STEP-BY-STEP TRAINING GUIDE

iPRO2 CONTINUOUS GLUCOSE MONITORING SYSTEM

Uncover more in less time*
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Part 1: Overview and Setup

- Setting up and charging your iPro 2 recorder
- Creating your CareLink iPro account*

*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 fingersticks 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.
OVERVIEW AND SETUP

Setting Up and Charging Your iPro2 Recorder

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

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

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

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 1/8 of an inch, and release.

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

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.
Creating Your CareLink iPro Profile

1. Use Firefox, Internet Explorer or Safari, go to www.carelinkipro.com

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.

ADVANCED SOFTWARE SUPPORT HELPLINE:
Monday through Friday, 5 AM to 5 PM (PST)
877-874-7717, option 3
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 myLog 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.

ADVANCED SOFTWARE SUPPORT HELPLINE:
Monday through Friday, 5 AM to 5 PM (PST)
877-874-7717, option 3
Installing the CareLink iPro Uploader

**IMPORTANT:** You must have administrative rights before completing these steps. If you do not, contact your IT for help.


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. Click on Download CareLink Uploader Installer link.
Installing the CareLink iPro Uploader

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.
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.
Part 2: Starting Patient Evaluation

- Inserting Sensor and Connecting Recorder
- Logging Patient Events

View the iPro2 sensor insertion video at www.carelinkipro.com and click on Training.
Gather your Supplies:

- Enlite™ Serter
- Enlite™ Sensor
- iPro2 Recorder
- Tape
- Gloves
- Alcohol Swabs

Additional Optional Items:

- Patient Instructions
- Patient Consent Form
- Clinic Equipment Log

These forms can be downloaded and printed. Log into www.carelinkipro.com and click the Resources link.
Patient Setup

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

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

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

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. Clean site with alcohol swab.

Inserting sensor and connecting recorder

1. Open the sensor package.

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

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.

7. Press and release the bump on the green button.

8. Keep the serter against the skin for 5 seconds.

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

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

**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

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

14

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

15

16. Remove paper liner marked 1 from tape.

16

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

17

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

18

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

19
**STARTING PATIENT EVALUATION**

**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 helpline at 877-874-7717, option 3 or insert a new sensor.

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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 myLog 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.
Logging Patient Events – iPro2 myLog App

1. Confirm that the patient has a smart phone. Recommend using the iPro2 myLog app.

2. Explain that the app 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.

3. Download the app on the patient’s phone by searching for “iPro2 myLog” in the app store.

4. Help the patient setup their account. During setup, the app will ask for your Clinic ID (USXX-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 www.carelinkipro.com. Follow the steps within the app by creating a password, inputting patient information, and adding the clinic ID to complete setup.

NOTE: If the patient is unable to use the iPro2 myLog app, move to the next section and review the Patient Log Sheet.
Logging Patient Events – iPro2 myLog 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.
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 37 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.

<table>
<thead>
<tr>
<th>Day 1</th>
<th>Date: <strong><strong>/</strong></strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>**TIME</td>
<td>**BG</td>
</tr>
<tr>
<td>8:00 AM</td>
<td>165</td>
</tr>
<tr>
<td>1</td>
<td>:</td>
</tr>
</tbody>
</table>

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:
- myLog 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.
Part 3: After an Evaluation

- Removing Recorder
- Cleaning and Disinfecting Recorder
- Uploading Recorder and Printing Reports
- Charging and Storing Recorder
Removing 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.

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

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*: 1 ounce detergent to 1 gallon 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.
4. Submerge recorder in the solution for at least 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**.

8. Submerge recorder in the bleach solution for 30 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 Pro2 Recorder using Clorox® Regular Bleach (EPA registration number 5813–50, distributed by The Clorox Company). Robustness testing for the Pro2 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 www.carelinkipro.com and sign in.

2. Search for or create a New patient record.
   - If patient is a first time iPro2 user AND used the iPro2 myLog 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.
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**.
3. For myLog users who entered BGs, you will see this screen. Click on Print all reports to view, print or send all reports.

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.
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.
**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.

**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.
Part 4: **Forms and Resources**
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.
PATIENT CONSENT FORM

Patient Name: ___________________________________________ Date: ____________________

Therapy Evaluation __________________________________________________________________________

My healthcare provider has provided me with a Medtronic Diabetes iPro™2 Continuous Glucose Monitor (CGM). I understand that the iPro2 CGM system is designed to record glucose values in the interstitial fluid and allows my healthcare provider to review glucose patterns and trends. The iPro2 CGM system does not allow me to visualize glucose values and is not a replacement for blood glucose monitoring.

Potential Risks
I understand that the iPro2 CGM system requires the insertion of a glucose sensor into the skin. Adverse events associated with the glucose sensor insertion are highly uncommon and are limited to bleeding, irritation, pain, rash, infection, raised bump and irritation at the site from tape used to secure the sensor to the skin.

Patient Instructions
- Continuously wear the iPro2 recorder and glucose sensor.
- Complete the Patient Log Sheet or iPro2 myLog App daily as instructed.
- Test blood glucose (BG) 3-4 times daily using a Blood Glucose Meter.
- Protect the iPro2 recorder and glucose sensor from accidental removal.
- Keep the tape intact on your skin.
- Do not administer insulin within one inch of the glucose sensor site.

Patient Acknowledges
- I have read and understand the above information.
- I will return the iPro2 recorder to my healthcare provider.
- I have discussed the goals of the iPro2 CGM evaluation with my healthcare provider and I agree to follow my usual diabetes management activities and lifestyle.

NOTICE OF POSSIBLE INSURANCE NON-COVERAGE
I understand that my insurance MAY NOT COVER the Continuous Glucose Monitor (CGM) evaluation, including interpretation. If my insurance does not cover the evaluation, I agree to be responsible for all the charges which may be billed to me for this procedure.

Patient Signature: ___________________________________________ Date: ____________________
PATIENT CONSENT FORM

Dear Patient,

Please read this Patient Consent Form carefully, as you will be asked to provide your agreement and consent to the terms and instructions below regarding your use of the Medtronic iPro™2 digital recorder (“iPro2”), a continuous glucose monitor, and this office’s use of the CareLink™ iPro™ web-based application for your diabetes therapy. If there is anything in this Consent Form that you do not understand or have concerns with, please contact our office. Please note that if you do not agree to the terms of this Consent Form, our office cannot place an iPro2 on you, nor use the CareLink iPro application for your diabetes treatment.

This Consent Form is separate from, and in addition to, any other consent or authorization form you have received from our office.

iPro2

The iPro2 is a continuous glucose monitor placed on your body for a period of a few days (as specified by our office and/or your physician), that will continuously record your glucose levels. The results of the recordings can be recorded, placed in a report, analyzed, etc. (through the CareLink iPro website), and will assist our office in helping you manage your diabetes more effectively. The iPro2 should only be used pursuant to our instructions. When wearing the iPro2, you agree and commit to the following:

a) You agree to collect 3-4 blood glucose fingerstick tests per day.
b) You agree to enter all meals, medication, and other relevant activities on a log sheet.
c) You agree to check the insertion site daily, to verify the sensor is fully inserted and that the site is not irritated, excessively red or painful. (You understand that the possible risks include inflammation, infection, and/or bleeding at the sensor insertion site.)
d) You agree to return the iPro2 within ________ days of completing the wear period.
e) You agree to take every precaution when handling the iPro2, and understand it is a sensitive medical device. You may be responsible for the loss or theft of the iPro2, or any damage or malfunction caused by any unreasonable or unusual activity.
f) In addition, you agree to follow any other specific instructions we provide regarding the iPro2, and to call our office immediately if you experience problems or have questions.

If you have any questions about the iPro2, please contact our office and, if necessary, your physician or health care professional.

CareLink iPro – General Information & Patient Privacy

The iPro2 uses a software application called CareLink iPro. This is a centralized, web-based software from Medtronic used by health care professionals to upload, store and analyze glucose readings from patients who have worn an iPro2. In addition to the glucose readings from the iPro2, we may also upload certain background information for identification purposes, including your name, date of birth, a patient ID number, and limited information regarding your type of diabetes (collectively referred to as “Protected Information”). Once your Protected Information is uploaded through the CareLink iPro website (http://www.carelinkipro.com in the U.S.; http://ipro.medtronic.com outside of the U.S.), it will be stored on a secured computer server (database) located in a U.S. Medtronic facility (Minnesota) for patients in the U.S., or a secured computer server located in a Medtronic facility in Heerlen, Netherlands, for all non-U.S. patients. Accordingly, please note that your Protected Information may cross country borders when transmitted to a CareLink iPro server.
PATIENT CONSENT FORM

CareLink™ iPro™ – General Information & Patient Privacy

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

Medtronic Access to PHI

Please note that Medtronic is responsible for hosting and maintaining the CareLink iPro servers, and therefore will have access to your PHI that this office has or will upload through the CareLink iPro website. Medtronic may also study your PHI for purposes of advancing or improving its products, therapies or services for the benefit of future patients. Medtronic may do this by analyzing, studying, conducting education, and/or monitoring the data (usually in aggregate form) stored on the CareLink iPro servers. Please note that Medtronic will not review any PHI 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 PHI, 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 contractors utilized will comply with applicable standards and policies for maintaining the privacy of patient data.

Your PHI stored on a CareLink iPro server 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 PHI with any outside entity or third party. Limited exceptions exist to this prohibition, such as where the PHI is (1) completely de-identified (made anonymous) 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.

* * * *

By signing below, I acknowledge that I have read, fully understand, and agree to the above terms of this Consent Form, including those terms regarding the use of the iPro2 and the storage and use of my PHI (as described above) through the CareLink iPro website. I have had an opportunity to ask questions and to receive answers. I realize that my consent is voluntary, and I may refuse to participate or utilize the iPro2 and the benefits of CareLink iPro.

Signature of Patient (or Legal Representative) ___________________________ Date _____________________

Print Patient Name
iPRO™2 PATIENT INSTRUCTIONS

Things to Know

1. The evaluation will last 6 days.

2. You can bathe and shower normally.

Things to Do

1. Day 1 Check and record BG:
   - 1 hour after iPro2 placement
   - 3 hours after leaving the clinic
   - Right before you go to bed

2. For the remaining days, check and record your BG 3-4 times per day before each meal and before bedtime.

3. Eat, exercise and take medications as you normally do.
   The goal is to understand how your glucose levels respond to food, activity and treatment during your normal routine. This helps the doctor make therapy adjustments.

4. If the tape begins to pull off the body, put more tape over failing tape. If the iPro2 recorder comes off, put it in plastic bag and return it to the doctor’s office.
   **DO NOT throw it away.**

5. Return your iPro2 recorder (and log sheet if you used one) to your doctor’s office at the end of the evaluation.

6. **Important:** For iPro2 myLog app users, do not manually change your phone’s time. If traveling let your phone time change automatically. Do not change the date or time on your glucose meter at any time during the evaluation.
Sample Patient Log Sheet

<table>
<thead>
<tr>
<th>TIME</th>
<th>BG</th>
<th>CARBS</th>
<th>MEDICATION</th>
<th>DOSAGE</th>
<th>ACTIVITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:00AM</td>
<td>165</td>
<td>30</td>
<td>Humalog</td>
<td>1 unit</td>
<td>9:20AM 30 min. walk</td>
</tr>
</tbody>
</table>

Discuss Time Zone With Patient

First BG test after 1 hour:
Second BG test after 3 hours:
Third BG test before bedtime:
### Sample Patient Log Sheet

**Test Before:** Breakfast, Lunch, Dinner and Bedtime

<table>
<thead>
<tr>
<th>TIME</th>
<th>BG</th>
<th>FOOD/DRINK &amp; PORTION SIZE</th>
<th>CARBS</th>
<th>TIME</th>
<th>MEDICATION</th>
<th>DOSAGE</th>
<th>ACTIVITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8:00AM</td>
<td>165</td>
<td>2 EGGS, 1 PIECE TOAST, BLACK COFFEE</td>
<td>30</td>
<td>8:05AM</td>
<td>HUMALOG</td>
<td>1 UNIT</td>
<td>9:20AM</td>
</tr>
<tr>
<td>8:20AM</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Notes:**

_____________________________________________________________________________________________
_____________________________________________________________________________________________
_____________________________________________________________________________________________
Sample Patient Log Sheet

<table>
<thead>
<tr>
<th>TIME</th>
<th>BG</th>
<th>TIME</th>
<th>FOOD/DRINK &amp; PORTION SIZE</th>
<th>CARBS</th>
<th>MEDICATION</th>
<th>DOSAGE</th>
<th>ACTIVITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:00AM</td>
<td>165</td>
<td>8:20AM</td>
<td>2 EGGS, 2 PIECE TOAST, BLACK COFFEE</td>
<td>30</td>
<td>HUMALOG</td>
<td>1 UNIT</td>
<td>WALK</td>
</tr>
<tr>
<td>8:05AM</td>
<td></td>
<td>9:20AM</td>
<td></td>
<td>30</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9:20AM</td>
<td></td>
<td>30 MIN</td>
<td></td>
<td></td>
<td>WALK</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Discuss Time Zone With Patient

First BG test after 1 hour:
Second BG test after 3 hours:
Third BG test before bedtime:

Test Before: Breakfast, Lunch, Dinner and Bedtime:

Name: _____________________________________

Day 1: ___________________ Date: ______/_______
## Sample Patient Log Sheet

<table>
<thead>
<tr>
<th>TIME</th>
<th>BG</th>
<th>TIME</th>
<th>FOOD/DRINK &amp; PORTION SIZE</th>
<th>CARBS</th>
<th>TIME</th>
<th>MEDICATION</th>
<th>DOSAGE</th>
<th>ACTIVITY</th>
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<tbody>
<tr>
<td>8:00AM</td>
<td>165</td>
<td>8:20AM</td>
<td>2 EGGS, 2 PIECE TOAST, BLACK COFFEE</td>
<td>30</td>
<td>8:05AM</td>
<td>HUMALOG</td>
<td>1 UNIT</td>
<td>9:20AM 30 MIN. WALK</td>
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<td>9:00AM</td>
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<td>9:50AM</td>
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**Test Before:** Breakfast, Lunch, Dinner and Bedtime

**Notes:**
_____________________________________________________________________________________________
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### Sample Equipment Log Sheet

<table>
<thead>
<tr>
<th>IPRO SERIAL NUMBER</th>
<th>PATIENT NAME</th>
<th>RETURNED</th>
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</table>
Sample Equipment Log Sheet

**Equipment Log Sheet**

iPro™2 Serial Number __________________________

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<thead>
<tr>
<th>PATIENT NAME</th>
<th>PATIENT PHONE</th>
<th>START DATE</th>
<th>END DATE</th>
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</table>

42
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 myLog 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
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 myLog app, go straight to Print all reports.**
## Troubleshooting

### Dock light descriptions

<table>
<thead>
<tr>
<th>Dock Lights</th>
<th>Description</th>
<th>What it means</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Light Off" /></td>
<td>All lights are off.</td>
<td>The Dock is not plugged into an outlet or computer USB port.</td>
</tr>
<tr>
<td><img src="image" alt="Power Light On" /></td>
<td>The white power light is on.</td>
<td>The Dock is connected to power.</td>
</tr>
<tr>
<td><img src="image" alt="All Lights Flash" /></td>
<td>All three lights flash once.</td>
<td>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.</td>
</tr>
<tr>
<td><img src="image" alt="Power Light + Charging Light" /></td>
<td>The white power light is on and the green charging light is flashing continuously.</td>
<td>The iPro2 is charging or the iPro2 contains data that must be uploaded using CareLink Pro. After you upload data, if the green charging light continues to flash, the iPro2 is still charging.</td>
</tr>
<tr>
<td><img src="image" alt="Power Light + Charging Light" /></td>
<td>The white power light and the green charging light are on.</td>
<td>All previous data has been cleared from the iPro2. The iPro2 is fully charged and ready for the next patient study.</td>
</tr>
<tr>
<td><img src="image" alt="Power Light + Charging Light" /></td>
<td>The white power light flashed five times and the green charging light is flashing continuously.</td>
<td>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.</td>
</tr>
<tr>
<td><img src="image" alt="Power Light + Warning Light" /></td>
<td>The white power light and the red-warning light are on.</td>
<td>There may be a problem with the iPro2 recorder. See instructions below.</td>
</tr>
</tbody>
</table>
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 iPro 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.
Reimbursement coverage for Continuous Glucose Monitoring (CGM) is continuing to expand. This document provides general guidance on billing for Professional and Personal CGM.

**CGM Reimbursement Facts**
- Approximately 92% of commercial health plans in the U.S. are covered by an insurer with a written policy for Personal and Professional CGM.
- All local Medicare contractors currently cover Professional CGM.

*Sources: Internal Data on File.*

**CGM Billing Codes**

<table>
<thead>
<tr>
<th>Codes</th>
<th>Description</th>
<th>Who Can Bill</th>
</tr>
</thead>
<tbody>
<tr>
<td>E/M codes 99212-99215</td>
<td>Office visit for the evaluation and management of an established patient</td>
<td>Physicians, Physician Assistants, Nurse Practitioners</td>
</tr>
<tr>
<td>CPT® code 95250</td>
<td>Sensor Placement&lt;br&gt;Hemoglobin A1C (HbA1C) Determination&lt;br&gt;Hook-up and Calibration&lt;br&gt;Patient Training&lt;br&gt;Catheter Insertion&lt;br&gt;Sensor Removal and Printout of Recording</td>
<td>Any qualified staff member under the direct supervision of a physician, a physician assistant, or a nurse practitioner</td>
</tr>
<tr>
<td>CPT® code 95251</td>
<td>CGM Data Interpretation</td>
<td>Physicians, Physician Assistants, Nurse Practitioners</td>
</tr>
</tbody>
</table>


**CGM Billing Protocols**

The following billing protocols can be used for Professional and Personal CGM. Criteria for Professional and Personal CGM may differ, so always verify coverage policy directly with the payer.

### Professional CGM

1. **Office Visit (Pre-CGM Evaluation)**<br>   E/M 99212 - 99215
2. **CGM Startup and Instruction**<br>   CPT 95250
3. **CGM Removal and Download**<br>   No Billing
4. **CGM Data Interpretation**<br>   CPT 95251
5. **Office Visit (Post-CGM Evaluation)**<br>   E/M 99212 - 99215

**Billing Notes**
- Use modifier “-25” with an E/M code when billing 95250 or 95251 on the same day.
- E/M can only be billed separately on the same day when a significant and separately identifiable service took place above and beyond the services associated with CGM.
- CGM data interpretation (95251) can be billed on an ongoing basis, but should not be billed more than once per month, per patient.**

### Personal CGM

1. **Office Visit (Pre-CGM Evaluation)**<br>   E/M 99212 - 99215
2. **CGM Startup and Training**<br>   CPT 95250
3. **CGM Data Interpretation**<br>   CPT 95251
4. **Office Visit (Post-CGM Evaluation)**<br>   E/M 99212 - 99215

*For Personal CGM, the glucose sensor must be provided at the expense of the billing provider in order for the provider to bill 95250. Check with the payer on coding for personal CGM, since reporting requirements may vary. Personal CGM is not covered by Medicare and does not meet Medicare Benefit Category requirements.**

**Payers may have varying coverage policies for 95250; and are not obligated to pay on a monthly basis, so always check with payers to verify coverage and limits on frequency.*
CGM Billing Guidance from the AMA

The American Medical Association (AMA) published an article in CPT® Assistant in December 2009 that clarified the following use of CPT® codes 95250 and 95251 for Professional and Personal CGM.

- **95250** can be billed for Professional and Personal CGM at the time of hook-up.
- **95250** and **95251** can be used for Professional and Personal CGM.
- **95251** does not require a face-to-face (in person) visit.
- **95250** and **95251** should only be reported once monthly per patient.
- **95250** requires that the service period be at least 72 hours.
- **95251** requires at least 72 hours of CGM data from a patient.


Personal CGM is not covered by Medicare and does not meet Medicare Benefit Category requirements. For Personal CGM, the glucose sensor must be provided at the expense of the billing provider in order for the provider to bill 95250.

Sample Claim Form

The following steps indicate the key information on the CMS-1500 claim form when billing for CGM.

**Step 1 - Diagnosis Codes (Box 21)**
- Document the primary diagnosis code and the appropriate ICD indicator.
- Example: Diagnosis code: E10.65 (Type 1 diabetes mellitus with hyperglycemia)

**Step 2 - Place of Service (Box 24B)**
- Specify the location where the service was performed.
- Examples: 11 = Office
  22 = Outpatient Hospital

**Step 3 - Procedure Codes (Box 24D)**
- Document the startup and initiation of CGM with 95250.
- Document CGM data interpretation with 95251.
- If relevant, enter the appropriate E/M code for separately identifiable service(s) concurrent with CGM (e.g., for diagnosis and/or therapy changes).

**Step 4 - Modifiers as Needed (Box 24D)**
- Use the -25 modifier on an E/M code to distinguish a significant and separately identifiable service, above and beyond the services associated with CGM, provided on the same day.

**Step 5 - Diagnosis Pointer (Box 24E)**
- Specify the diagnosis code reference from Box 21 (1, 2, 3, or 4) that relates to the procedure code(s) listed in Box 24D.
- If only 1 diagnosis code is listed in Box 21, then list "A" in 24E.