

BIGFOOT UNITY™ PROGRAM NOW AVAILABLE IN US, REVOLUTIONIZES HOW CLINICIANS SUPPORT PATIENTS TO SUCCESSFULLY MANAGE THEIR DIABETES

- The program features first-of-its-kind technologies and a cloud-based platform that seamlessly connects clinics and health care providers to their Bigfoot Unity patients to enable continuous, proactive care — with or without an office visit
- Bigfoot CEO Jeffrey Brewer and noted endocrinologist Dr. George Grunberger to present as part of ADA 81st Scientific Sessions on Monday, June 28 at 11:30 a.m. ET.

Milpitas, CA, June 24, 2021 - Bigfoot Biomedical announced today that its innovative Bigfoot Unity™ Diabetes Management Program is now available to diabetes clinics and endocrinology practices in select markets across the U.S. The groundbreaking program reimagines how clinicians treat and manage their patients with Type 1 or Type 2 diabetes who rely on multiple daily injection insulin therapy. Instead of reviewing patient data infrequently and making episodic therapy adjustments, the program provides clinicians with tools, support services and access to data for their Bigfoot Unity patients in order to monitor therapy adherence, analyze data and make any needed proactive therapy adjustments. Additionally, it enables clinicians to deliver Remote Physiologic Monitoring for those patients in a scalable, efficient way.

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Jeffrey Brewer
CEO, Bigfoot Biomedical

“As an industry, we need to fix the broken therapy cycle for treating diabetes so both patients and clinicians can be successful in realizing better outcomes,” said Jeffrey Brewer, CEO of Bigfoot Biomedical and former CEO of JDRF. “With these innovative, connected technologies, we can address many of the challenges faced by clinicians. Our Bigfoot Unity Program is designed to act as a real-time partner in diabetes management so clinicians focus on what really matters.”

Clinicians who treat diabetes face unique challenges not only in helping patients follow their insulin therapies but also managing new technologies and the vast amounts of patient data they generate. “As referenced in the new AACE Guideline, it’s vital with the emergence of new technologies that clinicians have the support, training and infrastructure to leverage and manage these tools as we work to realize better outcomes for our patients,” said George Grunberger, MD, of the Grunberger Diabetes Institute and AACE task force co-chair. “Bigfoot’s holistic approach looks at the entire treatment ecosystem to support both clinicians and patients to be successful.”

The patient-facing component of the Bigfoot Unity Program is the recently FDA-cleared Bigfoot Unity System with first-of-its-kind smart pen caps and integration with Abbott’s FreeStyle® Libre 2 iCGM sensor. The system is the first and only solution to translate continuously monitored glucose data into on-demand insulin dose recommendations based on clinician’s instructions and displayed right on the pen-cap screen for ease of use.

For clinicians, the innovative approach of the Bigfoot Unity Program is centered around the Bigfoot Clinic Hub™, a secure, cloud-based platform. Data from their patients using the Bigfoot Unity System and a FreeStyle Libre 2 sensor is passively captured and uploaded to the Clinic Hub from the System's smart pen caps whenever WiFi or cellular signal is present providing on-demand access.

The Bigfoot Clinic Hub makes it possible for providers to make informed, timely therapy adjustments and address potential issues between office visits — before they become critical. Patient reports with integrated glucose and insulin data help clinicians identify patterns and gain visibility to patient adherence to their prescribed therapy. Through the hub, clinics can track their Bigfoot Unity patient population, easily sorting as needed, for example by patients who are more frequently experiencing low or high glucose values.

It's this interaction with passively captured patient data that allows the Bigfoot Unity Program to support an integral component of telemedicine — Remote Physiologic Monitoring (RPM). “This innovative approach redefines the traditional treatment cycle, allowing clinicians like me to effectively scale therapies to a broad patient population and have the patient and clinic tools to realize reimbursement for delivering proactive, remote care,” said Grunberger.

Bigfoot Biomedical introduces a very different commercial model by entering into partnerships with contracted endocrinology practices and diabetes clinics. The program is offered as a bundle of devices, supplies and services and delivered as a convenient 30-day subscription to eliminate any upfront costs. The Bigfoot Unity Program is eligible for insurance coverage and generally should be covered by insurance although copays will vary. The Bigfoot Unity Program is supported by a dedicated team of Bigfoot specialists to help clinicians integrate its tools into their existing workflows. Bigfoot Certified Diabetes Care and Education Specialists onboard and train patients through a 1:1 platform.

“Advances in technology are moving at a rapid pace, necessitating a radical change in diabetes care,” said Brewer. “It's long overdue, especially for those who rely on multiple daily injections of insulin and their clinicians.”

The Bigfoot Unity Program is now available in California, Texas, Florida, Pennsylvania, Ohio, New York, New Jersey, Massachusetts, and other New England states. Availability will expand to other markets throughout 2021 and 2022.

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.

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 provider must supply appropriate settings for the device based on user specific criteria. It is not intended to be used by individuals who dose insulin in 1/2 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.

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

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