ACCU·CHEK®
SmartGuide

USER'S MANUAL

ACCU-CHEK SMARTGUIDE DEVICE

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1 About This User's Manual

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.

Before You Start

A compatible app must first be installed on your mobile device. Scan the QR code on the packaging or go to **go.roche.com/smartguideapp** to download the app.

Read this User's Manual and the User's Manual for your app before using this product. This User's Manual is available directly at **go.roche.com/CGM-instructions**.

Read the Compatibility Document to make sure your mobile device is compatible with the app. The User's Manuals and Compatibility Document are available to download from **go.roche.com/download-portal**.

Follow all safety instructions, safety information, technical data, and performance data.

2 Product Information

NOTE

See chapter *Applying Your Sensor* to get started with your sensor.

2.1 Intended Use

The continuous glucose monitoring device (CGM device) is intended for continuous measurement of real-time glucose values in the subcutaneous interstitial fluid.

2.2 Intended Users

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

2.3 Indications, Contraindications, and Limitations

Indications

The device is indicated for people with diabetes (not in a clinical setting).

Contraindications

- The device shall not be used by critically ill patients or patients on dialysis.
- The sensor must be removed prior to entering special environments (according to IEC 60601-1-2). Special environments include military areas, heavy industrial areas, and medical treatment areas with high-powered medical electrical equipment (such as magnetic resonance imaging (MRI), computed tomography (CT), X-ray, radiotherapy, or diathermia).

Limitations

- The sensor may only be used by a single patient and is not intended for a clinical setting.
- The sensor may only be used once. Don't reuse the 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 arrow in your 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.
- Only use CGM values to make therapy decisions, such as insulin dosing, after you have calibrated your sensor as requested by the app.
- 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 your healthcare professional. See chapter *Technical Data* for a list of interfering substances.

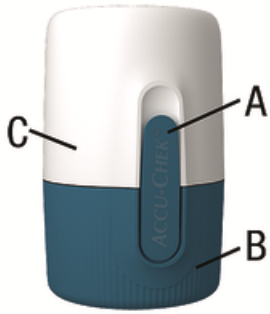
2.4 Contents of the Pack

- 1 device (sensor applicator with sensor inside)
- 1 leaflet

2.5 Proper Storage

- Store your unopened device in a cool, dry place.
- Store between 2 and 27 °C.
- Do not store in a parked car on hot or cold days.
- See chapter *Technical Data* for the transport and storage conditions.

2.6 Component Overview



A Pull tab

When you flip the pull tab, you can open the device.

B Twist cap

The label on the bottom of the twist cap shows the 6-digit PIN that is required to pair your sensor with the app. The sensor must be applied immediately after the twist cap is removed from the applicator.

C Sensor applicator

The sensor applicator contains the sensor with a needle. The sensor is sterilized by irradiation. The needle is retracted into the sensor applicator after application. Keep the used sensor applicator away from children. If the sensor applicator housing is damaged and the needle becomes accessible, discard the sensor applicator according to local regulations, so that no one is injured by it. Also discard the sensor applicator if you have dropped it or something has dropped on the sensor applicator after you pull off the twist cap.

2.7 Additional Materials Required

- A compatible app must first be installed on your mobile device. Scan the QR code on the packaging or go to **go.roche.com/smartguideapp**.
- You must have an alternative method for glucose testing, for use in emergencies when the app or sensor is not working.

⚠ WARNING

Risk of serious harm
Don't modify the product. Always follow the instructions. Otherwise, the product doesn't work as intended. This may lead to one or several harms, including adverse reactions of the skin, reactions to a foreign body, encapsulations, infections, or abscesses.

⚠ WARNING

Risk of suffocation
This product contains small parts that can be swallowed. Keep the small parts away from small children and people who might swallow small parts.

⚠ WARNING

Risk of pain
Applying and removing the sensor may cause slight pain. The pain usually stops after application. If the pain remains, seek medical attention.

⚠ WARNING

Risk of injury
This product contains a button battery. If swallowed, a lithium button battery can cause severe or fatal injuries within 2 hours.

Keep batteries out of reach of children and people who might swallow batteries. If you think batteries may have been swallowed or placed inside any part of the body, seek immediate medical attention.

⚠ PRECAUTION

Risk of prolonged bleeding
Coagulation disorders or anticoagulant medications can lead to prolonged bleeding at the application site. Consult your healthcare professional before using the product.

⚠ PRECAUTION

Risk of serious harm
Only make therapy decisions, such as insulin dosing, based on multiple current glucose values, and the direction in which your glucose values are trending. 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.

⚠ PRECAUTION

Risk of serious harm
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.

⚠ 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.

- Only pair the sensor in a secure, trusted area. This reduces the risk of other people connecting to your sensor.
- Frequent connection loss between the sensor and app may decrease the battery life of the sensor. Keep your sensor and mobile device close together.
- Visually inspect the packaging, device, sensor, and needle for damages or manipulation. If the pull tab is sticking out before use, the sensor is unsterile. If you notice anything unusual, don't use the sensor. Use a new sensor.
- Don't use the device if you have allergic reactions to adhesives on your skin.
- 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.
- In rare cases, the needle can remain in your body after you have applied the sensor. This may lead to adverse reactions to a foreign body, encapsulations, infections, or abscesses. In case of an adverse reaction, seek medical attention.
- 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.
- The sensor is a type BF applied part according to IEC 60601-1 and protected against electric shock.
- The sensor can send information to a mobile device within a range of 10 meters (33 feet) (line of sight). The actual range might be reduced depending on the mobile device and your environment (e.g. other nearby devices).
- 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.

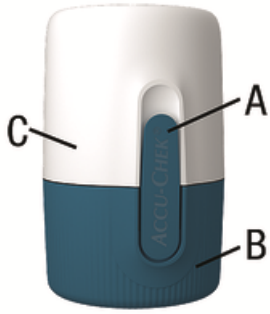
- If the connection to your sensor is lost, you will no longer receive glucose values or alarms until the connection is restored. The sensor will store the data for 8 hours in case the data can't be transferred to the app. To avoid data loss, the sensor must transfer data before the sensor battery is empty.
- The sensor sends 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.
- If the use by date has passed, the sensor can no longer be paired with the app. Don't use a device that is past the use by date as it may cause infections and abscesses. The use by date is printed next to the ⌛ symbol on the packaging of the product (format: YYYY-MM-DD). The use by date applies for new, unopened products.

4 Applying Your Sensor

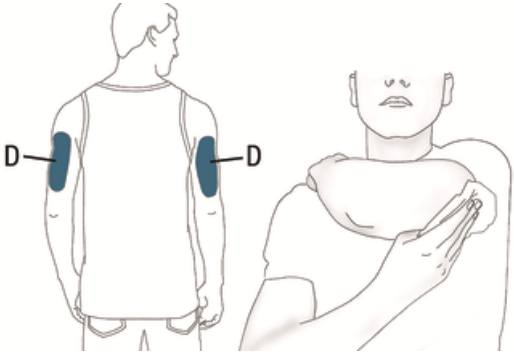
NOTE

An app that is compatible with your sensor must first be installed on your mobile device. Download the app by scanning the QR code on the packaging with the camera on your mobile device.

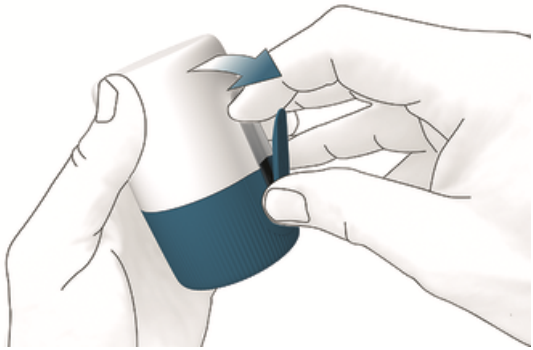
1 Hold the device upright. Notice the pull tab (A). The white sensor applicator (C) is at the top. The blue twist cap (B) is at the bottom.



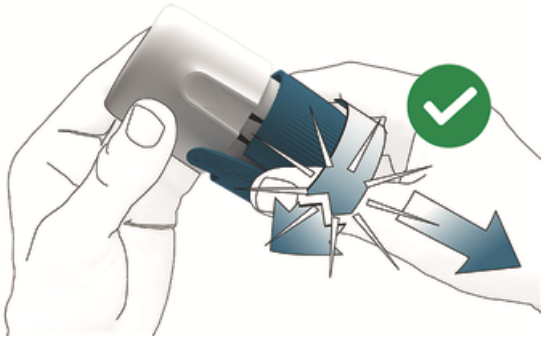
2 Select an application site (D) on the back of your right or left upper arm: If the application site is hairy, shave it. Wash the application site to clean the skin. Disinfect the application site with an alcohol wipe and let the skin dry completely. Avoid recently used application sites, as well as scars, stretch marks, liver spots, knots, or blood vessels. Stay at least 7.5 cm (3 inches) away from insulin injection sites.



3 Slightly flip the pull tab (A) open. If the pull tab has already been opened before use, discard the device and use a new one.



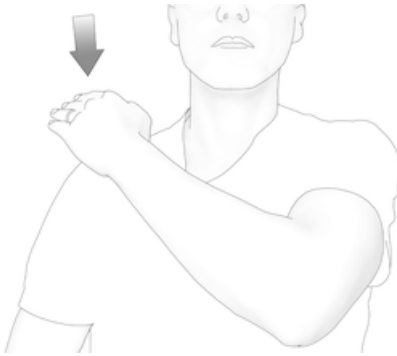
4 Don't press on the device. Turn the blue twist cap of the white sensor applicator to open the sterile barrier. You will feel a slight resistance and hear a cracking sound. Pull the blue twist cap from the white sensor applicator. Don't touch the needle inside. Don't put the blue twist cap back on after you have removed it.



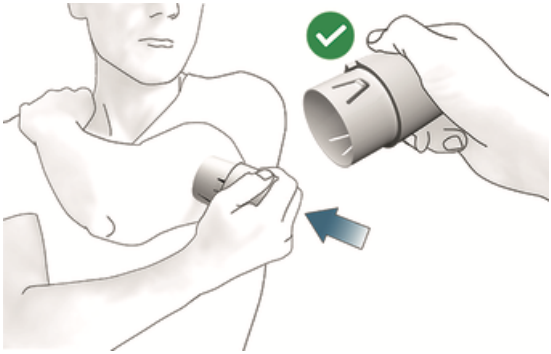
NOTE

Save the 6-digit PIN on the twist cap in a secure location to prevent another person from accessing it. The PIN is required to pair your sensor with the app. You also need the PIN when pairing to 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.

5 Place the hand of the disinfected arm on your opposite shoulder. This helps to tighten the skin.



6 Reach **under** your arm and place the white sensor applicator on the application site. Don't touch the inner part. Hold the white sensor applicator by the external housing, as shown in the picture. Make sure the entire bottom of the applicator is flat against your skin.



7 Press down firmly to apply the sensor.

8 Remove the white sensor applicator in the same direction without rotating or wiggling it. Swipe over the adhesive pad firmly with your finger to make sure the adhesive pad is properly attached.

NOTE

Normally the sensor applicator can be easily removed. If you have trouble removing the sensor applicator, press it back down firmly and attempt to remove it again.

☑ The sensor is now ready to be paired to the app on your mobile device. Follow the instructions in the app to pair and calibrate your sensor.

NOTE

- After applying a new sensor, pair it with the app within 30 minutes. After 30 minutes, the sensor will take longer to pair, in order to save battery life. The sensor should also be paired with the app within 30 minutes after the connection has been lost.
- The sensor must be active for a certain period before CGM values are displayed and calibration is possible. This is called warm-up time.

5 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 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.

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.

To calibrate your sensor:

1. Test your blood glucose with your blood glucose meter, according to the manufacturer's instructions.
2. Enter the glucose value into your app. This value should be entered no later than 3 minutes after performing the test. The sensor goes into **Therapy Mode**. CGM values can now be used to make therapy decisions, such as insulin dosing.
3. 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. If this step is skipped, the sensor returns to **Trend Mode**.

NOTE

Refer to the User's Manual for your app for more information.

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.

You can wear the sensor for 14 days. Then remove and discard the sensor.

Your sensor is water-resistant. It can be worn during bathing, swimming, or showering. Don't immerse it for longer than 60 minutes or deeper than 1 meter (3.3 feet).

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.

Hygiene and Skin Care

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.

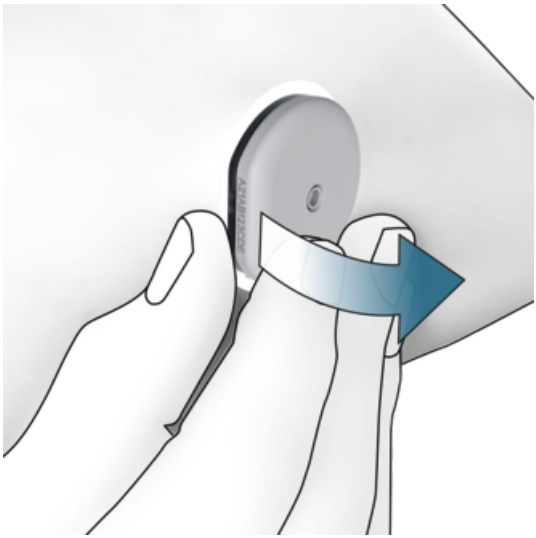
Your body may react to the sensor or the adhesive pad. Inspect the application site regularly for skin irritation or inflammation. If in doubt, or if the application site becomes inflamed or if localized skin reactions (for example, allergic reaction, eczema) occur, remove the sensor immediately and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

Airports

When at the airport, you may leave the sensor on your body while passing through full-body scanners. Keep your medical certificate ready for any queries from security personnel. Spare sensors inside your luggage may also pass through airport screenings.

7 Removing Your Sensor

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.

8 Disposal Information

⚠ PRECAUTION

Risk of infection
Used components that have come into contact with human bodily 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 bodily fluids during use, it carries a risk of infection. Dispose of the sensor 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).

Contact Us

If you encounter problems, have questions, or need more information about the Accu-Chek SmartGuide device, contact customer support.

Armenia
Concern Enegomash CJSC
Address: RA, Yerevan, Azatutyan ave 26/8
Tel: +374 44 44 01 45
E-mail: cgm@c-e.am

Australia
Roche Diabetes Care Australia Pty Limited
2 Julius Avenue
North Ryde NSW 2113 Australia
Accu-Chek SmartGuide Customer Care: 1800 434 121
www.accu-chek.com.au

Central America and the Caribbean
Call center Accu-Chek®:
Costa Rica: 800 007 6278
Panama: 800-9898
Jamaica: 1 844 972 4706
Trinidad & Tobago: 1 844 613 1709
Bahamas: 1 800 300 0415
Barbados: 1 833 857 0252
www.accu-chekcac.com

Cyprus
Varnavas Hadjipanayis LTD
226 Giannou Kranidioti Avenue,
2234 Latsia, Nicosia, Cyprus
E-mail: info@hadjipanayis.com.cy
Tel: +357 22207700

Hong Kong
HKMD No. 251921
Roche Diagnostics (Hong Kong) Limited
Level 17, Tower 1 Metroplaza,
223 Hing Fong Road,
Kwai Chung, Hong Kong
Tel: 24813387
Enquiry hotline: +852-2485 7522 (office hours)
E-mail: smartguide.hk@roche.com
www.accu-chek.com.hk

India
Accu-Chek SmartGuide Customer Care
Toll Free Tel: 1800 313 5568
Monday to Saturday, 7.30am to 9.30pm
E-mail: smartguide.in@roche.com
www.accu-chek.in

Kuwait
Roche for the trade in medicines, equipment, devices and medical supplies S.P.C
Burj Alshaya plot 6, Floor 5, Office 11, Al Mirqab P.O. Box: 467, Safat-13005 Kuwait
Phone : +965 25 770 444
CGM Customer Support Line: 22069164
CGM Customer Support E-mail: smartguide.kw@roche.com

Macedonia
Eurofarm dooel
Anton Pavlov 5,

1000 Skopje,
North Macedonia
Tel.: 389 47 609741
E-mail: info@eurofarm.mk

Malaysia
Customer Support and Service Centre:
Toll-Free Line: 1-800-22-1313
smartguide.my@roche.com

Pakistan
Contact: 111-124-675
E-mail: smartguide.pk@roche.com

Qatar
Roche Diabetes Care Middle East FZCO
P.O.BOX 263990 Jabal Ali Free Zone
Dubai, UAE
Qatar CGM Customer Support Line: 00800101658
Qatar CGM Customer Support E-mail: smartguide.qa@roche.com

Saudi Arabia
Roche Diagnostics Saudi Arabia LLC
6469 Northern Ring Road, Al Aqeeq District
Riyadh 13519, 3212, Saudi Arabia
Phone : +966 11 414 900
Customer Support Number: 08008500311
Customer Support E-mail: smartguide.sa@roche.com

Singapore
Accu-Chek SmartGuide
ExtraCare line: 1800 2722056
E-mail: smartguide.sg@roche.com

South Africa
Roche Diabetes Care South Africa (Pty) Ltd.
Hertford Office Park, 90 Bekker Road
Vorna Valley, 1686
South Africa
Tel: 080 007 9425 (South Africa only)
E-mail: smartguide.za@roche.com
www.accu-chekafrica.com

United Arab Emirates
Roche Diabetes Care Middle East FZCO
P.O.BOX 263990 Jabal Ali Free Zone
Dubai, UAE
Locally Distributed by:
Pharmatrade LLC Co.
P.O. Box 11397
Dubai, UAE
UAE CGM Customer Support Line: 80006512116
UAE CGM Customer Support Email: smartguide.ae@roche.com

United Kingdom / Republic of Ireland
Accu-Chek Customer Care
UK Freephone number: 0800 0211 241
ROI Freephone number: 1 800 121 416
(Calls may be recorded for training purposes. Some mobile operators may charge for calls to these numbers.)
www.accu-chek.co.uk

Reporting of Serious Incidents

Report any serious incidents that result from using this device to Roche 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 **go.roche.com/download-portal**.*

* Download may incur data usage/charges.

Product Name

Accu-Chek SmartGuide device

Transport and Storage

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 1060 hPa

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

Operating Conditions

- 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 1060 hPa
- Maximum altitude: 3000 m (9842 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.

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 can cause you to miss an occurrence of very low glucose. If you are taking any of the listed interfering substances, consult your healthcare professional.

Operating Principle

The continuous glucose monitoring (CGM) device consists of an applicator and a sensor. The applicator is discarded after use, while the sensor remains on the skin, with its electrochemical sensor inserted subcutaneously. An electronic component processes sensor data and facilitates communication.

The sensor connects to an app, which serves as the primary display and receiver of data. During calibration, blood glucose values are entered into the app and sent to the sensor. The sensor then measures glucose levels in the interstitial fluid and sends this data to the app every 5 minutes.

Sensor Dimensions

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

Communication Interface

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	*Bluetooth*® Low Energy 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.
Bluetooth® Low Energy range	10 m
Access to *Bluetooth*® Low Energy connection with mobile device	On the mobile device, *Bluetooth*® Low Energy technology 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 standard.

⚠ 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 the 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 (MHz)	Service	Modulation	Immunity test level (V/m)
385	380 to 390	TETRA 400	Pulse modulation 18 Hz	27
450	430 to 470	GMRS 460, FRS 460	FM ± 5kHz deviation 1 kHz sine	28
710	704 to 787	LTE Band 13, 17	Pulse modulation 217 Hz	9
745				
780				
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28
870				
930				

Test Frequency (MHz)	Band (MHz)	Service	Modulation	Immunity test level (V/m)
1720	1700 to 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	28
1845				
1970				
2450	2400 to 2570	*Bluetooth*®, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28
5240	5100 to 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9
5500				
5785				

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 temporary immersion in water at a depth of 1 meter for up to 60 minutes.

Method of Sterilization

Radiation

Battery

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 % 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.

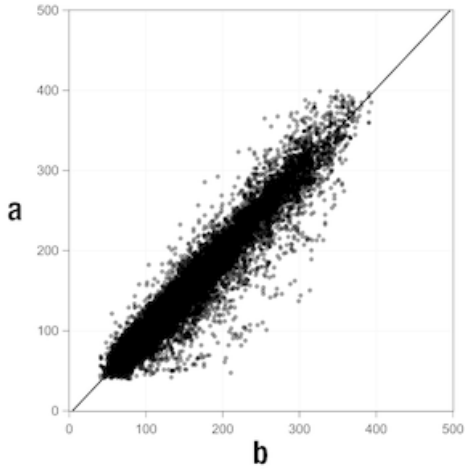
Performance Data

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 3 sensors over 14 days on the back of the upper arms. During the study,

3 sampling days with glucose manipulations were conducted, where capillary glucose measurements were taken as comparison values. In the study, 3 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 CGM 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 CGM 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 that had been calibrated by the user. In the study described, sensors that had not been calibrated by the user showed an overall MARD of 10.2 %.

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.

Declaration of Conformity

Roche hereby declares that the radio equipment type Accu-Chek SmartGuide sensor is in compliance with Directive 2014/53/EU.

The full text of the EU declaration of conformity is available at the following internet address:

https://declarations.accu-chek.com

11 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.

11 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
	For Spain and Portugal only: This symbol indicates local waste disposal instructions applicable to Spain and Portugal.
	The compliance mark indicates that the product complies with the applicable standard and establishes a traceable link between the equipment and the manufacturer, importer or their agent responsible for compliance and for placing it on the Australian and New Zealand market.

11 Explanation of Symbols

Symbol	Description
	This product contains a button battery.
	This product fulfils the requirements of the Independent Communications Authority of South Africa.

Roche Diabetes Care GmbH
Sandhofer Strasse 116
68305 Mannheim, Germany

CE 0123

www.accu-chek.com

Last update: 2025-09

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