bigfoot | unity™

User Guide

Welcome to Bigfoot Unity™

The Bigfoot Unity™ Diabetes Management System consists of a set of connected devices for people who use disposable insulin pens for their diabetes care.

With Bigfoot Unity you get a set of connected devices to:

- Monitor your glucose continuously and give you readings on demand without fingersticks.[1]
- Do the math for you to calculate the correction and meal doses recommended by your health care provider.
- Let you see your glucose range and insulin dose information directly on your mobile phone.[2]
- Provide the capability for alerts when your glucose is low.
- Help you remember when you took your last insulin dose.

Bigfoot Unity App

Black Cap for Long-Acting Insulin

White Cap for Rapid-Acting Insulin

Abbott FreeStyle Libre 2 Sensor

Bigfoot Blood Glucose Meter

The System offers a suite of tools to help you streamline your diabetes care using two Bigfoot Unity™ Caps (Caps) with digital displays (that replace the pen caps from your disposable long-acting and rapid-acting insulin pens), a FreeStyle Libre 2 Sensor (Sensor) for continuous glucose monitoring, a Bigfoot™ Blood Glucose Meter (Meter), and the Bigfoot Unity™ Mobile App (App) on your mobile phone (phone).

[1] Fingersticks are required for treatment decisions when you see "Use Meter" on the White Cap, when symptoms do not match System readings, when you suspect readings may be inaccurate, or when you experience symptoms that may be due to high or low blood glucose.

[2] The Bigfoot Unity App is compatible with iPhone 7 or later. Use of the Bigfoot Unity App requires registration with Bigfoot Biomedical.

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1 Tips for Reading and Understanding this User Guide

Before starting to use the Bigfoot Unity™ Diabetes Management System for your diabetes care, you will need to complete tutorials in the App on how to set up Bigfoot Unity and use the App, Caps, Sensor and Meter. Information about viewing this User Guide online can be accessed in the App under MY SETTINGS –> Help and Support.

To start using Bigfoot Unity, download the Bigfoot Unity App on your mobile phone and create an account. You will use the App to set up Bigfoot Unity and get started.

1.1 Abbreviations and Conventions used throughout this User Guide, the App and Cap displays

App	Software Application on phone
Black Cap	The connected cap that replaces the cap on your disposable long-acting insulin pen
BG	Blood Glucose
Carbs	Carbohydrates
CT	Computerized Tomography
Meter	Blood Glucose Meter
MRI	Magnetic Resonance Imaging
NFC	Near Field Communication
Pair/Pairing	Creating a secure line of data communication between devices
Phone	Mobile phone
Sensor	Device used to continuously monitor interstitial glucose
White Cap	The connected cap that replaces the cap on your disposable rapid-acting insulin pen

1.2 Symbols that appear in this User Guide, the App and Cap displays

Symbol	What it means
	Warning, Caution, Precaution, Limitation or other safety issue that requires immediate attention.
	Low glucose (possible hypoglycemia).
	Sensor not able to provide glucose readings or glucose alerts.
	Possible missed insulin dose from your long-acting insulin pen.
	Information previously saved and can be edited/ updated.
	Battery icon indicating how much battery power remains in Caps.
	Caps attempting to communicate with App.
	*Bluetooth*® indicator icon.

1.3 Customer Care and Technical Service

Contact Bigfoot Biomedical Customer Care using any of the following:

Phone: (551) BIGFOOT or 244-3668
(888) 523-3662

Web: www.support.bigfootbiomedical.com

Email: customercare@bigfootbiomedical.com.

2 Before you Begin Using Bigfoot Unity

2.1 Overview

The Bigfoot Unity™ Diabetes Management System is designed to help persons with insulin-requiring diabetes manage their insulin pen injections and glucose levels. Although the actual decision on how much insulin to take is yours, Bigfoot Unity can help you with this decision by displaying how long it has been since your last insulin dose, your current glucose level, and your health care provider's insulin recommendations.

This User Guide describes how Bigfoot Unity works, important safety information, how you set up and use Bigfoot Unity, and what to do if you need help.

Bigfoot Unity is available only with a prescription in the U.S.

2.2 The Bigfoot Unity App

The App guides you through entering your insulin settings, connecting all of the devices, and learning how to use Bigfoot Unity.

Data sharing between the App and the Caps provides the benefit of having helpful information on the Caps and the App when it's time to take an insulin dose from either of your pens.

The Sensor continuously sends information to the App so you can get a sense of your glucose range on your App Home screen. Additionally, the App provides the capability for a real-time alert when your glucose is low or if there is a problem with your Sensor. The App can also alert you if you may have missed your long-acting insulin dose.

Bigfoot Unity App

2.3 The Black Cap for Long-Acting Insulin

Example: Black Cap with insulin pen

The Black Cap is designed to help you remember the long-acting insulin dose that your health care provider recommends and shows how long it has been since you took your last dose of long-acting insulin. It replaces the cap that came with your long-acting insulin pen.

You can choose to receive an alert on your phone to let you know if you may have missed a long-acting insulin dose. This alert is based on the use of the Black Cap and *Bluetooth*® communication between the Cap and the App.

2.4 The White Cap for Rapid-Acting Insulin

Example: White Cap with insulin pen

The White Cap is designed to help you remember the rapid-acting insulin doses that you take before meals (Mealtime Insulin) and to bring down a high glucose (Correction Insulin). It replaces the cap on your rapid-acting insulin pen. The timer on the White Cap also helps you remember when you took your last dose of rapid-acting insulin from your pen.

The White Cap works with the FreeStyle Libre 2 Sensor to help you continuously monitor your glucose. You can scan the Sensor with the White Cap to get current glucose readings on-demand without fingersticks.

The White Cap can also receive glucose results from the connected blood glucose Meter.

The connected devices of Bigfoot Unity allow for easy transfer of data between the White Cap, the Sensor, the blood glucose Meter, and the App. Information in the App lets you review your glucose and insulin history and share it with your health care provider.

When you use the White Cap to scan and display your current glucose level from the Sensor, the Cap will show where your glucose level is headed with a Trend Arrow. The White Cap will record and send the past 8 hours of continuous glucose information to the App.

The White Cap can also display the amount of Correction Insulin and Mealtime Insulin based upon the settings your health care provider has recommended for you. If you take an insulin dose, the time of the last dose is displayed on the Cap and sent to the App.

2.5 Monitoring Glucose with the Sensor

Bigfoot Unity uses the Sensor to measure your glucose in the interstitial fluid just below the skin surface. Sensor readings are displayed on your White Cap. To help keep you informed, glucose or Sensor status messages will appear on the App Home screen.

Abbott FreeStyle Libre 2 Sensor

You will need to actively scan your Sensor with the White Cap to display your current glucose reading and Trend Arrow. Every time you scan the Sensor with the White Cap, the last 8 hours of Sensor glucose data will be recorded in the App history. Sensor glucose patterns and trends in history may help you with your diabetes self-care. Behind the scenes, your App is also continuously monitoring your Sensor readings and can alert you on your phone if your glucose level is low or if there is a problem with your Sensor.

2.6 Monitoring Glucose with the Meter

When you use a Meter, you use a drop of blood from your fingertip to measure your blood glucose. Blood glucose results taken with the Bigfoot Meter can be displayed on the White Cap and on the App.

Bigfoot Blood Glucose Meter

Because a Meter measures glucose in blood versus fluid under the skin, there may be a slight difference between Meter and Sensor results, especially when glucose is changing rapidly. This small difference should not affect your diabetes self-care. Talk to your health care provider to learn more about the difference between the two methods of measuring glucose.

There will be times when a meter blood glucose reading is required to confirm a Sensor glucose reading. This will be described later in this User Guide.

Having a Sensor and a Meter available to measure your glucose provides flexibility for obtaining a glucose measurement when you need it.

2.7 About Cloud Services and Wireless Communication

The White and Black Caps use *Bluetooth*® communication to share data with the App on your phone. Your phone must have internet service through a cellular or WiFi connection to set up the System, and it must connect to the internet periodically to back up data to the cloud. After Bigfoot Unity has been set up, daily activities can be done without internet service. Cloud-based services let you share your data with your health care provider. Having information securely stored in the cloud also makes it easier to restore the information back into the App if you replace your phone.

3 Indications and Safety Information

3.1 Indications for Use

The Bigfoot Unity™ Diabetes Management System is indicated for the management of diabetes in persons age 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 device is intended for single patient use only and requires a prescription.

Bigfoot Unity is also intended to communicate autonomously with digitally connected medical devices where the user manually controls therapy decisions.

3.2 Benefits and Risks Associated with Bigfoot Unity

As with any medical device, there are benefits and risks associated with the use of Bigfoot Unity. Pay attention to safety information, especially Warnings and Cautions associated with its use. Always consult with your health care provider if you have questions regarding the best way to maximize the benefits and minimize the risks of using Bigfoot Unity.

⚠ **CAUTION:** Review all product and safety information and instructions in this User Guide and other accompanying materials before use. Take standard precautions for transmission of bloodborne pathogens to avoid contamination.

Benefits

Bigfoot Unity is designed to help you manage your diabetes by:

- Connecting several devices commonly used to manage insulin-dependent diabetes into one convenient system.

- Letting you easily set up and adjust your insulin and insulin dosing information on your phone and having that information displayed on your Caps to use when you need to inject a dose.
- Scanning your Sensor with your White Cap to view your current glucose level and Trend Arrow at the time you dose.
- Recording the last time you dosed insulin, and doing some of the calculations for deciding how much insulin to take to cover meals and/or bring down a high glucose.
- Giving you access for reviewing your insulin and glucose history in the App.
- Providing two ways to measure your glucose: (1) a Sensor that continuously measures glucose in the fluid below your skin and (2) a Meter that provides you a blood glucose result using a drop of blood from your fingertip.
- Incorporating continuous glucose monitoring and the capability for a real-time Low Glucose Alert so the App can alert you to situations when your glucose levels require your immediate attention. Glucose alerts are an important safety feature for some people, for example, those that have impaired awareness of hypoglycemia or a history of severe hypoglycemia. Before you turn alerts off or change their settings, please consult your health care provider.

Risks

There are risks associated with using Bigfoot Unity. Some of these are inherent in using Bigfoot Unity and others are related to making decisions about managing your diabetes.

- There is always the risk of dosing too much or too little insulin. While Bigfoot Unity is designed to give you as much information as possible at the time you inject insulin from your pens, the final decision on when and how much to dose is up to you. Taking too much or too little insulin can lead to serious injury.
- You may make an incorrect treatment decision if you enter incorrect insulin settings or if you don't update your settings when your insulin needs change over time.
- You may make an incorrect treatment decision if you accidentally use the wrong insulin pen.
- You may make an incorrect treatment decision if you misread or misinterpret insulin recommendations.

- Bigfoot Unity is intended to be used after you have consulted with your health care provider so that the insulin and glucose information entered in the App is right for you. Bigfoot Unity has no way of ensuring that the information you have entered is correct. Always consult with your health care provider before you begin using Bigfoot Unity and for the information you are required to enter in the App.
- Bigfoot Unity provides the capability of Notifications and Alerts to help you know if your glucose level requires your immediate attention or if there is a problem with the Sensor. It is possible that you may not see, hear, or feel the Notification or Alert, depending on how you set up the App and your phone and what you are doing at the time. Make sure you read all safety information in this User Guide and know what to do if you receive a Notification or Alert.
- If Bigfoot Unity is not working properly, you may need another way to track insulin dosing and/or make insulin dosing decisions until you can resume using Bigfoot Unity. You will still be able to use your insulin pens without the Caps, App or Meter. Consult with your health care provider about a backup glucose monitoring and insulin dosing plan, supplies and what to do in case of an emergency.
- If you do not have your phone, or if your phone is not charged, you will not receive any Alerts or Notifications. Because you will not receive any Alerts, you should monitor your glucose frequently until your phone is restored. You will still be able to scan your Sensor with your White Cap, use your Meter, and use your insulin pen.

IMPORTANT: Do NOT use Bigfoot Unity with the FreeStyle LibreLink or FreeStyle Libre 14 day Readers. Bigfoot Unity is not compatible with these devices.

3.3 Contraindications

Automated Insulin Dosing: Bigfoot Unity must not be used with automated insulin dosing (AID) systems, including closed loop and insulin suspend systems.

MRI/CT/Diathermy: The FreeStyle Libre 2 Sensor must be removed prior to Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or high-frequency electrical heat (diathermy) treatment. The effect of MRI, CT scans, or diathermy on the performance of the Sensor has not been evaluated. The exposure may damage the Sensor and may impact proper function of the device which could cause incorrect readings.

3.4 Who should not use Bigfoot Unity

⚠ CAUTIONS and LIMITATIONS

- Do NOT use in people less than 12 years of age. Bigfoot Unity is not cleared for use in people under 12 years of age.
- Do NOT use if you are pregnant, on dialysis or critically ill. Bigfoot Unity is not cleared for use in these groups and it is not known how different conditions or medications common to these populations may affect performance.
- Performance of Bigfoot Unity when used with other implanted medical devices, such as pacemakers, has not been evaluated.
- Bigfoot Unity does not support insulin doses in half-unit increments. You should not use Bigfoot Unity if you take half-unit doses of insulin.
- Bigfoot Unity supports once daily dosing of long-acting insulin. You should not use Bigfoot Unity if you take more than one daily dose of long-acting insulin.

3.5 Bigfoot Unity Components

⚠ WARNINGS

- Use your blood glucose meter to make diabetes treatment decisions when you see “Use Meter” on the White Cap during the first 12 hours of wearing a Sensor, if your Sensor glucose reading does not match how you feel, or if the reading does not include a number.
- Choking Hazard: Bigfoot Unity contains small parts that may be dangerous if swallowed.

⚠ CAUTIONS and LIMITATIONS

- Make sure Bigfoot Unity is kept in a safe place under your control. This is important to help prevent anyone from accessing or tampering with your Bigfoot Unity components and supplies.
- Bigfoot Unity must not be used by more than one person due to the risk of providing incorrect glucose and insulin information.
- Do NOT use if the Caps appear damaged due to risk of electric shock and/or no results.
- Make sure to select a location for charging the Caps that allows the power adapter to be easily unplugged. Do NOT block access to the charger due to the potential risk of electrical shock.
- Use USB charging cable only as directed, and store safely. Misuse of the USB charging cable can be a strangulation risk.

- Do NOT use cell phone adapters or other third party USB cables to charge medical devices including the Bigfoot Unity Caps. Connecting the Caps to any device other than the supplied USB charging cord and power adapter may result in electrical shock.

3.6 Cap and App Usage

What to know Before you Begin Use

⚠ WARNINGS

- Do NOT ignore symptoms that may be due to low or high blood glucose: If you are experiencing symptoms that are not consistent with your glucose readings, consult your health care provider.
- Consult with your health care provider to make sure you have a backup diabetes management plan and diabetes supplies if parts of Bigfoot Unity are lost or stop working. Having a backup plan and supplies can help avoid severe high or low glucose if you cannot use Bigfoot Unity.
- Bigfoot Unity only records doses taken with the insulin pens you use with the Caps. If you take a dose of insulin without using Bigfoot Unity, make sure you keep track of the time you took insulin and check your glucose frequently. Allowing time for the insulin to work prior to taking another dose can help prevent severe low glucose.
- Bigfoot Unity does NOT adjust insulin doses on your insulin pen and does NOT record how much insulin you take. When Bigfoot Unity displays insulin dose information, you are responsible for deciding how much insulin to take and giving the injection.
- Always use your Bigfoot Meter for diabetes treatment decisions when: (1) Sensor data is not available, (2) when you see the words “Use Meter” on the White Cap, or (3) if your Sensor glucose reading does not match how you feel. Using your Meter will provide you with a glucose reading that you may use to decide how much insulin to take and help prevent severe low or high glucose.

What to know about Daily Use

⚠ WARNINGS

- Always check that the insulin name displayed on the Cap matches the name on the insulin pen you intend to use before making a diabetes treatment decision. If you take a dose with the wrong insulin you could take too much or too little insulin, which may result in severe low or high glucose.

- Place the Bigfoot Unity Cap back onto the insulin pen immediately after taking an insulin dose. If you do not replace the Cap promptly, the time since last dose may not be accurate. This may result in you taking too much or too little insulin, which can lead to severe low or high glucose.
- Use caution when using Bigfoot Unity to choose an insulin dose if the Cap does not display the time since last dose or if you think the time since last dose is not correct. If you are unsure about how much insulin to take, follow your health care provider's recommendations.
- Do NOT ignore alerts from Bigfoot Unity. Alerts help inform you about Sensor availability, low glucose, or if you may have missed your long-acting insulin dose. Paying attention to alerts can help prevent severe low or high glucose.
- Do NOT use the glucose ranges displayed in your App to make diabetes treatment decisions. Always use the White Cap to scan the Sensor or read the Meter before deciding appropriate treatment. The App only displays ranges of glucose values and you need more specific information for diabetes treatment decisions. If you base your treatment on the glucose range in the App, you might take too much or too little insulin, which may lead to severe low or high glucose.
- Always check the Black Cap for the time since last dose if you receive a Long-Acting Dose Alert on your phone.

  Checking the Black Cap for the time since last dose will help ensure you take the next dose of insulin at the correct time, and help avoid severe low or high glucose.

⚠ CAUTIONS and LIMITATIONS

- Use MY SETTINGS in the App to update your insulin settings whenever your health care provider recommends changes. If your App does not have your most recent insulin settings, information displayed on the App and Caps may not be accurate for taking your next insulin dose. This may result in taking too much or too little insulin, which could lead to severe low or high glucose.
- Make sure your phone is within communication range (within 20 ft) of your Caps after you make any changes to your insulin settings within the App. If your Caps do not have the most current settings, you could take too much or too little insulin, which may result in severe low or high glucose.

What to know about Setting up Notifications and Alerts

⚠ WARNINGS

- You must allow Notifications for the Bigfoot Unity App in order to receive Bigfoot Unity Alerts even when your phone is locked and not showing the Bigfoot Unity App. Remember also to keep your phone sufficiently charged to receive alerts.

  If you do not allow or receive alert Notifications, or if your phone is not on, you might miss knowing that your glucose is low, that your Sensor has stopped working, or that you may have missed a dose of long-acting insulin.

- You must allow Critical Alerts on your phone to receive Alerts even when your phone is muted or set to “Do Not Disturb”.

  If you do not allow Critical Alerts, you may not be aware of a low glucose or if your sensor glucose information is not available.

- Alerts and Notifications appear on the phone only and do NOT appear on the Caps or the Sensor itself. Make sure to have your Bigfoot Unity App and phone set up properly to receive alerts. Receiving Alerts and Notifications on your App/phone can help prevent severe low or high glucose.

- Always keep your Bigfoot Unity App open (do not force close) on your phone and keep your phone nearby (within 20 ft). This will help you receive and hear Notifications and Alerts, which may prevent severe low or high glucose.

⚠ CAUTIONS and LIMITATIONS

- Do NOT leave headphones connected to the phone when you are not using them. If you have headphones connected to the phone, Notifications and Critical Alerts will not sound or vibrate on the phone.

- Always keep your phone’s *Bluetooth* setting ON when you are using Bigfoot Unity. *Bluetooth* is required to view current glucose range information on the App Home screen and receive low glucose and Sensor Unavailable Alerts. If your phone does not receive glucose information from the Sensor, you may not know if you have low or high glucose.

3.7 Sensor Glucose

What should you know about Wearing a Sensor

⚠ CAUTIONS and LIMITATIONS

- Wash application site on the back of your upper arm using a plain soap, dry, and then clean with an alcohol wipe. This will help remove any oily residue that may prevent the Sensor from sticking properly. Allow site to air dry before proceeding. Carefully preparing the site according to these instructions will help the Sensor stay on your body for the full 14 day wear period and help prevent it from falling off early.
- The Sensor can be worn for up to 14 days. Remember to always have your next Sensor available before your current one ends so you can keep getting your glucose readings.
- You must scan the Sensor to get your real-time current glucose level as the Bigfoot Unity App will not provide this information.
- When using Bigfoot Unity, in the event that your Sensor stops working and you do not have another Sensor readily available, you must use an alternate method to measure your glucose levels and inform your treatment decisions.
- Bigfoot Unity is designed to detect certain conditions which may occur where the Sensor is not working as intended and shut it off, telling you to replace your Sensor. This may occur if the Sensor gets knocked off from the skin or the Sensor may not be performing as intended. Contact Bigfoot Customer Care at (551) 244-3668 if you receive a “Sensor Error: Apply and start new Sensor” message on your White Cap before the end of the 14 day wear period.
- Some individuals may be sensitive to the adhesive that keeps the Sensor attached to the skin. If you notice significant skin irritation around or under your Sensor, remove the Sensor and stop using the Sensor. Contact your health care provider before continuing to use the Sensor.
- Intense exercise may cause your Sensor to loosen due to sweat or movement of the Sensor. If the Sensor is becoming loose or if the Sensor tip is coming out of your skin, you may get no readings or unreliable low readings. Remove and replace your Sensor if it starts to loosen and follow the instructions to select an appropriate application site. Do not attempt to reinsert the Sensor. Contact Bigfoot Customer Care at (551) 244-3668 if your Sensor becomes loose or falls off before the end of the wear period.

- Do NOT re-use Sensors. The Sensor and Sensor Applicator are designed for single-use. Re-use may result in no glucose readings and infection. Not suitable for re-sterilization. Further exposure to irradiation may cause unreliable low results.
- If a Sensor breaks inside your body, call your health care provider.

How to Store the Sensor Kit

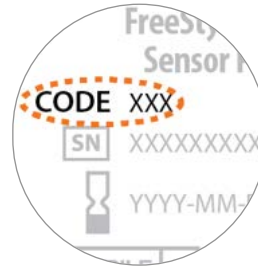
- Store the Sensor Kit between 36°F and 82°F. Storage outside of this range may cause inaccurate Sensor glucose readings.
- If you suspect that the temperature may exceed 82°F (for example, in an un-airconditioned home in summer), you should refrigerate your Sensor Kit. Do NOT freeze your Sensor Kit.
- Store your Sensor Kit in a cool, dry place. Do NOT store your Sensor Kit in a parked car on a hot day.
- Store the Sensor Kit between 10-90% non-condensing humidity.

When not to use the Sensor

- Do NOT use if the Sensor Kit package, Sensor Pack, or Sensor Applicator appear to be damaged or already opened due to risk of no results and/or infection.
- Do NOT use if Sensor Kit contents are past expiration date.

What to know before you Apply the Sensor

- The Sensor Pack and Sensor Applicator are packaged as a set and have the same Sensor code. Check that the Sensor codes match before using your Sensor Pack and Sensor Applicator. Do NOT use Sensor Packs and Sensor Applicators with different Sensor codes together as this will result in incorrect glucose readings.



- Wash the application site on the back of your upper arm using a plain soap, dry, and then clean with an alcohol wipe. This will help remove any oily residue that may prevent the Sensor from sticking properly. Allow site to air dry before proceeding. Carefully preparing the site according to these instructions will help the Sensor stay on your body for the full 14 day wear period and help prevent it from falling off early.

- Clean hands prior to Sensor handling/insertion to help prevent infection.
- Change the application site for the next Sensor application to prevent discomfort or skin irritation.
- Only apply the Sensor to the back of the upper arm. If placed in other areas, the Sensor may not function properly.
- Select an appropriate Sensor site to help the Sensor stay attached to the body and prevent discomfort or skin irritation. Avoid areas with scars, moles, stretch marks, or lumps. Select an area of skin that generally stays flat during normal daily activities (no bending or folding). Choose a site that is at least 1 inch away from an insulin injection site.

When is Sensor Glucose Different from Blood Glucose

- Physiological differences between the interstitial fluid and capillary blood may result in differences in glucose readings between the Sensor and results from a fingerstick test using a blood glucose meter. Differences in glucose readings between interstitial fluid and capillary blood may be observed during times of rapid change in blood glucose, such as after eating, dosing insulin, or exercising.

What to know about X-Rays

- The Sensor should be removed prior to exposing it to an X-ray machine. The effect of X-rays on the performance of Bigfoot Unity has not been evaluated. The exposure may damage the Sensor and may impact proper function of the device to detect trends and track patterns in glucose values during the wear period.

When to Remove the Sensor

- If the Sensor is becoming loose or if the Sensor tip is coming out of your skin, you may get no readings or unreliable readings, which may not match how you feel. Check to make sure your Sensor has not come loose. If it has come loose, remove it, apply a new one, and contact Bigfoot Customer Care at (551) 244-3668.
- If you believe your glucose readings are not correct or are inconsistent with how you feel, perform a blood glucose test on your finger to confirm your glucose. If the problem continues, remove the current Sensor, apply a new one, and contact Bigfoot Customer Care at (551) 244-3668.

3.8 Interfering Substances

Taking ascorbic acid (vitamin C) supplements while wearing the Sensor may falsely raise Sensor glucose readings. Taking more than 500 mg of ascorbic acid per day may affect the Sensor readings which could cause you to miss a severe low glucose event. Ascorbic acid can be found in supplements including multivitamins. Some supplements, including cold remedies such as Airborne® and Emergen-C®, may contain high doses of 1000 mg of ascorbic acid and should not be taken while using the Sensor. See your health care provider to understand how long ascorbic acid is active in your body.

4 Bigfoot Unity Welcome Kit

4.1 Working With Your Health Care Provider

To get started using the Bigfoot Unity™ Diabetes Management System, you and your health care provider will work together to decide the information that makes up your personal insulin settings. This information is entered in the App where it is stored and available as needed for you to make changes. A reference tool is available in Appendix B for you to use with your health care provider.

4.2 Bigfoot Unity Welcome Kit Package Contents

Bigfoot Unity packaging includes:

A - Bigfoot Unity Black Cap

B - Bigfoot Unity White Cap

C - Bigfoot Meter Kit, containing

- Bigfoot Meter User Manual
- Bigfoot Test Strips and Control Solution
- Bigfoot Test Strip and Control Solution Inserts

D - FreeStyle Libre 2 Sensor Kit (2), each containing

- Sensor Pack
- Sensor Applicator
- Alcohol Wipe
- Product Insert

E - USB Power Adapter for charging Caps

F - USB C charging cord to charge both Caps

G - Alcohol Prep Pads

H - Bigfoot Pen Needles

I - User Guide

Note: Do NOT connect the Caps to any device other than the supplied USB charging cord and power adapter. If you need a replacement USB charging cord or power adapter, or any other parts or accessories, contact Bigfoot Customer Care at (551) 244-3668.

Check Shipments of Supplies and Equipment

Check that your packaging includes all of the items listed above. Check the supplies and equipment shipped to you for damage or evidence of being opened and do not use any materials that appear so. Contact Bigfoot Customer Care at (551) 244-3668 if any items are missing or appear to be damaged or already opened.

Maintain Secure Control of your Bigfoot Unity Components.

Maintain secure custody of Bigfoot Unity components and supplies to avoid unauthorized access or tampering.

4.3 Compatible Insulin Pens

Your rapid-acting and long-acting insulin pens will be packaged and provided separately and require a separate prescription from your health care provider.

The White and Black Caps work with commercially-available insulin pens from various insulin manufacturers. The Caps are reusable and replace the caps that come with the disposable insulin pens. You must use a specific Cap that is configured by Bigfoot to match the kind of insulin in your pen.

Visit www.bigfootbiomedical.com/compatible for complete information on compatible insulin pens. Refer to the manufacturer's instructions that come with the insulin pens for how to use, store and discard the pens.

Note: All insulin names are trademarks of their respective holders. Use of them does not imply affiliation or endorsement.

4.4 Compatible Insulin Pen Needles

The Bigfoot Needles that come with Bigfoot Unity are designed to fit your insulin pens. Visit www.bigfootbiomedical.com/compatible for compatible insulin pen needles.

4.5 Compatible Mobile Phones

The App works on your compatible personal, mobile phone.

Visit www.bigfootbiomedical.com/compatible for the current list of compatible phones.

You are responsible for keeping your cell phone secure and up-to-date, for example by using a strong password, installing updates, and using only secure WiFi networks.

5 First Time Setup of Bigfoot Unity

5.1 Getting Ready to Set Up Bigfoot Unity

The App will walk you through the steps for setting up and using the Bigfoot Unity™ Diabetes Management System. You may also refer to other sections in this User Guide for additional information on using Bigfoot Unity, including your Sensor, Meter and USB Charger.

The App includes a series of short tutorials and instructional videos to help you learn how to use Bigfoot Unity. These screens display a play button ( ) to proceed. Before you can proceed to the next section during setup, you must complete the current section. This helps ensure you understand the basic ideas in one section before you can build on those in the next. A check mark ( ) will appear to indicate that you have completed a section and are able to proceed to the next section. If you close the App before you finish a section, your information will not be saved for the section. The next time you launch the App, you will start at the beginning of the section you had not finished.

Note that many App Setup screens have the option to 1) tap **< Back** on the top left of the screen to return to the previous screen, 2) tap **Edit** on the top right of the screen to make changes to the information displayed on that screen, 3) Tap to scroll down to view additional information not visible on the screen, including button options to start or complete an action, or 4) tap **Need Help?** for more information about that screen.

Information you enter in the App is intended to be sent to your White and Black Caps where it is available when it is time to take insulin injections with your pens. It's important you work with your health care provider to have the right information entered so that it is available at the time you dose. Always consult with your health care provider for the diabetes information to enter in the App. A handy reference tool is available in Appendix B for you to use with your health care provider.

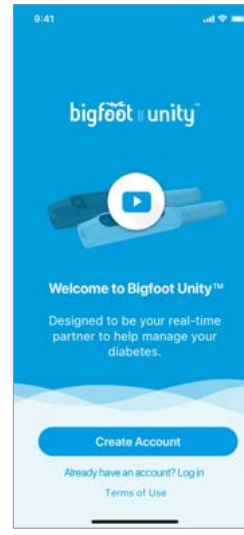
5.2 Download the App and Create an Account

1. Download and install the Bigfoot Unity App from the App Store.

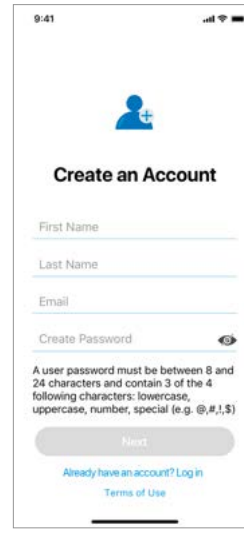
   After the installation completes, make sure the App icon appears on the phone screen.

2. Launch the App on your phone.

3. Tap **Create Account** on the Welcome screen.



4. Enter your first and last name, your email address, a password and tap **Next** to continue.
   - A link will be sent to the email address you entered. Click on the link in the email to complete the email verification. Once your email has been verified, return to the App and tap **Continue** to Login.



5. Login to your account with your email address and password

   Note: If you forget your App password when you log in, tap **Forgot Password?** on the Login screen. Instructions for re-setting your password will be sent to your email address.

6. Review the Terms and Conditions by tapping **Terms of Use**. On the initial Terms of Use screen, tap **Agree** on the lower right of the screen to continue.

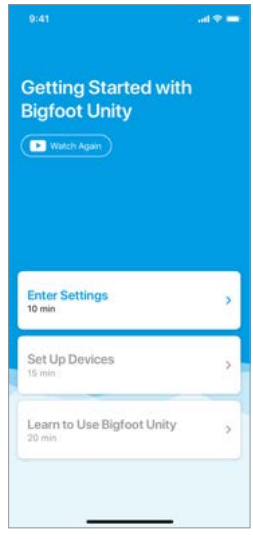
   - Your App account is now set up and ready for use. Simply tap the App icon on your phone whenever you want to launch the App.
   - After logging in, the App will prompt you to watch a short instructional video introducing you to Bigfoot Unity.

7. Tap the play button (▶) to watch the video.

5.3 Enter Settings

The Getting Started with Bigfoot Unity screen displays the three main *App Setup* sections that need to be completed in the order presented. You will only need to complete these three *Setup* sections the first time you set up your App. Once you complete first time setup, you can update settings under MY SETTINGS (See section 8.4).

1. Tap **Enter Settings** to begin the first *App Setup* section.

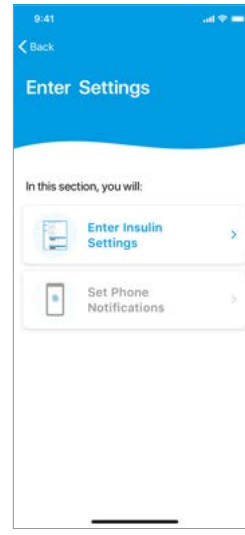


Enter Insulin Settings

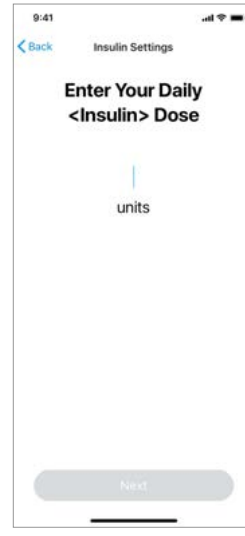
You are now ready to enter your insulin settings in the App, and how you want your phone to notify you of certain events. You will need insulin information from your health care provider to complete this section.

Entering Long-Acting Insulin Settings

1. Tap **Enter Insulin Settings**.



2. Once you have your insulin information from your health care provider (see Appendix B) tap **Next** on the Enter Insulin Settings screen.
3. Select your long-acting insulin by tapping on the insulin you use.
4. Enter the daily insulin dose (1 to 160 units) for your long-acting insulin using the pop-up numeric keypad. Tap **Done** when finished and **Next** to continue.



Entering Rapid-Acting Insulin Settings

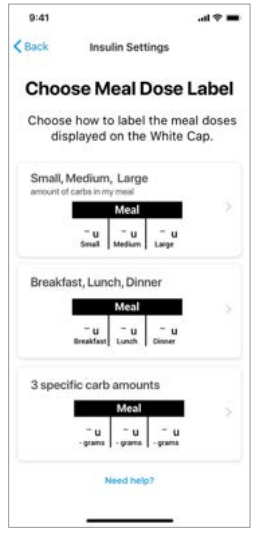
1. Select your rapid-acting insulin by tapping on the insulin you use.

Mealtime Insulin

Bigfoot Unity lets you enter how much rapid-acting insulin you take for meals (Mealtime Insulin).

1. Use the insulin settings sheet from your health care provider (see Appendix B) to determine Mealtime Insulin selection.
   - If Mealtime Insulin is recommended, tap **Yes, Enter Mealtime Insulin**.
   - If no Mealtime Insulin is recommended, tap **No, I Don't Take Mealtime Insulin** to skip this section.

Bigfoot Unity offers three options for how to display Mealtime Insulin on your White Cap for rapid-acting insulin when it's time to dose. Only one option can be used at any given time, but you can switch between options anytime.



2. Tap **Label Meal Doses**.

   The Choose Meal Dose Label screen will be displayed.

   Read the descriptions that follow, as the meal dose labels may be new to you, and discuss with your health care provider. You will only enter values for the one choice that best describes your Mealtime Insulin. You can easily change the method for displaying Mealtime Insulin later or decide not to use the Mealtime Insulin feature at all.

Small, Medium, Large: Based on how certain meal sizes affect your glucose

In this category, enter the units of rapid-acting insulin to account for how large an effect meals have on your glucose. For practical purposes, you may consider this category as covering a small, medium, or large amount of carbs in your meal.

Breakfast, Lunch, Dinner: Based on how meals at certain times of the day affect your glucose

In this category, enter the units of rapid-acting insulin you take for each type of meal.

Three specific carb amounts: Based on how the amount of carbohydrates in meals you commonly eat affect your glucose

In this category, pick three different carb amounts (in grams) that you commonly eat and then enter the units of rapid-acting insulin you take for each.

3. Choose the label that best describes how you dose Mealtime Insulin by tapping that selection from the list.

Mealtime Insulin – Most common Meal sizes (Small, Medium, Large)

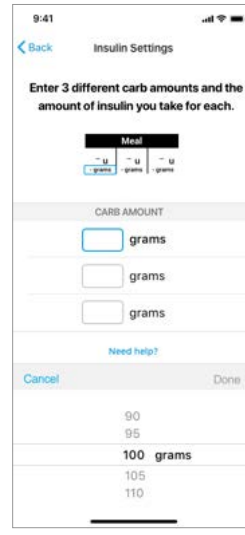
- Tap the first meal size. Then scroll to the *insulin units* (0 to 80) to select the amount you typically take to cover that meal size and tap **Done** when you are finished.
- Repeat for your second and third meal sizes.
- Tap **Next** when you are finished.

Mealtime insulin - Most common Meal times (Breakfast, Lunch and Dinner)

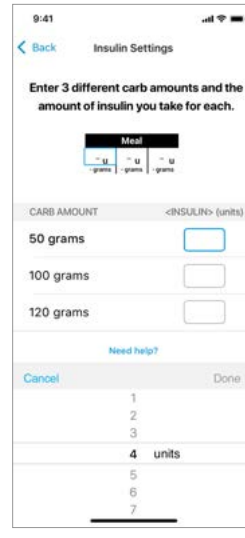
- Tap the first meal time. Then scroll to the *insulin units* (0 to 80) to select the amount you typically take to cover that meal time and tap **Done** when you are finished.
- Repeat for your second and third meal times.
- Tap **Next** when you are finished.

Mealtime insulin - Most common Carb Amounts

- Tap a Carb Amount and then scroll to a common amount of grams of carbohydrate (0 to 125) in that meal and tap **Done** when you are finished.
- Repeat for your two other most common meals.



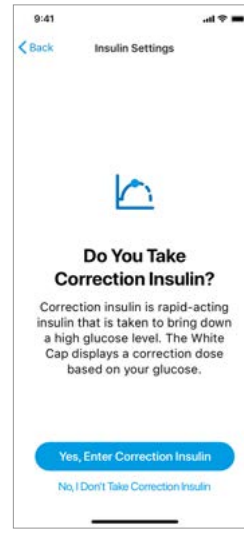
- For the first Carb Amount entered, under the insulin (units) column, tap and scroll to the *insulin units* (0 to 80) you typically take to cover that number of grams (of carbohydrate) amount and tap **Done** when you are finished.
- Repeat for your two other Carb Amounts.
- Tap **Next** when you are finished.



Example: Carb Amounts and unit selection

Correction Insulin

Bigfoot Unity lets you enter how much rapid-acting insulin you take to bring down a high glucose (Correction Insulin).

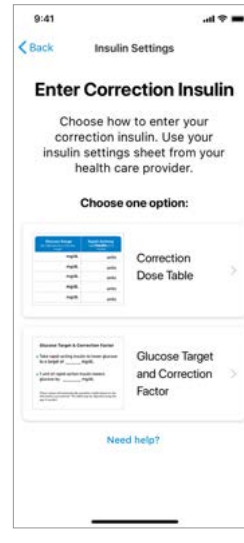


1. Use the insulin settings sheet from your health care provider (see Appendix B) to determine Correction Insulin selection.
   - If you do take insulin to bring down a high glucose, tap **Yes, Enter Correction Insulin**.
   - If you don't take insulin to bring down a high glucose, tap **No, I Don't Take Correction Insulin** to skip this section.

Bigfoot Unity offers two options for how to enter your glucose ranges and correction units. Only one option can be used at any given time, but you can switch between options anytime as needed.

Correction Dose Table: Where you enter glucose ranges and the associated units of rapid-acting insulin to bring down a high glucose in this range. For example, your table might include six glucose ranges and you will enter the rapid-acting insulin associated with each range.

Glucose Target and Correction Factor: Where you enter a target glucose and how much one unit of rapid-acting insulin lowers your glucose in mg/dL. This automatically fills a table with how much rapid-acting insulin to take at different glucose ranges.



2. Decide if you want to enter your Correction Dose Table (Correction Dose Table) or have it automatically filled in (Glucose Target and Correction Factor).
   - To enter your Correction Dose Table, tap **Correction Dose Table** and continue with the *Enter your Correction Dose Table* section that follows.
   - To have your Correction Dose Table automatically filled in based on your Glucose Target and Correction Factor, tap **Glucose Target and Correction Factor**. Then continue with the *Enter your Glucose Target and Correction Factor* section that follows.

Enter your Correction Dose Table

The Correction Insulin screen displays six pre-set, but adjustable, glucose correction ranges. For each glucose range you will enter the units of rapid-acting insulin you typically take to bring down a high glucose.

Pre-set ranges, along with their upper and lower limits, will be displayed the first time you set up the App. The number of insulin units that apply to each range will be empty (blank).

The App and White Cap use this table to determine the glucose range that applies to your current Sensor glucose reading, or Meter result, and to display the Correction units you entered for that range.

You are able to edit ranges (add or delete ranges or change limits) and units in the Correction Table at any time.

Enter/modify your ranges

1. If you want to make changes to your ranges, first tap **Edit** at the top right.

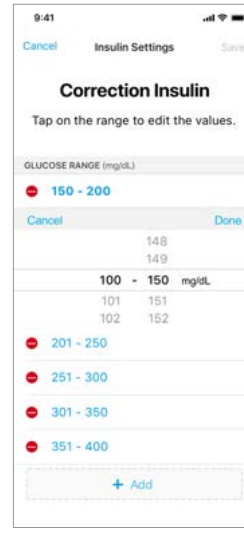
2. Then tap the number range to change to the desired values. Scroll through the range values (between 100 and 400 mg/dL) to select your new range limits and then tap **Done**.

   Once a new range limit is selected, the lower limit of the next range is automatically adjusted to start at 1 plus the upper limit of the range you just changed. When you adjust a range so that it overlaps another range in its entirety, that range will be deleted.

   - To delete a range, first tap the edit icon (⛔) next to the range.

     Then tap **Delete** for the range displayed.

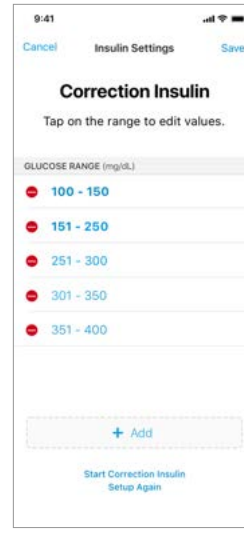
   - To add a range, first tap **+ Add** on the bottom of the screen.



Example: Editing glucose range

3. Repeat Step 2 to change the lower or upper limits on any other range.

4. When you are finished editing ranges, tap **Save**.



Example: Custom glucose ranges

Enter/modify your units

1. Tap the insulin units for the first range.

2. Enter the desired units (0 to 40) by scrolling through the units for that range and then tap **Done**.

- Repeat this step to enter the units for other ranges.

Note: If you tap **Edit**, you will be prompted to confirm that any previously entered insulin amounts will be cleared. Tap **OK** to continue.

3. Once you are finished entering/editing units, tap **Next**.

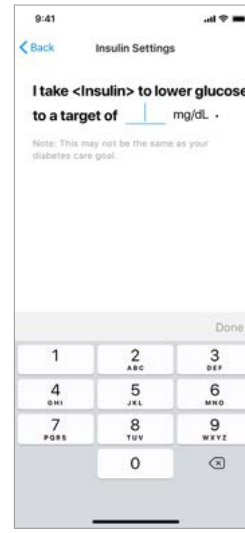
Enter your Glucose Target and Correction Factor

With this option, the Correction Table will fill in when you enter these two values.

When you enter a Glucose Target or Correction Factor, any previous Correction Dose Table values will be replaced by new values.

1. Enter your Glucose Target (100 to 250 mg/dL), then tap **Done**.

Your Glucose Target is the number you aim for to correct your high glucose. Note that your Glucose Target may be different from the glucose value that you typically like to be at.



2. Enter your Correction Factor (10 to 250 mg/dL), then tap **Done**.

Your Correction Factor is how much one unit of rapid-acting insulin lowers your glucose.

Example: Glucose Target of 120 mg/dL

3. When you tap **Next**, your Correction Dose Table will be completed automatically using the Glucose Target and Correction Factor just entered.

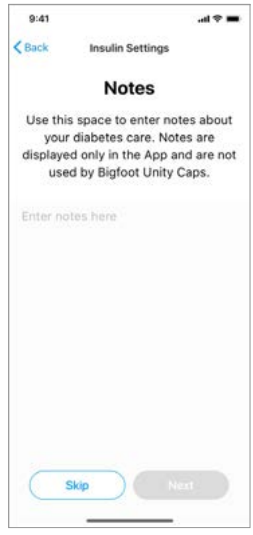
   Each row of the new table represents a glucose range. The lower limit of the first range is your Glucose Target plus your Correction Factor. The higher limit of the first range is your Glucose Target plus 2 times your Correction Factor. For each successive row, the lower limit is derived by adding 1 to the upper limit of the previous range, and the upper limit is derived by adding your Correction Factor to upper limit of the previous range. Rows will be added until the upper range of a row exceeds 400 mg/dL. One additional insulin unit is added to each row to represent approximately how much insulin would be needed to bring your current glucose level down to the lower limit of that range. You can edit this table as necessary as described in previous sections.

4. Tap **Next** to continue.

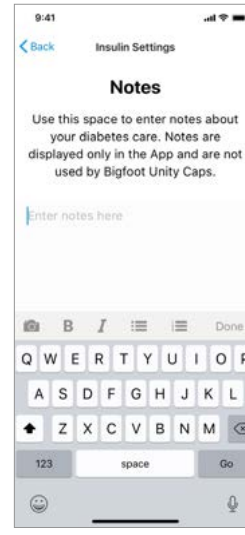
Entering Notes

Enter any Notes that will serve as reminders or tips for taking care of your diabetes. Notes only appear within the App and not on your Caps when it is time to dose insulin from your pens. Any Notes you enter about adjusting the number of insulin units will not be taken into consideration when viewing insulin information on your Caps.

1. Decide if you would like to include notes in your insulin settings.
   - If you do not want to enter any Notes, tap **Skip** to skip this section.

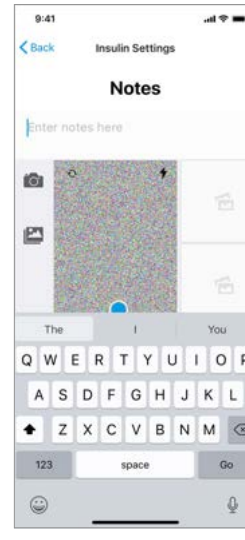


2. Tap the Notes entry box and use the pop-up keyboard to enter your new Note.
   - More than one Note can be entered in the same box.
   - While entering Notes, the App will display a menu of text formatting options.
   - Tap the camera icon ( ) to add photos to your Notes. You have the option to add a stored photo, or take a new photo with your phone.



Note: If this is your first time setting up your App, two pop-up messages will appear asking if Bigfoot Unity can access your camera and photos. Tap **Allow** to allow. Access can be changed in your phone settings.

3. To add photos after tapping the camera icon ( ), first tap **Allow** to let Bigfoot Unity access the camera settings on your phone.
   - If you tap **Don't Allow**, and then decide to add photos by tapping the camera icon again, you will be redirected to your phone Settings where you can get access. Tap **Go to Settings** when prompted.
4. Decide if you want to add a previously taken photo or take a new photo.
   - To add a previously taken photo, tap the gallery icon ( ).
   - To take a new photo, tap the camera icon ( ) and then use your phone to take a photo.
5. When you are finished entering Notes, and adding photos, tap **Done**. Then tap **Next**.



> ⚠ **CAUTION:** Any information you enter into the "Notes" screen in the App is for your information only. Any insulin dosing instructions that are listed in "Notes" are not sent to your Caps or used in the insulin dosing information displayed on the Caps.

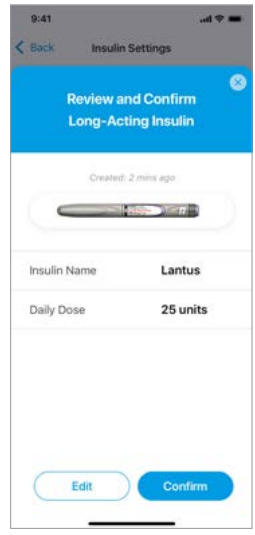
Review Insulin Settings

You must do a review of any insulin settings you made before you can complete this *Setup* section. Carefully check your entries on each screen to make sure that they are correct. This information will be sent to your Cap and used to display your insulin dosing information. You can make any edits during your review.

1. Tap **Let's Review**.

2. Check your entries on the Review and Confirm Long-Acting Insulin screen.
   - This screen lets you Confirm or Edit your long-acting Insulin Name and the Daily Dose.
   - Tap **Confirm** to accept the entries or **Edit** to update long-acting insulin settings.

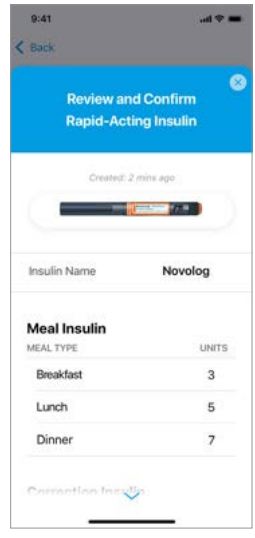
Note: If you make any changes, tap **Next** to return to the Review and Confirm Long-Acting Insulin screen. Then tap **Confirm** to continue with the next step.



Example: Long-acting insulin and dose

3. Check your entries on the Review and Confirm Rapid-Acting Insulin screen. You may need to swipe up (scroll) to see all your entries.
   - This screen lets you Confirm or Edit your Insulin Name, Mealtime Insulin and Correction Insulin.
   - Tap **Confirm** to accept the entries or **Edit** to update rapid-acting insulin settings.

Note: If you make any changes, tap **Next** to return to the Review and Confirm Rapid-Acting Insulin screen. Then tap **Confirm** to continue with the next step.



Example: Rapid-acting insulin and doses

4. Check your entries on the Review and Confirm Notes screen. You may need to swipe up (scroll) to see all your entries.
   - This screen lets you confirm, add or delete Notes.
   - Tap **Confirm** to accept the entries or **Edit** to update any entries.

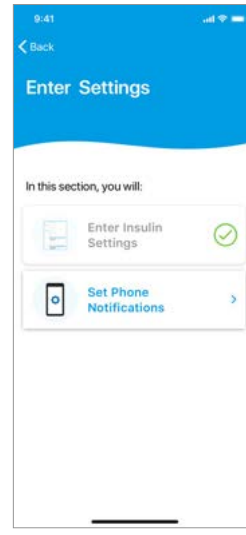
Note: If you make any changes, tap **Next** to return to the Review and Confirm Notes screen. Then tap **Confirm** to continue with the next step.

After tapping **Confirm**, the Enter Settings screen will be displayed. A check mark (✓) will indicate that the *Enter Insulin Settings* section is complete. You can update settings later under MY SETTINGS on the App Home screen.

Set Phone Notifications

The App is designed to have the capability of sending Notifications and Alerts about low Sensor glucose readings, Sensor status and if you may have missed a long-acting insulin dose.

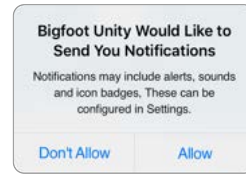
During first time setup, you have the option to allow Notifications and Alerts on your phone. Once setup is complete, you can change how you manage Notifications and Alerts as needed.



1. Tap **Set Phone Notifications**.

   The Set Phone Notifications screen will be displayed.

2. Tap **Next**.
3. Tap **Allow** to allow Notifications on your phone.



⚠ **WARNING:** You must allow Notifications for the Bigfoot Unity App in order to receive Bigfoot Unity Alerts even when your phone is locked and not showing the Bigfoot Unity App. Remember also to keep your phone sufficiently charged to receive alerts.

If you do not allow or receive alert Notifications, or if your phone is not on, you might miss knowing that your glucose is low, that your Sensor has stopped working, or that you may have missed a dose of long-acting insulin.

4. Tap **Allow** to allow Critical Alerts on your phone.

   Critical Alerts will come through to your App/phone on your lock screen even if your phone is muted or “Do Not Disturb” is on, as long as the App is open or running in the background.

After tapping **Allow**, the Enter Settings screen will be displayed. A check mark (✓) will indicate that the *Set Phone Notifications* section is complete.

5. Tap **Done**.

⚠ **WARNING:** You must allow Critical Alerts on your phone to receive Alerts even when your phone is muted or set to “Do Not Disturb”.

If you do not allow Critical Alerts, you may not be aware of a low glucose or if Sensor glucose information is not available.

⚠ **CAUTION:** Do NOT leave headphones connected to the phone when you are not using them. If you have headphones connected to the phone, Notifications and Critical Alerts will not sound or vibrate on the phone.

5.4 Set Up Devices

In this *App Setup* section, you will learn about your Bigfoot Unity devices and how they are connected.

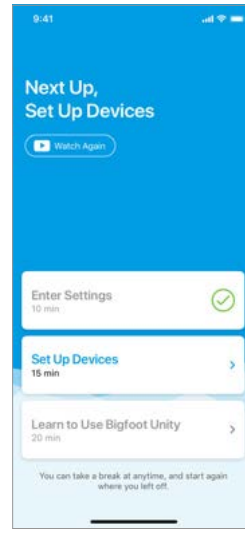
Certain Bigfoot Unity devices need to be paired with one another to share information. The Caps communicate with the App using *Bluetooth*® Low Energy (BLE) technology. The Sensor communicates with the App also using *Bluetooth* Low Energy technology, and also separately with the White Cap using a different method called near-field communication (NFC). The BLE communications between your Sensor, Caps, and the App let you see your glucose range and receive real-time alerts in the App and update your settings on your Caps.

⚠ **CAUTION:** Always keep your phone's *Bluetooth* setting ON when you are using Bigfoot Unity. *Bluetooth* is required to view current glucose range information on the App Home screen and receive low glucose and Sensor Unavailable Alerts. If your phone does not receive glucose information from the Sensor, you may not know if you have low or high glucose.

Note:

- Only one Black and White Cap, Meter, App and Sensor can be connected at one time. For example, if you pair a new White Cap, it will automatically unpair the current one. If you change insulin brands while using Bigfoot Unity, it may require that you obtain a new prescription from your health care provider for a different Cap. In this case, you must contact Bigfoot Customer Care at (551) 244-3668 to obtain a new, compatible Cap. You will also need to pair the new Caps with the other Bigfoot Unity devices.
- Your Caps should have enough battery power for setup when you first remove them from the box. Charge each of the Caps when they indicate low power. Weekly charging is recommended.

1. Tap **Set Up Devices**

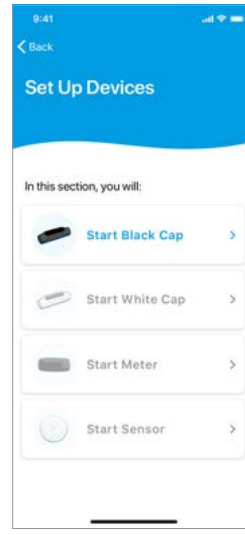


2. Tap **Allow** when prompted to turn your phone's *Bluetooth* setting on to allow communication with the other Bigfoot Unity devices.

Start Black Cap

You will need your Black Cap and your long-acting insulin pen for this section. Your Black Cap is used to replace the cap on your long-acting insulin pen. "Long-Acting" will be displayed on your Black Cap when you remove it from the box.

1. Tap **Start Black Cap**.



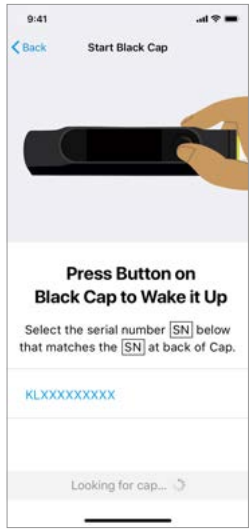
2. Tap **Next**.

3. Review your long-acting insulin information.
   - Tap **Confirm** to continue.
   - Tap **Edit** to make changes.

Make sure the *Bluetooth* phone setting is “On” in your phone. The App will remind you if the *Bluetooth* setting is not turned on. *Bluetooth* communication is automatically enabled in your Black Cap whenever you power it on.

4. Press the Black Cap button once to turn it on. The Cap display will prompt you to follow the instructions in the App for pairing.

   The App will automatically search for and display the Serial Numbers of any Black Caps it finds within range.



App Display

Black Cap Display

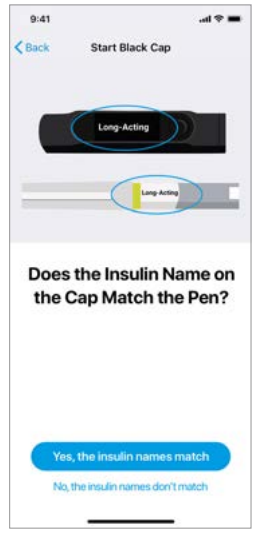
5. Tap the Serial Number on the App screen that matches the Serial Number on the back of your Black Cap. If more than one number is displayed, make sure the Serial Number on the screen selection matches the Serial Number on the Black Cap you intend to use.

The App will begin to pair with the selected Black Cap. Once the pairing is complete, the App and Cap will indicate that pairing was successful and the App will send your long-acting insulin information to the Black Cap.

6. Tap **Next** to continue.

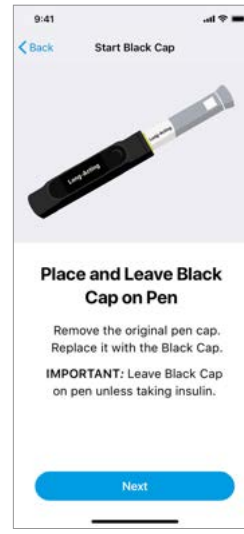
Note: If the Black Cap turns off before pairing is complete, press the Black Cap button again to turn it back on. If pairing is still unsuccessful, see *Chapter 10 - Troubleshooting* for more information.

7. Confirm that the insulin brand name displayed on the Black Cap matches the name on your long-acting insulin pen.



- If the names match tap **Yes, the insulin names match** to continue.
- If the names don't match, tap **No, the insulin names don't match**. You will be prompted to edit the long-acting insulin names you previously entered.
  - Tap **Yes, Edit** to go back and enter a new long-acting Insulin Name.
  - Tap **No**, if the name you previously entered is correct. You will need to obtain a new compatible Black Cap. Contact Bigfoot Care at (551) 244-3668 and your health care provider (as it may require a new prescription) to obtain the correct Black Cap.

8. Replace the original insulin pen cap with the Black Cap and leave Black Cap on pen unless taking insulin. Then tap **Next**.



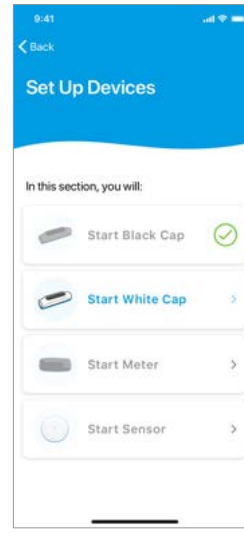
The Set Up Devices screen will be displayed. A check mark (✓) will indicate that the *Start Black Cap* section is complete.

Start White Cap

You will need your White Cap and rapid-acting insulin pen for this section. Your White Cap is used to replace the cap on your rapid-acting insulin pen. “Rapid-Acting” will be displayed on your White Cap when you remove it from the box.

1. Tap **Start White Cap**.

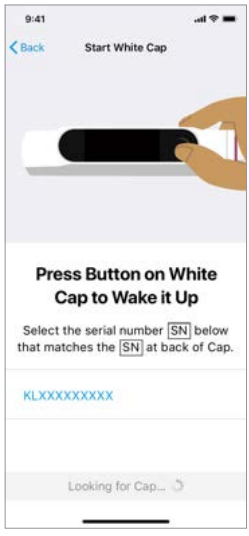
2. Tap **Next**.



3. Review your rapid-acting insulin information. You may need to swipe up (scroll) to view all the entries.
   - Tap **Confirm** to continue.
   - Tap **Edit** to make changes.

4. Press the White Cap button once to turn it on. The Cap display will prompt you to follow the instructions in the App for pairing.

   The App will automatically search for and display the Serial Numbers of any White Caps it finds within range.



App Display

White Cap Display

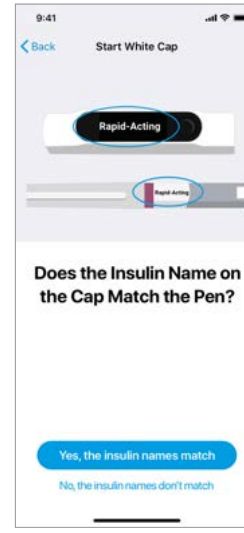
5. Tap the Serial Number on the App screen that matches the Serial Number on the back of your White Cap. If more than one number is displayed, make sure the Serial Number on the screen selection matches the Serial Number on the White Cap you intend to use.

The App will begin to pair with the selected White Cap. Once the pairing is complete, the App and Cap will indicate that pairing was successful and the App will send your rapid-acting insulin information to the White Cap.

6. Tap **Next** to continue.

   Note: If the White Cap turns off before pairing is complete, press the White Cap button again to turn it back on. If pairing is still unsuccessful, see *Chapter 10 - Troubleshooting* for more information.

7. Confirm that the insulin brand name displayed on the White Cap matches the name on your rapid-acting insulin pen.



   - If the names match tap **Yes, the insulin names match** to continue.
   - If the names don't match, tap **No, the insulin names don't match**. You will be prompted to edit the rapid-acting insulin names you previously entered.
     - Tap **Yes, Edit** to go back and enter a new rapid-acting Insulin Name.
     - Tap **No**, if the name you previously entered is correct. You will need to obtain a new compatible White Cap. Contact Bigfoot Customer Care at (551) 244-3668 and your health care provider (as it may require a new prescription) to obtain the correct White Cap.

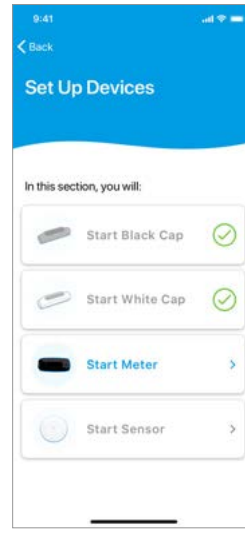
8. Replace the original insulin pen cap with the White Cap and leave White Cap on pen unless taking insulin. Then tap **Next**.

The Set Up Devices screen will be displayed. A check mark (✓) will indicate that the *Start White Cap* section is complete.

Start Meter

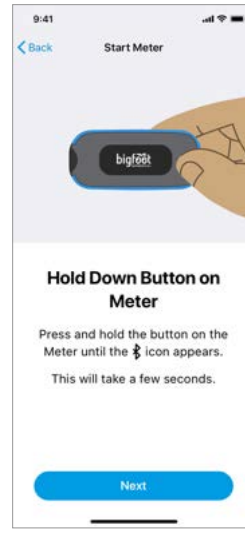
Note: You will need your White Cap and Meter for this section. You are only able to pair your White Cap to the Meter supplied by Bigfoot Biomedical.

1. Tap **Start Meter**.
2. Tap **Next**.



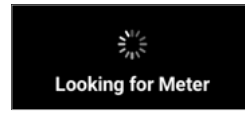
IMPORTANT: Use the Meter that is paired with Bigfoot Unity when checking blood glucose. If you use a different meter, blood glucose values will not display on the White Cap.

3. Press and hold the button on your Meter until you see the *Bluetooth* icon ( ) appear on the display and then tap **Next**.



4. With the Cap attached to the insulin pen, press the button on the White Cap to wake it up. The Cap display will indicate it is searching for your Meter.

App Display



White Cap Display

The App will automatically search for and pair with the first Meter it finds within range.

5. Confirm that the code displayed in the App matches the code displayed on the Meter you intend to use.

App Display

Meter Display

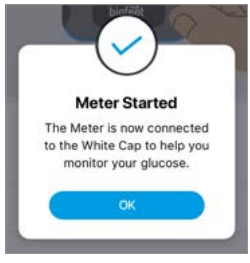
- If the codes match, tap **Confirm**, and proceed to the next step.
- If the codes do not match, tap **Doesn't Match** to display a list of Meters (codes) within range and tap the Meter (code) you intend to use.

App Display

White Cap Display

Meter Display

Once the pairing is complete, the White Cap and Meter will indicate that pairing was successful.



App Display

White Cap Display

Meter Display

6. Tap **OK**.

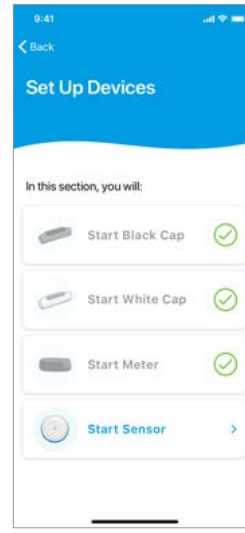
The Set Up Devices screen will be displayed. A check mark (✓) will indicate that the *Start Meter* section is complete.

Start Sensor

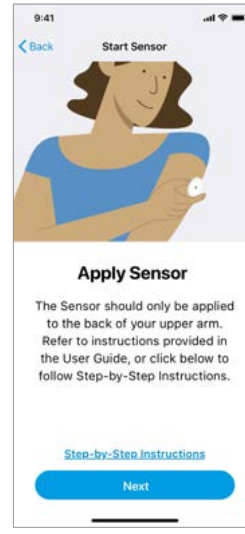
Have your White Cap available when you start a new Sensor. Starting your Sensor involves applying a new Sensor, starting it with your App/phone, and then scanning it with your White Cap. See *Chapter 7 - Using the Sensor* for information on how to apply a Sensor.

1. Tap **Start Sensor**.

2. Tap **Next**.



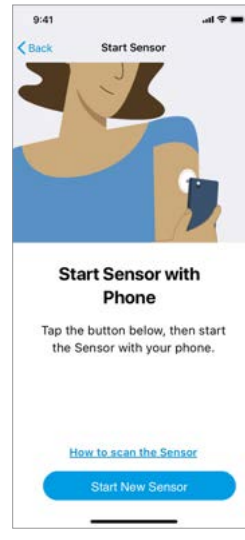
3. Apply a Sensor to the back of your upper arm (see Chapter 7). Decide if you want to view a series of informational screens about how to apply a Sensor.
   - Tap **Next** if you want to skip these screens.
   - Tap **Step-by-Step Instructions** if you want the informational screens displayed.



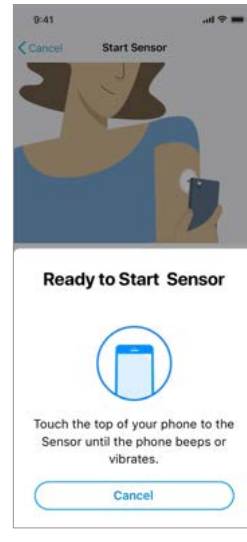
4. With the Cap attached to the insulin pen, press the White Cap button once to turn it on.

5. When the App and Cap are communicating, the Start Sensor with Phone screen will be displayed.

6. Decide if you want to view a series of informational screens about how to start (scan) a Sensor.
   - Tap **Start New Sensor** to proceed.
   - Tap **How to scan the Sensor** if you want the informational screens displayed

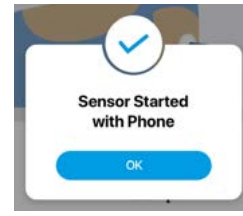


7. Touch the top of your phone over the Sensor insertion area as shown until the phone beeps or vibrates.

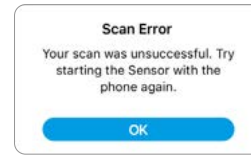


IMPORTANT: Scanning the Sensor with your phone is required to start the Sensor but note that the phone cannot be used to scan the Libre 2 sensor beyond start-up. Scanning the Sensor with the phone will not collect or display current glucose data.

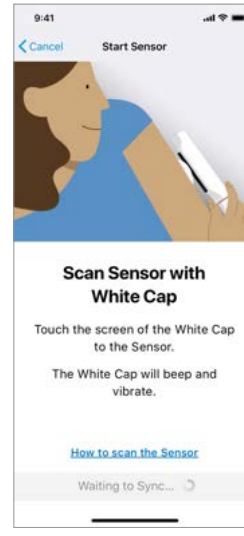
- Wait for the App to confirm that the Sensor was started. A check mark (✓) will indicate that the Sensor was successfully started. Tap **OK**.



Note: If there is a problem with starting your Sensor, you will be prompted to try starting the same Sensor again or using a new, replacement Sensor. Tap **OK**. See *Chapter 10 - Troubleshooting* for more information on problems with starting and scanning your Sensor and recommended next steps.

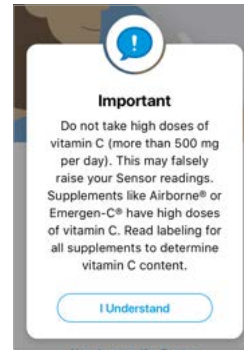


8. Decide if you want a series of informational screens about how to scan your Sensor with your White Cap.
   - Tap **How to scan the Sensor** if you want the informational screens displayed.

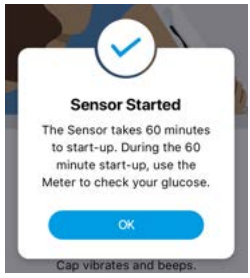


9. Touch the screen of the White Cap to the Sensor as shown, until you hear the Cap beep and feel it vibrate.

- Read Important message that taking more than 500 mg of Vitamin C supplements per day can falsely raise Sensor readings, and then tap **I Understand** to continue.



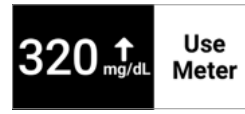
10. Wait for the App and White Cap display to confirm that the Sensor was started. Your Sensor requires a 60 minute start-up period and no Sensor glucose values will display during this time. During this time, use your Meter to make treatment decisions. Sensor readings will be available in 60 minutes.



App Display

White Cap Display

Note: After the 60 minute start-up period but during the first 12 hours after Sensor insertion, Sensor readings will be accompanied by a "Use Meter" message. Whenever "Use Meter" is displayed on the White Cap, check your blood glucose with your Meter to confirm the Sensor reading prior to treatment.



Example: White Cap "Use Meter" display

11. Tap **OK** to continue.

- You will go back to the Set Up Devices screen, with all devices having a check mark. Tap **Done** to proceed.

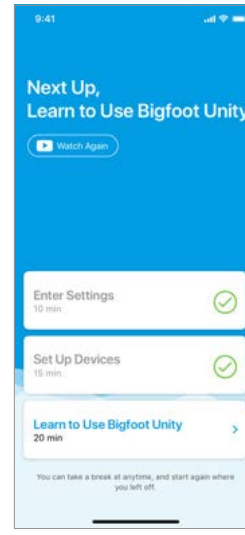
The Next Up, Learn to Use Bigfoot Unity screen will be displayed. A check mark (✓) will indicate that the *Set Up Devices* section is complete.

IMPORTANT: A maximum of 8 hours of glucose data is stored in the Sensor. To avoid gaps (missing data) in your Sensor glucose history graph, it is important to scan your Sensor with your White Cap and bring it within communication range (within 20 ft) of your App at least once every 8 hours.

5.5 Learn to Use Bigfoot Unity

The last *App Setup* section walks you through a series of short video clips, reviews screens, knowledge checks and final reminders intended to help you become more familiar with Bigfoot Unity.

1. Tap **Learn to Use Bigfoot Unity**.

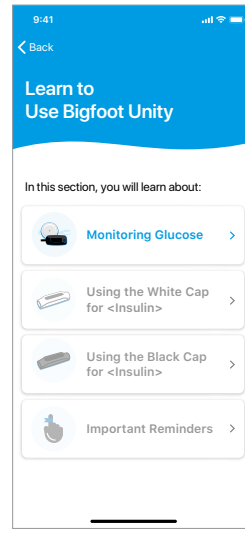


2. Read the Important pop-up message and tap **OK**.

Monitoring Glucose

This section will review how to monitor your glucose with Bigfoot Unity.

1. Tap **Monitoring Glucose**.

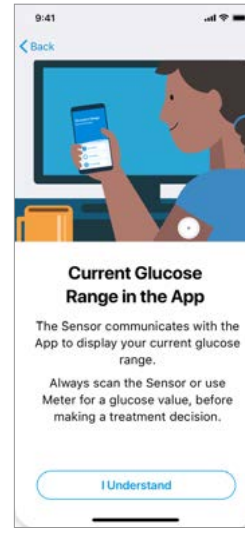


2. Tap the play button (▶) to start watching a short video clip.

3. When done watching, tap **Next** to begin displaying a series of Knowledge Review screens.
   - You can rewatch the video by tapping **Watch Again**.

4. Tap **Next** (or **I Understand**) at the bottom of each screen to continue to the next one.

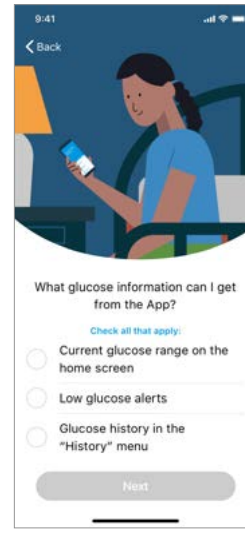
   After tapping **Next** (or **I Understand**) on the last Knowledge Review screen, you will be prompted to check your knowledge.



5. Tap **Let's Go!**

6. Follow the series of screen prompts to answer the Knowledge Check questions.
   - The App will confirm if your answer was correct or explain why it was wrong.
   - Tap **Next** to continue to the next question.

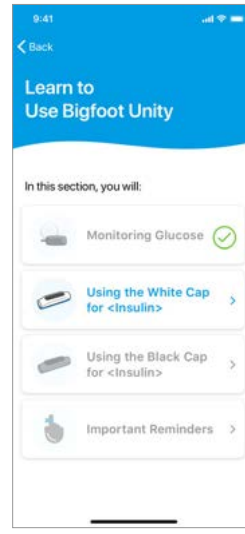
7. After tapping **Next** on the last Knowledge Check screen, the Learn to Use Bigfoot Unity screen will be displayed. A check mark (✓) will indicate that the *Monitoring Glucose* section is complete.



Using the White Cap for Rapid-Acting Insulin

This section will review how to use your White Cap.

1. Tap **Using the White Cap**.

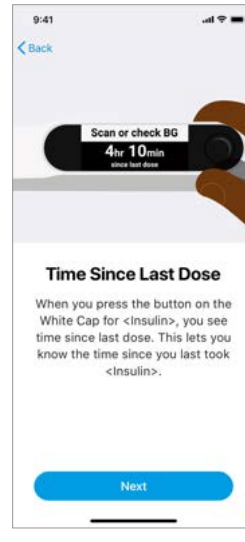


2. Tap the play button (▶) to watch a short video clip.

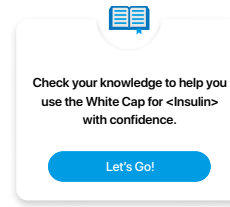
3. When done watching, tap **Next** to begin displaying a series of Knowledge Review screens.
   - You can rewatch the video by tapping **Watch Again**.

4. Tap **Next** at the bottom of each screen to continue to the next one.

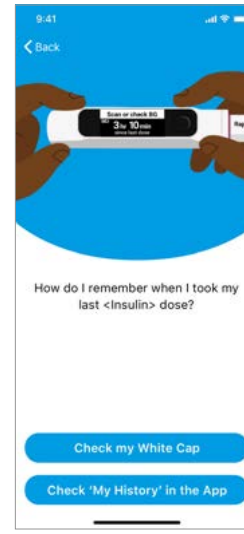
   After tapping **Next** on the last Knowledge Review screen, you will be prompted to check your knowledge.



5. Tap **Let's Go!**



6. Follow the series of screen prompts to answer the Knowledge Check questions.
   - The App will confirm if your answer was correct or explain why it was wrong.
   - Tap **Next** to continue to the next question.

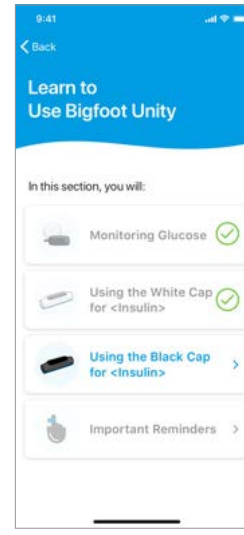


7. After tapping **Next** on the last Knowledge Check screen, the Learn to Use Bigfoot Unity screen will be displayed. A check mark (✓) will indicate that the *Using the White Cap* section is complete.

Using the Black Cap for Long-Acting Insulin

This section will review how to use your Black Cap.

1. Tap **Using the Black Cap**.



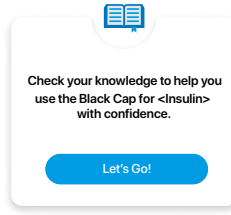
2. Tap the play button (▶) to watch a short video clip.

3. When done watching, tap **Next** to begin displaying a series of Knowledge Review screens.
   - You can rewatch the video by tapping **Watch Again**.

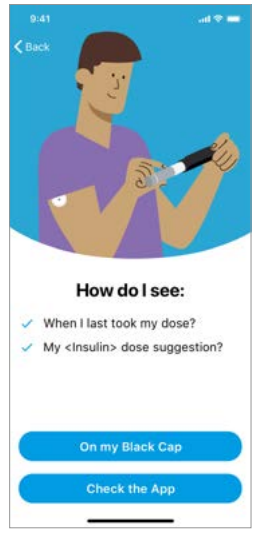
4. Tap **Next** at the bottom of each Knowledge Review screen to continue to the next one.

   After tapping **Next** on the last Knowledge Review screen, you will be prompted to check your knowledge.

5. Tap **Let's Go!**



6. Follow the series of screen prompts to answer the Knowledge Check questions.
   - The App will confirm if your answer was correct or explain why it was wrong.
   - Tap **Next** to continue to the next question.



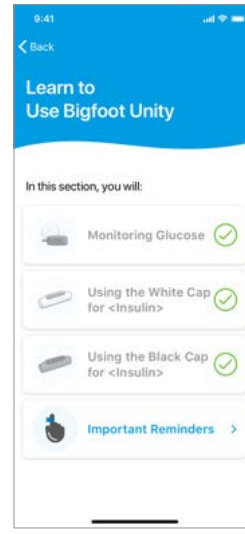
7. After tapping **Next** on the last Knowledge Check screen, the Learn to Use Bigfoot Unity screen will be displayed. A check mark (✓) will indicate that the *Using the Black Cap* section is complete.

Important Reminders

1. Tap **Important Reminders**.

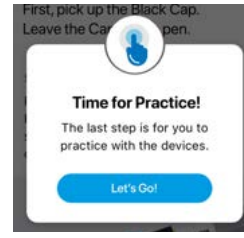
   This section provides a final review of important reminders about Bigfoot Unity.

   - Read each of the reminder screens carefully and tap **I Understand** at the bottom of each screen to continue to the next one.



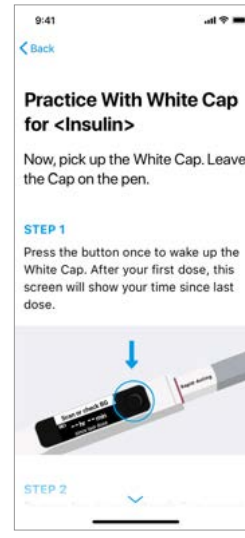
2. After viewing the Important Reminder screens you will have an opportunity to practice with Bigfoot Unity.

   - Tap **Let's Go!**



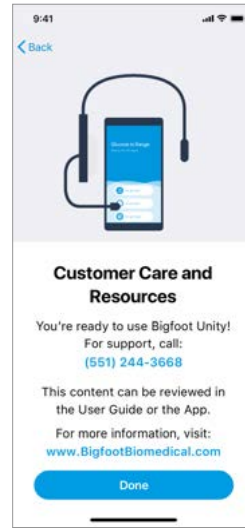
3. With the Cap attached to the insulin pen, follow the screen prompts for practice tips for using the Black Cap and White Cap.

   - Tap **Next** at the bottom of each screen to continue to the next one.



4. After tapping **Next** on the last practice screen, Customer Care information will be displayed.
    - Tap **Done**.

Congratulations on completing the App Setup.



6 Using Bigfoot Unity Caps

Your Caps are used to help you keep track of how long it's been since you injected your last insulin dose using the pen. The White Cap also captures glucose data from your Meter and Sensor and sends the data to the App. The insulin settings from your health care provider, displayed directly on the Caps, is helpful information for you to consider when taking a dose of insulin from the pens.

Both Caps should have enough battery power to begin using them when you first remove them from the packaging. If you see a "Charge Cap" message or a Low Battery  symbol when you turn on or use the Cap, you will need to charge the Caps according to the instructions later in this chapter.

6.1 Pairing the Black and White Caps

If this is the first time connecting your Caps with the App, the devices will need to be paired. See *Chapter 5 - First Time Setup of Bigfoot Unity* for more information on first time pairing during App Setup.

See *Chapter 10 - Troubleshooting* if you are having problems pairing your devices.

6.2 Using the Black and White Caps

Once your Caps are paired with the App, they will continue to display your long-acting and rapid-acting insulin names when the Caps are turned off. This feature does not require any battery power.

IMPORTANT: Your App and Caps are designed to communicate and share data on an ongoing basis. It's important to keep your Caps within a 20 ft range of your phone so communication between the App and Caps can take place regularly and information is up-to-date.

⚠ **CAUTION:** Make sure your phone is within communication range (within 20 ft) of your Caps after you make any changes to your insulin settings within the App. If your Caps do not have the most current settings, you could take too much or too little insulin, which may result in severe low or high glucose.

Insulin information that appears on your Caps is based on what you and your health care provider have entered in your App. Within the App, you can choose to turn certain features on or off. Turning the Mealtime Insulin and/or Correction Insulin feature off means you will not see that information on your White Cap. You can turn these two features on or off anytime within the App as needed.

Whenever a Cap is turned on, it will try to communicate wirelessly with your phone and send the time of your last insulin dose and, for the White Cap, any other stored glucose information that hasn't already been sent. When a Cap is turned off but has data to be sent to the App, it will automatically attempt to communicate with the App and send the stored data every 10 minutes. The Cap will display an Attempting To Communicate icon () if there is information waiting to be sent.

When changes are made to your long-action and/or rapid-acting insulin dose settings by you and your health care provider in the App, those updates will be communicated to and displayed on the Caps. This way you will have the most current insulin information available when you consider taking your next insulin dose.

⚠ **CAUTIONS:**

- Use MY SETTINGS in the App to update your insulin settings whenever your health care provider recommends changes. If your App does not have your most recent insulin settings, information displayed on the App and Caps may not be accurate for taking your next insulin dose. This may result in taking too much or too little insulin, which could lead to severe low or high glucose.
- Any information you enter into the "Notes" screen in the App is for your information only. Any insulin dosing instructions that are listed in "Notes" are not sent to your Caps or used in the insulin dosing information displayed on the Caps.

Always refer to your Cap displays to see how long it's been since your last insulin injection with your pen. Remember that the Black Cap is always used with your long-acting insulin pen, and the White Cap with your rapid-acting insulin pen.

It is important to always put the Caps back on your pens after an injection so the timer accurately tracks when you took your last dose. Placing the Cap back on the pen will re-set the timer to 0 hr 0 min. The timer re-sets whenever a Cap is removed for more than 4 seconds and placed back on the pen. If you place the Caps back in less than 4 seconds, the timer will not restart and a dose will not be recorded. This gives you the chance to check your current pen or to put the Caps on a new insulin pen when insulin has been used up, without restarting the timer and a dose will not be recorded.

IMPORTANT: Remember, remove your Caps only when you take an insulin dose or to replace your insulin pen. Every time you remove the Cap for 4 or more seconds and place the Cap back on the pen, Bigfoot Unity thinks you took a dose of insulin and re-starts counting the "time since last dose".

⚠ **WARNING:** Always place the Bigfoot Unity Cap back onto the insulin pen immediately after taking an insulin dose. If you do not replace the Cap promptly, the time since last dose may not be accurate. This may result in you taking too much or too little insulin, which can lead to severe low or high glucose.

Insert the pen until you hear or feel the Cap click onto the pen. Make sure that "Cap is off Pen" is no longer displayed on the Cap before continuing use. Always check the timer when you place the Caps back on the pens after dosing to make sure the timer has re-started.

Example: Insertion of insulin pens into Caps

Each time you use the Caps, always check that the insulin name displayed on the Cap matches the insulin name on the inserted insulin pen. Because it is possible to insert a pen into the wrong Cap, it is important to always check that you are using the correct pen with the matching Cap.

The insulin name is stored in the Cap, is shared with the App, and will be available on your Cap display the next time you want to dose insulin.

Your Cap display will inform you if you have removed the insulin pen from the Cap.

Note:

- Once you take the Cap off the insulin pen, it will no longer show your time since last dose or insulin dose recommendations. Make sure to determine how much insulin to take before removing the Cap from the insulin pen.
- Your Cap does not know if you have actually taken an insulin injection.
- Your Cap does not track how much insulin you have taken.
- Your Cap does not know if you have taken a Correction Insulin or Meal Insulin dose.

Viewing Time Since Last Long-Acting Dose on the Black Cap

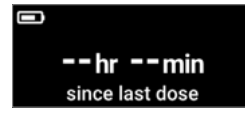
1. When the Black Cap is powered off it displays the long-acting insulin name you entered in the App.

2. Press the Black Cap button once to turn the Cap on.

The hours and minutes recorded since your last long-acting insulin dose will appear on the display.

The time since last dose helps you remember when you took your last dose and when you should take your next dose of long-acting insulin.

Note: If this is the first time using the Black Cap to track your last insulin dose, the screen will show dashes (--) in place of the hours and minutes since your last dose.



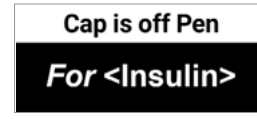
Viewing Long-Acting Dose Amount on the Black Cap

3. Continuing from the previous steps for viewing the time since last dose, press the Black Cap button again to display the Daily Dose of long-acting insulin that you and your health care provider have entered in the App.

Example: Daily Dose on Black Cap screen

4. Press the Black Cap button again to go back to the Time Since Last Dose screen

5. Consider what steps to take based on the information on the Black Cap and your health care provider's recommendations, including how much insulin to dose from your pen.
   - To dose insulin from your long-acting insulin pen, first remove the insulin pen from the Black Cap. Follow the manufacturer's instructions for delivering a dose based on the type of pen and insulin you are using.
   - When you remove the insulin pen, the Black Cap will indicate the Cap is off. When the Black Cap is off for more than 4 seconds, the timer is automatically re-set to 0 when the Cap is placed back on the insulin pen.



   - After 30 seconds of inactivity, the Black Cap will time out and turn off, and then display your long-acting insulin name.

⚠ **WARNINGS:**

- Always check that the insulin name displayed on the Cap matches the name on the insulin pen you intend to use before making a diabetes treatment decision. If you take a dose with the wrong insulin you could take too much or too little insulin, which may result in severe low or high glucose.
- Use caution when using Bigfoot Unity to choose an insulin dose if the Cap does not display the time since last dose or if you think the time since last dose is not correct. If you are unsure about how much insulin to take, follow your health care provider's recommendations.
- Bigfoot Unity only records doses taken with the insulin pens you use with the Caps. If you take a dose of insulin without using Bigfoot Unity, make sure you keep track of the time you took insulin and check your glucose frequently. Allowing time for the insulin to work prior to taking another dose can help prevent severe low glucose.

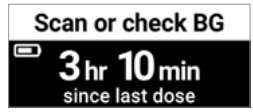
Note: Your Black Cap is not used to communicate with your Sensor or Meter.

Viewing Time Since Last Rapid-Acting Dose on the White Cap

You will need to press the White Button more than once to continue displaying information on the Cap display, and to continue to the next screen. The number of button pushes is a function of whether you have enabled the Correction Insulin and Mealtime Insulin features.

1. When the White Cap is powered off it displays the rapid-acting insulin name you entered in the App.

2. Press the White Cap button once to turn the Cap on.
   - The hours and minutes recorded since your last insulin dose will appear on the display.



   - The time since your last insulin dose serves as a reminder to help prevent you from taking another dose of rapid-acting insulin too soon, and not to forget your next insulin dose.
   - Your White Cap displays helpful insulin information that can help you decide how much insulin to dose based on whether you need to lower (correct) a high blood glucose and/or cover carbs in a meal or snack.

Note: If this is the first time using the White Cap to track your last insulin dose, the screen will show dashes (--) in place of the hours and minutes since your last dose.

3. Decide if you want to measure your current glucose level either by scanning the Sensor or using a blood sample from your finger using your Meter.
   - You may also choose to skip getting a Sensor reading or Meter result by pressing the button on the White Cap and continue with displaying your Mealtime Insulin amounts on the Cap.

Using your White Cap to View Current Glucose

You have the option to scan your Sensor and/or have a result from your Meter sent to your White Cap. Work with your health care provider to put together a plan for managing your diabetes that includes when to use the Sensor glucose readings for making treatment decisions.

Note: Bigfoot Unity will only use a glucose result taken from the Meter or Sensor to display a Correction Insulin dose on your Cap if the glucose value was recorded within the last 10 minutes. This will help make sure you are using your most current glucose level to make an insulin dosing decision.

Scanning the Sensor with the White Cap

Scanning your Sensor means turning the White Cap on and touching the screen side of the Cap to the Sensor to obtain Sensor glucose readings. The Cap must be within 1.0 cm of the Sensor. Your current Sensor glucose reading will be sent to the Cap, and the past 8 hours of Sensor glucose readings that are available will be sent to the App. Those 8 hours of historical glucose data will be viewable within the MY HISTORY feature in the App.

Your current Sensor glucose reading should appear on the Cap display as long as the Sensor was started with the White Cap and the Sensor is providing glucose readings.

IMPORTANT: A maximum of 8 hours of glucose data is stored in the Sensor. To avoid gaps (missing data) in your Sensor glucose history graph, it is important to scan your Sensor with your White Cap and bring it within communication range (within 20 ft) of your App at least once every 8 hours.

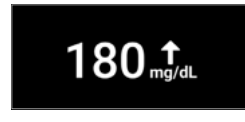
IMPORTANT: Scanning the Sensor with your phone is required to start the Sensor but note that the phone cannot be used to scan the Libre 2 sensor beyond start-up. Scanning the Sensor with the phone will not collect or display current glucose data.

1. Press the button on the White Cap to turn it on.

2. Touch the screen of the White Cap to the Sensor and wait for the Cap to vibrate and beep after scanning the Sensor.

- Your Sensor glucose level will appear on the White Cap along with a Glucose Trend Arrow indicating the direction your glucose is going.

Example:
Sensor glucose reading



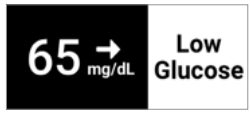
Example:
Sensor glucose reading

Glucose Trend Arrows and What They Mean

Arrow	What it means
↑	Glucose is rising quickly (more than 2 mg/dL per minute)
↗	Glucose is rising (between 1 and 2 mg/dL per minute)
→	Glucose is changing slowly (less than 1 mg/dL per minute)
↘	Glucose is falling (between 1 and 2 mg/dL per minute)
↓	Glucose is falling quickly (more than 2 mg/dL per minute)

Glucose Messages and What They Mean

- There are times when a "Low Glucose" or "Going Low" message will appear along with Sensor glucose reading and Glucose Trend Arrow.
  - "Low Glucose" means your Sensor glucose reading is below 70 mg/dL and possible hypoglycemia.
  - "Going Low" means your Sensor glucose reading is expected to go below 70 mg/dL within the next 15 minutes.
  - Treat either condition according to your health care provider's recommendations.



Example: "Low Glucose" Sensor glucose reading

Example: "Going Low" Sensor glucose reading

IMPORTANT: During the first 12 hours of Sensor wear "Use Meter" will display on the White Cap, and you cannot use Sensor values to make treatment decisions during this time. Confirm Sensor glucose readings with a blood glucose test before making treatment decisions during the first 12 hours of Sensor wear when you see "Use Meter".

- There are other situations where your Sensor is not able to provide glucose readings or there is a problem with the Sensor. See *Chapter 10 - Troubleshooting* for more information about these situations and what to do.

Checking Blood Glucose with the Meter

Checking your blood glucose means using your Meter to measure your glucose from a drop of blood from your fingertip. Results from your Meter will be sent to the White Cap when the Meter is paired to it and within communication range (within 20 ft). See the instructions that came with your Meter for more details on how to use the lancing device, the Meter and all safety information.

1. Place a test strip into the Meter to turn it on and wait to be prompted to apply the sample.
2. Obtain a drop of blood from your fingertip using appropriate lancing device and apply to the end of the strip.
3. Turn the White Cap on by pressing the button one time to display the Time Since Last Dose screen and be prompted to "Scan or check BG".

4. Wait for the blood glucose value to be sent to the White Cap.

- There are other situations when your Meter is not ready to provide a glucose result or there is a problem with the Meter. See *Chapter 10 - Troubleshooting* for more information about these situations and what to do.

> **IMPORTANT:** Use the Meter that is paired with Bigfoot Unity when checking blood glucose. If you use a different meter, blood glucose values will not display on the White Cap.

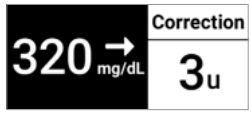
Note: If either the Meter or White Cap shuts off, press the button one time to turn them on. Both must be on for the most recent blood glucose value to be sent to the White Cap.

Viewing Correction Dose Amount on the White Cap

1. Continue from the previous steps for viewing the time since last dose and viewing your current Sensor or Meter glucose reading.

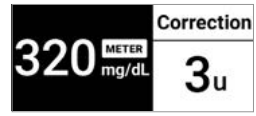
2. View your Correction Insulin units.

   - If you set up Correction Insulin as part of your insulin settings in the App, the White Cap display will show a Correction Insulin unit amount as part of your result screen. A Meter value will be sent to the White Cap only if the blood glucose result was recorded within the past 10 minutes.



Example:
Result screen using
Sensor scan reading

or



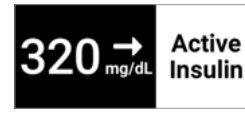
Example:
Result screen using
Meter measurement

   - Bigfoot Unity will first determine which Correction range your most recent Sensor scan or Meter measurement falls within. The Correction units are the units associated with that range. Correction ranges and units are those that you entered in the App.

IMPORTANT: Only the current Sensor reading displayed on the White Cap is used to calculate the Correction Insulin dose recommendation. The Trend Arrow is not used in the dose calculation. Speak with your health care provider for recommendations on how best to utilize the arrows for your correction bolus dosing.

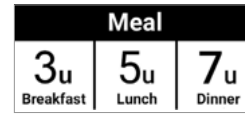
Note: Correction Insulin units will not appear on the display if you turned this feature off in the App, or if the Sensor or Meter were not able to provide a valid glucose reading. If you remove the White Cap from your insulin pen, Correction Insulin units will no longer be displayed.

IMPORTANT: If your last rapid-acting insulin dose was taken within the past 3 hours, the White Cap will display "Active Insulin" and will not display a correction dose. This is because the last dose may be still working to bring down your glucose. Taking another insulin dose on top of the previous dose that is still working may lead to hypoglycemia.



Viewing Meal Dose Amounts on the White Cap

3. Continuing from the previous steps for viewing Correction Insulin units, press the White Cap button to continue.



Example: Meal doses on White Cap screen

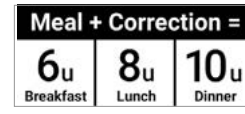
4. View your Mealtime Insulin Units.
   - If Mealtime Insulin was entered in the App and the feature is turned on, the White Cap will display the information to help you decide how much to take to cover your meal according to how you take Mealtime Insulin.

   Note: Mealtime Insulin units will not appear on the display if you turned this feature off in App.

Viewing Meal + Correction Dose Amounts on the White Cap

5. Continuing from the previous steps for viewing mealtime insulin units, press the White Cap button once to continue.

6. View your Total (Mealtime + Correction) Insulin Units.
   - If Mealtime and Correction Insulin were entered in the App and the features are turned on, the White Cap will display the information to help you decide how much total insulin to take to cover your meal and correct for a high glucose. Meal + Correction Insulin units are the total of Correction units and Mealtime units explained in the previous sections.

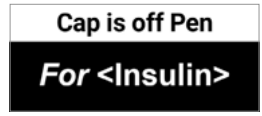


Example: Meal + Correction doses on White Cap screen

   Note:
   - The Meal + Correction screen will not be shown if a dose has been recorded within the last 3 hours, or if the Sensor glucose is not valid for use in a treatment decision.
   - Neither Mealtime nor Correction Insulin units will appear on the display if you turned these features off in the App.

7. Consider what steps to take based on the information on the White Cap display and your health care provider's recommendations, including how much insulin to dose from your pen.

   - To dose insulin from your rapid-acting insulin pen, first remove the insulin pen from the White Cap. Follow the manufacturer's instructions for delivering a dose based on the type of pen and insulin you are using.
   - When you remove the insulin pen, the White Cap will indicate the White Cap is off. When the White Cap is off for more than 4 seconds, the timer is automatically re-set to 0 when the Cap is placed back on the insulin pen.



   - After 30 seconds of inactivity, the White Cap will time out and turn off, and then display your rapid-acting insulin name.

⚠ **WARNINGS:**

- Always check that the insulin name displayed on the Cap matches the name on the insulin pen you intend to use before making a diabetes treatment decision. If you take a dose with the wrong insulin you could take too much or too little insulin, which may result in severe low or high glucose.
- Use caution when using Bigfoot Unity to choose an insulin dose if the Cap does not display the time since last dose or if you think the time since last dose is not correct. If you are unsure about how much insulin to take, follow your health care provider's recommendations.
- Bigfoot Unity only records doses taken with the insulin pens you use with the Caps. If you take a dose of insulin without using Bigfoot Unity, make sure you keep track of the time you took insulin and check your glucose frequently. Allowing time for the insulin to work prior to taking another dose can help prevent severe low glucose.

6.3 Using your Caps when Replacing Insulin Pens

When you have depleted your insulin pen and need to replace it with a new one, make sure you have your new insulin pen and empty pen with the Black or White Cap still on it. When you are ready to replace your empty insulin pen, remove the cap that came with your new pen, and quickly (within 4 seconds) insert your new pen into the correct Black or White Cap to avoid recording a false dose. Confirm that the insulin brand name displayed on the Cap matches the insulin name on the pen.

IMPORTANT: Remember, remove your Caps only when you take an insulin dose or to replace your insulin pen. Every time you remove the Cap for 4 or more seconds and place the Cap back on the pen, Bigfoot Unity thinks you took a dose of insulin and re-starts counting the "time since last dose".

⚠ **WARNING:** Always check that the insulin name displayed on the Cap matches the name on the insulin pen you intend to use before making a diabetes treatment decision. If you take a dose with the wrong insulin you could take too much or too little insulin, which may result in severe low or high glucose.

6.4 Making Diabetes Treatment Decisions

Work with your health care provider to put together a plan for managing your diabetes that includes when to scan your Sensor and how to use Bigfoot Unity information for making treatment decisions. Treatment decisions for your diabetes management include dosing insulin, treating a low or high glucose result, or choosing not to act. Consider scanning your Sensor before a period when you will not be monitoring your glucose, such as before driving, exercise or sleeping. The insulin amounts displayed on your White Cap are for your review and consideration when it is time to take your next dose. The units for Correction or Meal Insulin shown may not take into account all the factors that may affect how much insulin you should take, such as whether you are exercising or are sick. Consult with your health care provider on insulin dosing in various situations.

⚠ **WARNING:** Always use your Bigfoot Meter for diabetes treatment decisions when: (1) Sensor data is not available, (2) when you see the words "Use Meter" on the White Cap, or (3) if your Sensor glucose reading does not match how you feel. Using your Meter will provide you with a glucose reading that you may use to decide how much insulin to take and help prevent severe low or high glucose.

Before you start using glucose readings from the Sensor for diabetes treatment decisions, make sure you have a good understanding of how the Sensor works for your body. **Continue to use your Meter for treatment decisions until you are comfortable with the information you receive from your Sensor**. This includes understanding that: Sensor performance can vary between Sensors, within a Sensor wear period (up to 14 days), and in different situations.

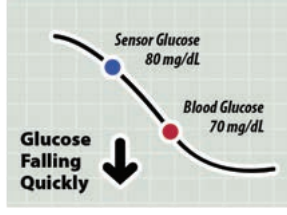
⚠ **WARNING:** Bigfoot Unity does NOT adjust insulin doses on your insulin pen and does NOT record how much insulin you take. When Bigfoot Unity displays insulin dose information, you are responsible for deciding how much insulin to take and giving the injection.

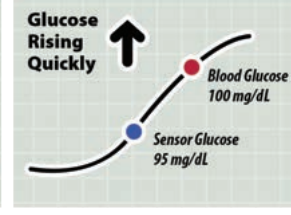
Getting familiar with the Sensor could take days, weeks, or even months. The more you check readings from the Sensor with your Meter, the better you will understand how the Sensor works for you.

Helpful Tips

Confirm your Sensor glucose readings with your Meter until you understand:

- Sensor accuracy may vary between Sensors.
- Sensor accuracy may vary during a Sensor wear session.
- Sensor accuracy may vary in different situations (meals, exercise, first day of use, etc.).
- Scan your Sensor often to see how carbs, medication, exercise, illness, or stress levels impact your Sensor glucose readings. The information you get can help you figure out why your glucose sometimes goes too high or too low, and how to prevent it from doing so in the future.
- Talk to your health care provider about how your insulin works. The more you understand about your insulin, including how long it takes to start working and how long it lasts in your body, the more likely you will be to make better treatment decisions.
- Making a treatment decision doesn't just mean taking insulin. Treatment decisions can also include things like taking fast-acting carbs, eating, or even waiting and scanning again later.
- Your health care provider can also help you to understand when waiting and scanning again later is the right treatment decision. For example, if your glucose is high and going up, your first instinct may be to take more insulin to lower your glucose, however depending on when you last took insulin or your recent activity, the right treatment decision may be to wait for your recent dose of rapid-acting insulin to bring down your glucose level. Avoid "insulin stacking".
- Sensor glucose values, which are based on interstitial fluid glucose levels, can be different from blood glucose levels (fingersticks), particularly during times when your blood glucose is changing quickly. If your glucose readings and alerts from Bigfoot Unity do not match your symptoms or expectations, use a fingerstick blood glucose value from a blood glucose meter to make diabetes treatment decisions. Images below show how Sensor values may be different from blood glucose values.





When Not to Use Sensor Glucose for Treatment Decisions

While certain Sensor readings and Glucose Trend Arrows (and accompanying messages) can be used to indicate when to use a blood glucose measurement from your Meter to make a treatment decision, there are times when you should act based on how you feel rather than relying on Bigfoot Unity. Review the following scenarios carefully as to when to use a blood glucose measurement from your Meter rather than a Sensor reading to decide what to do next.

⚠ **WARNING:** Always use your Bigfoot Meter for diabetes treatment decisions when: (1) Sensor data is not available, (2) when you see the words "Use Meter" on the White Cap, or (3) if your Sensor glucose reading does not match how you feel. Using your Meter will provide you with a glucose reading that you may use to decide how much insulin to take and help prevent severe low or high glucose.

No Current Glucose Number

When there is no current glucose number, such as when you receive an error message, you don't have enough information to make a treatment decision. Do a blood glucose test and treat based on that result. If after scanning, your White Cap displays "< 40 mg/dL" or "> 400 mg/dL", you may want to get additional information by using your Meter.

When you see "Use Meter" during the first 12 hours of wearing a Sensor

During the first 12 hours of Sensor wear "Use Meter" will display on the White Cap, and you cannot use Sensor values to make treatment decisions during this time. Confirm Sensor glucose readings with a blood glucose test before making treatment decisions during the first 12 hours of Sensor wear when you see "Use Meter".

Think Your Readings are Incorrect?

Don't trust Sensor glucose readings that you think may be incorrect or that don't match what you would expect based on your recent activity. For example, if you ate dinner but forgot to take insulin before eating, you would expect your glucose to be high. If your glucose reading is low, then it doesn't match your recent activity, so don't use it to make treatment decisions. Don't make treatment decisions if you think your Sensor glucose readings are incorrect. Do a blood glucose test and treat based on that result.

Symptoms Don't Match Readings

There may be times when your symptoms don't match your Sensor glucose readings. For example, you are feeling shaky, sweaty, and dizzy – symptoms you generally get when you have low glucose, but your glucose reading is within your target range. When symptoms don't match readings, do a blood glucose test and treat based on that result. Don't ignore symptoms that may be due to low or high blood glucose.

If you're the caregiver, pay attention to times when the symptoms of the one you're caring for don't match their Sensor glucose readings. When symptoms don't match readings, do a blood glucose test and treat based on that result. A message/symbol will NOT display in these situations.

When to Wait and Scan Again Later

Your health care provider can help you understand when waiting and scanning again later is the right treatment decision. For example, if your glucose is high and going up, your first instinct may be to take more insulin to lower your glucose, however depending on when you last took insulin or your recent activity, the right treatment decision may be to wait and scan again later.

IMPORTANT: If your last rapid-acting insulin dose logged using the White Cap was taken within the past 3 hours, the Cap will display "Active Insulin" and will not display a correction dose. This is because the last dose may be still working to bring down your glucose. Taking another insulin dose on top of the previous dose that is still working may lead to hypoglycemia.

Considerations Before Injecting Rapid-Acting Insulin

Deciding how much rapid-acting insulin to take for different meals and situations can be difficult. Work with your health care provider to discuss different situations and what might work best for you. Here are some questions to consider:

Meal dosing

- What do you do if your before meal glucose is high?
- What do you do if your before meal glucose is low?
- How much time do you wait to eat after taking your Mealtime Insulin?

- Do you adjust the amount of Mealtime Insulin based on the number of carbs or how much you are planning to eat?
- Do you adjust your Mealtime Insulin dose for high fat foods such as pizza?
- Do you know how to adjust your insulin doses when drinking alcoholic beverages?

High glucose corrections

- Do you take extra insulin if your glucose is high?
- How do you decide how much insulin to take for a high glucose?
- How long do you wait between insulin doses to avoid insulin stacking?

Bedtime

- How often do you check your glucose before bed?
- What do you consider a safe bedtime glucose?
- What do you do if your bedtime glucose is high?
- What do you do if your bedtime glucose is low?
- When should you eat a bedtime snack?
- What do you do if your before bedtime glucose is high?
- What do you do if your before bedtime glucose is low?

Other factors

- For Bigfoot Unity, given that the Trend Arrow is not used in the correction dose calculation, how do you adjust your insulin dose based on the Glucose Trend Arrow?
- How do you adjust your insulin dose for different types of exercise or activities?
- How do you adjust your insulin doses for stress?
- How do you adjust your insulin doses for illness?

Considerations if You Record a Dose You Did Not Take

Bigfoot Unity records that you took a dose of insulin every time the Cap is replaced after being removed for more than 4 seconds. This re-sets the dose timer and displays the "time since last dose" as 0 min 0 sec.

There are times that you may re-set the dose timer accidentally when you did not actually take a dose. Some examples of this might be:

- Removing your Cap to check the insulin in your insulin pen takes longer than 4 seconds.
- The Cap falls off the insulin pen in your backpack or pocketbook.
- You do not snap the Cap into place after you take a dose.

For any of these, or other reasons, Bigfoot Unity will record a dose at the time the Cap is placed back on the insulin pen.

If the dose is recorded at the wrong time, you will need to take extra precautions for a period of time.

- The White Cap will re-set the "time since last dose" after it records a dose (even if you didn't actually take the dose). For the next 3 hours, the Cap screen will display "Active Insulin" instead of giving you a suggested correction dose. If your glucose is high, you will need to use a backup method to determine if a correction dose is needed. Three hours after your White Cap has been placed back on the pen, it will go back to showing correction doses for high glucose.
- The Black Cap will re-set the "time since last dose" after it records a dose (even if you didn't actually take the dose). If you have set the Long-Acting Dose Alert to remind you to check that you took your long-acting insulin dose after a certain period of time, it may not alert you at the time you are expecting. This means that you may need to remember when to take your next dose of long-acting insulin and not rely on Bigfoot Unity to remind you. Follow your health care provider's instructions if you do not know whether or not you took a long-acting dose of insulin.

IMPORTANT: If your last rapid-acting insulin dose logged using the White Cap was taken within the past 3 hours, the Cap will display "Active Insulin" and will not display a correction dose. This is because the last dose may be still working to bring down your glucose. Taking another insulin dose on top of the previous dose that is still working may lead to hypoglycemia.

If Bigfoot Unity records a dose when you did not actually take one, you can "flag" the dose as "not taken" in the MY HISTORY List View section of the App. This will keep your dosing history more accurate in the App, but it will not change the "time since last dose" that is displayed on your Caps. See the *MY HISTORY* section (8.3) for more information.

⚠ **CAUTION:** When you flag an insulin dose as "not taken", it is for your information only. It does not change the "time since last dose" displayed on the Caps.

- The White Cap will not display a correction dose for 3 hours after it records a dose (even if you flag the dose as not taken). Use a backup method for calculating a correction dose if your glucose is high.
- The Black Cap will re-set the timer after it records a dose (even if you flag the dose as not taken). If the "time since last dose" on your Black Cap is not correct, you may not know when to take your next dose of long-acting insulin. Follow your health care provider's instructions if you do not know whether or not you took a long-acting dose of insulin.

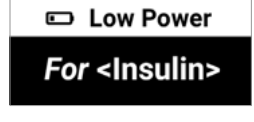
6.5 Charging your Caps

Each Cap has an internal rechargeable lithium ion battery. Caps should have enough power to last 2 weeks on a full charge with typical usage. Cap screens will display a battery icon showing the approximate percentage of battery power left. Cap screens indicate when battery power is less than 25% so you'll know when to recharge. The charger that comes with Bigfoot Unity will work with both Caps for charging.

Note:

- When the Caps are turned off they will continue to display the insulin name. This feature does not require battery power.
- You should leave your insulin pens inside the Caps when charging them, but you will not be able to use the Caps until you are done charging.

When you turn the Caps on, the display will alert you if it is time to charge the Caps (less than 25% battery power remaining). You are able to charge the Cap battery when the Caps are on the insulin pens.



The Time Since Last Dose screen will include a battery icon that indicates about how much battery power is left in the Cap.

Always charge the Caps if you see the “Charge Cap” message or the symbol.

> ⚠ **CAUTION:** Make sure to select a location for charging the Caps that allows the power adapter to be easily unplugged. Do NOT block access to the charger due to the potential risk of electrical shock.

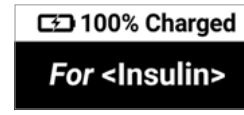
Note: If the Cap battery has no power remaining, you will be prompted to charge the Cap before you can continue using it. While the Cap is charging, you will not be able to use it to track insulin dosing, communicate with the App or display insulin information.

1. Connect the small end of the USB cable to either Cap and the other end to the power adapter. Then plug the power adapter into a wall outlet.

   The display will show that the Cap is charging.

2. Wait about six hours for the Cap to fully charge.

   The display will show when the Cap is fully charged.



3. Repeat these steps for the second cap.

4. Unplug the USB cable from the Cap and wall outlet.

Note: Only use the USB 2.0 compatible cable with USB-C connector and the power adapter that is included with Bigfoot Unity for charging.

Battery States

Battery symbols	What it means
	No power remaining. (Charge Cap immediately.)
	25% or lower (Charge Cap)
	50%
	75%
	100%
	Cap is charging/charging cable plugged in

7 Using the Sensor

7.1 About your Sensor

The Bigfoot Unity™ Diabetes Management System only works with Abbott FreeStyle Libre 2 Sensors and cannot be used with other sensors. When in range of each other, your Sensor continuously sends glucose readings to your App/phone. Information about your glucose range or Sensor status is displayed on the Home screen. You may also receive alerts about low glucose or if your sensor is unavailable. However, in order to obtain your most current glucose reading and Trend Arrow, you will need to scan your Sensor with your White Cap on a regular basis. Your most current glucose reading and Trend Arrow will appear on your Cap display, and the past 8 hours of your glucose data will be stored in your App where you are able to track and look for trends in your data.

IMPORTANT:

- During the first 12 hours of Sensor wear "Use Meter" will display on the White Cap, and you cannot use Sensor values to make treatment decisions during this time. Confirm Sensor glucose readings with a blood glucose test before making treatment decisions during the first 12 hours of Sensor wear when you see "Use Meter".
- Talk to your health care provider about how you should use your Sensor glucose information to help manage your diabetes.

Sensor Kit

The Sensor Kit includes:

- Sensor Pack
- Sensor Applicator
- Alcohol wipe
- Product insert

Sensor Pack

Used with the Sensor Applicator to prepare the Sensor for use.

Sensor Applicator

Applies the Sensor to your body.

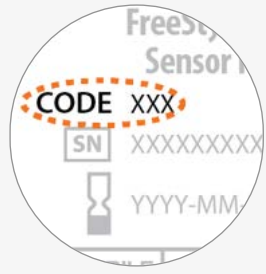
The Sensor measures and stores glucose readings when worn on your body. It initially comes in two parts: one part is in the Sensor Pack and the other part is in the Sensor Applicator. By following the instructions, you prepare and apply the Sensor on the back of your upper arm. The Sensor has a small, flexible tip that is inserted just under the skin. The Sensor can be worn for up to 14 days.

Sensor

Measures your glucose while on your body (only visible after applied).

Using Your Sensor

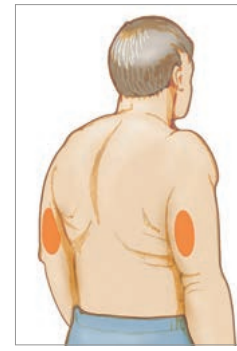
⚠ CAUTIONS:



- The Sensor Pack and Sensor Applicator are packaged as a set and have the same Sensor code. Check that the Sensor codes match before using your Sensor Pack and Sensor Applicator. Do NOT use Sensor Packs and Sensor Applicators with different Sensor codes together as this will result in incorrect glucose readings.
- Intense exercise may cause your Sensor to loosen due to sweat or movement of the Sensor. If the Sensor is becoming loose or if the Sensor tip is coming out of your skin, you may get no readings or unreliable low readings. Remove and replace your Sensor if it starts to loosen and follow the instructions to select an appropriate application site. Do not attempt to reinsert the Sensor. Contact Bigfoot Customer Care at (551) 244-3668 if your Sensor becomes loose or falls off before the end of the wear period.

Applying Your Sensor

1. Apply Sensors only on the **back of your upper arm**. If placed in other areas, the Sensor may not function properly and could give inaccurate readings. The application of the Sensor is not approved for other sites. Avoid areas with scars, moles, stretch marks, or lumps.



Select an area of skin that generally stays flat during your normal daily activities (no bending or folding). Choose a site that is at least 1 inch (2.5 cm) away from an insulin injection site. To prevent discomfort or skin irritation, you should select a different site other than the one most recently used.

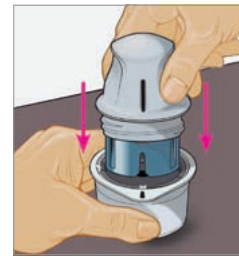
2. Wash application site using a plain soap, dry, and then clean with an alcohol wipe. This will help remove any oily residue that may prevent the Sensor from sticking properly. Allow site to air dry before proceeding.

Note: The area **MUST** be clean and dry following these instructions, or the Sensor may not stay on for the full 14 day wear period.

3. Open the Sensor Pack by peeling the lid off completely. Unscrew the cap from the Sensor Applicator and set the cap aside.

> ⚠ **CAUTION:** Do NOT use if the Sensor Pack or the Sensor Applicator seem to be damaged or already opened. Do NOT use if past expiration date.

4. Line up the dark mark on the Sensor Applicator with the dark mark on the Sensor Pack. On a hard surface, press firmly down on the Sensor Applicator until it comes to a stop.

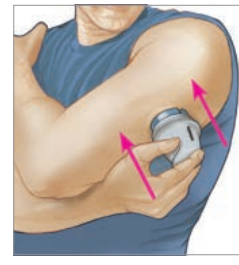


5. Lift the Sensor Applicator out of the Sensor Pack.

6. The Sensor Applicator is prepared and ready to Apply the Sensor.

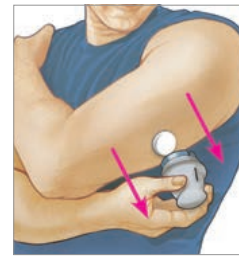
> ⚠ **CAUTION:** The Sensor Applicator now contains a needle. Do NOT touch inside the Sensor Applicator or put it back into the Sensor Pack.

7. Place the Sensor Applicator over the prepared site and push down firmly to apply the Sensor to your body.



> ⚠**CAUTION:** Do NOT push down on the Sensor Applicator until placed over prepared site to prevent unintended results or injury.

8. Gently pull the Sensor Applicator away from your body. The Sensor should now be attached to your skin.



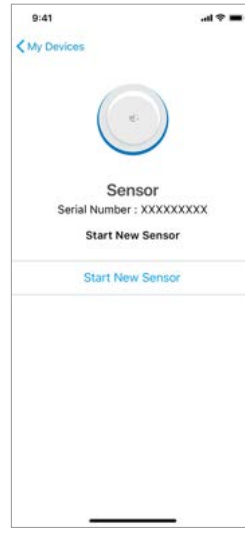
Note: Applying the Sensor may cause bruising or bleeding. If there is bleeding that does not stop, remove the Sensor and contact your health care provider.

9. Make sure the Sensor is secure after Application. Put the cap back on the Sensor Applicator. Discard the used Sensor Pack and Sensor Applicator according to local regulations.

7.2 Starting (and Scanning) a New Sensor

Whenever you insert a new Sensor, you will need to start the Sensor from within your App. You will also need your White Cap as part of the process.

1. In the App and referring to *Sensor (Status and Start a New Sensor)* in section 8.3, go to "MY DEVICES" and tap **Sensor** to initiate the process. If you want to start a new Sensor, tap **Start New Sensor** on the Sensor Device screen.



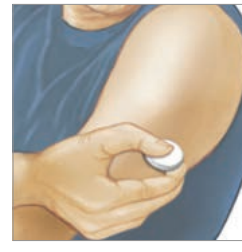
Note:

- Once a new Sensor is started, the Cap and App will inform you that the Sensor is started and that you can begin scanning the Sensor to obtain glucose readings in 60 minutes. While you can begin scanning your Sensor after the 60 minute start-up period ends, you should not use Sensor readings to make treatment decisions for the first 12 hours of Sensor wear. Instead, check your blood glucose with your Meter when the White Cap displays "Use Meter".
- If you are having troubles scanning the Sensor, review instructions for proper scanning technique within the *Scanning the Sensor with the White Cap* section in Chapter 6.

7.3 Removing your Sensor

1. Pull up the edge of the adhesive that keeps your Sensor attached to your skin. Slowly peel away from your skin in one motion.

   Note: Any remaining adhesive residue on the skin can be removed with warm soapy water or isopropyl alcohol.



2. Discard the used Sensor following directions from your health care provider. See *Chapter 9 - Care, Maintenance and Disposal of Bigfoot Unity*. When you are ready to apply a new Sensor, follow the instructions in the *Applying Your Sensor* section in this chapter. If you removed your last Sensor before it ended, you will be prompted to confirm that you would like to start a new Sensor when you initiate the start new Sensor process in the App.

7.4 Replacing your Sensor

Your Sensor automatically stops working after 14 days and must be replaced. You should also replace your Sensor if you notice any irritation or discomfort at the application site, or if the White Cap or App reports a problem with the Sensor currently in use. Acting early can keep small problems from turning into larger ones.

⚠ **CAUTION:** If the Sensor is becoming loose or if the Sensor tip is coming out of your skin, you may get no readings or unreliable readings, which may not match how you feel. Check to make sure your Sensor has not come loose. If it has come loose, remove it, and apply a new one, and contact Bigfoot Customer Care at (551) 244-3668.

1. Pull up the edge of the adhesive that keeps your Sensor attached to your skin. Slowly peel away from your skin in one motion.

   Note: Any remaining adhesive residue on the skin can be removed with warm soapy water or isopropyl alcohol.

2. Discard the used Sensor following directions from your health care provider. See *Chapter 9 - Care, Maintenance and Disposal of Bigfoot Unity*. When you are ready to apply a new Sensor, follow the instructions in the *Applying Your Sensor* section in this chapter. If you removed your last Sensor before the 14-day period, you will be prompted to confirm that you would like to start a new Sensor using the App.

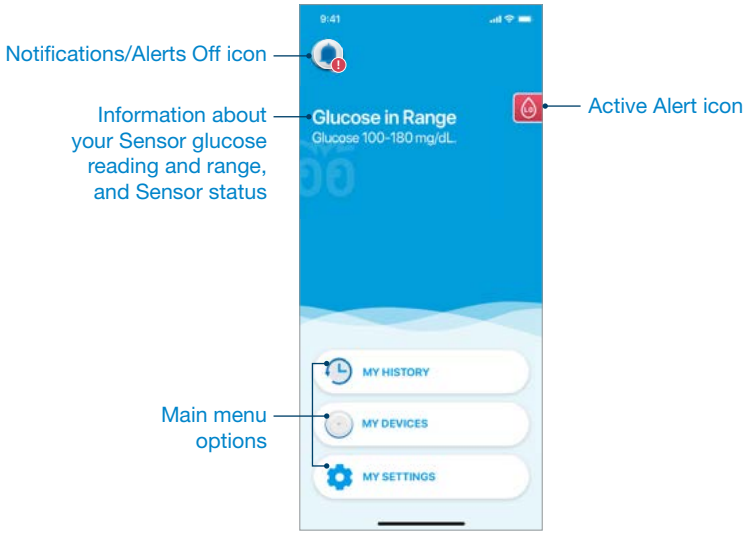
8 Daily Use and Additional Features

8.1 Home Screen

The Home screen will display every time you open the App. The Bigfoot Unity™ Diabetes Management System is designed so that your Sensor is always communicating with the App regarding your glucose and Sensor status. The Home screen is where you have access to that information.

The top of the Home screen is where you will receive information about your Sensor glucose reading and range, and the status of your Sensor. It's also where you will receive Notifications and Alerts.

The bottom of the Home screen displays the three main menu options where you have access to all Bigfoot Unity features.



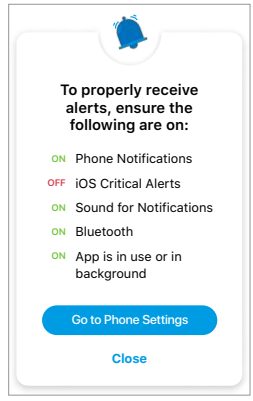
Note: If Notifications or Alerts are turned off in your phone, a "Notifications/Alerts Off" icon ( ) will appear at the top of the Home screen.

This may appear when:

- Notifications are turned off in your phone settings.
- Critical Alerts are turned off in your phone settings.
- Notifications sounds are turned off in your phone settings.
- *Bluetooth*® settings are off on your phone.

Tap the “Notifications/Alerts Off” icon ( ) to display the current receiving status of Notifications and Critical Alerts on your App/phone.

Tap **Go To Phone Settings** to adjust how you manage Notifications and Critical Alerts with Bigfoot Unity.



Home Screen Glucose Ranges

The Home screen is where your glucose range or information about your Sensor status is displayed. This information can be used to determine if you need to scan your Sensor using your White Cap or read the Meter before deciding appropriate treatment.

The Home screen will let you know when:

- Your glucose is very low (below 54 mg/dL).
- Your glucose is low (between 55 mg/dL and 69 mg/dL).
- Your glucose is at the low end of your target range (between 70 mg/dL and 99 mg/dL).
- Your glucose is within your target range (between 100 mg/dL and 180 mg/dL).
- Your glucose is above your target range (between 181 mg/dL and 250 mg/dL).
- Your glucose is high (above 250 mg/dL).
- Your Sensor is not able to obtain or send glucose readings to the App.

Example: Displays

Your target range and pre-set thresholds are based on input from health care providers who specialize in diabetes care. Ranges and thresholds come pre-set and cannot be changed.

Bigfoot Unity provides some flexibility for how and when you receive Alerts in the App and on your phone. Settings on your phone allow you to adjust how Alerts might appear, sound and/or vibrate on your phone.

⚠**WARNING:** Do NOT ignore symptoms that may be due to low or high blood glucose: If you are experiencing symptoms that are not consistent with your glucose readings, consult your health care provider.

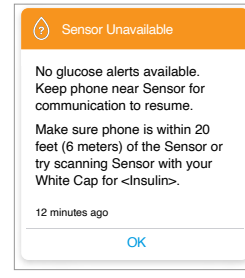
⚠**WARNING:** Do NOT use the glucose ranges displayed in your App to make diabetes treatment decisions. Always use the White Cap to scan the Sensor or read the Meter before deciding appropriate treatment. The App only displays ranges of glucose values and you need more specific information for diabetes treatment decisions. If you base your treatment on the glucose range in the App, you might take too much or too little insulin, which may lead to severe low or high glucose.

See the *Alerts* section that follows for more information. Also see *Chapter 10 - Troubleshooting* for a complete list of Notifications and Alerts that might occur and suggestions for what to do.

Alerts

Certain situations regarding your glucose and Sensor status are important for your diabetes management and can result in an Alert on your App/phone regardless of whether you have scanned the Sensor with the White Cap. Alerts require your immediate attention. These include a Low Glucose Alert, Sensor Unavailable Alerts, and a Long-Acting Dose Alert.

IMPORTANT: Glucose alerts are an important safety feature for some people. For example, those that have impaired awareness of hypoglycemia or a history of severe hypoglycemia. Before you turn alerts off or change their notification settings, please consult your health care provider.



Example: Alerts

When you set up the App for the first time, you were given the option to allow Alerts to come through to your App/phone even if it is muted, your screen is locked or is set to “Do Not Disturb”. It is possible to have multiple Alerts active at any time. Always keep your Bigfoot Unity App open (do not force close) on your phone and keep your phone near you when you are wearing your Sensor (within 20 ft). This will help you receive and hear Notifications and Alerts, which may prevent severe low or high glucose. In addition, having your App within communication range of your Black Cap (within 20 feet) after you take a dose of long-

acting insulin helps ensure that you will receive the Long-Acting Dose Alert at the appropriate time. However, you should always check the Black Cap for the time since last dose to be sure.

Alerts will display on your App. When multiple Alerts are active, you can swipe left to display the other Alerts. Active Alert screens appear in priority order, beginning with the most important. After tapping **OK** to acknowledge an Alert, the pop-up Alert screen will no longer appear on the Home screen. Alerts may also display on a compatible watch depending on the settings.

An "Active Alert" icon for Low Glucose ( ) will appear on the Home screen if it is still active (initial problem not yet resolved). Tap the Active Alert icon on the Home screen to display that Alert.

Note: if you ignore an alert, you will receive it again if the condition still exists.

You can always go back into MY SETTINGS in your App to turn Alerts on or off as needed. You can use your phone Settings to adjust how you want Alerts to display/sound/vibrate.

See *Appendix A* for a complete list of Alerts you may receive on your phone/App, and recommended next steps.

⚠ **WARNINGS:**

- You must allow Notifications for the Bigfoot Unity App in order to receive Bigfoot Unity Alerts even when your phone is locked and not showing the Bigfoot Unity App. Remember also to keep your phone sufficiently charged to receive alerts.

  If you do not allow or receive alert Notifications, or if your phone is not on, you might miss knowing that your glucose is low, that your Sensor has stopped working, or that you may have missed a dose of long-acting insulin.

- You must allow Critical Alerts on your phone to receive Alerts even when your phone is muted or set to "Do Not Disturb".

  If you do not allow Critical Alerts, you may not be aware of a low glucose or if your sensor glucose information is not available.

- Do NOT ignore Alerts from Bigfoot Unity. Alerts help inform you about Sensor availability, low glucose, or if you may have missed your long-acting insulin dose. Paying attention to alerts can help prevent severe low or high glucose.

⚠ **WARNINGS:**

- Alerts and Notifications appear on the phone only and do NOT appear on the Caps or the Sensor itself. Make sure to have your Bigfoot Unity App and phone set up properly to receive alerts. Receiving Alerts and Notifications on your App/phone can help prevent severe low or high glucose.
- Always check the Black Cap for the time since last dose if you receive a Long-Acting Dose Alert on your phone.

  Checking the Black Cap for the time since last dose will help ensure you take the next dose of insulin at the correct time, and help avoid severe low or high glucose.
- Always keep your Bigfoot Unity app open (do not force close) on your phone and keep your phone nearby (within 20 ft). This will help you receive and hear Notifications and Alerts, which may prevent severe low or high glucose.

⚠ **CAUTION:** Do NOT leave headphones connected to the phone when you are not using them. If you have headphones connected to the phone, Notifications and Critical Alerts will not sound or vibrate on the phone.

Home Screen Main Menu Options

MY HISTORY

MY DEVICES

MY SETTINGS

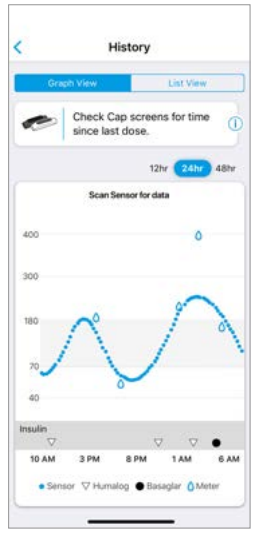
Additional information may appear under the MY DEVICES and MY SETTINGS menu options, indicating an actionable item for you.

8.2 MY HISTORY

In MY HISTORY, you can review available glucose data from your Sensor and Meter, and the time of insulin doses captured with the Caps. You can also review if any updates were made to your insulin settings. The App conveniently combines the data into a single view where you can see how insulin doses affect your glucose levels and helps you spot trends and patterns.

Tap either selection on the screen.

- Graph View
- List View



Example:
History screen

Graph View

The Graph View screen displays your Sensor readings in 15-minute intervals over the past 48 hours.

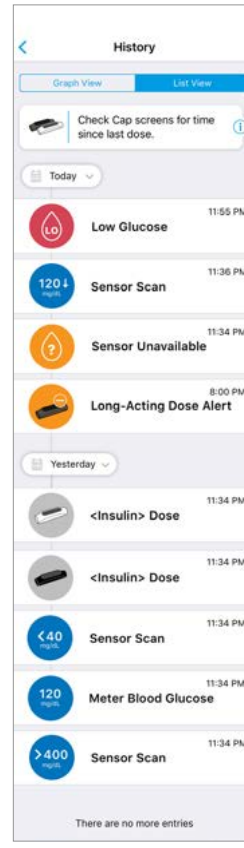
The Graph View screen includes:

- Glucose data from your Sensor over the past 12 to 48 hours graphed as a trend line, ending with the most current glucose reading on the far right.
  - Tap the graph at any glucose data point to highlight the associated value.
  - You can switch between a 48-hour, a 24-hour and a 12-hour view of your glucose data by tapping on the desired view duration above the graph.
- Blood glucose results from your Meter and long-acting and rapid-acting insulin injections from your Caps, appear as coded symbols at the time recorded for each event. Tap any symbol to display detailed information about the event.

IMPORTANT: A maximum of 8 hours of glucose data is stored in the Sensor. To avoid gaps (missing data) in your Sensor glucose history graph, it is important to scan your Sensor with your White Cap and bring it within communication range (within 20 ft) of your App at least once every 8 hours.

List View

The List View screen serves as a digital "Logbook" that displays key events captured over the past 48 hours, sorted by date and time for each event.



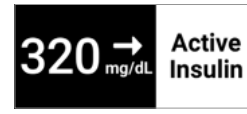
The List View screen includes:

- The time and result of your last scanned Sensor glucose reading, along with any Trend Arrow.
- The time and result of your last blood glucose measurement taken with your Meter.
- The time of your last rapid-acting and long-acting insulin dose recorded with your Caps.
- The time and type of any Alert.
- The last time insulin updates were sent to your Caps.

Swipe up (scroll) to view previously recorded events.

IMPORTANT:

- Remember, remove your Caps only when you take an insulin dose or to replace your insulin pen. Every time you remove the Cap for 4 or more seconds and place the Cap back on the pen, Bigfoot Unity thinks you took a dose of insulin and re-starts counting the "time since last dose".
- If your last rapid-acting insulin dose was taken within the past 3 hours, the White Cap will display "Active Insulin" and will not display a correction dose. This is because the last dose may be still working to bring down your glucose. Taking another insulin dose on top of the previous dose that is still working may lead to hypoglycemia.

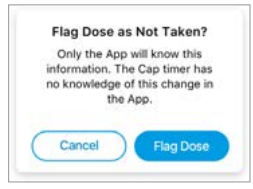


Dose Not Taken

If Bigfoot Unity records a dose when you did not actually take one, you can "flag" the dose as "not taken" in the MY HISTORY List View section of the App. This will indicate that the dose was never actually taken and will help keep your insulin dosing more accurate when viewing your history.

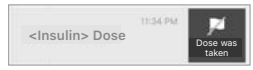
- Tap the insulin dose you want to flag to display the "Dose Not Taken" flag.
- Tap the "**Dose Not Taken**" flag.

- Then tap **Flag Dose** when prompted.



The record of that dose will appear grayed out when you display the List View or Graph View screens again.

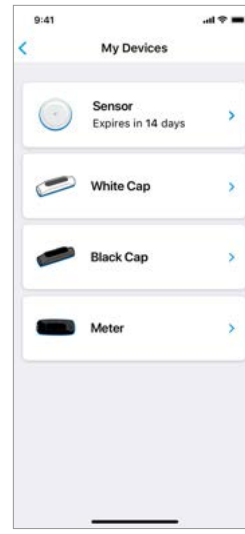
If you mistakenly flag a dose as "not taken" and want to add the dose back into MY HISTORY records as a dose you took, tap the grayed out dose and then tap **Dose was taken.**



⚠ **CAUTION:** When you flag an insulin dose as "not taken", it is for your information only. It does not change the "time since last dose" displayed on the Caps.

- The White Cap will not display a correction dose for 3 hours after it records a dose (even if you flag the dose as not taken). Use a backup method for calculating a correction dose if your glucose is high.
- The Black Cap will re-set the timer after it records a dose (even if you flag the dose as not taken). If the "time since last dose" on your Black Cap is not correct, you may not know when to take your next dose of long-acting insulin. Follow your health care provider's instructions if you do not know whether or not you took a long-acting dose of insulin.

8.3 MY DEVICES (Status and Starting New Devices)



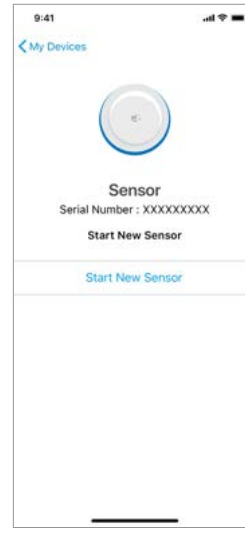
MY DEVICES lets you review the status of current connected Bigfoot Unity devices, start a new Sensor, connect a new Black or White Cap, and connect a new Meter. When starting a new White Cap, you will need your Meter to connect to it and you will need to start a new Sensor.

Tap any device icon on the My Devices screen to display the device status and/or start the process for starting/connecting a new device.

Note:

- Only one Black and White Cap, Meter, App and Sensor can be connected at one time. For example, if you pair a new White Cap, it will automatically unpair the current one. If you change insulins while using Bigfoot Unity, it may require that you obtain a new prescription from your health care provider for a different Cap. In this case, you must contact Bigfoot Customer Care at (551) 244-3668 to obtain a new, compatible Cap. You will also need to pair the new Caps with the other Bigfoot Unity devices.
- Remember to leave your Caps attached to your insulin pens as instructed by the App screens when setting up new devices.

Sensor (Status and Start a New Sensor)



Shows the number of days, hours or minutes before you need to replace the Sensor. If you started the Sensor within the last 60 minutes, the screen shows the number of minutes before the new Sensor may be scanned for glucose readings.

1. Tap **Start New Sensor**.
   - If your current Sensor has > 12 hours of use remaining, you will be prompted to confirm you still want to start a new Sensor. Tap **OK** to continue.
2. Repeat the steps for starting a new Sensor (see *Start Sensor* section in Chapter 5).

   You can tap **< My Devices** to return to the Sensor device screen if you do not want to proceed.

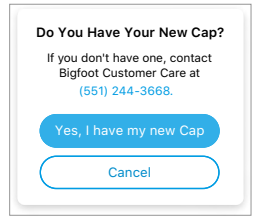
White Cap (Status and Start a New White Cap)

Shows the last time the App communicated with your White Cap.

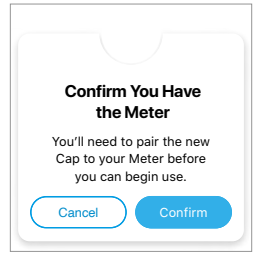
1. Tap **Start New White Cap** to start a new White Cap.
   - When you start a new White Cap, you will also need to start a new Sensor and start/pair your Meter.

⚠ **CAUTION:** When you get a new Cap, always pair it using the Bigfoot Unity App on your phone. The pairing process sends your most recent insulin settings to the new Cap. If you do not pair your new Cap, you will not be able to use it.

2. You will be prompted to have your new White Cap ready. Tap **Yes, I have my new Cap** to continue.
   - If you don't have your new White Cap, tap **Cancel** and then contact Bigfoot Customer Care at (551) 244-3668.



3. You will be prompted to have your Meter ready. Tap **Confirm** to continue.
   - If you don't have your new Meter and White Cap ready, tap **Cancel**. Repeat the steps for starting/pairing your new White Cap when it is ready.

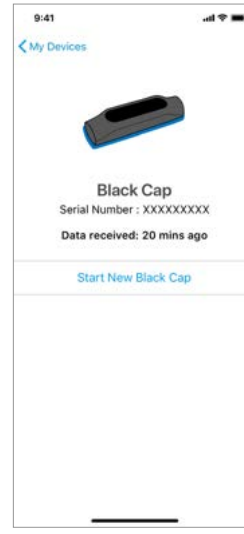


4. Repeat steps for starting/pairing a White Cap, Meter and Sensor in Chapter 5.

   You can tap **< Back** to return to the White Cap device screen if you do not want to proceed.

Black Cap (Status and Start a New Black Cap)

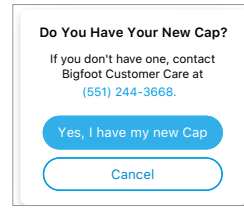
Shows the last time the App communicated with your Black Cap.



1. Tap **Start New Black Cap** to start a new Black Cap.

> ⚠ **CAUTION:** When you get a new Cap, always pair it using the Bigfoot Unity App on your phone. The pairing process sends your most recent insulin settings to the new Cap. If you do not pair your new Cap, you will not be able to use it.

2. You will be prompted to have your new Black Cap ready. Tap **Yes, I have my new Cap** to continue.



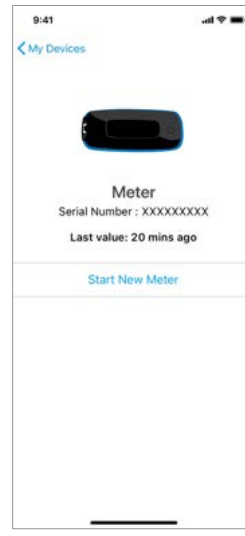
   - If you don't have your new Black Cap, tap **Cancel** and then contact Bigfoot Customer Care at (551) 244-3668.

3. Repeat the steps for starting a new Black Cap (see *Start Black Cap* section in Chapter 5).

   You can tap **< Back** to return to the Black Cap device screen if you do not want to proceed.

Meter (Status and Start a New Meter)

Shows the last time your blood glucose reading was sent from your Meter to the White Cap.



1. Tap **Start New Meter** to start a new Meter.
2. Repeat the steps for starting a new Meter (see *Start Meter* section in Chapter 5).

   You can tap **< Back** to return to the Meter device screen if you do not want to proceed.

Phone Replacement

If you replace your phone, you will need to download and re-install the Bigfoot Unity App on your new phone. Cloud data services will restore your previous diabetes settings in the App. You will also need to pair your Caps with the App on the new phone.

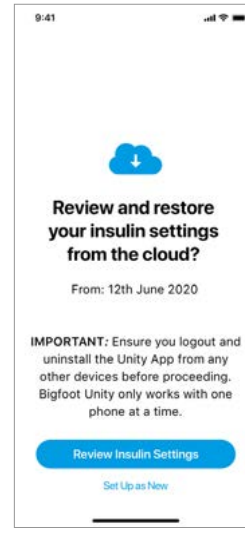
Note:

- Your last insulin information in the cloud may not match the current information in your Caps if your Caps and App have not yet communicated since your last set of updates.
- Pairing devices may take up to a few minutes.

1. Download and install the Bigfoot Unity App from the App Store.
   - Launch the App.

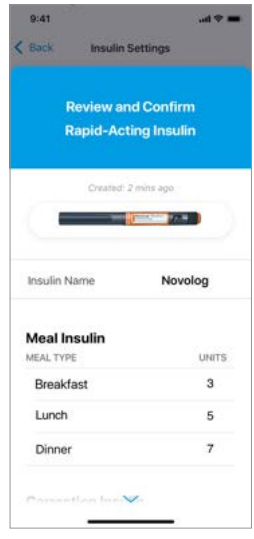
2. Login with your email and Password as before, and agree to the Terms and Conditions.

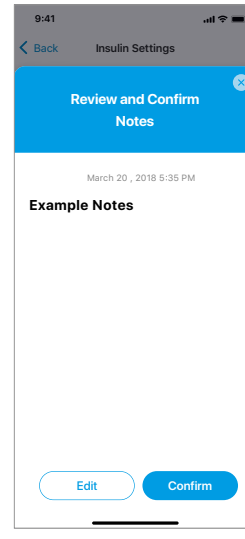
3. You have the option to restore your previous insulin settings or create new insulin settings. Remember, when you are setting up a new phone, follow the App instructions for when to leave the White and Black Caps attached to your pens so you do not record an incorrect insulin dose.



- Bigfoot Unity will first check if your previous insulin information is available in the cloud. If it is, the date of your last insulin settings is displayed.
- To restore your last insulin settings tap **Review Insulin Settings**. Then continue to Review and Confirm (or Edit) your last insulin settings.
- To create new insulin settings, tap **Set Up as New**. Repeat the steps in the *Enter Insulin Settings* section in Chapter 5.

4. Review and Confirm (or Edit) your last insulin settings on each Insulin Settings screen.

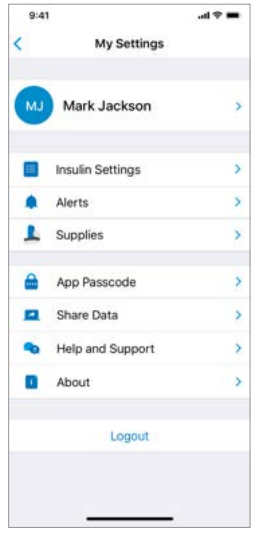




5. Tap **Confirm** to accept your previous entries, or tap **Edit** to make changes to your previous entries.
   - If you tap **Edit**, you will need to repeat the *Enter Insulin Settings* section in Chapter 5 for each type of insulin you edit, and confirm for each type.

6. When you are finished reviewing your Notes, tap **Confirm** to restore your previous insulin settings.
   - A confirmation screen with a check mark (✓) will indicate that your previous insulin settings have been restored. Tap **Done**.
7. Tap **OK** and repeat the steps for starting your Caps with your new phone.

8.4 MY SETTINGS



Your name (account name) will appear at the top of the My Settings screen. Tap your name to access and update your account information by selecting your name.

Tap any one of the selections that appear underneath your account name on the My Settings screen in order to:

- Make updates to your insulin settings
- Set Alerts
- Order supplies
- Set a Passcode to protect personal diabetes information stored in the App from being edited by someone other than you
- Share your personal diabetes information with your health care provider
- Get help and support when using Bigfoot Unity
- View technical information about your Bigfoot Unity hardware and software
- Logout of your App account.

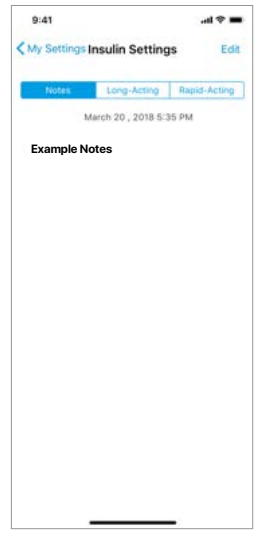
Insulin Settings

In Insulin Settings, you can make updates to the information you and/or your health care provider entered during App Setup. As long as the Caps are within communication range (20 ft), changes will then be sent to your Caps so they contain and display the latest insulin information. You will need to accept any changes you may have made to your insulin information in the App before they will be saved in the Caps. If you change your insulin brand, Bigfoot Unity will check to see if you need a new White or Black Cap that is compatible with your new insulin and instruct you accordingly.

Making changes to your insulin settings

Notes

View and edit your Notes as needed.



1. Tap **Insulin Settings** on the My Settings screen.
2. Tap **Notes** to display your current Notes.
   - To edit, add or delete your Notes, tap **Edit** on the top right of the screen.
3. Tap anywhere on your current Notes and then use the pop-up keyboard to edit, add or delete Notes and/or pictures.
4. After making your changes, tap **Done** on the pop-up keyboard or **Save** on the top right of the screen.

Long-Acting Insulin

View and edit your long-acting insulin information as needed.

1. Tap **Insulin Settings** on the My Settings screen.
2. Tap **Long-Acting** to display your current long-acting Insulin Name and Daily Dose.
3. To change your current Insulin Name and Daily Dose, tap **Edit** on the top right of the screen.

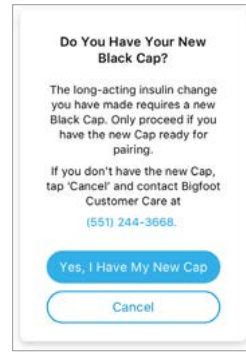
Example: Long-acting insulin and dose

4. If you want to change your Daily Dose, tap on the units.
   - Scroll to the desired units and then tap **Done**. If you need to make edits to your Insulin Name go to Step 5 that follows. If you are done making edits to your Long-Acting Insulin Settings tap **Save**. Then follow the App prompts for turning the Black Cap on and sending insulin settings to your Black Cap (see *Sending Insulin Updates to your Caps* section that follows).

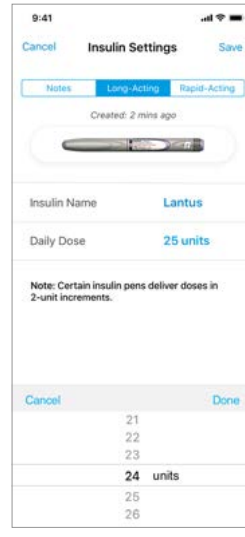
5. If you need to change your Insulin Name (the long-acting insulin you are using), tap your current Insulin Name to change it.

   - Scroll to your new long-acting insulin from the list and then tap **Done**.
   - Tap **Save** when you are finished.

- If your new long-acting insulin requires a new Black Cap, you will be prompted to confirm you already have the Cap. Tap **Yes, I Have My New Cap** or **Cancel** to contact Customer Care for assistance. Once you have your new Black Cap, you will need to follow the App prompts for Reviewing and Confirming your long-acting insulin settings. Then proceed to pair your new Black Cap with your App and send updated long-acting insulin settings to the Black Cap.



- If your new long-acting insulin does not require a new Black Cap, you will be prompted to review your new Insulin Name and current dose.
  - Tap **Review** to display your updated insulin settings where you can change your units as needed. When you are finished, tap **Save**. Then follow the App prompts for turning the Black Cap on and sending insulin settings to your Black Cap (see *Sending Insulin Updates to your Caps* section that follows).



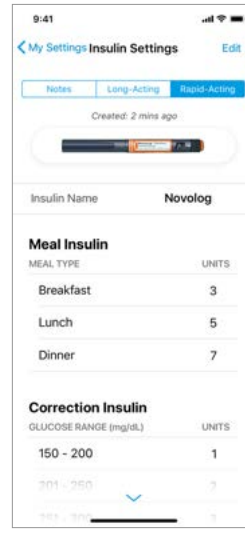
Example: Long-acting insulin and dose

  - Tap **Cancel** to cancel the change you made to your Insulin Name and return to the Insulin Settings screen where you can start over.

Rapid-Acting Insulin

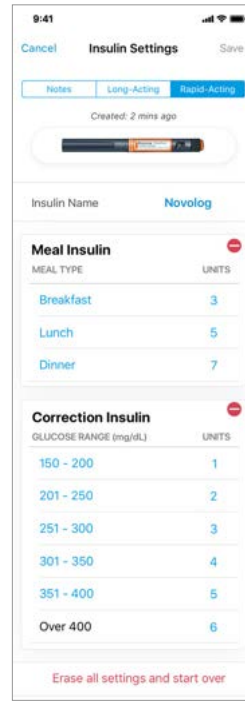
View and edit your rapid-acting insulin information as needed.

1. Tap **Insulin Settings** on the My Settings screen.
2. Tap **Rapid-Acting** to display your current rapid-acting Insulin Name along with your Meal and Correction Insulin information.
3. To change your current Insulin Name, and remove, add or change your Meal or Correction Insulin, tap **Edit** on the top right of the screen.



Example: Rapid-acting insulin and doses

- An edit icon (⛔) will appear next to Meal and/or Correction Insulin if you have previously entered and saved this information. You must tap that icon to completely remove that category and start over to change any saved Meal or Correction Insulin information.
- **+ Add Meal Insulin** will appear if Meal Insulin is not currently included in your insulin settings.
- **+ Add Correction Insulin** will appear if Correction Insulin is not currently included in your insulin settings.
- At any point, you can tap **Erase all settings and start over** to start with a clean slate.



Example: Editing Rapid-acting insulin and doses

4. If you choose to start over, tap **Erase all settings and start over**. You will be prompted to confirm your selection by tapping **Erase**.

- Follow the App prompts for entering new rapid-acting insulin information (see *Entering Rapid-Acting Insulin Settings* section in Chapter 5).
- Tap **Save** on the Insulin Settings screen when finished. Then follow the App prompts for turning the White Cap on and sending insulin settings to your White Cap (see *Sending Insulin Updates to your Caps* section that follows).

⚠ **CAUTION:** Use MY SETTINGS in the App to update your insulin settings whenever your health care provider recommends changes. If your App does not have your most recent insulin settings, information displayed on the App and Caps may not be accurate for taking your next insulin dose. This may result in taking too much or too little insulin, which could lead to severe low or high glucose.

5. To edit your Meal Insulin information you will need to do one of the following:

- *Remove* Meal Insulin information previously entered and saved by tapping the edit icon (⛔) next to the Meal Insulin section. This will completely remove current Meal Insulin information from your insulin settings.
- *Add* Meal Insulin information by tapping **+ Add Meal Insulin**. Follow the App prompts for entering Meal Insulin Information (see *Entering Rapid-Acting Insulin Settings* section in Chapter 5).
- *Change* Meal Insulin information previously entered and saved by first tapping the edit icon (⛔) next to the Meal Insulin section to completely remove the information, and then tap **+ Add Meal Insulin** and follow the App prompts for entering Meal Insulin information (see *Entering Rapid-Acting Insulin Settings* section in Chapter 5).

If you need to make edits to your Correction Insulin and/or Insulin Name go to Steps 6 and 7 that follow.

If you are done making edits to your Rapid-Acting Insulin Settings tap **Save**. Then follow the App prompts for turning the White Cap on and sending insulin settings to your White Cap (see *Sending Insulin Updates to your Caps* section that follows).

6. To edit your Correction Insulin information you will need to do one of the following:

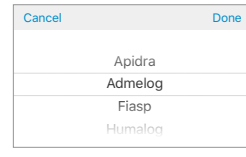
- *Remove* Correction Insulin information previously entered and saved by tapping the edit icon (⛔) next to the Correction Insulin section. This will completely remove current Correction Insulin information from your insulin settings.
- *Add* Correction Insulin information by tapping **+ Add Correction Insulin**. Follow the App prompts for entering Correction Insulin Information (see *Entering Rapid-Acting Insulin Settings* section in Chapter 5).
- *Change* Correction Insulin information previously entered and saved by first tapping the edit icon (⛔) next to the Correction Insulin section to completely remove the information, and then tap **+ Add Correction Insulin** and follow the App prompts for entering Correction Insulin information (see *Entering Rapid-Acting Insulin Settings* section in Chapter 5).

If you need to make edits to your Insulin Name go to Step 7 that follows.

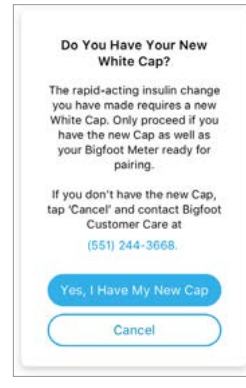
If you are done making edits to your Rapid-Acting Insulin Settings tap **Save**. Then follow the App prompts for turning the White Cap on and sending insulin settings to your White Cap (see *Sending Insulin Updates to your Caps* section that follows).

7. If you need to change your Insulin Name (the rapid-acting insulin you are using), tap your current Insulin Name to change it.

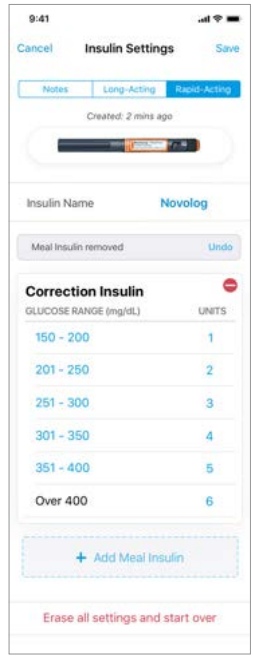
- Scroll to your new rapid-acting insulin from the list and then tap **Done**. When you are finished tap **Save**.



  - If your new rapid-acting insulin requires a new White Cap, you will be prompted to confirm you already have the Cap. Tap **Yes, I Have My New Cap** or **Cancel** to contact Customer Care for assistance. Once you have your new White Cap, you will need to follow the App prompts for Reviewing and Confirming your rapid-acting insulin settings. This also includes pairing your new White Cap with your App and Meter, starting a new Sensor, and sending your updated rapid-acting insulin settings to the White Cap.



- If your new rapid-acting insulin does not require a new White Cap, you will be prompted to review your new Insulin Name and Meal and Correction Insulin amounts.
    - Tap **Review** to display your updated insulin settings where you can change your Meal and Correction Insulin settings as needed. When you are finished, tap **Save**. Then follow the App prompts for turning the White Cap on and sending updated rapid-acting insulin settings to your White Cap (see *Sending Insulin Updates to your Caps* section that follows).



Example: Rapid-acting insulin and doses

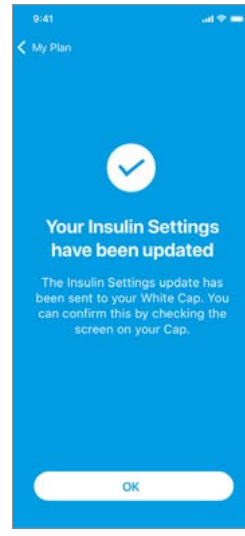
    - Tap **Cancel** to cancel the change you made to your Insulin Name and return to the Insulin Settings screen where you can start over.

Sending insulin updates to your Caps

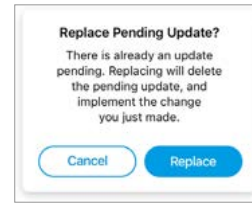
Once insulin updates are saved in your App, you will need to send them to your Caps. Make sure you have your Caps available, turned on and within communication range of your phone. Bigfoot Unity will always check to see if you might already have updates pending before sending any new updates.

⚠ **CAUTION:** Make sure your phone is within communication range (within 20 ft) of your Caps after you make any changes to your insulin settings within the App. If your Caps do not have the most current settings, you could take too much or too little insulin, which may result in severe low or high glucose.

1. Follow the instructions on the App screens for sending rapid-acting insulin updates to your White Cap and wait for the confirmation screen and check mark (✓) to appear. Follow the same steps for sending long-acting insulin updates to your Black Cap.



- If your Cap is unable to communicate with the App, if you tap **< Back** to go back to the Home screen, or if you tap **I don't have my Cap right now** (tap **OK** on next screen) insulin updates will be saved and sent at a later time. Under MY SETTINGS (and under Insulin Settings) there will be an "Update Pending" note.



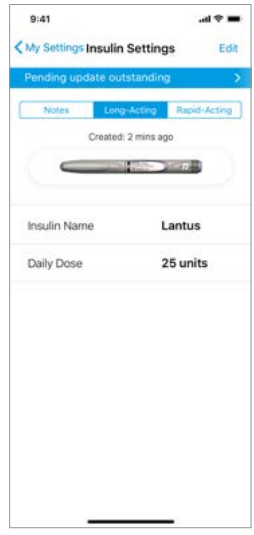
- If you try to edit and save insulin settings but have previously pending updates to your long-acting or rapid-acting insulin, Mealtime Insulin or Correction Insulin, you will first be prompted if you want to replace those pending updates with the changes just made. Tap **Replace** to replace pending updates with your new updates and continue, or tap **Cancel** to review and accept the pending update. See the *Accepting pending insulin updates* section that follows for more information on pending updates.

Accepting pending insulin updates

Whenever you have made changes to insulin information in the App but have not yet sent them to your Caps, a **Pending update outstanding** banner will appear on the My Settings/Insulin Settings screens to remind you. This happens when you have made changes to insulin information but did not have your Cap available or it was not within communication range of your App.

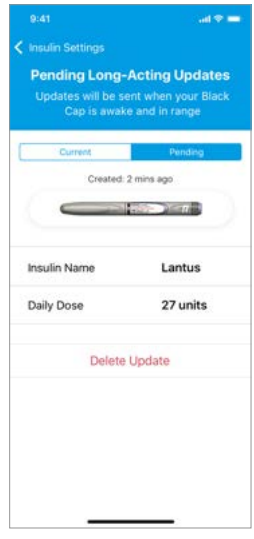
Note: If you have a Pending update, and wake up your Cap by pressing the button within communication range of the App, the update will automatically be sent to the Cap. If you would like to review the Pending update, follow these steps.

1. Tap **Long-Acting** and/or **Rapid-Acting** to see what updates are pending.
2. Tap the **Pending update outstanding** banner on any Insulin Settings screen where it appears.



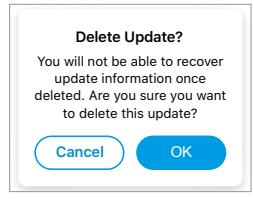
Example: Long-acting insulin and dose

3. For updates to your long-acting insulin, confirm the changes to the Insulin Name and units on the Pending Long-Acting Updates screen.
   - You can toggle between current and pending settings by tapping **Current** or **Pending**.



Example: Long-acting insulin and dose

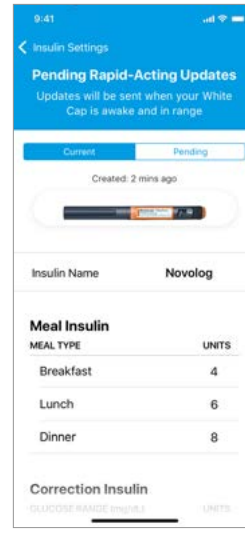
   - Tap **Delete Update** if you do not want to accept the update. You will be prompted to confirm that you want to delete the update. Your previously saved long-acting insulin information will be displayed where you have the option to use or edit the information.



4. If you accept the Pending update, pressing the button on the Black Cap to turn it on (within communication range of the App) will allow the update to be sent to the Cap.

5. Tap **< Insulin Settings** on the Pending Long-Acting Updates screen to return to the Insulin Settings screen. You may tap **Edit** to make new changes to your long-acting insulin information.

6. For updates to your rapid-acting insulin, confirm the changes to the Insulin Name, Meal Insulin and Correction Insulin on the Pending Rapid-Acting Updates screen.
   - You can toggle between current and pending settings by tapping **Current** or **Pending**.
   - You may need to swipe up (scroll) to see all your entries.
   - Tap **Delete Update** if you do not want to accept the updates. You will be prompted to confirm that you want to delete the update. Your previously saved rapid-acting insulin, Meal Insulin and Correction Insulin information will be displayed where you have the option to use or edit the information.



Example: Rapid-acting insulin and dose

7. If you accept the Pending update, pressing the button on the White Cap to turn it on (within communication range of the App) will allow the update to be sent to the Cap.

8. Tap **< Insulin Settings** on the Pending Rapid-Acting Updates screen to return to the Insulin Settings screen. You may tap **Edit** to make new changes to your rapid-acting insulin information.

Alerts

The Alerts screen lets you set your App to prompt you when certain conditions occur that require your attention.

These include:

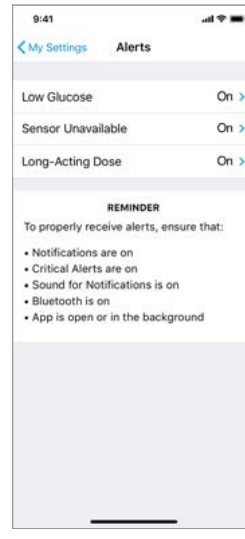
- When your glucose is low.
- When your Sensor is unable to obtain and send a glucose reading or Alert to your App.
- When Bigfoot Unity thinks you may have missed a long-acting insulin dose.

All Alerts are pre-set to “On” when you first begin using your App.

Alerts will display, sound and vibrate on your App/phone. You will be prompted to acknowledge the Alert and resolve the condition that triggered the Alert. Your phone provides a “Critical Alerts” feature that lets you receive Alerts on your lock screen even when your phone is muted or set to “Do Not Disturb”, as long as your App is open or running in the background. The “Critical Alerts” feature covers any Low Glucose Alert or any Alert regarding Sensor status. If you did not “Allow” this feature when first setting up the App, you can do so at any time under the settings feature on your phone.

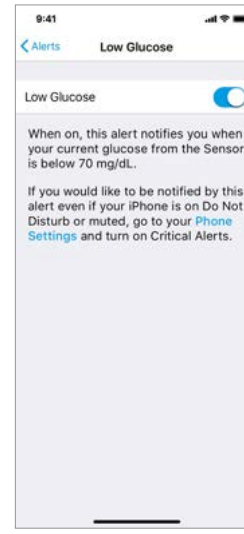
- Tap **Alerts** on the My Settings screen.

  The current status (“On” or “Off”) of your Alerts will be displayed.
- Tap **On** (**Off**) for any of the Alerts you want turned on (off).



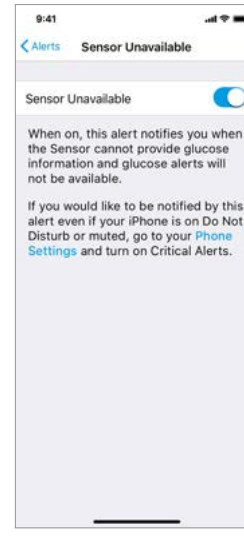
Low Glucose Alert

- The Low Glucose Alert is triggered when your Sensor glucose falls below 70 mg/dL.
  - Slide the On/Off button to “On” or to “Off” to turn this Alert on or off.
  - Tap **< Alerts** to return to the Alerts screen.



Sensor Unavailable Alert

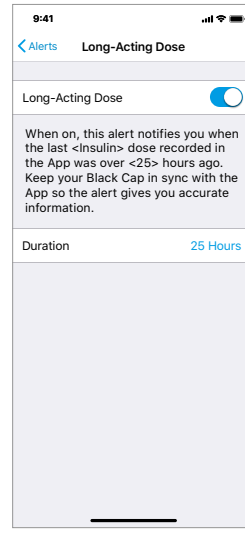
- The Sensor Unavailable Alert is triggered if there is a condition preventing the Sensor from sending an accurate glucose reading or glucose Alert to the App.
  - Slide the On/Off button to “On” or to “Off” to turn this Alert on or off.
  - Tap **< Alerts** to return to the Alerts screen.



Long-Acting Dose Alert

- The Long-Acting Dose Alert is triggered when Bigfoot Unity thinks you have missed a long-acting insulin dose from your Black Cap. The pre-set duration time for this Alert is 25 hours.

  - Slide the On/Off button to “On” or to “Off” to turn this Alert on or off.



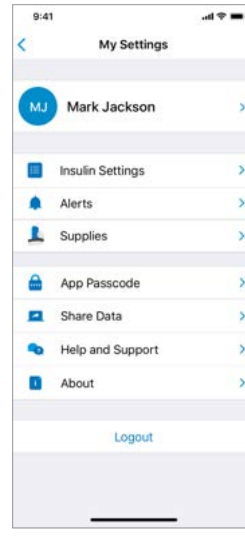
  - If you want to change the pre-set or currently set duration time for this Alert, tap the duration hours. Scroll through the duration options (24 to 48 hours) to select your duration time. Then tap **Done**.

  - Tap **< Alerts** to return to the Alerts screen.

Supplies

From the Supplies menu option you can manage your Bigfoot Unity supplies.

- Tap **Supplies** on the My Settings screen and follow the instructions to order new supplies.



App Passcode

Your Passcode keeps others from entering your App or making any changes to your App information without your permission.

- Tap **App Passcode** on the My Settings screen.
- Slide the On/Off button to “On” (pre-set is “Off”).
- Enter your personal 4-digit Passcode on the Set Passcode pop-up screen.
- Re-enter your Passcode on the Confirm Passcode pop-up screen.

  - Your Passcode is now set and required when you access the following sections in the App.

    - Alerts (for editing any settings)
    - My Devices (for all menu selections)
    - Insulin Settings (when editing any settings)
    - Passcode (when turning the Passcode feature off)

If you forget your Passcode, the App will let you try re-entering it five times before logging you out. Logging back in with your username and password will allow you to re-set the App Passcode.

- Tap **< My Settings** to return to the My Settings screen

Share Data

From the Share Data menu option you can access a report of your past data.

- Tap **Share Data** on the My Settings screen and follow the instructions to download and share your glucose and insulin information.

Help and Support

Help and Support provides an easy way to access helpful information when using Bigfoot Unity.

- Tap **Help and Support** on the My Settings screen and follow the instructions.

About

The About screen displays details about the Bigfoot Unity devices (App software and firmware versions, serial numbers, etc.), and terms of use.

- Tap **About** on the My Settings screen to display this information.
- Tap **< My Settings** to return to the My Settings screen.

9 Care, Maintenance and Disposal of Bigfoot Unity

9.1 Living with your Bigfoot Unity™ Diabetes Management System

Activity	What to do
Bathing, Showering, and Swimming	Your Caps should not be used or carried when bathing, showering or swimming. Your Sensor is water-resistant and can be worn while bathing, showering, or swimming. **Note:** Do NOT take your Sensor deeper than three feet (one meter) or immerse it longer than 30 minutes in water.
Sleeping	Your Sensor should not interfere with your sleep. It is recommended that you scan your Sensor before going to sleep and when you wake up because your Sensor holds only 8 hours of data at a time. For example, if you sleep for 9 hours without scanning your Sensor, 1 hour of data will not be collected and a gap will Appear on your App glucose graph. Keep your phone within communication range (20 ft) to receive alerts and close enough to hear any audible alerts.
Traveling by Air	When you are traveling, always carry extra diabetes supplies with you. Do NOT put your diabetes supplies with your checked baggage, as they may be lost or not maintained at the required temperature, especially your insulin. Consult your health care provider before traveling. When traveling by air, always check with TSA and other international airport security organizations for current rules and regulations regarding travel through security. You may find it helpful to carry a letter from your health care provider that states you have diabetes and are wearing/carrying a medical device, and any medications you take.

Activity	What to do
Traveling by Air (continued)	When traveling across time zones or between Standard and Daylight Saving Time, allow your phone to update the date and time automatically. If you update the date and time manually, you will not be able to use Bigfoot Unity. You can safely use Bigfoot Unity at all times while on an aircraft. • The Caps are classed as Medical-Portable Electronic Devices (M-PED) that meet all required M-PED emission standards for safe use onboard an aircraft: RTCA/DO-160, Section 21, Category M for radiated emission. • Some airport full-body scanners include x-ray or millimeter radio-wave, to which you cannot expose your Bigfoot Unity. The effect of these scanners has not been evaluated and the exposure may damage Bigfoot Unity or cause inaccurate results. To avoid removing Bigfoot Unity (i.e., the Sensor), you may request a pat-down screening. If you do choose to go through a full-body scanner, you must remove your Sensor. • Bigfoot Unity can be exposed to common electrostatic (ESD) and electromagnetic interference (EMI), including airport metal detectors. You can keep Bigfoot Unity on while going through these.

9.2 Cleaning

Clean your Bigfoot Unity Cap as needed or if it is visibly dirty. Cleaning helps remove dirt or other residue from the surfaces of your Cap. Cleaning does not kill bacteria or viruses. If you get insulin on the Cap clean it off right away. Do not submerge, soak or wash the Cap. Make sure the USB port is dry before charging. Only use water, or isopropyl alcohol wipes for cleaning. The Caps have a mean use life of 2 years and have been validated for 156 cleaning cycles.

Cleaning the Outside of the Cap

1. Using only alcohol or water, wipe down the outside of the Cap with a Bigfoot alcohol prep pad or a clean, damp paper towel.
2. Wipe the Cap dry before using the Cap.

Cleaning the Inside of the Cap

1. Remove the Cap from the insulin pen.
2. Wipe down the inside of the Cap that comes into contact with the insulin pen. Use a Bigfoot alcohol prep pad or a clean, damp paper towel, along with a six inch long cotton swab to clean the inner cavity of the Cap.
3. Wipe the Cap dry and make sure there is no residue remaining before using the Cap.

⚠ **WARNING:** Do NOT place sharp objects inside the inner tubes of the Caps. Sharp objects can damage the inner lining of the Caps.

Consider cleaning the Cap each time you change to a new insulin pen, or every two weeks.

IMPORTANT: If you require assistance or if you notice any signs of deterioration on the Caps (such as clouding or fading on the display of the Cap, corroding or eroding of the plastic housing, or cracking of plastic housing or display) or if the Caps do not turn on, discontinue use of the Caps and contact Bigfoot Customer Care at (551) 244-3668.

Cleaning and Disinfecting your Meter

See the instructions that came with your Meter for cleaning and disinfecting. Additional information about the risks for transmitting bloodborne pathogens to persons undergoing fingerstick procedures for blood sampling can be found in the instructions that came with your Meter.

9.3 Pen Needles

Refer to the instructions on your Bigfoot Unity Needles package for steps on inserting, storing and removing your pen needles.

9.4 Insulin Pens

Refer to the manufacturer's instructions that came with your insulin pens for steps on using, storing and discarding your pens.

9.5 Disposal

If you receive new Caps, Bigfoot Biomedical will request that you return your old Caps. Instructions, packaging, and postage will be provided when you receive your new Caps. Other parts of the Bigfoot Unity System should be disposed of in accordance with all applicable local regulations related to the disposal of electronic equipment, batteries, sharps, and materials potentially exposed to body fluids. Contact Bigfoot Customer Care at (551) 244-3668 for further information on the appropriate disposal of Bigfoot Unity components.

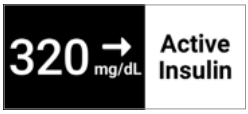
10 Troubleshooting

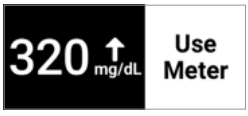
This chapter lists problems you may have with the Bigfoot Unity™ Diabetes Management System, the possible cause(s), and recommended actions.

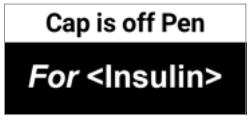
IMPORTANT: Contact Bigfoot Biomedical through the Customer Care page in the App or the company website (support.bigfootbiomedical.com). You can also reach Bigfoot Customer Care at (551) 244-3668.

10.1 Caps

Usage Notifications

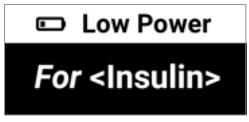
Problem	What it may mean
 *"Active Insulin" is displayed on my White Cap.*	Your Cap shows "Active Insulin" instead of Correction units when you just scanned your Sensor. This message indicates that you have dosed rapid-acting insulin within the past 3 hours and it is still active in your body.
What to do	
Follow your health care provider's recommendations for managing a high glucose. Taking another insulin dose on top of the previous dose that is still working may lead to hypoglycemia.	

Problem	What it may mean
 *"Use Meter" is displayed on my White Cap.*	"Use Meter" appears when it is recommended to check your blood glucose with your Meter and use that measurement to make treatment decisions. This message appears when it's still within the first 12 hours of wearing a Sensor.
What to do	
Take a fingerstick test with your Meter and use that result to make treatment decisions.	

Problem	What it may mean
	Your Cap is off your rapid-acting or long-acting insulin pen.

What to do

Unless you are taking an insulin injection or replacing your insulin pen, you should keep your Caps on the pens at all times. When the Cap is left off the pen for more than 4 seconds, the timer will not re-set to 0 and start tracking your latest time since last dose until you re-insert your pen into the Cap.

Problem	What it may mean
	Your Cap has less than 25% battery power remaining.

What to do

Charge your Cap as soon as possible. Caps should be charged while still attached to your insulin pens.

Problem	What it may mean
	Your Cap has no battery power remaining. You cannot continue to use your Cap until you charge it.

What to do

Charge your Cap immediately.

Problem	What it may mean
	There is a problem with your Cap. You will not be able to use your Cap until the problem is resolved.

What to do

Contact Bigfoot Customer Care at (551) 244-3668 as soon as possible for assistance.

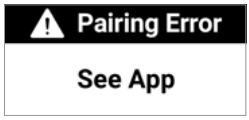
Cap Display Issues

Problem	What it may mean
Cap/Cap screen is unresponsive	There is a problem with your Cap. You will not be able to use your Cap until the problem is resolved.
What to do	
Press and hold the Cap button for about 20 seconds. If this does not resolve the problem, contact Bigfoot Customer Care at (551) 244-3668.	

Problem	What it may mean
Battery won't charge	Caps can no longer be used.
What to do	
Check if there is debris in the charging dock on the Cap that may be blocking normal charging functions and remove it.	

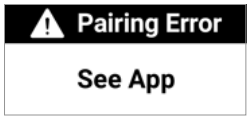
Problem	What it may mean
The Meal + Correction screen did not appear after pressing the button on my White Cap when I was deciding how much rapid-acting insulin to dose.	The Meal + Correction screen will not appear when 1) you want to make a treatment decision using a Sensor glucose value within the first 12 hours of wearing a Sensor; 2) the White Cap displays "Active Insulin" indicating that you are still within 3 hours of your last rapid-acting insulin dose logged using the White Cap; 3) a valid glucose reading from the Sensor or Meter was not received by the White Cap.
What to do	
The Meal + Correction screen will display if you are beyond the initial 12 hour Sensor wear period and it's been at least 3 hours since your last rapid-acting insulin dose was recorded by the White Cap. If you want to use your current glucose level as part of the displayed Meal + Correction unit amounts, you must have a valid Sensor glucose reading or a Meter glucose value from the White Cap within the last 10 minutes.	

Pairing and Communication Problems

Problem	What it may mean
	Your White or Black Cap is unable to pair with the App.

What to do

Your App will also display a Pairing Error message. Check to see that the *Bluetooth*® setting is enabled on your phone and WiFi is turned on and follow the instructions in your App for pairing your App with your White or Black Caps. Make sure the devices are within communication range (within 20 ft), and the Caps wake up with a button press.

Problem	What it may mean
	Your White Cap is unable to pair with your Meter.

What to do

Your App will also display a Pairing Error message. Follow the instructions in your App for pairing your Meter with your White Cap. Make sure the devices are both turned on, are within communication range, and the *Bluetooth* icon appears on the Meter display. Also, see the instructions that came with your Meter for troubleshooting pairing problems.

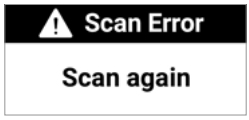
Problem	What it may mean
 *Symbol appears and remains fixed on Cap*	The Cap has information to send to the App, but is not able to communicate with the Cap.

What to do

Make sure the App and Caps are within communication range (within 20 ft) of each other. Make sure that *Bluetooth* settings are enabled on your phone.

10.2 Sensor

Scanning and Communication Problems

Problem	What it may mean
	Your White Cap is unable to scan your Sensor.

What to do

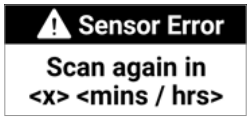
Try scanning again. Review instructions for proper scanning technique within this User Guide.

Note: You may need to move away from potential sources of electromagnetic interference and try scanning again.

Problem	What it may mean
	The Sensor is still in its start-up period (within 60 minutes from first application).

What to do

Wait the number of minutes indicated to scan again, or check your blood glucose with your Meter using a drop of blood from your fingertip.

Problem	What it may mean
	Your Sensor is unable to provide a glucose reading.

What to do

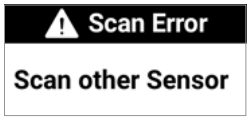
Wait the number of minutes indicated to scan again or check your blood glucose with your Meter.

Note: If you receive this error during your first 12 hours of wearing a Sensor, it may mean that your body is still adjusting to the Sensor. Use your Meter to check your glucose while you wait. You do not need to remove your Sensor.

Problem	What it may mean
	There is a problem with your Sensor.

What to do

Replace your Sensor. Follow the instructions in your App for starting a new Sensor.

Problem	What it may mean
	Your Sensor was already started by another App.

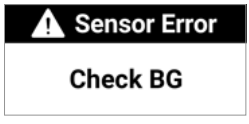
What to do

Your Sensor can only be used with the App that started it. Scan the Sensor with the White Cap that was originally used with the App to start this Sensor. Or, apply and start a new Sensor.

Problem	What it may mean
	Your Sensor wear period (up to 14 days) has ended.

What to do

Replace your Sensor. Follow the instructions in your App for starting a new Sensor.

Problem	What it may mean
	There is a problem with your Sensor.

What to do

Check your blood glucose with your Meter using a drop of blood from your fingertip.

Problem	What it may mean
	Your Sensor is too hot (above its normal operating range) to provide a glucose reading.

What to do

Try moving to an area with an ambient temperature of 50°F to 113°F (10°C to 45°C). Wait 10 minutes for your Sensor to reach the new temperature and begin sending glucose readings again.

Problem	What it may mean
	Your Sensor is too cold (below its normal operating range) to provide a glucose reading.

What to do

Try moving to an area with an ambient temperature of 50°F to 113°F (10°C to 45°C). Wait 10 minutes for your Sensor to reach the new temperature and begin sending glucose readings again.

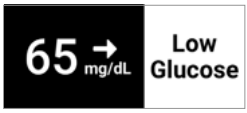
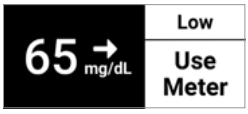
Problem	What it may mean
Glucose data from my Sensor did not appear on my App screen after I scanned my Sensor with my phone.	Your phone should only be used to scan your Sensor when starting a new Sensor and not beyond start-up. Do NOT scan your Sensor with your phone to collect or display current glucose data.

What to do

Always use your White Cap to scan your Sensor to collect and display glucose data on your History screen.

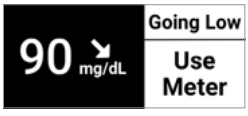
Low and High Sensor Glucose Messages

On your White Cap for rapid-acting insulin, special messages will appear along with your Sensor reading/Trend Arrow when your Sensor glucose is low or high. A "Use Meter" message will also appear if it's still within the first 12 hours after wearing the Sensor.

Problem	What it may mean
 *or*  Example: "Low Glucose" Sensor glucose reading	Your scanned glucose result is low (< 70 mg/dL). "Use Meter" appears when it is important for you to use your meter for a treatment decision. This message appears during the first 12 hours of wearing a Sensor.

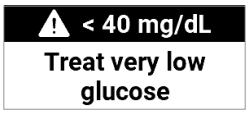
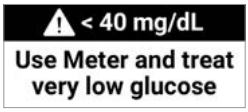
What to do

Treat low glucose according to your health care provider's recommendations. Use your Meter to check your glucose if it's still within 12 hours of wearing your Sensor.

Problem	What it may mean
 *or*  Example: "Going Low" Sensor glucose reading	Your scanned glucose result is trending low (expected to go below < 70 mg/dL within the next 15 minutes). "Use Meter" appears when it is important for you to use your meter for a treatment decision. This message appears during the first 12 hours of wearing a Sensor.

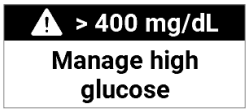
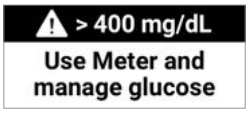
What to do

Monitor your glucose closely, and scan again in 15 minutes. Treat low glucose according to your health care provider's recommendations. Use your Meter to check your glucose if it's still within 12 hours of wearing your Sensor.

Problem	What it may mean
 *or* 	Your scanned glucose result is very low (< 40 mg/dL).

What to do

Treat very low glucose according to your health care provider's recommendations. Use your Meter to check and obtain a glucose value if it's still within 12 hours of wearing your Sensor.

Problem	What it may mean
 *or* 	Your scanned glucose result is very high (> 400 mg/dL).

What to do

Treat very high glucose according to your health care provider's recommendations. Use your Meter to check and obtain a glucose value if it's still within 12 hours of wearing your Sensor.

Sensor Wear Problems

Problem	What it may mean
Your Sensor is not sticking to your skin.	The site is not free of dirt, oil, hair, or sweat.
What to do	
Remove Sensor and shave and/or clean site with soap and water. Apply new Sensor following instructions in your App.	

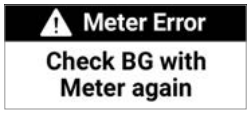
Problem	What it may mean
Skin irritation at your Sensor application site.	Seams or other constrictive clothing or accessories causing friction at the site.
What to do	
Ensure that nothing rubs on the site.	

Problem	What it may mean
Redness, swelling or itchiness at your Sensor application site.	You may be sensitive to the adhesive material.
What to do	
If the irritation is where the adhesive touches skin, contact your health care provider to identify the best solution.	

10.3 Meter

These Meter notifications apply to how your Meter works with Bigfoot Unity, and that might appear on your White Cap display. See the instructions that came with your Meter for a complete list of error messages that might appear on your Meter display.

Problem	What it may mean
	There is a problem with your Meter and you will not be able to have a blood glucose result sent to your White Cap.
What to do	
Contact Bigfoot Customer Care at (551) 244-3668 to request a replacement Bigfoot Meter. Only a Meter supplied by Bigfoot should be used with Bigfoot Unity. Refer to your backup plan for obtaining a blood glucose result while you await a new Meter.	

Problem	What it may mean
	Your Meter is unable to provide an accurate result.
What to do	
Re-test with a new test strip. If the problem continues, you may need to replace your Meter.	

Problem	What it may mean
⚠ < 20 mg/dL Treat very low glucose and monitor	Your Meter glucose result is below 20 mg/dL. This low result may indicate hypoglycemia (low blood glucose). It also indicates that your result is below the Meter measuring range.

What to do

If you feel symptoms such as weakness, sweating, nervousness, headache or confusion, follow your health care provider's recommendations to treat a low glucose. If you get a low blood glucose result but have no symptoms of low blood glucose, then re-check with a new test strip. If you still get a low blood glucose result, follow the treatment plan recommended by your health care provider team or contact your health care provider immediately.

Problem	What it may mean
⚠ > 600 mg/dL Manage high glucose and monitor	Your Meter glucose result is above 600 mg/dL This high result may indicate hyperglycemia (high blood glucose). It also indicates that your result is above the Meter measuring range.

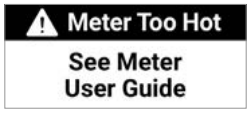
What to do

If you feel symptoms such as fatigue, thirst, excessive urination, or blurry vision, follow your health care provider's recommendations. If you get a high blood glucose result but have no symptoms of high blood glucose, then re-check with a new test strip. If you still get a high blood glucose result, follow your health care provider's recommendations. Checking ketones may be advisable.

Problem	What it may mean
	Your Meter is below its operating temperature range of 50°F to 104°F (10°C to 40°C).

What to do

See the instructions that came with your Meter. Try moving to an area with an ambient temperature of 50°F to 104°F (10°C to 40°C). Wait for your Meter and test strips to reach the new temperature (usually 10-20 minutes) before using your Meter or checking your blood glucose.

Problem	What it may mean
	Your Meter is above its operating temperature range of 50°F to 104°F (10°C to 40°C).

What to do

See the instructions that came with your Meter. Try moving to an area with an ambient temperature of 50°F to 104°F (10°C to 40°C). Wait for your Meter and test strips to reach the new temperature (usually 10-20 minutes) before using your Meter or checking your blood glucose.

Problem	What it may mean
My Meter glucose result did not appear on my White Cap.	You checked your blood glucose with your Meter but the result is not being displayed on your White Cap.

What to do

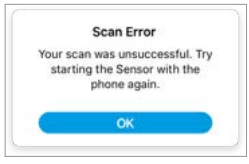
Only blood glucose tests taken within the last 10 minutes will be displayed on the Cap. If it has been longer than 10 minutes, take another blood glucose reading. Make sure the Meter and Cap are turned on and within range of each other. If Meter results still do not appear on the White Cap, use the App to re-pair the Meter to the Cap. Within the App go to “MY DEVICES”, select “Meter” and tap **Start New Meter** as described in this User Guide.

10.4 App

Problem	What it may mean
	Internet connection is not currently available. The App will not be able to respond to some of your actions.

What to do

Wait a few seconds and tap **Try Again** to see if an internet connection is re-established. Make sure your phone is connected to a wireless network, your phone is not in Airplane mode, and wireless communication is turned on. If you continue to have connection problems, call Bigfoot Customer Care at (551) 244-3668.

Problem	What it may mean
	Scan was unsuccessful.

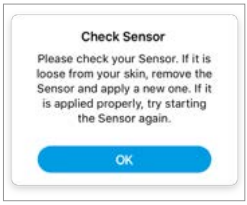
What to do

Tap **OK**. Try starting the Sensor again with your Phone. If the problem persists, remove the Sensor and apply a new one.

Problem	What it may mean
	There is a problem with your Sensor.

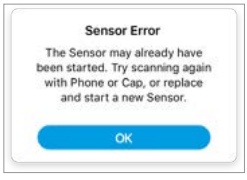
What to do

Tap **OK**. Apply and start a new Sensor.

Problem	What it may mean
	Your Sensor may not be applied properly.

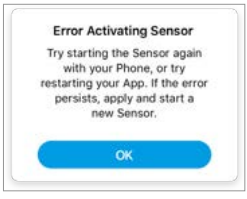
What to do

Tap **OK**. Check if your Sensor may be loose. If it is, remove the Sensor and apply a new one. If it is applied properly, try starting the Sensor again with your Phone. If the problem persists, remove the Sensor and apply a new one.

Problem	What it may mean
	You may have already started the Sensor.

What to do

Try scanning the Senor again. If the problem persists, remove the Sensor and start a new one.

Problem	What it may mean
	There is a problem activating your Sensor.

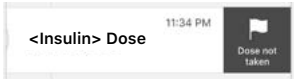
What to do

Tap **OK**. Try starting the Sensor again with your Phone. If the problem persists, remove the Sensor and apply a new one.

Problem	What it may mean
 *MY HISTORY records in your App indicate you injected an insulin dose but you did not*	Your insulin pen may have accidentally separated from your Cap and you may (or may not) have been aware of it at the time. In either case, your App and Cap would record that you injected an insulin dose (even if you did not), and that record would appear in MY HISTORY.

What to do

Bigfoot Unity lets you flag (mark) a rapid-acting or a long-acting insulin dose as "not taken" in the MY HISTORY List View section to remind you that the recorded dose was not actually injected. Flagging (marking) the dose as "not taken" in MY HISTORY is for your information only. It will not affect the "time since last dose" displayed on your Cap. After you flag (mark) an insulin dose as "not taken", the dosing record will be grayed out when reviewing MY HISTORY.



Make sure you note this information when it's time to decide how much insulin to dose the next time you inject insulin from your pens. Not knowing how much or when you injected insulin may result in taking too much or too little insulin, which can lead to severe low or high glucose.

Problem	What it may mean
My Cap may have been damaged when I dropped it with my insulin pen inserted. MY HISTORY records indicate I injected an insulin dose when I did not.	Your insulin pen may have dislodged from the Cap and recorded a dose. The Cap may be damaged.

What to do

Check that your Cap is not damaged, and that the insulin pen can still be inserted into the Cap. When you insert the pen you should hear or feel the Cap click onto the pen. Make sure that "Cap is off Pen" is not displayed on the Cap after inserting. If your Cap incorrectly recorded a dose that you did not take, follow the same steps in the previous troubleshooting Problem for how to remove that dose from MY HISTORY records.

Problem	What it may mean
You are not receiving Low Glucose, Sensor Unavailable or Missed Long-Acting Dose Alerts.	Your Bigfoot Unity is not set up correctly to receive Notifications and Alerts, or there is a communication problem between some of the devices.

What to do

Check that 1) your phone's *Bluetooth* setting is "On"; 2) you have allowed Notifications and Critical Alerts to come through to your Phone; 3) Phone and/or watch sounds/vibrations for Notifications and Alerts are "On"; 4) you didn't already dismiss the Notification/Alert; 5) Sensor wear period has ended or there is a problem with the Sensor; 6) your phone is sufficiently charged and the Sensor and App/phone are in communication range.

Problem	What it may mean
You are not receiving high glucose Alerts on your App/phone.	Bigfoot Unity is designed to alert you only when your glucose is too low. It will not alert you to high glucose events.

What to do

Follow your health care provider's recommendations for managing high glucose. Bigfoot Unity will not alert you when your glucose is high.

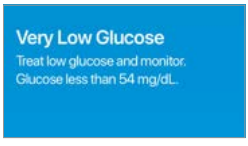
Appendix A: Receiving and Responding to Notifications/Alerts on your App/Phone

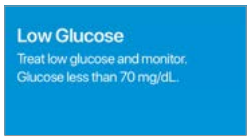
Bigfoot Unity is designed to make you aware of situations regarding your glucose readings and Sensor, including those that require your immediate attention. You can change how you receive certain Notifications and Alerts by going to MY SETTINGS on the Home screen and Settings on your phone. The tables that follow let you know when to expect certain Notifications and Alerts and what to do. Some Notifications are considered critical to your glucose management and will be followed by an Alert.

A.1 Home Screen Display Information

Your Home screen provides updated information regarding what range your current Sensor reading falls within. It also lets you know when your Sensor is not available to obtain or send glucose readings or Alerts to your App/phone. The target range used to trigger this information is pre-set by Bigfoot Unity and cannot be changed.

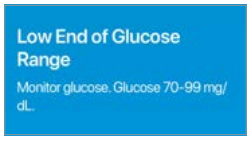
Glucose and Sensor Status

Notification	What it may mean
	Your Sensor glucose is very low (below < 54 mg/dL).
What to do	
An Alert will follow this Notification. Follow the steps for what to do in the *Alerts* section that follows.	

Notification	What it may mean
	Your Sensor glucose is low (between 55 mg/dL and 69 mg/dL).

What to do

An Alert will follow this Notification. Follow the steps for what to do in the *Alerts* section that follows.

Notification	What it may mean
	Your Sensor glucose is at the low end of the pre-set target range (between 70 mg/dL and 99 mg/dL).

What to do

Monitor your glucose with your Sensor or Meter to make sure it is not going low. Follow your health care provider's recommendations for managing your glucose in this range.

Notification	What it may mean
	Your Sensor glucose is within the Bigfoot Unity pre-set target range (between 100 mg/dL and 180 mg/dL).

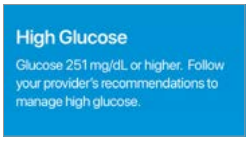
What to do

Monitor your glucose with your Sensor or Meter. Follow your health care provider's recommendations for managing your glucose in this range.

Notification	What it may mean
	Your Sensor glucose is at the high end of the Bigfoot Unity pre-set target range (between 181 mg/dL and 250 mg/dL).

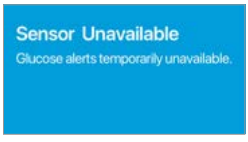
What to do

Monitor your glucose with your Sensor or Meter. Follow your health care provider's recommendations for managing your glucose in this range.

Notification	What it may mean
	Your Sensor glucose is high (above 250 mg/dL).

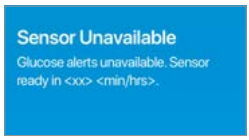
What to do

Monitor your glucose with your Sensor or Meter. Follow your health care provider's recommendations for managing high glucose.

Notification	What it may mean
	Your Sensor is temporarily unavailable to send glucose readings or generate alerts to your App/phone.

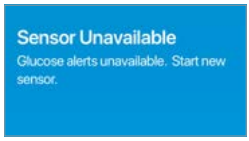
What to do

The Sensor problem should resolve itself and begin sending glucose readings and alerts within a few minutes. If the problem continues, you may need to replace your Sensor.

Notification	What it may mean
	Your Sensor is not yet ready to send glucose readings and generate alerts to your App/phone, but should be ready in the indicated period of time.

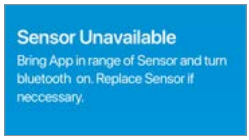
What to do

Wait the indicated period of time for the Sensor to start sending glucose readings and alerts to your App/phone.

Notification	What it may mean
	Your Sensor is not able to send glucose readings or generate alerts to your App/phone.

What to do

There is a problem with your Sensor that will not resolve itself. You will need to replace your Sensor.

Notification	What it may mean
	Your phone/App is not communicating with your Sensor.

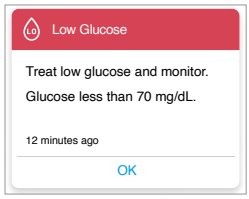
What to do

Make sure your phone/App is within communication range (20 feet) of your Sensor and *Bluetooth*® connection is “On”. Replace the Sensor if necessary.

A.2 Alerts

All Alerts may be turned on or off as needed. When turned on, alerts will initially vibrate and will sound later if you do not respond.

Glucose Alerts

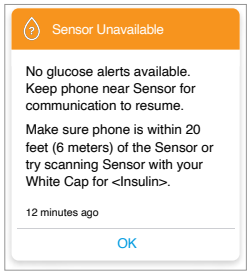
Alert	What it may mean
	Your Sensor glucose is low (< 70 mg/dL).

What to do

Tap **OK** to acknowledge Alert. Scan your Sensor or measure your blood glucose, and treat low glucose according to your health care provider's recommendations. Alert will repeat in 45 minutes if your Sensor glucose is still low.

If you do not tap **OK**, Alert will repeat every five minutes.

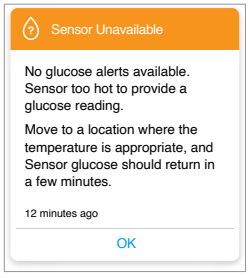
Sensor Unavailable Alerts

Alert	What it may mean
	The Sensor has not communicated with your App/phone in the last 20 minutes. No glucose alerts can be sent without communication.

What to do

Tap **OK** to acknowledge Alert. Make sure your phone is within communication range (20 ft) of your Sensor. Initial Alert will not repeat but new Alert will be triggered up until Sensor is able to communicate with App/phone. At that time, glucose alerts will resume.

If you do not tap **OK**, Alert will repeat every five minutes.

Alert	What it may mean
	The Sensor is too hot to communicate with your App/phone. No glucose alerts can be sent without communication.

What to do

Tap **OK** to acknowledge Alert. Try moving to an area where the temperature is within the allowable range for your Sensor. Initial Alert will not repeat but new Alert will be triggered up until Sensor is able to communicate with App/phone. At that time, glucose alerts will resume.

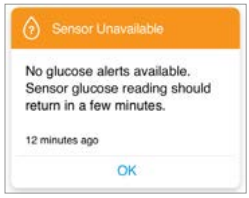
If you do not tap **OK**, Alert will repeat every five minutes.

Alert	What it may mean
	The Sensor is too cold to communicate with your App/phone. No glucose alerts can be sent without communication.

What to do

Tap **OK** to acknowledge Alert. Try moving to an area where the temperature is within the allowable range for your Sensor. Initial Alert will not repeat but new Alert will be triggered up until Sensor is able to communicate with App/phone. At that time, glucose alerts will resume.

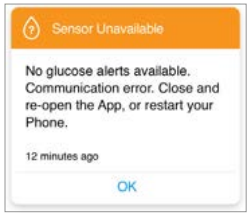
If you do not tap **OK**, Alert will repeat every five minutes.

Alert	What it may mean
	The Sensor is temporarily unable to communicate with your App/phone. No glucose alerts can be sent without communication.

What to do

Tap **OK** to acknowledge Alert. The communication problem should resolve itself in a few minutes. Initial Alert will not repeat but new Alert will be triggered up until Sensor is able to communicate with App/phone. At that time, glucose alerts will resume.

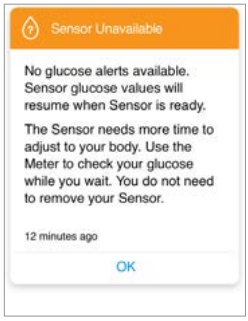
If you do not tap **OK**, Alert will repeat every five minutes.

Alert	What it may mean
	The Sensor is temporarily unable to communicate with your App/phone. No glucose alerts can be sent without communication.

What to do

Tap **OK** to acknowledge Alert. Try closing and re-opening the App, or restarting your phone. Initial Alert will not repeat but new Alert will be triggered up until Sensor is able to communicate with App. At the time, Glucose Alerts will resume.

If you do not tap **OK**, Alert will repeat every five minutes.

Alert	What it may mean
	The Sensor needs more time to adjust to your body before it can begin sending glucose readings to your App/phone. No glucose alerts can be sent until the Sensor begins sending glucose readings to your App/phone.

What to do

Tap **OK** to acknowledge Alert. Wait a few minutes to see if the Sensor starts communicating with the App/phone. Initial Alert will not repeat but new Alert will be triggered up until Sensor is able to communicate with and send glucose readings to your App/phone. At that time, glucose alerts will resume.

If you do not tap **OK**, Alert will repeat every five minutes.

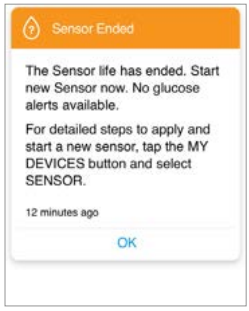
Permanent Sensor Loss Alerts

Alert	What it may mean
	There is a problem with your Sensor and it needs to be replaced. No glucose alerts can be sent until the new Sensor begins sending glucose readings to your App/phone.

What to do

Tap **OK** to acknowledge Alert. Initial Alert will not repeat but new Alert will be triggered up until you replace the Sensor. You will need to apply and start a new Sensor and wait for Sensor to begin sending glucose readings to your App/phone. At that time, glucose alerts will resume.

If you do not tap **OK**, Alert will repeat every five minutes.

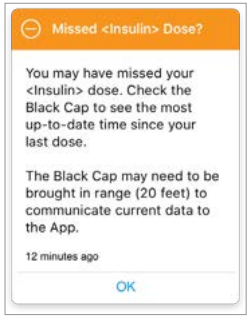
Alert	What it may mean
	The Sensor's (up to) 14-day wear period has ended. No glucose alerts can be sent until the new Sensor begins sending glucose readings to your App/phone.

What to do

Tap **OK** to acknowledge Alert. Initial Alert will not repeat but new Alert will be triggered up until you replace the Sensor. You will need to apply and start a new Sensor and wait for Sensor to begin sending glucose readings to your App/phone. At that time, glucose alerts will resume.

If you do not tap **OK**, Alert will repeat every five minutes.

Long-Acting Dose Alert

Alert	What it may mean
	Bigfoot Unity thinks you may have missed your long-acting insulin dose since it did not record a dose with the Cap in the time period you set for keeping track of long-acting insulin dosing.

What to do

Check the Time Since Last Dose on your Black Cap to verify if a long-acting dose is needed. You may have received this Alert in error if your App and Caps have not communicated recently. Tap **OK** to acknowledge Alert. Treat a missed dose according to your health care provider's recommendations.

If you do not tap **OK**, Alert will repeat every 15 minutes.

Appendix B: Settings for Bigfoot Unity App

Information to Enter in the App

⚠ **CAUTION:** Bigfoot Unity does not support insulin doses in half-unit increments.

Long-Acting Insulin

Name of long-acting insulin _____

Long-acting once a day dose _____ *units*

Note: *Certain insulin pens deliver doses in 2-unit increments.*

Rapid-Acting Insulin

Name of rapid-acting insulin _____

Rapid-acting insulin for meals *optional*

Label my "Meal Insulin"

Choose one *approach from below*

☐ **Option A**

Small | Medium | Large	*units of rapid-acting*

Meal		
-- u Small	-- u Medium	-- u Large

Small _____

Medium _____

Large _____

Enter the typical rapid-acting insulin dose for small, medium, and large amount of carbs in a meal.

☐ **Option B**

Breakfast | Lunch | Dinner	*units of rapid-acting*

Meal		
-- u Breakfast	-- u Lunch	-- u Dinner

Breakfast _____

Lunch _____

Dinner _____

Enter the typical rapid-acting insulin dose for each meal.

☐ **Option C**

Carb Amounts	*grams*	*units of rapid-acting*

Meal		
-- u -- grams	-- u -- grams	-- u -- grams

_____ _____

_____ _____

_____ _____

Enter 3 specific carb amounts (in grams) and then enter the amount of rapid-acting insulin to take for each specific carb amount.

Rapid-acting insulin for meals *optional*

Correction Insulin *(to bring down a high glucose)* *optional*

Choose one approach from below

Important: Bigfoot Unity will not display a correction dose if you have taken rapid-acting insulin in the past 3 hours. Speak to your health care provider about how to avoid "stacking" doses of rapid-acting insulin to prevent low glucose in the hours after the injection.

☐ **Option A**

Correction Dose Table

Glucose Range *(for high glucose in this range)*	Rapid-Acting Insulin *(take this amount of insulin)*
mg/dL	*units*
mg/dL	*units*
mg/dL	*units*
mg/dL	*units*
mg/dL	*units*
mg/dL	*units*

The numbers in this table may be adjusted, and more rows may be added in app. Number ranges should continue with the next number and not overlap (i.e. 100-200, 201-300).

☐ **Option B**

Glucose Target & Correction Factor

- Take rapid-acting insulin to lower glucose to a target of _____ mg/dL.
- 1 unit of rapid-acting insulin lowers glucose by _____ mg/dL.

These values will automatically populate a table based on the information you entered. The table may be adjusted using the app if needed.

Notes

(Write any diabetes care notes to enter into the app)

Appendix C: Technical Information

C.1 Labeling Symbols

Symbols	What it means
	Consult instructions for use
	Temperature
	Manufacturer
	Batch code
	Type BF applied part
	Use-by date
	Catalog number
	Serial number
	Keep dry
	Non-ionizing radiation
CODE	Sensor code

	Do NOT re-use
	MRI unsafe
	FCC Declaration of Conformity mark
	Not made with natural rubber latex
	Warnings and Cautions
	Sterilized using radiation
	Humidity limitation
	Do NOT use if package is damaged
R_x Only	CAUTION: Federal law restricts this device to sale by or on the order of a physician.
	This product contains electronic equipment, batteries, sharps and materials that may contact bodily fluids during use. Dispose of product in accordance with all applicable local regulations.

C.2 Sensor Specifications

Sensor glucose assay method	Amperometric electrochemical sensor
Sensor glucose reading range	40 to 400 mg/dL
Sensor size	0.19 in height and 1.38 in diameter (5 mm in height and 35 mm diameter)
Sensor weight	0.18 oz (5 grams)
Sensor power source	One silver oxide battery
Sensor data	Up to 14 days
Sensor memory	8 hours (glucose readings stored every 15 minutes)
Sensor transmission range	20 feet (six meters) unobstructed
Operating temperature	50 °F to 113 °F (10.0 °C to 45.0 °C)
Sensor Applicator and Sensor Pack storage temperature	36 °F to 82 °F (2.2 °C to 27.8 °C)
Operating and storage relative humidity	10-90%, non-condensing
Sensor water resistance	IP27: Can withstand immersion into three ft (one meter) of water for up to 30 minutes. Protected against insertion of objects > 12 mm diameter
Operating and storage altitude	-1,250 ft (-381 meters) to 10,000 ft (3,048 meters)
Radio Frequency	2.402 to 2.480 GHz BLE; GFSK; 0dBm EIRP

C.3 Cap Specifications

Dimensions	108 mm X 24 mm X 28 mm
Weight	Less than 1.4 oz (40 g) without insulin pen
Power supply	Rechargeable lithium ion battery - not replaceable
Operating voltage	3.7 V DC
Charging voltage	5 V DC
Lifetime	Mean use life of 2 years
Moisture protection	IP22 protection against large objects and dripping water
Protection against electrical shock	Type BF applied part
Biocompatibility	The primary skin-contacting material used is Makroblend M525, a polycarbonate blend developed specifically for wearable devices. Makroblend has a wide history of use in wearable medical devices and meets the biocompatibility testing requirements of ISO 10993-5 (Cytotoxicity) and ISO 10993-10 (Irritation and Sensitization).
Operating Environment	
Temperature range	41 °F to 104 °F (5 °C to 40 °C)
Relative humidity range	15% to 90%, non-condensing
Atmospheric pressure range	700 hPa to 1,060 hPa
Altitude range	-1,250 ft to +10,000 ft (-381 m to + 3,048 m)
USB Charging Cable and Adapter Specifications	
Cable Type	USB 2.0 cable with USB-C connector; Part Number BFMHP-BF-0002 (Bigfoot Biomedical PN-300008)
Adapter Type	USB 2.0; Model: A18A-050100U-US2 (Bigfoot Biomedical PN-300007)
Supply Input	100-240 V AC, 50/60 Hz, Max 0.2A
Supply Output	5 V DC, 1A

Transport and Storage Between Use	
Temperature range	-13 °F to 158 °F (-25 °C to 70 °C)
Relative humidity range	up to 90%, non-condensing
Atmospheric pressure range	700 hPa to 1,060 hPa
Altitude range	-1,250 ft to +10,000 ft (-381 m to +3,048 m)

C.4 Communications Specifications

Cap and Phone Communication	
Compatible Phones	iPhone 7 and later; for full list visit www.bigfootbiomedical.com/compatible
NFC scan distance	1.0 cm
Radio Frequency	Near Field Communication (13.56 MHz RFID); 2.402 to 2.480 GHz BLE, GFSK

C.5 Bigfoot Unity™ Diabetes Management System Specifications

Bigfoot Unity System Specifications	
Operating Temperature	50 ºF to 95 ºF (10 ºC to 35 ºC)

C.6 Kit Specifications

Bigfoot Unity Welcome Kit Specifications	
Storage and transport temperature range	46 ºF to 82 ºF (8 ºC to 28 ºC) Individual components of the kit have different storage and transport temperature ranges.

IMPORTANT: Follow the insulin manufacturer's instructions for using and storing insulin pens, particularly when insulin pen is placed into the Cap. The temperature ranges for using and storing your insulin pens may be more restrictive than those for the Caps.

C.7 Security Measures

The communication between the White Cap and Sensor during a scan is a short range Near Field Communication (NFC) method which makes it difficult to interfere with or intercept during transmission. The transmitted data is protected by a proprietary data format, encryption, and memory map. The integrity of transmitted data is ensured by a cyclic redundancy check (CRC) generated by the Sensor and verified by the White Cap. The communication between the App and Sensor for Alert data is a standard *Bluetooth*® Low Energy (BLE) connection. The pairing of the Sensor to the App is accomplished during activation with an authenticated login procedure that uses an Out-of-band key exchange (NFC). This prevents unauthorized devices from connecting to the Sensor. The transmitted data is protected by a proprietary data format and encryption. This prevents unauthorized devices from accessing the data if they are within range and intercept the transmission. Under normal operation, the industry standard BLE protocols allow for many users to be in the same vicinity. In the case where the connection is lost due to out-of-range or interference, reconnection is only possible with the authenticated App that activated the Sensor.

C.8 Quality of Service (QoS)

QoS for the White Cap and Sensor wireless communications using NFC is assured within the effective range of 1.0 cm between the Sensor and Cap that is specified to occur within 15 seconds. QoS for the wireless communication using BLE is assured between the App and Sensor at regular 1-minute intervals. If connection is lost between the App and Sensor for five minutes, “Sensor Unavailable - Glucose alerts temporarily unavailable” displays on the App Home screen. If connection is lost for 20 minutes, the App also alerts the user if the alert is turned on. If connection is lost between the Sensor and the App, up to 8 hours of glucose results can be retrieved by performing a scan with the White Cap. The App and Cap are designed to only accept radio frequency (RF) communications from recognized and paired Sensors.

C.9 Meter Specifications

See the instructions that came with your Meter and the inserts that came with your test strips and control solution for specifications for those devices.

C.10 Performance Characteristics of the FreeStyle Libre 2 Flash Glucose Monitoring System*

Overview of Clinical Studies

Two studies were conducted in the United States (US) to evaluate the performance, safety, effectiveness, and precision of the FreeStyle Libre 2 Flash Glucose Monitoring System (System). One study included adults (Adult study) and the other study included children (Pediatric study). All subjects in both studies required insulin to manage their diabetes. To measure the precision of the System, each subject wore two Sensors, one on the back of each upper arm, for a period of up to 14 days. While in the clinic, subjects had their venous blood glucose analyzed using a laboratory reference method, the Yellow Springs Instrument Life Sciences 2300 STAT Plus™ Glucose & Lactate Analyzer (YSI). Sensor glucose readings were then compared to the YSI glucose results to evaluate the System's performance.

Adult study: The Adult study was conducted at 5 centers with 146 subjects in total (91.1% Type 1, 8.9% Type 2), all aged eighteen and older. Subjects had their venous blood glucose analyzed over three separate visits to the clinical center. Each visit lasted up to ten hours. 144 subjects were analyzed during the beginning of the Sensor wear period (day 1, 2, or 3), 91 subjects were analyzed during the early middle period (day 7 or 8), 55 subjects were analyzed during the late middle period (day 9 or 12), and 76 subjects were analyzed during the end period (day 13 or 14). During each visit, adult subjects had their glucose levels deliberately manipulated per the study protocol to raise or lower glucose. This was done to assess performance over the range that the System measures glucose (40 – 400 mg/dL).

Pediatric study: The Pediatric study was conducted at 4 centers with 139 subjects in total (98.6% Type 1, 1.4% Type 2), all aged four to seventeen. Subjects age six and older had their venous blood glucose analyzed for up to 16 hours over one or two separate visits to the clinical center. Each visit lasted up to eight hours. During each visit, subjects age 11 and older had their glucose levels deliberately manipulated per the study protocol to raise or lower glucose. This was done to assess performance over the range that the System measures glucose (40 – 400 mg/dL). Results are presented for 87 children aged 12 – 17 years old; 35 subjects were analyzed during the beginning of the Sensor wear period (day 1 or 2), 35 subjects were analyzed during the early middle period (day 7 or 8), 34 subjects were analyzed during the late middle period (day 9 or 12), and 42 subjects were analyzed during the end period (day 13 or 14). All subjects tested their blood glucose using fingerstick capillary samples at least four times during each day of the study.

* The contents of this section are based on clinical studies conducted by Abbott Diabetes Care in support of K193371. This summary includes elements of the studies that support features present in Bigfoot Unity. Data from these studies that do not support features in Bigfoot Unity are not included.

Accuracy

Accuracy of the System was measured by comparing paired continuous glucose monitoring (CGM) and YSI blood glucose values. The percentage of total System readings that were within 20 mg/dL for YSI blood glucose values < 70 mg/dL or 20% of YSI for blood glucose values ≥ 70 mg/dL is displayed in **Table 1a**. The Mean Absolute Relative Difference (MARD) gives an indication of the average percent disagreement between the CGM and the reference. For example, in the Adult study, 92.4% of the readings fell within ± 20 mg/dL of YSI blood glucose values < 70 mg/dL and within ± 20% of YSI blood glucose values ≥ 70 mg/dL. The total number of data pairs considered in the analysis was 18,735. In the Adult study, the Mean Absolute Relative Difference was 9.2% for the comparison with YSI reference. In the Pediatric study, the Mean Absolute Relative Difference was 9.8% for the comparison with YSI reference.

Table 1a: Overall Accuracy to YSI

Subject Group	Number of CGM-Reference Pairs	Number of Subjects	Percent Within ±20% / ±20 mg/dL	Percent Within ±20% / ±20 mg/dL on Day 1	Percent Within ±20% / ±20 mg/dL in first 12 hours	MARD (%)
Adults	18735	144	92.4	87.5	81.7	9.2
Children (age 12 – 17)	5086	86	91.5	83.3	80.1	9.8

The accuracy of different CGM glucose ranges versus YSI reference was assessed by calculating the percentage of System readings that were within 15%, 20%, and 40% for reference values ≥ 70 mg/dL, and within 15 mg/dL, 20 mg/dL, and 40 mg/dL for values < 70 mg/dL. For blood glucose values < 70 mg/dL, the difference in mg/dL between the CGM and YSI blood glucose values was calculated. For values ≥ 70 mg/dL, the relative difference (%) to the YSI blood glucose values was calculated. The results categorized within CGM glucose ranges are presented in **Tables 1b and 1c**. The results categorized within YSI glucose ranges are presented in **Tables 1d and 1e**.

Table 1b: Accuracy to YSI within CGM Glucose Ranges (Adult; n=144)

CGM Glucose Level† (mg/dL)	Number of CGM-Reference Pairs	Percent Within ±15 mg/dL	Percent Within ±20 mg/dL	Percent Within ±40 mg/dL	Percent Within ±15%	Percent Within ±20%	Percent Within ±40%	Mean bias (mg/dL)	MARD (%)
<54	518	85.9	93.8	99.4				-6.4	13.8
54-69	3012	89.5	94.2	99.1				-3.3	10.8
70-180	7785				76.5	86.6	99.2	-4.8	10.6
181-250	3037				89.1	95.0	99.9	-10.1	7.8
>250	4383				94.0	97.9	100.0	-6.3	6.1

† System range is 40-400 mg/dL.

Table 1c: Accuracy to YSI within CGM Glucose Ranges (Pediatric; n=86)

CGM Glucose Level† (mg/dL)	Number of CGM-Reference Pairs	Percent Within ±15 mg/dL	Percent Within ±20 mg/dL	Percent Within ±40 mg/dL	Percent Within ±15%	Percent Within ±20%	Percent Within ±40%	Mean bias (mg/dL)	MARD (%)
<54	125	70.4	77.6	96.8				-10.9	17.8
54-69	772	86.5	90.4	96.9				-4.9	12.0
70-180	1963				76.9	86.6	98.5	-4.1	10.9
181-250	957				87.0	96.0	99.9	-11.7	8.1
>250	1269				93.5	98.1	99.7	-5.7	7.1

† System range is 40-400 mg/dL.

Table 1d: Accuracy to YSI within YSI Glucose Ranges (Adult; n=86)

CGM Glucose Level (mg/dL)	Number of CGM-Reference Pairs	Percent Within ±15 mg/dL	Percent Within ±20 mg/dL	Percent Within ±40 mg/dL	Percent Within ±15%	Percent Within ±20%	Percent Within ±40%	Mean bias (mg/dL)	MARD (%)
<54	440	91.1	97.5	100.0				7.4	15.5
54-69	3028	94.7	98.6	100.0				1.5	10.2
70-180	7504				77.5	86.9	99.4	-4.8	10.4
181-250	2937				87.9	93.7	99.7	-8.0	8.0
>250	4826				90.9	95.9	99.7	-11.8	6.9

Table 1e: Accuracy to YSI within YSI Glucose Ranges (Pediatric; n=86)

CGM Glucose Level (mg/dL)	Number of CGM-Reference Pairs	Percent Within ±15 mg/dL	Percent Within ±20 mg/dL	Percent Within ±40 mg/dL	Percent Within ±15%	Percent Within ±20%	Percent Within ±40%	Mean bias (mg/dL)	MARD (%)
<54	117	94.0	98.3	100.0				6.7	14.6
54-69	670	96.1	98.7	100.0				0.9	9.5
70-180	2001				73.3	83.3	97.7	-4.5	11.7
181-250	806				87.5	92.9	98.6	-6.0	8.3
>250	1492				91.1	98.1	99.9	-12.8	7.7

Agreement with '< 40 mg/dL' and '> 400 mg/dL' CGM Reading against YSI Reference*

The System reports glucose concentrations between 40 and 400 mg/dL. When the System determines that glucose level is below 40 mg/dL, it will report as '< 40 mg/dL' on the White Cap. When the System determines that glucose level is above 400 mg/dL, it will report as '> 400 mg/dL' on the White Cap. **Tables 2a and 2b** display the concurrence between the CGM and YSI reference glucose when CGM reads '< 40 mg/dL'. For example, in the Adult study, when CGM reading was '< 40 mg/dL', YSI glucose values were less than 50 mg/dL 20.0% of the time, less than 60 mg/dL 40.0% of the time, less than 70 mg/dL 40.0% of the time, less than 80 mg/dL 80.0% of the time, and equal to or above 80 mg/dL 20.0 % of the time.

Table 2a: Concurrence Analysis with '< 40 mg/dL' CGM Reading (Adult; n=144)

CGM-Reference Pairs	YSI (mg/dL)					N
	<50	<60	<70	<80	≥80	
n	1	2	2	4	1	5
Cumulative %	20.0	40.0	40.0	80.0	20.0	

* The User's Manual for the FreeStyle Libre 2 Flash Glucose Monitoring System refers to these as 'LO' and 'HI'

Table 2b: Concurrence Analysis with '< 40 mg/dL' CGM Reading (Pediatric; n=86)

CGM-Reference Pairs	YSI (mg/dL)					N
	<50	<60	<70	<80	≥80	
n	0	1	2	2	0	2
Cumulative %	0.0	50.0	100.0	100.0	0.0	

Tables 2c and 2d display the concurrence between the CGM and YSI reference glucose when CGM reads '> 400 mg/dL'. In the Adult study, when CGM reading was '> 400 mg/dL', YSI glucose values were above 350 mg/dL 97.5% of the time, above 300 mg/dL 100.0% of the time, above 250 mg/dL 100.0 % of the time, and less than or equal to 250 mg/dL 0.0% of the time.

Table 2c: Concurrence Analysis with '> 400 mg/dL' CGM Reading (Adult; n=144)

CGM-Reference Pairs	YSI (mg/dL)				N
	>350	>300	>250	≤ 250	
n	118	121	121	0	121
Cumulative %	97.5	100.0	100.0	0.0	

Table 2d: Concurrence Analysis with '> 400 mg/dL' CGM Reading (Pediatric; n=86)

CGM-Reference Pairs	YSI (mg/dL)				N
	>350	>300	>250	≤ 250	
n	26	28	30	0	30
Cumulative %	86.7	93.3	100.0	0.0	

Concurrence of System and Reference (CGM vs. YSI)

The percentage of concurring glucose values (CGM vs. YSI) in each glucose reference range is presented for each CGM range in **Tables 3a and 3b** and for each YSI range in **Tables 3c and 3d**. For example, in the Adult study, when the System glucose readings were within the 81 to 120 mg/dL range, actual blood glucose values were between 40 and 60 mg/dL 0.2% of the time, between 61 and 80 mg/dL 11.0% of the time, between 81 and 120 mg/dL 70.1% of the time, between 121 and 160 mg/dL 17.8% of the time, between 161 and 200 mg/dL 0.8% of the time, and between 201 and 250 mg/dL 0.1% of the time.

Table 3a: Concurrence Analysis by CGM Glucose Level (Adult; n=144)

CGM Glucose Level (mg/dL)	YSI Glucose Level (mg/dL)											N
	<40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	>400	
<40†	20.0	20.0	40.0	20.0	.	.	.	.	.	.	.	5
40-60	0.4	52.9	43.3	3.3	.	0.1	.	.	.	.	.	1889
61-80	.	18.9	62.7	18.1	0.4	0.0	.	.	.	.	.	3090
81-120	.	0.2	11.0	70.1	17.8	0.8	0.1	.	.	.	.	3040
121-160	.	.	0.1	9.1	69.9	18.9	1.6	0.3	0.2	.	.	2407
161-200	.	.	.	.	10.6	60.6	26.9	1.6	0.3	.	.	1745
201-250	.	.	.	.	.	7.0	65.5	25.6	1.9	0.1	.	2181
251-300	.	.	.	.	.	0.1	8.4	66.9	22.7	1.8	0.1	2327
301-350	.	.	.	.	.	.	0.4	13.6	68.8	16.0	1.2	1522
351-400	.	.	.	.	.	.		0.6	27.5	63.3	8.6	534
>400†	.	.	.	.	.	.	.	.	2.5	62.8	34.7	121

† Levels out of System dynamic range.

Table 3b: Concurrence Analysis by CGM Glucose Level (Pediatric; n=86)

CGM Glucose Level (mg/dL)	YSI Glucose Level (mg/dL)											N
	<40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	>400	
<40†	.	50.0	50.0	.	.	.	.	.	.	.	.	2
40-60	0.6	47.7	42.9	8.1	0.6	.	.	.	.	.	.	480
61-80	.	13.1	61.2	23.8	1.8	.	.	.	.	.	.	776
81-120	.	0.3	12.0	68.7	17.5	1.4	0.1	.	.	.	.	798
121-160	.	.	.	10.6	70.0	17.3	2.1	.	.	.	.	577
161-200	.	.	.	0.2	16.2	59.5	23.9	0.2	.	.	.	444
201-250	.	.	.	.	.	7.8	52.8	38.3	1.1	.	.	742
251-300	.	.	.	.	.	.	10.1	62.1	26.8	1.1	.	665
301-350	.	.	.	.	.	.	0.2	20.0	60.0	19.6	0.2	455
351-400	.	.	.	.	.	1.3	.	0.7	34.2	58.4	5.4	149
>400†	.	.	.	.	.	.	.	6.7	6.7	16.7	70.0	30

† Levels out of System dynamic range.

Table 3c: Concurrence Analysis by YSI Glucose Level (Adult; n=144)

YSI Glucose Level (mg/dL)	CGM Glucose Level (mg/dL)											N
	<40†	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	>400†	
<40	12.5	87.5	.	.	.	.	.	.	.	.	.	8
40-60	0.1	62.9	36.6	0.4	.	.	.	.	.	.	.	1591
61-80	0.1	26.4	62.6	10.8	0.1	.	.	.	.	.	.	3093
81-120	0.0	2.1	18.8	71.7	7.3	.	.	.	.	.	.	2971
121-160	.	.	0.5	22.3	69.6	7.7	.	.	.	.	.	2418
161-200	.	0.1	0.1	1.5	26.9	62.5	9.0	0.1	.	.	.	1694
201-250	.	.	.	0.1	1.8	21.9	66.8	9.1	0.3	.	.	2139
251-300	.	.	.	.	0.3	1.2	23.7	66.0	8.8	0.1	.	2359
301-350	.	.	.	.	0.3	0.3	2.3	29.8	58.9	8.3	0.2	1777
351-400	.	.	.	.	.	.	0.3	6.1	34.7	48.1	10.8	703
>400	.	.	.	.	.	.	.	1.9	16.7	42.6	38.9	108

* Levels out of System dynamic range.

Table 3d: Concurrence Analysis by YSI Glucose Level (Pediatric; n=86)

YSI Glucose Level (mg/dL)	CGM Glucose Level (mg/dL)											N
	<40†	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	>400†	
<40	.	100.0	.	.	.	.	.	.	.	.	.	3
40-60	0.3	68.6	30.5	0.6	.	.	.	.	.	.	.	334
61-80	0.1	26.5	61.1	12.3	.	.	.	.	.	.	.	778
81-120	.	4.7	22.2	65.7	7.3	0.1	.	.	.	.	.	834
121-160	.	0.5	2.2	22.1	63.8	11.4	.	.	.	.	.	633
161-200	.	.	.	2.5	23.0	60.7	13.3	.	.	0.5	.	435
201-250	.	.	.	0.2	2.1	18.3	67.7	11.6	0.2	.	.	579
251-300	.	.	.	.	.	0.1	35.9	52.1	11.5	0.1	0.3	792
301-350	.	.	.	.	.	.	1.6	34.8	53.3	10.0	0.4	512
351-400	.	.	.	.	.	.	.	3.7	47.3	46.3	2.7	188
>400	.	.	.	.	.	.	.	.	3.3	26.7	70.0	30

† Levels out of System dynamic range.

Glucose Rate of Change Accuracy

The System's glucose rate of change (ROC) accuracy, as assessed by concurrence analysis, is presented in **Tables 4a and 4b**. For example, in the Adult study, when the Sensor glucose ROC indicated that glucose was changing slowly downward (-1 to 0 mg/dL/min (→)), actual glucose levels in the body were falling quickly (<-2 mg/dL/min) 1.2% of the time, falling (-2 to -1 mg/dL/min) 8.3% of the time, changing slowly downward (-1 to 0 mg/dL/min) 67.1% of the time, changing slowly upward (0 to 1 mg/dL/min) 19.7% of the time, rising (1 to 2 mg/dL/min) 2.6% of the time, and were rising quickly (>2 mg/dL/min) 1.2% of the time. Digitally connected systems which do not utilize the System's Trend Arrow calculations may see different glucose rate of change accuracy.

Table 4a: Concurrence Analysis by Glucose Rate of Change (Adult; n=144)

CGM (mg/dL/min)	YSI (mg/dL/min)						N
	< -2	[-2, -1)	[-1, 0)	[0, 1]	(1, 2]	>2	
<-2 (↓)	34.4	44.9	18.3	2.2	0.3	.	323
-2 to -1 (↘)	6.8	46.5	41.2	4.0	0.9	0.6	1090
-1 to 0 (→)	1.2	8.3	67.1	19.7	2.6	1.2	9389
0 to 1 (→)	0.9	3.4	26.0	46.9	15.5	7.3	5420
1 to 2 (↗)	0.1	1.7	7.7	31.6	38.4	20.5	1151
>2 (↑)	0.1	0.2	3.1	14.6	32.9	49.0	881

Table 4b: Concurrence Analysis by Glucose Rate of Change (Pediatric; n=86)

CGM (mg/dL/min)	YSI (mg/dL/min)						N
	< -2	[-2, -1)	[-1, 0)	[0, 1]	(1, 2]	>2	
<-2 (↓)	46.3	43.8	8.3	1.7	.	.	121
-2 to -1 (↘)	12.7	51.2	30.8	4.4	0.3	0.6	338
-1 to 0 (→)	1.9	10.7	60.5	20.9	4.0	2.1	2084
0 to 1 (→)	0.9	5.0	25.8	43.0	15.3	9.9	1606
1 to 2 (↗)	0.3	2.6	8.9	28.2	36.3	23.8	383
>2 (↑)	.	0.6	3.7	16.1	30.0	49.6	347

Alert Performance

The tables in this section show the accuracy of the System's Low Glucose Alert. The Alert Rate tells you how often the alert is right or wrong. The Detection Rate tells you how often the System is able to recognize and notify you about a low glucose event.

Low Glucose Alert Performance

Tables 5a and 5b display the percentages for these parameters:

True Alert Rate
Tells you: When you got a Low Glucose Alert, were you actually low?

Definition: Percentage of time the alert issued and blood glucose was below the alert level within 15 minutes before or after the alert.

False Alert Rate
Tells you: Did you get a Low Glucose Alert that you shouldn't have?

Definition: Percentage of time the alert issued and blood glucose was not below the alert level within 15 minutes before or after the alert.

Detection Rate
Tells you: When you were low, did you get a Low Glucose Alert?

Definition: Percentage of time blood glucose was below the alert level and the alert issued within 15 minutes before or after the glucose event.

Missed Detection Rate
Tells you: When you were low, did you miss a Low Glucose Alert?

Definition: Percentage of time blood glucose was below the alert level and the alert didn't issue within 15 minutes before or after the glucose event.

For example, the Adult study found that for a Low Glucose Alert level set to 70 mg/dL:
86.0% of the time a Low Glucose Alert was received when blood glucose was indeed below the alert level but 14.0% of the time a Low Glucose Alert was received when blood glucose wasn't actually below the alert level. 89.3% of the time blood glucose was below the alert level and a Low Glucose Alert was appropriately issued but 10.7% of the time the glucose event was missed and no alert was issued.

Table 5a: Low Glucose Alert Performance (Adult; n=144)

Low Glucose Alert level (mg/dL)	Alert Rate			Detection Rate		
	Number of Events (n)	True Alert Rate (%)	False Alert Rate (%)	Number of Events (n)	Correct Detection Rate (%)	Missed Detection Rate (%)
70	21504	86.0	14.0	3652	89.3	10.7

Table 5b: Low Glucose Alert Performance (Pediatric; n=186)

Low Glucose Alert level (mg/dL)	Alert Rate			Detection Rate		
	Number of Events (n)	True Alert Rate (%)	False Alert Rate (%)	Number of Events (n)	Correct Detection Rate (%)	Missed Detection Rate (%)
70	1133	80.1	19.7	800	93.5	6.5

Sensor Accuracy Over Time

The Sensor can be worn for up to 14 days. The percentage of System readings within YSI values and the Mean Absolute Relative Difference (MARD) is presented for the following different wear periods in **Tables 6a and 6b**: Beginning (Adult: 144 Subjects, Day 1, 2 or 3; Pediatric: 35 Subjects, Day 1 or 2) Early Middle (Adult: 91 Subjects, Day 7 or 8; Pediatric: 35 Subjects, Day 7 or 8), Late Middle (Adult: 55 Subjects, Day 9 or 12; Pediatric: 34 Subjects, Day 9 or 12), and End (Adult: 76 Subjects, Day 13 or 14; Pediatric: 42 Subjects, Day 13 or 14). For values 70 mg/dL and above, the percentage of readings within 15%, 20%, and 40% of the YSI value was calculated. For values below 70 mg/dL, the percentage of readings within 15 mg/dL, 20 mg/dL, and 40 mg/dL of the YSI value was calculated.

Table 6a: Sensor Accuracy Relative to YSI over the wear duration (Adult; n=144)

Wear Period	Number of CGM-reference pairs	MARD (%)	Within ±15% / ±15 mg/dL	Within ±20% / ±20 mg/dL	Within ±40% / ±40 mg/dL
Beginning	6955	9.9	83.4	90.4	99.3
Early Middle	4522	8.5	87.7	94.5	99.8
Late Middle	3503	8.8	86.8	93.4	99.7
End	3755	9.1	86.4	92.9	100.0

Table 6b: Sensor Accuracy Relative to YSI over the wear duration (Pediatric; n=86)

Wear Period	Number of CGM-reference pairs	MARD (%)	Within ±15% / ±15 mg/dL	Within ±20% / ±20 mg/dL	Within ±40% / ±40 mg/dL
Beginning	1403	10.9	79.3	88.0	98.2
Early Middle	1307	8.0	90.0	94.3	98.2
Late Middle	1068	9.8	84.1	92.6	99.8
End	1308	10.2	83.9	91.8	99.4

Sensor Wear Duration

The Sensor can be worn for up to 14 days. To estimate how long a Sensor will work over the wear duration, 146 Sensors were evaluated in the Adult study and 87 Sensors were evaluated in the Pediatric study to determine how many days of readings each Sensor provided. Subjects did not wash the insertion site with soap and water before applying the Sensors and wore two Sensors simultaneously. Of the 146 Sensors in the Adult study, 71.1% lasted until the final day of use. 6 Sensors (4.1%) had "early sensor shut-off" where the Sensor algorithm detected that the Sensors did not function as intended and presented the user with a Replace Sensor message. In the Pediatric study, 80.3% of the Sensors lasted until the final day of use. 2 Sensors (2.3%) had "early sensor shut-off" where the Sensor algorithm detected that the Sensors did not function as intended and presented the user with a Replace Sensor message. **Tables 7a and 7b** display the data for each day in the wear duration for the Adult & Pediatric studies.

A third clinical study was also conducted to further evaluate wear duration in subjects who first washed the insertion site with a plain soap and water, according to the full instructions in the labeling and wore only a single Sensor. Of the 39 Sensors evaluated in this study, 97% lasted until the final day of use.

Table 7a: Sensor Survival Rate Over Wear Duration (Adult; n=146)

Day of Wear	Number of Sensors	Survival Rate (%)
1	145	99.3
2	142	97.3
3	140	95.9
4	137	93.8
5	134	91.8
6	133	91.1
7	132	90.4
8	127	87.0
9	123	84.9
10	119	82.2
11	112	77.3
12	111	76.6
13	104	71.8
14	100	71.1

Table 7b: Sensor Survival Rate Over Wear Duration (Pediatric; n=87)

Day of Wear	Number of Sensors	Survival Rate (%)
1	85	97.7
2	84	96.6
3	83	95.4
4	82	94.3
5	82	94.3
6	82	94.3
7	82	94.3
8	82	94.3
9	79	90.8
10	77	88.5
11	77	88.5
12	76	87.4
13	74	85.1
14	67	80.3

Glucose Reading Availability

The System is designed to show a Sensor glucose reading after each scan that is performed throughout the wear period after the start-up time. **Tables 8a and 8b** show the glucose reading capture rate for each day of the wear duration.

Table 8a: Glucose Reading Capture Rate Over Wear Duration (Adult; n=146)

Day of Wear	Number of Sensors	Capture Rate (%)
1	146	98.3
2	145	98.1
3	143	98.3
4	140	98.3
5	138	98.4
6	135	98.3
7	134	98.4
8	131	98.4
9	128	98.4
10	123	98.4
11	120	98.4
12	113	98.5
13	112	98.5
14	104	98.6

Table 8b: Glucose Reading Capture Rate Over Wear Duration (Pediatric; n=87)

Day of Wear	Number of Sensors	Capture Rate (%)
1	87	95.4
2	85	95.2
3	84	95.6
4	82	95.7
5	83	95.9
6	82	96.1
7	83	96.5
8	82	96.8
9	81	96.9
10	78	96.9
11	78	96.9
12	76	97.1
13	75	97.1
14	74	97.2

Precision

Precision of the System was evaluated by comparing the results from two separate Sensors worn on the same subject at the same time. **Table 9a** provides data from 146 subjects in the Adult study; **Table 9b** provides data from 86 subjects in the Pediatric study. For adults, the paired absolute relative difference (PARD) between the two Sensors was 8.1% with coefficient of variation (CV) of 5.7%. For children ages 12-17, PARD was 8.4% with CV of 6.0%. Paired absolute difference (PAD) is a measurement of absolute difference (in mg/dL) between paired CGM readings, while PARD is the absolute relative difference (in %) between paired CGM readings.

Table 9a: Overall between Sensor Precision (Adult; n=146)

	Coefficient of Variation (%)	Paired Absolute Difference (mg/dL)	Paired Absolute Relative Difference (%)	Number of Paired Readings
Adults ages 18+	5.7	12.4	8.1	26791

Table 9b: Overall between Sensor Precision (Pediatric; n=86)

	Coefficient of Variation (%)	Paired Absolute Difference (mg/dL)	Paired Absolute Relative Difference (%)	Number of Paired Readings
Children ages 12-17	6.0	13.2	8.4	7659

Adverse Events

No device related serious adverse events occurred during the studies. In the Adult study, mild skin irritations, such as erythema, bruising, bleeding, and scabbing were reported around the insertion site and adhesive area by a small number of subjects (10 out of 146 or 6.8%). Pain was mostly reported as none with only one instance of mild pain. In the Pediatric study, for children ages 12-17 there were 7 instances of erythema (4 “well-defined redness”, and 3 “slight pink”), 5 instances of edema (3 slight edema, 2 slight edema with defined edges), 2 instances of mild bleeding, and one instance of mild induration.

Ascorbic Acid Interference

Taking ascorbic acid (vitamin C) supplements while wearing the Sensor may falsely raise Sensor glucose readings. Taking more than 500 mg of ascorbic acid per day may affect the Sensor readings which could cause you to miss a severe low glucose event. Ascorbic acid can be found in supplements including multivitamins. Some supplements, including cold remedies such as Airborne® and Emergen-C®, may contain high doses of 1000 mg of ascorbic acid and should not be taken while using the Sensor. See your health care provider to understand how long ascorbic acid is active in your body.

Additional notes for Health Care Providers

A clinical study was conducted to evaluate the effect of ascorbic acid on Sensor performance. Data from 57 adult subjects with diabetes was collected over a 13-hour period. Each subject had a one-hour baseline phase where venous blood was collected every 10 minutes. After this first hour, a dose of 1000 mg ascorbic acid was given with a meal and venous samples were collected every 20 minutes for the next four hours. A maximum average sensor bias of 9.3 mg/dL was observed around 3 hours after the 1000 mg ascorbic acid dose. Subjects then received a second dose of 1000 mg ascorbic acid with a meal and the same process was continued for another 4 hours. A third dose of 1000 mg ascorbic acid was then given and study subjects were followed for 4 more hours. After the second dose of ascorbic acid the maximum average sensor bias increased, with minimal change in sensor bias after the third dose, suggesting that saturation had occurred by the second 1000 mg dose of ascorbic acid. The maximum average sensor bias after the three 1000 mg doses of ascorbic acid was less than 20 mg/dL.

C.11 Electromagnetic Compatibility (EMC)

Bigfoot Unity has been tested and found to be appropriate for use at home. In most cases, Bigfoot Unity should not interfere with other home electronic devices if used as instructed. However, the Caps, Sensor, Meter, and your phone give off radio frequency (RF) energy. The low level of RF energy emitted by the system is not likely to cause interference in nearby electronic equipment. However, if not used correctly, these Bigfoot Unity devices may interfere with your TV, radio, or other electronic devices that receive RF signals.

In addition, except for your Bigfoot Unity-related devices, other electronic wireless devices that are in use nearby, such as another cell phone or a wireless network, may prevent or delay the transmission of data between the different devices that make up the Bigfoot Unity System. If you find that glucose values are not sent to your White Cap from the Meter, or if Sensor or Cap data is not being sent to the App, it may be due to electromagnetic interference. To avoid interference, you may be able to move to a different location to Use Bigfoot Unity. Alternatively, you could turn off other nearby electronic devices or antennas to avoid interference. Similarly, if you find that the White Cap will not scan the Sensor, try moving to another location.

If you experience problems receiving data on your Cap or App after moving Bigfoot Unity away from any potential source of interference, contact Bigfoot Customer Care at (551) 244-3668.

Special precautions must be taken to avoid increased emissions of RF or decreased immunity to RF, including:

- Installing and using Bigfoot Unity in accordance with the instructions provided in this User Guide.
- Using only accessories, transducers, and cables specified by Bigfoot Biomedical.
- Avoiding using Bigfoot Unity adjacent to other electrical equipment, or if adjacent use is necessary, Bigfoot Unity should be observed to verify normal system operation.
- Not making any modifications to Bigfoot Unity components that are not approved by Bigfoot Biomedical.

FCC Compliance

The Bigfoot Unity System complies with Part 15 of the Federal Communications Commission (FCC) rules that state the following two conditions:

(1) this device may not cause harmful interference, and

(2) this device must accept any interference received, including interference that may cause undesired operation.

Bigfoot Unity Transmitter Module FCC IDs:

Bigfoot Unity Device	FCC ID
White Cap	2AVAYUR001
Black Cap	2AVAYUL001
Meter	QOQBLE113

Guidance and manufacturer's declaration – electromagnetic emissions

Bigfoot Unity is intended for use in the electromagnetic environment specified below. The customer or the user should assure that Bigfoot Unity is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	Bigfoot Unity uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Bigfoot Unity is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity

Bigfoot Unity is intended for use in the electromagnetic environment specified below. The customer or the user should assure that Bigfoot Unity is used in such an environment.

Immunity test	IEC 60601 test level	Compliance Level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV input/ output lines	±2 kV for power supply lines ±1 kV input/ output lines	Mains power quality should be that of a typical domestic, commercial, or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical domestic, commercial, or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 seconds	<5% U_T (>95% dip in U_T) for 0.5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 seconds	Mains power quality should be that of a typical domestic, commercial, or hospital environment. If the user of Bigfoot Unity requires continued operation during power mains interruptions, it is recommended that Bigfoot Unity be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical domestic, commercial, or hospital environment.
Conducted RF IEC 61000-4-6	6 Vrms 150 kHz to 80 MHz	6 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of Bigfoot Unity, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	**Recommended separation distance** $d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 800 MHz to 2.5 GHz

Immunity test	AIM 7351731: 2017 test level	Performance
RFID Magnetic Immunity	≥65 A/m 134.2kHz ≥7.5A/m 13.56MHz	Equipment operating in the 13.56 MHz frequency range in the vicinity of the RCAP was found to have a temporary effect on the scanning functionality of the Sensor. After removing the source of interference, the scanning function resumed with no degradation of performance. Equipment operating in the 134.2 kHz frequency range had no effect on the scanning function. BLE communication was not impacted at either frequency.

Note: U^T is the a.c. mains voltage prior to application of the test level.

P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and **d** is the recommended separation distance in meters (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b].

Interference may occur in the vicinity of the equipment marked with the following symbol: 

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which Bigfoot Unity is used exceeds the applicable RF compliance level above, Bigfoot Unity should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating Bigfoot Unity.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Recommended separation distances between portable and mobile RF communications equipment and Bigfoot Unity

Bigfoot Unity is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of Bigfoot Unity can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Bigfoot Unity. The Bigfoot Unity System was tested with several common electronic products that could potentially cause interference, including a WiFi router, a *Bluetooth* speaker, a Fitbit, a cordless phone, a baby monitor, a laptop computer, and a microwave oven. At a separation of 1 meter (about 3 feet), none of these products affected the operation of Bigfoot Unity.

Recommended separation distances between transmitters and Bigfoot Unity can be calculated using the table below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	**80 MHz to 800 MHz** $d=1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

C.12 Warranty

For warranty information, please reference the Terms of Use for Bigfoot Unity within the App, or online at: www.bigfootbiomedical.com/terms-of-use

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