S9 CGM System

Continuous Glucose Monitoring System

User Guide

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Simplify Your Diabetes

Medtrum

S9 CGM System

Continuous Glucose Monitoring System

User Guide

Medtrum Technologies Inc.
Building 3 and Building 8, No. 200,
Niudun Road
Shanghai 201203, China
Tel: +86-21-50274781
Fax: +86-21-50274779
www.medtrum.com

EC REP

Medtrum B.V.
Nijverheidsweg 17
5683 CJ Best
The Netherlands
Tel: +31 (0) 499745037

CE 0197

This product complies with Directive 93/42/EEC (MDD) and Directive 2014/53/EU (RED).

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Content

1.1 Before You Begin

The S9 CGM System incorporates a Glucose Sensor and a Transmitter. The Glucose Sensor measures the glucose level of interstitial fluid. The Transmitter wirelessly transmits your real-time Sensor glucose information to the Medtrum EasySense moible app on your phone.

Not all devices or accessories are available in all countries where the TouchCare® Continuous Glucose Monitoring System is approved. To order supplies, contact your local representatives.

1.2 Indications

The TouchCare® Continuous Glucose Monitoring System is indicated for use in people (age 2 -75 years) with diabetes. The system is intended for single patient use.

The CGM System is indicated for continuous monitoring of interstitial fluid glucose levels, and detecting possible low and high glucose episodes. Interpretation of the CGM System results should be based on the glucose trends and several sequential readings.

1.3 Contraindications

The S9 CGM System is not recommended for people who are unwilling or unable to:

- Maintain contact with their healthcare provider.
- Test their blood glucose levels at least once per day. Test your blood glucose and use blood glucose to make decision when your glucose is falling or rising rapidly or sensor glucose reading don’t match your feelings.
- Recognize and respond to alerts and alarms. (Sufficient vision and/or hearing are required.)

1.4 User Safety

1.4.1 Warnings and Precautions

General

Make sure that you have read and are familiar with the *User Guide* before using the CGM System. Failure to follow the instructions may result in pain or injury and may also affect the system's performance. If you do not understand something or have questions, ask your healthcare provider, call customer support, or contact your local Medtrum distributor.

No modification of this system is allowed.

Do NOT use the S9 CGM System if you have delicate skin or if you are allergic to acrylic adhesives.

Do NOT use anything other than the accessories specified in this *User Guide*, which could permanently damage your system and voids its warranty.

Do NOT allow young children to hold the Transmitter or Sensor without adult supervision. The Transmitter and Sensor contain small parts and could pose a choking hazard.

Do NOT operate your S9 CGM System in the presence of flammable anesthetics or explosive gases.

Do NOT use protector solar or insect repellent.

The S9 CGM System includes active medical devices. When you dispose of any device in the system, follow the local waste disposal regulations.

Do NOT ignore symptoms of high or low glucose. If you believe your sensor glucose readings are inconsistent with how you feel, manually measure your blood glucose with a blood glucose meter. If the problem continues, discard

the old Sensor and insert a new one.

The Sensor may create special needs regarding your medical conditions or medications. Please discuss these conditions and medications with your healthcare provider before using the Sensor.

If you suspect your Sensor is broken during usage, do NOT attempt to remove it yourself. Contact your healthcare provider for assistance in removing the Sensor.

Operating Temperature Range

Your S9 CGM System is designed to operate between 5°C (41°F) and 40°C (104°F). Do NOT expose the system to temperatures outside that range. Do NOT expose the system to direct sunlight for a long period of time.

Cleaning

Do NOT use household cleaners, chemicals, solvents, bleach, scouring pads or sharp instruments to clean your Transmitter. Small amounts of rubbing alcohol can be used to clean the surface of your Transmitter. Never put your Transmitter in the dishwasher or use very hot water to clean it.

Do NOT use a hair dryer, microwave oven or conventional oven to dry your Transmitter. Use a soft towel.

Do NOT clean any part of the system while it is in use.

X-rays, MRIs and CT Scans

The S9 CGM System may be affected by strong radiation or magnetic fields. If you are going to have an X-ray, MRI, CT scan or other type of exposure to radiation, remove your Sensor and Transmitter, and put them outside the treatment area. Change the Sensor after the test or procedure is completed.

The S9 CGM System is designed to tolerate common electromagnetic and electrostatic fields, including airport security systems and cellular phones.

1.4.2 Consumables

Glucose Sensor—The Transmitter (MD1160) is only used with the Medtrum Glucose Sensor (MD3660). Change your Glucose Sensor every fourteen days.

Warning: For your protection the Transmitter has undergone extensive testing to confirm appropriate operation when used with Glucose Sensors manufactured or distributed by Medtrum. We recommend using Medtrum Glucose Sensors as we cannot guarantee appropriate operation if the CGM system is used with sensors offered by third-parties and therefore we are not responsible for any injury or malfunctioning of the CGM system that may occur in association with such use.

1.4.3 Radio Frequency (RF) Communication

The S9 CGM System can generate, use, and radiate radio frequency energy, and may cause harmful interference to radio communications. There are no guarantees that interference will not occur in a particular installation. If the S9 CGM System does cause harmful interference to radio or television reception, you are encouraged to try to correct the interference by one of the following measures:

- Move or relocate the S9 CGM System.
- Increase the distance between the S9 CGM System and the other device that is emitting/receiving interference.

Common consumer electronic devices that transmit in the same frequency band used by the S9 CGM System may prevent communication between your Transmitter and smart device. This interference, however, does not cause any incorrect data to be sent and does not cause any harm to your device.

Based on GFSK modulation, the system communicates at frequencies between 2402 and 2480 MHz with power level 0 dBm. RF communication between your Transmitter and smart device works up to a distance of 10

meters (33 feet).

1.4.4 Water

The Sensor is water resistant when showering, bathing or swimming if the Transmitter is fully snapped in. They form a water-tight seal to a depth of 2.5meters for up to 60 minutes. However, hot water may decrease Sensor life. After exposure to water, rinse the device with clean water and dry it with a towel.

Warning: The Transmitter may not be able to send sensor information normally in water. Do NOT expose your Sensor and Transmitter to water at depths greater than 2.5 meters (8 feet) or for more than 60 minutes. Check often to make sure the Transmitter and Sensor are securely attached and in place.

1.4.5 Storage

Store the Sensor at temperatures between 2°C (36°F) and 30°C (86°F), and at humidity levels between 20% and 90% relative humidity for the length of the Sensor's shelf life. For temperatures greater than 30°C (86°F), the Sensor will require cooled storage at temperatures no lower than 2°C (36°F). You may store the Sensor in the refrigerator if it is within this temperature range. The Sensor should not be stored in the freezer. Allow the Sensor to warm to room temperature before usage to prevent condensation. Storing the Sensor improperly may cause the Sensor glucose readings to be inaccurate, and you might miss a low or high blood glucose value.

Store the Transmitter at temperatures between -10°C (14°F) and 55°C (131°F), and at humidity levels between 20% and 90% relative humidity.

1.5 Warranty Information

Medtrum Technologies Inc. ("Medtrum") warrants its Transmitter against defects in materials and workmanship for the period of 1 year from the original date of shipment of the Transmitter to the original end use purchaser (the "Warranty Period"). During the Warranty Period, Medtrum will, at its discretion, either repair or replace (with a new or recertified Transmitter at Medtrum's discretion) any defective Transmitter, subject to the conditions and exclusions stated herein. This Warranty applies only to new devices and, in the event the Transmitter is repaired or replaced, the warranty period shall not be extended.

The warranty is valid only if the Transmitter is used in accordance with Medtrum's instructions and will not apply:

- If damage results from changes or modifications made to the Transmitter by the user or third persons after the date of manufacture;
- If damage results from service or repairs performed to any part of the Transmitter by any person or entity other than Medtrum;
- If a non-Medtrum Glucose Sensor is used with the Transmitter;
- If the Transmitter has been used in conjunction with accessories, ancillary products, or peripheral equipment, whether hardware or software, not furnished or approved by Medtrum.
- If damage results from a *Force Majeure* or other event beyond the control of Medtrum; or
- If damage results from negligence or improper use, including but not limited to improper storage or physical abuse such as dropping or

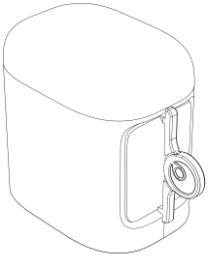
otherwise.

This warranty shall be personal to the original end use purchaser. Any sale, rental or other transfer or use of the Transmitter covered by this warranty to or by a user other than the original end use purchaser shall cause this warranty to immediately terminate. This warranty only applies to the Transmitter and does not apply to other products or accessories.

THE REMEDIES PROVIDED FOR IN THIS WARRANTY ARE THE EXCLUSIVE REMEDIES AVAILABLE FOR ANY WARRANT CLAIMS. NEITHER MEDTRUM NOR ITS SUPPLIERS OR DISTRIBUTORS SHALL BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL, OR SPECIAL DAMAGE OF ANY NATURE OR KIND CAUSED BY OR ARISING OUT OF A DEFECT IN THE PRODUCT. ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, ARE EXCLUDED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

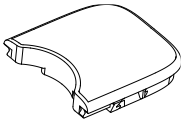
The S9 CGM System consists of three parts: a wireless Transmitter, a Glucose Sensor and Medtrum EasySense Mobile App on your smart device. The Sensor detects the glucose level in interstitial fluid and the glucose reading is updated every 2 minutes. You can upload the Sensor data to your smart device after a period of use, or you can keep the Sensor connected to your smart device and enjoy real-time readings, graphs, and alerts.

The Glucose Sensor (MD3660) contains a flexible Sensor that can be inserted just under your skin. Each inserted Sensor is intended to remain in place and provide continuous glucose readings for up to 14 days. The Sensor is the applied part in the CGM system.



Glucose Sensor
(MD3660)

The wireless Transmitter (MD1160) is a small electronic device that connects to the Sensor and sends your sensor glucose information to your smart device every 2 minutes.



Transmitter
(MD1160)

Medtrum EasySense Mobile App downloaded to your smart device works as a receiver. It displays all your sensor information, statistics and alerts. It also allows you to calibrate the Sensor, edit all the settings, and capture the events.

Medtrum EasySense Mobile App

3.1 Install the app

IOS

If you are using a smart device with the IOS, you can download the Medtrum EasySense Mobile App from the Apple App Store.

Android

If you are using a smart device with the Android system, you can download the Medtrum EasySense Mobile App from Google Play.

The smart device you install the app on must comply with EN 62368/IEC 62368-1.

If your smart device has been jailbroken, do not install the app. For information on how to install an app see your smart device's user guide.

Medtrum EasySense Mobile App cannot override your smart device settings.

If you installed the app on an IOS device, to receive alerts and use other app features you must:

1. Make sure your smart device's Bluetooth is available and turned on.
2. Make sure Silent and Do Not Disturb are off.
3. Make sure your smart device's volume is loud enough for you to hear alerts and reminders.
4. Make sure the notifications for the Medtrum EasySense Mobile App are turned on.
5. Make sure the app is allowed to use WLAN and mobile data.
6. Make sure the smart device is connected to the Internet.
7. Make sure you allow the Medtrum EasySense Mobile App to access the camera so that you can use the app to scan a transmitter serial number.
8. Make sure you allow the Medtrum EasySense Mobile App to access

photos so that you can select a photo as your profile photo in the app.

9. Make sure the Medtrum EasySense Mobile App is open and running in the background.
10. Restart the Medtrum EasySense Mobile App after your smart device is restarted.

If you installed the app on an Android device, to receive alerts and use other app features you must:

1. Make sure your smart device's Bluetooth is available and turned on.
2. For Android system 8.0 to 11.0, make sure you allow the App to access device's location so that the App can use the Bluetooth feature.
3. For Android 12.0 system or later, make sure you turn on Nearby Devices so that the App can use the Bluetooth feature to connect other device.
4. Make sure Silent and Do Not Disturb are off.
5. Make sure your smart device's volume is loud enough for you to hear alerts and reminders.
6. Make sure you permit the Medtrum EasySense Mobile app to send notifications when you are using other apps.
7. Make sure the app is allowed to use WLAN and mobile data.
8. Make sure the smart device is connected to the Internet.
9. Make sure you allow the Medtrum EasySense Mobile app to take pictures and record video so that you can use the app to scan a transmitter serial number.
10. Make sure you allow the Medtrum EasySense Mobile app to access photos, media and files on your device so that you can select a photo as your profile photo in the app.
11. Make sure the Medtrum EasySense Mobile App is open and running in the background.

12. Restart the Medtrum EasySense Mobile App after your smart device is restarted.

For information on how to set your smart device, see your smart device's user guide.

Note: Do not change your smart device's time because it can make the time on the monitor screen wrong and the app may stop displaying sensor status.

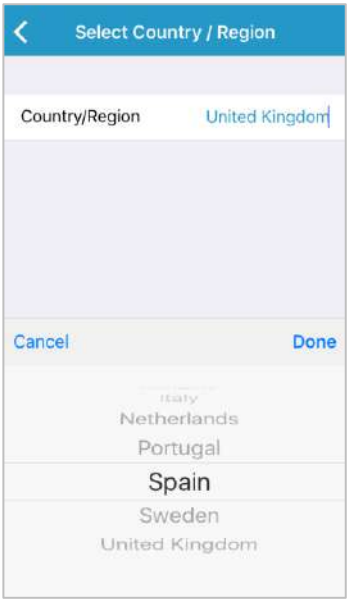
3.2 Login/Register

Make sure your smart device is connected to the Internet. Open the Medtrum EasySense Mobile App and enter the **Login** screen.

If you already have a Medtrum account, tap the national flag on the top right corner and select the country you chose upon registration, and then login with your account and password.

If you do not have a Medtrum account yet, tap **Register** at the bottom left corner to enter the register screen.

Tap the Flag Icon on the top right corner. You will now go into another screen to select the right Country/Region. Select the back arrow to return to the previous screen.



Enter your email address as your account name.

Tap the **Get Code** box once and you will receive a 6-digit Verification Code sent to you in an email by the Medtrum Team. Please make sure that you check the junk mails as well just in case the email went into that.

Enter the 6-digit Verification Code. Please take note that there is an expiry time frame of 24 hours for you to enter the code or you will have to request

for a new Verification Code and then enter the latest code sent to you.

Enter your full name so that your healthcare providers can identify you easily.

Create a password and remember that. Please tap the icon on the right side to see the password that you have entered.

- ✓ The password must contain characters from three of the following four categories:
  English uppercase characters (A through Z)
  English lowercase characters (a through z)
  Base 10 digits (0 through 9)
  Non-alphabetic characters, including ~!@#$%^&*()_-+=`{}|[]\:";'<>,.
- ✓ The password must be between 6 and 20 characters long.
- ✓ The password must be different from your username (your email address).
- ✓ The password cannot contain 3 consecutive numbers (eg: 123, 321).
- ✓ The password cannot contain 3 consecutive letters (eg: abc, cba).
- ✓ The password cannot contain spaces.

Then tap **Next**.

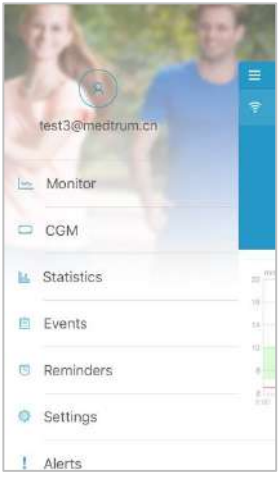
After you have read and agreed to the privacy policy and terms of use, tick the small boxes and tap **Create Account** to register your Medtrum account.

Then return to the login screen and log in with your email and password.

3.3 Main Menu

Once you log in, the **Monitor** screen will appear.

Tap ☰ at the top-left corner to open the **Main Menu** from where you can access all the features of the Medtrum EasySense Mobile App: **Monitor**, **CGM**, **Statistics**, **Events**, **Reminders**, **Settings**, and **Alerts**.



3.4 Add Transmitter SN to Your Account

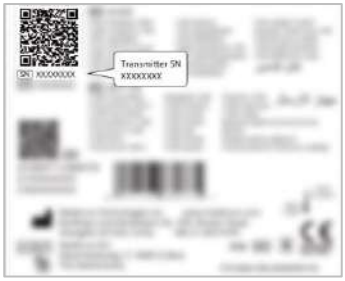
3.4.1 Add SN

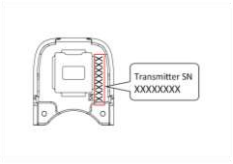
If you haven't added a Transmitter serial number (SN) to the app, you can tap "Add Transmitter" on the Monitor screen.

Or you can also tap "Add Transmitter" on the CGM screen.

Then the following screen will appear.

You can use the camera to scan the QR code on the back of your transmitter or on the transmitter box.





The transmitter SN will appear on your screen. Check if it matches the SN printed on the transmitter or on the box.

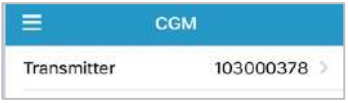
Once confirmed, your transmitter will be automatically paired with the app.

If unable to use App's camera, tap **Enter SN manually** to go to the following screen and enter the transmitter SN by hand.

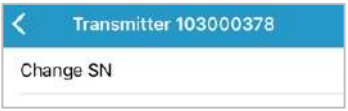
3.4.2 Change SN

Every time you change to a new Transmitter, you need to change the transmitter SN on your app.

Tap **CGM** on the **Main Menu** to enter the **CGM** screen.



Tap the existing transmitter SN, and the following screen will appear.



You can change the transmitter SN by tapping “Change SN”.

Then the following screen will appear. You can use the camera to scan the QR

code on the back of your transmitter or on the transmitter box.

Or you can enter SN manually by tapping “Enter SN manually”.

3.4.3 Delete SN

Tap **Settings** on the **Main Menu** to enter the **Settings** screen.

Tap **CGM System** to enter the CGM System settings screen.

Tap the existing transmitter SN, and the following screen will appear.

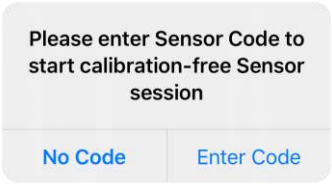
Tap **Delete Transmitter** and then confirm.

3.5 CGM

3.5.1 Start Sensor

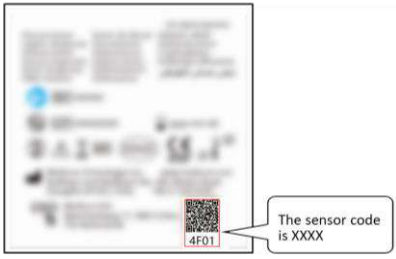
If you haven't connected a sensor, you can tap "Start Sensor" on the **Monitor** screen.

When connected to the sensor, you will be reminded to enter the sensor code.

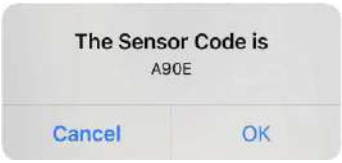


You can tap **Enter Code** to enter the sensor code, the following screen will appear. Or tap **No Code** to skip this step.

Use the camera to scan the QR code on the back of the sensor package which is unique for each sensor.



A 4-digit sensor code will be identified and displayed on your screen. Tap OK to confirm it.



If you are unable to use App's camera, tap **Enter Code Manually** to go to the following screen and enter the sensor code manually.

Once the sensor code is entered, the calibration-free sensor session will start, and no calibration is required.

3.5.2 Stop Sensor

You may stop sensor by tapping "Stop sensor" on CGM menu.

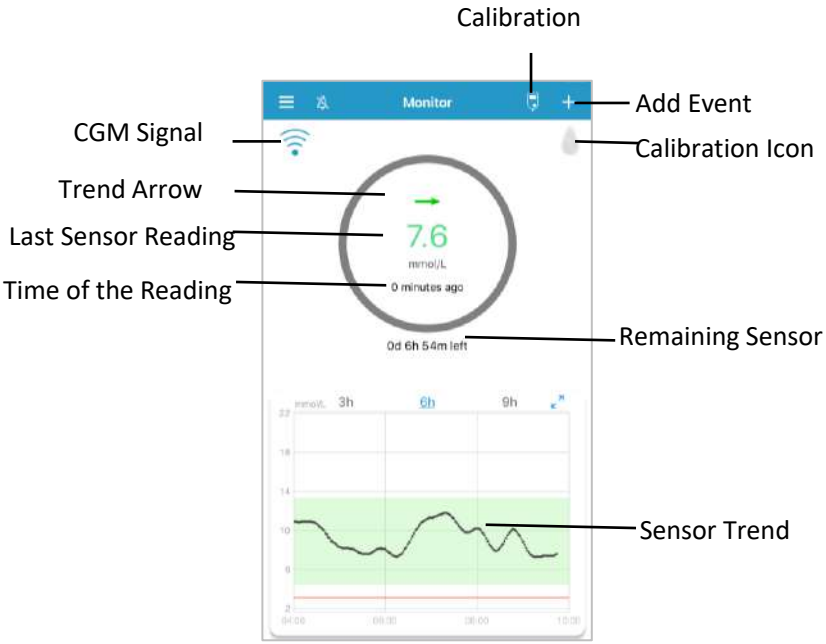
Warning: After you stop sensor, you will not be able to connect to this

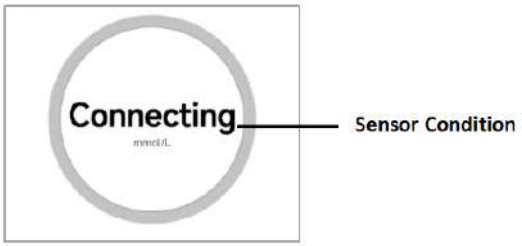
sensor again or receive any sensor glucose data or alerts.

3.6 Monitor Sensor Status

Once your Sensor and Transmitter are connected with the app, you can use the app to monitor your real-time glucose information.

Tap **Monitor** on the **Main Menu** to enter the **Monitor** screen.





i. CGM Signal

The CGM Signal icon shows the Bluetooth signal strength between the Transmitter and your smart device.

ii. Add Event

The Add Event icon provides a shortcut to add an event. The *Events* section contains more relevant information.

iii. Trend Arrow

The trend arrow shows the speed and direction of your sensor glucose readings.

Constant	→
Slowly rising	↗
Rising	↑
Rapidly rising	⇈
Slowly falling	↘
Falling	↓
Rapidly falling	⇊

No rate of change information	No arrow

iv.Last Sensor Reading & Time of the Reading

Under the trend arrow, you can find the most recent sensor reading received by the app and the time of the reading.

v.Calibration Icon

 No calibration is needed.

 A calibration is needed now.

vi.Sensor Condition

The present sensor condition is displayed under the calibration icon:

Warm-Up- the Sensor is warming up.

ERR - the Sensor shall be recalibrated after 15 minutes.

BG- the Sensor shall be recalibrated now.

??? - No readings.

LOST - Sensor signal is lost.

HIGH - Sensor glucose is above 22.2 mmol/L (400mg/dL).

LOW - Sensor glucose is below 2.2 mmol/L (40mg/dL).

Underlined reading (Only appears when no sensor code is entered) - Calibration overdue. A new meter BG is needed for calibration.

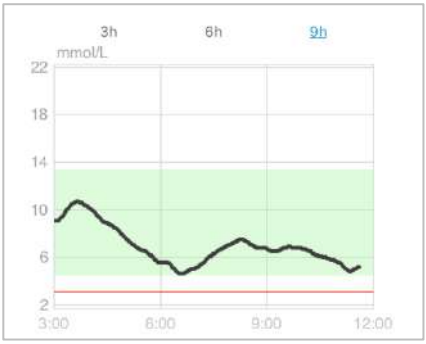
Connecting - If this message remains for long time, it indicates Bluetooth communication issue or incorrect SN.

Connecting Sensor - If this message remains for long time, it indicates sensor insertion failure.

vii.Remaining Sensor Life

Under the sensor condition is the operating life left in a total of 14 days.

1. The **Sensor Trend Graph** shows the glucose trend of the most recent 3 hours, 6 hours or 9 hours. Tap the duration to change the graph range.



3.7 Detailed Glucose Information

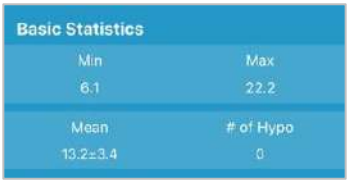
Tap the **Sensor Trend Graph** to view more detailed glucose information.
You can view the glucose data of any day when a sensor was connected to your account by either tapping  and selecting a day or tapping < / > to move back / forward.

Touch and hold in the graph area to generate a cursor. Move the cursor along the x-axis to view the sensor glucose (SG) or sensor status at different time points. The cursor will disappear after 5 seconds of no operation.

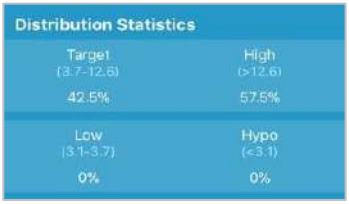
You can also pinch to zoom in on the graph area.

The Basic Statistics includes the minimum, maximum, and mean value of

sensor glucose, and the number of hypoglycemic episodes (below 3.1 mmol/L / 56 mg/dL).



The Distribution Statistics includes the percentage of target SG (target range set by user), the percentage of high SG (above the high limit of SG target range), the percentage of low SG (below the low limit of SG target range) and the percentage of hypoglycemia (below 3.1 mmol/L / 56 mg/dL).



3.8 Calibrate Your Sensor

After sensor warm-up, tap the calibration icon on the **Monitor** screen to enter the **Calibration** screen.

Enter your current finger stick blood glucose level to calibrate your sensor.

If you skip the sensor code input step, you must calibrate your sensor twice on the first day. The app will prompt you when a calibration is needed. After the initial calibration, your sensor data will be displayed in real time.

If you have entered sensor code successfully, the system won't require any calibration. But you can calibrate the sensor if you want.

Note: The calibration icon will disappear under the following circumstances:

- Smart device Bluetooth off
- Sensor warm-up
- No Readings
- Within 15 min after the Sensor Calibration Error alert
- No CGM signal

3.9 Statistics

Tap **Statistics** on the **Main Menu** to enter the **Daily Sensor Report** screen.

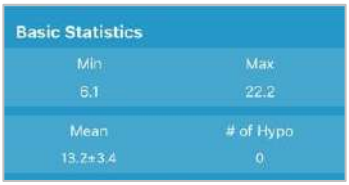
Swipe left to go to **Sensor Overlay, Trend Analysis** and **Event Summary** successively. Swipe right to return to the previous screen. If you want to view a graph in landscape mode, double tap the graph or hold your smart device horizontally.

3.9.1 Daily Sensor Report

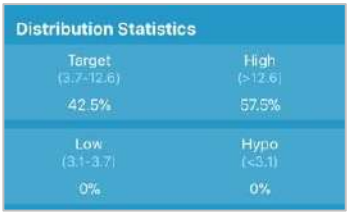
You can view the glucose data of any day when a sensor was connected to your account by either tapping and selecting a day or tapping < / > to move back / forward.

If you want to view a graph in landscape mode, double tap the graph or hold your smart device horizontally.

The **Basic Statistics** includes the minimum, maximum, and mean value of sensor glucose, and the number of hypoglycemic episodes (below 3.1 mmol/L / 56 mg/dL).



The **Distribution Statistics** includes the percentage of target SG (target range set by user), the percentage of high SG (above the high limit of SG target range), the percentage of low SG (below the low limit of SG target range) and the percentage of hypoglycemia (below 3.1 mmol/L / 56 mg/dL).



3.9.2 Sensor Overlay (iOS only)

This screen displays the sensor data overlay 7 days before a selected date, along with the daily mean SG, maximum SG, minimum SG, and times of hypo. All the daily SG curves are displayed in an overlap graph so that you can easily see the pattern of glucose levels in a given period.

The default end date is today. Tap to change the date or tap ‹ to move back, › forward.

3.9.3 Trend Analysis

This screen shows the sensor reading distribution within a given number of days (7, 30 or 90) before a certain date which can be changed by tapping and selecting a day or tapping < / > to move back / forward.

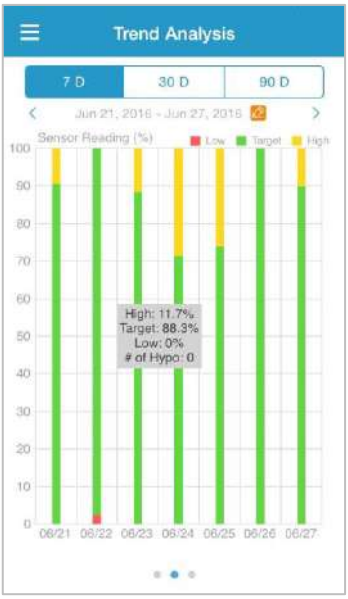
High: above the high limit

Target: between the high limit and low limit

Low: below the low limit

The high limit and low limit can be set under the settings menu. *CGM System Settings* contains more information.

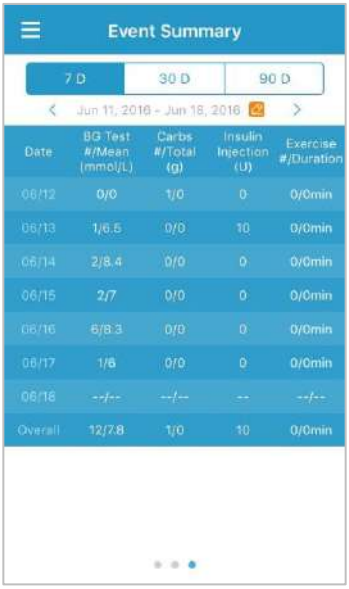
Tap a column, and then the percentages of high glucose, target glucose, and low glucose, and the number of hypoglycemic episodes will be displayed in a gray text box.



3.9.4 Event Summary

This screen shows the event summary within a given number of days (7, 30 or 90) before a certain date which can be changed by tapping and selecting a day or tapping < / > to move back / forward.

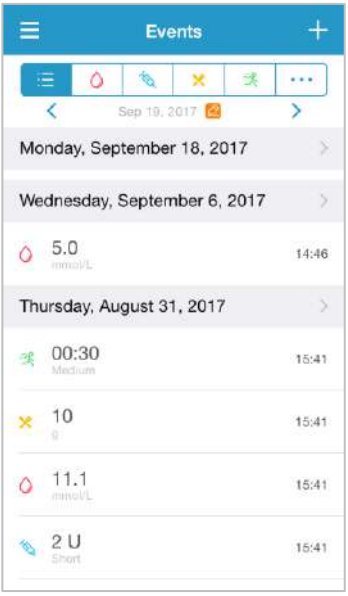
The event summary table includes the number of BG tests and the average BG, the times of food intake and the grams of carbs, the total amount of insulin injected, and the times and duration of exercise.



3.10 Events

3.10.1 Events Screen

Tap **Events** on the **Main Menu** to enter the **Events** screen. This screen shows all of the events before a certain date which can be changed by tapping and selecting a day or tapping < / > to move back / forward. Tap an event to view its details or to edit it.

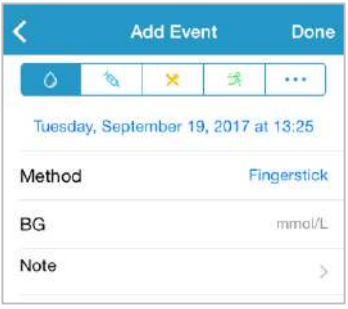


3.10.2 Add Event Screen

Tap ⊞ to enter the **Add Event** screen. Select a category.

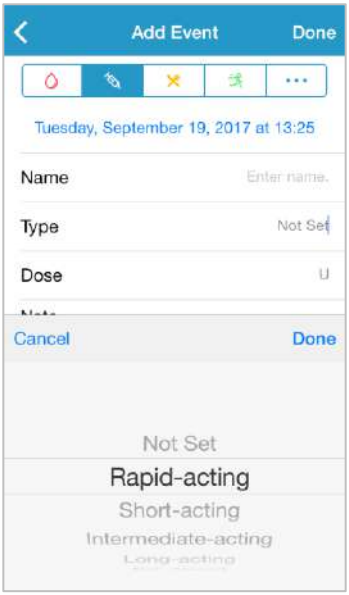
1. Add BG

The default date and time are the current date and time. Tap the date and time to change if needed. Tap **Fingerstick** or **Lab Calibration** to select the test method. Enter the BG level. Tap **Note** to add a note if needed. Tap **Done** to save the note and return to the **Add Event** screen.



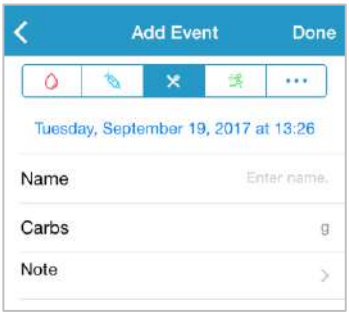
2. Add Insulin Injection

The default date and time are the current date and time. Tap the date and time to change if needed. Enter a name for this insulin injection record (optional). Select the type of insulin from **Not Set**, **Rapid-acting**, **Short-acting**, **Intermediate-acting**, **Long-acting**, and **Pre-mixed**. Enter the insulin dose. Tap **Note** to add a note if needed. Tap **Done** to save the note and return to the **Add Event** screen.



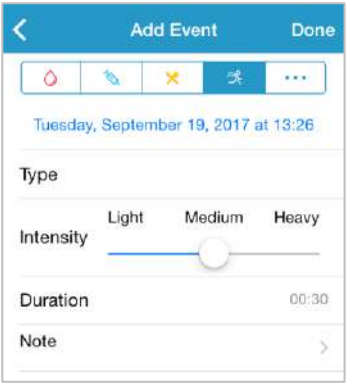
3. Add Carbs

The default date and time are the current date and time. Tap the date and time to change if needed. Enter a name for this carbs record (optional). Enter the grams of carbs. Tap **Note** to add a note if needed. Tap **Done** to save the note and return to the **Add Event** screen.



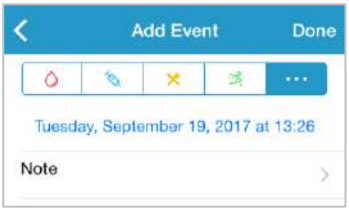
4. Add Exercise

The default date and time are the current date and time. Tap the date and time to change if needed. Enter the type of exercise (optional). Select the intensity and duration of exercise. Tap **Note** to add a note if needed. Tap **Done** to save the note and return to the **Add Event** screen.



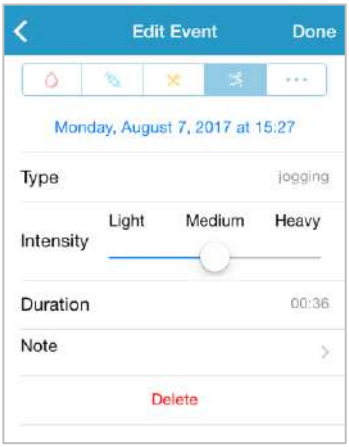
5. Others

The default date and time are the current date and time. Tap the date and time to change if needed. Tap **Note** to add a note about other health information like medication and menstruation. Tap **Done** to save the note and return to the **Add Event** screen.



3.10.3 Edit Event Screen

Tap an event on the **Events** screen to enter the **Edit Event** screen. After editing, tap **Done** to save the changes. You can also tap **Delete** to delete the event.



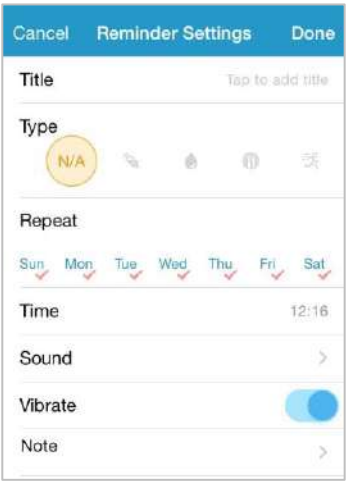
3.11 Reminders (For IOS device only)

Tap **Reminders** on the **Main Menu** to enter the **Reminders** screen.

3.11.1 Reminder Settings Screen

Tap ⊞ at the top-right corner to add new reminders.

You can enter the title of reminder, select the reminder type, repeat days, time of notification, and sound, turn on/off vibration and add a note if needed. Tap **Done** to save the changes.



3.11.2 Reminder Screen

1. This screen shows a list of saved reminders, each with an ON/OFF switch. Tap a switch to turn on/off the reminder. If no reminder has been saved, this screen would be blank.

2. To edit a reminder, tap it to enter the **Reminder Settings** screen. To delete a reminder, swipe left and tap **Delete**.

3.12 Settings

Tap **Settings** on the **Main Menu** to enter the **Settings** screen.

3.12.1 CGM System Settings

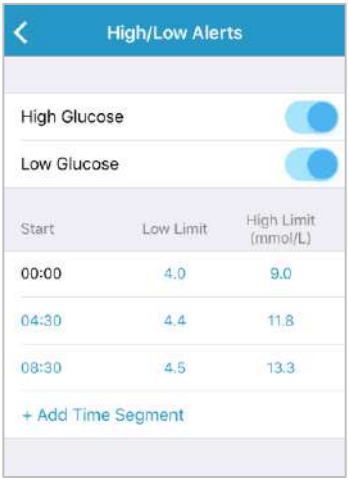
Tap **CGM System** on the **Settings** screen to enter the **CGM System** screen.

CGM Type: If you want to connect to the S9 CGM, please change the CGM type to S9.

Glucose Alerts: The default setting is off. After you turn it on, you can view the following list of alert settings.

1. High/Low: The default setting of High Glucose and Low Glucose are both off. After you turn **High Glucose** on, you can set up to eight High Limits throughout a day and receive alerts when your glucose is above the set High Limit. After

you turn **Low Glucose** on, you can set up to eight Low Limits throughout a day and receive alerts when your glucose is below the set Low Limit.
The highest high limit and the lowest low limit among all the time segments are used to determine the high glucose, target glucose, and low glucose in **Trend Analysis**. *Statistics* contains more information.



2. High Predicted: The default setting is off. After you turn it on and set a time period, you can receive alerts when your glucose is predicted to reach the set high limit in the set period of time. You can set the time between 5 min and 30 min with an increment of 5 min.

3. Low Predicted: The default setting is off. After you turn it on and set a time period, you can receive alerts when your glucose is predicted to reach the set low limit in the set period of time. You can set the time between 5 min and 30 min with an increment of 5 min.

4. Rapid Rise: The default setting is off. After you turn it on and set a rise rate limit, you can receive alerts when your glucose is rising faster than the set rate limit. You can set the rate between 0.065 mmol/L/min and 0.275 mmol/L/min

(1.1 mg/dL/min and 5.0 mg/dL/min) with an increment of 0.005 mmol/L/min (0.1 mg/dL/min).

5. Rapid Fall: The default setting is off. After you turn it on and set a fall rate limit, you can receive alerts when your glucose is falling faster than the set rate limit. You can set the rate between 0.065 mmol/L/min and 0.275 mmol/L/min (1.1 mg/dL/min and 5.0 mg/dL/min) with an increment of 0.005 mmol/L/min (0.1 mg/dL/min).

Sensor life: The sensor can be used for 14 days. When the sensor is about to expire, you will receive sensor expiration alerts.

Factory calibration: The factory setting for this feature is off. If your sensor is factory-calibrated, you can turn on this setting and enter the sensor code on the back of the sensor while connecting sensor.

3.12.2 General Settings

Tap **General Settings** on the **Settings** screen to enter the **General Settings** screen.

You can turn on/off **Audio** and **Vibrate,** set the snooze time between 10 min and 3 hours, and customize unit settings here.

Choose the Tone Types for App Reminders and Alerts under ALERT TONES.

Note: We recommend that you turn **Audio** and **Vibrate** on. If you turn them both off, you might miss an alert/alarm.

3.12.3 Account Security

Tap **Account Security** on the **Settings** screen to enter the **Account Security** screen.

Password

Tap **Password** to change the password.

Passcode Lock (For IOS device only)

Tap **Passcode Lock** to set a 4-digit passcode to protect access to the app.

Re-enter the passcode. If correct, the passcode lock will be turned on.

Once the passcode lock is on, you will be required to enter the correct passcode to gain access to the Medtrum EasySense Mobile App.

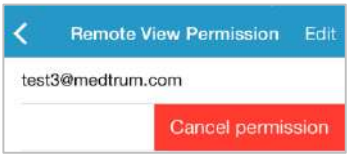
The correct passcode would be required if you want to turn the passcode lock off.

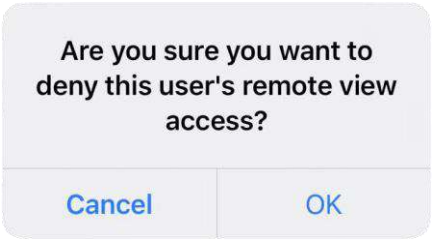
Remote View Permission

If your app receives an application from another user for remotely viewing your account, you can choose to allow or deny their access. If you want to stop a user's access to your account, go to **Account Security** under **Settings** and tap **Remote View Permission**.

For iOS device, swipe left on the selected user and tap on **Cancel permission** to cancel remote view permission.

For Android device, hold down the selected user and confirm in the dialogue to cancel remote view permission.





3.12.4 Reset

Tap **Reset** on the **Settings** screen to enter the **Reset** screen. You can reset the app settings to factory defaults.

Note: When the app is paired with an active sensor, you cannot reset any settings.

3.12.5 Widget

If you are using an iPhone, swipe right across the lock screen or the home screen to view the widgets.

In the EasySense widget, you can see your real-time CGM data including the last sensor reading, the trend arrow, the calibration icon and the sensor status.

By tapping **Show More**, you can view the sensor glucose curve of the past 6 hours.

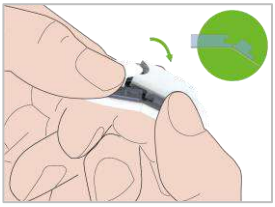
If you are using an Android phone, swipe down to view the EasySense notification.

4.1 Remove the Current Sensor and Disconnect the Transmitter

Your Sensor gives glucose readings for up to fourteen days. After your Sensor expires, your Sensor session will be shut off automatically, and glucose readings won't be displayed on your smart device. You must remove your Sensor after it expires.

1. Gently peel the adhesive patch off your skin in one continuous motion to remove the Sensor and Transmitter.

2. Fold and break the sensor support mount, and gently pull the Transmitter away from the sensor support mount.



3. Discard the sensor support mount and reuse the Transmitter.

Note: Make sure that you completely disconnect the Transmitter from the Sensor when you do.

4.2 Insert a New Sensor

4.2.1 Select an Insertion Site

When choosing the location for the Sensor, consider the following:

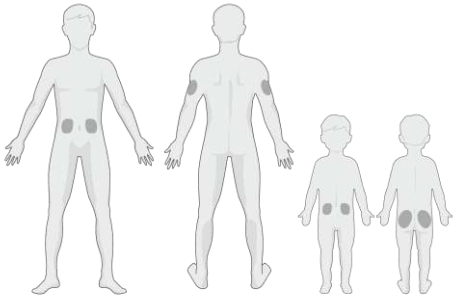
- That you can comfortably reach the Sensor.
- That you apply the Sensor to a flat area of skin with adequate subcutaneous fat.
- That the area stays flat during normal daily activities without bending or creasing.

When choosing the location for the Sensor, avoid the following:

- Areas that are constrained by clothing.
- Curved or rigid areas due to muscle or bone.
- Areas that involve rigorous movement during exercise.
- Areas of skin with scars, tattoos, or irritation.
- Areas with excess hair.
- Within 7.5 cm (3 inches) of an insulin pump infusion site or manual injection site.

If you choose an insertion site on the upper arm, apply the Sensor vertically.

If you choose an insertion site on your abdomen (buttock for children), apply the Sensor horizontally.



Have a rotation schedule for choosing a new site. Using the same site too often might not allow the skin to heal, and can possibly cause scarring or skin irritation.

4.2.2 Prepare the Insertion Site

1. Wash your hands thoroughly with soap and water and let them dry.
2. Wipe the selected insertion area with rubbing alcohol and allow the area to dry. This may help prevent infection. Do NOT insert the Sensor until the cleaned area is dry. This will allow the sensor adhesive to stick better.

Warning: If the Sensor dislodges due to the sensor support adhesive failing to adhere to the skin, you may get unreliable or no results. Improper site selection and improper site preparation may cause poor adhesion.

4.2.3 Unpack the Glucose Sensor

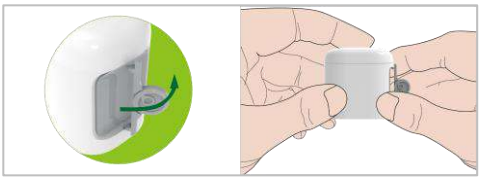
Open the Sensor package by peeling off the paper on the back of the package.

Warning: Do NOT use a Sensor if its sterile package has been damaged or opened, or the Sensor has expired, or the Sensor is damaged in any way.

Note: Wash your hands with soap and water and let them dry before opening the Sensor package and handling Sensor. After opening the package, avoid touching any Sensor surface that will come in contact with the body, i.e., adhesive surface. You may contaminate the insertion site and suffer an infection if you have dirty hands while inserting the Sensor.

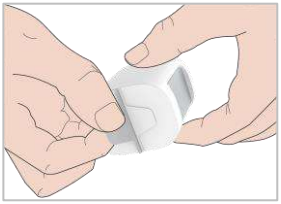
4.2.4 Unlock the Safety Lock

Bend the two-piece protective liner slightly on the edge so you can see the seam between the two pieces. Hold the inserter part of the Sensor and try not to touch the adhesive surface. Remove the liners from the Sensor support mount one after another. Use your thumb and finger to bend off the safe lock by pushing it to the left or right.



4.2.5 Remove the Protective Liner from the Sensor Support Mount

Bend the two-piece protective liner slightly on the edge so you can see the seam between the two pieces. Hold the inserter part of the Sensor and try not to touch the adhesive surface. Remove the liners from the Sensor support mount one after another.

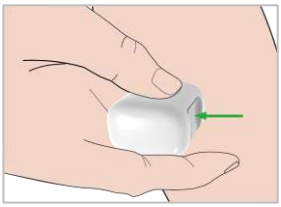


4.2.6 Locate the Sensor Support Mount

Place the Sensor vertically on the upper arm.

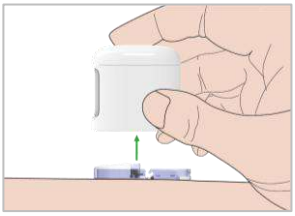
4.2.7 Insert the Sensor

Hold the inserter as shown below and press swiftly the inserter. You might feel a slight pinch as the Sensor is placed just under your skin.



4.2.8 Remove the Inserter

Lift the inserter vertically away from the mount. Only the Sensor support mount will be left on your body.



4.2.9 Check the Sensor Support Mount

Confirm that the sensor support mount remains tightly adhered to your skin by sliding your finger along the edges of the adhesive pad and examine for any gaps sin adhesion.

Warning: If bleeding occurs at the insertion site, do not attach the Transmitter to the Sensor. Apply steady pressure using a sterile gauze or clean cloth for up to 3 minutes. If bleeding stops, attach the Transmitter to the Sensor. If bleeding does not stop, remove the Sensor, treat the site as necessary, and insert a new Sensor at a different site.

Warning: Check the insertion site frequently for infection or inflammation—redness, swelling or pain. Remove the Sensor and seek professional medical help if one of these conditions occurs.

4.2.10 Discard the Sensor Inserter Safely

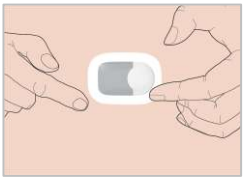
Follow local waste disposal regulations when discarding the inserter. We recommend discarding the sensor inserter into a sharp container or a puncture-proof container with a tight lid.

4.3 Attach Your Transmitter

When you change the Transmitter, you need to enter the SN of a new Transmitter on your App before attaching the new Transmitter to the sensor.

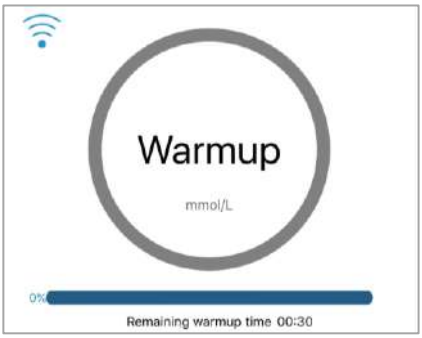
Note: You can refer to chapter 3.4 for guidance to change the transmitter SN on your App.
Make sure the triangle marked on the Transmitter is aligned with the round edge of Sensor support mount.

Keep the transmitter parallel to the sensor support mount, then snap the Transmitter into place.
Note: Make sure you hear a click when you snap the Transmitter in place. If it is not fully snapped in, poor electrical connection and compromised waterproof performance may result, which can lead to inaccurate sensor glucose readings. If you are changing Sensor, make sure your Transmitter was disconnected from the old Sensor at least 90 seconds before connected to the new Sensor.



After you install the transmitter, the green light on the transmitter will flash 3 times immediately, indicating that the transmitter is correctly connected with the sensor. The green light will flash another 6 times within one minute,

indicating that the system has completed its self-check. Then the following screen will appear on your App.



Note: It will take **30 minutes** for the sensor to warm up.

To make you aware of a condition that is outside normal CGM system activity or a potentially serious condition, your smart device with the Medtrum EasySense Mobile App vibrates or emits a tone on an alert and displays an on-screen message. If the app is running in the foreground, an alert message appears with a prompt; if the app is running in the background, an alert message appears as a notification. In the former case, when there are multiple messages, you need to acknowledge the first one by tapping it before you see the next. In the latter case, all messages are displayed simultaneously in the notification list. Discuss with your healthcare provider about what actions to take when an alert happens.

List of Alerts

Condition	App Message	Actions to Take
LOST SENSOR	Lost sensor. Check communication distance.	Move your smart device close to the Transmitter.
SENSOR BATTERY LOW	Sensor Battery Low. Change sensor soon.	Change Sensor soon.
CHANGE SENSOR NOW	Sensor battery depleted. Change sensor now.	Change Sensor now.
TRANSMITTER ERROR	Transmitter error. Call customer support.	Call customer support.

NO READINGS	Check if the sensor stays in place.	Check if the sensor gets bumped or dislodged. If the sensor is properly inserted, wait and keep monitoring. If the sensor is dislodged, change sensor.
SENSOR CALIBRATION ERROR	Sensor calibration error. Enter BG after 15 minutes.	Enter meter BG after 15 minutes.
SENSOR FAILURE	Sensor failure. Replace sensor now.	Change Sensor.
METER BG NOW	Calibrate sensor now.	Enter a new meter BG for calibration.
SENSOR END IN 6 HOURS	Sensor will expire in 6 hours. Change sensor soon.	Change sensor in 6 hours.
SENSOR END IN 2 HOURS	Sensor will expire in 2 hours. Change sensor soon.	Change sensor in 2 hours.
SENSOR END IN 30 MINUTES	Sensor will expire in 30 minutes. Change sensor soon.	Change sensor in 30 minutes.
SENSOR EXPIRED	Sensor expired. Change sensor now.	Change Sensor.
RAPID RISE	Sensor glucose is rising rapidly.	Monitor trend and glucose level. Follow instructions from your healthcare provider

RAPID FALL	Sensor glucose is falling rapidly.	Monitor trend and glucose level. Follow instructions from your healthcare provider.
HIGH PREDICTED	Sensor glucose approaching High Limit.	Check blood glucose and treat as necessary. Continue to monitor blood glucose.
LOW PREDICTED	Sensor glucose approaching Low Limit.	Check blood glucose and treat as necessary. Continue to monitor blood glucose.
HIGH GLUCOSE	Sensor glucose above High Limit.	Check blood glucose and treat as necessary. Continue to monitor blood glucose.
LOW GLUCOSE	Sensor glucose below Low Limit.	Check blood glucose and treat as necessary. Continue to monitor blood glucose.
BELOW 3.1 mmol/L (BELOW 56 mg/dL)	Sensor glucose below 3.1 mmol/L. Please treat as necessary. (Sensor glucose below 56 mg/dL. Please treat as necessary.)	Check blood glucose and treat as necessary. Continue to monitor blood glucose.

Note: When **BELOW 3.1 mmol/L (BELOW 56 mg/dL)** occurs, the app will sound an alert even if audio was turned off.

6.1 Electromagnetic Emissions

Emissions Test	Compliance
RF emissions EN 60601-1-2:2015+A1:2021, IEC 60601-1-2:2014+A1:2020, CISPR 11:2015+A1+A2	Group 1
RF emissions EN 60601-1-2:2015+A1:2021, IEC 60601-1-2:72014+A1:2020, CISPR 11:2015+A1+A2	Class B

6.2 Electromagnetic Immunity

Immunity Test	Compliance Level	Electromagnetic Environment
Electrostatic Discharge IEC 61000-4-2	±8kV contact ±2kV,±4kV,±8kV, ±15kV air	For home healthcare environment and professional healthcare facility environment
RF electromagnetic field immunity test IEC 61000-4-3	80 MHz~2.7 GHz, 10 V/m (for home healthcare environment) 80 % AM at 1 kHz 3V/m (for professional healthcare facility environment) 80 % AM at 1 kHz	Suitable for most environments. Keep portable RF communications equipment at least 0,3 m away.

Field strengths

A. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasts and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Insulin Management System is used exceeds the applicable RF compliance level above, the Insulin Management system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Insulin Management system.

B. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Electrostatic discharge

Although your Insulin Management system is designed to be unaffected by typical levels of electrostatic discharge (ESD), very high levels of ESD can result in reset of the Insulin Management system. If the EasyPatch App restarts, please verify the App settings to ensure all settings are set to the desired values. If Pump Restarted occurs, please change a new patch.
For more information on changing a new patch, see Chapter "How to use Patch Pump".
For more information on re-entering your EasyPatch App settings, see Section "Recommended Smart Device Settings" in Chapter "How to use the App".
If you are unable to re-enter your EasyPatch App settings, change a new patch, or otherwise believe there is a problem with your device, contact your local representative.

Warning:

1) EMC (Electromagnetic Compatibility) information in this guide should be referred before installing and using the Patch Pump.
2) The Patch Pump is not designed to be used in an environment with high voltage, high-intensity magnetic field, where the intensity of EM DISTURBANCES is high.
3) Portable RF Communications equipment should be used no closer than 30 cm (12 inches) to any part of the Medtrum products. Otherwise, degradation of the performance of this equipment could result.
4) It should be avoided to use this equipment adjacent to or stacked with other medical equipment, because it could result in improper operation. If such use is necessary, this equipment and the other medical equipment should be observed to verify that they are operating normally.
5) Other cables and accessories may negatively affect EMC performance.

Recommended separation distances between portable and mobile RF communications equipment and the Patch Pump

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430-470	GMRS 460 FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation	0.2	0.3	9
745						

780			217Hz			
810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217Hz	2	0.3	28
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450,	Pulse modulation 217Hz	2	0.3	28

		LTE Band 7				
5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9
Note: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.						
a) For some services, only the uplink frequencies are included. b) The carrier shall be modulated using a 50 % duty cycle square wave signal. c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.						

Appendix I: Symbols and Icons

Product Label Symbols

Symbol	Meaning	Symbol	Meaning
LOT	Batch code		Do not use if package is damaged and consult instructions for
REF	Catalogue number	STERILE EO	Sterilized using ethylene oxide
	Manufacturer	STERILE R	Sterilized using radiation
	Use by: (yyyy-mm-dd)		Single sterile barrier system with protective packaging outside
	Caution		Follow instructions for use
	Temperature limit		Radio communication
	Do NOT reuse	IP28	Protection Against Insertion of Large Objects and Immersion in Water for up to 2.5 m for 1 hour
CE 0197	CE mark by notified body	SN	Serial number

Symbol	Meaning	Symbol	Meaning
	Waste Electrical and Electronic Equipment		Type BF applied part
IP22	Protection Against Insertion of Large Objections and		Authorized representative in the European Community
	Date of Manufacture		Importer
	Unique device identifier		Humidity limitation
	Indicates the item is a Medical Device		

8.1 Transmitter Specifications

Model: MD1160
Size: 18.5 mm x 17.8 mm x 4 mm
Weight: 1.03 g
Operating Temperature Range: +5°C ~+40°C
Operating Relative Humidity Range: 20%~90%RH
Operating Atmospheric Pressure: 700~1060 hPa
Storage Temperature Range: -10°C~+55°C
Storage Relative Humidity Range: 20%~90%RH
Storage Atmospheric Pressure: 700~1060 hPa
Dustproof and Waterproof Rating: IP28 (2.5 m, 60 min)
Classification: Type BF equipment, Continuous operation
Data Storage: Automatically stores the previous 14 days' data
Wireless Communication Distance: 10 m
Limited Warranty: 1 year

8.2 Glucose Sensor Specifications

Model: MD3660
Storage Temperature Range: +2°C~+30°C
Storage Relative Humidity Range: 20%~90%RH
Storage Atmospheric Pressure: 700~1060 hPa
Glucose Range: 2.2~22.2 mmol/L (40~400 mg/dL)
Sterilization Method: By radiation
Battery: Powered by one button batteries (3.0 V*1)
Sensor Life: Up to 14 days

8.3 Essential Performance

The continuous glucose monitoring system should measure, store and display patient's glucose level with specific accuracy in the specific environmental conditions.

8.4 CGM System Accuracy

A clinical study was designed to determine the sensor accuracy in adults with Type 1 and Type 2 aged eighteen and older. In-clinic testing consisted of frequent venous blood sample testing using the Yellow Spring Instrument Life Sciences 2300 STAT Plus™ Glucose Analyzer (YSI) on a random day in the sensor life. The accuracy was based on the percentage of CGM glucose readings that are within ±20%, ±30% and ±40% for reference values 100 mg/dL (5.6 mmol/L) and above, and ±20 mg/dL (1.1 mmol/L), ±30 mg/dL (1.7 mmol/L) and ±40 mg/dL (2.2 mmol/L) for reference values below 100 mg/dL (5.6 mmol/L).

Table. Percentage of CGM Glucose Reading within ±20% / ±20 mg/dL, ±30% / ±30 mg/dL and ±40% / ±40 mg/dL of the YSI.

Number of Matched Pairs CGM-YSI	**Within ±20% / ±20 mg/dL**	**Within ±30% / ±30 mg/dL**	**Within ±40% / ±40 mg/dL**
13116	89.0%	97.8%	99.4%

App	A mobile app is a computer program designed to run on mobile devices such as smartphones and tablet computers. The Medtrum EasySense Mobile App is used with the EasySense system for continuous glucose monitoring.
BG	Abbreviation for blood glucose. See *Blood Glucose*.
Blood Glucose (BG)	The amount of glucose present in the blood.
Calibration	The process of using a meter blood glucose reading or a venous blood glucose value to calculate sensor glucose values.
Carb	The complex carbohydrate starch or simple carbohydrates, such as sugar.
Continuous Glucose Monitoring (CGM)	A Sensor is inserted under the skin to check glucose levels in interstitial fluid. A Transmitter sends sensor glucose readings to a display device.
High Limit	The value you set to determine when the system will alert you of a high sensor glucose condition.
Hypo	Your glucose level is under 3.1 mmol/L (56 mg/dL).
Low Limit	The value you set to determine when the system will alert you of a low sensor glucose condition.
Note	A note provides helpful information.
Sensor Glucose (SG)	The amount of glucose that is present in the interstitial fluid and is measured by a glucose sensor.
Sensor Session	The 14-day monitoring period after inserting a new sensor. During this time frame, your glucose is being monitored and reported every two minutes, with data

	being sent to your display device(s).
SG	Abbreviation for sensor glucose. See *Sensor Glucose (SG).*
Smart Device	A smart device is an electronic device that is cordless (unless charging), mobile (easily transportable), connected (via Wi-Fi, 3G, 4G, etc.) that can operate to some extent autonomously. Examples of smart devices are smartphones, tablets, or phablets.
Warning	A warning notifies you of a potential hazard.

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