



Manual 39
Continuous Glucose Monitoring Procedures
ARIC Visit 12

Version 1.3
August 6, 2026



**Continuous Glucose Monitoring (CGM)
Manual of Procedures
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0. MANUAL REVISIONS

Version Number	Date	Author	Section(s)	Description of Update
0.1	July 28, 2025	Liz Selvin, Arielle Valint	All	Initial Draft for Visit 12 CGM Manual. For review (no procedural change from V11 V1.6, study aims have been updated.)
0.2	Sep 5, 2025	Arielle Valint	All	Update 14 day wear time to 15 day wear time throughout. Update sensor from Libre 3 to Libre 3 plus. Both sensors are in the Libre 3 system.
1.0	October 31, 2025	Arielle Valint	1.41.6, 5.1	1.4, 1.6: Remove information about imaging exclusions not relevant to the current visit. 5.1: Add section detailing blinded reader QC procedures. See accompanying CGM Reader QC log in separate document.
1.1	November 26, 2025	Arielle Valint	2.6; 5.1	2.6: Update post-return shipments to Abbott to be twice monthly on the 2 nd and 4 th Tuesday of each month. 5.1: Reduce frequency of QC procedures to once monthly.
1.2	January 13, 2026	Arielle Valint	1.9;5.2	1.9: Update schematic to show that the device placement day is "Day 0" of the device wear. 5.2: Add option to mark CGMR form as permanently missing if participant declines to participate, in line with decisions on Operations call in July 2024.
1.3	May 11, 2026	Betty Rupp	1.4.1	Updated exclusions and noted exceptions for implanted medical devices.
1.3	May 21, 2026	Betty Rupp	2.6, 2.7	Added info on sensor return instructions for spouse pairs and adding padded envelopes as an alternative to the mailer kit box for device.
1.3	July 30, 2026	Betty Rupp	2.1, 2.3, 5.1	Updated CGM Reader sections with instructions for using the CSDP Mobile app to activate and sync sensors, added that reader QC procedures will only be needed for 3 months.

1. STUDY OVERVIEW

1.1 Study Aims

- 1) To characterize glucose patterns detected by continuous glucose monitoring (CGM) technology (measures of glycemic variability, hyperglycemia, and hypoglycemia) in adults aged 80+ with and without diabetes.
- 2) To quantify the cross-sectional associations of CGM-detected glucose patterns with health conditions in older adults. We will evaluate the associations of CGM parameters (measures of glycemic variability, hyperglycemia, and hypoglycemia) with frailty and poor physical and cognitive function.
- 3) Using also data from prior visits, examine changes in CGM patterns in older adults over time. We will also link CGM-detected glucose patterns with clinical outcomes and determine if these associations are independent of traditional risk factors in old age.

To achieve these aims, we will conduct 15-day CGM in all participants at ARIC Visit 12 to evaluate glucose patterns during the 15-day wear period.

1.2 Background and Rationale

Older adults are less able to maintain homeostasis or maintain physiological constancy and, although diabetes is common in old age, glucose instability is an underappreciated concern. Diabetes exists along a continuum and there is no clear glycemic threshold above which complications occur. Indeed, approaches to diagnosis and thresholds have changed substantially over time as our understanding of diabetes and its treatments have evolved. We contend that disordered glucose patterns among very old adults (80+) may be present even in the absence of overt diabetes and may be related to concurrent health status and future clinical outcomes.

Continuous glucose monitoring (CGM) technology is the recommended approach to the assessment of glycemic variability and hypoglycemia and is being increasingly used in diabetes care. The burden of disordered glucose homeostasis and its link to clinical outcomes in very old adults (80+) with diabetes is uncharacterized and no prior studies have included older adults without diabetes. Indeed, the evidence-base for understanding CGM-detected hypoglycemia and glycemic variability in older non-diabetic adults is practically non-existent.

Wearable CGM technology is an opportunity to rigorously characterize glucose patterns in older adults across the glycemic spectrum (from no diabetes, to prediabetes, to diabetes) and evaluate associations with concurrent and prospective health outcomes. Because we have conducted CGM assessments at prior visits, we will also be able to examine variability and changes in CGM patterns over time.

The data generated by this project will provide information on 'normal' glucose patterns in old age and possible associations of disordered glucose patterns (e.g. high variability, episodes of low glucose) with outcomes. In persons with diabetes, our results will assist

clinicians in formulating more specific recommendations regarding diabetes treatment goals and the health consequences of disordered glucose homeostasis in old age. The lack of information on normal glucose patterns in older adults and uncertainty regarding clinical utility of CGM in type 2 diabetes are motivations for this project.

1.3 Key Measures

- Up to 15 days of continuous glucose monitoring (CGM) data (glucose measured every 5 minutes using Libre 3 Plus sensor in blinded mode)

1.4 Study Participants

The continuous glucose monitoring (CGM) protocol will be offered to all consenting participants returning for the Visit 12 examination. ARIC staff may also apply the CGM sensor during home visits.

1.4.1 Exclusions

If any of the following exclusions apply to a study participant, the CGM protocol will not be offered:

- The participant has a history of allergic skin reaction to adhesive tape
- The participant cannot mail the device back to the field center or deliver the device back to the Field Center.
- If the participant has a battery-operated or electrically active implanted medical device such as a pacemaker or defibrillator. The performance of the Abbott system has not been evaluated when used with implanted medical devices. The Abbott system has been tested and found to be safe with one brand of implantable pacemaker devices but has not been extensively tested with other brands of pacemakers. This exclusion is made out of an abundance of caution.
- Battery-operated or electrically active implanted medical device exceptions that are allowed include: cochlear implants, Watchman or other battery-less cardiac implants, heart monitor recorders (including LINQ or loop implantable recorders), and optical implants. Implanted devices such as mitral valve clips, other stents or heart valve replacements, radiation therapy ports, and knee replacements are also allowed as they are not considered battery-operated or electrically active.

If the study participant is excluded from the CGM protocol at the time of their Visit 12 appointment, but still eligible for the study (i.e. the participant is interested in the study and does not have an allergic skin reaction to adhesive tape), the protocol should be offered to the participant at the closest time point when monitoring is possible.

Note: Participants will **not** be excluded if they already use a continuous glucose monitoring device. They can wear both devices simultaneously. The sensor being used in this protocol is blinded (participants cannot obtain real-time information on glucose from the sensor). If participants have diabetes, they should be advised to continue to take their medications and continue their normal routine for self-monitoring of their glucose levels.

1.4.2 Contraindications

The Libre 3 Plus sensor must be removed prior to high-frequency electrical heat (diathermy) treatment. The effect of diathermy on the performance of the System has not been evaluated. The exposure may damage the Sensor and may impact proper function.

Some individuals may be sensitive to the adhesive that keeps the sensor attached to the skin. If a participant notices significant skin irritation around or under their sensor, they should remove the sensor.

1.4.3 Participant Reimbursement

Participants will be reimbursed \$25 when the sensor is returned to the clinic.

1.5 Equipment, Materials, and Supplies

- 1 Abbott FreeStyle Libre 3 System
 - o 1 blinded reader
 - o 1 sensor pack (single use only)
- Alcohol wipe
- Skin Tac adhesive
- 1 participant mailer kit
 - o 1 padded cardboard mailer with paid postage
 - o 1 biohazard bag
 - o Printed participant mailing instructions

1.5.1 Forms

- Continuous Glucose Monitoring – Device Initialization and Tracking Form (CGMR)
- Continuous Glucose Monitoring Results Form (CGX)

1.6 Consent Process

The CGM Consent Process has been moved out of MOP39 and is stored with the Visit Consent.

1.7 Overview of Study Procedures

Participants returning for Visit 12 will be invited to participate in the protocol. Staff will place a small CGM sensor on the underside of the upper arm and secure the sensor using a liquid adhesive (to prevent it from being accidentally dislodged during the wear-period). Participants will wear the sensor for up to 15 days. On day 3, staff will call participants to answer any questions and to encourage participants to wear the device for the full 15-day period. On day 15, staff will call participants to remind them to remove the device, and provide instructions regarding removal if needed.

Participants who cannot come to the Visit 12 exam will be offered home visits and the CGM sensor will also be applied to participants during the home visits using the same protocol.

The estimated time for placing the CGM sensor during the ARIC Visit is 5 to 15 minutes, mostly involving time for consent and explaining the study. The total dedicated time for the participant once they leave the clinic is approximately 15 minutes: 5 minutes for each follow up phone call (on day 3 and day 15) and an extra 5 minutes to remove, package, and return the sensor via mail.

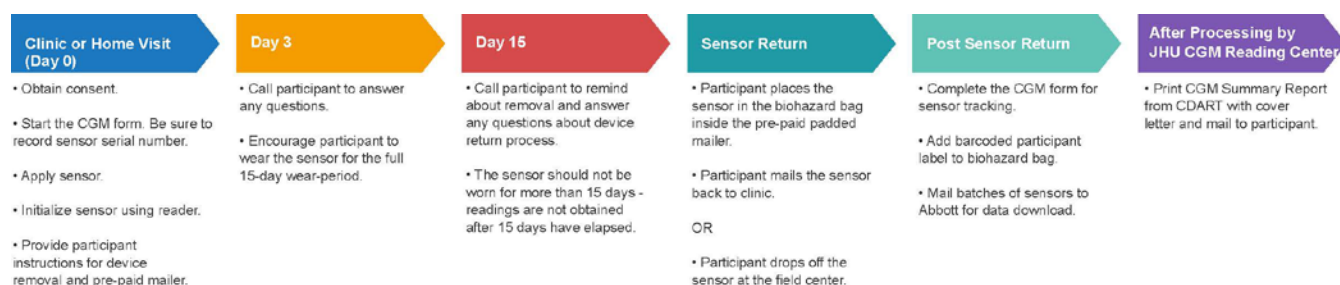
1.8 Overview of the Continuous Glucose Monitoring Device

We have selected the Abbott Libre 3 Continuous Glucose Monitoring (CGM) System for this protocol because of its ease of use and acceptability to participants. The Abbott Libre 3 Plus CGM sensor is small (the size of two pennies stacked on top of one another) and is worn on the arm for 15 days and is factory calibrated (no fingerstick is required). The blinded Libre 3 system we are using in ARIC records interstitial glucose once every 5 minutes and stores the 15 days of data. Participants do not interact with the device, and they are masked to the glucose readings. The sensor is small, discrete, and designed to be worn while going about one's daily life. After 15 days, the sensor will be returned by participants in a pre-paid mailer.

The sensors will be mailed in batches by the ARIC field centers to Abbott for data download.

The Abbott Libre 3 system is an FDA cleared device. The Libre 3 Plus sensor is a CGM device indicated for detecting trends and tracking patterns in persons with diabetes. Outside of the research setting, the system is intended for use by health care professionals and requires a prescription.

1.9 CGM Timeline Schematic



2. DETAILED STUDY PROCEDURES

2.1 Overview of the Abbott FreeStyle Libre 3 System

Libre 3 Glucose Monitoring System involves a single-use disposable CGM sensor and a handheld Reader (we are using a blinded version provided by Abbott specifically for this study that is a dedicated cellular phone with the CSDP Mobile app installed to activate patches and sync sensors). The CSDP Mobile app is used to initiate the sensors on multiple participants.

Note: Sites will be supplied with 3 or more readers. Please label them: #1, #2, #3, etc. with a label, sticker, or permanent marker on the back side of the device to identify the readers.

Sensor Kit

The FreeStyle Libre 3 Sensor Kit includes:

- Sensor Applicator
- Product insert



Sensor Applicator

Applies the Sensor to your body.

The sensor measures and stores glucose readings when worn on the body. By following the instructions, prepare and apply the sensor to the underside of the back of the participant's upper arm. The sensor has a small, flexible tip that is inserted under the skin. The sensor can be worn for up to 15 days. The back of the arm is where the sensor has been shown to be most accurate.

Figure 1. Left: the sensor applicator; Right: the sensor from three angles



Figure 2. Examples of Proper placement of the sensor



Figure 4 shows proper placement of the sensor. Staff at each field center have some flexibility regarding placement of the sensor, as long it is located somewhere on the back of the arm. Note that the sensor has a small hole in the center which allows air to circulate and escape from under the skin. This reduces moisture accumulation and helps with adhesion.

Note: some of the images above are of the larger, Libre Pro sensor; placement location for the Libre Pro and Libre 3/ Libre 3 Plus is the same.

2.2 Procedures for CGM Sensor Application

0. The CGM Sensor is placed on the back of the upper arm using the disposable applicator. Only apply the Sensor on the back of the upper arm. The optimal area for placement can be determined by having the participant place their arm like they are going to flex their bicep and then place the sensor under the arm. The ideal location is where the sensor will not be exposed but also so it doesn't touch the inner torso. Avoid areas with scars, moles, stretch marks or lumps. Select an area of skin that generally stays flat during normal daily activities (no bending or folding). If relevant, choose a site that is at least 1 inch (2.5 cm) away from any insulin injection site.	 An illustration of a person's back and upper arms. Two orange oval shapes are marked on the back of each upper arm, indicating the optimal placement area for the CGM sensor. The person is wearing blue shorts.
1. Clean hands and put on protective gloves prior to sensor handling/insertion to help prevent infection.	
2. Clean the application site using an alcohol wipe and ensure that it is dry prior to sensor insertion. This helps the Sensor stay attached to the body. If the participant's arm is abundantly hairy, shaving the application site may also be helpful to aid in sensor application.	

Note: The area **MUST** be clean and completely dry, or the sensor may not stick to the site.

Adhesion of the sensor to the skin for the full 15-day wear period is very important. If the sensor falls off, data will no longer be collected. If the sensor is loose, bad data may be collected.

To help with adhesion, wipe the placement site with a **Skin Tac wipe** (single use). Skin Tac is a liquid adhesive that will help keep the sensor in place during the wear-period. The Skin Tac is packaged and used like an alcohol wipe but it is sticky and will help the sensor stay on the skin for the 15-day period. The Skin Tac should be applied over the entire sensor placement area on the participant's arm. There is no wait period between applying the Skin Tac and completing the sensor application.

Additionally, a Tegederm-style cover or Kinesio tape may be placed over the CGM to help keep the CGMs secure for the full 15 day period. Do not cover the hole in the middle of the sensor when adding additional adhesive. The hole in the middle of the sensor allows airflow to the skin under the sensor during the wear period.



3. Place the Sensor Applicator over the prepared site and push down firmly to apply the Sensor to the body.

CAUTION: Do NOT push down on the Sensor Applicator until placed over prepared site to prevent unintended results or injury.
4. Gently pull the Sensor Applicator away from the body. The Sensor should now be attached to the skin.

Note: Applying the Sensor may cause bruising or bleeding. If there is bleeding that does not stop, remove the Sensor, and apply a new one at a different site.
5. Make sure the Sensor is secure after application. Put the cap back on the Sensor Applicator.

Discard the used Sensor Applicator according to your facility's procedures.

After assembling and applying the Sensor to the participant, use the Reader to start the Sensor and confirm it is working.

NOTE: For our study, the optimal location for the sensor is **under the back part of the arm** (NOT on the outer arm as might be seen in various other images of people wearing the Abbott Libre 3 Plus sensor). There is some discretion of where the sensor can be placed on the back of the arm. Field Center staff can have the participants hold their arms loosely down at their sides to help determine most comfortable location for placement of the sensor, i.e., where it will not rub against the torso.

Figure 3. The blue arrow indicates proper location for placement of the sensor.



2.3 Procedures for starting the CGM Sensor

1. Connect the phone/reader to your local Wi-Fi to help ensure the timestamp is properly synced
2. Unlock the phone using the passcode “1111”
3. After Sensor insertion, open the CSDP app (yellow butterfly icon)
4. Follow the step-by-step CSDP instructions with screenshots in Appendix 5.1.

CSDP stands for combined sensor data platform.

Note: When activating multiple patches please wait for the first Clinical Lifecount in the app to be received from the scanned patch before scanning the next patch. Do not scan patches rapidly one after the other.



Please sync a maximum of four sensors to the app. If you need to sync additional sensors, first terminate one of the sensors that is already synchronized, and then sync the new sensor.

2.4 Procedures for Reapplication of CGM Sensor

For some participants, the CGM sensor may fall off before the 15-day wear period is completed. If this happens, participants should be instructed not to attempt to reapply the sensor and to instead call their field center. If the sensor was worn for fewer than 10 days and the participant is willing, field center staff should set up an appointment as soon as possible to replace the dislodged sensor and restart the 15-day wear period. When the participant returns to the center, they should bring their dislodged sensor and

mailer kit with them. If the sensor falls off a second time or the sensor was worn for 10 or more days, the participant should be instructed to use the mailer kit to return the sensor to the field center and the sensor will not be replaced. In the case where the participant does not want the sensor to be replaced, they may mail the sensor back to the field center using the prepaid mailer kit.

Multiple occurrences are allowed for data entry on the CGMR form. Staff should record each sensor initialization in a separate occurrence in the CGMR form.

2.5 Sensor Removal and Return Instructions

Before leaving the clinic (or at the end of the home visit), participants will be provided with 1) information about the sensor and instructions for removal of the sensor after 15 days of continuous wear; 2) “Tac-Away” adhesive remover wipe to help with removal of the device (if needed); and 3) a prepaid mailer kit for returning the sensor, prelabeled with the participant’s ARIC ID and sensor serial number. To label the sensor serial number, the site may cut the bottom flap of the sensor packaging containing the sensor QR code and tape this to the biohazard bag. Before taping the sensor packaging to the biohazard bag, the flap should be copied and stored with the participant’s file to ensure that the serial number is not lost if the participant loses the shipping kit. For sites where participants are blinded to their ARIC ID, the ARIC ID label can be omitted from the mailer kit in favor of alternative identification to ensure the sensor is linked to the correct participant.

Figure 4. Cut the bottom flap off the CGM sensor box. Copy the flap using a scanner and save a copy with the participant’s file. Then, tape the flap to the biohazard bag to assist with sensor identification upon return to the clinic.

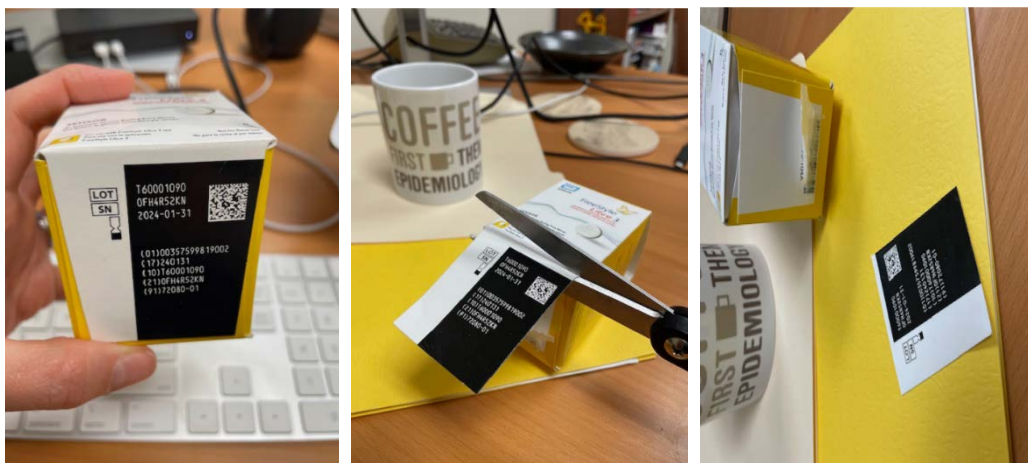


Figure 5. TacAway is used to remove adhesive residue to remove the CGM sensor.



Participants will be given the option of returning to the clinic to have the sensor removed. They can also call the clinic for help in removing the sensor if desired.

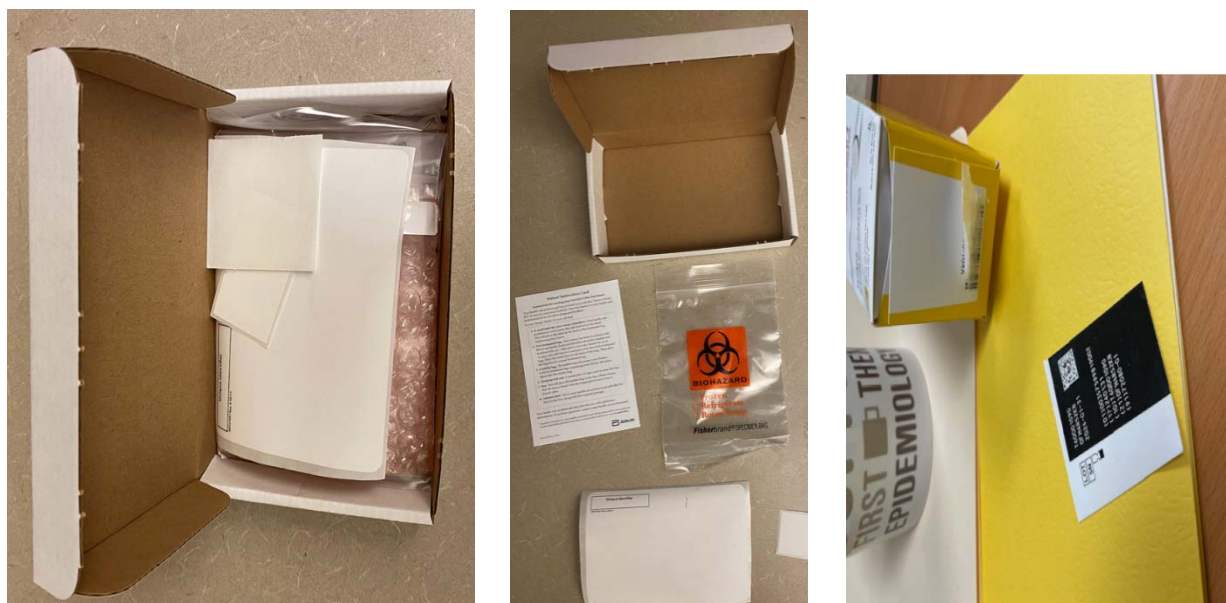
Participants will be provided with a kit and instructions for mailing the CGM sensor back to the ARIC clinic. The mailer kit will contain either a padded cardboard or padded envelope mailer and biohazard bag for the sensor.

2.6 Sensor Return Instructions for Spouse Pairs

To ensure sensors are returned in the correctly assigned biohazard bag when spouse pairs live in the same household, sites may add a color-coded sticker to one participant's return biohazard bag and participant handout, then a differently color-coded sticker to the other participant's return biohazard bag and participant handout. Instruct the spouse pair to note their assigned color to help ensure that the right sensor makes it into the correct biohazard bag for return. Alternatively, Abbott approved the use of a sharpie or placing colored stickers on the CGM devices to differentiate devices between spousal pairs. However, please note that neither option has been fully tested for being able to last on the device over the entire wear period.

Figure 6. On the left: a sensor packaged and prepared for shipment back to the field center via cardboard mailer. In the middle: contents of the padded cardboard mailer include a cardboard box or padded envelope (not pictured), bubble wrap, biohazard bags, instructions, and postage. On

the right: the bottom flap of the CGM sensor packaging to be taped to the biohazard bag for sensor identification.



Each ARIC site will need to arrange for US postal service postage prior to providing the mailer kit to participants.

2.7 CGM Post-Return Field Center instructions

Upon receipt of the used sensor via mail, field center staff will apply a barcoded ARIC participant ID label to the biohazard return bag. The Coordinating Center will provide sites a pdf of barcoded participant labels. Please use Avery Address labels (1" x 2-5/8") ex. Avery 5960 and print locally on any laser or inkjet printer.

Weekly, all sensors received from participants in the previous week will be gathered by the Field Center Staff and mailed to Abbott Diabetes Care for data download and processing.

The used sensor should remain in a biohazard bag and placed in the mailer kit box or padded envelope with the ARIC ID marked on the outside. All biohazard bags and mailer kits should be labeled with ARIC ID to facilitate tracking. For sites where participants are blinded to their ARIC ID, sites must add the appropriate barcoded participant ID to the biohazard bags and mailer kits before shipment to Abbott. All mailer kits should be put in a larger box with a CGM Shipping and Receiving form and FedEx label for shipment to Abbott.

If shipping the second/replacement sensor for a participant, then sites should handwrite the letter "R" on whitespace of the ID label of the biohazard bag to ensure that the data is processed as a replacement for the participant. Sites should also include an "R" on the ID line of the shipping log. Both the replacement and original sensor should be shipped to Abbott for processing when possible.

Figure 7. Example of replacement sensor line item recorded on CGM shipping log.

<u>/isit: 11</u>		Field Center Comments: _____
Itemized Listing of Shipment Contents		
ARIC ID		Serial Number
F123456	R	

All tracking information should be shared with Abbott Diabetes Care in advance and Abbott will acknowledge that sensors were received.

FedEx shipments to Abbott should happen on the 2nd and 4th Tuesday of each month.

Shipping information:

Attention: Annette Peinado
 1360 South Loop Road
 Alameda CA 94502

Data downloads (at Abbott Diabetes Care) will be supervised by Annette Peinado and performed by Robbie Scott and Nelson Rosa

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3. DATA AND RESULTS REPORTING

3.1 CGM Sensor Tracking

Field Center staff will need to associate the ARIC participant ID with the serial number (containing 9 alphanumeric characters) of each Libre 3 Plus sensor in the CGMR form at the time of the clinic visit. There is a matching unique serial number on the box of the device and the applicator. The biohazard bags in the mailers should also be labeled with the participant's ARIC ID and sensor serial number to facilitate tracking. When the sensor is returned to the clinic, the CGM serial number should be verified against the serial number that was entered at initialization in the CGMR form. In the case of a mismatch, the serial number should be reconciled with the serial number recorded in the CGMR form and the Coordinating Center should be notified with any discrepancies.

Figure 8. The sensor serial number is the alphanumeric 9-character string found next to the "SN" box on the CGM sensor pack.



3.2 Results Reporting

There are no alerts as the data are not available in real-time and the data collected are not clinically actionable at the time of the data download. Hemoglobin A1C, a measure of diabetes and glucose control, is already reported to participants as part of the parent ARIC NCS protocol.

JHU CGM Data Processing Center will receive all CGM data from Abbott and produce a 1-page auto-generated CGM Summary Report, which is a summary of the 15-day glucose data (graph of glucose values with information on the normal range). These reports will be uploaded to CDART. Field Center staff will retrieve the CGM Summary Reports from CDART and send with a cover letter to participants and/or their health care provider with permission.

Once the JHU CGM Data Processing Center posts the CGM Summary Report to CDART, field centers will be notified of results availability for each participant using the CDART Results Status Report. Field center staff will print the CGM cover letter from the ARIC website and the CGM Summary Report directly from the CGX form under the participant's ARIC ID.

If the sensor wear period was fewer than 15 days, the participant may still be provided with the data summary. However, in cases where the wear-period was fewer than 10 days, this summary may not be completely representative of the participant's glucose profile. If the participant had the sensor replaced, they should be provided with only the summary of results for the sensor that was worn for the longest time. See **Appendix 5.2** for more detailed instructions on handling multiple sensors.

3.3 Rationale for Reporting

CGM technology is often used in the care of adults with type 1 diabetes. It is not standard of care for adults with type 2 diabetes and it is not commonly used in this population. In adults with type 2 diabetes not on insulin therapy, CGM is currently considered to be of little clinical benefit.

The CGM device being used in this protocol does not provide real-time information on glucose readings (participants are masked to any glucose readings). The device is designed to be worn for 15 days and, at the end of the wear period, the sensor will be returned via mail and the data are downloaded at the ARIC clinic. Thus, participants will not be aware of their glucose measures collected during the 15-day period. Even if subsequent analysis of the CGM data reveals clinically relevant information (e.g. very low or very high glucose values), this information is not directly clinically actionable at the later date.

Participants, especially those participants with diabetes, may be interested in seeing a summary of their glucose patterns. We will return a cover letter and one-page summary if requested by a participant.

Interpretation of results (information for Field Center staff)

The data from the Abbott Libre 3 system is not intended for the diagnosis or screening of diabetes. In persons with a diagnosis of diabetes, the Abbott Libre 3 system is sometimes used to guide and adjust diabetes treatment, typically in persons who are using insulin to manage their diabetes. The data we are collecting in this study are for research purposes only. For participants with a diagnosis of diabetes, the 1-page report provided by JHU may be of particular interest and they may wish to review it with their doctor. It is helpful if the data from the Libre 3 Plus sensor is reviewed and interpreted with the assistance of a medical professional.

We will provide training to Field Center staff on the interpretation of the Abbott Libre 3 system results to ensure that Field Center staff are comfortable answering any questions participants may have about results that are reported to them.

Figure 9. Continuous Glucose Monitoring Report Sample

CGM Summary Report

ARIC ID: F100000

Date Range: March 29, 2023 - April 11, 2023 (13 Days)

Glucose Statistics and Targets

% of Time Sensor Active: 99.5%

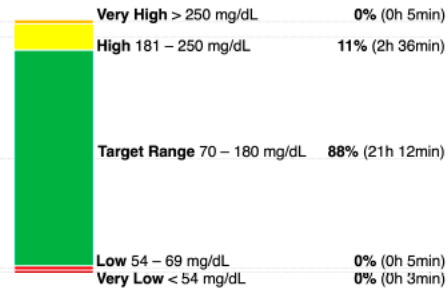
Ranges	Targets
Above 250 mg/dL	Less than 5% (1h 12min)
181 – 250 mg/dL	Less than 20% (4h 48min)
70 – 180 mg/dL	Greater than 70% (16h 48min)
54 – 69 mg/dL	Less than 3% (43min)
Below 54 mg/dL	Less than 1% (14min)

Average Glucose: 140.1 mg/dL

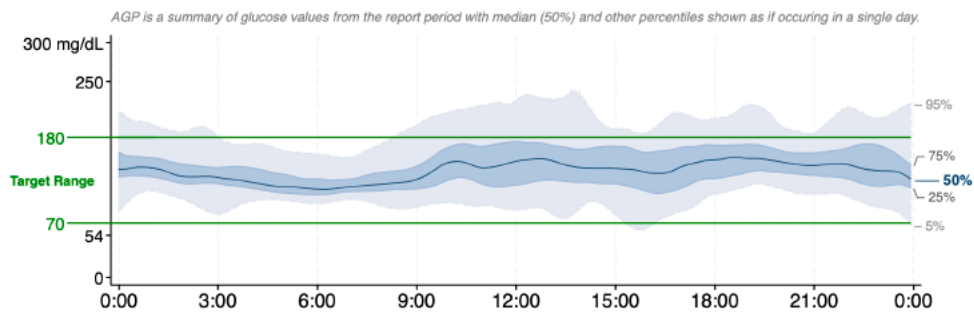
Glucose Variability*: 22.8 %

*Defined as percent coefficient of variation (%CV); target is $\leq 36\%$

Time in Range

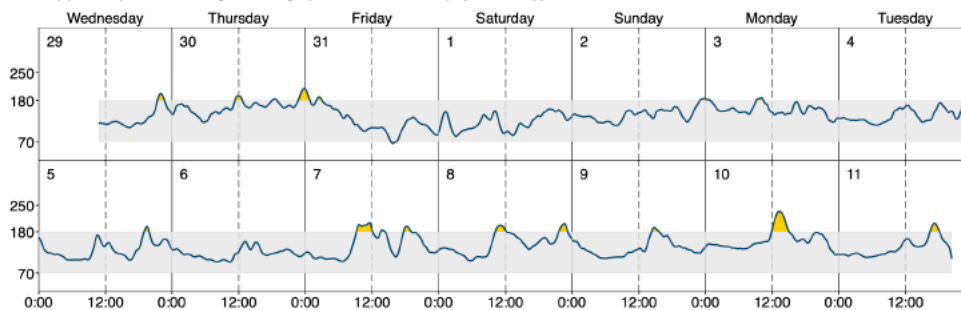


Average Glucose Profile



Daily Glucose Profiles

Each daily profile represents a midnight to midnight period with the date displayed in the upper left corner



Battelino T, Danne T, Bergenstal RM, et al. Clinical targets for continuous glucose monitoring data interpretation: recommendations from the international consensus on time in range. Diabetes Care. 2019;42(8):1593-1603. doi: 10.2337/xc19-0028

4. TRAINING AND CERTIFICATION

All ARIC Field Center Staff involved in the CGM protocol will participate in a central web-based training. This training will cover application and initialization of the CGM device and data entry and processing in CDART. During a portion of the training, a representative from Abbott Diabetes Care, the maker of the CGM sensor, will be available for questions. The complete training will be recorded for future reference in case any questions arise. In addition to this centralized training, ARIC Field Center Staff should review Manual 2 for Field Center Procedures as well as Manual 39 which details the CGM protocol.

4.1 Certification Checklist:

1. Procedure is explained to participant including length of wear, what to do about bathing/showering, who to call with questions, etc.
2. Technician uses proper technique for site preparation including: removal of clothing covering installation site, selecting an area free of blemishes, scars, etc., sensor placement site is prepped using the correct technique using alcohol wipe, Skin Tac liquid adhesive wipe is applied appropriately, technician washes hands prior to installation, and technician wears gloves.
3. Technician uses proper technique for sensor placement: preparing participant with instructions for discomfort, technician applies the sensor placement tool against skin, technician places sensor cover correctly, technician asks participant about any final questions, technician cleans area of debris and disposes of any potentially biohazardous waste appropriately.
4. Technician initializes the sensor, correctly records sensor serial number, sensor application date and time, the time on the reader at sensor application, and reader # used within CDART, and labels biohazard bag with participant ID# and sensor serial number.

Any staff member who successfully completes the CGM training and successfully places 2-3 CGM sensors (observed by a coordinator or senior staff member) is considered certified for the CGM protocol. The placed sensors do not need to be worn, just placed.

5. APPENDIX

5.1 FreeStyle Libre 3 Blinded Reader Instructions

Step-by-step instructions/images for use of the CSDP app are provided below. Be sure to first connect the phone to the local Wi-Fi. The phone passcode is “1111”. Please note that these blinded readers will only be used to initialize the sensors in ARIC participants. ARIC staff will not be using the readers to obtain CGM data.

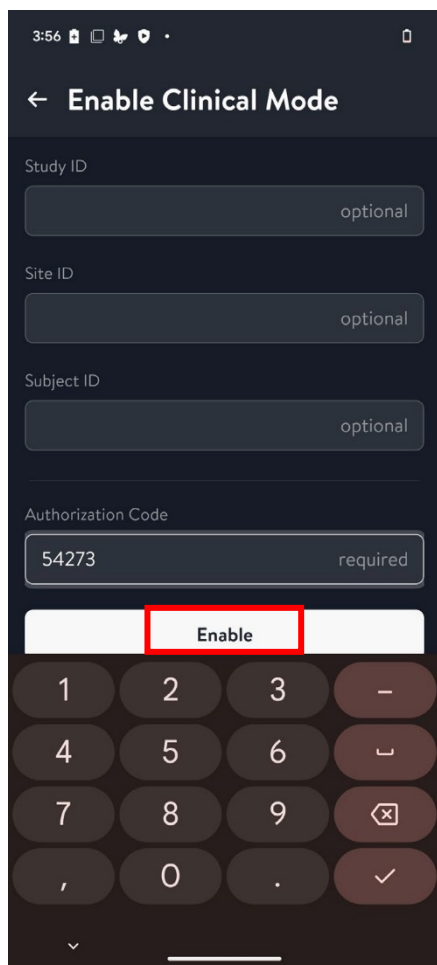
1. Open the app (yellow butterfly icon) after Sensor insertion



2. Click “Enter Clinical Mode”



3. Type “54273” for Authorization Code then click the Enable button



4. Click the “+” icon in top right of the screen



5. Click “Activate”

4:09 [status icons]

← **Activate via NFC**

AUTO

Press the activate button below and place the phone near the sensor to activate.

Condition Code

[optional]

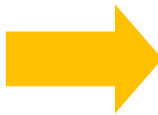
Accepts 3 alphanumeric characters

Activation Passcode

[optional]

Used for MDC, if supported

[button: Activate]



6. Scan the sensor

4:09 [status icons]

← **Activate via NFC**

AUTO

Press the activate button below and place the phone near the sensor to activate.

Condition Code

[optional]

Accepts 3 alphanumeric characters

Activation Passcode

[optional]

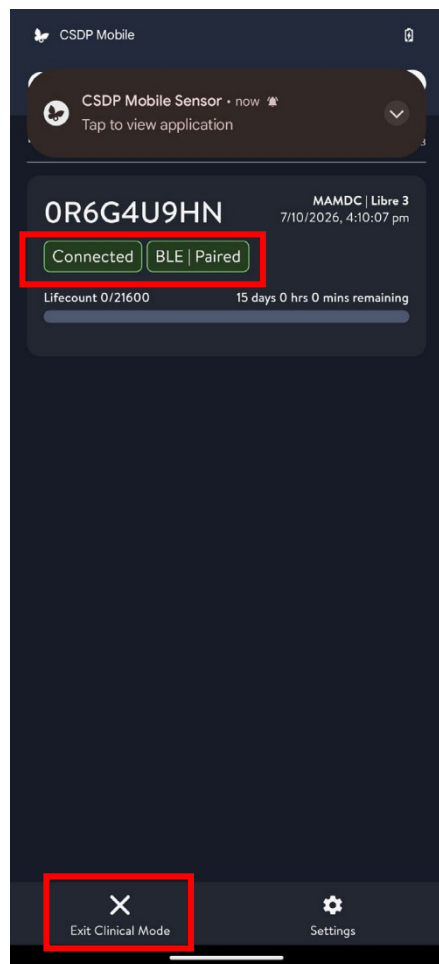
Ready to Scan

[blue dot] [phone icon]

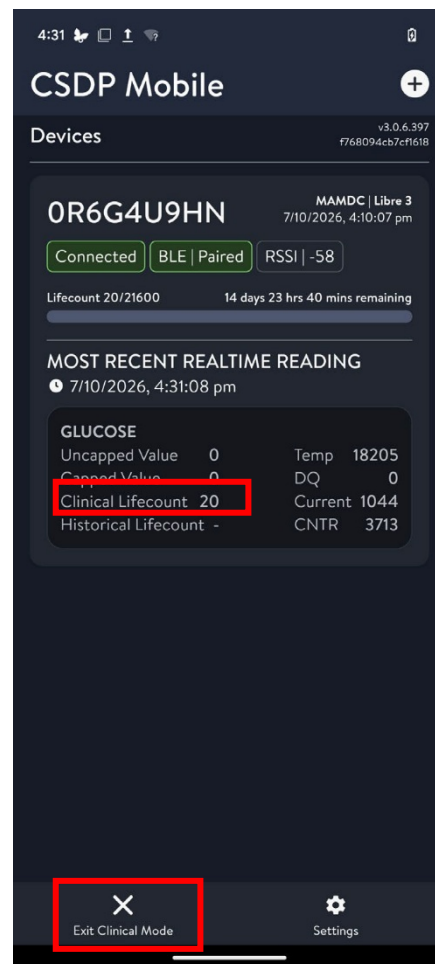
Hold the back of your phone near the sensor.

[button: Cancel]

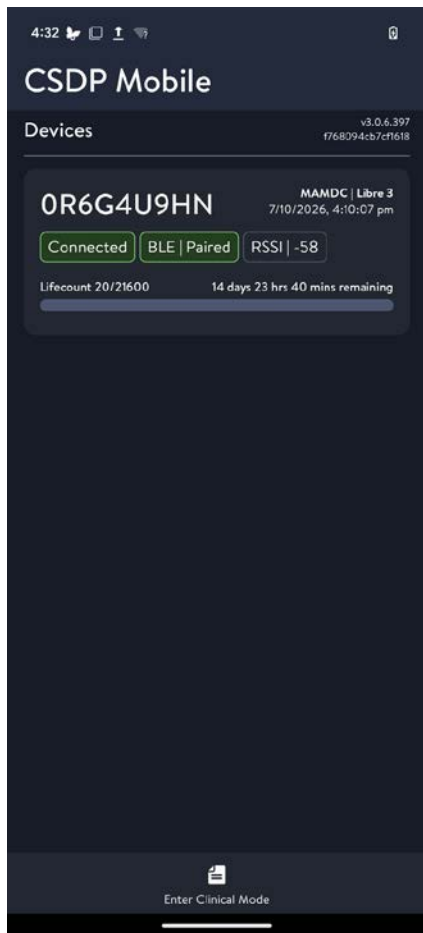
7. Check that both statuses are green then click the “X” button to exit Clinical Mode



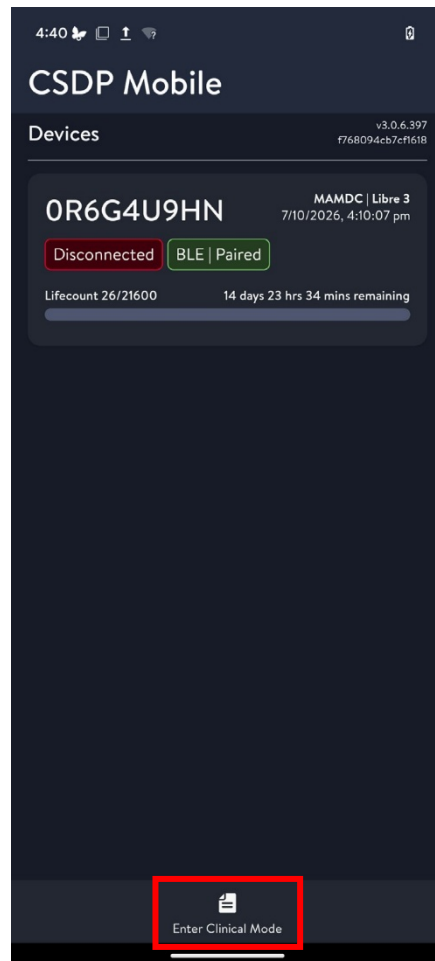
8. Wait for the first Clinical Lifecount to be received, then click the “X” button again (this can take up to 10 minutes in a busy signal environment)



9. When you see the screen below the participant is done and may leave



10. Once they are out of range and you see the screen below click “Enter Clinical Mode”



11. Enter the Authorization Code
“54273” again then click “Enable”

3:56

← Enable Clinical Mode

Study ID optional

Site ID optional

Subject ID optional

Authorization Code required

54273

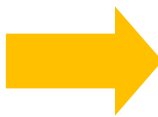
Enable

1 2 3 -

4 5 6 _

7 8 9 ✕

, 0 . ✓



12. Tap the sensor card to display
the sensor details screen

4:33

CSDP Mobile

Devices v3.0.6.397 f768094cb7cf1618

0R6G4U9HN MAMDC | Libre 3 7/10/2026, 4:10:07 pm

Connected BLE | Paired RSSI | -71

Lifecount 22/21600 14 days 23 hrs 38 mins remaining

MOST RECENT REALTIME READING 7/10/2026, 4:33:07 pm

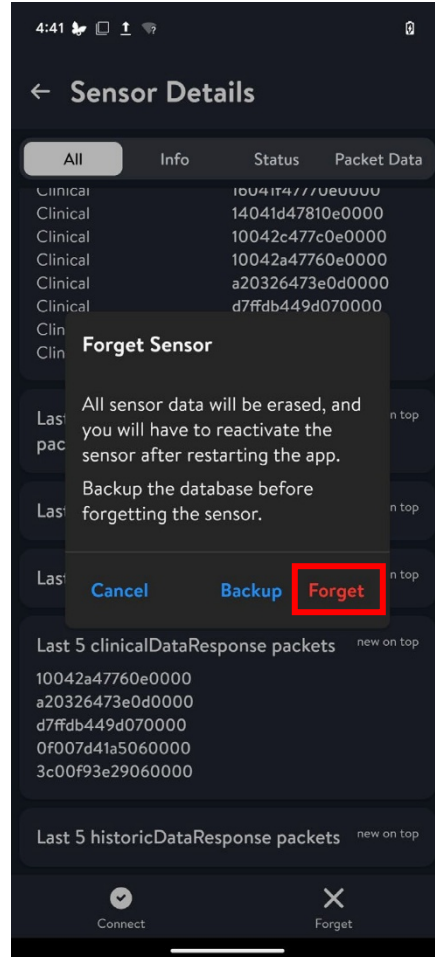
GLUCOSE	
Uncapped Value	0
Capped Value	0
Clinical Lifecount	22
Historical Lifecount	-
Temp	18218
DQ	0
Current	1040
CNTR	3702

✕ Exit Clinical Mode ⚙ Settings

13. Click “Disconnect” at the bottom of the screen



14. Click “Forget” in the pop-up menu



15. You will then see the screen below. You can activate another sensor by clicking “+” or exit by clicking “X”



Note: When activating multiple patches please wait for the first Clinical Lifecount in the app to be received from the scanned patch before scanning the next patch. Do not scan patches rapidly one after the other.

Please sync a maximum of four sensors to the app. If you need to sync additional sensors, first terminate one of the sensors that is already synchronized, and then sync the new sensor.

Make sure to record the time on the clock as well as the time on the reader display in the CGMR form at time of sensor application (Q5a and 5b). It is very important to record times exactly and not round to the nearest 5 minute. Clock times should be recorded using a computer time or a clock that automatically syncs to Coordinated Universal Time (UTC), e.g. cell-phone that is connected to the internet. Also record the # on the reader in CGMR form (Q5c).

Reader QC Procedures

The following Reader QC Procedures will be continually executed for 3 more months starting from the use of the CSDP readers. Once the CGM data processing center at JHU confirmed that there is no time drifting of the CSDP readers, the Reader QC Procedures will be terminated.

This is the Reader QC Procedures: To ensure time consistency for CGM measurements, a QC log will be required starting in Visit 12. The QC log should be used to document a monthly observation (e.g. one Monday each month) comparing CGM reader time with computer clock time. A separate log should be used for each reader maintained at the site. In addition to maintaining a log, take a photograph of **all readers** next to the computer clock at the time of each observation. Please ensure that **reader number label**, and **all clock times on the readers and the computer** are clearly visible in the photograph.

Written logs should be sent to ARIChelp@unc.edu monthly.

5.2 CGM Recruitment and Wear Outcomes and Form Actions

Outcome	Actions
The participant has the CGM sensor successfully placed. The participant wears the sensor for 10 or more days. This is the most common scenario.	1. Answer all prompts in the CGMR form as needed to initialize the sensor. 2. The participant returns the sensor, complete the remaining items in the CGMR form. Mail the sensor to Abbott Diabetes Care. 3. Once notified results are available in the results status report, print and mail the PDF results and cover letter to the participant.
The participant declines participation in the CGM study.	1. Open the CGMR form and answer the prompts in the Administrative Information section of the form indicating the reason why the participant declined participation then save and close the form OR mark the form as "Permanently Missing".
The participant meets the additional exclusion criteria in the CGMR form and does not agree to future participation in the CGM study.	1. Answer all eligibility prompts in the CGMR form then save and close the form. Do not assign a sensor to the participant.
The participant meets the additional exclusion criteria in the CGMR form and agrees to future participation in the CGM study.	1. Answer all eligibility prompts in the CGMR form then save and close the form. Do not assign a sensor to the participant. 2. Wait at least 2 weeks before attempting further recruitment for the CGM study. 3. With each subsequent recruitment attempt, the same CGMR form occurrence should be used and updated to reflect the most recent attempt. 4. Continue recruitment attempts until the participant can have the sensor placed OR the participant does not agree to future participation in the CGM study. If participant does not agree, record this response in the CGMR form.
The participant has the CGM sensor successfully placed. The sensor is removed on or before day 9 of the 15-day wear period. The participant agrees to have the sensor replaced.	1. Initialize the sensor following instructions in the CGMR form. To replace the original sensor, schedule a clinic or home visit as soon as possible to replace the sensor. 2. To initialize the replacement sensor, a second occurrence of the CGMR form is completed in CDART. Answer each prompt in the CGMR form (including the exclusion criteria questions) before assigning the sensor. 3. Send both sensors to Abbott Diabetes Care for processing. When results are returned, send one results pdf to the participant corresponding with the sensor that was worn for the longest amount of time.
The participant has the CGM sensor successfully placed. The sensor is removed on or before day 9 of the 15-day wear period is complete. The participant does not agree to have the sensor replaced	1. Initialize the sensor following instructions in the CGMR form. 2. When the sensor is removed, ask the participant to return the CGM sensor by mail. 3. Once the participant returns the sensor, complete the remaining items in the CGMR form. Mail the sensor to Abbott Diabetes Care. 4. Once notified results are available in the results status report, print and mail the PDF results and cover letter to the participant.

