



BIOSENSORS FOR GLUCOSE MONITORING

Author/Analysis: Chetan Marwah & Ravi Shankar

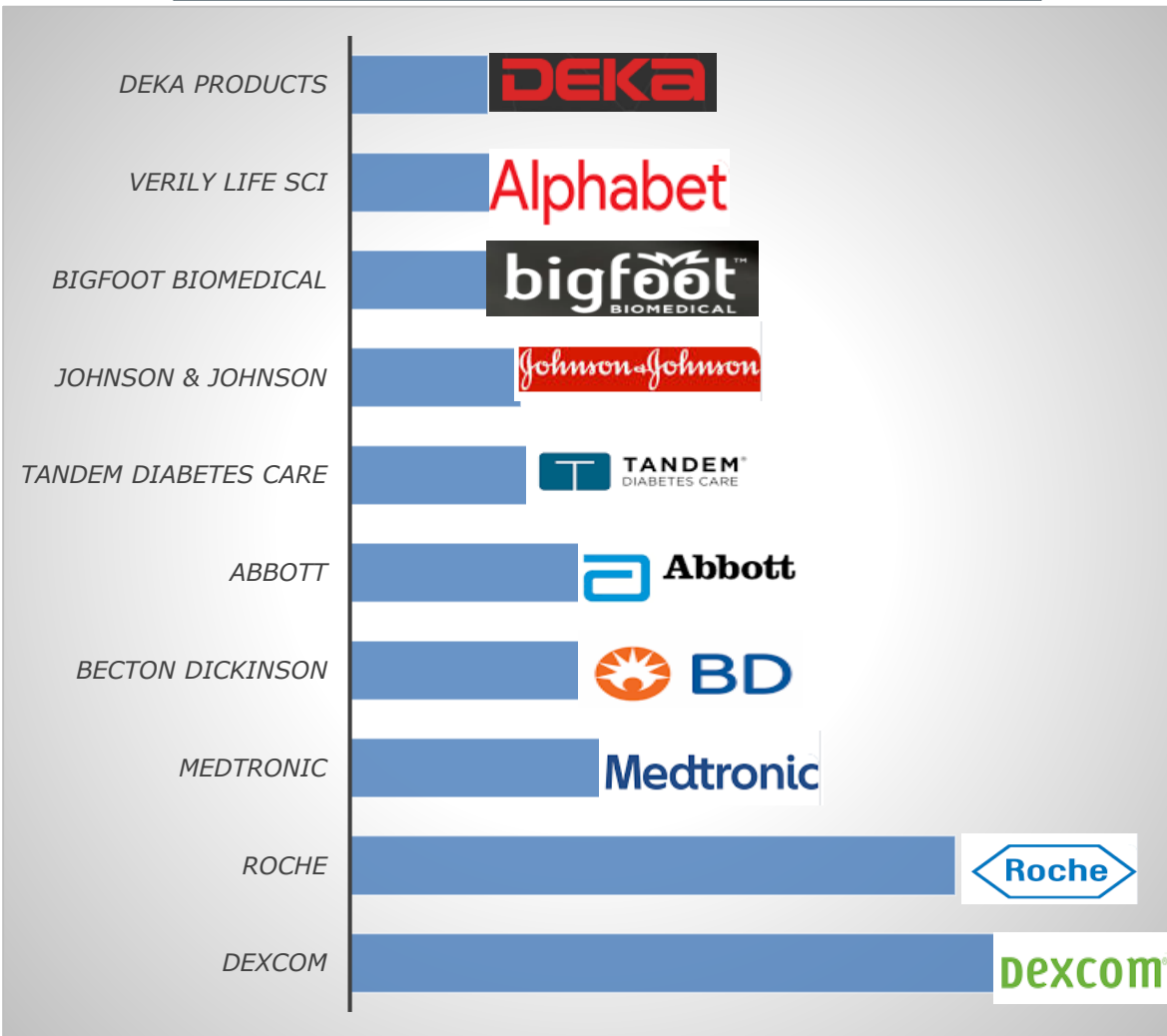


*Continuous Glucose Monitoring
(CGMs) in Diabetes Management-In
Trend*

Continuous Glucose Monitoring

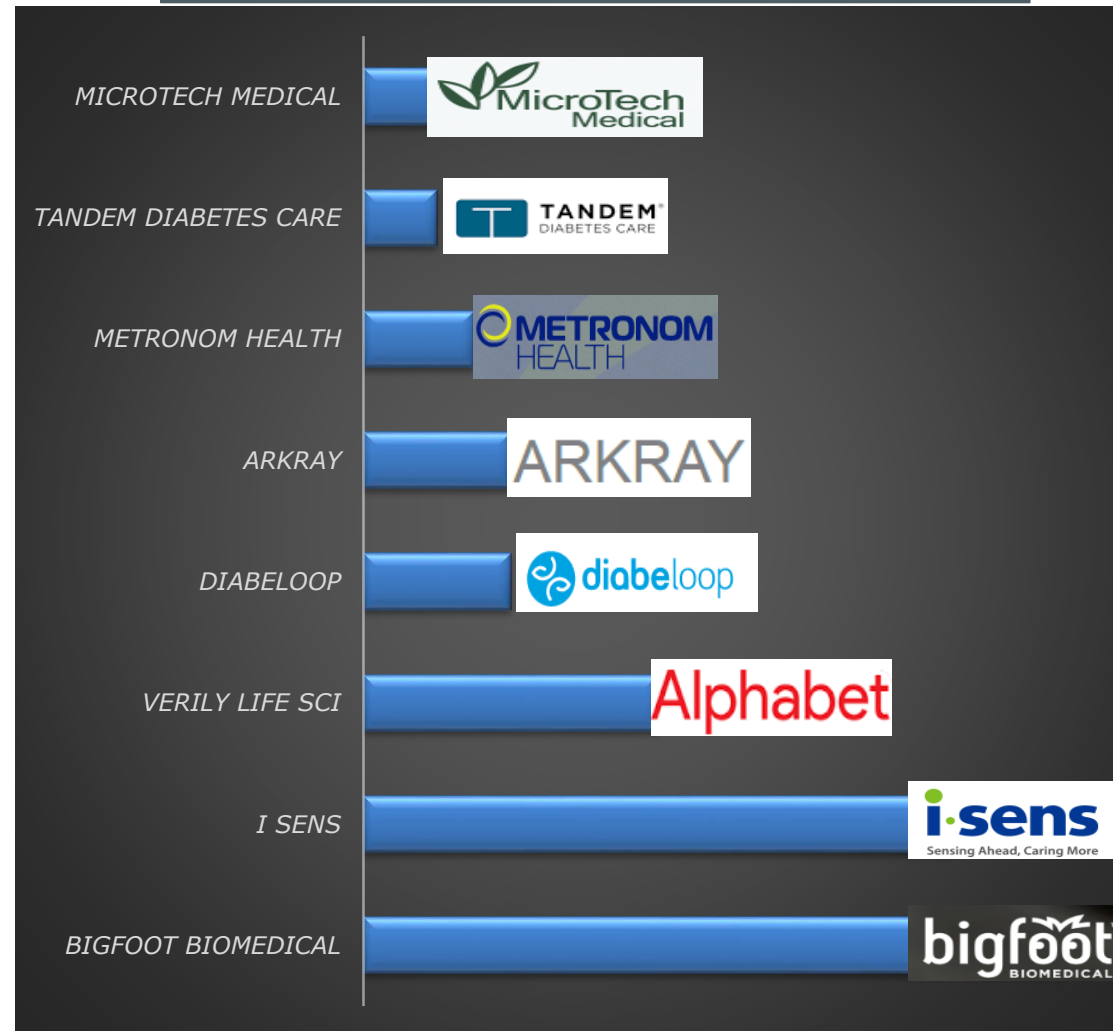
Key Assignee vs Emerging Assignee

KEY ASSIGNEES ACTIVE FILING IN PAST 5 YEARS







Vs

EMERGING ASSIGNEE ACTIVE FILING IN PAST 2 YEARS



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

| FEATURES | FREESTYLE LIBRE  | DEXCOM G5/G6  | MEDTRONIC GUARDIAN (670G)  | SENSEONICS EVERSENSE  |
|---|--|---|---|---|
| Fingerstick Calibration | 0 - Factory Calibrated | G5 – yes – 2x daily G6 – Factory Calibrated | 2/day minimum | 2/day minimum |
| Labeling | Replaces fingersticks for treatment decisions | Replaces fingersticks for treatment decisions | Requires fingerstick confirmation | Requires fingerstick confirmation |
| Age | 18+ years | 2+ Years | 7+ Years (670G) 14+ Years (Guardian Connect) | 18+ Years |
| Medicare coverage | Yes | Yes | No | No |
| Warmup | 1 hour | 2 Hours | 2 Hours | 24 hours |
| Wear length | 14 Days | 10 Days | 7 Days | 90 Days |
| Alarms for Lows, Highs | None in US | Yes | Yes | Yes |
| Data display | Reader device or iPhone app (FreeStyle Libre Link) | Receiver, Android and iPhone apps, smartwatches, Tandem X2 insulin pump | 670G pump only Guardian Connect app only on iPhone | Android and iPhone apps |
| Transmitter design and on-body form factor | ~2 stacked quarters, one-press insertion Fully disposable transmitter integrated with sensor patch | Small eraser sized re-usable transmitter, one-button inserter Three-month use transmitter separate from sensor | ~2 stacked quarters (clamshell), inserter device Rechargeable transmitter separate from sensor | Watchface-sized transmitter. Sensor is inserted by a healthcare provider via in-office procedure Rechargeable transmitter separate from sensor |
| MARD | ~10% | ~9% | 9-10% | 8.5%* * Data on file |
| Cost | ~ \$60 for scanner \$40 per sensor Covered by Medicare and most private insurance plans | ~ \$300 per transmitter \$80 per sensor \$600 per receiver G5 covered by Medicare and most private insurance plans | Approx \$1000 per transmitter \$80 per sensor Coverage Pending | ~ \$1400 Coverage Pending |

CHOOSE YOUR HEAD: CGMs

Bigfoot Biomedical exploiting proprietary smart pump & Abbott Freestyle Libre to deliver an appropriate trickle of insulin through the day



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**)

TIDEPPOOL

Future Development-Continuous Glucose Monitoring

Based on recent IP focus- Abbott Vs key competitors



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



Enhancing data security to prevent unauthorized access to medical data



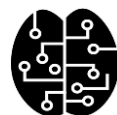
Cloud computing to provide on-demand network access



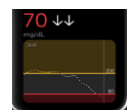
Controlled flow of info. alerts as per assigned order of person/devices



Intelligent real time mode switching as per required user interaction with device



Electrochemical spectroscopy for impedance identification of effective/sensor data



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



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



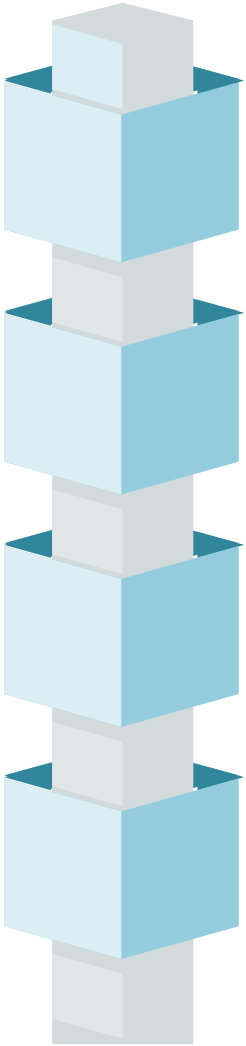
Automatic data update based on real time/quasi-continuous monitoring without user interaction

Future Development-Continuous Glucose Monitoring

FEATURE COMPARISON

| FEATURES TYPE | ABBOTT | DEXCOM | MEDTRONIC | ROCHE |
|---|--------|--------|-----------|-------|
| SECURITY | X | ✓ | X | X |
| CALIBRATION FREE/MINIMIZING CALIBRATION | ✓ | X | ✓ | X |
| DATA IMPROVEMENT | X | ✓ | ✓ | ✓ |
| HARDWARE MODIFICATION | ✓ | X | ✓ | ✓ |
| SENSOR ACCURACY/IMPROVEMENT | ✓ | X | ✓ | X |
| INSULIN DELIVERY MANAGEMENT | X | X | X | ✓ |
| USER INTERACTION/IMPROVEMENT | X | ✓ | ✓ | ✓ |

Key Takeaways



- ✓ 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



Contact details

Email:-services@iebrain.com

Web:- www.iebrain.com



INDIA

207-208, 2nd Floor, Welldone
Tech Park Sohna Road, Sector 48
Gurugram, Haryana 122018,
Phone - +91 124 429 4218



USA

4 Heinrick Way
Bridgewater, New Jersey
Phone - + 1 347 480 2054



UK

13 Freeland Park, Poole, Dorset,
United Kingdom, BH16 6FH
Phone - + 44 207 193 3548



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