S6 EasySense

Disposable CGM System

User Guide

©2015, Medtrum Technologies Inc. All rights reserved.

MEDTRUM

CE 0197

Medtrum Technologies Inc.
7F, Building 8, No. 200,
Niudun Road
Shanghai 201203, China
Tel：+86-21-50274781
Fax：+86-21-50274779
www.medtrum.com

This product complies with Directive 93/42/EEC (MDD) and Directive 1995/5/EC (R&TTE).

REF MD-MY-013
Version: 1.0
Publication date: Jan 01, 2016
UG883013
348010

EC REP

Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany
+49-40-2513175

Contents

Contents 0

Introduction 0
Before You Begin 0
Indications 0
Contraindications 1
User Safety 1
Warnings and Precautions 1
General 1
Operating Temperature Range 3
Cleaning 4
X-rays, MRIs and CT Scans 4
Consumables 5
Radio Frequency (RF) Communication 5
Water 7
Storage 8
Warranty Information 9

Basics of the S6 EasySense System 12
How the S6 EasySense System Works 12
Key Features of the S6 EasySense System 14
7-day Sensor 14
Mobile App Monitoring 15
Recorder for Healthcare Providers 15

How to Change the Sensor 17
Remove the Current Sensor and Disconnect the

Transmitter 17
Insert a New Sensor 19
Select an Insertion Site 19
Prepare the Insertion Site 20
Remove the Glucose Sensor from the Package . 21
Remove the Protective Liner from the Sensor Support Mount 22
Locate the Sensor Support Mount 22
Remove the Safety Lock 23
Insert Sensor 24
Remove Inserter 25
Check the Sensor Support Mount 26
Discard the Sensor Inserter Safely 26
Attach Your Transmitter 27
Tape the Sensor Support Mount (Optional) 28

How to Use Medtrum EasyTouch Mobile App 30
Install the App 30
Login/Register 32
Connect Transmitter With App 33
Monitor Sensor Status 36
Calibrate Your Sensor 41
Sensor Trend Graph 42
Understand the Statistics 45
Sensor Overlay 46
Trend Analysis 47
SG Distribution 48

Event Distribution 49
Log Summary 50
Enter the Logs 52
Set Your Reminders.....59
Customize Your Settings.....61
CGM System Settings..... 62
Alert Settings 62
Statistics Settings..... 64
General Settings..... 66
Remote Viewing.....67
Remote View Other Accounts..... 67
Allow Others to Remote View Your Account 69
Safety System and Alerts.....72
List of Alerts 72

Manufacturer's Declaration 78
Electromagnetic Emissions 78
Electromagnetic Immunity 79

Appendix I: Symbols and Icons 80
Product Label Symbols 80

Appendix II: Specifications 84
Transmitter Specifications.....84
Glucose Sensor Specifications 85
CGM System Accuracy.....85

Glossary 87

Introduction

Before You Begin

The S6 EasySense Disposable CGM System is composed of three parts: a Transmitter, a Sensor and Medtrum EasyTouch Mobile App on your smart device. Not all devices or accessories are available in all countries where the CGM system is approved. To order supplies, contact your local representatives.

Indications

The S6 EasySense Disposable CGM System is indicated for use in persons (ages 2 and older) with diabetes for continuously recording interstitial fluid glucose levels. 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. Interpretation of the CGM System results should be based on the glucose trends and several sequential readings. The system is intended for single patient use.

Contraindications

The S6 EasySense Disposable 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 twice per day.
- Recognize and respond to alerts and alarms. (Sufficient vision and/or hearing are required.)

User Safety

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 S6 EasySense Disposable 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 S6 EasySense Disposable CGM System in the presence of flammable anesthetics or explosive gases.

The S6 EasySense Disposable 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 professional 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 S6 EasySense Disposable 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 S6 EasySense Disposable CGM System may be affected by strong radiation or magnetic fields. If you are going to have 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 S6 EasySense Disposable CGM System is

designed to tolerate common electromagnetic and electrostatic fields, including airport security systems and cellular phones.

Consumables

Glucose Sensor — The Transmitter (MD-TY-015) is only used with the Medtrum Glucose Sensor (MD-JY-006). Change your Glucose Sensor every seven 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.

Please take attention that changes or modification not expressly approved by the party responsible for compliance could void user's authority to operate the equipment

Radio Frequency (RF) Communication

The S6 EasySense Disposable CGM System complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- This device may not cause harmful interference, and
- This device must accept any interference received, including interference that may cause undesired operation.

Note: The S6 EasySense Disposable CGM System has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. The S6 EasySense Disposable 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 S6 EasySense Disposable 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 S6 EasySense Disposable CGM System.

- Increase the distance between the S6 EasySense Disposable 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 S6 EasySense Disposable 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.

RF communication between your Transmitter and smart device works up to a distance of 10 meters (33 feet).

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 2.5 m for up to 1 hour. However, hot water may decrease Sensor life.

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 1 hour. Check often to make sure the Transmitter and Sensor are securely attached and in place.

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.

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 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

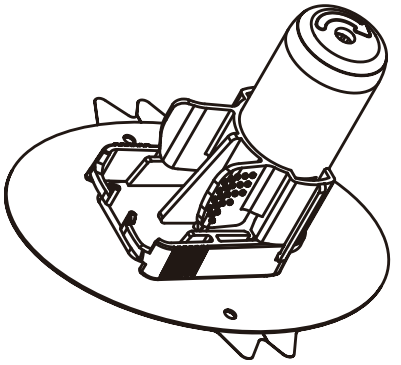
MEDTRUM NOR ITS SUPPLIERS OR DISTRIBUTORS SHALL BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL, OR SPECIAL DAMAGE OF ANY NATURE OR KIND CAUSED BY OR ARISING OUT OF A DEFECT IN THE PRODUCT. ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, ARE EXCLUDED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

Basics of the S6 EasySense System

How the S6 EasySense System Works

The S6 EasySense Disposable CGM System consists of three parts: a wireless Transmitter, a Glucose Sensor and Medtrum EasyTouch 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.

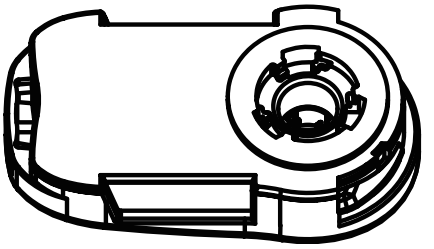
The Glucose Sensor (MD-JY-006) contains a flexible Sensor that can be inserted just under your skin. Each inserted Sensor is intended to remain in place and provide continuous glucose readings for up to 7 days. The Sensor is the applied part in the CGM system.



Glucose Sensor

(MD-JY-006)

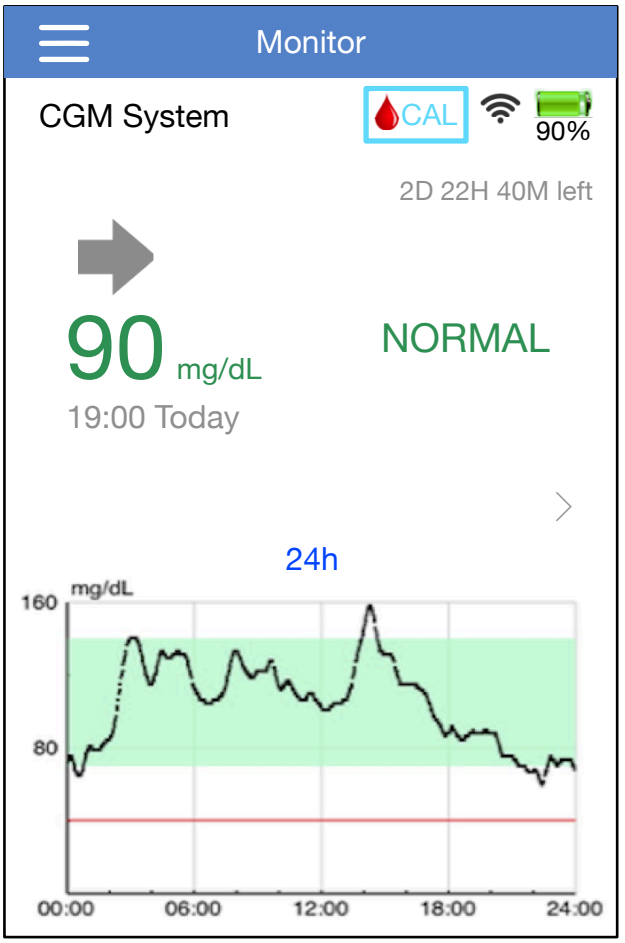
The wireless Transmitter (MD-TY-015) is a small reusable electronic device that connects to the Sensor and sends your sensor glucose information to your smart device every 2 minutes. The Transmitter contains a built-in 3.0 V button cell which can last for 30 days.



Transmitter

(MD-TY-015)

Medtrum EasyTouch 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 enter the logs.



Medtrum EasyTouch Mobile App

Key Features of the S6 EasySense System

7-day Sensor

The 7-day Sensor combines excellent

performance with features designed to provide exceptional comfort and ease of use. The ultra-sensitive and flexible Sensor goes just under your skin to read glucose levels. The Transmitter snaps into the Sensor to form a small and discreet patch.

Mobile App Monitoring

From Medtrum EasyTouch Mobile App, not only will you always know where your glucose level is, you'll know which way it is heading, how fast it's moving there and, as you approach your glucose limits, you'll be warned to take action. Everything you want to see about your glucose is at a glance.

Recorder for Healthcare Providers

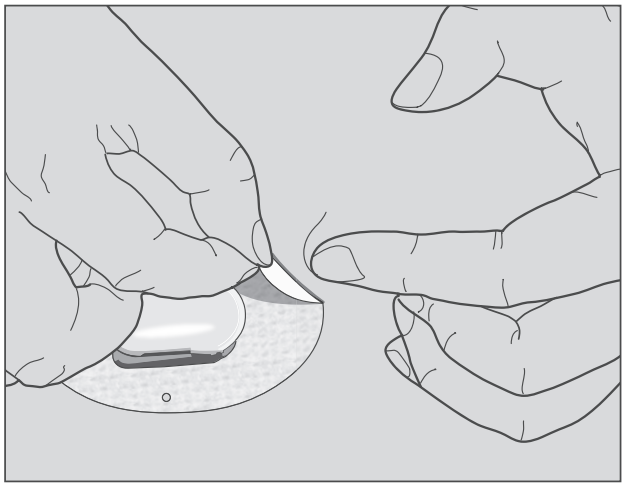
The Transmitter has a built-in recorder to record sensor data of up to 7 days. This feature is designed for healthcare providers to evaluate their patients' glucose control.

How to Change the Sensor

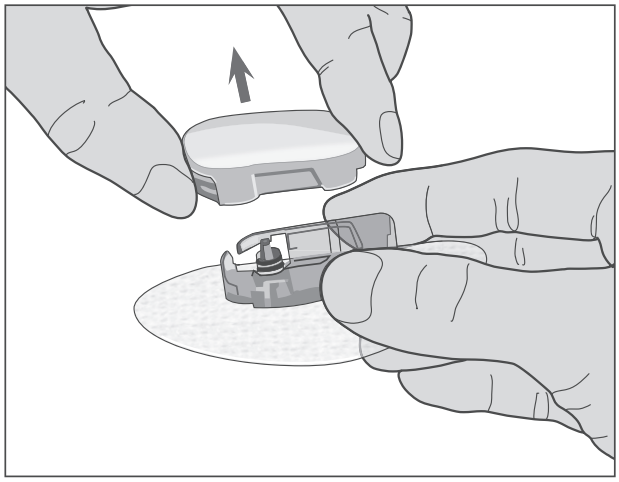
Remove the Current Sensor and Disconnect the Transmitter

Your Sensor gives glucose readings for up to seven 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. Pinch the center of the ribbed release tabs on the sides of 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: Do NOT discard your Transmitter after one

use. A Transmitter can be used for up to four sensor sessions.

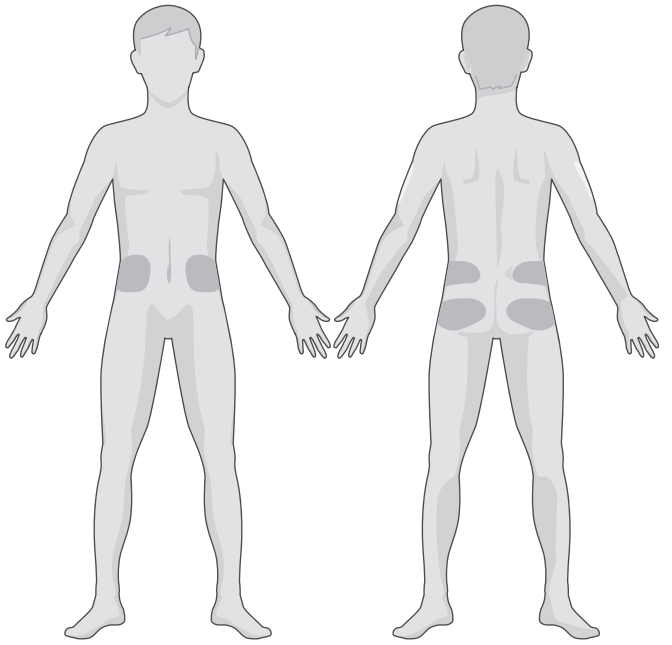
Insert a New Sensor

Select an Insertion Site

When inserting the senor, choose an area with adequate subcutaneous fat. This area should stay flat during normal daily activities without bending or creasing. The sensor site should be at least 7.5 cm (3 inches) away from an insulin Pump infusion site or manual injection site. The insulin might affect Sensor performance, and you might miss a low or high blood glucose value.

Avoid inserting the Sensor into areas of skin with scarring, tattoos, or irritation. Do not place the Sensor in areas that are constrained by clothing, such as the belt line or waist. Also do not place the Sensor in areas that involve rigorous movement during exercise. Avoid sites 5 cm (2 inches) around navel. Avoid areas with excess hair, or consider shaving the area.

Shown here are the best body areas (shaded) for Sensor insertion.



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. Select a new insertion site at least 5 cm (2 inches) from the previous site.

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 adherence to the skin.

Remove the Glucose Sensor from the Package

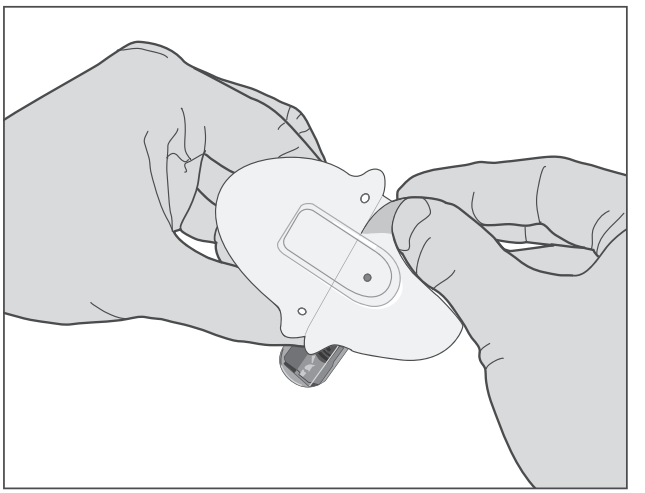
Remove the Glucose Sensor from its sterile package by peeling off the paper on the back of the package.

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.

Remove the Protective Liner from the Sensor Support Mount

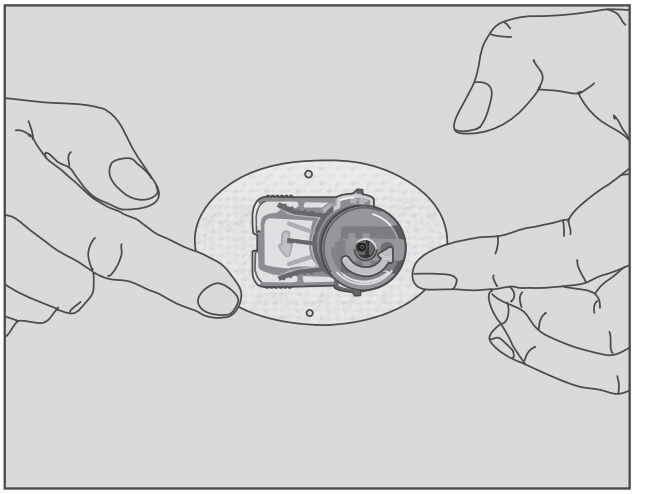
Bend the two-piece protective liner slightly so you can see the seam between the two pieces. Remove the liner from the sensor support mount one half at a time, using the white tabs on the backing. Hold the Sensor by the inserter, and try not to touch the adhesive surface.



Locate the Sensor Support Mount

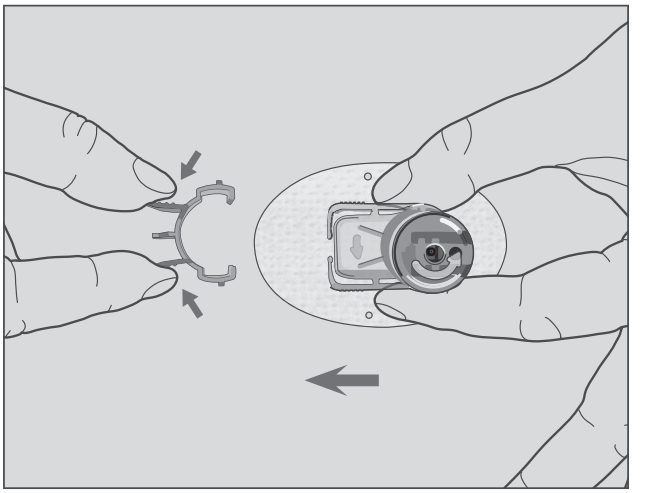
If you are inserting the Sensor on your abdomen or lower back, place the Sensor horizontally on your skin.

Move your fingers around the adhesive patch to secure it to your skin.



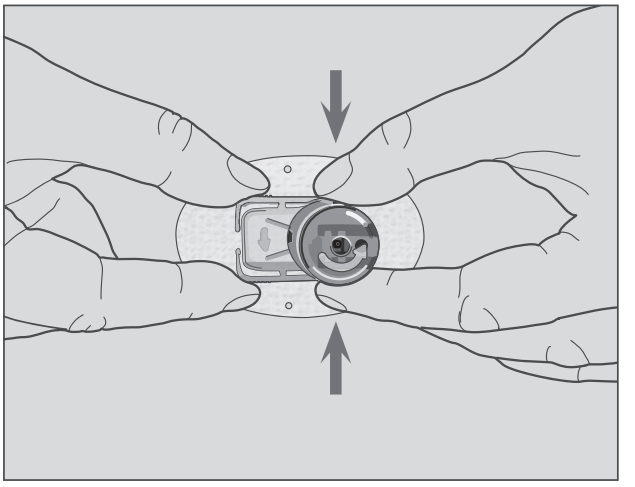
Remove the Safety Lock

Hold the Glucose Sensor with one hand. Firmly squeeze the two release tabs of the safety lock with your thumb and index finger of the other hand, as you lift the safety lock away from the inserter. Save the safety lock, you will need it later.



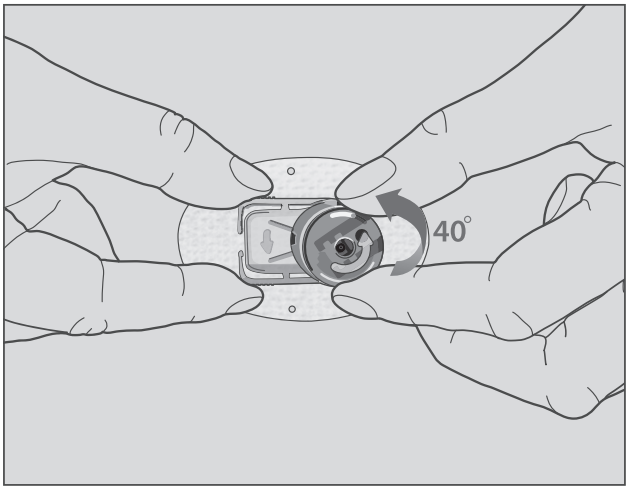
Insert Sensor

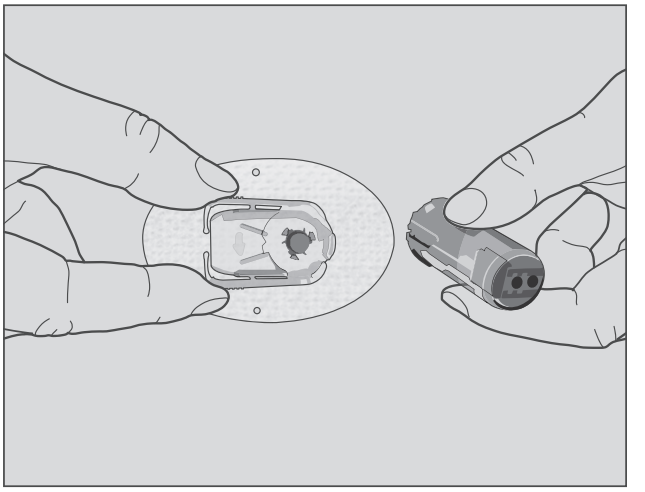
Hold the inserter as shown and press the two buttons at the same time. You might feel a slight pinch as the Sensor is placed just under your skin.



Remove Inserter

Twist the inserter about a 40° turn in the direction shown, and lift the inserter away from the mount. Only the sensor support mount will be left on your body.





Check the Sensor Support Mount

Confirm 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 in 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.

Discard the Sensor Inserter Safely

Attach the safety lock on the inserter to cover its opening and hide the needle inside. Follow local

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

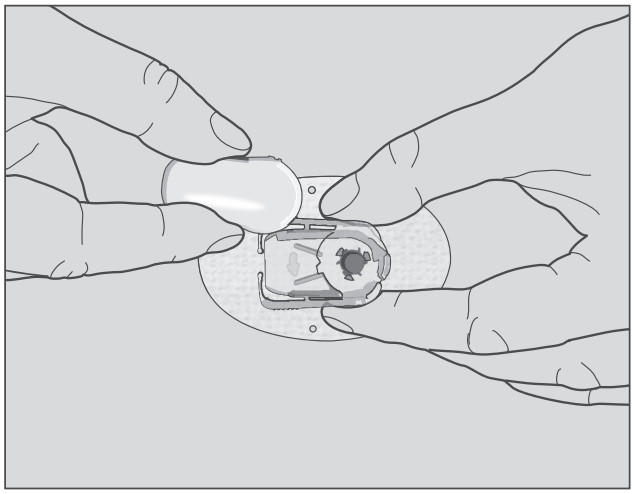
Attach Your Transmitter

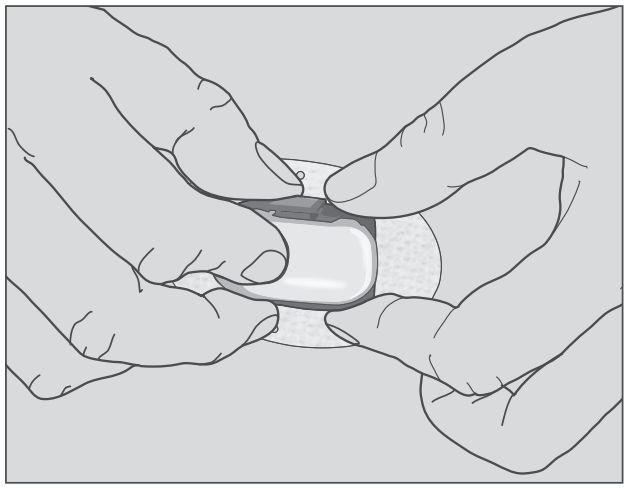
After the Sensor is inserted, follow these steps to attach your Transmitter:

1. Wipe the bottom of the Transmitter with an alcohol wipe and let it dry before every use.

2. Snap the Transmitter into the sensor support mount until the two flexible arms fit into the notches on the Transmitter. The indicator light will flash green after successful connection.

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.





Tape the Sensor Support Mount (Optional)

The sensor support mount should stay on your skin using its own adhesive. But, if you find that the sensor support mount is not adhering well during daily activities, you can use medical tape for extra support. Only tape over the white

adhesive patch on all sides for even support. Do NOT tape over the Transmitter or any of the plastic parts of the sensor support mount.

How to Use Medtrum EasyTouch Mobile App

Install the App

Compatible smart devices: iPhone 4S, iPhone 5, iPhone 5C, iPhone 5S, iPhone 6, iPhone 6 Plus, iPhone 6S, iPhone 6S Plus, iPod touch 5th Gen, iPad 3, iPad 4, iPad Air, iPad Air 2, iPad Mini, iPad Mini 2, iPad Mini 3

Supported operating systems: IOS 7.0 and above

The smart device you install the App on and the charger for that smart device must comply with IEC60950-1.

To install the EasyTouch Mobile App provided by Medtrum Technologies Inc., just download it from your smart device's App store.

For information on how to install an App see your

smart device's user guide.

Medtrum EasyTouch Mobile App cannot override your smart device settings.

To receive sensor status and alerts 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 EasyTouch Mobile App are turned on in the setting's menu of your smart device.
5. Make sure the Medtrum EasyTouch Mobile App is open and running in the background.
6. Restart the Medtrum EasyTouch Mobile App after your smart device is restarted.

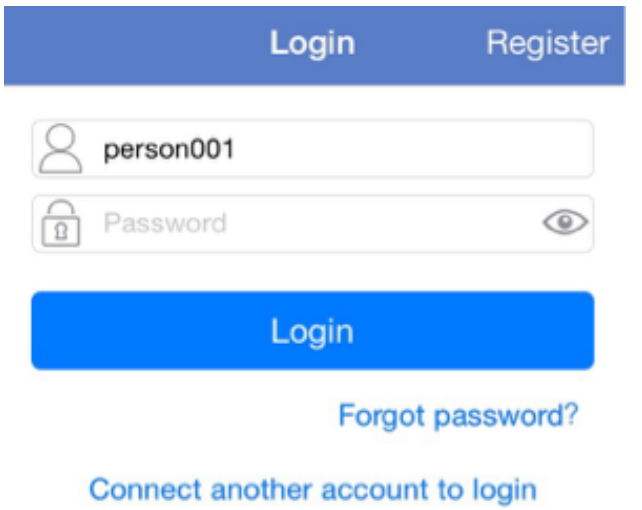
For information on how to set your smart device, see your smart device's user guide.

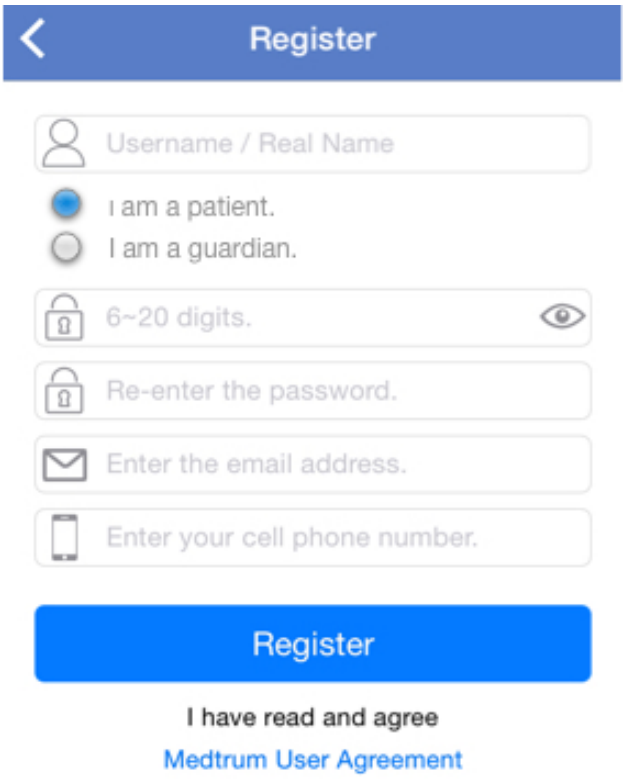
Note: Do not change your smart device's time because it can make the time on the monitor screen wrong and the App may stop displaying sensor status.

Login/Register

Make sure your smart device is connected to the Internet. Open the Medtrum EasyTouch Mobile App and enter the **Login** screen. If you have a Medtrum account, login with your account and password.

If you don’t have a Medtrum account, tap **Register** to set your username and password. The username must be 4-20 characters. The password must be 6-20 characters.

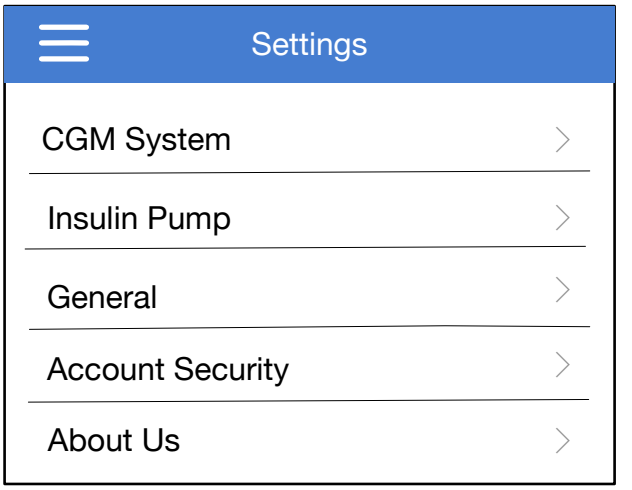




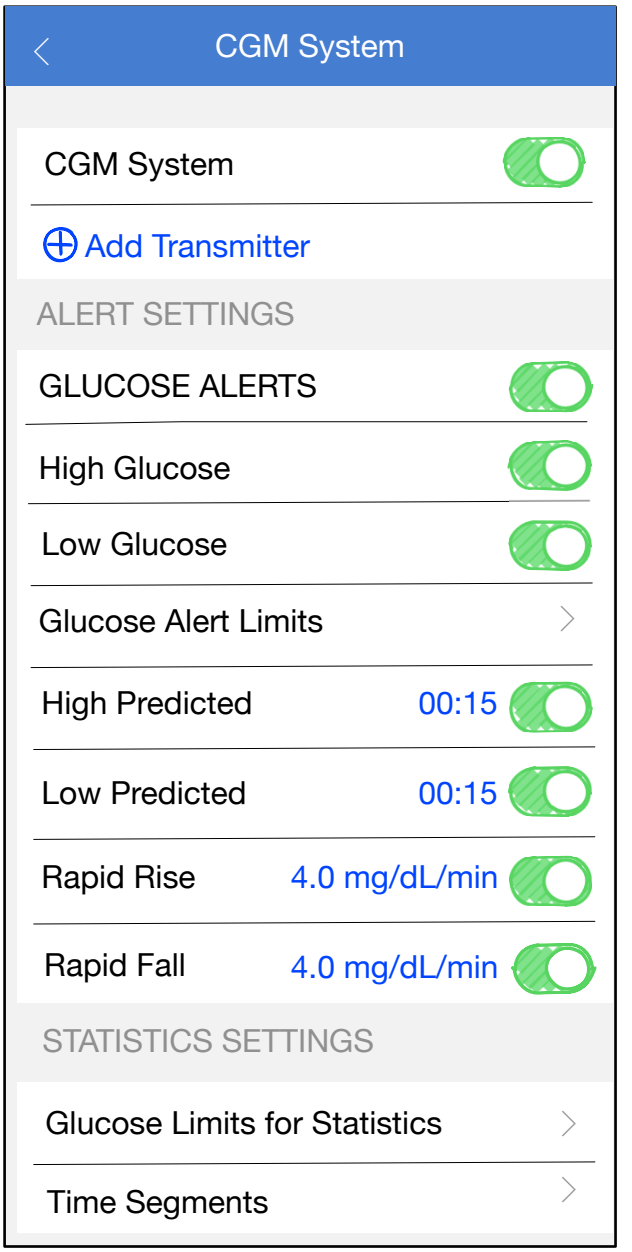
Connect Transmitter With App

Every time you change to a new Transmitter, you need to add the Transmitter SN to your App. After that your App and Transmitter will connect automatically for each sensor session.

Tap ☰ at the top-left corner of the screen to view the **Main Menu**. Tap **Settings** on the **Main Menu** to enter the **Settings** screen.

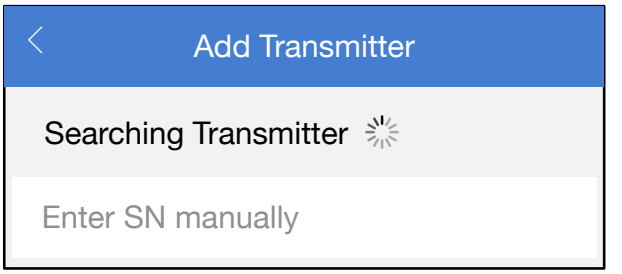


Tap **CGM System** to enter the CGM System settings screen. Turn the CGM feature On.



Connect your Transmitter to a Sensor. Make sure your Transmitter and smart device are within ten meters of each other, and your smart device is connected to the Internet. Tap **Add Transmitter**

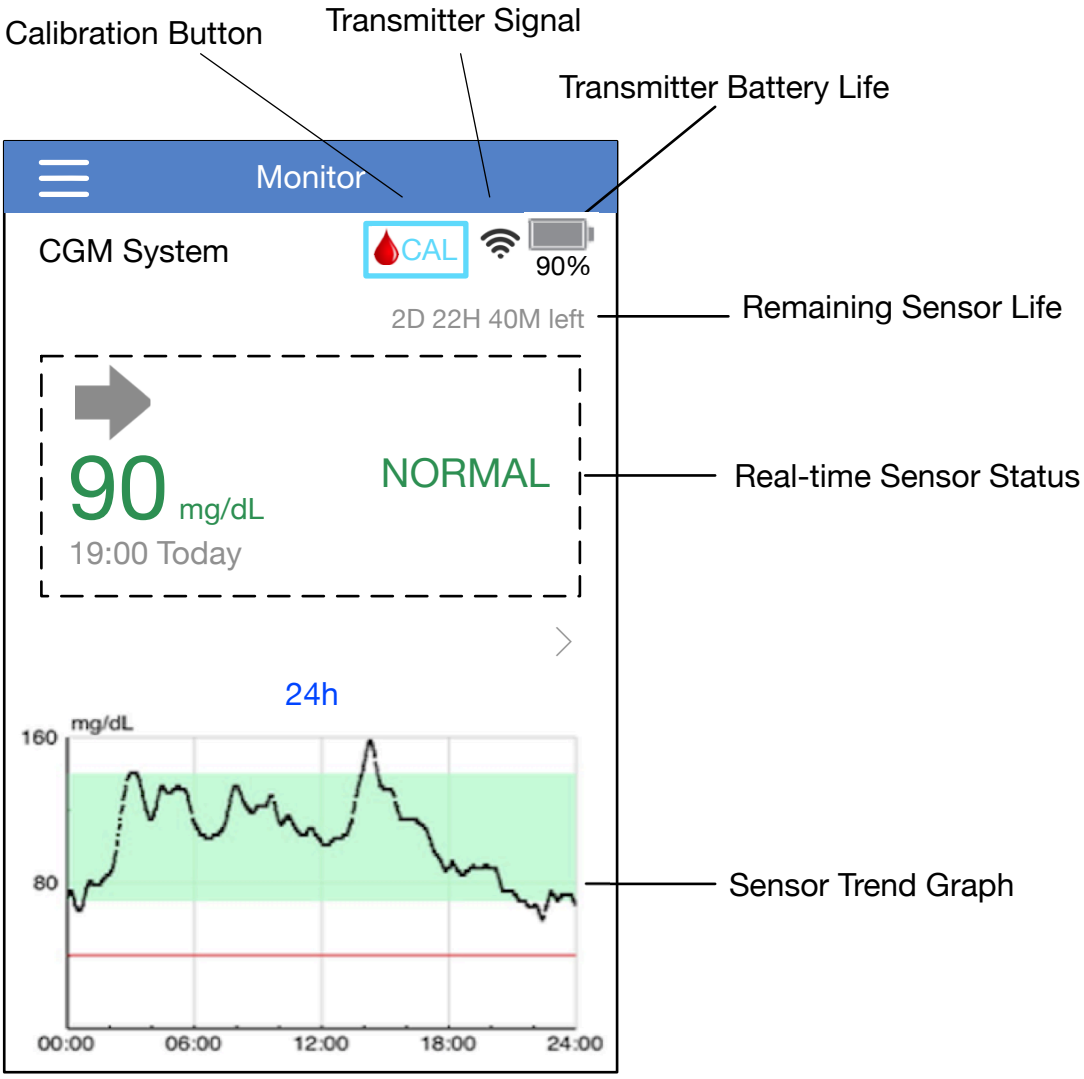
to add this Transmitter to your Medtrum account and to start communication between your Transmitter and smart device. You can use your smart device to search for your Transmitter, or you can enter the SN printed on your Transmitter manually.



Monitor Sensor Status

Once your Transmitter is connected with the App, you can use the App to monitor your real-time sensor status.

Tap at the top-left corner of the screen to view the **Main Menu**. Tap **Monitor** on the **Main Menu** to enter the **Monitor** screen.



1. The **Calibration Button** is explained in the next section *Calibrate Your Sensor*.

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

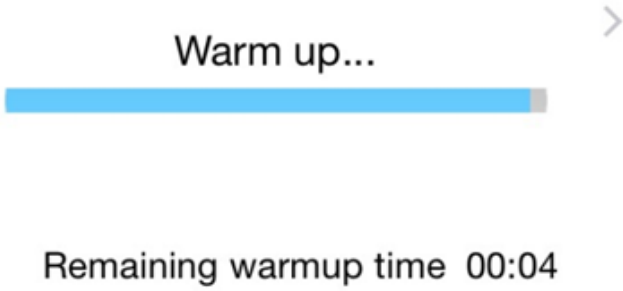
3. The **Transmitter Battery Life** icon shows the

remaining Transmitter battery life.

4. The **Remaining Sensor Life** shows the operating sensor life left in a total of 7 days.

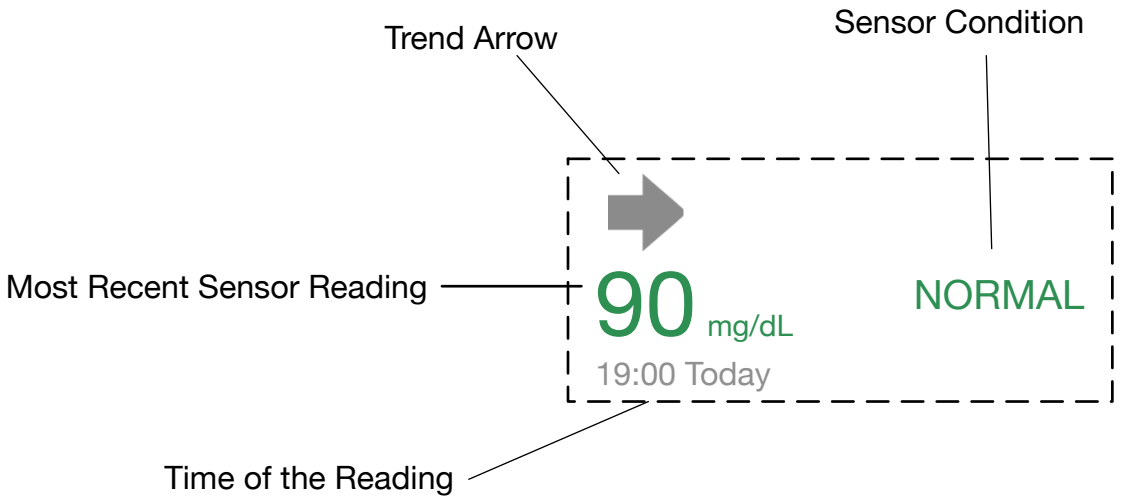
5. The **Real-time Sensor Status** area shows your current sensor status.

- Sensor Warmup



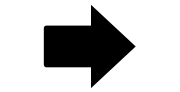
After you connect the Transmitter to a new Sensor, it takes 2 hours for the Sensor to warm up.

- After Calibration



After Sensor warmup is completed, you can calibrate your Sensor and monitor the real-time sensor status.

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



Constant

Slowly rising

Rising

Rapidly rising

Slowly falling

Falling

Rapidly falling

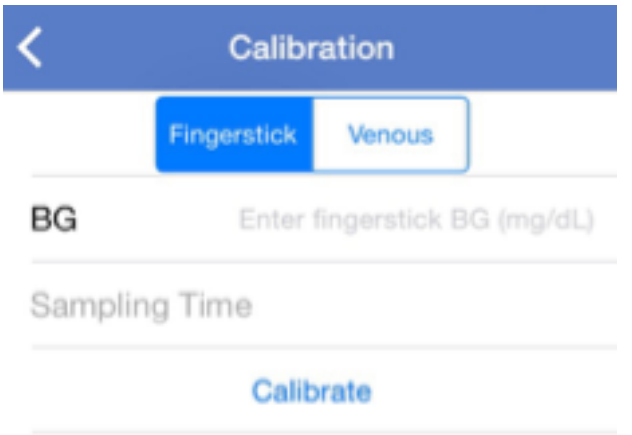
No arrow — No rate of change information

6. The **Sensor Trend Graph** shows your glucose level and trend. See *Sensor Trend Graph* in this chapter for more information.

Calibrate Your Sensor

After Sensor warm-up, tap

on the **Monitor** screen to enter the **Calibration** screen.



Select **Fingerstick** and enter the current fingertip blood glucose level, or select **Lab Calibration** and enter a venous blood glucose level. The blood sampling time must be 8 minutes to 2 hours before the current time.

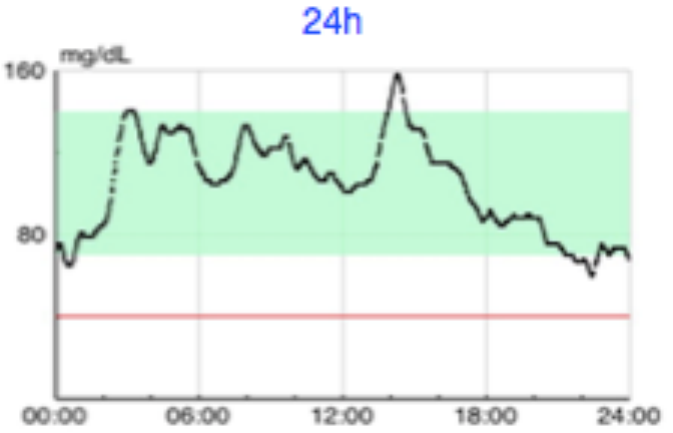
After the initial calibration, your sensor data will be displayed in real time. You must calibrate the Sensor at least once every 12 hours to ensure data accuracy. The App will prompt you when a calibration is needed.

Note: The button will disappear under the following circumstances:

- Smart device Bluetooth off
- Sensor warmup
- Sensor error
- Within 1 hour after the alert Sensor Calibration Error 1
- Sensor glucose rises/falls too quickly
- No Sensor signal

Sensor Trend Graph

The **Sensor Trend Graph** on the **Monitor** screen shows the glucose information of the most recent 3 hours, 12 hours or 24 hours. Tap the duration to change the graph range.



Tap the **Sensor Trend Graph** from the **Monitor** screen to enter the **Sensor** screen and view detailed CGM information.

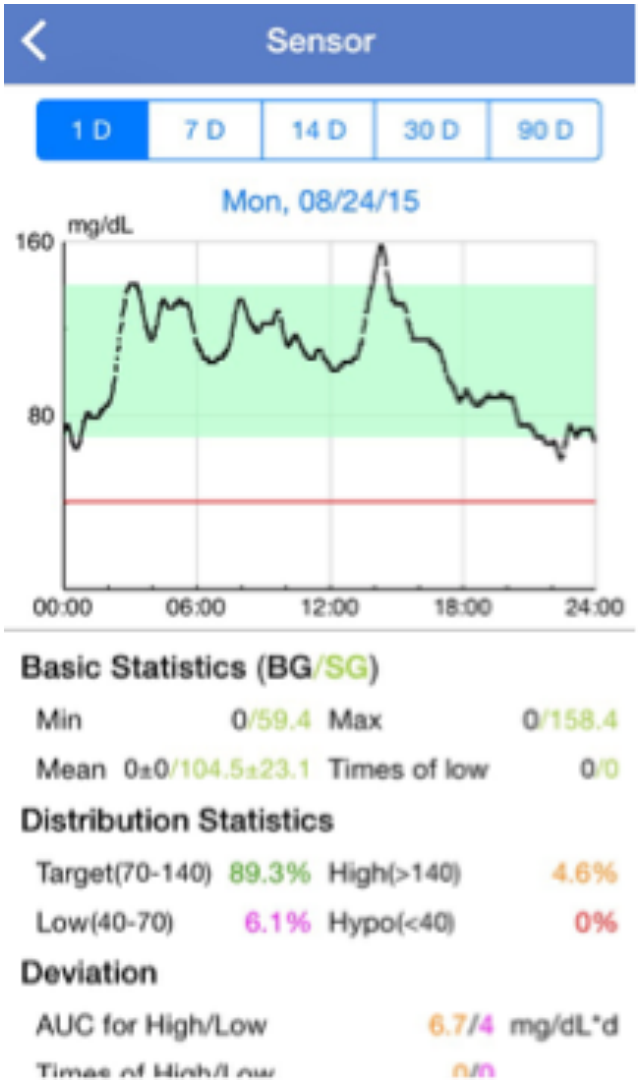
You can view the sensor data of 1 day, 7 days, 14 days, 30 days, or 90 days before the end date. The default end date is today. Tap the date to change. Touch and hold in the graph area to generate a cursor. Move the cursor along x-axis to view the sensor glucose (SG) and event at different time points. The cursor will disappear after 5 seconds of no operation.

The **Basic Statistics** includes the minimum of BG and SG, the maximum of BG and SG, the mean of BG and SG, and the number of occurrence of hypo.

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 the hypoglycemic threshold).

The **Deviation** includes the area under the curve (AUC) above the high limit of SG target range, the AUC below the low limit of SG target range, and the times of high and low SG.



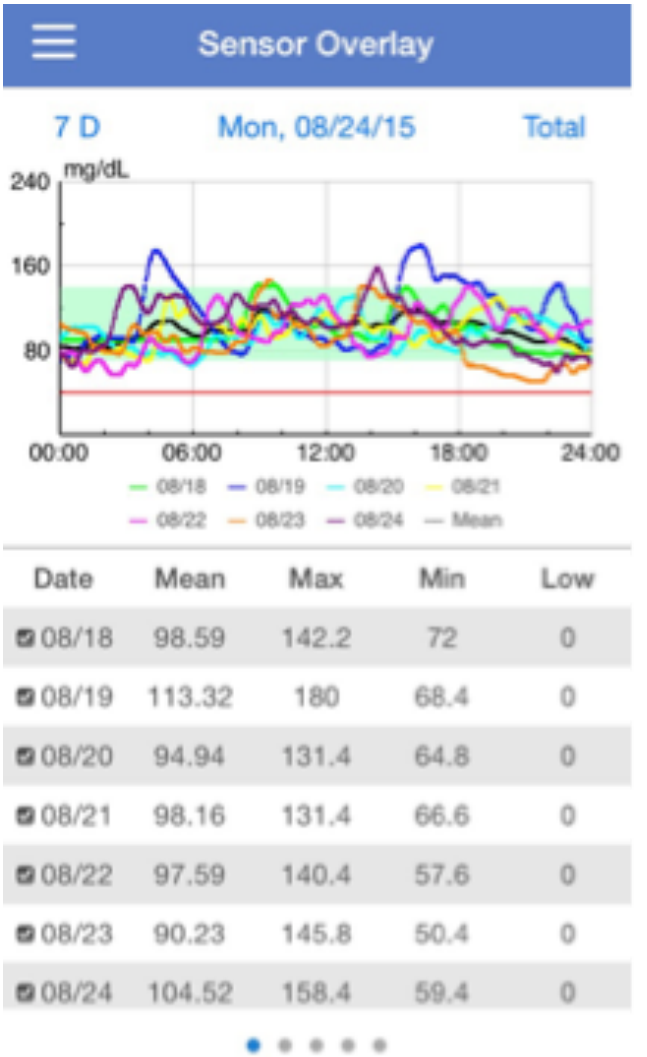
Understand the Statistics

Tap ☰ at the top-left corner of the screen to view the **Main Menu**. Tap **Statistics** on the **Main Menu** to enter **Sensor Overlay** screen. Swipe left to go to **Trend Analysis**, **SG Distribution**, **Event Distribution** and **Log Summary** screens

successively. Swipe right to return to the previous screen. Double tap a graph or hold your smart device horizontally to view the graph in full-screen mode.

Sensor Overlay

This screen displays the sensor data overlay within a given number of days before a selected date, along with the daily mean SG, maximum SG, minimum SG, and times of hypo. All daily SG curves are displayed in an overlap graph so that you can easily see the SG level change in a given period. The default end date is today. Tap the date to change if needed. Tap **7 D** on the top-left to edit the number of days. Tap **Total** on the top-right to select the displayed time segment from **Total**, **Breakfast**, **Lunch**, **Dinner** and **Night**. You can set the start and end time of each time segment under **Settings** menu. See *CGM Settings* in this chapter.



Trend Analysis

Here shows the sensor reading histogram within a given number of days before a selected date. The default end date is today. Tap the date to change if needed. You can view the data of 7 days, 14 days, 30 days, or 90 days before the end date.

SG Distribution

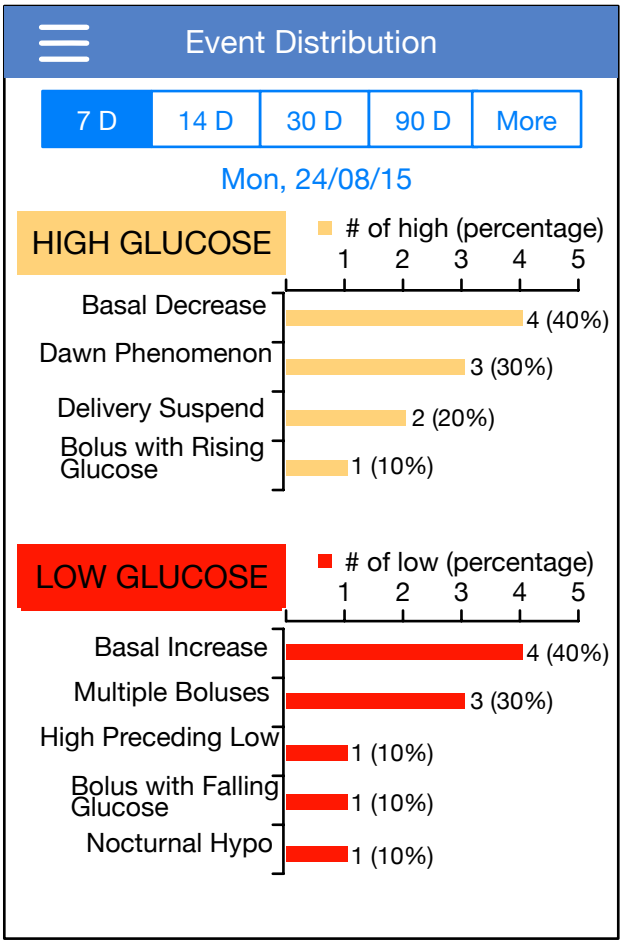
Here shows the SG distribution within different time segments, each pie chart demonstrating the proportions of low, target and high glucose. Red represents low, green represents target, and yellow represents high. You can set the time range of each segment. Select any pie chart and a corresponding histogram will be displayed below. The default end date is today. Tap the date to change if needed. You can view the data of 7 days, 14 days, 30 days, or 90 days before the end date, or you can change the number of days by selecting **More** and entering a number.

Event Distribution

Note: This screen appears only when your smart device is connected to a sensor and a Medtrum insulin pump at the same time.

Here shows the distribution of events that can

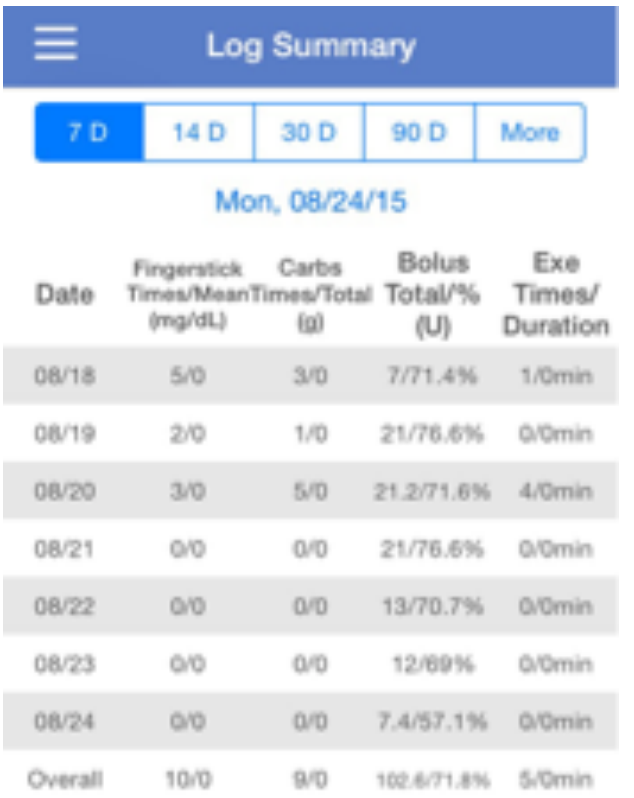
cause high/low glucose. The default end date is today. Tap the date to change if needed. You can view the data of 7 days, 14 days, 30 days, or 90 days before the end date, or you can change the number of days by selecting **More** and entering a number.



Log Summary

Here shows the log summary in a given period.

The table includes the times of BG tests and the mean BG, the times of food intake and the grams of carb, the total amount of insulin injected, and the times and duration of exercise. You can view the data of 7 days, 14 days, 30 days, or 90 days before the end date, or you can change the number of days by selecting **More** and entering a number. The default end date is today. Tap the date to change if needed.



Enter the Logs

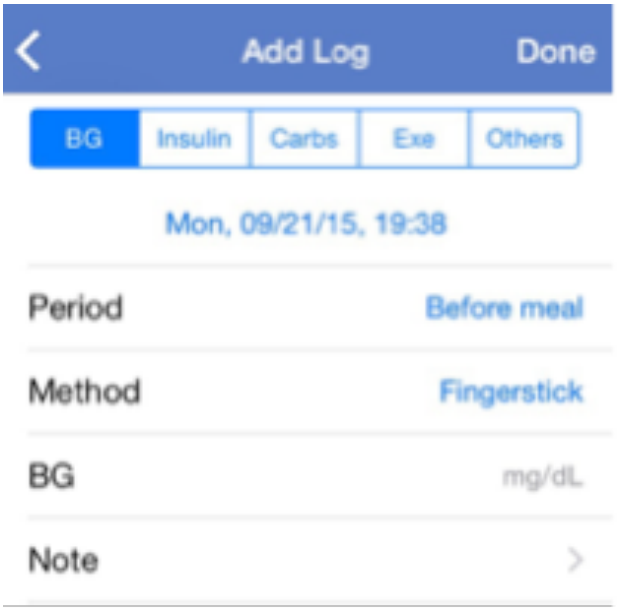
Tap at the top-left corner of the screen to view the **Main Menu**. Tap **Logs** on the **Main Menu** to enter the **Logs** screen. Tap to add new logs.

Add Log Screen

Select a category in **Add Log** screen to record data or events. Tap to return to the **Log** screen.

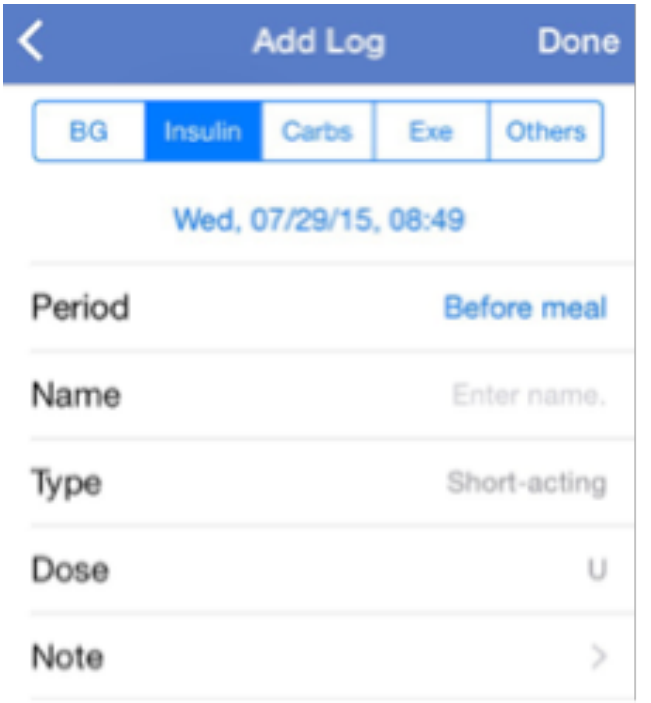
1. Add BG

The default date and time are the current date and time. Tap the date and time to change if needed. Tap **Before Meal** or **After Meal** to select the period. 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 Log** screen.



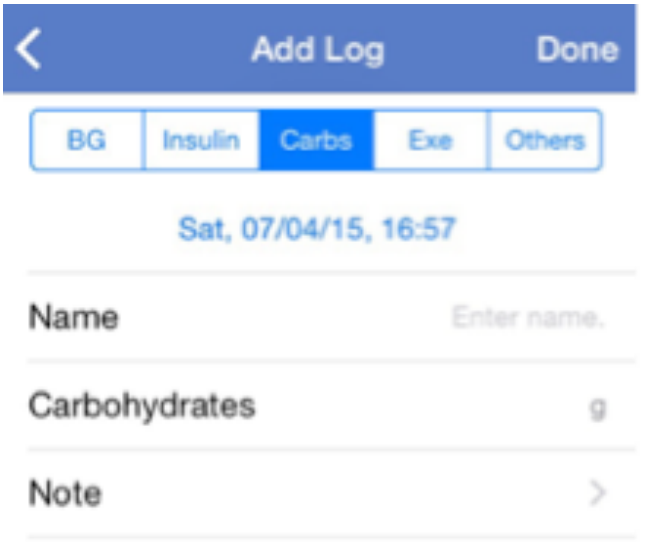
2. Add Injection

The default date and time are the current date and time. Tap the date and time to change if needed. Tap **Before Meal** or **After Meal** to select the period. Enter a name for this insulin injection record. Select from **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 Log** screen.



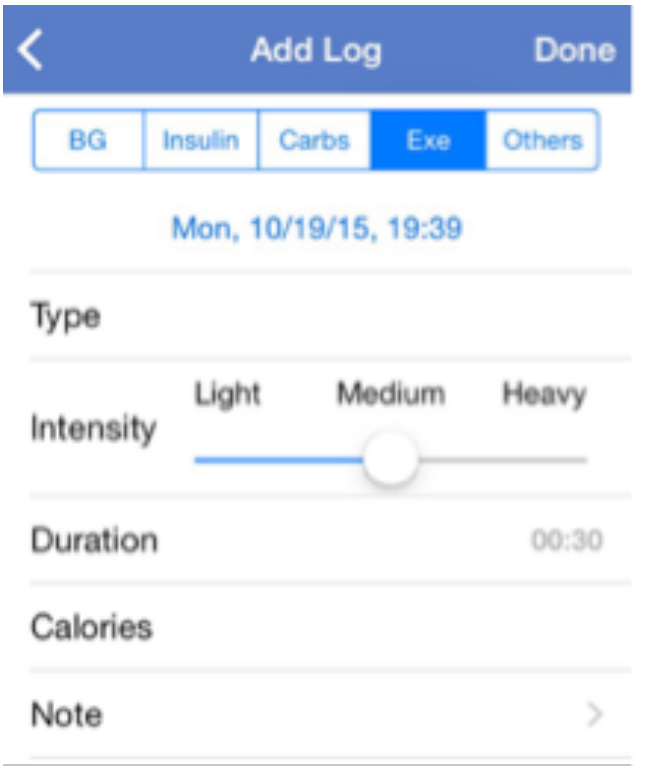
3. Add Carbs

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. Enter the grams of carbs. Tap **Note** to add a note if needed.



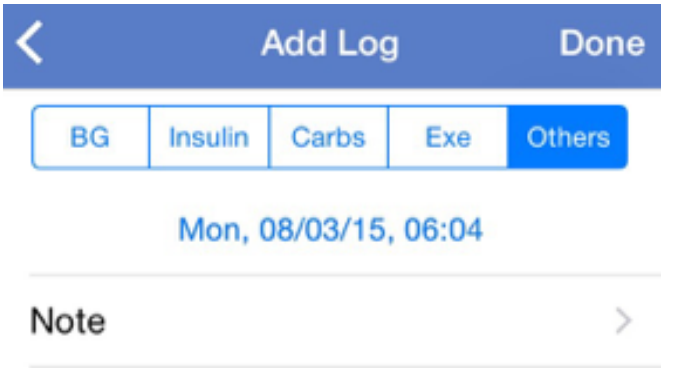
4. Add Exercise

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. Select the intensity and duration of exercise. Enter the calories burned. Tap **Note** to add a note if needed.



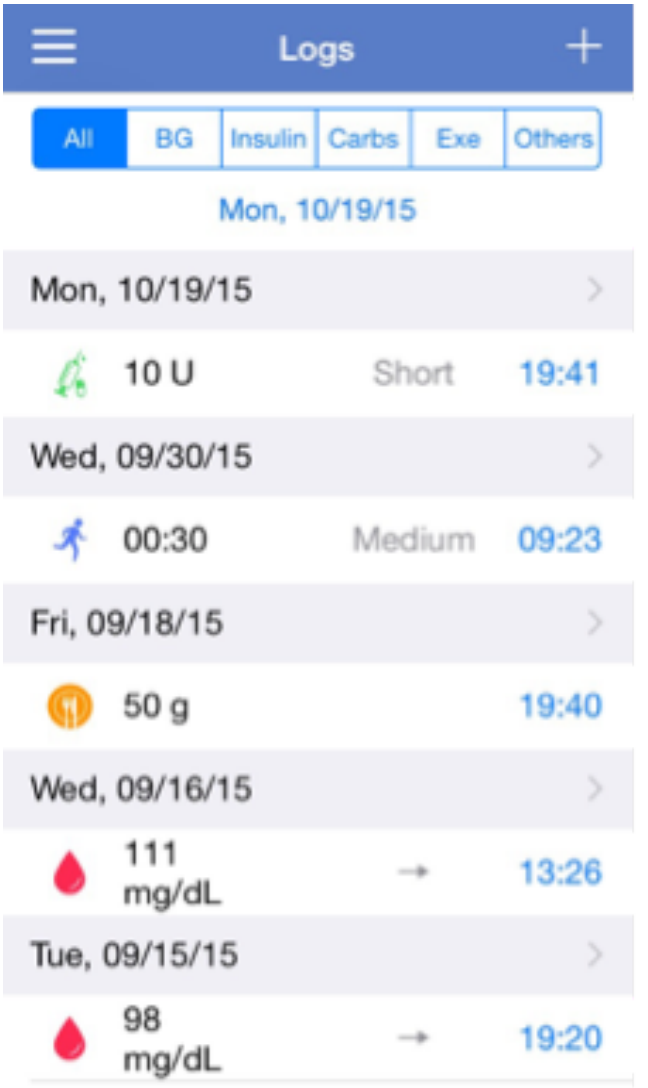
5. Others

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.



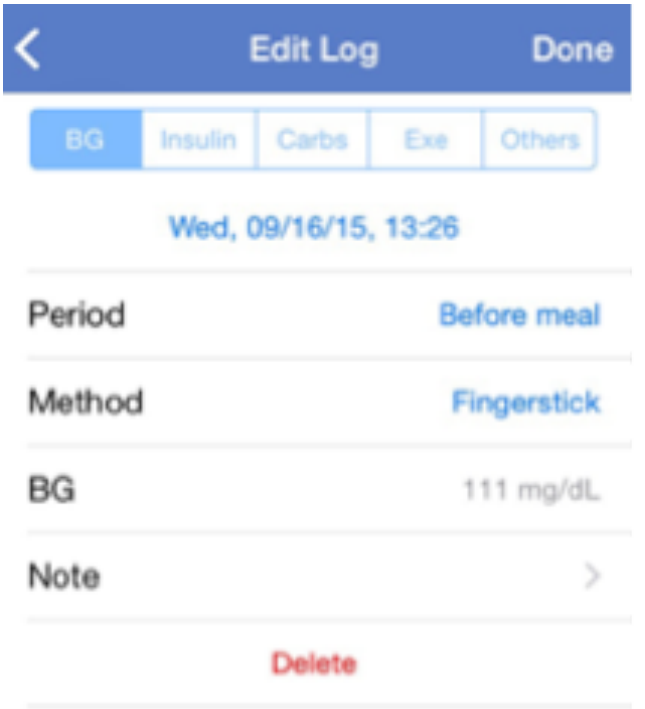
Logs Screen

Here show all the logs before the end date. Tap the end date to change if needed. Tap a log to view its details or to edit.



Edit Log Screen

You can tap a log to edit it on the **Edit Log** screen. After editing, tap **Done** to save the changes. You can also tap **Delete** to delete the log.



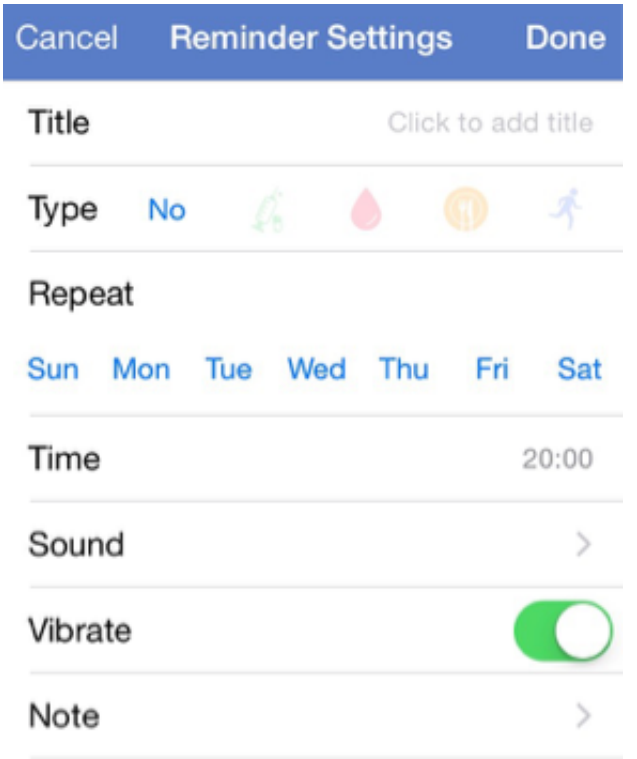
Set Your Reminders

Tap ☰ at the top-left corner of the screen to view the **Main Menu**. Tap **Reminder** on the **Main Menu** to enter the **Reminder** screen. Tap ＋ at the top-right corner to add new reminders. Tap **Done** to save changes.

Reminder Settings Screen

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

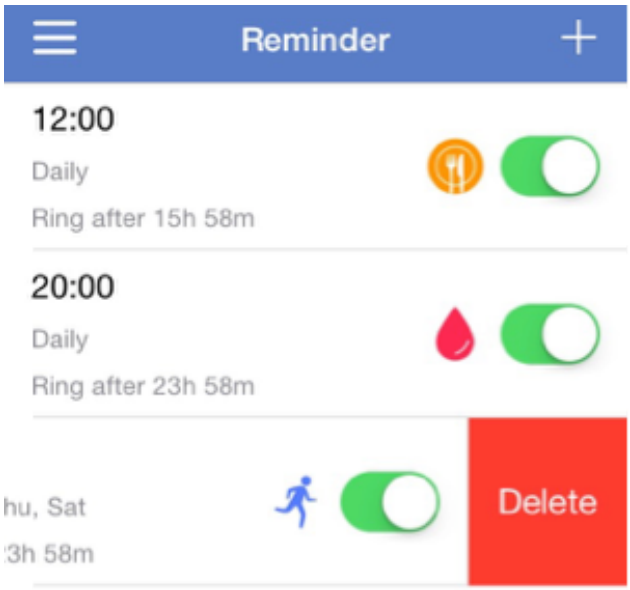
needed. Tap **Done** to save the changes.



Reminder Screen

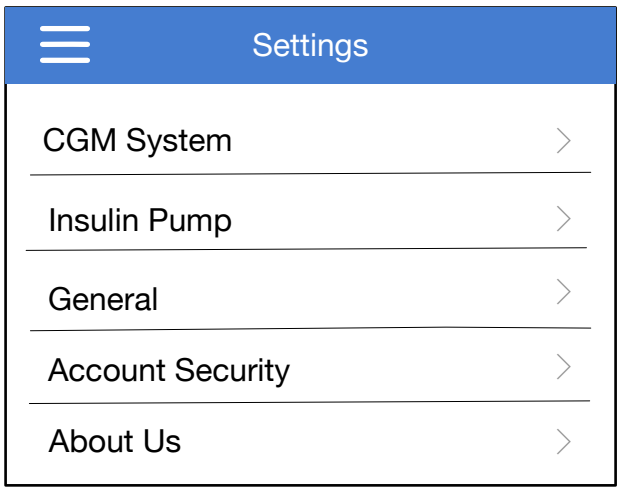
1. Here shows a list of saved reminders, each reminder with an ON/OFF switch. Tap a switch to turn on/off the reminder.

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



Customize Your Settings

Tap ☰ at the top-left corner of the screen to view the **Main Menu**. Tap **Settings** on the **Main Menu** to enter the **Settings** screen.

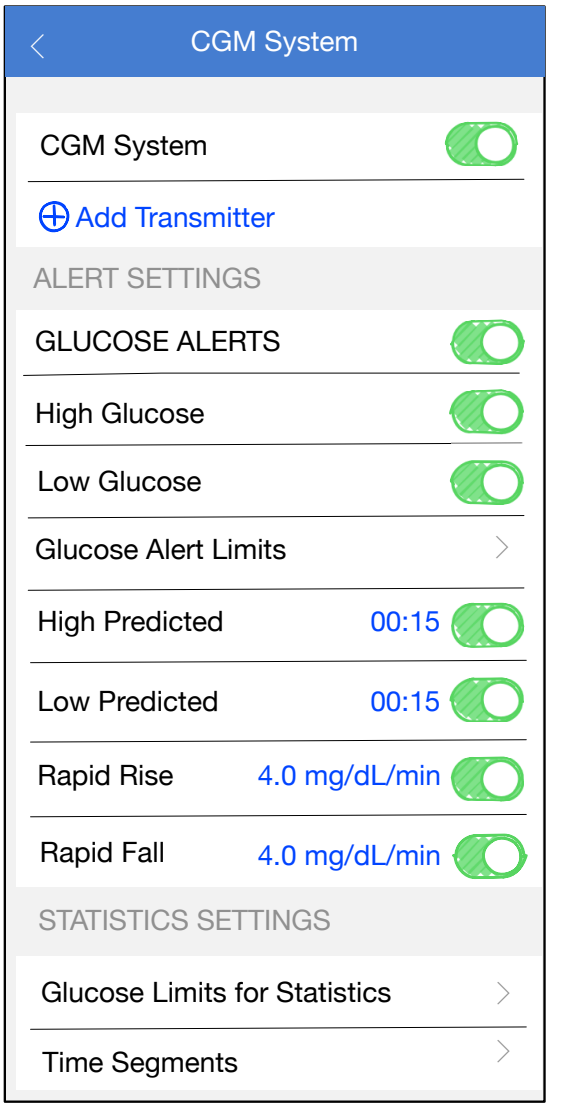


CGM System Settings

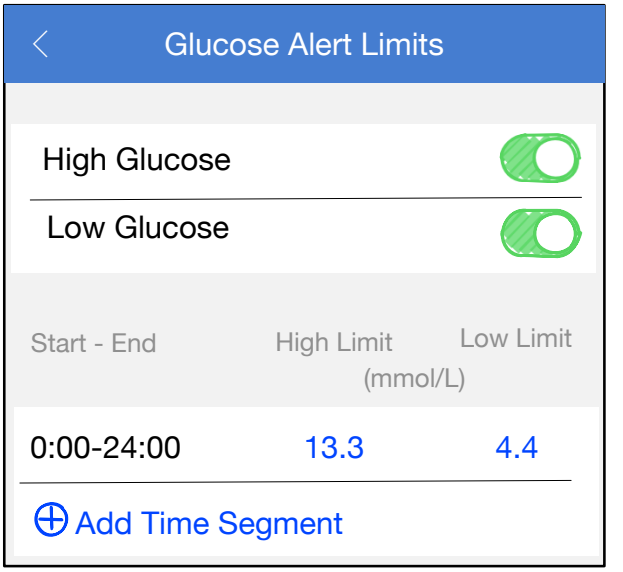
Make sure the CGM feature is turned on.

Alert Settings

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 High and Low Limits are also used in statistics.



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.

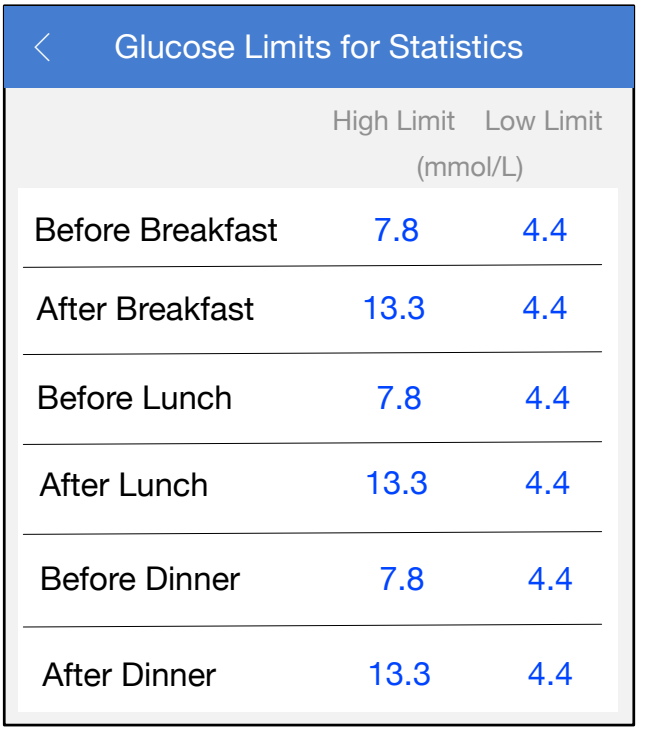
3. Low Predicted: The default setting is off. After you turn it on and set a time period, you can receive alerts when your glucose is predicted to reach the set low limit in the set period of time.

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.

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.

Statistics Settings

Glucose Limits (for Statistics): These values are used in **Sensor Overlay**, **SG Distribution**, and **Event Distribution**. You can set different glucose limits for different time segments. The period before each meal is fixed to 0~1h before each meal. The period after each meal can be set on the **Time Segments** screen.

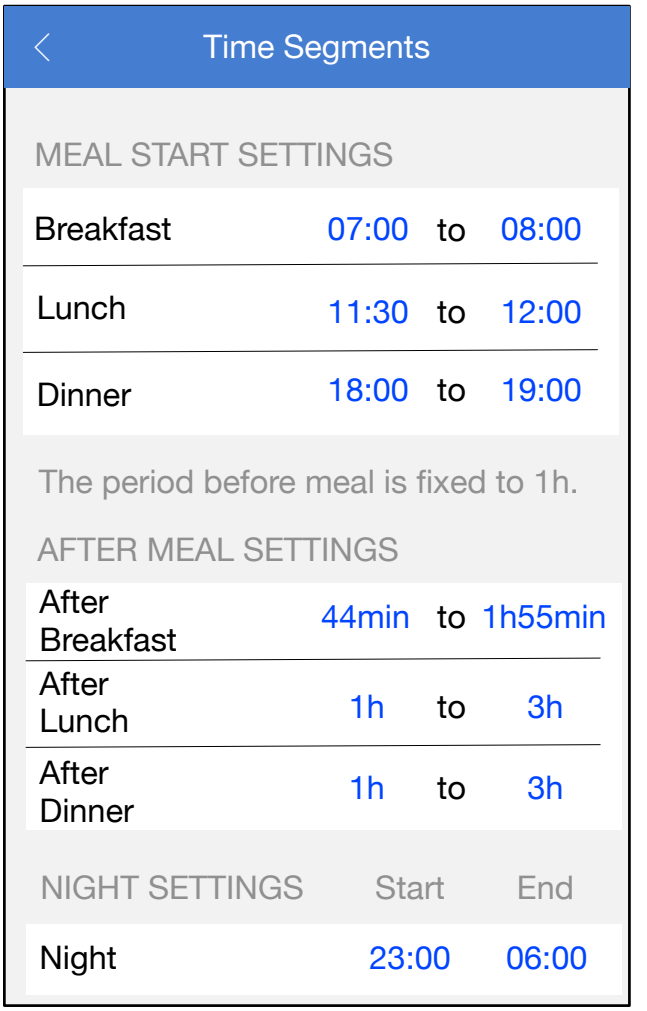


Time Segments:

1. Meal Start Time Settings: Set the periods within which **Breakfast**, **Lunch**, and **Dinner** starts. Each period cannot exceed 1 hour.

2. After Meal Settings: Set the after-meal segments.

3. Night Settings: Set the start and end time of night.

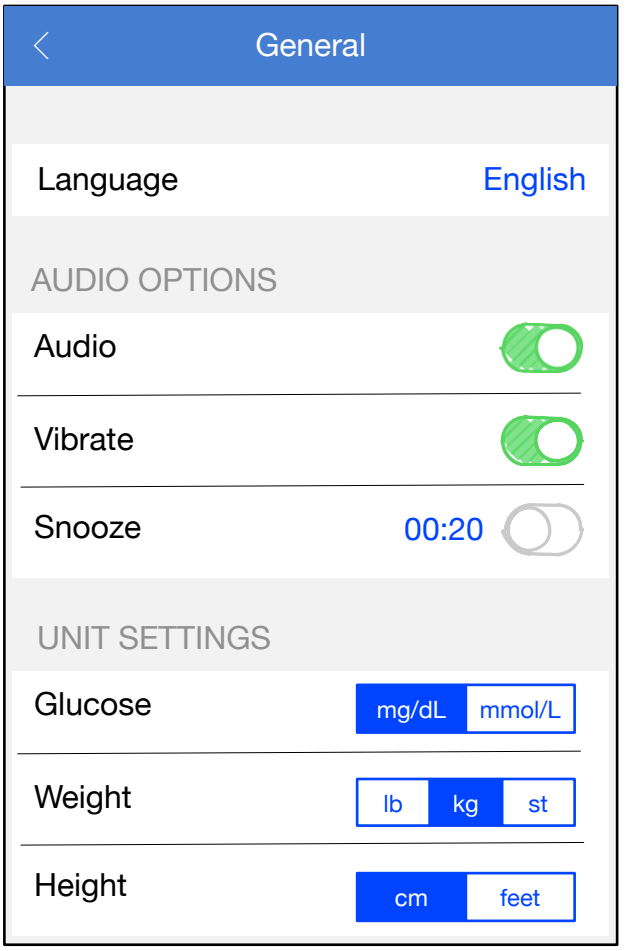


General Settings

You can select a display language, turn on/off **Audio**, **Vibrate** and **Snooze**, set the snooze time between 5 min and 1 hour, and customize unit settings here.

Note: We recommend that you turn **Audio** and **Vibrate** on. If you turn them both off, you might

miss an alert/alarm.

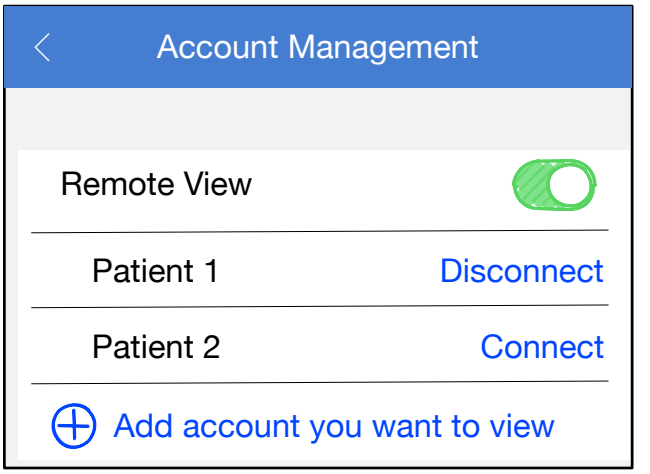


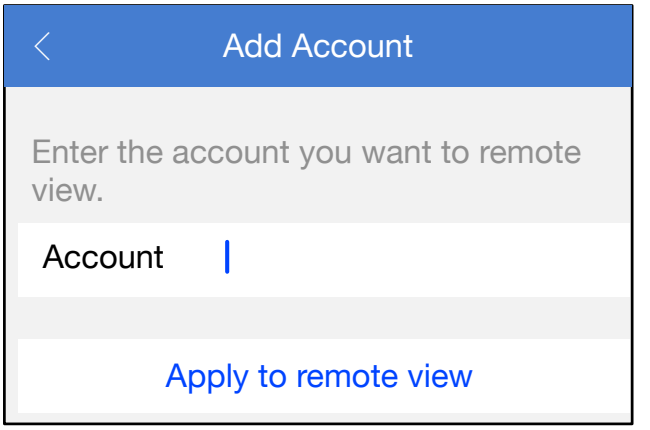
Remote Viewing

Remote View Other Accounts

Tap at the top-left corner of the screen to view the **Main Menu**. Tap **Remote View** on the **Main Menu** to enter the **Account Management** screen.

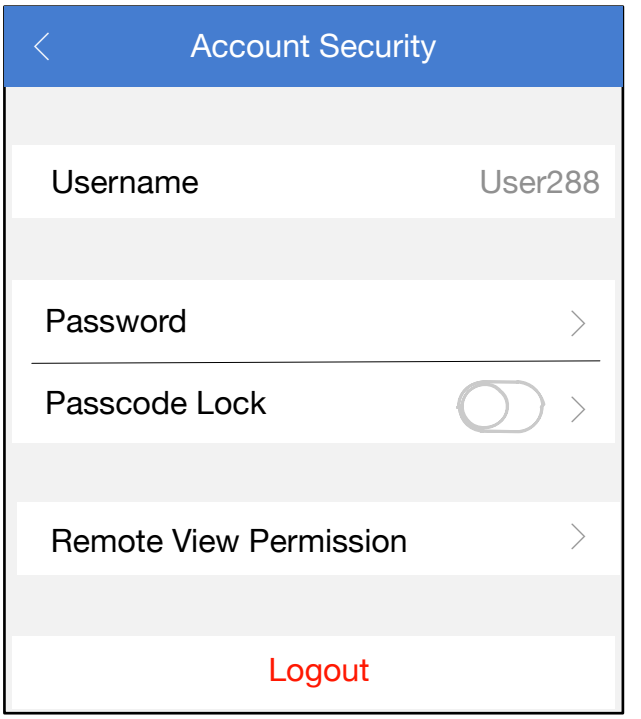
Tap the switch to turn on **Remote View**. Tap **Add account you want to view** to enter the **Add Account** screen. Enter an account name and apply to connect. If permitted by the user, you will have access to their **Monitor** screen and view their real-time sensor status.

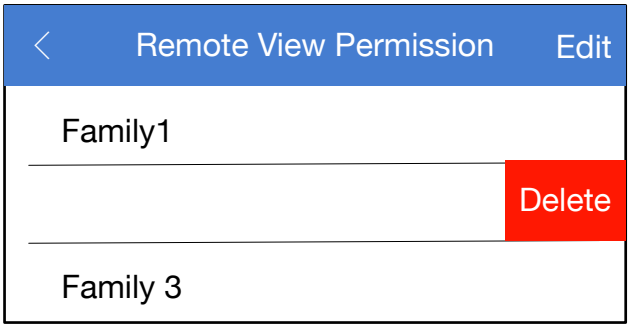




Allow Others to Remote View Your Account

If your App receives an application from another user for remote 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**. Swipe left on the selected user to cancel permission.




Remote View Permission
Edit
Family1
Delete
Family 3

Safety System and Alerts

To make you aware of a condition that is outside normal CGM system activity or potentially serious condition, your smart device with the Medtrum EasyTouch Mobile App vibrates or emits a tone on an alert and displays a 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 professional about what actions to take when an alert happens.

List of Alerts

Condition	App Message	Actions to Take

LOST SENSOR	Lost sensor. Check communicatio n distance.	Move your smart device close to the Transmitter.
TRANSMITTER BATTERY LOW	Transmitter battery low.	Change Transmitter soon.
TRANSMITTER ERROR	Transmitter error. Call customer support.	Call customer support.
SENSOR ERROR	Sensor error. Check or change sensor.	Check or change sensor.
SENSOR CALIBRATION ERROR 0	Sensor calibration error. Enter BG after 15 minutes.	Enter meter BG after 15 minutes.
SENSOR CALIBRATION ERROR 1	Sensor calibration error. Enter BG after 1 hour.	Enter meter BG after 1 hour.

SENSOR FAILURE	Sensor failure. Replace sensor now.	Change Sensor.
SENSOR CALIBRATION REMINDER	Calibrate sensor soon.	Enter a new meter BG soon.
CALIBRATE 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 professional.
RAPID FALL	Sensor glucose is falling rapidly.	Monitor trend and glucose level. Follow instructions from your healthcare professional.
LOW PREDICTED	Sensor glucose approaching Low Limit.	Check blood glucose and treat as necessary. Continue to monitor blood glucose.

HIGH PREDICTED	Sensor glucose approaching High 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 **Transmitter Error** occurs, the indicator light on the Transmitter flashes red.

Manufacturer's Declaration

The S6 EasySense Disposable CGM system (consisting of MD-TY-015 Transmitter and MD-JY-006 Glucose Sensor) is intended for use in the electromagnetic environment specified below. The customer or the user of the CGM System should make sure that it is used in such an environment.

Electromagnetic Emissions

Emissions Test	Compliance
RF emissions EN 60601-1-2:2007+AC:2010, IEC 60601-1-2:2007 and CISPR 11:2009+A1:2010	Group 1
RF emissions EN 60601-1-2:2007+AC:2010, IEC 60601-1-2:2007 and CISPR 11:2009+A1:2010	Class B

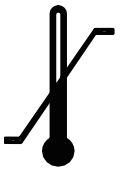
Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level
Electrostatic discharge (ESD) IEC 61000-4-2	±2.0 kV, ±4.0 kV, ±6.0 kV, ±8.0 kV contact discharge ±2.0 kV, ±4.0 kV, ±8.0 kV, ±15.0 kV air discharge	±2.0 kV, ±4.0 kV, ±6.0 kV, ±8.0 kV, 56% RH ±2.0 kV, ±4.0 kV, ±8.0 kV, ±15.0 kV air (56% RH)
RF electromagnetic field immunity test IEC 61000-4-3	10 V/m	10 V/m
Power frequency magnetic fields IEC 61000-4-8	3 A/m	3 A/m

Appendix I: Symbols and Icons

Product Label Symbols

Symbol	Meaning
	Lot number
	Reference number
	Manufacturer
	Use by: (yyyy-mm-dd)

	Caution: See Instructions for use
	Storage temperature
	Do NOT reuse
EC REP	Authorized representative in the European Community
	Do NOT use if package is damaged
CE 0197	CE mark by notified body

STERILE R	Sterilized using radiation
	Follow instructions for use
	Radio communication
IPX8	Waterproof to 2.5 m for 1 hour
SN	Device serial number
	Waste Electrical and Electronic Equipment

	Type BF equipment (Protection from electrical shock)

Appendix II: Specifications

Transmitter Specifications

Model: MD-TY-015
Size: 36.1 mm x 19.4 mm x 12 mm
Weight: 4.8 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
Battery: Built-in 3.0 V button cell battery
Waterproof Rating: IPX8 (2.5 m, 1 hour)
Category: Type BF equipment, Continuous operation
Data Storage: Automatically stores the previous 15 days' data
Wireless Communication Distance: 10 m
Duration of Use: 4 sensor sessions
Limited Warranty: 1 year

Glucose Sensor Specifications

Model: MD-JY-006
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
Sensor Life: Up to 7 days

CGM System Accuracy

A multi-center, randomized clinic study is designed to determine the sensor accuracy in persons with Type 1 or Type 2 diabetes. In-clinic testing consisted of frequent venous blood sample testing (by Yellow Springs Instrument 2300 STAT Plus™ Glucose Analyzer, YSI) on a random day in the 7-day sensor life. The accuracy is based on the percentage of CGM glucose readings that are within (±) 20%, 30% or 40% of YSI values at glucose values at or above

(>=) 75 mg/dL (4.2 mmol/L), or within 20 mg/dL (1.1 mmol/l), 30 mg/dL (1.7 mmol/L) or 40 mg/dL (2.2 mmol/L) of YSI values at glucose values below (<) 75mg/dL (4.2 mmol/L).

Table. Percentage of CGM Glucose Readings within ±20%/20, ±30%/30, or ±40%/40 of the YSI; Calibrating every 12 hours, Abdomen insertion site.

Number of Matched Pairs CGM-YSI	±20%/20	±30%/30	±40%/40
1734	90%	96%	99%

Glossary

App	A mobile app is a computer program designed to run on mobile devices such as smartphones and tablet computers. The Medtrum EasyTouch Mobile App is used with the S6 EasySense system for continuous glucose monitoring.
AUC	The area under the curve (mathematically known as definite integral) in a plot of glucose level against time.
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 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.
Glucose Limits for Alerts	The values you set to determine when the system will alert you of a high/low sensor glucose condition.
Glucose Limits for Statistics	The values you set to distinguish High, Low, and Target glucose range in the statistics graphs.
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	The amount of glucose that is present in the interstitial fluid

(SG)	and is measured by a glucose sensor.
Sensor Session	The 7-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.

UG883013

348010