



/ User Guide





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/ 1 GlucoMen Day Continuous Glucose Monitoring System

1.1 Introduction

Thank you for choosing the GlucoMen Day Continuous Glucose Monitoring (CGM) System. The GlucoMen Day CGM System provides current glucose levels. The system tracks your glucose every minute by measuring the amount of glucose in the interstitial fluid. A sensor, inserted in your skin, sends glucose readings to the GlucoMen Day App. The app then displays your glucose levels and long-term glucose trends. The app also provides alerts if your glucose is in or projected to be in an unsafe zone.

The GlucoMen Day CGM System allows you to:

- Monitor your glucose by providing a new glucose reading every minute.
- See how your glucose changes throughout the day and night.
- Receive alerts when something happens that requires your attention, such as a low glucose reading.

 **IMPORTANT:** • Children using this device should be assisted by an adult. When the GlucoMen Day CGM system is used by a child, a paired smart device with the app must remain with the child.

- For use on children, it is recommended that you choose a sensor insertion site that is least accessible to the child to prevent manipulation by the child.
- When using the GlucoMen Day CGM, always carry a blood glucose meter. There may be situations when you need to perform a blood glucose test before making treatment decisions. See **SECTION 14.1** for details.

CAUTION

Please read all the instructions provided in this user guide before using the system.

 **IMPORTANT:** Illustrations in this guide are for instructional purposes only and are not shown at actual size.

The display of the GlucoMen Day CGM App may appear slightly different depending on the smart device (Android or iOS) on which the app is displayed. Images of the GlucoMen Day CGM App in this guide are for instructional purposes only. When there is a significant difference between the Android and iOS versions of the app, both screens are shown. In all other cases, the Android version is used for reference.

 **IMPORTANT:** The GlucoMen Day CGM App supports both units of measure for glucose: mg/dL and mmol/L. Images in this guide are for instructional purposes only and may not use the same units as your app.

1.2 Indications for use

The GlucoMen Day CGM is:

- Intended for the management of diabetes.
- Intended to replace fingerstick testing for making diabetes treatment decisions. See **CHAPTER 14** for limitations.
- Intended for use in the abdomen and lower sides only.
- Intended only for single patient use.
- Intended as an aid in the detection of episodes of hyperglycaemia and hypoglycaemia, facilitating both acute and long-term therapy adjustments.

Limitations

- Dialysis patients should not calibrate during a dialysis procedure.
- This CGM is intended to augment and not replace glucose monitoring of critically ill patients.
- The GlucoMen Day CGM is not safe for use in magnetic resonance (MR) environments. Remove the GlucoMen Day CGM (sensor and transmitter) before Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or high-frequency electrical heat (diathermy) treatment.
- Placement of the GlucoMen Day sensor is not approved for sites other than the skin of the abdomen and lower sides.
- Do not reuse the sensor or use it beyond 14 days.
- Inspect the sensor assembly sterile pouch prior to use. Do not use the sensor assembly if the sterile pouch is open or damaged.
- Do not wear the sensor in a hot tub.
- Do not swim with the transmitter and sensor in place for longer than 30 minutes and at depths greater than 1 metre (3 feet).
- The GlucoMen Day CGM is not intended for use outside of the transmitter operating temperature range of 5°C to 45°C (41°F to 113°F).
- The GlucoMen Day CGM System contains small parts that may be a choking hazard.

⚠ CAUTION

The GlucoMen Day CGM System requires the use of a blood glucose meter for calibration. Check your meter's owner's guide for additional restrictions.

Important user information

The GlucoMen Day CGM sends a glucose reading once per mi-

nute and provides a trend arrow that shows the direction and rate of change of your glucose. It's important to understand where your glucose is and how it's changing (trending) rather than focusing only on individual CGM readings. As you use your CGM, remember two important things about trends:

- Trends highlight the direction in which your CGM glucose levels are heading and the rate at which they are changing. Trends can tell you if your glucose has been rising, falling, or stable over several minutes or hours up to the previous 24 hours.
- Understanding and adjusting your insulin levels based on trends is more useful than a single CGM glucose reading. The CGM displays glucose levels from the interstitial fluid that surrounds the sensor, which is similar but may vary from your actual glucose level.

⚠ CAUTION

Avoid exposing your GlucoMen Day CGM to insect repellent and sunscreen. Contact with these skin care products may cause damage to your CGM.

1.3 Getting started

The GlucoMen Day CGM is designed to replace fingerstick testing for making diabetes treatment decisions. Before using the GlucoMen Day CGM to make treatment decisions, it is important to understand how you can use the information from your CGM. Your current glucose level, current glucose trend, and your past readings can all be used to make informed decisions.

It is also important to know when you should not use your CGM for treatment decisions and should instead use your blood glucose meter.

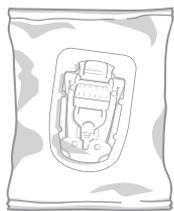
You should work with your healthcare professional to de-

termine how to use the GlucoMen Day CGM to manage your diabetes.

/ 2 Parts of the system

2.1 System overview

The GlucoMen Day CGM uses a single-use, disposable sensor inserted into the interstitial fluid that converts glucose levels into the electrical signal. The sensor is located within the sensor assembly, which includes the sensor, sensor adhesive patch, and sensor guide. A rechargeable transmitter attaches to the sensor assembly, which is secured to the skin with the adhesive patch. The transmitter sends the glucose readings to the GlucoMen Day App using *Bluetooth*[®] low energy technology.



Sensor Assembly



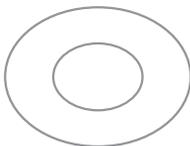
Transmitter



Sensor Insertion Tool



Transmitter
Charger



Overpatch



App

⚠ CAUTION

- Check the expiration date on the pouch before using.
- Do not modify any part of the GlucoMen Day CGM or use components other than those specified in this guide.
- The GlucoMen Day CGM System contains small parts that may be a choking hazard.

/ 2.2 Sensor Assembly

⚠ CAUTION

- Do not use the sensor assembly if the sterile pouch is open or damaged. Do not handle the sensor assembly until you are ready to insert the sensor because the sensor can become contaminated.
- Do not wear the sensor in a hot tub.

⚠ IMPORTANT: The transmitter and sensor adhesive patch can be worn while bathing and showering. You can also swim with the transmitter and sensor in place up to a depth of 1 metre (3 feet) for up to 30 minutes. If you do not have an overpatch, you can use medical tape around the edges of the adhesive patch.

⚠ CAUTION

Do not throw away the transmitter, the sensor insertion tool, or the transmitter charger when you dispose of the sensor. The transmitter is intended to be recharged and used again.

⚠ IMPORTANT: If you do not have an overpatch, you can use medical tape around the edges of the adhesive patch.

/ 3 Setting up the system

3.1 Download the app

The GlucoMen Day App serves as the display for the GlucoMen Day CGM and supports Android and iOS devices (smart devices). The app is available on Google Play (Android) and the App Store (iOS). To see a list of compatible smart devices, visit www.menarinidiagnostics.com.

IMPORTANT: • The app stores sensitive health-related information on your smart device. It is recommended to keep your smart device up-to-date with the latest security software. For details on updating your smart device and keeping your information safe, contact the manufacturer of your smart device.

• Review the GlucoMen Day CGM App's operating system compatibility before updating the operating system on a smart device that has the app installed.

Only install operating system updates when a session is not active. If you are in the middle of a session, wait until it has ended to install an operating system update.

CAUTION
Do not install the app on a smart device that has been jailbroken or rooted. Doing so may compromise the security and functionality of the app.
.....



3.2 Create an account

Before using the GlucoMen Day CGM App, you need to answer a few simple questions and create an account.

Your account will be used to store all of your CGM data. You can always update your information under **PROFILE (CHAPTER 11)**.

IMPORTANT: The country you select determines the glucose units used in the app (mg/dL or mmol/L).

NOTE: If your app only supports one country, you will not see the **COUNTRY** screen.

1.

Tap the GlucoMen Day CGM App icon to open the app.



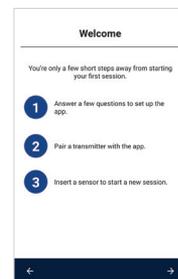
2.

Tap **SIGN UP**.



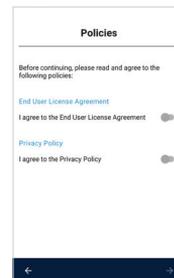
3.

On the **WELCOME** screen, tap the (→) icon.



4.

Read and agree to the **END USER LICENSE AGREEMENT** and the **PRIVACY POLICY**.



5. Read and agree to the **CUSTOMER SERVICE** disclaimer and tap **I UNDERSTAND**.



7. Select your **Country** and tap the (→) icon.

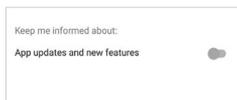
Enter your **First Name** and **Last Name** and tap the (→) icon.

Select your **Birth year** and tap the (→) icon.

Select your **Gender** and tap the (→) icon.

Select **Type of diabetes** and tap the (→) icon.

9. Choose your email communication settings.



6. Read the **DISCLAIMER** and tap **I UNDERSTAND**.

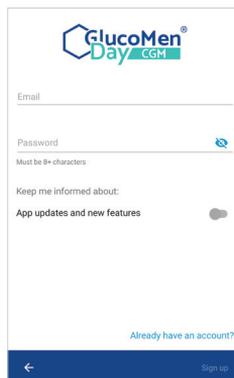


8. Read the explanation of why notifications are important and tap the (→) icon. Enter your email and create a password.



On iOS: If you see a message asking for permission to send notifications or critical alerts, tap **ALLOW** so you don't miss any alerts. Passwords must be at least 8 characters. NOTE: Tap the (👁) icon to show or hide your password.

10. Tap **SIGN UP**.



11. Review the **CONSENT TO DATA PROCESSING BY AGAMATRIX** to decide if you want to consent to sharing data. At the bottom of the agreement, choose a sharing option and tap **CONFIRM**.

Agamatrix would like your consent to process the personal data that you send to Agamatrix when you use the GlucoMen Day CGM App. "Personal data" is defined as information that can be used to identify a person. Your data will be stored in the European Union on servers controlled by Agamatrix, which process your data in a manner consistent with EU law and the GlucoMen Day CGM App Privacy Policy.

Why allow us to process your data?

- Your data will be backed up and can be accessed upon request.
- We can provide better Customer Support if you request such support.
- You have access to features that allow you to easily share data with third parties that you choose.

If you do not consent, you will still be able to use our GlucoMen Day CGM App on your smart device, but you will not be able to obtain any services that require your data to be available from Agamatrix servers.

You may change your consent settings under Profile.

- Share data with Agamatrix
- Do not share data with Agamatrix

CONFIRM

On Android: if you see a message asking for **DO NOT DISTURB** access, tap **GO TO SETTINGS** and follow the prompts to enable permissions so that you don't miss any alerts.

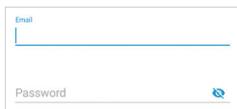
/ 3.3 Log into an existing account

If you already have an account for the GlucoMen Day CGM App, you can log in to your existing account.

1. Tap the GlucoMen Day CGM App icon to open the app.



3. Enter your email and password.



If you forgot your password, see **SECTION 11.6** for steps to reset your password.

NOTE: Tap the (👁️) icon to show or hide your password.

3.4 Connect a transmitter

The GlucoMen Day CGM Devices kit includes two transmitters so that you can use one while charging the other. The transmitters communicate with the GlucoMen Day App using Bluetooth and must be connected to the app before they can be used. This process is also called *pairing*.

- **IMPORTANT:** Your transmitter communicates with the app using Bluetooth wireless technology. Your smart device must have Bluetooth turned on to continue.
- Read all pairing instructions before attempting to pair

2. Tap **LOG IN**.



4. Tap **LOG IN**.



your transmitter. Once you press the button on the charger, the transmitter will be in pairing mode for 60 seconds. If you are unable to successfully pair the transmitter during this time, you will need to restart the pairing process.

⚠️ CAUTION You can only connect a transmitter to one smart device at a time. If you connect the transmitter to a second smart device, it will no longer be connected to the first smart device.

📢 IMPORTANT: If this is the first time you have connected a transmitter, the app will display hints to point out the next step and highlight important features. When you are done reading the hints, tap **OK**.



1. Locate the 6-digit numeric PIN (A) on the bottom of the transmitter. Record the 6-digit numeric PIN, which you will need in step 7.



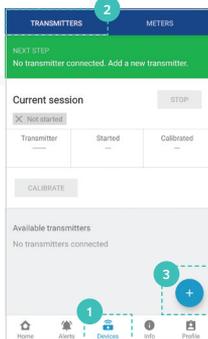
2. Place the transmitter in the charger and connect to a power source. Keep the transmitter in the charger until pairing is complete. The light on the charger may flash red for up to 5 seconds. Make sure the light has turned green (flashing if not fully charged or solid if fully charged) before starting step 3. See **SECTION 8.4** for details about charging the transmitter.



3.

Open the app:

1. Tap the **DEVICES** button. On Android devices you may need to tap the **BACK ARROW** until you see the bottom buttons.
2. Tap **TRANSMITTERS**.
3. On Android: Tap the (+) button.
On iOS: Tap **ADD A NEW TRANSMITTER**.

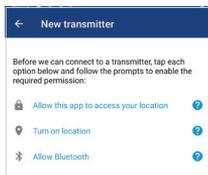


4.

On Android devices only:

Depending on your device's permission settings, you may see any or all of these messages on the **NEW TRANSMITTER** screen:

- Allow this app to access your location.
- Turn on location.
- Allow Bluetooth.



If any of these messages appear, tap the message and follow the prompts to enable permissions.

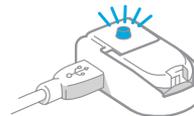
⚠ CAUTION

All of these permissions must be enabled to connect to a transmitter.

5.

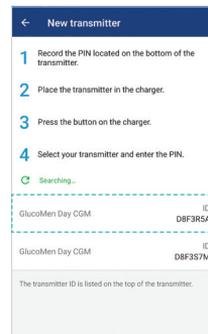
Press the button on the charger. A flashing blue light indicates the transmitter is ready to pair.

NOTE: Once you press the button on the charger, the transmitter will be in pairing mode for 60 seconds.



6.

On the **NEW TRANSMITTER** screen, select your transmitter when it appears in the list. If multiple transmitters are listed, check the 7-digit alphanumeric ID (A) on the top of your transmitter to make sure you select the correct transmitter.



7.

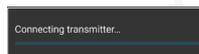
When the *Bluetooth Pairing Request* appears, enter the 6-digit numeric PIN that you recorded in step 1.

Tap **PAIR**.

8.

The app indicates that the transmitter is connecting. Once pairing is complete, your paired transmitter will be listed under **AVAILABLE TRANSMITTERS** on the **TRANSMITTERS** screen. You can now use this transmitter to start a CGM session.

Home screen:



Transmitters screen:



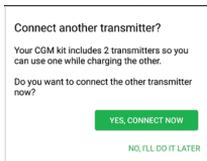
9.

If this is the first transmitter you have connected, you will see a message asking if you want to connect your second transmitter.

- If you tap **YES**, repeat steps 1-7 with the second transmitter.
- If you tap **NO**, follow steps 1-7 when you are ready to pair.

 **IMPORTANT:** If more than one transmitter is connected, a message will appear indicating that another transmitter is already active. Only the active transmitter can be used for a session.

See **SECTION 8.6** for details about activating a transmitter.



- Overpatch (optional)
- GlucoMen Day app (see **SECTION 3.1** for instructions to download the app)

CAUTION

- Check the expiration date on the sensor assembly pouch. If the sensor has expired, do not use it. Using an expired sensor may result in inaccurate glucose readings.
- Follow the sensor insertion instructions carefully. Failure to do so may result in accidental deployment of the sensor.
- There are several moving parts on the bottom of the sensor insertion tool. These may pinch your fingers if you do not follow the instruction for preparing and using the sensor insertion tool.

/ 4 Inserting a sensor and starting a session

4.1 Prepare for sensor insertion

To start a CGM session, you must insert a sensor. The insertion process should be done in a clean, dry place. Wash and dry your hands before beginning.

To prepare for sensor insertion, gather the following parts:

- Sensor insertion tool
- Sealed sensor assembly pouch
- Fully charged and paired transmitter (see **SECTION 8.4** for details about charging the transmitter and **SECTION 3.3** for details about pairing the transmitter)
- SKIN-PREP™ wipes (or equivalent product)

4.2 Choose a sensor insertion site

Before you insert the sensor, take a moment to consider where the best insertion site may be.

Choose a sensor insertion site on your abdomen or lower side that:

- Is easy to reach also out of the way of tight clothing and belts.
- Is at least 4 cm (1.5 inches) from an insulin injection site or insulin pump, measured from the edge of the adhesive patch.
- Is smooth. If needed, shave the area to allow the adhesive patch to stick to the skin.



Right side



Front



Left side

✗ It is best to avoid choosing a site in the following areas:

- On your midline (the vertical line through your navel).
- In areas that become creased or folded when you move (such as along the waistline).
- In areas that are heavily scarred.
- In areas that have a rash or other skin irritation.
- In areas where clothing, belts, or seat belts may rub and irritate.
- In areas on which you frequently sleep.

⚠ CAUTION

- You should only insert the sensor on your abdomen or lower side, roughly between your ribs and beltline. Ask your healthcare professional about the best sensor insertion site for you. Bleeding, swelling, bruising, or infection at the sensor insertion site are possible risks of sensor use. If any of these conditions occur, get treatment advice from your healthcare professional.
- You should choose a new insertion site every time you insert a new sensor. Using the same site may cause irritation at the insertion site.

4.3 Clean the sensor insertion site

Clean the chosen insertion site before inserting the sensor. Careful cleaning of the insertion site disinfects the skin and helps the sensor adhesive patch to stick tightly to your skin.

⚠ CAUTION

- Do not allow anything to touch the insertion site after cleaning and before you insert the sensor.
- The insertion site must be dry before applying a SKIN-PREP™ wipe (or equivalent product) and MUST be completely dry before inserting the sensor.
- Failure to clean the insertion site, or improper cleaning technique may result in an infection.

1.

Remove the SKIN-PREP™ wipe (or equivalent product) from its sealed package.

2.

Place the wipe on the insertion site and wipe in a circular pattern outward, away from that spot. Continue cleaning until you have cleaned the area about 15-20 cm (6-8 inches) across without returning to any areas you already cleaned.



3.

Allow the cleaned area to dry completely, for two minutes.

⚠ CAUTION

Keep clothing from touching the cleaned area.

4.4 Select a transmitter

Identify the transmitter you want to use. Make sure the transmitter is fully charged by placing it in the charger and checking that the light on the charger is solid green. See **SECTION 8.4** for details about charging the transmitter.

⚠ CAUTION

- If the transmitter is not fully charged, the app will display a message at the start of the session, that lets you know the transmitter might not last for the full 14-day session. You cannot switch transmitters in the middle of a session. If the transmitter battery dies, you will need to insert a new sensor to start a new session.
- Check the transmitter for any visible defects, such as cracks. Do not use the transmitter if you see any defects.

4.5 Activate the transmitter

Although you can connect multiple transmitters to the app, only one transmitter can send CGM readings to the app at a time. That transmitter is referred to as the active transmitter.

See **SECTION 8.6** how to activate a transmitter.

4.6 Place the transmitter into the sensor assembly

To complete these steps, you will need the active transmitter and the sensor assembly.

1. Remove the sensor assembly from the sterile pouch.

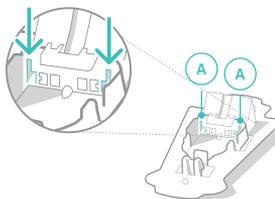


2. Remove the sensor assembly from the inner tray.



- ⚠ CAUTION Do not peel off the protective paper on the sensor assembly until immediately before insertion.

3. Set the sensor assembly on a hard, clean surface (such as the inside of the sterile pouch) with the sensor adhesive patch facing down.



4. Locate the transmitter arms (B).



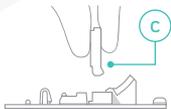
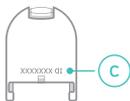
⚠ CAUTION

Avoid touching the transmitter contacts, located between the transmitter arms.

5.

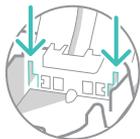
Hold the transmitter, with the arms pointing down, perpendicular to the sensor assembly.

The side of the transmitter with the ID (C) should face the wide end of the sensor assembly.

**6.**

Lower the transmitter and steer the arms into the guide slots of the sensor assembly.

Guide slots:

**7.**

Tilt the curved end of the transmitter downward to meet the sensor assembly.

**8.**

Press the transmitter down firmly until it snaps into place and you hear a click.

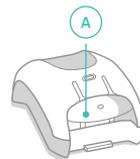
**4.7 Prepare the sensor insertion tool**

Now that you have inserted the transmitter into the sensor assembly, you can prepare the sensor insertion tool. To complete these steps, you will need the sensor insertion tool.

1.

Place the sensor insertion tool on a hard, clean surface.

Locate the plastic lever (with 1 bump) (A) on the sensor insertion tool.

**2.**

Lift this lever up until you hear a click, then lower to its starting position. An orange tab indicates that the sensor insertion tool is ready to use.

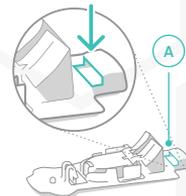
**4.8 Attach the sensor insertion tool to the sensor assembly**

Next, attach the sensor insertion tool to the sensor assembly.

1.

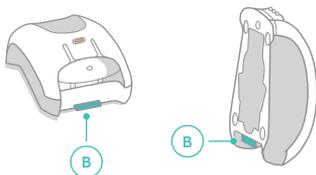
Set the sensor assembly on a hard, clean surface (such as the inside of the sterile pouch) with the sensor adhesive patch facing down.

Locate the opening (A) at the wide end of the sensor assembly.



2.

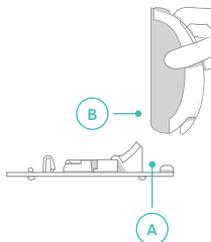
Locate the tab (B) on the sensor insertion tool at the end with the lever (1 bump).



3.

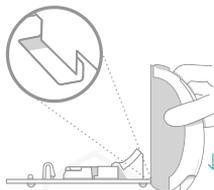
Hold the sensor insertion tool, with the tab (B) pointing down, perpendicular to the sensor assembly. Align the tab directly above the opening (A) on the sensor assembly.

NOTE: The sensor assembly opening (A) is for alignment and positioning of sensor insertion tool tab (B).



4.

Lower the sensor insertion tool, steering the tab into the opening on the sensor assembly.



5.

Tilt the raised end of the sensor insertion tool downward to meet the sensor assembly, until you hear a click.



6.

The sensor insertion tool and sensor guide should snap together without a gap.

Check for a gap between the sensor insertion tool and sensor guide. If there is a gap, see **SECTION 15.7**.



CLICK



4.9 Remove the sensor adhesive liner

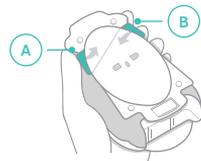
Once you have cleaned the insertion site, you are ready to remove the liner on the sensor adhesive patch. To complete this step, you need the sensor insertion tool with the sensor assembly attached.

⚠ CAUTION

The adhesive is sterile; do not touch the centre of the adhesive material. Only touch the perimeter of the adhesive when removing the liner.

1.

Hold the sensor insertion tool with the sensor adhesive liner facing up. Locate the tabs (A and B) on each side of the liner.



2.

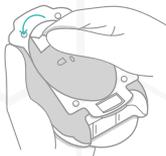
Grip the right tab and peel it back to remove the first section of the liner.



3.

Grip the left tab and peel it back to remove the second section of the liner.

Make sure the adhesive does not fold onto itself before or during application.



4.10 Apply the sensor assembly to the insertion site

Now that you have removed the liner on the sensor adhesive patch, you are ready to apply the patch to your skin.

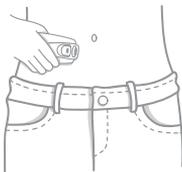
⚠ CAUTION

Failure to follow insertion instructions carefully may cause the sensor to slide along the skin instead of inserting into the skin. If this occurs, the session may not start or the sensor will provide low-quality data, which will not be displayed in the app. Follow the instructions carefully to ensure proper sensor insertion.

1.

Holding the sensor insertion tool, place the adhesive patch firmly on the insertion site, parallel to your beltline.

Point the release button (3 bumps) on the sensor insertion tool toward your navel.



2.

Press down firmly to ensure the adhesive patch is secured to your skin. Then apply normal pressure to your skin during insertion.

3.

Press the insertion button (2 bumps) until you hear a click. Continue holding the sensor insertion tool in place.

Do not try to adjust the placement of the adhesive patch after application.



4.

While holding the sensor insertion tool in place, press the release button (3 bumps) until you hear a click.



5.

Carefully lift the sensor insertion tool away from your body, in a straight outward motion.

If you feel resistance, repeat steps 4-5.

IMPORTANT: The sensor guide remains connected to the sensor insertion tool, leaving only the transmitter, sensor, and adhesive patch on your body.

6.

Smooth the sensor adhesive patch to make sure it is fully adhered to your skin. Gently smooth out any wrinkles around the edges to make sure there are no gaps.

IMPORTANT: The CGM session starts automatically when the sensor is inserted.

⚠ CAUTION

- If the transmitter was not fully charged, a message lets you know that the transmitter might not last for the full 14-day session. You cannot switch transmitters in the middle of a session. If the transmitter battery dies, you will need to remove the sensor and insert a new sensor to start a

new session.

- Do not remove the transmitter while the sensor assembly is attached to you.
- If you feel resistance when removing the sensor insertion tool with two separate sensor assemblies, call Customer Service.

Once you have inserted a new sensor, it may take 1-3 minutes for the app to detect the sensor.

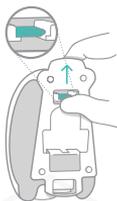
NOTE: If the edges of the adhesive patch begin to peel up at any time during your session, you may apply the overpatch. See **SECTION 15.7** for instructions on how to apply the overpatch.

4.11 Remove the sensor guide from the sensor insertion tool

After you insert the sensor, you need to remove the sensor guide from the sensor insertion tool, so you can use the sensor insertion tool the next time you insert a sensor.

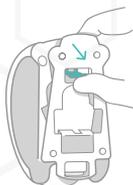
1.

Locate the release tab on the bottom of the sensor insertion tool. Press and hold the release tab.



2.

While pressing up on the release tab, pull back on the sensor guide.



3.

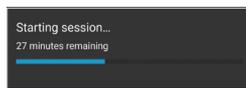
Discard the used plastic sensor guide. Store the reusable sensor insertion tool with the other supplies for your GlucoMen Day CGM.



4.12 Wait for the sensor to stabilise

Once you have inserted a new sensor, you must wait approximately 45 minutes for the sensor to stabilise before you can calibrate the system. While the sensor is stabilising, the app will display a progress bar and number of minutes until calibration within the **HOME** screen and **TRANSMITTERS** screen.

Home screen:



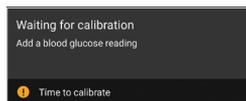
Transmitters screen:



Once the sensor has stabilised, it is time to calibrate. If you have allowed the app to send notifications and have turned on the calibration alert, you will receive a notification that it is time to calibrate. See **CHAPTER 7** for details about alerts.

The **HOME** screen and **TRANSMITTERS** screen will indicate that it is time to calibrate. See **CHAPTER 5** for details about calibration.

Home screen:



Transmitters screen:



4.13 How will I know when to replace my sensor?

The sensor is designed to work for 14 days. After 14 days, the app will let you know that the session has ended, and the sensor needs to be replaced.

Approximately 24 hours before the session is scheduled to end, the app provides the following indications:

- If you have allowed the app to send notifications, you will receive a notification that the session will end soon.
- The app displays a message that the session will end soon.

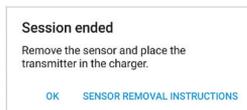
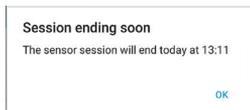
When it is time to replace your sensor, the app provides the following indications:

- If you have allowed the app to send notifications, you will receive a notification that the session has ended.
- The app displays a message that the session has ended.
- The **HOME** screen and **TRANSMITTERS** screen show instructions indicating that a session is not in progress.

You can also replace the sensor sooner if:

- You have pain, tenderness, or swelling at the sensor insertion site.
- You are undergoing a medical procedure, such as an MRI, that requires you to remove the sensor.
- The app instructs you to remove the sensor.

Session ending soon message: Session ended message:



Home screen:



Transmitters screen:



/ 5 Calibrating the system

5.1 When to calibrate

Calibration is an important part of using the GlucoMen Day CGM system to obtain the highest accuracy possible for your CGM.

NOTE: No extra calibrations are allowed in the first six hours.

 **IMPORTANT:** When using the GlucoMen Day CGM, always carry a blood glucose meter for calibrating the system.

DAY 1	DAY 2	DAY 3-14
<p>First calibration: Enter your first calibration reading once the sensor stabilisation period ends, approximately 45 minutes after inserting the sensor.</p> <p>Second calibration: Enter your second calibration reading 6 hours after inserting the sensor.</p>	<p>Third calibration: Enter your third calibration reading 24 hours after inserting the sensor.</p>	<p>Subsequent calibrations: Enter your calibration reading 24 hours after the previous calibration.</p>

IMPORTANT: After the second calibration, you can always calibrate early in order to shift your calibration schedule to a more convenient time. For example, if the next calibration is due at 23:00, you may choose to calibrate at 19:00 instead if that is a more convenient time. In that case, your next scheduled calibration would be at 19:00 (24 hours later).

In the app, there are a few ways to tell when it is time to calibrate:

- On the **HOME** screen, the **TIME TO CALIBRATE** banner appears. Tap the banner to calibrate.
 - On the **TRANSMITTERS** screen, the message area indicates that it is time to calibrate. Tap **CALIBRATE** to calibrate.
- If you have allowed the app to send notifications and have turned on the calibration alert, you will receive a notification when it is time to calibrate.

5.1.1 What happens without calibration

If you do not enter a calibration reading, the CGM will continue to display glucose levels for a period of time, but they will appear with an **ESTIMATED GLUCOSE** banner to indicate that the data quality may be lower than usual. Estimated glucose levels appear as light grey points on the trend chart. See **SECTION 6.5** for details about estimated glucose.

Estimated glucose

NOTE: The **ESTIMATED GLUCOSE** banner does not always mean you need to calibrate. Tap the banner for information about why glucose levels are estimated. See **SECTION 6.5** for details about estimated glucose.

5.2 Entering a calibration reading

In order to calibrate, all of the following must be true:

- Your glucose, according to the BGM, is between 3.9-13.9 mmol/L.
- Your glucose is changing less than 0.11 mmol/L per minute.
- A session is in progress.
- The **CALIBRATE** button is enabled.

If any of the above are not true, you will not be able to **CALIBRATE**.

1.

Perform a blood glucose test. Follow the instructions for your blood glucose meter to perform a blood glucose test.

⚠ CAUTION

Only use a blood glucose meter reading from your fingertip to calibrate your CGM. Do not use a reading from an alternate site.

2.

In the app:

1. Tap the **HOME** button. On Android devices, you may need to tap the **BACK ARROW** until you see the bottom buttons.
2. Tap **CALIBRATE**.

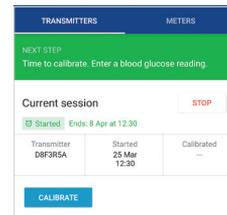
OR

1. Tap the **DEVICES** button. On Android devices, you may need to tap the **BACK ARROW** until you see the bottom buttons.
2. Tap **TRANSMITTERS**.
3. Tap **CALIBRATE**.

Home screen:



Transmitters screen:



3. On the **NEW CALIBRATION** screen, tap the **NEW READING** field and enter your blood glucose reading.

New calibration SAVE

Choose a calibration reading

Must be 3.9-13.9 mmol/L, and within the last 5 minutes.

3

New reading

3.9-13.9 mmol/L

Recent meter readings

No recent meter readings. If you just performed a blood glucose test, eject the test strip to see your reading.

4. Tap **SAVE**.

New calibration SAVE

Choose a calibration reading

Must be 3.9-13.9 mmol/L, and within the last 5 minutes.

New reading

3.9-13.9 mmol/L

Recent meter readings

No recent meter readings. If you just performed a blood glucose test, eject the test strip to see your reading.

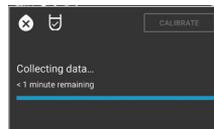
5. When asked to confirm the reading, make sure the reading is correct, and tap **CONFIRM**.

Confirm value

Your calibration reading is 12.0 mmol/L.

CANCEL CONFIRM

6. If this is the first calibration for the session, there is a 10-minute data collection period during which the system will not display glucose levels. At the end of the data collection period, the app will begin displaying glucose levels.



/ 6 Viewing continuous glucose readings

6.1 Navigating to the Home screen

You can view your continuous glucose readings using the GlucoMen Day App. The **HOME** screen is the main screen for monitoring your CGM readings.

In the app, tap the **HOME** button.

On Android devices, you may need to tap the **BACK ARROW** until you see the bottom buttons.



6.2 Home screen overview

The Home screen is divided into two sections: the current status (top) and the trend chart (bottom).

Current status (top)

The current status section displays the most recent glucose level and glucose trend.

See **SECTION 6.3** for details.

A. Current CGM glucose reading

B. Trend arrow

C. Status icons

D. Calibrate button

E. Information banner

NOTE: The banner is not always visible. It only appears when there is information to display.



Trend chart (bottom)

The trend chart displays recent glucose readings.

See **SECTION 6.4** for details.

A. Chart area

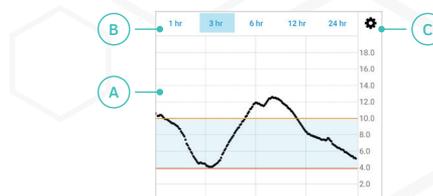
B. Chart display options

Tap to choose the amount of data to show on the trend chart.

C. Chart settings

Tap to adjust the high and low glucose lines and the target range.

NOTE: You can rotate the Home screen to landscape orientation to view a larger trend chart.



6.3 Current status

6.3.1 Current glucose

The current glucose reading is the most recent reading from the CGM sensor. The time label indicates when the reading occurred. The background colour is based on the current glucose level.

Home screen background colours

A. High (yellow)

The current glucose level is above the high glucose line set in **CHART SETTINGS**. See **SECTION 6.4.3** for details.



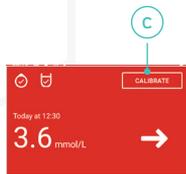
B. Between high and low (blue)

The current glucose level is between the high and low glucose lines set in **CHART SETTINGS**. See **SECTION 6.4.3** for details.



C. Low (red)

The current glucose level is below the low glucose line set in **CHART SETTINGS**. See **SECTION 6.4.3** for details



D. No glucose (grey)

A grey background appears if the app is not receiving glucose readings from the transmitter or if there is a temporary sensor issue preventing glucose from being displayed.



The screen will either show:

- - - - instead of a glucose level
- OR a message explaining what is happening.

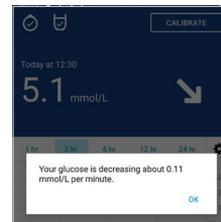
⚠ CAUTION

If the app is not displaying a current glucose reading, do not use your GlucoMen Day CGM to make treatment decisions. Perform a blood glucose test before making treatment decisions.

🔔 IMPORTANT: Glucose levels below 2.2 mmol/L are displayed as **< 2.2 mmol/L**. Glucose levels above 22.2 mmol/L are displayed as **> 22.2 mmol/L**.

6.3.2 Trend arrow

The trend arrow indicates how much your glucose is changing. There are 7 trend arrows, each indicating a different rate of change. The app only displays the arrow if there are enough readings to determine the trend. Whenever a trend arrow is visible, you may tap the trend arrow for a description of what it means.



Trend arrow	What it means
	Your glucose level is rising at a rate of 0.19 mmol/L per minute or greater. You cannot calibrate if this arrow is visible.
	Your glucose level is rising at 0.14-0.19 mmol/L per minute. You cannot calibrate if this arrow is visible.
	Your glucose level is rising at 0.08-0.14 mmol/L per minute.
	Your glucose level is changing less than 0.08 mmol/L per minute.
	Your glucose level is falling at 0.08-0.14 mmol/L per minute.
	Your glucose level is falling at 0.14-0.19 mmol/L per minute. You cannot calibrate if this arrow is visible.
	Your glucose level is falling at a rate of 0.19 mmol/L per minute or greater. You cannot calibrate if this arrow is visible.

⚠ CAUTION

If the app is not displaying a trend arrow, do not use your GlucoMen Day CGM to make treatment decisions. Perform a blood glucose test before making any treatment decisions.

IMPORTANT: When using the GlucoMen Day CGM, always carry a blood glucose meter.

6.3.3 Status icons

The status icons indicate the current status for calibration and transmitter signal.

Calibration icons		
The calibration icons indicate if it's time to calibrate or if the system cannot be calibrated right now.		Cannot calibrate right now.
		Time to calibrate. Add a blood glucose reading.
		System is calibrated.

Transmitter signal icons		
The transmitter signal icons indicate the connection status of the active transmitter.		The active transmitter signal is not detected.
		The active transmitter signal is detected.

6.3.4 Calibrate button

Tap the **CALIBRATE** button when you want to enter a blood glucose reading from a meter. This button is disabled if you cannot calibrate right now.



See **CHAPTER 5** for details about calibration.

6.3.5 Information banner

The information banner appears when there is information to display. In some cases, you can tap the banner for details.

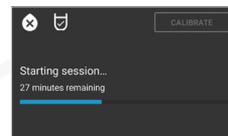


What the banner says	What it means
Sensor insertion instructions	A session is not currently in progress. Tap to view instructions for inserting a sensor and starting a new session.
Time to calibrate	It is time to calibrate. Tap the banner or the CALIBRATE button to enter a blood glucose reading from a meter.

What the banner says	What it means
Cannot calibrate right now	You cannot calibrate the system right now. Tap the banner for details about why you cannot calibrate. See SECTION 15.3 for details about why calibration may not be possible.
Saving calibration	The system is saving the calibration reading.
Estimated glucose	Glucose levels are currently estimated. Tap the banner for details about why glucose levels are estimated. See SECTION 6.5 for details about estimated glucose.
Temporary issue	Something has gone wrong and the app cannot display glucose readings. This is a system-level issue that should resolve itself. Contact Customer Service if the issue is not resolved after 1 hour.

6.3.6 Home screen messages

If the GlucoMen Day App cannot display a current glucose level, it may display a message indicating what is happening. The message either indicates an ongoing process or provides instructions for the next step.



Home screen message	What it means
No transmitter	There is no transmitter connected to the app. Tap Connect transmitter to CONNECT A TRANSMITTER . See SECTION 8.5 for details about connecting a transmitter.
Connecting transmitter...	The system is connecting to your transmitter.
Activating transmitter... Remove transmitter [TRANSMITTER ID] from the charger to activate.	The system is trying to activate the transmitter indicated by [TRANSMITTER ID]. You must remove the transmitter from the charger in order to activate it. See SECTION 3.3 for details about activating a transmitter.
Ready to start Follow sensor insertion instructions. It may take 1-3 minutes to detect the sensor.	A transmitter is connected, but a session has not been started. See CHAPTER 4 for details about starting a session.
Starting session...	The session is starting. A progress bar indicates the amount of time remaining before the session has started.
Waiting for calibration Add a blood glucose meter reading.	The system is ready to be calibrated. See CHAPTER 5 for details about calibration.
Collecting data...	After the first calibration of a session, the system needs time to collect data. A progress bar indicates the amount of time remaining.

Home screen message	What it means
Stopping session...	The session is stopping.
Bluetooth is off Turn on Bluetooth to use your CGM.	Bluetooth is turned off. Bluetooth must be turned on, so the transmitter and app can communicate.
Out of space Free up space on your phone to use your CGM.	Your smart device is out of storage space and the app cannot display glucose readings. If you free up space, the app will display glucose readings.
Signal lost Make sure your transmitter is nearby. It may take time to reconnect.	The app does not detect a signal from the transmitter. Make sure the transmitter is near the app.

6.4 Trend chart

6.4.1 Chart area

The trend chart shows recent glucose levels, so you can see your trends over time. The transmitter sends one glucose reading per minute. The CGM displays glucose levels from 2.2-22.2 mmol/L.

A. Time (x-axis)

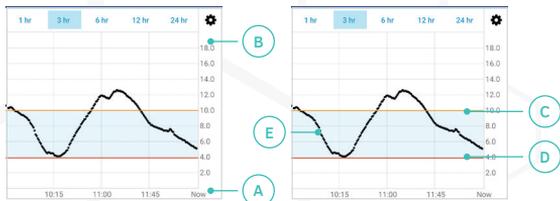
B. Glucose level (y-axis)

C. High glucose line

D. Low glucose line

E. Target range

See **SECTION 6.4.3** for details.



IMPORTANT: Glucose levels below 2.2 mmol/L are plotted at 2.2 mmol/L. Glucose levels above 22.2 mmol/L are plotted at 22.2 mmol/L.

NOTE: If your transmitter loses connection with the app during a session, there may be blank areas on the trend chart. Those areas will be filled in when the transmitter reconnects.

6.4.2 Chart display options

The chart display options allow you to choose the amount of data shown on the trend chart.

You can choose to display the last 1, 3, 6, 12, or 24 hours of glucose data. The right side of the chart always starts with the current time and past readings are plotted to the left.



6.4.3 Chart settings

CHART SETTINGS lets you choose where to display the high and low glucose lines and the target range on the trend chart.



Changing chart settings

Navigate to **CHART SETTINGS** to change your settings.

NOTE: The settings in **CHART SETTINGS** only affect the way information is displayed on the **HOME** screen and do not affect any of your alerts. See **CHAPTER 7** for details about alerts.

1.

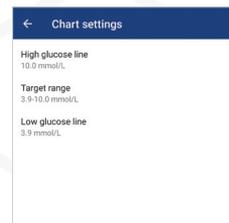
Tap the **SETTINGS** icon.



2.

Tap the setting you want to change and make your adjustments:

- High glucose line
- Target range
- Low glucose line



3.

On Android: Tap **OK** to save your selection.
On iOS: Your selection is automatically saved.

4.

Tap the **BACK BUTTON** to return to the **HOME** screen.

6.5 Estimated glucose

⚠ CAUTION

If the app is displaying estimated glucose values and you experience symptoms of high or low glucose, perform a blood glucose test before making any treatment decisions.

There are multiple reasons glucose levels may be estimated. Tap on the **ESTIMATED GLUCOSE** banner for details about why glucose is currently estimated.

Home screen message	What it means
<p>Estimated glucose Glucose levels are currently estimated because the system needs to be calibrated.</p>	<p>The system needs to be calibrated.</p> <ul style="list-style-type: none"> • After the first calibration: Glucose levels are estimated if the system is not calibrated within 6 hours of the session start. • After the second calibration: Glucose levels are estimated if the system is not calibrated within 24 hours of the session start. • After all other calibrations: Glucose levels are estimated if the system is not calibrated within 26 hours of the previous calibration. <p>Once you calibrate, new glucose levels will no longer be estimated. See CHAPTER 5 for details about calibration.</p>
<p>Estimated glucose Glucose levels are currently estimated because there is a temporary issue with the sensor.</p>	<p>The system detects an issue with the sensor. Glucose levels will be estimated until the system is sure the issue has been resolved (about 1 hour).</p> <p>If the ESTIMATED GLUCOSE banner is still visible after 1 hour, contact Customer Service.</p>

/ 7 Alerts

7.1 Navigating to the Alerts screen

The **ALERTS** screen allows you to set up alerts to let you know if a certain event is occurring, such as low glucose, that requires your attention.

In the app, tap the **ALERTS** button.

On Android devices, you may need to tap the **BACK ARROW** until you see the bottom buttons.



7.2 Alerts screen overview

The **ALERTS** screen is divided into three main sections: glucose alerts, devices alerts, and alert history.

You can move between the sections by tapping the tabs on the top of the screen.

A. Alert settings

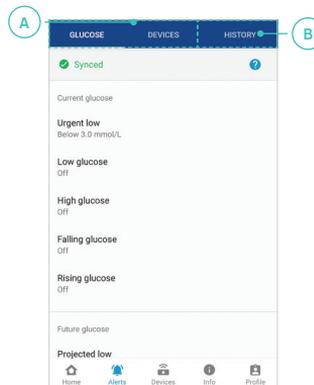
The **GLUCOSE** and **DEVICES** tabs allow you to set up your alerts.

- Tap **GLUCOSE** for alerts related to current and future glucose levels. See **SECTION 7.6** for details.
- Tap **DEVICES** for alerts related to the transmitter or your smart device. See **SECTION 7.7** for details.

See **SECTION 7.4** for details about setting up alerts.

B. Alert history

The **HISTORY** tab allows you to see a list of alerts that occurred in the past 14 days.



7.3 Allowing notifications

If you want alerts to appear as notifications on your smart device, you need to give the GlucoMen Day App permission to send notifications.

If the app is in the background, an alert will appear as a notification if:

- The app has permission to send notifications.
- The alert is turned on.

NOTE: If the app is in the foreground, an alert will appear as a message in the app.

1.

Navigate to the Settings app on your device.

NOTE: This is outside the GlucoMen Day App.

3.

In the list of apps, tap the GlucoMen Day App.

4.

Adjust your notification settings to allow the GlucoMen Day App to send notifications.

IMPORTANT: • The transmitter and app must be communicating in order to receive alerts. This requires Bluetooth to be turned on.

• If an alert starts while your transmitter and app are not communicating, the app will display the alert when the transmitter and app resume communication if the alert still applies.

• For instructions to enable notifications on your device, please refer to the user manual that came with your smart device.

⚠ CAUTION

If your smart device is set to Silent or Do Not Disturb, you may miss important alerts.

7.4 Setting up alerts

The GlucoMen Day App includes a variety of alerts you can set up to notify you if something occurs that requires your attention. Each alert has options you can set to customise the alert. Most alerts can also be turned on or off.

2.

Tap **NOTIFICATIONS**.



IMPORTANT: The **URGENT LOW** and **CRITICAL LOW BATTERY** alerts cannot be turned off.

1.

In the app, tap the **ALERTS** button.

On Android devices, you may need to tap the **BACK ARROW** until you see the bottom buttons.



2.

Select the type of alert you want to set:

- Tap **GLUCOSE** for alerts related to current and future glucose levels. See **SECTION 7.6** for details.
- Tap **DEVICES** for alerts related to the transmitter or your smart device. See **SECTION 7.7** for details.



3.

Tap the alert you want to set up.

Each alert has a title (A) and a current setting (B).

If the alert is currently off, the current setting will be **OFF**.



4.

Tap the switch to turn the alert on or off.

If you turn the alert off, you will not be able to edit any of the alert's settings.

NOTE: Some alerts cannot be turned off.

5.

Tap the alert level to define when the alert will occur. The alert level is different for each alert. For example, if you choose 13.9 mmol/L for the high glucose alert level, **GLUCOSE ABOVE 13.9 mmol/L** will be displayed.

On Android: Tap **OK** to save your selection.

On iOS: Your selection is automatically saved.



6.

Tap the **REPEAT** setting to determine when the alert will repeat if the alert level still applies.

On Android: Tap **OK** to save your selection.

On iOS: Your selection is automatically saved.

NOTE:

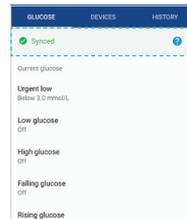
- The projected high and low alerts cannot be assigned an alert level because the alert level is automatically determined based on the high and low glucose alerts, respectively.
- The calibration alert does not have an alert level because it is defined by when the system needs to be calibrated.
- The urgent low and critical low battery alert levels cannot be changed.

⚠ CAUTION

After changing the alert settings, there may be a delay before you receive alerts based on the new settings. During this delay, alerts will be based on the previous settings. See **SECTION 7.5** for details.

7.5 Alert status indicators

The alert status indicators let you know if the GlucoMen Day App and the transmitter are using the same alert settings and if your notification settings could prevent alerts from behaving as expected.



NOTE: Alert status is the same for all alerts. If at least one alert is changed, the status is **PENDING** until the new settings are synced with the transmitter.

Statuses	
	Alert settings are in sync with the transmitter.
	Alert settings will sync with the transmitter the next time the app communicates with the transmitter. Until then, you might get alerts based on your previous settings.
	Your current notification settings may prevent notifications from occurring as expected.

7.6 Glucose alerts

You can set alerts associated with your current and future glucose levels. These alerts will notify you when your glucose is high, low, or rapidly changing.

**Glucose levels and rates of change are examples only.*

⚠ CAUTION

Talk to your healthcare professional about what actions to take if you experience high or low glucose. Follow the advice of your healthcare professional to raise or lower your glucose to your target range.

Alert type	When the alert occurs	Alert message *
Urgent Low	Your current glucose is below the urgent low alert limit of 3.0 mmol/L. This alert cannot be turned off and the glucose alert limit cannot be changed. <ul style="list-style-type: none"> You can customise the REPEAT setting for this alert. See SECTION 7.4 for details. 	Urgent low alert Your glucose is 2.9 mmol/L.
Low glucose	Your current glucose is below your low glucose alert limit. <ul style="list-style-type: none"> You can set the low glucose alert to 3.3-4.4 mmol/L. You can customise the REPEAT setting for this alert. See SECTION 7.4 for details. 	Low glucose alert Your glucose is 3.8 mmol/L.
High glucose	Your current glucose is above your high glucose alert limit. <ul style="list-style-type: none"> You can set the high glucose alert to 6.7-19.4 mmol/L. You can customise the REPEAT setting for this alert. See SECTION 7.4 for details. 	High glucose alert Your glucose is 14.3 mmol/L.

Alert type	When the alert occurs	Alert message *
Falling glucose	Your glucose is decreasing at the selected rate of decrease or faster. <ul style="list-style-type: none"> You can set the rate of decrease to 0.1 or 0.2 mmol/L per minute. You can customise the REPEAT setting for this alert. See SECTION 7.4 for details. 	Falling glucose alert Your glucose is 6.2 mmol/L and decreasing at 0.17+ mmol/L per minute.
Rising glucose	Your glucose is increasing at the selected rate of increase or faster. <ul style="list-style-type: none"> You can set the rate of increase to 0.1 or 0.2 mmol/L per minute. You can customise the REPEAT setting for this alert. See SECTION 7.4 for details. 	Rising glucose alert Your glucose is 6.2 mmol/L and increasing at 0.11 mmol/L per minute.
Projected low	If the current trend continues, your glucose will be below your low glucose alert limit in 15 minutes. The low glucose alert limit is based on the level set for the low glucose alert. <ul style="list-style-type: none"> You can customise the REPEAT setting for this alert. See SECTION 7.4 for details. 	Projected low alert If the current trend continues, your glucose will be below 3.9 mmol/L in 15 minutes.

Alert type	When the alert occurs	Alert message *
Projected high	<p>If the current trend continues, your glucose will be above your high glucose alert limit in 15 minutes. The high glucose alert limit is based on the level set for the high glucose alert.</p> <ul style="list-style-type: none"> You can customise the REPEAT setting for this alert. See SECTION 7.4 for details. 	<p>Projected high alert</p> <p>If the current trend continues, your glucose will be above 13.9 mmol/L in 15 minutes.</p>

*Glucose levels and rates of change are examples only.

7.7 Devices alerts

Devices alerts let you know when you need to calibrate, when the transmitter is no longer communicating with the app, when the transmitter battery is low, and when your phone storage is getting low.

⚠ CAUTION

Transmitter alerts only apply to the active transmitter. See **SECTION 8.6.1** for details about the active transmitter.

Alert type	When the alert occurs	Alert message
Calibration	<p>It is time to calibrate. Perform a blood glucose test with your blood glucose meter.</p> <ul style="list-style-type: none"> You can customise the REPEAT setting for this alert. See SECTION 7.4 for details. 	<p>Time to calibrate</p> <p>Enter a blood glucose reading from your meter.</p>

Alert type	When the alert occurs	Alert message
Signal loss	<p>The app cannot detect the transmitter. The transmitter may be too far from the app or something may be blocking the transmitter signal.</p> <ul style="list-style-type: none"> You can choose how long the signal must be lost before you are alerted. You can customise the REPEAT setting for this alert. See SECTION 7.4 for details. 	<p>Transmitter signal loss</p> <p>Make sure Bluetooth is on and your transmitter is nearby.</p>
Critical low battery	<p>The transmitter battery is low and might not last for the full 14-day session.</p> <p>This alert will repeat when the battery is at 30%, 25%, 20%, 15%, 10%, and 5%.</p> <p>This alert cannot be turned off.</p>	<p>Low transmitter battery</p> <p>30% remaining.</p>
Phone storage	<p>Your smart device storage is getting full.</p> <p>⚠ CAUTION Once your smart device is full, the app will no longer display glucose readings.</p> <ul style="list-style-type: none"> You can choose how full your smart device must be before you are alerted. You can customise the REPEAT setting for this alert. See SECTION 7.4 for details. 	<p>Phone storage low</p> <p>CGM data will not be saved if your phone runs out of storage space.</p>

/ 8 Transmitters

8.1 Navigating to the Transmitters screen

The transmitter is a rechargeable component that sends your continuous glucose data to the app using Bluetooth wireless technology.

In the app, you can manage your transmitters on the **TRANSMITTERS** screen.

1.

In the app, tap the **DEVICES** button.

On **Android** devices, you may need to tap the **BACK ARROW** until you see the bottom buttons.



2.

Tap **TRANSMITTERS**.

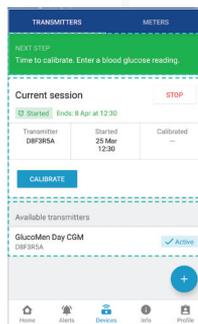


8.2 Transmitters screen overview

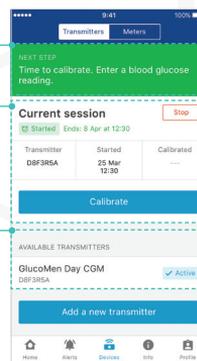
The **TRANSMITTERS** screen is where you manage your transmitters. You can also manually stop a session from this screen.

The **TRANSMITTERS** screen has four main sections: a message area (**A**, this section only appears when there is relevant information to display), current session details (**B**), a list of available transmitters (**C**), and a button to add a new transmitter (**D**). See **SECTION 8.3** for details.

Android:



iOS



8.3 Transmitters screen details

8.3.1 Message area

When a message appears in the message area, it either indicates an ongoing process or provides instructions for the next step.

Transmitters screen message	What it means
NEXT STEP No transmitter connected. Add a new transmitter.	There is no transmitter connected to the app. See SECTION 3.3 for details about connecting a transmitter.

Transmitters screen message	What it means
Connecting transmitter...	The system is connecting to your transmitter.
Remove transmitter [TRANSMITTER ID] from the charger to activate. Activating transmitter...	The system is trying to activate the transmitter indicated by [TRANSMITTER ID]. You must remove the transmitter from the charger in order to activate it. See SECTION 8.6 for details about activating a transmitter.
NEXT STEP Follow sensor insertion instructions. It may take 1-3 minutes to detect the sensor.	A transmitter is connected, but a session has not been started. See CHAPTER 4 for details about starting a session.
Starting session...	The session is starting. A progress bar indicates the amount of time before you can calibrate.
NEXT STEP Time to calibrate. Enter a blood glucose reading.	See CHAPTER 5 for details about calibrating.
Saving calibration...	The system is saving the calibration reading.
Collecting data...	After the first calibration of a session, the system needs time to collect data. A progress bar indicates the amount of time remaining.
Stopping session...	The session is stopping.

8.3.2 Current session

The current session details section provides information about the current session.

A. Session status

Status is either **STARTED** or **NOT STARTED**.

B. Active transmitter

ID of the active transmitter.

C. Start time of current session

D. End time of current session

End time is 14 days after the start time. The end time is only visible if a session is in progress.

E. Time of last calibration

F. Calibrate button

Tap to calibrate. This button will be disabled if calibration is not possible.

G. Stop button

Tap to stop the session. This button will be disabled if a session is not in progress.



8.3.3 Available transmitters

This section shows the transmitters that are connected to the app. The active transmitter is marked with an **ACTIVE** badge.

Tap on a row to view details for that transmitter.



8.4 Charging a transmitter

The transmitter is a rechargeable component. When fully charged, the transmitter can last for the entire 14-day session.

1.

Place the transmitter in the charger.



2.

Insert the Micro USB end of the USB cable into the charger.



3.

Insert the other end of the USB cable into a computer.

Make sure the computer is turned on.

NOTE: If necessary, you can use an AC wall adapter that complies with the specifications in **SECTION 17.4.5**.

The light on the charger indicates the status of the transmitter.

See **SECTION 8.4.1** for details about the charger light.

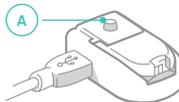
This transmitter may take up to 4 hours to be fully charged.

⚠ CAUTION

If you want to use a computer to charge the transmitter, a USB port supporting a minimum charging current of 100 mA is required. Check your computer user manual or contact the computer manufacturer to make sure the device meets these requirements. The USB port on your PC must comply with 60601-1 ed. 3.1 at a minimum.

8.4.1 Charger light

While the transmitter is in the charger, the light (A) on the charger indicates the transmitter status.



Charger light	What it means	
	Flashing green light	The transmitter is charging. This transmitter may take up to 4 hours to be fully charged.
	Solid green light	The transmitter is fully charged and ready to use for a session.
	Flashing blue light	The transmitter is ready to pair with the app. This light appears when you press the button on the charger. See SECTION 3.3 for details about connecting a transmitter to the app.
	Solid blue light	The transmitter is successfully paired with the app. After 60 seconds this light will turn green (flashing or solid) to indicate that the transmitter is charging or charged.
	Flashing red light	Lasting up to 5 seconds: The transmitter has been detected but is not communicating with the charger. This may occur when the transmitter is placed into the charger. Lasting longer than 5 seconds: An error has occurred. See SECTION 15.6 for details about charger errors.
	Solid red light	An error has occurred. The transmitter is either not charging or did not successfully pair with the app. See SECTION 15.6 for details about charger errors.

8.5 Connecting a transmitter

Please refer to **SECTION 3.3** for Connecting a transmitter instructions.

8.6 Activating a transmitter

Although you can connect multiple transmitters to the app, only one transmitter can send CGM readings to the app. That transmitter is referred to as the active transmitter. It is important to understand which transmitter is active before you start a session.

If you only have one transmitter connected to the app, it is automatically the active transmitter.

If you have multiple transmitters connected to the app, you can choose which one to activate.

8.6.1 Identifying the active transmitter

Before you start a session, it is important to make sure that you are using the active transmitter.

1.

In the app, tap the **DEVICES** button.

On Android devices, you may need to tap the **BACK ARROW** until you see the bottom buttons.



3.

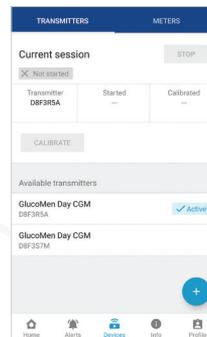
Under **CURRENT SESSION**, locate the ID listed under **TRANSMITTER**. This is the ID of the active transmitter.

OR

In the list of **AVAILABLE TRANSMITTERS**, locate the transmitter with the **ACTIVE** label. The 7-digit alphanumeric ID listed in that row is the ID of the active transmitter.

2.

Tap **TRANSMITTERS**.



4.

Now that you have identified the active transmitter, you can use that transmitter to start a session.

If you want to use a different transmitter, follow the steps in **SECTION 8.6.2** to activate that transmitter.

8.6.2 Activating a different transmitter

If you want to use a transmitter other than the one that is currently active, you must activate that transmitter.

1.

Identify the transmitter you want to activate.

See **SECTION 8.6.1** if you need help identifying the active transmitter.



2.

If the transmitter is currently charging, remove the transmitter from the charger.

The transmitter cannot be activated while in the charger.

3.

In the app, tap the **DEVICES** button.

On Android devices, you may need to tap the **BACK ARROW** until you see the bottom buttons.



4.

Tap **TRANSMITTERS**.

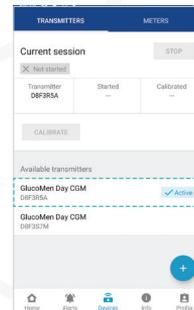


5.

Locate the transmitter in the list of **AVAILABLE TRANSMITTERS**.

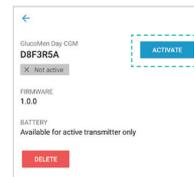
Tap the row for your transmitter.

You can identify the transmitter using the 7-digit alphanumeric ID (A) on the top of the transmitter.



6.

Tap **ACTIVATE**.



7.

If a confirmation message appears, tap **ACTIVATE** to confirm that you want to change the active transmitter.

Your transmitter is now activated and ready to use.

Make sure the transmitter is fully charged before proceeding. See **SECTION 8.4** for details about charging the transmitter.

Change transmitters?

Another transmitter is already active.

Do you want to activate this transmitter instead?

CANCEL ACTIVATE

Change transmitters?

Another transmitter is already active and a session is in progress.

Do you want to stop receiving CGM data and activate this transmitter instead?

CANCEL ACTIVATE

8.7 Deleting a transmitter

Deleting a transmitter will remove the connection between the transmitter and the app. You will no longer be able to use the transmitter.

If you want to use the transmitter again in the future, you will need to go through the steps to connect the transmitter.

1.

In the app, tap the **DEVICES** button.

On Android devices, you may need to tap the **BACK ARROW** until you see the bottom buttons.

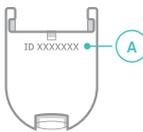


3.

Locate the transmitter in the list of **AVAILABLE TRANSMITTERS**.

Tap the row for your transmitter.

You can identify the transmitter using the 7-digit alphanumeric ID (A) on the top of the transmitter.

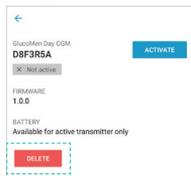
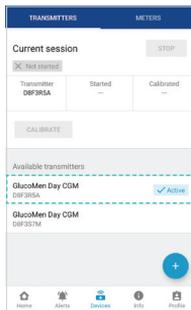


4.

Tap **DELETE**.

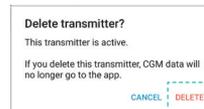
2.

Tap **TRANSMITTERS**.



5.

When the confirmation message appears, tap **DELETE**.

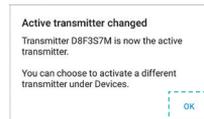


6.

If the deleted transmitter was the active transmitter, a message indicates which transmitter is now active.

Tap **OK**.

To activate a different transmitter, see **SECTION 8.6**.



/ 9 Meters

When using the GlucoMen Day CGM, always carry a blood glucose meter for calibrating the system.

The calibration can be performed by using the GlucoMen Day METER system (provided separately), or by any commercially available blood glucose meter.

9.1 Navigating to the Meters screen

If you use the GlucoMen Day METER system to measure your blood glucose (provided separately), you can connect the meter to the app so that blood glucose readings automatically transfer to the app and you can select them for calibration.

In the app, you can manage your meters on the **METERS** screen.

1.

In the app, tap the **DEVICES** button.

On Android devices, you may need to tap the **BACK ARROW** until you see the bottom buttons.



2.

Tap **METERS**.



9.2 Meters screen overview

The **METERS** screen is where you manage the meters that are connected to the app.

The **METERS** screen has three sections: a button to view compatible meters, a list of connected meters, and a button to add a new meter.

A. COMPATIBLE METERS button

This button displays a list of compatible meters that can be connected to the app.

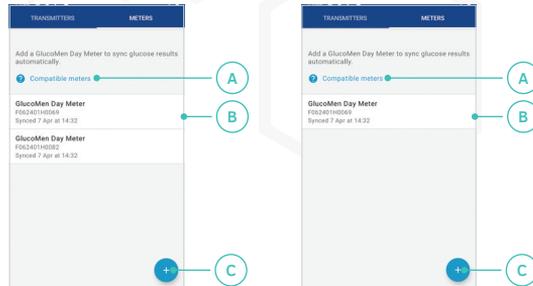
B. Connected meters list

This section lists all of the meters connected to the app. Tap a meter row for details about that meter.

C. Add meter button

On Android: Tap the (+) button
On iOS: Tap **ADD A NEW METER**

This button lets you add a new meter. See **SECTION 9.3** for details about connecting a meter.



9.3 Connecting a meter

The app is compatible with the GlucoMen Day METER system, which communicates with the app using Bluetooth wireless technology and must be connected to the app before it can transfer readings to the app. This process is also called *pairing*.

IMPORTANT: The app pairs with the GlucoMen Day METER system only. If you want to use a different meter to calibrate the CGM, you can enter your calibration readings manually.

Once you connect your meter to the app, the meter will automatically send your blood glucose readings to the app so that you do not have to manually enter your glucose level when you calibrate. This is known as *syncing*.

The meter will automatically sync when:

- ✔ You turn on the meter or perform a blood glucose test and eject the test strip.
- ✔ The meter and app are within 3 metres (10 feet) of each other and Bluetooth is on.
- ✔ The app is open. The app can be in the foreground or background.

When you calibrate, readings from your meter that were taken within the last 5 minutes and after your most recent calibration will appear under **RECENT METER READINGS**.

 **IMPORTANT:** Your GlucoMen Day METER communicates with the app using Bluetooth wireless technology. Your smart device must have Bluetooth turned on to continue.

NOTE: The app will update the time on the meter each time it syncs.

1.

In the app, tap the **DEVICES** button.

On Android devices, you may need to tap the **BACK ARROW** until you see the bottom buttons.



3.

On Android: Tap the (+) button.

On iOS: Tap **ADD A NEW METER**.

4.

On Android devices only:

Depending on your device's permission settings, you may see any or all of these messages on the **NEW METER** screen:

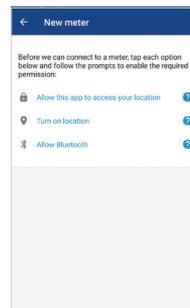
- Allow this app to access your location.
- Turn on location.
- Allow Bluetooth.

If any of these messages appear, tap the message and follow the prompts to enable permissions.

2.

Tap **METERS**.

If you are unsure about which meters are compatible with the app, tap **COMPATIBLE METERS** to view a list of compatible meters.



⚠ CAUTION

All of these permissions must be enabled to connect to a meter.

5.

The top part of the **NEW METER** screen displays step-by-step instructions to connect the meter to the app. After performing each step, swipe left to view the next step.

After following the on-screen instructions, when your meter appears under **DETECTED METERS**, tap the row for your meter.

You can identify the meter using the last 4 digits of the serial number on the back of the meter.

6.

When the *Bluetooth Pairing Request* appears in the app, enter the 6-digit PIN displayed on the meter.

Tap **PAIR**.

9.4 Deleting a meter

Deleting a meter will remove the connection between the meter and the app. You will no longer be able to transfer readings from the meter to the app.

If you want to transfer readings from the meter to the app again in the future, you will need to go through the steps to connect the meter.

1.

In the app, tap the **DEVICES** button.

On Android devices, you may need to tap the **BACK ARROW** until you see the bottom buttons.



2.

Tap **METERS**.



3.

Locate the meter in the list of meters.

Tap the row for your meter.

You can identify the meter using the serial number on the back of the meter.



4.

Tap **DELETE**.



5.

When the confirmation message appears, tap **DELETE**.



/ 10 Info

10.1 Navigating to the Info screen

The app includes an **INFO** section where you can view a glucose overview report, export your raw data, and find helpful information such as sensor insertion instructions and the User Guide.

In the app, tap the **INFO** button.

On Android devices, you may need to tap the **BACK ARROW** until you see the bottom buttons.



10.2 Glucose overview report

The glucose overview report allows you to create and share a report of your previous glucose data, up to the last 28 days.

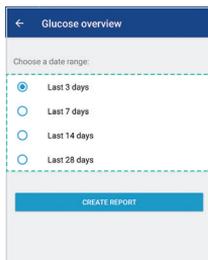
1. In the app, tap the **INFO** button.

On Android devices, you may need to tap the **BACK ARROW** until you see the bottom buttons.



3. Select the date range for which you want to create a report.

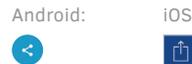
2. Tap **GLUCOSE OVERVIEW**.



4. Tap **CREATE REPORT** to create a PDF report for the selected date range.



5. Once the report is displayed, tap the **SHARE** button.



6. Select an option to email or save the report. Sharing options may vary based on your smart device.

10.3 CSV data report

The CSV data export allows you to export a comma-separated values (CSV) file containing your CGM data.

1. In the app, tap the **INFO** button.

On Android devices, you may need to tap the **BACK ARROW** until you see the bottom buttons.



3. Select the date range for which you want to create a report.

4. Tap **CREATE REPORT** to create a CSV report for the selected date range.



2. Tap **CSV DATA EXPORT**.

5. Once the report is displayed, tap the **SHARE** button.



6. Select an option to email or save the report. Sharing options may vary based on your smart device.

10.4 Sensor insertion instructions

The **SENSOR INSERTION INSTRUCTIONS** section provides in App step by step instructions for sensor insertion.

10.5 Sensor removal instructions

The **SENSOR REMOVAL INSTRUCTIONS** section provides in App step by step instructions for sensor removal.

10.6 Icons and colours

The **ICONS AND COLOURS** section provides information about the icons and colours used within the App.

10.7 FAQs

The **FAQ** section provides answers to frequently asked questions.

10.8 Comprehensive User Guide

The **COMPREHENSIVE USER GUIDE** section provides a digital version of the GlucoMen Day CGM system user's guide.

1.

In the app, tap the **INFO** button.

On Android devices, you may need to tap the **BACK ARROW** until you see the bottom buttons.



3.

The Comprehensive User Guide is available in multiple languages. Select the language you want to view.

2.

Tap **COMPREHENSIVE USER GUIDE**.

- Guides listed under **DOWNLOADED GUIDES** are stored locally and do not require a network connection to view.
- Guides listed under **AVAILABLE GUIDES** require a network connection to download and view.

10.9 Customer Service

1.

In the app, tap the **INFO** button.

On Android devices, you may need to tap the **BACK ARROW** until you see the bottom buttons.



2.

Tap **CUSTOMER SERVICE**.

3.

Customer Service information is listed by country. Locate the Customer Service contact information for your country.

/ 10.10 Technical and medical support

The App includes access to 24/7 technical and medical support.

NOTE: 24/7 support is not available in all countries.

If you need technical support, tap **REQUEST TECHNICAL SUPPORT**. This will open a chat session to assist with troubleshooting.



IMPORTANT: You must have a network connection to access technical support. The chat session will open in an internet browser on your smart device.

If you need medical support, tap **REQUEST MEDICAL SUPPORT**. This will display the medical support phone num-

ber for your country, based on the country selected in the app. See **SECTION 11.3** for details about selecting our country. When the phone number appears, tap **CALL** or the button with a phone icon (depending on the device) to dial the number. You will be connected with a healthcare professional who can assist you.

REQUEST MEDICAL SUPPORT

 **IMPORTANT:** Your phone must allow outgoing phone calls to access medical support.

/ 10.11 Legal

The **LEGAL** section provides access to legal documents and agreements related to the GlucoMen Day CGM App.

1.

In the app, tap the **INFO** button.

On Android devices, you may need to tap the **BACK ARROW** until you see the bottom buttons.

2.

Tap the legal document you want to review.

/ 11 Profile

11.1 Navigating to the Profile screen

The Profile screen is where you can change your account information, such as name and country.

In the app, tap the **PROFILE** button.

On Android devices, you may need to tap the **BACK ARROW** until you see the bottom buttons.



11.2 Changing personal information

You can change your name, birth year, gender and type of diabetes.

11.3 Changing your country

The country selected in the **PROFILE** determines the glucose units used throughout the app (mg/dL or mmol/L).

1.

In the app, tap the **PROFILE** button.

On Android devices, you may need to tap the **BACK ARROW** until you see the bottom buttons.



2.

Tap the **COUNTRY** field.

NOTE: If your app only supports one country, you will not be able to select this field.

3.

Select your country.

On Android: Tap **OK** to save your selection.

On iOS: Your selection is saved automatically.

4.

If you select a country that uses different glucose units from your current country, you will see a message letting you know that the glucose units in the app will change.

Tap **CHANGE** to change your country.

The app will display glucose values in the units of the selected country (mg/dL or mmol/L).

Change country?

Italy measures glucose in mg/dL. Changing the country will convert all glucose readings to mg/dL.

These readings may be different from what appears on your meter.

CANCEL CHANGE

/ 11.4 Changing your email

Your email address is used to log in to your account, as well as for important communications about your CGM.

1.

In the app, tap the **PROFILE** button.

On Android devices, you may need to tap the **BACK ARROW** until you see the bottom buttons.

2.

Tap the **EMAIL** field.

Current email
johnanderson@mail.com

4.

Enter the new email address again.

Confirm new email

6.

Tap **SAVE**.

SAVE

3.

Enter the new email address you want to use.

New email

5.

Enter your current password.

Password

If you forgot your password, see **SECTION 11.6** for the steps to reset your password. NOTE: Tap the (👁️) icon to show or hide your password.

1.

In the app, tap the **PROFILE** button.

On Android devices, you may need to tap the **BACK ARROW** until you see the bottom buttons.

2.

Tap the **PASSWORD** field.

Password

4.

Enter your new password.

New password
Must be 8+ characters

Passwords must be at least 8 characters.

NOTE: Tap the (👁️) icon to show or hide your password.

3.

Enter your current password.

Current password

If you have forgotten your password, see **SECTION 11.6** for the steps to reset your password.

5.

Tap **SAVE**.

SAVE

/ 11.6 Resetting your password

If you have forgotten your password, you can reset it and create a new password.

1.

Tap **FORGOT PASSWORD?**

The **FORGOT PASSWORD?** button appears when:

- Logging in to your account (**SECTION 3.3**)
- Changing your email (**SECTION 11.4**)
- Changing your password (**SECTION 11.5**)

Email

Password

Forgot password?

/ 11.5 Changing your password

A good password is important to keep your health data safe. It is good practice to change your password occasionally, especially if you believe your password may have been compromised.

2. On the **RESET PASSWORD** screen, if your email address is not displayed, tap the **EMAIL** field and enter the email address associated with your account.

4. Enter the reset code into the **CODE** field.

6. Tap **SAVE**.

/ 11.7 Email communication settings

The **EMAIL COMMUNICATION** settings allow you to opt in or out of certain email communications.

1. In the app, tap the **PROFILE** button.

3. Tap **GET A RESET CODE**.

A reset code will be sent to your email.

5. Enter a new password in the **NEW PASSWORD** field.

Passwords must be at least 8 characters.
NOTE: Tap the (👁️) icon to show or hide your password.

2. In the **EMAIL COMMUNICATION** section, tap the switch next to each option to opt in or out.

/ 11.8 Sharing data with AgaMatrix

When you create an account to use the GlucoMen Day CGM App, your data is stored on AgaMatrix's secure servers.

If you prefer to use the app without sharing your data, you have that option. In that case, your data is stored locally on your smart device only and cannot be retrieved from the server if something happens to your smart device.

However, certain features in the GlucoMen Day CGM App require the ability to share data in order to function. Those features will not be available unless you turn on **SHARE DATA WITH AGAMATRIX**.

1. In the app, tap the **PROFILE** button.

2. Tap the switch next to **SHARE DATA WITH AGAMATRIX** to opt in or out of sharing data.
Tap **READ FULL AGREEMENT** to review the entire agreement.

/ 11.9 Connected Partners

The **CONNECTED PARTNERS** feature allows you to automatically share your data with a trusted healthcare professional or service.

 **IMPORTANT:** The **CONNECTED PARTNERS** feature is only available if you have agreed to share data with AgaMatrix. See **SECTION 11.8** for details.

1.

In the app, tap the **PROFILE** button.

On Android devices, you may need to tap the **BACK ARROW** until you see the bottom buttons.

2.

In the **SHARING** section, tap **CONNECTED PARTNERS**. See **CHAPTER 16** for details about connected partners.

/ 11.10 Analytics

The **ANALYTICS** section allows you to opt in or out of sharing app analytics.

The analytics data is anonymised and cannot be used to identify you.

1.

In the app, tap the **PROFILE** button.

On Android devices, you may need to tap the **BACK ARROW** until you see the bottom buttons.

2.

In the **ANALYTICS** section, tap the switch next to **SHARE APP ANALYTICS** to opt in or out of sharing app analytics.

Tap **PRIVACY POLICY** to review how analytics are collected and used.



 **IMPORTANT:** The GlucoMen Day CGM App stores sensitive health-related information on your smart device. We recommend keeping your device up to date with the latest iOS or Android OS version to help ensure the highest level of security. For extra protection measures, set and use a password on your smart device.

11.11 Customer Service Access

The **CUSTOMER SERVICE ACCESS** feature allows the user to give permission for Customer Service to access their anonymised data.

By default, the permission is off.

 **IMPORTANT:** The **CUSTOMER SERVICE ACCESS** feature is only available if you have agreed to share data with AgaMatrix. See **SECTION 11.8** for details.

1.

In the app, tap the **PROFILE** button.

On Android devices, you may need to tap the **BACK ARROW** until you see the bottom buttons.

2.

Under **CUSTOMER SERVICE ACCESS**, Tap the switch next to **ALLOW ACCESS TO ANONYMISED DATA** to opt in or out of allowing access.

3.

Tap **READ FULL AGREEMENT** to read the agreement and tap **AGREE** to allow access to your anonymised data.

4.

In order to share your anonymised data, you need an access code to provide to Customer Service. The access code will appear under **CUSTOMER SERVICE ACCESS** after you have agreed to the **DATA ACCESS AGREEMENT**.

The permission allows Customer Service to view the last 60 days of your anonymised CGM readings, alerts, and

calibration data to assist with troubleshooting. This access will expire 30 days after it is enabled or when you turn off this setting, whichever occurs first. If you need assistance from Customer Service in the future, you may need to turn on this feature again.

/ 12 Stopping a session

12.1 Automatically stopping a session

Your GlucoMen Day CGM sensor lasts for 14 days. After 14 days, the CGM session will automatically stop.

There are other reasons a session may stop automatically:

- The system detects a problem with the sensor.
- You activate a different transmitter.
- You remove the transmitter and place it in the charger.

1.

In the app, you will see a message indicating that the session has ended.

Tap **SENSOR REMOVAL**

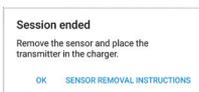
INSTRUCTIONS for information about removing the sensor.

OR Tap **OK**.

NOTE: The **SESSION ENDED** message may include information about why the session ended.

Once the session has stopped, you should remove the sensor and place the transmitter in the charger.

See **CHAPTER 13** for details about removing the sensor.



12.2 Manually stopping a session

If you choose to stop a session before the end of the 14 days, you will need to stop it manually.

Reasons you may want to stop a session early:

- Medical procedure (MRI, CT Scan, etc.).
- You have pain, tenderness, or swelling at the sensor insertion site.
- Convenience; you may choose to stop the session early if needed.

1.

In the app, tap the **DEVICES** button.

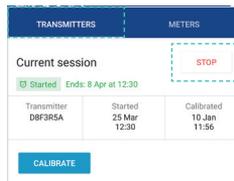
On Android devices, you may need to tap the **BACK ARROW** until you see the bottom buttons.



2.

Tap **TRANSMITTERS**.

Tap **STOP**.



4.

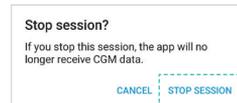
In the app, you will see a message indicating that the session has ended.

Tap **SENSOR REMOVAL INSTRUCTIONS** for information about removing the sensor.

OR Tap **OK**.

3.

When the confirmation message appears, tap **STOP SESSION**.



Once the session has stopped, you should remove the sensor and place the transmitter in the charger.

See **CHAPTER 13** for details about removing your sensor.

/ 13 Removing a sensor

Once a session stops, you should remove the sensor and place the transmitter in the charger.

⚠ CAUTION

- The sensor is for single-use only, up to 14 days. Do not reuse the sensor or use it beyond 14 days.
- Do not remove the transmitter while the sensor assembly is attached to you.

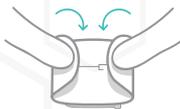
1.

Remove the sensor adhesive patch, starting at the end closest to the flat back side of the transmitter. Peel the patch away from your body.



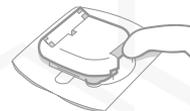
2.

After removal, fold back the sides of the sensor adhesive patch to cover the sensor.



3.

Pull back on the transmitter release tab.



4.

Lift the transmitter away from the sensor adhesive patch.



5.

Place the transmitter in the charger. Make sure the transmitter is fully charged before using it again.

See **SECTION 8.4** for details about charging the transmitter.

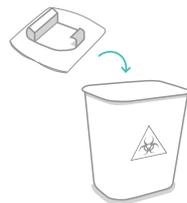


6.

Discard the used sensor adhesive patch as medical waste.

⚠ CAUTION

Do not discard your transmitter.



/ 14 Limitations

14.1 When to use your blood glucose meter for treatment decisions

You can use your GlucoMen Day CGM to make treatment decisions without taking a blood glucose test. Although in most cases you can use your GlucoMen Day CGM to make treatment decisions, it is important to understand situations when you do need to perform a blood glucose test before making treatment decisions.

 **IMPORTANT:** When using the GlucoMen Day CGM, always carry a blood glucose meter.

When to use your blood glucose meter	Why you need to use your blood glucose meter
You have symptoms of low blood glucose or your symptoms don't match the glucose level displayed on the CGM.	If the glucose level on the CGM does not match your symptoms, you should perform a blood glucose test using your meter and treat accordingly.
You question the glucose level displayed on the CGM.	If the glucose level displayed on the CGM is not what you expected to see, perform a blood glucose test to ensure you make the correct treatment decision.
Your CGM does not display a current glucose level.	If the CGM does not display a glucose level, the only way to know your current glucose level is to perform a blood glucose test with your meter.
Your CGM does not display a trend arrow.	If the CGM does not display a trend arrow, the CGM does not have enough information to provide a trend and should not be used for treatment decisions.

When to use your blood glucose meter	Why you need to use your blood glucose meter
Your CGM is displaying estimated glucose values (ESTIMATED GLUCOSE banner appears).	If the CGM is displaying estimated glucose values, the quality of CGM glucose readings may be lower than usual. Perform a blood glucose test to ensure you make the correct treatment decision.

14.2 Travelling with your GlucoMen Day CGM

When travelling with your GlucoMen Day CGM, you may encounter situations that require special consideration. These include going through security and travelling by aeroplane.

The GlucoMen Day System has been tested up to an altitude of 3048 metres (10,000 feet).

What you encounter	What you need to know
Metal detector	It is safe to wear your GlucoMen Day CGM when going through metal detectors.
Full-body scanner	Use of the GlucoMen Day CGM has not been studied in full-body scanners. Request a different screening method, such as hand-wanding or full body pat down and visual inspection.
X-ray	Use of the GlucoMen Day CGM has not been studied in X-rays. Request a different screening method, such as visual inspection.
On an aeroplane	It is safe to use your GlucoMen Day CGM on an aeroplane. You will continue to receive CGM readings as long as your smart device has Bluetooth turned on with your smart device in aeroplane mode.

/ 15 Troubleshooting

15.1 Continuous glucose reading issues

Issue	Solution
CGM readings are not displayed on the HOME screen	<p>If the HOME screen shows a message instead of a glucose reading, see SECTION 6.3.6 for details about the message.</p> <p>If the HOME screen shows - - - instead of a glucose level:</p> <ul style="list-style-type: none"> You may need to calibrate. Tap CALIBRATE or the TIME TO CALIBRATE banner (if it is visible) to calibrate. See CHAPTER 5 for details about calibration.
	<ul style="list-style-type: none"> Your transmitter may have lost communication with the app. Make sure the transmitter and app are within 3 metres (10 feet) of each other and Bluetooth is on. Check to make sure the HOME screen shows a check mark inside of the transmitter signal icon. There may be a temporary sensor issue. When this happens, the time on the HOME screen will update but glucose levels will not be displayed. The issue generally resolves itself and, once resolved, glucose levels will begin displaying again.
Data missing on the trend chart on the HOME screen	If your transmitter and app lose communication, there may be a gap in the data because readings were not sent to the app. Once communication is restored, the gap may be filled in if the transmitter was collecting data during that time.

Issue	Solution
CGM readings are significantly different from blood glucose meter readings	<p>The GlucoMen Day CGM measures glucose levels in the interstitial fluid that surrounds cells in the body, while blood glucose meters measure glucose levels in blood.</p> <p>These two glucose levels can be different because glucose usually moves first to blood vessels and capillaries and then into the interstitial fluid. That means there may be a delay between when blood glucose levels change and when interstitial fluid glucose levels change. This difference can be more pronounced when your glucose is rapidly changing.</p>
The HOME screen shows an ESTIMATED GLUCOSE banner	See SECTION 6.5 for details about estimated glucose.
The HOME screen shows > 22.2 mmol/L	The CGM only displays glucose levels 2.2-22.2 mmol/L. Glucose levels above 22.2 mmol/L are displayed as > 22.2 mmol/L .
The HOME screen shows < 2.2 mmol/L	The CGM only displays glucose levels 2.2-22.2 mmol/L. Glucose levels below 2.2 mmol/L are displayed as < 2.2 mmol/L .
Glucose readings are in the wrong unit of measure (mg/dL or mmol/L)	<p>The glucose units of the app are determined by the country selected under PROFILE.</p> <p>See SECTION 11.2 for details about changing your country.</p>

15.2 Alert issues

Issue	Solution
Not receiving alerts	<p>Try the following:</p> <ul style="list-style-type: none"> • Make sure the alert is turned on. See SECTION 7.4. • Make sure you have allowed notifications on your smart device. See SECTION 7.3. • Make sure that a session is in progress. See CHAPTER 4.

15.3 Calibration issues

There are times when calibration is not possible. The following table describes common issues that prevent you from calibrating.

Issue	Solution
CALIBRATE button disabled	<p>The CALIBRATE button is disabled when calibration is not possible.</p> <p>There are several reasons you may not be able to calibrate:</p> <ul style="list-style-type: none"> • Your glucose is changing more than 0.11 mmol/L per minute. This corresponds to a trend arrow that points up or down on the HOME screen. • Your sensor current is changing more than the acceptable amount. • Another process is in progress, such as the sensor stabilisation period. • You are in the first 6 hours of the session and have already calibrated once. • The session has not started. <p>On the HOME screen, tap the icon (⊗) or the CANNOT CALIBRATE RIGHT now banner (if it is visible) for details about why calibration is not possible.</p>

Issue	Solution
<p>SAVE button is disabled on the NEW CALIBRATION screen.</p>	<p>The SAVE button is disabled if:</p> <ul style="list-style-type: none"> • You have not manually entered a blood glucose reading. • OR your manually entered blood glucose reading is outside the range of 3.9-13.9 mmol/L. <p>If you haven't entered a blood glucose reading, enter one.</p> <p>If your blood glucose is outside of 3.9-13.9 mmol/L, wait until your blood glucose is within 3.9-13.9 mmol/L before trying to calibrate. Follow instructions from your healthcare professional to raise or lower your blood glucose level as needed.</p>
<p>A CALIBRATION ERROR message appears.</p> <p>Message: Make sure your hands are clean and dry and retest within 10 minutes.</p>	<p>You have entered a calibration reading that the system cannot accept because the difference between the blood glucose meter reading and the CGM reading is too large.</p> <p>Closely follow the instructions in the app, which will direct you to perform additional calibrations that will eventually be accepted by the system.</p> <p>The number of additional calibrations depends on how many hours into the session you are:</p> <ul style="list-style-type: none"> • In the first 48 hours, you will need to perform one additional calibration. • After 48 hours, you may need to perform up to three additional calibrations after the initial error message. <p>This message can also appear if the calibration reading cannot be used because the system has detected a temporary issue with the sensor.</p>

Issue	Solution
<p>A CALIBRATION ERROR message appears.</p> <p>Message: Wait at least one hour before trying again.</p>	<p>You have entered a calibration reading that the system cannot accept because the difference between the blood glucose meter reading and the CGM reading is too large.</p> <p>Closely follow the instructions in the app, which will direct you to perform additional calibrations that will eventually be accepted by the system.</p>
<p>A CALIBRATION ERROR message appears.</p> <p>Message: The calibration reading is more than 5 minutes old. Please try again.</p>	<p>The calibration reading cannot be used because the blood glucose meter reading is more than 5 minutes old. This can happen if the app loses the connection with the transmitter and cannot immediately send the calibration reading.</p> <p>Retest.</p>
<p>Calibration reading not accepted after tapping SAVE.</p>	<p>In rare cases, your calibration reading may not be accepted after you tap SAVE.</p> <p>There are several reasons you may not be able to calibrate:</p> <ul style="list-style-type: none"> Your glucose is changing more than 0.11 mmol/L per minute. This corresponds to a trend arrow that points up or down on the HOME screen. Your sensor current is changing more than the acceptable amount. <p>If any of the above apply, the app will display a CANNOT CALIBRATE message explaining why it cannot save the reading. You may need to wait for your glucose to stabilise before you can calibrate.</p>

15.4 Sensor issues

Issue	Solution
<p>Gap between the sensor insertion tool and sensor assembly</p>	<p>If there is a gap, the sensor insertion tool is not correctly attached to the sensor assembly and cannot be used to insert the sensor.</p> <p>See SECTION 15.7 to fix the gap and reattach the sensor assembly to the sensor insertion tool.</p>
<p>Sensor adhesive patch will not stick to skin</p>	<ul style="list-style-type: none"> Prior to insertion, make sure the site is properly cleaned and dried. See SECTION 4.3 for cleaning instructions. If you notice the edges of the adhesive patch are becoming frayed or not sticking to your skin, apply the overpatch (SECTION 15.7) or medical tape to the edges to help secure the patch.
<p>Broken sensor</p>	<p>If the sensor filament appears to be broken, contact Customer Service to determine the proper course of action.</p>
<p>The sensor is no longer fully inserted.</p>	<p>Solution: Stop the session and remove the sensor. Insert a new sensor to start a new session.</p>
<p>Discomfort or irritation at the insertion site or when inserting the sensor</p>	<p>You should only insert the sensor on your abdomen or lower side. See SECTION 4.2 for details about choosing an insertion site.</p> <p>Ask your healthcare professional about the best sensor insertion site and rotation pattern for you. Although unlikely, you may experience bleeding, swelling, bruising, or infection at the sensor insertion site are possible.</p> <p>If any of these conditions occur, get treatment advice from your healthcare professional.</p>
<p>Sensor not working after immersing in water</p>	<p>If the issue is not resolved after 1 hour, stop the session, remove the sensor and insert a new sensor to start a new session.</p>

Issue	Solution
<p>A SENSOR STATUS message appears.</p> <p>Message: Is your sensor still inserted?</p>	<p>If the sensor is inserted, select YES and the session will continue. If the sensor is still not detected after 2 hours, the session will end automatically.</p> <p>If the sensor is not inserted, select NO to end the session.</p> <p>The sensor removal detected event will be logged in the Alert History.</p>

15.5 Transmitter issues

Issue	Solution
Cannot connect a transmitter to the app	<p>Check the following:</p> <ul style="list-style-type: none"> • The transmitter is in the charger. • The transmitter and app are within 3 metres (10 feet) of each other and Bluetooth is on. <p>If the transmitter was previously connected to your smart device but now will not connect:</p> <ol style="list-style-type: none"> 1. Navigate to the Bluetooth settings on your smart device (not in the GlucoMen Day App). 2. Check the list of paired devices. If the transmitter is listed, delete it. 3. Try pairing again. See SECTION 3.3 for details.
Transmitter is not listed as an AVAILABLE TRANSMITTER	The transmitter and the app are not connected. See SECTION 3.3 for details about connecting a transmitter.
Cannot activate a transmitter	<p>Check the following:</p> <ul style="list-style-type: none"> • Is the transmitter in the charger? The transmitter cannot be activated while in the charger. • Are the transmitter and app within 3 metres (10 feet) of each other and is Bluetooth on?

Issue	Solution
Cannot start a session	<p>Once you have inserted a new sensor, it may take 1-3 minutes for the app to detect the sensor.</p> <p>Reasons a session may not be able to start:</p> <ul style="list-style-type: none"> • There is a problem with the sensor. Follow the instructions in CHAPTER 13 to remove the sensor.
The session ended early	<p>The session will end early if:</p> <ul style="list-style-type: none"> • There is an issue with the sensor that cannot be corrected. • OR the system detects that the sensor may have been removed, and when prompted, you confirm that the sensor is no longer inserted. <p>Follow the instructions in CHAPTER 13 to remove the sensor.</p> <p>Contact Customer Service for further information.</p>
Transmitter battery is low	<p>If you are currently using the transmitter for a session, you may continue to use it, but the transmitter might not last for the full 14-day session. A LOW TRANSMITTER BATTERY message will appear when the transmitter battery has 30% remaining and will continue to appear with each 5% decrease. Do not remove the transmitter during a session. If you want to remove the transmitter, stop the session, remove the sensor, and charge the transmitter. You will need to insert a new sensor to start a new session.</p> <p>If you are not currently using the transmitter for a session, place it in the charger. When the charger light is solid green, the transmitter is fully charged.</p> <p>See SECTION 8.4 for details about charging the transmitter.</p> <p>NOTE: To see the transmitter battery level, in the app, tap the DEVICES button and tap TRANSMITTERS. Under AVAILABLE TRANSMITTERS, tap the active transmitter. The battery level of the transmitter is displayed under BATTERY LEVEL, along with the time since the battery level was last updated.</p>

15.6 Transmitter charger issues

Issue	Solution
Charger light is flashing red	<p>There is an issue with either charging or pairing the transmitter.</p> <p>If you are trying to charge the transmitter and the light is flashing red instead of green, the transmitter is not charging. Try the following options to correct the issue:</p> <ul style="list-style-type: none"> • Remove the transmitter and place it back in the charger. • Remove the USB cable and reinsert it into the USB port. • If the charger is plugged into a computer, make sure the computer is on. • If the charger is plugged into a wall adapter, unplug the adapter and plug it in again. <p>If the issue is not resolved, contact Customer Service for a replacement.</p>
Charger light is solid red	<p>There may be a temporary issue with either the charger or the transmitter.</p> <p>If you are trying to pair the transmitter and the charger light turns solid red for 10 seconds, the transmitter was not successfully paired with the app. Try pairing again (SECTION 3.3). Make sure the transmitter and app are within 3 metres (10 feet) of each other and Bluetooth is on.</p> <p>If the charger light is solid red for more than 10 seconds, try the following to correct the issue:</p> <ol style="list-style-type: none"> 1. Leave the transmitter in the charger and disconnect the charger from its power source (wall adapter or computer USB port) for five seconds. 2. Reattach the charger to the power source. <p>If the issue is not resolved, disconnect the charger from its power source and contact Customer Service.</p>

15.7 Sensor insertion issues

Issue

There is a gap between the sensor insertion tool and the sensor assembly.

If there is a gap between the sensor insertion tool and the sensor assembly, the sensor insertion tool is not properly attached to the sensor assembly and should not be used to insert the sensor.

Solution

Follow the next steps to remove the sensor assembly so you can try to attach it again.

1. Locate the release tab on the bottom of the sensor insertion tool.

NOTE: You will need to slightly peel back the narrow end of the sensor adhesive patch to find the release tab



2. While pushing up on the release tab, pull back on the sensor assembly. Once you have removed the sensor assembly from the sensor insertion tool, go back to **SECTION 4.8**.



Issue

Edges of the adhesive patch are peeling up.

Solution

Follow the next steps to apply the overpatch, if needed.

NOTE: The overpatch is only needed if you notice that the edges of the adhesive patch are starting to come up.

1. Fold the overpatch along the line that divides the two halves of the liner, with the liner side facing outwards. Peel off the liner, starting in the centre, where the two halves of the liner meet.



IMPORTANT: Make sure the overpatch does not fold on itself before or during application.

2. Apply the overpatch so that it covers the edges of the adhesive patch.



/ 16 Connected Partners

16.1 Adding a connected partner

In order to add a connected partner, you need an activation code from the partner with whom you want to share. If you have not received a code, contact the partner to request one.

1. In the app, tap the **PROFILE** button. On Android devices, you may need to tap the **BACK ARROW** until

you see the bottom buttons.

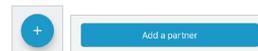
2. Tap **CONNECTED PARTNERS**.



4. In the **ENTER CODE** field, enter the activation code you received from your connected partner software or app.



3. On Android: Tap the (+) button. On iOS: Tap **ADD A PARTNER**.



5. Tap **ACTIVATE**. The partner will be listed under **YOUR PARTNERS** on the **CONNECTED PARTNERS** screen. Your data will be automatically sent to the partner until you deactivate the partner.



16.2 Deactivating a connected partner

1. In the app, tap the **PROFILE** button.

On Android devices, you may need to tap the **BACK ARROW** until you see the bottom buttons.

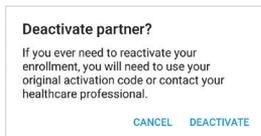
2.
Tap **CONNECTED PARTNERS**.

3.
Under **YOUR PARTNERS**, tap the partner you want to deactivate.

4.
Tap **DEACTIVATE**.



5.
Tap **DEACTIVATE** to confirm the deactivation. The partner will be removed from your list of partners and your data will no longer be sent to the partner.



 **IMPORTANT:** If you ever need to reactivate your enrollment, you will need to use the original activation code or contact your healthcare professional.

/ 17 Additional information

17.1 Customer Service information

For help with your GlucoMen Day CGM system, call Customer Service. A list of Customer Service numbers can be found in the **INFO** section of the app.

In case of emergency, contact your healthcare professional or emergency medical response.

17.2 Cleaning your system

The GlucoMen Day CGM System is for single patient use.

Clean in general

Your CGM system parts should be cleaned only as needed to remove visible dirt and debris. This does not reduce the risk for transmission of infectious diseases. For more assistance, call Customer Service.

Clean the sensor insertion tool and transmitter

Clean the transmitter and exterior of the sensor insertion tool with a moist (not wet) lint-free tissue. You should use one of the following:

- Water
- Isopropyl alcohol 70% solution
- Mild detergent

Carefully wipe dry all parts with a dry lint-free tissue.

CAUTION

- Do not share the system parts with anyone, including other family members! Do not use on multiple patients! The sensor and sensor assembly are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning.
- Do not clean the transmitter charger, as cleaning solutions may cause USB port connection issues or corrosion of electrical contacts.
- Do not clean the transmitter while it is in use or placed in the charger.

- Be careful and gentle while cleaning the transmitter contacts.

17.3 System disposal

Consult your local regulations when disposing of the sensor insertion tool, the sensor guide, the transmitter, and the charger.

Dispose of the sensor adhesive patch as medical waste.

17.4 Product specifications

17.4.1 Sensor specifications

Specification	Description
Glucose range	2.2–22.2 mmol/L
Sensor life	Up to 14 days
Calibration	GlucoMen Day METER (provided separately) or commercially available blood glucose meter.
Calibration range	3.9–13.9 mmol/L
Storage temperature	5°C to 35°C (41°F to 95°F)
Storage humidity	10% - 90% Relative humidity
Operating temperature	5°C to 45°C (41°F to 113°F)
Sterilization	Sterile by irradiation
Altitude	Up to 3048 metres (10,000 feet)
Atmospheric pressure	700 hPa - 1060 hPa

17.4.2 Transmitter specifications

Specification	Description
Transmitter battery type	Non-serviceable, rechargeable lithium-ion polymer battery
Transmitter battery life	14 days of typical use
Transmitter life	5 years of average continuous use
Transmitter data storage	14 days of calculated glucose data, sampled once per minute
Transmitter dimensions	Length: 33.0 mm, width: 24.0 mm, thickness: 9.0 mm
Transmitter weight	5 grams
Ingress Protection	IP27: Protection against insertion of large objects and immersion in 1 metre (3 feet) of water for up to 30 minutes.
Operating temperature	5°C to 45°C (41°F to 113°F)
Operating humidity	10% - 100% Relative humidity, condensing
Storage temperature	5°C to 45°C (41°F to 113°F)
Storage humidity	10% - 100% Relative humidity, condensing
Protection against electrical shock	Type BF applied part
TX Frequency	2.402–2.480 GHz
Reading Frequency	Every 1 minute
Bandwidth	1.06 MHz
Maximum Output Power	-2.93 dBm
Modulation	Gaussian FSK
Altitude	Up to 3048 metres (10,000 feet)
Atmospheric pressure	700 hPa - 1060 hPa

17.4.3 Sensor insertion tool specifications

Specification	Description
Life	5 years

17.4.4 Transmitter charger specifications

Specification	Description
Life	5 years
Storage temperature	5°C to 45°C (41°F to 113°F)
Operating temperature	5°C to 45°C (41°F to 113°F)
Altitude	Up to 3048 metres (10,000 feet)
Atmospheric pressure	700 hPa - 1060 hPa

17.4.5 AC wall adapter specifications

NOTE: the AC wall adapter is not included.

Specification	Description
Class	II, 60601-1-2 4th ed. and 60601-1 ed. 3.1 compliant
Input	AC Input 100-240 Vac, 50/60Hz, 0.2A, 0.2A rms at 100 Vac
DC output	5VDC (fixed), 0.1A (minimum)
Output connector	USB type A receptacle

17.4.6 USB charging cable specifications

The USB charging cable can be used for powering the transmitter charger. The USB charging cable can be connected to a PC USB port that can meet the input and connector type specifications listed to the right.

The charger can be isolated by unplugging the USB charging cable from the PC. Misuse of the USB cable can present electric shock hazards.

NOTE: If necessary, the USB charging cable can be used with an AC wall adapter, connected to an AC power outlet that can meet the specifications listed in **SECTION 17.4.5**.

⚠ CAUTION

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Specification	Description
Operating temperature	5°C to 45°C (41°F to 113°F)
Storage temperature	5°C to 45°C (41°F to 113°F)
Input/output	5 VDC, 0.5A
Connector type	USB A (male) to USB micro B (male)
Length	1 metre (3 feet)

17.5 Labelling symbols

These symbols can be found on your GlucoMen Day CGM System packaging.

Symbol	Description
	Operating instructions
	Manufacturer
	Caution
	Use-by date
	Do not reuse
	Type BF applied part
	MR unsafe
	Do not use if package is damaged
	Contents
	Recycle: Electronic equipment
	NSerial number
	Batch/Lot number
	Part/Catalogue number

Symbol	Description
	Authorised Representative in the European Community
	CE Mark
	Sterilised using irradiation
	Non-ionizing radiation
	Keep dry
	Humidity limitation
	Temperature limitation
	Bluetooth® trademark
	Protection against insertion of large objects and immersion in water
	Direct current
	Medical Device
	Assembler

17.6 Accuracy Summary

Refer to www.glucomenday.com website.

17.7 Electromagnetic compatibility

The GlucoMen Day CGM system complies with the EU Radio Equipment Directive for wireless transmission and electromagnetic compatibility requirements defined in 2014/53/EU.

The complete text of the declaration of EU conformity is available at www.red.menariniagnostics.com.

The Transmitter meets the essential data transmission requirements for operating in the 2.4 GHz ISM band per ETSI EN 300 328 v2.1.1. Due to the continuous nature of the CGM system's wireless communication, the user should not enter or discontinue use in locations where mobile phones and other radio transmitters are not permitted, such as some hospitals and healthcare professional offices. Refer to **SECTION 14.2** Travelling with your GlucoMen Day CGM for additional locations.

The GlucoMen Day CGM system complies with the electromagnetic compatibility immunity requirements defined in ETSI EN 301 489-1 v2.1.1, ETSI EN 301 489-17 v3.1.1, and IEC 60601-1-2.

Emissions from nearby electronic equipment are not likely to interfere with the GlucoMen Day CGM system when used in a home healthcare environment. These may interfere with the proper operation of the GlucoMen Day CGM system. Moving away from or turning off these electronic devices may allow communication.

If interference does occur and the following device behaviour is observed:

- Loss or incorrect CGM measurements
- Loss of transmitter charging capabilities

The user can mitigate the situation by following the solutions recommended in **CHAPTER 15** Troubleshooting.

⚠ CAUTION

- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the GlucoMen Day CGM system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

17.7.1 Guidance and manufacturer's declaration — electromagnetic emissions

The GlucoMen Day CGM system is intended for use in the electromagnetic environment as specified below. The customer or the user of the GlucoMen Day CGM system should assure that it is used in such an environment.

Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B

17.7.2 Guidance and manufacturer's declaration — electromagnetic immunity

The GlucoMen Day CGM system is intended for use in the electromagnetic environment specified below. The customer or the user of the GlucoMen Day CGM system should assure that it is used in such an environment.

NOTE: U_T is the a.c. mains voltage prior to application of the test level.

NOTE: At 80 MHz and 800 MHz, the higher frequency range applies.

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

Immunity test	Nível de conformidade
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact $\pm 2, 4, 8, 15$ kV air
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines 100 kHz
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_r for 0.5 cycle @ 8 phase angles 0% U_r for 1 cycle 70% U_r (30% dip in U_r) for 25 cycles @ 0 degrees 0% U_r for 250 cycles
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80% AM @ 1kHz
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz

17.8 Warranty

We extend a limited warranty to customers who buy a new CGM System. Under this limited warranty, your new CGM transmitter is covered for a period of Two (2) years from the date of manufacture, your new Sensor Insertion Tool

is warranted for Two (2) years from its date of manufacture, your new CGM Charger is warranted for Two (2) years from its date of manufacture and your new CGM Sensor is warranted up its date of expiration. This warranty is in effect as long as the components of your CGM System have not been modified, altered, or misused. Under this warranty we will replace, free of charge, any CGM component that is defective in material or workmanship. In order to have Your CGM replaced under this warranty, please call Customer Service. No other warranties, express or implied, are made. We will not be liable for any incidental or consequential damages you may incur. This warranty gives You specific legal rights, and You may also have other rights that vary from state to state. We may discontinue this program at any time without notice.

/ 18 Glossary of terms

Blood glucose meter

A device used to measure the levels of glucose in the blood.

Blood glucose reading

The concentration of glucose in the blood, measured as either milligrams of glucose per deciliter of blood (mg/dL) or millimoles of glucose per liter of blood (mmol/L).

Calibration

The act of comparing measurements to check, adjust, or set to a standard; provides the necessary information to ensure that the GlucoMen Day App accurately displays your glucose levels.

Continuous glucose monitor (CGM)

A CGM uses a small sensor inserted below your skin to measure the amount of glucose in the fluid in your skin, called interstitial fluid. Those glucose readings are then sent to an app, where they are displayed as glucose levels and long-term glucose trends.

Hyperglycaemia (high blood glucose)

High levels of glucose in the blood, also known as high blood glucose. When left untreated, hyperglycaemia can lead to serious complications.

Talk to your healthcare profes-

sional to determine your high glucose level.

Hypoglycaemia (low blood glucose)

Low levels of glucose in the blood, also known as low blood glucose. When left untreated, hypoglycaemia can lead to serious complications.

Talk to your healthcare professional to determine your low glucose level.

Insulin

A hormone produced by the pancreas that regulates the metabolism of glucose and other nutrients. Insulin injections may be prescribed by a healthcare professional to help people with diabetes process glucose (sugar), if their pancreas is damaged and does not produce insulin.

Gaining unauthorised access to a smart device's operating system by removing restrictions set by the manufacturer. This presents a security risk.

Do not install the GlucoMen Day app on a smart device that has been jailbroken or rooted.

Ketones

Chemicals that the body creates when breaking down fats for energy. If ketones build-up in the blood, they can lead to serious complications.

Limitations

A safety statement outlining specific situations in which the GlucoMen Day CGM should not be used because it may be harmful to you or damage the system.

mg/dL

Milligrams per deciliter; one of two standard units of measure for the concentration of blood glucose (sugar).

mmol/L

Millimoles per liter; one of two standard units of measure for the concentration of blood glucose (sugar).

Smart device

To see a list of compatible smart devices, visit www.menarinidiagnostics.com



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