ACCU-CHEK® Connect

Diabetes Management App

Instruction Manual

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Overview

The Accu-Chek Connect diabetes management app (hereafter referred to as the app) is designed to help you:

- Transfer data from your Accu-Chek blood glucose meter.
- Transfer data to your Accu-Chek Connect online diabetes management system account (online account) and optionally share this data with your healthcare provider (HCP) or caregiver.
- Receive insulin bolus advice.
- Perform structured testing (3-Day Profile or Testing in Pairs).
- Assist in general diabetes management through logging of contextual data.

Click on the links below to view that section:

Disclaimer

Users of this software should interpret the results in the context of their clinical history and symptoms and should not make changes in their treatment without consulting a physician or other qualified healthcare provider.

Failure to perform blood glucose tests could delay treatment decisions and lead to a serious medical condition. If your physical condition does not seem to match the blood glucose value you are seeing, you may want to retest. Refer to your meter instructions for proper testing techniques. Contact your healthcare provider if you are unable to perform blood glucose testing.

Uninstalling the app without making a backup of your data will result in a loss of all of your historical data. Always back up your data before updating your app or upgrading your mobile device operating system.

Consult your healthcare provider about what actions you should take when using multiple time blocks and traveling to a different time zone.

This app is intended for use by a single user. Do not share the use of the app with any other user.

The Accu-Chek Bolus Advisor, as a component of the Accu-Chek Connect diabetes management app, is indicated for the management of diabetes by calculating an insulin dose or carbohydrate intake based on user-entered data. Before use by carbohydrate counting patients, a physician or healthcare provider must activate the bolus calculator and provide the patient-specific target blood glucose, insulin-to-carbohydrate ratio, and insulin sensitivity parameters to be programmed into the software. Before use by assigned meal bolus patients (age 22 and older), a physician or healthcare provider must activate the bolus calculator and provide patient-specific target blood glucose, assigned meal insulin doses, and insulin sensitivity parameters to be programmed into the software.

In some countries, before its use, a physician or healthcare provider must prescribe the Accu-Chek Bolus Advisor and provide the patient-specific target blood glucose, insulin sensitivity, and insulin-to-carbohydrate ratio (Count Carbohydrates Bolus Advisor only) parameters to be programmed into the Accu-Chek Bolus Advisor.

Contact

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App Essentials

Getting the most out of your app requires setting up a few key features. These include:

- Online Account
- Pair Meter
- Bolus Advisor

To setup app essentials, select Settings from the Home screen menu.

Online Account

The default settings for your Accu-Chek Connect online account can be set from the online account screen. An online account will help you better manage your diabetes by letting you view data entered from your mobile device.

To create your online account or update settings:

1. Select menu (⋮).
2. Select **Send to Online Account**.
3. If you **already have** an Accu-Chek Connect online account, enter your username and password and proceed to Step 6.
4. If you **do not** have an Accu-Chek Connect online account, select the create account link and follow the on-screen prompts to enter your account information.
5. After you finish entering your account information, you will receive an email confirmation. Select the mobile link in the confirmation email to complete the account creation process. You will be automatically logged in to your online account in the app. If this process was interrupted and you are not logged in, you can enter your username and password and select **Login**.

6. Select whether you would like the app to send pictures to your online account using your mobile network, or only while connected to a Wi-Fi network.

Pair Meter

To see all compatible devices, go to the Google Play Store or iTunes App Store.

Pairing your blood glucose meter via *Bluetooth*® wireless technology will allow you to transfer blood glucose values from the meter to your mobile device. When pairing a meter with the app, information from the blood glucose meter will automatically be transferred to the app by default. The app will also automatically set the time on your meter.

To pair your meter:

1. Select menu (⋮).
2. Select Settings.
3. Select Pair Meter.
4. Choose the type of meter (Multi-Button, One-Button, or Accu-Chek Guide Me) you will pair.
5. Follow the on-screen directions for putting your meter in pairing mode.
6. Select Next on the app.
7. Select the meter identifier (either "Accu-Chek" or "meter" followed by the serial number, depending on your meter).
8. Enter the meter's PIN and select Done / OK.
9. View pairing confirmation screen.

Data Transfer from Meter

To transfer test results from your blood glucose meter, the meter must be within 2 meters (6 feet) of the mobile device. Typical transfer times can be up to 10 seconds. Automatic transfer will occur when Auto-Send is enabled on your blood glucose meter.

To transfer test results automatically:

1. Perform a blood glucose test with your mobile device turned on and within 2 meters (6 feet) of your blood glucose meter.
2. Assign an event to the blood glucose test result, select either Comment or Add Comment depending on your meter, select the event you want to assign, and select OK to send the test result.
3. If you do not want to assign an event, select the back arrow button and the test result will be sent.

Note: Adding Comment not available on One-Button or Accu-Chek Guide Me meters. Results transfer immediately on One-Button meters.

To manually transfer blood glucose test results (Multi-Button meter):

1. Perform a blood glucose test with your mobile device turned on and within 2 meters (6 feet) of your blood glucose meter.
2. Select the menu icon (⋮).
3. Select Download from device.
4. Ensure the meter is in data transfer mode (Select My Data, Data Transfer, Wireless).

To manually transfer blood glucose test results (One-Button or Accu-Chek Guide Me meter):

1. Press button on side of meter (do not hold).
2. Meter will attempt to transfer data once screen is turned on.

Accu-Chek Bolus Advisor Setup

The Bolus Advisor (or Advisor) calculates insulin dosage based on the time of day, your blood glucose level, what you have eaten, and other events. To use the Advisor you will need to receive setup parameters and training from your healthcare provider. When you have completed the basic setup for the Advisor, you can update these and other settings by selecting Bolus Insulin Advisor from the Settings menu.

Assigned Meal Dose

Tap meal to change the insulin value for each assigned meal dose. This option is only available when you use the assigned meal dose.

To add a New Time Block:

1. Select Time Blocks, Target Ranges, Carb Ratios, and Insulin Sensitivities.
2. Select the + button to open a new time block, update the start time, and select Set.
3. Update Target Range, Carb Ratio, and Insulin Sensitivity as needed and select Save.

Note: Carb ratio is only present when you are carb counting.

Meal Rise
Meal Rise is the increase in blood glucose levels during or after meals that is considered allowed within a certain range, even though a bolus has been delivered.

To update the Meal Rise Setting:

1. Select Meal Rise and Snack Size, or Assigned Meal Dose and Meal Rise if using the Assigned Meal Dose.
2. Select the Meal Rise text entry section and update the amount your blood glucose normally increases after a meal.
3. Select the Snack Size text entry section to update the amount of carbs which will trigger a meal rise.
   Note: Snack size is only present when you are carb counting.
4. Select Done.

Insulin Details

Insulin Details includes the Bolus Insulin Name/Type, Max Bolus, Offset Time, Acting Time, and Insulin Increment.

To update Insulin Details:

1. Select Insulin Details.
2. Select the Max Bolus text entry section, use the app keypad to enter the maximum as required, and select Done.

3. Select the Offset Time text entry section, enter the amount of time before the insulin you have defined begins to lower blood glucose levels, and select Set.
4. Select the Acting Time text entry section, enter the period of time from the start of a bolus until your blood glucose level is expected to return to the target level, and select Set.
5. Select the appropriate Insulin Increment.
6. Select the Rapid or Short-Acting Insulin dropdown and select the appropriate insulin.
7. Select Save.

Note: You should ask the advice of your healthcare provider / caregiver before delivering large doses of insulin.

Exercise

Exercise includes pre-set and custom exercise events that can be used in your Bolus Advisor recommendation.

To update Exercises:

1. Select Exercises.
2. Select text entry section for the exercise you want to update, change the percentage the exercise impacts the amount of insulin you require, and select Set.
3. Repeat this process until you have updated all of the exercises you want to change.
4. When all exercises have been updated, select Save.

To add new exercises:

1. Select + Add Exercise.
2. Select the Name text entry section, enter the exercise name, and select Done.
3. Select Increase by (+) or Decrease by (-) as appropriate.
4. Update the percentage the exercise impacts your insulin requirement.
5. When all information has been entered, select Set.

Health Events

Health Events includes pre-set and custom health events that can be used in your Bolus Advisor recommendation

To update Health Events:

1. Select Health Events.
2. Select the health event you want to edit, update percent the health event impacts your insulin requirement, and select Set.

To add new Health Events:

1. Select +Add Health Event
2. Enter the name of the health event, and select Done/Set.
3. Update the percent the health events impact the amount of insulin you require, and select Set.
4. Select Save.

Accu-Chek Bolus Advisor Use

Note: On first time use or first use after reinstalling the app, active insulin may not be accurate due to lack of historical insulin data.

Make sure you log all bolus insulin you take, along with the time and date. This includes insulin outside of the Advisor. Complete insulin information is needed to ensure the accuracy of the Bolus Advisor.

After measuring your blood glucose and transferring the data, you should see the new value on your home screen. The reading is medically valid for the Bolus Advisor for up to 15 minutes (timer shows how much time you have left).

1. Select the Advisor button.
2. Optionally add carbs and any other information appropriate for your bolus advice and select Next.
3. Your insulin recommendation will be displayed. Enter how much bolus insulin you will actually inject.
4. Confirm by selecting Save.

Note: The app will not provide bolus advice for HI readings. If you receive a HI reading, consider rechecking BG, checking ketones and insulin, and consulting your healthcare provider.

If your blood glucose is below the hypo limit (the default setting can be modified under blood glucose settings), no bolus advice will be provided. Instead, you will receive a recommendation to eat fast-acting carbs, and for carb-counting only, a calculated amount of carbs to eat in order to raise your blood glucose into your target range.

- Your "Eat Carbs" recommendation will be displayed.
- Enter the amount of carbs you will actually eat.
- Confirm by selecting Save.

Note: Assigned Meal Dose Bolus Advisor users will only receive a static message to eat fast-acting carbs. To enter fast-acting carbs, go to the Add screen and enter this information in the Meal area.

Note: The app will not provide advice based on LO readings. If you receive a LO reading, retest BG. Contact your healthcare provider.

Note: Consult your healthcare provider about what to do for bolus insulin advice if your app is not available (for example, mobile device battery is exhausted).

Structured Testing

3-Day Profile
3-Day Profile (3DP) provides an easy and convenient way to record and track your test results before and after meals and at bedtime over a three-day period, and provides a view of how meals and activity affect your blood glucose. At least five out of seven blood glucose entries (within 24-hours) are required to complete a day. One or two days can be skipped; so, three out of five days are required to complete the 3DP.

To start a new 3DP:

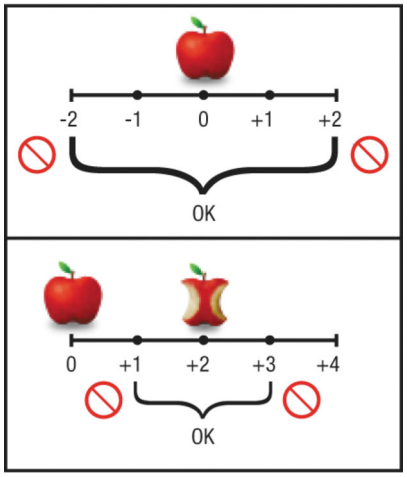
1. Select Menu.
2. Select Structured Tests.
3. Select Schedule New Test and update the meal and bedtime information as desired.
4. Select Choose Start Date, set the start date, and select Done.

5. If you would like to update reminder settings or change your 3DP target ranges, select More Settings.

Note: By default, the 3DP target range is the same as the target range used for other reports. If you change to dual target ranges, they are used only in the 3DP report.

To use 3DP, follow the instructions below:

- Perform a blood glucose test based on reminders.
- Before Meal test time can be 2 hours before to 2 hours after scheduled meal time. After Meal test time can be from 1 to 3 hours after actual Before Meal test time.



- Add blood glucose, meal and other data.
- See trends in blood glucose on Home screen and Report.

To stop 3DP, follow the instructions below:

The 3DP will end 24 hours after the start of the last complete day. To stop earlier, touch and hold the active 3DP.

Note: If a 3DP is running and you are logged into an online account, all data is sent automatically only at the end of each completed day (24 hours or when next day is started).

Testing In Pairs (TIP)
Testing In Pairs (TIP) is a simple tool that helps you see changes in your blood glucose before and after an event. You can use TIP for 7 days to focus on how one part of your daily routine affects your blood glucose levels. For example:

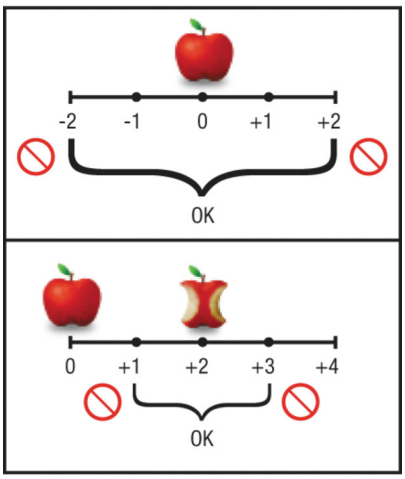
- How does a particular food or drink affect your blood glucose levels?
- How does a specific type of exercise affect your blood glucose levels?

To start TIP, follow the instructions below:

1. Select Menu.
2. Select Structured Tests.
3. Select the TIP tab.
4. Select Start New Test.
5. Select Testing In Pairs.
6. Select the event you want to test for and select Set.

To use TIP, follow the instructions below:

- Perform blood glucose test before and after an event.
- Before Meal test time can be 2 hours before to 2 hours after scheduled time. After Meal test time can be from 1 to 3 hours after actual Before Meal test time.



- Add blood glucose, meal and event information.
- Blood glucose changes will be shown on the Home screen and Reports.

To stop TIP, follow the instructions below:

TIP will end 24 hours after the last pair. To end it earlier, select and hold the active TIP.

Note: If a TIP is running and you are logged into an online account, all data is sent automatically only at the end of each completed pair (24 hours or when next pair is started).

Other Settings

Reminders
Reminders are audio tones and vibrations that are used to remind you to perform a specific task (such as taking medication or a dose of insulin). There are separate checkboxes to enable the reminder and to make it recurring.

Units of Measurement
The units of measurement used by your app defaults to the appropriate setting for your location, but the setting can be customized. You can select custom units of measure used for:

- Blood Glucose Units of Measurement*
- Calorie Units
- Carbohydrate Units*
- Weight Units
- Blood Pressure Units

***Note:** Blood glucose and carbohydrate units cannot be changed when Advisor is on.

Meal Times
The meal times stored in the app indicate when you usually eat your meals. These times act as defaults for TIP and 3DP Testing.

Change Data Order
The order in which details such as energy level, exercise, insulin, and health events appear on the add screen can be customized so that the things you use most often are located near the top of the list. The order you set will also be used for the data you see in the diary and Home screen (blood glucose and next two selected items are shown in standard view).

Note: When Advisor is enabled, blood glucose and insulin are shown at all times. Assigned Meal value or carbs are also always shown, depending on the Bolus Advisor type being used.

Personal Information
Your first name, last name, and date of birth are required to share your trend, 3DP, and TIP reports.

Registration
By registering your blood glucose meter through the app, it allows us to keep you informed of important warranty information, updates, and support.

Medical Details

Blood Glucose Settings
Blood Glucose Target Range and Hypo settings are used to determine how your data is presented in reports and on the Home screen. For example, green is within target range, blue is above, and red is below your hypo limit. Yellow is used if there is a gap between the bottom of your target range and your hypo limit.

Insulin
To make data entry easier, you can set up to three different default insulin types to be used in the app. Insulin types can be set for:

- INS 1: Bolus (Rapid or Short-Acting) Insulin.
- INS 2: Basal (Long-Acting) Insulin.
- INS 3: Other Insulins or either of the previous two categories.

Note: The INS 3 option is removed when Bolus Advisor is activated.

Adding Data

Your daily blood glucose test results, energy level, exercise, and other details can be manually entered into the app.

1. Select + Add from the Home screen.
2. Enter blood glucose test data, energy level, event label, meal size, carbohydrates, insulin, notes, and other details and select Save.

Adding Pictures
You can add pictures to your data entries as a visual reminder and to help provide context to your diary entries.

To add pictures:

1. Scroll to the bottom of the Add New Entry screen.
2. Select a picture from your mobile device's gallery or use the camera to take a picture.

Note: Up to 6 pictures are allowed for each diary entry.

Protecting your Data

To protect your personal information, the data on your mobile device is stored in an encrypted file. You should always protect access to your mobile device with a strong password.

The transmission of your data might make use of unencrypted e-mail, text, and / or software on your mobile device, and data will be transmitted through networks that are not controlled by Roche. If the user chooses to transmit data by such means, Roche is not responsible in any way for the security or reliability of such transfers.

Data Reporting

Trend Reports

Trend reports display your blood glucose trends using diary data.

To display a Trend report:

1. Select Menu.
2. Select Trend.
3. Set the time period of the Trend report.
4. Select how you want the data displayed.
5. To share data, select Share. Sharing allows you to send (email/text), print, or save a PDF version of the Trend report.

The Diary

Diary entries are stored automatically in order of time and date, with the newest records appearing first.

To edit a diary entry:

1. Select Diary from the Home screen.
2. Select the diary entry you want to edit and select Edit.
3. When you have finished editing, select Done, Save, and Close.

Sharing Data

The app lets you use SMS text messaging or the Accu-Chek Connect online account to share your information.

To share blood glucose records via SMS Text Message:

1. Select Settings.
2. Select Blood Glucose SMS Text.
3. Select Share Recorded BGs via text and / or Include Name and Date of Birth in text.
4. Add recipients manually or from your contact list.

Sending Data to your Accu-Chek Connect Online Account

Data is sent automatically once you have logged in. If you have been offline for a while, you can make sure the data has been sent.

To send data:

1. Select menu ().
2. Select Send to Online Account.

Note: When a structured test is running, all data is sent automatically only at the end of each completed day (or pair).

Data Backup
Backup lets you send an email copy of your data to the email address you choose.

1. Select Settings.
2. Select Data Sharing.
3. Select Backup.
4. Select Email for backup.
5. Enter the recipient's email address.
6. Select Send.

To restore data to your mobile device:

1. Use Data Backup to email a copy of your data to your email account.
2. Open the backup email on your mobile device and open the attached backup file with the app to import the data.
3. If you back up your data during a structured test, the test data will be saved but the structured test in the backup files will be inactive and cannot be restarted from the backup location.

Explanation of Symbols

You may encounter the following symbols while viewing the Instructions for Use, shown here with their meaning.

Manufacturer

Explanation of Symbols

You may encounter the following symbols while viewing the Instruction manual, shown here with their meaning.

	Manufacturer
CE 0123	This product fulfils the requirements of the European Directive 93/42/EEC on medical devices.

07250444011-0620

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CE 0123