EN

yuwell Anytime

Anytime 5

Series Continuous Glucose Monitoring System

Quick Start Guide

① Download the App

Yuwell Anytime

Download on the App Store

GET IT ON Google Play

Please search for and download the Yuwell Anytime App from the App Store or Google Play.

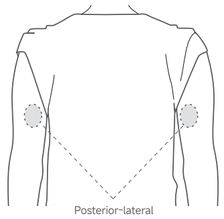
② Login/Register



Enter the email address to register/ log in an account.

Click 'Next' and follow the instructions to start wearing.

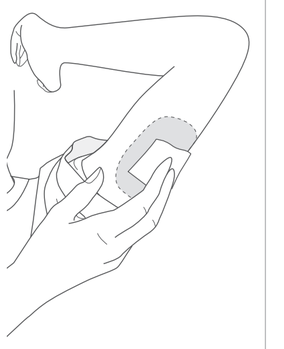
③ Selection of the Area



Posterior-lateral side of the upper arm

The posterior-lateral side of the upper arm can be selected as the implantation site.
Note: Avoid areas with muscles and scars.

④ Skin Preparation



Clean and disinfect the application area with an alcohol swab, and proceed to the next step after it has dried completely.

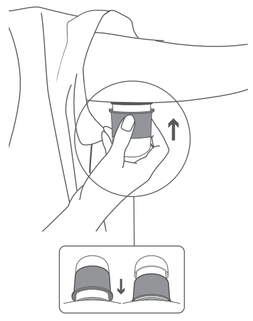
⑤ Remove the Bottom Cover



Do not discard the bottom cover during this step.

Turn the bottom cover counterclockwise in the direction of the arrow and remove it.

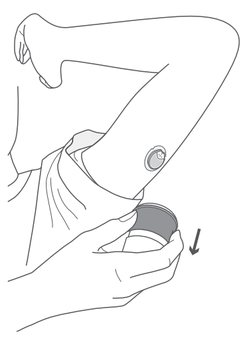
⑥ Push the Colored Retaining Ring Forward.



Firmly attach the product to the skin before push.

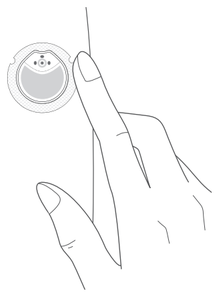
Place the product firmly against the precleaned and dried surface. Push the colored ring.

⑦ Remove the Applicator



Slowly remove the applicator.
At this point, the product has been successfully implanted.

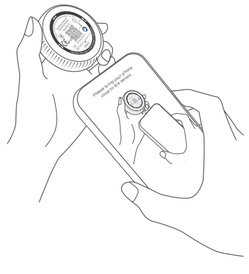
⑧ Press the Adhesive Tape



Gently press around the edges of the product's medical adhesive tape to ensure it adheres more closely to the skin.

⑨ Connect Devices

NFC Activation



Place the top of the phone close to the bottom cover until the phone prompts and enters the initialization interface.

You may need to move the phone up, down, left, or right to ensure the phone's NFC connects to the device.

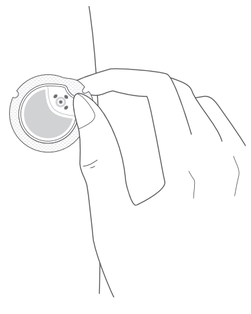
⑨ Connect Devices

If NFC startup is unavailable, you can scan the QR code.



Use the app to scan the QR code on the bottom cover to complete the device connection and enter the initialization interface.

Remove the Device



After the wearing period has ended, gently lift the edge of the medical adhesive tape and slowly remove both the tape and the device from the application site. Dispose of it as medical waste.

yuwell Anytime

5

Anytime 5 Series
Continuous Glucose Monitoring System

Anytime 5, Anytime 5P, Anytime 5Pro,
Anytime 5H, Anytime 5H SE

Instructions for Use

Welcome

Thanks for choosing the Yuwell Continuous Glucose Monitoring (CGM) System! Using this medical device, you'll see your glucose readings on your display device just by wearing a tiny sensor!
Here are some of the benefits of using CGM to manage your glucose:

- Reduce fingersticks: Anytime 5 Series allows you to make treatment decisions without fingersticks. (If your glucose alerts and readings from the Anytime 5 Series do not match symptoms or expectations, use a blood glucose meter to make diabetes treatment decisions.)
- Predict and prevent highs and lows: With Anytime 5 Series, you have the information regarding direction and rate of glucose change, alerting you to take action to prevent hypoglycemia or hyperglycemia.
- Real-time knowledge of glucose: Anytime 5 Series provides your glucose levels every 3 minutes for 16 days and a summary of standardized glucose metrics to facilitate more rapid, better informed decision making.

1 Getting to know your system

1.1 Product composition

- The continuous glucose monitoring system consists of a sensor, a transmitter, an applicator and software. The sensor, transmitter and applicator are integrated into a whole and disposable.
- The software includes continuous glucose data monitoring applications (mobile apps) Yuwell Anytime and Follow Anytime, and Anytime View (desktop glucose management system).

Windows version refers to the hospital glucose management system software installed on the terminal device of Windows system.

Product model	Anytime 5	Anytime 5P	Anytime 5Pro	Anytime 5H	Anytime 5H SE
Components	Sensor + Transmitter + Applicator + Software				
Anytime View	Optional	Optional	Optional	Optional	Optional
Yuwell Anytime and Follow Anytime	Standard	Standard	Standard	Standard	Standard
Useful life	16	16	16	14	16
Application scenarios	Medical institutions & home				

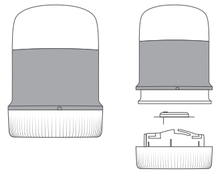


Figure 1 Product image

1.2 Operating Principle

Interstitial fluid glucose undergoes an enzyme-catalyzed reaction with the sensor's glucose oxidase, and an electrochemical oxidation reaction occurs at the electrode. The current signal represents the glucose concentration. The transmitter collects the sensor signal and converts it to a glucose reading, and the software in the receiver displays the glucose data.

1.3 Calibration Method

The product is factory calibrated.

2 Important safety information

2.1 Device description

- The Anytime 5 series Continuous Glucose Monitoring System is an integrated continuous glucose monitoring system (iCGM) that provides continuous glucose measurements every 3 minutes to provide glucose levels, trends and alerts. It can be applied to the upper arm for up to 16 days and is suitable for use in both healthcare settings (inpatient and outpatient) and home settings (including various out-of-hospital settings).The System is factory-calibrated, doesn't require fingerstick calibration. It is single-use and disposable.

2.2 Intended Purpose

- The Anytime 5 series System is intended for real-time continuous glucose monitoring of interstitial fluid glucose levels.

2.3 Indications for use

- The Anytime 5 series Continuous Glucose Monitoring System is a real time continuous glucose monitoring (CGM) device with alert capability indicated for the management of type 1 or type 2 diabetes mellitus in persons age 18 and older.
- The System 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 readings should be based on the glucose trends and several sequential readings over time. It is also intended to replace fingerstick blood glucose testing for diabetes treatment decisions including insulin dosing, unless otherwise indicated. It can be used in conjunction with the digitally connected devices where the user manually controls actions for therapy decisions.

2.4 Intended patient population

- The system intended for diabetic patients aged 18 and older, excluding pregnant women or breastfeeding mothers.

2.5 Intended user

- Used by patients aged 18 and older with type 1 or type 2 diabetes mellitus, medical professional.

2.6 Contraindications

- Patients with bleeding risks, prone to skin ulcers, or who have allergies to disinfectants or medical adhesives should avoid use. Individuals with sensitive skin or allergic tendencies should also refrain from using it.
- The system must be removed before undergoing magnetic resonance imaging (MRI), computed tomography (CT) scans, or diathermic therapy.
- The System must not be used with automated insulin dosing (AID) systems, including closed loop and insulin suspend systems.

2.7 Warning

- The product is not intended for life-sustaining or life-supporting purposes. In the event of product failure, please remove the sensor without special intervention. In special cases, if the user feels unwell, it is recommended that a finger prick blood test be conducted to confirm the glucose level, as failure to do so may pose risks such as hypoglycemia coma or long-term hyperglycemia leading to complications.
- Symptoms of hypoglycemia or hypoglycemia should never be ignored. If your Sensor glucose reading does not match how you feel, or if the reading does not include a number, it is recommended to confirm with a glucose meter test, in case of a blood glucose test, you should be aware that if you have severe anemia or abnormal hematocrit levels, the reliability of finger blood or venous blood measurements may be compromised, and please consult your healthcare professionals.
- Some individuals may be sensitive to the adhesive that keeps the Sensor attached to the skin. If you notice significant skin irritation around or under your Sensor, remove the Sensor and stop using the System. Contact your healthcare professional before continuing to use the System.
- Keep the product out of the reach of unsupervised children. Please do not swallow the small parts contained in the system, so as to avoid physical injury and danger.

2.8 Precautions

- Before using the continuous glucose monitoring system, please read this manual. In case of any doubt, please consult healthcare providers or contact customer service personnel.
- Do not reuse the device. The device is designed for single use. Reuse may result in no glucose readings and infection. Not suitable for re-sterilization.
- Protect the product from accidental detachment. For a few people, the adhesive tape does not stick firmly enough on the skin, so the product can be fixed with external adhesive tape or bandage if necessary. If the adhesive tape of the product base is not firmly stuck to the skin, it may cause the sensor electrode to detach from the body, thus leading to the unreliable glucose data.
- Avoid excessive sweating caused by strenuous exercise. Sweating may affect the stickiness of the adhesive tape and cause the product to fall off. Product fault, poor contact, sweating and water seepage at the wearing site will cause abnormal data. When the receiving end continuously displays abnormality prompts, the product should be removed.
- If the user uses an insulin pump, the distance between this product and the insulin infusion site should be not less than 5 cm.
- The components of the system can be only used together, and shall not be connected with other devices or application.
- Used products should not be discarded at will to prevent cross-contamination.
- If the patient's skin is damaged, scarred, red and swollen, or infected, it may affect the accuracy of continuous blood glucose monitoring.
- The distance between the receiver (that is, the smart device for which the APP is installed) and the transmitter should not exceed 6m, and the mobile phone should be always carried. If the APP loses contact, it will affect the prompting function, resulting in the failure to prompt whether the blood glucose exceeds the preset range in time.
- Taking ascorbic acid (vitamin C) supplements while wearing the Sensor may falsely raise Sensor glucose readings. Taking more than 1000 mg of ascorbic acid per day may affect the Sensor readings which could cause you to miss a severe low glucose event. Ascorbic acid can be found in supplements including multivitamins. Some supplements, including cold remedies such as Airborne® and Emergen-C®, may contain high doses of 1000 mg of ascorbic acid and should not be taken while using the Sensor. See your healthcare professional to understand how long ascorbic acid is active in your body.
- If taking or preparing to take medication, before using the CGM, you should discuss with your healthcare provider about your health condition and possible effects of the medication being used on the CGM.
- If the user is the expected operator, the continuous glucose monitoring system has no repairable parts by the user. If the product fails during use, please contact the manufacturer or agent directly, and do not dismantle it for repair, inspection, replacement or modification.
- If it is found that the aluminum foil packaging of the product is damaged or the bottom cover of the product is disassembled in advance, the aseptic state of the product may be polluted. At this time, the sensor should not be used, and it should be treated according to the provisions of "6.5 Waste Disposal".
- The Sensor tail contains two biomaterials derived from microorganisms, namely glucose oxidase and recombinant human serum albumin (rHSA).

3 Starting your Sensor with APP

3.1 APP download

You can go to the App Store or Google Play Store, search for "Yuwell Anytime App" and download and install it. If you have already installed the app, you can also check for updates in the app store and upgrade it to the latest version.

3.2 APP login

- Login
  -Open the APP software after the installation is completed(Figure 1).
  -Install Yuwell Anytime and open the App. If it is the first time, follow the on-screen prompt to create your account. Use your email address as your account number and create a password to complete registration. For normal use, log in your account by entering your email address and password. Then click Login to log into your account.
- Completion of personal information
  -For the customer using it for the first time, the interface of "Complete personal information" appears after logging in, and the basic information is input according to the prompt to complete the personal information.(Figure 2).

3.3 Device connection

- Select Anytime 5 Series, and click to enter the next step (Figure 3).
- Prepare the product , and click the "Next" button(Figure 4).
- Skin preparation
  -Select the back of the upper arm (avoiding muscles and scars) for implantation (Figure 5):
  1)Avoid the sites of scars, skin damage, redness or infection.
  2)The distance from the insulin infusion site is not less than 5cm.
  3)Avoid the muscles.
  4)Avoid the sites that squeeze the product when sleeping.
  5)Avoid areas where clothing is restrictive, such as under a belt.
  -Clean and disinfect the skin with alcohol or other suitable disinfection methods, and proceed to the next step after drying (Figure 6).
- Device Checking
  -Check the expiration date on the package before opening it. Do not use expired products.
  -Inspect the product carefully. Do not use it if the aluminum-plastic bag is damaged.

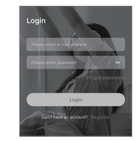


Figure1 Login

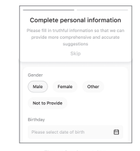


Figure2 Information



Figure 7 Removing the bottom cover



Figure 8 Ring



Figure 9 Removing the Applicator



Figure 10 NFC



Figure 3 Started

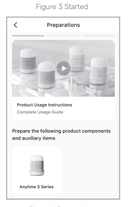


Figure 4 Preparations

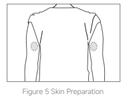


Figure 5 Skin Preparation



Figure 6 Disinfection



Figure 11 Initialization



Figure 12 APP interface

3.4 Product implantation

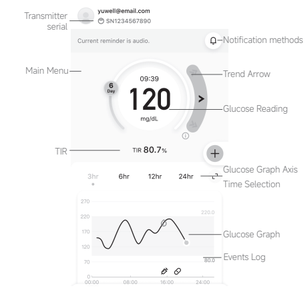
- Remove the bottom cover: rotate the bottom cover of the product in the direction of the arrow in Figure 7 and remove it, and proceed to the next step according to the APP prompt.
- Attach the product to the skin: put the product close to the part cleaned and dried in advance, as shown in Figure 8.
- Push down the ring.
- Remove the Applicator: remove the Applicator, and the product has been implanted, as shown in Figure 9, and proceed to the next step according to the APP prompt.
- Place the bottom cover close to the back of your phone to activate the device using NFC, as shown in Figure 10.
- If your phone does not have NFC function or if NFC recognition fails, please follow the prompts provided by the app to scan the QR code.

3.5 Initialization

- After the implantation, the APP starts the sensor initialization countdown mode, and the total initialization duration is 45 minutes (Anytime 5, Anytime 5P, Anytime 5Pro, Anytime 5HSE) and 60 minutes (Anytime 5H), as shown in Figure 11.

3.6 APP interface display and menu content

- After the APP is initialized, the glucose value, and the continuous glucose curve will be displayed, as shown in Figure 12.
- Continuous glucose monitoring page:
  1)Display the latest glucose value and its measurement time, and display the glucose value data every 3 minutes.
  2)Show the current trend of glucose value and glucose curve.
  3)Areas with different colors represent different ranges of glucose values.
  4)Users may choose the glucose curves of different time axes in 3/6/12/24 hours.
  5)The current connection status, TIR and event record can be displayed.
  6)The connection will be reestablished when opening the APP after disconnection.
  7)Anytime 5 Series has the ability to calculate rate of change in glucose levels and displays the information as trend arrows. Trend arrows can be an important aid to assist decision-making of insulin dose. However, trend arrows can be influenced by exercise, meal time and amount of insulin.
  8)The treatment according to trend arrows must follow the guidance from healthcare professionals before making any decisions. See Figure 13 for the meanings of arrows.



3.7 Event record

- Click the Event Record button on the main page to add event records. Users can select the event type and enter the details. Click the "Event Record" button in the menu to enter the event record page and display the event list (click to view and modify). Users may click below the page to add event records, slide the event from right to left, and click " " to delete.

3.8 End of glucose monitoring

- During the wearing process, the application will display the timing. When it stops, the APP will automatically disconnect and prompt confirmation.
  -Remove the device: slowly tear the device together with the adhesive tape off from the wearing site, as shown in Figure 14, and dispose of it as medical waste.
  -Check the skin at the wearing site for congestion, infection, redness, swelling, etc. If there is any anomaly, take photos for medical personnel to check, or ask medical personnel to check.

3.9 Device setting

- High and low limit targets of glucose
  -Click the menu of "High/ Low Target". Users can set the low and high limit targets of glucose according to their own conditions, select the values respectively and click the "Save" button to complete the settings of the high and low limit targets of glucose, as shown in Figure 15.
- Reminder Setting
  -Click the "Reminder Setting" menu, as shown in Figure 16.



Figure 13 Trend arrows



Figure 14 Tearing off the adhesive tape and removing the device



Figure 15 Setting of high and low limit targets of glucose

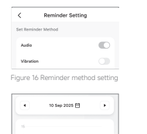


Figure 16 Reminder method setting



Figure 17 CGM device interface



Figure 18 Unbound state interface

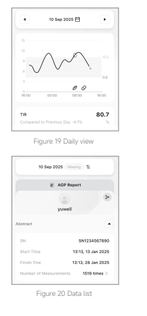


Figure 19 Daily view

Figure 20 Data list

Users can set or modify the reminder method and type according to the page prompts. The device triggers the reminder according to the set ranges of high and low glucose values.

- CGM device
  -Click the "CGM Device" menu, and the serial number of the currently connected device is displayed when the device is connected to the APP.
  -The device is equipped with the function of forcibly ending wearing. Users can click "End Wearing" when necessary, as shown in Figure 17. When performing the operation of ending wearing, the system will give a second confirmation reminder.
  -When the device is not being worn, the interface displays a prompt asking the user to wear it to access data, as shown in Figure 18.

3.10 Glucose analysis

- Daily Pattern
  -Click the "Daily Pattern" menu, and the data of the current day will be displayed by default on the page. Users can click the dates to view the historical data, and show the glucose curve and the main parameters, as shown in Figure 19.
- Data report
  -Click the "Data report" tab to enter the data list. Users can view detailed data records and access the AGP (Ambulatory Glucose Profile) Report generated for each sensor session (as shown in Figure 20).

3.11 Other functions

- Share your monitoring data with Followers
  -You can share your real time monitoring results with your HCP, guardians, and family members via the Follow Anytime App. Your Followers shall download Follow Anytime App on the smartphones and create an account first. They can setup their Follower's page and view your glucose monitoring information after you send them an invitation.
- Share with Followers
  -Tap the top left corner of the home screen to go to the menu. Tap share.
  -Tap Add to invite your Followers. Enter the Follower's email address and add notes.
- Yuwell Anytime View:
  -Yuwell Anytime View software is used by medical staff. It can establish a connection with Yuwell Anytime APP software through email account. Yuwell Anytime APP transmits glucose data to Yuwell Anytime View software through the network.

3.12 Notification

- Prompt for high glucose: The prompt limit for high glucose value can be set on the menu, and users can set according to the situation or doctor's advice. When the glucose in the interstitial fluid measured by the sensor is higher than the set limit, it needs to be confirmed by measuring the fingertip glucose with a glucose meter.
- Prompt for low glucose: Low glucose prompt is the most important function of continuous glucose monitoring system, especially for diabetic patients with unconscious hypoglycemia. When the glucose value measured by the sensor is lower than the low glucose threshold, the low glucose prompt will be triggered. It is suggested to set the low glucose threshold according to the doctor's advice and actual needs. When the glucose in the interstitial fluid measured by the sensor is lower than the set limit, it needs to be confirmed by measuring the fingertip blood glucose with a glucose meter.
- Prediction of high and low glucose:
  -Prediction of high glucose: when the glucose measured by the sensor will reach 400 mg/dL (22.22 mmol/L) within 3 to 15 min, a prediction prompt will be given. The threshold cannot be adjusted.
  -Prediction of low glucose: when the glucose measured by the sensor will reach 54 mg/dL (3.0 mmol/L) within 3 to 15 min, a prediction prompt will be given. The threshold cannot be adjusted.
- The APP loses contact with the transmitter. Generally, this may be because the distance is beyond the effective range of Bluetooth wireless communication or there is a lot of interference around. For example, the signal may be temporarily lost at railway stations, airports, exhibitions, etc. At this time, the data will not be lost, but the glucose information prompt cannot be received in time. Usually, this can be restored when the APP and the transmitter are within the effective range.
- Serious hypoglycemia: The threshold system is set to 56 mg/dL (3.1 mmol/L), which cannot be changed by users. When the glucose concentration is lower than 56 mg/dL (3.1 mmol/L), a prompt will be given. A sound will appear and the screen will display the prompt. When this prompt appears, it needs to be confirmed by measuring the fingertip blood glucose with a glucose meter.
- The sensor falls off unexpectedly: If the sensor falls off, it is usually caused by excessive sweating and exercise, or due to oily skin, and the failure to fix the sensor with adhesive tape in a few cases. Users can only choose to terminate or change a new sensor.
- The adhesive tape is not firmly stuck: During wearing, it is found that the adhesive tape is seriously warped, and it can be reinforced by medical adhesive patch.
- The glucose data is not updated in time: After confirming whether the Bluetooth of the mobile phone is bound, contact the customer service staff.
- Prompt for other anomalies: When there is a fault during wearing, the system will give a prompt according to the fault type. Users can operate according to the prompt information or contact customer service staff.
- For other faults, please contact customer service staff for consultation.

⚠ Caution

In order to receive prompts in time, it is recommended to carry the mobile phone all the time. Please make sure that the Bluetooth of the mobile phone is always turned on. The APP must always run in the background, which may drain your smartphone battery. Close as many applications as possible to ensure the normal operation of Anytime APP background. Never clear Anytime application cache during monitoring, or else a major error will occur. This may force you to restart the sensor and all stored data will be cleared.

4 Starting Your Sensor with Follow Anytime

4.1 Login

Your Follower downloads, installs and opens Follow Anytime. They create their Follow Anytime account with their email address, set password and log in to Follow Anytime, as shown in Figure 1.

4.2 Add Sharer

Your Followers can tap Add to add a sharer, enter Sharer's email address, add notes and send an invitation, as shown in Figure 2. The Sharer will receive request notifications on their Yuwell Anytime.

4.3 Sharers list

Your Followers will see Sharers' list on their home screen, including the Sharer and the Sharer's glucose readings, as shown in Figure 3. They can tap specific Sharer to go to details and swipe to go to Notifications list.

4.4 Notifications list

The Notifications list shows both invitations received and sent, as shown in Figure 4.

4.5 Details

• Real-time Follow

Your Followers can select a Sharer to go to detailed real-time monitoring results, i.e., trend graph, glucose readings, diagram, events logs and daily view, as shown in Figure 5.

• Daily Overview

Your Followers will see your readings of the day and choose date to look at your diagram, events records and daily view, as shown in Figure 6.

• Settings

Your followers can tap on the top right corner of the Real-time Follow screen to access Settings where they can view information, set notes, customize notifications, and stop following, as shown in Figure 7.

1. Urgent Low Alert

Urgent Low Alert level is set at 56 mg/dL (3.1 mmol/L). Your Followers cannot change it in their Follow Anytime. When reading is below 56 mg/dL (3.1 mmol/L), they will receive an audible alert.

2. Low Alert

The default Low Alert level is set at 70 mg/dL (3.9 mmol/L). When reading go below 70 mg/dL (3.9 mmol/L), alerts will be sent. Your Followers can change Low Alert level, switch off Low Alert, set alert intervals on their Follow Anytime as advised by HCP or as needed, as shown in Figure 8.

3. High Alert

The default High Alert level is set at 200 mg/dL (11.1 mmol/L). When your readings go above 200 mg/dL (11.1 mmol/L), alerts will be sent. Your Followers can change High Alert level, switch off High Alert, set alert intervals as advised by HCP or as needed on their Follow Anytime.

4.6 Set up profile on Follow Anytime

Your Followers can tap the icon on the top left corner of the home screen to go to the menu. Tap Personal Data to view or edit information.

4.7 Unit Settings

Your Followers can tap Unit Settings on the menu to go to unit settings.

4.8 About

Your Followers can tap About on the menu to view details i.e., software updates, user license agreement and terms of use, legal statements and privacy policies.

4.9 Logout

Your Followers can enter the menu and tap Logout to log out of the current account.



Figure 1 Login Follow Anytime

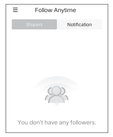


Figure 2 Add sharer



Figure 3 Sharers list

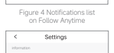


Figure 4 Notifications list on Follow Anytime



Figure 7 Follow Anytime settings



Figure 5 Real-time follow

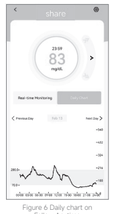


Figure 6 Daily chart on Follow Anytime



Figure 8 Low alert settings on Follow Anytime

5 Making Treatment Decisions

Work with your health care professional to put together a plan for managing your diabetes that includes when to use the System information for making treatment decisions. You should also talk to your health care professional about the best times to check your glucose.

⚠ Caution

The System can replace blood glucose testing but blood glucose testing is required in the following cases to ensure accurate treatment decisions. These are the times when you need to do a blood glucose test before deciding what to do or what treatment decision to make as Sensor readings may not accurately reflect blood glucose levels.



- Do a blood glucose test if you think your glucose readings are not correct or do not match how you feel. Do not ignore symptoms that may be due to low or high glucose. For example, you are feeling shaky, sweaty, and dizzy – symptoms you generally get when you have low glucose, but your glucose reading is within your target range.
- Do a blood glucose test during the first 12 hours after insertion. The Sensor accuracy may vary in the first 12 hours of wearing session.
- Do a blood glucose test if the System displays an error message, 'LO'/'HI' range, or missing glucose values.

5.1 Making Treatment Decisions – Getting Started

- Before you start using the System for treatment decisions, make sure you have a good understanding of how the System works for your body. Continue to use your blood glucose meter for treatment decisions until your health care professional confirms you understand the System's data patterns. This includes understanding that: Sensor performance can vary between Sensors, within a Sensor wear period (duration specified by your Sensor insert), and in different situations.
- Getting familiar with the System could take days, weeks, or even months. The more you check readings from the System with a blood glucose meter, the better you will understand how the System works for you. Work with your health care professional to put together a plan for managing your diabetes that includes when to use the System information for making treatment decisions.

5.2 Helpful Tips

- Check your glucose often to see how carbs, medication, exercise, illness, or stress levels impact your Sensor glucose readings. The information you get can help you figure out why your glucose sometimes goes too high or too low, and how to prevent it from doing so in the future.
- Talk to your health care professional about how your insulin or oral hypoglycemia agent works. The more you understand about your insulin, including how long it takes to start working and how long it lasts in your body, the more likely you will be to make better treatment decisions.
- Making a treatment decision doesn't just mean taking insulin. Treatment decisions can also include things like taking fast-acting carbs, eating, taking oral hypoglycemic agents, or even doing nothing and checking again later.
- Your health care professional can also help you to understand when doing nothing and checking again later is the right treatment decision. For example, if your glucose is high and going up, your first instinct may be to take more insulin to lower your glucose, however depending on when you last took insulin or your recent activity, the right treatment decision may be to do nothing and check again later. Avoid "insulin stacking". "Insulin stacking" (taking additional insulin before previous doses have fully acted) may cause severe hypoglycemia. Always confirm time since last insulin dose with your health care professional.
- Sensor glucose values, which are based on interstitial fluid glucose levels, can be different from blood glucose levels (fingersticks), particularly during times when your blood glucose is changing quickly. If your glucose readings and alerts from the System do not match your symptoms or expectations, use a fingerstick blood glucose value from a blood glucose meter to make diabetes treatment decisions.

5.3 Using Your Glucose Reading to Make a Treatment Decision

After you check your glucose, use all of the information on the screen when deciding what to do or what treatment decision to make.

Important: Treatment decisions require multiple data points. Never make a treatment decision based solely on the Glucose Trend Arrow or a single glucose value. This table provides some information on how you can take the Glucose Trend Arrow into your treatment decisions. Remember that you should never make a treatment decision based on the Glucose Trend Arrow alone.

Glucose Trend Arrow	Treatment Decision Considerations		
	Low glucose (< 70 mg/dL)	Glucose in Target Range	High glucose (> 200 mg/dL)
↘	Treat low glucose according to your health care professional's recommendation.	If you are about to eat, take insulin to cover your meal. Consider whether to take a little less according to your health care professional's recommendation since glucose is falling. If this is between meals, consider eating a snack or fast-acting carbohydrates to stay within target and check again later.	If you are about to eat, take insulin to cover your meal. Consider whether to take a little less according to your health care professional's recommendation since glucose is falling quickly. If this is between meals, consider doing nothing and check again later. Avoid "insulin stacking".
→	Treat low glucose according to your health care professional's recommendation.	If you are about to eat, take insulin to cover your meal. Consider whether to take a little less according to your health care professional's recommendation since glucose is falling quickly. If this is between meals, consider eating a snack or fast-acting carbohydrates to stay within target and check again later.	If you are about to eat, take insulin to cover your meal. Consider whether to take a little less according to your health care professional's recommendation since glucose is falling quickly. If this is between meals, consider doing nothing and check again later. Avoid "insulin stacking".
↙	Treat low glucose according to your health care professional's recommendation.	Treat low glucose according to your health care professional's recommendation.	Treat low glucose according to your health care professional's recommendation.

5.4 Other considerations

Deciding how much rapid-acting insulin to take for different meals and situations can be difficult. Work with your health care professional to discuss different situations and what might work best for you. Here are some questions to consider:

1) Meal dosing
- What do you do if your before meal glucose is high?
- What do you do if your before meal glucose is low?
- How much time do you wait to eat after taking your meal insulin?
- Do you adjust the amount of meal insulin based on the number of carbs or how much you are planning to eat?
- Do you adjust your meal insulin dose for high fat foods such as pizza?
- Do you know how to adjust your insulin doses when drinking alcoholic beverages?

2) High glucose corrections
- Do you take extra insulin if your glucose is high?
- How do you decide how much insulin to take for a high glucose?
- How long do you wait between insulin doses to avoid insulin stacking?

3) Bedtime
- How often do you check your glucose before bed?
- What do you consider a safe bedtime glucose?
- What do you do if your bedtime glucose is high?
- What do you do if your bedtime glucose is low?
- When should you eat a bedtime snack?
- What do you do if your before meal glucose is high?
- What do you do if your before meal glucose is low?

4) Other factors
- How do you adjust your insulin dose based on the Glucose Trend Arrow?
- How do you adjust your insulin dose for different types of exercise or activities?
- How do you adjust your insulin doses for stress?
- How do you adjust your insulin doses for illness?

5) Important Reminder:
- The Anytime 5 Series just a tool to support diabetes management.
- All treatment decisions must be made under the guidance of your health care professional.
- Failure to verify abnormal readings with a blood glucose meter may lead to incorrect treatment and health risks.

6 Continuous Glucose Monitoring (CGM) System Software Suite

6.1 Basic information

- Software: Yuwell Anytime
  Model & specification: Anytime Series for android.
  Anytime Series for iOS
  Software release version: V2
  Software operating environment

	iOS client	Android client	Server
Typical hardware configuration:			
CPU	2.5 GHz	2.0 GHz	2.40 GHz
Memory	4 GB	6+1 GB	16 GB
Hard disk	64 GB	64 GB	500 GB
Display screen	1792*828	2408*1080	Network conditions 10 M
Bluetooth	5.0 and compatible versions	5.1 and compatible versions	
Typical software configuration:			
Operating system	iOS 16 and compatible versions	Android 11 and compatible versions	Linux Database MySQL5.7 and compatible versions

- Software: Follow Anytime
  Software release version: V2
  Software operating environment: Consistent with Yuwell Anytime software.
- Software: Anytime View
  Software release version: V2
  Software operating environment:
  Operating system Windows Server 2019 Datacenter (64bits) and compatible versions.
  Database MySQL5.7 and compatible versions.

6.2 Interface

- Software and transmitter
  1)Transmission protocol: Bluetooth transmission protocol; 2)Data format: hexadecimal array format.
- Software and server
  -Transmission protocols: MQTT and HTTPS protocols;
  -Data format: JSON format.
- Types of input and output data
  -Input: Original information of patient's glucose;
  -Output: Statistical data of glucose, glucose maps and glucose reports.
- Access control
  -Users can log into the APP through email and password. After scanning the QR code of product serial number or NFC, the connection can be established after the correct serial number is paired.
- Maximum concurrency
  -The maximum concurrency is 100 when single glucose data in the APP is synchronized to the server.
- Performance efficiency
  -Under the premise of 10 M broadband and the maximum concurrency of 100, when the single glucose data in the APP is synchronized to the server, the average synchronization time is within 3 s.

6.3 Transmitter software information

- Basic information
  -Software: transmitter software;
  -Software release version: V1.

6.4 Maintenance

The product is disposable, and there are no parts to be replaced or repaired. If the product fails during use, please contact the manufacturer or agent directly, and do not dismantle it for repair, inspection, replacement or modification. Maintenance personnel shall be appointed by the manufacturer, and maintenance shall be carried out according to the information provided by the manufacturer.

6.5 Waste disposal

- The product is disposable, and shall be disposed of according to the regulations of medical waste after use. Do not discard the used products at will, and the disposal of wastes should meet the local waste management requirements for electronic equipment, batteries, sharp objects and materials that may be exposed to human body fluids.
- The product contains electronic components, and shall be treated as electronic medical waste at the end of its service life.
- About how to dispose of the waste generated after the use of this product, users can contact the manufacturer for further details.

7 Electromagnetic Compatibility (EMC)

- This device complies with the electromagnetic compatibility requirements of IEC 60601-1-2.
- For this device, special precautions regarding electromagnetic compatibility (EMC) must be taken, and it must be installed and used in accordance with the EMC information provided in this manual.
- Portable and mobile RF communication devices may affect this device. To avoid strong electromagnetic interference, keep it away from devices such as mobile phones and microwave ovens during use.
- The product has no essential performance.
- Guidance and manufacturer's statements are detailed in the appendix.
- This device should not be used close to or stacked with other devices. If it must be used in close proximity or stacked, ensure that it operates correctly in that configuration.
- Even if other devices meet the relevant national emission standards, the device or system may still be subject to interference from those devices.
- Wireless module information:

1) Warning: This device may still be affected by interference from other devices, even if those other devices comply with the relevant national emission standards.

2) Transmitter: Frequency 2.4 GHz, modulation type GFSK, bandwidth 2400-2483.5 MHz, effective radiated power 0 dBm.

Guidance and manufacturer's declaration – electromagnetic emissions

The Anytime 5, Anytime 5P, Anytime 5Pro, Anytime 5H and Anytime 5H SE Continuous Glucose Monitoring Systems are intended for use in the electromagnetic environment specified below. The customer or the user of the Anytime 5, Anytime 5P, Anytime 5Pro, Anytime 5H and Anytime 5H SE Continuous Glucose Monitoring Systems should assure that it is used in such an environment.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the System. Otherwise degradation of the performance of the System could result.

EMISSIONS Test	IEC 60601 test level	Conformity
Conducted DISTURBANCES (conducted EMISSIONS) CISPR 11	Minimum and maximum RATED voltage Any one frequency	Group 1; 100 V~240 V; Frequency: 50/60 Hz
Electromagnetic radiation disturbance (radiated EMISSIONS) CISPR 11	Any one voltage Any one frequency	Class B; 100 V~240 V; Frequency: 50/60 Hz
Harmonic current EMISSIONS IEC 61000-3-2	For ME EQUIPMENT and ME SYSTEMS RATED 220 V to 240 V or 380 V to 415 V: If RATED at a single voltage,that voltage. If single-phase and a range is specified, 230 V if three-phase and a range is specified, 400 V	AC 220 V to 240 V
Voltage changes,voltage fluctuations and flicker EMISSIONS IEC 61000-3-3	For ME EQUIPMENT and ME SYSTEMS RATED 220 V to 250 V line to neutral: If RATED at a single voltage,that voltage. If single-phase and a range is specified, 230 V if three-phase and a range is specified, 400 V	AC 220 V to 240 V

a) The test may be performed at any one power input voltage within the ME EQUIPMENT or ME SYSTEM RATED voltage range.If the ME EQUIPMENT or ME SYSTEM is tested at one power input voltage, it is not necessary to re-test at additional voltages.
b) The test may be performed at any one power frequency within the ME EQUIPMENT or ME SYSTEM RATED frequency range. If the ME EQUIPMENT or ME SYSTEM is tested at one power frequency, it is not necessary to re-test at additional frequencies.
c) If the difference between the maximum and the minimum RATED input voltage is less than 25% of the highest RATED input voltage, then the test may instead be performed at any one RATED voltage.
d) ME EQUIPMENT and ME SYSTEMS with power input voltage selection by transformer taps shall be tested at only one tap setting.

Guidance and manufacturer's declaration – electromagnetic immunity(Enclosure port)

The Anytime 5, Anytime 5P, Anytime 5Pro, Anytime 5H and Anytime 5H SE Continuous Glucose Monitoring Systems are intended for use in the electromagnetic environment specified below. The customer or the user of the Anytime 5, Anytime 5P, Anytime 5Pro, Anytime 5H and Anytime 5H SE Continuous Glucose Monitoring Systems should assure that it is used in such an environment.

Immunity Test	IEC 60601 test level	Conformity
ELECTROSTATIC DISCHARGE (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±15 kV air
Radiated RF EM fields[d] IEC 61000-4-3	10 V/m [1] 80 MHz–2.7 GHz [2] 80 %AM at 1 kHz [c]	10 V/m
Proximity fields from RF wireless communications equipment IEC 61000-4-3	See table "Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment"	
RATED power frequency magnetic fields[e] IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical domestic, commercial.
Proximity magnetic fields IEC 61000-4-39	See table of "Test specifications for Enclosure port immunity to proximity magnetic fields"	See table of "Test specifications for Enclosure port immunity to proximity magnetic fields"

a) The interface between the PATIENT physiological signal simulation, if used,and the ME EQUIPMENT or ME SYSTEM shall be located within 0.1 m of the vertical plane of the uniform field area in one orientation of the ME EQUIPMENT or ME SYSTEM.
b) ME EQUIPMENT and ME SYSTEMS that intentionally receive RF electromagnetic energy for the purpose of their operation shall be tested at the frequency of reception. Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.This test assesses the BASIC SAFETY and ESSENTIAL PERFORMANCE of an intentional receiver when an ambient signal is in the passband. It is understood that the receiver might not achieve normal reception during the test.
c) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.
d) Applies only to ME EQUIPMENT and ME SYSTEMS with magnetically sensitive components or circuitry.
e) Void
f) Before modulation is applied.

Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields

Test frequency	Modulation	IMMUNITY TEST LEVEL (A/m)
30 kHz [a]	CW	8
134.2 kHz	Pulse modulation [b] 2.1 kHz	65 [c]
13.56 MHz	Pulse modulation [b] 50 kHz	7.5 [c]

a) This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT.
b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
c) r.m.s., before modulation is applied.

Guidance and manufacturer's declaration – electromagnetic immunity (Input a.c.power PORT)

The Anytime 5, Anytime 5P, Anytime 5Pro, Anytime 5H and Anytime 5H SE Continuous Glucose Monitoring Systems are intended for use in the electromagnetic environment specified below. The customer or the user of the Anytime 5, Anytime 5P, Anytime 5Pro, Anytime 5H and Anytime 5H SE Continuous Glucose Monitoring Systems should assure that it is used in such an environment.

Immunity test	IEC 60601 Test level	Conformity
Electrical fast transients / bursts[m] IEC 61000-4-4	±2 kV 100 kHz repetition frequency	±2 kV 100 kHz repetition frequency
Surges [i][j][k] Line-to-line IEC 61000-4-5	±0.5 kV, ±1 kV	±1 kV differential mode ±2 kV common mode
Conducted disturbances induced by RF fields [l][m] IEC 61000-4-6	3 V[e] 0.15 MHz–80 MHz 6V[e] in ISM and amateur radio bands between 0.15 MHz and 80 MHz[e] 80% AM at 1 kHz[e]	3 V[e] 0.15 MHz–80 MHz
Voltage dips [g][m] IEC 61000-4-11	0% U_T; 0.5 cycle [f] At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° [f]	0% U_T; 0.5 cycle [f] At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° [f]
	0% U_T; 1 cycle and 70% U; 25/30 cycles [c] Single phase: at 0°	0% U_T; 1 cycle and 70% U; 25/30 cycles [c] Single phase: at 0°
Voltage interruptions[h][m] 61000-4-11	0% U_T; 250/300 cycle [g]	0% U_T; 250/300 cycle [g]

a) Void
b) All ME EQUIPMENT and ME SYSTEM cables are attached during the test.
c) Calibration for current injection clamps shall be performed in a 1500 system.
d) If the frequency stepping skips over an ISM or amateur band, as applicable,an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.
e) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.
f) ME EQUIPMENT and ME SYSTEMS with a d.c.power input intended for use with a.c.–to-d.c.converters shall be tested using a converter that meets the specifications of the MANUFACTURER of the ME EQUIPMENT or ME SYSTEM.The IMMUNITY TEST LEVELS are applied to the a.c.power input of the converter.
g) Applicable only to ME EQUIPMENT and ME SYSTEMS connected to single-phase a.c.mains.
h) E.g. 10/12 means 10 periods at 50 Hz or 12 periods at 60 Hz.
i) ME EQUIPMENT and ME SYSTEMS with RATED input current greater than 16 A/phase shall be interrupted once for 250/300 cycles at any angle and at all phases at the same time (if applicable). ME EQUIPMENT and ME SYSTEMS with battery backup shall resume line power operation after the test. For ME EQUIPMENT and ME SYSTEMS with RATED input current not exceeding 16A, all phases shall be interrupted simultaneously.
j) ME EQUIPMENT and ME SYSTEMS that do not have a surge protection device in the primary power circuit may be tested only at ±2 kV line(s)to earth and ±1 kV line (s)to line(s).
k) Not applicable to CLASS IME EQUIPMENT and ME SYSTEMS.
l) Direct coupling shall be used.
m) r.m.s.,before modulation is applied.
n) The ISM (industrial,scientific and medical)bands between 0.15 MHz and 80 MHz are 6, 765 MHz to 6, 795 MHz; 13, 553 MHz to 13, 567 MHz; 26, 957 MHz to 27, 283 MHz;and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2, 0 MHz, 3, 5 MHz to 4, 0 MHz, 5, 3 MHz to 5, 4 MHz, 7 MHz to 7, 5 MHz, 10, 1 MHz to 10, 15 MHz, 14 MHz to 14, 2 MHz, 18, 07 MHz to 18, 17 MHz, 21, 0 MHz to 21, 4 MHz, 24, 89 MHz to 24, 99 MHz, 28, 0 MHz to 29, 7 MHz and 50,0 MHz to 54, 0 MHz.
o) Applicable to ME EQUIPMENT and ME SYSTEMS with RATED input current less than or equal to 16 A/phase and ME EQUIPMENT and ME SYSTEMS with RATED input current greater than 16 A/phase.
p) Applicable to ME EQUIPMENT and ME SYSTEMS with RATED input current less than or equal to 16 A/phase.
q) At some phase angles,applying this test to ME EQUIPMENT with transformer mains power input might cause an overcurrent protection device to open. This can occur due to magnetic flux saturation of the transformer core after the voltage dip. If this occurs, the ME EQUIPMENT or ME SYSTEM shall provide BASIC SAFETY during and after the test.
r) For ME EQUIPMENT and ME SYSTEMS that have multiple voltage settings or auto ranging voltage capability, the test shall be performed at the power input voltage specified in Table 1.

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the System. Otherwise，degradation of the performance of the System could result.

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation	IMMUNITY TEST LEVEL (V/m)
385	380 to 390	TETRA 400	Pulse modulation [b] 18 Hz	27
450	430 to 470	GMRS 460,FRS 460	FM [c] ±5 kHz deviation 1 kHz sine	28
710 745 780	704 to 787	LTE Band 13,17	Pulse modulation [b] 217 Hz	9
810 870 930	800 to 960	GSM 800/900,TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	28
1720 1845 1970	1700 to 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	28
2450	2400 to 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	28
5240 5500 5785	5100 to 5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	9

If necessary to achieve the IMMUNITY TEST LEVEL,the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.
a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50% duty cycle square wave signal.
c) As an alternative to FM modulation, the carrier may be pulse modulated using a 50% duty cycle square wave signal at 18 Hz. While it does not represent actual modulation, it would be worst case.

ME Equipment that intentionally receives RF energy shall include: frequency and/or band and bandwidth of receiving section.
ME Equipment that include transmitters shall include frequency and/or band, modulation, and ERP.

8 Technical Information

8.1 Product specifications

Model	Anytime 5 Series
Glucose Range	30–500 mg/dL (1.7 - 27.8 mmol/L)
Useful Life	Anytime 5、Anytime 5P、Anytime 5Pro、Anytime 5H SE: 16 days Anytime 5H: 14 days
Sterilization	Electron beam irradiation sterilization
Warmup Time	Anytime 5、Anytime 5P、Anytime 5Pro、Anytime 5H SE: 45 minutes Anytime 5H: 1 hour
Data Refresh Interval	5 minutes
Memory Storage	Anytime 5、Anytime 5P、Anytime 5Pro、Anytime 5H SE: 16 days Anytime 5H: 14 days
Power Source	1.55 V
Battery Longevity (Typical)	at least 16 days
Storage Temperature	2~~ 30 °C
Transportation temperature	2~~40 °C
Operational Temperature	5~~40 °C
Operating and Storage Humidity	10% RH~~90% RH
Operating Pressure	700~~1060 hPa
Ingress Protection	IP58 (1.5 M 1 hour)
Applied Part	BF
TX/RX Frequencies	2.40 GHz ~ 2.48 GHz
Bandwidth	2 MHz
Maximum Output Power	0 dBm
Modulation	GFSK
Data Rate	1 m bps
Data Communication Range	6 m

8.2 Clinical performance

A multi-center self-controlled clinical investigation was conducted by comparing the Anytime 5 System with the glucose concentration in venous blood detected by laboratory method to evaluate the effectiveness and safety, in which 72 diabetic patients aged 18 years and older were enrolled and analyzed.

Table 1. Primary outcomes

Primary Outcomes	Results
Percentage of CGM readings within 20% of the reference values (agreement rate)	94.97%
The percentage of measuring points in zones A+B of Clarke error grid analysis	98.80%
The percentage of measuring points in the zones A+B of Consensus error grid analysis	99.99%
Mean absolute relative difference (MARD%)	8.58%

Table 2. Secondary outcomes

Secondary Outcomes	Results
Alert accuracy	Correct detection rate of hypoglycemia (<3.9 mmol/L): 87.19% True alert rate of hypoglycemia (<3.9 mmol/L): 94.34%
	Correct detection rate of hyperglycemia (>11.1 mmol/L): 93.21% True alert rate of hyperglycemia (>11.1 mmol/L): 95.49%
Sensor stability	Beginning MARD: 8.57% Middle MARD: 8.30% End MARD: 8.88%.
Sensor reproducibility	Upper-arm PARD: 9.39% Abdomen PARD: 11.19%
Trend accuracy	Concurrence rate of glucose rates of change >0.06 mmol/l/minutes if true rate of change <-0.11 mmol/l/minutes: 0.12% Concurrence rate of glucose rates of change <-0.06 mmol/l/minutes if true rate of change >0.11 mmol/l/minutes: 0%

9 Symbols

Graphics and identification	Definition	Graphics and identification	Definition
	Consult instructions for use		Type BF applied part
	Read Instructions manual		Direct current
STERILE R	Sterilized using irradiation	EU REP	EU Authorized representative
	Do not re-use		Non-ionized electromagnetic radiation
	Do not use if package is damaged and consult instructions for use		Do not dispose in unsorted municipal waste stream
	Do not re-sterilize	2°C 30°C	Temperature range limit (2~30 °C)
	Caution	10% 90%	Humidity limitation 10%~90%
	Keep dry	700 hPa 1060 hPa	Atmospheric pressure limitation (700 hPa~1060 hPa)
	Stacking limit by number		Keep away from sunlight
	Manufacturer		This side up
MD	Medical device	UDI	Unique device identifier
	Use-by date		Date of manufacture
REF	Catalogue number	LOT	Batch code
#	Model number	SN	Serial number
CE 0123	CE mark	MR	MR unsafe
IP58	5 Dust-protected 8 Protected against the effects of continuous immersion in water		Single sterile barrier system with protective packaging outside
	Importer		

10 Manufacturer information

Product batch number: See the package label
Production date and expiration date: See the package label
Shelf life: 12 months
Distributed and service provided by:
Jiangsu Yuyue Medical Equipment & Supply Co., Ltd.
Customer service: service@yuwell.com

Jiangsu Yuwell POCTech Biotechnology CO.,Ltd.
No.5 Baisheng Road Development Zone,
Danyang, Jiangsu 212300 CHINA.

EU REP Metrax GmbH
Rheinwaldstr.22, 78628 Rottweil, GERMANY

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If there is any change, a new version of the User's Manual will be released.

CE 0123

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