

# HEALTH-CHEM DIAGNOSTICS, LLC

3341 S.W. 15<sup>th</sup> Street – Pompano Beach, FL 33069 – Phone: (954) 979-3845 – Fax: (954) 979-7997

## NON-INVASIVE GLUCOSE MONITORING

The *TD Glucose Monitoring System* is completely non-invasive, non-toxic and safe. A skin patch provides diabetics with a painless, bloodless, easy to use and rapid method to monitor their glucose levels. After the patch has been placed on the forearm for about five minutes, a small electronic meter is held up to the patch and produces an instant glucose reading. The single-use patch is then removed and easily disposed of.

The *TD Glucose Monitoring System* combines proprietary and patented transdermal technology with Health Chem membrane-based diagnostic technology. The alliance of these technologies permits dermal glucose to be drawn and transported into the patch where it causes an end-point chemical reaction and color change in the membrane. Special optics in a patented electronic meter detects the color change and provides a glucose reading.

The retail price of the *TD Glucose Monitoring System* is expected to be competitive with currently available finger-stick blood glucose monitoring systems.

### ***Benefits of the TD Glucose Monitoring System***

- Painless
- Bloodless
- Cost Effective
- Easy to Use
- Rapid Results
- Greater Accuracy than Present Home Diabetic Invasive Test Methods

### **Marketing Partners**

Heath Chem presently has a definitive licensing agreement for the *TD Glucose Monitoring System* for a regional area with a large European pharmaceutical company. We are also in preliminary discussions with several other pharmaceutical and diagnostic companies, with respect to additional global/regional marketing and distribution rights.



### **Development Status and Next Steps**

- Development of *TD Glucose Monitoring System* has been completed.
- US patent No 6,503,198 issued Jan. 7, 2003 for transdermal diagnostic systems and *TD Glucose Monitoring System* technology. The Meter (US patent No. 6,574,425) issued on June 3, 2003.
- US Patent No 6,952,263 issued October 4, 2005 – Reflectometer.
- Worldwide equivalents have been issued, as well as separate patents obtained in: Israel, Peoples Republic of China, India, Japan, Korea, Mexico, Taiwan, Brazil and Argentina. A new, all-encompassing US patent application is in the final stage of issuance.

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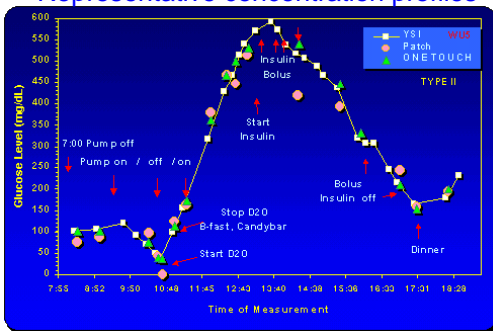
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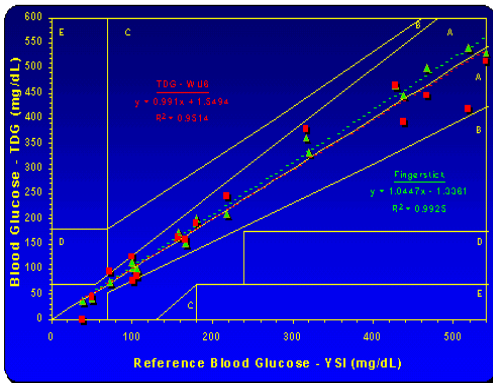
- Patient Clinical trials (to prove patients can perform the testing at home) are ongoing. A CE mark (EU approval) – is also in process.
- Engineering and building of new production machinery capable of producing and packaging approx. six million TD Glucose patches every eight hours is ongoing.

August 1998, the first algorithms (complex mathematical formulas) used to calibrate the *TD Glucose Meter* were confirmed and presented at the 1998 European Association for the Study of Diabetes conference in Barcelona, Spain. The *TD Glucose Meter* demonstrates a high degree of correlation between finger stick technology as well as excellent meter-to-meter and patch-to-patch reproducibility.

Representative concentration profiles



Corresponding Clarke-Error Grid

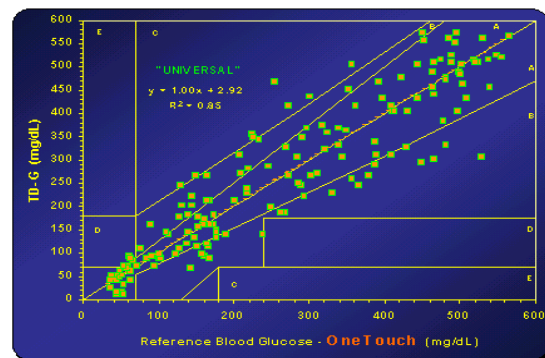


TDG-MS parallels venous and capillary measurements. The patch data track the venous and the finger stick results into the hypo- as well as the hyperglycemic concentration range very well. Clarke Error Grid analysis shows clustering of the TDG-MS data in the A & B grid regions.

A 13 patient study performed in 1999 at Washington University School of Medicine (St. Louis, MO.) confirmed the relationship between the *TD Glucose Monitoring System* and both Capillary and Venous Blood.

Correlation analysis using both a Universal Algorithm and Individual Algorithms were shown to be equal to (or in the case of an Individual Algorithm), better than the most commonly used finger stick method in the U.S. The findings were presented at the 17<sup>th</sup> International Diabetes Federation Congress at Mexico City, Mexico, in November 2000.

All Patients **UNIVERSALLY** calibrated  
Fingerstick reference



## Comparison Study Data

More than 20 years have been spent in research and development of the Company's non-invasive glucose monitoring technology. In

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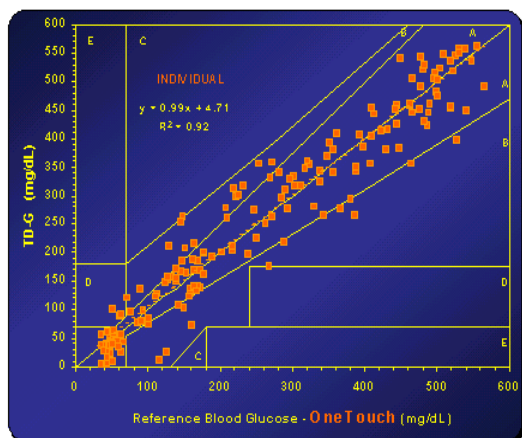


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All Patients **INDIVIDUALLY** calibrated  
Fingerstick reference



TDG-MS data correlate very well with both reference methods. At this stage of the development it appears that individual patient calibration generates a better overall correlation.

Correlation Coefficients	Venous Blood	Capillary Blood
Individual	93%	92%
Universal	84%	85%

## About Diabetes and Glucose Monitoring

Diabetes is a chronic disease in which the body does not produce or properly use insulin, a hormone that is needed to convert sugar, starches and other food into energy needed for daily life. At present, there is no cure for diabetes and the cause is unknown, although such factors as obesity and lack of exercise appear to play a role.

Worldwide there are in excess of 230 million people with diabetes ---some 16 million are in the United States---and only about 24 million regularly monitor their glucose levels. Diabetes is the fourth leading cause of death by disease in the U.S. and can also lead to other life

threatening conditions, including blindness, kidney and neurological disease, limb amputation, heart disease and stroke. Medical costs in the U.S. for the treatment of diabetes and diabetes related conditions are estimated at more than 140 billion annually.

According to the American Diabetes Association, a person's blood glucose level will vary depending upon diet, insulin availability, exercise, stress and illness. Blood glucose testing several times a day enables diabetics to better manage their disease by keeping blood glucose levels in a narrow and normal range.

The availability of fast and accurate self-monitoring finger stick blood glucose monitoring systems in the late 1970's gave diabetics a tool to manage the disease more effectively and improve their quality of medical care.

According to the National Institutes of Health, glucose monitoring is recommended 4-6 times a day. However, the NIH and other studies estimate diabetics, on average, test their blood glucose levels less than once per day. Such non-compliance is largely believed to be due to the pain, inconvenience and risk of infection associated with the use of conventional finger/arm stick blood glucose monitoring systems.

The worldwide market for glucose monitoring products was over \$8 billion in 2005, for just at home testing, and is growing by approximately 15% -18% a year. The market is projected to reach the \$12 billion mark by the year 2010, with more than \$3.5 billion from the U.S. market alone.

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