- if you drop or damage the meter.

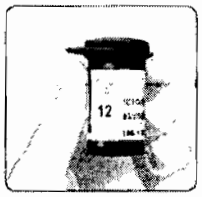
NOTE:
- Use only OneTouch® Ultra® Control Solution with your OneTouch® UltraMini® Meter.
- Control solution tests must be done at room temperature (68–77°F). Make sure your meter, test strips, and control solution are at room temperature before testing.

⚠ **CAUTION: Do Not** swallow control solution; it is not for human consumption. **Do Not** apply control solution to the skin or eyes as it may cause irritation.

How to test with control solution

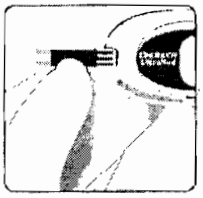
Start with the meter off. If you have turned the meter on to change settings or review past results, turn it off.

❶ Check the code on the test strip vial before inserting the test strip



❷ Insert a test strip to turn on the meter

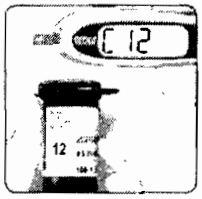
Make sure the three contact bars are facing you. Push the test strip in as far as it will go. **Do Not** bend the test strip.



❸ Match the code on the meter with the code on the test strip vial

If the code on the meter does not match the code on the test strip vial, press ▲ or ▼ to match the code number on the test strip vial. The new code number will flash on the display for three seconds, and then stay constant for three seconds. The display will advance to the screen with the flashing blood drop icon.

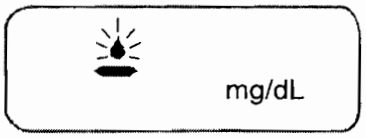
If the codes already match, wait three seconds. The display will advance to the screen with the flashing blood drop icon.



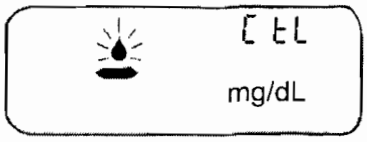
(Example)

❹ Mark the test as a control solution test

IMPORTANT:
- Mark all control solution tests with **CtL**. This will stop them from being stored as blood glucose results.
- Control solution results marked with **CtL** are not stored in the meter's memory.

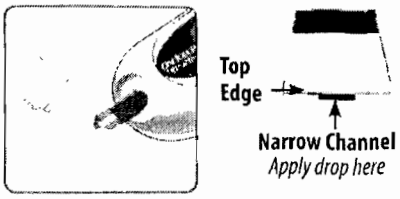


Press ▲ so that the control solution test symbol **CtL** appears in the upper right corner of the display. You must mark the test before you apply control solution. Once you have completed the test, you cannot change the marking. The meter is now ready to perform a control solution test. If you decide not to do a control solution test, press ▲ again to remove **CtL** from the display.



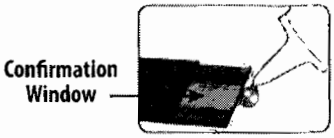
5 Prepare and apply control solution

Shake the control solution vial before each test. Remove the cap and squeeze the vial to discard the first drop. Then wipe the tip with a clean tissue or cloth. Hold the vial upside down and gently squeeze a hanging drop. Touch and hold the hanging drop of control solution to the narrow channel in the top edge of the test strip. Make sure the confirmation window fills completely. Control solution should not be applied to the flat face of the test strip.



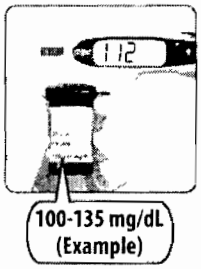
6 Read your result

When the confirmation window is full, the meter will count down from 5 to 1. Your result will then appear on the display, along with **CtL** and the unit of measure.



7 Check if the result is in range

Compare the result displayed on the meter to the control solution range printed **on the test strip vial.** Each vial of test strips may have a different control solution range. If the results you get are not within this range, the meter and test strips may not be working properly. Repeat the control solution test.



Out-of-range results may be due to:

- not following the instructions detailed in steps 1–7,
- expired or contaminated control solution,
- expired or damaged test strip,
- use of a test strip or control solution past its discard date, or
- a problem with the meter.

⚠ **CAUTION:** The control solution range printed on the test strip vial is for OneTouch® Ultra® Control Solution only. It is not a recommended range for your blood glucose level.

⚠ **CAUTION:** If you continue to get control solution results that fall outside the range printed on the test strip vial, **Do Not** use the meter, the test strips, or the control solution. Call LifeScan Customer Service at 1 800 227-8862 (available 24 hours a day, seven days a week).

6 Caring for your system

Replacing the battery

Your OneTouch® UltraMini® Meter uses one 3.0 Volt CR 2032 lithium battery (or equivalent). Replacement batteries can be found in most stores where batteries are sold. Your meter comes with the battery already installed. A battery icon appears in the far right-hand side of the meter display to indicate low battery.

When there is enough power for a minimum of 100 more tests, the battery icon will appear.

After each test and when reviewing past results, the battery icon will now flash to remind you to change the battery as soon as possible.

When the battery icon is flashing by itself on the display, **you cannot perform a test**. You must install a new battery before using your meter.

Replacing the battery

❶ Remove the old battery
Start with the meter off. Open the battery door and pull up on the battery ribbon.

⚠ WARNING: To avoid a possible shock, Do Not change the battery while the meter is connected to a computer with the OneTouch® Interface Cable.

❷ Insert the new battery
With the "+" side facing up toward you, place the battery in the compartment within the fold of the ribbon. Push the battery until it snaps into place. Insert the two battery door tabs into the matching holes, and push down until you hear the door click into place.

If the meter does not power on after you have replaced the battery, check that the battery is correctly installed with the "+" side up. If the meter still does not power on, call LifeScan Customer Service at 1 800 227-8862 (available 24 hours a day, seven days a week).

❸ Check the time and date
After replacing the battery, turn the meter on by pressing and holding the ▼ button for five seconds to access the set-up mode. The start-up test screen will be briefly displayed; then the date and time will appear in the top right corner of the display. Check that the time and date are set correctly. If they are not, use the ▲ and ▼ buttons to re-set the meter before testing. See *Setting the time and date* in Section 2.

NOTE: Removing the meter battery will not affect your stored results. However, you may need to re-set the time and date.

❹ Dispose of batteries according to your local environmental regulations
Lithium ion battery(ies) contains perchlorate material. Special handling may apply, see www.dtsc.ca.gov/hazardouswaste/perchlorate. California Code of Regulations Title 22, Section 67384.4.

Caring for your system

Your OneTouch® UltraMini® Blood Glucose Monitoring System does not need any special maintenance.

Storing your system

Store your meter, test strips and control solution in your carrying case after each use. Store each item in a cool, dry place below 86°F, but **Do Not** refrigerate. Keep all items away from direct sunlight and heat. Tightly close the cap on the test strip vial and/or control solution vial immediately after use to avoid contamination or damage. Store test strips only in their original vial.

Checking for expiration or damage to test strips and control solution

Test strips and control solution have expiration dates printed on their vials. When you first open a test strip or control solution vial, you must record the discard date in the space provided on the label:

- **Test Strips:** date opened plus six **(6)** months
- **Control Solution:** date opened plus three **(3)** months

⚠ **CAUTION: Do Not** use the test strips or control solution after the expiration date printed on the vial or the discard date, whichever comes first, or your results may be inaccurate.

⚠ **CAUTION: Do Not** use your test strips if your vial is damaged or left open to air. This could lead to error messages or tests that read higher than the actual value. Call LifeScan Customer Service at 1 800 227-8862 (available 24 hours a day, seven days a week) immediately if the test strip vial is damaged.

Cleaning your meter

To clean your meter, wipe the outside with a soft cloth dampened with water and mild detergent. **Do Not** use alcohol or another solvent to clean your meter.

Do Not get any liquids, dirt, dust, blood, or control solution inside the meter through the test port or the data port. Never spray cleaning solution on the meter or immerse it in any liquid.

Cleaning your lancing device and clear cap

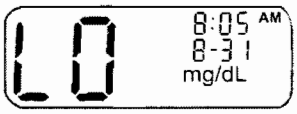
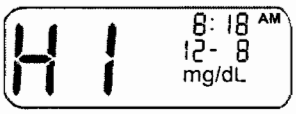
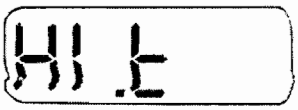
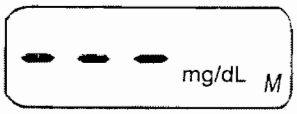
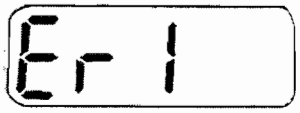
To clean these items, wipe them with a soft cloth dampened with water and mild detergent. **Do Not** immerse the lancing device in any liquid.

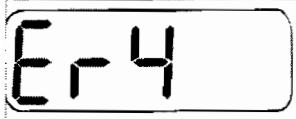
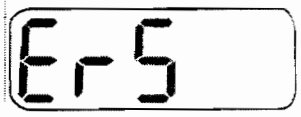
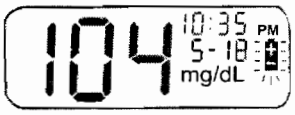
To disinfect these items, prepare a solution of one part household bleach to ten parts water. Wipe the lancing device with a soft cloth dampened with this solution. Immerse the **caps only** in this solution for 30 minutes. After disinfecting, rinse briefly with water and allow both to air dry.

7 Error messages and details about your system

Understanding error and other messages

The OneTouch® UltraMini® Meter displays messages when there are problems with the test strip, with the meter, or when your blood glucose levels are higher than 600 mg/dL or lower than 20 mg/dL. Messages do not appear in all cases when a problem has occurred. Improper use may cause an inaccurate result without producing a warning message.

Message	What it means	What to do
	You may have a very low blood glucose level (severe hypoglycemia), lower than 20 mg/dL.	**This may require immediate treatment according to your healthcare professional's recommendations.** Although this message could be due to a test error, it is safer to treat first and then do another test.
	You may have a very high blood glucose level (severe hyperglycemia), over 600 mg/dL.	Re-check your glucose level. If the result is HI again, obtain and follow instructions from your healthcare professional without delay.
	The meter has detected that the temperature is above the system operating range. **Do Not** perform a test until the meter and test strips reach a temperature within the operating range of 43–111°F.	Repeat the test after the meter and test strips have reached a temperature within the operating range.
	The meter has detected that the temperature is below the system operating range. **Do Not** perform a test until the meter and test strips reach a temperature within the operating range of 43–111°F.	Repeat the test after the meter and test strips have reached a temperature within the operating range.
	No result in memory, such as the first time use of the meter. *or*. Your meter was unable to recall this result.	You can still perform a blood glucose test and get an accurate test result. Contact LifeScan Customer Service at 1 800 227-8862 (available 24 hours a day, seven days a week) to report this occurrence if this is **not** your first time use of the meter.
	Error message indicates there is a problem with the meter.	**Do Not** use the meter. Contact LifeScan Customer Service at 1 800 227-8862 (available 24 hours a day, seven days a week).
	Error message could be caused either by a used test strip or a problem with the meter.	Repeat the test with a new test strip; see Section 3, Testing your blood glucose. If this message continues to appear, contact LifeScan Customer Service at 1 800 227-8862 (available 24 hours a day, seven days a week).
	Error message indicates that the blood or control solution sample was applied before the meter was ready.	Repeat the test with a new test strip. Apply a blood or control solution sample only after the flashing blood drop icon appears on the display. If this message continues to appear, contact LifeScan Customer Service at 1 800 227-8862 (available 24 hours a day, seven days a week)

Message	What it means	What to do
	***One of the following may apply:*** You may have high glucose and have tested in an environment near the low end of the system's operating temperature range (43–111°F). *or,*	If you tested in a cool environment, repeat the test in a warmer environment with a new test strip; see Section 3, Testing your blood glucose. If this error message appears again, contact LifeScan Customer Service at 1 800 227-8862 (available 24 hours a day, seven days a week).
	There may be a problem with the test strip. For example, it may have been damaged or moved during testing. *or,*	If you tested in a normal or warm environment, repeat the test with a new test strip; see Section 3, Testing your blood glucose. If this error message appears again, contact LifeScan Customer Service at 1 800 227-8862 (available 24 hours a day, seven days a week).
	The sample was improperly applied. *or,*	If you applied the sample incorrectly, review blood application (see Section 3, Testing your blood glucose) or control solution testing (see Section 5, Control solution testing) and repeat the test with a new test strip. If the error message appears again, contact LifeScan Customer Service at 1 800 227-8862 (available 24 hours a day, seven days a week).
	There may be a problem with the meter.	If this error message appears again, contact LifeScan Customer Service at 1 800 227-8862 (available 24 hours a day, seven days a week).
	The meter has detected a problem with the test strip. Possible causes are test strip damage or an incompletely filled confirmation window.	Repeat the test with a new test strip. Refer to blood application (see Section 3, Testing your blood glucose) or control solution testing (see Section 5, Control solution testing).
	Meter battery is low but there is enough power to perform a test.	When the flashing battery icon first appears, there is enough power for a minimum of 100 more tests. Test results will still be accurate, but replace the battery as soon as possible.
	The icon flashes on the display by itself when there is not enough battery power to perform a test or view previous results.	Replace the meter battery

Detailed information about your system

Comparing meter and laboratory results

Test results with the OneTouch® UltraMini® Meter are plasma-calibrated. This helps you and your healthcare professional to compare your meter results with laboratory tests. If you have been using another type of meter—one that provides whole blood-calibrated results—you may notice that your test results with the OneTouch® UltraMini® Meter are approximately 12% higher. OneTouch® UltraMini® Meter test results and laboratory test results both are expressed in plasma-equivalent units. However, your meter result may differ from your laboratory result due to normal variation. Meter results can be affected by factors and conditions that do not affect laboratory results in the same way.

Your OneTouch® UltraMini® Meter glucose value is considered accurate when it is within ±20% of the laboratory measurement. There are some specific situations that could cause a difference of more than ±20%:

You have eaten recently. The blood glucose level from a fingertip can be up to 70 mg/dL higher than blood drawn from a vein (venous sample) used for a lab test.[1]
Your hematocrit (percentage of blood that is red blood cells) is high (above 55%) or low (below 30%).
You are suffering from severe dehydration.
You tested at a temperature near the low end of the operating range (43°F) and you get a high glucose result (i.e., greater than 180 mg/dL). In this situation, repeat the test in a warmer environment with a new test strip as soon as possible.

For accuracy and precision data and for important information on limitations, see the insert that comes with your test strips. To maximize your chances of an accurate comparison between meter and laboratory results, follow a few basic guidelines:

Before going to the lab

Perform a control solution test to make sure the meter is working properly.
Do Not eat for at least eight hours before you test your blood.
Take your meter with you to the lab.

While at the lab

- Conduct your meter test within 15 minutes of the lab test.
- Use only fresh, capillary blood obtained from the fingertip.
- Follow all instructions in this User Guide for performing a blood glucose test with your meter.

Sacks, D.B.: "Carbohydrates" Burtis, C.A., and Ashwood, E.R. (ed.), *Tietz Textbook of Clinical Chemistry*. Philadelphia: W.B. Saunders Company (1994), 959.

Technical specifications

Reported result range	20–600 mg/dL
Calibration	Plasma-equivalent
Sample	Fresh capillary whole blood
Test time	5 seconds
Assay method	Glucose oxidase biosensor
Meter power source	One replaceable 3.0 Volt CR 2032 lithium battery (or equivalent)
Unit of measure	mg/dL
Memory	500 blood glucose test results
Automatic shutoff	2 minutes after last action
Size	4.25 x 1.26 x .67 inches
Weight	Approximately 1.4 ounces, with battery
Operating ranges	Temperature: 43–111°F Altitude: up to 10,000 feet Relative humidity: 10–90% Hematocrit: 30–55%
Battery ratings	One 3.0 V d.c., 3 mA (one CR 2032 battery) ⎓ direct current

Symbols

⚠ Cautions and Warnings: Refer to safety-related notes in the User Guide and inserts that came with your meter and testing supplies.

⎓ Direct current Low battery SN Serial Number

Electrical and safety standards

The meter has been tested for immunity to Level 4 electrostatic discharge as specified in IEC 61000-4-2. This meter has been tested for immunity to radio frequency interference over the frequency range 80 MHz to 2.5 GHz at 3 V/m as specified in IEC 61000-4-3. Degree of protection rating: Minimum of IP2X. This meter complies with CISPR 11:2003, Class B (Radiated Only). Emissions of the energy used are low and are *not* likely to cause interference in nearby electronic equipment.

CAN/CSA C22.2 61010-1:04, UL 61010-1:04, IEC 61010-1 and IEC 61010-2-101.

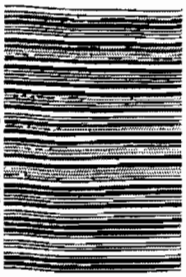
Guarantee

LifeScan guarantees that the OneTouch® UltraMini® Meter will be free of defects in material and workmanship for three years, valid from the date of purchase. The guarantee extends only to the original purchaser and is not transferable.

EXHIBIT P

OneTouch Ultra Blue Test Strips
Tiras reactivas OneTouch Ultra Azules

ONETOUCH Ultra Blue
Test Strips/Tiras reactivas
OneTouch Ultra Blue Test Strips
Tiras reactivas OneTouch Ultra Azules



Health Care Professionals: Please visit www.LifeScan.com or call the OneTouch® Customer Care Line at 1 800 227-8862 (English) 1 800 381-7226 (Español) for additional instructions on using OneTouch® Meters in a clinical setting (e.g., long term care facilities and physician offices).

Profesionales del cuidado de la salud: por favor, visiten www.LifeScan.com o llamen a la Línea de Asistencia al Cliente OneTouch® al 1 800 381-7226 (Español) para obtener instrucciones adicionales sobre cómo usar los medidores OneTouch® en un entorno clínico (por ejemplo, centros de cuidado a largo plazo y consultorios médicos).

As your partner in diabetes care, we offer valuable diabetes-related knowledge, tools and special offers online.
www.OneTouchDiabetes.com
www.OneTouchEnEspanol.com

Should you need additional assistance, we welcome you to contact us 7 days a week, 8 a.m. – 10 p.m. Eastern Time.
1 800 227 8862 (English)
1 800 381 7226 (Español)
For assistance outside of these hours, please contact your healthcare professional.

In vitro diagnostic. For self-testing.

IMPORTANT: Please read this information and your OneTouch® Ultra® Family of Meters and OneTouch® Ping™ Meter Remote User Guide before using OneTouch® Ultra® Blue Test Strips. Do Not use your OneTouch® Ultra® Blue Test Strips if your vial is open or damaged in any way as this could lead to error messages or inaccurate blood glucose values. Contact LifeScan Customer Service at 1 800 227-8862 immediately if the test strip vial is open or damaged, or if these instructional materials or your meter results seem unclear. (Contact us 7 days a week, 8 a.m. – 10 p.m. Eastern Time. For assistance outside of these hours, please contact your healthcare professional.)

Intended Use

OneTouch® Ultra® Blue Test Strips are used with the OneTouch® Ultra® Family of Meters (OneTouch® Ultra®, OneTouch® Ultra®2, OneTouch® UltraSmart®, OneTouch® UltraMini®, and OneTouch® UltraLink®) and the OneTouch® Ping™ Meter Remote for quantitatively measuring glucose in fresh capillary whole blood. The OneTouch® Ultra® Blue Test Strips and associated meters are intended for use by people with diabetes at home and health care professionals in the clinical setting. OneTouch® Ultra® Blue Test Strips and associated meters are for use in fingertip, forearm, and palm testing.

Storage and Handling

- Store the test strip vial in a cool dry place below 86°F (30°C). **Do Not** refrigerate. Keep away from direct sunlight and heat. Exposure to temperatures and/or humidity outside the required storage conditions may result in inaccurate readings.
- Store your test strips in their **original vial only.** To avoid damage or contamination, **Do Not** transfer test strips to any other container.
- **Do Not** open the test strip vial until you are ready to test. **Only open vial when removing test strips.**
- After removing a test strip from the vial, immediately close the vial lid tightly. Use each test strip immediately after **removing it from the vial.**
- **Do Not** use test strips from any vial that is damaged or left open to air.
- Write the discard date (date opened plus 6 months) on the vial label when you first open it.
- **Do Not** use test strips beyond the expiration (printed on vial label) or discard date, whichever comes first.
- Avoid getting dirt, food, or liquids on the test strip. With clean, dry hands, you may touch the test strip anywhere on its surface.
- **Do Not** bend, cut, or alter the test strip in any way.
- Test strips are for single use only. **Never reuse a test strip that had blood or control solution applied to it.**
- Make sure your meter and test strips are about the same temperature before you test.
- Apply only control solution or a blood sample to the test strip.
- After performing a test, **Do Not** return the used test strip to the vial.
- Used test strips may be considered biohazardous waste in your area. Be sure to follow your health care professional's recommendations or your local regulations for proper disposal.

⚠ **WARNING: Keep the test strip vial away from children; test strips are a choking hazard. Do Not swallow test strips. The test strip vial may contain drying agents that are harmful if inhaled or swallowed and may cause skin or eye irritation. Do Not ingest or swallow any items.**

Blood Glucose Test Procedure

For instructions on performing a blood test (including blood sample collection), refer to the User Guide that came with your system.

- Patients undergoing oxygen therapy may yield falsely low results.
- Test results may be falsely low if the patient is severely dehydrated, in shock, or in a hyperosmolar state (with or without ketosis). Critically ill patients should not be tested by blood glucose meters.
- Lipemic samples: Cholesterol levels up to 700 mg/dL (18.1 mmol/L) and triglycerides up to 3000 mg/dL (33.9 mmol/L) do not affect the results. Grossly lipemic patient samples have not been tested and are not recommended for testing with the OneTouch® Ultra® Family of Meters.

Test Principle

The OneTouch® Ultra® Family of Meters and OneTouch® Ping™ Meter Remote are plasma-calibrated to allow easy comparison of results with laboratory methods. Glucose in the blood sample mixes with special chemicals on the test strip and a small electrical current is produced. This current is measured by the OneTouch® Ultra® Family of Meters and OneTouch® Ping™ Meter Remote and displayed as your blood glucose result. The strength of this current changes with the amount of glucose in the blood sample.

Reagent Composition

Each test strip contains: Glucose oxidase *(Aspergillus niger)* ≥ 0.08 IU; ferricyanide ≥ 22 µg; other ingredients (buffer, etc.). The test strip vial contains a drying agent.

Performance Characteristics

The performance of OneTouch® Ultra® Blue Test Strips has been evaluated both in laboratory and in clinical tests.[3]

Measurement Range: The measurement range of the OneTouch® Ultra® Family of Meters is 20 to 600 mg/dL (1.1–33.3 mmol/L).

System Accuracy: Diabetes experts have suggested that glucose meters should agree within 15 mg/dL (0.83 mmol/L) of a laboratory method when the glucose concentration is lower than 75 mg/dL (4.2 mmol/L), and within 20% of a laboratory method when the glucose concentration is 75 mg/dL (4.2 mmol/L) or higher. Samples from 100 diabetic patients at 1 clinical center were tested using both the OneTouch® Ultra®2 System and the YSI Model 2300 Glucose Analyzer (laboratory test).[3]

System Accuracy Results for Glucose Concentrations <75 mg/dL (4.2 mmol/L)

	Within ± 5 mg/dl (0.28 mmol/L)	Within ± 10 mg/dl (0.56 mmol/L)	Within ± 15 mg/dl (0.83 mmol/L)
Percent (and number) of meter results that match the laboratory test	48.8% (41/84)	84.5% (71/84)	100.0% (84/84)

System Accuracy Results for Glucose Concentrations ≥75 mg/dL (4.2 mmol/L)

	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
Percent (and number) of meter results that match the laboratory test	38.0% (196/516)	68.0% (351/516)	88.2% (455/516)	95.7% (494/516)

System Accuracy Results across the entire Glucose Range

	Within ± 15 mg/dL (0.83 mmol/L) or ± 20%
Percent (and number) of meter results that match the laboratory test	96.3% (578/600)

Therefore, 96.3% of the total results obtained with the OneTouch® Ultra®2 System achieved the goal suggested by the diabetes experts.

IMPORTANT: Some OneTouch® Ultra® Meters and the OneTouch® Ping™ Meter Remote require coding. For meters that require coding, matching the code on the meter to the code on the test strip vial is essential to obtain accurate results. Refer to the User Guide that came with your system to determine if your meter requires coding and get detailed instructions on coding.

Test Results

Low Glucose Values

If your test result is below 20 mg/dL (1.1 mmol/L), a warning message will appear indicating a low glucose level. This may indicate severe hypoglycemia (low blood glucose). **Treat this condition immediately, according to your health care professional's recommendations.** Although this message could be due to a test error, it is safer to treat first, and then do another test.

High Glucose Values

If your test result is above 600 mg/dL (33.3 mmol/L), a warning message will appear indicating a high glucose level. This may indicate severe hyperglycemia (high blood glucose). You should retest your glucose level. If the message appears again, call your health care professional immediately.

If You Get Unexpected Results

If your blood glucose result is below 70 mg/dL (3.9 mmol/L), indicating low blood glucose, or above 180 mg/dL (10.0 mmol/L), indicating high blood glucose, you should contact and follow your health care professional's treatment advice.[1] If you continue to get unexpected results, check your system with control solution. If you are experiencing symptoms that are not consistent with your blood glucose test results AND you have followed all instructions described in your User Guide, call your health care professional. Never ignore symptoms or make significant changes to your diabetes control program without speaking to your health care professional.

Range of Expected Values

Blood glucose management requires the help of a health care professional. Together you can set your own range of expected blood glucose values, arrange your testing times, and discuss the meaning of your blood glucose results.

Expected blood glucose levels for people without diabetes:[2]

Time	Range, mg/dL	Range, mmol/L
Fasting	Less than 100	Less than 5.6
2 hours after meals	Less than 140	Less than 7.8

Checking the System

Use OneTouch® Ultra® Control Solutions

A control solution test is performed to check that the meter and test strips are working together properly and that you are performing the test correctly. For instructions on how and when to check the system by performing a control solution test, refer to the User Guide that came with your system.

Limitations of Procedure

OneTouch® Ultra® Blue Test Strips give accurate results when the following limitations are observed:

- **Do Not** use for the diagnosis of diabetes or for testing of newborns.
- Test strips are for single use only. **Do Not** reuse.
- The test strips are specific to D-glucose and do not react to other sugars, which may be present in blood.
- Use only fresh capillary whole blood. **Do Not** use serum or plasma.
- Hematocrit is the percentage of red blood cells in the blood. Extremes in hematocrit may affect test results.[3] Hematocrit levels below 30% may cause falsely high readings and hematocrit levels over 55% may cause falsely low readings. If you do not know your hematocrit level, consult your health care professional.
- OneTouch® Ultra® Blue Test Strips may be used at altitudes up to 10,000 feet (3048 meters) without an effect on test results. Accurate results were demonstrated in clinical studies performed at altitudes up to 5,280 feet (1609 meters) and in studies simulating altitudes up to 10,000 feet (3048 meters).

Health care professionals: please note these additional limitations of procedure:

- Fresh capillary blood may be collected into heparin-containing test tubes if the blood is used within 10 minutes. **Do Not** use other anticoagulants or preservatives.
- Interferences: Acetaminophen, salicylates, uric acid, ascorbic acid (vitamin C), and other reducing substances (when occurring in normal blood or normal therapeutic concentrations) do not significantly affect results. However, abnormally high concentrations in blood may cause inaccurately high results.

Regression Statistics: Samples were tested in duplicate on each of 3 test strip lots. Results indicate that the OneTouch® Ultra®2 System compares well with a laboratory method.

Number of Subjects	Number of Tests	Slope	Intercept mg/dL (mmol/L)	95% CI Slope	95% CI Intercept mg/dL (mmol/L)	Std. Error ($S_{y.x}$) mg/dL (mmol/L)	R^2
100	600	0.972	2.657 (0.012)	0.958 to 0.985	-5.415 to 0.102 (-0.168 to 0.145)	17.743 (1.000)	0.973

Precision:

Within Run Precision (100 venous blood tests per glucose level)

Target Glucose mg/dL (mmol/L)	Mean Glucose mg/dL (mmol/L)	Standard deviation mg/dL (mmol/L)	Coefficient of variation (%)
40 (2.2)	41.0 (2.28)	1.02 (0.057)	2.50
100 (5.6)	97.4 (5.40)	1.74 (0.096)	1.78
130 (7.2)	120.7 (6.70)	2.10 (0.116)	1.74
200 (11.1)	200.9 (11.15)	2.87 (0.160)	1.43
300 (16.7)	305.6 (16.96)	3.55 (0.197)	1.16

Total Precision (200 control solution tests per glucose level)

Glucose Levels	Mean Glucose mg/dL (mmol/L)	Standard deviation mg/dL (mmol/L)	Coefficient of variation (%)
LOW	46.6 (2.59)	1.01 (0.056)	2.18
MID	115.1 (6.39)	2.19 (0.121)	1.90
HIGH	350.8 (19.47)	5.48 (0.304)	1.56

Results show that the greatest variability observed between test strips when tested with blood is 2.5% or less.

Data generated using OneTouch® Ultra®2 Meter. OneTouch® Ultra®2 is representative of the OneTouch® Ultra® Family of Meters (OneTouch® Ultra®, OneTouch® Ultra®2, OneTouch® UltraMini®, OneTouch® UltraSmart®, and OneTouch® UltraLink®) and the OneTouch® Ping™ Meter Remote

IMPORTANT: For complete operating instructions and other important technical information, refer to the User Guide that came with your system. IF YOU HAVE QUESTIONS ABOUT THE USE OF ANY LIFESCAN PRODUCT, PLEASE CONTACT LIFESCAN CUSTOMER SERVICE AT 1 800 227-8862. (Contact us 7 days a week, 8 a.m. – 10 p.m. Eastern Time. For assistance outside of these hours, please contact your healthcare professional.)

References

1. Beaser, R.S. and Hill, Joan: The Joslin Guide to Diabetes. New York: Simon and Schuster (1995), p. 158.
2. American Diabetes Association, Position Statement, Diagnosis and Classification of Diabetes Mellitus, Diabetes Care 31:S55-S60, 2008.
3. Data on file.

OUR COMMITMENT TO YOU:
As your partner in diabetes care, we offer valuable diabetes-related knowledge, tools and special offers online.
www.OneTouchDiabetes.com

Should you need additional assistance, we welcome you to contact us 7 days a week, 8 a.m. – 10 p.m. Eastern Time. For assistance outside of these hours, please contact your healthcare professional.
1 800 227-8862 (English)

Description of Symbols

For a complete description of all symbols used, refer to the User Guide that came with your system.

Somos su asociado en atención para la diabetes, y le ofrecemos conocimientos valiosos, herramientas y ofertas especiales en línea relacionados con la diabetes.
www.OneTouchEnEspanol.com

Nuevo horario de Servicio al Cliente

Lo invitamos a comunicarse con nosotros los 7 días de la semana, de 8 a.m. a 10 p.m., hora del Este.
1 800 381-7226 (Español)
Para obtener asistencia fuera de este horario, comuníquese con su profesional de la salud.

Diagnóstico *In-vitro*. Para hacer sus propias pruebas.

IMPORTANTE: Antes de utilizar las tiras reactivas OneTouch® Ultra® Azules, lea esta información y la Guía del usuario correspondiente a la Familia de medidores OneTouch® Ultra® y al medidor-control remoto OneTouch® Ping™. No utilice las tiras reactivas de la marca OneTouch® Ultra® Azules si el frasco está abierto o presenta algún tipo de daño, ya que podría obtener mensajes de error o valores inexactos de la glucosa en la sangre. Llame inmediatamente al Servicio al Cliente de LifeScan al 1-800-381-7226 si el frasco de tiras reactivas está abierto o dañado, o si las instrucciones o los resultados del medidor le resultan confusos. (Comuníquese con nosotros los 7 días de la semana, de 8 a.m. a 10 p.m., hora del Este. Para obtener asistencia fuera de este horario, comuníquese con su profesional de la salud.)

Uso recomendado

Las tiras reactivas OneTouch® Ultra® Azules se utilizan con la Familia de medidores OneTouch® Ultra® (OneTouch® Ultra®, OneTouch® Ultra® 2, OneTouch® UltraSmart®, OneTouch® UltraMini®, y OneTouch® UltraLink®) y con el medidor-control remoto OneTouch® Ping™ para la medición cuantitativa de la glucosa en sangre capilar completa recién extraída. Las tiras reactivas OneTouch® Ultra® Azules y los medidores respectivos están diseñados para el uso doméstico por parte de personas que padecen de diabetes y por parte de los profesionales de la salud en las clínicas. Las tiras reactivas OneTouch® Ultra® Azules y los medidores respectivos están diseñados para realizar pruebas en la punta del dedo, en la palma de la mano y en el antebrazo.

Almacenamiento y manipulación

- Guarde el frasco de tiras reactivas en un lugar fresco y seco a una temperatura inferior a 86° F (30° C). **No** refrigere. Mantenga las tiras reactivas alejadas del calor y de la luz directa del sol. La exposición a temperaturas y/o humedad que no cumpla con las condiciones de almacenamiento requeridas puede ocasionar lecturas inexactas.
- Guarde las tiras reactivas en el **frasco original únicamente.** Para evitar que se estropeen o se contaminen, **no** las transfiera a ningún otro recipiente.
- **No** abra el frasco de tiras reactivas sino hasta que se encuentre preparado para realizar la prueba. **Abra el frasco únicamente para sacar las tiras reactivas.**
- Después de sacar una tira reactiva del frasco, vuelva a colocar de inmediato la tapa del frasco y ciérrelo herméticamente. Utilice la tira reactiva inmediatamente **después de haberla sacado del frasco**.
- **No** utilice las tiras reactivas de ningún frasco que esté dañado o que se haya dejado abierto.
- Cuando abra el frasco por primera vez, anote la fecha de descarte (fecha en que se abrió más 6 meses) en la etiqueta del frasco.
- **No** use las tiras reactivas después de la fecha de vencimiento (impresa en la etiqueta del frasco) o de descarte, lo que suceda primero.
- Evite que entren polvo, alimentos o líquidos en la tira reactiva. Con las manos limpias y secas puede tocar cualquier parte de la superficie de la tira reactiva.
- **No** doble, corte ni altere de ninguna manera las tiras reactivas.
- Las tiras reactivas deben utilizarse solamente una vez. **Nunca vuelva a utilizar una tira reactiva en la que se haya aplicado previamente sangre o solución de control.**
- Antes de realizar la prueba, asegúrese de que su medidor y las tiras reactivas estén aproximadamente a la misma temperatura.
- Aplique únicamente solución de control o una muestra de sangre en la tira reactiva.
- Después de realizar una prueba, **no** vuelva a colocar la tira reactiva que utilizó en el frasco.
- Es posible que las tiras reactivas usadas se consideren en su área como un desecho de riesgo biológico. Asegúrese de seguir las indicaciones de su profesional de la salud o los reglamentos de su localidad para la eliminación adecuada.

⚠ ADVERTENCIA: El frasco de tiras reactivas debe mantenerse fuera del alcance de los niños, ya que las tiras presentan riesgo de asfixia. Las tiras reactivas no deben ingerirse. El frasco de tiras reactivas puede contener agentes desecantes que podrían ser nocivos si se inhalan o se ingieren, así como producir irritación de la piel o de los ojos. No ingiera ni trague ningún componente.

Procedimiento para la prueba de glucosa en la sangre

Para obtener instrucciones sobre cómo realizar una prueba de sangre (incluida la

- Los pacientes que reciben terapia con oxígeno pueden generar falsos resultados bajos.
- Si el paciente se encuentra seriamente deshidratado, en choque o en estado hiperosmolar (con o sin cetosis), se pueden producir falsos resultados bajos. A los pacientes que estén gravemente enfermos no se les deben realizar pruebas con medidores de glucosa en la sangre.
- Muestras lipémicas: los niveles de colesterol de hasta 700 mg/dL (18.1 mmol/L) y de triglicéridos de hasta 3,000 mg/dL (33.9 mmol/L) no afectan los resultados. No se han analizado muestras de pacientes extremadamente lipémicas y no se recomiendan para pruebas con la Familia de medidores OneTouch® Ultra®.

Principio de la prueba

La Familia de medidores OneTouch® Ultra® y el medidor-control remoto OneTouch® Ping™ están calibrados con plasma, a fin de permitir una fácil comparación de los resultados con los métodos de laboratorio. La glucosa de la muestra de sangre se mezcla con químicos especiales contenidos en la tira reactiva y se produce una pequeña corriente eléctrica. La Familia de medidores OneTouch® Ultra® y el medidor-control remoto OneTouch® Ping™ miden esta corriente, la cual se muestra como su resultado de glucosa en la sangre. La potencia de esta corriente cambia con la cantidad de glucosa contenida en la muestra de sangre.

Composición del reactivo

Cada tira reactiva contiene: glucosa oxidasa (Aspergillus niger) ≥0.08 IU; ferricianida ≥22 µg; otros ingredientes (solución neutralizadora, etc.).
El frasco de tiras reactivas contiene un agente desecante.

Características de rendimiento

El rendimiento de las tiras reactivas OneTouch® Ultra® Azules se ha evaluado tanto en laboratorio como en pruebas clínicas.[3]

Rango de medición: El rango de medición de la Familia de medidores OneTouch® Ultra® es de 20 a 600 mg/dL (1.1–33.3 mmol/L).

Exactitud del sistema: Según los especialistas en diabetes, los medidores de glucosa deben coincidir con los métodos de laboratorio dentro de un margen de 15 mg/dL (0.83 mmol/L) cuando la concentración de glucosa es inferior a 75 mg/dL (4.2 mmol/L), y dentro de un margen del 20% de los métodos de laboratorio cuando la concentración de glucosa es de 75 mg/dL (4.2 mmol/L) o superior. Se analizaron muestras de 100 pacientes diabéticos en un centro clínico utilizando tanto el sistema OneTouch® Ultra®2 como el analizador de glucosa YSI modelo 2300 (prueba de laboratorio).[3]

Resultados de exactitud del sistema con concentraciones de glucosa <75 mg/dL (4.2 mmol/L)

	Dentro del rango ± 5 mg/dl (0.28 mmol/L)	Dentro del rango ± 10 mg/dl (0.56 mmol/L)	Dentro del rango ± 15 mg/dl (0.83 mmol/L)
Porcentaje (y cantidad) de resultados del medidor que coinciden con la prueba de laboratorio	48.8% (41/84)	84.5% (71/84)	100.0% (84/84)

Resultados de exactitud del sistema con concentraciones de glucosa ≥75 mg/dL (4.2 mmol/L)

	Dentro del rango ± 5%	Dentro del rango ± 10%	Dentro del rango ± 15%	Dentro del rango ± 20%
Porcentaje (y cantidad) de resultados del medidor que coinciden con la prueba de laboratorio	38.0% (196/516)	68.0% (351/516)	88.2% (455/516)	95.7% (494/516)

Resultados de exactitud del sistema a lo largo de todo el intervalo de glucosa

	Dentro del rango ± 15 mg/dL (0.83 mmol/L) o ± 20%
Porcentaje (y cantidad) de resultados del medidor que coinciden con la prueba de laboratorio	96.3% (578/600)

Por lo tanto, el 96.3% de los resultados totales obtenidos con el sistema OneTouch® Ultra®2 alcanzó el objetivo sugerido por los especialistas en diabetes.

Estadísticas de regresión: Se realizaron pruebas por duplicado de las muestras en tres lotes diferentes de tiras reactivas. Los resultados indican que el sistema OneTouch® Ultra® 2 equivale a un método de laboratorio.

Cantidad de sujetos	Cantidad de pruebas	Pendiente	Intersección mg/dL (mmol/L)	Pendiente CI del 95%	Intersección CI del 95% mg/dL (mmol/L)	Error estándar ($S_{y.x}$) mg/dL (mmol/L)	R^2
100	600	0.972	2.657 (0.012)	0.958 a 0.985	-5.415 a 0.102 (0.168 a 0.145)	17.743 (1.000)	0.973

IMPORTANTE: Algunos medidores OneTouch® Ultra® y el medidor-control remoto OneTouch® Ping™ deben ser codificados. Para obtener resultados exactos en este tipo de medidores, es fundamental que el código del medidor coincida con el código del frasco de tiras reactivas. Consulte la Guía del usuario que viene con su sistema para determinar si su medidor se debe codificar y para obtener instrucciones detalladas sobre cómo realizar la codificación.

Resultados de las pruebas

Valores de glucosa bajos

Si el resultado de su prueba es inferior a 20 mg/dL (1.1 mmol/L), aparecerá un mensaje de advertencia que indica un nivel de glucosa bajo. Esto podría indicar una hipoglucemia grave (baja concentración de glucosa en la sangre). **Deberá tratar esta situación inmediatamente, según las indicaciones de su profesional de la salud.** Si bien este mensaje podría deberse a un error de la prueba, es más seguro tratarse primero y luego realizar otra prueba.

Valores de glucosa elevados

Si el resultado de su prueba es superior a 600 mg/dL (33.3 mmol/L), aparecerá un mensaje de advertencia que indica un nivel de glucosa alto. Esto podría indicar una hiperglucemia grave (alta concentración de glucosa en la sangre). Debe repetir la prueba de su nivel de glucosa. Si vuelve a aparecer el mensaje, llame de inmediato a su profesional de la salud.

Si obtiene resultados inesperados

Si su resultado de glucosa en la sangre es inferior a 70 mg/dL (3.9 mmol/L), lo que indica un nivel bajo de glucosa en la sangre, o si por el contrario, es superior a 180 mg/dL (10.0 mmol/L), lo que indica un nivel alto de glucosa en la sangre, debe comunicarse con su profesional de la salud y seguir su recomendación de tratamiento.[1] Si continúa obteniendo resultados inesperados, pruebe su sistema con solución de control. Si presenta síntomas que no corresponden con los resultados de su prueba de glucosa en la sangre y siguió todas las instrucciones descritas en su Guía del usuario, comuníquese con su profesional de la salud. Nunca ignore síntomas ni realice cambios significativos en su programa de control de la diabetes sin consultar a su profesional de la salud.

Rango de valores esperados

El control de glucosa en la sangre requiere de la ayuda de un profesional de la salud. Juntos pueden establecer su propio rango de valores esperados de glucosa en la sangre, establecer sus horas de prueba y discutir el significado de sus resultados de glucosa en la sangre.

Niveles esperados de glucosa en la sangre en personas que no padecen diabetes:[2]

Hora	Rango en mg/dL	Rango en mmol/L
En ayuno	Menos de 100	Menos de 5.6
2 horas después de comer	Menos de 140	Menos de 7.8

Revisión del sistema

Utilice soluciones de control OneTouch® Ultra®

La prueba con solución de control se utiliza para comprobar que el medidor y las tiras reactivas estén funcionando adecuadamente en conjunto, así como para verificar que se esté realizando la prueba correctamente. Para obtener instrucciones sobre cómo y cuándo revisar el sistema mediante una prueba con solución de control, consulte la Guía del usuario que viene con su sistema.

Limitaciones del procedimiento

Las tiras reactivas OneTouch® Ultra® Azules proporcionan resultados precisos cuando se observan las siguientes limitaciones:

- **No** las use para el diagnóstico de la diabetes ni para realizar muestras de sangre a neonatos.
- Las tiras reactivas deben utilizarse sólo una vez. **No** las vuelva a utilizar.
- Las tiras reactivas son específicas para glucosa D y no reaccionan ante otros azúcares que puedan estar presentes en la sangre.
- Utilice únicamente sangre capilar completa recién extraída. **No** utilice suero ni plasma.
- El hematocrito es el porcentaje de glóbulos rojos en la sangre. Los extremos en el valor de hematocrito pueden afectar los resultados de la prueba.[3] Los niveles de hematocrito inferiores a 30% pueden producir falsas lecturas altas y los niveles de hematocrito superiores a 55% pueden ocasionar falsas lecturas bajas. Si no conoce su nivel de hematocrito, consulte con su profesional de la salud.
- Las tiras reactivas OneTouch® Ultra® Azules se pueden utilizar en altitudes de hasta 10,000 pies (3,048 metros) sin causar ningún efecto en los resultados de la prueba. Se comprobó la precisión de los resultados en estudios clínicos efectuados en alturas de hasta 5,280 pies (1,609 metros) y en estudios que simulaban altitudes de hasta 10,000 pies (3,048 metros).

Los profesionales de la salud deberán tener en cuenta las siguientes limitaciones adicionales del procedimiento:

- Se puede recolectar sangre capilar recién extraída en tubos de prueba que contengan heparina si la sangre se utiliza dentro de los 10 minutos siguientes. **No** utilice otros anticoagulantes ni preservantes.
- Interferencias: el acetaminofén, los salicilatos, el ácido úrico y el ácido ascórbico (vitamina C) y otras sustancias reductoras (cuando se producen en sangre normal o en concentraciones terapéuticas normales) no afectan los resultados de manera significativa. No obstante, las concentraciones anormalmente altas en la sangre pueden causar resultados altos inexactos.

Precisión total (100 pruebas con sangre venosa por nivel de glucosa)

Nivel de glucosa objetivo mg/dL (mmol/L)	Nivel de glucosa medio mg/dL (mmol/L)	Desviación estándar mg/dL (mmol/L)	Coeficiente de variación (%)
40 (2.2)	41.0 (2.28)	1.02 (0.057)	2.50
100 (5.6)	97.4 (5.40)	1.74 (0.096)	1.78
130 (7.2)	120.7 (6.70)	2.10 (0.116)	1.74
200 (11.1)	200.9 (11.15)	2.87 (0.160)	1.43
300 (16.7)	305.6 (16.96)	3.55 (0.197)	1.16

Precisión total (200 pruebas con solución de control por nivel de glucosa)

Niveles de glucosa	Nivel de glucosa medio mg/dL (mmol/L)	Desviación estándar mg/dL (mmol/L)	Coeficiente de variación (%)
BAJOS	46.6 (2.59)	1.01 (0.056)	2.18
MEDIANOS	115.1 (6.39)	2.19 (0.121)	1.90
ALTOS	350.8 (19.47)	5.48 (0.304)	1.56

Los resultados indican que, cuando se realizan pruebas de sangre, la mayor variabilidad observada en las tiras reactivas es de 2.5% o menos.

Datos generados utilizando el medidor OneTouch® Ultra®2. El medidor OneTouch® Ultra® 2 es representativo de la Familia de medidores OneTouch® Ultra® (OneTouch® Ultra®, OneTouch® Ultra® 2, OneTouch® UltraMini®, OneTouch® UltraSmart® y OneTouch® UltraLink®) y el medidor-control remoto OneTouch® Ping™.

IMPORTANTE: Para obtener instrucciones completas sobre el funcionamiento y otra información técnica de importancia, consulte la Guía del usuario que viene con su sistema. SI TIENE PREGUNTAS ACERCA DEL USO DE CUALQUIERA DE LOS PRODUCTOS DE LIFESCAN, COMUNÍQUESE CON EL SERVICIO AL CLIENTE DE LIFESCAN AL 1 800 381-7226. (Comuníquese con nosotros los 7 días de la semana, de 8 a.m. a 10 p.m., hora del Este. Para obtener asistencia fuera de este horario, comuníquese con su profesional de la salud.)

Referencias

1. Beaser, R.S. y Hill, Joan: The Joslin Guide to Diabetes. Nueva York: Simon & Schuster (1995), p. 158.
2. American Diabetes Association, Position Statement, Diagnosis and Classification of Diabetes Mellitus, Diabetes Care 31:S55-S60, 2008.
3. Datos en archivo.

NUESTRO COMPROMISO CON USTED:
Somos su asociado en atención para la diabetes, y le ofrecemos conocimientos valiosos, herramientas y ofertas especiales en línea relacionados con la diabetes.
www.OneTouchEnEspanol.com

En caso de necesitar asistencia adicional, lo invitamos a comunicarse con nosotros los 7 días de la semana, de 8 a.m. a 10 p.m., hora del Este. Para obtener asistencia fuera de este horario, comuníquese con su profesional de la salud.
1 800 381-7226 (español)

Descripción de los símbolos
Para obtener una descripción completa de todos los símbolos utilizados, consulte la Guía del usuario que viene con su sistema.

LIFESCAN
a Johnson & Johnson company

Distributed by:/Distribuido por:
LifeScan, Inc.
Milpitas, CA 95035

For:/Para:
LifeScan Europe, Division of
Cilag GmbH International
6300 Zug
Switzerland

Rev. Date/Fecha de rev.: 12/2010
AW 06626602C

EXHIBIT Q

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 30, 2012

Shasta Technologies, LLC
c/o Mr. Mark DuVal
1820 Medical Arts Building
825 Nicollet Mall
Minneapolis, MN 55402

Re. k103542
Trade/Device Name: Gen Strip Test Strips
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW, CGA
Dated: November 7, 2012
Received: November 8, 2012

Dear Mr. DuVal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k103542

Device Name: GenStrip™ Test Strip

Indications for Use:

GenStrip™ Test Strips with calibration codes 4, 10, and 13 are for use with OneTouch® Ultra®, Ultra®2 and UltraMini® Meters purchased before July 2010. They are used to quantitatively measure glucose in fresh capillary whole blood samples taken from the finger, forearm or palm. Testing is done outside the body (in vitro diagnostic use). They are indicated for use by people with diabetes in their home as an aid to monitor the effectiveness of diabetes control. The system is not intended for the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates.

Prescription Use _____ (21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use _xx_ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

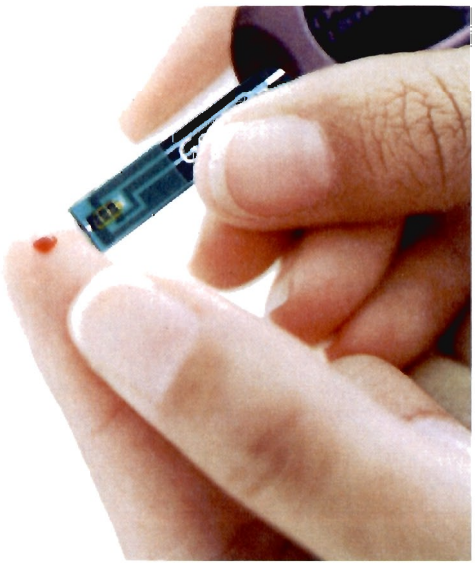
Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k103542

EXHIBIT R

Decision Diagnostics Corp.



Introducing Genstrip

Blood Glucose Test Strip

For use with Lifescan One Touch® Ultra®, Ultra 2®, Ultra Smart® and Ultra Mini® meters

Frequent and accurate testing of blood glucose is essential to the treatment of diabetes. Unfortunately, high costs of testing supplies puts regular monitoring out of reach for many diabetics.

Shasta's GenStrip® Blood Glucose Test Strips make blood glucose testing fast, easy, convenient, and more affordable for anyone living with diabetes. This new diagnostic product will be comparable to the existing consumable provided by the platform manufacturer, but priced significantly (50%) lower.

EXHIBIT S

Products

Glucose Monitering Systems

Wound Care and Ostomy Products

GenStrip

Blood Glucose Test Strip

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Features for Diabetics

- Requires just a speck of blood
- Results in as little as 5 seconds
- Easy to see when there is enough blood
- Increased accuracy

- Available in quantities of 50 test strips
- Priced significantly lower than the existing consumable provided by the platform manufacturer
- Available at nationwide chains
- Widely affordable
- Covered by Medicare Parts B & D

Products

Glucose Monitering Systems

Wound Care and Ostomy Products

GenStrip

Benefits

You have enough to worry about, the cost of diabetic testing supplies shouldn't be one of them.

- The convenience of low cost helps in managing diabetes
- Small blood sample required means less pain
- Frequent, accurate results leads to better results and better informed lifestyle decisions
- Affordability of test strips means you can worry less about money and concentrate about what's more important -- your health

Proof

An estimated 20.8 million people in the United States are living with diabetes.

- A rising population of people diagnosed with diabetes – an estimated 6 million are unaware they have the disease!
- Individuals with diabetes need to test frequently to maintain a healthy lifestyle
- Increasing demand for low-cost alternatives for diabetic testing supplies

EXHIBIT T

Shasta Technologies

Navigate

Diabetes
- GenStrip
- Meters
- Accessories
- Diabetes Information

Shasta Technologies
- About Us
- Contact Us

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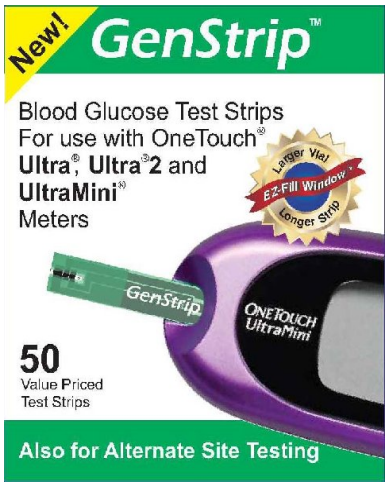
- Members Save!
- Shipping & Privacy
- Purchase Orders

Shasta Genstrip®

Blood Glucose Test Strip

For use with Lifescan One Touch® Ultra®, Ultra 2®, Ultra Smart® and Ultra Mini® meters



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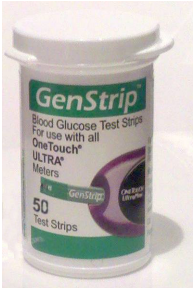

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-

Contact | Register | Site Map

EXHIBIT U

William N. Walling, Jr.
Chartered Financial Analyst

May 24, 2011

To: The Board of Directors
instaCare Corp. (ISCR)

SUBJECT: UPDATED GENSTRIP SALES GUIDANCE: 2011-2012

INTRODUCTION

You recently engaged me to work with you and to write Financial Guidance Memos for shareholders and other interested parties. The dates of these memos have been: January 10, 2011: Initial Genstrip Guidance; January 24, 2011: 2011 Full Year Guidance; and May 24, 2011: Updated Genstrip Guidance 2011-2012; and the upcoming full year 2011 update due on June 30, 2011. This document constitutes the Financial Guidance Memo of May 24, 2011, which is solely concerned with ISCR's recently executed and revised three-party agreement ("Revised Distribution Agreement") by and between Instacare's subsidiary Pharma Tech Solutions, Inc., Broadtree, Inc. and Shasta Technologies LLC for the distribution of a new diabetic diagnostic product called Genstrip. Therefore, the text and numbers in this Memo replace their previous counterparts contained in my January 10, 2011 Financial Guidance Memo.

To repeat my earlier introduction, you have in effect retained me to be the surrogate for your shareholders regarding financial guidance issued by ISCR into the public domain. I am pleased to have the opportunity to work with you in this capacity on their behalf. This protocol emphasizes how seriously you regard the subject of comprehensive and straight-forward communication with your shareholders about your Company's issues, plans, and goals for the future. I think your decision to retain an experienced external financial analyst to evaluate management's guidance forecasts has much merit and that other publicly traded companies should consider adopting this practice.

Further, the Company has more recently retained me to evaluate and report to the Board (and to include in my June 30, 2011 Financial Guidance Memo) whether shareholders would benefit from InstaCare listing on the NASDAQ BX VENTURE EXCHANGE.

FORECASTS FOR GENSTRIP SALES

Original Forecast For Genstrip Sales: 1/10/11 Financial Guidance Memo

This Original Forecast was for $48.2 million in sales throughout 2011. This outlook was based on the terms contained in the original Distribution Agreement.

William N. Walling, Jr.
Chartered Financial Analyst

Revised Forecast For Genstrip Sales: 5/24/11 Financial Guidance Memo

This Revised Forecast is based upon the expanded Revised Distribution Agreement subsequently signed by the three original parties. This Revised Forecast estimates sales of Genstrip to be $41.8 million in 2011 (for the period July-December only) and then increase exponentially to $206.6 million during 2012 (for full calendar year).

The sales breakdown by end market and period, based on an average unit market price of $17.40, is:

GENSTRIP SALES: 2011-2012(E)

	2011 (July-Dec. only) (mil.)	2012 (Full Year) (mil.)
Wholesale	$ 21.8	$ 87.0
Retail	10.4	50.8
Medicare	7.5	35.7
International	2.1	33.1
Total	$ 41.8	$ 206.6

Source: Pharma Tech Solutions, Inc. (subsidiary of InstaCare, Inc.)

The Revised Distribution Agreement contains several important and advantageous provisions for ISCR. In consequence, ISCR will obtain:

- Five-year license (exclusive).
- World-wide distribution rights in all markets.
    - One-half of existing diabetics are overseas.
- Complete control of the Genstrip diabetes diagnostic product including regulatory responsibility with the U.S. FDA, Medicare and Medicaid, and in Europe CE Mark responsibility. In addition the Company will control manufacturing forecast responsibility, and the hiring of master distributors

The Company believes that the economic results for it from this Revised Distribution Agreement will be:

- The opportunity of garnering as much as $600 million (5%) of the U.S. glucose monitoring market within a few years, beyond the 2011-2012 forecasts already cited.
- The realization of much higher profit margins, at least gross margins in the high 30s% (This prospect will be discussed in a subsequent Financial Guidance Memo to be prepared by the undersigned).

William N. Walling, Jr.
Chartered Financial Analyst

MY EVALUATION OF YOUR FORECASTS

These forecasts have been prepared by your management. In addition we have relied on both formal and informal market research obtained and authored by a certain large market research firm. It is my belief that ISCR's management has taken considerable care to be as accurate as possible in making these forecasts. My confidence is based on: (a) a number of years of experience dealing with your management and (b) your inductive process of creating them on a "bottom-up" and line-by-line basis. Nonetheless, because the future is always fundamentally uncertain, most forecasts seldom achieve perfect accuracy. Hence, getting "reasonably close" is about the best a forecaster can usually do. As an external analyst, I have reviewed and evaluated the data presented to me to the best of my ability. **My conclusion is that your forecasts for revenues in 2011-2012 are reasonable, based on the information you have supplied me, including more comprehensive information obtained since the previous guidance memos. I have also weaved into my analysis my knowledge of financial analysis, the healthcare industry and the financial performance of revolutionary new products.** My line of reasoning follows:

Revenues

1. The Company's financial statements, audited by an SEC qualified accounting firm, have shown that revenues have increased sharply and steadily from $6.3 million in 2007 to $19.7 million in 2009, more than a tripling in just three years. Revenues for FY 2010 were $18.9 million. This mild 4% dip was caused by the continued illness of the principal operating officer and the lagging effects of the 2008-2009 recession, the worst for any year since the Great Depression. Thus, strong growth momentum has been in place, and is still intact, when the effects of these two caveats are taken into account.

2. Despite the recent economic weakness in the U.S. economy, secular (long-term) demand forces should continue to spur healthcare spending even with the confusion and indecision brought on by the new health care legislation.

- The U.S. population of approximately 310 million people is graying (elsewhere, too), with the average age having crept up to 77 years here.
- For the first time in U.S. history, the average age of our voting population is over 45.
- For the average person, 80% of their lifetime medical outlays occurs after age 55.
- Healthcare spending is huge, accounting for about 1/6 of gross domestic product, or over $2 trillion annually.
- While Type I Diabetes commences in youth, the more prevalent Type II Diabetes disease state is adult onset, occurring more frequently as people age. Thus, the increasing average age in most populations throughout the world is an intensifying driver of the onset of diabetes.

The diabetic market contains 15 million patients in the U.S. alone (plus approximately an equal number outside the U.S.). And, in the U.S. an estimated 15 million people are either borderline diabetics or untreated. Glucose-level monitoring is a "must" for these people (at least daily) because,

William N. Walling, Jr.
Chartered Financial Analyst

while untreated diabetes is a slow killer, insulin-treated diabetes without glucose monitoring can produce insulin shock which can be fatal at the maximum and incapacitating at the minimum. Testing is most conveniently performed by patients on themselves at home: this has created a nearly $10 billion annual market in the U.S. in 2009 and over $10 billion presently.

Heretofore, a diabetic has had to use a proprietary glucose test strip in conjunction with a proprietary FDA-approved test meter. Now, however, with the launch of Genstrip, the first alternative glucose monitoring product that works only with the testing meters sold by the current at-home glucose testing market leader will be introduced into the market by its innovator soon, This revolutionary diagnostic can be profitably sold by Pharma Tech at a market price of approximately one-half that of the cost of leading brands currently on the market, creating an immediate consumer value in important market segments. Importantly, ISCR (through a subsidiary) has signed an exclusive new five-year agreement to manage, forecast and distribute this dynamic new product. There are enormous positive quantitative implications for ISCR in future revenues and profits from this. It is also evident, that because ISCR was solicited for this agreement, it has major interest in developing a mutual strategic relationship for this first product and other prospective upcoming products.

This new glucose strip will have several key and positive economic features after its imminent introduction into the marketplace.

- Although the diagnostic product uses its own proprietary methodologies, its performance characteristics are almost identical to those of the leading brand, including accuracy (which is paramount), and time-to-result.
- Demand will be recurring because testing must be administered multiple times daily by the average diabetic user and the strips are not re-usable.
- Its projected market price will be 50% below that of the current market-share leader's product.
- This diagnostic will provide a superb value proposition for major retailers (chain pharmacies, omni-store retailers, etc.)

In our opinion, this new Revised Distribution Agreement and a recently signed agreement with the world's largest retailer should prove to be epochal events in the corporate history and growth of ISCR. We believe that your forecast of obtaining approximately $41 million of incremental revenue from Genstrip sales in 2011 and $207 million in 2012 has attractive probabilities of occurring because of: (1) the solidarity of demand for glucose monitoring in the large diabetic market; (2) the specific competitive advantages of your new product; (3) the exclusivity of the new omnibus agreement for ISCR; and, the in-place agreement with the world's largest retailer; and (4) the fact that all of your key projected distributors of Genstrip are already marketing other diabetic test strips (albeit less economically attractive ones).

William N. Walling, Jr.
Chartered Financial Analyst

RISK FACTORS AND UNCERTAINTIES

Notwithstanding the forecasts for substantial growth in revenues and profits expressed above, uncertainties are ever present. Among these are the following:

1. Healthcare Reform - Although new federal health legislation was enacted in March 2010, a populist backlash has evolved which could create an environment having an adverse impact on spending for new healthcare technologies, possibly including instaCare's new mobile digital EMR products. There are also issues of the law's constitutionality.

2. Management Distractions - Current management has continued to deal with some adverse consequences caused by actions of a former senior officer and directors. If this continues, it would distract management's focus and impede its efforts to promptly exploit ISCR's attractive product opportunities, and would entail other costs as well. In addition, the CFO, the management person with the requisite market and diagnostic background, was ill throughout 1Q 2010 and in late 2010 was hospitalized. While the ailment is not believed to be life-threatening and is being treated, it has somewhat limited his time and focus available for corporate matters and it is estimated by management that revenues for 2010 were lowered by $1.9 million and gross profit by $325,000 as a direct result of this health issue. It is estimated that 1Q 2011 revenues have likewise been affected.

3. Need For Equity Capital - Full capitalization of your promising new diagnostic and digital mobile products would require procurement of additional equity funds. These may be difficult to obtain, especially in a still-constrained capital market environment, and could be dilutionary.

DISCLAIMER

This report contains forward-looking statements about a client company's business, or financial condition and prospects that reflect my assumptions and beliefs based on information currently available. I can give no assurance that the expectations indicated by such forward-looking statements will be realized. There may be other risks and circumstances that I am unable to predict. When used in this report, words such as "believes," "expects," "intends," "plans," "anticipates," "estimates" and similar expressions are intended to identify forward-looking statements, although there may be certain forward-looking statements not encompassed by such expressions. This report is accurate as of May 24, 2011. Subsequent Financial Guidance Memos may show changes as events and markets change over time. I was solicited by ISCR which will pay me in cash/stock for the preparation of this Financial Guidance Memo and each of the other ones that I have and will prepare. This compensation has not influenced my evaluation of ISCR's Forecast in any way. This document is not an investment research report nor is it a recommendation to purchase the Company's stock.

Respectfully submitted,

William N. Walling, Jr., CFA

EXHIBIT V

10-K 1 f10k123111_10k.htm DECEMBER 31, 2011 10K

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended **December 31, 2011**

or

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission file number 000-33187

Decision Diagnostics Corp.

(Exact name of registrant as specified in its charter)

Nevada	91-2105842
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

2660 Townsgate Road, Suite 300 Westlake Village, California	91361
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code (805) 446-1973

Securities registered pursuant to Section 12(b) of the Exchange Act: None

Securities registered pursuant to Section 12(g) of the Exchange Act: Common Stock, $0.001 par value

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by checkmark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by checkmark whether the registrant has submitted electronically and posted on its corporation Website, if any, every Interactive Date File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☐ No ☒

Indicate by checkmark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by checkmark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed first fiscal quarter. $2,945,041 based on a share value of $0.04.

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date. The company had, as of April 13, 2012, 10,155,313 shares of common stock, $0.001 par value, issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

DECISION DIAGNOSTICS CORP
FORM 10-K
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FORWARD-LOOKING STATEMENTS

This document contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical fact are "forward-looking statements" for purposes of federal and state securities laws, including, but not limited to, any projections of earnings, revenue or other financial items; any statements of the plans, strategies and objections of management for future operations; any statements concerning proposed new services or developments; any statements regarding future economic conditions or performance; any statements or belief; and any statements of assumptions underlying any of the foregoing.

Forward-looking statements may include the words "may," "could," "estimate," "intend," "continue," "believe," "expect" or "anticipate" or other similar words. These forward-looking statements present our estimates and assumptions only as of the date of this report. Accordingly, readers are cautioned not to place undue reliance on forward-looking statements, which speak only as of the dates on which they are made. We do not undertake to update forward-looking statements to reflect the impact of circumstances or events that arise after the dates they are made. You should, however, consult further disclosures we make in this Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K.

Although we believe that the expectations reflected in any of our forward-looking statements are reasonable, actual results could differ materially from those projected or assumed in any of our forward-looking statements. Our future financial condition and results of operations, as well as any forward-looking statements, are subject to change and inherent risks and uncertainties. The factors impacting these risks and uncertainties include, but are not limited to:

- deterioration in general or regional economic, market and political conditions;
- our ability to successfully compete in the pharmaceutical supply industry;
- increased competitive pressures from existing competitors and new entrants;
- increases in interest rates or our cost of borrowing or a default under any material debt agreements;
- loss of customers or sales weakness;
- the fact that our accounting policies and methods are fundamental to how we report our financial condition and results of operations, and they may require management to make estimates about matters that are inherently uncertain;
- adverse state or federal legislation or regulation that increases the costs of compliance, or adverse findings by a regulator with respect to existing operations;
- changes in U.S. GAAP or in the legal, regulatory and legislative environments in the markets in which we operate;
- inability to efficiently manage our operations;
- inability to achieve future sales levels or other operating results;
- the unavailability of funds for capital expenditures;
- the other risks and uncertainties detailed in this report.

In this form 10-K references to "Decision Diagnostics", "the Company", "we," "us," and "our" refer to Decision Diagnostics Corp. and its operating subsidiaries, Decision IT, Pharma Tech Solutions, Inc., PharmTech Direct Corp., and PDA Services, Inc.

AVAILABLE INFORMATION

We file annual, quarterly and special reports and other information with the SEC. You can read these SEC filings and reports over the Internet at the SEC's website at www.sec.gov or on our website at www.decisiondiagnostics.com. You can also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, NE, Washington, DC 20549 on official business days between the hours of 10:00 am and 3:00 pm. Please call the SEC at (800) SEC-0330 for further information on the operations of the public reference facilities. We will provide a copy of our annual report to security holders, including audited financial statements, at no charge upon receipt to of a written request to us at Decision Diagnostics Corp, 2660 Townsgate Road, Suite 300, Westlake Village, California 91361.

PART I

Item 1. Business.

Overview

Decision Diagnostics Corp. (formerly instaCare Corp) is a nationwide prescription and non-prescription diagnostics and home testing products distributor. Diagnostic test kits and at-home patient testing products are regulated by the U.S. FDA in a manner similar to prescription drugs but the products we distribute, for the most part, do not require a doctor's prescription for anything other than insurance benefit compliance. Our subsidiaries, Pharma Tech Solutions, Inc., Pharmtech Direct Corp. and PDA Services, Inc. operate in several healthcare products distribution channels. We distribute brand name prescription and non-prescription diagnostics products, as well as several lines of ostomy, wound care and post-surgery medical products. Throughout 2011 we began the process of gearing up to introduce to several market channels, a proprietary diagnostic product, the Shasta Genstrip, for at-home testing of blood glucose, an estimated $22.5 billion worldwide market. Shasta Genstrip is the first alternative glucose testing strip that has been launched in this decade and will be the first sold into the market since early 2008. Shasta Genstrip will compete with a predicate product currently used daily by over 3 million diabetes afflicted Americans, and an estimated 2 million diabetes afflicted people outside of the United States.

Typically, and except for our own Shasta Genstrip, which is an alternative product, we distribute name brand diagnostic products. The company directs its marketing efforts to ambulatory and semi-ambulatory older Americans afflicted with diabetes and complications caused by diabetes and old age. The company, originally a medical IT company with proprietary IT product lines, acquired its medical products distribution business in late 2004 through a merger with Phoenix, Arizona based CareGeneration, Inc. Decision Diagnostics has spent the last 7 years building this business. We have grown the original CareGeneration business through subsequent acquisitions of private businesses and strategic partnerships with larger private pharmacies. In November and December 2011 we acquired two private concerns, both acquisitions intended to assist our launch of Shasta Genstrip, and to ease the patient service commitment that Shasta Genstrip will acquire.

We intend to acquire additional private companies in this industry to achieve our goal of becoming a full service, vertically integrated, value added provider of products and services to an ever-growing market.

Decision Diagnostics, through its PDA Services, Inc. and Decision IT Corp. subsidiaries, also offers information technology solutions in several medical care market channels by providing physicians with information at the point of care. Our products, unlike those from many other medical information companies, make use of smart cell phones such as the Apple iPhone, the Palm Pre, the Google Droid and a wide selection of Microsoft Windows based smart phones and operate in either in a wireless or "wired" mode, which allow physicians to carry, access and update their patients' histories, also known as electronic medical records or EMR/EHR, medication data, and best care guidelines - *all at the point of care*, or from any other location the physician may be located. In addition, the company's products employ proprietary mathematical game theory features adapted by the company for medical use that allow acceptance of diagnoses and treatment protocols where the medical information may have originated from one or several locations and one time or several times.

We have entered into eight partnerships with freestanding pharmacies in the states of New York, Texas, New Jersey and Arizona. We believe that we will be able to provide value added services to our customers by cost reductions brought about by increased efficiencies and cross marketing opportunities.

We have received multiple inquiries from companies interested in perhaps partnering with the company for the implementation of its cell phone centric technologies MD@Hand and MD@Work. The interested companies range from clinical laboratories, service organizations owned or aligned with medical health insurers, a medical content provider and legacy healthcare systems companies. We continue to discuss various partnerships and ventures with these companies, but with the federal Medicare, Medicaid and the new Affordable Care Act programs in a state of flux, the federal government has been slow to release the necessary communication protocols that will make products like our MD@Hand and MD@Work have great value. All of these proposed ventures are with companies that are much larger than Decision Diagnostics. We may or may not entertain additional proposed partnerships in the future. We may also find that the launch of our Shasta Genstrip might make selling our proprietary IT products a viable alternative to the proposed ventures.

We currently employ five full-time staff at our executive office located at 2660 Townsgate Road, Suite 300, Westlake Village, California 91361. In addition, we maintain two full-time and seven part-time positions between our properties located in Florida, Arizona, California and New Jersey. These positions are for sales and marketing, distribution and customer service representatives. Our telephone number is (805) 446-1973 and our website address is www.decisiondiagnostics.com.

Business Development

We were originally incorporated in the State of Nevada on March 2, 2001 as ATR Search Corporation ("ATR"). In June of 2002, ATR merged with Medicius, Inc. whereby Medicius, at the close of the merger, was to become a wholly- owned subsidiary of ATR. However, because of several issues that arose post-merger, Medicius, Inc., while a subsidiary of ATR, operated its own business. Following the merger, whereby Medicius, Inc. sold certain software assets to ATR, as a part of the merger, these assets became a part of ATR's portfolio of technology and when the Medicius, Inc. assets became commercially ready, the operations were conducted through ATR. The former operations of ATR were conducted through Care Technologies, LLC, a wholly-owned subsidiary of ATR. Under the terms of the merger agreement, the Shareholders of Medicius received 412,110 shares of ATR's common stock and 103,028 warrants in exchange for 100% of the outstanding shares of Medicius' common stock. Medicius remained an operating entity from the closing of the merger until September 30, 2007. On August 2, 2002, we amended our Articles of Incorporation to change our name from ATR to CareDecision Corporation. CareTechnologies, LLC was dissolved on May 20, 2003, with CareDecision parent continuing all operations of CareTechnologies. On November 19, 2004, we incorporated two Nevada subsidiary companies, Pharma Tech Solutions, Inc. and PDA Services, Inc. In March 2006, we incorporated an additional Nevada corporation subsidiary, Pharmtech Direct Corp. In May 2008, we incorporated an additional Nevada corporation subsidiary, Decision IT Corp.

In April 2005, we amended our Articles of Incorporation to change our name from CareDecision Corporation to instaCare Corp.

As a part our efforts to transition the company toward a full service and vertically integrated provider of at-home diagnostics, on November 1, 2011, as a condition of the merger of Diagnostics Newco LLC, from its sole owner, the company completed a name change action through the office of Nevada Secretary of State (NVSOS). The surviving entity is known as Decision Diagnostics Corp. This action through the office of the NVSOS was effective as of November 25, 2011.

OUR BUSINESS

From April 1, 2005 through November 15, 2009, we focused our business attention towards providing prescription and non-prescription diagnostics, at-home testing and medical/surgical products through several medical distribution channels. Our secondary business objective has been to provide medical information technology (IT) for use with Internet-based communication, and network software systems and applications, that originally resided and functioned through Microsoft Windows CE-Based PDAs (Personal Data Assistants), which are popular and commonly available from most major computer brand name companies such as Sony, Dell, IBM and Palm -to the medical fields and the lodging industries. In May 2009, the company began the port of its technologies and software from then current PDA based products to late generation smart cell phones. This re-development was completed November 12, 2009. Subsequently the company filed patent applications in February 2010 to secure its latest product developments. Our patent application was published during the month of September 2011. Publication of the patent is the final step before the patent claims are prosecuted with USPTO staff. USPTO staff is currently overwhelmed with IT patent applications, many of which have been put on hold due to various litigation involving individuals and companies who oppose broadly, the granting of IT patents. This litigation was met with challenges made by several software technology companies who had filed patent applications previously and who would have been affected. In the event the Supreme Court not ruled on these matters, patents involving software applications would have been burdened with severe obstacles as companies attempted to secure their proprietary technology and software. In June 2011 the U.S. Supreme Court ruled that, among other things, patents similar in nature to the patent filed by the company could be reviewed by the U.S. Patent and Trademark Office in a similar manner to their pre-2008 practices, thereby making the company's patent prosecution possible. We await the final disposition of our patent application, and each of its 104 proprietary claims, from USPTO.

In May 2010 the company entered into an agreement to distribute, on an exclusive basis, a new diagnostic product in the developmental stage manufactured by Shasta Technologies, LLC ("Shasta"). This diagnostic product was specifically designed to compete in the $22.5 billion diabetes testing market. Due to delays in the processes that would otherwise have brought this diagnostic product to market, in January 2011, management began negotiations with Shasta to secure a perpetual and exclusive license to the diagnostic product known as Shasta Genstrip, as well as other rights, including management of many of the on-going tasks, including manufacturing forecasts, customer service and the 510(k) regulatory process..

On March 31, 2011 the company came to agreement with Shasta and as a result of this new agreement, memorialized on April 8, 2011, the company now has complete control over the regulatory process, manufacturing forecast process, customer support, and worldwide distribution. The market for at-home diagnostic testing, primarily blood glucose testing by diabetics and suspected diabetics, is estimated to be $22.5 billion worldwide. The company anticipates achieving significant market share and if successful would become the fifth largest product distribution company in a market where there are over one hundred different product platforms sold, but where four companies control over 90% of the total sales.

The company's business on a day-to-day basis includes the distribution of prescription and non-prescription diagnostics, at-home testing, post-surgical products, and as soon as the 510(k) is approved by the U.S. FDA, the sales and distribution of Shasta Genstrip. In early March 2012 the company, along with representative of Shasta met with the U.S. FDA to iron out any unresolved issues regarding Shasta's 510(k) application. The company believes it has now answered all of the issues brought to its attention by the writings and discussions with the FDA and hopes for a quick resolution.

Beginning in November 2009, we introduced our cell-phone centric medical IT products that offer solutions in medical care and management by providing physicians with information at the point of care. Unlike other medical information systems using standard computer terminals or even palm-sized computers (PDA's), our software applications operate on a series of late generation smart e-cell phones including the Apple iPhone, the Palm Pre, the Google Droid, several makes of RIM's Blackberry and many versions of the Microsoft Windows smart phones. Our products allow physicians to access and update their patients' histories, medication data, and best care guidelines - *all at the point of care*. The company's Electronic Medical Records software is believed to be the first EMR application running on any palm sized mobile device.

Our business objectives include:

1. The practice of specializing in the distribution of brand-name medical diagnostic and medical disposable products associated with the on-going care of diabetes-inflicted patients now that our new proprietary diagnostic product Shasta Genstrip is coming to the market.

   Combining our newly acquired wholesale and direct to patient drug distribution model with our cell phone centric technologies, creating wholesale and retail ePharmacies similar in function to existing Internet pharmacies but directed to serving the large base of underinsured and uninsured Americans; and

   Providing medical communication and EMR medical history and storage devices based on networks of smart cell phones These products are believed to provide benefits of on demand medical information to private practice physicians, licensed medical service providers such as diagnostic testing laboratories, and medical insurers. We have created cell phone-centric products and a suite of Internet enhanced software applications that include those features that specifically respond to the requirements of the practicing physician and the regulations currently being promulgated by the Federal government.

We also have adapted our medical communications and EMR technologies to service the real estate management and hotel/motel/convenience industries in their own commercial settings. In March 2010, our Board approved the sale of the company's hotel/motel technologies and business base so we can focus on our core medical IT and medical distribution businesses. We have recently received several inquiries. In the past when we had market focus on the hotel/motel industry, our real estate and hotel/motel objectives include building electronic commerce networks based on personal digital assistants (PDA) and pad based computers to the hotels, motels and single building, multi-unit apartment buildings with a desire to offer local advertising and electronic services to their tenants/guests.

Prescription and Non-prescription Diagnostics Distribution

Our medical distribution business has allowed us to specialize in the distribution of medical diagnostic and medical disposable products associated with the on-going care of diabetes inflicted patients. This decision was made because the treatment and care of diabetes patients is an on-going lifetime process. Included in our current business plan is the distribution of wound care, ostomy and post-surgical products to diabetes-inflicted patients and other parallel markets. We have also just entered into a broad-based agreement with Shasta Technologies, LLC where we will have exclusive rights to their Shasta Genstrip diagnostic product that we anticipate achieving significant market share in the $22.5 billion annually at-home testing market for chronically afflicted patients, most commonly diabetics.

Specializing in rapid delivery of prescription and non-prescription diagnostic products, we are in the final stages of augmenting our distribution business by creating a nationwide network. Through a proprietary use of the Internet, we have completed a pharma distribution management system that allows our mail order pharmacy to begin the servicing of the 30+ million Americans who are either uninsured or underinsured. Since 2005 one of our target markets has been the same patient base targeted by the national healthcare reform legislation signed into law. In that regard, we have a head start and expect to reap rewards in the months ahead.

Our medical distribution efforts are directed towards practitioners who treat long-term care patients, the uninsured and underinsured. This concept already has enlisted organizations that manage or finance the indigent practices of more than 2,500 doctors. We are establishing our fulfillment centers to service these uninsured and underinsured patients in Phoenix, Arizona, and most recently, Houston, Texas. We have also secured, through a strategic partnership the use of a retail prescription license to transact prescription fulfillment in Arizona. We have also partnered with eight pharmacies, piggybacking our business model onto their licenses for the distribution of medical and pharmaceutical products.

By using wireless technology to link our centrally located prescription and non-prescription diagnostics distribution centers are positioned to bring economic and administrative efficiencies to the projected $8 billion marketplace for delivering prescriptions to the uninsured and underinsured.

The at home testing and direct to patient diagnostics markets include millions of existing patients – that are often subsidized or funded by government benefits. For us, this is a developing enterprise moving forward to take advantage of the tremendous opportunity created by the national healthcare reform recently signed into law. In addition to our existing medical distribution focus, we also acquired and can employ a proprietary, retail mail order methodology for the distribution of other healthcare supplies

Prescription and Non-prescription Diagnostics

The prescription and non-prescription diagnostics business is often subsidized or funded by government benefits, this business model being popularized even before the recent healthcare reform laws. With the advent of what is known as Medicare Part D in 2006, the entire direct to patient service market seems to be aggressively moving to take advantage of the tremendous opportunity in direct to patient solutions via direct mail order distribution of prescription and non-prescription diagnostics and related products/supplies. There are many market leaders in these endeavors. However, the most aggressive participant is Wal-Mart, with their $4 generic prescription plan. The company's subsidiary Pharma Tech Solutions, Inc. has executed a Supplier Agreement with Wal-Mart for their sale of the new Shasta Genstrip product.

Through our acquisition of Care Generation, Inc. we originally acquired a retail mail order business concept for the distribution of pharmaceutical and healthcare supplies. We have focused our distribution activities to patients who lack prescription drug coverage and patients who qualify for government or institutional programs such as Medicare, Medicaid, children's health insurance programs and long-term care institutions and organizations.

Our retail prescription business maintains three operating units:

1. Licensed wholesale prescription drug distribution business, where we deliver bulk prescription drugs on a wholesale basis to clients;
2. Licensed distribution of diabetes diagnostics and supplies, where we deliver diabetic testing strips and associated diagnostic products under several business models; and
3. Internet pharmacy/prescription fulfillment, which we are cautiously, entering.

Our plan is to combine the wholesale and direct to patient distribution businesses and couple these businesses with the capabilities to connect physicians, using our smart cell phone technologies, creating wide-ranging ventures similar in function to existing Internet pharmacies but directed to serving the large base of institutionalized, underinsured and uninsured Americans through their physicians.

Prescription and Non-prescription Diagnostics Methods

To augment our drug distribution efforts our subsidiary Pharma Tech Solutions, Inc. entered into a series of strategic partnerships with pharmacies in throughout the state of Arizona. Through these strategic partnerships we have eliminated the need to expend our capital resources building what would have amounted to duplicate pharma distribution facilities. The strategic partnership model has met and exceeded our expectations and in April 2009, we expanded the Arizona model and entered into a strategic partnership with pharmacies and licensed durable medical goods distributors in the states of California, Maryland and Michigan.

PDA Services, Inc.

In May of 2009, we renewed our agreements originating in 2005, through our subsidiary PDA Services, Inc. with Mr. Svetislav Milic. Pursuant to these agreements, Mr. Milic, has conveyed, free and clear of all liens, encumbrances and liabilities, the wholesale drug distribution license (License Number 5003178) granted to Mr. Milic by the State of New Jersey, and all rights and benefits thereto, plus the goodwill and know-how of Mr. Milic, and other related rights including the use of Colonia's Medicare Provider Identification Number granted the Licensee by virtue of this conveyance. Unless otherwise agreed to, Mr. Milic shall remain the control party of the transferred license for a period of three years after transfer, registration and conveyance. This agreement has been renewed four times since the initial term expired.

In tandem with the Intangible Property License Acquisition Agreement, the parties entered into an Exclusive Agreement Regarding Wholesale Drug Distribution License and Wholesale Drug Distribution Operations wherein the conveyance included the rights to the use of Colonia Natural Pharmacy Inc.'s office and warehouse facility approved for the storage and delivery of pharmaceuticals, and Colonia will have no role, and thus, no responsibility or liability, in the conduct of the "d/b/a" business, including ordering, distribution, or business management of the wholesale business conducted by us or our subsidiaries.

Medical Field Applications

Our medical technologies are grounded in the central need/desire to furnish the practicing physician with crucial point-of-care patient information and historical patient medical information using electronic medical records rapidly and reliably via a smart cell phone. The technologies utilize the power of the Internet to move large amounts of data to and from a variety of platforms securely via a number of commercially available smart cell phones, designed for portability and upgradeability. Compliant with the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and the regulations that have since been promulgated, this smart cell phone technology offers real-time point of care applications and EMR via proprietary technologies that allow for patient medical data for ten years or more on the cell phone itself.

Our software is designed to integrate point of service applications. Our medical appliance, the longest available product, monitors treatment protocols and up to the moment patient histories coupled with real-time on-line medical insurance claims submission. Our ultimate key to success resides in providing the private practice physician with the capability to, sequentially, learn about the history of the patient during, or prior to, entering the examining room, treat the patient and update the insurer of the episode of care. Accomplishing these objectives resolves a major dilemma for the health care provider; instantaneous communication of vital patient related information at or before the patient encounter.

Medical field distribution methods

Since inception, we have and will continue to focus our marketing efforts towards general medical and pharmaceutical medical applications through our E-Health and EMR smart cell phone information appliance) software application package, and a permanently affixed handheld information appliance and commercial national cell phone network. Specifically we have marketed our line of MD@Hand smart cell phone-based medical communication network products to the medical insurance and pharmacy benefits management segments of the healthcare markets.

We have implemented a targeted marketing campaign to educate healthcare providers about our medical technology solutions; targeting the physician providers who specialize in care for the indigent through the provision of technology, products and services that specifically respond to the needs and requirements of that market. We market our suite of medical software products by emphasizing their simplicity, portability, convenience and ease of use. We have chosen this focus due in part that state Medicaid and state and local welfare service providers are agencies who do not typically participate in electronic services networks. This is primarily because care for the poor and indigent is logistically and financially burdensome due to a lack of resources at administrative levels. Put another way, there is usually no shortage of volunteer physicians but there is a shortage of program administrators, clinics, medical supplies and patient access. Additionally, we believe that a company that enters this loop to complete the link by providing utility and value to participants will be embraced. It is incumbent on us to therefore extend our marketing strategy to facilitate this reality.

Implicit to our medical marketing strategy is the contracting of state Medicaid and welfare programs, pharmacy benefit management entities, and medical case management entities within a targeted region that provides for system integration to our products and services. Once the network has been established our IT driven mail order pharmacy services will be distributed to those physicians included within the Medicaid or welfare agency Provider Network. We will rely on those contracted agencies to support and assist in the distribution of the product to the physicians.

Medical field competition

The medical industry is highly competitive in the attraction and retention of physician customers, insurers, government agency payers'/sponsors and other medical providers. The number of competing companies and the size of such companies vary in different geographic areas. Generally, we are in competition with other smart cell phone technology companies that offer medically related software suites, with the most effective competition coming from companies that possess greater capital resources, have longer operating histories, larger customer bases, greater name recognition and significantly greater financial, marketing and other resources than do we.

There are a number of small and large companies that provide some type of IT services at the point of care tying physicians to the healthcare systems. There is substantial turnover and business failure in this industry as well as substantial consolidation:

1. Large publicly traded companies.
2. PDA technology-based companies.

These companies, and others, offer products and services similar to ours: only delivering older PDA based data management to physicians.

There can be no assurance that we will be able to compete successfully against current and future competitors, and competitive pressures faced by us may have a material adverse effect on our business, prospects, financial condition and results of operations. Further, as a strategic response to changes in the competitive environment, management may from time to time make certain pricing, service or marketing decisions or acquisitions that could have a material adverse effect on our business, prospects, financial condition and results of operations.

Advancing the Practice of Medicine at the Point of Care

We are also a developer of products that offer unique solutions in medical care and management by providing physicians with essential information instantaneously as they meet with their patients. Unlike other medical information systems using standard computer terminals, we use smart cell phones as the information delivery vehicle that allow physicians to carry access and update their patients' histories (EMR), medication data, and best care guidelines – *all at the point of care* – streamlining and revolutionizing the practice of medicine.

In addition, we market our *MD@Hand*™ and *MD@Work*™ software application, which also leverages the connectivity of smart cell phone devices via the Internet. This first-in-class smart cell phone software application offers the user access to job specific information (I.E. patient histories or databases), instant messaging, and prescription fulfillment for pharmacists. Our versatile, smart cell phone-based software application is also used in other, information-intensive industries.

Our proprietary *ResidenceWare*™ is a similar collection of Internet-enhanced communication, integration, and networking tools developed for the real estate marketplace in cooperation with prominent commercial and residential real estate management companies. Numerous sales professionals, lodging managers and hoteliers currently use the software to access such information as tenant histories and property databases, as well as for instant messaging directly with occupying tenants. In March 2010 the company's Board of Directors authorized the sale of the Residenceware technologies and customer list.

MD@Hand and MD@Work

Information supplied to and from the physician via the smart cell phone device includes:

Case/Episode diagnosis and Treatment Information:

- Episode by episode multiple diagnosis and physician chosen treatment pathways
- Patient cumulative treatment (electronic medical record) histories, including hospitalizations and histories from patient encounters with other physicians
- Eight levels best care medical protocols
- Tentacle links to the physician desktop reference (PDR) and prescription drug databases

Medical Order Entry and Fulfillment:

- Full Pharmacy Benefits Management programs with electronic script writing with drug formulary and drug to drug interaction checks prior to script transmission
- Lab Order Entry with complete reporting including results, pending, ticklers, out of limits, historical, summary, etc.
- Accident/Worker's Compensation intervention modules. In addition, our software applications provide both on-line and off-line (fax) order entry.

Payer-Related Applications

- Plan and Procedure Eligibility
- Procedure/Drug Authorization
- Patient Referral
- Hospitalization Admit Decision Tree and schema.

Benefit for Physicians

- All access to medication and drug data, interaction databases and formulary information is provided free of charge to all participating physicians via the smart cell phone through Decision Diagnostics' network
- Lowers office costs by centralizing all formulary and prescription m
- Medical data on one or multiple smart cell phones and by reducing paperwork and phone time

- Improves quality of care by providing timely information including *Best Care Guidelines* to help assure an excellent standard of care
- Improves office workflow by providing a compendium of prescription, lab results, referable physicians
- Reduces time pulling and refilling charts reduces errors by offering immediate access to drug data, current formulary tables, lab results and *Best Care Guidelines*

Benefit for Health Plans

- High degree of formulary compliance
- Expedites claims and Improves outcomes
- Helps in creating excellent standard for quality healthcare for all patients
- Reduces cost of operations in many ways (i.e.: cutting down paperwork and phone support)
- Reduces errors
- Assures correct utilization of resources

Source of Principal Suppliers

Our suite of software that runs and manages medical applications is proprietary code and does not require raw materials or principal suppliers. Our software is utilized through over-the-counter smart cell phones and computer products, as previously discussed. We employ a proprietary microchip with laser imbedded patient data to store on smart cell phones, offering a physician current and historical information on his/her patients for ten years or more. Our applications run on smart phones manufactured by Apple, Palm, Motorola, Samsung and many more.

Dependence on a Few Major Customers

We generated revenues primarily through our medical prescription and non-prescription pharmaceutical distributions from six companies. We maintain strategic relationships with these companies whereby these companies place orders and then we service these orders and supply product directly to the patients and/or those entities where the patients reside. We then accept assignment for the billing and future servicing of these patients. We maintain relationships with these original five resellers but have also added twelve additional customers and books of business with institutional care clients whereby we sell product and then receive revenues from the direct filing of reimbursement claims with medical insurance companies. In the future, we expect the majority of the growth in our business to come as a direct result of our direct to patient distribution.

Government Approval and Effect on Us

Medical applications

Recent government and industry legislation and rulemaking, especially the 2010 Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act and Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), and industry groups such as the Joint Commission on Accreditation of Healthcare Organizations ("JCAHO"), require the use of standard transactions, standard identifiers, security and other standards and requirements for the transmission of certain electronic health information. New national standards and procedures under HIPAA include the "Standards for Electronic Transactions and Code Sets" (the "Transaction Standards"); the "Security Standards" (the "Security Standards"); and "Standards for Privacy of Individually Identifiable Health Information" (the "Privacy Standards"). The Transaction Standards require the use of specified data coding, formatting and content in all specified "Health Care Transactions" conducted electronically. However, because all HIPAA Standards are subject to change or interpretation and because certain other HIPAA Standards, not discussed above, are not yet published, we cannot predict the future impact of HIPAA on our business and operations. Additionally, certain state laws are not pre-empted by the HIPAA Standards and may impose independent obligations upon our customers or us.

Failure to comply with HIPAA, as well as other government organizations, may have a material adverse effect on our business. Government regulation of healthcare and healthcare information technology, are in a period of ongoing change and uncertainty and creates risks and challenges with respect to our compliance efforts and our business strategies. The healthcare industry is highly regulated and is subject to changing political, regulatory and other influences. Federal and state legislatures and agencies periodically consider programs to reform or revise the United States healthcare system. These programs may contain proposals to increase governmental involvement in healthcare or otherwise change the environment in which healthcare industry participants operate. Particularly, compliance with HIPAA and related regulations are causing the healthcare industry to incur substantial cost to change its procedures. Healthcare industry participants may respond by reducing their investments or postponing investment decisions, including investments in our products and services. Although we expect these regulations to have the beneficial effect of spurring adoption of our software products, we cannot predict with any certainty what impact, if any, these and future healthcare reforms might have on our business. Existing laws and regulations also could create liability, cause us to incur additional cost or restrict our operations.

Specific risks include, but are not limited to, risks relating to:

Electronic Prescribing: The use of our software by physicians to perform a variety of functions, including electronic prescribing, electronic routing of prescriptions to pharmacies and dispensing, is governed by state and federal law. States have differing prescription format requirements, which we have programmed into our software. Many existing laws and regulations, when enacted, did not anticipate methods of e-commerce now being developed. While federal law and the laws of many states permit the electronic transmission of prescription orders, the laws of several states neither specifically permit nor specifically prohibit the practice. Given the rapid growth of electronic transactions in healthcare, and particularly the growth of the Internet, we expect the remaining states to directly address these areas with regulation in the near future. It is possible that aspects of our MD@Hand software tools could become subject to government regulation. Compliance with these regulations could be burdensome, time-consuming and expensive. We also could become subject to future legislation and regulations concerning the development and marketing of healthcare software systems. These could increase the cost and time necessary to market new services and could affect us in other respects not presently foreseeable. We cannot predict the effect of possible future legislation and regulation; and,

Medical Devices: The United States Food and Drug Administration (the "FDA") has promulgated a draft policy for the regulation of computer software products as medical devices under the 1976 Medical Device Amendments to the Federal Food, Drug and Cosmetic Act. To the extent that computer software is a medical device under the policy, we, as a manufacturer of such products, could be required, depending on the product, to:

- register and list our products with the FDA;
- notify the FDA and demonstrate substantial equivalence to other products on the market before marketing such products; or
- obtain FDA approval by demonstrating safety and effectiveness before marketing a product.

Depending on the intended use of a device, the FDA could require us to obtain extensive data from clinical studies to demonstrate safety or effectiveness, or substantial equivalence. If the FDA requires this data, we would be required to obtain approval of an investigational device exemption before undertaking clinical trials. Clinical trials can take extended periods of time to complete. We cannot provide assurances that the FDA will approve or clear a device after the completion of such trials. In addition, these products would be subject to the Federal Food, Drug and Cosmetic Act's general controls, including those relating to good manufacturing practices and adverse experience reporting. Although it is not possible to anticipate the final form of the FDA's policy with regard to computer software, we expect that the FDA is likely to become increasingly active in regulating computer software intended for use in healthcare settings.

Anti-Kickback Regulation: As a distributor of prescription drugs along the distribution chain that ultimately supply physicians, we are subject to the federal anti-kickback statute, which applies to Medicare, Medicaid and other state and federal programs. The statute prohibits the solicitation, offer, payment or receipt of remuneration in return for referrals or the purchase, or in return for recommending or arranging for the referral or purchase, of goods, including drugs, covered by the programs.

Licensure and Prescription Drug Distribution: As a distributor of drugs, we are subject to regulation by and licensure with the Food and Drug Administration (FDA), the Drug Enforcement Agency (DEA) and various state agencies that regulate wholesalers or distributors. We are subject to periodic inspections of our facilities by regulatory authorities, and adherence to policies and procedures for compliance with applicable legal requirements.

Currently, we do not bear any costs or any effects regarding compliance with environmental laws (federal, state, and local).

American Recovery and Reinvestment Act of 2009: The American Recovery and Reinvestment Act of 2009 stimulus funding of 2009, has allocated $20 billion for healthcare IT investment. Some of this funding will provide direct incentives to physicians and hospitals and should ensure aggressive implementation of new patient information systems starting in 2011. Spending on Decision Diagnostics' type of advanced health information technology is anticipated to be greatly expanded due to the ARRA of 2009 increasing our market potential.

Personnel

We currently employ five full-time employees and nine sales and service representatives. No full-time employees are covered by labor agreements or employment contracts.

IT Patents, Proprietary Rights and Licenses

On February 26, 2010 we filed a full utility patent application, Management and Communications System and Method, Serial No. 13/034,639. The patent application covers one hundred four (104) separate processes and encompasses the method, system and apparatus of our software technology and the integration of our software technology into commercial computer networks through commercial smart cell phone devices. In September 2011, the USPTO published our patent application. We expect approval in 2012. Given that our patent application lists a substantial number of claims, the company felt it prudent to engage counsel to prosecute any of these claims against persons and entities that have breached our patent. The company has created an asset pool for the purpose of prosecuting any claims that may arise as a result of our patent approval. Claims prosecution is standard fare for high technology companies.

Our MD@Hand and MD@Work systems allow for patient information to be gathered from multiple authorized sources and then this information is provided at the point-of-care, and coordinated and compared with prescription formulary compliance, medical services providers and their payers', and multiple-rules based treatment plans provided by various sources (content). Patient case and episode information and care management, in coordination with the implementation of substantially paperless ordering and fulfillment of lab tests, prescriptions and referrals, is made available to attending health care professionals and support personnel via networked computer systems and smart cell phone systems running our proprietary software methods. The inventive system includes, in seamless essentially real-time communication over the Internet, a network of fully secure private sub-networks among the participants in the system. A suite of software applications, including medical, communications and database applications are resident on each smart cell phone, and communications modules resident in the system automatically link to the network via the cell phones' networks, which seamlessly connect to the Internet to update those databases by a novel packet transmission method to maintain confidentiality of the transmitted information.

Item 1A. Risk Factors.

In the course of conducting our business operations, we are exposed to a variety of risks that are inherent to our industry. The following discusses some of the key inherent risk factors that could affect our business and operations, as well as other risk factors, which are particularly relevant to us in the current period of significant economic and market disruption. Other factors besides those discussed below or elsewhere in this report also could adversely affect our business and operations, and these risk factors should not be considered a complete list of potential risks that may affect us.

Risks Relating To Our Business and Marketplace

Declining economic conditions could negatively impact our business

Our businesses and earnings are affected by general business and economic conditions in the United States and abroad. General business and economic conditions that could affect us include the level and volatility of short-term and long-term interest rates, inflation, home prices, employment levels, bankruptcies, household income, consumer spending, fluctuations in both debt and equity capital markets, liquidity of the global financial markets, the availability and cost of credit, investor confidence, the cash flows of our customers, the incomplete implementation and status of the new healthcare law, and the strength of the U.S. economy and the local economies in which we operate.

Economic conditions in the United States and abroad deteriorated significantly during the second half of 2008, and the United States, Europe and Japan currently are either in a recession or a prolonged period of slow growth. Many lenders and institutional investors have reduced or ceased providing funding to borrowers, including to other financial institutions, reflecting concern about the stability of the financial markets generally and the strength of counterparties. This market turmoil and tightening of credit have led to a significant reduction in consumer confidence, increased market volatility and widespread reduction of business activity generally. The resulting economic pressure on consumers and lack of confidence in the financial markets has adversely affected liquidity and access to capital and credit. We do not expect that the difficult conditions in the United States and international financial markets are likely to improve in the near future. A worsening of these conditions would likely exacerbate the adverse effects of these difficult market conditions on us. The 2010 earthquake, tsunami and the resultant business conditions in Japan are particularly troublesome and lowered market growth rates from 25% annually to 10-12% annually.

Continued instability of the U.S. financial system may have a negative impact on our business.

Beginning in the fourth quarter of 2008, the U.S. government has responded to the ongoing financial crisis and economic slowdown by enacting new legislation and expanding or establishing a number of programs and initiatives. Each of the U.S. Treasury, the FDIC and the Federal Reserve Board have developed programs and facilities, including, among others, the U.S. Treasury's Troubled Asset Relief Program ("TARP") Capital Purchase Program and other efforts designed to increase inter-bank lending, improve funding for consumer receivables and restore consumer and counterparty confidence in the banking sector. In addition, Congress recently passed the American Recovery and Reinvestment Act of 2009 (the "ARRA"), legislation intended to expand and establish government spending programs and provide tax cuts to stimulate the economy. Congress and the U.S. government continue to evaluate and develop various programs and initiatives designed to stabilize the financial and housing markets and stimulate the economy, including the U.S. Treasury has recently announced Financial Stability Plan and the U.S. governments recently announced foreclosure prevention program. The final form of any such programs or initiatives or related legislation cannot be known at this time. There can be no assurance as to the impact that ARRA, the Financial Stability Plan or any other such initiatives or governmental programs will have on the financial markets, including the extreme levels of volatility and limited credit availability currently being experienced. The failure of these efforts to stabilize the financial markets and a continuation or worsening of current financial market conditions could materially and adversely affect our business, financial condition, results of operations, access to credit, or the trading price of our securities.

We have historically lost money, which means that we may not be able to continue operations unless we obtain additional funding.

We have historically incurred significant losses from operations and have an accumulated deficit of $20,134,069. For the year ended December 31, 2011, we had net loss of $2,117,006 compared to net loss of $471,837 for the year ended December 31, 2010. We cannot assure you that we will be able to continue to achieve revenue growth, profitability or positive cash flow on either a quarterly or annual basis. Although we believe that we have adequate sales to fund our current level of operating activities through December 31, 2012, if we are unable to sustain profitability, we may not be financially viable in the future and may have to curtail, suspend or cease operations.

We have been dependent on a small number of major customers to support our prescription and non-prescription diagnostics distribution plan and to refer direct to patient business (assignment of medical benefit) to the company.

In fiscal 2011 our four largest customers accounted for approximately 88% of our net sales, these sales occurring both from direct sales to our customers and the acceptance of benefit for those patients we service directly. We expect that a small but growing number of customers will continue to account for a substantial majority of our sales and that the relative dollar amount and mix of products sold to these customers can change significantly from year to year and how we are paid for business generated, assigned and referred by these customers can change as well. There can be no assurance that our major customers will continue to purchase products or refer business to us at current levels, or that the mix of products purchased will be in the same ratio. The loss of our largest customers, who not only buy product directly, but also refer substantial "direct to patient" business upon which we accept assignment or may provide direct billing and collection services or accept medical assignment for "direct to patient" business, or a decrease in product sales would have a material adverse effect on our business and financial condition.

Our internal controls may be inadequate, which could cause our financial reporting to be unreliable and lead to misinformation being disseminated to the public.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. As defined in Exchange Act Rule 13a-15(f), internal control over financial reporting is a process designed by, or under the supervision of, the principal executive and principal financial officer and effected by the board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that: (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company, and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

We have one individual performing the functions of all officers. This individual is responsible for monitoring and ensuring compliance with our internal control procedures. As a result, our internal controls may be inadequate or ineffective, which could cause our financial reporting to be unreliable and lead to misinformation being disseminated to the public. Investors relying upon this misinformation may make an uninformed investment decision.

We may not be able to retain our key personnel or attract additional personnel, which could affect our ability to generate revenue sufficient to continue as a going concern diminishing your return on investment.

Our performance is substantially dependent on the services and on the performance of our Management. Decision Diagnostics is, and will be, heavily dependent on the skill, acumen and services of our CFO, Secretary and Treasurer, Keith Berman and our Chairman Robert Jagunich. Our performance also depends on our ability to attract, hire, retain and motivate our officers and key employees. The loss of the services of our executives could result in lost revenue depending on the length of time and effort required to find a qualified replacement. We have not entered into long-term employment agreements with our key personnel and currently have no "Key Employee" life insurance policies

Our future success may also depend on our ability to identify, attract, hire, train, retain and motivate other highly skilled technical, managerial, marketing and customer service personnel. Competition for personnel with these skill sets is intense, and there can be no assurance that we will be able to successfully attract, assimilate or retain sufficiently qualified personnel. If we are unable to attract, retain, and train the necessary technical, managerial, marketing and customer service personnel, our expectations of increasing our clientele could be hindered, and the profitability of Decision Diagnostics reduced.

Achieving market acceptance of new or newly integrated products and services is likely to require significant efforts and expenditures.

Achieving market acceptance for new or newly integrated products and services is likely to require substantial marketing efforts and expenditure of significant funds to create awareness and demand by participants in the healthcare industry. In addition, deployment of new or newly integrated products and services may require the use of additional resources for training our existing sales and customer service personnel and for hiring and training additional salespersons and customer service personnel. There can be no assurance that the revenue opportunities from new or newly integrated products and services will justify amounts spent for their development, marketing and rollout.

We could be subject to breach of warranty claims if our software products, information technology systems or transmission systems contain errors, experience failures or do not meet customer expectations.

We could face breach of warranty or other claims or additional development costs if the software and systems we sell or license to customers or use to provide services contain undetected errors, experience failures, do not perform in accordance with their documentation, or do not meet the expectations that our customers have for them. Undetected errors in the software and systems we provide or those we use to provide services could cause serious problems for which our customers may seek compensation from us. We attempt to limit, by contract, our liability for damages arising from negligence, errors or mistakes. However, contractual limitations on liability may not be enforceable in certain circumstances or may otherwise not provide sufficient protection to us from liability for damages.

We do not have the financial resources to litigate actions involving our copyrights or patent applications or for claims of the receipt of defective or expired medical products, or a drug-counterfeiting claim.

We have applied to receive patent rights, and trademarks relating to our software. However, patent and intellectual property legal issues for software programs, such as our products, are complex and currently evolving. Patent applications are secret until patents are issued in the United States, or published in other countries, therefore, we cannot be sure that we are first to file any patent application for our technologies, primarily the technology that allows for the safe, secure and near seamless transmission of sensitive medical information from the point of care, directly to our mail order pharmacy. Should any of our patent claims be compromised or if, for example, one of our competitors has filed or obtained a patent before our claims have been prosecuted, or should a competitor with more resources desire to litigate and force us to defend or prosecute any patent rights, our ability to develop the market for our mail order pharmacy could be severely compromised, for we do not have the financial resources to litigate actions involving our patents and copyrights.

Even though we purchase name brand products through our distribution business, and manage the manufacturing of our new Shasta Genstrip product, from time to time we do receive defective, expired or recalled product from suppliers. If the entities that we purchase product from fail to replace the defective or damaged product, our only recourse is to withhold payment. These actions could lead to litigation. In addition, pharmaceutical manufacturers have recently taken advantage of prior case law allowing them to prosecute certain distribution activities as drug counterfeiting claims. While the company maintains general liability, product liability and executive and management liability policies we may not have the financial resources to litigate disputes with companies larger than us and with substantially more resources.

Our risk management policies and procedures may leave us exposed to unidentified risks or an unanticipated level of risk.

The policies and procedures we employ to identify, monitor and manage risks may not be fully effective. Some methods of risk management are based on the use of observed historical market behavior. As a result, these methods may not predict future risk exposures, which could be significantly greater than the historical measures indicate. Other risk management methods depend on evaluation of information regarding markets, clients or other matters that are publicly available or otherwise accessible by us. This information may not be accurate, complete, up-to-date or properly evaluated. Management of operational, legal and regulatory risk requires, among other things, policies and procedures to properly record and verify a large number of transactions and events. We cannot assure you that our policies and procedures will effectively and accurately record and verify this information.

We seek to monitor and control our risk exposure through a variety of separate but complementary financial, credit, operational and legal reporting systems. Nonetheless, the effectiveness of our ability to manage risk exposure can never be completely or accurately predicted or fully assured.

Changes in accounting standards, especially those that relate to management estimates and assumptions, are unpredictable and may materially impact how we report and record our financial condition.

Our accounting policies and methods are fundamental to how we record and report our financial condition and results of operations. Some of these policies require use of estimates and assumptions that may affect the value of our assets or liabilities and financial results and are critical because they require management to make difficult, subjective and complex judgments about matters that are inherently uncertain. From time to time the Financial Accounting Standards Board ("FASB") and the SEC change the financial accounting and reporting standards that govern the preparation of our financial statements. In addition, accounting standard setters and those who interpret the accounting standards (such as the FASB, the SEC, banking regulators and our outside auditors) may change or even reverse their previous interpretations or positions on how these standards should be applied. These changes can be hard to predict and can materially impact how we record and report our financial condition and results of operations. In some cases, we could be required to apply a new or revised standard retroactively, resulting in our restating prior period financial statements. For a further discussion of some of our significant accounting policies and standards and recent accounting changes, see Note 1 to the Consolidated Financial Statements.

Our auditors have expressed substantial doubt as to our ability to continue as a going concern.

Due to our accumulated deficit and our lack of revenue sufficient to support existing operations, there is substantial doubt about our ability to continue as a going concern. We may need to obtain additional financing in the event that we are unable to realize sufficient revenue. We may incur additional indebtedness from time to time to finance acquisitions, provide for working capital or capital expenditures or for other purposes There can be no assurance that we will have funds sufficient to continue operations, and the failure to do so could lead to an inability to meet our financial obligations and therefore result in bankruptcy and the loss of your entire investment in Decision Diagnostics' common shares.

Risks Relating To Our Common Stock

If we fail to remain current on our reporting requirements, we could be removed from the OTC Bulletin Board, which would limit the ability of broker-dealers to sell our securities and the ability of Shareholders to sell their securities in the secondary market.

Companies trading on the OTC Bulletin Board, such as us, generally must be reporting issuers under Section 12 of the Securities Exchange Act of 1934, as amended, and must be current in their reports under Section 13, in order to maintain price quotation privileges on the OTC Bulletin Board. More specifically, FINRA has enacted Rule 6530, which determines eligibility of issuers quoted on the OTC Bulletin Board by requiring an issuer to be current in its filings with the Commission. Pursuant to Rule 6530(e), if we file our reports late with the Commission three times in a two-year period or our securities are removed from the OTC Bulletin Board for failure to timely file twice in a two-year period then we will be ineligible for quotation on the OTC Bulletin Board. As a result, the market liquidity for our securities could be severely adversely affected by limiting the ability of broker-dealers to sell our securities and the ability of Shareholders to sell their securities in the secondary market.

Because our common stock is deemed a low-priced "Penny" stock, an investment in our common stock should be considered high risk and subject to marketability restrictions.

Since our common stock is a penny stock, as defined in Rule 3a51-1 under the Securities Exchange Act, it will be more difficult for investors to liquidate their investment even if and when a market develops for the common stock. Until the trading price of the common stock rises above $5.00 per share, if ever, trading in the common stock is subject to the penny stock rules of the Securities Exchange Act specified in rules 15g-1 through 15g-10. Those rules require broker-dealers, before effecting transactions in any penny stock, to:

- Deliver to the customer, and obtain a written receipt for, a disclosure document;
- Disclose certain price information about the stock;
- Disclose the amount of compensation received by the broker-dealer or any associated person of the broker-dealer;
- Send monthly statements to customers with market and price information about the penny stock; and
- In some circumstances, approve the purchaser's account under certain standards and deliver written statements to the customer with information specified in the rules.

Consequently, the penny stock rules may restrict the ability or willingness of broker-dealers to sell the common stock and may affect the ability of holders to sell their common stock in the secondary market and the price at which such holders can sell any such securities. These additional procedures could also limit our ability to raise additional capital in the future.

Recent and possible future issuances of common stock will have a dilutive effect on existing shareholders.

Our Certificate of Incorporation authorizes the Board of Directors to issue up to 1,750,000,000 shares of common stock and 5,000,000 shares of preferred stock. The power of the Board of Directors to issue shares of common stock, preferred stock or warrants or options to purchase shares of common stock or preferred stock is generally not subject to shareholder approval. Accordingly, any additional issuance of our common stock, or preferred stock that may be convertible into common stock, may have the effect of diluting one's investment.

By issuing preferred stock, we may be able to delay, defer or prevent a change of control.

We are authorized to issue a total of 5,000,000 shares of "blank check" preferred stock and up to; 2,500 shares of Series B, 10,000 shares of Series C, and 1,250,000 shares of Series E, Convertible Preferred Stock (for a combined total of 1,262,500 shares of preferred stock). Our Board of Directors can determine the rights, preferences, privileges and restrictions granted to, or imposed upon, the shares of preferred stock and to fix the number of shares constituting any series and the designation of such series. It is possible that our Board of Directors, in determining the rights, preferences and privileges to be granted when the preferred stock is issued, may include provisions that have the effect of delaying, deferring or preventing a change in control, discouraging bids for our common stock at a premium over the market price, or that adversely affect the market price of and the voting and other rights of the holders of our common stock.

FINRA sales practice requirements may also limit a Shareholder's ability to buy and sell our stock.

In addition to the "penny stock" rules described above, FINRA has adopted rules that require that in recommending an investment to a customer, a broker-dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending speculative low priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status, investment objectives and other information. Under interpretations of these rules, the FINRA believes that there is a high probability that speculative low priced securities will not be suitable for at least some customers. The FINRA requirements make it more difficult for broker-dealers to recommend that their customers buy our common stock, which may limit your ability to buy and sell our stock and have an adverse effect on the market for our shares.

Item 1B. Unresolved Staff Comments.

None

Item 2. Properties.

We currently maintain an executive office at 2660 Townsgate Road, Suite 300, Westlake Village, CA 91361. The space consists of approximately 2,300 square feet. The monthly rental for the space is $4,140 per month on a month-to-month basis.

On June 7, 2005, we entered into an agreement for the right to use offices, warehouses and shipping facilities for the storage and shipping of pharmaceuticals located at 515 Inman Avenue, Colonia, NJ 07067 and 25 Minna Street, Rahway, NJ 07065 for a monthly rental fee of $3,850. These buildings total 4,000 square feet but our right to use is not exclusive.

Item 3. Legal Proceedings.

We transact commerce in several medical products market channels. We also transact commerce by licensing our proprietary medical software that functions by moving confidential medical data through our proprietary medical information technology devices and networks. Our new Shasta Genstrip product required initial regulatory approval by the USFDA as well as on-going USFDA approvals during the product life cycle. Further, Shasta Genstrip required medical patient trials and will compete directly with a major platform manufacturer.

Healthcare, especially those segments where the company competes, is a very litigious. The medical industry is also intertwined. From time to time, we may become involved in claims and litigation that arise out of the normal course of business, such as litigation that emerges from disputes over damaged, missing or contaminated product. We may also become involved in disputes that arise over the business or business practices of our suppliers, payers and customers. The company maintains substantial insurance coverage against suits that may arise over issues of damaged, recalled or counterfeit product and other product liability issues. In addition, the company accrues contingent legal fees and product liability fees. The accrual totaled $205,500 for each of the years ended December 31, 2011 and 2010.

From time to time, the company may also be subject to demands from individuals or entities. These demands and disputes may consume management time and company resources. Other than as noted below there are no pending matters at the current time that in management's judgment may be considered potentially material to us.

Monarch Pointe Fund, Ltd (BVI) in receivership vs. Decision Diagnostics Corp. et al.

On June 24, 2010, Monarch Point Fund, Ltd. (BVI) (in receivership) brought an action in United States District Court, Central District of California, Case # CV 10 4703 against Decision Diagnostics Corp., Keith Berman and Robert Cox alleging conversion by Decision Diagnostics of certain Convertible Preferred Series C Stock allegedly owned by Monarch, breach of contract and breach of a promissory note. On August 12, 2010 the company received an initial formal settlement offer through the counsel for the Liquidator. Subsequently there have been additional offers and counter-offers. Among other stated issues these offers of settlement are intended to bring an end to the litigation. The company settled this litigation in May 2011 by issuing to Monarch 214,286 (post-split) shares of its $0.001 par value common stock.

Lifescan Scotland, LLC vs. Shasta Technologies LLC, InstaCare Corp. (now known as Decision Diagnostics Corp.), Pharma Tech Solutions, Inc. et al.

On September 9, 2011 Lifescan Scotland, Ltd. brought suit against Shasta Technologies, LLC (Shasta), InstaCare Corp. (now known as Decision Diagnostics Corp.), Pharma Tech Solutions, Inc. et al in the United States District Court, Northern District of California, San Jose Division, Case # CV11-04494-MEJ, alleging patent infringement, seeking injunctive relief and damages as a result of an alleged infringement on Patents 5,708,247 and 6,241,862. InstaCare Corp. (now known as Decision Diagnostics Corp.) and Pharma Tech Solutions have answered the complaint, denying all of its material allegations and asserting a number of affirmative defenses. InstaCare Corp. (now known as Decision Diagnostics Corp.) and Pharma Tech Solutions, Inc. are entitled to be indemnified by Shasta, and the attorney for Shasta has notified Shasta's insurance carrier that InstaCare Corp. (now known as Decision Diagnostics Corp.) and Pharma Tech Solutions, Inc. are entitled to a defense under Shasta's insurance policy. The companies also carry insurance and have demanded a defense from its own carriers. Since the suit remains in its early stages it is too soon to determine the course of the litigation. Management intends to vigorously defend this lawsuit."

Item 4. (removed and reserved)

PART II

Item 5. Market for Registrant's Common Equity, Related Shareholder Matters and Issuer Purchases of Equity Securities.

(a) Market Information

Our Common Stock traded sporadically on the over-the-counter bulletin board market (OTCBB) through January of 2011 and currently trades on the OTCQB under the symbol DECN. Our common stock has traded infrequently on the OTCQB, which limits our ability to locate accurate high and low bid prices for each quarter within the last two fiscal years. Therefore, the following table lists the available quotations for the high and low bid prices for the fiscal years 2011 and 2010. The quotations from the OTC Bulletin Board reflect inter-dealer prices without retail mark-up, markdown, or commissions and may not represent actual transactions.

	2011		2010	
	High	Low	High	Low
1st Quarter	$ 1.12	$ 0.57	$ 0.174	$ 0.091
2nd Quarter	$ 0.76	$ 0.25	$ 0.115	$ 0.063
3rd Quarter	$ 0.61	$ 0.17	$ 0.080	$ 0.057
4th Quarter	$ 0.65	$ 0.10	$ 0.060	$ 0.037

(b) Holders of Common Stock

As of March 15, 2012, there were approximately 848 holders of record of our Common Stock and 10,155,313 shares outstanding. As of March 31, 2012, the closing price of our shares of common stock on the OTCQB was $0.29 per share.

(c) Dividends

In the future we intend to follow a policy of retaining earnings, if any, to finance the growth of the business and do not anticipate paying any cash dividends in the foreseeable future. The declaration and payment of future dividends on the Common Stock will be the sole discretion of board of directors and will depend on our profitability and financial condition, capital requirements, statutory and contractual restrictions, future prospects and other factors deemed relevant.

(d) Securities Authorized for Issuance under Equity Compensation Plans

2004 Stock Option Plan

Effective April 21, 2004, we adopted the "2004" Stock Option Plan, as amended, with a maximum number of 450,893 (post-split) shares that may be issued. We have granted a total of 398,104 (post-split) options under this plan all of which have been exercised. As of December 31, 2011, 52,789 (post-split) options remain available for issuance under this plan.

2005 Merger Consolidated Stock Option Plan

Effective February 5, 2005, we adopted the "2005" Merger Consolidated Stock Option Plan. The maximum number of shares that may be issued pursuant to the plan is 80,357 (post-split) shares. We have granted a total of 77,307 (post-split) options under this plan of which 63,021 (post-split) options have been exercised or expired and 14,286 are exercisable. As of December 31, 2011, 3,050 (post-split) options remain available for issuance under this plan.

2006 Business Development Stock Option Plan

Effective December 8, 2006, we adopted our "2006" Employee Stock Option Plan" as amended with a maximum number of 1,821,429 (post-split) shares that may be issued. We have granted a total of 1,023,725 (post-split) options under this plan all of which have been exercised or expired. As of December 31, 2011, 797,704 (post-split) options remain available for issuance under this plan.

Our Stock Option Plans are intended to encourage directors, officers, employees and consultants to acquire ownership of common stock. The opportunity so provided is intended to foster in participants a strong incentive to put forth maximum effort for our continued success and growth, to aid in retaining individuals who put forth such efforts, and to assist in attracting the best available individuals to the Company in the future.

Officers (including officers who are members of the board of directors), directors (other than members of the stock option committee to be established to administer the stock option plans) and other employees and consultants and its subsidiaries (if established) will be eligible to receive options under the stock option plans. The committee will administer the stock option plans and will determine those persons to whom options will be granted, the number of options to be granted, the provisions applicable to each grant and the time periods during which the options may be exercised. No options may be granted more than ten years after the date of the adoption of the stock option plans.

Non-qualified stock options will be granted by the committee with an option price equal to the fair market value of the shares of common stock to which the non-qualified stock option relates on the date of grant. The committee may, in its discretion, determine to price the non-qualified option at a different price. In no event may the option price with respect to an incentive stock option granted under the stock option plans be less than the fair market value of such common stock to which the incentive stock option relates on the date the incentive stock option is granted.

Each option granted under the stock option plans will be exercisable for a term of not more than ten years after the date of grant. Certain other restrictions will apply in connection with the plans when some awards may be exercised. In the event of a change of control (as defined in the stock option plans), the date on which all options outstanding under the stock option plans may first be exercised will be accelerated. Generally, all options terminate 90 days after a change of control.

The following table sets forth information as of December 31, 2011 regarding outstanding options granted under the plans, warrants issued to consultants and options reserved for future grant under the plan.

Plan Category	Number of share to be issued upon exercise of outstanding options, warrants and rights (post-split) (a)	Weighted- average exercise price of outstanding options, warrants and rights (post-split) (b)	Number of shares available for future issuance under equity compensation plans (excluding shares reflected in column(a)) (c)
Equity compensation plans approved by shareholders	-	$ -	-
Equity compensation plans not approved by shareholders	14,286	$ 0.80	710,686 (1)
Total	14,286	$ 0.80	710,686

(1) Includes 52,789 (post-split) options remaining for issuance under the 2004 Option Plan, 3,050 (post-split) options remaining for issuance under the 2005 Option Plan, and 654,847 (post-split) options remaining under the 2006 Option Plan.

Recent Sales of Unregistered Securities

On January 5, 2011, we issued 272 (post-split) shares of our restricted common stock to Alpha Credit Resources for our December 2010 financing fees valued at $182 in connection with our line of credit. We believe that the issuance of the shares was exempt from the registration and prospectus delivery requirements of the Securities Act of 1933 by virtue of Section 4(2). The recipient of the shares was afforded an opportunity for effective access to files and records of the Company that contained the relevant information needed to make its investment decision, including the Company's financial statements and 34 Act reports. We reasonably believe that the recipient, immediately prior to issuing the shares, had such knowledge and experience in our financial and business matters that it was capable of evaluating the merits and risks of its investment. The recipient had the opportunity to speak with our president and directors on several occasions prior to its investment decision.

On January 5, 2011, we issued 2,857 (post-split) shares of our restricted common stock to two individuals, Mr. Walling and Ms. Lucas, for research, communication, sales and marketing services performed for the Company valued at $2,000. We believe that the issuance of the shares was exempt from the registration and prospectus delivery requirements of the Securities Act of 1933 by virtue of Section 4(2). The recipient of the shares was afforded an opportunity for effective access to files and records of the Company that contained the relevant information needed to make its investment decision, including the Company's financial statements and 34 Act reports. We reasonably believe that the recipient, immediately prior to issuing the shares, had such knowledge and experience in our financial and business matters that it was capable of evaluating the merits and risks of its investment. The recipient had the opportunity to speak with our president and directors on several occasions prior to its investment decision.

On March 8 and March 23, 2011, we issued a total of 14,286 (post-split) shares of our restricted common stock to Cadence Consulting as consulting fees valued at $12,400. We believe that the issuance of the shares was exempt from the registration and prospectus delivery requirements of the Securities Act of 1933 by virtue of Section 4(2). The recipient of the shares was afforded an opportunity for effective access to files and records of the Company that contained the relevant information needed to make its investment decision, including the Company's financial statements and 34 Act reports. We reasonably believe that the recipient, immediately prior to issuing the shares, had such knowledge and experience in our financial and business matters that it was capable of evaluating the merits and risks of its investment. The recipient had the opportunity to speak with our president and directors on several occasions prior to its investment decision.

On March 8, 2011, we issued 61,429 (post-split) shares of our restricted common stock to Michelle Abraham upon her election to exercise options for cash totaling $30,100. We believe that the issuance of the shares was exempt from the registration and prospectus delivery requirements of the Securities Act of 1933 by virtue of Section 4(2). The recipient of the shares was afforded an opportunity for effective access to files and records of the Company that contained the relevant information needed to make its investment decision, including the Company's financial statements and 34 Act reports. We reasonably believe that the recipient, immediately prior to issuing the shares, had such knowledge and experience in our financial and business matters that it was capable of evaluating the merits and risks of its investment. The recipient had the opportunity to speak with our president and directors on several occasions prior to its investment decision.

On March 8, 2011, we issued 61,225 (post-split) shares of our restricted common stock to Leslie Michelle Wolf upon her election to exercise options for services valued at $30,000. We believe that the issuance of the shares was exempt from the registration and prospectus delivery requirements of the Securities Act of 1933 by virtue of Section 4(2). The recipient of the shares was afforded an opportunity for effective access to files and records of the Company that contained the relevant information needed to make its investment decision, including the Company's financial statements and 34 Act reports. We reasonably believe that the recipient, immediately prior to issuing the shares, had such knowledge and experience in our financial and business matters that it was capable of evaluating the merits and risks of its investment. The recipient had the opportunity to speak with our president and directors on several occasions prior to its investment decision.

On April 15, 2011 and June 9, 2011, we issued 2,500 and 2,857 (post-split) shares, respectively of our restricted common stock to William Walling for his marketing services valued at $3,000. We believe that the issuance of the shares was exempt from the registration and prospectus delivery requirements of the Securities Act of 1933 by virtue of Section 4(2). The recipient of the shares was afforded an opportunity for effective access to files and records of the Company that contained the relevant information needed to make its investment decision, including the Company's financial statements and 34 Act reports. We reasonably believe that the recipient, immediately prior to issuing the shares, had such knowledge and experience in our financial and business matters that it was capable of evaluating the merits and risks of its investment. The recipient had the opportunity to speak with our president and directors on several occasions prior to its investment decision.

During the year ended December 31, 2011, we issued a total of 955 (post-split) shares of our restricted common stock to Alpha Credit Resources for 2011 financing fees valued at $37,175 in connection with our line of credit. We believe that the issuance of the shares was exempt from the registration and prospectus delivery requirements of the Securities Act of 1933 by virtue of Section 4(2). The recipient of the shares was afforded an opportunity for effective access to files and records of the Company that contained the relevant information needed to make its investment decision, including the Company's financial statements and 34 Act reports. We reasonably believe that the recipient, immediately prior to issuing the shares, had such knowledge and experience in our financial and business matters that it was capable of evaluating the merits and risks of its investment. The recipient had the opportunity to speak with our president and directors on several occasions prior to its investment decision.

During the year ended December 31, 2011, we issued 677,500 (post-split) shares of our restricted common stock to Alpha Credit Resources upon their election to convert 189,700 preferred series "E" shares into common stock. We believe that the issuance of the shares was exempt from the registration and prospectus delivery requirements of the Securities Act of 1933 by virtue of Section 4(2). The recipient of the shares was afforded an opportunity for effective access to files and records of the Company that contained the relevant information needed to make its investment decision, including the Company's financial statements and 34 Act reports. We reasonably believe that the recipient, immediately prior to issuing the shares, had such knowledge and experience in our financial and business matters that it was capable of evaluating the merits and risks of its investment. The recipient had the opportunity to speak with our president and directors on several occasions prior to its investment decision.

On May 31, 2011, we issued 214,286 (post-split) shares of our restricted common stock to Monarch Point Fund Limited to settle Monarch's case against us. The value of the shares on the date of issuance was $120,000. We believe that the issuance of the shares was exempt from the registration and prospectus delivery requirements of the Securities Act of 1933 by virtue of Section 4(2). The recipient of the shares was afforded an opportunity for effective access to files and records of the Company that contained the relevant information needed to make its investment decision, including the Company's financial statements and 34 Act reports. We reasonably believe that the recipient, immediately prior to issuing the shares, had such knowledge and experience in our financial and business matters that it was capable of evaluating the merits and risks of its investment. The recipient had the opportunity to speak with our president and directors on several occasions prior to its investment decision.

On June 14, 2011, we issued 57,143 (post-split) shares of our restricted common stock to Daniel Myers upon his election to exercise options for services valued at $32,000. We believe that the issuance of the shares was exempt from the registration and prospectus delivery requirements of the Securities Act of 1933 by virtue of Section 4(2). The recipient of the shares was afforded an opportunity for effective access to files and records of the Company that contained the relevant information needed to make its investment decision, including the Company's financial statements and 34 Act reports. We reasonably believe that the recipient, immediately prior to issuing the shares, had such knowledge and experience in our financial and business matters that it was capable of evaluating the merits and risks of its investment. The recipient had the opportunity to speak with our president and directors on several occasions prior to its investment decision.

On November 29, 2011, we issued 35,714 (post-split) shares of our restricted common stock to TPC Holdings Group upon its election to exercise options for services valued at $7,729. We believe that the issuance of the shares was exempt from the registration and prospectus delivery requirements of the Securities Act of 1933 by virtue of Section 4(2). The recipient of the shares was afforded an opportunity for effective access to files and records of the Company that contained the relevant information needed to make its investment decision, including the Company's financial statements and 34 Act reports. We reasonably believe that the recipient, immediately prior to issuing the shares, had such knowledge and experience in our financial and business matters that it was capable of evaluating the merits and risks of its investment. The recipient had the opportunity to speak with our president and directors on several occasions prior to its investment decision.

On December 19, 2011, we issued 275 (post-split) shares of our restricted common stock to two individuals, Kimberly Binder and Patrick DeParini for consulting services performed in connection with our business development activities. The fair value of the services totaled $126. We believe that the issuance of the shares was exempt from the registration and prospectus delivery requirements of the Securities Act of 1933 by virtue of Section 4(2). The recipient of the shares was afforded an opportunity for effective access to files and records of the Company that contained the relevant information needed to make its investment decision, including the Company's financial statements and 34 Act reports. We reasonably believe that the recipient, immediately prior to issuing the shares, had such knowledge and experience in our financial and business matters that it was capable of evaluating the merits and risks of its investment. The recipient had the opportunity to speak with our president and directors on several occasions prior to its investment decision.

On December 30, 2011, we issued 847,566 (post-split) shares of our restricted common stock to our shareholders of record pursuant to a 10% stock dividend approved by our Board of Directors.

Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during the years ended December 31, 2011 or 2010.

Item 6. Selected Financial Data.

Not applicable.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Overview of Current Operations

We are a publicly traded distributor of life-saving and life-enhancing prescription and non-prescription diagnostics to several channels in the healthcare industry, a developer of patent-pending technologies for e-health and EMR applications that we employ to leverage and add value to our prescription and non-prescription diagnostics business, and a technology provider to the lodging industry. We have recently added modules to our medical and EMR applications that allow for the management of medical products distribution and reporting management. We are in the initial stages of marketing these new modules under the trade name Decision IT.

Our proprietary MD@Work, MD@Hand and MD@Practice-Probe technologies manage critical data, enhance productivity and e-commerce, and facilitate communication with applications in the healthcare, medical distribution and hotel/motel markets and industries. We have recently focused our business attention towards providing prescription drugs and medical diagnostics through several medical distribution channels. In March 2010, the Board of Directors authorized the sale of our Residenceware technologies and customer list.

During the next 12 months, we plan to continue to focus our efforts on the following primary businesses:

- Providing medical communication devices based on networks of personal digital assistants (smart cell phone). These products are believed to provide benefits of on demand medical information to private practice physicians, licensed medical service providers such as diagnostic testing laboratories, and medical insurers;

- The distribution of medical diagnostic products primarily aimed at institutions that service patients with diabetic and asthma related diseases and ailments. Our current market focus for these products is the assisted living and long term care sector of the larger healthcare market, however we plan to expand into additional sectors where we can service certain chronic ambulatory disease states;

- Providing medical communication devices based on networks of personal digital assistants (smart cell phone) and desktop computers with software that manages decision, control, audit and fulfillment for the medical products distribution markets. These products are believed to provide benefits of on demand medical information to medical products manufacturers as part of their financial management of distribution contracts;

- The distribution and fulfillment of prescriptions for ethical pharmaceuticals primarily aimed at the indigent and uninsured sectors of the greater medical service markets. Our first market focus for these products will be those state Medicaid and federally chartered clinics (and initiatives) where funding for pharmaceutical fulfillment enterprises exists.

Seasonality

The distribution of medical products and medical diagnostics in aggregate account for the overwhelming percentage of our revenues. Our experiences point to a business that displays certain seasonal trends. In each of the last four operating years, our order intake was concentrated in the first five months of the calendar year and to an identifiable but lesser degree in the last two months of the calendar year. One explanation is that these months correspond with the beginning of a prescription drug plan years where new prescription drug cards are distributed by insurers to their insured in January along with new plan formularies (price schedules). This in turn trends to influence "stocking up" buying/ordering behavior on the part of the insured. We anticipate that these trends will be affected by the introduction of Shasta Genstrip where initial stocking by the company's retail customers and distribution chains.

Results of Operations for the years ended December 31, 2011 and 2010 compared.

The following tables summarize selected items from the statement of operations for the years ended December 31, 2011 compared to 2010.

INCOME:

	For the Years Ended December 31,		Increase (Decrease)	
	2011	2010	$	%
Revenue	$ 12,112,093	$ 18,913,712	$ (6,801,619)	(36%)
Cost of sales	9,236,052	17,277,058	(8,041,006)	(47%)
Gross profit	$ 2,876,041	$ 1,636,654	$ 1,239,387	76%
Gross profit margin	23.75%	8.65%		174%

Revenue for the fiscal year ended December 31, 2011 was $12,112,000 compared to revenue of $18,914,000 in the fiscal year ended December 31, 2010. The significant 36% decline in revenue is the result of limited access to our credit facility, which is a necessary component in facilitating our conversion cycle. In addition, we also attribute a portion of the decline to general economic conditions evidenced by a decrease in our accounts receivable turnover ratio in 2011.

We experienced a 47% decrease in our cost of goods due in part to our revenue decrease but more significantly was the result of managements re-negotiated wholesale costing of our largest volume product from our major suppliers. As a result of stronger buying power and despite our limited liquidity, our increase gross profit margin increased 174% over the previous fiscal year from 9% to 24%.

OPERATING EXPENSES:

	For the Years Ended December 31,		Increase (Decrease)	
	2011	2010	$	%
Expenses:				
General & administrative	$ 307,488	$ 337,154	$ (29,665)	(9%)
Consulting	139,924	310,449	(170,525)	(55%)
Payroll expense	54,641	58,524	(3,883)	(7%)
Professional fees	111,373	146,227	(34,854)	(24%)
Operating expenses	613,426	852,354	(238,927)	(28%)
Bad debt expense	3,269,908	-	3,269,908	-
Total operating expenses	3,883,334	852,354	3,030,981	356%
Net operating (loss) income	$ (1,007,293)	$ 784,300	$ (1,791,594)	

Our normal operating expenses decreased by approximately 28% over the previous year. The most significant decrease related to a decline in the amounts paid to our consults. As we become more established in our business segment and with our customer relationships, we are less dependent on outside sources for market entry points as evidenced by the $171,00 decline in fees. However, we do anticipate a continuation in our consulting expense primarily in connection with market expansion and the introduction of new products. We will also continue to utilize outside consultants in our efforts to secure additional financing for the stability and growth of the Company.

Total overall operating expenses incurred during 2011 increased 356% specifically due to the amount of uncollectible accounts receivable and the addition of a collection allowance which we have not previously required. During 2011, we experienced an increase in the number of days for conversion of our accounts receivable. Historically our accounts receivable turnover ratio approximated 7.0, at December 31, 2011 this ratio declined to 3.72. We believe the change in turnover is directly related to the impact of a depressed economic environment. Our customer base is concentrated among four significant purchasers and when combined, they represent 88% of our total sales and 95% of our accounts receivable balance at December 31, 2011. In 2010, the amounts owed to us by this group totaled $2.6M, all of which was within payment terms. At December 31, 2011, this same group had outstanding balances totaling $3.8M of which $2.6M exceeded normal payment terms. Due to the uncertainty of the collectability, we have recorded a reserve allowance of $1.2M and a direct write-down of $2M. We believe it necessary to maintain a conservative approach with respect to presentation however, we are also confident that as economic conditions improve, we will experience a return to historical trends.

OTHER INCOME (EXPENSE):

	For the Years Ended December 31,		Increase (Decrease)	
	2011	2010	$	%
Other income (expense)				
Financing costs	$ (488,843)	$ (186,899)	$ 301,994	162%
Interest expense	(483,720)	(458,280)	25,440	6%
Settlement expense	(179,000)	(648,004)	(469,004)	(72%)
Gain on debt settlement	41,850	34,046	7,804	23%
Other income	-	3,000	(3,000)	-
Total operating expenses	(1,109,713)	(1,256,137)	(136,766)	(11%)
Net (loss)	$ (2,117,006)	$ (471,837)	$ 1,645,170	347%

Our other income and expense represents costs related to our financing activities, more specifically the costs associated with our line of credit with Alpha Credit Resources LLC ("Alpha Credit"), formerly Centurion Credit Resources LLC. Alpha Credit had provided us a line of credit up to $2,500,000. Our credit line came to term on December 31, 2011. Our costs associated with maintaining our line of credit include the issuance of shares of our common stock equal to 80% of each advance. During 2011, we were advanced a total of $5,500,000 compared to $15,800,000 in 2010. The fair value of shares issued in connection with these advances is included in financing costs. In addition to the share issuances, pursuant to the term of our agreement with Alpha Credit, we are charged interest at a rate of 2% per month on the unpaid principal balance. During 2011, we recorded $457,000 compared to $401,000 in 2010. The remaining interest expense of $27,000 originates from two notes payable with a total principal balance of $184,000 and credit card interest.

For the years ended December 31, 2011 and 2010, management has entered into various agreements for the settlement of the Company's historic debt obligations. As a result of these negotiated settlements, the Company's obligations have been reduced from their historical carrying amounts. In 2010, settlements were negotiated down $34,000 compared to $42,000 in 2011. In addition to the negotiated gains, we also agreed to pay a settlement fee of $117,214 to one note holder upon the conversion of the principal balance of the note. We do not anticipate further gains on debt settlement or other settlement cost during 2012.

Liquidity and Capital Resources

A critical component of our operating plan impacting our continued existence is the ability to obtain additional capital through additional equity and/or debt financing. We do not anticipate generating sufficient positive internal operating cash flow until such time as we can deliver our product to market, complete additional financial service company acquisitions and generate substantial revenues, which may take the next few years to fully realize. In the event we cannot obtain the necessary capital to pursue our strategic plan, we may have to cease or significantly curtail our operations. This would materially impact our ability to continue operations.

The following table summarizes our current assets, liabilities and working capital at December 31, 2011 compared to December 31, 2010.

	December 31,		Increase (Decrease)	
	2011	2010	$	%
Current assets	$ 4,537,949	$ 4,690,218	$ (24,971)	(29%)
Current liabilities	2,532,217	2,127,110	405,107	19%
Working capital	$ 2,005,732	$ 2,563,108	$ (557,376)	(22%)

Internal and External Sources of Liquidity

MAG Entities Agreement

On February 7, 2005, we entered into agreements with Mercator Momentum Fund, LP and Monarch Pointe Fund, Ltd. (collectively, the "Purchasers") and Mercator Advisory Group, LLC, later known as MAG Capital, LLC ("MAG"). Under the terms of the agreements, we agreed to issue and sell to the Purchasers, and the Purchasers agreed to purchase from the Company, 20,000 shares of Series "C" Convertible Preferred Stock at $100.00 per share. Additionally, we issued 1,250,000 warrants to purchase share of our common stock at $1.60 per share, all of the warrants expired on February 7, 2008. However, prior to the expiration of the warrants, MAG ordered the company to transfer the warrants originally issued to Mercator Momentum Fund, LP and Monarch Pointe Fund, Ltd. to MAG Capital, LLC, in breach of the agreements.

Through September 30, 2009, MAG had converted 2,140 shares of their Series "C" preferred into 1,372,901 shares of our restricted common stock. Subsequently MAG attempted to convert shares without seeking the company's concurrence, a breach of the agreements. On several occasions, MAG succeeded. In addition, MAG pre-sold shares that would have resulted from conversions, a breach of the anti-short sale provisions of the agreements. On October 8, 2008 the company received a letter from Kroll (BVI) Limited of the British Virgin Islands ("Receiver" or "Liquidator") informing the company that the Monarch Pointe Fund, Ltd ("Monarch") had lapsed into receivership and/or liquidation. The company was advised to cease all written and/or oral communications with MAG Capital, LLC.

Beginning in late 2009 we have received and exchanged additional letters regarding this liquidation whereupon the Liquidator made specific demands for certain stock and repayment of a certain Promissory Note. However these demands were never made specific enough for the company to respond in any way other than to ask the Liquidator to provide full documentation supporting their alleged claims. Subsequently on June 24, 2010, Monarch Point Fund, Ltd. (in receivership) brought an action in federal district court against Decision Diagnostics Corp., Keith Berman and Robert Cox. The company and Mr. Berman intend to vigorously defend this suit and also intend to file counterclaims in this matter. On August 12, 2010 we received an initial settlement offer through the counsel for the Liquidator. Subsequently there have been additional offers and counter-offers. Among other stated issues these offers of settlement will bring an end to the litigation.

On May 31, 2011, we issued 214,286 (post-split) shares of our $0.001 par value common stock to Monarch Point Fund, Ltd. to settle the case out of court. The value of the shares on the date of issuance was $120,000.

Convertible Loan Payment Agreement

On July 17, 2006, we entered into a convertible loan payment agreement with Wayne G. Knapp wherein Mr. Knapp agreed to loan the Company the sum of $200,000. The loan is for 120 days. On October 17, 2006, we renewed the note. On January 17, 2007, the parties verbally agreed to a renewal that expires on May 16, 2007. The note accrues monthly interest at a rate of 1.50% and the interest is payable quarterly in cash. The total amount owing pursuant to the agreement, was convertible at the option of Mr. Knapp at any time from July 17, 2006 until November 30, 2006, at the strike price equal to $0.32 per share or 90% of the final bid price of our common stock on the day prior to conversion with a floor price of $0.10 per share. We renewed Mr. Knapp's conversion option on January 17, 2007. We also issued Mr. Knapp a warrant to purchase 3,571 (post-split) shares of our common stock at $4.48 per share through December 31, 2009. Mr. Knapp exercised his option on March 30, 2007. In March 2010, Mr. Knapp elected to convert his note and accrued interest into 207,143 common stock shares.

Alpha Credit Resources LLC (formerly Centurion Credit)

On November 17, 2007, we entered into an agreement with Alpha Credit Resources LLC to secure a $1,000,000 revolving credit facility that is geared specifically to our business. As of October 2008, the company renewed its agreement with Alpha Credit Resources LLC until November 17, 2009 and as an inducement to renew the credit line was increased to $2,000,000, with additional seasonal increases to $2,500,000. In June 2010 we began discussions with Alpha Credit for an additional $6.0 million credit facility to provide available credit to finance sales of our new at-home testing diagnostic product. The company last borrowed funds using the credit line in the period ended September 30, 2011. The agreement matured on December 31, 2011 without renewal. In March of 2012, we executed a renewal agreement with Alpha Credit. The renewal period matures on December 31, 2012. As of the date of this filing we have not utilized the line of credit available.

Cragmont Capital, LLC

In March 2008, we entered into a Convertible Promissory Note Purchase Agreement with Cragmont Capital, LLC ("Cragmont") wherein Cragmont agreed to loan the Company an aggregate sum of $250,000. As of September 30, 2008, we have received $75,000. Cragmont contends the loan was for one year, maturing on February 28, 2009. The total amount owing pursuant to the agreement, was convertible at the option of the lender, at a strike price equal to $0.015 per share. Further, we agreed subject to certain conditions to issue 100 warrants with a strike price of $0.03 expiring on December 31, 2010 for every dollar loaned by Cragmont.

The warrant transaction was conditioned upon Cragmont purchasing the warrant at closing. No agreement was ever reached with Cragmont as to the purchase price for the warrants, and they were never purchased by Cragmont at the closing. During the year ended December 31, 2008, we terminated our relationship with Cragmont. On March 10, 2010, we issued payment in the amount of $75,000 to Cragmont, representing the return of partial funding pursuant to our rescission of the March 1, 2008 agreement. The company entered formal settlement discussions covering the remainder of the agreement in dispute in July 2010 and completed the settlement in October, 2010.

Cash Flow.

Since inception, we have primarily financed our cash flow requirements through the issuance of common stock, the issuance of notes and sales generated income. With anticipated growth in 2012 we may, during our normal course of business, experience net negative cash flows from operations, pending receipt of revenue, which often are delayed because of the nature of the healthcare industry. Further, we may be required to obtain financing to fund operations through additional common stock offerings and bank or other debt borrowings, to the extent available, or to obtain additional financing to the extent necessary to augment our available working capital.

Satisfaction of our cash obligations for the next 12 months.

As of December 31, 2011, our cash balance was $14,869. Our plan for satisfying our cash requirements for the next twelve months is through additional equity, third party financing, and/or debt financing. We anticipate sales-generated income during that same period of time, but do not anticipate generating sufficient amounts of positive cash flow to meet our working capital requirements. Consequently, we intend to make appropriate plans to insure sources of additional capital in the future to fund growth and expansion through additional equity or debt financing or credit facilities.

As we expanded operational activities, we may continue, from time to time, to experience net negative cash flows from operations, pending receipt of sales or development fees, and will be required to obtain additional financing to fund operations through common stock offerings and debt borrowings to the extent necessary to provide working capital. It was not until the company entered into the agreement with Alpha Credit Resources LLC that the company could fill orders for patients and customers on a continuous basis. Until the Alpha Credit line was put in place, we managed to keep a small portion of our distribution activities going when our limited resources allowed us which remains true as of this filing.

Predictions of future operating results are difficult to ascertain due to our historic operating activities. The recent addition of a credit line has helped but we have found it increasingly difficult to transact commerce in the very cash intensive prescription drug industry. Thus, our prospects must be considered in light of the risks, expenses and difficulties frequently encountered by companies in their early stages of commercial viability, particularly companies in new and rapidly evolving technology markets. Such risks include, but are not limited to, an evolving and unpredictable business model and the management of growth. To address these risks we must, among other things, implement and successfully execute our business and marketing strategy, continue to develop and upgrade technology and products, respond to competitive developments, and continue to attract, retain and motivate qualified personnel. There can be no assurance that we will be successful in addressing such risks, and the failure to do so can have a material adverse effect on our business prospects, financial condition and results of operations.

Expected purchase or sale of plant and significant equipment.

We do not anticipate the purchase or sale of any plant or significant equipment; as such, items are not required by us at this time.

Going Concern

The financial statements included in this report have been prepared in conformity with generally accepted accounting principles that contemplate the continuance of the Company as a going concern. The Company's cash position is currently inadequate to pay all of the costs associated with testing, production and marketing of products. Management intends to use borrowings and security sales to mitigate the effects of its cash position, however no assurance can be given that debt or equity financing, if and when required will be available. The financial statements do not include any adjustments relating to the recoverability and classification of recorded assets and classification of liabilities that might be necessary should the Company be unable to continue existence.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results or operations, liquidity, capital expenditures or capital resources that is material to investors.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

Not applicable.

Item 8. Financial Statements and Supplementary Data.

Management Responsibility for Financial Information

We are responsible for the preparation, integrity and fair presentation of our financial statements and the other information that appears in this annual report on Form 10-K. The financial statements have been prepared in accordance with accounting principles generally accepted in the United States and include estimates based on our best judgment.

We maintain a system of internal controls and procedures designed to provide reasonable assurance, with an appropriate cost-benefit relationship, that our financial information is accurate and reliable, our assets are safeguarded, and our transactions are executed in accordance with established procedures.

We retained Weaver Martin & Samyn LLC (2011) and Seale & Beers, CPA's (2010) independent registered public accounting firms, to audit our consolidated financial statements. Their accompanying reports are based on audits conducted in accordance with the standards of the Public Company Accounting Oversight Board (United States).

Index to Financial Statements

Report of Independent Registered Public Accounting Firm

Shareholders and Directors
Decision Diagnostics Corp
Westlake Village, California

We have audited the accompanying consolidated balance sheet of Decision Diagnostics Corp. (formerly instaCare Corp) as of December 31, 2011 and the related consolidated statement of operations, shareholders' equity, and cash flows for the year then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatements. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Decision Diagnostics Corp (formerly instaCare Corp) as of December 31, 2011 and the consolidated results of its operations, shareholders' equity, and cash flows for the year then ended in conformity with U.S. generally accepted accounting principles.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses from operations. This factor raises substantial doubt about the Company's ability to continue as a going concern. Management's plans with regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Weaver Martin & Samyn LLC
Kansas City, Missouri
April 13, 2012

SEALE AND BEERS, CPAs
PCAOB & CPAB REGISTERED AUDITORS
www.sealebeers.com

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Decision Diagnostics Corp. (formerly InstaCare Corp)
Westlake Village, CA

We have audited the accompanying consolidated restated balance sheet of Decision Diagnostics Corp (formerly InstaCare Corp) as of December 31, 2010, and the related consolidated statements of operations, stockholders' equity and cash flows for the year then December 31, 2010. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audit in accordance with standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Decision Diagnostics Corp (formerly InstaCare Corp) as of December 31, 2010 (restated), and the related consolidated statements of operations, stockholders' equity and cash flows for the year then December 31, 2010, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses from operations, which raises substantial doubt about its ability to continue as a going concern. Management's plans concerning these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

As discussed in Note 11 to the financial statements, the Company has restated its balance sheet.

/s/ Seale and Beers, CPAs

Seale and Beers, CPAs
Las Vegas, Nevada
April 15, 2011, except for Notes 1 and 3, which the date is May 20, 2011

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Decision Diagnostics Corp.
(Formerly InstaCare Corp.)
Consolidated Balance Sheet

	December 31, 2011	2010 (Restated)
Assets		
Current assets:		
Cash	$ 14,869	$ 220,390
Accounts receivable, net of allowance	3,256,504	3,155,184
Prepaid expenses	1,266,576	1,314,644
Total current assets	4,537,949	4,690,218
Other assets		
Intellectual property	69,535	9,950
Total other assets	69.535	9,950
Total assets	$ 4,607,484	$ 4,700,168
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable and accrued liabilities	$ 222,659	$ 188,043
Accrued interest	134,712	116,521
Line of credit – related party	-	1,598,801
Line of credit	1,992,168	-
Notes payable and short term borrowings	182,678	223,745
Total current liabilities	2,532,217	2,127,110
Contingencies	205,500	205,500
Shareholders' Equity		
Preferred stock, $0.001 par value, 3,237,500 shares authorized, no shares issued and outstanding as of December 31, 2011 and 2010, respectively	-	-
Preferred series "B" stock, $0.001 par value, 2,500 shares authorized 1,000 and no shares issued and outstanding as of December 31, 2011 and 2010, respectively	1	-
Preferred series "C" stock, $0.001 par value, 10,000 shares authorized, 1,250 and no shares issued and outstanding as of December 31, 2011 and 2010, respectively	1	-
Preferred series "E" stock, $0.001 par value, 1,750,000 shares authorized, 1,095,300 and 1,110,000 shares issued and outstanding as of December 31, 2011, and 2010, respectively	1,095	1,110
Common stock, $0.001 par value, 1,750,000,000 shares authorized, 9,307,934 and 7,332,198shares issued and outstanding as of December 31, 2011 and 2010, respectively	9,308	7,332
Subscription receivable	(68,315)	(80,000)
Additional paid in capital	22,061,746	20,456,179
Accumulated (deficit)	(20,134,069)	(18,017,063)
Total Shareholders' equity	1,869,767	2,367,558
Total liabilities and Shareholders' equity	$ 4,607,484	$ 4,700,168

The accompanying notes are an integral part of these consolidated financial statements.

Decision Diagnostics Corp.
(Formerly InstaCare Corp.)
Consolidated Statements of Operations

	The Years Ended December 31,	
	2011	**2010**
Revenue:		
Sales	$ 12,112,093	$ 18,913,712
Cost of sales	9,236,052	17,277,058
Gross profit	2,876,041	1,636,654
Expenses:		
General & administrative	3,577,396	337,153
Consulting	139,924	310,449
Payroll expense	54,641	58,524
Professional fees	111,373	146,227
Total expenses	3,883,334	852,353
Net operating income (loss)	(1,007,293)	784,301
Other income (expense):		
Financing costs	(488,843)	-
Financing costs – related party	-	(186,899)
Interest expense	(483,720)	(57,499)
Interest expense – related party	-	(400,781)
Other income	-	3,000
Settlement expense	(179,000)	(648,004)
Gain on debt forgiveness	41,850	34,046
Total other income (expense)	(1,109,713)	(1,256,137)
Net (loss)	(2,117,006)	(471,837)
Add: Dividends declared on preferred	-	-
(Loss) available to common shareholders'	$ (2,117,006)	$ (471,837)
Weighted average common shares outstanding – basic and fully diluted	8,080,645	6,684,291
Net (loss) per share –basic and fully diluted	$ (0.26)	$ (0.07)

The accompanying notes are an integral part of these consolidated financial statements.

Decision Diagnostics, Corp.
(formerly InstaCare Corp.)
Consolidated Statement of Changes in Shareholders' Equity

	Preferred "B" Stock		Preferred "C" Stock		Preferred "E" Stock		Common Stock		Additional Paid-in Capital	Unamortized Share Issuances	Amortizable Equity Compensation	Accumulated (Deficit)	Total
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount					
Balance, December 31, 2009	-	$ -	-	$ -	932,216	$ 932	5,475,160	$ 5,475	$18,825,679	$ -	$ (67,363)	$(17,545,226)	$1,219,496
Shares issued for services	-	-	-	-	-	-	43,929	44	55,946	-	-	-	55,990
Options and warrants issued for services	-	-	-	-	-	-	-	-	119,774	-	-	-	119,774
Shares issued for financing	-	-	-	-	-	-	3,261	3	122,314	-	-	-	122,317
Options exercised for cash	-	-	-	-	-	-	523,810	524	311,476	(80,000)	-	-	232,000
Conversion of Series E preferred stock	-	-	-	-	(222,216)	(222)	561,786	562	(341)	-	-	-	-
Series E escrow shares issued for financing	-	-	-	-	200,000	200	-	-	(200)	-	-	-	-
Series E issued for renewal fee	-	-	-	-	200,000	200	-	-	399,800	-	-	-	400,000
Shares issued for debt conversion	-	-	-	-	-	-	724,253	724	621,731	-	-	-	622,455
Amortization of prepaid finance fees	-	-	-	-	-	-	-	-	-	-	21,250	-	21,250
Amortization – equity compensation	-	-	-	-	-	-	-	-	-	-	46,113	-	46,113
Net (loss)	-	-	-	-	-	-	-	-	-	-	-	(471,837)	(471,837)
Balance, December 31, 2010	-	-	-	-	1,110,000	1,110	7,332,199	7,332	20,456,179	(80,000)	-	(18,017,063)	2,367,558
Shares issued for services	-	-	-	-	-	-	174,000	174	85,081	-	-	-	85,255
Shares released to escrow	-	-	-	-	175,000	175	-	-	84,825	-	-	-	85,000
Shares issued for financing	-	-	-	-	-	-	954	1	37,174	-	-	-	37,175
Shares issued to escrow for financing	1,000	1	-	-	-	-	-	-	(1)	-	-	-	-
Shares issued for exercise options for cash	-	-	-	-	-	-	61,429	61	30,039	-	-	-	30,100
Conversion of Series E preferred stock	-	-	-	-	(189,700)	(190)	677,500	678	(488)	-	-	-	-
Shares issued for debt settlement	-	-	-	-	-	-	214,286	214	119,786	-	-	-	120,000
Shares for patent legal defense	-	-	1,250	1	-	-	-	-	1,249,999	-	-	-	1,250,000
Subscription payment	-	-	-	-	-	-	-	-		11,685	-	-	11,685
10% stock dividend	-	-	-	-	-	-	847,566	848	(848)	-	-	-	-
Net (loss)	-	-	-	-	-	-	-	-	-	-	-	(2,117,006)	(2,117,006)
Balance, December 31, 2011	1,000	$ 1	1,250	$ 1	1,095,300	$ 1,095	$9,307,934	$ 9,308	$22,061,746	$ (68,315)	$ -	$(20,134,069)	$1,869,767

The accompanying notes are an integral part of these consolidated financial statements.

Decision Diagnostics, Corp.
(Formerly InstaCare Corp.)
Consolidated Statements of Cash Flows

	For the Years Ended December 31,	
	2011	2010
Cash flows from operating activities		
Net (loss)	$ (2,117,006)	$ (471,837)
Adjustments to reconcile net income to net cash provided (used) by operating activities		
Shares and options issued for services	85,255	175,767
Shares issued for financing	122,174	122,317
Amortization of financing fees	366,667	54,583
Bad debt allowance	1,241,043	1,156,750
Shares issued for settlement expenses	120,000	-
Gain on debt settlement	(41,849)	(34,046)
Changes in operating assets and liabilities:		
Accounts receivable	(1,342,363)	(699,287)
Prepaid expenses	1,298,068	(863,605)
Accounts payable	(24,971)	6,053
Accrued liabilities	59,587	(82,383)
Accrued interest	24,705	35,874
Net cash (used) by operating activities	(208,690)	(599,817)
Cash flows (used) in investing activities		
Intellectual property	(59,585)	(9,950)
Net cash (used) by investing activities	(59,585)	(9,950)
Cash flows from financing activities		
Proceeds (payments), line of credit	26,701	-
Proceeds (payments), line of credit – related party	-	371,902
Payments on notes payable	(5,732)	(13,047)
Options exercised for cash	41,785	232,000
Net cash provided by financing activities	62,754	590,855
Net (decrease) in cash	(205,521)	(18,912)
Cash – beginning	220,390	239,302
Cash – ending	$ 14,869	$ 220,390
Supplemental disclosures:		
Interest paid	$ 458,239	$ 418,247
Income taxes paid	$ -	$ -
Non-cash transactions:		
Shares and options issued for services	$ 85,255	$ 175,767
Shares issued for settlement expenses	$ 120,000	$ -
Shares issued for financing activities	$ 122,174	$ 122,317
Shares issued for debt conversion	$ -	$ 622,454

The accompanying notes are an integral part of these consolidated financial statements

Decision Diagnostics Corp.
(Formerly InstaCare Corp.)
Notes to Consolidated Financial Statements

Note 1 – Significant accounting policies and procedures

Organization

We were organized July 6, 2000 (Date of Inception) under the laws of the State of Nevada as Promedicius, Inc. In May 2001, we changed our name to Medicius, Inc. On June 21, 2002, we merged with ATR Search Corp., a development stage company, and a Nevada corporation. The merger has been accounted for as a recapitalization and the historical financial statements of Medicius Inc. are presented herein.

On June 21, 2002, we filed an amendment to its articles of incorporation changing our name to CareDecision Corporation and subsequently changed our name to Decision Diagnostics Corp. effective April 14, 2005.

On November 19, 2004, we incorporated two Nevada subsidiary companies, Pharma Tech Solutions, Inc. and PDA Services, Inc. On November 24, 2004, we entered into an "Agreement and Plan of Merger", as amended on December 27, 2004, between Pharma Tech Solutions, Inc. and CareGeneration, Inc. ("CareGen"), a Nevada corporation. This agreement included CareGen's private acquisition of retail pharmaceutical license applications, client lists, receivables, business contacts, relationships, goodwill and the rights to use the wholesale pharmaceutical distribution license, trade names and sales names of Kelly Company World Group, Inc., a Delaware corporation. On February 25, 2005, the merger was completed whereby CareGen merged with Pharma Tech wherein CareGen ceased to exist and Pharma Tech continued as a majority owned subsidiary.

On January 4, 2005, we commenced prescription drug distribution, which are, currently being conducted through our Pharma Tech Solutions, Inc. and PDA Services, Inc. subsidiaries. We specialize in rapid delivery of prescription drugs and diagnostic products; we are in the final stages of augmenting its prescription drug and prescription diagnostics distribution business by creating a nationwide network over the internet. We have also created a fully integrated prescription fulfillment program through which physicians can directly submit prescriptions using a hand-held device, tablet PC, or smart cell phone that is enabled through a Wi-Fi link to the Internet.

Since 2005, we have established five fulfillment centers to service primarily diabetic patients in the states of New Jersey, New York, Arizona and Maryland.

Through the acquisition of CareGen, we acquired a retail mail order business concept for the distribution of pharmaceutical and healthcare supplies and are currently developing our distribution platform.

On October 25, 2011 the Board of Directors approved the payment of a ten percent (10%) stock dividend to all shareholders of record, said dividend payable to shareholders of record no later than December 31, 2011.

As a part our efforts to transition the company toward a full service and vertically integrated provider of at-home diagnostics, on November 1, 2011, as a condition of the merger of Diagnostics Newco LLC, from its sole owner, the company completed a name change action through the office of Nevada Secretary of State (NVSOS). The surviving entity is known as Decision Diagnostics Corp. This action through the office of the NVSOS was effective as of November 25, 2011.

As part our efforts to secure a listing on a new stock exchange, we completed another action with the NVSOS, where a previously approved board resolution to reverse split our shares was finalized. Our stock was split whereby one new share of the company's common stock was exchanged for every fourteen previously issued and outstanding shares of our $.001 par value common stock. This action was effective as of November 25, 2011. All share references included herein have been retroactively restated to reflect the 1:14 reverse split.

Principles of Consolidation

The financial statements include those of: Decision Diagnostics Corp. ("Decision Diagnostics"); and its wholly owned subsidiaries, PDA Services, Pharmtech, Inc. Pharmatech Solutions, Inc. and Decision IT. All significant inter-company transactions and balances have been eliminated. Decision Diagnostics and its subsidiaries are collectively referred to herein as the "Company". Investments in unconsolidated subsidiaries representing ownership of at least 20% but less than 50% are accounted for under the equity method. Non-marketable investments in which the Company has less than 20% ownership and in which it does not have the ability to exercise significant influence over the investee are initially recorded at cost and periodically reviewed for impairment. As of December 31, 2011 and 2010, we did not have non-marketable investments.

Cash and cash equivalents

Cash and cash equivalents include all cash balances in non-interest bearing accounts and money-market accounts. We place our temporary cash investments with quality financial institutions. At times, such investments may be in excess of Federal Deposit Insurance Corporation (FDIC) insurance limit. We do not believe it is exposed to any significant credit risk on cash and cash equivalents. For the purpose of the statements of cash flows, all highly liquid investments with an original maturity of three months or less are considered to be cash equivalents. There are no cash equivalents as of December 31, 2011 and 2010.

Credit Risks

Financial instruments that potentially subject us to concentrations of credit risk consist principally of cash deposits. Accounts at each institution are insured by the Federal Deposit Insurance Corporation (FDIC) up to $250,000. At December 31, 2011 and 2010, we did not have balances in excess of FDIC insured limits.

Accounts receivable and Allowance for Doubtful Accounts Receivable

Trade accounts receivables are non-interest bearing and are stated at gross invoice amounts less an allowance for doubtful accounts receivable.

Credit is extended to customers based on an evaluation of their financial condition and other factors. The Company generally does not require collateral or other security to support accounts receivable. The Company performs ongoing credit evaluations of its customers and maintains an allowance for doubtful accounts.

The Company estimates its allowance for doubtful accounts by evaluating specific accounts where information indicates the customers may have an inability to meet financial obligations, such as bankruptcy proceedings and receivable amounts outstanding for an extended period beyond contractual terms. In these cases, the Company uses assumptions and judgment, based on the best available facts and circumstances, to either record a specific allowance against these customer balances or to write off the balances. In addition, the Company calculates an overall reserve based on a percentage of the overall gross accounts receivable. This percentage is based on management's assessment of the aging of accounts receivable, historical write-offs of receivables and the associated risk profile of the Company's customer base. As of December 31, 2011, the Company believed all its receivables to be collectible and had zero in the allowance.

Accounts receivable balances were $3,256,504 (net of allowance for doubtful accounts of $1,241,043) and $3,155,184 (net of allowance for doubtful accounts of $0) for the years ended December 31, 2011 and 2010, respectively.

Inventory

Inventories are stated at the lower of cost or market. Cost is determined on a standard cost basis that approximates the first-in, first-out (FIFO) method. Market is determined based on net realizable value. Appropriate consideration is given to obsolescence, excessive levels, deterioration, and other factors in evaluating net realizable value. As of December 31, 2011 and 2010, inventory was $0 and $0, respectively.

Revenue recognition

We recognize revenue in accordance with ASC subtopic 605-10 (formerly SEC Staff Accounting Bulletin No. 104 and 13A, "Revenue Recognition") net of expected cancellations and allowances. As of December 31, 2011 and 2010, we evaluated evidence of cancellation in order to make a reliable estimate and determined there were no material cancellations during the years and therefore no allowances has been made.

We recognize revenue from our sales of pharmaceutical supplies upon delivery to its customer where the fee is fixed or determinable, and collectability is probable. Cash payments received in advance are recorded as deferred revenue. We are not generally obligated to accept returns, except for defective products.

Revenue from proprietary software sales that does not require further commitment from the company is recognized upon shipment. Consulting revenue is recognized when the services are rendered. License revenue is recognized ratably over the term of the license.

Advertising costs

We expense all costs of advertising as incurred. There were no advertising costs included in general and administrative expenses as of December 31, 2011 and 2010, respectively.

Use of estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates. As of December 31, 2011 and 2010, we have accrued contingent legal fees and product liability fees totaling $205,500.

Fair value of financial instruments

Fair value estimates discussed herein are based upon certain market assumptions and pertinent information available to management as of December 31, 2011 and 2010. The respective carrying value of certain on-balance-sheet financial instruments approximated their fair values. These financial instruments include cash, accounts receivable, accounts payable, accrued liabilities and notes payable. Fair values were assumed to approximate carrying values because they are short term in nature and their carrying amounts approximate fair values or they are payable on demand.

Impairment of long-lived assets

The Company reviews its long-lived assets and intangibles periodically to determine potential impairment by comparing the carrying value of the long-lived assets with the estimated future cash flows expected to result from the use of the assets, including cash flows from disposition. Should the sum of the expected future cash flows be less than the carrying value, the Company would recognize an impairment loss. An impairment loss would be measured by comparing the amount by which the carrying value exceeds the fair value of the long-lived assets and intangibles. The Company recognized no impairment losses during the years ended December 31, 2011 and 2010.

Earnings per share

Earnings per share are provided in accordance with ASC Topic 260 "Earnings per Share" (as amended). The Company presents basic earnings per share ("EPS") and diluted EPS on the face of consolidated statements of operations. Basic EPS is computed by dividing reported earnings by the weighted average shares outstanding. Diluted EPS is computed by adding to the weighted average shares the dilutive effect if stock options and warrants were exercised into common stock. Basic loss per share is computed by dividing losses available to common Shareholders by the weighted average number of common shares outstanding during the period. Basic earnings per common share are based on the weighted average number of common shares outstanding during the year. Diluted earnings per share is based on the weighted average number of common shares, plus all stock options and warrants convertible into common stock for an additional 60,714 common shares; all preferred stock converted into common stock for an additional 3,964,286 common shares; and all convertible debt converted into common stock for an additional 345,238 common shares.

Income Taxes

The Company follows ASC subtopic 740-10 (formerly Statement of Financial Accounting Standard No. 109, "Accounting for Income Taxes") for recording the provision for income taxes. ASC 740-10 requires the use of the asset and liability method of accounting for income taxes. Under the asset and liability method, deferred tax assets and liabilities are computed based upon the difference between the financial statement and income tax basis of assets and liabilities using the enacted marginal tax rate applicable when the related asset or liability is expected to be realized or settled. Deferred income tax expenses or benefits are based on the changes in the asset or liability each period. If available evidence suggests that it is more likely than not that some portion or all of the deferred tax assets will not be realized, a valuation allowance is required to reduce the deferred tax assets to the amount that is more likely than not to be realized. Future changes in such valuation allowance are included in the provision for deferred income taxes in the period of change.

Deferred income taxes may arise from temporary differences resulting from income and expense items reported for financial accounting and tax purposes in different periods. Deferred taxes are classified as current or non-current, depending on the classification of assets and liabilities to which they relate. Deferred taxes arising from temporary differences that are not related to an asset or liability are classified as current or non-current depending on the periods in which the temporary differences are expected to reverse.

Concentrations

In 2011, four of our customers accounted for approximately 88% of our net sales compared to 99% of total sales being attributable to six major customers in 2010. Since January 1, 2006 our operations require maintaining strategic relationships with our customers whereby we deliver product and services directly to the patient base that underlies these strategic relationships, accepting assignment of insurance benefit through our Colonia Natural Pharmacy strategic partnership for the billing and future servicing of these patients. We also maintain relationships with the entities where the patients reside. As of December 31, 2011 and 2010, we obtained the majority of our pharmaceutical products from five major suppliers. There can be no assurance that our major customers will continue to purchase products. The loss of our largest customers or a decrease in product sales would have a material adverse effect on our business and financial condition.

Reclassifications

Certain reclassifications have been made to the prior years' financial statements to conform to the current year presentation. These reclassifications had no effect on previously reported results of operations or retained earnings.

New Accounting Standards Adopted During the Year Ended December 31, 2011

In January 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update 2011-01 (ASU 2011-01) Receivables (Topic 310): Deferral of the Effective Date of Disclosures about Troubled Debt Restructurings in Update No. 2010-20. ASU 2011-01 temporarily delays the effective date of the disclosures about troubled debt restructurings. The effective date of the new disclosures about troubled debt restructurings for public entities and the guidance for determining what constitutes a troubled debt restructuring will then be coordinated. Currently, the guidance is effective for interim and annual periods ending after June 15, 2011. We do not expect the provisions of ASU 2011-01 to have a material effect on our financial position, results of operations or cash flows.

Other pronouncements issued by the FASB or other authoritative accounting standards groups with future effective dates are not applicable or are not expected to be significant to our financial statements.

Previous year financial information has been presented to conform to current year financial statement presentation.

Year-end

We have adopted December 31 as our fiscal year end.

Note 2 – Going concern

The accompanying consolidated financial statements have been prepared assuming that we will continue as a going concern. Our ability to continue as a going concern is dependent upon attaining profitable operations based on the development of distributions platforms through which our products that can be sold. We intend to use borrowings and security sales to mitigate the effects of our cash position, however, no assurance can be given that debt or equity financing, if required, will be available. The condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded assets and classification of liabilities that might be necessary should we be unable to continue in existence.

Note 3 – Fair value

Our financial instruments consist principally of notes payable and lines of credit. Notes payable and lines of credit are financial liabilities with carrying values that approximate fair value. Management determines the fair value of notes payable and lines of credit based on the effective yields of similar obligations and believe all of the financial instruments' recorded values approximate fair market value because of their nature and respective durations.

We comply with the provisions of ASC 820, *"Fair Value Measurements and Disclosures"* ("ASC 820"). ASC 820 defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements required under other accounting pronouncements. ASC 820-10-35, *"Fair Value Measurements and Disclosures - Subsequent Measurement"* ("ASC 820-10-35"), clarifies that fair value is an exit price, representing the amount that would be received from the sale of an asset or paid to transfer a liability in an orderly transaction between market participants. ASC 820-10-35 also requires that a fair value measurement reflect the assumptions market participants would use in pricing an asset or liability based on the best information available. Assumptions include the risks inherent in a particular valuation technique (such as a pricing model) and/or the risks inherent in the inputs to the model. The Company also follows ASC 825 *"Interim Disclosures about Fair Value of Financial Instruments"*, to expand required disclosures.

ASC 820-10-35 establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (level 1 measurement) and the lowest priority to unobservable inputs (level 3 measurements). The three levels of the fair value hierarchy under ASC 820-10-35 are described below:

Level 1. Valuations based on quoted prices in active markets for identical assets or liabilities that an entity has the ability to access.

Level 2. Valuations based on quoted prices for similar assets or liabilities, quoted prices for identical assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable data for substantially the full term of the assets or liabilities.

Level 3. Valuations based on inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The Company utilizes the best available information in measuring fair value. The following table summarizes, by level within the fair value hierarchy, the financial assets and liabilities recorded at fair value on a recurring basis as of December 31, 2011:

	Fair Value Measurements			
	Level 1	Level 2	Level 3	Total Fair Value
Liabilities				
Notes payable	$ -	$ 182,678	$ -	$ 182,678
Line of credit	-	1,992,168	-	1,992,168
Total	$ -	$ 2,174,846	$ -	$ 2,174,846

Note 4 – Line of credit (formerly deemed a related party)

In December of 2010, we executed our renewal agreement with Alpha Credit for an additional one-year term which matures on December 31, 2011. Pursuant to the renewal terms, our line of credit was increased from $2,000,000 to a maximum of $2,500,000. Further, pursuant to the terms of the agreement, we agreed to issue 200,000 shares of our preferred Series "E" stock as a renewal fee valued at $400,000. The loan renewal fee is amortized using the straight-line method over the one-year renewal period. As of December 31, 2011 and 2010, we have recorded $366,667 and $33,333, respectively in financing expense related to this fee. The line of credit requires interest to be paid in shares equal to 5% of each advance, and an additional 2% to be paid in cash and accrues monthly on the unpaid principal balance. In January of 2011, we were notified of a discrepancy in the principal loan balance through confirmation requests. Pursuant to paragraph 6 of our amended and restated loan agreement dated December 31, 2010, any recourse that would have been afforded to us is negated by agreement to "remise, release and forever discharge lender from any and all claims, losses, liabilities demands and causes of action of any kind whatsoever, whether absolute or contingent, known or unknown, matured or un-matured". The discrepancy in balance was the result of an interpretation of the interest calculation and amount to $573,004. At December 31, 2010, we recorded a settlement expense in this amount. During the current, our line of credit activity included advances of $5,473,721 and repayments of $5,447,020. We did not utilize our line of credit during the fourth quarter of 2011. At December 31, 2010, Alpha Credit was deemed to be a related party. However, during the year ended December 31, 2011, the Company no longer deemed the related party status applicable.

The following summarizes our line of credit activity for the years ended December 31:

	2011	2010
Balance, January 1	$ 1,598,801	$ 1,593,566
Add: advances	5,447,020	15,465,797
Less: repayments	(5,473,721)	(15,837,699)
	1,992,168	1,965,468
Less: Amortizable loan fee	-	(366,667)
Balance, December 31	$ 1,992,168	$ 1,598,801

As of December 31, 2011 and 2010 we recorded interest and financing expenses in connection with our line of credit in the amount of $945,825 and $587,680, respectively

Note 5 – Notes payable

Notes payable consisted of the following as of December 31:

	2011	2010
(a) Convertible promissory note, bearing interest at a 1.25% per month, matured on October 31, 2007, currently in default.	$ 145,000	$ 145,000
(b) Promissory note, bearing interest at 9% per annum, maturing June 20, 2012.	37,678	78,745
Total notes payable	182,678	223,745
Less current portion	182,678	223,745
Total long-term notes payable	$ -	$ -

a) In 2005, our former CEO determined that it was in the best interests of the company to borrow funds by offering a series of convertible promissory notes to private investors. The principal sum of these notes was $170,000. Pursuant to these notes, we agreed to pay these note holders the principal balance plus accrued interest at an annual rate of 15% maturing in one year from the date of issuance. Our former CEO employed the services of a sales agent and paid this agent certain fees in 2005 and 2006. On March 30, 2010 after a dispute arose, we entered into a debt settlement agreement with the one investor for the payment of his principal balance of $25,000 and accrued interest of $15,938 for a total amount owed of $40,938. Pursuant to the settlement agreement, we issued 21,429 (post-split) shares of our common stock valued at $34,500 and agreed to pay an additional $15,000 in cash to the investor for a total sum of $49,500. The excess payment of $8,562 was recorded as interest expense. As of December 31, 2011, the principal balance owed to the remaining investors was $145,000 with accrued interest of $277,938.

b) On June 20, 2007, we entered into a promissory note with Invacare for the principal amount of $160,385, bearing interest at a rate of 9% per annum and maturing on June 10, 2010. Pursuant to the terms of the note, we are required to make monthly principal and interest payments of $3,300. On March 1, 2011, Invacare issued a new note superseding the June 2007 note, whereby extending the maturity and re-stating the principal amount due to eliminate debt forgiveness of $41,849 comprise of accrued interest of $6,514 and principal of $35,335. As of December 31, 2011 the unpaid principal balance together with accrued interest was $40,708.

We have recorded interest expense in connection with these notes of $24,704 and $30,026 for the years ended December 31, 2011 and 2010, respectively.

Note 6 – Income taxes

At December 31, 2010, the Company had approximately $20,100,000 of federal and state net operating losses. For the years ended December 31, 2011 and 2010, the Company reported net losses of $2,117,006 and $471,836, respectively. No provision for income tax expense has been record. In addition no benefit for income taxes has been recorded due to the uncertainty of the realization of any tax assets. The net operating loss carry forwards, if not utilized will begin to expire in 2017-2023.

The components of the Company's deferred tax asset are as follows:

	As of December 31,	
	2011	2010
Deferred tax assets:		
Net (loss)	$ (2,117,006)	$ (471,837)
Stock, options, and warrants issued	327,429	298,084
Taxable (loss)	(1,798,577)	(173,753)
Net operating loss carry forwards	18,190,816	18,017,063
Total deferred tax asset	19,989,393	18,190,816
Income tax rate	35%	35%
	6,996,288	6,366,786
Less: valuation allowance	(6,996,288)	(6,366,786)
Net deferred tax asset	$ -0-	$ -0-

For financial reporting purposes, the Company has incurred historical losses. Based on the available objective evidence, including the Company's history of its loss, management believes it is more likely than not that, the net deferred tax assets will not be fully realizable. Accordingly, the Company provided for a full valuation allowance against its net deferred tax assets at December 31, 2011.

A reconciliation between the amounts of income tax benefit determined by applying the applicable U.S. and State statutory income tax rate to pre-tax loss is as follows:

	Years Ended December 31,	
	2011	2010
Federal and state statutory rate	35%	35%
Change in valuation allowance on deferred tax assets	(35%)	(35%)
	-0-	-0-

Note 7 – Shareholder's equity

We are authorized to issue up to 1,750,000,000 shares of $0.001 par value common stock and 6,262,500 shares of various classes of $0.001 par value preferred stock. In March of 2011, we amended our preferred stock designations as follows: 1) withdrawal of Series "A" designation on 750,000 shares of preferred stock, 2) withdrawal of Series "C" designation on 1,000,000 shares of preferred stock, 3) Designation of Series "B" on 2,500 shares of preferred stock and Series "C" on 10,000 shares of preferred stock, and 4) increased the number of preferred shares designated as Series "E" from 1,000,000 to 1,250,000. All presentation of preferred stock contained herein has been retroactively presented to reflect the 2011 amendments.

Series "B" convertible preferred stock

We have designated 2,500 shares of our $0.001 preferred stock as Series "B". Holders of series "B": convertible stock shall not have the right to vote on matters that come before the shareholders. Series "B" convertible preferred stock may be converted, the number of shares into which one share of Series "B" Preferred Stock shall be convertible into common stock shares shall be 50. Series "B" convertible stock shall rank senior to common stock in the event of liquidation. Holders' of Series "B" convertible stock shall not be entitled to a mandatory monthly dividend. Series "E" convertible stock shall have a redemptions price equal to 101% of the purchase price per share, subject to adjustments resulting from stock splits, recapitalization, or share combination.

Series "C" convertible preferred stock

We have designated 10,000 shares of our $0.001 preferred stock as 2011 Series "C". Each share of 2011 Series C Preferred stock is valued at $10,000. Holders of series "C": convertible stock shall not have the right to vote on matters that come before the shareholders. 2011 Series "C" convertible preferred stock may be converted after 36 months, but not before, the number of shares into which one share of 2011 Series "C" Preferred Stock shall be convertible on a pro-rata basis into common stock shares, each share of common stock valued at $.50. 2011 Series "C" convertible stock shall rank junior to all other classes of Preferred stock in the event of liquidation. Holders' of 2011 Series "C" convertible stock shall not be entitled to a mandatory monthly dividend.

Series "E" convertible preferred stock

We have designated 1,250,000 shares of our $0.001 preferred stock as Series "E". Holders of series "E": convertible stock shall not have the right to vote on matters that come before the shareholders. Series "E" convertible preferred stock may be converted, the number of shares into which one share of Series "E" Preferred Stock shall be convertible into common stock shares shall be 14. Series "E" convertible stock shall rank senior to common stock in the event of liquidation. Holders' of Series "E" convertible stock shall not be entitled to a mandatory monthly dividend. Series "E" convertible stock shall have a redemptions price equal to 101% of the purchase price per share, subject to adjustments resulting from stock splits, recapitalization, or share combination.

2010 Issuances

Preferred

During the year ended December 31, 2010, we issued 254,100 shares of our preferred Series "E" from the 2009 escrowed stock to Alpha Credit Resources as financing fees in connection with our line of credit. We have recorded financing fees in the amount of $107,993 in connection with these issuances. Throughout the year, Alpha Credit has elected to convert 222,216 shares of their preferred series "E" into 561,786 (post-split) shares of common stock.

In December 2010, we entered into our second "Amended and Restated Promissory Note" with Alpha Credit Resources LLC ("Alpha Credit"). Pursuant to the amended agreement, we issued 200,000 shares of our Series "E" preferred stock as a renewal fee. The fair value of the issuance totaled $400,000 and was amortized over the renewal period of one-year. As of December 31, 2010, we recorded $33,333 in financing fees and have a remaining unamortized balance of $366,667.

In October 2010, we entered into an "Escrow Agreement" pursuant to the aforementioned "Amended and Restated Promissory Note" whereby agreeing to issue an additional 200,000 shares of our preferred Series "E" stock to be held in escrow for the benefit of Alpha Credit as collateral against the aforementioned line of credit. As of December 31, 2010, we recorded $200, the par value of the shares held in escrow, as additional paid-in capital.

Common

As of December 31, 2010, we issued 724,253 (post-split) shares of our common stock for the conversion of various promissory notes and accrued interest (See Note 4). The fair value of the shares issued totaled $622,455.

During the year ended December 31, 2010, we issued a total of 43,929 (post-split) shares of our common stock to various consultants for services rendered to us. The fair value of the services received was $55,990 and was recorded as consulting fees.

As of December 31, 2010, we issued 523,810 (post-split) shares of our common stock pursuant for the exercise of options. Total proceeds from the exercise were $312,000. At December 31, 2010, $80,000 remained outstanding and was recorded as a miscellaneous receivable.

During the year ended December 31, 2010, we authorized the issuance of 3,261 (post-split) shares of common stock to Alpha Credit resources as financing fees in connection with our line of credit. The fair value of the shares is $14,324 and was recorded as financing costs.

2011 Issuances

Preferred

During the year ended December 31, 2011, we issued 1,000 shares of our preferred series "B" stock to Alpha Credit Resources for financing costs valued at $1.

During the year ended December 31, 2011, we issued 1,250 shares of our preferred series "C" stock to our patent attorney for prepaid patent defense legal fees valued at $1,250,000.

During the year ended December 31, 2011, we issued 189,700 shares of our preferred series "E" from the 2010 escrowed stock to Alpha Credit Resources as financing fees in connection with our line of credit. We have recorded financing fees in the amount of $488,843 in connection with these issuances. Throughout the year, Alpha Credit has elected to convert 189,700 shares of their preferred series "E" into 677,500 (post-split) shares of common stock.

Common

On December 31, 2011, we affected a 1:14 reverse split of our $0.001 par value common stock. All common stock references have been retroactively restated to reflect the reverse split.

On December 31, 2011, we issued 847,566 shares of our $0.001 par value common stock pursuant to a 10% stock dividend declared by our board of directors on October 25, 2011.

During the year ended December 31, 2011, we issued a total of 174,000 (post-split) shares of our common stock to various consultants for services rendered to us. The fair value of the services received was $85,225 and was recorded as consulting fees.

As of December 31, 2011, we issued 61,429 (post-split) shares of our common stock pursuant for the exercise of options. Total proceeds from the exercise were $30,100.

During the year ended December 31, 2011, we authorized the issuance of 954 (post-split) shares of common stock to Alpha Credit Resources as financing fees in connection with our line of credit. The fair value of the shares is $37,175 and was recorded as financing costs.

During the year ended December 31, 2011, we issued 677,500 (post-split) shares of common stock to Alpha Credit Resources upon their election to convert shares of preferred series "E" stock into shares of our common stock.

During the year ended December, 31, 2011, we issued 214,286 (post-split) shares of our common stock to an investment fund in order to settle debt valued at $120,000.

Note 8 – Options

2004 Stock Option Plan

Effective April 21, 2004, we adopted the "2004" Stock Option Plan, as amended, with a maximum number of 450,893 (post-split) shares that may be issued. As of December 31, 2011, 398,104 (post-split) options have been granted and exercised or expired under this plan. There are 52,789 options which remain available for issuance.

2005 Merger Consolidated Stock Option Plan

On February 5, 2005, we adopted our "2005" Merger Consolidated Stock Option Plan. The maximum number of shares that may be issued pursuant to the plan is 80,357 (post-split) shares. As of December 31, 2011, 77,307 (post-split) shares have been granted under this plan and 3,050 remain available for issuance.

During the year ended December 31, 2010, we issued options to purchase up to 14,286 (post-split) shares of par value common stock at a weighted average exercise price of $0.80 per share for various consulting services received. We recorded an expense in the amount of $21,293 the fair value of the options using the Black-Scholes pricing model.

2006 Stock Option Plan

On December 8, 2006 we adopted our "2006 Employee Stock Option Plan, as amended and granted incentive and nonqualified stock options with rights to purchase 1,821,429 (post-split) shares of our $0.001 par value common stock. As of December 31, 2011, 1,023,725 (post-split) options were granted and exercised or expired under this plan and 797,704 remain available for issuance.

During the year ended December 31, 2010, we issued options to purchase up to 150,000 (post-split) shares of par value common stock at a weighted average exercise price of $0.59 per share for various consulting services received. We recorded an expense in the amount of $98,481 the fair value of the options using the Black-Scholes pricing model. As of December 31, 2010, the options were exercised in exchange for cash in the amount of $80,000 which has been recorded as a subscription receivable.

During the year ended December 31, 2011, we issued options to purchase up to 159,439 (post-split) shares of par value common stock at a weighted average exercise price of $0.30 (post-split) per share for various consulting services received. We recorded an expense in the amount of $85,255 the fair value of the options using the Black-Scholes pricing model.

During the year ended December 31, 2011, 61,429 (post-split) options were exercised for cash totaling $30,100.

The following is a summary of activity of outstanding stock options under all Stock Option Plans:

	Number of Shares (post-split)	Weighted Average Exercise Price
Balance, January 1, 2010	321,429	$ 0.77
Options granted	176,072	0.66
Options cancelled	-	-
Options exercised	(483,215)	0.73
Balance, December 31, 2010	14,286	$ 0.80
Balance, January 1, 2011	14,286	$ 0.80
Options granted	159,439	0.46
Options cancelled	-	-
Options exercised	(159,439)	0.46
Balance, December 31, 2011	14,286	$ 0.80

Note 9 – Warrants

On December 5, 2010, we issued a warrant to purchase 17,857 (post-split) shares of our common stock with an exercise price of $0.658 pursuant to a service agreement. The fair market value of the warrants based on the Black-Scholes model is $10,047 using the following assumptions: Strike Price $0.047; Stock Price $0.035; Volatility 275%; Term 1 year; Dividend Yield 0%; Interest Rate 0.28%. As of December 31, 2010, we have recorded consulting expense in the amount of $10,047.

The following is a summary of activity of outstanding warrants:

	Number of Shares (post-split)	Weighted Average Exercise Price
Balance, January 1, 2010	652,381	$ 0.56
Warrants granted	17,857	0.49
Warrants cancelled	(564,286)	1.09
Warrants exercised	(59,524)	0.42
Balance, December 31, 2010	46,428	$ 0.86
Balance, January 1, 2011	46,428	$ 0.86
Warrants granted	-	-
Warrants cancelled	(28,571)	1.09
Warrants exercised	-	-
Balance, December 31, 2011	17,857	$ 0.49

Note 10 – Commitments and Contingencies

Leases

We currently maintain an executive office at 2660 Townsgate Road, Suite 300, Westlake Village, CA 91361. The space consists of approximately 2,300 square feet. The monthly rental for the space is $4,140 per month on a month-to-month basis.

On June 7, 2005, we entered into an agreement for the right to use offices, warehouses and shipping facilities for the storage and shipping of pharmaceuticals located at 515 Inman Avenue, Colonia, NJ 07067 and 25 Minna Street, Rahway, New Jersey

Rent expense amounted to $99,098 and $81,710 for the years ended December 31, 2011 and 2010, respectively.

Contingencies

Given the nature and liability of our industry, we periodically review our litigation contingencies that may result from damaged product, product liability and the related legal fees. As of December 31, 2011 and 2010, we accrued $205,500 for these contingencies.

Note 11 – Restatement of financial statements

In connection with the review of our financial statements for the three-month period ended March 31, 2011, it was determined by our independent registered accounting firm, that the application of accounting principles with respect to the recording of stock issued in lieu of cash for annual loan renewal fees, was not applicable to our transaction with Alpha Credit Resources. We have restated our balance sheet for the year ended December 31, 2010 to reflect the reclassification of the fair value of the renewal fee, net of amortization as a discount against the line of credit liability verses the previously presentation as an amortizable asset. The effects of the change in application of accounting principal is limited solely to the balance sheet whereby decreasing total assets and liabilities by $366,667.

The following table presents the effect of the restated adjustment by financial statement line item for the Consolidated Balance Sheet for the year ended December 31, 2010:

	For the Year Ended December 31, 2010		
	As re-stated	Adjust-ments	As previously Stated
Assets			
Current assets:			
Cash	$ 220,390		$ 220,390
Accounts receivable	3,155,184		3,155,184
Prepaid expenses	1,314,644		1,314,644
Total current assets	4,690,218		4,690,218
Fixed assets:			
Furniture and fixtures	2,530		2,530
Computer equipment	232,365		232,365
Less accumulated depreciation	234,895		234,895
Fixed assets, net	-		-
Other assets			
Intellectual property	9,950		9,950
Amortizable loan fees	-	(366,667)	366,667
Total other assets	9,950		376,617
Total assets	$ 4,700,168		$ 5,066,835
Liabilities and Shareholders' Equity			
Current liabilities:			
Accounts payable	$ 87,235		$ 87,235
Accrued liabilities	100,808		100,808
Accrued interest	116,521		116,521
Notes payable and short term borrowings	1,822,546	366,667	2,189,213
Total current liabilities	2,127,110		2,493,777
Contingencies	205,000		205,500
Shareholders' Equity			
Preferred series "B" stock, $0.001 par value, 2,500 shares authorized no shares issued and outstanding as of December 31, 2010 and 2009, respectively	-		-
Preferred series "C" stock, $0.001 par value, 20,000 shares authorized, no shares issued and outstanding as of December 31, 2010 and 2009, respectively	-		-
Preferred series "E" stock, $0.001 par value, 1,250,000 shares authorized, 1,110,000 and 932, 616 shares issued and outstanding as of December 31, 2010, and 2009, respectively	1,110		1,110
Common stock, $0.001 par value, 1,750,000,000 shares authorized, 7,332,199 and 5,475,160 shares issued and outstanding as of December 31, 2010 and 2009, respectively	102,651		102,651
Subscription receivable	(80,000)		(80,000)
Additional paid in capital	20,360,860		20,360,860
Accumulated (deficit)	(18,017,063)		(18,017,063)
Total Shareholders' equity	2,367,558		2,367,558
Total liabilities and Shareholders' equity	$ 4,700,168		$ 5,066,835

Note 12 – Subsequent events

On January 11, 2012, we issued 294,000 (post-split) shares of common stock to Alpha Credit Resources upon their election to convert 21,400 shares of preferred series "E" stock into shares of our common stock.

On January 18, 2012, we issued 53,354 (post-split) shares of common stock pursuant to a note holders' election to convert his note payable.

On March 5, 2012, we issued 500,000 (post-split) shares of common stock to various consultants for advisory services.

On March 30, 2012, we issued 238 (post-split) shares of common stock and 124,700 preferred series "E" stock to Alpha Credit Resources in connection with our line of credit renewal.

In accordance with ASC 855, management evaluated all activity of the Company through the issue date of the financial statements and concluded that no other subsequent events have occurred that would require recognition or disclosure in the financial statements.

Item 9. Changes in and Disagreements With Accountants On Accounting and Financial Disclosure.

On August 5, 2011, we dismissed Seale & Beers, CPA's as our independent auditor and engaged Weaver Martin & Samyn, LLC for the year ended December 31, 2011. This is a change in accountants recommended and approved by our Executive Management and our Board of Directors. During the most recent two fiscal years and the portion of time preceding the decision to engage Weaver Martin & Samyn LLC, we did not nor did anyone engaged on our behalf consult with Weaver Martin & Samyn LLC regarding (i) either the application of accounting principles to a specified transaction, either completed or proposed; or the type of audit opinion that might be rendered on our financial statements; or (ii) any matter that was either the subject of a disagreement (as defined in Item 304(a)(1)(iv) of Regulation S-K) or a reportable event.

The audit reports issued by Seale & Beers, CPA's with respect to our financial statements for the fiscal years ended December 31, 2010did not contain an adverse opinion or disclaimer of opinion, and were not qualified or modified as to uncertainty, audit scope, or accounting principles, except that Seale & Beers CPA's report contained an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern. From January of 2011 through the notice date, there were no disagreements between us and Seale & Beers CPA's on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of Seale & Beers, CPA's would have caused it to make a reference to the subject matter of the disagreement in connection with its audit report.

The change in accountants is as a result of dissatisfaction with the quality of professional services rendered by Seale & Beers, CPA's, as the independent accountants of the Registrant. The firm of Seale & Beers, CPA's proved to be difficult to work with, and unreasonable in the application of certain audit procedures during the performance of its audit function.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) are designed to ensure that information required to be disclosed in reports filed or submitted under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms and that such information is accumulated and communicated to management, including the chief executive officer and the chief financial officer, to allow timely decisions regarding required disclosures.

In connection with the preparation of this Report, Keith Berman, our Chief Financial Officer, conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2011. Based on that evaluation our Chief Financial Officer has concluded that our disclosure controls and procedures were effective as of December 31, 2011.

Management's Report on Internal Control over Financial Reporting.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as is defined in the Securities Exchange Act of 1934. These internal controls are designed to provide reasonable assurance that the reported financial information is presented fairly, that disclosures are adequate and that the judgments inherent in the preparation of financial statements are reasonable. There are inherent limitations in the effectiveness of any system of internal control, including the possibility of human error and overriding of controls. Consequently, an effective internal control system can only provide reasonable, not absolute, assurance, with respect to reporting financial information.

Management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework and criteria established in Internal Control — Integrated Framework, issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2011.

This annual report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit us to provide only management's report in this annual report.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Our executive officers, directors, and key employees are:

Name	Age	Position
Keith Berman	59	Chief Financial Officer and Director
William Lyons	59	Director
Robert Jagunich	64	Director

Our shareholders elect our directors annually and our board of directors appoints our officers annually. As of the date of this filing, we have not held an annual meeting. All current directors have been held over until such time the annual meeting is held. Vacancies in our board are filled by the board itself. Set forth below are brief descriptions of the recent employment and business experience of our executive officers and directors.

Keith Berman has served as President, Chief Financial Officer, Secretary, Treasurer and Director of the Company since January of 2003. For over the past 15 years, Mr. Berman has been involved in the development of healthcare software including Intranet and Internet systems. From July 1999 to present, Mr. Berman has held the position of President, founder and director of Caredecision.net, Inc. a private company engaged in e-health technology development. From March 2001 through June 2002 Mr. Berman also held the Position of President and Director or Medicius, Inc. From January 1996 to June 1999 Mr. Berman was the President and founder of Cymedix, the operating division of Medix Resources, Inc., now Ramp Corp. (RCO). Cymedix was a pioneer company in what was then known as i-health (Internet healthcare) now the e-health industry. Mr. Berman's professional background provides the Company with business management experience and an in depth knowledge of our industry. Mr. Berman received a BA in 1975 and an MBA in 1977, from Indiana University.

Robert Jagunich has served as a Director of the Company since January of 2003. Mr. Jagunich has 27 years of experience in the medical systems and device industry. From August 1992 to present, he has held the position of President at New Abilities Systems, a privately held manufacturer of advanced electronic systems used in rehabilitation. He also provides consulting services to companies such as Johnson and Johnson and has served as a senior executive in such publicly held companies as Laserscope and Acuson. From April 1996 to December 1997 Mr. Jagunich acted as a director of Cymedix Corporation, the operating entity of Medix Resources, Inc., and later, Ramp Corp. (formerly AMEX:RCO). Mr. Jagunich's professional focus on medical devices as well as the professional relationships he has developed throughout his career provides the Company with opportunities to expand current markets and utilize additional product resources not previously available. He received his BS in 1969, and his MS and MBA in 1971, from the University of Michigan.

William Lyons has served as a Director of the company from January 2003 through October 2003 and most recently from January 2010 to the present time. Mr. Lyons is currently President and COO of Beacon Medical, Inc. a company specializing in the development, manufacturing, marketing and distribution of medical devices and instruments targeted primarily to the Plastic Surgery medical specialty. Prior to that, Mr. Lyons was co-founder, Executive Vice President and Director of BioElectronics Corporation. Mr. Lyons has successfully performed as President or Executive Vice President of several healthcare start-up communication technology and digital integration corporations. Mr. Lyons has also served in various executive positions for several fortune 500 companies such as American Sterilizer Company, Everest and Jennings and Allscrips. Mr. Lyon's professional experience with start-up companies in the medical technology industry as well as his knowledge in finance provide the Company with guidance in capital formation and sustainability. He holds an MBA in finance and a BA in Philosophy.
Mr. Berman, officer and director, devotes his complete business time to the Company. Mr. Jagunich attends meetings of the board of directors when held and provides 33% of his business time in a professional capacity to the Company.

Code of Ethics

We have not yet adopted a code of ethics that applies to our principal executive officers or persons performing similar functions, since we have been focusing our efforts on obtaining financing for the company. We expect to adopt a code by the end of the current fiscal year.

Audit Committee

The entire board of directors acts as our audit committee. We do not have an audit committee financial expert serving on our audit committee at this time. We propose to expand our board of directors in the near future to include a financial expert.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934 requires our officers, directors, and persons who beneficially own more than 10% of our common stock to file reports of securities ownership and changes in such ownership with the Securities and Exchange Commission ("SEC"). Officers, directors and greater than 10% beneficial owners are also required by rules promulgated by the SEC to furnish us with copies of all Section 16(a) forms they file.

Based solely upon a review of the copies of such forms furnished to us, or written representations that no Form 5 filings were required, we believe that during the fiscal year ended December 31, 2011, there was no compliance with Section 16(a) filing requirements applicable to our officers, directors and greater than 10% beneficial owners.

Item 11. Executive Compensation

The following table sets forth information the remuneration of our Principal Executive officer for the years ended December 31, 2011 and 2010 and earned in excess of $100,000 per annum during any part of our last two fiscal years:

Summary Compensation Table

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Keith Berman,	2011	$ -0-	-0-	$ -0-	-0-	-0-	-0-	-0-	$ -0-
CFO and PEO [1] [2][3]	2010	$ -0-	-0-	$ -0-	-0-	-0-	-0-	-0-	$ -0-

Mr. Berman has served as Chief Financial Officer since January 2003 and as Principal Executive Officer since August 2006.During the fiscal years ended December 31, 2011 and 2010, Mr. Berman has not received any form of compensation as a result of our limited cash flow; Mr. Berman has agreed to accept stock awards as his sole compensation until such time the Company has the necessary resources available to provide a traditional compensation plan.

Grants of Plan-Based Awards in Fiscal 2011

We did not grant any plan-based awards to our named executive officer during the fiscal year ended December 31, 2011.

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END

Name (a)	Number of Securities Underlying Unexercised Options (#) Exercisable (b)	Number of Securities Underlying Unexercised Options (#) Un-exercisable (c)	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#) (d)	Option Exercise Price (S) (e)	Option Expiration Date (f)	Number of Shares or Units of Stock That Have Not Vested (#) (g)	Market Value of Shares or Units of Stock That Have Not Vested ($) (h)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#) (i)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested (j)
Keith Berman, Secretary/Treasurer	-0-	-0-	-0-	$ -0-	- 0-	-0-	-0-	-0-	-0-

Option Exercises for 2011

There were no options exercised by our named executive officer in fiscal 2011.

Director Compensation

The following table sets forth compensation paid to our board member during the year ended December 31, 2011.

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards ($)	Non-Equity Incentive Plan Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Keith Berman	-	-	-	-	-	-
Robert Jagunich	-	-	-	-	-	-
William Lyons	-	-	-	-	-	-

Amount represents the aggregate fair market value of the underlying shares of common stock issued for services as a Director in accordance with FASB ASC Topic 718, as discussed in the notes to the audited financial statements included in this report.

All directors will be reimbursed for expenses incurred in attending Board or committee, when established, meetings. From time to time, certain directors who are not employees may receive shares of our common stock.

Stock Option Plans

2004 Stock Option Plan

Effective April 21, 2004, we adopted the "2004" Stock Option Plan, as amended, with a maximum number of 450,893 shares that may be issued. As of December 31, 2011, 398,104 options have been granted, and exercised or expired under this plan.

2005 Merger Consolidated Stock Option Plan

On February 5, 2005, we adopted our "2005" Merger Consolidated Stock Option Plan. The maximum number of shares that may be issued pursuant to the plan is 80,357 shares. As of December 31, 2010, 77,307 options have been granted and exercised or expired under this plan.

2006 Stock Option Plan

On December 8, 2006, we adopted our "2006 Employee Stock Option Plan" as amended and granted incentive and nonqualified stock options with rights to purchase 1,821,429 shares of our $0.001 par value common stock. As of December 31, 2011, 1,023,725 options have been granted and exercised or expired under this plan.

ITEM 12. Security Ownership of Certain Beneficial Owners and Management and Related Shareholder Matters.

The following table presents information, to the best of our knowledge, about the ownership of our common stock on December 31, 2011 relating to those persons known to beneficially own more than 5% of our capital stock and by our directors and executive officers. The percentage of beneficial ownership for the following table is based on 9,307,976 shares of common stock outstanding.

Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission and does not necessarily indicate beneficial ownership for any other purpose. Under these rules, beneficial ownership includes those shares of common stock over which the shareholder has sole or shared voting or investment power. It also includes shares of common stock that the shareholder has a right to acquire within 60 days after December 31, 2011 pursuant to options, warrants, conversion privileges or other right. The percentage ownership of the outstanding common stock, however, is based on the assumption, expressly required by the rules of the Securities and Exchange Commission, that only the person or entity whose ownership is being reported has converted options or warrants into shares of our common stock.

Name of Beneficial Owner, Officer or Director[1]	Number of Shares	Percent of Outstanding Shares of Common Stock [2]
Keith Berman, Chief Financial Officer and Director[3]	480,103	5.1%
Robert Jagunich, Director[3][4]	929,301	9.9%
William Lyons	-	-
Directors and Officers as a Group	1,409,404	15%
Barbara Asbell 7061 Los Coyotes Camarillo, CA 93012	1,162,590	29.7%
Directors, Officers and Beneficial Owners as a Group	2,571,994	44.8%

(1) As used in this table, "beneficial ownership" means the sole or shared power to vote, or to direct the voting of, a security, or the sole or shared investment power with respect to a security (i.e., the power to dispose of, or to direct the disposition of, a security).
(2) Figures are rounded to the nearest tenth of a percent.
(3) The address of each person is care of Decision Diagnostics: 2660 Townsgate Road, Suite 300, Westlake Village, CA 91361.
(4) Includes 89,286 shares r/n/o Michael Petras, an affiliate of Mr. Jagunich

Changes in Control Agreements

None.

Item 13. Certain Relationships and Related Transactions, and Director Independence

Other than as set forth below, we were not a party to any transactions or series of similar transactions that have occurred during fiscal 2011 in which:

- The amounts involved exceeds the lesser of $120,000 or one percent of the average of our total assets at year end for the last two completed fiscal years ($46,538); and
- A director, executive officer, holder of more than 5% of our common stock or any member of their immediate family had or will have a direct or indirect material interest.

None

Future Transactions

All future affiliated transactions will be made or entered into on terms that are no less favorable to us than those that can be obtained from any unaffiliated third party. A majority of the independent, disinterested members of our board of directors will approve future affiliated transactions. We believe that of the transactions described above have been on terms as favorable to us as could have been obtained from unaffiliated third parties as a result of arm's length negotiations.

Conflicts of Interest

In accordance with the laws applicable to us, our directors are required to act honestly and in good faith with a view to our best interests. In the event that a conflict of interest arises at a meeting of the board of directors, a director who has such a conflict will disclose the nature and extent of his interest to the meeting and abstain from voting for or against the approval of the matter in which he has a conflict.

Director Independence

Our common stock trades in the OTC Bulletin Board. As such, we are not currently subject to corporate governance standards of listed companies, which require, among other things, that the majority of the board of directors be independent.

Since we are not currently subject to corporate governance standards relating to the independence of our directors, we choose to define an "independent" director in accordance with the NASDAQ Global Market's requirements for independent directors (NASDAQ Marketplace Rule 4200). The NASDAQ independence definition includes a series of objective tests, such as that the director is not an employee of the company and has not engaged in various types of business dealings with the company.

We do not have any directors that may be considered an independent director under the above definition. We do not list that definition on our Internet website.

We presently do not have an audit committee, compensation committee, nominating committee, executive committee of our Board of Directors, stock plan committee or any other committees.

Item 14. Principal Accountant Fees and Services

(5)(i) The Board of Directors has not established an audit committee. However, the Board of Directors, as a group, carries out the responsibilities, which an audit committee would have. In this respect, the Board of Directors has the responsibility of reviewing our financial statements, exercising general oversight of the integrity and reliability of our accounting and financial reporting practices, and monitoring the effectiveness of our internal control systems. The Board of Directors also recommends selection of the auditing firm and exercises general oversight of the activities of our independent auditors, principal financial and accounting officers and employees and related matters.

The Board of Directors delegates to management of Mr. Berman, the terms of engagement, before we engage independent auditors for audit and non-audit services, except as to engagements for services outside the scope of the original terms, in which instances the services have been provided pursuant to pre-approval policies and procedures, established by management. These pre-approval policies and procedures are detailed as to the category of service and the Board of Directors is kept informed of each service provided.

(7) Weaver Martin & Samyn LLC was retained as our new auditing firm by the Board of Directors in August 2011, for the fiscal year ended December 31, 2011 replacing Seale & Beers, LLC. For the years ended December 31, 2011 and 2010 we were billed the following by each Firm for their respective years:

	For the Fiscal Years Ended December 31,	
	2011	2009
Audit Fees (a)	$ 35,500	$ 35,500
Audit-Related Fees (b)	-0-	-0-
Tax Fees (c)	-0-	-0-
All Other Fees (d)	-0-	-0-
Total fees paid or accrued to our principal accountants	$ 35,500	$ 35,500

(a) Includes fees for audit of the annual financial statements and review of quarterly financial information filed with the Securities and Exchange Commission.
(b) For assurance and related services that were reasonably related to the performance of the audit or review of the financial statements and not included in the Audit Fees category. The company had no Audit-Related Fees for the periods ended December 31, 2011, and 2010, respectively.
(c) For tax compliance, tax advice, and tax planning services, relating to any and all federal and state tax returns as necessary for the periods ended December 31, 2011 and 2010, respectively.
(d) For services in respect of any and all other reports as required by the SEC and other governing agencies.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

The following information required under this item is filed as part of this report:

(a) 1. Financial Statements

(b) 2. Financial Statement Schedules

None.

(c) 3. Exhibit Index

Exhibit number	Exhibit description	Filed herewith	Incorporated by reference			
			Form	Period ending	Exhibit No.	Filing date
3(i)(a)	Articles of Incorporation – Filed March 2, 2001		10-SB		3a	9/27/01
3(i)(b)	Articles of Amendments to Articles of Incorporation – Filed May 9, 2001		10-SB		3b	9/27/01
3(i)(c)	Articles of Amendments to Articles of Incorporation – Filed August 2, 2002		10-QSB	6/30/02	3.1c	8/22/02
3(ii)	Bylaws of CareDecision Corporation – March 16, 2001		10-SB		3c	9/27/01
10.1	Subscription Agreement – Mercator Momentum Fund, LP, Monarch Pointe Fund, LTD & Mercator Advisory Group, LLC – February 7, 2005		SB-2/A		10.1	2/11/05
10.2	Certificate of Designation of Preferences and Rights of Series C Convertible Preferred Stock – Mercator Momentum Fund, LP, Monarch Pointe Fund, LTD & Mercator Advisory Group, LLC – February 2005		SB-2/A		10.2	2/11/05
10.3	Registration Rights Agreement – Mercator Momentum Fund, LP, Monarch Pointe Fund, LTD & Mercator Advisory Group, LLC – February 2005		SB-2/A		10.3	2/11/05
10.4	Warrant Agreement ($0.02) – Mercator Advisory Group, LLC – February 7, 2005		SB-2/A		10.4	2/11/05
10.5	Warrant Agreement ($0.02) – Mercator Momentum Fund, LP – February 7, 2005		SB-2/A		10.5	2/11/05
10.6	Warrant Agreement ($0.02) - Monarch Pointe Fund, Ltd. – February 7, 2005		SB-2/A		10.6	2/11/05
10.7	Warrant Agreement ($0.03) - Mercator Advisory Group, LLC – February 7, 2005		SB-2/A		10.7	2/11/05
10.8	Warrant Agreement ($0.03) - Mercator Momentum Fund, LP – February 7, 2005		SB-2/A		10.8	2/11/05
10.9	Warrant Agreement ($0.03) – Monarch Pointe Fund, Ltd. – February 7, 2005		SB-2/A		10.9	2/11/05
10.10	Secured Convertible Promissory Note – Pinnacle Investment Partners, LP – March 24, 2004		SB-2/A		10.10	2/11/05
10.11	Pledge and Security Agreement – Pinnacle Investment Partners, LP – March 24, 2004		SB-2/A		10.11	2/11/05
10.12	Securities Purchase Agreement – Pinnacle Investment Partners, LP – March 24, 2004		SB-2/A		10.12	2/11/05
10.13	Note Extension Agreement – Pinnacle Investment Partners, LP – September 24, 2004		SB-2/A		10.13	2/11/05
10.14	Note Extension – Pinnacle Investment Partners, LP – February 10, 2005		SB-2/A		10.14	2/11/05
10.15	Intangible Property, License Acquisition Agreement – CN Pharmacy, Svetislav Milic, & Nathan Kaplan – June 7, 2005		8-K		10.1	10/21/05
10.16	Secured Promissory Note – Mercator Momentum Fund, LP – August 25, 2005		8-K		10.2	10/21/05
10.17	Secured Promissory Note – Monarch Pointe Fund, LTD – August 25, 2005		8-K		10.3	10/21/05
10.18	Amended and Restated Promissory Note – Alpha Credit Resources LLC – November 9, 2009		10-K/A		10.18	03/23/11
16.1	Letter of change in certifying accountant		8-K		16.1	04/12/11
23.1	Consent of Independent Registered Public Accounting Firm	X				
31.1	Certification of Principal Executive and Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X				
32.1	Certification of Principal Executive and Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X				

SIGNATURES

In accordance with Section 13 or 15(d) of the Securities Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Decision Diagnostics Corp.

By: */s/ Keith Berman*
Keith Berman, Chief Financial Officer

Date: May 17, 2011

Pursuant to the requirements of the Securities Exchange Act of 1934, the following persons on behalf of the Registrant, in the capacities, and on the dates indicated have signed this report below.

Name	Title	Date
/s/ Keith Berman Keith Berman	Chief Financial Officer, Director, Secretary (Principal Executive Officer and Principal Accounting Officer)	April 13, 2012
/s/ Robert Jagunich Robert Jagunich	Director	April 13, 2012
/s/ William Lyons William Lyons	Director	April 13, 2012

EXHIBIT W

10-Q 1 f10q093012_10q.htm SEPTEMBER 30, 2012 10-Q

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

☒ Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the quarterly period ended **September 30, 2012**

☐ Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the transition period from _____ to _____

Commission File Number: **000-29315**

DECISION DIAGNOSTICS CORP.

(Exact name of registrant as specified in its charter)

Nevada	**91-2105842**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
2660 Townsgate Road, Suite 300, Westlake Village California	**91361**
(Address of Principal Executive Offices)	(Zip Code)

(805) 446-1973
(Registrant's telephone number, including area code)

Decision Diagnostics Corp.
(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes ☐ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ☐ No ☒

Indicate the number of shares outstanding of each of the issuer's classes of common equity as of the latest practicable date: As of October 31, 2012 there were 11,477,726 shares of common stock, par value $0.001, outstanding.

PART I - FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS.
DECISION DIAGNOSTICS CORP.
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2012 (Unaudited)	December 31, 2011
Assets		
Current assets:		
Cash	$ 7,590	$ 14,869
Accounts receivable, net	3,109,124	3,256,504
Prepaid expenses	1,250,104	1,266,576
Total current assets	4,366,818	4,537,949
Other assets:		
Intellectual property	106,760	69,535
Total other assets	106,760	69,535
Total assets	$ 4,473,578	$ 4,607,484
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued liabilities	$ 773,644	$ 222,659
Accrued interest	132,638	134,712
Line of credit	2,288,376	1,992,168
Notes payable and short term debt (Note 5)	162,678	182,678
Total current liabilities	3,357,336	2,532,217
Contingencies	171,069	205,500
Stockholders' equity:		
Preferred stock, $0.001 par value, 2,247,500 shares authorized, 0 shares issued and outstanding as of September 30, 2012 and December 31, 2011, respectively	-	-
Preferred series "B" stock, $0.001 par value, 2,500 shares authorized, 1,000 and no shares issued and outstanding as of September 30, 2012 and December 31, 2011, respectively	1	1
Preferred series "C" stock, $0.001 par value, 1,000,000 shares authorized, 1,250 shares issued and outstanding as of September 30, 2012 and December 31, 2011, respectively	1	1
Preferred series "D" stock, $0.001 par value, 500 shares authorized, and no shares issued and outstanding as of September 30, 2012 and December 31, 2011, respectively	-	-
Preferred series "E" stock, $0.001 par value, 1,750,000 shares authorized, 1,199,000 and 1,095,300 shares issued and outstanding as of September 30, 2012 and December 31, 2011, respectively	1,187	1,095
Common stock, $0.001 par value, 494,950,000 shares authorized, 11,477,726 and 9,307,934 shares issued and outstanding as of September 30, 2012 and December 31, 2011, respectively	11,477	9,308
Subscription receivable	-	(68,315)
Additional paid-in capital	22,354,944	22,061,746
Accumulated (deficit)	(21,422,437)	(20,134,069)
Total stockholders' equity	945,173	1,869,767
Total liabilities and stockholders' equity	$ 4,.473,578	$ 4,607,484

(See accompanying notes to these condensed consolidated financial statements)

DECISION DIAGNOSTICS CORP.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(UNAUDITED)

	FOR THE THREE MONTHS ENDED SEPTEMBER 30,	
	2012	2011
Revenue	$ 1,223,060	$ 3,585,006
Cost of sales	747,550	2,617,756
Gross profit	475,511	967,250
Expenses:		
General and administrative	553,597	1,111,276
Consulting services	34,905	12,928
Compensation expense	7,886	6,228
Professional fees	88,876	34,375
Total Expenses	685,264	1,164,807
Net loss from operations	(209,753)	(197,557)
Other Expenses:		
Financing costs	(5,000)	(109,040)
Interest expense	(178,443)	(127,755)
Settlement (loss)	(51,942)	(7,500)
Total Other Expenses	(235,385)	(244,295)
Net loss	$ (445,138)	$ (441,852)
Net loss per share – basic and diluted	$ (0.04)	$ (0.05)
Weighted average shares outstanding – basic and diluted	10,919,897	8,424,156

(See accompanying notes to these condensed consolidated financial statements)

DECISION DIAGNOSTICS CORP.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(UNAUDITED)

	FOR THE NINE MONTHS ENDED SEPTEMBER 30,	
	2012	2011
Revenue	$ 6,049,471	$ 10,604,519
Cost of sales	4,561,938	8,500,912
Gross profit	1,487,533	2,103,607
Expenses:		
General and administrative	1,822,949	1,616,042
Consulting services	224,807	116,688
Compensation expense	33,408	39,688
Professional fees	243,361	126,899
Total Expenses	2,324,525	1,899,317
Net income (loss) from operations	(836,992)	204,290
Other Expenses:		
Financing costs	(5,036)	(422,173)
Interest expense	(394,399)	(367,598)
Settlement (loss)	(51,942)	(135,650)
Total Other Expenses	(451,377)	(925,421)
Net loss	$ (1,288,369)	$ (721,131)
Net loss per share – basic and diluted	$ (0.12)	$ (0.09)
Weighted average shares outstanding – basic and diluted	10,332,779	8,080,645

(See accompanying notes to these condensed consolidated financial statements)

DECISION DIAGNOSTICS CORP.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(UNAUDITED)

	FOR THE NINE MONTHS ENDED SEPTEMBER 30,	
	2012	2011
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net (loss)	$ (1,288,368)	$ (721,131)
Adjustments to reconcile net loss to net cash used in operating activities:		
Shares issued for financing	36	242,175
Shares issued for interest expense	80,483	-
Bad debt expense	1,669,451	1,241,043
Shares issued for consulting fees	197,440	77,400
Loss on debt settlement	-	(41,849)
Changes in operating assets and liabilities		
Accounts receivable	(1,453,756)	(3,217,737)
Prepaid and other assets	16,472	1,293,582
Accounts payable and accrued liabilities	368,554	549,739
Accrued interest	294,134	18,391
Contingencies	148,000	-
Net cash (used in) operating activities	32,446	(558,387)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Intellectual property	(37,225)	(5,490)
Net cash (used) in investing activities	(37,225)	(5,490)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from line of credit, net	-	313,327
(Payments) on notes payable	(2,500)	(4,475)
Proceeds from options exercised for cash	-	41,786
Net cash provided by financing activities	(2,500)	350,638
Net (decrease) in cash	(7,279)	(213,239)
Cash, beginning of period	14,869	220,390
Cash, end of period	$ 7,590	$ 7,151
Supplemental cash flow information:		
Cash paid for interest	$ -	$ 343,336
Cash paid for income taxes	$ -	$ -
Supplemental disclosure of non-cash investing and financing activities:		
Shares and options issued for services	$ 197,440	$ 77,400
Shares issued for financing	$ 36	$ 242,175
Shares issued for accrued interest	$ 80,483	$ -

(See accompanying notes to these condensed consolidated financial statements)

DECISION DIAGNOSTICS CORP.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - UNAUDITED

NOTE 1 – BASIS OF PRESENTATION AND ACCOUNTING POLICIES

Basis of Presentation

The condensed consolidated interim financial statements included herein, presented in accordance with United States generally accepted accounting principles and stated in US dollars, have been prepared by the Company, without audit, pursuant to the rules and regulations of the Securities and Exchange Commission. Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to such rules and regulations, although the Company believes that the disclosures are adequate to make the information presented not misleading.

These statements reflect all adjustments, consisting of normal recurring adjustments, which, in the opinion of management, are necessary for fair presentation of the information contained therein. It is suggested that these consolidated interim financial statements be read in conjunction with the consolidated financial statements of the Company for the period ended December 31, 2011 and notes thereto included in the Company's Form 10-K. The Company follows the same accounting policies in the preparation of consolidated interim reports.

Results of operations for the interim periods are not indicative of annual results.

Recent Accounting Pronouncements

Management has analyzed all pronouncements issued during the nine months ended September 30, 2012 by the FASB or other authoritative accounting standards groups with future effective dates, and have determined that they are not applicable or are not expected to be significant to the financial statements of the Company.

NOTE 2 – GOING CONCERN

The accompanying consolidated financial statements have been prepared assuming that we will continue as a going concern. Our ability to continue as a going concern is dependent upon attaining profitable operations based on the development of distributions platforms through which our products that can be sold. We intend to use borrowings and security sales to mitigate the effects of our cash position, however, no assurance can be given that debt or equity financing, if required, will be available. The condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded assets and classification of liabilities that might be necessary should we be unable to continue in existence.

NOTE 3 - LINE OF CREDIT

During the nine months ended September 30, 2012, we authorized the release of an additional 124,700 shares of preferred series “E” stock valued at $80,483 for accrued interest due to Alpha Credit Resources as of March 1, 2012. In addition, as a condition of authorizing the excess advance, Alpha Credit Resources required collateral in the form of our preferred series “B” stock, to be issued in their name and held by their legal counsel as escrow agent for this transaction. In the event of default, Centurion maintains the ability to convert the aforementioned shares into common shares at a rate of 7,143 to 1 in order to cure any potential default. The outstanding shares of this issue, if fully converted, would create 7,142,858 shares of new $.001 par value common stock. The fair value of the underlying common shares at the date of issuance totaled $5,900,000. As of September 30, 2012, the balance owed was $2,288,376.

	SEPTEMBER 30, 2012	DECEMBER 31, 2011
Line of credit with interest being paid in shares equal to 5% of each advance, and an additional 2% accruing monthly on the unpaid principal balance	$ 2,288,376	$ 1,992,168

We have recorded interest and financing expense of $376,691 and $348,898 for the nine months ended September 30, 2012 and 2011, respectively.

NOTE 4 – NOTES PAYABLE

Notes payable consisted of the following as of September 30 and December 31:

	SEPTEMBER 30, 2012	DECEMBER 31, 2011
(a) Convertible promissory note, bearing interest at a 15% per annum, matured on October 31, 2007, currently in default.	$ 125,000	$ 145,000
(b) Promissory note, bearing interest at 9% per annum, maturing June 30, 2012.	37,678	37,678
Total notes payable	$ 162,678	$ 182,678

a) In 2005, our former CEO determined that it was in the best interests of the company to borrow funds by offering a group of investor's future promises to offer convertible promissory notes to private investors. The former CEO, who had been removed by the Board as CEO at the time of this determination, broke long standing and memorialized Board approved company policy, did not receive the necessary officer approvals called for under this memorialized policy, did not receive Board approval for his actions, and never provided proof of any consideration received by the company. On August 14, 2006 the former CEO was terminated. The principal sum of these promissory notes was $170,000. According to the terms provided to the company, who some six years later has yet to receive an executed document or note, each note holder was due their principal balance and accrued interest at an annual rate of 15% maturing in one year from the date of issuance. On March 30, 2010 after a dispute arose, we entered into a debt settlement agreement for the payment of principal of $25,000 and accrued interest of $15,938 for a total amount owed of $40,938. Pursuant to the settlement agreement, we issued 300,000 shares of our common stock valued at $34,500 and agreed to pay an additional $15,000 in cash to the investor for a total sum of $49,500. The excess payment of $8,562 was recorded as interest expense. During the month of May 2012 the company entered into an additional settlement agreement requiring a one-time payment of $5,000 cash and the issuance of 53,354 shares, for a total sum of $22,500. The unpaid principle together with accrued interest on the settlement amount at the date of settlement totaled $38,873. As of September 30, 2012, the Company recorded a gain on debt settlement in the amount of $16,373. The remaining principal balance was $125,000 with accrued interest of $128,252.

b) On June 20, 2007, we entered into a promissory note with Invacare for the principal amount of $160,385, bearing interest at a rate of 9% per annum and maturing on June 10, 2010. On March 4, 2011, we re-negotiated this note whereby the principal balance and accrued interest were reduced by $35,335 and $6,541, respectively. In addition, the maturity was extended an additional twelve months to March 2012. As a result of the amendments to the note, we recognized a gain on the settlement of debt in the amount of $41,849. Pursuant to the amended terms of the note, we are required to make monthly principal and interest payments of $1,900. As of September 30, 2012, the principal balance totaled $35,335 and accrued interest was $4,386.

We have recorded interest in connection with our notes totaling $16,800 and $18,700 for the nine months ended September 30, 2012 and 2011, respectively.

NOTE 5 – FAIR VALUE

Our financial instruments consist principally of notes payable and lines of credit. Notes payable and lines of credit are financial liabilities with carrying values that approximate fair value. Management determines the fair value of notes payable and lines of credit based on the effective yields of similar obligations and believe all of the financial instruments' recorded values approximate fair market value because of their nature and respective durations.

We comply with the provisions of ASC 820, *"Fair Value Measurements and Disclosures"* ("ASC 820"). ASC 820 defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements required under other accounting pronouncements. ASC 820-10-35, *"Fair Value Measurements and Disclosures - Subsequent Measurement"* ("ASC 820-10-35"), clarifies that fair value is an exit price, representing the amount that would be received from the sale of an asset or paid to transfer a liability in an orderly transaction between market participants. ASC 820-10-35 also requires that a fair value measurement reflect the assumptions market participants would use in pricing an asset or liability based on the best information available. Assumptions include the risks inherent in a particular valuation technique (such as a pricing model) and/or the risks inherent in the inputs to the model. The Company also follows ASC 825 *"Interim Disclosures about Fair Value of Financial Instruments"*, to expand required disclosures.

ASC 820-10-35 establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (level 1 measurement) and the lowest priority to unobservable inputs (level 3 measurements). The three levels of the fair value hierarchy under ASC 820-10-35 are described below:

	Fair Value Measurements			
	Level 1	Level 2	Level 3	Total Fair Value
Liabilities				
Notes payable	$ -	$ 153,654	$ -	$ 153,654
Line of credit	-	2,243,505	-	2,243,505
Total	$ -	$ 2,397,159	$ -	$ 2,397,159

NOTE 6 – STOCKHOLDER'S EQUITY

We are authorized to issue up to 494,995,000 shares of $0.001 par value common stock and 5,000,000 shares of various classes of $0.001 par value preferred stock. In March of 2011, we amended our preferred stock designations as follows: 1) withdrawal of Series "A" designation on 750,000 shares of preferred stock, 2) withdrawal of Series "C" designation on 1,000,000 shares of preferred stock, 3) Designation of Series "B" on 2,500 shares of preferred stock and Series "C" on 10,000 shares of preferred stock, and 4) increased the number of preferred shares designated as Series "E" from 1,000,000 to 1,250,000. All presentation of preferred stock contained herein has been retroactively presented to reflect the 2011 amendments.

Series "B" convertible preferred stock

We have designated 2,500 shares of our $0.001 preferred stock as Series "B". Holders of series "B": convertible stock shall not have the right to vote on matters that come before the shareholders. Series "B" convertible preferred stock may be converted, the number of shares into which one share of Series "B" Preferred Stock shall be convertible into common stock shares shall be 50. Series "B" convertible stock shall rank senior to common stock in the event of liquidation. Holders' of Series "B" convertible stock shall not be entitled to a mandatory monthly dividend. Series "B" convertible stock shall have a redemptions price equal to 101% of the purchase price per share, subject to adjustments resulting from stock splits, recapitalization, or share combination.

Series "C" convertible preferred stock

We have designated 10,000 shares of our $0.001 preferred stock as 2011 Series "C". Each share of 2011 Series C Preferred stock is valued at $10,000. Holders of series "C": convertible stock shall not have the right to vote on matters that come before the shareholders. 2011 Series "C" convertible preferred stock may be converted after 36 months, but not before, the number of shares into which one share of 2011 Series "C" Preferred Stock shall be convertible on a pro-rata basis into common stock shares, each share of common stock valued at $.50. 2011 Series "C" convertible stock shall rank junior to all other classes of Preferred stock in the event of liquidation. Holders of 2011 Series "C" convertible stock shall not be entitled to a mandatory monthly dividend.

Series "D" convertible preferred stock

We have designated 500 shares of our $0.001 preferred stock as 2012 Series "D". Holders of series "D": convertible stock shall not have the right to vote on matters that come before the shareholders. 2012 Series "D" convertible preferred stock may be converted immediately upon distribution. The number of shares into which one share of 2012 Series "D" Preferred Stock shall be convertible into common stock shares is 1 for 120,000 shares of $0.001 par value common stock. 2012 Series "D" convertible stock shall rank junior to all other classes of Preferred stock in the event of liquidation. Holders of 2012 Series "D" convertible stock shall not be entitled to a mandatory monthly dividend.

Series E convertible preferred stock

We have designated 1,250,000 shares of our $0.001 preferred stock as Series "E". Holders of series "E": convertible stock shall not have the right to vote on matters that come before the shareholders. Series "E" convertible preferred stock may be converted, the number of shares into which one share of Series "E" Preferred Stock shall be convertible into common stock shares shall be 14. Series "E" convertible stock shall rank senior to common stock in the event of liquidation. Holders' of Series "E" convertible stock shall not be entitled to a mandatory monthly dividend. Series "E" convertible stock shall have a redemptions price equal to 101% of the purchase price per share, subject to adjustments resulting from stock splits, recapitalization, or share combination.

Preferred E Issuances

During the nine-month period ended September 30, 2012, we authorized the release of 124,700 shares of our preferred Series "E' stock to Alpha Credit Resources for accrued interest totaling $80,483.

During the nine-month period ended September 30, 2012, Alpha Credit Resources elected to convert 21,000 shares of their preferred series "E" into 294,000 shares of common stock.

Common Issuances

On January 16, 2012, we issued 53,354 shares of our common stock to an individual pursuant to a settlement agreement for in the amount of $17,500.

During the nine months ended September 30, 2012, we issued 1,650,000 shares of our common stock to entities as consulting fees earned during the nine months ended September 30, 2012. The fair value of the shares totaled $197,440, and has been recorded as a consulting expense.

During the nine months ended September 30, 2012 we authorized the issuance of 238 shares of common stock to Alpha Credit Resources as financing fees in connection with our line of credit. The fair value of the shares was $36, and was recorded as financing costs.

NOTE 7 – OPTIONS

2004 Stock Option Plan

Effective April 21, 2004, we adopted the "2004" Stock Option Plan, as amended, with a maximum number of 450,893 shares that may be issued. As of June 30, 2012, 398,104 options have been granted and exercised or expired under this plan. There are 52,789 options which remain available for issuance.

2005 Merger Consolidated Stock Option Plan

On February 5, 2005, we adopted our "2005" Merger Consolidated Stock Option Plan. The maximum number of shares that may be issued pursuant to the plan is 80,357 shares. As of June 30, 2012, 77,307 shares have been granted and exercised or expired under this plan. There are 3,050 options which remain available for issuance.

2006 Stock Option Plan

On December 8, 2006 we adopted our "2006 Employee Stock Option Plan, as amended and granted incentive and nonqualified stock options with rights to purchase 3,250,000 shares of our $0.001 par value common stock. As of June 30, 2012, 2,366,582 options were granted and exercised or expired under this plan. There are 883,419 options which remain available for issuance.

The following is a summary of activity of outstanding stock options under all Stock Option Plans:

	NUMBER OF OPTIONS	WEIGHTED AVERAGE EXERCISE PRICE
Balance, December 31, 2011	14,286	$ 0.80
Options granted	-	-
Options cancelled	-	-
Options exercised	-	-
Balance, September 30, 2012	14,286	$ 0.80

NOTE 8 – WARRANTS

The following is a summary of activity of outstanding warrants as of September 30, 2012:

	NUMBER OF WARRANTS	WEIGHTED AVERAGE EXERCISE PRICE
Balance, December 31, 2011	17,857	$ 0.49
Warrants granted	-	-
Warrants cancelled	-	-
Warrants exercised	-	-
Balance, September 30, 2012	17,857	$ 0.49

NOTE 9 – COMMITMENTS AND CONTINGENCIES

Leases

We currently maintain an executive office at 2660 Townsgate Road, Suite 300, Westlake Village, CA 91361. The space consists of approximately 2,300 square feet. The monthly rental for the space is $4,140 per month on a month-to-month basis.

On June 7, 2005, we entered into an agreement for the right to use offices, warehouses and shipping facilities for the storage and shipping of pharmaceuticals located at 515 Inman Avenue, Colonia, NJ 07067 and 25 Minna Street, Rahway, New Jersey. The company may or may not continue this arrangement in the future.

Rent expense totaled $80,910 and $81,828 for the nine months ended September 30, 2012 and 2011, respectively.

Contingencies

We transact commerce in several medical products market channels. We also transact commerce by licensing our proprietary medical software that functions by moving confidential medical data through our proprietary medical information technology devices and networks. Our new Shasta Genstrip product required initial regulatory approval by the USFDA as well as on-going USFDA approvals during the product life cycle. Further, Shasta Genstrip required medical patient trials and will compete directly with a major platform manufacturer.

Healthcare, especially those segments where the company competes, is a very litigious. Competing companies often use litigation as a marketing tool, bringing litigation as a means to protect market share and limit market exposure. The medical industry is also intertwined. From time to time, we may become involved in claims and litigation that arise out of the normal course of business, such as litigation that emerges from disputes over damaged, missing or contaminated product, litigation that arises over payment disputes or claims of fair value. We may also become involved in disputes that arise over the business or business practices of our suppliers, payers and customers. It is not uncommon in our industry to find that a litigant has filed claims in multiple jurisdictions involving the same transaction or a single transaction. The company maintains substantial insurance coverage against suits that may arise over issues of damaged, recalled or counterfeit product and other product liability issues. The company has also been a victim of the unapproved acts of prior management. These acts have resulted in claims from individuals and entities since the Board relieved former management of duty in 2006. Nonetheless, these claims have resulted in the use of management time and company resources to investigate, litigate, or settle. In addition, the company accrues contingent legal fees and product liability fees. As of September 30, 2012, our accrual was $171,069.

From time to time, the company may also be subject to demands from individuals or entities. These demands and disputes may consume management time and company resources. Other than as noted below, if there is such a disclosure, there are no pending matters at the current time that in management's judgment may be considered potentially material to us.

NOTE 10 – SUBSEQUENT EVENTS

In accordance with ASC 855, management evaluated all activity of the Company through the issue date of the financial statements and concluded than that described below, no other subsequent events have occurred that would require recognition or disclosure in the financial statements.

FORWARD LOOKING STATEMENTS

This document contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical fact are "forward-looking statements" for purposes of federal and state securities laws, including, but not limited to, any projections of earnings, revenue or other financial items; any statements of the plans, strategies and objections of management for future operations; any statements concerning proposed new services or developments; any statements regarding future economic conditions or performance; any statements or belief; and any statements of assumptions underlying any of the foregoing.

Forward-looking statements may include the words "may," "might," "could," "estimate," "intend," "continue," "believe," "expect" or "anticipate" or other similar words. These forward-looking statements present our estimates and assumptions only as of the date of this report. Accordingly, readers are cautioned not to place undue reliance on forward-looking statements, which speak only as of the dates on which they are made. We do not undertake to update forward-looking statements to reflect the impact of circumstances or events that arise after the dates they are made. You should, however, consult further disclosures we make in this Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K.

Although we believe that the expectations reflected in any of our forward-looking statements are reasonable, actual results could differ materially from those projected or assumed in any of our forward-looking statements. Our future financial condition and results of operations, as well as any forward-looking statements, are subject to change and inherent risks and uncertainties. The factors influencing these risks and uncertainties include, but are not limited to the following:

- deterioration in general or regional economic, market and political conditions;
- our ability to successfully compete in the pharmaceutical supply industry;
- increased competitive pressures from existing competitors and new entrants;
- increases in interest rates or our cost of borrowing or a default under any material debt agreements;
- loss of customers or sales weakness;
- the fact that our accounting policies and methods are fundamental to how we report our financial condition and results of operations, and they may require management to make estimates about matters that are inherently uncertain;
- adverse state or federal legislation or regulation that increases the costs of compliance, or adverse findings by a regulator with respect to existing operations;
- changes in U.S. GAAP or in the legal, regulatory and legislative environments in the markets in which we operate;
- inability to efficiently manage our operations;
- inability to achieve future sales levels or other operating results;
- the unavailability of funds for capital expenditures;
- the other risks and uncertainties detailed in this report.

REFERENCES

As used in this quarterly report: (i) the terms "we", "us", "our", "Decision Diagnostics" (formerly "InstaCare Corp.") and the "Company" mean Decision Diagnostics Corp. and its operating subsidiaries, Decision IT Corp., Pharma Tech Solutions, Inc., PharmTech Direct Corp., and PDA Services, Inc. ; (ii) "SEC" refers to the Securities and Exchange Commission; (iii) "Securities Act" refers to the United States *Securities Act of 1933*, as amended; (iv) "Exchange Act" refers to the United States *Securities Exchange Act of 1934*, as amended; and (v) all dollar amounts refer to United States dollars unless otherwise indicated.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

Overview

Decision Diagnostics Corp. is a nationwide prescription and non-prescription diagnostics and home testing products distributor. The U.S. FDA, in a manner similar to prescription drugs, regulates diagnostic test kits and at-home patient testing products similarly to the regulation of prescription medicine. The company has, since 2005, contracted with independent pharmacies for use of their prescription drug distribution licenses. However, the products we currently distribute, for the most part, do not require a doctor's prescription for anything other than insurance benefit compliance. Our business model works well in this regulated environment.

Our subsidiaries, Pharma Tech Solutions, Inc. and PDA Services, Inc. operate in several healthcare products distribution channels. We distribute brand name prescription and non-prescription diagnostics products, as well as several lines of ostomy, wound care and post-surgery medical products. We have also continued to ready the company, subject only to receipt of an expected FDA 510(k) approval, to introduce a proprietary diagnostic product, the Shasta Genstrip, for at-home testing of blood glucose. The worldwide market for at-home blood glucose testing is an estimated $22.5 billion. Shasta Genstrip will compete directly with one of the largest worldwide platform manufacturer for at-home blood glucose testing, a product currently used daily by over 3 million diabetes afflicted Americans. In anticipation of the introduction of Genstrip, which is in the final stages of FDA approval, and currently completing that approval process, we have evaluated our brand-name distribution model, a model that provides streams of revenue but extremely low profit margins, and over the course of the last 15 months has phased out sales of those brand name products that have been a backbone of our current distribution business but provide low profit margins, if any at all, and will, in the future, compete directly with our Shasta Genstrip. Phasing out these products lowered our order intake by approximately $8,450,000 in FY2011 and $7,400,000 through the period ending June 30, 2012.

Typically, and except for our own Shasta Genstrip, which is an alternative product, we distribute name brand products manufactured primarily by large U.S. and international pharmaceutical companies. The company directs its marketing efforts to ambulatory and semi-ambulatory older Americans afflicted with diabetes and complications caused by diabetes and old age. The company, originally a medical IT company with proprietary IT product lines, acquired its medical products distribution business in late 2004 through a merger with Phoenix, Arizona based CareGeneration, Inc. We have grown the original CareGeneration business through subsequent acquisitions of private businesses and strategic partnerships with larger private pharmacies.

On November 1, 2011 we completed the acquisition of Diagnostic Newco LLC from its owner Kimberly Binder. Diagnostic Newco LLC is a design company that specializes in product packaging design, medical products advertising design and graphic art. Ms. Binder has joined the staff of the company's Pharma Tech Solutions, Inc. subsidiary and has worked closely with the contract manufacturer for Genstrip, making subtle changes to packaging design among other responsibilities. She will also be responsible for the package design for new diagnostic products the company is currently working on. We also intend to acquire additional private companies, focusing on small engineering companies that have developed technology requiring either regulatory approval, distribution or both. In December 2011 we made another small acquisition, to acquire the services of Mr. Patrick DiParini. We are moving quickly to achieve our goal of becoming a vertically integrated, full service value added provider of products and services to an ever-growing market. The at-home diabetes testing market continues to grow as diabetics continue to be diagnosed. The market for diabetes testing products is expected to grow from a current $22.5+ billion worldwide base in 2010 to over $32 billion in 2017.

The company's current proprietary product offering, although not yet approved by the FDA for commercial distribution, is the Shasta Genstrip blood glucose diagnostic test strip for at-home testing. Shasta Genstrip is a product conceived and designed by Shasta Technologies LLC, and fits into a diagnostic product niche and will sell into the world-wide self-test (home test) market that is expected to grow to $32 billion worldwide by 2017. The company has been involved with Genstrip since early 2010. Products like Genstrip require FDA approval but travel toward this approval through a well defined albeit slow and unresponsive regulatory process. The company believes that all regulatory hurdles have been addressed and satisfied, but as of this writing, Genstrip has not received final regulatory approval or disapproval from the FDA. In March 2012 and then again in September 2012, representatives of the company met face-to-face with the FDA, the September 2012 meeting at FDA's request, in an effort to iron out remaining FDA questions, and in the case of the September 2012 meeting, to address two final issues, both concerns related to certain post-approval manufacturing processes. Subsequent to each of these meetings with FDA the company has received and responded to a series of follow up questions and comments by FDA. In September 2012 these FDA comments and questions were changed to a semi-informal process indicating to the company the approaching end of the approval process. In early November 2012 the company received an informal communication from FDA staff asking for clarification of two issues remaining from the September 2012 face to face meeting. The company responded to these requests. Within the body of the communication received from FDA staff the company was informed that we [FDA] was close to reaching resolution on this issue.

The company maintains a practice where comments and questions are responded to as quickly as practical. Since Genstrip is a unique offering, employing a razor blade only model (diagnostic test strip) into a razor (diagnostic meter)-razor blade (diagnostic test strip) market, the Genstrip 510(k) application has presented some unusual challenges for the FDA and an educational challenge/opportunity for the company. Since the company plans additional similar products in the future for other diagnostic platforms, the Genstrip experience, however slow and unresponsive, has provided lessons and experience.

Two years (and growing) is a standard development to market timeline for in-vitro diagnostic products similar to Genstrip. As a result of previous delays by Shasta Technologies in completing its FDA approval application [510(k)] and then problems Shasta encountered in prosecuting its original application with FDA staff, the company changed its contractual responsibilities and obligations in June 2011 to include program management, regulatory process management, management of the manufacturing forecasting and distribution processes, and new products planning and development. As of October 31, 2012 the company has narrowed the issues with FDA to two issues, the publication of two post-manufacturing protocols. All other issues have been resolved.

In June 2010 the company was approached by the largest retailer in the world for the distribution and sale of Genstrip at over 5,000 retail stores worldwide. A contract with this retailer was negotiated in September 2010 and subsequently renegotiated and renewed in April 2011, and as soon as the retail contract was agreed to and as a means to conduct market research, the company began seeking pre-conditioned letters of intent (pre-orders) for Genstrip, while continuing the prosecution of the 510(k) application before the FDA. During this process it became clear that initial market interest in Genstrip outstripped the initially available manufacturing capacity. Thus the company quickly ended its pre-order initiative. Management is confident that there is a very large market available for Genstrip. Currently that market is dominated by four large pharmaceutical manufacturers who provide very similar and equally focused products, selling at essentially equal prices. Genstrip's introduction should not only allow the company to achieve market share but because of the business model to be employed by Genstrip is different than those models employed by the major market players, the company may be able to change the market, lowering average price or allowing for increased testing by diabetics for a lesser price, thereby affecting all market segments.

We also offer information technology solutions in several medical care market channels by providing physicians with information at the point of care. Our products, unlike those from many other medical information companies, make use of smart cell phones such as the Apple iPhone, the Palm Pre, the Google Droid and a wide selection of Microsoft Windows based smart phones and operate in either in a wireless or "wired" mode, which allow physicians to carry, access and update their patients' histories, also known as electronic medical records or EMR, medication data, and best care guidelines - *all at the point of care*, or from any other location the physician may be located. In addition, the company's products employ proprietary mathematical game theory features adapted by the company for medical use that allow acceptance of diagnoses and treatment protocols where the medical information may have originated from one or several locations and one time or several times.

On February 26, 2010 we filed a full utility patent application, Management and Communications System and Method, Serial No. 13/034,639. The patent application covers one hundred four (104) separate processes and encompasses the method, system and apparatus of our software technology and the integration of our software technology into commercial computer networks through commercial smart cell phone devices. In September 2011, the USPTO published our patent application. In April 2011 the patent reached the prosecution stage with the USPTO. We expect approval in a matter of a few months. Given that our patent application lists a substantial number of claims, and that the company's technologies are truly unique, we felt it prudent to engage counsel to prosecute any of these claims against persons and entities that may have or will in the future breach our patent. The company has created an asset pool for the purpose of prosecuting any claims that may arise as a result of our patent approval. Claims prosecution is standard fare for high technology companies.

We have entered into nine partnerships with freestanding pharmacies and Durable Medical Goods distributors in the states of New York, Maryland, New Jersey, Texas and Arizona. We believe that we will be able to provide value added services to our customers by cost reductions brought about by increased efficiencies and cross marketing opportunities.

We have received multiple inquiries from companies interested in perhaps collaborating with the company for the implementation of its cell phone centric technologies MD@Hand and MD@Work. However, the market available for products similar to MD@Hand and MD@Work has changed since its introduction in 2009. The legal challenges to the new health care law, and the federal government's inability to enact regulations have altered the landscape, again. We remain in discussions with multiple concerns for the marketing of our MD@ products, and any agreement we may enter will require us to provide contract software programming, providing a new source of revenue for the company. In addition to any proposed partnerships, we continue to discuss alternative propositions with other interested companies ranging from clinical laboratories, service organizations owned or aligned with medical health insurers, a medical content provider and legacy healthcare systems companies. There remains sustained interest in our MD@ products and technology. All of our discussions are with companies are much larger than Decision Diagnostics. We may or may not entertain additional proposed partnerships for our implementation of the cell phone centric technologies, which has been hindered, as has the overall market, by the slow implementation of regulations, protocols and data formats by the Federal government, as well as a change in previously announced Federal government monetary incentives.

In May 2010, we entered into agreement with Shasta Technologies, Inc. and Broadtree, Inc. This agreement granted our Pharma Tech Solutions, Inc. subsidiary the exclusive marketing rights to a new diagnostic product not yet on the market named Shasta Genstrip ("Genstrip"). The Genstrip product was developed to compete against the market leader in the $20 billion at home testing market. In April 2011, the company renegotiated its agreement changing its many roles and adding responsibility for regulatory approval, manufacturing and forecasting, international sales and additional sales markets in the U.S.

We currently employ five full-time staff at our executive office located at 2660 Townsgate Road, Suite 300, Westlake Village, California 91361. In addition, we maintain two full-time and seven part-time positions between our distribution centers located in Florida, Arizona, California and New Jersey. The company is currently hiring pharmaceutical detail representatives and three medically trained college interns across the country and three additional interns to work out of its California office.. All of our positions existing, and newly listed, are for sales and marketing, distribution, product development and customer service representatives. Our telephone number is (805) 446-1973 and our website address is www.decisiondiagnostics.com.

Business activities throughout the next twelve months:

The company's business on a day-to-day basis includes the distribution of prescription and non-prescription diagnostics, at-home testing, post-surgical products, and, as soon as the FDA grants pre-market approval, the sales and distribution of Shasta Genstrip.

Beginning in November 2009, we introduced our cell-phone centric medical IT products that offer solutions in medical care and management by providing physicians with information at the point of care. Unlike other medical information systems using standard computer terminals or even palm-sized computers (PDA's), our software applications operate on a series of late generation smart e-cell phones including the Apple iPhone, the Palm Pre, the Google Droid, several makes of RIM's Blackberry and many versions of the Microsoft Windows smart phones. Our products allow physicians to access and update their patients' histories, medication data, and best care guidelines - *all at the point of care*. The company's Electronic Medical Records software is believed to be the first EMR application running on any palm sized mobile device. Recently we ported our software to run on a series of pad computers such as Apple iPad and the 'Droid powered pads.

Our business objectives include:

1. The practice of specializing in the distribution of Shasta Genstrip and several brand-name medical diagnostic and medical disposable products associated with the on-going care of diabetes-inflicted patients and upon receipt of the pre-market letter from the U.S. FDA, the world-wide distribution of our new proprietary diagnostic product Shasta Genstrip.

2. Combining our wholesale and retail drug distribution with our cell phone centric technologies, creating wholesale and retail ePharmacies similar in function to existing Internet pharmacies but directed to serving the large base of underinsured and uninsured Americans; and

3. Providing medical communication and EMR medical history and storage devices based on networks of smart cell phones These products are believed to provide benefits of on demand medical information to private practice physicians, licensed medical service providers such as diagnostic testing laboratories, and medical insurers. We have created cell phone-centric products and a suite of Internet enhanced software applications that include those features that specifically respond to the requirements of the practicing physician and the regulations currently being promulgated by the Federal government.

We also have adapted our medical communications and EMR technologies to service the real estate management and hotel/motel/convenience industries in their own commercial settings. In March 2010, our Board approved the sale of the company's hotel/motel technologies and business base so we can focus on our core medical IT and medical distribution businesses. In past years when we had market focus on the hotel/motel industry, our real estate and hotel/motel objectives include building electronic commerce networks based on personal digital assistants (PDA) and pad based computers to the hotels, motels and single building, multi-unit apartment buildings with a desire to offer local advertising and electronic services to their tenants/guests.

Financing Requirements

At September 30, 2012, we had cash of $7,590 and working capital of $892,215. We anticipate that we will require $56 million in trade debt financing to finance our expected first year sales of Genstrip. In March 2012 we renewed our agreement with Alpha Credit Resources to obtain this debt financing. We will continue to seek a combination of equity and long-term debt financing as well as other traditional cash flow and asset backed financing to meet our financing needs and to reduce our overall cost of capital. Additionally, in order to accelerate our growth rate and to finance general corporate activities, we may supplement our existing sources of funds with financing arrangements at the operating system level or through additional short-term borrowings. As a further capital resource, we may sell or lease certain rights or assets from our portfolio as appropriate opportunities become available. However, there can be no assurance that we will be able to obtain any additional financing, on acceptable terms or at all.

Results of Operations for the three months ended September 30, 2012 and 2011 compared.

The following tables summarize selected items from the statement of operations for the three months ended September 30, 2012 compared to 2011.

	For the Three Months Ended September 30,			
	2012	2011		
			3 Months	**%Δ**
Revenue	$ 1,223,060	$ 3,585,006	(2,361,946)	(65.88)
Cost of sales	747,550	2,617,756	(1,870,206)	(71.44)
Gross profit	475,511	967,250	(491,739)	(50.84)
Expenses:				
General & administrative expenses	553,597	1,111,276	(557,679)	(50.18)
Consulting	34,905	12,928	21,977	170.00
Compensation expense	7,886	6,228	1,658	26.62
Professional fees	88,876	34,375	54,501	158.55
Total expenses	685,264	1,164,807	(479,543)	41.17
Net operating (loss)	(209,753)	(197,557)	(12,196)	6.17
Other income (expense):				
Financing costs	(5,000)	(109,040)	104,040	(95.41)
Interest expense, net	(178,443)	(127,755)	(50,688)	39.68
Settlement expense	(51,942)	(7,500)	(44,442)	592.56
Total other income (expense)	(235,385)	(244,295)	8,910	(3.65)
Net (loss)	$ (445,138)	$ (441,852)	(3,286)	(0.74)

The following discussion should be read in conjunction with the unaudited interim condensed consolidated financial statements (including the notes thereto) included under Item 1 in this Form 10-Q.

Revenues and cost of sales

During the 3rd quarter of 2012, we experienced a decline in revenue compared to the same period in the previous year. We attribute the decline in revenue to the phasing out of sales of those brand name diagnostic products that will directly compete with our new Shasta Genstrip. In addition, the overall at home testing market is being hindered by the general poor economic conditions, longer payment cycles from insurers, and because the company's business model does not include the sale of retail brand-name products. These conditions have continued into the current year. Our decrease in cost of sales is primarily the direct result of our revenue decline. However, we were able to achieve an increase in our overall gross profit margin based on our re-negotiated wholesale pricing.

Operational Expenses

Operational expenses include general and administration expenses, compensation expense consulting and professional fees.

General and administration expenses include office expenses (including bad debt, rent, cleaning and maintenance, utilities, and telephone), insurance, and bank charges. During the 3rd quarter of 2012, general and administration expenses decreased by $557,679 to $553,597 (3rd quarter 2011 - $1,111,276). The decrease was due primarily to bad debt expense recorded in the 3rd quarter 2011. General and administration expenses normally account for approximately 2% of our total revenue and are not expected to increase significantly during the remainder of 2012 in relation to revenue. As we experience growth in revenues, general and administration expenses are expected to decrease on a percentage of revenue basis.

Consulting expenses during the 3rd quarter 2012 increased by $21,977to $34,905 (3rd quarter 2011 - $12,928). Historically, management shifts its labor requirements between, outside consultants, casual labor and in-house management dependent upon availability and cost effectiveness of resources. During 2012, the majority of our labor was derived from the use of outside consultants. Our compensation structure is comprised of both cash and equity of the Company.

Professional fees include accounting services, legal fees and regulatory reporting compliance. The increase of $54,501 is the result of an increase in our contingency for legal fees. During the 3rd quarter of 2011, we engaged additional legal counsel to assist in the review of potential new sales/distributing agreements as well as to review general corporate matters. We anticipate our legal fees to continue until all ongoing litigation issues are resolved.

Other Income and Expense

Our other income and expense includes costs related to our financing activities, more specifically the interest expense associated with our line of credit with Alpha Credit Resources, LLC. ("Alpha"). Alpha has provided us a line of credit up to $2,500,000. The interest rate of our line of credit is 24% per annum. Interest expense increased by $50,688 to $178,443 (3rd quarter 2011 - $127,755).

For the three-month periods ended September 30, 2012 and 2011, management has entered into various agreements for the settlement of the Company's historic debt obligations. As a result of these negotiated settlements, the Company's obligations have been reduced from their historical carrying amounts. In 2012, settlement losses were $51,942 as compared to settlement losses of $7,500 in 2011. We may incur further gains or losses on debt settlement or other settlement cost during 2012.

Net Income (Loss)

We recorded a net loss for the 3rd quarter of 2012 of $445,138 compared $441,852 for the 3rd quarter of 2011, representing a change of $3,286.

Results of Operations for the nine months ended September 30, 2012 and 2011 compared.

The following tables summarize selected items from the statement of operations for the nine months ended September 30, 2012 compared to 2011.

	For the Nine Months Ended September 30,			
	2012	2011	**9 Months**	**%Δ**
Revenue	$ 6,049,471	$ 10,604,519	(4,555,048)	(42,95)
Cost of sales	4,561,938	8,500,912	(3,938,974)	(46.34)
Gross profit	1,487,533	2,103,607	(616,074)	(50.84)
Expenses:				
General & administrative expenses	1,822,949	1,616,042	206,907	12.80
Consulting	224,807	116,688	108,119	92.66
Compensation expense	33,408	39,688	(6,280)	(15.82)
Professional fees	243,361	126,899	116,462	91.78
Total expenses	2,324,525	1,899,317	425,208	22.39
Net operating (loss)	(836,992)	204,290	(1,041,282)	(509.71)
Other income (expense):				
Financing costs	(5,036)	(422,173)	417,137	(98.81)
Interest expense, net	(394,399)	(367,598)	(26,801)	7.29
Settlement expense	(51,942)	(135,650)	83,709	(61.71)
Total other income (expense)	(451,377)	(925,421)	(474,045)	(51.22)
Net (loss)	$ (1,288,369)	$ (721,131)	(567,237)	(78.66)

The following discussion should be read in conjunction with the unaudited interim condensed consolidated financial statements (including the notes thereto) included under Item 1 in this Form 10-Q.

Revenues and cost of sales

During the 3rd quarter of 2012, we experienced a decline in revenue compared to the same period in the previous year. We attribute the decline in revenue to the phasing out of sales of those brand name diagnostic products that will directly compete with our new Shasta Genstrip. In addition, the overall at home testing market is being hindered by the general poor economic conditions, longer payment cycles from insurers, and because the company's business model does not include the sale of retail brand-name products. These conditions have continued into the current year. Our decrease in cost of sales is primarily the direct result of our revenue decline. However, we were able to achieve an increase in our overall gross profit margin based on our re-negotiated wholesale pricing.

Operational Expenses

Operational expenses include general and administration expenses, compensation expense consulting and professional fees.

General and administration expenses include office expenses (including bad debt, rent, cleaning and maintenance, utilities, and telephone), insurance, and bank charges. During the nine months ended September 30, 2012, general and administration expenses increased by $206,907 to $1,822,949 (2011 - $1,616,042). The increase was due primarily to bad debt expense. General and administration expenses normally account for approximately 2% of our total revenue and are not expected to increase significantly during the remainder of 2012 in relation to revenue. As we experience growth in revenues, general and administration expenses are expected to decrease on a percentage of revenue basis.

Consulting expenses during the nine months ended September 30, 2012 increased by $108,119 to $224,807 (2011 - $116,688). Historically, management shifts its labor requirements between, outside consultants, casual labor and in-house management dependent upon availability and cost effectiveness of resources. During 2012, the majority of our labor was derived from the use of outside consultants. Our compensation structure is comprised of both cash and equity of the Company.

Professional fees include accounting services, legal fees and regulatory reporting compliance. The increase of $116,462 is primarily attributable to an increase in contingent legal fees. During the nine months ended September 30, 2012, we engaged additional legal counsel to assist in the review of potential new sales/distributing agreements as well as to review general corporate matters. We anticipate our legal fees to continue until all ongoing litigation issues are resolved.

Other Income and Expense

Our other income and expense includes costs related to our financing activities, more specifically the interest expense associated with our line of credit with Alpha Credit Resources, LLC. ("Alpha"). Alpha has provided us a line of credit up to $2,500,000. The interest rate of our line of credit is 24% per annum. Interest expense increased by $26,801 to $394,399 (2011 - $367,598).

For the nine-month periods ended September 30, 2012 and 2011, management has entered into various agreements for the settlement of the Company's historic debt obligations. As a result of these negotiated settlements, the Company's obligations have been reduced from their historical carrying amounts. In 2012, settlement losses were $51,942 as compared to settlement losses of $135,650 in 2011. We may incur further gains or losses on debt settlement or other settlement cost during 2012.

Net Income (Loss)

We recorded a net loss for the nine months ended September 30, 2012 of $1,288,369 compared to a net loss for the nine months ended September 30, 2011 of $721,131, representing a total change of $567,238.

Liquidity and Capital Resources

A critical component of our operating plan affecting our continued existence is the ability to obtain favorable capital through additional equity and/or debt financing. We do not anticipate generating sufficient positive internal operating cash flow until we can increase our existing market share and improve operating margins, which may take several years. In the event we cannot obtain the necessary capital to pursue our strategic plan, we may have to cease or significantly curtail our operations. This would materially impact our ability to continue operations.

The following table summarizes our current assets, liabilities and working capital at September 30, 2012 compared to December 31, 2011.

	SEPTEMBER 30, 2012	DECEMBER 31, 2011	INCREASE (DECREASE) $	INCREASE (DECREASE) %
Current assets	$ 4,366,818	$ 4,537,949	$ (171,131)	(3.77%)
Current liabilities	3,357,336	2,532,217	825,119	32.58%
Working capital	$ 1,009,482	$ 2,005,732	$ (996,250)	(49.67%)

Cash to Operating Activities

During the nine months, ended September 30, 2012, operating activities provided cash of $32,466 compared to using cash of $558,387 in 2011. Our loss for 2012 was $1,288,368, and included bad debt write-downs of $1,669,451 (2011 - $1,241,043); and consulting expenses settled with equity $197,440 (2011 - $77,400). Our accounts receivables have increased by $1,453,756 (2011 – $3,217,737) due to a slowdown in our revenue cycle. Prepaid expenses decreased by $16,472 (2011 – $1,293,582) due to the expiration of prepaid insurance in 2012. Accounts payable and accrued liabilities have increased by $368,554 (2011 –$524,739) due to a slowdown in our revenue cycle. Our contingent liabilities increased $148,000 (2011 – $0.00) due to the uncertainty of our involvement in legal matters.

Cash from Investing Activities

During the nine months ended September 30, 2012, investing activities used cash of $37,225 (2011 - $5,490).

Cash from Financing Activities

During the nine months ended September 30, 2012, financing activities used cash of $2,500 (2011 – 350,638). Cash was used for payments on notes payable of $2,500 (2011 - $4,475).

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

Our Chief Financial Officer, Keith Berman, has evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report pursuant to Rule 13a-15(b) under the Securities Exchange Act of 1934 (the "Exchange Act"). Based on that evaluation, the Company's Principal Executive Officer and Principal Financial Officer has concluded that, as of the end of the period covered by this report, our disclosure controls and procedures are effective in ensuring that information required to be disclosed in our Exchange Act reports is (1) recorded, processed, summarized and reported in a timely manner, and (2) accumulated and communicated to our management, including our Principal Executive Officer and Principal Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Controls

There has been no change in the Company's internal controls over financial reporting that occurred during our last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

Internal control systems, no matter how well designed and operated, have inherent limitations. Therefore, even a system, which is determined to be effective, cannot provide absolute assurance that all control issues have been detected or prevented. Our systems of internal controls are designed to provide reasonable assurance with respect to financial statement preparation and presentation.

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

We transact commerce in several medical products market channels. We also transact commerce by licensing our proprietary medical software that functions by moving confidential medical data through our proprietary medical information technology devices and networks. Our new Shasta Genstrip product required initial regulatory approval by the USFDA as well as on-going USFDA approvals during the product life cycle. Further, Shasta Genstrip required medical patient trials and will compete directly with a major platform manufacturer.

Healthcare, especially those segments where the company competes, is a very litigious. Competing companies often use litigation as a marketing tool, bringing litigation as a means to protect market share and limit market exposure. The medical industry is also intertwined. From time to time, we may become involved in claims and litigation that arise out of the normal course of business, such as litigation that emerges from disputes over damaged, missing or contaminated product, litigation that arises over payment disputes or claims of fair value. We may also become involved in disputes that arise over the business or business practices of our suppliers, payers and customers. It is not uncommon in our industry to find that a litigant has filed claims in multiple jurisdictions involving the same transaction or a single transaction. The company maintains substantial insurance coverage against suits that may arise over issues of damaged, recalled or counterfeit product and other product liability issues. The company has also been a victim of the unapproved acts of prior management. These acts have resulted in claims from individuals and entities since the Board relieved former management of duty in 2006. Nonetheless, these claims have resulted in the use of management time and company resources to investigate, litigate, or settle. In addition, the company accrues contingent legal fees and product liability fees. As of September 30 30, 2012, our accrual was $171,069.

From time to time, the company may also be subject to demands from individuals or entities. These demands and disputes may consume management time and company resources. Other than as noted below, if there is such a disclosure, there are no pending matters at the current time that in management's judgment may be considered potentially material to us.

Lifescan Scotland, LLC vs. Shasta Technologies LLC, Decision Diagnostics Corp. (now known as Decision Diagnostics Corp.), Pharma Tech Solutions, Inc. et al.

On September 9, 2011 Lifescan Scotland, Ltd. brought suit against Shasta Technologies, LLC (Shasta), InstaCare Corp. (now known as Decision Diagnostics Corp.), Pharma Tech Solutions, Inc. et al in the United States District Court, Northern District of California, San Jose Division, Case # CV11-04494-MEJ, alleging patent infringement, seeking injunctive relief and damages as a result of an alleged infringement on Patents 5,708,247 and 6,241,862. InstaCare Corp. (now known as Decision Diagnostics Corp.) and Pharma Tech Solutions have answered the complaint, denying all of its material allegations and asserting a number of affirmative defenses. Decision Diagnostics Corp. and Pharma Tech Solutions, Inc. are entitled to be indemnified by Shasta Technologies LLC, and Shasta's intellectual property insurer is providing a defense for Decision Diagnostics Corp. (formerly known as InstaCare Corp.) and Pharma Tech Solutions, Inc. The companies also carry insurance and have demanded a defense from its own carriers. Since the suit remains in its early stages, despite the passage of over a year in time, it is yet too soon to determine the course of the litigation. Management intends to continue to vigorously defend this lawsuit, which it believes is without merit. The company intends to file its own counter-claims in December 2012 and has moved the federal court to allow amendment for such an amendment.

ITEM 1A. RISK FACTORS.

Not applicable.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES.

During the nine months ended September 30, 2012, we issued 1,650,000 shares of our restricted common stock as consulting fees for services performed for the Company valued at $197,440. We believe that the issuance of the shares was exempt from the registration and prospectus delivery requirements of the Securities Act of 1933 by virtue of Section 4(2). The recipient of the shares was afforded an opportunity for effective access to files and records of the Company that contained the relevant information needed to make its investment decision, including the Company's financial statements and 34 Act reports. We reasonably believe that the recipient, immediately prior to issuing the shares, had such knowledge and experience in our financial and business matters that it was capable of evaluating the merits and risks of its investment. The recipient had the opportunity to speak with our president and directors on several occasions prior to its investment decision.

During the nine months ended September 30, 2012, we issued 238 shares of our restricted common stock to Alpha Credit Resources as financing fees valued at $36 in connection with our line of credit. We believe that the issuance of the shares was exempt from the registration and prospectus delivery requirements of the Securities Act of 1933 by virtue of Section 4(2). The recipient of the shares was afforded an opportunity for effective access to files and records of the Company that contained the relevant information needed to make its investment decision, including the Company's financial statements and 34 Act reports. We reasonably believe that the recipient, immediately prior to issuing the shares, had such knowledge and experience in our financial and business matters that it was capable of evaluating the merits and risks of its investment. The recipient had the opportunity to speak with our president and directors on several occasions prior to its investment decision.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. (REMOVED AND RESERVED).

ITEM 5. OTHER INFORMATION.

None.

ITEM 6. EXHIBITS

The following exhibits are included with this Quarterly Report on Form 10-Q:

Exhibit Number	Description of Exhibit
31.1	Rule 13a-14(a)/15(d)-14(a) Certification of Principal Executive Officer and Principal Financial Officer
32.1	18 U.S.C. Section 1350 Certification of Principal Executive Officer and Principal Financial Officer

SIGNATURES

In accordance with the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

DECISION DIAGNOSTICS CORP.

By: */s/Keith Berman*
Keith Berman
Chief Financial Officer and a Director
(Principal Financial Officer and Principal Accounting Officer)

Date: November 19, 2012

EXHIBIT X

OneTouch® Ultra® System Accuracy (2001–2009)

Key points

- Most published studies on meter accuracy are of short duration and include a small sample of test strips, providing a limited view of long-term product performance.
- In smaller studies, it can be difficult to collect a sufficient number of native patient samples to demonstrate accuracy in glucose concentration ranges where important medical decisions are made.
- In this report, accuracy data on over 71,000 OneTouch® Ultra® Test Strips collected in over eight years of clinical testing with 828 test strip lots provide a unique long-term perspective on system reliability and performance.
- Consistently high levels of accuracy were found at all glucose levels in each year of the study and in American Diabetes Association preprandial and postprandial target ranges for capillary plasma glucose.

Introduction

Self-monitoring of blood glucose provides important information for assessing short-term glucose control and making appropriate and timely changes in diabetes management. Most published studies on meter accuracy are of short duration, use a small sample of test strips, and include only a small number of patient samples in lower blood glucose ranges, where hypoglycemia is a concern. As patients may self-monitor using the same product over many years and test with many batches of test strips, it is important to understand the quality and stability of product performance over time.

The OneTouch® Ultra® System was introduced in 2000. Performance data published at product launch[1] showed that the system produced highly accurate results, with over 98% of patient tests falling within zone A of the Clarke Error Grid.[2]

Since January 2001, ongoing studies have evaluated the performance of the OneTouch® Ultra® System in a clinical setting. These studies have produced a large volume of accuracy data collected in a clinical environment, where fresh, native (unaltered) fingertip blood samples were tested in a consistent manner. Previous analyses[3,4] presented results through 2004 and 2007, respectively. In the current report, linear regression and Parkes' Consensus Error Grid Analysis[5] were applied to more than 71,000 OneTouch® Ultra® System results. In addition, system accuracy criteria based on the medical requirements for glucose monitoring published by the International Organization for Standardization (ISO)[6] were used to evaluate test results. These evaluations provide an important perspective on the long-term accuracy and reliability of the OneTouch® Ultra® System in the low, normal, and high blood glucose ranges.

Methods

- All OneTouch® Ultra® System results used in the accuracy analyses were obtained from ongoing product evaluations at three clinical sites in the United Kingdom.
- During 227 clinical evaluations conducted over a 99-month period (January 2001 to March 2009), trained operators performed OneTouch® Ultra® System tests with 71,437 fingertip blood samples from subjects with diabetes, using test strips from 828 different lots (batches).
- Additional capillary blood was collected from the subjects, and reference glucose measurements were made in duplicate using the YSI 2300 Glucose Analyzer (YSI, Inc., Yellow Springs, Ohio, USA).
- OneTouch® Ultra® System results were analyzed using linear regression and Parkes' Consensus Error Grid Analysis, which categorizes meter results according to the degree of clinical risk posed by an inaccurate measurement.
- The number and percentage of accurate OneTouch® Ultra® System results were determined according to the ISO 15197 standard, which states that the minimum acceptable accuracy criteria is fulfilled if at least 95% of the individual glucose meter

results fall within the ISO boundaries for error tolerance (±15 mg/dL [0.83 mmol/L] of the reference method at glucose concentrations <75 mg/dL [4.2 mmol/L] and within ±20% at glucose concentrations ≥75 mg/dL [4.2 mmol/L].

- Using ISO error tolerances, the number and percentage of accurate results falling within American Diabetes Association (ADA) published preprandial and postprandial target ranges[7] were determined.

Results

- A total of 71,437 capillary blood samples were analyzed. The samples presented a wide range of blood glucose concentrations (YSI plasma: 22–629 mg/dL, 1.2–34.9 mmol/L)
- Regression analysis for paired OneTouch® Ultra® System and reference YSI results gave a slope of 0.974, a y-intercept value of –1.06 mg/dL (–0.059 mmol/L), a correlation coefficient (r) of 0.982, and a standard error of the estimate value (Sy.x) of 15.88 mg/dL (0.88 mmol/L).
- Parkes' Consensus Error Grid Analysis (Figure 1) identified six (6) OneTouch® Ultra® System results (0.01%), each prior to 2007, that would affect clinical outcome (zone C) and no results that would have significant medical risk (zones D or E). OneTouch® Ultra® System results showed similarly high levels of clinical accuracy when analyzed on a year-to-year basis (Table 1).
- At glucose concentrations below, within, and above the ADA target range of 70–130 mg/dL (3.9–7.2 mmol/L), the OneTouch® Ultra® System gave ≥98% of results within ISO error tolerances (Table 2).
- Of the 71,437 OneTouch® Ultra® System results collected during the study, 70,526 (98.7%) were evaluated as accurate according to the ISO criteria. Year-to-year analyses show consistently high levels of OneTouch® Ultra® System accuracy (Table 3).
- At glucose concentrations <75 mg/dL (4.2 mmol/L), year-to-year analyses of 2,520 OneTouch® Ultra® System results show consistent accuracy, with >95% of results within ±15 mg/dL of the reference method in each year (Table 3). Similarly, at glucose concentrations ≥75 mg/dL (4.2 mmol/L), results from 68,917 blood glucose tests show >97% of results within ±20% of the reference method for each year of the study.

Figure 1.

Error grid analysis of all results

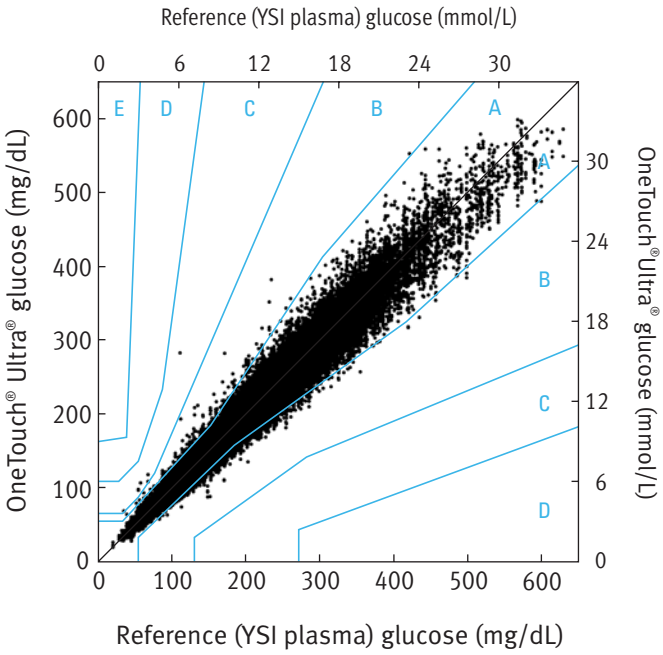

Table 1.

Error grid analysis by year

		% of results in Zone				
Year	n	A	B	C	D	E
2001	8904	97.8	2.2	0.0	0.0	0.0
2002	18697	98.8	1.2	0.0	0.0	0.0
2003	9739	99.0	1.0	0.0	0.0	0.0
2004	6521	98.7	1.2	0.0	0.0	0.0
2005	5089	98.6	1.4	0.0	0.0	0.0
2006	5566	96.3	3.7	0.0	0.0	0.0
2007	4420	97.3	2.7	0.0	0.0	0.0
2008	7599	97.8	2.2	0.0	0.0	0.0
2009	4902	97.7	2.3	0.0	0.0	0.0
All	71437	98.2	1.8	0.0	0.0	0.0

ZONE DEFINITIONS
A: No effect on clinical action.
B: Altered clinical action — little or no effect on clinical outcome.
C: Altered clinical action — likely to affect clinical outcome.
D: Altered clinical action — could have significant medical risk.
E: Altered clinical action — could have dangerous consequences.

Table 2.
Accuracy of OneTouch® Ultra® System results by ADA target ranges for capillary plasma glucose

Glucose level mg/dL (mmol/L)	n	% within ISO error tolerances
<70 (3.9)	1922	98.0
70–129 (3.9–7.2)*	17303	98.3
130–179 (7.2–9.9)	18095	98.8
>180 (10.0)*	34117	98.9

*ADA preprandial plasma glucose target range: 70–130 mg/dL (3.9–7.2 mmol/L); peak postprandial capillary plasma glucose: < 180 mg/dL (10.0 mmol/L)

Table 3.
Accuracy of OneTouch® Ultra® System results by year

	RESULTS BY GLUCOSE LEVEL				ALL RESULTS	
	<75 mg/dL (4.2 mmol/L)		≥75 mg/dL (4.2 mmol/L)			
YEAR	n	% within ±15 mg/dL (0.83 mmol/L)	n	% within ±20%	n	% within ISO error tolerances
2001	336	98.8	8568	98.9	8904	98.9
2002	630	98.6	18067	99.4	18697	99.4
2003	288	97.6	9451	99.5	9739	99.5
2004	178	95.5	6343	99.4	6521	99.2
2005	178	98.3	4911	98.5	5089	98.5
2006	206	97.1	5360	97.7	5566	97.7
2007	135	97.8	4285	98.0	4420	98.0
2008	335	95.5	7264	97.8	7599	97.7
2009	234	97.9	4668	97.4	4902	97.4
All	**2520**	**97.6**	**68917**	**98.8**	**71437**	**98.7**

Conclusions

The results of this study confirm that the high level of clinical accuracy observed with the OneTouch® Ultra® System in a small pre-launch study has been sustained over more than eight years of product manufacturing and testing with hundreds of test strip lots and tens of thousands of meter results. Across all glucose levels, including clinically important ADA target ranges, the analyses show that ISO system accuracy requirements were exceeded. Unlike most published studies on meter accuracy, this study includes long-term data from a large number of capillary blood samples with abnormally high and low glucose concentrations, including over 2,500 samples having glucose values < 75 mg/dL (4.2 mmol/L) and over 1,900 samples with glucose levels < 70 mg/dL (3.9 mmol/L). In these important glucose ranges where hypoglycemia occurs, the OneTouch® Ultra® System was shown to deliver consistently accurate results. Studies demonstrating the equivalence of OneTouch® Ultra® System Meters* suggest that all meters using OneTouch® Ultra® Test Strips would show similarly consistent levels of performance over time.

* OneTouch® Ultra® System Meters include OneTouch® Ultra®, OneTouch® UltraSmart®, OneTouch® Ultra®2, OneTouch® UltraMini®, OneTouch® UltraEasy™, OneTouch® UltraLink™, OneTouch® Ping™, and OneTouch® UltraVue™.

References

1. LifeScan, Inc.: Clinical Accuracy and User Acceptance of the OneTouch® Ultra® Blood Glucose Monitoring System. Milpitas (CA); 12/2000. AW 057-426A.
2. Clarke WL, Cox D, Gonder-Frederick LA, Carter W, Pohl SL: Evaluating clinical accuracy of systems for self-monitoring of blood glucose. *Diabetes Care* 10:622 – 628, 1987.
3. LifeScan, Inc.: OneTouch® Ultra® System Accuracy (2001–2004). Milpitas (CA); 05/2005. AW 085-322.
4. LifeScan, Inc.: OneTouch® Ultra® System Accuracy (2001–2007). Milpitas (CA); 08/2008. AW 091-970B.
5. Parkes JL, Pardo S, Slatin SL, Ginsberg BH: A new consensus error grid to evaluate the clinical significance of inaccuracies in the measurement of blood glucose. *Diabetes Care* 23:1143 – 1148, 2000.
6. International Organization for Standardization. In vitro diagnostic test systems — Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus. ISO 15197:2003E.
7. American Diabetes Association: Standards of Medical Care in Diabetes – 2009. *Diabetes Care* 32 (Suppl 1): S13 – S61, 2009.

EXHIBIT Y

OUR GIVING

COMMUNITY INVOLVEMENT

CHARITABLE CONTRIBUTIONS

EDUCATIONAL GRANTS AND EVENT SPONSORSHIPS

POLICIES

RESEARCH FUNDING

COUNTERFEIT PRODUCTS

Being a Responsible Corporate Citizen

We are responsible to the communities in which we live and work, and the world community as well. That is part of the Johnson & Johnson CREDO — and part of being a responsible corporate citizen. At LifeScan, we take this role very seriously.

Our vision is to create a world without limits for people with diabetes. Toward that end, LifeScan provides product and monetary support to many non-profit organizations on a local, national and international level. Our primary goal is to increase awareness of diabetes as a serious illness, educate people with diabetes and their families and promote awareness that diabetes complications can be reduced with proper management.

Part Of The Diabetes Community
LifeScan is deeply committed to our partnership with the diabetes community.
Read more >

News Updates
Find out the latest news relating the LifeScan and OneTouch® Brand systems.
Read more >

Community Involvement

In support of Our CREDO, LifeScan Community Relations provides a foundation for charitable giving, strategic partnerships and volunteerism that enhances the quality of life in our communities and engages our employees. We encourage our employees to volunteer, teach others and support activities that help meet the social, economic and cultural needs of our community, and provide positive change with measurable results.

Our employees around the world actively support their local communities with work categorized in four areas: education, health and human services, civic and cultural and the environment. LifeScan's Community Relations program allows employees and local non-profit organizations to partner for positive outcomes around the globe.

Our employees participate and support local events and organizations such as:

ADA Tour de Cure — From Philadelphia to Silicon Valley to Inverness to Aguadilla Puerto Rico, Diabetes Care Franchise employees take to their bikes to raise money for the American Diabetes Association's Tour de Cure, the Tour de France or other related events. LifeScan employees raise tens of thousands of dollars every year for diabetes research, building top corporate teams in the American Diabetes Association Tour de Cure bicycle ride and the Juvenile Diabetes Research Foundation Walk to Cure Diabetes.

Back Pack Drive — Provides backpack and other school supplies for children in need in our community, and assists the Support Network for Battered Women.

Blood Drive — Supports the Stanford Blood Center since 2000 — LifeScan also helps to sponsor remote blood drives at local high schools and community centers. Please join other LifeScan volunteers in this important effort.

Bridge to Employment — Through the Johnson & Johnson Bridge to Employment (BTE) program, employees encourage high school students to pursue higher education while introducing them to career opportunities in healthcare.

Environmental Events — Through a partnership between Community Relations and Environmental Affairs, we are committed to protecting and preserving our environment, and striving to keep it healthy. Programs have included the Creek Clean Up, Save the Bay and other environmental activities.

Family Giving Tree — Help brighten the holiday season for Milpitas families in need by donating a gift for a child, senior or homeless individual in our community.

JDRF Walk for a Cure — Raises funds for the Juvenile Diabetes Research Foundation (JDRF), a leading charitable funder and advocate of Type 1 diabetes research worldwide.

in kick-off of the United Way campaign.

One Child, One Blanket — Part of the J&J Disaster Relief Program, this year-round program collects new blankets from employees, which are then added to a kit full of J&J consumer products.

Second Harvest Food Sort — Provides donated, surplus and purchased food for non-profit agencies in Santa Clara and San Mateo Counties.

United Way Campaign — Works with hundreds of poverty-fighting non-profits, government and social services agencies to create pathways out of poverty.

World Diabetes Day Awareness Activity— Franchise employees around the world recognize World Diabetes Day — November 14th — by partnering with diabetes organizations to help raise awareness and help educate local community members.

Our Giving to the Diabetes Community

Within the global diabetes community, LifeScan seeks to improve the lives of people with diabetes through three forms of giving: (1) alliances with professional organizations and patient advocacy groups, (2) educational grants and sponsorships for Healthcare Professionals, patients and their families, and (3) contributions to diabetes charities.

Professional & Patient Alliances

Professional Organizations

LifeScan promotes and celebrates best practices in diabetes care and education worldwide by providing grants and sponsorships to professional associations that lead the local, national and global response to diabetes and diabetes complications. Ongoing partnerships between LifeScan and leading organizations in the diabetes industry include: American Association of Diabetes Educators, American Association of Clinical Endocrinologists, American Dietetic Association, European Association for the Study of Diabetes, Federation of European Nurses for Diabetes, International Society for Pediatric and Adolescent Diabetes, The Endocrine Society, the American Academy of Family Physicians, the American Academy of Nurse Practitioners and the American Academy of Physician Assistants.

Patient Advocacy Groups

LifeScan also supports diabetes advocacy organizations that stand up and speak out for patients and persons living with diabetes. These patient advocacy groups are often the first stops for newly diagnosed people and their families, so supporting their work provides a wide range of benefits to the diabetes community. Our long-time associations with groups such as the American Diabetes Association, the International Diabetes Federation, and the Juvenile Diabetes Research Foundation help us fulfill our J&J CREDO responsibility to give back to the communities in which we live and work, and to the world community as well.

Find out more about the LifeScan *One Child, One Blanket* program

Our Giving to the Diabetes Community

Within the global diabetes community, LifeScan seeks to improve the lives of people with diabetes through two forms of giving: (1) educational grants and sponsorships for Healthcare Professional organizations and patient advocacy groups, and (2) financial and product contributions to diabetes charities.

Ongoing partnerships between LifeScan and leading organizations in the diabetes industry include: American Association of Diabetes Educators, American Association of Clinical Endocrinologists, International Society for Pediatric and Adolescent Diabetes, The Endocrine Society, and the American Academy of Family Physicians, to name a few.

LifeScan also supports diabetes advocacy organizations that stand up and speak out for patients and persons living with diabetes. These patient advocacy groups are often the first stops for newly diagnosed people and their families, so supporting their work provides a wide range of benefits to the diabetes community. Our long-time associations with groups such as the American Diabetes Association, the International Diabetes Federation, and the JDRF help us fulfill our J&J CREDO responsibility to give back to the communities in which we live and work, and to the world community as well.

Helping Those In Need

LifeScan values contributing around the world whenever help is needed most.
Read more >

News Updates

Find out the latest news relating the LifeScan and OneTouch® Brand systems.
Read more >

Find out more about Team J&J's top national honors at the Tour de Cure.

The site is best viewed on Internet Explorer 7+,Firefox,Safari and versions onwards.

OUR GIVING

COMMUNITY INVOLVEMENT

CHARITABLE CONTRIBUTIONS

Guidelines & Requirements For Contributions

EDUCATIONAL GRANTS AND EVENT SPONSORSHIPS

POLICIES

RESEARCH FUNDING

COUNTERFEIT PRODUCTS

Responsibility > Our Giving > Charitable Contributions

Charitable Contributions

LifeScan makes monetary and product donations to diabetes charities in the United States, and to international causes that seek to prevent, alleviate and cure diabetes worldwide. Our largest giving programs are for diabetes summer camps in the United States and the International Diabetes Federation's Life for a Child Program in the developing world. LifeScan also works with international relief organizations during natural and man-made disasters around the world, contributing blood glucose testing supplies in times of life-threatening emergencies.

Related Links

Guidelines & Requirements for Contributions

You must review the Guidelines & Requirements for Charitable Contributions

OUR GIVING

COMMUNITY INVOLVEMENT

CHARITABLE CONTRIBUTIONS

EDUCATIONAL GRANTS AND EVENT SPONSORSHIPS

Guidelines & Requirements For Grants

Grant FAQs

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COUNTERFEIT PRODUCTS

Responsibility > Our Giving > Educational Grants and Event Sponsorships

Event Sponsorships and Educational Grants

LifeScan provides a variety of educational grants and sponsorships for Healthcare Professionals and patients. Some of these funds are for Continuing Medical Education (CME) for physicians and allied professionals or Continuing Education (CE) credits for other health-related professions. The remaining grants are for non-credited instruction, primarily for patients.

Related Links

Guidelines & Requirements for Grants

Grant FAQs

LifeScan proudly sponsors dozens of diabetes events every year, including outreach programs for communities disproportionately impacted by diabetes, as well as fundraising events such as walks, rides, galas and other activities to raise funds for diabetes research, education and advocacy. Through a variety sponsorships we support major diabetes organizations, including the American Diabetes Association and the JDRF, as well as smaller groups such as the Diabetes Education and Camping Association and Insulindependence. All sponsorship requests must go through an application process similar to educational grants and charitable contributions.

To review guidelines for grants and sponsorships, and to submit a request, please visit Guidelines & Requirements for Grants.

After you have reviewed these guidelines, return here and click the button below to be directed to the external portal for submitting requests. Thank you for your interest in LifeScan and our educational grants and sponsorships.

Submit Request

EXHIBIT Z

Johnson & Johnson

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Providing advanced training in diabetes care for health professionals

At the Johnson & Johnson Diabetes Institute, our vision is to transform diabetes care. We see a world without limits for people with diabetes.

We seek to make this world a reality by empowering healthcare professionals in countries worldwide to improve the quality of life for people with diabetes.

Learn more about the Institute by **playing our video** - and **joining us now**.

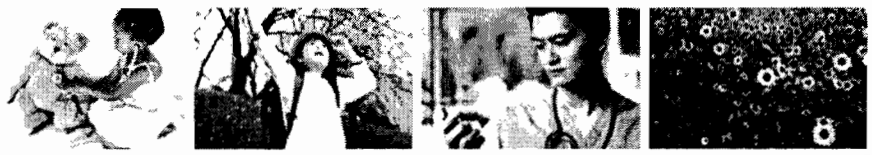
Join Us

Sign In

Learn More
About the Curriculum
About the Faculty
About the Online Community

BENEFITS OF MEMBERSHIP:

- ***FREE for healthcare professionals to join and participate***
- ***Webinars (live and archived!) on hot topics:***
  - *Behavior change and treating to target*
  - *Using diabetes tools effectively & early insulinization*
  - *Pattern recognition*
  - *Reimbursement*
- ***Blogs and articles by world class experts***
- ***Opportunity to interact with thought leaders!!***
- ***Connect with a community of 8000+ diabetes healthcare professionals like you!***
- ***REGISTER to attend a LIVE class (US,Canada only)***



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The Institute

"Today, diabetes has reached epidemic proportions in the United States and in the rest of the world and no one entity, government or private, can do it all... Some of the greatest barriers lie in communication and in health literacy... The opportunities are boundless: We now know more and more about this disease, we now have more and more medications and devices to help manage [diabetes]. We can leverage this, using the Johnson & Johnson Diabetes Institute as a home for the diabetes family, to master diabetes."
-- From An Interview with Kenneth Moritsugu, MD, MPH, FACPM, Head of the Institute

The Johnson & Johnson Diabetes Institute

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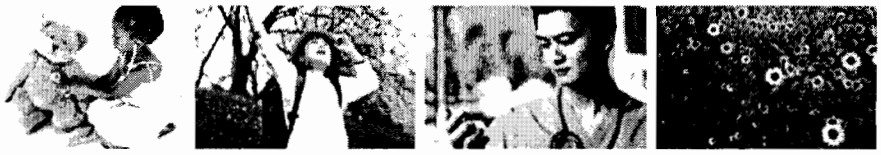
The Online Community

A revolutionary approach to diabetes education.

Our Mission is to improve the paradigm of diabetes care -- transforming the intent from managing diabetes to mastering diabetes.

The Johnson & Johnson Diabetes Institute is both a global online community and a collection of facilities, where healthcare professionals learn from each other and from our faculty to transform care.

Learn More
About the Silicon Valley Institute
About the Online Community



Education

At the Johnson & Johnson Diabetes Institute, we are patient-centered in our approach to care. Through the education we provide in our collaborative learning environment for healthcare professionals, through service, and through technology, our alumni empower patients with self-mastery of their condition. You don't have to wait to attend a course at the Institute to begin your educational experience – become a member of The Community and join the Institute now. The strength of our relationships with healthcare professionals, and the deep insights that we gain from understanding patients' needs, inform and influence how we create global networks and transform healthcare.

Silicon Valley Curriculum & Faculty

The Silicon Valley curriculum is tailored to the needs of patients and the healthcare professionals who care for them in the United States. While the Johnson & Johnson Diabetes Institute curricula vary by country, course examples include guidelines and standards of care, in-person product training, insulin pump therapy, communication with patients and families, new tools and technologies, blood glucose pattern management and software solutions, and reimbursement for diabetes care. The Silicon Valley Institute Curriculum covers

- Guidelines and Standards of Diabetes Care
- Decision Points in Therapy
- Product Training
- Chronic Care Model
- Communication Techniques and Behavior Change
- Reimbursement for Diabetes Care

Our faculty is comprised of over 30 experts in the diabetes field, who take turns leading sections of the two-day course. Meet the Silicon Valley Institute faculty.

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The Institute Faculty

Meet the faculty at the Silicon Valley Institute To read each member's biography, click on their picture
Remember you can start interacting with our faculty right away by becoming a member of the Institute.


Mary M Austin MA, RD, CDE


Steven V. Edelman, MD


Maree Kelland RN, CCRN


Reinhard Wolfgang Beel CEC, CDT Business Manager


Mary P Ettari, MPH PA-C


Davida F Kruger MSN, APRN-BC, BC-ADM


Richard R Rubin, PhD, CDE


James Bennett, RPh, FACA, CDE


Edwin Fisher, PhD


Lori M B. Laffel, MD, MPH


Laurie Ruggiero, PhD


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Jerry Meece, RPh, FACA, CDE


Joe Solowiejczyk, RN, MSW, CDE


Bruce Buckingham, MD


Amparo Gonzalez, RN, BSN, CDE


Marc Steinberg, MD

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About the Faculty


Paula Clinton, RD, CDE


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Susan Cornell, BS, PharmD, CDE, FAPhA, FAADE


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