ACCU-CHEK® Solo

Roche

USER'S MANUAL

ACCU-CHEK SOLO MICROPUMP SYSTEM

This **person with diabetes** is reliant on a regular supply of insulin. The insulin is delivered to this person via a micropump worn on the body.

If this person is confused or unconscious, please do the following:

- Call the emergency services.
- If this person is able to swallow, give them sugar immediately, for example, juice.

SOS

Emergency card

Name _____

Address _____

Phone _____

In case of emergency, please contact:

Name _____

Phone _____

Important information

- You can call up important handling steps for the micropump system as a video via the **Help** function on the diabetes manager.
- If the diabetes manager does not work, recharge the battery using the supplied charger or connect the USB cable to a PC.
- For more information, refer to the printed User's Manual of the micropump system or on your local Accu-Chek homepage. From this website, you can download the User's Manual as a PDF file.
- You can contact the Accu-Chek customer support by calling
  UK: Accu-Chek Pump Careline [1]: UK Freephone number: 0800 731 22 91
  ROI Freephone number: 1 800 88 23 51

  [1] calls may be recorded for training purposes
  Some mobile operators may charge for calls to these numbers.

  Australia: Insulin Pump Support: 1800 633 457, Accu-Chek Enquiry Line: 1800 251 816

My notes

Delivering a bolus with the micropump

1. Press and hold both quick bolus buttons for approximately 3 seconds.
2. Simultaneously press both quick bolus buttons repeatedly until the desired insulin amount is reached. Check the (number of) tones.
3. Simultaneously press both quick bolus buttons to confirm the insulin delivery.

Setting the quick bolus increment

The quick bolus increment is set to 0.2 U by factory default.

The quick bolus increment I have set is ☐ U.

You can change the quick bolus increment here:
Main menu > Settings > Bolus settings

Medical certificate

This is to certify that

Name

Date of birth

has DIABETES MELLITUS.

This person relies on a regular supply of insulin through a body-worn Accu-Chek Solo micropump.

Place and date

Healthcare professional name

Phone Fax

Healthcare professional signature

Stamp

About this User's Manual

Read this User's Manual carefully before using your Accu-Chek® Solo micropump system for the first time. This User's Manual provides you with the information you need to safely operate the micropump system. In addition, this User's Manual provides you with the information you need for maintenance and troubleshooting. You must be familiar with the screens on the display, the sounds and signals of the diabetes manager and micropump as well as the functionality and characteristics of the system components, in order to be able to use the micropump system properly and reliably.

Therapy using the micropump system may only be started after completion of the required training from a qualified instructor. Children and vulnerable persons should only use the micropump system with the support of a trained adult.

This User's Manual is intended for people with diabetes, their caregivers, for parents whose children have diabetes as well as for healthcare professionals. This User's Manual is your first source of information for the micropump system or in case of any problems using it.

If you have any questions, contact customer support.

Also consult the instructions for use enclosed with the components of the Accu-Chek Solo micropump system.

The screens shown in this User's Manual may differ slightly from the screens shown on the display of the diabetes manager. The units, numbers and settings of the screens shown in this User's Manual are only examples.

The following information is highlighted in a special way:

⚠ WARNING

A WARNING indicates a foreseeable serious hazard.

NOTE

A NOTE contains helpful information and tips.

Example

An example shows you how a feature could be used in an everyday situation. Note that medical- or therapy-related details are provided for illustration purposes only, and are not intended to match your personal medical needs.

Instructions for the screens shown on the diabetes manager are structured in this User's Manual as in the following example. You can see the specific situation for the instruction on the display of your diabetes manager.

❶— **1**

❷— *Language:*

❸— Tap the desired language. If required, scroll the list upwards to view additional languages.

❹— Tap Save.

❶	Number of the instruction/action step
❷	Title of the screen on the diabetes manager
❸	Text of the instruction/action step
❹	Screen text/button text

Screens are shown in some of the instructions.

To help you fully benefit from the micropump system, a distinction between **basic** and **advanced** is made with regard to the various features and properties.

Chapters highlighted in **blue** refer to features that are required to be able to use the micropump system. Read these chapters before using the Accu-Chek Solo micropump system.

Chapters highlighted in **purple** refer to features that are recommended for fully benefiting from the micropump system. Read these chapters before using the respective features.

Content of the kit

The kit contains the following components:

The Accu-Chek Solo pump base, the Accu-Chek Guide Solo diabetes manager, rechargeable battery for the Accu-Chek Guide Solo diabetes manager, the Accu-Chek Solo insertion device, charger, USB cable, user's manual, envelope containing PIN unlock code and pump key.

Only use the following Roche sterile consumables, which are not supplied with the micropump system packaging (system kit):

- The Accu-Chek Solo reservoir assembly
- The Accu-Chek Solo cannula assembly & pump holder

Additional materials not supplied with the micropump system packaging (system kit).

- The Accu-Chek Guide test strips
- The Accu-Chek Guide control solution
- A finger pricker

NOTE

- Only use consumables and accessories from Roche.
- Order a new pump base in time before the operating life of the first pump base expires so that you always have one in reserve.
- Ensure an adequate supply of pump holder, cannula and reservoir items are kept in reserve so that replacements are available when needed.
- Keep the PIN unlock code and the pump key in a safe place to protect them against misuse.

CONTENTS

1 Purpose of the Micropump System

The Accu-Chek Solo micropump system is intended for the subcutaneous continuous delivery of insulin via customizable hourly rates, for the management of diabetes mellitus in persons requiring insulin. The Accu-Chek Solo micropump system is intended for single patient use in home environment, public and community settings, including office environment.

The Accu-Chek Solo micropump system can be used by people with diabetes either on their own or with the support of a healthcare professional or a trained individual. The micropump system is intended for people with diabetes who are at least 2 years of age.

The Accu-Chek Solo micropump system consists of the following components:

- The Accu-Chek Solo pump base
- The Accu-Chek Solo reservoir assembly
- The Accu-Chek Solo cannula assembly & pump holder
- The Accu-Chek Solo insertion device
- The Accu-Chek Guide Solo diabetes manager.

To use the Accu-Chek Solo micropump system, you also need short- or rapid-acting U100 insulin or insulin analogues and test strips for the blood glucose measurement.

The micropump system can be used with the following U100 insulin types: Humalog®, NovoLog®, NovoRapid®, Apidra®, Insuman® Infusat or Fiasp®. The exact insulin type for treating your diabetes mellitus will be prescribed by your healthcare professional. Consult the manufacturer's package insert.

1.1 Intended Use

The Accu-Chek Solo **pump base** is part of the micropump. It contains the mechanical parts as well as the electronics to control and monitor the operation of the pump. The Accu-Chek Solo pump base is intended for continuous insulin infusion in the treatment of diabetes mellitus requiring insulin.

The Accu-Chek Solo **reservoir assembly** (including the filling aid and the handle of the piston rod) is a part of the micropump in addition to the Accu-Chek Solo pump base. The reservoir is a sterile container for holding the insulin that the micropump delivers to the body.

The Accu-Chek Solo **cannula assembly & pump holder** consists of the cannula casing, the sterile cannula and the pump holder. The Accu-Chek Solo **cannula assembly** consists of the cannula casing and the sterile cannula. It creates a connection between the micropump and the body to channel the insulin into the body.

The Accu-Chek Solo **pump holder** is a plate that is adhered to the skin to fix the cannula in place. It also holds the Accu-Chek Solo micropump in place.

The Accu-Chek Solo **insertion device** is used to attach the infusion assembly (pump holder and cannula) to the body and insert the cannula into the subcutaneous tissue.

The Accu-Chek Guide Solo **diabetes manager** is used to configure and control the micropump. The Accu-Chek Guide Solo

diabetes manager is needed to fulfil the intended purpose of the Accu-Chek Solo micropump.

The bolus advice of the Accu-Chek Guide Solo diabetes manager gives an advice for correction boluses or meal boluses.

The Accu-Chek Guide Solo diabetes manager includes a blood glucose monitoring system that is intended for self-testing.

1.2 Contraindications

The micropump system should not be used by children under 2 years of age or by people who regularly require less than 0.1 U/h of basal insulin. It is the responsibility of the healthcare professional to decide whether the accuracy of the delivery rate is adequate for the patient in question.

Your healthcare professional must decide whether insulin pump therapy is suitable for the treatment of your diabetes mellitus.

Continuous Subcutaneous Insulin Infusion (CSII) with the micropump system is not recommended or only recommended with limitations for the following groups of people:

- People who are not able or willing to either perform at least 4 blood glucose tests per day or use a continuous glucose monitoring (CGM) system reliably.
- People who are not able to be in regular contact with their healthcare professional.
- People who do not understand what is required for insulin pump therapy or who are not able to follow the instructions for use of the micropump system.
- People who cannot be relied upon due to drug addiction, substance abuse or mental illness.
- People who are exposed to high ambient temperatures on a regular basis.
- People with skin that does not tolerate adhesive pads.
- People who often experience a cannula occlusion.
- People who are not able to notice alarms because of physical limitations.

1.3 Compatible Insulins

The Accu-Chek Solo micropump system is designed to use rapid-acting U100 insulin. The following U100 rapid-acting insulin analogues have been tested and found to be safe for use in the micropump: NovoRapid®, Insuman® Infusat, NovoLog® (insulin aspart), Apidra® (insulin glulisine), Fiasp® (insulin aspart) or Humalog® (insulin lispro). NovoLog®, Fiasp®, and Humalog® are compatible with the system for use up to 96 hours (4 days). Apidra® is compatible with the system for use up to 48 hours (2 days). If you have questions about using other insulins, contact your healthcare professional. Fiasp® has a faster initial absorption than other rapid-acting U100 insulins. Always consult your healthcare professional and refer to the instructions for use of the insulin manufacturer prior to use.

1.4 Risks and Benefits

Talk to your healthcare professional about the benefits and potential risks that are associated with using the micropump system.

The intended clinical benefit of the Accu-Chek Solo micropump system for the patient is that it enables the intensive insulin therapy (IIT), allowing the patient to flexibly adjust basal-bolus insulin delivery to changing insulin requirements in order to achieve individual treatment goals.

To ensure that insulin pump therapy is safe and successful, you must actively take part in your therapy, test your glucose value regularly and monitor the functions of the micropump regularly.

In case of improper use of the micropump system or non-compliance with your healthcare professional's instructions, you risk experiencing, for example, hypoglycaemia, hyperglycaemia, ketoacidosis or infections of the infusion site. Follow the treatment plan you agreed on with your healthcare professional as well as the setting for basal rate profiles and bolus advice defined therein. Read and follow the safety instructions in the chapter *1.5 General Safety Information* for safe and proper use of the micropump system.

1.4.1 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 micropump system or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority.

1.4.2 Summary of Safety and Clinical Performance (SSCP)

You find the SSCP after the launch of the European database on medical devices (Eudamed) here: https://ec.europa.eu/tools/eudamed

1.5 General Safety Information

⚠ WARNING

- **Risk of infection**
  - All objects which can come into contact with human blood carry a potential risk of infection. The use of the micropump system by more than one person, even by family members, can lead to the transmission of infections.
    The micropump system may only be used by a single person for insulin therapy. The same micropump system must not be used by other people or healthcare professionals for insulin therapy or blood glucose testing for different patients.
  - Used system components carry a risk of infection.
    Discard used system components according to local regulations so that no one can get infected.

- If system components of the micropump system have come into contact with blood, they can transmit infections. Discard the used system components as infectious material in accordance with the regulations in your country.
- Sterile consumables (reservoir assembly, cannula assembly & pump holder) whose use by date has expired or whose packaging is damaged or if they have been stored improperly may be infectious.
  Use sterile consumables only once and only if the use by date has not expired and the related sterile packaging is not damaged.

■ **Risk of suffocation**

The micropump system contains small parts that can be swallowed.
Keep the small parts away from small children and people who might swallow small parts.

■ **Risk of wrong therapy decisions**

- Incorrect therapy settings can lead to an overdose or underdose of insulin.
  Do not change your therapy without consulting your healthcare professional first.
- Strong electromagnetic fields, for example, from radar or antenna installations, sources of high voltage or X-Ray, MRI (magnetic resonance imaging) and CT (computed tomography) could interfere with the micropump system.
  Do not use the micropump system close to strong electromagnetic fields or ionizing radiation. Stop the micropump and remove it from your body before you enter areas with electromagnetic or ionizing radiation.
- Mechanical stress caused by shocks (for example during sports by a punch or a ball) or dropping can impair the correct operation of the micropump system.
  If the micropump has been subjected to mechanical shocks, check your blood glucose level at least once within 1 to 3 hours.
- If there are irregularities or damage to the display, important information or messages regarding the management your therapy may not be displayed correctly.
  Correct micropump system operations that rely on the display are no longer ensured.
  Do not use the diabetes manager if the display is damaged or defective. Contact customer support.

■ **Risk of serious harm**

- The use of third-party accessories may cause the micropump system to malfunction. Proper operation of your Accu-Chek Solo micropump system cannot be guaranteed if you use third-party accessories.
  Use only accessories, software and apps available in your country that are intended by Roche for use with the Accu-Chek Solo micropump system.
- Sources of Radio Frequency (RF) (for example *Bluetooth* devices, cell phones, Wi-Fi router, access points, microwave ovens) may impair the

micropump and the diabetes manager or interfere with device communication.
Maintain a distance of more than 30 cm between the micropump system and sources of Radio Frequency (RF).

- The repeated use of the same infusion site to administer insulin may lead to changes in the subcutaneous fatty tissue. Insulin absorption may be altered at sites where such changes occur.
  Make sure that a new infusion site is at least 5 cm away from the last infusion site.

- **Risk of hypoglycaemia (low blood glucose level) or hyperglycaemia (high blood glucose level)**
  - Failure to follow the information displayed on the status screen and the messages from the diabetes manager, may result in hyperglycaemia or hypoglycaemia. Regularly check the information on the Status screen of your diabetes manager. For example, if the micropump is in STOP mode, no insulin will be delivered. This can lead to hyperglycaemia.
  - Exposing your micropump system to extreme acceleration forces may interrupt or impair insulin delivery. High g-forces occur, for example, when riding a roller coaster.
    In these cases, first remove the micropump from the pump holder.
  - Mechanical, electrical or connection problems can cause the micropump system not to work properly. This may cause insulin delivery to be impaired, which in turn may cause your blood glucose value to be improperly adjusted.
    Check your blood glucose value at least four times a day.
  - Patients with high insulin sensitivity may have more fluctuating glucose levels.
    Check your blood glucose level more than four times a day if your insulin sensitivity is high.
  - Use or storage of the micropump system under inappropriate ambient conditions (for example extreme temperatures) will impair the function of the micropump system. This can lead to incorrect glucose values, overdose or underdose of insulin and delivery inaccuracy of the micropump.
    Only use or store the micropump system within the permissible ambient conditions, see chapter *16 Technical Data*.
  - The micropump system can be damaged by the ingress of moisture, water or other liquids.
    Do not immerse the micropump in water or other liquids.
    Remove the micropump from the pump holder before showering, bathing, diving or swimming.
  - Modifying or repairing the micropump system by the user may result in malfunctions of the micropump system, incorrect glucose values and overdose or underdose of insulin.

Never attempt to repair or modify the micropump system yourself.

- Use of insulin at lower or higher concentrations than U100 may result in overdose or underdose of insulin. This may lead to hypoglycaemia or hyperglycaemia.
  Only use the micropump to deliver rapid-acting U100 insulin.

NOTE

- Before starting the insulin pump therapy, find out where and how you can obtain alternative therapy supplies (for example, a blood glucose meter or insulin pen) at short notice in case the micropump system does not function properly.
- Refer to the Accu-Chek Guide test strip and Accu-Chek Guide control solution package inserts for additional health-related information.
- DO NOT make changes or modifications to any component of the Accu-Chek Solo micropump system that has not been authorised by Roche. Unauthorised tampering with the system can revoke your right to operate it.
- The micropump system contains sharp parts which can cause injury. Keep pointed or sharp-edged parts away from small children and people who could be injured by them.

1.6 Components of the Micropump System

The Accu-Chek Solo micropump system is a system that primarily consists of a tubeless micropump and a diabetes manager, which serves as a remote control.

Accu-Chek Guide Solo diabetes manager

The Accu-Chek Guide Solo diabetes manager is used to configure and control the micropump. The diabetes manager has an LCD display and communicates with the micropump via *Bluetooth*® wireless technology.

1 **LED**
For signalizing system messages.

2	**Lanyard eyelet** For attaching a lanyard.
3	**Power button** For turning the diabetes manager on or off.
4	**Headphone port** Port for connecting passive headphones.
5	**Display** LCD touchscreen.
6	**Function buttons** Buttons for operating context-sensitive functions.
7	**Navigation buttons** For moving between menus and process steps.
8	**Insulin button** Button for confirming a previously set insulin delivery.
9	**Test strip ejector** Button for removing the test strips.
10	**Test strip slot** For inserting test strips.
11	**Camera** For scanning the pairing code.
12	**Micro USB port** Port for connecting the USB cable (micro-B plug).
13	**Battery door** Removable cover for the battery compartment.

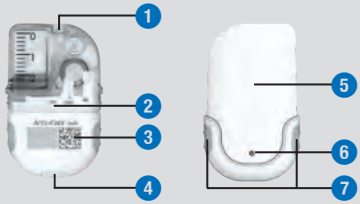
NOTE

- Only use the headphone port for connecting passive headphones, for example, headphones without their own power supply.
- Close the cover of the headphone port after use.

Accu-Chek Solo micropump

The Accu-Chek Solo pump base contains the mechanical parts as well as the electronics to control and monitor the operation of the pump.

Pump base



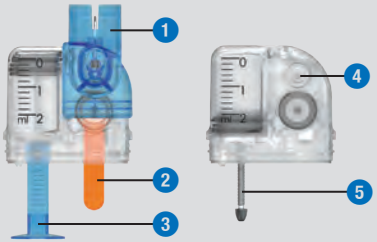
1	Recess for attaching the pump holder
2	Pump base with reservoir mounted
3	Pairing code
4	Recess for attaching the pump holder
5	Pump shield
6	Opening for ventilation
7	Quick bolus buttons

1 PURPOSE OF THE MICROPUMP SYSTEM

Accu-Chek Solo reservoir assembly

The reservoir is a sterile container for holding the insulin that the micropump delivers to the body. The reservoir contains a battery that acts as an energy source for the micropump.

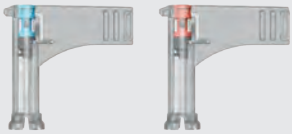
Reservoir

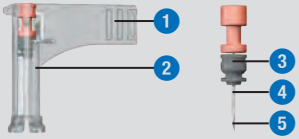


1	Filling aid
2	Protective film for battery
3	Handle for piston rod
4	Reservoir needle
5	Piston rod

Accu-Chek Solo cannula assembly

The Accu-Chek Solo cannula assembly creates a connection between the micropump and the body. The Accu-Chek Solo cannula assembly is available with cannula lengths of 6 mm (orange) or 9 mm (blue).

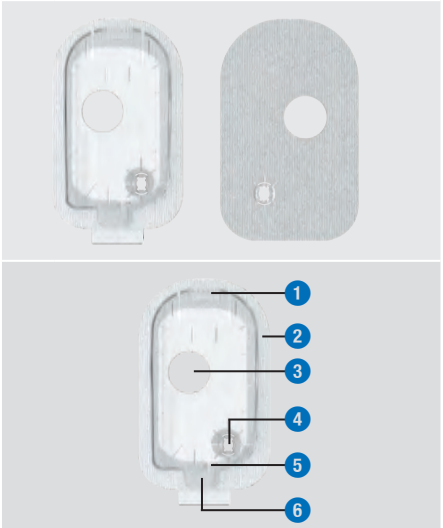




1	Handle
2	Cannula casing
3	Cannula head
4	Soft cannula
5	Introducer needle

Accu-Chek Solo pump holder

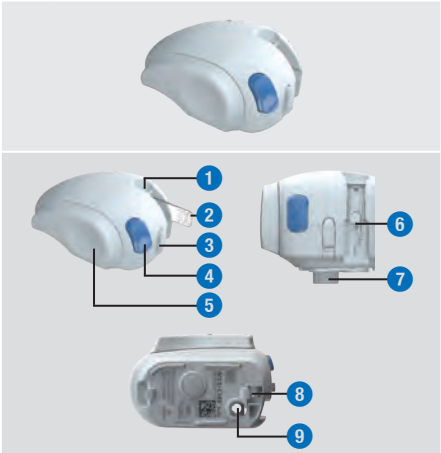
The Accu-Chek Solo pump holder is an adhesive pad that is adhered to the skin to fix the cannula in place. It also holds the micropump in place.



1	Hook for attaching the micropump
2	Adhesive pad
3	Opening for safety release of the insertion device
4	Cannula opening with cannula support
5	Hook for attaching the micropump
6	Flap for detaching the micropump

Accu-Chek Solo insertion device

The Accu-Chek Solo insertion device is used to attach the infusion assembly (pump holder and cannula) to the body and insert the cannula into the subcutaneous tissue.



1	Positioning aid
2	Inserted cannula assembly
3	Detach button
4	Release button
5	Priming handle
6	Cannula assembly slot
7	Safety release
8	Lock
9	Cannula opening

⚠ WARNING

- Check all components for visible damage before using them with the micropump system.
- The reservoir, cannula and pump holder are intended for single use and are sterile packaged. They must not be used if their sterile packaging was previously opened or damaged or if the use by date has expired. If the sterile packaging is damaged or already open, the product can be unsterile and lead to infection.
- If the infusion assembly may have come into contact with infectious material, replace the infusion assembly immediately. There is a risk that infections (for example, hepatitis or HIV) could be transmitted.
- If there is an unexpected rise in your glucose level or an occlusion message occurs, check the micropump and the infusion assembly for occlusions and leaks. Replace your infusion assembly if you are not sure whether the infusion assembly is working properly.
- Check regularly to make sure that the pump holder does not detach itself from the infusion site and that the adhesive pad is not wet. Insulin delivery may be interrupted by a loose fitting or displaced cannula.

1.7 Using the Micropump System in Daily Life

The micropump system is intended to be used continuously, every day in any everyday situation. There are only a few situations in which it is necessary to pay special attention to the system or remove the micropump in order to protect it. Use the micropump system only if it is functioning properly and does not show any signs of damage. Always have alternative therapy supplies at hand for your own safety.

NOTE

- Check at regular intervals whether the micropump system has visible or tangible signs of damage. This applies in particular if the system components were dropped or were exposed to particular mechanical stress.
- Check the micropump system for damages or leaks if you notice the scent of insulin.
- Do not use any consumables that are damaged or were dropped.

Showering, bathing, swimming, diving

Protect the diabetes manager from moisture and water. The micropump is splashproof, but it must not be immersed in liquids. Therefore, remove the micropump from the pump holder before taking a shower or bath, diving or going for a swim.

Exercise

You can wear the micropump during a variety of physical activities. Do not wear the pump for sports that involve frequent, high-impact bodily contact, such as martial

arts, football or hockey. The micropump could suffer damage by being hit or kicked or if it is hit by a ball.

Sleeping

Place the diabetes manager within reach so that you can hear reminders and system messages. We recommend that you recharge the diabetes manager when you go to bed.

Temperature

Do not expose the micropump to direct sunlight, UV radiation or heat. The operating temperature of the micropump is between +5 °C and +40 °C. At temperatures outside this range, the insulin contained in the reservoir could be rendered ineffective. There may also be damage to the micropump system.

NOTE

Protect the micropump and consumables from sunlight and heat. If the micropump has been exposed to sunlight or heat, check your blood glucose.

Air pressure and altitude

Rapid and significant changes in air pressure or temperature can influence insulin delivery, especially if there are air bubbles in the reservoir. Such changes may occur, for example, when you are on an airplane (especially during take-off and landing) or if you engage in a sport such as hang-gliding.

In such cases, do the following: Remove any air bubbles from the reservoir (see chapter *9.5 Removing Air Bubbles*) and test your blood glucose at frequent intervals. If in doubt, remove the micropump and change to an alternative therapy method.

Do not use the micropump system at an air pressure below 70 kPa. This corresponds to an altitude of up to 3,000 metres above sea level. Do not use the supplied charger in altitudes above 2,000 metres above sea level.

Travelling and flights

Before travelling, ask your healthcare professional about any special preparations you need to make. Take sufficient supplies with you for blood glucose testing and for your insulin pump therapy.

Some airlines and governments do not permit the use of wireless radio devices during flight. In these situations you can activate airplane mode. Airplane mode enables the micropump system to comply with these regulations.

Communication between micropump and diabetes manager

For wireless communication between the micropump and the diabetes manager, it is not necessary for the devices to be right next to each other. Obstacles, such as walls or furniture, between the pump and the diabetes manager can reduce or interrupt the communication range.

2 Getting to Know the Micropump System

2.1 Diabetes Manager Overview

The Accu-Chek Guide Solo diabetes manager is a remote control with an integrated blood glucose meter that is used to control the micropump. The diabetes manager supports you in your diabetes treatment and is only suitable for self-testing.

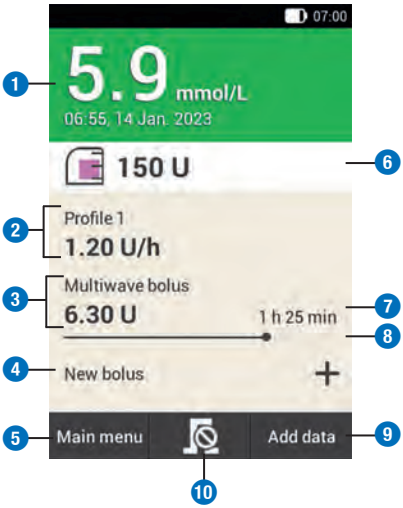
NOTE

- Always have the diabetes manager with you.
- A rechargeable battery supplies power to the diabetes manager. Charge the battery on a regular basis.
- If the environment you are in has a high noise level, or if the diabetes manager is in a bag, you may not hear the system messages. Set the sound mode to a setting that is loud enough, and pay attention to the screens and signals on the diabetes manager to make sure that the micropump system is functioning properly.

2.2 Status Screen

On the Status screen, you can see the most important, current and most common therapy information on glucose value, basal rate, ongoing boluses and reservoir level at a glance. You can access other information and menus from the Status screen.

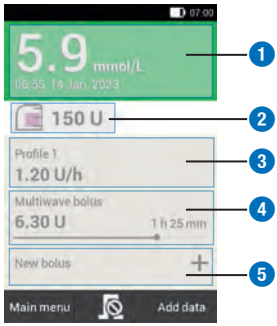
Depending on the situation (for example, whether you are using pump therapy or injection therapy), other content and symbols are displayed.



	Description
1	**Glucose value** Shows the most recent glucose value with the time and date of the test. The background colour indicates whether the glucose value falls within the target range.
2	**Basal rate** Shows the active basal rate profile with the current basal rate. If a temporary basal rate is active, the corresponding percentage is also displayed.
3	**Bolus** Shows the active bolus type and the remaining insulin units.

	Description
4	**New bolus** Tap New bolus or + to program a new bolus.
5	**Main menu** Tap this button to display the main menu.
6	**Reservoir level** Shows how many insulin units are in the reservoir.
7	**Remaining bolus time** Shows the amount of time remaining of an extended or multiwave bolus.
8	**Bolus progress bar** Shows the amount and duration of the active bolus in the form of a bar.
9	**Add data** Tap this button to add further data to the logbook (for example, glucose value or time of test).
10	**Cancel bolus** Tap to cancel one or all active boluses.

The touch-sensitive areas on the Status screen allow you to quickly access important menus and features. When you tap the areas, the corresponding menus or features are opened.

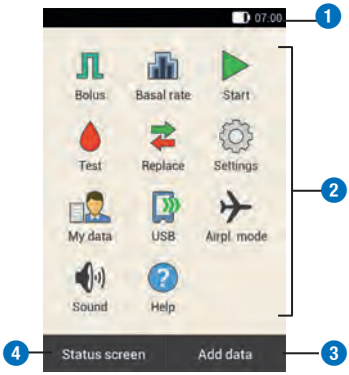


	Description
1	Logbook entries menu
2	Replace system components menu
3	Basal rate menu
4	Cancel bolus
5	Bolus menu

2.3 Main Menu

The main menu is an overview of the most important features of the diabetes manager.

Depending on the situation (for example, pump therapy or injection therapy), other menus can be displayed.



	Description
1	**Status bar** Shows the current status symbols (for example, level of rechargeable battery).
2	**Menu icons** Tap a menu icon to open the desired menu or to turn on the desired feature.
3	**Add data** Tap this button to add further data to the logbook (for example, glucose value or time of test).
4	**Status screen** Tap this button to display the Status screen.

The status bar at the top edge of the screen shows the current time. In addition, the following symbols may be displayed.

Symbols in the status bar

Symbol	Description
	**Status of rechargeable battery** Shows the current level of the rechargeable battery in the diabetes manager.
	**No communication** Is displayed when the communication between the diabetes manager and the micropump is not established or interrupted.
	**Airplane mode** Is displayed when airplane mode is turned on.
	**No sound** Is displayed when tones are turned off.
	**Sounds temporarily muted** Is displayed when sounds for reminders and pump warnings are temporarily muted.
	**Vibration** Is displayed when the vibration feature is turned on.

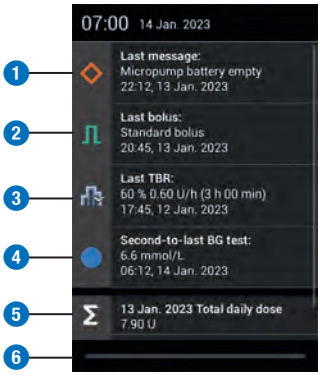
Menu icons in the Main menu

Menu icon	Description
	Deliver manual bolus, use bolus advice, cancel bolus
	Select or set basal rate profiles, set and cancel Temporary Basal Rates (TBR)
	Micropump is in STOP mode, start micropump
	Stop micropump (cancel bolus and TBR and interrupt basal rate)
	Test blood glucose, enter glucose value, perform control test
	Replace system components (infusion assembly, reservoir, pump base)
	View or change settings, view system information, switch therapy mode
	Display or edit logbook data

Menu icon	Description
	Connect diabetes manager to a PC in order to transfer data
	Turn airplane mode on or off
	Set sounds
	Watch Help videos

2.4 Information Screen

The Information screen is a representation of important device, status and therapy information as well as system events. When you tap the events, the respective menus open.



	Description
1	**Event data**
2	**Bolus data for boluses delivered by the micropump**
3	**TBR data**
4	**Logbook entries**
5	**Total daily dose delivered by the micropump**
6	**Sliding pane**

The bar on the sliding pane lights up blue while it is being moved.

Slide your finger from the upper screen edge downwards.

2.5 Navigation and Operation

You navigate and operate the diabetes manager by means of the touchscreen and navigation buttons. The insulin button is an exception. The insulin button is for confirming a previously set insulin delivery.

You can use the navigation buttons below the display to move forwards and backwards or to go to the Status screen.

Button	Function
⮌	Back Go back to the previous screen within the process step. **If you press the** Back **button in a process step, the settings will not be saved.**
⌂	Status screen Switch to the Status screen.
→	Forward Go to the next screen within the process step. In many process steps, this button performs the same function as the Next or OK buttons.

Insulin Button

Press the insulin button to start a basal rate or bolus. When the diabetes manager is ready to deliver basal or bolus insulin, the button lights up green.

Example: Check whether the settings for insulin delivery are correct. Press ✓ button below the diabetes manager display to start insulin delivery.

Entering Numbers

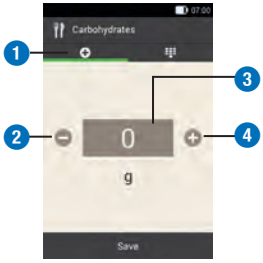
You can either use a numeric keypad to enter numbers or use the minus/plus buttons to set them.

Some numbers and values can only be set using the minus/plus buttons or only be entered by means of the numeric keypad.

Numeric keypad

	Description
1	Field for data entry
2	Decimal separator
3	Numeric keypad
4	Back arrow: Deletes the entered data one character at a time

Minus/plus buttons



	Description
1	Buttons minus/plus
2	Decrease the value entered
3	Field for data entry
4	Increase the value entered

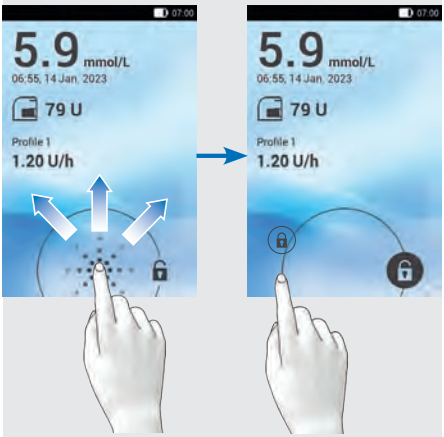
Tap -/+ to decrease or increase the numeric value on the screen.

Keep your finger on one of the minus/plus buttons for a bit longer to decrease or increase the numeric values in a fast scroll mode.

Screen Lock

If the diabetes manager has been inactive for approx. 60 seconds, the screen is automatically locked. You can also lock the screen by pressing the power button. A locked screen is indicated by ⓐ.

You unlock the screen by swiping your finger from the middle of the screen in any direction. If you have activated PIN entry, you will have to enter the four- to eight-digit PIN on the next screen to unlock the diabetes manager screen. You may change the settings in the menu Settings > Screen lock.



Swipe across the screen with your finger, starting from ⓐ, until the lock symbol is outside the circle shown, then remove your finger.

3 Putting the Diabetes Manager into Operation

Before you start using the diabetes manager, you must charge the battery. Connect the diabetes manager to a PC or charger by means of a USB cable. The preferred method is to use a charger and wall socket since charging takes less time this way. It takes approx. 4 hours to charge a fully drained battery using a charger that is connected to a wall socket.

When the battery level is low, the diabetes manager automatically deactivates communication via *Bluetooth* wireless technology to save power. As a result, communication with the micropump is interrupted. After you have recharged the battery, the diabetes manager automatically restores communication via *Bluetooth* wireless technology.

NOTE

- While the diabetes manager is being charged, you cannot perform any blood glucose tests.
- Recharge the battery regularly so that it does not become fully drained. Keeping the diabetes manager plugged in for a longer period to charge does not harm the battery.
- If you insert a replacement battery, charge the replacement battery completely before using the diabetes manager.
- Check regularly whether the time and date of the diabetes manager are set correctly.

⚠ WARNING

- Use only the supplied charger and the associated USB cable, or a certified USB charger (for example, a laptop certified according to IEC 60950-1/ 62368-1 or an equivalent safety standard).
- Use only the rechargeable battery from Roche.

Do not remove the tab on the battery. The tab makes it easier to remove the battery from the battery compartment.

3.1 Charging the Battery

1

Open the battery compartment by pushing the battery door up in the direction of the arrow.

2

Place the rechargeable battery into the battery compartment of the diabetes manager.

The plus sign (+) and the minus sign (-) on the rechargeable battery must match the respective symbols in the battery compartment.

3 Close the battery compartment by pushing the battery door in a downward direction until it clicks into place.

3.1.1 Charging the Battery Using a Wall Socket

1 Plug the larger end (USB type A) of the USB cable into the USB socket of the charger.

2 Plug the smaller end (USB type micro-B) of the USB cable into the USB socket of the diabetes manager.

3 Plug the charger into a wall socket.

3.1.2 Charging the Battery Using a Computer

1 Plug the smaller end (USB type micro-B) of the USB cable into the USB socket of the diabetes manager.

2

Plug the larger end (USB type A) of the USB cable into a free USB charging port on your computer. The USB charging port is often indicated by ϟ.

3 The Status screen or Main menu displays ⚡ in the status bar. It indicates that the battery is being charged.

To end the charging process, first remove the USB cable from the diabetes manager and then from the PC.

NOTE

The blue LED lights up to indicate that the battery is being charged. If the rechargeable battery has been completely depleted, it may take up to 15 minutes until the blue LED of the diabetes manager lights up.

If the LED does not light up after 15 minutes, proceed as follows:

- Disconnect the charger from the diabetes manager.
- Wait for a short time.
- Reconnect the charger to the diabetes manager.
- If the problem cannot be resolved using the suggested solutions, contact customer support.
- If the battery level of the diabetes manager is very low, the screen is black at first.

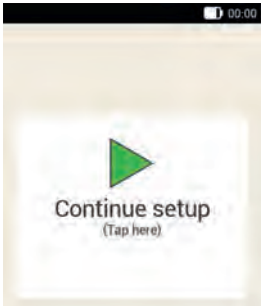
3.2 Setup Wizard

The first time you turn the diabetes manager on, the setup wizard is displayed. You must complete the setup wizard before you start using the micropump or test your blood glucose.

The setup wizard is displayed every time you turn the diabetes manager on until you complete the setup.

⚠ WARNING

- Discuss your individual settings for insulin dose, warning limits, time blocks and bolus advice with your healthcare professional.
- Wrong basal rate settings may lead to hyperglycaemia or hypoglycaemia.
- Having the time and date set precisely is essential in order for your micropump system to function properly. Having the wrong time set may result in the delivery of incorrect insulin amounts, thus leading to hyperglycaemia or hypoglycaemia.



The data and settings you enter are cached at specific points during setup. These so-called resume points are points during the setting process at which the settings made so far are saved. If you want to resume setup after an interruption, Continue setup appears on the screen.

If you press the Back button ⮌ during setup, you will be taken to the previous resume point. All data and settings that you have made after the last resume point are deleted.

Tap the screen *Continue setup* to continue setting up the system.

1 If the diabetes manager is off, press and hold the power button on the top of the diabetes manager until the diabetes manager turns on.

If the diabetes manager is turned on, briefly press the power button to activate the energy-saving standby mode.

2 *Start screen:*

The diabetes manager vibrates, issues the Start sound, and the signal LED lights up. The start screen appears briefly.

3 *Language:*

Tap the desired language. If required, scroll the list upwards to view additional languages.

Tap Save.

4 *Enter PIN:*

Enter a PIN (secret identification number) of your choice with 4 to 8 digits.

Choose a PIN that is easy to remember. Note down the PIN and keep it in a safe place.

Tap OK.

5 *Confirm PIN:*

Enter the PIN a second time to confirm.

Tap OK.

If you have forgotten the PIN you chose, you can unlock the diabetes manager with a PIN unlock code.

You will find the label with the 8-digit PIN unlock code in the envelope in the micropump system packaging (system kit).

6 *Setup mode:*

Tap Manual setup.

Note: It is not currently possible to perform the setup on the PC.

Setting the time and date

Times and time periods are always displayed or entered in the following format HH:MM (HH = hours, MM = minutes). If you select the 12-hour format, *am* or *pm* is displayed.

The date is always displayed or entered in the format DD MMM YYYY (DD = day, MMM = month, YYYY = year), for example, 29 Mar 2023.

7 *Time and date:*

Tap Time format. Tap the desired time format (12 or 24 hours). Tap Save.

8 *Time and date:*

Tap Time.

Set the hours and minutes in the Time screen.

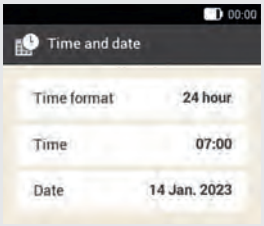
Tap OK.

9 *Time and date:*

Tap Date.

Set the day, month and year in the Date screen.

10



Once you have entered all settings for time and date, tap OK.

Setting the carbohydrate unit

The diabetes manager offers the following carbohydrate units for selection:

Abbre-viation	Unit of measurement	Gram equivalent
g	Gram	1 gram
BE	Broteinheit (bread equivalent)	12 grams
KE	Kohlenhydrateinheit (carbohydrate unit)	10 grams
CC	Carbohydrate choice	15 grams

NOTE

You cannot change the selected carbohydrate unit in the diabetes manager later on.

11 *Carbohydrate unit:*

Tap the carbohydrate unit you want to set.

12 *Information - Selected carbohydrate unit:*

Tap Yes if the correct unit is displayed.

If you want to change the unit, tap No. You then return to Step 11.

Setting warning limits

You can set warning limits for hyperglycaemia and hypoglycaemia that best fit your needs.

Whenever your glucose value is above the hyper warning limit or below the hypo warning limit, the diabetes manager displays a warning.

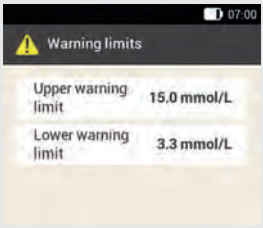
13 *Warning limits:*

The default warning limits are displayed.

Tap Upper warning limit. Set the upper warning limit. Tap OK. Tap Lower warning limit. Set the lower warning limit. Tap OK.

If you do not want to change the warning limits, tap Done.

14



The warning limits currently set are displayed.

Tap Done.

15 *Information - Set up bolus advice?:*

If you want to set up bolus advice now, tap Yes. In section *7.1 Setting Up Bolus Advice,* you will find the explanations and steps for setting up this feature.

If you do not want to set up bolus advice now, tap No.

If you do not want to set up bolus advice now, the setup wizard skips the steps for setting up bolus advice. You can set up bolus advice at a later time. The next steps show the setup wizard if you have selected No in step 15.

Setting time blocks

The diabetes manager allows you to define blood glucose target ranges for certain times of day. For this purpose, the day is divided into time blocks. By dividing the day into time blocks, you can adjust the blood glucose target range to your specific needs.

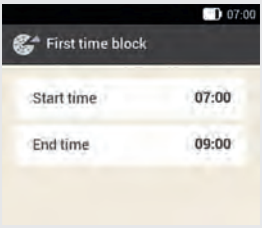
16 *Information - Set up time blocks:*

Tap OK.

17 *First time block:*

Tap Start time. Set the start time (for example, 07:00). Tap OK. Tap End time. Set the end time (for example, 09:00). Tap OK.

18



Tap Done.

19 *Target range:*

In this screen you set the target range values for all time blocks. You can adjust the values for each time block later.

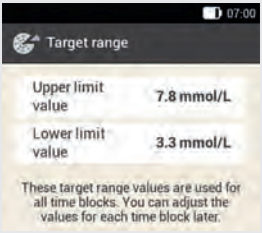
Tap Upper limit value. Set the upper limit value (for example, 7.8 mmol/L).

Tap OK.

Tap Lower limit value. Set the lower limit value (for example, 3.3 mmol/L).

Tap OK.

20



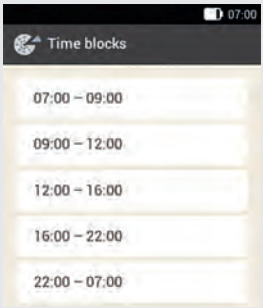
Tap Done.

21 *Information - Set up time blocks:*

Tap OK.

You can set one blood glucose target range for all time blocks or different ones for the various time blocks. The settings for the first time block are used in all copied time blocks. Tap the appropriate time blocks to change these settings.

22



If you want to change the settings for a time block, tap on the desired time block. Repeat the previous steps, beginning with the screen *Warning limits* in step 13 to make the desired settings for this time block.

Once you have changed all desired time blocks, tap Done.

23 *Information - Time blocks complete:*

Tap OK.

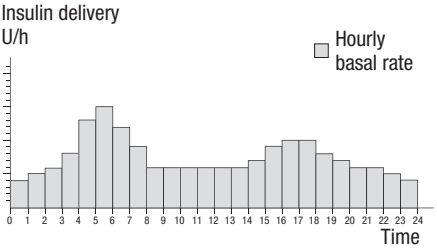
3.3 Programming a Basal Rate Profile

The basal rate covers the basal, meal-independent insulin requirement. Basal rates are specified in insulin units per hour

(U/h = Units per hour). The distribution of the basal insulin requirement over up to 24 time blocks results in the basal rate profile.

To put the micropump into operation and begin therapy, you must program at least one basal rate profile.

Example: Basal rate profile



Setup wizard > Create basal rate profile

1 *Information - Create basal rate profile:*

Tap OK to set up a basal rate profile.

↩ is deactivated.

NOTE

The first time block always starts at 00:00. The last time block always ends at 00:00.

The factory settings provide 24 time blocks with one hour each. A time block can range from 15 minutes to a maximum of 24 hours.

All time blocks have a basal rate of 0 U/h set by factory default.

2 *Basal rate profile:*

The basal rate profile is displayed.

Tap ⌨ if you want to change the name of the profile. Enter a name for the basal rate profile using the keyboard.
Tap Done.

3 *Basal rate profile:*

Define the end time for the first time block.
To do so, tap the top entry field in the End column.

4 *End time:*

Set the end time for the first time block.
Tap OK.

5 *Information - Overwrite time block?:*

When the end time of a time block shortens or overwrites the next time block, this information screen appears.
Tap Yes.

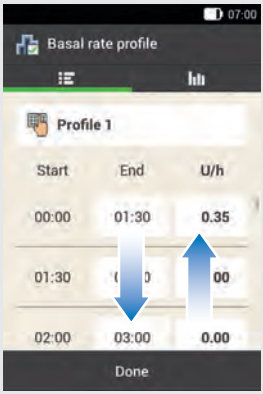
6 *Basal rate profile:*

Define the insulin units per hour for the first time block.
To do so, tap the top entry field in the U/h column.

7 *Basal rate:*

Set the insulin units per hour for the first time block.
Tap OK.

8



Repeat Steps 3 to 7 for each time block you want to edit.

Scroll the screen upwards or downwards to display all time blocks.

If you want to view the basal rate profile as a graph, tap .

Once you have set all time blocks, tap Done.

9 *Information - Prepare micropump:*

Next, you have to prepare the micropump. Tap OK to confirm.

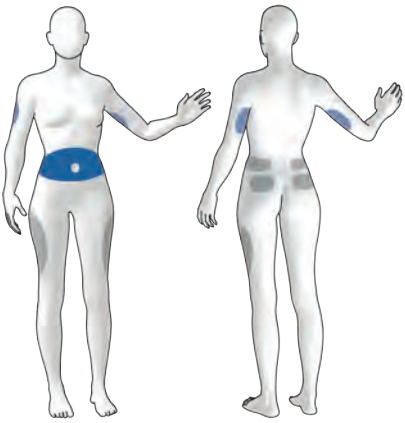
4 Putting the Micropump into Operation

This chapter explains all steps necessary to prepare the micropump before using it for the first time. To put the micropump into operation, you need the following:

Diabetes manager, pump base, reservoir assembly, insulin, cannula assembly & pump holder, insertion device, disinfectant or sterile alcohol wipe.

4.1 Recommended Infusion Sites

Choose a suitable infusion site before inserting a new infusion assembly. Consult your healthcare professional for advice. Sites with sufficient subcutaneous tissue are the most suitable. For example:



Blue areas: Recommended infusion sites
Gray areas: Possible infusion sites

NOTE

- The pump holder must not be attached to sites on the body with scars, birthmarks and moles, tattoos, injuries, bruises or rashes.
- Before you attach the pump holder to the body, the infusion site must be completely dry.
- A new infusion site must be at least 5 cm away from the last infusion site.
- A steel introducer needle is used to insert the flexible soft cannula into the skin. The introducer needle is part of the cannula assembly. To avoid injury and infection, never touch the introducer needle or the cannula.
- If the pump holder frequently becomes detached from the skin, consult your healthcare professional to find a method that may improve adhesion to the skin.
- If the infusion site becomes inflamed or localised skin reactions (for example, allergic reaction, eczema) occur, then replace the infusion assembly immediately and choose a new infusion site.

4.2 Putting the Components into Operation

After programming a basal rate profile you have to prepare the micropump. Proceed with the next steps using the setup wizard.

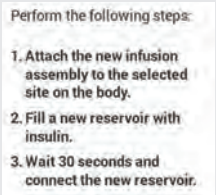
Setup wizard > Prepare micropump

1 *Information - Prepare micropump:*

After setting up the diabetes manager, the Prepare micropump screen appears.

Tap OK.

2 *Prepare micropump:*



Follow the instructions shown on the Prepare micropump screen.

If you want to see the action steps as an animated video, tap Help.

Once you have performed all 3 steps, tap Done.

4.2.1 Attaching the Infusion Assembly to the Body

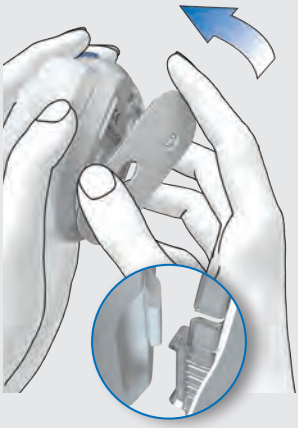
1 Wash your hands and dry them thoroughly.

2 Select a suitable site on the body.

Disinfect the site on your body according to the instructions given by your healthcare professional. Make sure that the infusion site is dry and free from residues.

3 Remove the pump holder from the packaging.

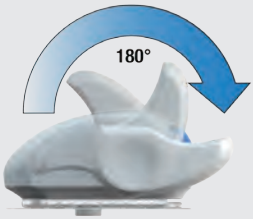
4



Attach the hook on the pump holder to the underside of the insertion device.

Press the pump holder onto the underside of the insertion device until it locks into place. Check whether the pump holder is correctly locked into place.

5

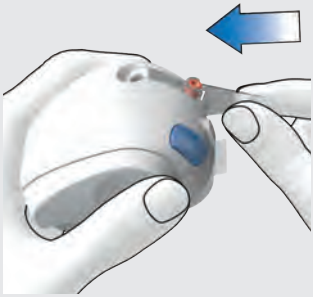


Prime the insertion device by rotating the priming handle clockwise in the direction of the arrow, as far as it will go.

When the insertion device is fully primed, you will hear a click.

4 PUTTING THE MICROPUMP INTO OPERATION

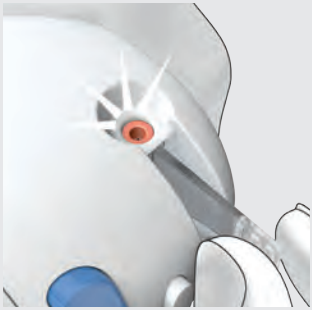
6



Insert the cannula assembly into the insertion device.

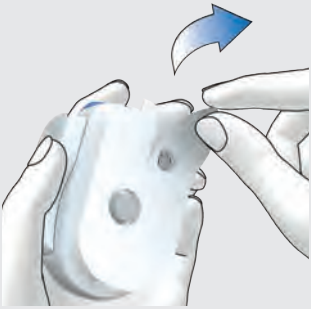
Push the cannula assembly into the slot until you hear it click into place.

7



Use the positioning aid to check whether the cannula assembly is in the correct position.

8



Remove both parts of the protective film from the adhesive pad.

Do not touch the adhesive surface of the adhesive pad.

9 Holding the skin taut, press the insertion device firmly against the selected site on your body.

10 Press the blue release button to insert the cannula under the skin.

11

Smooth over the adhesive pad around the infusion assembly so that the infusion assembly is in good contact with the skin.

12 Press the white detach button and detach the insertion device from the infusion assembly. If possible, keep the adhesive pad in position with the other hand.

13 Press the infusion assembly and the edges of the adhesive pad against the skin so that the adhesive pad is smooth on the skin.

14

Check whether the gray cannula head in the cannula opening is visible and flush with the opening.

If this is not the case, repeat Steps 1 to 16 using a new pump holder and a new cannula assembly.

15 Remove the used cannula casing from the insertion device.

16 Dispose of the used cannula casing according to local regulations.

⚠ WARNING

Risk of hyperglycaemia (high glucose level)

If you trigger the insertion device without inserting a cannula assembly, you reduce the useful lifetime of the insertion device. This may lead to incorrect insertion of the cannula and insufficient delivery of insulin. Do not use the insertion device without inserting a cannula assembly.

Risk of infection

Used components carry a risk of infection. Dispose of the cannula assembly safely, in such a way that the introducer needle does not cause injury to anyone.

NOTE

- Before storing the insertion device, ensure that there is **no** cannula assembly in the insertion device.
- Never store the insertion device in a primed state. Storing the insertion device incorrectly may weaken the spring tension, which will impair the operation of the insertion device.
- Check at regular intervals whether the micropump system has visible or tangible signs of damage. This applies in particular if the system components were dropped or were exposed to particular mechanical stress.

4.2.2 Filling the Reservoir with Insulin

In addition to the reservoir assembly, you need an insulin vial with U100 insulin and a form of disinfectant, such as a sterile alcohol wipe.

- Use and store the insulin in compliance with the manufacturer's specifications and pay attention to the use by date.
- Use the reservoir immediately after filling it.
- Occlusions may occur if the temperature of the insulin or micropump system is too low.

- During filling, make sure you remove any air bubbles from the reservoir.

⚠ WARNING

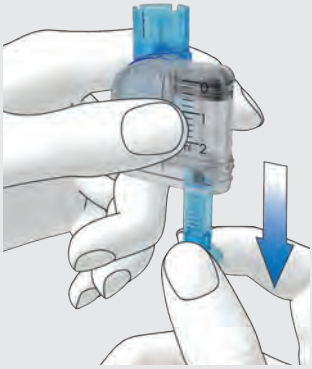
- Only use the micropump to deliver rapid-acting U100 insulin.
- If you connect an empty reservoir to the micropump (for example, for training purposes), insulin delivery (basal rate and bolus delivery) is nevertheless displayed, although no insulin is delivered because of the empty reservoir.
- Make sure that the insulin is at room temperature before you fill the reservoir. If insulin is used which is not at room temperature, the insulin may expand in volume. This can lead to inaccuracy in insulin delivery.

1 Disinfect the top of the insulin vial with a sterile alcohol wipe. Allow the disinfected top of the insulin vial to dry.

2 Remove the new reservoir assembly from the packaging.

3 Slowly and carefully pull out the battery's protective film to activate the battery.

4



Hold the round part of the handle firmly and pull it downwards in the direction of the arrow in order to fill the reservoir with air.

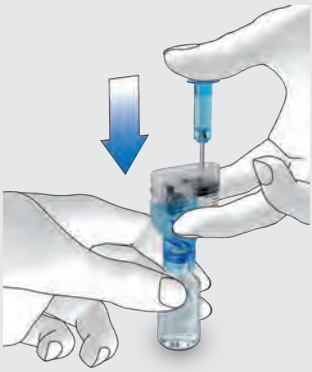
Fill the reservoir with the volume of air that you later want to fill with insulin.

NOTE

- The reservoir must be filled with at least 80 U.
- The reservoir has a maximum holding capacity of 200 U (2.0 ml).
- Take care not to touch the reservoir needle. You might injure yourself.

5 Place the insulin vial on a flat and solid surface (for example, a table top) and hold it firmly. Place the filling aid onto the vial. Push the filling aid downwards until you hear it click into place.

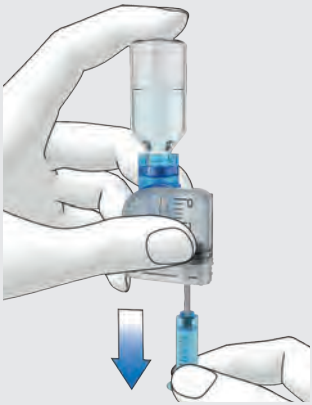
6



Press the handle all the way down in the direction of the arrow to fill the insulin vial with air.

7 Turn the reservoir assembly together with the insulin vial upside down so that the vial is above the reservoir.

8



Slowly pull the handle downwards in the direction of the arrow to fill the reservoir with insulin.

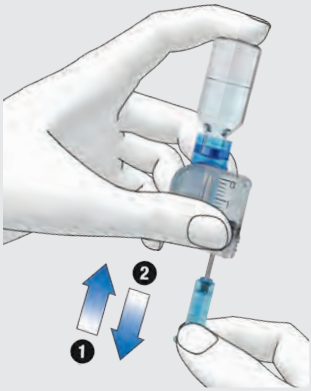
Try to ensure that as few air bubbles as possible form in the reservoir.

9 Check the reservoir from several angles to make sure that there are as few air bubbles as possible in the reservoir.

To release air bubbles from the reservoir, hold the reservoir at an angle.

Gently flick your finger against the reservoir several times.

10



Slowly push the handle upwards in the direction of the arrow ❶ to remove air bubbles from the reservoir.

Slowly pull the handle downwards in the direction of the arrow ❷ until the reservoir is filled with the required amount of insulin again.

⚠ WARNING

Risk of serious harm

Air bubbles can cause incorrect insulin delivery. Air bubbles may be present in the insulin or adhere to the inner surfaces of the reservoir. Air bubbles equal or larger than the air bubble indicated as a blue circle in the illustration above, must be removed. If it is not possible to remove these air bubbles you must replace the reservoir.

11 Remove the filling aid from the reservoir by pulling it off laterally.

Dispose of the filling aid according to local regulations.

⚠ WARNING

During disposal, ensure that no third party could injure themselves.

12

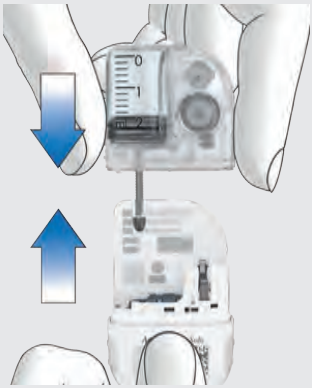
Compress the handle on the ribbed surface ❶ and then remove the handle laterally from the piston rod ❷.

Dispose of the handle.

4.2.3 Connecting the Reservoir to the Pump Base

1 Remove the blue reservoir cap from the pump base.

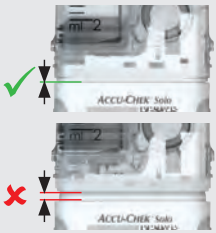
2



Push the filled reservoir onto the pump base until both parts are tightly connected.

3 When the reservoir and the pump base are connected to each other correctly and the battery is activated, the micropump issues the Start sound. If this sound is not issued, check whether the battery is activated and repeat Steps 1 to 3.

4



Make sure that there is no gap between the reservoir and the pump base.

The pump base and the reservoir are only connected correctly when the Start sound is issued **and** when the pump base and the reservoir are seamlessly connected.

NOTE

- Do not exert too much force when connecting the pump base to the reservoir.
- Make sure that the opening for ventilation of the micropump is always clear so that the battery is fully functional.
- Check whether the pump issues the Start sound when the pump base and the reservoir are connected (see *17.3 Sounds*). Otherwise, see chapter *15 Messages and Troubleshooting*.

5

Read the reservoir level using the reservoir scale.

With 2.0 ml (200 U), the reservoir shown in the figure above is full. Read the entered level as closely as possible. The entered level will be used for all further calculations.

6 Use the diabetes manager to set the insulin units.

Reservoir fill amount:

Set the number of insulin units (for example, 200 U) with which you filled the reservoir.

The set fill amount is saved as the default setting for when the reservoir is filled the next time.

Tap Save.

4.2.4 Pairing the Diabetes Manager and Micropump

To be able to operate the micropump using the diabetes manager, you must pair the devices. The Accu-Chek Solo micropump system uses *Bluetooth* Low Energy (*Bluetooth* LE) wireless technology to securely exchange data between the micropump and the diabetes manager.

4 PUTTING THE MICROPUMP INTO OPERATION

You will find the pump key(s) in the envelope in the micropump system packaging (system kit) or on the inside of the micropump packaging lid.

Once the diabetes manager and the pump have been paired, the pairing settings are stored in both devices so that you do not have to repeat this process.

Ensure that the micropump and diabetes manager are no more than 2 metres apart and that there are no obstacles between them. See the notes on possible connection problems between diabetes manager and micropump in chapter *15.5 General Troubleshooting*. If the radio connection between the diabetes manager and the micropump is stopped or interrupted, it will automatically be restored once the devices are within an appropriate range of each other.

If several micropumps are within the communication range of the diabetes manager, you must select the micropump serial number from a list that is displayed.

NOTE

Each pump base can only be paired **once** with a diabetes manager. So if you are using a different diabetes manager than before, for example, a replacement device, it cannot be paired with the micropump that has been in operation so far. If this is the case, you have to use a new pump base.

1

Hold the diabetes manager close to the micropump to establish the radio connection.

Tap Next.

The diabetes manager establishes the radio connection to the micropump. Wait a moment.

2 *Detect micropump:*

Tap Scan pairing code.

3

Point the camera of the diabetes manager at the pairing code on the pump base. Hold the diabetes manager in such a way that the pairing code can be read in full. A sound is emitted if the pairing code was

detected, and a prompt to fill the reservoir needle is displayed.

Entering the pump key manually

If the pairing code cannot be scanned, the pump key can be entered manually.

You will find the pump key(s) in the envelope of the micropump system packaging (system kit) or on the inside of the micropump packaging lid.

4 *Detect micropump:*

If no sound is emitted, the pairing code was not detected.

Tap ⮌ to return to the Detect micropump screen.

Tap Enter pump key.

5 *Select pump serial number:*

If there are several micropumps within range, tap the pump serial number of your micropump.

6 *Enter pump key:*

Tap Enter here and enter the pump key using the keyboard.

If pairing was successful, a sound is emitted.

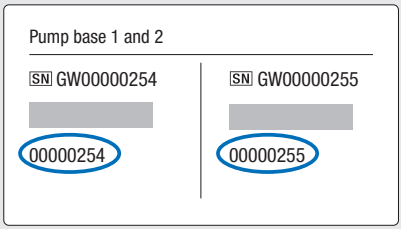
Tap Done.

NOTE

Failure to complete the process of connecting the micropump and diabetes manager may result in the micropump becoming unusable.

The pump serial number of the micropump is on the pump shield label and on the packaging label next to the SN symbol.

Pump key example:



4.2.5 Filling the Reservoir Needle

⚠ WARNING

Risk of hypoglycaemia (low blood glucose level)

Make sure that the micropump is not attached to your body. There is a risk of uncontrolled insulin delivery. Never fill the micropump while attached to your body.

1 *Prepare for filling:*

Press the flap of the pump holder to detach the micropump and remove the pump from the infusion assembly. Hold the pump with the reservoir needle in an upright tilted position.

To start filling, press ✓.

2

Pay attention to the opening of the reservoir needle during filling.

If you can see a drop of insulin at the tip of the needle, the reservoir needle is filled.

3 *Wait for insulin drop:*

Tap OK once you can see a drop of insulin on the reservoir needle.

If you **cannot** see a drop of insulin at the tip of the needle after 2 minutes, tap Cancel.

NOTE

- If you do not see a drop of insulin at the tip of the needle after a maximum of 2 minutes, there is still too much air in the reservoir. If no insulin drop is visible even after a second attempt of filling, you must use a new reservoir.
- If you tap Cancel or do not enter any data, an information message is displayed after 2 minutes saying that filling failed. You can then replace the reservoir or restart filling.
- ⮌ is deactivated during filling.

4.2.6 Attaching the Micropump

To properly attach the micropump to the pump holder, the recesses for attaching the micropump need to be clicked onto the hooks on the pump holder.

Hook on the top of the reservoir

Hook on the bottom of the pump base

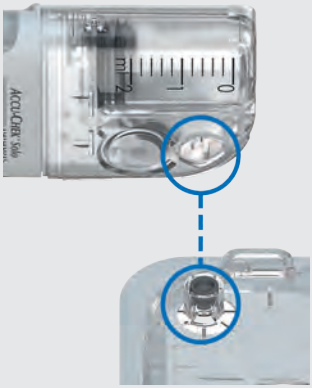
⚠ WARNING

Check the micropump and the pump holder for damage before you attach the micropump to the pump holder. Deformations or cracks can cause the micropump system to become leaky. This can lead to hyperglycaemia.

NOTE

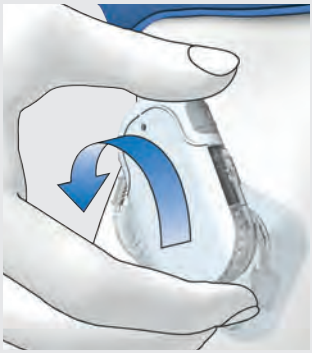
- Check the site on your body with the adhesive pad of the infusion assembly at least once a day.
- If you insert the micropump into the infusion assembly (pump holder and cannula) frequently or incorrectly, the micropump system can become leaky.

1



Hold the micropump in a position so that the reservoir needle is above the gray cannula head of the pump holder.

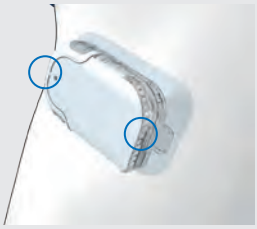
2



Keep the micropump straight and parallel to the pump holder. Turn the micropump carefully in place. You may apply light pressure on the pump shield to make sure the reservoir needle stays inside the cannula head of the pump holder. Try to avoid tilting movements.

After one eighth turn (approx. 45 degrees), the micropump clicks into the front and rear hooks on the pump holder.

3



Examine the front and back hooks of the pump holder to make sure the micropump properly clicked in place.

The micropump is now ready for insulin delivery.

4 *Attach micropump:*

Tap Next.

A small amount of insulin is delivered in order to fill the soft cannula.

4.2.7 Activating the Basal Rate Profile

Setup wizard > Attaching the Micropump > Activate basal rate profile

After having completed all preparatory steps for using the micropump for the first time, you can activate the set basal rate profile.

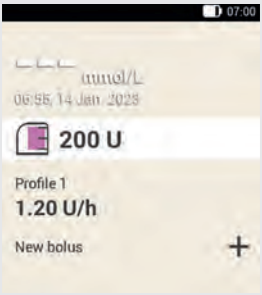
Once you have activated the basal rate profile, the micropump system setup is complete. The basal rate is delivered and you can use other system features.

Follow the settings for basal rate profiles you agreed on with your healthcare professional. For more information on programming a basal rate profile, see chapter *3.3 Programming a Basal Rate Profile*.

1 *Deliver insulin:*

To confirm this step, press the insulin button lit up in green, on the diabetes manager.

2



The Status screen displays the activated basal rate profile.

4.3 Stopping and Starting the Micropump

The Stop and Start items in the Main menu enable you to interrupt or restart insulin delivery.

Discuss with your healthcare professional when and for how long insulin delivery may be interrupted.

NOTE

If insulin delivery is interrupted, check your glucose level. If needed, deliver the missing insulin using a syringe or pen for example, when:

- You stop or remove the pump for a longer period of time.
- There is a technical problem with the pump.
- There is an occlusion in the cannula/ infusion assembly.
- The reservoir or infusion assembly is leaking.
- The infusion assembly has come loose at the infusion site.

Stopping insulin delivery

1 *Main menu:*

Tap Stop.

2 *Information - Stop insulin delivery?:*

Tap Yes.

While the micropump is in STOP mode, the micropump issues the Cancel sound once an hour to remind you that no insulin is being delivered.

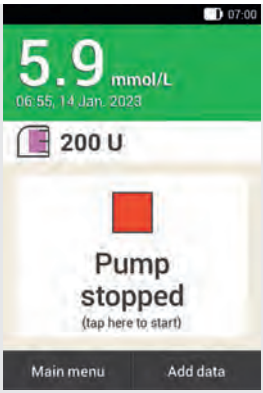
⚠ WARNING

Should you be unable to stop the micropump for any reason, remove the micropump from the infusion assembly, or pull the infusion assembly's adhesive pad together with the micropump off your skin.

NOTE

When you stop the micropump, all insulin delivery is stopped. All ongoing boluses are canceled. The selected basal rate profile will be stopped until the micropump will be restarted again.

Starting insulin delivery



On the Status screen, tap ■ to restart the micropump.

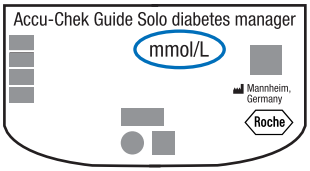
or

In the Main menu, tap Start ▶.

In the next step, you are prompted to activate the basal rate profile. After pressing the insulin button lit up in green to confirm, the micropump is set into operation again.

5 Testing or Entering Your Glucose Level

Glucose values can be specified in two different units of measurement (mmol/L and mg/dL). As a result, two versions of the same diabetes manager are available. Check whether the diabetes manager displays the unit of measurement familiar to you. The unit of measurement your diabetes manager displays is shown on the back of your diabetes manager. If you do not know which unit of measurement is correct for you, contact your healthcare professional.



NOTE

- You cannot change the unit of measurement of the diabetes manager. Contact customer support if the wrong unit of measurement is printed on the back.
- Never use a diabetes manager with an incorrect unit of measurement. This may cause the wrong therapy decision to be made and thus produce serious adverse health effects.
- You need the diabetes manager, a test strip, a finger pricker and a lancet drum.
- Set up the diabetes manager before testing your blood glucose for the first time.
- Read the test strip package insert. In the package insert, you will find further important information on storage, accuracy and precision of glucose values, and possible causes of incorrect glucose values.

5.1 Performing a Blood Glucose Test

⚠ WARNING

- A blood glucose test that was performed incorrectly can lead to incorrect glucose values and thus to wrong therapy recommendations being made, which can result in serious adverse health effects.
- A contaminated puncture site may lead to incorrect glucose values and infections. Wash your hands and the puncture site with warm water and soap. Rinse your hands with clean water. Then dry your hands and puncture site thoroughly.
- The diabetes manager is only intended for blood glucose testing with fresh capillary blood from the fingertip.

NOTE

- You cannot perform a blood glucose test while the diabetes manager is being charged.

- When the diabetes manager prompts you to apply a drop, you have approximately 2 minutes to apply blood to the test strip. If you do not apply any blood during this time, the diabetes manager turns itself off.
- When you insert a test strip, the illumination of the test strip slot is activated to assist you even in dark environments.
- Use only the Accu-Chek Guide test strips for the blood glucose test.

1 Wash your hands with warm water and soap and rinse them well. Dry your hands thoroughly with a clean towel before obtaining blood.

2 Check the use by date that is indicated on the test strip container next to the symbol.

Use only test strips that are not past the use by date.

NOTE

- If the diabetes manager is completely turned off (not in standby mode), turn it on. Press and hold the power button on the top of the diabetes manager until the diabetes manager turns on.
- Do not insert the test strip into the test strip slot until the diabetes manager has turned on and the Status screen appears.

3

If the diabetes manager is off, turn it on.

Insert the test strip into the test strip slot of the diabetes manager in the direction of the arrow. The LED at the test strip slot lights up. If the tone for blood glucose tests is turned on, a sound is emitted.

4 *Apply drop:*

The Apply drop screen appears. The test strip is ready for testing.

NOTE

- Do not allow any liquid to enter the test strip slot of the diabetes manager.
- Remove the test strip in case of a test strip error, and repeat the blood glucose test using a new test strip.
- Only apply blood to the test strip when the test strip is in the test strip slot and Apply drop is displayed.
- When a test strip is in the diabetes manager, the touchscreen and the buttons, including the power button, are deactivated. The buttons are activated again when you remove the test strip or the test is complete.

5

Use your finger pricker to prick the side of a fingertip.

6 Encourage a blood drop to form by gently massaging the finger in the direction of the fingertip.

7

Touch the blood drop to the front yellow edge of the test strip.

Do not put blood on top of the test strip.

8 Remove your finger from the test strip when the progress circle screen appears.

The blood glucose test starts when enough blood has been drawn up by the test strip.

9 *Glucose values:*

The glucose value is displayed and saved.

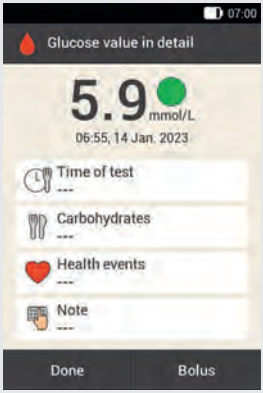
If the tone for blood glucose tests is turned on, a sound is emitted.

Tap OK.

NOTE

- The glucose value can be used for bolus advice for a period of 15 minutes.
- When performing a blood glucose test: If the control test screen with the control bottle appears on the display with your glucose value, an error has occurred.
  - Do not act on the glucose value.
  - Discard the test strip and repeat the blood glucose test with a new test strip.

10



After approximately 3 seconds the Glucose value in detail screen appears.

If you want to add information (Time of test, Carbohydrates, Health events, Note) to the glucose value, follow the instructions in the following section.

If you want to complete the blood glucose test without adding any information or delivering a bolus, tap Done.

If you want to deliver a bolus, tap Bolus once you have completed all the necessary information.

NOTE

- You can subsequently change the added information in the My data menu.
- If bolus advice has been calculated based on information you added about health events and carbohydrates, you can no longer change this information.

11 Press the test strip ejector to remove the used test strip. Alternatively, you can remove the used test strip from the test strip slot without using the test strip ejector.

Dispose the used test strip according to local regulations.

5.1.1 Adding Information

You can save additional information for a glucose value to describe certain events in connection with this glucose value or particular characteristics of the glucose value.

If you are using the bolus advice feature, also see the information in chapter *7 Bolus Advice*.

⚠ WARNING

Incorrect entries for carbohydrate amounts or health events may lead to incorrect bolus advice.

Entering the time of test

You can assign exactly one time of test to each blood glucose test. This information may be helpful later on for determining patterns in your glucose level.

1 *Glucose value in detail:*

Tap Time of test.

2 *Time of test:*

Tap the desired time of test (for example, Before meal).

Tap Save.

Entering carbohydrates

If you test your blood glucose in connection with a meal, it is advisable to save the carbohydrate amount you wish to eat.

If you are using bolus advice, the entered carbohydrate amount is used to calculate the insulin amounts you need.

3 *Glucose value in detail:*

Tap Carbohydrates.

4 *Carbohydrates:*

Set the carbohydrate amount you consumed. Alternatively, you can enter the carbohydrate amount using the numeric keypad. To do so, tap ▦.

Tap Save.

Setting health events

Health events provide information about your current health or activities.

If you have set up bolus advice and select a health event, bolus advice will be adjusted by the percentage you specified.

Discuss health event adjustments with your healthcare professional, who will help you to determine the suitable percentage for the adjustment.

5 *Glucose value in detail:*

Tap Health events.

6 *Health events:*

Choose from 1 to a maximum of 4 health events. Tap the appropriate health events.

Tap Save.

7 *Health events:*

If you have selected more than one 1 health event, enter the total percentage for the selected health events.

Tap Save.

Entering a note

You can enter a personal note (max. 280 characters) to save with the glucose value.

8 In the Glucose Value in detail menu, tap Note. Type a note to save with this entry.*

Tap Done.

* The note feature may not be available in all languages.

9 *Note:*

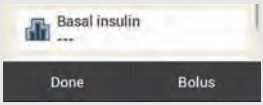
Type a note to save with this entry.

Tap Done.

Entering basal insulin (injection mode)

Injection mode allows you to save the amounts of basal insulin you injected in the diabetes manager. This is done most easily when you test your blood glucose. Note that the basal insulin you specify does not have any influence on bolus advice calculation.

10



Glucose value in detail:

If the diabetes manager is not connected to the micropump (injection mode): Tap Basal insulin.

11 *Basal insulin:*

Set the desired amount of basal insulin.

Tap OK.

5.1.2 Evaluating Glucose Values

Glucose Values reflect the current status of the glucose level. Glucose values are influenced by different factors, including type of diet, medication taken, state of health, stress and physical activity.

Certain substances can interfere with the glucose value. This can lead to falsely elevated or lowered glucose values. For more information, see the test strip package insert.

⚠ WARNING

- If your glucose value is very high, test for ketones. If the test returns a positive result and you are experiencing symptoms of ketoacidosis (for example, headache and vomiting), contact a healthcare professional or accident and emergency unit immediately.
- If the glucose value does not match how you feel, test your blood glucose again to rule out an incorrect glucose value. If glucose values repeatedly do not match how you feel, check the items in the section *Causes of Implausible Glucose Values* in this chapter.

NOTE

Do not change your therapy based on individual glucose values.

5.1.3 Colour Coding of Glucose Values

On the Glucose value in detail screen, a coloured dot appears to the right of the glucose value. The colour of the dot shows whether the glucose value of the test for the respective time block is above, below or within the target range. The colours refer to the individually defined warning limits and target ranges of the time blocks.

Overview of meaning of colours:

Colour of dot	Glucose value is
Blue, Hyper	above the hyper warning limit. It is strongly recommended that you test for ketones and test your blood glucose more frequently.
Blue	above your target range, but below your hyper warning limit.
Green	within your target range.
Yellow	below your target range, but above your hypo warning limit.
Red, Hypo	below the hypo warning limit. Eat a sufficient amount of fast-acting carbohydrates immediately.

Setting warning limits: You can set the upper (Hyper) and lower (Hypo) warning limits in the settings, see chapter *11.1 Warning Limits*.

Setting target ranges: You can set the upper and lower limit of your target range for each time block in the settings, see chapter *7.1.3 Changing Time Block Settings*.

Being aware of the symptoms of low or high blood glucose can help you to better understand your glucose values and decide what to do.

Symptoms of low blood glucose may include:
Anxiety, shakiness, sweating, headache,

increased hunger, dizziness, pale skin colour, fatigue, sudden change in mood or irritability, difficulty concentrating, clumsiness, palpitations, and/or confusion.
Symptoms of high blood glucose may include:
Increased thirst, frequent urination, blurred vision, drowsiness, abdominal pain/cramps, nausea, dizziness.

Blue with Hyper

Glucose value - Blue dot with Hyper:

If the glucose value exceeds the hyper warning limit, the diabetes manager will issue the *W-75 - Warning limit exceeded* warning before displaying the glucose value. Follow the warning instructions and confirm the warning with OK to go to the glucose value.

Blue dot with the additional information Hyper:
The glucose value exceeds the hyper warning limit.

Blue

Glucose value - Blue dot:

The glucose value is above the target range for the current time block.

The glucose value does not exceed the hyper warning limit.

Green

Glucose value - Green dot:

The glucose value is within the target range for the current time block.

Yellow

Glucose value - Yellow dot:

The glucose value is below the target range for the current time block.

The glucose value does not fall below the hypo warning limit.

Red with Hypo

Glucose value - Red dot with Hypo:

If the glucose value falls below the hypo warning limit, the diabetes manager will issue the *W-80 - Hypoglycaemia* warning before displaying the glucose value. This warning does **not** show the glucose value. Follow the warning instructions and confirm the warning with OK to go to the glucose value.

Red dot with the additional information Hypo:
The glucose value falls below the hypo warning limit.

Eat or drink a sufficient amount of fast-acting carbohydrates immediately.

LO Screen

The LO screen means that the glucose value is outside the value range.

NOTE

The LO screen means that your glucose value might be very low.

Being aware of the symptoms of low blood glucose can help you to better understand your glucose values and decide what to do.

Glucose value - LO:

The glucose value is below the measuring range of the diabetes manager. If you are experiencing a symptom of low blood glucose, proceed as follows:

- Immediately eat or drink fast-acting carbohydrates, such as juice or dextrose.
- Then test your blood glucose and again within the next half hour.
- If hypoglycaemia persists, consume additional carbohydrates and consult your healthcare professional.

HI Screen

The HI screen means that the glucose value is outside the value range.

NOTE

The HI screen means that your glucose value might be very high.

Being aware of the symptoms of high blood glucose can help you to better understand your glucose values and decide what to do.

Glucose value - HI:

The glucose value is above the measuring range of the diabetes manager. If you are experiencing any of the common symptoms of high blood glucose, proceed as follows:

- Test your blood glucose again and test ketones.
- Follow the instructions of your healthcare professional.

5.1.4 Causes of Implausible Glucose Values

If the diabetes manager repeatedly displays implausible glucose values or error messages, check the items listed below. If you cannot answer the questions with Yes, correct the respective item and repeat the test:

- Did you perform the blood glucose test as instructed in the User's Manual?
- Did you wash your hands with warm water and soap and dry them thoroughly?
- Did you only apply blood after the Apply drop screen appeared on the display?
- Did you apply the blood drop immediately after it had formed?
- Did you perform the blood glucose test within the correct temperature range?

- Did you use the test strip immediately after removing it from the test strip container?
- Are the test strips still valid (see the label on the test strip container next to the symbol)?
- Did you observe the storage conditions for the diabetes manager and the test strips?
- Was the cap on the test strip container always closed tightly?
- Did you observe the sources of error mentioned in the test strip package insert?

If you have observed all these items and are still experiencing implausible glucose values or receiving error messages, perform a control test.

If you are not sure whether the diabetes manager is working properly, contact customer support.

5.2 Entering Your Glucose Value

If you do not want to test your blood glucose with the diabetes manager, you can manually enter a glucose value that was measured using another blood glucose meter, a continuous glucose monitor* (CGM) or a flash glucose monitor* (FGM) intended for making diabetes treatment decisions on the screen.

* Blood samples from the fingertip are needed for diabetes management decisions when symptoms or expectations do not match readings.

Note that a glucose value or a CGM/FGM reading is only valid for a bolus advice within the first 15 minutes.

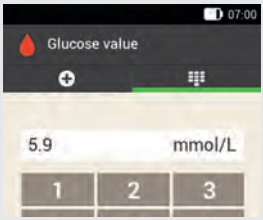
1 *Main menu:*

In the Main menu, tap Test.

2 *Information - Test BG or enter glucose value?:*

Tap No.

3



Enter the glucose value you measured with your meter using the numeric keypad.

Tap OK.

4 *Glucose value:*

Tap OK.

5 *Glucose value in detail:*

If you want to add information to the entered glucose value, follow the instructions in the section *Adding Information* on the previous pages.

If you want to complete entering the glucose value without adding any information or delivering a bolus, tap Done.

If you want to deliver a bolus, tap Bolus once you have completed all the necessary information.

6 Delivering a Bolus

A bolus represents the required insulin amount to be delivered in addition to the basal rate to cover the intake of food or correct an elevated glucose level. The bolus type and bolus amount are determined by your healthcare professional's guidelines, your glucose level, your eating behaviour, your state of health as well as the type and duration of physical activity.

A prerequisite for insulin therapy is that you are able to understand and apply the basic principles of bolus calculation according to the specifications of your healthcare professional.

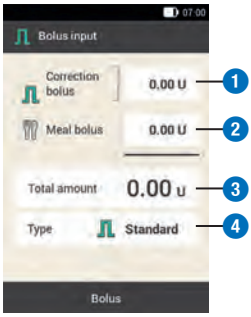
NOTE

When you test your blood glucose and deliver a bolus, keep in mind that if there is an occlusion, up to 5 U may accumulate before an occlusion message (M-24) is issued. If the occlusion suddenly dissolves, the bolus and the insulin that accumulated due to the occlusion will be delivered. This can lead to hypoglycaemia.

6.1 Manual Bolus Delivery

You can deliver a bolus manually or by means of the bolus advice feature. This chapter explains manual bolus delivery with different bolus types. Moreover, it describes the options to cancel bolus delivery.

6.2 Bolus Input Screen



1	**Correction bolus** Tap this entry field to enter the insulin amount needed to bring a glucose value outside the target range back into the target range.
2	**Meal bolus** Tap this entry field to enter the insulin amount to compensate for the food intake.
3	**Total amount** In this entry field, you can enter the total amount for the bolus. The total amount is the sum of correction bolus and meal bolus.
4	**Bolus type** Tap this element to select one of the following bolus types: Standard bolus, extended bolus, multiwave bolus, quick bolus, pen/syringe.

Note the following for bolus input:

- When the Bolus input screen appears for the first time, there is no bolus amount specified. You must enter the bolus amount.

- If you set the **correction bolus** or the **meal bolus** first, the total amount is deactivated and cannot be adjusted. However, the value is updated accordingly.
- Consider the following when you enter the **total amount**:
  - The entry fields for correction bolus and meal bolus are deactivated.
  - If you increase the total amount, the value for the correction bolus is increased accordingly. The correction bolus is always delivered as a standard bolus or as an immediate amount of a multiwave bolus.
  - If you reduce the total amount, the value for the meal bolus is reduced, if one exists. Once the meal bolus reaches the value “0”, the correction bolus is reduced accordingly.

6.3 Bolus Types

You can choose the bolus types Standard bolus, Extended bolus or Multiwave bolus on the Bolus input screen.

In addition, you can choose a quick bolus or a bolus with pen or insulin syringe.

Standard bolus
The standard bolus delivers the programmed insulin dose all at once. Use this bolus for foods that contain fast-acting carbohydrates, such as juice or bread.

Use the standard bolus if you want to correct an elevated glucose level.

Extended bolus
The extended bolus does not deliver the bolus insulin all at once, but over a programmable period of time.
Use the extended bolus for meals that are digested slowly, for example, foods with complex carbohydrates or foods that are high in fat and protein. An extended bolus can also be helpful for meals that extend over a longer period of time (for example, a buffet).

Multiwave bolus
A multiwave bolus combines a standard bolus with an extended bolus. A part of the bolus amount is delivered immediately, whereas the other part is delivered over a programmable period of time.
Use this bolus for meals that contain both fast and slowly digestible carbohydrates, proteins and fats. You can also use this bolus for meals that extend over a longer period of time.
If you are planning to eat slowly digestible carbohydrates but have an elevated glucose level before the meal, you can use this bolus type as well. In this case, you program the immediate part of the bolus to correct the glucose level and the extended part for the carbohydrates.

Quick bolus
A quick bolus is a standard bolus that is programmed and delivered using the quick bolus buttons on the micropump.

6.4 Programming a Bolus

You can program a bolus in different ways. Start with one of the following three options:

1 **Glucose value > Bolus**

After testing your blood glucose: On the Glucose value in detail screen, tap Bolus. Continue with Step 3.

Alternatively, you can proceed as follows:

Status screen > Bolus

On the Status screen, tap New bolus +.

or

Main menu > Bolus

In the Main menu, tap the Bolus menu.

2 *Bolus:*

Tap Manual bolus.

3 *Bolus input:*

Tap the entry fields that are appropriate to your situation to enter the correction bolus, meal bolus or total amount.

4 *Proportion mealtime insulin:*

Set the desired amount for the meal bolus.

Tap OK.

5 *Proportion correction insulin:*

Set the desired amount for the correction bolus.

Tap OK.

6.4.1 Standard Bolus

1 *Bolus input:*

The Standard bolus type is set as the default in the factory settings.

Tap Bolus.

2 *Deliver insulin - Deliver standard bolus:*

Check the total amount displayed.

To confirm this step and deliver the bolus, press ✓.

3

The micropump delivers the standard bolus. The Status screen is displayed with the current bolus information.

You can add an extended bolus to an ongoing standard bolus.

6.4.2 Extended Bolus

The duration of bolus delivery can be programmed in 15-minute increments for a period of up to 24 hours. Delivery begins immediately after you confirm the bolus. Throughout bolus delivery, the Status

screen shows the remaining time and remaining amount of the extended bolus.

The extended bolus must not be used to correct glucose values. Therefore, you cannot select this bolus type if the bolus you programmed contains correction insulin.

1 *Bolus input:*

Tap Type on the Bolus input screen.

2 *Bolus type:*

Tap Extended bolus.

Then tap OK.

3 *Extended bolus:*

Tap Duration.

4 *Duration:*

Set the hours and minutes for the extended bolus duration.

Tap OK.

The duration you set for the extended bolus will be used as the default setting when the extended bolus is delivered the next time.

5 *Extended bolus:*

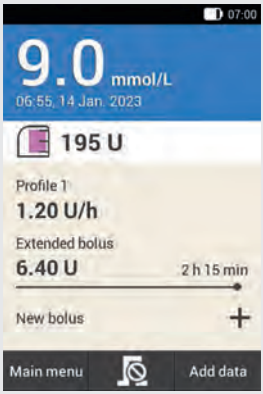
Tap Bolus.

6 *Deliver insulin - Deliver extended bolus:*

Check the total amount and duration displayed.

To confirm this step and deliver the bolus, press ✓.

7



The micropump delivers the extended bolus. The Status screen is displayed with the current bolus information.

You can add a standard bolus, an extended bolus, or a multiwave bolus to an extended bolus that is currently being delivered.

6.4.3 Multiwave Bolus

The duration of the delayed bolus part can be programmed in 15-minute increments for a period of up to 24 hours. Delivery begins immediately after you confirm the bolus.

It is only possible to select a multiwave bolus if a meal bolus has been programmed. The immediate amount of the bolus cannot be set to a value less than the correction bolus. The minimum insulin amounts for the immediate amount and the delayed amount are 0.1 U respectively.

1 *Bolus input:*

Tap Type on the Bolus input screen.

2 *Bolus type:*

Tap Multiwave bolus.

Tap OK.

3 *Multiwave bolus:*

Tap Immediate amount to enter the bolus part that is to be delivered immediately. Alternatively, you can tap Delayed amount to enter the bolus part that is to be delivered with a delay.

4 *Immediate amount:*

Set the immediate amount.

The immediate amount must not be less than the proportion set for the correction insulin.

Tap OK.

5 *Multiwave bolus:*

After you have set the immediate amount or the delayed amount, the other amount will be adjusted automatically, since the total amount is known.

Tap Duration.

6 *Duration:*

Set the duration of the delayed amount.

Tap OK.

The duration you set for the delayed part will be used as the default setting when the multiwave bolus is delivered the next time.

7 *Multiwave bolus:*

Tap Bolus.

8 *Deliver insulin - Deliver multiwave bolus:*

Check the displayed total amount, immediate amount, delayed amount and the duration.

To confirm this step and deliver the bolus, press ✓.

9

The micropump delivers the multiwave bolus. The Status screen is displayed with the current bolus information.

You can add an extended bolus to an ongoing multiwave bolus. As soon as the immediate part of a multiwave bolus was delivered, you can add a standard bolus or another multiwave bolus.

6.5 Quick Bolus

A quick bolus behaves like a standard bolus that can be programmed and delivered using the quick bolus buttons on the micropump.

A quick bolus allows a bolus to be discreetly delivered if the diabetes manager is not

available or cannot communicate with the micropump. This is the case, for example, when airplane mode is turned on.

The bolus amount can only be programmed in defined increments. The factory setting for the quick bolus increment is 0.2 U. Therefore, you can set the bolus amount to be 0.2 U, 0.4 U, 0.6 U and so on. If necessary, you can change the quick bolus increment to 0.5 U, 1.0 U or 2.0 U.

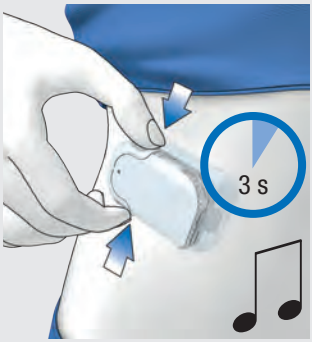
⚠ WARNING

Make sure that you know and use the set quick bolus increment. If you use a different quick bolus increment to the one you intended, an incorrect insulin dose will be delivered.

NOTE

- Fill in the increment you set for the quick bolus on the detachable quick reference instructions supplied in the cover page of this User's Manual.
- The bolus advice feature initially treats quick boluses as correction insulin. Mark the quick boluses in the logbook as a meal bolus or correction bolus according to their purpose. Enter consumed carbohydrates in the logbook.

1



Press and hold both quick bolus buttons simultaneously for approximately 3 seconds until you hear the sound for the quick bolus.

2 Simultaneously press both quick bolus buttons repeatedly until the desired insulin amount is programmed.

To exit the input, wait approximately 3 seconds without pressing the quick bolus buttons.

3 The micropump issues a "Quick bolus increment" tone for each programmed quick bolus increment.

Check whether the acoustic feedback for the quick bolus increments corresponds to the desired insulin amount.

4 If the acoustic feedback corresponds to the desired insulin amount and you want to deliver the quick bolus, press both quick bolus buttons simultaneously until you hear the sound for delivering the bolus.

NOTE

- If you do not confirm the acoustic feedback in step 3 by pressing the quick bolus buttons, no bolus will be delivered and the Cancel sound is emitted.
- Enter the insulin and carbohydrate amounts associated with the quick bolus in the logbook. Be sure to assign correction bolus and meal bolus correctly. Otherwise, subsequent data entries in the logbook as well as future bolus advice calculations might not be correct.

Example

You want to deliver a quick bolus with 2.5 U:

- With a quick bolus increment of 0.5 U, you have to press the quick bolus buttons 5 times to deliver an insulin amount of 2.5 U.
- Wait approximately 3 seconds to complete the input.
- Check the acoustic feedback of the micropump.
- If the programmed insulin amount is correct, press both quick bolus buttons.
- The pump issues the Execute sound.

6.6 Delivering a Bolus with a Pen or Syringe

If you want to deliver a bolus with a pen or syringe, you can document the insulin amounts delivered on the Bolus input screen.

The insulin amounts you documented will be saved in the diabetes manager. The entered insulin amounts are taken into account for future bolus advice calculations. This improves the result of further bolus advice calculations.

1 *Bolus input:*

Select one of the 3 options for programming a bolus described in chapter *6.4 Programming a Bolus*. Perform the appropriate steps until the Bolus input screen is displayed.

Tap Type.

2 *Bolus type:*

Tap the Pen/syringe bolus type.

3 *Bolus input:*

Tap the desired entry field.

If you tap Total amount, the entered insulin amount is added to the correction bolus.

4 *Total amount:*

Set the insulin amount you want to deliver using a pen or syringe.

Tap OK.

5 *Bolus input:*

Tap Bolus.

6 *Information - Deliver bolus:*

If the total amount to be delivered is correct, tap OK.

7

Inject the insulin units with a pen or syringe.

6.7 Cancelling a Bolus

In the Main menu and on the Status screen, you can cancel a bolus by tapping .

In the Bolus menu, you can tap the Cancel bolus item. You can cancel both a single bolus or all ongoing boluses.

⚠ WARNING

Should you be unable to stop the micropump for any reason, remove the micropump from the infusion assembly, or pull the infusion assembly's adhesive pad together with the micropump off your skin.

NOTE

If you cancel a bolus that has already been completely delivered, the M-77 maintenance message will be displayed. If you cancel several boluses, the M-77 maintenance message will only be displayed for the ongoing boluses. For all boluses that were fully delivered, no maintenance message is displayed. You can view the fully delivered bolus amount in the My data menu.

6.7.1 Cancelling a Single Bolus

1 On the Status screen or in the Main menu, tap .

2 *Cancel bolus:*
Tap the bolus you want to cancel.

3 *Information - Cancel multiwave bolus?:*
If you want to cancel the bolus now, tap Yes.

4 *Warning - Bolus canceled:*
The W-38 warning is displayed.
Tap OK to confirm the warning.

5 The bolus has been canceled and deleted from the Status screen.

6.7.2 Cancelling All Boluses

1 *Status screen:*
On the Status screen or in the Main menu, tap .

2 *Cancel bolus:*
Tap Cancel all boluses.

3 *Information - Cancel all boluses?:*
Tap Yes.

4 *Warning - Bolus canceled:*
For each canceled bolus, the W-38 warning is displayed.
Tap OK to confirm the warning.

5 *Status screen:*

All boluses have been canceled and deleted from the Status screen.

6.8 Setting the Delivery Lag Time

In some situations (for example, if you have gastroparesis) it may be helpful to only start a bolus after you have started eating. You can use the delivery lag time setting to specify an interval between programming a bolus and the actual start of bolus delivery.

Discuss using the delivery lag time setting with your healthcare professional.

If you want to make use of the delivery lag time, you must activate this feature in the *Bolus settings* menu first.

NOTE

If a bolus contains correction insulin it is not possible to enter a delivery lag time. Correction insulin must always be delivered immediately.

1 *Bolus input:*

Select one of the 3 options for bolus delivery described in chapter *6.4 Programming a Bolus*. Perform the appropriate steps until the Bolus input menu is displayed.

Tap Bolus.

2 *Standard bolus:*

Tap Delivery lag time.

3 *Delivery lag time:*

Set the delivery lag time. The delivery lag time can be 0, 15, 30, 45 or 60 minutes.

Tap OK.

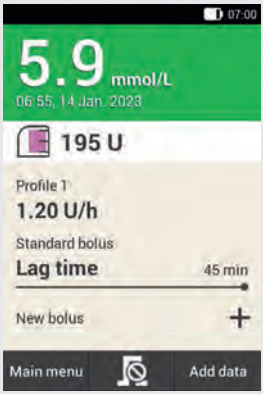
4 *Standard bolus:*

Tap Bolus.

5 *Deliver insulin - Deliver standard bolus:*

To confirm this step and deliver the bolus, press ✓.

6



The Status screen is displayed with the current bolus information and the set delivery lag time.

7 Bolus Advice

The bolus advice feature aims to bring your glucose level back into the target range defined for you, by delivering an insulin amount that was calculated in advance. However, the bolus advice feature only makes a recommendation if you set up bolus advice beforehand.

The bolus advice feature of the diabetes manager consists of two components: First, a recommendation for a correction bolus to adjust your glucose level if it is not within the target range. Secondly, a recommendation for a meal bolus that covers the carbohydrates contained in your meals.

The recommendation for the correction bolus is positive if your current glucose level is above your target range. If the glucose level is below the target value and a meal bolus is recommended at the same time, a negative correction bolus lowers the total insulin amount of the bolus advice.

If your glucose value is below the hypo warning limit, no bolus advice is issued. Instead, you receive a recommendation to consume a certain carbohydrate amount to bring your glucose level back to within the target range.

NOTE

The diabetes manager cannot correct input errors.

- Warnings are issued for entries that exceed possible limit values.
- No warning will be issued for entries that are incorrect yet still possible (for example, within acceptable ranges).
- Insulin that was not delivered via the micropump system can only be taken into account by the bolus advice feature if you enter it in the diabetes manager beforehand.
- After bolus advice is set up, you can change the options or turn off bolus advice, if required.
- **If you turn off bolus advice that has already been configured, all bolus advice options will be deleted.**

In the glossary, you will find explanations of the terms time blocks, target range, insulin sensitivity, carbohydrate ratio, meal rise, snack size, acting time, and offset time. Familiarise yourself with these terms. For more information, see chapter *19 Glossary*.

7.1 Setting Up Bolus Advice

Main menu > Settings > Bolus settings

After turning on bolus advice, you must make the default settings for the carbohydrate ratio and the insulin sensitivity. These default settings will be adopted for all time blocks. Afterwards, the time blocks are set up. All time blocks add up to a time period of 24 hours. The diabetes manager factory settings contain 5 default time blocks. You can set up a maximum of 8 time blocks.

The bolus advice feature uses the time blocks that you have already set while

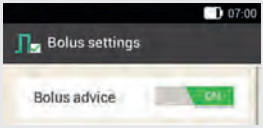
executing the setup wizard. If required, you can change the time block settings.

⚠ WARNING

Discuss intended changes to your bolus advice options with your healthcare professional in advance.

7.1.1 Time Block and Target Range

1



Tap Bolus advice.

2 *Information - Set up bolus advice?:*

Tap Yes.

3 *First time block:*

The screen for defining the first time block appears.

Tap Start time and End time one after the other to enter the times for the first time block.

If you want to keep the start and end times, tap Done.

↩ is deactivated.

4 *Start time:*

Set the start time for the first time block.

You can set the minutes in 15-minute increments.

Tap OK.

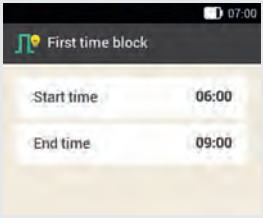
5 *End time:*

Set the end time for the first time block.

You can set the minutes in 15-minute increments.

Tap OK.

6



The changed start and end times for the first time block are displayed.

Tap Done.

7 *Target range:*

Tap Upper limit value and Lower limit value one after the other to enter the limit values for the target range.

If you do not want to modify the limit values for the target range, tap Next.

8 *Upper limit value:*

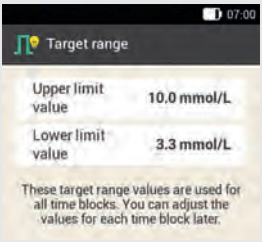
Set the upper limit value (for example, 10 mmol/L).

Tap OK.

9 *Lower limit value:*

Set the lower limit value (for example, 3.3 mmol/L).

10



The limit values currently set for the target range are displayed.

Tap Next.

7.1.2 Default Settings

1 *Default settings:*

To define the default settings, tap the entry fields for the Carbohydrate ratio and the Insulin sensitivity.

NOTE

The Done button on the Default settings screen remains deactivated (gray) until the entries for Carbohydrate ratio and Insulin sensitivity are complete.

Example

Carbohydrate ratio:

1.00 U : 10 g

In this example, one insulin unit compensates for 10 g of carbohydrates.

2 *Carbohydrate ratio:*

Set the insulin units for the carbohydrate ratio.

Tap OK.

3 *Carbohydrate ratio:*

Set the carbohydrate amount for the carbohydrate ratio.

Tap OK.

Example

Insulin sensitivity:

1.00 U : 2.2 mmol/L

In this example, one insulin unit lowers the glucose value by 2.2 mmol/L.

4 *Insulin sensitivity:*

Set the insulin units for the insulin sensitivity (for example, 1.00 U).

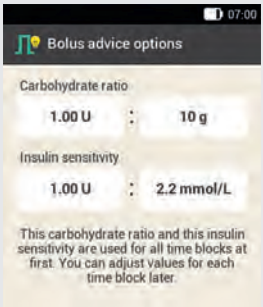
Tap OK.

5 *Insulin sensitivity:*

Set the glucose value for the insulin sensitivity (for example, 2.2 mmol/L).

Tap OK.

6



Tap Done.

7 *Information - Settings are being copied:*

The default settings for carbohydrate ratio and insulin sensitivity are copied to all time blocks.

You can change the settings for each time block separately.

Tap OK.

7.1.3 Changing Time Block Settings

1 *Time blocks:*

Tap the time block you want to change.

If you do not want to change the copied settings for the other time blocks, tap Done. Continue with section *Health Events*.

2 *Set up time block:*

Tap End time.

NOTE

You can change the start time for the first time block only.

Changes to the target range, carbohydrate ratio and insulin sensitivity can be made for each time block.

3 *End time:*

Set the end time for the selected time block.

Tap OK.

4 *Set up time block:*

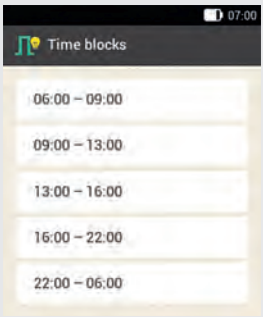
Tap Next.

5 *Target range:*

Set the upper and lower limit values.

Tap Next.

6



Tap Done when you have completed the desired settings for all time blocks.

7.1.4 Health Events

Your state of health and your activities have an impact on your glucose level. Bolus advice calculation takes health events into account.

Each health event adjusts bolus advice by the percentage set by you. A positive percentage (+) increases the bolus amount and a negative percentage (-) decreases the bolus amount.

You can choose between 5 default health events and 3 customised health events:

Exercise 1, Exercise 2, Stress, Illness, Premenstrual, Customised: Name 1-3

You can also enter health events at a later time.

The percentage for a health event must be between -50 % and +50 %. You can

change the percentage in increments of 5 %.

Example

You like running, so you create the customised health event *Run* with a percentage of -20 %, for example.

When you select the *Run* health event during bolus calculation, the bolus amount is decreased by 20 %.

1 *Health events:*

Tap the health event for which you want to make settings (for example, Stress).

2 *Percentage:*

Enter a percentage for the selected health event.

Tap Save.

Repeat Steps 1 and 2 to set the percentage for other health events.

3 *Health events:*

If you want to set a customised health event, tap .

4 *Customised health event 1:*

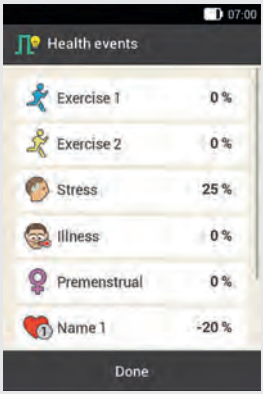
Tap to enter a name for the customised health event (for example, Run).

5 *Percentage:*

Set the percentage for the customised health event.

Tap Save.

6



Tap Done.

7.1.5 Bolus Advice Options

1 *Bolus advice options:*

Tap Meal rise, Snack size, Acting time and Offset time to adjust the respective settings.

The Done button on the Bolus advice options screen remains deactivated (gray) until you make a numeric entry for the snack size.

2 *Meal rise:*

Set the meal rise value (for example, 3.3 mmol/L).

Tap OK.

3 *Snack size:*

Set the snack size value (for example, 12 g).

Tap OK.

4 *Acting time:*

Set the hours and minutes for the acting time (for example, 3 hours, 30 minutes).

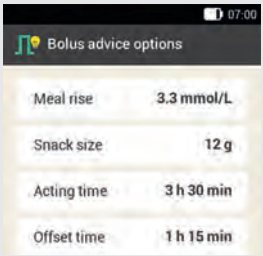
Tap OK.

5 *Offset time:*

Set the hours and minutes for the offset time (for example, 1 hour, 15 minutes).

Tap OK.

6



Tap Done to complete the setup wizard.

7 *Information - Configuration complete:*

All settings for calculating bolus advice are now complete.

Tap OK.

7.2 Changing Bolus Advice and Time Blocks

7.2.1 Bolus Advice Options

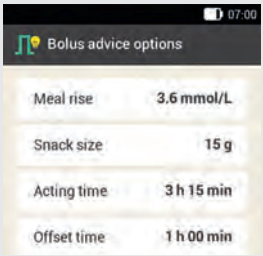
This section describes how to change the values for meal rise, snack size, acting time and offset time.

Main menu > Settings > Bolus settings

1 *Bolus settings:*

Tap Bolus advice options.

2



Tap the respective entries to set the Meal rise, Snack size, Acting time and Offset time.

Tap Done after making changes to all the settings.

7.2.2 Percentages for Health Events

1 *Bolus settings:*

Tap Health events.

2 *Health events:*

Tap the health event for which you want to make changes (for example, Stress).

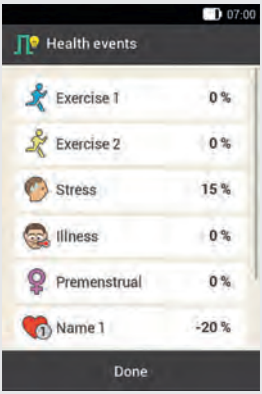
3 *Percentage:*

Enter a percentage for the selected health event.

Tap Save.

Repeat steps 2 and 3 to set the percentage for other health events.

4



The health events are displayed with the percentages that were set.

Tap Done after setting the health events.

7.2.3 Deleting a Single Time Block

In order to delete a single time block, decrease the end time of the time block until it is the same as its start time.

After time blocks have been deleted, it may be necessary to change the end times and other information for the remaining time blocks until all of the time blocks are set up the way you want them.

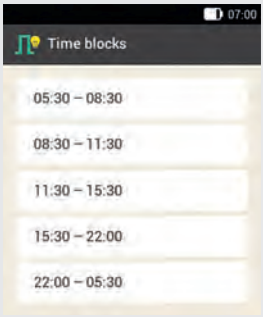
1 *Main menu:*

In the Main menu, tap the Settings menu.

2 *Settings:*

Tap Time blocks.

3



Tap the time block to be deleted.

In this example, the time block from 11:30 to 15:30 is to be deleted.

4 *Set up time block:*

Decrease the end time until it equals the start time (for example, End time = 11:30).

Tap Next.

5 *Target range:*

Set the upper limit value and lower limit value for the new time block.

Tap Next.

6 *Bolus advice options:*

Set the carbohydrate ratio and insulin sensitivity for the new time block.

Tap Done.

7 *Time blocks:*

It may be necessary to adjust the end times and settings of the remaining time blocks.

Once you have finished editing the time blocks, tap Done.

7.2.4 Deleting Several Time Blocks

You can delete one or more time blocks by merging different time blocks.

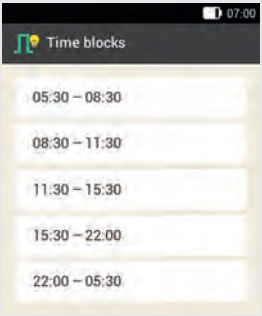
1 *Main menu:*

In the Main menu, tap the Settings menu.

2 *Settings:*

Tap Time blocks.

3



Select the first time block that is to be merged with one or more time blocks.

In this example, the three time blocks between 08:30 and 22:00 are being merged.

4 *Set up time block:*

Increase the end time until it equals the end time of the last time block to be deleted (for example, End time = 22:00).

Tap Next.

5 *Target range:*

Set the upper limit value and lower limit value for the merged time block.

Tap Next.

6 *Bolus advice options:*

Set the carbohydrate ratio and insulin sensitivity for the merged time block.

Tap Done.

7 *Time blocks:*

It may be necessary to adjust the end times and settings of the remaining time blocks.

Tap Done when you have finished editing the time blocks.

7.2.5 Adding a Time Block

This section describes how to add a new time block.

To add a time block, decrease the end time of the last time block.

After the new time block has been created, you may have to adjust the end time and other information for each time block.

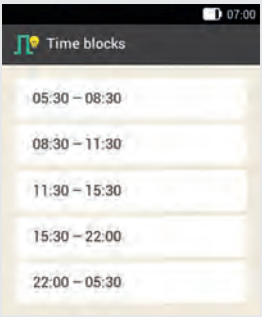
1 *Main menu:*

In the Main menu, tap the Settings menu.

2 *Settings:*

Tap Time blocks.

3



Tap the **last** time block (for example, 22:00 - 05:30).

4 *Set up time block:*

Tap End time and decrease the end time in order to create a new time block (for example, End time = 03:30). However, do not decrease the end time until it equals the start time because this will delete the time block.

Tap Next.

5 *Target range:*

Set the upper limit value and lower limit value for the new time block.

Tap Next.

6 *Bolus advice options:*

Set the carbohydrate ratio and insulin sensitivity for the new time block.

Tap Done.

7 *Time blocks:*

A new time block has been added (for example, 03:30 - 05:30). It may be necessary to change the end times and settings of other time blocks.

Tap Done when you have finished editing the time blocks.

7.2.6 Resetting All Time Blocks

1 *Time blocks:*

Tap Reset.

2 *Information - Reset time blocks?:*

If you want to reset all time blocks, tap Yes.

3 *First time block:*

Set the start time and end time for the first time block.

Tap Done.

4 *Target range:*

Set the upper limit value and lower limit value that are to be used for all time blocks for the time being.

Tap Done.

5 *Bolus advice options:*

Set the carbohydrate ratio and the insulin sensitivity that are to be used for all time blocks for the time being.

Tap Done.

6 *Information - Set up time blocks:*

The target range and default settings of the first time block were applied to all other time blocks.

Tap OK.

7 It may be necessary to change the end times and settings of the other time blocks.

Tap Done when you have finished editing the time blocks.

7.3 Using Bolus Advice

You can use the bolus advice feature directly after testing your blood glucose or entering a glucose value manually. Note that a glucose value is only valid for bolus advice **within 15 minutes of the blood glucose test**.

You can also call up bolus advice from the Status screen or Main menu.

⚠ WARNING

- Review manually entered data (for example, carbohydrate amount) used to calculate the bolus advice. Incorrectly entered values may lead to incorrect bolus advice.
- Note that the diabetes manager may give incorrect bolus advice if insulin is delivered manually (for example, by syringe or pen). Insulin that was not delivered via the micropump system can only be taken into account if you specify this in the diabetes manager.

Consider the following:

- Boluses for which bolus advice was used are indicated by in the logbook. If no bolus advice is set up, bolus advice is turned off or a manual bolus was delivered, is displayed.
- If you deliver a quick bolus, the information on the total bolus amount is taken into account for future bolus advice. However, the total bolus amount is considered as a correction bolus, and no meal rise is registered.
  If this bolus was used for food intake, you should edit the bolus in your logbook to assign the bolus part that was used for the carbohydrates. This ensures that you receive bolus advice that is as accurate as possible during the acting time.
- If you provide carbohydrates and health events to calculate bolus advice, you will obtain the best results.

7.3.1 Bolus Input Screen

1	**Correction bolus** Tap this entry field to enter the insulin amount needed to bring a glucose value outside the target range back into the target range.
2	**Meal bolus** Tap this entry field to enter the insulin amount to compensate for the food intake.

3	**Total amount** In this entry field, you can enter the total amount for the bolus. The total amount is the sum of correction bolus and meal bolus.
4	**Bolus type** Tap this element to select one of the following bolus types: Standard bolus, extended bolus, multiwave bolus, quick bolus, pen/syringe.
5	**Carbohydrate amount** The carbohydrate amount entered after performing a blood glucose test is displayed. If no carbohydrate amount was entered, --- is displayed.
6	**Active insulin** If bolus advice is activated, the amount of active insulin that is to be considered is displayed. If there is no active insulin, --- is displayed. Active insulin is a calculated value representing the amount of insulin currently in the body that still has a lowering effect on the blood glucose level after a correction bolus.
7	**Glucose value** The current glucose value is displayed. If no current glucose value exists, --- is displayed.

7.3.2 Starting Bolus Advice After a BG Test

1 *Glucose value in detail:*

Tap the respective entries to add information on Time of test, Carbohydrates or Health events.

Tap Bolus.

NOTE

You can select a maximum of 4 health events.

If you have selected more than one health event, you will have to enter a total percentage for the selected health events in the next step.

Discuss health event adjustments with your healthcare professional, who will help you to determine the suitable percentage for the adjustment.

2 *Health events:*

If you have selected multiple health events, enter the total percentage.

Tap Save.

3 *Glucose value in detail:*

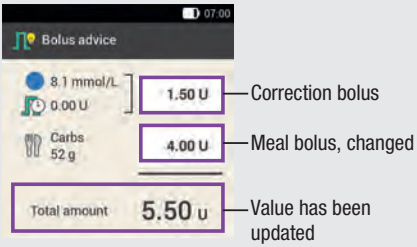
The bolus advice feature calculates a suggestion and transfers the recommended values to the entry fields in the bolus advice screen.

Tap the respective entry fields if you want to change the suggested values.

Tap Bolus.

Changing bolus advice values

Example



If you change the correction bolus or meal bolus first, the total amount can no longer be directly changed after that. The value, however, is updated accordingly (see figure).

If you change the total amount first, the correction bolus and meal bolus can no longer be directly changed after that. If you increase the total amount, the correction bolus is increased accordingly. If you decrease the total amount, the meal bolus is decreased accordingly. Once the meal bolus reaches “0”, the correction bolus is decreased accordingly.

Selecting the bolus type

4

Tap Type to select the desired bolus type.
Tap Bolus.

Not every bolus type can be selected, depending on the situation. You cannot select an extended bolus, for example, if a correction bolus is to be delivered.

5 *Bolus advice:*

Tap Bolus.

6 *Deliver insulin - Deliver standard bolus:*

To confirm this step and deliver the bolus, press ✓.

7

The Status screen is displayed showing the current bolus information.

7.3.3 Entering Glucose Values

You can enter your glucose value that was measured using another method and the carbohydrate amount you want to eat. If you then tap Bolus on the Bolus advice screen, a bolus advice is shown.

We recommend using the built-in meter of the diabetes manager to rule out transfer errors of entered glucose values.

1 *Status screen:*

On the Status screen, tap New bolus +.

or

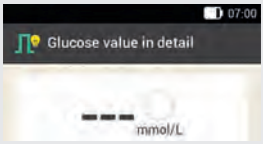
Main menu:

In the Main menu, tap the Bolus menu.

2 *Bolus:*

Tap Bolus advice.

3



Tap the field for manually entering the glucose value.

4 *Information - Test BG or enter glucose value?:*

Tap No if you want to enter the glucose value manually.

5 *Glucose value:*

Enter the glucose value using the numeric keypad and tap OK.

Alternatively, you can set the glucose value using ⊖ or ⊕. To do so, tap ⊕.

6 *Glucose value:*

The entered glucose value is displayed. Tap OK if the glucose value is correct.

7 *Glucose value in detail:*

Tap the Carbohydrates entry.

8 *Carbohydrates:*

Set the carbohydrate amount you want to eat. Alternatively, you can enter the carbohydrate amount using the numeric keypad. To do so, tap ▦.

Tap Save.

9 *Glucose value in detail:*

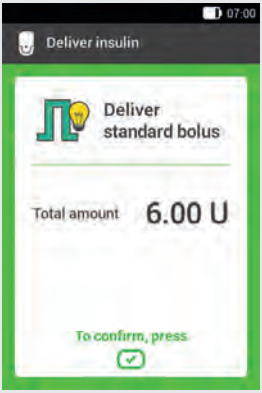
If necessary, enter any health events.

Tap Bolus.

10 *Bolus advice:*

Once all entries are correct, tap Bolus.

11



To confirm this step and deliver the bolus, press ✓.

7.3.4 Bolus Advice without Glucose Value

If you do not want to test or enter your blood glucose, you can enter the carbohydrate amount you wish to eat. If you then tap Bolus on the Bolus advice screen, a suggestion for a meal bolus is displayed.

1 *Status screen:*

On the Status screen, tap New bolus +.

or

Main menu:

In the Main menu, tap the Bolus menu.

2 *Bolus:*

Tap Bolus advice.

3 *Glucose value in detail:*

Tap Carbohydrates.

4 *Carbohydrates:*

Set the carbohydrate amount you want to eat. Alternatively, you can enter the carbohydrate amount using the numeric keypad. To do so, tap ▦.

Tap Save.

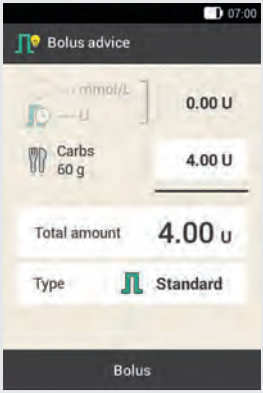
5 *Glucose value in detail:*

Tap Bolus.

6 *Information - No valid glucose value:*

Tap No to use bolus advice without performing a blood glucose test.

7



Once all entries are correct, tap Bolus.

8 *Deliver insulin - Deliver standard bolus:*

To confirm this step and deliver the bolus, press ✓.

7.3.5 Bolus Advice for Pen/ Syringe

You can also deliver the bolus with a pen or syringe. Make sure that the insulin amount saved by the micropump system is identical to the amount you delivered.

Also consult the instructions for use for your insulin pen or syringe.

1 *Bolus advice:*

Start bolus advice with or without testing your blood glucose.
Tap Type.

2 *Bolus type:*

Tap Pen/syringe.

3 *Bolus advice:*

Once you have completed your entries, tap Bolus.

4 *Information - Deliver bolus:*

Tap OK.
This way you confirm to the system that you are delivering this insulin amount. The bolus advice feature will take the corresponding insulin amount into account in the next calculations.

5 *Status screen:*

The Status screen is displayed.

6

Inject the insulin units you confirmed with a pen or syringe.

7.4 Turning Off Bolus Advice

This section describes how to turn off bolus advice.

NOTE

If you turn off bolus advice, all bolus advice options will be deleted. If you want to use bolus advice again, you must set it up once again.

Main menu > Settings > Bolus settings

1 *Bolus settings:*

Tap Bolus advice. The switch turns to OFF.

2 *Information - Delete settings?:*

Tap Yes if you want to turn off bolus advice now.
The bolus advice options will be deleted.

8 Basal Rate Profiles and Temporary Basal Rates

In this chapter you will learn how you can adapt your basal insulin supply to your life situations using different basal rate profiles and Temporary Basal Rates (TBR).

The basal rate covers the basal, meal-independent insulin requirement. The size of the basal rate depends on your personal circumstances and the time of day.

A basal rate profile consists of a combination of basal rates that are defined according to your personal requirements and cover 24 hours a day. If your insulin needs vary on certain weekdays, on weekends, during illness or on holiday, you can create and use different basal rate profiles. You can program up to 5 basal rate profiles in the diabetes manager.

Basal rate profiles are defined through time blocks. Each time block needs a start time and an end time as well as an hourly basal rate, which is specified in insulin units per hour (U/h).

⚠ WARNING

Wrong basal rate settings may lead to hyperglycaemia or hypoglycaemia.

NOTE

If you activate a different basal rate profile, all ongoing insulin deliveries (basal rate, boluses) will be canceled.

8.1 Creating and Editing a Basal Rate Profile

A basal rate profile can be programmed, edited and deleted in different ways. Start by using one of the following two options:

1 *Status screen:*

On the Status screen, tap the area indicating the basal rate.

or

Main menu:

In the Main menu, tap the Basal rate menu.

2 *Basal rate:*

In the Basal rate menu, tap Basal rate profiles.

8.1.1 Programming a Basal Rate Profile

NOTE

- Basal rate time blocks are not identical to or shared with the time blocks for bolus advice. You can set up a maximum of 24 time blocks, each of which may be between 15 minutes and 24 hours long. When supplied, the system shows 24 time blocks of 1 hour each.
- You are only able to edit the end times of basal rate time blocks. The start time of each time block is identical to the end time of the previous time block.
- To add a new time block, set the end time of the last time block to the

desired start time of the new time block.

- To delete a time block, decrease the end time of the time block to equal the start time of the same time block.

Main menu > Basal rate > Basal rate profiles

1 *Basal rate profiles:*

Tap + to add a basal rate profile.

Once the maximum possible number of 5 basal rate profiles has been reached, the Basal rate profiles screen does not show the + symbol.

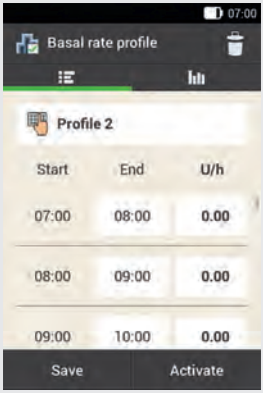
2 *Basal rate profile:*

Tap .

Enter the desired name for the basal rate profile (for example, Weekend). The name may have up to 12 characters.

Tap Done.

3



Tap the first time block. Set the end time and the insulin amount.

4 *End time:*

Set the end time for the time block.

Tap OK.

5 *Information - Overwrite time block?:*

When the end time of a time block shortens or overwrites the next time block, this information screen appears.

Tap Yes.

6 *Basal rate:*

Set the basal rate for the time block (for example, 1.50 U/h).

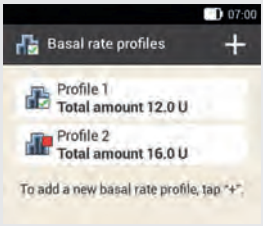
Tap OK.

7 *Basal rate profile:*

Repeat this process until the correct basal rate has been programmed for all 24 hours of the day.

Tap Save.

8



The newly programmed basal rate profile is displayed in the overview of the existing basal rate profiles.

Check whether the total amount displayed corresponds to the total amount defined by your healthcare professional.

If the total amount displayed does not correspond to the total amount defined by

your healthcare professional, check all the time blocks and correct the entries.

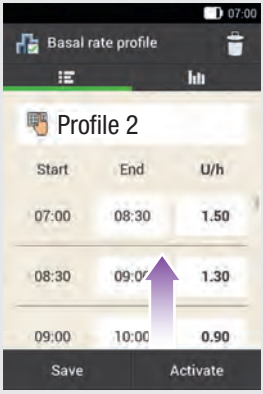
8.1.2 Activating a Basal Rate Profile

1 *Basal rate profiles:*

Tap the basal rate profile you want to activate (for example, Profile 2).

The currently selected basal rate profile is indicated by .

2



If required, scroll the screen upwards to check all time blocks of the basal rate profile.

Once all settings are correct, tap Activate.

3 *Information - Cancel insulin delivery?:*

While a basal rate profile is being activated, insulin delivery is interrupted. Note that ongoing boluses are also interrupted.

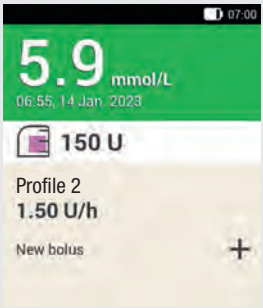
Tap Yes.

4 *Deliver insulin: Activate basal rate profile:*

To confirm this step and activate the basal rate profile, press .

Tapping cancels the activation of the selected basal rate profile and takes you to the previous screen. The basal rate profile that was previously active, remains active.

5



The activated basal rate profile is displayed on the Status screen.

8.1.3 Changing a Basal Rate Profile

1 *Basal rate profiles:*

Tap the basal rate profile you want to change (for example, Profile 2).

The currently selected basal rate profile is indicated by .

2 *Basal rate profile:*

If required, scroll the screen upwards to check all time blocks of the basal rate profile.

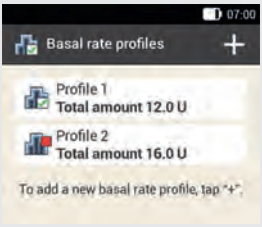
Tap an end time to change the end time for the time block. Tap a basal rate to change the basal rate for the time block.

3 *Basal rate profile:*

Repeat this process until the correct basal rate has been programmed for all 24 hours of the day.

Tap Save.

4



The changed basal rate profile is displayed in the overview of existing basal rate profiles.

Check whether the total amount displayed corresponds to the total amount defined by your healthcare professional.

8.1.4 Deleting a Basal Rate Profile

1 *Basal rate profiles:*

Tap the basal rate profile you want to delete (for example, Profile 3).

Note that the selected basal rate profile cannot be deleted. The selected basal rate profile is indicated by .

2 *Basal rate profile:*

Tap in the upper right corner of the screen.

3 *Information - Delete entry?:*

Tap Yes to delete the basal rate profile.

4 *Basal rate profiles:*

The deleted basal rate profile no longer appears in the list of available basal rate profiles.

8.2 Temporary Basal Rates

A Temporary Basal Rate (TBR) allows you to temporarily increase or decrease your active basal rate profile on a percentage basis for a specific duration. This helps you to better control your glucose level during illness, physical activity or in other situations. Temporary Basal Rates can be set in increments of 10 % over a period of 15 minutes to 24 hours.

If you activate a Temporary Basal Rate of less than 100 % in addition to a low basal rate, this may be less than the minimum possible output amount of the micropump. In this case an information screen with the following text is shown: It may be that no basal insulin will be delivered during the next 60 minutes with the selected low temporary basal rate. Test your blood glucose more frequently.

TBR	Settings range
Decrease	0–90 %
Increase	110–250 %

The percentage and the duration of a TBR are saved. Each time a Temporary Basal

Rate is selected, the last used settings are displayed.

NOTE

- A TBR cannot be programmed if the micropump is in STOP mode.
- Stopping the pump (STOP mode) stops TBR delivery as well as any bolus delivery.
- When the duration of the TBR has expired, you are informed that the programmed basal rate has finished.

8.3 Creating and Editing a TBR

A temporary basal rate can be programmed, edited and deleted in different ways. Start by using one of the following two options:

1 *Status screen:*

On the Status screen, tap the area indicating the basal rate.

or

Main menu:

In the Main menu, tap the Basal rate menu.

2 *Basal rate:*

Tap Temporary basal rate.

8.3.1 Programming a TBR

Main menu > Basal rate > Temporary basal rate

1 *Temporary basal rate:*

Tap Standard TBR.

2 *Standard TBR:*

Tap Percentage to enter the percentage of the temporary basal rate.

3 *Percentage:*

Set the percentage for adjusting the Temporary Basal Rate.

Tap Save.

4 *Standard TBR:*

Tap Duration to enter the running time for the temporary basal rate.

5 *Duration:*

Set the hours and minutes for the duration of the standard TBR.

Tap OK.

6 *Standard TBR:*

Tap Activate.

NOTE

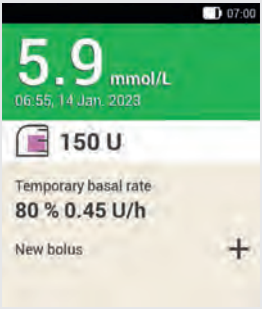
You can only activate the TBR if the percentage is less than or greater than 100 % (for example, 90 % or 110 %).

Tapping ⮌ cancels the activation and takes you to the previous screen.

7 *Deliver insulin - Start standard TBR:*

To confirm this step and start the standard TBR, press ✓.

8



The diabetes manager shows the Status screen with the current TBR information.

8.3.2 Programming a Customised TBR

You can program and save customised Temporary Basal Rates for recurring situations that change your insulin needs. For a customised TBR, the percentage and the duration are saved. These settings are used as default values each time you select this TBR. You also have the option of entering a name for a customised TBR.

Example

You go running for 1 hour twice a week. You know that your body needs 20 % less insulin during this activity and the subsequent recovery phase of 2 hours. You program a TBR of 80 % for 3 hours.

Main menu > Basal rate > Temporary basal rate

1 *Temporary basal rate:*

Tap + to add a customised TBR.

2 *Customised TBR:*

Tap ✎.

Enter the desired name for the customised TBR (for example, Run). The name may have up to 12 characters.

Tap Done.

3 *Customised TBR:*

Tap Percentage to enter the percentage for the customised TBR.

4 *Percentage:*

Set the percentage for adjusting the customised TBR.

Tap Save.

5 *Customised TBR:*

Tap Duration to enter the running time for the customised TBR.

6 *Duration:*

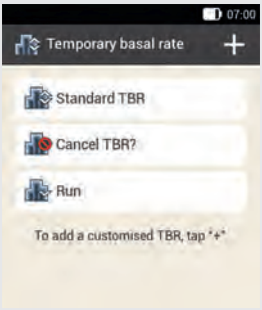
Set the hours and minutes for the duration of the customised TBR.

Tap OK.

7 *Customised TBR:*

To save your settings for the customised TBR without starting it, tap Save.

8



The newly programmed customised TBR is displayed.

NOTE

A customised TBR less than 100 % is indicated by . A TBR greater than 100 % is indicated by .

8.3.3 Activating a Customised TBR

1 *Temporary basal rate:*

To activate a saved TBR, tap the desired entry in the list of Temporary Basal Rates.

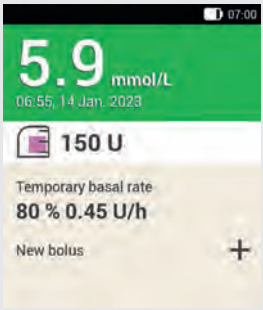
2 *Customised TBR:*

To save and start the TBR straight away, tap Activate.

3 *Deliver insulin - Start customised TBR:*

To confirm this step and start the TBR, press .

4



The activated TBR is displayed on the Status screen.

8.3.4 Cancelling a TBR

1 *Temporary basal rate:*

Tap Cancel TBR?.

2 *Information - Cancel TBR?*

Tap Yes.

3 *Warning - TBR canceled:*

The percentage and the duration of the TBR so far are displayed in the W-36 warning.

Tap OK to confirm the warning.

4 *Status screen:*

The TBR has been canceled and deleted from the Status screen.

9 Replacing System Components

In this chapter you will learn when and how to replace the infusion assembly, reservoir, pump base, insertion device and how to remove air bubbles from the reservoir.

The following table contains guidelines on the period of use of these system components:

System component	Period of use*
Insertion device 	4 years
Pump base 	up to 6 months
Reservoir 	up to 4 days
Infusion assembly 	up to 3 days

Always have enough consumables ready so that a replacement is available after a given period of use.

* Important information for the Accu-Chek Solo products: for the Reservoir and Infusion assembly products, the expiry date indicated by ⌸ on the packaging reflects the date by which these consumable items should be used by. The expiry date indicated by ⌸ on the Pump base and Insertion device products reflects the date by which use should be commenced, not by when the period of use must be completed (for example for a pump base with packaging showing ⌸ June 2023 should be started by June 2023 and use would be completed by December 2023).

⚠ WARNING

Check your glucose level after replacing system components at least once within 1 to 3 hours.

NOTE

- The life expectancy of the battery used to supply the micropump with power is 4 days.
- Replace the system components in the early morning. Do not replace the system components before longer sleeping phases.
- You will find animated videos on replacing system components and operating the micropump system in the Main menu of the diabetes manager under the Help menu item.
- In order to receive a timely reminder to replace the insertion device, you can set a reminder in the diabetes manager.

9.1 Starting the Replacement

1 Always start as follows when replacing the infusion assembly, reservoir or pump base:

On the Status screen, tap  .

or

In the Main menu, tap Replace .

Always use the diabetes manager to start the process of replacing one or more system components. This is the only way that the micropump system will be able to give you a timely reminder to replace a component.

9.2 Replacing the Infusion Assembly

Have the following system components at hand for this process:

Pump holder, Cannula, Insertion device, Diabetes manager, Disinfectant or sterile alcohol wipe.

NOTE

- Check the pulled out cannula to ensure that it has been completely removed.
- If you dampen the infusion assembly with warm water or apply an oily ointment, it becomes easier to pull off the adhesive pad.

1 *Replace system components:*

The screen for selecting the system components appears.

Tap Infusion assembly.

Tap Replace.

The micropump switches to STOP mode and issues the Cancel sound.

2

Press the flap to detach the micropump and remove the pump from the infusion assembly.

3 Remove the infusion assembly by loosening the edges of the adhesive pad and pulling it off towards the centre.

4 *Discard system components:*

Dispose of the used infusion assembly according to local regulations.

Tap Done.

5 *Prepare micropump:*

If you want to see an animated video on how to replace the infusion assembly, tap Help.

Attach the new infusion assembly to the selected site on the body. Follow the action steps in chapter *4.2.1 Attaching the Infusion Assembly to the Body*.

Tap Done when you have finished the action step shown on the screen.

6 *Attach micropump:*

Attach the micropump to the infusion assembly.

Tap Next.
The infusion assembly is now filled automatically.

7 *Deliver insulin - Activate basal rate profile:*
To confirm this step and then restart the micropump and return to the Status screen, press ✓.

9.3 Replacing the Reservoir

Have a reservoir assembly, an insulin vial with U100 insulin and disinfectant or a sterile alcohol wipe at hand for this process.

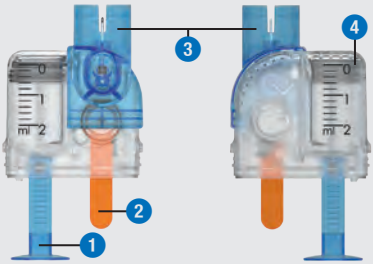
⚠ WARNING

If the insulin is in the reservoir for too long, it may lose its effectiveness. You can use an insulin-filled reservoir for up to 4 days.

NOTE

Always fill the reservoir with at least 80 U. The reservoir has a maximum holding capacity of 200 U (2.0 ml).

Front and back view of the reservoir assembly



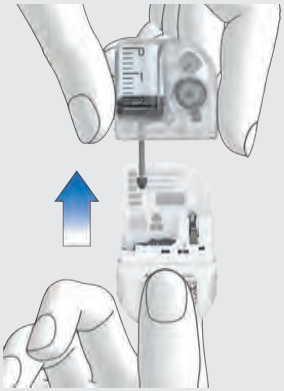
1	Handle for piston rod
2	Protective film for battery
3	Filling aid
4	Reservoir

1 *Replace system components:*
The screen for selecting the system components appears.
Tap Reservoir.

2 *Replace system components:*
Tap Replace.
The micropump switches to STOP mode and issues the Cancel sound.

3 Press the flap to detach the micropump and remove the pump from the infusion assembly.

4



Remove the used reservoir from the pump base.

5 *Discard system components:*

Dispose of the used reservoir according to local regulations.

Tap Done.

6 *Prepare micropump:*

If you want to see an animated video on how to replace the reservoir, tap Help.

Follow the action steps in chapter *4.2.2 Filling the Reservoir with Insulin*.

Wait 30 seconds after removing the used reservoir before you connect a new reservoir to the pump base.

Follow the action steps in chapters *4.2.3 Connecting the Reservoir to the Pump Base, 4.2.5 Filling the Reservoir Needle, 4.2.6 Attaching the Micropump, 4.2.7 Activating the Basal Rate Profile*.

9.4 Replacing the Pump Base

The expected period of use must not be exceeded. Otherwise, the delivery accuracy may be impaired. You will be reminded regularly to replace the pump base before the deadline expires. For information on the remaining running time of the micropump, see the settings in the System information menu. If you replace the pump base, you must also replace the reservoir.

Have a new pump base, a new reservoir assembly, an insulin vial with U100 insulin and disinfectant or a sterile alcohol wipe at hand for this process.

NOTE

- When you replace the pump base, all settings saved for the pump in the diabetes manager are preserved.
- Each pump base can only be paired **once** with a diabetes manager.
- Do not disconnect the reservoir before starting the replacement process. Leave the reservoir on the pump base until you have confirmed the information screen in step 2.

1 *Replace system components:*

The screen for selecting the system components appears.

Tap Pump base. The reservoir is automatically selected as well.

Tap Replace.

The micropump switches to STOP mode and issues the Cancel sound.

The used pump base can no longer be used after the replacement process.

2 *Information - Replace pump base?:*

Tap Yes, if you want to replace the pump base now.

3 Press the flap of the infusion assembly. Remove the used micropump from the infusion assembly.

4 *Discard system components:*

Dispose of the used reservoir and the used pump base according to local regulations.

Tap Done.

5 *Prepare micropump:*

If you want to see an animated video on how to replace the reservoir and the pump base, tap Help.

Perform the steps shown on the Prepare micropump screen.

Tap Done when you have finished the action steps shown on the Prepare micropump screen.

Refer to these chapters for details on the procedure: *4.2.2 Filling the Reservoir with Insulin*, *4.2.3 Connecting the Reservoir to the Pump Base*, *4.2.4 Pairing the Diabetes Manager and Micropump*, *4.2.5 Filling the Reservoir Needle*, *4.2.6 Attaching the Micropump*, *4.2.7 Activating the Basal Rate Profile*.

9.5 Removing Air Bubbles

If you notice that air bubbles have formed in the reservoir during use, you can remove these air bubbles with the Remove air bubbles from reservoir feature. The micropump is stopped automatically when doing this. Insulin delivery for temporary basal rates and any ongoing boluses is stopped.

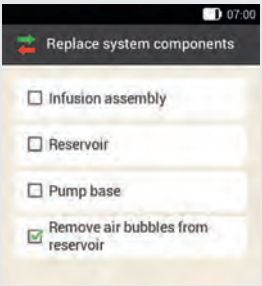
The prerequisite for using the Remove air bubbles from reservoir feature is that the micropump is in regular operation. If malfunctions are present, for example if there are maintenance tasks ongoing, they must first be resolved. The delivered insulin for removing air bubbles is not considered in the calculations for therapeutic insulin deliveries. See also Warning in Chapter *4.2.2 Filling the Reservoir with Insulin*.

⚠ WARNING

Risk of hypoglycaemia (low blood glucose level)

Make sure that the micropump is not attached to your body. There is a risk of uncontrolled insulin delivery. Never fill the reservoir needle while the micropump is attached to your body.

1



Tap Remove air bubbles from reservoir.
The micropump is stopped.
Tap Next.

2 *Prepare for filling:*

Hold the pump with the reservoir needle in an upright tilted position.
To start filling, press ✓.
The micropump delivers insulin to remove the air bubbles. Gently flick your finger against the reservoir several times.

3 *Wait for insulin drop:*

Tap OK once you can see a drop of insulin on the reservoir needle. Check whether the air bubbles have been removed from the reservoir.
If the air bubbles have not been removed, tap Cancel.
Repeat step 1 to 3 until there are as few air bubbles as possible in the reservoir.

4 *Attach micropump:*

Properly attach the micropump to the infusion assembly.
Tap Next.

5 *Deliver insulin:*

To activate the basal rate profile, press the insulin button ✓ lit up in green, on the diabetes manager.

10 My Data

Analyzing your therapy data saved in the diabetes manager helps you and your healthcare professional to determine how your diabetes is developing. This analysis is a valuable tool to help making improvements to the treatment of your diabetes.

The diabetes manager generates charts and reports to help you analyse the information saved in the device. Each event in the logbook can be viewed separately. The diabetes manager can also display compilations of therapy data in the form of charts and overviews.

10.1 Logbook

You can display each single logbook entry on the display of the diabetes manager. There, you will find all the information about glucose values along with time of test, carbohydrates, health events and boluses. In addition, you can change the entries in the logbook or add new ones.

The diabetes manager automatically stores up to 5,000 logbook entries with the time and date. You can view the most recent 250 logbook entries in the diabetes manager. If you are using a PC with compatible software, you can view all logbook entries.

A logbook entry can contain the following information:

Date and time, glucose value, time of test, carbohydrate intake, health events, bolus amounts, bolus type and notes.

Note the following:

- The Logbook screen shows the entries in the order in which they occurred with the most recent entry shown on top.
- If you want to add data to a logbook entry, you can also tap the Add data button on the Status screen or in the Main menu.
- Bolus data from the micropump is automatically saved on the diabetes manager. However, the bolus advice feature will treat quick boluses that you deliver manually as correction insulin. Therefore, you should edit the quick boluses recorded in the logbook with regard to bolus distribution (meal/correction insulin) and carbohydrates consumed.
- Logbook data that has been used for bolus advice cannot be subsequently adjusted.
- You should enter any boluses that were delivered independently of the diabetes manager using an insulin pen or syringe as new data in the logbook.
- Once 5,000 entries have been saved in the logbook, adding a new entry causes the oldest logbook entry to be deleted. Save the entries on a PC if you want to keep all entries.
- Although control results are saved in the diabetes manager, they can only be viewed on a computer with suitable software.
- Before reviewing logbook entries on a PC, you first have to transfer the saved logbook entries to a PC that has specific diabetes management software.

10.1.1 Understanding the Logbook

Main menu > My data > Logbook

1	**Column for displaying blood glucose information** Glucose value range and glucose value
2	**Column for displaying bolus information** Bolus type, bolus advice and bolus amount
3	**Column for displaying carbohydrate information** Symbol for carbohydrates and carbohydrate amount
4	Symbol for glucose value range information
5	Symbol for bolus advice
6	Symbol for bolus type
7	Symbol for carbohydrates
8	Carbohydrate amount
9	Bolus amount
10	Glucose value
11	Symbol for STOP mode
12	Symbol for health event
13	Symbol for note
14	Time of entry
15	Symbol for general time of test
16	Date of entry

Symbol description

Glucose value range
The symbol colours have the following meaning:
Blue ●: above the target range
Green ●: within the target range
Yellow ●: below the target range
Red ●: below the hypo warning limit

Standard bolus
Bolus insulin from a standard bolus

Extended bolus
Bolus insulin from an extended bolus

Multiwave bolus
Bolus insulin from a multiwave bolus

Micropump
Bolus insulin from a quick bolus

Symbol description
Basal insulin  Basal insulin from an injection
Manual bolus with pen/syringe  Bolus was delivered using an insulin pen or syringe.
Bolus advice accepted  Bolus advice from the diabetes manager was accepted.
Bolus advice not accepted  Bolus advice from the diabetes manager was changed prior to delivery.
Carbohydrates  Carbohydrate data exists for the logbook entry.
Time of test  Data regarding the time of test exists for the logbook entry.
Health event  Health event data exists for the logbook entry.
Pump stopped  The micropump was stopped.
Notes  You entered a note.

10.1.2 Viewing and Adjusting Logbook Data

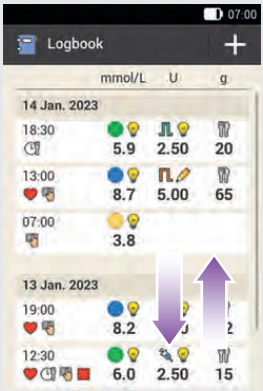
1 *Main menu:*

Tap My data.

2 *My data:*

Tap Logbook.

3



Scroll the screen upwards or downwards to view additional logbook entries.

Tap a logbook entry if you want to view or adjust the details.

4 *Logbook entries:*

Tap the entry you want to view or adjust (for example, Time of test).

5 *Time of test:*

On the Logbook entries screen, tap Time of test. Tap a time of test (for example, Before meal).

Tap Save.

6 *Carbohydrates:*

On the Logbook entries screen, tap Carbohydrates. Enter the amount of carbohydrates you consumed (for example, 20 g).

Tap Save.

7 *Health events:*

On the Logbook entries screen, tap Health events.

Tap the appropriate entries (for example, Exercise 1). You can select up to 4 health events.

Tap Save.

8 *Bolus input:*

On the Logbook entries screen, tap Bolus.

The screen informs you about the bolus delivered.

Tap Bolus.

NOTE

The bolus advice feature initially treats quick boluses as correction insulin. Mark the quick boluses in the logbook as a meal bolus or correction bolus according to their purpose. Enter consumed carbohydrates in the logbook.

9 *Note:*

On the Logbook entries screen, tap Note.*

Type a note to save with this entry.

Tap Done.

* The note feature may not be available in all languages.

10.1.3 Adding New Data

1 *Logbook:*

On the Logbook screen, tap + to add new data to the logbook.

2 *Add data:*

Tap the entries you want to add.

Then tap Save.

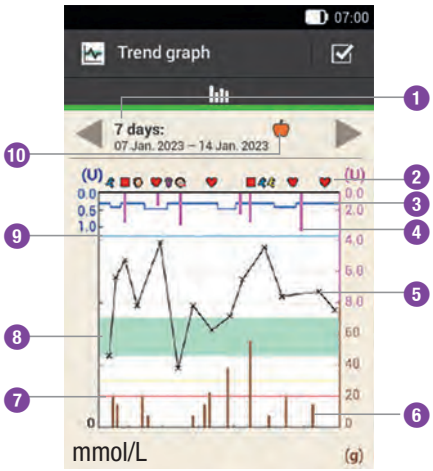
NOTE

You can also access the Add data screen by tapping the Add data function button on the Status screen or in the Main menu.

10.2 Trend Graph

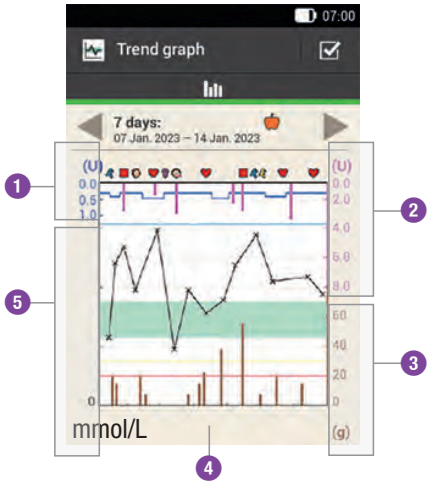
Main menu > My data > Trend graph

The trend graph displays your blood glucose trends, basal rates, boluses, carbohydrates and other information. The logbook entries for the time period selected by you are used. Using the ◀▶ buttons, you can move backwards or forwards in time according to the selected time scale.



1 **Time scale**
Illustrated time period

2	**Events** Displays health events or indicates that the micropump was stopped.
3	**Basal rate** Blue line: The distance from the top edge of the graph shows the basal rate.
4	**Bolus** Pink bars: Show the amounts of bolus insulin
5	**Glucose value** Crosses (x): Individual glucose values that are connected by lines
6	**Carbohydrates** Brown bars: Show the carbohydrate amount consumed
7	**Hypo warning limit** Red line: Hypo warning limit
8	**Blood glucose target range** Green area: Range between the lower and upper blood glucose threshold
9	**Hyper warning limit** Light blue line: Hyper warning limit
10	**Selected time of test** Displays logbook entries entered for this time of test.



1	Basal insulin amount
2	Bolus values
3	Carbohydrate amount
4	Time scale
5	Glucose values

On the **upper left side** (U = Units per hour) of the graph, the amount of basal insulin is displayed. The scale comprises a range of 1, 2, 5, 10, 20 or 40 U/h. By means of the scale, you can read the basal rate, which is represented by the blue basal insulin line. Scaling depends on the largest basal rate delivered during the selected time period.

Example

For example, if the highest basal rate in the selected time period is 3 U/h, the scale will show the range from 0 to 5 U/h.

On the **lower left side** (**mmol/L**) of the graph, the glucose value is displayed. By means of the scale, you can read the glucose values, which are represented by a black line. The black line connects the individual glucose values indicated by a cross. Scaling depends on the largest glucose value measured during the selected time period.

On the **upper right side** (U) of the graph, the bolus amount is displayed. By means of the scale, you can read the bolus values of the pink bars. The scale comprises a range of 1, 5, 15, 30 or 60 U. Scaling depends on the largest bolus delivered during the selected time period.

Example

For example, if the largest bolus delivered during the selected time period is 8 U, the scale will show the range from 0 to 15 U.

On the **lower right side** (g) of the graph, the carbohydrate amount is displayed. By means of the scale, you can read the carbohydrate values, which are represented by the brown bars. The scale comprises a range of 40, 80, 120, 160, 200 or 240 g, or the equivalent scale for BE, KE or CC. Scaling depends on the largest carbohydrate amount consumed during the selected time period.

Example

For example, if the largest carbohydrate amount in the selected time period is 86 g, the scale will show the range from 0 to 120 g.

10.2.1 Displaying the Trend Graph

1 *Trend graph:*

Tap ☑ to change the trend graph representation.

2 *Trend graph options:*

Tap the setting you want to change.

3 *Time scale:*

Tap the desired time period (for example, 3 days).

Tap Save.

4 *Graph options:*

Tap one or more of the available graph options (for example, Bolus) to be displayed in the graph.

Tap Save.

5 *Time of test:*

Tap the appropriate time of test (for example, After meal).

Tap Save.

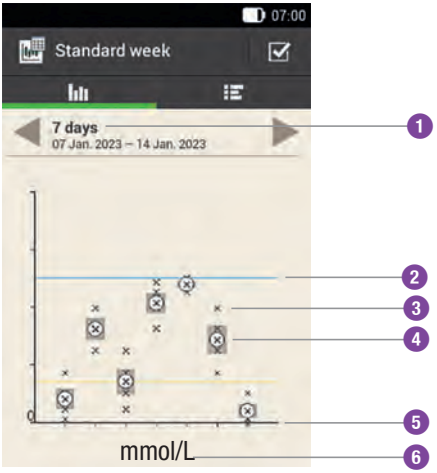
On the Time of test screen you can select which logbook entries are to be represented. Only the logbook entries are displayed for which you entered the selected time of test.

10.3 Standard Week

Main menu > My data > Standard week

The standard week graph displays your blood glucose averages, the individual tests and the standard deviations for the days of a standard week. Using the ◀ ▶ buttons,

you can move backwards or forwards in time according to the selected time scale.



1	**Time scale** Represented time period, for example, 7 days
2	**Hyper warning limit** Blue line: Hyper warning limit
3	**x** Single glucose value
4	Ⓧ Average value
5	**Time axis** Monday to Sunday
6	**Unit of measurement** mmol/L

The standard deviation indicates how the glucose values are scattered around the blood glucose average. A high standard deviation means that the glucose values are scattered away from the glucose average.

Tap to switch to the standard week table. The standard week table displays the data of the standard week graph in table format. To return to the standard week graph, tap . Using the buttons, you can move backwards or forwards in time according to the selected time scale.

1	**Time scale**
2	**Selected time of test**
3	**Number of tests on the day of the standard week**
4	**Standard deviation (SD) of the day of the standard week**
5	**Highest glucose value of the day of the standard week**
6	**Blood glucose average of the day of the standard week**
7	**Lowest glucose value of the day of the standard week**
8	**Day of the week**

10.3.1 Displaying the Standard Week Graph

1 *Standard week:*

Tap ☑ to change the representation of the standard week graph.

2 *Standard week options:*

Tap one of the entries available for selection.

Make the desired settings.

Tap Done.

3 *Time scale:*

Tap the desired time period (for example, 30 days).

Tap Save.

4 *Time of test:*

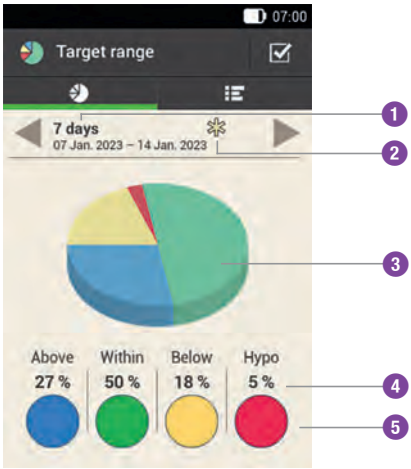
Tap the appropriate time of test (for example, Fasting).

Tap Save.

10.4 Target Range

Main menu > My data > Target range

This screen displays a pie chart and a table illustrating your glucose values for the time period and time of test you selected. The chart is divided into the following glucose value ranges: Above, Within, Below and Hypo. Using the ◀▶ buttons, you can move backwards or forwards in time within the selected time period.



1	**Time scale** Illustrated time period
2	**Selected time of test** Shows logbook entries entered for this time of test.
3	**Target range chart** Shows the target ranges of glucose values as a pie chart.
4	**Percentage distribution** Shows the percentage of glucose values in each glucose value range.
5	**Glucose value ranges** Coloured representation of the glucose value ranges

Tap ☰ to switch to the target range table. The target range table displays the target range data in table format. To return to the target range chart, tap ◔. Using the ◀▶ buttons, you can move backwards or forwards in time according to the selected time period.

1	**Time scale** Illustrated time period
2	**Glucose value ranges** Coloured representation of the glucose value ranges
3	**Number** Number of glucose values in one of the ranges
4	**Times of test** Shows the logbook entries for this time of test.

10.4.1 Displaying the Target Range Data

1 *Target range:*

Tap ☑ to change the representation of the target range.

2 *Target range options:*

Tap one of the entries available for selection.

Make the desired settings and then tap Done.

3 *Time scale:*

Tap the desired time period (for example, 7 days).

Tap Save.

4 *Time of test:*

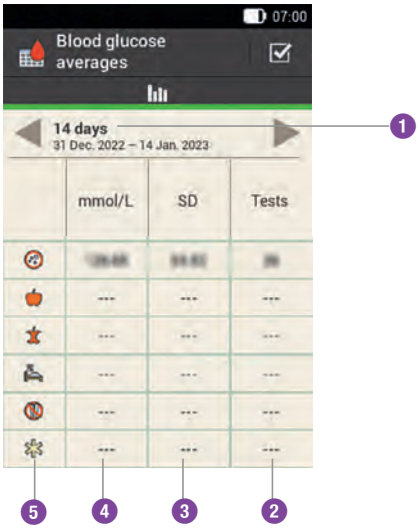
Tap the appropriate time of test (for example, Bedtime).

Tap Save.

10.5 BG Averages Table

Main menu > My data > Blood glucose averages

The BG averages table displays your blood glucose averages and standard deviations (SD) for the time period and time of test you selected.



1	**Time scale** Illustrated time period
2	**Number of tests** Shows the number of glucose values used for the calculation.
3	**Blood glucose standard deviation** Indicates how the glucose values are scattered around the blood glucose average.
4	**Blood glucose average** Average for the selected time period.
5	**Times of test** Shows the logbook entries for this time of test.

10.5.1 Displaying the BG Averages Table

1 *Blood glucose averages:*

Tap ☑ to change the settings for the time period.

2 *Time scale:*

Tap the desired time period (for example, 30 days).

Tap Save.

10.6 System Events

Main menu > My data > System events

The following system events can be accessed directly on the diabetes manager:

Event data	The last 90 maintenance, warning and error messages
Bolus data	The last 90 boluses delivered by the micropump
TBR data	The last 90 increases and decreases in the basal rate
Total daily dose	The last 90 daily insulin totals delivered by the micropump
Information	Information about the micropump currently in use

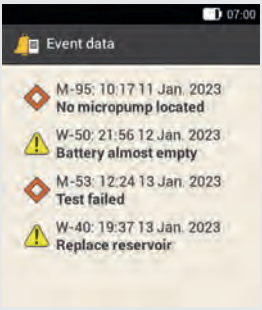
NOTE

If a record could not be read correctly because of an error, ---X--- is displayed instead.

10.6.1 Event Data

This screen lets you access the last 90 maintenance, warning, reminder and error messages, with the most recent entry displayed first.

Example

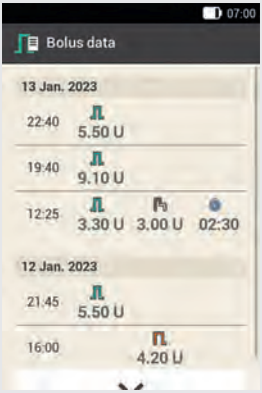


Each entry includes the following data: Type and number of the maintenance/ warning/reminder/error message, title of the maintenance/warning/reminder/error message, time, date

10.6.2 Bolus Data

This screen lets you access the last 90 boluses delivered by the micropump, with the most recent entry displayed first.

Example

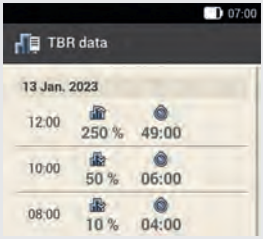


Each entry includes the following data: Start date, start time, immediate amount for the bolus (for quick, standard or multiwave bolus), delayed bolus amount (for extended or multiwave bolus), bolus duration (for extended or multiwave bolus)

10.6.3 TBR Data

This screen lets you access the last 90 temporary basal rates, with the most recent entry displayed first.

Example

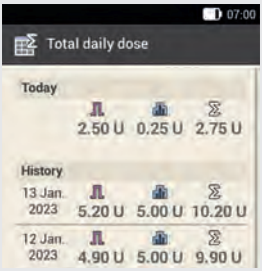


Each entry includes the following data: Start date, start time, TBR as a percentage, TBR duration

10.6.4 Total Daily Dose

This screen lets you access the last 90 daily insulin totals delivered (in each case from midnight to midnight, including basal rate and boluses), with the most recent entry displayed first.

Example



Each entry includes the following data: Daily insulin total delivered as a bolus, daily insulin total delivered as a basal rate, daily insulin total delivered, date

10.6.5 Information

This screen lets you access information about the micropump currently in use.

Example

This view includes the following data: Micropump remaining running time, micropump serial number, micropump battery status, micropump firmware version

10.7 Data Transfer

You can display and evaluate the data on a PC using an Accu-Chek diabetes management software, such as the Accu-Chek Smart Pix software.

For more information, see the User's Manual for the software used.

Install the software before you begin the data transfer.

⚠ WARNING

Only use the supplied USB cable.

1 *Main menu:*

In the Main menu, tap USB.

2

The Connect to PC screen appears.

3 Plug the smaller end (micro-B plug) of the USB cable into the USB socket of the diabetes manager.

4 Plug the larger end (USB-A plug) of the USB cable into a free USB port on your computer.

Do **not** use the USB charging port (often indicated by ⚡), as data is not transferred via this port.

5 *Establishing data connection to PC:*

Launch the Accu-Chek diabetes management software on your PC.

6

This screen shows that data connection between the diabetes manager and the PC was successfully established. You can now use the Accu-Chek diabetes management software.

11 Changing Settings

Main menu > Settings

In the *Settings* menu, you can make changes to the factory settings or change the settings you made. This allows you to adjust the micropump system to your individual treatment requirements and your personal preferences.

For information on changing time blocks and health events, and on settings for insulin sensitivity, carbohydrate ratio, meal rise, snack size, acting time and offset time, see chapter *7 Bolus Advice*.

For information on reminder settings, see chapter *12 Reminders*.

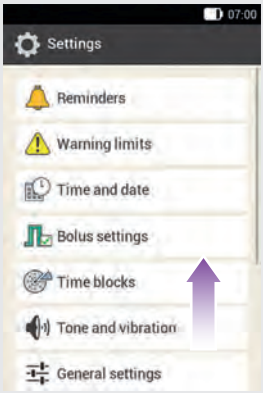
NOTE

When you edit a setting, any unsaved changes will be discarded when the diabetes manager turns off or a test strip is inserted into the test strip slot.

1 *Main menu:*

In the Main menu, tap the Settings menu.

2



Scroll the list upwards to view additional list entries.

Tap the desired entry to change the respective settings.

11.1 Warning Limits

Main menu > Settings > Warning limits

You can set the hyper and hypo warning limits that best fit your needs. Whenever your glucose value is above the hyper warning limit or below the hypo warning limit, the diabetes manager displays a warning.

1 *Warning limit:*

Tap Upper warning limit or Lower warning limit.

2 *Upper warning limit:*

Set the upper warning limit (for example, 15.5 mmol/L).

Tap OK.

3 *Lower warning limit:*

Set the lower warning limit (for example, 3.3 mmol/L).

Tap OK.

4 *Warning limits:*

Tap ⮌ to return to the list of settings. If you want to make additional settings, tap the respective entry.

The warning limit for the remaining running time of the micropump indicates the number of days as of which you want to receive a warning regarding the remaining running time of the micropump.

5 *Warning limits:*

Tap Micropump running time left (days).

6 *Micropump remaining running time:*

Set the number of days as of which you want to receive a warning (for example, 30 days).

Tap Save.

The warning limit for the reservoir level indicates the number of insulin units as of which you want to receive a warning regarding the remaining insulin amount. The remaining insulin amount is the insulin amount that is still available in the micropump reservoir.

7 *Warning limits:*

Tap Reservoir level.

8 *Remaining insulin amount:*

Set the number of insulin units at which you want to receive a warning (for example, 40.00 U).

Tap Save.

The automatic off function is a safety feature for emergency situations. If you have not touched any button on your micropump and not operated the diabetes manager for the specified number of hours, the micropump stops insulin delivery. This could happen, for example, if you are no longer able to stop the pump yourself due to severe hypoglycaemia.

The automatic off function is turned off by default.

NOTE

If using this function, use a time span that is longer than your usual bedtime period. Otherwise, you risk that the micropump turns off automatically during your bedtime.

9 *Warning limits:*

Tap Automatic off.

10 *Automatic off:*

Tap Status to turn the automatic off function on or off.

11 *Automatic off:*

Tap Inactivity.

12 *Duration:*

Set the number of hours after which the insulin delivery will be interrupted (for example, 14 hours).

Tap OK.

13 *Automatic off:*

Tap Done.

11.2 Time and Date

⚠ WARNING

- Having the time and date set precisely is essential for your micropump system to function properly. Having the wrong time set may result in the delivery of incorrect insulin amounts, thus leading to hyperglycaemia or hypoglycaemia.
- Switching the system time to the respective time zone (local time) of your long-distance journey may result in the basal rate and bolus advice to be inappropriate. When travelling across multiple time zones, discuss the adjustments necessary for basal rate and bolus advice with your healthcare professional in advance.

Main menu > Settings > Time and date

1 *Time and date:*

Tap Time format, Time or Date to make the respective settings.

Then tap OK.

2 *Time format:*

Tap the desired time format, for example, 24 hours.

Tap Save.

3 *Time:*

Set the hours and minutes for the current time.

Tap OK.

4 *Date:*

Set the day, month and year.

Tap OK.

5 *Time and date:*

Then tap OK.

11.3 Bolus Settings

⚠ WARNING

The therapy settings must be specified by your healthcare professional and you may only change them after prior consultation. Otherwise, there is a risk of experiencing hyperglycaemia or hypoglycaemia.

A quick bolus is a standard bolus that is programmed and delivered using the quick bolus buttons on the micropump.

The factory setting for the quick bolus buttons is ON.

Main menu > Settings > Bolus settings

1 *Bolus settings:*

Tap Quick bolus buttons to activate or deactivate the quick bolus buttons of the micropump.

Set the Maximum quick bolus to define the maximum insulin amount that may be delivered with a quick bolus.

NOTE

You cannot define a maximum quick bolus that is greater than the maximum bolus amount.

2 *Bolus settings:*

Tap the Maximum quick bolus entry to set the maximum bolus amount that can be programmed.

3 *Maximum insulin amount for quick bolus:*

Set the maximum amount for the quick bolus.

Tap Save.

The quick bolus increment indicates the amount by which your insulin dose is increased with each press of the quick bolus buttons while programming a quick bolus.

You can set the following quick bolus increments: 0.2 U, 0.5 U, 1.0 U, 2.0 U.

Note down the set quick bolus increment in the detachable quick reference instructions supplied in the cover of this User's Manual.

Example

With a quick bolus increment of 0.5 U, you have to press the quick bolus buttons 5 times to deliver an insulin amount of 2.5 U.

4 *Bolus settings:*

Tap Quick bolus increment.

5 *Quick bolus increment:*

Tap the desired quick bolus increment (for example, 1.00 U).

Tap Save.

Set the maximum bolus amount to define the maximum insulin amount that may be delivered in any bolus. Bolus advice that exceeds the maximum bolus amount requires additional confirmation or must be reduced. A manual bolus is upwardly limited by the maximum bolus amount selected.

6 *Bolus settings:*

Tap Maximum bolus amount to set the maximum insulin amount for a bolus.

7 *Maximum bolus amount:*

Set the maximum bolus amount (for example, 20.0 U).

Tap OK.

In some situations (for example, if you have gastroparesis) it may be helpful to only start a bolus after you have started eating. You can use the delivery lag time setting to specify an interval between programming a bolus and the actual start of bolus delivery.

NOTE

- While programming a bolus, you can set a delivery lag time of 0, 15, 30, 45 or 60 minutes.
- If a bolus contains correction insulin or if the glucose value is above the target range, it is not possible to enter a delivery lag time. Correction insulin must always be delivered immediately.

8 *Bolus settings:*

Tap Delivery lag time to turn the lag time for bolus delivery on or off.

Tap Done.

11.4 Time Blocks

For information on changing time blocks, target ranges, and health events, and on settings for insulin sensitivity, carbohydrate ratio, meal rise, snack size, acting time and offset time, see chapter *7 Bolus Advice*.

11.5 Tone and Vibration

You can define how the diabetes manager should attract your attention in case of an event (for example, a warning). You can choose whether the diabetes manager issues a sound, vibrates or both. The settings you make are referred to as *signal mode* in the rest of this User's Manual. You can also mute the sound for warnings and reminders for a specific period of time (for example, overnight).

⚠ WARNING

If you ignore or do not notice the messages from the micropump system, there is a risk of hypoglycemia or hyperglycemia, which may culminate in ketoacidosis.

Main menu > Settings > Tone and vibration

1 *Settings:*

Tap Tone and vibration.

2 *Tone and vibration:*

Tap Loud, Normal, Quiet or Vibration to set the desired signal mode.

Then tap Done.

3 *Normal:*

Set the volume for the default setting by moving the slider.

- Right: loud
- Middle: normal
- Left: quiet

Turn vibration on or off.

Tap OK.

NOTE

When the volume slider is set to 0 percent in the far left position, vibration is automatically turned on.

4 *Vibration:*

Tap Vibration.

Tap OK.

5 *Tone and vibration:*

Tap Blood glucose test to turn the sound for a blood glucose test on or off.

Once you have made the desired setting, tap Done.

6 *Tone and vibration:*

Tap Touchscreen feedback to set how the diabetes manager reacts when you make a selection using the touchscreen.

Once you have made the desired setting, tap Done.

7 *Touchscreen feedback:*

Tap the desired touchscreen setting (for example, Tone).

Tap OK.

8 *Insulin delivery signal:*

Tap Insulin delivery signal.

If you turn on the signal, the diabetes manager issues a sound when you confirm delivery of a basal rate or bolus.

Tap Done.

11.6 Mute Warnings and Reminders

This function allows you to temporarily mute the sounds for pump warnings and reminders. You cannot, however, turn off maintenance and error messages because these events require your attention.

You can set up the feature as a one-time event or as an event that is repeated at the same time every day.

NOTE

- Mute warnings and reminders applies only for micropump warnings and reminders.
- Warnings that occur during Mute warnings and reminders activation are displayed once the diabetes manager is turned on or Mute warnings and reminders activation ends.
- When Mute warnings and reminders is turned on,  is displayed in the status bar. This symbol is also displayed outside the set time period for the sound suppression.

Main menu > Sound > Mute warnings and reminders

1 *Main menu:*

In the Main menu, tap Sound.

2 *Sound:*

Tap Mute warnings and reminders.

3 *Mute warnings and reminders:*

Tap Status to turn on the Mute warnings and reminders feature.

4 *Mute warnings and reminders:*

Tap Start time to set the start of Mute warnings and reminders.

5 *Start time:*

Set the hours and minutes for the start time.

Tap OK.

6 *Mute warnings and reminders:*

Tap End time to set the end of Mute warnings and reminders.

7 *End time:*

Set the hours and minutes for the end time (for example, 07:00).

Tap OK.

8 *Mute warnings and reminders:*

Tap Frequency to set the repetition interval (for example, Once) for Mute warnings and reminders.

Tap Done.

NOTE

If you select Once, the signals for warnings and reminders are turned off only once for the time period you specified.

If you select Repeat, the signals for warnings and reminders are turned off daily during the time period you specified.

Once the Mute warnings and reminders time has expired, the signals for the warnings and reminders that occurred are issued again.

11.7 General Settings

You can make the settings for Language and Brightness in the general settings. You can also use Check system functions to check the proper operation of the micropump system.

Main menu > Settings > General settings

1 *General settings:*

Tap Language or Brightness to make the desired settings.

2 *Language:*

Tap the entry for the language in which you want the menus and texts to appear on the display.

3 *Brightness:*

Set the display brightness by moving the slider.

- Right: bright
- Left: dark

Tap Save.

4 *General settings:*

Tap Done to return to the list of settings.

11.8 Screen Lock

The diabetes manager is equipped with a screen lock, which can be used to protect the device against unauthorised access. You can define a personal identification number (PIN) to be used for access. The PIN is an identification code with four to eight digits that you enter and change in the Screen lock menu.

⚠ WARNING

To prevent unauthorised access, you should always leave the screen lock turned on; this way the therapy settings cannot be changed by third parties.

NOTE

- The screen lock is turned on by factory default.
- If you want to change the PIN, you have to turn the screen lock off and on again.
- Choose a PIN that you can easily memorise and enter.

Main menu > Settings > Screen lock

1 *Settings:*

Tap Screen lock.

2 *Screen lock:*

Tap Status (PIN) to turn off the screen lock.

3 *Information - Deactivate PIN?*

When you turn off the screen lock, this information screen appears for your information.

Tap Yes if you do **not** want to enter a PIN or if you want to **change the PIN**.

4 *Enter PIN:*

Enter the PIN to confirm it.

Tap OK.

5 *Screen lock:*

Tap Status (PIN) to turn on the screen lock.

6 *Enter PIN:*

Enter a PIN with 4 to 8 digits.

Tap OK.

7 *Confirm PIN:*

Enter the PIN again to confirm it.

Tap OK.

NOTE

If you have forgotten the PIN you chose, you can unlock the diabetes manager with a PIN unlock code.

You will find the label with the 8-digit PIN unlock code in the envelope in the micropump system packaging (system kit).

8 *Screen lock:*

Tap Background image to set the pattern for the background of the active screen lock.

Then tap Done.

9 *Select wallpaper:*

Tap the tile with the desired background image.

Tap None if you do not want to have a background image.

Tap Done.

11.9 System Information

The system information provides various details on the micropump system.

In addition, you can read legal information and the License Terms and Conditions.

Some of this information may be requested by customer support.

Main menu > Settings > System information

1 *Settings:*

Tap System information.

2 *System information:*

The list of system information is displayed.

Scroll the screen upwards to see additional system information.

3 *System information:*

Tap the Legal information entry to view the stored license agreements.

4 *Legal information:*

Scroll the screen upwards to be able to read more text.

Tap ⮌ to return to the previous screen.

11.10 Travelling and Airplane Mode

Having the time and date set precisely is essential for your micropump system to function properly.

⚠ WARNING

Switching the system time to the respective time zone (local time) of your long-distance journey may result in the basal rate and bolus advice to be inappropriate. When travelling across multiple time zones, discuss the adjustments necessary for basal rate and bolus advice with your healthcare professional in advance.

If you change the time of the micropump system, the basal rate will be delivered according to the time set. This also holds true for changing the clocks in summer and winter time.

Example

You change the time of the micropump system from 10:00 to 13:00. After the change, the micropump delivers the basal rate for that time at 13:00.

For information on how to change the date and time settings of the micropump system, see section *11.2 Time and Date*.

If the use of *Bluetooth* wireless technology is not allowed for flights, you can turn on airplane mode. In airplane mode the micropump system stops communication via *Bluetooth* wireless technology.

If the quick bolus feature was activated, you can continue to deliver boluses using the quick bolus buttons on the micropump. As soon as airplane mode is turned off, the diabetes manager and micropump synchronise and update the event data.

All ongoing insulin delivery (basal rate, bolus) are not affected by the airplane mode. However, if you want to change settings, you must switch off the airplane mode.

11.10.1 Turning On Airplane Mode

1 *Main menu:*

In the Main menu, tap the Airplane mode menu.

2 *Airplane mode:*

Tap Status to put the switch in the ON position.

Tap Done.

3 *Information - Airplane mode on:*

Confirm the displayed information by tapping OK.

The communication with the micropump via *Bluetooth* wireless technology will be turned off.

The diabetes manager cannot remotely control the micropump.

4 *Status screen:*

The symbol ✈ in the status bar indicates that airplane mode is turned on.

No micropump data is displayed in airplane mode.

11.10.2 Turning Off Airplane Mode

1 *Main menu:*

In the Main menu, tap the Airplane mode menu.

2 *Airplane mode:*

Tap Status to put the switch in the OFF position.

Tap Done.

3 *Information - Airplane mode off:*

Confirm the displayed information by tapping OK.

The communication with the micropump via *Bluetooth* wireless technology will be turned on.

The diabetes manager automatically reconnects to the micropump.

4 *Status screen:*

Airplane mode is turned off.

The airplane mode symbol is no longer displayed in the status bar.

12 Reminders

You can set reminders for specific appointments and events. This can be useful when you have to make specific preparations, for example, for replacing the infusion assembly. A message on the display and a sound attract your attention to the respective reminder at the set time.

You can select any tone from the option list for each reminder. In the factory settings, all reminders are deactivated. You can turn the reminders on or off by using the ON and OFF switch.

You can make different settings for the various reminder types:

Setting	Explanation
Time	The time of day the reminder occurs.
Date	The date the reminder occurs.
Remind after	Period of time following an event (for example, glucose value being too high) after which a reminder is to occur.
Tone	The tone that is used for the reminder.
Frequency	One-time reminder or regular reminder that is to occur every day at the same time.

12.1 Overview of Reminders

Reminder
Replace infusion assembly Reminds you to replace the infusion assembly after a specified number of days.
Alarm clock/Customised The alarm clock sounds at the specified time.
Test blood glucose Reminds you to test your blood glucose at a specified time.
After meal Reminds you to test your blood glucose after eating if you have previously marked a glucose value as Before meal.
Test after low glucose value Reminds you to test your blood glucose if your glucose value was below the set glucose value.
Test after high glucose value Reminds you to test your blood glucose if your glucose value was above the set glucose value.
Missed bolus This reminder occurs if no bolus was delivered within 2 hours prior to the programmed time.
Inject basal insulin Reminds you to deliver basal insulin (available in injection mode only).
Healthcare professional visit/Lab test Reminds you that you have a healthcare professional visit or lab test.

12.2 Programming Reminders

Set the desired time and frequency for each reminder. If you choose Repeat, you will be reminded of the event at certain intervals, for example, daily.

Some reminders only appear when certain conditions are met.

You can add more reminders by tapping +. Once the maximum number of reminders has been reached, you will see the information that no more reminders can be added, instead of +. By tapping 🗑, you can delete reminders you added.

You can assign a tone from an option list to each programmed reminder. Tap ♫ in the option list to listen to the tone.

Main menu > Settings > Reminders

1 *Tone:*

Tap the desired tone to use for the reminder.

Tap ♫ to listen to the tone beforehand.

Tap OK.

2 *Frequency:*

Choose Once or Repeat.

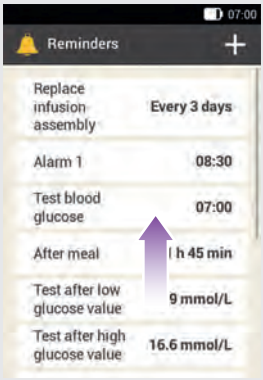
Depending on the reminder type, the system offers different repetition intervals.

Tap OK.

Reminder: Replace Infusion Assembly

This reminder informs you to replace your infusion assembly.

1



Tap Replace infusion assembly.

2 *Replace infusion assembly:*

Tap Status to put the switch in the ON position. Tap Recurrence, Time, Tone to make the desired settings.

Once you have made all settings, tap Done.

Reminder: Alarm Clock

1 *Reminders:*

Tap Alarm clock 1.

2 *Alarm clock:*

Tap ✋ to assign a name to the alarm clock reminder.

Enter a name for the alarm clock reminder using the keyboard. The name may have up to 15 characters.

Tap Done.

3 *Alarm clock:*

Tap Status to put the switch in the ON position. Tap Time, Tone or Frequency to make the desired settings.

Once you have made all settings, tap Done.

Reminder: Test Blood Glucose

This reminder alerts you to test your blood glucose at a time that was specified beforehand.

1 *Reminders:*

Tap Test blood glucose.

2 *Blood glucose test:*

Tap Status to put the switch in the ON position. Tap Time, Tone or Frequency to make the desired settings.

Once you have made all settings, tap Done.

NOTE

When you test your blood glucose, the diabetes manager dismisses any blood glucose test reminders that are pending within the next 30 minutes.

Reminder: After meal

This reminder alerts you to test your blood glucose if a previously measured glucose value was marked as *Before meal*.

1 *Reminders:*

Tap After meal.

2 *Blood glucose test after meal:*

Tap Remind after to enter the time after which you want the reminder to appear.

Once you have made all settings, tap Done.

Reminder: Test after low glucose value

This reminder reminds you to test your blood glucose again when the previous glucose value was too low. The BG threshold in this reminder can be set individually and is independent of the hypo warning limit set by you.

1 *Reminders:*

Tap the Test after low glucose value entry.

2 *Test after low glucose value:*

Tap Status to put the switch in the ON position. Tap BG threshold, Remind after or Tone to make the desired settings.

Once you have made all settings, tap Done.

Reminder: Test after high glucose value

This reminder reminds you to test your blood glucose again when the previous glucose value was too high. The BG threshold in this reminder can be set individually and is independent of the hyper warning limit set by you.

1 *Reminders:*

Tap the Test after high glucose value entry.

2 *Test after high glucose value:*

Tap Status to put the switch in the ON position. Tap BG threshold, Remind after or Tone to make the desired settings.

Once you have made all settings, tap Done.

Reminder: Missed Bolus

This reminder occurs if no bolus was delivered within 2 hours prior to the programmed time. You can program up to 5 reminders of the Missed bolus type.

Example

The missed bolus reminder is programmed for 14:00.

- If no bolus is delivered between 12:00 and 14:00, the previously programmed reminder will occur at 14.00.
- If a bolus was delivered between 12:00 and 13:59, no reminder will occur.

1 *Reminders:*

Tap the Missed bolus entry.

2 *Missed bolus:*

Tap Status to put the switch in the ON position. Tap Time, Tone or Frequency to make the desired settings.

Once you have made all settings, tap Done.

Appointment Reminders

Appointment reminders are a helpful way of reminding you of an upcoming healthcare professional visit or lab test. In addition, you can set customised appointment reminders.

These reminders are displayed when you turn on the diabetes manager on the specified reminder date.

1 *Reminders:*

Tap Healthcare professional visit.

2 *Visit healthcare professional:*

Tap Status to put the switch in the ON position. Tap Time, Date or Tone to make the desired settings.

Once you have made all settings, tap Done.

12.3 Deleting Reminders

If required, you can delete customised reminders you added yourself. The reminders that are predefined in the system, however, cannot be deleted.

1 *Reminders:*

Tap the reminder you want to delete, for example, Custom 2.

2 *Customised reminder:*

Tap to delete the reminder.

3 *Information - Delete entry?*

Tap Yes if you want to permanently delete the reminder now.

12.4 Issuing Reminders

When turned on, the diabetes manager displays a reminder as soon as the specified time has been reached. The diabetes manager vibrates and the respective reminder is accompanied by the selected tone. The volume corresponds to the set sound mode.

You can confirm the reminder with OK or you can specify to be reminded again in 15 minutes by tapping Snooze.

When turned off, no reminders are issued. If an event occurs during that time, the reminder will be issued after the diabetes manager is turned on.

Example

Tap OK to confirm the reminder. The reminder will no longer be displayed.

Tap Snooze if you want to be reminded again at a later point in time. The reminder will be issued again in 15 minutes.

13 Injection Therapy Mode

If you do not want to use your micropump for a while, you can switch to injection therapy mode. This could be the case, for example, if you want to do without your insulin pump while on holiday.

Discuss pausing your pump therapy with your healthcare professional. Switch to alternative therapy methods only after consultation.

When you switch to injection therapy, your diabetes manager supports you as follows:

- Bolus advice results are rounded to the increment of your pen.
- You can note down your basal insulin injections in the detailed glucose value and in the logbook entries of the diabetes manager.
- A reminder is available that you can use to be reminded about basal insulin injections.

NOTE

- If you are using bolus advice, carry out the injections in a timely fashion and using the dosage you confirmed. If you inject a different insulin amount, you should adjust the respective logbook entry.
- You should enter any boluses that were delivered independently of the diabetes manager using an insulin pen or syringe as new data in the logbook.
- Store the micropump and consumables according to the permitted ambient conditions.

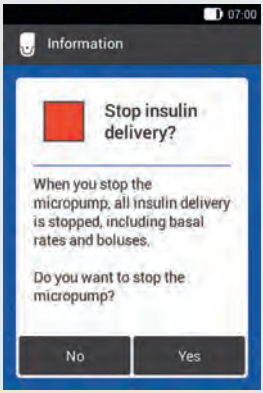
13.1 Removing the Micropump Temporarily

While you are delivering insulin by injection, set the micropump to STOP mode, take the micropump off and remove the infusion assembly.

1 *Main menu:*

In the Main menu, tap Stop to interrupt insulin delivery.

2



Tap Yes.

3 To remove the pump from the infusion assembly, press the flap of the pump holder to detach the micropump.

4 Remove the infusion assembly by loosening the edges of the adhesive pad and pulling it off towards the centre.

5 Remove the used reservoir from the pump base.

Keep the pump base in a safe place.

6 Dispose of the used infusion assembly and used reservoir according to local regulations.

13.1.1 Activating Injection Therapy Mode

1 *Main menu:*

In the Main menu, tap the Settings menu.

2 *Settings:*

Tap the Change to injection therapy entry.

3 *Information - Change to injection therapy?:*

Tap Yes.

The functions for controlling the micropump will be turned off.

4 *Insulin increment:*

Tap the desired insulin increment for the pen (0.5 U or 1.0 U).

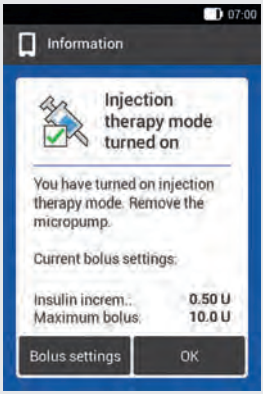
Tap Save.

5 *Maximum bolus amount:*

Set the maximum bolus amount you want to deliver with the pen/syringe (for example, 10.0 U).

Tap OK.

6



The screen informs you that injection therapy mode is turned on. The current bolus settings are displayed.

Tap OK if you want to continue with these settings.

13.1.2 Deactivating Injection Therapy Mode

1 *Main menu:*

In the Main menu, tap the Settings menu.

2 *Settings:*

Tap the Change to pump therapy entry.

3 *Information - Change to pump mode?:*

Tap Yes.

4

If you want to use the micropump with the most recently saved settings, tap No.

- The diabetes manager establishes a connection to the most recently used micropump, and you are taken to the Replace menu. Replace the reservoir.

If you would like to review the pump therapy settings, tap Yes.

- Check the bolus settings as well as the settings for the basal rate.
- Select the Replace menu. Replace the reservoir.

5 *Replace system components:*

Replace the components as needed.

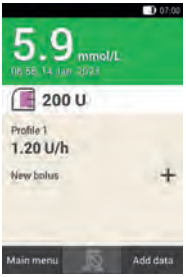
If you do **not** replace any components, the micropump will remain in STOP mode. In this case, start the pump from the Main menu.

13.2 Injection Therapy Screens

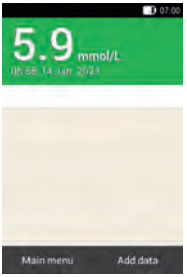
Once you turn on injection therapy mode, some of the displays and menus on the diabetes manager change. The elements necessary for pump therapy are no longer available on the Status screen. In the Main menu, some of the menus are omitted from the menu selection.

to cancel an ongoing bolus is omitted in injection therapy mode.

Screen elements omitted on the Status screen

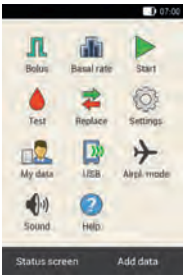


Status screen in pump therapy mode.

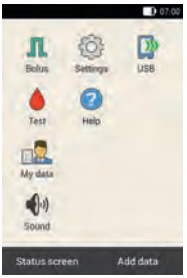


Status screen in injection therapy mode.

Symbols omitted in the Main menu

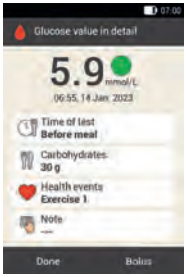


Main menu in pump therapy mode.

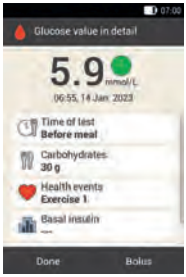


Main menu in injection therapy mode.

Glucose value in detail



Glucose value in detail screen in pump therapy mode.

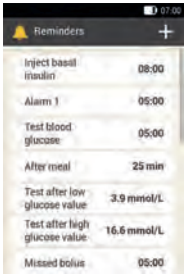


Glucose value in detail screen in injection therapy mode.

You will also see the entry field for basal insulin.

Reminders

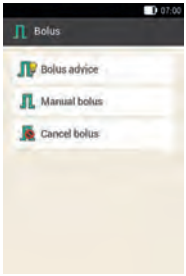
Reminders screen in pump therapy mode.



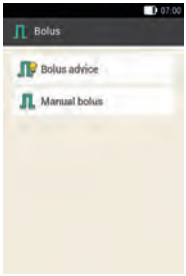
Reminders screen in injection therapy mode.

Instead of the Replace infusion assembly reminder, the Inject basal insulin reminder appears.

Bolus



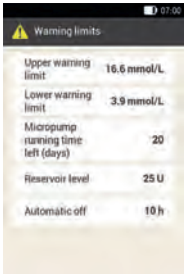
Bolus screen in pump therapy mode.



Bolus screen in injection therapy mode.

The Cancel bolus element is omitted.

Warning limits



Warning limits screen in pump therapy mode.

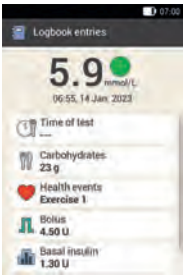
Warning limits screen in injection therapy mode.

The Micropump running time left (days), Reservoir level and Automatic off options are omitted.

13 INJECTION THERAPY MODE

My data

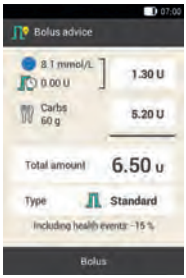
Logbook entries screen in pump therapy mode.



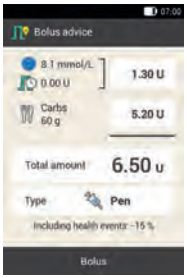
Logbook entries screen in injection therapy mode.

You can enter or change the amount of basal insulin delivered in the Basal insulin entry.

Bolus advice



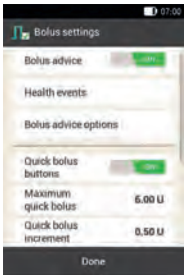
Bolus advice screen in pump therapy mode.



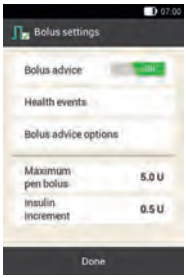
Bolus advice screen in injection therapy mode.

The Type entry provides only the Pen option.

Bolus settings



Bolus settings screen in pump therapy mode.



Bolus settings screen in injection therapy mode.

Instead of the quick bolus elements, the elements for setting the insulin increment and the maximum bolus amount appear.

14 Care and Maintenance

This chapter provides information on how to care for and maintain the micropump system. In the *Control Test of the Diabetes Manager* section, you will learn how to check whether the micropump system is working properly.

If a problem cannot be solved or if you have any questions about caring for and maintaining the micropump system, contact customer support. Do not attempt to repair the diabetes manager or micropump yourself.

Replace the consumables for the micropump system if they are soiled or damaged.

14.1 Cleaning the System Components

Use exclusively lint-free cloths and distilled water to clean the system components.

14.1.1 Cleaning the Diabetes Manager

Use only distilled water. Use neither soap nor abrasive cleaning agents, as they may cause the display to become scratched. If the display of the diabetes manager is scratched, it may be difficult to read under certain circumstances. In this case, the diabetes manager must be replaced.

⚠ WARNING

- The diabetes manager must be turned off for cleaning. Make sure the diabetes manager is turned off and not in standby mode.
- Do not clean the diabetes manager while performing a blood glucose or control test.
- Use only distilled water to clean the diabetes manager.
- Do not get any moisture in slots or openings.
- Do not spray anything onto the diabetes manager.
- Do not immerse the diabetes manager in liquid.

Liquid can impair the functionality of the device electronics and lead to malfunctions. Failure to follow the cleaning and disinfection instructions will damage the diabetes manager and stop it from working properly.

1 Turn off the diabetes manager by pressing and holding the power button until the *Turn Off* screen appears. Tap the *Turn Off* button.

Close the cover of the USB socket and the cover of the headphone socket.

2

Remove any large contaminants with a lint-free cloth moistened with distilled water.

Be careful not to wipe any dirt into the openings on the diabetes manager.

Wipe the surfaces of the diabetes manager for at least 3 minutes using a second, lint-free cloth moistened with distilled water. Clean in particular hard-to-reach places, for example, around the openings.

3 Wipe the diabetes manager using a dry, lint-free cloth.

14.1.2 Cleaning the Micropump

Clean the micropump only with the reservoir attached, before the reservoir is due to be replaced. Replace the reservoir afterwards.

⚠ WARNING

- Clean the micropump only with the reservoir attached to the pump base.
- Set the micropump into STOP mode for cleaning.
- Always use a lint-free cloth moistened with distilled water for cleaning the micropump.
- Do not get any moisture in slots or openings.
- Do not spray anything onto the micropump.
- Do not immerse the micropump in liquid.

Liquid can impair the functionality of the device electronics and lead to malfunctions. Failure to follow the cleaning instructions will damage the micropump and stop it from working properly.

1

Remove any large contaminants with a lint-free cloth moistened with distilled water.

Be careful not to wipe any dirt into the openings on the pump base.

Wipe the surfaces of the micropump for at least 3 minutes using a second, lint-free cloth moistened with distilled water. Clean in particular hard-to-reach places, for example, around the openings.

2 Wipe the surfaces of the pump base using a fresh, dry, lint-free cloth.

Check that the opening for ventilation is clean and not blocked.

Replace the reservoir.

NOTE

Perform visual inspection of the micropump and verify it is clean. If necessary, repeat steps 1 and 2 until all visible contamination is removed.

If you notice any of the following signs of deterioration after cleaning the micropump, stop using it and contact customer support: residue around buttons, cracks, discolouration or if stains remain after cleaning.

14.1.3 Cleaning the Insertion Device

Clean the insertion device using the stipulated cleaning agents.

⚠ WARNING

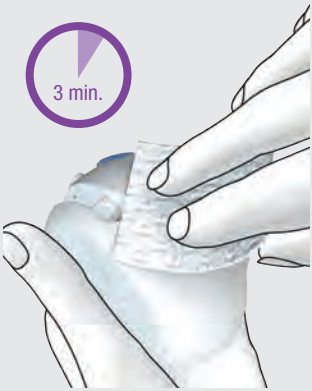
Clean the insertion device only if no cannula assembly is inserted.

- Always use a lint-free cloth moistened with distilled water for cleaning the insertion device.
- Do not get any moisture in slots or openings.
- Do not spray anything onto the insertion device.
- Do not immerse the insertion device in liquid.

Failure to follow the cleaning instructions will damage the insertion device and stop it from working properly.

Before cleaning the insertion device, ensure that the insertion device is not primed and there is **no** cannula assembly in the insertion device.

1



Remove any large contaminants with a lint-free cloth moistened with distilled water.

Be careful not to wipe any dirt into the openings on the insertion device.

Wipe the surfaces of the insertion device for at least 3 minutes using a second, lint-free cloth moistened with distilled water. Clean in particular hard-to-reach places, for example, around the openings.

14.2 Control Test of the Diabetes Manager

You can check whether the diabetes manager is delivering correct glucose values by performing a control test.

Perform a control test using control solution whenever

- you open a new test strip box.
- you have left the test strip container open.
- you think the test strips might be damaged.
- the test strips were exposed to extreme temperatures or humidity.
- you want to check the diabetes manager and test strips.
- the diabetes manager has fallen on the floor.
- your glucose value does not match how you feel.
- you want to check if you are performing the test correctly.

Instead of applying blood to the test strip, you apply glucose control solution for this control test. The diabetes manager is able to detect that glucose control solution was used and shows whether the control result falls within the correct range. The control results are not displayed in the logbook.

Observe the package insert for the control solution.

NOTE

Use only the Accu-Chek Guide control solutions: Control 1 with low glucose concentration or Control 2 with high glucose concentration.

14.2.1 Preparing a Control Test

A control test works the same way as a blood glucose test.

To perform a control test, you need the diabetes manager, the Accu-Chek Guide test strips, the Accu-Chek Guide control solution Control 1 or Control 2 and a clean, dry paper towel.

NOTE

- When performing a control test: If the control test screen with the control bottle DOES NOT appear on the display with your control result, an error has occurred.
  - Do not act on the control result.
  - Discard the test strip and repeat the control test with a new test strip.
- If a control test delivers results that are outside the specified concentration range, you cannot be sure that the diabetes manager and test strips are functioning properly.
- If a test strip error occurs, remove and dispose of the test strip, and repeat the test with a new test strip.
- When a test strip is in the diabetes manager, the touchscreen and the buttons, including the power button, are deactivated. The buttons are activated

again when you remove the test strip or the test is complete.

- Another way to start a control test is from the Main menu. In the Main menu, tap Test.
- Do not apply control solution to the test strip before you have inserted the test strip into the test strip slot.

14.2.2 Performing a Control Test

1 Check the use by date that is indicated on the test strip container next to the symbol.

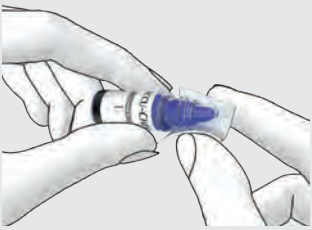
Use only test strips that are not past the use by date.

2 Insert the test strip into the test strip slot of the diabetes manager in the direction of the arrow. The device turns on automatically and the LED at the test strip slot lights up. If the tone for blood glucose tests is turned on, a sound is emitted.

3 Select the control solution (Control 1 or Control 2) to test.

4 Place the diabetes manager on a flat and solid surface (for example, a table top).

5



Remove the bottle cap. Wipe the tip of the bottle with a paper towel.

6

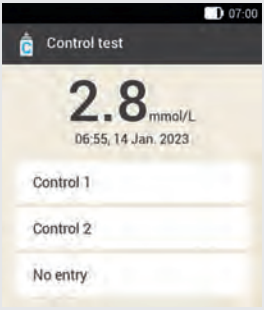
Squeeze the bottle until a tiny drop forms at the tip. Touch the drop to the yellow edge of the test strip. Do not put control solution on top of the test strip.

Testing starts when there is enough control solution in the test strip.

7 Wipe the tip of the bottle with a paper towel. Cap the bottle tightly.

Displaying the control result

8



The control result is displayed.

Tap the control solution you used (for example, Control 1).

NOTE

If you choose No entry, the control test screen shown in the next step will not appear. The control result will not be analysed.

9

If the control result is within the permitted concentration range, the diabetes manager and test strips are working properly.

If the control result is outside the permitted concentration range, contact customer support.
Tap OK.

NOTE

Outside the permitted concentration range, LO or HI means that the control result is outside the permitted range.

Disposing of test strips

10 Remove the used test strip and dispose of it according to local regulations.

14.2.3 Causes of Control Tests with Errors

If the control result is outside the concentration range, check the items listed below. If you cannot answer the questions with Yes, correct the respective item and repeat the test.

- Did you perform the control test as instructed in the User's Manual?
- Did you use a new test strip?
- Did you wipe the tip of the bottle before applying the control solution to the test strip?
- Did you apply a hanging drop of control solution?
- Did you apply only one drop of control solution?
- Was the drop free from any air bubbles?
- Did you apply control solution only after the tone sounded and the Apply drop screen appeared?

- Was the test strip kept still before and during the test?
- Was the test strip straight (not bent)?
- Did you perform the control test within the correct temperature range?
- Did you select the control solution on the Control test screen that corresponds to the control solution you used?
- Is the test strip slot clean?
- Has the control solution bottle been open for less than 3 months?
- Did you observe the information and instructions in the control solution package insert?
- Did you observe the storage conditions for the diabetes manager, test strips and control solutions?
- Did you pay attention to the use by date of the test strips and the control solution?

For details on the correct temperature range and storage conditions, see chapter *16 Technical Data*.

If you have observed all these items and the control result is still outside the concentration range, contact customer support.

14.3 Checking the System Functions

The micropump system must be working perfectly for all system messages (information messages and warnings, maintenance and error messages) to be issued correctly.

If you cannot feel or hear the vibrations and sounds of the diabetes manager or suspect that there might be other defects, you can perform a system function test. This test checks whether the display, vibration, signal and sound features are working properly.

If the micropump emits unexpected sounds or cannot be controlled with the diabetes manager, perform a micropump function test.

If the diabetes manager and the micropump does not work as described in the explanations of the system function test, contact customer support.

1 *Main menu:*

In the Main menu, tap the Settings menu.

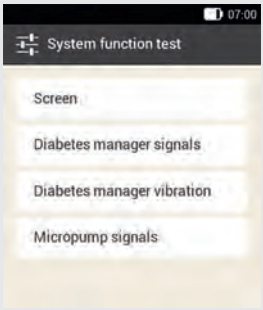
2 *Settings:*

Tap General settings.

3 *General settings:*

Tap Check system functions.

4



Tap Screen.

Checking the screen: The screen shows different colours (red, green, blue and white) in quick succession. In addition, the diabetes manager vibrates whenever the screen changes.

5 *System function test:*

Checking the diabetes manager signals: Tap Diabetes manager signals.

The diabetes manager emits 1 sound.

6 *System function test:*

Checking the diabetes manager vibration: Tap Diabetes manager vibration.

The diabetes manager vibrates.

7

Checking the micropump: Briefly press both quick bolus buttons of the micropump simultaneously. The pump emits a short beep and after three seconds the sound for cancelling the quick bolus is heard.

must not be displayed in the status bar.

8 *System function test:*

Checking the micropump signals: Tap Micropump signals.

The micropump emits 1 sound.

NOTE

- If you are using injection therapy mode, the Micropump signals entry will be deactivated and grayed out.
- If the micropump should emit signals continuously, there is an electronic defect in the pump. See chapter *15.5 General Troubleshooting* how to eliminate the error.

15 Messages and Troubleshooting

The micropump system uses error messages, maintenance messages, warnings and information messages to inform you about the status of the micropump.

The diabetes manager issues messages on the display and can emit tones, vibration signals or both, depending on the setting. In addition, the LED of the diabetes manager lights up to signal warnings, maintenance messages and error messages.

When the diabetes manager is turned off or in standby mode (display is turned off), the micropump issues messages through signals. The micropump does not signal any warnings if it is connected to the diabetes manager and the diabetes manager is active (display is turned on).

⚠ WARNING

If you ignore or do not notice the messages from the micropump system, there is a risk of hypoglycemia or hyperglycemia, which may culminate in ketoacidosis. Always follow the information and calls to action of the micropump system.

When a message is displayed, pick up the diabetes manager to receive further information and be able to react to the message. In the lower part of the screen, selection or confirmation buttons are displayed. The buttons are briefly deactivated so that you cannot inadvertently confirm the message before you have read it.

Error and maintenance messages are repeated every 5 seconds and cannot be muted. The cause of the error or maintenance message must be confirmed and corrected.

Warnings and reminders are repeated every 30 seconds and can be muted as often as desired for 5 minutes. Tones and vibration signals are stopped for a certain time period. In this case, the message remains visible on the display and the LED lights up.

All micropump system messages are stored in the event data. To access a past message, drag the Information screen down from the top of the display and tap the message. Event data is retained even if power to the diabetes manager is interrupted (for example, when changing the battery).

If you are unsure whether the micropump system is working properly, switch to alternative therapies according to the instructions given by your healthcare professional and check the system functions. If the problem cannot be resolved using the suggested solutions, contact customer support.

NOTE

- If the micropump signals a maintenance or error message and you do not have the diabetes manager at hand, you can mute the message for 5 minutes using the quick bolus buttons on the micropump. Note that you cannot use the quick bolus buttons to deliver a

quick bolus before you have muted the message.

- If the micropump issues the Error sound and the diabetes manager does **not** display any error messages even though the diabetes manager and micropump are in communication range, the micropump might have turned off due to an electronic defect (E-7).

15.1 Information

Information messages inform you about a particular state or event.

Confirm the information messages with OK or, if it is a question, answer it with Yes or No.

Examples of information messages:

1	Information on the micropump Information on the diabetes manager
2	Title of information message
3	Information message symbol
4	Information or explanation
5	Buttons (OK, No, Yes)

15.2 Warnings

Warnings inform you about relevant technical states of the micropump system or about possible risks for your therapy or health. Warnings signalise an imminent maintenance message. You are thus notified at an early stage that you will have to intervene in the short term to ensure the complete functionality of the micropump system.

When a warning is displayed, the diabetes manager issues the Warning sound and vibrates.

Examples of warnings:

1	Warning code
2	Warning refers to the micropump Warning refers to the diabetes manager
3	Title of warning
4	Warning symbol
5	Explanation of warning or corrective measure
6	Button for confirming the warning (OK)

Code	Title of warning	Information/possible cause	Information/possible solution
Warnings triggered by the micropump.			
W-25	Running time of the pump will end soon	The period of use of the pump base will end soon.	Ensure that you have a new pump base at hand as a replacement. Replace the pump base after the remaining time that is displayed.
W-31	Low level of insulin in the reservoir	There is only a small amount of insulin in the reservoir.	Be prepared to replace the reservoir soon.
W-32	Battery almost empty	The battery level is low.	Replace the reservoir.
W-35	Limited battery power	The opening that is intended for battery ventilation is covered; this means that the energy supplied by the battery is restricted.	Make sure that there is an unrestricted air supply to the opening for ventilation on the micropump.
W-36	TBR canceled	An active temporary basal rate was canceled.	Make sure that the cancellation was intentional. Program a new temporary basal rate if required.
W-37	Low amount delivered	The micropump cannot deliver the insulin amount that is programmed for the basal rate or bolus in the specified time.	At present, the micropump cannot deliver a programmed insulin amount within the time specified. Check whether the delivered insulin amounts are sufficient for your insulin needs. Test your blood glucose at shorter intervals.
W-38	Bolus canceled	An ongoing bolus was canceled.	Make sure that the cancellation was intentional. Note the insulin amount already delivered, and program a new bolus if necessary.

Code	Title of warning	Information/possible cause	Information/possible solution
W-40	Replace reservoir	The operating life of the reservoir will soon come to an end.	Replace the reservoir as soon as possible.
W-41	Micropump stopped	The micropump has been in STOP mode for at least an hour and is not delivering any insulin.	Start the micropump if you want to continue with insulin delivery.
Warnings triggered by the diabetes manager.			
W-50	Battery almost empty	The rechargeable battery level is low.	Recharge the battery of your diabetes manager.
W-71	Connection interrupted	No current data from the micropump is available. The data for calculating the bolus advice may not be up to date.	Ensure that the micropump and diabetes manager are no more than 2 metres apart and that there are no obstacles between them.
W-73	No connection to the micropump	No current data from the micropump is available. The data for calculating the bolus advice may not be up to date.	The data is updated when the connection between the diabetes manager and the micropump is re-established.
W-75	Warning limit exceeded	High glucose value	Test ketones and your blood glucose. Check the insulin delivery. Follow the instructions of your healthcare professional.
W-76	HI screen	Your glucose value may be very high.	Test ketones and your blood glucose. Check the insulin delivery. Follow the instructions of your healthcare professional.

Code	Title of warning	Information/possible cause	Information/possible solution
W-80	Hypoglycaemia	Blood glucose has fallen below the hypo warning limit.	Eat or drink fast-acting carbohydrates. Then test your blood glucose. If hypoglycaemia persists, consult your healthcare professional.
W-81	LO screen	Your glucose value may be very low.	Eat or drink fast-acting carbohydrates. Test your blood glucose again and then again within the next half hour. If hypoglycaemia persists, consult your healthcare professional.
W-84	Testing not possible	You cannot test your blood glucose while the diabetes manager is connected to a USB cable.	Remove the USB cable from the diabetes manager.
W-85	Bolus data missing	A problem was encountered when determining active insulin. The current value may not be correct.	No action required. Consider that insulin from a previous bolus may still be active in your body. The message may reoccur for up to 9 hours. After that active insulin should automatically be displayed correctly.

Code	Title of warning	Information/possible cause	Information/possible solution
W-86	Airplane mode on	Data cannot be synchronised between the diabetes manager and the micropump because airplane mode is turned on. Therefore, the entries saved for the bolus advice may not be up to date. The diabetes manager can currently only give bolus advice based on the entries saved in the diabetes manager.	You can still use the bolus advice feature. Note, however, that the diabetes manager is not receiving any information (for example, errors) from the micropump. When airplane mode is turned off and the diabetes manager and micropump are within communication range, the data will be synchronised. The data for bolus advice will then be up to date again.
W-88	Airplane mode on	The saved logbook entries may not be up to date.	When airplane mode is turned off and the diabetes manager and micropump are within communication range, the logbook entries will be synchronised.
W-89	Check logbook entries	It was not possible to assign a bolus delivered by the micropump to a bolus confirmed in the bolus advice function.	Correct the logbook entries as required.
W-90	Time synchronised with micropump	The time difference between the diabetes manager and the micropump was corrected.	Check the time on the diabetes manager.

Code	Title of warning	Information/possible cause	Information/possible solution
W-92	TBR without insulin delivery	Due to the set TBR, the amount to be delivered in the current time block is so low that it falls below the smallest delivery amount the pump can technically deliver.	Check whether it is acceptable for you for no insulin to be delivered in this time period. The insulin amount that was not delivered will be delivered later on during the next time blocks.

15.3 Maintenance Messages

Maintenance messages inform you about a temporary loss of certain features of the micropump system. Maintenance messages require you to intervene in order to solve the problem. Once the cause of the maintenance message has been eliminated, you can use all features of the micropump system again.

When a maintenance message is displayed, the diabetes manager issues a Maintenance sound and vibrates. This sound is also issued when the Mute warnings and reminders feature is turned on.

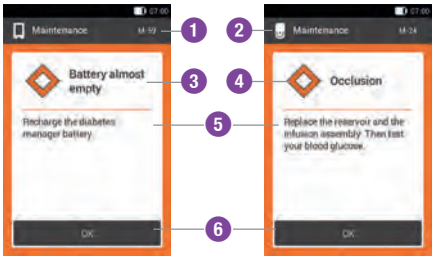
⚠ WARNING

Risk of hyperglycaemia (high blood glucose level)

If the Occlusion message M-24 is displayed, the micropump changes to STOP mode. The occlusion may cause insulin delivery to be impaired or not work at all. This can lead to hyperglycaemia.

Replace the reservoir and the infusion assembly. Then test your blood glucose. If the message is displayed repeatedly, contact customer support.

Examples of maintenance messages:



1	Code of maintenance message
2	Maintenance activity refers to the micropump Maintenance activity refers to the diabetes manager
3	Title of maintenance message
4	Maintenance symbol
5	Explanation of maintenance message or corrective measure
6	Button to confirm (OK) the maintenance message

Code	Title of maintenance message	Possible cause/ consequences	Further information
Maintenance messages triggered by the micropump.			
M-18	Replace micropump	The operating life of your micropump has come to an end.	Select the Replace menu and replace the pump base and the reservoir now.
M-19	Discrepancy in reservoir level	The entered insulin amount does not correspond to the measured reservoir level.	Replace the reservoir, if required, with a new reservoir.
M-21	Reservoir empty	The insulin in the reservoir has been used up.	Select Replace and replace the reservoir.
M-22	Micropump battery empty	The micropump battery, which is located in the reservoir, is empty.	Select Replace and replace the reservoir.
M-23	Automatic off	The automatic off feature has stopped insulin delivery. The micropump is in STOP mode.	Start the micropump to resume insulin delivery.
M-24	Occlusion	An occlusion was detected which means that insulin delivery is not working at all or is restricted.	Replace the reservoir and the infusion assembly. Then test your blood glucose. If the message is displayed repeatedly, contact customer support.
M-26	Fill reservoir needle	The reservoir needle must be refilled after replacing the reservoir.	Remove the micropump from the infusion assembly. Select Replace and replace the reservoir. After that, follow the instructions for filling the reservoir.

Code	Title of maintenance message	Possible cause/ consequences	Further information
M-27	No data connection	The micropump system setup was interrupted.	Hold the diabetes manager close to the micropump to ensure that data is exchanged between the pump and the diabetes manager. Resume setting up the micropump system when the connection has been re-established. If the message is displayed repeatedly, replace the pump base.
Maintenance messages triggered by the diabetes manager.			
M-51	Test strip error	The test strip is used, damaged or not completely inserted into the test strip slot.	Use a new test strip or re-insert the test strip into the test strip slot.
M-53	Test failed	The blood glucose test did not work properly.	Repeat the blood glucose test with a new test strip.
M-54	Drop too small	The amount of blood or control solution is not sufficient to perform a test.	Repeat the test with a new test strip. Make sure the blood drop or drop of control solution is large enough.
M-56	Drop applied too early	The drop was drawn into the test strip before the Apply drop screen appeared.	Repeat the test with a new test strip and a fresh blood drop or drop of control solution.
M-58	Temperature too high or too low	The ambient temperature for testing blood glucose or performing a control test is outside the permitted range.	Make sure the ambient temperature is within the permitted range. Wait 5 minutes before testing your blood glucose again or performing a control test.

Code	Title of maintenance message	Possible cause/ consequences	Further information
M-59	Battery almost empty	The level of the rechargeable battery is very low.	The diabetes manager automatically deactivates communication via *Bluetooth* wireless technology to save power. As a result, communication with the micropump is interrupted. Recharge the battery of your diabetes manager.
M-60	Clock error	A discrepancy in the internal clocks of the micropump system was detected.	Set the current time and the current date on the diabetes manager.
M-62	Pairing failed	The pairing code was not scanned successfully. This may be the case, for example, if it is too dark or if the code or camera lens is dirty and the code cannot be read correctly.	Clean lens and try rescanning the pairing code on the micropump. Alternatively, you can enter the pump key manually.
M-64	Bolus delivery not possible	The connection between the diabetes manager and micropump was lost.	Hold the diabetes manager close to the micropump and ensure that data communication is not disrupted. You can deliver a quick bolus straight from the micropump.
M-65	Bolus delivery not possible	The micropump is in STOP mode.	If you want to deliver a bolus, start the micropump first.

Code	Title of maintenance message	Possible cause/ consequences	Further information
M-67	Bolus delivery failed	There is no connection to the micropump.	Hold the diabetes manager close to the micropump. You can deliver a quick bolus straight from the micropump.
M-77	Operation failed	The requested operation failed.	Try again or contact customer support.
M-78	Outside of temperature range	The temperature of the diabetes manager is too high or too low.	Make sure the ambient temperature is within the permitted range. Wait 5 minutes until the diabetes manager has adapted itself to this temperature.
M-85	Micropump incompatible	You tried to pair the diabetes manager with a pump base that is incompatible.	Contact customer support.
M-86	Micropump not started	The micropump cannot be started because ongoing processes have not finished yet.	Check whether you need to react to prior error messages or maintenance messages. Example: The prior message was Reservoir empty (M-21). Only after replacing the reservoir, will you be able to start the micropump.
M-87	Micropump not stopped	The micropump cannot be stopped.	Try to stop the micropump again. If the pump does not stop, remove the micropump from your body, switch to an alternative therapy method and contact customer support.

Code	Title of maintenance message	Possible cause/ consequences	Further information
M-94	Operation failed	There is a communication problem between the micropump and the diabetes manager.	Press the quick bolus buttons to check if the micropump is still working. If no acoustic signal is heard, replace the reservoir. If no sound is heard even after changing the reservoir, replace the pump base. Keep the diabetes manager and the micropump close together to ensure *Bluetooth* communication.
M-95	No micropump located	A connection to the micropump could not be established.	Check whether the micropump is too far away and restart the locating process.
M-96	USB connection failed	The USB connection between the diabetes manager and the software on the computer failed.	Check whether the software is correctly installed on the computer.

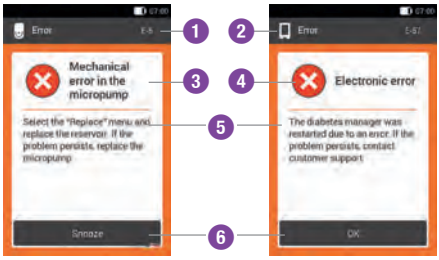
15.4 Error Messages

Error messages inform you about important malfunctions of the micropump system. The micropump switches to STOP mode and does not deliver any insulin. Once the cause of the error message has been eliminated, you can use all features of the micropump system again.

When an error message is displayed, the diabetes manager issues the Error sound and vibrates. This sound is also issued when the Mute warnings and reminders feature is turned on. The vibration feature cannot be turned off.

For most problems, the diabetes manager displays a message with a short description of the problem and a proposed solution. If the problem cannot be resolved using the suggested solutions, switch to alternative therapy methods and contact customer support.

Examples of error messages:



1	Code of error message
2	Error refers to the micropump Error refers to the diabetes manager
3	Title of error message
4	Error symbol
5	Explanation of error message
6	Button to confirm (OK) or postpone the error message (Snooze)

Code	Title of error	Possible cause/ consequences	Possible solutions
Error messages triggered by the micropump.			
E-6	Mechanical error in the micropump	The micropump switches to STOP mode and does not deliver any insulin.	Select Replace and replace the reservoir. If the problem persists, replace the micropump.
E-7	Electronic error	Communication between the micropump and diabetes manager is not possible. The micropump switches to STOP mode and does not deliver any insulin.	Select Replace and replace the reservoir. Wait at least 30 seconds after removing the used reservoir before connecting a new reservoir to the pump base. If the problem persists, replace the micropump.
E-8	Micropump battery error	The energy supply is defective. The micropump switches to STOP mode and does not deliver any insulin. After 10 seconds the pump turns off.	Select Replace and replace the reservoir.
Error messages triggered by the diabetes manager.			
E-57	Electronic error	The diabetes manager was restarted due to an electronic error.	If the problem recurs, contact customer support.

15.5 General Troubleshooting

This chapter deals with general error situations that do not necessarily result in a message on the micropump system.

If the problem cannot be resolved using the suggested solutions, contact customer support.

Problem	Possible cause	Possible solutions
The screen is blank or the diabetes manager cannot be turned on.	The level of the rechargeable battery is low.	Recharge the battery.
	The rechargeable battery may be damaged.	Replace the rechargeable battery if the diabetes manager cannot be charged.
	An electronic error has occurred in the diabetes manager.	Reset the diabetes manager by pressing and holding the power button for at least 5 seconds.
	The ambient temperature is higher or lower than the operating temperature recommended for the diabetes manager.	Move the diabetes manager to an area with the suitable temperature. Wait 5 minutes before turning on the diabetes manager. Do not heat or cool the diabetes manager using any aids.
	The display is damaged or the diabetes manager is defective.	Contact customer support.
The battery is not being charged while the diabetes manager is connected to a PC via a USB cable.	The USB port on the PC is not supplying any charging current.	Recharge the battery with a charger using a wall socket.
The screen freezes or does not respond.	An electronic error has occurred in the diabetes manager.	Reset the diabetes manager by pressing and holding the power button for at least 5 seconds until the display turns off.
		Remove the rechargeable battery from the diabetes manager and reinsert it.

Problem	Possible cause	Possible solutions
The display is defective or the colours are not represented correctly.	The display is damaged or the diabetes manager is defective.	Perform the system function test for the diabetes manager display. If the system function test of the display shows a problem, contact customer support.
The sound is faulty. You cannot hear the sounds.	The feature Mute warnings and reminders is activated or the volume is set too low.	Check whether the Mute warnings and reminders option is turned on.
		Check whether the sound modes (Normal, Vibration, Quiet, Loud) have sound activated and whether the volume is set to a level that is audible.
	The speakers are damaged or the diabetes manager is defective.	Perform the system function test for the diabetes manager. If the system function test shows a problem with the signals and sounds of the diabetes manager or micropump, contact customer support.
The start time for the first time block cannot be changed.	Initial setup is already complete and, therefore, the start time for the first time block cannot be changed any more.	To change the start time for the first time block, select the Reset option on the Time blocks screen. After resetting the time blocks, you have to re-enter all time block settings.
You cannot feel any vibrations from the diabetes manager.	The active sound mode does not include a vibration signal.	Check the settings on the Tone and vibration screen. The diabetes manager only vibrates if the active sound mode (Normal, Vibration, Quiet, Loud) includes vibration.
	The vibration feature is turned off.	Check the touchscreen feedback settings (Tone, Vibration, Tone and vibr., Off).
The occlusion message of the micropump was triggered.	The micropump was exposed to a temperature that was too low.	Make sure the ambient temperature is suitable. Replace the reservoir and the infusion assembly. Then test your blood glucose. If the message is displayed repeatedly, contact customer support.

Problem	Possible cause	Possible solutions
The micropump does not issue a message and the diabetes manager displays ⊘ even though the diabetes manager and micropump are within communication range.	The airplane mode is turned on.	Turn off airplane mode on the diabetes manager.
	The micropump was turned off by the automatic off feature.	Check the settings for the automatic off feature.
	The micropump turned off without prior notice due to an electronic defect. The micropump is not working.	Check whether the micropump is turned off. To do this, with the quick bolus feature activated, press and hold both quick bolus buttons simultaneously for approximately 3 seconds. ■ If you hear the sound for the quick bolus, wait 5 seconds without pressing the quick bolus buttons in order to cancel the quick bolus. ■ If you do **not** hear the sound for the quick bolus, replace the reservoir. If you still do not hear the sound for the quick bolus replace the pump base.
	The micropump and diabetes manager are no longer paired.	Check that the serial number of the micropump is entered in the System information screen. To do this, tap on Settings -> System information -> Micropump serial number. If the serial number is not shown there, proceed as follows: 1. Turn off the diabetes manager completely. Then turn the diabetes manager back on. 2. Pair the new pump base with the diabetes manager. If the pairing of the new pump base fails, contact customer support.

Problem	Possible cause	Possible solutions
The micropump does not react and cannot be controlled with the diabetes manager.	Connection between diabetes manager and micropump is disturbed.	1. Remove the reservoir from the pump base for at least 20 seconds. 2. Turn off the diabetes manager completely. Then turn the diabetes manager back on. 3. Check that the serial number of the micropump is entered in the System information screen. To do this, tap on Settings -> System information -> Micropump serial number. a) If the serial number is shown there, proceed as follows: Connect the reservoir back on the pump base and wait until pump emits the Start sound. If the connection is not established again, replace the pump base. b) If the serial number is not shown there, proceed as follows: Replace the pump base. 4. Ensure that the micropump and diabetes manager are no more than 2 metres apart and that there are no obstacles between them.
The micropump issues the Error sound and the diabetes manager displays even though the diabetes manager and micropump are within communication range.	The micropump turned off due to an electronic defect (E-7).	Select Replace and replace the reservoir. Wait at least 30 seconds after removing the used reservoir before connecting a new reservoir to the pump base. If the problem persists, replace the micropump.

Problem	Possible cause	Possible solutions
During bolus or basal rate delivery, the displayed reservoir level on the Status screen jumps to 48 U and then continues to decrease.	The set reservoir fill amount deviates from the actually filled amount. The set value during reservoir replacement was **too high**. The micropump has detected the actual fill level and set the reservoir remaining amount automatically.	Make sure, when filling and replacing the reservoir, to set the reservoir fill amount as accurate as possible to the number of insulin units you filled the reservoir. See chapter *4.2.3 Connecting the Reservoir to the Pump Base* and chapter *9.3 Replacing the Reservoir*.
During bolus or basal rate delivery, the displayed reservoir level on the Status screen freezes at 49 U and continues later to decrease.	The set reservoir fill amount deviates from the actually filled amount. The set value during reservoir replacement was **too low**. The micropump has detected the actual fill level and set the reservoir remaining amount automatically.	
Insulin delivery is interrupted or insufficient.	The micropump is no longer properly attached to the pump holder.	Ensure that the micropump is properly attached to the pump holder. For more information see chapter *4.2.6 Attaching the Micropump*.
	The infusion assembly has come detached from the infusion site or is loose.	If the infusion assembly is no longer properly attached to the skin, replace the infusion assembly. For more information see chapter *4.2.1 Attaching the Infusion Assembly to the Body*.

16 Technical Data

16.1 Micropump System

Permitted insulin types
U100 insulins:
Humalog®, NovoLog®, NovoRapid®, Apidra®, Insuman® Infusat, Fiasp®.

Electromagnetic compatibility
The micropump system meets the EMC requirements for home healthcare environments in accordance with IEC 60601-1-2.

Electromagnetic emission
Classified in accordance with CISPR 11, group 1, class B (residential).

Safety
The safety concept is based on a control system that consists of two microprocessors and a supervisor microprocessor (supervising system). The control system has a dual channel software architecture that performs all safety-relevant functions twice. Whenever a defect or fault occurs in the control system, it is identified by the supervisor microprocessor and vice versa. The control and supervising systems signalise errors by means of sounds and messages on the diabetes manager display.

Communication between micropump and diabetes manager
Bluetooth Low Energy (BLE) wireless technology

Transmission frequency
2402–2480 MHz

Transmission power
1 mW / 0 dBm
Channels: 37*FHSS + 3*DSSS advertising channels
Modulation: GFSK
Bandwidth: 1 MHz “single hop frequency”

Communication range
2 m (the range may be impaired by obstacles)

16.2 Diabetes Manager

Device type
Accu-Chek Guide Solo diabetes manager
The Accu-Chek Guide Solo diabetes manager is suitable for continuous operation.

Expected Service Life
4 years

Access control
PIN-based protection

Dimensions
124 × 64 × 17 mm (L × W × H)

Weight
140 g

Signal reproduction
Graphical user interface, status LED, speakers, vibration alarm

Display
Capacitive colour LCD multi-touch screen with backlight

Display size
3.5"

Display resolution
320 × 480 pixels

Display timeout
After 2 minutes of no activity

Camera
2 megapixels for scanning the pairing code (2D data matrix code) at a minimum of 300 lx up to a maximum of 20,000 lx.

Admissible temperature range
Storage and transport, with packaging: -20 °C to +50 °C
During operation: +5 °C to +40 °C
Storage between periods of use: -25 °C to +70 °C
Cooling-down time from maximum storage temperature between periods of use to operating temperature, at an ambient temperature of 20 °C: 15 minutes [1]
Warming-up time from minimum storage temperature between periods of use to operating temperature, at an ambient temperature of 20 °C: 15 minutes [1]

Admissible humidity range
Storage and transport, with packaging: 5 % to 85 %
During operation: 15 % to 90 % [2]

Atmospheric pressure
Storage and transport, with packaging: 54.9 kPa to 106 kPa (549 mbar to 1060 mbar)
During operation: 70 kPa to 106 kPa (700 mbar to 1060 mbar)
During charging: 80 kPa to 106 kPa (800 mbar to 1060 mbar)
Storage between periods of use: 54.9 kPa to 106 kPa (549 mbar to 1060 mbar)

Operating height
Up to 3,000 m above sea level (diabetes manager)
Up to 2,000 m above sea level (charger)

Signal types
Visual, acoustic, vibration

Sound pressure level of the sound
≥ 45 dBA at a distance of 1 m

Frequency of the signals
1–3 kHz

Interface to PC
USB 2.0 (micro-B)

Memory capacity
5,000 blood glucose tests, 5,000 logbook entries, 5,000 pump events

Power supply
Rechargeable lithium polymer battery
Model: Nugen

Battery voltage
3.7 V

Battery capacity
1,530 mAh / 1,590 mAh

Charging voltage via USB
5 V

[1] according to IEC 60601-1-11:2015

[2] but not requiring a water vapor partial pressure greater than 50 hPa

Max. charging current
700 mA

USB charger
Technics switch-mode power supply, model TS051X110-0502R / Lucent Trans Electronics Wall Charger, 5V1A level VI / USB

IP rating
IP20

Bolus calculator
Accu-Chek Bolus Advisor

Test strip slot
Illuminated test strip slot for the Accu-Chek Guide test strips

Measuring range
0.6–33.3 mmol/L

Test principle
Refer to the test strip package insert

Test time
Refer to the test strip package insert

Blood sample
Refer to the test strip package insert

Sample type
Refer to the test strip package insert

16.3 Micropump

Dimensions
Approx. 63 × 39 × 14 mm

Weight
Micropump with filled reservoir < 29 g

Pump casing
Impact and scratch-resistant plastic (polycarbonate)

Quick bolus buttons
Silicone buttons for delivering quick boluses, turning airplane mode on/off and muting messages temporarily

Admissible temperature range [3]
Storage and transport, with packaging (pump base): -20 °C to +50 °C
Storage and transport, with packaging (reservoir): +10 °C to +30 °C
During operation and storage between uses: +5 °C to +40 °C
Cooling-down time from maximum storage temperature between periods of use to operating temperature, at an ambient temperature of 20 °C: 10 minutes [4]
Warming-up time from minimum storage temperature between periods of use to operating temperature, at an ambient temperature of 20 °C: 10 minutes [4]

Admissible humidity range
Storage and transport, with packaging (pump base): 5 % to 85 %
Storage and transport, with packaging (reservoir): 20 % to 80 %
During operation and storage between uses: 15 % to 90 % [5]

[3] For information on the admissible temperature range for usage, storage and transport of the insulin used, see the instructions for use of the insulin manufacturer.

[4] according to IEC 60601-1-11:2015

[5] but not requiring a water vapour partial pressure greater than 50 hPa

Atmospheric pressure
Storage and transport, with packaging: 54.9 kPa to 106 kPa (549 mbar to 1060 mbar)
During operation: 70 kPa to 106 kPa (700 mbar to 1060 mbar)
Storage between periods of use: 54.9 kPa to 106 kPa (549 mbar to 1060 mbar)

Motor type
Stepper motor

Power supply
1.4 V zinc-air battery for internal power supply

Life expectancy of the battery
If used in a typical usage pattern (50 U/day using U100 insulin; room temperature: 23 °C ± 2 °C), life expectancy of the battery is up to 4 days.

Basal rate
Minimum: 0.1 U/h
Maximum: 25.0 U/h

Basal rate delivery accuracy
± 16 % or better at 0.1 U/h
± 5 % or better at 1.0 U/h

Basal rate, increments
0.1 U/h up to under 5.0 U/h: increments of 0.01 U/h
5.0 U/h up to under 25.0 U/h: increments of 0.1 U/h

Basal rate profiles
Up to 5 customised profiles

Temporary Basal Rate (TBR)
0–90 % for basal rate reductions and 110–250 % for basal rate increases in increments of 10 %
The duration is adjustable in 15-minute increments for a time period of up to 24 hours. Up to 5 individual TBRs can be programmed.

Bolus types
Standard bolus, quick bolus, extended bolus, multiwave bolus

Bolus amount
Minimum: 0.2 U
Maximum: 50 U

Bolus delivery accuracy [6]
± 30 % or better at 0.2 U up to < 1.0 U
± 5 % or better at 1.0 U up to 50.0 U

Bolus amount, increments
0.2 U up to under 5.0 U: increments of 0.1 U
5.0 U up to under 10.0 U: increments of 0.2 U
10.0 U up to under 20.0 U: increments of 0.5 U
20.0 U up to 50.0 U: increments of 1.0 U
The duration of an extended bolus or a multiwave bolus is adjustable in 15-minute increments for a time period of up to 24 hours.

Delivery lag time
Adjustable in 15-minute increments from 0 to 60 minutes

Quick bolus increment
0.2 U / 0.5 U / 1.0 U and 2.0 U

[6] tested per IEC 60601-2-24

Delivery speed
Boluses: 1.0–2.5 U/min.
Filling the reservoir needle: 1.0–2.5 U/min.

Sound pressure level of the sound
≥ 45 dBA at a distance of 1 m

Sound output
Main buzzer and backup buzzer

Occlusion detection
Rotation detector

Maximum amount of time until occlusion message M-24
50 hours at a basal rate of 0.1 U/h
5 hours at a basal rate of 1 U/h

Maximum insulin amount until occlusion message M-24
5.0 U

Maximum pressure
150 kPa (1.5 bar)

Reservoir fill amount
Maximum: 200 U
Minimum: 80 U

Maximum overdelivery in the event of an error
0.4 U

IP rating
IP22

16.4 Infusion Assembly

Pump holder
Dimensions: Approx. 67 × 32 × 6.5 mm

Adhesive pad
Dimensions: Approx. 85 × 52 mm

Cannula
Orange: 6 mm, soft catheter, 90° insertion angle
Blue: 9 mm, soft catheter, 90° insertion angle

Cannula fill amount
0.18 U

Maximum period of use
up to 3 days

Sterility
Sterilised using ethylene oxide for single use according to EN ISO 11135

16.5 Insertion Device

Dimensions
82 × 53 × 49 mm

Weight
85 g

Period of use
4 years
You can program a reminder in the diabetes manager to remind you to replace the insertion device before the end of the period of use.

16.6 Delivery Rate Accuracy

It is the responsibility of the healthcare professional to decide whether the accuracy of the delivery rate is adequate for the patient in question. The delivery accuracy

does not depend on the length of the cannula used.

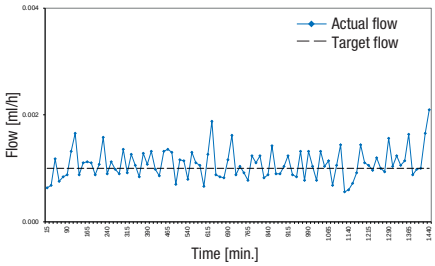
The measurements were carried out according to IEC 60601-2-24 under the following conditions:

Description	Value	Unit
Temperature	21 ± 6	°C
Relative humidity	50 ± 30	%
Atmospheric pressure	1013 ± 50	hPa

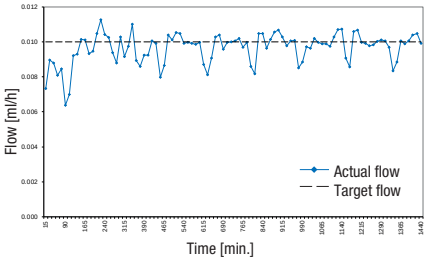
16.6.1 Startup Chart

The startup chart shows changes in the delivery rate over the stabilisation period.

0.1 U/h, 6 mm cannula



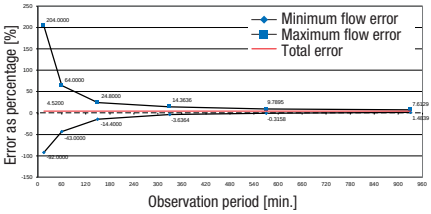
1 U/h, 9 mm cannula



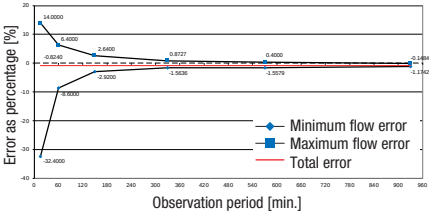
16.6.2 Trumpet Curve

The trumpet curve shows the delivery rate accuracy during the observation period.

0.1 U/h, 6 mm cannula



1 U/h, 9 mm cannula



16.7 Electromagnetic Compatibility (EMC)

Essential Performance

The Accu-Chek® Solo micropump system maintains the following conditions during its expected lifetime:

- The system will not over deliver or under deliver a clinically significant amount of insulin.
- Correct communication between the diabetes manager and the micropump.
- Correct functionality of the bolus advice feature.
- Correct functionality of the integrated blood glucose meter.
- Data integrity during data transfer via USB Interface.

Wireless Communication

The Accu-Chek Solo micropump system uses *Bluetooth* Low Energy (*Bluetooth* LE) wireless technology to securely exchange data between the micropump and the diabetes manager. *Bluetooth* LE is operating in the 2.4 GHz ISM frequency band.

Data Security

The micropump is designed to only accept *Bluetooth* LE commands from the diabetes manager after successful out of band bonding. “Out of band bonding” means to set up a secure authenticated connection between the two devices. The two devices ensure data confidentiality via encryption and data integrity using error checking processes, such as end-to-end counters and end-to-end cyclic redundancy checks.

Wireless Quality of Service and Coexistence

The Accu-Chek Solo micropump system is designed to work safely and effectively in the presence of nearby wireless devices typically found at home, work, retail shops, and places of leisure where daily activities occur, and will not affect their performance. To improve quality of service when other devices operating in the 2.4 GHz band are around, the system uses the built-in coexistence features provided by *Bluetooth* LE. However, as with all wireless communication technologies, availability of communication cannot be ensured and certain operating conditions can interrupt communication. For example, electric appliances such as microwave ovens and electric machinery located in manufacturing environments may cause interference. This interference does not cause any incorrect data to be sent and does not cause any harm to your devices. Moving away from, or turning off, these other devices may enable communication.

In the case of an interrupted wireless communication:

- The micropump continues the preprogrammed basal rate delivery, ongoing bolus, ongoing TBR and allows the user to deliver a bolus on demand via the quick bolus buttons.
- The micropump stores in a non-volatile memory all therapy-relevant actions, warnings and errors. After re-establishing the wireless communication, the diabetes manager is able to access all data from the memory of the micropump.

- The diabetes manager detects when the data exchange with the micropump is not possible and notifies the user accordingly.

EMC Separation Distances

The Accu-Chek Solo micropump system is intended for use in an electromagnetic environment typically found in the home, at work, retail stores, and places of leisure, where daily activities occur.

The Accu-Chek Solo micropump system meets the EMC requirements for home healthcare environments in accordance with IEC 60601-1-2.

⚠ WARNING

Portable RF communications equipment should be used no closer than 30 cm to any part of the Accu-Chek Solo micropump system. Otherwise, degradation of the performance of this equipment could result.

⚠ WARNING

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Precautions regarding electromagnetic compatibility:
On airfields your Accu-Chek Solo micropump system may be exposed to strong radar radiation. To avoid possible interferences of radar with your insulin pump, we recommend switching off the *Bluetooth* function on your Accu-Chek Solo micropump system during boarding, deboarding, in aircrafts on airfields, or in aircrafts approaching airfields.

Electromagnetic Emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
The Accu-Chek Solo micropump system is intended for use in the electromagnetic environment specified below. Always make sure that the system is used in such an environment. Requirements that are specified in IEC 60601-1-2 that are not applicable to the Accu-Chek Solo micropump system are not mentioned in the table below.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Accu-Chek Solo micropump system must emit electromagnetic energy in order to perform its intended function. In rare cases, nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	The Accu-Chek Solo micropump system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The Accu-Chek Solo micropump system is intended for use in the electromagnetic environment specified below. Always make sure that the system is used in such an environment. Requirements that are specified in IEC 60601-1-2 that are not applicable to the Accu-Chek Solo micropump system are not mentioned in the table below.			
Immunity test standard	**Test level/conditions**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.

Immunity test standard	Test level/conditions	Compliance level	Electromagnetic environment - guidance
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	
Radiated RF IEC 61000-4-3	3 V/m 2.7 to 6 GHz	3 V/m 2.7 to 6 GHz	
Power frequency (50/69 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	
Power frequency (50/69 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	
Radiated RF electromagnetic field AIM Standard 7351731, table 3	65 A/m@0.1342 MHz, 7.5 A/m@13.567 MHz, 7.5 A/m@13.567 MHz, 5 A/m@13.56 MHz, 12 A/m@13.56 MHz, 3 V/m@433 MHz, 54 V/m@860 to 960 MHz, 54 V/m@2450 MHz	65 A/m@0.1342 MHz, 7.5 A/m@13.567 MHz, 7.5 A/m@13.567 MHz, 5 A/m@13.56 MHz, 12 A/m@13.56 MHz, 3 V/m@433 MHz, 54 V/m@860 to 960 MHz, 54 V/m@2450 MHz	
Conducted disturbance IEC 61000-4-6*	3V; 150 kHz - 80 MHz	3V; 150 kHz - 80 MHz	
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11*	0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	

* applicable to diabetes manager only

Table 9 of IEC 60601-1-2 was performed to evaluate immunity from other wireless devices such as terrestrial trunked radio, GMRS, LTE, cell phone (GDM 800/900 and 1,800 MHz), *Bluetooth*, Wi-Fi.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Accu-Chek Solo micropump system is used exceeds the applicable RF compliance level above, the Accu-Chek Solo micropump system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Accu-Chek Solo micropump system.

17 Symbols, Abbreviations, Sounds

17.1 Symbols

The following symbols appear on the packaging and on the micropump system components:

Symbol	Meaning
	Consult instructions for use or consult electronic instructions for use
	Caution, refer to safety-related notes in the instructions for use accompanying this product.
	Follow instructions for use
	Temperature limit
	Use only once
	Use by
	Sterilised using ethylene oxide
	Manufacturer
	Date of manufacture
	Catalogue number
	Batch code

Symbol	Meaning
	Serial number
	Medical device
	Single patient multiple use
	Unique device identifier
	Single sterile barrier system
	Complies with the provisions of the applicable EU Legislation
FCC ID	The FCC ID (Federal Communications Commission Identification) indicates that the radio frequency equipment has passed the equipment authorization process for the United States of America.
	This equipment is not entitled to protection against harmful interference and may not cause interference in duly authorised systems.
	Registry of telecommunication activities and materials; radio frequency logotype for Argentina
	Keep away from sunlight

Symbol	Meaning
	Keep dry
	Do not use if package is damaged and consult instructions for use
	Humidity limitation
	Atmospheric pressure limitation
	Do not throw away
	*Bluetooth*® wireless technology
	Biological risks
	Electronic device of type BF according to the standard IEC 60601-1. Protection against electrical shock.*
Rx only	Federal law (USA) restricts this device to sale by or on the order of a physician
IP20	Device is protected against access to hazardous parts with a finger.
IP22	Device is protected against access to hazardous parts with a finger and protected against the effects of dripping water when the casing is tilted at an angle of up to 15°.

Symbol	Meaning
	Non-ionizing radiation
	Warning against device use in electromagnetic or high electrical fields or environments
	Device of protection class II
	Suitable for indoor use only

* The micropump is an applied part BF. The diabetes manager is not an applied part.

17.2 Abbreviations

Abbreviation	Meaning
am	Ante meridiem: Before midday (12-hour clock notation for times before 12 noon)
BE	Broteinheit (bread equivalent)
BG	Blood Glucose
°C	Degrees Celsius (or Centigrade)
CC	Carbohydrate Choice
°F	Degrees Fahrenheit
FCC	Federal Communications Commission (United States)
g	Gram
h	Hour(s)
IEC	International Electrotechnical Commission
ISO	International Organisation for Standardization
KE	Kohlenhydrateinheit (carbohydrate unit)
LCD	Liquid Crystal Display
mg/dL	Milligrams per deciliter
min.	Minutes
mmol/L	Millimoles per liter
kPa	Kilopascal
PC	Personal Computer
PIN	Personal Identification Number (secret code)
pm	Post meridiem: After midday (12-hour clock notation for times after 12 noon)
SD	Standard Deviation
sec.	Seconds
TBR	Temporary Basal Rate
U	Unit (*International Unit*, also *IU*) Unit of measurement for the amount of a biologically active substance, for example insulin, referring to the biological activity.
U/h	Insulin amount delivered in units per hour
U100	Insulin concentration. Each milliliter of liquid contains 100 units of insulin.
USB	Universal Serial Bus

17.3 Sounds

Both the diabetes manager and the micropump can issue sounds.

The diabetes manager can issue the following sounds:

Designation	Occurrence
Start	Turning on the diabetes manager
Error	Issuing error messages
Maintenance	Issuing maintenance messages
Warning	Issuing warnings
Connect USB	Establishing a USB connection between the diabetes manager and a PC
Disconnect USB	Disconnecting the USB connection between the diabetes manager and a PC

17 SYMBOLS, ABBREVIATIONS, SOUNDS

The micropump can issue the following sounds:

Designation	Occurrence	Tone sequence
Start	Plugging together pump base and reservoir	5 short, ascending tones
Quick bolus	Start of programming a quick bolus	7 short, ascending tones
Quick bolus increment	Acoustic feedback for every programmed quick bolus increment	A long, deep tone
Execute	Start of the quick bolus delivery End of insulin delivery	5 long, ascending tones. The last tone is longer.
Cancel	Timeout while programming a quick bolus Programming of a quick bolus not possible Stopping the micropump	4 short tones alternating high/low, followed by 1 pause and 1 long tone
Maintenance Error	Issuing error messages Issuing maintenance messages Energy storage after battery error	3 short tones followed by 1 pause and 1 high tone. The sequence of tones is repeated every 5 seconds.
Warning	Issuing warnings	1 long tone followed by 1 pause and 1 higher tone. The sequence of tones is repeated every 30 seconds.
Function test of the micropump	Determining the operational readiness of the micropump	7 short, descending tones
Beep	Starting a bolus Starting a basal rate Starting a TBR	A long, high tone
Invalid selection	Exceeding the maximum insulin amount for a bolus	4 long tones alternating low/high

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 License Information

License 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 Declaration of Conformity, Radio Equipment Directive

Roche hereby declares that the radio equipment type Accu-Chek Solo micropump system conforms with the Directive 2014/53/EU. The full text of the EU declaration of conformity may be found at the following Internet address: http://declarations.accu-chek.com

18.4 Connecting Non-System Devices

Additional equipment connected to the diabetes manager must demonstrably comply with the relevant IEC or ISO standards (for example, IEC 60950-1 or IEC 62368-1 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 the system being compliant with the normative requirements for systems. If you have any questions, contact your local authorised dealer or customer support.

18.5 Customer Support

If you encounter problems, have questions regarding operation or need additional information about the Accu-Chek Solo micropump system, contact customer support.

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.

Following you will find the contact data of the Accu-Chek customer support.

Distributed in the United Kingdom by:
Roche Diabetes Care Limited
Charles Avenue, Burgess Hill
West Sussex, RH15 9RY, **United Kingdom**
Accu-Chek Customer Careline [1)]

UK Freephone number: 0800 731 22 91
ROI Freephone number: 1 800 88 23 51
[1)] calls may be recorded for training purposes
Some mobile operators may charge for calls to these numbers.
burgesshill.insulinpumps@roche.com
www.accu-chek.co.uk
www.accu-chek.ie

Australia
Roche Diabetes Care Australia Pty. Limited
Insulin Pump Support: 1800 633 457
australia.insulinpumps@roche.com
www.accu-chek.com.au

18.6 Supplies and Accessories

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

⚠ WARNING

- Use only the supplied charger and the associated USB cable, or a certified USB charger (for example, a laptop certified according to IEC 60950-1/ 62368-1 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 glucose values and over-delivery or under-delivery of insulin.

Supplies for the micropump system

- The Accu-Chek Solo reservoir assembly
- The Accu-Chek Solo cannula assembly & pump holder
- The Accu-Chek Solo pump base
- The Accu-Chek Solo insertion device

Supplies for the blood glucose test

- The Accu-Chek Guide test strips
- The Accu-Chek Guide control solutions
- The Accu-Chek finger pricker
- The Accu-Chek lancets/lancet drums

Accessories*/replacement components for the Accu-Chek Guide Solo diabetes manager

- Carry case
- Rechargeable battery
- Battery door
- Charger
- USB cable

If you need to replace defective system components or need another User's Manual for the micropump system, contact customer support.

* not available in all countries

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.

This product includes an internal constituent containing a Substance of Very High Concern (SVHC), D4, D5 and D6 (CAS 556-67-2; CAS 541-02-6; CAS 540-97-6), in a concentration above 0.1 % weight by weight, as identified under REACH and added to the Candidate List.

There is no direct exposure to the substance and therefore no risk when the instrument is operated according to the instructions for use.

18.8 Bolus Calculation

The bolus that is recommended by the bolus advice feature consists of two components: a recommendation for a meal bolus that covers your intake of food and a recommendation for a correction bolus to adjust your glucose level. The correction bolus may be positive if your current glucose level is above your target BG, or negative, if it falls below your target BG.

18.8.1 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. It is calculated as follows:

Meal bolus = carbohydrate amount × carbohydrate ratio

The following applies here:

Carbohydrate ratio = insulin : carbohydrates

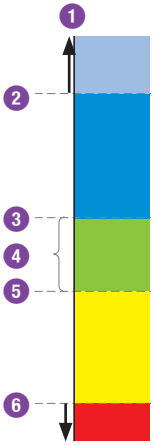
18.8.2 Correction Bolus

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

The following applies here:

Insulin sensitivity = insulin : change in glucose

BG thresholds



1. Glucose value
2. Hyper warning limit
3. Upper target limit value
4. Target range (target BG)
5. Lower target limit value
6. Hypo warning limit

The calculation of the proposed correction bolus is based on your current glucose value, your insulin sensitivity in the current time block, your target range and on whether you plan a meal. The target BG is calculated as the mean value from the lower and upper target limit value.

18.8.3 Subsequent Meal Boluses

If you intend to eat several meals or snacks within a short time period, you should deliver a meal bolus for each meal.

18.8.4 Correction Bolus After a Meal

After a meal, it is normal for your glucose level to increase even if you delivered the correct meal bolus. The allowed increase in the glucose level is called “meal rise”. After a certain period of time, the so-called offset time, the glucose level drops from the peak value until it reaches the target level again. The period of time from the start of the glucose increase until the glucose level returns to the target level is defined as the acting time. During this time, a correction bolus is only recommended if your glucose level exceeds the allowed value after a meal. The allowed value depends on the glucose target value and the meal rise.

18.8.5 Subsequent Correction Boluses

The difference between your current glucose level and your glucose target value is called delta glucose value. A correction bolus that was delivered according to the conditions mentioned above covers this difference. When the correction bolus starts to act, your current glucose level should drop, and the respective delta BG value decreases after the offset time. At the end of the acting time, your glucose level should have reached the target range again. You will only receive a recommendation for an additional correction bolus if your current glucose value is higher than the current delta BG value.

19 Glossary

Term	Definition
Acting time	The acting time is the period of time from the start of bolus delivery until the glucose level is expected to return to the target value. The acting time includes the offset time.
Active insulin	A calculated value representing the amount of insulin currently in the body that still has a lowering effect on the glucose level after a correction bolus. This value does not include any insulin amounts that were delivered to compensate for carbohydrate intake.
Airplane mode	Setting that deactivates all wireless communication of the micropump system. Activate airplane mode when you are in an airplane or when other situations require the *Bluetooth* wireless technology feature to be deactivated. Exchanging data between the diabetes manager and the micropump is not possible in airplane mode.
Automatic off	The automatic off function is a feature for emergency situations. If you have not touched any buttons on your micropump and not operated the diabetes manager for the specified number of hours, the micropump stops insulin delivery.
Basal rate	The basal rate is the insulin amount delivered per hour to cover your meal-independent insulin needs. In insulin pump therapy, your basal rate is determined together with your healthcare professional and can be adjusted to meet your individual physiological needs that can change as the day progresses.
Basal rate profile	A basal rate profile consists of up to 24 time blocks. An individual basal rate can be programmed for each time block. The Accu-Chek Solo micropump offers you up to 5 different basal rate profiles in order to easily adjust insulin delivery to meet your changing insulin needs (for example, during the week compared to at the weekend).
BG threshold	A limit value that triggers a test reminder when the glucose level is above or below this value. The BG thresholds do not affect the target ranges or the warning limits.
Blood glucose (BG)	The glucose level in the blood
Bluetooth wireless technology	Wireless transfer technology that digital devices use to exchange data

19 GLOSSARY

Term	Definition
Bolus	The insulin amount required to cover the intake of food or correct an elevated glucose level. The bolus type and bolus amount are determined by your healthcare professional's guidelines, your glucose level, the food you ate, your current state of health or your physical activity.
Bolus advice options	Settings that are independent of the time of day and affect exclusively bolus advice calculation. These settings include meal rise, snack size, acting time and offset time. Bolus advice calculation is also affected by the parameters target range, insulin sensitivity and carbohydrate ratio, which are dependent of the time of day and can be saved in the respective time blocks.
Bolus advice	A feature that provides the user with suggestions as to how much insulin should be delivered for a meal or to correct the glucose level
Broteinheit (Bread Equivalent) (BE)	One of the 4 units for the carbohydrate amount that you can select when setting up the micropump system. 1 BE = 12 grams of carbohydrates
Carbohydrate Choice (CC)	One of the 4 units for the carbohydrate amount that you can select when setting up the micropump system. 1 CC = 15 grams of carbohydrates
Carbohydrate ratio	The carbohydrate ratio defines the insulin amount necessary to compensate for a certain amount of carbohydrates consumed.
Carbohydrate unit (KE)	One of the 4 units for the carbohydrate amount that you can select when setting up the micropump system. 1 KE = 10 grams of carbohydrates
Carbohydrates	Carbohydrates are nutrients that are broken down into glucose during digestion and increase glucose level in the blood. Carbohydrates are generally counted to calculate a bolus insulin dose.
Control result	The value displayed on the diabetes manager after a control test. If the control result is within the range shown on the label of the test strip container, the test strips and the integrated meter of the diabetes manager are working properly.
Control test	A meter test using control solution that lets you know whether the integrated meter of the diabetes manager and the test strips are working properly.

Term	Definition
Current time	The time you set via the *Settings* menu on the *Time and date* screen.
Delivery lag time	Period of time before delivery of a programmed bolus begins.
End time	Time at which a time block ends
Error	Error messages are displayed when relevant malfunctions of the micropump system are registered. In case of micropump errors, the micropump switches to STOP mode. The micropump system can only be used again once the problem has been solved.
Extended Bolus	The extended bolus does not deliver the bolus insulin all at once, but over a programmable period of time.
Factory settings	The initial settings on the micropump system before you change or customise them.
Glucose value	Result of a blood glucose test
Gram	One of the 4 units for the carbohydrate amount that you can select when setting up the micropump system.
Health event	Information on your current state of health or your activities. Each health event stands for a certain percentage according to your settings and is used to adjust bolus advice recommendations. Up to 4 health events can be selected and stored with a glucose value.
HI	Appears on the screen when the glucose value is above the diabetes manager's measuring range. HI stands for high.
Hyper	Hyperglycaemia
Hypo	Hypoglycaemia
Immediate amount	Insulin amount that is delivered at the beginning of a multiwave bolus and corresponds to a standard bolus.
Infusion site	Site at which the cannula is inserted into the subcutaneous tissue for insulin delivery.
Insulin	Insulin is a hormone that is necessary to process glucose. Insulin is produced in the beta cells of the pancreas.
Insulin increment	The amount in units (U) by which your insulin dose is adjusted when programming a bolus or when making a manual logbook entry.
Insulin sensitivity	The insulin sensitivity (U : mmol/L) defines the insulin amount required to lower your glucose level by a certain value.

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Term	Definition
Limit value	The upper limit value and lower limit value together define the blood glucose target range. For bolus calculation, the mean value from the upper limit value and lower limit value is used as the glucose target value.
LO	Appears on the screen when the glucose value is below the diabetes manager's measuring range. LO stands for low.
Maintenance	Maintenance messages inform you about a temporary loss of certain features of the micropump system. Maintenance messages require you to intervene in order to solve the problem. Maintenance messages of the micropump switch the micropump to STOP mode.
Meal rise	The initially allowed increase in glucose level after a meal bolus. During or after meals, an increase in the glucose level is considered normal within a certain range, even if a bolus was delivered beforehand. When setting up bolus advice enter the maximum increase in your glucose level that is to be tolerated without an additional correction bolus.
Multiwave Bolus	A multiwave bolus combines a standard bolus with an extended bolus. A part of the bolus amount is delivered immediately, whereas the other part is delivered over a programmable period of time.
Occlusion	An occlusion prevents the insulin from flowing correctly from the micropump into your body.
Offset time	The offset time is the time period after which the insulin is expected to start lowering an elevated glucose level significantly and to start returning to the original glucose level after a meal.
Paired	The diabetes manager and the micropump communicate with each other and transfer information to each other when they are paired.
Pen/syringe bolus	A bolus delivered using an insulin pen or syringe.
Quick bolus	Bolus that is programmed and delivered using the quick bolus buttons on the micropump.
Regular insulin	Insulin that has the same chemical structure as insulin produced by the human pancreas. Regular insulin usually needs 30 to 45 minutes to take effect.
Reminder	A feature the diabetes manager can use to remind you of an event, a task or a planned activity.

Term	Definition
Settings	Settings are individually adjustable values and parameters that define the way the micropump system works.
Snack size	The snack size defines a carbohydrate threshold; when this is exceeded, a meal rise should be taken into account for bolus advice. Thus, the snack size indicates the carbohydrate amounts up to which no increase in the glucose level is to be tolerated after a meal.
Snooze	Reschedules a reminder or message to reoccur after a preset period of time (for example, after 15 minutes).
Standard Bolus	The standard bolus delivers the programmed insulin dose all at once.
Standard deviation (SD)	The standard deviation indicates how the values are scattered around the average. A high standard deviation means that the values are scattered away from the average.
Start time	The start time of a time block.
STOP mode	When your micropump is in STOP mode, it does not deliver any insulin. Insulin delivery is only stopped if you switch to STOP mode, change the basal rate profile, make settings using a PC or when error messages or maintenance messages are issued. Ongoing boluses or temporary basal rates are interrupted when the micropump switches to STOP mode.
Target range	The target range describes which glucose values are considered acceptable before a meal or when fasting. The target range is specified by the lower and upper BG thresholds. The midpoint between the lower and upper BG threshold is automatically included in the calculation as the target value.
Temporary Basal Rate (TBR)	Temporary increase or decrease in your basal rate profile to match changing insulin needs due to increased or decreased activity level, illness or stress.
Time block	Time blocks help you to set the target range and the parameters insulin sensitivity and carbohydrate ratio for bolus advice for specific times of day. Time blocks allow you to divide the day into different time periods according to your individual lifestyle. You can set up a maximum of 8 time blocks.

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Term	Definition
Time of test	Information on the point in time when a glucose value was obtained. The information can be stored together with a glucose value. When the results are subsequently analysed, either all glucose values can be displayed or only the glucose value for a specific time of test.
Total daily dose	The total amount of insulin (basal rate plus boluses) delivered in a 24-hour period, beginning at midnight.
U100	U100 indicates the insulin concentration. Each milliliter of liquid contains 100 units of insulin.
Unit (U)	Unit of measurement for insulin.
Warning	Warnings inform you about situations that require your attention or draw your attention to a possible hazardous situation. The micropump system triggers a warning message if an action of your part is required in the near future.
Warning limit	When your glucose value is above or below the hyper or hypo warning limit, a warning is displayed. You should set the hyper and hypo warning limits together with your healthcare professional. In case of glucose values below the lower warning limit, no bolus advice will be calculated.

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CE 0123

Approved/listed/registered under the product name:
Accu-Chek Solo pump base
Accu-Chek Guide Solo diabetes manager
Accu-Chek Solo reservoir assembly
Accu-Chek Solo cannula assembly & pump holder
Accu-Chek Solo insertion device

Roche Diabetes Care GmbH
Sandhofer Strasse 116
68305 Mannheim, Germany
www.accu-chek.com

The compliance mark indicates that the product complies with the applicable standard and establishes a traceable link between the equipment and the manufacturer, importer or their agent responsible for compliance and for placing it on the Australian and New Zealand market.

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