

# dreamed ADVISOR<sup>Pro</sup>

## HCP USER MANUAL



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**In the US:**

For in-vitro diagnostic use only.

dreamed  
ADVISOR<sup>Pro</sup>

SW ver. 01.08.04



2021-06-15

R<sub>x</sub> Only



(01)7290017735016(11)210615(10)010804



**Note:**

This Healthcare professional (HCP) User Manual is subject to periodic review, update and revision.

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

The product has been used according to the accompanying operating instructions.

All updates, extensions, readjustments, changes, or repairs have been carried out by DreaMed Diabetes' authorized representatives.

Improper use or repair of this product, faulty maintenance, unauthorized service, damage, or alteration by anyone other than DreaMed Diabetes may result in malfunction.

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**Note:**

To request additional information, ask questions or report safety issues, contact the Diabetes Management System (DMS) customer service/ support and indicate in the support form that your request / complaint is related to the DreaMed Advisor Pro. The DMS will forward your request/complaint to DreaMed Diabetes if needed.

Direct contact information for DreaMed is also available on the DMS support/help page as well as at DreaMed Diabetes website, [www.dreamed-diabetes.com/support](http://www.dreamed-diabetes.com/support) in addition to in this HCP User Manual. You may also contact DreaMed Diabetes and ask for a paper User Manual to be sent to you.

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



## Before you Begin

### Using this user manual

This HCP user manual contains valuable information about using DreaMed Advisor Pro. To help you find the information 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 Glossary

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
	For prescription use only
 <b>Note</b>	<b>Note:</b> A note provides helpful information
 <b>Caution</b>	<b>Caution:</b> A caution notifies you of a potential hazard which, if not avoided, may result in minor or moderate injury or damage. The caution will include the <b>precaution</b> that should be taken to avoid the hazard
 <b>WARNING</b>	<b>WARNING:</b> A <b>warning</b> is a statement that alerts you to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of Advisor Pro

## Acronyms and abbreviations

Table 2 defines acronyms and abbreviations used in the manual:

Table 2: Acronyms and abbreviations

Acronym and abbreviation	What does it mean?
ADA	American Diabetes Association
BG	Blood Glucose
CF	Correction Factor [(mg/dl)/UI or (mmol/l)/UI].
CGM	Continuous Glucose Monitoring device
CR	Carbohydrate Ratio [gr/UI]
DKA	Diabetic Ketoacidosis
DMS	Diabetes Management System
HCP	Healthcare Professional
ISF	Insulin Sensitivity Factor. In this Manual we use the term CF as a replacement to ISF
ISPAD	International Society for Pediatric and Adolescent Diabetes
IV	Intravenous
PC	Personal Computer
SMBG	Self-Monitoring Blood Glucose device
TDD	Total Daily Dose

## User Safety

### Indication for Use

DreaMed Advisor Pro is a decision-support software intended for assisting healthcare professionals in the management of patients with Type 1 diabetes who:

- use insulin pumps as their insulin delivery therapy;
- monitor their glucose levels using continuous glucose monitoring (CGM) and/or self-monitoring blood glucose (SMBG) meter;
- are above the age of 6; and
- use rapid acting U-100 insulin analogs in their pump

DreaMed Advisor Pro is indicated for use by healthcare professionals when analyzing CGM, SMBG and pump data to generate recommendations for optimizing a patient's insulin pump settings for basal rate, carbohydrate ratio (CR), and correction factor (CF); without considering the full clinical status of a particular patient. DreaMed Advisor Pro does not replace clinical judgement.



#### Note:

DreaMed Advisor Pro was tested in limited pilot clinical studies for the pediatric and young adult age groups only.

To request additional information, ask questions or report safety issues, contact the DMS customer service/support and indicate in the support form that your request/complaint is related to the DreaMed Advisor Pro. The DMS will follow your request/complaint to DreaMed Diabetes if needed.

Direct contact information for DreaMed is also available on the DMS support/help page as well as at DreaMed Diabetes website, [www.dreamed-diabetes.com/support](http://www.dreamed-diabetes.com/support) in addition to in this HCP User Manual. You may also contact DreaMed Diabetes and ask for a paper User Manual to be sent to you.



## Contraindications

- DreaMed Advisor Pro is not intended to send recommendations directly to patients without initially being reviewed and approved by an HCP.
- DreaMed Advisor Pro is not intended for use with patients who use automated insulin dosing (AID) systems (e.g., "closed-loop", "artificial pancreas", see Table 3b for a list of the contraindicated devices). Advisor Pro hasn't been tested with these devices. Therefore, the DMS will not allow you to analyze data from these devices by Advisor Pro.
- DreaMed Advisor Pro is not intended for use with patients who use insulin(s) other than U-100. Advisor Pro hasn't been tested with other types of insulins and is designed to consider the pharmacodynamics and pharmacokinetics of U-100 insulin only. Using Advisor Pro with other types of insulin may lead to potential harm.
- DreaMed Advisor Pro is not intended for use with patients treated with insulin injections, intravenous (IV) insulin, or a combination of insulin injections and/or IV insulin and insulin pump therapy. Since Advisor Pro analyzes the insulin dosing history from the insulin pump, it will be blind to insulin delivered by injections and/or IV insulin. This could result to a false conclusion about the changes to the patient's insulin pump settings and may lead to the potential harm.
- DreaMed Advisor Pro is not intended for patients using other concomitant glucose lowering therapies. Since Advisor Pro analyze the insulin dosing history from the insulin pump, reducing glucose levels by other means will not be taken into consideration by Advisor Pro. This could result to a false conclusion about the changes to the patient's insulin pump settings and may lead to the potential harm.
- DreaMed Advisor Pro is not recommended for pregnant women. Advisor Pro hasn't been tested in this population.
- DreaMed Advisor Pro is not recommended for patients who are taking medications that might affect CGM/SMBG values. Please refer to the warnings and contraindications of the patient's CGM/SMBG to determine whether said medications may falsely raise glucose readings. The level of inaccuracy depends on the amount of said medication active in the patient's body and may be different for each person. Using Advisor Pro in these cases may lead to potential harm.
- For prescription use only

Please ensure your patient is an appropriate candidate for DreaMed Advisor Pro before starting them on this program.



**Note:** DreaMed Advisor Pro does not screen for the above listed contraindications.

### Potential Harms

DreaMed Advisor Pro leverages historical glucose and insulin data, transmitted from a DMS to DreaMed Advisor Pro, to recommend changes to the patient insulin pump settings. The recommendations of DreaMed Advisor Pro are presented to you through a DMS and are bounded by the indication for use and the contraindications. Thus, there are risks associated with use of DreaMed Advisor Pro within the contraindications as well as risks related to the cyber security, data integrity and infusion of insulin through the patient's insulin pump. These general harms may include:

- Hyperglycemia
- Ketosis
- Diabetic Ketoacidosis (DKA)
- Mild hypoglycemia
- Severe hypoglycemia
- Data Confidentiality
- Data Availability
- Data Integrity

This user manual provides information regarding the safety features incorporated into DreaMed Advisor Pro 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. The DreaMed Advisor Pro is not a substitute for, but rather an adjunct to clinical reasoning.
2. The DreaMed Advisor Pro recommendations are based on DreaMed Diabetes' proprietary algorithm which relies on glucose and insulin data only drawn from the patient's insulin pump, CGM and/or blood glucose meter. 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 the DreaMed Advisor Pro as necessary before sharing them with your patient. For example, the following factors are not considered by DreaMed Advisor Pro and you may want to consider them 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 or CGM experience
  - Duration of diabetes diagnosis - honeymoon phase
  - Illness
  - Hospitalization
  - Use of steroids
  - Extreme physical activity
  - Significant change of diet
  - Holiday
3. Do not use the DreaMed Advisor Pro before receiving training and reading this manual. Training will be provided by the DMS or by DreaMed Diabetes personnel. Training for DreaMed Advisor Pro will consist of a review of this manual and a review of the app functions. Contact the DMS for training. See Table 6: DreaMed Advisor Pro Qualified DMS for contact information for training.
4. Advisor Pro is still able to 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 CGM, insulin pump and/or blood glucose meter are not aligned,

the recommendation may be affected. Therefore, DreaMed Advisor Pro should not be used when:

- a. An error message appears when downloading the data from the device to the DMS indicating a time difference between either the insulin pump, CGM or blood glucose meters and the PC or mobile phone you are using to download the data to.
- b. The patient has indicated traveling to another time zone in the past 21 days
- c. There is an indication on the DMS that the patient has changed the clock of either the insulin pump, CGM and/or blood glucose meters.

## About DreaMed Advisor Pro

This HCP User Manual provides information for DreaMed Advisor Pro software version 01.08.04.

The DreaMed Advisor Pro 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 the insulin pump's bolus calculator to recommend adjustments to the patient-specific insulin pump settings (carbohydrate ratio, CF and basal plan) as well as suggestions for Personalized Diabetes Management Tips (such as timing of meal boluses and bolus delivery compliance).

The DreaMed Advisor Pro was developed to assist HCPs in decision making when treating patients with type 1 diabetes who use insulin pump therapy and monitor their glucose level using CGM and/or SMBG.

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

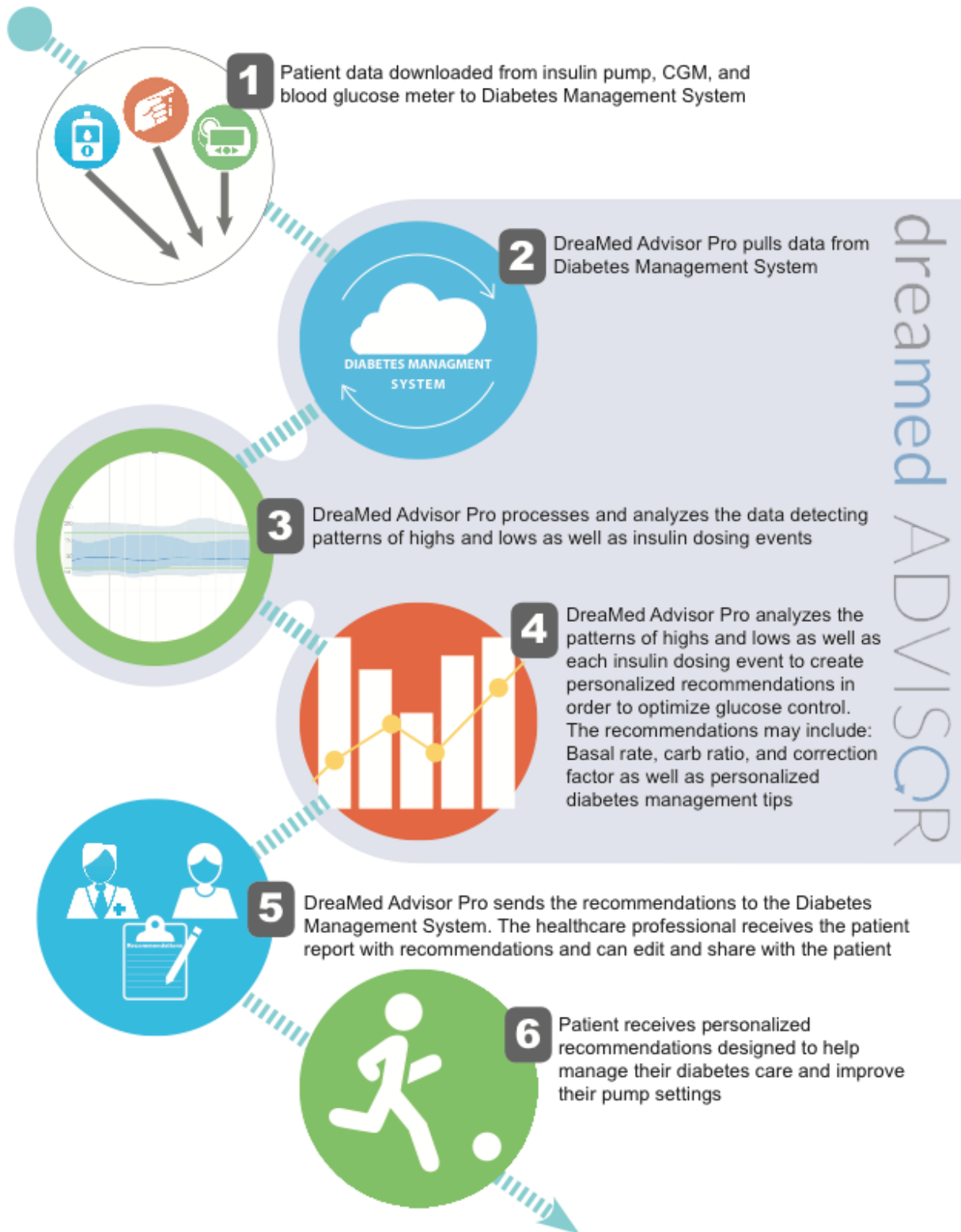


Figure 1: How DreaMed Advisor Pro Works

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## Step 1: Patient data downloaded from insulin pump, CGM, and blood glucose meter to DMS

Check that your patient is an appropriate candidate for DreaMed Advisor Pro (see User Safety: Contraindications, General Warnings, and Precautions). Then, sign up your patient for DreaMed Advisor Pro through the DMS. In order to get a recommendation for the patient, download the data from their insulin pump, CGM and/or self monitoring blood glucose meter and send it to the DMS. The patient or care-team should consult the manuals of the DMS for information on how to send the data from the different devices.



**Note:** The patient must download data from their insulin pump, CGM and/or meter so the data can be analyzed by DreaMed Advisor Pro. No other data sources are used in DreaMed Advisor Pro's analysis.



**WARNING:** Do not use DreaMed Advisor Pro with data that was downloaded with errors from the devices to the DMS.

## Authorized and contraindicated devices

Table 3a details the devices that are currently authorized to be used with DreaMed Advisor Pro. Quarterly updates to this list will be available at [www.dreadmed-diabetes.com/support](http://www.dreadmed-diabetes.com/support).

Table 3a: Authorized Devices for use with DreaMed Advisor Pro

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

Table 3b details the devices that are currently contraindicated to be used with DreaMed Advisor Pro. Quarterly updates to this list will be available at [www.dreadmed-diabetes.com/support](http://www.dreadmed-diabetes.com/support).



Table 3b: Contraindicated Devices not to be used with DreaMed Advisor Pro

Device Type	Device Manufacturer	Brand Name
Automated Insulin Dosing Systems (pump and CGM)	Medtronic Diabetes	MiniMed 670G or 770G Insulin Pumps with Guardian Sensor 3
	Tandem Diabetes Care	t:slim X2 using Control IQ with Dexcom G6

## Step 2: DreaMed Advisor Pro pulls data from the DMS

The data is sent to the DreaMed Advisor Pro system once the patient finishes sending the data from the treatment devices to the DMS. DreaMed Advisor Pro pulls data from the DMS during a period of 12-21 days from the last date of data download. Of the data pulled, DreaMed Advisor Pro requires at least 12 valid days to produce recommendations (defined in Table 4a), at least 3 records from the bolus calculator and a valid recent insulin pump settings plans (i.e. basal plan, CR plan, CF plan, bolus calculator glucose targets plan and insulin activity time, defined in Table 4b). In the event that these conditions are not met, DreaMed Advisor Pro will not provide recommendations on new insulin pump settings.

Table 4a: Definition of a Valid Day for DreaMed Advisor Pro Analysis

Data source	Requirement
CGM	At least 67% of CGM sensor readings per day according to the sensor's sample rate (i.e., for a sensor that presents glucose readings every 5 minutes at least 192 samples are required and for that presents glucose readings every 15 minutes at least 64 samples)
or	
SMBG	At least 4 BG measurements a day that are separated from each other by at least 160 minutes.
Basal rate	At least 1 basal record
Bolus	At least 1 bolus record



**Caution:** Advisor Pro 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 sensor with reduced accuracy could cause Advisor Pro to analyze inaccurate sensor data.

Table 4b: Definition of a Valid Insulin Pump Settings for DreaMed Advisor Pro Analysis

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 3-70gr/u
CF [mg/dl/u]	Each value in the CF plan is within 10-280mg/dl/u
Bolus Calculator Targets [mg/dl]	Equal to or below 150 mg/dl



**Caution:** 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 being pulled automatically from the DMS to DreaMed Advisor Pro. You cannot edit, change, replace, or flag out the data from analysis. In addition, the patient can't flag out data from analysis

### DreaMed Advisor Pro data integrity security and privacy

DreaMed Advisor Pro 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 limitation. These security functions are important components of a comprehensive security system. DreaMed Advisor receives patient health information in a de-identified manner, which cannot be used to identify a specific patient.

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



**Caution:** Implementing and managing a comprehensive and up-to-date security system, customized to individual needs is necessary and may result in additional specific preventive measures to ensure 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, etc.

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

### Step 3: DreaMed Advisor Pro processes and analyzes the data

First, DreaMed Advisor Pro 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 – DreaMed Advisor Pro may ignore some of the CGM/SMBG 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 – DreaMed Advisor Pro uses the following thresholds to detect patterns of hypo and hyperglycemia:
  - Hypoglycemia threshold is under 70 mg/dl (3.9 mmol/l)
  - Mean daily euglycemic level is 154 mg/dl (8.5 mmol/l)
  - Hyperglycemia threshold is over 180 mg/dl (10 mmol/l)
- Insulin dosing decisions events by the 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, DreaMed Advisor Pro uses the patient's insulin pump settings to estimate if carbohydrates were consumed at the time of a bolus.

## Step 4: DreaMed Advisor Pro analyzes patterns and creates recommendations

DreaMed Advisor Pro evaluates the following events:

- each insulin dosing decision made by the patient, and
- hyperglycemia and hypoglycemia 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 (Appendix A: Advisor Pro Personalized Diabetes Management Tips List provides a detailed description of Personalized Diabetes Management Tips that could be suggested by DreaMed Advisor Pro, specifically hyperglycemia patterns, and hypoglycemia patterns)



**Caution:** DreaMed Advisor Pro considers the active insulin time and the bolus calculator glucose target plan that are set in the insulin pump when recommending changes to basal rate, CR, and CF. Therefore, if you would like to change either the active insulin time or the bolus calculator glucose target plan consider whether the DreaMed Advisor Pro recommendations need to be modified.

DreaMed Advisor Pro integrates safeguards into its recommendations to ensure the safety of the patient. First, DreaMed Advisor Pro will not issue recommendations beyond what is considered valid insulin pump settings as detailed in Table 4b. Second, Table 5 presents the particular safeguards and limitations used in recommending a change to the patient's insulin pump settings.

Table 5: DreaMed Advisor Pro limitations when recommending changes to patient's insulin pump setting

Variable Name	Limitations	How is it used in DreaMed Advisor Pro analysis process
Basal Plan	Limitation on the highest hourly basal rate that could be recommended by DreaMed Advisor Pro	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 could be recommended by DreaMed Advisor Pro	Current Basal Rate Lower Limit: -20% of the current hourly basal rate based on the patient's current insulin pump settings minus $0.05 \left[ \frac{U}{Hour} \right]$
	Additional limitations depending on the patient TDD*	<p>Advisor Pro has a second layer of limitations which dependent on the patient TDD, whereas the recommended basal rates should be within the range of:</p> <ul style="list-style-type: none"> <li>TDD Upper Limit: 150% of the hourly average basal rate calculated from the patients TDD, whereas the hourly average basal rate is the TDD/2/24</li> <li>TDD Lower Limit: 50% of the hourly average basal rate calculated from the patients TDD, whereas the hourly average basal rate is the TDD/2/24.</li> </ul> <p>These limitations overrule the Current Basal Rate Upper/Lower Limits stated above.</p>

\* If the patient's current basal rate settings are outside of TDD Upper/Lower Limits as appear in Table 5 (marked with \*) – Advisor Pro changes these settings towards the acceptable range only if there is a 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 (i.e. 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 DreaMed Advisor Pro 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 there is clinical evidence to increase basal rate then DreaMed Advisor Pro will not recommend a change.

Variable Name	Limitations	How is it used in DreaMed Advisor Pro analysis process
	Potential maximum number of basal periods	24 per day
CR Plan	Limitation on the highest CR value that could be recommended by DreaMed Advisor Pro	+ 30% of the current CR value based on the patient's current insulin pump settings plus $1 \left[ \frac{gr}{U} \right]$
	Limitation on the lowest CR value that could be recommended by DreaMed Advisor Pro	-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 could be recommended by DreaMed Advisor Pro	+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 could be recommended by DreaMed Advisor Pro	-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

**Note:**

- The values appearing in Table 5 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 Advisor Pro algorithm recommends a maximum percentage of the allowed change, which results in a smaller change than the insulin pump's resolution, the final change will be 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 DreaMed Advisor Pro recommends increasing the basal rate by 20%, it may increase to 0.1 – still within the specifications detailed in Table 5.

- The DreaMed Advisor Pro 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 & 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.

DreaMed Advisor Pro 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 on how to avoid unbalanced glucose levels. The recommendations could 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 DreaMed Advisor Pro was not able to create a recommendation, DreaMed Advisor Pro will indicate as such.





**Caution:** DreaMed Advisor Pro requires a certain number of events to generate a recommendation about a particular time of day. Please note, that the recommendation could be generated by a limited number of events analyzed.

### Step 5: Recommendations are sent to the DMS

The recommendations of DreaMed Advisor Pro are sent to the DMS in a secure machine-readable format. All data security provisions that were applied to the data when sent to the DMS are applied to this data being sent back to the DMS as well.

The recommendations of DreaMed Advisor Pro are presented to you through the DMS user interface. The sections below (First Steps) explain how to view and edit the recommendations of DreaMed Advisor Pro from the DMS user interface.

### Step 6: Recommendations are shared with the patient

Once you have reviewed the patient's recommendation, you can approve and share it from the DMS user interface. The patient receives the recommendation through the DMS mobile app once they have been shared.

## First Steps

This chapter gives you an overview on how to access and start a new patient on DreaMed Advisor Pro. Before using DreaMed Advisor Pro you must receive training. Training is provided through the DMS, contact information for the DMSs working with DreaMed Advisor Pro are listed in the table below. Training consists of reviewing the User Manual and receiving an introduction to the software.

### Add Your Patient to the DMS Platform

To access DreaMed Advisor Pro, the patient needs to be registered in the DMS working with DreaMed Advisor Pro. The list of current qualified DMS is provided in Table 6. Please refer to the relevant DMS instructions for use for more details on how to register a patient to the DMS.

Table 6: DreaMed Advisor Pro Qualified DMS

DMS Company	Contact information
Glooko Inc	<a href="http://www.glooko.com">www.glooko.com</a>  For questions, to request training, or for support: <a href="https://support.glooko.com/hc/en-us/requests/new">https://support.glooko.com/hc/en-us/requests/new</a>  For privacy policy: <a href="https://www.glooko.com/privacy/">https://www.glooko.com/privacy/</a>  For terms of use: <a href="https://www.glooko.com/terms-of-use/">https://www.glooko.com/terms-of-use/</a>



#### Note:

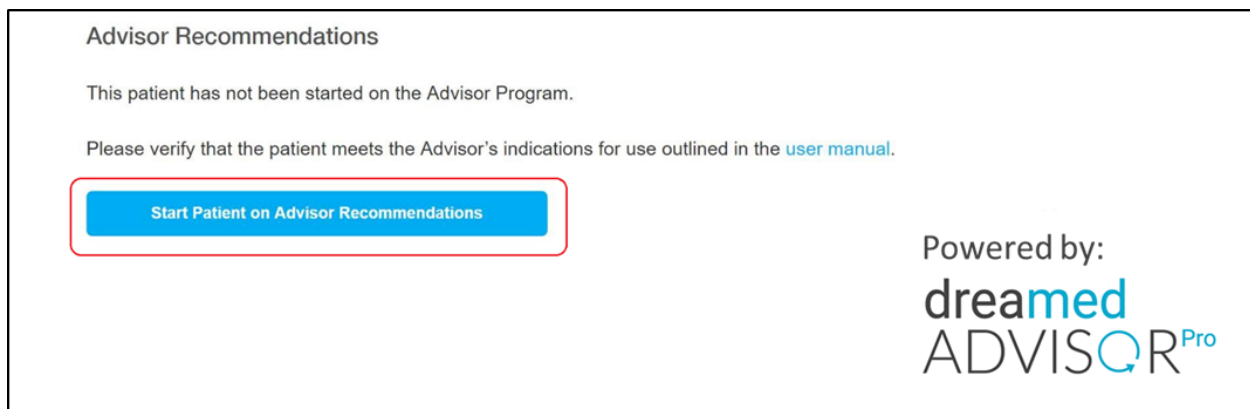
DreaMed Diabetes will update this list on a quarterly basis (if needed). Updated list can be found on [www.dreadmed-diabetes.com/support](http://www.dreadmed-diabetes.com/support) in the electronic version of this manual.

## Start a new patient on DreaMed Advisor Pro

Starting a patient on DreaMed's Advisor Pro will initiate a continuous learning algorithm that monitors patients' data and provides periodic treatment recommendations for the patient's insulin pump settings.

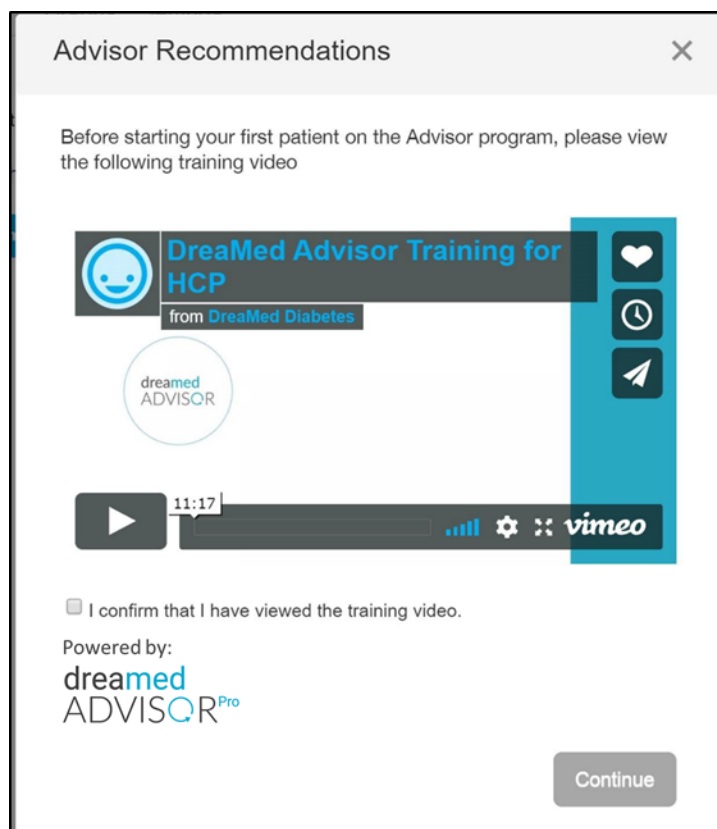
When starting a new patient for the first time, you will need to view the training video and acknowledge viewing it before you can start the patient on DreaMed Advisor Pro.

Figure 2: Patient Registration Screen



When clicking on **Start Patient on Advisor Recommendation** for the first time, the following screen will appear

Figure 3: Video Training Screen



**Note:**

The DMS may allow a group of patients to be registered at one time to DreaMed Advisor

Once you have confirmed that you viewed the video training, you will be able to click **Start Patient on Advisor Recommendations** to begin a patient on the DreaMed Advisor Pro program. Once DreaMed Advisor Pro has been initiated, it may take a few minutes to determine if the patient account has sufficient data to begin the program.



**Note:**

Once the patient is registered in the DreaMed Advisor Pro program, it will run automatically when new, valid data is available for analysis by DreaMed Advisor Pro. No further action from you is needed to activate the DreaMed Advisor Pro analysis.

## Data requirements

To receive DreaMed recommendations, the patient needs to have **valid data** from at least **12 of the past 21 days**. A valid day is defined according to the following requirements:

- **At least 1 basal and at least 1 bolus** record per day
- **Minimum glucose data:**
  - **More than 67% of CGM sensor** readings per day according to the sensor's sample rate (i.e., for a sensor that presents glucose readings every 5 minutes at least 192 samples are required and for that presents glucose readings every 15 minutes at least 64 samples), OR
  - At least **4 SMBG measurements** a day that are **separated** from each other by at least 160 minutes.
- At least **3 records from the bolus calculator**

In addition, the Advisor Pro requires receiving 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 DreaMed Advisor Pro will not provide a recommendation)**
- Active insulin time

If there is not currently enough data to initiate DreaMed Advisor Pro or in the event that the above criteria were not met, the following message will be displayed: “The patient has not received any pump suggestions yet. Once the patient has synced pump data for a minimum of 3 weeks, pump suggestions will be available.” You can reload this page by clicking **Refresh Page** to view if the patient has met the minimum requirements for running DreaMed Advisor Pro.

Figure 4: Insufficient Data Message

Advisor Recommendations

This patient has not received any pump suggestions yet. Once the patient has synced pump data for a minimum of 3 weeks, pump suggestions will be available.

Refresh Page

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ADVISOR<sup>Pro</sup>

## Review and Share Recommendations

### Advisor Main Screen

Once the patient is already started on DreaMed Advisor Pro, you can click the **Advisor** tab to go to the Advisor Main Screen (Figure 5) and see if new recommendations are available for your patients. This page is divided into two sections:

1. The Current Advisor Recommendations section lists active reports available for your patient, including the following information:

- Report date;
- If it was shared with the patient (if so, then the date it was shared is also displayed);
- Patient confirmed status: confirmation of receipt and implementation of the recommendations (Yes/No); and
- View Report - click to view the full Advisor Recommendation Report.

2. The Advisor Recommendations History section displays a historical list of Recommendation Reports, including the following information:

- Report date;
- If it was shared with the patient (if so, then the date it was shared is also displayed);
- Patient confirmed status: confirmation of receipt and implementation of the recommendations (Yes/No); and
- View Report - click to view the full Advisor Recommendation Report.



**Note:**

Each qualified DMS (Table 6 above) may have additional indications that a new recommendation is available for your patient. Please refer to the relevant user manual for additional information.

Figure 5: Advisor Main Screen

Current Advisor Recommendations

REPORT DATE	SHARED WITH PATIENT	PATIENT CONFIRMED	REPORT
11/29/2017	Yes - 11/29/2017	Yes - 11/29/2017	<a href="#">View Report</a>

Advisor Recommendation History

REPORT DATE	SHARED WITH PATIENT	PATIENT CONFIRMED	REPORT
10/28/2017	Yes - 10/28/2017	No	<a href="#">View Report</a>
9/28/2017	Yes - 9/28/2017	No	<a href="#">View Report</a>
8/29/2017	Yes - 8/29/2017	No	<a href="#">View Report</a>

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ADVISOR<sup>Pro</sup>

## Pre-checks before reviewing Advisor Report

Each time you would like to review the recommendation of Advisor Pro, ask yourself the following:

### Is the patient a good candidate for Advisor Pro?

Make sure that:

- The patient meets the indication for use requirements
- The patient **does not** fall within the contraindication requirements

If you do not remember you can always refer to this user manual by pressing the link "Advisor Help" on Advisor report page (see figure 5 above).



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

Advisor Pro analyze history glucose and insulin data and use this to recommend changes to the pump settings that should be implemented now and into the future. Therefore, please avoid using Advisor recommendations when special circumstances occur that could affect the data you and Advisor is using for analysis. Examples for special circumstances may be:

- Illness
- Medications
- Hospitalization
- Used 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:

Advisor Pro is still able to 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 the DMS indicating a time difference between either the insulin pump, CGM or blood glucose meters and the PC or mobile phone you are using to download the data to. Please refer to the DMS user manual for details how this message appears in their platform.
- The patient has **not** indicated traveling to another time zone in the past 21 days
- There is **no** indication on the DMS that the patient has changed the clock of either the insulin pump, CGM or blood glucose meters. Please refer to the DMS user manual for details how this message appears in their platform.

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## Get Familiarized with Advisor Report

Figure 5: Review and Share Recommendations Screen

01/20/2018 - 02/08/2018

Review and Share Recommendations
[Advisor Help](#)

✓  
Basal Rate

2  
Carb Ratio

3  
Correction Factor

Next

basal 1 - Current

TIME	BASAL RATE (u/hr)
12:00 AM	0.775
2:00 AM	0.75
7:00 AM	1.1
1:30 PM	1.25
4:00 PM	1.3
9:00 PM	0.9
TOTAL UNITS	24.775

Recommended Basal Rate
Edit

TIME	BASAL RATE (u/hr)
12:00 AM	0.775
2:00 AM	0.75
7:00 AM	<b>1</b>
11:00 AM	0.95
1:00 PM	<b>1</b>
1:30 PM	1.15
3:00 PM	1.3
9:00 PM	<b>1</b>
11:00 PM	0.9
TOTAL UNITS	24.125

Updated values in bold

[View Active Insulin Time](#)   [View BG Target](#)

**Comments**

When you have 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.

- **Navigation:** The Navigation Bar at the top of the screen displays the three Recommendation categories: [Basal Rate](#), [Carb Ratio](#), and [Correction Factor](#). 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 Advisor.

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- 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:** Patient-facing tips suggested by Advisor Pro intended to enhance the effectiveness of the insulin therapy. The patient can view these comments when reviewing the Recommendations.
- **Advisor Help:** Click on **Advisor Help** link to access DreaMed Advisor IFU.

## Basal Rate Settings

- To edit the Recommended Basal Rate, click **Edit**.

Figure 6: Review Basal Rate Screen

01/20/2018 - 02/08/2018

Review and Share Recommendations [Advisor Help](#)

✓

2

3

Basal Rate

Carb Ratio

Correction Factor

Next

basal 1 - Current

TIME	BASAL RATE (u/hr)
12:00 AM	0.775
2:00 AM	0.75
7:00 AM	1.1
1:30 PM	1.25
4:00 PM	1.3
9:00 PM	0.9
TOTAL UNITS	24.775

Recommended Basal Rate **Edit**

TIME	BASAL RATE (u/hr)
12:00 AM	0.775
2:00 AM	0.75
7:00 AM	<b>1</b>
11:00 AM	0.95
1:00 PM	<b>1</b>
1:30 PM	1.15
3:00 PM	1.3
9:00 PM	<b>1</b>
11:00 PM	0.9
TOTAL UNITS	24.125

Updated values in bold

[View Active Insulin Time](#)
[View BG Target](#)

- Click within a TIME or BASAL RATE(u/hr) cell to adjust the corresponding value.
  - **TIME** values must adhere to “HH:MM:AM/PM” format.

- Click **Add New Row** to add additional Basal Rate times.
  - **NOTE:** When new rows are added, the rows will be 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:** once you clicked the **edit** mode you will be able to either click Done to save your changes or click Cancel to exit this view without saving.

Figure 7: Edit Basal Rate Screen

TIME	BASAL RATE (u/hr)
12:00 AM	0.050
3 : 00 AM	0.350 X
11 : 00 AM	0.550 X
4 : 30 PM	0.100 X
7 : 00 PM	0.550 X
11 : 00 PM	0.050 X

Add New Row

Comment

After saving your updates, the values will be listed in chronological order.

Click **Next** to continue to Carb Ratio Settings.

## Carbohydrates Ratio Settings

- To edit the Recommended Carb Ratio, click **Edit**.

Figure 8: Review CR Screen

01/20/2018 - 02/08/2018

Review and Share Recommendations [Advisor Help](#)

✓ Basal Rate
 ✓ Carb Ratio
 3 Correction Factor
 Prev Next

Carb Ratio - Current

TIME	CARB RATIO (g/U)
12:00 AM	12

Recommended Carb Ratio Edit

TIME	CARB RATIO (g/U)
12:00 AM	12
11:00 AM	11
3:00 PM	13
7:00 PM	12

Updated values in bold

[View Active Insulin Time](#) [View BG Target](#)

- Click within a TIME or CARB RATIO (g/U) cell to adjust the corresponding value.
  - TIME** values must adhere to “HH:MM:AM/PM” format.
- Click **Add new row** to add additional Carb Ratio times.
  - NOTE:** When new rows are added, the rows will be 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:** once you clicked the **edit** mode you will be able to either click Done to save your changes or click Cancel to exit this view without saving.



**Note:**

The recommended CR is in gram per unit of insulin.

Figure 9: Edit CR Screen

Recommended Carb Ratio
Cancel Done

TIME	CARB RATIO (g/U)
12:00 AM	15.0
2 : 00 PM	28.0 X
7 : 00 PM	25.0 X

Add New Row

Comment

After saving your updates, the values will be listed in chronological order.

Click **Next** to continue to Correction Factor Settings.

## Correction Factor Settings

- To edit the Recommended Correction Factor, click **Edit**.
- Click within a TIME or CORRECTION FACTOR (mg/dL/U) cell to adjust the corresponding value.
  - TIME** values must adhere to “HH:MM:AM/PM” format.
- Click **Add a new row** to add additional Correction Factor times.
  - NOTE:** When new rows are added, the rows will be placed in chronological order after the settings are saved.
- Delete a row by clicking the **X**.

Figure 10: Review CF Screen

**Jenny Woods** [Profile](#)

DOB: **01/01/2008** Diabetes: **Type 1** [Upload Omnipod® PDM](#) [Create PDF Report](#)

04/11/2019 - 04/29/2019 [Advisor Help](#)

Review and Share Recommendations

[Previous](#) ✓ Basal Rate ✓ Carb Ratio ✓ Correction Factor [Approve](#)

Correction Factor - Current	
Time	CORRECTION FACTOR (mg/dL/U)
12:00 AM	120
7:00 AM	80
9:00 PM	120

Recommended Correction Factor		<a href="#">Edit</a>
Time	CORRECTION FACTOR (mg/dL/U)	
12:00 AM	120	
<b>4:00 AM</b>	<b>84</b>	
<b>7:00 AM</b>	<b>65</b>	
9:00 PM	120	
Updated values in bold		

- 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:** once you clicked the **edit** mode you will be able to either click Done to save your changes or click Cancel to exit this view without saving.

Figure 11: Edit CF Screen

Recommended Correction Factor
Cancel Done

TIME	CORRECTION FACTOR (mg/dL/U)
12:00 AM	80
11 : 00 AM	40 X
2 : 00 PM	44 X
7 : 00 PM	25 X

Add New Row

Comment

After saving your updates, the values will be listed in chronological order.

Once the Recommendations have been reviewed, the Recommendations can be [Approved and Shared](#).

## Personalized Diabetes Management Tips

In addition to Advisor Pro's dosing recommendation regarding a patient's basal rate, carb ratio and correction factor, Advisor Pro generate 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 A: Advisor Pro Personalized Diabetes Management Tips List for the full list of Personalized Diabetes Management Tips.

Figure 12: Comments Screen

### Comments

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.



### Note:

You may add or edit comments to the Diabetes Management Tips generated by Advisor Pro by entering text in the Comments box.

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## Approve Recommendations

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

- Click **Approve**.
- An Approve and Share Summary prompt will appear. Review the information and click **Approve and Share** to approve the Recommendations to share them with the patient. Click **Cancel** to return to the previous screen. Note that the patient will not be able to view the recommendations until you have clicked, **Approve and Share**.

Figure 13: Approve and Share Screen

**Approve and Share**

By clicking "Approve and Share" below, you are approving and sending the updated pump suggestions to Emma Weir. The suggestions will be delivered to the patients Glooko mobile app and web dashboard.

**Comments**

Basal Rate (u/hr)	Comments
12:00 AM 0.4	
10:00 PM 0.675	

**Carb Ratio (g/U)**

TIME	Comments
12:00 AM 11	
11:00 AM 10	
5:00 PM 9	

**Correction Factor (mg/dL/U)**

Comments
12:00 AM 65

**Buttons:** Cancel, Approve and Share

**Right Panel:** Sync 422, DOB: 01/01/70, Prev, Approve, Edit, TION FACTOR (mg/dL/U) 65, 65

## Troubleshooting

Provides a guide to solving problems that may occur while working with the DreaMed Advisor Pro system:

### Why can't I access DreaMed Advisor Pro?

*Cause: This may occur when you are using an unqualified DMS.*

**Solution:** Make sure you are using a qualified DMS. The list of qualified DMSs are presented at [www.dreadmed-diabetes.com/support](http://www.dreadmed-diabetes.com/support). Contact DreaMed Diabetes support by sending an email to [support@dreadmed-diabetes.com](mailto:support@dreadmed-diabetes.com) if the DMS is qualified and you still cannot access the DreaMed Advisor Pro system.

### Why can't I start a new patient on DreaMed Advisor Pro?

*Cause: This can happen mainly when your patient is not registered or when you have not completed the procedure for starting a new patient on DreaMed Advisor Pro.*

**Solutions:**

1. Make sure your patient is registered in the DMS (a list of approved DMS can be found at [www.dreadmed-diabetes.com/support](http://www.dreadmed-diabetes.com/support)). Once the patient is registered, you should follow the instructions that are found in the 'Start a new patient on DreaMed Advisor Pro' section.
2. Make sure you read and acknowledge the Information for safe use by checking the box that indicates that you read and understand the 'Information for safe use' screen before pressing the 'Start Patient On DreaMed Program' button.

Contact DreaMed- Diabetes support by email to [support@dreadmed-diabetes.com](mailto:support@dreadmed-diabetes.com) in case you are still not able to start a new patient.

### Why didn't I receive a recommendation after starting a new patient on DreaMed Advisor Pro?

*Cause: The main reason for not getting recommendation is because the data was found to be insufficient for providing a new recommendation.*

**Solution:** Once you have started a new patient on the DreaMed Advisor Pro program, 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

will be displayed (note this message is only displayed before a patient receives their first recommendation):

#### Advisor Recommendations

This patient has not received any pump suggestions yet. Once the patient has synced pump data for a minimum of 3 weeks, pump suggestions will be available.

Refresh Page

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ADVISOR<sup>Pro</sup>

This means that one of the following criteria did not meet:

1. The patient needs to have **valid data** from at least **12 of the past 21 days**. A valid day is defined according to the following requirements:
  - **At least 1 basal** and **at least 1 bolus** record per day
  - **Minimum glucose data:**
    - **More than 67% of CGM sensor** readings per day according to the sensor's sample rate (i.e., for a sensor that presents glucose readings every 5 minutes at least 192 samples are required and for that presents glucose readings every 15 minutes at least 64 samples), OR
    - At least **4 SMBG measurements** a day that are **separated** from each other by at least 160 minutes.
  - **At least 3 uses of the bolus calculator**
2. Advisor Pro requires receiving 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 DreaMed Advisor Pro will not provide a recommendation)**

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- Active insulin time
3. If clock shifting was detected by DreaMed Advisor Pro, a recommendation will not be provided for that 21 days period.

Once the patient is registered in the DreaMed Advisor Pro program, it will run automatically when new, valid data is available for analysis by DreaMed Advisor Pro. No further action from you is needed to activate the DreaMed Advisor Pro analysis. Therefore, you may instruct the patient to continue using the pump, CMG and 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 and wait for 21 days before uploading the data and getting a new recommendation, otherwise, DreaMed Advisor Pro will not provide a recommendation. If the patient is never using the bolus calculator, advise the patient to use it occasionally, as Advisor requires at least 3 bolus calculator events to generate a recommendation.

#### Why didn't I receive a new recommendation for a patient that has already been registered for DreaMed Advisor Pro (not a first-time patient) and has already uploaded data from their treatment devices?

*Cause: The main reason for not receiving a recommendation is because the data was found to be insufficient for providing a new recommendation.*

**Solution:** Once the patient has uploaded the insulin pump, blood glucose meter and/or CGM data to the DMS system, DreaMed Advisor Pro will run automatically and test the validity of the data. No further action from you is needed to activate the DreaMed Advisor Pro analysis. Therefore, if no new recommendation is available, it means that the one of the following criteria was not met:

1. The patient needs to have **valid data** from at least **12 of the past 21 days**. A valid day is defined according to the following requirements: **At least 1 basal** and **at least 1 bolus** record per day
2. **Minimum glucose data:**
  - a. **More than 67% of CGM sensor** readings per day according to the sensor's sample rate (i.e., for a sensor that presents glucose readings every 5 minutes at least 192 samples are required and for that presents glucose readings every 15 minutes at least 64 samples), OR

- b. At least **4 SMBG measurements** a day that are **separated** from each other by at least 160 minutes.
3. Advisor pro requires at least 3 records from the bolus calculator during the last 21 days' time-period
4. Advisor Pro requires receiving 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 DreaMed Advisor Pro will not provide a recommendation)**
  - Active insulin time
5. If clock shifting was detected by DreaMed Advisor Pro, a recommendation will not be provided for that 21 days 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 valid insulin pump settings is not met consider advising the patient to change this setting and advise the patient to wait 21 days before uploading the data and getting a new recommendation, otherwise, DreaMed Advisor Pro will not provide a recommendation.

## Frequently Asked Questions (FAQ)

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

You can check if a new recommendation is ready by clicking the Advisor tab while logged into your patient information screen of the DMS, from which you will be transferred to the Advisor Main Screen. There, look for the active recommendations under the Current Advisor Recommendation section, where you can see a list of all recommendations that have not been approved and shared with the patient. Each qualified DMS (Table 6 above) may have its own additional indications that a new recommendation is available for your patient. Please refer to the relevant user manual for additional information.

### Can I change or edit the recommendation provided by the DreaMed Advisor Pro?

Yes, you can edit each of the Advisor Pro recommendations by clicking the edit button in each pump setting window (basal rate/CR/ CF). You can also add comments to each of these settings recommendations by typing inside the comments box that is found at the bottom of each pump settings recommendation window.

### Can I remove data from the uploaded data that is transferring to DreaMed Advisor Pro?

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

### Can I change the parameters that the DreaMed Advisor Pro is using for providing recommendations (such as the hypo and hyper threshold etc.)?

No, you cannot configure these parameters.

### What are the pump settings that the DreaMed Advisor Pro is recommended to change?

The DreaMed Advisor Pro recommendation may include the following pump settings:

1. Basal rate plan
2. CR plan
3. CF plan

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

### What is the maximum change that DreaMed Advisor Pro may advise?

These are the maximum changes that DreaMed Advisor Pro can advise in each of the pump settings:

- Basal rate plan:
  - -20% of the current CR value based on the patient's current insulin pump settings minus  $0.05 \left[ \frac{U}{Hour} \right]$  and,
  - +20% of the current CR value based on the patient's current insulin pump settings plus  $0.05 \left[ \frac{U}{Hour} \right]$
- CR plan:
  - -30% of the current CR value based on the patient's current insulin pump settings minus 1 gr/Units and,
  - +30% of the current CR value based on the patient's current insulin pump settings plus 1 gr/Units.
- CF plan:
  - -30% of the current CF value based on the patient's current insulin pump settings minus 1 mg/dl/U and,
  - +30% of the current CF value based on the patient's current insulin pump settings plus 1 mg/dl/U.

### What happens when my patient changes pump settings during the 21 days period?

The DreaMed Advisor Pro 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 & CF at the time of each bolus for its analysis over the 21 days 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 pump's bolus calculator glucose target and active insulin plans?

You can view the patient pump's bolus calculator glucose target and active insulin plans by clicking on 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 window.

### How can I send the patient additional instructions?

You can use the comments boxes that are found in each pump setting window to add any additional instructions to the patient.

### Can I add a comment for specific plan (basal or CR, or CF)?

Yes, you can add a comment for each of the pump setting recommendations by selecting Edit and then entering text in the Comments box at the bottom of each of the DreaMed Advisor Recommendation windows.

### What are the personalized diabetes management tips that DreaMed Advisor Pro advises?

The personal diabetes management tips are textual messages that DreaMed Advisor pro generates that may help the patient avoid hypo and hyperglycemia events. These messages are based on DreaMed Advisor Pro 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 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.
- 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 improve.

**Note:**

1. Every recommendation can be adjusted to one of the following parts of the day: early morning, morning, late morning, noon, after noon, evening and all day (as presented above). See Appendix A for the full list including parts of the day.
2. DreaMed Advisor Pro decides on which message to present based on its relevance to the hypo and hyper events and its priority.

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

The patient will receive a notification on his/her device where the DMS app is installed. This notification alerts him/her about a new recommendation that is waiting for review. Once the patient acknowledges the recommendation it will be automatically updated in the Advisor Recommendation History display, there you will be able to see the time that the patient confirmed the recommendation.

### How do I know that the patient received my recommendation?

You can know that your patient received and acknowledged the recommendation by looking in the Advisor recommendation history display. There, you can check if the patient confirmed (Yes/ No) that he received the recommendation along with the date of confirmation.

However, please note that you cannot know if the patient implemented the shared recommendation.

### How do I know if the patient implemented my recommendations?

You cannot know if your patient implemented the recommendations that were shared with him/her. However, you can know that the patient received and acknowledged it by looking in the Advisor recommendation history display.

## 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 carbohydrates intake. As opposed to the basal rate that describe a continuous flow of insulin throughout the day.
Carbohydrate ratio (CR)	Indicates the number of grams of carbohydrates are covered by one unit of insulin. The ratio is used by the bolus calculator for treating carbohydrates intake.
CGM	Abbreviation for 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.
Glucose sensor	Any interstitial glucose meter
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.
ISF	Abbreviation for Insulin Sensitivity Factor. In this Manual we use the term CF as a replacement to ISF

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Term	Definition
TDD	Abbreviation for Total Daily Dose, that is the representative total amount of insulin given per day across all days in the investigated period.
DKA	Abbreviation for Diabetic Ketoacidosis, that is a life-threatening complication of diabetes mellitus.
Glucometer	Any blood glucose meter
Pump	Any insulin pump
U-100	Type of insulin in which every milliliter (ml) of liquid contains 100 units of insulin.

## Appendix A: Advisor Pro Personalized Diabetes Management Tips List

The list below includes all Personalized Diabetes Management Tips that can be provided by the Advisor Pro.

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

#	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.

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#	Personalized Diabetes Management Tip
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.
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.

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#	Personalized Diabetes Management Tip
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.

#	Personalized Diabetes Management Tip
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.
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. <sup>1</sup>
38	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.
39	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.
40	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.
41	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.
42	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.
43	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.
44	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.
45	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.
46	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.



#	Personalized Diabetes Management Tip
47	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.
48	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.
49	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.
50	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.
51	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.
52	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.
53	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.
54	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.
55	When you have high episode in the afternoon, remember to use the bolus calculator to give a correction bolus.
56	When you have high episode, remember to use the bolus calculator to give a correction bolus.

#	Personalized Diabetes Management Tip
57	When you have high episode in the early morning, remember to use the bolus calculator to give a correction bolus.
58	When you have high episode in the late morning, remember to use the bolus calculator to give a correction bolus.
59	When you have high episode in the evening, remember to use the bolus calculator to give a correction bolus.
60	When you have high episode in the late evening, remember to use the bolus calculator to give a correction bolus.
61	When you have high episode in the morning, remember to use the bolus calculator to give a correction bolus.
62	When you have high episode at night, remember to use the bolus calculator to give a correction bolus.
63	When you have high episode at noon, remember to use the bolus calculator to give a correction bolus.
64	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.
65	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.
66	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.
67	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.
68	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.

#	Personalized Diabetes Management Tip
69	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.
70	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.
71	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.
72	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.
73	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.
74	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.
75	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.
76	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.
77	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.
78	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.
79	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.

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#	Personalized Diabetes Management Tip
80	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.
81	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.
82	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.
83	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.
84	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.
85	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.
86	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.
87	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.
88	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.
89	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.

#	Personalized Diabetes Management Tip
90	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.
91	Many of your lows in the afternoon may be avoided. Trusting the bolus calculator's recommendation may lead to better results.
92	Many of your lows may be avoided. Trusting the bolus calculator's recommendation may lead to better results.
93	Many of your lows in the early morning may be avoided. Trusting the bolus calculator's recommendation may lead to better results.
94	Many of your lows in the late morning may be avoided. Trusting the bolus calculator's recommendation may lead to better results.
95	Many of your lows in the evening may be avoided. Trusting the bolus calculator's recommendation may lead to better results.
96	Many of your lows in the late evening may be avoided. Trusting the bolus calculator's recommendation may lead to better results.
97	Many of your lows in the morning may be avoided. Trusting the bolus calculator's recommendation may lead to better results.
98	Many of your lows at night may be avoided. Trusting the bolus calculator's recommendation may lead to better results.
99	Many of your lows at noon may be avoided. Trusting the bolus calculator's recommendation may lead to better results.
100	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.
101	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.

#	Personalized Diabetes Management Tip
102	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.
103	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.
104	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.
105	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.
106	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.
107	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.
108	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.
109	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.
110	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.
111	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.
112	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.

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#	Personalized Diabetes Management Tip
113	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.
114	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.
115	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.
116	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.
117	I noticed that many of your lows at noon are a result of delivering extra temporary basal. Watching your glucose when using temporary basal may help you improve.
118	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.
119	I noticed that many of your lows may be avoided. Remember to check your glucose level and bolus before you start eating.
120	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.
121	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.
122	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.
123	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.

#	Personalized Diabetes Management Tip
124	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.
125	I noticed that many of your lows at night may be avoided. Remember to check your glucose level and bolus before you start eating.
126	I noticed that many of your lows at noon may be avoided. Remember to check your glucose level and bolus before you start eating.
127	I noticed that many of your lows in the afternoon come after a manual bolus. Using your bolus calculator may help you improve.
128	I noticed that many of your lows come after a manual bolus. Using your bolus calculator may help you improve.
129	I noticed that many of your lows in the early morning come after a manual bolus. Using your bolus calculator may help you improve.
130	I noticed that many of your lows in the late morning come after a manual bolus. Using your bolus calculator may help you improve.
131	I noticed that many of your lows in the evening come after a manual bolus. Using your bolus calculator may help you improve.
132	I noticed that many of your lows in the late evening come after a manual bolus. Using your bolus calculator may help you improve.
133	I noticed that many of your lows in the morning come after a manual bolus. Using your bolus calculator may help you improve.
134	I noticed that many of your lows at night come after a manual bolus. Using your bolus calculator may help you improve.
135	I noticed that many of your lows at noon come after a manual bolus. Using your bolus calculator may help you improve.