bigfoot | unity

REPORT USER GUIDE

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1 Understanding Your Bigfoot Unity Report

Your Bigfoot Unity Report (Report) is generated from your Bigfoot Unity® Diabetes Management System App (My Settings, My Data). The Report includes a standard set of glucose and insulin statistics and graphs relating to your diabetes management **over the past 14 days**.

The Report can be used to help you and your health care professional evaluate your data to inform treatment decisions. You can share your Bigfoot Unity Report with whomever you want, but remember it has information you may want to protect such as your name, date of birth and information about your diabetes.

IMPORTANT: Work with your health care professional to understand your Bigfoot Unity Report. The Report provides standardized information that can be used to identify trends to inform treatment decisions. The Report is not intended to replace medical advice from your health care professional.

IMPORTANT: PDF files can be difficult to read on a phone. Print the Report or view it on a tablet or full-sized computer screen for the best ability to review the information.

IMPORTANT: The Bigfoot Unity Report includes data from the previous 14 days. This date range cannot be changed. If you want a complete history of Reports, you must access and save a new Report every 14 days.

Note: The Report is in the local time zone of the person using Bigfoot Unity. It includes 14 days of data up to 11:59 PM of the previous day.

1.1 Intended Use

The Bigfoot Unity Report is intended for use by both patients and health care professionals to assist people with diabetes and their health care professionals in the review, analysis and evaluation of historical glucose and insulin data to support effective diabetes management. It is intended to be used with Bigfoot devices with data interface capabilities.

In addition,

- The Report is not intended to provide treatment decisions or to be used as a substitute for professional health care advice.
- The Report is not intended to be used for immediate treatment decisions and is not intended to replace self-monitoring practices as advised by a physician.
- People using Bigfoot Unity should consult a health care professional before making any medical interpretation or therapy adjustments from the information in the Report.
- Health care professionals should use information in the Report in conjunction with other clinical information available to them.

1.2 System Requirements

The Bigfoot Unity Report can be generated from any phone that runs the Bigfoot Unity App.

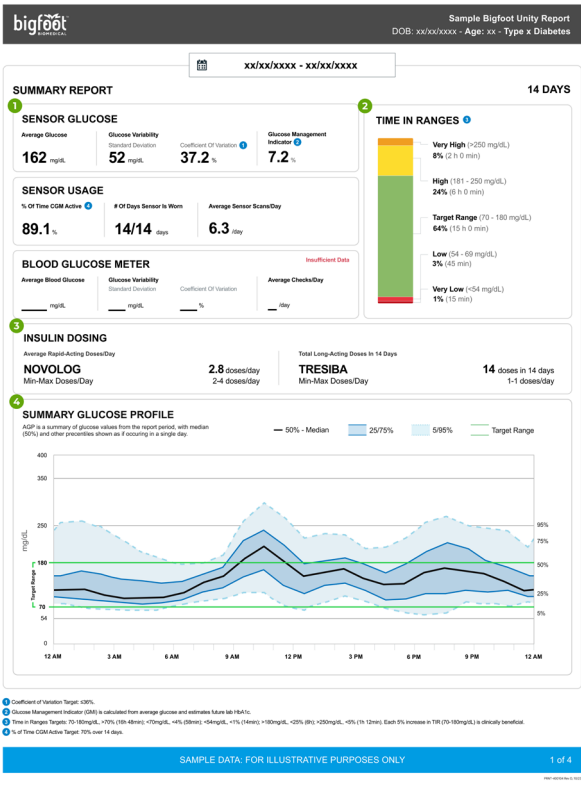
2 Overview of Your Bigfoot Unity Report

The Report will have a similar layout each time it is generated. The Report time frame is displayed at the top of the page and reflects data for the past 14 days. To better understand the information, use the labels and legends that are included in your Report. The Bigfoot Unity Report is informed by the International Diabetes Center's Ambulatory Glucose Profile (AGP) Report.[1]

2.1 Summary Report (Page 1)

Provides a snapshot of your Sensor Glucose, Sensor Usage, Blood Glucose (from your Bigfoot Meter), and Insulin Dosing.

1. Sensor & Meter Statistics provide an overview of glucose management.
2. The colored bar shows the percentage of time Sensor values are in Target Range (Green) and percentage of time above and below the Target Range.
3. Insulin Dosing information for both rapid-acting and long-acting insulin provide a snapshot of insulin use.
4. The Summary Glucose Profile helps translate Sensor Glucose statistics from the entire Report period, presenting in an average glucose profile (AGP) as if occurring in a single 24 hour day.

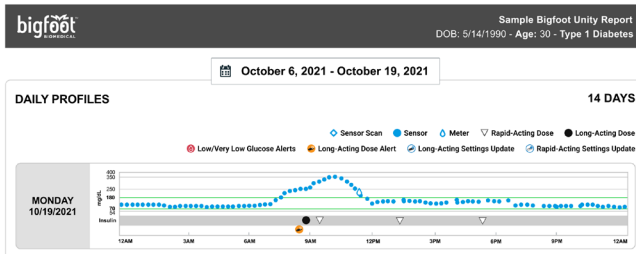


Example:
Glucose Statistics and Insulin Dosing Information

Note: The Report reflects data for the past 14 days. A Report generated within the first few days of using Bigfoot Unity will always reflect Sensor Usage and other statistics over a 14-day period. It is recommended that you view another Report after 14 days of use.

2.2 Daily Profiles (Pages 2-3)

A sample day is displayed below. A Daily Profile graph for each day of the 14-day reporting period will be provided in the Report.



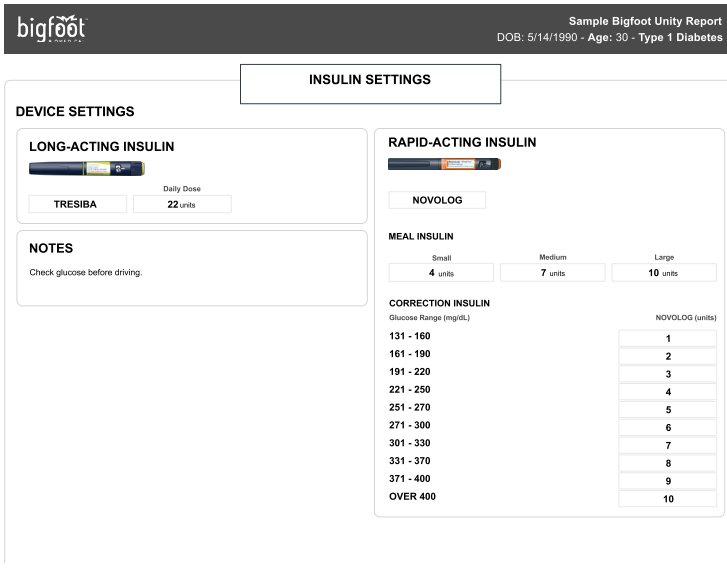
Example:
Daily Profile of Glucose, Dosing, and Alert Information

Note: The (🩸) icon is the same for Low Glucose and Very Low Glucose Alerts.

Note: The (💉) and (💉) icons will appear the first time you set up the Bigfoot Unity System and when you change your insulin settings.

2.3 Device Settings (Page 4)

Your current device settings will be displayed.



Example:
Insulins, Device Settings and Notes

2.4 What to Know about Missing Information

Sometimes information may be missing from your reports. A minimum of 7 days of information is required or you may see 'Insufficient Data' in some fields. To avoid gaps of information in your Sensor glucose graphs, make sure to:

- Wear your Sensor as much as possible
- Scan your Sensor at least once every 8 hours
- Bring devices within communication range often
- Make sure your App is connected to the internet

Refer to the Bigfoot Unity® Diabetes Management System User Guide for more information.

3 Details of Your Bigfoot Unity Report

Use the following information to better understand the details within your Bigfoot Unity Report. See the references below for more information about these parameters and goals.[2,3]

3.1 Summary Report (Page 1)

Note: For the most complete Report, wear your Sensor for the entire time frame, replace your Sensor when it is no longer functioning, and scan your Sensor at least once every 8 hours as described in the Bigfoot Unity® Diabetes Management System User Guide.

Sensor Glucose Statistics:

- Sensor Average Glucose (mean): All Sensor glucose values (obtained by scanning your Sensor with your White Cap) are added together and divided by the number of readings.
- Sensor Glucose Variability: The Standard Deviation of Sensor Average Glucose is a measure of how spread apart the data are from the average. The Coefficient of Variation describes how far apart (wide) glucose values are and is a measure of glucose variability. According to International Consensus, a low number equal to or less than 36% [percent coefficient of variation] is considered a goal.[2]
- Glucose Management Indicator (GMI): Calculated from average Sensor glucose, GMI provides an indication of the current state of your glucose management and estimates your value of a laboratory measured A1C. Discuss GMI and HbA1c with your health care team to learn more about the differences between them.

Sensor Usage:

- % of time CGM Active: Hours the Sensor collected data, divided by the number of hours in the Report.
- # of Days Sensor is worn: The number of days the Sensor was worn in the past 14 days.
- Average Sensor Scans/day: The average number of Sensor scans you perform each day using the White Cap.

Blood Glucose Meter Statistics:

- Average Blood Glucose (mean): All Meter values added together, divided by the number of readings.

- Meter Glucose Variability: The Standard Deviation of Average Blood Glucose is a measure of how spread apart the data are from the average. The Coefficient of Variation describes how far apart (wide) blood glucose values are and is a measure of glucose variability. In both cases, lower values are considered better.
- Average Checks/Day: Indicates the average number of blood glucose checks you perform per day with the Meter that is paired with your White Cap.

Time in Ranges:

In the Time in Ranges bar chart, your Sensor glucose information will be displayed as an average percent (%) of device readings; average time in that range is also shown in hours and minutes of a 24-hour day. Recommendations for time in each range are from the International Consensus on Time in Range for Adults.[2] Goals for adolescents and older adults should be discussed with your health care professional.

- Time in Target Range (70-180 mg/dL): The average time Sensor glucose values are in target range. As a goal, the average time in range should be greater than 70%. Each 5% increase in Time in Target Range is clinically beneficial.[2]
- Time Low (less than 70 mg/dL): The goal is to have few low Sensor glucose values with an average time spent low of less than 4%.[2]
- Time Very Low (less than 54 mg/dL): The goal is to have infrequent very low Sensor glucose values with an average time spent very low of less than 1%.[2]
- Time High (more than 180 mg/dL): The goal is to reduce high glucose values with an average time spent high of less than 25%.[2]
- Time Very High (more than 250 mg/dL): The goal is to reduce very high glucose values with an average time spent very high of less than 5%.[2]

Summary Glucose Profile Graph:

In the Summary Glucose Profile graph, your daily glucose profiles are combined to make a one day (24-hour) picture. Target profiles are from the International Consensus on Time in Range.[2]

- **Green lines:** These horizontal lines represent the target range of 70-180 mg/dL.
- **Black line:** Represents the median (middle) line where half of the Sensor glucose values are above and half are below; it is considered ideal if the black line is mostly flat and mostly within the green horizontal lines.

- **Dark blue:** Area shaded darker blue shows the range in which 50% of the Sensor glucose values were observed (25% above the median and 25% below the median); the closer together the upper and lower dark blue lines are, the better.[3]
- **Light blue:** Area shaded lighter blue indicates the range in which 90% of the Sensor glucose values were observed. This means that 5% of Sensor glucose values are above (95%, top dashed line) and 5% are below (5%, bottom dashed line). The closer the dotted blue lines and the light blue shaded area is to the dark blue shaded area, the better.[3]

Insulin Dosing Information:

This section displays summary information about your insulin dosing over the past 14 days.

- Rapid-Acting insulin: The average number of rapid-acting insulin doses taken per day, as well as the minimum and maximum doses per day.
- Long-Acting Insulin: The total number of long-acting insulin doses taken over the past 14 days, as well as the minimum and maximum doses per day.

Note: Bigfoot Unity lets you flag (mark) a rapid-acting or a long-acting insulin dose as "not taken" in the Bigfoot Unity App if a dose was recorded but not actually injected. Doses that you flag (mark) as "not taken" do not appear in your Bigfoot Unity Report.

3.2 Daily Profiles (Pages 2-3)

Daily Profile Graphs:

Each box contains a graph of your glucose and insulin history for a single day for up to the last 14 days. Use the icons at the top of the page to identify Sensor and blood glucose Meter readings, the times of rapid- and long-acting insulin doses, any rapid- or long-acting insulin settings updates, and any Glucose or Insulin Alerts you may have received from Bigfoot Unity. These Daily Profiles may help you detect useful trends and patterns.

Note: If you had several events close together in time, there may be overlap of icons. This may make it difficult to see each unique event.

Note: Because Sensor data is reported in your local time, you may see gaps or duplicate Sensor data traces during daylight savings time transitions or traveling across time zones.

3.3 Current Insulin Settings (Page 4)

The date and time for your most recent insulin settings are displayed on the top of the page. The insulin settings information is based on what you and your health care professional have entered in your Bigfoot Unity App. This is the same information that is displayed on your Black and White Caps for use when it is time to take a dose of insulin. Remember that you can choose to turn certain features on or off in your App. For example, turning the Mealtime Insulin and/or Correction Insulin feature off means you will not see that information in your App, on your White Cap, or in the Bigfoot Unity Report.

Long-Acting Insulin Settings:

Your current long-acting insulin settings information, based on settings in your App, will be displayed and includes the long-acting insulin brand name and the suggested Daily Dose.

Rapid-Acting Insulin Settings:

Your current rapid-acting insulin settings information includes the rapid-acting insulin brand name and the suggested dose information. If you take Mealtime Insulin, the number of units for common meals will be displayed based on how you set up Meal Insulin in the App (i.e., 3 different Carb Amounts; Small, Medium, and Large; or Breakfast, Lunch, and Dinner). Similarly, if you take Correction Insulin, the number of suggested units for each glucose range will be displayed.

Notes:

Notes and pictures that you have entered in the App will be displayed.

3.4 Help and Support

If you need help, you can contact Bigfoot Customer Care using any of the following:

Phone: (551) BIGFOOT or (551) 244-3668
Web: support.bigfootbiomedical.com

3.5 References

1. International Diabetes Center. About the Ambulatory Glucose Profile (AGP). http://www.agpreport.org/agp/about. Accessed April 28, 2021.
2. Battelino et al. Diabetes Care. 2019;42(8):1593-1603. Available at: https://care.diabetesjournals.org/content/42/8/1593.long. Accessed April 28, 2021.
3. International Diabetes Center. Ambulatory Glucose Profile (AGP) Reports. http://www.agpreport.org/agp/agpreports. Accessed April 28, 2021.

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