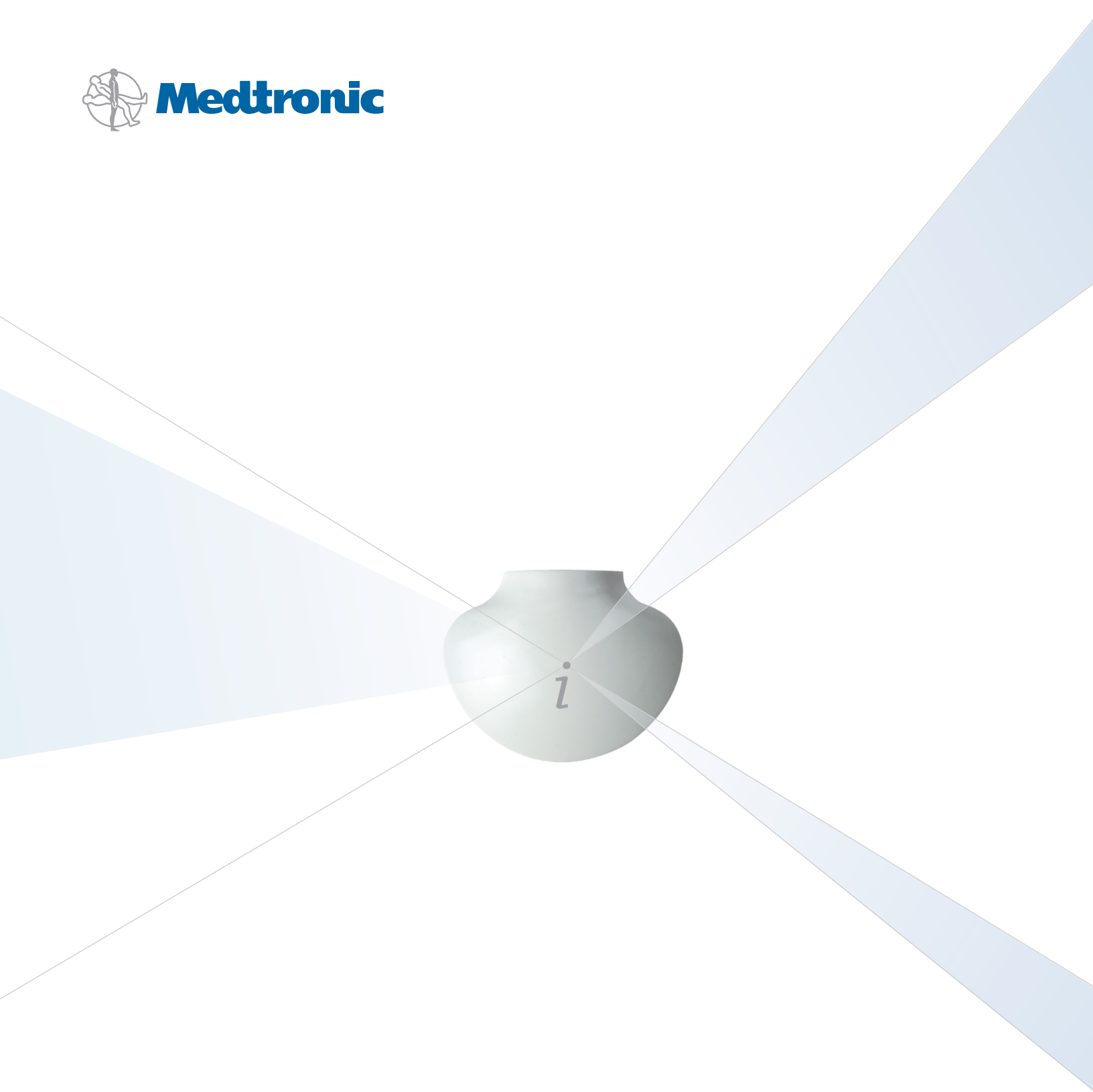
Medtronic



iPro®2

User Guide

Medtronic MiniMed
18000 Devonshire Street
Northridge, CA 91325
USA
800 646 4633
818 576 5555
www.medtronicdiabetes.com

℞ *Only*

10542428-011DOC_a
REF MMT-7745

Contacts:

Africa:
Medtronic Africa (Pty) Ltd.
Tel: +27 (0) 11 677 4800

Argentina:
Corpomedica S.A.
Tel: +(11) 4 814 1333
Medtronic Directo 24/7: +0800 333 0752

Australia:
Medtronic Australasia Pty. Ltd.
Tel: 1800 668 670

Azerbaijan:
Isomed
Tel: +994 (12) 464 11 30

Bangladesh:
Sonargaon Healthcare Pvt Ltd.
Mobile: (+91)-9903995417
or (+880)-1714217131

Belarus:
ОДО "Баджин"
Tel: +375 17 313 0990

België/Belgique:
N.V. Medtronic Belgium S.A.
Tel: 0800-90805

Bosnia and Herzegovina:
Medimpex d.o.o.
Tel: +387 33 476 444
or +387 33 476 400
Fax: +387 33 476 401
or +387 33 432 241

Brasil:
Medtronic Comercial Ltda.
Tel: +(11) 2182-9200
Medtronic Directo 24/7: +0800 773 9200

Bulgaria:
RSR Ltd.
Tel: +359 885 428 900

Canada:
Medtronic of Canada Ltd.
Tel: 1-800-284-4416 (toll free/sans-frais)

Chile:
Medtronic Chile
Tel: +(9) 66 29 7126
Medtronic Directo 24/7: +1 230 020 9750
Medtronic Directo 24/7 (From Santiago): +(2) 595 2942

China:
Medtronic (Shanghai) Ltd.
24 Hour Help (Cell): +86 400-820-1981
24 Hour Help (Landline): +86 800-820-1981

Colombia:
Medtronic Latin America Inc. Sucursal Colombia
Tel: +(1) 742 7300
Medtronic Directo 24/7 (Landline): +01 800 710 2170
Medtronic Directo 24/7 (Cellular): +1 381 4902

Croatia:
Medtronic Adriatic d.o.o.
Tel: +385 1 488 11 20
Fax: +385 1 484 40 60

Danmark:
Medtronic Danmark A/S
Tel: +45 32 48 18 00

Deutschland:
Medtronic GmbH
Geschäftsbereich Diabetes
Telefon: +49 2159 8149-370
Telefax: +49 2159 8149-110
24-Stdn-Hotline: 0800 6464633

Eire:
Accu-Science LTD.
Tel: +353 45 433000

España:
Medtronic Ibérica S.A.
Tel: +34 91 625 05 42
Fax: +34 91 625 03 90
24 horas: +34 900 120 330

Europe:
Medtronic Europe S.A. Europe, Middle East and Africa Headquarters
Tel: +41 (0) 21-802-7000

France:
Medtronic France S.A.S.
Tel: +33 (0) 1 55 38 17 00

Hellas:
Medtronic Hellas S.A.
Tel: +30 210677-9099

Hong Kong:
Medtronic International Ltd.
Tel: +852 2919-1300
To order supplies: +852 2919-1322
24-hour helpline: +852 2919-6441

India:
India Medtronic Pvt. Ltd
Tel: (+91)-80-22112245 / 32972359
Mobile: (+91)-9611633007

Indonesia:
Medtronic International Ltd.
Tel: +65 6436 5090
or +65 6436 5000

Israel:
Medtronic World Trade Corporation
Tel: +972 9972 4400

Italia:
Medtronic Italia S.p.A.
Tel: +39 02 24137 261
Fax: +39 02 24138 210
Servizio assistenza tecnica:
Nº verde: 800 60 11 22

Japan:
Medtronic Japan Co. Ltd.
Tel: +81-3-6776-0019
24 Hr. Support Line: 0120-56-32-56

Kazakhstan:
Medtronic BV in Kazakhstan
Tel: +7 727 311 05 80 (Almaty)
Tel: +7 717 224 48 11 (Astana)
Круглосуточная линия поддержки: 8 800 080 5001

Latin America:
Medtronic, Inc.
Tel: 1(305) 500-9328
Fax: 1(786) 709-4244

Latvija:
Ravemma Ltd.
Tel: +371 7273780

Macedonia:
Alkaloid Kons Dooel
Tel: +389 2 3204 430

Magyarország:
Medtronic Hungária Kft.
Tel: +36 1 889 0688

Malaysia:
Medtronic International Ltd.
Tel: +603 7946 9000

Middle East and North Africa:
Regional Office
Tel: +961-1-370 670

Montenegro:
Glosarij
Tel: +382 20 642 495
Fax: +382 20 642 540

México:
Medtronic Servicios S. de R. L. de C.V.
Tel (México DF): +(11) 029 058
Tel (Interior): +01 800 000 7867
Medtronic Directo 24/7 (from México DF):
+(55) 36 869 787
Medtronic Directo 24/7: +01 800 681 1845

Nederland, Luxembourg:
Medtronic B.V.
Tel: +31 (0) 45-566-8291
Gratis: 0800-3422338

New Zealand:
Medica Pacifica
Phone: 64 9 414 0318
Free Phone: 0800 106 100

Norge:
Medtronic Norge A/S
Tel: +47 67 10 32 00
Fax: +47 67 10 32 10

Philippines:
Medtronic International Ltd.
Tel: +65 6436 5090
or +65 6436 5000

Россия:
ООО «Медтроник»
Tel: +7 495 580 73 77
Круглосуточная линия поддержки: 8 800 200 76 36

Polska:
Medtronic Poland Sp. z o.o.
Tel: +48 22 465 6934

Portugal:
Medtronic Portugal Lda
Tel: +351 21 7245100
Fax: +351 21 7245199

Puerto Rico:
Medtronic Puerto Rico
Tel: 787-753-5270

Republic of Korea:
Medtronic Korea, Co., Ltd.
Tel: +82.2.3404.3600

Romania:
Medtronic BV Reprezentanta
Tel: +40 372 188 000

Schweiz:
Medtronic (Schweiz) AG
Tel: +41 (0)31 868 0160
24-Stunden-Hotline: 0800 633333
Fax Allgemein: +41 (0)318680199

Serbia:
Medtronic B.V. Serbia
Tel: +381 11 2095 900

Singapore:
Medtronic International Ltd.
Tel: +65 6436 5090
or +65 6436 5000

Slovenija:
Zaloker & Zaloker d.o.o.
brezplačna številka: 080 1880
Tel: +386 1 542 51 11

Slovenská republika:
Medtronic Slovakia, s.r.o.
Tel: +421 26820 6942
HelpLine: +421 26820 6986

Sri Lanka:
Swiss Biogenics Ltd.
Mobile: (+91)-9003077499
or (+94)-777256760

Suomi:
Medtronic Finland Oy
Tel: +358 20 7281 200
Help line: +358 400 100 313

Sverige:
Medtronic AB
Tel: +46 8 568 585 20
Fax: +46 8 568 585 11

Taiwan:
Medtronic (Taiwan) Ltd.
Tel: 02-21836000
Toll free: +886-800-005285

Thailand:
Medtronic (Thailand) Ltd.
Tel: +662 232 7400

Türkiye:
Medtronic Medikal Teknoloji
Ticaret Ltd. Sirketi.
Tel: +90 216 4694330

USA:
Medtronic Diabetes Global Headquarters
24 Hour HelpLine: +1-800-646-4633
To order supplies: +1-800-843-6687

Ukraine:
Medtronic B.V. Representative office in Ukraine
Tel: +38 044 392 04 01
Лінія цілодобової підтримки:
0 800 508 300

United Kingdom:
Medtronic Ltd.
Tel: +44 1923-205167

Österreich:
Medtronic Österreich GmbH
Tel: +43 (0) 1 240 44-0
24 – Stunden – Hotline: 0820 820 190

Česká republika:
Medtronic Czechia s.r.o.
Tel: +420 233 059 111
Non-stop helpLine (24/7):
+420 233 059 059

Zákaznický servis (8:00 - 17:00):
+420 233 059 950

Contents

1

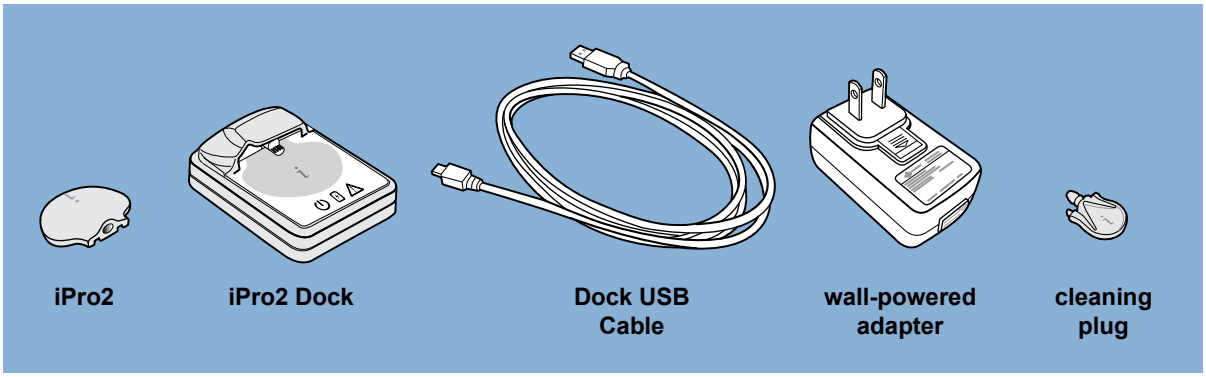
Introduction

Welcome to iPro®2 Continuous Glucose Monitoring (CGM)

Thank you for your trust in Medtronic products and services. We hope you will find iPro2 to be the simplest and most convenient CGM product that you have ever used.

- This User Guide provides the information that you need for setting up and using the iPro2 CGM system.
- You will find a page like this at the beginning of each chapter. This page gives you a basic overview of that chapter, and the steps you will take to complete each task.
- You will also see a "Key Notes" area on each chapter overview page. These are the important points for you to remember from that chapter.

iPro2 system



These are the components of the iPro2 CGM system, MMT-7745:

- iPro®2 digital recorder, MMT-7741 (iPro2)

  The iPro2 collects and stores data from a glucose sensor. The data can be uploaded into CareLink iPro® Therapy Management Software for Diabetes (CareLink iPro, MMT-7340), to generate reports and store the data. The iPro2 can collect up to seven 24-hour periods of data, after which it shuts off automatically.

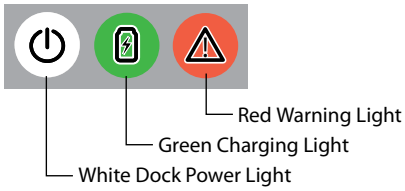
  The iPro2 has an internal green light.  This light flashes when you connect the iPro2 to an inserted glucose sensor. It will only flash if the iPro2 detects an adequately hydrated sensor, is fully charged, and does not already contain any data.

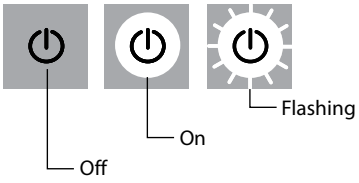
  The iPro2 can be used up to 60 times. Keep track of iPro2 uses by entering each use on the Clinic Equipment Log. Discard the iPro2 after 60 uses. If you continue to use the iPro2 beyond 60 times, the disinfection process may damage the device.

- iPro®2 Docking Station, MMT-7742 (Dock)

  The Dock has two main functions: charging the iPro2 and uploading data from the iPro2 to CareLink iPro. The Dock has three lights to provide status information. The white Dock power light indicates whether power is supplied to the Dock. When you connect the iPro2 to the Dock, the green charging light and the red warning light indicate the status of the iPro2. If the green charging light is on, the iPro2 is 100% ready to use.

  In this User Guide, you will see the three Dock lights described using the following conventions. Each light is always either off, on, or flashing.





- iPro®2 Dock USB cable (refer to MMT-7747 if re-ordering)

  The small end of the Universal Serial Bus (USB) cable connects to the Dock. The other end of the cable connects to a USB port on a computer, so that you can upload data into CareLink iPro® and charge the iPro2. You can also connect the USB cable to a wall-powered adapter.
- Wall-powered adapter (refer to MMT-7747 if re-ordering)

  The wall-powered adapter lets you charge the iPro2 by connecting the Dock to a regular electrical socket, instead of a computer.
- Three (3) iPro®2 Cleaning Plugs, MMT-7744 (cleaning plug)

  The cleaning plugs provide a watertight seal to protect the connector pins on the iPro2. Always use a cleaning plug when cleaning and disinfecting the iPro2.

  Do not clean the o-rings on the cleaning plug, as this can damage the o-rings.

  The cleaning plug can be used to clean the iPro2 30 times. Keep track of cleaning plug uses and discard the cleaning plug after 30 uses. If you continue to use the cleaning plug beyond 30 times, the iPro2 connector pins could be damaged, because the cleaning plug cannot continue to provide a watertight seal.

  Keep only one unwrapped cleaning plug at hand, so that you can keep track of its use and will know when to unwrap a new cleaning plug.

  To order more cleaning plugs, contact your local representative or call Medtronic Diabetes at 800 843 6687.

You will also need the following:

- Serter, MMT-7510
- Enlite® sensor, MMT-7008 (Glucose sensor)
- A computer with Internet access to CareLink iPro, MMT-7340 (http://www.carelinkipro.com)
- Patient Log Sheet
- Patient Consent Form
- Patient Instructions Sheet
- Clinic Equipment Log Sheet
- Clinic Checklist (for patient setup and for uploading iPro2 data and printing reports)
- Occlusive adhesive dressing

User safety

This section includes important safety information such as indications, contraindications, warnings, and precautions.

Indications for use

The iPro2 Recorder is to be used with either Enlite sensor or Sof-sensor and is intended to continuously record interstitial glucose levels in persons with diabetes mellitus. This information is intended to supplement, not replace, blood glucose information obtained using standard home glucose monitoring devices. The information collected by the iPro2 digital recorder may be uploaded to a computer (with Internet access) and reviewed by healthcare professionals. The information may allow identification of patterns of glucose-level excursions above and below a desired range, facilitating therapy adjustments, which may minimize these excursions.

This iPro2 system:

- is intended for prescription use only.
- does not allow data to be made available directly to patients in real time.
- provides data that will be available for review by physicians after the recording interval (up to 144 hours).
- is intended for occasional rather than everyday use.
- is to be used only as a supplement to, and not a replacement for, standard invasive measurement.

Contraindications

None known.

Warnings

- This product contains small parts and may pose a choking hazard for young children.
- The glucose sensor should be removed if redness, bleeding, pain, tenderness, irritation, or inflammation develops at the sensor insertion site, or if the patient experiences unexplained fever.

- An optional occlusive adhesive dressing should be removed if irritation or reaction to the tape develops.
- The glucose sensor may create special needs regarding your patients' medical conditions or medications. Bleeding, swelling, irritation or infection at the insertion site are possible risks associated with inserting the sensor and sometimes result from improper insertion and maintenance of insertion site. Taking medications with acetaminophen while wearing the sensor may falsely raise your sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen active in your body and may be different for each person. Always use BG meter readings to verify your glucose level before making therapy decisions. Healthcare professionals should discuss this with their patients before they use the glucose sensor.
- Do not modify this product, as modification could result in a safety hazard.
- The iPro2 must be disinfected after every use on a patient. Users must adhere to universal precautions when handling or using this device to prevent transmission of diseases. For more information, refer to "Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007." www.cdc.gov/hicpac/2007ip/2007isolationprecautions.html. For more information on cleaning and disinfection, see *Cleaning and disinfecting the iPro2 on page 24*.
- Do not expose your iPro2 or sensor to Magnetic Resonance Imaging (MRI) equipment, x-ray equipment, Computed Tomography (CT) scanners, Intensity-Modulated Radiation Therapy (IMRT), diathermy devices, or other devices that generate strong magnetic fields or ionizing radiation. This equipment has strong magnetic fields or ionizing radiation that can cause the device to malfunction. If the iPro2 or sensor is inadvertently exposed to a strong magnetic field, discontinue use and contact the 24 Hour HelpLine for further assistance.

Precautions

- If performing multiple iPro2 studies on the same patient, establish a rotation schedule for choosing new sensor sites.
- Avoid inserting a sensor in areas on the body that are constrained by clothing, have scar tissue, or are subject to rigorous movement during exercise.
- Before connecting the iPro2, do the following:
  - Make sure that the sensor insertion site is not bleeding before connection. If you find blood on top of the sensor adhesive, do not connect the iPro2. This is to prevent body fluids from getting into the iPro2 connector opening. If blood gets inside the iPro2's connector opening, it may not be properly cleaned and disinfected without damaging the connector pins. So the iPro2 will have to be discarded.
  - If bleeding occurs, apply steady pressure with a sterile gauze or cloth at the insertion site until bleeding stops. After bleeding stops, attach the iPro2 to the sensor.
  - If bleeding persists after three minutes, remove the sensor and discard. Insert a new sensor in a different location.

- If body fluid comes into contact with the cleaning plug's connector or the Dock's connector, the contaminated device must be discarded to prevent contamination of the iPro2.
- Do not allow fluids (including water, cleaning fluids, and disinfectants) on the iPro2's connector opening or connector pins. Fluids can cause the connector pins to corrode and may affect the iPro2's performance.

Meters supported by CareLink iPro for uploading

For a list of supported meters, see your *CareLink iPro Software User Guide*.

Compliance information

The iPro2 and Dock comply with the United States Federal Communications Commission (FCC) and international standards for Electromagnetic Compatibility. For the specific regulations and test results for your area, please contact your local representative.

These devices comply with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. These devices may not cause harmful interference.
2. These devices must accept any interference received, including interference that may cause undesirable operation.

These standards are designed to provide reasonable protection against excessive radio frequency interference and prevent undesirable operation of the device from unwanted electromagnetic interference.

Interference from wireless devices

Common wireless consumer devices, such as cellular (mobile) phones or cordless phones, may disrupt communication during iPro2 uploads to the computer. It is likely that other wireless devices using similar frequency ranges will have a similar effect. This interference, however, will not cause any incorrect data to be sent, and will not cause any harm to your iPro2 system.

To reduce the likelihood of data communication errors, you should relocate either the wireless device or the iPro2 system devices. Testing conducted with several different cellular phones suggests that interference will not be a problem if the phone is at least 12 inches (30 centimeters) from the iPro2 system devices. Please keep your mobile device no closer than 12 inches from your iPro2 device. Please note that mobile devices kept on your belt or in your pocket may be closer than 12 inches from the iPro2 device and may cause interference.

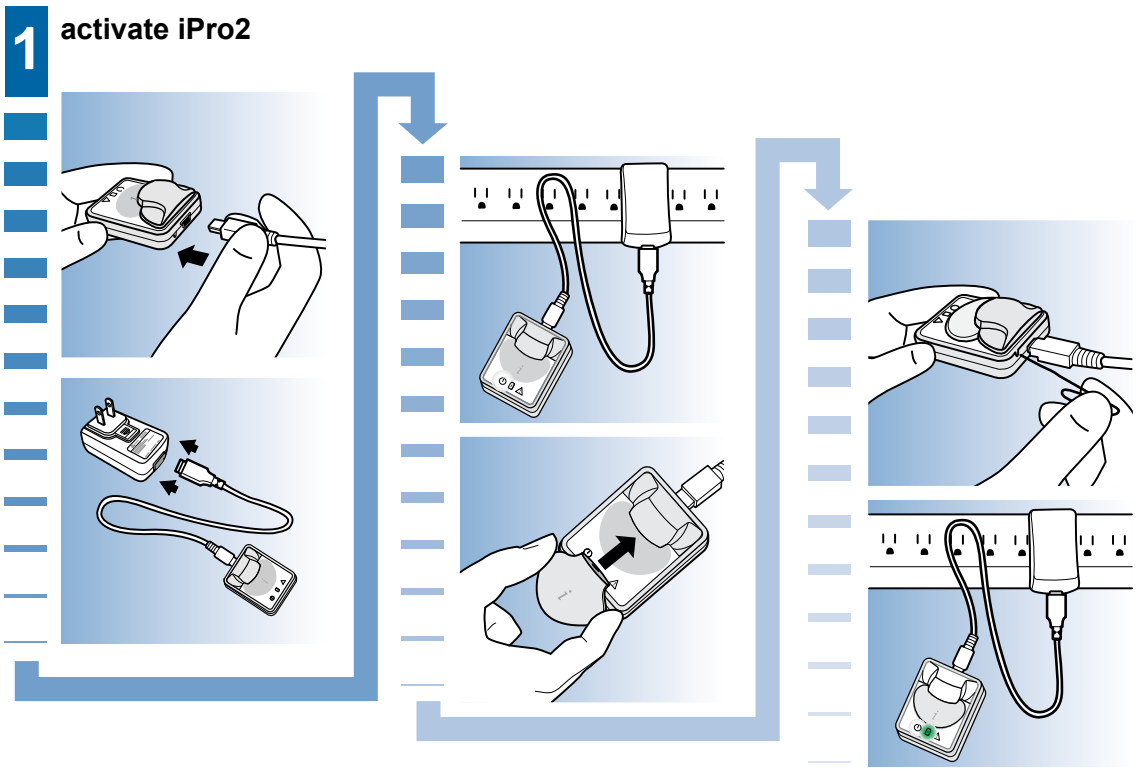
Assistance

If you need help, contact one of the following resources:

Support	Contact information
24 Hour HelpLine, Advanced Software Support Monday through Friday, 5 a.m. to 5 p.m. (PST)	800 646 4633 818 576 5555
Medtronic Diabetes website	www.medtronicdiabetes.com

2

One-time device setup



Key Notes:

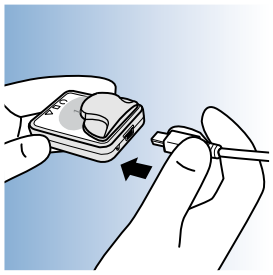
- The reset button on the Dock is used to wake up (or activate) the iPro2 because it is shipped in a special sleep mode. This is a one-time task. In the future, doing this will erase all sensor data that is on the iPro2.
- Never connect an iPro2 to any device other than the Dock, sensor, or cleaning plug.
- For cleaning, use only the cleaning plug.

One-time iPro2 activation

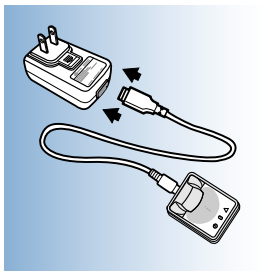
The iPro2 is shipped in a special sleep mode to protect its battery. You need to wake it up by following this one-time procedure. This should be done a minimum of eight hours before your first iPro2 patient setup.

CAUTION: Do not perform this procedure if you already have sensor data on the iPro2. If you press the reset button while the iPro2 is connected to the Dock, all sensor data on the iPro2 will be erased. This procedure is only for activating the iPro2 for the first time.

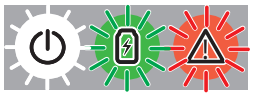
1 Connect the small end of the USB cable to the Dock.



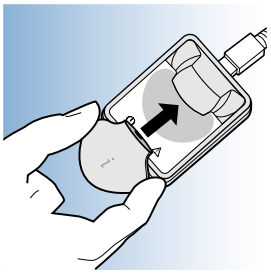
2 Connect the other end of the USB cable to the wall-powered adapter.



3 Connect the wall-powered adapter into an electrical socket. The three lights on the Dock will flash once, and then the white Dock power light will remain on, indicating that the Dock is plugged in.



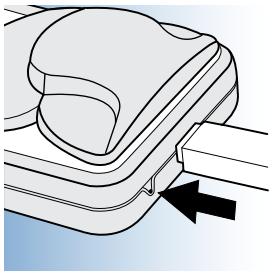
4 Place the iPro2 into the Dock.



The green charging light will start flashing. 

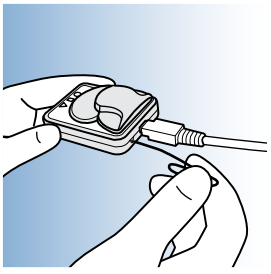
NOTE: The red warning light may turn on if you do not immediately complete the next steps. This is normal because the iPro2 has not been activated. You can continue to follow these instructions even if you see the red warning light.

5 Find the small hole on the back of the Dock, next to the USB cable. This is the reset button.



6 Insert the end of a small paper clip into the hole about 1/8 inch (0.30 cm). Push the reset button once and release. The white Dock power light will flash  . After a few seconds, the green light on the iPro2 will flash. 

Important: Do not apply excessive pressure, or the reset button may be damaged.



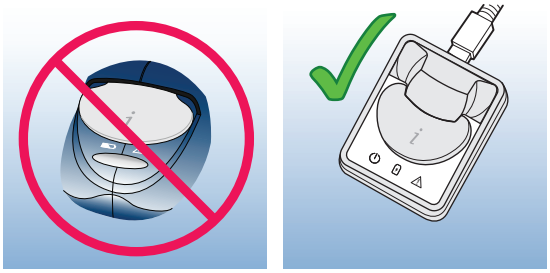
The iPro2 is now activated. It will never return to sleep mode.

7 Leave the iPro2 on the Dock to continue charging. During charging, the white Dock power light will be on, and the green charging light will flash.

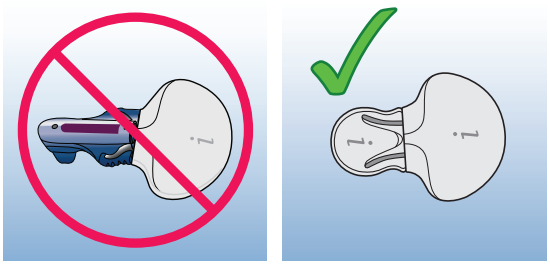
8 Allow up to eight (8) hours for the iPro2 to fully charge. Once the iPro2 is charged, the green charging light on the Dock will stop flashing and will remain on. This means that the iPro2 is fully charged.

Key notes about iPro2

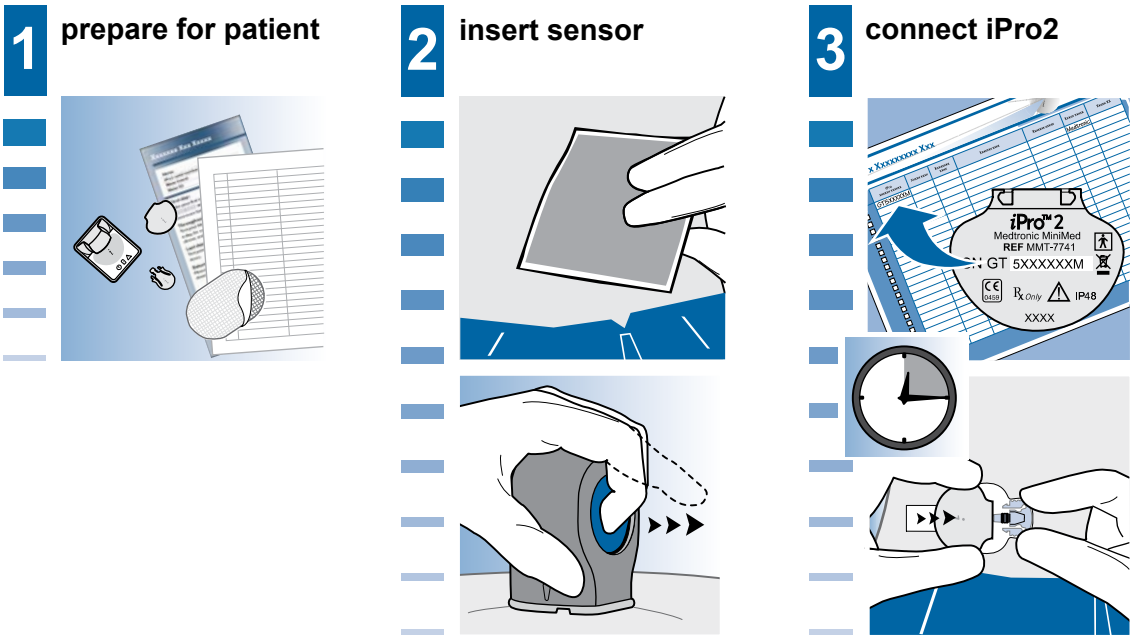
- The reset button on the Dock is used to wake up (or activate) the iPro2 because it is shipped in a special sleep mode. This is a one-time task. In the future, doing this will erase all sensor data that is on the iPro2.
- Never connect an iPro2 to any device other than the Dock, sensor, or cleaning plug. For example, never connect the iPro2 to the charger for the MiniLink®, shown here, because any patient data on the iPro2 could be erased.



- For cleaning, use only the cleaning plug.



Patient setup

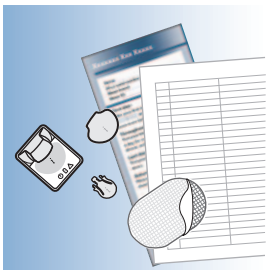


Key Notes:

- Use universal precautions when handling the sensor and iPro2.
- Do not use IV Prep prior to sensor insertion. It can damage the sensor.
- Before setting up any patients on iPro2, make sure that your clinic has completed the one-time CareLink iPro software and computer setup instructions. For more information, see your *CareLink iPro User Guide*.

Preparing for study

Before the patient arrives in your office, make sure that all the necessary equipment and supplies are available and ready.



Materials needed for patient setup:

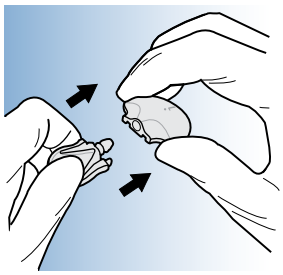
- Cleaning plug
- Alcohol swabs
- Gloves
- Serter
- Glucose sensor
- Sharps container
- iPro2, charged and disinfected. The green charging light on the Dock must be on (not flashing) before you remove the iPro2 from the Dock.
- Patient Log Sheets
- Patient Consent Form
- Patient Instructions
- Clinic Equipment Log
- Occlusive adhesive dressing
- Optional: Clinic Checklist

NOTE: Use universal precautions when handling the sensor and iPro2.

Wiping the iPro2 with alcohol before a patient study

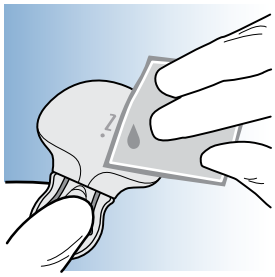
The iPro2 is intended for multiple patient use and must be properly cleaned and disinfected. The following steps can only be taken once the iPro2 has been cleaned and disinfected.

1 While wearing gloves, attach the cleaning plug to the iPro2 to make sure that fluids do not contact the iPro2's connector opening. Fluids can cause the connector pins to corrode and affect the iPro2's performance.

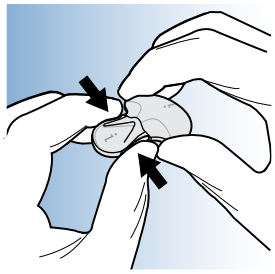


CAUTION: Do not twist the cleaning plug while it is attached to the iPro2. This will damage the iPro2.

2 Wipe the iPro2 with an alcohol swab or rinse with alcohol.



3 Disconnect the cleaning plug from the iPro2 by gently squeezing the arms of the cleaning plug.



CAUTION: The o-rings on the cleaning plug have lubricant to help make a watertight seal with the iPro2. This lubricant may wear off after approximately 30 uses. At that time, the cleaning plug must be discarded. Keep only one unwrapped cleaning plug at hand, so that you can keep track of its use and will know when to unwrap a new cleaning plug.

Tips for a successful patient study

- Keep the sensor hydrated and fully inserted throughout the study:

  - Make sure to follow the sensor insertion instructions carefully.
  - Choose a good sensor insertion site.
  - Use the proper angle for insertion.
  - Apply an adhesive dressing over the sensor and iPro2.
- If you see gaps in sensor data, it could be caused by any of the following reasons:
  - The sensor was partially removed during the study, which means that no data was being collected for that period of time.
  - The iPro2 lost its connection with the sensor. If the iPro2 is disconnected from the sensor and then reconnected during the study, it will continue recording. However, there will be a gap in the sensor data. The length of the gap depends on how long the iPro2 was disconnected.
  - The sensor was not continuously hydrated while connected to the body. It is possible for the sensor to lose hydration and then regain it, even if it does not pull out.
  - CareLink iPro does not have good BG meter readings within 12 hours of each other to calibrate all of the sensor data.
- Emphasize to the patient, ideally by using a Patient Instructions Sheet, the importance of following instructions for blood glucose testing throughout the study. Patients should complete at least **four BG meter readings per day** to avoid data gaps. If a patient does not record accurate BG meter readings frequently enough, CareLink iPro will not have enough BG meter readings to fully calibrate the sensor data. This can cause gaps in data on the patient's reports. CareLink iPro needs at least one BG meter reading within an expected range every 12 hours. Erroneous BG meter readings may be ignored by CareLink iPro and may stop the sensor plot until the next good BG meter reading.
- Make sure that your patient tests blood glucose at least one hour after the iPro2 is connected to the sensor. The iPro2 takes one hour to start up a sensor. If the patient does the first BG meter reading too soon, sensor data will not be available for calibration. Therefore, the sensor trace in the reports will begin at the time of the next BG meter reading. This will be apparent in CareLink iPro reports because the data will begin later than you expect.
- Make sure that the patient does another BG meter reading two hours after the first one. This BG meter reading is a backup, in case the first BG meter reading was a few minutes too early.
- Mid-study upload: Uploading sensor data from an iPro2 clears the data from the iPro2. The first upload will be shown as its own study in CareLink iPro. When the iPro2 is reconnected to the sensor, it will begin the one-hour start up again and start a new study, assuming that it also has enough charge to start a new study. You cannot combine two separate uploads into one set of reports in CareLink iPro.
- Do not change the sensor during the study. The iPro2 will keep recording, but the values on the second sensor will vary widely for many hours because the iPro2 will not properly start the second sensor. For the best results, upload data after each sensor use.

Preparation for sensor insertion

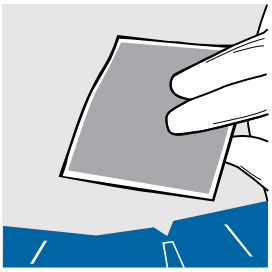
1 Ask your patient about sleeping position and about his or her normal daily routine. Does the patient exercise or do a lot of bending or lifting at work? What kind of clothing does the patient normally wear? Are there other activities that could disturb a sensor site, such as prolonged sitting in a driving position in a car? Choose a site that will be protected.

2 Wash your hands thoroughly.

3 Put on gloves.

4 Ask the patient to stand.

5 Clean the insertion site with alcohol and allow to air dry.



NOTE: Do not use sticky skin preparation solutions before inserting the sensor. A sticky intravenous (I.V.) preparation solution may be used after the sensor is inserted, and before applying an occlusive adhesive dressing, to help the adhesive stick to the patient's skin.

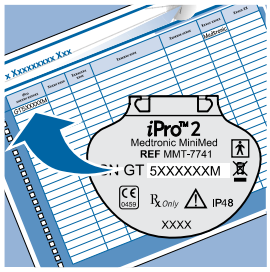
Always refer to the instructions that came with the glucose sensor and the sensor insertion device.

Inserting the sensor

1 Refer to your serter user guide for information on sensor insertion.

CAUTION: If you see body fluid on the metal sensor contacts or black o-rings, do not connect the iPro2. Remove and dispose of the sensor, and insert a new sensor. This will prevent contamination of the iPro2.

2 Make an entry on the Clinic Equipment Log and the Patient Log Sheet. Make sure to write down the serial number (SN) of the iPro2, the patient's name or ID, and the date that you placed it on the patient.



3 Connect the sensor to the iPro2 recorder.

4 Brief your patient on what to do when he or she goes home.

Briefing the patient

The patient must receive detailed instructions on wearing the sensor and iPro2, study compliance, meter use and maintaining a log sheet. Ideally, provide the patient with a Patient Log Sheet and a Patient Instructions Sheet. Go over the items listed on each of the documents and make sure that your patient understands his or her responsibilities to ensure a successful study.

Key points:

- Wear the iPro2 continuously while following normal daily activities.
- Record meals, blood glucose, exercise or strenuous activities, and medications on a Patient Log Sheet.
- Keep the Patient Log Sheet accessible at all times so that information can immediately be written down after each event. Record the time and date within five minutes of each BG meter reading.
- Use the same glucose meter and the same lot of strips for the entire study.
- Do not let anyone else use the meter during the study.
- Do not use control solution during the study.
- Do not change any settings on the meter during the study, even if a daylight saving time change occurs.
- Take at least four blood glucose (BG) meter readings per day, such as before each meal and before bed.
- Take the first BG meter reading at least one hour after leaving the office, and another about two hours after the first one.

- Only BG values between 40 and 400 mg/dL (2.2 and 22.2 mmol/L) will be used for calibration. If a meter reading is outside of this range, it does not count, and another BG meter reading will be needed when the patient's blood glucose is within the range.

CAUTION: The patient must return the iPro2 to the clinic within 10 days of the end of the study. After 10 days, if the iPro2 is not connected to a powered Dock, the iPro2 battery may lose its charge, and all data on the iPro2 could be lost. Make sure to schedule the patient's return of the iPro2 well within this time period.

What to do while briefing the patient

1. Give the patient the materials they need, including at least one Patient Log Sheet and a Patient Instructions Sheet.
2. On the Patient Log Sheet, write the patient's name, iPro2 serial number, meter brand, meter ID, and the times for the first two BG meter readings.
3. Make sure that the patient's blood glucose meter has a good battery that will last for the entire length of the study.
4. Check the date and time on the blood glucose meter.

Meter use

Instruct the patient that BG meter readings are required to calibrate the sensor data, and that for successful study data, the patient must follow these guidelines for meter use.

First day

The patient must do three blood glucose (BG) meter readings on the first day at these times:

- At least one hour after you connect the iPro2 and the patient leaves the office (but not any sooner than one hour). Write this time on the front of the Patient Log Sheet.
- Two hours after the first BG meter reading (three hours after the iPro2 is connected)
- Once more before midnight

Remaining days

- For the remaining days of the study, collect at least **four BG meter readings per day**, preferably before breakfast, lunch, dinner, and bedtime.
- The patient should do at least three BG meter readings on the last day before the sensor is removed.

Care and wearing instructions

The patient can shower and swim without removing the iPro2 or sensor. The iPro2 and sensor are watertight for up to 30 minutes, up to a depth of 8 feet (2.4 meters). There is no time limit for swimming on the surface of the water or showering.

The patient should periodically check the sensor site to ensure that the sensor and iPro2 are tightly connected, that the sensor is fully inserted and that there is no bleeding or irritation at the sensor site.

- If the sensor is partly pulled out, attempt to gently push it back into place.
- Remove the sensor if there is redness, pain, tenderness, or swelling at the site. The patient should notify the physician's office if experiencing any of these symptoms.

Insulin should be injected at least 3 inches (7.5 centimeters) away from the sensor insertion site, and insulin pump infusion should be at least 2 inches (5 centimeters) from the sensor insertion site.

The iPro2 and sensor must be removed prior to an x-ray, CT scan or MRI.

Make sure that the patient can return the iPro2 to the clinic well within 10 days of the end of the study. After 10 days, if the iPro2 is not connected to a powered Dock, the iPro2 battery may lose its charge, and all data on the iPro2 could be lost.

Preparing to connect the iPro2 (after briefing the patient)

1 If bleeding has occurred:
   a. Apply steady pressure with a sterile gauze or cloth at the insertion site until bleeding stops.
   b. When bleeding stops, attach the iPro2 to the sensor.

CAUTION: If bleeding does NOT stop, do NOT connect the iPro2 to the sensor.

2 If bleeding does not stop after three minutes, do the following:
   a. Remove the sensor and discard.
   b. Reapply pressure using a sterile gauze or cloth until the bleeding stops.
   c. Insert a new sensor in a different location.

Connecting the iPro2 to the sensor

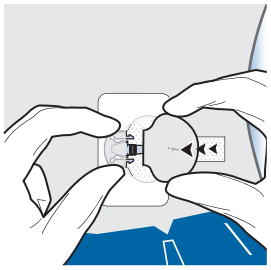
Important: The iPro2 must be fully charged and cleared of data before connecting to a sensor. You can verify this by connecting the iPro2 to the Dock. When you connect the iPro2 to the Dock, if the green charging light is on (not flashing), as shown below, the iPro2 is fully ready to use.

If you see a red warning light while the iPro2 is connected to the Dock, do not connect the iPro2 to the sensor. See *Troubleshooting reference on page 37*.

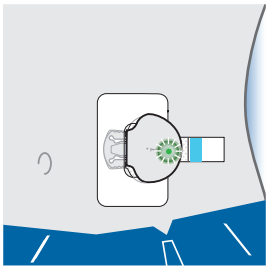
1 Make sure that the sensor insertion site is not bleeding before connection.

2 Hold the end of the inserted sensor to prevent it from moving during connection.

3 Hold the iPro2 as shown. The flat side of the iPro2 should face the skin.



4 Push the iPro2 onto the sensor until the sensor's flexible side arms snap into the notches on the iPro2. If the iPro2 is properly connected, and if the sensor has had enough time to become hydrated, within 20 seconds the iPro2's green light will flash six times. The flashing takes about 10 seconds.



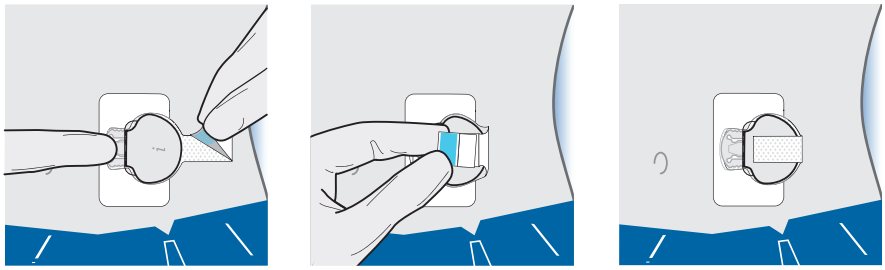
5 If the iPro2's green light flashes, then the sensor is fully hydrated and the iPro2 has successfully started the study.

6 If the iPro2's green light does not flash, and the Dock displayed a solid green charging light before you removed the iPro2 from it, then the sensor is not fully hydrated. You can do either of the following:

   a. Remove the iPro2 from the sensor and then try connecting the iPro2 again. This can be repeated every five minutes until the sensor is hydrated.

   b. Remove the sensor from the patient's body and insert a sensor in a new site on the body. Wait for the new sensor to become hydrated before connecting the iPro2 again.

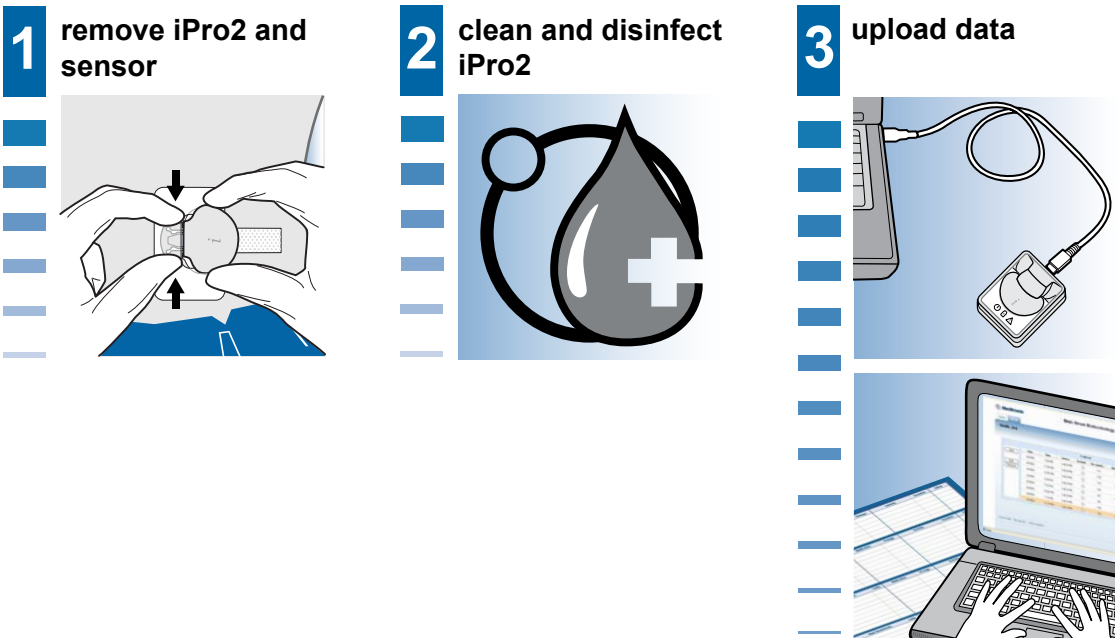
7 Gently cover the iPro2 with the adhesive tab.



Important: If the sensor is pulled out by more than a millimeter, the iPro2 will stop collecting data until the sensor is pushed back in place. When the sensor is pushed back in, the iPro2 will start collecting data 30 minutes later.

4

Uploading data to CareLink iPro



Key Notes:

- Always clean and disinfect the iPro2 as described in *Cleaning and disinfecting the iPro2 on page 24* before connecting it to the Dock. Always discard used gloves immediately after disinfecting the iPro2. The Dock connector cannot be disinfected.
- If you see any body fluid in the iPro2 connector opening, do not connect the iPro2 to the Dock. Instead, you must discard the iPro2 after disinfecting it as described in *Cleaning and disinfecting the iPro2 on page 24*.
- Always protect the iPro2's connector pins with a watertight cleaning plug when cleaning and disinfecting. Replace the cleaning plug after 30 uses to maintain a watertight seal.

- Do not connect more than one Dock or blood glucose meter to the computer at one time. Make sure that both ends of the Dock USB cable are completely connected.

Before you begin

When the patient returns after wearing the iPro2, you will need the following:

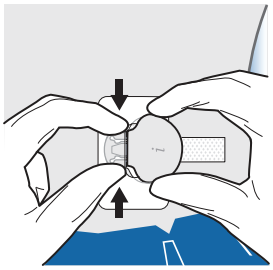
- Items from patient:
  - iPro2 (which has been worn by the patient)
  - Patient's blood glucose meter
  - Completed Patient Log Sheet(s)
- Gloves
- Access to running water
- Cleaning plug
- Optional: adhesive remover, such as Detachol®
- ENZOL® Enzymatic Detergent
- Soft-bristled brush
- Bleach (6% sodium hypochlorite)
- Gauze pad or cloth
- 70% isopropyl alcohol
- Bio-waste container
- Clinic Equipment Log (if used by your office)
- Dock, with the USB cable connected to a computer with Internet access
- Meter manufacturer's cable

Disconnecting the iPro2 and removing the sensor

Disconnecting the iPro2 from the sensor

1. Put on gloves.
2. Carefully remove any adhesive dressing from the iPro2 and sensor assembly.

3 Hold iPro2 as shown, and pinch the flexible side arms of the sensor between your thumb and forefinger. Do not twist the iPro2 relative to the sensor.



4 Gently pull the iPro2 away from the sensor assembly.

Removing the sensor from the patient

While wearing gloves, gently lift the adhesive tape away from the patient's body to remove the sensor. Place the sensor in a bio-waste container.

Cleaning and disinfecting the iPro2

The iPro2 is intended for multiple patient use. It is important to always inspect and perform the entire cleaning and disinfection process between uses. Users must adhere to universal precautions when handling or using this device. For more information, refer to "Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007." www.cdc.gov/hicpac/2007ip/2007isolationprecautions.html. Always inspect, clean, and disinfect the iPro2 before connecting it to the Dock. The Dock cannot be disinfected. See Warnings for additional information.

The iPro2 can be used up to 60 times. Keep track of iPro2 uses by entering each use on the Clinic Equipment Log. Discard the iPro2 after 60 uses. If you continue to use the iPro2 beyond 60 times, the disinfection process may damage the device.

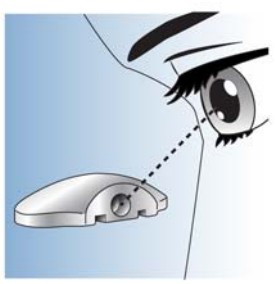
1 It is strongly recommended to print a copy of the Clinic Checklist to guide you through these steps. As you complete each step, mark it as complete on the checklist to make sure that you do not miss any steps.

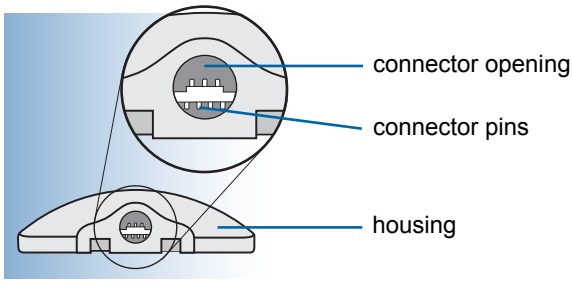
2 Put on gloves.

3 Inspect the inside of the connector opening for any sign of body fluid.

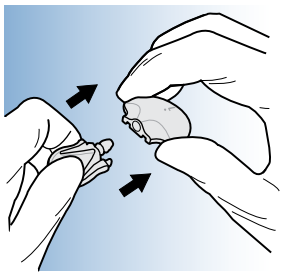
CAUTION: The person inspecting the iPro2 must have sufficient vision that enables him or her to see small drops of body fluid or debris.

WARNING: If you see any body fluid in the connector opening, you must discard the iPro2. Because the iPro2 contains a battery, do not discard in a bio-waste container. Instead, continue to clean and disinfect the iPro2, and then discard according to local regulations for battery disposal (non-incineration).





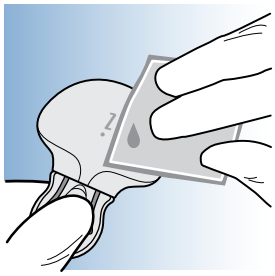
4 Attach the cleaning plug to the iPro2.



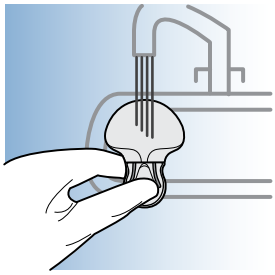
Important:

- The cleaning plug is a required component for cleaning and disinfecting. The cleaning plug ensures that fluids do not contact the iPro2's connector pins. Fluids can cause the connector pins to corrode and affect the iPro2's performance.
- Do not twist the cleaning plug while it is attached to the iPro2. This will damage the iPro2.

5 If there is adhesive residue on the iPro2, you can remove it with adhesive remover (for example, Detachol®) between each patient use. Follow adhesive remover manufacturer instructions.



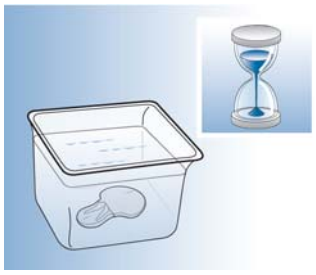
6 Rinse the iPro2 under cool tap water for at least one minute, or until any visible debris is gone.



7 Prepare ENZOL® Enzymatic Detergent solution using one ounce of detergent per gallon of water.

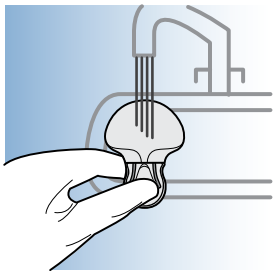
NOTE: Cleaning efficacy testing and robustness testing were conducted on the iPro2 using ENZOL® Enzymatic Detergent. Robustness testing for the iPro2 included a contact time of one minute per cycle for 61 cycles, which is equivalent to cleaning every three days for six months.

8 With the cleaning plug still attached, fully submerge the iPro2 in the detergent solution for at least one minute.

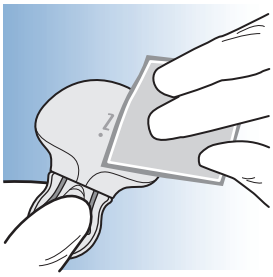


9 Holding the cleaning plug, remove the iPro2 from the solution. Brush the entire surface of the iPro2 using a soft-bristled brush, paying close attention to hard-to-clean areas, until visibly clean.

10 Rinse the iPro2 under cool tap water until any visible detergent is gone.



11 Dry any excess moisture by wiping the outside of the iPro2 with a clean, dry cloth.

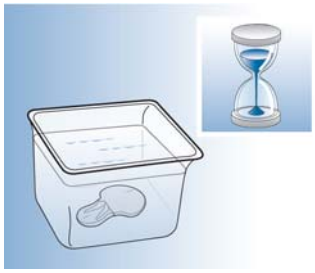


12 Prepare a 1:10 bleach solution by using one (1) part 6% bleach to nine (9) parts water, for a final concentration of 0.6%. Make sure to prepare a fresh solution for each use.

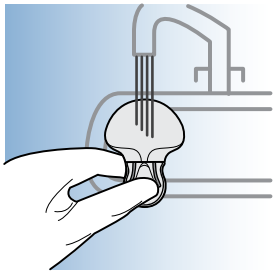
NOTE: Disinfecting efficacy testing and robustness testing were conducted on the iPro2 using Clorox® Regular Bleach (EPA registration number 5813–50, distributed by The Clorox Company). Robustness testing for the iPro2 included a contact time of 30 minutes per cycle for 61 cycles, which is equivalent to cleaning every three days for six months.

13 With cleaning plug still attached, soak the iPro2 in the bleach solution for 30 minutes.

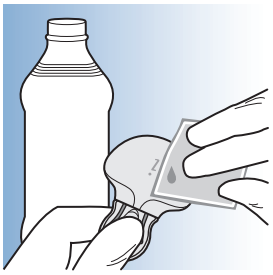
NOTE: Be sure to set a timer to remove the iPro2 from the bleach solution at 30 minutes.



14 Rinse the iPro2 under cool tap water for at least three minutes.

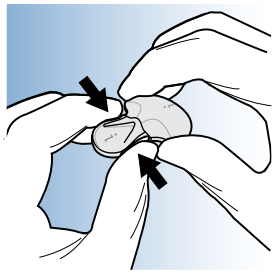


15 Holding the cleaning plug, wipe the iPro2 with 70% isopropyl alcohol.



16 **Important:** If you saw any body fluid inside the connector opening on earlier inspection, you must now discard the iPro2 with cleaning plug still attached, according to local regulations for battery disposal (non-incineration).

17 Disconnect the cleaning plug from the iPro2 by gently squeezing the arms of the cleaning plug.



18 Inspect the housing of the iPro2 for any signs of cracking, flaking, or damage. If you see any of these signs, you must now discard the disinfected iPro2 according to local regulations for battery disposal (non-incineration).

WARNING: Cracking, flaking, or damage of the housing are signs of deterioration and the performance of the device may be compromised. This may affect the ability to properly clean and disinfect the iPro2. If these signs are noted, the device must be discarded according to local regulations for battery disposal (non-incineration).

19 Place the iPro2 on a clean, dry, non-shedding cloth and air dry completely.

20 Discard used gloves before proceeding.

Proper performance of the iPro2 is indicated by the lights on the Dock. After you finish the disinfection process, you must upload the patient data as instructed in the following sections. If you see a red warning light on the Dock after connecting the iPro2, see *Troubleshooting reference on page 37*.

One-time CareLink iPro software and computer setup

Before uploading the iPro2 data, make sure that your office has completed the one-time CareLink software and computer setup. For more information, see your *CareLink iPro User Guide*.

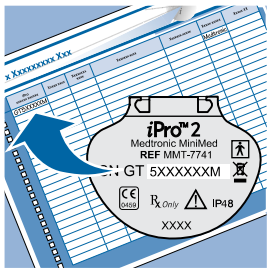
Uploading iPro2 data

NOTE: Always navigate using the buttons and links in CareLink iPro.

1 Verify that the iPro2 you are about to upload is for the patient whose record you are viewing in CareLink iPro:

a. Find the serial number on the Clinic Equipment Log and on the Patient Log Sheet. These should match the serial number on the back of the iPro2.

b. On the Clinic Equipment Log, indicate that the iPro2 has been returned.



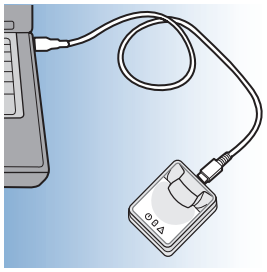
CAUTION: Always make sure to verify that you are uploading the correct iPro2.

2 Click the **Upload iPro2** button.

3 Follow the on-screen instructions.

If you see a security warning asking if you want to continue, this is asking if you trust that the content of this system is safe. Your trust is based on the fact that Medtronic MiniMed® has stated that is safe. Select the check box **Always trust content from this publisher**, and then click **Yes**.

4 Make sure that the Dock is connected to the computer by checking both ends of the Dock USB cable for a complete connection. The white Dock power light indicates that it is connected to a power source such as a computer or wall-powered adapter.

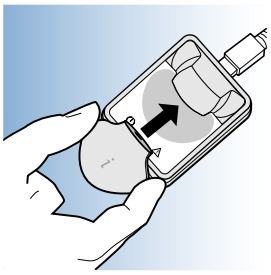


If you do not see the white Dock power light, the Dock may have insufficient power to operate. If it is the only device connected, try plugging the Dock into a different USB port directly on the computer. Not all USB ports may get sufficient power for the Dock to operate.

You can also connect the Dock to the computer using a USB hub. However, if the white Dock power light does not turn on, then try using a powered USB hub, which has its own electrical plug that is connected to an electrical socket.

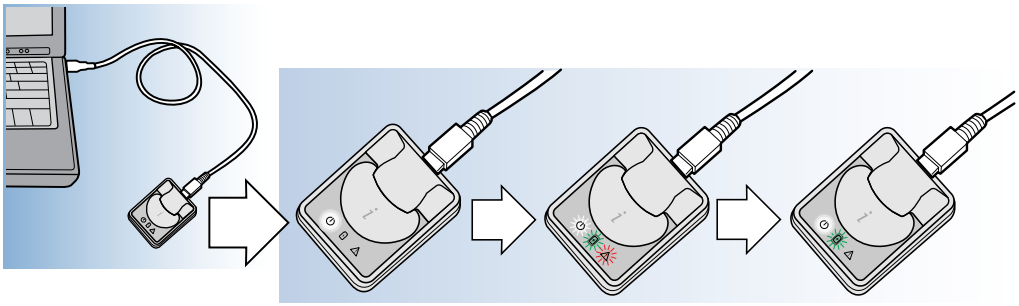
5 When instructed by CareLink iPro, connect the iPro2 to the Dock.

WARNING: Always inspect the iPro2 connector opening for body fluid. Always clean and disinfect the iPro2 after removing it from the patient and before attaching it to the Dock.



CAUTION: Do not connect more than one Dock to the computer at one time. Only connect the iPro2 associated with the opened patient record to the Dock.

The three lights on the Dock will flash once when you connect the iPro2. Then the green charging light on the Dock will start flashing  . This indicates that the iPro2 contains data that needs to be uploaded (or that the iPro2 is charging).



6 Click **Continue**. CareLink iPro tells you when the upload is successfully completed.

If you see a message that instructs you to see the User Guide, please look up that message in *Troubleshooting reference on page 37*.

7 Check the green charging light on the Dock.

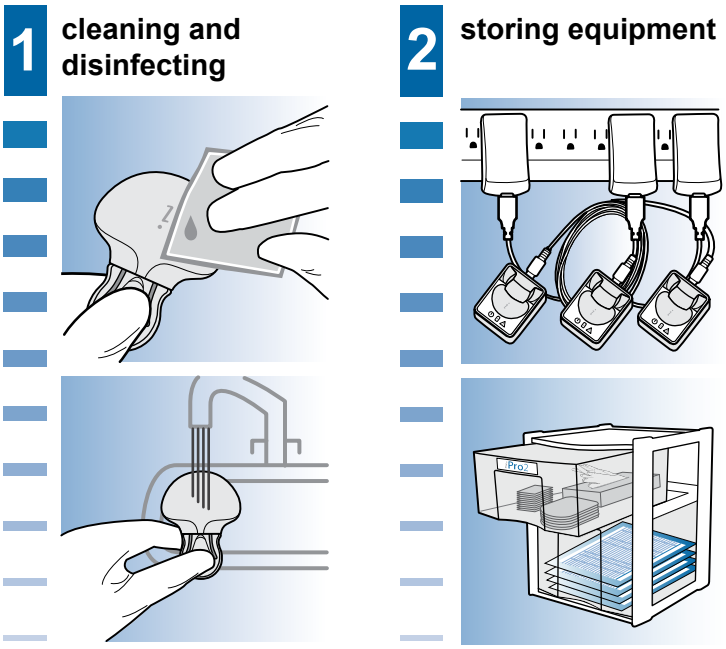
- If the green charging light on the Dock is on and no longer flashing, the iPro2 is charged and ready for the next patient.

- If the green charging light is still flashing after the upload, leave the iPro2 on the Dock to charge it, so that it is ready for the next patient.

- You can also choose to move the Dock to the wall-powered adapter for charging the iPro2, or move the iPro2 to another Dock that is connected to a wall-powered adapter, if you have multiple iPro2 systems.

5

System maintenance



Key Notes:

- Always connect the cleaning plug to the iPro2 before cleaning.
- When not in use, leave the iPro2 connected to the Dock, so it will be ready for use with the next patient.
- If an iPro2 is unused for several weeks, you must store it on a powered Dock. Otherwise, the iPro2 battery could become damaged.
- Keep extra Patient Log Sheets and other iPro2 supplies in an organized cabinet.

Cleaning the iPro2

Always clean and disinfect the iPro2 after removing it from a patient. Make sure to connect the cleaning plug to the iPro2 before cleaning and disinfecting. For complete instructions, see *Cleaning and disinfecting the iPro2 on page 24*.

Cleaning the Dock

The Dock cannot be disinfected. This procedure is for general cleaning as required, based on physical appearance.

WARNING: Always clean and disinfect the iPro2 after removing it from the patient and before attaching it to the Dock. If the Dock's connector comes in contact with blood, the Dock must be discarded because the Dock's connector cannot be disinfected. Dispose of the Dock according to the local regulations for electronic devices.

CAUTION: The Dock is not watertight. Do not immerse in water or any other cleaning agent. Do not allow liquid to come in contact with the Dock's connector, USB port, or reset button. Repeated exposure to liquid could damage the connector and affect the performance of the device. If liquid comes in contact with the connector, allow the Dock to air dry before proceeding with the cleaning instructions.

1. Disconnect the Dock USB cable from the computer or wall-powered adapter.
2. Disconnect the Dock from the USB cable.
3. Use a damp cloth with mild cleaning solution, such as a dishwashing detergent, to clean any dirt or foreign material from the outside of the Dock. Never use organic solvents such as paint thinner or acetone to clean the Dock.
4. Place the Dock on a clean, dry cloth and allow it to air dry completely.
5. When the Dock is completely dry, you can reconnect it to the computer or wall-powered adapter with the USB cable.

Components that cannot be cleaned

You cannot clean the following components of the iPro2 system:

- Cleaning plugs (discard each cleaning plug after 30 uses)
- Wall-powered adapter
- Dock USB cable

Charging the iPro2 between studies

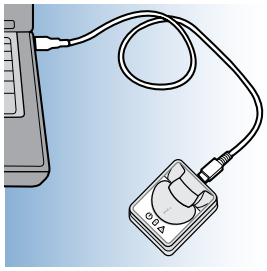
Charge the iPro2 in the Dock. The Dock can be connected to the computer or to the wall-powered adapter, which lets you use a regular power outlet for charging. While the iPro2 is charging, the green charging light on the Dock is flashing, as shown:

Between patient studies, the iPro2 should take less than 30 minutes to reach a full charge. When the iPro2 is fully charged, the green charging light on the Dock remains on:

CAUTION: If the green charging light continues to flash and never turns solid, this indicates that the iPro2 contains patient data that you have not uploaded. You cannot use the iPro2 for another study until you upload the data. If you need to clear the data without uploading it, you can perform a reset. For details, see *Resetting the iPro2 on page 42****.***

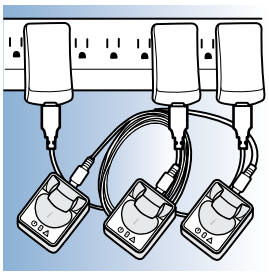
Always leave the iPro2 connected to a powered Dock when not in use. This maintains the life of the iPro2 battery and keeps the iPro2 ready for the next patient study.

If your clinic has only one iPro2, you can leave the Dock connected to the computer and connect the iPro2 to the Dock when not in use. The computer supplies enough power to charge the iPro2, as long as the computer is on and the white Dock power light is on  .



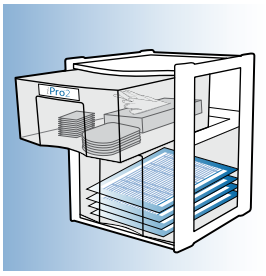
If you have multiple iPro2s, you can use the wall-powered adapters to keep them charged at power outlets, and leave one Dock connected to the computer at all times so that it is ready to upload data.

Tip: To extend the life of your Docks, mark your calendar to periodically exchange the Dock that you have connected to the computer with a Dock that is connected to an electrical socket. The Dock connected to the computer gets the most use, and the connector pins can wear out over time.



Storage and organization tips

When not in use, store the iPro2 on the Dock and keep the Dock plugged in, so that the iPro2 remains charged. Otherwise, the iPro2 battery could become damaged.



You can organize your other iPro2 supplies in a small drawer organizer, such as the one shown here. These are some of the items that you will want to keep on hand and ready for the next patient:

- Serter
- Glucose sensors
- Occlusive adhesive dressings
- Alcohol swabs
- Liquid dishwashing detergent
- Adhesive remover
- Gloves
- Documents and forms, including:
  - Patient Log Sheets
  - Patient Consent Forms
  - Patient Instructions Sheets
  - Clinic Equipment Log Sheets
  - Clinic Checklists

- A printed copy of this User Guide

- Cleaning plugs
- Gauze pads or cloth
- 70% isopropyl alcohol
- ENZOL® Enzymatic Detergent
- Bleach (6% sodium hypochlorite)
- Soft-bristled brush

A

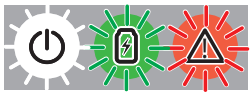
Troubleshooting

This appendix contains troubleshooting information for the iPro2 CGM System. Please refer to these instructions before contacting the 24 Hour HelpLine.

Troubleshooting reference

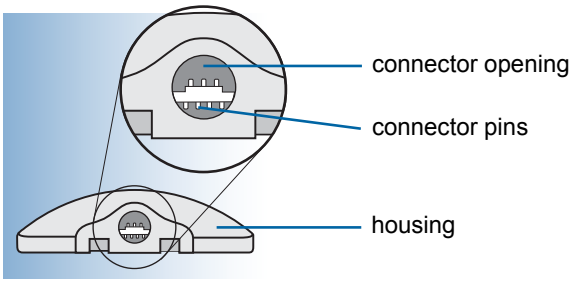
Problem	Possible causes	What to do
I connected the iPro2 to the sensor, and the iPro2 did not flash after 20 seconds.	Either the sensor is not adequately hydrated, the iPro2 is not connected properly, or the iPro2 is not ready to begin a study.	Did you take the iPro2 directly from a powered Dock, and did the Dock display a solid green charging light?  • If yes, then the iPro2 may not be connected properly, or the sensor may not be fully hydrated. Disconnect and reconnect the iPro2. If this does not work, wait another five minutes and then connect the iPro2 to the sensor. If the iPro2 still does not flash, wait another five minutes and try again. In some cases, it can take up to two hours for the sensor to become hydrated. If the iPro2 still does not flash after two hours, you can remove the sensor and insert a new sensor in a different site on the body. • If no, or if you are not sure, the iPro2 may not be fully charged, or may still contain data from a previous study. In these cases, the green light will not flash when connected to the sensor. Disconnect the iPro2 from the sensor. Clean and disinfect it (see *Cleaning and disinfecting the iPro2 on page 24*), and then connect it to the Dock. If the green charging light on the Dock turns solid after two minutes, the iPro2 is ready to start a study on a new patient. If not, the iPro2 needs to be charged or still contains patient data from the previous study. If these steps do not work, use the Dock to reset the iPro2. For instructions, see *Resetting the iPro2 on page 42*.

Troubleshooting reference		
Problem	**Possible causes**	**What to do**
The iPro2 has been connected to the Dock with adequate power for two to three hours, but the green charging light keeps flashing. 	The iPro2 most likely contains data that has not been uploaded.	• Check the Clinic Equipment Log or Patient Log Sheets to find out which patient's data was last collected. Open CareLink iPro and check to see if a study was uploaded for the dates on the log sheet. If there is no study, upload the iPro2 into that patient's record in CareLink iPro. CareLink iPro clears the data off of the iPro2 as part of the upload process. You must then wait for the green charging light on the Dock to turn solid before the iPro2 is ready to use for the next patient. • If you are unable to identify which patient's data is still on the iPro2, or if you are unable to upload the iPro2 successfully, you may need to reset the iPro2. For instructions, see *Resetting the iPro2 on page 42*.
I connected the iPro2 to the Dock and no lights came on.	The Dock may not be connected to the computer, or it may not have sufficient power. The white Dock power light  must be on before connecting the iPro2.	Try connecting the Dock to a different USB port on the computer. Wait for all three lights to flash, followed by a solid white light. If the Dock is connected to the computer but none of the lights turn on, there may be other USB devices connected that are using up power. Disconnect other devices. Do not connect more than one Dock at a time to a computer. You can also try connecting the Dock to another computer. If the white Dock power light is on, but the three lights do not flash when you connect the iPro2, check the iPro2 connector pins for damage or moisture. For assistance in locating the connector pins, see *Checking the iPro2 connector pins on page 40*. If the pins are damaged or corroded, the iPro2 cannot communicate with the Dock or CareLink iPro. Contact the 24 Hour HelpLine. It may be time to replace the iPro2.

Troubleshooting reference		
Problem	**Possible causes**	**What to do**
I connected the iPro2 to the Dock and all three lights are flashing on and off repeatedly. 	This could mean that the iPro2 is not properly connected to the Dock.	Disconnect and reconnect the iPro2 to the Dock.
The iPro2 is connected to the Dock and the red warning light is on. 	This could mean that the iPro2 is not properly connected to the Dock or needs to be reset. It also could mean that there is damage to the iPro2 battery, circuitry, or connector pins. The iPro2 may need to be replaced.	Disconnect the iPro2 and check the connector pins for damage, corrosion, or moisture. For assistance in locating the connector pins, see *Checking the iPro2 connector pins on page 40*. After you confirm that the pins are not damaged or corroded, reconnect the iPro2 to the Dock. If another Dock is available, try connecting the iPro2 to the other Dock. If there is sensor data on the iPro2, upload the sensor data using CareLink iPro. If the red warning light turns on again, perform a reset as described in *Resetting the iPro2 on page 42*. Allow the iPro2 to charge for 20 minutes. **Please note that by performing a reset, all iPro2 sensor data will be erased**. If the red warning light continues to turn on, or if the iPro2 pins are damaged or corroded, contact the 24 Hour HelpLine. It may be time to replace the iPro2.

Checking the iPro2 connector pins

If the troubleshooting reference advises you to check the connector pins of the iPro2, use the following image to assist you. This image is an example of how the connector pins should look.



Look inside the iPro2's connector opening to make sure that the connector pins are not damaged or corroded. If the connector pins are damaged or corroded, the iPro2 cannot communicate with the Dock or CareLink iPro. Contact the 24 Hour HelpLine. It may be time to replace the iPro2.

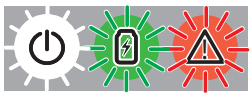
Also look for moisture inside the connector opening. If you see any moisture, allow the iPro2 to dry for at least one hour. Moisture inside the connector opening could cause the iPro2 to not work properly, and could cause corrosion and damage over time.

To help prevent damage to the pins:

- Make sure to carefully connect the cleaning plug or sensor to the iPro2.
- Do not twist or bend the cleaning plug or sensor when connecting to the iPro2.

For instructions on how to properly clean the iPro2 using the cleaning plug, see *Cleaning and disinfecting the iPro2 on page 24*. For instructions on how to properly connect the iPro2 to a sensor, see *Connecting the iPro2 to the sensor on page 19*.

Dock lights quick reference

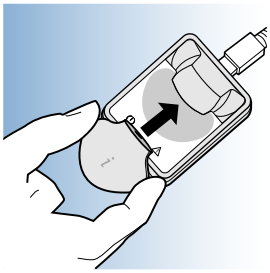
Dock lights	Description	What it means
	All of the lights are off.	The Dock is not plugged into an electrical outlet or computer USB port. If it is plugged in, it may not be receiving enough power.
	The white Dock power light is on.	The Dock is connected to power. If connected to an electrical outlet, it is ready to charge an iPro2. If connected to a computer USB port, it is ready to charge an iPro2 or upload data from an iPro2. The iPro2 is not connected to the Dock.
	All three lights flash once.	All of the Dock lights flash once when you first connect the Dock to a sufficient power source, or when you connect the iPro2 to the Dock.
	The white Dock power light is on and the green charging light is flashing continuously.	The iPro2 is charging **or** the iPro2 contains data that must be uploaded using CareLink iPro. After you upload data, if the green charging light continues to flash, the iPro2 is still charging and is not ready to begin a new patient study.
	The white Dock power light and green charging light are on.	All previous data has been cleared from the iPro2. The iPro2 is fully charged and ready for the next patient study.
	The white Dock power light flashed five times and the green charging light is flashing continuously.	The white Dock power light will flash five times after you press the reset button. The green charging light will continue to flash as the iPro2 charges. When the iPro2 is fully charged, the green charging light will stop flashing and remain on.
	The white Dock power light and the red warning light are on.	There may be a problem with the iPro2. See *Troubleshooting reference on page 37* for details.

Resetting the iPro2

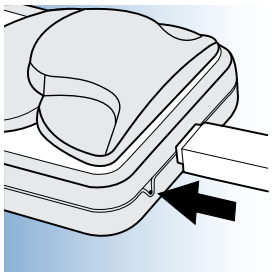
CAUTION: This procedure erases all patient data from the iPro2. Do not perform these steps unless you have already uploaded the last patient study, or you are prepared to erase any data that may be on the iPro2.

1 Connect the Dock to power and make sure that the white Dock power light is on.

2 Place the iPro2 into the Dock.

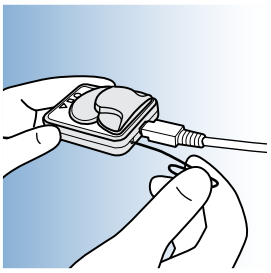


3 Find the small hole on the back of the Dock, next to the USB cable.



4 Insert the end of a small paper clip into the hole about 1/8 inch (0.30 cm). Push the reset button once and release. The white Dock power light will flash . After a few seconds, the green light on the iPro2 will flash.

Important: Do not apply excessive pressure, or the reset button may be damaged.



5 Wait for the Dock to show a solid green charging light  . This indicates that the data has been cleared, and the iPro2 is fully charged and ready for the next patient study.

B

Enlite Sensor Performance for the iPro2

CGM performance

The iPro2 Continuous Glucose Monitoring (CGM) is intended to continuously record interstitial glucose levels in persons with diabetes mellitus. This information is intended to supplement, not replace, blood glucose information obtained using standard home glucose monitoring devices. The information collected by the iPro2 digital recorder may be uploaded to a computer (with Internet access) and reviewed by healthcare professionals. The information may allow identification of patterns of glucose-level excursions above and below a desired range, facilitating adjustments, which may minimize these excursions.

Clinical study description

The performance of the Enlite sensor was evaluated in a clinical study[1]. This inpatient (in-clinic) and outpatient (at home) study included subjects 18 to 75 years in age. The study design was a multi-center, prospective single-sample correlational design without controls. All subjects were assigned to treatment. Each subject was instructed to wear two Enlite sensors connected to two MiniLink transmitters and two Revel™ 2.0 pumps (which use the same CGM technology as the MiniMed 530G insulin pump). Bayer's CONTOUR® NEXT LINK Wireless Meter was used as the study meter, and was used for all calibrations in this study. This system was tested with Bayer's CONTOUR® NEXT LINK Wireless Meter, but has not been tested with other meters. Therefore, the performance of this system with other blood glucose meters may differ from the performance with the Bayer's CONTOUR® NEXT LINK Wireless Meter described below.

On days 1, 3, and 6, frequent sample testing (FST) was performed. Reference blood (plasma) glucose values were obtained with a Yellow Springs Instrument (YSI®) Glucose Analyzer every 5-15 minutes and compared with sensor glucose values. During the FSTs, the subjects were instructed to calibrate one sensor three to four times spread throughout the day, and calibrate the other sensor, once every 12 hours. During home use (outside the clinic), subjects were instructed to calibrate both sensors three to four times spread throughout the day.

A total of 111 subjects previously diagnosed with type 1 or 2 diabetes were enrolled in the study, 20 subjects failed the screening, 61 subjects with abdominal insertions completed the study, and one subject enrolled after the study was completed. During each FST, subjects with an established insulin sensitivity ratio and insulin carbohydrate ratio underwent a hypoglycemic challenge and a hyperglycemic challenge. Subjects were instructed to continue with their current diabetes regimen (including glucose monitoring with their own meter when desired) independent of their use of the study devices. The Revel 2.0 pumps were not used to infuse insulin or manage diabetes during this study. The meter was used for confirmation of alarms, treatment decisions and sensor calibrations. The sensor signal is retrospectively calibrated with CareLink iPro and evaluated against YSI reference glucose values.

1 Medtronic Inc., A Performance Evaluation of the Enlite Glucose Sensor to Support a Full 144 hours (6 Days) of Use, CER247/Z25/C, May 2012

Results

Mean and median absolute relative difference, by number of daily calibrations

The overall mean absolute relative difference (ARD) between the Enlite sensor (CGM readings) and the reference YSI values was 15.6% and the median ARD was 11.1%, from inpatient frequent sample testing (FST) during hypoglycemic and hyperglycemic challenges.

Table 1. CGM difference to YSI within YSI glucose ranges; Calibrating three to four times daily, Abdomen insertion site

YSI glucose ranges (mg/dL)	Number of paired CGM-YSI	Mean percent difference (%)	Median percent difference (%)	Mean absolute percent difference (%)	Median absolute percent difference (%)
Overall	7272	7.40	5.19	15.57	11.11
<40*	3	23.52	10.65	23.52	10.65
40-60*	604	9.55	8.82	13.97	11.05
61-80*	1369	10.07	9.85	15.94	12.75
81-180	3200	7.04	6.12	13.57	10.08
181-300	1613	0.77	1.12	10.79	7.90
301-350	313	0.58	0.31	9.30	7.97
351-400	143	-5.81	-3.24	9.57	6.41
>400	27	-16.04	-14.03	16.04	14.03

**For YSI reference range ≤ 80 mg/dL, the differences in mg/dL are included instead of percent difference (%).*

NOTE: CGM Readings are within 40-400 mg/dL.

Table 2. CGM difference to YSI within YSI glucose ranges; Calibrating every 12 hours, Abdomen insertion site.

YSI glucose ranges (mg/dL)	Number of paired CGM-YSI	Mean percent difference (%)	Median percent difference (%)	Mean absolute percent difference (%)	Median absolute percent difference (%)
Overall	7729	5.47	3.83	14.44	10.15
>40*	3	10.52	11.90	10.52	11.90
40-60*	546	10.97	9.93	14.96	12.28
61-80*	1394	8.34	7.15	14.40	11.12
81-180	3280	5.71	5.25	12.76	9.87
181-300	1922	-1.24	0.00	10.40	7.43
301-350	360	-1.91	-1.56	9.06	6.58
351-400	173	-4.50	-1.92	8.25	6.18
>400	51	-12.71	-11.60	12.71	11.60

**For YSI reference range ≤ 80 mg/dL, the differences in mg/dL are included instead of percent difference (%).*

NOTE: CGM Readings are within 40-400 mg/dL.

Table 3. CGM difference to YSI within CGM glucose ranges; Calibrating three to four times a day, Abdomen insertion site.

CGM glucose ranges (mg/dL)	Number of paired CGM-YSI	Mean percent difference (%)	Median percent difference (%)	Mean absolute percent difference (%)	Median absolute percent difference (%)
Overall	7272	-3.37	-4.94	14.28	10.65
40-60*	510	9.82	8.50	11.35	9.38
61-80*	892	-1.89	-3.95	10.63	8.95
81-180	3642	-7.27	-7.74	15.30	11.81
181-300	1734	-2.46	-3.25	10.49	8.20
301-350	298	-2.31	-1.58	8.46	7.02
351-400	196	-7.69	-8.25	10.61	9.15

**For CGM range ≤ 80 mg/dL, the differences in mg/dL are included instead of percent difference (%).*

Table 4. CGM difference to YSI within CGM glucose ranges; Calibrating every 12 hours, Abdomen insertion site.

CGM glucose ranges (mg/dL)	Number of paired CGM-YSI	Mean percent difference (%)	Median percent difference (%)	Mean absolute percent difference (%)	Median absolute percent difference (%)
Overall	7729	-1.76	-3.69	13.62	9.86
40-60*	464	10.66	9.95	12.18	10.07
61-80*	983	-4.08	-5.25	9.49	7.85
81-180	3792	-4.40	-6.05	14.86	11.31
181-300	1904	-0.41	-1.88	9.90	7.28
301-350	345	-1.59	-1.30	8.48	6.61
351-400	241	-4.37	-3.61	8.94	6.62

**For CGM range ≤ 80 mg/dL, the differences in mg/dL are included instead of percent difference (%).*

Percent agreement, by number of daily calibrations

The accuracy of the Enlite sensor (CGM) was also evaluated by calculating the percentage of CGM readings within ±15%, ±20%, ±30%, and ±40% of the YSI values (or within ±15, ±20, ±30, or ±40 mg/dL in the low glucose range of 40–80 mg/dL). These results are shown for various YSI glucose ranges when calibrating three to four times a day and also for calibrating every 12 hours. For example, 90.6% of all Enlite sensors readings (from 40 to 400 mg/dL) were within 30% of the YSI value when calibrating three to four times per day.

Table 5. Agreement (%) of CGM-YSI paired points within YSI Glucose Ranges, Abdomen insertion site, calibrating three to four times a day.

YSI glucose ranges (mg/dL)	Number of paired CGM-YSI	Percent of CGM within 15/15% of YSI	Percent of CGM within 20/20% of YSI	Percent of CGM within 30/30% of YSI	Percent of CGM within 40/40% of YSI	Percent of CGM greater than 40/40% of YSI
Overall	7272	67.10%	78.60%	90.60%	96.40%	3.60%
<40*	3	66.70%	66.70%	66.70%	66.70%	33.30%
≥40-60*	604	64.60%	76.20%	88.60%	96.50%	3.50%
>60-80*	1369	56.80%	70.70%	86.40%	95.60%	4.40%
>80-180	3200	65.50%	77.20%	90.10%	95.70%	4.30%
>180-300	1613	76.40%	85.80%	94.40%	97.70%	2.30%
>300-350	313	79.90%	90.10%	98.10%	99.40%	0.60%
>350-400	143	83.20%	88.80%	93.00%	97.90%	2.10%
>400	27	55.60%	81.50%	88.90%	92.60%	7.40%

For YSI reference range ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

NOTE: CGM Readings are within 40-400 mg/dL.

Table 6. Agreement (%) of sensor-YSI paired points within YSI Glucose Ranges, Abdomen insertion site, calibrating every 12 hours.

YSI glucose ranges (mg/dL)	Number of paired CGM-YSI	Percent of CGM within 15/15% of YSI	Percent of CGM within 20/20% of YSI	Percent of CGM within 30/30% of YSI	Percent of CGM within 40/40% of YSI	Percent of CGM greater than 40/40% of YSI
Overall	7729	70.50%	81.70%	92.80%	96.70%	3.30%
<40*	3	66.70%	100.00%	100.00%	100.00%	0.00%
≥40-60*	546	58.10%	75.80%	90.80%	95.20%	4.80%
>60-80*	1394	63.60%	75.50%	90.50%	95.30%	4.70%
>80-180	3280	68.10%	80.50%	92.70%	96.90%	3.10%
>180-300	1922	79.70%	87.20%	94.20%	97.00%	3.00%
>300-350	360	81.90%	90.60%	96.90%	99.40%	0.60%
>350-400	173	87.30%	91.90%	96.00%	98.80%	1.20%
>400	51	66.70%	88.20%	94.10%	96.10%	3.90%

For YSI reference range ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

NOTE: CGM Readings are within 40-400 mg/dL.

Similarly, the accuracy of the Enlite (CGM) sensor was also evaluated by calculating the percentage of Enlite sensor readings within ±15%, ±20%, ±30%, and ±40% (or within ±15 , ±20, ±30, or ±40 mg/dL in the low glucose range of 40–80 mg/dL) of the YSI values. These results are shown for various CGM glucose ranges when calibrating three to four times a day and also for calibrating every 12 hours. For example, 91.7% of all Enlite sensors readings (from 40 to 400 mg/dL) were within 30% of the YSI value when calibrating three to four times per day.

Table 7. Agreement (%) of sensor-YSI paired points within CGM glucose ranges, Abdomen insertion site, calibrating three to four times a day.

CGM glucose ranges (mg/dL)	Number of paired CGM-YSI	Percent of YSI within 15/15% of CGM	Percent of YSI within 20/20% of CGM	Percent of YSI within 30/30% of CGM	Percent of YSI within 40/40% of CGM	Percent of YSI greater than 40/40% of CGM
Overall	7272	68.80%	79.80%	91.70%	97.00%	3.00%
≥40-60*	510	77.30%	87.10%	94.90%	97.60%	2.40%
>60-80*	892	79.40%	89.60%	96.50%	97.90%	2.10%
>80-180	3642	59.30%	71.40%	87.20%	95.70%	4.30%

Table 7. Agreement (%) of sensor-YSI paired points within CGM glucose ranges, Abdomen insertion site, calibrating three to four times a day.

CGM glucose ranges (mg/dL)	Number of paired CGM-YSI	Percent of YSI within 15/15% of CGM	Percent of YSI within 20/20% of CGM	Percent of YSI within 30/30% of CGM	Percent of YSI within 40/40% of CGM	Percent of YSI greater than 40/40% of CGM
>180-300	1734	77.20%	87.00%	96.00%	98.40%	1.60%
>300-350	298	84.20%	94.30%	98.70%	99.70%	0.30%
>350-400	196	77.60%	88.30%	98.00%	100.00%	0.00%

**For CGM reference range ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.*

Table 8. Agreement (%) of sensor-YSI paired points within CGM glucose ranges, Abdomen insertion site, calibrating every 12 hours.

CGM glucose ranges (mg/dL)	Number of paired CGM-YSI	Percent of YSI within 15/15% of CGM	Percent of YSI within 20/20% of CGM	Percent of YSI within 30/30% of CGM	Percent of YSI within 40/40% of CGM	Percent of YSI greater than 40/40% of CGM
Overall	7729	71.00%	82.30%	92.70%	96.90%	3.10%
≥40-60*	464	71.80%	83.40%	96.80%	98.50%	1.50%
>60-80*	983	80.20%	91.80%	98.30%	99.40%	0.60%
>80-180	3792	62.20%	74.80%	88.50%	95.30%	4.70%
>180-300	1904	79.80%	88.90%	95.70%	97.80%	2.20%
>300-350	345	85.80%	93.60%	97.70%	99.40%	0.60%
>350-400	241	79.30%	91.70%	97.50%	99.20%	0.80%

**For CGM reference range ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.*

Table 9 and 10. The number and percentage of YSI values collected when CGM readings displayed 'Low' (less than 40 mg/dL) and 'High' (greater than 400 mg/dL); Calibrating three to four times a day, Abdomen insertion site.

		YSI mg/dL					
CGM readings	CGM-YSI pairs	<55	<60	<70	<80	>80	Total
'LOW'	Cumulative, n	0	0	0	0	0	0
'LOW'	Cumulative %	0%	0%	0%	0%	0%	

YSI mg/dL							
CGM readings	**CGM-YSI pairs**	**>340**	**>320**	**>280**	**>240**	**<240**	**Total**
'HIGH'	Cumulative, n	0	0	0	0	0	0
'HIGH'	Cumulative %	0%	0%	0%	0%	0%	

Tables 11 and 12. The number and percentage of YSI values collected when CGM readings displayed 'Low' (less than 40 mg/dL) and 'High' (greater than 400 mg/dL); Calibrating every 12 hours, Abdomen insertion site.

YSI mg/dL							
CGM readings	**CGM-YSI pairs**	**<55**	**<60**	**<70**	**<80**	**>80**	**Total**
'LOW'	Cumulative, n	0	0	0	0	0	0
'LOW'	Cumulative %	0%	0%	0%	0%	0%	

YSI mg/dL							
CGM readings	**CGM-YSI pairs**	**>340**	**>320**	**>280**	**>240**	**<240**	**Total**
'HIGH'	Cumulative, n	0	0	0	0	0	0
'HIGH'	Cumulative %	0%	0%	0%	0%	0%	

The following tables show the percentage of concurrent CGM readings with YSI reference values. With ideal performance the CGM readings would match the YSI values, therefore the bold percentages would ideally be 100 percent.

Table 13.The concurrence of YSI values and CGM readings using YSI glucose ranges; Calibrating three to four times a day, Abdomen insertion site.

Percent of Matched Pairs-in Each CGM Glucose Range for Each YSI Glucose Range CGM Glucose Ranges (mg/dL)												
YSI Glucose Ranges (mg/dL)	Number of Paired CGM-YSI	<40	>=40 -60	>60-80	>80-120	>120 -160	>160 -200	>200 -250	>250 -300	>300 -350	>350 -400	>400
<40	3	**0.0 %**	66.7 %	0.0%	33.3 %	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
>=40-60	604	0.0%	**44.5 %**	38.6 %	16.7 %	0.2%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Table 13.The concurrence of YSI values and CGM readings using YSI glucose ranges; Calibrating three to four times a day, Abdomen insertion site.

Percent of Matched Pairs-in Each CGM Glucose Range for Each YSI Glucose Range CGM Glucose Ranges (mg/dL)												
>60-80	1369	0.0%	15.6 %	**39.3 %**	43.2 %	1.8%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
>80-120	1412	0.0%	1.6%	7.8%	**61.0 %**	28.2 %	1.2%	0.2%	0.0%	0.0%	0.0%	0.0%
>120-160	1253	0.0%	0.0%	0.9%	9.6%	**61.9 %**	25.1 %	2.4%	0.1%	0.0%	0.0%	0.0%
>160-200	973	0.0%	0.0%	0.0%	1.7%	11.4 %	**60.1 %**	25.5 %	1.0%	0.2%	0.0%	0.0%
>200-250	680	0.0%	0.3%	0.0%	1.2%	4.0%	16.6 %	**59.0 %**	17.4 %	1.5%	0.1%	0.0%
>250-300	495	0.0%	0.0%	0.0%	0.6%	0.0%	2.0%	23.2 %	**53.9 %**	16.8 %	3.4%	0.0%
>300-350	313	0.0%	0.0%	0.0%	0.0%	0.0%	0.6%	2.6%	22.7 %	**47.3 %**	26.8 %	0.0%
>350-400	143	0.0%	0.0%	0.0%	0.0%	0.0%	2.1%	3.5%	7.0%	33.6 %	**53.8 %**	0.0%
>400	27	0.0%	0.0%	0.0%	0.0%	3.7%	0.0%	3.7%	3.7%	25.9 %	63.0 %	**0.0 %**

Table 14.The concurrence of YSI values and CGM readings using YSI glucose ranges; Calibrating every 12 hours, Abdomen insertion site.

Percent of Matched Pairs-in Each CGM Glucose Range for Each YSI Glucose Range CGM Glucose Ranges (mg/dL)												
YSI Glucose Ranges (mg/dL)	Number of Paired CGM-YSI	<40	>=40 -60	>60-80	>80-120	>120 -160	>160 -200	>200 -250	>250 -300	>300 -350	>350 -400	>400
<40	3	0.0%	100 .0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
>=40-60	546	0.0%	**39.6 %**	45.8 %	13.7 %	0.9%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
>60-80	1394	0.0%	16.5 %	**45.8 %**	35.4 %	2.1%	0.3%	0.0%	0.0%	0.0%	0.0%	0.0%
>80-120	1327	0.0%	0.9%	7.0%	**59.8 %**	31.2 %	1.1%	0.1%	0.0%	0.0%	0.0%	0.0%
>120-160	1389	0.0%	0.0%	0.1%	13.4 %	**63.2 %**	22.1 %	1.2%	0.0%	0.1%	0.0%	0.0%
>160-200	1045	0.0%	0.3%	0.0%	1.1%	18.7 %	**59.6 %**	19.3 %	0.7%	0.1%	0.2%	0.0%
>200-250	857	0.0%	0.0%	0.1%	1.9%	4.7%	19.1 %	**58.1 %**	14.9 %	1.1%	0.1%	0.0%
>250-300	584	0.0%	0.0%	0.0%	0.0%	0.9%	5.5%	18.0 %	**56.0 %**	17.3 %	2.4%	0.0%

Table 14.The concurrence of YSI values and CGM readings using YSI glucose ranges; Calibrating every 12 hours, Abdomen insertion site.

Percent of Matched Pairs-in Each CGM Glucose Range for Each YSI Glucose Range CGM Glucose Ranges (mg/dL)												
>300-350	360	0.0%	0.0%	0.0%	0.0%	0.0%	1.4%	3.9%	24.7 %	**48.6 %**	21.4 %	0.0%
>350-400	173	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	2.9%	5.8%	30.1 %	**61.3 %**	0.0%
>400	51	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	3.9%	3.9%	11.8 %	80.4 %	**0.0 %**

Table 15.The concurrence of CGM readings and YSI values using CGM glucose ranges; Calibrating three to four times a day, Abdomen insertion site.

Percent of Matched Pairs-in Each YSI Glucose Range for Each CGM Glucose Range YSI Glucose Ranges (mg/dL)												
YSI Glucose Ranges (mg/dL)	Number of Paired CGM-YSI	<40	>=40 -60	>60-80	>80-120	>120 -160	>160 -200	>200 -250	>250 -300	>300 -350	>350 -400	>400
>=40-60	510	0.4%	**52.7 %**	42.0 %	4.5%	0.0%	0.0%	0.4%	0.0%	0.0%	0.0%	0.0%
>60-80	892	0.0%	26.1 %	**60.3 %**	12.3 %	1.2%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
>80-120	1703	0.1%	5.9%	34.8 %	**50.6 %**	7.0%	1.0%	0.5%	0.2%	0.0%	0.0%	0.0%
>120-160	1339	0.0%	0.1%	1.9%	29.7 %	**58.0 %**	8.3%	2.0%	0.0%	0.0%	0.0%	0.1%
>160-200	1045	0.0%	0.0%	0.0%	1.6%	30.1 %	**56.0 %**	10.8 %	1.0%	0.2%	0.3%	0.0%
>200-250	811	0.0%	0.0%	0.0%	0.4%	3.7%	30.6 %	**49.4 %**	14.2 %	1.0%	0.6%	0.1%
>250-300	478	0.0%	0.0%	0.0%	0.0%	0.2%	2.1%	24.7 %	**55.9 %**	14.9 %	2.1%	0.2%
>300-350	298	0.0%	0.0%	0.0%	0.0%	0.0%	0.7%	3.4%	27.9 %	**49.7 %**	16.1 %	2.3%
>350-400	196	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.5%	8.7%	42.9 %	**39.3 %**	8.7%

Table 16.The concurrence of CGM readings and YSI values using CGM glucose ranges; Calibrating every 12 hours, Abdomen insertion site.

Percent of Matched Pairs-in Each YSI Glucose Range for Each CGM Glucose Range YSI Glucose Ranges (mg/dL)												
YSI Glucose Ranges (mg/dL)	Number of Paired CGM-YSI	<40	>=40 -60	>60-80	>80-120	>120 -160	>160 -200	>200 -250	>250 -300	>300 -350	>350 -400	>400
>=40-60	464	0.6%	**46.6 %**	49.6 %	2.6%	0.0%	0.6%	0.0%	0.0%	0.0%	0.0%	0.0%
>60-80	983	0.0%	25.4 %	**64.9 %**	9.5%	0.1%	0.0%	0.1%	0.0%	0.0%	0.0%	0.0%
>80-120	1575	0.0%	4.8%	31.3 %	**50.3 %**	11.8 %	0.8%	1.0%	0.0%	0.0%	0.0%	0.0%
>120-160	1566	0.0%	0.3%	1.9%	26.4 %	**56.1 %**	12.5 %	2.6%	0.3%	0.0%	0.0%	0.0%
>160-200	1149	0.0%	0.0%	0.3%	1.2%	26.7 %	**54.2 %**	14.3 %	2.8%	0.4%	0.0%	0.0%
>200-250	843	0.0%	0.0%	0.0%	0.1%	1.9%	24.0 %	**59.1 %**	12.5 %	1.7%	0.6%	0.2%
>250-300	563	0.0%	0.0%	0.0%	0.0%	0.0%	1.2%	22.7 %	**58.1 %**	15.8 %	1.8%	0.4%
>300-350	345	0.0%	0.0%	0.0%	0.0%	0.3%	0.3%	2.6%	29.3 %	**50.7 %**	15.1 %	1.7%
>350-400	241	0.0%	0.0%	0.0%	0.0%	0.0%	0.8%	0.4%	5.8%	32.0 %	**44.0 %**	17.0 %

Table 17. Ranges for every 2 hour post calibration period.

YSI Glucose Ranges (mg/dL)	Number of paired CGM-YSI	Percent of CGM within 15/15% of YSI	Percent of CGM within 20/20% of YSI	Percent of CGM within 30/30% of YSI	Percent of CGM within 40/40% of YSI	Percent of CGM greater than 40/40% of YSI
Overall	15001	68.90%	80.20%	91.70%	96.50%	3.50%
0-2 hours	7010	70.40%	81.10%	92.20%	96.90%	3.10%
2-4 hours	5320	69.20%	80.50%	91.60%	96.40%	3.60%
4-6 hours	2153	64.90%	77.60%	90.60%	95.90%	4.10%
6-8 hours	363	59.50%	73.60%	89.50%	93.10%	6.90%
8-10 hours	106	67.00%	81.10%	96.20%	99.10%	0.90%
10-12 hours	33	81.80%	90.90%	97.00%	97.00%	3.00%
Beyond 12hrs	4	50.00%	100.00%	100.00%	100.00%	0.00%
Before Calibration	12	50.00%	66.70%	83.30%	100.00%	0.00%

**For YSI reference range ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL. For CGM reference range ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.*

Sensor life

After calibration, 83.2% of sensors operated more than five days and up to the full six days of wear (120–144 hours).[1]

1 Medtronic Inc., A Performance Evaluation of the Enlite Glucose Sensor to Support a Full 144 hours (6 Days) of Use, CER247/Z25/C, May 2012

Safety

There were no moderate or severe device-related or procedure related adverse events, device-related or procedure-related serious adverse events, or unanticipated adverse device effects after six days of use.

C

Specifications and notices

iPro2 system specifications

Atmospheric pressure range	iPro2: 57.6 kPa - 106 kPa (16,000 to -1,300 feet [4,880 to -400 meters] elevation) Dock: 62 kPa - 106 kPa (13,000 to -1,300 feet [3,965 to -400 meters] elevation)
Applied Parts	iPro2 (MMT-7741) Sensor (MMT-7008)
Biocompatibility	iPro2: Complies with ISO 10993-1 for long-term body contact
Operating Conditions	iPro2 temperature: +23 °F to +113 °F (-5 °C to 45 °C) Caution: When the iPro2 is connected to the Dock in air temperatures greater than 106°F (41°C), the temperature of the iPro2 may exceed 109°F (43°C). iPro2 relative humidity: 5% to 95% with no condensation Dock temperature: +23 °F to +113 °F (-5 °C to +45 °C) Dock relative humidity: 5% to 95% with no condensation
Storage Conditions	iPro2 temperature: -13 °F to +131 °F (-25 °C to +55 °C) iPro2 relative humidity: 10% to 100% with condensation Dock temperature: -13 °F to +131 °F (-25 °C to +55 °C) Dock relative humidity: 10% to 100% with condensation
iPro2 Battery Life	7 days of continuous glucose monitoring (CGM) immediately following a full charge, plus 10 days of additional battery life immediately following a CGM study. Any data on the device will be lost when the battery loses its charge.
iPro2 Dimensions and Weight	Width: 1.4 inches (3.5 centimeters) Length: 1.1 inches (2.8 centimeters) Height: 0.4 inches (0.9 centimeters) Weight: 0.2 ounces (5.7 grams)
Dock Dimensions and Weight	Width: 2 inches (5.1 centimeters) Length: 2.5 inches (6.4 centimeters) Height: 1.1 inches (2.8 centimeters) Weight: 0.8 ounces (22.7 grams)

- The iPro2 is an internally powered device. The mode of operation is continuous. The iPro2 is not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
- All components of the iPro2 CGM system are suitable for use in a clinical environment. The iPro2 recorder is suitable for use with a glucose sensor in the patient environment.

Guidance and manufacturer's declaration

<table>
<tr><th colspan="3">Guidance and Manufacturer's Declaration - Electromagnetic Emissions</th></tr>
<tr><td colspan="3">The iPro2 CGM system is intended for use in the electromagnetic environment specified below. The customer or the user of the iPro2 CGM system should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions Test</th><th>Compliance</th><th>Electromagnetic Environment - Guidance</th></tr>
<tr><td>RF emissions

CISPR 11</td><td>Group 1</td><td>The iPro2 CGM system does not use RF energy for system communication functions.</td></tr>
<tr><td>RF emissions

CISPR 11</td><td>Class B</td><td rowspan="3">The iPro2 CGM system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions

IEC 61000-3-2</td><td>Complies by exemption</td></tr>
<tr><td>Voltage fluctuations/flicker emissions

IEC 61000-3-3</td><td>Complies by exemption</td></tr>
</table>

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The iPro2 CGM system is intended for use in the electromagnetic environment specified below. The customer or the user of the iPro2 CGM system should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV indirect ±8 kV air	±8 kV, 30%–60% relative humidity ±22 kV air (<5% relative humidity)	Relative humidity should be at least 5%.
Electrical fast transient/ burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV ±1 kV	Mains power should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV ±2 kV	Mains power should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 seconds	<5% U_T 40% U_T 70% U_T <5% U_T	Mains power should be that of a typical commercial or hospital environment. If the user of the iPro2 CGM system requires continued operation during power mains interruptions, it is recommended that the iPro2 CGM system be powered from uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: *U_T is the a.c. mains voltage prior to application of the test level.*			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The iPro2 CGM system is intended for use in the electromagnetic environment specified below. The customer or user of the iPro2 CGM system should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the iPro2 CGM system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80 MHz to 800 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 6.0 GHz	3 V/m	$d=2.3\sqrt{P}$ 800 MHz to 6.0 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: *At 80 MHz and 800 MHz, the higher frequency range applies.* ***NOTE 2:*** *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption, and reflection from structures, objects and people.*			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the iPro2 CGM system is used exceeds the application RF compliance level above, the iPro2 CGM system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the iPro2 CGM system. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the iPro2 CGM system

This section provides information on the recommended separation distance between portable and mobile RF communications equipment and the iPro2 CGM system. The iPro2 CGM system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or users of the iPro2 digital recorder can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the iPro2 digital recorder as recommended below, according to the maximum output power of the communications equipment.

	Separation distance according to the frequency of transmitter (m)		
Rated maximum output power of transmitter (W)	**150 kHz to 80 MHz** $d=1.2\sqrt{P}$	**80 MHz to 800 MHz** $d=1.2\sqrt{P}$	**800 MHz to 6.0 GHz** $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.74
1	1.2	1.2	2.3
10	3.8	3.8	7.4
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *p* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: *At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.*

NOTE 2: *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption, and reflection from structures, objects and people.*

Warranty

Medtronic Diabetes warrants the iPro2 and Dock to the purchaser of the product against defects in material and workmanship for a period of one year from the date of purchase.

During the warranty period, Medtronic Diabetes will repair or replace, at its discretion, any defective iPro2 or Dock, subject to the conditions and exclusions stated herein. This warranty applies only to new devices. In the event a iPro2 or Dock is repaired or replaced, the warranty period will not be extended past its original expiration date.

This warranty is valid only if the iPro2 or Dock is used in accordance with the manufacturer's instructions. Without limitation, this warranty will not apply:

- If damage results from changes or modifications made to the iPro2 or Dock by the user, or third parties, after the date of sale;
- If service or repairs are performed by any person or entity other than the manufacturer;
- If damage results from a *Force Majeure* or other event beyond the control of the manufacturer;
- If damage results from negligence or improper use, including but not limited to: improper storage, submersion in fluid, physical abuse (such as dropping); or
- If fluid has entered the inside of the iPro2 connector opening or the Dock.

This warranty shall be personal to the original user. Any sale, rental or other transfer or use of the product covered by this warranty to or by a user other than the original user shall cause this warranty to immediately terminate. This warranty does not apply to glucose sensors and other accessories.

The remedies provided for in this warranty are the exclusive remedies available for any defects in material or workmanship in the product. Neither Medtronic Diabetes nor its suppliers or distributors shall be liable for any incidental, consequential, punitive or special damages of any nature or kind caused by or arising out of a defect in the product.

All other warranties, expressed or implied, are excluded and specifically disclaimed, including, but not limited to, any warranty of merchantability or fitness for a particular purpose.

Icon table

Description	Icon
Follow instructions for use	
Attention: Read all warnings and precautions in instructions for use.	
Stand-by power	
Charging/uploading status	
Date of manufacture (year - month)	
Manufacturer	
Batch code	LOT
Catalogue number	REF
Device serial number	SN
Configuration	CONF
Storage humidity range	
Storage temperature range	
Fragile product	
Ingress protection safety rating. An object one millimeter in diameter cannot penetrate the device and cause harm to the user, property, or the environment. This device can withstand immersion under water for 30 minutes at a depth of 8 feet (2.4 meters).	IP48
Type BF equipment (Protection from electrical shock)	
Recycle	
One per container/package	(1x)
Three per container/package	(3x)
Keep dry	

Description	Icon
MEDICAL EQUIPMENT WITH RESPECT TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL 60601-1, CAN/CSA C22.2 No. 601 and IEC 60601-1-1.	

Glossary

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.

BG - Blood Glucose

BG reading - Blood glucose measurement that is taken by a blood glucose meter.

Calibrate - Check, adjust, or set to a standard. Sensor data is calibrated using BG meter readings.

Cleaning plug - Small plastic plug that you connect to the iPro2 before cleaning and disinfecting it. The cleaning plug protects the iPro2's connector pins from being damaged by water or cleaning fluids.

Docking Station (Dock) - Device that performs two functions: uploading glucose sensor data from an iPro2 to CareLink iPro; and charging the iPro2. The Dock can be connected to a computer or to an electrical socket.

iPro2 Recorder (iPro2) - Device that continuously records sensor glucose data while connected to a glucose sensor. You can upload the data to CareLink iPro by connecting the iPro2 to a Dock, and view the sensor data on reports.

Logbook - A screen in CareLink iPro that lets you manually enter events such as BG meter readings, meals, exercise, and medication taken, so that these events show up on reports. The Logbook also displays BG meter readings, and possibly other events, that you upload from a supported blood glucose meter into CareLink iPro.

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

Mean Absolute Difference (MAD) - Represents the level of accuracy in calibration of the sensor to BG meter readings. The lower this number, the greater the calibration accuracy. MAD is calculated by taking the difference between closely occurring pairs of sensor glucose and BG meter readings 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.

Serter - The Serter is an aid for the insertion of a Medtronic Diabetes glucose sensor.

Study - The period of time that a patient wears a glucose sensor and iPro2. This word also refers to an upload of glucose sensor data from an iPro2 into CareLink iPro, along with any meter upload and Logbook entries for that iPro2 upload. Each study has its own set of reports.

Upload - The process of transferring diabetes device data to the CareLink iPro server.

Index

Numerics

A

B

C

D

E

F

G

I

L

M

N

P

Q

R

S

T

U

W