ACCU-CHEK® SugarView

Roche

USER'S MANUAL

APP AND COLOR CARD

Quick Start Guide

⚠ WARNING

Risk of hypoglycemia (low blood glucose level) or hyperglycemia (high blood glucose level)

If you are on insulin therapy or if you take hypo-inducing oral antidiabetics (for example, sulfonylureas), this may lead to incorrect test results.

In such a case do **not** use this app for testing your blood glucose. Do **not** use test results of this app as a basis for making therapy decisions.

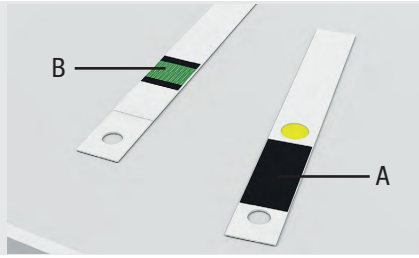
NOTE

The following instructions guide you through your first blood glucose test. This Quick Start Guide does not replace the detailed User's Manual of your app. Be sure to comply with the safety information in the User's Manual following this Quick Start Guide.

Camera Check and Blood Glucose Test

You must always do 2 scans of the Accu-Chek Active test strip attached to the color card with the app. Scan 1 checks the camera of your mobile device and the quality of the test strip. Scan 2 is for the blood glucose test. For scan 1 you do **not** need to prick your finger. **Do not apply blood until the instructions tell you to do so!**

Before you scan, look at the test strip closely. It has 2 sides and each side has a function. The side with the black rectangle (A) is used to see and scan the color change of the round window. The side with the square green test area (B) is used to apply a blood drop.



Get Everything Ready

1 Tap on your mobile device to open the app.

2 Tap TEST NOW on the Welcome! screen. Or tap from the Dashboard and mark when you are doing your blood glucose test.

3 Wash your hands with warm water and soap. Dry your hands thoroughly.

4 Get a finger pricker, a sterile lancet, an Accu-Chek Active test strip, and an Accu-Chek SugarView color card ready.

5 Check the use by date on the test strip container.

6 Clean and disinfect the color card and the table before each measurement.

7 Insert the sterile lancet into your finger pricker.

NOTE

For scan 1 and scan 2 the app will guide you to position your camera correctly through a color card image on screen and short pop-up messages, if necessary. It is important that you read these messages.

⚠ WARNING

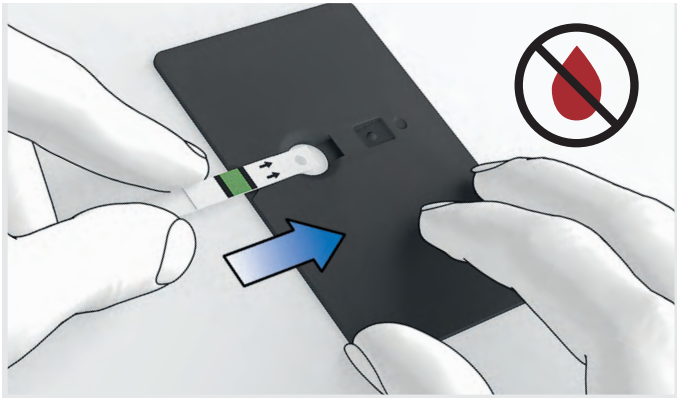
Risk of infection

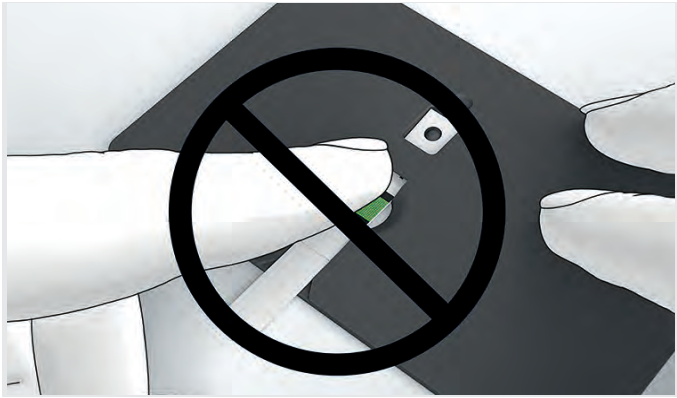
- Any object coming into contact with human blood is a potential source of infection.
- Follow the cleaning instructions to avoid self-infection and infection of third parties by contaminated material.

Preparation

1 Put the color card on a table. Make sure that the **black side** of the color card is facing **upwards**.

2 Insert the test strip into the test strip slot of the color card. Make sure that the side of the test strip with the **square green** test area in the center is facing **upwards**.



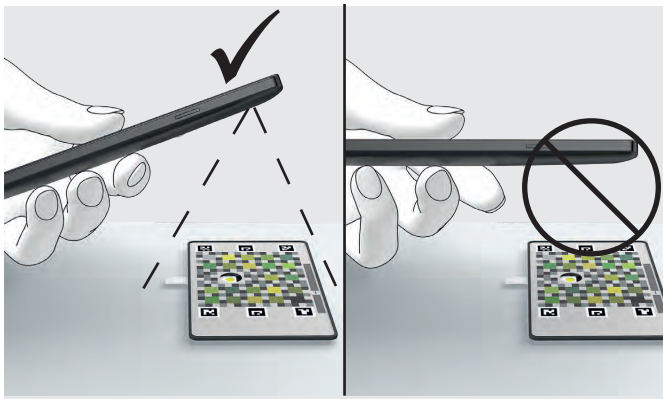


3 Turn the color card around. Make sure that the **black side** of the color card is facing **downwards**.

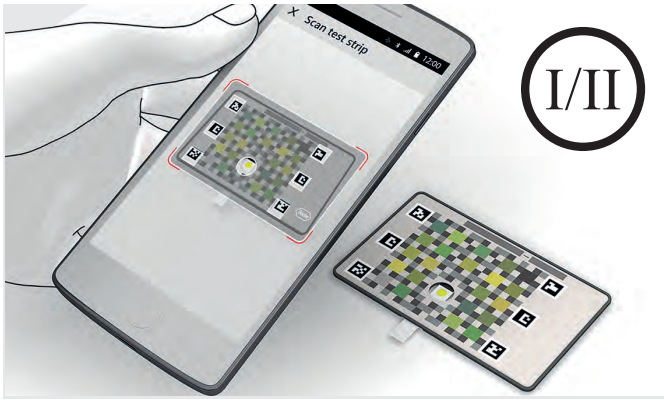
Scan 1 of 2 – Quality Check

1 The first scan is a quality check. **Do not apply blood yet!** Tap LET'S DO THE FIRST SCAN!

2 The scan starts automatically. To successfully take a measurement, tilt your phone so the color card and the frame displayed on the screen match.



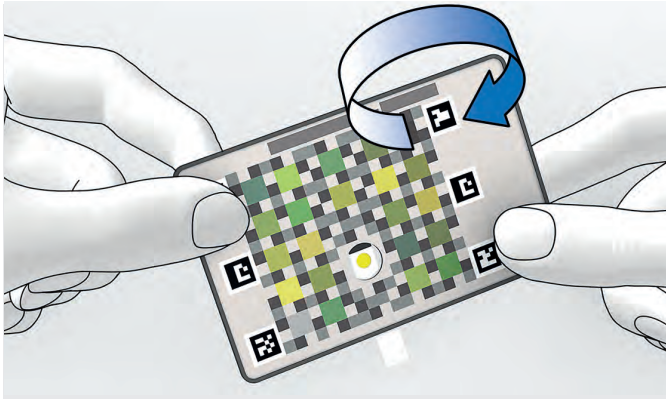
3 **Match the 4 corners of the color card with the 4 white corners showing in the screen.** If you have difficulty to hold your phone steady, you can steady your arms on the table. The app will guide you to position your camera correctly through short pop-up messages. When the color card is matched correctly, the frame on the screen turns green.



4 Prepare for scan 2 immediately. If too much time passes between scan 1 and scan 2, the app shows a timeout message. You can no longer use the test strip. You have to repeat scan 1 with a new test strip.

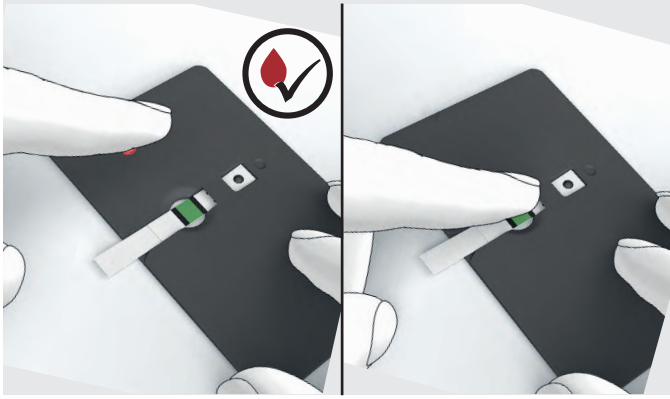
Scan 2 of 2 – Blood Glucose Test

1 Turn the color card around. Make sure that the **black side** of the color card is facing **upwards**. Do not remove the test strip from the color card. Use the same test strip as for the first scan. Follow the prompts on the app.



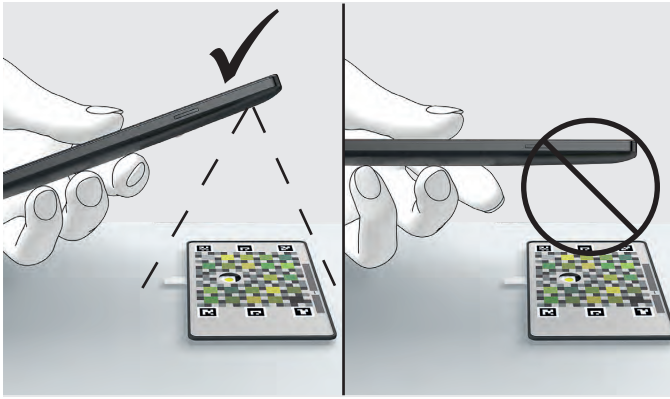
2 Prick your finger using the finger pricker.

3 Apply the blood drop onto the **square green test area** on the test strip. **Do not apply blood on the colored side of the color card.**

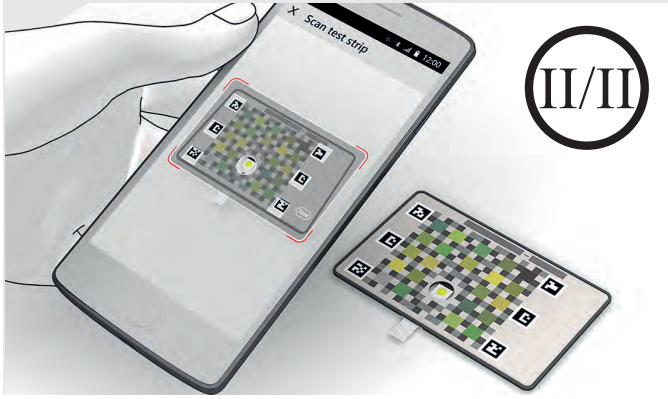


4 Wait for 3 seconds. Then, turn the color card around. Make sure that the **colored side** of the color card is facing **upwards**.

5 The scan starts automatically. To successfully take a measurement, tilt your phone so the color card and the frame displayed on the screen match.



6 **Match the 4 corners of the color card with the 4 white corners showing in the screen.** When the color card is matched correctly, the frame on the screen turns green. Afterwards the app displays your blood glucose range as a position on a 6-level target range indicator.



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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, don't worry! Simply head to our troubleshooting section (chapter 16) of this User's Manual.

We're here to help! Just contact our customer support. For more details, see chapter 20.

This User's Manual features the following boxes:

⚠ WARNING

A warning contains safety information that requires your careful attention and informs you about risks to your health. Neglecting this information may lead to life-threatening situations.

NOTE

Check out our note boxes! They give you additional practical hints.

Download Version and Printed Copy

This User's Manual is available to download* from https://www.accu-chek.com. Alternatively, you may order a printed copy from customer support.

* download may incur data usage/charges

2 Intended Use

The Accu-Chek SugarView app is used together with the Accu-Chek SugarView Color Card (V4.0 or higher, both CE-labeled, non-ISO). The Accu-Chek SugarView app together with the Accu-Chek SugarView Color Card are intended to be used as a digital visual check of the color change on the Accu-Chek Active test strip once a capillary blood sample has been applied onto the test field. The app interprets the color change on the test strip using the standard color information provided by the accessory Accu-Chek SugarView Color Card. A blood glucose result is displayed on the smartphone display, expressed in form of a semi-quantitative blood glucose range. The results are saved into the app and can be used as an electronic blood glucose result diary. The Accu-Chek SugarView app (V4.0 or higher) used together with the Accu-Chek SugarView Color Card is intended to provide semi-quantitative information on the blood glucose concentration and how it is influenced by food intake, physical activity, illness and other factors. The app is primarily intended to be used by the user himself, but a third party (e.g. relative, caregiver) may also employ it. Not for patients on insulin therapy or on hypo-inducing NIADs (e.g. Sulfonylureas). The BG range displayed by the Accu-Chek SugarView app **must not be used** for insulin dose or therapy adjustments.

Intended users are

- adults (≥ 18 years) with type 2 diabetes on lifestyle intervention and/or noninsulin anti-diabetics (NIADs)
- adults (≥ 18 years) with pre-diabetes
- health care professionals (physicians, assistants/nurses) who may use the app for training and assisting the user
- caregivers, who may use the app to assist the user

3 Release Notes

See distribution platform (for example Google Play) for the latest release notes of the app.

4 The Main Features

- **Digital visual test**

  Perform a digital visual test of your blood glucose range using your mobile device's camera. All you need is the app installed on your mobile device, an Accu-Chek Active test strip, an Accu-Chek SugarView color card, a finger pricker, and a lancet.

- **Step by step guide & video**

  An optional step by step guide in the app guides you through the blood glucose test. In addition, a video shows you the most important steps of blood glucose testing.

- **Target range indicator**

  A 6-level target range indicator shows if your blood glucose is within the target range or not.

- **Testing goals**

  You can optionally select a pre-set testing goal to learn when to test and to get the most out of the test strips available to you.

- **Goal tracking**

  Track your selected goal and check your goal progress.

- **Marking test results**

  You can mark test results with different symbols which indicate different events connected to the test results, such as "before meal" or "after meal".

- **Data transfer**

  The app transfers your test results to your Roche account. An internet connection is required. You can test without an existing internet connection. The test results will be transferred automatically as soon as the connection is back.

- **Dashboard**

  The Dashboard allows you to view all relevant data at a glance such as when to test your blood glucose range next (if you have selected a testing goal) or your previous tests.

- **Previous blood glucose tests**

  Take a look at your previous blood glucose tests. You can switch between 3 different views (day, week, and month) to see more details.

- **Account creation**

  Create a Roche account to access the app and receive up-to-date information about managing diabetes.

- **Encrypted Data**

  Data stored by the app on your mobile device or shared with your Roche account is encrypted.

- **Selectable time periods**

  You can filter your measurements in selectable time periods.

5 Installation and Updates

5.1 Installing and Starting the App

Download and Installation

First you need to download the app on your mobile device. You can download the app from the following distribution platform:

- Google Play

You can find the app by searching for “Roche”, “Accu-Chek” or “Accu-Chek SugarView”.

Download the app and install it on your mobile device. Information on how to install apps on the mobile device is contained in the User’s Manual of your mobile device as well as in Google Play.

System Requirements

The app requires the following operating system:

- Android™

The app works with various mobile devices available on the market. The app checks if your mobile device is compatible. If your mobile device is not compatible, a message appears. For more details, see chapter 19.

Starting the App

After you have downloaded and installed the app, you can start the app.

1 Go to the app menu of your operating system.
2 Tap .

Permissions Required by the App

The app requires the following permissions:

- Full network access to share data with your Roche account and the Roche Diabetes Care cloud system.
- Access to your mobile device’s camera.
- Access to your mobile device’s memory.

NOTE

The app requires access to your mobile device's camera and memory. The first time you start a blood glucose test, a message appears asking for your permission to access the camera and memory. If you don't grant permission, you won't be able to use the app properly.

5.2 Data Protection

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

5.3 Closing the App

For information on closing apps, refer to the User's Manual of your mobile device or the operating system.

5.4 Uninstalling the App

For information on uninstalling apps, refer to the User's Manual of your mobile device or the operating system.

5.5 Updating the App

The app only runs correctly on compatible operating systems. Check the distribution platform (for example Google Play) to verify if the app is compatible for the new operating system version, before you update your mobile device's operating system. If the app is not suitable, decline the update.

The app notifies you when you open the app and a new version is available.

6 Getting to Know the App

6.1 Navigation Elements

You'll find the following navigation elements on some screens of the app:

- Tap on the Dashboard to start a blood glucose test.
- Tap ← to return to the previous screen or element (for example the previous day in the calendar).
- Tap → to move to the next screen or element (for example the next day in the calendar).
- Tap ⊗ to close a menu.
- Dots in a horizontal line ● ○ ○ indicate that you can swipe left or right through the sections. The section you are currently looking at is marked with a bolder dot.

6.2 Buttons

You can access the Buttons from almost any screen.

- Tap HOME (1) to go to the Dashboard.
- Tap GOAL (2) to select a goal or to track your selected goal.
- Tap PROFILE (3) to go to the Account Settings.

Buttons

7 Account

7.1 Introduction

The first time you open the app, you'll be given a brief walk-through to help you understand some of the features. After this, you have 2 options:

- Tap SIGN IN, if you have already created a Roche account.
- Tap CREATE AN ACCOUNT, if you are using this app for the first time.

Before you can use the app, you must confirm that you are at least 18 years old. The app asks you to confirm your age when you create an account.

7.2 Create an Account

If you don't have a Roche account, you can register with your email address.

1. Tap CREATE AN ACCOUNT.

   Tap the text fields and enter the required information to create an account.
2. Tap REGISTER NOW.

   An account confirmation email has been sent to your email address. Follow the confirmation link in your email.
3. Tap OK.

   You've created an account. You arrive at the SIGN IN screen.

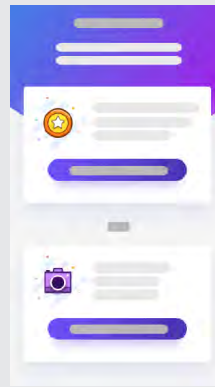
7.3 Sign In

To sign in, enter the email and password of your Roche account.

1 Tap the text fields and enter the required information to sign in.

2 Tap SIGN IN.

The first time you sign in, you will arrive at the Welcome! screen. From the second sign in onwards the Dashboard appears directly.



Welcome! screen

NOTE

You must be signed in to test your blood glucose range. We recommend you stay signed in between blood glucose tests, so you can easily test your blood glucose range even when you are offline. That way, your blood glucose ranges are safely stored in the app.

7.4 Sign Out

1 Tap PROFILE from the buttons.

2 Tap Sign Out.

A confirmation message appears.

3 Tap SIGN OUT again to confirm, or tap Cancel.

After signing out, you return to the Sign In screen.

NOTE

You only can sign out when your mobile device is connected to the internet. Therefore, the Sign Out menu is only shown when your mobile device is online.

7.5 Reset Password

If you forgot your Roche account password, you can reset it.

1 Tap Forgot password? from the Sign In screen.

2 Enter your email address and tap SUBMIT. A password reset email has been sent to your email address.

3 Open the email and tap on the link in it.

4 Enter a new password and confirm it.

5 Go back to the app and tap BACK TO SIGN IN.
After resetting the password, you return to the Sign In screen.

8 Welcome Screen

You have 2 options on the Welcome! screen:

- To select a goal, tap GO TO GOAL OVERVIEW (1). For more details, see chapter 9.
- To test your blood glucose, tap TEST NOW (2).

Welcome! screen

9 Select Your Goal

9.1 Goal Types

You can select 1 of 3 goals, all of which have a start and an end. The goals give you guidance on how and when to test your blood glucose range.

- 3-Day Profile – Blood glucose levels fluctuate over the course of your day and are affected by many environmental factors such as eating, physical activity or stress. With the goal 3-Day Profile you can learn more about yourself and the collected results can support the next consultation with your doctor.
- My Meals – To learn how your eating habits affect your blood glucose ranges, select My Meals and test in pairs before and after meals.
- Start Small – Perhaps you're not sure which is the right goal for you, Start Small is designed to help you learn how to stay on track by introducing you to a more structured way of testing your blood glucose range.

9.2 Select a Goal

1. From the Welcome! screen tap GO TO GOAL OVERVIEW.
2. Tap on one goal you're interested in to see more details.
3. Once you've found the goal you would like to achieve, scroll down and tap SELECT THIS GOAL.
   After you've selected a goal, you arrive at the Dashboard.

NOTE

We think selecting a goal is a helpful feature because it gives you guidance on when to test your blood glucose range. However, if you prefer to test your blood glucose range at the most convenient time for you, just tap Skip. You can select a goal at any time. Tap GOAL from the buttons or tap SELECT A NEW GOAL from the Dashboard.

After you've accomplished a goal you arrive at the Congratulations! screen.

- Tap SELECT A NEW GOAL to select a new goal or tap RETURN TO DASHBOARD, if you don't want to select a new goal.

9.3 Change a Selected Goal

1. Tap GOAL from the buttons.
2. Tap CHANGE MY GOAL.
3. Tap on the goal you would like to achieve.
4. Scroll down and tap SELECT THIS GOAL.
5. Tap CHANGE GOAL.
   After you've selected a goal, you arrive at the Dashboard.

9.4 Track Your Goal

Once you've selected a goal, you can access the Your goal tracking screen. There you'll find information about your selected goal. A circle at the top of the Your goal tracking screen shows your goal progress.

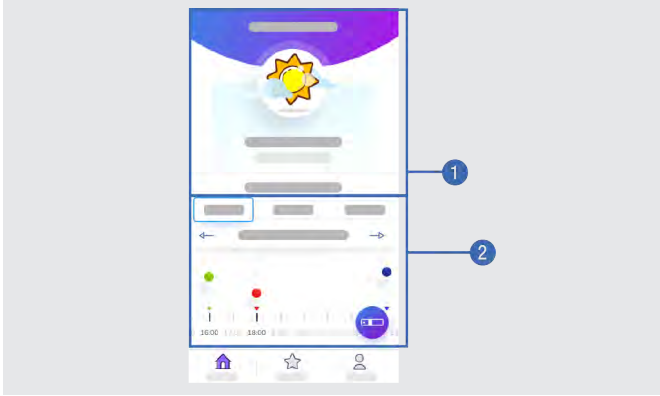
Here's how to access the Your goal tracking screen:

- Tap GOAL from the buttons.

10 Dashboard

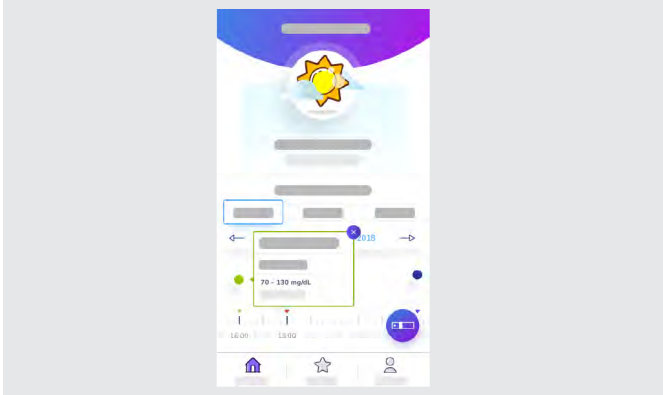
10.1 Dashboard Sections

The Dashboard is the center of the app and is divided into 2 sections. If you have selected a goal, you can see in the upper section (1) when you should test your blood glucose range next according to your selected goal. In the lower Previous tests section (2), you'll find information about the blood glucose tests you have already performed. The lower section has different views. Tap DAY, WEEK, or MONTH for more details on your blood glucose ranges.



2 sections of the Dashboard

10.2 Day View



The day view on the Dashboard.

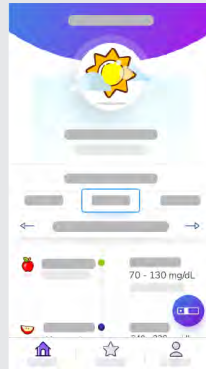
The day view graph shows the time of the day you've tested your blood glucose range over the course of 1 day.

- A dot equals a blood glucose test.
- The color and the position of the dot tells you your blood glucose range.
- Tap a colored dot to see which test type you marked (for example Before meal, After meal etc.) and your blood glucose range.
- An arrow tip (▼) shows the time of the day you tested your blood glucose. The arrow tip has the same color as the corresponding dot, depending on your blood glucose range.

Here's how to use the day view:

1. Tap DAY.
2. Use the arrows (← or →) to move from day to day.
3. Tap a colored dot to get more information (for example blood glucose range).
4. Move the graph with your finger to the left or to the right to view the different hours in a day.

10.3 Week View



The week view on the Dashboard.

The week view lists your blood glucose ranges over the course of a week. A dot equals a blood glucose test at a certain time. Next to each dot you'll find the following information:

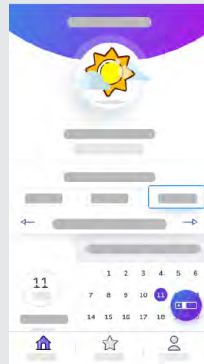
- Time and range of your blood glucose test.
- Which test type you marked (for example Before meal, After meal etc.).

Here's how to use the week view:

1 Tap WEEK.

2 Scroll up or down to view each day of a week.

10.4 Month View



The month view on the Dashboard.

The month view displays a calendar. A dot underneath a calendar day shows that you tested your blood glucose range that day. Tap that day and the number of blood glucose tests you performed on that day appears on the left side of the screen.

Here's how to use the month view:

1. Tap MONTH.
2. Use the arrows (← or →) to skip between months. Or, simply tap a day in the calendar to view it.
3. Tap Details to see more about your blood glucose tests on the selected day.

Tap Details to see the following information:

- Time and range of your blood glucose test.
- Which test type you marked (for example Before meal, After meal etc.) and your blood glucose range.

NOTE

To view Details, you must have made **at least** 1 blood glucose test on that day. Such days are marked with a dot below the date in the calendar.

11 Test Your Blood Glucose

11.1 Required Equipment

Before you test your blood glucose range, you need the following equipment:

- A finger pricker
- A sterile lancet
- An Accu-Chek Active test strip
- An Accu-Chek SugarView color card

NOTE

The app only works with the Accu-Chek Active test strips. You cannot get a blood glucose range with other test strips. Go to PROFILE > Support Information > Additional Test Strip Information and read the additional information.

11.2 Preparing a Blood Glucose Test

1. Wash your hands with warm water and soap. If you can't wash your hands with water, clean your hands with alcohol wipes. Dry your hands thoroughly.
2. Get a finger pricker, a sterile lancet, an Accu-Chek Active test strip, and an Accu-Chek SugarView color card ready.
3. Check the use by date of the test strip on the test strip container. Do not use test strips past the use by date.
4. Insert the sterile lancet into your finger pricker.
5. If there is too much light, move to a room with less light.

11.3 Start a Blood Glucose Test

⚠ WARNING

Risk of hypoglycemia (low blood glucose level) or hyperglycemia (high blood glucose level)

If you are on insulin therapy or if you take hypo-inducing oral antidiabetics (for example, sulfonylureas), this may lead to incorrect test results.

In such a case do **not** use this app for testing your blood glucose. Do **not** use test results of this app as a basis for making therapy decisions.

You can start a blood glucose test in 2 different ways.

Start a Test from the Welcome! Screen

- Tap TEST NOW.

NOTE

The Welcome! screen is only visible after the first time you sign in.

Start a Test from the Dashboard

1. Tap .
2. Mark when you are doing your blood glucose test. Tap on one of the following test types:
   - Fasting (When you wake up)
   - Before meal
   - After meal
   - Bedtime
   - Other

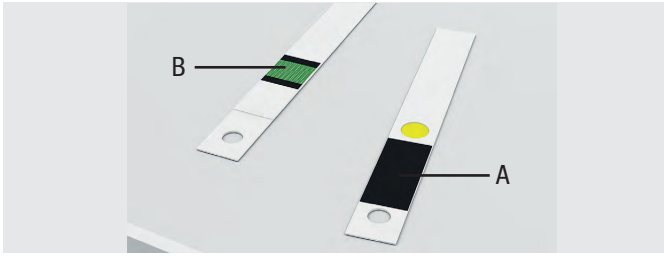
NOTE

A step by step guide and a video appear in the app, that guides you through a blood glucose test. Follow the instructions or, if you know how it works, simply tap Skip.

11.4 Scan the Color Card With the Test Strip Inserted

You must always do 2 scans of the Accu-Chek Active test strip attached to the color card with the app. Scan 1 checks the camera of your mobile device and the quality of the test strip. Scan 2 is for the blood glucose test. For scan 1 you do **not** need to prick your finger. **Do not apply blood until the instructions tell you to do so!**

Before you scan, look at the test strip closely. It has 2 sides and each side has a function. The side with the black rectangle (A) is used to see and scan the color change of the round window. The side with the square green test area (B) is used to apply a blood drop.



The Accu-Chek Active test strip

NOTE

For scan 1 and scan 2 the app will guide you to position your camera correctly through a color card image on screen and short pop-up messages, if necessary. It is important that you read these messages.

⚠ WARNING

Risk of infection

- Any object coming into contact with human blood is a potential source of infection.
- Follow the cleaning instructions to avoid self-infection and infection of third parties by contaminated material.

Preparation

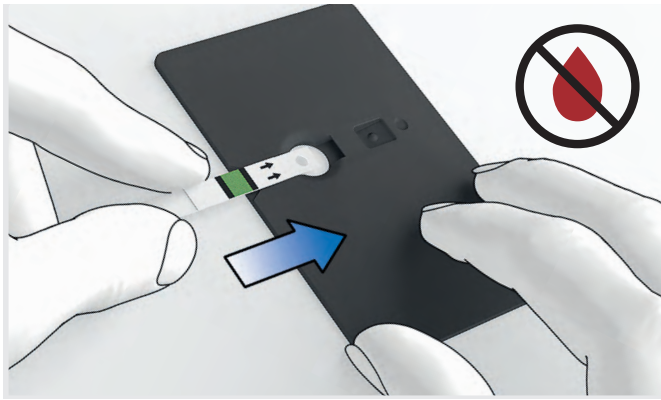
1 Remove a test strip from the test strip container. Close the test strip container tightly with its original cap.

2 Put the color card on a table. Make sure that the **black side** of the color card is facing **upwards**.

NOTE

Make sure the color card lies directly on the table and **not on a tablecloth or tissue**.

3 Insert the test strip into the test strip slot of the color card. Make sure that the side of the test strip with the **square green** test area in the center is facing **upwards**.



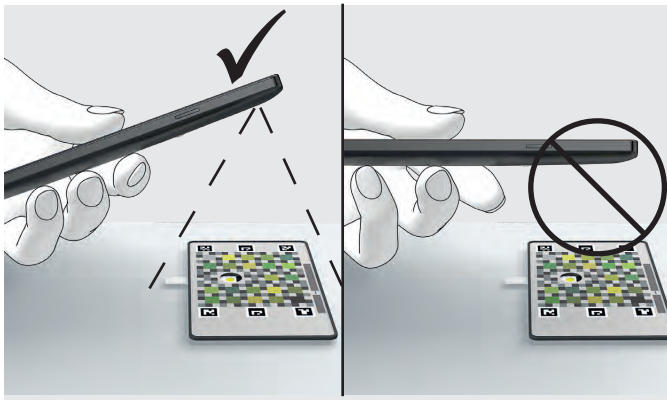
4 Turn the color card around. Make sure that the **black side** of the color card is facing **downwards**.

Scan 1 of 2 – Quality Check

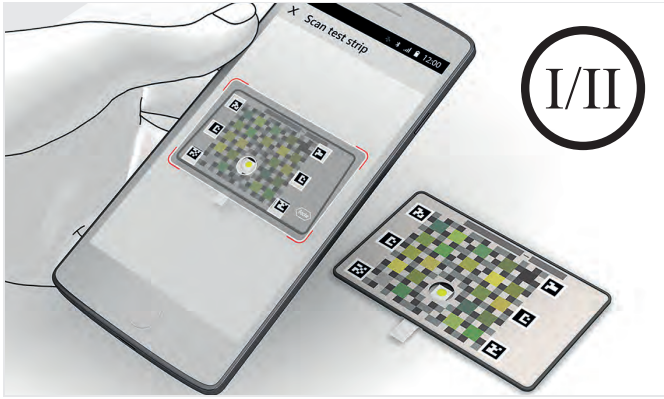
First, scan the color card **without** applying blood on the test strip to ensure that the test strip is good for use and the camera settings fit the environmental light conditions.

1 **Do not apply blood yet!** Tap LET'S DO THE FIRST SCAN!

2 The scan starts automatically. To successfully take a measurement, tilt your phone.



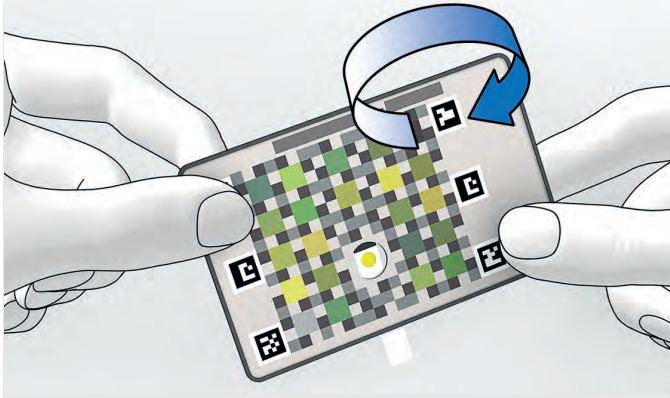
3 **Match the 4 corners of the color card with the 4 white corners showing in the screen.** If you have difficulty to hold your phone steady, you can steady your arms on the table. The app will guide you to position your camera correctly through short pop-upmessages. When the color card is matched correctly, the frame on the screen turns green. The app takes the scan automatically. A confirmation message appears on the display after a successful scan.



4 Prepare for scan 2 immediately. If too much time passes between scan 1 and scan 2, the app shows a timeout message. You can no longer use the test strip. You have to repeat scan 1 with a new test strip.

Scan 2 of 2 – Blood Glucose Test

1 Turn the color card around. Make sure that the **black side** of the color card is facing **upwards**. Do not remove the test strip from the color card. Use the same test strip as for the first scan. Follow the prompts on the app.



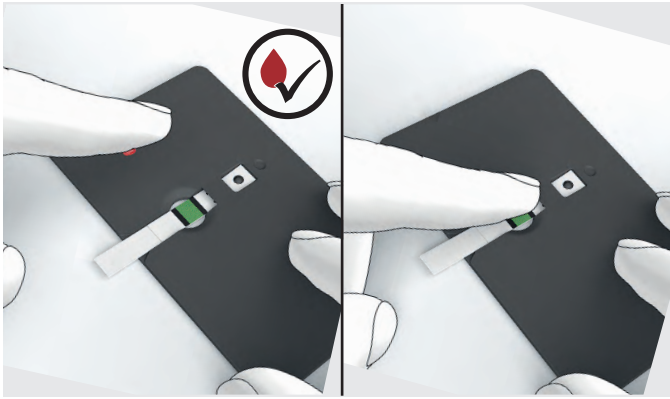
2 Prick your finger using the finger pricker.

NOTE

In general, you can get blood from any of your fingers. However, if you have a skin or fingernail infection it is better to choose another finger. We recommend obtaining blood from the sides of the fingertips as these areas are the least sensitive to pain. This area doesn't hurt so much while pricking, and the puncture site may heal faster. If possible, prick a finger that you use less in everyday life. For example, the middle finger.

3 Gently squeeze your finger to assist the blood flow. If you cleaned your finger with an alcohol wipe, then wipe off the first blood drop to remove residual alcohol. Gently squeeze your finger again to get a second blood drop. If you need to clean your finger with an alcohol wipe, always use an unused alcohol wipe.

4 Apply the blood drop onto the **square green test area** on the test strip. The black side of the color card is still facing upwards. **Do not apply blood on the colored side of the color card.** Do not press your finger onto the square green test area. This can lead to incorrect test results.

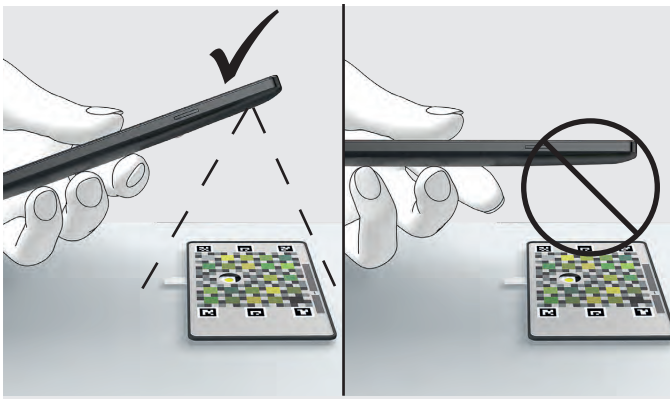


5 Wait for 3 seconds. Then, turn the color card around. Make sure that the **colored side** of the color card is facing **upwards**.

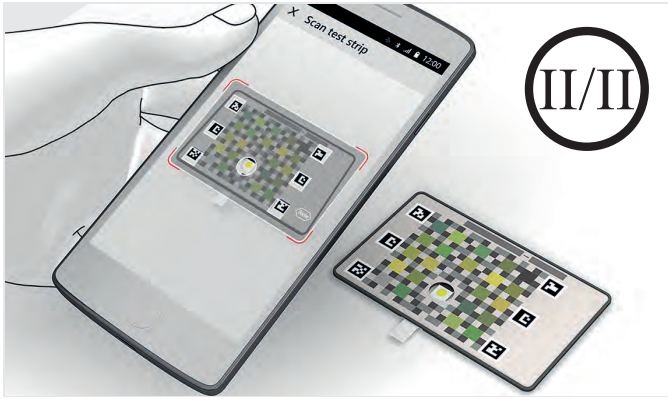
NOTE

Make sure the color card lies directly on the table and **not on a tablecloth or tissue**.

6 The scan starts automatically. To successfully take a measurement, tilt your phone.



7 **Match the 4 corners of the color card with the 4 white corners showing in the screen.** Steady your arms on the table or stand up. The app will guide you to position your camera correctly through short pop-up messages. When the color card is matched correctly, the frame on the screen turns green.



8 A confirmation message appears on the display after a successful scan.

The app displays your blood glucose range as a position on a 6-level target range indicator and gives you feedback based on your blood glucose range. For more details, see chapter 12.

9 Tap DONE to return to the Dashboard.

10 If the Congratulations! screen appears, you have 2 options:

- Tap SELECT A NEW GOAL to select a new goal.
- Tap RETURN TO DASHBOARD, if you don't want to select a new goal.

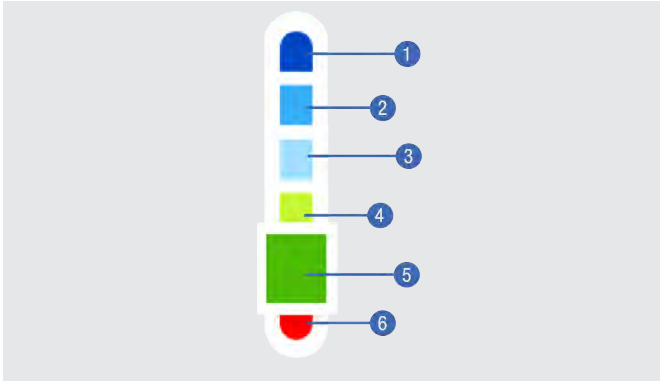
NOTE

Your blood glucose range can vary, depending on several things: food, medicine, your overall health, stress level, travel and/or physical activity.

12 Target Range Indicator

12.1 How to Read the Target Range Indicator

After you have tested your blood glucose, your range is shown as a position on a 6-level target range indicator. This shows where your blood glucose is on the scale, and if you are within the blood glucose target range or not. The levels in the range are based on the 2017 American Diabetes Association (ADA) standards[1].



The Target Range Indicator

1. You are above the blood glucose target range. The blood glucose range is very high: between 301 to 600 mg/dL (between 16.7 to 33.3 mmol/L).
2. You are above the blood glucose target range. The blood glucose range is high: between 181 to 300 mg/dL (between 10.0 to 16.6 mmol/L).
3. If you tested before a meal, you are above the blood glucose target range. The blood glucose range is slightly high: between 131 to 180 mg/dL (between 7.3 to 10.0 mmol/L).
4. If you tested after a meal, your blood glucose range is good. You are within the blood glucose target range: between 131 to 180 mg/dL (between 7.3 to 10.0 mmol/L).
5. You are within the blood glucose target range and right on target: between 71 to 130 mg/dL (between 3.9 to 7.2 mmol/L).
6. You are below the blood glucose target range. The blood glucose range is low: between 20 to 70 mg/dL (between 1.1 to 3.9 mmol/L).

[1] "Diabetes Care 2017;40:S48-56"

The app displays the test results in the unit of measurement **mg/dL** or **mmol/L**. The app sets the unit of measurement when you create your account. The unit of measurement depends on the country you select. If you do not know which unit of measurement is correct for you, contact your doctor or pharmacist. Using the wrong unit of measurement may cause misinterpretation of your actual blood glucose range. You can change the unit of measurement. For more details, see chapter 14.

12.2 Evaluating Test Results

⚠ WARNING

Risk of hypoglycemia (low blood glucose level) or hyperglycemia (high blood glucose level)

If the test result does not match how you feel, for example, it is unexpectedly low or high, repeat the blood glucose test.

If the new test result still does not match how you feel, contact your doctor.

Your blood glucose range can vary, depending on several things:

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

Above Target Range (Hyperglycemia)

This can happen when you eat too much sugary foods. You get glucose from the foods you eat. We differentiate between high and very high blood glucose ranges.

- **High** (between 181 to 300 mg/dL (between 10.0 to 16.6 mmol/L)): Have you eaten something that could have made your blood glucose rise high? Avoid sugary foods and do some exercise to lower your blood glucose.
- **Very high** (between 301 to 600 mg/dL (between 16.7 to 33.3 mmol/L)): Traces of food on your fingers can affect the test result. Wash your hands again and repeat the test. If your blood glucose is still in a high range, you should discuss this with your doctor as soon as possible. If you have symptoms such as dizziness and blurry vision, immediately seek medical attention.

Below Target Range (Hypoglycemia)

A low blood glucose can be caused by missing a meal, delaying a meal, exercising more than usual or taking too much medication.

- **Low** (between 20 to 70 mg/dL (between 1.1 to 3.9 mmol/L)): If your blood glucose range is low, eat or drink fast acting carbohydrates such as fruit juice, a sugary snack or drink (not diet). Wait 15 minutes and test your blood glucose again. If your blood glucose is still low, **immediately** seek medical attention. If you feel too weak to move without help, call an ambulance.

12.3 Symptoms of Low or High Blood Glucose

When your blood glucose is **low**, symptoms could be (but are not limited to):

- Anxiety
- Shakiness
- Sweating
- Headache
- Increased hunger
- Dizziness
- Pale skin color
- Sudden change in mood or irritability
- Fatigue
- Difficulty in concentrating
- Clumsiness
- Palpitations
- Confusion

When your blood glucose is **high** or **very high**, symptoms could be (but are not limited to):

- Increased thirst
- Frequent urination
- Blurred vision
- Drowsiness
- Unexplained weight loss

13 My Progress

Within the My Progress menu, you'll find detailed information on previous blood glucose tests. You can see all details at a glance, for example:

- A summary of your blood glucose results.
- How often you have been in a specific blood glucose range.
- The last completed goal and the last expired goal.

Here's how to access the My Progress menu:

- Tap from the Dashboard.

The My Progress screen appears.

You can share the information given in the My Progress menu as a PDF file with other people.

- Tap in the right top corner.

If you have not tested your blood glucose in the last 90 days, you have 2 options:

- Tap SELECT A GOAL, if you want to select a goal.
- Tap TEST NOW, if you want to take a measurement.

14 Account Settings

14.1 Change the Unit of Measurement

Within the Unit of Measurement menu, you can change the unit of measurement for your blood glucose results. This app displays test results in **mg/dL** and **mmol/L**. The initial setting depends on the country you select during account creation. **Ask your doctor or pharmacist about your unit of measurement before changing it in the app.**

1 Tap PROFILE from the buttons.

2 Tap Unit of Measurement.

The Unit of Measurement screen appears.

3 Select the unit of measurement you want to use.

- Tap mg/dL for setting mg/dL as your unit of measurement.
- Tap mmol/L for setting mmol/L as your unit of measurement.

4 Tap Confirm.

By tapping Confirm you assure that you are aware of your unit of measurement. From now on the app uses the selected unit of measurement for all future and past blood glucose results. You can change the unit of measurement again at any time.

14.2 Change the Privacy Settings

Within the Privacy Settings menu, you'll find the settings to control your privacy. Some settings are mandatory to use the app. If you disable such mandatory settings, a message appears and asks you if you want to delete your account. If you tap YES, your Accu-Chek SugarView account and your personal data will be deleted. In exceptional cases, longer storage may be required. This can be the case in the following situations:

- To fulfill post-contractual obligations
- To comply with statutory storage obligations
- Disclosure duties
- To assert, exercise, or defend legal claims (limitation periods)

1 Tap PROFILE from the buttons.

2 Tap Privacy Settings.

The Privacy Settings screen appears. Now you can change the privacy settings according to your preferences.

NOTE

You can only change privacy settings when your mobile device is connected to the internet. If your mobile device is offline, a message appears.

14.3 Support Information

Within the Support Information menu, you'll find several information, such as a video explaining how to perform a measurement or a logbook, where you can see all events of the app at a glance.

1 Tap PROFILE from the buttons.

2 Tap Support Information.

The Support Information screen appears. Now you can access several sub-menus to see the information you require (for example this User's Manual or contact information for your country in case you need support).

14.4 About Menu

Within the About menu, you'll find the trademark statement, copyright, and regulatory related information.

1 Tap PROFILE from the buttons.

2 Tap About.

14.5 Terms of Use Menu

Within the Terms of Use menu, you'll find detailed information regarding the app usage.

1 Tap PROFILE from the buttons.

2 Tap Terms of Use.

14.6 Sign Out Menu

Within the Sign Out menu, you can sign out from the app. For more details, see chapter 7.

1 Tap PROFILE from the buttons.

2 Tap Sign Out.

15 Data Exchange

If you are signed in and a network connection is available, your data (for example, your blood glucose ranges, unit of measurement, app version etc.) will be automatically exchanged with the following devices and systems:

- Roche Diabetes Care cloud system
- Your mobile device
- Your mobile device's operating system

16 Troubleshooting

16.1 Problems and Possible Causes

In some cases, the blood glucose test doesn't work as you might expect. This can happen due to several causes. Let's learn how you can avoid an incorrect blood glucose test and make it work properly.

Environmental Conditions

Some environmental conditions can cause errors during the blood glucose test.

- Go to a location with room temperature and enough shade, if any of the following applies:
  - The location temperature is too warm or too cold
  - The location has too much light or sunlight
  - The location is too humid

Test Strips and Handling

- Use a **new** test strip and repeat the blood glucose test, if any of the following applies:
  - Test strip has already been used
  - Test strip has expired
  - Test strip is soiled or sticky (for example, due to glucose residue from food or drink)
  - Test strip is damaged
  - Wrong type of test strip has been used
  - Blood drop has been applied on the back of the test strip and not as described in chapter 11
  - Hands have not been washed and dried as described in chapter 11
  - Test strip has been put on a table with a tablecloth or tissue and not as described in chapter 11
  - Test strip has been put on a table that contains glucose residue or dirt

16.2 Unexpected Blood Glucose Ranges

Have you put the color card and the test strip on a table with a tablecloth or tissue?

If so, remove the tablecloth or tissue from the table and repeat the blood glucose test. A tablecloth or tissue may soak up the blood drop of the test strip. This can lead to an incorrect blood glucose range.

Were the test strips expired?

Check the use by date on the test strip container. Discard the test strips, if they are past the use by date. Repeat the blood glucose test with an unexpired test strip.

Was the cap on the test strip container always closed tightly?

Only use test strips, if the cap is properly and tightly closed. If the container was not closed tightly, use a new test strip, and repeat the quality check.

Was the test strip used immediately after it was removed from the test strip container?

If not, use a new test strip and repeat the blood glucose test.

Were the test strips stored in a cool, dry place?

If not, repeat the blood glucose test with a properly stored test strip.

Did you follow the instructions?

If not, read chapter 11 and repeat the blood glucose test. Still having problems? Contact customer support.

NOTE

Contact information for your country can be found in the main menu. Go to PROFILE > Support Information > Support Contact.

16.3 Warning Messages

Warning messages inform you about relevant technical states of the app or about possible risks for your therapy or health.

Below you can find a description of all warning messages and how to solve them.

Phone too far away

Your mobile device's camera is too far away from the color card. Move your camera closer to the color card to enable scanning. Match the color card with the frame displayed on the screen.

Phone too close

Your mobile device's camera is too close to the color card. Move your camera further away from the color card to enable scanning. Match the color card with the frame displayed on the screen.

Test strip not found

The app could not find the test strip. Make sure that the test strip is inserted correctly into the color card. Tilt your mobile device's camera above the color card. Match the color card with the frame displayed on the screen. The app will guide you to position your camera correctly.

Color card not found

Tilt your mobile device's camera above the color card. Match the color card with the frame displayed on the screen.

Too much rotation

Reduce the rotation of your mobile device. Tilt your mobile device's camera above the color card. Match the color card with the frame displayed on the screen.

Tilt your phone a bit more

Tilt your mobile device a bit more. Match the color card with the frame displayed on the screen.

Tilt your phone a bit less

Tilt your mobile device a bit less. Match the color card with the frame displayed on the screen.

Too much light, change lighting conditions

Change lighting conditions or tilt your mobile device a bit more. There are too many reflections on the color card. Tilt your mobile device's camera above the color card. Match the color card with the frame displayed on the screen.

16.4 Error Messages

Error messages inform you about important malfunctions of the app. For most problems, the app displays a message with a short description of the problem and a proposed solution.

Below you can find a description of all error messages and how to solve them.

There is too much light

There is too much light to scan the color card. Move to a darker space and test again. If this is not possible, return the test strip to the test strip container immediately.

The test strip you are using is defective

The test strip you are using is defective. Use a new test strip and test again.

The scan took too long

The blood glucose test took too long. Use a new test strip and test again.

Low battery charge

The battery charge of your mobile device is low. Charge the battery of your mobile device and test again.

Measurement out of range

The app is not able to identify the blood glucose range. The blood glucose range is either too low (below 20 mg/dL (below 1.1 mmol/L)) or too high (above 600 mg/dL (above 33.3 mmol/L)). Use a new test strip and test again.

The app doesn’t support your mobile device

The app doesn’t support your mobile device. Contact customer support.

Color card unsupported

The app doesn’t support the color card you are using. Use another original Accu-Chek SugarView color card or update the app. Contact customer support.

Something went wrong

The app is not able to scan the color card. Use a new test strip and test again.

New test strip required

Make sure that you scan an unused test strip in an area with not too much light. Use a new test strip and test again.

Not enough blood

There is not enough blood on the test strip. Use a new test strip and test again. Make sure the color card lies directly on the table and not on a tablecloth or tissue.

17 Cleaning and Disinfecting

NOTE

- Use only cold water as a cleaning agent for the color card.
- Clean the color card using a lightly moistened tissue.

If the color card is dirty, it may be necessary to clean it. The color card may become contaminated. Tissues, which are lightly moistened, are suitable for cleaning.

1. Wipe the color card surface using a tissue lightly moistened with water.
2. Dab the hole of the color card and its surrounding area from both sides.

If the table is dirty, it may be necessary to clean it.

- Wipe the table using a tissue lightly moistened with water or 70 % isopropanol.

18 Disposal

18.1 Accu-Chek Active Test Strips

For information on disposal of the Accu-Chek Active test strips go to PROFILE > Support Information > Additional Test Strip Information.

18.2 Accu-Chek SugarView Color Card

Discard used, damaged, or expired color cards according to local regulations.

19 Technical Data

19.1 Accu-Chek SugarView App

Product Name
Accu-Chek SugarView app

App Type
App for mobile devices

App Version
Go to PROFILE > About

Supported Operating Systems
Android 7.0 or higher

Supported Mobile Devices
See distribution platform (for example Google Play) for supported mobile devices.

Product Classification
IVDD 98/79/EC, Annex II, list B, self-testing

Test Principle
The test area on the front of the test strip contains reagents. On the back of the test strip there is a round, colored control window. When blood is applied to the test area, the glucose dehydrogenase enzyme (Mut. Q-GDH 2) reacts with the blood glucose. The subsequent chemical reaction changes the color of the test area and of the control window. The app performs a digital visual test of the color of the control window, interprets the color change, and indicates on the display of the mobile device if your test result falls above, below, or within your blood glucose target range.

Performance Characteristics
The performance data was obtained using capillary blood from diabetic patients (system accuracy), venous blood (repeatability) and control solution (intermediate precision).

Calibration and Traceability
The system (app, color card and test strips) is calibrated with whole blood containing various glucose concentrations as a calibrator. The

reference values are obtained using the hexokinase method which is calibrated using the ID-GCMS method. The ID-GCMS method as the method of highest metrological quality (order) is traceable to a primary NIST standard. Using this traceability chain, the results obtained with these test strips for control solutions can also be traced back to the NIST standard.

System Accuracy
Overall accuracy: 97.4 %
100 % of all observations are in the target category ±1 category

Repeatability
Overall repeatability: 99.8 %
100 % of all observations are in the target category ±1 category

Intermediate Precision
Overall precision: 100 %
100 % of all observations are in the target category ±1 category

Performance Assessment by the User
100 % of the individual glucose ranges obtained by the subject were either within the correct target range or ± one target range when compared to the reference result.
73.3 % of the individual glucose ranges obtained by the subject were within the correct target range when compared to the reference result.

Temperature
During testing: +15 to +40 °C

Atmospheric Humidity
During testing: 15–85 % relative humidity

Measurement Start
App waits 13 seconds before the measurement starts after blood has been applied and confirmed.

Test Time
13–45 seconds

Measuring Range
20–600 mg/dL (1.1–33.3 mmol/L)

Blood Volume
1–2 µL (1 µL (microliter) = 1 thousandth of milliliter)

Interface

The app has an interface to the following systems:

- Roche Diabetes Care cloud system; requires a Roche account and an internet connection.
- Mobile device; requires access to mobile device's camera, memory and network connections.

Supported Platforms

Roche Diabetes Care cloud system

Special Requirements for Installing the App

- Mobile device with minimum 1 GB of RAM
- Mobile device with a camera with a minimum resolution of 1920×1080 pixels
- Access to Google Play

Maintenance

Download and installation of the Accu-Chek SugarView app updates (if available).

Memory

The app stores information related to the blood glucose tests, such as blood glucose ranges, day, time, and events like error or warning messages. The amount of information shown in the Dashboard is unlimited. The app stores 50 blood glucose tests in the measurement logbook.

Exchanged Data

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

- App version
- Mobile device model information
- Mobile device serial number
- Mobile device firmware information
- Name and version of operating system
- Blood glucose ranges and values measured
- Image of scan 1 and scan 2
- Filename of image of scan 2
- Encrypted patient ID (FHIR ID)

- Manufacturer information
- Time event classification
- Unit of measurement
- Selected country
- Color card ID (only color card)
- Color card LOT ID
- Information if the measurement was successful or unsuccessful
- Errors occurred during measurement
- Measurement logbook

License Information

For information on license agreements for open source software go to PROFILE > Software Licenses.

19.2 Required Supplies

- Accu-Chek SugarView app

  System component. For the latest technical information as well as key information on product specifications and limitations refer to this User's Manual. Go to PROFILE > Support Information > App Manual.

- Accu-Chek Active test strips

  System component. For the latest technical information as well as key information on product specifications and limitations on the Accu-Chek Active test strips go to PROFILE > Support Information > Additional Test Strip Information.

- Accu-Chek SugarView color card

  System component. The color card is an accessory that is intended for single person use only.

- Finger pricker
- Sterile lancets

Ask your customer support where you can obtain test strips, a finger pricker, sterile lancets, and a color card.

19.3 Color Card Storage and Handling

- Keep the color card away from sunlight.
- Avoid mechanical stress on the color card as this can cause scratches or dents, for example.
- Keep the color card away from abrasive material, for example, sand.
- Do not bend the color card, for example, by putting it into a pants pocket.
- Do not expose the color card to extreme temperatures (for example, in a glove compartment of a car).
- Store the color card between -20 and +45 °C.
- If the color card is very wet or has been exposed to high levels of humidity, let the color card dry thoroughly before using it.

20 Customer Information

Customer Support

If you encounter problems, have questions about operation or need more information about the app, contact the customer support. Go to PROFILE > Support Information > Support Contact.

Disease effects and prevalence

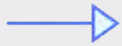
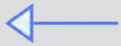
For information on the effects and prevalence of diabetes in your area, visit the International Diabetes Federation website at www.idf.org or send an email to info@idf.org. For further advice or helpline information, refer to the national diabetes organization for your country.

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.

21 Explanation of App Icons

Symbol	Description
	Correct / Done
	Goal: 3-Day-Profile
	Error messages / Wrong
	My Progress
	Share
	Goal: My Meals
	No goal selected

	Goal: Start Small
	Warning message
	Arrow right
	Arrow left
	Blood glucose test
	Close menu
	Fasting (when you wake up)
	Before meal

	After meal
	Bedtime
	Others
	HOME
	GOAL
	PROFILE

22 Explanation of Symbols

Symbol	Description
	Consult electronic instructions for use
	Caution, refer to safety-related notes in the package insert accompanying this product.
	Temperature limit
	Use by
	Date of manufacture
IVD	In vitro diagnostic medical device
	Device for self-testing
	Manufacturer
UDI	Unique device identifier
REF	Catalogue number
LOT	Batch code
CE	Complies with the provisions of the applicable EU Legislation

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