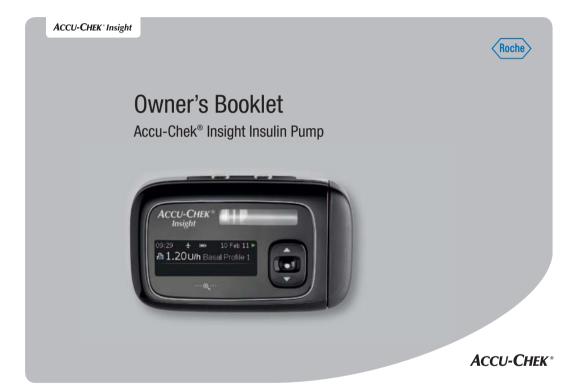
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68305 Mannheim, Germany
www.accu-chek.com

C € 0088



// 001110E//

Your insulin pump



Note



If you do not press \blacksquare , \blacktriangle or \blacktriangledown key for more than 30 seconds, these keys will be locked. Press \blacktriangle and then \blacktriangledown , or \blacktriangledown and then \blacktriangle , to unlock the keys to continue the programming.



Your contact for assistance with and additional information about your Accu-Chek Insight insulin pump:

Pump details and accessories





Cartridge







Adapter & tubing

Pump



Dear Accu-Chek Insight insulin pump user,

This User Guide is provided for you, as a person with diabetes, parent or caregiver for a person with diabetes and for healthcare professionals. It contains all the information you need for the safe and efficient use of your new Accu-Chek Insight insulin pump. Regardless of your level of experience with pump therapy, please read this manual carefully before using your pump. This manual should be your first source of information for any questions or problems you may have when you use your insulin pump. If you cannot find the answer in these pages, we recommend that you contact your local pump support (see inside back cover). Your Accu-Chek Insight insulin pump has been developed exclusively for the continuous delivery of U100 short-acting regular human insulin or rapid-acting insulin analogue. The exact insulin type for the treatment of your insulin-dependent diabetes mellitus will be prescribed by your healthcare professional.

Whether insulin pump therapy is the appropriate way of treating your diabetes mellitus must be decided by your healthcare professional.

You should not begin pump therapy unless you have attended the required training course. Do not use your insulin pump for the delivery of medication other than U100 short-acting regular human insulin or rapid-acting insulin analogue.



About this Owner's Booklet

To ensure the safe and convenient use of your Accu-Chek Insight insulin pump, this User Guide includes the following features for quick and easy navigation:



WARNING

A Warning is a safety information that requires your careful attention and informs you about risks to your health.

Neglecting this information may lead to life-threatening situations.

Note

A Note contains important information relating to the efficient and smooth operation of your Accu-Chek Insight insulin pump.

Example

An Example shows you how a feature could be used in an everyday life situation. Please note that medical- or therapy-related details are provided for illustration purposes only, and are not intended to match your personal medical needs. Always discuss your personal therapy requirements with your healthcare professional.





Note

The illustrations in this book may differ slightly from the design of your actual device.



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1 Pump features

Guided handling sequences (Wizards)

Pump therapy sometimes involves complex steps. For several functions which need to be performed in a specific order, your pump offers pre-programmed Wizards to guide you through the process.

You will find Wizards to help you with:

- Inserting a new cartridge
- ► Filling the infusion set
- Inserting a new battery
- Pairing
- Bluetooth® wireless communication

3 basic modes

RUN mode: When working normally, your pump is in RUN mode. In this mode your pump is delivering insulin to your body in terms of the basal rate, boluses and Temporary Basal Rates (TBR).

PAUSE mode: When you remove the battery or cartridge while your pump is in RUN mode, or after some maintenance messages, your pump switches to PAUSE mode. The insulin delivery stops automatically and restarts as soon as you confirm the according messages and insert a new battery or cartridge where required. Current Temporary Basal Rates and boluses will continue.

STOP mode: When the pump is in PAUSE mode for more than 15 minutes, it switches to STOP mode. The Pump stopped screen appears and the pump stops completely and cancels all current Temporary Basal Rates and boluses. From STOP mode, you have to restart your pump from the main Menu and program your Temporary Basal Rates and boluses again. See chapter 3.2, page 39. If you want to stop your pump for any reason, you can also switch it to STOP mode using the main Menu.

Adjust the display to suit your needs

You can adjust the brightness of your pump's full colour display to best suit your needs. You can also change its background colour to your personal preference. Rotating the display allows you to read it from an awkward angle (for example, when the pump is attached to your belt). See chapter 8.3.5, page 112, *Adjust the display*.

Enlarge the display texts for better readability

Using the Zoom key you can enlarge the size of the display text for better readability. See chapter 1.1.4, page 12, *Zoom mode*.

Convenient pump handling if you are acoustically or visually impaired

If you have problems with your vision you can choose the user profile Expressive.

The scrolling functions of the pump are disabled in this profile so that all values can only be programmed in distinct increments. Additionally, sound patterns will help you verify that you programmed a value correctly. For more information, please contact your local pump support (see inside back cover). If you are acoustically impaired, you can choose the user profile Diminished. All acoustic signals will then occur one octave lower. See chapter 8.3.2, page 108, *User profile*.

Lock the keys against accidental pressing

The Key lock disengages your pump's keys so they cannot be pressed accidentally when you wear your pump under clothing. The Key lock is engaged by default. It can be opened by first pressing ▲ and then ▼ in a fast sequence or first pressing ▼ and then ▲. See chapter 8.3.3, page 109.

Use a standard, easy-to-purchase battery

The power source for your new pump is readily available. To power up your pump, all you need is a standard AAA, 1.5 V lithium (FR03) or alkaline (LR03) battery.

Set hourly basal rates from 0.02 to 25 U/h

You can program individual hourly basal rates for every hour of the day in up to 24 time blocks from 15 minutes to 24 hours. The hourly basal rate can be set low as 0.02 up to 25 U/h. Remember that your basal-rate profile should always be provided by, or discussed with your healthcare professional.

Program up to 5 different Basal profiles

You can define up to 5 Basal profiles, each aligned with a different daily routine. For example, you can create one profile for work days and one for weekends. See chapter 5, page 67, *Basal profile options*.

Use self- or pre-filled cartridges

Your usual insulin works with the 2 ml Accu-Chek Insight insulin pump cartridge. The Accu-Chek Insight insulin pump cartridge filling system allows you to fill the cartridges from vials. You can also use the pre-filled 1.6 ml NovoRapid® PumpCartTM (please check the availability in your country at www.novonordisk.com or ask your local pump support).

Detect occlusions

Your pump detects any blockage in the infusion set that could prevent insulin delivery. You will be prompted with an appropriate Maintenance. However, the pump cannot detect when the infusion set is leaking or where the cannula has slipped out of the infusion site.

2 Standard Bolus types

To program and deliver a Standard Bolus, you have 2 options: either walk through the menus or use the Quick Bolus that allows you to program a Standard Bolus in distinct increments without even looking at the display. See chapter 4.1, page 53, *Standard Bolus*. See chapter 4.2, page 55, *Quick Bolus*.

Adjustable bolus speed

You can adjust the delivery speed of the boluses. This is very helpful if you have high bolus amounts that cause insulin to leak from your skin after delivery or if you experience pain during the bolus delivery. See chapter 8.4.2, page 118, *Bolus settings*.

Use a delay (lag time) before the bolus delivery

If you have delayed digestion (gastroparesis), it might be helpful to start a bolus after you start eating. With the lag setting you can specify a delay between programming a bolus and the actual beginning of the bolus delivery. Discuss using the lag setting with your healthcare team. See chapter 8.4.2, page 118, *Bolus settings*.

Extended Bolus

For situations that require delivery of the bolus insulin over a period of time instead of all at once, you can use an Extended Bolus. The Extended Bolus amount is delivered over a period of time that you can adjust as necessary. This can be especially helpful when you eat slowly digestible foods or attend long-lasting buffets. See chapter 4.4, page 60, *Extended Bolus*.

Multiwave Bolus

In situations where you eat meals containing both slow- and fast-acting carbohydrates, you might consider having a fast and a long bolus together. The Multiwave Bolus combines a Standard and an Extended Bolus, providing both an immediate and a long-acting part. This could also be a good option when you plan to eat slow-acting carbohydrates and need to correct an elevated blood glucose level at the same time. See chapter 4.5, page 63, *Multiwave Bolus*.

Different modes for different life situations

Your pump offers a range of modes to fit a variety of life situations.

For example:

- During meetings your pump can be switched to the Quiet mode. At night it can delay non-critical Warning messages to a specified wake-up time
- ► In Flight mode your pump automatically shuts down the Bluetooth wireless communication

See chapter 7, page 83, *Modes for different life situations*.

Customisable reminders for missed bolus, change infusion set, deliver bolus, and alarm clock

Many aspects of your diabetes management require regular attention and action. Your pump can assist you with a set of reminders that help you remember:

- To deliver a bolus
- ► To change the infusion set
- ▶ To check when you might have missed a bolus

You can even program alarm clocks for your personal convenience. See chapter 8.1, page 89, *Using reminders*.

1.1 Navigating through the menus



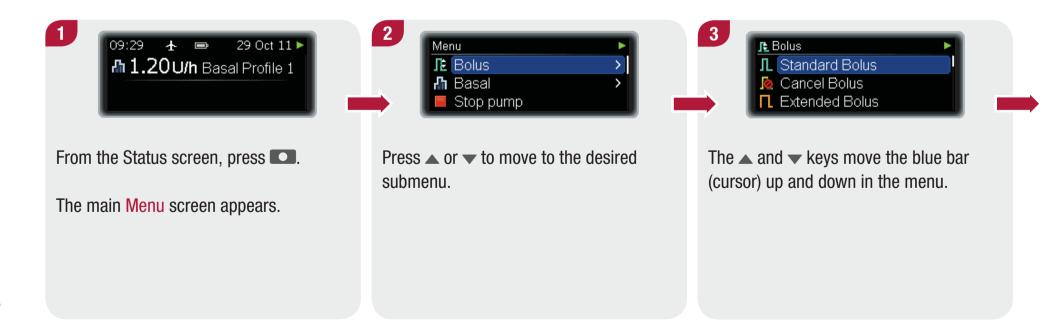
Key	Function
	Moves to the next menu levelConfirms a settingStarts a function
	In most situations the 2 keys have an identical function and can be used alternatively: • Moves to previous entry field • Cancels a setting • Stops a function • Starts the Quick Bolus programming • Sets the Quick Bolus amount • Cancels a bolus (press and hold for 3 seconds) • Moves to the status screen (double click)
A	 Moves you up in a menu screen Increases a setting Function to access quick info screen
•	Moves you down in a menu screenDecreases a settingFunction to access quick info screen
▲ and then ▼or▼ and then ▲	▶ Opens the Key lock

Key	Function
⊕,	Enlarges the characters on the displayReduces enlarged characters on the display

In many cases the screen gives you additional information about using the keys.

1.1.1 Navigating through the screens

This chapter describes in general how to navigat through the screen and use your pump's functions.

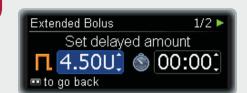




When the blue bar highlights the menu item of your choice, press to enter the next menu level.



When a specific setting is highlighted and shown with small Up and Down arrows, the ▲ and ▼ keys will increase and decrease the value.



To confirm a value, press the key.

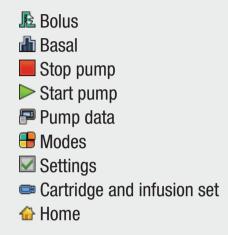
After you complete the setting, press again to confirm and start the function.



1.1.2 Understanding the screen



In the main menu you will find the following functions:





A scroll bar on the right indicates when there are more items available than currently visible on the screen.



In each menu you can use the Home function to return to the Status screen:

Press ve to move to Home.

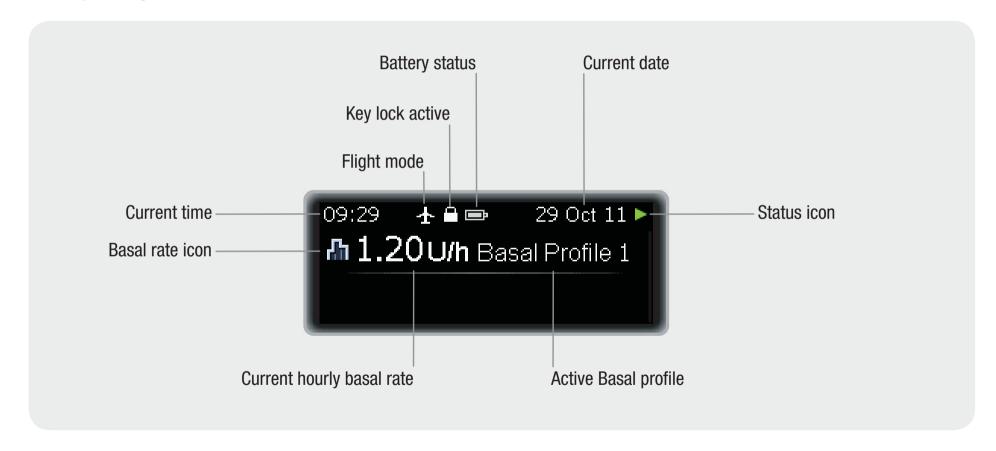
Press to select.



If several steps are part of a sequence (Wizard), numbers in the upper right corner of the screen indicate how many steps still need to be completed.

1.1.3 Status screen

The Status screen shows the current state of your pump. For example you can see whether your pump is in RUN, STOP or PAUSE mode and if boluses or Temporary Basal Rates are currently running.



1.1.4 The screen design

You can choose between different designs for your pump's screen. By default the pump will use the dark background colour and normal font size.

You will learn how to personalise the screen design in the chapter about Settings. See chapter 8.3.5, page 112, *Adjust the display*.

Background colour dark



With the Background colour dark the screen will show white characters on black background.

Background colour light



With the Background colour light the screen will show black characters on white background.

Zoom mode



When you press • , the characters on the screen will be enlarged.

When you press @ again, the characters will be shown in normal size again.

Note

In Zoom mode not all screen content may be visible.

The silluminated as long as the Zoom mode is switched on.

2 Starting your pump

This chapter explains how to prepare your new insulin pump and begin pump therapy.

Before you can start your pump, you need to:

- Insert the battery
- Set the time and date
- Program at least one Basal profile
- Insert the cartridge
- Connect the infusion set's tubing to the pump and fill it with insulin
- Connect the tubing to the infusion set's head set and fill the head set with insulin

Remember that successful pump therapy requires you to check your blood glucose level frequently. It is therefore recommended that you use a blood glucose meter as often as instructed by your doctor or healthcare team (at least 4 times a day).

2.1 Inserting the battery

Your Accu-Chek Insight insulin pump requires a 1.5 V AAA alkaline (LR03) or lithium (FR03) battery.



Your pump turns on as soon as you insert the battery. When you remove the battery, your pump stores the time and date for about 1 hour.

When you remove the battery while your pump is delivering insulin (RUN mode), the insulin delivery stops automatically (PAUSE mode) and restarts as soon as you insert a new battery. After a confirmation, Temporary Basal Rates and boluses that are currently running will continue.

However, the pump stops completely and cancels Temporary Basal Rates and boluses when it is without a battery for more than 15 minutes (STOP mode). You then have to restart it from the main Menu screen and program any Temporary Basal Rates and boluses again. See chapter 3.2, page 39.

Your insulin pump settings (such as the basal rates and bolus increment) and event memory (bolus and alarm history, history of

daily insulin totals and Temporary Basal Rates) are always saved, regardless of battery condition or the amount of time your pump has been without power.

To ensure your pump remains watertight the battery compartment cover needs to be changed every 3 months.

Use of batteries other than those recommended may significantly reduce battery life. Such batteries may also leak and corrode the battery contacts in your pump. They could also lead to an electronic short circuit resulting in dangerous heat development. The use of batteries not supplied or recommended by Roche Diagnostics may void the warranty. Before inserting batteries make sure that they are not damaged (e.g. damaged plastics isolation coating) or leaking as damaged or leaking batteries could damage your pump.

Insert the battery

When you start your pump for the first time, begin with step 4.



To avoid accidental insulin delivery, ensure that the infusion set is not connected to your body.



Turn the adapter anti-clockwise to a 120° position.

Note

You can change the battery without removing the adapter if you turn the adapter to only 90°.



3



Push the battery cover release in the direction of the arrow (towards the cartridge compartment).



You can use the flip up handle to easily remove the battery cover.

5



Remove the battery cover and the old battery.

6



Insert the new battery into the battery compartment, positive end first, negative end pointing out.

7



Place the battery cover on top of the battery.

8



Push the battery cover all the way into the battery compartment until you hear the release click.

After you insert the battery, the pump begins its start-up process. If the pump does not begin the start-up process after the battery is inserted, make sure that the battery is inserted correctly (positive end first).

The first time you insert a battery or after the pump has been without battery for more than 1 hour, the Setup Wizard launches to help you program your pump's initial settings, such as the time and date.

Start-up process and Setup Wizard

After you insert a new battery, your pump immediately performs a self-test. Check the display and the beeps and vibrations to be sure that your pump is working properly.

If anything in the self-test does not seem to work properly contact your local pump support.

The start-up process is different when you:

- Start your pump for the first time
- Start your pump after it has been out of power for more than 1 hour
- Insert a new battery while the pump is in RUN mode

You will learn more about this in the following chapter.

Note



If you do not press ■, ▲ or ▼ key for more than 30 seconds, these keys will be locked.

Press \blacktriangle and then \blacktriangledown , or \blacktriangledown and then \blacktriangle , to

unlock the keys to continue the programming. You can adjust the time before the Key lock engages. See chapter 8.3.3, page 109.

Self-test sequence



After the battery cover is closed, the Pump self-test starts automatically.



The display turns red. Make sure that the area is completely red.



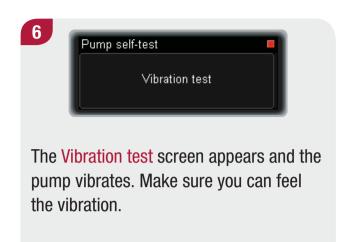
The display turns green. Make sure that the area is completely green.

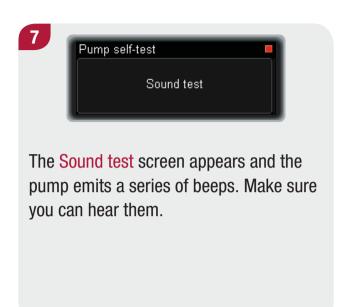


The display turns blue. Make sure that the area is completely blue.



The display turns black. Make sure that the area is completely black.





If this is the first time you have started your pump, or if it has been without power for over 1 hour, the Setup Wizard guides you through the time and date setting steps. Otherwise, the start-up process continues with step 6 on the next page.

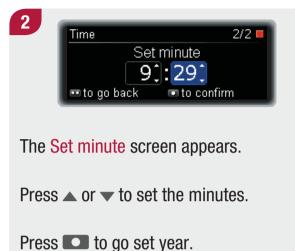
Set the time, date and battery type



The Set hour screen appears.

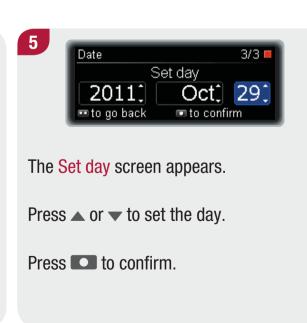
Press ▲ or ▼ to set the hour.

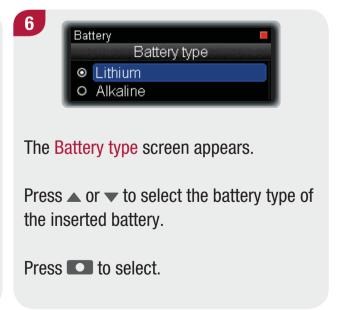
Press **t** o go set minutes.

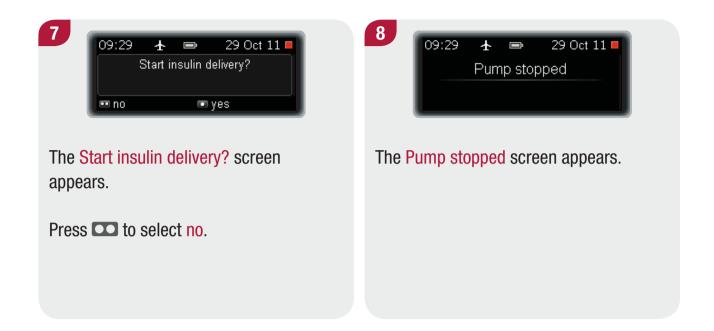












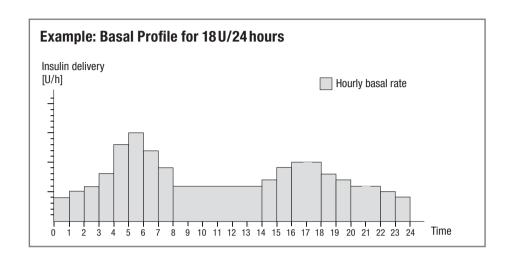
Before using your pump, you must program at least one Basal profile. Continue with programming Basal Profile 1 on the next page.

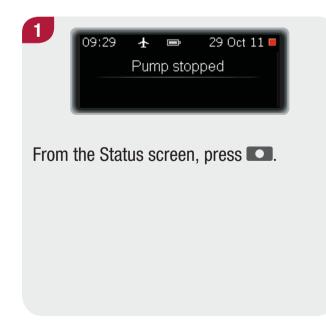
If there is already a programmed Basal profile you can only select yes.

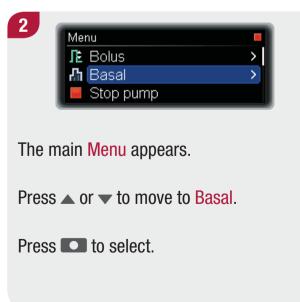
Program Basal Profile 1

Your delivers a continuous stream of insulin to cover your basic insulin need. You can program this in time blocks with different houry basal rates to cover your variing basal insulin reqirement throughout the day. you can program up to 24 time blocks with a minimum duration of 15 minutes. The total of all time blocks is called a basal profile or basal rate profile. Make sure that you have programmed an hourly basal rate for all 24 hours of the day.

Your peronal settings for the basal profiled should be provided by your healthcare professional.











Press ▲ or ▼ to move to Basal Profile 1.

Press to select.



The Basal Profile 1 screen appears. The Start time is always midnight. The End of the first time block is highlighted.

Press ▲ or ▼ to set the time.

Press .



The hourly basal rate of the first time block is highlighted.

Press ▲ or ▼ to set the hourly basal rate.

Press .



The **End** of the second time block is highlighted.



Note

When you start editing the entry in the lower line it will shift to the top line.

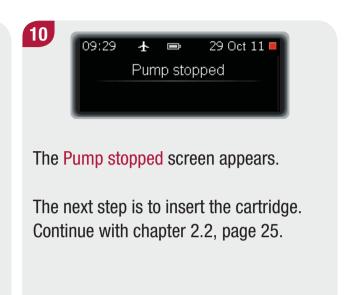


Continue programming the End time and hourly basal rate for the total of 24 hours. After you have programmed an hourly basal rate for all 24 hours, press



The Basal Profile daily total screen for the Basal Profile 1 appears. Make sure the daily total matches your therapy requirement.

Press **t** to confirm.



Note

If necessary, you can press to go back to a previous field.



2.2 Inserting a new cartridge

Before starting your insulin pump for the first time you must insert a new cartridge.

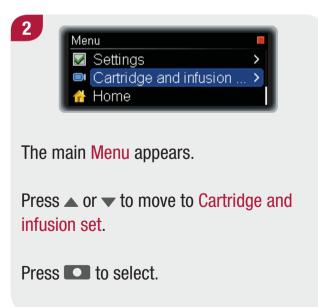
When the insulin in your cartridge is running low, you will be prompted with a Warning W31: Cartridge low which means that there is only a specified number of insulin units left. You can adjust the Cartridge warning level in the Therapy settings. When the cartridge is completely empty, your pump sends a Maintenance M21: Cartridge empty and you must change the cartridge immediately.

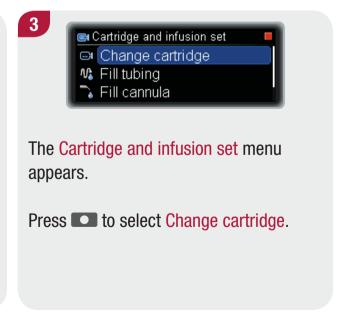
Have the following materials ready:

- An Accu-Chek Insight insulin pump cartridge (self-filled) or a NovoRapid® PumpCart™ (pre-filled)
- ▶ A new Accu-Chek Insight infusion set

Insert the cartridge









The Change cartridge screen appears.





When you reach an angle of about 120°, remove the adapter.



Remove the cartridge.

Press to confirm that you have removed the adapter and the cartridge.



The pump automatically starts rewinding the piston rod.



When the pump finishes rewinding, you are prompted to insert the new cartridge and connect the adapter.

10



Insert the new cartridge – plunger first – into the cartridge compartment.

11



Replace the adapter on the bayonet socket of the cartridge compartment (about 120° angle).

12



Make sure you correctly insert the nose of the adapter into the notches of the pump's housing.

13



Turn the adapter clockwise all the way to the stop.

14



The adapter is correctly positioned when it is aligned with the pump's housing.

Press **t** to confirm.

15



The Cartridge type screen appears.

Press ▲ or ▼ to select the appropriate cartridge type.

Press to select.



You are prompted to disconnect the infusion set from your body

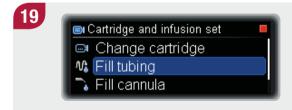
Press **t** to confirm.



The pump detects the position of the plunger in the cartridge.



The pump then performs a self-test. See chapter 2.1, page 14.



After the self-test, the pump returns to the Cartridge and infusion set menu. Fill tubing is selected by default. Continue with the next chapter.

2.3 Filling the infusion set tubing and cannula



WARNING

Never fill an infusion set that is connected to your body, as you risk uncontrolled insulin delivery. Always follow the instructions for use for the infusion set you are using.



WARNING

Air bubbles in the cartridge and infusion set may result in the infusion of air instead of insulin. If this happens, your body will not receive the required amount of insulin. Remove bubbles when you fill the cartridge and the infusion set, while the infusion set is disconnected from your body.

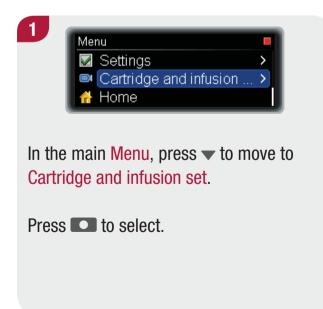
After you connect the adapter of a new infusion set, it is essential that you fill the infusion set tubing with insulin. Make sure it is free of air bubbles.

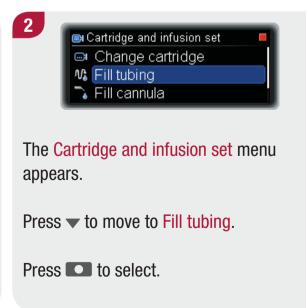
By default, the pump stops filling at 11 units of insulin. If no insulin emerges from the connector, or if there are air bubbles in the tubing after filling, repeat the filling process until the infusion set is bubble-free and completely filled with insulin. When insulin appears at the tip of the connector, press to stop filling. The amount of insulin used for filling is not added to the pump's history of daily insulin totals. You will learn how to adjust the fill amount in the chapter about Settings. See chapter 8.4.3, page 125.

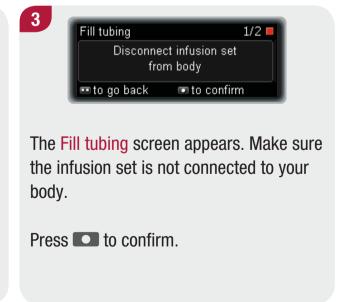
Fill the infusion set tubing

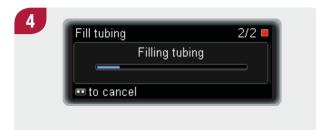
Hold your pump upright during filling. The adapter should point upwards to help release any remaining air bubbles from the cartridge and tubing.

If you just inserted a new cartridge, start with step 2.

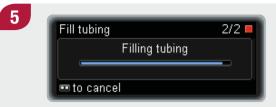








The pump automatically starts to fill the tubing.



Your pump stops filling at 11 units. You can stop the filling process at any time by pressing ••.

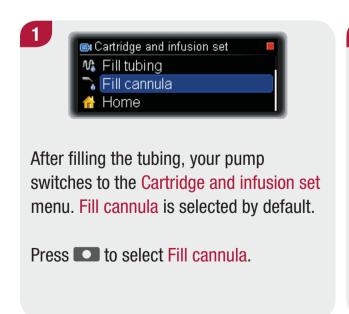


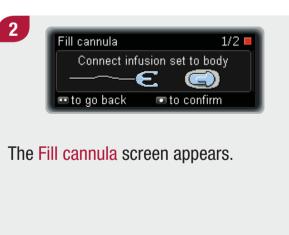
When the filling is completed, the pump switches to the Cartridge and infusion set menu. Fill cannula is selected by default.

You can now insert the cannula into your body. Carefully read and follow the instructions that came with your infusion set. You need to fill the head set and cannula with insulin before you start your pump. See the next chapter (Filling the cannula). See chapter 8.4.3, page 125 if you need to adjust the tubing or cannula fill amount.

Fill the cannula

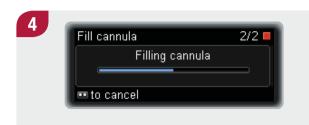
By default the fill amount is set to 0.7 units. It is possible to adjust this fill amount. See chapter 8.4.3, page 125.



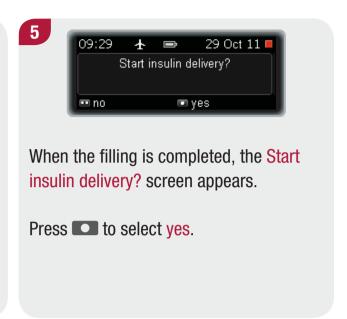




Press **t** to confirm.



The pump automatically starts to fill the cannula.



Note

If you do not want to start the insulin delivery now for any reason, press to select no.

3 Using your pump in daily life

3.1 Wearing your pump

Attach your pump safely to your body or clothes to prevent damage. You can do this with one of our special carrying systems. In cold weather wear your pump under your clothes or directly on your body.



WARNING

Make sure that the infusion set is never kinked nor compressed. Otherwise the insulin cannot flow freely, which could result in under or over delivery of insulin.

Note

When wearing your pump, prevent any contact with objects in your pockets, such as key chains, keys, pocket knives or coins. These could damage the pump or accidentally press its keys.

3.1.1 When and when not to wear your pump

There are a few situations where it is recommended that you take off your pump, because your pump could be damaged or other risks could arise. Take off your pump in these situations and change to alternative therapy if needed. Examples of such situations are listed on the following pages.

Electromagnetic fields and hazardous areas

\triangle

WARNING

Do not use your pump near electromagnetic fields such as radar or antenna installations, high-voltage sources, X-Ray sources, computer tomography (CAT scan), and MRI. These and all other sources of electrical current may cause your pump to fail. Insulin delivery may stop and the Error E7 occurs.

Always stop your pump, remove it from your body, and leave it outside these areas. See Appendix A: *Technical Data*, page 151 for more information about electromagnetic fields.

Your pump has been tested against, and complies with, the regulations on electromagnetic interference. Security systems in airports and anti-theft monitoring devices, such as those in department stores, should not affect the functioning of your pump.

There are many devices that emit electromagnetic radiation, for example mobile phones. It cannot be completely ruled out that one of such devices could affect your pump. It is therefore recommended that you keep your pump at least 10 cm (4 inches) away from these devices while they are active.

Barometric pressure

Your pump is designed to work in normal barometric conditions (from 550 to 1060 mbar).

Do not use your pump in hyperbaric chambers, or in hazardous areas where, for example, flammable gases or vapors could be present. This could cause an explosion.

Always stop and disconnect your pump from your body before you enter hazardous areas. For more information, contact your local pump support (see inside back cover).

Note

Rapid and extreme changes in air pressure or temperature can influence insulin delivery, especially if there are air bubbles in the cartridge or tubing.

Such changes could occur when you are, for example:

- ▶ in an airplane without pressure balance during takeoff
- when practicing sports like hang-gliding
- leaving a heated room and going outside in cold weather.

Wear your pump close to your body, remove any air bubbles from the cartridge and tubing and measure your blood glucose more frequently in such situations. Where in doubt, take off the pump and change to alternative therapy method.



Sport and exercise

You can wear your pump while performing a range of sporting activities. However, it is important that you protect your pump before you begin exercise or sporting activities. Do not wear your pump when practicing sports that involve high-impact body contact such as boxing, football, or hockey. Rough contact could damage your pump.

Consult our accessories catalogue for more information about carrying systems, or contact your local pump support (see inside back cover).

Travelling with your pump

Before travelling, ask your doctor or healthcare team about any special steps you need to take. Take extra blood glucose testing and pump supplies with you, and find out where to obtain supplies while you are travelling.

For more information, contact your local pump support (see inside back cover).

3.2 Stopping and starting your pump

You should discuss with your doctor or healthcare team about when and for how long the insulin delivery may be interrupted. Check your blood glucose level regularly during any insulin interruption. If necessary, use a syringe or insulin pen to inject insulin according to the instructions of your doctor or healthcare team.

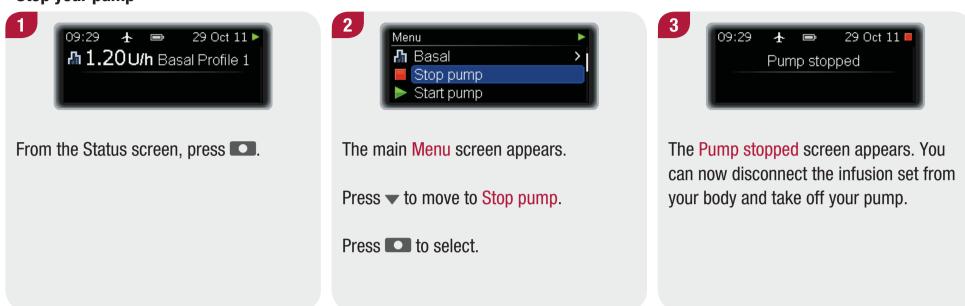


WARNING

Check your blood glucose level and replace the missing insulin immediately if your insulin delivery is interrupted for any reason, for example:

- You stop the pump
- ▶ There is a technical problem with the pump
- ▶ The cartridge and / or the infusion set is leaking
- ▶ There is an occlusion in the infusion set or in the head set
- ▶ The cannula has slipped out of the infusion site

Stop your pump



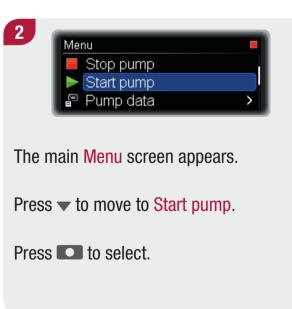
STOP Warning

As long as the pump is in STOP mode, it will emit a beep every minute to remind you that no insulin is being delivered. You can suppress this STOP warning by pressing of for 3 seconds.

Start your pump

W







The RUN screen appears and the pump starts to deliver insulin.

Long interruptions

Use the following procedure if you need to interrupt your pump therapy for more than one day.



Switch your pump to STOP mode. See chapter 3.2, page 39.

Disconnect the infusion set from your body.



Remove the adapter, cartridge and battery from the pump. See chapter 2, page 13.

Make sure you store your pump properly. See chapter 9.5, page 134.

3.3 Your insulin pump and water

Your pump is waterproof according to the IPX8 standard. That means you may wear it while showering, bathing and swimming. However, since the adapter of the infusion set is not watertight, water may enter the cartridge compartment. You must then remove the cartridge and dry the cartridge compartment as described later. You must not dive deeper than 2 meters when wearing your pump.

However, if your pump has been dropped, it may no longer be waterproof due to hairline cracks. Therefore it is highly recommended that you no longer wear it while swimming, bathing, or showering.

When water has entered the cartridge or battery compartment

Water may enter into the cartridge compartment through the adapter if the pump is dropped in water. If water has entered the cartridge or battery compartment, put your pump into STOP mode and disconnect the pump from your body. Use a soft cloth to dry the outside of the pump, turn your pump upside down to let the water run out, and leave it to dry. Do not use warm air such as a hair dryer or microwave to dry the pump as this could damage the pump's housing. Make sure that the cartridge and battery compartment is completely dry before reinserting the cartridge or battery. Please make sure that you use a new battery cover.

Contact with other liquids

You do not need to worry about contact between your pump and perspiration or saliva. However, you must check your pump immediately after contact with other liquids or chemicals, such as:

- Cleaning solutions
- Alcohol
- Drinks
- Oil or fat

Avoid any contact between the pump and infusion set with health and beauty products (for example; antiseptics, antibiotic creams, soaps, perfumes, deodorants, body lotions, or other cosmetics). These substances could discolour your pump or fog the display.

3.4 Changing the transfer set (adapter and tubing)

Change the transfer set (adapter and tubing):

- As directed by the instructions accompanying the set
- When the infusion site shows signs of irritation or infection
- ▶ If the pump displays Maintenance M24: Occlusion
- If you think that there might be an occlusion in the tubing (even without an alarm)

Your pump cannot detect infusion set leakage. Inspect all parts of your infusion set regularly during the day and before you go to sleep. If there seems to be any loss of insulin and all parts are correctly tightened, look for and immediately replace any leaking component. Check your blood glucose level immediately, as insulin delivery has been interrupted. Take appropriate action according to your doctor's or healthcare team's instructions. Always disconnect your infusion set before changing a cartridge or filling the infusion set. Otherwise, you risk uncontrolled insulin delivery into your body. Always follow the instructions for the infusion set and cartridge you are using.

Note

You can also review how to change the cartridge. See chapter 2.2, page 26



Change the transfer set (adapter and tubing)

Note

Disconnect and remove the infusion set's head set and insert a new one at a new site as described in the infusion set's instructions.



\triangle

WARNING

Inspect your infusion site at least twice each day for irritation or infection. Signs of infection may include, but are not limited to: pain, lumps, redness, heat, or discharge. If you see redness or swelling, change the infusion set's head set and the infusion site immediately and contact your doctor or healthcare team.

Change the head set according to the instructions for the infusion set you are using and your doctor's or healthcare team's recommendations.



Turn the adapter with the tubing anticlockwise.

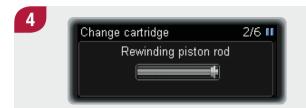


When you reach an angle of about 120°, remove the adapter with the cartridge.



The Rewind piston rod? screen appears.

Press to select yes.



The pump automatically starts rewinding the piston rod.



When the pump finishes rewinding, you are instructed to insert the new cartridge and connect the adapter.



Insert the cartridge – plunger first – into the cartridge compartment.

7



Replace the adapter on the bayonet socket of the cartridge compartment (about 120° angle).

8



Make sure you correctly insert the nose of the adapter into the notches of the pump's housing. 9

6

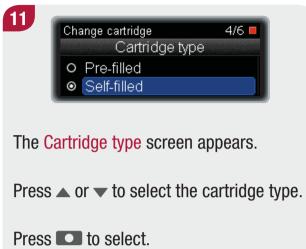


Turn the adapter clockwise all the way to the stop.



The adapter is correctly positioned when it is aligned with the pump's housing.

Press **t**o confirm.



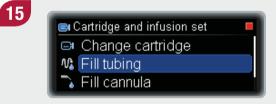




The pump automatically detects the position of the plunger in the cartridge.



The pump then performs a self-test. See chapter 2.1, page 19



After the self-test, the pump returns to the Cartridge and infusion set menu. Fill tubing is selected by default. See chapter 2.3, page 30.

3.5 Quick info screens

The Quick info screens allow you to quickly access important information about the status of your pump and recent therapy events.

The sequence of Quick info screens includes information about:

- Current insulin amount in your cartridge and energy status of your battery
- Last bolus
- ► Total daily dose of insulin
- ► Last safety event (Error, Maintenance or Warning message)
- Current time and date



From the Status screen, press .



The Cartridge and battery screen appears.

Press **▼**.

Press ▲ if you want to go back.

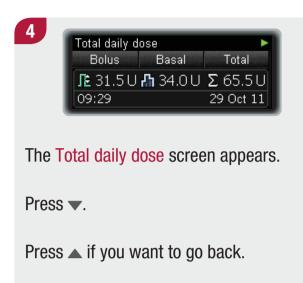


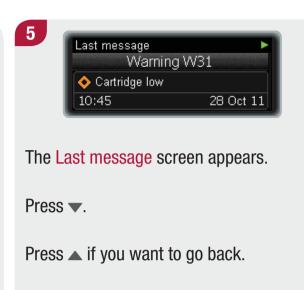
The Last Bolus screen appears.

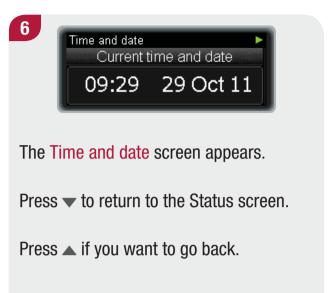
Press **▼**.

3

Press ▲ if you want to go back.







3.6 General safety information



/! WARNING

Do not place your insulin pump in direct sunlight. Overheating of the insulin and the pump must be avoided. Protect your insulin pump from direct exposure to cold wind and temperatures over 37 °C (99 °F) and below 5 °C (41 °F). These conditions may damage the insulin and the housing of your insulin pump and could also cause a malfunction of the battery. See the instructions for the insulin you are using to determine the acceptable temperature range.

Note

Check the amount of insulin remaining in the cartridge at least once a day. Press from the Status screen to display the remaining cartridge content in units. Before going to sleep, make sure that:

- ▶ The pump is in RUN mode
- ► The cartridge contains enough insulin to last through the night
- ► The battery level is OK
- ▶ The time and date are set correctly
- ► The display is working properly



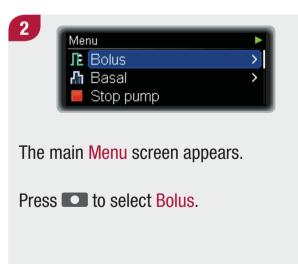
4 Administering boluses

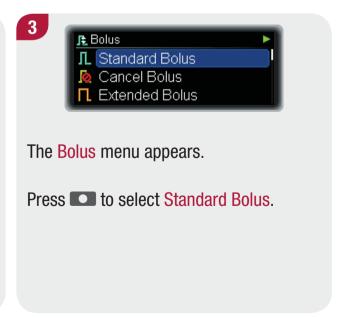
4.1 Standard Bolus

The Standard Bolus delivers the programmed insulin dose all at once. This bolus can be helpful for foods that are digested quickly, such as cake or bread. The Standard Bolus is also the best option for correcting high blood glucose levels. If necessary, you can adjust the speed of the bolus delivery. See chapter 8.4.2, page 118.

Program a Standard Bolus

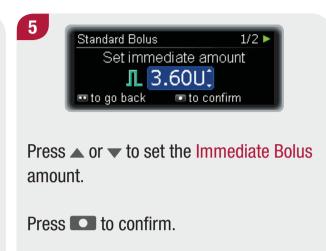








The Standard Bolus screen appears with the immediate bolus amount highlighted.







Your pump returns to the Status screen showing a progress bar for the remaining bolus amount.

Note

You can cancel the bolus during delivery by pressing of for 3 seconds.



4.2 Quick Bolus

As with the Standard Bolus, the Quick Bolus delivers the programmed insulin dose all at once. However, you do not need to switch to the main Menu screen to set up a Quick Bolus. In fact, with experience you will be able to program this bolus type without even looking at the display.

This bolus type lets you discreetly deliver a bolus while your pump is hidden in your clothing. However, it is only possible to program the bolus amount in distinct increments. The default setting for this increment is 0.5 units, which means you can set the bolus amount to 0.5, 1.0, 1.5 units, and so on. If needed, you can change the increment to 0.1, 0.2, 1.0, 2.0 or 5.0 units in the Therapy Settings. See chapter 8.4.2, page 118.



WARNING

Make sure that you know and use the correct bolus increment. Using the incorrect bolus increment will deliver the wrong insulin dose.

And as with the Standard Bolus, this bolus is suitable for meals that contain mainly fast digestible carbohydrates as well as for the correction of high blood glucose levels.

If necessary, you can adjust the speed of the bolus delivery. See chapter 8.4.2, page 118.

Program a Quick Bolus



In RUN mode, press and hold one of the keys until you hear a beep and feel a vibration (about 3 seconds).



The Quick Bolus screen appears with the bolus amount highlighted.

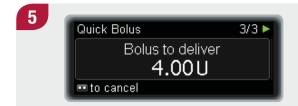


Press **the other** key once for each increment until the required bolus amount is reached.

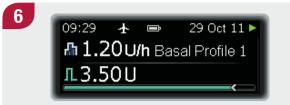
Each time you press the key, your pump beeps and vibrates simultaneously – once for each programmed bolus increment.



5 seconds after your final key press, your pump confirms the bolus amount with one beep and vibration for each bolus increment programmed.



The pump displays the Bolus to deliver screen for another 5 seconds.



Your pump returns to the Status screen showing a progress bar for the remaining bolus amount.

Note

You can cancel the bolus while the Bolus to deliver screen is displayed or during delivery by pressing of for 3 seconds.



4.3 Cancelling a bolus

4.3.1 Cancelling a bolus during programming

Standard, Extended and Multiwave Bolus

While programming, press to go back and program a new value.

Quick bolus

During confirmation or as long as the Bolus to deliver screen is displayed press to cancel the bolus completely.

The bolus delivery stops completely and your pump displays a Warning W38: Bolus cancelled.

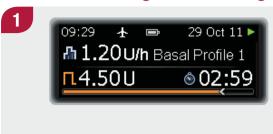
4.3.2 Cancelling boluses during delivery

During delivery of a Standard, Quick or the immediate part of a Multiwave Bolus press for 3 seconds to cancel the bolus.

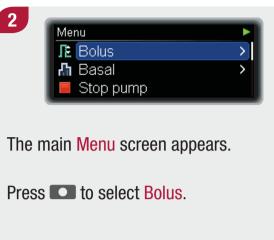
The bolus delivery stops completely and your pump displays a Warning W38: Bolus cancelled.

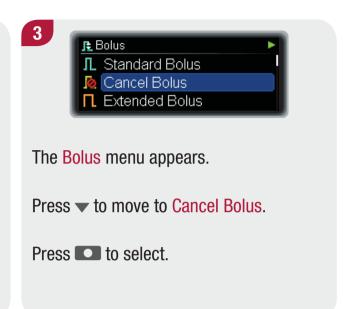


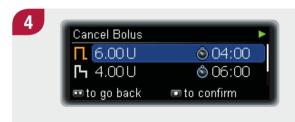
4.3.3 Cancelling a bolus using the Cancel Bolus menu



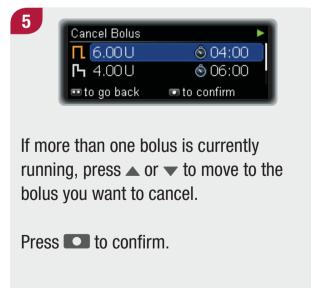
From the Status screen, press .







The Cancel Bolus screen appears.





4.4 Extended Bolus

An Extended Bolus delivers your programmed insulin dose over a specified period of time.

This bolus type can be helpful for meals that are slowly digestible, for example, foods with complex carbohydrates or foods that are high in fat.

The duration of the bolus delivery can be programmed in 15-minute intervals for up to 24 hours, and begins immediately after you confirm the bolus. Throughout the bolus delivery, your pump displays the remaining time and amount of the Extended Bolus in the RUN screen.

You can add a Standard or Quick Bolus to an ongoing Extended Bolus and one additional Extended or Multiwave Bolus.

Example

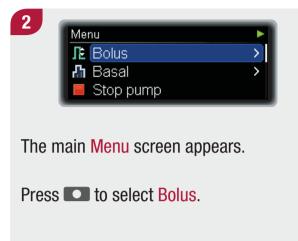
lan Insight is planning to eat a pizza. He knows it contains a lot of fat and slowly digestible carbohydrates, and few fast-acting carbohydrates. Therefore, he programs an Extended Bolus for his pizza.

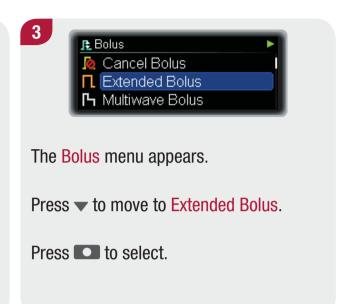


Program an Extended Bolus



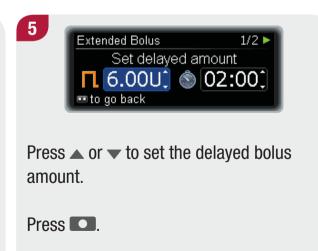
From the Status screen, press .





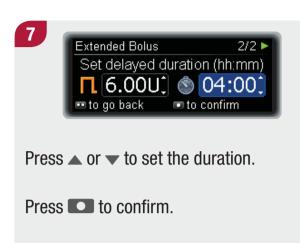


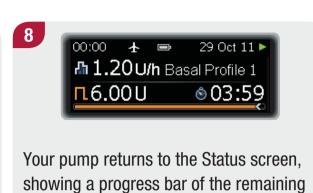
The Extended Bolus screen appears with the delayed bolus amount highlighted.





The bolus duration is highlighted.
The duration of your last Extended Bolus is given as a default.





bolus amount and duration, in addition to

the hourly basal rate.

4.5 Multiwave Bolus

The Multiwave Bolus combines a Standard Bolus with an Extended Bolus; one part of the bolus amount is delivered immediately while the other is delivered over a specified period of time.

This bolus can be helpful when you eat meals that contain both fast and slowly digestible carbohydrates or long meals with several courses. You can also use this bolus type when you are planning to eat slowly digestible carbohydrates but have an elevated blood glucose level before the meal. You program the immediate part of the bolus for the correction of the blood glucose level and the extended part for the carbohydrates.

The duration of the delayed Bolus delivery can be programmed in 15-minute intervals for up to 24 hours, and begins immediately after you confirm the bolus. Throughout the bolus delivery, your pump displays the remaining time and amount of the bolus in the Status screen.

You can add a Standard or Quick Bolus to an ongoing Multiwave Bolus, and one additional Extended or Multiwave Bolus.

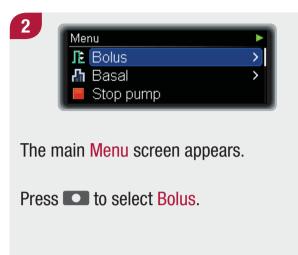
Example

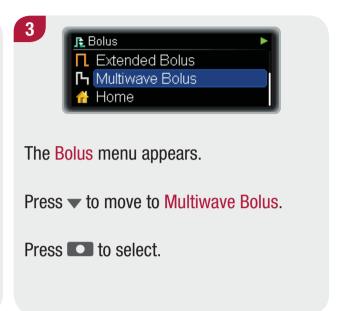
lan Insight is invited to dinner. He will have pastry as a starter and steak with potatoes as his main course. In addition, his blood glucose level is slightly out of the target range before the meal. He programs a Multiwave Bolus of 15 units in total: an immediate dose of 5 units for the starter and the correction of his high blood glucose level, and 10 units over a period of 3 hours.



Program a Multiwave Bolus

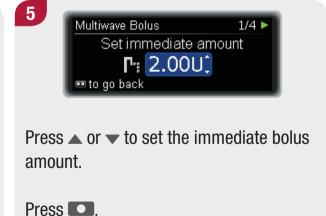


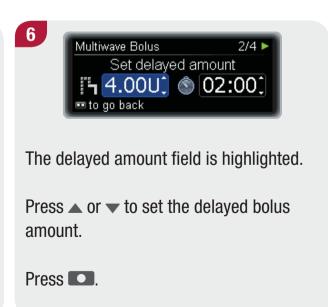






The Multiwave Bolus screen appears with the immediate amount field highlighted.





7



The duration of the delayed bolus is highlighted.

The duration of your last Multiwave Bolus is given as a default.

Multiwave Bolus 3/4 Set delayed duration (hh:mm)

4.00U 02:30

to go back to confirm

Press ▲ or ▼ to set the duration.

Press **t** to confirm.

.... to go back

The Bolus to deliver screen appears, displaying the insulin units that are still to be delivered for the immediate bolus. If necessary, you can press and program the bolus anew.

10



Your pump displays the Status screen, showing the units and a progress bar of the remaining bolus amount and duration of the delayed bolus in addition to the hourly basal rate.

Note

You can cancel the bolus during delivery of the immediate part by pressing of for 3 seconds.

You can also cancel the Extended Bolus

part if necessary. See chapter 4.3, page 58.

5 Basal profile options

In this chapter you will learn how to adjust your basal insulin supply to different life situations:

- ► Temporary Basal Rates help you to adjust your basal rate to short term changes of your basal insulin requirement like for example when your are ill or when you are playing sports.
- You can also program additional Basal profiles to meet your insulin need for different daily routines; for example, working days versus weekends.
- Once programmed you can activate the different Basal profiles when needed with a few key presses.

5.1 Temporary Basal Rate (TBR)

Using the Temporary Basal Rate (TBR), you can increase or decrease your current basal rate profile on a percentage basis for a specified period of time. This helps you adjust your basal insulin dose in situations where your insulin need has temporarily changed. For example, when you are playing sports you might need less insulin, and when you are ill you might need more insulin. Discuss the use of Temporary Basal Rates with your doctor or healthcare team.

Your current basal rate profile represents 100 %. When you increase or decrease the basal rate with a TBR, the shape of your profile does not change, but each hourly basal rate is either increased or decreased by the percentage that you program. You can activate only 1 TBR at a time, between 0 and 250 % in 15-minute intervals for up to 24 hours.

Example

lan Insight is planning to play tennis for 1 hour. He knows that his body needs 40 % less insulin during this kind of activity and for another 2 hours while recovering. He programs a TBR of 60 % for the next 3 hours.



Note

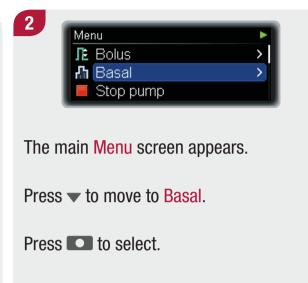
Setting a TBR does not affect any boluses you have set up.

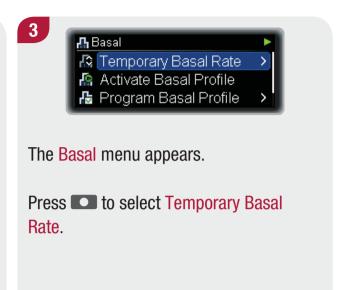


Program a Temporary Basal Rate



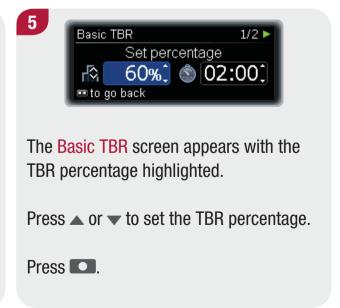
From the Status screen, press .

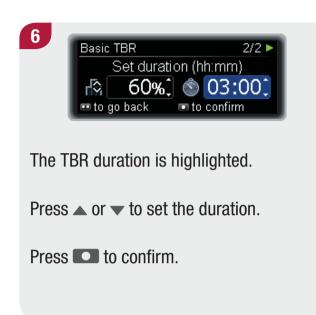


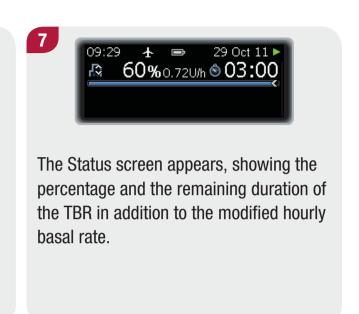




Press to select Basic TBR.





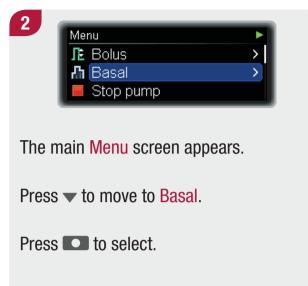


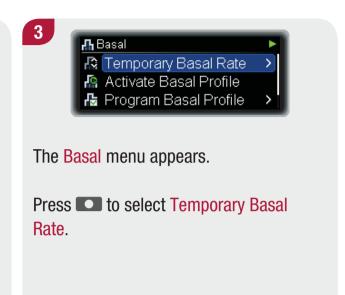
When the duration of the TBR has expired, your pump sends a Reminder R7: TBR over.

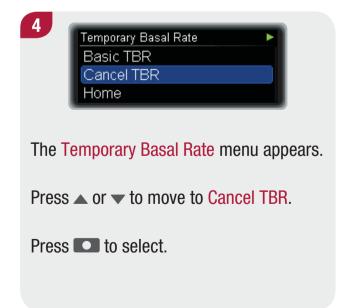
Cancel a TBR

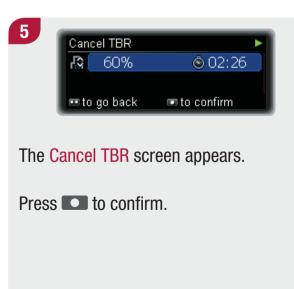


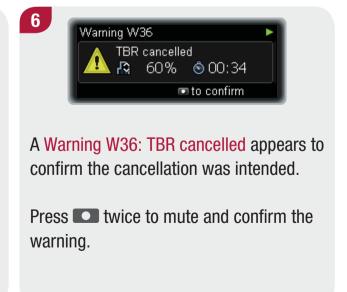
From the Status screen, press .











5.2 Additional Basal profiles

As well as your initial Basal profile you may want to use other Basal Profile for different daily routines.

You can program up to 5 different Basal profiles. Discuss using different Basal Profile with your doctor or healthcare team.

Example

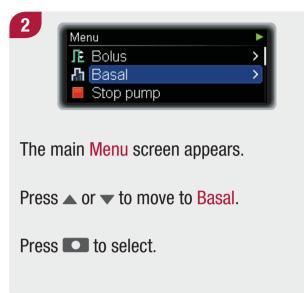
lan Insight is a construction worker and from Monday to Friday he is on his feet from early morning until knocking-off time. On the weekend, he likes to sleep in late and reading books for hours. After discussing his varying daily routines with his doctor, lan Insight programmed Basal Profile 1 for working days. He also programmed Basal Profile 2 that provides more basal insulin for Saturdays and Sundays.



Program Basal Profile 2 (3, 4, or 5)



From the Status screen, press .







The Program Basal Profile screen appears.

Press ▲ or ▼ to move to Basal Profile 2 (3, 4, or 5).

Press to select.



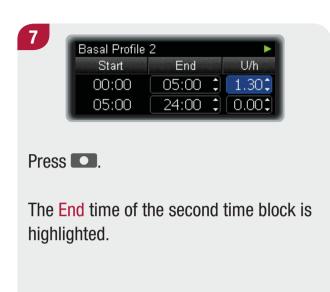
The Basal Profile 2 (3, 4, or 5) screen appears. The End of the first time block is highlighted.

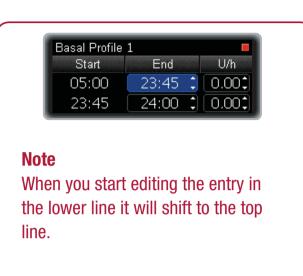
Press ▲ or ▼ to set the end time of the first time block, press ■.



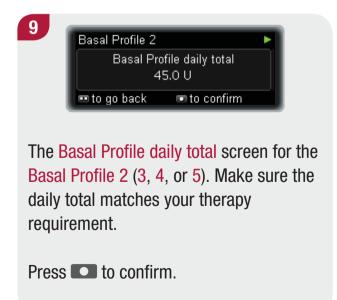
Press to move to the hourly basal rate for the first time block.

Press ▲ or ▼ to set the hourly basal rate of the first time block, press ■.

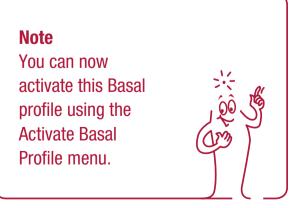












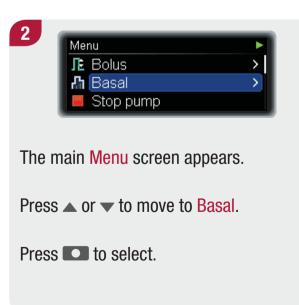
5.3 Activating a Basal profile

Example

lan Insight is planning a lazy weekend with sleeping late in the morning and relaxing for hours. On Friday night, when he returns from work, he switches from Basal Profile 1 that is for working days to Basal Profile 2 that matches his weekend habits.

Activate Basal Profile 2 (1, 3, 4, 5)





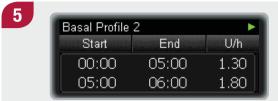




The Activate Basal Profile screen appears.

Press ▲ or ▼ to move to Basal Profile 2 (1, 3, 4, or 5).

Press **t** to select.



The Basal Profile 2 (1, 3, 4, or 5) summary screen appears. Make sure you selected the correct profile.

Press .



The Basal Profile daily total screen appears. Make sure the daily total matches your requirement.

Press **to** confirm.



The Status screen appears. The new Basal profile is active immediately.

Viewing your data

Your insulin pump stores up to 9000 of all the events (Maintenances, Warnings and Errors, programming operations and insulin delivery records). This data corresponds to about the last 6 months of use, and can be accessed on a personal computer using appropriate Accu-Chek software products.

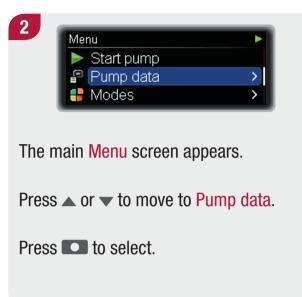
The following data can be reviewed directly on your insulin pump:

Event data	Last 90 Maintenances, Warnings, and Errors.
Bolus data	Last 90 boluses.
Temporary Basal Rate data	Last 90 increases and decreases in basal rate.
Daily insulin totals	Last 90 daily totals of insulin delivered.
Pump timer	Remaining time in days until the Roche warranty expires.
Pump timer (loan pumps)	Remaining time in days until the pump timer expires.
Version	Version of your pump's software.

Viewing your data



From the Status screen, press .



Press to go back to the Pump data





Menu screen or press ● twice to return to the Status screen.

The relevant data screen appears starting with the most recent entry.

Press **v** to view older entries.

Press **\(\rightarrow\)** to move back to younger results.

6.1 Event data

The Event data screen allows you to view up to the last 90 Maintenances, Warnings, and Errors starting with the most recent entry.

Each Event data screen displays:

- ► Type and number of the Maintenance, Warning, or Error (for example, Warning: W32)
- ► The text of the Maintenance, Warning or Error (for example, Battery low)
- ▶ Time
- Date

6.2 Bolus data

The Bolus data screen allows you to view up to the last 90 bolus deliveries starting with the most recent entry.

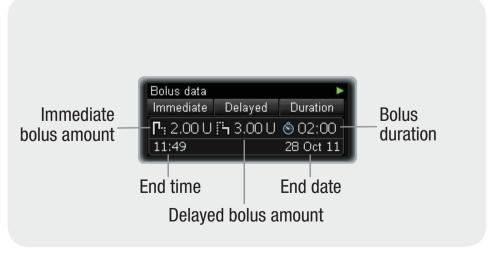
Each Bolus data screen displays:

- Immediate bolus amount (only Quick, Standard, or Multiwave Bolus)
- Delayed bolus amount (only Extended or Multiwave Bolus)
- Bolus duration (only Extended or Multiwave Bolus)
- Fnd time
- Fnd date

Event data screen



Bolus data screen



6.3 TBR data

The TBR data screen allows you to view up to the last 90 Temporary Basal Rates (TBR), starting with the most recent entry.

Each TBR data screen displays:

- ▶ TBR in percentage
- ▶ TBR duration
- End time
- End date

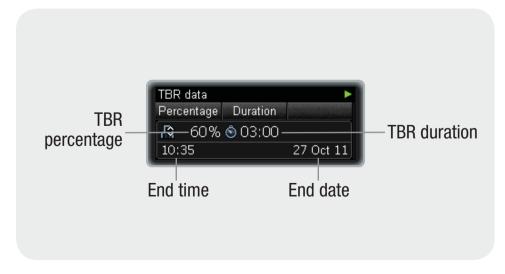
6.4 Daily totals

The Daily totals screen allows you to view up to the last 90 daily totals of insulin delivered (from midnight to midnight; including basal rate, plus boluses), starting with the most recent entry.

Each screen displays:

- Daily total of insulin delivered as boluses
- Daily total of insulin delivered as basal rate
- Daily total of insulin delivered
- Date

TBR data screen



Daily totals screen



6.5 Pump timer

The Pump timer screen shows the time until the warranty for your pump expires.

For loan pumps, a pump timer limits the operating time. When you begin using the pump, the timer starts the countdown of the number of remaining days. Before the pump timer expires, a Warning W39: Loantime Warning will remind you that the operating life of the pump is coming to an end, so that you can take appropriate action in good time. When the timer expires, the Maintenance M25: Loantime over occurs, and your pump goes into STOP mode. It can no longer be put into RUN mode.

6.6 Version

For reference purposes, you can view the software version that is active on your pump.

Pump timer screen



Version screen



Modes for different life situations

The different modes on your pump help you to adjust the signals and other functions of your pump to different situations. By default your pump will be in the Normal mode. In this chapter, you will learn how to switch from one mode to another.

You will learn how to program a mode to best suit your preferences in the chapter about Settings. See chapter 8.3.1, page 103.

You have 4 different signal modes:

Normal	Set the signal that you prefer in most of your every day life situations
Vibrate	Set the signal to vibrate only
Quiet	Set the signal to not disturb for example during meetings
Loud	Set the signal to be audible in a loud environment

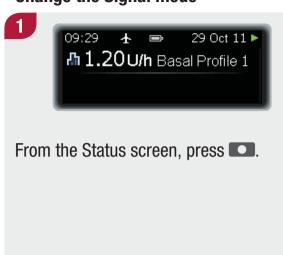
Signal suspension

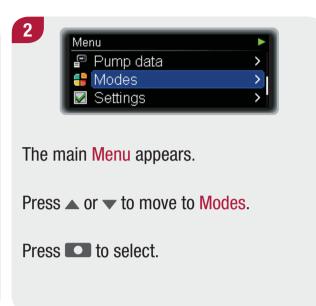
You can set the signal to not disturb while sleeping. (Warnings can be suspended until your usual wake-up time.) This function is available in all 4 signal modes.

Flight mode

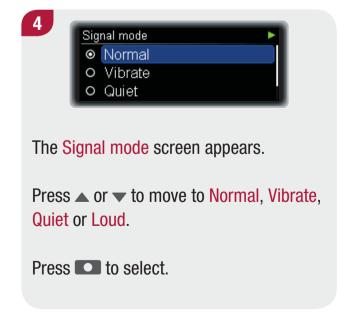
The Flight mode will not change the signal but will switch off the *Bluetooth* function of your pump. You need this mode when you travel by airplane, where you are not allowed to use *Bluetooth* communication.

Change the Signal mode





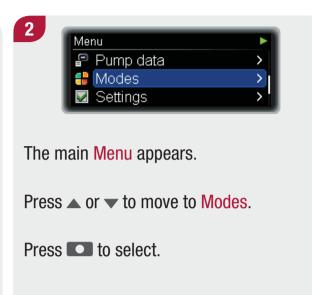




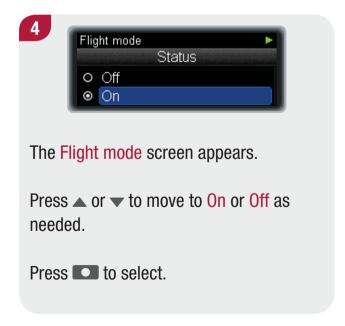
The pump returns to the Status screen and the new mode is active immediately. You can learn how to adjust the Signal modes to your personal needs in the chapter about Settings. See chapter 8.3.1, page 103.

Switch the Flight mode on or off









The pump returns to the Status screen. The Flight mode is active immediately and *Bluetooth* communication is switched off. In the Status screen the airplane icon appears.

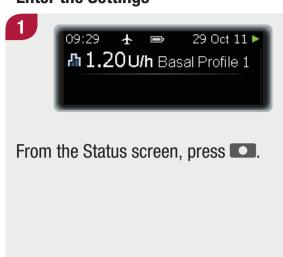
8 Personalising your pump

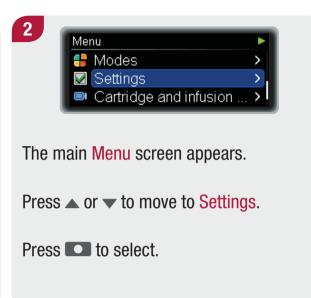
Your pump offers a wide range of options to adjust it to your individual therapy requirements and personal preferences.

You can make adjustments to:

Reminders	Help you to remember the tasks of your diabetes management.
Communication	With the communication settings, you can manage the interfaces of your pump to other devices.
Device settings	There are a wide range of options to adapt your pump to your personal preferences to best match your day-to-day needs.
Therapy settings	Help you to optimally adjust your pump to your personal therapy requirements.
Time and date	Ensure that your insulin supply is always on time.

Enter the Settings







8.1 Using reminders

To help you remember all the tasks that are related to the management of your diabetes, your pump offers a variety of Reminders.

Each reminder can be set to Off, Once or Repeat. When set to Once, the reminder will only sound on the specified day. When set to Repeat, the reminder will sound each day at the same time.

You can use the following options:

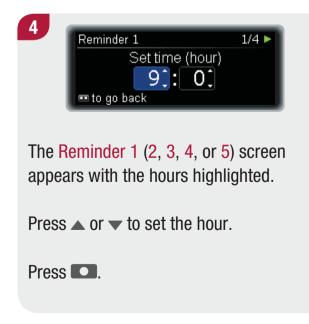
Deliver Bolus	Reminds you to deliver a bolus at a specified time. You can program up to 5 deliver bolus reminders.
Missed Bolus	This reminder occurs if no bolus was delivered within 2 hours prior to the programmed time. You can program up to 5 missed bolus reminders.
Alarm clock	Sounds at specified time. You can program up to 5 alarm clocks.
Infusion set change	Reminds you to change the infusion set after a specified number of days.

Set a Deliver Bolus reminder, Missed Bolus reminder or Alarm clock

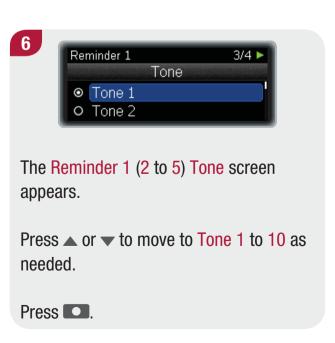


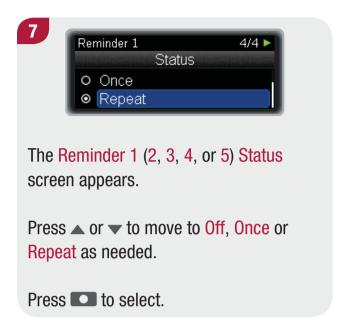










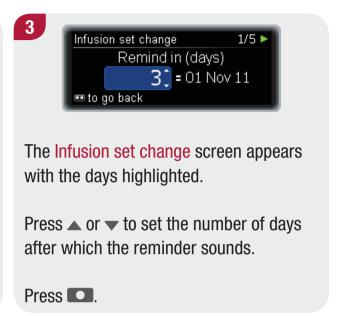




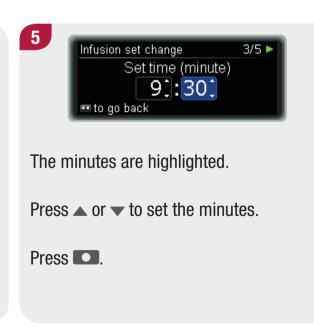
Set the Infusion set change reminder

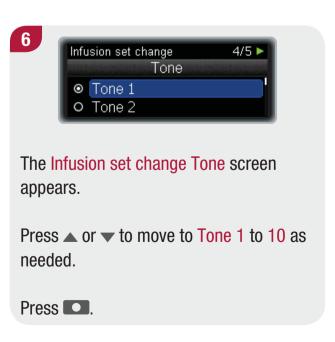


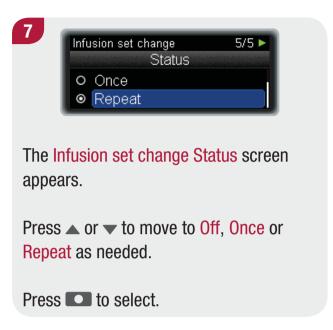












8.2 Communicating with other devices

Using *Bluetooth* wireless technology, your pump can exchange data and even commands with other Accu-Chek devices such as a blood glucose meter or a personal computer using Accu-Chek software. For a list of Accu-Chek devices that can communicate with your pump, contact your local pump support (see inside back cover) or see www.accu-chek.com.

Before your pump can communicate with another device it must be paired. That means the devices must be enabled to recognise each other with an individual code. When the pump is paired with another device they can exchange data using a stable and secure *Bluetooth* connection.

Your pump can be paired with up to 5 other devices in total. If you want to pair another device when 5 devices are already paired with your pump, you have to delete the pairing of one of the paired devices first.

In this chapter you will learn how to:

- Switch Bluetooth on and off
- Make your pump visible to other devices
- View the list of paired devices (Device list)
- Pair your pump with another device
- Remove a device from the list of paired devices (delete the pairing)

Note

Communication with another device is only possible when the display of the pump is off, the devices are paired and both devices have *Bluetooth* switched on.

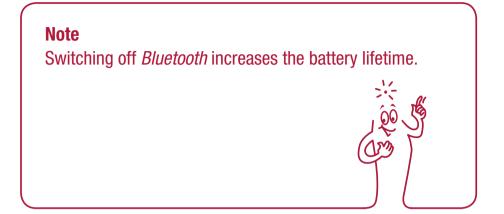


8.2.1 Switching *Bluetooth* on and off

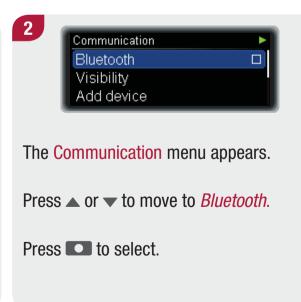
There are 2 ways to switch the *Bluetooth* function on and off:

- ► You can use Flight mode. When Flight mode is on, the Bluetooth function is switched off.
- ▶ You can switch *Bluetooth* on or off in the Communication menu.

When the *Bluetooth* function is turned off, the airplane icon appears on the Status screen.







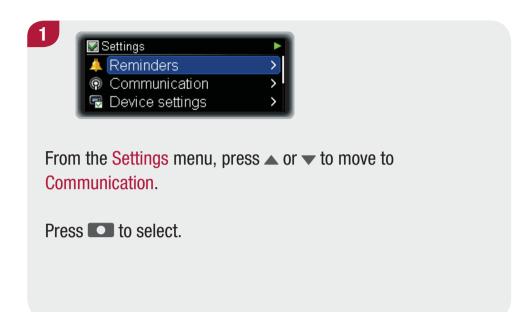


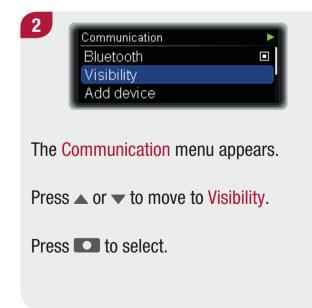
8.2.2 Making the pump visible to other devices

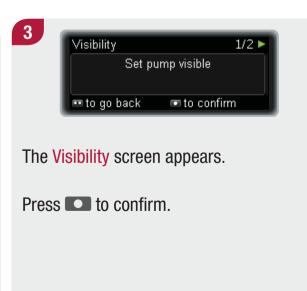
For communication with some devices, it is necessary to make the pump visible. That means the pump will send a signal that the other device can detect to notice the pump.

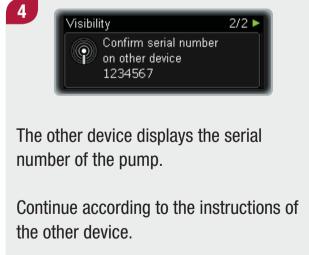
For further explanations and instructions also consult the documents accompanying the device the pump is supposed to communicate with.

Ensure that *Bluetooth* is switched on before switching Visibility on.



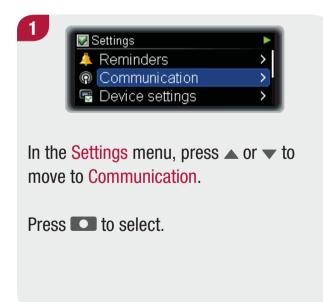




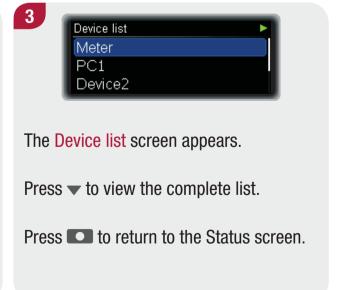


8.2.3 Viewing the list of paired devices

In this list you can view all devices currently paired with your pump. Your pump can be paired with up to 5 other devices in total.







8.2.4 Pairing the pump with other devices

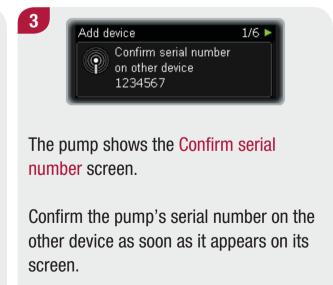
To pair your pump with another device, you must also know how to enable the communication on the other device. It is recommended that you have the user instructions of the other device available when starting the pairing procedure. Before you start the pairing procedure, make sure *Bluetooth* wireless communication is enabled on both devices.

Put the devices as close to each other as possible. It is recommended to do the pairing in a private environment where no other devices are sending *Bluetooth* or radio signals. Also, make sure that the batteries are charged.

Start the pairing function on the device you want to pair with the pump following its instructions for use or the instructions of the used PC-software.









While the other device sends a confirmation to the pump, the pump shows the Add device screen.

Please wait ...



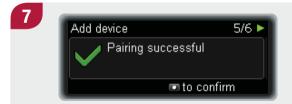
Both devices will then display a code.

If the codes on both devices are identical, press to confirm.



The pump shows the Add device screen while it continues the pairing.

Please wait ...



The pump shows the Pairing successful screen.

Press **t**o confirm.



Before the devices can start communicating the pump display has to be turned off.

Press **t** to confirm.

Note

If the pairing was not successful for any reason, the pump will show the Connection failed screen.



Try again, preferably in a less crowded environment and with new batteries.



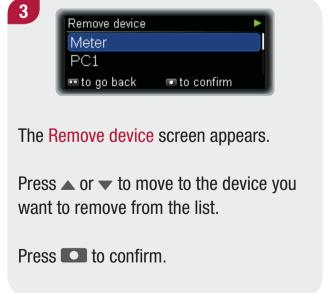
8.2.5 Removing a device from the list

If you remove a device from the list, the pairing between the pump and this device is deleted. The pump can no longer communicate with this device using *Bluetooth* wireless technology.

If you want the pump to be able to communicate with this device, you must re-do the pairing as described earlier in this chapter. See chapter 8.2.4, page 98.







8.3 Device settings

The Device settings offer a wide range of options to adapt your pump to your personal preferences to best match your day-to-day needs.

You can make adjustments for:

Mode settings	Personalise the settings for Normal, Quiet, Vibrate, and Loud.
User profile	Select Expressive if you have poor eyesight or Diminished if you have poor hearing.
Key lock	Protect your pump against accidental operation. Select the key lock timeout.
Language	Select your preferred language.
Display	Personalise the display design.

8.3.1 Personalising your Mode Settings

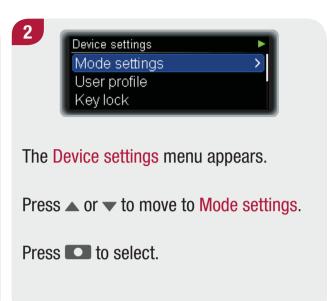
For all Signal modes you can adjust the sound volume and select whether you want your pump to sound, vibrate or both at the same time as an event (Warning, Reminder, Error, Maintenance) occurs.

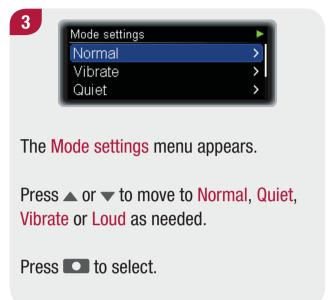
You can also suspend the signals of Warnings for a specified period of time.

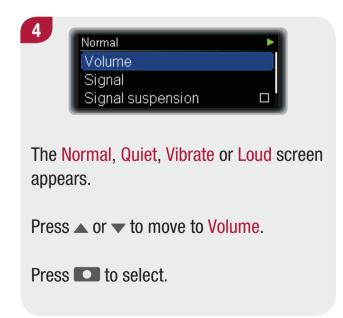
However, since Errors and Maintenances require your immediate attention, you cannot pause these event signals. Also, the Reminders you programmed will not be silenced.

Adjust the volume for a mode





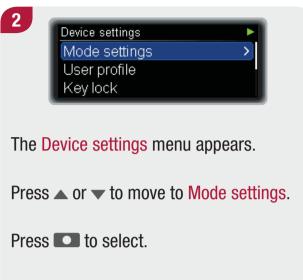


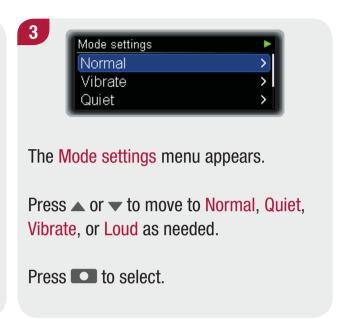


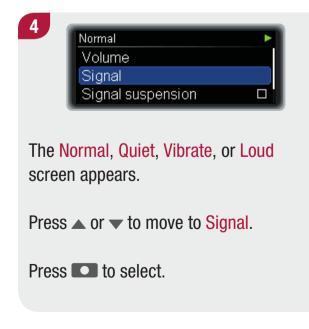


Select the Signal for Reminder, Warning, Maintenance, Error









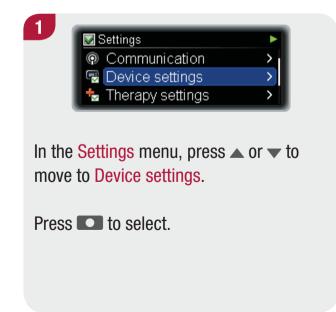


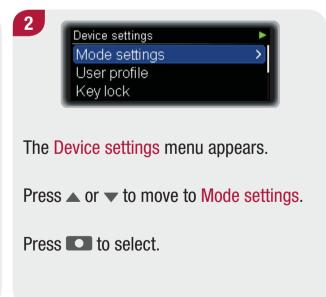
Set the Signal suspension

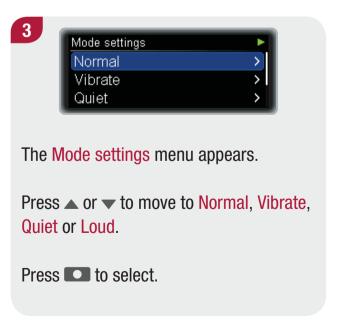
You can suspend the signals of Warnings for all modes for a specified period of time.

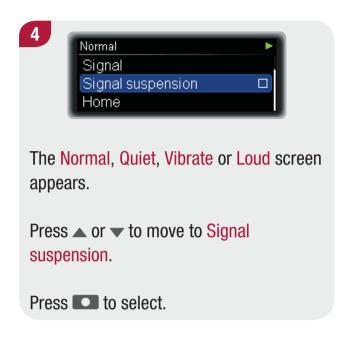
However, since Errors and Maintenances require your immediate attention, you cannot suspend these event signals.

Also, the Reminders you programmed will not be silenced.



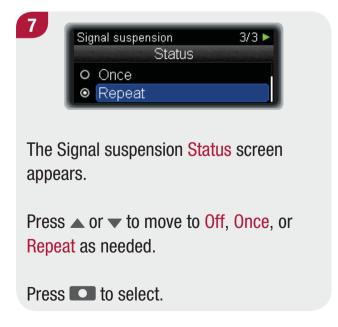












When set to Once, the signal will be paused only once. When set to Repeat the signal will be paused each day for the specified time.

When the suspension time has expired, the suspended warnings will occur.

8.3.2 Selecting the User profile

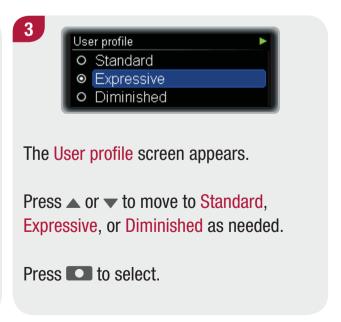
If you have problems with your vision you can choose the user profile Expressive. The scrolling functions of the pump are disabled in this profile so that all values can only be programmed with distinct increments. Additionally, sound patterns will help you to verify that you programmed a value correctly. For more information, please contact your local pump support (see inside back cover).

If you are acoustically impaired you can choose the user profile Diminished. All acoustic signals will then occur one octave lower.

Select the User profile







8.3.3 Adjusting the Key lock

With the Key lock function, the ♠, ♠ and ▶ keys of your pump will be disengaged automatically when you do not press any of thoose keys for a specified amount of time. This helps you to avoid accidental operation of your pump when a ♠, ♠ and ▶ key is pressed unintentionally (for example when the pump is under your clothing and an object in your pocket touches a key). In this section you will learn to set the time until the keys are locked. The count down of this timeout starts as soon as the pump has returned to the status screen.

Note



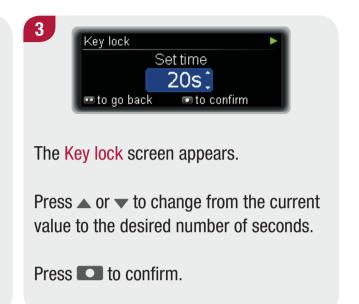
If you do not press ♠ or ▼ key for more than 30 seconds, these keys will be locked.

Press ▲ and then ▼, or ▼ and then ▲, to unlock the keys to continue the programming.

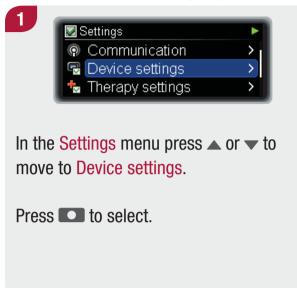
Adjust the Key lock



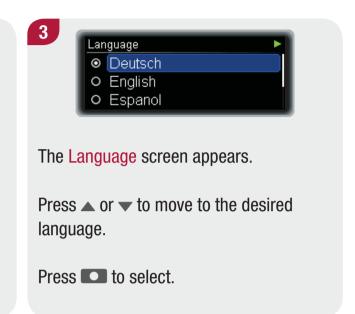




8.3.4 Select the Language



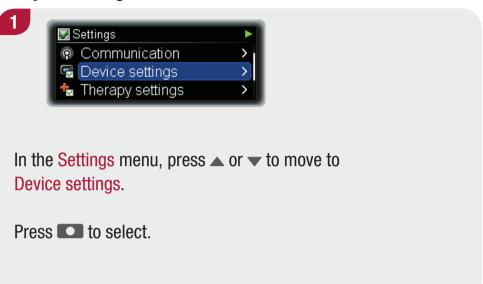


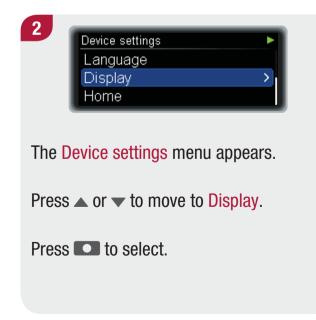


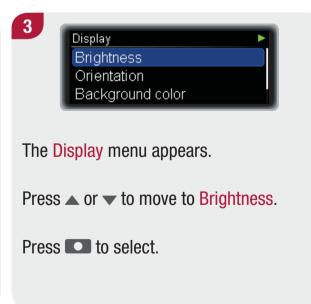
8.3.5 Adjusting the display

You can change the brightness, background colour, and orientation of your pump's display to your own preferences and to help you read the display under different conditions.

Adjust the brightness



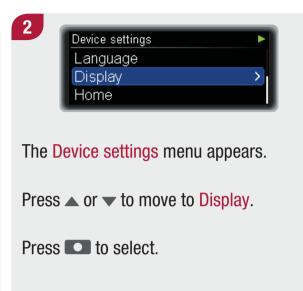






Change the Orientation





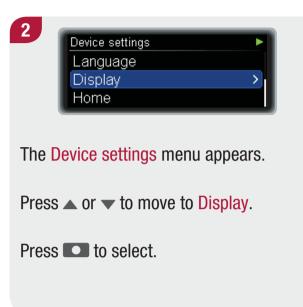




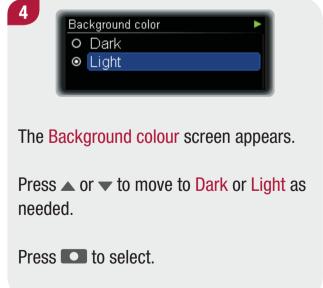
As long as the pump display is switched to Rotated, the functions of the ▲ and ▼ keys are also reversed.

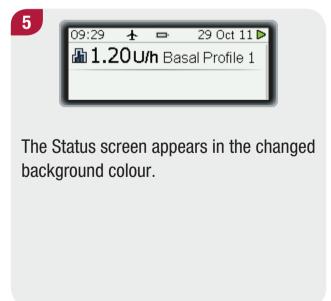
Change the Background colour











8.4 Therapy settings

With the Therapy settings, you can personalise your pump with regard to your insulin requirement.



WARNING

It is vital that you use the correct therapy settings. Otherwise, you might get a wrong amount of insulin with the risk of hypo- or hyperglycemia. The Therapy settings should be provided by your healthcare profrssionals and you should discuss with them before making any changes.

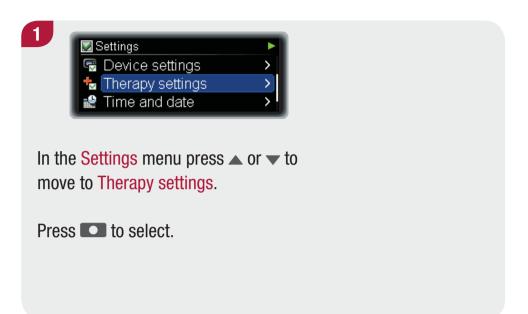
You can adjust the:

Automatic off	Set the time for the Maintenance M23: Automatic off.
Bolus settings	Set the increment for the Quick Bolus, the delivery speed, the maximum bolus amount, and the lag setting.
Infusion set settings	Set the filling amount for the infusion set tubing and cannula.
Cartridge warning level	Set the amount for the Warning W31: Cartridge low.

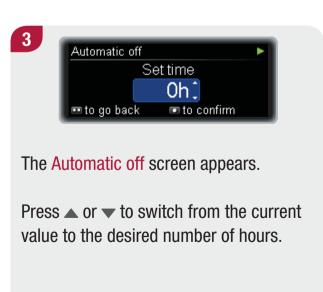
8.4.1 Adjusting the Automatic off function

The Automatic off function is a safety feature for emergency situations. It will trigger Maintenance M23: Automatic off and terminate the insulin flow if you did not touch any key of your pump or communicate with your pump using *Bluetooth* for the selected number of hours.

By default, Automatic off is set to 0 h which means it is switched off.





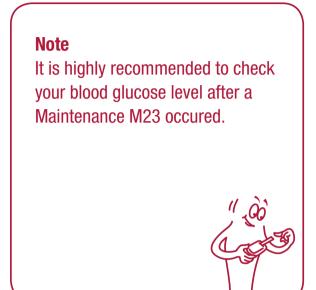




Respond to the Maintenance M23: Automatic off







8.4.2 Adjusting your Bolus settings

The Bolus settings help you to personalise your pump with regard to your bolus insulin requirement.

You can adjust:

- ▶ The Quick Bolus increment
- ▶ The Delivery speed
- ▶ The Maximum bolus amount
- ▶ The Lag setting

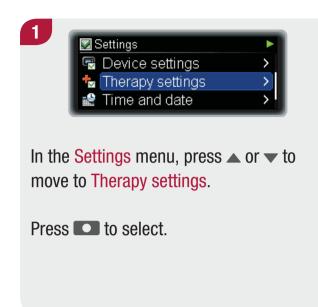
Adjust the Quick Bolus increment

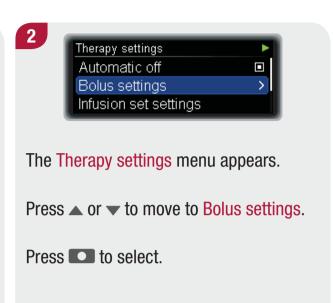


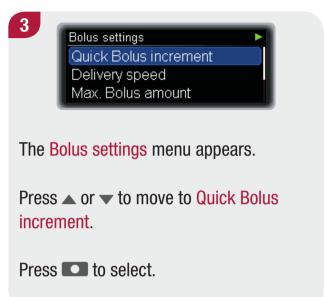
/!\ WARNING

It is vital that you use the correct Quick Bolus increment. Otherwise, you might get a wrong amount of insulin with the risk of hypo- or hyperglycemia.

The Quick Bolus increment is the number of insulin units programmed by each pressing of in the Quick Bolus function. You can set 0.1, 0.2, 0.5, 1.0, 2.0 or 5.0 units per key press. See chapter 4.2, page 55.







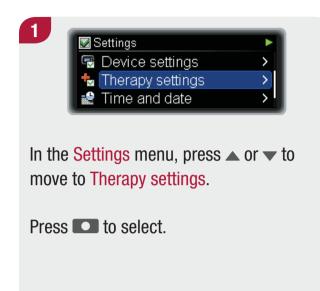


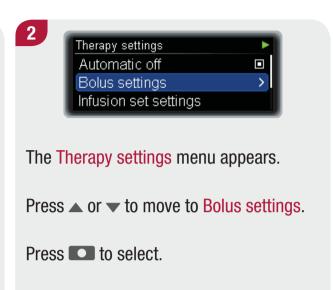
Adjust the Delivery speed

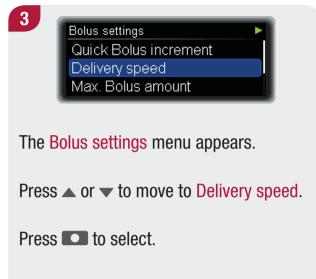
For more convenience during the insulin delivery, you can adjust the delivery speed. A standard Delivery speed makes the bolus delivery very fast. A low Delivery speed can be more convenient if you need high bolus amounts and/or you experience pain or insulin leaking from the infusion site during bolus delivery.

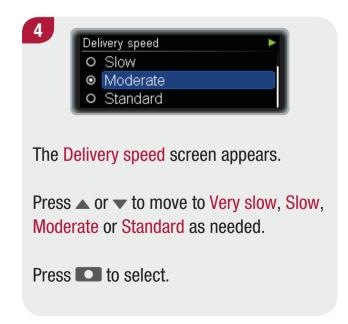
You can set the delivery speed to:

- Very slow (3 U/min)
- ► Slow (6 U/min)
- ► Moderate (9 U/min)
- ► Standard (12 U/min)



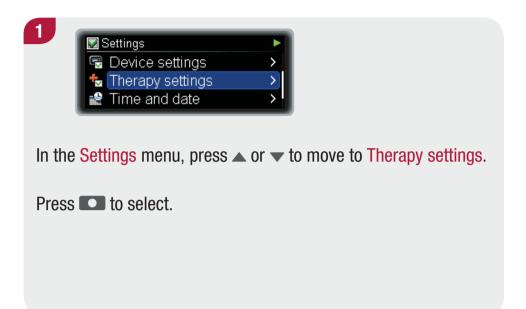


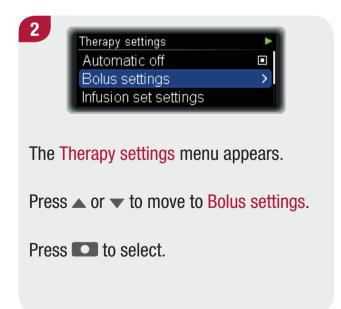


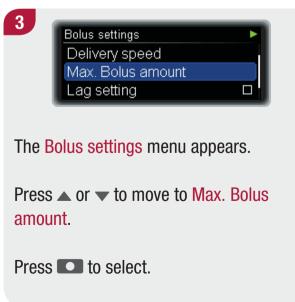


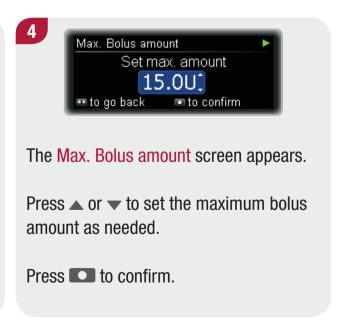
Adjust the Maximum Bolus amount

With the Max. Bolus amount function, you can limit the bolus amount that can be programmed. This helps to avoid accidental overdosing of insulin.



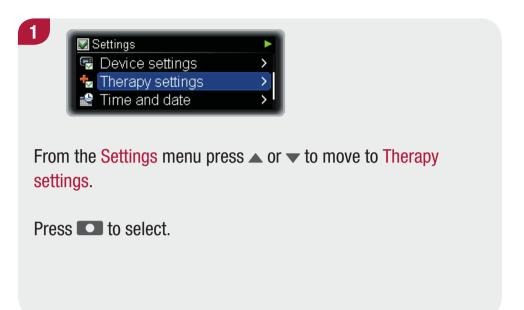


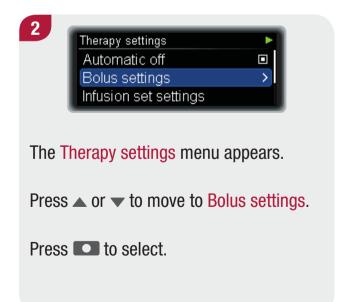


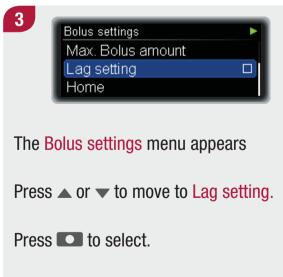


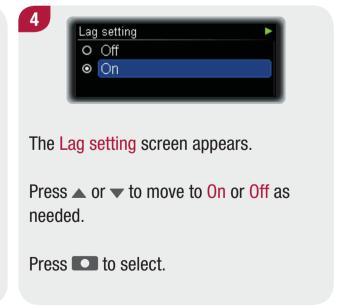
Adjust the Lag setting

If you have delayed digestion (gastroparesis) it may be helpful to start a bolus after you started eating. With the Lag setting you can specify a delay between programming a bolus and the actual beginning of the bolus delivery. Discuss using the Lag setting with your healthcare team.









Note

How to set the lag time

With Lag setting switched on, you can program a lag time each time you program a new bolus.

After programming the bolus amount (Standard bolus) or the delayed duration (Extended or Multiwave bolus) the Set lag time screen appears:



Press ▲ or ▼ to set the lag time.

Press **to confirm.**

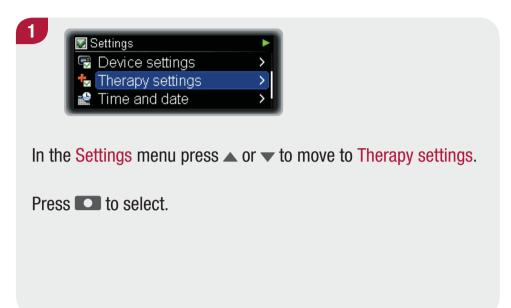
The bolus programming will then continue as usual.

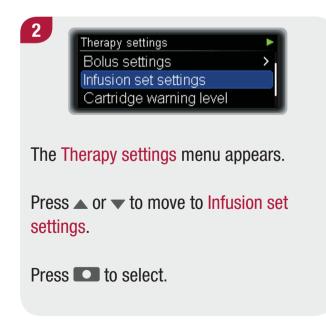
The bolus delivery will start after the lag time has exipred.

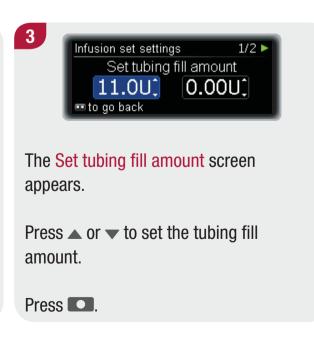
8.4.3 Adjusting the Infusion set settings

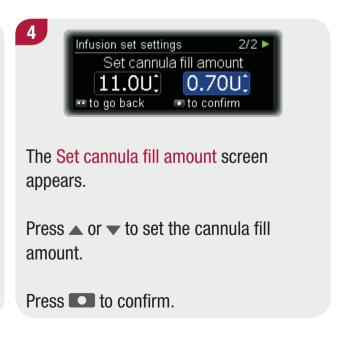
With the Infusion set settings you can adjust the fill amount of the tubing and the cannula of your infusion set.

For the correct fill amount for your infusion set refer to the infusion set's instructions.





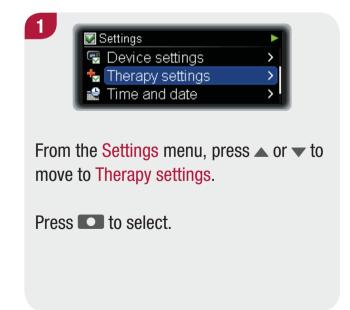




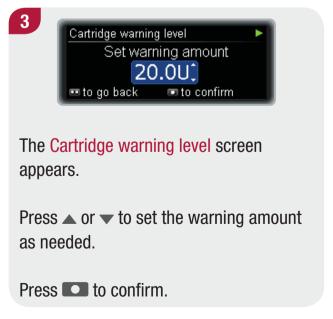
8.4.4 Adjusting the Cartridge warning level

When the insulin amount in your pump's cartridge is low your pump triggers a Warning W31: Cartridge low to remind you that you need to change the cartridge soon.

You can specify the number of insulin units remaining in your cartridge that will trigger the Warning.







8.5 Setting the time and date

/! WARNING

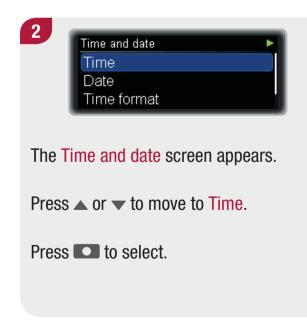
It is vital that you set the correct time and date on your pump. Otherwise, you might not get the correct amount of insulin at the correct time.

Set the time

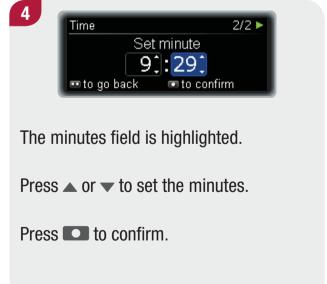


From the Settings menu, press ▲ or ▼ to move to Time and date.

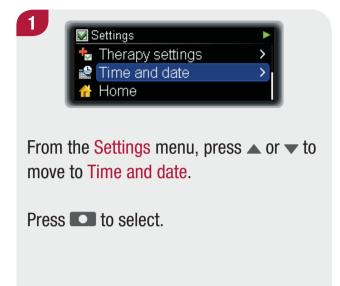
Press to select.

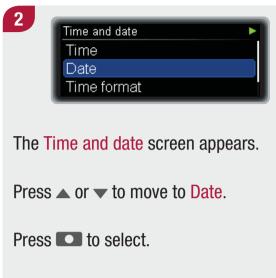






Set the date





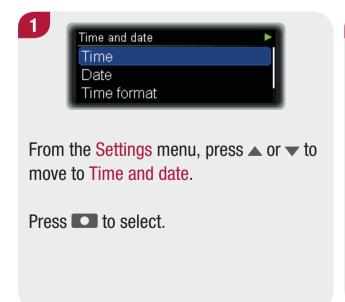


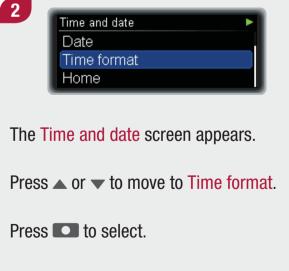


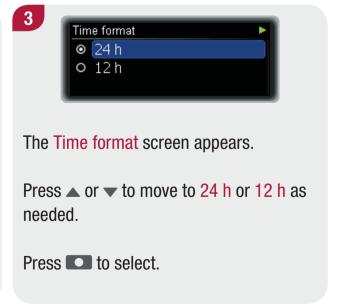


Adjust the Time format

You can choose whether your pump shows the 24-hour time format or 12-hour time format (including a.m. and p.m. tag).







9 Maintaining your pump

9.1 Inspecting your pump

Your pump must be properly maintained to guarantee accurate insulin delivery.

Check the pump and display regularly during the day and before you go to sleep, and especially if for any reason you might not be able to hear the beeps or feel the vibrations.

Accessories

Use only Accu-Chek insight sterile products and accessories designed to be used with your pump. You will find a list of sterile product and accessories in Appendix XYZ. Replace and discard these items according to your doctor's or healthcare team's recommendations, and follow the instructions that come with these items.

9.2 Damage to your pump

Dropping the pump could damage it and cause the waterproof seal to crack. Use the specially designed pump carrying system to help avoid dropping your pump. See the Accu-Chek sterile products and accessories catalogues and brochures for more information, or contact your local pump support (see inside back cover).

If you drop your pump:

- Check that all the connections in your infusion set are still tight, and if they are not, reconnect or tighten them
- Check your pump and its sterile products, and accessories for chips and cracks
- Change the cartridge if it is damaged

When you have completed these checks, take out and reinsert the battery so that the self-test is started.

9.3 Repair of your pump

Do not perform any service or repair on your pump. Do not use any lubricants on the pump mechanism. If you have questions, contact your local pump support (see inside back cover).

9.4 Maintaining your pump

9.4.1 Cleaning your pump

The best time to clean your pump is when you change the cartridge. Use a soft cloth to clean the outside of the pump. If necessary, use a clean cotton cloth dampened with water or a soap solution, ensuring that no water enters the pump. If this is not successful, contact your local pump support (see inside back cover) for more information.



WARNING

Always remove the cartridge and adapter and put your pump in STOP mode while cleaning. Avoid pressing the keys of your pump during cleaning, as this may accidentally change your settings. Do not use alcohol, solvents, strong detergents, bleaching agents, scouring pads or sharp instruments for cleaning, as they may damage the pump.

9.4.2 Batteries

It is important to change your battery regularly and to keep sufficient spare batteries available. The lifetime of any battery is affected by how you use your pump, your personal settings, delivery rates, temperature, and other factors. See Appendix A: Technical Data, page 151 for recommended batteries and their respective lifetimes. See chapter 2.1, page 14 for instructions on how to change the battery.

9.4.3 Battery cover

To ensure your pump remains watertight, replace the battery cover when it looks used or dirty and at least every 3 months.

9.5 Storing your pump



/! WARNING

If your pump will not be in use for a long period of time, it must be properly stored to prevent any subsequent malfunction.

To store your pump, place it in STOP mode, then:

- ▶ Remove the battery to preserve the battery life
- ► Remove the cartridge
- ▶ Insert the battery cover and the adapter
- Store your pump in its packaging

Storage conditions

Temperature	+5 to +45 °C (41 to 113 °F)
Air humidity	20 to 85 % relative humidity
Atmospheric pressure	70 kPa to 106 kPa (700 to 1060 mbar)

9.6 Disposing of your pump

Since your insulin pump may come into contact with blood during use, it can carry a risk of infection. As such it falls outside the scope of the European Directive 2002/96/EC and may not be disposed of with other electronic devices. If you need to dispose of your insulin pump, return it to Roche Diagnostics (address inside the back cover) for professional disposal.

Cartridge, infusion set, and accessories

For instructions on how to dispose of the cartridge, infusion set, and accessories, refer to the instructions that came with the according product.

Battery

Make sure that you dispose of dead batteries correctly and recycle them according to the local regulations.

10 Responding to a pump message

Your pump helps you in your diabetes management with a variety of messages and safety information. It is vital that you pay attention to these messages and take action as necessary.

Your pump provides these messages using beeps and vibrations. You can turn off either the beeps or the vibrations, but for your safety you cannot turn off both at the same time for the initial alarm signal.

Your pump can signal the following messages:

Reminders	You can program a variety of Reminders to assist you in remembering the tasks of your diabetes management. Reminders will not stop insulin delivery.
Warnings	A Warning will be triggered by the pump when it requires your attention soon. For example, when the cartridge is nearly empty, the Warning W31: Cartridge low will occur. Warnings will not stop insulin delivery.
Maintenances	A Maintenance will be triggered when the pump requires your immediate action to maintain its functionality. For example, when the cartridge is empty a Maintenance M21: Cartridge empty will sound. After a Maintenance occurs the pump will be in PAUSE or STOP mode. Restart insulin delivery as needed.

Errors

An Error message indicates that your pump is not working properly at the moment. After an Error the pump will be in STOP mode. You will learn about appropriate action in response to an Error later in this chapter.

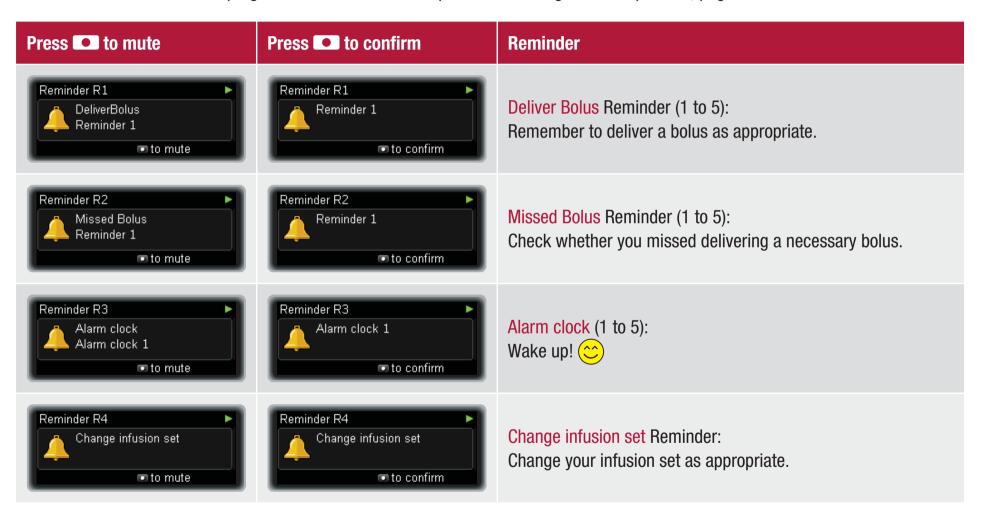
Respond to a Reminder, Warning, Maintenance or Error



If you do not confirm a message within 60 seconds, it will be repeated. Even when the sound is turned off or programmed at lower than maximum volume, the sound volume will rise to the loudest volume level if not confirmed. Both the sound and vibration will then continue at maximum level until confirmed.

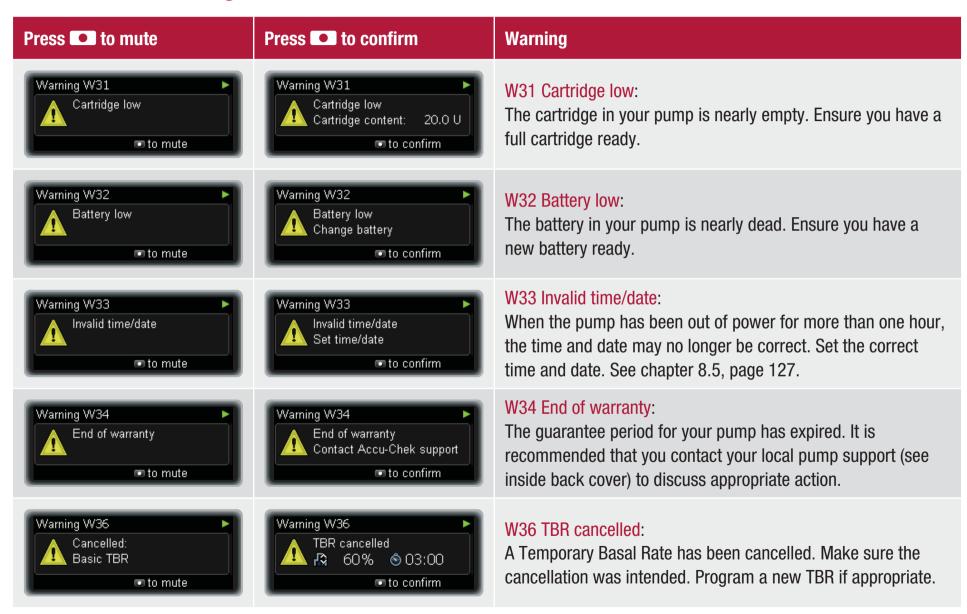
10.1 List of Reminders

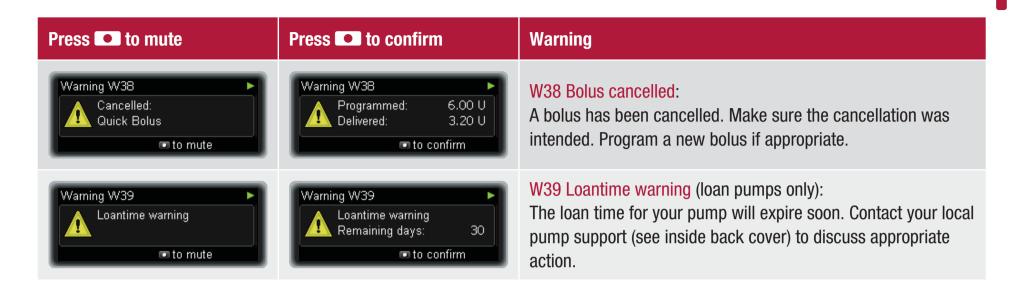
You can learn how to use and program Reminders in the chapter about Settings. See chapter 8.1, page 89.





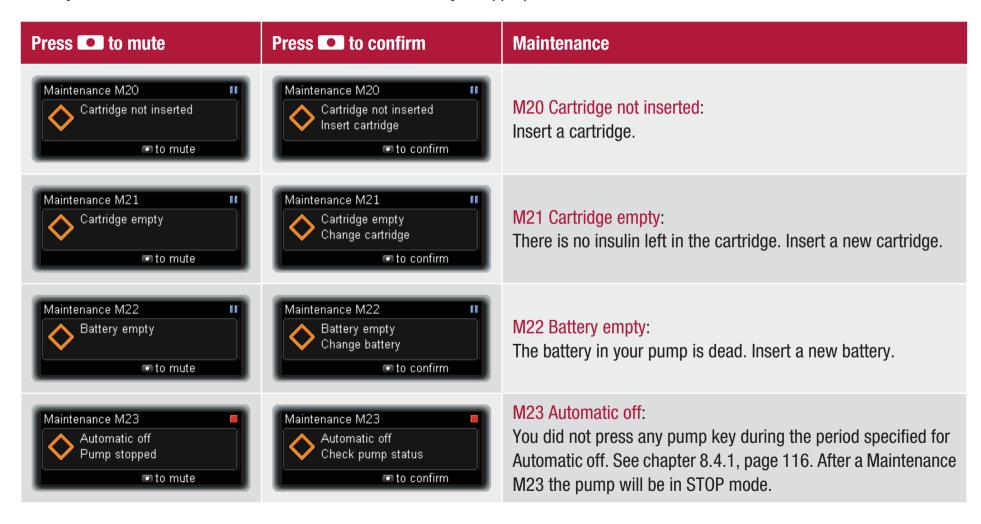
10.2 List of Warnings

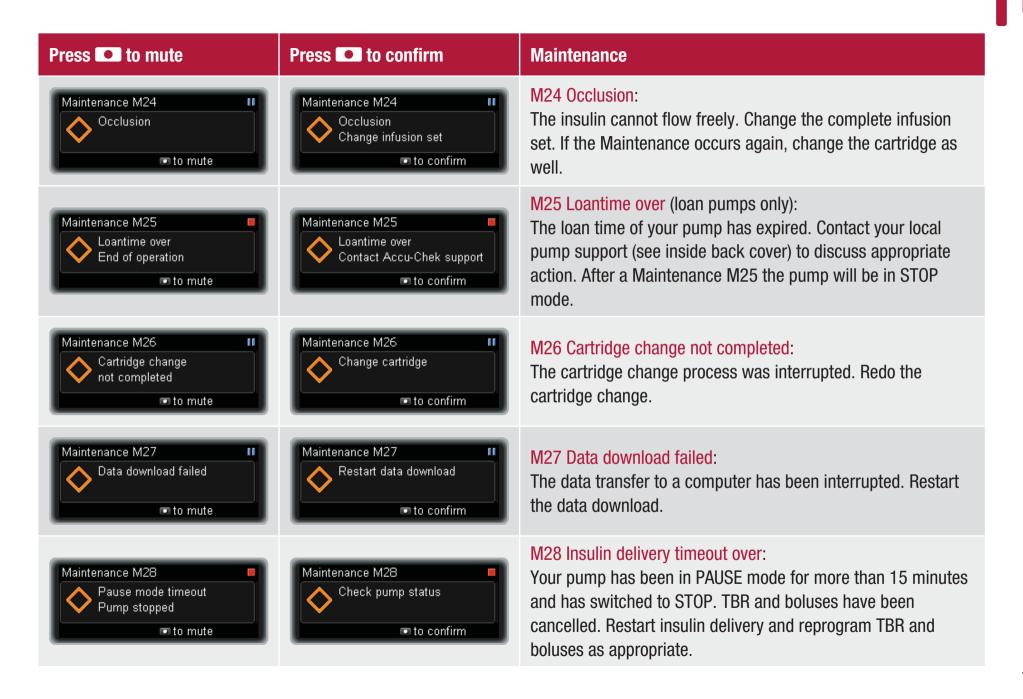


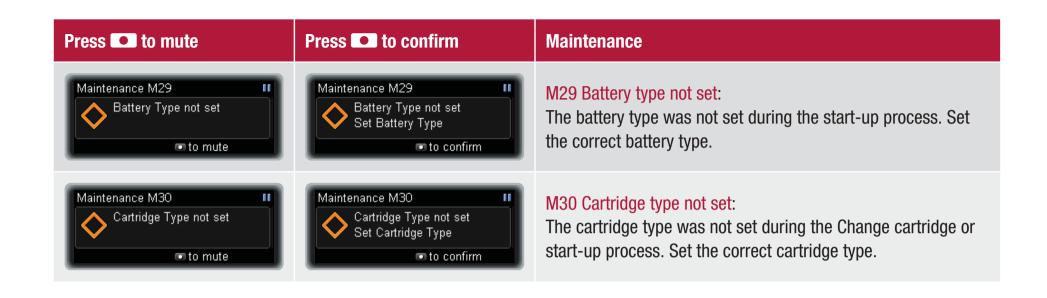


10.3 List of Maintenances

After a Maintenance has occurred, your pump will be in STOP or PAUSE mode and will switch to STOP if you do not restart the insulin delivery within the next 15 minutes. Restart the insulin delivery as appropriate.

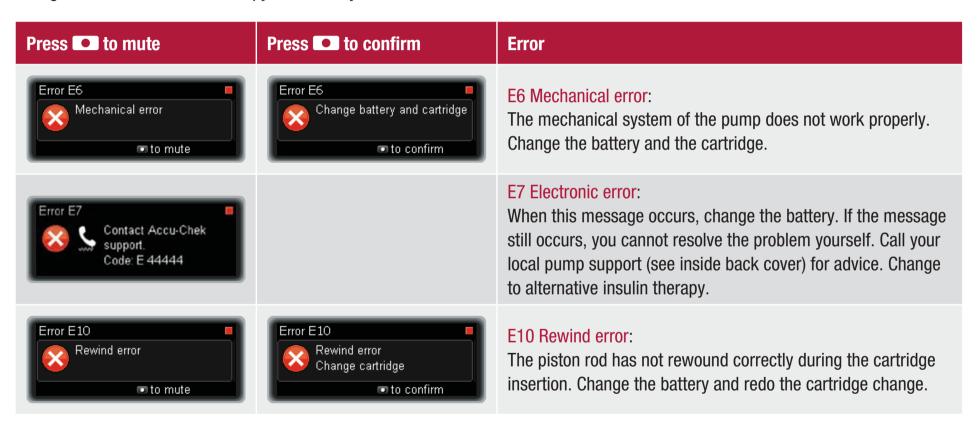


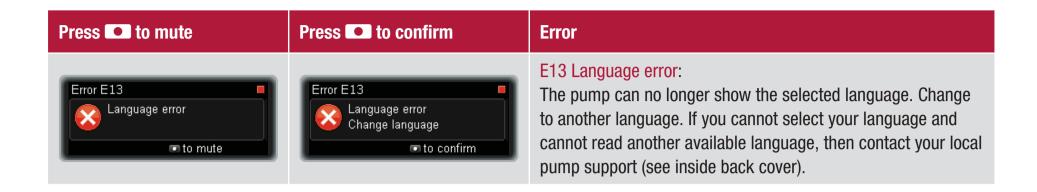




10.4 List of Errors

When an Error message occurs, the pump has detected a more severe problem and will be in STOP mode. If you cannot resolve the problem at the first attempt and the Error keeps recurring, contact your local pump support (see inside back cover) for advice and change to alternative insulin therapy if necessary.





Appendices

Appendix A: Technical Data

General Technical Data	
Maximum dimensions (with adapter)	Approx. $84 \times 52 \times 19$ mm (3.3 × 2.0 × 0.7 inches)
Weight	An empty insulin pump: approx. 99 g (3.5 ounces) Pump including cartrige, battery and infusion set: approx. 115 g
Pump casing	Shock- and scratch-resistant plastic, resistant to pharmaceuticals, all edges rounded
Temperature ranges*	During operation: $+5$ °C to $+37$ °C ($+41$ °F to $+99$ °F) During storage in its shipping case: $+5$ °C to $+45$ °C ($+41$ °F to $+113$ °F) During transport: -20 °C to 50 °C (-4 °F to $+122$ °F)
Air humidity	During operation: 20 % to 90 % relative humidity During storage in its shipping case: 20 % to 85 % relative humidity During transport: 5 % to 95 % relative humidity

^{*} See the instructions for use of the insulin you are using for information on the acceptable temperature range for storage and handling.

General Technical Data	
Barometric pressure	During operation: 55 to 106 kPa (550 to 1060 mbar) During storage in its shipping case: 70 to 106 kPa (700 to 1060 mbar) During transport 50 to 106 kPa (500 to 1060 mbar)
Power supply	One 1.5 V AAA Alkaline (LR03) or Lithium (FR03) battery. Batteries should have a minimum capacity of 1200 mAh. Do not use carbon zinc or rechargeable (NiCd/NiMH) batteries.
Lifetime of battery	If used in a typical usage pattern (50 U/day using U100 insulin; operating temperature 23 °C \pm 2 °C [73 °F \pm 4 °F]), the battery life is approximately: Alkaline (1200 mAh): 5 days for <i>Bluetooth</i> off Lithium (1200 mAh): 14 days for <i>Bluetooth</i> off
Data storage time	The time and date are safely stored in the memory for about 1 hour after the battery has been removed. Other insulin pump settings (the hourly basal rates, remaining cartridge content, bolus increments, and active user menu) and the event memory (bolus history, history of daily insulin totals, Temporary Basal Rate history, alarm history) are saved, regardless of battery power and the time your insulin pump has been without a battery.

General Technical Data	
Basal rate	Min. 0.02 U/h, max. 40 U/h.
Bolus	The max. bolus amount per delivery is 50 insulin units. The bolus amount for the Quick Bolus is adjustable in increments of 0.1, 0.2, 0.5, 1.0, 2.0 and 5.0 units. For the Standard Bolus, Extended Bolus, and Multiwave Bolus, the amount is adjustable in increments of 0.05 units. The duration of the Extended Bolus and the Multiwave Bolus is adjustable in intervals of 15 minutes up to 24 hours.
Temporary Basal Rate	Adjustable in 10% increments, $0-90\%$ for decreases, $110-250\%$ for increases. The duration is adjustable in 15 minute intervals, up to a maximum of 24 hours. The last programmed duration is given by default for the next Temporary Basal Rate change programmed.
Bolus delivery speed	very slow = 3 U/min, slow = 6 U/min, moderate = 9 U/min, standard = 12 U/min

General Technical Data			
Maximum time for an Maintenance M24: OCCLUSION**	Self-filled cartridges: • at medium basal rate 1.0 U/h: ≤2.5 h • at minimum basal rate 0.02 U/h: ≤125 h Pre-filled cartridges: • at medium basal rate 1.0 U/h: ≤5 h • at minimum basal rate 0.02 U/h: ≤257 h		
Maximum volume before Maintenance M24: OCCLUSION**	Self-filled cartridges: 2.5 U Pre-filled cartridges: 5 U		
Maximum pressure	400 kPa (4.0 bar)		
Flow (delivery rate)	Variable		
Maximum quantity delivered at a single fault condition	≤0.5 U		
Cartridge	Self-filled 2.0 ml Accu-Chek Insight insulin pump cartridge Pre-filled 1.6 ml NovoRapid® PumpCart™ (please check the availability in your country at www.novonordisk.com or ask your local pump support)		

General Technical Data	
Infusion sets	Accu-Chek Insight infusion sets with a proprietary connector.
Remote control and data transfer	Bluetooth wireless technology, ISM 2.4 GHz communication channel
Safety	The safety concept is based on a control system which consists of two microprocessors and a supervisor microprocessor (supervising system). The control system is based on a dual channel software architecture which performs all safety relevant functions two times. Whenever a defect or fault occurs in the control system, it is identified by the supervising microprocessor and vice versa. The motor is immediately switched off and an Error E7: Electronic error occurs. The control system and supervising system signalize the Error E7 acoustically (beeps) and tactile (vibrations). Additionally the control system shows the specific Error E7 number on the pump display. The motor also constitutes an important safety component, as the combination of the control and supervising processors and brushless motor provides the best possible reliability and accuracy in insulin delivery.
IPX8	Protected against the effects of temporary immersion in water under standardised conditions.

Technical standards

Table 201: Electromagnetic emission

Guidance and manufacturer's declaration – electromagnetic emissions

The Accu-Chek Insight insulin pump is intended for use in the electromagnetic environment specified below. The customer or the user of the Accu-Chek Insight insulin pump should ensure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 2	The Accu-Chek Insight insulin pump must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	The Accu-Chek Insight insulin pump is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	that supplies buildings used for domestic purposes.

Table 202: Electrostatic discharge (ESD) and power frequency magnetic fields (all devices)

Guidance and manufacturer's declaration – electromagnetic immunity

The Accu-Chek Insight insulin pump is intended for use in the electromagnetic environment specified below. The customer or the user of Accu-Chek Insight insulin pump should assure that it is used in such an environment.

Immunity test standard	IEC 60601 test level*	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient / burst IEC 61000-4-4	±2 kV for power supply lines	Not applicable	
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	Not applicable	
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	<5% UT (0,5 cycle) 40% UT (5 cycles) 70% UT (25 cycles) <5% UT for 5s	Not applicable	

Note: UT is the A.C. mains voltage prior to application of the test level.

Immunity test standard	IEC 60601 test level*	Compliance level Electromagnetic environment – guidance	
Power frequency (50 / 60 Hz) magnetic field IEC 61000-4-8	400 A/m	400 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 203: Immunity electromagnetic fields (life-supporting devices)

Guidance and manufacturer's declaration - electromagnetic immunity

The Accu-Chek Insight insulin pump is intended for use in the electromagnetic environment specified below. The customer or the user of the Accu-Chek Insight insulin pump should assure that it is used in such an environment.

Electromagnetic environment – guidance

Portable and mobile RF communications equipment should be used no closer to any part of the Accu-Chek Insight insulin pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Immunity test standard	IEC 60601 test level	Compliance level	Recommended separation distance c)	
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	V1 = 10 Vrms 150 kHz to 80 MHz	$d = 1.2\sqrt{P}$	150 kHz to 80 MHz
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 800 MHz	E1 = 10 V/m 80 MHz to 800 MHz	$d = 1.2\sqrt{P}$	80 MHz to 800 MHz
Radiated RF IEC 61000-4-3	10 V/m 800 MHz to 2,5 GHz	d)E2a = 2 V/m for 2.3 GHz to 2.5 GHz e)E2b = 10 V/m for 800 MHz to 2.3 GHz and 2.5 to 2.7	$da = 11.7\sqrt{P}$ $db = 2.3\sqrt{P}$	2.3 GHz to 2.5 GHz 800 MHz to 2.3 GHz and 2.5 GHz to 2.7 GHz

Guidance and manufacturer's declaration - electromagnetic immunity

Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).

Field strengths from fixed RF transmitters as determined by an electromagnetic site survey, a) should be less than the compliance level in each frequency range. b) $((\bullet))$

Interference may occur in the vicinity of equipment marked with the following symbol:

Note: At 80 MHz and 800 MHz, the higher frequency range applies.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- a) Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Accu-Chek Insight insulin pump is used exceeds the applicable RF compliance level above, the Accu-Chek Insight insulin pump or the device, which contains it should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device containing the Accu-Chek Insight insulin pump.
- b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.
- c) Possible shorter distances outside ISM bands are not considered to have a better applicability of this table.
- d) Exclusion band for Bluetooth ISM 2.4 GHz communication channel
- e) Compliance band for the system equipment

Table 205: Recommended separation distances (life-supporting devices)

Recommended separation distances between portable and mobile RF communications equipment and the Accu-Chek Insight insulin pump.

The Accu-Chek Insight insulin pump is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Accu-Chek Insight insulin pump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Accu-Chek Insight insulin pump as recommended below, according to the maximum output power of the communication equipment.

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter (m)			
(W)	150 kHz to 80 MHz d = $1.2 \sqrt{P}$	80 MHz to 800 MHz d = $1.2 \sqrt{P}$	800 MHz to 2.3 GHz db = $2.3 \sqrt{P}$	2.3 GHz to 2.5 GHz da = $11.7 \sqrt{P}$
0.01	12 cm	12 cm	23 cm	118 cm
0.1	38 cm	38 cm	73 cm	373 cm
1	1.2 m	1.2 m	2.3 m	11.8 m
10	3.8 m	3.8 m	7.3 m	37.3 m
100	12 m	12 m	23 m	118 m

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

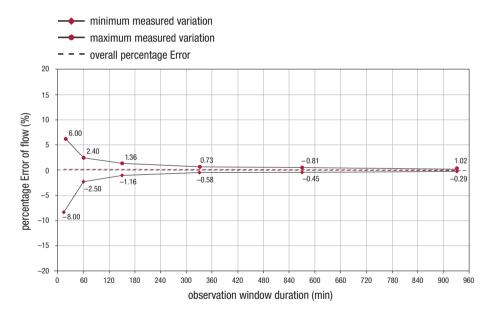
Note: An additional factor of 10/3 is used in calculating the recommended separation distance to decrease the likelihood that mobile / portable communications equipment could cause interference if it is inadvertenly brought into the vicinity of the user.

Accuracy of flow rate for both Accu-Chek Insight insulin pump cartridge and NovoRapid[®] PumpCart™

The maximum deviation of the delivered amount (overall mean percentage flow Error) for U100 insulin is $\leq \pm 5 \%^*$.

Trumpet curve plotted from data after the end of the stabilization period

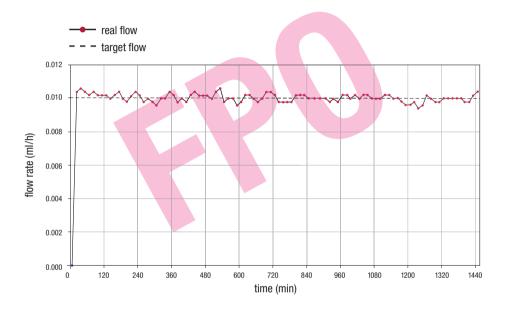
The trumpet curve shows the accuracy of the delivery rate in relation to the observation period.



^{*} The measurements were made at a medium basal rate of 1.0 U/h according to IEC 60601-2-24:1998 with an Accu-Chek Adapter and Tubing transfer set 100 cm at room temperature.

Start-up graph over the stabilization period

The start-up graph shows changes in the flow rate over the stabilization time.



Influence of height on delivery accuracy

The maximum deviation of the delivered amount (overall mean percentage flow Error) for U100 insulin is $\leq \pm 10\%^*$ where your Accu-Chek Insight insulin pump is located ≤ 1 m (3.3 feet) above/below the infusion site.

Bolus

For U100 insulin the maximum deviation of a maximum bolus is $\leq \pm 5\%$ and the maximum deviation of a minimum bolus is $\leq \pm 30\%$.**

^{*} The measurements were made at a medium basal rate of 1.0 U/h according to IEC 60601-2-24:1998 with an Accu-Chek Adapter and Tubing transfer set 100 cm at room temperature.

^{**} The measurements were made according to IEC 60601-2-24:1998 with a Accu-Chek Adapter and Tubing transfer set 100 cm at room temperature.

Appendix B: Configuration parameters

Parameter	Standard parameter settings	Typical range available on the pump
Hourly basal rate + max. TBR (hourly basal rate combined with temporary basal rate, max. increase)	62.5 U/h	max. amount: 0-100 U/h
Hourly basal rates increment	0.01 (from 0.02U/h to 5.00 U/h) and 0.1 (from 5.00 U/h up to 40.0 U/h)	
Max. Hourly basal rates	0.02-25.0 U/h	0.02-40.0 U/h
Temporary Basal Rate TBR increases or decreases in increments of TBR duration TBR duration increments	100 % 10 % 2 h 15 min	0–250 % 10 % 15 min–24 h 15 min
Basal profiles available	5	5
Bolus amount per bolus delivery	25.0 U	0–50.0 U
Bolus amount increments for Quick Bolus	0.5 U	0.1, 0.2, 0.5, 1.0, 2.0, 5.0 U
Bolus amount increments for Standard Bolus, Extended Bolus and Multiwave Bolus	0.05 U (-2.0 U) 0.1 U (2-5 U) 0.2 U (5-10 U) 0.5 U (10-20 U) 1.0 U (20-50 U)	
Bolus duration (Extended Bolus, Multiwave Bolus)	2 h	15 min to max. 24 h

Parameter	Standard parameter settings	Typical range available on the pump
Bolus duration increments	15 min	
Bolus delivery speed	Standard: 12 U/min	Standard: 12 U/min Moderate: 9 U/min Slow: 6 U/min Very slow: 3 U/min
Lag time	Off	Off or On If On: 15 to 60 min in 15 min increments
Infusion set fill amount	11.0 U	0-50.0 U
Cannula fill amount	0.7 U	0.0-5.0 U
Display orientation	Standard	Standard or rotated
Display brightness	2	1–5 Steps
Display timeout	30 sec. (15 sec. dark timeout + 15 sec. off timeout)	
Display Background colour	Dark	Dark or light
Display format	Normal	Normal or zoom
Volumes (for beeps)	3	1–5 (0 = quiet)
Signal	Accoustic and tactile	Accoustic, tactile or accoustic and tactile

Parameter	Standard parameter settings	Typical range available on the pump
Modes	Normal: Volume 3 / sound & vibration	Normal: Volume 3 / sound & vibration
		Vibrate: Volume 0 / vibration
		Quiet: Volume 1 / vibration
		Loud: Volume 4 / sound & vibration
Battery type	AAA (LR03) ALKALINE 1.5V, AAA (FR03) LITHIUM 1.5V	
Key lock timeout	30 sec.	4 – 60 sec.
Automatic off	off	on (1 – 24 h) or off (0 h)
Reminder	off	Deliver Bolus, Missed Bolus, Alarm Clock, Infusion set change on or off When on: once or repeatedly
Time format	24 h	24 h or 12 h am / pm

Parameter	Standard parameter settings	Typical range available on the pump
Bluetooth	off (if delivered with an other Bluetooth enabled device the standard parameter is on)	off or on
Cartridge Warning level	25 U	0–100 U
User Profile	Standard	Standard, Expressiv, Diminished

Appendix C: Abbreviations

Abbreviation	Meaning
approx.	Approximately
h	Hour(s)
IEC	International Electrotechnical Commission
I.U., U	International Units in context with biological effectiveness of certain insulin amount
kPa	Kilopascal
sec.	Seconds
TBR	Temporary Basal Rate
U	See I.U.
U/h	Amount of International Units of insulin delivered per hour
U100	Insulin concentration. Each millilitre of liquid contains 100 International Units of insulin
dd.mmm.yy	Date format
hh:mm	hours and minutes

Appendix D: Icons and Symbols

Display Icons

Icon	Meaning
	Pump running (RUN Mode)
	Pump stopped
	PAUSE mode
	Check mark
×	Connection failed
	Battery full
	Battery low
	Battery empty

Icon	Meaning
	Cartridge full
	Cartridge low
<u>_</u>	Cartridge empty
	Key lock activated
	OK Key
	Quick Bolus Key
	Up Key
	Down Key

lcon	Meaning
	Cartridge and infusion set menu
	Change cartridge menu
3	Fill cannula menu
W	Fill tubing menu
R	Bolus
	Bolus data
	Cancel Bolus
	Standard Bolus
П	Extended Bolus
B	Multiwave Bolus

Icon	Meaning
	Immediate amount Multiwave Bolus
門	Delayed amount Multiwave Bolus
	Basal Rate
	Activate Basal Profile
	Temporary Basal Rate
	TBR Data
	Program Basal Profile
	Modes
F	Signal mode
	Reminder

Icon	Meaning	Icon	Meaning
	Event data	Σ	Total icon
	Settings		Daily totals
	Therapy settings		Time and date settings
	Device settings	\mathbb{V}	Software version
	Pump data		Maintenance
	Pump timer		Warning
	Flight mode	8	Bluetooth wireless technology
	Home		Error
	Duration		Error Contact
\blacksquare	Please wait/Lag time		Communication

Icon	Meaning
0	Radio button selected
	Radio button not selected
	lcon on
	Icon off

General Symbols

Symbol	Meaning
\triangle	Caution, refer to safety-related notes in the manual accompanying this device
$\widehat{\mathbf{u}}$	Consult instructions for use
STERILE EO	Sterilized using ethylene oxide
STERILE R	Sterilized using irradiation
STERILE A	Sterile using aseptic processing techniques
LOT	Batch code
REF	Catalogue number
SN	Serial number
	Use by

Symbol	Meaning
***	Manufacturer
	Admissible temperature range during operation
	Temperature limitation
	Admissible humidity range
kPa •••	Admissible air pressure range
PYROGEN	Does not contain pyrogen
2	Use only once
	Do not use if package is damaged
Ţ	Fragile – handle with care

Symbol	Meaning
	Keep dry
类	Keep away from sunlight
	Recycling
X	Do not throw away
	Flammable
*	Bluetooth® wireless technology
$\Big(\big((\bullet) \big) \Big)$	Non-ionizing radiation
*	Electronic device of type BF according the standard IEC 60601-1. Protection against electrical shock.
IPX8	Symbol for protection against the effect of temporary immersion of water (up to 60 minutes and 2.5 meters [8 feet]), according to IEC 60529.

Symbol	Meaning	
C € 0088	Marking of conformity according to the European Medical Device Directive MDD 93/42/EEC with the number of the notified body. Includes also RTTE DIRECTIVE 1999/5/EC.	
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.	
[LR03 (AAA)+]]	Recommended battery	
Rx only	Federal law (USA) restricts this device to sale by or on the order of a physician.	

Symbol	Meaning
C xxxxx	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.
MR CT US X-Ray	Warning against device use in electro- magnetic or high electrical field or environments

Appendix E: Warranty

Any changes or modification to the devices not expressly approved by Roche Diagnostics could void your operating warranty for the Accu-Chek Insight insulin pump.

Appendix F: List of Accessories

Cartridge

Accu-Chek Insight insulin pump

cartridge

Accu-Chek Insight insulin pump

cartridge filling system

Battery cover

Accu-Chek Insight insulin pump battery

cover

Carrying system

A wide variety of carrying systems made of different materials has been specially designed to suit your individual needs while wearing your insulin pump.

Infusion Set

Accu-Chek Insight Flex infusion set

\triangle

WARNING

Do not use infusion sets or other accessories not branded Accu-Chek as this could lead to leakage or malfunction of the pump and under or over delivery of insulin.

Note

For additional Accu-Chek products and accessoeries available in your country, ask your local pump support.



Glossary

Automatic off

Automatic off is a safety feature that stops insulin delivery and triggers a Maintenance if no keys are pressed within a programmed time period in RUN mode. See chapter 8.4.1, page 116.

Basal rate

This is the amount of insulin delivered per hour that is required to cover your basal, meal-independent insulin needs. In insulin pump therapy, your basal rate is determined together with your doctor or healthcare team and can be adjusted to meet your individual physiological needs throughout the day. Your basal rate is delivered by your insulin pump according to the curve of your personal Basal profile or profiles.

Basal profile

Your Accu-Chek Insight insulin pump offers you the option of delivering up to 5 different Basal profiles in order to easily meet your changing insulin needs (for example during the week rather than at the weekend). A Basal profile consists of 1 up to 24 hourly basal rates.

Basal profile total

The sum of all 24 hourly basal rates in one Basal profile is called the (daily) Basal profile total.

Bluetooth wireless technology

The term *Bluetooth* refers to a wireless technology that allows digital devices to transfer data at high speed. This technology is common in many portable devices such as portable PCs, Personal Digital Assistants, and mobile phones.

Bolus	The amount of insulin delivered (in addition to the basal rate) to cover the intake of food and to correct high blood glucose levels. The bolus amount is	Cartridge compartment	The chamber in your insulin pump for the cartridge.
	determined by your doctor or healthcare team's guidelines, your blood glucose level, your food intake and your activity level.	Daily insulin total	The total amount of insulin (basal rate plus boluses) delivered in a 24-hour day beginning at midnight. This amount does not include any insulin needed for the filling of infusion sets.
Delivery speed	This is the delivery speed of a Bolus. It can be adjusted to 3, 6, 9 or 12 U/min.	Error	An Error message indicates that your pump is not working properly at the moment. After an Error the pump will be
Carrying system Cartridge	A wide variety of carrying systems made of different materials has been specially designed to suit your individual needs while wearing your insulin pump. The insulin reservoir of your insulin pump.	in STOP mode.	
		Flight mode	Activate the Flight mode when airborne or in other situations where it is required to switch off the <i>Bluetooth</i>
			communication. In Flight mode your pump cannot communicate with any other device.

Hourly basal rate	An hourly basal rate is the amount of insulin delivered by your Accu-Chek Insight insulin pump for each hour.	Insulin analogue (rapid-acting)	A type of insulin created using recombinant DNA technology. The onset time of insulin analogue is shorter than the onset time of regular insulin.
Infusion set	Infusion sets connect your insulin pump to your body. The insulin is delivered from the cartridge through the infusion set tubing and cannula or needle into your subcutaneous tissue. Infusion sets can be disconnected.	Insulin, regular (short-acting)	Insulin that has the same chemical structure as insulin produced by the human pancreas. The onset time of regular insulin is 30 to 45 minutes.
Infusion site	The place where the infusion set cannula or needle is inserted into your subcutaneous tissue to deliver insulin.	IPX8 according to IEC 60529	Protection against the effects of temporary immersion in water. Ingress of water in quantities causing damage is not possible when the device is temporarily immersed in water under standardised conditions (maximum
Insulin	A hormone that helps cells transform glucose into energy. Insulin is produced in the beta cells of the pancreas (also called islets of Langerhans).		60 minutes a day and 2.5 meters [8 feet]).

Maintenance

A Maintenance will be triggered when the pump requires your immediate action to maintain its functionality. After a Maintenance the pump will be in PAUSE or STOP mode. Restart insulin delivery as needed.

Modes

With Modes, you can pre-define the way your pump signals messages in different life situations. By default you can adjust the modes for Normal, Vibrate, Quiet and Loud.

Occlusion

An occlusion is a blockage which prevents the insulin from flowing correctly from the insulin pump into the body.

PAUSE

When you open the adapter and after some Maintenances, your pump switches to PAUSE mode and interrupts the insulin delivery. However, if you close the adapter within 15 seconds, the insulin delivery will restart after confirmation, and the missing amount of basal insulin will be delivered additionally as well as boluses, and TBRs will continue. If the pump is in PAUSE mode for more than 15 minutes, it will switch to STOP mode.

Personal settings

Your insulin pump must be programmed with your personal settings prior to starting insulin pump therapy. Personal settings include the Basal profile(s), the correct time and date, and all other variable values that can be tailored to your individual needs on your insulin pump.

Pump stopped screen	The Pump stopped screen is displayed while your pump is in STOP mode.	RUN	During normal use, your insulin pump is in RUN mode and insulin is continuously delivered.
Quick Info	Set of screens that inform you about the status of your pump and recent therapy events.	Scrolling	Scrolling allows fast and easy programming of a range of values.
Rapid-acting insulin analogue	See Insulin analogue (rapid-acting).	Settings	Settings are individually programmable values and parameters that affect the way your insulin pump works.
Regular insulin (short-acting)	See Insulin, regular (short-acting).		
Reminder	You can program a variety of Reminders to assist you in remembering the tasks of your diabetes management. A Reminder will not stop insulin delivery.		

Status screen

The Status screen indicates if your pump is in RUN, PAUSE or STOP mode. You can program Boluses, Temporary Basel Rates and other functions from the Status screen. Your insulin pump displays the Status screen when no programming is being performed and no messages (error, maintenance, warning or reminder) are present. The time, current hourly basal rate, selected Basal profile, and some currently activated functions appear on the screen. Additionally, a progress bar indicates when a Bolus or TBR is currently running.

STOP

When your insulin pump is in STOP mode, it does not deliver any insulin. The insulin delivery is only stopped if an Error or some Maintenances occurs, if it is in PAUSE mode for more than 15 minutes or if you switch it to STOP mode. Functions such as Bolus or Temporary Basal Rate are interrupted by putting your insulin pump into STOP mode.

Temporary Basal Rate

Temporary increase or decrease of your Basal profile in percentages (from 0–250%) to match changing insulin needs due to increased or decreased activity level, illness or stress.

U100

This is the insulin concentration. Each millilitre of liquid contains 100 International Units of insulin. Your insulin pump has been developed exclusively for delivery of U100 short-acting regular human insulin or rapid-acting insulin analogue.

Warning

A Warning will be triggered by the pump when it requires your attention soon.

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Bluetooth® registration

Please note that in Italy and France *Bluetooth*® wireless technology is for indoor use only.

((0123

FCC ID VWI1239 IC ID 3100B1239

This Class B digital apparatus complies with Canadian ICES-003. Cet appareil numérique de la classe B est conforme à la norme NMB-003 du Canada.

This device complies with part 15 of the FCC Rules. Operation is subject to the following 2 conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures: Reorient or relocate the receiving antenna. Increase the separation between the equipment and receiver. Connect the equipment into an outlet on a circuit different from that to which the receiver is connected. Consult the dealer or an experienced radio/TV technician for help. Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

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.

