DreaMed Advisor Pro
Patient Manual - Android

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Website: www.dreamed-diabetes.com

In the US:
For in-vitro diagnostic use only.
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.

Note:

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 forward your request/complaint to DreaMed Diabetes if needed.

Direct contact information for DreaMed and DreaMed’s Authorized Representative is also available on the DMS support/help page as well as at DreaMed Diabetes website, www.dreamed-diabetes.com/support 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 Patient 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 Page 30.

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

<table>
<thead>
<tr>
<th>Symbol</th>
<th>What it means</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Manufacturer" /></td>
<td>Manufacturer</td>
</tr>
<tr>
<td><img src="image" alt="Authorized Representative in the European Union" /></td>
<td>Authorized Representative in the European Union</td>
</tr>
<tr>
<td><img src="image" alt="CE Compliance Symbol" /></td>
<td>CE Compliance Symbol</td>
</tr>
<tr>
<td><img src="image" alt="Refer to instruction manual/booklet" /></td>
<td>Refer to instruction manual/booklet</td>
</tr>
<tr>
<td><img src="image" alt="For prescription use only" /></td>
<td>For prescription use only</td>
</tr>
</tbody>
</table>

Note: A note provides helpful information

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: 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
### Acronyms and abbreviations

Table 2 defines acronyms and abbreviations used in the manual:

**Table 2: Acronyms and abbreviations**

<table>
<thead>
<tr>
<th>Acronym and abbreviation</th>
<th>What does it mean?</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADA</td>
<td>American Diabetes Association</td>
</tr>
<tr>
<td>BG</td>
<td>Blood Glucose</td>
</tr>
<tr>
<td>BMI</td>
<td>Body Mass Index</td>
</tr>
<tr>
<td>CF</td>
<td>Correction Factor [(mg/dl)/UI or (mmol/l)/UI].</td>
</tr>
<tr>
<td>CGM</td>
<td>Continuous Glucose Monitoring device</td>
</tr>
<tr>
<td>CR</td>
<td>Carbohydrate Ratio [gr/UI]</td>
</tr>
<tr>
<td>DKA</td>
<td>Diabetic Ketoacidosis</td>
</tr>
<tr>
<td>DMS</td>
<td>Diabetes Management System</td>
</tr>
<tr>
<td>HCP</td>
<td>Healthcare Professional</td>
</tr>
<tr>
<td>ISF</td>
<td>Insulin Sensitivity Factor. In this Manual, we use the term CF as a replacement to ISF</td>
</tr>
<tr>
<td>ISPAD</td>
<td>International Society for Pediatric and Adolescent Diabetes</td>
</tr>
<tr>
<td>IV</td>
<td>Intravenous</td>
</tr>
<tr>
<td>PC</td>
<td>Personal Computer</td>
</tr>
<tr>
<td>TDD</td>
<td>Total Daily Dose</td>
</tr>
</tbody>
</table>
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 either of the following:
  - CGM, or
  - CGM and self-management blood glucose meter;
- are above the age of 6 and under 65 years old; and
- use rapid acting U-100 insulin analogs in their pump

DreaMed Advisor Pro is indicated for use as by healthcare professionals when analyzing continuous glucose monitoring (CGM), self-monitoring blood glucose (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.

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 cannot generate recommendations for patients who are unwilling or unable to use a CGM.
- DreaMed Advisor Pro is not intended for use with patients who use automated insulin delivery systems (e.g., "closed-loop", "artificial pancreas"; see “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 harms listed below.
• 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 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 harms listed below.

• 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 harms listed below.

• DreaMed Advisor Pro is not intended for use with patients under the age of 6 or above the age of 65.

• 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 values, such as acetaminophen. Please refer to the warnings and contraindications of your CGM to determine whether said medications may falsely raise glucose readings of the sensor. 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 the potential harms listed below.

• 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 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. Thus, there are risks associated with use of DreaMed Advisor Pro 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. Contact your HCP if you have any questions or concerns and in particular if you:
   - Do not understand the recommendations
   - Think the recommendation is not appropriate for you
   - Experience large changes in your glucose control after implementing the recommendations (for example hypoglycemia or hyperglycemia that does not go down).

2. 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, CGM, and 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
   - BMI
   - A1c
   - Insulin sensitivity
   - Duration of diabetes diagnosis - honeymoon phase
   - Hypoglycemia unawareness
   - High risk or recent history of DKA and/or severe hypoglycemia
   - Glucose toxicity
   - Degree of pump or CGM experience
4. Contact your healthcare professional to receive training on how to use DreaMed Advisor Pro. Training consists of reviewing this manual and reviewing the app functions. Do not use DreaMed Advisor Pro if you have not received training.

5. If the clocks in the CGM, insulin pump, and 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. You have travelled across time zones within the past 21 days.
   c. You have changed the clock on your insulin pump, CGM or blood glucose meter within the past 21 days.
About DreaMed Advisor Pro

DreaMed Advisor Pro analyzes diabetes data to recommend insulin pump settings (carbohydrate ratio, CF 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 the Advisor section of your Diabetes Management System app.

This Patient User Manual provides information for DreaMed Advisor Pro software version 01.07.XX.

The sections below provide a general description of how DreaMed Advisor Pro analyzes the data to generate recommendations.
1. Patient data downloaded from insulin pump, CGM, and blood glucose meter to Diabetes Management System.

2. DreaMed Advisor Pro pulls data from Diabetes Management System.

3. DreaMed Advisor Pro processes and analyzes the data detecting patterns of highs and lows as well as insulin dosing events.

4. DreaMed Advisor Pro analyzes the patterns of highs and lows as well as each insulin dosing event to create personalized recommendations in order to optimize glucose control. The recommendations may include: Basal rate, carb ratio, and correction factor as well as personalized diabetes management tips.

5. DreaMed Advisor Pro sends the recommendations to the Diabetes Management System. The healthcare professional receives the patient report with recommendations and can edit and share with the patient.

6. Patient receives personalized recommendations designed to help manage their diabetes care and improve their pump settings.
Step 1: Patient data downloaded from insulin pump, CGM, and blood glucose meter to DMS

To start receiving recommendations through DreaMed Advisor Pro, you will need to be

- signed up for a compatible Diabetes Management System (see table below) and have the app installed on a compatible smart phone (check the DMS manual for a list of phones)
- able to send your diabetes data to your healthcare professional electronically through the DMS including your pump, CGM, and blood glucose meter (check the DMS manual for how to do this)
- signed up for DreaMed Advisor Pro (ask your healthcare professional to sign you up)

The DMS manual will explain how to connect your account to your healthcare professional’s account for transferring data. Then your healthcare professional can register you for DreaMed Advisor Pro through the DMS. The list of the current qualified DMS is provided in the table below.

<table>
<thead>
<tr>
<th>DMS Company</th>
<th>Contact information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glooko Inc</td>
<td><a href="https://www.glooko.com">www.glooko.com</a></td>
</tr>
<tr>
<td></td>
<td>For questions, to request training, or for support:</td>
</tr>
<tr>
<td></td>
<td>For privacy policy:</td>
</tr>
<tr>
<td></td>
<td><a href="https://www.glooko.com/privacy/">https://www.glooko.com/privacy/</a></td>
</tr>
<tr>
<td></td>
<td>For terms of use:</td>
</tr>
<tr>
<td></td>
<td><a href="https://www.glooko.com/terms-of-use/">https://www.glooko.com/terms-of-use/</a></td>
</tr>
</tbody>
</table>

**Note:** DreaMed Diabetes will update this list on a quarterly basis. An updated list can be found on [www.dreamed-diabetes.com/support](https://www.dreamed-diabetes.com/support) in the electronic version of this manual.
**Note:** You must use your DMS to import data from your insulin pump, CGM and 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 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](http://www.dreamed-diabetes.com/support).

<table>
<thead>
<tr>
<th>Device Type</th>
<th>Device Manufacturer</th>
<th>Brand Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Glucose Meter</td>
<td>All meters with regulatory approval (dependent on location: EU / US/ Rest of the World [ROW]).</td>
<td></td>
</tr>
<tr>
<td>Insulin Pump</td>
<td>All insulin pumps with regulatory approval (dependent on location: EU / US/ ROW), including those with low glucose suspend or predicted low glucose suspend features.</td>
<td></td>
</tr>
<tr>
<td>CGM</td>
<td>DexCom</td>
<td>G4, CGM</td>
</tr>
<tr>
<td></td>
<td></td>
<td>G5, CGM</td>
</tr>
<tr>
<td></td>
<td></td>
<td>G6, CGM (U.S)</td>
</tr>
<tr>
<td></td>
<td>Medtronic Diabetes</td>
<td>Enlite</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IPro</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Guardian Sensor 3</td>
</tr>
<tr>
<td>Abbott</td>
<td></td>
<td>Libre</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Libre Pro</td>
</tr>
</tbody>
</table>
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.

<table>
<thead>
<tr>
<th>Device Type</th>
<th>Device Manufacturer</th>
<th>Brand Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Automated Insulin Delivery</td>
<td>Medtronic Diabetes</td>
<td>MiniMed 670G Insulin Pump Systems</td>
</tr>
<tr>
<td>Systems</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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 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: DreaMed Advisor Pro pulls data from the DMS

The data is sent to the DreaMed Advisor Pro system once you finish uploading the data from the treatment devices to the DMS. DreaMed Advisor Pro pulls data from the DMS from the last 21 days from the last date of data download. DreaMed Advisor Pro makes sure the data is complete enough for a recommendation to be provided. No recommendation will be provided until there is enough information. Appendix A describes the minimum amount of data needed to make a recommendation.

Note: Data is being pulled automatically from the DMS to DreaMed Advisor Pro. You cannot edit, change, replace, flag out the 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 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

Then, 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 CR plan
- Changes to your CF plan
- Providing a personalized diabetes management tips

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 you
experienced a glucose imbalance, and DreaMed Advisor Pro was not able to create a recommendation, DreaMed Advisor Pro will indicate as such.

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

**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.

Your healthcare professional can now review, edit if needed, and approve your recommendation.

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

Once your healthcare professional has approved your recommendation, it can be shared with you through the Advisor section in the DMS app.
Review Recommendations

Accessing DreaMed Advisor Pro

When your healthcare professional starts you on DreaMed Advisor Pro, you will see a new Advisor menu item on your Side Menu.

- **Access the Side Menu** by tapping the icon in the top left of your screen.
- **Tap “Advisor”** to access DreaMed Advisor Pro.
Viewing Advisor Recommendation History

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

Recommendations labeled, “Current”, indicate that the new recommendations are available for review and require your action to accept or not accept the recommended insulin pump settings.

<table>
<thead>
<tr>
<th>Date</th>
<th>Report</th>
<th>Current</th>
</tr>
</thead>
<tbody>
<tr>
<td>11/02/2017</td>
<td>View Report</td>
<td></td>
</tr>
<tr>
<td>10/01/2017</td>
<td>View Report</td>
<td></td>
</tr>
</tbody>
</table>
Reviewing Recommendations

To view a specific recommendation, tap “View Report.” DreaMed Advisor Pro and your healthcare professional use data collected by your DMS, 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.

![Report Example](image-url)
**Recommended Insulin Pump Settings**

Your healthcare professional may recommend changes to your basal rate, carbohydrate ratio, or insulin 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 u/hr
- Carb ratio units are in g/U
- Correction factor units are in mg/dL/U

### New Basal Plan Settings (IC Ratio)

<table>
<thead>
<tr>
<th>Time</th>
<th>u/hr</th>
</tr>
</thead>
<tbody>
<tr>
<td>12:00 AM</td>
<td>0.5</td>
</tr>
<tr>
<td>5:00 AM</td>
<td>0.6</td>
</tr>
<tr>
<td>6:00 AM</td>
<td>0.7</td>
</tr>
<tr>
<td>8:00 AM</td>
<td>0.75</td>
</tr>
<tr>
<td>5:00 PM</td>
<td>1.2</td>
</tr>
<tr>
<td>8:00 PM</td>
<td>1.1</td>
</tr>
<tr>
<td>10:00 PM</td>
<td>0.65</td>
</tr>
</tbody>
</table>

**Total Units:** 18.35

**Basal Comments**

During the afternoon, your glucose level was high. I suggest to increase your basal rate at that time.

### New Carb Ratio Plan

<table>
<thead>
<tr>
<th>Time</th>
<th>g/U</th>
</tr>
</thead>
<tbody>
<tr>
<td>12:00 AM</td>
<td>40.0</td>
</tr>
<tr>
<td>7:00 AM</td>
<td>18.0</td>
</tr>
<tr>
<td>9:00 PM</td>
<td>40.0</td>
</tr>
</tbody>
</table>

### New Carb Ratio Plan Settings (IC Ratio)

<table>
<thead>
<tr>
<th>Time</th>
<th>g/U</th>
</tr>
</thead>
<tbody>
<tr>
<td>12:00 AM</td>
<td>40.0</td>
</tr>
<tr>
<td>7:00 AM</td>
<td>18.0</td>
</tr>
<tr>
<td>9:00 PM</td>
<td>40.0</td>
</tr>
</tbody>
</table>

**Carb Ratio Comments**

I noticed that your glucose is still high after breakfast and lunch. I suggest to decrease the carb ratio at that time.

### New Correction Factor Plan Settings (insulin Sensitivity)

<table>
<thead>
<tr>
<th>Time</th>
<th>mg/dL/U</th>
</tr>
</thead>
<tbody>
<tr>
<td>12:00 AM</td>
<td>120</td>
</tr>
<tr>
<td>7:00 AM</td>
<td>65</td>
</tr>
<tr>
<td>9:00 PM</td>
<td>120</td>
</tr>
</tbody>
</table>

**Correction Factor Comments**

I noticed that your glucose level was still high after correction boluses. I recommend to increase the correction factor during the day.
Respond to DreaMed Advisor Pro Recommendations

After reviewing your recommendations, you should respond to your healthcare professional and indicate if the changes were made.

- Select **Confirm** to confirm that you have made these changes to your insulin pump, or
- Select **Don’t Adjust** to not accept the insulin pump settings recommendations.

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

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

**Confirm Recommendations**

- If you agree to make the recommended changes to your insulin pump settings, use the recommendations to **update your insulin pump settings**.
- After updating the settings on your insulin pump, tap **Confirm**.
- Review the pop up and confirm you have made the changes. If you have, tap **Confirm Updates**.
- If you want to return to the Recommendations screen without confirming, tap **Cancel**.

When a Recommendation is confirmed, your healthcare professional will be able to view that you accepted the Advisor Recommendations.
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Note: You must make the changes on the pump, the app cannot change any pump settings.
Do Not Adjust Settings

- If you do not agree to make the recommended changes to your insulin pump settings, tap Don’t Adjust.
- Select the reason why you do not agree to make the recommended changes. Options include:
  - Not currently convenient
  - I don’t agree with the settings
  - Other reason
    - If you select Other Reason, enter an explanation in the Comments box.
- Tap Save to send the response to your healthcare professional.
What to do if you are travelling

Inform your HCP 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 HCP is aware you travelled and told you otherwise. The impact of switching timezones could lead to recommendations that are not suitable.
Troubleshooting

This section 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 in my DMS app?**

*Cause: This may be because your healthcare professional didn’t start you on Advisor Pro yet, you do not have enough data uploaded, or your healthcare professional did not approve your first recommendation yet.*

Solution: Ask your healthcare professional if they have started you on Advisor Pro and if they have sent you a recommendation. Ask them to help make sure you are uploading the data correctly and have enough data for receiving a recommendation.

**Why didn’t I receive a recommendation after starting DreaMed Advisor Pro?**

*Cause: Your data may be insufficient for providing a recommendation.*

Solution: Ask your healthcare professional to help make sure you are uploading the data correctly and have enough data for receiving a recommendation.

**Why didn’t I receive a new recommendation after uploading data?**

*Cause: Your data may be insufficient for providing a recommendation, or your healthcare professional may not have approved your recommendation.*

Solution: Ask your healthcare professional if they sent you a recommendation. Ask them to help make sure you are uploading the data correctly and have enough data for receiving a recommendation.
Frequently Asked Questions (FAQ)

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

You can go to the Advisor section of your DMS app and look for your most recent report. Select “View Report” to see the recommendations on the most recent report to see your current recommendations.

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. CR plan
3. CF plan

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

Is there a maximum change that DreaMed Advisor Pro may advise?

Yes, DreaMed Advisor Pro has safeguards and limits in place to prevent large dosing changes.

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.
What blood glucose values are DreaMed Advisor Pro targeting?

DreaMed Advisor Pro is set to maximize the daily CGM readings to be between 70-180 mg/dl while also considering the individual glucose targets set in the pump’s bolus calculator.

Does the DreaMed Advisor Pro section of my DMS App 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 can select “Don’t adjust” and enter an explanation to let your healthcare professional know that you did not implement the changes.

Can my healthcare professional add comments for specific plans (basal or CR, or CF)?

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. However, they can know if you received the recommendation.
## Glossary

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active insulin</td>
<td>Amount of insulin that has been delivered and is still having an effect in lowering the blood glucose.</td>
</tr>
<tr>
<td>Active insulin time</td>
<td>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.</td>
</tr>
<tr>
<td>Basal insulin</td>
<td>Insulin that is continuously delivered by the pump to meet individual insulin needs between meals and during sleep.</td>
</tr>
<tr>
<td>Basal plan</td>
<td>A set of one or more basal rates that covers a full day period.</td>
</tr>
<tr>
<td>Basal rate</td>
<td>The amount of continuous basal insulin that is programmed in the pump to automatically deliver per hour.</td>
</tr>
<tr>
<td>Bolus</td>
<td>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.</td>
</tr>
<tr>
<td>Carbohydrate ratio (CR)</td>
<td>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.</td>
</tr>
<tr>
<td>CGM</td>
<td>Abbreviation for Continuous Glucose Monitoring device which is the sensor that continuously measures the interstitial glucose levels.</td>
</tr>
<tr>
<td>Correction factor (CF)</td>
<td>Indicates how much one unit of insulin reduces glucose levels. This factor is used in the bolus calculator for correcting high glucose levels.</td>
</tr>
<tr>
<td>Glucose sensor</td>
<td>Any interstitial glucose meter</td>
</tr>
<tr>
<td>Bolus Calculator Glucose target</td>
<td>Indicates the value toward which the glucose level is corrected. This target is used in the bolus calculator for correcting high glucose levels.</td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
</tr>
<tr>
<td>--------</td>
<td>------------</td>
</tr>
<tr>
<td>ISF</td>
<td>Abbreviation for Insulin Sensitivity Factor. In this Manual, we use the term CF as a replacement to ISF.</td>
</tr>
<tr>
<td>TDD</td>
<td>Abbreviation for Total Daily Dose, that is the representative total amount of insulin given per day across all days in the investigated period.</td>
</tr>
<tr>
<td>DKA</td>
<td>Abbreviation for Diabetic Ketoacidosis, that is a life-threatening complication of diabetes mellitus.</td>
</tr>
<tr>
<td>Glucometer</td>
<td>Any blood glucose meter</td>
</tr>
<tr>
<td>Pump</td>
<td>Any insulin pump</td>
</tr>
<tr>
<td>U-100</td>
<td>Type of insulin in which every milliliter (ml) of liquid contains 100 units of insulin.</td>
</tr>
</tbody>
</table>
### Appendix A: Data Requirements for DreaMed Advisor Pro

The table below shows what data is needed to count as a valid day for DreaMed Advisor Pro Analysis.

<table>
<thead>
<tr>
<th>Data source</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>CGM</td>
<td>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)</td>
</tr>
<tr>
<td>Basal rate</td>
<td>At least 1 basal record</td>
</tr>
<tr>
<td>Bolus</td>
<td>At least 1 bolus record</td>
</tr>
</tbody>
</table>

The table below shows what insulin pump settings are required for DreaMed Advisor Pro Analysis.

<table>
<thead>
<tr>
<th>Data source</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basal Rates [u/h]</td>
<td>Each rate in the basal plan is within 0.025-3 u/h</td>
</tr>
<tr>
<td>CR [gr/u]</td>
<td>Each value in the CR plan is within 3-70gr/u</td>
</tr>
<tr>
<td>CF [mg/dl/u]</td>
<td>Each value in the CF plan is within 10-280gr/u</td>
</tr>
<tr>
<td>Bolus Calculator Targets [mg/dl]</td>
<td>Equal to or below 150 mg/dl</td>
</tr>
</tbody>
</table>
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:

- **CGM data filtration** – DreaMed Advisor Pro may ignore some of the CGM 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.

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 the table above. Second, the table below presents the particular safeguards and limitations used in recommending a change to the patient’s insulin pump settings.

<table>
<thead>
<tr>
<th>Variable Name</th>
<th>Limitations</th>
<th>How is it used in DreaMed Advisor Pro analysis process</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basal Plan</td>
<td>Limitation on the highest hourly basal rate that could be recommended by DreaMed Advisor Pro</td>
<td>Current Basal Rate Upper Limit: +20% of the current hourly basal rate based on the patient’s current insulin pump settings plus $0.05 \left[ \frac{U}{\text{Hour}} \right]$</td>
</tr>
<tr>
<td>Variable Name</td>
<td>Limitations</td>
<td>How is it used in DreaMed Advisor Pro analysis process</td>
</tr>
<tr>
<td>---------------</td>
<td>-------------</td>
<td>-----------------------------------------------------</td>
</tr>
<tr>
<td>Limitation on the lowest hourly basal rate that could be recommended by DreaMed Advisor Pro</td>
<td>Current Basal Rate Lower Limit: -20% of the current hourly basal rate based on the patient’s current insulin pump settings minus 0.05 ( \frac{U}{\text{Hour}} )</td>
<td></td>
</tr>
<tr>
<td>Additional limitations depending on the patient TDD*</td>
<td>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:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• 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</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• 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.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>These limitations overrule the Current Basal Rate Upper/Lower Limits stated above.</td>
<td></td>
</tr>
<tr>
<td>Potential maximum number of basal periods</td>
<td>24 per day</td>
<td></td>
</tr>
</tbody>
</table>

* 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.
<table>
<thead>
<tr>
<th>Variable Name</th>
<th>Limitations</th>
<th>How is it used in DreaMed Advisor Pro analysis process</th>
</tr>
</thead>
<tbody>
<tr>
<td>CR Plan</td>
<td>Limitation on the highest CR value that could be recommended by DreaMed Advisor Pro</td>
<td>+ 30% of the current CR value based on the patient’s current insulin pump settings plus $1\left[\frac{gr}{U}\right]$</td>
</tr>
<tr>
<td></td>
<td>Limitation on the lowest CR value that could be recommended by DreaMed Advisor Pro</td>
<td>-30% of the current CR value based on the patient’s current insulin pump settings minus $1\left[\frac{gr}{U}\right]$</td>
</tr>
<tr>
<td></td>
<td>Potential maximum number of CR periods</td>
<td>8</td>
</tr>
<tr>
<td>CF Plan</td>
<td>Limitation on the highest CF value that could be recommended by DreaMed Advisor Pro</td>
<td>+30% of the current CF value based on the patient’s current insulin pump settings plus $1\left[\frac{mg}{dl+U}\right]$</td>
</tr>
<tr>
<td></td>
<td>Limitation on the lowest CF value that could be recommended by DreaMed Advisor Pro</td>
<td>-30% of the current CF value based on the patient’s current insulin pump settings minus $1\left[\frac{mg}{dl+U}\right]$</td>
</tr>
<tr>
<td></td>
<td>Potential maximum number of CF periods</td>
<td>8</td>
</tr>
</tbody>
</table>
Note:

- The values appearing in the table 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 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 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.