ACCU·CHEK®
SmartGuide

USER'S MANUAL

ACCU-CHEK SMARTGUIDE APP

Contents

1 About This User's Manual

To help you get familiar with all the functions of the app, read the instructions carefully. If the app doesn't work as you expect, see the troubleshooting section of this User's Manual. If you still can't find what you are looking for, contact customer support.

This User's Manual highlights the following information in a special way:

⚠ WARNING

A ⚠ **WARNING** indicates a foreseeable serious hazard.

⚠ PRECAUTION

A ⚠ **PRECAUTION** describes a measure you should take to use the product safely and effectively or to prevent damage to the product.

NOTE

A NOTE contains helpful information and tips.

This User's Manual contains all the information, instructions, and technical data you need to use the app and the sensor. For information and instructions on applying the sensor using the sensor applicator, refer to the package insert provided with the Accu-Chek SmartGuide device.

2 Product Information

2.1 Intended Use

The continuous glucose monitoring app (CGM app) is intended for continuous display and read-out of real-time glucose values from a connected device sensor.

2.2 Intended Users

⚠ PRECAUTION

Risk of various harms
If you are not an intended user, proper and safe operation of the application can't be guaranteed.

- Adults, 18 years of age and older
- People with diabetes mellitus
- Caregivers of people with diabetes mellitus

2.3 Indications, Contraindications, and Limitations

Indications

The app is indicated for people with diabetes mellitus (or their caregivers) using the Accu-Chek SmartGuide device.

Contraindications

There are no known contraindications.

Limitations

App

- The app communicates with the sensor via *Bluetooth*® Low Energy technology. Devices supporting Bluetooth Low Energy versions prior to version 5.0 might not be compatible.
- The user will only receive alarms if the sensor is connected to the app and notifications are activated by the user.
- The app is not designed for use by persons who can't read information displayed on a mobile device.
- The app doesn't provide medical advice.
- The app notifies you about alarms primarily through sound. In addition, other notification methods can be used, for example, tactile or visual notifications. If you are hard of hearing or deaf, awareness of notifications may be limited. In such cases, only use the notification method for alarms that is appropriate for you.
- The notification of alarms can't be guaranteed in all cases, due to limitations of the alarm system. **Don't** rely solely on alarms. Otherwise, you can miss severe low blood glucose and/or high blood glucose.
  Open the app on a regular basis to check your glucose levels according to the instructions of your healthcare professional or if you feel that your glucose level may be low or high. Never ignore symptoms of low or high blood glucose.
- The app issues alarms based on CGM values provided by the sensor. If the sensor is in Trend Mode, CGM values may be less accurate. As a result, alarms may be issued even when your true glucose value is normal. It is also possible that no alarms are issued even when your true glucose value is high or low.
- The app displays CGM values provided by the sensor. If the sensor is in Trend Mode, these CGM values may be less accurate. Follow the instructions for use provided with the sensor.

Sensor

- Interstitial fluid glucose levels measured by the sensor may not reflect the actual blood glucose level. This can happen during rapid decreases or increases in glucose levels in the body. The interstitial fluid glucose levels may be higher or lower than the actual blood glucose levels. Such periods can be detected by viewing the Trend arrows and Home graph on the Home screen of the app. In these cases, you must base therapy decisions, such as insulin dosing, on additional blood glucose results obtained with a blood glucose meter.
- If a CGM value doesn't match your symptoms, the value should be verified by a blood glucose test using a blood glucose meter.
- The sensor should only be applied at the indicated application site on the upper arm. Otherwise, the safety of the patient and the accuracy of the CGM data can't be guaranteed.
- The sensor can send information to a mobile device within a range of 6 meters (20 feet) (line of sight). The actual range might be reduced depending on the mobile device and your environment (e.g. other nearby devices).
- Only use CGM values to make therapy decisions, such as insulin dosing, after you have calibrated your sensor as requested by the app. See chapter *Calibrating Your Sensor*.
- Taking interfering substances may falsely raise CGM values, which could cause you to miss severe hypoglycemia. If you are taking any of the listed interfering substances, consult with your healthcare professional. See chapter *Technical Data of the Accu-Chek SmartGuide Device* for a list of interfering substances.

2.4 Main Features

Real-Time CGM Values

Access real-time CGM values directly on your mobile device or on your Apple Watch. Use the app connected to the sensor that you have applied to your upper arm. The app communicates with the sensor via Bluetooth Low Energy. Every 5 minutes, the sensor sends a CGM value to the app. Each sensor has a wear time up to 14 days and requires calibration, using a blood glucose meter, in order to use CGM values to make therapy decisions, such as insulin dosing. After 14 days, you must remove the sensor. Replace the sensor with a new one.

Home Screen

The home screen displays important information to help you manage your diabetes, such as your current glucose values and trends. A snapshot of your latest logbook entries allows you to keep track of recent insulin injections, carbohydrate intake, or personal notes. This information can help you take the necessary action to optimize your glucose control, and make better therapy decisions, such as insulin dosing.

Graphs and Statistics

Reviewing your historical glucose values may help you identify patterns or factors that influence your glucose control. This allows you to identify potential areas for improvement.

- The Trend Graph presents your glucose values and logbook activities for the past 6, 12, and 24 hours.
- The Time in Ranges graph has 5 ranges, and provides a summary of the percentage of time your glucose values stayed within these ranges (including your personal target range) over the last 7, 14, and 28 days. The ranges are personalized according to the settings you make in the therapy settings of the app.
- The glucose management indicator (GMI) estimates the expected laboratory HbA1c level. The HbA1c level provides information about your average glucose levels over a longer period of time.

Alarms

When alarms are turned on, you receive an alarm when your glucose value falls below or exceeds your defined limits. You receive a very low glucose alarm when your glucose value falls below 54 mg/dL (3.0 mmol/L). The app prompts you to take the necessary action as recommended by your healthcare professional. You can turn off these alarms if you don't want to receive alarms.

Customizable Settings

Meet your personal needs and preferences through customizable settings. Adjust the target range, alarm limits for very high glucose and low glucose, reminders, and more.

App

⚠ WARNING

Risk of wrong therapy decisions
Don't estimate or make assumptions of any missing CGM data. Estimating or assuming any missing CGM data can lead to wrong therapy decisions, such as insulin dosing.

In case of missing CGM data, make sure that your app is set up correctly and your sensor and mobile device are connected. For more information on setting up the app and your sensor correctly, see chapter *Getting Started*. If you aren't sure whether the app or the sensor is working properly, use an alternative method for testing your glucose and contact customer support.

⚠ WARNING

Risk of serious harm
Modification of components or failure to follow the instructions for use may prevent the app from working as intended.

Carefully read and follow the instructions for use.

⚠ PRECAUTION

Risk of serious harm
Changes to your diabetes management or overall therapy may only be made by healthcare professionals.

If you have questions about your therapy, consult your healthcare professional.

⚠ PRECAUTION

Risk of unavailable CGM data
The app may not always be able to display glucose values. Here are two examples:

- If the battery of your mobile device is dead.
- If you lose your mobile device.

Make sure you have access to alternative methods for testing your glucose.

⚠ PRECAUTION

Risk of incorrect calibration values
For example, children or others might accidentally add calibration values. Incorrect calibration values can negatively affect the CGM data provided by the sensor. Follow the instructions for data protection to prevent third parties from gaining access to the app. See section *Access Protection*.

⚠ PRECAUTION

Risk of serious harm
Mobile devices aren't dedicated medical devices. Only use mobile devices compatible with the app. See chapter *Technical Data of the Accu-Chek SmartGuide App*. Don't operate the app on mobile devices that aren't compatible or have been manipulated. If in doubt, contact the manufacturer of your mobile device.

⚠ PRECAUTION

Risk of wrong therapy decisions
Always have alternative methods for testing your glucose available. If you lose your mobile device or in case of a system malfunction, switch to an alternative method for testing your glucose.

For information on environmental conditions of your mobile device, refer to the User's Manual of your mobile device or the operating system (OS) of your mobile device.

Anybody connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible for ensuring that the system complies with the requirements for medical electrical systems.

Your mobile device has to comply with the respective IEC or ISO standards (for example, IEC 60950 or IEC 62368). Configurations shall comply with the requirements for medical electrical systems (see clause 16 of the latest valid version of IEC 60601-1). If in doubt, contact the manufacturer of your mobile device.

The app is intended for single-person use only.

Check your mobile device settings before using the app. The app requires sound to properly signal important information. Otherwise, the information can be missed.

Using font sizes other than the default font size for a device may result in the app not working as intended.

Sensor

Take particular note of all safety information in the package insert provided with the device.

⚠ PRECAUTION

Risk of serious harm
Only make therapy decisions, such as insulin dosing, based on multiple current glucose values and the resulting glucose trends. Glucose values displayed by the app may not always be accurate. Always check the app's trend graph prior to making therapy decisions, such as insulin dosing. Also consider your current health condition and physical activity levels when making therapy decisions, such as insulin dosing.

Don't ignore symptoms of hypoglycemia or hyperglycemia. Don't make significant changes to your therapy by yourself. If your displayed glucose value doesn't match how you feel:

1 Switch to an alternative method for testing your glucose.
2 If your symptoms still don't match your glucose value, consult your healthcare professional.

For more information, see section *General Troubleshooting*.

⚠ PRECAUTION

Risk of serious harm
A damaged sensor may not work properly.

If the sensor is exposed to an impact, for example, if it was hit by a ball, visually inspect the sensor for damages. If you notice anything unusual, remove the sensor and apply a new one.

⚠ PRECAUTION

Risk of serious harm
Operate your mobile device only as advised by the manufacturer (for example, don't use a damaged or manipulated device). If in doubt, contact the manufacturer of your mobile device.

Make sure you don't miss episodes of low or very high glucose. Open the app on a regular basis to check your glucose levels according to the instructions of your healthcare professional, or if you feel that your glucose level may be low or high. Never ignore symptoms of low or high blood glucose.

Follow your regular hygiene routine, but avoid excessive contact of soap and shampoo with the sensor. Use only the minimum amount of soap to keep the sensor clean.

Don't apply skin care and hygienic products to the sensor or the application site (insect repellent, sunscreen, etc.). These products may damage the sensor or the adhesive pad.

Your body may react to the sensor or the adhesive pad. Inspect the application site regularly for skin irritation or inflammation. If in doubt, or if the application site becomes inflamed or if localized skin reactions (for example, allergic reaction, eczema) occur, remove the sensor immediately and consult your healthcare professional.

If the outer edges of the adhesive pad lift slightly from the skin, the sensor will still function properly. However, if any part of the adhesive pad underneath the sensor lifts from the skin, don't attempt to reapply the sensor or tape the sensor to the skin. A reapplied sensor may not function properly. Apply a new sensor instead.

If the sensor falls off, don't apply the used sensor again. A reapplied sensor may not function properly. Apply a new sensor instead.

Certain pharmacological substances and medications may interfere with the accuracy of the sensor. If in doubt, consult your healthcare professional.

4 Using the App

4.1 Prerequisites for Using the App

Required Supplies

- You need an Accu-Chek SmartGuide device consisting of an applicator and a sensor. Take particular note of all safety information in the package insert provided with the device.
- You need a mobile device with an iOS or Android OS to run the app. For more information on compatible mobile devices, tap **https://tools.accu-chek.com/documents/dms/index.html**.

Required Accounts

- You need an Apple ID to download the app on iOS devices.
- You need a Google account to download the app on Android devices.
- You need an Accu-Chek Account to set up the app.
- You need a personal email address to create an Accu-Chek Account.

System Requirements

You may only use the app if the system requirements are met.
Tap **https://tools.accu-chek.com/documents/dms/index.html** to see the system requirements.

Before you update your mobile device to a newer OS version, make sure that the app is compatible with the new OS version. If in doubt, check the list of compatible devices: **https://tools.accu-chek.com/documents/dms/index.html**. If you still need assistance, contact customer support.

4.2 Installing and Uninstalling the App

Installing the App

When using your mobile device with the app, your mobile device becomes part of a medical system. See chapter *General Safety Information*.

You don't need any special knowledge for installing the app.

1 Scan the QR code on the Accu-Chek SmartGuide device packaging with the camera app of your mobile device. If you can't scan the QR code, go to *https://go.roche.com/smartguideapp*.

✓ You are redirected to the appropriate download page for your mobile device.

2 Install the app following the instructions of your mobile device.

✓ You installed the app on your mobile device.

Uninstalling the App

NOTE

When uninstalling the app, all CGM data that was collected by the app will be deleted.

Note that your CGM data is always sent to your Accu-Chek Account while using the app.

iOS devices

1 Tap and hold the app icon.

2 Tap **Remove App**.

3 Tap **Delete App**, then tap **Delete** to confirm.

✓ You uninstalled the app.

Android devices

1. Tap **Play Store**.
2. Tap the profile icon in the upper right corner.
3. Tap **Manage apps & devices** > **Manage**.
4. Tap the app icon.
5. Tap **Uninstall**.

✓ You uninstalled the app.

4.3 Starting and Shutting Down the App

Starting the App

Tap the app icon on your mobile device to start the app.

NOTE

Android devices display an app notification in the notification bar as long as the app is running.

Shutting down the app

Shutting down the app is **not recommended**. If you shut down the app, the app no longer receives glucose values from your sensor.

If you need to shut down the app, proceed as follows:

1. Start by viewing all running apps on your mobile device.
2. Swipe the app off the screen to shut down the app.

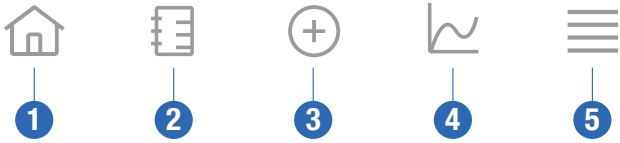
✓ The app shuts down.

4.4 Navigation Elements

The following navigation elements are displayed in the upper part of the screen.

- Tap < to return to the previous screen.
- Tap ✕ to close a screen.

The following navigation elements are displayed in the lower part of the screen.



1 **Home** icon: Tap to access the Home screen.
2 **Logbook** icon: Tap to access the logbook and browse existing logbook entries.
3 **Add Entry** icon: Tap to add a new entry to your logbook.
4 **Graphs** icon: Tap to access the graphs and statistics for your CGM data.
5 **Menu** icon: Tap to access additional menu options, such as sensor settings, therapy settings, or app settings.

When you start the app for the first time, the app guides you through the following configuration process.

Step 1 of 5

Sign in with your Accu-Chek Account or create a new account.

For more information on your Accu-Chek Account, see chapter *"Accu-Chek Account"*.

Step 2 of 5

The units of measurement for glucose values and carbohydrates are preselected by the app. The preselected units of measurement depend on the country you select during account creation. **Ask your healthcare professional about your units of measurement before changing them in the app.**

Choose the same unit of measurement that your blood glucose meter uses for glucose values. You can choose from the following values:

- **mg/dL**
- **mmol/L**

Select the unit of measurement that you use for carbohydrate counting. You can choose from the following values:

- **g (grams)**
- **BE (bread unit, 1 BE equals 12 g)**
- **KE (carbohydrate unit, 1 KE equals 10 g)**
- **CC (carbohydrate choice, 1 CC equals 15 g)**

NOTE

You can select the units of measurement **only once**.

If you selected the wrong unit of measurement by mistake, you need to uninstall and reinstall the app. If you then start the app again, you can reselect the unit of measurement.

Tap **Next** to proceed.

Step 3 of 5

Enter the upper and lower values for your target range. These values are used for graphs and statistics.

The target range is the range in which your glucose values should be. In the app graphs, the target range is displayed as a green area.

The target range may vary for each individual. Discuss your individual target range settings with your healthcare professional.

NOTE

Target range values don't trigger alarms or notifications.

Default target range values

Upper target value	Lower target value
180 mg/dL or 10.0 mmol/L	70 mg/dL or 3.9 mmol/L

Tap **Next** to proceed.

Step 4 of 5

Enter your limits for very high glucose and low glucose alarms. The app can warn you if your glucose values go too high or too low. All glucose alarms are active by default, but you can turn them off from the app Menu.

Default glucose alarms

Very high glucose alarm	Low glucose alarm
250 mg/dL or 13.9 mmol/L	70 mg/dL or 3.9 mmol/L

For your safety, the very low glucose limit can't be edited. The very low glucose limit is 54 mg/dL or 3.0 mmol/L.

Tap **Next** to proceed.

Step 5 of 5

All glucose alarms are active by default, but you can turn them off from the app Menu. To make sure that you receive glucose values and notifications, be familiar with how your mobile device operates, and regularly check its settings:

- CGM app is running.
- App notifications are ON.
- Power saving modes are OFF.
- Volume is loud.
- Ringer is ON.
- Do Not Disturb or Focus is OFF.
- Airplane Mode is OFF.
- Bluetooth service is ON.
- Your mobile device is near you.

For more information on how to configure your mobile device correctly, see chapter *Configuring Your Mobile Device*.

Tap **I Understand** to proceed.

iOS Devices

If you are using an iOS device, you will be asked if the app is allowed to issue notifications. If the app isn't allowed to issue notifications, all notifications and alarms of the app will be blocked.

▶ Tap **Allow**.

You will be asked if the app is allowed to issue Critical Alerts. The Critical Alerts feature impacts the sound for alarms if your ringer is turned off. If the app isn't allowed to issue Critical Alerts, all notifications and alarms of the app will be muted when you turn on Do Not Disturb or Focus on your mobile device.

1. Tap **Next**.
2. Tap **Allow**.

If required, you can change these settings later on. For more information, see chapter *Configuring Your Mobile Device*.

Android Devices

If you are using an Android device, you may be asked if the app is allowed to send you notifications. If the app isn't allowed to send you notifications, you will not be able to override Do Not Disturb.

▶ Tap **Allow**.

You will be asked if the app is allowed to run in the background. If the app isn't allowed to run in the background, you may not receive glucose values, notifications, or alarms.

▶ Tap **Allow**.

You will be asked if the app is allowed to override Do Not Disturb. If the app isn't allowed to override Do Not Disturb, all notifications and alarms of the app will be muted when you turn on Do Not Disturb on your mobile device.

1. Tap **Next**.
2. Turn on **Do Not Disturb Override**.

This setting may vary, depending on the OS version and manufacturer of your mobile device. For more information, see the User's Manual of your mobile device.

If required, you can change these settings later on. For more information, see chapter *Configuring Your Mobile Device*.

6.1 General Requirements

Mobile Device Care

Communication with your sensor may increase the battery usage of your mobile device. Make sure you have means to charge your mobile device with you.

Frequent connection loss between the sensor and app may decrease the battery life of the sensor. Keep your sensor and mobile device close together.

Don't use the app on a mobile device with a cracked or damaged display. If the display is cracked or damaged, you may not be able to see everything that's displayed. Use the app only on a properly functioning mobile device.

Only use the app on mobile devices that you trust. A malicious device may be able to read and send data between the CGM app and sensor. A malicious device may also negatively affect the CGM app.

Only run applications from trusted sources on the same mobile device. Only grant Bluetooth permissions to trusted applications, as a malicious app may be able to read and send data between the CGM app and sensor.

Don't use the CGM app on a mobile device that has been jailbroken or rooted. Don't use the CGM app on a mobile device that is in debug or developer mode. These conditions can make your mobile device less secure.

6.2 Access Protection

Data Protection

Protect your app data from unknown access or misuse. Use the security functions available on your mobile device or in the OS, for example, password protection.

All of your diabetes data is also encrypted and secured in your Accu-Chek Account in the cloud of Roche Diabetes Care.

Mobile Device Protection

Anyone with access to the app can enter calibration values for your sensor and manipulate the logbook or app settings. Incorrect calibration values can negatively affect the accuracy of the sensor.

Protect the app against third-party access. Allow access only to trusted caregivers.

- Don't lend your mobile device to others, including children.
- Set a screen lock in the security settings of your mobile device.
- Configure the screen lock to automatically lock your mobile device after a certain period of inactivity.

Account Protection

Keep your Accu-Chek Account information private. Don't share your account with others unless they are your caregivers.

If you switch mobile devices, or stop using your mobile device for another reason, sign out of your Accu-Chek Account.

If you need to lend your mobile device to a person other than your trusted caregiver, sign out of your Accu-Chek Account. However, try to avoid such situations. If you sign out, you will stop receiving alarms, notifications, and data from your sensor. For more information, see section *Signing Out*.

Protect your mobile device from changes to your apps and OS. Make sure that a password is required for installations from the app store (for example, App Store or Google Play).

For information on changing the password settings of your Apple or Google account, see the instructions for your download platform.

To change password settings for your Accu-Chek Account, go to **Menu** > **Account** > **Manage Account**.

6.3 Notification Settings

Certain OS settings can affect the output of notifications and alarms. Therefore, it is important that you check these settings on your mobile device at regular intervals.

If you connect other devices to your mobile device in addition to a sensor, for example, an Apple Watch, this may affect the notification and alarm settings. First, familiarize yourself with other connected devices and verify that the notification and alarm settings described in this User's Manual are not affected.

The app must always be running in order to properly output information signals and alarms. The behavior of the app depends on whether the app is running in the foreground or in the background. When the app is open and you are using it to analyze your data, the app runs in the foreground. When the app is running in the foreground, all information signals and alarms are displayed on the screen of your mobile device and no sound or vibration is issued. When the app is running in the background, it uses the OS notifications to issue information signals and alerts. It is sufficient for the app to run in the background when you are using another app on your mobile device. Notifications will behave according to your notification settings for the app. Vibration, sound, and visualization of information signals and alarms are influenced by your notification settings.

You, your caregivers, or others authorized to use the app must be familiar with the settings for receiving notifications and alarms.

NOTE

Some settings and related icons may vary, depending on the OS version and manufacturer of your mobile device.

For more information on these settings, and to familiarize yourself with their related icons, see the User's Manual of your mobile device.

App Notification Settings

If the app isn't allowed to issue notifications, all notifications and alarms of the app will be blocked.

- To make sure that the app can issue notifications and alarms, turn on app notifications for the app in the system settings of your mobile device.
- For more information on how to do this, see the User's Manual of your mobile device.

Certain events can impact notifications and alarms; for example, if you accidentally drop your mobile device or your sensor. Regularly check the functionality of your mobile device, sensor, and OS. In addition, check the notification settings of your OS on a regular basis.

Do Not Disturb and Focus

If Do Not Disturb or Focus is turned on, app notifications and alarms are muted while your mobile device is locked. If Do Not Disturb or Focus is turned on, this will be indicated in the status bar.

- To make sure that you receive app notifications and alarms when Focus (iOS) or Do Not Disturb (Android) is turned on, enable Critical Alerts or Do Not Disturb Override.
- You can also add the Accu-Chek SmartGuide app to the list of allowed app notifications.
- These settings and related icons may vary, depending on the OS version and manufacturer of your mobile device. For more information, see the User's Manual of your mobile device.

Volume

Having the volume set too low can prevent you from hearing the notifications and alarms of the app. Depending on the OS version and mobile device, there may be separate settings and icons for ringtone volume and notification volume.

Some Android devices only display a mute icon if the ringtone volume is set to 0, but not if the volume of the notifications is set to 0. For such devices, no mute icon is displayed even though the alarms may not be audible.

- Set the volume in such a way that you hear all notifications and alarms.
- Some mobile devices allow you to set different volume levels. You can set the volume level above the ambient noise level, for example, if the surrounding area is too noisy. Make sure you can hear notifications in the area you are in.
- These settings and related icons may vary, depending on the OS version and manufacturer of your mobile device. For more information, see the User's Manual of your mobile device.

Bluetooth Wireless Technology

If communication via Bluetooth wireless technology is turned off, the app is unable to communicate with your sensor. Usually, the icon is grayed out when communication via Bluetooth wireless technology is turned off. This icon may vary, depending on the OS version and manufacturer of your mobile device.

- To make sure the app is able to communicate with your sensor, check that Bluetooth wireless technology is turned on.
- This setting and related icon may vary, depending on the OS version and manufacturer of your mobile device. For more information, see the User's Manual of your mobile device.

Airplane Mode

If airplane mode is turned on, Bluetooth is turned off automatically, and the app is unable to communicate with your sensor. If Airplane Mode is turned on, this will be indicated in the status bar.

- To make sure the app is able to communicate with your sensor even when airplane mode is turned on, turn Bluetooth back on.
- This setting and related icon may vary, depending on the OS version and manufacturer of your mobile device. For more information, see the User's Manual of your mobile device.

Power Saving

If power saving is turned on, some background processes are disabled to save battery life on your mobile device. If power saving is turned on, this will be indicated in the status bar. Power saving also affects the communication with your sensor.

NOTE

Some mobile device manufacturers disable background processes even when power saving is turned off.

- To make sure the app is able to communicate with your sensor, turn off power saving.
- This setting and related icon may vary, depending on the OS version and manufacturer of your mobile device. For more information, see the User's Manual of your mobile device.

Accessories

Accessories that are connected to your mobile device may influence the output of notifications and alarms. For example, in the following cases:

- **If headphones are still connected to your mobile device and you are no longer wearing them, you may no longer hear notifications and alarms.**
- **After connecting a smartwatch, your settings might be changed.**

When using accessories, such as headphones, speakers, or a smartwatch, make sure that you are still aware of **alarms and notifications** that are issued by the app.

You must pair your sensor to your mobile device. Otherwise, the app can't receive glucose values from your sensor.

Only pair the sensor in a secure, trusted area. This may reduce the risk of other people connecting to your sensor.

Before you start pairing your sensor, get the serial number and 6-digit PIN from the bottom label of the blue twist cap.

- Find the 6-digit PIN of your sensor next to the word PIN.
- Find the serial number of your sensor next to the SN icon.

Pairing is also possible if you have already paired a sensor and it is still currently active. When you pair a new sensor, your current sensor expires.

The numbers shown here only serve as examples.

How to Pair Your Sensor

You can start pairing a new sensor in 3 different ways:

- If you have never paired a sensor with the app, the app will automatically display the option to pair a new sensor.
- If your sensor expires, the app will automatically display the option to pair a new sensor.
- If you would like to pair a new sensor manually before the current sensor expires, tap **Menu** > **Manage CGM Sensor** > **Pair New Sensor**.

1. Make sure that you have turned on communication via Bluetooth wireless technology on your mobile device.
2. Tap **Pair Now** if it is your first sensor. Or tap **Pair New Sensor** when replacing the sensor.
3. Apply your sensor to your body. If you need help, tap **View Tutorial**.
4. Tap **Next**.
5. Tap **Search** to look for your sensor.

✓ The app displays all nearby sensors, but usually only 1 sensor will be found.

6. Select the sensor that matches the serial number on the bottom label of the blue twist cap.
7. Get your 6-digit PIN from the bottom label of the blue twist cap.

8 Tap **Next**.

✓ A request for pairing via Bluetooth wireless technology is displayed.

9 Enter your 6-digit PIN from the bottom label of the blue twist cap.

NOTE

- Make sure you correctly enter the PIN.
- The PIN has exactly 6 digits. Make sure you don't enter some other number (like the serial number).
- The PIN will never be 000000 or 123456.
- After selecting your sensor's serial number, do each step quickly. If you pause or delay, you may run out of time to enter the PIN.

10 Tap **Pair** to confirm the pairing request.

11 Tap **OK**.

NOTE

Once inserted, the sensor must be active for a certain period before CGM values are displayed, and calibration is possible. This is called warm-up time.

✓ Your sensor is now paired with the app. After applying a new sensor, the sensor needs a 1 hour warm-up time. During this period, no glucose values are displayed in the app. Have an alternative method for testing your glucose available. The app requires calibration by the user in order to display glucose values that can be used to make therapy decisions, such as insulin dosing.

If the app doesn't find your sensor, see section *General Troubleshooting*.

Save the 6-digit PIN in a secure location to prevent another person from accessing it. Also, save the 6-digit PIN in case you need to pair the sensor with a different mobile device.

If you discard the blue twist cap before the sensor has expired, make sure the 6-digit PIN is unreadable. This reduces the chance of another person pairing your sensor with their mobile device.

8 Calibrating Your Sensor

Calibrating your sensor allows you to use CGM values to make therapy decisions, such as insulin dosing, and increases the accuracy of CGM values. You calibrate your sensor by entering a current glucose value from your blood glucose meter into the app. The app prompts you to do so within the first day of use.

There are 2 modes of CGM values: **Trend Mode** and **Therapy Mode**. The mode the sensor is currently in is indicated directly below the CGM value on the Home screen.

When the sensor is in **Trend Mode**:

- CGM values should not be used to make therapy decisions, such as insulin dosing.
- CGM values can be used only to see trends and as a general reference.
- To make therapy decisions, such as insulin dosing, test your blood glucose with your blood glucose meter.

When the sensor is in **Therapy Mode**:

- CGM values can be used to make therapy decisions, such as insulin dosing.

The glucose measurements of the sensor are more accurate if you calibrate at a point in time when your blood glucose level is relatively stable.

Do **not** calibrate shortly **after a meal, after insulin administration, or after physical activity**, and avoid environments with very hot or very cold temperatures, or rapidly changing temperatures.

The calibration routine consists of two steps:

After a warm-up time of 1 hour, the sensor is in **Trend Mode**, and sends CGM values to the app every 5 minutes. Don't use these initial CGM values to make therapy decisions, such as insulin dosing. 12 hours after insertion of the sensor, the app prompts you to calibrate.

Step 1: Perform a blood glucose test and enter the glucose value into the app. The sensor goes into **Therapy Mode**. CGM values can now be used to make therapy decisions, such as insulin dosing.

Step 2: 30 minutes to 3 hours later, perform another blood glucose test and enter the glucose value into the app. This is to confirm the first measurement. Note: If step 2 is missed, the sensor returns to **Trend Mode**.

The calibration routine is completed for the sensor.

To calibrate your sensor:

1. Test your blood glucose with your blood glucose meter, according to the manufacturer's instructions.
2. Tap **Calibrate Now** on your Home screen.
3. Enter the glucose value from your blood glucose meter in the **Calibrate** screen. The glucose value should be entered no later than 3 minutes after performing the test.
4. Tap **Save**.
5. Check that you entered the same glucose value into the app that was displayed on your blood glucose meter and tap **Confirm**. If you accidentally entered an incorrect value, tap **Cancel** and enter the correct value.

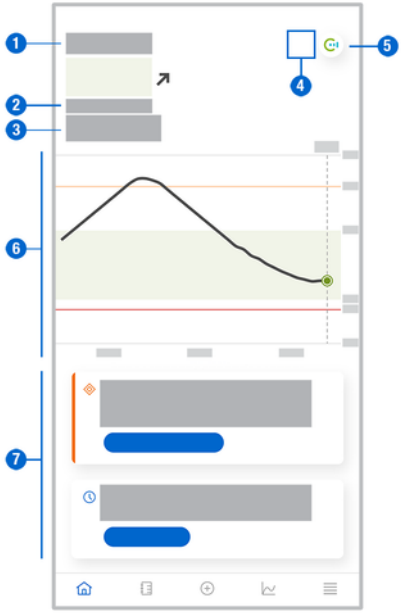
✓ Your sensor is calibrated.

If calibration is unsuccessful, wait approximately 15–30 minutes before repeating the process. When repeating the process, use a new glucose value from your blood glucose meter.

System performance can't be guaranteed if an incorrect blood glucose value is used for calibration.

If you confirm an incorrect calibration value, it can't be deleted. Remove the sensor and apply a new one.

The Home screen is the central app screen and displays various information.



1 Textual and numerical display of your current glucose value. The Trend arrow indicates the current direction in which your glucose values are trending:

↑ rising quickly

↗ rising

→ steady

↘ falling

↓ falling quickly

2 Unit of measurement

3 Trend Mode or Therapy Mode. This icon indicates which mode the sensor is currently in.

4 Status of alarms and notifications:

- (no icon) notification settings of mobile device are optimal

- indicates unread message that notification settings of mobile device are not optimal; tap icon to read message and change settings

- indicates message has been read, but notification settings of mobile device are still not optimal; tap icon again to change settings.

5 Switch to the Accu-Chek SmartGuide Predict app.

6 Home graph. The Home graph is a graphical representation of your glucose values over the last 3 hours.

7 Message area. The message area gives you a quick overview of current events. For example, the estimated duration of the warm-up time after you have paired a new sensor. Tap the buttons in the message area to react to the respective message.

NOTE

When the CGM value falls outside the measuring range of the device (above 400 mg/dL / 22.2 mmol/L or below 40 mg/dL / 2.2 mmol/L), the app will display HI or LO instead of a numerical value.

10 Logbook

Each logbook entry may contain the following information:

- Date and time of event
- Glucose value from your blood glucose meter
- Amount of carb intake
- Amount of insulin units (bolus and basal insulin units)
- Notes

Adding a Logbook Entry

Logbook entries can be added as follows:

1. Tap **Add Entry**.
2. ✓ The **New Entry** screen is displayed.
3. Tap the field you want to edit. You must fill in at least one field before you can save an entry.
4. Tap **Save**.
5. ✓ You've added a new entry to your logbook. The entry will be displayed in the message area of the Home screen for the next 4 hours.

Editing a Logbook Entry

Logbook entries can be edited as follows:

1. Tap **Logbook**.
2. Tap a logbook entry.
3. Tap the fields you want to edit.
4. Tap **Save**.
5. ✓ You saved your edits.

NOTE

You can't edit logbook entries containing glucose values that were used for calibrating your sensor.

Deleting a Logbook Entry

Logbook entries can be deleted as follows:

1. Tap **Logbook**.
2. Tap a logbook entry.
3. Tap **Delete Entry**.
4. Confirm that you want to delete this entry.
5. ✓ You deleted an entry from the logbook.

NOTE

You can't delete logbook entries containing glucose values that were used for calibrating your sensor.

11.1 Using the Graphs and Statistics

Reviewing your CGM data with your healthcare professional may provide insight into your diabetes management and help identify potential areas for therapy adjustment. The different graphs and statistics are valuable tools to help you make improvements to your diabetes management.

The following graphs are available:

- *Trend Graph*
- *Time in Ranges*
- *Statistics*

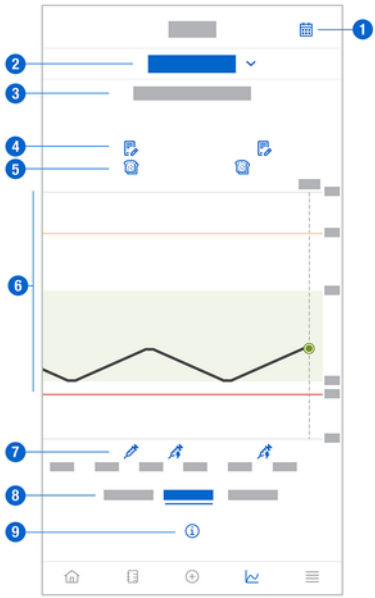
11.2 Trend Graph

The Trend Graph is an extended view of your Home screen that includes your logbook entries. You can select a 6, 12, or 24-hour view of your CGM data.

Swipe to the right to see values further in the past or tap the calendar button to jump to a specific date.

Tap the icons in the graph to see more information.

- Notes
- Carbohydrates
- Basal insulin injections
- Bolus insulin injections



1 Calendar button: Enables you to select a specific date.
2 Indicates Trend Graph is displayed; tap to select a different graph.
3 Selected time range
4 Notes

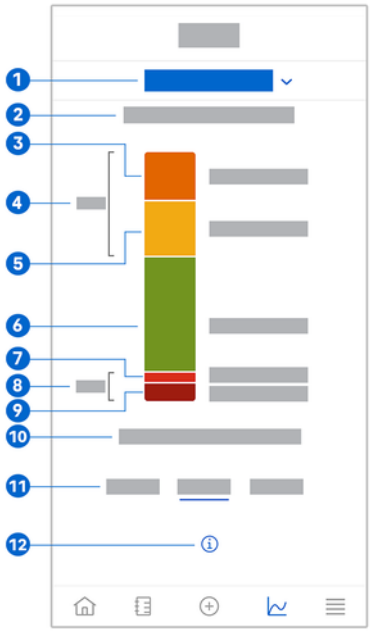
5 Carbs
6 Graphical representation of your glucose values over the selected time range.
7 Bolus and basal insulin injections
8 Select 6, 12, or 24-hour view
9 Tap to see more information on the Trend Graph.

To view your Trend Graph, proceed as follows:

1. Tap **Graphs**.
2. Select **Trend Graph** from the drop-down menu.
✓ The **Trend Graph** is displayed.
3. Tap the time range you want the graph to represent.
    - **6 Hours**
    - **12 Hours**
    - **24 Hours**

11.3 Time in Ranges

The Time in Ranges graph shows what percentage of your glucose values were within each of the 5 ranges (Very High, High, In Range, Low, Very Low) over the last 7, 14, or 28 days.



1 Indicates Time in Ranges graph is displayed; tap to select a different graph.
2 Selected time range
3 Very High: Percentage of glucose values that were above your very high glucose limit.
4 Combined percentage of glucose values that were above your high/very high glucose limits.

5 High: Percentage of glucose values that were above your target range but below your very high glucose limit.

6 In Range: Percentage of glucose values that were in your target range.

7 Low: Percentage of glucose values that were below your target range but above your very low glucose limit.

8 Combined percentage of glucose values that were below your low/very low glucose limits.

9 Very Low: Percentage of glucose values that were below your very low glucose limit.

10 Duration of time your glucose was below your very low glucose limit.

11 Select 7, 14, or 28-day view.

12 Tap to see more information on the Time in Ranges graph.

To view your Time in Ranges graph, proceed as follows:

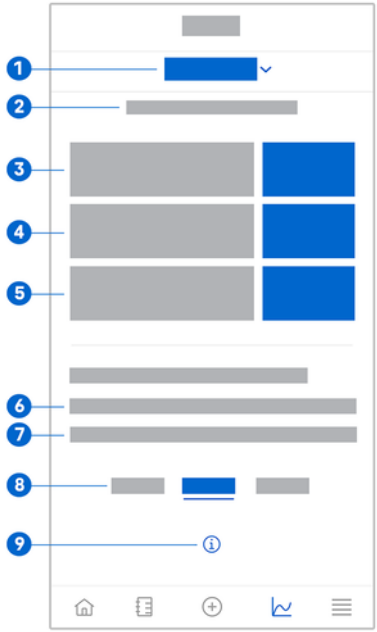
1. Tap **Graphs**.
2. Select **Time in Ranges** from the drop-down menu.

✓ The **Time in Ranges** graph is displayed.

3. Tap the time range you want the graph to represent.
   - **7 Days**
   - **14 Days**
   - **28 Days**

11.4 Statistics

The Statistics report gives a quick overview of key indicators involving your therapy and glucose values over the last 7, 14, or 28 days.



1 Indicates Statistics graph is displayed; tap to select a different graph.

2 Selected time range

3 Average glucose value over the number of days your sensor has been active, within the selected time range.

4 Glucose management indicator (GMI): the GMI is calculated from your average glucose and estimates your HbA1c for the selected time range.

5 Glucose variability: indicates degree of fluctuation in glucose values within the selected time range.

6 Active Days: Number of days between the first and last glucose measurement, within the selected time range.

7 Percentage of time you have worn your sensor and it has been active, within the selected time range.

8 Select 7, 14, or 28-day view.

9 Tap to see more information on the Statistics graph.

To view your Statistics, proceed as follows:

1. Tap **Graphs**.
2. Select **Statistics** from the drop-down menu.
- ✓ The **Statistics** screen is displayed.
3. Tap the time range you want the statistics to represent.
    - **7 Days**
    - **14 Days**
    - **28 Days**

12 Managing Your Sensor

The **Manage CGM Sensor** screen is used to manage your CGM session.

A CGM session is the continuous glucose monitoring over a certain period of time.

A dial on the screen indicates the remaining time until your sensor expires.

To manage your sensor, proceed as follows:

1. Tap **Menu**.
2. Tap **Manage CGM Sensor**.

✓ The **Manage CGM Sensor** screen appears. From here, you can pair a new sensor or view the sensor removal tutorial.

▶ If you want to pair a new sensor, tap **Pair New Sensor**.
You can pair a new sensor even if the currently paired sensor has not expired yet.

▶ If you want to view the sensor removal tutorial, tap **Sensor Removal Tutorial**.

13.1 Glucose Alarms

The app can warn you if your glucose values go very high, low, or very low. The following glucose alarms are available:

- The very high glucose alarm warns you when your glucose value goes above your very high glucose limit.
- The low glucose alarm warns you when your glucose value goes below your low glucose limit.
- The very low glucose alarm warns you when your glucose value goes below 54 mg/dL or 3 mmol/L. For your safety, the very low glucose limit can't be changed.

You will only receive one glucose alarm when your glucose value goes above your very high glucose limit or below your low glucose limit. However, you will continue to receive a glucose alarm every 5 minutes for as long as your glucose value remains below the very low glucose limit. You can also dismiss the alarm to stop receiving it.

Glucose alarms are active 24 hours a day, unless sleep alarms have been turned on.

Sleep alarms allow you to set different alarm levels during night. This way you aren't disturbed unnecessarily during sleep.

All glucose alarms are active by default, but you can turn them off from the app Menu.

To configure your glucose alarms, proceed as follows:

1. Tap **Menu**.
2. Tap **Glucose Alarms**.
3. Tap the toggles to turn the desired alarms on or off. When you turn on sleep alarms, you can adjust the **Bedtime** (start time) and **Wake-Up Time** (end time) for **Sleep Alarms** in 15-minute increments.

   NOTE

   If you turn on any glucose alarm, the connection loss alarm is automatically turned on as well. See section *Sensor Connection Loss Alarm*.

4. Enter the limits for each alarm.
   For information on default values, see chapter *Getting Started*.

   NOTE

   The allowed limits of your glucose alarms can be impacted by your target range settings. For example, if your target range is set to a certain range, you can't set your low glucose limit any higher without increasing the lower value of the target range.

5. Tap **Save**.

13.2 Target Range

The target range is the range in which your glucose values should be. In the app graphs, the target range is displayed as a green area.

The target range may vary for each individual. Discuss your individual target range settings with your healthcare professional.

NOTE

Target range values don't trigger alarms or notifications.

NOTE

The allowed target range values can be impacted by your glucose alarm settings. For example, if your low glucose alarm is set to a certain limit, you can't decrease the lower value of your target range without decreasing the limit of your low glucose alarm.

To configure your target range, proceed as follows:

1. Tap **Menu**.
2. Tap **Target Range**.
3. Enter the upper and lower values for your target range.
   If your unit of measure is set to mg/dL:
   - The default upper target value is 180 mg/dL (you can enter a value between 90 mg/dL and 300 mg/dL).
   - The default lower target value is 70 mg/dL (you can enter a value between 60 mg/dL and 140 mg/dL).

   If your unit of measure is set to mmol/L:
   - The default upper target value is 10.0 mmol/L (you can enter a value between 5.0 mmol/L and 16.7 mmol/L).
   - The default lower target value is 3.9 mmol/L (you can enter a value between 3.3 mmol/L and 7.8 mmol/L).
4. Tap **Save**.

13.3 Unit of Measure

The units of measure for the app are preselected based on the units commonly used in your country.

For safety reasons, you can select the units of measure for glucose values and carbohydrates only once during initial setup. After that, you can only display the selected units of measure. If you selected the wrong unit of measure by mistake, you need to uninstall and reinstall the app. If you then start the app again, you can reselect the unit of measure.

To view the selected units of measure, proceed as follows:

1. Tap **Menu**.
2. Tap **Unit of Measure**.

✓ The units of measure you selected during first-time use are displayed.

14.1 Sensor Expiration Reminders

The app can remind you when you need to change your CGM sensor.

To turn the expiration reminders on or off, proceed as follows:

1. Tap **Menu**.
2. Tap **Sensor Expiration Reminders**.
3. Tap the toggles to turn the desired reminders on or off.

The sensor expiration reminders are turned on by default.

14.2 Sensor Connection Loss Alarm

If the connection to your sensor is lost, you will no longer receive glucose values or alarms until the connection is restored. The sensor will store the data for 8 hours in case the data can't be transferred to the app. To avoid data loss, the sensor must transfer data before the sensor battery is empty.

The app can warn you when the connection to your CGM sensor is lost. This allows you to take the appropriate action to restore the connection.

You may miss episodes of very high, low, or very low glucose if the connection loss alarm is turned off.

For more information on how to restore the connection to your sensor, see section *General Troubleshooting*.

The connection loss alarm is turned on by default.

NOTE

The connection loss alarm is automatically turned on when you turn on any of the glucose alarms.

To turn the connection loss alarm on or off, proceed as follows:

1. Tap **Menu**.
2. Tap **Sensor Connection Loss**.
3. Tap the toggle to turn the **Connection loss alarm** on or off. If you turn off this alarm, a notification appears informing you that if the connection to your sensor is lost, you will not receive glucose alarms. To confirm that you want to turn off the Connection loss alarm, tap **Disable**. If you want to cancel this action, tap **Cancel**.

15 Account Settings

In your account settings, you can manage your Accu-Chek Account, manage your privacy settings, sign out, or delete your Accu-Chek Account.

To manage your privacy settings, proceed as follows:

1. Tap **Menu**.
2. Tap **Account**.
3. Tap **Privacy Settings**.
4. Use the toggles to give or withdraw your consent.

NOTE

If you withdraw a mandatory consent, you will no longer be able to use the app.

For more information on signing out of your Accu-Chek Account, see chapter *Accu-Chek Account*.

16 Accu-Chek Account

16.1 Creating an Account

If you don't have an Accu-Chek Account, you can create a new account with your email address.

1. Tap **Create Account** on the **Sign In** screen.
2. Fill in the text fields and tap **Next**.
3. Read the privacy and legal information. Tap the checkboxes, then tap **Create** to indicate your agreement to the terms.

✓ A confirmation email is sent to your email address.

4. Open the confirmation email in your email inbox. If you didn't receive a confirmation email, check your spam folder. To have the confirmation email sent to you again, tap **Resend email** in the app.
5. Tap **Verify** in the confirmation email.
6. Tap **Sign In** on the web page that opens.

✓ Your Accu-Chek Account is ready.

16.2 Signing In

To sign in with your Accu-Chek Account, proceed as follows:

1. Tap **Sign In**.
2. Enter the email address and password for your Accu-Chek Account.
3. Tap **Sign In**.

✓ You are now signed in.

16.3 Signing Out

NOTE

You must be signed in with your Accu-Chek Account to use this app. If you sign out, you will not receive glucose values or alarms.

To sign out of your Accu-Chek Account, proceed as follows:

1. Tap **Menu**.
2. Tap **Account**.
3. Tap **Sign Out**.

✓ You are now signed out.

16.4 Deleting an Account

To delete your Accu-Chek Account, proceed as follows:

1. Tap **Menu**.
2. Tap **Account**.
3. Tap **Delete Account**.
4. Tap **Delete Anyway**.

✓ Your account is now deleted.

Note that the Accu-Chek SmartGuide app will no longer be usable without an Accu-Chek Account.

17 Evaluating CGM Values

Your glucose values can vary depending on several factors, including, but not limited to:

- Food
- Medicine
- Your overall health
- Stress level
- Travel
- Physical activity

For more information on how these factors can affect your glucose values, consult your healthcare professional.

18.1 Event Log

The Event Log contains all events that occur during the use of your sensor and can help with troubleshooting. Such events can be, for example, all past, current, and inactive alarms.

To view the event log, proceed as follows:

1. Tap **Menu**.
2. Tap **Event Log**.

✓ A list of all past events is displayed.

18.2 General Troubleshooting

What to do if the app doesn't find your sensor?

After applying a new sensor, pair it within 30 minutes. After 30 minutes, the sensor will take longer to pair, in order to save battery life. If the app can't find the sensor, tap **Try Again** and wait until the app has found your sensor.

In general, you should pair your sensor with the app as soon as possible. When the sensor is reconnected to the app, the app will automatically retrieve the missing data from the sensor.

What to do if the app doesn't display glucose values?

It seems that your sensor may have lost the connection to the app.

If the connection to your sensor is lost, proceed as follows to restore a connection:

- ▶ Make sure that communication via Bluetooth wireless technology is turned on.
- ▶ The sensor can send information to a mobile device within a range of 6 meters / 20 feet (line of sight). The actual range might be reduced depending on the mobile device and your environment (such as other nearby devices).
- ▶ Tap **Menu** > **Event Log** and check whether the sensor issued a notification or alarm before losing connection to the app. For example, if the battery of your sensor is dead, you will find a corresponding notification in the event log.

Other factors that can cause CGM values not to be displayed include:

- sensor is warming up
- sensor is too warm or cold
- CGM session ended / sensor expired
- user signed out of the app

The app receives your current glucose value every 5 minutes. If the app doesn't display glucose values for more than 20 minutes without issuing a notification or alarm in the event log, contact customer support and remove the sensor if instructed.

To re-establish a connection after a connection loss alarm, see section *Sensor Connection Loss Alarm*.

What to do if your glucose value doesn't match how you feel?

Don't ignore symptoms of low or high glucose, and don't change your therapy without talking to your healthcare professional. If your glucose value doesn't match how you feel, proceed as follows:

1. Test your blood glucose with your blood glucose meter.
2. Perform a second test with your blood glucose meter to rule out an incorrect test result.
3. If test results from your blood glucose meter repeatedly don't match how you feel, consult your healthcare professional.

What to do if the app doesn't start?

Every time you start the app, the app performs an integrity check of its database. If the app detects any compromised data, the app deactivates itself for safety reasons. You can then no longer use the app. In this case, switch to an alternative method for testing your glucose and contact customer support.

18.3 Notification Overview

The app uses different types of notifications to inform you about the status of your sensor, errors, or upcoming maintenance. These notifications are:

- *Error Messages*
- *Maintenance Messages*
- *Warnings*
- *Information*
- *Reminders*

If the sensor has lost connection to your mobile device, you will no longer receive notifications from your sensor.

18.3.1 Error Messages

Jailbreak Detected (iOS Devices)

Your device is jailbroken. For security and privacy reasons, you can't use the app on this phone.

Rooted Device Detected (Android Devices)

Your device is rooted. For security and privacy reasons, you can't use the app on this phone.

Sensor Stopped Working

Please remove your used CGM sensor. Apply a new sensor and tap **Pair New Sensor**.

Software Error

The app may have been modified. For security and privacy reasons, please delete the app and reinstall it from the app store.

Software Error

Please close and reopen the app. If the error persists, contact customer support.

18.3.2 Maintenance Messages

Calibration Available

(Before first calibration, and 3 hours after first calibration): Calibrate your sensor if you want to use CGM values to make therapy decisions, such as insulin dosing.

(30 minutes after first calibration): Calibrate your sensor before <HH:MM> to keep your sensor in Therapy mode.

Calibration Unavailable

Calibration is unavailable. This could be due to rapid changes in your glucose or the sensor temperature. Please try again later.

Calibration Failed

For more information, see chapter *Calibrating Your Sensor*.

Unexpected Calibration

The app discovered an unexpected calibration on the sensor from <date/time>. Please confirm you performed this calibration.

Sensor Expired

Please remove your used CGM sensor. Apply a new sensor and tap **Pair New Sensor**.

Sensor Connection Lost

The app is unable to communicate with your CGM sensor. Make sure that Bluetooth is turned ON and that your mobile device is nearby.

The app is not receiving data from your CGM sensor. Open the app and keep it open to resume receiving glucose values and notifications.

Sensor Too Cold

The app is not receiving data from your CGM sensor because the sensor temperature is too low. Please move to a warmer environment.

Sensor Too Warm

The app is not receiving data from your CGM sensor because the sensor temperature is too high. Please move to a cooler environment.

Signed Out

For the best possible experience, you must be signed in to your Accu-Chek Account.

Sensor Battery Low

Please remove your used CGM sensor. Apply a new sensor and tap **Pair New Sensor**.

18.3.3 Warnings

⚠ Very High Glucose Detected

(While sensor is in Therapy Mode): Treat your high blood glucose as recommended by your healthcare professional.

(While sensor is in Trend Mode): Confirm your current glucose value with your blood glucose meter. If it is still very high, treat your high blood glucose as recommended by your healthcare professional.

⚠ Low Glucose Detected

(While sensor is in Therapy Mode): Consider eating or drinking fast-acting carbs as recommended by your healthcare professional.

(While sensor is in Trend Mode): Confirm your current glucose value with your blood glucose meter. If it is still low, consider eating or drinking fast-acting carbs as recommended by your healthcare professional.

⚠ Very Low Glucose Detected

(While sensor is in Therapy Mode): Immediately eat or drink fast-acting carbohydrates as recommended by your healthcare professional.

(While sensor is in Trend Mode): Confirm your current glucose value with your blood glucose meter. If it is still very low, immediately eat or drink fast-acting carbs as recommended by your healthcare professional.

18.3.4 Information

ⓘ Now Showing Trend Mode Values

Use these values as a general reference. If you want to use values to make therapy decisions, such as insulin dosing, calibrate after <HH:MM>.

ⓘ Calibration Available Soon

Calibrate your sensor between <HH:MM> and <HH:MM> to keep your sensor in Therapy Mode.

ⓘUnexpected Calibration

The app discovered an unexpected calibration on the sensor from <date/time>.

18.3.5 Reminders

Your CGM sensor expires tomorrow

Your CGM sensor needs to be changed within 24 hours. Apply a new CGM sensor before your current sensor expires.

Your CGM sensor expires soon!

Your CGM sensor will stop working within 2 hours. Apply a new CGM sensor soon!

Information on the Apple Watch

If you use an iPhone, you can use the app in combination with an Apple Watch.

Once the Apple Watch is connected to your iPhone, you can view the following information on your Apple Watch:

- Latest glucose value
- Trend arrow
- Trend graph

In addition, you receive all error, maintenance, and warning messages as well as reminders directly on your Apple Watch.

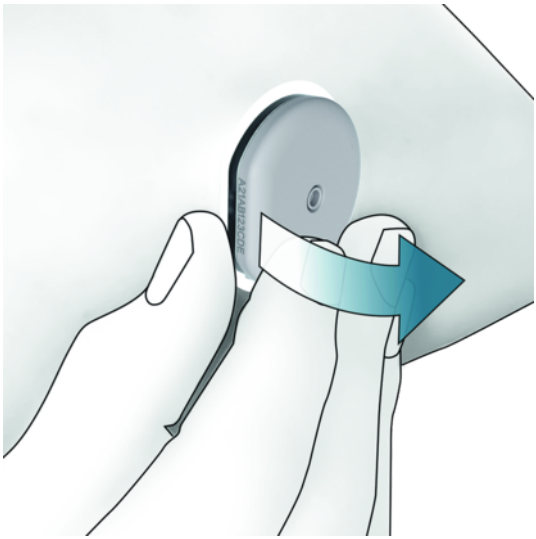
Complications

A complication is a visual element that you can add to the watch face of your Apple Watch. This visual element can display useful information.

The complication of the Accu-Chek SmartGuide app includes the following information:

- Latest glucose value
- Trend arrow

1 Start peeling off the adhesive pad on the flattened side of the sensor.



2 Inspect the back of the sensor: Make sure that the sensing element of the sensor has been completely removed from the application site after removing it. Check the application site by using your finger or check it visually. If the sensing element remained in your skin or the application site feels unusual (for example, painful, swollen, or red), consult your healthcare professional.

NOTE

An unusual feeling at the application site can still occur a few days after removal of your sensor. In this case, consult your healthcare professional.

21 Disposal Information

⚠ PRECAUTION

Risk of infection
Used components that have come into contact with human body fluids can transmit infections.

Discard the sensor as potentially infectious material according to local regulations. For information on how to discard used components correctly, contact your local council or authority.

Other components of the pack can be discarded in domestic waste.

A damaged sensor applicator or an exposed sensor needle can cause injury.

Discard sharp objects according to local regulations. Make sure that sharp objects don't cause injury to you and others.

Since your sensor may come into contact with human body fluids during use, it carries a risk of infection. Dispose according to local regulations. Since the sensor is for single use only, it falls outside the scope of the European Directive 2012/19/EU (directive on waste electrical and electronic equipment).

This product includes a battery containing a Substance of Very High Concern (SVHC), 1,2-dimethoxyethane (CAS 110-71-4), in a concentration above 0.1% weight by weight, as identified under REACH and added to the Candidate List. There is no direct exposure to the substance, and therefore no risk when the sensor is operated according to the instructions for use.

Contact Us

If you encounter problems, have questions, or need more information about the Accu-Chek SmartGuide app or device, contact customer support. In the app, go to **Menu** > **Contact Us**.

Reporting of Serious Incidents

For a patient/user/third party in the European Union and in countries with identical regulatory regime; if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority.

Printed User's Manual

If you would like a printed version of this User's Manual, contact customer support. The printed version is free of charge and will be sent to you within a few days.

Download of User's Manual

Download the User's Manual while connected to the Internet and save it to your mobile device for situations without an internet connection. This User's Manual is available to download from
https://tools.accu-chek.com/documents/dms/index.html.*

Download of Package Insert

The package insert is available to download from
https://tools.accu-chek.com/documents/dms/index.html.*

* download may incur data usage/charges

23 Release Notes

You can find the release notes for each version of the app in the respective app store.

iOS devices

1. Tap **App Store**.
2. Tap **Search**.
3. Search for *Accu-Chek SmartGuide app*.
4. Select the app from the search results.
5. Tap **Version History**.

✓ The release notes are displayed.

Android devices

1. Tap **Play Store**.
2. Search for *Accu-Chek SmartGuide app*.
3. Select the app from the search results.
4. Tap **What's new**.

✓ The release notes are displayed.

24 Technical Data

24.1 Technical Data of the Accu-Chek SmartGuide App

Product Name

Accu-Chek SmartGuide app

For more information about the product name, tap **Menu** > **Product Info**.

App Type

Application for mobile devices

App Version

For more information about the app version you are using, tap **Menu** > **Product Info**.

Supported Operating Systems

The app is only available for specific operating systems. Only use the app if the operating system is supported by the app.

For the latest information on compatible operating systems and their versions, tap **https://tools.accu-chek.com/documents/dms/index.html**.

Supported Mobile Devices

You can only download the app if the mobile device supports the iOS or Android version required for operation.

For the latest information on compatible mobile devices, tap **https://tools.accu-chek.com/documents/dms/index.html**.

Supported Platforms

Accu-Chek Care: Connects healthcare professionals and people with diabetes seamlessly.

Storage Space

The app saves CGM session and logbook data as long as there is enough storage space on the mobile device. If there is not enough storage space, the app notifies and prevents you from pairing a new sensor.

Data stored by the app on your mobile device is encrypted.

Exchanged Data

The app exchanges the following data with the cloud of Roche Diabetes Care:

- CGM data
- Logbook data
- Error messages
- Maintenance messages
- Warnings
- Reminders
- User settings (for example, target ranges or reminders).

The app can restore the last 6 months of data from the cloud of Roche Diabetes Care when you sign in to the app after installation.

Don't use restored data to make therapy decisions, such as insulin dosing. Only use current data from a connected sensor to make therapy decisions, such as insulin dosing.

Operating Principle

The Accu-Chek SmartGuide app serves as the primary display and receiver of CGM data.

Interfaces

The app has an interface to the following system:

- Mobile device: Requires access to Bluetooth wireless technology.

Special Requirements for Installing the App

- iOS devices require access to the Apple App Store.
- Android devices require access to Google Play.

Maintenance

Download and install app updates (if available). It is recommended to set the app to update automatically.

Check the event log on a regular basis.

Make sure your mobile device has enough free storage space.

Download and install OS updates (if available). For OS updates, follow the instructions of your mobile device. However, before you update your mobile device to a newer OS version, make sure that the app is compatible with the new OS version. If in doubt, check the list of compatible devices **https://tools.accu-chek.com/documents/dms/index.html**. If you still need assistance, contact customer support.

Default Measuring Ranges and Limits

Ranges and limits	mg/dL	mmol/L
Very high glucose limit	> 250 mg/dL	> 13.9 mmol/L
High glucose range	> 180 to ≤ 250 mg/dL	> 10.0 to ≤ 13.9 mmol/L
Target range (low to high)	≥ 70 to ≤ 180 mg/dL	≥ 3.9 to ≤ 10.0 mmol/L
Low glucose range	≥ 54 to < 70 mg/dL	≥ 3.0 to < 3.9 mmol/L
Very low glucose limit	< 54 mg/dL	< 3.0 mmol/L

All ranges and limits are configurable, except for the Very low glucose limit.

To change the glucose alarm limits, go to **Menu** > **Glucose Alarms**.

To change the target range values, go to **Menu** > **Target Range**.

The measuring range of the system is 40 mg/dL to 400 mg/dL (2.2 mmol/L to 22.2 mmol/L).

24.2 Technical Data of the Accu-Chek SmartGuide Device

Product Name

Accu-Chek SmartGuide device

Operating Principle

The device comprises an applicator and a sensor. While the applicator is discarded after the application of the sensor, the sensor remains on the user's skin with the electrochemical sensor inserted in the user's subcutaneous tissue. The sensor is discarded after the end of its wear time.

To calibrate the sensor, a glucose value is taken from a blood glucose meter, entered into the app, and sent to the sensor. To monitor glucose levels continuously, interstitial fluid glucose data are sent by the sensor every 5 minutes to the app. The app runs on a mobile device.

Product Dimensions

Height (incl. adhesive pad)	5.9 mm
Needle length	8.2 mm
Diameter of sensor without adhesive pad	33.3 mm
Weight	5 g

Data Transfer

The sensor transfers the following data to the app:

- Serial number
- Firmware version
- Hardware version
- Sensor information (System ID / MAC address)
- Time for next calibration
- CGM values
- Status information

CGM values generated while the sensor is in Trend Mode are indicated by the Sensor Status Annunciation-Bit 'Calibration required'.

The sensor receives the following data from the app:

- Blood glucose value for calibration
- CGM session start time

Radio Frequency

Purpose of interface	Communication interface. Allows the sensor to exchange data with a mobile device.
Interface specification	Bluetooth Low Energy 5.0 or higher
Frequency band of radio frequency reception and transmission	Frequency band of BLE 5.0: 2.402–2.480 GHz
Type and frequency characteristics of the modulation	GFSK (Gaussian Frequency-Shift Keying)
Effective radiated power of transmission	Less than 10 mW
Method of time synchronization	The sensor synchronizes according to the synchronization intervals of the mobile device.
Range of Bluetooth Low Energy	6 m
Access to Bluetooth Low Energy connection with mobile device	On the mobile device, Bluetooth Low Energy must be turned on for establishing a connection.
Radio frequency interferences	Communication may be affected by other radio frequency devices.

Electromagnetic Compatibility (EMC)

All EMC tests were carried out in accordance with the IEC 60601-1-2:2014, IEC 60601-1-2:2014/AMD1:2020 standards.

⚠ WARNING

Risk of interference
Electromagnetic fields and electromagnetic radiation may interfere with the proper operation of the sensor, resulting in incorrect CGM values. The sensor can influence other equipment (for example, through transmitted Bluetooth signals) if it is used outside its technical specifications. Only use the sensor within its technical specifications.

⚠ WARNING

Risk of malfunction
Don't place other devices close to or on top of the sensor. Use of the sensor alongside or with other devices may result in incorrect operation. If such use is necessary, observe the sensor and the other devices. Verify that the sensor and other devices are operating as intended.

Don't bring portable radio frequency communication devices (including peripherals such as antenna cables and external antennas) closer than 30 cm (12 inches) to the sensor. This may affect the performance of the sensor.

Electromagnetic Emissions

The sensor complies with the following Emissions Standards.

Radiated RF emission according to:

- CISPR 11 (EN 55011) class B, group 1
- RTCA DO160G Section 21, category M for in-cabin use

Electromagnetic Immunity

The sensor complies with the following Immunity Standards and Immunity Test Levels.

Electrostatic discharge (IEC 61000-4-2), Test Level:

- Contact: ± 2 kV, ± 4 kV, ± 6 kV, ± 8 kV
- Air: ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV

Radiated RF Electromagnetic fields (IEC 61000-4-3), Test Level:

- 10 V/m, 80 MHz–2.7 GHz, 80 % AM at 1 kHz

Proximity fields from RF wireless communications equipment (IEC 60601-1-2 Table 9), Test Level:

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] ± 5kHz deviation 1 kHz sine	28

Test Frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation	IMMUNITY TEST LEVEL (V/m)
710	704 to 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	9
745				
780				
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	28
870				
930				
1 720	1 700 to 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	28
1 845				
1 970				
2 450	2 400 to 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	28
5 240	5 100 to 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	9
5 500				
5 785				

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 doesn't represent actual modulation, it would be worst case.

Rated power frequency magnetic fields (IEC 61000-4-8), Test Level:

- 30 A/m, 50 Hz
- 30 A/m, 60 Hz

Proximity magnetic fields (IEC 61000-4-39), Test Level:

- 8 A/m, 30 kHz, CW modulation
- 65 A/m, 134.2 kHz, pulse modulated, duty cycle 50 %, 2.1 kHz Repetition rate
- 7.5 A/m, 13.56 MHz, pulse modulated, duty cycle 50 %, 50 kHz Repetition rate

Protection Against Electrical Shock

Electronic device of type BF according to the standard IEC 60601-1. Protection against electrical shock.

Protection Against Ingress of Fluids

IP28: The sensor is protected against the effects of continuous immersion in water at a depth of 1 meter for up to 60 minutes.

Method of Sterilization

Radiation

Interfering Substances

Taking the following interfering substances while wearing the sensor may falsely raise CGM values displayed in the app:

- Ascorbic Acid (vitamin C): more than 500 mg / day orally, or any amount intravenously
- Supplements with Gentisic Acid
- Methyldopa

Falsely raised CGM values can lead to insulin overdosing and/or could cause you to miss an occurrence of very low glucose. If you are taking any of the listed interfering substances, consult with your healthcare professional.

Environmental Conditions

Transport and storage conditions of the sensor in its unopened packaging:

- Temperature range: 2 to 27 °C
- Humidity range: 10 to 90 % (non-condensing)
- Air pressure range: 549 to 1,060 hPa

  Make sure that you only store unopened products. Insert the sensor immediately after opening the packaging.

Operating conditions of the sensor:

- Temperature range: 10 to 40 °C
- Humidity range: 15 to 90 % (non-condensing, water vapor partial pressure less than 50 hPa)
- Air pressure range: 700 to 1,060 hPa
- Maximum altitude: 3,000 m (9,842 ft)

The time to warm up the CGM device from lowest storage temperature (2 °C) to lowest operating temperature (10 °C) is less than 17 minutes.

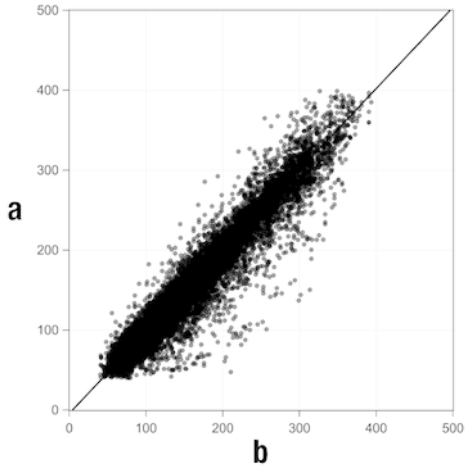
The surface temperature of the sensor will remain below 43 °C and will only exceed 41 °C for a limited time.

Performance Data

Consult your healthcare professional to discuss the use of the following data.

The performance of the Accu-Chek SmartGuide sensor was evaluated in a controlled clinical trial (data on file). The study was conducted in 3 clinical centers and included 48 people with Type 1 or insulin-dependent Type 2 diabetes (18 years and older). Each study participant was wearing three sensors over 14 days on the back of the upper arms. During the study, sampling days with glucose manipulations were conducted, where capillary glucose measurements were taken as comparison values. In the study, three sensor batches were investigated.

Figure 1: *Regression analysis of sensor values in comparison to capillary measurements*



a = CGM Value [mg/dL]; **b** = Comparator Value [mg/dL]

Table 1: *Regression analysis*

Slope	1.02
Axis intercept	-4.2 mg/dL (-0.2 mmol/L)
Correlation (Pearson's r)	0.96
N	15993
Range	40-400 mg/dL (2.2-22.2 mmol/L)
Overall MARD	9.2 %

Table 2: *Sensor performance compared to capillary measurements at different glucose ranges*

Glucose	**Overall MAD/MARD***
< 54 mg/dL (3.0 mmol/L)	7.5 mg/dL (0.42 mmol/L)*
54-69 mg/dL (3.0-3.8 mmol/L)	7.0 mg/dL (0.39 mmol/L)*
70-180 mg/dL (3.9-10.0 mmol/L)	9.8 %
> 180-250 mg/dL (10.0-13.9 mmol/L)	8.0 %
> 250-350 mg/dL (13.9-19.4 mmol/L)	7.3 %
> 350 mg/dL (19.4 mmol/L)	4.9 %
* For glucose < 70 mg/dL (3.9 mmol/L), the differences in mg/dL (mmol/L) are presented instead of relative differences (%).	

NOTE

MARD (Mean Absolute Relative Deviation) is the mean of the absolute relative deviations of the CGM values from the simultaneously measured blood glucose values. MARD is determined as follows:

- The simultaneously measured blood glucose value is subtracted from the continuous glucose value. The absolute amount of the difference is put into percentage relation to the blood glucose value. The percentages of all pairs of values are added together and the result divided by the number of pairs of values (n).

MAD (Mean Absolute Deviation) is the mean of the absolute deviations of the CGM values from the simultaneously measured blood glucose values. MAD is determined as follows:

- The simultaneously measured blood glucose value is subtracted from the continuous glucose value and the absolute amount of the difference is taken. The amounts of all pairs of values are added together and the result divided by the number of pairs of values (n).

Table 3: *Sensor performance compared to capillary measurements over sensor wear time*

	Beginning	**Middle**	**End**
Overall MARD	8.3 %	9.0 %	10.8 %

Table 4: *Sensor performance according to agreement rates*

	Total number of pairs	Within ±15 mg/dL (±0.8 mmol/L) and ±15 % of the capillary measurements	Within ±20 mg/dL (±1.1 mmol/L) and ±20 % of the capillary measurements	Within ±30 mg/dL (±1.7 mmol/L) and ±30 % of the capillary measurements	Within ±40 mg/dL (±2.2 mmol/L) and ±40 % of the capillary measurements
Sensor performance overall	15993	13345 (83.4 %)	14471 (90.5 %)	15510 (97.0 %)	15803 (98.8 %)
Sensor performance < 70 mg/dL (3.9 mmol/L)	1121	998 (89.0 %)	1057 (94.3 %)	1112 (99.2 %)	1118 (99.7 %)
Sensor performance 70 - 180 mg/dL (3.9 - 10.0 mmol/L)	9793	7923 (80.9 %)	8718 (89.0 %)	9444 (96.4 %)	9660 (98.6 %)
Sensor performance > 180 mg/dL (10.0 mmol/L)	5079	4424 (87.1 %)	4696 (92.5 %)	4954 (97.5 %)	5025 (98.9 %)

Note that all performance data shown represents data from sensors in Therapy Mode. In the study described, sensors in Trend Mode showed an overall MARD of 10.2 %. Insulin dosing decisions are only possible in Therapy Mode. For more information, see chapter *Calibrating Your Sensor*.

Adverse Events

No serious adverse events, or device-related serious adverse events, occurred during the study. There were a total of 35 adverse events which occurred during the study. Of these, 15 were related, or possibly related, to the device. All of these 15 adverse events were related to reactions at the application site, such as short bleeding, pain, hematoma, erythema, mild inflammation, or pruritus.

25 License Information

Roche Diabetes Care GmbH
Sandhofer Strasse 116
68305 Mannheim, Germany

www.accu-chek.com

calibration

Entering a glucose value from a blood glucose meter test into the app, to improve the accuracy of the sensor. This action is necessary every time a new sensor is inserted into the arm and paired with the app. This enables glucose values from the sensor to be used to make therapy decisions, such as insulin dosing.

calibration values

Current glucose values that are taken from a blood glucose meter test and entered into the app, to improve the accuracy of the sensor. This enables glucose values from the sensor to be used to make therapy decisions, such as insulin dosing.

interfering substance

A specific substance (in a medicine or food, for example), that once administered is known to adversely affect the accuracy of glucose values.

interstitial fluid glucose

Glucose in the thin layer of fluid that surrounds tissue cells, just below the skin.

mg/dL (milligrams per deciliter)

mg/dL indicates how much the particles (glucose) present in a deciliter weigh. It is a weight indication.

mg/dL is commonly used in Argentina, Austria, Belgium, Brazil, Chile, Colombia, Cyprus, Egypt, France, Germany, Greece, India, Iran, Israel, Italy, Japan, Luxembourg, Mexico, New Zealand, Poland, Portugal, Romania, South Korea, Spain, Taiwan, Thailand, Turkey, United Arab Emirates, United States of America.

mmol/L (millimoles per liter)

mmol/L indicates the number of particles (glucose) per liter. It is the indication of a quantity of substance in 1 liter.

mmol/L is commonly used in Australia, Bosnia-Herzegovina, Bulgaria, Canada, China, Croatia, Czech Republic, Denmark, Estonia, Finland, Germany, Hungary, Kazakhstan, Latvia , Lithuania, Malaysia, Netherlands, North Macedonia, Norway, Russia, Serbia, Singapore, Slovakia, Slovenia, Sweden, Switzerland, South Africa, United Kingdom.

mobile device

A smartphone or tablet computer that runs the app.

therapy decision

Any treatment performed or administered in order to bring one's glucose values back to, or keep within, normal levels.

Therapy Mode

The status the sensor is in after the user has performed calibration. In this status, CGM values can be used to make therapy decisions, such as insulin dosing.

Trend Mode

The status the sensor is in before the user has performed calibration. In this status, CGM values can only be used to see trends and as a general reference.

27 Abbreviations

BE: Bread Unit

A unit of measurement for carbohydrate counting. 1 BE equals 12 g.

CC: Carbohydrate Choice

A unit of measurement for carbohydrate counting. 1 CC equals 15 g.

CGM: Continuous Glucose Monitoring

A system for measuring glucose levels through a tiny sensor inserted under the skin, and displaying these glucose levels in an app.

g: Gram

A metric unit of mass equal to one thousandth of a kilogram.

GMI: Glucose Management Indicator

This value is calculated from your average glucose and estimates your HbA1c.

KE: Carbohydrate Unit

A unit of measurement for carbohydrate counting. 1 KE equals 10 g.

MAD: Mean Absolute Deviation

The mean of the absolute deviations of the continuous glucose values from the simultaneously measured blood glucose values.

MARD: Mean Absolute Relative Deviation

The mean of the absolute relative deviations of the continuous glucose values from the simultaneously measured blood glucose values.

OS: Operating System

A collection of software that manages computer and mobile device hardware resources, and provides common services for computer programs and apps.

U: Units

A standard of measurement of a physical quantity.

Symbol	Description
App navigation	
	Home
	Logbook
	Add Entry
	Graphs
	Menu
Screen navigation	
	Back
	Close
	Checkmark
	Drop-down menu
	Additional Information
App menu	
	Manage CGM Sensor
	Event Log

Symbol	Description
	Glucose Alarms
	Target Range
	Unit of Measure
	Critical Alerts
	Sensor Expiration Reminders
	Sensor Connection Loss
	Account
	User's Manual
	Quick Start Guide
	Product Info
	Contact Us
Home Screen	
	Indicates unread message that notification settings of mobile device are not optimal

Symbol	Description
	Indicates message has been read, but notification settings of mobile device are still not optimal
	Switch to Accu-Chek SmartGuide Predict app
	Trend arrow: Your glucose value is rising quickly
	Trend arrow: Your glucose value is rising
	Trend arrow: Your glucose value is stable
	Trend arrow: Your glucose value is falling
	Trend arrow: Your glucose value is falling quickly
	Information
	Your CGM sensor is warming up
	Error message
	Maintenance message
	Warning message
Graphs	
	Basal insulin injection

Symbol	Description
	Bolus insulin injection
	Carb amount
	Notes
	Calendar
Glucose Alarms	
	All Day Alarms / Awake Alarms
	Sleep Alarms
Logbook	
	The logbook entry can't be edited or deleted because it was used for calibrating the sensor.

29 Explanation of Symbols

The following symbols appear on the device and packaging:

Symbol	Description
	Consult instructions for use or consult electronic instructions for use
	Follow instructions for use (blue symbol)
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	Use by
	Do not use if package is damaged
	Sterilized using irradiation
	Use only once
IP28	Device is protected against access to hazardous parts with a finger and protected against the effects of continuous immersion in water (up to 60 minutes and up to 1 meter in depth).
	Electronic device of type BF according to the standard IEC 60601-1. Protection against electrical shock.

29 Explanation of Symbols

Symbol	Description
	Date of manufacture
	Medical device
	Manufacturer
	Indicates the authorized representative in Switzerland
	Unique device identifier
	Catalogue number
	Serial number
	Batch code
	Complies with the provisions of the applicable EU Legislation

Roche Diabetes Care GmbH
Sandhofer Strasse 116
68305 Mannheim, Germany

www.accu-chek.com

Last update: 2024-11
1000050883(02)

CE 0123