iPRO™2 PROFESSIONAL CONTINUOUS GLUCOSE MONITORING SYSTEM

Uncover more in less time*

Clinic ID

(_____ - _____)
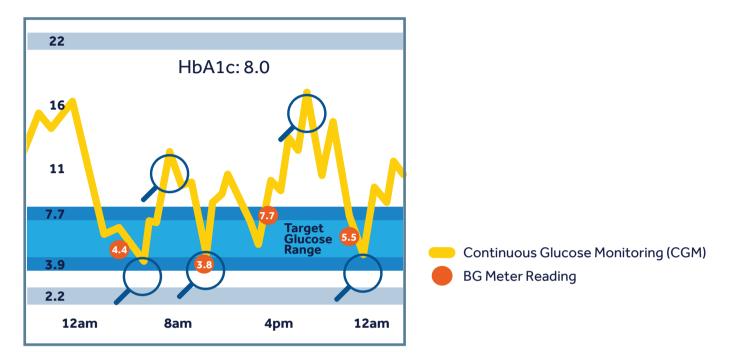
Medtronic

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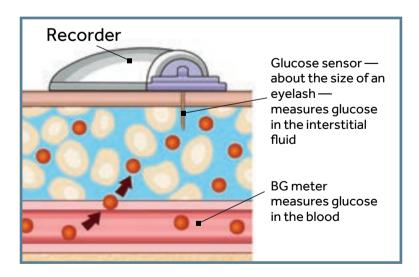
*Your system may require you to have Administrative Access for necessary downloads.

iPro2 Overview

In this training, you will learn to use the iPro2 Continuous Glucose Monitoring (CGM) system. Your patient will wear iPro2 CGM 3 to 6 days. During that time It measures and records glucose every 5 minutes (up to 288 readings per day), revealing hidden glucose excursions and trends which finger sticks miss.

The iPro2 sensor, measures glucose in the fluid just under the skin called interstitial fluid. It surrounds all of the fat and muscles cells.

Glucose measured in the interstitial fluid is similar to glucose levels measured in the blood.

Setting Up and Charging Your iPro2 Recorder

1

Docking Station

Wall-powered Adapter

iPro2 Recorder

Paper-clip

USB Cable

1. Find these iPro2 CGM components required for set-up. You will also need a small paper-clip.

2

2. Connect the USB cable to the docking station and wall-powered adapterPlug into the wall.

3

3. Once the dock is plugged into the wall, place the iPro2 into the docking station.

4

4. The recorder is delivered in sleep mode to preserve battery life and it must be activated. Find the small hole on the back of the docking station. Use the end of a paper-clip to push in about 3mm and release.

5

5. The white docking station power light will flash. After a few seconds the green light on the iPro2 recorder will flash green.

6

6. The recorder is now activated. Allow up to eight (8) hours for the iPro2 to charge. Once fully charged, the green light on the docking station will remain on solid. 🔋
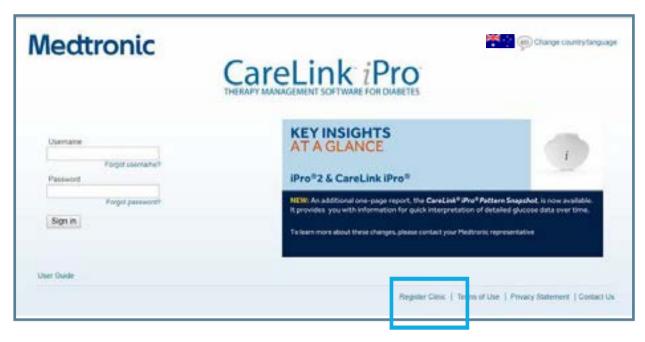
IMPORTANT:
The red warning light will turn on if you did not activate the iPro2 recorder properly.
If you see the red warning light, try steps 4 & 5 again.

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Creating Your CareLink iPro Profile

1. Use Firefox, Internet Explorer or Safari, go to **https://www.carelink.minimed.eu/ipro**

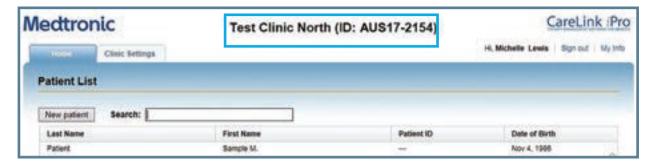**2.** Click on **Register Clinic**

3. You will see a series of screens for you to indicate country/language, acknowledge Terms of Use/Privacy Policy, and enter information about your clinic.

4. Create the administrative user profile and click **Continue.** You are now finished with the setup. You can now sign in to your account.

24/7 Global Help Line
1 800 777 808
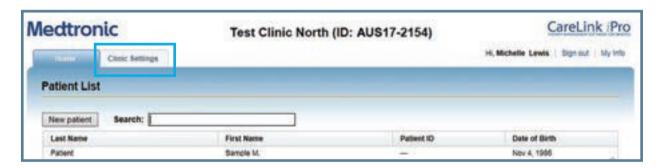
Clinic ID and Settings

5. Once you login, you will notice an ID number next to the name of your clinic. Write it down on the front cover. Your patients will need it to use the iPro2 app (covered later).
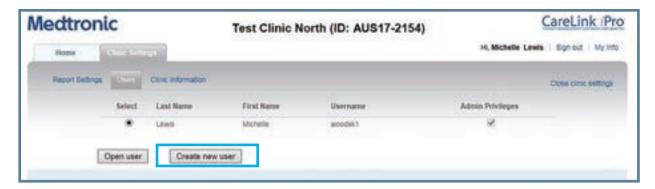
TIP: Make sure to give multiple users Administrative Privileges. If the only admin user leaves, and you don't know their login information, then you will lose access to your account.
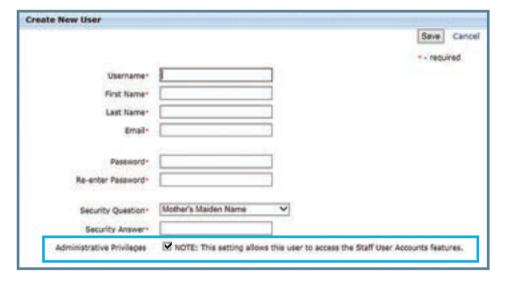
6. On the Home screen, click on the tab, **Clinic Settings.**

7. Click on **Users** to view active users.

8. Click on **Create new user** to setup additional Administrative and Standard users.

9. Create additional users by completing the form information. Check the Administrative Privileges box for Administrative users only.

24/7 Global Help Line
1 800 777 808

Installing the CareLink iPro Uploader

> **IMPORTANT:** You must have administrative rights **before** completing these steps. If you do not, contact your IT for help.
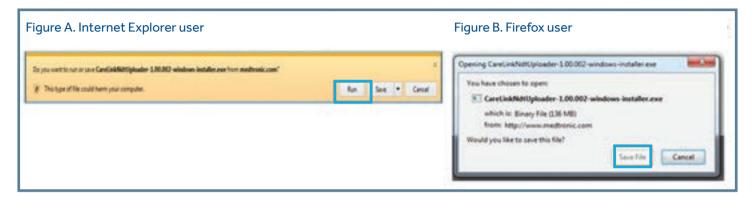
1. Sign into **https://www.carelink.minimed.eu/ipro**. Double click on **Sample M. Patient.**

2. Click on **Upload iPro2.** If you see a message asking you if you want to upload another study for the same patient click **Yes.**

3. Download CareLink Uploader Installer link.

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Installing the CareLink iPro Uploader

Figure A. Internet Explorer user

Figure B. Firefox user
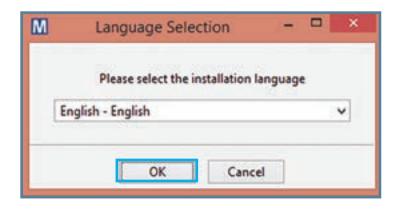
4. If using Internet Explorer, click **Run.** If using Firefox, click **Save File**
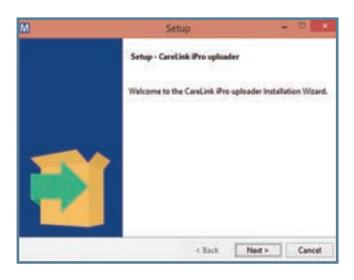
5. The installer will now begin to download to your computer.
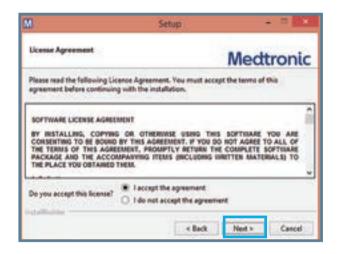
6. If prompted, enter your local admin username and password.
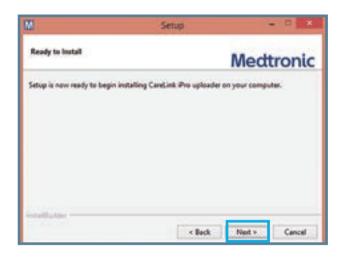
7. Select the installation language,then click **OK.**

8. Click **Next** and follow the on-screen instructions.

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Installing the CareLink iPro Uploader
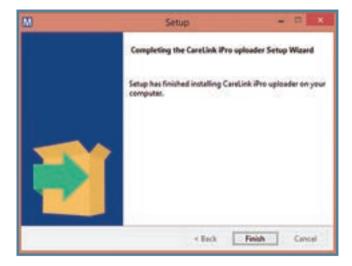
9. Read the License Agreement.
Select **I Accept** and click **Next.**

10. Click Next again on the Ready
to Install window.

11. Ensure all devices are disconnected.
Click **Ok** to continue.
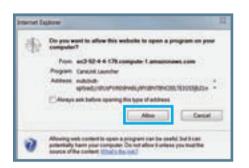
12. The install is now complete. Click **Finish.**

Installing the CareLink iPro Uploader
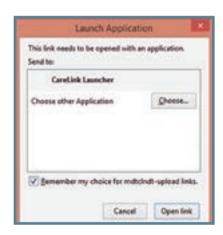
13. The CareLink Uploader Installation window will still be open. Click the **red "x"** to close the window.

14. Click **Upload iPro2** again. If you receive a message asking you to upload another study for the same patient, click **YES.**

15. Depending on the internet browser you are using, you will need to check or uncheck a box so the warnings will not continue to appear.

16. The new CareLink Uploader window will open. This completes the process.

NOTE: Complete this one-time process on every computer that you will upload iPro2 recorders on.

iPRO2 CGM

Part 2: Starting Patient Evaluation

■ Inserting Sensor and Connecting Recorder

■ Logging Patient Events

View the Enlite™ sensor insertion video at
https://www.medtronic-diabetes.com.au/support/my-learning/cgm
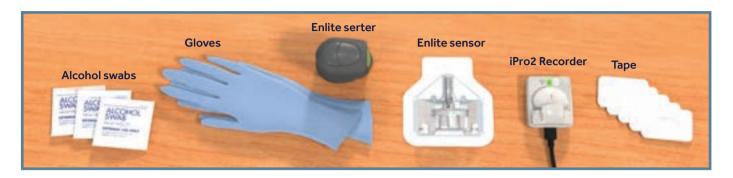
THE NEW ONE-PRESS SERTER-SIMPLIFYING SENSOR INSERTION

We are pleased to introduce a new Serter. As well as simplifying the sensor insertion process - it is also more intuitive to use. The One-press Serter can be used with sensors that come in the white Enlite™ sensor box.

Gather your Supplies:

- Enlite™ Serter
- Enlite™ Sensor
- iPro2 Recorder
- iPro2 Recorder Tape
- Gloves
- iAlcohol Swabs
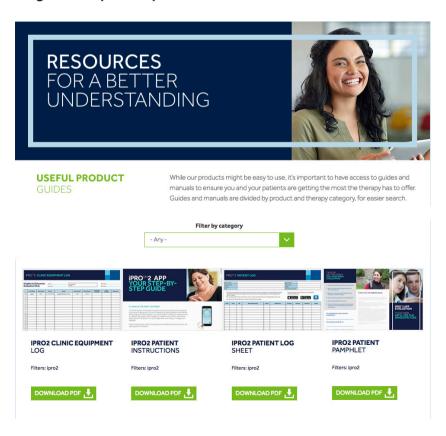
Additional Optional Items:

- Patient Instructions
- Patient Log Sheets
- Patient Consent Form
- Clinic Equipment Log

These forms can be downloaded and printed.
Log into https://hcp.medtronic-diabetes.com.au/resources

Patient Setup

1

1. Find the 7-digit iPro2 Serial Number following GT.

2

2. Log patient's name and iPro2 Serial Number on Equipment Log.

3

3. Put on gloves and wipe iPro2 with alcohol swab.

4

4. Select an insertion site:
- Fatty area
- free from skin folds
- free from scar tissue
- not restricted by clothing
- 2 inches from naval above
- or below the belt line

5

5. Clean site with alcohol swab.

Inserting sensor and connecting recorder

1

1. Open the sensor package.

2

2. Hold the plastic pedestal. Remove the sensor and put it on a flat surface.

3

3. Line up the sensor with the serter and push the serter down until you hear a click.

Inserting sensor and connecting recorder

4. Put fingers on each pedestal arm and pull the serter straight up.

5. The sensor is now inside the serter and ready for insertion.

6. Place the serter against the skin.

1st Press

7. Press and release the bump on the green button.
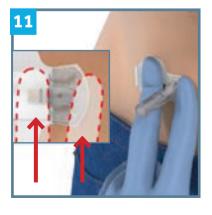
8. Keep the serter against the skin for 5 seconds.

2nd Press and Hold

9. Do not push serter into the skin. Press and hold in the green button.

Keep Holding

10. Pull the serter away while holding in the button.
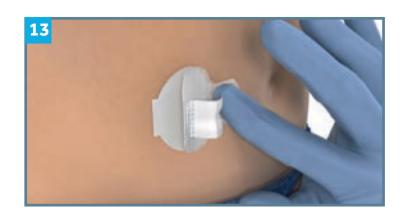
11. Use one hand to hold the sensor against the body. The blue boxes on the inset image shows where to place fingers.

12. Use the other hand to pull needle housing straight out. Discard in sharps container.

CAUTION: Check to see if there is bleeding at the insertion site. Do not secure tape or connect recorder if you see blood on the sensor connector. Apply pressure with gauze until bleeding stops.

13. Hold the sensor down. Grab the lower flap of paper backing under the adhesive pad.

14. Pull the lower flap straight out to remove the paper backing.

15. Untuck the adhesive tab from under the sensor connector. Lay the tab flat but do not remove the strip paper backing.

16. Remove paper liner marked 1 from tape.

17. Place tape so that half is on the skin, and half is on the sensor.

18. Make sure the other side of the tape is under the sensor connectors.

19. Remove tabs on each side marked 2. Press on tape to make sure it sticks well.

TROUBLESHOOTING:

1.   If there is no green flashing light, squeeze both sides of the sensor and disconnect the recorder.

2. Wait a minute and then reconnect the recorder.

3. If there is still no green light flash, call the 24/7 Global Help Line 1 800 777 808 or insert a new sensor.

20. Connect the iPro2 recorder to the sensor by pushing onto the sensor. You should hear a click.

21. Wait for a green flashing light. It may take up to 20 seconds to flash.

22. Remove paper liner from the adhesive tab.

23. Fold adhesive tab over and onto recorder. Important: Do not pull tab too tightly. It may cause recorder to pull from sensor connection.

24. Apply a second piece of tape that covers the back end of the recorder and the skin.

Instructions for Your Patient

After you insert the sensor and connect the iPro2 recorder:

1. Ask your patient how they wish to record their events: using the iPro2 app or a paper log sheet.

2. CRITICAL: Let your patient know Blood Glucose (BG) readings are essential during the evaluation. On day 1, test three times:

> **1st:** One (1) hour after leaving the clinic.
>
> **2nd:** Three (3) hours after leaving the clinic.
>
> **3rd:** Before bedtime.

For remainder of the evaluation period test BG 3-4 times per day - before meals and bedtime.

3. Tell your patient when to return the device.

4. Important: Do not change the date or time on your glucose meter at any time during the evaluation.

NOTE: If the patient is unable to use the iPro2 App, move to the next section and review the Patient Log Sheet.

Logging Patient Events – iPro2 App

1. Confirm that the patient has a smart phone. (Apple or Android) Recommend using the iPro2 App

2. Explain that the app is used to log BG, meals, medication, insulin activity and sleep. This information greatly improves the quality of the study and allows both patient and doctor to see potential causes of glucose changes.

3. Download the app on the patient's phone by searching for "iPro2" in the app store.

4. Help the patient setup their account. During setup, the app will ask for your Clinic ID (AUSXX-XXXX) that you wrote on the cover of this booklet. You can also find this at the top of the page when you sign in to https://www.carelink.minimed.eu/ipro. Follow the steps within the app by creating a password, inputting patient information, and adding the clinic ID to complete setup.
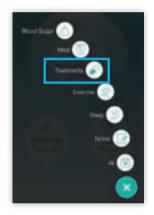
Logging Patient Events – iPro2 App
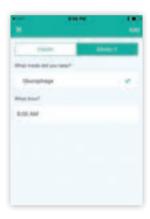
5. Show your patient how to log BGs by pressing the Blood Sugar icon, entering in a BG, and tapping Add Common events — exercise and meals — are also quickly available from the main screen.
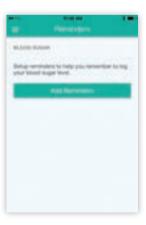
6. Demonstrate how to expand the events menu by pressing the "+" button. Here you can log additional events such as treatments (oral medications and insulin), sleep, and notes.
Important: Do not use emojis when typing notes as it will affect the reports.

7. Set reminders for the patient to test and log BGs 4 times daily.

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Logging Patient Events – Patient Paper Log Sheet

1. Provide the patient with a Patient Log Sheet. Sample log sheets can be found beginning on page 41 of this booklet.

2. Explain that the log is used to log BG, meals, medication and activity. This information greatly improves the quality of the study and allows both patient and doctor to see potential causes of glucose changes.

First BG Test after 1 hour:_____

Second BG Test after 3 hours: _____

Third BG Test Before Bedtime:_____

Discuss Time Zone With Patient

3. Fill in the BG test times for the first day to help your patient remember.

Date	Time	BG	Meal (food/drink)	Carbs	Medication	Dosage	Activity	Duration	Other
	8.20am	17	2 Eggs, 2 Toast, Black Coffee	30	Humalog	1 Unit	Walk	30 min	

**4.** Explain to the patient how to log each type of activity - BG, Meals, Medications (Oral or Insulin), and Activity (i.e. exercise, physical labor, sleep).

CAUTION: For your patients traveling to a different time zone:
- Pro2 app users should not manually change their phone's time. Let the phone time change automatically.
- paper log sheet users should record their events in the clinic's time zone. BG
- meters that would be uploaded should stay in the clinic's time zone.

iPRO2 CGM

Part 3: After an Evaluation

Removing Recorder

> **NOTE:** If patient has already removed the sensor and recorder themselves, skip to Cleaning and Disinfecting section.
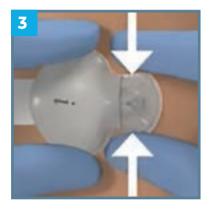
You or the patient can remove the sensor and recorder.

1. Put on gloves. If needed use adhesive remover to loosen tape from the skin.

2. Pull the tape, sensor and recorder off the patient's body all at once.

3. Remove the tape off of the recorder. Pinch the side arms of the sensor and pull the recorder to disconnect them from each other.

4. Be sure to check and make sure no blood is inside the recorder before inserting the cleaning plug in the next step. Important: If there is blood inside the recorder, throw it in a sharps container.

5. Keep the recorder for cleaning, disinfecting, and uploading. Throw the sensor in a sharps container.

Cleaning and Disinfecting Recorder

Supplies Needed:

- Gloves Adhesive
- Remover Enzymatic
- Detergent

- Soft-Bristled Brush
- Bleach 6% Concentrate
- Rubbing Alcohol

- Two Containers or Two Small
- Buckets Cleaning Plug

Enzymatic detergent

Cleaning Plug

Bleach 6% concentrate

Soft-bristled brush

Cloth or Towel

Rubbing alcohol

Adhesive remover

1. Put on gloves. Insert a cleaning plug onto recorder. Use adhesive remover to clean off any residue if necessary.

2. Rinse recorder under cool tap water for at least 1 minute.

3. Prepare Enzol enzymatic detergent solution*: 200ml detergent to 1 litre water.

* Cleaning efficacy testing and robustness testing were conducted on the iPro2 Recorder 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.

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4. Submerge recorder in the solution for at least 1 minute.

1 Minute

5. Remove recorder from solution and lightly brush entire surface.

6. Rinse recorder under tap water and dry with a cloth or paper towel.

7. Prepare bleach solution: 1 part bleach to 9 parts water**.

30 Minutes

8. Submerge recorder in the bleach solution for 30 minutes.

3 Minutes

9. Rinse the recorder for 3 minutes.
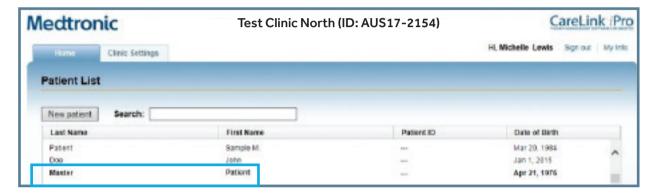
10. Then, hold the cleaning plug and wipe the iPro2 with 70% isopropyl alcohol. Let recorder to air dry.
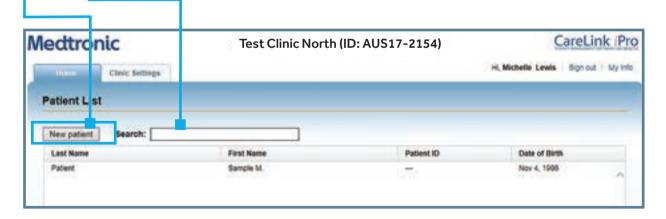
** Disinfecting efficacy testing and robustness testing were conducted on the iPro2 Recorder using Clorox® Regular Bleach (EPA registration number 5813 50, distributed by The Clorox Company). Robustness testing for the iPro2 included a contact time of 30 minutes per cycle for 61 cycles, which is equivalent to cleaning every three days for six months.

Uploading Recorder and Generating Reports
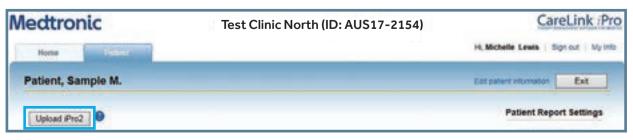
1. Go to https://www.carelink.minimed.eu/ipro and sign in.

2. Search for or create a New patient record.

- If patient is a first time iPro2 user <u>AND</u> used the iPro2 app to record event data, type name in **Search** field. Double-click the **BOLD patient's name.** Confirm your patient's information, and click Save.
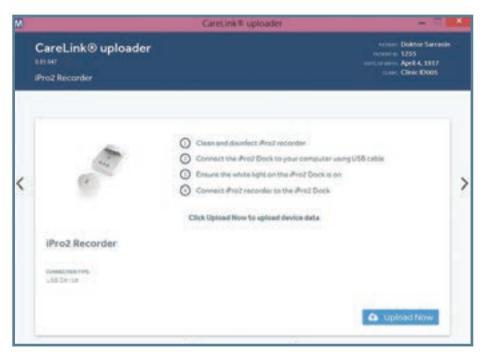
- If patient is a first time iPro2 user and used a paper log sheet to record event data, click **New patient** to create their patient record.

- If patient has previously had an iPro2 evaluation, type name in the **Search** field. Double-click the patient's name to open the record.
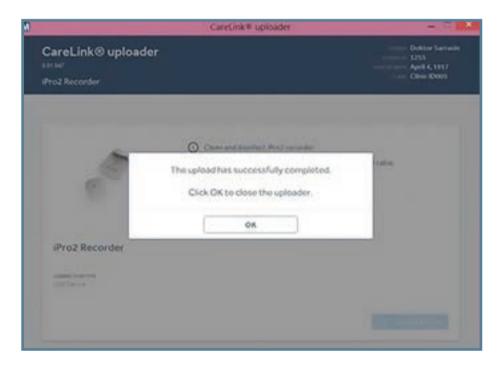
3. Click on **Upload iPro2**.

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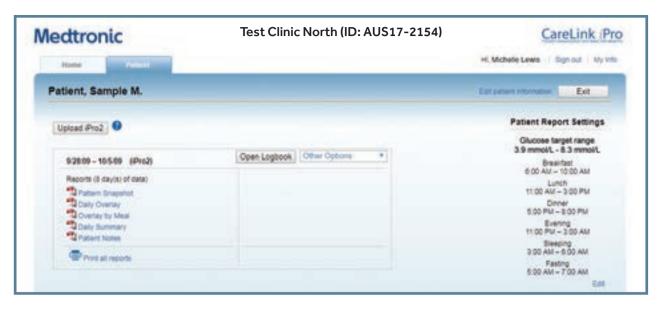
Uploading Recorder and Generating Reports
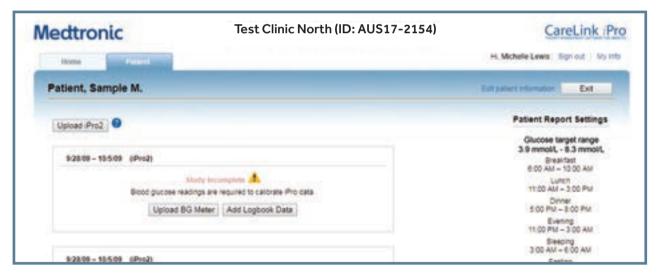
1. Make sure USB cable is connected from your computer to your dock. Slide iPro recorder onto the dock, and click **Upload Now.**

2. When upload is completed, Click **OK.**

Test Clinic North (ID: AUS17-2154)

3. For iPro2 app users who entered BGs, you will see this screen. Click on Print all reports to view, print or send all reports.

Test Clinic North (ID: AUS17-2154)

4. For the patient who used a paper log sheet, you can select either Upload BG Meter, or Add Logbook Data.
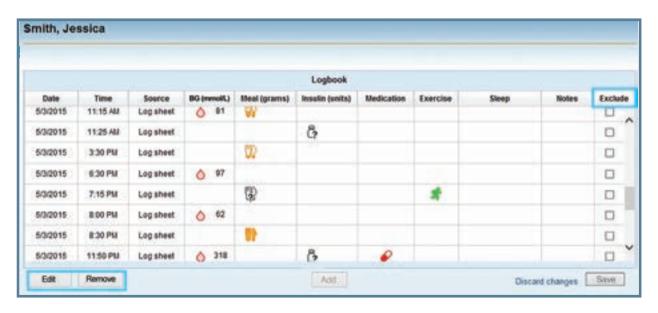
4a. To upload a BG meter, click on the meter type and follow the instructions.
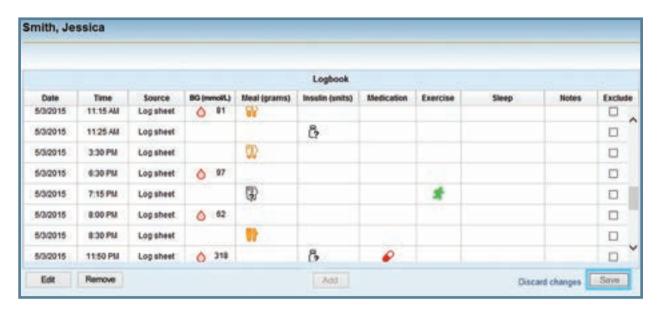
4b. To type in BGs and events from a paper log sheet, click **Add.**

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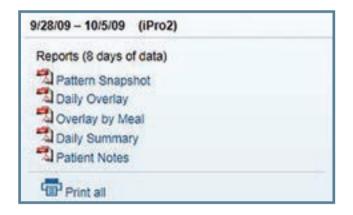
5. Enter the date, time, and BG value from the log sheet. Then click **Enter.** When done entering all events, click the red 'X'.

6. If you need to make any edits, click **Edit, Remove** or **Exclude.**

7. Click **Save** to generate the reports.

8. Click on **Print all** to view or print all reports.

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Charging and Storing Recorder

1. Charge the iPro2 while the docking station is connected to a computer or to the wall-powered adapter. Between uses, it should only take about 30 minutes to fully charge the recorder.

2. The recorder is fully charged when the green 🔋 light remains on (not flashing).

3. Store recorders by connecting a cleaning plug or leave on a docking station that is plugged into a wall.

> ℹ **IMPORTANT:** Do not leave recorder connected to docking station when the docking station is not connected to a power source. This will damage the recorder battery.

iPRO™2 CGM

Part 4: Forms and Resources

Available for download at: https://hcp.medtronic-diabetes.com.au/resources

- Patient Consent Form
- Patient Instructions
- Patient Log
- Equipment Log
- iPro2 Clinic Quick Reference Guide
- Troubleshooting

Sample Consent Forms

Please note that these are only sample forms and should be customized to meet any specific needs of your office. Medtronic cannot guarantee that the language contained herein is exhaustive and addresses all legal, regulatory and operational requirements and standards. THESE SAMPLE CONSENT FORMS ARE provided on an "AS IS" basis and Medtronic disclaims all warranties, express or implied, regarding them.

PRIVACY STATEMENT AND CONSENT FORM
iPro™2 System & Medtronic Carelink® iPro™ software

Dear Patient,

Medtronic (Medtronic) is the manufacturer and distributor of the iPro2TM System (the iPro2 System), a continuous glucose monitoring system, which includes an iPro2 Recorder. Medtronic also provides the Medtronic Carelink® iPro web-based software application (Medtronic Carelink) to support your diabetes therapy.

The iPro2 Recorder is a continuous glucose monitor which may be placed on your body (as advised by your physician) for the purpose of continuously recording your glucose levels. When using Medtronic Carelink with the iPro2 System, healthcare professionals can upload, store and analyse glucose readings from patients who have worn an iPro2 Recorder.

This purpose of this document is to:

▪   Inform you of the way in which your personal information, including information for identification purposes (i.e. your name, date of birth, a patient ID number, and limited information regarding your diabetes) (Protected Infor-mation) may be collected and used by your treating doctor's medical practice (This Practice) and Medtronic if you choose to use the iPro2 System together with Medtronic Carelink; and
▪   Obtain your written, informed consent and agreement to collect and use your Protected Information on the terms set out in the Privacy Statement below.

If there is anything in this Form that you do not understand or have concerns with, please contact either This Practice or Medtronic, on the contact details provided below.

Collection and use of your Protected Information

In addition to the glucose readings from the iPro2 Recorder, healthcare professionals in This Practice may also upload certain Protected Information. Once your Protected Information is uploaded through the Medtronic Carelink website (http://ipro.medtronic.com), it will be stored on a secured computer server (database) located in a secured computer server located in a Medtronic facility in Heerlen, Netherlands. Accordingly, please note that your Protected Information will cross country borders when transmitted to Medtronic Carelink.

This Practice and Medtronic place great importance in maintaining the privacy and confidentiality of your Protected Information (i.e. your medical and personal information). Medtronic has established significant security measures and safeguards for your Protected Information when used and stored via Medtronic Carelink. All Protected Information sent through the Medtronic Carelink website will be transmitted to the Medtronic Carelink server using HTIPS protocol and strong (128-bit) encryption. In addition, each Medtronic Carelink server features a secure architecture consisting of a three-tier firewall system, as well as password protection, designed to protect the privacy of your Protected Information.

Please note that Medtronic is responsible for hosting and maintaining the Medtronic Carelink servers, and therefore will have access to Protected Information that This Practice has or will upload through the Medtronic Carelink website. Medtronic may also study your Protected Information for purposes of advancing or improving its products, therapies or services for the benefit of future patients.

Medtronic may do this by analysing, studying, conducting education, and/or monitoring the data (usually in aggregate form) stored on the Medtronic Carelink servers. Medtronic will not review any Protected Information for purposes of identifying clinical or medical issues regarding you or other individual patients.

In addition to the system protections mentioned above, Medtronic as a company enforces important patient privacy safeguards and policies internally to protect your Protected Information, including restricting access to only those employees (and certain contractors) who may need access to this information to do their jobs. Medtronic will take all appropriate steps to ensure that any third -party contractors used will comply with applicable standards and policies for maintaining the privacy of patient data.

Your Protected Information stored in Medtronic Carelink will never be used to market to you, place you on any mailing lists, or sold to anyone for marketing purposes. Also, Medtronic will not share your Protected Information with any outside entity or third party other than parties that may from time to time provide information technology support for the server. Limited exceptions exist to this prohibition, such as where the Protected Information is

1. completely de-identified so that you (or any other individual patient) cannot be identified in any way;

2. requested by a government office or agency, court order, or a similar authority; or

3. disclosed to protect an individual's health, safety or welfare.

Medtronic, Inc. manufacturers the iPro2 System and iPro2 Recorder. In Australia, the iPro2 and Medtronic Carelink software are distributed by Medtronic Australasia Pty Ltd., and in New Zealand, they are distributed for Medtronic New Zealand Limited by InterMed Medical Limited. The term 'Medtronic' in this document refers to all these companies and any affiliated Medtronic companies. If you wish to contact Medtronic in Australia, please call 1800 668 670. If you wish to contact Medtronic New Zealand Limited, please call 0800 337 807. More information is also available at www.medtronic-diabetes.com.au.   For more information about privacy and Medtronic, please refer to our Privacy Policy at www.medtronic.com.au.

Patient Consent

I CONSENT to the use of the iPro2 Recorder and the storage of information about me including my name, date of birth, patient identification number and information about my health and diabetes (Protected Information) through the Medtronic Carelink® iPro website.

I grant consent on the understanding that:

1. Medtronic may record certain Protected Information for identification purposes and otherwise use such information as set out in the Privacy Statement above.

2. The Protected Information will be stored on a secured computer server in a Medtronic facility in Europe.

3. Medtronic may study my Protected Information for the purpose of advancing or improving its products, therapies or services for the benefit of future patients.

4. Medtronic will not review any Protected Information for the purpose of identifying clinical or medical issues, apart from automatically generating reports for my health care professionals, which may highlight issues of clinical significance.

5. Medtronic will ensure that any contractors utilised will comply with privacy protocols.

6. My Protected Information stored on a Medtronic Carelink® server will not be used for marketing purposes and will not be shared with any third party except where:

    a. the Protected Information is de-identified so that I cannot be identified from the information (i.e. it is anonymous); or

    b. Medtronic is required at law to produce the Protected Information or is directed to do so by an authorised person or entity, which has the power to make such a direction; or

    c. otherwise as set out in the Privacy Statement above.

Signature _____ Date _____

Name (please print) _____

Sample Patient Instructions

iPRO™2 APP
YOUR STEP-BY-STEP GUIDE

1. WHAT IS THE iPRO™2 SYSTEM?

The iPro2 System is designed to capture your glucose levels continuously 24 hours a day. It allows your clinician to review your glucose patterns and trends. While wearing the iPro2 System, you will still need to check your blood glucose to calibrate the system and manage your diabetes. You will be continuously wearing the iPro2 System for up to 6 days while continuing to manage your diabetes

Please note that you will not see the glucose readings during the time you are wearing the iPro2 System.

2. INSTUCTIONS FOR YOUR iPRO2 EVALUATION:

- While the monitor is worn, it will be essential to measure **at least four** or more blood sugars per day.

- You will also be keeping a detailed record of food intake, insulin dosages and daily activities using a **Patient Log Sheet or the iPro2 app.**

- The days on the monitor should represent typical days. If you become ill or have any factors affecting your blood sugar such as cortisone medication, please call as early as possible to re-schedule your appointment.

- Please wear the iPro2 recorder **until you return** on your scheduled return date.

- Use the same blood glucose meter for all BG meter readings.

- Insulin should be injected at least 7.5 centimetres away from the sensor insertion site and insulin pump infusion should be at least 5 centimetres from the sensor insertion site.

- The iPro™2 recorder must be removed (but the sensor can be left in) prior to an X-ray, CT scan or MRI. Simply reconnect the iPro™2 recorder afterward.

3. ON THE FIRST DAY:

FIRST BG meter reading 1 hour after you leave your HCPs office   Time: _____

SECOND BG meter reading 2 hours after first reading   Time: _____

COLLECT AT LEAST ONE MORE BG meter reading **before going to bed.**

COLLECT AT LEAST 4 BG meter readings each day, such as before breakfast, lunch, dinner and bedtime.

You may shower and swim while wearing the iPro2 recorder and sensor. The iPro2 recorder is watertight at a depth of 2.4 metres for 30 minutes. There is no limit if you are swimming on the surface of a pool or showering.

Sample Patient Instructions

iPRO™2 APP YOUR STEP-BY-STEP GUIDE

Clinic ID: _____

Ensure you keep this number close as it is essential to log into your app

1. DOWNLOAD the app from iTunes store or Google Play by searching **iPro 2 App**[1,2]

Download on the App Store • GET IT ON Google Play • Medtronic

2. SET UP AN ACCOUNT

Follow the steps within the app by creating a password, inputting your information, and adding the clinic ID to complete setup. You will receive the clinic ID from your healthcare professional[1]. In Settings, select the appropriate treatment (medication and insulin) and units.

3. FOR THE NEXT 6 DAYS, LOG IN YOUR EVENTS

- For best accuracy, enter data immediately
- Check and record your **BGs 3-4 times per day**, before meals and bedtime

Events will be automatically uploaded to your CareLink™ iPro™ reports

BLOOD SUGAR
Record blood sugar with exact time and date

MEDICATION
Record your diabetes medications, time and date

SLEEP
Record sleep start time, end time and date

MEALS
Record meal size, time and date. Optional to record carbs and a take picture of your meal

EXERCISE
Record physical activity intensity, time and date

INSULIN
Record your insulin type, number of units, time and date

4. AT THE END OF THE EVALUATION

- Please ensure that all events are recorded in the app
- Have internet access to ensure all events have been uploaded to CareLink™ iPro™ software
- Return your iPro™ 2 recorder to your HCP. Review reports with your healthcare professional
- You do not need to end the evaluation in the app. It will end automatically after 7 days

5. INFORMATION ON DATA COLLECTION, STORAGE AND USAGE:

- The iPro App software captures your Personal identifiers during your registration process, for the purposes of providing you with the iPro App software and services. This can help you and your healthcare provider to discover trends and other information that can lead to improved therapy management. Data is stored in the live CareLink database and maybe processed inside and outside your country or region.

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Sample Patient Log Sheet

iPRO™2 PATIENT LOG

Patient Name	Date of Birth
Diabetes Type	Home Phone
Address	Mobile
HCP	iPro2TM Recorder SN:

- Write down your BG meter readings, food or drink and the amount of carbohydrates consumed, physical activity and duration, medications and dosages and other events (such as feeling hypoglycaemic and/or hyperglycaemic, stress, or illness).
- Keep the log sheet with you at all times so you can write down the information immediately after each event.
- Record the time and date within 5 minutes of each BG meter reading.

Download the app from the iTunes store or Google Play by searching iPro 2 App

Date	Time	BG	Meal (food/drink)	Carbs	Medication	Dosage	Activity	Duration	Other

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iPRO™2 Patient Log

Sample Patient Log Sheet

Date	Time	BG	Meal (food/drink)	Carbs	Medication	Dosage	Activity	Duration	Other

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iPRO™2 Patient Log

Sample Equipment Log Sheet

iPRO™2 CLINIC EQUIPMENT LOG

Insights to Outcomes Evaluation Clinic

Clinic ID _____

Clinic Time _____

iPro2 recorder serial#: _____

MDT Name: _____

MDT Phone: _____

	Last Name	First Name	Phone	Email	Start Date?	Finish Date?	Collection Consent	iPro2 Consent	Returned
Eg	Jagger	Mick	12 3456 7890	mjagger@rolling.com.au	9 Jun	10 Jun			
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									
11									
12									
13									
14									
15									

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iPRO™2 Clinic Equipment Log ———

iPRO™2 CLINIC
QUICK REFERENCE GUIDE

iPro™2
Professional CGM

STARTING AN EVALUATION

NOTE: For complete instructions, go to http://www.carelinkipro.com and click the User Guide.
Follow cleaning and disinfection instructions to ensure that your iPro2 has been properly cleaned and disinfected.

Materials needed for patient setup

☐ Gloves
☐ Alcohol swabs
☐ Sensor insertion device
☐ Glucose sensor
☐ iPro2 recorder

☐ Patient Log Sheets
☐ Patient Consent Form
☐ Patient Instructions Sheet
☐ Clinic Equipment Log
☐ Tape

Prepare iPro2

☐ iPro2 should only be used after the iPro2 has been properly cleaned and disinfected.
☐ Verify iPro2 is charged
☐ Enter the iPro2 serial number and blood glucose meter ID on the Clinic Equipment Log and on the Patient Log Sheet.

If you see a red warning light on the Dock, do not connect the iPro2 to a sensor on a patient. See the Troubleshooting section.

Insert Sensor and Connect Recorder

☐ Put on gloves.
☐ Select & prep the site* for insertion.
☐ Insert sensor using the sensor insertion device.
☐ Hold sensor in place while gently removing introducer needle. Dispose in sharps container.
☐ Apply tape.

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.

☐ Connect iPro2 to sensor. Avoid twisting.
☐ Verify that iPro2 flashes. If iPro2 does not flash within 20 seconds, disconnect from sensor and try again.
☐ Apply adhesive tab to iPro2.
☐ Apply a second piece of tape

Patient Instructions

☐ Test 3-4 times a day.
☐ Record BGs and events in the **iPro2** app, or on a paper log sheet.
☐ Return the iPro2 recorder (and paper log sheet if one was used) after the evaluation.
☐ Showering and swimming with the device is OK.
☐ If traveling to a different time zone, see page 20.

*approved for use on abdomen

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iPRO2 CLINIC
QUICK REFERENCE GUIDE

iPro™2
Professional CGM

AFTER AN EVALUATION

Materials needed for disinfecting and uploading

- [ ] Gloves
- [ ] iPro2 (which has been worn by the patient)
- [ ] Bio-waste container
- [ ] Cleaning plug
- [ ] Optional: adhesive remover, such as Detachol®
- [ ] Enzymatic Detergent
- [ ] Soft-bristled brush
- [ ] Bleach

- [ ] Gauze pad or cloth
- [ ] 70% isopropyl alcohol
- [ ] Dock, connected to a computer

Inspect, clean, and disinfect iPro2

INSPECT

- [ ] Wash hands and put on gloves.
- [ ] Remove iPro2 from sensor.
- [ ] Inspect the inside of the iPro2 connector opening for body fluid. Warning: If you see body fluid in the connector opening, you must dispose of the iPro2 after completing the disinfection process. Do not connect it to the Dock.

CLEAN

- [ ] Connect a cleaning plug to the iPro2.
- [ ] Remove adhesive residue using adhesive remover (Detachol®).
- [ ] Rinse the iPro2 under cool tap water for one minute.

DISINFECT

- [ ] Prepare Enzymatic Detergent solution*. With cleaning plug still attached, fully submerge the iPro2 in the detergent solution for at least one minute.
- [ ] Remove the iPro2 from the solution, and brush the entire surface of the iPro2.
- [ ] Rinse the iPro2 with cool tap water and then dry with a clean, dry cloth.
- [ ] 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. With cleaning plug still attached soak the iPro2 in the bleach solution for 30 minutes.
- [ ] Rinse the iPro2 under cool tap water for at least three minutes.
- [ ] Disconnect cleaning plug and inspect the iPro2 housing for any signs of cracking, discoloration, or damage. **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).**
- [ ] Allow the iPro2 to air dry.

Upload data and generate reports

- [ ] Go to **www.carelinkipro.com** and find patient record or create a new patient record if needed.
- [ ] Make sure you have the correct recorder before uploading into the patient record.
- [ ] Click **Upload iPro2.** Follow on-screen instructions for uploading data from iPro2 recorder.
- [ ] Add events in logbook for patients using paper log sheet or **For patients using iPro2 app, go straight to Print all reports.**

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Troubleshooting

Dock light descriptions

| Dock Lights	Description	What it means
	All lights are off.	The Dock is not plugged into an outlet or computer USB port.
	The white power light is on.	The Dock is connected to power.
	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 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.
	The white power light and the 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 power light flashed five times and the green charging light is flashing continuously.	The white 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 power light and the red-warning light are on.	There may be a problem with the iPro2 recorder. See instructions below.

Troubleshooting
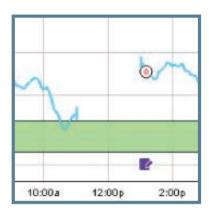
If the docking station flashes red after you have used and charged an iPro™2 recorder:

Reset the iPro2 recorder by inserting a paper clip into the white docking station. See page 3 for pictures.

- if the reset is successful, the green charging light on the dock will begin to flash. After a few seconds, the green light on the iPro2 recorder will flash.
- if the reset was not successful, the iPro2 recorder will not flash.

Best Practices to Avoid Data Gaps

1. Make sure the patient knows to test their BG no sooner than 1 hour after the iPro2 CGM start-up.

2. Remind patient to test BGs 3-4 times a day.

iPro2 Recorder does not flash green after sensor is inserted into the body and recorder is connected:

1. Remember that it can take up to 20 seconds for the recorder to flash green.

2. Make sure the iPro recorder and sensor are connected. You should hear or feel a 'click' when connecting the two together.

3. If you're sure they are connected and the green light has not flashed after 20 seconds, know that the sensor may not have fully "wetted" or the recorder may not be charged.

4. Try removing the recorder from sensor. Wait a minute, and then reconnect the recorder to the sensor.

Notes

Notes

Notes

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medtronic.com.au