

User's Manual

Accu-Chek Solo micropump system



I am a **person with diabetes** being treated with insulin. The insulin is delivered to my body by a micropump. If I am confused or unconscious, please do the following:

Call the emergency services.

If I am able to swallow, give me sugar immediately, for example, juice.

Remove the micropump from my body.

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 the Internet at www.accu-chek.com. From this website, you can download the User's Manual as a PDF file.

To contact the Customer Support and Service Centre:

UK: Accu-Chek Pump Careline¹⁾: 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: Accu-Chek Enquiry Line: 1800 251 816, Pump Support: 1800 633 457.

Emergency card

Name _____

Address _____

Phone _____

In case of emergency, please contact:

Name _____

Phone _____

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.

She/He relies on a regular supply of insulin from the Accu-Chek Solo micropump, which she/he carries on her/his body.

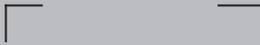
Place and date _____

Healthcare professional name _____

Phone _____ Fax _____

Healthcare professional signature _____

Stamp _____



Approved/listed/registered under the product name:
Accu-Chek Solo micropump system

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ACCU-CHEK[®]

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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 displays on the screen, the 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.

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 the Customer Support and Service Centre. For more information, see chapter *18.5 Customer Support and Service Centre*.

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

The following information is highlighted in a special way:

 **WARNING**

A warning must be heeded because it indicates a risk of injury or of damage to your health or the health of others. Not heeding the warnings can lead to life-threatening situations.

Note

A note contains helpful information and tips to help you get the most out of using the micropump system.

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.

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 good therapy and for fully benefiting from the micropump system. Read these chapters before using the respective features.

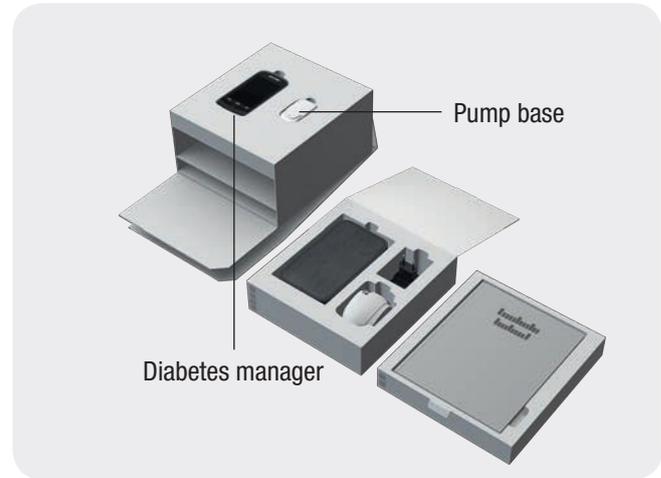
The following abbreviations are used in this User's Manual:

- ▶ *Blood glucose* is shortened to BG.
- ▶ *Temporary basal rate* is shortened to TBR.
- ▶ For more abbreviations, see chapter *17 Symbols, Abbreviations, Signals*.

Scope of delivery

The scope of delivery includes the following components:

- ▶ Accu-Chek Solo pump base (2×)
- ▶ Accu-Chek Aviva Solo diabetes manager (1×)
- ▶ Rechargeable battery for the Accu-Chek Aviva Solo diabetes manager (1×)
- ▶ Accu-Chek Solo insertion device (1×)
- ▶ Charger with plug (1×)
- ▶ USB cable (1×)
- ▶ Accu-Chek Solo carry case (1×)
- ▶ Finger pricker (1×)
- ▶ Lancet drums for finger pricker (2×)
- ▶ Instructions for use



Consumables

Only use consumables and accessories from Roche.

Not included, but necessary for using the micropump system:

- ▶ Accu-Chek Solo reservoir assembly
- ▶ Accu-Chek Solo infusion assembly, consisting of Accu-Chek Solo cannula assembly and Accu-Chek Solo pump holder
- ▶ Accu-Chek Aviva test strips and Accu-Chek Aviva control solution

Note

- ▶ 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.
- ▶ Make sure you have a second pump holder and a second reservoir available so that you have replacements if needed.

1 What is the Purpose of the Micropump System?

1.1 Intended Use

The Accu-Chek Solo micropump system is a prescription medical device intended for the subcutaneous, continuous delivery of rapid-acting U100 insulin with variable delivery quantities and for the quantitative determination of blood glucose in fresh capillary blood.

The micropump system is intended to be used by people with insulin-dependent diabetes mellitus. It is intended for personal use only and may only be used by one and the same person. The micropump system may only be used after having been prescribed by a healthcare professional.

The 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. It is intended for people with diabetes who are at least 2 years of age.

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.

The micropump system can support you in calculating the recommended insulin or carbohydrate amounts based on your blood glucose values and your personal data. The micropump system can measure your blood glucose values, record and represent the delivered insulin amounts and the consumed carbohydrate amounts, as well as collect and display information for evaluation purposes.

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.

1.2 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 perform at least 4 blood glucose tests per day.
- ▶ 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. For more information, see chapter *16 Technical Data*.

- ▶ 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 Risks and Benefits

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

To ensure that insulin pump therapy is safe and successful, you must actively take part in your therapy, test your blood glucose values 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.

1.4 General Warnings

WARNING

- ▶ **The micropump system may only be used by a single person for insulin therapy.**

All objects which can come into contact with human blood carry a potential risk of infection. There is a risk of infections being transmitted if the same micropump system is used by other people, even by family members, or if healthcare professionals use the same micropump system for insulin therapy or blood glucose tests for different people.

- ▶ Only use the micropump to deliver rapid-acting U100 insulin.
- ▶ Use sterile consumables only once and only if the use by date has not expired and the related sterile packaging is not damaged.
- ▶ Used devices and consumables carry a risk of infection. Dispose of used system components according to local regulations.
- ▶ Do not change your therapy without consulting your healthcare professional first.

WARNING

- ▶ Check your blood glucose level at least four times a day.
- ▶ Check your blood glucose level more than four times a day if your insulin sensitivity is high.
- ▶ If the micropump has been subjected to mechanical shocks, check your blood glucose level at least once within 1 to 3 hours.
- ▶ Keep all parts of the micropump system away from small children and vulnerable persons. There is a risk of suffocation if small parts are swallowed.
- ▶ Keep pointed or sharp-edged parts away from small children and vulnerable persons. There is a risk of injury.
- ▶ Use or store the micropump system only within the permitted ambient conditions. Otherwise, you risk malfunctions of the micropump system, incorrect test results and over-delivery or under-delivery of insulin.

 **WARNING**

- ▶ Do not expose the micropump system to extreme acceleration forces (for example, roller coaster rides). This can lead to hyperglycaemia or hypoglycaemia.
- ▶ Do not use the micropump system close to strong electromagnetic fields or ionising radiation. Strong electromagnetic fields, for example, from radar or antenna installations, sources of high voltage or X-Ray, magnetic resonance and computed tomography could interfere with the micropump system. Stop the micropump and remove it from your body before you enter areas with electromagnetic or ionising radiation.
- ▶ Maintain a distance of at least 30 cm between the micropump system and portable HF communication devices. Portable and mobile HF communication devices may impair the micropump and the diabetes manager.

 **WARNING**

- ▶ Never attempt to repair or modify the micropump system yourself. Otherwise, you risk malfunctions of the micropump system, incorrect test results and over-delivery or under-delivery of insulin.
- ▶ Do not use the diabetes manager if the screen is damaged or defective.

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 pen) at short notice in case the micropump system does not function properly.

1.5 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. The interactive displays on the diabetes manager screen, help you to make individual settings and control the micropump.

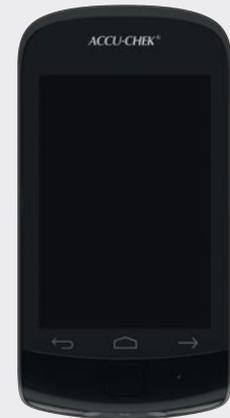
Accu-Chek Solo pump base

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.



Accu-Chek Aviva Solo diabetes manager

The Accu-Chek Aviva Solo diabetes manager is used to configure and control the micropump. It has an LCD screen and communicates with the micropump via *Bluetooth*[®] wireless technology. The diabetes manager can display important system messages such as information, warnings, maintenance and error messages.



Accu-Chek Solo reservoir

The Accu-Chek Solo reservoir is the second part of the micropump in addition to the pump base. 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.



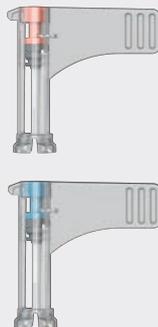
Accu-Chek Solo pump holder

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.



Accu-Chek Solo cannula assembly

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. The Accu-Chek Solo cannula assembly is available with cannula lengths of 6 mm (orange) or 9 mm (blue).



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.



1.6 Characteristics of the Micropump System

Tubeless insulin pump

- ▶ Small, light and removable micropump (29 g)
- ▶ Transparent reservoir (up to 200 U), usable for up to 4 days
- ▶ Soft Teflon[®] cannula with a length of 6 mm or 9 mm
- ▶ Can be worn at different sites directly on the body
- ▶ Filling aid for easy and controlled filling
- ▶ Can be used with rapid-acting U100 insulin from different manufacturers

Convenient handling with the help of the diabetes manager

- ▶ Control of the micropump system via touchscreen and *Bluetooth* wireless technology
- ▶ Direct access to important features, such as bolus, basal rates, and blood glucose values, via the Status screen
- ▶ Preview of therapy and system events by means of the information screen
- ▶ Adjustable user menus in several languages

Customised bolus and basal features

- ▶ Bolus delivery (up to 50 U) with diabetes manager or programmable directly on the micropump
- ▶ Selectable bolus types: standard, extended, multiwave
- ▶ Basal rates from 0.1 U per hour up to 25 U per hour
- ▶ 5 basal rate profiles for different daily routines
- ▶ Temporary basal rates from 0 to 250 %
- ▶ Functional support when temporarily using a syringe or pen

Support for therapy decisions

- ▶ Built-in bolus advice feature
- ▶ Visual representation of therapy trends and logbook features
- ▶ Interface to common data management software of different providers on the PC

Assisted setup and application

- ▶ Micropump system is set up using a setup wizard
- ▶ Guided setup of basal rate profiles and bolus advice feature
- ▶ Guided replacement of system components
- ▶ Videos explaining action steps on the diabetes manager

Comfort and safety features

- ▶ Built-in blood glucose meter in the diabetes manager
- ▶ Optional entry of blood glucose results that were measured with other blood glucose meters
- ▶ Illumination for test strip slot and test strip
- ▶ Rechargeable battery in the diabetes manager
- ▶ Optional key lock with PIN
- ▶ Programmable volume setting and vibration mode for different environments
- ▶ Built-in self-tests and automatic detection of malfunctions
- ▶ Information before maintenance is required

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 aeroplane (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 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 (consumables, test strips, insulin and so on), and find out where you can obtain supplies while you are travelling.

We recommend that you always have the quick reference instructions and emergency card (SOS) with you, which can be detached from the cover of this User's Manual.

Some airlines and governments do not permit the use of wireless radio devices during flight. In these situations you can activate flight mode. Flight 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.

When communication is interrupted, a message is displayed on the screen. For more information, see chapter *15 Messages and Troubleshooting*. Communication is automatically re-established when the cause of the interruption no longer exists. As long as communication between the micropump and the diabetes manager is interrupted, new data is saved on the respective device. Once communication between the diabetes manager and the pump has been re-established, the micropump automatically transfers your saved data to the diabetes manager.

2 Getting to Know the Micropump System

2.1 Diabetes Manager Overview

The Accu-Chek Aviva 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.

The diabetes manager has a coloured LCD touchscreen. You can use the diabetes manager to program the delivery of basal insulin and boluses. The diabetes manager can calculate bolus advice tailored to your individual needs and situations. The diabetes manager communicates with the micropump using *Bluetooth* wireless technology. It transmits commands to and receives data from the micropump and saves the data for insulin delivery in the electronic logbook.

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 signal mode to a setting that is loud enough, and pay attention to the displays and signals on the diabetes manager to make sure that the micropump system is functioning properly.

Getting to Know the Micropump System



	Name	Description
1	Power button	Turns the diabetes manager on or off.
2	Lanyard eyelet	Used to attach a lanyard.
3	Headphone socket	Socket for connecting passive headphones.
4	LED	LED to signalise error, maintenance and warning messages as well as reminders.
5	Micro USB connector	Socket for connecting the USB cable (micro-B plug) in order to recharge the battery or establish a connection to a PC.
6	Screen	LCD touchscreen for calling up the diabetes manager menus and displaying information.
7	Function buttons	Buttons for operating context-sensitive functions.
8	Navigation buttons	Navigation controls for moving between menus and process steps.
9	Insulin button	Button for confirming a previously set insulin delivery.
10	Test strip slot	For inserting test strips for blood glucose tests and control tests.
11	Camera	Used to scan the pairing code on the pump base to pair the micropump and the diabetes manager.
12	Battery door	Removable cover for the battery compartment.

Note

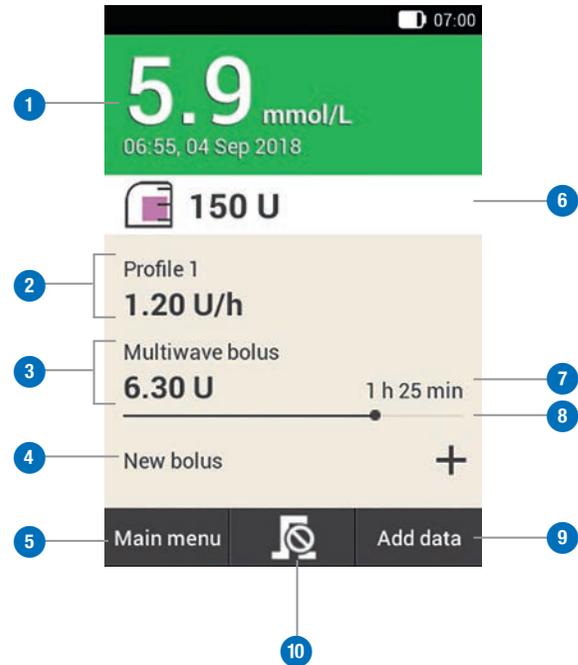
- ▶ Only use the headphone socket for connecting passive headphones, i.e. headphones without their own power supply.
- ▶ Close the cover of the headphone socket after use.

2.2 Status Screen

2.2.1 Overview

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

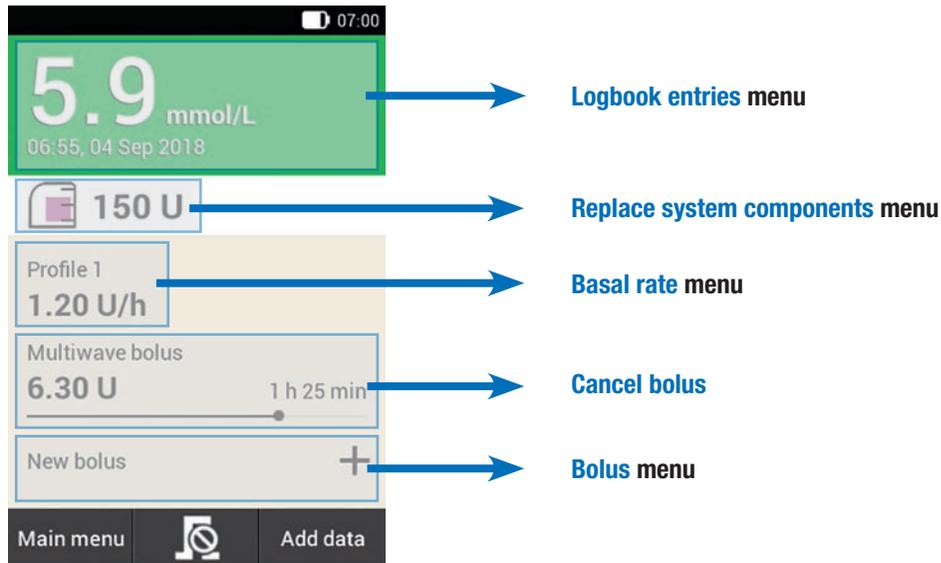
Depending on the situation (for example, whether you are using pump therapy or injection therapy), other content and symbols will be displayed.



	Name	Description
1	Blood glucose result	Shows the most recent blood glucose result with the time and date of the test. The background colour indicates whether the test result falls within the target range. For more information, see chapter <i>5.1.5 Colour Coding of Test Results</i> .
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.
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, blood glucose result or time of test).
10	Cancel bolus	Tap the  button to cancel one or all active boluses.

2.2.2 Shortcuts on the Status screen

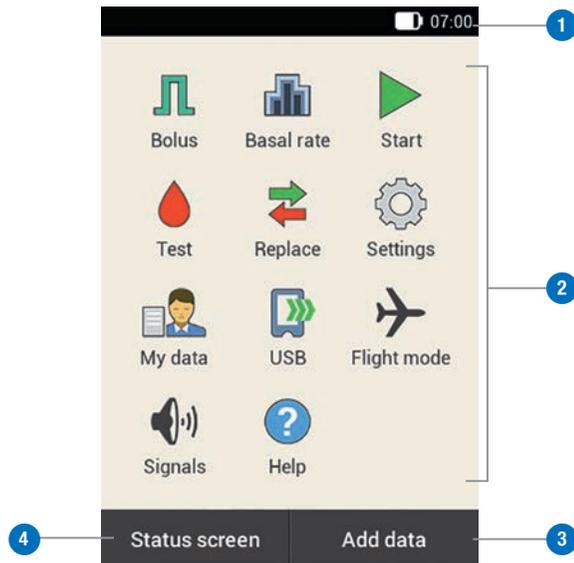
The touch-sensitive areas on the Status screen allow you to quickly access important menus and features. When you tap the areas, the corresponding menus or features are opened.



2.3 Main Menu

The main menu is an overview of the most important features of the diabetes manager. From here, you can open the basic menus and features, go to the Status screen or add data.

Depending on the situation (for example, pump therapy or injection therapy), other menus can be displayed. For more information, see chapter *13.2 Injection Therapy Displays*.



	Name	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, blood glucose result 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.

Symbol	Name	Description
	Status of rechargeable battery	Shows the current level of the rechargeable battery in the diabetes manager.
	No communication	Is displayed when communication between the diabetes manager and the micropump is interrupted.
	Flight mode	Is displayed when flight mode is turned on.
	No acoustic signal	Is displayed when tones are turned off.
	Signals turned off	Is displayed when signals for reminders and warnings are turned off temporarily.
	Vibration	Is displayed when the vibration feature is turned on.

Menu icons in the Main menu

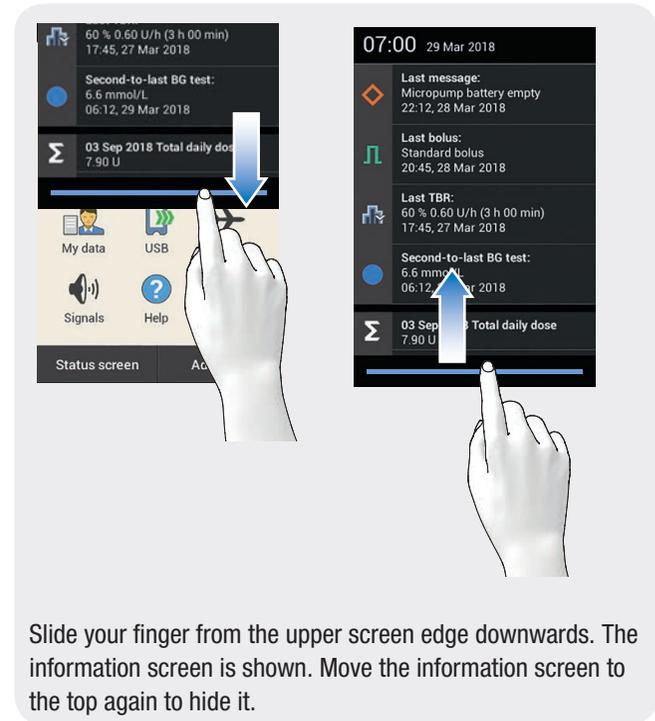
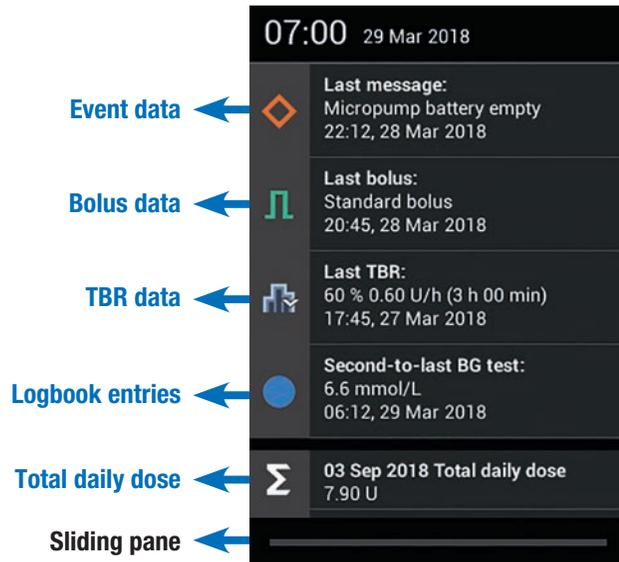
Menu icon	Description
	Deliver manual bolus, use bolus advice, cancel bolus
	Select or set basal rate profiles, set and cancel Temporary Basal Rates (TBR)
	Micropump is in STOP mode, Start micropump
	Stop micropump (cancel bolus and TBR and interrupt basal rate)
	Test blood glucose, enter test result, perform control test
	Replace system components (infusion assembly, reservoir, pump base)

Menu icon	Description
	View or change settings, view system information, switch therapy mode
	Display or edit logbook data
	Connect diabetes manager to a PC in order to transfer data
	Turn flight mode on or off
	Set signals
	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. For more information on the menus, see chapter *10 My Data*.

If you slide the upper screen edge downwards, the information screen is shown. The bar on the sliding pane lights up blue while it is being moved.



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. Press the insulin button to start a basal rate or bolus.

2.5.1 Navigation buttons

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

Button	Function
	Back Go back to the previous display 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 display within the process step. In many process steps, this button performs the same function as the Next or OK buttons.

In some menus and when system messages are displayed, not all navigation buttons are available.

2.5.2 Insulin Button

The insulin button is only used to confirm a previously set insulin delivery. 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 the  button to start insulin delivery. If the displayed insulin amount is not correct, tap  in order to correct your entries.

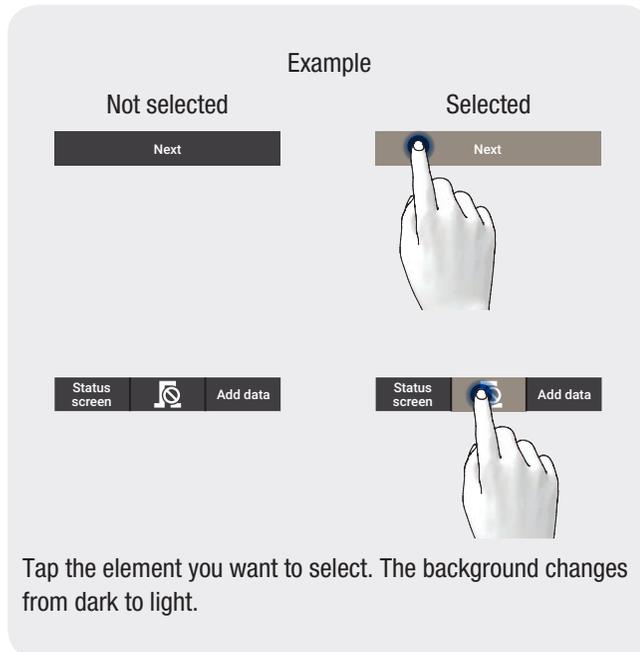
2.5.3 Entries

There are various methods of making entries in order to execute commands, select values, set features and select display elements.

The various entry methods are explained on the following pages.

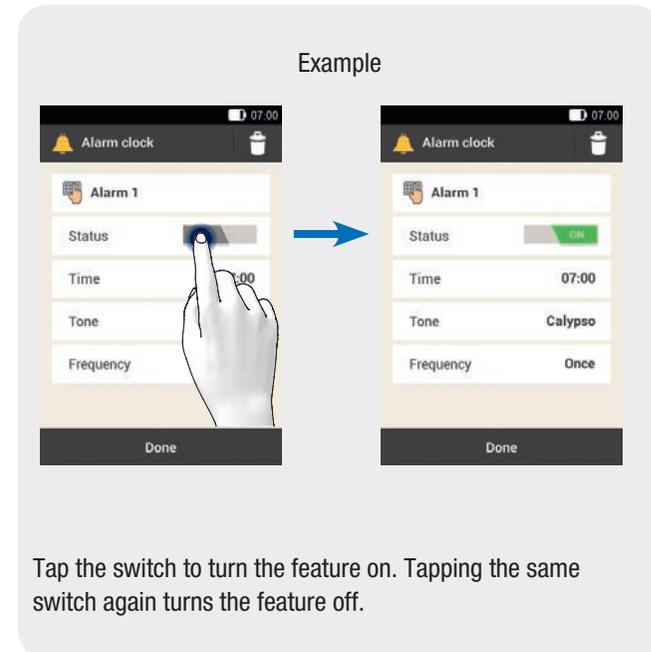
Executing commands

Whenever you tap a command on the screen, the background colour changes.



Switching a feature on or off

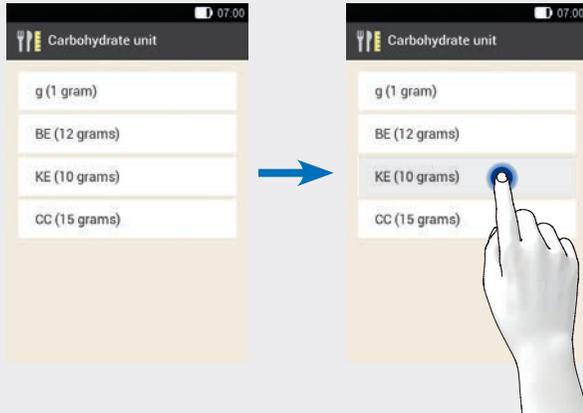
By tapping a switch, you can turn a feature on or off. Inactive function buttons and switches are greyed out.



Simple lists or menus

No element is preselected in simple lists or menus. You can select an element.

Example

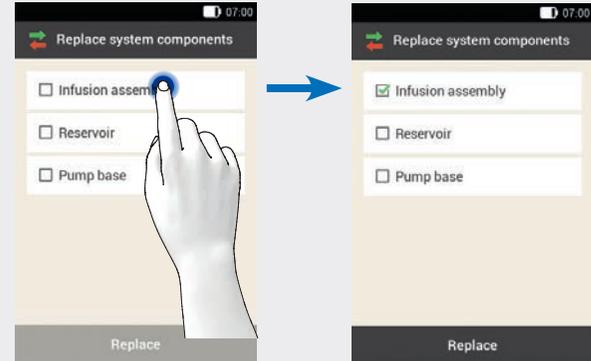


Tap the element you want to select. The background changes from light to dark. When you have selected an element, the next display appears.

Lists with checkboxes

In these lists, you can select either one or more elements simultaneously or no element.

Example

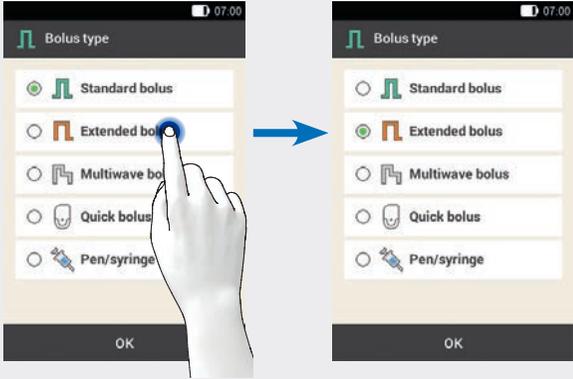


Tap the element you want to select. A green tick is displayed in the checkbox. If you tap the element once more, the tick disappears and the element is no longer selected.

Lists with radio buttons

In these lists, one element is always selected, for example, by the factory settings. By tapping the desired element, you can change the selection.

Example

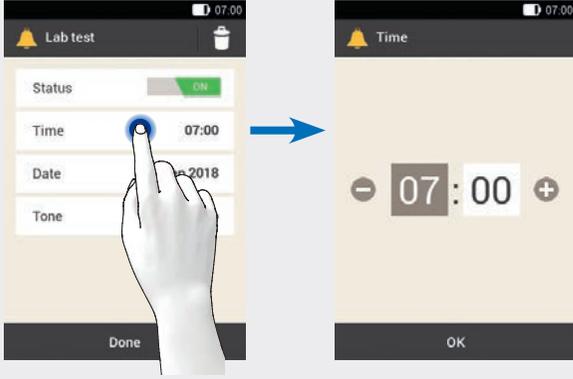


Tap the element you want to select. The green dot is displayed in the circle in front of the newly selected element.

Editing an element

To edit the desired element, it must be selected.

Example



Tap the element you want to edit. You can edit the element on the display that follows.

Scrolling lists

In long menus and lists, you can scroll the list to display the elements that are not visible.

Example

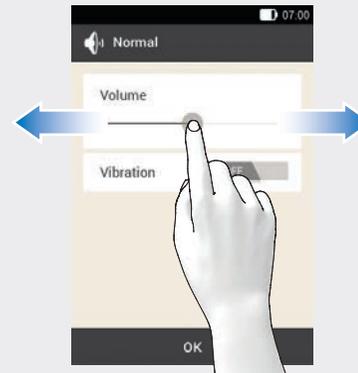


Scroll the list upwards to view additional list elements or menus. Scroll the list downwards to view the top list elements or menus.

Slider

You can make the desired setting by moving the slider.

Example



Move the slider to the desired position.

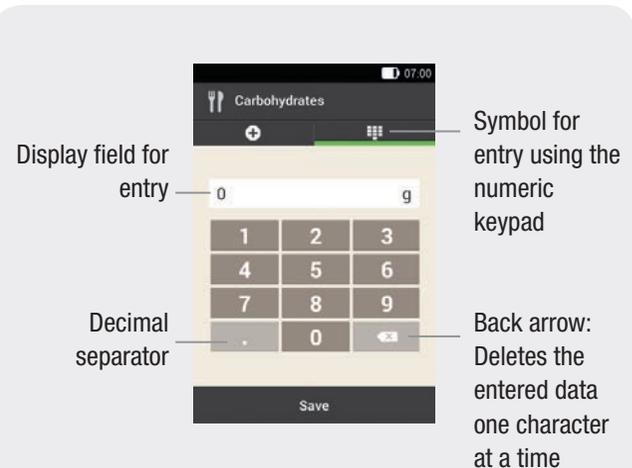
2.5.4 Entering Numbers

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

When you use the carbohydrate unit g, you can alternatively enter the carbohydrate amount using the numeric keypad.

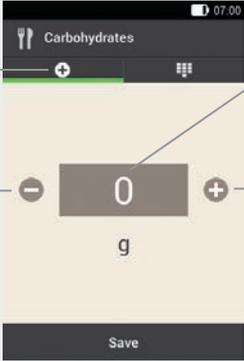


Enter the desired numeric value using the numeric keypad.

Minus/plus buttons

⊕ and ⌨ allow you to switch between entering data using the minus/plus buttons and the numeric keypad.

Explanation/Example



Symbol for entering text using the minus/plus buttons

Button to decrease the value entered

Button to increase the value entered

Display field for entry

g

Save

Tap ⊕ to increase the numeric value on the display. Tap ⊖ to decrease the numeric value on the display. 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.

2.5.5 Entering Text

Text is entered using a keyboard. Depending on the language, key assignments may differ.

Explanation/Example



Switches between lowercase and uppercase

Deletes the entered data one character at a time

Switches between a keyboard with letters and a keyboard with numbers, punctuation and special characters

Confirms the entry

Enter the desired text using the letter keyboard.

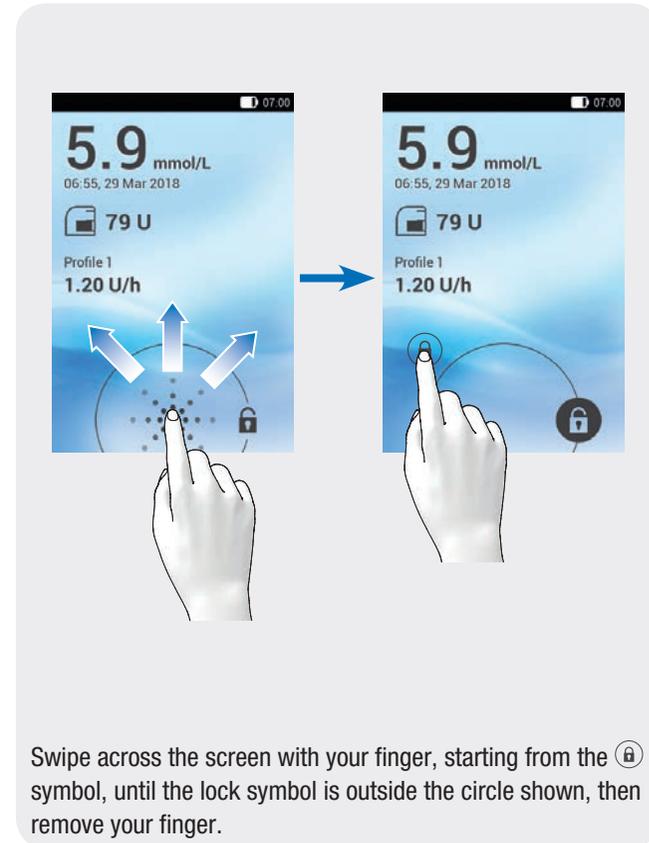
2.5.6 Screen Lock

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 the  symbol.

The lock prevents others from viewing the screen and prevents functions from being activated unintentionally on the touchscreen while you are not using the device. The last blood glucose result, the time and date, the reservoir level and the basal rate are displayed even when the screen is locked.

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 display to unlock the diabetes manager screen. You have the option of changing the settings in the menu [Settings > Screen lock](#).

Unlocking the screen



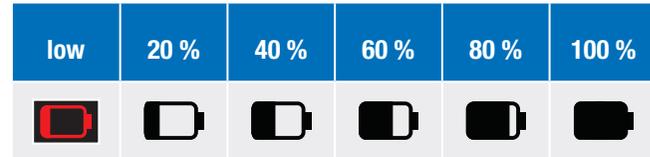
3 Putting the Diabetes Manager into Operation

3.1 Charging the Battery

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. Charging the battery using the USB connector on a PC may take longer.

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.

Symbols for different battery levels:



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.

3.1.1 Inserting the Rechargeable Battery in the Diabetes Manager

! 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 or an equivalent safety standard).
- ▶ Use only the rechargeable battery from Roche.



Have the diabetes manager, rechargeable battery, charger and USB cable ready.



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



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.

3.1.2 Charging the Battery Using a Wall Socket

4



Close the battery compartment by pushing the battery door in the direction of the arrow until it clicks into place.

1



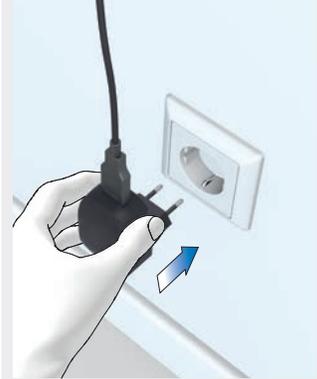
Plug the larger end (USB type A) of the USB cable into the USB socket of the charger.

2



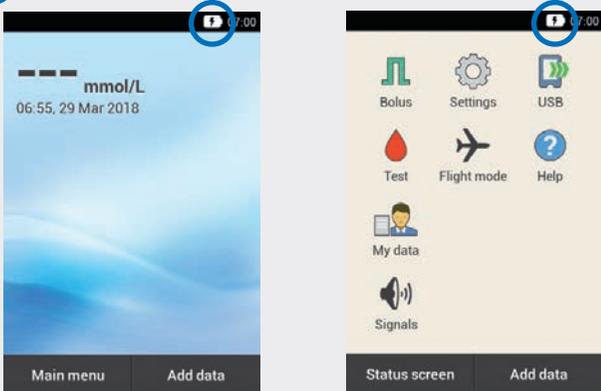
Plug the smaller end (USB type micro-B) of the USB cable into the USB socket of the diabetes manager.

3



Plug the charger into a wall socket (the images show a 2-pin plug but you will use a 3-pin plug).

4



The Status screen or Main menu displays the  symbol 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, then unplug the charger from the wall socket.

Note

The blue LED lights up to indicate that the battery is being charged. If the rechargeable battery of the diabetes manager has been run right down, 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 your Customer Support and Service Centre.

3.1.3 Charging the Battery Using a Computer

1



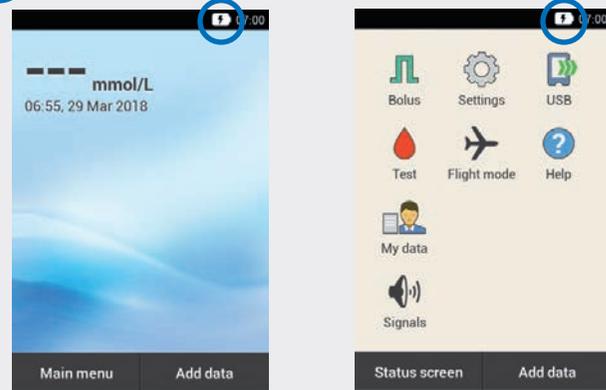
Plug the smaller end (micro-B plug) of the USB cable into the USB socket of the diabetes manager.

2



Plug the larger end (USB-A plug) of the USB cable into a free USB charging port on your computer. The USB charging port is often indicated by a lightning bolt symbol ⚡.

3



The Status screen or Main menu displays the  symbol 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 computer must usually be turned on in order for the battery to be charged. With some PC models, the computer must not be in sleep or standby mode if you want to charge the battery.
- ▶ If the battery level of the diabetes manager is very low, the screen is black at first.
- ▶ If you want to transfer data to the computer via the USB cable, follow the instructions in chapter *10.8 Data Transfer*.

3.2 Setup Wizard

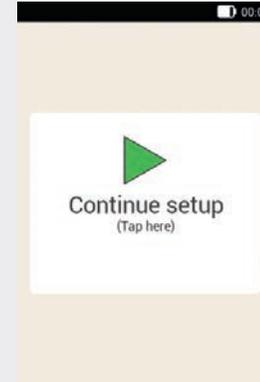
The first time you turn the diabetes manager on, the setup wizard is displayed. You must complete the setup wizard before you start using the micropump or test your blood glucose.

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.

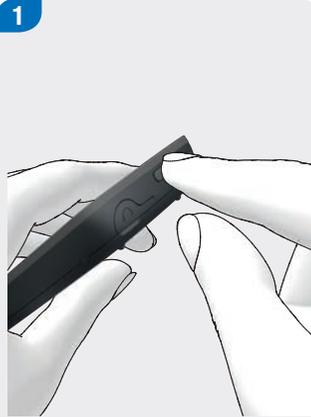
Caching the setup



The data and settings you enter are cached at specific points during setup. If you want to resume setup after an interruption, [Continue setup](#) appears on the screen.

Tap this display to continue setting up the system.

Power on/Standby



Press and hold the power button on the top of the diabetes manager until the diabetes manager turns on.

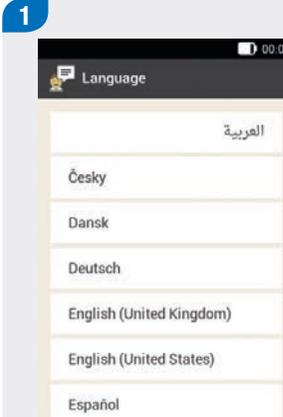
If the diabetes manager is turned on: Briefly press the power button to activate the energy-saving standby mode.



The diabetes manager vibrates, issues the “Start” signal sequence, and the signal LED lights up. The start display appears briefly.

For more information on the sequences of signals, see chapter 17.3 *Signals*.

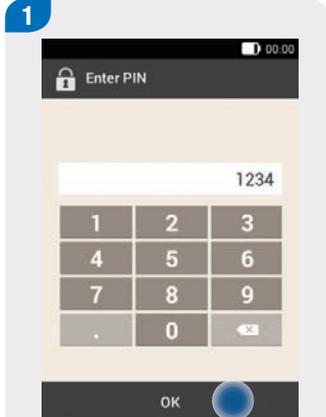
Setting the language



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

Tap **Save**.

Entering the 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**.

2



Enter the PIN a second time to confirm.

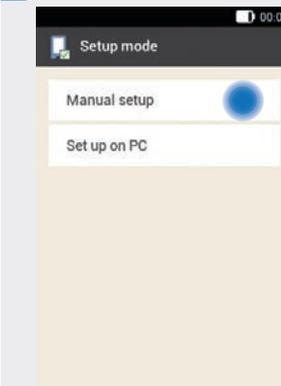
Tap **OK**.

Note

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

You can find the label with the 8-digit PIN unlock code on the back cover of the User's Manual.

1



Tap **Manual setup** and continue with the section *Setting the time and date*.

Note

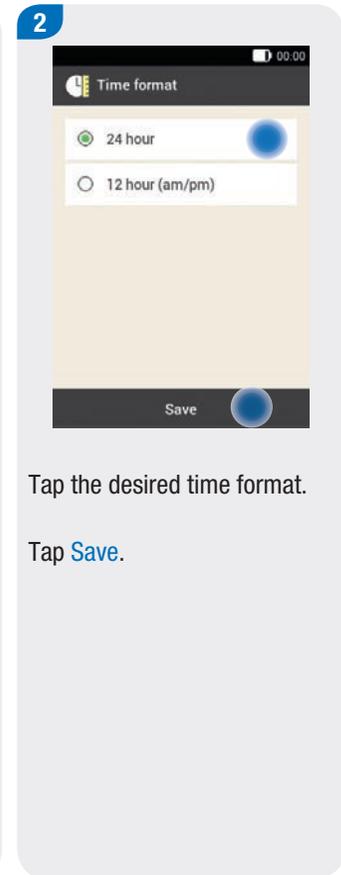
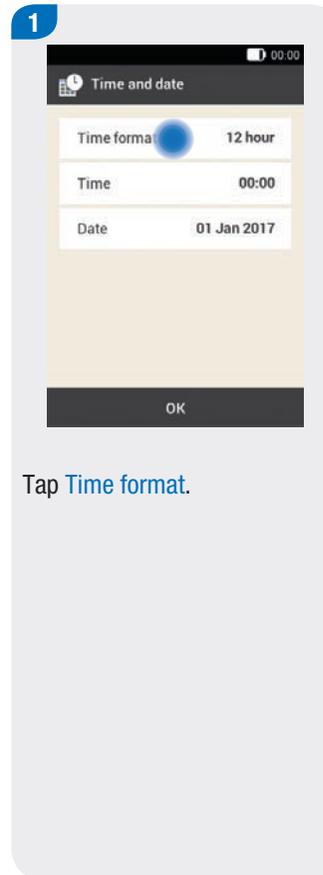
It is not currently possible to perform the setup on the PC.

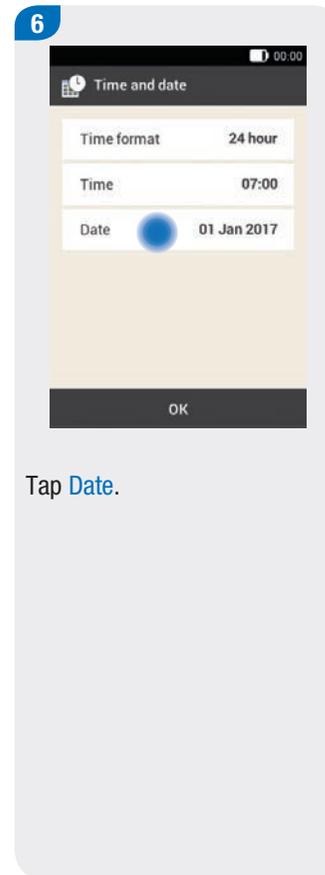
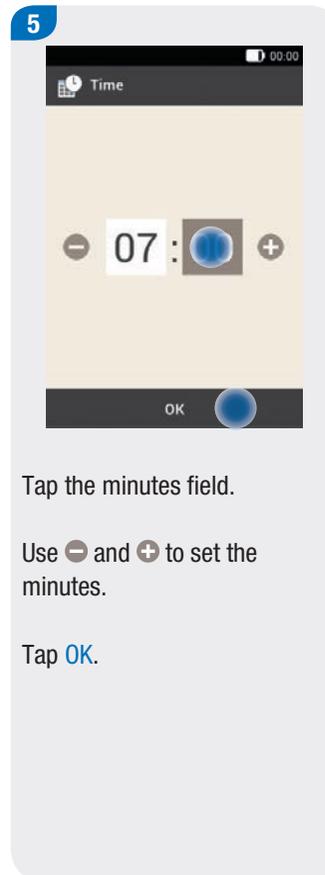
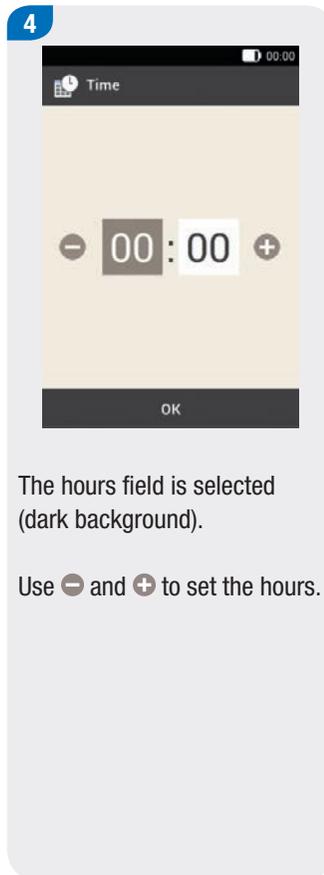
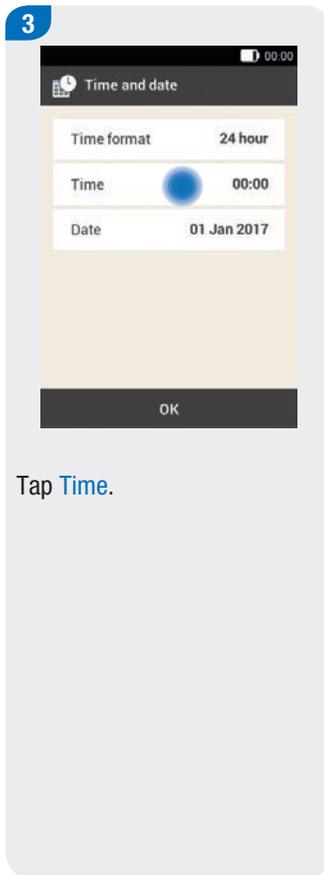
Setting the time and date

Times and time periods are always displayed or entered in the following format HH:MM (HH = hours, MM = minutes).

24-hour time format	01:07 16:15	HH:MM
12-hour time format	01:07 am 04:15 pm	HH:MM am or pm
Time period	02:35	2 hours and 35 minutes

The date is always displayed or entered in the format DD MMM YYYY (DD = day, MMM = month, YYYY = year), for example, 29 Mar 2018.





7



The day field is highlighted.

Use **-** and **+** to set the day.

8



Tap the month field.

Use **-** and **+** to set the month.

9

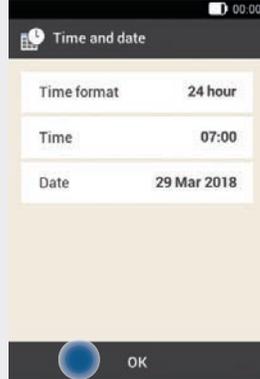


Tap the year field.

Use **-** and **+** to set the year.

Tap **OK**.

10



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

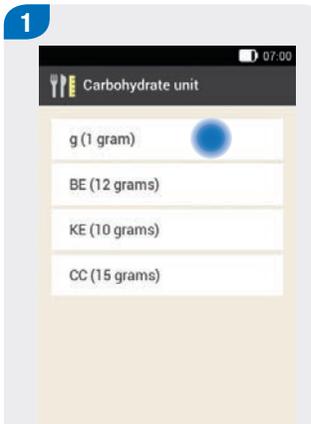
Setting the carbohydrate unit

The diabetes manager offers the following carbohydrate units for selection:

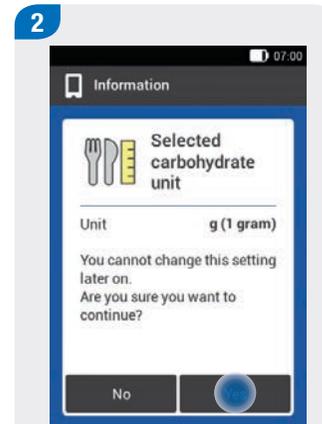
Abbreviation	Unit of measurement	Gram equivalent
g	Gram	1 gram
BE	Broteinheit (bread equivalent)	12 grams
KE	Kohlenhydrateinheit (carbohydrate unit)	10 grams
CC	Carbohydrate choice	15 grams

Note

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



Tap the carbohydrate unit you want to set.



Tap **Yes** if the correct unit is displayed.

If you want to change the unit, tap **No**. You then return to Step 1.

Setting warning limits

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

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

1



The default warning limits are displayed.

Tap **Upper warning limit**.

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

2



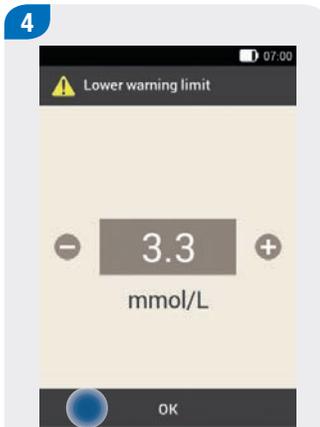
Use **-** and **+** to set the upper warning limit.

Tap **OK**.

3

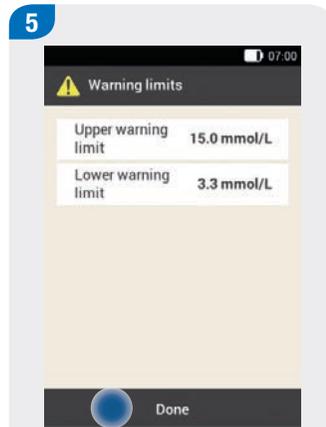


Tap **Lower warning limit**.



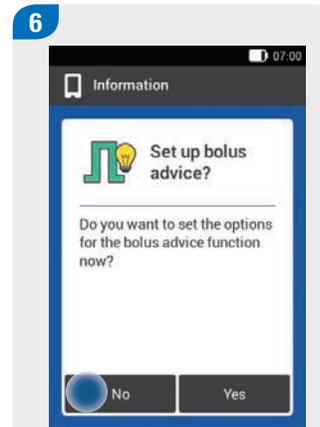
Use **-** and **+** to set the lower warning limit.

Tap **OK**.



The warning limits currently set are displayed.

Tap **Done**.



If you want to set up bolus advice now, tap **Yes**. In chapter 7.2 *Setting Up Bolus Advice*, you will find the explanations and steps for setting up this feature.

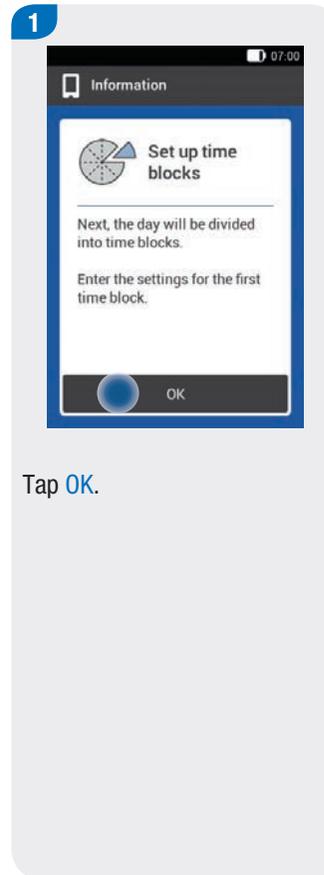
If you do not want to set up bolus advice now, tap **No**.

Note

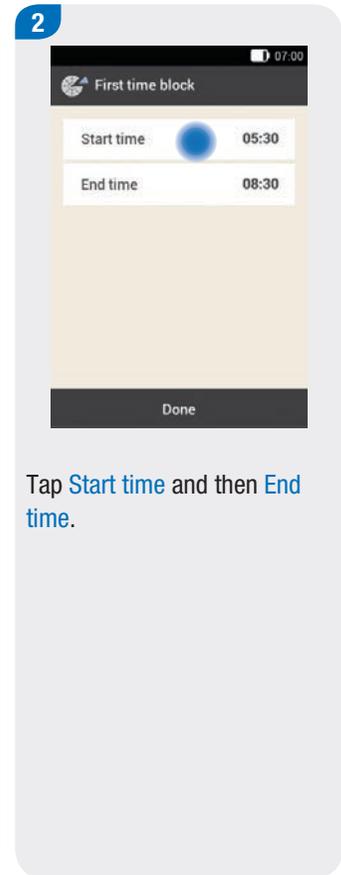
If you do not want to set up bolus advice now, the setup wizard skips the steps for setting up bolus advice. You can set up bolus advice at a later time.

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.



Tap **OK**.



Tap **Start time** and then **End time**.

3



Use **-** and **+** to set the start time.

Tap **OK**.

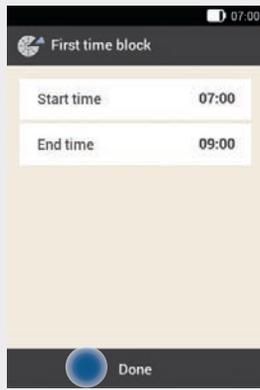
4



Use **-** and **+** to set the end time.

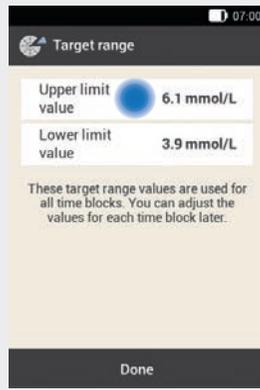
Tap **OK**.

5



Tap **Done**.

6



Tap **Upper limit value**.

7



Upper limit value

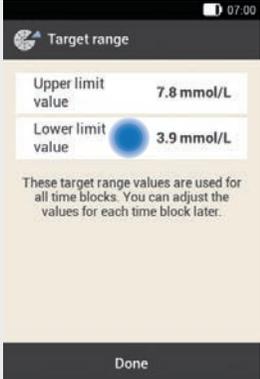
7.8 mmol/L

OK

Use **-** and **+** to set the upper limit value.

Tap **OK**.

8



Target range

Upper limit value	7.8 mmol/L
Lower limit value	3.9 mmol/L

These target range values are used for all time blocks. You can adjust the values for each time block later.

Done

Tap **Lower limit value**.

9



Lower limit value

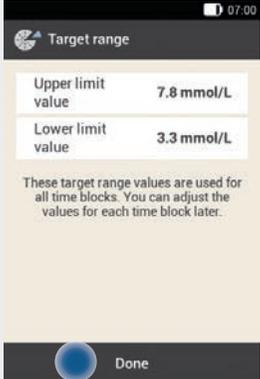
3.3 mmol/L

OK

Use **-** and **+** to set the lower limit value.

Tap **OK**.

10



Target range

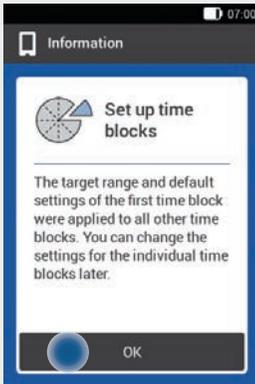
Upper limit value	7.8 mmol/L
Lower limit value	3.3 mmol/L

These target range values are used for all time blocks. You can adjust the values for each time block later.

Done

Tap **Done**.

11



Tap **OK**.

Note

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.

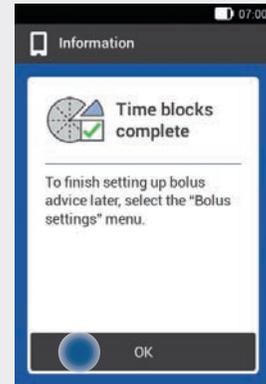
12



Repeat the previous steps if you want to change more time blocks.

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

13



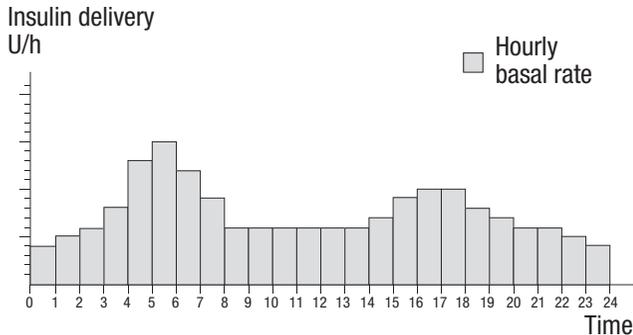
Tap **OK**.

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



1

Information

Create basal rate profile

First create a basal rate profile in order to start using the micropump.

OK

Tap **OK** to set up a basal rate profile.

The button is deactivated.

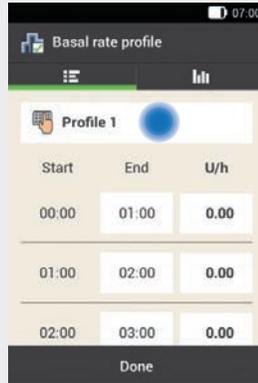
Note

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.

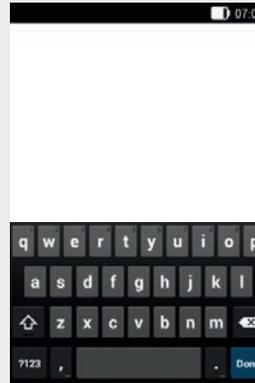
2



The basal rate profile is displayed.

Tap the option with the  symbol (here: **Profile 1**) if you want to change the name of the profile.

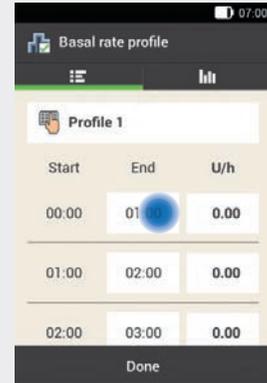
3



Enter a name for the basal rate profile using the keyboard.

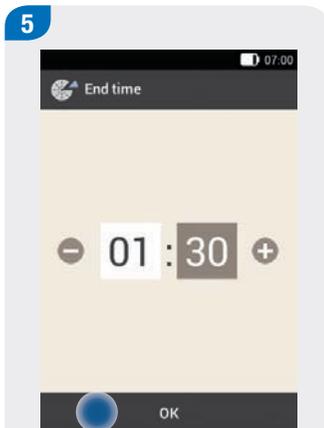
Tap **Done**.

4



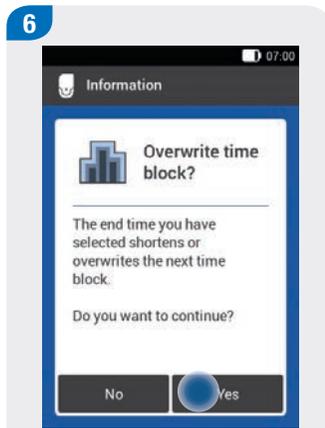
Define the end time for the first time block.

To do so, tap the top entry field in the **End** column.



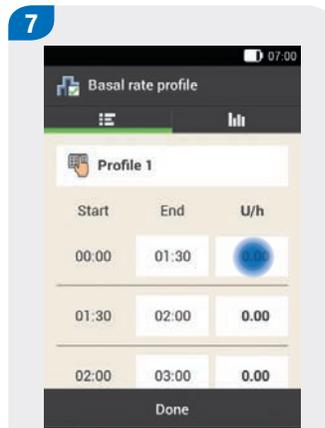
Use **-** and **+** to set the end time for the first time block.

Tap **OK**.



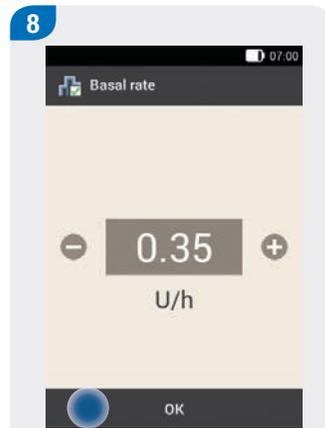
When the end time of a time block shortens or overwrites the next time block, this display appears.

Tap **Yes**.



Define the insulin units per hour for the first time block.

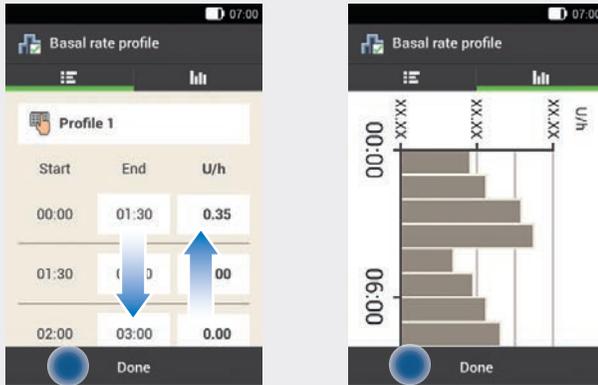
To do so, tap the top entry field in the **U/h** column.



Use **-** and **+** to set insulin units per hour for the first time block.

Tap **OK**.

9



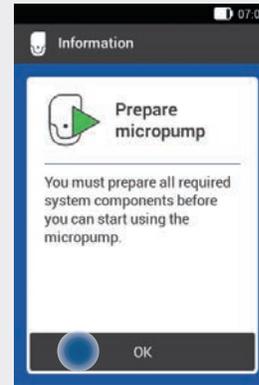
Repeat Steps 4 to 7 for each time block you want to edit.

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

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

Once you have set all time blocks, tap [Done](#).

10



Next, you have to prepare the micropump. For more information, see chapter *4 Putting the Micropump into Operation*.

Tap [OK](#) to confirm.

4 Putting the Micropump into Operation

4.1 Overview

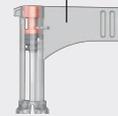
This chapter explains all steps necessary to prepare the micropump before using it for the first time. To put the micropump into operation, you need the following:

- ▶ Diabetes manager
- ▶ Pump base
- ▶ Reservoir assembly
- ▶ Insulin
- ▶ Pump holder and cannula assembly
- ▶ Insertion device
- ▶ Disinfectant or sterile alcohol wipe

The following steps are necessary to put the micropump into operation:

- ▶ Use the insertion device to attach the pump holder to the body and insert the cannula
- ▶ Fill the new reservoir with insulin
- ▶ Connect the reservoir to the pump base
- ▶ Pair the micropump with the diabetes manager
- ▶ Fill the reservoir needle
- ▶ Attach the micropump to the pump holder
- ▶ Start the basal rate

Cannula assembly 6 mm
(orange)



Cannula assembly 9 mm
(blue)



Reservoir assembly

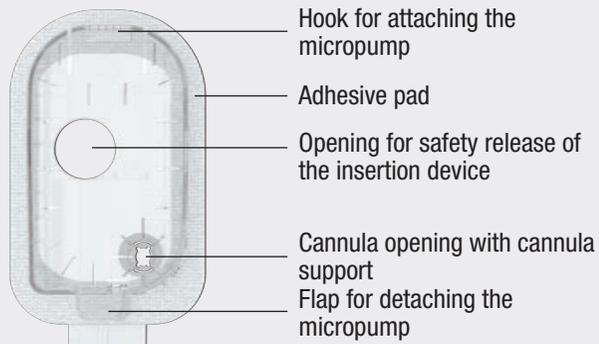


Pump holder

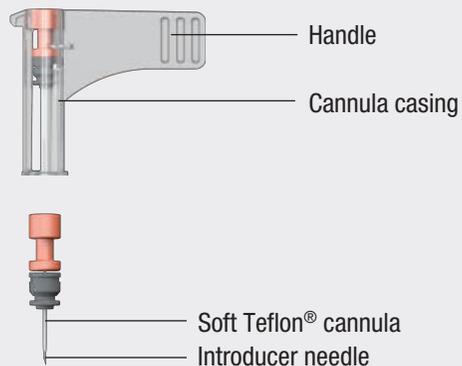


Infusion assembly

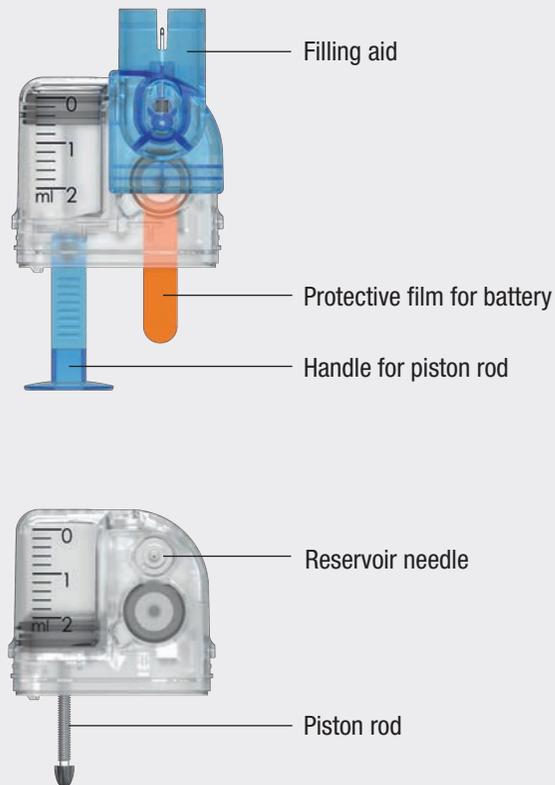
Pump holder



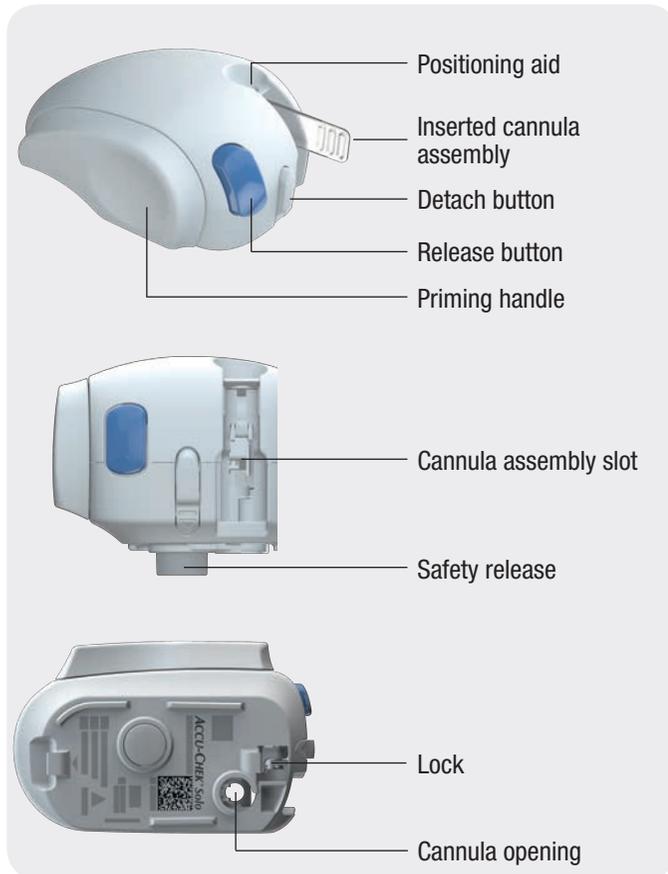
Cannula assembly



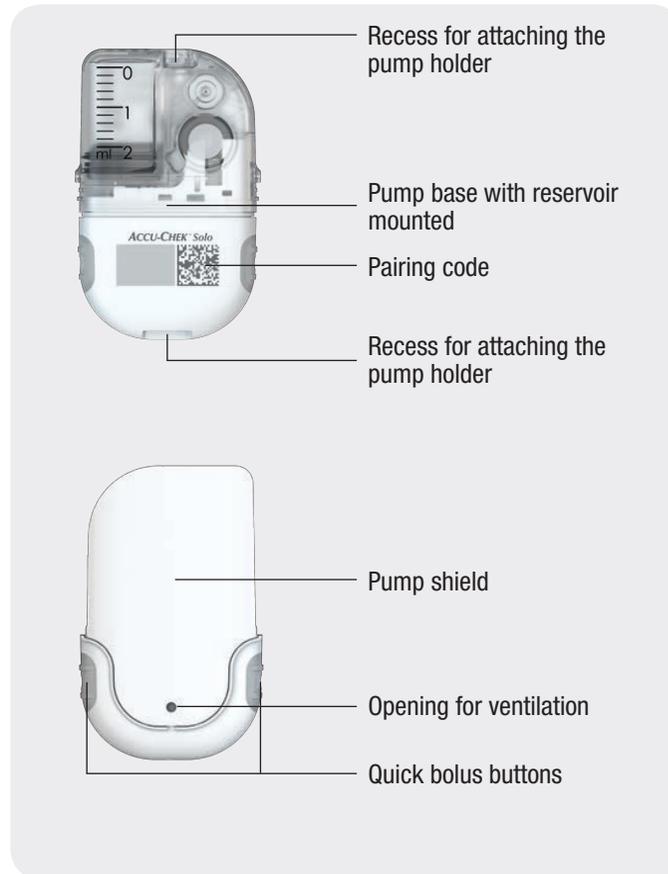
Reservoir assembly



Insertion device



Micropump

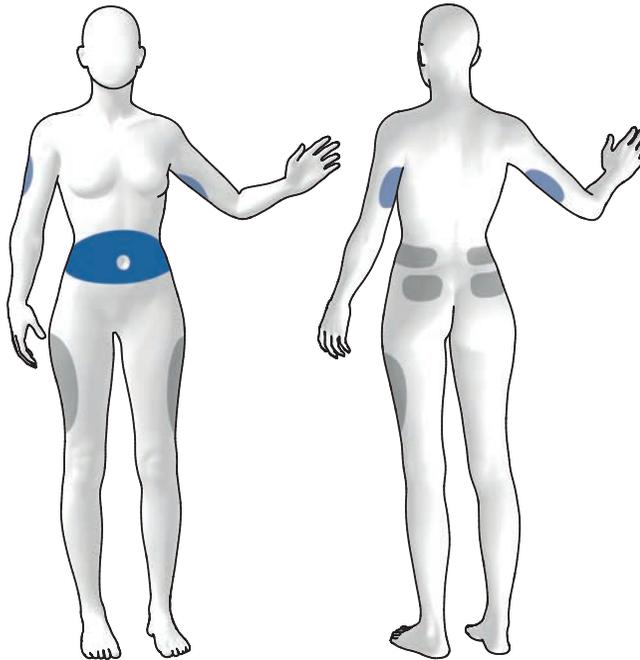




WARNING

- ▶ 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 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 blood 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.

4.2 Recommended Infusion Sites



Blue areas: Recommended infusion sites
 Grey areas: Possible 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:

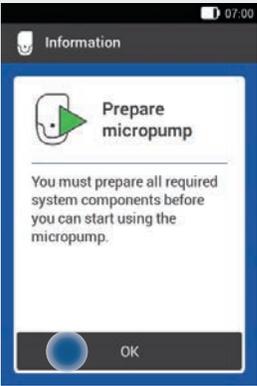
Infusion site	Characteristics
Abdominal region	Common infusion site with good insulin absorption.
Upper arm	Slower insulin absorption compared to the abdominal region.
Thigh	Slower insulin absorption compared to the abdominal region.
Hip, lower back, buttocks	Slower insulin absorption compared to the abdominal region. Also suitable for physically active users or if not much subcutaneous tissue is available.

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.
- ▶ 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, replace the infusion assembly immediately and choose a new infusion site.

4.3 Putting the Components into Operation

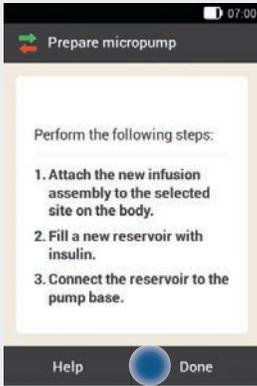
1



After setting up the diabetes manager, the [Prepare micropump](#) display appears.

Tap [OK](#).

2



Follow the instructions shown on the [Prepare micropump](#) display.

If you want to see the action steps as an animated video, tap [Help](#).

Once you have performed all 3 steps, tap [Done](#).

4.3.1 Attaching the Infusion Assembly to the Body

1



Wash your hands and dry them thoroughly.

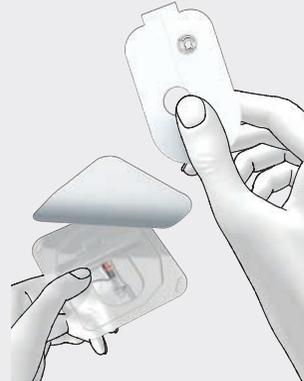
2



Select a suitable site on the body.

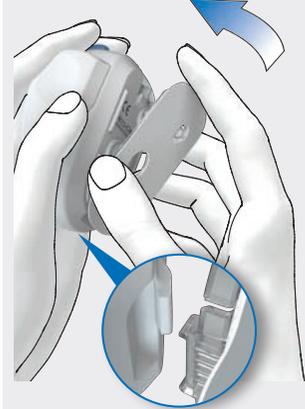
Disinfect the site on your body according to the instructions given by your healthcare professional. Make sure that the infusion site is dry and free from residues.

3



Remove the pump holder from the packaging.

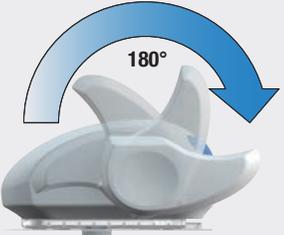
4



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.

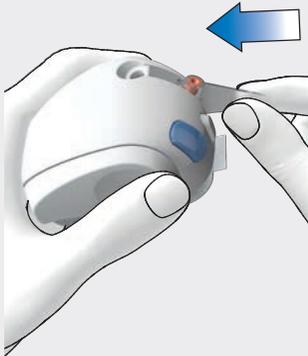
5



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.

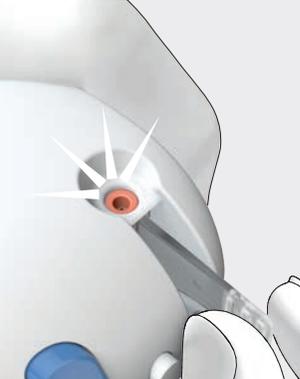
6



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. This could impair the adhesive properties.

9



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

10



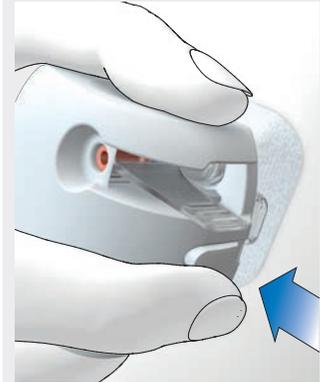
Press the blue release button to insert the cannula under the skin.

11

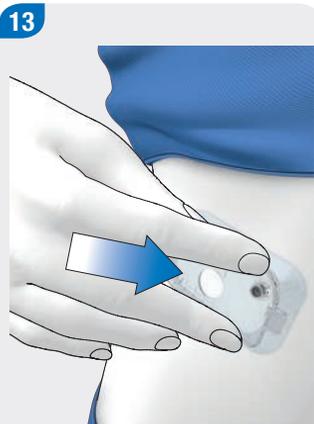


Smooth over the adhesive pad around the infusion assembly so that the infusion assembly is in good contact with the skin.

12



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

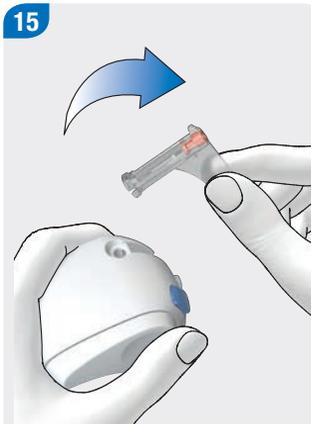


Press the infusion assembly and the edges of the adhesive pad against the skin so that the adhesive pad is smooth on the skin.



Check whether the grey 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.



Remove the used cannula casing from the insertion device.



Dispose of the used cannula casing according to local regulations.

**WARNING**

During disposal, ensure that no third party could injure themselves and risk an infection.

Note

- ▶ Do not use the insertion device without first inserting the cannula assembly. 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.

4.3.2 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.
- ▶ Make sure that the insulin is at room temperature before using it in the micropump. 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.

1



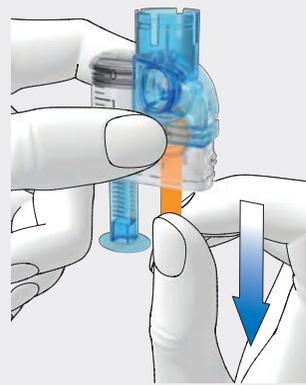
Disinfect the top of the insulin vial with a sterile alcohol wipe. Allow the disinfected top of the insulin vial to dry.

2



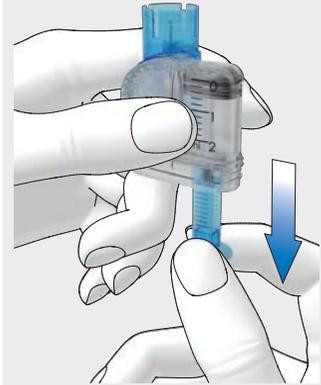
Remove the new reservoir assembly from the packaging.

3



Carefully pull out the battery's protective film downwards in the direction of the arrow 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.

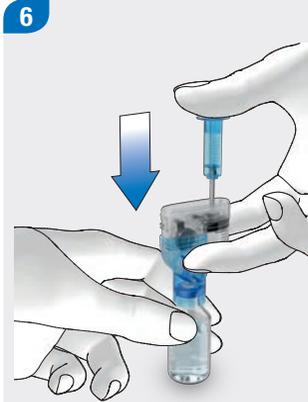
Fill the reservoir with the volume of air that you later want to fill with insulin.

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.



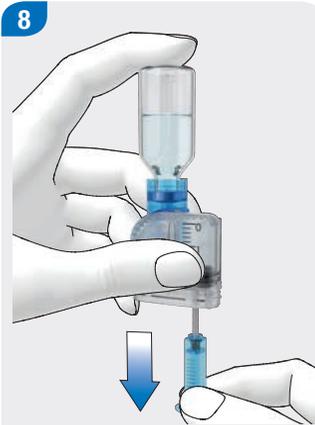
Place the insulin vial on a flat and solid surface (for example, a table top) and hold it firmly. Place the filling aid onto the vial. Push the filling aid downwards until you hear it click into place.



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



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



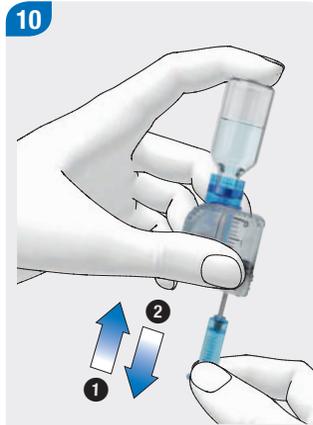
Slowly pull the handle downwards in the direction of the arrow to fill the reservoir with insulin.

Try to ensure that no air bubbles form 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.



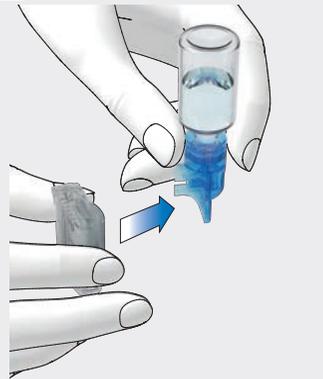
Slowly push the handle upwards in the direction of the arrow ① to remove air bubbles from the reservoir.

Slowly pull the handle downwards in the direction of the arrow ② until the reservoir is filled with the required amount of insulin again.

Note

Check the reservoir from several angles to make sure that there are no air bubbles in the reservoir.

11

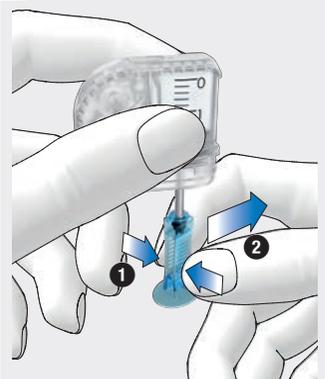


Remove the filling aid from the reservoir by pulling it off laterally in the direction of the arrow.

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 **1** and then remove the handle laterally from the piston rod **2**.

Dispose of the handle.

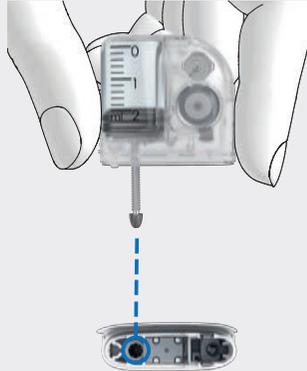
4.3.3 Connecting the Reservoir to the Pump Base

1



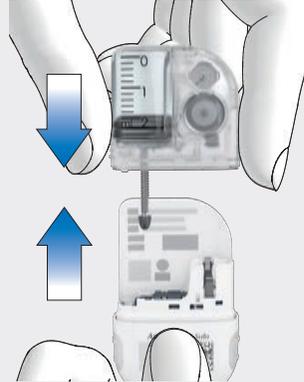
Remove the blue reservoir cap from the pump base.

2



Align the piston rod of the filled reservoir such that you can insert it into the piston rod opening of the pump base

3



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

4



When both components are connected to each other correctly and the battery is activated, the micropump issues the “Start” signal sequence. If this sequence of signals is not issued, check whether the battery is activated and repeat Steps 2 to 4.

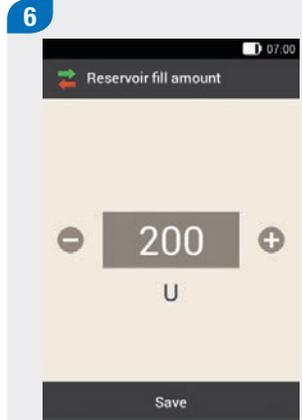
Note

- ▶ Make sure that there is no gap between the reservoir and the pump base.
- ▶ 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.
- ▶ For more information on the sequences of signals, see chapter 17.3 *Signals*.



Read the reservoir level using the reservoir scale.

With 2.0 ml (200 U), the reservoir shown in the figure above is full.



Use **-** and **+** to set the number of insulin units with which you filled the reservoir.

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

Tap **Save**.

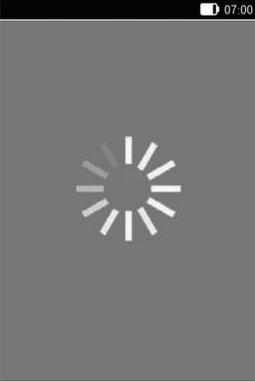
1



After you have connected the reservoir to the pump base, hold the diabetes manager close to the micropump to establish the radio connection.

Tap [Next](#).

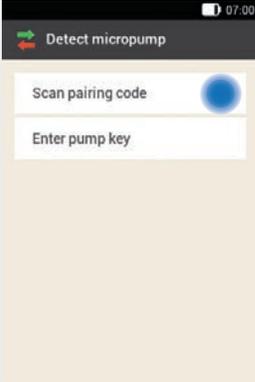
2



The diabetes manager establishes the radio connection to the micropump.

Wait a moment.

3



Tap [Scan pairing code](#).

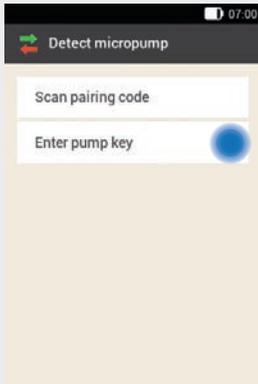
4



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 signal sounds if the pairing code was detected, and a prompt to fill the reservoir needle is displayed.

Entering the pump key manually

1



If no signal sounds, the pairing code was not detected.

Tap  to return to the [Detect micropump](#) display.

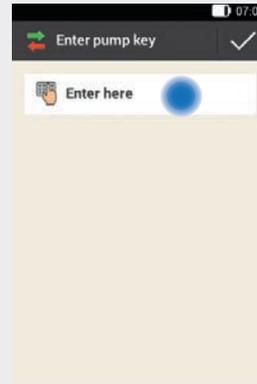
Tap [Enter pump key](#).

2



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

3



Tap [Enter here](#) and enter the pump key using the keyboard.

If pairing was successful, a signal sounds.

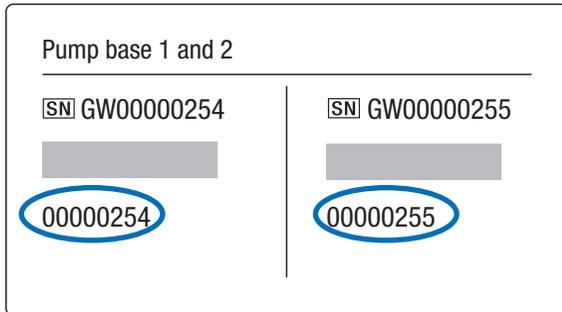
Tap [Done](#).

Note

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

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:



4.3.5 Filling the Reservoir Needle

1

The micropump is now ready to fill the reservoir needle and displays a message to this effect.

Tap **Fill**.

! WARNING

Never fill the reservoir needle while it is connected to an infusion assembly attached to your body. There is a risk of uncontrolled insulin delivery.

2



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

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

3



If you can see a drop of insulin at the tip of the needle, tap **OK**.

If you **cannot** see a drop of insulin at the tip of the needle, 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 refilling, 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.
- ▶ The  button is deactivated during filling.

4.3.6 Attaching the Micropump

To properly attach the micropump to the pump holder, the recess for attaching the micropump needs to be clicked onto the hook on the pump holder.



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



Fit the recess on the micropump onto the hook on the pump holder.

2



Using pressure on the pump shield, press the micropump onto the pump holder until there is a clearly audible **CLICK**.

3



Check whether the micropump is securely attached to the pump holder.

The micropump is now ready for insulin delivery.

4



Tap **Next**.

A small amount of insulin is delivered in order to fill the soft Teflon[®] cannula.

4.3.7 Activating the 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, see chapter 8 *Basal Rate Profiles and Temporary Basal Rates*.

1



Deliver insulin 07:00

Activate basal rate profile

Profile 1

Total amount 20.0 U

To confirm, press

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

2



mmol/L

06:55, 29 Mar 2018

200 U

Profile 1

1.20 U/h

New bolus +

Main menu Add data

The Status screen displays the activated basal rate profile.

4.4 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.

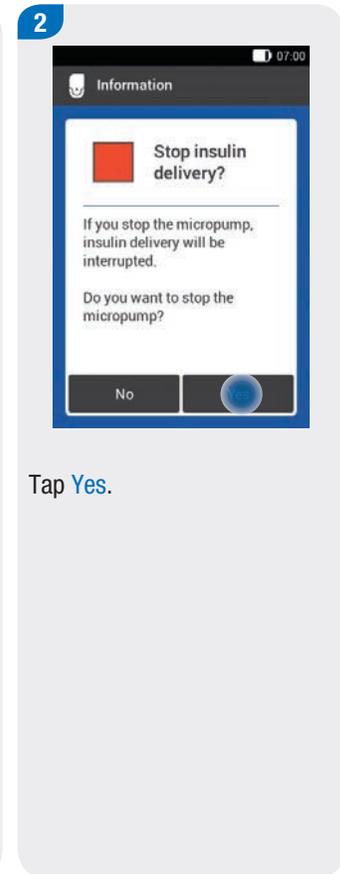
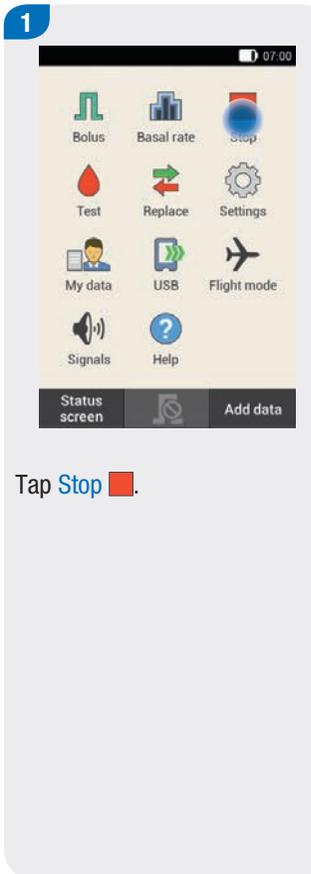
If necessary, use a syringe or insulin pen to deliver insulin according to the instructions of your healthcare professional.

Note

If insulin delivery is interrupted, check your blood 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



Putting the Micropump into Operation

While the micropump is in STOP mode, the micropump issues the “Cancel” signal sequence once an hour to remind you that no insulin is being delivered. For more information on the sequences of signals, see chapter *17.3 Signals*.

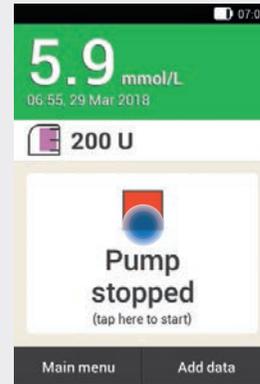
WARNING

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.

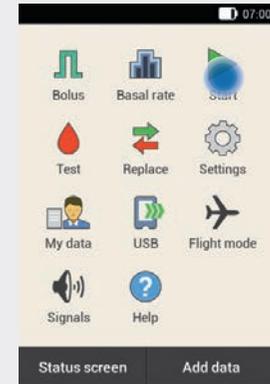
Note

Stopping the micropump cancels all ongoing boluses and the Temporary Basal Rate.

Starting or stopping insulin delivery



or



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

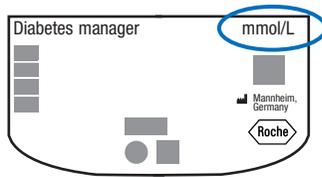
In the Main menu, tap **Start** .

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 Blood Glucose Level

5.1 Testing Blood Glucose

5.1.1 Checking the Unit of Measurement



Blood glucose results can be specified in two different units of measurement (mg/dL and mmol/L). 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

- ▶ The unit of measurement that your diabetes manager displays cannot be changed. Contact your Customer Support and Service Centre 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 recommendation 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 test results, and possible causes of incorrect test results.

5.1.2 Performing a Blood Glucose Test

After inserting a lancet drum into the finger pricker and setting the penetration depth, you can start the blood glucose test.

 **WARNING**

- ▶ A blood glucose test that was performed incorrectly can lead to incorrect test results and thus to wrong therapy recommendations being made, which can result in serious adverse health effects.
- ▶ A contaminated puncture site may lead to incorrect test results and infections. Wash your hands and the puncture site with warm water and soap and rinse them well.
- ▶ 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 Aviva test strips for the blood glucose test.

Prior to the 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.

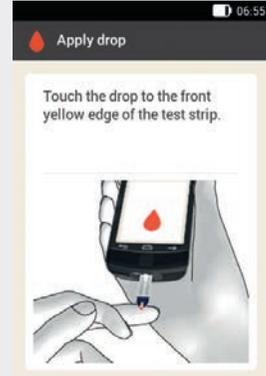
Inserting the test strip

3



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 signal sounds.

4



The **Apply drop** display 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.

Obtaining blood

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.

Applying blood

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



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

Displaying the test result

9



The test result is displayed and saved.

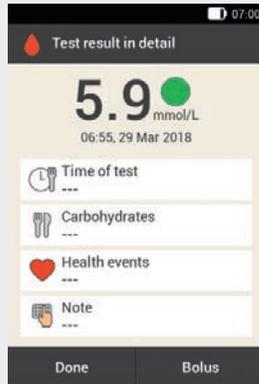
If the tone for blood glucose tests is turned on, a signal sounds.

Tap **OK**.

Note

- ▶ For more information about blood glucose results, see chapter 5.1.4 *Evaluating Test Results*.
- ▶ The blood glucose result can be used for bolus advice for a period of 15 minutes.

10



After approximately 3 seconds the **Test result in detail** display appears.

If you want to add information (Time of test, Carbohydrates, Health events, Note) to the test result, 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



Remove the used test strip and dispose of it according to local regulations.

5.1.3 Adding Information

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

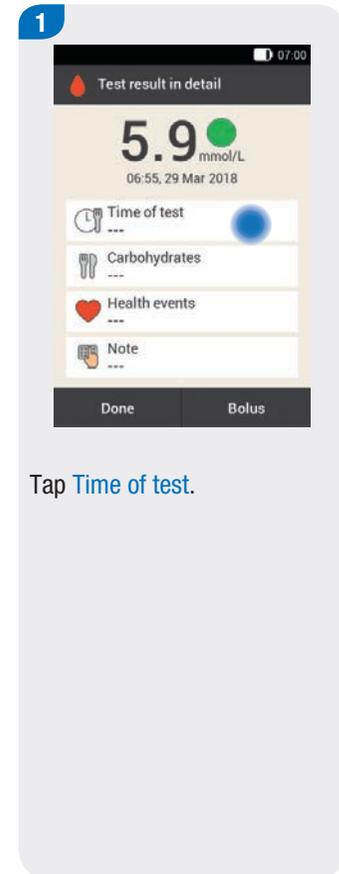
If you are using the bolus advice feature, also see the information in chapter 7 *Bolus Advice*.

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 blood glucose level.



2



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

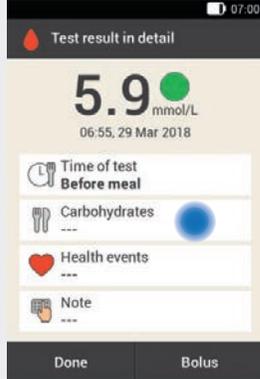
Tap [Save](#).

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



Tap [Carbohydrates](#).

4



Use **-** or **+** to set the carbohydrate amount you consumed. Alternatively, you can enter the carbohydrate amount using the numeric keypad. To do so, tap the **⌨** symbol.

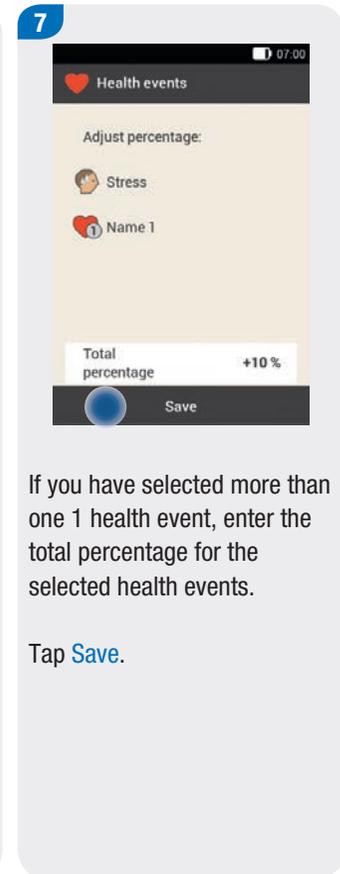
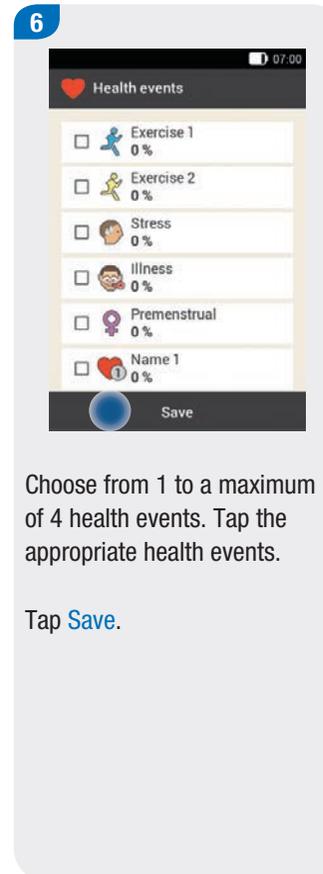
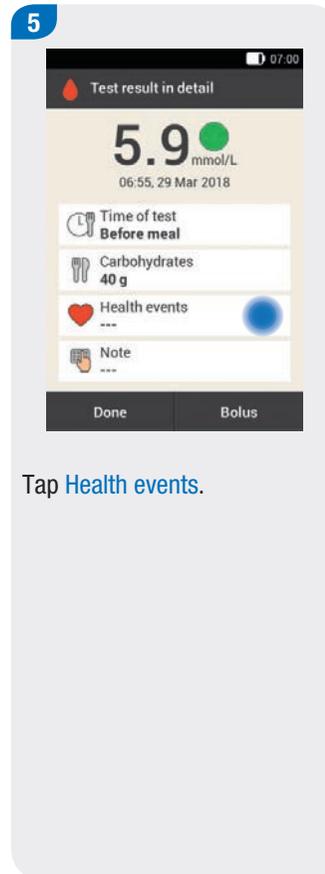
Tap [Save](#).

Setting health events

Health events help you with the evaluation of your blood glucose results.

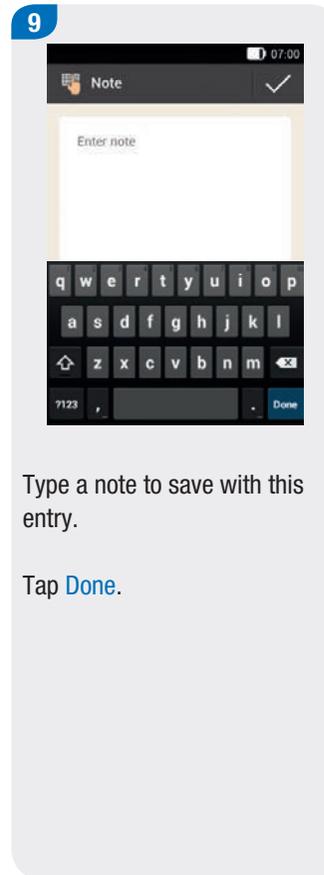
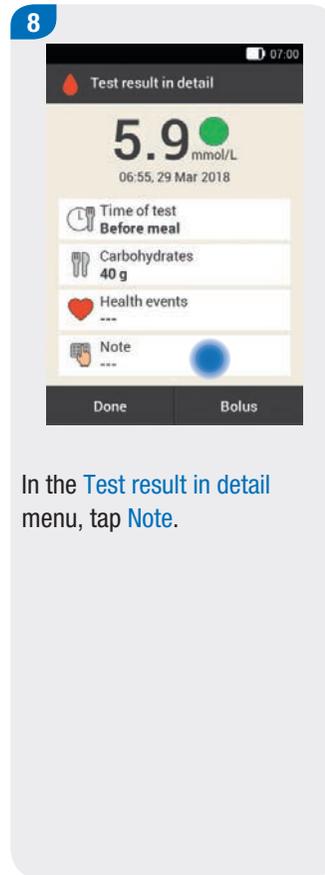
If you have set up bolus advice and select a health event, bolus advice will be adjusted by the percentage you specified.

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



Entering a note

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

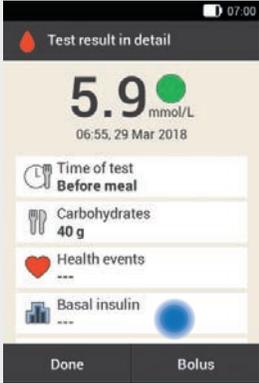


Entering basal insulin (injection mode)

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.

For more information on injection mode, see chapter *13 Injection Therapy Mode*.

10



Test result in detail

5.9 mmol/L

06:55, 29 Mar 2018

Time of test
Before meal

Carbohydrates
40 g

Health events

Basal insulin

Done Bolus

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

11



Basal insulin

20.0

U

OK

Use **-** and **+** to set the desired amount of basal insulin.

Tap **OK**.

5.1.4 Evaluating Test Results

Blood glucose results reflect the current status of the blood glucose level. Test results are influenced by different factors, including type of diet, medication taken, state of health, stress and physical activity.

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

Note

Do not change your therapy based on individual blood glucose results.



WARNING

- ▶ If your blood 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 test result does not match how you feel, test your blood glucose again to rule out an incorrect test result. If test results repeatedly do not match how you feel, check the items in chapter *5.1.8 Causes of Implausible Test Results*.

5.1.5 Colour Coding of Test Results

On the [Test result in detail](#) display, a coloured dot appears to the right of the test result. The colour of the dot depends on how high the test result is in relation to the defined blood glucose target range for the current time block.

Overview of meaning of colours:

Colour of dot	Blood glucose result 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.

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

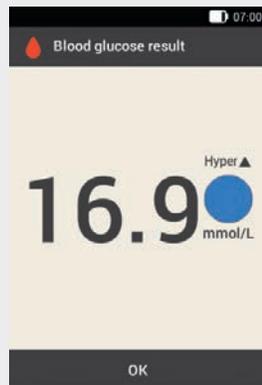
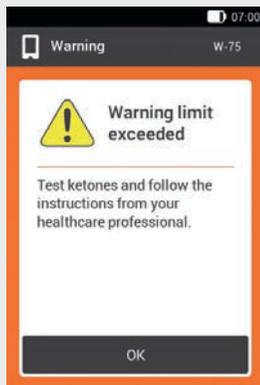
Symptoms of low blood glucose may include:

- ▶ 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

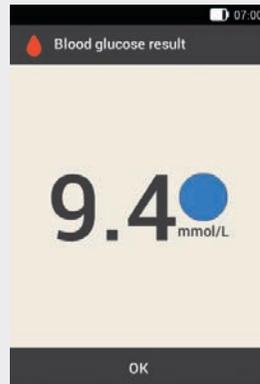
Blue with Hyper



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

Blue dot with the additional information **Hyper**:
The blood glucose result exceeds the hyper warning limit.

Blue



Blue dot:
The blood glucose result is above the target range for the current time block.

The blood glucose result does not exceed the hyper warning limit.

Green



Green dot:
The blood glucose result is within the target range for the current time block.

Yellow

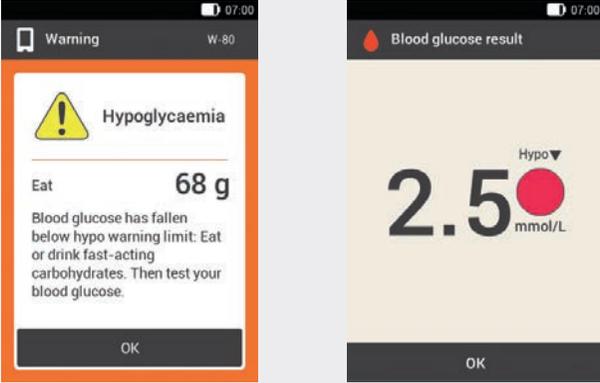


The smartphone screen displays "Blood glucose result" at the top. The main display shows "3.8" in large black font, followed by a yellow circle and "mmol/L" in smaller black font. At the bottom, there is a black bar with the text "OK".

Yellow dot:
The blood glucose result is below the target range for the current time block.

The blood glucose result does not fall below the hypo warning limit.

Red



The first smartphone screen shows a "Warning" message with a yellow warning triangle icon. The text reads "Hypoglycaemia" and "Eat 68 g". Below this, it says "Blood glucose has fallen below hypo warning limit: Eat or drink fast-acting carbohydrates. Then test your blood glucose." At the bottom is a black bar with "OK".

The second smartphone screen shows "Blood glucose result" at the top. The main display shows "2.5" in large black font, followed by a red circle and "mmol/L" in smaller black font. Above the red circle is the word "Hypo" with a downward arrow. At the bottom, there is a black bar with the text "OK".

If the blood glucose result falls below the hypo warning limit, the diabetes manager will issue the W-80 warning before displaying the test result. This warning does **not** show the blood glucose result. Follow the warning instructions and confirm the warning with [OK](#) to go to the blood glucose result.

Red dot with the additional information [Hypo](#):
The blood glucose result falls below the hypo warning limit.

5.1.6 LO Display

The **LO** display means that the blood glucose result is outside the value range.

Note

The **LO** display means that your blood glucose value might be very low.

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

LO display



The blood glucose result 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.

5.1.7 HI Display

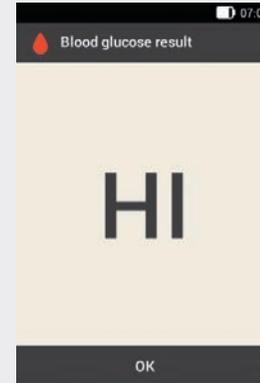
The **HI** display means that the blood glucose result is outside the value range.

Note

The **HI** display means that your blood glucose value might be very high.

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

HI display



The blood glucose result 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.

5.1.8 Causes of Implausible Test Results

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

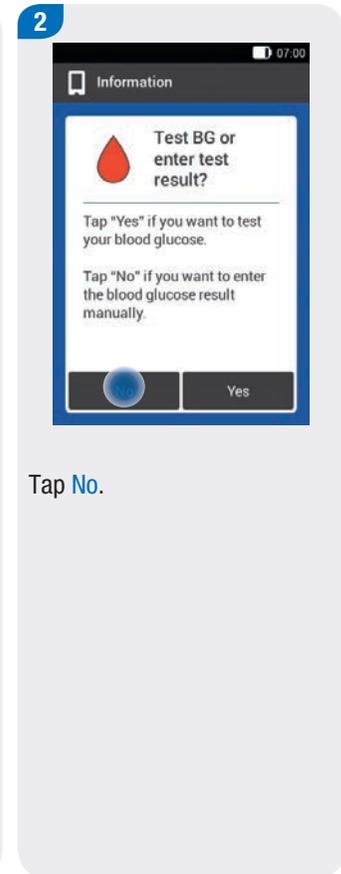
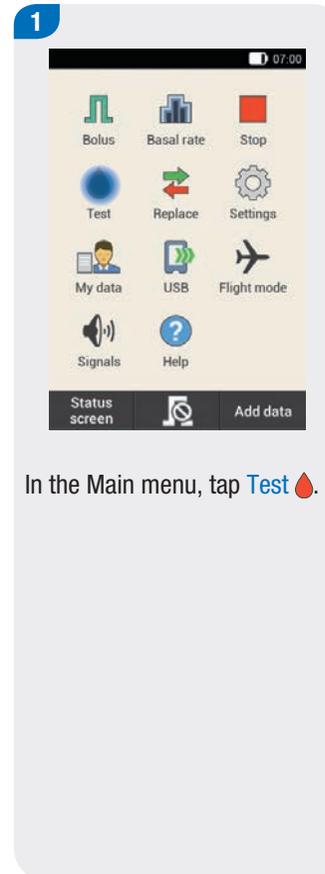
- ▶ Did you perform the blood glucose test as instructed in the User's Manual?
- ▶ Did you wash your hands with warm water and soap and dry them thoroughly?
- ▶ Did you only apply blood after **Apply drop** appeared on the screen?
- ▶ Did you apply the blood drop immediately after it had formed?
- ▶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

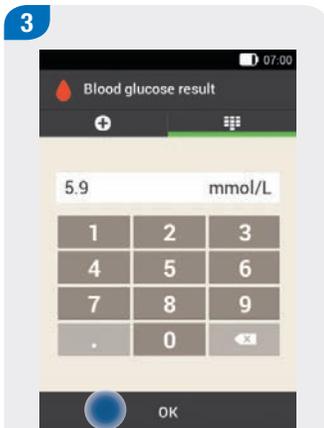
If you have observed all these items and are still experiencing implausible test results or receiving error messages, perform a control test. For more information, see chapter *14.2 Control Test of the Diabetes Manager*.

If you are not sure whether the diabetes manager is working properly, contact the Customer Support and Service Centre.

5.2 Entering Your Blood Glucose Value

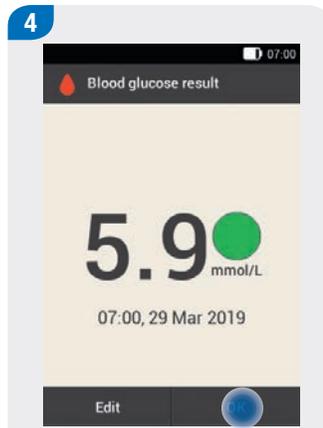
If you do not want to test your blood glucose with the diabetes manager, you can manually enter a blood glucose value that was measured using another meter on the screen intended for that purpose.



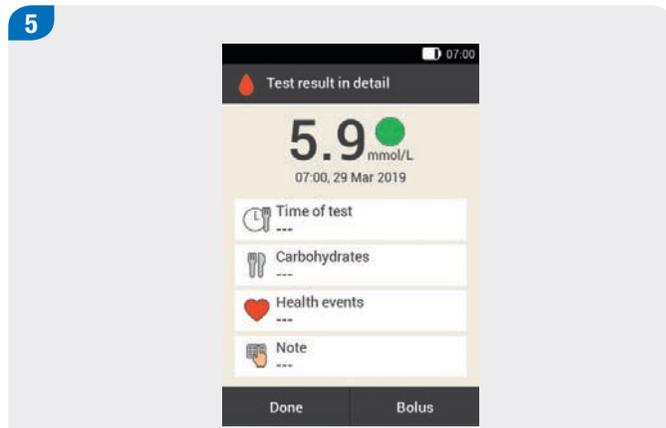


Enter the blood glucose value you measured with your meter using the numeric keypad. Alternatively, you can set the blood glucose value using the minus/plus buttons. To do so, tap the **+** symbol.

Tap **OK**.



Tap **OK**.



If you want to add information (Time of test, Carbohydrates, Health events, Note) to the entered blood glucose value, follow the instructions in the section *Adding Information* on the previous pages.

If you want to complete entering the blood 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 blood glucose level. The bolus type and bolus amount are determined by your healthcare professional's guidelines, your blood 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 Display

Blood glucose result

The current test result is displayed.
If no current test result exists, --- is displayed.

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.

Carbohydrate amount

The carbohydrate amount entered after performing a blood glucose test is displayed.
If no carbohydrate amount was entered, --- is displayed.

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.

Correction bolus

Tap this entry field to enter the insulin amount needed to bring a blood glucose value outside the target range back into the target range.

Meal bolus

Tap this entry field to enter the insulin amount to compensate for the food intake.

Bolus type

Tap this element to select one of the following bolus types: Standard bolus, extended bolus, multiwave bolus, quick bolus, pen/syringe.



6.3 Bolus Types

Note the following for bolus input:

- ▶ When the **Bolus input** display 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.

You can choose from the following bolus types on the **Bolus input** display:

- ▶ Standard bolus
- ▶ Extended bolus
- ▶ Multiwave bolus

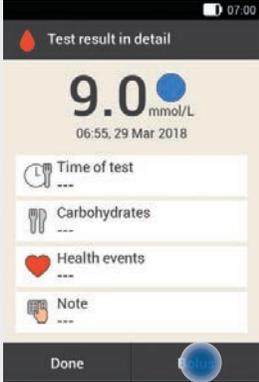
In addition, you can choose a quick bolus or a bolus with pen or syringe.

Symbol	Name	Description
	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 blood 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 blood 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 blood 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



Test result > Bolus

Option 1:

After testing your blood glucose: On the [Test result in detail](#) display, tap [Bolus](#). Continue with Step 3.

or



Status screen > Bolus

Option 2:

On the Status screen, tap [New bolus](#) or the **+** symbol.

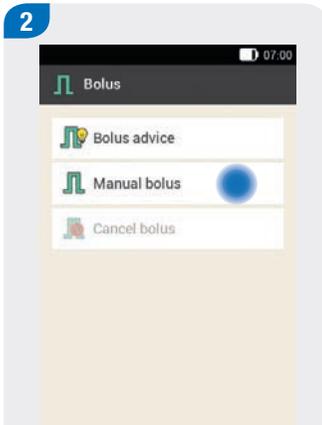
or



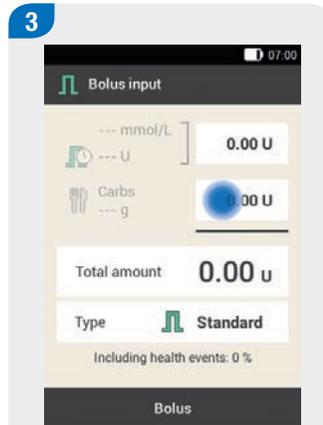
Main menu > Bolus

Option 3:

In the Main menu, tap the [Bolus](#) menu.



Tap **Manual bolus**.

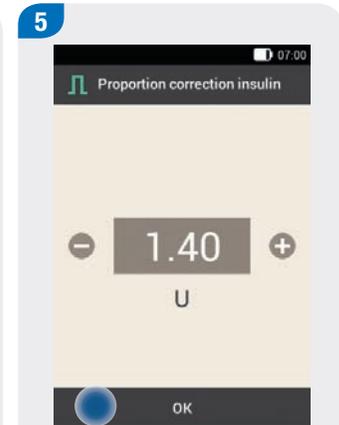


Tap the entry fields that are appropriate to your situation to enter the correction bolus, meal bolus or total amount.



Use **-** and **+** to set the desired amount for the meal bolus.

Tap **OK**.



Use **-** and **+** to set the desired amount for the correction bolus.

Tap **OK**.

6.4.1 Standard Bolus

1



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

Tap **Bolus**.

2



Check the total amount displayed.

To confirm this step and deliver the bolus, press the insulin button lit up in green  below the diabetes manager screen.

3



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

Note

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 blood glucose values. Therefore, you cannot select this bolus type if the bolus you programmed contains correction insulin.

1



Tap **Type** on the **Bolus input** display.

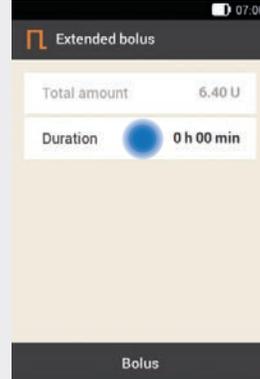
2



Tap **Extended bolus**.

Then tap **OK**.

3



Tap **Duration**.

4



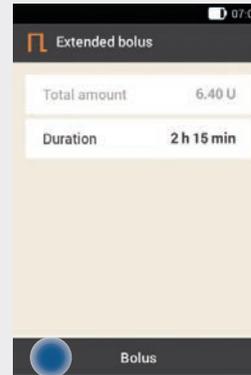
Use **-** and **+** to set the hours and minutes for the extended bolus duration.

Tap **OK**.

Note

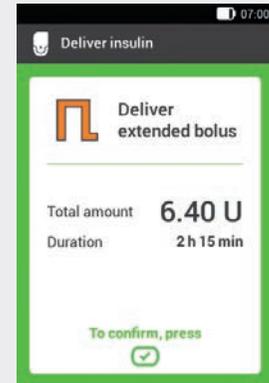
The duration you set for the extended bolus will be used as the default setting when the extended bolus is delivered the next time.

5



Tap **Bolus**.

6



Check the total amount and duration displayed.

To confirm this step and deliver the bolus, press the insulin button lit up in green  below the diabetes manager screen.

7



The screenshot shows a mobile application interface for insulin management. At the top, a blue header displays a glucose level of 9.0 mmol/L and the time 06:55, 29 Mar 2018. Below this, a white bar shows a bolus amount of 195 U. The main area is divided into sections: 'Profile 1' with a rate of 1.20 U/h, 'Extended bolus' with a total of 6.40 U and a duration of 2 h 15 min, and 'New bolus' with a plus sign icon. At the bottom, there are buttons for 'Main menu', a pump icon, and 'Add data'.

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

Note

You can add a standard bolus to an ongoing extended bolus and an additional extended bolus or a multiwave bolus.

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



Tap **Type** on the **Bolus input** display.

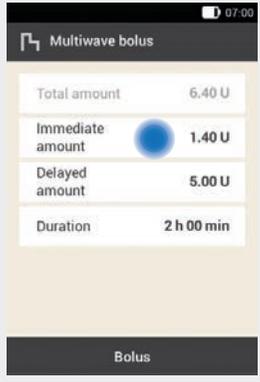
2



Tap **Multiwave bolus**.

Then tap **OK**.

3



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

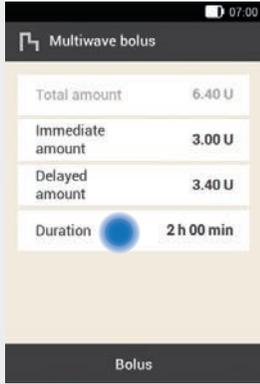


Use **-** and **+** to set the immediate amount.

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

Tap **OK**.

5



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

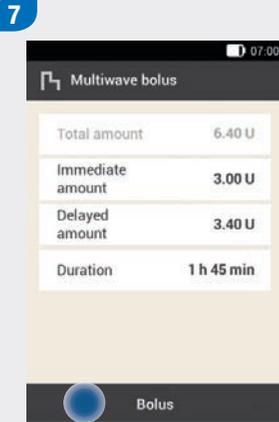


Use **-** and **+** to set the duration of the delayed amount.

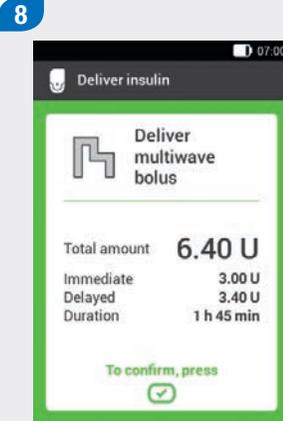
Tap **OK**.

Note

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

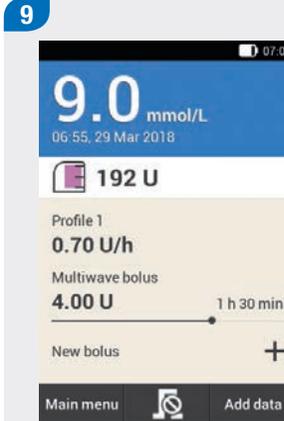


Tap **Bolus**.



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

To confirm this step and deliver the bolus, press the insulin button lit up in green  below the diabetes manager screen.



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

Note

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 flight mode is turned on.

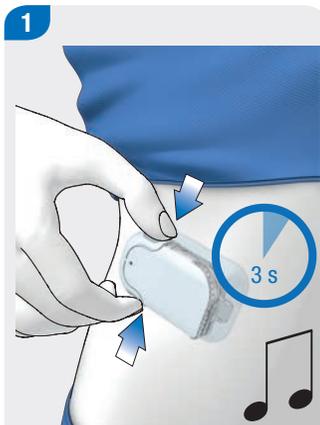
The bolus amount can only be programmed in defined increments. The factory setting for the quick bolus increment is 0.2 U. Therefore, you can set the bolus amount to be 0.2 U, 0.4 U, 0.6 U and so on. If necessary, you can change the quick bolus increment to 0.5 U, 1.0 U or 2.0 U. For more information, see chapter *11.3 Bolus Settings*.

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 sequence of signals for the quick bolus.



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

To exit the input display, 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 sequence of signals 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” signal sequence will sound.
- ▶ 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.
- ▶ For more information on the sequences of signals, see chapter *17.3 Signals*.

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 approx. 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” signal sequence.

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](#) display.

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.

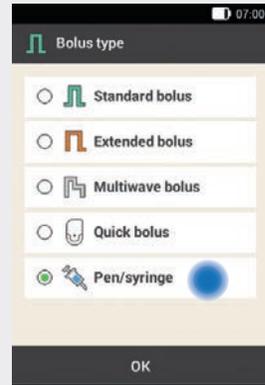
1



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](#) display is shown.

Tap [Type](#).

2



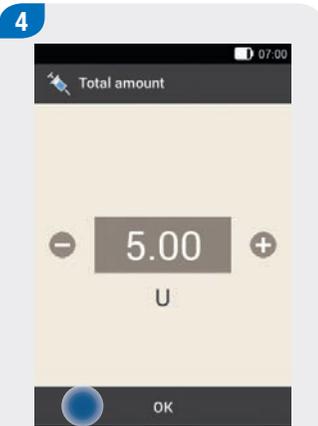
Tap the [Pen/syringe](#) bolus type.

3



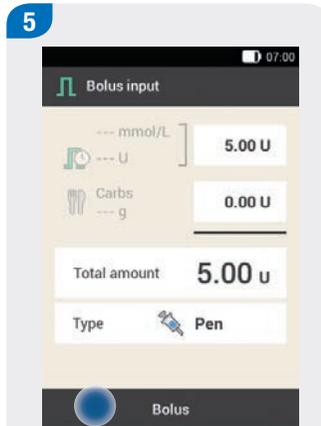
Tap the desired entry field.

If you tap [Total amount](#), the entered insulin amount is added to the correction bolus.

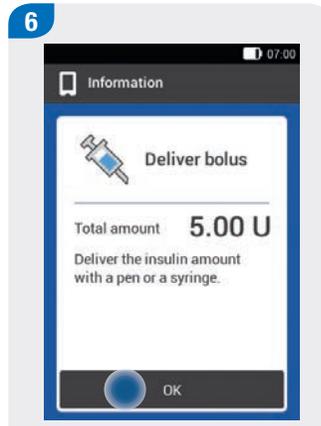


Use **-** and **+** to set the insulin amount you want to deliver using a pen or syringe.

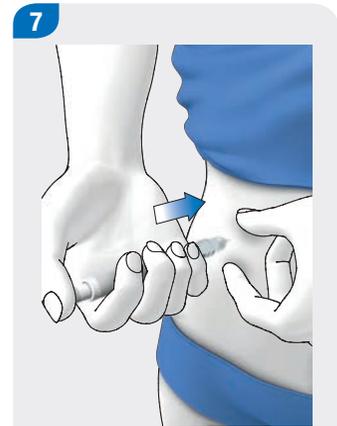
Tap **OK**.



Tap **Bolus**.



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



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 the  symbol.

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



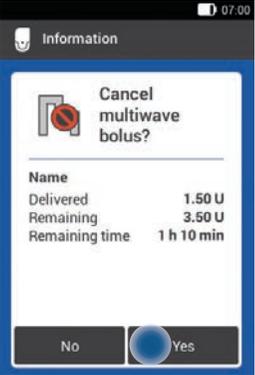
2



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

Tap the bolus you want to cancel.

3



The screenshot shows an 'Information' dialog box with a red 'X' icon. The title is 'Cancel multiwave bolus?'. Below the title, there is a table with the following data:

Name	
Delivered	1.50 U
Remaining	3.50 U
Remaining time	1 h 10 min

At the bottom of the dialog, there are two buttons: 'No' and 'Yes'.

If you want to cancel the bolus now, tap **Yes**.

4



The screenshot shows a 'Warning' dialog box with a yellow warning triangle icon. The title is 'Warning' and the subtitle is 'W-38'. The main text is 'Bolus cancelled'. Below this, there is a table with the following data:

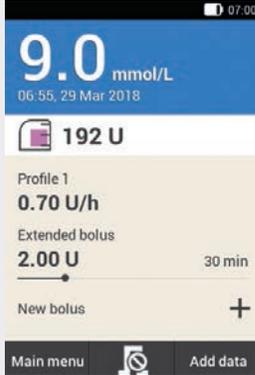
Delivered	1.50 U
Programmed	5.00 U

At the bottom of the dialog, there is an 'OK' button.

The W-38 warning is displayed.

Tap **OK** to confirm the warning.

5



The screenshot shows the Status screen with the following information:

- Glucose level: **9.0 mmol/L**
- Date and time: 06:55, 29 Mar 2018
- Total bolus: **192 U**
- Profile 1: **0.70 U/h**
- Extended bolus: **2.00 U** (30 min)
- New bolus: **+**
- Buttons: Main menu, Add data

The bolus has been cancelled and deleted from the Status screen.

6.7.2 Cancelling All Boluses

1



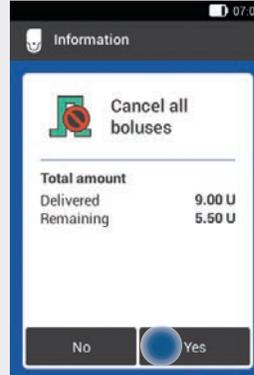
On the Status screen or in the Main menu, tap the option with the  symbol.

2



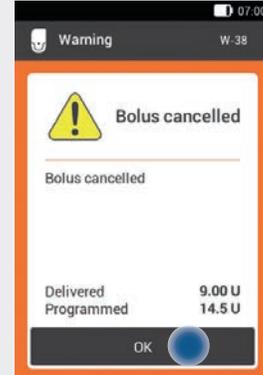
Tap **Cancel all boluses**.

3



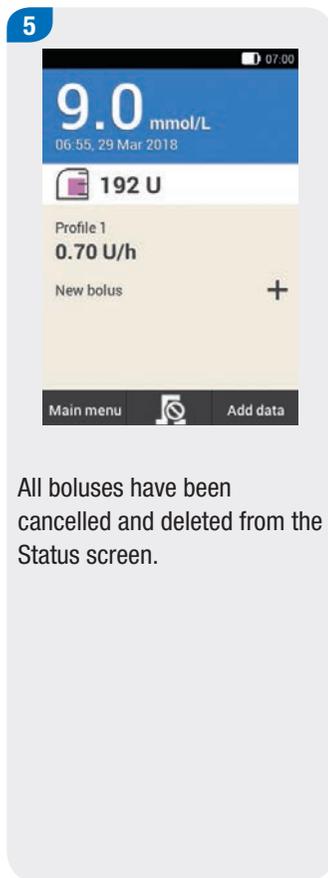
Tap **Yes**.

4



For each cancelled bolus, the W-38 warning is displayed.

Tap **OK** to confirm the warning.



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

6.8 Setting the Delivery Lag Time

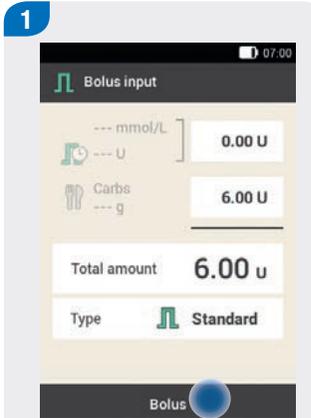
In some situations (for example, if you have gastroparesis) it may be helpful to only start a bolus after you have started eating. You can use the delivery lag time setting to specify an interval between programming a bolus and the actual start of bolus delivery.

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. For more information, see chapter 11.3 *Bolus Settings*.

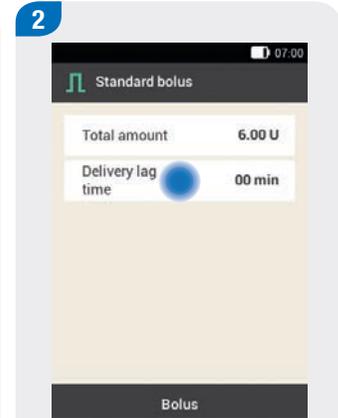
Note

If a bolus contains correction insulin or if the blood glucose result is above the target range, it is not possible to enter a delivery lag time. Correction insulin must always be delivered immediately.



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**.



Tap **Delivery lag time**.

3



Use **-** and **+** to set the delivery lag time. The delivery lag time can be 0, 15, 30, 45 or 60 minutes.

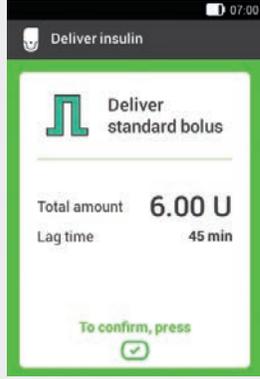
Tap **OK**.

4



Tap **Bolus**.

5



To confirm this step and deliver the bolus, press the insulin button lit up in green  below the diabetes manager screen.

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 blood 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.

7.1 Overview

The bolus advice feature of the diabetes manager consists of two components: First, a recommendation for a correction bolus to adjust your blood 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 blood glucose level is above your target range. If the blood 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 blood 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 blood glucose level back to within the target range.

Advantages of bolus advice:

- ▶ Bolus advice is calculated based on the current blood glucose value, your carbohydrate intake and other factors.
- ▶ Insulin from a previous bolus that is still acting is taken into account automatically.
- ▶ Errors that can occur in manual bolus calculations are prevented.
- ▶ The blood glucose values after meals are better.
- ▶ The metabolic adjustment is improved.
- ▶ Therapy schemes can be adhered to more consistently.
- ▶ Blood glucose values can be kept within the target range for a longer time period more easily.

Note the following:

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.

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 (i.e. within acceptable ranges).

Terminology for setting bolus advice

Time blocks

Time blocks allow you to divide the day into different time periods according to your individual lifestyle.

The target range, insulin sensitivity and carbohydrate ratio can be set individually for each time block.

Target range

The target range describes which blood glucose values are considered acceptable when fasting or before a meal. 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.

Insulin sensitivity

The insulin sensitivity defines the insulin amount required to lower your blood glucose level by a certain value.

Carbohydrate ratio

The carbohydrate ratio defines the insulin amount necessary to compensate for a certain amount of ingested carbohydrates.

Meal rise

During or after meals, an increase in the blood glucose level is considered normal within a certain range, even if a bolus was delivered beforehand. Enter the maximum increase in your blood glucose level that is to be tolerated without an additional correction bolus.

Snack size

The snack size defines a carbohydrate threshold; when this is exceeded, a meal rise should be taken into account. Thus, the snack size indicates the carbohydrate amounts up to which no increase in the blood glucose level is to be tolerated after a meal.

Acting time

The acting time is the period of time from the start of bolus delivery until the blood glucose level is expected to return to the target level.

The acting time includes the offset time.

Offset time

The offset time is the period of time after which the insulin is expected to start lowering the blood glucose level in the body.

Note

- ▶ 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.**

7.2 Setting Up Bolus Advice

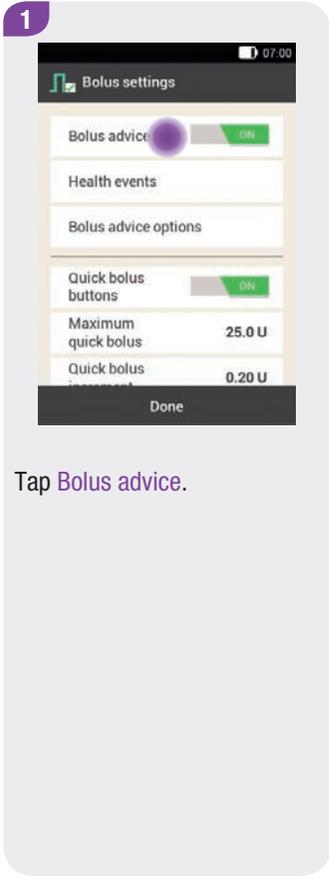
Main menu > Settings > Bolus settings

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.

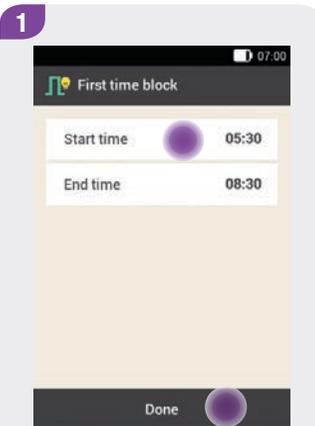


Tap **Bolus advice**.



Tap **Yes**.

Defining a time block

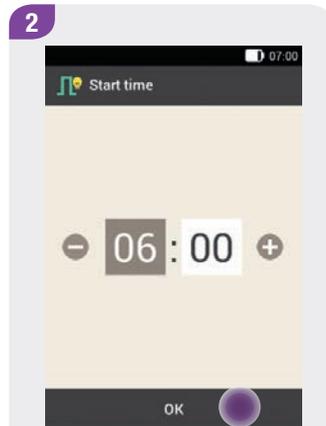


The display for defining the first time block appears.

Tap **Start time**.

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

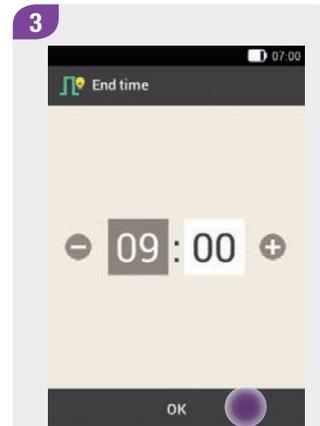
The  button is deactivated.



Use  and  to set the start time for the first time block.

You can set the minutes in 15-minute increments.

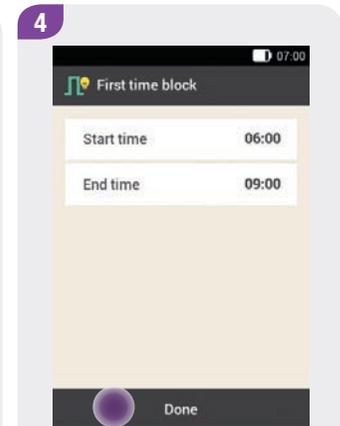
Tap **OK**.



Use  and  to set the end time for the first time block.

You can set the minutes in 15-minute increments.

Tap **OK**.

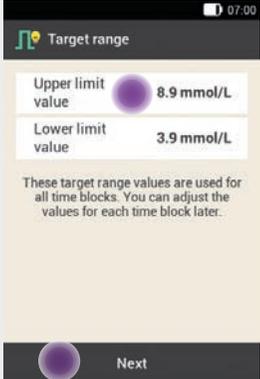


The changed start and end times for the first time block are displayed.

Tap **Done**.

Setting the target range

1



Target range

Upper limit value 8.9 mmol/L

Lower limit value 3.9 mmol/L

These target range values are used for all time blocks. You can adjust the values for each time block later.

Next

Tap **Upper limit value**.

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

2



Upper limit value

10.0

mmol/L

OK

Use **-** and **+** to set the upper limit value.

Tap **OK**.

3



Lower limit value

3.3

mmol/L

OK

Use **-** and **+** to set the lower limit value.

Tap **OK**.

4



Target range

Upper limit value 10.0 mmol/L

Lower limit value 3.3 mmol/L

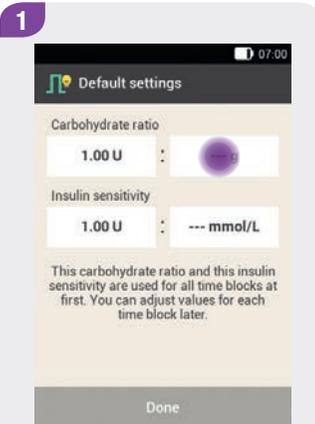
These target range values are used for all time blocks. You can adjust the values for each time block later.

Next

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

Tap **Next**.

Defining the default settings



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

Note

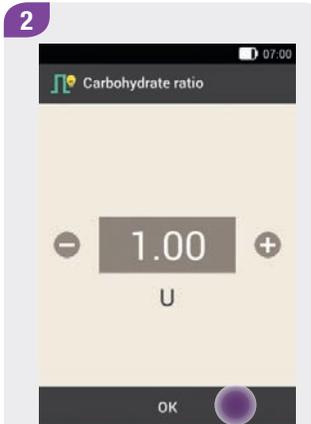
The **Done** button on the **Default settings** display remains deactivated (grey) until the entries for **Carbohydrate ratio** and **Insulin sensitivity** are complete.

Example

Carbohydrate ratio:
1.00 U : 10 g

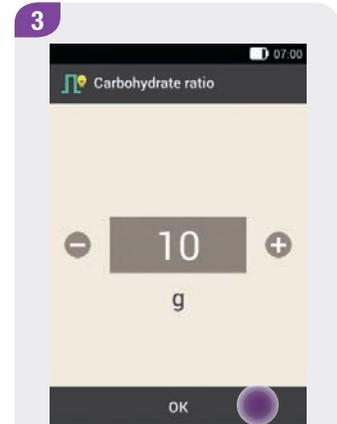
In this example, one insulin unit compensates for 10 g of carbohydrates.

Carbohydrate ratio



Use **−** and **+** to set the insulin units for the carbohydrate ratio.

Tap **OK**.



Use **−** and **+** to 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 blood glucose value by 2.2 mmol/L.

Insulin sensitivity



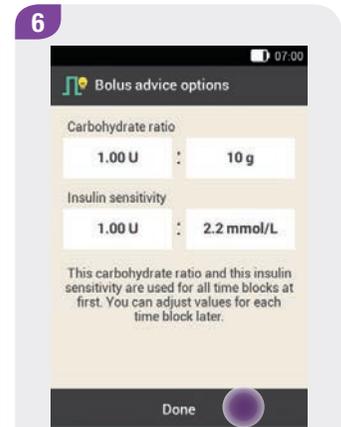
Use **-** and **+** to set the insulin units for the insulin sensitivity.

Tap **OK**.



Use **-** and **+** to set the blood glucose value for the insulin sensitivity.

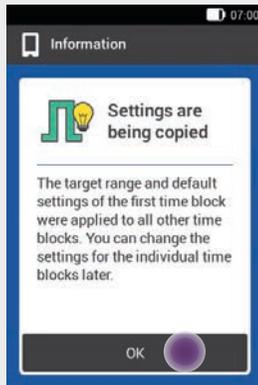
Tap **OK**.



Tap **Done**.

Changing time block settings

7



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**.

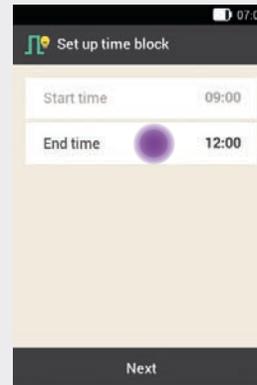
1



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 *Setting a health event*.

2



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.

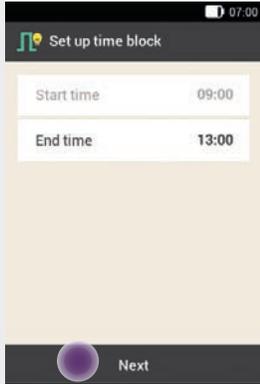
3



Set the end time for the selected time block.

Tap **OK**.

4



Tap **Next**.

5



Set the upper and lower limit values.

Tap **Next**.

6



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

Setting health events

Your state of health and your activities have an impact on your blood 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 %.

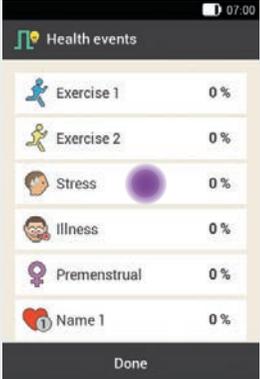
Example

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 %.

Setting a health event

1



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

2



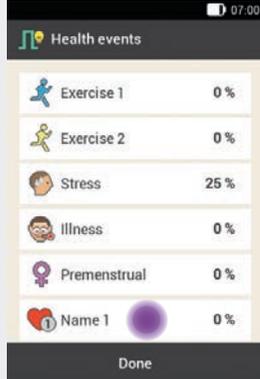
Enter a percentage for the selected health event.

Tap **Save**.

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

Setting a customised health event

1

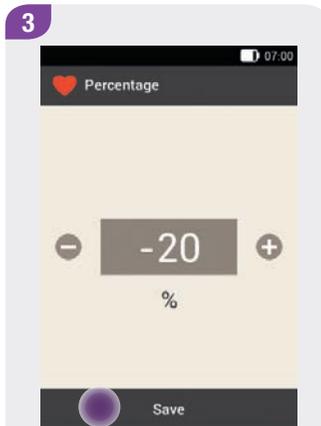


If you want to set a customised health event, tap .

2

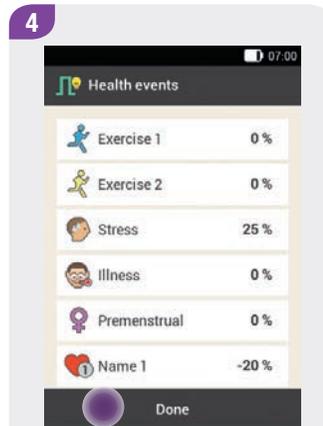


Tap  to enter a name for the customised health event (for example, Run).



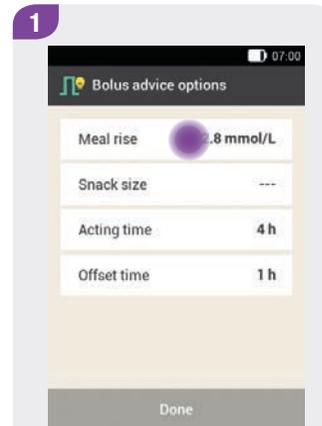
Use **−** and **+** to set the percentage for the customised health event.

Tap **Save**.



Tap **Done**.

Bolus advice options



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

Note

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

Meal rise

2

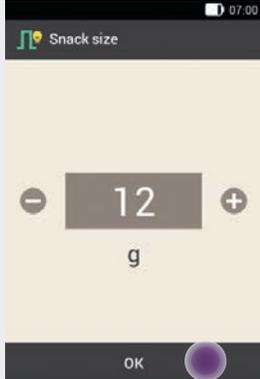


Use **-** and **+** to set the meal rise value.

Tap **OK**.

Snack size

3



Use **-** and **+** to set the snack size value.

Tap **OK**.

Acting time

4



Use **-** and **+** to set the hours and minutes for the acting time.

Tap **OK**.

Offset time

5



Use **-** and **+** to set the hours and minutes for the offset time.

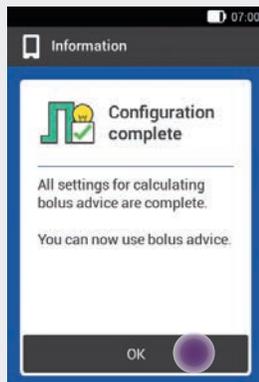
Tap **OK**.

6



Tap **Done** to complete the setup wizard.

7



All settings for calculating bolus advice are now complete.

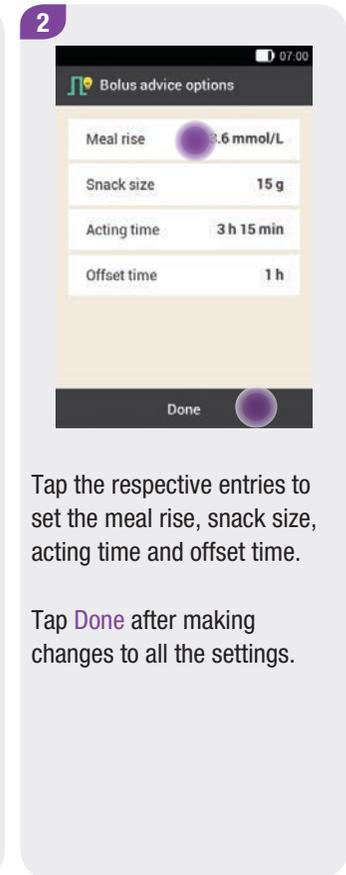
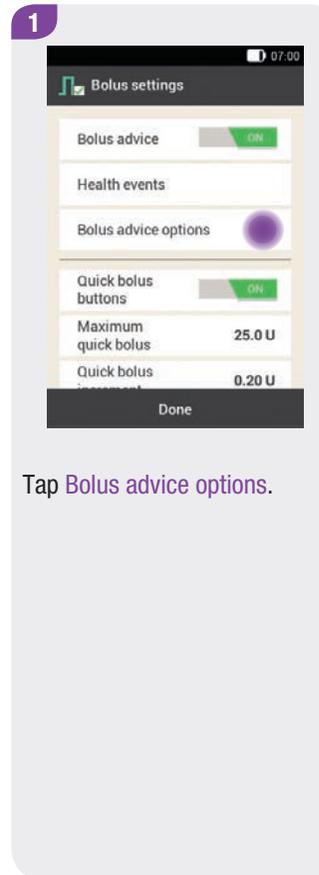
Tap **OK**.

7.3 Changing Bolus Advice and Time Blocks

Main menu > Settings > Bolus settings

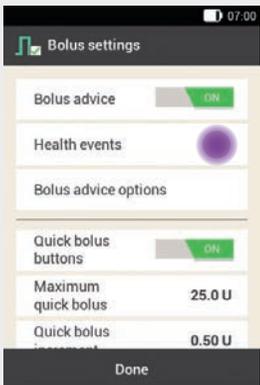
7.3.1 Changing Bolus Advice Options

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



7.3.2 Changing Percentages for Health Events

1



Bolus settings

Bolus advice

Health events

Bolus advice options

Quick bolus buttons

Maximum quick bolus 25.0 U

Quick bolus increment 0.50 U

Done

Tap **Health events**.

2



Health events

Exercise 1 0 %

Exercise 2 0 %

Stress 25 %

Illness 0 %

Premenstrual 0 %

Name 1 -20 %

Done

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

3



Percentage

- 15 +

%

Save

Enter a percentage for the selected health event.

Tap **Save**.

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

4



Health events

Exercise 1 0 %

Exercise 2 0 %

Stress 15 %

Illness 0 %

Premenstrual 0 %

Name 1 -20 %

Done

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

Tap **Done** after setting the health events.

7.3.3 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

A screenshot of the main menu of a mobile application. The menu consists of a 3x3 grid of icons with labels: Bolus (green line graph), Basal rate (blue bar chart), Stop (red square), Test (red drop), Replace (green and red arrows), Settings (purple circle), My data (person icon), USB (blue USB symbol), Flight mode (black airplane), Signals (speaker icon), and Help (blue question mark). At the bottom, there are three buttons: 'Status screen', a circular arrow icon, and 'Add data'. The top status bar shows the time as 07:00.

In the Main menu, tap the **Settings** menu.

2

A screenshot of the 'Settings' menu. The menu items are: Reminders (yellow bell icon), Warning limits (yellow warning triangle icon), Time and date (clock icon), Bolus settings (green line graph icon), Time blocks (purple circle icon), Tone and vibration (speaker icon), and General settings (gear icon). A purple circle is positioned over the 'Time blocks' option. The top status bar shows the time as 07:00.

Tap **Time blocks**.

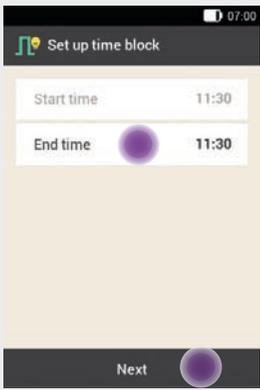
3

A screenshot of the 'Time blocks' list. The list contains five time ranges: 05:30 – 08:30, 08:30 – 11:30, 11:30 – 15:30, 15:30 – 22:00, and 22:00 – 05:30. A purple circle is positioned over the 11:30 – 15:30 time block. At the bottom, there is a 'Done' button. The top status bar shows the time as 07:00.

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

Start time 11:30

End time 11:30

Next

Decrease the end time until it equals the start time.

Tap **Next**.

5



Target range

Upper limit value 7.5 mmol/L

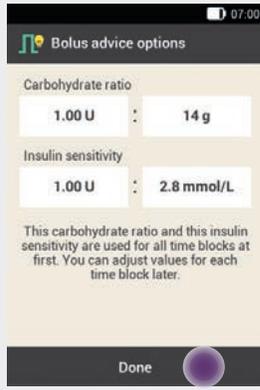
Lower limit value 3.6 mmol/L

Next

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

Tap **Next**.

6



Bolus advice options

Carbohydrate ratio

1.00 U : 14 g

Insulin sensitivity

1.00 U : 2.8 mmol/L

This carbohydrate ratio and this insulin sensitivity are used for all time blocks at first. You can adjust values for each time block later.

Done

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

Tap **Done**.

7



Time blocks

05:30 - 08:30

08:30 - 11:30

11:30 - 22:00

22:00 - 05:30

Done

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**.

7.3.4 Deleting Several Time Blocks

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

1

A screenshot of the main menu of a mobile application. The menu is organized into a grid of icons with labels: Bolus, Basal rate, Stop, Test, Replace, Settings, My data, USB, Flight mode, Signals, and Help. At the bottom, there are buttons for 'Status screen' and 'Add data'. The time 07:00 is displayed in the top right corner.

In the Main menu, tap the **Settings** menu.

2

A screenshot of the 'Settings' menu. The menu items are: Reminders, Warning limits, Time and date, Bolus settings, Time blocks, Tone and vibration, and General settings. A purple circular highlight is positioned over the 'Time blocks' option. The time 07:00 is displayed in the top right corner.

Tap **Time blocks**.

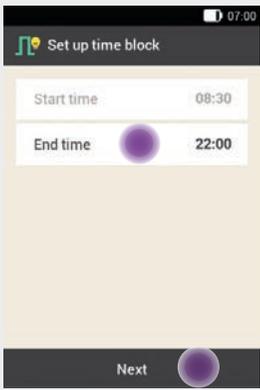
3

A screenshot of the 'Time blocks' list. It shows a list of time intervals: 05:30 – 08:30, 08:30 – 11:30, 11:30 – 15:30, 15:30 – 22:00, and 22:00 – 05:30. A purple circular highlight is positioned over the 08:30 – 11:30 block. A 'Done' button is at the bottom. The time 07:00 is displayed in the top right corner.

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

Start time 08:30

End time 22:00

Next

Increase the end time until it equals the end time of the last time block to be deleted.

Tap **Next**.

5



Target range

Upper limit value 7.8 mmol/L

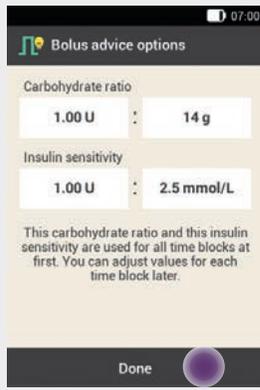
Lower limit value 3.9 mmol/L

Next

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

Tap **Next**.

6



Bolus advice options

Carbohydrate ratio

1.00 U : 14 g

Insulin sensitivity

1.00 U : 2.5 mmol/L

This carbohydrate ratio and this insulin sensitivity are used for all time blocks at first. You can adjust values for each time block later.

Done

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

Tap **Done**.

7



Time blocks

05:30 - 08:30

08:30 - 22:00

22:00 - 05:30

Done

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

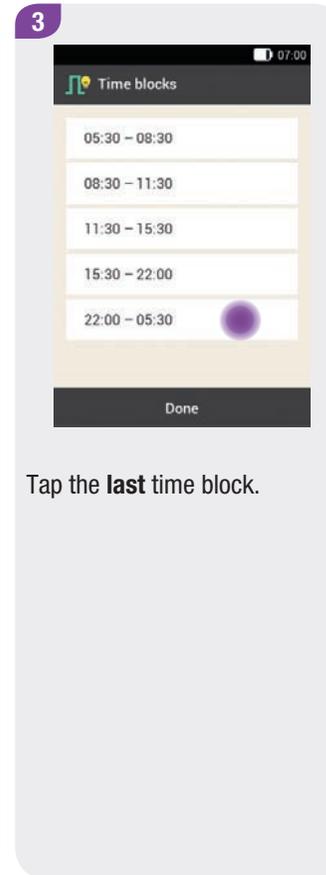
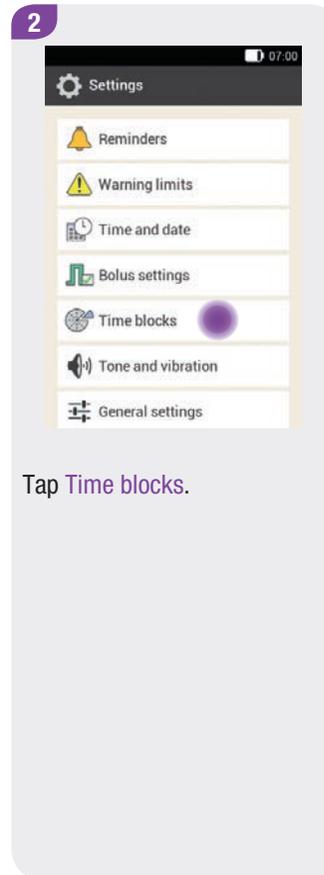
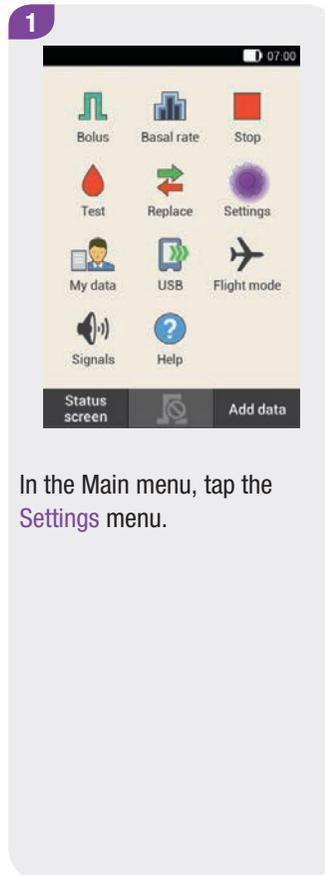
Tap **Done** when you have finished editing the time blocks.

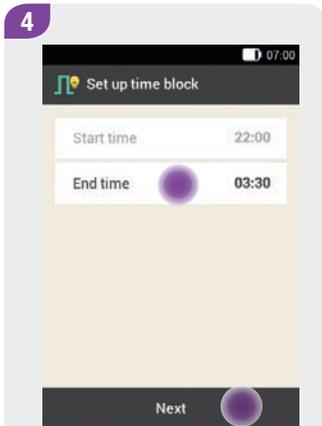
7.3.5 Adding a Time Block

This section describes how to add a new time block.

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

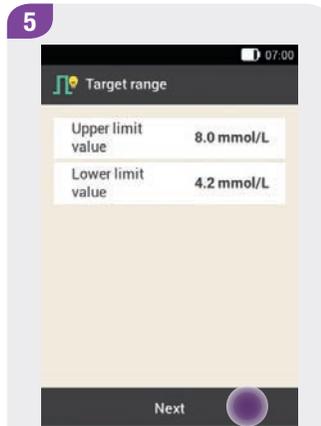
After the new time block has been created, you may have to adjust the end time and other information for each time block.





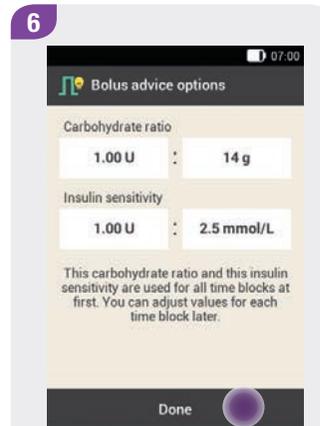
Tap **End time** and decrease the end time in order to create a new time block. However, do not decrease the end time until it equals the start time because this will delete the time block.

Tap **Next**.



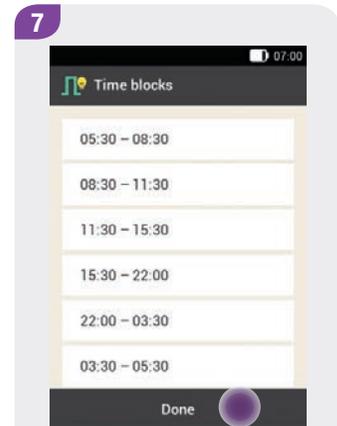
Set the upper limit value and lower limit value for the new time block.

Tap **Next**.



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

Tap **Done**.



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.

7.3.6 Resetting All Time Blocks

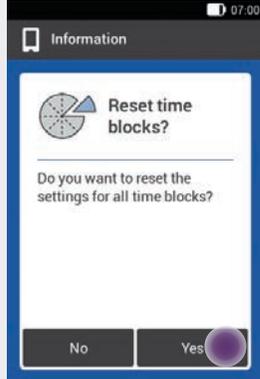
This section describes how to restore the settings for all time blocks to the factory settings and then re-enter them. Changing the start time of the first time block, for example, may be one reason for resetting all time blocks.

1



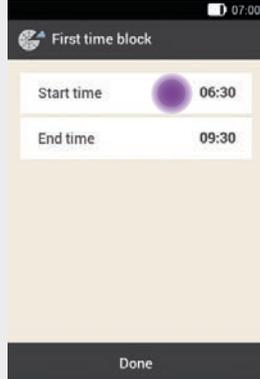
Tap **Reset**.

2



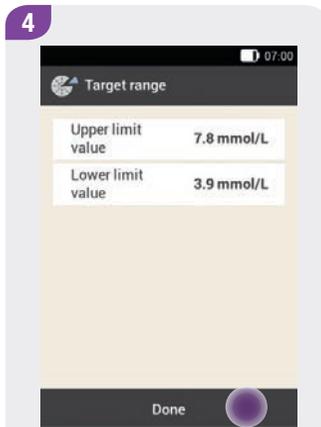
If you want to reset all time blocks, tap **Yes**.

3



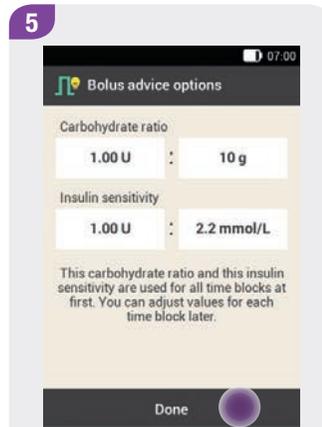
Set the start time and end time for the first time block.

Tap **Done**.



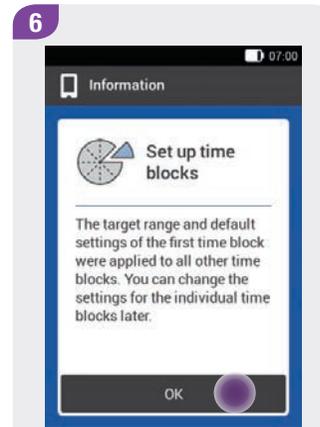
Set the upper limit value and lower limit value that are to be used for all time blocks for the time being.

Tap **Done**.

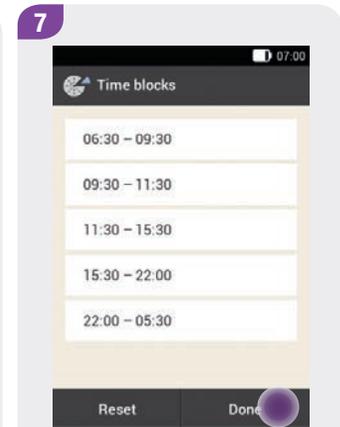


Set the carbohydrate ratio and the insulin sensitivity that are to be used for all time blocks for the time being.

Tap **Done**.



Tap **OK**.



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.

7.4 Using Bolus Advice

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

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



WARNING

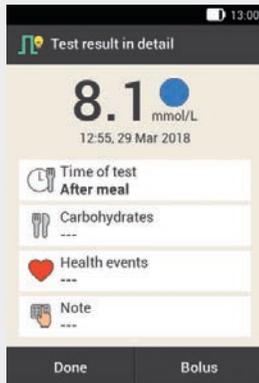
- ▶ Review manually entered data (for example, carbohydrate amount) used to calculate the bolus advice. Incorrectly entered values may lead to incorrect bolus advice.
- ▶ Note that the micropump system may give incorrect bolus advice if insulin is delivered manually (for example, by syringe or pen).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

In doing so, consider the following:

- ▶ Boluses for which bolus advice was used are indicated by the  symbol in the logbook. If no bolus advice is set up, bolus advice is turned off or a manual bolus was delivered, the  symbol 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 values for blood glucose results, carbohydrates and health events to calculate bolus advice, you will obtain the best results.

7.4.1 Starting Bolus Advice After a BG Test

1



Tap the respective entries to add information on time of test, carbohydrates or health events.

Tap **Bolus**.

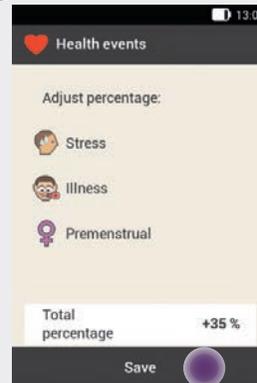
Note

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.

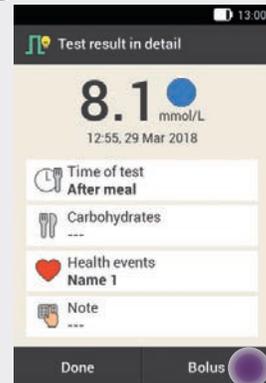
2



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

Tap **Save**.

3

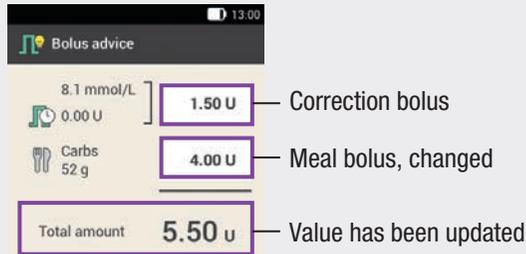


The bolus advice feature calculates a suggestion and transfers the recommended values to the entry fields in the bolus advice display. Tap the respective entry fields if you want to change the suggested values.

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**.

Note

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

For more information about the different bolus types, see chapter *6.3 Bolus Types*.

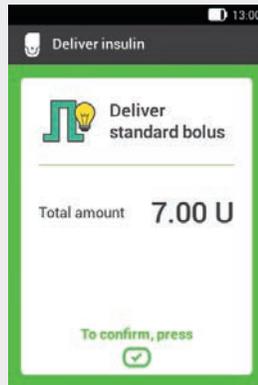
Confirming the bolus

5



Tap **Bolus**.

6



To confirm this step and deliver the bolus, press the insulin button lit up in green  below the diabetes manager screen.

7

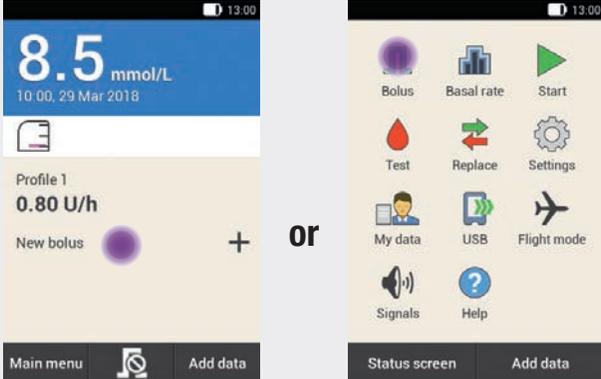


The Status screen is displayed showing the current bolus information.

7.4.2 Starting Bolus Advice With Manually Entered Test Result

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

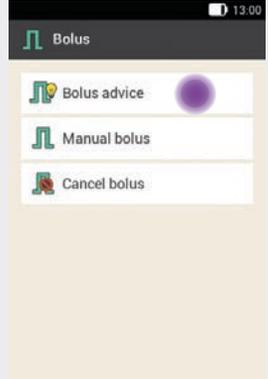
1



On the Status screen, tap **New bolus** or the **+** symbol.

In the Main menu, tap the **Bolus** menu.

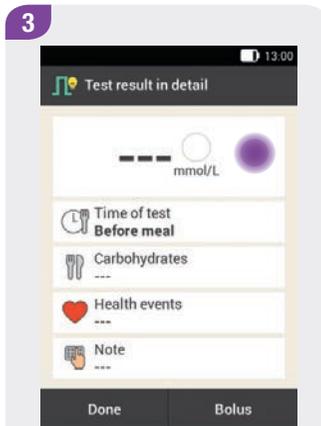
2



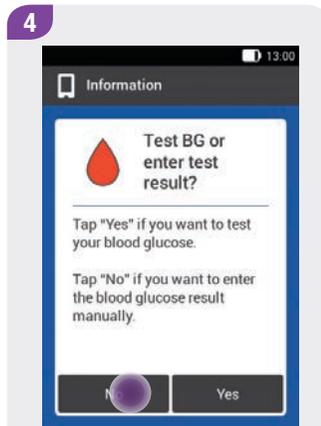
Tap **Bolus advice**.

Note

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

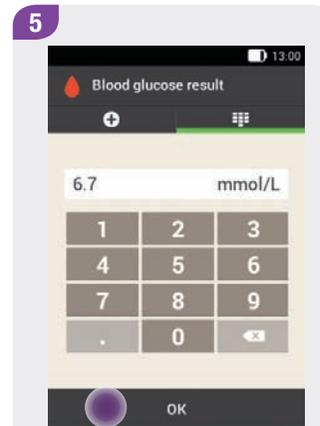


Tap the field for manually entering the blood glucose result.



Tap **No** if you want to enter the test result manually.

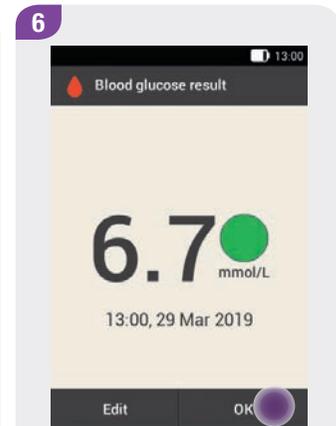
Entering the test result



Enter the test result using the numeric keypad and tap **OK**.

Alternatively, you can set the test result using **-** or **+**. To do so, tap the **+** symbol.

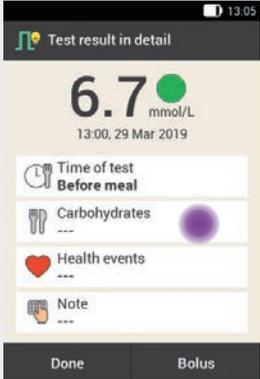
Confirming the test result



The entered test result is displayed. Tap **OK** if the test result is correct.

Entering carbohydrates

7



Tap the **Carbohydrates** entry.

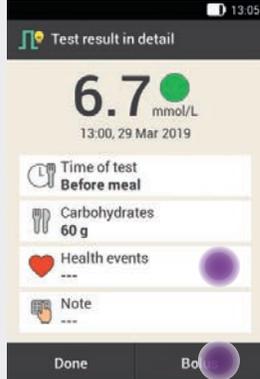
8



Use **-** or **+** to set the carbohydrate amount you want to eat. Alternatively, you can enter the carbohydrate amount using the numeric keypad. To do so, tap the **⌨** symbol.

Tap **Save**.

9



If necessary, enter any health events.

Tap **Bolus**.

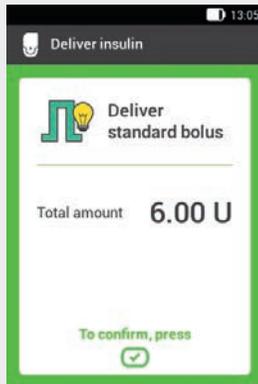
10



Once all entries are correct, tap **Bolus**.

Confirming the bolus

11

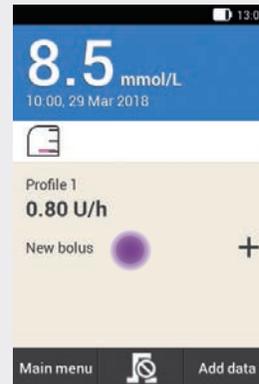


To confirm this step and deliver the bolus, press the insulin button lit up in green  below the diabetes manager display.

7.4.3 Starting Bolus Advice Without a BG Result

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** display, a suggestion for a meal bolus is displayed.

1

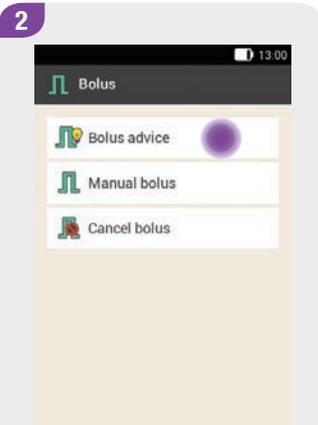


On the Status screen, tap **New bolus** or the **+** symbol.

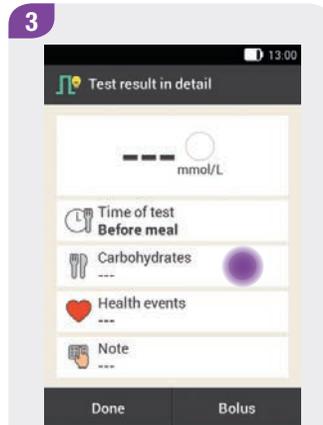
or



In the Main menu, tap the **Bolus** menu.

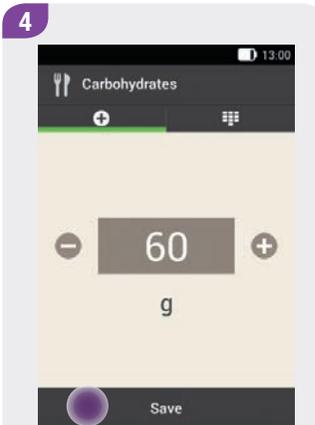


Tap **Bolus advice**.



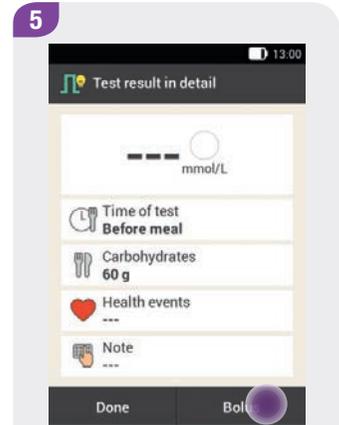
Tap **Carbohydrates**.

Entering carbohydrates



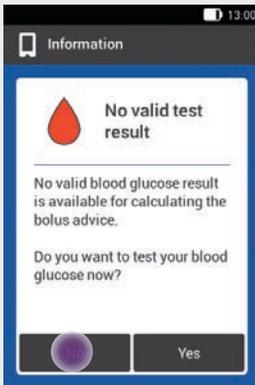
Use **-** or **+** to set the carbohydrate amount you want to eat. Alternatively, you can enter the carbohydrate amount using the numeric keypad. To do so, tap the **⌨** symbol.

Tap **Save**.



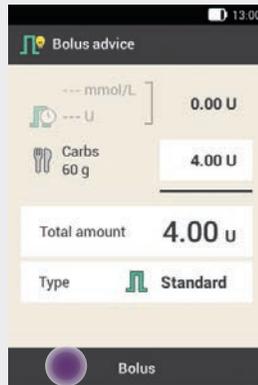
Tap **Bolus**.

6



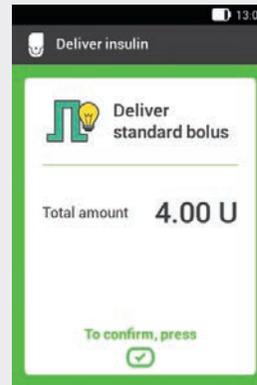
Tap **No** to use bolus advice without performing a blood glucose test.

7



Once all entries are correct, tap **Bolus**.

8



To confirm this step and deliver the bolus, press the insulin button lit up in green  below the diabetes manager screen.

7.4.4 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



The screenshot shows the 'Bolus advice' screen with the following data:

0.8 mmol/L	1.50 U
0.00 U	
Carbs 40 g	3.00 U
Total amount	4.50 U
Type	Standard

Bolus

Start bolus advice with or without testing your blood glucose.

Tap **Type**.

2

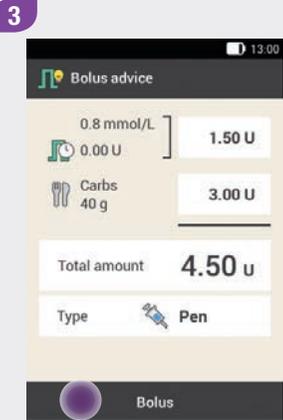


The screenshot shows the 'Bolus type' screen with the following options:

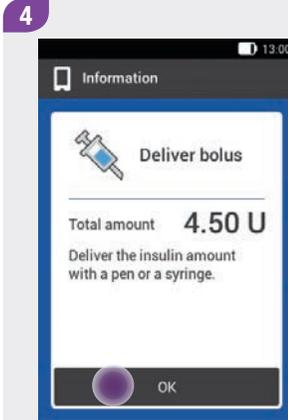
- Standard bolus
- Extended bolus
- Multiwave bolus
- Quick bolus
- Pen/syringe

OK

Tap **Pen/syringe**.

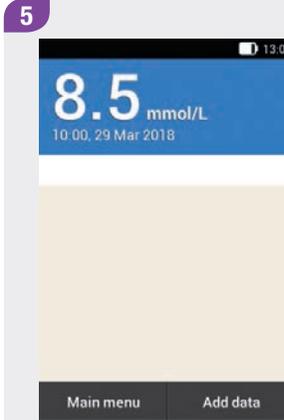


Once you have completed your entries, tap **Bolus**.

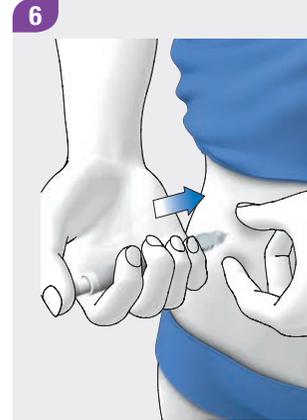


Tap **OK**.

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.



The Status screen is displayed.



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

7.5 Turning Off Bolus Advice

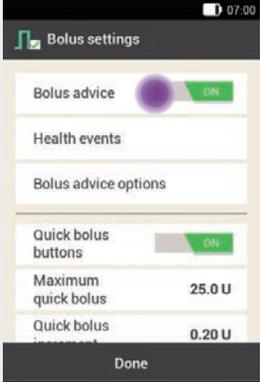
Main menu > Settings > Bolus settings

This section describes how to turn off bolus advice.

Note

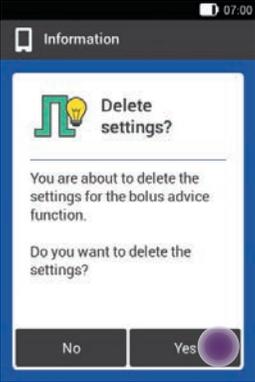
If you turn off bolus advice, all bolus advice options will be deleted. If you want to use bolus advice again, you must set it up once again.

1



Tap **Bolus advice**.

2



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

8.1 Basal Rate Profiles

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 differ 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 cancelled.

8.2 Creating and Editing a Basal Rate Profile

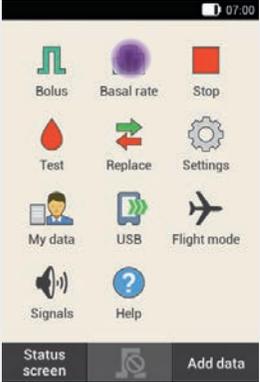
A basal rate profile can be programmed, edited and deleted in different ways. Start by using one of the following two options:

1



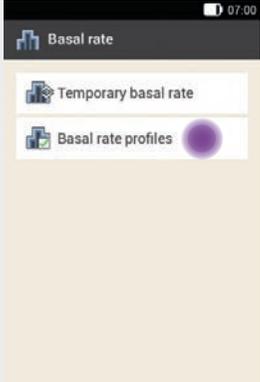
On the Status screen, tap the area indicating the basal rate.

or



In the Main menu, tap the Basal rate menu.

2

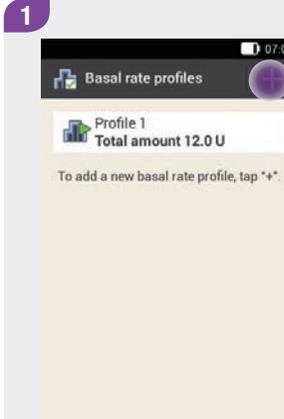


In the Basal rate menu, tap Basal rate profiles.

8.2.1 Programming a Basal Rate Profile

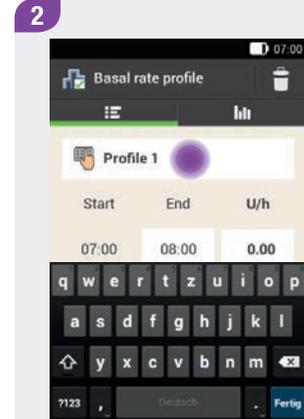
Note

- ▶ 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 delivered, 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.



Tap + to add a basal rate profile.

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

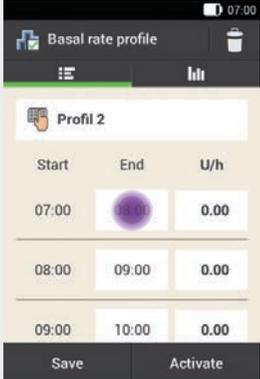


Tap the item with the  symbol.

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

Tap **Done**.

3



The screenshot shows the 'Basal rate profile' screen for 'Profil 2'. It features a table with three columns: 'Start', 'End', and 'U/h'. The first row shows a time block from 07:00 to 08:00 with a basal rate of 0.00 U/h. The second row shows a block from 08:00 to 09:00 with 0.00 U/h. The third row shows a block from 09:00 to 10:00 with 0.00 U/h. At the bottom, there are 'Save' and 'Activate' buttons.

Start	End	U/h
07:00	08:00	0.00
08:00	09:00	0.00
09:00	10:00	0.00

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

4



The screenshot shows the 'End time' screen with a time picker set to 08:30. There are minus and plus buttons on either side of the time display, and an 'OK' button at the bottom.

Use **-** and **+** to set the end time for the time block.

Tap **OK**.

5



The screenshot shows an 'Information' dialog box with the title 'Overwrite time block?'. The text inside reads: 'The end time you have selected shortens or overwrites the next time block. Do you want to continue?'. There are 'No' and 'Yes' buttons at the bottom.

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

Tap **Yes**.

6

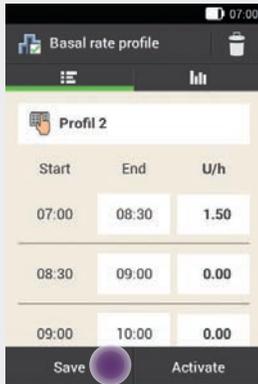


The screenshot shows the 'Basal rate' screen with a basal rate of 1.50 U/h. There are minus and plus buttons on either side of the rate display, and an 'OK' button at the bottom.

Use **-** and **+** to set the basal rate for the time block (for example, 1.50 U/h).

Tap **OK**.

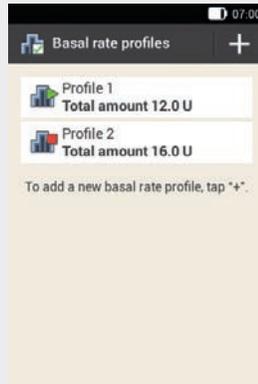
7



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.

Note

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. For more information, see chapter *8.2.3 Changing a Basal Rate Profile*.

8.2.2 Activating a Basal Rate Profile

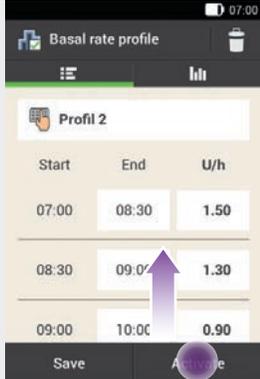
1



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

The currently active basal rate profile is indicated by the  symbol.

2



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

Once all settings are correct, tap **Activate**.

3



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

Tap **Yes**.

4

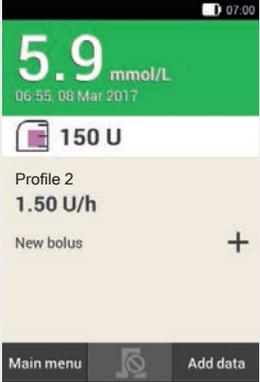


To confirm this step and activate the basal rate profile, press the insulin button lit up in green  below the diabetes manager screen.

Note

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

5



The screenshot shows a mobile application interface. At the top, a green bar displays a glucose reading of 5.9 mmol/L and the time 06:55, 08 Mar 2017. Below this, a white bar shows a bolus of 150 U. The main area is light beige and displays 'Profile 2' with a basal rate of 1.50 U/h and a 'New bolus' field with a plus sign. At the bottom, there are three buttons: 'Main menu', a circular icon with a diagonal line, and 'Add data'.

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

8.2.3 Changing a Basal Rate Profile

1



Basal rate profiles

Profile 1
Total amount 12.0 U

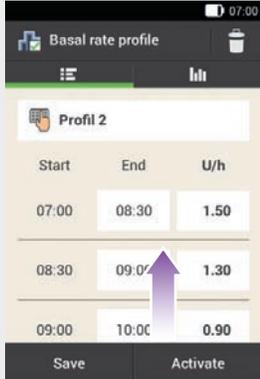
Profile 2
Total amount 16.0 U

To add a new basal rate profile, tap "+".

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

The currently active basal rate profile is indicated by the  symbol.

2



Basal rate profile

Profil 2

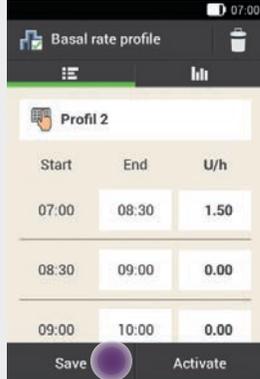
Start	End	U/h
07:00	08:30	1.50
08:30	09:00	1.30
09:00	10:00	0.90

Save Activate

If required, scroll the display 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

Profil 2

Start	End	U/h
07:00	08:30	1.50
08:30	09:00	0.00
09:00	10:00	0.00

Save Activate

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

Tap **Save**.

4



Basal rate profiles

Profile 1
Total amount 12.0 U

Profile 2
Total amount 16.0 U

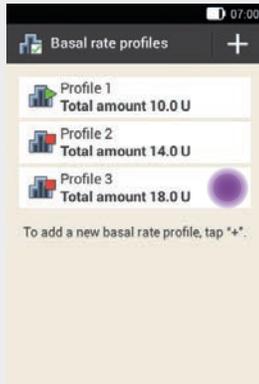
To add a new basal rate profile, tap "+".

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.

8.2.4 Deleting a Basal Rate Profile

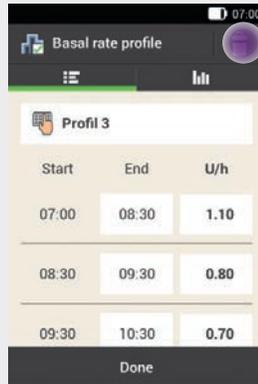
1



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

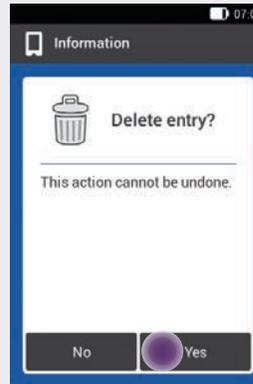
Note that the active basal rate profile cannot be deleted. The active basal rate profile is indicated by the  symbol.

2



Tap the  symbol in the upper right corner of the screen.

3



Tap **Yes** to delete the basal rate profile.

4



The selected basal rate profile was deleted from the list of available basal rate profiles.

8.3 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 blood 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.

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.

8.4 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



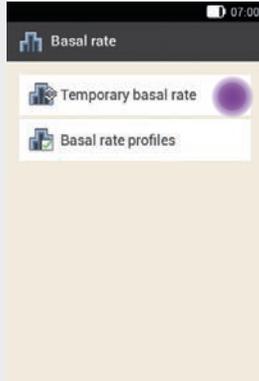
On the Status screen, tap the area indicating the basal rate.

or



In the Main menu, tap the **Basal rate** menu.

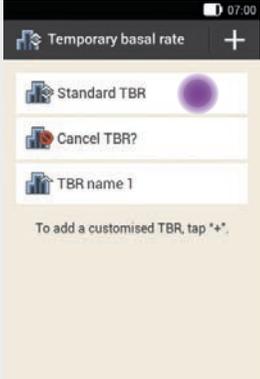
2



Tap **Temporary basal rate**.

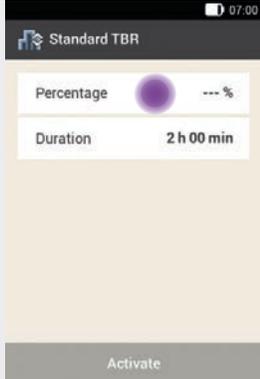
8.4.1 Programming a TBR

1



Tap **Standard TBR**.

2



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

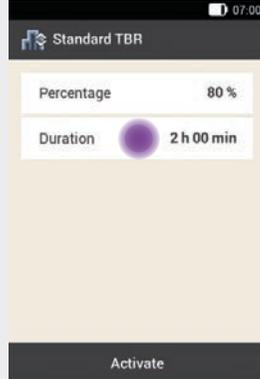
3



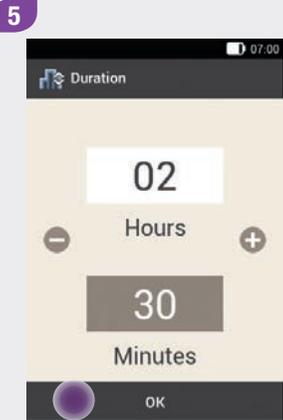
Use **-** and **+** to set the percentage for adjusting the Temporary Basal Rate.

Tap **Save**.

4

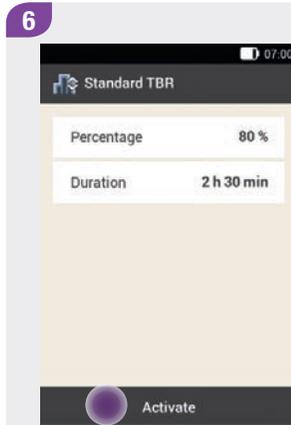


Tap **Duration** to enter the running time for the temporary basal rate.



Use **−** and **+** to set the hours and minutes for the duration of the standard TBR.

Tap **OK**.

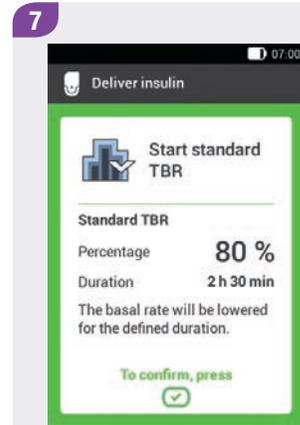


Tap **Activate**.

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 display.



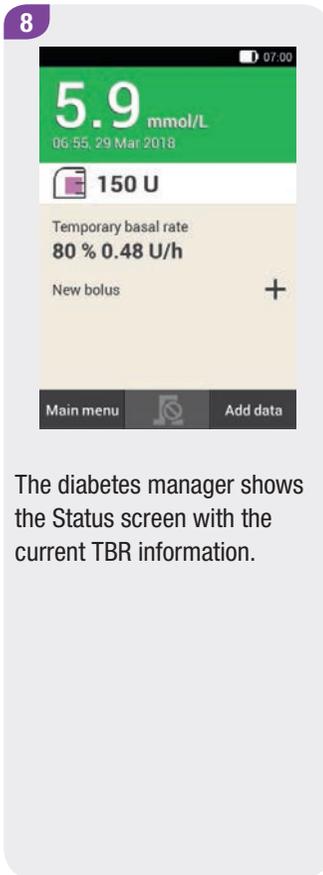
To confirm this step and start the standard TBR, press the insulin button lit up in green **✓** below the diabetes manager screen.

8.4.2 Programming a Customised TBR

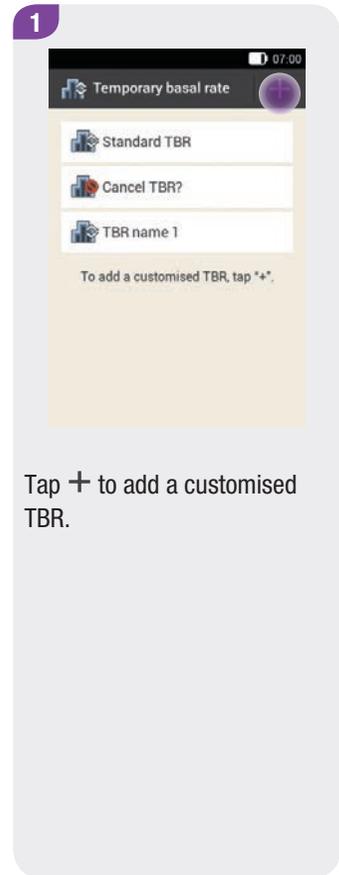
You can program and save customised Temporary Basal Rates for recurring situations that change your insulin needs. For a customised TBR, the percentage and the duration are saved. These settings are used as default values each time you select this TBR. You also have the option of entering a name for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

Example

You go running for 1 hour twice a week. You know that your body needs 25 % less insulin during this activity and the subsequent recovery phase of 2 hours. You program a TBR of 75 % for 3 hours.



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



Tap + to add a customised TBR.

2

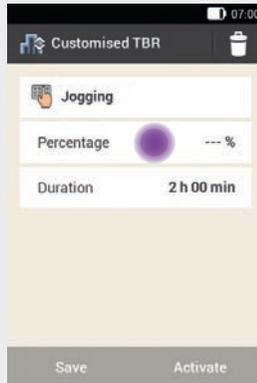


Tap the  symbol.

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

Tap **Done**.

3



Tap **Percentage** to enter the percentage for the customised TBR.

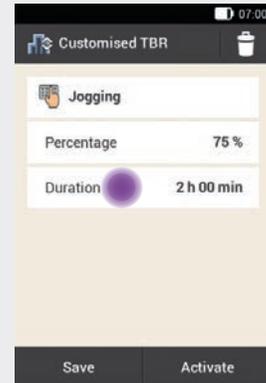
4



Use  and  to set the percentage for adjusting the customised TBR.

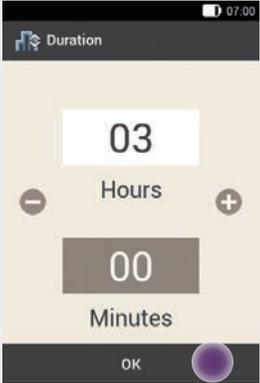
Tap **Save**.

5



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

6



Use **-** and **+** to set the hours and minutes for the duration of the customised TBR.

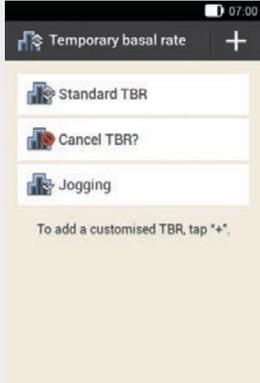
Tap **OK**.

7



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

8



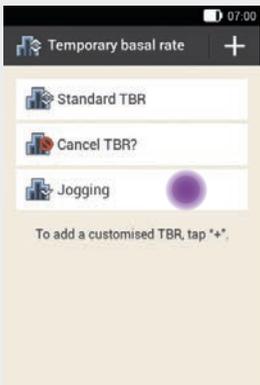
The newly programmed customised TBR is displayed.

Note

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

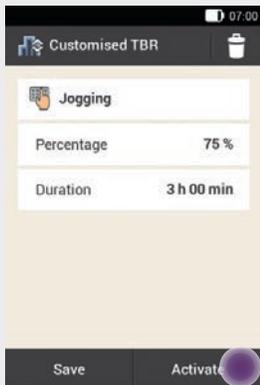
8.4.3 Activating a Customised TBR

1



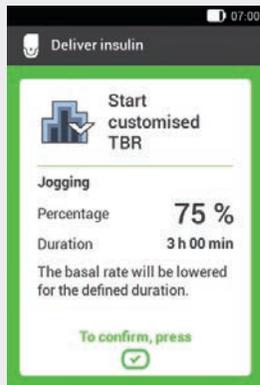
To activate a saved TBR, tap the desired entry in the list of Temporary Basal Rates.

2



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

3



To confirm this step and start the TBR, press the insulin button lit up in green  below the diabetes manager screen.

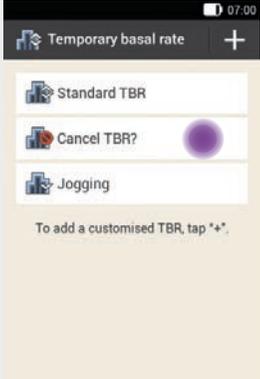
4



The activated TBR is displayed on the Status screen.

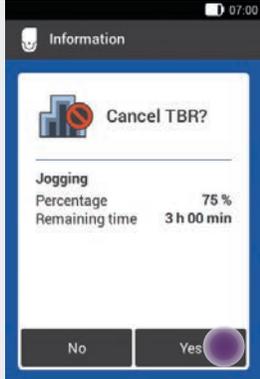
8.4.4 Cancelling a TBR

1



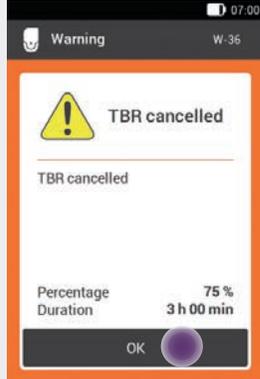
Tap **Cancel TBR?**.

2



Tap **Yes**.

3



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

Tap **OK** to confirm the warning.

4



The TBR has been cancelled 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 and insertion device.

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

System component		Period of use
Insertion device		720 uses (about 4 years)
Pump base		up to 4 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.

WARNING

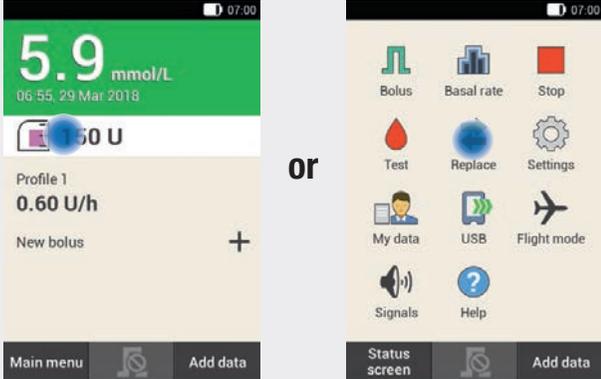
Check your blood glucose level after replacing system components at least once within 1 to 3 hours.

Note

- ▶ The average life expectancy of the battery used to supply the micropump with power is 4 days. It may last longer than this, depending on your usage pattern and the insulin amount needed daily.
- ▶ 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. For more information, see chapter *12 Reminders*.

9.1 Starting the Replacement

1



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

On the Status screen, tap the reservoir symbol .

or

In the Main menu, tap the **Replace**  menu.

Note

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.

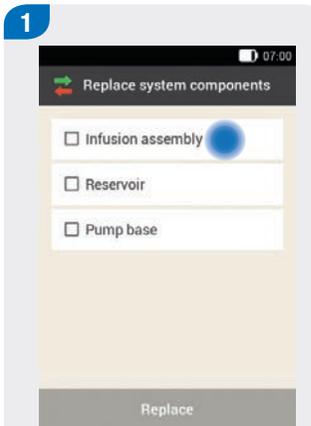
9.2 Replacing the Infusion Assembly

Have the following system components at hand for this process:

- ▶ Pump holder
- ▶ Cannula
- ▶ Insertion device
- ▶ Diabetes manager
- ▶ Disinfectant or sterile alcohol wipe

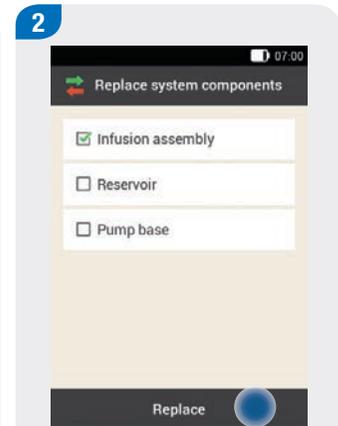
Note

- ▶ 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.



The display for selecting the system components appears.

Tap **Infusion assembly**.



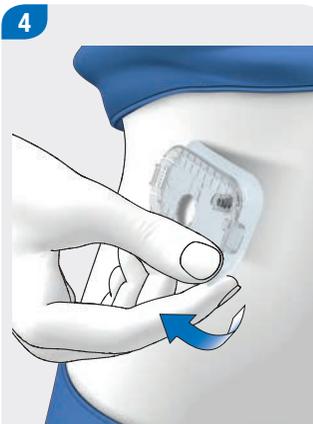
Tap **Replace**.

The micropump switches to STOP mode and issues the "Cancel" signal sequence.

Removing the used infusion assembly



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

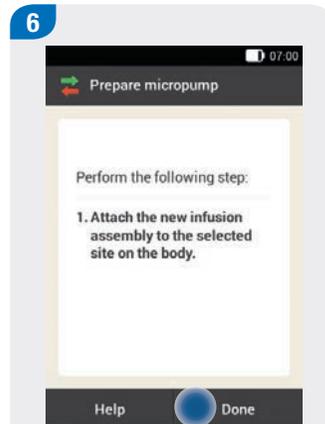


Remove the infusion assembly by loosening the edges of the adhesive pad and pulling it off to the centre.



Dispose of the used infusion assembly according to local regulations.

Tap **Done**.



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

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

Attaching the infusion assembly to the body

7

Follow the action steps in chapter 4.3.1 *Attaching the Infusion Assembly to the Body*.

8

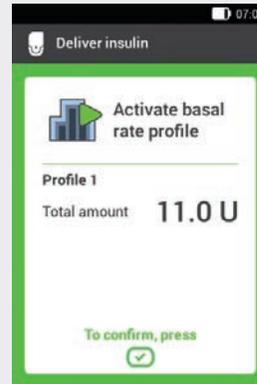


Attach the micropump to the infusion assembly.

Tap **Next**.

The infusion assembly is now filled automatically.

9



To confirm this step and then restart the micropump and return to the Status screen, press the insulin button lit up in green below the diabetes manager screen.

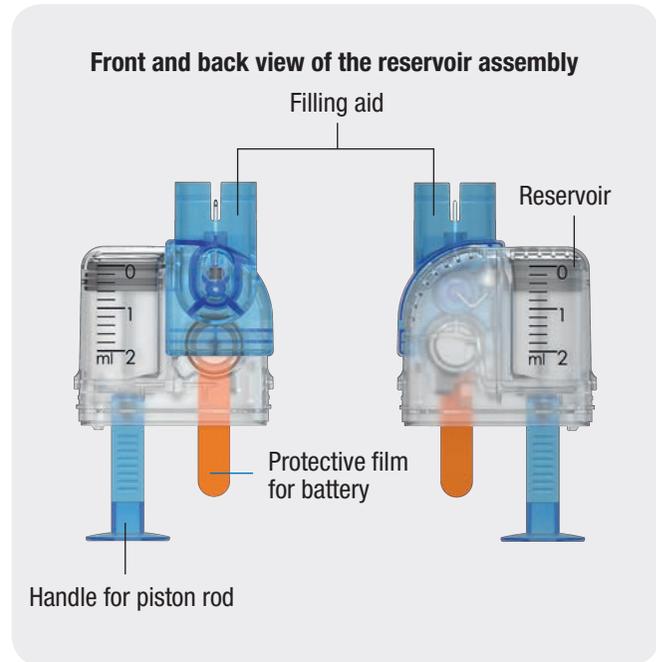
9.3 Replacing the Reservoir

Have the following at hand for this process:

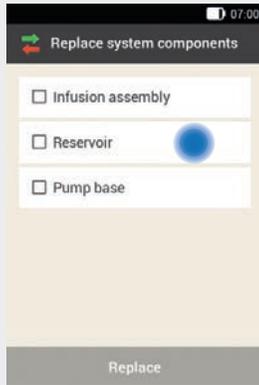
- ▶ Reservoir assembly
- ▶ Insulin vial with U100 insulin
- ▶ Disinfectant or sterile alcohol wipe

Note

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



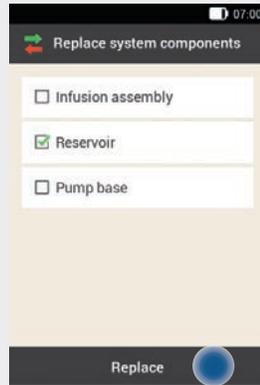
1



The display for selecting the system components appears.

Tap **Reservoir**.

2



Tap **Replace**.

The micropump switches to STOP mode and issues the "Cancel" signal sequence.

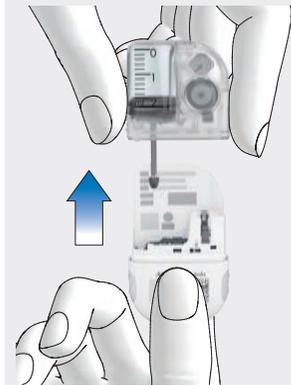
Removing the reservoir

3



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

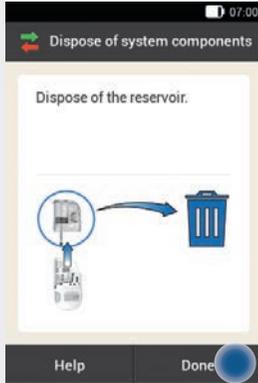
4



Remove the used reservoir from the pump base.

Wait at least 15 seconds after removing the used reservoir before you connect a new reservoir to the pump base.

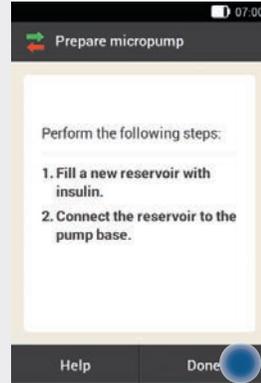
5



Dispose of the used reservoir according to local regulations.

Tap **Done**.

6



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

Once you have completed the steps shown on the display, tap **Done**.

7

Replacing the reservoir

Follow the action steps in chapters

- 4.3.2 Filling the Reservoir with Insulin,*
- 4.3.3 Connecting the Reservoir to the Pump Base,*
- 4.3.5 Filling the Reservoir Needle,*
- 4.3.6 Attaching the Micropump,*
- 4.3.7 Activating the Basal Rate Profile.*

9.4 Replacing the Pump Base

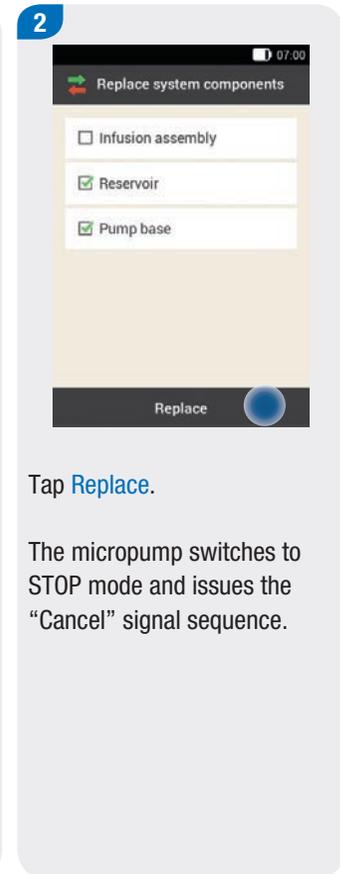
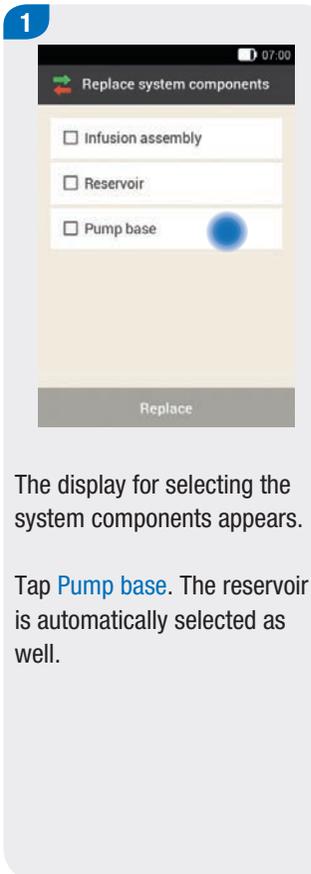
The pump base can be used for up to 4 months. It must not be used for longer than that because otherwise the delivery accuracy may be impaired. You will be reminded regularly to replace the pump base before the deadline expires. For information on the remaining running time of the micropump, see the settings in the [System information](#) menu. If you replace the pump base, you must also replace the reservoir.

Before starting this process, have the following components ready:

- ▶ A new pump base
- ▶ A new reservoir assembly
- ▶ An insulin vial with U100 insulin
- ▶ Disinfectant or a sterile alcohol wipe

Note

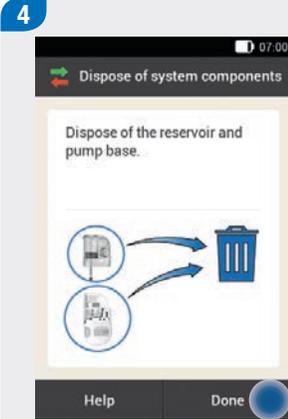
- ▶ Refer to the information in chapter 4 *Putting the Micropump into Operation*.
- ▶ When you replace the pump base, all settings saved for the pump in the diabetes manager are preserved.
- ▶ Each pump base can only be paired once with a diabetes manager.



Removing the pump

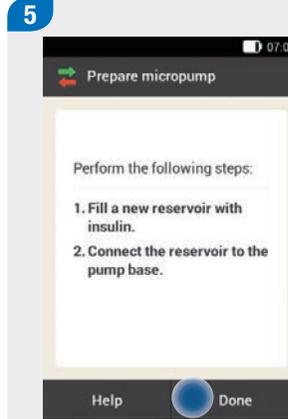


Press the flap of the infusion assembly. Remove the used micropump from the infusion assembly.



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

Tap **Done**.



Follow the instructions on the screen.

Tap **Done**.

Follow the action steps in chapters
4.3.2 Filling the Reservoir with Insulin,
4.3.3 Connecting the Reservoir to the Pump Base,
4.3.4 Pairing the Diabetes Manager and Micropump,
4.3.5 Filling the Reservoir Needle,
4.3.6 Attaching the Micropump,
4.3.7 Activating the Basal Rate Profile.

10 My Data

10.1 Overview

Analysing your therapy data saved in the diabetes manager is an effective way for you and your healthcare professional to determine how your diabetes is developing. This analysis is a valuable tool for 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.

10.2 Logbook

You can display each single logbook entry on the screen of the diabetes manager. There, you will find all the information about blood glucose results 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:

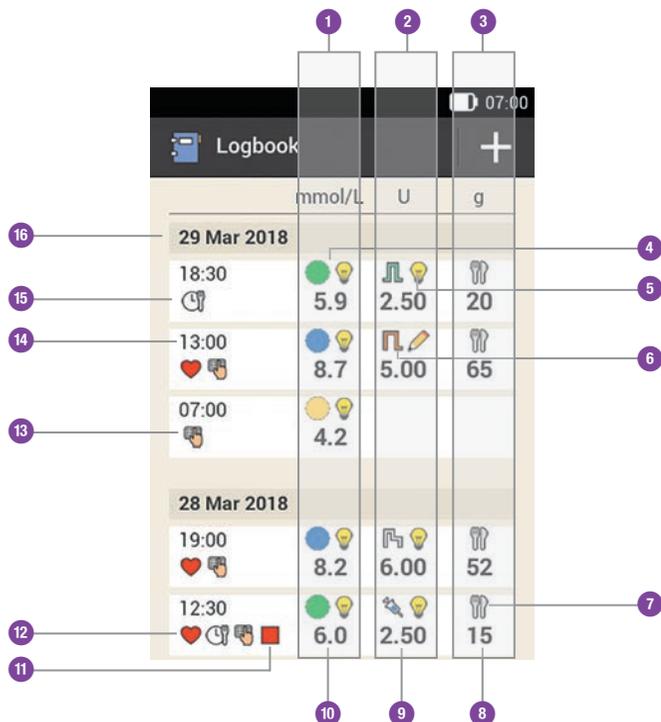
Date and time, blood glucose result, time of test, carbohydrate intake, health events, bolus amounts, bolus type and notes.

Note the following:

- ▶ The **Logbook** display shows the entries in the order in which they occurred with the most recent entry shown on top.
- ▶ Blood glucose results cannot be entered manually or be subsequently adjusted.
- ▶ 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.

10.2.1 Understanding the Logbook

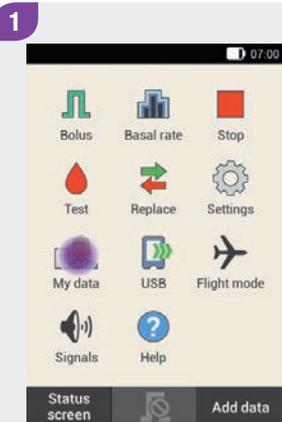
Main menu > My data > Logbook



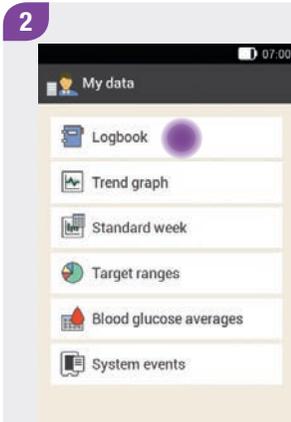
1	Column for displaying blood glucose information Blood glucose result range and blood glucose result.
2	Column for displaying bolus information Bolus type, bolus advice and bolus amount.
3	Column for displaying carbohydrate information Symbol for carbohydrates and carbohydrate amount.
4	Symbol for blood glucose result range information
5	Symbol for bolus advice
6	Symbol for bolus type
7	Symbol for carbohydrates
8	Carbohydrate amount
9	Bolus amount
10	Blood glucose result
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	Symbol name	Description
	Blood glucose result 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
	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.

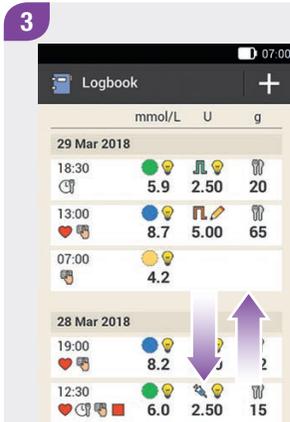
10.2.2 Viewing and Adjusting Logbook Data



Tap **My data**.

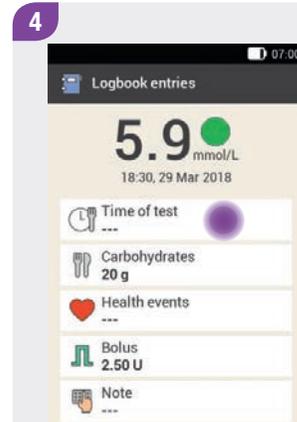


Tap **Logbook**.



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

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



Tap the entry you want to view or adjust.

Time of test

5

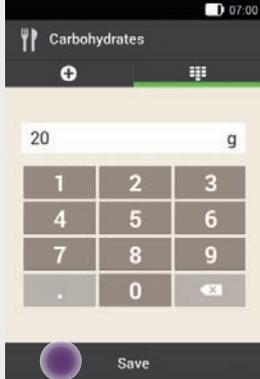


On the **Logbook entries** display, tap **Time of test**. Tap a time of test (for example, **Before meal**).

Tap **Save**.

Carbohydrates

6

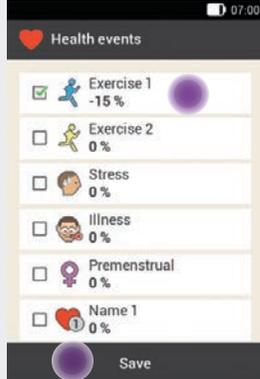


On the **Logbook entries** display, tap **Carbohydrates**. Enter the amount of carbohydrates you consumed.

Tap **Save**.

Health events

7



On the **Logbook entries** display, tap **Health events**.

Tap the appropriate entries. You can select up to 4 health events.

Tap **Save**.

Bolus

8



On the **Logbook entries** display, tap **Bolus**.

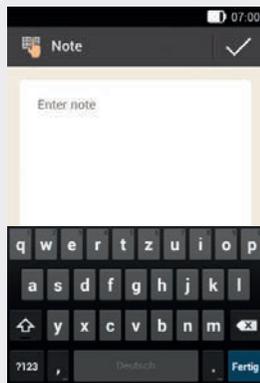
The display informs you about the bolus delivered.

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



On the [Logbook entries](#) display, tap [Note](#).

Type a note to save with this entry.

Tap [Done](#).

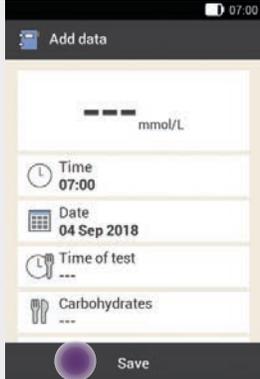
10.2.3 Adding New Data

1



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

2



Tap the entries you want to add.

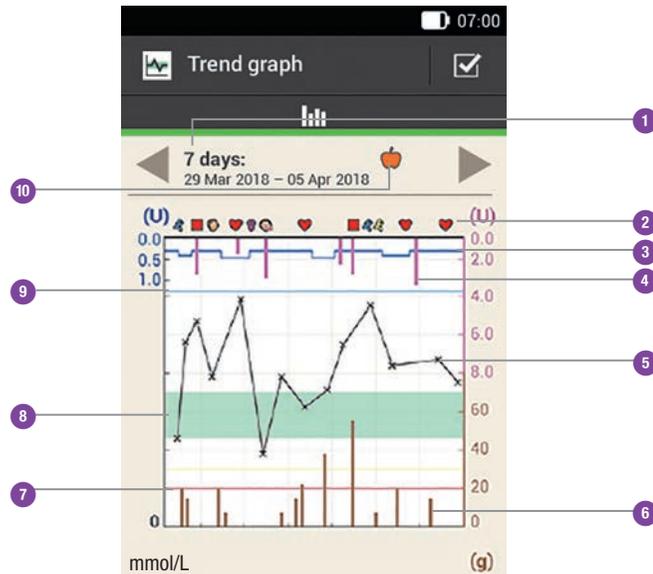
Then tap **Save**.

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

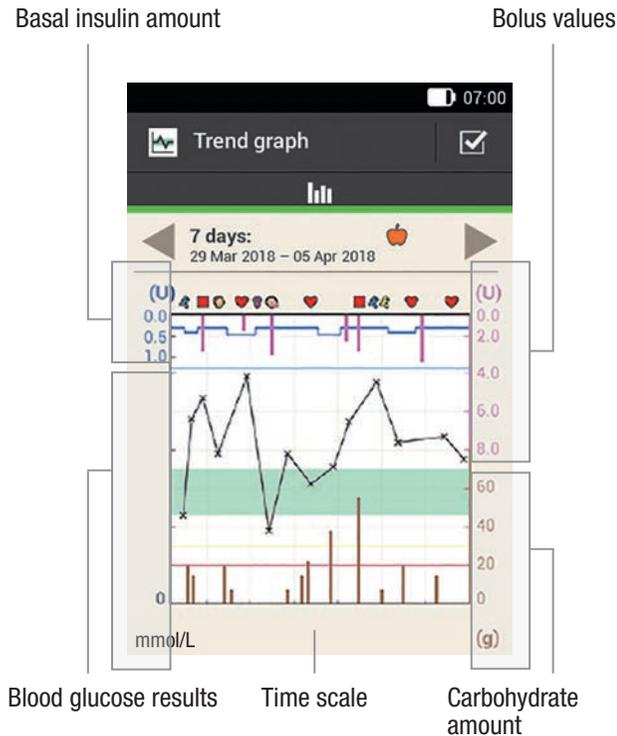
10.3 Trend Graph

Main menu > My data > Trend graph

The trend graph displays your blood glucose trends, basal rates, boluses 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	Blood glucose result	Crosses (x): Individual blood glucose results 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	Blue line: Hyper warning limit
10	Selected time of test	Displays logbook entries entered for this time of test.



On the **upper left side (U)** 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 blood glucose result is displayed. By means of the scale, you can read the blood glucose results, which are represented by a black line. The black line connects the individual test results indicated by a cross. Scaling depends on the largest blood 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.

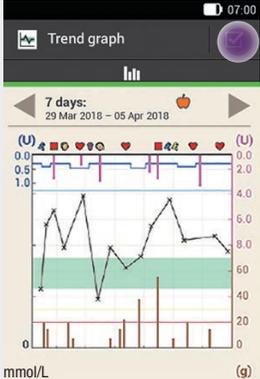
On the **lower right side (g)** of the graph, the carbohydrate amount is displayed. By means of the scale, you can read the carbohydrate values, which are represented by the brown bars. The scale comprises a range of 40, 80, 120, 160, 200 or 240 g, or the equivalent scale for BE, KE or CC. Scaling depends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

10.3.1 Displaying the Trend Graph

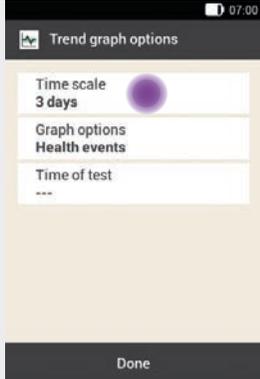
1



The screenshot shows the 'Trend graph' interface. At the top, it says 'Trend graph' and '7 days: 29 Mar 2018 - 05 Apr 2018'. The main area contains a multi-axis chart with a line graph for glucose (mmol/L), a bar chart for bolus, and another bar chart for carbs. A green shaded area represents the target range. A checkmark icon in the top right corner is highlighted with a purple circle.

Tap to change the trend graph representation.

2



The screenshot shows the 'Trend graph options' menu. It has three sections: 'Time scale' with '3 days' selected, 'Graph options' with 'Health events' selected, and 'Time of test' with '---'. A purple circle highlights the '3 days' option.

Tap the setting you want to change.

3

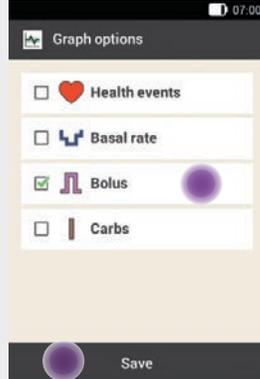


The screenshot shows the 'Time scale' menu with options: 6 hours, 12 hours, 1 day, 3 days (selected), and 7 days. A purple circle highlights the '3 days' option.

Tap the desired time period.

Tap **Save**.

4



The screenshot shows the 'Graph options' menu with checkboxes for 'Health events', 'Basal rate', 'Bolus' (checked), and 'Carbs'. A purple circle highlights the 'Bolus' checkbox.

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

Tap **Save**.

Time of test

5



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

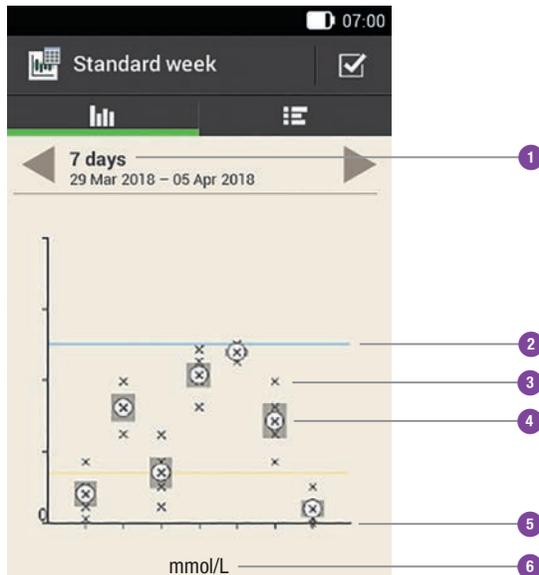
Tap [Save](#).

On the [Time of test](#) display 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.

10.4 Standard Week

Main menu > My data > Standard week

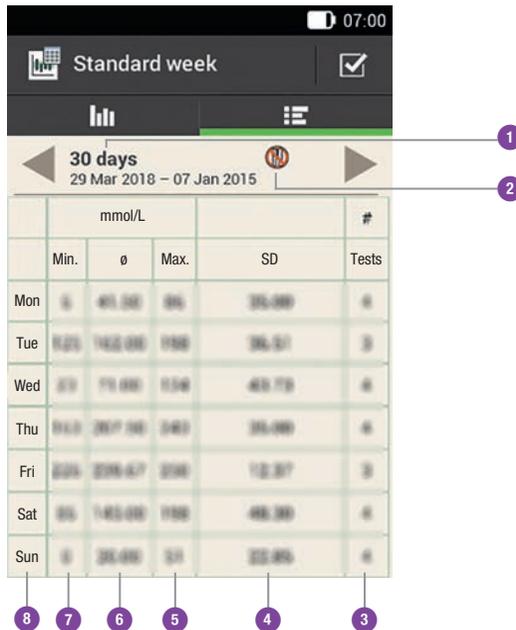
The standard week graph displays your blood glucose averages, the individual tests and the standard deviations for the days of a standard week. Using the ◀▶ buttons, you can move backwards or forwards in time according to the selected time scale.



1	Time scale	Represented time period, for example, 7 days
2	Hyper warning limit	Blue line: Hyper warning limit
3	x	Single blood glucose result
4	⊗	Average
5	Time axis	Monday to Sunday
6	Blood glucose unit of measurement	mmol/L

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



	mmol/L			SD	# Tests
	Min.	ø	Max.		
Mon	5	40.00	56	25.00	4
Tue	5.25	142.00	150	26.57	3
Wed	5.75	70.00	150	43.75	4
Thu	5.5	207.00	240	25.00	4
Fri	5.25	200.57	200	12.37	3
Sat	5.5	142.00	150	43.00	4
Sun	5	20.00	57	22.85	4

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 blood glucose result of the day of the standard week

6 Blood glucose average of the day of the standard week

7 Lowest blood glucose result of the day of the standard week

8 Day of the week

10.4.1 Displaying the Standard Week Graph

1



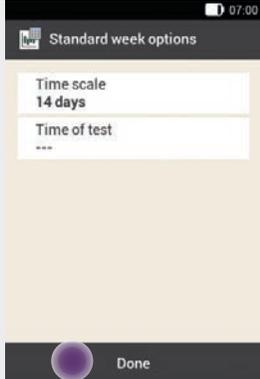
Standard week

7 days
29 Mar 2018 – 05 Apr 2018

mmol/L

Tap to change the representation of the standard week graph.

2



Standard week options

Time scale
14 days

Time of test

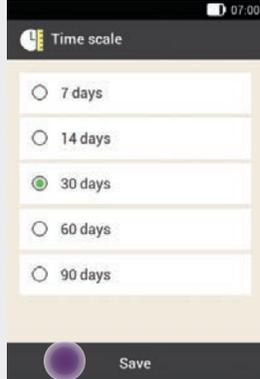
Done

Tap one of the entries available for selection. Make the desired settings.

Tap Done.

Time scale

3



Time scale

7 days

14 days

30 days

60 days

90 days

Save

Tap the desired time period.

Tap Save.

Time of test

4



Time of test

All

Before meal

After meal

Bedtime

Fasting

Other

Save

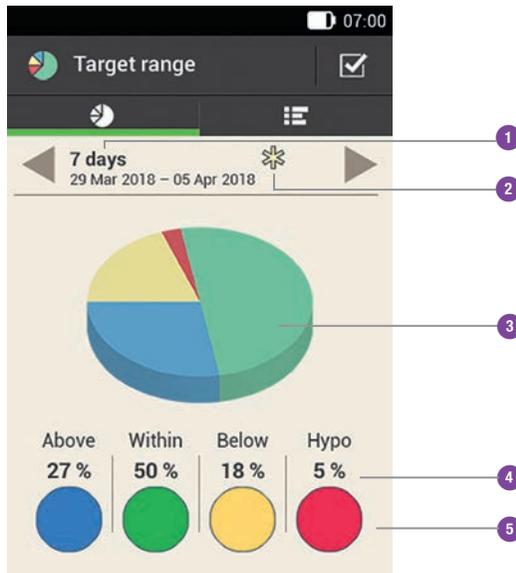
Tap the appropriate time of test.

Tap Save.

10.5 Target Range

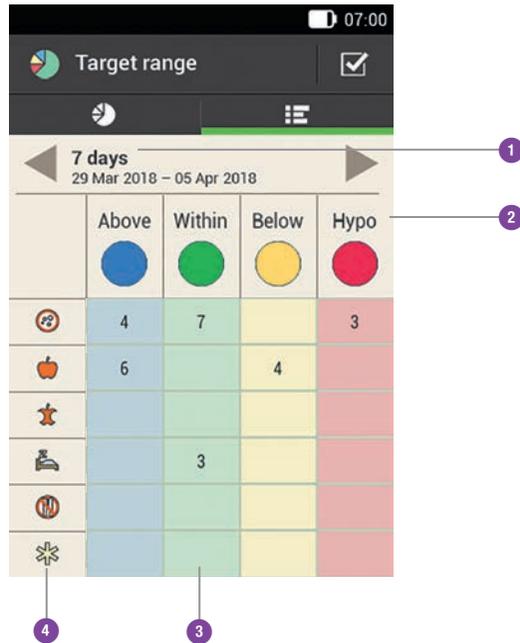
Main menu > My data > Target range

This screen displays a pie chart and a table illustrating your blood glucose results for the time period and time of test you selected. The chart is divided into the following blood glucose result 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	Displays logbook entries entered for this time of test.
3	Target range chart	Shows the target ranges of blood glucose results as a pie chart.
4	Percentage distribution	Shows the percentage of blood glucose results in each blood glucose result range.
5	Blood glucose result ranges	Coloured representation of the blood glucose result 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	Blood glucose result ranges	Coloured representation of the blood glucose result ranges
3	Number	Number of test results in one of the ranges
4	Times of test	Shows the logbook entries for this time of test.

10.5.1 Displaying the Target Range Data

1



Tap to change the representation of the target range.

2

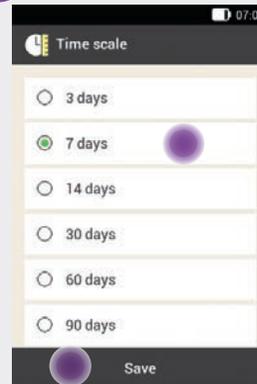


Tap one of the entries available for selection.

Make the desired settings and then tap **Done**.

Time scale

3



Tap the desired time period.

Tap **Save**.

Time of test

4



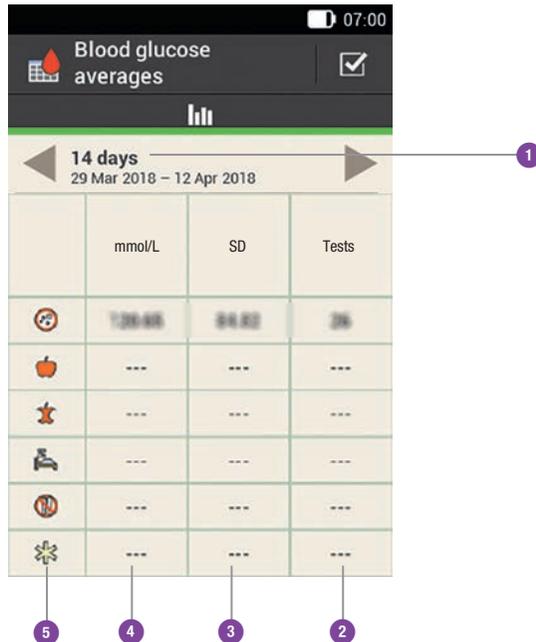
Tap the appropriate time of test (for example, **Bedtime**).

Tap **Save**.

10.6 BG Averages Table

Main menu > My data > Blood glucose averages

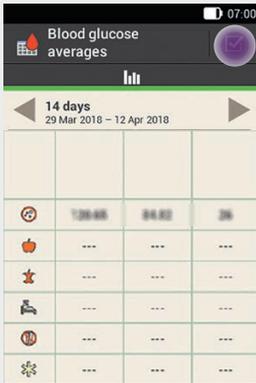
The BG averages table displays your blood glucose averages and standard deviations (SD) for the time period and time of test you selected.



1	Time scale	Illustrated time period
2	Number of tests	Shows the number of test results used for the calculation.
3	Blood glucose standard deviation	Indicates how the blood glucose results 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.

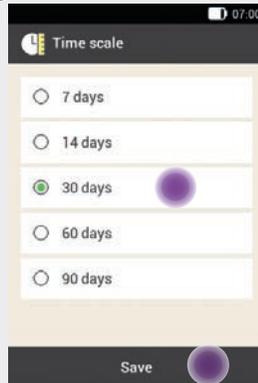
10.6.1 Displaying the BG Averages Table

1



Tap to change the settings for the time period or time of test.

2



Tap the desired time period.

Tap **Save**.

10.7 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
TBR data	The last 90 increases and decreases in the basal rate
Total daily dose	The last 90 daily insulin totals delivered
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.

10.7.1 Event Data

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

Example



Each entry includes the following data:

- ▶ Type and number of the maintenance, warning or error message
- ▶ Title of the maintenance, warning or error message
- ▶ Time
- ▶ Date

10.7.2 Bolus Data

This display lets you access the last 90 bolus deliveries, 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)

10.7.3 TBR Data

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

Example

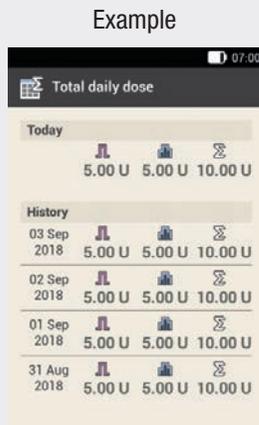


Each entry includes the following data:

- ▶ Start date
- ▶ Start time
- ▶ TBR as a percentage
- ▶ TBR duration

10.7.4 Total Daily Dose

This display 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.



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

10.7.5 Information

This display lets you access information about the micropump currently in use



This view includes the following data:

- ▶ Micropump remaining running time
- ▶ Micropump serial number
- ▶ Micropump battery status
- ▶ Micropump firmware version

10.8 Data Transfer

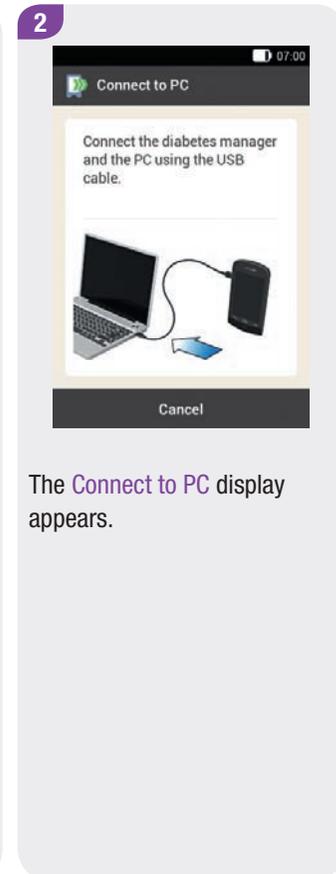
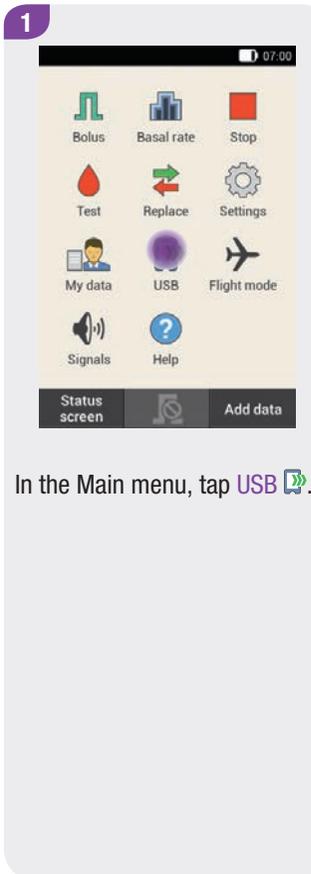
You can display and evaluate the data on a PC using an Accu-Chek diabetes management software, such as the Accu-Chek Smart Pix software.

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.





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

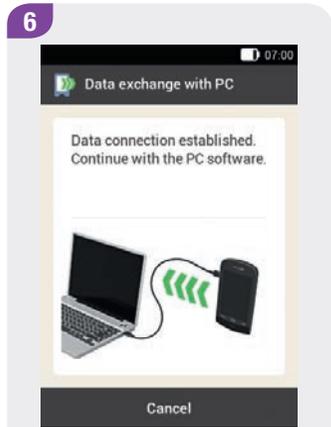


Plug the larger end (USB-A plug) of the USB cable into a free USB port on your computer.

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



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



This display 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

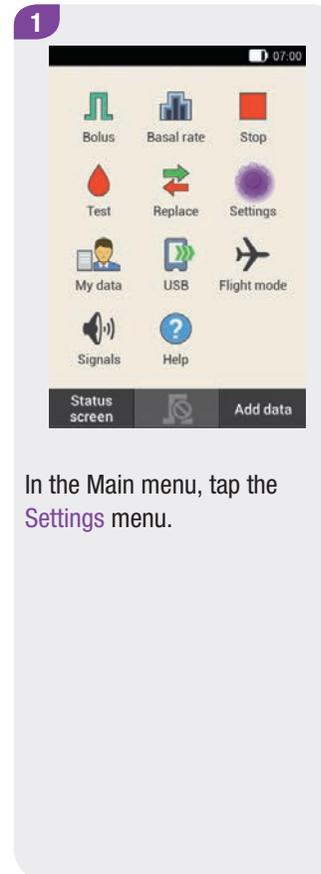
In the *Settings* menu, you can make changes to the factory settings or change the settings you made. This allows you to adjust the micropump system to your individual treatment requirements and your personal preferences.

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*.

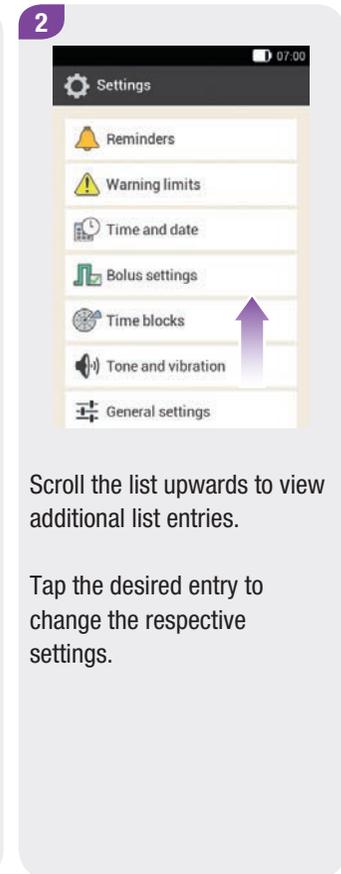
For information on reminder settings, see chapter 12 *Reminders*.

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.



In the Main menu, tap the **Settings** menu.



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 blood glucose result is above the hyper warning limit or below the hypo warning limit, the diabetes manager displays a warning.

1



Warning limits

Upper warning limit	6 mmol/L
Lower warning limit	3.9 mmol/L
Micropump remain. running time (days)	21
Reservoir level	25 U
Automatic off	12 h

Tap **Upper warning limit** or **Lower warning limit**.

Upper limit value

2



Upper warning limit

15.5 mmol/L

OK

Use **-** and **+** to set the upper warning limit.

Tap **OK**.

Lower limit value

1



Use **-** and **+** to set the lower warning limit.

Tap **OK**.

2

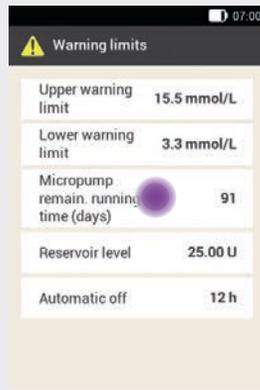


Tap **←** to return to the list of settings. If you want to make additional settings, tap the respective entry.

Remaining running time

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.

1



Tap **Micropump remain. running time (days)**.

2



Micropump remaining running time

30 days

Save

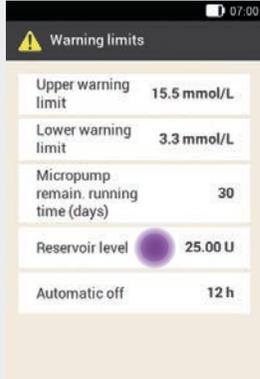
Use **-** and **+** to set the number of days as of which you want to receive a warning.

Tap **Save**.

Reservoir level

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.

1



Warning limits

Upper warning limit	15.5 mmol/L
Lower warning limit	3.3 mmol/L
Micropump remain. running time (days)	30
Reservoir level	25.00 U
Automatic off	12 h

Tap **Reservoir level**.

2



Remaining insulin amount

40.00 U

Save

Use **-** and **+** to set the number of insulin units at which you want to receive a warning.

Tap **Save**.

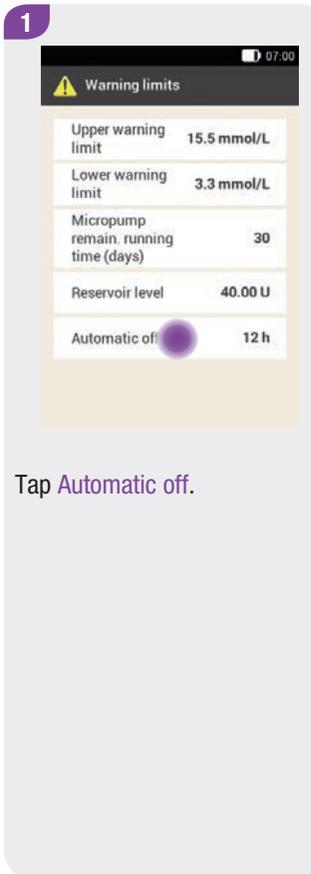
Automatic off

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.

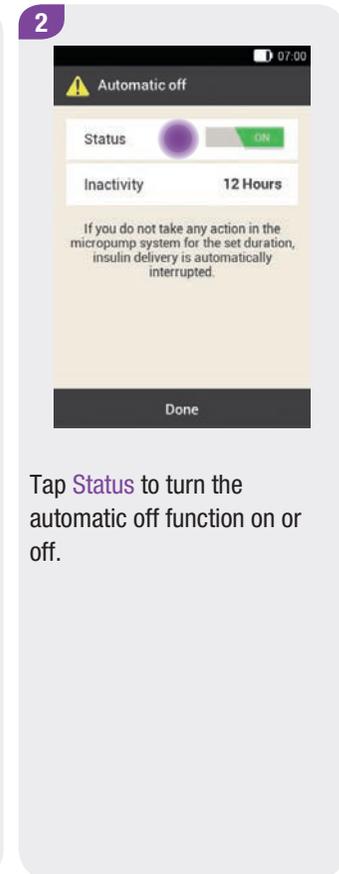
The automatic off function is turned off by default.

Note

It is advisable to set a time span for the automatic off function that is longer than your usual bedtime period.

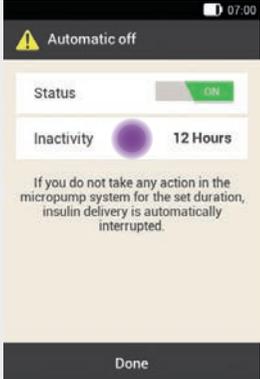


Tap **Automatic off**.



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

3



Tap **Inactivity**.

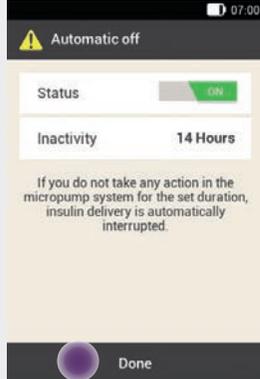
4



Use **-** and **+** to set the number of hours after which the bolus delivery will be interrupted.

Tap **OK**.

5



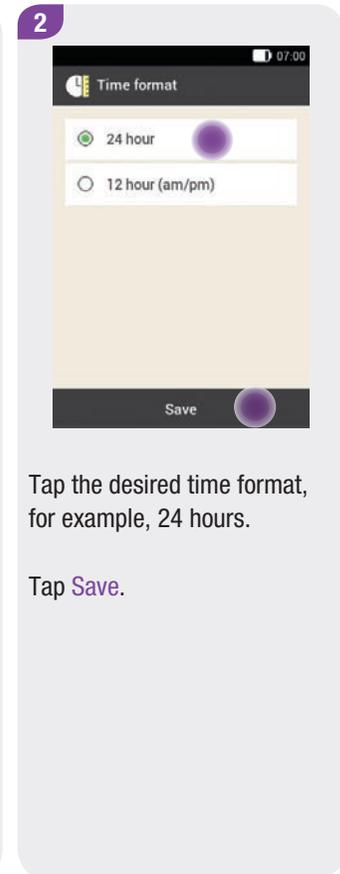
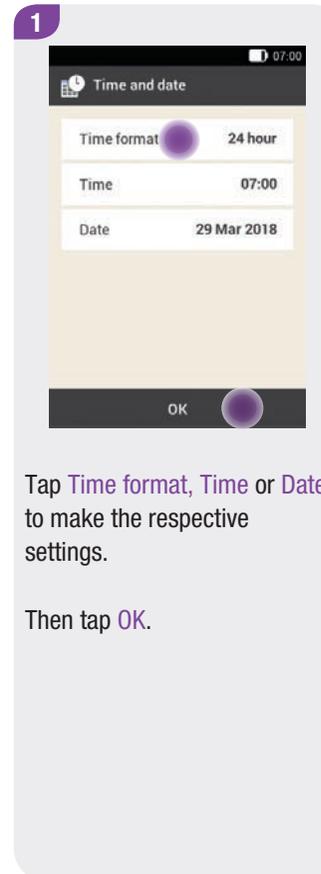
Tap **Done**.

11.2 Time and Date

Main menu > Settings > 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.



3



Use **-** and **+** to set the hours and minutes for the current time.

Tap **OK**.

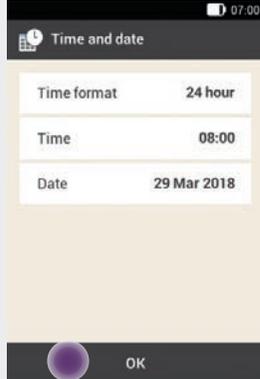
4



Use **-** and **+** to set the day, month and year.

Tap **OK**.

5



Then tap **OK**.

11.3 Bolus Settings

Main menu > Settings > Bolus settings

This section provides information on the following settings:

- ▶ Quick bolus buttons
- ▶ Maximum quick bolus
- ▶ Quick bolus increment
- ▶ Maximum bolus amount
- ▶ Delivery lag time

WARNING

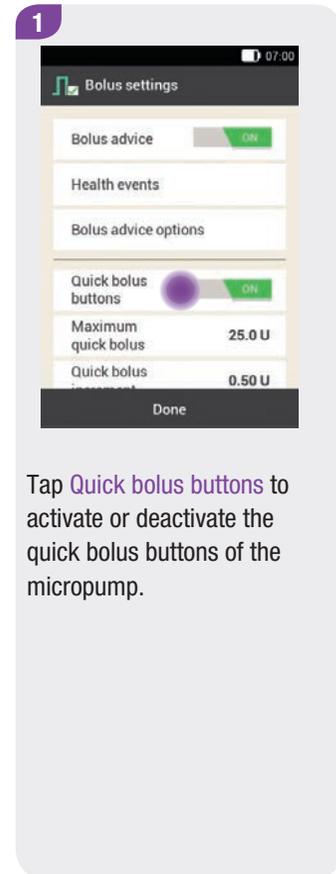
The therapy settings must be specified by your healthcare professional and you may only change them after prior consultation. Otherwise, there is a risk of experiencing hyperglycaemia or hypoglycaemia.

Quick bolus buttons

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*.

For more information on the quick bolus, see chapter *6.5 Quick Bolus*.



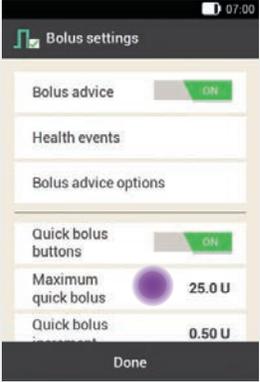
Maximum quick bolus

You use this setting 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. For more information, see section *Maximum bolus amount*.

1



Bolus settings

Bolus advice ON

Health events

Bolus advice options

Quick bolus buttons ON

Maximum quick bolus 25.0 U

Quick bolus 0.50 U

Done

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

2



Maximum insulin amount for quick bolus

5.00 U

Save

Use **-** and **+** to set the maximum amount for the quick bolus.

Tap **Save**.

Quick bolus increment

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.

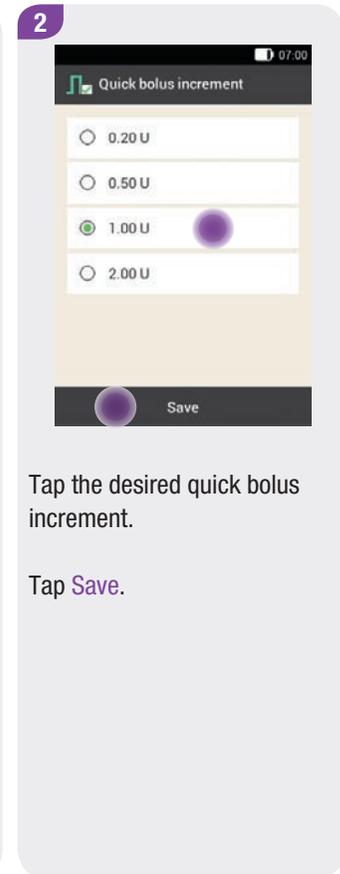
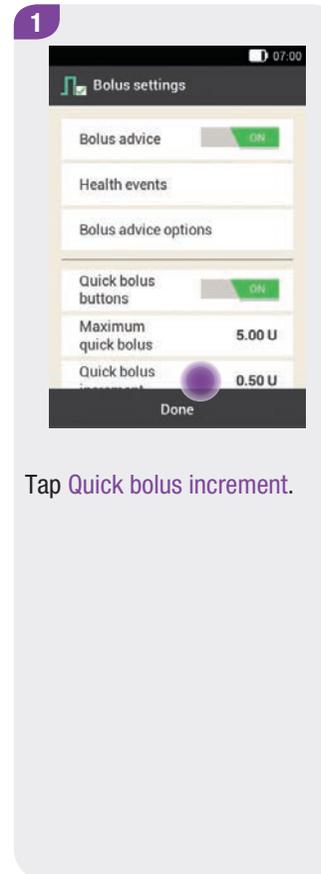
You can set the following quick bolus increments:

- ▶ 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.



Maximum bolus amount

This setting specifies 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.

Note

For the maximum bolus, you can set an amount between 1 U and 50 U.

1



Bolus settings

quick bolus	5.00 U
Quick bolus increment	1.00 U
Maximum bolus amount	25.0 U
Delivery lag time	OFF
Maximum pen bolus	5.00 U
Insulin increment	1 U

Done

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

2



Maximum bolus amount

20.0 U

OK

Use **-** and **+** to set the maximum bolus amount.

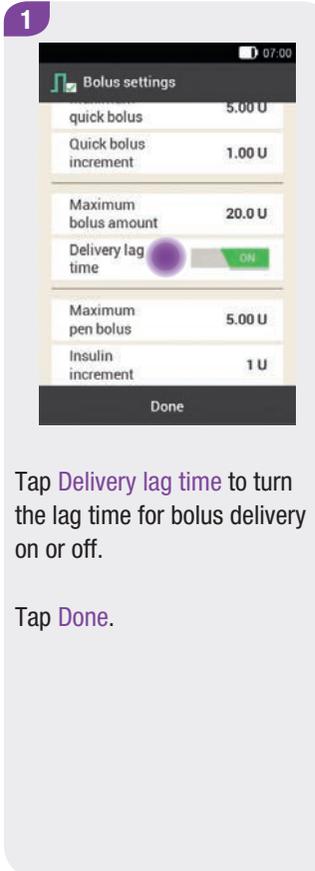
Tap **OK**.

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. For more information, see chapter 6.8 *Setting the Delivery Lag Time*.

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 blood glucose result is above the target range, it is not possible to enter a delivery lag time. Correction insulin must always be delivered immediately.



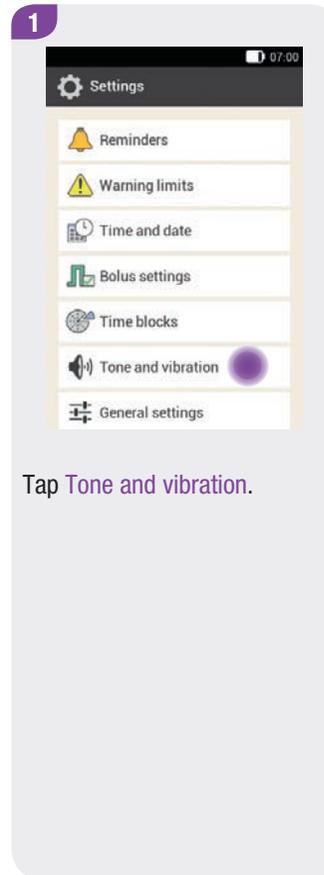
11.4 Tone and Vibration

Main menu > Settings > 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 an acoustic signal, vibrates or both. The settings you make are referred to as *signal mode* in the rest of this User's Manual. You can also suspend the signals for warnings for a specific period of time (for example, over night).

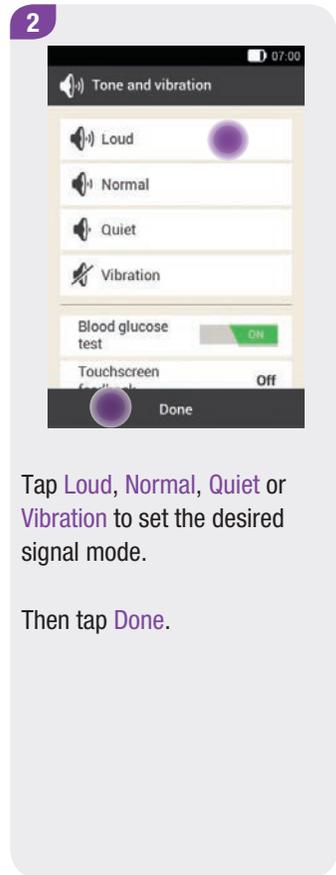
WARNING

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



Tap **Tone and vibration**.

Signal modes



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

Then tap **Done**.

Volume

3



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.

Vibration

4

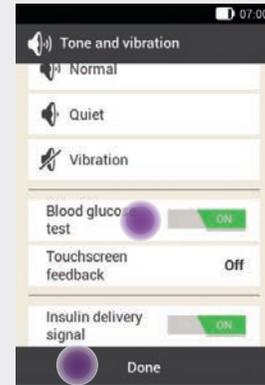


Tap **Vibration**.

Tap **OK**.

Blood glucose test

5



Tap **Blood glucose test** to turn the signals for a blood glucose test on or off.

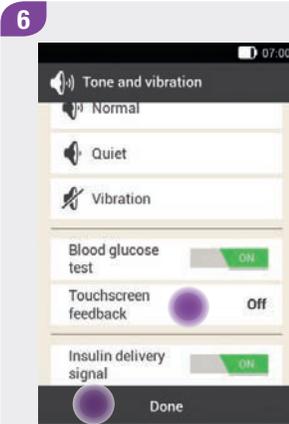
Once you have made the desired setting, tap **Done**.

Note

Signals during a blood glucose test:

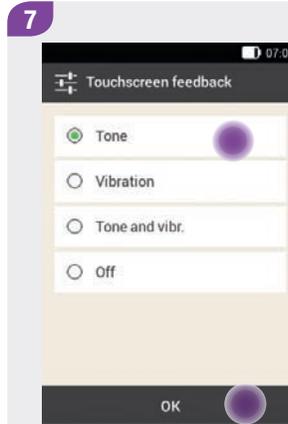
- ▶ Insert test strip
- ▶ Blood application detected
- ▶ Test completed

Touchscreen feedback



Tap **Touchscreen feedback** to set how the diabetes manager reacts when you make a selection using the touchscreen.

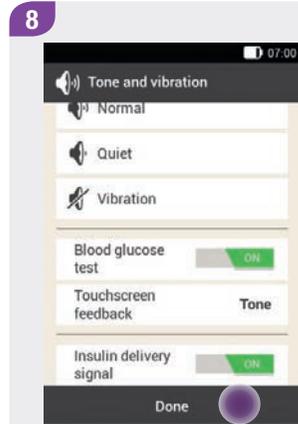
Once you have made the desired setting, tap **Done**.



Tap the desired touchscreen setting.

Tap **OK**.

Insulin delivery signal



Tap **Insulin delivery signal**.

If you turn on the signal, the diabetes manager issues a signal when you confirm delivery of a basal rate or bolus.

Tap **Done**.

11.5 Turning Off Signals Temporarily

Note

Signals for system messages:

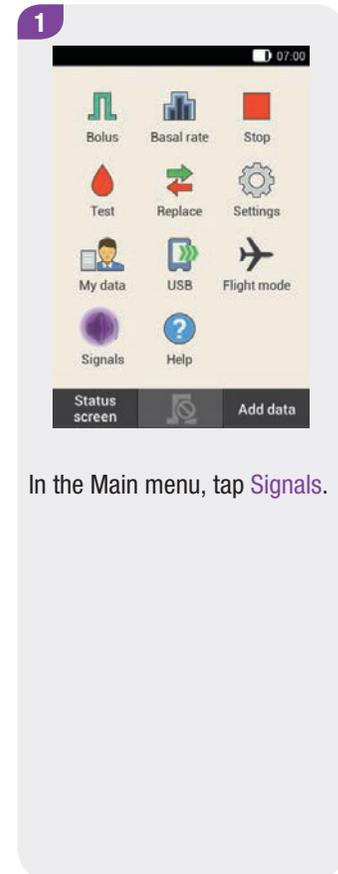
- ▶ USB plug connected to USB socket
- ▶ USB plug removed from USB socket
- ▶ Diabetes manager restart
- ▶ Communication via *Bluetooth* wireless technology completed

This function allows you to temporarily turn off the diabetes manager signals for reminders and warnings. You cannot, however, turn off maintenance and error messages because these events require your attention.

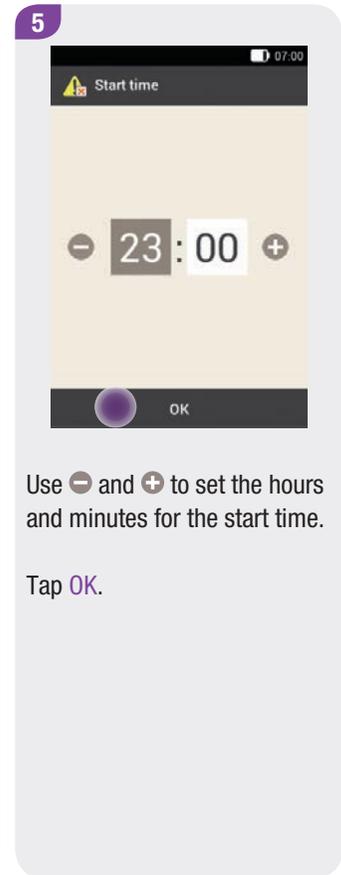
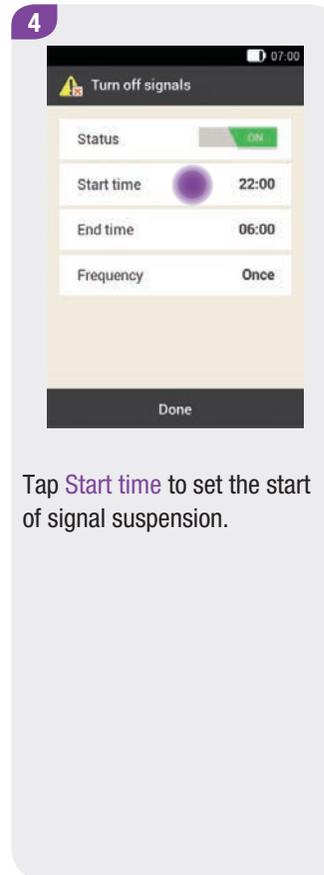
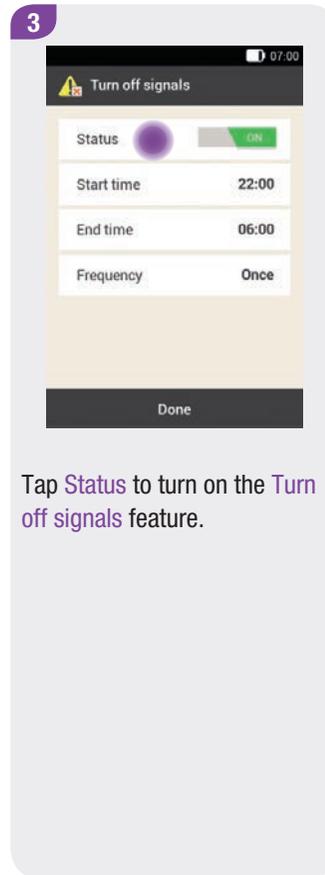
You can set up signal suspension as a one-time event or as an event that is repeated at the same time every day.

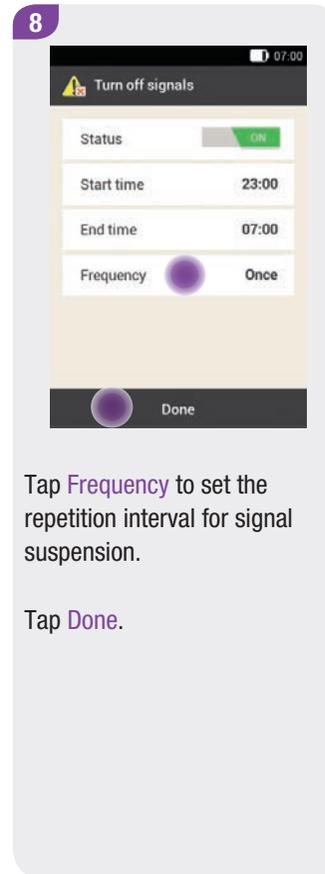
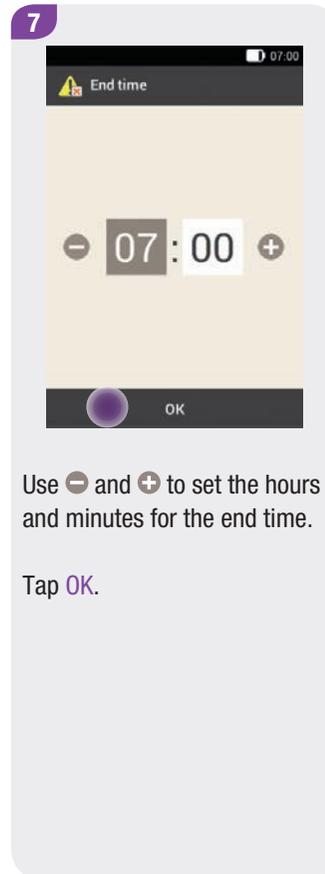
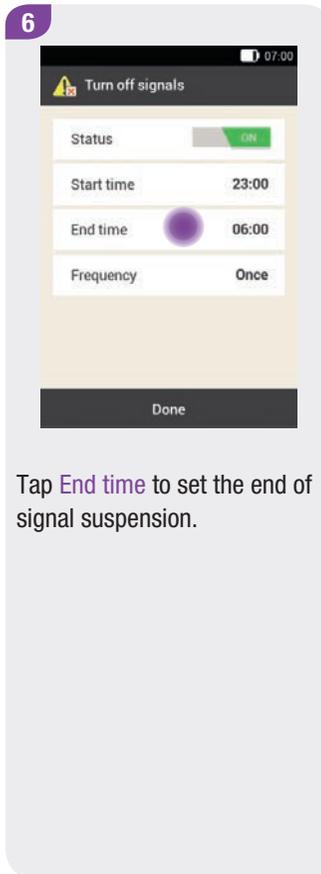
Note

- ▶ Signal suspension applies only for the diabetes manager and micropump warnings.
- ▶ Warnings that occur during signal suspension are displayed once the diabetes manager is turned on or signal suspension ends.



In the Main menu, tap **Signals**.



**Note**

If you use the **Once** setting, the signals for reminders and warnings are turned off only once for the time period you specified.

If you use the **Repeat** setting, the signals for reminders and warnings are turned off daily during the time period you specified.

Once the signal suspension time has expired, the signals for the reminders and warnings that occurred are issued again.

11.6 General Settings

Main menu > Settings > General settings

You can make the following settings in the general settings:

▶ **Language**

You can select the language for the texts displayed on the screen from a predefined list of languages.

▶ **Brightness**

You can adjust the brightness of the diabetes manager screen for different lighting conditions.

▶ **Check system functions**

For more information, see chapter 14 *Care and Maintenance*.

Language

1



Tap **Language** or **Brightness** to make the desired settings.

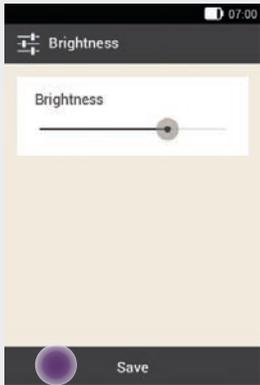
2



Tap the entry for the language in which you want the menus and texts to appear on the screen.

Brightness

1

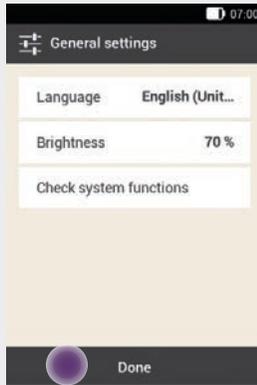


Set the screen brightness by moving the slider.

- ▶ Right: bright
- ▶ Left: dark

Tap **Save**.

2



Tap **Done** to return to the list of settings.

11.7 Screen Lock

Main menu > Settings > Screen lock

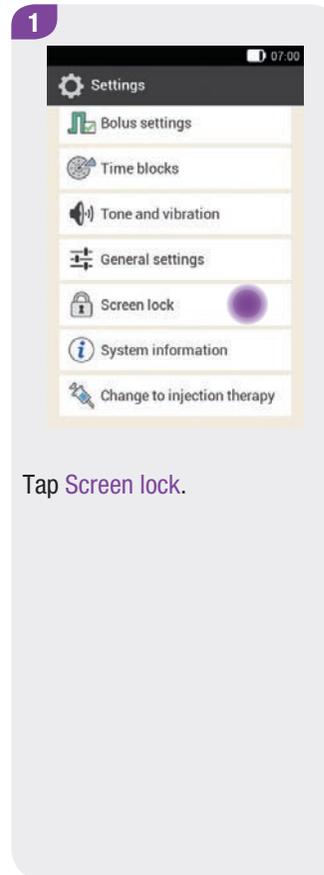
The diabetes manager is equipped with a screen lock, which can be used to protect the device against unauthorised access. You can define a personal identification number (PIN) to be used for access. The PIN is an identification code with four to eight digits that you enter and change in the [Screen lock](#) 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.

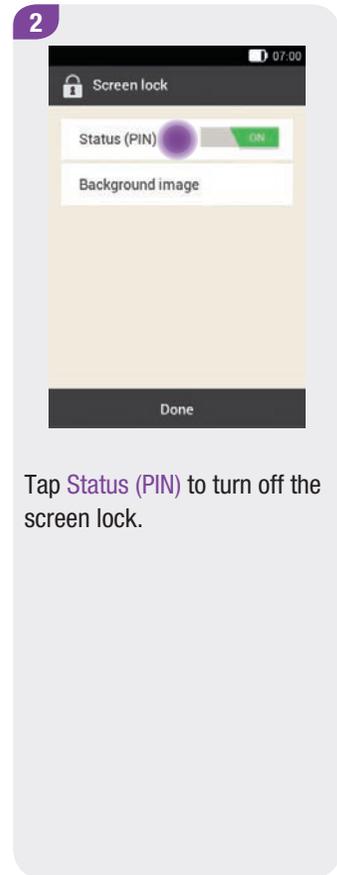
Note

- ▶ 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.



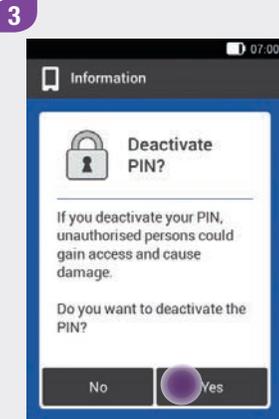
Tap [Screen lock](#).

Turning off the screen lock



Tap [Status \(PIN\)](#) to turn off the screen lock.

Turning on the screen lock



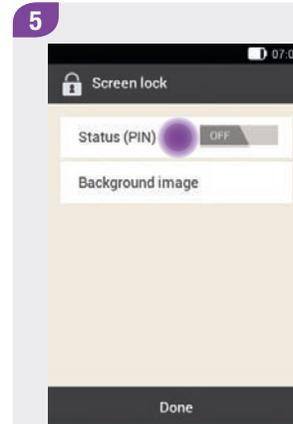
When you turn off the screen lock, the above display appears for your information.

Tap **Yes** if you do **not** want to enter a PIN or if you want to **change the PIN**.

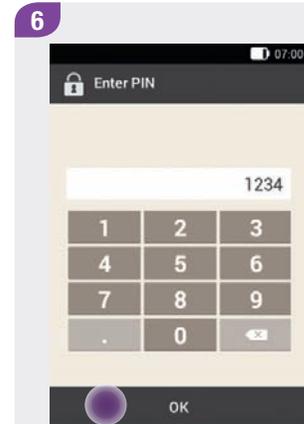


Enter the PIN to confirm it.

Tap **OK**.



Tap **Status (PIN)** to turn on the screen lock.



Enter a PIN with 4 to 8 digits.

Tap **OK**.

7



Enter the PIN again to confirm it.

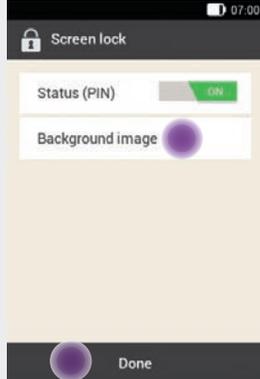
Tap **OK**.

Note

If you have forgotten the PIN you chose, you can unlock the diabetes manager with a PIN unlock code. You can find the label with the 8-digit PIN unlock code on the back cover of the User's Manual.

Changing the background image

1



Tap **Background image** to set the pattern for the background of the active screen lock.

Then tap **Done**.

2



Tap the tile with the desired background image.

Tap **None** if you do not want to have a background image.

Tap **Done**.

11.8 System Information

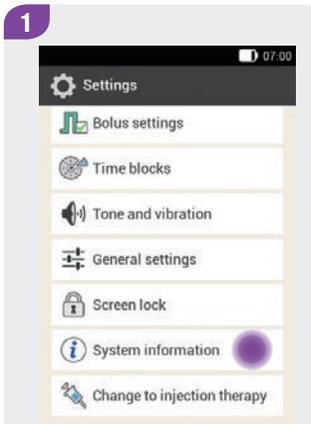
Main menu > Settings > System information

The system information provides various details on the micropump system:

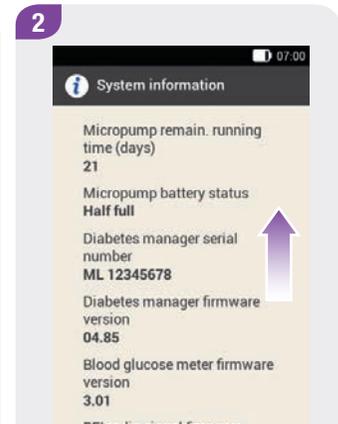
- ▶ Micropump remaining running time
- ▶ Serial number of the diabetes manager
- ▶ Firmware of the diabetes manager
- ▶ Firmware of the blood glucose meter in the diabetes manager
- ▶ Radio frequency signal of the RFI firmware
- ▶ Selected language
- ▶ Status of rechargeable battery
- ▶ Date of manufacture
- ▶ Diabetes manager hardware update
- ▶ Number of resets/times switched on/off
- ▶ Number of blood glucose tests/control tests
- ▶ Serial number, micropump battery status, micropump firmware version

In addition, you can read legal information and the License Terms and Conditions.

Some of this information is primarily used by technical customer support and may be requested by your Customer Support and Service Centre.



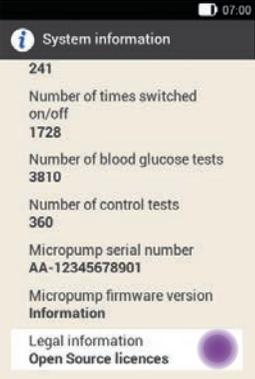
Tap **System information**.



The list of system information is displayed.

Scroll the display upwards to see additional system information.

3



System information

241

Number of times switched on/off
1728

Number of blood glucose tests
3810

Number of control tests
360

Micropump serial number
AA-12345678901

Micropump firmware version
Information

Legal information
Open Source licences

Tap the **Legal information** entry to view the stored license agreements.

4



Legal information

Open Source licence agreement

Sed sodales pretium risus, nec consequat urna viverra sed. Sed ornare auctor tortor quis feugiat. Duis porta sagittis justo, ac ultricies nisl commodo non. Interdum et malesuada fames ac ante ipsum primis in faucibus. Quisque consequat, velit blandit sagittis ultrices, odio nibh aliquam est, in placerat tortor sapien ut ante. Curabitur vehicula lorem sit amet arcu cras aliquam. Donec accumsan libero elit. Sed maximus augue tristique sit amet. Sed est quis justo sagittis tincidunt. Sed egestas quam sed mi sollicitudin suscipi que ultricies iaculis ipsum, id blandit et lentesque ut. Praesent ultrices moris at maximus tristique.

Duis ut sapien nec ante iaculis suscipit. Nam condimentum tincidunt sem, quis facilisis augue hendrerit ac. Aenean vel semper arcu. Ut posuere arcu lorem, hendrerit maximus. Etiam tincidunt non. Etiam tincidunt non.

Scroll the display upwards to be able to read more text.

Tap **←** to return to the previous display.

11.9 Travelling and Flight Mode

Time zone changes

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 chapter *11.2 Time and Date*.

Flight mode

If the use of *Bluetooth* wireless technology is not allowed for flights, you can turn on flight mode. In flight mode, the diabetes manager and the micropump stop all activities of *Bluetooth* wireless technology, and communication between the two devices is suspended.

If the quick bolus feature was activated, you can continue to deliver boluses using the quick bolus buttons on the micropump. As soon as flight mode is turned off, the diabetes manager and micropump synchronise and update the event data.

11.9.1 Turning On Flight Mode

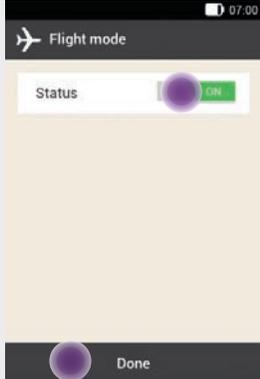
1



In the Main menu, tap **Flight mode**.

The screenshot shows a grid of icons: Bolus, Basal rate, Stop, Test, Replace, Settings, My data, USB, Flight mode, Signals, and Help. At the bottom are 'Status screen', a gear icon, and 'Add data'.

2

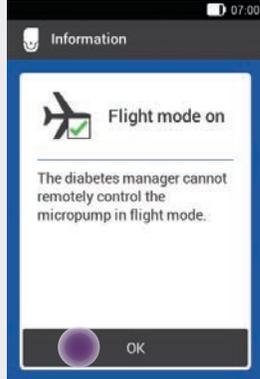


Tap **Status** to put the switch in the **ON** position.

Tap **Done**.

The screenshot shows a 'Flight mode' header with an airplane icon. Below it is a 'Status' label and a toggle switch that is currently in the 'ON' position. A 'Done' button is at the bottom.

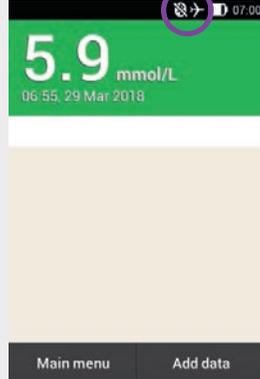
3



Confirm the displayed information by tapping **OK**. The micropump is automatically set to flight mode.

The screenshot shows an 'Information' dialog box with a blue border. It contains an airplane icon and the text 'Flight mode on'. Below this is a warning: 'The diabetes manager cannot remotely control the micropump in flight mode.' At the bottom is an 'OK' button.

4



The **✈** symbol in the status bar indicates that flight mode is turned on.

No micropump data is displayed in flight mode.

The screenshot shows the top of the app with a green header displaying '5.9 mmol/L' and '06:55, 29 Mar 2018'. In the status bar at the top, an airplane icon is circled in purple. At the bottom are 'Main menu' and 'Add data' buttons.

11.9.2 Turning Off Flight Mode

1



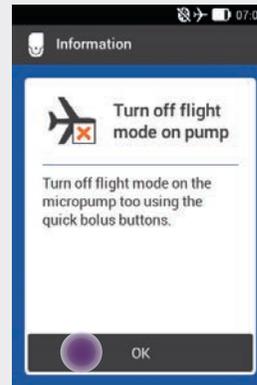
In the Main menu, tap the **Flight mode** menu.

2



Tap **Status** to put the switch in the **OFF** position.

3



Confirm the displayed information by tapping **OK**.

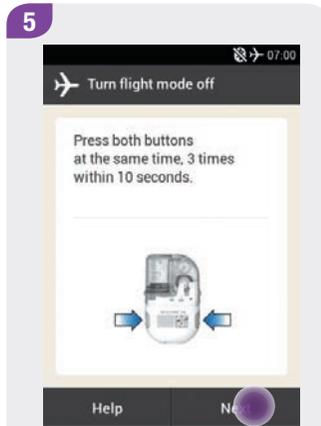
Note

It is not possible to turn off flight mode on the micropump using the diabetes manager.

To turn off flight mode on the pump, you must use the quick bolus buttons.

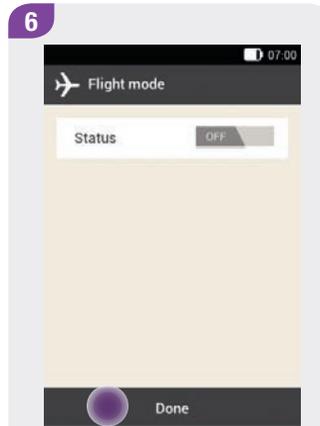


Press both quick bolus buttons 3 times simultaneously in quick succession in quick succession. A maximum of 3 seconds may pass between each key press.

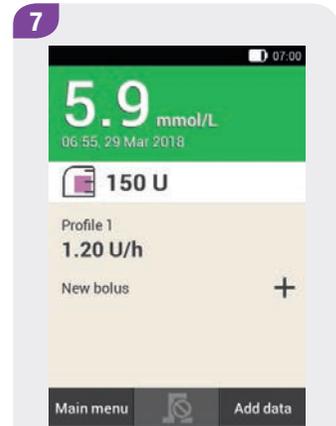


When flight mode is turned off, the micropump issues the “Flight mode deactivated” signal sequence.

Tap **Next**.



Tap **Done**.



Flight mode is turned off.

The flight mode symbol is no longer displayed in the status bar.

12 Reminders

Main menu > Settings > 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 screen and a signal 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, blood 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	Explanation
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 blood glucose result as Before meal .
Test after low blood glucose result	Reminds you to test your blood glucose if your test result was below the set blood glucose value.
Test after high blood glucose result	Reminds you to test your blood glucose if your test result was above the set blood 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

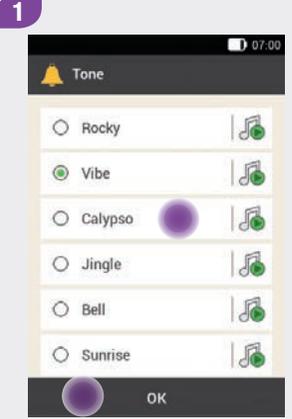
Set the desired time and frequency for each reminder. If you choose **Repeat**, you will be reminded of the event at certain intervals, for example, daily.

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 the **+** symbol. 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.

1

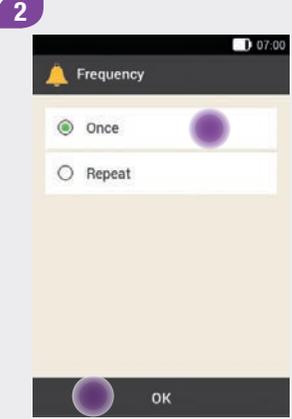


Tap the desired tone to use for the reminder.

Tap  to listen to the tone beforehand.

Tap **OK**.

2



Choose **Once** or **Repeat**.

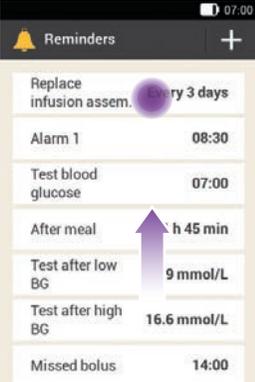
Depending on the reminder type, the system offers different repetition intervals.

Tap **OK**.

12.2.1 Reminder: Replace Infusion Assembly

This reminder reminds you to replace your infusion assembly.

1

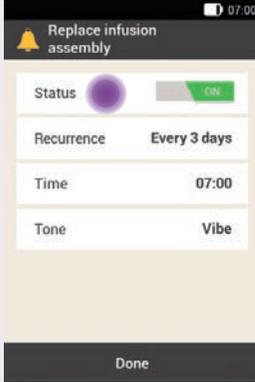


Reminders

Replace infusion assem.	Every 3 days
Alarm 1	08:30
Test blood glucose	07:00
After meal	1 h 45 min
Test after low BG	9 mmol/L
Test after high BG	16.6 mmol/L
Missed bolus	14:00

Tap **Replace infusion assem..**

2



Replace infusion assembly

Status	<input checked="" type="checkbox"/> ON
Recurrence	Every 3 days
Time	07:00
Tone	Vibe

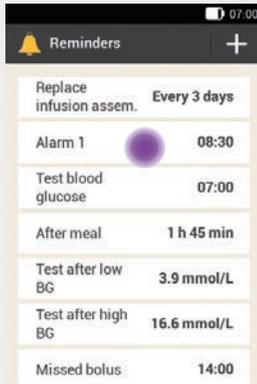
Done

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**.

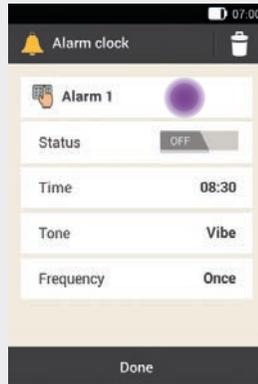
12.2.2 Reminder: Alarm Clock

1



Tap **Alarm clock 1**.

2



Tap  to assign a name to the alarm clock reminder.

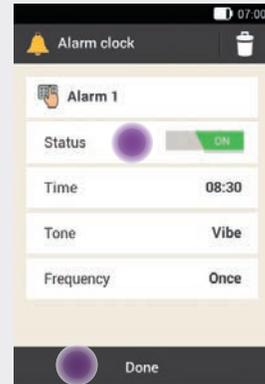
3



Enter a name for the alarm clock reminder using the keyboard. The name may have up to 15 characters.

Tap **Done**.

4



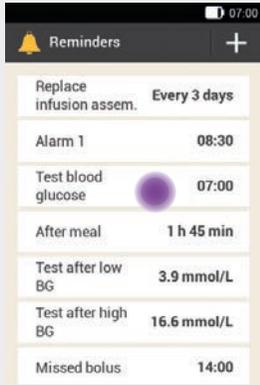
Tap **Status** to put the switch in the **ON** position. Tap **Time**, **Tone** or **Frequency** to make the desired settings.

Once you have made all settings, tap **Done**.

12.2.3 Reminder: Test Blood Glucose

This reminder reminds you to test your blood glucose at a time that was specified beforehand.

1

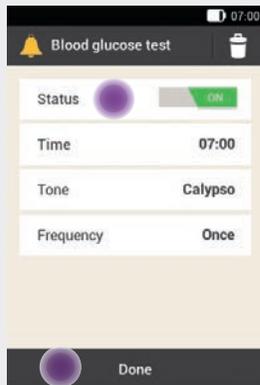


Reminders

Replace infusion assem.	Every 3 days
Alarm 1	08:30
Test blood glucose	07:00
After meal	1 h 45 min
Test after low BG	3.9 mmol/L
Test after high BG	16.6 mmol/L
Missed bolus	14:00

Tap **Test blood glucose**.

2



Blood glucose test

Status ON

Time 07:00

Tone Calypso

Frequency Once

Done

Tap **Status** to put the switch in the **ON** position. Tap **Time**, **Tone** or **Frequency** to make the desired settings.

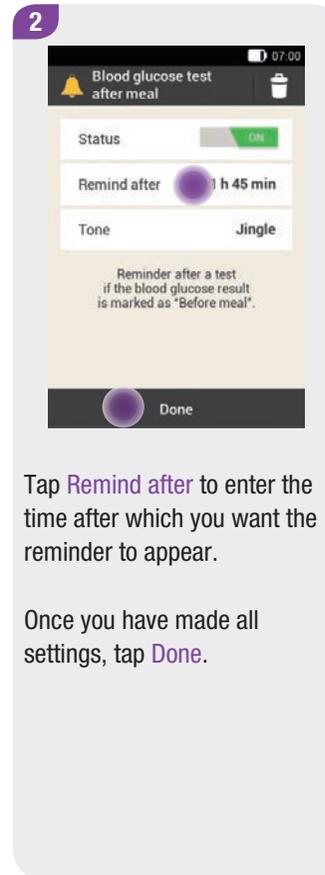
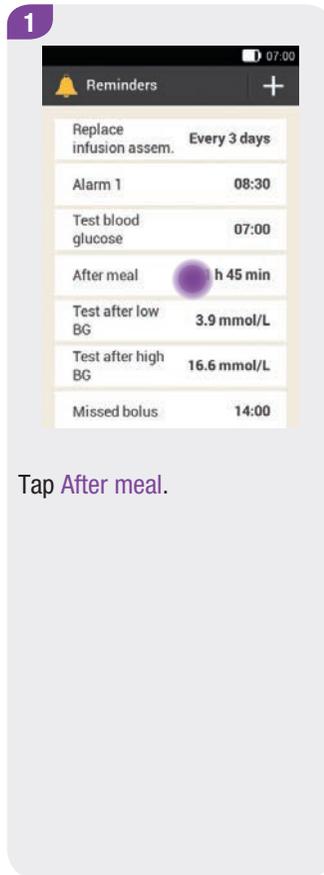
Once you have made all settings, tap **Done**.

Note

When you test your blood glucose, the diabetes manager dismisses any blood glucose test reminders that are pending within the next 30 minutes.

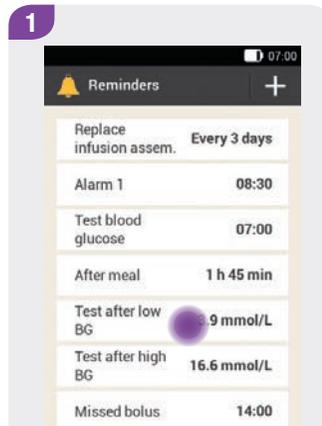
12.2.4 Reminder: After meal

This reminder reminds you to test your blood glucose if a previously measured blood glucose result was marked as *Before meal*.

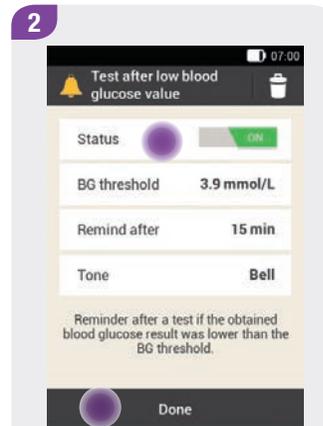


12.2.5 Reminder: Test After Low BG

This reminder reminds you to test your blood glucose again when the previous test result was too low. The BG threshold in this reminder can be set individually and is independent of the hypo warning limit set by you.



Tap the **Test after low BG** entry.



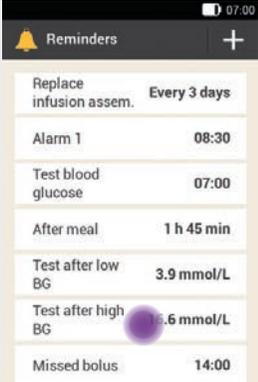
Tap **Status** to put the switch in the **ON** position. Tap **BG threshold**, **Remind after** or **Tone** to make the desired settings.

Once you have made all settings, tap **Done**.

12.2.6 Reminder: Test After High BG

This reminder reminds you to test your blood glucose again when the previous test result 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

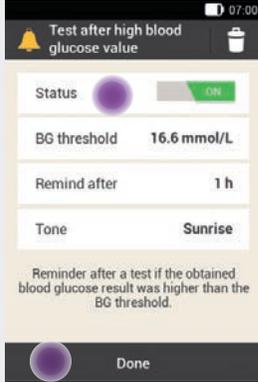


Reminders

Replace infusion assem.	Every 3 days
Alarm 1	08:30
Test blood glucose	07:00
After meal	1 h 45 min
Test after low BG	3.9 mmol/L
Test after high BG	16.6 mmol/L
Missed bolus	14:00

Tap the **Test after high BG** entry.

2



Test after high blood glucose value

Status

BG threshold 16.6 mmol/L

Remind after 1 h

Tone Sunrise

Reminder after a test if the obtained blood glucose result was higher than the BG threshold.

Done

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**.

12.2.7 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

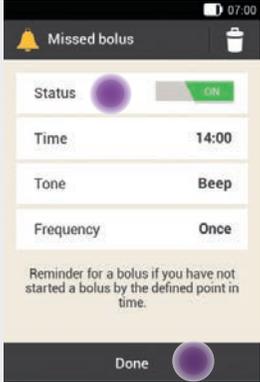


Reminders

Replace infusion assem.	Every 3 days
Alarm 1	08:30
Test blood glucose	07:00
After meal	1 h 45 min
Test after low BG	3.9 mmol/L
Test after high BG	16.6 mmol/L
Missed bolus	14:00

Tap the **Missed bolus** entry.

2



Missed bolus

Status ON

Time 14:00

Tone Beep

Frequency Once

Reminder for a bolus if you have not started a bolus by the defined point in time.

Done

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**.

12.2.8 Appointment Reminders: Healthcare Professional Visit, Lab Test, Customised

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

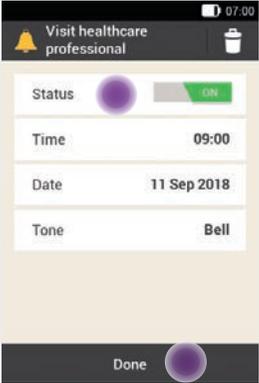


Reminder	Date
Test after low BG	3.9 mmol/L
Test after high BG	16.6 mmol/L
Missed bolus	14:00
Healthcare professional visit	11 Sep 2018
Lab test	16 Sep 2018
Custom 1	04 Nov 2018

To add a customised reminder, tap "+".

Tap **Healthcare professional visit**.

2



Visit healthcare professional

Status ON

Time 09:00

Date 11 Sep 2018

Tone Bell

Done

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 reminders you added yourself. The reminders that are predefined in the system, however, cannot be deleted.

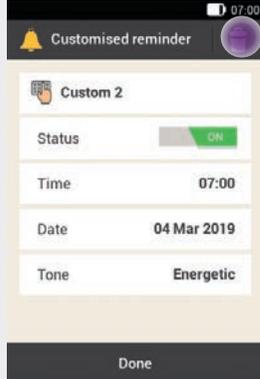
1



The screenshot shows a list of reminders under the heading 'Reminders'. The items are: 'Fastener high BG' with a value of '16.6 mmol/L', 'Missed bolus' at '14:00', 'Healthcare professional visit' on '11 Sep 2018', 'Lab test' on '16 Sep 2018', 'Custom 1' on '04 Nov 2018', and 'Custom 2' on '04 Mar 2019'. A purple circle highlights the 'Custom 2' entry. At the bottom, there is a note: 'To add a customised reminder, tap "+".'

Tap the reminder you want to delete, for example, **Custom 2**.

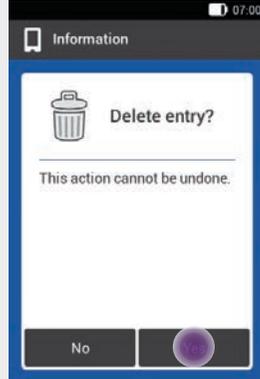
2



The screenshot shows the details for 'Custom 2'. It includes a status bar at the top with a bell icon and the text 'Customised reminder'. Below that, there is a trash can icon and the text 'Custom 2'. The details listed are: 'Status' (ON), 'Time' (07:00), 'Date' (04 Mar 2019), and 'Tone' (Energetic). A 'Done' button is at the bottom. A purple circle highlights the trash can icon.

Tap the  symbol to delete the reminder.

3



The screenshot shows a confirmation dialog titled 'Delete entry?'. It features a trash can icon and the text 'Delete entry?'. Below this, it says 'This action cannot be undone.' At the bottom, there are two buttons: 'No' and 'Yes'. A purple circle highlights the 'Yes' button.

Tap **Yes** if you want to permanently delete the reminder now.

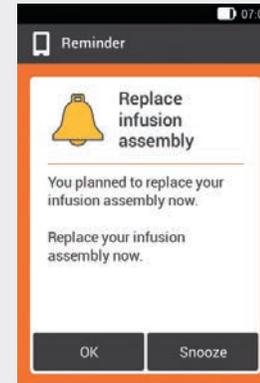
12.4 Issuing Reminders

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 signal 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



Reminder: Replace infusion assembly

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 test result and in the logbook entries of the diabetes manager.
- ▶ A reminder is available that you can use to be reminded about basal insulin injections.

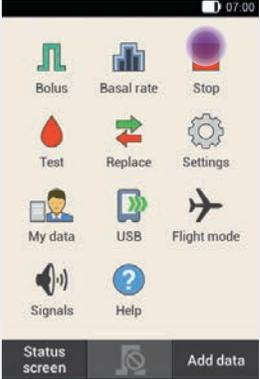
Note

- ▶ 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. For more information, see chapter *16 Technical Data*.

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



The screenshot shows the main menu of the micropump application. The menu is organized into a grid of icons with labels: Bolus (green waveform), Basal rate (blue bar chart), Stop (purple circle with a red slash), Test (red drop), Replace (green and red arrows), Settings (grey gear), My data (person icon), USB (blue USB symbol), Flight mode (black airplane), Signals (speaker icon), and Help (blue question mark). At the bottom, there are three buttons: 'Status screen', a micropump icon, and 'Add data'. The 'Stop' option is highlighted with a purple glow.

In the Main menu, tap **Stop** to interrupt insulin delivery.

2



The screenshot shows an 'Information' dialog box with a red square icon. The text reads: 'Stop insulin delivery? If you stop the micropump, insulin delivery will be interrupted. Do you want to stop the micropump?'. At the bottom, there are two buttons: 'No' and 'Yes'. The 'Yes' button is highlighted with a purple glow.

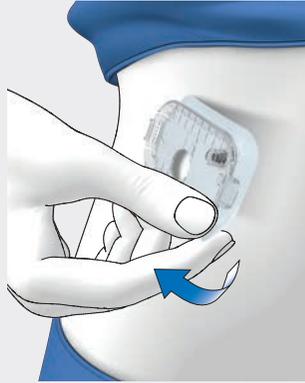
Tap **Yes**.

3



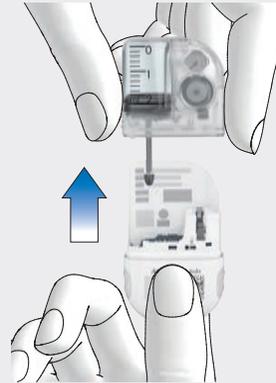
Press the flap to detach the micropump and remove the pump from the infusion assembly.

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.

6



Dispose of the used infusion assembly and used reservoir according to local regulations.

Keep the pump base in a safe place.

13.1.1 Activating Injection Therapy Mode

1



The screenshot shows a grid of icons on a light beige background. The icons are: Bolus (green waveform), Basal rate (blue bar chart), Start (green play button), Test (red blood drop), Replace (green and red arrows), Settings (purple gear), My data (person icon), USB (blue USB symbol), Flight mode (black airplane), Signals (black speaker), and Help (blue question mark). At the bottom, there are two buttons: 'Status screen' and 'Add data'. The top status bar shows the time as 07:00.

In the Main menu, tap the **Settings** menu.

2



The screenshot shows a list of settings on a light beige background. The items are: Bolus settings (with a green waveform icon), Time blocks (with a clock icon), Tone and vibration (with a speaker icon), General settings (with a gear icon), Screen lock (with a lock icon), System information (with an 'i' icon), and Change to injection therapy (with a purple syringe icon). The 'Change to injection therapy' item is highlighted with a purple circle. The top status bar shows the time as 07:00.

Tap the **Change to injection therapy** entry.

3



The screenshot shows a dialog box with a blue border on a light beige background. At the top, it says 'Information' with a document icon. Below that is a syringe icon and the text 'Change to injection therapy?'. A warning message follows: 'All micropump functions will be deactivated if you change to injection therapy mode.' Below the warning is the question 'Do you want to continue?'. At the bottom, there are two buttons: 'No' and 'Yes'. The 'Yes' button is highlighted with a purple circle. The top status bar shows the time as 07:00.

Tap **Yes**.

The functions for controlling the micropump will be turned off.

4



The screenshot shows a dialog box with a syringe icon and the title 'Insulin increment' on a light beige background. There are two radio button options: '0.5 U' (which is selected) and '1.0 U'. At the bottom, there is a 'Save' button. The '0.5 U' option and the 'Save' button are highlighted with purple circles. The top status bar shows the time as 07:00.

Tap the desired insulin increment for the pen.

Tap **Save**.

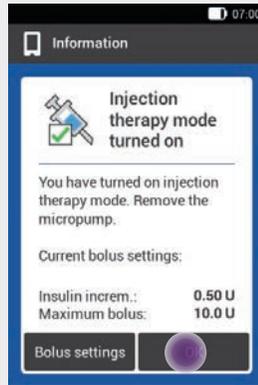
5



Use **-** and **+** to set the maximum bolus amount you want to deliver with the pen/syringe.

Tap **OK**.

6



The display 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



The screenshot shows the main menu of the application. At the top, there is a status bar with the time 07:00. Below it, there are several icons: Bolus (a green waveform), Settings (a purple gear), USB (a blue USB symbol), Test (a red blood drop), Help (a blue question mark), My data (a person icon), and Signals (a speaker icon). At the bottom, there are two buttons: 'Status screen' and 'Add data'.

In the Main menu, tap the **Settings** menu.

2



The screenshot shows the Settings menu. At the top, there is a status bar with the time 07:00. Below it, there is a 'Settings' header with a gear icon. The menu items are: Bolus settings (with a green waveform icon), Time blocks (with a clock icon), Tone and vibration (with a speaker icon), General settings (with a list icon), Screen lock (with a lock icon), System information (with an information icon), and Change to pump therapy (with a purple gear icon). The 'Change to pump therapy' entry is highlighted with a purple circle.

Tap the **Change to pump therapy** entry.

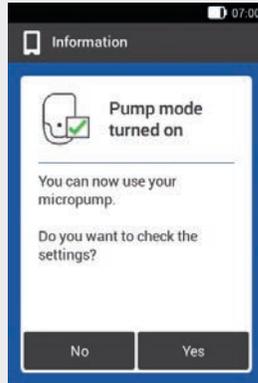
3



The screenshot shows a dialog box titled 'Change to pump mode?'. It features a pump icon on the left. The text inside the dialog box reads: 'If you change to pump therapy mode, all injection therapy functions will be deactivated. Do you want to continue?'. At the bottom, there are two buttons: 'No' and 'Yes' (highlighted with a purple circle).

Tap **Yes**.

4



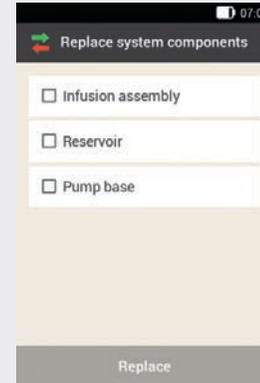
If you want to use the micropump with the most recently saved settings, tap **No**.

- ▶ 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 the components as needed. For more information, see chapter 9 *Replacing System Components*.

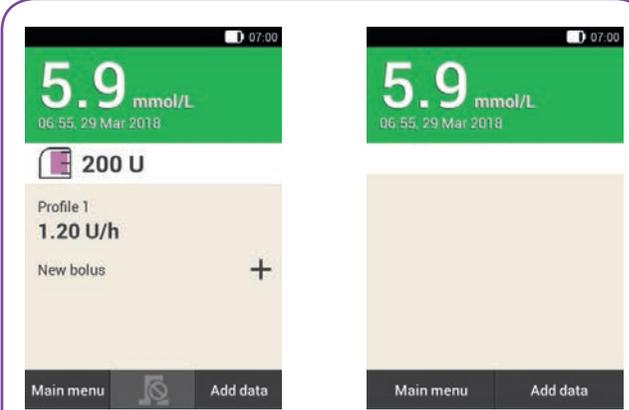
If you do **not** replace any components, the micropump will remain in STOP mode. In this case, start the pump from the Main menu.

13.2 Injection Therapy Displays

Once you turn on injection therapy mode, some of the displays and menus on the diabetes manager change. The displays 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.

The  button to cancel an ongoing bolus is omitted in injection therapy mode.

Display elements omitted on the Status screen



The image shows two side-by-side screenshots of the Status screen. The left screenshot is for pump therapy mode, showing a green header with '5.9 mmol/L' and '06:55, 29 Mar 2018'. Below the header is a reservoir icon and '200 U'. A large section shows 'Profile 1' with a basal rate of '1.20 U/h' and a 'New bolus' button with a plus sign. The bottom navigation bar has 'Main menu', a cancel bolus button, and 'Add data'. The right screenshot is for injection therapy mode, showing the same green header with '5.9 mmol/L' and '06:55, 29 Mar 2018'. The area below the header is empty. The bottom navigation bar has 'Main menu' and 'Add data'.

Status screen in pump therapy mode.

Status screen in injection therapy mode.

Display element	Status screen for injection therapy
	Reservoir symbol omitted
Basal Rate Profile 1 0.50 U/h	Basal rate information omitted
Standard 6.50 U	Ongoing bolus information omitted

Symbols omitted in the Main menu



Main menu in pump therapy mode.



Main menu in injection therapy mode.

Menu icon	Main menu for injection therapy
	Start and Stop menu is omitted
	Basal rate menu is omitted
	Replace menu is omitted
	Flight mode menu is omitted

Test result in detail



Test result in detail display in pump therapy mode.



Test result in detail display in injection therapy mode.

You will also see the entry field for basal insulin.

Bolus

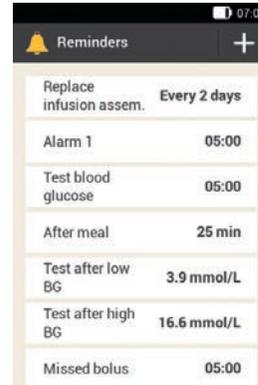


Bolus display in pump therapy mode.

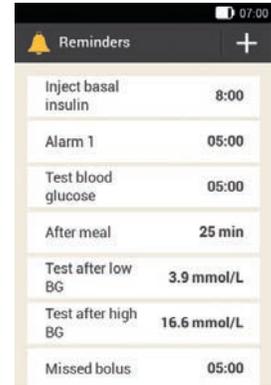


Bolus display in injection therapy mode.
The **Cancel bolus** element is omitted.

Reminders



Reminders display in pump therapy mode.



Reminders display in injection therapy mode.

Instead of the **Replace infusion assem.** reminder, the **Inject basal insulin** reminder appears.

Warning limits



Warning limits display in pump therapy mode.



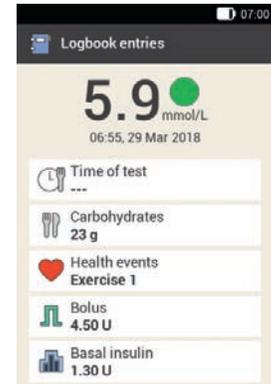
Warning limits display in injection therapy mode.

The **Micropump remain. running time (days)**, **Reservoir level** and **Automatic off** options are omitted.

My data



Logbook entries display in pump therapy mode.



Logbook entries display in injection therapy mode.

You can enter or change the amount of basal insulin delivered in the **Basal insulin** entry.

Bolus advice



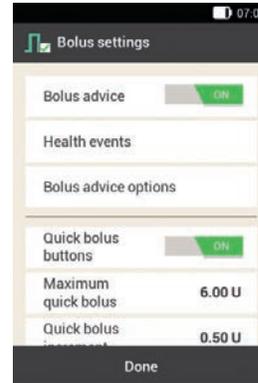
Bolus advice display in pump therapy mode.



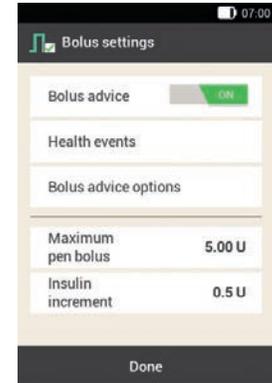
Bolus advice display in injection therapy mode.

The Type entry provides only the Pen option.

Bolus settings



Bolus settings display in pump therapy mode.



Bolus settings display 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 Tests* 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 your Customer Support and Service Centre. Do not attempt to repair the diabetes manager or micropump yourself.

Replace the consumables for the micropump system if they are soiled.

14.1 Cleaning the Micropump System

Use exclusively lint-free cloths and demineralised water to clean the micropump system.

WARNING

Use exclusively demineralised water to clean the micropump system.

Note

- ▶ Avoid liquid or moisture entering the openings on the diabetes manager.
- ▶ Do not spray demineralised water directly onto the diabetes manager or micropump.
- ▶ Do not immerse the diabetes manager or micropump in liquids.

14.1.1 Cleaning the Diabetes Manager

Use only demineralised water. Use neither soap nor abrasive cleaning agents, as they may cause the screen to become scratched. If the screen of the diabetes manager is scratched, it may be difficult to read under certain circumstances. In this case, the diabetes manager must be replaced.



1
Turn off the diabetes manager and 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 demineralised water.

Be careful not to wipe any dirt into the openings on the diabetes manager.

3



Wipe the surface of the diabetes manager for at least 3 minutes using a second, lint-free cloth moistened with demineralised water. Clean in particular hard-to-reach places, for example, around the openings.

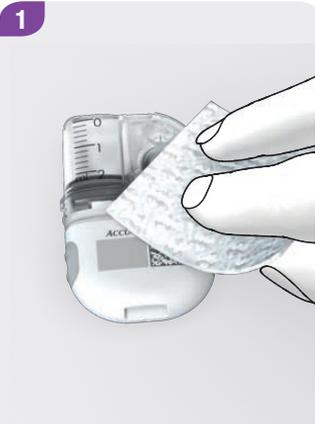
4



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.



1
Remove any large contaminants with a lint-free cloth moistened with demineralised water.

Be careful not to wipe any dirt into the openings on the pump base.



2
Wipe the surface of the micropump for at least 3 minutes using a second, lint-free cloth moistened with demineralised water. Clean in particular hard-to-reach places, for example, around the openings.



3
Wipe the surface 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

Cleaning the opening for ventilation is important for the battery in the reservoir to work properly.

14.1.3 Cleaning the Insertion Device

Clean the insertion device using the stipulated cleaning agents.

Before cleaning the insertion device, ensure that the insertion device is not primed and there is **no** cannula assembly in the insertion device.



Remove any large contaminants with a lint-free cloth moistened with demineralised water.

Be careful not to wipe any dirt into the openings on the insertion device.



Wipe the surface of the insertion device for at least 3 minutes using a second, lint-free cloth moistened with demineralised water. Clean in particular hard-to-reach places, for example, around the openings.

14.1.4 Cleaning the Finger Pricker

To prevent infections from being transmitted, you must regularly clean the finger pricker and cap:

- ▶ at least 1 time per week,
- ▶ when there is blood on it,
- ▶ always before another person picks up the finger pricker to help you, for example.

Observe the cleaning and disinfection notes in the instructions for use for the finger pricker.



Wipe the surface of the finger pricker for at least 3 minutes using a lint-free cloth moistened with demineralised water. Clean in particular hard-to-reach places.



Wipe the outside and inside of the cap in the same manner.

Wipe the finger pricker and cap using a dry cloth.

14.2 Control Test of the Diabetes Manager

You can check whether the diabetes manager is delivering correct test results 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 test result 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 Aviva 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 following items:

- ▶ Diabetes manager
- ▶ Accu-Chek Aviva test strips
- ▶ Accu-Chek Aviva control solution Control 1 or Control 2
- ▶ A clean, dry paper towel

Note

- ▶ 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 the [Test](#)  menu.
- ▶ 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 signal sounds.

3



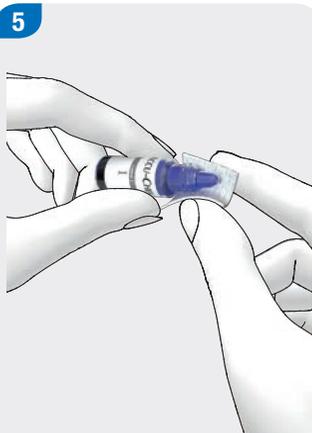
Select the control solution to test.

4



Place the diabetes manager on a flat and solid surface (for example, a table top).

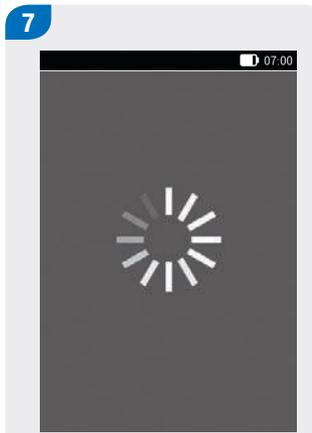
Applying a drop



Remove the bottle cap. Wipe the tip of the bottle with a paper towel.



Squeeze the bottle until a tiny drop forms at the tip. Touch the drop to the **front edge** of the yellow window of the test strip. Do not put control solution on top of the test strip.



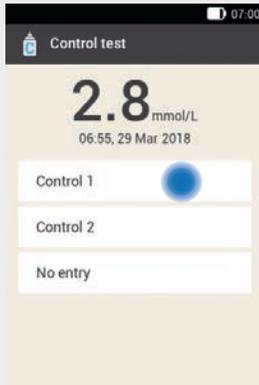
Testing starts when there is enough control solution in the test strip.



Wipe the tip of the bottle with a paper towel. Cap the bottle tightly.

Displaying the control result

9



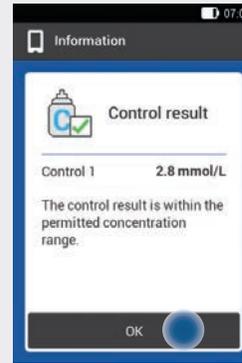
The control result is displayed.

Tap the control solution you used (for example, [Control 1](#)).

Note

If you choose [No entry](#), the control test display shown in the next step will not appear. The control result will not be analysed. Continue with Step 12.

10



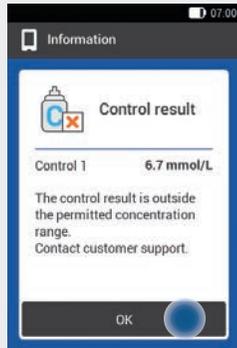
If the control result is within the permitted concentration range, the diabetes manager and test strips are working properly.

Tap [OK](#).

Note

Outside the permitted concentration range, LO or HI means that the control result is outside the permitted range. For more information, see chapter [14.2.3 Causes of Control Tests with Errors](#).

11



The table in the following section lists the causes of a control result outside the permitted concentration range or of the LO and HI displays.

Tap **OK**.

12



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 signal sounded and the **Apply drop** display 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** display 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 sections *Performing a Control Test* and *Important Information* 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*.

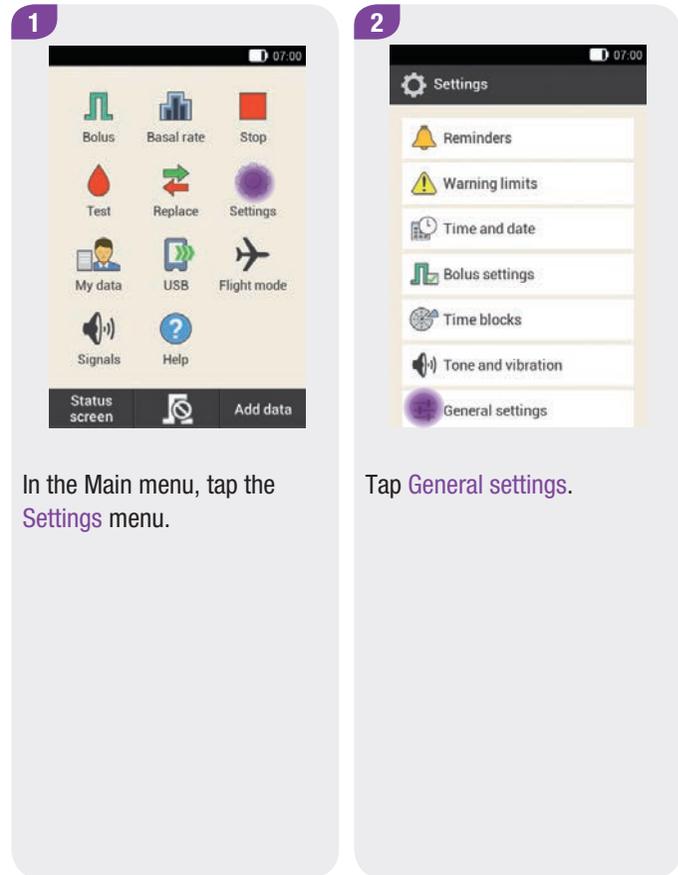
If you have observed all these items and the control result is still outside the concentration range, contact your Customer Support and Service Centre.

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 signals of the diabetes manager or suspect that there might be other defects, you can perform a system function test. This test checks whether the screen, vibration and signal features are working properly.

If the diabetes manager does not work as described in the explanations of the system function test, contact your Customer Support and Service Centre.

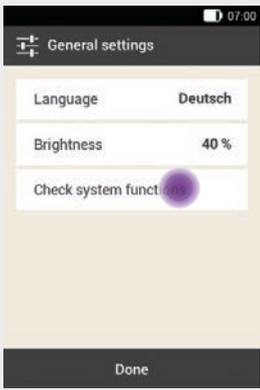


In the Main menu, tap the **Settings** menu.

Tap **General settings**.

Checking the screen

3



General settings

Language Deutsch

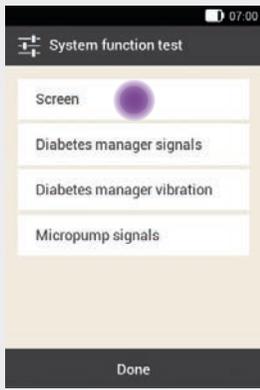
Brightness 40 %

Check system functions

Done

Tap **Check system functions**.

4



System function test

Screen

Diabetes manager signals

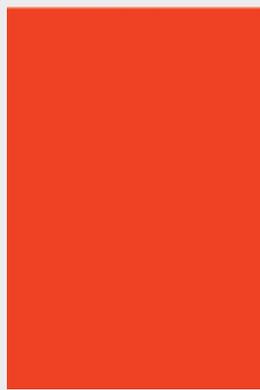
Diabetes manager vibration

Micro pump signals

Done

Tap **Screen**.

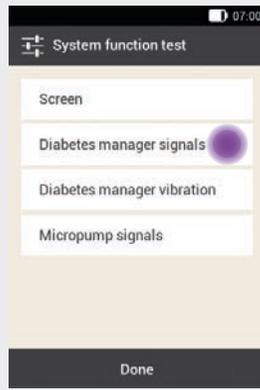
5



The screen shows different colours (red, green, blue and white) in quick succession. In addition, the diabetes manager vibrates whenever the display changes.

Diabetes manager signals

6



System function test

Screen

Diabetes manager signals

Diabetes manager vibration

Micro pump signals

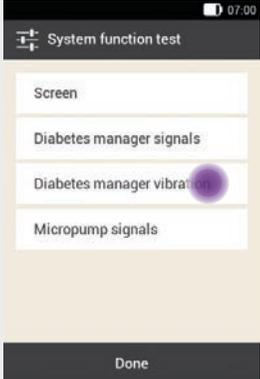
Done

Tap **Diabetes manager signals**.

The diabetes manager sounds 1 signal.

Diabetes manager vibration

7



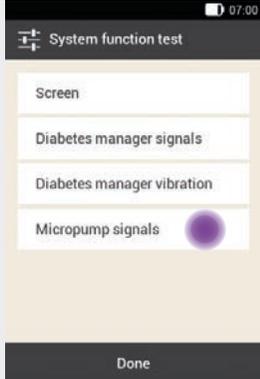
The screenshot shows a mobile application interface titled 'System function test'. It has a status bar at the top with a battery icon and the time '07:00'. Below the title bar, there are four menu items: 'Screen', 'Diabetes manager signals', 'Diabetes manager vibration', and 'Micropump signals'. A purple circular highlight is positioned over the 'Diabetes manager vibration' option. At the bottom of the screen is a dark grey bar with the word 'Done' in white text.

Tap **Diabetes manager vibration**.

The diabetes manager vibrates.

Micropump signals

8



The screenshot shows the same 'System function test' interface as in step 7. The menu items are the same, but now a purple circular highlight is positioned over the 'Micropump signals' option.

Tap **Micropump signals**.

The micropump sounds 1 signal.

Note

If you are using injection therapy mode, the **Micropump signals** entry will be deactivated and greyed out.

15 Messages and Troubleshooting

There are different types of messages that the micropump system uses to inform you about the status of the micropump system, problems or errors. These messages are:

- ▶ error messages
- ▶ maintenance messages
- ▶ warnings
- ▶ information messages

The diabetes manager issues messages on the screen 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 (screen 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 (screen is turned on).



WARNING

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

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 display, 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 screen 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 screen 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 according to the instructions provided in chapter 14.3 *Checking the System Functions*. If the problem cannot be resolved using the suggested solutions, contact your Customer Support and Service Centre.

Note

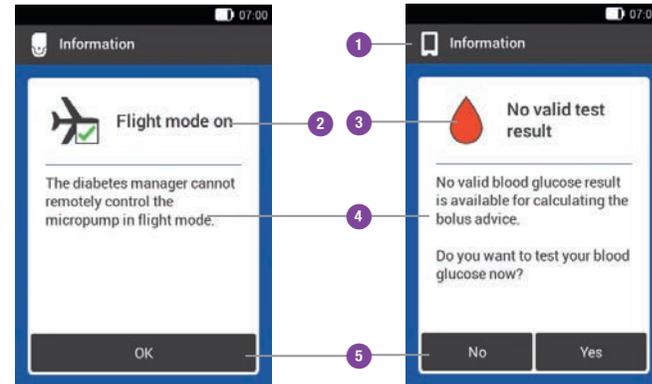
- ▶ If the micropump signals a maintenance or error message and you do not have the diabetes manager at hand, you can mute the message for 5 minutes using the quick bolus buttons on the micropump. Note that you cannot use the quick bolus buttons to deliver a quick bolus before you have muted the message.
- ▶ If the micropump issues the “Error” signal sequence 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). For more information, see chapter 15.4 *Error Messages*.

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:



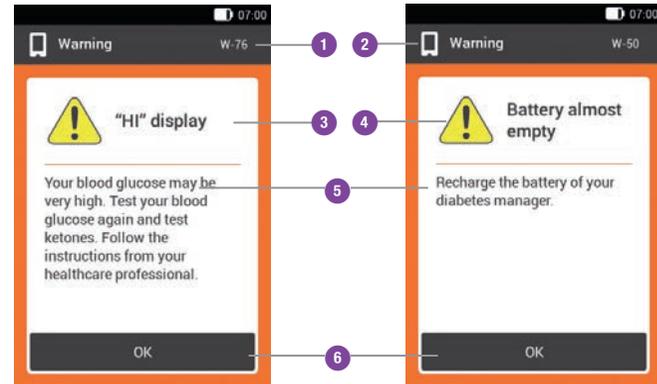
1	<ul style="list-style-type: none"> Information on the micropump Information on the diabetes manager
2	Title of information message
3	Information message symbol
4	Information or explanation
5	Buttons (OK , No , Yes)

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 warning 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” signal sequence and vibrates. For more information on the sequences of signals, see chapter 17.3 *Signals*.

Examples of warnings:



1	Warning code
2	<ul style="list-style-type: none"> 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
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 **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 cancelled	An active temporary basal rate was cancelled.	Make sure that the cancellation was intentional. Program a new temporary basal rate if required.

Code	Title of warning	Information/possible cause	Information/possible solution
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 cancelled	An ongoing bolus was cancelled.	Make sure that the cancellation was intentional. Note the insulin amount already delivered, and program a new bolus if necessary.
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.

Code	Title of warning	Information/possible cause	Information/possible solution
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 **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 blood glucose value	Test ketones and your blood glucose. Check the insulin delivery. Follow the instructions of your healthcare professional.
W-76	“HI” display	Your blood glucose 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” display	Your blood glucose result 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.	—

Code	Title of warning	Information/possible cause	Information/possible solution
W-86	Flight mode on	Data cannot be synchronised between the diabetes manager and the micropump because flight 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 flight 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	Flight mode on	The saved logbook entries may not be up to date.	When flight 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.

Messages and Troubleshooting

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

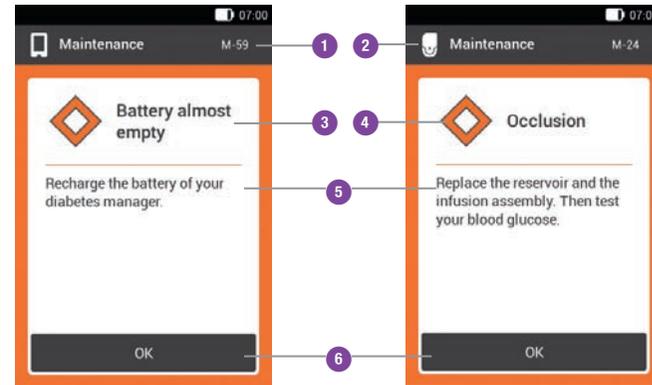
Maintenance messages inform you about a temporary loss of certain features of the micropump system. Maintenance messages require you to intervene in order to solve the problem. Once the cause of the maintenance message has been eliminated, you can use all features of the micropump system again.

When a maintenance message is displayed, the diabetes manager issues a “Maintenance” signal sequence and vibrates. The signal sequence also sounds when the [Turn off signals](#) feature is turned on. For more information on the sequences of signals, see chapter [17.3 Signals](#).

WARNING

If you do not correct the cause of the occlusion message M-24, insulin delivery may not function or may function only to a limited extent. This can lead to hyperglycaemia.

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) or postpone the maintenance message (Snooze)

Code	Title of maintenance message	Possible cause/consequences	Further information
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 **Maintenance messages triggered by the micropump.**

M-18	Replace micropump	The operating life of your micropump has come to an end.	Replace your 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 the Replace  menu and replace the reservoir.
M-22	Micropump battery empty	The micropump battery, which is located in the reservoir, is empty	Select the Replace  menu 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.

Code	Title of maintenance message	Possible cause/consequences	Further information
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 your Customer Support and Service Centre.
M-26	Fill reservoir needle	The reservoir needle must be refilled after replacing the reservoir.	Remove the micropump from the infusion assembly. Select the Replace  menu and replace the reservoir. After that, follow the instructions for filling the reservoir.
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.

Code	Title of maintenance message	Possible cause/consequences	Further information
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 **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 Apply drop appeared on the screen.	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 <i>Bluetooth</i> 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	Connection 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.	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 your Customer Support and Service Centre.
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 your Customer Support and Service Centre.
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.

Code	Title of maintenance message	Possible cause/consequences	Further information
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 your Customer Support and Service Centre.
M-88	Flight mode turned off	The micropump and the diabetes manager are not within communication range. Flight mode could not be turned on on the micropump.	Hold the diabetes manager close to the micropump.
M-94	Connection failed	There is a communication problem between the micropump and the diabetes manager.	Hold the diabetes manager close to the micropump and ensure that data communication is not disrupted. Check the micropump.
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.

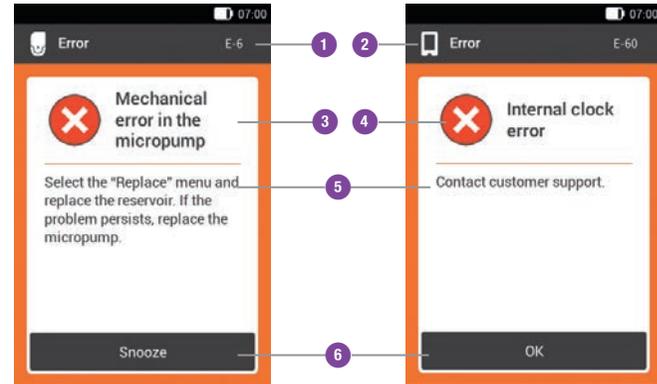
15.4 Error Messages

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” signal sequence and vibrates. The signal sequence also sounds when the **Turn off signals** feature is turned on. The vibration feature cannot be turned off. For more information on the sequences of signals, see chapter *17.3 Signals*.

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 your Customer Support and Service Centre.

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
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 **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 the Replace  menu 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 the Replace  menu 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 the Replace  menu and replace the reservoir.

Code	Title of error	Possible cause/consequences	Possible solutions
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 **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 your Customer Support and Service Centre.
E-60	Internal clock error	Internal clock error in the diabetes manager	Contact your Customer Support and Service Centre.

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 your Customer Support and Service Centre.

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. For more information, see chapter <i>3 Putting the Diabetes Manager into Operation</i> .
	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 screen is damaged or the diabetes manager is defective.	Contact your Customer Support and Service Centre.

Problem	Possible cause	Possible solutions
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 screen turns off.
		Remove the rechargeable battery from the diabetes manager and reinsert it.
The screen is defective or the colours are not represented correctly.	The screen is damaged or the diabetes manager is defective.	Perform the system function test for the diabetes manager screen. For more information, see chapter <i>14.3 Checking the System Functions</i> . If the system function test of the screen shows a problem, contact your Customer Support and Service Centre.

Problem	Possible cause	Possible solutions
The sound is faulty. You cannot hear the signals.	The feature Turn off signals is activated or the volume is set too low.	<p>Check whether the Turn off signals option is turned on. For more information, see chapter <i>11.5 Turning Off Signals Temporarily</i>.</p> <p>Check whether the signal modes (Normal, Vibration, Quiet, Loud) have sound activated and whether the volume is set to a level that is audible. For more information, see chapter <i>11.4 Tone and Vibration</i>.</p>
	The speakers are damaged or the diabetes manager is defective.	Perform the system function test for the diabetes manager. For more information, see chapter <i>14.3 Checking the System Functions</i> . If the system function test shows a problem with the signals of the diabetes manager or micropump, contact your Customer Support and Service Centre.
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 display. 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 signal mode does not include a vibration signal.	Check the settings on the Tone and vibration display. The diabetes manager only vibrates if the active signal mode (Normal , Vibration , Quiet , Loud) includes vibration.
	The vibration feature is turned off.	Check the touchscreen feedback settings (Tone , Vibration , Tone and vibr. , Off).

Problem	Possible cause	Possible solutions
<p>The occlusion message of the micropump was triggered.</p>	<p>The micropump was exposed to a temperature that was too low.</p>	<p>Make sure the ambient temperature is suitable. Replace the reservoir and the infusion assembly. Then test your blood glucose. Contact your Customer Support and Service Centre if the message is displayed repeatedly.</p>
<p>The micropump does not issue a message and the diabetes manager displays the  symbol even though the diabetes manager and micropump are within communication range.</p>	<p>The micropump is in flight mode.</p>	<p>Turn off flight mode on the micropump. For more information, see chapter <i>11.9.2 Turning Off Flight Mode</i>.</p>
	<p>The micropump was turned off by the automatic off feature.</p>	<p>Check the settings for the automatic off feature. For more information, see chapter <i>11.1 Warning Limits</i>.</p>
	<p>The micropump turned off without prior notice due to an electronic defect.</p>	<p>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.</p> <ul style="list-style-type: none"> ▶ If you hear the sequence of signals for the quick bolus, wait 5 seconds without pressing the quick bolus buttons in order to cancel the quick bolus. Check whether the connection between the diabetes manager and the micropump is being disturbed by other electronic devices. ▶ If you do not hear the signal sequence for the quick bolus, replace the pump base and the reservoir. For more information, see chapter <i>9 Replacing System Components</i>.

Problem	Possible cause	Possible solutions
<p>The micropump issues the “Error” signal sequence and the diabetes manager displays the  symbol even though the diabetes manager and micropump are within communication range.</p>	<p>The micropump turned off due to an electronic defect (E-7).</p>	<p>Select the Replace  menu 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. For more information, see chapter 9 <i>Replacing System Components</i>.</p>

16 Technical Data

16.1 Micropump System

Technical data of the 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 acoustic signals and messages on the diabetes manager screen.
Communication between micropump and diabetes manager	<i>Bluetooth</i> Low Energy (BLE) wireless technology
Transmission frequency	2402–2480 MHz

Technical data of the micropump system

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

Technical data of the diabetes manager	
Device type	Accu-Chek Aviva Solo diabetes manager The Accu-Chek Aviva 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
Screen	Capacitive colour LCD multi-touch screen with backlight
Screen size	3.5"
Screen resolution	320 × 480 pixels
Screen 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.

Technical data of the diabetes manager	
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 ²
Admissible humidity range	Storage and transport, with packaging: 5 % to 85 % During operation: 15 % to 90 %
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 signal	≥ 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

Technical data of the diabetes manager	
Power supply	Rechargeable lithium polymer battery Model: Nugen
Battery voltage	3.7 V
Battery capacity	1,530 mAh
Charging voltage via USB	5 V
Max. charging current	700 mA
USB charger	Technics switch-mode power supply, model TS051X110-0502R
IP rating	IP20
Bolus calculator	Accu-Chek Bolus Advisor
Test strip slot	Illuminated test strip slot for Accu-Chek Aviva test strips
Measuring range	0.6–33.3 mmol/L (10–600 mg/dL)
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

Technical data of the 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 flight mode on/off and muting messages temporarily
Admissible temperature range³	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 ⁵
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 %
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)

324 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.

^{4,5} according to IEC 60601-1-11:2015

Technical data of the micropump	
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 \pm 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	\pm 16 % or better at 0.1 U \pm 5 % or better at 1.0 U
Basal rate, increments	0.1 U up to under 5.0 U: increments of 0.01 U 5.0 U up to under 25.0 U: increments of 0.1 U
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

Technical data of the micropump	
Bolus delivery accuracy	±30 % or better at 0.2 U ±5 % or better at 50.0 U
Bolus amount, increments	0.2 U up to under 2.0 U: increments of 0.05 U 2.0 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
Delivery speed	Boluses: 1.0–2.5 U/min. Filling the reservoir needle: 1.0–2.5 U/min.
Sound pressure level of the signal	≥ 45 dBA at a distance of 1 m
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)

Technical data of the micropump	
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

Technical data of the infusion assembly	
Pump holder	Dimensions: Approx. 67 × 32 × 6.5 mm
Adhesive pad	Dimensions: Approx. 85 × 52 mm
Cannula	Orange: 6 mm, soft Teflon® catheter, 90° insertion angle Blue: 9 mm, soft Teflon® catheter, 90° insertion angle
Cannula fill amount	0.7 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

Technical data of the insertion device	
Dimensions	82 × 53 × 49 mm (L × W × H)
Weight	85 g
Period of use	720 insertions This corresponds to a period of use of approximately 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.

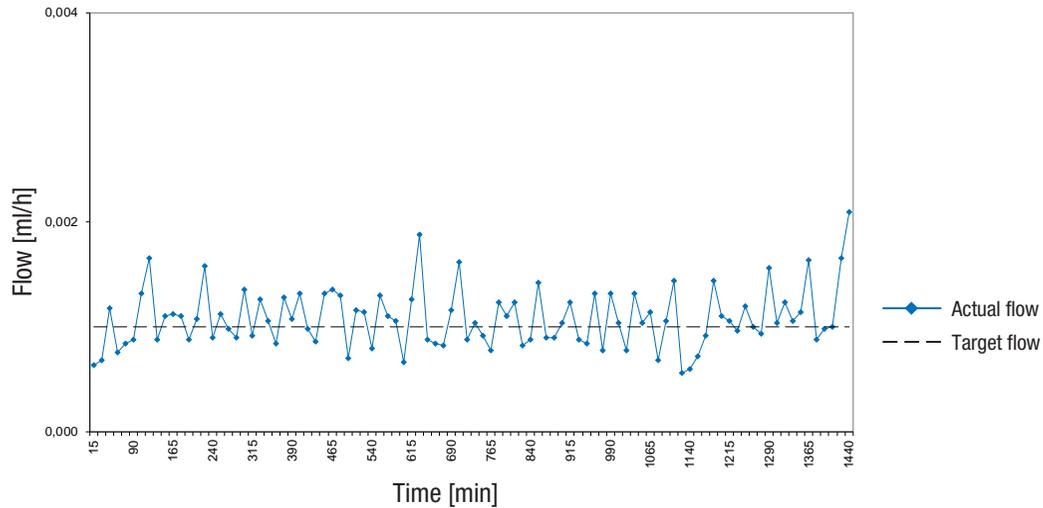
The measurements were carried out according to IEC 60601-2-24 under the following conditions:

Description	Value	Unit
Temperature	21 ± 6	°C
Relative humidity	50 ± 30	%
Atmospheric pressure	1013 ± 50	hPa

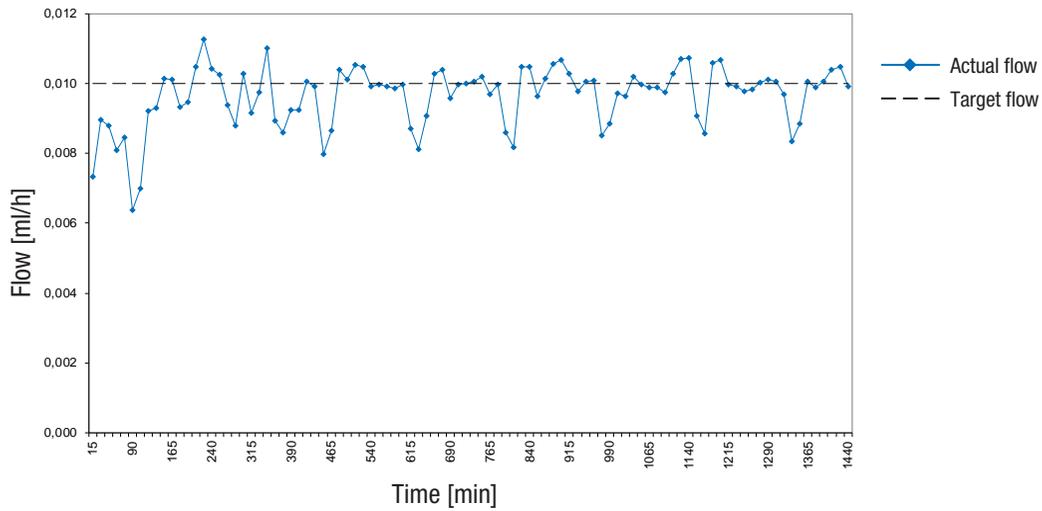
16.6.1 Startup Chart

The startup chart shows changes in the delivery rate over the stabilisation period.

0,1 U/h, 6 mm cannula



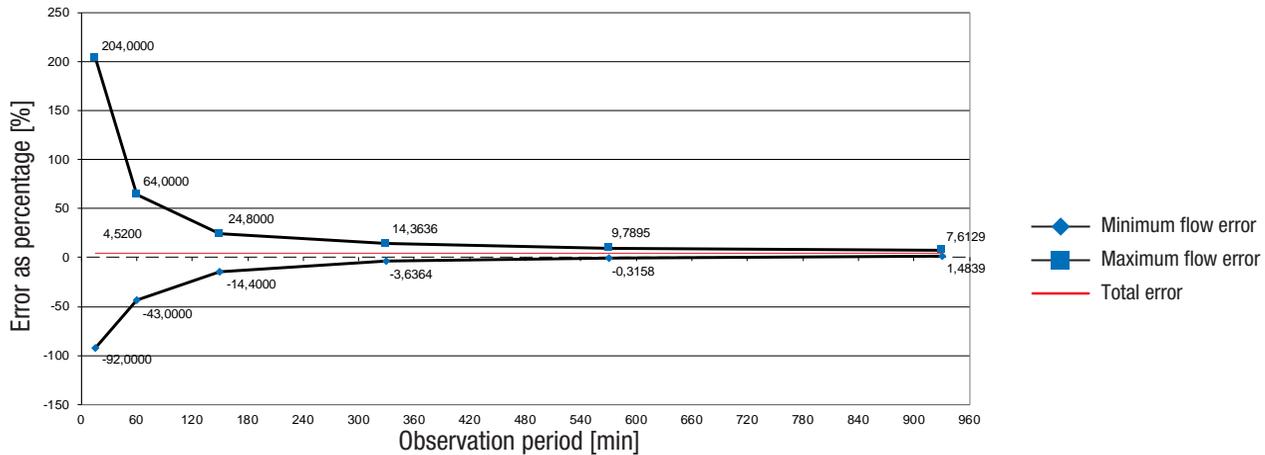
1 U/h, 9 mm cannula



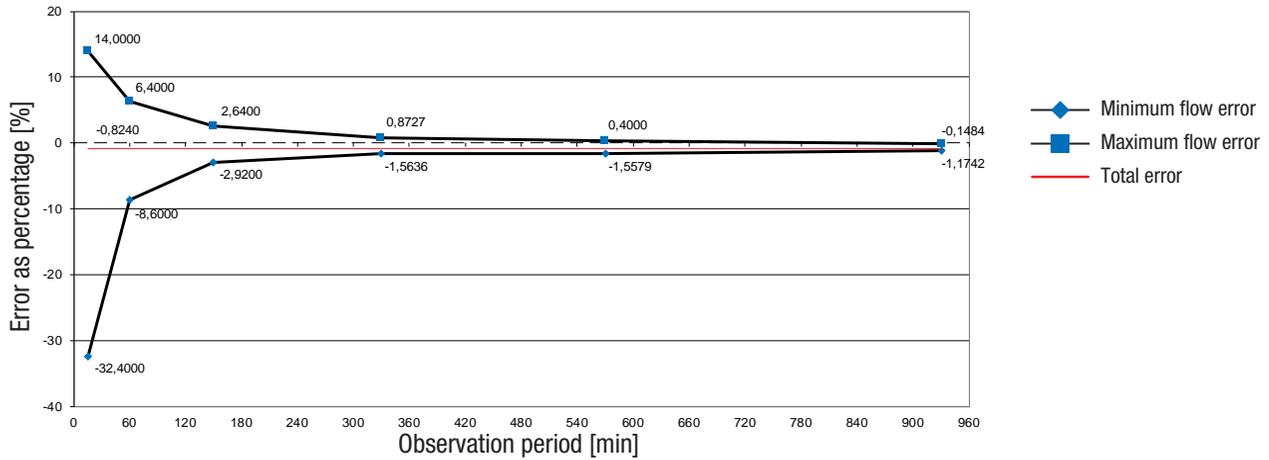
16.6.2 Trumpet Curve

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



17 Symbols, Abbreviations, Signals

17.1 Symbols

The following symbols appear on the packaging and on the micropump system components:

Symbol	Meaning
	Consult instructions for use
	Caution, refer to safety-related notes in the instructions for use accompanying this product.
	Follow instructions for use
	Temperature limitation (store at)
	Use only once
	Use by

Symbol	Meaning
	Sterilized using ethylene oxide
	Manufacturer
	Date of manufacture
	Catalogue number
	Batch code
	Serial number

Symbol	Meaning
	Global Trade Item Number
	This product fulfils the requirements of the European Directive 93/42/EEC on medical devices.
	This product also fulfils the requirements of the following directives: <ul style="list-style-type: none"> ▶ European Directive 2014/53/EU on the provision of radio equipment (RED). ▶ European Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).
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.
IC ID	The IC ID (Industry Canada Identification) indicates that the radio frequency equipment has passed the equipment authorization process for Canada.

Symbol	Meaning
	Keep away from sunlight
	Keep dry
	Do not use if package is damaged
	Admissible humidity range
	Admissible air pressure range
	Do not throw away
	<i>Bluetooth</i> [®] wireless technology
	Electronic device of type BF according to the standard IEC 60601-1. Protection against electrical shock. The micropump is an applied part BF. The diabetes manager is not an applied part.
Rx only	Federal law (USA) restricts this device to sale by or on the order of a physician

Symbol	Meaning
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°.
	Warning against device use in electromagnetic or high electrical fields or environments
	Device of protection class II
	Suitable for indoor use only
	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.

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)
IC	Industry Canada (Canadian telecommunications authority)
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization

Abbreviation	Meaning
KE	Kohlenhydrateinheit (carbohydrate unit)
LCD	Liquid Crystal Display
mg/dL	Milligrams per decilitre
mmol/L	Millimoles per litre
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.

Abbreviation	Meaning
U/h	Insulin amount delivered in units per hour
U100	Insulin concentration. Each millilitre of liquid contains 100 units of insulin.
USB	Universal Serial Bus

17.3 Signals

Both the diabetes manager and the micropump can issue signals.

17.3.1 Signals of the Diabetes Manager

The diabetes manager can issue the following sequences of signals:

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

17.3.2 Signals of the Micropump

The micropump's acoustic signals are based on the C-major scale.



The micropump uses the following frequencies:

Tone	Frequency ($\pm 2.5\%$)
A6	1760 Hz
AIS6	1864 Hz
B6	1975 Hz
C7	2093 Hz
CIS7	2217 Hz
D7	2349 Hz
DIS7	2489 Hz

The micropump can issue the following sequences of signals:

Designation	Occurrence	Notes representation
Start	▶ Plugging together pump base and reservoir	 <p>A6 AIS6 B6 C7 CIS7</p> <p>5 short, ascending tones</p>
Quick bolus	▶ Start of programming a quick bolus	 <p>A6 AIS6 B6 C7 CIS7 D7 DIS7</p> <p>7 short, ascending tones</p>
Quick bolus increment	▶ Acoustic feedback of the programmed quick bolus increments	 <p>A6</p> <p>A long, deep tone</p>
Execute	<ul style="list-style-type: none"> ▶ Confirming the programmed quick bolus increments ▶ Confirming the end of insulin delivery 	 <p>A6 AIS6 B6 C7 CIS7</p> <p>5 long, ascending tones. The last tone is longer.</p>
Cancel	<ul style="list-style-type: none"> ▶ Timeout while programming a quick bolus ▶ Programming of a quick bolus not possible ▶ Stopping the micropump 	 <p>DIS7 A6 DIS7 A6 DIS7</p> <p>4 short tones alternating high/low, followed by 1 pause and 1 long tone</p>

Designation	Occurrence	Notes representation
Maintenance Error	<ul style="list-style-type: none"> ▶ Issuing error messages ▶ Issuing maintenance messages ▶ Energy storage after battery error 	 <p>3 short tones followed by 1 pause and 1 high tone. The sequence of signals is repeated every 5 seconds.</p>
Warning	<ul style="list-style-type: none"> ▶ Issuing warnings 	 <p>1 long tone followed by 1 pause and 1 higher tone. The sequence of signals is repeated every 30 seconds.</p>
Flight mode off	<ul style="list-style-type: none"> ▶ Deactivating flight mode on the micropump 	 <p>7 short, descending tones</p>
Beep	<ul style="list-style-type: none"> ▶ Starting a bolus ▶ Starting a basal rate ▶ Starting a TBR 	 <p>A long, high tone</p>
Invalid selection	<ul style="list-style-type: none"> ▶ Exceeding the maximum insulin amount for a bolus 	 <p>4 long tones alternating low/high</p>

18 Appendix

18.1 Guarantee

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

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

18.2 Licence Information

Licence agreement for open source software:

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

18.3 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 or IEC 62368 for data processing equipment). Moreover, all configurations must comply with the normative requirements for medical systems (see section 16 of the latest edition of IEC 60601-1). Anyone who connects additional equipment to medical electrical equipment is deemed to be the system configurer, and is therefore responsible for the system being compliant with the normative requirements for systems. If you have any questions, contact your local authorised dealer or the Customer Support and Service Centre.

18.5 Customer Support and Service Centre

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

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 responsible Customer Support and Service Centre.

Distributed in the United Kingdom by:

Roche Diabetes Care Limited
Charles Avenue, Burgess Hill
West Sussex, RH15 9RY, **United Kingdom**

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.

burgesshill.insulinpumps@roche.com

www.accu-chek.co.uk

www.accu-chek.ie

Australia

Roche Diabetes Care Australia Pty. Limited

Pump Support: 1800 633 457

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 the responsible Customer Support and Service Centre.



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 or an equivalent safety standard).
- ▶ Use only the rechargeable battery from Roche.
- ▶ Use only supplies and accessories from Roche and do not modify them. Otherwise, you risk malfunctions of the micropump system, incorrect test results and over-delivery or under-delivery of insulin.

Supplies for the micropump system

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

Supplies for the blood glucose test

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

Accessories*/replacement components

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

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

* 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.

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 blood glucose level. The correction bolus may be positive if your current blood glucose level is above your target range, or negative, if it falls below your target range.

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

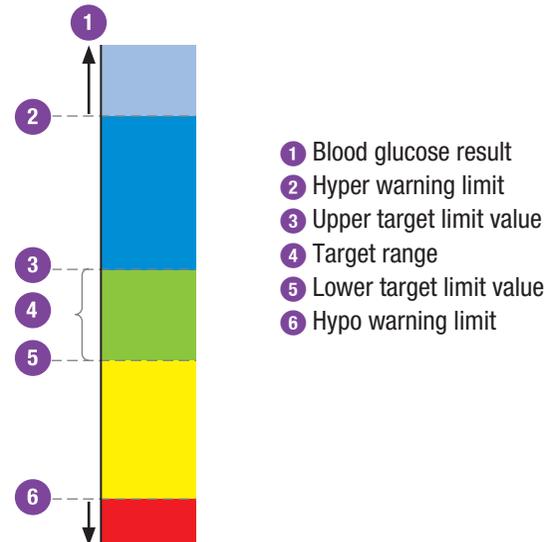
The following applies here:

Carbohydrate ratio = insulin : carbohydrates

18.8.2 Correction Bolus

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

BG thresholds



The calculation of the proposed correction bolus is based on your current blood glucose result, your insulin sensitivity factor 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.

Examples of bolus advice calculations

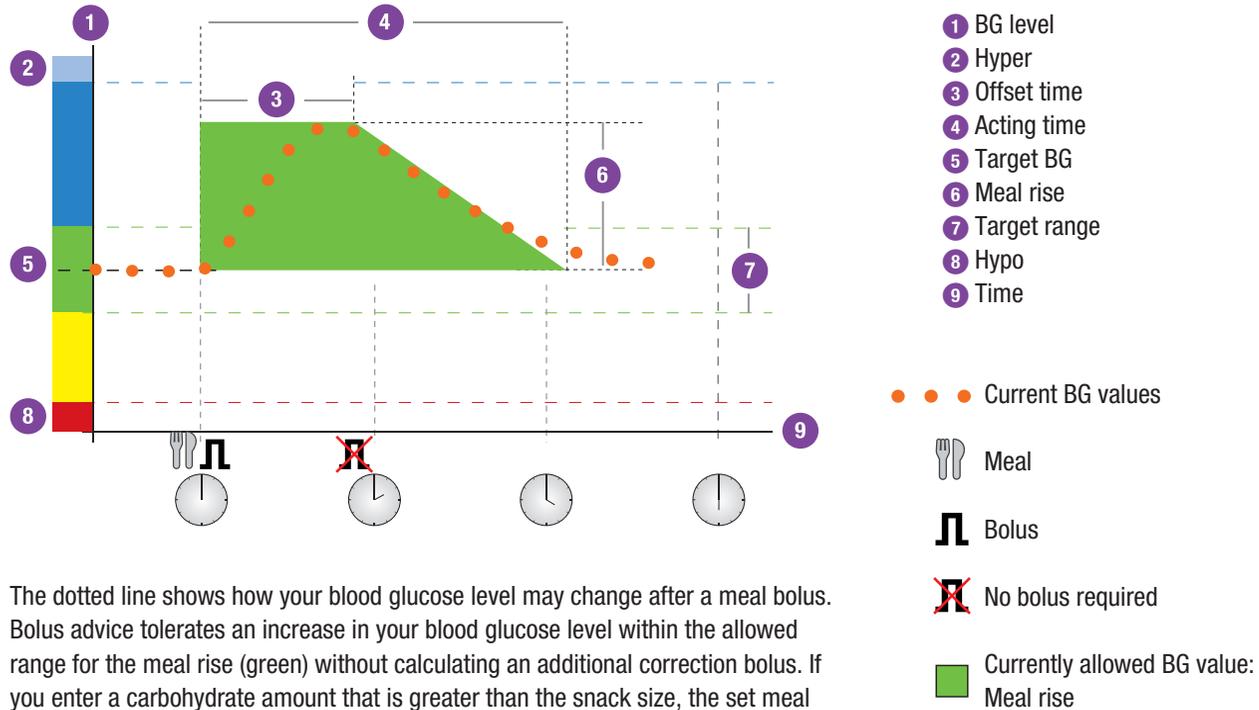
Blood glucose level	Without food intake/carbohydrates	Before a meal
Above the upper target limit value	$(\text{Current BG} - \text{target BG}) \times \text{insulin sensitivity factor}$	$(\text{Current BG} - \text{target BG}) \times \text{insulin sensitivity factor} + \text{meal bolus}$
Within target range	No correction bolus necessary.	$(\text{Current BG} - \text{target BG}) \times \text{insulin sensitivity factor} + \text{meal bolus}$. The correction bolus can be negative.
Between lower target limit value and hypo warning limit	No bolus recommended. The correction bolus is negative.	$(\text{Current BG} - \text{target BG}) \times \text{insulin sensitivity factor} + \text{meal bolus}$. The correction bolus is negative.
Below hypo warning limit	A hypo warning is displayed. You receive the advice to eat fast-acting carbohydrates. No bolus advice available.	A hypo warning is displayed. You receive the advice to eat fast-acting carbohydrates. No bolus advice available.

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

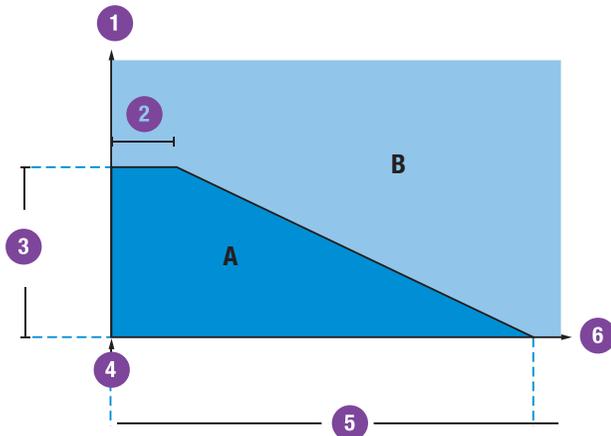
After a meal, it is normal for your blood glucose level to increase even if you delivered the correct meal bolus. The allowed increase in the blood glucose level is called “meal rise”. After a certain period of time, the so-called offset time, the blood glucose level drops from the peak value until it reaches the target level again. The period of time from the start of the blood glucose increase until the blood glucose level returns to the target level is defined as the acting time. During this time, a correction bolus is only recommended if your blood glucose level exceeds the allowed value after a meal. The allowed value depends on the blood glucose target value and the “meal rise”.



The dotted line shows how your blood glucose level may change after a meal bolus. Bolus advice tolerates an increase in your blood glucose level within the allowed range for the meal rise (green) without calculating an additional correction bolus. If you enter a carbohydrate amount that is greater than the snack size, the set meal rise is added to the current blood glucose target value. The shape of the meal rise (the width of the green area) is determined by the offset time and the acting time.

18.8.5 Subsequent Correction Boluses

The difference between your current blood glucose level and your blood glucose target value is called delta BG 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 blood glucose level should drop, and the respective delta BG value decreases after the offset time. At the end of the acting time, your blood glucose level should have reached the target range again. You will only receive a recommendation for an additional correction bolus if your current blood glucose result is higher than the current delta BG value.



- 1 Blood glucose result
- 2 Offset time
- 3 Delta BG
- 4 Correction bolus
- 5 Acting time
- 6 Time

If your blood glucose result is within range A of the graph, no correction bolus will be recommended. If your blood glucose result is within range B of the graph, a correction bolus will be recommended.

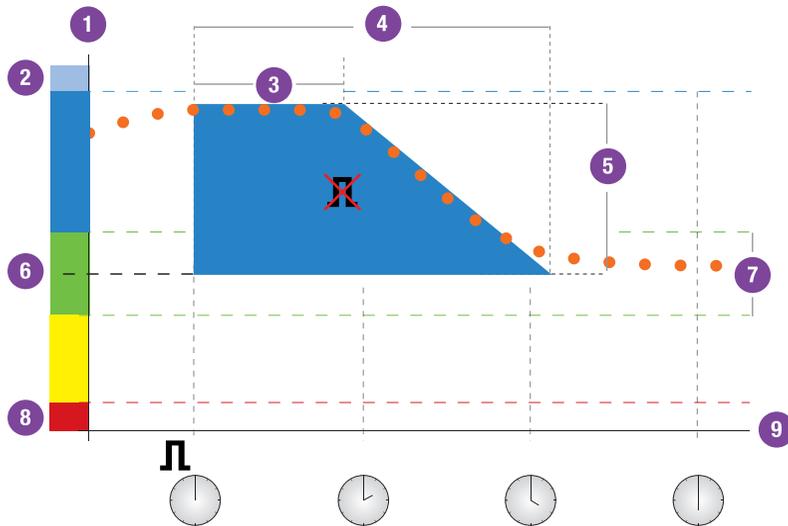
18.8.6 Examples

The following charts show various examples of how bolus advice takes different factors into account for the calculations.

The currently allowed blood glucose value considers the following factors:

- ▶ Target BG
- ▶ Meal rise
- ▶ Delta BG

After a correction bolus



- 1 BG level
- 2 Hyper
- 3 Offset time
- 4 Acting time
- 5 Delta BG
- 6 Target BG
- 7 Target range
- 8 Hypo
- 9 Time

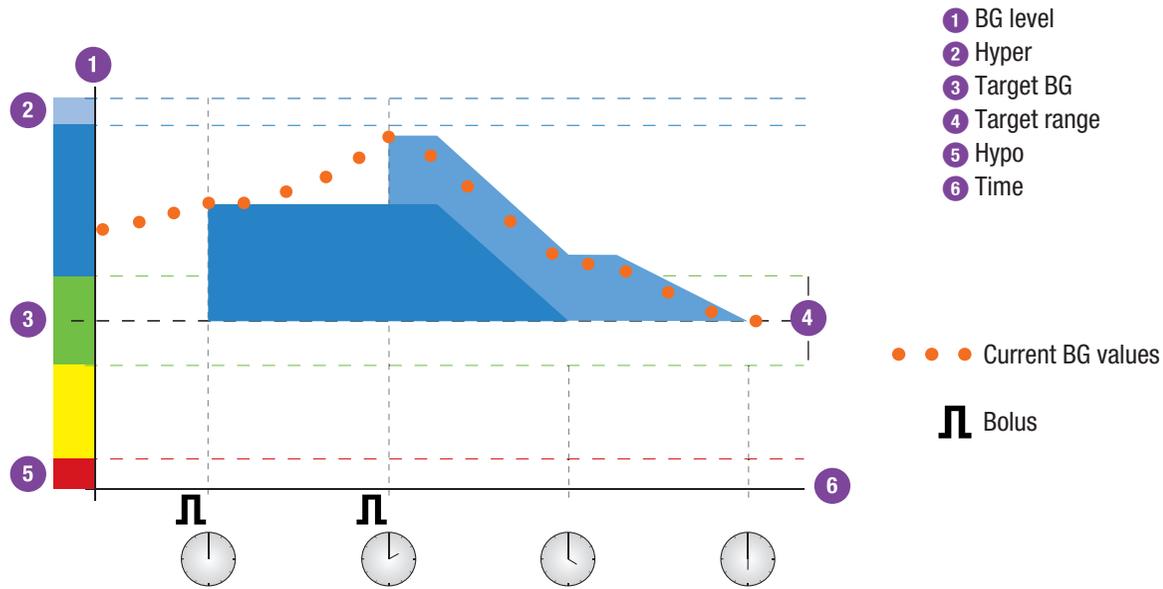
● ● ● Current BG values

⌌ Bolus

~~⌌~~ No bolus required

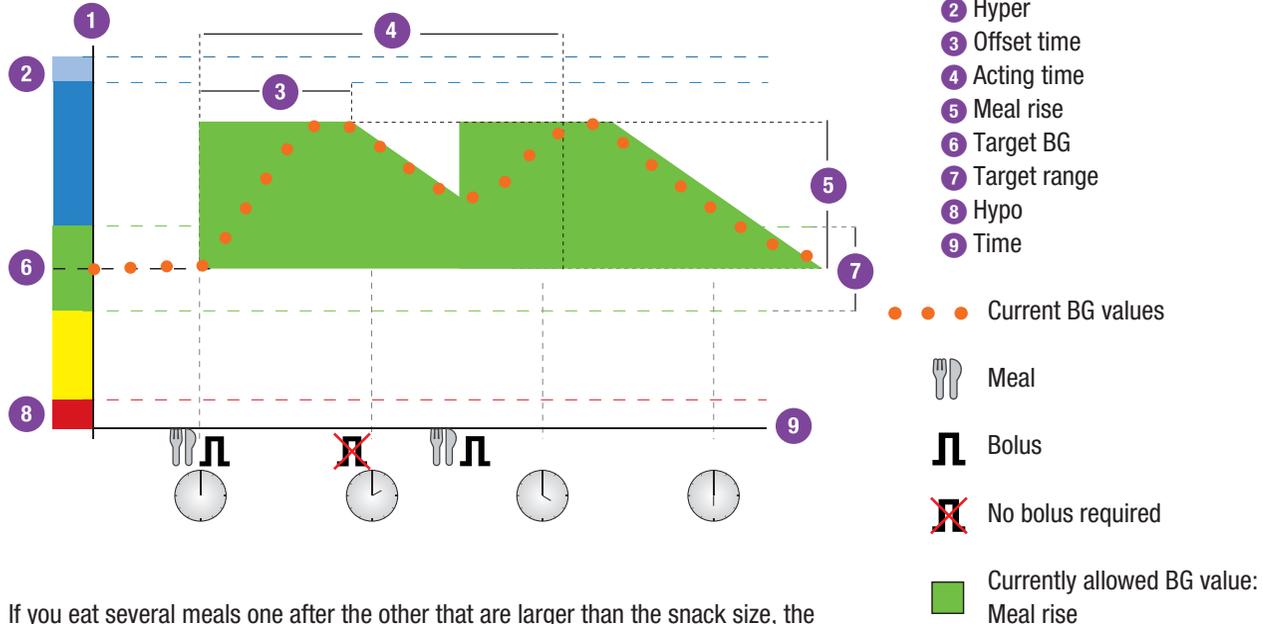
■ Currently allowed BG value:
Corrected BG

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



If a blood glucose result is above the currently allowed blood glucose value, a bolus will be calculated (light blue) that considers only the difference between the current blood glucose value (orange dots) and the currently allowed blood glucose value (upper edge of the dark blue area).

Subsequent Meals



If you eat several meals one after the other that are larger than the snack size, the meal rise is newly started for each meal bolus. Even if you eat several meals in succession, the allowed “meal rise” is not greater than for one meal alone.

19 Glossary

Term	Definition
Acting time	The acting time is the period of time from the start of bolus delivery until the blood glucose level is expected to return to the target value.
Active insulin	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. This value does not include any insulin amounts that were delivered to compensate for carbohydrate intake.
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 blood glucose level is above or below this value. The BG thresholds do not affect the target ranges or the warning limits.

Term	Definition
Blood glucose (BG)	The blood glucose level
Blood glucose result	Result of a blood glucose test
<i>Bluetooth</i> [®] wireless technology	Wireless transfer technology that digital devices use to exchange data
Bolus	The insulin amount required to cover the intake of food or correct an elevated blood glucose level. The bolus type and bolus amount are determined by your healthcare professional's guidelines, your blood glucose level, the food you ate, your current state of health or your physical activity.
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 blood glucose level
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.
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.

Term	Definition
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 blood glucose. 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 meter unit of the diabetes manager are working properly.
Control test	A meter test using control solution that lets you know whether the meter unit of the diabetes manager and the test strips are working properly.
Current time	The time you set via the <i>Settings</i> menu on the <i>Time and date</i> display.
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.

Term	Definition
Flight mode	Setting that deactivates all wireless communication of the micropump system. Activate flight mode when you are in an aeroplane or when other situations require the <i>Bluetooth</i> wireless technology feature to be deactivated. Exchanging data between the diabetes manager and the micropump is not possible in flight mode.
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 blood glucose result.
HI	Appears on the screen when the test result is above the diabetes manager's measurement 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.

Term	Definition
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 defines the insulin amount required to lower your blood glucose level by a certain value.
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 blood glucose target value.
LO	Appears on the screen when the test result is below the diabetes manager's measurement 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 blood glucose level after a meal 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 blood glucose level significantly and to start returning to the original blood 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.

Term	Definition
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.
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 blood 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.

Term	Definition
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 blood glucose values are considered acceptable before a meal or when fasting. The target range is specified by the lower and upper BG thresholds.
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. You can set up a maximum of 8 time blocks.
Time of test	Information on the point in time when a blood glucose result was obtained. The information can be stored together with a blood glucose result. When the results are subsequently analysed, either all test results can be displayed or only the test results 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 millilitre 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.

Term	Definition
Warning limit	When your blood glucose result 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 blood glucose results below the lower warning limit, no bolus advice will be calculated.

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