# CareLink<sup>®</sup> System

Therapy Management Software Tool for Diabetes

## User Guide



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## Introduction

Thank you for choosing Medtronic Diabetes as your partner in helping you better manage your patient's diabetes therapy. We believe you will benefit from the latest evolution of CareLink<sup>™</sup> system that allows you freedom to access reports from devices.

CareLink<sup>™</sup> system allows you to acquire, store, and report patient therapy and diagnostic data. You can also use it to access pump, meter, and sensor-based glucose data your patients have uploaded to CareLink<sup>™</sup> Personal software, a web-based therapy management software for patients.

NOTE: This document shows samples of the software screens. The screens of the actual software may be slightly different. Not all products listed in this user guide are approved or available in all regions.

## Features

CareLink<sup>™</sup> system is a diabetes therapy management software for users who have access to the Internet. It includes these features:

- Patient records can be created to store data gathered from a patient's device.
- Insulin pumps, continuous glucose monitors, and third-party blood glucose meters can be uploaded by interfacing with the CareLink<sup>™</sup> uploader application.
- Data from insulin pumps, monitors, and blood glucose meters can be sent to the software. This data can be stored, and then used to generate reports.
- CareLink<sup>™</sup> system can interface with the patient's CareLink<sup>™</sup> Personal software, allowing access to device data stored in the software. This allows you to create current reports between office visits, and may make it unnecessary for you to upload device data during a patient's office visit.
- Therapy reports can be generated from device data stored in the patient's record. Reports can be used to find answers on how to best meet the patient's therapy needs.

## Security

- CareLink<sup>™</sup> system is password protected.
- Two-factor authentication process may be available for certain geographies. This provides extra protection for your patient's health information.
- The software uses Transport Layer Security (TLS), which ensures a secure link between your computer and the server. TLS is the successor to Secure Sockets Layer (SSL) technology.

## Assistance

For further help with CareLink<sup>™</sup> system, contact the local Medtronic support representative.

## How to use this guide

NOTE: This user guide shows samples of the software screens. The screens of the actual software may be slightly different.

Refer to the Glossary for definitions of terms and functions. The conventions used in this guide are defined in the following table:

Term or Style	Meaning
NOTE:	Provides additional information for a procedure or step.
CAUTION:	Alerts you to a potential hazard which, if not avoided, may result in minor or moderate damage to the software program or equipment.
WARNING:	Notifies you of a potential hazard which, if not avoided, could result in death or a serious injury. It may also describe potential serious adverse reactions and safety hazards.

## **User safety**

### Indications for use

CareLink<sup>™</sup> system is intended for use as a tool to help manage diabetes. The purpose of this software is to take information transmitted from insulin pumps, glucose meters, and continuous glucose monitoring systems, and create CareLink<sup>™</sup> reports. The reports provide information that can be used to identify trends and track daily activities, for example carbohydrates consumed, meal times, insulin delivery, and glucose readings.

### Warnings

- This software is intended to be used by a healthcare professional familiar with the management of diabetes.
- Software results are not intended to produce medical advice and should not be relied upon for such purpose.
- This product should only be used with supported devices. You can access the supported device list through the CareLink<sup>™</sup> system by hovering over the **question mark** drop-down arrow on the Clinic Dashboard screen and selecting **FAQ**.
- Patients should be advised not to make any changes to their treatment without consulting their healthcare professional.

#### Contraindications

This product should not be used for the treatment of medical conditions other than diabetes.

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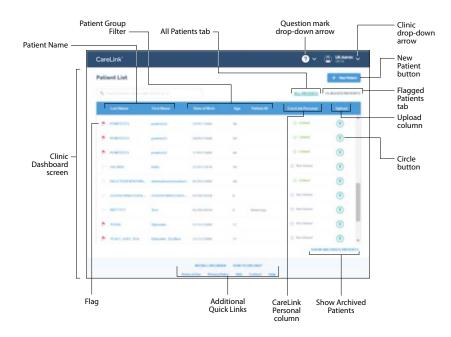
## **Getting started**

The following information will guide you through starting the CareLink<sup>™</sup> system, adding clinic users, promoting clinic users, understanding migration, and verifying clinic report settings that apply to all patients in the software.

## **Before you begin**

All reports settings are preset to default settings. If this is your first time using CareLink<sup>m</sup> system or generating reports, be sure to verify the Clinic Report Settings (see *Verifying Clinic Report Settings on page 7*). These settings determine how certain items display in the software and in reports.

Before working with CareLink<sup>™</sup> system, you should get acquainted with the Clinic Dashboard screen.



Migration helps you get started by copying your patient information from your previous CareLink<sup>™</sup> Pro desktop software to this new CareLink<sup>™</sup> system online software. For more information on migration, see *Understanding Migration to CareLink<sup>™</sup> system on page 7*.

## **Primary tasks**

The following table outlines the main tasks users perform when setting up and using CareLink<sup>™</sup> system. It also provides the location in this user guide where you can find information on each task.

Task	Location
Create account for new clinic users.	Adding Clinic Users on page 6
Promote clinic users to clinic administrator.	Promoting to Clinic Administrator Role on page 6
Verify clinic report settings.	Verifying Clinic Report Settings on page 7
Create profiles for each of your patients.	Adding New Patient Profiles on page 10
Link to your patient's CareLink <sup>™</sup> Personal software account.	Linking to CareLink™ Personal software on page 12
Connect your patient's device to the PC.	Connecting devices on page 15
Upload data from your patient's pump and meters.	Add and Upload a New Device on page 16 Uploading Device Data on page 16
Set up and generate reports for your patients.	Creating reports on page 20

CAUTION: Do not register more than one clinic account for your clinic. If each clinic's user registers his or her own clinic account, your patient records will be separated among these different clinic accounts and they will not be accessible to all your users.

## **Clinic Administrator**

A clinic administrator can maintain clinic information, add and maintain clinic users, add and maintain patient records, establish clinic-wide defaults for report settings, and alter patient settings and manage clinic security policy.

It is a good idea to give administrative privileges to **at least two users** because of possible staff changes at a clinic. To give administrative privileges to another user, see *Promoting to Clinic Administrator Role on page 6* 

## **Adding Clinic Users**

Each staff member who might upload data from devices, or review or print reports needs a CareLink<sup>™</sup> system user account.

- 1 Get a list of names and email addresses for staff members who need CareLink<sup>™</sup> system user accounts.
- 2 Hover over the clinic drop-down arrow at the top right.
- 3 Select Clinic Management.
- 4 Click the New Clinic User Account button.
- **5** Fill in the fields in the clinic user section.
- **6** Make a note of the username so that you can provide it to the user. The user will need this information to sign in and select a new password.

Email to set a new password will be sent to the email address provided.

7 Click Submit.

Repeat this procedure for each user account that you need to create.

## **Promoting to Clinic Administrator Role**

As staff changes at a clinic, make sure that two or more staff members have administrative privileges. A user can be promoted to a clinic administrator as follows:

- 1 Hover over the clinic drop-down arrow at the top right.
- 2 Select Clinic Management.
- **3** Find the clinic user you want to promote.
- 4 Hover over the three vertical dots on the clinic user entry.
- 5 Select Promote to Admin.
- 6 Click **Promote**.

## Understanding Migration to CareLink<sup>™</sup> system

Migration allows you to transfer patient records from CareLink<sup>™</sup> Pro desktop software to CareLink<sup>™</sup> system.

NOTE: The option to migrate is not supported for all countries. Contact the local Medtronic support representative for further information.

NOTE: Only a CareLink<sup>TM</sup> system user with administrative privileges can migrate patient records from CareLink<sup>TM</sup> Pro desktop software.

- Migrated patients from CareLink<sup>™</sup> Pro desktop software will be visible to the clinic user on CareLink<sup>™</sup> system Patient List once the migration is complete.
- Migrated patients will be listed under the patient group name given at the time of migration.
   Click the **Patient Group** filter on the Clinic Dashboard screen to find patients within a migrated group. The default filter is **All Groups**.
- Data from unsupported devices migrated from CareLink<sup>™</sup> Pro desktop software will not be visible to the clinic user on CareLink<sup>™</sup> system.
- Migration will include current device data from patient devices that are supported by CareLink<sup>™</sup> system.
- CareLink<sup>™</sup> Pro desktop software clinic preferences can be included in the migration.

## **Verifying Clinic Report Settings**

The Clinic Report Settings are set by a clinic administrator and are default settings for each new patient record and clinic user. A clinic user can customize their report settings. For more information on customizing your clinic settings, see *Customizing My Report Settings on page 24*.

- 1 Hover over the clinic drop-down arrow at the top right.
- 2 Select Clinic Management.
- 3 Click CLINIC REPORT SETTINGS to open the page.
- 4 Make sure the **Glucose Settings** are at the desired values. To edit **Glucose Units**, click the dropdown field and select the option you want. To edit **Glucose Target**, click the field you want to edit and enter a new number.
- 5 Make sure the **Carbohydrate Settings** are at the desired values. To edit **Carb Units**, click the drop-down field and select the option you want. To edit **Carb Exchange Ratio**, click the field you want to edit and enter a new number.

- 6 Make sure the **Time Format Settings** are at the desired values. To edit **Time Format Settings**, click the drop-down field and select the option you want.
- 7 If you made any edits, click **UPDATE**.

## **Defining Report Settings**

The General Report Settings determine how glucose and time information will be displayed in patient reports. The default setting is included for each glucose target range.

- **Glucose Units**: The appropriate units for reporting glucose amounts.
- **Glucose Target** range: The glucose target range used in the reports.
  - Highest Limit: The glucose measurement that is considered to be the highest limit of hyperglycemia for this patient. The software uses the Highest Limit glucose range in reports to show the range that is above the high glucose range.
  - **High**: The glucose measurement that is considered to be the upper limit of euglycemia (target) for this patient. The software uses the **High** value in reports to show the range that is above the euglycemic or glucose target range.
  - **Low**: The glucose measurement that is considered to be the lower limit of euglycemia (target) for this patient. The software uses the **Low** value in reports to show the range that is below the euglycemic or glucose target range.
  - **Lowest Limit**: The glucose measurement that is considered to be lowest limit of hypoglycemia for this patient. The software uses the **Lowest Limit** glucose range in reports to show the range that is below the low glucose range.

## **Manage Clinic Security Policy**

Clinic administrators can adjust the clinic security policy for their clinic users and administrators. The security policy for all clinic users and administrators may be set to different settings. Only when the password is changed, the security policy is enforced.

## Workstation security advisory

Your safety and the privacy of your information are of highest importance to Medtronic. To help us ensure that our CareLink<sup>™</sup> system products work correctly and securely, please consider these good practices and precautions to help keep your computer system safe and secure:

- Keep your PC or Mac<sup>™</sup> system up-to-date with the most current updates for your operating system and browser. Medtronic responds to newly discovered security issues with updates.
- Use a strong password. CareLink<sup>™</sup> system provides a password strength meter to help with this. The most important factors are length and avoiding common spellings of words. Some password vaults offer the ability to create very strong passwords and provide them on demand.

- Do not disclose your password to anybody. The local Medtronic support representative will
  never ask for your password. If you get a request to disclose your password by email, please
  contact the local Medtronic support representative immediately and do not reply to the
  email. Refuse to provide your password and request to speak to a manager immediately if any
  local Medtronic support representative asks for your password.
- Change your password immediately if you think your password has been compromised.
- Change your password every three to six months.
- Contact the local Medtronic support representative immediately if you suspect your account may have been accessed by somebody with whom you have not shared your password.
- Use reputable security software on your PC or Mac<sup>™\*</sup> that provides protection against viruses, "adware" and other forms of malicious software ("malware").
- Take advantage of "software firewall" features in your security software as added protection for your PC or Mac<sup>™\*</sup>.
- Consult with your Internet Service Provider about security for your access point (typically your modem) and router. Additional protection, such as firewall features, may be available to you.
- Be aware that many websites and emails are malicious and are designed to compromise your computer system. Always be careful about opening email from somebody you do not know or going to websites from links in emails.
- Use the strongest settings on your PC or Mac<sup>™\*</sup> security software that you can to help guard against accidental contact with malicious software.
- Use a supported operating system and browser. Even though CareLink<sup>™</sup> system may let you proceed with an operating system or browser that is not validated, it is better to use one of the fully supported configurations.

## **Managing Patients**

A patient record can be accessed by clicking on the patient name from the patient list. The patient record includes three pages - Reports, Report Settings, and Patient Profile. When opening a patient record, the default page is Reports. A patient profile is required before device data can be gathered and used to create therapy reports.

The patient profile also allows you to set up a link to a patient's CareLink<sup>m</sup> Personal software account. Once the link is established, you can retrieve patient data stored in CareLink<sup>m</sup> Personal software anytime without the need to have the patient present.

## **Adding New Patient Profiles**

- 1 On the Clinic Dashboard screen, click the **New Patient** button.
- **2** Fill in the fields in the Patient Profile section.

NOTE: You may add notes regarding the patient's therapy needs in the patient profile section if they are needed.

3 Click Submit.

## **Editing Patient Profiles**

- 1 In the **Patient List**, select the patient's name you want to edit.
- 2 Click **PATIENT PROFILE** to open the page.
- 3 Edit the information in the **PATIENT PROFILE** section as needed.
- 4 Click Update.

## **Archiving Patients**

After archiving a patient record, the patient record will not be visible from the clinic dashboard screen. This allows a clinic user to clean up the patient list without deleting old patients. To see archived patients, click **SHOW ARCHIVED PATIENTS.** A user can archive a patient record as follows:

- 1 In the **Patient List**, select the patient's name you want to archive.
- 2 Click **PATIENT PROFILE** to open the page.
- 3 Click the **Archive** button.
- 4 Confirm by clicking **Archive**.

## **Activating Patients**

After activating a patient record, the patient record will be visible from the clinic dashboard screen. Any archived patient record can be reactivated. A user can activate a patient record as follows:

- 1 In the Patient List, click the SHOW ARCHIVED PATIENTS filter.
- **2** Find the patient's name.
- **3** Under the **Activate** column, click the circle button.
- 4 Confirm by clicking **Activate**.

To return to Clinic Dashboard screen, click SHOW ACTIVE PATIENTS.

## **Flagging Patients**

Flagging patients will allow you to quickly access your list of patients.

NOTE: If you flag a patient record, that record won't be flagged for other clinic users.

- 1 In the **Patient List**, find the patient's name.
- 2 Click the flag next the patient's last name.

To see flagged patients, click the **FLAGGED PATIENTS** tab on the Clinic Dashboard screen.

## **Unflagging Patients**

- 1 In the **Patient List**, find the patient's name.
- 2 Click the red flag next the patient's last name.

## Linking to CareLink<sup>™</sup> Personal software

With your patient present, you can set up a link to his or her CareLink<sup>™</sup> Personal software account. After you link to the patient's CareLink<sup>™</sup> Personal software account, that patient's data in CareLink<sup>™</sup> system will be automatically updated when the patient uploads device data to CareLink<sup>™</sup> Personal software. This is useful for generating CareLink<sup>™</sup> system reports between office visits, and eliminating the need to upload the patient's device in the office.

If your patient does not have a CareLink<sup>™</sup> Personal software account, you can send them an email invite to create one.

## Linking to an Existing Account

The patient must be present to complete the following steps.

- 1 In the **Patient List**, select the patient's name you want to link.
- 2 Click **PATIENT PROFILE** to open the page.
- 3 Click the Link to Personal button.

The Link CareLink Personal to patient record screen is displayed.

- **4** Have the patient do the following:
  - a. Type in his or her Username and Password.
  - b. Click Link.

The patient will be presented with Terms of Use.

5 Click Accept to agree to terms.

### **Sending an Email Invitation**

To send an email inviting a patient to create a CareLink<sup>™</sup> Personal software account, follow these steps:

- 1 In the **Patient List**, select the patient's name you want to email.
- 2 Click **PATIENT PROFILE** to open the page.
- 3 Click the **Invite to Personal** button.
- **4** Enter the patient's email address.
- 5 Click Send.

### **Unlinking from an Existing Account**

You can unlink a patient's CareLink<sup>™</sup> Personal software account from CareLink<sup>™</sup> system after it has been linked. It prevents CareLink<sup>™</sup> system from continuing to retrieve data from the patient's CareLink<sup>™</sup> Personal software account. It does not affect the patient's personal usage of his or her CareLink<sup>™</sup> Personal software account. NOTE: After unlinking a patient's CareLink<sup>™</sup> Personal software account, all historic data will still remain available to the clinic.

CAUTION: Once a patient record is linked to a CareLink<sup>™</sup> Personal software account, it cannot be linked to any other CareLink<sup>™</sup> Personal software account even after it is unlinked.

- 1 In the **Patient List**, select the patient's name you want to unlink.
- 2 Click **PATIENT PROFILE** to open the page.
- 3 Click the **Unlink from Personal** button.

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## **Uploading Devices**

Information that you need to upload a patient's device, such as the manufacturer, model, and serial number, is stored in the uploader application after the first time you supply it.

## **Installing Uploader Application**

CareLink<sup>™</sup> system needs the uploader application installed in order to add devices and upload patient data. The first time you click the upload button, you will be presented with information to download and install the uploader application.

#### Before you begin, please note:

- Some operating systems may require that you have administrative privileges for the computers in the office to complete this task. Ask a user with administrative privileges, such as your network administrator, to sign into each computer to allow the installation of required software components.
- You must do this for each computer that may be used to upload data on CareLink<sup>™</sup> system.

## **Hardware Setup**

To upload data directly from a device, you must have the patient's device, and any cables or communications devices required to transfer data to your computer.

## **Connecting devices**

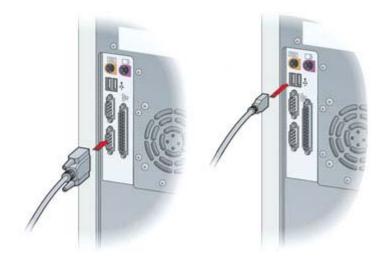
The diagrams that follow show the communication setup between different devices. Review the diagrams to see how to connect devices to communicate with your computer.

## Connection example for devices with a USB connector:

The following example shows the CareLink $^{\text{\tiny M}}$  USB used as a communication device between the pump and the computer.



Serial and USB cable connection examples:



## Add and Upload a New Device

Follow these steps to add and upload from a patient's device.

**NOTE:** The first time you upload a new device, the device will be added to the patient's device list so you can quickly select and upload in the future. Refer to section Uploading Device Data on page 16, for future uploads of devices in the patient's device list.

### **Uploading a Medtronic Pump**

- 1 In the **Patient List**, find the patient's name.
- 2 Under the **Upload** column, click the circle button to launch the uploader application. The **Upload Device** button is also available in every patient record to launch the uploader application.

If the uploader application does not display, hover over the question mark drop-down arrow on the Clinic Dashboard screen and select **FAQ** for troubleshooting information.

- **3** Select the correct pump type.
- **4** Follow the instructions on the uploader application.

## **Uploading a Meter**

- 1 In the **Patient List**, find the patient's name.
- 2 Under the **Upload** column, click the circle button to launch the uploader application. The **Upload Device** button is also available in every patient record to launch the uploader application.

If the uploader application does not display, hover over the question mark drop-down arrow on the Clinic Dashboard screen and select **FAQ** for troubleshooting information.

- **3** Select the correct device type.
- 4 Select the correct brand of meter, and then select the correct model.
- **5** Follow the instructions on the uploader application.

## **Uploading Device Data**

One way to get device data is to link to the patient's existing CareLink<sup>M</sup> Personal software account. (See *Linking to CareLink*<sup>M</sup> *Personal software on page 12*.) Another way is to upload it directly from his or her device, as described here.

**NOTE: Refer to section** Add and Upload a New Device on page 16, to upload data from a new device.

Data from your patient's device can be uploaded by the uploader application if it is in communication with the computer. You can access the supported device list through CareLink<sup>™</sup> system by hovering over the **question mark** drop-down arrow on the Clinic Dashboard screen and selecting **FAQ**. After you get the data, you can use it to create reports that will help you assess the patient's therapy management.

WARNING: Please cancel or finish any temp basals or active boluses, and clear any active alarms. The pump may be suspended for uploading, depending on the pump model. Once the upload is complete, please verify the pump has resumed delivery if it was suspended. If, for some reason, the pump does not resume delivery after the upload, the pump will beep or vibrate about every 15 minutes to remind you that it is not delivering insulin.

CAUTION: If the pump battery is low, the pump will not send data to the PC. Replace the battery if the status indicates battery power is low.

If the uploader application is unable to get data from the device, see Troubleshooting on page 27.

- 1 In the **Patient List**, find the patient's name.
- 2 Under the **Upload** column, click the circle button to launch the uploader application. The **Upload Device** button is also available in every patient record to launch the uploader application.
- **3** Select the device you want to upload data from on the device list.
- **4** Follow the instructions on the uploader application.

## **Removing Device**

You can remove a device from the uploader application.

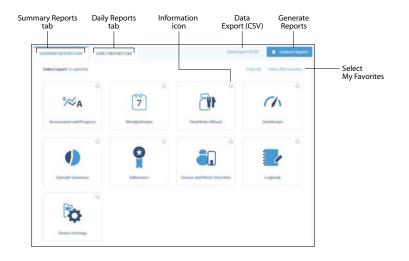
NOTE: If you remove a device from the patient's device list, all of the previous uploaded data for that device will continue to be available in the patient record.

- 1 In the **Patient List**, find the patient's name.
- 2 Under the **Upload** column, click the circle button to launch the uploader application. The **Upload Device** button is also available in every patient record to launch the uploader application.
- **3** Find the device to remove from the patient devices shown on the screen.
- 4 Click **Remove device**.

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## **Reports**

CareLink<sup>™</sup> system provides a variety of reports to help you better manage your patient's diabetes therapy.



Reports can be generated on screen, reviewed, printed, and saved as a PDF. You can generate several report types at once.

The data displayed through these reports is captured from the patient's devices, from the patient's CareLink<sup>™</sup> Personal software account, or from both.

NOTE: Details about the report components, as well as sample reports, are contained in the Report Reference Guide. You can access the Report Reference Guide through CareLink<sup>™</sup> system. Hover over the question mark drop-down arrow on the Clinic Dashboard screen > click Help and select the Report Reference Guide (PDF).

NOTE: The Report Reference Guide shows sample reports, portions of which have the glucose units not shown since the standard for glucose unit measurements varies by country. As a consequence, the scale and range of numbers shown in the sample reports may differ from the scale and range seen on your reports. Also, reports may look slightly different based on the device used, and not all reports are compatible with all devices. You can access the supported device list through CareLink<sup>™</sup> system by hovering over the question mark drop-down arrow on the Clinic Dashboard screen and selecting FAQ.

## **Before you begin**

Make sure you upload the latest data from the patient's device.

Be sure to review the *Verifying Patient Report Settings* step before you generate a report. This is where you can fine-tune a report to capture the patient data you want.

## **Verifying Patient Report Settings**

- 1 In the patient record, click **REPORT SETTINGS** to open the page.
- 2 Click the **Meals** tab to verify each meal setting.

NOTE: Select the Per meal option to verify settings for each meal. Select the All meals option to verify the settings for all of the patient's meals.

- 3 Make sure the meal settings are at the desired values. Type in these values, or click the dropdown fields to raise or lower the values. The target blood glucose settings you select will apply to the reports you generate. The reports will not show target ranges set on the pump or in CareLink<sup>™</sup> Personal software.
  - **Time Period**: hours during which the meal occurs.
  - **Pre-Meal BG Target:** low and high ends of the patient's before-meal glucose target range.
  - Pre-Meal Analysis Period: time period that glucose will be analyzed prior to the start of a meal. The sensor glucose uploads captured during this time are used in a detailed report analysis.
  - **Post-Meal BG Target:** low and high ends of the patient's post-meal glucose target range.
  - **Post-Meal Analysis Period:** time period that glucose will be analyzed after a meal. The sensor glucose uploads captured during this time are used in a detailed report analysis.

## NOTE: Meal periods cannot overlap, but start and end lines can border one another. Meal periods must be at least 60 minutes in length.

- **4** Make sure the Analysis Periods settings are at the desired values. You may set the start and end time of the analysis periods duration.
- 5 Make sure you select the desired source data by clicking on the Data Source Preferences tab. Different reports are generated based on insulin pump data or Guardian<sup>™</sup> Connect system data. When the Prefer pump data over Guardian data when both are present setting is checked, insulin pump-supported reports that feature basal and bolus insulin information are generated. When this setting is unchecked, Guardian<sup>™</sup> Connect system-supported reports are generated.

Click the bubble next to **In the Pump** or **In the Link Meter(s)**. You also have the option to include Manual BG entries in the reports. To include, check the **Include Manual BG Entries** box.

- In the pump: The advantage of this selection is that you only have to upload data from the patient's pump. BG uploads are time stamped by the pump, and tied directly to any Bolus Wizard<sup>™</sup> calculations used. A disadvantage is that if there are communication difficulties between the pump and the linked meter, BG uploads during that time may not get reported.
- In the link meter(s): The advantage of this selection is that all uploads stored in the linked meter are reported. The disadvantage is that to correlate meter and pump data, you must make sure that the pump and meter clocks were synchronized with one another. You must also upload data from the pump and the linked meter separately.
- 6 After you finish editing a meal period, click **UPDATE**.

## **Creating reports**

The following sections will help you better understand the process you use to create and generate the reports.

1 In the **Patients List**, select the patient's name.

The **REPORTS** page is displayed.

### Selecting the reporting period

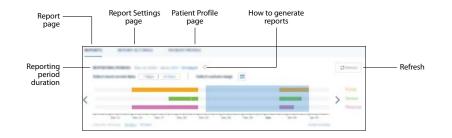
1 By default, the last 14 days of available data will be selected and displayed. To change the reporting period reflected in a report, click the **calendar** icon and select or enter the number of days you want reflected on a report. (The maximum duration is 90 days.)

NOTE: If you have uploaded the device data and do not see the patient's latest device data available, click the Refresh button. If you still do not see the latest device data available, please try uploading the device data again and click the Refresh button.

2 Click Apply.

### Data calendar

By default, the data calendar shows a 30-day window of reporting information. When the clinic user selects a reporting period more than 21 days, the data viewing area will display a 90-day view.



The orange bars represent the presence of pump data. The green bars represent the presence of sensor data. The purple bars represent the presence of meter data. The transparent blue rectangle overlapping the color bars represents the reporting period that you selected.

The data calendar area initially displays the most current data available for the last 30 days. To see other months, click the arrow buttons on either end of the months. To see if there is data up to today, click **Today**.

### **Checking for device data**

- 1 Look at the data calendar to see if the transparent blue rectangle representing the reporting period overlaps with the orange, green and purple bars representing device data.
- 2 If the bars do not overlap or there is not enough overlap, you have a few choices:
  - adjust the reporting period
  - get additional device data

### **Generating reports**

You are able to select and deselect a single report or multiple reports. Informational text on each report is provided by hovering over the information icon on the top right of each report.

1 On the **SUMMARY REPORTS** tab, select the reports you want to generate.

The reports you selected will have a check mark and be highlighted.

A clinic user has the option to click **Select My Favorites**. The reports the user has selected as their favorite will automatically have a check mark and be highlighted.

NOTE: If you have not selected your favorite reports yet, the first time you click Select My Favorites, a message will appear with a link to set your favorite reports. Click My Report Settings. For more information on selecting your favorite reports, see Selecting Favorite Reports on page 22. 2 After you verify your report selections, click Generate Reports.

#### **Generating Assessment and Progress reports**

If you select the **Assessment and Progress** report, a **PROGRESS FROM** selection will be available next to the **REPORTING PERIOD** duration to allow you to compare data between two different time periods. By default, 3 months ago will be selected.

- 1 Click Assessment and Progress report.
- 2 Make sure the Progress Comparison Range is at the desired time range. To edit Progress Comparison Range, click the PROGRESS FROM drop-down field > select the desired time range and click Apply.

NOTE: If data is not available for the selected time, data range B will be blank. The duration of data range B is equal to the duration of data range A, and no dates can overlap.

3 Click Generate Reports.

#### **Daily Report Selection**

You are able to select the specific number of days for which you will generate Daily Reports based on the selected Reporting Period date range. You may select up to 14 days from the selected report date range for the daily reports.

1 On the **REPORTS** page, click the **DAILY REPORTS** tab.

The day's selection will indicate the current day.

2 Select the days you want reports for, or select Max or Last 7 days.

NOTE: Selecting Max allows you to select at a maximum the last 14 days of a selected reporting range. If there are days that have no available device data in the reporting range, the days selected may be less than 14. Selecting Last 7 days will allow you to select the last 7 days that have available device data from the selected report range.

**3** Click **Generate Reports**.

#### **Selecting Favorite Reports**

After favorite reports have been selected, the clinic user may click **Select My Favorites** when generating reports. A clinic user can select their favorite reports as follows:

- 1 Hover over the clinic drop-down arrow at the top right.
- 2 Select My Profile.
- 3 Click MY REPORT SETTINGS tab.
- 4 Check the boxes below My Favorite Reports.
- 5 Click UPDATE.

## **Exporting data**

You can export device data that is acquired and stored by CareLink<sup>™</sup> system. This gives you patient's device data to use for statistics or the creation of specialized reports or charts. The .csv file can be imported into Microsoft<sup>™\*</sup> Excel<sup>™\*</sup> or certain clinical statistics programs where you can further manipulate the data.

The .csv file contains data that recorded the actions of the device. For example, it lists the recording of meter uploads, the pump receiving the meter upload value, and change in basal rate.

NOTE: This is an advanced feature and requires you to be familiar with the raw device data. It also requires proficiency with any software into which you import the .csv file.

Follow these steps to use the export feature:

- In the **Patient List**, select the patient's name.
   The **REPORTS** page is displayed.
- 2 Use the Data Calendar to set the dates and length of the report.The maximum duration you can select is 90 days.
- 3 Click Data Export (CSV).

## **Clinic Account Management**

A clinic user may customize their own report settings, but only administrative users can add, modify, and delete CareLink<sup>™</sup> system user accounts. Always make sure more than one person has administrative privileges.

## **Customizing My Report Settings**

A clinic user has the option to customize their report settings or use the default clinic report settings. Customizing report settings will affect all patient reports, but it will not affect the reports other clinic users generate for patients.

NOTE: The generated patient reports will use either the clinic report settings or the customized my report settings depending on the option you have selected.

- 1 Hover over the clinic drop-down arrow at the top right.
- 2 Select My Profile.
- 3 Click MY REPORT SETTINGS tab.
- 4 In MY REPORT SETTINGS, set the Glucose Settings and the Carbohydrate Settings. You may also set your favorite reports. These reports will automatically be selected when you click Select My Favorites on the Reports page.
- 5 When you are finished, click **UPDATE**.

## **Removing Administrator Role**

After removing the administrator role, the clinic user will no longer be able to perform clinic administrator tasks. A clinic administrator can remove the administrator role from a user as follows:

- 1 Hover over the clinic drop-down arrow at the top right.
- 2 Select Clinic Management.
- **3** Find the clinic user you want to remove.
- 4 Hover over the three vertical dots on the clinic user entry.
- 5 Select Remove Admin Privileges.
- 6 Click Remove Privileges.

## **Suspending Clinic Users**

After suspending a clinic user account, the user will not be able to login using his or her login information. A clinic administrator can inactivate a user as follows:

- 1 Hover over the clinic drop-down arrow at the top right.
- 2 Select Clinic Management.
- **3** Find the clinic user you want to inactivate.
- **4** Hover over the three vertical dots on the clinic user entry.
- 5 Select Inactivate User.
- 6 Click Suspend.

## **Activating Clinic Users**

After activating a clinic user account, the user will be able to log in using his or her login information. A clinic administrator can activate a user as follows:

- 1 Hover over the clinic drop-down arrow at the top right.
- 2 Select Clinic Management.
- 3 Click SUSPENDED ACCOUNTS.
- **4** Find the clinic user you want to activate.
- **5** Hover over the three vertical dots on the clinic user entry.
- 6 Select Activate User.
- 7 Click Activate.

## **Unlocking Clinic Users**

After unlocking a clinic user account, the user will be able to log in to their account. A clinic administrator can unlock a clinic user account by navigating to the clinic management page and hovering over the three vertical dots on a clinic user entry.

## **Two-Factor Authentication**

Two-factor authentication process may be available for certain geographies. This provides extra protection for your patient's health information. This security feature prevents others from accessing or using your account.

CareLink<sup>™</sup> system provides ability to Clinic Administrators to manage Two-factor authentication settings for clinic users. Authentication expiration period and Verification code expiration settings can be set as per the clinic's security needs and will apply to all clinic users.

Clinic Administrators can update these settings using the following steps:

- 1 Hover over the clinic drop-down arrow at the top right.
- 2 Select Security.
- 3 Click Authentication tab.
- **4** Update setting value as preferred.
- 5 Click Update.

In order to successfully complete the Two-factor authentication procedure, you need to have a valid email address, along with your user name and password. Whenever prompted, enter the authentication code sent to the email address to access your account.

NOTE: The email address associated with your CareLink<sup>™</sup> system account will be used for the Two-factor authentication procedure. Go to My Profile to change your email address.

7

## Troubleshooting

This chapter contains troubleshooting information for CareLink<sup>™</sup> system. Please refer to these instructions before contacting the local Medtronic support representative.

## **Report creation errors**

#### Multiple data entries for the same date

If you were unable to generate a report because of conflicting data, first try selecting a different reporting range.

#### Software is going to ignore data

If the time on a device has been changed causing overlaps or gaps in data of three hours or longer, the software does not include that portion of data when creating reports.

8

## **Icon table**

The following icons and symbols may appear in the software. For definitions, go to http://www.medtronicdiabetes.com/symbol-definitions.

Description	lcon
Manufacturer	
Catalogue or model number	REF
European conformity. This symbol means that the device complies with MDD 93/42/EEC.	CE
Authorized representative in the European community	EC REP

A

## **CSV data**

When you export report data from CareLink<sup>m</sup> system, it is exported into a .csv file. This file can then be imported into a spreadsheet application, such as Microsoft<sup>m\*</sup> Excel<sup>m\*</sup>. See the CSV file column definitions for a complete listing of the data that can be contained in a CSV file.

The CSV file contains the name and Patient ID for the patient, and the reporting period. It also identifies each device included in the report.

Column heading	Definition
Index	The order in which data was recorded in the device.
Date	The date data was recorded in the device.
Time	The time data was recorded in the device.
New Device Time	The new date and time if this was changed in the device.
BG Reading	The blood glucose reading recorded by the meter, Guardian <sup>™</sup> Connect system, or pump. If the data is from a pump or Guardian <sup>™</sup> Connect system, this column reflects manual BGs and BGs received from a Link meter.
Linked BG Meter ID	The serial number for the meter that sent a blood glucose reading to the device.
Basal Rate (U/h)	The active basal insulin delivery rate in units per hour.
Temp Basal Amount	If a temp basal was applied on the pump, this value is the temp basal amount.
Temp Basal Type	The type of temporary basal adjustment (insulin rate or percent of basal).
Temp Basal Duration (m)	The length of time in minutes for the temporary basal insulin delivery (see type above).

## **Column data definitions**

Column heading	Definition
Bolus Type	The bolus insulin delivery type [Normal, Square, Dual (normal part), or Dual (square part)].
Bolus Volume Selected (U)	The number of insulin units selected to be delivered during the bolus insulin delivery.
Bolus Volume Delivered (U)	The number of insulin units actually delivered during the bolus insulin delivery.
Bolus Duration (h)	Duration of a square bolus or the square portion of a Dual Wave <sup>™</sup> bolus.
Prime Type	Prime type can be manual or fixed. Manual is used just after a rewind, to fill the infusion set tubing with insulin before inserting it. Fixed is used after infusion set insertion to fill the soft cannula with insulin after removing the introducer needle.
Prime Volume Delivered (U)	The number of units of insulin actually delivered for the prime.
Alarm	The name of the alarm that occurred.
Suspend	Identifies the suspended state of the pump.
Rewind	Date and time the device was rewound.
BWZ Estimate (U)	The bolus insulin estimate calculated by the Bolus Wizard <sup>™</sup> feature.
BWZ Target High BG	The setting for the high end of the blood glucose target range, used by the Bolus Wizard <sup>™</sup> feature.
BWZ Target Low BG	The setting for the low end of the blood glucose target range, used by the Bolus Wizard <sup>™</sup> feature.
BWZ Carb Ratio	The setting for insulin-to-carbohydrate ratio. If grams are used as the units, the ratio is the number of grams covered by one unit of insulin. If exchanges are used for units, the ratio is the number of insulin units used to cover one exchange.
BWZ Insulin Sensitivity	The setting for insulin sensitivity. Insulin sensitivity is the amount the blood glucose level is reduced by one unit of insulin. This is used by the Bolus Wizard <sup>™</sup> feature.
BWZ Carb Input	Amount of carbohydrates entered into the Bolus Wizard <sup>™</sup> and used to estimate a bolus.
BWZ BG Input	Blood glucose reading when entered into the Bolus Wizard <sup>™</sup> and used to estimate a bolus.
BWZ Correction Estimate (U)	Units of bolus insulin to give for blood glucose level correction, as calculated by the Bolus Wizard <sup>™</sup> feature.
BWZ Food Estimate (U)	The estimated units of bolus insulin to give to cover the expected amount of carbohydrate consumption, as calculated by the Bolus Wizard <sup>™</sup> feature.
BWZ Active Insulin (U)	The amount of active insulin calculated to be left in the body from prior bolus insulin deliveries when determining the estimated bolus amount by the Bolus Wizard <sup>™</sup> feature.
Sensor Calibration BG	The BG value used for calibrating the sensor.
Sensor Glucose	The sensor glucose value.

Column heading	Definition
ISIG value	Input signals (ISIG), which are read from the sensor, measured in nanoamperes (nA).
Event Marker	<ul> <li>A record of the following events entered by the user including:</li> <li>BG</li> <li>Injection</li> <li>Food (Carb amount)</li> <li>Exercise (Duration)</li> <li>Other</li> </ul>

## More about CSV files exported by CareLink<sup>™</sup> system

The title at the top of the CSV file includes the following:

- patient's name
- a list of selected devices and their serial numbers
- selected date range

Each block of columns has a title that includes the following:

- name of the device to which the block of data applies
- serial number of that device

## If data is not displaying as expected

A number of different factors can cause the CSV data to display differently than expected.

- Date or time changes on the device can change the sequence or cause records outside the selected date range to be shown.
- If there is a large gap between device uploads, data for that device may be displayed in multiple blocks.

## Glossary

Activate - To provide authority or enable someone to do something.

- Archive Patient A collection of historical records providing information about a patient.
- **BG** Abbreviation for blood glucose.
- **Carb units** The food entry when using the Bolus Wizard<sup>™</sup> feature. Entered as (carbohydrate) grams or exchanges.
- **CareLink**<sup>™</sup> **Personal software -** An online service that allows management of diabetes data via the Internet.
- **Meter** A medical device for determining the approximate concentration of glucose in the blood. A small drop of blood is placed on a disposable test strip, which the meter reads and uses to calculate the blood glucose level.

Promote User - To give user higher administrative privileges.

- **Suspend User** Temporarily prevent a user from continuing login privileges.
- **Upload** The process for transferring pump or meter data to the CareLink<sup>™</sup> server.

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