# **ACCU-CHEK**<sup>®</sup> Aviva Expert



© 2015 Roche Diabetes Care

Roche Diabetes Care GmbH Sandhofer Strasse 116 68305 Mannheim, Germany

www.accu-chek.com

 $\mathsf{ACCU}\text{-}\mathsf{CHEK}, \mathsf{ACCU}\text{-}\mathsf{CHEK} \mathsf{AVIVA}, \mathsf{and} \mathsf{ACCU}\text{-}\mathsf{CHEK} \mathsf{AVIVA} \mathsf{EXPERT}$  are trademarks of Roche.

35636922001(05)-0615

IVD

**( (** 0088



#### United Kingdom

Roche Diabetes Care Limited Charles Avenue, Burgess Hill West Sussex, RH15 9RY, United Kingdom Accu-Chek Customer Careline <sup>1)</sup> UK Freephone number: 0800 701 000 ROI Freephone number: 1 800 709 600 <sup>1)</sup> calls may be recorded for training purposes www.accu-chek.co.uk www.accu-chek.ie

### **Contents**

Introduction	
1 Bolus Advice	5
1.1 Overview	6
1.2 Before Using Bolus Advice	8
1.3 Calculating a Bolus Using Bolus Advice	12
Appendices	17
Appendix A: Bolus Advice	17
Appendix B: Bolus Advice Calculations	37
Appendix C: Explanation of Symbols	41
Index	43

### Introduction

Whether the Accu-Chek Aviva Expert meter is your first blood glucose meter or you have used a meter for some time, please take the time to read the Getting Started Guide, the Standard Owner's Booklet and the Advanced Owner's Booklet carefully before you use your new meter. To use it correctly and dependably, you need to understand its operation, screen displays and all individual features.

Your new meter includes three booklets:

- Getting Started Guide: Use this booklet to set up the meter.
- Standard Owner's Booklet: Use this booklet for instructions on how to operate the standard features of the meter.
- Advanced Owner's Booklet: Use this booklet for instructions on how to operate the advanced features of the meter.

#### Suitable for self-testing

Should you have any questions, please contact one of our customer support and service centers. A listing is at the back of the Standard Owner's Booklet.

This booklet includes information about:

- Taking bolus advice
- Bolus advice calculations



1.1 Overview	6
1.2 Before Using Bolus Advice	8
1.3 Calculating a Bolus Using Bolus Advice	12

### **1.1 Overview**

Important information regarding the use of bolus advice is presented in this chapter. Read it carefully and completely before you begin using bolus advice.

- It is recommended you discuss your bolus advice settings with your healthcare professional prior to setting up this feature.
- Bolus advice is intended exclusively for use by well-trained individuals who perform their own insulin therapy.
- Bolus advice is only available if you have set up bolus advice on your meter. For instructions on how to set up bolus advice, see the Standard Owner's Booklet.
- Bolus advice calculates insulin doses for you based on many different pieces of information, such as:
  - The values you entered in the setup of bolus advice
  - Your current blood glucose test result
  - The amount of carbohydrates you estimated for a meal
  - Your current health event status
  - The blood glucose lowering due to prior correction doses
  - The blood glucose influence of your most recent meal

#### **1** NOTE

• This booklet shows sample screens. The screens in this booklet may look slightly different from the screens on your Accu-Chek Aviva Expert meter. If you have any questions about the meter screens, contact the Accu-Chek Customer Careline on 0800 701 000 (UK) or 1 800 709 600 (ROI).

• Blood glucose and bG are interchangeable and mean the same thing.

#### 🕂 WARNING

Choking hazard. Small parts. Keep away from children under the age of 3 years.

### **1.2 Before Using Bolus Advice**

#### **Intended Users**

As with any specialised feature, you need to understand certain information in order to use bolus advice. Working closely with your healthcare professional, you must be completely familiar with your diabetes therapy. You must also be able to judge your current situation accurately. Bolus advice calculates boluses for you. This can help you determine the amount of insulin you currently require. You provide the information on which the bolus advice calculations are based.

Bolus advice is not able to judge your current situation independently of your own estimation. It cannot correct possible input errors. This is particularly true for the carbohydrate amount entered. Entries that exceed possible limits are recognised as such and in this case you are prompted to check the entry and correct it, if necessary. However, as long as the entries fall within a possible range, the accuracy cannot be checked by your meter. No warning message is displayed if the data are possible (within the acceptable ranges) but incorrect. Therefore, it is important to carefully review all of your entries.

#### 🕂 WARNING

- It is very important you follow the safety information in this chapter.
- Always compare your result with how you actually feel and adjust the recommended bolus, if necessary.
- Always carry out the actions entered into bolus advice in a timely fashion. Eat the carbohydrate amount you entered and administer the insulin dose.
- Bolus advice should not be used if you are using an intermediate-acting insulin like Neutral Protamine Hagedorn (NPH) insulin or any other intermediate-acting insulin.
- Remember, long-acting insulin should not be used as a meals bolus or as a correction bolus.

#### The following information is not taken into account when bolus advice is used:

- It is possible the values entered when setting up bolus advice do not match how your body actually feels. In this case, you can increase or decrease the bolus insulin dose to adjust it to your needs.
- Bolus insulin doses and meals taken before bolus advice is used for the first time cannot be reflected in the calculation. The same applies for bolus insulin doses and meals that were taken but not entered into your meter.
- If you delivered a bolus without using bolus advice, you can enter the bolus into your diary. It is important that you enter carbohydrate information into the diary with this bolus in order to obtain accurate bolus advice recommendations. For information on how to enter information into the diary, see the Standard Owner's Booklet.
- The basal insulin doses you record do not influence the bolus advice.

#### Warning messages about your blood glucose test result

After performing a blood glucose test, warning messages about your blood glucose test result may be displayed. Please take careful note of these messages. If your blood glucose test result is too low, you are prompted to eat a certain amount of fast acting carbohydrates to prevent the risk of hypoglycaemia. A bolus is not calculated in this situation. Treat your low blood glucose as recommended by your healthcare professional.

#### Summary

- It is recommended you set up bolus advice with your healthcare professional.
- Carefully check all of your entries.
- Make sure all recent meals and insulin doses are in My Data for accurate bolus advice recommendations.
- Take note of all warning messages, especially those regarding high or low blood glucose test results. Immediate action may be necessary.
- Always compare your result with how you actually feel and adjust the bolus, if necessary.
- Always carry out the actions entered in bolus advice in a timely fashion.

### **1.3 Calculating a Bolus Using Bolus Advice**



Recommended Bolus
 Amount

#### To Deliver a Bolus

#### Main Menu > Bolus Advice

bG Test	
Bolus Advice	
My Data	
/ Settings	

 From the Main Menu, select Bolus Advice and press .

#### 2.

📑 Bolus Ad	vice
🍐 5.8 mmol/L	
U 📭	0.0 U
숱 19 g	2.1 U
Exercise 1	-0.1 U
L Bolus	2 U
r Basal	10 U
Cancel	Confirm

If you have not completed a recent blood glucose test (this is indicated when "bG Test" is displayed near the top of the meter screen rather than an actual bG value), it is recommended you complete a blood glucose test. Select bG Test and press . See the Standard Owner's Booklet for information on how to perform a blood glucose test. When the detailed bG Result screen appears, select Bolus.

#### To Enter a Carbs Amount:

- Select the Carbs entry field and press .
- Set the amount of Carbohydrates and press .

#### To Enter a Health Event:

- Select the Health entry field and press .
- Select a health event and press .

#### To Adjust the Bolus Amount:

- Select the Bolus entry field and press .
- Set the bolus insulin amount and press .

#### To Adjust the Basal Amount:

- Select the Basal entry field and press .
- Set the basal insulin amount and press .

To confirm the entries, select Confirm.

3.	
📑 Confirm	n Bolus
Pen/S	yringe
Inject I	nsulin
L Bolus	🖪 Basal
2 U	10 U
Back	OK

The bolus amount is displayed on the meter screen.

- Inject the bolus using an insulin pen or syringe or, if necessary, select Back and return to the Bolus Advice screen to adjust the bolus.
- Select OK to go to the Main Menu.

#### 🕂 WARNING

- Bolus advice provided by the meter is solely advice. Contact your healthcare professional prior to changing your diabetes therapy.
- It is important to make the correct selection for the carbohydrate ratio and insulin sensitivity. If you select the wrong ratio (the basis for all calculations), all future bolus advice recommendations will be wrong.
- Ensure the bolus information in the diary is correct prior to starting a new bolus advice calculation. For information on how to view and edit diary data, see the Standard Owner's Booklet.

#### **1** NOTE

- Bolus advice can also be accessed after you perform a bG Test (see the Standard Owner's Booklet).
   When the detailed bG Result screen is displayed, press 
   This is not available if your bG result is below your hypo warning limit (red colour bar is displayed).
- You can only select one health event for each bolus recommendation.

### Appendices Appendix A: Bolus Advice

Bolus advice is only available if you have set up bolus advice on the Accu-Chek Aviva Expert meter. For instructions on how to set up bolus advice, see the Standard Owner's Booklet.

Along with the basic blood glucose and carbohydrate values, there are several meter settings required to optimize the bolus advice feature so the recommendations match your insulin needs to the greatest possible extent. You must set up bolus advice correctly. Bolus advice is not available without these settings. It is important to discuss the bolus advice settings with your healthcare professional.

#### 1 NOTE

- Blood glucose and bG are interchangeable and mean the same thing.
- Bolus advice factors are items that influence the bolus calculations of the meter.

#### **Bolus Advice Meter Settings**

This section contains an overview of the information that must be entered into the meter for accurate bolus advice recommendations.

#### **Carbohydrate Units**

- Bolus advice recommendations are based on the units of carbohydrates selected.
- The right choice of carbohydrate units is important for bolus advice recommendations to be accurate.
- Carbohydrate units must be selected, whether or not you set up bolus advice.

The following carbohydrate units are available on the meter:

Abbreviation	Unit of Measurement	Gram Equivalent
g	Grams	1 gram
KE	Kohlenhydrateinheit	10 grams
BE	Bread Equivalent	12 grams
CC	Carbohydrate Choice	15 grams

#### **Insulin Increment**

- The meter rounds off the insulin amount to be delivered, which the meter calculates if bolus advice is set up, or when you manually enter bolus and basal insulin data into the diary.
- The insulin increment can be set to 0.5 or 1 U.

#### **Max Bolus**

- The maximum amount of bolus insulin to be delivered at one time. A bolus that is larger than the max bolus amount requires an additional confirmation. This serves as a safety measure against unintended large boluses.
- The max bolus can be set up to a maximum of 50 U in increments of 0.5 U.

#### Warning Limits

- You can select hyper (high) and hypo (low) blood glucose limits that best fit your needs.
- Whenever a blood glucose test result is above the hyper warning limit or below the hypo warning limit, the meter displays a warning.
- Set the hyper warning limit greater than the target range of all time blocks.
- Set the hypo warning limit less than the target range of all time blocks.
- Bolus advice is not available if your blood glucose test result is below the hypo warning limit.

#### **Time Blocks**

Time blocks allow you to select settings to take into account the fact that your insulin requirement varies throughout the day. Using the same values and factors for the day would not necessarily match your insulin needs and could lead to inaccurate bolus advice recommendations.

The meter comes with five preset time blocks. You may set up to eight time blocks (time periods) depending on your insulin needs. For each time block, you must set the target range, the carb ratio, and the insulin sensitivity. You can define all of these values separately for each time block. The meter automatically takes these values into account.

Target Range

- The desired upper and lower limits of your blood glucose level considered acceptable as set by your healthcare professional.
- The meter automatically calculates the target blood glucose level as the average between the upper and lower blood glucose target limits.
- Talk with your healthcare professional to determine the appropriate target range.

Upper Blood Glucose Target Limit

- The upper limit of the blood glucose target range for the current time block.
- Blood glucose test results within the lower target limit and the upper target limit are considered within the target range.

Lower Blood Glucose Target Limit

- The lower limit of the blood glucose target range for the current time block.
- Blood glucose test results within the lower target limit and the upper target limit are considered within the target range.

Carb Ratio

- For the current time block, the carb ratio is the amount of insulin necessary to account for a certain number of carbohydrates.
- Talk with your healthcare professional to determine the appropriate carbohydrate ratio.

Insulin Sensitivity

- For the current time block, the insulin sensitivity (correction factor) is the amount of insulin necessary to lower your blood glucose by a certain amount.
- Talk with your healthcare professional to determine the appropriate insulin sensitivity settings.

Your meter con	nes with the	following	preset time	blocks:
----------------	--------------	-----------	-------------	---------

Time Block	24-Hour Format
1	0:00-5:30
2	5:30-11:00
3	11:00–17:00
4	17:00–21:30
5	21:30-0:00

Talk to your healthcare professional about setting up time blocks to help you manage your diabetes. Here is a suggested pattern:

Time Block	Start Time	End Time
1. Night time	Midnight	The time you normally wake up
2. Breakfast	The time you normally wake up	$1\!\!\!/_2$ hours before you normally eat lunch
3. Lunch	$1\!\!\!/_2$ hours before you normally eat lunch	1½ hours before you normally eat dinner
4. Dinner	$1\!\!\!/_2$ hours before you normally eat dinner	$1\!\!\!/_2$ hours before you normally go to bed
5. Bedtime	$1\!\!\!/_2$ hours before you normally go to bed	Midnight

#### **Setting Up Time Blocks: Important Information**

- Time blocks cover a 24-hour time period (from midnight to midnight).
- You can change the time period for any of the preset time blocks.
- When setting up bolus advice, you must complete and save the settings in at least one time block.
- Each time block must be at least 30 minutes long and can only be set in 30-minute increments.
- When you set the end time for a time block, the meter automatically sets this end time as the start time for the next time block.
- You can set a different target blood glucose range, carb ratio and insulin sensitivity for each time block.
- The target range for each time block must be within the hypo and hyper warning limits.
- When a time block is edited for the first time, the settings (target range, carb ratio and insulin sensitivity) are applied to all of the other time blocks.

#### **Health Events**

Health events allow you to select settings to take into account various activities or events that increase or decrease your insulin need. Health events can be selected to indicate how you are feeling or what you are doing that might affect your diabetes. The meter allows you the option of setting a percentage for each health event except for Fasting. Fasting is not adjustable and does not scale bolus advice calculations. When a health event is selected, the set percentage is used to increase or decrease the bolus insulin amount. Discuss the appropriate percentage for each health event with your healthcare professional.

Health events available on the meter are:

- Exercise 1
- Exercise 2
- Stress
- Illness
- Premenstrual
- Fasting

#### **Bolus Advice Options**

Meal rise, snack size, acting time and offset time are bolus advice options. Below are detailed descriptions of each of these settings.

Meal Rise

- During or after meals, an increase in blood glucose levels is considered normal within a certain range, even though a meal bolus has been delivered. A meal rise is in effect for a specified time period.
- Enter the maximum increase in your blood glucose test result that is to be tolerated without an additional correction bolus.

Snack Size

• The snack size is the amount of carbohydrates that should not be counted as a regular meal with the expected meal rise.

Acting Time

- The period of time from the start of the meal rise or the delivery of a correction bolus until your blood glucose level is expected to return to the target level.
- You can adjust the length of the acting time to fit your individual needs, within a specified time interval (1½ hours to 8 hours).

Offset Time

• Offset time takes into account the expected delay for the blood glucose level to actually fall during the acting time of insulin in the body. It describes the first time period within the acting time.

#### **Active Insulin**

- Bolus insulin that has been given to lower your blood glucose, but has not yet been fully used.
- The meter automatically calculates the active insulin amount and it is displayed on the bolus advice screen.

#### **Bolus Calculation**

The bolus recommended by the bolus advice feature of the meter consists of two components: A recommendation for a meal bolus that covers your food intake and a recommendation for a correction bolus to adjust your blood glucose level if it is not within the target range. The correction bolus can be positive if your current blood glucose level is above your target range or negative if it is below your target range.

#### **Meal Bolus**

A meal bolus is the amount of insulin that needs to be administered to cover the amount of carbohydrates you are planning to eat. It is calculated as:



#### **Correction Bolus**

If your current blood glucose level is not within your target range, a correction bolus is recommended.

#### **Blood Glucose Limits**



Discuss your blood glucose limits with your healthcare professional.

The calculation for the recommended correction bolus depends on your current blood glucose test result, your insulin sensitivity for the current time block, and whether you are planning to eat.

#### **Example Bolus Advice Calculations**

Blood Glucose Level	Without Food Intake (No Carbs)	Prior to a Meal
Above Upper Target Limit	(bG –Target bG) x Insulin Sensitivity	(bG –Target bG) x Insulin Sensitivity + Meal Bolus
Between Upper and Lower Target Limit	No correction bolus is necessary.	(bG –Target bG) x Insulin Sensitivity + Meal Bolus. A correction bolus can be negative.
Between Lower Target Limit and Hypo Warning	No bolus recommended. The correction bolus is negative.	(bG –Target bG) x Insulin Sensitivity + Meal Bolus. The correction bolus is negative.
Below Hypo Warning	Hypo warning appears. It is recommended you eat fast-acting carbohydrates. Bolus advice is not available.	Hypo warning appears. It is recommended you eat fast-acting carbohydrates. Bolus advice is not available.

#### **Other Boluses**

#### **Subsequent Meal Boluses**

If you are planning to eat several meals or snacks in a short period of time, you should administer a meal bolus for each meal. The calculation is always the same as a meal bolus.

#### **Correction Bolus After a Meal**

After a meal, it is normal to allow for a rise of your blood glucose level even if you administered the correct meal bolus. The allowed blood glucose level rise is called meal rise. After a certain period of time (offset time) the meal rise decreases from its maximum until your blood glucose level has returned to the target level. The period of time from the start of the meal rise until your blood glucose level returns to the target level is defined as acting time. During this time, a correction bolus is only recommended if your blood glucose level exceeds the current meal rise level.



The dotted line shows how your blood glucose level might change after a meal bolus. Bolus advice tolerates an increase in your blood glucose 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 blood glucose target value. The shape of the meal rise (the width of the green area) is determined by the offset time and the acting time.

#### **Subsequent Correction Boluses**

The difference between your current blood glucose level and your target blood glucose level is called Delta bG. A correction bolus administered according to the previous conditions covers this difference for a certain period of time. As the correction bolus starts to take effect, your current blood glucose level should fall and the covered Delta bG decreases after the offset time. At the end of the acting time, your blood glucose level should return to the target limit. You receive a recommendation for another correction bolus only if your current blood glucose test result exceeds the current Delta bG level.



Subsequent Correction Boluses: If your blood glucose test result is within Section 1 of the graph, a correction bolus is not recommended. If your blood glucose test result is within Section 2 of the graph, a correction bolus is recommended.

#### **Examples of Bolus Advice Recommendations**

The following graphs provide differing examples of how bolus advice considers different factors when calculations are made.

The currently allowed blood glucose value considers the following factors:

- Target Range Mean Value
- Meal Rise
- Correction Bolus

#### After a Correction Bolus



The above diagram shows an example of the effect of this rule. The first correction bolus at 12:00 remains active during the acting time (the width of the blue area). If the blood glucose value at 14:00 falls below the currently allowed blood glucose value (top of the blue area), another correction bolus is not calculated.



When a blood glucose test result is greater than the currently allowed blood glucose value, a bolus is calculated (light blue) that only considers the difference between the current blood glucose value (orange dots) and the currently allowed blood glucose value (the top of the blue area).



#### **Subsequent Meals**

If you eat several meals in a row, the meal rise is restarted for each new meal bolus.

### **Appendix B: Bolus Advice Calculations**

#### The Mathematical Basis for Bolus Calculations

The following is a list of the most important formulas and the calculation principles on which bolus advice is based. It is difficult to accurately calculate a bolus yourself using these formulas when the acting time and offset time of recent meals and correction boluses are considered.

#### **Carbohydrate Suggestion**

This calculation is made when the blood glucose test result falls below the hypo warning limit. It is based on the other values defined for the current time block and the result is calculated as a carbohydrate intake recommendation.



### 1 NOTE

- A minimum amount of 12g (or equivalent BE, KE, or CC units) is always given. If the calculated value is below 12g, then 12g is used.
- The carbohydrate suggestion is displayed in the carb unit of measure you have selected (g, BE, KE, or CC).

#### **Meal Bolus**

The following formula is used to calculate the bolus for meals:



#### **Currently Allowed Blood Glucose Value**

The target range average value used in the calculation of the correction bolus, as shown below, changes with the definition for the time blocks.

Consequently, the currently allowed blood glucose value is calculated as follows:



When no meal rise or correction bolus acting time is currently in effect, a value of "0" is substituted for these parameters in the formula.

#### **Correction Bolus**

Generally, a correction bolus is only calculated if the current blood glucose value is above the hypo bG warning limit and outside the target range. If the current blood glucose value is above the target range, the currently allowed blood glucose value must also be exceeded. Only correction boluses greater than "0" trigger a corresponding acting time.



The blood glucose correction portion depends on the following requirements:

- If current bG > currently allowed blood glucose value, then blood glucose correction portion = current bG – currently allowed blood glucose value
- If current bG > hypo warning limit and current bG < target range lower limit, then bG correction portion = current bG target range average value

#### **Correction Bolus with Carbohydrate Intake**

Whenever carbohydrates have been entered, the related meal bolus is always offset against any (even negative) correction bolus.

When a meal is eaten, the correction bolus is also calculated for blood glucose test results that fall within the target range if:

- The current blood glucose test result falls below the target range average value, or
- The current blood glucose test result is above the currently allowed blood glucose value.

Mathematically negative overall boluses are displayed as "0".

#### **Active Insulin**

The active insulin field shows you if a prior bG correction bolus may possibly reduce your current bolus calculation.

### **Appendix C: Explanation of Symbols**

You may encounter the following symbols on the packaging, on the type plate (back of meter), and in the instructions for the meter, shown here with their meaning.

	Consult instructions for use
$\wedge$	Caution, refer to safety-related notes in the instructions for use accompanying this product.
0	A NOTE is used to provide additional information.
X	Temperature limitation (Store at)
	Manufacturer
REF	Catalogue number
IVD	In vitro diagnostic medical device
GTIN	Global Trade Item Number
<b>C E</b> 0088	This product fulfils the requirements of the European Directive 98/79/EC on in vitro diagnostic medical devices.
( <del>+</del> ]	1.5V AAA

## Index

#### A

acting time, 26 active insulin, 26, 40

#### В

basal amount, adjust, 14 basal insulin. 10 bolus advice, intended users, 8 meter screen features, 12 overview, 6-7, 17-26 safety. See safety information bolus advice calculations, carbohydrate suggestion, 37 correction bolus, 39 correction bolus with carbohydrate intake, 40 currently allowed blood glucose value, 38 meal bolus, 38

bolus advice options, 25–26 bolus advice recommendations, examples, 33–36 bolus amount, adjust, 14 bolus calculation, correction bolus, 28 examples, 29 meal bolus, 27 bolus, delivery using bolus advice, 13–16

#### C

carbohydrate, units of measure, 18 carb ratio, 21 carbs amount, 13 correction bolus, 30–32

#### D

deliver a bolus. *See* bolus, delivery using bolus advice

#### Η

health events, 14, 24-25

insulin increment, 19 insulin sensitivity, 22

L lower blood glucose target limit, 21

#### Μ

max bolus, 19 meal rise, 25

#### Ν

neutral protamine hagedorn (NPH), 9

#### 0

offset time, 26

#### S

safety information, bolus advice, 9–11 bolus delivery, 15–16 snack size, 26 symbols, explanation, 41

#### T

target range, 21 time blocks, 20, 22–24

#### U

upper blood glucose target limit, 21

#### W

warning limits, 20