

DreaMed Advisor Pro

User Manual for Personal Use – DreaMed Advisor Pro App iOS



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In the US:

For in-vitro diagnostic use only.

dreamed
ADVISOR^{Pro} Rx Only

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(01)7290017735016(11)200517(10)010803



Note:

This Patient 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 DreaMed's customer service/support, available at the DreaMed Diabetes website, <http://www.dreamed-diabetes.com/support-dm> in addition to in this Patient 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 user manual contains valuable information about using DreaMed Advisor Pro with DreaMed Advisor iOS mobile app. 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 available.

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
 Note	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 will include 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 Advisor Pro

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 as 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, and correction factor (also known as insulin sensitivity; without considering the full clinical status of a particular patient. DreaMed Advisor Pro does not replace clinical judgement.

Contraindications

- DreaMed Advisor Pro is not intended to send recommendations directly to patients without initially being reviewed and approved by a health care professional health-care professional.
- DreaMed Advisor Pro is not intended for use with patients who use automated insulin dosing (AID) systems (e.g., "closed-loop", "artificial pancreas"; see the "Contraindicated devices" table for a list of the contraindicated devices).
- 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 who are treated with insulin injections, intravenous (IV) insulin, or a combination of insulin injections and/or intravenous 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 intravenous 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 continuous glucose monitoring/blood glucose meter values. Please refer to the warnings and contraindications of your continuous glucose monitoring/blood glucose meter 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

Contact your healthcare professional if you are not sure if you are an appropriate candidate for DreaMed Advisor Pro.

Potential Harms

DreaMed Advisor Pro leverages historical glucose and insulin data, transmitted from a diabetes management system or from apple Health to DreaMed Advisor Pro, to recommend changes to the insulin pump settings. The recommendations of DreaMed Advisor Pro are presented to you through a diabetes management system. Thus, there are risks associated with use of DreaMed Advisor Pro related to the cyber security, data integrity and infusion of insulin through the 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. Contact your health care professional if you have any questions or concerns and in particular if you:
 - Do not understand the recommendations
 - Think the recommendation is not appropriate for you
 - Experience large changes in your glucose control after implementing the recommendations (for example hypoglycemia or hyperglycemia that does not go down).

2. The DreaMed Advisor Pro is not a substitute for, but rather an adjunct to clinical reasoning.

3. The DreaMed Advisor Pro recommendations are based on DreaMed Diabetes' proprietary algorithm which relies on glucose and insulin data only drawn from your insulin pump, continuous glucose monitoring and/or blood glucose meter. Your clinical history and other personal information such as age, gender, other diseases and medications are not considered in the analysis. Therefore, your healthcare professional may consider your clinical history and use his/her professional opinion to modify the recommendations made by the DreaMed Advisor Pro as necessary before sharing them with you. For example, the following factors are not considered by DreaMed Advisor Pro and your healthcare professional may consider them when reviewing the recommendation for you:
 - Age
 - Gender
 - Height
 - Weight
 - Body Mass Index (BMI)
 - A1c
 - Insulin sensitivity
 - Hypoglycemia unawareness
 - High risk or recent history of Diabetes ketoacidosis (DKA) and/or severe hypoglycemia
 - Glucose toxicity
 - Degree of pump or continuous glucose monitoring experience
 - Duration of diabetes diagnosis - honeymoon phase
 - Illness
 - Hospitalization
 - Use of steroids
 - Extreme physical activity
 - Significant change of diet
 - Holiday

4. Contact your healthcare professional to receive training on how to use DreaMed Advisor Pro. Training consists of reviewing this manual and reviewing the application functions. Do not use DreaMed Advisor Pro if you have not received training.
5. 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 insulin pump, continuous glucose monitoring 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 diabetes management system, indicating a time difference between either the insulin pump, continuous glucose monitoring or blood glucose meters and the personal computer or mobile phone you are using to download the data to.
 - b. You have travelled across time zones within the past 21 days.
 - c. You have changed the clock on your insulin pump, continuous glucose monitoring and/or blood glucose meter within the past 21 days.



WARNING: Do not use DreaMed Advisor Pro when the clocks in the continuous glucose monitoring, insulin pump and/or blood glucose meter are not aligned!

About DreaMed Advisor Pro

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

This user manual provides information for DreaMed Advisor Pro software version 01.08.03.

The sections below provide a general description of how DreaMed Advisor Pro analyzes the data to generate recommendations.

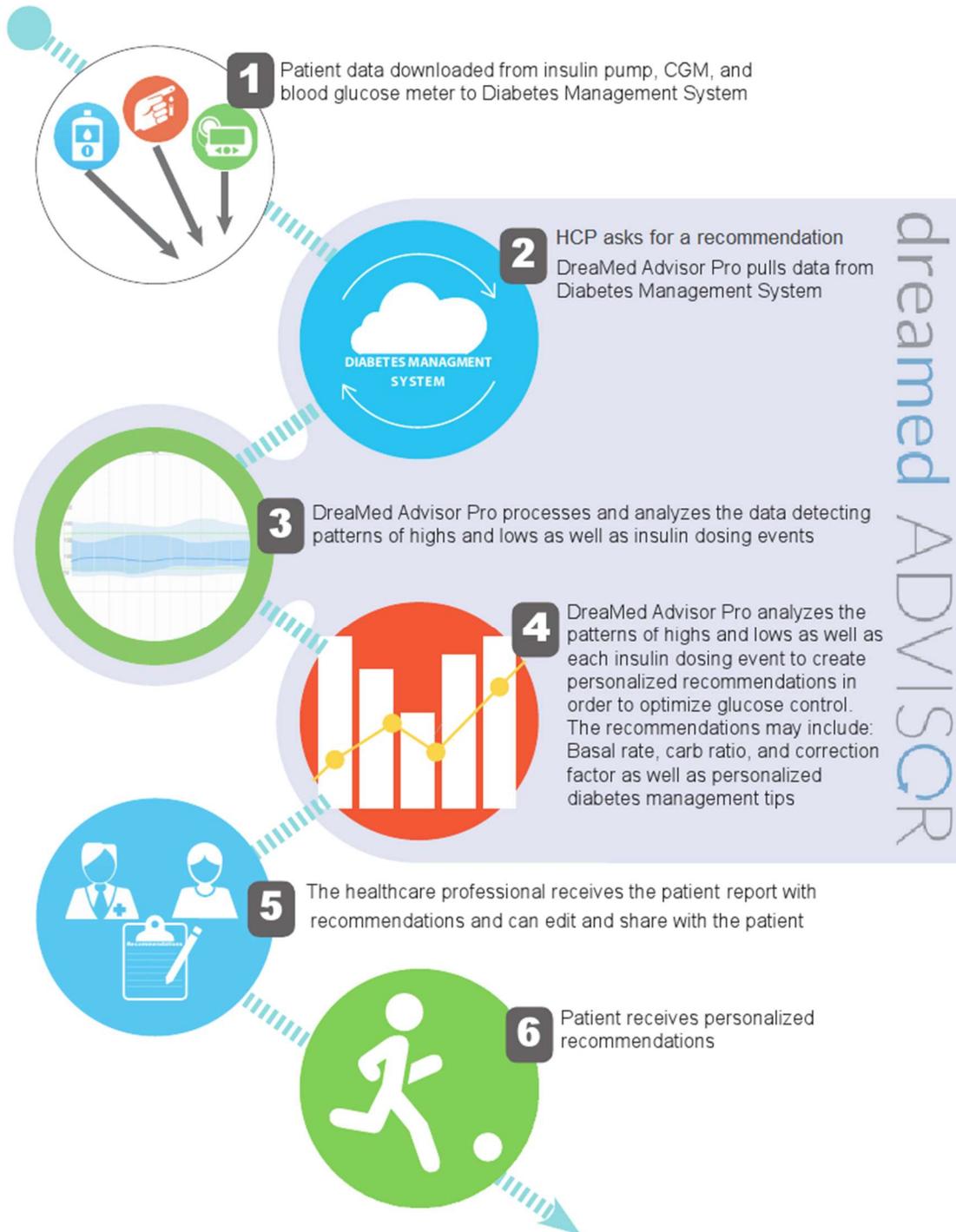


Figure 1: How DreaMed Advisor Pro works

Step 1: Data is downloaded from insulin pump, continuous glucose monitoring, and blood glucose meter to Diabetes Management System

To begin using Advisor Pro, your healthcare professional must start Advisor Pro for you. For your healthcare professional to be able to start the Advisor Pro for you, you will need to:

- Be part of a clinic that uses Tidepool as their diabetes management system and Advisor Pro (see table below for more details).
- Be able to send your diabetes data to your healthcare professional electronically through Tidepool including your pump, continuous glucose monitoring, and blood glucose meter - from home or in the clinic (check the [Tidepool manual](#) for more details).
- Accept Advisor Pro terms and privacy policy by [Joining a Clinic](#)

After Advisor has been started by your healthcare professional, she/he will be able to generate new recommendations once every 21 days. If you want to access Advisor Pro web or mobile application, you will need to [Register](#) for Advisor Pro.

The list of current qualified diabetes management system is provided in the table below:

Diabetes Management System	Contact information
Tidepool Inc	<p>www.tidepool.org</p> <p>For questions, to request training, or for support: support.tidepool.org</p> <p>For privacy policy: developer.tidepool.org/privacy-policy</p> <p>For terms of use: developer.tidepool.org/terms-of-use</p>



Note: DreaMed Diabetes will update this list on a quarterly basis (if needed). An updated list can be found on www.dreamed-diabetes.com/support-dm in the electronic version of this manual.

To upload your data from home, use the [Tidepool diabetes management system manual](#) to learn about how to connect your account to your healthcare professional’s account and how to upload your data.



Note: You must use your diabetes management system or apple Health to import data from your insulin pump, continuous glucose monitoring and meter so the data can be analyzed by DreaMed Advisor Pro. No other data sources are used in DreaMed Advisor



WARNING: Do not use DreaMed Advisor Pro with data that was downloaded with errors from the devices to the diabetes management system.

Authorized devices

The table below lists the devices that are currently authorized to be used with DreaMed Advisor Pro. Quarterly updates to this list will be available at www.dreamed-diabetes.com/support-dm.

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.	
Contiguous glucose monitoring	DexCom	G5, CGM
		G6, CGM
	Medtronic Diabetes	Enlite
		IPro
		Guardian Sensor 3
	Abbott	Libre
Libre Pro		

Contraindicated devices

The table below lists the devices that are currently contraindicated to be used with DreaMed Advisor Pro. Quarterly updates to this list will be available at www.dreamed-diabetes.com/support-dm.

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



Caution: Advisor Pro uses contiguous glucose monitoring 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 will calibrate the sensor according to the manufacturer's instructions. Otherwise, a sensor with reduced accuracy could cause Advisor Pro to analyze inaccurate sensor data.

Training

Before using DreaMed Advisor Pro, you must receive training. Training is provided through your healthcare professional. Training consists of reviewing the user manual and receiving an introduction to the app.

Step 2: Health care professional asks for a recommendation

Once your data was uploaded to the diabetes management system, your health care professional can start Advisor Pro and generate a new treatment plan recommendation. DreaMed Advisor Pro pulls data from the diabetes management system and analyses the last 21 days. DreaMed Advisor Pro makes sure the data is sufficient for a recommendation to be provided. No recommendation will be provided by Advisor Pro until there is enough information. [Appendix A](#) describes the minimum amount of data needed to generate a recommendation.



Note: Data is being pulled from the diabetes management system to DreaMed Advisor Pro 'as-is'. You cannot edit, change, replace or 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.

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, use of strong passwords, network security, installing the latest security patches etc.

Step 3: DreaMed Advisor Pro processes and analyzes the data

DreaMed Advisor Pro uses your diabetes data to look for patterns such as times that your glucose levels were high or low.

Step 4: DreaMed Advisor Pro analyzes patterns and creates recommendations

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

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

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

DreaMed Advisor Pro has safeguards and limits to ensure your safety so that changes that are recommended are not too large.

Step 4: Health care professional reviews and shares recommendations

The recommendations of DreaMed Advisor Pro are sent to your healthcare professional. Your healthcare professional can review, edit if needed, and approve your recommendation.

Step 5: receiving personalized recommendations

Once your healthcare professional has approved your recommendation, they are shared with you. You can now view them via Advisor Pro web or mobile applications and implement them in your insulin pump settings.

First Steps

Join a Clinic and Registration

Join clinic

The privacy and security of your information is important to us. With your permission, and only with your explicit consent, you will allow Advisor Pro to access your data and generate a recommendation.

For Advisor pro to access your data, you need to join a specific clinic.

First, make sure you have your **invitation email** from your clinic, or a **clinic code and an invitation code**. If you don't have them, contact your clinic.

Join using an invitation email

Download Advisor Pro mobile app and click on the invitation link in the invitation email.

Enter your full name, date of birth as they appear in your clinic records. In addition, enter your email that will be used as your username.

You will also need to accept the Terms of Use and Privacy Policy. Then, click the register button.

15:46
Mail

REGISTER

Enter your personal information as it appears in your clinic records:

Full Name

Date of birth

Email

I have read and agreed to Advisor Pro [Privacy Policy](#) and [Terms of Use](#)

Join using a clinic code and invitation code

Download Advisor Pro app and in the main screen click on the **Register** button. (If you already have a username and password, click on the **Login** button to log into the app).

In the Registration screen, enter your full name, date of birth and, clinic code and invitation code (as received from your clinic), and a valid email (that will be used as your username). You will also need to accept the Terms of Use and Privacy Policy. Then click **Register**.

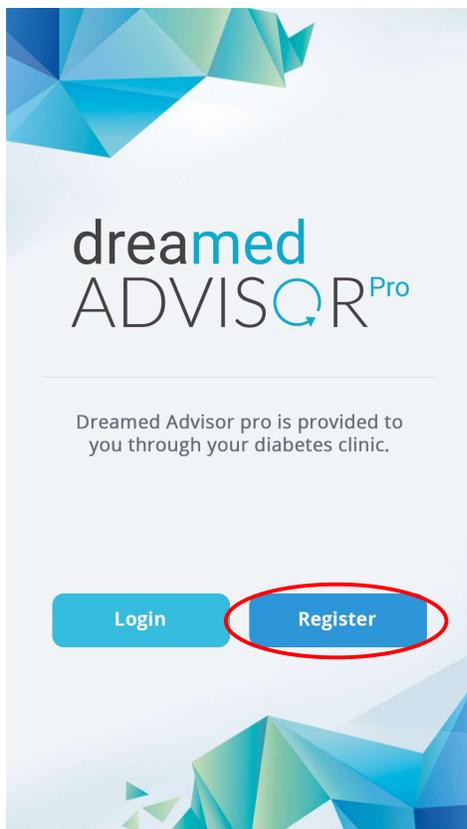


Figure 2: Welcome screen

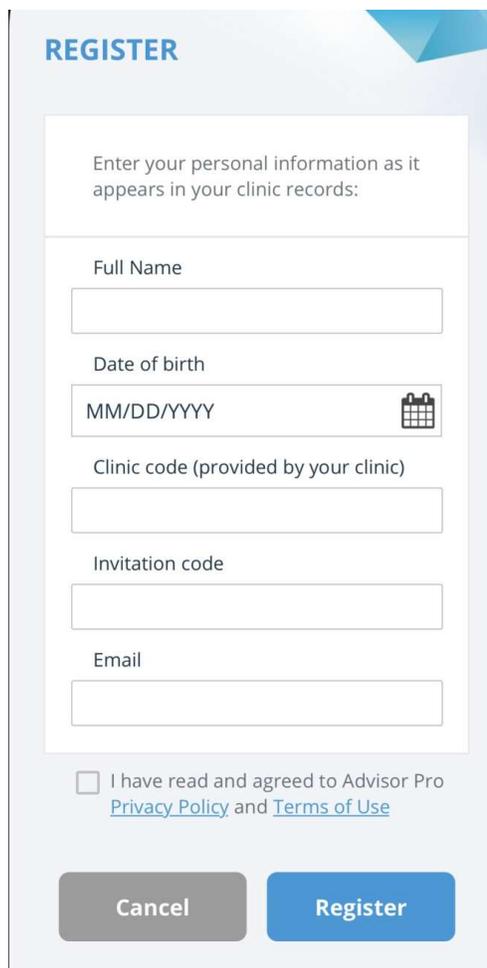


Figure 3: Registration screen



Note:

For identification matters, your name, date of birth and email (when provided to your clinic) must match the information available in your clinic records.



Note:

You can also register using the web, and login to the app later. Visit dreamedadvisor.com/join or click on the “New member? Join your clinic” link on the login screen, to join a clinic and register.

A verification email will be sent to your email address. Click on the link that appears in the email to verify your email address. If you didn’t get the email – try re-sending it, using the **Re-send email** button.

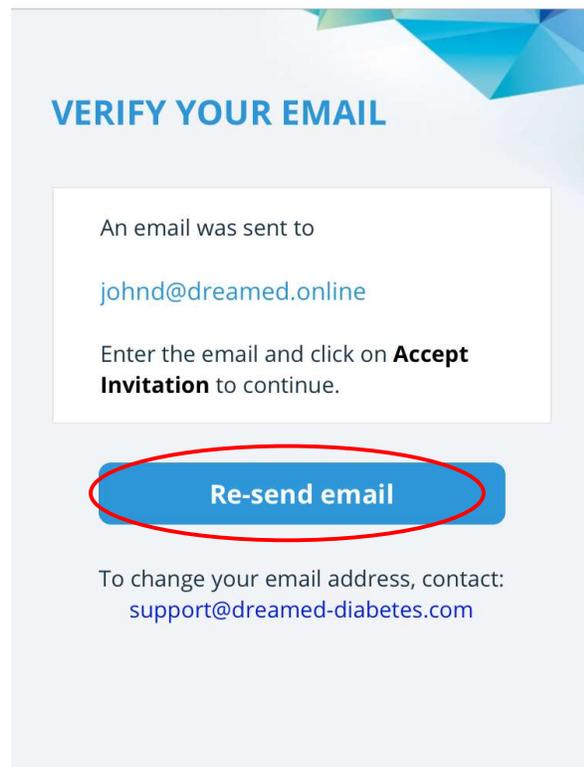


Figure 4: ‘Verify your email’ screen

Doc # PR-4023, Version 7.0

Now, you should select your password for the service and click on **Ok. Take me to login**. Once selecting your password, you're ready to use Advisor Pro. The password should be at least 8 characters long, and include upper case letters, lower case letters and a number or a symbol.

The screenshot shows a mobile application interface for a user named JOHN DAVIES. At the top left is a blue back arrow. Below the name, there is a white box containing the text 'Please select your password:'. Underneath this are two input fields: 'Password' and 'Confirm password', both filled with black dots. At the bottom of the white box is a blue button with the text 'Ok. take me to login'.

Figure 5: Select password

Accessing DreaMed Advisor Pro

Once registered, you can login to Advisor Pro app to review your recommendations. Click on **Login** from the welcome screen.

Enter your credentials and click **Login**.

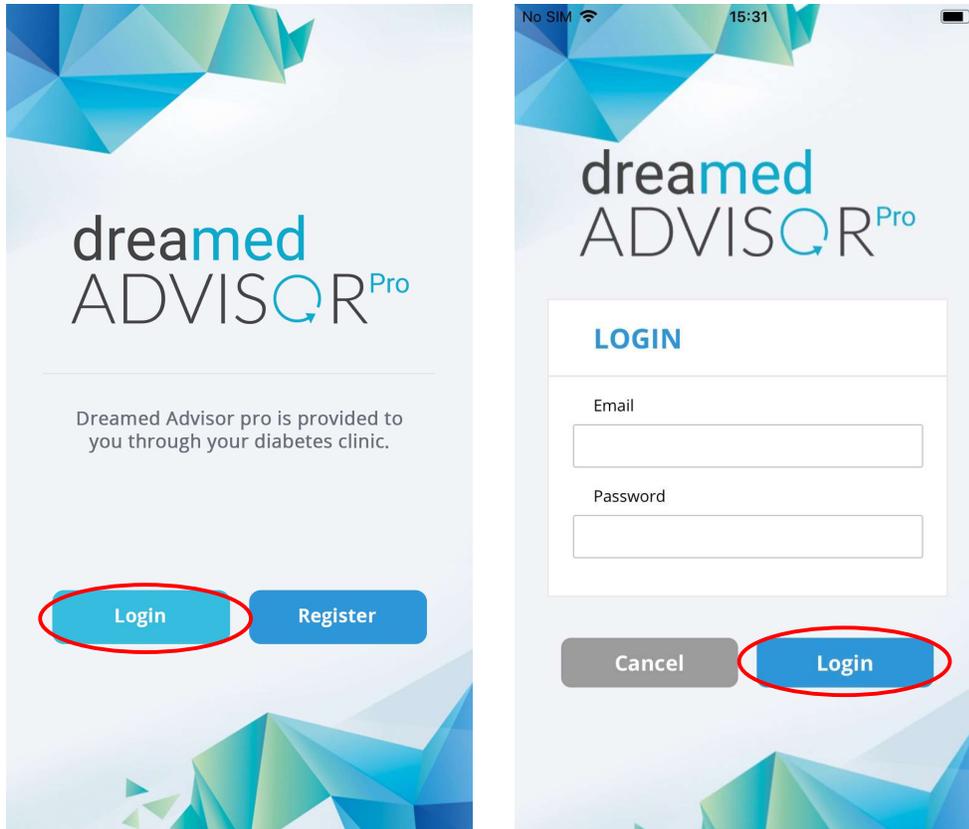


Figure 6: Login into Advisor Pro app

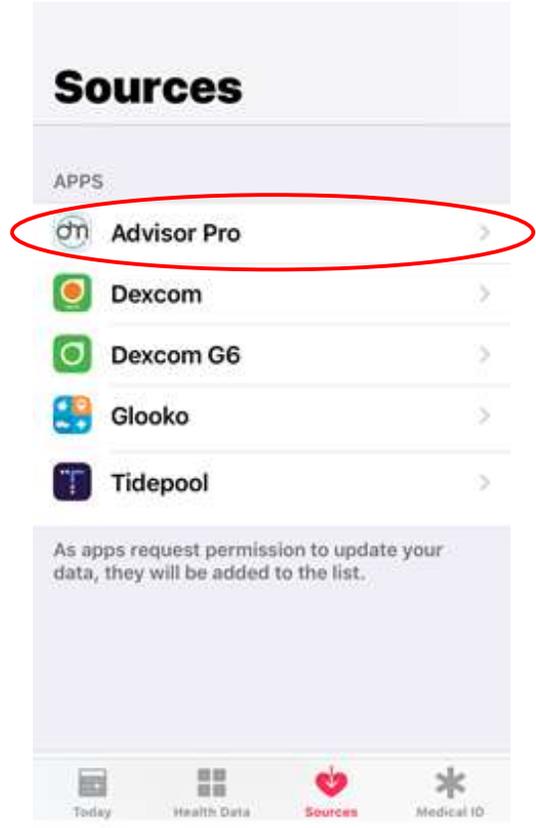
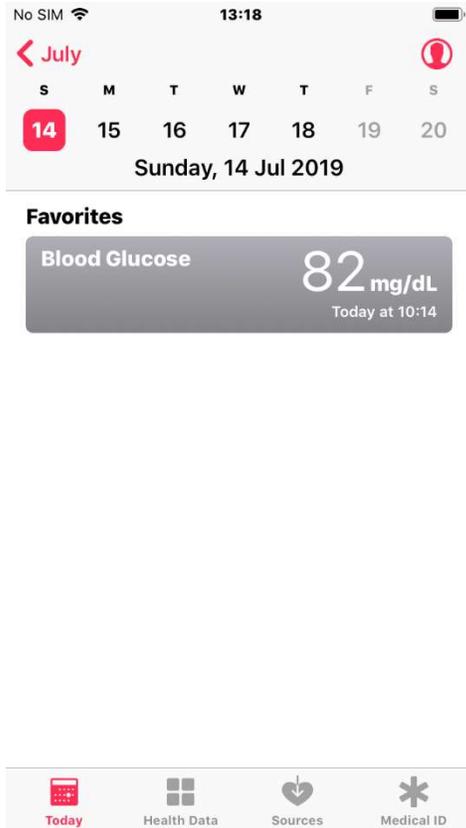
Sync your glucose data via Apple Health

You can connect your Apple Health account with Advisor Pro to share your glucose data with your doctor and to allow Advisor to use this data as part of the analysis and recommendation process. To share your data:

1. Go to the sensor or glucometer app on your iPhone and allow them to write their data in Apple Health app.
2. In some cases, you will need to go to the Apple Health app directly, go to **Sources**, then choose the glucose measuring device app (for example **Dexcom**) and allow the device application to **'write'** your glucose data into Apple Health app.



- Apple Health app



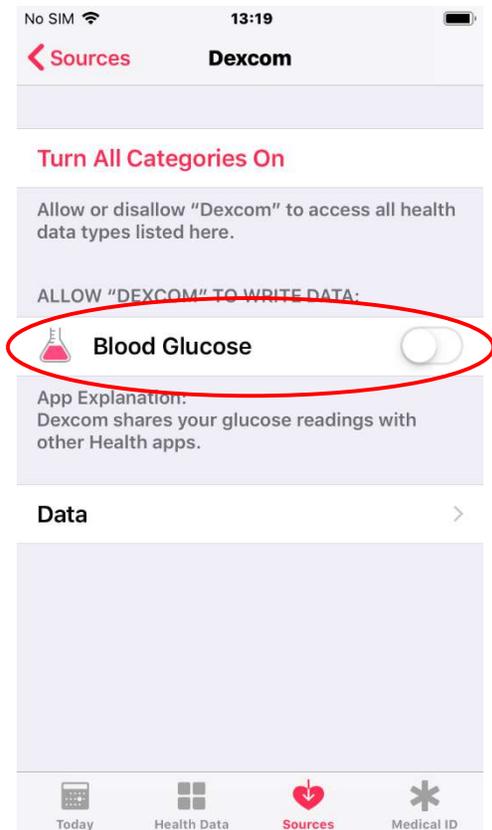


Figure 7: Allow sensor app to write to Apple Health

3. Open your Advisor Pro app, and when the **'Connect with Health'** screen is displayed, click on **Allow**.

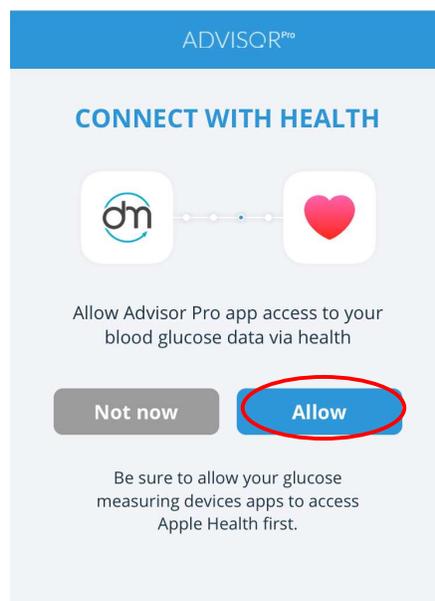


Figure 8: Allow Advisor app to read from Apple Health

4. If you want to allow Advisor access to your glucose data at a later time, you can always go to the **profile menu**, and click on the **Connect with Health** option.

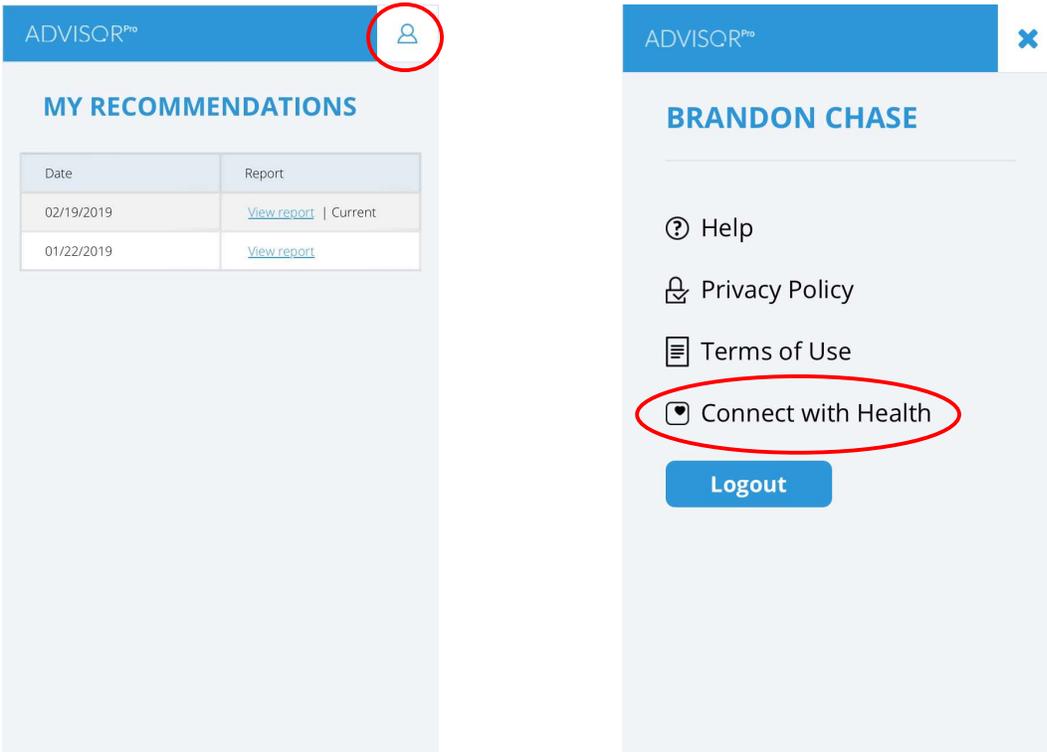


Figure 9: Connect with Apple Health

Review Recommendations

Viewing Advisor Recommendation List

After DreaMed Advisor Pro has been started by your healthcare professional, and the first recommendation is ready for you, you will be able to view your recommendations in Advisor Recommendations List on your Advisor Pro mobile app. The Recommendations are listed by the date of recommendation.

The first recommendation, labeled by “**Current**”, indicate the latest recommendation received from your healthcare professional. Once you receive it, you should review it and implement it in your insulin pump settings.

If you think the new settings may not be right for you – contact your health care professional first.

Date	Report
02/19/2019	View report Current
01/22/2019	View report

Figure 10: Recommendation list screen

Reviewing Recommendations

To view a specific recommendation, tap **View Report**. DreaMed Advisor Pro and your healthcare professional use data collected by your diabetes management system and/or by apple Health, to provide personalized insulin treatment optimization recommendations. Recommendations may include Personalized Diabetes Management Tips (found in Comments) and suggested changes to:

- Basal Rate
- Carbohydrate ratio
- Correction factor

Personalized Diabetes Management Tips

You may receive personalized diabetes management tips found in the **General Comments** at the top of each Report. Your healthcare professional may add additional comments there as well. Following these tips may help you improve your diabetes care.

The screenshot shows the 'ADVISOR Pro' interface. At the top, there is a blue header with a back arrow, the text 'ADVISOR Pro', and a user icon. Below the header, the main content area is titled 'INSULIN PUMP SETTINGS RECOMMENDATION'. Under this title, it says 'Report from 02/09/2019 - 03/01/2019'. A paragraph follows: 'On 03/03/2019 your provider recommended that you change your pump settings to the following values:'. Below this is a rounded rectangular box with a red border, titled 'General Comments'. Inside this box, there are two bullet points: '- When you have high episode in the evening, remember to use the bolus calculator to give a correction bolus.' and '- 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.' Below the comments box, there is a section titled 'NEW BASAL PLAN SETTINGS' which contains a table with two columns: 'Time' and 'Basal rate (U/hr)'. The table has two rows: '12:00 am' with a basal rate of '0.5', and '4:00 am' with a basal rate of '0.55'.

Figure 11: General comments

Recommended Insulin Pump Settings

Your healthcare professional may recommend changes to your basal rate, carbohydrate ratio, or correction factor settings on your insulin pump. Your healthcare professional may include specific comments for each setting that would be listed below the particular recommendation.

The recommended settings are listed according to time of day.



Note:

Basal rate units are in Units/hour

Carb ratio units are in grams/Units

Correction factor units are in mg/dL/Unit

<
ADVISOR^{Pro}
>

INSULIN PUMP SETTINGS RECOMMENDATION

Report from 02/09/2019 - 03/01/2019

On 03/03/2019 your provider recommended that you change your pump settings to the following values:

General Comments

- When you have high episode in the evening, 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.

NEW BASAL PLAN SETTINGS

Time	Basal rate (U/hr)
12:00 am	0.5
4:00 am	0.55

<
ADVISOR^{Pro}
>

NEW BASAL PLAN SETTINGS

Time	Basal rate (U/hr)
12:00 am	0.5
4:00 am	0.55
6:00 am	0.7
8:00 am	0.75
5:00 pm	1.2
8:00 pm	1.1
9:00 pm	1
10:00 pm	0.65
Total Units	18.25

No comments

NEW CARB RATIO PLAN SETTINGS (IC RATIO)

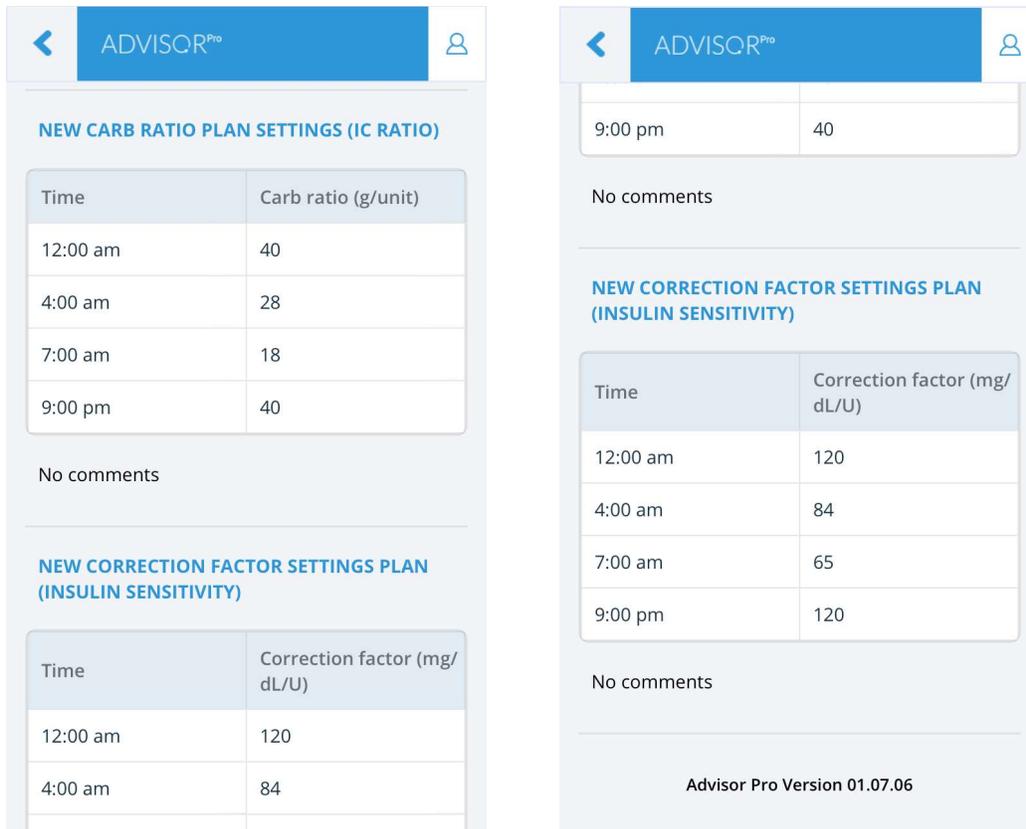


Figure 12: Recommendation screens



Caution: Contact your health care professional if you have any questions or concerns and in particular if you:

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



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

What to do if you are travelling across time zones

Inform your health care professional if you are going to be travelling and switching time zones while using DreaMed Advisor Pro.

Don't use recommendations from DreaMed Advisor Pro until 21 days have passed after returning from your trip, unless your health care professional is aware you travelled and told you otherwise. The impact of switching time zones could lead to recommendations that are not suitable for you.

Frequently Asked Questions (FAQ)

How can I sign up after I joined the clinic?

You can always visit the 'Join clinic' page (dreadmedadvisor.com/join) or register to the mobile app again and re-enter your personal information with the 'Sign up for Advisor Pro' option checked. An invitation will be sent to you automatically.

What should I do if my invitation has expired?

You can always visit the 'Join clinic' page (dreadmedadvisor.com/join) or register to the mobile app again and re-enter your personal information with the 'Sign up for Advisor Pro' option checked. An invitation will be sent to you automatically.

How can I connect my sensor or my connected glucometer to Advisor Pro?

If you are using a device that supports Apple Health you should:

1. First, allow the device application to send data to Apple Health app:
 - a. Enter into Apple Health app, and go to **Sources**
 - b. Select your connected device's app
 - c. Turn on the "Allow app to write data" for your glucose data
2. Then:
 - a. Enter Advisor app and from the menu on the top right corner
 - b. Select **Connect with Health** and click on the **Allow** button
 - c. Turn on the "**Allow app to read data**" for your glucose data.

Can I use Advisor Pro without having an Email address?

Yes, you can use Advisor Pro without having an Email address. In the 'Join clinic' screen you can leave the Email field empty and uncheck the 'sign up for Advisor Pro' option. You will not be able to view your recommendation on-line however; you can ask your health care professional to print the recommendation for you.

You need to use your email to use Advisor Pro mobile app.

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

You can enter the DreaMed Advisor Pro app and look for your most recent report. Select **View Report** to see the recommendations on the most recent report.

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.

What are the pump settings that DreaMed Advisor Pro can recommend changing?

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

1. Basal rate plan
2. Carbohydrate ratio plan
3. Correction factor plan

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

If I have more than one program in my pump, which program is DreaMed Advisor Pro recommending changing?

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

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

Yes, DreaMed Advisor Pro takes into account the actual amount of insulin that was delivered during the 21-day period. It looks at the actual basal rate, including temp/suspend basal as well as the parameters of the bolus calculator used to deliver the bolus.

Does DreaMed Advisor Pro actually change my pump settings for me?

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

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

You are in charge of your health. In case you have questions or disagrees with your healthcare professional's recommendation, you should contact them for clarifications.

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

Yes, your healthcare professional can add specific comments for each plan.

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

The personal diabetes management tips are messages that DreaMed Advisor pro generates that may help you avoid hypo and hyperglycemia events (highs and lows).

Will my healthcare professional know if I implemented the recommendations?

No, your healthcare professional cannot know if you implemented the recommendations.

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	A bolus calculator setting that allows the user to determine the time (measured in hours) it will take until the bolus of insulin stops affecting the blood glucose. This time is used by the 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	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.
Continuous Glucose Monitoring	Abbreviation for Continuous Glucose Monitoring device which is the sensor that continuously measures the interstitial glucose levels.
Correction factor	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.

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Term	Definition
Insulin Sensitivity Factor (ISF)	In this Manual, we use the term correction factor as a replacement to ISF.
Total Daily Dose	That is the representative total amount of insulin given per day across all days in the investigated period.
Diabetes Ketoacidosis (DKA)	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: Data Requirements for DreaMed Advisor Pro

Dreamed Advisor Pro required that within the analyzed 21 days, there will be at list 12 valid days. The table below shows what data is needed to count as a valid day for DreaMed Advisor Pro Analysis

Data source	Requirement
Continuous Glucose Monitoring	At least 67% of continuous glucose monitoring 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 Blood glucose meter	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

In addition, Advisor Pro requires at least 3 records from the bolus calculator.

The table below shows what insulin pump settings are required 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
Carbohydrate Ratio [gr/u]	Each value in the carbohydrate ratio plan is within 3-70gr/u
Correction Factor [mg/dl/u]	Each value in the correction factor plan is within 10-280 mg/dl/u
Bolus Calculator Targets [mg/dl]	Equal to or below 150 mg/dl

Appendix B: DreaMed Advisor Pro Data Analysis

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:

- Continuous glucose monitoring data filtration – DreaMed Advisor Pro may ignore some of the continuous glucose monitoring and/or blood glucose meter values in cases where the algorithm considers them non-physiological or in cases that the blood glucose meter value contradicts the continuous glucose monitoring value at a given time stamp.
- Hypoglycemia/ euglycemia / hyperglycemia patterns – 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 pump user – the algorithm uses the insulin pump and continuous glucose monitoring /meter data to characterize each insulin dosing event. In cases where there is no carbohydrate information available for a bolus delivery, DreaMed Advisor Pro uses the insulin pump settings to estimate if carbohydrates were consumed at the time of a bolus.

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

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 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 current insulin pump settings minus $0.05 \left[\frac{U}{Hour} \right]$
	Additional limitations depending on the total daily dose*	<p>Advisor Pro has a second layer of limitations which dependent on the total daily dose, whereas the recommended basal rates should be within the range of:</p> <ul style="list-style-type: none"> Total daily dose upper limit: 150% of the hourly average basal rate calculated from the total daily dose, whereas the hourly average basal rate is the $\frac{\text{total daily dose}/2}{24}$ Total daily dose lower limit: 50% of the hourly average basal rate calculated from the total daily dose, whereas the hourly average basal rate is the $\frac{\text{total daily dose}/2}{24}$. <p>These limitations overrule the current basal rate upper/lower limits stated above.</p>
	Potential maximum number of basal periods	24 per day

* If the current basal rate settings are outside of total daily dose 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. For example, if the pump user had a total daily dose of 30 units a day and in one basal period a basal rate of 1 u/h (i.e. the total daily dose Upper/Lower Limits are 0.93/0.31, respectively) and there is evidence that it should be decreased to reach the total daily dose 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
Carbohydrate Ratio Plan	Limitation on the highest carbohydrate ratio value that could be recommended by DreaMed Advisor Pro	+ 30% of the current carbohydrate ratio value based on the current insulin pump settings plus $1 \left[\frac{gr}{U} \right]$
	Limitation on the lowest carbohydrate ratio value that could be recommended by DreaMed Advisor Pro	-30% of the current carbohydrate ratio value based on the current insulin pump settings minus $1 \left[\frac{gr}{U} \right]$
	Potential maximum number of carbohydrate ratio periods	8
Correction Factor Plan	Limitation on the highest correction factor value that could be recommended by DreaMed Advisor Pro	+30% of the current correction factor value based on the current insulin pump settings plus $1 \left[\frac{mg}{dl*U} \right]$
	Limitation on the lowest correction factor value that could be recommended by DreaMed Advisor Pro	-30% of the current correction factor value based on the current insulin pump settings minus $1 \left[\frac{mg}{dl*U} \right]$
	Potential maximum number of correction factor periods	8

**Note:**

- The values appearing in the table are not configurable.
- The insulin pump has discrete possible values for basal, carbohydrate ratio and correction factor. 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 a pump 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 the table.

- 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 carbohydrate ratio & 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.