

endo.digital Platform HCP User Manual



ENDO.DIGITAL WAS DEVELOPED BY -



DreaMed Diabetes Ltd.

14 Kaplan st., The Endocrinology Center, Schneider Children's Medical Center, Petah Tikva, 4920235, Israel

Phone - +972-52-3166684 Email – info@dreamed.ai Website - www.dreamed.ai

Contact information for support:

In an event of any product fault, malfunction, performance changes, deterioration, complaints and/or incidents contact DreaMed Diabetes professional team:

P.O Box 3271, Petah Tikva 4952701, Israel

Email: support@dreamed.ai

Website: https://dreamed-diabetes.com/support-dm/

In the US: For in-vitro diagnostic use only









© Copyright 2023 DreaMed Diabetes Ltd. All rights reserved.

No part of this publication may be reproduced, stored in a retrieval system or transmitted in any form by any means, electronic, mechanical, photo reproductive, recording or otherwise without the express prior written permission of DreaMed Diabetes Ltd.

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

TABLE OF CONTENTS

CHAPTER 1 – BEFORE YOU BEGIN	7
Using This User Manual	7
Acronyms and Abbreviations	
User Safety	9
CHAPTER 2 – ABOUT ENDO.DIGITAL	14
endo.digital Data Integrity Security and Privacy	14
Signing Up a Patient	15
CHAPTER 3 – ENDO.DIGITAL WORKFLOW — INSULIN PUMP	16
Step 1: Patient Data is Downloaded	17
Step 2: HCP Asks for a Recommendation	18
Step 3: endo.digital Pulls Data from Various Data Sources	18
Step 4: endo.digital Generates Recommendations	19
Step 5: HCP Reviews and Shares Recommendations	22
Step 6: Patient Receives Personalized Recommendations	23
CHAPTER 4 – ENDO.DIGITAL WORKFLOW — MDI	2 4
Step 1: Patient Data is Downloaded	25
Step 2: HCP Asks for a Recommendation	26
Step 3: endo.digital Pulls Data from Various Data Sources	26
Step 4: endo.digital Generates Recommendations	27
Step 5: HCP Reviews and Shares Recommendations	31
Step 6: Patient Receives Personalized Recommendations	31
CHAPTER 5 – FIRST STEPS	32
Register	32
Logging In	32
View the Training Video	34
Add a Patient to the Clinic	34
Patients List	40
Get Familiar with Your Patients List	41
Start a New Patient on endo.digital	42
Setting a Patient's Initial Plan — For MDI Plans	47
CHAPTER 6 – REVIEW AND SHARE RECOMMENDATIONS	61
Upload devices data to endo.digital	61
Patient Recommendations List	61
Connecting with a CGM Device Account	64
View Current Data	66
Patient Settings	68
Update patient's MDI plan	69

New Recommendation	72
Preliminary Checks Before Reviewing an endo.digital Report	75
Familiarize Yourself with an endo.digital Report	78
Personalized Diabetes Management Tips	118
Approved Recommendations	119
Reports	119
CHAPTER 7 – ACCOUNT MANAGEMENT	129
Reset Password	129
Profile	130
Automatic Log Off	130
Account Locked	130
CHAPTER 8 – TROUBLESHOOTING	131
Why can't I access endo.digital?	131
Why didn't I receive a recommendation after clicking New Recommendation?	131
CHAPTER 9 – FREQUENTLY ASKED QUESTIONS (FAQS)	135
How do I know if a new recommendation is ready for a patient?	135
Can I change or edit the recommendation provided by endo.digital?	135
Can I remove data from the uploaded data that is transferring to endo.digital?	136
Can I change the parameters endo.digital uses for recommendations (such as hypo/hyper threshold)	? 136
How are the recommendations generated by endo.digital affected by selecting "insulin resistant type setting?	
Can I get the latest patient's data report without generating a recommendation?	
How can I view the current plan in use in the DreaMed Diary App?	
What are the treatment plan parameters that the endo.digital algorithm can recommend changing?	
What is the maximum change that endo.digital may advise?	
When editing a recommendation, how does the carbs unit settings affect the permitted values in car	
counting treatment plan?	139
What happens if my patient changes their pump settings during the 21-day period?	
How can I view the patient's pump's Bolus Calculator glucose target and active insulin plans?	139
How can I send the patient additional instructions?	
Can I add a comment for a specific plan?	
What are the personalized diabetes management tips that endo.digital advises?	
How does the patient know that a new recommendation is waiting?	141
APPENDIX A – GLOSSARY	142
APPENDIX B – ENDO.DIGITAL PERSONALIZED DIABETES MANAGEMENT TIPS	144
APPENDIX C – NEW RECOMMENDATIONS TROUBLESHOOTING	151

List of Figures

Figure 1 – How endo.digital Works	15
Figure 2 – endo.digital Workflow – Insulin Pump	16
Figure 3 – endo.digital Workflow – MDI	24
Figure 4 – The adaptive thresholds used by the system to define patterns of low/eu and high glucose patterns as defined by the patient pre-mea	1
glucose targets	28
Figure 5 – Set password screen	
Figure 6 – Login Screen	33
Figure 7 – Training Video Screen	34
Figure 8 – Patients List Screen – Add Patient	35
Figure 9 – Add Patient Screen	36
Figure 10 – Add Patient Screen	37
Figure 11 – Patients List Screen – Add Patient	38
Figure 12 – Add Patient Screen	39
Figure 13 – Patients List Screen	
Figure 14 – Start Patient Screen – Selecting a Treatment Plan Type	42
Figure 15 – Initial BASAL PLAN – MD	47
Figure 16 – Bolus Plan – MDI – Sliding Scale	49
Figure 17 – Adding a New Bolus Plan Row – MDI – Sliding Scale	50
Figure 18 – Copy morning plan button	51
Figure 19 – Bolus Plan – MDI – Carbs Counting	52
Figure 20- Bolus Plan – MDI – Meal Estimation and Sliding Scale Correction	54
Figure 21 – Adding a new row to the correction plan in MDI – Meal Estimation and Sliding Scale Correction	55
Figure 22 - Bolus Plan – MDI – Fixed Meal and Sliding Scale Correction	58
Figure 23 – Adding a new row to the correction plan in MDI – Fixed Meal and Sliding Scale Correction	59
Figure 24 – Recommendations Screen	62
Figure 25 – Patient Recommendation List Screen	62
Figure 26 – History Recommendation Notification	63
Figure 27 – Treatment Type Recommendation Notification	63
Figure 28 – Connect with Dexcom Account	
Figure 29 – Log In with Dexcom Account	65
Figure 30 – Recommendation History While Connected to Dexcom	65
Figure 31 – Patient Screen – Patient settings button	68
Figure 32 – Generating a New Recommendation Screen	72
Figure 33 – Example Manual Recommendation Message Due to Insufficient Data Message	73
Figure 34 – Manual Recommendation – 1	
Figure 35 – Manual Recommendation – 2	
Figure 36 – Review Basal Messages	
Figure 37 – Top Half of Review and Share Recommendations Screen – Insulin Pump	79
Figure 38 – Review Basal Rate Screen – Insulin Pump – Basal Rate Plan	
Figure 39 – Edit Basal Rate Screen – Insulin Pump	
Figure 40 – Review Carb Ratio Screen – Insulin Pump	84
Figure 41 – Edit Carb Ratio Screen – Insulin Pump	
Figure 42 – Review Correction Factor Screen – Insulin Pump	87
Figure 43 – Edit Correction Factor Screen – Insulin Pump	
Figure 44 – Approve and Share Screen – Insulin Pump Treatment Type	90
Figure 45 – Top Half of Basal Plan Recommendations Page – MDI – Sliding Scale	90
Figure 46 – Review Basal Plan Page	91
Figure 47 – Edit Basal Plan Page – MDI	92
Figure 48 – Adding a New Basal Plan Row – MDI	
Figure 49 – Review Bolus Plan Page – MDI –Sliding Scale	
Figure 50 – Edit Bolus Plan Page – MDI –Sliding Scale	
Figure 51 – Adding a New Bolus Plan Row – MDI – Sliding Scale	
Figure 52 – Selecting the Insulin Type – MDI – Sliding Scale	
Figure 53 – Copy morning plan button	
Figure 54 – Review Page – MDI – Sliding Scale	
Figure 55 – Review Bolus Plan Page – MDI – Fixed meal and sliding scale correction	
Figure 56 - edit most holus plan - MDI - Fixed most and sliding scale correction	102



Figure 57 – edit bolus insulin type – MDI – Fixed meal and sliding scale correction	102
Figure 58 – edit bolus correction table – MDI – Fixed meal and sliding scale correction	103
Figure 59 – Add a new row to the bolus correction table – MDI – Fixed meal and sliding scale correction	104
Figure 60 – Review page – MDI – Fixed meal and sliding scale correction	105
Figure 61 – Review Bolus Plan Page – MDI – Meal estimation and sliding scale correction	107
Figure 62 – Edit meal bolus plan – MDI – Meal estimation and sliding scale correction	
Figure 63 – edit bolus correction table – MDI – Fixed meal and sliding scale correction	
Figure 64 – Add a new row to the bolus correction table – MDI – Meal estimation and sliding scale correction	110
Figure 65 – Review page – MDI – Meal estimation and sliding scale correction	
Figure 66 – Review Bolus Plan Page – MDI – Carbs Counting	
Figure 67 – Edit Bolus Plan Page – MDI – Carbs Counting	114
Figure 68 – Changing Carb Ratio Units	
Figure 69 – Recommended Changes in Bolus Plan Page – MDI – Carbs Counting	115
Figure 70 – Review Page – MDI – Carbs Counting	
Figure 71 – Generic Treatment Plan – Edit Recommendation	
Figure 72 – Generic Treatment Plan – Approved	
Figure 73 – Comments Screen	
Figure 74 – Approved Report Screen – Insulin Pump	
Figure 75 – AGP Report – Clock Shift Alert	
Figure 76 – AGP Report – 1	
Figure 77 – AGP Report – 2	
Figure 78 – AGP Report – 3	
Figure 79 125	
Figure 80 – MDI patient daily report	126
Figure 81 – Bottom Half of Review and Share Recommendations Screen Including Legend	
Figure 82 – Reset Password Screen	
Figure 83 – User Profile Screen	
Figure 84 – Example of the Insufficient Data Message – Insulin Pump Treatment Type	
Figure 85 – Example of the Insufficient Data Message – MDI Treatment Types	
List of Tables	
Table 1 – Symbols and Concepts Used in This Manual	
Table 2 – Acronyms and Abbreviations	
Table 3 – Authorized Devices for Use with endo.digital	
Table 4 – Contraindicated Devices not to be used with endo.digital	
Table 5 – Definition of a Valid Day for endo.digital Analysis	
Table 6 – Acronyms and Abbreviations	
Table 7 – endo.digital Limitations When Recommending Changes to a Patient's Insulin Pump Setting	
Table 8 – Authorized Devices for Use with endo.digital MDI Algorithm	
Table 9 – Approved Insulins for use with endo.digital Algorithm for MDI patients	
Table 10 – Definition of a Valid Day for endo.digital algorithm Analysis	
Table 11 – endo.digital Limitations When Recommending Changes to a Patient's MDI treatment plan	
Table 12 – Caution Messages – MDI Treatment Plan	
Table 13 – Glossary	
Table 14 – MDI Personalized Diabetes Management Tips	
Table 15 – Pump Personalized Diabetes Management Tips	
Table 16 – Pump Troubleshooting – New Recommendations	
Table 17 – MDI Troubleshooting – New Recommendations	153



Chapter 1 – Before You Begin

Using This User Manual

This healthcare professional (HCP) 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, which starts on page 142.

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
R _{X 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.



Acronyms and Abbreviations

The following table defines acronyms and abbreviations used in the manual.

Table 2 – Acronyms and Abbreviations

Acronym and Abbreviation	Definition/Description	
ADA	American Diabetes Association.	
AID	Automated Insulin Dosing	
BG	Blood Glucose.	
CF	Correction Factor [(mg/dl)/UI or (mmol/l)/UI].	
СССС	Continuous Glucose Monitoring device.	
CR	Carbohydrate Ratio [gr/UI].	
DKA	Diabetic Ketoacidosis.	
DMS	Diabetes Management System.	
НСР	Healthcare Professional.	
ISF	Insulin Sensitivity Factor. In this manual, the term CF is used instead of ISF.	
ISPAD	International Society for Pediatric and Adolescent Diabetes.	
IV	Intravenous.	
MDI	Multiple Daily Injections, such as with an insulin pen.	
PC	Personal Computer.	
SMBG	Self-Monitoring Blood Glucose.	
T1DM	Type 1 diabetes	
T2DM	Type 2 diabetes	
TDD	Total Daily Dose.	

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.

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.



endo.digital Bolus Calculator

endo.digital Bolus Calculator, a component of the DreaMed Diary App, is a diabetes management tool for people with type 1 diabetes above the age of 6 and type 2 diabetes above the age of 10, who use subcutaneous insulin injections therapy (not for pump use). This tool can help calculate their rapid acting analogs for insulin bolus doses based on user-entered blood glucose and/or meal information.

The initial setup of the user's treatment plans, and bolus calculator settings must be performed by a healthcare provider.

Contraindications for endo.digital Algorithm

- endo.digital Algorithm is not intended to send recommendations directly to patients without initially being reviewed and approved by a certified HCP who considers the entire clinical status of the patient.
- 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 Algorithm is not recommended for pregnant women. endo.digital has not been tested in this population.
- endo.digital Algorithm is not intended for use with patients who use automated insulin dosing (AID) systems (e.g., "closed-loop", "artificial pancreas", see Table 4 for a list of the contraindicated devices). endo.digital Algorithm hasn't been tested with these devices. endo.digital Algorithm cannot identify the pump model or operating mode, and although endo.digital Algorithm has some design mitigations to help detect when AID systems are used in closed loop mode and will usually prevent the system from providing recommendations for pump parameter changes, it cannot detect closed loop insulin delivery 100% of the time. Therefore, pay attention to pump information and the pump's operating mode and do not accept endo.digital Algorithm recommendations if the user was using the AID system in closed loop mode.



- 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.

Please ensure that your patient is an appropriate candidate for the endo.digital algorithm before starting them on this program.

Potential Harms

endo.digital leverages historical glucose and insulin data transmitted from diabetes devices or data sources to endo.digital, in order to recommend changes to a patient's insulin treatment plan. The recommendations of endo.digital are presented to you through endo.digital 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 delivery of insulin. 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 endo.digital is not a substitute for, but rather an adjunct to clinical reasoning.
- endo.digital recommendations are based on DreaMed Diabetes' proprietary algorithm, which relies on glucose and insulin data only drawn from the patient's treatment plan, reported insulin data, CGM and/or blood glucose meter. Patients' clinical history and other personal information such as age, gender, other diseases and medications are not considered in the analysis. Therefore, you should consider the patient's clinical history and use your professional opinion to modify the recommendations made by endo.digital as necessary before sharing them with your patient. For example, the following factors are not considered by endo.digital, which you should consider when reviewing the recommendation for your patient:
 - 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
- 3 endo.digital recommendations generated by DreaMed Diabetes' proprietary algorithm may rely on CGM data. endo.digital recommendations should not be used if the patient has not been using their CGM according to the manufacturer's instructions.
- 4 Do not use endo.digital before receiving training and reading this manual. Training for endo.digital consists of a review of this manual and a review of the app functions. Please contact DreaMed using the DreaMed support webpage at https://dreamed-diabetes.com/support-dm or email to DreaMed's support (support@dreamed.ai).



- 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 endo.digital Uploader or Tidepool 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.
 - The patient traveled to another time zone in the past 21 days.
 - There is an indication in endo.digital Uploader or Tidepool that the patient has changed the clock of the insulin pump, CGM and/or blood glucose meters.

Chapter 2 – About endo.digital

This HCP 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).

endo.digital is a tool for healthcare professionals to communicate with their patients about their insulin titration. It also allows healthcare professionals to use the endo.digital Algorithm and prescribe patients with the endo.digital Bolus Calculator.

endo.digital algorithm software is a proprietary algorithm, designed to provide a comprehensive analysis of individual diabetes data consisting of glucose levels, insulin delivery history and meal consumption reported through automatic and/or manual reporting, such as an insulin pump's Bolus Calculator or the DreaMed Diary App to recommend adjustments to the patient-specific treatment plan as well as suggestions for personalized diabetes management tips (such as timing of meal boluses and bolus delivery compliance).

endo.digital was developed to assist HCPs in decision making when treating patients with diabetes who use insulin therapy and monitor their glucose level using CGM and/or a blood glucose meter.

The sections below and Figure 1 provide a general description of how endo.digital analyzes the data in order to generate recommendations.

endo.digital Data Integrity Security and Privacy

endo.digital includes security functions to ensure the safe and secure operation of the product, including 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).



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 secure operation of your site. For example, limiting access to connected devices, network security, installing the latest security patches, separating networks, physically protecting system components, user training, multi-level defensive measures and so on.

It is recommended to always comply with industry-standard protocols to protect against the latest data security threats.



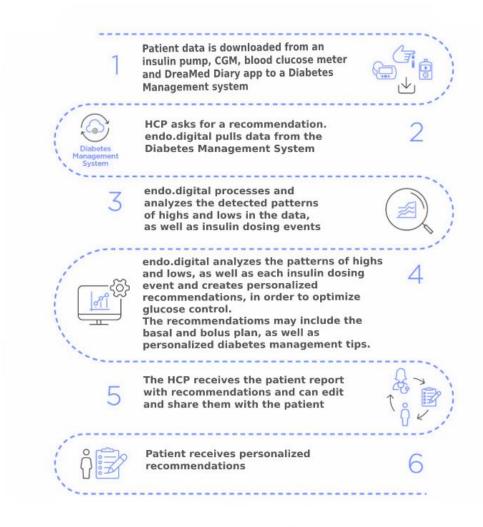


Figure 1 – How endo.digital Works

Signing Up a Patient

For a patient to use the endo.digital system, you must first add the patient in the system, as described in <u>Adding a Patient</u>. After adding a patient, you determine the appropriate treatment type for that patient, as described in <u>Start a New Patient on endo.digital and whether they are appropriate candidates for the endo.digital Algorithm.</u>

Chapter 3 – endo.digital Workflow – Insulin Pump

The following steps describe the general workflow for using endo.digital with an Insulin Pump treatment type. For the endo.digital MDI workflow, see page 24.

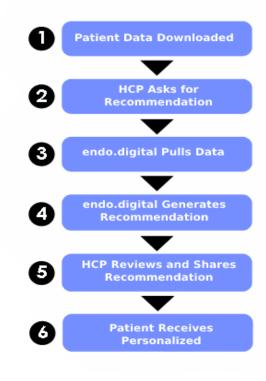


Figure 2 - endo.digital Workflow - Insulin Pump



Step 1: Patient Data is Downloaded

Check that your patient is an appropriate candidate for endo.digital (see User Safety: Contraindications for endo.digital Algorithm, General Warnings and Precautions). Then, sign up your patient for endo.digital. In order to get a recommendation for the patient, download the data from the patient's insulin pump, CGM and/or blood glucose meter into endo.digital Uploader or Tidepool. If the patient is using Dexcom CGM, once their Dexcom account is connected with endo.digital, there is no need to download the data. The patient or care team should consult the endo.digital Uploader/Tidepool manual for information about how to send the data from the different devices.



NOTE: The patient must download data from their insulin pump, CGM and/or meter so that the data can be analyzed by endo.digital. No other data sources are used in endo.digital's analysis.



WARNING:

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

Authorized and Contraindicated Devices

Table 3 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 3 – Authorized Devices for Use with endo.digital

Device Type	Device Manufacturer	Brand Name
Blood Glucose Meter	All meters with regulatory approval (de	ependent 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
		G7
	Abbott	Libre
		Libre 2
		Libre 3
		Libre Pro
	Senseonics	Eversense Continuous Glucose Monitoring System



Table 4 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 4 – Contraindicated Devices not to be used 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

Step 2: HCP Asks for a Recommendation

Using the endo.digital user interface, you can enter a patient screen and click the **New Recommendation** button to start endo.digital.

Step 3: endo.digital Pulls Data from Various Data Sources

After an HCP asks for a new recommendation using the **New Recommendation** button, the data is pulled by the endo.digital system from the supported data sources.

endo.digital requires at least 12 **valid days** to produce recommendations (as defined in Table 5), at least three records from the Bolus Calculator and a **valid recent insulin pump settings plan** (for example, basal plan, CR plan, CF plan, Bolus Calculator glucose targets plan and insulin activity time, as defined in Table 6. If these conditions are not met, endo.digital does not provide recommendations on new insulin pump settings.

Table 5 – Definition of a Valid Day for endo.digital Analysis

Data Source	Requirement
ССБМ	At least 67% of CGM sensor readings per day according to the sensor's sample rate (meaning, for a sensor that presents glucose readings every five minutes, at least 192 samples are required and for one that presents glucose readings every 15 minutes, at least 64 samples)
Or Blood glucose meter	At least three BG measurements a day that are separated from each other by at least 210 minutes
Basal rate	At least one basal record
Bolus	At least one bolus record





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 you advise your patient to calibrate the sensor according to the manufacturer's instructions. Otherwise, a sensor with reduced accuracy may cause endo.digital to analyze inaccurate glucose data.

Table 6 – Acronyms and Abbreviations

Data Source	Requirement
Basal Rates [u/h] Each rate in the basal plan is within 0.025–3 u/h	
CR [gr/u]	Each value in the CR plan is within 3–70 gr/u
CF [mg/dl/u]	Each value in the CF plan is within 10–280 gr/u
Bolus Calculator Targets [mg/dl]	Equal to or below 150 mg/dl



Changing the Insulin Pump Settings Immediately Before Downloading the Data

In case your patient's insulin pump settings do not currently meet the system requirements and you decide to change the patient's insulin pump settings, you should advise the patient to wait 21 days before uploading the data and getting a new recommendation.



NOTE: Data is pulled automatically to endo.digital. You cannot edit, change, replace or flag the data for analysis. In addition, a patient cannot flag data for analysis.

Step 4: endo.digital Generates Recommendations

endo.digital Processes and Analyzes the Data

First, 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:

- CGM/blood glucose meter data filtration: endo.digital may ignore some of the values in cases where the algorithm considers them non-physiological or in cases that the blood glucose meter value contradicts the CGM value at a given time stamp.
- Hypoglycemia/euglycemia/hyperglycemia patterns: endo.digital uses the following thresholds to detect patterns of hypoglycemia and hyperglycemia:
 - Low threshold is under 70 mg/dl (3.9 mmol/l).
 - Mean daily euglycemic level is 154 mg/dl (8.5 mmol/l).
 - High threshold is over 180 mg/dl (10 mmol/l).
- Insulin dosing decision events by the patient: The algorithm uses the insulin pump and CGM/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 patient's insulin pump settings to estimate if carbohydrates were consumed at the time of a bolus.



endo.digital Analyzes Patterns and Creates Recommendations

endo.digital evaluates the following events:

- Each insulin dosing decision made by the patient
 And
- Low and high glucose patterns

Potential recommendations may include:

- Changes to the patient's Basal plan
- Changes to the patient's CR plan
- Changes to the patient's CF plan

Providing a personalized diabetes management tip relating to the way the patient delivers insulin (<u>Appendix B</u> provides a detailed description of personalized diabetes management tips that may be suggested by endo.digital, specifically hyperglycemia patterns and hypoglycemia patterns).



CAUTION: endo.digital considers the active insulin time and the Bolus Calculator glucose target plan that are set in the insulin pump when recommending changes to the basal rate, CR and CF. Therefore, if you want to change either the active insulin time or the Bolus Calculator glucose target plan, consider whether the endo.digital recommendations need to be modified.

endo.digital integrates safeguards into its recommendations to ensure the safety of the patient. Firstly, endo.digital does not issue recommendations beyond what is considered **valid insulin pump settings**, as described in Table 6. Secondly, Table 7 presents the particular safeguards and limitations used in recommending a change to a patient's 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*	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: 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/2/24.
		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/2/24.
		These limitations override the Current Basal Rate Upper/Lower Limits stated above.
	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 $1[\frac{gr}{U}]$
	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, as described in Table 7 (marked with *), 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.

endo.digital uses the results of the analysis of each event to create the patient's recommendation. This recommendation aims to treat patterns of high and/or low glucose values that occur throughout the day. The recommendation may include changes to the basal rate, CR plan, CF plan and diabetes management tips about how to avoid unbalanced glucose levels. The recommendations may include the creation of new basal rates, CR and CF periods or modifications of existing ones by changing the values or timing of each period. If the patient experienced a glucose imbalance and endo.digital was not able to create a recommendation, endo.digital will indicate as such.



endo.digital requires a certain number of events to complete a recommendation about a particular time of day. Note that the recommendation may be generated by a limited number of analyzed events.

Step 5: HCP Reviews and Shares Recommendations

The recommendations of endo.digital are presented to you through the endo.digital user interface, in which you can review and edit them. The sections below (<u>First Steps</u>) explain how to view and edit the recommendations of endo.digital.

After you have reviewed the patient's recommendation, you can approve it and share it with the patient. The patient can view the recommendation through the endo.digital user interface once the recommendation has been shared.

In addition, you can also save the report as a PDF file and send it to the patient or print the recommendation and hand a hard copy to the patient.

Step 6: Patient Receives Personalized Recommendations

A patient can view the recommendation shared with them via the endo.digital patient application. If the patient did not register with the endo.digital patient application, you can invite the patient to register. In addition, the patient can also use a hard copy of the recommendations received from the clinic.

Chapter 4 – endo.digital Workflow — MDI

The following steps describe the general workflow for using endo.digital for a Multiple Daily Injection (MDI) treatment type.

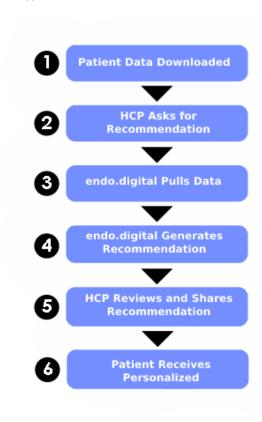


Figure 3 – endo.digital Workflow – MDI



Step 1: Patient Data is Downloaded

Check that your patient is an appropriate candidate for endo.digital (see: Contraindications, General Warnings and Precautions). In order to get a recommendation for the patient, verify that the patient downloaded their CGM and/or blood glucose meter into endo.digital Uploader or Tidepool. If the patient is using a Dexcom CGM, verify their Dexcom account is connected to endo.digital; if the patient is using a Dexcom receiver, verify that the receiver was downloaded to Clarity. The patient or care team should consult the endo.digital Uploader/Tidepool manual for information about how to send the data from the various devices.



WARNING:

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



NOTE: The patient must download data from their CGM and/or blood glucose meter, and report their insulin and meal using the Diary App so that the data can be analyzed by endo.digital. No other data sources are used in endo.digital's analysis.

Authorized Devices

Table 8 details the devices that are currently authorized to be used with endo.digital.

Table 8 – Authorized Devices for Use with endo.digital MDI Algorithm

Device Type	Device Manufacturer	Brand Name
Blood Glucose Meter	All meters with regulatory approval (dependent on location: EU/US/Rest of the World [ROW])	
CGM	Medtronic Diabetes	Enlite
		IPro
		Guardian Sensor 3
	Dexcom	G5
		G6
		G7
	Abbott	Libre
		Libre 2
		Libre 3
		Libre Pro
	Senseonics	Eversense Continuous Glucose Monitoring System
Connected insulin injectors	All communicating insulin injectors with regulatory approval (dependent on location: EU/US/Rest of the World [ROW])	



Table 9 – Approved Insulins for use with endo.digital Algorithm for MDI patients

Type of Insulin	Insulin Brand Name
Rapid Acting Analogs	Novolog, Apidra, Humalog U-100, Humalog U-200, Admelog, Fiasp, Lyumjev U-100, Lyumjev U-200
Regular Insulin	Humulin-R U-100, Novolin-R, Velosulin
Long Acting Insulin	Levemir, Lantus, Rezvoglar, Semglee, Toujeo, Basaglar, Tresiba U-100, Tresiba U-200, Xultophy, Soliqua



NOTE: Insulin should be used according to manufacturer's labeling.

Step 2: HCP Asks for a Recommendation

Using the endo.digital user interface, you may enter a patient's page and click on the **New Recommendation** button to start endo.digital.

Step 3: endo.digital Pulls Data from Various Data Sources

Once a healthcare provider asks for a new recommendation using the **New Recommendation** button, the data is pulled by the endo.digital system from the supported data sources and the DreaMed Diary App.

endo.digital algorithm provides treatment recommendations for patients on MDI-Carbs counting and MDI-Sliding scale treatment plans. For patients who are on MDI-Fixed meal, MDI-Meal estimation, or Generic treatment plans, the endo.digital system will automatically direct you to a <u>manual recommendation</u> where you can create a treatment recommendation for your patient based on your professional knowledge and judgment and not based on endo.digital's algorithm.

endo.digital algorithm requires at least 12 **valid days** for Type 1 diabetes patients (including Type 1 with insulin resistance) and at least 6 **valid days** for Type 2 diabetes patients to produce recommendations (as defined in Table 10), including an insulin injection plan. If the conditions are not met, endo.digital algorithm will not provide recommendations on new insulin treatment plans. If there is not enough insulin data at certain times of the day, endo.digital algorithm will generate a recommendation, but it may not recommend changes for specific times of the day where the data is missing.



Table 10 – Definition of a Valid Day for endo.digital algorithm Analysis

Data source	Requirement
Glucose	T1DM and Insulin resistant type 1:
	CGM: At least 67% of the expected sensor measurements per day according to the sensor's sample rate.
	-OR-
	Glucometer: At least 3 BG measurements a day that are at least 210 minutes
	apart.
	T2DM:
	CGM or Glucometer : Fasting glucose level. A fasting glucose level is considered as any glucose measurement found between 4AM and 12PM.



endo.digital uses CGM data from approved devices. As part of this approval process, the accuracy of the sensors was evaluated when the sensor was used according to the manufacturer's instructions. It is recommended that you advise your patient to calibrate the sensor according to the manufacturer's instructions. Otherwise, a less accurate sensor could cause endo.digital to analyze inaccurate sensor data.



NOTE: Data is pulled automatically into endo.digital. All data is analyzed as-is. You cannot edit, change, replace or flag out the data, nor can the patient do so.

Step 4: endo.digital Generates Recommendations

endo.digital Processes and Analyzes the Data

First, 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:

• **CGM/SMBG Data Filtration** – endo.digital may ignore some of the CGM/SMBG values in cases where the algorithm considers them non-physiological or in cases where the blood glucose meter value contradicts the CGM value at a given time stamp.

• **High/ Eu / Low Glycemic Patterns** – endo.digital uses adaptive thresholds to detect patterns of low and high glycemic patterns. These thresholds are based on the patient Pre-meal glucose targets, as defined by the HCP in the patient's personal information page as follows:

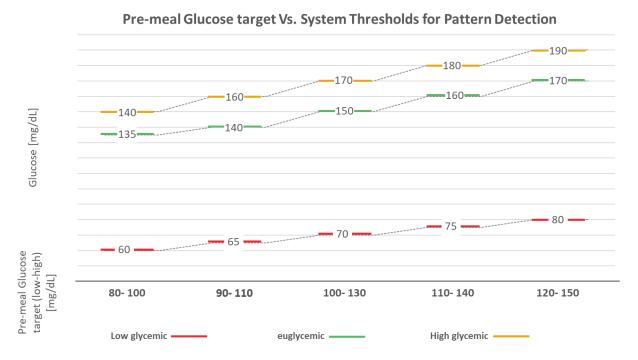


Figure 4 – The adaptive thresholds used by the system to define patterns of low/eu and high glucose patterns as defined by the patient pre-meal glucose targets

• Insulin Dosing Decisions Events by the Patient – The algorithm uses the reported insulin, glucose, and meal data and CGM/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 patient's insulin treatment plan to estimate whether carbohydrates were consumed at the time of a bolus.

endo.digital Analyzes Patterns and Creates Recommendations

endo.digital evaluates the following events:

- Each insulin dosing decision made by the patient
- High and low glycemic patterns.

Potential recommendations may include:

- Changes to the patient's Basal plan
- Changes to the patient's Bolus plan
- Providing a personalized diabetes management tip relating to the way the patient delivers insulin



endo.digital integrates safeguards into its recommendations in order to ensure the patient safety. The information in $\underline{\text{Table 11}}$ below presents the particular safeguards and limitations used in recommending a change to the patient's insulin treatment plan.

Table 11 – endo.digital Limitations When Recommending Changes to a Patient's MDI treatment plan

Variable Name	Limitation	How is It Used in the endo.digital Analysis Process?
Basal Plan (Long acting insulin)	Limitation on the changes for the daily basal amount	±20% of the current daily basal amount.
	Limitation on the daily basal amount	The recommended basal plan cannot go outside hard boundaries depending on the type of diabetes: • T1DM - below 1 and above 72 units a day • T2DM / insulin resistant T1DM - below 1 and above 250 units a day
	Potential number of basal injections	1 or 2, depending on the input basal plan and/ or the basal plan as identified by the system from the patient basal injection records. Note that the system will not recommend changing
		the long acting insulin type
CR Plan	Limitation on the CR changes that can be recommended by endo.digital	\pm 30% of the current CR value based on the patient's current CR settings and up to $\pm 1 \left[\frac{gr}{U} \right]$
	Limitation on the CR values that can be recommended by endo.digital	The recommended CR plan cannot go outside hard boundaries depending on the type of diabetes: • T1DM - below 3 and above 70 $\left[\frac{gr}{U}\right]$ • T2DM / insulin resistant T1DM - below 2 and above 70 $\left[\frac{gr}{U}\right]$ Note that the limits are reflective of the selected carbs unit (units to 10 or 15 grams exchange)
	Potential number of CR periods	Always 4: morning, afternoon, evening and night time.
CF Plan	Limitation on the CF changes that can be recommended by endo.digital	\pm 30% of the current CF value based on the patient's current CF settings and up to $\pm 5 \left[\frac{mg/dL}{U} \right]$
	Limitation on the CF values that can be recommended by endo.digital	The recommended CF plan cannot go outside hard boundaries depending on the type of diabetes: • T1DM - below 10 and above 280 $\left[\frac{mg/dL}{U}\right]$ • T2DM/ insulin resistant T1DM - below 5 and above 280 $\left[\frac{mg/dL}{U}\right]$
	Potential number of CF periods	Always 4: morning, afternoon, evening and night time.
Other bolus plans:	Limitation on the changes that can be recommended by endo.digital	\pm 30% of the current plan values based on the patient's current settings $\pm 1[U]$



- Fixed meal - Meal Estimation - Sliding scale table for correction - Sliding scale table for meal + correction	Limitation on the values that can be recommended by endo.digital	The recommended plan cannot go outside hard boundaries depending on the type of diabetes: • T1DM - below 0 and above 30 [U] • T2DM / insulin resistant T1DM - below 0 and above 99 [U] In case of sliding scale table, the increments between the table scales cannot go above: • T1DM: 5 [U] • T2DM/ insulin resistant T1DM: 10 [U]
	Potential number of day periods	Always 4: morning, afternoon, evening and night time.
Bolus target plan	Limitation on the target changes that can be recommended by the endo.digital	- 20 mg/dL, only if the bolus target plan is above 150 mg/dL Note that the endo.digital only recommends changes to the bolus target plan if it's above 150 mg/dL.
	Limitation on the target plan values that can be recommended by endo.digital	The recommended bolus target plan cannot go below 70 or above 180 mg/dL. In addition, the bolus target plan cannot exceed more than ±20 mg/dL of the patient pre-meal target ranges, as defined by the HCP in the patient settings page.
	Potential number of target periods	Always 4: morning, afternoon, evening and night time.



NOTES:

- Plan threshold values in <u>Table 11</u> are not configurable.
- An insulin pen only enables discrete injection unit values. Some pens only enable whole injection units (such as 1.0, 2.0, 3.0 and so on) and other pens enable half injection units (such as 0.5, 1.0, 1.5 and so on). endo.digital rounds the recommended value for basal plan and sliding scale plans to the closest value that is supported by the pen. For example, for a pen that supports half units, a value of 1.25 is rounded to 1.0 and a value of 1.26 is rounded to 1.5.
- The endo.digital system always uses the actual amount of insulin that was delivered (basal and bolus) for its analysis. In case there is no basal delivery data reported, the endo.digital will use the basal plan from the DreaMed Diary App. In addition, if the actual values of CR and CF at the time of each bolus are available, endo.digital will use this data as well. However, the recommended changes to the patient's plan are always calculated as a percentage of the most recent settings that were in the DreaMed Diary App.
- endo.digital will not recommend changes to the patient's insulin type.



endo.digital uses the results of the analysis of each event to create the patient's recommendation. This recommendation aims to treat patterns of high and/or low glucose values that occur throughout the day. The recommendation may include changes to the Basal Plan and Bolus Plan, and diabetes management tips about how to avoid unbalanced glucose levels. The recommendations could include the creation of new injection dosages or modifications of existing ones by changing the values of each. If the patient experienced a glucose imbalance and endo.digital was not able to create a recommendation, endo.digital will indicate it.



CAUTION: endo.digital requires a certain number of bolus events to conclude a recommendation about a particular time of day. Please note that the recommendation could be generated by a limited number of analyzed events. For example, a patient may have had only a few injections in the morning. endo.digital may change this patient's morning insulin based on a small amount of data.

Step 5: HCP Reviews and Shares Recommendations

endo.digital recommendations are presented to you in the endo.digital user interface, where you can review and edit them. The sections below (First Steps) explain how to view and edit these endo.digital recommendations.

Once you have reviewed the recommendation for a patient, you can approve and share it.

Step 6: Patient Receives Personalized Recommendations

The new plan is automatically sent to the patient's Diary App plan settings where it can be viewed by the patient and approved or rejected.

In addition, you can also save the report as a PDF file and send it to the patient or print the recommendation and hand a hard copy to the patient.

Chapter 5 – First Steps

Register

Note: this section is not relevant if you are logging in via EMR

You must have an account to access endo.digital and manage your patients list.

Your DreaMed customer success manager will send you a registration email containing your endo.digital username (email) and a link that redirects you to set your password.

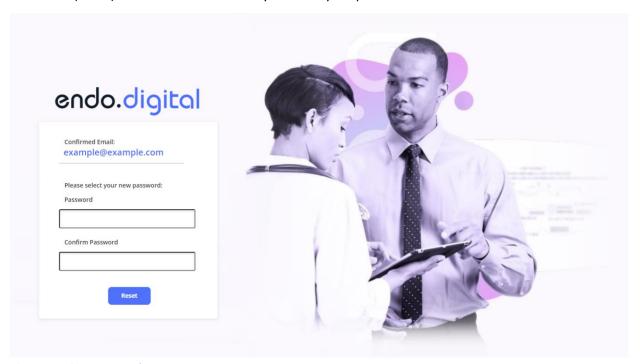


Figure 5 – Set password screen

If you have not received an email from your DreaMed customer success manager or if you need to connect with the DreaMed team about getting set up with endo.digital, please email support@dreamed.ai.

Logging In

Note: this section is not relevant if you are logging in via EMR

To access endo.digital, locate the web browser window and enter the URL

http://www.dreamedadvisor.com



NOTE: In case your clinic uses a single-sign-on, use your clinic's endo.digital URL, then log in using your hospital's credentials.

Enter your email address and password and click Login.

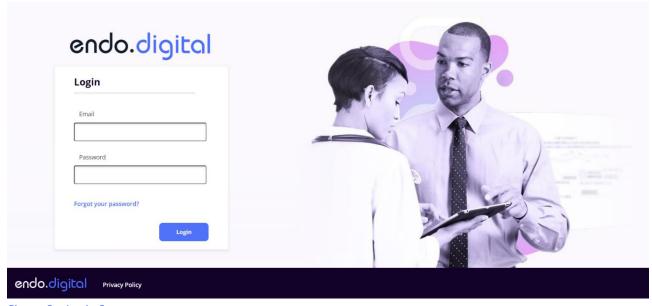


Figure 6 – Login Screen



View the Training Video

Before using endo.digital, you must undergo training. Training consists of reviewing the user manual and receiving an introduction to the software.

When logging in for the first time, you must view the training video and acknowledge viewing it before you can access the patients list.

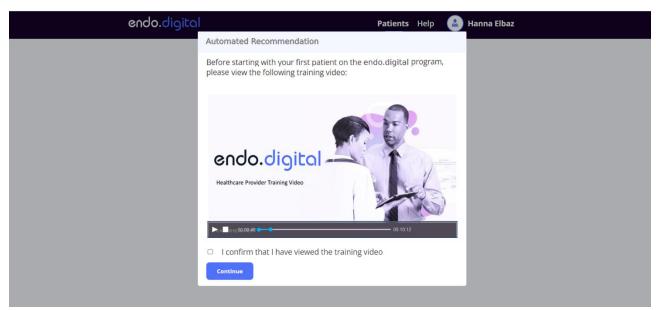


Figure 7 – Training Video Screen

Once you have confirmed that you viewed the training video, you can access the patients list and start a patient on the endo.digital.

Add a Patient to the Clinic

endo.digital can be used with either Tidepool Uploader or endo.digital Uploader. This may vary between clinics.

- 1 <u>endo.digital Uploader</u>: The patient is required to interact with endo.digital and consent to the terms of the service.
- 2 <u>Tidepool Uploader</u>: The clinic team captures the patient consent and adds the patient. For this method, patient interaction is not required.



NOTE: For endo.digital to add a patient and access their data when using Tidepool Uploader, it must receive an explicit consent from the patient.

endo.digital Uploader

To add a patient to the patients list with endo.digital Uploader:

Click the **Add Patient** button in the patients list.

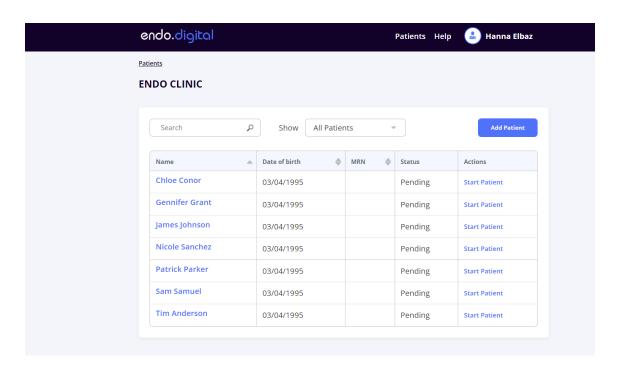


Figure 8 – Patients List Screen – Add Patient

When clicked, the **Add patient** screen displays:



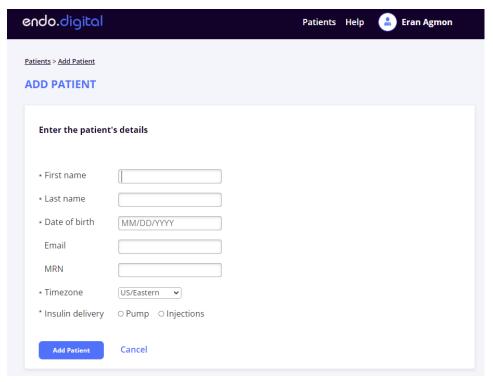


Figure 9 - Add Patient Screen

Enter the patient's first and last name and date of birth. You may enter the patient's email address to send the patient an invitation to allow them to log into endo.digital, endo.digital Uploader and the DreaMed Diary mobile app.

Add the patient's Medical Record Number (MRN), this may be required based on the clinic preferences. The time zone below will show the clinic's time zone. In case the patient lives in a different time zone, change this field to the correct time zone. The patient's time zone is used when pulling the patient's devices' data into endo.digital and syncing the data between the devices.

Finally, select the patient's current insulin delivery method as best known to you. You may select either insulin pump or injections. If the 'injections' option is selected, and an email address was not entered, endo.digital will prompt the user if they want to add it.

The patient now appears in the clinic's patients list, and the patient will receive an invitation to endo.digital based on their insulin delivery option. The invitation will allow the patient to select their own password and enter endo.digital, download and use endo.digital Uploader and log into the Diary mobile app (for injections users).

endo.digital Uploader when logged in via EMR

To add a patient when logged in via EMR:



When opening endo.digital for a patient for the first time, the Add patient screen is loaded:

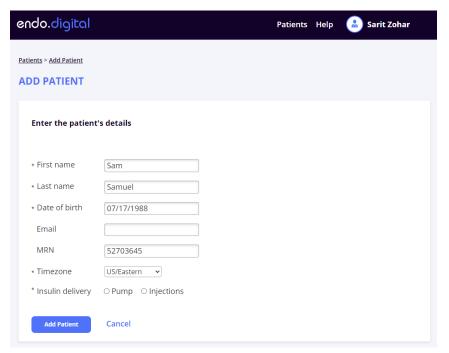


Figure 10 - Add Patient Screen

The patient's first and last name, MRN and date of birth are automatically populated with data from the EMR. You may enter the patient's email address to send the patient an invitation to allow them to log into endo.digital, endo.digital Uploader and the DreaMed Diary mobile app.

The time zone below will show the clinic's time zone. In case the patient lives in a different time zone, change this field to the correct time zone. The patient's time zone is used when pulling the patient's devices' data into endo.digital and syncing the data between the devices.

Finally, select the patient's current insulin delivery method as best known to you. You may select either insulin pump or injections. If the 'injections' option is selected, and an email address was not entered, endo.digital will prompt the user if they want to add it.

The patient will receive an invitation to endo.digital based on their insulin delivery option. The invitation will allow the patient to select their own password and enter endo.digital, download and use endo.digital Uploader and log into the Diary mobile app (for injections users).



Tidepool Uploader



NOTE: When logging in for the first time, you must enter your credentials for Tidepool. Enter your Tidepool email address and password and click Login. By signing in to your Tidepool account, you are allowing endo.digital to access and display your patient's data in the endo.digital web platform.

Only the first clinician to enter endo.digital is requested to enter the clinic's Tidepool.

To access endo.digital, the patient must be registered in Tidepool. Refer to Tidepool instructions for more details about how to register a patient in Tidepool.

To add a patient to the patients list with Tidepool Uploader:

Click the Add Patient button in the patients list.

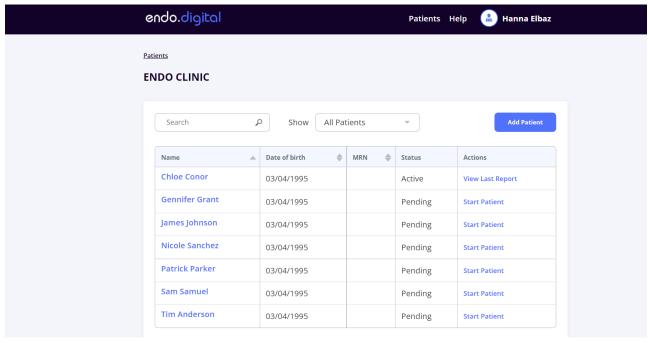


Figure 11 - Patients List Screen - Add Patient

When clicked, the Add patient screen displays:



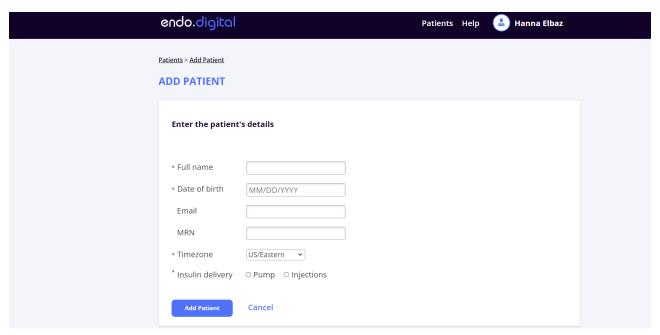


Figure 12 – Add Patient Screen

Enter the patient's full name and date of birth as they appear in Tidepool. You may enter the patient's email address to send the patient an invitation to allow them to log into endo.digital and the DreaMed Diary mobile app.

Then, select the patient's current insulin delivery method as best known to you. You may select either insulin pump or injections.

After receiving consent from the patient, check the 'The patient agreed to be part of endo.digital...
'checkbox, and then click the Add Patient button. If the patient's details match exactly a patient in Tidepool, the patient is created. The patient now appears in the clinic's patients list, and the patient will receive an invitation to endo.digital based on their insulin delivery option. The invitation will allow the patient to select their own password and enter endo.digital, and log into the Diary mobile app (for injections users).

Adding a Patient's Email Address

If a patient already joined your clinic without adding their email address or registering with endo.digital, you can add an email address in the patient settings page.

Patients List

Note: this section is not relevant if you are logging in via EMR

Only a registered user can access the patients list. After logging into endo.digital, you enter the Patients List screen.

You can always click **Patients** at the top of the screen to return to the Patients List screen.

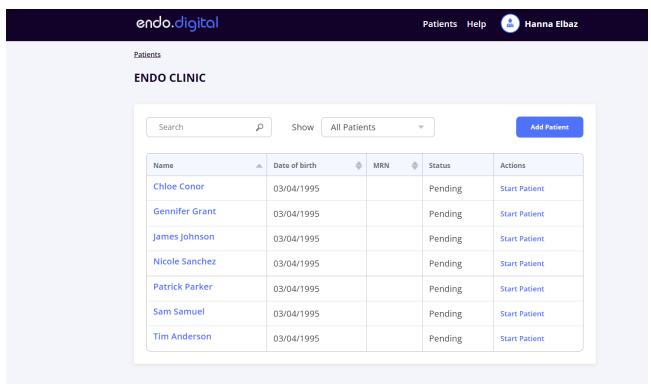


Figure 13 – Patients List Screen

Get Familiar with Your Patients List

Note: this section is not relevant if you are logging in via EMR

The patients list includes the following information:

- Name: The patient's name that was entered by the patient and cannot be edited.
- Date of Birth: The patient's date of birth that was entered by the patient and cannot be edited.
- MRN: The patient's MRN that was entered when adding the patient (for Advisor clinics) or that was in Tidepool when adding the patient (Tidepool clinics). The MRN may be changed in the personal information screen.
- Status: Indicates whether the patient has been started on endo.digital:
 - Pending: Indicates that the patient has not yet been started on the endo.digital program.
 - Active: Indicates that the patient has been started on the endo.digital program. It does not indicate whether a recommendation has been generated.

Actions:

- View Last Report: The patient has been started on the endo.digital program. Click this action to view the patient's last report. If a recommendation was never generated for this patient, you are redirected to the Recommendations List screen, which is described on page 78.
- * Start Advisor: The patient has not yet been started on endo.digital. Clicking this action redirects you to the Start Patient screen, which is described on page 42.
- Send Invitation: Invites the patient to endo.digital. The patient is asked to select a password. Once their account is set, they can view the approved recommendations that were shared with them. This action is available only for patients with an email address. If a patient did not add their email address, you may add in in the patient settings page.
- Resend Invitation: Click this action to resend an invitation for the patient.

Reorder the Columns

Click Name or Date of birth to reorder them based on ascending or descending order.

Search for a Patient

Click the **Search** box and start to type the search criteria. A list of matches displays. Select a patient's name or MRN in the narrowed list or click the X to cancel the search.



Show Patients by Enrollment Status

To filter the patient population by their enrollment status, click the box next to **Show** and select your choice from the dropdown options.

Enrollment status options are:

- **Pending:** A patient that joined the clinic, but was not approved to use endo.digital yet, meaning that the patient was not <u>started on endo.digital</u> yet.
- Active: A patient that joined your endo.digital clinic and was approved to use endo.digital.

After filtering the patients list, the list adjusts accordingly.

View Patient Information

Click the patient's name to view their recommendation history and generate a new recommendation.

Start a New Patient on endo.digital

Starting a patient on endo.digital enables you to select the proper treatment plan type for the patient, as described below.

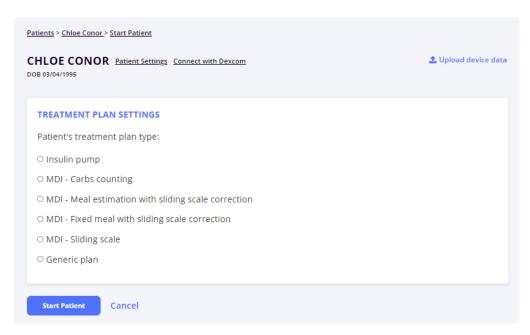


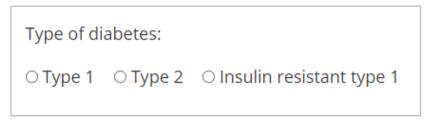
Figure 14 – Start Patient Screen – Selecting a Treatment Plan Type



- Select the treatment type for the patient by clicking the relevant radio button:
 - Insulin Pump: For patients who use an insulin pump and require adjustment of their basal, carb ratio and correction factor plans and meet the endo.digital Algorithm <u>Indications for Use</u> and don't meet any of the <u>Contraindications</u>.
 - MDI Carbs Counting: For people who use multiple daily injections and calculate their boluses by using carb ratios and correction factors and meet the endo.digital Algorithm Indications for Use and do not meet any of the Contraindications. Patients will be invited to use the DreaMed Diary mobile app.
 - MDI Meal estimation with sliding scale correction: for people with multiple daily injections who calculate their bolus by matching their meal size to corresponding insulin amount and matching their pre-meal glucose level to corresponding insulin amount, who meet the endo.digital Algorithm Indications for Use and do not meet any of the Contraindications. Patients will be invited to use the DreaMed Diary mobile app.
 - MDI Fixed meal with sliding scale correction: for people with multiple daily injections who calculate their bolus by matching their meal to corresponding insulin amount and matching their pre-meal glucose level to corresponding insulin amount, who meet the endo.digital Algorithm Indications for Use and do not meet any of the Contraindications. Patients will be invited to use the DreaMed Diary mobile app.
 - MDI Sliding Scale: For people who use multiple daily injections and calculate their boluses by matching their pre-meal glucose level with a predefined insulin amount and meet the endo.digital Algorithm Indications for Use and do not meet any of the Contraindications. Patients will be invited to use the DreaMed Diary mobile app.
 - Generic Treatment Plan: A free-text generic treatment plan that enables you to view the patient's reports and send the patient the new treatment plan in a textual form without making use of the endo.digital Algorithm. Patients will be invited to use the DreaMed Diary mobile app.



Select the patient's type of diabetes: Type 1, Type 2, Insulin resistant type 1.
Selecting the type of diabetes determines endo.digital's recommendation parameters.
For more details see Table 11 - Chapter 4 - Step 4: endo.digital Generates Recommendations





NOTE: The definition of Insulin Resistant Type 1 is a unique endo.digital System specification and is not a clinical definition. You should choose insulin resistant type 1 for your patient if your type 1 patient requires a basal or bolus plan which exceeds the maximum amount as specified in <u>Table 11</u>



NOTE: Insulin resistant Type 1 patients still require a higher amount of data (minimum 12 valid days) then Type 2 patients to account for their glucose variability which is typical of a Type 1 patient for the algorithm to provide a recommendation.

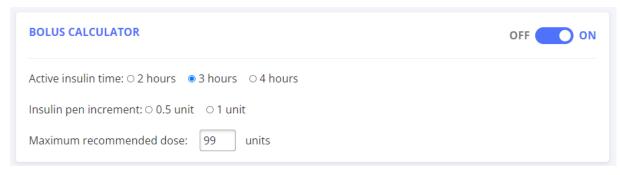
3 Select one of the displayed Pre meal glucose target ranges, shown below. This is the patient fasting blood glucose level to be aimed at by the treatment plan.

For more details see Chapter 4 - Step 4: endo.digital Generates Recommendations

```
Pre meal glucose target range:

○ 80-100 mg/dL ○ 90-110 mg/dL ● 100-130 mg/dL ○ 110-140 mg/dL ○ 120-150 mg/dL
```

4 If you selected the **MDI – Carbs counting** treatment type, then the **BOLUS CALCULATOR** section will appear in the screen, as shown below. Bolus calculator should only be turned on for patients meeting the bolus calculator's indications for use.





NOTE: The BOLUS CALCULATOR is considered a prescription device.

This section enables you to determine whether a patient that uses the DreaMed Diary App (which is described in the <u>DreaMed Diary App User Manual</u>) is able to use a Bolus Calculator in the app.





NOTE: If you turn the **BOLUS CALCULATOR** switch **ON** or **OFF** after the patient is already using the DreaMed Diary App, then their DreaMed Diary app will only be updated the next time the patient has an Internet connection.

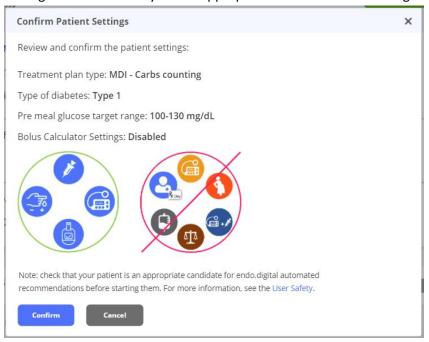
To prescribe the patient the bolus calculator in their DreaMed Diary application:

- Set the BOLUS CALCULATOR switch on the right to ON.
- In the **Active insulin time** field, according to the patient's parameters (such as the type of insulin that you prescribed) and your medical recommendation, specify the amount of time (measured in hours) it takes until the bolus of insulin stops affecting the blood glucose: **2**, **3** or **4** hours. This field is used to calculate the insulin on board.
- In the **Insulin pen precision unit** field, specify whether the dosage setting of the pen can be incremented by 1 **unit** at a time (whole numbers) or by 0.5 **unit** at a time.
- In the **Maximum recommended dose** field, specify the maximum dosage that the Bolus Calculator can recommend. When switching the bolus calculator on the default value will be 99 units.



5 Click the Start Patient button.

When starting a patient on Pump or MDI treatment plans you are required to review the patient's settings and confirm they are an appropriate candidate for endo.digital.



- You can then generate a recommendation and use endo.digital for this patient. The type of recommendation generated is specific to the treatment type you specify here. Patients started on MDI treatment plans are required to set an initial plan before generating a recommendation, see Setting a Patient's Initial Plan For MDI Plans
- After a patient is started, an invitation is sent to the patient with a link that enables them to set their password for endo.digital.
- Patients started on an insulin pump can log into their web account and view approved recommendations and reports displaying data from their insulin pump and CGM/glucometer. Pump patients can access the patient user manual through the Help section of their web account or through the DreaMed website.
- Patients started on an MDI or generic plan are asked to download the DreaMed Diary App and start using it. MDI patients can access the app user manual through the **Help** section of the app or through DreaMed website where they can find additional information about using the app and bolus calculator.
- As long as the patient did not accept their invitation and select their password, you can click the **Resend Invitation** link in the patients list to resend the patient an invitation.



NOTE: When you start a patient on a specific treatment type, the recommendations generated for that patient are specific to that treatment type for the duration of the patient's treatment.





NOTE: To start a patient on an MDI plan, we recommend that you verify the email address for the patient. Otherwise, he will not be able to use the Diary App.

Setting a Patient's Initial Plan - For MDI Plans

After selecting an MDI Carbs Counting or an MDI Sliding Scale treatment plan for a patient (as described above), the Initial Plan screen is automatically displayed in which you must define the first plan for this patient including the basal and bolus plan. After you define and save it, this plan automatically appears in the patient's DreaMed Diary App as the patient's initial plan (which is described in the <u>DreaMed Diary App User Manual</u>).

To define the initial **Basal** treatment plan, see page 47.

To define the initial MDI Sliding Scale treatment plan, see page 48.

To define the initial MDI Carbs Counting treatment plan, see page 52.

To define the initial MDI Fixed meal with sliding scale correction treatment plan, see page 52.

To define the initial MDI Meal estimation with sliding scale correction treatment plan, see page 52

Initial Basal Plan

You must define at least one basal injection (row) and up to two.

- To define the patient's initial basal plan:
 - In the BASAL PLAN area, click in the Time, Amount (Units) and Insulin type cell in the BASAL PLAN table to define the corresponding value.

BASAL PLAN

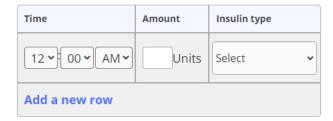


Figure 15 – Initial BASAL PLAN – MD



2 To add a new row specifying an additional Basal dose, click the **Add a new row** link, as shown above.



NOTE: When new rows are added, the rows are placed in chronological order after the settings are saved.

To delete a row, click the **X** to the right of the corresponding row.

Initial Bolus Plan

Define the bolus plan according to the MDI treatment plan type, for each part of a day, as follows:

Morning: 5 AM – 11 AM
 Afternoon: 11 AM – 5 PM
 Evening: 5 PM – 10 PM
 Night: 10 PM – 5 AM

The following types of Bolus Plans are provided according to the patient's treatment type:

- MDI –Sliding Scale, as described below.
- MDI Carbs Counting, as described on page 52.
- MDI Meal estimation with sliding scale correction, as described on page 55
- MDI Fixed meal with sliding scale correction, as described on page 58

Bolus Plan - MDI - Sliding Scale

The Bolus plan consists of a range of pre-meal glucose levels and their corresponding insulin amount to deliver. Different plan tables are provided for different times of the day **morning**, **afternoon**, **evening** and **night**. You can specify the type of insulin for each part of the day, which may vary for different times of the day.

The Bolus Plan shows a row for each range of glucose levels (mg/dL) and the recommended quantity of insulin units to be injected for every meal according to the patient's blood glucose. The top row of each plan table represents the low glucose values and the bottom row represents the high glucose levels.

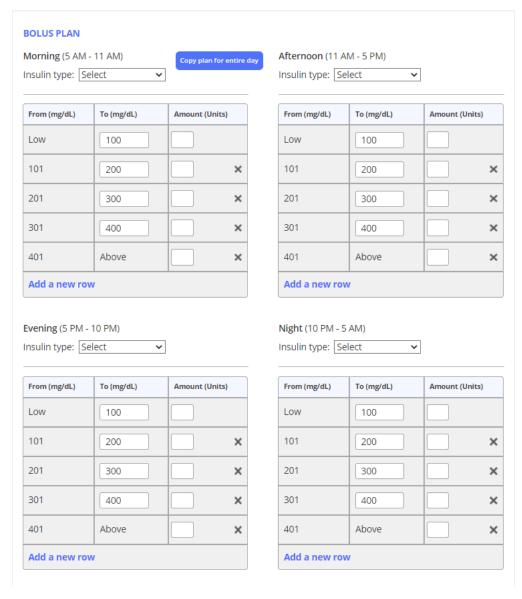


Figure 16 – Bolus Plan – MDI – Sliding Scale

The procedure described below is the same for the Morning, Afternoon, Evening and Night table.

- To define the bolus plan for each part of the day (morning, afternoon, evening and night):
 - 1 In the Insulin Type field, select the type of insulin to be to be added to the plan, such as Humalog.
 - 2 In the next steps, you will specify various ranges of pre-meal glucose and the Bolus amount (quantity of units) of the dosages to be administered for each.
 - 3 In the **To (mg/dL)** cell of the first row, specify the upper range value of the pre-meal glucose.



- In the **Amount (units)** cell, specify the quantity of insulin to administer when your pre-meal glucose is within the range defined above.
- To add a new row, click the **Add a new row** link and then click the + button between the two rows where you want to add the new row (the **From (mg/dL)** field automatically shows the value in the **To (mg/dL)** cell + 1), as shown below –

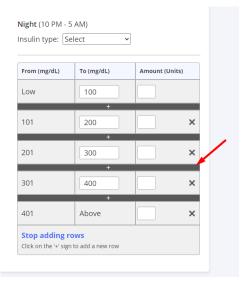


Figure 17 – Adding a New Bolus Plan Row – MDI – Sliding Scale

- 6 In the **To** (mg/dL) cell, specify the upper range value of the pre-meal glucose.
- 7 In the **Amount** cell, specify the quantity of insulin to administer when your pre-meal glucose is within the range defined above.
- 8 Define the values of this row, as described above.
- 9 Repeat the steps above as many times as necessary in order to define all possible ranges of pre-meal glucose and the quantity of insulin to administer for each.
 - a. Click the **Stop adding rows** link to stop adding rows to the plan.
 - b. Delete a row by clicking the **X** to the right of the corresponding row.



NOTE: You can use the copy plan to entire day to duplicate the morning plan to all other parts of the day, this can be used to save time when relevant. For more information, see "**Copy plan to entire day**" below.

10 Click **Save** to save the plan in the patient's Diary App.



NOTE: To save the initial plan you created, the plans for all parts of the day must be complete including all insulin amounts and insulin type



NOTE: Once you click save, you will be prompted to confirm it in a pop up

Copy plan to entire day

Copy plan for entire day

Figure 18 – Copy morning plan button

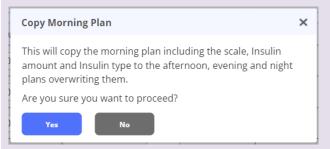
By using this button, you can copy the entire bolus morning plan, including the glucose range, insulin amount and insulin type to the other parts of the day. This will allow you to easily set up the patient's initial plan.



NOTE: Once copied you can edit the plans separately.



NOTE: Once you click the button you will be prompted to confirm it in a pop-up message





Bolus Plan - MDI - Carbs Counting

The MDI – Carbs Counting Bolus treatment plan is for patients who know how to count carbs and calculate the insulin needed for meals and/or correction boluses.

Different plan tables are provided for different times of the day **morning**, **afternoon**, **evening**, and **night**, as shown below



Figure 19 - Bolus Plan - MDI - Carbs Counting

To define the BOLUS PLAN:

- In the Carbs Units field, select the units of the values in the Carbs ratio field One Gram, Exchange (10 grams) or Exchange (15 grams). For example, if Carb Units: Exchange (15 grams) is selected, then for example entering 2 in the Carbs ratio Morning column represents 30 grams.
- 2 In each cell of the **Carbs ratio** row, enter a value for each part of a day.
- 3 In each cell of the **Correction factor** row, enter a value for each part of a day.
- 4 In each cell of the **Blood glucose target** row, enter a value for each part of a day.
- 5 In each cell of the **Insulin type** row, select the type of insulin to be administered for each part of a day.



NOTE: The bolus plan cannot be defined until the carb units is selected.

Bolus Plan - MDI - Meal Estimation and Sliding Scale Correction

The Bolus plan consists of two parts: meal bolus and correction bolus. The meal bolus includes 4 meals of the day: Breakfast, Lunch, Dinner, and Night meal, corresponding to the 4 time periods of the day: Morning, Afternoon, Evening, and Night, respectively.



For each meal there are 3 different meal sizes: small, normal, or large, and the corresponding insulin amount for each meal size. You can specify the type of bolus insulin for each part of the day, which may vary for different times of the day. If your patient uses the same doses for all meals of the day, you can enter the insulin amount and insulin type in the Breakfast section and click "Copy for entire day" button. See instructions below.

The correction bolus plan entails a sliding scale which includes a range of pre-meal glucose levels and their corresponding insulin amount to deliver. The glucose range is one for the entire day. The corresponding insulin amount can be adjusted for each period of the day **morning**, **afternoon**, **evening** and **night**. The top row of each sliding scale correction table represents the low glucose values and therefore has 0 insulin amount. The bottom row represents the high glucose levels. Here too you can enter the morning correction doses and copy them to the rest of the day.

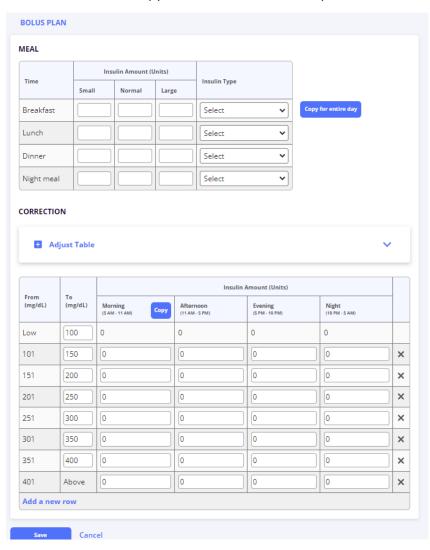




Figure 20- Bolus Plan – MDI – Meal Estimation and Sliding Scale Correction

To define the bolus plan:

- In the meal bolus table, enter the **Amount** of insulin (quantity of units) to be administered for each size of the meals of the day: **Breakfast, Lunch, Dinner,** and **Night meal**. For example, for a small breakfast, normal size breakfast, or large breakfast, enter the amount of insulin to be administered.
- 2 In the **Insulin Type** field, select the type of insulin to be administered for each meal and part of the day.
- After you enter the Breakfast plan, you can use the **Copy for entire day** button to automatically copy the insulin amount values and the insulin type from the breakfast to the rest of the meals in the day.

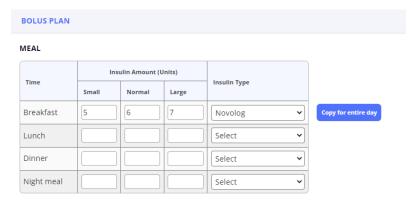


Figure 21- Meal plan - MDI - Meal Estimation and Sliding Scale Correction

- In the correction bolus table, you will specify various ranges of pre-meal glucose levels and the corresponding Bolus amount (quantity of units) to be administered at each period of the day: **Morning, Afternoon, Evening,** and **Night**.
- 5 To build the glucose ranges in your correction table, you can do in two ways:
 - a. To enter the ranges manually.
 - b. Use the 'Adjust table' feature to automatically adjust the glucose ranges.

To enter the ranges manually:

- In the To (mg/dL) cell of the correction table, specify the upper range value of the pre-meal glucose.
- b) In the **Insulin Amount (units)** cells, specify the quantity of insulin to administer when the glucose is within the range defined on the left columns.



- c) The first row will define the low glucose levels that the patient should not be taking any insulin for (correction threshold). In the **To (mg/dL)** cell of the first row specify the upper range value of the premeal glucose level, with zero insulin units for correction.
- d) To add a new row, click the Add a new row link at the bottom of the table and then click the + button between the two rows where you want to add the new row (the From (mg/dL) field automatically shows the value in the To (mg/dL) cell + 1), as shown below –

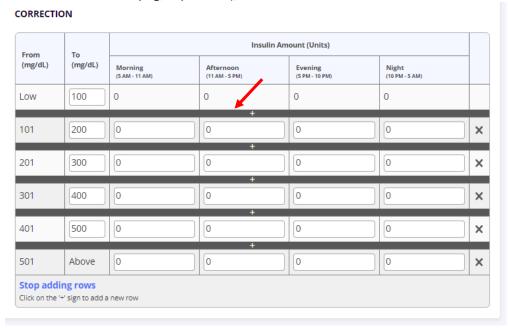


Figure 22 – Adding a new row to the correction plan in MDI – Meal Estimation and Sliding Scale Correction

- e) Define the values of this row, as described above.
- f) Repeat the steps above as many times as necessary in order to define all possible ranges of pre-meal glucose and the quantity of insulin to administer for each.
 - Click the **Stop adding rows** link to stop adding rows to the plan.
 - O Delete a row by clicking the **X** to the right of the corresponding row.

Use the 'Adjust table' feature:

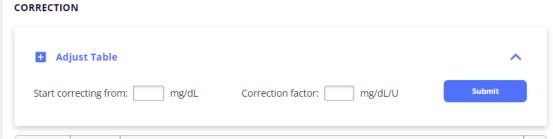


Figure 23 – Adjusting glucose correction ranges – Meal Estimation and Sliding Scale Correction



- a) Click 'Adjust Table'.
- b) Enter the 'Start correcting from' field that indicates the correction threshold in which below that glucose value the patient will not take any additional insulin.
- c) Enter the Correction factor which will impact the glucose ranges within each row.
- d) Click **submit** to automatically adjust the table accordingly.



NOTE: Once you submit the Adjust Table parameters, the corresponding insulin amounts in the table will be zeroed.

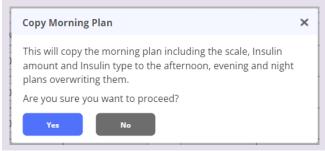
- In the **Insulin Amount (units)** cells, specify the quantity of insulin to administer when the glucose is within the range defined on the left columns.
- 7 Using the Copy button, you can copy the morning insulin amounts in the correction table, to the rest of the day.



NOTE: Once copied you can still edit each part of the day.



NOTE: Once you click the button you will be prompted to confirm it in a pop-up message



8 Click **Save** to save the plan in the patient's Diary App.



NOTE: To save the initial plan you created, the plans for all parts of the day must be complete including all insulin amounts and insulin type



NOTE: Once you click save, you will be prompted to confirm it in a pop up



Bolus Plan – MDI – Fixed Meal and Sliding Scale Correction

The Bolus plan consists of two parts: meal bolus and correction bolus. The meal bolus includes 4 meals of the day: Breakfast, Lunch, Dinner, and Night meal, corresponding to the 4 time periods of the day: Morning, Afternoon, Evening, and Night, respectively. You can specify the type of bolus insulin for each meal, which may vary for different times of the day. If your patient uses the same doses for all meals of the day, you can enter the insulin amount and insulin type in the Breakfast section and click "Copy for entire day" button. See instructions below.

The correction bolus plan entails a sliding scale which includes a range of pre-meal glucose levels and their corresponding insulin amount to deliver. The glucose range is one for the entire day. The corresponding insulin amount can be adjusted for each period of the day **morning**, **afternoon**, **evening** and **night**. The top row of each sliding scale correction table represents the low glucose values and therefore has 0 insulin amount. The bottom row represents the high glucose levels. Here too you can enter the morning correction doses and copy them to the rest of the day.

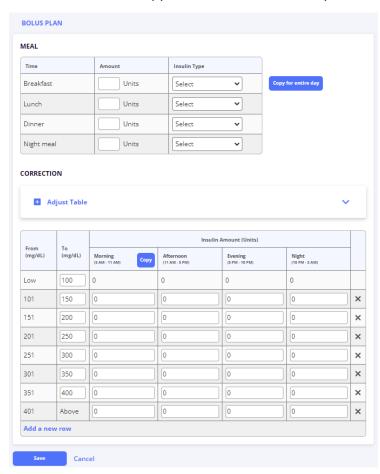




Figure 24 - Bolus Plan - MDI - Fixed Meal and Sliding Scale Correction

To define the bolus plan:

- 1 In the meal bolus table, enter the **Amount** of insulin (quantity of units) to be administered for each meal of the day: **Breakfast, Lunch, Dinner,** and **Night meal**.
- In the Insulin Type field, select the type of insulin to be administered for each meal and part of the day.
- You can also enter just the Breakfast insulin amount and type, and then use the **Copy for entire day** button to automatically copy the insulin amount values and the insulin type from the breakfast to the rest of the meals in the day.
- In the correction bolus table, you will specify various ranges of glucose levels and the corresponding Bolus amount (quantity of units) to be administered at each period of the day: **Morning, Afternoon, Evening,** and **Night**.
- 5 To build the glucose ranges in your correction table, you can do in two ways:
 - a. To enter the ranges manually.
 - b. Use the 'Adjust table' feature to automatically adjust the glucose ranges.

To enter the ranges manually:

- a) In the **To (mg/dL)** cell of the correction table, specify the upper range value of the pre-meal glucose.
- b) In the **Insulin Amount (units)** cells, specify the quantity of insulin to administer when the pre-meal glucose is within the range defined on the left columns.
- c) The first row will define the low glucose levels that the patient should not be taking any insulin for (correction threshold). In the **To** (mg/dL) cell of the first row specify the upper range value of the pre-meal glucose level, with zero insulin units for correction.
- d) To add a new row, click the Add a new row link at the bottom of the table and then click the + button between the two rows where you want to add the new row (the From (mg/dL) field automatically shows the value in the To (mg/dL) cell + 1), as shown below –





Figure 25 – Adding a new row to the correction plan in MDI – Fixed Meal and Sliding Scale Correction

- e) Define the values of this row, as described above.
- f) Repeat the steps above as many times as necessary in order to define all possible ranges of pre-meal glucose and the quantity of insulin to administer for each.
 - Click the Stop adding rows link to stop adding rows to the plan.
 - Delete a row by clicking the **X** to the right of the corresponding row.

Use the 'Adjust table' feature:



Figure 26 – Adjusting glucose correction ranges – Fixed Meal and Sliding Scale Correction

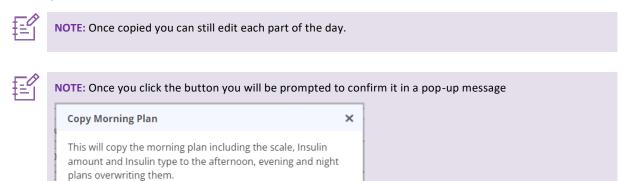
- a) Click 'Adjust Table'.
- b) Enter the 'Start correcting from' field that indicates the correction threshold in which below that glucose value the patient will not take any additional insulin.
- c) Enter the **Correction factor** which will impact the glucose ranges within each row.
- d) Click **submit** to automatically adjust the table accordingly.



NOTE: Once you submit the Adjust Table parameters, the corresponding insulin amounts in the table will be zeroed.



- In the **Insulin Amount (units)** cells, specify the quantity of insulin to administer when the glucose is within the range defined on the left columns.
- 7 Using the Copy button, you can copy the morning insulin amounts in the correction table, to the rest of the day.



8 Click **Save** to save the plan in the patient's Diary App.

Are you sure you want to proceed?



NOTE: To save the initial plan you created, the plans for all parts of the day must be complete including all insulin amounts and insulin type



NOTE: Once you click save, you will be prompted to confirm it in a pop up

Chapter 6 – Review and Share Recommendations

Upload devices data to endo.digital

For creating an endo.digital recommendation, first upload the patient's device data using endo.digital Uploader. You may access the Uploader by clicking the **Upload Data** link:



You may find more information on how to upload data in the Uploader user guide at: https://dreamed-diabetes.com/uploader/

Patient Recommendations List

For a patient that was started on endo.digital for the first time, the following screen appears.

- To generate a patient's first recommendation:
 - Click the **New Recommendation** button to generate the patient's first recommendation.



NOTE: The **Set Initial Plan** button appears instead of the **New Recommendation** button until the initial plan has been defined and saved.

If the patient uses a Dexcom sensor, he/she can click **Connect with Dexcom** to enable endo.digital to directly access the patient's Dexcom data. A patient's data can be uploaded to their Dexcom account either by using the Dexcom mobile application or by uploading the receiver data into their Clarity account. For more information, see <u>Connecting with a Dexcom Account</u>.



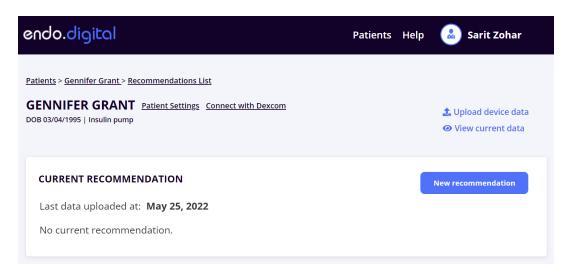


Figure 27 – Recommendations Screen



NOTE: To display or edit a patient's personal information, click the Patient Settings button.

When the first recommendation is available for the patient, the Recommendations screen includes the following information:

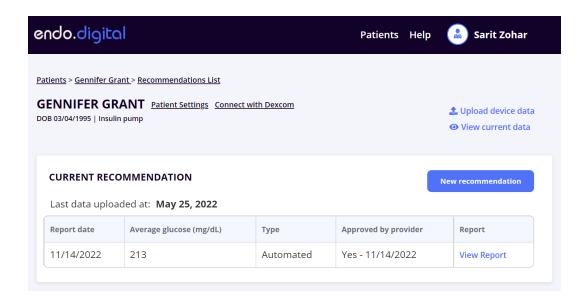


Figure 28 – Patient Recommendation List Screen



The Recommendations List screen is divided into two sections: The **CURRENT RECOMMENDATION** section lists recently created reports, and the **PAST RECOMMENDATIONS** section displays a list of historical recommendation reports

- Each section includes the following information:
 - Report date.
 - Average glucose (mg/dL).
 - **Type:** Indicates the type of recommendation. Displays **Advisor** when the recommendation was generated by the endo.digital algorithm or **Manual** when endo.digital could not generate a recommendation and the treatment plan was generated manually.
 - Approved by provider: Indicates whether the recommendation was approved by the HCP.
 - Patient approval status: Indicates whether the recommendation was approved by the patient in the Diary mobile app. This column will appear only for patients with MDI treatment plans.
 - View Report: Click to view the full endo.digital Recommendation report, which is described on page 78.
- Recommendation report alert messages may appear on the screen, as follows:
 - When viewing a recommendation report from the history section, the following message is displayed at the top of the screen:



Figure 29 – History Recommendation Notification

When viewing a recommendation report with a different treatment type than the patient's current treatment type, the following message is displayed at the top of the screen:



Figure 30 – Treatment Type Recommendation Notification



Connecting with a CGM Device Account

endo.digital enables to connect the patient's Dexcom account directly. Once connected, endo.digital can access the patient's data in a cloud to cloud connection, without additional upload actions from the patient or the clinic team.

The clinical staff can connect the patient's Dexcom account through the endo.digital web application.

A patient can connect his Dexcom account either from the patient web application or DreaMed Diary App.

To connect a Dexcom account, visit the Patient screen and click the Connect Devices link.

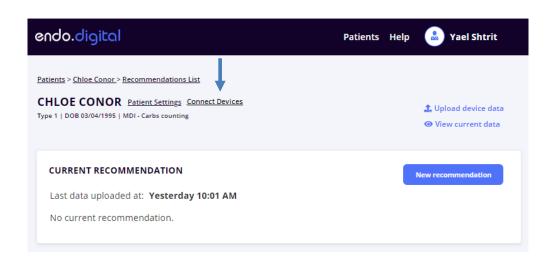
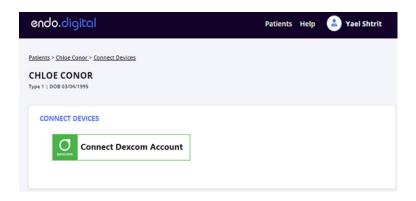


Figure 31 – Connect Devices

Then click the **Connect Dexcom Account** button.





The following screen displays. The patient may log in with an existing Dexcom account or with a new one.

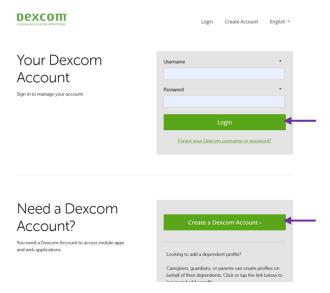


Figure 32 - Log In with Dexcom Account

Once logged in, the Dexcom screen closes and the screen indicates that the patient is connected with Dexcom.

You may disconnect the patient's Dexcom account by clicking the Disconnect Dexcom account link

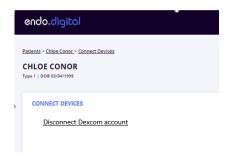
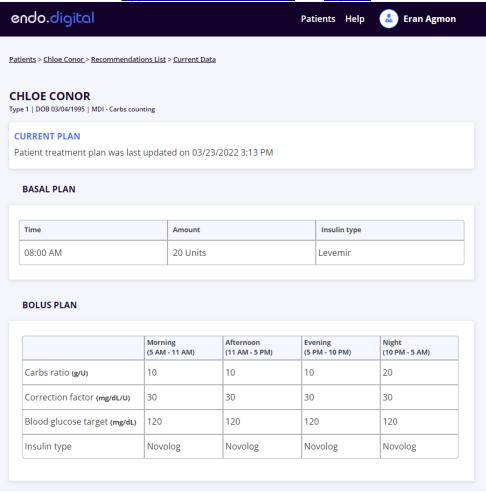
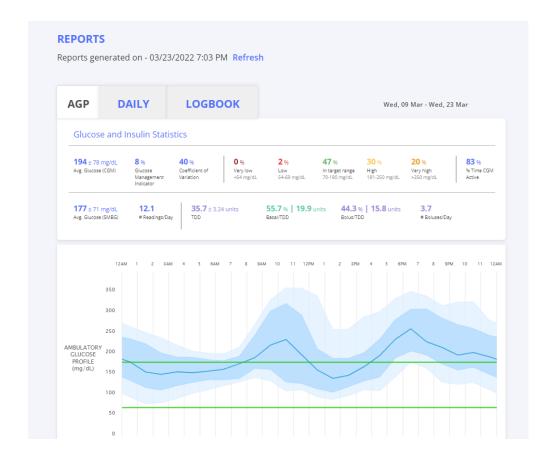


Figure 33 – Device connection page – disconnect Dexcom

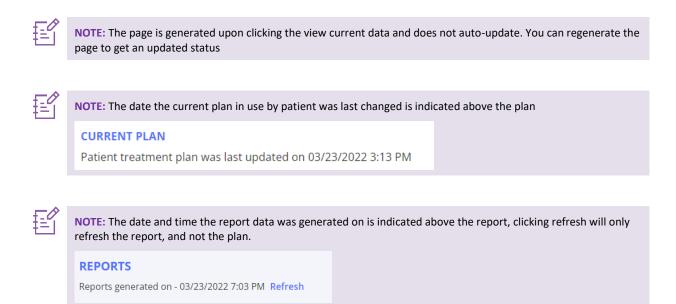
View Current Data

You can click the view current data to generate and view the current plan used by the patient in the Diary App and the latest data report available. The report will contain all available data that was uploaded from the supported data sources or logged in the DreaMed Diary App during the last 21 days. For more information see the Approved Recommendations and Reports section.









Patient Settings

To view and edit the patient's settings, click the **Patient Settings** link next to the patient's name.

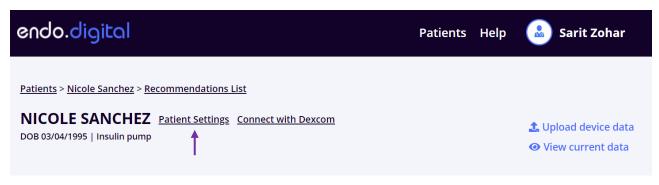


Figure 34 – Patient Screen – Patient settings button

In this screen you can view and manage the patient's information and treatment plan settings.

At the top of the screen is the patient information. The patient's email can be edited any time before the patient has logged into the service for the first time.



The patient's treatment plan section, as well as the bolus calculator section (when applicable) displays settings that can be modified when needed. These settings are used by endo.digital algorithm for providing recommendations.

If you wish to change the patient's treatment plan type between the available treatment plans (see <u>Start a New Patient on endo.digital</u>), click the **Change treatment plan type** link.



NOTE: endo.digital can provide a recommendation only after a patient used their plan for at least 21 days. Changing a patient's treatment plan type will prevent endo.digital algorithm recommendations for a 21-day period after changing the treatment plan type. You will be able to provide manual recommendations during that period.

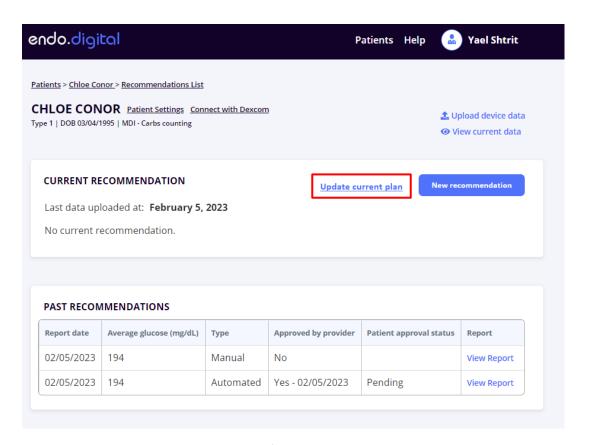
Once clicked, you can start your patient with the treatment plan of your choice (and set their initial plan for MDI patient) as described in the Start a New Patient on endo.digital section.

Update patient's MDI plan

Patients that are on multiple daily injections (MDI) therapy may change their insulin injections regimen on their own, in between their visits with the provider. Therefore, you may want to review the treatment plan that is saved in endo.digital and update it based on what the patient states is his actual current treatment regimen. Updating the current treatment plan should be done **before** generating a new treatment recommendation.

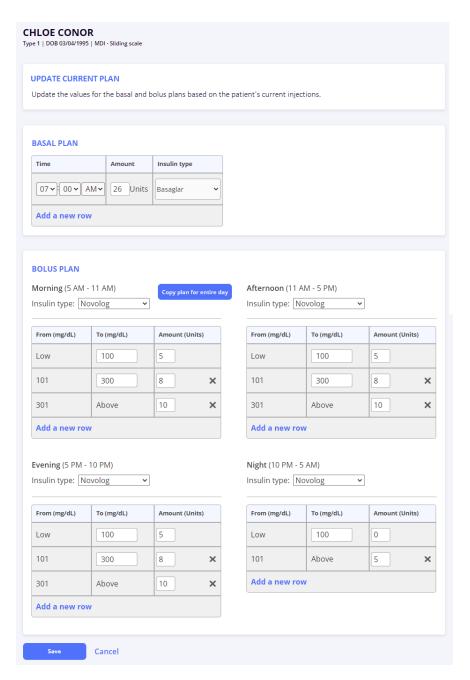
You click on the 'Update current plan' link, in the 'Current Recommendation' box to review and update the patient's current treatment plan.





You will reach the screen with the patient's current treatment plan as saved in the endo.digital system and in the patient's Diary app. Review the plan and edit it if the patient changed his treatment regimen and is not following this plan. Instructions on how to edit the plan are identical to 'Setting a Patient's Initial Plan'.





If you click cancel or leave this page without saving, changes will not be saved.

Click **Save** to save the plan in the patient's Diary App, and to generate a new treatment recommendation automatically.



NOTE: Once you click save, you will be prompted to confirm it in a pop up

New Recommendation

After the patient has been started on endo.digital, you can click **New recommendation** to receive new recommendations for the data already uploaded from the supported data sources and/or logged in the DreaMed Diary App and/or Dexcom account (when available).

After clicking **New recommendation**, it may take up to one minute to pull the patient's data, analyze it and provide a recommendation.

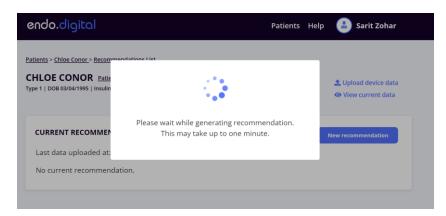


Figure 35 – Generating a New Recommendation Screen



Manual Recommendation Message and endo.digital Recommendation Errors

If a recommendation cannot be automatically generated by endo.digital due to any of the reasons listed in Appendix C, you can manually provide a recommendation for the patient.

Manual recommendations are created based on your professional knowledge and judgment and are not based on endo.digital's algorithm calculation methodology. You can use the patient's current plan data, if it exists, and the glucose and insulin reports to create your recommendation. In some cases, endo.digital may not have any data for a patient. In this case, you can also create a recommendation and then use endo.digital to track these recommendations and share them with the patient.

When this happens, the software will display a message. The top part of the message explains the specific reason for the recommendation failure. You can continue to edit the patient's plan manually or click **Cancel**, correct the problem and then click the **New recommendation** button again.

For example, you can create a manual recommendation if there is not currently enough data to generate a recommendation with endo.digital (for example, if you forgot to upload the patient data). In this case, you can click **Cancel**, upload the data and try again. If the patient's data was uploaded and there is still insufficient data, you can manually create the recommendation yourself.

Simply click the Continue manually button to manually create a recommendation.

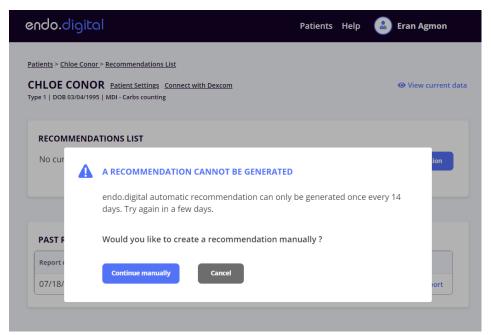


Figure 36 – Example Manual Recommendation Message Due to Insufficient Data Message



To manually create a recommendation:

9 In the screen appearing in the figure above, click Continue manually. The following displays:

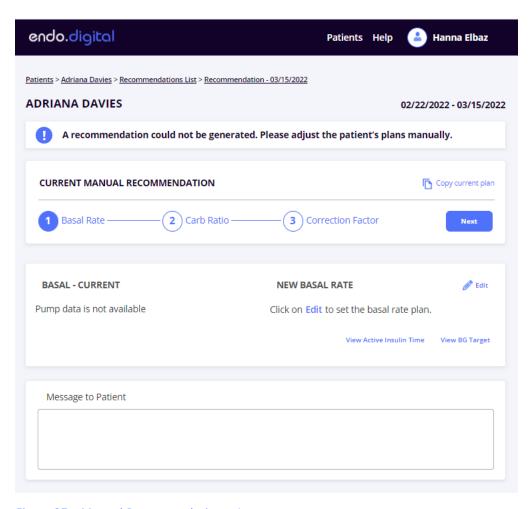


Figure 37 – Manual Recommendation – 1

When a current plan exists, its data appears in the current plan section. When no current plan exists, text will indicate so.

Appendices



10 To edit the basal plan, click the **Edit** button in the new plan area. The new plan initially shows the data from the current plan until you change it. When no current plan exists, you edit the new plan data from scratch. Once clicking the Edit button, the following displays:



Figure 38 – Manual Recommendation – 2

- 11 Modify the relevant part of the plan as described in Familiarize Yourself with an endo.digital Report.
- Once all the plan screens are set (for pump patients: basal, carbs ratio and correction factor; for MDI patients: basal and bolus) continue to review and approve the new treatment plan.
- Once approved, a manual recommendation can be used by the patient in the same manner as regular endo.digital recommendations.

After creating a manual recommendation, it will appear in the patient's recommendations list. Its **Type** would indicate that this is a manual recommendation, as detailed in the <u>Patient Recommendations List</u> section.

Preliminary Checks Before Reviewing an endo.digital Report

Each time you want to review the recommendations of endo.digital, ask yourself the following:

Is the patient a good candidate for endo.digital?

Make sure that:

- The patient meets the <u>indications for use</u> requirements.
- The patient does not fall within the contraindication.



- The patient is using the recommended treatment plan and the recommended insulin type.
- If you do not remember, you can always refer to this user manual by clicking the **Help** link at the top section of endo.digital.

Are there any special circumstances with the patient that could affect their glucose and insulin delivery data in the past 21 days?

endo.digital analyzes historical glucose and insulin data and uses it to recommend changes to the insulin treatment plan that should be implemented for future treatment dosage. Therefore, please avoid using endo.digital recommendations when special circumstances occur that could affect the data you and endo.digital use for analysis. Examples of special circumstances could include:

- Illness
- Medications
- Hospitalization
- Use of steroids
- Extreme physical activity
- · Significant change of diet
- Holidays

Is there a chance that the insulin pump, glucometer and sensor clocks are not synchronized?



NOTE: 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.

Please check that:

- An error message does not appear when downloading the data from the device to endo.digital
 Uploader/Tidepool, 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. Refer to the relevant
 endo.digital Uploader/Tidepool user manual for details about how this message appears in the
 respective platform.
- The patient has not traveled to another time zone in the past 21 days.



• There is **no** indication on endo.digital Uploader/Tidepool that the patient has changed the clock of the insulin pump, CGM or blood glucose meters. Refer to the relevant endo.digital Uploader/Tidepool user manual for details about how this message appears in their platform.

Have I Reviewed the Cautionary Messages in the Recommendation?

When you view a recommendation report for either of the MDI Plans, one or more cautionary messages may appear in the report to notify the HCP of situations in the patient's data reporting or in the recommendation process that should be considered while evaluating that recommendation. These messages may appear in the Basal plan or in the Bolus plan pages. For example, the following message may appear in the BASAL section to indicate a significant gap between a patient's basal plan and the actual insulin delivery indicated by the patient's data.



The system identified a gap between the bolus plan and the actual insulin doses delivered during the afternoon.

Figure 39 – Review Basal Messages

The messages may differ according to the MDI treatment plan type and when applicable some of these messages specify the relevant part of day – morning, afternoon, evening, night. The following are cautionary messages that may appear in a recommendation.

Table 12 – Caution Messages – MDI Treatment Plan

#	UI Message
1	The system identified a gap between the bolus plan and the actual insulin doses delivered during the morning/afternoon/evening/night.
2	The size of the morning/afternoon/evening/night boluses was inconsistent. Make sure the patient is following their treatment plan.
3	The system identified a gap between the basal plan and the actual insulin doses delivered.
4	The size of the basal doses was inconsistent. Make sure the patient is following their treatment plan.
5	Not enough basal injections were reported to verify the current basal plan. Verify the patient is using the current basal plan and adjust accordingly before approving the new recommendation.
6	Not enough bolus injections were reported to verify the current bolus plan. Verify the patient is using the current bolus plan and adjust accordingly before approving the new recommendation.

endo.digital

Familiarize Yourself with an endo.digital Report

A patient's endo.digital recommendation report is dependent on the treatment type for the patient. In general, recommendation reports contain similar information and are organized similarly. However, their recommendations differ, based on the treatment type of the patient as follows –

- Insulin Pump, page 79
- MDI Sliding Scale, page 94
- MDI Fixed meal and sliding scale correction, page 101
- MDI- Meal estimation and sliding scale correction, page 106
- MDI Carbs Counting, page 113
- Generic Treatment Plan, page 117

endo.digital

Insulin Pump

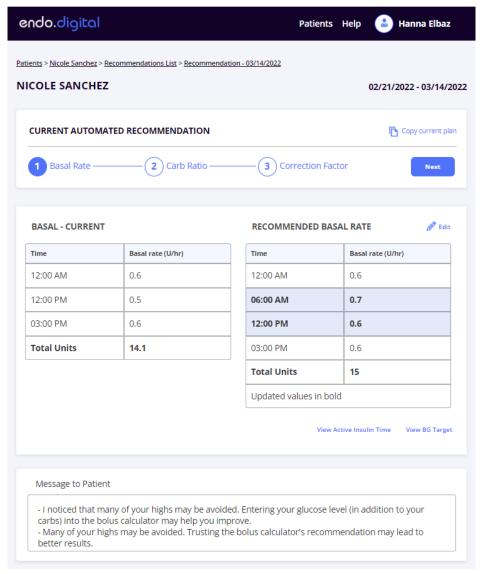


Figure 40 – Top Half of Review and Share Recommendations Screen – Insulin Pump

- **Navigation**: The navigation bar at the top of the screen displays the three recommendation categories: <u>Basal Rate</u>, <u>Carb Ratio</u> and <u>Correction Factor</u>. All categories must be reviewed and approved before recommendations can be shared with the patient. Navigate between the categories by clicking **Next** and **Prev**.
- **Current Settings**: The table(s) on the left shows the patient's current settings. The patient's current basal plan is listed on top. Other basal plans that the patient has in their pump are listed beneath it.

- **Recommended Settings**: The table on the right shows the new settings suggested by endo.digital. The updated values are displayed in bold.
- View Active Insulin Time and Bolus Calculator Glucose Target: Click View Active Insulin Time or View BG Target to view these reference values.
- Personalized Diabetes Management Tips: These are tips for the patient that are suggested by endo.digital, intended to enhance the effectiveness of the insulin therapy. The patient can view these comments when reviewing the recommendations.
- **Copy current plan**: Clicking the **Copy current plan** link will copy to your clipboard the information about the patient, the current date, their current treatment plan and their statistics. This data may be pasted anywhere, including in an EMR for documentation purposes.
- endo.digital Reports: See Reports.

Basal Rate Settings

To edit the recommended basal rate, click Edit.



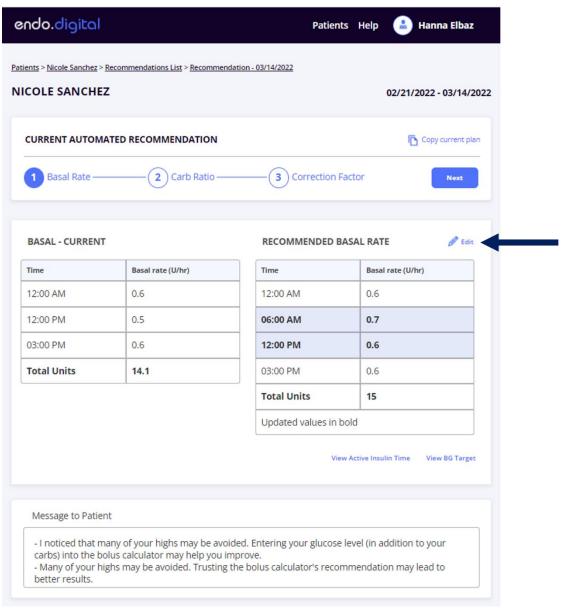


Figure 41 – Review Basal Rate Screen – Insulin Pump – Basal Rate Plan



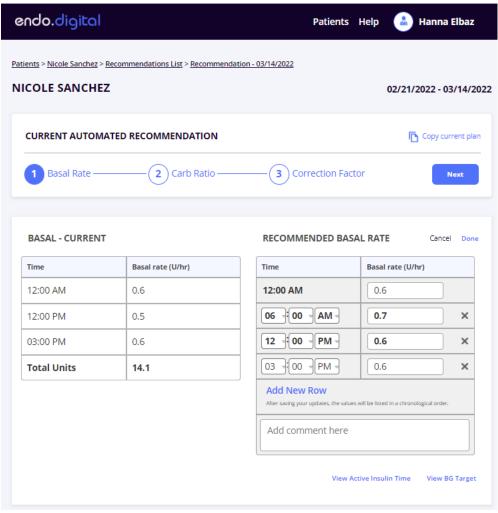


Figure 42 – Edit Basal Rate Screen – Insulin Pump

- Click within a **Time** or **Basal Rate** (U/hr) field to adjust the corresponding value.
- Click Add New Row to add additional Basal Rate times.

NOTE: When new rows are added, the rows are placed in chronological order after the settings are saved.

- Delete a row by clicking the **X** to the right of the corresponding row.
- Append comments to this recommendation by entering text in **Comments** at the bottom.
- Click **Done** to exit this view and save your changes.
- · Click Cancel to exit this view without saving





NOTE: After you click the **Edit** button, you can either click **Done** to save your changes or click **Cancel** to exit without saving.

Click **Next** to continue to <u>Carbohydrates Ratio Settings</u>.



Carbohydrates Ratio Settings

To edit the Recommended Carb Ratio, click Edit.

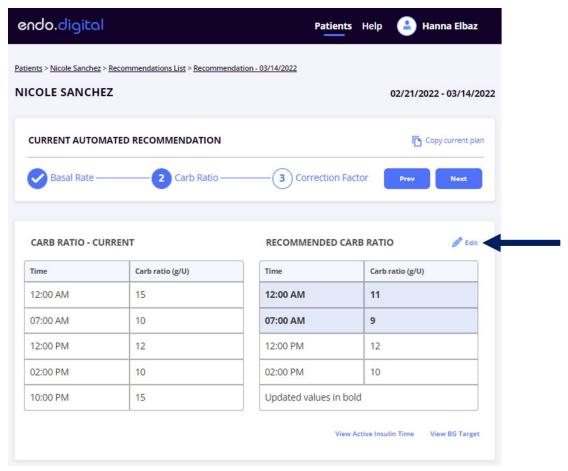


Figure 43 – Review Carb Ratio Screen – Insulin Pump



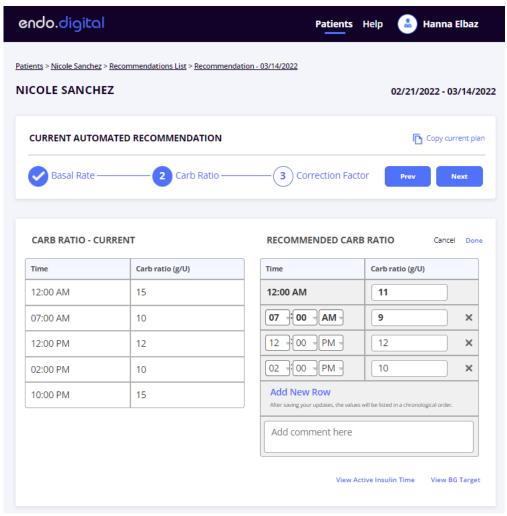


Figure 44 – Edit Carb Ratio Screen – Insulin Pump

- Click within a **TIME** or **Carb Ratio** (g/U) cell to adjust the corresponding value.
- Click Add New Row to add additional Carb Ratio times.

NOTE: When new rows are added, the rows are placed in chronological order after the settings are saved.

- Delete a row by clicking the X to the right of the corresponding row.
- Append comments to this recommendation by entering text in Comments at the bottom.
- Click **Done** to exit this view and save your changes.
- Click Cancel to exit this view without saving.





NOTE: After you click the **Edit** button, you can either click **Done** to save your changes or click **Cancel** to exit without saving.



NOTE: The Carb Ratio appears in grams per unit of insulin.

Click **Next** to continue to <u>Correction Factor Settings</u>.



Correction Factor Settings

To edit the recommended Correction Factor, click Edit.

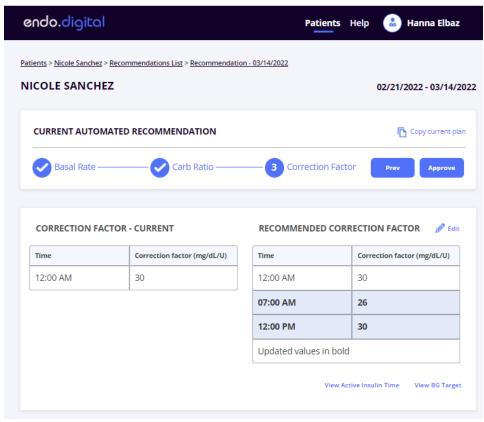


Figure 45 – Review Correction Factor Screen – Insulin Pump



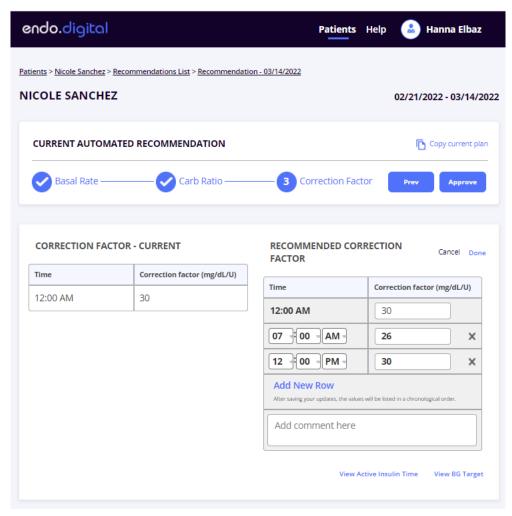
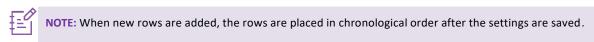


Figure 46 – Edit Correction Factor Screen – Insulin Pump

- Click within a **Time** or **Correction Factor** (mg/dL/U) cell to adjust the corresponding value.
- Click Add New Row to add additional Correction Factor times.



- Delete a row by clicking the X.
- Append comments to this recommendation by entering text in Comments at the bottom.
- Click **Done** to exit this view and save your changes.
- Click **Cancel** to exit without saving.





NOTE: After you click the **Edit** button, you can either click **Done** to save your changes or click **Cancel** to exit without saving.

Approve and Share

An Approve and Share prompt displays. Review the information and click the **Approve and Share** button to approve the recommendations to share them with the patient. Click **Cancel** to return to the previous screen. Note that the patient cannot view the recommendations until you click **Approve and Share**. See Approved Recommendations for more details.

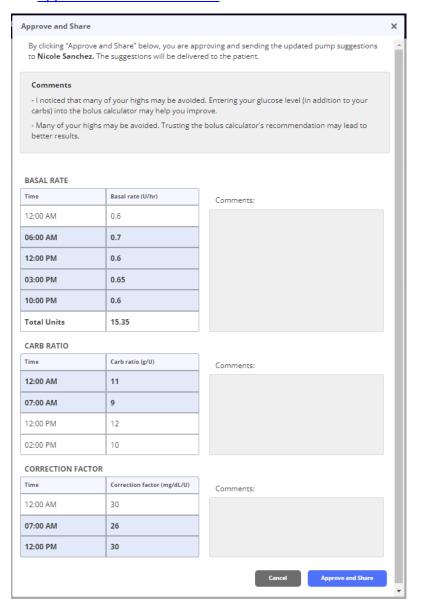




Figure 47 – Approve and Share Screen – Insulin Pump Treatment Type

MDI Treatment Plans

General

The following apply for all the MDI treatment types.

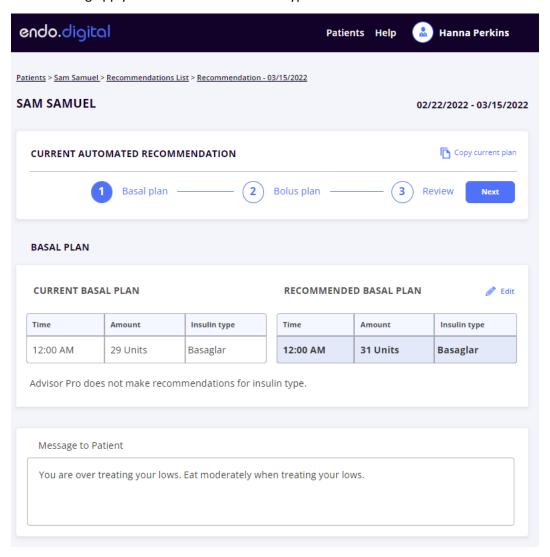


Figure 48 – Top Half of Basal Plan Recommendations Page – MDI – Sliding Scale

These recommendations must be reviewed and approved before Recommendations can be shared with the patient. Navigate between the categories by clicking Next and Prev.

First

Steps

Current Settings: The table(s) on the left shows the patient's current settings.



- Recommended Settings: The table on the right shows the new insulin treatment plan suggested by endo.digital. The updated values are displayed in bold and highlighted in blue.
- Copy current plan: Clicking the Copy current plan link will copy to your clipboard the information about the patient, the current date, their current treatment plan and their statistics. This data may be pasted anywhere, including in an EMR for documentation purposes.

Basal Plan

The Basal Plan shows a row for each recommended injection. It specifies the time, the quantity of units and the insulin type of each injection. You may only select one or two injections for a patient.

The Basal Plan applies for all MDI treatment types.

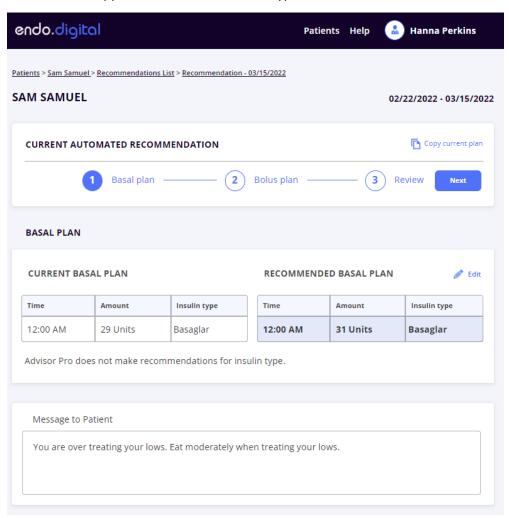


Figure 49 - Review Basal Plan Page

FAQs

Appendices



The left side of the page shows the patient's plan as it is currently in the patient's Diary App. The right side shows the new recommended plan.

To edit the Recommended Basal Plan, click * Edit. The following displays –

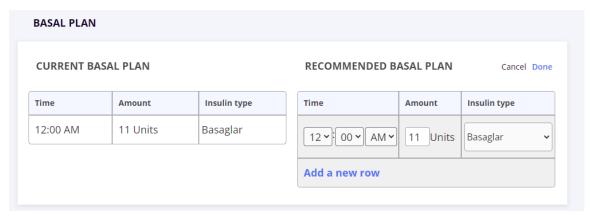
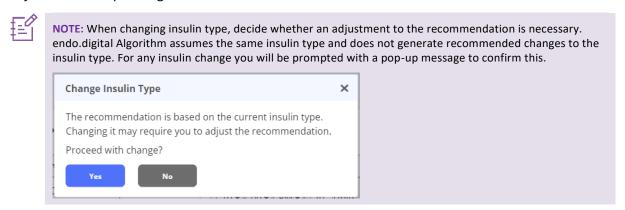


Figure 50 - Edit Basal Plan Page - MDI

• Click in a **Time**, **Amount (Units)** or **Insulin type** cell in the **RECOMMENDED BASAL PLAN** table to adjust the corresponding value.



endo.digital

To add a new row specifying an additional Basal dose, click the Add a new row link, as shown below –

RECOMMENDED BASAL PLAN

Cancel Done

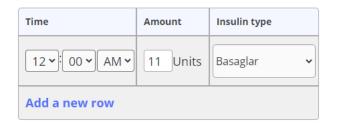


Figure 51 – Adding a New Basal Plan Row – MDI



NOTE: When new rows are added, the rows are placed in chronological order after the settings are saved.

- Delete a row by clicking the **X** to the right of the corresponding row.
- Click **Done** to exit this view and save your changes.
- Click **Cancel** to exit this view without saving.



NOTE: Once you click Edit, you can either click Done to save your changes or click Cancel to exit this view without saving.

- Click **Done** if you have finished editing.
- Click **Next** to continue to the Bolus plan.

Bolus Plan

The following types of Bolus Plans are provided according to the patient's treatment type —

- MDI Sliding Scale, as described on page 95.
- MDI Fixed Meal and Sliding Scale Correction, as described on page 102.
- MDI Meal Estimation and Sliding Scale Correction, as described on page 107.
- MDI Carbs Counting, as described on page 114.



Bolus Plan - MDI - Sliding Scale

The Bolus plan consists of a range of pre-meal glucose levels and their corresponding insulin amount to deliver. Different plan tables are provided for different times of the day **morning**, **afternoon**, **evening** and **night**. You can specify the type of insulin for each part of the day, which may vary for different times of the day. The Bolus Plan shows a row for each range of glucose levels (mg/dL) and the recommended quantity of units to be injected for every meal according to the patient's blood glucose. The top row of each plan table represents the low glucose values and the bottom row represents the high glucose levels.





Figure 52 – Review Bolus Plan Page – MDI –Sliding Scale

The left side of the page shows the current plan (which was recommended previously) and the right side shows the new recommended plan.

To edit the Recommended Bolus Plan:

Click **Edit**. The following displays:



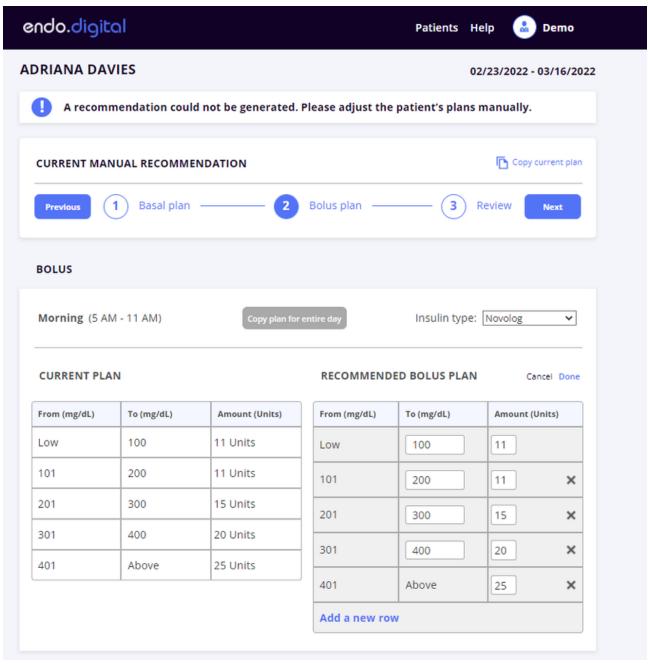


Figure 53 – Edit Bolus Plan Page – MDI –Sliding Scale



Click in a **To** or **Amount** cell in the **RECOMMENDED PLAN** table to adjust the corresponding value. Each time you change a value in a **To** cell, the value in the **From** cell in the preceding row changes automatically.

To add a new row, click the Add a new row link and then click the + button between the two rows
where you want to add the new row, as shown below

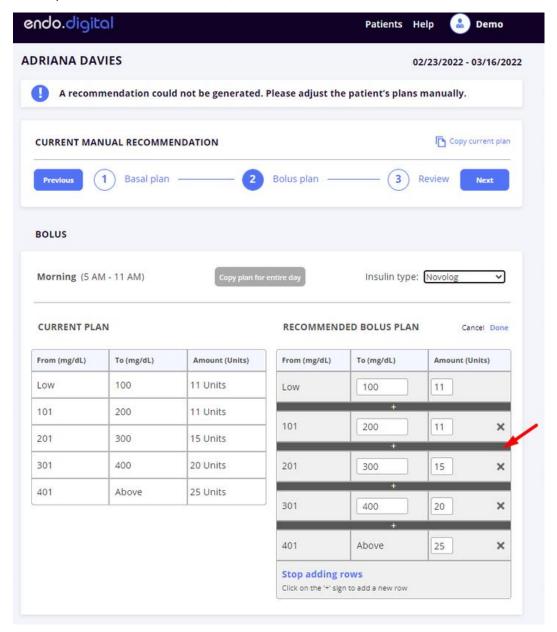


Figure 54 – Adding a New Bolus Plan Row – MDI – Sliding Scale

Click the **Stop adding rows** link to stop adding rows to the plan.



You can also change the type of insulin per time of day using the applicable dropdown list.

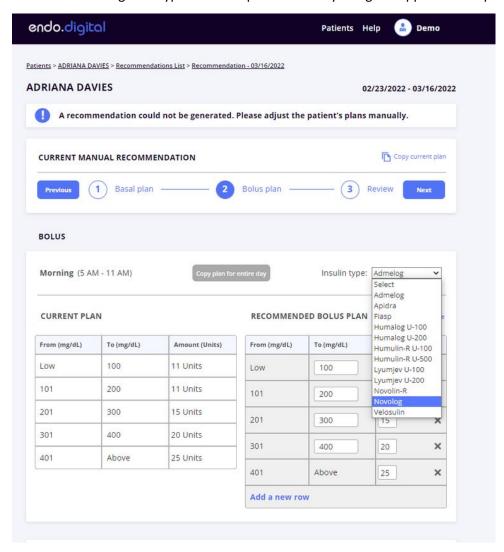


Figure 55 – Selecting the Insulin Type – MDI – Sliding Scale



NOTE: When changing insulin type, decide whether an adjustment to the recommendation is necessary. endo.digital Algorithm assumes the same insulin type and does not generate recommended changes to the insulin type. For any insulin change you will be prompted with a pop-up message to confirm this





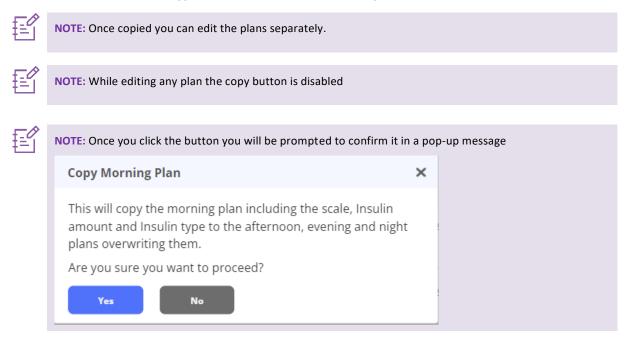
- Delete a row by clicking the **X** to the right of the corresponding row.
- Click **Done** to exit this view and save your changes.
- Click Cancel to exit this view without saving.
 - NOTE: After you click **Edit**, you can either click **Done** to save your changes or click **Cancel** to exit this view without saving.
- Click **Done** if you have finished editing.

Copy plan to entire day

Copy plan for entire day

Figure 56 – Copy morning plan button

By using this button, you can copy the **recommended** bolus morning plan, including the glucose range, insulin amount and insulin type to the rest of the times of day.





Click Next to continue to the Review page.

This page shows the entire plan. While reviewing the entire plan, you can add comments to the patient in the **Message to Patient** field and then approve the plan.

After you have reviewed the entire plan (which includes scrolling down to the end of the page), you can approve the plan by clicking the **Approve** button so that it is shared with the patient.



Figure 57 – Review Page – MDI – Sliding Scale





NOTE: endo.digital ensures that you have viewed the entire plan by only enabling the **Approve** button after the entire Review page has been displayed. This may involve scrolling the page down.

MDI - Fixed Meal and Sliding Scale Correction

The Bolus plan consists of two parts: meal bolus and correction bolus. The meal bolus includes 4 meals of the day: Breakfast, Lunch, Dinner, and Night meal, corresponding to the 4 time periods of the day: Morning, Afternoon, Evening, and Night, respectively. You can specify the type of bolus insulin for each meal, which may vary for different times of the day.

The correction bolus plan entails a sliding scale which includes a range of pre-meal glucose levels and their corresponding insulin amount to deliver. The glucose range is one for the entire day. The corresponding insulin amount can be adjusted for each period of the day **morning**, **afternoon**, **evening** and **night**. The top row of each sliding scale correction table represents the low glucose values and therefore has 0 insulin amount and the bottom row represents the high glucose levels.

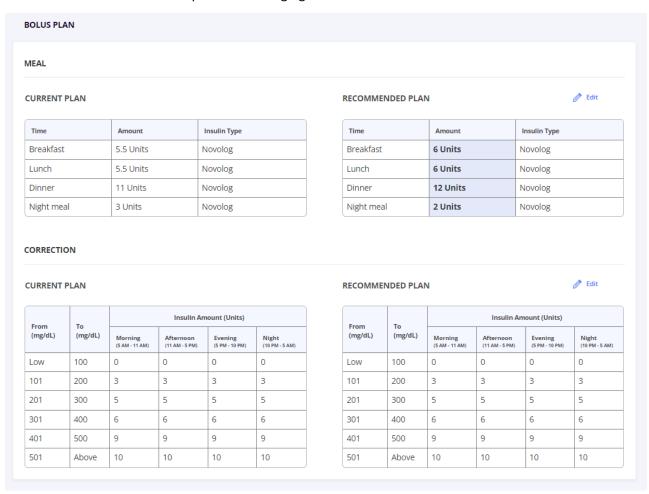


Figure 58 – Review Bolus Plan Page – MDI – Fixed meal and sliding scale correction



The left side of the page shows the current plan and the right side shows the new recommended plan.

► To edit the Recommended Meal Bolus Plan:

• Click * Edit. The following displays:



Figure 59 – edit meal bolus plan – MDI – Fixed meal and sliding scale correction

You can adjust the **Amount** of insulin (quantity of units) to be administered for each meal of the day: **Breakfast, Lunch, Dinner,** and **Night meal.**

You can also change the type of insulin per meal using the applicable dropdown list.

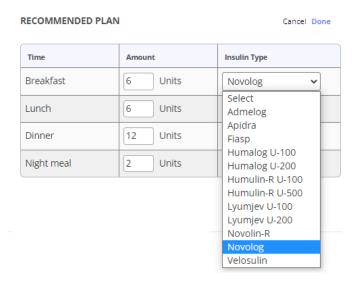
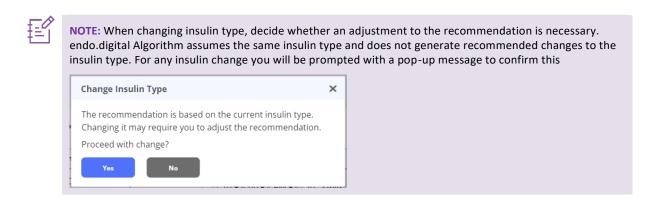


Figure 60 – edit bolus insulin type – MDI – Fixed meal and sliding scale correction





► To edit the Recommended Correction Bolus Plan:

Click Sedit. The following displays:

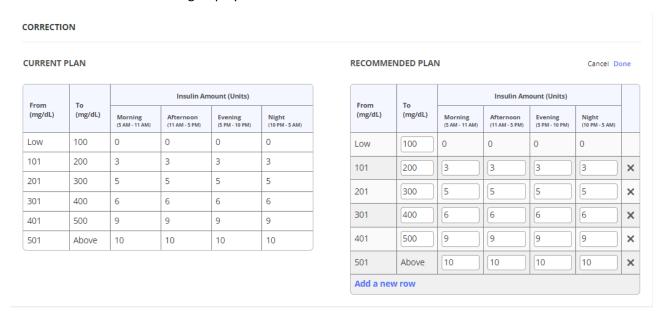


Figure 61 – edit bolus correction table – MDI – Fixed meal and sliding scale correction

You can adjust the ranges of pre-meal glucose levels and the corresponding Bolus amount (quantity of units) to be administered at each period of the day: **Morning, Afternoon, Evening,** and **Night**.

In the **To (mg/dL)** cell of the correction table, specify the upper range value of the pre-meal glucose.

In the **Insulin Amount (units)** cells, specify the quantity of insulin to administer when the pre-meal glucose is within the range defined on the left columns.



The first row will define the low glucose levels that the patient should not be taking any insulin for (correction threshold). In the **To (mg/dL)** cell of the first row specify the upper range value of the pre-meal glucose level, with zero insulin units for correction.

To add a new row, click the **Add a new row** link at the bottom of the table and then click the **+** button between the two rows where you want to add the new row (the **From (mg/dL)** field automatically shows the value in the **To (mg/dL)** cell **+** 1), as shown below –

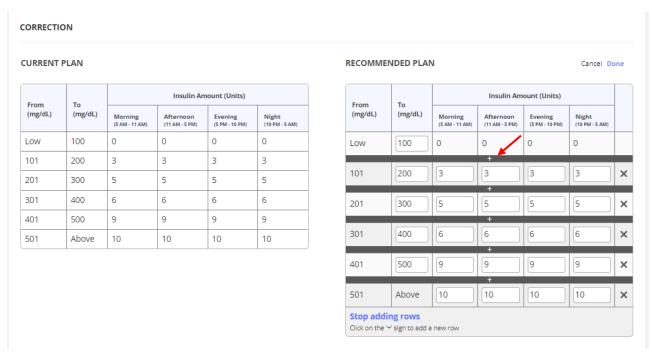


Figure 62 – Add a new row to the bolus correction table – MDI – Fixed meal and sliding scale correction

Define the values of this row, as described above.

Repeat the steps above as many times as necessary in order to define all possible ranges of pre-meal glucose and the quantity of insulin to administer for each.

- c. Click the **Stop adding rows** link to stop adding rows to the plan.
- d. Delete a row by clicking the **X** to the right of the corresponding row.

Click **Done** to exit this view and save your changes.

Click Cancel to exit this view without saving.



NOTE: After you click **Edit**, you can either click **Done** to save your changes or click **Cancel** to exit this view without saving.



Click Next to continue to the Review page.

This page shows the entire plan. While reviewing the entire plan, you can add comments to the patient in the **Message to Patient** field and then approve the plan.

After you have reviewed the entire plan (which includes scrolling down to the end of the page), you can approve the plan by clicking the **Approve** button so that it is shared with the patient.

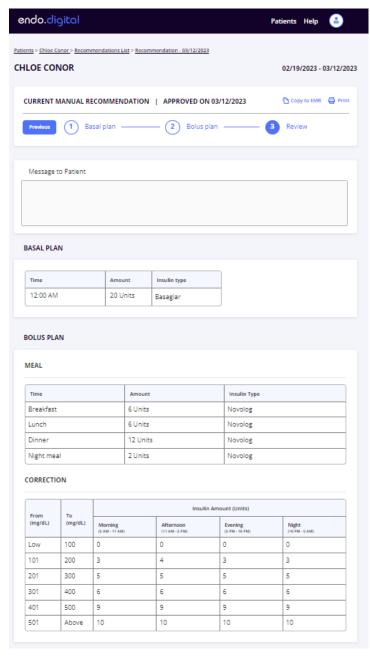


Figure 63 – Review page – MDI – Fixed meal and sliding scale correction





NOTE: endo.digital ensures that you have viewed the entire plan by only enabling the **Approve** button after the entire Review page has been displayed. This may involve scrolling the page down.

Bolus Plan - MDI - Meal Estimation and Sliding Scale Correction

The Bolus plan consists of two parts: meal bolus and correction bolus. The meal bolus includes 4 meals of the day: Breakfast, Lunch, Dinner, and Night meal, corresponding to the 4 time periods of the day: Morning, Afternoon, Evening, and Night, respectively.

For each meal there are 3 different meal sizes: small, normal, or large, and the corresponding insulin amount for each meal size. You can specify the type of bolus insulin for each part of the day, which may vary for different times of the day.

The correction bolus plan entails a sliding scale which includes a range of pre-meal glucose levels and their corresponding insulin amount to deliver. The glucose range is one for the entire day. The corresponding insulin amount can be adjusted for each period of the day **morning**, **afternoon**, **evening** and **night**. The top row of each sliding scale correction table represents the low glucose values and therefore has 0 insulin amount and the bottom row represents the high glucose levels.



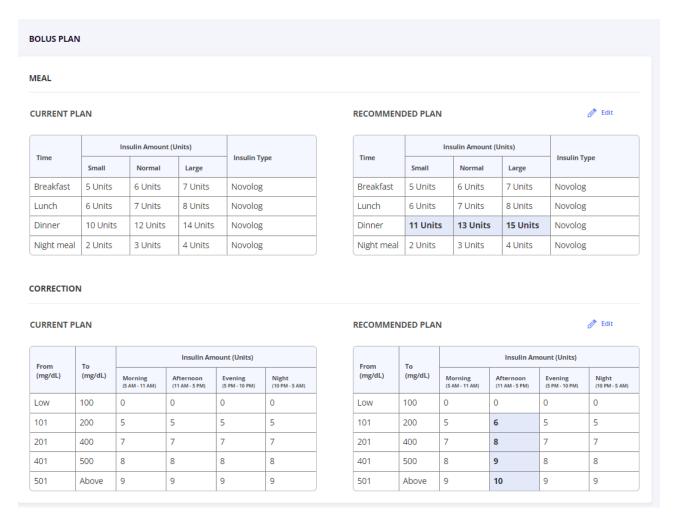


Figure 64 – Review Bolus Plan Page – MDI – Meal estimation and sliding scale correction

To edit the Recommended Meal Bolus Plan:

Click Sedit. The following displays:



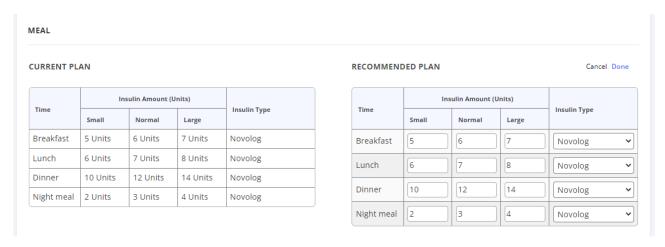
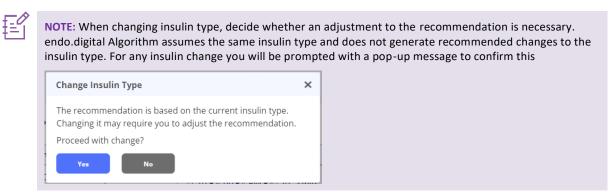


Figure 65 – Edit meal bolus plan – MDI – Meal estimation and sliding scale correction

You can adjust the **Amount** of insulin (quantity of units) to be administered for each size of the meals of the day: **Breakfast, Lunch, Dinner,** and **Night meal**. For example, for a small breakfast, normal size breakfast, or large breakfast, enter the amount of insulin to be administered.

You can also change the type of insulin per meal using the applicable dropdown list.



- ▶ To edit the Recommended Correction Bolus Plan:
 - Click Sedit. The following displays:



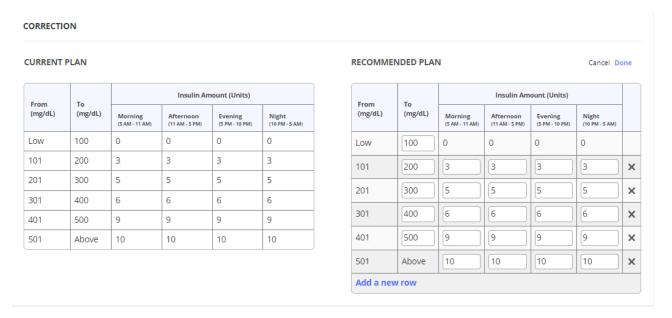


Figure 66 – edit bolus correction table – MDI – Fixed meal and sliding scale correction

You can adjust the ranges of pre-meal glucose levels and the corresponding Bolus amount (quantity of units) to be administered at each period of the day: **Morning, Afternoon, Evening,** and **Night**.

In the **To (mg/dL)** cell of the correction table, specify the upper range value of the pre-meal glucose.

In the **Insulin Amount (units)** cells, specify the quantity of insulin to administer when the pre-meal glucose is within the range defined on the left columns.

The first row will define the low glucose levels that the patient should not be taking any insulin for (correction threshold). In the **To (mg/dL)** cell of the first row specify the upper range value of the pre-meal glucose level, with zero insulin units for correction.

To add a new row, click the **Add a new row** link at the bottom of the table and then click the **+** button between the two rows where you want to add the new row (the **From (mg/dL)** field automatically shows the value in the **To (mg/dL)** cell **+** 1), as shown below –



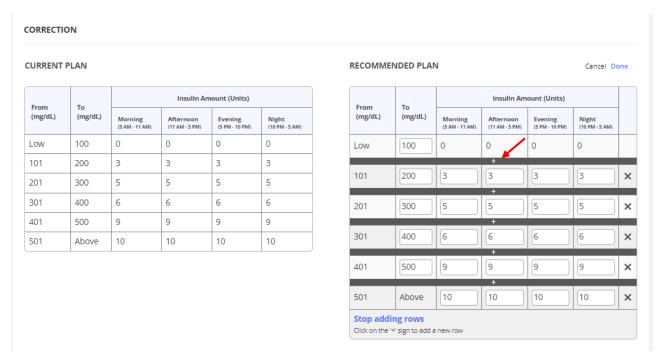


Figure 67 – Add a new row to the bolus correction table – MDI – Meal estimation and sliding scale correction

Define the values of this row, as described above.

Repeat the steps above as many times as necessary in order to define all possible ranges of pre-meal glucose and the quantity of insulin to administer for each.

- e. Click the **Stop adding rows** link to stop adding rows to the plan.
- f. Delete a row by clicking the **X** to the right of the corresponding row.

Click **Done** to exit this view and save your changes.

Click Cancel to exit this view without saving.



NOTE: After you click **Edit**, you can either click **Done** to save your changes or click **Cancel** to exit this view without saving.



Click Next to continue to the Review page.

This page shows the entire plan. While reviewing the entire plan, you can add comments to the patient in the **Message to Patient** field and then approve the plan.

After you have reviewed the entire plan (which includes scrolling down to the end of the page), you can approve the plan by clicking the **Approve** button so that it is shared with the patient.





Figure 68 – Review page – MDI – Meal estimation and sliding scale correction



NOTE: endo.digital ensures that you have viewed the entire plan by only enabling the **Approve** button after the entire Review page has been displayed. This may involve scrolling the page down.



Bolus Plan - MDI - Carbs Counting

This Bolus Plan (Carbs Ratio, Correction Factor and Blood Glucose Target) is for patients who know how to count carbs and calculate the insulin needed for meals and/or correction boluses.

Different plan tables are provided for different times of the day **morning**, **afternoon**, **evening** and **night**, as shown below:

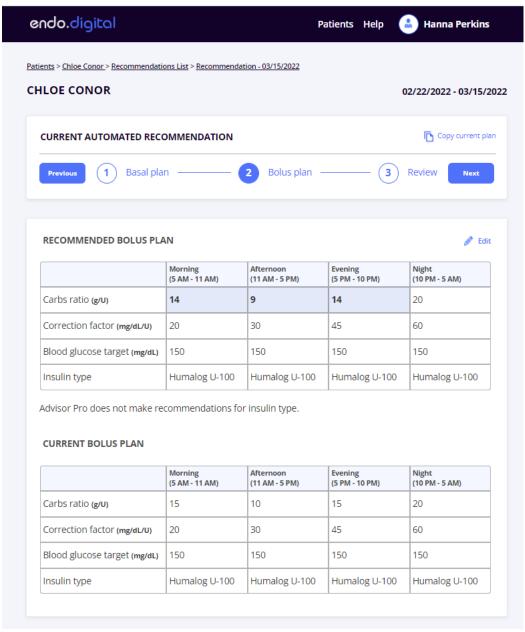


Figure 69 – Review Bolus Plan Page – MDI – Carbs Counting



The top table shows the recommended plan and the bottom table shows the current plan (which is taken from the patient's Diary App when generating the new recommendation).

► To edit the Recommended Bolus Plan:

• Click • Edit. The following displays:

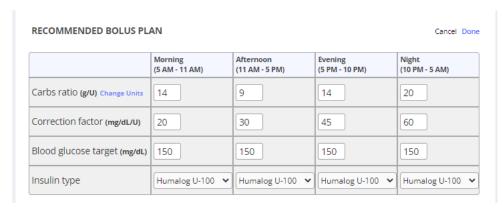
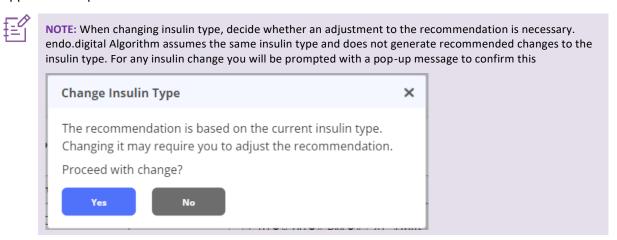


Figure 70 – Edit Bolus Plan Page – MDI – Carbs Counting

- Click in a Carbs ratio, Correction factor or Blood Glucose target cell in the RECOMMENDED BOLUS
 PLAN table to adjust the corresponding value.
- In the **Insulin type** field, you have the option to change the type of insulin per time of day using the applicable dropdown list.



The Carbs ratio field, provides a Change Units link that enables you to change the units of the values that you enter in this row to Grams Carbs Units of 10 grams or Carbs Units of 15 grams. For example, if Carbs Units (15 grams) is selected, then enter 2 in the Morning column (for example) to specify 30 grams. Click this link to display the following popup –



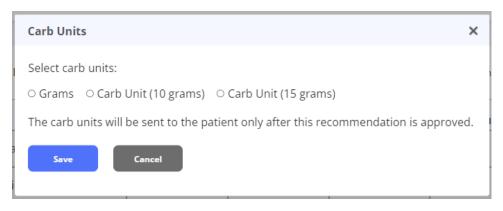


Figure 71 – Changing Carb Ratio Units

Select a **carb unit** and click **Save**. Previously enter values in the **Carb ratio** row are erased from the table (shown above) and must be reentered. Make sure to enter these values according to the newly selected units.

- Click **Done** to exit this view and save your changes.
- Click Cancel to exit this view without saving



NOTE: After you click **Edit**, you can either click **Done** to save your changes or click **Cancel** to exit this view without saving.

Click Done if you have finished editing.

The changes between the current plan and the previous plan are highlighted in blue, whether they were made by endo.digital's recommendation or by you, as shown below.

RECOMMENDED BOLUS PLAN				
	Morning (5 AM - 11 AM)	Afternoon (11 AM - 5 PM)	Evening (5 PM - 10 PM)	Night (10 PM - 5 AM)
Carbs ratio (g/U)	9	9	9	20
Correction factor (mg/dL/U)	30	30	30	30
Blood glucose target (mg/dL)	120	120	120	120
Insulin type	Novolog	Novolog	Novolog	Novolog

endo.digital does not make recommendations for insulin type.

Figure 72 – Recommended Changes in Bolus Plan Page – MDI – Carbs Counting

Click **Next** to continue to the Review page.

Before endo.digital About endo.digital First Review Trouble-**FAQs Appendices** Account You Begin endo.digital Workflow -Workflow - MDI Steps and Share Management shooting Insulin Pump



Review Page

When reviewing the entire plan, you can add comments to the patient in the **Message to Patient** field and then approve the plan. After the plan is approved, it is shared with the patient.

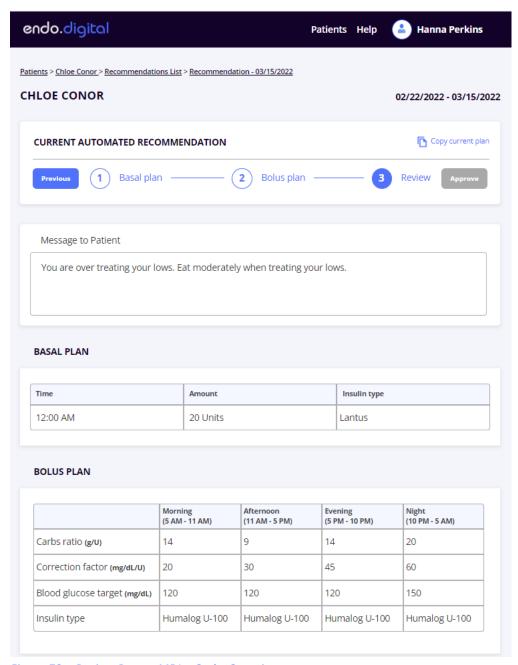


Figure 73 – Review Page – MDI – Carbs Counting

endo.digital ensures that you have viewed the entire plan by only enabling the **Approve** button after the entire Review page has been displayed. This may involve scrolling the page down.

Before	About	endo.digital	endo.digital	First	Review	Account	Trouble-	FAQs	Appendices
You Begin	endo.digital	Workflow –	Workflow – MDI	Steps	and Share	Management	shooting		
		Insulin Pump							



Generic Treatment Plan

The Generic Treatment Plan shows a text message for the patient. In this treatment type, you can view patient data and enter a text message to the patient with their plan information.



Figure 74 – Generic Treatment Plan – Edit Recommendation

Figure 75 – Generic Treatment Plan – Approved

Personalized Diabetes Management Tips

In addition to endo.digital's dosing recommendation, endo.digital generates personalized diabetes management tips for the patient intended to enhance the effectiveness of the insulin therapy.

These comments are directly targeted at the patient. See Appendix B for the full list of personalized diabetes management tips.

Message to Patient

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

Figure 76 – Comments Screen



NOTE: You may add or edit comments to the diabetes management tips generated by endo.digital by entering text in the Comments field.

About endo.digital endo.digital Workflow -Insulin Pump

endo.digital Workflow - MDI First Steps Review

Account Management shooting

Trouble-

FAQs

Appendices

endo.digital HCP User M



Approved Recommendations

Recommendations must be approved before sharing them with the patient. To approve the recommendations:

- For an insulin pump treatment type, click the **Approve and Share** button, as described on page 89.
- For an MDI treatment plan and for a generic treatment plan, review the recommendation in the window and then click the **Approve** button.

Recommendations for each treatment type must be approved separately. All recommendations behave in the same manner once approved.

After approving the recommendation, the date that the recommendation was approved is displayed in the Report screen. Once approved, the recommendation can no longer be edited, as it represents a recommendation already shared with the patient.

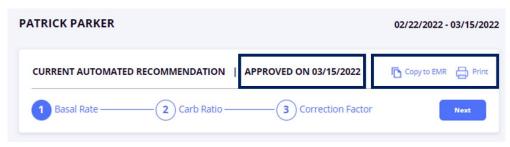


Figure 77 – Approved Report Screen – Insulin Pump

To print the report and hand it to the patient or save it as a PDF, click the **Print** button.

To copy the recommendation content and paste it in your Electronic Medical Record, click the **Copy to EMR** button. The copy to EMR action copies the patient name, data analysis period, the new recommendation for basal and bolus as well as the comments you shared with the patient to your clipboard. In addition, the copy to EMR functionality includes some statistics for the sensor, including the time within range.

Reports

endo.digital provides three reports with the generated recommendation:

- An Ambulatory Glucose Profile (AGP) and a bolus insulin graph, as well as summary statistics.
- A <u>Daily report</u> displaying a day-by-day view of the patient's glucometer, CGM and self reported events
 using the mobile app. The self reported events include: blood glucose, carbs in grams or meal
 estimation (determined by the patient's mobile app meal settings), insulin bolus and basal, activity, and
 patient notes.



A Logbook report displaying event-level bolus data for bolus insulin, carbs and blood glucose.

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

Clock Shift Alert

It is extremely important that patients maintain their clocks and set all their devices and applications to the correct time.

endo.digital should not be used when patient traveled to another time zone in the past 21 days. See <u>General Cautions</u> for more information.

If endo.digital detects a clock shift, an endo.digital recommendation cannot be generated, and you can continue manually. In such cases, the report shows an alert indicating the detection of clock discrepancies in the patient's data, as shown below:



Figure 78 – AGP Report – Clock Shift Alert





Since endo.digital may not always be able to detect all clock shift events, if the patient has traveled to another time zone within the last 21 days, do not use the endo.digital algorithm generated recommendation.

Ambulatory Glucose Profile (AGP) Report

The Ambulatory Glucose Profile report provides statistical information of the patient's 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. The AGP report displays the data of the last 14 days.

- 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.

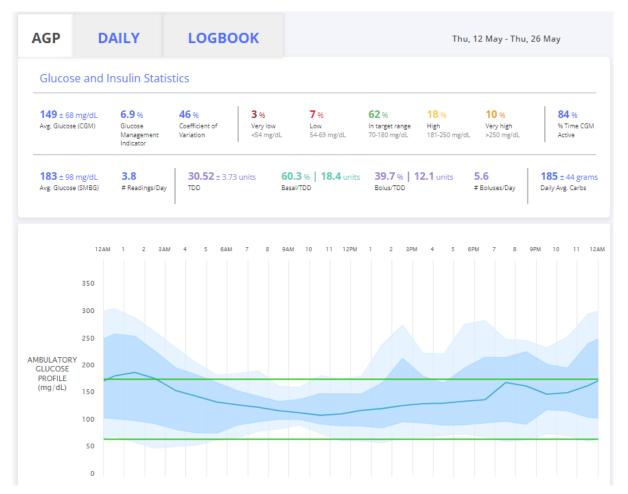


Figure 79 – AGP Report – 1

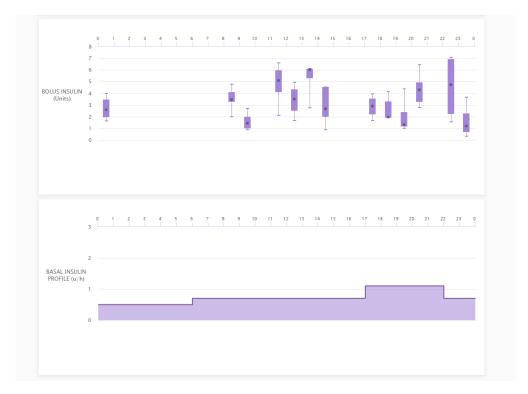


Figure 80 – AGP Report – 2

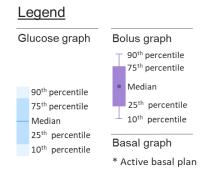


Figure 81 – AGP Report – 3



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 the patient's current data. The report may present the data in one of 3 time periods: 1 day, 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: glucose (including time in range), carbs/meal, insulin, activity, and notes. Activity and notes are available for MDI and Generic patients only.

Glucose

The top shows the daily glucose time within range for the patient, according to the common ranges displayed below. Only the single day 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 by the patient it will be indicated as manual, and meter when it came from a device.

Carbs / Meal

This section displays the daily carbs or meal events reported by the patient. For pump patients the amount of carbs reported in the bolus calculator will be displayed in grams. For MDI patients the carbs reported by the patient using the mobile app will be displayed by the app's setting:

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



Insulin

The insulin section displays the basal and bolus events.

For pump patients the following also applies:

- Basal may appear as scheduled basal or temp basal.
- Bolus event may include an override indication
- 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

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

The activity can be reported from the mobile app and will be displayed for patients using MDI or generic treatment plans.

Notes

Any notes the patient 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.

The notes can be reported from the mobile app and will be displayed for patients using MDI or Generic treatment plans.

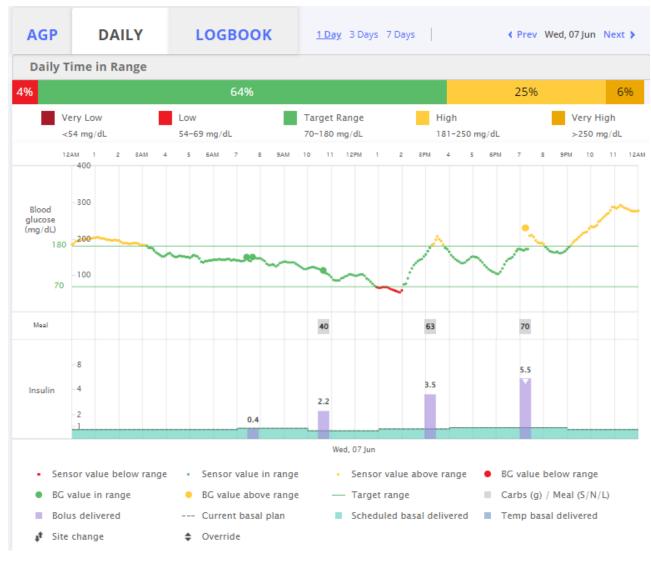


Figure 82 – Pump patient daily report

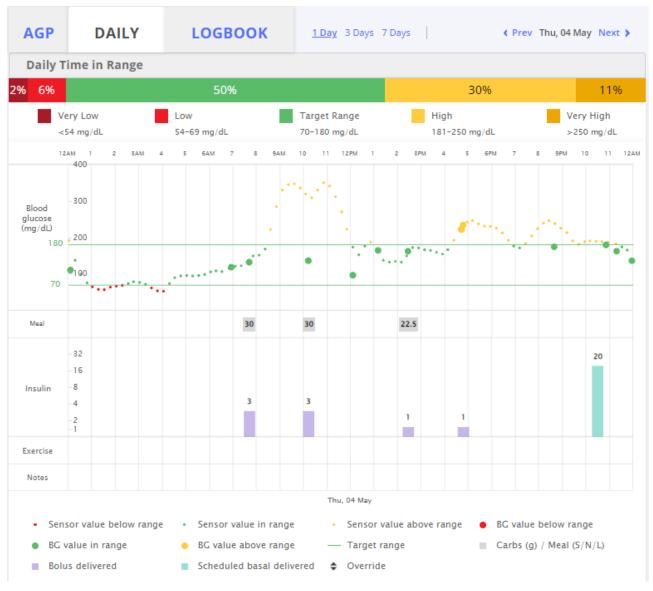


Figure 83 – MDI patient daily report

Logbook Report

The LOGBOOK report enables you to view the daily data for the last 21 days before the recommendation.

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, percent and amount of basal of the total daily dose, and number of boluses:

- Glucose value: The most extreme value in that hour (mg/dL).
- Meal: Meal or the total number of carbs reported in that hour (grams).
- Insulin amount: The total amount of insulin delivered in that hour (units).
- Basal:
 - For insulin pumps, the fourth record displays basal suspend and temporary basal events.
 - For MDI, the fourth record displays the basal amount delivered.



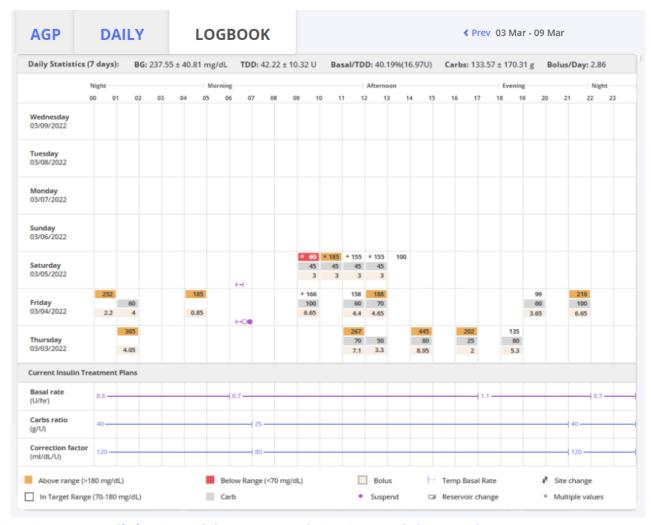


Figure 84 – Bottom Half of Review and Share Recommendations Screen Including Legend



NOTE: When using a Medtronic 670G automated insulin delivery system (closed loop), the entire days when an automated insulin delivery algorithm was used in, are excluded from the graph, and from the statistics. In this event the Total Daily Dose and the Basal / Total Daily Dose are not calculated

Chapter 7 – Account Management

Reset Password

Should you forget your password, click Forgot your password?

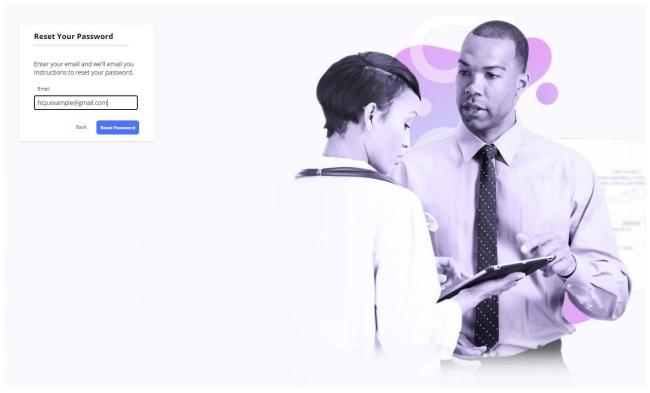


Figure 85 – Reset Password Screen

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.

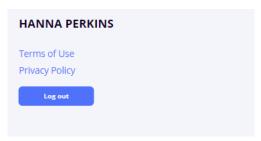


Figure 86 – User Profile Screen

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 a user types an incorrect password five consecutive times, their account is locked. Click the <u>Reset</u> Password link to unlock an account.



Chapter 8 – Troubleshooting

This section describes problems that may occur when working with the endo.digital system and how to resolve them.

Why can't I access endo.digital?

Cause: This may occur when you are using incorrect credentials.

Solution: Make sure that you are using the username and password provided to you by your clinic. If the problem repeats, contact your clinic administrator or DreaMed Diabetes support by sending an email to support@dreamed.ai.

Why didn't I receive a recommendation after clicking New Recommendation?

Cause: Various causes may prevent endo.digital from generating a recommendation. The main reason for not getting a recommendation is either because the treatment plan type is not supported by our algorithm, or the data was found to be insufficient for providing a new recommendation.

Solution: When a recommendation cannot be generated, a clear error message displays stating the reason why the recommendation was not generated. You may also refer to endo.digital Recommendation Errors in this manual for more information. You can also use the View Current Data to view the current plan and recent report, if the data is indeed missing, discuss this with your patient.

In addition, you can also create a manual recommendation, as described on page <u>Manual Recommendation</u> <u>Message and endo.digital Recommendation Errors</u>.

For MDI, you can create the Generic Treatment Plan interface to view the patient's reports and to send a message for the patient, as described on page 117.



Data Insufficiency – Insulin Pump Treatment Type: After you click **New recommendation**, the data that was uploaded gets tested to determine if the patient account contains sufficient and valid data to begin the program. If the data does not meet this requirement, the following message displays:

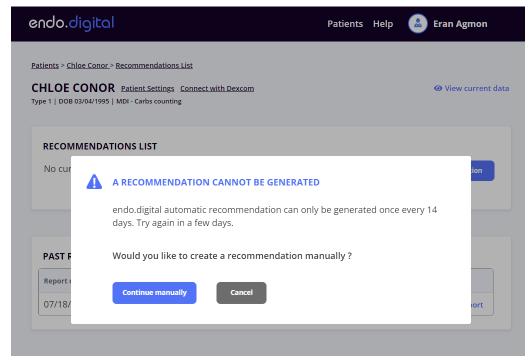


Figure 87 – Example of the Insufficient Data Message – Insulin Pump Treatment Type

This means that one of the following criteria was not met:

- The patient must have **valid data** from at least **12 of the past 21 days**. A valid day is defined according to the following requirements:
 - At least one basal and at least one bolus record per day.
 - Minimum glucose data:
 - More than 67% of CGM 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), OR
 - At least 3 SMBG measurements a day that are separated from each other by at least 210 minutes.
- 2 endo.digital requires at least three Bolus Calculator uses during the last 21 days.



- 3 endo.digital must receive the following pump settings:
 - Basal rate plan:
 - Each rate in the basal rate plan should be within the range of 0.025–3 U/h.
 - Carbohydrate ratio plan:
 - Each value in the CR plan should be within the range of 3–70 gr/U.
 - Correction factor plan:
 - Each value in the CF plan should be within the range of 10–280 mg/dl/U.
 - Bolus calculator glucose targets plan:
 - Below or equal to 150 mg/dl. If the Bolus Calculator is set to a target above 150 mg/dl, endo.digital does not provide a recommendation.
 - Active insulin time.
- 4 If a clock shift was detected by endo.digital, a recommendation is not provided for that 21-day period.

You may instruct the patient to continue using the pump, CGM and/or blood glucose meter and to try and upload the data again. If one of the requirements for a valid insulin pump setting is not met, consider advising the patient to change these settings. Otherwise, endo.digital cannot provide a recommendation.

Data Insufficiency – MDI –Sliding Scale or MDI – Carbs Counting Treatment Types: After you click **New Recommendation**, the data that was uploaded gets tested to determine if the patient account contains sufficient and valid data to begin the program. If the data has not passed the requirement, the following message displays:

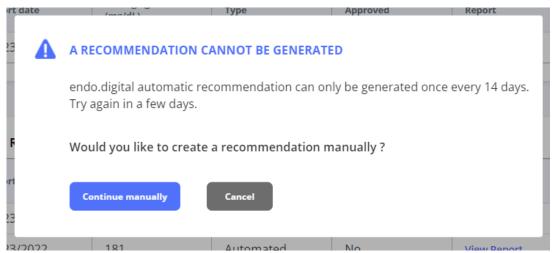


Figure 88 – Example of the Insufficient Data Message – MDI Treatment Types



This means that one of the following criteria was not met:

- 1 The patient must have **valid data** from at least **12 of the past 21 days** for Type 1 and insulin resistant type 1 patients and **6 valid days of the past 21 days** for Type 2 patients. A valid day is defined according to the following requirements:
 - Minimum glucose data for Type 1 and insulin resistant type 1 patients to be considered a valid day:
 - More than 67% of CGM 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), OR
 - At least 3 SMBG measurements a day that are separated from each other by at least 210 minutes.
 - Minimum glucose data for Type 2 patients to be considered a valid day:
 - Fasting glucose which is defined as any glucose reading found between 4AM and 12PM.
- If a clock shift was detected by endo.digital, a recommendation is not provided for that 21-day period.

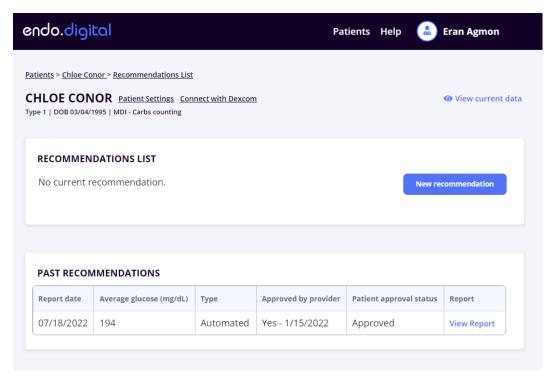
You may instruct the patient to continue using the DreaMed Diary App, CGM and/or blood glucose meter and to try and upload the data again.

Alternatively, you can also create a Generic Treatment Plan for the patient, as described on page 117.

Chapter 9 – Frequently Asked Questions (FAQs)

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

You can check if a new recommendation is ready by entering the Recommendations List inside your patient information screen. There, you can see the Current Advisor Recommendation section, which includes the last recommendation generated for the patient today. In case the current recommendation is empty, click the 'New recommendation' button to create a recommendation.



Can I change or edit the recommendation provided by endo.digital?

Yes, you can edit the last recommendation generated by endo.digital so long as it is unapproved. You can do so by clicking the Edit button in each of the plan parts. You can also add comments to the recommendation by typing inside the Comments field.



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

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

Can I change the parameters endo.digital uses for recommendations (such as hypo/hyper threshold)?

Yes, by selecting the patient's pre meal glucose target range (either when starting the patient or when changing it in the patient settings) the hypo / hyper thresholds adjust accordingly. For more information see Figure 4 in Step 4: endo.digital Generates Recommendations

How are the recommendations generated by endo.digital affected by selecting "insulin resistant type 1" setting?

When starting a patient with insulin resistant type 1 as the type of diabetes, the dose limits that endo.digital can recommend are increased to the same as type 2 diabetes. This allows for the HCP to generate a recommendation for type 1 diabetes patients who require higher doses. Note that the patient is still considered a type 1 patient and will require 12 valid days of data in order to receive a recommendation using the endo.digital Algorithm.

Can I get the latest patient's data report without generating a recommendation?

Yes, you use the View Current Data button in the recommendation list, using it will not generate a recommendation.

How can I view the current plan in use in the DreaMed **Diary App?**

You can use the View Current Data to get the current plan in use in the DreaMed Diary App, using it will not generate a recommendation.

Share



What are the treatment plan parameters that the endo.digital algorithm can recommend changing?

The endo.digital recommendation may include the following recommended parts:

Insulin Pump treatment type: Basal rate plan, Carb Ratio plan and Correction Factor plan



NOTE: The system does not recommend changing the pump Bolus Calculator glucose target plan or the active insulin time.

- MDI -treatment types: Fixed meal or Meal estimation or Sliding scale: Basal plan and Bolus plan
- MDI Carbs Counting treatment type: Basal plan and Bolus plan (CR, CF and Target)



NOTE: endo.digital does not recommend changes to insulin type for MDI patients.

What is the maximum change that endo.digital may advise?

For the Insulin Pump Treatment Type: These are the maximum changes that endo.digital can advise in each of the pump settings:

- Basal rate plan:
 - -20% of the current hourly basal rate based on the patient's current insulin pump settings minus $0.05 \left[\frac{U}{Hour} \right]$
 - +20% of the current hourly basal rate based on the patient's current insulin pump settings plus $0.05 \left[\frac{U}{Hour} \right]$
- Carb ratio plan:
 - -30% of the current carb ratio value based on the patient's current insulin pump settings minus 1 gr/Units
 - +30% of the current carb ratio value based on the patient's current insulin pump settings plus 1 gr/Units
- Correction factor plan:
 - -30% of the current correction factor value based on the patient's current insulin pump settings minus 1 mg/dl/U
 - +30% of the current correction factor value based on the patient's current insulin pump settings plus 1 mg/dl/U



For the MDI Treatment Types: These are the maximum changes that endo.digital can advise in each of the treatment plan components:

For the basal plan, the changes are limited, regardless of the bolus plan, as follows:

- Maximum change of the current daily amount: ±20%
- Daily basal insulin amount permitted values per type of diabetes:
 - Type 1 1 – 72 units a day
 - Type 2 / Insulin resistant type 1 1 - 250 units a day

For the bolus for fixed meal or meal estimation with sliding scale correction:

- The maximum percentage of bolus change is \pm 30% from the current plans.
- Bolus permitted values per type of diabetes:

```
Type 1
0 - 30 units
Type 2 / Insulin resistant type 1
0 - 99 units
```

The maximum increments between the sliding scale table rows are:

```
Type1: 5 units
```

- Type 2 / Insulin resistant type 1: 10 unitsFor bolus for carbs counting:
- The maximum percentage of CR change is \pm 30% from the current plans.
- CR permitted values per type of diabetes:

```
Type 1
3 - 70 grams/U
Type 2 / Insulin resistant type 1
2 - 70 grams/U
```

- Target:
 - endo.digital does not recommend changes to bolus targets under 150 mg/dL. The recommended bolus target plan can be between 70 to 180 mg/dL, endo.digital may recommend changes up to ±20mg/dL.

Share



When editing a recommendation, how does the carbs unit settings affect the permitted values in carbs counting treatment plan?

When changing the carb units (grams, 10 grams and 15 grams) the range scales accordingly:

gram: 1-70 g/U

10-gram exchange unit: 0.1-10 U/10g

15-gram exchange unit: 0.1-15 U/15g

What happens if my patient changes their pump settings during the 21-day period?

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 carb ratio and correction factor 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.

How can I view the patient's pump's Bolus Calculator glucose target and active insulin plans?

You can view the patient's pump's Bolus Calculator glucose target and active insulin plans by clicking the **View BG Target** and **View Active Insulin Time** links, respectively, which are found below the Recommended Basal Rate table in the Review and Share Recommendations screen.

How can I send the patient additional instructions?

For pump patients, you can use the **Comments** fields that are found in each setting window to add any additional instructions to the patient.

For MDI patients, you can use the Message to Patient field that can be found in the basal and review pages.

First

Steps



Can I add a comment for a specific plan?

For pump patients, you can add a comment for each of the pump setting recommendations by selecting **Edit** and then entering text in the **Comments** field at the bottom of each of the endo.digital Recommendation screen.

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

The personal diabetes management tips are text messages that endo.digital generates that may help the patient avoid hypoglycemia and hyperglycemia events. These messages are based on endo.digital analysis and may include one or more of the following messages:

- I noticed that many of your highs may be avoided. Entering your glucose level (in addition to your carbs) into the Bolus Calculator may help you improve.
- I noticed that many of your highs may be avoided. Remember to bolus before you start eating.
- You are overtreating your lows. Eat moderately when treating your lows.
- Many of your highs may be avoided. Trusting the Bolus Calculator's recommendation may lead to better results.
- I noticed that many of your highs may be avoided. Replacing your pump tubing/pod every 2–3 days may help you get better results.
- I noticed that many of your highs are a result of suspending your pump or using temporary basal. Watching your glucose when using suspend/temporary basal may lead to better results.
- When you have a high episode, remember to use the Bolus Calculator to give a correction bolus.
- I noticed that many of your highs may be avoided. Delivering an insulin bolus for every meal and snack may help you get better outcomes.
- I noticed that many of your lows may be avoided. Entering your glucose level (in addition to your carbs) into the Bolus Calculator may help you improve.
- I noticed you sometimes deliver boluses too close together. Waiting at least 1.5–2 hours before delivering an additional bolus may help you avoid a low episode.
- Many of your lows may be avoided. Trusting the Bolus Calculator's recommendation may lead to better results.

Share



- I noticed that many of your lows may be avoided. Entering your current glucose level into the pump's Bolus Calculator may help you improve.
- I noticed that many of your lows are a result of delivering extra temporary basal. Watching your glucose when using temporary basal may help you improve.
- I noticed that many of your lows may be avoided. Remember to check your glucose level and bolus before you start eating.
- I noticed that many of your lows come after a manual bolus. Using your Bolus Calculator may help you

Notes:

- Every recommendation can be adjusted to one of the following parts of the day: early morning, morning, late morning, noon, afternoon, evening and all day (as presented above). See Appendix A for the full list, including parts of the day.
- endo.digital decides on which message to present based on its relevance to the hypoglycemia and hyperglycemia event and its priority.

How does the patient know that a new recommendation is waiting?

If the patient has their email address configured in endo.digital, the patient will receive a notification by email that alerts them about a new recommendation that is waiting for them. Patients using the DreaMed Diary App will receive a message upon entering their app.

If a patient wants to add their email address to endo.digital, they can either go through the Join Clinic process again and add their email address, or a clinic staff member can add their email using the Add Patient screen.

Share

Appendix A – Glossary

Table 13 – 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.
Carbs counting	MDI treatment type - Carbohydrate counting along with Carbohydrate Ratio (CR) and Correction Factor (CF) to calculate insulin injection amount
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.
Insulin resistant type 1 / T1DM	Type 1 diabetes patient with insulin resistance, requiring higher doses of insulin compared to type 1 diabetes patients, setting the type of diabetes in the patient settings to "insulin resistant type 1" will allow Advisor to recommend higher insulin doses as defined for type 2 diabetes patient.
ISF	Insulin Sensitivity Factor. In this manual, we use the term CF instead of ISF.
MDI	Multiple daily injections of insulin



Pre meal glucose target range	Indicates the desired glucose range before a meal, specifically before breakfast. This glucose target range is used in endo.digital recommendations
Pump	Any insulin pump.
Sliding scale	MDI treatment type – Using pre meal glucose measurement and the insulin amount matching scale for injection
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 B – endo.digital Personalized Diabetes Management Tips

The list below includes all personalized diabetes management tips that can be provided by endo.digital.

Every recommendation can be adjusted to one of the following parts of the day: early morning, morning, late morning, noon, afternoon, evening, night and all day. These recommendations all reflect good diabetes management practices and do not contradict each other.

Table 14 – MDI Personalized Diabetes Management Tips

#	Personalized Diabetes Management Tip
1	I noticed that many of your highs may be avoided. Delivering an insulin bolus for every meal and snack may help you get better outcomes.
2	I noticed that many of your highs may be avoided. Delivering your bolus 15-20 minutes before eating may help you get better outcomes.
3	You are over treating your lows. Eat moderately when treating your lows.
4	I noticed that many of your lows may be avoided. Remember to check your glucose level and bolus before you start eating.

Table 15 – Pump Personalized Diabetes Management Tips

#	Personalized Diabetes Management Tip
1	I noticed that many of your highs in the afternoon may be avoided. Entering your glucose level (in addition to your carbs) into the Bolus Calculator may help you improve.
2	I noticed that many of your highs may be avoided. Entering your glucose level (in addition to your carbs) into the Bolus Calculator may help you improve.
3	I noticed that many of your highs in the early morning may be avoided. Entering your glucose level (in addition to your carbs) into the Bolus Calculator may help you improve.
4	I noticed that many of your highs in the late morning may be avoided. Entering your glucose level (in addition to your carbs) into the Bolus Calculator may help you improve.
5	I noticed that many of your highs in the evening may be avoided. Entering your glucose level (in addition to your carbs) into the Bolus Calculator may help you improve.
6	I noticed that many of your highs in the late evening may be avoided. Entering your glucose level (in addition to your carbs) into the Bolus Calculator may help you improve.
7	I noticed that many of your highs in the morning may be avoided. Entering your glucose level (in addition to your carbs) into the Bolus Calculator may help you improve.
8	I noticed that many of your highs at night may be avoided. Entering your glucose level (in addition to your carbs) into the Bolus Calculator may help you improve.
9	I noticed that many of your highs at noon may be avoided. Entering your glucose level (in addition to your carbs) into the Bolus Calculator may help you improve.
10	I noticed that many of your highs in the afternoon may be avoided. Remember to bolus before you start eating.
11	I noticed that many of your highs may be avoided. Remember to bolus before you start eating.

#	Personalized Diabetes Management Tip		
12	I noticed that many of your highs in the early morning may be avoided. Remember to bolus before you start eating.		
13	I noticed that many of your highs in the late morning may be avoided. Remember to bolus before you start eating.		
14	I noticed that many of your highs in the evening may be avoided. Remember to bolus before you start eating.		
15	I noticed that many of your highs in the late evening may be avoided. Remember to bolus before you start eating.		
16	I noticed that many of your highs in the morning may be avoided. Remember to bolus before you start eating.		
17	I noticed that many of your highs at night may be avoided. Remember to bolus before you start eating.		
18	I noticed that many of your highs at noon may be avoided. Remember to bolus before you start eating.		
19	You are over treating your lows in the afternoon. Eat moderately when treating your lows.		
20	You are over treating your lows. Eat moderately when treating your lows.		
21	You are over treating your lows in the early morning. Eat moderately when treating your lows.		
22	You are over treating your lows in the late morning. Eat moderately when treating your lows.		
23	You are over treating your lows in the evening. Eat moderately when treating your lows.		
24	You are over treating your lows in the late evening. Eat moderately when treating your lows.		
25	You are over treating your lows in the morning. Eat moderately when treating your lows.		
26	You are over treating your lows at night. Eat moderately when treating your lows.		
27	You are over treating your lows at noon. Eat moderately when treating your lows.		
28	Many of your highs in the afternoon may be avoided. Trusting the Bolus Calculator's recommendation may lead to better results.		
29	Many of your highs may be avoided. Trusting the Bolus Calculator's recommendation may lead to better results.		
30	Many of your highs in the early morning may be avoided. Trusting the Bolus Calculator's recommendation may lead to better results.		
31	Many of your highs in the late morning may be avoided. Trusting the Bolus Calculator's recommendation may lead to better results.		
32	Many of your highs in the evening may be avoided. Trusting the Bolus Calculator's recommendation may lead to better results.		
33	Many of your highs in the late evening may be avoided. Trusting the Bolus Calculator's recommendation may lead to better results.		
34	Many of your highs in the morning may be avoided. Trusting the Bolus Calculator's recommendation may lead to better results.		
35	Many of your highs at night may be avoided. Trusting the Bolus Calculator's recommendation may lead to better results.		
36	Many of your highs at noon may be avoided. Trusting the Bolus Calculator's recommendation may lead to better results.		

#	Personalized Diabetes Management Tip
37	I noticed that many of your highs may be avoided. Replacing your pump tubing/pod every 2–3 days may help you get better results. ¹
38	I noticed that many of your highs in the afternoon are a result of suspending your pump or using temporary basal. Watching your glucose when using suspend/temporary basal may lead to better results.
39	I noticed that many of your highs are a result of suspending your pump or using temporary basal. Watching your glucose when using suspend/temporary basal may lead to better results.
40	I noticed that many of your highs in the early morning are a result of suspending your pump or using temporary basal. Watching your glucose when using suspend/temporary basal may lead to better results.
41	I noticed that many of your highs in the late morning are a result of suspending your pump or using temporary basal. Watching your glucose when using suspend/temporary basal may lead to better results.
42	I noticed that many of your highs in the evening are a result of suspending your pump or using temporary basal. Watching your glucose when using suspend/temporary basal may lead to better results.
43	I noticed that many of your highs in the late evening are a result of suspending your pump or using temporary basal. Watching your glucose when using suspend/temporary basal may lead to better results.
44	I noticed that many of your highs in the morning are a result of suspending your pump or using temporary basal. Watching your glucose when using suspend/temporary basal may lead to better results.
45	I noticed that many of your highs at night are a result of suspending your pump or using temporary basal. Watching your glucose when using suspend/temporary basal may lead to better results.
46	I noticed that many of your highs at noon are a result of suspending your pump or using temporary basal. Watching your glucose when using suspend/temporary basal may lead to better results.
47	When you have a high episode in the afternoon, remember to use the Bolus Calculator to give a correction bolus.
48	When you have a high episode, remember to use the Bolus Calculator to give a correction bolus.
49	When you have a high episode in the early morning, remember to use the Bolus Calculator to give a correction bolus.
50	When you have a high episode in the late morning, remember to use the Bolus Calculator to give a correction bolus.
51	When you have high episode in the evening, remember to use the Bolus Calculator to give a correction bolus.
52	When you have a high episode in the late evening, remember to use the Bolus Calculator to give a correction bolus.
53	When you have a high episode in the morning, remember to use the Bolus Calculator to give a correction bolus.

#	Personalized Diabetes Management Tip	
54	When you have a high episode at night, remember to use the Bolus Calculator to give a correction bolus.	
55	When you have a high episode at noon, remember to use the Bolus Calculator to give a correction bolus.	
56	I noticed that many of your highs in the afternoon may be avoided. Delivering an insulin bolus for every meal and snack may help you get better outcomes.	
57	I noticed that many of your highs may be avoided. Delivering an insulin bolus for every meal and snack may help you get better outcomes.	
58	I noticed that many of your highs in the early morning may be avoided. Delivering an insulin bolus for every meal and snack may help you get better outcomes.	
59	I noticed that many of your highs in the late morning may be avoided. Delivering an insulin bolus for every meal and snack may help you get better outcomes.	
60	I noticed that many of your highs in the evening may be avoided. Delivering an insulin bolus for every meal and snack may help you get better outcomes.	
61	I noticed that many of your highs in the late evening may be avoided. Delivering an insulin bolus for every meal and snack may help you get better outcomes.	
62	I noticed that many of your highs in the morning may be avoided. Delivering an insulin bolus for every meal and snack may help you get better outcomes.	
63	I noticed that many of your highs at night may be avoided. Delivering an insulin bolus for every meal and snack may help you get better outcomes.	
64	I noticed that many of your highs at noon may be avoided. Delivering an insulin bolus for every meal and snack may help you get better outcomes.	
65	I noticed that many of your lows in the afternoon may be avoided. Entering your glucose level (in addition to your carbs) into the Bolus Calculator may help you improve.	
66	I noticed that many of your lows may be avoided. Entering your glucose level (in addition to your carbs) into the Bolus Calculator may help you improve.	
67	I noticed that many of your lows in the early morning may be avoided. Entering your glucose level (in addition to your carbs) into the Bolus Calculator may help you improve.	
68	I noticed that many of your lows in the late morning may be avoided. Entering your glucose level (in addition to your carbs) into the Bolus Calculator may help you improve.	
69	I noticed that many of your lows in the evening may be avoided. Entering your glucose level (in addition to your carbs) into the Bolus Calculator may help you improve.	
70	I noticed that many of your lows in the late evening may be avoided. Entering your glucose level (in addition to your carbs) into the Bolus Calculator may help you improve.	
71	I noticed that many of your lows in the morning may be avoided. Entering your glucose level (in addition to your carbs) into the Bolus Calculator may help you improve.	
72	I noticed that many of your lows at night may be avoided. Entering your glucose level (in addition to your carbs) into the Bolus Calculator may help you improve.	
73	I noticed that many of your lows at noon may be avoided. Entering your glucose level (in addition to your carbs) into the Bolus Calculator may help you improve.	
74	I noticed you sometimes deliver boluses too close together in the afternoon. Waiting at least 1.5–2 hours before delivering an additional bolus may help you avoid a low episode.	
75	I noticed you sometimes deliver boluses too close together. Waiting at least 1.5–2 hours before delivering an additional bolus may help you avoid a low episode.	

#	Personalized Diabetes Management Tip		
76	I noticed you sometimes deliver boluses too close together in the early morning. Waiting at least 1.5–2 hours before delivering an additional bolus may help you avoid a low episode.		
77	I noticed you sometimes deliver boluses too close together in the late morning. Waiting at least 1.5–2 hours before delivering an additional bolus may help you avoid a low episode.		
78	I noticed you sometimes deliver boluses too close together in the evening. Waiting at least 1.5–2 hours before delivering an additional bolus may help you avoid a low episode.		
79	I noticed you sometimes deliver boluses too close together in the late evening. Waiting at least 1.5–2 hours before delivering an additional bolus may help you avoid a low episode.		
80	I noticed you sometimes deliver boluses too close together in the morning. Waiting at least 1.5–2 hours before delivering an additional bolus may help you avoid a low episode.		
81	I noticed you sometimes deliver boluses too close together at night. Waiting at least 1.5–2 hours before delivering an additional bolus may help you avoid a low episode.		
82	I noticed you sometimes deliver boluses too close together at noon. Waiting at least 1.5–2 hours before delivering an additional bolus may help you avoid a low episode.		
83	Many of your lows in the afternoon may be avoided. Trusting the Bolus Calculator's recommendation may lead to better results.		
84	Many of your lows may be avoided. Trusting the Bolus Calculator's recommendation may lead to better results.		
85	Many of your lows in the early morning may be avoided. Trusting the Bolus Calculator's recommendation may lead to better results.		
86	Many of your lows in the late morning may be avoided. Trusting the Bolus Calculator's recommendation may lead to better results.		
87	Many of your lows in the evening may be avoided. Trusting the Bolus Calculator's recommendation may lead to better results.		
88	Many of your lows in the late evening may be avoided. Trusting the Bolus Calculator's recommendation may lead to better results.		
89	Many of your lows in the morning may be avoided. Trusting the Bolus Calculator's recommendation may lead to better results.		
90	Many of your lows at night may be avoided. Trusting the Bolus Calculator's recommendation may lead to better results.		
91	Many of your lows at noon may be avoided. Trusting the Bolus Calculator's recommendation may lead to better results.		
92	I noticed that many of your lows in the afternoon may be avoided. Entering your current glucose level into the pump's Bolus Calculator may help you improve.		
93	I noticed that many of your lows may be avoided. Entering your current glucose level into the pump's Bolus Calculator may help you improve.		
94	I noticed that many of your lows in the early morning may be avoided. Entering your current glucose level into the pump's Bolus Calculator may help you improve.		
95	I noticed that many of your lows in the late morning may be avoided. Entering your current glucose level into the pump's Bolus Calculator may help you improve.		
96	I noticed that many of your lows in the evening may be avoided. Entering your current glucose level into the pump's Bolus Calculator may help you improve.		
97	I noticed that many of your lows in the late evening may be avoided. Entering your current glucose level into the pump's Bolus Calculator may help you improve.		

Before	About	endo.digital	endo.digital	First	Review	Account	Trouble-	FAQs	Appendices
You Begin	endo.digital	Workflow –	Workflow – MDI	Steps	and Share	Management	shooting		
		Insulin Pump							

#	Personalized Diabetes Management Tip		
98	I noticed that many of your lows in the morning may be avoided. Entering your current glucose level into the pump's Bolus Calculator may help you improve.		
99	I noticed that many of your lows at night may be avoided. Entering your current glucose level into the pump's Bolus Calculator may help you improve.		
100	I noticed that many of your lows at noon may be avoided. Entering your current glucose level into the pump's Bolus Calculator may help you improve.		
101	I noticed that many of your lows in the afternoon are a result of delivering extra temporary basal. Watching your glucose when using temporary basal may help you improve.		
102	I noticed that many of your lows are a result of delivering extra temporary basal. Watching your glucose when using temporary basal may help you improve.		
103	I noticed that many of your lows in the early morning are a result of delivering extra temporary basal. Watching your glucose when using temporary basal may help you improve.		
104	I noticed that many of your lows in the late morning are a result of delivering extra temporary basal. Watching your glucose when using temporary basal may help you improve.		
105	I noticed that many of your lows in the evening are a result of delivering extra temporary basal. Watching your glucose when using temporary basal may help you improve.		
106	I noticed that many of your lows in the late evening are a result of delivering extra temporary basal. Watching your glucose when using temporary basal may help you improve.		
107	I noticed that many of your lows in the morning are a result of delivering extra temporary basal. Watching your glucose when using temporary basal may help you improve.		
108	I noticed that many of your lows at night are a result of delivering extra temporary basal. Watching your glucose when using temporary basal may help you improve.		
109	I noticed that many of your lows at noon are a result of delivering extra temporary basal. Watchin your glucose when using temporary basal may help you improve.		
110	I noticed that many of your lows in the afternoon may be avoided. Remember to check your glucose level and bolus before you start eating.		
111	I noticed that many of your lows may be avoided. Remember to check your glucose level and bolus before you start eating.		
112	I noticed that many of your lows in the early morning may be avoided. Remember to check your glucose level and bolus before you start eating.		
113	I noticed that many of your lows in the late morning may be avoided. Remember to check your glucose level and bolus before you start eating.		
114	I noticed that many of your lows in the evening may be avoided. Remember to check your glucose level and bolus before you start eating.		
115	I noticed that many of your lows in the late evening may be avoided. Remember to check your glucose level and bolus before you start eating.		
116	I noticed that many of your lows in the morning may be avoided. Remember to check your glucose level and bolus before you start eating.		
117	I noticed that many of your lows at night may be avoided. Remember to check your glucose level and bolus before you start eating.		
118	I noticed that many of your lows at noon may be avoided. Remember to check your glucose level and bolus before you start eating.		
119	I noticed that many of your lows in the afternoon come after a manual bolus. Using your Bolus Calculator may help you improve.		

9	D
7	3
Ĉ	5
ċ	
σ	ā
Š	ນ່
	_
Ċ	TO THE T
0	202
2	מצו
2	<u>.</u>
ζ	_
9	
	# T. T
;	ž
۲	•
ì	^
į	-
ò	×

	you improve.
121	I noticed that many of your lows in the early morning come after a manual bolus. Using your Bolus Calculator may help you improve.
122	I noticed that many of your lows in the late morning come after a manual bolus. Using your Bolus Calculator may help you improve.
123	I noticed that many of your lows in the evening come after a manual bolus. Using your Bolus Calculator may help you improve.
124	I noticed that many of your lows in the late evening come after a manual bolus. Using your Bolus Calculator may help you improve.
125	I noticed that many of your lows in the morning come after a manual bolus. Using your Bolus Calculator may help you improve.
126	I noticed that many of your lows at night come after a manual bolus. Using your Bolus Calculator may help you improve.
127	I noticed that many of your lows at noon come after a manual bolus. Using your Bolus Calculator may help you improve.

I noticed that many of your lows come after a manual bolus. Using your Bolus Calculator may help

Personalized Diabetes Management Tip

120

Appendix C – New Recommendations **Troubleshooting**

The list below includes all error messages that may occur when generating a new recommendation in endo.digital.

If multiple errors are relevant, only the most significant is displayed.

Table 16 – Pump Troubleshooting – New Recommendations

Pump Error Message	Comments
Advisor recommendation can only be generated once every 14 days. Try again in a few days. Try again later.	endo.digital recommendations can be generated once every 14 days. Wait until the 14-day cooling period passes from the last recommendation.
A general error has occurred. If the problem remains, contact support@dreamed.ai.	General error due to internal problem in the system, the patient's devices or the clinic environment. This may be a momentary problem. Try again later. If the problem repeats, contact DreaMed support.
endo.digital cannot generate a recommendation due to a possible clock shift in one of the patient's devices. Try again in a few days.	endo.digital analyses the data from various devices, assuming their clocks are synchronized and consistent. If the system detects that the patient changed the clock on their device, the system will not generate a recommendation. Wait for a 21-day period after the device's clock change event and try again.
endo.digital requires at least 12 days with sufficient pump data during the last 3 weeks. Try again in a few days.	There is not enough pump data downloaded in the last 21 days. Make sure that the insulin pump finished downloading its data and try again.
endo.digital requires at least 12 days with sufficient glucose and pump data during the last 3 weeks. Try again in a few days.	There is not enough pump data as well as glucose data downloaded in the last 21 days. Make sure the insulin pump, the sensor and/or blood glucose meter finished downloading their data and try again.
endo.digital requires at least 12 days with sufficient glucose readings during the last 3 weeks. Try again in a few days.	There is not enough glucose data downloaded in the last 21 days. Make sure the sensor or glucometer finished downloading its data and try again. If the patient did not wear their sensor for at least 67% of the day or measured their blood glucose at least three times a day with 210 minutes apart for at least 12 days, a recommendation is not generated.
endo.digital requires a BG target plan below 150 mg/dL. Update pump settings and wait 14 days before re-uploading the data and getting a new recommendation.	The patient's target plan configured in the insulin pump settings is above 150 mg/dL. These values are considered too high for endo.digital to treat. It is recommended to lower the target plan to a clinically acceptable value.
endo.digital requires glucose data. Upload patient device data to generate a recommendation.	No glucose data is available in the last 21 days.

	Download the patient's CGM and/or blood glucose device and try again. If the patient is using Dexcom, make sure their Dexcom account is connected and data is up to date.
endo.digital requires insulin pump and glucose data. Upload patient device data to generate a recommendation.	No insulin pump data, CGM and blood glucose meter data is available in the last 21 days. Download the patient's insulin pump, CGM and/or blood glucose meter device data and try again. If the patient is using Dexcom, make sure their Dexcom account is connected, and data is up to date.
endo.digital requires insulin pump data. Upload patient device data to generate a recommendation.	No insulin pump data is available in the last 21 days. Download the patient's insulin pump data and try again.
An error occurred while uploading this patient's data. Try re- uploading patient devices. If the problem remains, contact support@dreamed.ai.	The patient's data is corrupted. Try uploading the patient's data again and try again.
The access to this patient's data has been denied. Please ask the patient to share their data with your clinic account.	endo.digital cannot access the patient's account in Tidepool. This is usually caused when the patient cancels their data sharing with your Tidepool clinic account. Ask the patient to share their data with your clinic again or contact support.
endo.digital detected the use of an automatic insulin delivery system (closed-loop) in the last 21 days, which is a contraindication for endo.digital.	The patient is using an automated closed loop system (automated insulin delivery system) which is a contraindication for endo.digital. Use manual recommendation for viewing the patient's data and adjusting the plan manually.
Patient's Dexcom account was disconnected. Reconnect the Dexcom account to Advisor and then try again.	There was an issue connecting to the Dexcom account, likely due to a password change, reconnect and try again.
The report could not be generated. An unexpected error occurred while attempting to download the data from Tidepool. If the problem remains, contact support@dreamed.ai.	Tidepool general error.
The report could not be generated. An unexpected error occurred while attempting to download the data from endo.digital Uploader. If the problem remains, contact support@dreamed.ai.	endo.digital Uploader general error.
The report could not be generated. An unexpected error occurred while attempting to download the data from Dexcom. If the problem remains, contact support@dreamed.ai.	Dexcom general error.

Table 17 – MDI Troubleshooting – New Recommendations

MDI Error Message	Comments
Advisor automatic recommendation can only be generated once every 14 days. Try again in a few days.	endo.digital recommendations can be generated once every 14 days. Wait until the 14-day cooling period passes from the last recommendation.
A general error has occurred. If the problem remains, contact support@dreamed.ai.	General error due to internal problem in the system, the patient's devices, or the clinic environment. This may be a momentary problem. Try again later. If the problem repeats, contact DreaMed support.
Not enough glucose data to generate a recommendation, Advisor requires at least 12 / 6 days	There is not enough glucose data downloaded in the last 21 days. Make sure the sensor or glucometer finished downloading its data and try again. If your Type 1 or insulin resistant type 1 patient did not wear their sensor for at least 67% of the day or measured their blood glucose at least three times a day with 210 minutes apart for at least 12 days, a recommendation is not generated. If your Type 2 patient did not measure their fasting glucose in at least 6 days, a recommendation is not generated.
One or more patient's sliding scale plan is invalid. Insulin amount should be Non-descending with a maximum increment of 5 / 10 units between steps	For every step in the sliding scale plan, the bolus amount should be greater than or equal to the previous one. In addition, the increment in bolus amount between each step cannot exceed 5 units for Type 1 and 10 units for Type 2 and Insulin resistant type 1 patients. The plan must comply with these requirements to be valid.
Advisor requires either a basal treatment plan or at least 5 days with basal delivery information. Provide the required data and try again.	MDI only
Advisor supports basal plans with up to 2 daily injections. Please verify the patient's plan is as expected and try again.	MDI only
When the patient uses 2 daily basal injections, Advisor requires one injection in the morning and one in the evening. Please check the basal plan and try again.	MDI only
One or more of the patient's Morning/Afternoon/Evening/Night is missing, Verify all the plans are correct in the patient's Diary App and try again.	MDI only
No plan at all or morning/afternoon/evening/night plan is missing.	MDI only
Advisor cannot generate a recommendation due to a possible clock shift in one of the patient's devices. Try again in a few days.	endo.digital analyses the data from various devices, assuming their clocks are synchronized and consistent.

MDI Error Message	Comments
	If the system detects that the patient changed the clock on their device, the system will not generate a recommendation. Wait for a 21-day period after the device's clock change event and try again.
The access to this patient's data has been denied. Please ask the patient to share their data with your clinic account.	endo.digital cannot access the patient's account in Tidepool. This is usually caused when the patient cancels their data sharing with your Tidepool clinic account. Ask the patient to share their data with your clinic again or contact support.
The daily amount of basal insulin in the patient's recommended plan is outside Advisor's permitted range of 1-72 / 1-250 units.	For MDI patients, the permitted range is defined by the patient's selected type of diabetes: Type 1 – 1 to 72 units Type 2 / Insulin resistant type 1 – 1 to 250 units
One or more of the bolus amount in the patient's recommended plan exceeds Advisor's maximum value of 30 / 99 units	For SSI MDI patients, the maximum amount is defined by the patient's selected type of diabetes: Type 1 – 30 units Type 2 / Insulin resistant type 1 – 99 units
One or more of the carb ratio values in the patient's recommended plan is outside Advisor's permitted range of 3-70 g/u (Carbs counting T1DM), 2-70 g/u (Carbs counting T2DM, IRT1) units.	For Carbs counting MDI patients, the permitted range is defined by the patient's selected type of diabetes: Type 1 – 3 to 70 g/u Type 2 / Insulin resistant type 1 – 2 to 70 units
One or more of the correction factor values in the patient's recommended plan is outside Advisor's permitted range of 10-280 mg/dL (Carbs counting T1DM) 5-280 mg/dL (Carbs counting T2DM,) units.	For Carbs counting MDI patients, the permitted range is defined by the patient's selected type of diabetes: Type 1 – 10 to 280 mg/dL Type 2 / Insulin resistant type 1 – 5 to 280 mg/dL
One or more of the target values in the patient's recommended plan is outside Advisor's permitted range of 70-180 mg/dL.	MDI only
The number of insulin units required to bring the patient to their pre-meal glucose target range exceeds Advisor's maximum value of 20 mg/dL.	MDI only
A recommendation could not be generated.	MDI only
The patient had a significant time period in hypoglycemia for no known reason.	
The bolus glucose target and the pre-meal glucose range should be within 20 mg/dL of each other.	The glucose target does not match the pre-meal glucose set in the initial plan settings, you should correct one of them for best results.

	2000	ı	2
(;		5
	2		
	2	7	
	000	′	2
	3	<	
	222		
	2		
	:		•
			į
	1	,	
	8	5	,

MDI Error Message	Comments	
Patient's Dexcom account was disconnected. Reconnect the Dexcom account to Advisor and then try again.	There was an issue with connection to the Dexcom account, likely due to a password change.	
The report could not be generated. An unexpected error occurred while attempting to download the data from Tidepool. If the problem remains, contact support@dreamed.ai.	Tidepool general error.	
The report could not be generated. An unexpected error occurred while attempting to download the data from endo.digital Uploader. If the problem remains, contact support@dreamed.ai.	endo.digital Uploader general error.	
The report could not be generated. An unexpected error occurred while attempting to download the data from Dexcom. If the problem remains, contact support@dreamed.ai.	Dexcom general error.	

endo.digital



DreaMed Diabetes Ltd.

14 Kaplan st., the Endocrinology Center, Schneider Children's Medical Center, Petah Tikva, 4920235, Israel

Phone - +972-52-3166684 Email - info@dreamed.ai

Website - www.dreamed-diabetes.com

PR-131168 Version 12.0