NPI031-持续葡萄糖监测系统

使用说明书

NPI031- Continuous Glucose Monitoring System (CGMS)
User Manual

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产品使用说明书（UM）

Purpose 目的

按照法规要求输出TRUE VIE I3 实时持续葡萄糖监测系统产品使用说明书。

Output the TRUE VIE I3Continuous Glucose Monitoring System User Manual.

Scope 范围

本文件适用于本公司生产的在美国上市销售的TRUE VIE I3实时持续葡萄糖监测系统。

This document applies to the TRUE VIE I3 Continuous Glucose Monitoring System manufactured by Sinocare and marketed in the United States.

Terms, Definitions, Abbreviations 术语、定义、缩略语

详见说明书。

See the User Manual for details.

Reference Document 参考文件

NPI031-DP-001F_A.1 CGMS Documentation Plan (DP)
21 CFR Part 801 Labeling
21 CFR 862.1355 iCGM Special Control
FDA Guidance- Patient Labeling
FDA Guidance- Design Considerations for Devices Intended for Home Use
ISO 15223-1: 2021
FCC Certification
IEC 60601-1:2005+ AMD1:2012+AMD2:2020
IEC 60601-1-2:2014
FDA Guidance -Testing Labeling MRI Environment

1. Procedure 程序

N/A

2. Attachment 附件

附件 A TRUE VIE I3 CGM User Guide。

Attachment A TRUE VIE I3 CGM User Guide

TRUE VIE I3 CGM

Instructions for Use

TRIVIDIA HEALTH

TRUE VIE™

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IMPORTANT SAFETY INFORMATION

Before you use the TRUE VIE I3 Continuous Glucose Monitoring (CGM) System, read the instructions included with the System. The Instructions for Use includes important safety information. Discuss with your healthcare professional about how you should use the information from your TRUE VIE I3 CGM to help manage your diabetes.

Failure to use the TRUE VIE I3 CGM System and its components according to the instructions for use and all indications, contraindications, warnings, precautions, and cautions may result in you missing a severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) occurrence and/or making a treatment decision that may result in injury. If your glucose alerts and results from the TRUE VIE I3 CGM do not match your symptoms or expectations, use a fingerstick blood glucose (BG) value from your blood glucose meter to make diabetes treatment decisions. Seek medical attention when appropriate.

Getting Started with TRUE VIE I3 Continuous Glucose Monitoring System (CGM)

A Continuous Glucose Monitoring System (hereafter referred as CGM) gives you a more complete picture of your glucose control than fingerstick blood glucose (BG) monitoring alone. Using a CGM allows you to receive up to 480 glucose readings every 24 hours, filling the gaps between your BG checks. CGM alerts notify you of high and low glucose values. Graphs and trend arrows show the speed and direction your glucose levels are moving.

This Instructions for Use (also called User Guide) is provided to help you understand the setup and operation of your TRUE VIE I3 Continuous Glucose Monitoring (CGM) System. To help you find the information you need, you can use the table of contents at the beginning of the user guide and the Attachment at the end of the user guide. There is also a glossary of terms, which starts on page 66.

The following table describes certain terms, conventions, and concepts used in this user guide.

Convention	Description
Note	Provides additional helpful information.
CAUTION	Notifies you of a potential hazard which, if not avoided, may result in minor or moderate injury or damage to the equipment.
WARNING	Notifies you of a potential hazard which, if not avoided, could result in death or serious injury. It may also describe potential serious adverse reactions and safety hazards.
Bold text	Used to indicate screen items and buttons. For example, "Select **Next** to continue”

Resources

Tutorial:

Our online tutorial walks you through your first sensor session, including picking a display device, inserting the sensor, and using alerts.

The tutorial is available at: trividiahealth.com/tutorial

In-App Videos:

The in-App Videos can help you learn:

- **Overview:** See how your CGM shows where your glucose is now, where it is going, and where it has been
- **Sensor Insertion:** Walks you through inserting your sensor

You can watch these videos when you first set up the app or anytime at **Settings > Help > Videos**.

Guides:

- **Quick Start Guide:** guides you through setting up your display devices, inserting your sensor, and starting your first sensor session. You can find it with your TRUE VIE I3 CGM System box.
- **Instructions for Use (User Guide):** This User Guide is your encyclopedia. It gives you the most extensive overview of the TRUE VIE I3 CGM System, detailing features, important safety information, and so much more.

You can download both guides or ask for a printed version:

Download a PDF at trividiahealth.com/guides

Ask for a free copy by phone:

Toll free: 1-800-xxx-xxxx

Trividia provides a Customer Care helpline for assistance. If you experience problems using your TRUE VIE I3 CGM, report the issue to Customer Care. When calling Customer Care, please have the serial number of your device available. Please do not discard the sensor kit package after removing the sensor kit. The serial number and the Customer Care phone number are listed on your sensor kit package.

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Department	**Telephone number**
Customer Care, Monday – Friday, 8AM – 8PM EST (calls within the United States)	1-800-xxx-xxxx
Website	www.trividiahealth.com

Section 1: System Overview

- System Description
- Intended Purpose
- User Safety

1.1 System Description

Thank you for choosing the TRUE VIE I3 Continuous Glucose Monitoring System (hereafter referred as CGM). The TRUE VIE I3 CGM System consists of three main components: a Sensor Pack, a Bluetooth Low Energy (BLE) Transmitter Pack, and a mobile application (TRUE VIE I3 APP)

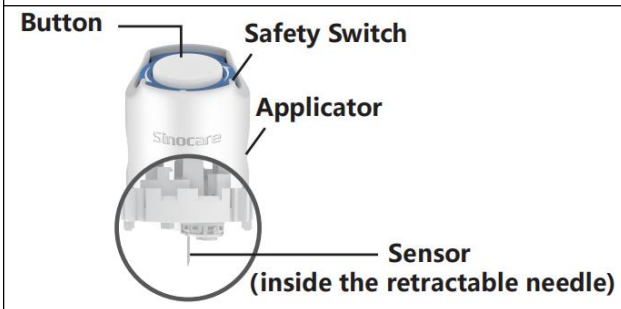
The TRUE VIE I3 CGM system provides glucose levels and allows you to continuously view your glucose values on your selected mobile device. The system tracks your glucose every 3 minutes by measuring the amount of glucose in the interstitial fluid. A sensor, inserted in your skin, sends glucose results to the TRUE VIE I3 APP. The APP then displays your glucose levels and long-term glucose trends. The APP also provides alerts if your glucose is in or projected to be in an unsafe zone.

The TRUE VIE I3 CGM system also detects trends and tracks patterns, and aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments. Interpretation of the system results should be based on the glucose trends and several sequential results over time.

The System can be used alone or in conjunction with digitally connected devices for the purpose of managing diabetes.

Note: Please read all the instructions provided in this Instructions for Use before using the system.

1.1.1 Device Components

What you see	What it's called	What it does
	Sensor Pack	This is a sterile package where the Sensor is stored. The Sensor Pack is designed for single use.
	Sensor-Applicator	The Sensor-Applicator helps you insert the Sensor under your skin. The Sensor has a small, flexible tip that is inserted just under the skin, it gets your glucose information. The Sensor can be worn

What you see	What it's called	What it does
		for up to 15 days. See **Chapter 2** for details on how to use your Sensor.
	Transmitter Pack	The Transmitter snaps into the Sensor and sends glucose readings wirelessly to your compatible display device via Bluetooth. When you use it, you don't need to take the Transmitter out of the Tray. See **Chapter 2** for details on how to use your Transmitter.

1.1.2 The TRUE VIE I3 CGM APP

The TRUE VIE I3 CGM APP serves as the display for the TRUE VIE I3 CGM and supports Android and iOS devices (mobile devices). The APP is available on Google Play (Android) and the APP Store (iOS). To see a list of compatible mobile devices, visit www.trividiahealth.com.

CAUTION: Missing alerts from the TRUE VIE I3 CGM APP may result in undetected

low and high glucose levels. Follow the instructions and safety warnings in this Instructions for Use to make sure you receive alerts as intended.

1.2 Intended Purpose

The TRUE VIE I3 Continuous Glucose Monitoring System is a continuous glucose monitoring device indicated for the management of diabetes for people age 2 and older. The system is intended to replace fingerstick blood glucose testing for diabetes treatment decisions.

The CGM also detects trends and tracks patterns, and aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments. Interpretation of the System results should be based on the glucose trends and several sequential readings over time.

The CGM can be used alone or in conjunction with digitally connected devices where the user manually controls actions for therapy decisions.

1.3 User Safety

This section includes important safety information such as indications, contraindications, safety warnings, potential adverse reactions, and how to protect the system from radiation exposure damage.

1.3.1 Contraindications

No MRI/CT/Diathermy

Do not wear your TRUE VIE I3 CGM for magnetic resonance imaging (MRI), computed tomography (CT) scan, or high-frequency electrical heat (diathermy) treatment.

The TRUE VIE I3 CGM has not been tested in those situations. The magnetic fields and heat could damage the components of the TRUE VIE I3 CGM, which may cause it to display inaccurate glucose results or may prevent alerts. Without TRUE VIE I3 CGM results or alert notifications, you might miss a severe low or high glucose event.

1.3.2 Safety Warnings

1.3.2.1 General Warnings

- **Do Not Ignore Low/High Symptoms**

Do not ignore symptoms that may be due to low or high blood glucose. If you have symptoms that do not match the glucose results or suspect that your results may be inaccurate, check the result by conducting a fingerstick test using a blood glucose meter. If you are experiencing symptoms that are not consistent with your glucose results, consult your healthcare professional.

- **No Treatment Decision if….**

If your TRUE VIE I3 CGM APP does not show a number or arrow, or your results do not match your symptoms, use your Blood Glucose Meter to make diabetes treatment decisions.

- **No modification is allowed.**

The patient is an intended operator. No modification of this equipment is allowed.

- **Contraindications**

Do not use the TRUE VIE I3 CGM if you are pregnant, on dialysis, implanted with a pacemaker or critically ill. It is not known how different conditions or medications common to these populations may affect performance of the system. TRUE VIE I3 CGM results may be inaccurate in these populations.

1.3.2.2 APP and Mobile Device

- When you start a new sensor, you will not get any CGM results or alerts during the 2-hour sensor warmup period. Use a blood glucose meter to make treatment decisions.
- Make sure Bluetooth is on, even if your mobile device is in Airplane mode. If Bluetooth is off, you will not get glucose information or alerts.
- Do not use the TRUE VIE I3 CGM APP if your mobile device screen or speakers are damaged. If your mobile device is damaged, you may not get glucose alerts and glucose information may not be shown correctly.
- Alerts for the TRUE VIE I3 CGM APP will sound through your headphones when headphones are connected. If you leave your headphones connected when not in use, you may not hear glucose alerts.
- If your mobile device restarts, the TRUE VIE I3 CGM APP may not restart automatically. If you do not open the APP again, you may not get glucose alerts. Always make sure to open the APP after your mobile device restarts.

1.3.2.3 Transmitter

- Do not use the device if you see any cracking, flaking, or damage to the transmitter. A damaged transmitter could cause injuries from electrical shocks and may make the TRUE VIE I3 CGM not work correctly.
- Do not allow children to put small parts in their mouth. This product poses a choking hazard for young children.
- Do not use the transmitter adjacent to other electrical equipment that may cause interference with the normal system operation. For more information on other electrical equipment that may compromise normal system operation, see Attachment B for details.
- Do not operate your transmitter in the presence of flammable anesthetics or explosive gases.
- Do not discard the transmitter in a medical waste container or expose it to extreme heat. The transmitter contains a battery that may ignite and result in injury.

1.3.2.4 Sensor

- Do not ignore broken or detached sensor tip. A sensor tip could remain under your skin. If this happens, please contact our Customer Care or your Healthcare Professional. If a sensor tip breaks off under your skin and you cannot see it, do not try to remove it. Seek professional medical help or contact our Customer Care.

- Store your TRUE VIE I3 CGM between 36°F (2°C) and 86°F (30°C). Do not store Sensors Pack in the freezer.
- Do not use a sensor past its expiration date because it may give incorrect results. The expiration date is in YYYY-MM-DD (Year-Month-Day) format on the sensor package label beside the hourglass symbol.
- Do not use sensor if its sterile package has been damaged or opened, because it might cause an infection.
- Do not open the sterile package until you are ready to insert the sensor because an exposed sensor can become contaminated.

1.3.2.5 Bleeding

- In order to insert the sensor to reach the interstitial fluid, the needle must penetrate the dermis layer of the skin, which has blood vessels scattered throughout. Penetration of these blood vessels may cause bleeding if the needle pierces them. If the sensor is inserted too deep into the body, bleeding can occur. Ensure you are not using excess pressure when inserting with the applicator.
- Do not use TRUE VIE I3 CGM if you are suffering from coagulation disorders or taking anticoagulant drugs.
- If bleeding occurs, do the following:
    - Apply steady pressure, using sterile gauze or a clean cloth placed on top of the sensor, for up to three minutes.
    - If bleeding stops, connect the APP to the sensor.
    - If bleeding does not stop, remove the sensor and clean the area using sterile gauze. Apply a new sensor on a different location at least 3 inches from the bleeding site.

1.3.3 Precautions

1.3.3.1 General precautions

- Avoid exposing your TRUE VIE I3 CGM to insect repellents and sunscreens. Contact with these skin care products may cause damage to your CGM.
- Do not wear the TRUE VIE I3 CGM in a hot tub.
- If you notice significant skin irritation around or under your sensor, remove the sensor and stop using the CGM. Contact your healthcare professional before continuing to use the CGM.
- The CGM system is designed for single use. Reuse may cause no glucose results and infection.

1.3.3.2 Testing Your Blood Glucose

Glucose levels in the interstitial fluid can be different to blood glucose levels and may mean that glucose results are different to blood glucose. You may notice this difference during times when your blood glucose is changing quickly; for example, after eating, taking insulin, or exercising. If you suspect that your result may be inaccurate, check the result by conducting a fingerstick test using a blood glucose meter.

1.3.3.3 Sensor Application

- Clean and dry your hands and your insertion site before inserting your sensor. Wash your hands with soap and water, not gel cleaners, and then dry them before opening the Sensor Pack. If your hands are dirty when you insert the sensor, you may get germs on the insertion site and get an infection.
- Clean your insertion site with alcohol swabs to prevent infections. Do not insert the sensor until your skin is dry. If your insertion site is not clean and completely dry, you run the risk of infection or the transmitter holder not sticking well.
- Make sure you do not have insect repellent, sunscreen, perfume, or lotion on your skin.
- Things to check before insertion:
  - Keep the safety guard locked until you put the armed applicator against your skin. If you remove the safety guard to unlock first, you may hurt yourself by accidentally pushing the button that inserts the sensor before you mean to.
  - Change your insertion site with each sensor. Using the same site too often might not allow the skin to heal, causing scarring or skin irritation.
- The sensor placement site must be:
  - At least 3 inches from insulin pump infusion set or injection site；
  - Away from waistband, scarring, tattoos, irritation, and bones；
  - Unlikely to be bumped, pushed, or laid on while sleeping

1.3.3.4 Potential risks related to sensor use

- Going Through Security Check Point

When wearing your TRUE VIE I3 CGM, ask for hand-wanding or full-body pat-down and visual inspection instead of going through the Advanced Imaging Technology (AIT) body scanner or putting any part of the TRUE VIE I3 CGM in the baggage x-ray machine. The effect of these scanners has not been evaluated and the exposure may damage the sensor or cause inaccurate results.

- Ascorbic acid (vitamin C) supplements

Taking ascorbic acid (vitamin C) supplements while wearing the sensor may falsely raise glucose results. The level of inaccuracy depends on the amount of ascorbic acid active in your body, and may be different for each person. Always use a blood glucose meter result to verify your glucose level if you are not sure.

- Bathing, Showering and Swimming
  - The sensor can be worn while bathing and showering but not in a hot tub; exposure to heat for a long time may damage the sensor or cause inaccurate results. You can also swim while wearing the sensor up to a depth of 8 feet for up to 120 minutes (IP28). Exceeding the depth or time may damage the sensor or cause inaccurate results.
  - Mild to severe related sensor-wear reactions

    e.g., allergic reaction, moderate to severe itching, rash, erythema, edema, induration, bleeding, insertion-site symptoms, bruising, pain, minor infection at the insertion site, discomfort during insertion.
  - Hyperglycemia or hypoglycaemia

Failure to use the TRUE VIE I3 CGM System according to the instructions for use and all indications, contraindications, warnings, precautions, and cautions may result in you missing a severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) occurrence.

- Underutilized or incorrect use of CGM

  There is significantly more data available to interpret. Users should read the instructions and work with your HCP to help you personalize your specific diabetes management and treatment plan.

1.3.4 Radio Frequency (RF) Communication

This device 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. This device generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this device does cause harmful interference to radio or television reception, which can be determined by turning the device off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Increase the separation between the device and the APP smart device
- Decrease the distance between the transmitter and the insulin pump to 6 feet (1.8 meters) or less
- Increase the separation between the transmitter and the equipment that is receiving or emitting interference

Special Precautions regarding Electromagnetic Compatibility (EMC)

This body worn device is intended to be operated within a reasonable residential, domestic, public or work environment, where common levels of radiated “E” (V/m) or “H” fields (A/m) exist; such as cellular phones, WiFi, Bluetooth, electric can openers, microwave and induction ovens. This device generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the provided instructions, may cause harmful interference to radio communications.

Portable and mobile RF communications equipment can affect Medical Electrical Equipment as well. If you encounter RF interference from a mobile or stationary RF transmitter, move away from the RF transmitter that is causing the interference.

1.3.5 TRUE VIE ACCESS and REACH APP safety statements

TRUE VIE ACCESS lets you send your sensor information from your App to your Care Partners’ smart devices (TRUE VIE REACH APP). REACH APP’s information is always older than your App. The information on REACH APP is not meant to be used for treatment decisions or analysis.

Section 2: Start Your Sensor

- Prepare the Sensor
- Choose a Site
- Pair Your Sensor with the Transmitter
- Apply Your Sensor
- Sensor Warmup

2.1 Prepare the Sensor

2.1.1 Before starting, make sure you have everything you need.

TRUE VIE I3 CGM System:

- Sensor Pack
  - Check expiration date on Sensor Pack. Do not use if expired.
  - Do not open the sensor sterile package until you are ready to insert the sensor
- Transmitter Pack
  - Check SN codes on the Sensor Pack and the Transmitter Pack are the same
- Alcohol swabs
- Your Blood Glucose Meter

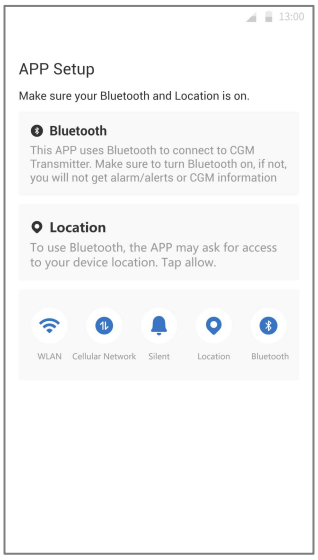
2.1.2 APP installation and set up

Step 1: APP Set up

Tap TRUE VIE I3 CGM APP to open the APP.

Step 2: Enable notification and location access

Tap "**Allow**" to enable Bluetooth, Location access, and allow notifications on your mobile device, so you will not miss the alerts or being denied of Bluetooth service.



Recommended Mobile Device Settings

See your mobile device instructions to learn how to change its settings.

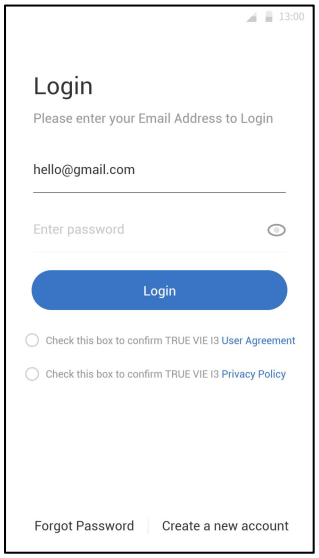
- Use the following with your CGM system:
- Bluetooth on: Your transmitter and APP communicate via Bluetooth. If it is not on, you will not get alerts and CGM results.
- Notifications on:
  - Enable TRUE VIE I3 CGM APP notifications so that you can get alerts.
  - Make sure you allow TRUE VIE I3 CGM APP notifications to show on your locked screen.

Battery charged: The APP must always be running in the background and may drain your battery. Keep the battery charged.

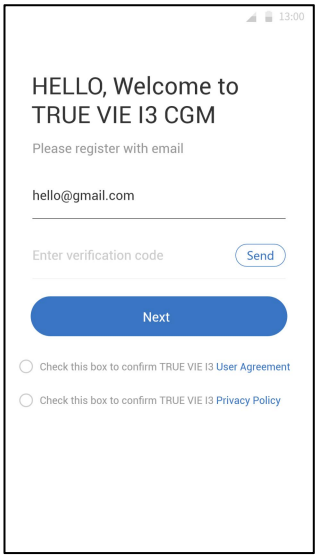
- Device and APP on: If you restart your mobile device, reopen the TRUE VIE I3 CGM APP.
- Update manually: Automatic updates of the APP or your device operating system can change settings or shutdown the APP. Always update manually and verify correct device settings afterward.
- Compatibility: For a list of mobile devices and operating systems that work with the TRUE VIE I3 CGM APP, check trividiahealth.com/compatibility.
- Time: If you are crossing time zones, DO NOT change your mobile device time manually, wait until you have arrived at your final destination to let your mobile device switch the time automatically. Note that CGM APP displays glucose readings (including historical reading within the same monitoring cycle) in your current time zone.

- **Step 3: Login**

Enter existing Username and Password.

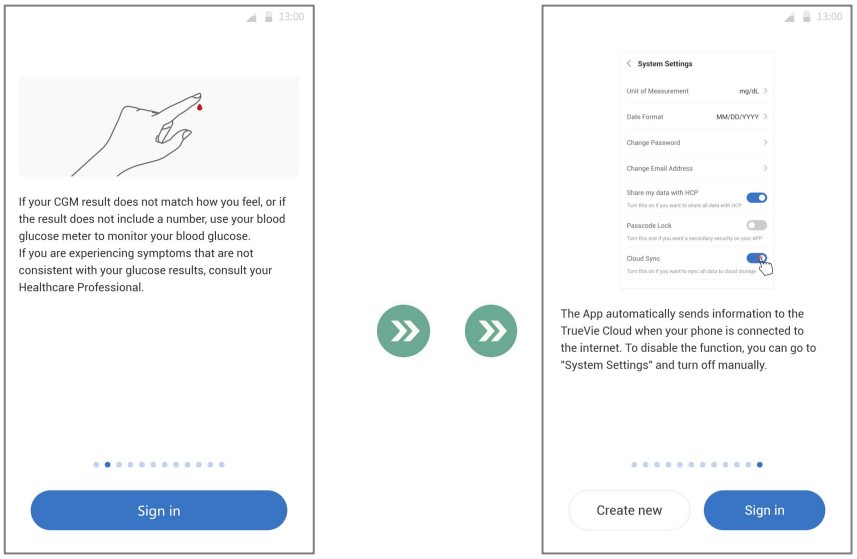


Or, if you need to create a TRUE VIE account, follow the onscreen instructions below.



Step 4: Review Tutorials

Next, the App will prompt you to review safety instructions including a tutorial video that guides you on using your TRUE VIE I3 system.



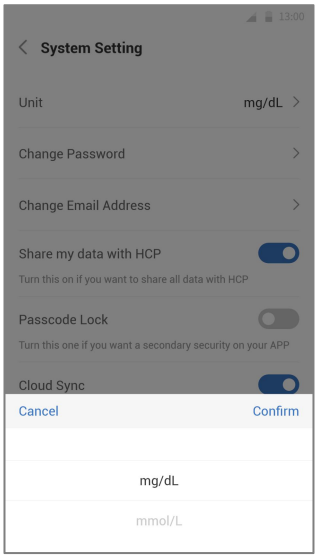
Note: This in-APP overview of TRUE VIE I3 system does not replace this Instructions for Use. Read all of the information in this Instructions for Use before using TRUE VIE I3 CGM APP.

2.1.3 System Settings

The "**System Settings**" option under "**Settings**" button is where you can change your account profile, such as password and email.

Changing the glucose unit of measurement used throughout the APP (mg/dL or mmol/L)

Tap the "**System Settings**" button, select "**Unit**". If you decide to use a different unit of measurement from the default setting, you will see a confirmation message notifying that the unit of measurement has been changed.



Changing your email

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

In the APP, tap the "**System Settings**" button, select "**Change Email Address**".

Enter the new email address you want to use, and press "**Next**".

You will receive a confirmation code through your new Email address, type it in and press **"Confirm**".

Changing your password

A good password is important to keep your health data safe. We recommend you change your password occasionally, especially when you believe your password may have been compromised.

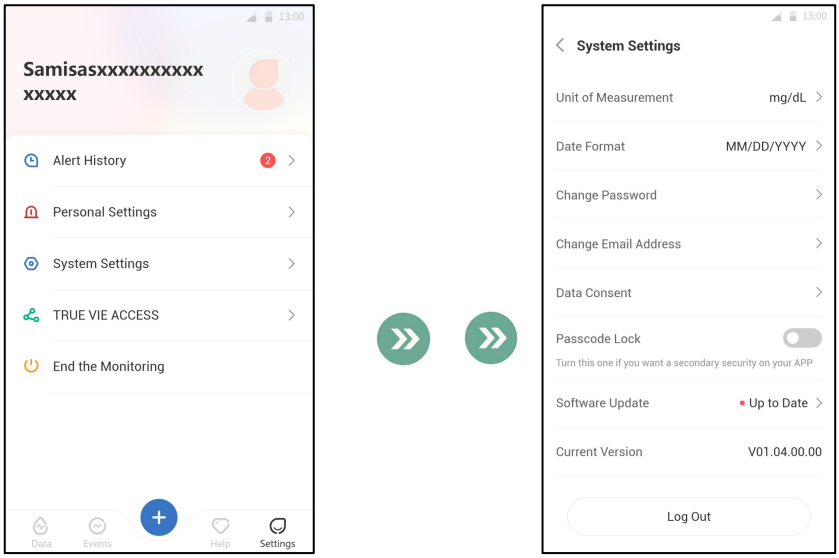
In the APP, tap the "**System Settings**" button, select "**Change Password**".

Enter the email address you use to sign in and tap "**Send**", a verification code will be sent to you.

Tap "**NEXT**" and enter your new password.

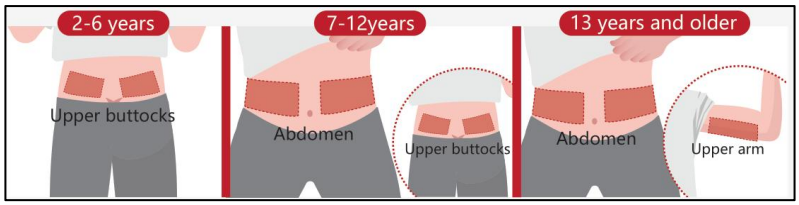
Data Consents

Please Review and revise data consents. In the APP, tap the "**System Settings**" button, select "**Data Consents**"



2.2 Choose a Site

Wash hands and thoroughly dry your hands. Choosing a comfortable, effective place for your sensor is important. Discuss ideal sensor insertion sites with your Healthcare Professionals (HCP). Clean the insertion site with alcohol swabs. Let the area air dry.



CAUTION: Do not choose other sites. As the other sites have not been clinically evaluated, your glucose results could be inaccurate.

TIPS:

- Place the sensor at least 3 inches from your insulin pump infusion set or injection site.
- Make sure the insertion area is dry, clean and free of lotions, perfumes, and medications. If needed, shave the area so adhesive patch sticks securely.
- Avoid areas near waistbands or with scars, tattoos, irritation, and bones. Contact your HCP if sensor adhesive irritates your skin.
- Do not use the same site for 2 sensors in a row.
- Do not use sites that have muscles or areas constrained by clothing or accessories, areas with rough skin or scar tissue, sites subjected to rigorous movement during exercise, or sites under a belt or on the waistline for best sensor performance and to avoid accidental sensor removal.

2.3 Pair Your Sensor with the Transmitter

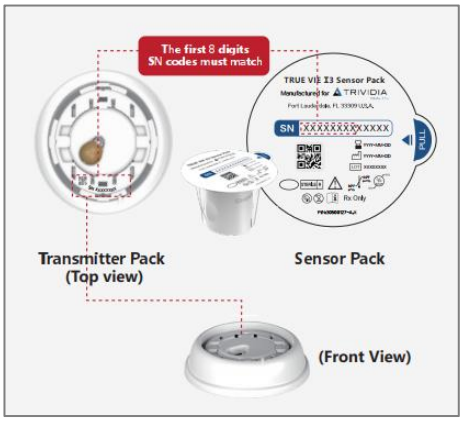
The TRUE VIE I3 CGM transmitters communicates with the TRUE VIE I3 CGM APP via Bluetooth, so it must be connected with the APP before using the system. This process is called "**Pairing**".

Step 1: APP Setup

Follow the instructions in Section.2.1.2 to setup your APP, make sure your phone Bluetooth is on. Location access must be granted in order to pair via Bluetooth.

Step 2: Check the 8-digit SN Code

The Sensor Pack and Transmitter Pack are packaged together and share the same first 8 digits in their respective serial numbers. It's important to ensure that the serial numbers match before pairing the Sensor with the Transmitter.

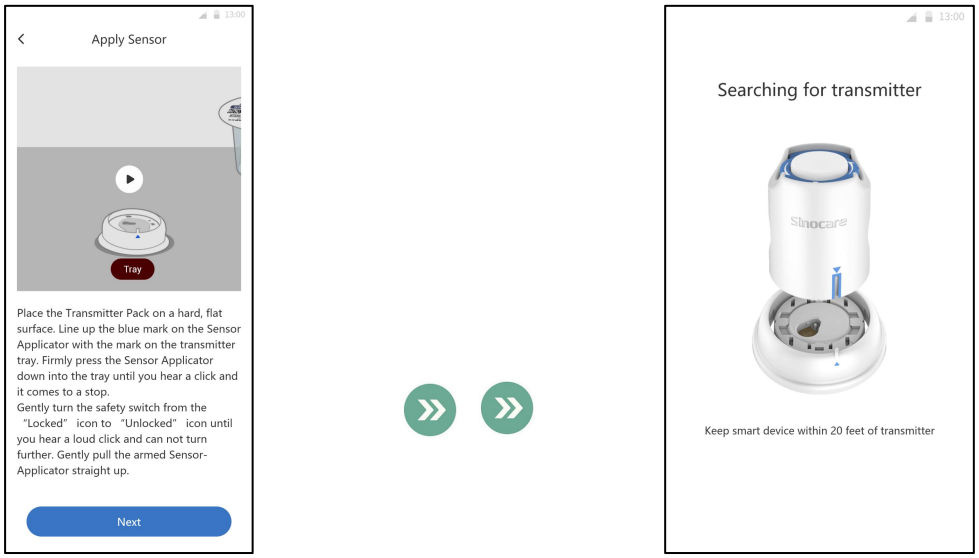


Step 3: Scan the SN Code

After watching guidance videos, follow the Step 4 from Sec 2.3, scan the SN 2D barcode located on the Sensor Pack label or enter the SN Code by typing manually. The pairing happens automatically after successfully scanning the SN Code. If you choose to type in the SN Code manually, make sure to tap on "**Next**" to proceed. The Sensor Pack and Transmitter Pack share the same first 8 digits in their respective serial numbers, make sure you enter the correct code. If you enter the wrong code or code from another Sensor Pack, you will not be able to use the TRUE VIE I3 CGM or your glucose result could be incorrect.

Step 4: Pairing

Next, the APP will instruct you how to attach the Sensor to the Transmitter. You can follow the in-APP video below to apply your CGM. Please make sure to keep your mobile device within 20 feet the entire time; the Pairing will start automatically once you complete the next step.



2.4 Apply Your Sensor

The sensor probe is inside the Sensor-Applicator. Before applying the sensor, get familiar with the Sensor-Applicator.

Button
Insert sensor under your skin

Sensor
Sensor inserts through this hole

Transmitter
Sends your glucose information from the sensor to the APP

Adhesive Tape
Keeps the sensor and transmitter on skin

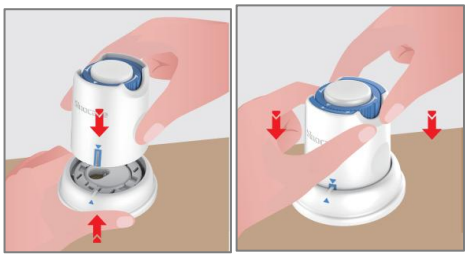
Step 1: Open the Sensor Pack

- Take the Sensor Pack you used from Sec 2.3. Do not use if the package is broken, damaged or opened. Do not open the package until you are ready to apply the Sensor.
- Check Sensor for damage.

CAUTION: The Sensor- Applicator contains a needle. DO NOT touch inside the Sensor Applicator or put it back into the Sensor Pack.

Step 2: Apply the Sensor

- Line up the blue arrow mark on the Sensor-Applicator with the matching blue arrow mark on the Transmitter Tray. On a hard surface, press down firmly until it comes to a stop and you hear a click.



- Gently turn the safety switch from the "Locked icon" to the "Unlocked icon" until you hear a click.

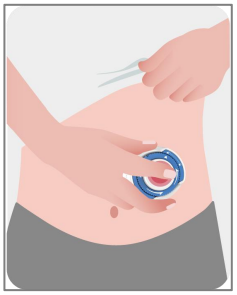
- Lift the Sensor-Applicator out of the Transmitter Tray

- Now it’s ready to apply the sensor.

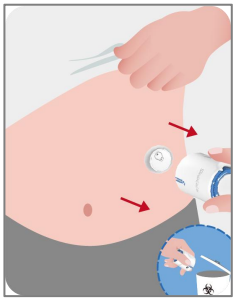
CAUTION: DO NOT touch the adhesive tape of the Sensor- Applicator, if you have to stop at this step, put it back into the Transmitter Tray.

Step 3: Apply the Sensor

- Place the Applicator against the selected sensor insertion site. Press down the button in the middle to apply the CGM Sensor. You will hear a click sound, that means the insertion is completed.

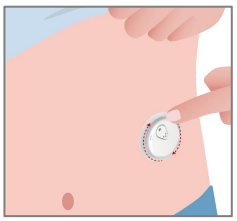


- Gently pull the Applicator away from your body.



CAUTION: Discard the used Applicator according to local regulations.

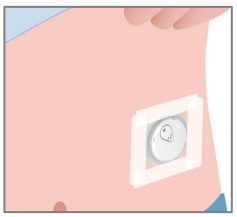
- Smooth down the Sensor adhesive tape with a finger to ensure the sensor stays on the body for the entire duration of wear.



Step 4: (Optional) Help the adhesive tape to stay on

- After inserting your Sensor, you may apply an over patch or medical tape around the edge of the adhesive patch for additional adhesive support.

Medical tape



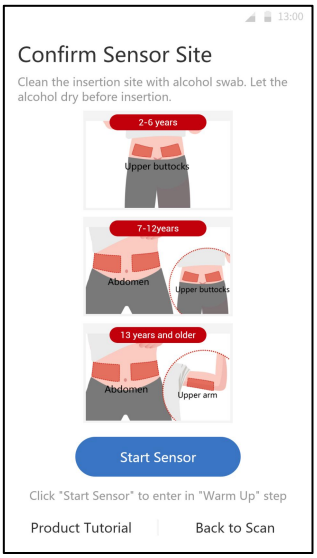
Overpatch

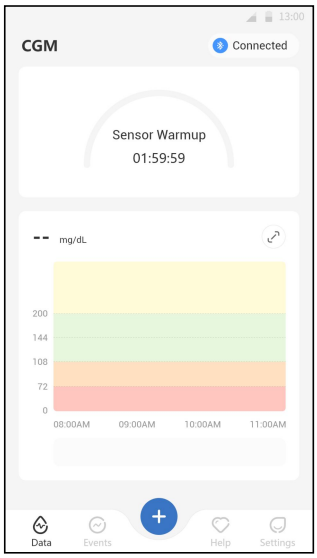
- Contact your HCP for specific questions regarding the use of medical tape, barrier wipes, or other adhesives.

CAUTION: Once inserted, the Sensor is waterproof up to 8 feet, but the mobile device may not be. If you are in or near water, the mobile device may need to be kept closer (less than 20 feet) to get Sensor readings. If the Sensor is under water, you may not be able to get Sensor readings until you emerge from the water.

2.5 Sensor Warmup

After inserting your Sensor, the transmitter will automatically pair with your TRUE VIE I3 CGM APP. Press "**Start Sensor**" to initiate the 2-hour Sensor warmup period.





During the warmup period, you will not receive alarm/alerts or CGM results. Your first results begin after the 2-hour Sensor warmup has passed. During Sensor warmup, use your blood glucose meter if needed.

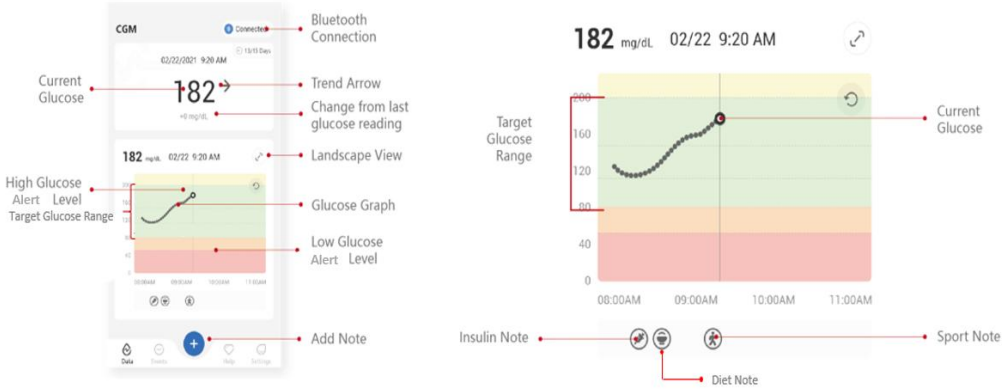
CAUTION: Keep your CGM Sensor and mobile device within 20 feet with no obstructions (i.e., walls or metal) between them. Otherwise, they might not be able to communicate. If water is between your Sensor and the mobile device – for example, if you are showering or swimming – keep them closer to each other. The range is reduced because Bluetooth® does not work as well through water.

Section 3: Understand your TRUE VIE I3 CGM Results

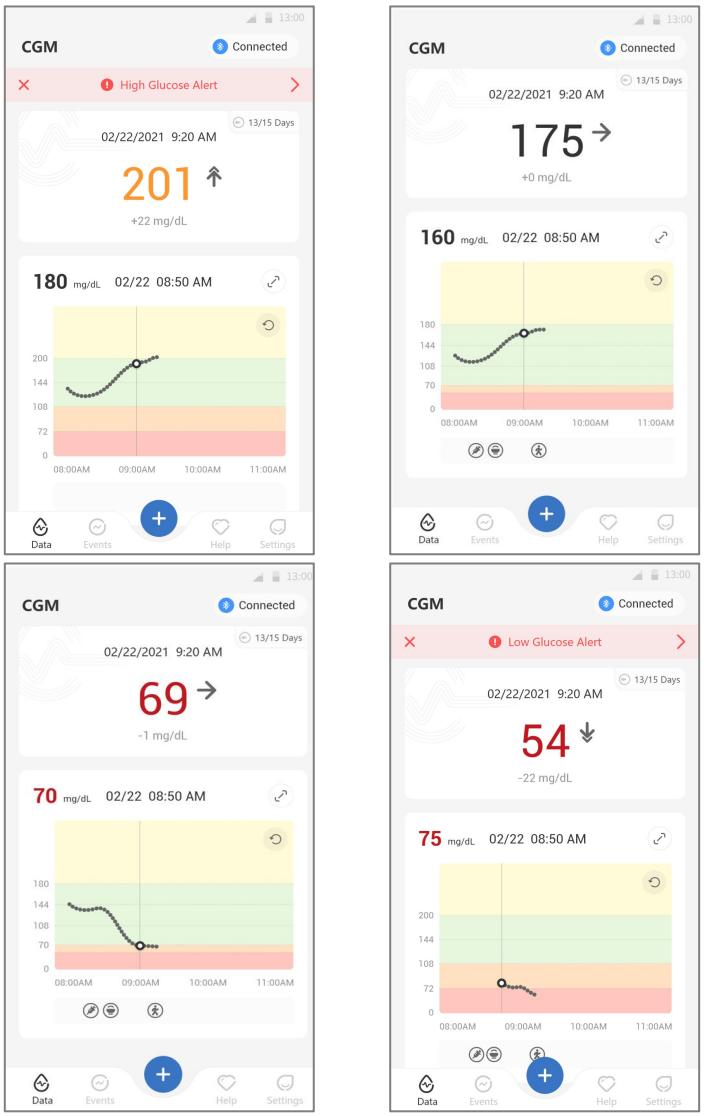
- Home Screen Overview
- Glucose Information
- Navigation and Status Bar
- Events
- Alerts

3.1 Home Screen Overview

The home screen below is from the iOS APP; the Android APP looks similar.



3.2 Glucose Information



1) Glucose Result

Starting at the top, the number shows where your current glucose is in milligrams per deciliter (mg/dL). The background color of the Glucose Graph can be yellow, green, orange, or red, which means:

200 mg/dL (11.1 mmol/L) Yellow: Above High Glucose Level (pre-set at 200 mg/dL)

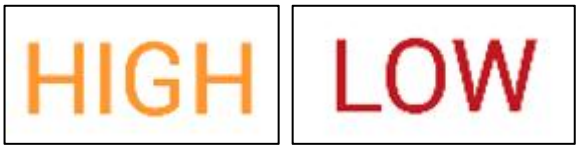
175 mg/dL **(9.7 mmol/L)** Green: Within the target range

69 mg/dL (3.8 mmol/L) Orange: Below Low Glucose Level (per-set at 70 mg/dL)

55 mg/dL (3.1 mmol/L) Red: Hypoglycemia Alert (set at 55 mg/dL)

When your most recent CGM result is above 450 mg/dL (25.0 mmol/L) or below 36 mg/dL (2.0 mmol/L), you will not get a number. Instead, your display device will display LOW (Low) or HIGH (High). If you do not have a number, use your blood glucose meter to measure your glucose.

These LOW or HIGH will be displayed as a blank spot on your trend graph.



2) Trend Arrow

Trend arrows show the speed and direction of your glucose trends based on your recent CGM results. Use the arrows to know when to take action before you are too high or too low.

Trend Arrow: Steady →

Glucose is changing but less than 1 mg/dL (0.05 mmol/L) per minute.

Trend Arrow: Falling or Rising slowly ↘ ↗

Glucose is changing slowly, 1 – 2 mg/dL (0.05 – 0.10 mmol/L) per minute or up to 60 mg/dL (3.3 mmol/L) in 30 minutes.

Trend Arrow: Falling or Rising quickly ↓ ↑

Glucose is changing quickly, 2 – 3 mg/dL (0.10- 0.17 mmol/L) per minute or up to 90 mg/dL (5.0 mmol/L) in 30 minutes.

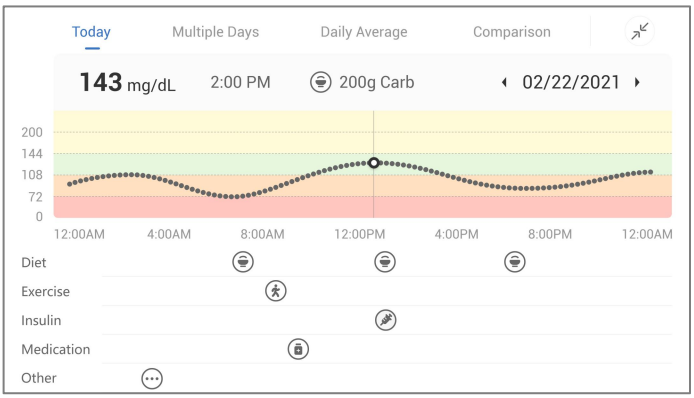
Trend Arrow: Falling or Rising rapidly ⇓ ⇑

Glucose is changing rapidly, more than 3 mg/dL per minute or more than 90 mg/dL (5.0 mmol/L) in 30 minutes.

3) Trend Graph

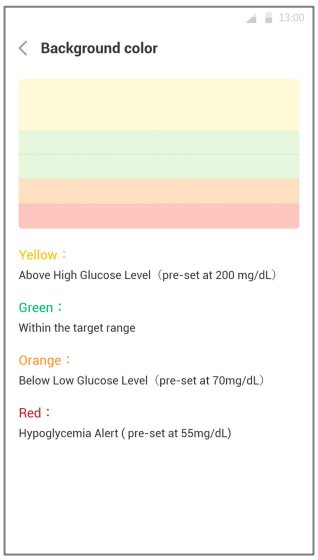
The graph below shows where your CGM results have been for the past few hours. It plots your CGM results every 3 minutes. The most recent CGM result is the black dot on the right. The white hollow dot in the middle is your glucose level at the selected time (for example in the picture below, 143 mg/dL (7.9 mmol/L) is the glucose result at 2:00 PM). The numbers on the left show glucose levels in mg/dL (mmol/L). The numbers on the bottom show the time.

CAUTION: If you are crossing various time zones, the CGM APP displays all the glucose readings of the on-going session with their testing time in the current time zone.



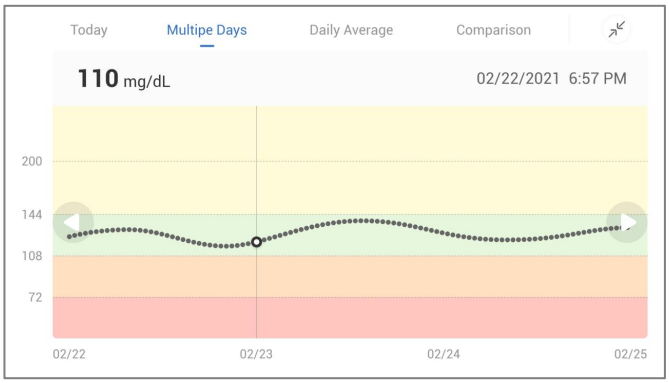
The horizontal lines show your High and Low Alert levels. Your glucose is:

- High when your dots are in the yellow area of the graph.
- In your target range (between your high and low alert settings) when in the green area
- Low when in the red area.



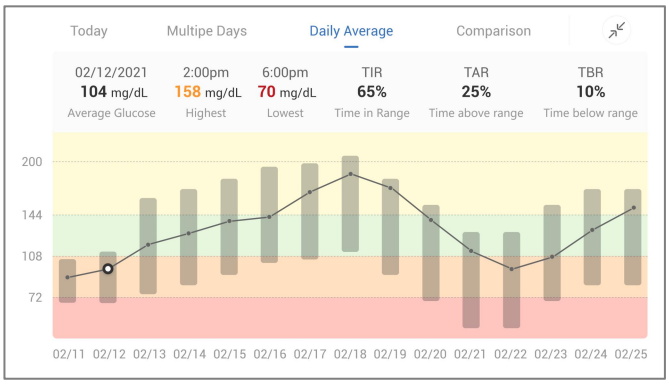
When the transmitter reconnects with the display device after a Signal Loss or similar issue, up to 360 hours of missed CGM results can fill in on the graph.

To see events with your graph and to see your graph over 24 hours, turn your mobile device on its side (for landscape view). Touch and hold a dot to see the time for a past CGM result, or slide your finger across the screen to view CGM results from other times. To switch between different days viewing on your APP, tap “Multiple Days” in the landscape view menu. The white hollow dot indicates a selected result in 1 of the days, the glucose result shows up on the top left panel.



4) Daily Average

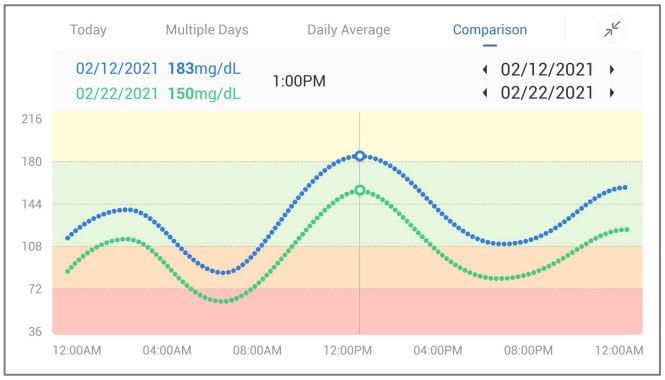
The APP shows your trends from your CGM data in 1-day segments that summarize the 15 days in view. The white hollow dot indicates the selected daily review you are looking at in the top panel.



A. Average Glucose is the average of all your CGM glucose results from the selected date. Knowing your average glucose gives you a good place to start when trying to get your numbers into target.
B. Highest/Lowest indicates the time that your glucose level reached the highest and lowest.
C. Time in Range (TIR) is the percentage of time that your glucose levels are in target range. TRUE VIE I3 APP default in-target range is 70-200 mg/dL, which may not be what you set for your CGM. You can change the ranges in Settings.
D. Time above Range (TAR) is the percentage of time that your glucose levels are high, above target range. TRUE VIE I3APP default high range is above 200 mg/dL.
E. Time below Range (TBR) is the percentage of time that your glucose levels are low, below target range. TRUE VIE I3 APP default low range is below 70 mg/dL.

5) Comparison

The TRUE VIE I3 APP allows you to select any 2 days from your past monitoring and compare your monitoring results. The color coded line in the graphic indicates the dates you select (on the right of the top panel), and the white hollow dot means the glucose level (on the left of the top panel) at a certain time.



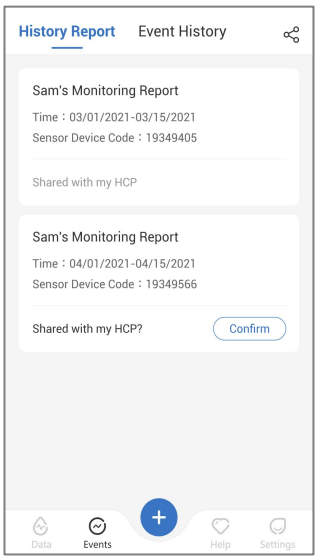
3.3 Navigation and Status Bar

The APP includes sections where you can view a glucose overview report, events history, and find helpful information such as Sensor insertion instructions and the full Comprehensive Instructions for Use.

3.3.1 Glucose overview report

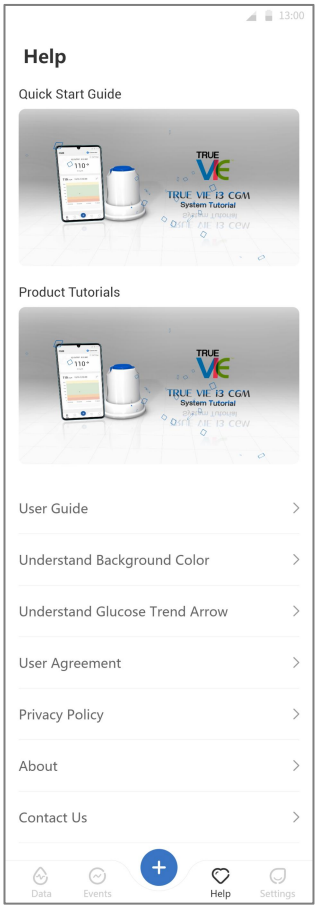
The glucose overview report allows you to create and share a report of your previous glucose data, up to the last 15 days.

- In the APP, tap the “Events” button on the status bar at the bottom.
- Tap “History Report” and select the date range you want to view.
- Tap “Event History” and you can review all Alerts information.
- Tap the “SHARE” button to email the report to those you want to share with.



3.3.2 Help Guide

The “Help” section provides a digital version of the TRUE VIE I3 CGM system user’s instructions including the “Quick Start Guide”, “Product Tutorials”, “Instructions for Use” and other device information.



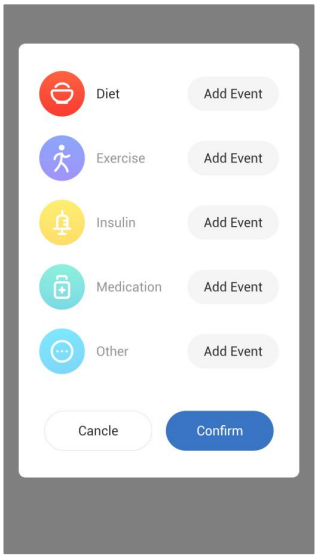
3.4 Events

An event is an action or situation that affects your glucose levels. With the TRUE VIE I3 CGM system you can track your daily events to reflect on their effect on your glucose trends. Once entered into the APP, events can be viewed in the home screen as well as in the reports. The reports help you review how each event influenced your glucose trends. You can review the reports with your healthcare professional （HCP） and create a plan to manage your diabetes.

3.4.1 Enter Insulin Event

Step 1: From the Home screen, tap "+"

Step 2: Then tap "Add Event" next to Insulin



Step 3: Choose the Insulin Type

Step 4: Enter insulin units for each dose, up to 99 units.

3.4.2 Other Events

You can add other events such as diet, exercise, medication and others. Adding these events is very similar to adding insulin.

For your convenience, there is no need to stop everything and enter your events as they are happening. When you have a moment, you can enter past events. Events are meant to be entered as individual occurrences.

3.5 Alerts

When your CGM result goes from your target range to your pre-set alerts level, your mobile device tells you with a visual notification, and vibrations or sound, depending on the alert and your mobile device. Until you confirm the glucose-related alert, every 3 minutes you get the alert screen along with a notification and a vibration. Until you are back in your target range, the alert information will stay on your home screen.

Before using the APP, go to **Attachment F** Alerts Vibrations and Sounds to check our iPhone and Android phone setting recommendation. Also talk with your HCP about your alert settings. They may suggest changing them to different values.

3.5.1 Urgent Low Alarm

While there are a variety of alerts, there is just one alarm: The Urgent Low Alarm (alarm) at 55 mg/dL (3.1 mmol/L) The urgent low alarm cannot be changed or turned off with one exception. If you have an Android phone, and you turned on Do Not Disturb, you will not get any alerts, including your Urgent Low.

What you hear, feel, and see:

- Initial alert: Vibrates 4 times and beeps 4 times
- Until confirmed: Vibrates and beeps 4 times every 5 minutes

Otherwise, as long as your mobile device is getting CGM results and notifications, you will get your alert at 55 mg/dL (3.1 mmol/L) or lower.

3.5.2 Alert

An alert is a message telling you your glucose trend levels or CGM system needs attention. You can customize the Alerts in your APP.

When you have your mobile device sound on, it vibrates and makes a noise on the alert. If you have turned off the sound, it only vibrates. Each alert has its own vibration pattern.

When making treatment decisions using your CGM, it is best to keep your device sound turned on.

WARNING: If you use headphones, you will not hear the alerts. If your device volume is not turned up, the device is muted, or headphones are plugged in, you will not hear the sound of any notifications, including urgent low alert

Low Alert

When your CGM result is below the target glucose range you set, you get your Low Alert.

What you hear, feel, and see:

- Initial alert: Vibrates and beeps with APP notification.
- Until confirmed: Vibrates and beeps 2 times every 3 minutes.

High Alert

This notifies you when your CGM result is above your target glucose range.

What you hear, feel, and see:

- Initial alert: Vibrates and beeps with APP notification.
- Until confirmed: Vibrates and beeps 2 times every 3 minutes.

Rise or Fall Rate Alert

- Slowly Rise or Fall: Until confirmation vibrates, and beeps 3 times every 3 minutes with APP notification.
- Quickly Rise or Fall: Until confirmation vibrates, and beeps 6 times every 3 minutes with APP notification.
- Rapidly Rise or Fall: Until confirmation vibrates, and beeps will be continuous.

Signal Loss Alert

This tells you when you are not getting TRUE VIE I3 CGM results. Your mobile device may be too far from your transmitter or there may be something, such as a wall or water, between your transmitter and your mobile device.

Unlike other alerts, Signal Loss cannot make a sound or vibrate, you will receive APP notification every 3 minutes until reconnected.

To fix this problem, keep your transmitter and display device within 20 feet of each other. If that does not work, turn Bluetooth off and on. Wait 10 minutes, if this still does not work, restart the mobile device and reopen the TRUE VIE I3 CGM APP.

During signal loss, use your BG meter to check your glucose and make any treatment decisions.

3.5.3 Customizing Your Alerts

How you set up your alerts can help you reach your diabetes management goals. Work with your HCP to come up with the best alert customization for you and your goals.

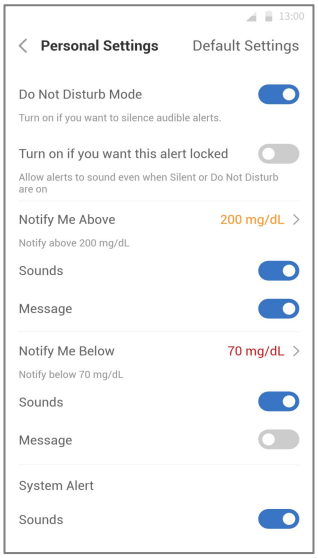
The default glucose alert settings are 200 mg/dL (11.1 mmol/L) (high) and 70 mg/dL (3.9 mmol/L) (low).

To change the default glucose alert levels:

a. Tap “Settings” at the bottom of the Sensor Warmup screen or the home screen.

b. Select “Personal Settings.”

c. Tap the alert level to be changed.



Low Glucose Alert

The Low Glucose Alert is on by default. Tap the slider to turn the alert off.

If the alert is on, you will be notified when your glucose falls below the pre-set level, which is initially set to 70 mg/dL (3.9 mmol/L). Tap to change to a value between 55 mg/dL (3.1 mmol/L) and 100 mg/dL (5.6 mmol/L).

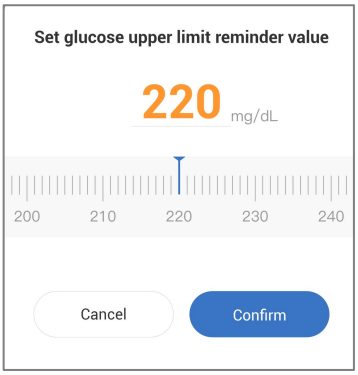
.

Choose the sound and message for this alert. Volume and vibration will match your mobile device settings.

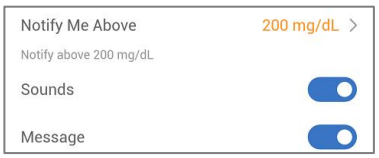
High Glucose Alert

The High Glucose Alert is on by default. Tap the slider to turn the alert off.

If the alert is on, you will be notified when your glucose rises above the pre-set level, which is initially set to 200 mg/dL (11.1 mmol/L). Tap to change to a value between 117 mg/dL (6.5 mmol/L) and 450 mg/dL (25.0 mmol/L).



Choose the sound and message for this alert. Volume and vibration will match your mobile device settings.

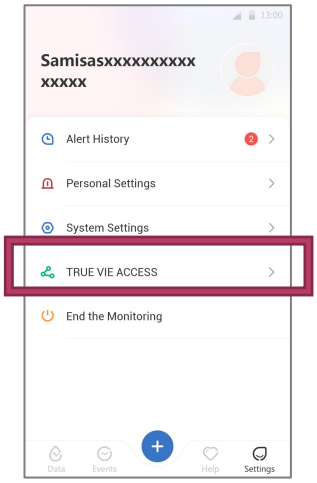


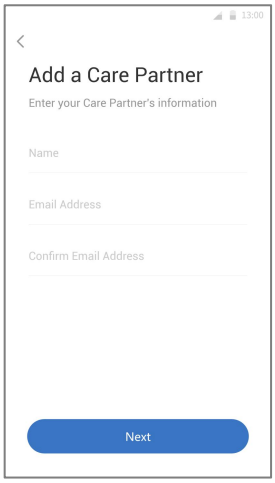
3.6 Access

Use TRUE VIE I3 CGM APP's "Access" feature to let up to 10 friends, family, or another trusted caregiver view your glucose information. You can give them access to just your Sensor readings and trend arrow, or include the trend graph. You can even set up glucose notifications for them to get when your glucose goes high or low, similar to the alerts you get on your TRUE VIE I3 CGM APP. You can edit, stop sharing with, or remove a "Care Partner" any time.

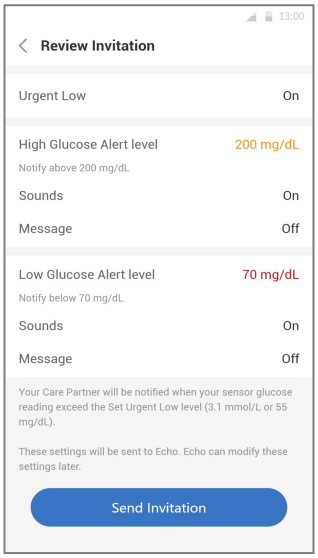
3.6.1 Invite "Care Partner"

Your "Care Partner" does not need to have the TRUE VIE I3 CGM APP on their mobile devices. They only need to download the TRUE VIE REACH APP. To invite someone to follow you, go to **Settings > TRUE VIE ACCESS**. Then follow the instructions on the APP screens. You can invite them by entering their name and email.



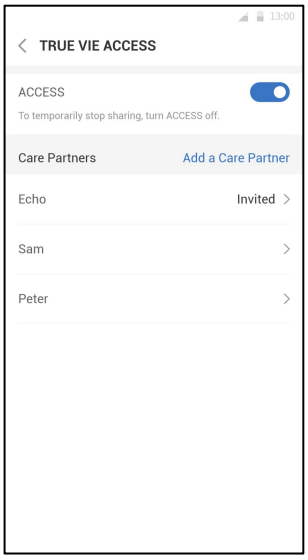


This shows what your "Care Partner" can see. To customize it, you can switch between "**On/Off**" to enable or disable an item, then tap "**Send Invitation**"



3.6.2 Edit status

The Access screen shows the status of your "Care Partner" and lets you invite new ones.



Section 4: Treatment Decisions

- Talk with your Healthcare Professionals (HCPs)
- When to Use Your Blood Glucose Meter
- Using Your CGM for Treatment Decisions

4.1 Talk with your Healthcare Professionals (HCPs)

Work with your HCP to define your target glucose range and your alert settings. Discuss how to stay within your target using the TRUE VIE I3 CGM System. Let your HCP guide you through the system features, including adjusting your alert settings to match your needs and goals, working with CGM results and trend arrows for treatment decisions, and managing your diabetes with the system.

Remember, changes to your insulin routine should be made cautiously and only under medical supervision.

4.2 When to Use Your Blood Glucose Meter

If your symptoms do not match your CGM results, use your blood glucose meter when making treatment decisions. If your CGM results do not consistently match your symptoms or blood glucose meter values, then talk to your healthcare professional.

4.3 Using Your CGM for Treatment Decisions

Work with your healthcare professional to figure out what's best for you when making treatment decisions. Always use their instructions to manage your diabetes. You should keep using your blood glucose meter until you're comfortable with TRUE VIE I3 CGM.

Trend arrows show the speed and direction of your CGM results so you can see where you are heading. Talk to your healthcare professional about using the trend arrows to determine how much insulin to take. The following information can assist you in making treatment decisions.

Steady Arrow

Actions to consider:

- Low: Eat
- High: Watch and wait if you took insulin recently. Otherwise, adjust insulin dose up
- In target range: No action needed

Arrows Going Up

Actions to consider:

- Low: Watch and wait
- High: Watch and wait if you took insulin recently. Otherwise, adjust insulin dose up
- In target range: Watch and wait if you took insulin recently. Otherwise, adjust insulin dose up

Arrows Going Down

Actions to consider:

- Low: Eat. Did you have too much insulin or exercise?
- High: Watch and wait. Did you have too much insulin or exercise?
- In target range: Eat

Section 5： End a Session

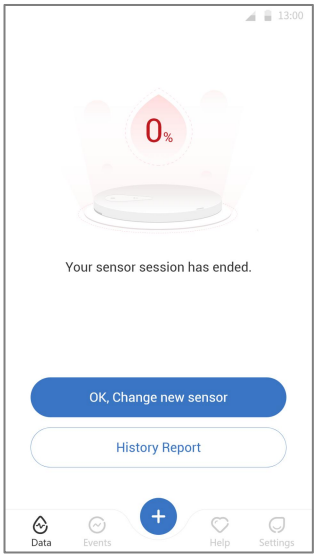
- End Your Sensor Session
- Remove Sensor
- Start New Sensor Session

5.1 End Your Sensor Session

Your TRUE VIE I3 CGM is intended to last for 15 days. The Sensor will automatically stop when the 15-day session is over. You can also end the sensor session early by manually stopping it. Before it ends, you will get notifications letting you know your sensor session is ending. Before you start a new sensor session, you must remove your existing sensor.

5.1.1 Automatically stopping a session

After 15 days, the CGM session will automatically stop. In the APP, you will see a notification indicating that the session has ended. Once the session has stopped, remove the sensor and tap “OK, Change New Sensor” to start a new CGM session



5.1.2 Manually stopping a session

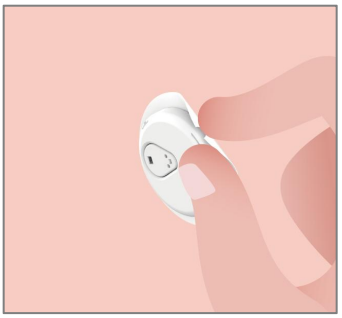
If you choose to stop a session before the end of the 15 days, you must stop it manually.

In the CGM APP, tap the “**Setting**” button and choose “**End the Monitoring**”, hold the button for 3 seconds to end the current session.

5.2 Remove Sensor

Pull up the edge of the adhesive tape that keeps your Sensor attached to your skin. Slowly peel away from your skin in one motion. Do not touch the Sensor. The Sensor cannot be re-used after removing.

CAUTIONS: Any remaining adhesive residue on the skin can be removed with warm soapy water or isopropyl alcohol.



Discard the used Sensor. See Disposal from Attachment C.

5.3 Start New Sensor Session

When you are ready to apply a new sensor, follow the instructions in **Section 2: Start Your Sensor** to start a new sensor session. You will need to scan or enter a new sensor code because the code is specific to each sensor.

Attachment A Troubleshooting

Troubleshooting sections are categorized by function or system component. The solutions here are meant to be brief and not all-inclusive. Go to specific sections for more detailed answers or preventive measures.

Are you still not sure what to do after reading this Section? If your problem is not listed, or the solution here does not fix the issue, contact Customer Care

Toll-free: 1-800-xxx-xxxx (available Monday – Friday, 8AM-8PM EST)

Web: www.trividiahealth.com

A.1 Sensor issues

Things to Examine / Questions to Ask	Solutions
Insertion site is red, irritated, or painful	Change the Sensor and insert it in a different location. • Avoid sites where clothes may rub, where your body bends a great deal or near the beltline, if possible. These areas present a higher risk of the sensor and transmitter being accidently pulled out. • Do not insert the sensor into an area that is lean, scarred, or hardened. If inserted in these areas, this may decrease the flow of interstitial fluid or the sensor may kink.
Sensor did not fully insert	If your Sensor is not fully inserted or comes loose, you may not get glucose readings on the APP. Stop the session and remove the sensor. Insert a new sensor to start a new session.
Insertion site is bleeding	Remove the sensor and discard. Check the site for bleeding, irritation, pain, tenderness or inflammation and treat accordingly. Insert a new sensor in a different location.
Broken Sensor	After removing the TRUE VIE I3 CGM from your body, if you can't see the Sensor Probe is attached to the transmitter or you suspect the Sensor Probe broke off under your skin, don’t try to remove it. Contact your healthcare professional immediately. You should also seek professional medical help if you experience symptoms of infection or inflammation (such as redness, swelling, or pain at the insertion site).

Things to Examine / Questions to Ask	Solutions
Sensor adhesive patch will not stick to skin	Prior to insertion, make sure the site is properly cleaned and dried. See Section 2 for cleaning instructions. If you notice the edges of the adhesive patch are becoming frayed or not sticking to your skin, apply the overpatch or medical tape to the edges to help secure the patch.
Sensor not working after immersing in water	If the issue is not resolved after 1 hour, stop the session, remove the sensor and insert a new sensor to start a new session.
Applicator sticks and will not come off your skin after you push the button to insert the sensor	Gently pull applicator up until you see the adhesive patch. Using your finger or thumb, hold the edge of the patch and peel the applicator from skin. While holding the edge of the adhesive patch, gently rock back applicator, away from your body. Check insertion site to make sure the Sensor Probe is not left on the skin. Do not try to reuse the applicator. If you have any concerns, call Customer Care

A.2 Transmitter issues

Things to Examine / Questions to Ask	Solutions

Transmitter did not pair with mobile device	Check the following:
	- The QR code on the Transmitter matches the one on the Sensor Pack (see Section 2 for details)
	- The Transmitter and the mobile device are within 20 feet of each other and Bluetooth is on
	- If the Transmitter was previously connected to your mobile device but now will not connect:
	  - Navigate to the Bluetooth settings on your mobile device (not in the TRUE VIE I3 CGMAPP).
	  - Try pairing again. See Section 2 for details.
	If these solutions do not fix the issue, contact customer care.

A.3 TRUE VIE I3 CGM APP issues

Things to Examine / Questions to Ask	Solutions

Things to Examine / Questions to Ask	Solutions
Your mobile device cannot download the TRUE VIE I3 CGM App	Check trividiahealth.com/compatibility for a list of mobile devices that work with the TRUE VIE I3 CGM APP. If your device is not listed, change to a new mobile device that is compatible. Install the APP on your new mobile device.
CGM results are not displayed on the HOME screen	The CGM is warming-up. During the first 2 hours, the HOME screen will not display CGM results. Your transmitter may have lost communication with the APP. Make sure the transmitter and APP are within 20 feet of each other and Bluetooth is on. Check to make sure the HOME screen shows a Bluetooth connection signal icon on the upper right.
Data missing on the trend chart on the HOME screen	If your Transmitter and APP lose communication, there may be a gap in the data because results were not sent to the APP. Once communication is restored, the gap may be filled if the transmitter was collecting data during that period.
Cannot Hear Alerts	If you cannot hear your alerts on your APP, verify that the APP, Bluetooth, volume, and notifications are on. If you restart your mobile device, reopen the TRUE VIE I3 CGM APP. Make sure that a Session is in progress.
Signal Loss	Keep your transmitter and display device within 20 feet of each other. If that does not work, turn Bluetooth off and on. Wait 10 minutes. If that does not work, restart the mobile device and reopen the TRUE VIE I3 CGM APP. Wait up to 30 minutes. System may correct the problem itself. If not, then contact Customer Care.
Home screen shows LOW (Low) or HIGH (High) instead of CGM result	System is working as it should. Use your Blood Glucose Meter and treat your high or low. When your result is between 36 and 450 mg/dL your TRUE VIE I3 CGM APP will display your result instead of Low or High.

Attachment B Security and Air Travel

For help with your TRUE VIE I3 CGM system, call Customer Care. The Customer Care number can be found in the HELP section of the APP.

In case of emergency, contact your HCP or emergency medical response.

B.1 Security Check

You can use any of the following methods to go through security when wearing or carrying your TRUE VIE I3 CGM without worrying about damaging your CGM components:

- hand-wanding,
- pat-downs,
- visual inspection,
- walk-through metal detectors

Security equipment to **AVOID**

Do not go through an advanced imaging technology (AIT) body scanner (also called a millimeter wave scanner).

Do not put your CGM components through x-ray machines.

If you are concerned about the security equipment, talk with the Security Officer and ask for hand-wanding or get a full-body pat-down with a visual inspection of your Sensor and transmitter. Let the Security Officer know you cannot remove the sensor because it is inserted under your skin.

B.2 During Your Flight

In order to use the APP while you are on the plane, make sure to switch your mobile device to airplane mode, and keep Bluetooth on.

Attachment C Taking Care of Your CGM

C.1 Maintenance

Components	What you shall do…….
Sensor-Applicator	• Keep it in the sterile package until ready to use • Do not use if Sensor has expired
Transmitter	• Keep it in box until ready for use. Check Transmitter and do not use if damaged • Don not spill liquid or soak it with water • Do not use if Transmitter has expired
Sensor	• After applying the Senor and wear it on the body, do not use lotions, sunscreen, insect repellent, or similar items on it

C.2 Storage and Transport

Store at temperatures between 36°F -86°F (2°C -30°C).

Store between 10% and 90% relative humidity.

CAUTION:

- Storing outside this range may cause inaccurate CGM results.
- You may store sensor in refrigerator if it is within temperature range.
- Store sensors in a cool, dry place. Do not store in parked car on a hot day or freezing cold or in a freezer.

C.3 Checking System Settings

You can check your APP for information about your CGM System any time.

Here are the recommended mobile device settings for your iPhone and Android mobile device.

Screen Time	Screen Time's Downtime and APP Limits can temporarily disable apps. You can: - Turn off Downtime and APP Limits or - Add TRUE VIE I3 CGM APP to the Always Allowed APP list
Do Not Disturb	Do Not Disturb silences all alerts except for the Urgent Low alert.

	For iOS, you can • Go to Settings, tap on Do Not Disturb, and turn it off.
Do Not Disturb Permission	You must allow Do Not Disturb Permission for the TRUE VIE I3 CGM APP to work. The Do Not Disturb Permission ensures you always get the Urgent Low alert and important TRUE VIE I3 CGM alerts even when you put your phone in the most restrictive Do Not Disturb setting. For Android, you can: • Follow in APP instructions, or go to Settings, find DND Permission or DND Access, choose TRUE VIE I3 CGM APP, tap Allow DND, and tap Allow.
Low Power Mode	Low Power Mode may prevent the TRUE VIE I3 CGM APP from running in the background. For iOS, you can • Go to Settings, tap Battery, and turn Low Power Mode off.
Battery Saver Mode	For Android, you can: • Go to Settings, and turn Battery Saver Mode off, or choose the highest battery performance on certain phones.
Device Bluetooth	Your TRUE VIE I3 CGM APP uses Bluetooth to connect with your transmitter. You must keep your phone Bluetooth turned on to get alerts and sensor results. You can: • Go to Settings, find Bluetooth, and turn it on.
App Bluetooth Permission	Apple requires you to give the TRUE VIE I3 CGM APP permission to use Bluetooth. You must keep Bluetooth Permission turned on for the TRUE VIE I3 CGM APP to work.
Notifications Permission	Notifications let you get alerts on your phone. If notifications for the TRUE VIE I3 CGM APP are off, you will not get any alerts. We recommend turning TRUE VIE I3 CGM APP notifications on. On iOS 15 and above, do not add the APP to Scheduled Summary. You can: • Go to Settings, choose TRUE VIE I3 CGM APP, tap Notifications, turn Allow

	Notifications on.
Background App Refresh	Background APP Refresh allows the TRUE VIE I3 CGM APP to continue running in the background. If Background APP Refresh is turned off, your TRUE VIE I3 CGM APP alerts may be delayed. You can: • Go to Settings, find TRUE VIE I3 CGM APP, and turn Background APP Refresh on.
Focus Mode	On iOS 15 and above, the Focus feature will silence alerts and notifications for chosen APPs. If you add TRUE VIE I3 CGM APP to any Focus mode, your TRUE VIE I3 CGM APP alerts may be delayed. You can: • Not use Focus modes • For iOS, Go to Settings, find Focus, choose a Focus mode, add TRUE VIE I3 CGM APP as an Allowed APP, and repeat for each Focus mode. • For Android, Go to Settings, find Digital Wellbeing, and confirm TRUE VIE I3 CGM APP is not in the Distracting APPs list.
Location	Location must be turned on to use Bluetooth. If Location is off, you will not get alerts, or sensor results. The location of each setting may be different based on your iOS version. Please refer to your mobile device instructions for detailed information. Android 10 and above: Go to Settings, find TRUE VIE I3 CGM APP, tap Location Permission, and choose Allow All the Time.

	Android 9 and below: Go to Settings, find TRUE VIE I3 CGM APP, tap Location Permission, and turn it on.
App Pause	On Android 10 and above, Pause temporarily disable apps. Using Pause with the TRUE VIE I3 CGM APP stops all alerts, and Sensor results. You can: Tap the TRUE VIE I3 CGM APP icon on the desktop or in the APP drawer, and tap Unpause APP.
Make sure your display devices is online	logging in, creating a new account, pairing the Transmitter require your display devices online, or you cannot use the CGM, which may cause a treatment delay. Sharing your glucose data with others also requires your display devices online, or you cannot share, which may cause inconvenience.

C.4 System Disposal

Different places have different requirements for disposing of electronics (Transmitter) and parts that have come in contact with blood or other bodily fluids (Sensor). Follow your area's local waste management requirements.

Attachment D Technical Information

D.1 Device Performance Characteristics

TBD (will be updated per 21 CFR 862.1355(b)(7) requirements)

D.2 Product Specifications

Specification	Description
Sensor	
Glucose assay method	Amperometric electrochemical sensor
Glucose result range	36.0 mg/dL – 450.0 mg/dL (2.0–25.0 mmol/L)
Sensor life	Up to 15 days
Storage temperature	36°F to 86°F (2°C to 30°C)
Storage humidity	10% - 90% Relative humidity
Operating temperature	50°F to 108°F (10°C to 42°C)
Operating humidity	10% - 90% Relative humidity
Transmitter	
Transmitter battery type	1 non-serviceable, non-rechargeable button cell inside the Transmitter, DC 1.5 V
Operation Mode	Continuous operation
TX Frequency	2.402 GHz–2.480 GHz
Bandwidth	1.06 MHz
Maximum Output Power	1±1 dBm
Applied part	Type BF applied part

Specification	Description
Modulation	Gaussian Frequency-Shift Keying
Data Communication Range	20 ft (6 meters) unobstructed
Storage temperature	36°F to 86°F (2°C to 30°C)
Storage humidity	10% - 90% Relative humidity
Operating temperature	50°F to 108°F (10°C to 42°C) Caution: When operating the transmitter in the air temperatures greater than 41°C (106°F) the temperature of the transmitter may exceed 42.7°C (109°F)
Operating humidity	10% - 90% Relative humidity
Operating Pressure	700 hPa-1060 hPa

The TRUE VIE I3 CGM APP operation environment minimum requirements:

Platform	Android 8.1 and above, iOS 14.1 and above
Network	4G, 5G and above, WiFi and above
Bluetooth version	Bluetooth 5.0
Memory	1G and above
CPU	Main frequency 1.4GHz and above
Screen	No less than 4.7 inch
Resolution	No less than 1280*720
Storage capacity	No less than 500M

D.3 Quality of Service Summary

Quality of Service for the TRUE VIE I3 CGM System wireless communication using Bluetooth Low Energy is assured within the effective range of 20 feet, unobstructed, between the TRUE VIE I3 Transmitter and paired display device at regular 3-minute intervals. If connection is lost between the transmitter and display device, upon re-connection any missed packets (up to 360 hours) will be transmitted from the transmitter to the display device. The TRUE VIE I3 CGM System is designed to only accept radio frequency (RF) communications from recognized and paired display devices.

D.4 Security Measures

The TRUE VIE I3 CGM System is designed to transmit data between the transmitter and designated display devices in accordance to the industry standard BLE protocols. It will not accept radio frequency (RF) communications using any other protocol, including Bluetooth classic communication protocols.

In addition to the security provided by the BLE connection, communication between the TRUE VIE I3 transmitter and mobile applications is protected by additional levels of security and safety mitigations using an encrypted and proprietary data format. This format embeds various methods to verify data integrity and to detect potential instances of data tampering. While the format is proprietary, industry standard encryption protocols (e.g., RSA and AES) are used in different parts of this proprietary data format.

Unless disabled, the TRUE VIE I3 CGM mobile application regularly communicates with local Servers. Communication between the TRUE VIE I3 CGM applications and local Servers is protected by a number of mechanisms, designed to safeguard against data corruption.

D.5 Guidance and manufacturer's declaration – electromagnetic emissions

Immunity Test	Transmitter Compliance Level
Radio Frequency Emissions CISPR 11/FCC part 15	Group 1, Class B

D.6 Guidance and manufacturer's declaration – electromagnetic immunity

The Transmitter is intended for use in the electromagnetic environment specified in the next table. The customer or the user of the transmitter should ensure that it is used in such an environment.

Immunity Test	Transmitter Compliance Level
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV Contact ± 15 kV Air
Magnetic Field (50Hz and 60Hz) IEC 61000-4-8	30 A/m
Radiated Fields Disturbance IEC 61000-4-3	10 V/m at 80 MHz to 2700 MHz (AM Modulation)

Electromagnetic interference can still occur in the home healthcare environment as control over the EMC environment cannot be guaranteed. An interference event can be recognized by gaps in CGM results or gross inaccuracies. The user is encouraged to try to mitigate these effects by one of the following measures:

If your symptoms do not match your CGM results, use your blood glucose meter when making treatment decisions. If your CGM results do not consistently match your symptoms or blood glucose meter values, then talk to your healthcare professional about how you should be using the TRUE VIE I3 CGM to help manage your diabetes. Your healthcare professional can help you decide how you should best use this device.

D.7 FCC Compliance Statements

FCC ID: 2AXH5002

This TRUE VIE I3 CGM transmitter comply 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

Harmful interference is defined by the FCC as follows. Any emission, radiation or induction that endangers the functioning of a radio navigation service or of other safety services or seriously degrades, obstructs or repeatedly interrupts a radio communications service operating in accordance with FCC rules.

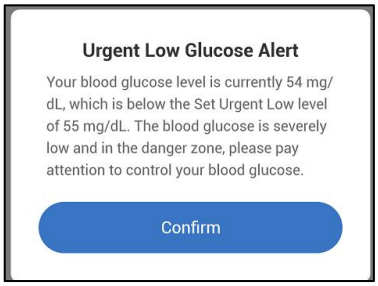
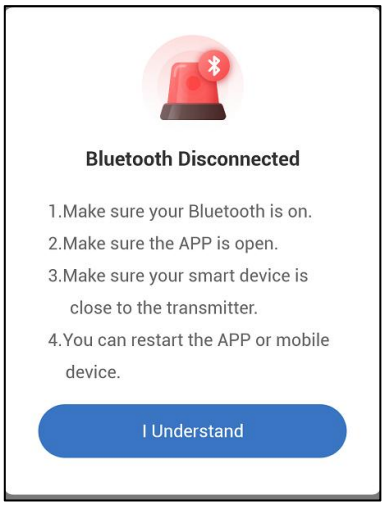
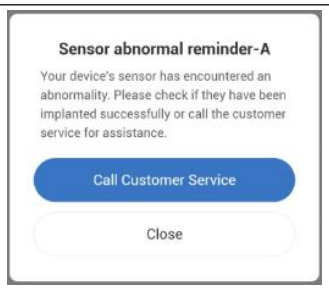
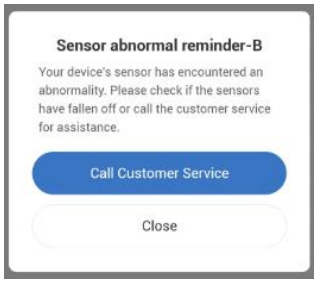
Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

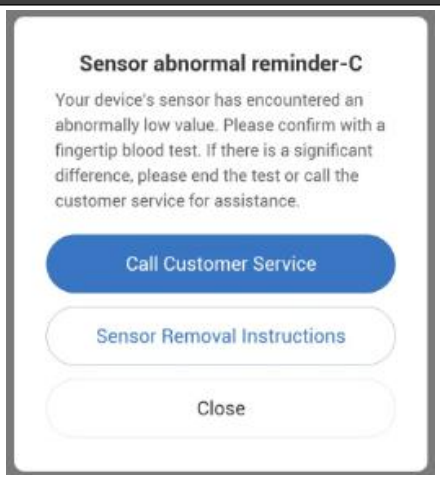
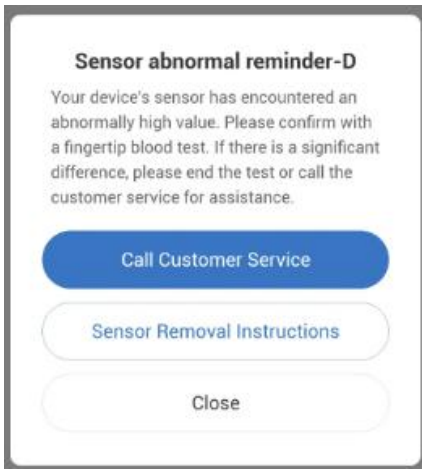
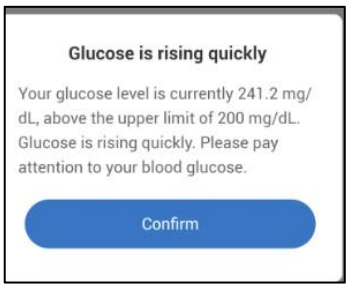
Attachment E Label Symbols

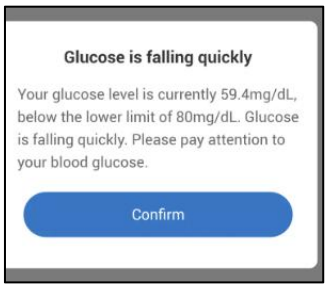
Symbol	Description
	Date of manufacture
	Expiration
SN	Serial number
MD	Medical device
LOT	Batch code
IP28	IP28: Protection Against Insertion of Large Objects and Immersion in Water
	Type BF Applied Part
STERILE R	Sterilized using irradiation
	Single sterile barrier system
	Temperature limit
	Humidity limitation
MR	MR Unsafe
	Do not re-use
	Do not use if package is damaged
	This product must not be disposed of via municipal waste collection. Separate collection for electrical and electronic equipment waste per Directive 2012/19/EC in the European Union is required. Contact the manufacturer for details.
	Caution
eIFU Indicator	Consult electronic instructions for use
	Keep Away from sunlight
	Keep Dry

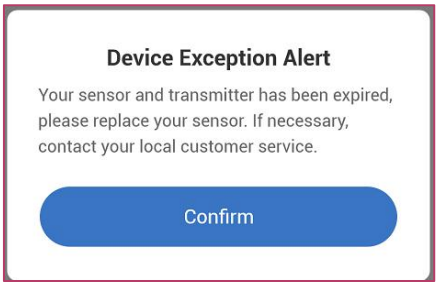
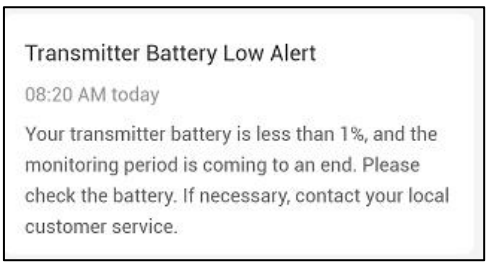
Symbol	Description
	Bluetooth
Rx Only	Prescription Required

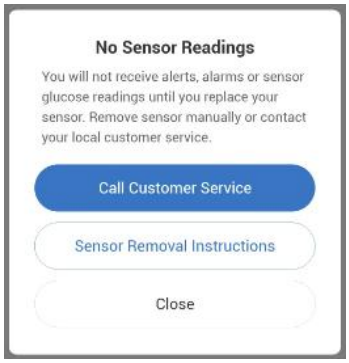
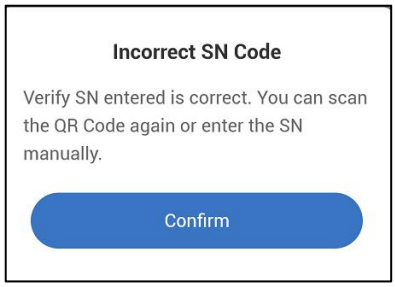
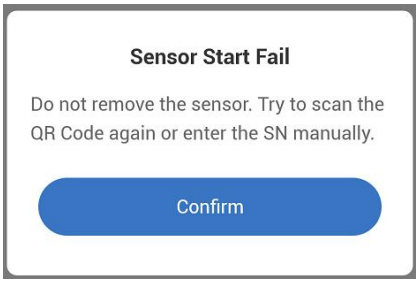
Attachment F Alerts, Vibrations and Sounds

Screen	Description
	Notify when the result is below the default low glucose level (default is 55 mg/dL)
	The transmitter and mobile device Bluetooth connection are not connected
	Notify when the sensor cannot produce electrical signal for a while.
	Notify when the sensor produces abnormal electrical signal for a while.

Screen	Description
	Notify when the sensor produces abnormal low value.
	Notify when the sensor produces abnormal high value.
	Rise rate alert. Notify when the glucose result is above the High Alert level and rising quickly.

Screen	Description
	Fall rate alert. Notify when the glucose result is below the Low Alert level and falling quickly.
	Notify when the glucose result is above the High Alert level
	Notify when the glucose result is below the Low Alert level.

Screen	Description
	Notify when the glucose result is above result range (default is 450 mg/dL)
	Notify when the glucose result is below result range (default is 36 mg/dL)
	Sensor expiring alert. Will remind in 24 hours and 30 minutes before the current session will end.
	Transmitter battery low alert.

Screen	Description
	Low operating temperature alert
	High operating temperature alert
	Sensor readings anomaly alert
	SN code anomaly alert
	Sensor start anomaly warning

Screen	Description
Monitering Period End Alert 06:20 AM today Your monitering period will end in 24 hours, please pay attention to replace your sensor.	Monitoring period end alert

Glossary

Blood glucose meter

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

Blood glucose result

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

Continuous glucose monitor (CGM)

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

Hyperglycemia (high blood glucose)

High levels of glucose in the blood, also known as high blood glucose. When left untreated, hyperglycemia can lead to serious complications. Talk to your healthcare professional to determine your high glucose level.

Hypoglycemia (low blood glucose)

Low levels of glucose in the blood, also known as low blood glucose. When left untreated, hypoglycemia can lead to serious complications. Talk to your healthcare professional to determine your low glucose level.

Interstitial fluid

The fluid that surrounds all the cells of the body.

Insulin

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

Limitations

A safety statement outlining specific situations in which the TRUE VIE I3 CGM should not be used because it may be harmful to you or damage the system.

mg/dL

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

mmol/L

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

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