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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 teams. 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 (see Chapter 18).

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

You can call up an electronic version of this User's Manual from the main menu of the diabetes manager under the Help menu.

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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 benefitting from the micropump system. Read these chapters before using the respective features.

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

- *Diabetes manager* is shortened to DM.
- *Blood glucose* is shortened to BG.
- *Micropump* is shortened to MP.
- *Temporary basal rate* is shortened to TBR.

For more abbreviations, see Chapter 17.

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Illustrated handling instructions

Instructions for handling system components are shown as in the following example:

Step number within a sequence of actions

1

Illustration of instruction

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

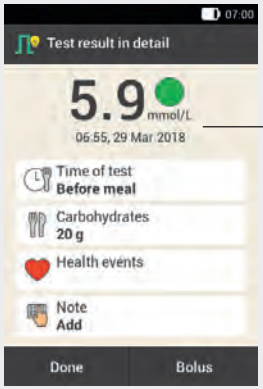
Handling instruction

Handling instructions with display images

Instructions referring to displays on the diabetes manager screen are shown as in the following example:

Step number within a sequence of actions

2



Display on the diabetes manager screen

Tap Carbohydrates.

Handling instruction
Texts in blue or purple font are texts that are shown on the display. These can include commands, menus or list elements.

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Quick navigation in the User's Manual

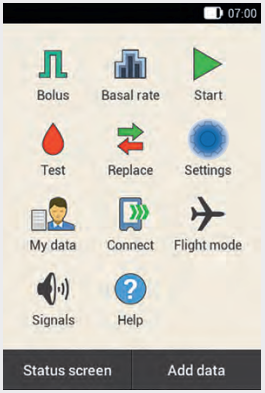
Some handling instructions in this User's Manual are summarised into a quick navigation path. At the beginning of some chapters or sections, for example, you will find the following information:

Main menu > Settings > Time blocks

This quick navigation path represents the following steps: "In the *Main menu* tap the *Settings* menu and then tap *Time blocks*".

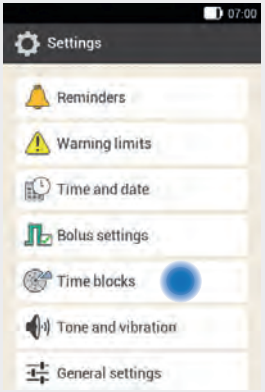
The blue or purple dot on the displays means "Tap the display element highlighted by the dot".

1



In the main menu, tap the Settings menu.

2



In the Settings menu, tap the Time Blocks item.

Info

- The screen displays in this User's Manual can differ slightly from the displays on the diabetes manager screen.
- Units, figures and settings on the screen displays in this User's Manual are only examples.

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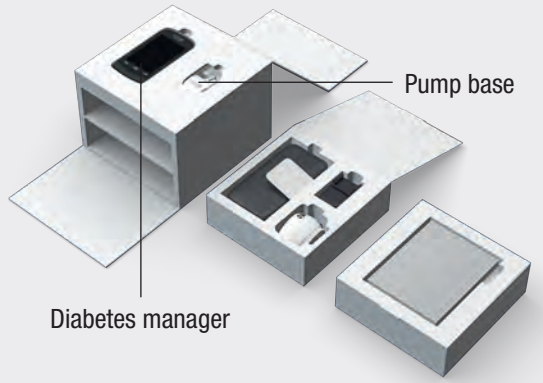
Scope of delivery

The starter kit contains the following system 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

Not included, but necessary for using the micropump system:

- Accu-Chek Solo reservoir assemblies
- Accu-Chek Solo cannula assemblies and Accu-Chek Solo micropump holders



Supplies

Only use supplies from Roche.

Note
To perform blood glucose tests and control tests with the Accu-Chek Aviva Solo diabetes manager, you need the Accu-Chek Aviva test strips and the Accu-Chek Aviva control solution.

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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 insulin-dependent persons with 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.

Therapy using the micropump system may only be started after completion of the required training from a qualified instructor. Users under the age of 12 should only use the micropump system with the support of a trained adult.

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

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 and carbohydrate amounts consumed, 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® or Insuman® Infusat. The exact insulin type for treating your diabetes mellitus will be prescribed by your healthcare team.

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1.2 Contraindications

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 team.
- 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 (see chapter *Technical Data*).

1.3 Risks and Benefits

Talk to your healthcare team 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 the therapy, test your blood glucose values regularly, calculate carbohydrate intake and monitor the micropump functions 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.

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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.
- Do not change your therapy without consulting your healthcare team first.
- Keep all system components away from small children or vulnerable persons. There is a risk of suffocation if small parts (e.g. covers, caps, or similar objects) are swallowed.
- Do not make any changes to the design of the micropump system.

WARNING

- Check your blood glucose level at least four times a day.
- Used devices and supplies carry a risk of infection. Dispose of used system components according to local regulations.
- Having the time and date set precisely is essential in order for your micropump system to function properly. A wrong time setting can have serious consequences.
- Always keep alternative therapy supplies at hand (for example, a blood glucose meter or pen) in case the micropump system stops working properly.
- Do not use or store the micropump system outside the permitted ambient conditions. This may lead to hyperglycaemia or hypoglycaemia.
- Use sterile supplies only once and only if the use by date has not expired.

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1.5 Components of the Micropump System

Accu-Chek Solo micropump system

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

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Accu-Chek Solo reservoir

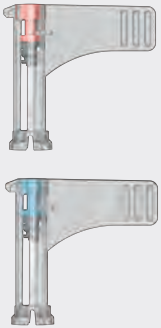
The Accu-Chek Solo reservoir is the second part of the micropump in addition to the pump base. The reservoir is a sterile container for holding the insulin that the micropump delivers to the body. The reservoir has a zinc-air battery, which serves as an energy source to the micropump.

Accu-Chek Solo micropump holder

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

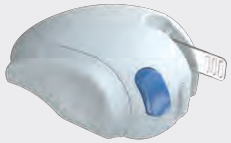
Accu-Chek Solo cannula assembly

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 (micropump holder and cannula) to the body and insert the cannula into the subcutaneous tissue.



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1.6 Characteristics of the Micropump System

Tubeless insulin pump

- Small, light and removable micropump (28 g)
- Transparent reservoir (up to 200 U), usable for approx. 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

- Controls 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 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
- Up to 5 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
- Electronic User's Manual and videos explaining handling steps on the diabetes manager

Comfort and safety features

- Built-in blood glucose meter in the diabetes manager
- Illumination for test strip slot and blood application area
- Rechargeable, long-life 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 on warnings and required maintenance activities

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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 you should 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
The micropump system is supplied with two pump bases. 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.

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. Place the protective caps on the cannula support of the infusion assembly (yellow protective cap) and on the opening with the reservoir needle (grey protective cap) if you are not using the micropump temporarily.

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. In temperatures outside this range, the insulin contained in the reservoir could damage the micropump system.

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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 can occur, for example, when you are

- in an aeroplane, especially during take-off and landing
- doing sports 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 in altitudes above 3,000 metres above sea level.

Travelling and flights

Before travelling, ask your healthcare team about any special preparations you need to make. Take sufficient supplies with you for blood glucose testing and for your micropump (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. The distance between the diabetes manager and the micropump should not be more than 10 metres. 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 (see chapter 15). Communication is automatically re-established when the cause of the interruption no longer exists. As long as communication is interrupted, the new data is saved on the micropump and the diabetes manager. Once communication between the pump and the diabetes manager has been re-established, the pump automatically transfers your saved data to the diabetes manager.

Distance from electrical devices

There are many devices that emit electromagnetic radiation, for

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example, mobile phones. It cannot be completely ruled out that a device of this kind could affect your micropump system. It is therefore recommended that you keep your micropump system at least 30 cm away from these devices while they are turned on. Remove the micropump from your body before you undergo examinations or treatments such as magnetic resonance imaging (MRI), computed tomography (CT), X-rays or ultrasound, or before you enter areas with strong electromagnetic fields.
The micropump system is not protected against effects which may occur when using a defibrillator on a person. If a defibrillator was used on a person wearing the micropump system, this may cause the micropump system to malfunction. Remove the micropump system.

⚠ WARNING

- Do not use the micropump system close to sources of strong electromagnetic radiation and ionizing radiation. Strong electromagnetic fields, for example, from radar or antenna installations, high-voltage sources, X-Ray sources, 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 ionizing radiation.
- Do not use or store the micropump system in environmental conditions other than those for which it is intended.

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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, you may not hear the system messages. Pay attention to the displays and signals on the diabetes manager to make sure that the micropump system is functioning properly.

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	Name	Description
1	**Power button**	Turns the diabetes manager on or off.
2	**Lanyard eyelet**	Used to attach a lanyard.
3	**Earphone socket**	Socket for connecting passive earphones.
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 for scanning the pairing code on the pump base to pair the micropump and the diabetes manager.
12	**Battery door**	Removable cover for the battery compartment.

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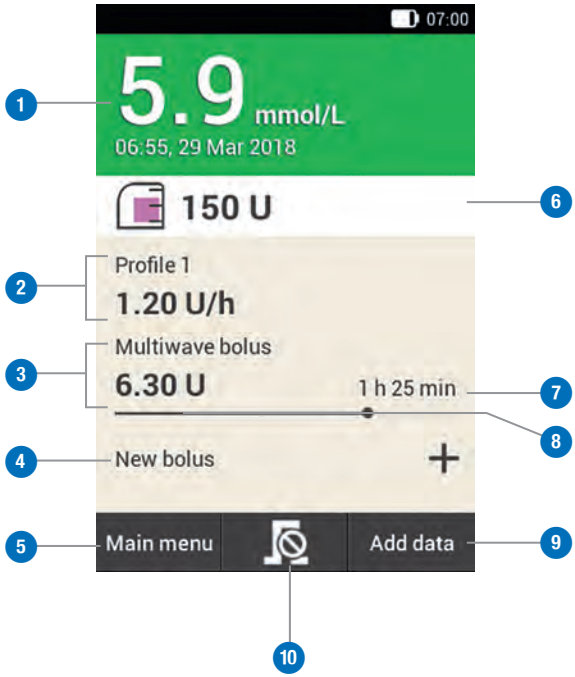
2.2 Status Screen

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 application (e.g. pump therapy or injection therapy), other contents and symbols are displayed.



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	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 (see also *Test Result Colour Coding* in chapter 5).
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 the units of insulin available in the reservoir.

	Name	Description
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 item to add further data to the logbook (for example, time of test).
10		Tap this button to cancel one or all active boluses.

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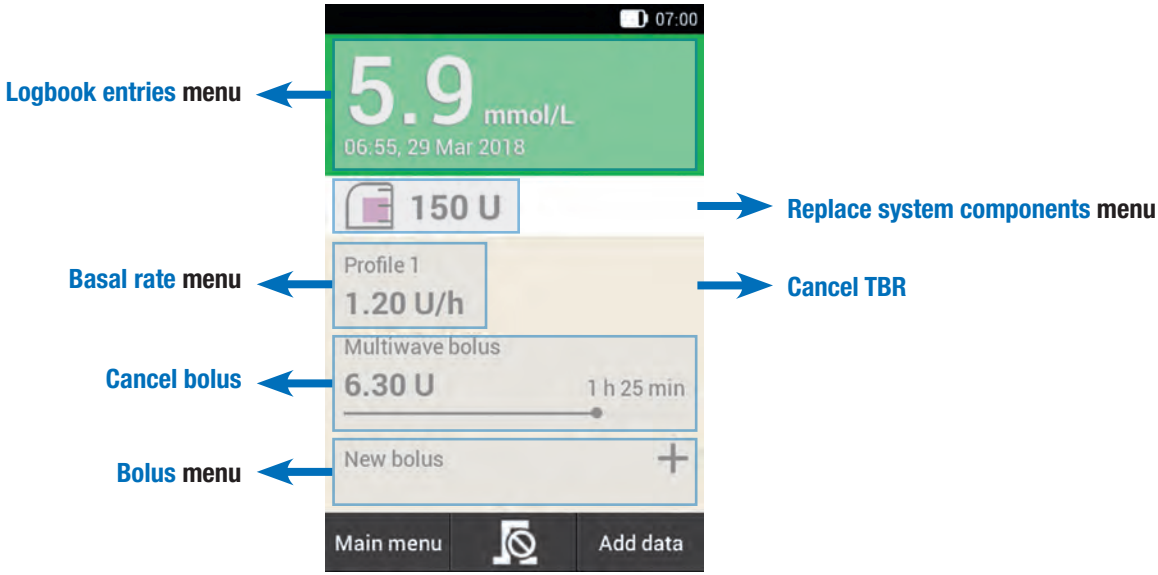
2.2.2 Shortcuts on the Status screen

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.



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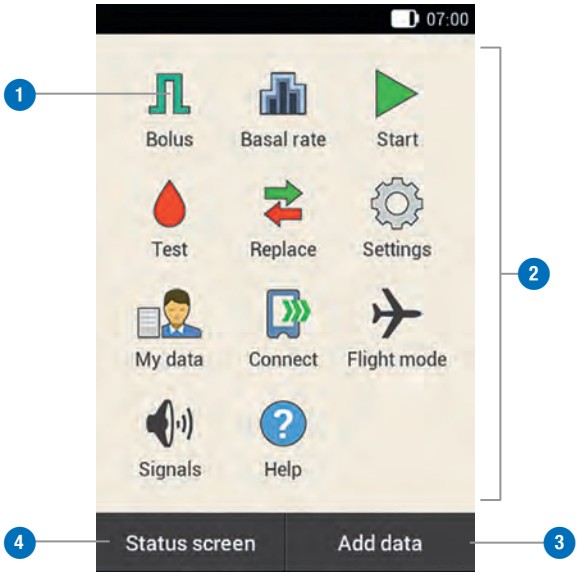
2.3 Main Menu

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.



	Name	Description
1	**Menu**	Tap the menu icon to open the desired menu or turn on the desired feature.
2	**Menu selection**	Provides access to menus and submenus as well as direct access to individual features.
3	**Add data**	Tap this button to add further data to the logbook (for example, time of test).
4	**Status screen**	Tap this button to display the Status screen.

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

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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.
	Temperature	Is displayed when the temperature of the diabetes manager is outside the temperature range allowed for performing blood glucose tests.
	Signals turned off	Is displayed when signals for warnings are turned off for a certain period of time.
	Vibration	Is displayed when the vibration feature is turned on. Signals are deactivated.

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Menus of 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)
	Start micropump
	Stop micropump (cancel bolus and TBR and interrupt basal rate)
	Test blood glucose, perform control test
	Replace system components (infusion assembly, reservoir, pump base)
	View or change settings, view system information, switch therapy mode
	Display or edit logbook data

Menu icon	Description
	Connect diabetes manager to PC in order to transfer data
	Turn flight mode on or off
	Set signals
	Watch Help videos, read User's Manual

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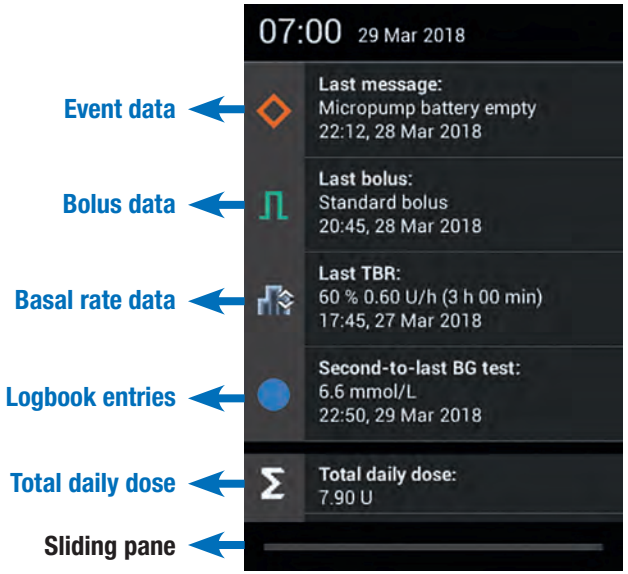
2.4 Information Screen

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 with detailed information open.



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.

Slide your finger from the upper screen edge downwards. The information screen is shown. Move the information screen to the top again to hide it.

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2.5 Navigation and Operation

Navigation and operation of the diabetes manager is done by means of the touchscreen and navigation buttons.

The insulin button is an exception. Insulin deliveries for basal rates or a bolus that have been programmed using the diabetes manager can only be started by pressing a separate insulin button.

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” navigation button: Go back to the previous display within the process step.
	“Status screen” navigation button: Switch to the Status screen.
	“Next” navigation button: 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. If you make settings in a process step and then press the button, the settings will **not** be saved.

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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.

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.

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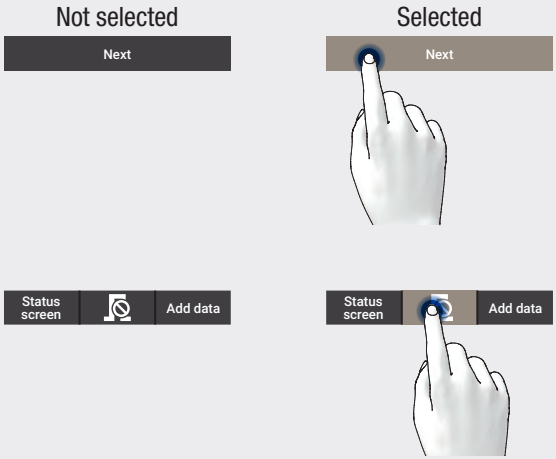
Executing commands

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

Example

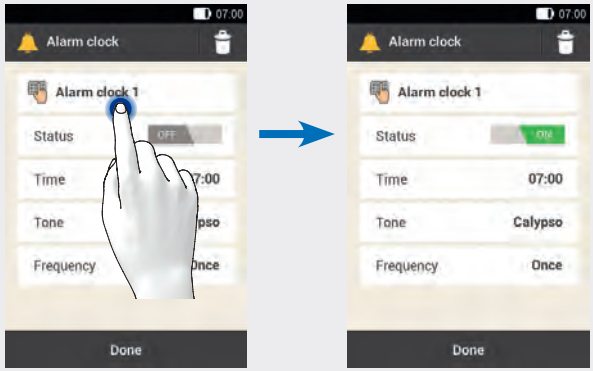


Tap the element you want to select. The background changes from dark to light.

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.

Example



Tap the switch to turn the feature on. Tapping the same switch again turns the feature off.

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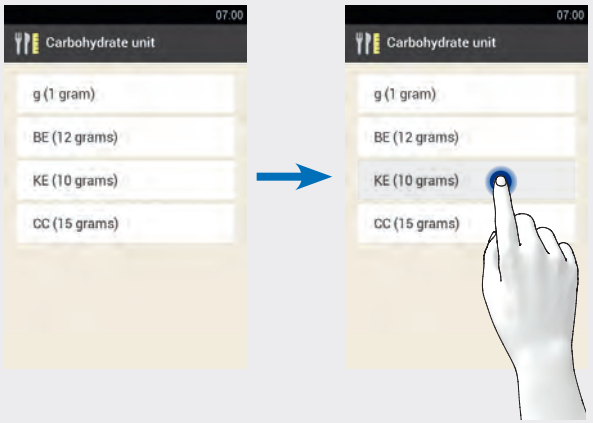
Simple lists or menus

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

Example

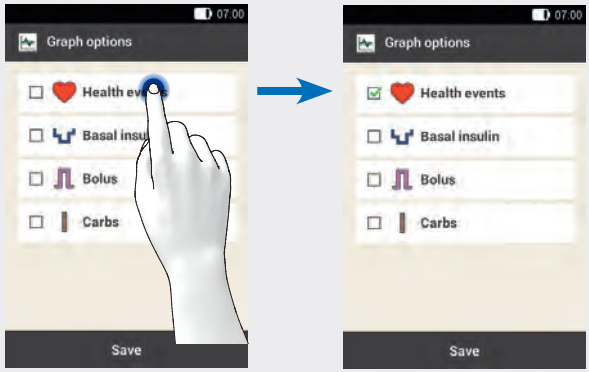


Tap the element you want to select. The background changes from light to dark. When you have selected an element, the next display appears.

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. Tap Save to save your selection.

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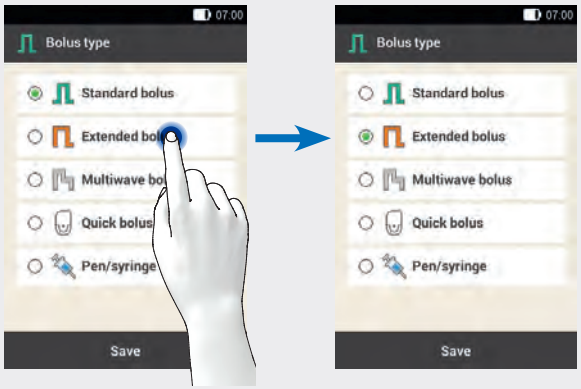
Lists with radio buttons

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

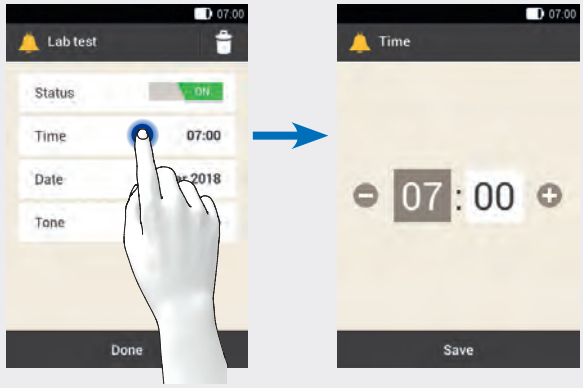


Tap the element you want to select. The green dot is displayed in the circle in front of the newly selected element.

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.

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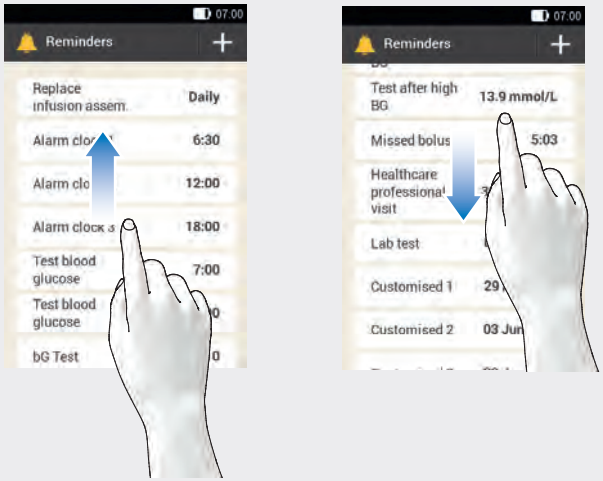
Scrolling lists

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

Example

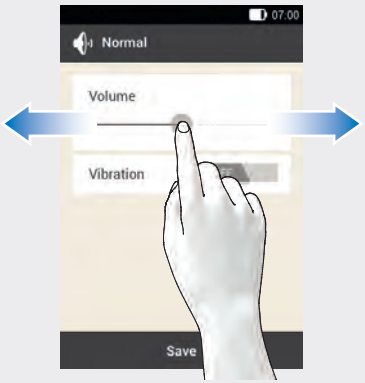


Scroll the list upwards to view additional list elements or menus. Scroll the list downwards to view the top list elements or menus.

Slider

You can make the desired setting by moving the slider.

Example



Move the slider to the desired position.

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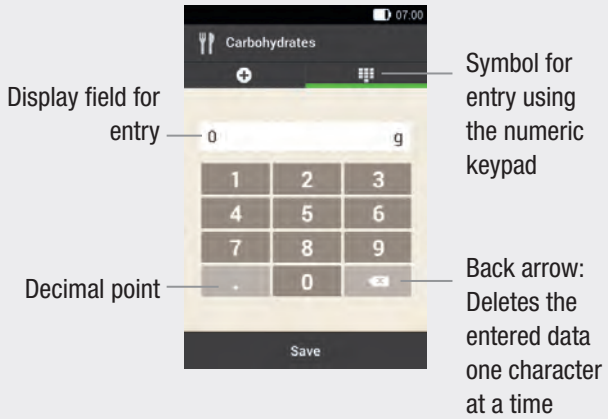
2.5.4 Entering Numbers

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

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

Numeric keypad

You can enter numeric values such as the carbohydrate amount using the numeric keypad.



Enter the desired numeric value using the numeric keypad.

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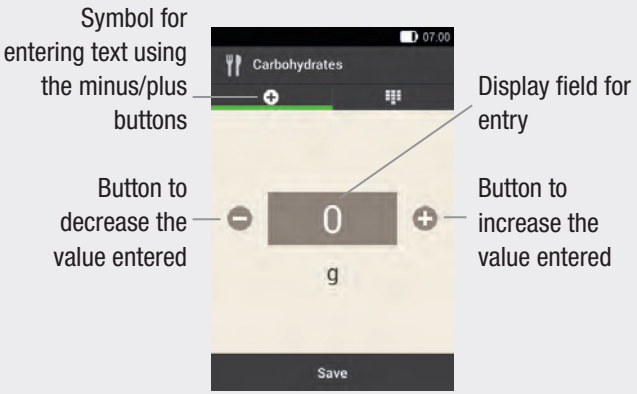
Minus/plus buttons

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

Explanation/Example

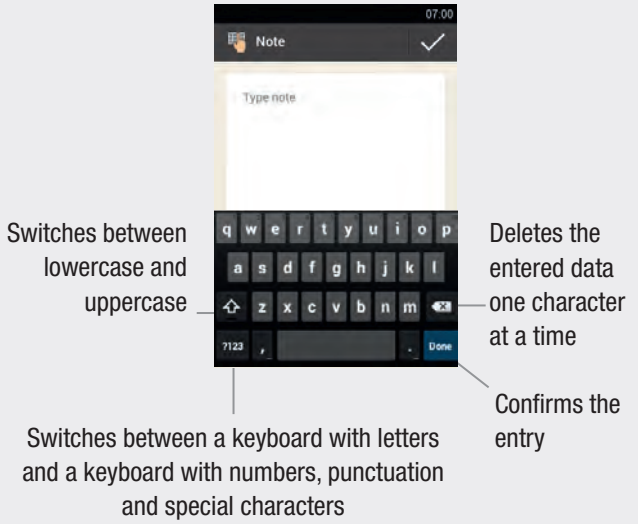


Tap ⊕ to increase the numeric value on the display. Tap ⊖ to decrease the numeric value on the display.
Keep your finger on one of the minus/plus buttons for a bit longer to decrease or increase the numeric values in a fast scroll mode.

2.5.5 Entering Text

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

Explanation/Example



Enter the desired text using the letter keyboard.

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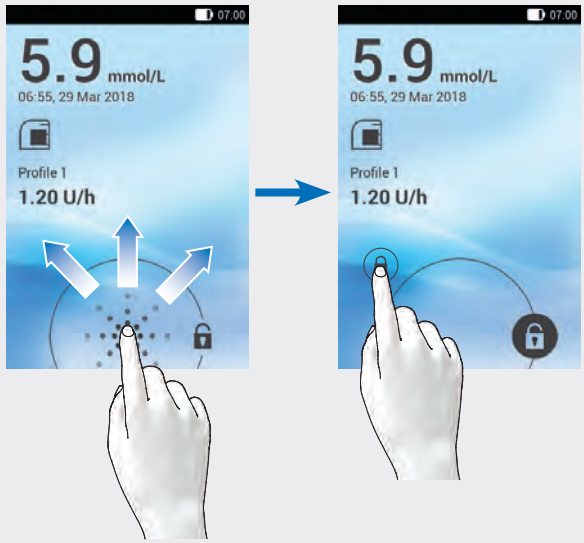
2.5.6 Screen Lock

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 display that follows to unlock the screen of the diabetes manager. You have the option of changing the settings in the menu Settings > Screen lock.

Unlocking the screen



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

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3 Setting Up the Micropump System

3.1 Recharging the Battery

Before you start using the diabetes manager, you must charge the battery.

Connect the diabetes manager to a PC or charger using the 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.

Symbols for different battery levels:

low	20 %	40 %	60 %	80 %	100 %

⚠ WARNING

- Use only the supplied charger with the appropriate USB cable.
- Use only the rechargeable battery from Roche.

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.
- Check regularly whether the time and date of the diabetes manager are set correctly.

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3.1.1 Inserting the Battery into the Diabetes Manager

1

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

2

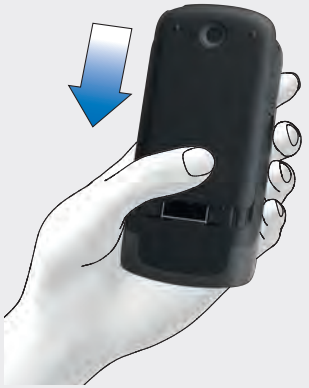
Open the battery compartment by pushing the battery door up in the direction of the arrow.

3

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.

4



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

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3.1.2 Charging the Battery Using a Wall Socket

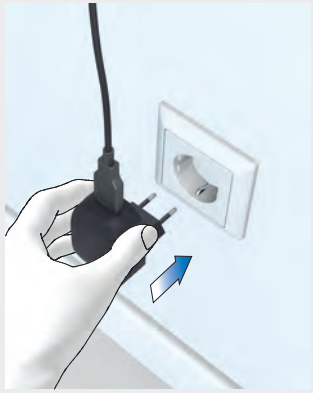
1

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

2

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

3



Plug the charger into a 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.

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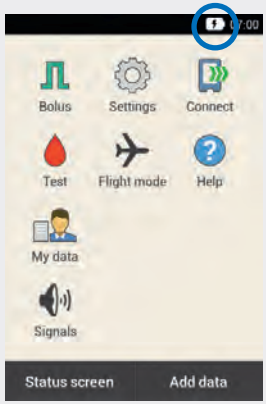
3.1.3 Charging the Battery Using a Computer

4



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

When the battery is fully charged, the symbol is displayed in the status bar. You can remove the charger from the wall socket and the USB cable from the diabetes manager.

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 port on your computer.

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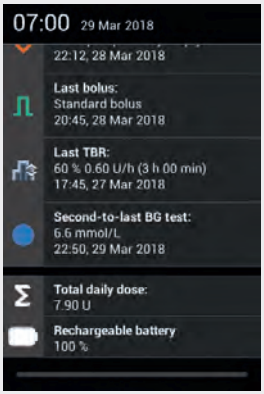
3

If the connection is successful, the diabetes manager displays the charging screen for 3 seconds.

4



On the information screen, the current status of the rechargeable battery is shown using the charging symbol and a percentage.

When the battery is fully charged, the ▬ symbol is displayed. You can remove the USB cable from the diabetes manager and 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.
- The USB port on a PC that is suitable for charging is often marked with a lightning symbol.
- 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 after connecting the USB cable, tap the Connect menu in the Main menu.

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3.2 Setting Up the System

You can set up the diabetes manager manually, directly on the device with the help of the setup wizard, or you can use the configuration software to do so on your PC.

3.2.1 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.

If you do not want to set up bolus advice during initial setup of the micropump system, you can do so at a later point in time.

⚠ 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.

Note
Check whether the settings you made match your requirements and the specifications of your healthcare professional.

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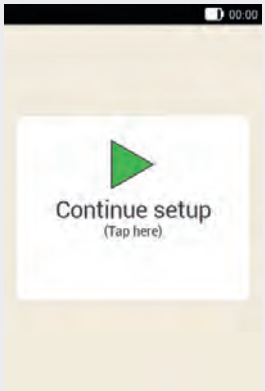
Caching the setup

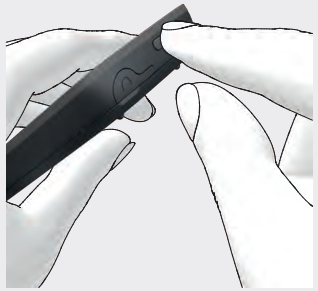


The data and settings you enter are cached at specific points during setup. If you want to resume setup after an interruption, Continue setup appears on the screen.

Tap this display to continue setting up the system.

Turning on the diabetes manager

1



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

2

The diabetes manager vibrates, issues a signal and the signal LED lights up. The start display appears briefly.

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Setting the language

1

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

Tap Save.

Entering the PIN

1

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 Save.

2

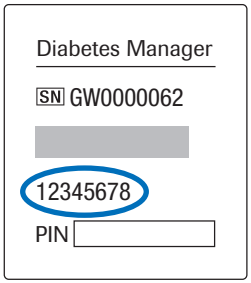
Enter the PIN a second time.

Tap Save.

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.

Example of a PIN unlock code:



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Selecting Setup mode

1

Tap the Setup mode you want to use.

Note

If you tapped Manual setup, proceed with the section *Time and date settings*.

If you tapped Set up on PC, proceed with the section *Configuration on the PC*.

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Time and date information

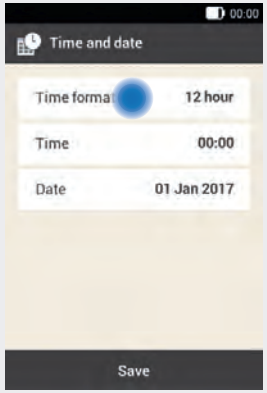
Times and time periods are always displayed or entered in the following format HH:MM (HH=hours, MM=minutes).

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, 23 Jun. 2017.

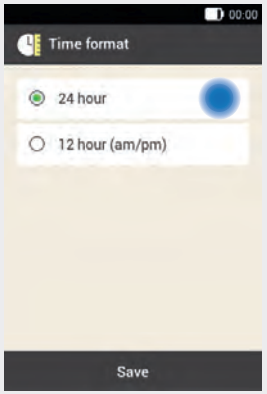
Setting the time and date

1



Tap Time format.

2



Tap the desired time format.

Tap Save.

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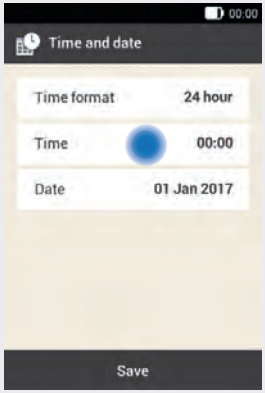
3



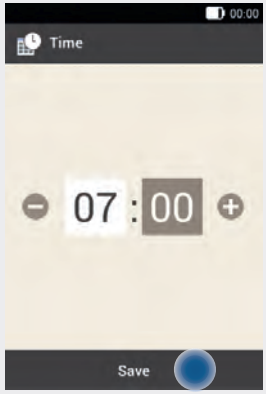
Tap Time.

4

The hours field is selected (dark background).

Use ⊖ and ⊕ to set the hours.

5

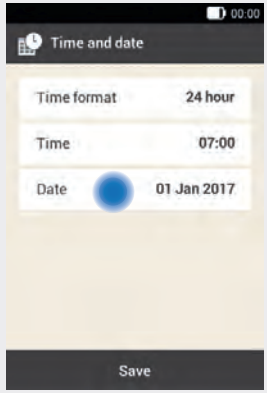


Tap the minutes field.

Use ⊖ and ⊕ to set the minutes.

Tap Save.

6



Tap Date.

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7

The day field is highlighted.

Use ⊖ and ⊕ to set the day.

8

Tap the month field.

Use ⊖ and ⊕ to set the month.

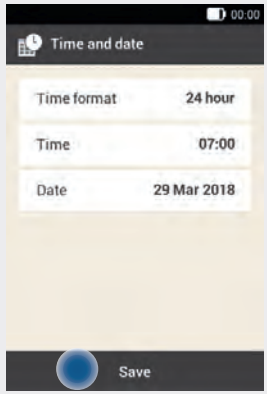
9

Tap the year field.

Use ⊖ and ⊕ to set the year.

Tap Save.

10



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

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Setting the carbohydrate unit

The diabetes manager offers the following carbohydrate units for selection:

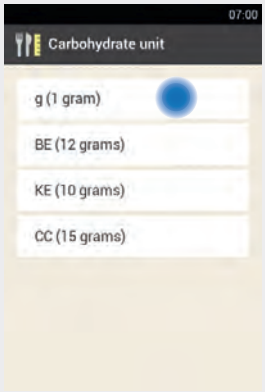
Abbreviation	Unit of measurement	Gram equivalent
g	Gram	1 gram
BE	Broteinheit (bread equivalent)	12 grams
KE	Kohlenhydrateinheit (carbohydrate unit)	10 grams
CC	Carbohydrate choice	15 grams

Note

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

Subsequent changes to the carbohydrate unit can only be made with the Accu-Chek 360° configuration software.

1



Tap the carbohydrate unit you want to set.

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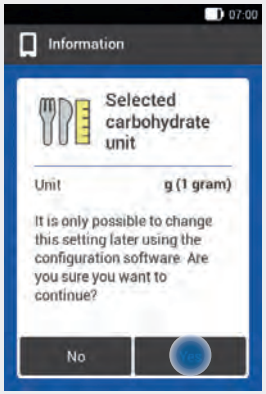
Setting warning limits

You can set warning limits for hyperglycaemia (hyper) and hypoglycaemia (hypo) 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.

2



Tap Yes if the correct unit is displayed.

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

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 Save.

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3

Tap Lower warning limit.

4

Use ⊖ and ⊕ to set the lower warning limit.

Tap Save.

5

The warning limits currently set are displayed.

Tap Done.

6

If you want to set up bolus advice now, tap Yes. In Chapter 7, *Setting Up Bolus Advice*, you will find the explanations on and steps for setting up this feature.

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

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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.

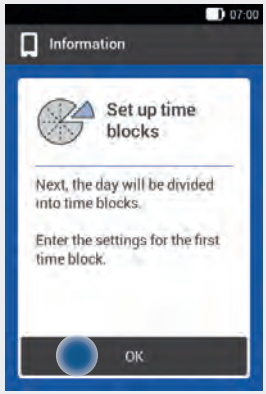
WARNING

Make sure that you enter carbohydrates and health events correctly when you set up bolus advice. Incorrect settings may lead to wrong bolus recommendations.

Note

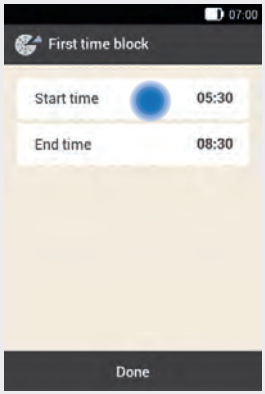
If you want to use bolus advice, you must set it up. If you do not want to set up bolus advice now, the setup wizard skips the steps for setting up bolus advice. You can set up bolus advice at a later time.

1



Tap OK.

2



Tap Start time and then End time.

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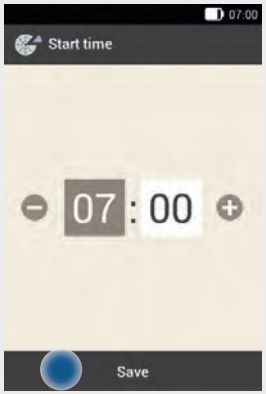
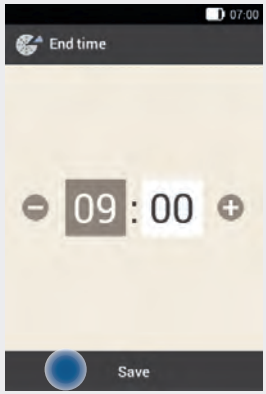
3



Use ⊖ and ⊕ to set the start time.

Tap Save.

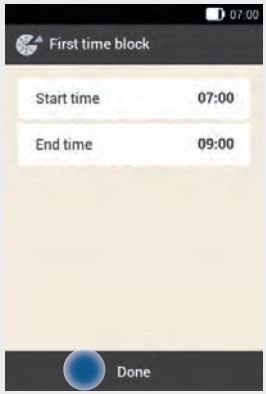
4



Use ⊖ and ⊕ to set the end time.

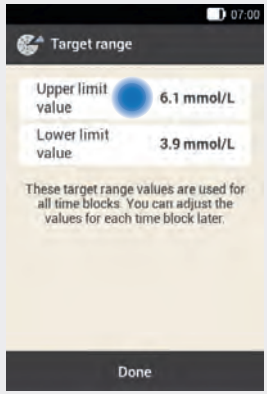
Tap Save.

5



Tap Done.

6



Tap Upper limit value.

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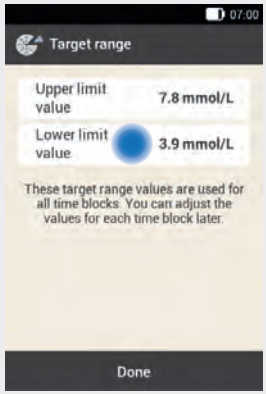
7

Use ⊖ and ⊕ to set the upper limit value.

Tap Save.

8



Tap Lower limit value.

9

Use ⊖ and ⊕ to set the lower limit value.

Tap Save.

10

Tap Done.

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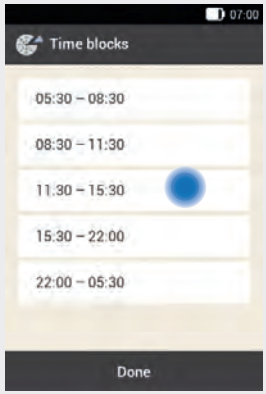
11

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.

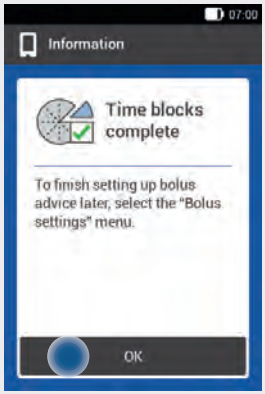
12



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.

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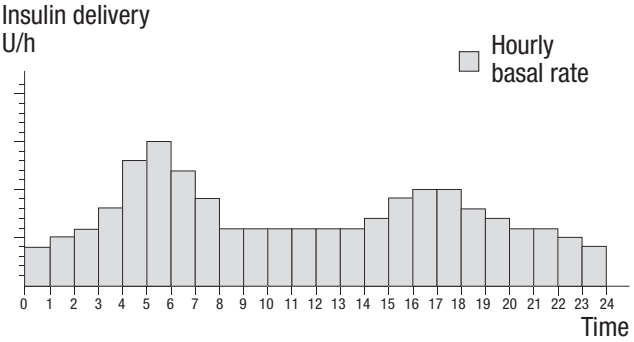
3.2.2 Programming the Basal Rate Profile

The aim of insulin pump therapy is to reproduce the natural biorhythm of insulin delivery of a healthy pancreas as far as possible.

The basal rate covers the basal, meal-independent insulin requirement. The basal rate is 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.

Example: Basal rate profile for 18 U/24 hours



1

Tap OK to set up a basal rate profile.

The ⮌ button is deactivated.

Note

The factory settings provide 24 time blocks with one hour each.

The first time block starts with the start time 00:00 and ends at 01:00. The last time block starts at 23:00 and ends at 00:00.

For each time block, 0 U/h is set by factory default.

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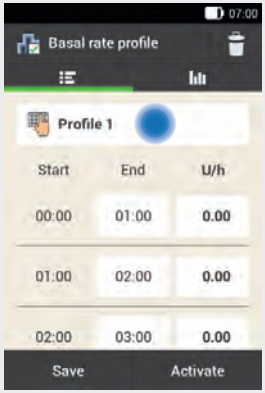
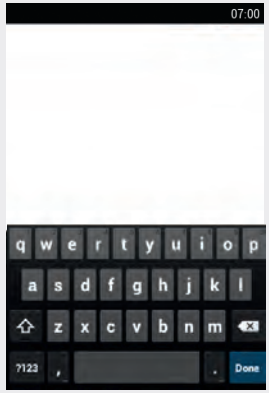
2



The basal rate profile with the name Profile 1 is displayed.

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

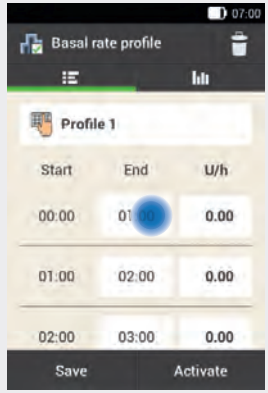
3



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

Tap Done.

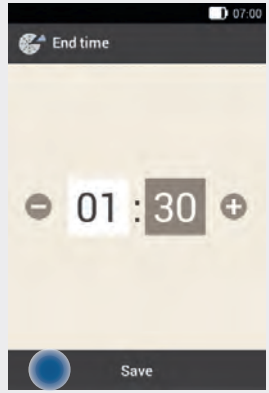
4



Define the end time for the first time block.

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

5



Use ⊖ and ⊕ to set the End time for the first time block.

Tap Save.

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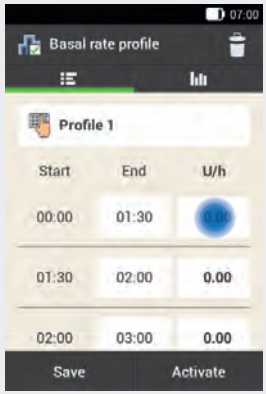
6



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

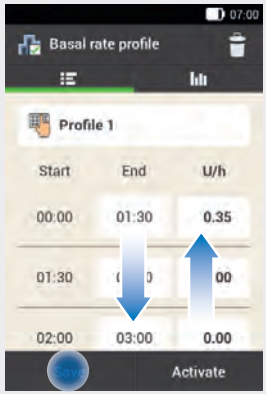
To do so, tap the top entry field in the U/h column.

7

Use ⊖ and ⊕ to set the insulin units for the first time block.

Tap Save.

8



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 Save.

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9

Next, you must prepare the micropump.

Tap OK to confirm the message, and see Chapter 4 to read how to prepare the micropump when using it for the first time.

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3.2.3 Configuration Software

You can use the Accu-Chek 360° configuration software to set up the micropump system on the PC. You can make all settings on the monitor of your PC in a clear, graphical representation.

Features and options of the configuration software:

- Setting up basal rate profiles
- Setting user-defined Temporary Basal Rates
- Setting up bolus advice
- Setting reminders
- Reviewing and editing all settings
- Printing and saving a configuration report to be exchanged with your healthcare team
- Copying device settings
- Communication via USB connection
- Setting micropump options
- Easy navigation due to a clearly structured user interface

The configuration software can be downloaded from the following web address on the Internet:

www.###.com

Refer to the configuration software for instructions for use. For more information, contact your Customer Support and Service Centre.

Note

- The current settings in the diabetes manager are replaced by the settings in the configuration software. All settings are saved in the configuration.
- After completing configuration, you must restart the micropump.

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Configuration on the PC

1

If you selected Set up on PC, connect the diabetes manager and the PC using a USB cable.

2

Start the configuration software for setting up the diabetes manager on the PC.

The diabetes manager establishes the data connection to the PC.

3

This display shows that data connection between the diabetes manager and the PC was successfully established. You can now use the configuration software.

Continue setting up the diabetes manager on the PC.

Note

For more information on Set up on PC, see the User's Manual of the Accu-Chek 360° configuration software.

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4 Putting the Micropump Into Operation

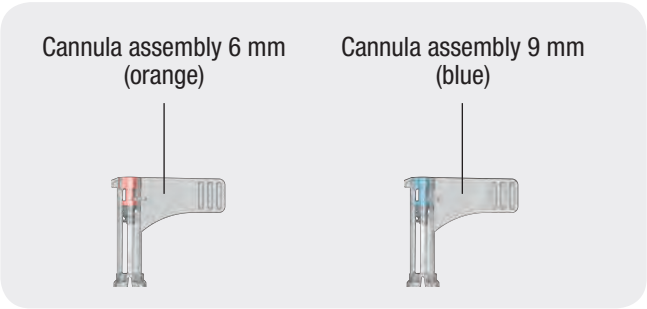
4.1 Overview

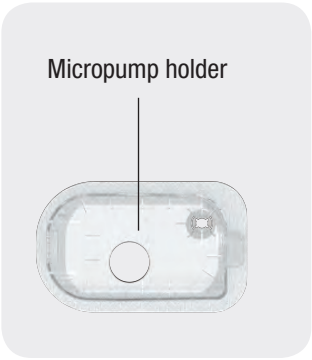
This chapter explains all steps necessary to prepare the micropump before using it for the first time. To put the micropump into operation, you need the following:

- Diabetes manager
- Pump base
- Reservoir assembly
- Micropump holder and cannula assembly
- Insertion device
- Disinfectant or a clean cloth

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

- Use the insertion device to attach the micropump 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 micropump holder
- Start the basal rate





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Infusion assembly

Micropump holder

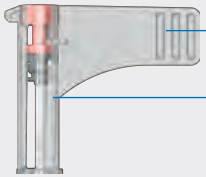
Hook for attaching the micropump

Opening for safety release of the insertion device

Opening for cannula with cannula support

Flap for detaching the micropump

Cannula assembly



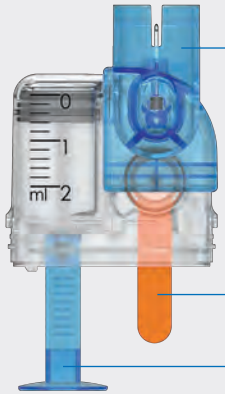
Handling aid

Cannula casing

Soft Teflon cannula

Introducer needle

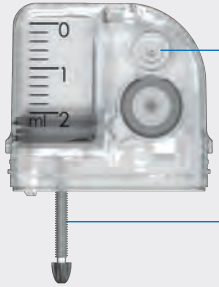
Reservoir assembly



Filling aid

Protective film for battery

Handle for piston rod



Reservoir needle

Piston rod

Protective cap for infusion assembly

Protective cap for reservoir needle

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