CareLink™ PRO

THERAPY MANAGEMENT SOFTWARE FOR DIABETES

User Guide

Medtronic

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Contents

Introduction

1

What's in this chapter

Overview

Thank you for choosing Medtronic Diabetes as your partner in helping you and your patients better manage diabetes therapy. We believe you will benefit from CareLink™ Pro software's leading edge technology and **simple**, menu-driven user interface.

This user guide describes how to use CareLink Pro to acquire, store and report patient treatment and diagnostic data. It also describes the option to access pump, meter, and sensor-based glucose data your patients have uploaded to CareLink™ Personal, a Web-based therapy management system that works with CareLink Pro.

Features

CareLink Pro is diabetes therapy management software for a personal computer (PC). It includes these features:

- Patient records can be created to store data gathered from a patient's device as well as therapy data from their CareLink Personal account.
- Data from insulin pumps, monitors, and blood glucose meters can be sent to the system, stored, and then used to generate reports.
- As an option, it interfaces with the CareLink Personal system, allowing access to device data patients have stored there. This is ideal for creating current reports between office visits, and may make the need to read device data during office visits unnecessary.
- Different treatment reports can be created from device data stored in the patient's record. Reports facilitate answers to therapy concerns such as patient adherence, patterns and exceptions.
- The system alerts you when software updates are available to be downloaded and installed. This ensures you have access to the latest features.
- There is a Guide Me feature to help users who are new to CareLink Pro. It gives hints and tips about the tasks they are performing.
- An integrated help system is available throughout the software to provide information on specific areas of interest.

Security

- CareLink Pro can be password protected.
- Transmission of patient data from CareLink Personal is encrypted using industry-standard Secure Sockets Layer (SSL) technology.

Related documents

Each of these Medtronic MiniMed documents has device-specific information that is not covered in detail in this user guide.

NOTE: For meters from other companies, see the instructions the manufacturer included with the meter.

- Paradigm Insulin Pump User Guide
- Sensor Features User Guide
- ComLink User Guide
- CareLink USB User Guide

Assistance

Medtronic MiniMed provides a number to call for residents of the United States and Canada for guidance with software problems. The hours are **Monday through Friday from 5:00 a.m. to 5:00 p.m. Pacific Standard Time**.

Support	Contact information
24 Hour HelpLine	(800) 646-4633 or (818) 576-5555
MiniMed Web site	www.medtronicdiabetes.com

NOTE: Some devices supported by this software may not be available in all countries where this software is approved for use.

Supported devices

CareLink Pro gets data from the following devices.

Insulin pumps	
Medtronic MiniMed pumps	508
MiniMed Paradigm pumps	511, 512, 712, 515 and 715
Paradigm REAL-Time System	522 and 722 522K and 722K

Manufacturer	Blood glucose meters
Medtronic Diabetes partner devices:	• LifeScan OneTouch® UltraLink™ • Bayer CONTOUR® LINK • BD Paradigm Link™ Blood Glucose Monitor
LifeScan:	• OneTouch® UltraSmart® • OneTouch® Profile® • OneTouch® Ultra® • OneTouch® Basic® • OneTouch® Fast*Take*® • OneTouch® SureStep® • OneTouch® Ultra®2 • OneTouch® UltraMini® • OneTouch® UltraEasy™
Bayer:	• Ascensia® BREEZE® • Ascensia® CONTOUR®
BD:	• Logic™
Bayer Ascensia® DEX® family, including these compatible meters:	• Ascensia® DEX® • Ascensia® DEX® 2 • Ascensia® DEXTER-Z® II • Glucometer® DEXTER-Z® • Ascensia® ESPRIT® 2 • Glucometer® ESPRIT® • Glucometer® ESPRIT® 2
Bayer Ascensia ELITE™ family, including these compatible meters:	• Ascensia ® ELITE® • Ascensia ® ELITE® XL

Manufacturer	Blood glucose meters
Abbott	• Precision Xtra™ • Abbott FreeStyle®, FreeStyle Flash™ • FreeStyle Papillion™ Mini • FreeStyle Mini™ • Optium Xceed™ • Precision Xceed™
Roche	• Accu-Chek® Aviva • Accu-Chek® CompactPlus • Accu-Chek® Compact • Accu-Chek® Active

Communication devices	
Com-Station	for use with the Medtronic MiniMed 508 Pump. (See the Com-Station User Guide for details about the required hardware.)
ComLink	for use with the MiniMed Paradigm Pump. (See the ComLink User Guide for details about the required hardware.)
Paradigm Link™ Blood Glucose Monitor	for use with a MiniMed Paradigm Pump. (See the Paradigm Link Blood Glucose Monitor User Guide for details about the required hardware.)
CareLink® USB	for use with a MiniMed Paradigm-series insulin pump.
Data communications cable	for use with third-party blood glucose meters. Each meter manufacturer supplies a data communications cable.

Equivalent devices

When you add a device to the system, you select its make and model from a list. If a device make and model is not on the list, refer to the following table to find an equivalent one to use.

If your patient uses one of these devices	Select this device
• Bayer Ascensia® DEX® 2 • Bayer Ascensia® DEX® • Bayer Ascensia® DEXTER-Z® • Bayer Glucometer® DEXTER-Z® • Bayer Ascensia® ESPRIT® 2 • Bayer Glucometer® ESPRIT® • Bayer Glucometer® ESPRIT® 2	The Bayer Ascensia® DEX®

If your patient uses one of these devices	Select this device
Bayer Glucometer ELITE® XL	The Bayer Ascensia ELITE™ XL

NOTE: Meters can be ordered from their respective companies.

Ordering

Contact one of the following to order Medtronic MiniMed products:

- 1-800-646-4633
- 1-818-362-5958

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/style	Meaning
Click	press the left mouse button over an object on the screen to select it
Double-click	press the left mouse button twice over an object on the screen to open it
Right-click	press the right mouse button over an object on the screen to display another window or menu
Bold text	used for a menu option or menu path. For example: **Patient > New Patient**
UPPER CASE text	indicates a button. For example: SAVE
Italicized text	used for screen and field names. For example: *Reports* screen
Indented	shows paths to files or directories. For example: **C:\Program Files\MM CareLink Pro**
NOTE:	additional information
CAUTION:	warns of a hazard which, if not avoided, may result in minor or moderate injury 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

The CareLink Pro system is intended for use as a tool to help manage diabetes. The purpose of this system is to take information transmitted from insulin pumps, glucose meters and continuous glucose monitoring systems, and turn it into CareLink Pro reports. The reports provide information that can be used to identify trends and track daily activities—such as carbohydrates consumed, meal times, insulin delivery, and glucose readings.

Warnings

- This system is intended to be used by a healthcare professional familiar with the management of diabetes.
- System results are not intended to produce medical advice and should not be relied upon for such purpose.
- This product should only be used with the supported devices listed in this document. (See *Supported devices, on page 4*.)
- Patients should be advised to monitor their blood glucose levels at least 4 -6 times a day.
- Patients should be advised not to make any changes to their treatment without consulting their healthcare professional.
- Patients should be advised to make treatment decisions based on healthcare professional guidelines and meter BG results, not glucose sensor results.

Contraindications

This software should not be used with devices that are not listed in *Supported devices, on page 4*. Nor should this product be used for the treatment of medical conditions other than diabetes.

Before opening this software, close any of the following software that is currently running on your computer:

- CGMS® System Solutions™ Software
- Solutions® Pumps & Meters Software
- Guardian® Solutions® Software
- ParadigmPAL™
- CareLink™ Personal
- Solutions® Software for CGMS® *i*Pro

Navigating the system 2

What's in this chapter

Overview

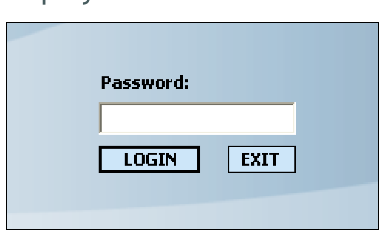
Use this chapter to familiarize yourself with the CareLink™ Pro graphical user interface (GUI). The user interface includes menus, a toolbar, a navigation bar, workspaces, and a Guide Me window.

Opening CareLink Pro

CareLink Pro desktop icon

1 Double-click the CareLink Pro icon on your computer desktop.

If your clinic requires you to enter a password, the login screen is displayed.

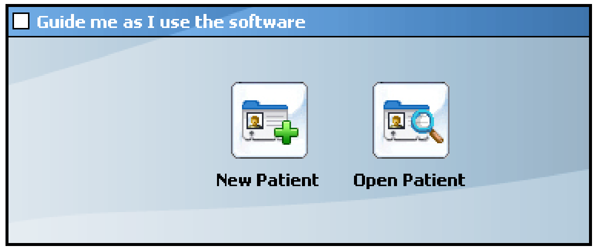


NOTE: Requiring a password is an optional feature that is set during the installation process.

a. Type your password into the *Password* field.

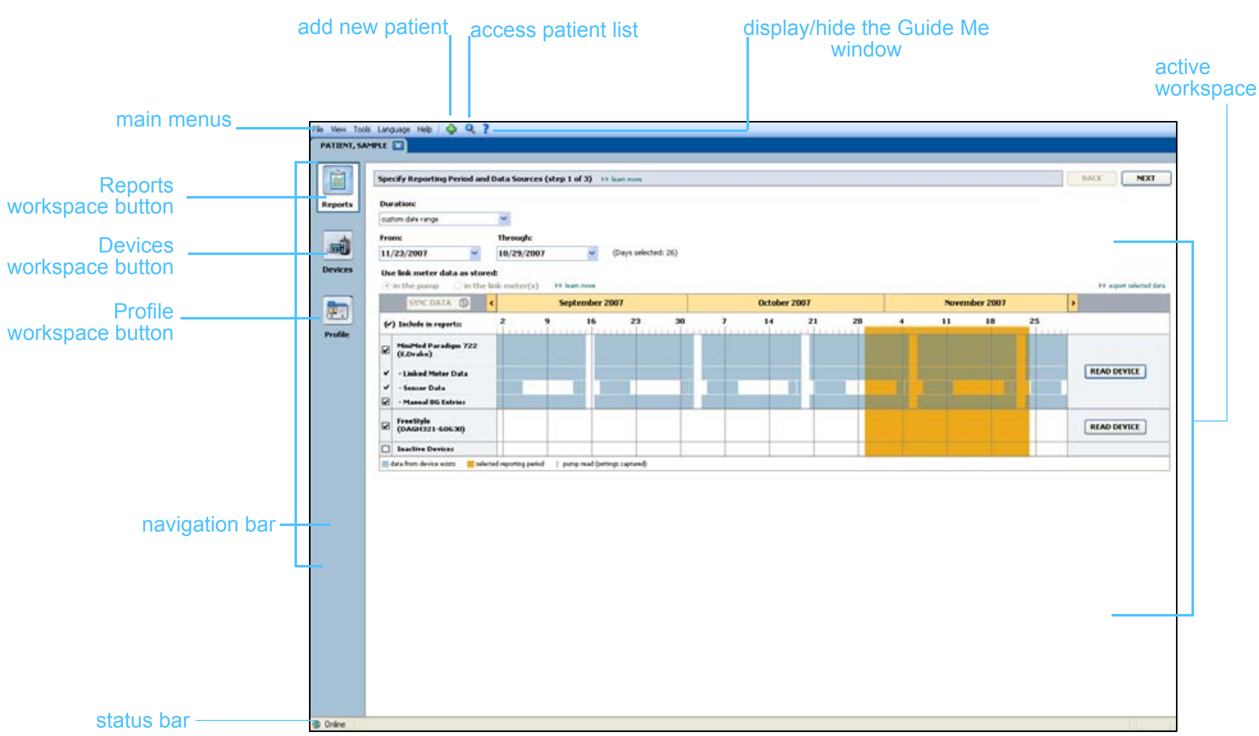
b. Click LOGIN.

The startup screen is displayed.



2 To start a new patient record, click NEW PATIENT. To open a patient record from a list of patients in the system, click OPEN PATIENT.

NOTE:If you see a message that the system is unavailable, it means a database backup or restore is in progress. See** When the system is unavailable, on page 59 **for more information.



Workspaces

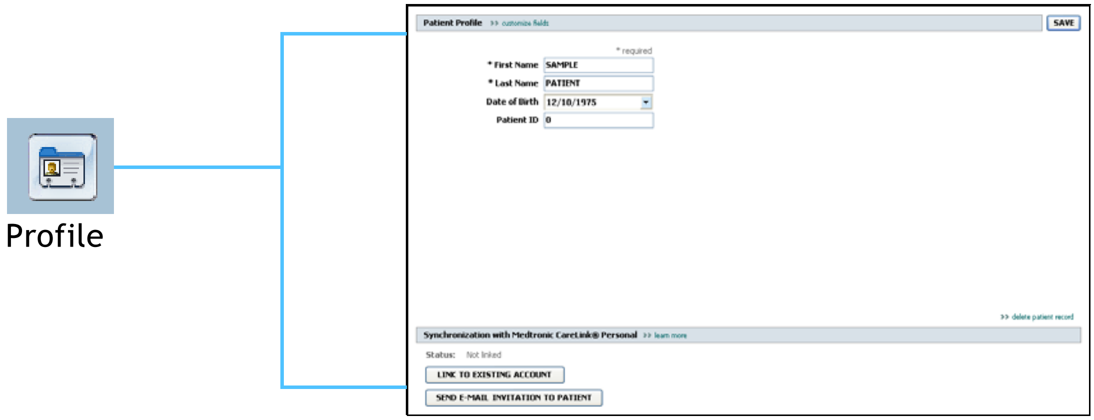
NOTE: See the other chapters of this user guide for details about the workspaces and how to use them.

If you have a patient’s record open, you can click one of the buttons on the navigation bar to display the corresponding workspace. Use these workspaces to enter or select information to perform CareLink Pro tasks for that patient.

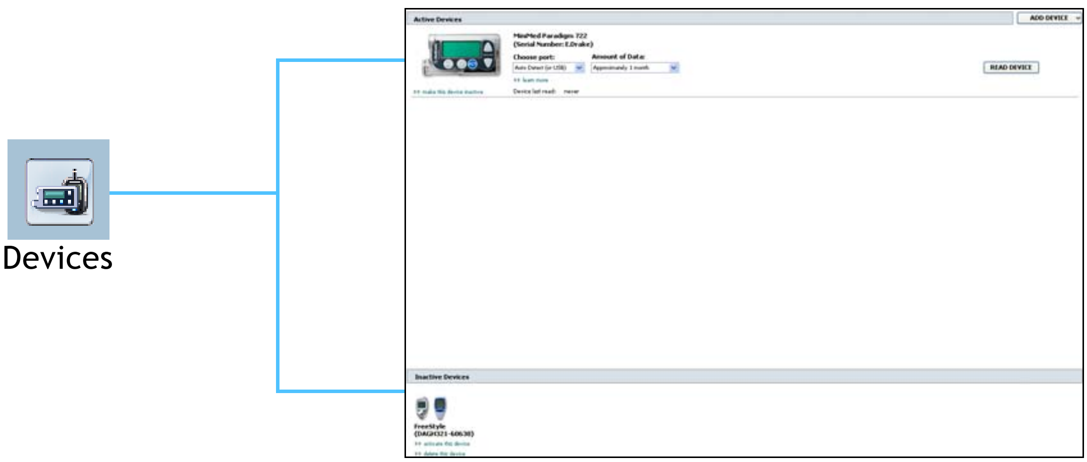
- **Profile:** Allows you to maintain such patient information stored as name and date of birth. This workspace also allows you to link to a patient’s CareLink Personal.
- **Devices:** Allows you to store information required to read a patient’s devices.
- **Reports:** Allows you to select parameters and choose reports to be generated for the patient.

Until a profile is added and saved for a patient, only the *Profile* workspace is accessible for that patient. Until devices are added for a patient, only the *Profile* and *Devices* workspaces are accessible for that patient.

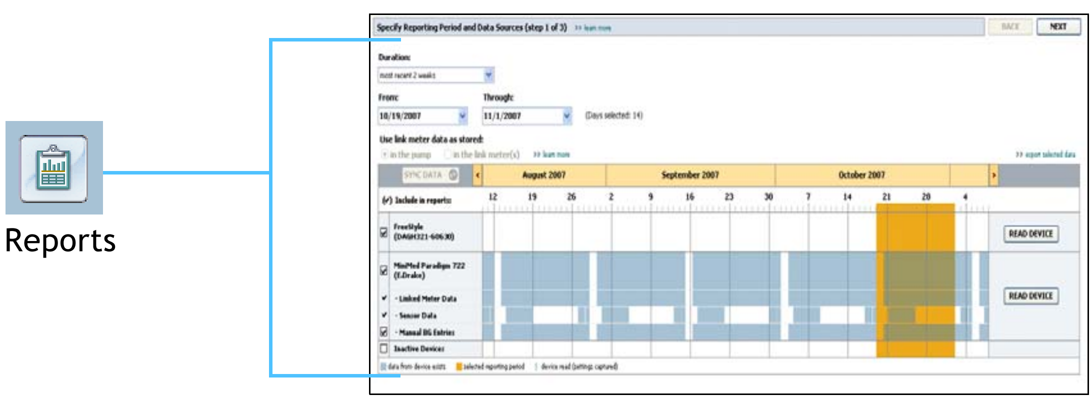
Workspaces



Profile workspace



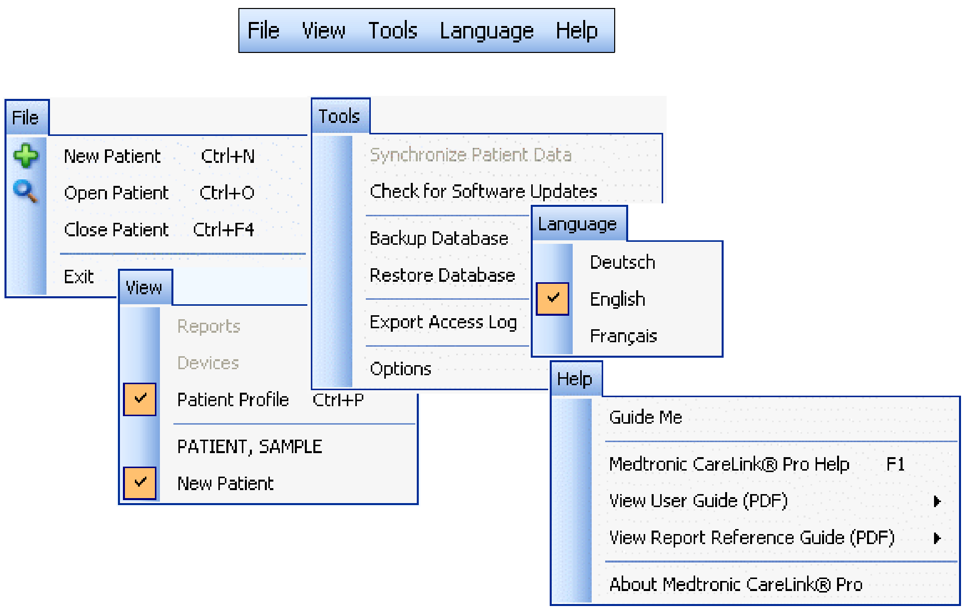
Devices workspace



Reports workspace

Main Menu bar

The following shows the options available through the main menu. Some of these menu options can also be accessed using the keyboard shortcut listed next to the menu option (e.g., Ctrl+N for New Patient). You can also use the navigation bar or the toolbar to access some menu options.



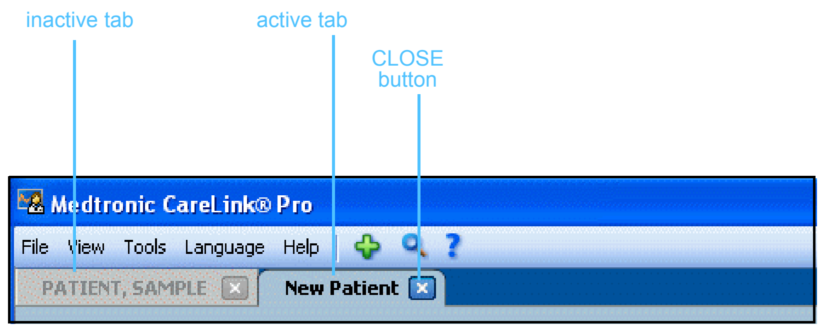
Toolbar

The CareLink Pro toolbar provides quick access to frequently used features. The toolbar contains the following buttons.

Button	Name	Functionality
	Add Patient	Opens a *Profile* workspace so you can add a new patient record to the system.
	Open Patient	Opens the Patient Lookup table where you can choose an existing patient's record to view.
	Guide Me	Displays or hides the Guide Me window. Click for context-aware system hints.

Patient tabs

Once you open a patient record, a tab is displayed along the toolbar with the patient's name on it. When a tab is active, it means that patient record and workspace are active, and you can perform CareLink Pro tasks for the patient.

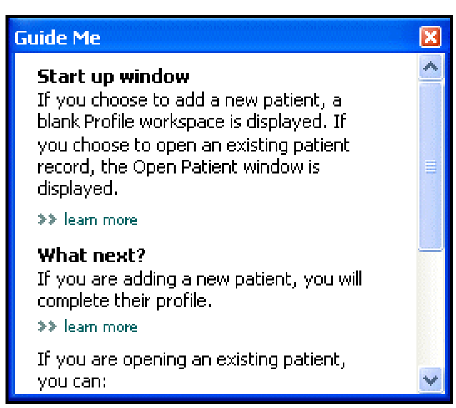



Close button

A patient's record can be made active simply by clicking on their patient tab. To close their record, click the CLOSE button on their tab.

The Guide Me feature

A Guide Me feature is provided throughout CareLink Pro. It opens a window with context-aware hints and tips for actions you might take from the part of system that is active. Guide Me windows might also include **>>learn more** links. When clicked, these links take you to the relevant section in the online help for more details. The Guide Me feature is enabled by default. However, you can turn it off at any time.



Turning Guide Me on and off

Guide Me button

Button option

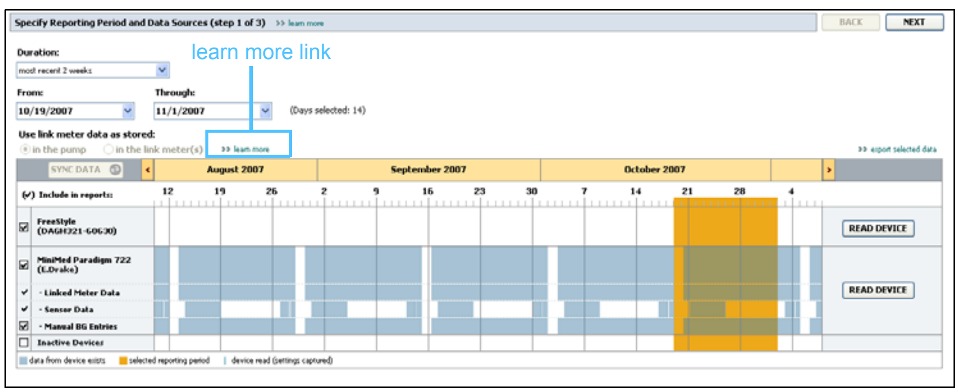
- Click the GUIDE ME button to either turn Guide Me on or off.

Menu option

- Select **Help** > **Guide Me** to select or deselect the feature.

Learn More links

Learn More links take you to a related topic in the online help system. They are provided throughout the system, within Guide Me windows or the software. Click **>> learn more** if you are unsure how to proceed or what values to enter.



Help system

The help system is available to assist you as you use CareLink Pro. It provides information about how to perform tasks in the software.

To access the help system, do one of the following:

- Select **Help** > **CareLink Pro Help**.
- Press the F1 button.

Getting Started

3

What's in this chapter

This chapter guides you through starting the CareLink™ Pro software, opening and closing patient records, and setting preferences that apply to all patients in the system.

Before you begin

If this is the first time you are using CareLink Pro, you should be sure to set the General preferences (see *General preferences, on page 18*). These preferences determine how certain items display in the software and in reports, and how you want the system to communicate with the Internet.

Preferences can be set at any time. You may want to wait until you are familiar with the CareLink Pro software to set the other preferences.

Primary system tasks

The following table outlines the main tasks you will want to perform when first setting up and using CareLink Pro. It also tells you which part of this user guide discusses each task.

Step	Location
Familiarize yourself with the CareLink Pro GUI.	*Chapter 2, Navigating the system*
Define the global system options your clinic will use.	*Setting system preferences, on page 18*
Create profiles for each of your patients.	*Adding new profiles, on page 25*
Link to your patients' CareLink Personal accounts.	*Linking to CareLink Personal (optional), on page 26*
Add your patient's pump and meters to their profile.	*Adding a device, on page 37*
Read data from your patient's pump and meters.	*Reading device data, on page 43*
Set up and generate reports for each of your patients.	*Creating reports, on page 46*
Regularly back up the CareLink Pro database.	*Backing up a database, on page 58*
Update the CareLink Pro software.	*Applying software updates, on page 57*

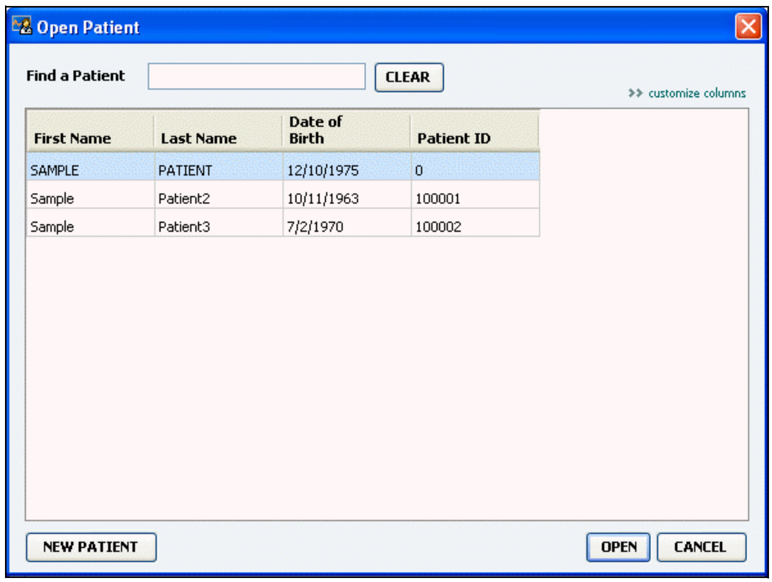
Opening and closing patient records

Opening patient records

As many as six patient records can be open at one time. If you have not yet created any patient profiles, see *Adding new profiles, on page 25*.

Open Patient button

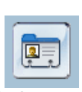
1 Select **File > Open Patient**, or click the OPEN PATIENT button. A patient list similar to the following is displayed.



NOTE: If you receive a message that you have too many patient records open, click OK, close a record, and continue.

2 Locate the patient's listing by typing some or all of their name in the *Find a Patient* field. When the patient's listing is highlighted, click OPEN, double-click the listing, or press ENTER. You can also navigate the list by using the up and down arrows on your keyboard.

The patient's *Devices* (if devices have not yet been added) or *Reports* workspace is displayed.



Profile button

3 To see the patient's *Profile* workspace, click the PROFILE button on the navigation bar.

Closing patient records

1 Make sure the patient record you want to close is active (the tab is highlighted).

2 Do one of the following:

a. Select **File > Close Patient.**

b. Click the CLOSE button on the patient tab.

close button

c. Press Ctrl-F4.

Setting system preferences

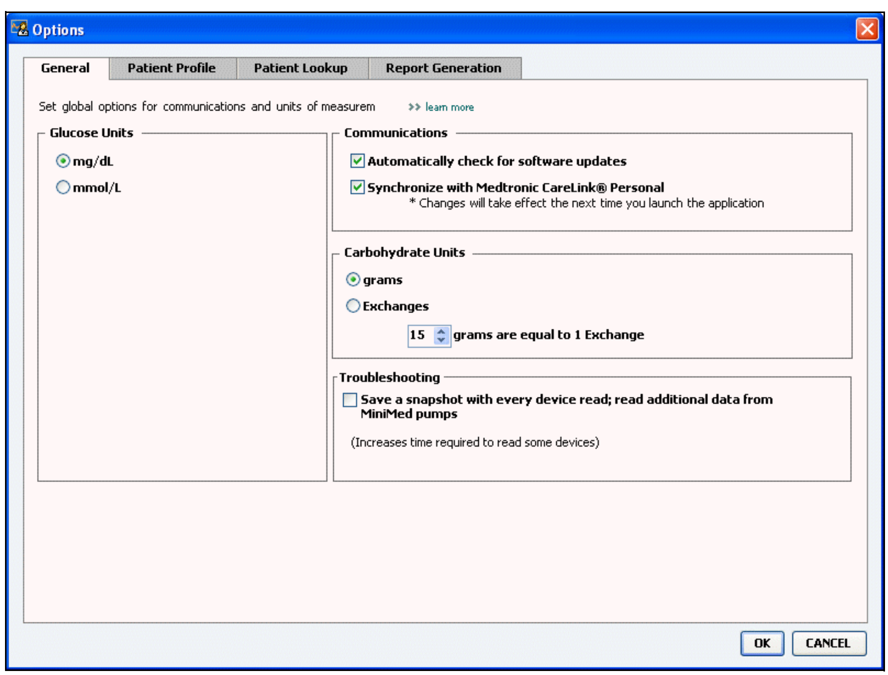
These preferences apply to all patients in the system. For preferences that affect only individual patients, see *Verifying report settings, on page 50*.

Preferences are displayed in the following groups:

- General
  - Glucose units
  - Carbohydrate units
  - Communications
  - Troubleshooting
- Patient Profile
  - Select and arrange data fields on patient profiles.
- Patient Lookup
  - Modify and change the order of fields displayed when you choose Open Patient to view a list of patients.
- Report Generation
  - Choose the data fields you want to display when selecting Daily Detail report input from the Data table.

General preferences

1 Select **Tools** > **Options**. The following window is displayed.



2 Click to select the option button for the value you want:

- *Glucose Units*: mg/dL or mmol/L
- *Carbohydrate Units*: grams or Exchanges

a. If you selected Exchanges for *Carbohydrate Units*, type the appropriate number in the *grams are equal to 1 Exchange* field.

3 For the following Communications, click to select the check box (enable), or to clear the check box (disable):

NOTE: Make sure you follow the guidelines of your clinic or IT department when setting communication preferences.

- ***Automatically check for software updates*****:** if selected, a notification will be sent to each system running CareLink Pro whenever a software update is available. The active user will then have the opportunity to download and install the updates. To prevent this from occurring and institute a controlled distribution of software updates, you can clear this check box.
- ***Synchronize with CareLink***™ Personal**:** If you want the system to automatically synchronize your patients' CareLink Personal data each time you open their profile, select the *Synchronize with CareLink Personal* check box. If you clear this check box, you will have to manually synchronize the CareLink Personal data for each patient.

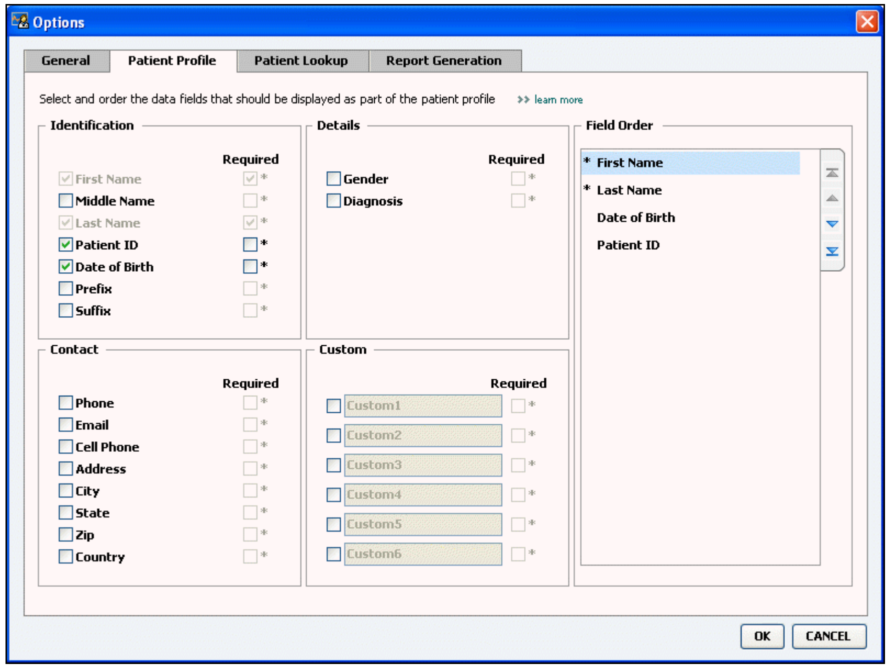
4 Click to select or clear the check box in the Troubleshooting section. If the check box is selected, the application will save a record of device reads for troubleshooting purposes.

5 Click OK to save the General preferences.

Patient profile preferences

1 Select **Tools> Options**.

2 Click the *Patient Profile* tab. The following window is displayed.



Use the check boxes to choose the fields you want on the profile. Use the up and down arrows to put the fields in order.

Choosing data fields

NOTE: First and Last Name cannot be removed.

1 Use the check boxes to add the fields you want.

2 To remove a field from the profile, clear its check box.

3 To make a field required, select the check box in the *Required* column. Any field that is required must be filled in before a profile can be created.

Adding a custom field

1 Select the check box to the left of an empty custom field.

2 Enter text to name the field (e.g., Emergency Contact). This is the field name that will display on the patient profile.

3 To make the field required, select the check box in the *Required* column.

NOTE: To remove a custom field from the profile, clear the check box next to the field(s) you want to remove.

Up & Down arrows

Changing the order of data fields

- Select the field you want to move, and click the up or down arrow to move it. (The arrows at the top and bottom move a field all the way to the top or bottom of the list.)

Finalizing patient profile preferences

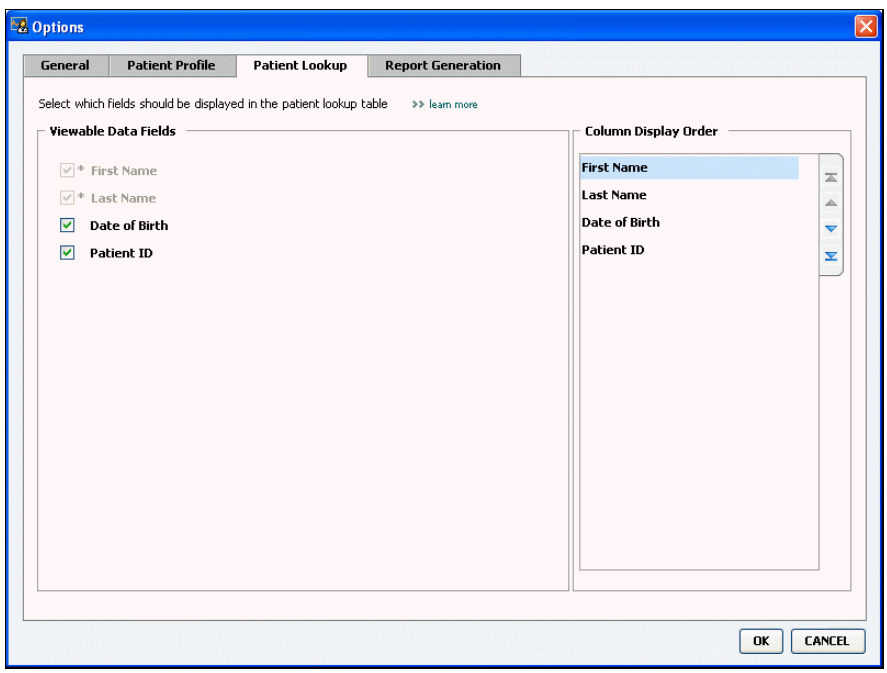
- When the Field Order list has all the fields you want in the correct order, click OK.

  Patient profiles now have the fields and field order you just selected.

Patient Lookup preferences

1 Select **Tools> Options**.

2 Click the *Patient Lookup* tab. The following window is displayed.



Use the check boxes to choose the data you want on the Patient Lookup table. Use the up and down arrows to put the columns in order.

Choosing data to display

- Use the check boxes to select the type of data you want to display, or to clear data you do not want to display on the Patient Lookup table.

NOTE: First and Last Name cannot be removed.

Up & Down arrows

Changing the column order

- To change the order of columns on the Patient Lookup table, select the column to move, and click the up or down arrows. (The arrows at the top and bottom move a data column all the way to the top or bottom of the list.)

NOTE: The data column at the top of the Column Display Order list will display in the first column of the Patient Lookup table. The data column at the bottom will be displayed in the last column of the table.

Finalizing patient lookup preferences

- When the Column Display Order list has all the data you want in the correct order, click OK.

  The Patient Lookup table will now have the data and column order you just selected.

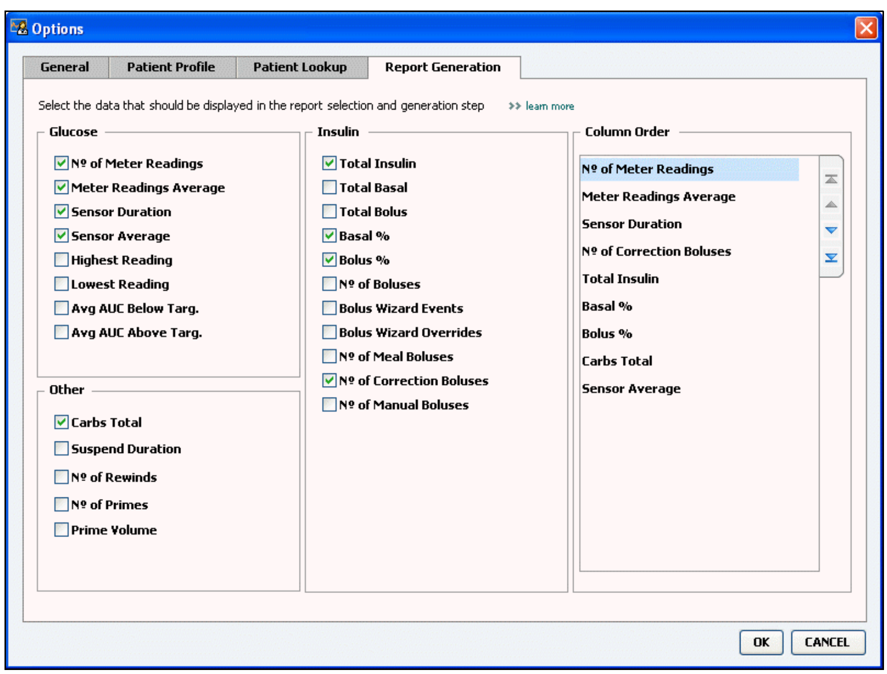
Report Generation preferences

The Data Table is displayed during the selection portion of the report generation process. This table should include data the healthcare professional finds most useful in deciding the dates for which they want to see Daily Detail reports.

NOTE: To see how these preferences apply to the Data Table during report creation, see Selecting report types and inclusion dates, on page 51.

1 Select **Tools> Options**.

2 Click the *Report Generation* tab. The following window is displayed.

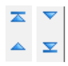


Use the check boxes to choose the type of data you want on the Data Table. Use the up and down arrows to put the columns in order.

Choosing data to display

- Use the check boxes to select the type of data you want to display or clear data you do not want to display on the Data Table.

Changing the column order



Up & Down arrows

- To change the order of columns on the Data Table, select the column to move, and click the up or down arrow. (The top and bottom arrows move a data column all the way to the top or bottom of the list.)

NOTE: Items at the top of the Column Order list will display in the first column of the Data Table. Items at the bottom will be displayed in the last column of the Data Table.

Finalizing report generation preferences

- When the Column Order list has all the data you want in the correct order, click OK.

  The Data Table will now have the data and column order you just selected.

Profile workspace

4

What's in this chapter

A profile is similar to the cover page of a medical chart. It stores patient data such as name and date of birth. A profile is required before device data can be gathered and used for therapy reports.

The Profile workspace also allows you set up a link to a patient's CareLink Personal account. Once the link is established, you can retrieve patient data stored on CareLink Personal anytime—without the need to have the patient present.

Before you begin

You may want to customize your patient profiles so they contain only the type of information you want to collect. To learn more, see *Patient profile preferences, on page 20*.

Also, a username and password is required when you set up the link to a patient's CareLink Personal account. The patient must be present to supply this data.

Adding new profiles

Each time you add a patient to the CareLink Pro system, you must start by filling out a profile for them.

Add Patient button

***NOTE:** To add or change fields on the patient profile, click* **>>customize fields.** *See Patient profile preferences, on page 20.*

1. Select **File > New Patient**, or click the ADD PATIENT button.

   The *Profile* workspace is displayed (see the example on *page 11*).

2. Fill in the fields in the *Patient Profile* section.
3. Click SAVE.

   The new patient profile is added to the CareLink Pro database. A message is displayed that confirms the profile was saved.

Completing required fields

1. If a required field is not complete when you save a patient profile, a message is displayed next to that field. You will not be allowed to save the profile until you make an entry in the field.
2. Complete the field.
3. Click SAVE.
4. When the confirmation message displays, click OK.

Editing patient profiles

1. Make sure the patient's *Profile* workspace is open.
2. Click EDIT.
3. Edit the data in the *Patient Profile* section as needed.
4. Click SAVE.

   A message is displayed that confirms the profile was saved.

Deleting patient data from the system

1. Make sure the patient's *Profile* workspace is open.
2. Verify that this is the patient you want to delete. Deleting a patient profile also removes all of their data from the CareLink Pro database and cannot be undone.
3. Click >> **delete patient record** above the synchronization section of the profile.

   A message is displayed to alert you that all of the patient's data will be erased when you delete the record.

4 Click YES to delete the patient's record.

Linking to CareLink Personal (optional)

If your patient permits it, you can set up a link to their CareLink Personal account. This Web-based tool allows patients to upload and store device-derived data, and to run various therapy reports.

Once you link to the patient's CareLink Personal account, you can retrieve the device data they store there. This is ideal for creating CareLink Pro therapy reports between office visits. It also reduces the need to read the patient's device in the office.

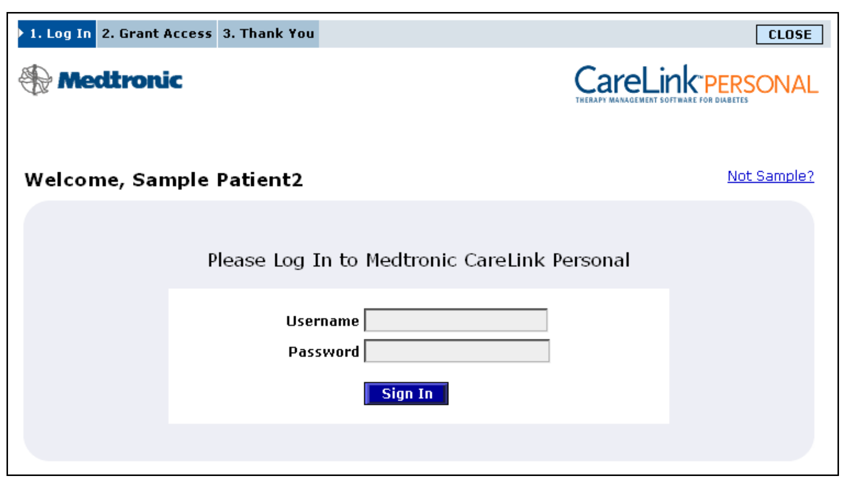
If a patient does not yet have a CareLink Personal account, you can send them an e-mail inviting them to establish one.

Linking to an existing account

NOTE: The patient must be present to complete these steps.

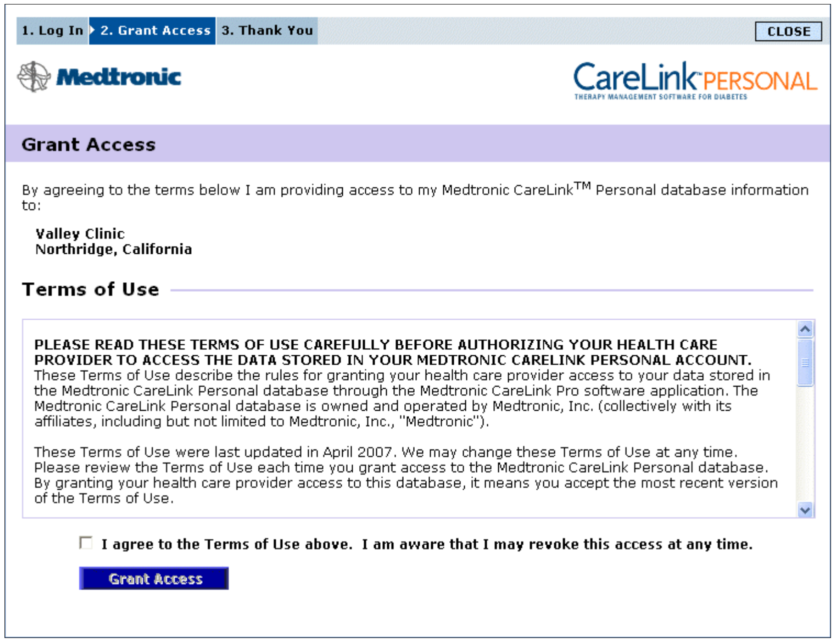
1. Make sure you are connected to the Internet.
2. Open the patient's *Profile* workspace.
3. Make sure all required fields in the *Patient Profile* section are filled in.
4. Click LINK TO EXISTING ACCOUNT.

   The CareLink Personal Log In screen is displayed.



5. Have the patient do the following:
   - a. Type in their Username and Password.
   - b. Click SIGN IN.

A Grant of Access page is displayed, based on the patient’s enrollment settings for language and region.



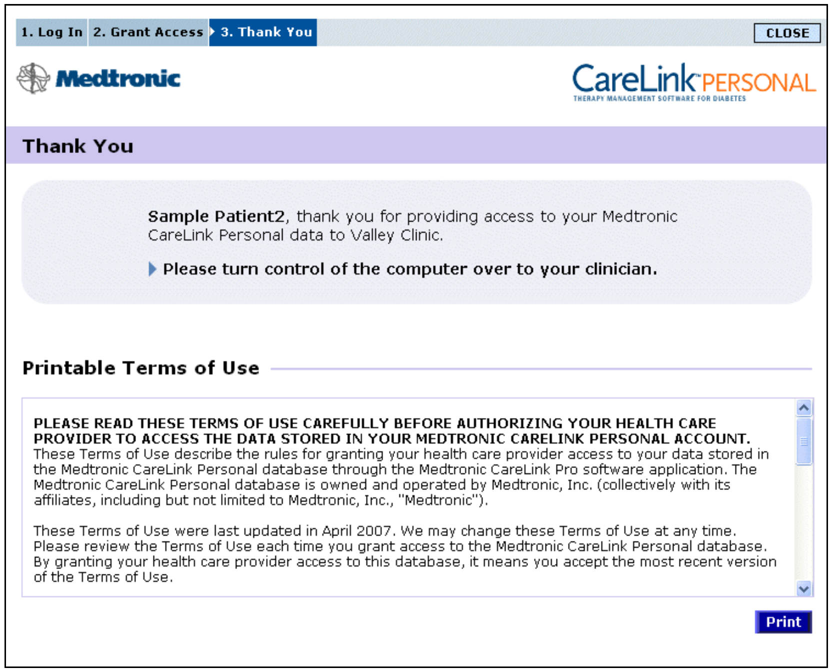
6 Have the patient do the following:

a. Read the Terms of Use.

b. Click to check the box next to *I agree to the Terms of Use above...*

c. Click GRANT ACCESS.

d. Let you know when the Thank You page is displayed.



You can print the Terms of Use for the patient by clicking the PRINT button.

You are now linked to this patient’s CareLink Personal account. See *Getting data from a linked account, on page 29*.

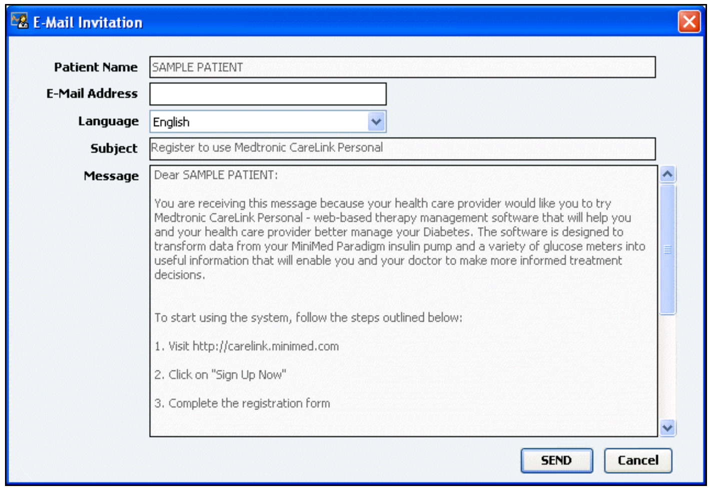
Sending an e-mail invitation

To send an e-mail invitation a patient to establish a CareLink Personal account, follow these steps:

1 Open the patient’s *Profile* workspace.

2 Make sure all required fields in the *Patient Profile* section are filled in.

3 Click SEND E-MAIL INVITATION TO PATIENT.



4 Make sure *Patient Name*, *Email* and *Language*... are filled in correctly.

5 Click SEND.

The patient’s profile status area confirms the e-mail was sent.

Unlinking a patient’s CareLink Personal account from CareLink Pro

You can unlink a patient’s CareLink Personal account from CareLink Pro. This option is only available after a patient has been linked. It prevents CareLink Pro from continuing to retrieve data from the patient's CareLink Personal account. It does not affect the patient's personal usage of their CareLink Personal account.

1 Open the patient's record and access the Profile workspace.

2 Click UNLINK ACCOUNT.

3 Click Yes at the confirmation message. The patient's personal profile is no longer linked to CareLink Pro.

The status is changed to "Not linked," and the LINK TO EXISTING ACCOUNT and SEND E-MAIL INVITATION TO PATIENT buttons are now displayed.

Getting data from a linked account

If you are linked to a patient’s CareLink Personal account, any new data from this account is automatically sent each time you open their patient profile in CareLink Pro.

NOTE: To ensure this happens, go to Tools > Options > General, *and make sure there is a check next to "Synchronize with CareLink Personal."*

Follow these steps to get a patient's CareLink Personal data any time after you have opened their patient profile:

1. Make sure the patient's *Profile* workspace is open, and that you are connected to the Internet.
2. Select **Tools > Synchronize Patient Data**.

   The sync icon on the patient's tab rotates. When the icon stops, the process is complete.

sync icon

NOTE: If the patient no longer wants to share their CareLink Personal data, a message displays to let you know.

3. Any additional data retrieved from CareLink Personal will show up in the patient's reports.

Hardware setup

5

What's in this chapter

This chapter provides diagrams that show how to set up a patient's device so your computer can read data from it.

You have to have the patient's device in order to read data directly from it. However, you can get device data from a patient's CareLink™ Personal account, without reading it from their device.

Before you begin

To read data directly from a device, you must have the patient's device. You must also have any cables or other communication devices you need to send device data to your computer.

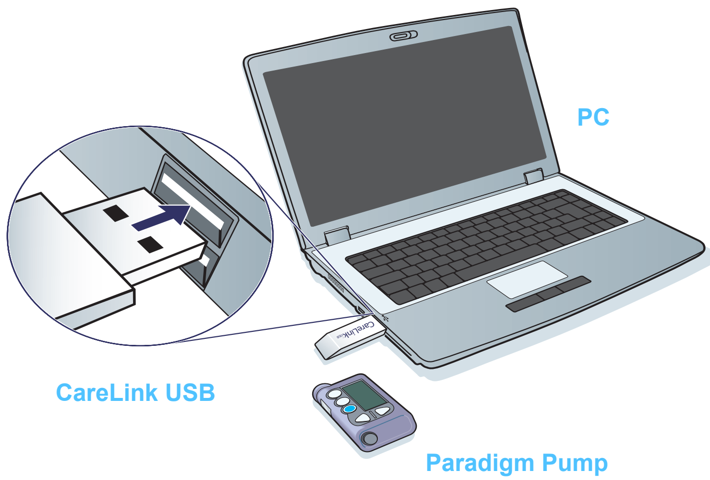
Connecting devices

NOTE: For more details, follow the instructions CareLink™ Pro displays as you are reading devices.

Review the overview diagram to get a general idea of how devices should be set up to communicate with the computer. The diagrams that follow illustrate specific aspects of device communication.

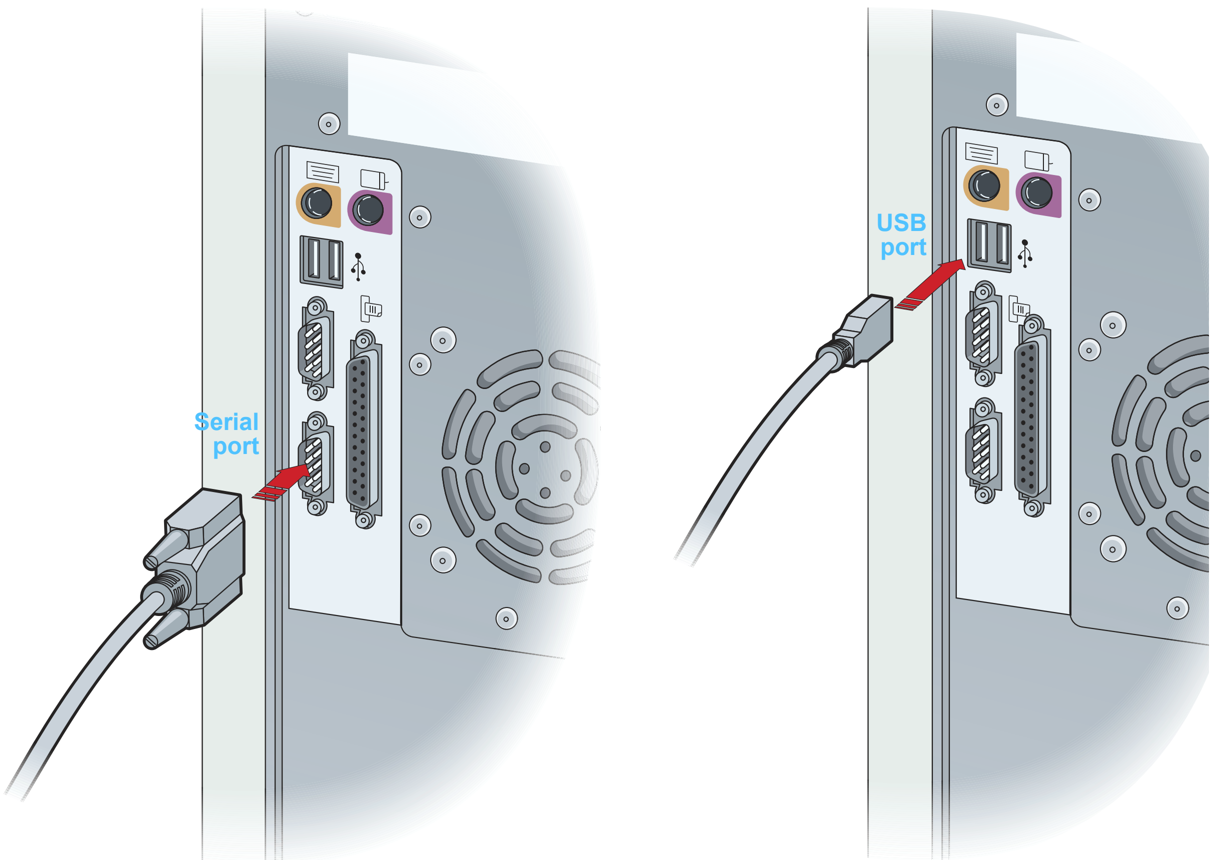
Overview of hardware setup

NOTE: This example shows the ComLink being used to communicate between the pump and the computer.

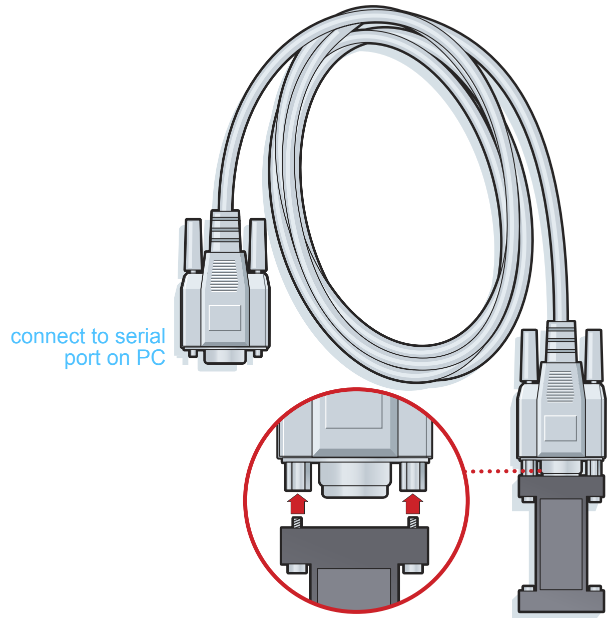


Hardware connection diagrams

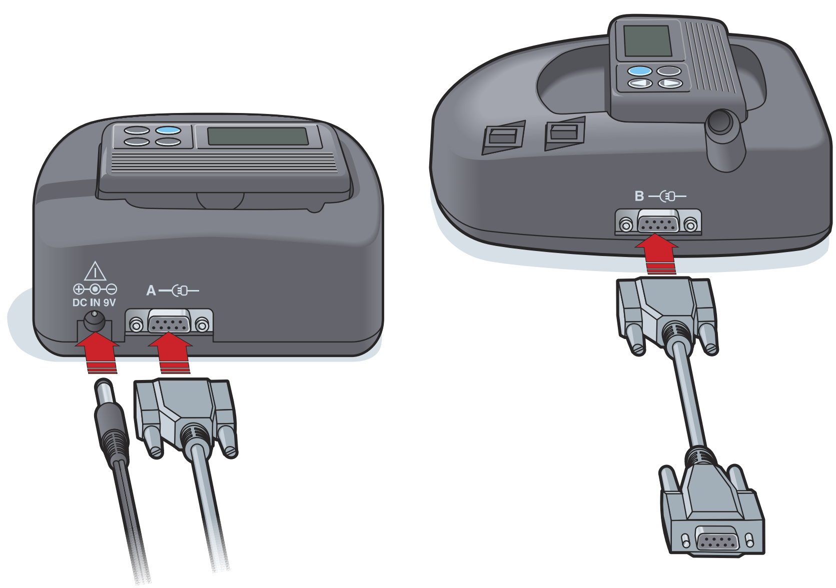
PC Connections



Optional components

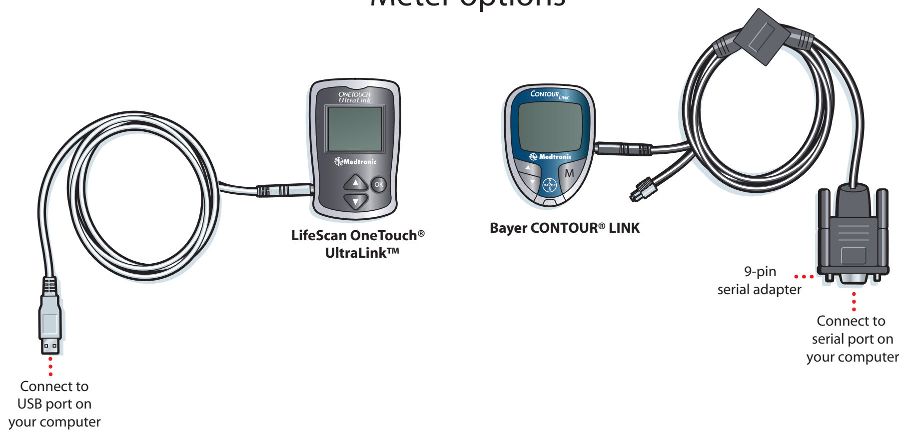


ComLink for use with the Paradigm series pump



Com-Station for use with MiniMed 508 pumps and for meter pass-through

Meter options



NOTE: The picture above shows a few examples of the many supported meters.

Devices workspace

6

What's in this chapter

Information you need to read a patient's device (make, model, serial number, etc.) is stored in the The *Devices* workspace. Thus, you do not have to supply it each time you read data from the device.

Devices on the *Devices* workspace are stored in one of two lists—*Active Devices* or *Inactive Devices*. When you add a device, it is automatically placed on the *Active Devices* list. You can only read data from devices displayed in the *Active Devices* list. These will likely be the devices your patient currently uses.

Other devices that belong to the patient, but are not currently used, can be stored in the *Inactive Devices* list. This keeps the information on file. These devices can be made active at any time.

Before you begin

Before you can open the *Devices* workspace for a patient, they must have a profile saved in the system. See *Chapter 4, Profile workspace.*

To add a device or read data directly from it, the device must be in communication with the computer. See *Chapter 5, Hardware setup* to learn how to set up devices to communicate with the computer.

Adding a device

To add a device to a patient's record, you must have the device in communication with the computer so the connection can be tested.

You can get data from the patient's CareLink Personal account for a device not yet added. Such devices will automatically be added when data is synchronized between CareLink Personal and CareLink Pro.

NOTE: There can only be one active pump per patient. Adding a new pump will move the existing one to the inactive list.

Adding a Medtronic pump

1 Make sure the pump you are adding is set up to communicate with the computer. (See *Chapter 5, Hardware setup* for connection steps.)

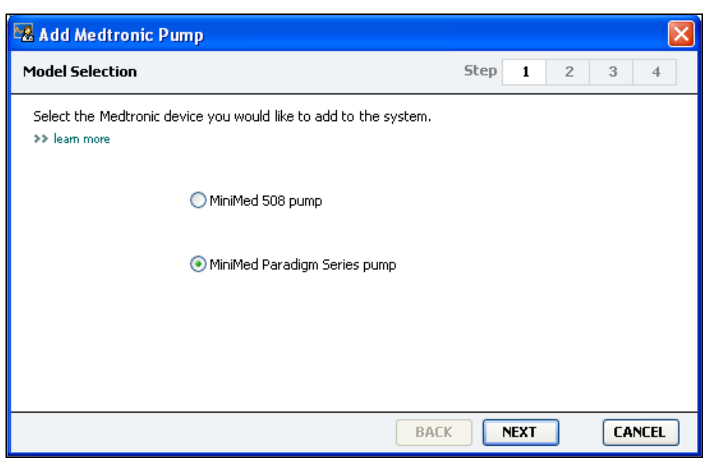
2 Click the patient's tab. Or double-click their name on the Patient Lookup table.

DEVICES button

3 Click DEVICES to access the patient's *Devices* workspace (see the example on *page 11*).

4 Click ADD DEVICE.

5 Select **Medtronic Pump**. The *Add Medtronic Pump* Wizard is displayed.

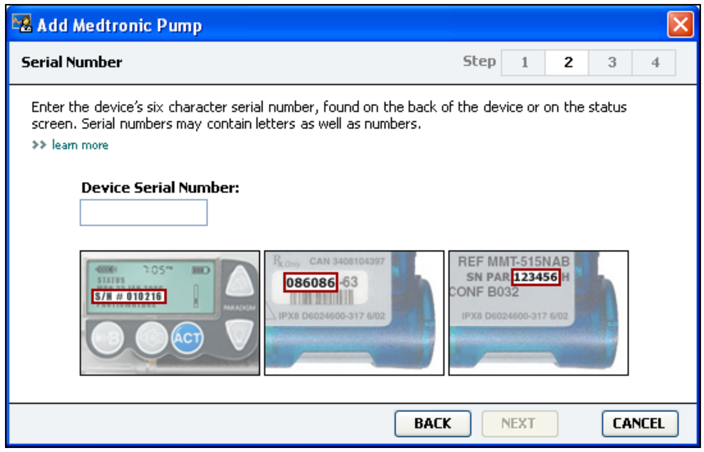


NOTE: The pump model is listed on the back of the pump or on the pump status screen.

6 Select the option button to specify the device you are adding.

If you selected the **MiniMed 508 pump** option, go to Step 9.

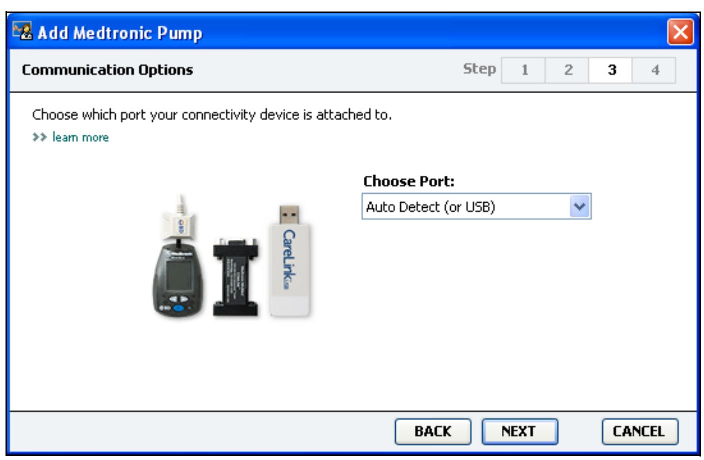
7 Click NEXT. The *Serial Number* page is displayed.



NOTE: An error message is displayed if you do not enter the correct serial number. Check the examples on this page, and verify that you are entering the correct characters from the back of the pump. If necessary, re-type the six characters.

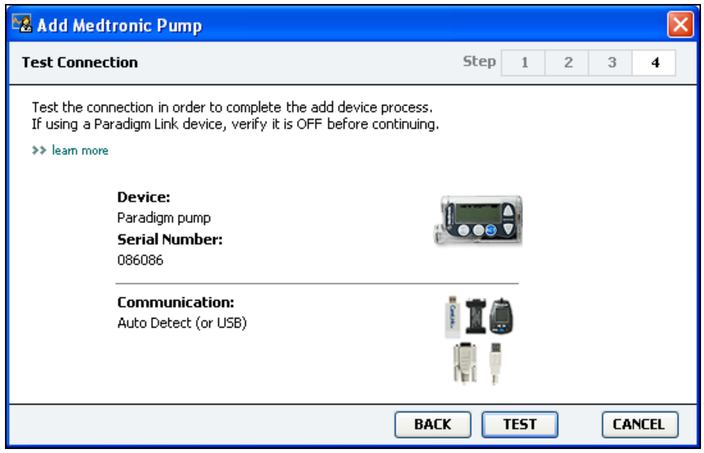
8 Use the examples on this page to help locate the six-character serial number on the device you are adding. (If you need more help in locating it, click **>>learn more**.) Type the six characters in the *Device Serial Number* field.

9 Click NEXT. A *Communication Options* page similar to the following is displayed.



10 Click the *Choose Port* arrow, and select the port that the ComLink, Paradigm Link, CareLink USB, or Com-Station connects to on your computer. If you are not sure which port to choose, select **Auto Detect (or USB)**.

11 Click NEXT. The *Test Connection* page similar to the following is displayed.



12 Follow any device instructions, and click TEST.

A message displays to let you know if the connection was successful. If it was, go to the next step.

NOTE: This Test does not read pump data, but verifies correct communications between the pump and the computer.

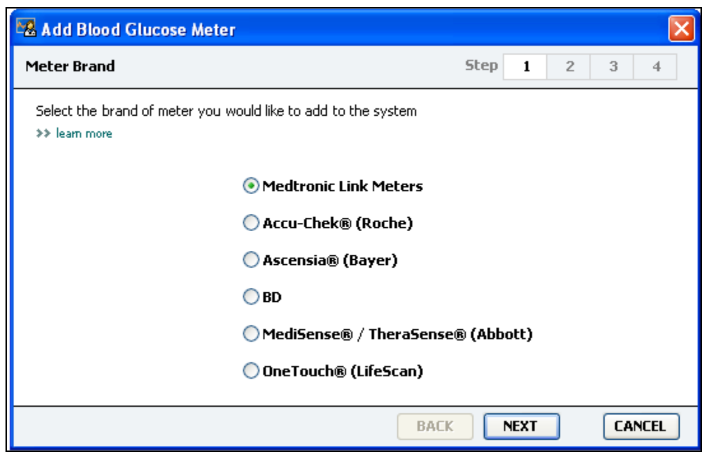
If not, make sure the hardware between the device and the computer is connected properly. Also, click BACK on the pages of the wizard to make sure the device data you have entered is correct.

13 Click DONE.

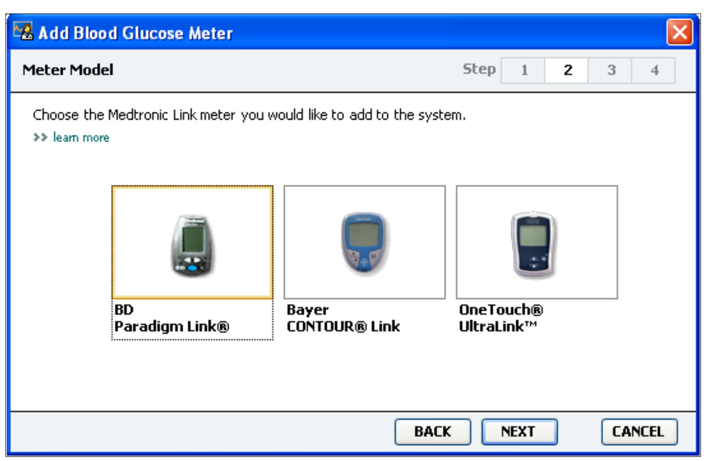
The pump is added to the patient's *Active Devices* list.

Adding a meter

1. Click the patient’s tab. Or double-click their name on the Patient Lookup table.
2. Make sure the meter you are adding is in communication with the computer. (See *Chapter 5, Hardware setup* for connection steps.)
3. Click DEVICES to access the patient’s *Devices* workspace (see the example on *page 11*).
4. Click the ADD DEVICE button.
5. Select **Blood Glucose Meter**. The *Add Blood Glucose Meter* Wizard is displayed.

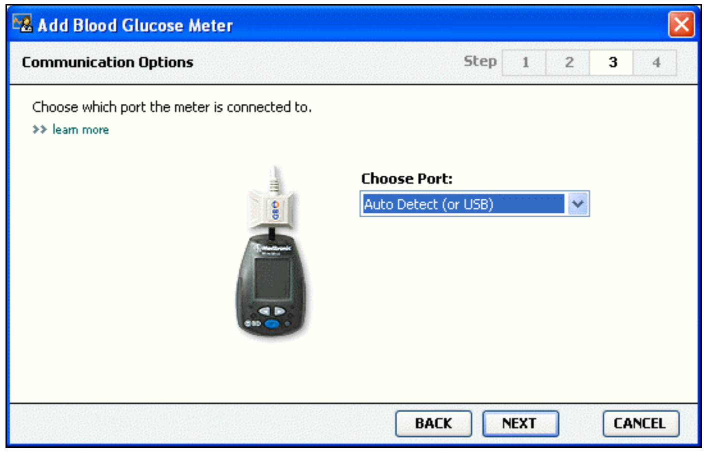


6. Click the option button to select the correct brand of meter.
7. Click NEXT. The *Meter Model* page is displayed (this page differs depending on the meter manufacturer).



8. Click to select the meter model you are adding.

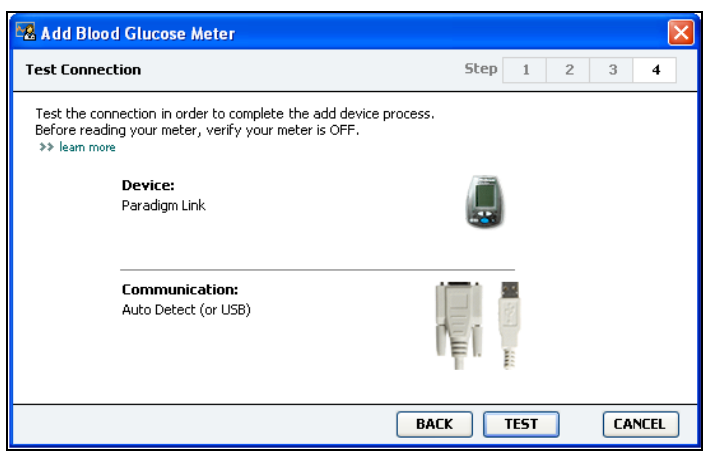
9 Click NEXT. The *Communication Options* page is displayed.



NOTE: Only those choices that are valid for the meter you are adding are available for selection.

10 Click the *Choose Port* arrow, and select the port that the ComLink, Paradigm Link, or CareLink USB connects to on your computer. If you are not sure which port to choose, select **Auto Detect (or USB)**.

11 Click NEXT. The *Test Connection* page is displayed.



12 Follow the instructions given for the meter, and click TEST.

A message displays to let you know if the connection was successful. If it was, go to the next step.

If not, make sure the hardware between the device and the computer is connected properly. Also, click BACK on the wizard to make sure the data you have entered is correct.

13 Click DONE.

The meter is added to the patient's *Active Devices* list.

Making a device active or inactive

Patient devices can be moved between the *Active Devices* list and the *Inactive Devices* list as needed. A device must be active in order to read data from it.

You can have as many meters as you want on the *Active Devices* list, but only one pump. Make sure you want to inactivate the current active pump before you add a new one.

Inactivating a device

1 Click the patient's tab. Or double-click their name on the Patient Lookup table.

2 Click DEVICES to access the patient's *Devices* workspace.

NOTE: Devices may be listed under an equivalent device name. See Equivalent devices, on page 5.

3 Click >> **make this device inactive** under the device you want to make inactive.

The device moves to the *Inactive Devices* list.

Re-activating a device

1 Click the patient's tab. Or double-click their name on the Patient Lookup table.

2 Click DEVICES. The patient's *Devices* workspace is displayed.

NOTE: Devices may be listed under an equivalent device name. See Equivalent devices, on page 5.

3 Click >> **activate this device** under the device you want to make active.

The device moves to the *Active Devices* list.

Deleting a device

These steps will delete a device and its data from the *Devices* workspace and the CareLink Pro system:

1 Click the patient's tab. Or double-click their name on the Patient Lookup table.

2 Click DEVICES to access the patient's *Devices* workspace.

NOTE: Devices may be listed under an equivalent device name. See Equivalent devices, on page 5.

3 Make sure the device is on the *Inactive Devices* list. If it is not, click >> **Inactivate this device** under its current listing.

4 Click >> **delete this device** under the device you want to delete.

A message is displayed to alert you that the device and all of its data will be removed from the patient's record.

5. Click YES to delete the device.

   The device and its data is removed from the *Devices* workspace and from the CareLink Pro system. Data from this device is no longer available for use in reports.

Reading device data

One way to get device data is to link to the patient's existing CareLink Personal account. (See *Linking to CareLink Personal (optional), on page 26*.) Another way is to read it directly from their device, as described in this chapter.

Data from your patient's device can be read by CareLink Pro if the device is on the *Active Devices* list and it is in communication with the computer. Once you get this data, you can use it to create reports that help assess the patient's therapy management. (See *Chapter 7, Reports workspace* to learn more about reports.)

CareLink Pro can also gather data from your insulin pump including:

- Various settings on the pump, such as the alert mode, the beep volume and the time display
- Basal insulin amounts delivered
- Bolus insulin types and amounts delivered
- Bolus Wizard entries
- Priming amounts
- Suspend periods
- Sensor glucose readings over a period of time

The system gathers blood glucose data from your glucose meter during a device read.

WARNING: Please cancel or finish any temp basals or active boluses, and clear any active alarms. The pump will be suspended for reading. Once the read is complete, please verify the pump has resumed.

CAUTION: Do not use the pump remote when the pump is being read.

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.

1 Click the patient's tab. Or double-click their name on the Patient Lookup table.

2 Make sure the patient's device is in communication with the computer. (See *Chapter 5, Hardware setup*.)

3 Click DEVICES to access the patient's *Devices* workspace.

***NOTE: Devices may be listed under an equivalent device name. See** Equivalent devices, on page 5.*

4 Find the device you want to get data from on the *Active Devices* list, and make sure the *Choose port* data is correct.

- For pumps click the *Amount of Data* arrow and select how much pump data you want CareLink Pro to read.

5 Click the associated READ DEVICE button.

6 Follow device-specific instructions, and click OK.

7 CareLink Pro displays a progress bar that updates to show how much of the device read has been completed.

If you click CANCEL as the device is being read, a message is displayed to alert you that cancelling the action may result in the loss of all of the data read so far.

- To cancel, click YES.
- To continue reading device data, click NO.

When the system finishes reading data from the device, you will see a message that confirms the device read is complete.

8 Click OK.

- For pumps, follow the instructions for taking it out of suspend mode.

If CareLink Pro is unable to get data from the device, see *Chapter 9, Troubleshooting* for further guidance.

Reports workspace

7

What’s in this chapter

The CareLink™ Pro Reports workspace allows you to transform device-derived data into clinically useful information. For the report types you can create see *About reports, on page 53*.

Reports can be generated on screen, sent directly to a printer, or saved as TIFF or PDF files that you can attach to an Electronic Medical Record (EMR). You can generate several report types through a single operation.

The data displayed through these reports is captured from the patient’s devices, from their CareLink Personal account, or from both.

Before you begin

If you have a period of time you want reflected in a report, you must have a patient’s device data for that time period. You may also need to have the patient’s device connected to the computer to get current data before running reports.

Be sure to take a close look at the *Verify Report Settings* step before running a report. This is where you can fine tune a report to capture the patient data you want.

Creating reports

The following sections describe the steps involved in creating one or more reports.

Opening the Reports workspace

Open Patient button

1 Click the patient's tab. Or, click the OPEN PATIENT button and double-click their name.

The *Reports* workspace is displayed (see the example on *page 11*).

Selecting the reporting period

NOTE: To make sure you have the latest device data from the patient's CareLink Personal account, click SYNC DATA.

1 To change how much time is reflected in the report(s), click the *Duration* arrow and select the amount of time. (The maximum duration is 12 weeks.)

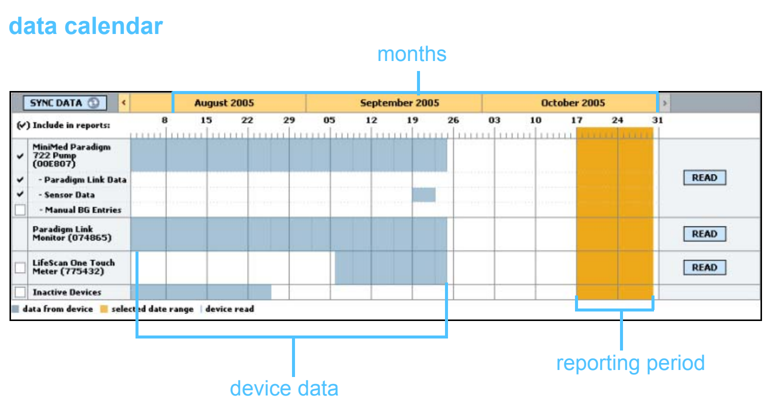
2 From and through dates are automatically set, unless you choose the *custom date range* option.

NOTE: If you select a date range longer than allowed, you get an error message. Adjust the duration or dates.

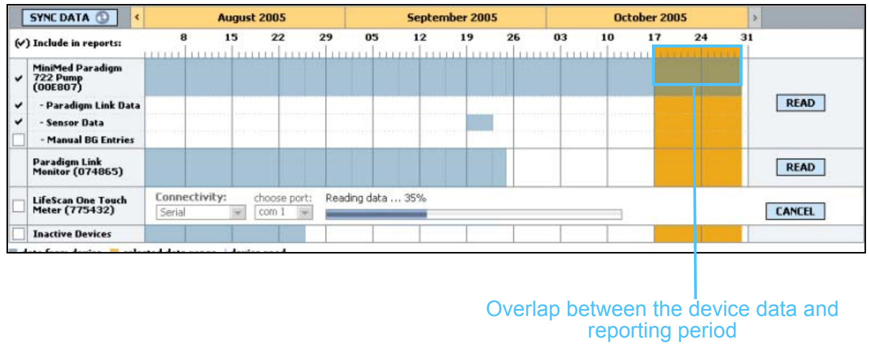
If you want a custom date range, click the *From* or *Through* drop-down arrows and select the desired month, date or year.

Data calendar

The data calendar area of the *Reports* workspace shows a three-month window of reporting information. It lists devices, and it shows how much device data is contained in the selected three months. It also shows the duration of the reporting period for the selected three months.



Overlap in the device data and reporting period means you have data for some or all of the displayed reporting period.




arrow buttons

The data calendar area initially displays the most current three months. To see other months, click the arrow buttons on either end of the months.

Selecting source data to include

1 If the patient uses a BG meter that links to their pump, click to choose one of the following options for reporting meter BG data:

- *in the pump*: Advantages of this selection include that you only have to read data from the patient's pump, BG readings are time stamped by the pump, and the readings are tied directly to any Bolus Wizard calculations used. A disadvantage is that if there are communication difficulties between the pump and the linked meter, BG readings during that time may not get reported. Also, for MiniMed Paradigm pumps prior to the 522/722, any BG readings from Bolus Wizard calculations that are not acted on do not get reported.
- *in the link meter(s)*: The advantage of this selection is that all readings stored in the linked meter are reported. The disadvantage is that to correlate meter and pump data, you must have made sure that the pump and meter clocks were synchronized with one another. You must also read data from the pump and the linked meter separately.

2 To add device data to reports, select the check box next to the relevant device.

You cannot add devices that were excluded due to your selection in step 1. To change this, select the other linked meter option.

3 To exclude device data from reports, clear the check box next to the relevant device.

You cannot clear check marks related to the option you selected in step 1. To change these, select the other linked meter option.

Checking for device data

1 Look at the data calendar area of the *Reports* workspace to see if the reporting period overlaps with the device data (see the example on *page 47*).

2 If the bars overlap for the entire reporting period, you have data for your report(s). You can click NEXT and go to *Verifying report settings, on page 50*.

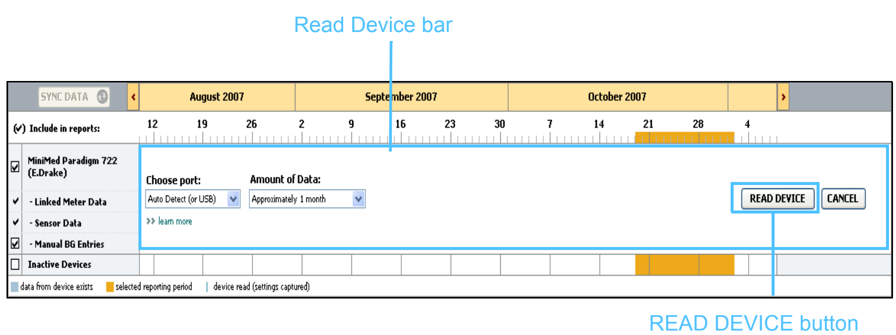
3 If the bars do not overlap, or there is not enough overlap, you have a few choices:

- Adjust the reporting period (see *Selecting the reporting period, on page 46*).
- Get additional device data (see *Getting additional device data (optional), on page 48*).

Getting additional device data (optional)

1 To get more data from a device, click the READ DEVICE button associated with the device.

The Read Device bar is displayed.



WARNING: Please cancel or finish any temp basals or active boluses, and clear any active alarms. The pump will be suspended for reading. Once the read is complete, please verify the pump has resumed.

CAUTION: Do not use the pump remote when the pump is being read.

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

2 Verify that the data in the *Choose port* field is correct for this device.

To change this setting, click the arrow for the field and select a different setting.

3 Make sure the device is connected to your computer.

4 If the device is a pump, you can specify how much data to get from it. Click the *Amount of Data* arrow and select an amount.

NOTE: If you select All available data, the system reads all data in the pump. This overwrites any existing duplicate data in the system.

5 Click READ DEVICE. Be sure to read the message that is displayed carefully because it provides specific instructions for reading the pump.

6 Follow the instructions and click OK.

The read device progress bar is displayed.

You can choose to cancel the read at any time by clicking CANCEL.

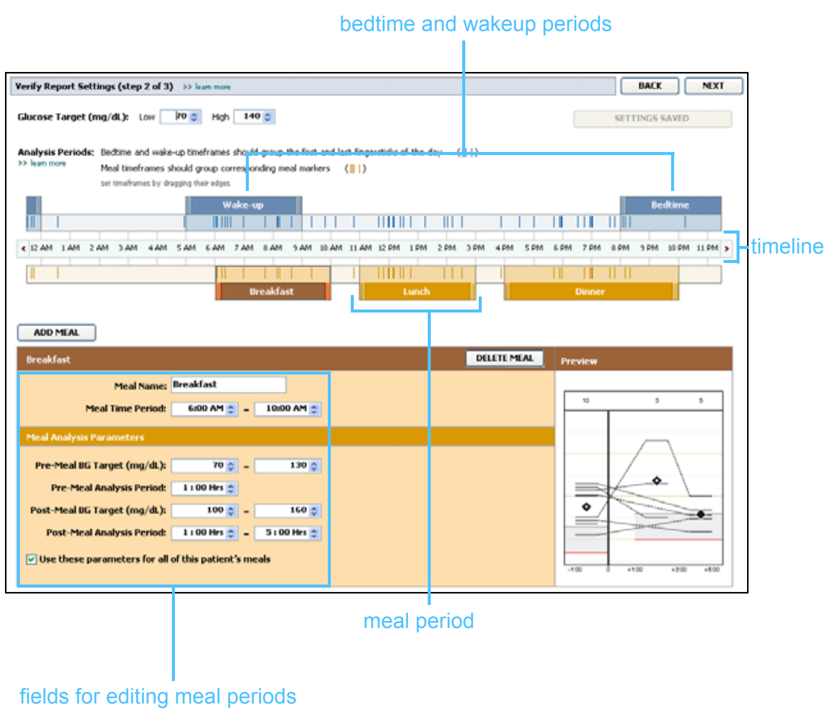
A message is displayed to confirm that the read is complete.

7 Click OK.

Device data should now overlap with the reporting period.

8 Click NEXT at the top of the *Reports* workspace.

The Verify Report Settings step is displayed. This allows you to make sure the settings for this patient are correct before you run the report(s).



Verifying report settings

1 Make sure the *Glucose Target* settings are correct. Type the correct values, or click the up or down arrows in the *Low* and *High* fields to raise or lower values.

NOTE: You can have as many as five meal periods. The defaults are breakfast, lunch and dinner.

2 To add a new meal period to the *Meal Settings*, click ADD MEAL. To edit an existing meal period, click anywhere within one of the meal periods along the timeline.

The Meal Period editor becomes active.

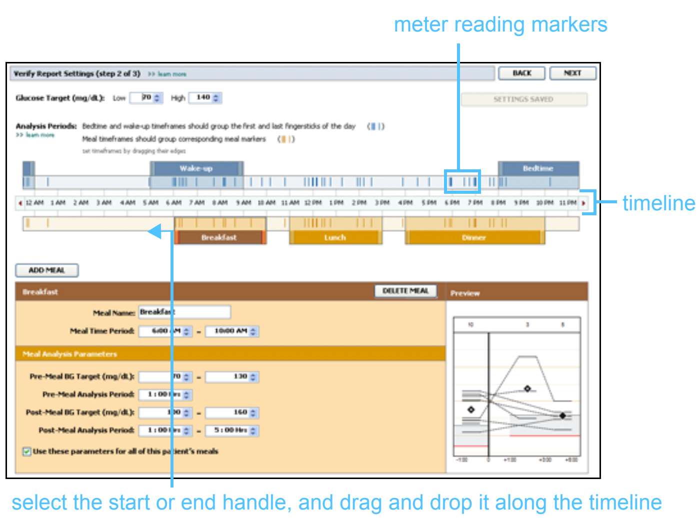
3 Enter text or click arrows to select the settings you want.

NOTE: If you only want to use these settings for this meal, de-select the check box next to Use these parameters for all of this patient's meals.

- **Meal Name:** name you want to assign to the meal period.
- **Meal Time Period:** hours between which the meal occurs.
- **Pre-Meal BG Target (mg/dL or mmol/L):** low and high ends of the patient's before-meal glucose target range.
- **Pre-Meal Analysis Period:** how much time before the start of the meal will glucose be analyzed for the report. The meter readings captured during this time are used in detailed report analysis.
- **Post-Meal BG Target (mg/dL or mmol/L):** low and high ends of the patient's post-meal glucose target range.
- **Post-Meal Analysis Period:** how much time after a meal will glucose be analyzed for the report. The meter readings captured during this time are used in 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.

You can change the length of an existing meal period or wakeup and bedtime period by clicking on the start or end handles, and dragging and dropping them along the timeline.



4 To use the settings from this meal for all of the patient's other meals, make sure the check box next to *Use these parameters for all of this patient's meals* is selected.

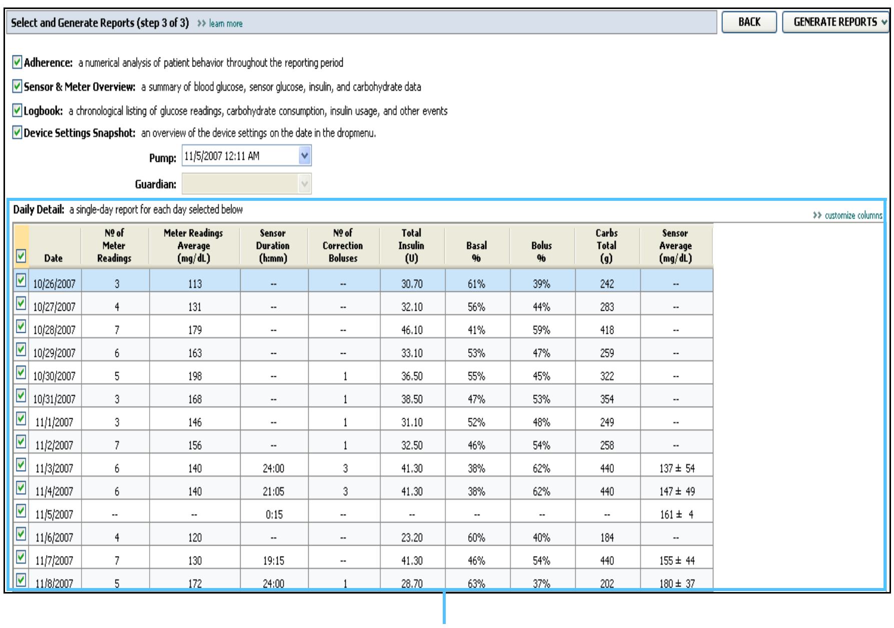
5 After you finish creating or editing a meal period, click SAVE.

6 To remove a meal period, click DELETE MEAL. Click DELETE when asked to confirm.

7 CareLink Pro can remember these settings for this patient the next time you run a report for them. To save them for this patient, click SAVE SETTINGS.

8 Click NEXT at the top of the *Reports* workspace.

This is the Select and Generate Reports step of the process. It provides a list of report types as well as a Data Table that helps you choose to include or exclude certain days of data from the Daily Detail report(s).



Date	№ of Meter Readings	Meter Readings Average (mg/dL)	Sensor Duration (h:mm)	№ of Correction Boluses	Total Insulin (U)	Basal %	Bolus %	Carbs Total (g)	Sensor Average (mg/dL)
10/26/2007	3	113	--	--	30.70	61%	39%	242	--
10/27/2007	4	131	--	--	32.10	56%	44%	283	--
10/28/2007	7	179	--	--	46.10	41%	59%	418	--
10/29/2007	6	163	--	--	33.10	53%	47%	259	--
10/30/2007	5	198	--	1	36.50	55%	45%	322	--
10/31/2007	3	168	--	1	38.50	47%	53%	354	--
11/1/2007	3	146	--	1	31.10	52%	48%	249	--
11/2/2007	7	156	--	1	32.50	46%	54%	258	--
11/3/2007	6	140	24:00	3	41.30	38%	62%	440	137 ± 54
11/4/2007	6	140	21:05	3	41.30	38%	62%	440	147 ± 49
11/5/2007	--	--	0:15	--	--	--	--	--	161 ± 4
11/6/2007	4	120	--	--	23.20	60%	40%	184	--
11/7/2007	7	130	19:15	--	41.30	46%	54%	440	155 ± 44
11/8/2007	5	172	24:00	1	28.70	63%	37%	202	180 ± 37

NOTE: To modify the Data Table display, click **>>customize columns**. *See* Report Generation preferences, *on page 22.*

Selecting report types and inclusion dates

1 Select the check box next to the report(s) you want to include in the report set.

2 If data has been read from a pump more than once during this reporting period, there may be multiple device snapshots:

a. Make sure the check box is selected next to *Device Settings Snapshot*.

b. Click the drop-down arrow and select a snapshot date and time.

If the field is dimmed, there are no snapshots available during the reporting period.

3 Scroll though the Data Table to review the available Daily Detail report information.

- You can sort the data in each column. Click the column heading to sort the data in ascending order. Click the heading again to sort the data in descending order.

NOTE: If there is no data for a certain date, that date cannot be selected.

4 Select the check box in the Data Table rows for any date for which you want a *Daily Detail* report.

- To include or exclude all Daily Detail report dates with one click, select the check box at the top of the Data Table check box column.

Generating reports

1 After you verify your report selections, click GENERATE REPORTS at the top of the *Reports* workspace.

A list of options is displayed.

2 Select an option to preview, print, or save the report(s).

If you selected *Preview*, the *Preview* window is displayed.

3 Click the arrow buttons to navigate through multi-page reports.

4 Click one of the other buttons at the top of the *Preview* window to save or print the report(s).

CLOSE PREVIEW button

5 To close this window, click the CLOSE button in the upper right corner of the window.

About reports

This section provides a description of each report. More 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 the CareLink Pro software:

1 **Help > View Report Reference Guide (PDF).**
2 Select a language for the Report Reference Guide.

The CareLink Pro reports share these common elements:

NOTE: If the reporting period is longer than 14 days, the report will have multiple pages.

- **Report header** — The report header contains identifying information, such as the name of the report, the patient's name, and the source of the data.
- **Carbohydrates and blood glucose levels** — Within the graphs and charts, carbohydrate units are displayed in italics and blood glucose levels are displayed in bold.
- **Weekend data** — Weekend days are in bold so you can easily identify them.
- **Legends** — A legend of symbols appears at the bottom of each report. While a symbol may be used in multiple reports, the legends are unique to each report.

Adherence Report

This report presents data that describes how insulin pumps and sensors are used and the patient's behavior relevant to their therapy. It answers the question, "Was there enough data to provide an accurate picture of how the patient uses their insulin pump and sensor, if applicable" It also answers the question, "Do patients adhere to the therapy as instructed?" It also indicates whether you may need to speak to your patient about the way they are managing their diabetes.

Sensor and Meter Overview Report

The Sensor and Meter Overview Report provides a graphical representation of the patient's daily meter-derived glucose levels and averages, including hourly breakdowns over 24 hours and as they relate to their meals and sleep patterns. Statistics on the patient's glucose readings and insulin usage are also included.

A similar analysis of sensor data is generated as the first page of this report if sensor data is available. When no sensor data is available, the meter data analysis page will be generated as the first page.

The final page(s) of the report shows the day-to-day level and quality of your patient’s glycemic, carbohydrate, and insulin control. Each page shows how that control varies during each day across the entire reporting period up to a 14 day maximum per page.

Logbook Report

The Logbook report provides meter glucose, carbohydrate, and insulin data for each day in the reporting period. It provides a diary of events recorded hourly, as well as daily averages and totals. Each page contains up to 14 days. If the reporting period exceeds 14 days, extra pages are generated.

Device Settings Snapshot

This report presents a snapshot of the settings for the patient's pump for a specific date and time. This can help you understand other reports or can simply document your patients' settings.

The pump settings are recorded only when the device is read. If the device was not read during the reporting period, no settings will be available.

Daily Detail Report

The Daily Detail report shows glucose data, carb amounts, and the patient’s insulin usage for the selected day. A separate report is generated for each day you select from the Data Table.

The Daily Detail report provides a detailed look at each day you select. It allows you to focus on a particular day if you feel something of interest to the patient’s therapy was occurring.

Exporting data

You can export device data that is acquired and stored by CareLink Pro. This gives you all of a patient’s device data to use for statistics or the creation of specialized reports or charts. The .csv file can be imported into Microsoft Excel or certain clinical statistics programs where you can further manipulate the data.

The .csv file contains data recording the actions of the device. For example, it lists the recording of meter readings, the pump receiving the meter reading value, or 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 CareLink Pro export feature:

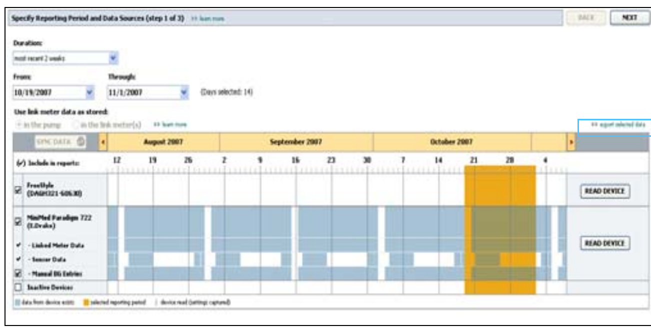
1 Click the patient's tab. Or, click the Open Patient button and double click their name.

2 Make sure the *Reports* workspace is displayed.

3 Use the *Duration* or *From/Through* fields to set the dates and length of the report.

The maximum duration you can select is 12 weeks.

4 Click the *export selected data* link.



The Export Data to CSV File dialog box is displayed.

5 To change where you store the .csv file on your computer, click the arrow to the right of the *Save in* field and select a location.

6 If you want to change the name of the file, type it into the *File name* box.

7 Click SAVE.

The .csv file is now saved on your computer in the location you selected. You can now choose to import it into any program that supports this file type.

NOTE: For more information about the data displayed in CSV files, see CSV data, on page 65.

System administration 8

What's in this chapter

It is important that you regularly back up the CareLink™ Pro database. The database stores all system data that has accumulated in your patient's records, including profile information, device-derived data, and report settings.

CareLink Pro lets you save copies of the database and restore them.

It is also important that you have the latest version of CareLink Pro. Updated versions are available periodically, and may contain important enhancements. You can choose to search for updates or to be notified when they are available.

Before you begin

It is a good idea to establish a regular schedule by which to perform database backups. This will help ensure that it is done regularly, and will minimize the risk of data loss.

During backup or restore, CareLink Pro detects other users who may be using the software on other computers, and offers them a chance to save their work. However, it is still good practice to check for other users before starting either process.

Applying software updates

Automatically receiving updates

There will be occasional updates to the CareLink Pro software. When notice of an update is displayed, take the following steps to download the latest software release.

***NOTE: The database should be backed up before a software update is applied. See** Backing up a database, on page 58.*

1 Make sure an Internet connection is available and active on your computer.

2 The CareLink Pro Update message is displayed when there is an update to CareLink Pro. It gives you the option to download the update.

3 Click DOWNLOAD. (If you click CANCEL, the update notice will close. You can download the update at a later time.)

A warning message is displayed that recommends backing up your database.

4 Click YES to create a backup of your database (see *Backing up a database, on page 58* for this procedure). Click NO if you do not choose to back up your data.

A message will display to confirm that the new version of CareLink Pro has been downloaded.

5 To begin using the latest version of CareLink Pro, click YES to close and re-open the software application. Click NO if you would prefer to wait before re-starting CareLink Pro.

Turning off automatic updates

If you do not want to receive automatic notification of CareLink Pro updates, follow these steps:

1 Select **Tools > Options**.

2 Click the *General* tab.

3 Under the Communications section, clear the check box next to *Automatically check for software updates*.

Manually checking for updates

You can manually check for CareLink Pro updates at any time.

NOTE: The database should be backed up before a software update is applied. See *Backing up a database, on page 58.*

1 Make sure an Internet connection is available and active on your computer.

2 Select **Tools > Check for Software Updates**

3 You will receive a message if no updates are currently available. If an update is available, a CareLink Pro Update message is displayed.

4 Follow the procedure in *Automatically receiving updates, on page 57*.

Backing up and restoring the database

Backing up a database

The following steps let you back up the current database to the location you select.

1 Make sure all patient records are closed.

2 Select **Tools > Backup Database**.

NOTE: Database backups can be saved on a network drive, or to removable storage (DVD, CD, USB drive, etc.).

3 To save the backup to a different location on your computer, click the arrow on the right of the *Save in* field and select a new location.

4 If you want to change the name of the backup file, type it into the *File name* box.

5 Click SAVE. A progress bar is displayed while the database is saved.

A message is displayed when the backup is complete.

6 Click OK to close the message.

Restoring a database

The current database may need to be replaced if it can no longer be accessed or used. The more current your backup, the less data you will lose if you replace the database.

CAUTION: Before you restore, make sure the existing database is no longer useful. When you restore with a backup copy, you lose all the new data created since the selected backup copy was made.

The following steps let you select a backup copy to replace the current database.

1 Make sure all patient records are closed.

2 Select **Tools > Restore Database**.

3 Use the *Look in* field to select the location from which to copy the backup database.

4 Select the backup file you want to use to replace the current database (usually the most recent).

5 Click OPEN. A warning message is displayed to remind you about the data that may be lost if you continue the database restore.

6 To continue, click OK. A progress bar is displayed while the database is being restored.

   A message is displayed when the database is restored.

7 Click OK to close the message.

When the system is unavailable

If you attempt to use the system, you may receive a message notifying you that the system is not available. This means that another user is already in the process of backing up or restoring the database. No other users can access the system until the task is complete.

Do one of the following:

- Wait for the process to complete and for the system to become available.
- Click CANCEL to exit and try again later.

Troubleshooting

9

What's in this chapter

This chapter is designed to help you solve issues that may occur while using CareLink™ Pro software. It also contains instructions for uninstalling the CareLink Pro software if the need for that should arise.

General application use errors

Privileges to download software upgrades over the Internet

If you try to download a software upgrade over the Internet, you may receive the message that you do not have sufficient privileges to do so. You must have administrative privileges to download CareLink Pro software upgrades.

1. Close the CareLink Pro software application, and restart your computer system.
2. Have someone with administrative privileges log in to the computer.
3. Follow the instructions in *Applying software updates, on page 57*.

Not connected to the database

An error message stating that you are not connected to the database indicates one of the following:

- The database has been moved. The database must be located in the same place that was selected during installation of the CareLink Pro software. If it has been moved, it must be moved back to the location selected during installation.
- You are not connected to the network drive where the database is located. If the database is located on a network drive, the network may occasionally experience problems that prevent you from accessing the drive. Contact your computer support department for help in reconnecting to the network drive where the database is located.

Forgot the clinic password for CareLink Pro

If no one can remember the password your clinic uses to log in to CareLink Pro, the only solution is for the CareLink Pro software to be re-installed, and a new database created.

Device read errors

Read Device Error	Explanation
The selected serial port could not be opened. Another operation might be in progress on that port. Please wait until the port is available, or select another port.	Please verify that the com port selected is not in use by another program, or select a different port. Try rebooting the computer you are using and then try the device read again. The hardware (cable, etc.) connected to the port or the port itself may be bad. Connect the hardware to another port and try the device read again to help determine the problem.
Auto Detect could not find the device on any available port. Please check the cable connection, device battery & status and try again, or try specifying a serial port.	Check the connection between the cable and the PC, and verify that the device battery status is fine. If so, try specifying the PC serial port to which the cable is connected, rather than selecting Auto Detect.
Device not found at selected serial port. Please check the cable connection, device battery & status and try again, try selecting a different port, or try to Auto Detect the device.	Check the connection between the cable and the PC, and verify that the device battery status is fine. If so, try either selecting a different PC serial port number, or choose the Auto Detect option.

Read Device Error	Explanation
Unable to communicate with the device. Please ensure you've attached and selected the correct device, check the cable connection, device battery and status, and try again.	Verify all settings selected for the device read, including device name, serial number and type of connection. Also check to make sure that the device, cable and PC are connected properly. Verify the battery and alarm status of the device is okay. Try the read again.
Unexpected response... retrying (n%)	An unexpected value was read from the device. The system retries communication until you cancel or communication succeeds.
The communication device was found, but the pump (<serial #>) is not responding. Please verify the pump's serial number, place the pump closer to the communication device to minimize interference, check pump battery and status.	Verify that the correct pump serial number was entered. If not, re-enter the correct serial number. If the serial number is correct, try moving the pump closer to the communication device, or locating the communication device and pump away from possible interference (such as other RF devices), or checking the pump battery and delivery status.
This pump is delivering a temp basal. Please cancel the temp basal or wait until it completes, and then try again.	The pump you are attempting to read is delivering a Temp basal. Either wait until the Temp basal completes to read the pump, or cancel the Temp basal and then read the pump.
This pump has active errors or alarms. Please clear the alarms and try again.	There are active alarms on the pump which prevent it from being read. Read the alarm instructions for clearing the alarm. Clear the alarm and try the pump read again.
This pump is delivering a bolus. Please cancel the bolus or wait until it completes, and then try again.	The pump you are attempting to read is delivering a bolus. Either wait until the bolus completes to read the pump, or cancel the bolus and then read the pump.
The device returned invalid entries; all data read will be discarded.	Contact the 24 Hour HelpLine or your local country representative (see *Assistance, on page 3*).

Report creation errors

Multiple data entries for the same date

If multiple data entries exist for the same date and time for the same device, the system considers this to be a conflict that it cannot resolve. Reports created using this device data will omit the portion of data that overlaps.

You can try to adjust the reporting period to miss the overlapping data. Or, you can remove the device from the system and then add it back again to clear the previous readings.

System 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 system does not include that portion of data when creating reports.

Backup and restore errors

The database cannot be locked

This means that you are using the system in a multi-user environment, and other users are logged in. The system will not allow a database backup to be performed while other users are potentially performing tasks that may affect the database. Once all other users exit CareLink Pro, you can perform the database backup.

A database backup or restore is not completing

Other users cannot log in and the backup or restore cannot complete. Please contact the helpline or your local country representative (see *Assistance, on page 3*).

A restore database fails

The database backup file you are attempting to use in the restore process is corrupt. Try restoring with a different backup file.

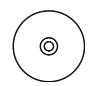
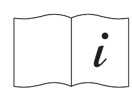
Uninstalling the software

If you need to uninstall CareLink Pro, take the following steps:

1. Open the *Control Panel* through your Windows **Start** menu.
2. Select **Add or Remove Programs.**The Windows Add or Remove Programs window is displayed.
3. Scroll down to *Medtronic Carelink Pro* and click on it.
4. Click REMOVE. The InstallShield Wizard is displayed.
5. Click NEXT. A message is displayed asking you to confirm that you want to remove the application.
6. Click YES. The uninstall program runs and removes the program and all of its files from your computer. When it is done, a message displays on the wizard screen confirming the uninstall.
7. Click FINISH.

Icon table

The icons and symbols on the packaging labels and the equipment are described in the following table:

Description	Icon
One Per Container/Package	(1x)
Attention: See Instructions for Use	
CD enclosed	
Important documents enclosed	
Catalogue number	REF
CE mark by notified body as a medical device	CE 0459

CSV data

Appendix A

This appendix defines the columns of the CareLink™ Pro data that you see when you export to CSV format. It also provides other information you may need to know about CSV files.

NOTE: All data is what was recorded in the device at the listed date and time.

Column data definitions

Consult this table to better understand the type of data in each column.

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 (mg/dL or mmol/L)	The blood glucose reading recorded by the meter or pump. If the data is from a pump, this column reflects manual BG's and BG's received from a Link meter.
Linked BG Meter ID	The serial number for the meter that sends blood glucose readings 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 amount (new insulin rate or percent of basal).
Temp Basal Type	The setting for temporary basal delivery type (insulin rate or percent of basal).
Temp Basal Duration (m or%)	The length of time in minutes or percentage for the temporary basal insulin delivery (see type above).

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 units of insulin 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.
Extended Bolus Duration (h)	Duration of the square portion of either a square bolus or a dual wave bolus.
Prime Type	The prime type—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	States “Suspended” when the pump is suspended, and “Resumed” when the pump is resumed.
Rewind	Rewind event at the date and time of the device read.
BWZ Estimate (U)	The bolus insulin estimate if calculated with the Bolus Wizard feature on the Paradigm pump.
BWZ Target High BG (mg/dL or mmol/L)	The Paradigm pump setting for the high end of the blood glucose target range, set through the Bolus Wizard feature.
BWZ Target Low BG (mg/dL or mmol/L)	The Paradigm pump setting for the low end of the the blood glucose target range, set through the Bolus Wizard feature.
BWZ Carb Ratio	The Paradigm pump 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 needed to cover one exchange. This is set through the Bolus Wizard feature.
BWZ Insulin Sensitivity	The Paradigm pump setting for insulin sensitivity. Insulin sensitivity is the amount the blood glucose level is reduced by one unit of insulin. This is set through the Bolus Wizard feature.
BWZ Carb Input	The input for expected amount of carbohydrate consumption when using the Bolus Wizard feature on the Paradigm pump to estimate a bolus.
BWZ BG Input (mg/dL or mmol/L)	The input for meter blood glucose reading when using the Bolus Wizard feature on the Paradigm pump to estimate a bolus.
BWZ Correction Estimate (U)	The estimated units of bolus insulin to give for blood glucose level correction, as calculated throughout the Bolus Wizard feature.
BWZ Food Estimate (U)	The estimated units of bolus insulin to give to cover the expected amount of carbohydrate consumption, as calculated through the Bolus Wizard feature.

Column heading	Definition
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 through the Bolus Wizard feature.
Sensor Calibration BG (mg/dL or mmol/L)	The BG value used for calibrating the sensor in mg/dL or mmol/L).
Sensor Glucose (mg/dL or mmol/L)	The calibrated sensor glucose value.
ISIG value	The ISIG value read from the pump.

More about CSV files

The title at the top of 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

There are a number of different factors that can cause the CSV data to display differently than expected. A few of these factors are listed below:

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

Glossary

A

A1c Glycosylated hemoglobin

A1c Test Hemoglobin A1c test, used to interpret blood glucose level over a period of time.

Area Under the Curve (AUC) Indicates the amount in high and low excursions as determined by preset values. Excursion data indicates the frequency of highs or lows. AUC indicates the magnitude of events by showing how far out of range and for how long.

Audio bolus The pump can be programmed so the user hears a beep when they select a bolus insulin amount (0.5 or 1.0 units) to be delivered. This is useful for situations when it is difficult to see the buttons on the pump.

B

Basal insulin An hourly, continuous infusion of insulin delivered automatically by an insulin pump based on preprogrammed profiles and personalized rates set in the pump. The pump delivers a daily infusion of insulin that typically covers "background" insulin needs during periods of fasting (i.e., overnight and between meals).

Basal patterns The user can program up to three different basal rate patterns into their pump for the delivery of basal insulin: Standard, A, and B. For each pattern there is the option of setting up to 48 basal rates.

Basal profile A basal rate with a start and stop time. The user can program several different profiles into their pump, each with a different basal rate, during a 24-hour period of time to achieve better glucose control.

Basal rate The pump setting that provides a continuous infusion of insulin to keep the blood glucose stable between meals and during the night. Basal insulin mimics pancreatic insulin delivery—which meets all the body’s non-food related insulin needs.

BG Blood Glucose

Bolus insulin A dose of insulin given to cover an expected rise in blood glucose (such as the rise after a meal or a snack) or to lower a high blood glucose down to target range.

C

Cal Reminder The pump will trigger a Meter BG By HH:MM alarm automatically every 12 hours, signaling that the current calibration value is no longer valid. The value of the Cal Reminder is the amount of time before the current calibration value expires by which the user wants to be reminded to calibrate. For example, if the Cal Reminder is set to 2 hours, the Meter BG By HH:MM alarm will occur 2 hours before calibration is required.

Carb ratio (carbohydrate ratio) The amount of carbohydrates covered by one unit of insulin. (Also see exch ratio.)

Carb units The food entry when using the Bolus Wizard. Entered as (carbohydrate) grams or exchanges.

CareLink® Personal An online service that allows management of diabetes data via the Internet.

CH Carbohydrate

Com-Station A device used to download MiniMed 508 pump and pass-through third-party meter data to the computer.

ComLink A radio frequency (RF) transceiver device used to download Paradigm pump data to the computer.

Correction bolus The amount of insulin needed to return a high blood glucose level back down to target range.

Correction bolus factor (Sensitivity factor) How much 1.0 unit of insulin will lower your blood glucose. This factor is used to calculate a correction bolus amount when your blood sugar is high.
(BG level) – (BG target) = X.
X ÷ (correction bolus factor) =
correction bolus amount

D

Dual Wave® bolus Combination of a Normal bolus that is delivered immediately, then followed by a Square Wave bolus. The Square Wave portion is delivered evenly over a period of time.

E

Easy Bolus™ Method of delivery for a Normal bolus by using the Easy Bolus button on the pump.

Exch ratio (exchange ratio) The amount of insulin required to cover one (1) carbohydrate exchange. (Also see carb ratio.)

Express bolus Method of delivery for any bolus type using the express bolus button on the pump.

F

Food bolus A dose of insulin given to cover the expected rise in blood glucose that occurs after eating.

H

HbA1c Glycosylated hemoglobin

HbA1c Test Hemoglobin A1c test, used to interpret blood glucose control or average of levels over a 2- to 3-month period of time.

High Glucose The pump will alarm if the sensor indicates that the user's sensor glucose is at or above this value. You have the option to turn this feature on or off.

Hyperglycemic Elevated blood glucose as seen by monitoring blood glucose levels with or without any or all of the following symptoms: nausea, vomiting, blurred vision, headache, gastric distress, frequent urination of large amounts, and lethargy.

Hypoglycemic Low blood glucose as seen by monitoring blood glucose levels, with or without any or all of the following symptoms: excessive hunger, shaking or tremors, perspiration, "dancing" visions, light-headedness, headache, blurred speech, sudden mood swings or personality change.

I

Infusion set The apparatus used for inserting and securing a cannula below the skin and transporting insulin to the insertion site via tubing from the pump.

Insulin concentration The strength or type of insulin the doctor has prescribed for the user. This affects the rate of insulin the pump delivers. If the user's insulin concentration changes, the basal patterns and the maximum basal and bolus rates must be reprogrammed in the pump.

Insulin sensitivity The amount of mg/dL (or mmol/L) that your blood glucose (BG) level is reduced by one unit of insulin. (Bolus Wizard data.)

ISIG Sensor values that indicate whether the transmitter electronics in a sensor-augmented system are working properly. If you see an ISIG value that is less than 24.00 nA or more than 29.00 nA, call for product assistance. It may be time to replace your transmitter.

K

Ketone test Ketone is a waste product that is produced when the body is forced to burn body fat instead of glucose for energy. It may be a sign of lack of insulin in the body. The Ketone test measures the amount of ketone concentrated in the blood or urine.

L

Link To turn on and setup the meter option that allows the pump to receive BG readings from the OneTouch® UltraLink™, CONTOUR® LINK, or Paradigm Link meter.

It is also used in this system to refer to hypertext links. When clicked on, hypertext links take you to another place in the system or to another Web site.

Low Glucose The pump will alarm if the sensor indicates that the user's sensor glucose is at or below this value. You have the option to turn this feature on or off.

Low reservoir warning Programmable warning that notifies you with an alert when either a specified number of units remain in the reservoir of your pump, or a specified amount of time remains before the reservoir will be empty.

M

Manual bolus Optional item available in the BOLUS MENU when the Bolus Wizard is active. One method of programming a bolus without the Bolus Wizard.

Max basal insulin The maximum amount of basal insulin that the pump will deliver at one time. (Set by the user).

Max bolus The maximum amount of bolus insulin that the pump will deliver at one time. (Set by the user).

Mean Absolute Difference (MAD) Represents the level of accuracy in calibration of the sensor to meter readings. The lower this number, the greater the calibration accuracy. MAD is calculated by taking the difference between closely occurring pairs of SG and meter readings, dividing by the meter reading and then averaging across all pairs.

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. The meter then displays the level in mg/dL or mmol/L.

Meter option Feature that allows the pump to receive BG readings from a linked BG meter.

N

Normal bolus An immediate delivery of a specified unit amount of insulin.

P

Pattern feature Extended pump feature that allows you to program optional basals (Pattern A, Pattern B) that support activities or glucose patterns that are not a part of your day-to-day routine, but are usual in your lifestyle. Such activities could be a sport that you do once a week, a change in your sleep pattern over the weekend, or hormonal changes during a menstrual cycle.

Pattern, standard Your normal basal that supports your usual day-to-day activity. When the Patterns feature is off, the pump uses your standard (basal) pattern.

R

RF Radio frequency (RF).

S

Square Wave® bolus Bolus delivered evenly over a specified time period (30 minutes to 8 hours).

Square Wave portion (Sq) The second part of a Dual Wave bolus. The Square Wave portion delivers evenly over a period of time after the NOW portion delivers.

Step Measurement of insulin that you set and use for Easy Bolus delivery.

Suspend Function on the pump that stops all insulin delivery. Any current bolus and/or prime deliveries are canceled. The basal delivery is paused until restarted.

T

Temp Temporary

Temp basal (tmp basal) Temporary one-time basal insulin with a specified amount and duration. Used to support insulin needs for special activities or conditions that are not part of the normal daily routine.

Transmtr ID The serial number of the transmitter currently in use.

U

μL micro liter

Upload The process for transferring pump or meter data to the CareLink™ Personal server.

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