

BIGFOOT CLINIC HUB™ PUTS CRITICAL DATA AT FINGERTIPS OF HEALTH CARE PROFESSIONALS TO ENABLE PROACTIVE CARE OF THEIR PATIENT POPULATIONS WITH TYPE 1 AND TYPE 2 DIABETES

- Cloud-based platform developed by Bigfoot Biomedical® automatically captures and presents insulin therapy data from the Bigfoot Unity System so clinics can proactively support patients at a distance
- For health care professionals Clinic Hub is the cornerstone of the new Bigfoot Unity™ Diabetes Management Program that features connected smart pen caps to provide dosing support for people who rely on multiple daily injections of insulin
- Says Endocrinologist Dr. Bantwal Baliga, “This technology is a game changer for me – I feel I am truly in charge of my patients with diabetes.”
- New updates to Clinic Hub announced today provide clinics with more flexible workflow and prescription management

Milpitas, CA, December 1, 2021 - Since launching in late summer 2021, the innovative Bigfoot Unity™ Diabetes Management Program and its Bigfoot Clinic Hub™ are demonstrating that technology can help transform how health care professionals (HCPs) manage their patient populations on multiple daily injections (MDI) of insulin.

“We’ve created a first-of-its-kind, HCP-centered solution that supports clinicians to efficiently deliver proactive care with a much-needed level of simplicity and convenience to facilitate both patient adherence and practice implementation.”

Dr. Jim Malone
Chief Medical Officer, Bigfoot Biomedical

“The traditional treatment plan for people with Type 1 or Type 2 diabetes on MDI therapy is simply not working for health care professionals or their patients,” said Dr. Jim Malone, chief medical officer for Bigfoot Biomedical. “We’ve created a first-of-its-kind, HCP-centered solution that supports clinicians to efficiently deliver proactive care with a much-needed level of simplicity and convenience to facilitate both patient adherence and practice implementation.”

MDI insulin therapy is common for patients with either Type 1 or Type 2 diabetes. But the therapy also depends heavily on patients closely following their HCP’s insulin dosing instructions and accurately recording their activities on paper logs. Most often it’s only during the patient’s quarterly, in-person appointments can the HCP review the patient’s logs to determine if the insulin dosing and instructions need to be adjusted.

With Bigfoot Unity, HCPs are able to review, on demand, patient data derived from the patient’s prescribed Bigfoot Unity System. The Bigfoot Unity System, which seamlessly integrates with Abbott’s FreeStyle® Libre 2, the leading sensor-based glucose monitoring system in the U.S. and worldwide,¹ includes a mobile app and smart insulin pen caps to provide dose decision support. Data, including CGM and insulin dose timing information, is automatically captured by the pen caps and mobile app and uploaded to Bigfoot Clinic Hub secure web portal whenever WiFi or a cellular signal is present.

“This technology is a game changer for me – I feel I am truly in charge of my patients with diabetes,” said Bantwal S. Baliga, MD, who oversees East Alabama Endocrinology with offices in Alabama and Georgia and was one of the first practices to partner with Bigfoot Biomedical. “In just one portal I can look at the CGM readings, look at the daily patterns, identify problematic glucose excursions such as hypos and hyperglycemic periods, verify their compliance, look at their therapeutic regimen and make changes, if necessary, on a daily basis.”

In designing Clinic Hub, Bigfoot focused on creating a streamlined, patient report format to provide meaningful, at-a-glance data. The first level report enables the HCP to quickly review the practice’s entire Bigfoot Unity patient population and filter for those who are experiencing more frequent high or low glucose periods. The HCP can then select the individual patient report, which includes an integrated graph tracking both CGM and time of insulin dose data. The report also displays Time in Range and other parameters that are part of an AGP report in a standardized format familiar to diabetes care professionals.

“As physicians treating our patients with diabetes, it sometimes feels like we are looking through a broken window, spending time during a patient’s appointment looking over incomplete data logs to make therapy recommendations,” said Dr. Malone. “Now we have Bigfoot Clinic Hub that presents the automatically captured data from our patient’s system to us, so it’s easy and efficient to identify key patterns and optimize the patient’s insulin therapy. This helps clinicians provide proactive care for a patient population across a broad geography.”

For Dr. Baliga, the ability of Bigfoot Unity to help his team proactively support patients at a distance was a key factor in partnering with Bigfoot Biomedical. “We have more than 1,200 patients on multiple daily injections of insulin and most live significant distances from our offices,” said Dr. Baliga. “Overall, the Bigfoot Unity Program has transformed my practice in a way I hardly imagined it would be possible until recently. They are fulfilling an unmet need in diabetes care.”

Updates to Clinic Hub announced today streamline patient onboarding and provide clinics with additional work-flow flexibility regarding patient updates and prescription management – built directly into the program. During this launch phase, Bigfoot is working closely with partner clinics like Dr. Baliga’s to continue to expand Clinic Hub functionality and provide more flexibility and customization to the clinics.

In addition to providing access to their patients’ data, Bigfoot Clinic Hub provides tools and technology to support the clinics in providing Remote Physiologic Monitoring (RPM) services.^{2,3} As part of this service, Bigfoot provides RPM billing guidance documenting relevant data collected by the Bigfoot Unity System⁴ and access to experienced RPM specialists to support practices with billing or RPM questions. Every practice is also matched with a Bigfoot Client Success Manager to provide the education and training on Clinic Hub and the larger Bigfoot Unity Diabetes Management Program.

“Our team approach helps practices onboard the Bigfoot Unity program so they can focus on what matters most, which is providing exceptional, proactive, continuous care to their patients,” said Dr. Malone. “Instead of spending valuable appointment time reading through paper logs, patient appointments can center on what we as health care professionals want to do – hearing from our patients, building trust and confidence, and helping them realize their best health outcomes.”

About Bigfoot Biomedical, Inc.

Bigfoot Biomedical was founded by a team of people with personal connections to Type 1 and Type 2 diabetes. We seek to change the paradigm of care for diabetes. Bigfoot is an unconventional company taking an unconventional approach. Unlike others, we're looking at insulin therapy holistically and utilizing services, support, and novel business models. We'll partner with health care providers to deliver simple, connected, and comprehensive solutions for the large number of people who have been overlooked by diabetes innovation. Learn more at www.bigfootbiomedical.com. Follow us on Twitter @BigfootBiomed, Instagram and Facebook.

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Important Safety Information for the Bigfoot Unity Diabetes Management System

The Bigfoot Unity System is indicated for management of diabetes in persons 12 years and older. Bigfoot Unity provides glucose monitoring data via the Abbott FreeStyle Libre 2 Flash Glucose Monitoring sensor. The system incorporates real-time alarm capabilities and is designed to replace blood glucose testing for diabetes treatment decisions, unless otherwise indicated. The device is intended to provide insulin dose information using the available glucose data to assist persons with diabetes mellitus who use disposable pen-injectors for the self-injection of insulin in implementing health care provider recommended insulin dose regimens. The system must not be used with automated insulin dosing (AID) systems, including closed loop and insulin suspend systems.

The Bigfoot Unity System requires a prescription. A health care professional must provide appropriate settings for the device based on user specific criteria. It is not intended to be used by individuals who dose insulin in ½ unit increments, take multiple daily doses of long-acting insulin or take high doses of vitamin C (more than 500 mg per day).

The system provides dose recommendations; however, the final decision on when and how to dose is up to the individual user. Failure to use the system according to the instructions for use may result in missing a severe low blood glucose or high blood glucose event and/or making a treatment decision that may result in injury.

For complete details of the system and its components, including warnings, contraindications, and precautions, please consult the Bigfoot Unity User Guide.

*Bigfoot Unity System does not automatically alert your health care provider to potentially serious glycemic conditions or other health conditions, and you should ask your health care providers about their intended data review plan. Bigfoot Unity does not relieve the patient (or their caregivers) of their responsibility to proactively monitor their glucose data and to contact their health care provider or emergency services (e.g., call 911) if there is a suspected emergency health condition, such as, but not limited to, a severe hypoglycemia or a severe hyperglycemia. Bigfoot does not automatically review, monitor, evaluate, or analyze any information generated or collected by the Bigfoot Unity System.

Important Safety Information for the Bigfoot Unity Diabetes Management Program

The Bigfoot Unity Diabetes Management Program incorporates components intended to support healthcare professions in remote physiologic monitoring of their enrolled patients, facilitating on-going diabetes therapy adjustments. The Program does not incorporate real-time monitoring (by either Bigfoot or any other entity, including the health care provider) and does not replace the enrolled patient's responsibility to proactively monitor their own glucose values and make appropriate treatment decisions.

The circular shape of the sensor housing, FreeStyle, Libre, and related brand marks are marks of Abbott and used with permission.

¹Data based on the number of users worldwide for FreeStyle Libre family of personal CGMs compared to the number of users for other leading personal CGM brands and based on CGM sales dollars compared to other leading personal CGM brands.

²RPM Services provided by a health care provider are subject to deductibles and coinsurance as applicable per individual health plan. Reimbursement rates, and thus costs to the patient for the Bigfoot Unity program, are set by their health plan and vary widely across all payers based on a number of factors including geography and contracted rates.

³Refer to individual Plan details for complete coverage information. As a courtesy to its customers, Bigfoot provides the most accurate and up-to-date information available, but it is subject to change and interpretation. The patients' providers are ultimately responsible for determining the appropriate codes, coverage, and payment policies for individual patients. Bigfoot does not guarantee third party coverage of payment for our products or reimburse patients for claims that are denied by third party payors.

⁴Each Superbill or any claim adjudication support provided under the Bigfoot Unity diabetes management program is for reference only, and is not a guarantee of coverage, a guarantee of reimbursement for any item or service reimbursed under any governmental or third-party payer, or advice that referenced CPT codes are applicable. With respect to any CPT code identified by Bigfoot, each HCP is solely responsible for all decisions regarding which CPT code(s) to report, if any, considering the items and services furnished, the patient's clinical facts and circumstances, and applicable coding rules, including the requirement to code to the highest level of specificity possible.