

endo.digital



endo.digital Platform Web User Manual (For Personal Use)

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In the US: For in-vitro diagnostic use only

endo.digital

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Rx Only



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DreaMed Diabetes Ltd. reserves the right to change or improve its products and accompanying instructions without specific notice of changes or improvements.



NOTE: This user manual is subject to periodic review, update and revision.

The safety, reliability and performance of this product can only be ensured under the following conditions:

- The product has been used according to the accompanying operating instructions.
- All updates, extensions, readjustments, changes or repairs have been carried out by DreaMed Diabetes' authorized representatives.
- Improper use or repair of this product, faulty maintenance, unauthorized service, damage or alteration by anyone other than DreaMed Diabetes may result in malfunction.



NOTE: To request additional information, ask questions or report safety issues, contact DreaMed's customer service/support, available at the DreaMed Diabetes website: www.dreaMed-diabetes.com/support-dm, in addition to this user manual. You may also contact DreaMed Diabetes and ask for a printed version of the User Manual to be sent to you.

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Chapter 1 – Before You Begin

Viewing Your Recommendations and Data Reports

It is mandatory to read the *User Safety* section on page 7 and to be familiar with the flow of endo.digital before you start using it, as described in *Chapter 2 – About endo.digital* on page 11. The following is a quick description of how to view your diabetes information (Reports and Recommendations) after you have performed the initial setup steps, which are described in *Chapter 3 – First Steps* on page 18.

Viewing Reports

You can view the diabetes data collected by your diabetes devices in endo.digital by clicking the **Reports** tab, as described on page 28. These reports also show a variety of analytics that provide useful information about the collected data.



NOTE: The **Reports** tab appears in endo.digital for all types of users.

Viewing Insulin Pump Settings Recommendations

Insulin pump users can see your personalized insulin treatment optimization recommendations from your HCP by clicking the **Recommendations** tab, as described on page 20.

endo.digital and your HCP use the data collected from your devices to provide these personalized insulin treatment optimization recommendations. Recommendations may include personalized diabetes management tips (found in comments) and suggested changes to the following:

- Basal rate.
- Carbohydrate ratio.
- Correction factor.



NOTE: The **Recommendations** tab does not appear in endo.digital for people who have not been started on an insulin pump treatment plan in endo.digital.






Using This User Manual

This user manual contains valuable information about using endo.digital. To help you find the information that you need, you can use the table of contents at the beginning of this manual. There is also a glossary of terms on page 46.

Symbols and Concepts Used in This Manual

The following table contains symbols and concepts used in this manual.

Table 1 – Symbols and Concepts Used in This Manual

Symbol	What It Means
	Manufacturer.
	Manufacturing Date.
Rx Only	For prescription use only.
	Note – A note provides helpful information.
 Caution	Caution – A caution notifies you of a potential hazard which, if not avoided, may result in minor or moderate injury or damage. The caution includes the precaution that should be taken to avoid the hazard.
 WARNING	WARNING – A warning is a statement that alerts you to the possibility of injury, death or other serious adverse reactions associated with the use or misuse of endo.digital.

User Safety

Indications for Use

endo.digital Platform

endo.digital Platform is intended for the management of diabetes by people with diabetes and their healthcare providers in order to report, upload, log, track, share, monitor and review their data using web and mobile applications. endo.digital Platform also enables communication between people with diabetes and their healthcare providers as well as among healthcare providers.

endo.digital Platform enables the healthcare provider to use endo.digital Algorithm for treatment recommendations as described below and prescribe endo.digital Bolus Calculator for patient use.

Before You Begin	About DreaMed endo.digital	First Steps	View Recommendations and Reports	Account Management	FAQs	Glossary	Appendices
----------------------------------	--	-----------------------------	--	------------------------------------	----------------------	--------------------------	----------------------------

endo.digital Algorithm

endo.digital Algorithm is a decision-support software intended for assisting healthcare professionals in the management of their patients with diabetes who monitor their glucose levels using continuous glucose monitor (CGM) and/or Self-Monitoring Blood Glucose (SMBG) meter; and use any of the following insulin types as their therapy to manage glucose levels via subcutaneous injections or continuous sub-cutaneous insulin infusion (CSII; insulin pump) reported either manually or automatically:

- Long acting insulins (for injections only)
- Short acting insulins:
 - Rapid acting analogs (for injections and insulin pump according to manufacturer indications for use)
 - Regular human insulin (for injections only)

endo.digital Algorithm is intended to be used for patients with:

- Type 1 diabetes over the age of 6 using an insulin pump or subcutaneous insulin injections.
- Type 2 diabetes over the age of 10 who use subcutaneous insulin injections.

endo.digital Algorithm is indicated for use by healthcare professionals when analyzing CGM, SMBG and/or insulin delivery data to generate recommendations for optimizing a patient's insulin treatment plan for basal therapy and/or bolus therapy and/or glucose targets; without considering the full clinical status of a particular patient. endo.digital Algorithm does not replace clinical judgement.

Contraindications

- endo.digital is not intended to send recommendations directly to patients without initially being reviewed and approved by an HCP.
- endo.digital Algorithm is not recommended for patients that change their concomitant glucose-lowering therapies or alter their current therapy dose while using the endo.digital device. Since endo.digital only analyzes the insulin dosing history data and assumes all other elements that affect glucose levels are stable, the effect of changing or altering the dose of other glucose-lowering therapies will not be taken into consideration by endo.digital. This could result in a false conclusion about the changes to the patient's insulin treatment plan and may lead to potential harm.
- endo.digital is not recommended for pregnant women. endo.digital has not been tested in this population.
- endo.digital is not intended for use with patients who use automated insulin delivery systems (for example, *closed-loop*, *artificial pancreas*). See Table 3 for a list of the contraindicated devices.

- endo.digital Algorithm is not intended for use with patients who use insulin(s) other than the types indicated above. endo.digital hasn't been tested with other types of insulins. Using endo.digital with other types of insulin may lead to potential harm.
- endo.digital Algorithm is not recommended for patients who have changed their insulin type within the last 21 days. Since endo.digital only analyzes the current plan, the effect of changing the insulin type during period for analysis is not taken into consideration. This could result in a false conclusion about the changes to the patient's insulin treatment plan and may lead to potential harm.
- endo.digital algorithm is not intended for use with patients treated with intravenous (IV) insulin injections, or a combination of insulin injections and/or IV insulin and insulin pump therapy. Since endo.digital analyzes the insulin dosing history, it assumes a certain insulin delivery methodology as per the physician settings of the patient profile. Using endo.digital in the above manner could result in a false conclusion about the changes to the patient's insulin treatment plan and may lead to potential harm.

Contact your HCP if you are not sure if you are an appropriate candidate for endo.digital.

Potential Harms

endo.digital leverages historical glucose and insulin data, transmitted from a Diabetes Management System (DMS) to endo.digital, in order to recommend changes to a patient's insulin pump settings. The recommendations of endo.digital are presented to you through a DMS and are bounded by the indications for use and the contraindications. Thus, there are risks associated with the use of endo.digital within the contraindications, as well as risks related to the cybersecurity, data integrity and infusion of insulin through the patient's insulin pump. These general harms may include:

- Hyperglycemia
- Ketosis
- Diabetic Ketoacidosis (DKA)
- Mild hypoglycemia
- Severe hypoglycemia
- Data confidentiality
- Data availability
- Data integrity

This user manual provides information regarding the safety features incorporated into endo.digital to help avoid the harms detailed above. Please follow the instructions in this manual to further reduce the risks of these harms.

General Cautions

- 1 Contact your HCP if you have any questions or concerns and in particular if you:
 - Do not understand the recommendations.
 - Think the recommendation is not appropriate for you.
 - Experience large changes in your glucose control after implementing the recommendations (for example hypoglycemia or hyperglycemia that does not go down).

- 2 endo.digital is not a substitute for, but rather an adjunct to clinical reasoning.
- 3 endo.digital recommendations are based on DreaMed Diabetes' proprietary algorithm, which relies on glucose and insulin data only drawn from the patient's insulin pump, CGM and/or blood glucose meter. Your clinical history and other personal information such as age, gender, other diseases and medications are not considered in the analysis. Therefore, your HCP may consider your clinical history and use his/her professional opinion to modify the recommendations made by endo.digital as necessary before sharing them with you. For example, the following factors are not considered by endo.digital and your HCP may consider them when reviewing the recommendation for you:
 - Age
 - Gender
 - Height
 - Weight
 - BMI
 - A1C
 - Insulin sensitivity
 - Hypoglycemia unawareness
 - High risk or recent history of DKA and/or severe hypoglycemia
 - Glucose toxicity
 - Degree of pump, injections or CGM experience
 - Duration of diabetes diagnosis – honeymoon phase
 - Illness
 - Hospitalization
 - Use of steroids
 - Extreme physical activity
 - Significant change of diet
 - Holidays
 - Other glucose-lowering therapies
- 4 Contact your HCP to receive training about how to use endo.digital. Training consists of reviewing this manual and reviewing the application functions. Do not use endo.digital if you have not received training.
- 5 Let your HCP know if you have not using your CGM properly or if you believe your CGM may be faulty or unreliable.
- 6 endo.digital can provide a recommendation during the start and end of daylight savings time by disregarding the day of the clock change and the day before. At all other times, if the clocks in the insulin pump, CGM and/or blood glucose meter are not aligned, the recommendation may be affected. Therefore, endo.digital should not be used when:
 - An error message appears when downloading the data from the device to the DMS indicating a time difference between the insulin pump, CGM or blood glucose meters and the PC or mobile phone to which you are downloading the data.
 - You traveled to another time zone in the past 21 days.
 - You changed the clock of the insulin pump, CGM and/or blood glucose meter within the past 21 days.

**WARNING:**

Do not use endo.digital when the clocks in the continuous glucose monitoring, insulin pump and/or blood glucose meter are not aligned.

Chapter 2 – About endo.digital

About endo.digital

endo.digital analyzes diabetes data to recommend insulin pump settings (carbohydrate ratio, correction factor and basal plan), as well as suggest personalized diabetes management tips. The suggestions are sent to your HCP who reviews them and then shares them with you through endo.digital.

This user manual provides information for endo.digital Platform (combined with endo.digital Algorithm for insulin injections version 02.05.xx, endo.digital Algorithm for insulin pumps version 01.09.xx, and endo.digital Algorithm Server version 02.01.xx).

The sections below provide a general description of how endo.digital analyzes the data to generate recommendations.

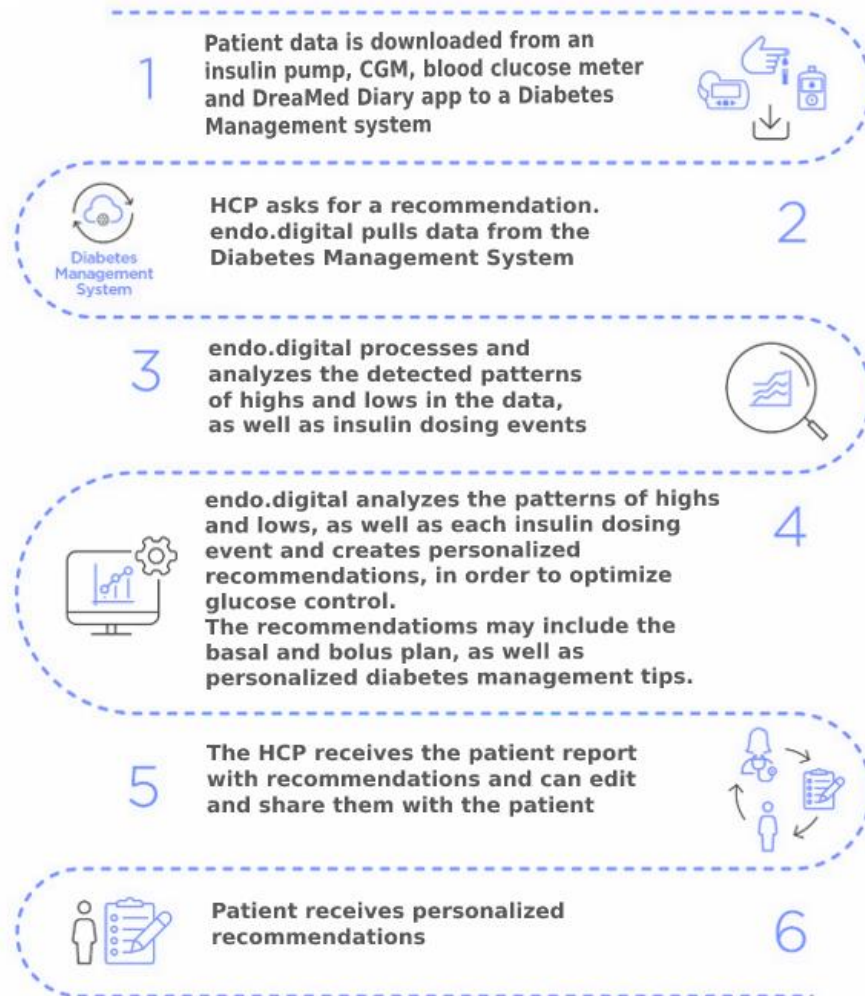


Figure 1 – How endo.digital Works

endo.digital Workflow — Insulin Pump

The following steps describe the general workflow for using endo.digital with an Insulin Pump treatment type.

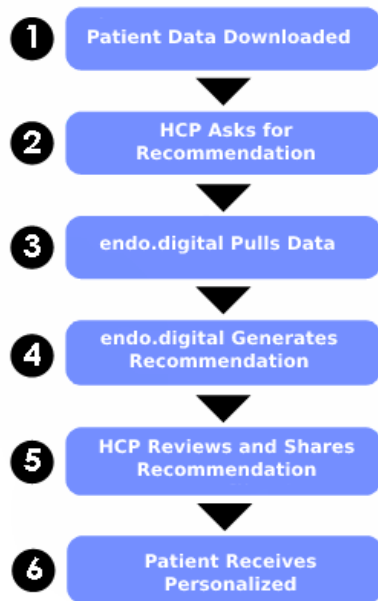


Figure 2 – endo.digital Workflow – Insulin Pump

Step 1 – Devices Data is Downloaded

To begin using endo.digital:

- 1 You must work with a clinic that uses endo.digital.
- 2 Your HCP must start endo.digital for you.
- 3 **Uploading Your Data:** Your data must be electronically uploaded from your diabetes devices through endo.digital Uploader or Tidepool, including your pump, CGM and blood glucose meter.
 - This can be done for you by your HCP in the clinic, if you bring in the devices.

– OR –

- You can do it yourself. If you want to do it yourself, then refer to the endo.digital Uploader or Tidepool Diabetes Management System manual for a description of how to connect your account to your HCP’s account and how to upload your data.



NOTE: endo.digital analyzes pump, CGM and meter data that was uploaded to your account. . No other data sources are used in endo.digital’s analysis.

- After endo.digital has been started by your HCP, he/she can generate new recommendations once every 14 days. If you want to access the endo.digital web or mobile application, you must register for endo.digital.



WARNING:

Do not use endo.digital with data that was downloaded with errors from the devices to the DMS.

Authorized Devices

Table 2 describes the devices that are currently authorized to be used with endo.digital. Quarterly updates to this list are available at www.dreamed-diabetes.com/support-dm.

Table 2 – Authorized Devices for Use with endo.digital

Device Type	Device Manufacturer	Brand Name	
Blood Glucose Meter	All meters with regulatory approval (dependent on location: EU/US/ Rest of the World [ROW])		
Insulin Pump	All insulin pumps with regulatory approval (dependent on location: EU/US/ROW), including those with low glucose suspend or predicted low glucose suspend features.		
CGM	Medtronic Diabetes	Enlite	
		IPro	
		Guardian Sensor 3	
	Dexcom	G4	
		G5	
		G6 (US Only)	
		G7	
	Abbott	Libre	
		Libre 2	
		Libre 3	
		Libre Pro	
	Senseonics	Eversense Continuous Glucose Monitoring System	

Contraindicated Devices

Table 3 describes the devices that are currently contraindicated for use with endo.digital. Quarterly updates to this list are available at www.dreamed-diabetes.com/support-dm.

Table 3 – Contraindicated Devices for Use with endo.digital

Device Type	Device Manufacturer	Brand Name
Automated Insulin Dosing Systems (pump and CGM)	Medtronic Diabetes	MiniMed 670G, 770G or 780G Insulin Pumps with Guardian Sensor 3
	Tandem Diabetes Care	t:slim X2 using Control IQ with Dexcom G6 or G7
	Insulet	OmniPod 5
	Tidepool	Tidepool Loop
	Beta Bionics	iLet



Caution

CAUTION: endo.digital uses CGM and/or blood glucose meter data from approved devices. As part of this approval process, the accuracy of the device was evaluated when used according to the manufacturer's instructions. It is recommended that HCPs advise their patients to calibrate the sensor according to the manufacturer's instructions. Otherwise, a sensor with reduced accuracy may cause endo.digital to analyze inaccurate sensor data.

Training

Before using endo.digital, you must receive training. Training is provided through your HCP. Training consists of reviewing the user manual and receiving an introduction to the app.

Step 2 – HCP Asks for a Recommendation

After your data was uploaded, your HCP can start endo.digital and generate a new treatment plan recommendation.

If you are using a Dexcom sensor, then it needs to be connected once, as described on page 18.

endo.digital pulls data from the DMS and analyzes the last 21 days. endo.digital makes sure that the data is sufficient for a recommendation to be provided. No recommendation is provided by endo.digital until there is sufficient information. [Appendix A](#) describes the minimum amount of data needed to generate a recommendation.



NOTE: Data is pulled from the DMS to endo.digital as is. You cannot edit, change, replace or flag data from analysis.

endo.digital Data Integrity Security and Privacy

endo.digital includes security functions to ensure the safe and secure operation of the product, including the secure transfer of data, safe data storage and backup, thorough quality checks and validation, monitoring and physical and logical access limitations. These security functions are important components of a comprehensive security system.

Regarding safety, privacy, risk analysis and controlled process, endo.digital follows the Health Insurance Portability and Accountability Act of 1996 (HIPAA).



Caution

CAUTION: Implementing and managing a comprehensive and up-to-date security system, customized to individual needs, is necessary and may result in additional specific preventive measures to ensure the secure operation of your site. For example, limiting access to connected devices, use of strong passwords, network security, installing the latest security patches and so on.

Step 3 – endo.digital Analyzes Patterns and Creates Recommendations

endo.digital analyzes your data and creates personalized recommendations. These recommendations aim to treat patterns of high and/or low glucose values that occur throughout the day. The recommendation may include:

- Changes to your basal plan.
- Changes to your carbohydrate ratio plan.
- Changes to your correction factor plan.
- Personalized diabetes management tips.

The recommendations may include the creation of new basal rates, carbohydrate ratios and correction factor periods or modifications of existing ones by changing the values or timing of each period.

endo.digital has safeguards and limits to ensure your safety so that changes that are recommended are not too large.

Step 4 – HCP Reviews and Shares Recommendations

The recommendations of endo.digital are sent to your HCP. Your HCP can review, edit if needed and approve your recommendation.

Step 5 – Patient Receives Personalized Recommendations

After your HCP has approved your recommendations, they are shared with you to be implemented in your insulin pump settings.

You can view these recommendations by clicking the **Recommendations** tab, as described on page 20.

All users can view the diabetes data collected by your devices and various analytical reports of this data in endo.digital by clicking the **Reports** tab, as described on page 28.

Chapter 3 – First Steps

Signing up

First, make sure that you have your **invitation email** from your clinic. Then click the ‘Accept invitation’ link appearing in the invitation. Now you can select your password for your endo.digital account. Remember to check the box for reading and accepting endo.digital terms of use and privacy policy.

Once you selected your password, you may use it for entering the endo.digital web, endo.digital Uploader app and the DreaMed Diary mobile app (for people who are using injections and not insulin pump).



NOTE: Keep in mind that the invitation is valid for 72 hours from the time it was sent to you. If more than 72 hours passed, you should contact your clinic and ask for a new invitation.

Connecting with Dexcom Account

To generate a recommendation, endo.digital must use your glucose levels. If you are using a Dexcom sensor in the United States, you can connect your Dexcom account to endo.digital. This helps your providers provide you with care faster.

When entering endo.digital for the first time, endo.digital asks you if you are using a Dexcom sensor.

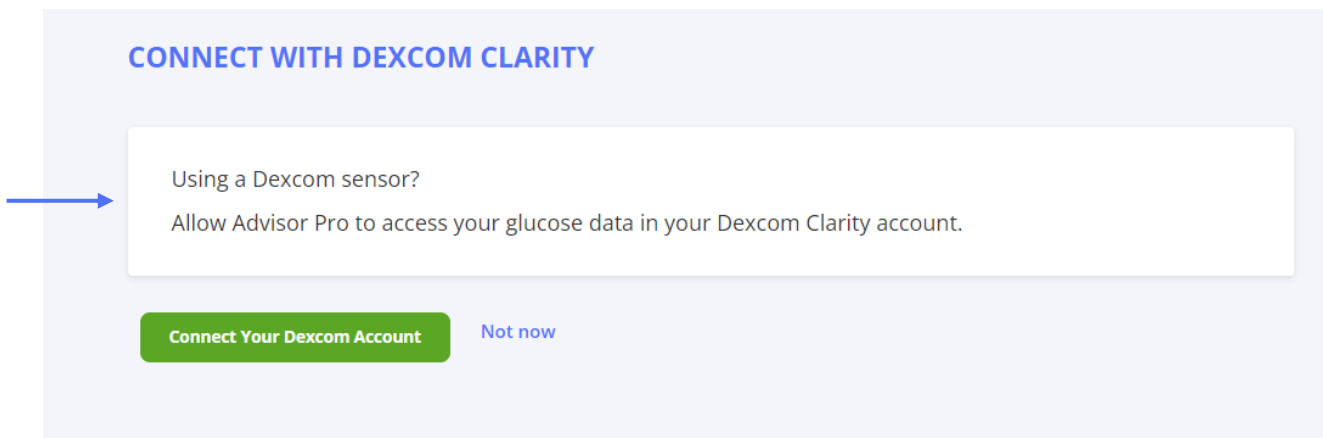


Figure 3 – Connect with Dexcom Account

If you are not using a Dexcom sensor, click the **Not now** link. You can always connect your account later if you start using one.

Click the **Connect Your Dexcom Account** button. Once clicked, you must log in with your Dexcom username and password in order to enable them to share your glucose data with endo.digital.

If you clicked the **Not now** link, you can still connect from your profile.

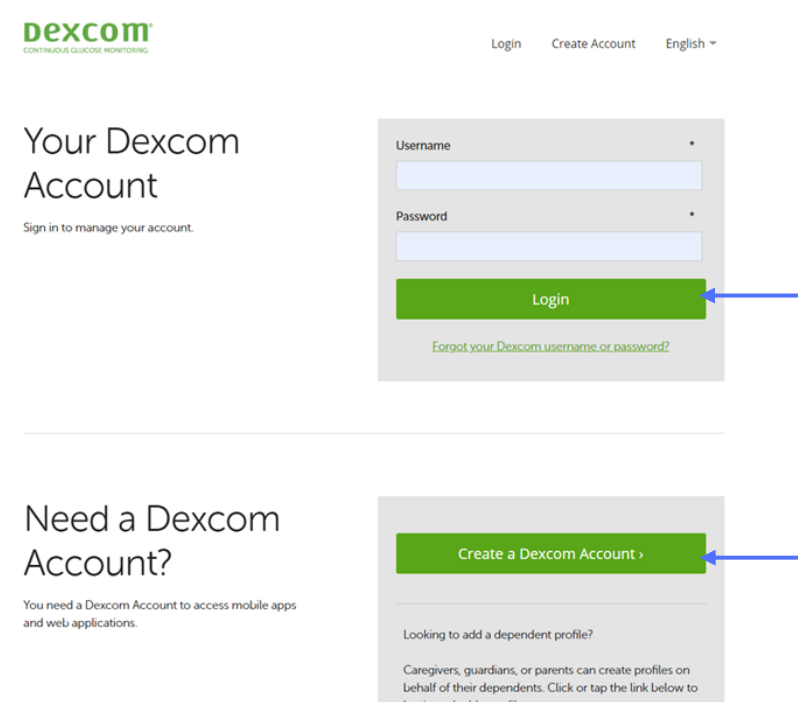


Figure 4 – Log in to Dexcom Account

You have successfully connected. Click the **Continue** button to proceed.

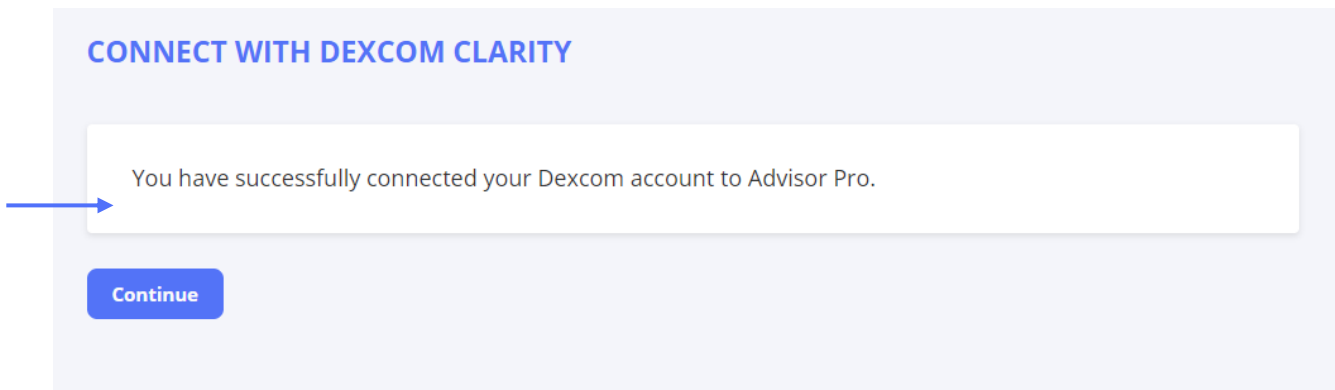


Figure 5 – Successfully Connected to Dexcom

Chapter 4 – View Recommendations and Reports

Accessing endo.digital

Once registered, you can enter the endo.digital web application, either via a desktop or a mobile browser. Go to dreadadvisor.com to access the endo.digital login page.

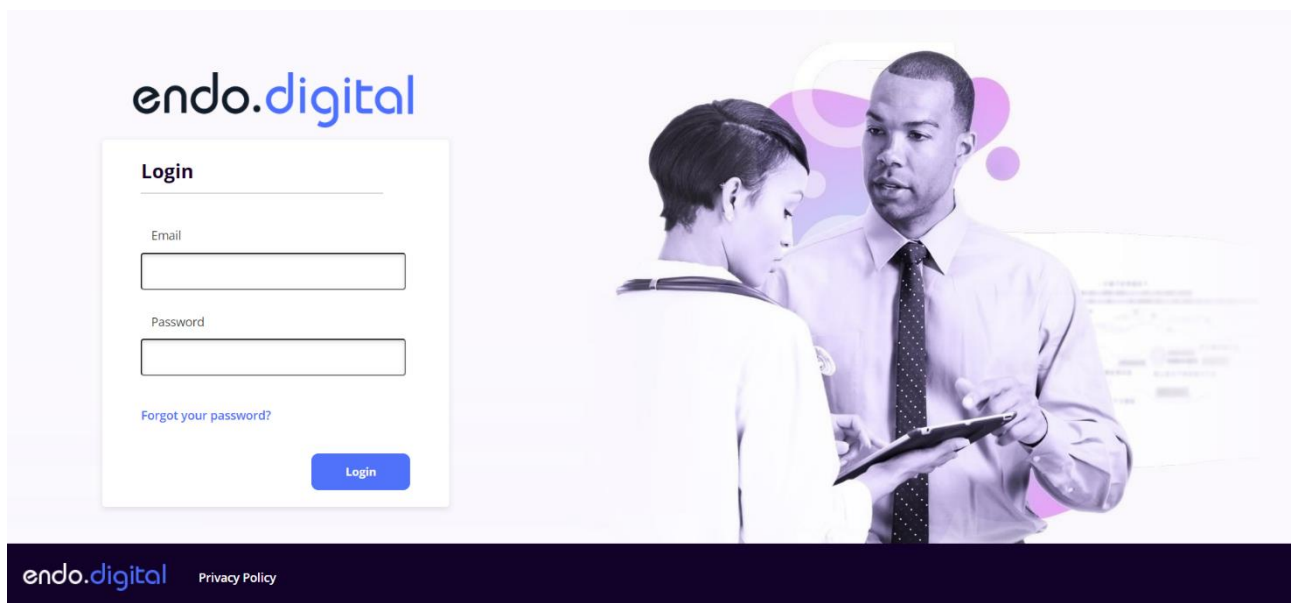


Figure 6 – Desktop View of the endo.digital Desktop Login Page

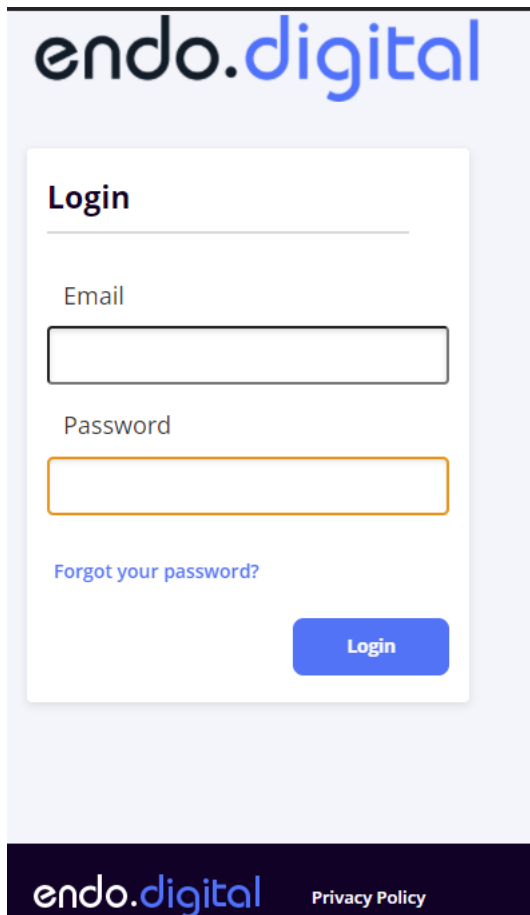


Figure 7 – Mobile View of the endo.digital Login Page

You can now decide to review your recommendations (as described below) or your data reports (as described on page 22).

What to Do If You are Travelling Across Time Zones

Inform your HCP if you were travelling and switching time zones while using endo.digital.

Do **not** use recommendations from endo.digital until 21 days have passed after returning from your trip, unless your HCP is aware that you have travelled and told you otherwise. The impact of switching time zones could lead to recommendations that are not suitable for you.

Viewing Your Recommendations

Insulin pump users can see your personalized insulin treatment optimization recommendations by clicking the **Recommendations** tab, as described on page 20.

endo.digital and your HCP use the data collected from your devices to provide these personalized insulin treatment optimization recommendations. Recommendations may include personalized diabetes management tips (found in comments) and suggested changes to the following:

- Basal rate.
- Carbohydrate ratio.
- Correction factor.



NOTE: The **Recommendations** tab does not appear in endo.digital for people who have not been started on an insulin pump treatment plan by their HCP.

Viewing the endo.digital Recommendation List

After endo.digital has been started for you by your HCP and your first recommendation is ready for you, you can view your recommendations in the endo.digital Recommendations history list. The recommendations are listed by date of recommendation. The first recommendation, labeled *Current*, indicates the latest recommendation received from your HCP. After you receive it, you should review it and implement it in your insulin pump settings. If you think the new settings may not be right for you, contact your HCP first. The recommendation at the top of the list says the word **Current**.

► **To view the current recommendation:**

Click the **View** link in the row that has the most recent date and the word **Current**, as shown below. The following pages describe the displayed recommendations.

ADRIANA DAVIES > Recommendations List

MY RECOMMENDATIONS

RECOMMENDATIONS HISTORY

Date	Recommendations
03/16/2022	View ← Current

Figure 8 – Desktop View of the My Recommendation List Screen

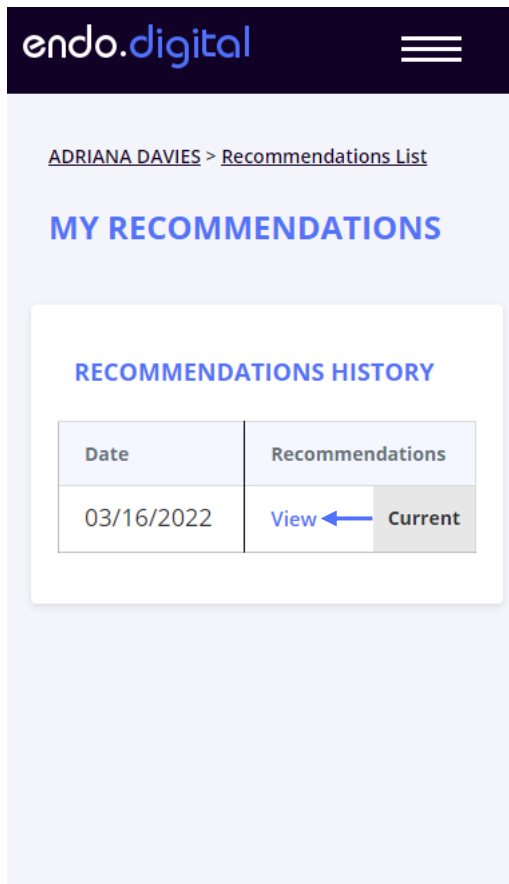



Figure 9 – Mobile View of the My Recommendation List Screen

Personalized Diabetes Management Tips

You may receive personalized diabetes management tips found in the **General Comments** at the top of each report.

[ADRIANA DAVIES_0](#) > [Recommendations List](#) > [Recommendation - 03/16/2022](#)

INSULIN PUMP SETTINGS RECOMMENDATION

ADRIANA DAVIES_0  Print report

RECOMMENDATION BASED ON PERIOD 02/23/2022 - 03/16/2022

On 03/16/2022 your provider recommended that you change your pump settings to the following values:

General Comments

-You are over treating your lows. Eat moderately when treating your lows.

NEW BASAL PLAN SETTINGS

Time	Basal rate (U/hr)
12:00 AM	0.5
06:00 AM	0.7
05:00 PM	1.1
10:00 PM	0.7
Total Units	17.6

Basal Comments

No Comment

Figure 10 – Desktop View of the Insulin Pump Recommendation Screen

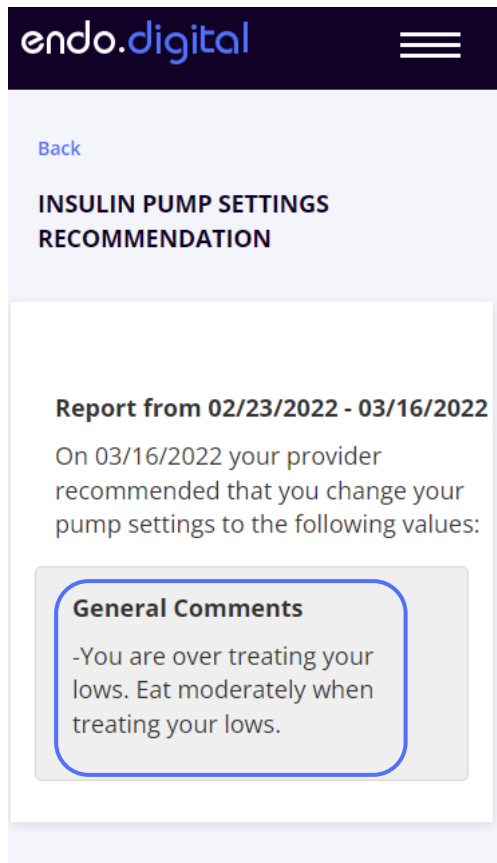


Figure 11 – Mobile View of the Insulin Pump Recommendation Screen

Recommended Insulin Pump Settings

Your HCP may recommend changes to your basal rate, carbohydrate ratio or correction factor settings on your insulin pump. Your HCP may include specific comments for each setting. These are listed next to the relevant section.

The recommended settings are listed according to the time of day.



NOTE: Basal rate units are in Units/hour. Carb ratio units are in grams/Unit. Correction factor units are in mg/dL/Unit.

INSULIN PUMP SETTINGS RECOMMENDATION

ADRIANA DAVIES_0 [Print report](#)

RECOMMENDATION BASED ON PERIOD 02/23/2022 - 03/16/2022

On 03/16/2022 your provider recommended that you change your pump settings to the following values:

General Comments
-You are over treating your lows. Eat moderately when treating your lows.

NEW BASAL PLAN SETTINGS

Time	Basal rate (U/hr)
12:00 AM	0.5
06:00 AM	0.7
05:00 PM	1.1
10:00 PM	0.7
Total Units	17.6

Basal Comments
No Comment

NEW CARB RATIO PLAN SETTINGS (IC RATIO)

Time	Carb ratio (g/unit)
12:00 AM	40
07:00 AM	25
09:00 PM	40

Carb Ratio Comments
No Comment

NEW CORRECTION FACTOR PLAN SETTINGS (INSULIN SENSITIVITY)

Time	Correction factor (mg/dLU)
12:00 AM	120
07:00 AM	80
09:00 PM	120

Correction Factor Comments
No Comment

Figure 12 – Desktop View of the Insulin Pump Recommendation Screen

Report from 02/23/2022 - 03/16/2022

On 03/16/2022 your provider recommended that you change your pump settings to the following values:

General Comments

-You are over treating your lows. Eat moderately when treating your lows.

NEW BASAL PLAN SETTINGS

Time	Basal rate (U/hr)
12:00 AM	0.5
06:00 AM	0.7
05:00 PM	1.1
10:00 PM	0.7
Total Units	17.6

Basal Comments

No Comment

NEW CARB RATIO PLAN SETTINGS (IC RATIO)

Time	Carb ratio (g/unit)
12:00 AM	40
07:00 AM	25
09:00 PM	40

Carb Ratio Comments

No Comment

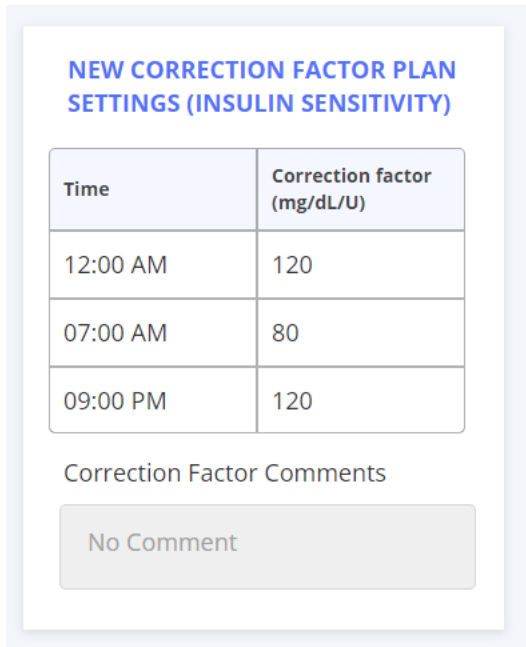


Figure 13 – Mobile View of the Insulin Pump Recommendation Screen

CAUTION: Contact your HCP if you have any questions or concerns and in particular if you:

- Do not understand the recommendation.
- Think the recommendation is not appropriate for you.
- Experience large changes in your glucose control after implementing the recommendations (for example, hypoglycemia or hyperglycemia that does not get better).



Caution



NOTE: You must implement the changes in your pump. The app cannot change any pump settings for you.

Viewing Your Data Reports



WARNING:

The data in these reports is provided for viewing purposes only and should not be used by you to change your insulin treatment plan without first discussing it with and getting the approval of your HCP.

endo.digital allows you to view reports of your data. Do this by clicking the **Reports** tab. After clicking the **Reports** link, your reports will display after approximately 10–20 seconds. The reports show your data from the last 21 days.

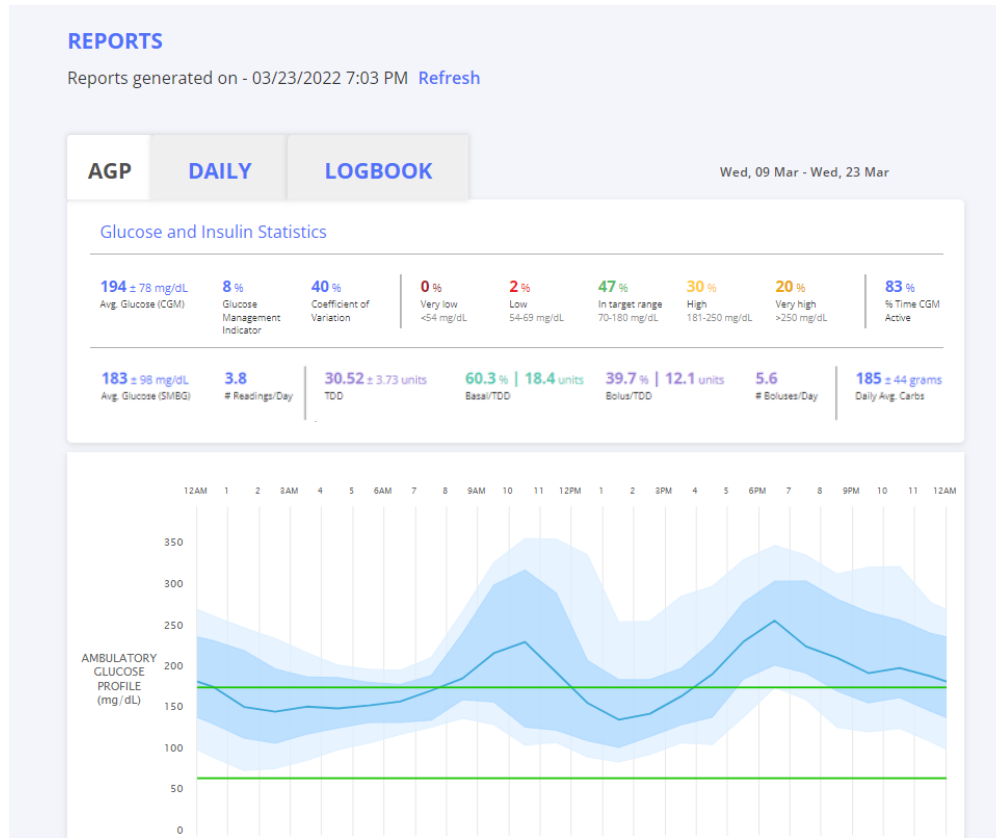


Figure 14 – Your Data Reports

endo.digital provides three reports describing your data:

- An **Ambulatory Glucose Profile (AGP)** and a bolus insulin graph, as well as summary statistics, as described on page 31.
- A **Glucose Daily report** displaying a day-by-day view of your glucose measurements from a CGM and glucometer, as described on page 35.
- A **Logbook report** displaying event-level bolus data (for bolus insulin, carbs and blood glucose), as described on page 39.

You can switch between the **Report** tabs to view the relevant report.

Clock Shift Alert

It is very important that you maintain the clock of your device at the correct time at all times. In some cases, you may change the clock in one device, which may result in a discrepancy in your data, as the glucose time does not match the insulin time.

If endo.digital detects such a clock shift, the report indicates an alert that a clock shift was detected in your data.

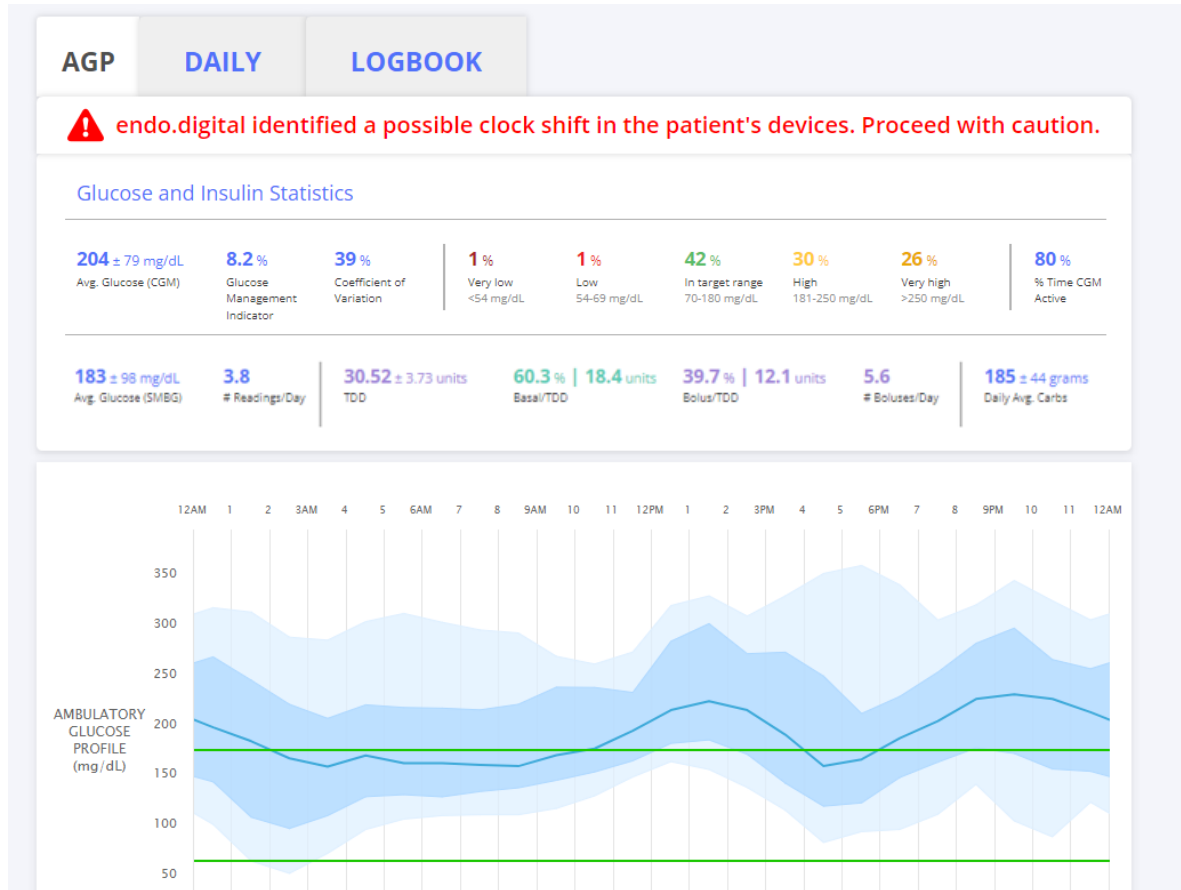


Figure 15 – AGP Report – Clock Shift Alert

Ambulatory Glucose Profile (AGP) Report

The Ambulatory Glucose Profile report provides statistical information of your glucose throughout the day, as well as the amount of insulin delivered via boluses, the current basal plan (insulin pump only) and general glucose profile statistics. This report presents data from the most recent 14 days uploaded to endo.digital.

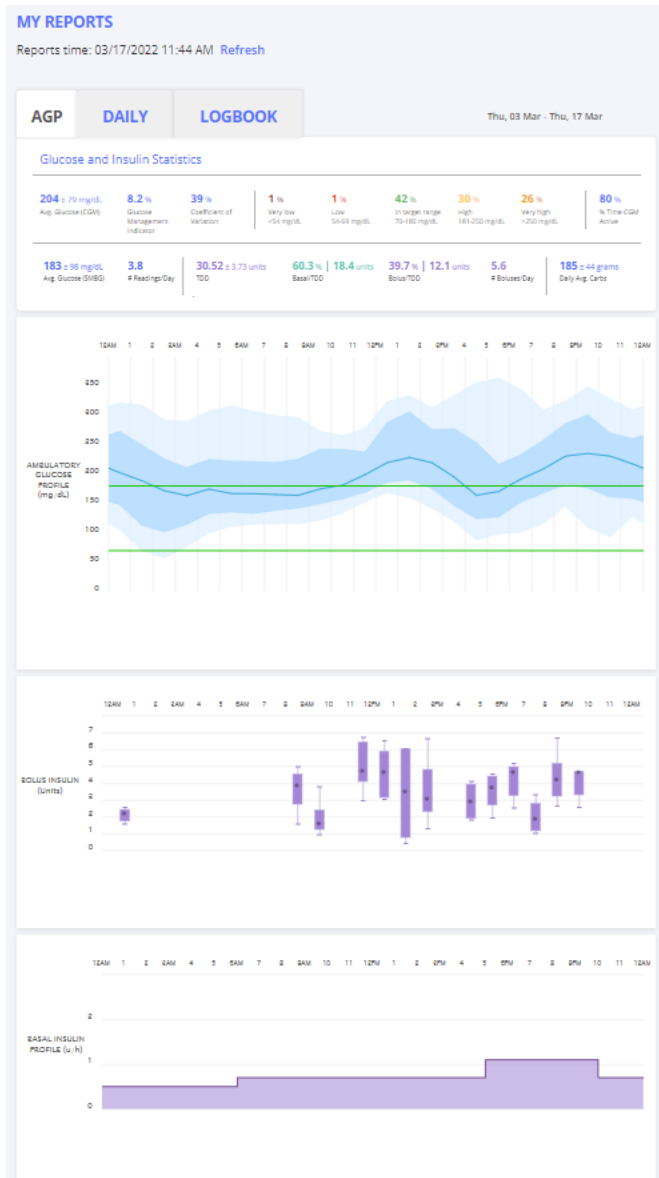


Figure 16 – AGP Report

If no data is displayed, then make sure to upload data from your diabetes devices (as described on page 13) and then click the **Refresh** link at the top of the page.

General Glucose Profile Statistics

The following describes the glucose profile statistics section across the top of the AGP report:

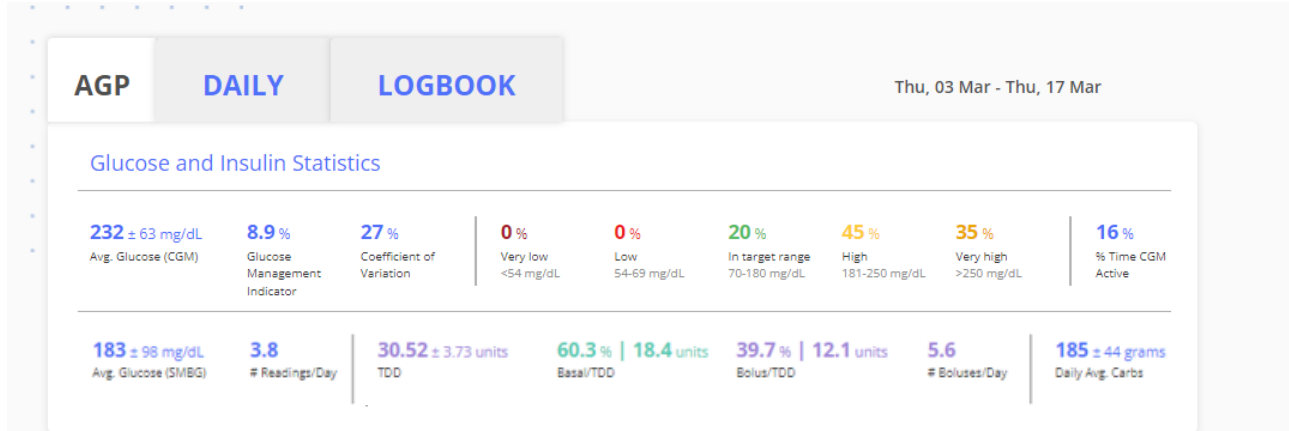


Figure 17 – AGP Report – Statistics Section

- **Average Glucose (CGM):** Represents the mean glucose values from your CGM. The value after the +/- sign represents the standard deviation. Standard deviation indicates the spread of your glucose values. A smaller standard deviation indicates tighter glycemic control (meaning that the values are in a narrower range), while a larger standard deviation may indicate that your glucose levels fluctuate between higher glucose values and lower glucose values. When you keep your glucose levels within your target range, the standard deviation is low.
- **Glucose Management Indicator (GMI):** Estimates your future A1C. It is calculated from the average glucose over the last 14 days.
- **Coefficient of Variation** (also called Glucose Variability): Indicates how far apart glucose values are. Ideally, this value should be a low number, less than or equal to 36% (percent coefficient of variation).
- **Low/Serious Low:** Ideally, you should only be in the **Low** range (under 70 mg/dL) a small percentage of the time and you should not be in the **Serious Low** range (under 54 mg/dL).
- **In Target Range:** Ideally, glucose values should be in the target range. Shows the percentage of device readings within the target range in hours/minutes of a 24-hour day.
- **High/Serious High:** Ideally, you should only be in the **High** range (over 180 mg/dL) a small percentage of the time and you should not be in the **Serious High** range (over 250 mg/dL). Reducing the highs, reduces your A1C over time.
- The **Serious Low, Low, In Target Range, High** and **Serious High** values across the top of the AGP report sums up to 99%-101%, the values range as follow:

Serious Low value includes all the values below 54 mg/dL.

The **Low** value includes all the values between 70-54 mg/dL.

In Target Range value includes all the values between 70-180 mg/dL.

The **High** value includes all the values between 180-250 mg/dL.

Serious High value includes all the values above 250 mg/dL.

Avg. Glucose (SMBG): Represents the mean glucose values from your glucometer. The value after the +/- sign represents the standard deviation. Standard deviation indicates the spread of your glucose values. A smaller standard deviation indicates tighter glycemic control (meaning that the values are in a narrower range), while a larger standard deviation may indicate that your glucose levels fluctuate between higher glucose values and lower glucose values. When you keep your glucose levels within your target range, the standard deviation is low.

Readings / Day: The average number of glucometer readings per day.

TDD (Total Daily Dose): Represents the mean daily insulin intake from all the reported bolus and basal values. The value after the +/- sign represents the standard deviation. Standard deviation indicates the spread of your daily insulin intake.

Basal / TDD: The percent of the basal insulin from your average daily total daily dose and the average amount of the basal insulin.

Bolus / TDD: The percent of the bolus insulin from your average daily total daily dose and the average amount of the bolus insulin.

Boluses / Day: The average number of boluses delivered per day.

Daily average carbs: The average number of carbs consumed per day

AGP Graph

For people with diabetes, tables show the goal as both a percentage of device readings and in hours/minutes of a 24-hour day that are the targets. The closer to the target, the better:

- Hover over a specific time to view the information corresponding to that data point. Move the cursor to the left or right to view other data points.
- Define a rectangular region to zoom-in by left-dragging a mouse. To return to normal view, click **Reset Zoom**.

Ambulatory Glucose Profile

Daily glucose profiles are combined to create a one-day (24-hour) picture from your last 14 days. Ideally, the horizontal color areas across the graphs should be between the two horizontal green lines (which is the target range):

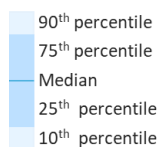


Figure 18 – Ambulatory Glucose Profile AGP Graph Legend

- **Dark Blue Line:** The median (middle) line shows where one-half of the glucose values are above the line and one-half of the glucose values are below the line.

- Dark Blue:** The dark-blue shaded horizontal area across the graph shows 50% of the glucose values. Ideally, the vertical height of the blue swish across the graph is narrow. This means that 50% of the glucose values are within this range. The more narrow this dark blue range, the better.

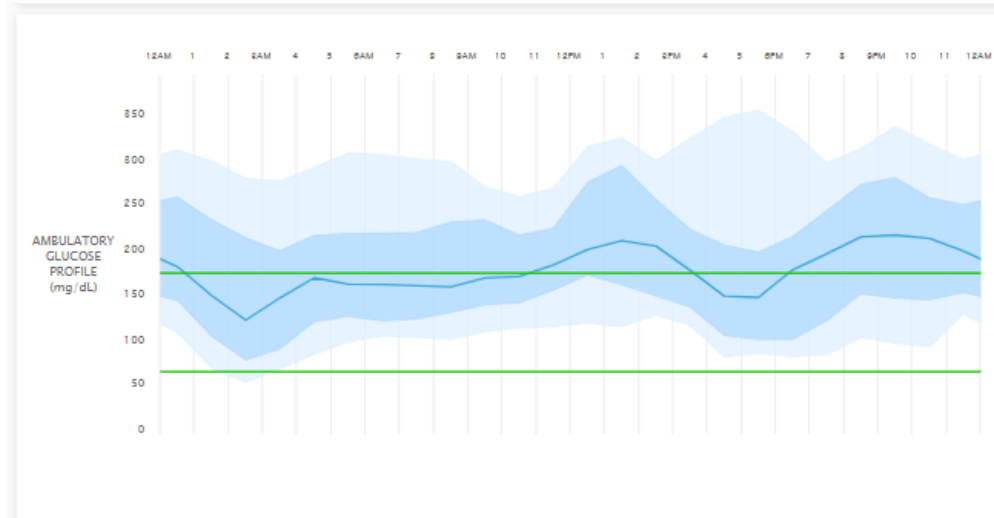


Figure 19 – Dark Blue 50% Glucose Value Mean

- Light Blue:** 10% of the values are above the 90% top line and 10% are below the 10% bottom line. Ideally, the closer the dotted blue lines and the light-blue shaded area are to the dark-blue shaded area, the better. Ideally, the vertical height of this light blue swish across the graph should also be narrow. The narrower this light blue range is, the better.

Bolus Insulin (Units)

This part of the graph shows your boluses from the last 14 days combined into a 24 hours view. A purple box indicates the amount of insulin given during this hour in all the boluses given during the last 21 days. The dark purple dot is the median amount of insulin, meaning that half of your boluses were bigger, and half of your boluses were smaller than this value. The purple rectangle shows the amount of insulin given in 50% of your boluses, and the thin lines indicate the range of the 80% of your boluses, after removing the largest and smallest 10% of the boluses.

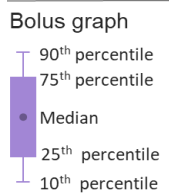


Figure 20 – Bolus Insulin AGP Graph Legend

Basal Insulin Profile

This line represents your current basal profile as defined in your insulin pump.

Daily Report

The Daily report enables you to view daily data for the last 21 days since the report was generated, either as part of a recommendation or when viewing your current data. The report may present the data in one of 3 time periods: daily, 3 days and 7 days. You can navigate the days in the report using the **Next** and **Prev** links above the graph.

The report is divided into sections: blood glucose (including time in range), carbs, insulin, activity, and notes. Activity and notes are available for people who are using injections and the DreaMed Diary app.

Blood glucose

The top shows the daily glucose time within range, according to the common ranges displayed below. Only the daily view includes the time in range section.

The bottom part displays glucose measurements from CGM, marked by the small dots, glucometer measurements and reported blood glucose are marked by the larger dots.

Hovering over the dots will display the glucose value (mg/dL) and time, and in the large dots in addition to the time and value, the source of the blood glucose is also displayed, when the event was reported it will be indicated as manual, and meter when it came from a device.

Meals

The Meals section display the daily meal events you have reported. For pump users, the amount of carbs reported in the bolus calculator will be displayed in grams. For people using injections the meals reported using the mobile app will be displayed by the app's setting:

- Meal estimation – Small/Normal/Large (S/N/L) as reported.
- Fixed meal – will be displayed as Meal (M).
- Carbs counting – Will always be displayed in grams regardless of if you are reporting in exchange units (10g, 15g).

Insulin

The insulin section displays the basal and bolus events.

For pump users the following also applies:

- Basal may appear as scheduled basal or temp basal.
- Site change events will be displayed at of the section
- A dotted line will display the current planned basal profile in use for comparison with the actual basal delivered.
- Hovering over events will display a tooltip with relevant information.

Activity – MDI, Generic

Activity events are displayed with an activity icon, and intensity can be viewed in the tooltip when hovering over it.

Notes

Any notes you have added when adding an event is displayed with a note icon, the content of the note can be viewed in the tooltip when hovering over it.

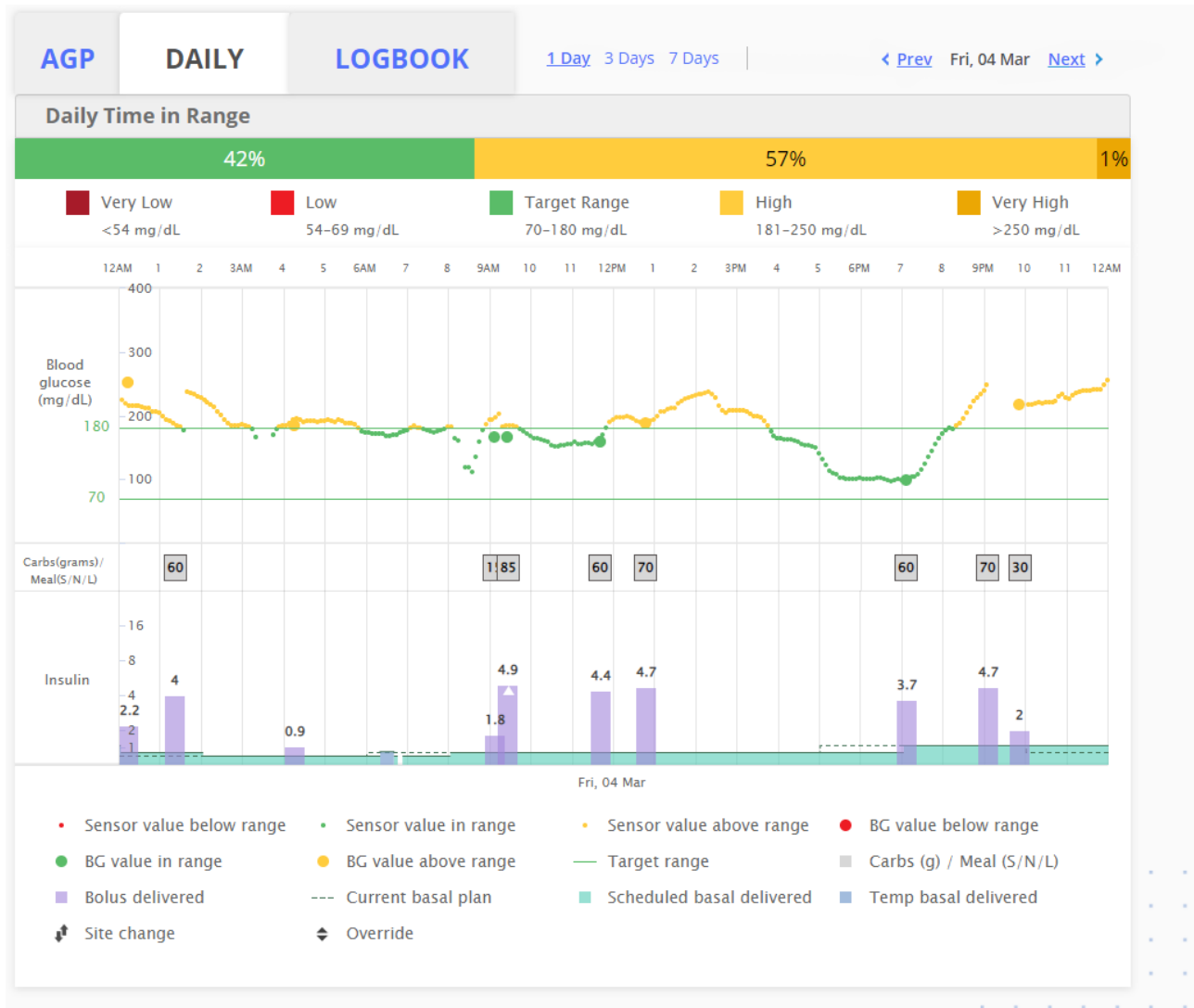


Figure 21 – Daily Report – Pump

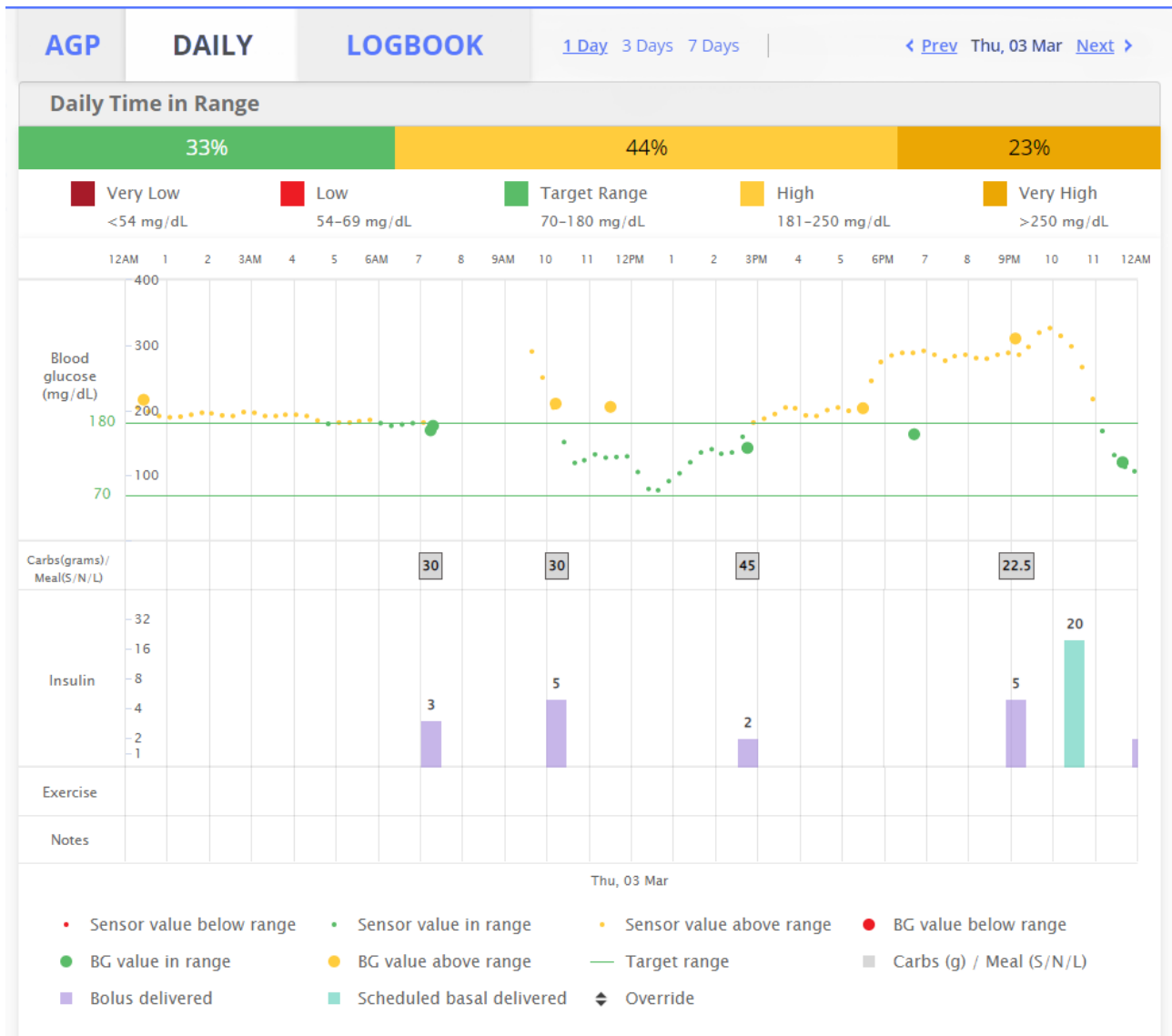


Figure 22 – Daily Report – Injections

You can scroll between days by clicking the **Next** and **Prev** links at the top right of the page.

Logbook Report

The Logbook report enables you to view daily data for the last 21 days.

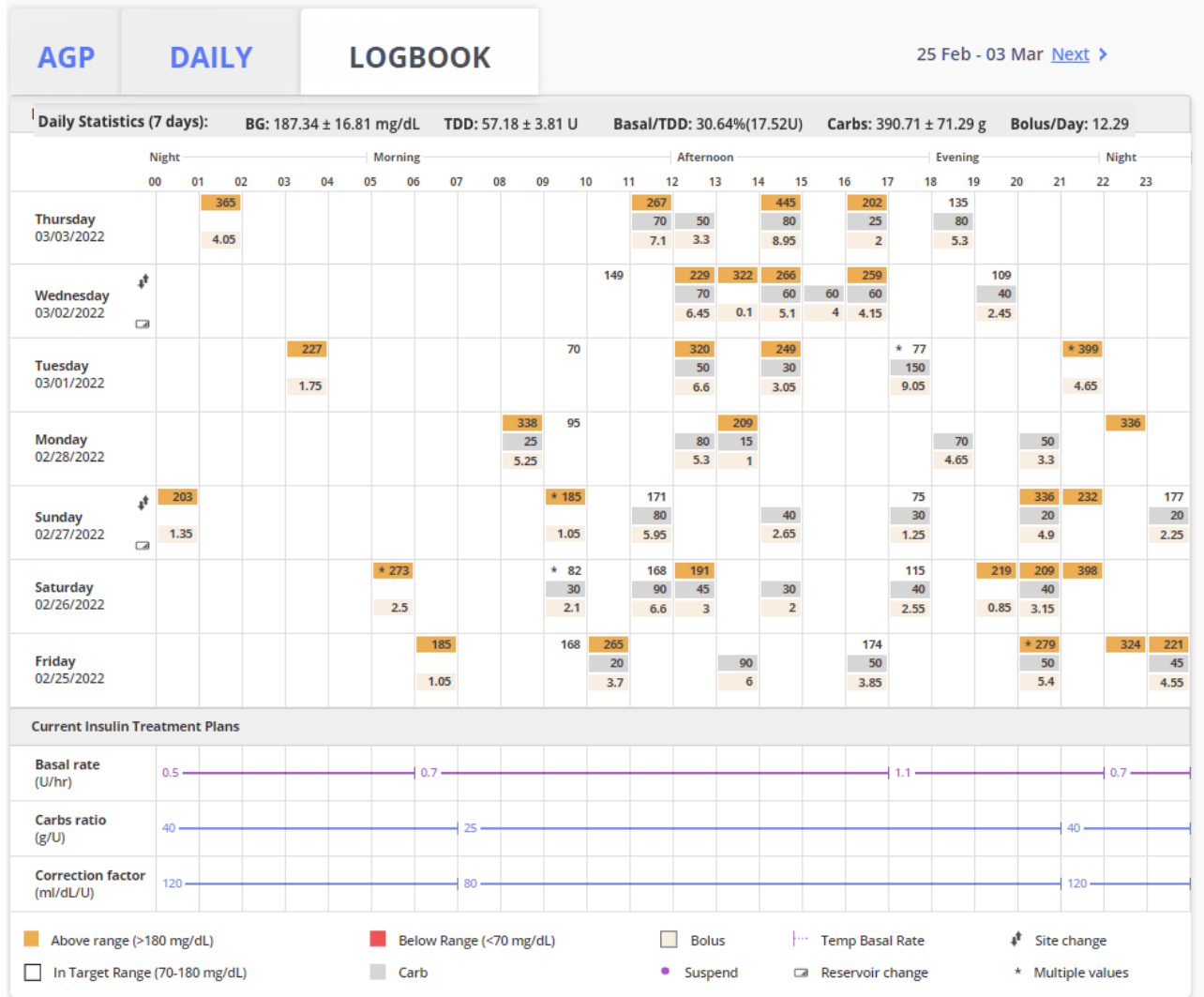


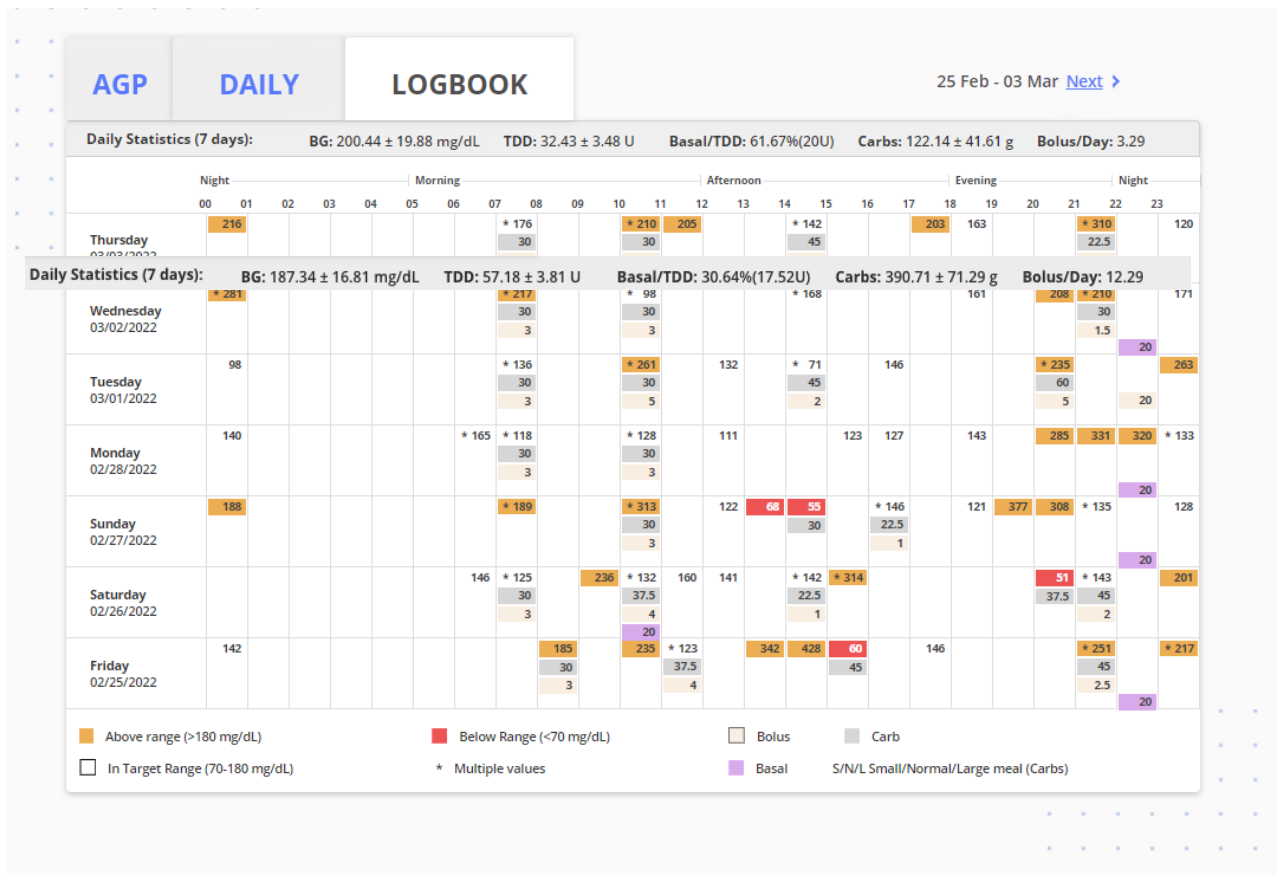
Figure 23 – Logbook Report – Insulin Pump Users

The report lists the glucose, insulin and carbs data aggregated per hour. In addition, the report provides statistics for average glucose, daily amount of insulin and number of boluses –

Basal: The graph of this report appears differently for insulin pump users and for people who have not been started on an insulin pump treatment plan, as shown below. Each day and each hour are represented by a cell. Each cell may contain various indicators that each represent a measurement or an event.

- Glucose Value:** The top bar in a cell represents most extreme glucose value during that hour (mg/dL). The color of this bar represents the range of the glucose value, as follows:
 - Red: Below range <70 mg/dL

- Yellow: Above range >180 mg/dL
- White: Within the target range 70 –180 mg/dL
- **Meals:** A gray bar in a cell shows the total number of carbs reported in that hour (grams) or the meal reported (M) or the meal size reported (S/N/L).
- **Insulin Amount:** A pink bar in a cell shows the total amount of insulin delivered in that hour (units).
- **Basal Suspend and Temporary Basal Events:** For insulin pumps users, a purple bar may appear at the bottom of a cell to indicate a basal suspend or a temporary basal event.
- Various icons may appear in a cell to indicate that an event occurred during that hour. A legend is provided at the bottom of the graph representing each event, such as site change reservoir, change and so on.
- **Current Insulin Treatment Plan** – For people who use insulin pump, this area displays the current settings of the basal plan, carbs ratio and correction factor as they are currently defined in your insulin pump.



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Figure 24 – Logbook Report – Non-Insulin Pump Treatment Plan Users

You can scroll between 7-day views by clicking the **Next** and **Prev** links at the top right of the page.

Chapter 5 – Account Management

Reset Password

Should you forget your password, click **Forgot your password?**

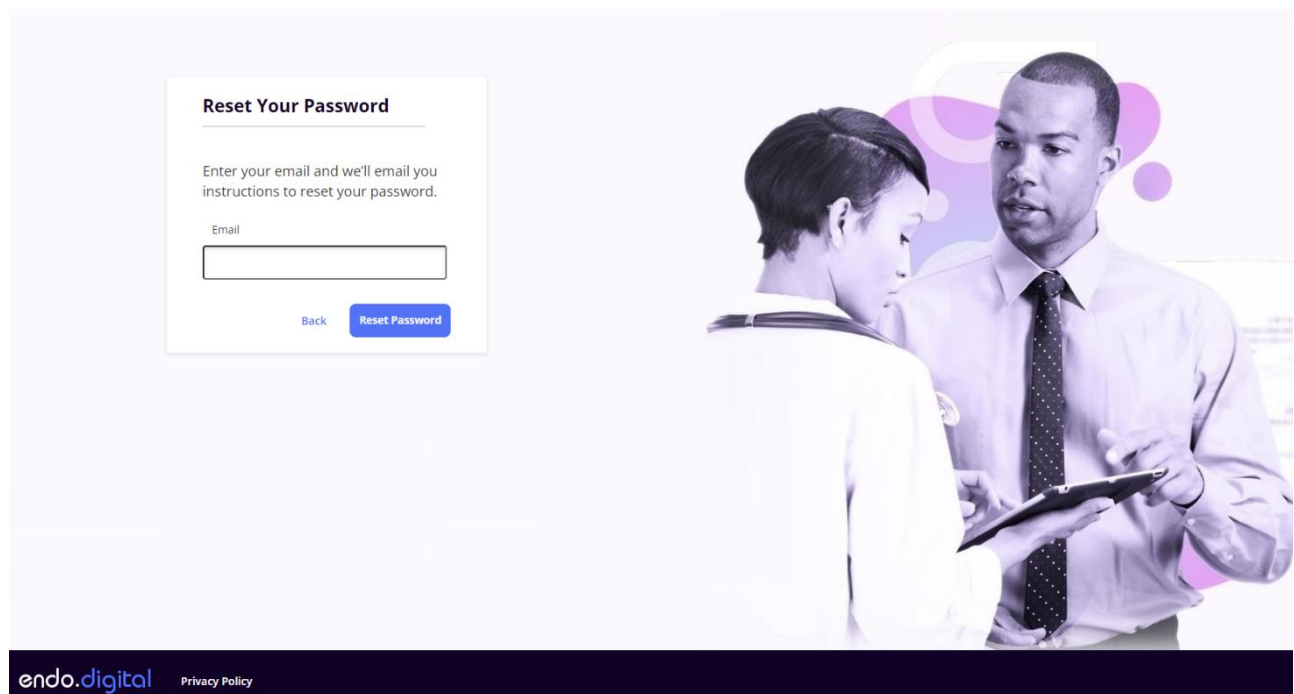


Figure 25 – Reset Password Screen

Then, enter your email address and click **Reset Password**.

In your email inbox, open the reset password email sent from DreaMed. In the email, click **Reset Password**. You are redirected to the *Choose Password* page. Enter your new password and confirm it. Click **Reset**.

Profile

You can always access the endo.digital profile screen.

In the profile screen, you can:

- Read endo.digital's terms of use and privacy policy.
- Log out of the system.

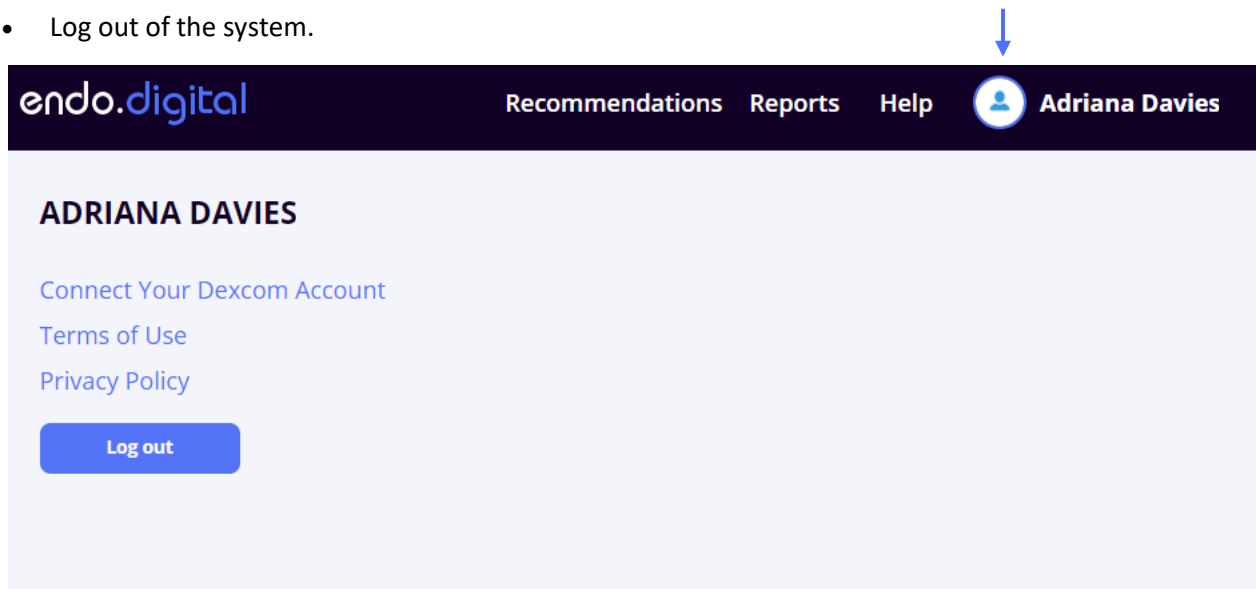


Figure 26 – User Profile Screen

Automatic Log Off

If the system is idle for 15 minutes, it automatically logs off and you must log in again.

For security reasons, at any given time, each user can only be logged in from one computer or tablet. When you log in from another device, the first device automatically logs off.

Account Locked

If you type an incorrect password five consecutive times, your account is locked. Click the [Reset Password](#) link to unlock an account.

Connecting to a Dexcom Account

If you want to connect your Dexcom account to endo.digital, you can always do so by clicking your profile.

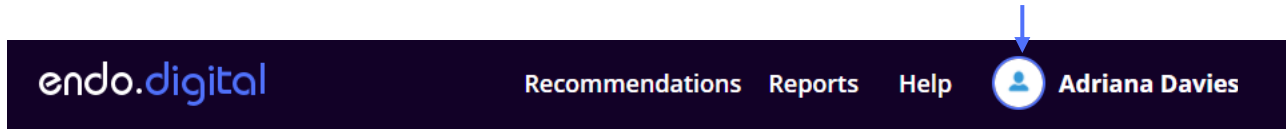


Figure 27 – Accessing the Profile Screen

Then, select **Connect Your Dexcom Account**.

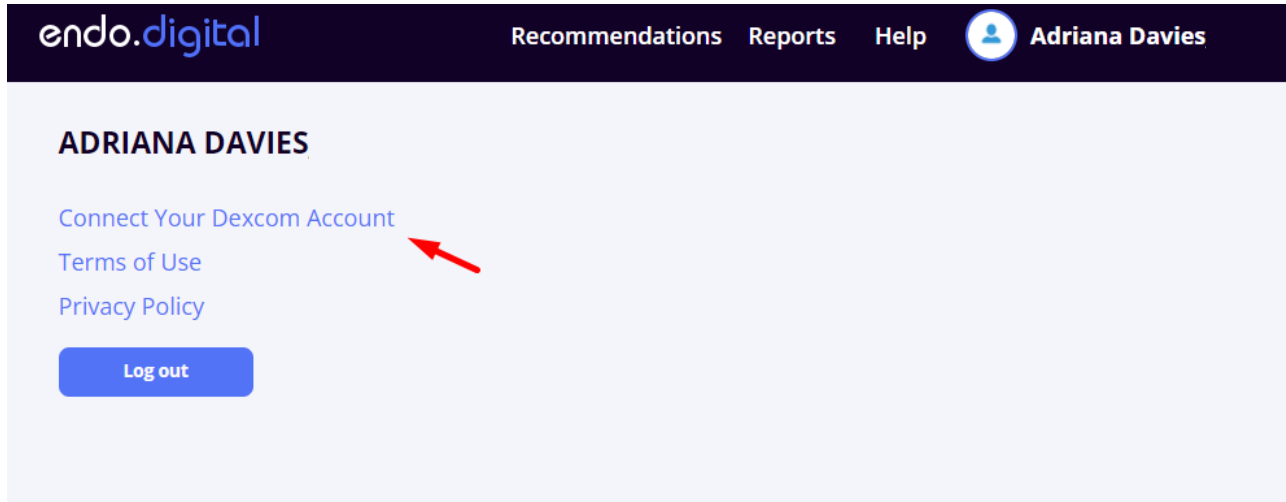


Figure 28 – Connecting with a Dexcom Account from the Profile Screen

If you want to disconnect your Dexcom account from endo.digital, click your name and then select **Disconnect**.

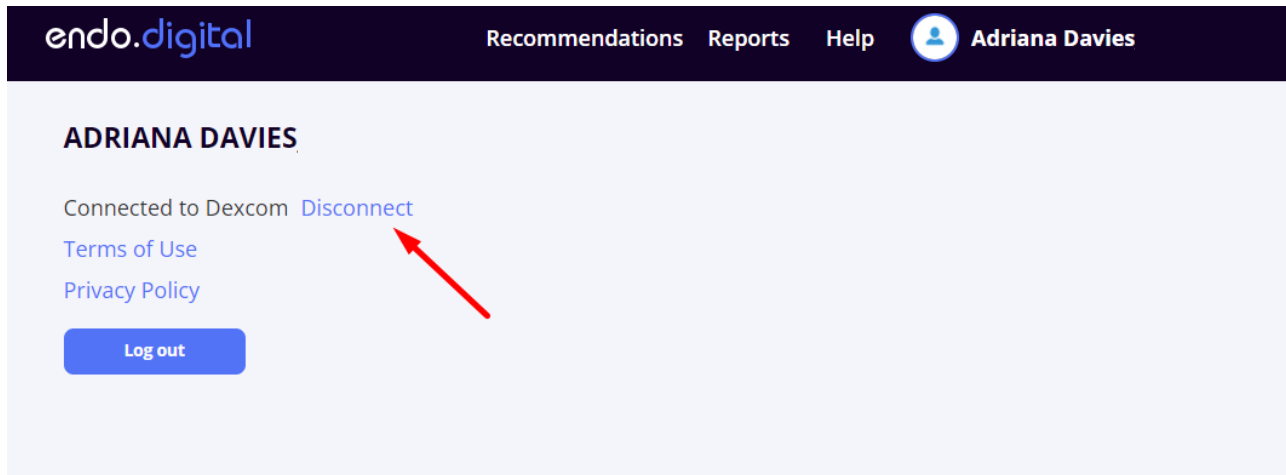


Figure 29 – Disconnecting a Dexcom Account

Chapter 6 – Frequently Asked Questions

What should I do if my invitation has expired?

Contact your clinic team and ask them to re-send you an invitation.

How do I know if a new recommendation is ready for me?

You can go to dreamedadvisor.com and look for your most recent report and look at the report date. Select **View Report** to see the recommendations on the most recent report.

Can I remove data from the uploaded data that is transferring to endo.digital?

No, you cannot edit, change, replace or flag any data from the analysis.

What are the pump settings that endo.digital can recommend changing?

endo.digital recommendations may include the following pump settings:

- Basal rate plan
- Carbohydrate ratio plan
- Correction factor plan

Note that the system does not recommend changing the bolus calculator glucose target plan or the active insulin time.

If I have more than one program in my pump, which program is endo.digital recommending changing?

endo.digital provides recommendations for changes only to the active plans (basal and bolus) that were in use at the time you uploaded your pump data.

Can I change my pump settings during the 21-day period?

Yes, endo.digital considers the actual amount of insulin that was delivered during the 21-day period. It looks at the actual basal rate, including the temp/suspend basal rate as well as the parameters of the bolus calculator used to deliver the bolus.

Does endo.digital actually change my pump settings for me?

No, the app does not make the changes. You must program the changes in your pump.

What do I do if I do not want to accept the recommendations?

You are in charge of your health. If you have questions or disagree with your HCP's recommendation, you should contact him/her for clarification.

Can my HCP add comments for specific plans (basal, carbohydrate ratio or correction factor)?

Yes, your HCP can add specific comments for each plan.

What are the personalized diabetes management tips that endo.digital advises?

The personal diabetes management tips are messages that endo.digital generates that may help you avoid hypoglycemia and hyperglycemia events (lows and highs).

Will my HCP know if I implemented the recommendations?

No, your HCP cannot know if you implemented the recommendations.

Chapter 7 – Glossary

Table 4 – Glossary

Term	Definition
Active insulin	Amount of insulin that has been delivered and is still having an effect in lowering the blood glucose.
Active insulin time	The time (measured in hours) it will take until the bolus of insulin stops affecting the blood glucose. This time is used by the insulin pump's bolus calculator in any given bolus.
Basal insulin	Insulin that is continuously delivered by the pump to meet individual insulin needs between meals and during sleep.
Basal plan	A set of one or more basal rates that covers a full-day period.
Basal rate	The amount of continuous basal insulin that is programmed in the pump to automatically deliver per hour.
Bolus	Amount of insulin that is given by the pump to treat high glucose levels and/or carbohydrate intake, rather than the basal rate, which describes a continuous flow of insulin throughout the day.
Bolus Calculator Glucose target	Indicates the value toward which the glucose level is corrected. This target is used in the bolus calculator for correcting high glucose levels.
Carbohydrate Ratio (CR)	Indicates the number of grams of carbohydrates that are covered by one unit of insulin. The ratio is used by the bolus calculator for treating carbohydrate intake.
CGM	A Continuous Glucose Monitoring device, which is the sensor that continuously measures the interstitial glucose levels.
Correction Factor (CF)	Indicates how much one unit of insulin reduces glucose levels. This factor is used in the bolus calculator for correcting high glucose levels.
DKA	Diabetic Ketoacidosis, which is a life-threatening complication of diabetes mellitus.
Glucometer	Any blood glucose meter.
Glucose sensor	Any interstitial glucose meter.
ISF	Insulin Sensitivity Factor. In this manual, we use the term CF instead of ISF.
Pump	Any insulin pump.
TDD	Total Daily Dose, which represents the total amount of insulin given per day across all days in the investigated period.
U-100	Type of insulin in which every milliliter (ml) of liquid contains 100 units of insulin.
U-200	Type of insulin in which every milliliter (ml) of liquid contains 200 units of insulin.

Appendix A – Data Requirements for endo.digital

endo.digital requires that within the analyzed 21 days, there are at least 12 valid days. Table 5 shows what data is needed to count as a valid day for endo.digital analysis.

Table 5 – endo.digital Valid Day Definition

Data Source	Requirement
Continuous Glucose Monitoring OR Blood Glucose Meter	At least 67% of continuous glucose monitoring sensor readings per day according to the sensor’s sample rate (meaning, for a sensor that presents glucose readings every 5 minutes, at least 192 samples are required and for one that presents glucose readings every 15 minutes, at least 64 samples). At least 3 BG measurements a day that are separated from each other by at least 210 minutes.
Basal Rate	At least 1 basal record.
Bolus	At least 1 bolus record.

In addition, endo.digital requires at least three records from the bolus calculator.

The table below shows what insulin pump settings are required for endo.digital analysis.

Table 6 – endo.digital Insulin Pump Settings

Data Source	Requirement
Basal Rates [u/h]	Each rate in the basal plan is within 0.025–3 u/h.
Carbohydrate Ratio [gr/u]	Each value in the carbohydrate ratio plan is within 3–70 gr/u.
Correction Factor [mg/dL/u]	Each value in the correction factor plan is within 10–280 mg/dL/u.
Bolus Calculator Targets [mg/dL]	Equal to or below 150 mg/dL.

Appendix B – endo.digital Data Analysis

endo.digital uses the raw data input to detect patterns and events for analysis. The detection process is based on the following methodologies and assumptions:

- Continuous glucose monitoring data filtration: endo.digital may ignore some of the continuous glucose monitoring and/or blood glucose meter values in cases where the algorithm considers them non-physiological or in cases that the blood glucose meter value contradicts the continuous glucose monitoring value at a given time stamp.
- Hypoglycemia/euglycemia/hyperglycemia patterns – endo.digital uses the following thresholds to detect patterns of hypoglycemia and hyperglycemia:
 - Hypoglycemia threshold is under 70 mg/dL (3.9 mmol/L).
 - Mean daily euglycemic level is 154 mg/dL (8.5 mmol/L).
 - Hyperglycemia threshold is over 180 mg/dL (10 mmol/L).
- Insulin dosing decisions events by the pump user: The algorithm uses the insulin pump and continuous glucose monitoring/meter data to characterize each insulin dosing event. In cases where there is no carbohydrate information available for a bolus delivery, endo.digital uses the insulin pump settings to estimate if carbohydrates were consumed at the time of a bolus.

Pro integrates safeguards into its recommendations to ensure the safety of the pump user. First, endo.digital will not issue recommendations beyond what is considered **valid insulin pump settings**, as detailed in the table above. Second, the table below presents the particular safeguards and limitations used in recommending a change to the insulin pump settings.

Table 7 – endo.digital Limitations When Recommending Changes to a Patient's Insulin Pump Setting

Variable Name	Limitation	How is It Used in the endo.digital Analysis Process?
Basal Plan	Limitation on the highest hourly basal rate that can be recommended by endo.digital	Current Basal Rate Upper Limit: +20% of the current hourly basal rate based on the patient's current insulin pump settings plus $0.05 \left[\frac{U}{Hour} \right]$
	Limitation on the lowest hourly basal rate that can be recommended by endo.digital	Current Basal Rate Lower Limit: -20% of the current hourly basal rate based on the patient's current insulin pump settings minus $0.05 \left[\frac{U}{Hour} \right]$
	Additional limitations depending on the patient TDD*	<p>endo.digital has a second layer of limitations that are dependent on the patient's TDD, whereas the recommended basal rates should be within the range of:</p> <ul style="list-style-type: none"> • TDD Upper Limit: 150% of the hourly average basal rate calculated from the patient's TDD, whereas the hourly average basal rate is the $TDD/24$. • TDD Lower Limit: 50% of the hourly average basal rate calculated from the patient's TDD, whereas the hourly average basal rate is the $TDD/24$. <p>These limitations override the Current Basal Rate Upper/Lower Limits stated above.</p>
	Potential maximum number of basal periods	24 per day
CR Plan	Limitation on the highest CR value that can be recommended by endo.digital	+ 30% of the current CR value based on the patient's current insulin pump settings plus $1 \left[\frac{gr}{U} \right]$
	Limitation on the lowest CR value that can be recommended by endo.digital	-30% of the current CR value based on the patient's current insulin pump settings minus $1 \left[\frac{gr}{U} \right]$
	Potential maximum number of CR periods	8
CF Plan	Limitation on the highest CF value that can be recommended by endo.digital	+30% of the current CF value based on the patient's current insulin pump settings plus $1 \left[\frac{mg}{dl*U} \right]$
	Limitation on the lowest CF value that can be recommended by endo.digital	-30% of the current CF value based on the patient's current insulin pump settings minus $1 \left[\frac{mg}{dl*U} \right]$
	Potential maximum number of CF periods	8

* If the patient's current basal rate settings are outside of TDD Upper/Lower Limits, endo.digital changes these settings towards the acceptable range only if there is support for such a recommendation by the glucose levels of the patient. For example, if the patient had a TDD of 30 units a day and in one basal period a basal rate of 1 u/h (for example, the TDD Upper/Lower Limits are 0.93/0.31, respectively) and there is evidence that it should be decreased to reach the TDD Upper/Lower limits, then endo.digital may suggest decreasing it to 0.8 u/h (20% less than the prior rate, which is the maximum % change that can be recommended for basal rate). If there is no clinical reason to decrease or even if there is clinical evidence to increase basal rate, then endo.digital does not recommend a change.



Notes:

- The values in Table 7 are not configurable.
- The insulin pump has discrete possible values for basal, CR and CF. The percentage of change is limited as described above and rounded to the nearest possible discrete value while not exceeding the limits. However, in a case where the endo.digital algorithm recommends a maximum percentage of the allowed change, which results in a smaller change than the insulin pump's resolution, the final change is the insulin pump's resolution, meaning more than the limits described above.
- For example, if the patient has a basal rate of 0.05 and the basal rate in the insulin pump can be adjusted in increments of 0.05 and endo.digital recommends increasing the basal rate by 20%, it may increase to 0.1 – still within the specifications described in Table 7.
- The endo.digital system always uses the actual amount of insulin that was delivered (basal and bolus) and, if this data is available, the actual values of CR and CF at the time of each bolus for its analysis over the 21-day period. However, the recommended changes in pump settings are always calculated as a percentage of the most recent settings that were in the pump at the upload time.

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