BIOSENSORS FOR GLUCOSE MONITORING

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Continuous Glucose Monitoring (CGMs) in Diabetes Management-In Trend
Continuous Glucose Monitoring
Key Assignee vs Emerging Assignee

**KEY ASSIGNEES**
ACTIVE FILING IN PAST 5 YEARS

- DEKA PRODUCTS
- VERILY LIFE SCI
- BIGFOOT BIOMEDICAL
- JOHNSON & JOHNSON
- TANDEM DIABETES CARE
- ABBOTT
- BECTON DICKINSON
- MEDTRONIC
- ROCHE
- DEXCOM

**EMERGING ASSIGNEE**
ACTIVE FILING IN PAST 2 YEARS

- MICROTECH MEDICAL
- TANDEM DIABETES CARE
- METRONOM HEALTH
- ARKRAY
- DIABELOOP
- VERILY LIFE SCI
- I SENS
- BIGFOOT BIOMEDICAL
**HEAD TO HEAD COMPARISON: CGMs**

**DEXCOM G5/G6** is a great option for anyone who wants a reliable, proven system that is simple and flexible. The customizable high-low alerts and “sharing” features make it ideal for those trying to ward off serious hypoglycemia, irrespective of low cost of freestyle libre.

<table>
<thead>
<tr>
<th>FEATURES</th>
<th>FREESTYLE LIBRE</th>
<th>Abbott</th>
<th>DEXCOM G5/G6</th>
<th>dexcom</th>
<th>MEDTRONIC GUARDIAN (670G)</th>
<th>Medtronic</th>
<th>SENSEONICS EVERSENSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fingerstick Calibration</td>
<td>0 - Factory Calibrated</td>
<td>G5 - yes – 2x daily</td>
<td>G6 - Factory Calibrated</td>
<td>2/day minimum</td>
<td>2/day minimum</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Labeling</td>
<td>Replaces fingersticks for treatment decisions</td>
<td>Replaces fingersticks for treatment decisions</td>
<td>Requires fingerstick confirmation</td>
<td>Requires fingerstick confirmation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>18+ years</td>
<td>2+ Years</td>
<td>7+ Years (670G)</td>
<td>14+ Years (Guardian Connect)</td>
<td>18+ Years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicare coverage</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Warmup</td>
<td>1 hour</td>
<td>2 Hours</td>
<td>2 Hours</td>
<td>24 hours</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wear length</td>
<td>14 Days</td>
<td>10 Days</td>
<td>7 Days</td>
<td>90 Days</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alarms for Lows, Highs</td>
<td>None in US</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Data display</td>
<td>Reader device or iPhone app (FreeStyle Libre Link)</td>
<td>Receiver, Android and iPhone apps, smartwatches, Tandem X2 insulin pump</td>
<td>670G pump only</td>
<td>Guardian Connect app only on iPhone</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transmitter design and on-body form factor</td>
<td>~2 stacked quarters, one-press insertion, Fully disposable transmitter integrated with sensor patch</td>
<td>Small eraser sized re-usable transmitter, one-button inserter, Three-month use transmitter separate from sensor</td>
<td>~2 stacked quarters (clamshell), inserter device, Rechargeable transmitter separate from sensor</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transmitter design and on-body form factor</td>
<td>Watchface-sized transmitter. Sensor is inserted by a healthcare provider via in-office procedure</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MARD</td>
<td>~10%</td>
<td>~9%</td>
<td>9-10%</td>
<td>8.5%*</td>
<td>* Data on file</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost</td>
<td>~ $60 for scanner $40 per sensor</td>
<td>~ $300 per transmitter $80 per sensor</td>
<td>Approx $1000 per transmitter $80 per sensor</td>
<td>~ $1400 Coverage Pending</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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*Covered by Medicare and most private insurance plans*

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*Data on file*
CHOOSE YOUR HEAD: CGMs

**DEXCOM G5/G6**
- DEXCOM G5/G6 is a great option for anyone who wants a reliable, proven system that is simple and flexible – particularly those who are treated with intensive insulin therapy. The customizable high-low alerts and “sharing” features make it ideal for those trying to ward off serious hypoglycemia. Although the sensors are a bit pricey, the ability to re-use them (until they stop working properly) helps keep the cost down. Those looking to improve their diabetes management and spend more time within their target range can certainly benefit.

**FREESTYLE LIBRE**
- FREESTYLE LIBRE is a nice choice for those who are at little risk of hypoglycemia, which includes most people with type-2 diabetes who are not taking insulin. The prolonged warm-up period and lack of high/low alerts can leave the user vulnerable to dangerous glucose levels. Also, the inability to calibrate the system may frustrate users who micro-manage their insulin and demand a high degree of accuracy.
  - It can also be a reasonable option for those who are easily distracted or annoyed by the alarms/alerts generated by the other CGM systems. Finally, Libre is a good option for those who must pay out-of-pocket for their equipment and supplies. The scanner costs a fraction of what the “hardware” costs with the other systems, and the sensors cost about half.

**MEDTRONIC GUARDIAN CONNECT**
- MEDTRONIC GUARDIAN CONNECT carries the Medtronic name, which means different thing to different people. The company invests a ton in research & development, and is financially secure for the long-haul. Their Carelink program and new Sugar IQ algorithm can be instrumental in helping users (and their clinicians) learn from the data and make therapeutic adjustments.

**SENSEONICS EVERSENSE**
- With Eversense, a trained health care provider numbs the area and places the sensor in the upper arm and you’re good to go for up to 3-months. In clinical studies, the Eversense system detected 95% of hypoglycemic episodes (70 mg/dL) and 99% of hyperglycemic episodes (180 mg/dL) within 15 minutes. The Eversense CGM System can be configured to provide three types of alerts: visual, auditory, and on-body vibe alerts, which can provide you with an additional safety advantage, even during sleep. The smart transmitter, with its low profile and flexibility to remove and reattach without wasting a sensor, enables a new level of discretion.

**New Product Launch-2019**
- Tandem Diabetes Care is planning a launch in second half of 2019 (closed-loop system)
Future Development - Continuous Glucose Monitoring

Based on recent IP focus - Abbott Vs key competitors

**Abbott**
- Addition of sealing members to prevent contamination of ports
- Minimizing error and data loss during transmission
- Improving sensor accuracy, real-time detection in the critical hypoglycemic ranges
- Avoiding multiple calibrations/sensor masking during the early stages

**Dexcom**
- Enhancing data security to prevent unauthorized access to medical data
- Cloud computing to provide on-demand network access
- Controlled flow of info. alerts as per assigned order of person/devices
- Intelligent real-time mode switching as per required user interaction with device

**Medtronic**
- Electrochemical impedance spectroscopy for effective/Intelligent sensor data identification
- Improved GUI optimization based on historical data pattern recognition
- Orthogonally redundant sensors to reduce lag, improve start-up time and improve accuracy
- Calibration free or near calibration free sensor for improved accuracy

**Roche**
- Body wearable electronic skin patch for long-term wear capability and improved user convenience
- Modified system using different sensors for continuous data tracking without extra batteries
- Control to range algorithm adjust/determine precise insulin with failsafe based on historical data
- Automatic data update based on real-time/quasi-continuous monitoring without user interaction
## Future Development - Continuous Glucose Monitoring

### FEATURE COMPARISON

<table>
<thead>
<tr>
<th>FEATURES TYPE</th>
<th>ABBOTT</th>
<th>DEXCOM</th>
<th>MEDTRONIC</th>
<th>ROCHE</th>
</tr>
</thead>
<tbody>
<tr>
<td>SECURITY</td>
<td>X</td>
<td>✓</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>CALIBRATION FREE/MINIMIZING CALIBRATION</td>
<td>✓</td>
<td>X</td>
<td>✓</td>
<td>X</td>
</tr>
<tr>
<td>DATA IMPROVEMENT</td>
<td>X</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>HARDWARE MODIFICATION</td>
<td>✓</td>
<td>X</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>SENSOR ACCURACY/IMPROVEMENT</td>
<td>✓</td>
<td>X</td>
<td>✓</td>
<td>X</td>
</tr>
<tr>
<td>INSULIN DELIVERY MANAGEMENT</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>✓</td>
</tr>
<tr>
<td>USER INTERACTION/IMPROVEMENT</td>
<td>X</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>
✓ The Glucose Biosensor Market is expected to exceed more than US$ 30.5 Billion by 2024 at a CAGR of 10.29%.

✓ Many companies have tried to develop non-invasive technology and device for glucose monitoring, but so far with no success. A few devices had obtained approval from the authorities in the USA or Europe before being abandoned: GlucoWatch (Cygnus), Pendra (Pendragon Medical), NBM-200G (OrSense) or HG1-c (C8 MediSensors).

✓ Recently, Integrity Applications received the European CE Mark and launched its GlucoTrack DF-F device late 2014 in Europe. While several minimally-invasive devices are now commercially available, bringing to the market a totally non-invasive device would represent a great change for the market and the diabetics.

✓ Bigfoot Biomedical is one of several startups planning to bring Closed-loop technology which mostly removes the user/patient from the process and delivers insulin to their body in a smart, real-time trickle, with the exception of mealtimes when a manual extra dose is still required. Although Medtronic's 670G was the first closed-loop system on the market in summer of 2017
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