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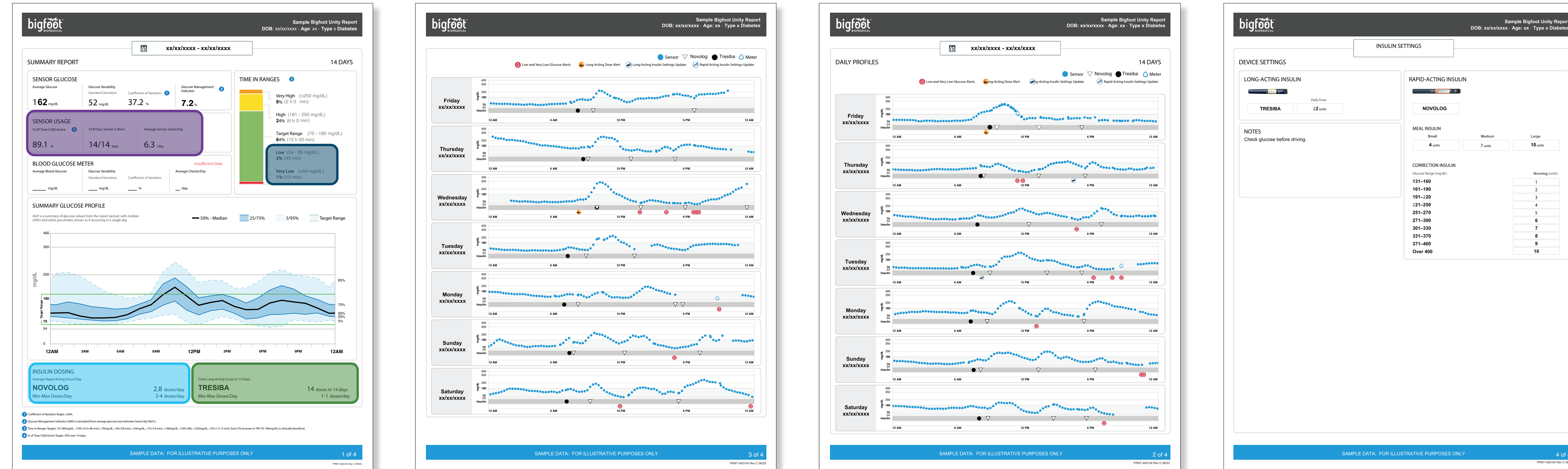
INTRODUCTION

The Bigfoot Unity[®] Diabetes Management System is an FDA-cleared smart pen cap system incorporating CGM data, real-time alerts, and clinician-directed dose recommendations for individuals using multiple daily injections. The Bigfoot Unity Report (Report) provides clinicians with detailed information into their patients CGM metrics and system engagement over the previous 14 days, including long-acting and rapid-acting dosing patterns and sensor usage. Clinicians may extract important insights from the Report to help provide coaching recommendations to the patient or identify patients in need of insulin titration.

The real-world data of hundreds of patients suggest that the Bigfoot Unity Report can be used to identify behaviors in need of attention and inform patient coaching opportunities. These behaviors may be important to address first, prior to titration. Use of the Bigfoot Unity Report leverages the ability of the Diabetes Care and Education Specialist (DCES) to address coaching and behaviors first, and then refer to prescriber to focus on dosing.

This project proposes a structure to systematically review data to help efficiently and comprehensively support people with diabetes using the Bigfoot Unity System.

THE BIGFOOT UNITY REPORT



CONCLUSION

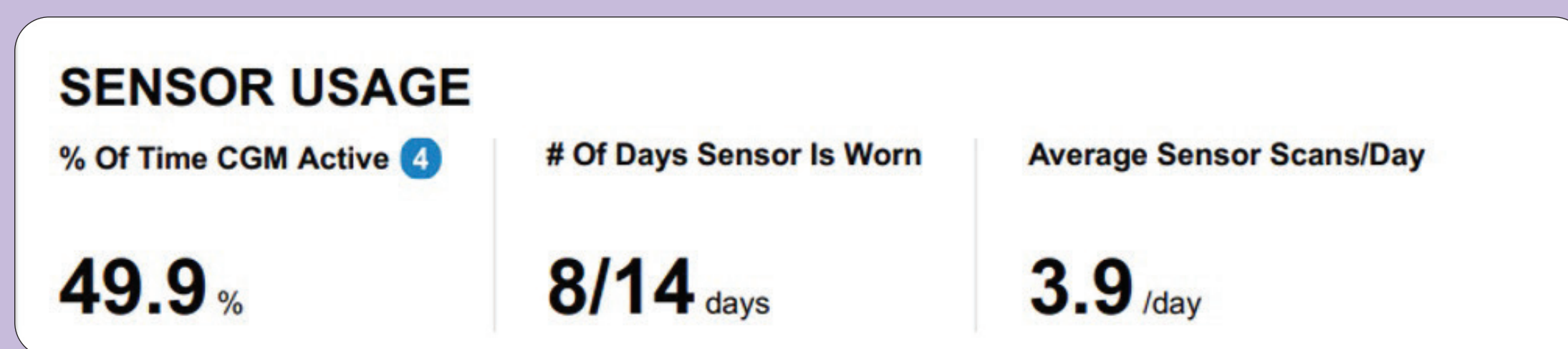
As new technologies become adopted by patients, the DCES must stay up to date on these technologies. The DCES role is to collaborate with the patient—in tandem with prescribers—to ensure the right technology is leveraged to its full potential to meet the individualized needs of the patients using MDI and CGM. The Bigfoot Unity Report helps the DCES excel in this role.

Using the framework described to investigate the Bigfoot Unity Report, the DCES can glean insights into patient behavior related to the patient's glucose and insulin dosing trends. Based on these insights, the DCES can have patient-centered conversations about insulin dosing behaviors, glucose and care management practices and provide individualized coaching. The combination of dosing adherence, dose timing and glucose patterns in a single report arms the DCES with data-driven conversations to focus directly on highest priority needs. Whether reinforcing diabetes basics, or individualizing care practices to best meet the patient where they are, the DCES can address behavior FIRST and then refer to a prescriber for titration of insulin doses to therapeutic levels. Using the Bigfoot Unity Report and a systematic method to review the data, the DCES has data to actively support meaningful behavior change in their patients on MDI and CGM.

Author Disclosures: S.V., E.O, and J.J. are full time employees of Bigfoot Biomedical, Inc. Funding: This project was funded by Bigfoot Biomedical Inc.

SENSOR USAGE	
Investigate	Coaching Opportunities
<p>Is the patient wearing a sensor regularly? How many days was the sensor worn?</p>	<ol style="list-style-type: none"> Understand sensor use patterns, including challenges: <ol style="list-style-type: none"> Access to sensors (i.e., cost, coverage, other) Questions related to how to use/place a sensor Sensor wear issues (e.g., adhesive, knocked off) Ask about monitoring glucose when not using a sensor: <ol style="list-style-type: none"> Fingerstick glucose with Bigfoot Unity Meter Fingerstick glucose with other meter Ask about patient's thoughts on value of CGM therapy.
<p>Is sufficient sensor data being captured? Are there gaps at consistent times of day?</p>	<ol style="list-style-type: none"> Educate patient on importance of scanning every 8 hours to avoid gaps in their sensor data. (e.g., scan when wake up, before meals, and at bedtime) Value of glucose monitoring in day-to-day management. Importance of glucose monitoring with Meter, if not using CGM.

Example



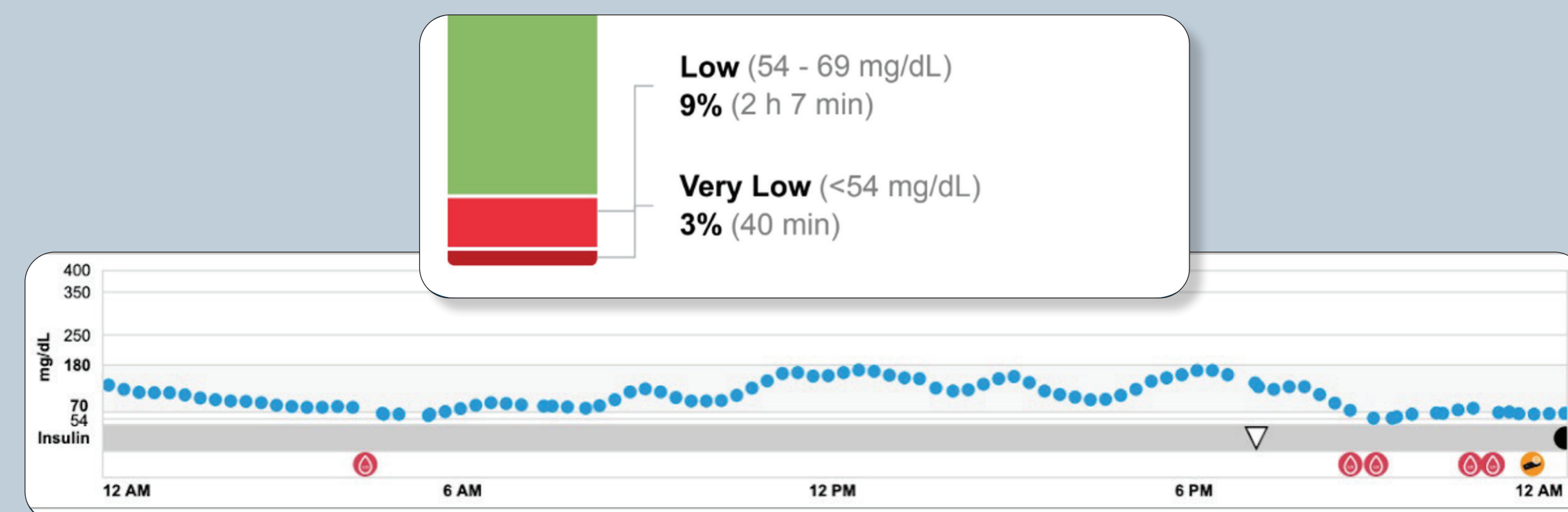
Patient wore a sensor 8 out of the previous 14 days. Less than 50% of available data was captured. When wearing a sensor, patient scans frequently enough to capture data.

DCES Coaching Opportunity

- Plan to have an open discussion on sensor wear and using CGM.
- Discuss any challenges with sensor access or questions on sensor placement or adhesive challenges.
- Reinforce value of glucose monitoring in day-to-day management of diabetes.

MANAGING HYPOGLYCEMIA	
Investigate	Coaching Opportunities
<p>Does percent time low and percent time very low meet the established ADA Standards of Care guidelines?</p>	<ol style="list-style-type: none"> Ask about low glucose patterns. Inquire if any precipitating factors related to low glucose (e.g., extra dosing of insulin, exercise, illness, missed meals). Teach about signs and symptoms associated with low glucose and assess risk for hypoglycemic unawareness. Explain risks related to low glucose, including treatment education. Discuss fear of hypoglycemia.
<p>Are the optional low glucose alerts on and active? Is the patient responding to low glucose alerts?</p>	<ol style="list-style-type: none"> Educate patient on the behaviors of alerts within the Bigfoot Unity System (very low glucose alarm is always on, optional low glucose alarm should be turned on for an earlier alert). Educate on importance of keeping phone in range of sensor to receive alerts (20 ft).
<p>Is the patient experiencing rebound highs after lows?</p>	<ol style="list-style-type: none"> Ask about individual hypoglycemic treatment regimen. Teach about best practices for low glucose treatment, (i.e., the Rule of 15 or use of glucagon).

Example



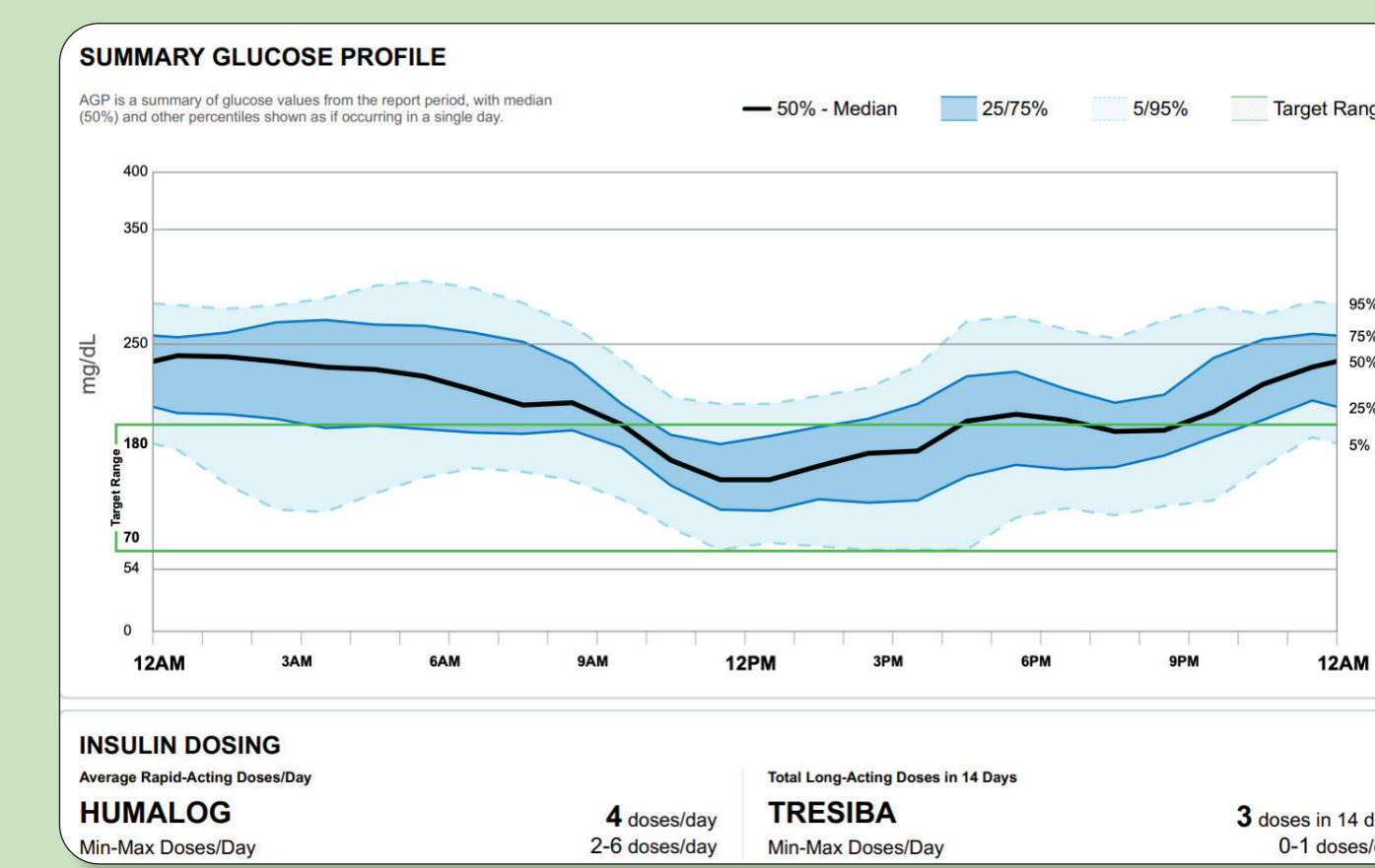
Patient with 9% of time low and 3% very low. Receives multiple low glucose alerts overnight. Patient does not appear to be responding to low glucose alerts, as lows last for an extended amount of time. Eventually, the very low glucose alerts wake the patient up.

DCES Coaching Opportunity

- Discuss glucose goals for diabetes management, specifically definition of low/very low glucose.
- Review the use of low glucose alerts with Bigfoot Unity.
- Educate on importance of keeping alerts on and active, and actions once acknowledging the alert.
- Discuss treatment plans when experiencing low glucose.

LONG-ACTING INSULIN	
Investigate	Coaching Opportunities
<p>Is the patient taking long-acting insulin around the same time every day?</p>	<ol style="list-style-type: none"> Don't forget the basics. Observe a demonstration of pen preparation and injection technique. Reinforce use of the Bigfoot Unity System's Black Cap. Ask about dosing habits: current timing of dosing, morning/night? Discuss the importance of timing of insulin dosing. Address barriers to dosing. (i.e., affordability, leaving pen/pen cap in accessible location). Option to adjust time of dose, to better align with lifestyle (e.g., taking at night—when brushing teeth).
<p>Does the patient have the long-acting dose alert active? Does a long-acting dose follow an alert?</p>	<ol style="list-style-type: none"> Educate on behavior of the long-acting alert, why it is going off, and action. Ability to customize the long-acting alert based on insulin timing.
<p>Is the patient's morning glucose out of range?</p>	<ol style="list-style-type: none"> Consider patient for referral for long-acting insulin titration.

Example



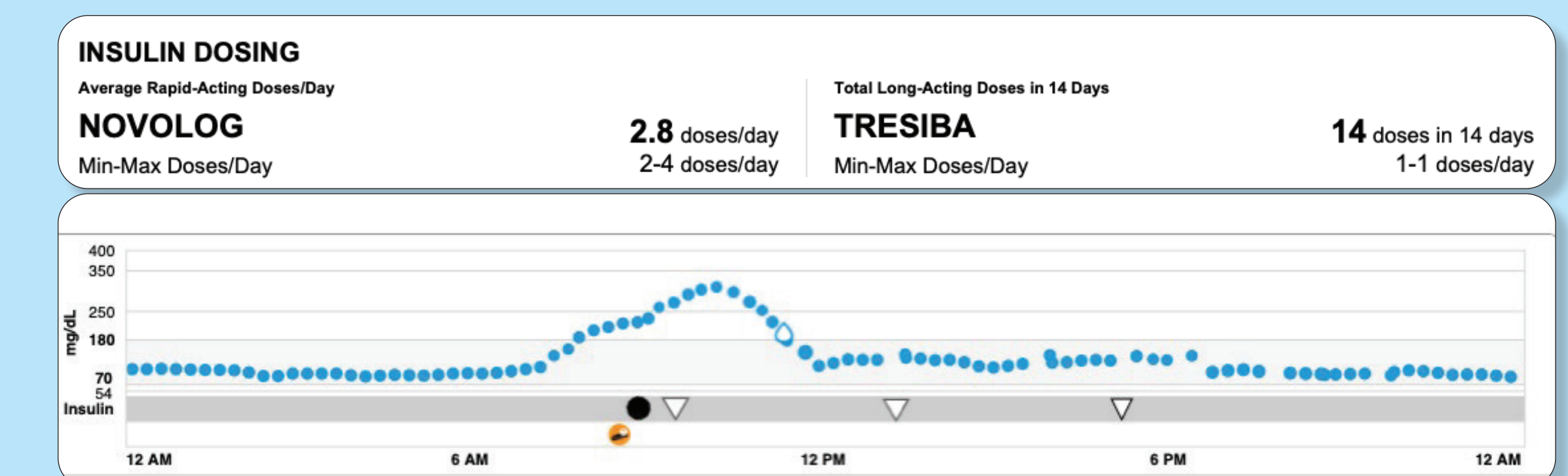
Patient not taking long-acting insulin as prescribed. Took 3 doses in the past 14 days. Noted high glucoses overnight, consistently >180 mg/dL.

DCES Coaching Opportunity

- Understand if any challenges with access or barriers to using long-acting insulin.
- Discuss importance of taking long-acting insulin at the same time every day.
- Option to change dosing to morning or night-time dependent on how best works in current schedule.
- Overview the Bigfoot Unity's long-acting dose alert and discuss to keep on and active to provide a reminder if may have missed a dose.

RAPID-ACTING INSULIN	
Investigate	Coaching Opportunities
<p>Is patient consistently taking rapid acting insulin dose?</p>	<ol style="list-style-type: none"> Don't forget the basics. Observe a demonstration of pen preparation and injection technique. Reinforce use of the Bigfoot Unity System's White Cap. Associate White Cap behavior with another behavior (e.g., One Press Scan & View, Two Press Meal, Three Press Meal+ Decide Dose & Take). Address any barriers to dosing (i.e., carry cap/insulin pen, storage, affordability). Reinforce 2-hr post meal glucose goals (<180 mg/dL). Discuss role of correction dosing, meaning and use.
<p>Is the timing of the rapid acting dose late?</p>	<ol style="list-style-type: none"> Educate on importance of taking rapid-acting insulin before 'taking first bite.'
<p>Is patient's postprandial glucose in range?</p>	<ol style="list-style-type: none"> Discuss relationship of insulin dose to carb intake (more carbs...more insulin) Consider patient for referral for rapid-acting insulin titration.

Example



Patient taking rapid-acting insulin ~3 doses/day. Two-hour post-meal glucoses >180 mg/dL. Glucose is rising prior to dose, indicating possible late dosing.

DCES Coaching Opportunity

- Discuss use of rapid-acting insulin, and best practice of dosing prior to meals.
- Discuss meal option dosing, and if appropriate to patient (breakfast, lunch and dinner (fixed) or small, medium or large (variable)).
- Educate on use of Bigfoot White Cap and steps prior to dosing: action to press buttons on White Cap to the view "meal + correction" screen.
- Overview concept of correction insulin, meaning and use of White Cap for correction dosing when not eating a meal.