

AiDEX™ Continuous Glucose Monitoring System (CGMS) App User Guide

Intended purpose

The Continuous Glucose Monitoring App is a receiver of the CGMS which is used for daily detection and self-management of blood glucose levels in people 2 years and older. It is intended for use by patients at home and in healthcare facilities. Interpretation of the real-time blood results should be based on the glucose trends and several sequential readings over time.

The App also aids in detection of episodes of hyperglycaemic and hypoglycaemia. The System is designed to replace fingerstick blood glucose (BG) testing.

If you have any questions, please contact us via email: bd@microtechmd.com or by telephone: +86 (0) 571-88566372.

CONTENTS

1. PRODUCT DESCRIPTION	5
1.1 BASIC INFORMATION	5
2. IMPORTANT USER INFORMATION	5
2.1 CONTRAINDICATIONS	5
2.2 PRECAUTIONS	5
2.3 INTENDED USER PROFILE	6
3 USER INSTRUCTIONS	6
3.1 SOFTWARE DOWNLOAD AND INSTALLATION	6
3.1.1 Software Download	6
3.1.2 Minimum Requirements for Software Installation	6
3.2 SOFTWARE REGISTRATION, LOGIN AND RESETING	7
3.2.1 Software Registration	7
3.2.2 Software Login	8
3.2.3 Password Reset	8
3.2.4 Software Logout	9
3.3 INTRODUCTION	9
3.3.1 Bluetooth Setting	10
3.3.2 Notification	10
3.3.3 Do Not Disturb	11
3.3.4 Alerts and Warnings Setting	12
3.3.5 Glucose Trend Arrows	12
3.3.6 Background Colors	13
3.3.7 Low Glucose Alert Setting	13
3.3.8 High Glucose Alert Setting	14
3.3.9 Connecting a Transmitter	15
3.3.10 Insert Sensor	15
3.3.11 Sensor Warm-up	16
3.4 FUNCTIONS	17
3.4.1 Home Dashboard	17
3.4.2 History Dashboard	17
3.4.3 Trends Dashboard	18
3.4.4 Blood Glucose (BG) Dashboard	19
3.4.5 Events Dashboard	20
3.5 TRANSMITTER MANAGEMENT	21
3.5.1 Pairing a Transmitter	21
3.5.2 Unpairing a Transmitter	22
3.6 ALERTS	23
3.6.1 Alert Settings	23
3.7 SHARING	24
3.7.1 Sharing Management	24
3.8 APPLE HEALTH	25
3.9 LANGUAGE	26
3.10 THEME	26
3.11 INSTRUCTIONS FOR USE	26
3.12 OTHERS	26
3.12.1 Feedback	26
3.12.2 Reset the password	26
3.12.3 Delete Account	27
3.13 APP INFO	27
3.13.1 Terms of Service	28
3.13.2 Privacy Policy	28

4. MAINTENANCE	28
5. DATA SECURITY	28
6. TROUBLESHOOTING	28
7. OTHER	29
8. EXPLANATION OF SYMBOLS	29
9.EXPECTED CLINICAL BENEFITS	30

1. Product Description

1.1 Basic Information

Product name: Continuous Glucose Monitoring App

Model:

No.	Operating System	Unit	Release Version
RC2101	iOS	mg/dL	V1
RC2102	iOS	mmol/L	V1
RC2103	Android	mg/dL	V1
RC2104	Android	mmol/L	V1

Blood glucose data measured by the CGMS is updated every 5 minutes.

The App synchronises and displays the sensor glucose data every 5 minutes.

The App is compatible with the following devices:

AiDEX™ Continuous Glucose Monitoring System

	MicroTech Medical Model No.
System	G7
Sensor	G7-S01
Transmitter	G7-T01
Personal Diabetes Assistant (PDA)	G7-P02

1.2 Operating principle

The Continuous glucose monitoring App can be used to pair with the transmitter through Bluetooth, the App can display and analysis the blood glucose readings which obtained from the transmitter. It can also transfer the data such as calibration value back to the transmitter. The App can also connect to the cloud servers through WLAN, and store the health data on the cloud servers.

1.3 Performance characteristics

- Wireless data transfer
- Blood glucose readings
- Trend display
- Calibration
- Hyperglycemia/hypoglycemia alert

2. Important User Information

2.1 Contraindications

No MRI – MR Unsafe

Do not wear your CGM (sensor, transmitter, receiver, or smart device) for magnetic resonance imaging (MRI)

2.2 Precautions

1. CGMS readings displayed on the App should only be used as a reference for the supplemental monitoring of diabetes mellitus and should not be used as a basis for clinical diagnosis.

2. Should there be rapid changes in blood glucose value displayed by the App (more than 0.1 mmol/L per minute or 1.8 mg/dL per minute), the displayed blood glucose levels may not be the same as the actual blood glucose levels. When the displayed blood glucose levels drop rapidly, the displayed value could be a higher-than-actual reading. When the displayed blood glucose levels rise rapidly, the displayed value could be a lower-than-actual reading. When experiencing symptoms of hypoglycaemic or hyperglycaemic, please take a fingertip blood glucose test and do not rely entirely on the displayed reading on the App.

3. If you think the displayed reading on the App is inaccurate or inconsistent, please take a blood glucose meter test to get your blood glucose value and calibrate the glucose sensor. If the problem persists, replace the sensor.

4. While extensive user testing has been done on AiDEX™ CGMS in Type 1 and Type 2 diabetic patients, the study groups did not include women with gestational diabetes

5. The performance of the App has not been evaluated when used with another implantable medical device, such as a pacemaker.

6. The App currently does not have available support for visually impaired users. Please do not use it if you are visually impaired.

7. Any incident that are related to the App should be reported to MicroTech Medical.

8. All pictures shown in this guide are for illustration purpose only. Actual product may vary due to product enhancement.

9. Avoid using the AiDEX™ App and CGMS in close proximity to a wireless transmitting device to maximise the AiDEX™ performance. Interference from other devices can cause disruption on the data transmission between the AiDEX™ App and CGMS.

10. Avoid using the AiDEX™ App and CGMS in environment that contains electrostatic discharge to maximise the AiDEX™ performance.

2.3 Intended user profile

Lay person and professionals (18 years and older) who need continuous or regular monitoring or others' glucose levels.

3 User Instructions

3.1 Software Download and Installation

3.1.1 Software Download

You can download the AiDEX™ App from App Store (iOS) or Google Play (Android). Please check the Operating System (OS) on your mobile device to make sure you get the correct App version. To download the App, search "AiDEX" in App Store (iOS) or Google Play (Android).



3.1.2 Minimum Requirements for Software Installation

iOS

Model No.: RC2101 (mg/dL), RC2102 (mmol/L)

Operating System (OS): iOS 14 and above

Memory: 2GB RAM

Storage: Minimum 200 MB

Network: WLAN (Wireless Local Area Network) or cellular network, as well as Bluetooth function

Screen Resolution: 1334 x 750 pixels

Android

Model No.: RC2103 (mg/dL), RC2104 (mmol/L)

Operating System (OS): Android 10.0 and above.

Memory: 3GB RAM

Storage: Minimum 200 MB

Network: WLAN (Wireless Local Area Network) or cellular network, as well as Bluetooth function

Screen Resolution: 480 x 320 pixels

3.2 Software Registration, Login and Resetting

3.2.1 Software Registration

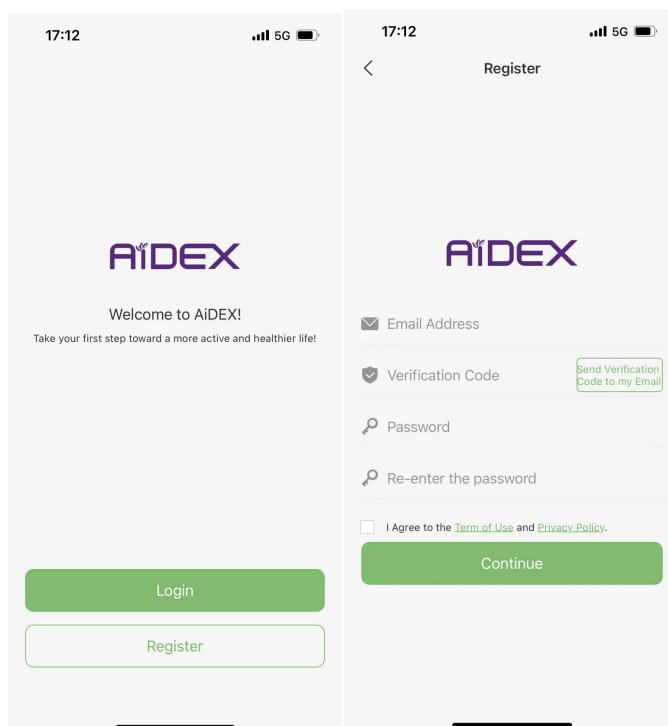
If you do not have an account, click “Register” button to enter the registration screen. Please input your email address and password. Read the Terms of Use and Privacy Policy before ticking the box. By ticking the box, you agree to comply with the Terms of Use and the Privacy Policy. Click “Send verification code to my email” to receive a six-digit code. After keying in the verification code, click “Continue” to complete your registration. The rules for setting username and password are:

Username:

- ✓ Use your email address as your username

Password:

- ✓ Password must contain at least 8 characters.
- ✓ Password must contain 1 capital letter, 1 small letter and 1 numerical number.

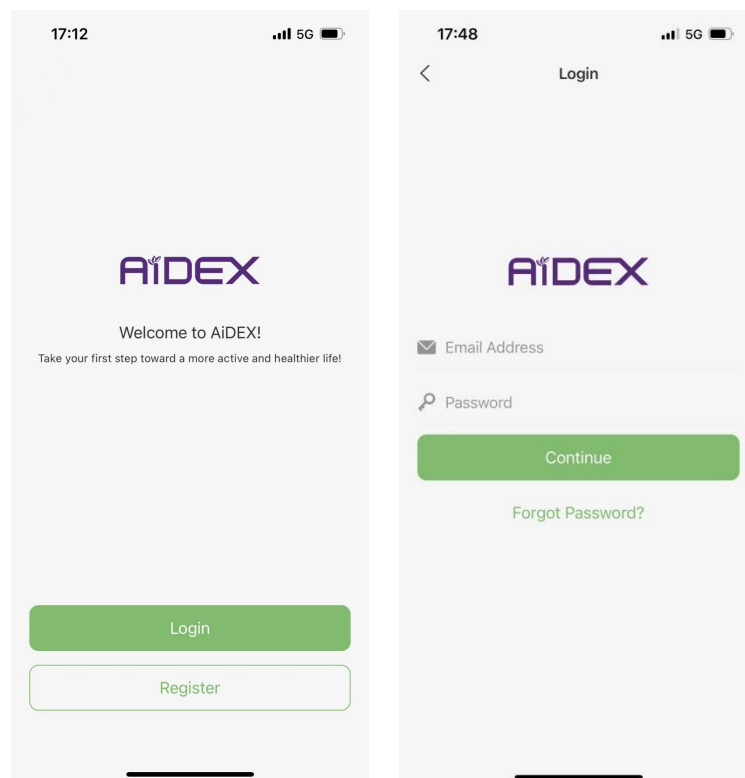


3.2.2 Software Login

Use your registered account email address and Password to log in to the AiDEX™ App.

Note: You may only log in your account in one mobile device at a time.

Note: You are responsible for properly securing and managing your phone. If you suspect an adverse cybersecurity event related to the AIDEX app, [contact local distributor](#). Make sure that your phone is kept in a safe place, under your control. Do not disclose your password to others. This is important to help prevent anyone from accessing or tampering with the System.

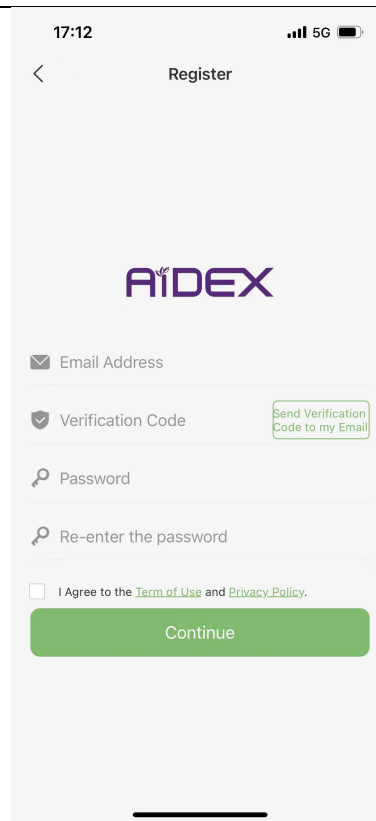


3.2.3 Password Reset

If you forget your password, click “Forgot Password” to enter the password “Reset” screen.

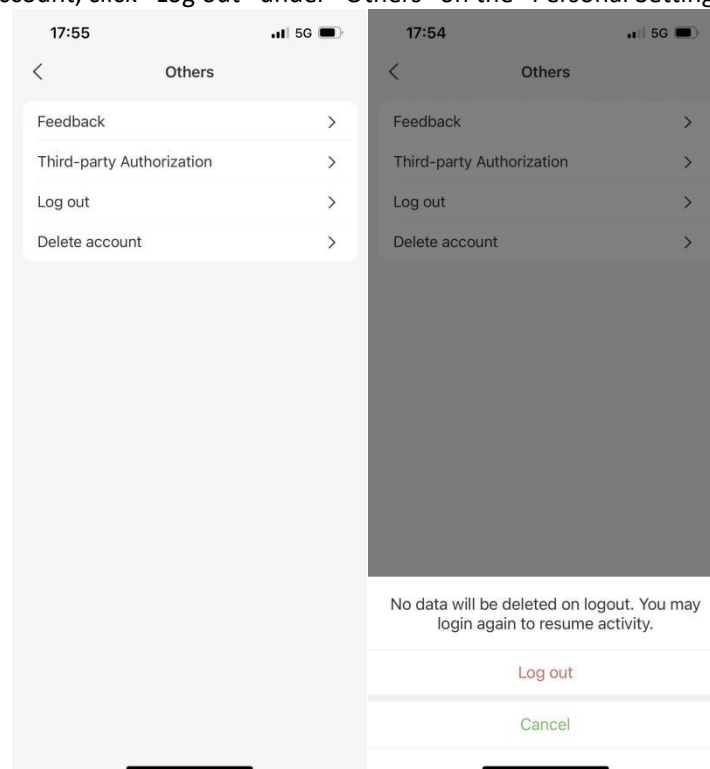
Type in your email address and your new Password, then get a verification code by clicking “Send Verification Code to my Email”. Find your verification code in your verification email and type in your verification code. Click “Continue” to complete the Password reset.

Note: the new Password and the old Password cannot be identical.



3.2.4 Software Logout

To log out of the current account, click “Log out” under “Others” on the “Personal Settings” page.



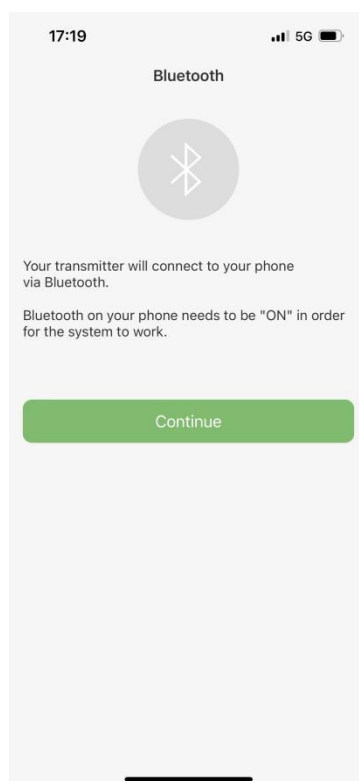
3.3 Introduction

When you login to the AiDEX™ App for the first time, there will be an introduction guiding you to complete the basic system setups.

3.3.1 Bluetooth Setting

You will need Bluetooth connection to pair your CGMS transmitter. Click “Continue” to enable the Bluetooth connection between your CGMS and the App, or enable the Bluetooth in your phone settings.

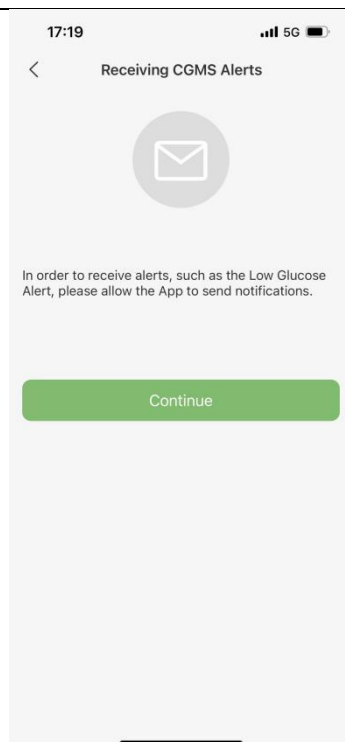
If you do not wish to enable the Bluetooth function, your App will not be able to pair with your CGMS to collect blood glucose data.



3.3.2 Notification

In the “Receiving CGMS Alerts” screen, choose “Continue” to enable the alert notification.

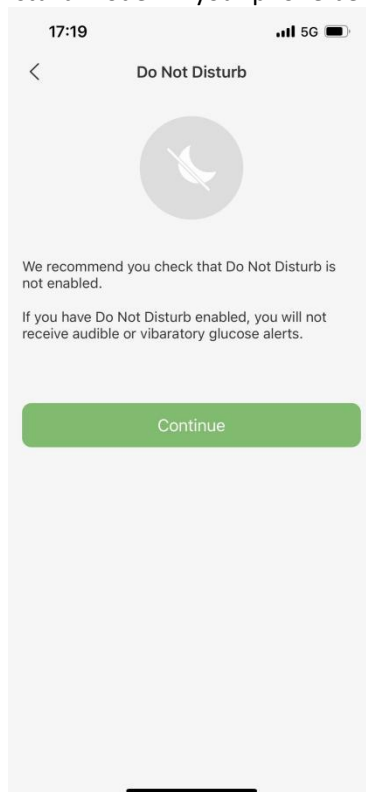
If you do not wish to receive alerts, you can disable the alert setting in “Personal Settings”. Home > Personal Settings > Alert Settings.



3.3.3 Do Not Disturb

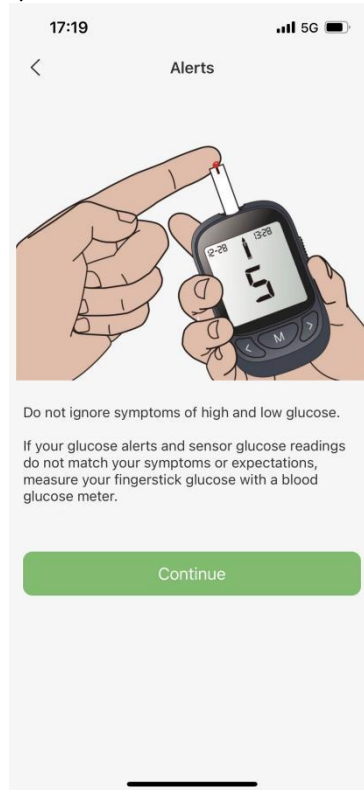
In the “Do Not Disturb” screen, reminder to check your “Do Not Disturb Mode” in your mobile device is displayed.

Ensure that you have turned off “Do Not Disturb Mode” in your phone before using the AiDEX™ App.



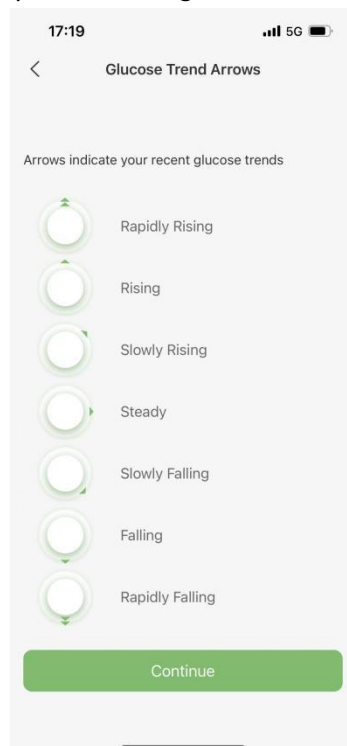
3.3.4 Alerts and Warnings Setting

In the “Alerts” screen, there are tips for blood glucose management when alerts appear. If your glucose alerts and sensor glucose readings do not match your symptoms or expectations, measure your fingerstick glucose with a blood glucose meter and consult your healthcare professional.



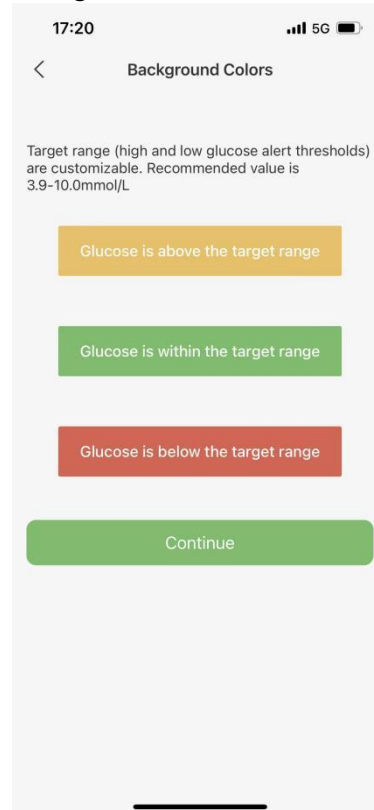
3.3.5 Glucose Trend Arrows

Trend arrows show the speed and direction of your glucose trends based on your recent AiDEX readings. Use the arrows to know when to take action before you're too high or too low.



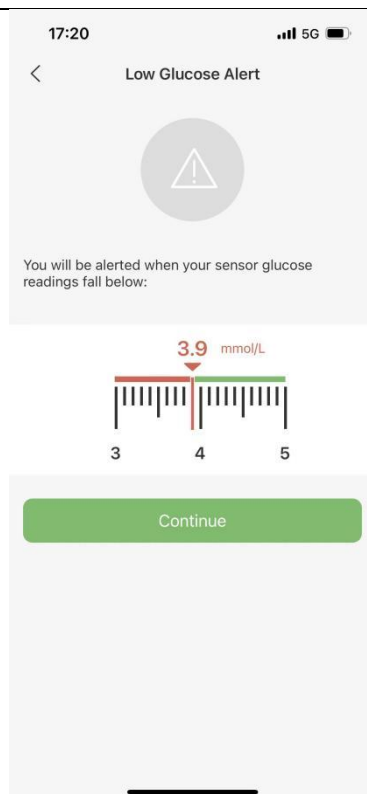
3.3.6 Background Colors

Your current glucose value determines the background colour on the HomeScreen.



3.3.7 Low Glucose Alert Setting

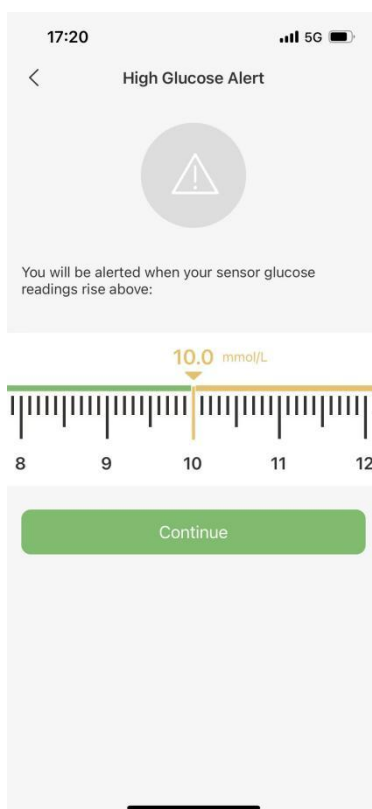
Set the lower glucose threshold in the low glucose alert setting screen. You can also change the alert threshold by clicking the "Personal Settings" icon on the upper-right corner of the "Home" screen. Home > Personal Settings > Alerts Setting.



3.3.8 High Glucose Alert Setting

After setting your low glucose alert, click “Continue” to enter the high glucose alert setting screen. Set your upper glucose limit in the high glucose alert setting screen.

You can also change the alert value by clicking the “Personal Settings” icon on the upper-right corner of the “Home” screen. Home > Personal Settings> Alerts Setting.



3.3.9 Connecting a Transmitter

Click “Continue” to enter the “Transmitter” setting screen. Input the SN (Serial Number) code on the transmitter package manually or scan the QR code on the transmitter package using the scan symbol  in the top right hand corner of the screen to complete the pairing automatically.



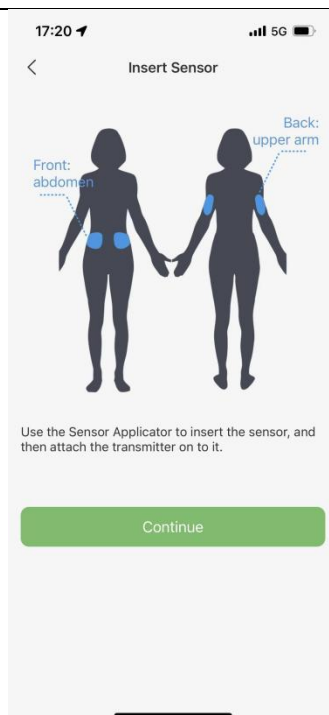
If you choose to skip the transmitter setting, you can also click the “Personal Settings” icon on the upper-right corner of the “Home” screen and choose “Transmitter” to connect a transmitter.

Home > Personal Settings > Transmitter

Please refer to Chapter 3.5 for detailed App functions.

3.3.10 Insert Sensor

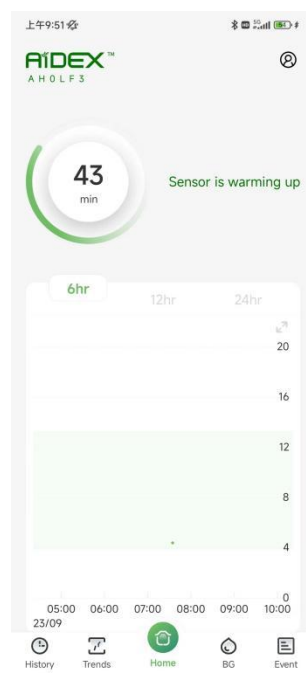
Use the sensor applicator of your CGMS to insert the AiDEX™ CGMS sensor.



3.3.11 Sensor Warm-up

When you have successfully paired the transmitter, you need to wait for one hour for your sensor to warm up. You will see the real-time glucose readings (updated every 5 minutes) on the “Home” screen after sensor warm-up has finished.

Cautions: If you are using a new sensor for the first time, please click “New Sensor” in a pop-up window that asks you to confirm that the AiDEX™ App is pairing with a new sensor. If the sensor is a used one, please click “A Used One”. If the sensor is a used one, you can skip the warm-up. The real-time glucose readings (updated every 5 minutes) will be displayed on the “Home” screen directly. In addition, please do not suspend or cancel the sensor warm-up before it is finished. Skipping sensor warm-up for new sensors can result in inaccurate blood glucose measurements and readings displayed on your App.



3.4 Functions

3.4.1 Home Dashboard

Home dashboard displays the overview of your blood glucose levels.

In the upper section of the dashboard, the real-time blood glucose level is displayed (updated every 5 minutes).

In the lower section of the dashboard, the blood glucose against time graph is displayed. You can select the time interval to see the glucose level history and trend in the past 6 hours, 12 hours or 24 hours.

Scroll the plot to view blood glucose levels over different periods. The data point gives you the blood glucose value and the time of measurement (updated every five minutes).

A pop-up notification box will appear two days before your sensor expires. When your sensor expires, the sensor status on the AiDEX™ App will also change to “expired”. Please replace the used sensor.

Notes:

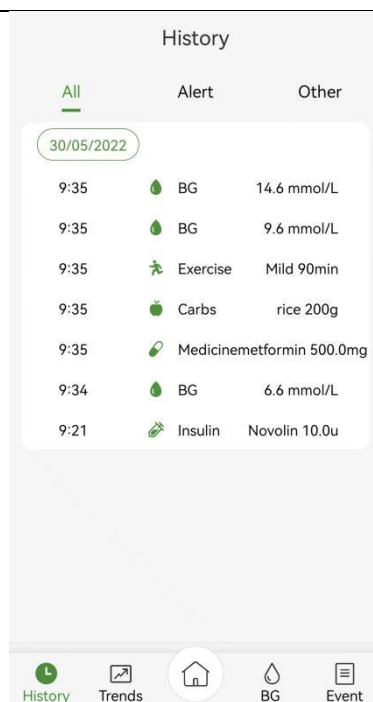
1. When "Sensor is stabilizing" or "Sensor Error Please wait ..." appears on the Home Dashboard, the user needs to wait patiently.
2. When "Replace sensor" appears on the Home Dashboard, the user needs to replace the sensor with a new one.
3. There is no need to unpair the transmitter when replacing the sensor.



3.4.2 History Dashboard

History dashboard displays glucose alert records, events, as well as glucose data in each day.

1. When the sensor blood glucose level is lower/higher than the pre-set alert value, the App will alert you every 30 minutes about your glucose levels. The alert and the time it took place is displayed in the History dashboard.
2. The events added on the “Home” screen will be displayed in the History dashboard.
3. The glucose levels recorded in the “Home” screen will be displayed in the History dashboard.
4. Click “All”, “Alerts” or “Other” to access different types of records.



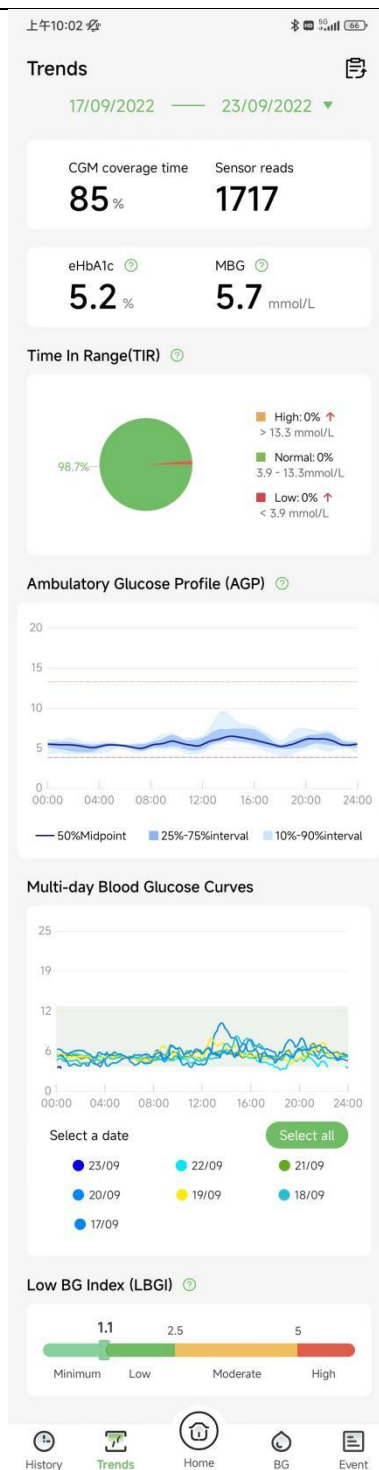
3.4.3 Trends Dashboard

The Trends dashboard displays the blood glucose analysis results, which displays the various analysis results over a certain period (Last 7 days, Last 14 Days, Last 30 Days, or your customized interval).

1. Display Estimated HbA1c, Average Glucose Value, Time in Range, AGP profile, Multi-day Bg curves and Low BG Index over a period of time.
2. Multi-day Bg curves: Users can freely select different dates to compare the daily blood glucoser curve.
3. Generate and share AGP reports.

Different periods can be switched to display.

Note: Please consult your healthcare professionals for the interpretation of the above parameters.



3.4.4 Blood Glucose (BG) Dashboard

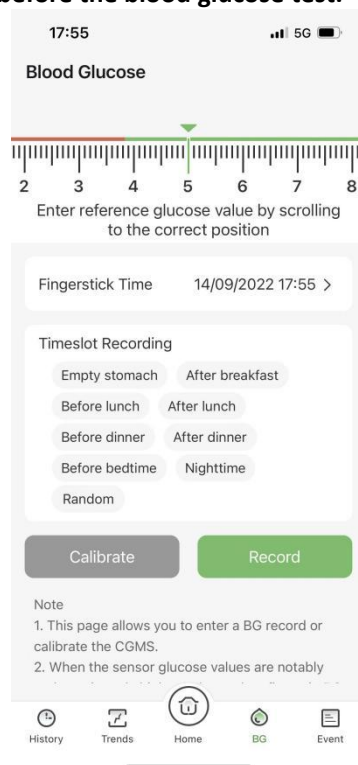
In the Blood Glucose (BG) dashboard, you can calibrate the CGMS and record the reference blood glucose level for sensor calibration.

In the Blood Glucose (BG) dashboard, there are two functions of “Calibration” and “Recording”.

1. Click “Record” to enter the glucose value measured (from CGMS, blood glucose meters or by your healthcare professionals). The record will be displayed on the Home and History dashboard.

- When the glucose value measured from other channels is different from the sensor glucose level displayed in the Home dashboard (percentage difference greater than 20%), user can manually input the calibration glucose level to calibrate the sensor. Alternatively, user can calibrate the sensor by clicking “Calibrate” in the suggested calibration automatic pop-up window.

Note: If you are pairing a new sensor, do not calibrate more than once in the first 6 hours after application. Do not calibrate the system frequently afterwards. Please calibrate only when your glucose value is stable. Do not calibrate while your blood glucose is rising or falling rapidly. The glucose value used for calibration should be the value measured no early than 5 minutes before the blood glucose test.

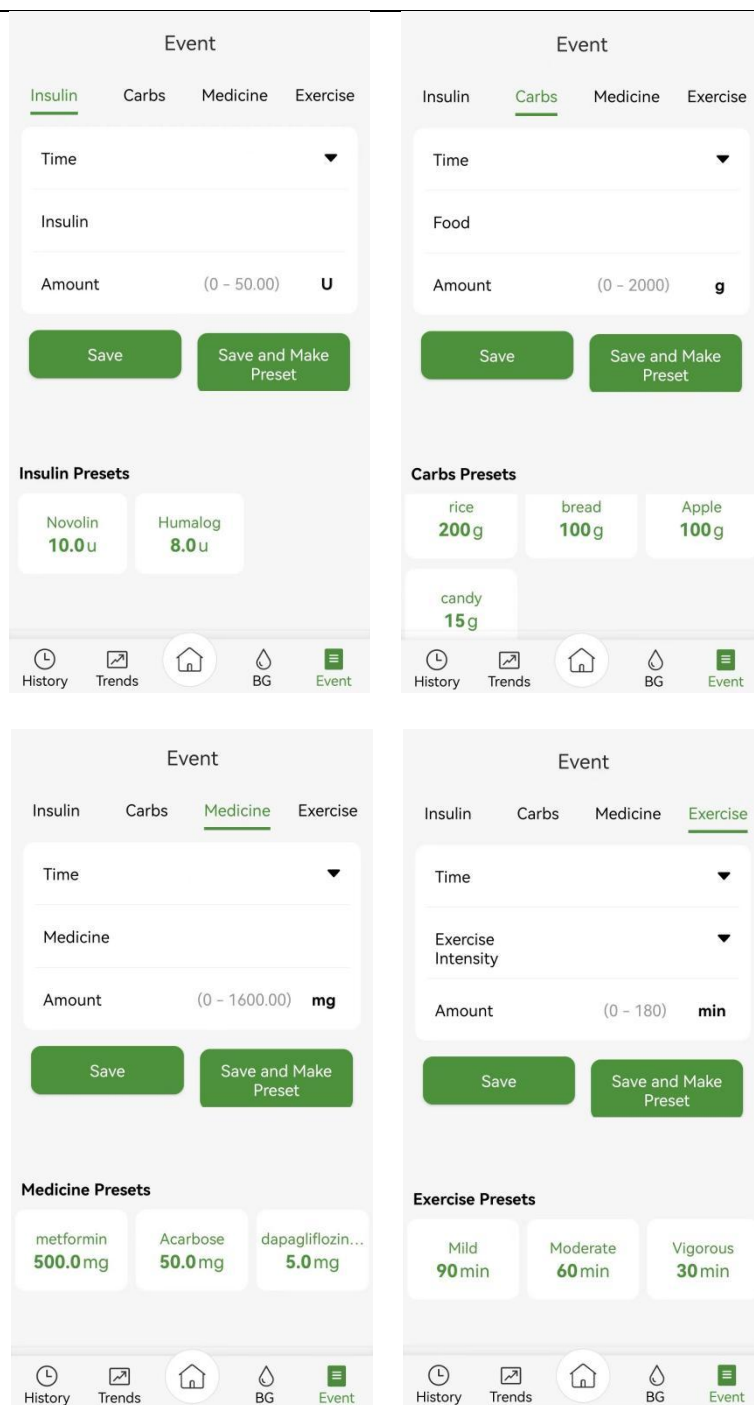


Scroll the slider to input your blood glucose test value. Once you have selected the right value, click “Calibrate” to complete the calibration.

3.4.5 Events Dashboard

The AiDEX™ CGMS system allows you to log and track events that can affect your blood glucose level.

- You can note down different types of events including “Insulin”, “Carbs”, “Medicine” and “Exercise” on the top of the Event dashboard.
- You can record the time that the event occurred.
- The added events will also be display in the History dashboard.
- You can pre-set up to 9 events for quick recording.
- The recorded events are uploaded to the Cloud Services. You can access the event history on the Cloud by using your AiDEX™ App account.



The 'Event' screen in the app has four tabs: Insulin, Carbs, Medicine, and Exercise. Each tab has a form for recording an event and a section for presets.

- Insulin Tab:**
 - Fields: Time (dropdown), Insulin (text), Amount (0 - 50.00) U.
 - Buttons: Save, Save and Make Preset.
 - Presets: Novolin 10.0u, Humalog 8.0u.
- Carbs Tab:**
 - Fields: Time (dropdown), Food (text), Amount (0 - 2000) g.
 - Buttons: Save, Save and Make Preset.
 - Presets: rice 200g, bread 100g, Apple 100g, candy 15g.
- Medicine Tab:**
 - Fields: Time (dropdown), Medicine (text), Amount (0 - 1600.00) mg.
 - Buttons: Save, Save and Make Preset.
 - Presets: metformin 500.0mg, Acarbose 50.0mg, dapagliflozin... 5.0mg.
- Exercise Tab:**
 - Fields: Time (dropdown), Exercise Intensity (dropdown), Amount (0 - 180) min.
 - Buttons: Save, Save and Make Preset.
 - Presets: Mild 90min, Moderate 60min, Vigorous 30min.

Each screen has a bottom navigation bar with icons for History, Trends, Home, BG, and Event.

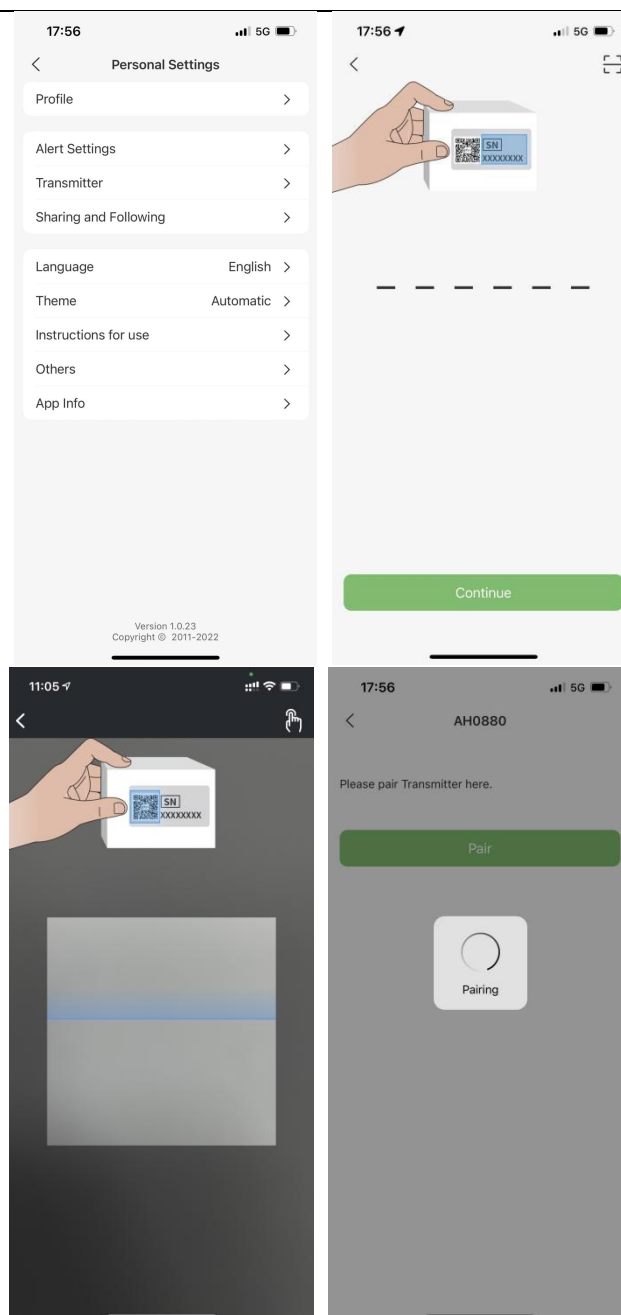
3.5 Transmitter Management

The transmitter sends your continuous glucose data to the App using Bluetooth wireless technology. You can manage your transmitter in the Home dashboard.

Home>Personal Settings>Transmitter .

3.5.1 Pairing a Transmitter

Click the “Personal Settings” icon on the top right-hand corner, then click “Transmitter”. Input the Serial Number (SN) code manually or scan the QR code on the package to pair the transmitter.

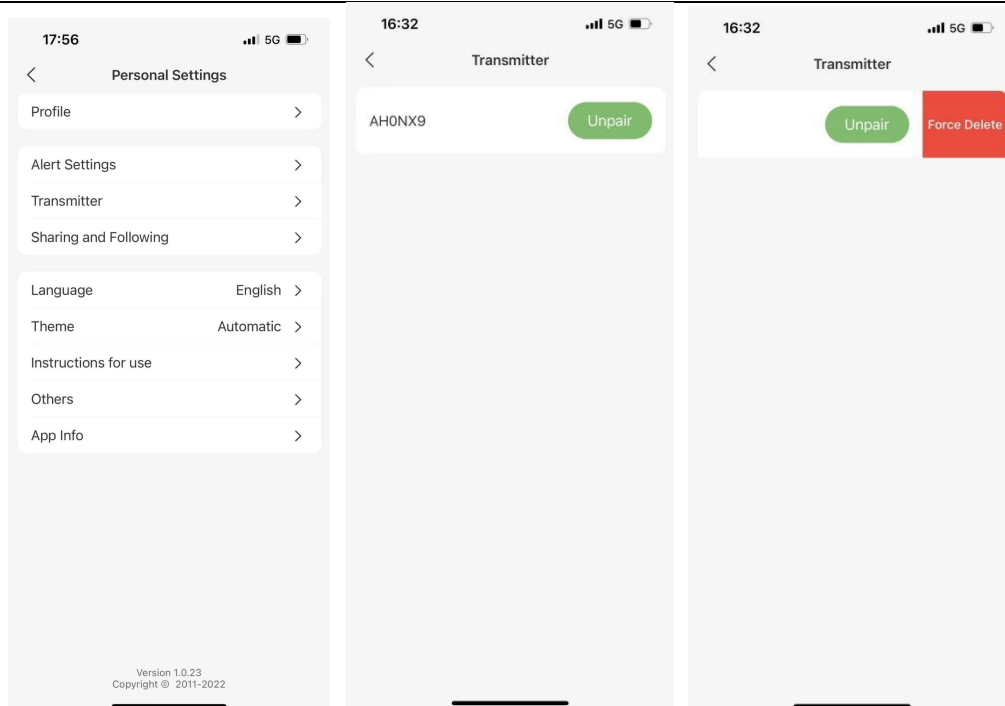


Note: Please enable the Bluetooth function in your mobile device. The communication radius between your mobile device and transmitter should be no more 2 meters without obstacle. If pairing fails, a notification box will appear. Users can choose to retry or input the serial number again. User can also choose to use the App with pairing a transmitter by skipping this step. Android 6.0 currently does not support pairing via QR code.

3.5.2 Unpairing a Transmitter

1. Click "Personal Settings" icon on the top right-hand corner of the Home dashboard.
2. Click "Transmitter"
3. Click the "Unpair" button. If unpairing fails, you can choose to delete the transmitter permanently.

Note: please make sure the App is connected with the transmitter before unpairing. If the transmitter is connected to the APP, you can delete the transmitter record permanently by clicking "Delete".



3.6 Alerts

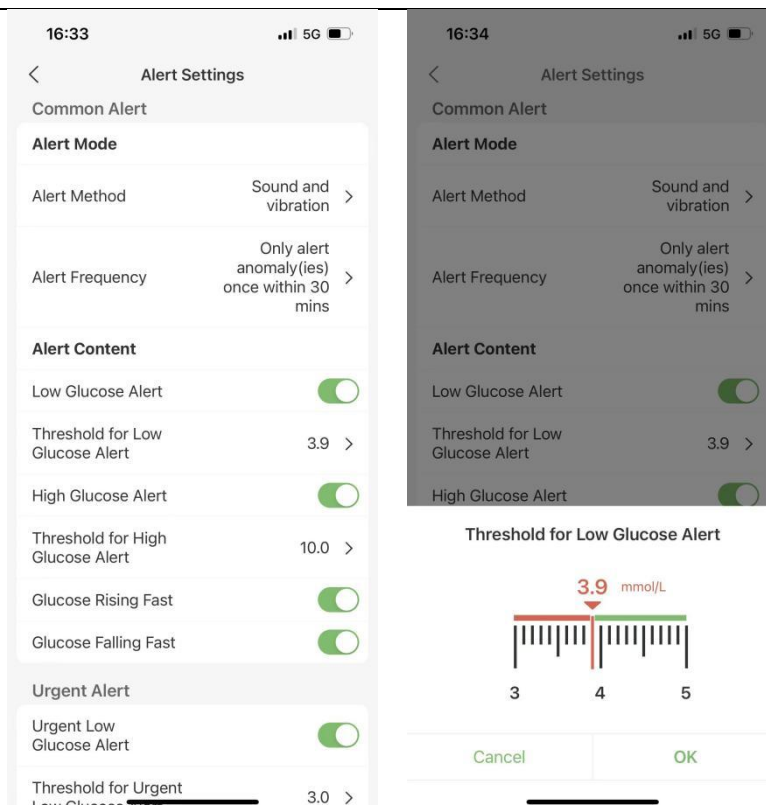
3.6.1 Alert Settings

On the Personal Settings page, click “Alert Settings” to enter the Alert Settings page.

1. You can adjust the alert method and frequency.
2. You can set the threshold for high/low blood glucose alert, and turn them on or off; When the current blood glucose level detected by the software is higher than the threshold for high blood glucose alert, the software will send a high blood glucose alert in the form of notification and dialog box. When the current blood glucose level detected by the software is lower than the threshold for low blood glucose alert, the software will send a low blood glucose alert in the form of notification and dialog box. At the same time, the record of high and low blood glucose alert will be displayed in the History section.
3. You can turn on or off the Glucose Rising/Falling Fast alert and the Transmitter Signal Lost alert. When they are turned on, the software will inform you through notifications and dialog boxes.
4. You can turn on or off the Urgent Low Glucose alert.

Notes:

1. Before setting the alerts, please make sure the AIDEX™ App is paired with the sensor and transmitter.
2. When low glucose alerts appear, please take a blood glucose test using blood glucose meter and test strips. If the test result is the consistent with the blood glucose level displayed on the App, please contact your healthcare professional for advice.
3. When high glucose alerts appear, please take a blood glucose test using blood glucose meter and test strips. If the test result is the consistent with the blood glucose level displayed on the App, please take medicine as advised by doctor or inject insulin until your blood glucose level returns to normal glucose range.
4. When the sensor glucose level on average rises more than 0.1 mmol/L per minute, alert notification appears.
5. When the sensor glucose level on average declines more than 0.1 mmol/L per minute, alert notification appears.



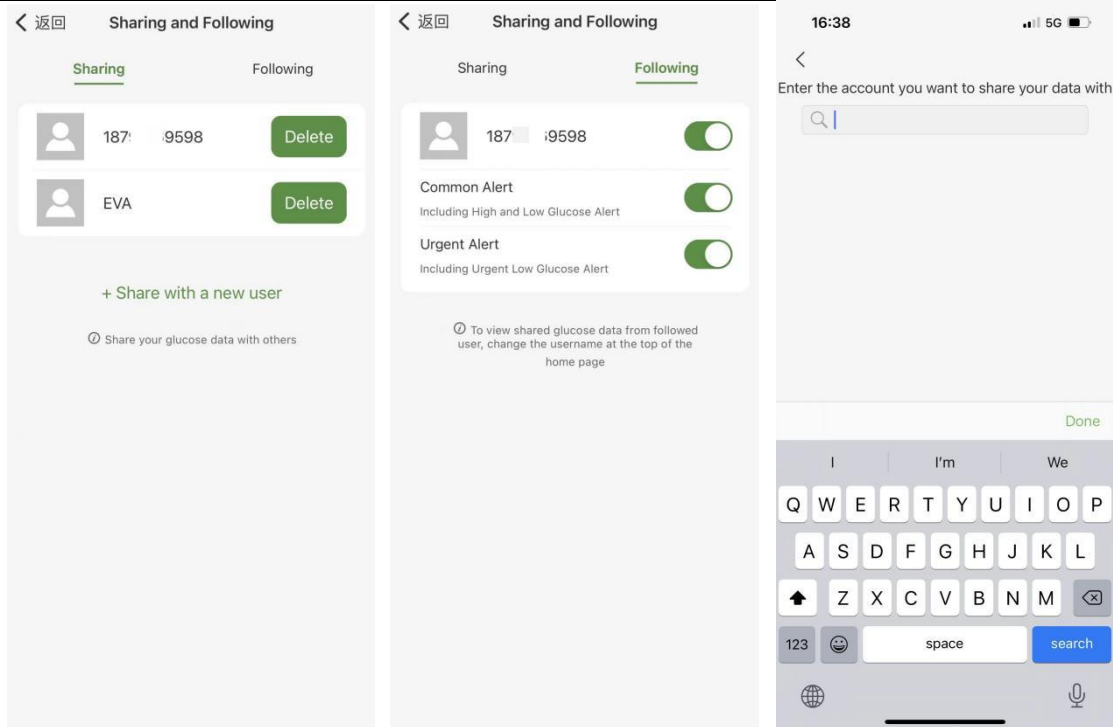
3.7 Sharing

3.7.1 Sharing Management

Click the “Personal Settings” icon on the top right-hand corner, then click “Sharing and Following” to setup glucose level data sharing.

1. Click “Share with a new user” to authorise other accounts to view your data. The authorised accounts will have access to your blood glucose data in their Home dashboard.
2. You can rename the accounts that you are “Sharing/Following”.
3. You can delete the accounts in the “Sharing” list. By doing so, you are suspending their access to your data.
4. You can remove your access to other accounts’ blood glucose data by turning of the switch.

Note: Blood glucose data is confidential information. Please think carefully before sharing your data with other accounts. Please also keep the blood glucose data shared from others confidential.

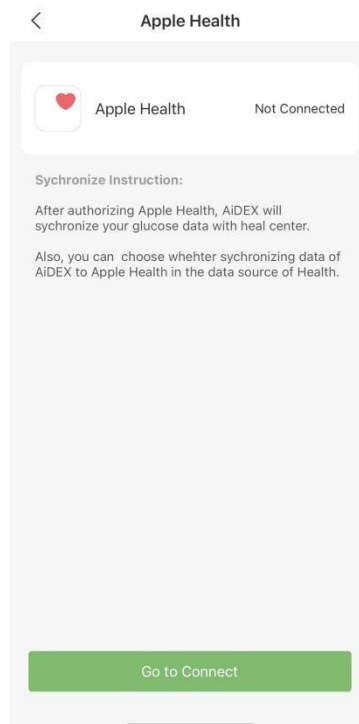


3.8 Apple Health

1. Click “Personal Settings” icon on the top right-hand corner of the Home dashboard.
2. Click “Go to Connect”

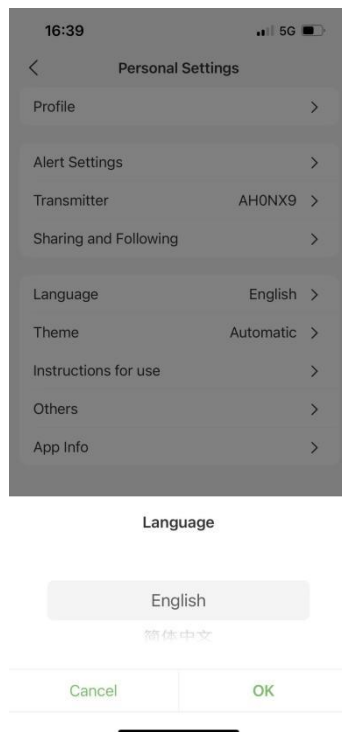
AIDEX can synchronize your glucose data with heal center.

Note: Apple Health reversed for iOS devices only.



3.9 Language

Click the “Personal Settings” icon on the top right-hand corner, then click “Language” to setup the AiDEX™ App language.



3.10 Theme

On the Personal Settings page, you can choose a light or dark style under “Theme”.

Note: Under iOS, there is an additional option “Automatic”, which allows you to follow the system’s theme.

3.11 Instructions for use

On the Personal Settings page, click “Instructions for use” to view the user guide of the software. The software only provides online viewing of the user guide, but does not contain printing function.

3.12 Others

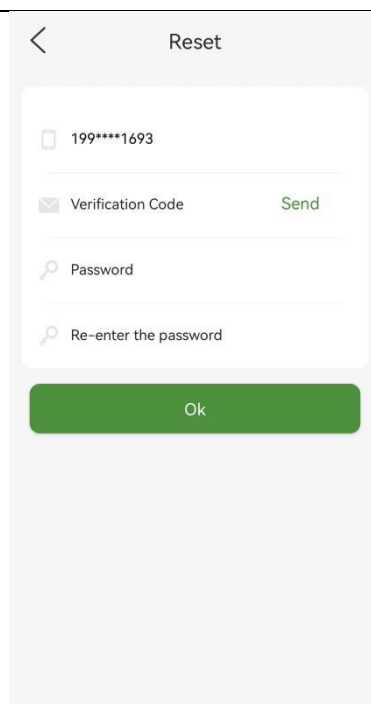
On the Personal Settings page, click “Others” to access Feedback, Reset the Password, Log Out, and Delete Account functions.

3.12.1 Feedback

Under Home > Personal Settings > Others > Feedback, you can use this function to give feedback on your user experience.

3.12.2 Reset the password

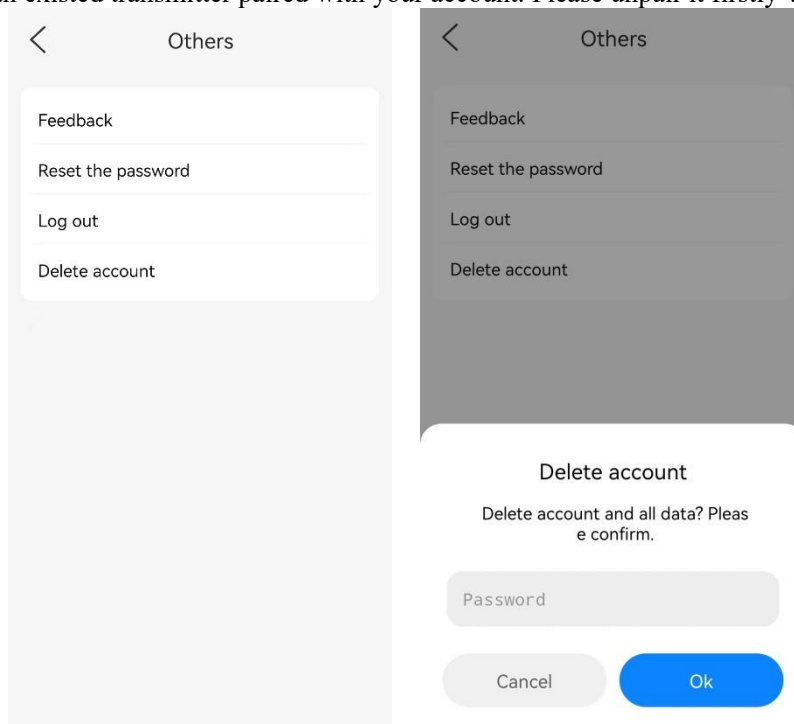
Under Home > Personal Settings > Others > Reset the password, you can reset your password of the current account.



3.12.3 Delete Account

Click “Delete account” to permanently delete your account and all your relevant data stored in the server. Enter your password, then click “OK” to delete your account and personal data.

Note: The transmitter must be unpaired before you delete your account. If there is a paired transmitter, the software will prompt "There is an existed transmitter paired with your account. Please unpair it firstly".



3.13 App Info

On the Personal Settings page, click “App Info” to display the Software Name, Software Number, Current Version, and Software Version, and provide the Version Update function.

3.13.1 Terms of Service

On the App Info page, click “Terms of Service” to view the terms of service of the software.

3.13.2 Privacy Policy

On the App Info page, click “Privacy Policy” to view the privacy policy of the software.

4. Maintenance

We pledge to continuously improve the App to improve customer experience. User feedback can be submitted to MicroTech Medical’s sales and customer services teams via customer care at bd@microtechmd.com.

5. Data Security

The data of this App is stored in AWS, and the data is backed up every day according to the backup plan. When the server or data is abnormal, the data can be restored through the data backup, ensuring that the user's data will not be lost.

The software has been strictly tested and has strong reliability. Even in the event of unforeseen circumstances, data will not be lost (the original data is saved on the device). After restarting the software, it can continue to be used, and the software data returns to the state before the abnormality. After re-reading, all unread data of the device will be read. If data reading failure occurs, you can restart the Bluetooth of the mobile terminal to re-pair the device with the software. If it still fails, give feedback to the customer service or sales personnel, and Microtech Medical Company will provide technical support.

The information stored in this App includes:

- Blood glucose information
- Personal information (e.g., name, gender, date of birth, etc.).
- Exercise patterns
- Diets
- Medicine history
- Insulin injection history

Note: It is recommended to use the protection system of your mobile phone, such as lock screen password, biometrics, to strengthen the data protection of APP.

Such information is not mandatory to be entered, and is only used to help users record their own condition and assist users in information memory and management. The data of this App is stored in AWS, and the data is protected by the specific password of the database and the security mechanism provided by the cloud service provider. The actual content of the data can only be presented by analyzing the algorithm through this software. Under the circumstance that the user's registered account and password are not leaked out, the leakage of user information will generally not be caused. At the same time, in case the user requests to delete all data in the cloud, the App has provided a “delete account” option, which can completely delete all the personal data of the user at any time.

You can clear your data stored in the cloud service by using the : “Delete account” function under Home > Personal Settings > Others > Delete account. By doing so, you can permanently delete your data stored in the Cloud and your account.

6. Troubleshooting

Data Lost

When the AiDEX™ is disconnected from the CGMS, please first check if the Bluetooth function in your mobile device has been turned on. If so, the pairing will be restored automatically. If the problem still persists, restart the App.

The AiDEX™ App can recover data after restarting. After restarting, the saved App data will be restored automatically. All the saved but not displayed data can be displayed again. If the App fails to display blood glucose data, please restart the Bluetooth and re-pair the App and the corresponding transmitter or contact MicroTech Medical.

Transmitter Signal Lost

When "Transmitter Signal Lost" notification pops up, please check if you have turned off your Bluetooth. After turning on your Bluetooth function, signal connection between the App and the transmitter will be restored automatically. If "Error" notification pops up, please restart the App. The blood glucose data is temporarily stored in the transmitter during signal lost. When connection between the App and the transmitter is restored, all relevant data will be transmitted to the App.

Fail to read data

Data reading failure can be caused by signal interference. Users are required to stay away from environments with strong electromagnetic interference or contact MicroTech Medical.

Note: When an abnormality occurs in the software, the user can click "Feedback" to upload the software log to the cloud, and the technical support staff will analyze and solve the problem.

7. Other

Do not use the APP when the Bluetooth function is turned off, in a complex Bluetooth environment or in a high electrostatic discharge environment, otherwise it will cause the data reading failure of the continuous glucose detection system. Because Bluetooth will have communication barriers in complex Bluetooth environments or high electrostatic discharge environments, users need to ensure that they stay away from complex Bluetooth environments or high electrostatic discharge environments, and ensure that the Bluetooth function is turned on. When the software retrieves data again, the system will automatically read all unread data, judge the uniqueness of the data, and ensure that the data is correct without affecting the use. No other external software or applications have been found to cause critical defects.

Any serious injury or death that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

8. Explanation of Symbols

Icon	Explanation	Icon	Explanation
	Manufacturer		European conformity
	Authorized representative in the European Union		Medical device

9. Expected Clinical Benefits

Complications of diabetes mellitus (including, but not limited to: diabetic retinopathy, diabetic nephropathy) are well documented^{*1}. Reviewing glucose monitoring device data patients with diabetes, caregivers and healthcare professionals can work to achieve and maintain specific glycaemic goals.

Given the results of the Diabetes Control and Complications Trial (DCCT)^{*2} and other studies, there is broad consensus on the health benefits of normal or near-normal blood glucose levels and on the importance, especially in insulin-treated patients, of glucose monitoring devices in treatment efforts designed to achieve these glycaemic goals. Based principally on the DCCT results, experts recommend that most individuals with diabetes should attempt to achieve and maintain glucose levels as close to normal as is safely possible. In addition, there is prevailing agreement that dense glucose data collection using continuous glucose monitoring (CGM) devices supports informed treatment and therapy decisions as it allows assessment of glucose variability and hyper- and/or hypoglycaemic risk^{*3}. This data is more actionable for HCPs than solely using A1c (glycated haemoglobin) information for patient care decisions. CGM and its associated dense glucose data is useful in supporting HCPs in the identification of dysglycaemia in other patient groups without diabetes (for example, pre-diabetes ^{*4}).

*1 Textbook of Diabetes, Volumes 1 & 2; Pickup and Williams, 1999.

*2 Diabetes Control and Complications Trial Research Group (DCCT): The effect of intensive treatment of diabetes on the development and progression of long term complications in insulin dependent diabetes mellitus. New Engl J Med, 329: 977-86; 1993.

*3 International Consensus Report - Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations From the International Consensus on Time in Range. Diabetes Care 2019 Aug; 42(8): 1593-1603.

*4 Continuous glucose monitoring is more sensitive than HbA1c and fasting glucose in detecting dysglycaemia in a Spanish population without diabetes. Diabetes Practice 142 (2018) 100-109.



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文件更改履历

修改后的版本号 及修订号	更改人	更改概述	更改日期
V1	王晓峰	文件新编	2021. 11. 19
V2	王晓峰	1、增加更换传感器的逻辑。 2、增加“关于”，提供软件名称、软件型号、发布版本号、软件版本号、检测版本功能，移动隐私协议和使用条款展示位置。 3、增加自动确认新传感器的逻辑。 4、增加风格设置。 5、趋势模块优化，根据周期生成 AGP 报告。 6、优化注销账户功能。	2022. 1. 13
V3	王晓峰	1、优化提醒设置，增加提醒频率，提醒方式等设置。 2、优化分享功能，支持开启或关闭提醒；支持删除；支持实时展示数据。 3、事件和指血记录允许删除。	2022. 5. 24
V4	谢锦	1、增加多日血糖曲线 2、趋势算法优化 3、高低血糖默认阈值和设置范围优化 4、增加语言	2022. 9. 23
V5	谢锦	1、事件模块更新 2、历史模块更新	2023. 3. 10
V6	谢锦	1、血糖数据接入 Apple health	2023. 5. 8