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Before you get started:
Be sure to complete the Accu-Chek Bolus Advisor Protocol sheet, provided to your Healthcare Provider by a Roche sales representative, which includes required and optional settings for customizing bolus advice for each patient.

Patient Selection/Preparation
It is important for the healthcare professional to consider the user’s ability to see and understand app content. In addition, it is important to ensure users have been properly prepared for use of the Accu-Chek Bolus Advisor and individualized parameters have been properly set.

Intended Use of the Accu-Chek Bolus Advisor
The Accu-Chek Connect diabetes management app is indicated as an aid in the treatment of diabetes. The software provides for electronic download of blood glucose meters, manual data entry, storage, display, transfer, and self-managing of blood glucose and other related health indicators which can be shown in report and graphical format.

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 professional 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 professional 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.

Device Description
The Accu-Chek Connect diabetes management app is designed to facilitate efficient collecting, transmitting, and analyzing of blood glucose results and other diabetes management data.

The App helps:

• Wireless transfer of data from Accu-Chek Aviva Connect Blood Glucose Meter.
• Assist in general diabetes management through logging of contextual data.
• Accu-Chek Bolus Advisor support of mealtime insulin dosing calculations.
• Perform structured testing.
• Wireless transfer of data from mobile devices to Accu-Chek Connect online diabetes management system and optionally share this data with healthcare provider (HCP) or caregiver.
Basic Setup and Use – Assigned Meal Dose

Bolus Advisor Setup

1. **Launch the Accu-Chek Connect app and select **Advisor**. Select **Assigned Meal Dose**.

   On the Bolus Insulin Advisor Setup screen, enter the activation code from the Accu-Chek Connect Bolus Advisor Protocol sheet.

2. **Select each meal icon and enter the appropriate meal insulin dose.**

   Enter **Insulin Sensitivity** (Correction Factor). **Target Range** and **Max Bolus** have default values which you can adjust if desired.

   Review the settings. Select the confirmation check box. Select **Finish**.

3. **Use the button on the home screen to enter all insulin given in the past 8 hours.**

   **Important note:** Because the Accu-Chek Bolus Advisor factors active insulin* into all calculations, you should enter **ALL** insulin boluses and carbohydrates if carb-counting into the Accu-Chek Connect app whether or not you use the Accu-Chek Bolus Advisor.

   *See definition of Active Insulin on Page 8

4. **Setup is complete.**

   Select **Close** to exit the Advisor or Advanced Options for Additional Bolus Advisor Settings (see page 6 in this guide).

---

Using Bolus Advisor with a current blood glucose reading

1. **Start by performing a blood glucose test with your Accu-Chek meter. After sending the bG test result from the meter, open the app and select **Advisor**.**

   **Note:** If meter and smartphone are not paired, perform steps to pair the devices. You have 15 minutes to get bolus advice for this blood glucose result. A countdown timer helps you monitor this deadline. It will turn **red** after time remaining is less than 1 minute.

2. **Select the appropriate meal icon. If desired, select **Add meal photo** to include a photo of the meal with this record.**

   You can take a photo of your meal using the smartphone camera. Select **Next**.

3. **Bolus recommendation is displayed. To administer an amount different from the recommendation, enter actual amount in the bottom field.**

   Select **Save** to confirm amount of insulin taken.

   **Note:** If desired, you can also add and save additional details about this record.

4. **The home screen appears with a summary of the bolus advice details.**

   From the home screen, you can select an entry to see all the details of a specific bolus recommendation.
Basic Setup and Use – Count Carbohydrates

Bolus Advisor Setup

1. Launch the Accu-Chek Connect app and select Advisor. Select Count Carbohydrates.
   On the Bolus Insulin Advisor Setup screen, enter the activation code from the Accu-Chek Connect Bolus Advisor Protocol sheet.

2. Enter Carb Ratio and Insulin Sensitivity (Correction Factor). Target Range and Max Bolus have default values which you can adjust if desired.
   Review the settings. Select the confirmation check box.
   Select Finish.

3. Use the button on the home screen to enter all insulin given and carbohydrates consumed in the past 8 hours.
   Important note: Because the Accu-Chek Bolus Advisor factors active insulin* into all calculations, you should enter ALL insulin boluses and carbohydrates if carb-counting into the Accu-Chek Connect app whether or not you use the Accu-Chek Bolus Advisor.
   *See definition of Active Insulin on Page 8

4. Setup is complete.
   Select Close to exit the Advisor or Advanced Options for Additional Bolus Advisor Settings (see page 6 in this guide).

Using Bolus Advisor with carb-counting and a current blood glucose reading

1. Start by performing a blood glucose test with your Accu-Chek meter. After sending the bG test result from the meter, open the app and select Advisor.
   Note: If meter and smartphone are not paired, perform steps to pair the devices. You have 15 minutes to get bolus advice for this blood glucose result. A countdown timer helps you monitor this deadline. It will turn red after time remaining is less than 1 minute.

2. Select the Carbs field to enter the estimated amount of carbs in the meal.
   If desired, select Add meal photo to include a photo of the meal with this record.
   You can take a photo of your meal using the smartphone camera. Select Next.

3. Bolus recommendation is displayed. To administer an amount different from the recommendation, enter actual amount in the bottom field.
   Select Save to confirm amount of insulin taken.
   Note: If desired, you can also add and save additional details about this record.

4. The home screen appears with a summary of the bolus advice details.
   From the home screen, you can select an entry to see all the details of a specific bolus recommendation.
Alternative Scenarios

Recording carbohydrates and bolus insulin delivered without using bolus advice

Use the Add (.addButton on the home screen to enter a record for additional insulin.

Important note: Because the Accu-Chek Bolus Advisor factors active insulin* into all calculations, you should enter ALL insulin boluses and carbohydrates if carb-counting into the Accu-Chek Connect app whether or not you use the Accu-Chek Bolus Advisor.

*See definition of Active Insulin on page 8

Bolus advice without entering blood glucose value

If desired, you can receive bolus advice without entering a current blood glucose value.

The recommended bolus amount will reflect only the insulin required for the meal or carbs you enter.

Note: Using a blood glucose result will ensure the most accurate bolus advice recommendation.

Bolus advice with hypo blood glucose result

If your blood glucose is below the hypo limit 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 sugar into your target range. Record the amount of carbs you will actually consume.

Bolus advice with low blood glucose result

If your pre-meal blood glucose is low but is not below your hypo limit, the Accu-Chek Bolus Advisor may calculate a negative (correction) bolus amount that will reduce the total recommended bolus for the meal or carbs you are about to consume.
Additional Bolus Advisor Settings

To access additional Bolus Advisor settings, select the menu icon, select Settings, and select Bolus Insulin Advisor.

**Time Block Settings**

To adjust current bolus advice settings for Carb Ratios (if counting carbohydrates), Insulin Sensitivities (Correction Factors), and Target Ranges, select **Time Blocks**.

Time Blocks allow for different settings at different times of day. To create a new time block, select **Add** and enter new settings for that time period. Enter start time for the new time block. Each time block ends when the next one begins. Select **Set**.

**Note:** If only one time block is set, it will cover a 24-hour period. See page 7 for traveling and multiple time blocks.

You can program up to 8 time blocks to cover a 24-hour period. The new time block will default to the current settings for the existing time block.

You can customize Target Range, Carb Ratio (if carb-counting), and/or Insulin Sensitivity settings for each time block.

**Meal Rise and/or Snack Size**

Select **Meal Rise (and Snack Size)**.

If desired, adjust the Meal Rise and/or Snack Size.

Select **Save**.

**Note:** Snack Size applies only when carb-counting.

**Insulin Details**

Select **Insulin Details**. Select the **Max Bolus** field to adjust the amount. Follow the same steps to change the settings for **Offset Time**, **Acting Time** and **Insulin Increment**, which should reflect the increment of the insulin pen/syringe used. Select the type of bolus insulin you use. Select **Save**.

**Note:** Whenever you change insulin, be sure to adjust all other insulin-related settings as necessary.

* See definitions of these terms on page 8

**Exercise & Health Events**

From the Advisor Settings menu, select **Exercises** or **Health Events**.

You can adjust the % by which different types of exercise or health events may affect the amount of insulin needed.

Select the field to change the setting.

If desired, select **+ Add Exercise** or **+ Add Health Event** to add a different type of exercise or health event. Exercise and Health Events allow up to 10 settings each.

To add an exercise or health event, select the **Name** field to enter a name (e.g., Tennis). Then enter the % Increase or Decrease. You can adjust % Increase or Decrease of insulin from 1–50%. Select **Set**.

When you are finished with settings, select **Save**.
Bolus Advisor Alternative Scenarios

**Time Blocks and traveling to a new time zone**

The time used by the app, including time blocks, always follows the phone time, which may automatically change with time zone changes, depending on settings.

The number and length of time blocks and their associated settings, including Target Range, Carb Ratio (carb-counting only), and Insulin Sensitivity, can only be changed manually by the user.

You should always consult your healthcare provider about actions to take (if any) when using multiple time blocks and traveling to a different time zone.

**Combining Exercise & Health Event Adjustments to Bolus Advice**

If your bolus calculation includes more than one exercise/health event, you must set the adjustment % for the combined events.

Appropriate adjustments can vary from person to person, so you should discuss this with your doctor, who can help you determine the correct % to use.

Choose **Increase by** or **Decrease by** and swipe the spinner to select the % setting.

Select **Set**.

**Changing Bolus Advisor Mode**

Turn off Bolus Advisor. This will reset all bolus advisor settings to defaults. Then select **Count Carbohydrates** or **Assigned Meal Dose** and follow the setup instructions.

**Note:** Changing the Bolus Advisor mode requires a new Bolus Advisor activation code which can be obtained from a healthcare provider.

**Adjustments to Assigned Meal Dose**

Please consult your healthcare provider regarding the need to follow consistent meal patterns, how to adapt assigned meal doses for meal variations, and how to review and adjust the suggested dose.
### Definitions for important settings referred to in this instruction guide:

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
<th>Allowable Range</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acting Time</strong></td>
<td>Total length of time the insulin is expected to be effective at lowering blood glucose.</td>
<td>1:30 – 8:00 hours</td>
</tr>
<tr>
<td><strong>Active Insulin</strong></td>
<td>Insulin currently in the body that is working to lower blood glucose. This amount does not include any insulin that is working to account for carbohydrate intake. It also does not include basal insulin.</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Assigned Meal Dose</strong></td>
<td>The amount of insulin assigned for each meal. You eat to match the assigned dose.</td>
<td>0–Max Bolus</td>
</tr>
<tr>
<td><strong>Carb Ratio</strong></td>
<td>The amount of insulin necessary to account for a specified amount of carbohydrates.</td>
<td>1U:1g – 1U:150g</td>
</tr>
<tr>
<td><strong>Hypo Warning Limit</strong></td>
<td>The setting below which the blood glucose level is considered hypoglycemic. The user is prompted with a recommendation to eat an appropriate amount of carbohydrates.</td>
<td>50 – 90 mg/dL</td>
</tr>
<tr>
<td><strong>Insulin Increment</strong></td>
<td>The amount in units (U), usually 0.5U or 1U, by which your insulin dose is adjusted.</td>
<td>0.5 or 1 U</td>
</tr>
<tr>
<td><strong>Insulin Sensitivity</strong></td>
<td>The amount of insulin necessary to lower your blood glucose by a specified amount.</td>
<td>1U:5 mg/dL – 1U:400 mg/dL</td>
</tr>
<tr>
<td><strong>Max Bolus</strong></td>
<td>The maximum amount of insulin to be delivered at one time. This serves as a safety measure against unintended large boluses by asking the user for added confirmation.</td>
<td>0 – 50 U</td>
</tr>
<tr>
<td><strong>Meal Rise</strong></td>
<td>The maximum increase in your blood glucose level that is to be tolerated after a meal without the need for an additional correction bolus.</td>
<td>30 – 200 mg/dL</td>
</tr>
<tr>
<td><strong>Offset Time</strong></td>
<td>Expected amount of time before insulin begins to lower blood glucose levels in the body.</td>
<td>0:45 – 8:00 hours</td>
</tr>
<tr>
<td><strong>Snack Size</strong></td>
<td>Eating more than this amount of carbohydrates will trigger a Meal Rise.</td>
<td>0 to 24 grams</td>
</tr>
<tr>
<td><strong>Target Range</strong></td>
<td>Acceptable upper and lower blood glucose level when fasting or before a meal.</td>
<td>Upper: 100 – 270 mg/dL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Lower: 50 – 140 mg/dL</td>
</tr>
</tbody>
</table>
The mathematical basis for bolus calculations

Below is a list of the most important formulas and principles that the Accu-Chek Bolus Advisor uses to calculate your bolus. It is difficult to accurately calculate a bolus yourself using these formulas (remembering to include the Acting Time and Offset Time of your most recent boluses). This is why bolus advice is so useful. It can save you a lot of time and avoids the risk of mistakes in your calculations.

\[
\text{Carbohydrate bolus} = \text{Carbohydrate intake} \times \left( \frac{\text{Insulin}}{\text{Carbohydrate from Carb Ratio}} \right)
\]

\[
\text{Correction bolus} = \left( \frac{\text{Current blood glucose} - \text{Currently allowed blood glucose}^*}{\Delta \text{Blood glucose}^{**}} \right) \times \left( \frac{\text{Insulin}}{\text{from Insulin Sensitivity}} \right)
\]

Generally, a correction bolus is calculated only if your current blood glucose value is above the hypo blood glucose warning limit and outside of the Target Range. Additionally, it must be above the currently allowed blood glucose value. Only correction boluses greater than 0 will trigger an Acting Time.

*Currently allowed blood glucose value = The blood glucose value used in the calculation of a correction bolus, taking into account time block settings (Target Range mean value), currently active meals (Meal Rise), and currently acting correction boluses (Active Insulin).

**\(\Delta \text{Blood glucose} = \) The difference between current blood glucose level and target blood glucose level.
Appendix

The insulin bolus calculations provided by the app are meant for patients undergoing multiple daily injection therapy. Bolus calculators, such as the Accu-Chek Bolus Advisor, have been demonstrated to facilitate the optimization of glycemic control in patients who are trained in multiple daily insulin injection therapy and under the supervision of healthcare professionals experienced in managing insulin-treated patients. Such calculators have also been shown to reduce patient fear of hypoglycemia and improve patient confidence in diabetes management.

1 R Ziegler et al: Use of an insulin bolus advisor improves glycemic control in multiple daily insulin injection (MDI) therapy patients with suboptimal control: first results from the ABACUS trial; Diabetes Care 36, 3613-3619 (2013).

Advice Options: Meal Rise, Acting Time, Offset Time and Snack Size

Advice Options help to make sure that Bolus Advice does not recommend a second bolus for a blood glucose event, such as a meal or a high bG level, that has already been covered by a previous bolus.

1 Meal Rise
After a meal, bG levels usually increase by a noticeable amount, even in people without diabetes. Depending on the type of meal, your bG can reach a maximum about an hour after your meal and return to its original level after another one to two hours. This is a normal process, so Bolus Advice takes this into account using Meal Rise.

2 The dotted line shows how your bG level might change after a carbohydrate bolus. Bolus Advice tolerates an increased bG level within the Meal Rise range (green) without calculating an extra correction bolus. When you enter a carbohydrate amount that is greater than the Snack Size, the Meal Rise setting is added to the bG target value. How long the Meal Rise lasts (the width of the green area) is determined by the Offset Time and the Acting Time.

3 The currently allowed bG value considers the following factors:
   - The upper limit of the Target Range for your current Time Block
   - bG values that were tolerated as a Meal Rise and which have had a carbohydrate bolus that is still active (Acting Time)
   - The expected reduction of your bG level due to the effect of insulin during the Acting Time (the decrease between the end of Offset Time and end of Acting Time)
   - Excursions beyond the Target Value that have had a correction bolus that is still active (Acting Time)
**Acting Time**

The Acting Time is the time for which the insulin delivered as a bolus is still effective. It is the whole time for which an increase in bG after a carbohydrate bolus or a correction bolus is taken into account. Bolus Advice will not recommend a correction bolus for this time if your current bG level is less than the bG level covered by the previous bolus (Meal Rise or a corrected high bG).

To choose the correct value for the Acting Time, you and your healthcare professional should discuss the following:

- The type of insulin that you use
- Your average bolus amount (the larger your average bolus amount, the longer the Acting Time should be)

You can program the Acting Time from 1½ to 8 hours.

**Offset Time**

The Offset Time is the time before the insulin begins to lower blood glucose levels. After the Offset Time, your bG level should decrease because of the insulin, and at the end of the Acting Time it should return to the target level. The Offset Time must be at least 45 minutes, and the maximum value will be limited by the Acting Time that you choose. You and your healthcare provider should discuss what Offset Time is appropriate for you.

**Correction bolus only**

Bolus Advice always compares your bG result with the currently allowed bG value, and not just with the target value for the current Time Block. The diagram to the left shows an example: The first correction bolus at 12:00 remains active during the Acting Time (the width of the blue area). If a measured value at 14:00 falls within the currently allowed bG value (height of the blue area), no new correction bolus is calculated.

**Snack Size**

The Snack Size defines the amount of carbohydrates below which no Meal Rise is triggered when calculating a bolus. No bG level above the Target Range or currently allowed bG is tolerated for this amount of carbohydrates, so Bolus Advice will calculate a correction bolus for any increase in bG after a snack. You and your healthcare provider should discuss what Snack Size is appropriate for you.