

BIGFOOT BIOMEDICAL® RECEIVES FDA CLEARANCE FOR BIGFOOT UNITY™ DIABETES MANAGEMENT SYSTEM, FEATURING FIRST-OF-ITS-KIND SMART PEN CAPS FOR INSULIN PENS USED TO TREAT TYPE 1 AND TYPE 2 DIABETES

- Integrated with Abbott's FreeStyle® Libre 2 system, the Bigfoot Unity System is the first and only to translate continuously monitored glucose data into on-demand insulin dose recommendations displayed right on the pen-cap screen for ease of use¹
- First and only FDA-cleared dose decision support system with real-time hypoglycemia alerts^{2,3} and compatible with all major U.S. brands of rapid- and long-acting disposable insulin pens
- Bigfoot Unity System is the centerpiece of the larger holistic program to simplify and connect key aspects of insulin management for patients and health care providers, allowing for individualized, proactive care

Milpitas, CA, May 10, 2021 - Bigfoot Biomedical, a company dedicated to better health outcomes for people with insulin-requiring diabetes, announced today that the FDA has granted 510(k) clearance for first-of-its-kind Bigfoot Unity™ Diabetes Management System, which features connected smart pen caps that recommend insulin doses for people using multiple daily injection (MDI) therapy. The Bigfoot Unity smart pen caps provide on-demand, insulin dose decision support to minimize guesswork and enable patients to follow their doctor's instructions in a convenient, simple way. The Bigfoot Unity System is the centerpiece of the larger Bigfoot Unity program that takes a holistic approach to simplify and connect key aspects of insulin management for patients and health care providers.



The Bigfoot Unity System is the first and only solution for people with Type 1 or Type 2 diabetes on MDI therapy that directly uses integrated continuous glucose monitoring system (iCGM) data from Abbott's FreeStyle Libre 2 system to provide an insulin dose recommendation, which is based on a physician's instructions. The dose is displayed directly on a proprietary, connected smart cap for the person's disposable insulin pens without the need to manually input glucose data on a separate device. Cleared for use by individuals aged 12

and up, the system is designed to clearly, and in real-time, help answer the question, "How much insulin would my doctor recommend I take right now?"

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Jeffrey Brewer
CEO, Bigfoot Biomedical

"Diabetes management is incredibly hard because insulin has no fixed dose or timing, leaving individuals to constantly determine their doses and configure devices as they make multiple critical decisions every day about how much insulin to take," said Jeffrey Brewer, CEO of Bigfoot Biomedical. "At Bigfoot, we want to ease the burden of diabetes for people taking insulin by minimizing the anxious guesswork involved with insulin dosing in a convenient, simple way."

The Bigfoot Unity System is the only FDA-cleared connected solution to:

- Display physician recommended dose at point-of-therapy using current iCGM data right on the pen cap
- Seamlessly integrate with Abbott's FreeStyle Libre 2 system, the leading sensor-based glucose monitoring system in the U.S. and worldwide⁴
- Compatible with all major U.S. brands of rapid- and long-acting disposable insulin pens — including those produced by Eli Lilly and Company, Novo Nordisk and Sanofi
- Upload iCGM and dose-time data without manual intervention from the patient or the health care provider to enable ongoing, proactive patient care through remote physiologic monitoring



“People with diabetes can be overwhelmed with the amount of data they get from multiple devices, so it’s important to develop connected technologies that simplify the experience,” said Jared Watkin, senior vice president, Diabetes Care, Abbott. “Through Abbott’s collaboration with Bigfoot Biomedical, we’re integrating our revolutionary, easy-to-use FreeStyle Libre 2 technology with the Bigfoot Unity System to provide automated information for personalized diabetes management.”

How the Bigfoot Unity System Works

The Bigfoot Unity System has three primary components — proprietary smart pen caps for both rapid- and long-acting insulin, mobile app and integrated FreeStyle Libre 2 iCGM sensor — that seamlessly fit into the person’s dose decision process when they need it throughout the day.

The Bigfoot Unity smart pen cap for rapid-acting insulin allows the user to scan the FreeStyle Libre 2 sensor, displaying the user’s current glucose value, trend arrow and any recommended correction dose. The smart pen cap also directly displays the health care provider’s suggested meal insulin doses with the correction dose. In just a few steps the system gives the person with diabetes support to make a real-time treatment decision.

While the Bigfoot Unity System’s dose recommendations are on demand as needed by the user, the system also provides continuous support with important reminders and alerts. The Bigfoot Unity System notifies the person if they may have missed their usual long-acting insulin dose. The Bigfoot Unity app also provides a very low glucose alert when the person’s glucose value falls below 55 mg/dL as well as an optional low glucose alert when the glucose value falls below 70 mg/dL.

Data from the iCGM and time-of-dose data from the Bigfoot Unity pen caps are automatically captured and uploaded to the cloud whenever WiFi or cellular signal is present, replacing the onerous manual logs typically kept by people on MDI therapy. The person’s health care provider also can view this patient data through a secure web portal, the Bigfoot Clinic Hub.

Health Care Providers Gain Real-Time Partner to Help Support Patients

The FDA-cleared Bigfoot Unity System is included as part of a more comprehensive program offering, focused on helping health care providers deliver individualized and proactive care to their patients with insulin-requiring diabetes. The Bigfoot Unity program supports treatment of a broad spectrum of patients on MDI therapy from

those with Type 1 diabetes not on insulin pumps to those with Type 2 diabetes needing to step up their insulin therapy. The program's holistic approach focuses upon the key aspects of insulin management for patients struggling with glycemic control, insulin dosing or those experiencing hypoglycemic unawareness.

"For health care providers the Bigfoot Unity™ diabetes management program could be a gamechanger by connecting them to data that can provide better insight into what their patients are actually doing," explained diabetologist Jim Malone MD, chief medical officer for Bigfoot Biomedical. "By replacing guesswork and complexity with connectivity and simplicity, the Bigfoot Unity program is truly serving as that real-time partner for both patients and providers when it comes to dose decision support and overall diabetes management."

Key benefits of the Bigfoot Unity program to health care providers:

- Enables providers to deliver individualized, proactive care remotely, and easily track their full population of MDI patients
- Introduces a simple, accessible system to patients with Bigfoot providing onboarding, training and ongoing customer support
- Ensures a smooth on-ramp to CGM technology for patients who are first-time users, and supports patients to make confident, personalized insulin dosing decisions
- Automatically collects data to support remote physiologic monitoring by physicians

"There are more than 7 million people in the U.S. on insulin therapy and many use insulin injections multiple times a day, yet there have been few advancements for this hugely underserved market," said Brewer. "Bigfoot Unity is specifically designed to be simple and accessible — no matter the person's level of technical expertise — removing a key barrier to health equity. We know people with diabetes want to be successful with their insulin therapy, and it's often complex and expensive technology that gets in the way."

The Bigfoot Unity program will be available through select diabetes clinics beginning in spring 2021. Providers who would like additional information should go to www.bigfootbiomedical.com.

[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're partnering 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.

[About Bigfoot Biomedical CEO Jeffrey Brewer](#)

Jeffrey Brewer is founder and CEO of Bigfoot Biomedical. Since his son's 2002 diagnosis of Type 1 diabetes, Jeffrey has been a thought leader and catalyst in the diabetes community, first as a philanthropist who funded and launched the Artificial Pancreas Project along with JDRF International, then as JDRF's CEO where he forged partnerships to drive medical device innovation. Prior, Jeffrey was an entrepreneur and founded and led highly successful dot-com start-ups including CitySearch and Overture/GoTo.com.

Indications and Important Safety Information

The Bigfoot Unity Diabetes Management System is indicated for the management of diabetes in people ages 12 years and older. The Bigfoot Unity System provides glucose monitoring data via Abbott's FreeStyle Libre 2 integrated continuous glucose monitoring system. 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 people with diabetes mellitus who use disposable pen-injectors for the self-injection of insulin in implementing health care provider recommended insulin dose regimens. The device is intended for single patient use only and requires a prescription. The Bigfoot Unity System is also intended to communicate autonomously with digitally connected medical devices where the patient manually controls therapy sessions.

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 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).

¹Based on products available in the U.S. as of May 2021

²Table 6.4 - Classification of hypoglycemia. American Diabetes Association. 6. Glycemic targets: Standards of Medical Care in Diabetes—2021. *Diabetes Care* 2021;44(Suppl. 1):S73–S84. <https://doi.org/10.2337/dc21-S006>

³In order to receive alerts, Notifications and Critical Alerts must be turned on and the sensor must be within 20 feet of the phone with the Bigfoot Unity Mobile App active. Alerts only available on the phone. For compatible phones, please visit www.bigfootbiomedical.com/compatible

⁴Data on file, Abbott Diabetes Care. Data based on the number of users worldwide for the FreeStyle Libre portfolio compared to the number of users for other leading personal use, sensor-based glucose monitoring systems.

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