

18 Appendix

18.1 Guarantee

The statutory provisions on rights in consumer goods sales in the country of purchase shall apply.

Any changes or modifications to the micropump system not expressly approved by Roche could render your operating guarantee for the Accu-Chek Solo micropump system invalid.

18.2 Licence Information

Licence agreement for open source software:

This product contains open source software components. For more information on open source software, see the *System information* item in the *Settings* menu of the diabetes manager.

18.3 Radio Frequency Communication

This device complies with Part 15 of the FCC Rules and with Industry Canada licence-exempt RSS standard(s).

Operation is subject to the following two conditions:

1. this device may not cause harmful interference, and
2. this device must accept any interference received, including interference that may cause undesired operation.

Changes or modifications made to this equipment not expressly approved by Roche Diabetes Care may void the FCC authorization to operate this equipment.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes:

1. l'appareil ne doit pas produire de brouillage, et
2. l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

18.4 Connecting Non-System Devices

Additional equipment connected to the diabetes manager must demonstrably comply with the relevant IEC or ISO standards (e.g. IEC 60950 or IEC 62368 for data processing equipment). Moreover, all configurations must comply with the normative requirements for medical systems (see section 16 of the latest edition of IEC 60601-1). Anyone who connects additional equipment to medical electrical equipment is deemed to be the system configurer, and is therefore responsible for ensuring that the system complies with the normative requirements for systems. If you have any questions, please contact your local authorised dealer or technical customer support.

18.5 Customer Support and Service Centre

If you encounter problems, have questions regarding operation or need additional information about the Accu-Chek Solo micropump system, contact your Customer Support and Service Centre.

Contact details for the responsible Customer Support and Service Centre are provided below.

Do not attempt to repair or modify the components of the micropump system yourself. Our staff will help solve any problems you might be experiencing with the micropump system from Roche.

18.6 Supplies and Accessories

For information on the availability of additional Accu-Chek products and accessories in your country, contact the responsible customer support and service centre.



WARNING

- ▶ Use only the supplied charger and the associated USB cable, or a certified USB charger (e.g. a laptop certified according to IEC 60950 or an equivalent safety standard).
- ▶ Use only the rechargeable battery from Roche.
- ▶ Use only supplies and accessories from Roche and do not modify them. Otherwise, you risk malfunctions of the micropump system, incorrect test results and over- or under-delivery of insulin.

Supplies for the micropump system

- ▶ Accu-Chek Solo reservoir assembly
- ▶ Accu-Chek Solo cannula assembly and micropump holder
- ▶ Accu-Chek Solo pump base
- ▶ Accu-Chek Solo insertion device

Supplies for the blood glucose test

- ▶ Accu-Chek Aviva test strips
- ▶ Accu-Chek Aviva control solutions
- ▶ Accu-Chek FastClix finger pricker
- ▶ Accu-Chek FastClix lancet drums

Accessories

- ▶ Charging cradle for the diabetes manager
- ▶ Carry case/fanny pack for the diabetes manager (Accu-Chek carry case)
- ▶ Rechargeable battery for the diabetes manager
- ▶ Battery door for the diabetes manager
- ▶ Charger for the diabetes manager
- ▶ USB cable

If you need to replace defective system components or need another User's Manual for the micropump system, contact your Customer Support and Service Centre.

18.7 Disposing of the Micropump System

 **WARNING**

All objects which can come into contact with human bodily fluids carry a potential risk of infection. There is a risk that the objects may transmit infections. Dispose of used micropump system components because using them more than once may result in infections being transmitted.

Since your micropump system may come into contact with human bodily fluids during use, it carries a risk of infection. Therefore, it falls outside the scope of the European Directive 2012/19/EU (directive on waste electrical and electronic equipment) and cannot be disposed of with other electronic devices.

Dispose of the used micropump system components according to local regulations.

Rechargeable battery of the diabetes manager

Dispose of the battery correctly and recycle it according to local regulations.

18.8 Bolus Calculation

The bolus advice feature calculates your insulin doses based on different pieces of information. Examples:

- ▶ Your current blood glucose result
- ▶ Your current blood glucose target value
- ▶ Your current insulin sensitivity
- ▶ Your estimated carbohydrate amount for a meal
- ▶ Your current carbohydrate ratio
- ▶ Your current health events
- ▶ Correction insulin that is still acting in the body
- ▶ Your bolus and/or meal history

Consider the following information when calculating bolus advice:

- ▶ How you are currently feeling: It may happen that the values entered when setting up bolus advice do not match how you are currently feeling. Increase or decrease the suggested bolus amount according to your current needs.
- ▶ Bolus amounts and meals that were delivered or consumed, but not entered in the diabetes manager.
- ▶ If you have delivered a bolus without using bolus advice, you can manually enter the bolus information in the electronic logbook. It is important that you enter bolus and carbohydrate information in the logbook in order to obtain accurate bolus advice recommendations.

18.8.1 Correction Bolus

If your current blood glucose level does not match your blood glucose target value, a correction bolus is suggested. The correction bolus calculation is based on your current blood glucose result and your insulin sensitivity in the current time block. Your insulin sensitivity is stated in insulin units per drop in blood glucose, e.g. 1 U : 40 mg/dL.

Calculation:

(Current BG - target BG) x insulin sensitivity

Example

Current BG: 149 mg/dL

Target BG: 110 mg/dL

Insulin sensitivity: 1 U : 30 mg/dL

Correction bolus = (149 mg/dL - 110 mg/dL) x (1 U : 30 mg/dL)
= **1.3 U**

18.8.2 Meal Bolus

A meal bolus is the amount of insulin that needs to be delivered to compensate for the amount of carbohydrates you are planning to eat.

The carbohydrate ratio is specified in insulin units per carbohydrate amount, for example, 1 U : 12 g.

Calculation:

Meal bolus = carbohydrate amount x carbohydrate ratio

Example

Carbohydrate amount: 63 g carbohydrate ratio: 1 U : 12 g

Meal bolus = 63 g x (1 U : 12 g) = **5.25 U**

18.8.3 Correction Bolus After a Meal

After a meal, it is normal for your blood glucose level to increase even if you delivered the correct meal bolus. The allowed increase in the blood glucose level is called *meal rise*. After a certain period of time, the so-called *offset time*, the meal rise decreases slowly. The period of time from the start of the meal rise until it goes away is defined as the *acting time*.

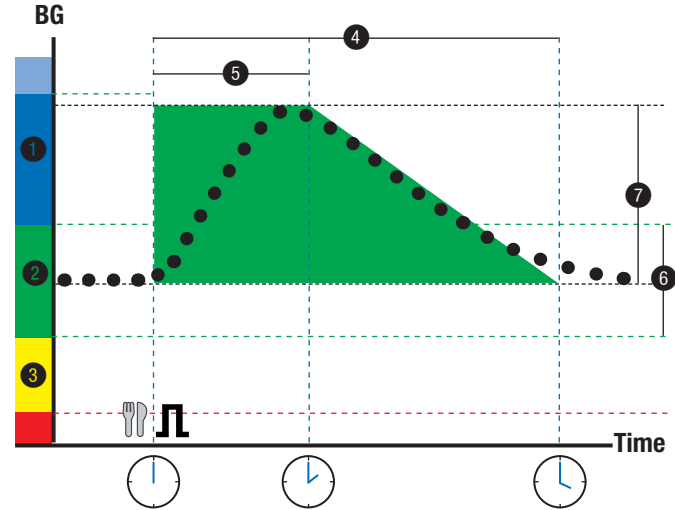
During this time, a correction bolus is only recommended if the increase in your blood glucose level exceeds the allowed meal rise value.

Chart

The dotted line in the adjacent graph shows how your blood glucose level might change after a meal bolus. Bolus advice tolerates an increase in your blood glucose level within the allowed meal rise range (green). If your blood glucose result is within the green range, a correction bolus will not be recommended. If your blood glucose result is above the green range, a correction bolus will be recommended.

If you enter a carbohydrate amount that is greater than the snack size, the meal rise is added to the current target blood glucose value. Since the meal rise is not taken into account when calculating bolus advice for meals up to the snack size, an increase in the blood glucose result above the target range is not tolerated after eating a snack.

The shape of the meal rise (the width of the green area) is determined by the offset time and the acting time.



- ● ● Current BG values
- Allowed BG value: Meal rise
- 🍴 Meal
- 📈 Bolus

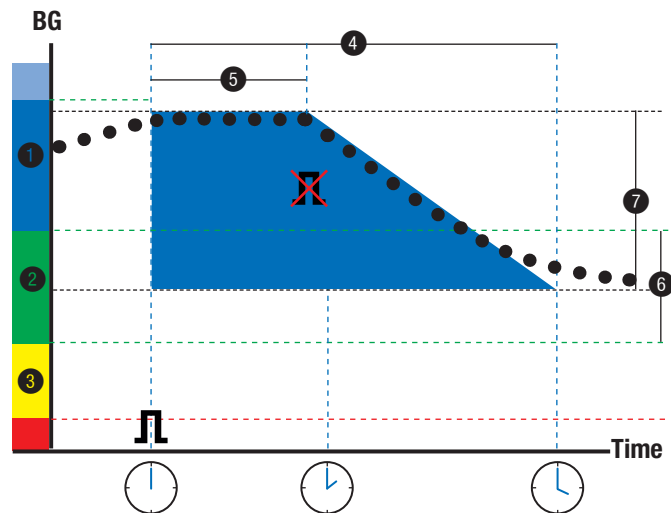
- ① Above target range
- ② Within target range
- ③ Below target range
- ④ Acting time
- ⑤ Offset time
- ⑥ Target range
- ⑦ Meal rise

18.8.4 Subsequent Correction Bolus

A delivered correction bolus covers the difference between your current blood glucose level and your blood glucose target value for a certain amount of time. When the correction bolus begins to act, your current blood glucose level should drop; after the delay, the difference between your current blood glucose level and your blood glucose target value will diminish. At the end of the acting time, your blood glucose level should have reached the target limit value again. You will only receive a recommendation for an additional correction bolus if your current blood glucose result is higher than the blood glucose value currently permitted.

Chart

The first correction bolus at 12:00 noon remains active during the acting time (width of the blue area). If the blood glucose value at 14:00 is below the blood glucose value currently permitted (upper edge of the blue area), no additional correction bolus will be calculated.



- ● ● Current BG values
- Allowed BG value: Corrected BG
- ⏏ Bolus
- ~~⏏~~ No bolus required

- ① Above target range
- ② Within target range
- ③ Below target range
- ④ Acting time
- ⑤ Offset time
- ⑥ Target range
- ⑦ Corrected BG