Diabetes Technologies and Devices: From Accuracy to Cybersecurity

– August 13, 2016 –

"FAST IS FINE, BUT ACCURACY IS EVERYTHING"
ACCURACY IS THE MOST IMPORTANT FEATURE IN A DIABETES DEVICE

ACCURATE INFORMATION REQUIRES ACCURATE MONITORING DEVICES

DIABETES THERAPY REQUIRES CORRECT DECISIONS

ACCURACY IS THE MOST IMPORTANT FEATURE IN A DIABETES DEVICE

CORRECT DECISIONS REQUIRE ACCURATE INFORMATION

GLUCOSE MONITORING

INSULIN DELIVERY

CYBERSECURITY
MINIMUM ACCURACY CRITERIA FOR OTC BLOOD GLUCOSE MONITORS FROM THE 2014 DRAFT FDA GUIDANCE

95% of glucose results must be within 15% of reference

99% of glucose results must be within 20% of reference

Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use

Draft Guidance for Industry and Food and Drug Administration Staff

Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use

Draft Guidance for Industry and Food and Drug Administration Staff

CLARKE ERROR GRID REPORTED IN 1987
The Surveillance Error Grid (PEG) is intended by FDA for post-market surveillance of cleared BGM systems. Inaccurate BG monitors are risky for making treatment decisions or calibrating CGMS.
A BLOOD GLUCOSE MONITOR THAT HAS A HIGH BIAS WHEN CALIBRATING A CGM WILL RESULT IN UNDERREPORTING HYPOGLYCEMIA

Continuous Glucose Monitoring in Newborn Infants: How Do Errors in Calibration Measurements Affect Detected Hypoglycemia?

Felicity Thomas, BSc(Hons), Mathew Siu, PhD, Deborah L. Harris, PhD(1), Philip J. Weston, MScMBB, Jane E. Harding, PhD(2), Geoffrey M. Shaw, MScMBB, and J. Geoffrey Chase, PhD(2), on behalf of the CHYLD Study Group

Abstract

Newborn hypoglycemia is common and can cause serious brain injury. Continuous glucose monitoring (CGM) could improve hypoglycemia detection, while reducing blood glucose (BG) measurements. Calibration algorithms use BG measurements to convert sensor signals into CGM data. Thus, inaccuracies in calibration BG measurements directly affect CGM values and treatment. We examined the effect of adding delayed and calibrated BG measurements (true BG) to CGM data sets to determine the percentage of false alarms and hypoglycemia errors. A Monte Carlo simulation (n = 100,000) was performed using true BG data and simulated true BG data with measurement error (5% of true BG) for simulated data. The number of hypoglycemia events, duration of hypoglycemia, and hypoglycemia indicators were then calculated using the CGM data and compared to baseline values. Timing error alone had little effect on hypoglycemia metrics, but measurement error caused substantial variation. Almost all intervals underestimated the number of hypoglycemia events by up to 90% and falsely overestimated the duration of hypoglycemia by up to 10%. CGM calibrated with a true BG that had a high bias resulted in underreporting hypoglycemia. A BLOOD GLUCOSE MONITOR THAT HAS A HIGH BIAS WHEN CALIBRATING A CGM WILL RESULT IN UNDERREPORTING HYPOGLYCEMIA.
Accuracy of Blood Glucose Meters for Self-Monitoring Affects Glucose Control and Hypoglycemia Rate in Children and Adolescents with Type 1 Diabetes

Claudia Boettcher, MD, Axel Dost, MD, Stefan A. Wudy, MD,
Markus Fliechtner-Mors, PhD, Martin Borkenstein, MD, Ralf Schiel, MD,
Dieter Weitzen, MD, Susanne Bechtold-Dalli Pozza, MD,
Johannes Wolf, MD, and Reinhard W. Holt, MD

for the German/Austrian Diabetes Prospective Documentation Initiative

9163 Type 1 pediatric patients from Germany & Austria

**Abstract**

Aims/Hypothesis: This study investigated the accuracy of blood glucose meters for self-monitoring and its influence on glycated hemoglobin (HbA1c) levels and the frequency of hypoglycemic coma.

**EFFECT OF BG MONITOR INACCURACY ON MEAN GLYCEMIC CONTROL**

![Graph showing effect of BG monitor inaccuracy on mean glycemic control](graph.png)

**INACCURACY OF A BGM CORRELATES WITH POOR GLYCEMIC CONTROL**

**EFFECT OF BG MONITOR INACCURACY ON FREQUENCY OF HYPOGLYCEMIC COMA PER 100 PATIENT-YRS**

![Graph showing effect of BG monitor inaccuracy on frequency of hypoglycemic coma](graph2.png)

**POSITIVE BIAS OF A BGM LEADS TO EXCESS Rx AND CORRELATES WITH HYPOGLYCEMIC COMA**

**DIABETES TECHNOLOGY SOCIETY SURVEILLANCE PROGRAM FOR CLEARED BGM SYSTEMS**

![Diagram showing Diabetes Technology Society Surveillance Program](diagram.png)
Performance of Cleared Blood Glucose Monitors

David C. Kloosoff, MD, FACP, FRCP (Edin), Fellow AIMBE, and Priya Prahalad, MD, PhD

Abstract
Cleared blood glucose monitor (BGM) systems do not always perform as accurately for users as they did to become cleared. We performed a literature review of recent publications between 2010 and 2014 that present data about the frequency of inaccurate performance using ISO 15197 2003 and ISO 15197 2013 as standards. We performed an additional literature review of publications that present data about the clinical and economic risks of inaccurate BGMs for making treatment decisions or calibrating continuous glucose monitors (CGMs). We found 11 publications describing performance of 98 unique BGM systems. Of these, 33 (34%) met ISO 15197 2003 and 31 of the 98 (32%) tested systems met ISO 15197 2013 analytical accuracy standards in all studies in which they were evaluated. Of the tested systems, 33 were identified as FDA-cleared. Among these FDA-cleared BGM systems, 24 of 32 (75%) met ISO 15197 2003 and 15 of 31 (48%) met ISO 15197 2013 in all studies in which they were evaluated. Among the non-FDA-cleared BGM systems, 29 of 65 (45%) met ISO 15197 2003 and 15 out of 65 (23%) met ISO 15197 2013 in all studies in which they were evaluated.

11 articles from 2010-2014: 98 BGM Systems

<table>
<thead>
<tr>
<th>ALL BGMSs REPORTED</th>
<th>FDA CLEARED</th>
<th>NON-FDA-CLEARED</th>
</tr>
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<tbody>
<tr>
<td>TOTAL BGMSs</td>
<td>n = 98</td>
<td>n = 33</td>
</tr>
<tr>
<td>% ISO 15197-2003 (+)</td>
<td>54%</td>
<td>75%</td>
</tr>
<tr>
<td>% ISO 15197-2013 (+)</td>
<td>32%</td>
<td>48%</td>
</tr>
</tbody>
</table>

Diabetes Technology Society Presents:
Verifying the Performance of Blood Glucose Monitors Following FDA Clearance
September 9, 2013 at the Hyatt Regency Bethesda
One Bethesda Metro Center, Bethesda, MD 20814

Diabetes Technology Society Begins Surveillance Testing Study of Cleared BG Monitor Systems

June 8, 2016 – Burlingame, California - Diabetes Technology Society (DTS) is pleased to announce the commencement of testing for the DTS Surveillance Program for Cleared Blood Glucose Monitor systems (BGMS).
MINIMUM ACCURACY CRITERIA FOR PRESCRIPTION POINT-OF-CARE BLOOD GLUCOSE MONITORS FROM THE 2014 DRAFT FDA GUIDANCE

99% of glucose results must be:
For glucose < 70 mg/dl – within 7 mg/dl of reference
For glucose ≥ 70 mg/dl – within 10% of reference

And 100% of glucose results must be:
For glucose < 75 mg/dl – within 15 mg/dl of reference
For glucose ≥ 75 mg/dl – within 20% of reference

“Critically ill patients should not be tested with a glucose meter because results may be inaccurate.”

2014 FDA Draft Guidance BGM Test Systems for Prescription POC Use. Page 31, lines 1113-1114
NEW YORK STATE DEPARTMENT OF HEALTH
Clinical Laboratory Evaluation Program

Off Label use of Glucose Meters
February 28, 2014

The New York State Department of Health’s (the Department) Clinical Laboratory Evaluation Program (CLEP) distributed a letter to laboratories located in NY on January 13, 2014 regarding the off-label use of glucose meters. This letter is available on our website at http://www.health.ny.gov/lab/legislation/whitepapers.html. It is not the intent of the Department to prohibit the off-label use of glucose meters but to inform facilities on the policies and requirements surrounding the off-label use of these devices. These policies and requirements for off-label use of a FDA cleared/approved device have not changed. The Department is providing this guidance in the form of frequently asked questions (FAQs).

Mayo Clin Proc. • October 2014;89(10):1331-1335

Timely Hospital Glucose Measurement: Here Today, Gone Tomorrow?

David C. Klonski, MD, FACP, FCRP (Ed), Fellow AIME; Robert A. Vigersky, MD; James H. Nichols, PhD; and Mark J. Rice, MD

Blood glucose meters (BGMs) have introduced a US market in the 1970s, revolutionized the care of patients with diabetes. Improved glucose control, enabled by frequent measurements, has greatly reduced long-term cardiovascular and renal complications. Although these devices were originally designed for and approved by the Food and Drug Administration (FDA) for "OTC self-monitoring by consumers," they have subsequently reached the mark of "low-turnover" standards of care for T1D.

In 2001, Van den Berghe et al reported that T1D targeting, a blood glucose level of 80 to 110 mg/dl (to convert to mmol/L multiply by 0.05551, using average values totaling significantly decreased mortality and morbidity in critically ill surgical patients. This report led to increased adoption of BGMs in hospitals. While glucose control was assessed in various settings, including the intensive care unit (ICU), surgery department

PRESS RELEASE

DIABETES LEADERS ASK CMS FOR A MORatorium ON ENFORCEMENT OF CLIA FOR POINT OF CARE BLOOD GLUCOSE MONITORS IN CRITICALLY ILL PATIENT POPULATIONS

Physicians Concerned that Abrupt Enforcement Could Have Significant Patient Consequences

May 16, 2014 — Leadership from the Centers for Medicare and Medicaid Services (CMS), the U.S. Food and Drug Administration (FDA), clinicians and patient advocates met on Tuesday, May 13, in Arlington, Virginia to identify potential joint solutions to ensure continued access to point of care blood glucose monitors (POC BGM) for critically ill patients. This event was convened by the Diabetes Technology Society (DTS), and chaired by David Klonski, M.D., FACP, Fellow AIME, Medical Director of the Diabetes Research Institute at Miami-Beach Health Services in Miami, Florida. The meeting of diabetes experts comes in response to concerns from hospital-based clinicians that switching access to these technologies would have grave patient consequences.

DEPARTMENT OF HEALTH SERVICES
Center for Clinical Standards and Quality/Survey & Certification Group

Date: November 31, 2014

TO: State Survey Agency Directors

FROM: Director

Survey Certification Group

SUBJECT: Directions re: OELabeled Use of Waived Blood Glucose Monitoring Systems (BGMs)

Memorandum Summary

- Off-Label Use of BGMs: Using a task outside of the Food and Drug Administration (FDA) approved labeling for BGMs is considered "off-label use.

- Waived Use: Obtained through the Medicare Administrative Contractors (MACs) for the Medicare waiver program.

- Directions re: OELabeled Use: Off-label use of BGMs must be in compliance with the Clinical Laboratory Improvement Amendments (CLIA) regulations. Clinical Laboratory Improvement Amendments (CLIA) regulations require all laboratories operating waived tests to follow the "Waived at Expired" (WAE) requirement.

- Surveyors Will Document OELabeled Use. Surveyors will document the identification of OELabeled Use. Documentation of the specific waiver of OELabeled Use will be included in the survey report.

- CMS 514 (Biennial Survey) will be submitted with the OELabeled Use documented in the applicable regulations and guidance document.

Proceedings of Meetings / Conferences

Hospital Diabetes Meeting: Arlington, Virginia, May 13, 2014

David C. Klonski, MD, FACP, Fellow, AIME, and Juliet S. Reyes

Meeting Summary

The Diabetes Technology Society, Foster City, California, organized a 1-day meeting on the topic of point-of-care (POC) blood glucose (BG) monitoring in the hospital. The meeting was designed to provide information on the use of POC BG monitors (BGMs) in critically ill patients (CIP) in the hospital. It is the preference of the authors to use POC BG monitors (BGMs) in critically ill patients (CIP) in the hospital, which is considered an off-label use, and to allow health care professionals (HCPs) and the public to state their respective perspectives and concerns regarding the new FDA Draft Guidance.

It is the preferential method for guiding ongoing management of patients. An empirical consequence of implementing POC BGMs is not to be used off label in CIPs; would be a reduction in the amount of glucose monitoring severely performed, with an increase in the risk for hyper- and hypoglycemia and associated adverse patient outcomes. The future of POC BGMs is a topic of ongoing discussion and debate.

Session 2: Clinical Perspectives on the Role of POC BG Monitoring in the Hospital

DEPARTMENT OF HEALTH SERVICES
Center for Clinical Standards and Quality/Survey & Certification Group

DATE: March 13, 2015

TO: State Survey Agency Directors

FROM: Director

Survey Certification Group

SUBJECT: Reinstatement of S&Cs 15-11 CLIA and Reinstatement of Draft Clarifications

We are temporarily withholding S&Cs 15-11, which was previously issued on November 21, 2014, and resuming it in draft-only form in order to...
PRIDE Statement on the Need for a Moratorium on the CMS Plan to Cite Hospitals for Performing Point-of-Care Capillary Blood Glucose Monitoring on Critically Ill Patients

David C. Klonoff, Boris Draznin, Andjela Drincic, Kathleen Dungan, Roma Gianchandani, Silvio E. Inzucchi, James H. Nichols, Mark J. Rice, and Jane Jeffreis Selye

Diabetes Research Institute (D.R.I.), Mill-Penninsula Health Services, San Mateo, California 94401; University of Colorado Denver, School of Medicine (E.D.I.), Aurora, Colorado 80045; The Nebraska Medical Center Diabetes Center (A.I.D.), Omaha, Nebraska 68198; The Ohio State University (K.D.), Columbus, Ohio 43210; University of Michigan (K.G.), Ann Arbor, Michigan 48109; Yale University School of Medicine (E.J.), New Haven, Connecticut 06510; Vanderbilt University School of Medicine (J.H.), Nashville, Tennessee 37232; and New York-Presbyterian HospitalWeill Cornell Medical College (C.W.S.), New York, New York 10021

CONTINUOUS GLUCOSE MONITORING

Clinical Accuracy of a Continuous Glucose Monitoring System With an Advanced Algorithm

Timothy S. Bailey, MD, Anna Chang, MD, and Mark Christiansen, MD

Abstract

Background: We assessed the performance of a modified Dexcom G4 Platinum system with an advanced algorithm, in comparison with frequent venous samples measured on a laboratory reference (VR) during a clinic session and in comparison to self-monitored blood glucose (SMBG) during home use.

Methods: Fifty-one subjects with diabetes were enrolled in a prospective multicenter study. Subjects were 1 sensor for 7-day use and participated in one 12-hour clinic session on day 1, 4, or 7 to collect VR reference versus glucose every 15 minutes and capillary SMBG test every 30 minutes. Carbohydrate consumption and insulin dosing during testing were manipulated to obtain data in low and high-glucose ranges.

Results: In comparison with the laboratory reference method (n = 1,280), the system provided a mean and median absolute relative differences (MARD) of 7.5% and 7.3%, respectively. The mean absolute difference for VR was 4.99 mmol/L, whereas the VR was within hypoglycemic ranges in 7.9% of the cases. The percentage of the clinically accurate 50% error grid A zone was 91.4% and the mean error was 7.7%. Majority of the sensors (73%) had an aggregated MARD in reference to VR > 10%. The HEMO-CARD/VR was higher than 10%.

TREND COMPASS FOR A CGM

Table 2. CGM difference to YSI within YSI glucose ranges: Calibrating every 12 hours, Addenbrooke's site

<table>
<thead>
<tr>
<th>YSI glucose ranges (mg/dL)</th>
<th>Number of paired CGM/YSI</th>
<th>Mean percent difference (%)</th>
<th>Median percent difference (%)</th>
<th>Mean absolute percent difference (%)</th>
<th>Median absolute percent difference (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>7432</td>
<td>0.75</td>
<td>0.74</td>
<td>10.01</td>
<td>10.80</td>
</tr>
</tbody>
</table>
Medtronic (NYSE: MDT) announced the U.S. launch of the MiniMed 630G insulin management system it developed to work with a blood glucose meter made by Ascensia Diabetes Care.
A standard is needed to determine the measurement method, test conditions, and tolerance of insulin pump dosing.

How accurate must a pen bolus be according to ISO?

- Minimum bolus of 0-2 U, allowed deviation is up to ±1 U (= 50 mg/dl)
- Mid bolus of ~30-40 U, allowed deviation is up to ±5% (~ 1.5-2 U = 75-100 mg/dl)
- Max bolus of ~60-80 U, allowed deviation is up to ±5% (~ 3-4 U = 150-200 mg/dl)

Comparative Dose Accuracy of Durable and Patch Insulin Infusion Pumps

Lore G. John, Ph.D., Jorge J. Cepero, M.D., and Brian L. Levy, M.D.

Abstract

Background:
As all major insulin pump manufacturers comply with the international insulin pump standard EN 60601-110999, there may be a general assumption that all pumps are equal in insulin delivery accuracy. This research investigates single-dose and stepped-dose delivery accuracy of commercially available insulin pumps for one single model and five different models of insulin pumps.

Methods:
For each pump model, discrete single-dose boluses during a 24-hour basal insulin infusion over a 24-hour period were measured using a time-averaged microenvironmental system. Dose accuracy was analyzed by comparing single doses and time-averaged doses to specific accuracy thresholds (±5% to ±10%).

Results:
The percentage of single doses delivered outside accuracy thresholds of (1%) of total, and (2%) were as follows: Animas Omnipod® (4.U, 1.25, and 1.3), Insulin Accu-Chek® Control (8.0, 12.0, and 15.0), Medtronic Paradigm® (7.5, 10.0, and 12.5), and Medtronic MiniMed® (7.5, 10.0, and 15.0). For all study, the percentage of doses delivered outside ±5% accuracy were: Animas Omnipod® (10.0, 15.0, and 20.0), Insulin Accu-Chek® Control (8.0, 12.0, and 15.0), Medtronic Paradigm® (7.5, 10.0, and 12.5), and Medtronic MiniMed® (7.5, 10.0, and 15.0).
OUTCOME MEASURES FOR ARTIFICIAL PANCREAS CLINICAL TRIALS

<table>
<thead>
<tr>
<th>Glycemic metrics</th>
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<tbody>
<tr>
<td>HbA1c</td>
<td></td>
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<tr>
<td>Mean CGM glucose</td>
<td></td>
</tr>
<tr>
<td>% CGM time &lt;50 mg/dl. (&lt;2.8 mmol/L)</td>
<td></td>
</tr>
<tr>
<td>% CGM time &lt;60 mg/dl. (&lt;3.3 mmol/L)</td>
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<tr>
<td>% CGM time &lt;70 mg/dl. (&lt;3.9 mmol/L)</td>
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<tr>
<td>% CGM time 70–140 mg/dl. (3.9–7.8 mmol/L)</td>
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<tr>
<td>% CGM time &gt;180 mg/dl. (&gt;10.0 mmol/L)</td>
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<tr>
<td>% CGM time &gt;250 mg/dl. (&gt;13.9 mmol/L)</td>
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<tr>
<td>% CGM time &gt;300 mg/dl. (&gt;16.7 mmol/L)</td>
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<tr>
<td>SD and coefficient of variation of CGM values</td>
<td></td>
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<tr>
<td>Fasting blood glucose, mg/dl. (mmol/L)</td>
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</table>

CONCLUDE: PUMPS DELIVER INSULIN MORE ACCURATELY THAN PENS

DOsing inACCURACY CONTRIBUTES TO VARIABLE INSULIN ABSORPTION

SECURITY = SAFETY

DEFINITION OF A CONNECTED MEDICAL SYSTEM
A device that monitors and transmits data and/or commands from or to a person connected with a hub (e.g. handheld controller/monitor, another device, smartphone, pad, computer, or the cloud.)

DEFINITION OF CYBERSECURITY
Protection of data and command information that are transmitted between connected medical devices.

CONFIDENTIALITY = HACKER CAN STEAL YOUR DATA

INTEGRITY = HACKER CAN MODIFY YOUR DATA

AVAILABILITY = HACKER CAN PREVENT YOU FROM ACCESSING YOUR OWN DATA
CONNECTED DIABETES DEVICES THAT REQUIRE SECURITY

- Blood Glucose Monitor
- Continuous Glucose Monitor
- Insulin Pump
- Artificial Pancreas System
- Smart Insulin Pen

RECENT MEDICAL DEVICE CYBERSECURITY MILESTONES

July 27, 2016
THE FIRST FDA-CLEARED SMART INSULIN PEN

Insulin Pumps Vulnerable to Hacking
AUGUST 04, 2011 ASSOCIATED PRESS
Cheney feared terrorists would 'hack' pacemaker

PRINCIPLES
- Identify and Protect
- Limit access to trusted users
- Ensure trusted content
- Detect, respond, recover
- CS documentation
- FDA will typically not need to review or approve medical device software changes made solely to strengthen cybersecurity

HACKING INTO DIABETES DEVICES

DO IT YOURSELF HACKING
Nightscout aka, CGM in the Cloud
We are not waiting to put our CGMs in the cloud.
This is a website run by a community of openers to put their Dexcom CGM in the cloud.

DIYPS.org
We are not waiting to make the world a better place

Introducing the #OpenAPS project

MALICIOUS
HACKING

8/13/2016

Can Hackers Commit the Perfect Murder By Sabotaging an Artificial Pancreas?

By Philip E. Ross
Posted 19 May 2015 | 16:00 GMT

Make the machine administer too little insulin, and the blood-glucose level may rise high enough to send the patient into a ketoacidosis coma. Make it administer too much, and the glucose falls until the brain fails causing the patient to faint, or even die. It might seem to bad guys like the way to commit the perfect murder.

WebMD

'Hacking' a Diabetes Cure?

By Sonya Collins
WebMD Health News
Reviewed by Arefa Cassoobhoy, MD

June 28, 2016 -- At least 85 people and counting are managing their type 1 diabetes with an artificial pancreas system they built themselves.
Ransomware Is Coming to Medical Devices

Chest pains send you into convulsions, then stop abruptly. Is something wrong with your pacemaker? As you pant for breath, a message pops up on your phone: "Want to keep living? Pay us a ransom now, or you die."

Kansas Heart Hospital was hit with ransomware; attackers demand two ransoms

Network World  May 22, 2016

Ransomware Attacks Can't Hide from HIPAA Anymore

Hospital and health system executives are on notice: Come clean about ransomware attacks as early as possible or be prepared to face sanctions.

Ransomware, the scourge of healthcare IT for much of 2016, is no longer something healthcare executives can try to sweep under the rug.

So It WAS Ransomware: The Implications of the Attack on MedStar Health

The cyberattack on the 10-hospital MedStar Health poses several important questions to patient care leaders nationwide.

DTSec: DIABETES TECHNOLOGY SOCIETY CYBERSECURITY STANDARD FOR CONNECTED DIABETES DEVICES
Common Criteria
A unified approach to evaluate IT products
PRESS RELEASE

New Standard to Raise Confidence in the Security of Network-Connected Medical Devices through Expert Evaluation

May 13, 2016 - DTSec Conference, San Jose, CA - Diabetes Technology Society today announced the first official public release of a new cybersecurity standard whose goal is to raise confidence in the security of network-connected medical devices through independent expert security evaluation.

This standard initially targets networked biocritical devices such as insulin pump controllers but inherently could be used in any medical product or component contributing to the protection of high value assets. This standard will provide the foundation for effective cybersecurity standards across other connected devices and the broader “Internet of Things” (IoT).

This new standard, known as DTSec, provides a framework for risk-based, multi-stakeholder definition of security requirements in the form of DTSec evaluated Protection Profiles (PPs) and product-specific Security Targets (STs), derived from the PP. DTSec approved labs evaluate the products to ensure they meet the DTSec security requirements. Successfully evaluated products are then publicly listed for the world to see.

THE DTSec STAKEHOLDERS

HEALTHCARE PROFESSIONALS
PATIENTS
PAYERs
HOSPITALS
REGULATORS
INDUSTRY ADOPTION OF DTSec

STAKEHOLDERS
DIFFERENTIATION

PUBLICITY FROM A HACK
LAWSUITS, FINES

ACCURACY IS THE
MOST IMPORTANT
FEATURE IN A
DIABETES DEVICE

GLUCOSE MONITORING
INSULIN DELIVERY
CYBERSECURITY