ACCU-CHEK® Insight

Roche

User's Manual

Accu-Chek Insight insulin pump

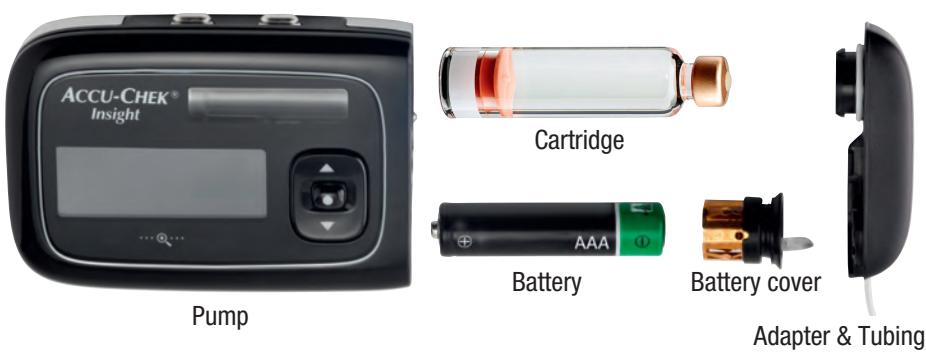
ACCU-CHEK®

Your Insulin Pump

Note

If you are in the status screen and you do not press the OK, ▲ or ▼ key for more than 10 seconds, these keys will be locked. The key lock does not lock the quick bolus keys. See chapter 8.3.3, page 72.

Pump Details and Accessories



Connected Insulin Pump

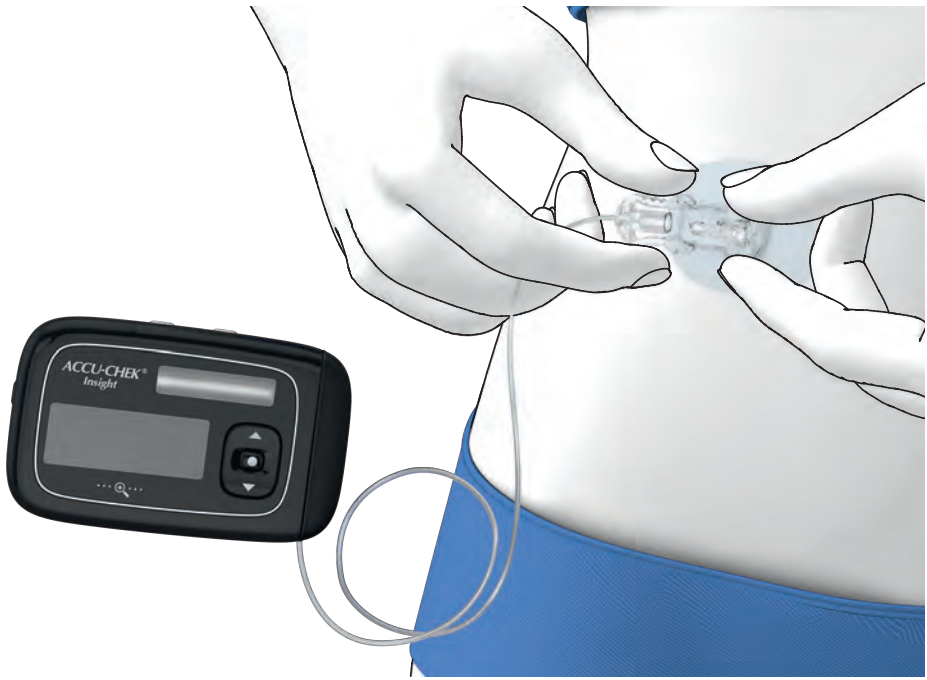


Table of Contents

Dear User of the Accu-Chek Insight insulin pump,

This User's Manual is provided for you as a person with diabetes, as a parent or caregiver of a person with diabetes or as a healthcare professional. 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, 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 using 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 page). Make sure that you carry out the instructions in this manual exactly as described. Failure to do so could lead to underdelivery or overdelivery of insulin and may result in death or serious consequences for your health. The Accu-Chek® Insight insulin pump is intended for continuous insulin infusion with short-acting regular human U100 insulin, or rapid-acting U100 insulin analogs in the treatment of diabetes mellitus requiring insulin.

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.

The exact insulin type for the treatment of your diabetes will be prescribed by your healthcare professional.

Your insulin pump is contraindicated for the delivery of medication other than U100 short-acting regular human insulin or rapid-acting insulin analogue.

Also consult the instructions that come with your insulin and infusion set.

⚠ WARNING

Do **not** modify the Accu-Chek Insight insulin pump or its system components. Only use the Accu-Chek Insight insulin pump or its system components as described in this User's Manual. Otherwise this may result in severe consequences for your health.

About this User's Manual

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

⚠ WARNING

A warning contains 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. 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.

Sections highlighted in blue refer to features that are part of the basic training lesson. It is highly recommended that you read these sections carefully before you start using the pump.

Sections highlighted in purple refer to features that are part of the optional training lesson. It is highly recommended that you read these sections carefully before you start using the according feature.

Note

The illustrations in this User's Manual may differ slightly from the design of your actual device.

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 technology

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 respective messages and insert a new battery or cartridge where required. Any current Temporary Basal Rates and boluses will continue. Furthermore, the basal rate missed while the pump was in PAUSE mode will be delivered on top of the ongoing basal rate once the pump is back in RUN mode.

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 34.
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 74.

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 15.

User profiles for special situations

With the user profile Expressive enabled, the scrolling functions of the pump are disabled so that all values can only be programmed in distinct increments. Additionally, sound patterns will help you verify that you programmed a value correctly. This may be helpful if you have impaired eyesight. For

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

With the user profile Diminished enabled, all acoustic signals will occur one octave lower. This may be helpful if you have impaired hearing. See chapter 8.3.2, page 71.

Lock the keys to prevent accidental pressing

The key lock disables the keys on the front of your pump so that they cannot be pressed accidentally when wearing your pump under clothing. The key lock is activated by default. The key lock does **not** lock the quick bolus keys. The quick bolus keys still work even if the key lock for the front keys is active. To unlock the front keys, press the following keys within 1 second: One of the keys and then ▲ and then ▼, or one of the keys and then ▼ and then ▲. See chapter 8.3.3, page 72.

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 from as 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 47.

Use pre-filled cartridges

You can use the following pre-filled cartridges with your Accu-Chek Insight insulin pump:

- NovoRapid® PumpCart® (prefilled cartridge containing 1.6 ml solution for injection)
- Fiasp®, PumpCart® (prefilled cartridge containing 1.6 ml solution for injection)

Check the availability in your country or ask your local pump support.

Detect occlusions

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

2 options to deliver a standard bolus

To program and deliver a standard bolus, you have 2 options: either walk through the menus or use the quick bolus feature that allows you to program a standard bolus in distinct increments without even looking at the display. See chapter 4.1, page 39. See chapter 4.2, page 40.

Adjustable bolus speed

You can adjust the delivery speed of the boluses. A lower bolus delivery speed may be helpful if you have high bolus amounts that cause insulin to leak from your skin after delivery or if you experience pain during bolus delivery. See chapter 8.4.2, page 77.

Use a delay (lag time) before bolus delivery

In some situations (for example 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 start of bolus delivery. Discuss using the lag setting with your healthcare team. See chapter 8.4.2, page 77.

Extended bolus

For situations that require delivery of 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 foods that are slow to digest or attend long-lasting buffets. See chapter 4.4, page 43.

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 44.

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 Quiet mode. At night it can delay non-critical warning messages to a specified wake-up time.
- In flight mode your pump's communication ability via *Bluetooth* wireless technology is turned off.

See chapter 7, page 57.

Customisable reminders

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 change the battery
- To check when you might have missed a bolus

You can even program alarm clocks for your personal convenience. See chapter 8.1, page 59.

1.1 Navigating Through Menus

Key	Function
	In most situations the 2 keys have an identical function and can be used alternatively: ■ Moves to previous entry field (back) ■ Cancels a setting ■ Stops a function
	■ Starts the quick bolus programming ■ Sets the quick bolus amount ■ Cancels a bolus ■ Moves to the status screen (double click) ■ Stops the repetitive STOP mode warning

Key	Function
▲	■ Moves you up in a menu screen ■ Increases a setting ■ Function to access quick info screen
	■ Moves to the next menu level ■ Confirms a setting ■ Starts a function
▼	■ Moves you down in a menu screen ■ Decreases a setting ■ Function to access quick info screen

Key	Function
🔍	■ Enlarges the characters on the display ■ Reduces enlarged characters on the display
One ⏺⏺ key and then ▲ and then ▼ or one ⏺⏺ key and then ▼ and then ▲	Unlocks the key lock when pressed in quick succession within 1 second

1.1.1 Navigating Through the Screens

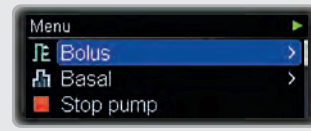
This chapter describes in general how to navigate through the screen and use your pump's functions.

1

From the status screen, press ⏺.

The main Menu screen appears.

2



Press ▲ or ▼ to move to the desired submenu.

Press ⏺ to enter the highlighted menu.

3

The ▲ and ▼ keys move the blue bar (cursor) up and down in the menu.

4

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

5

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

6

To confirm a value, press the ● key.

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

7

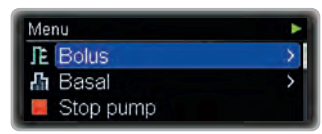
If you need to go back to the previous level and cancel a function, press ●●. However, when you do this any settings you made will not be saved.

Note

Single pressing of the ▲ or ▼ changes the value by increment, while pressing and holding ▲ or ▼ changes the value rapidly (“scrolling”).

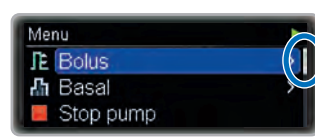
1.1.2 Understanding the Screen

In the main Menu you will find the following functions:

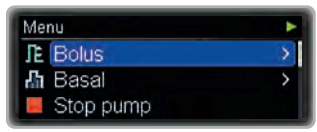


- Bolus
- Basal
- Stop pump
- Start pump
- Pump data
- Modes
- Settings
- Cartridge and infusion set
- Home

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:



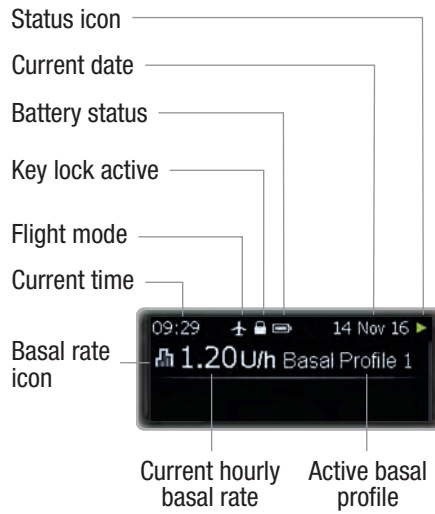
Press ▼ to move to Home.

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.



You can review the complete list of display icons in Appendix D: Icons and Symbols, page 114.

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.

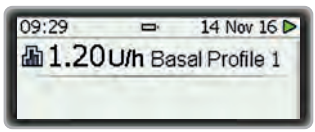
You will learn how to personalise the screen design in the chapter about settings. See chapter 8.3.5, page 74.

Background colour dark

With the dark background colour 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 🔍 for 1 second, the characters on the screen will be enlarged.

When you press 🔍 for 1 second again, the characters will be shown in normal size again.

Note

In Zoom mode not all screen content may be visible.

The 🔍 is illuminated 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 with the adapter 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 (prime the infusion set)

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).

⚠ WARNING

This product contains small parts. There is a risk of suffocation if small parts (e.g. covers, caps or similar objects) are swallowed.

2.1 Choosing the Correct Battery Type

Your Accu-Chek Insight insulin pump requires a 1.5 V AAA battery.

⚠ WARNING

We recommend Energizer® Ultimate Lithium batteries (FR03) as these were successfully tested with the Accu-Chek Insight insulin pump. See Appendix A: Technical Data, page 98 for more information about the lifetime of battery.

If you intend to use a different type of lithium battery, this battery must comply with IEC 60086-4. In this case contact your local pump support.

If you intend to use alkaline batteries, the batteries must be suitable for energy-intensive devices, such as camera flash units.

Alkaline batteries have a significantly shorter lifetime compared to lithium batteries. Use alkaline batteries only if you have no lithium batteries at hand.

Do not use any other batteries, such as carbon zinc batteries, rechargeable batteries, used or expired batteries. These batteries have a significantly reduced battery lifetime and may cause your insulin pump to shut down with no prior warning.

Make sure you specify the correct battery type on your insulin pump. Otherwise, the remaining battery lifetime may not be calculated correctly.

Battery selection screen

2.2 Changing the Battery

Ensure that you always have a new battery with you. It is vital to change the lithium battery every 2 weeks, regardless of the battery indicator.

Before changing the battery, make sure that it is not damaged (e.g. damaged plastic isolation coating) or leaking; a damaged or leaking battery could damage your pump. If you dropped the battery, use a new one.

After changing the battery, check the status screen of your insulin pump and make sure that time, date and basal rate are set properly. If this is not the case, put your insulin pump in STOP mode, then back in RUN mode or contact your local pump support.

You can optimise the battery lifetime by following these recommendations:

- If no device is paired with your insulin pump, you can switch off communication via *Bluetooth* wireless technology to reduce energy consumption.
- If your insulin pump is paired with a device that allows you to control the insulin pump, use this device to reduce frequent usage of the pump display.
- You can lower the display brightness.
- Protect your insulin pump from direct exposure to cold wind and temperatures over 40 °C (104 °F) and below 5 °C (41 °F).
- Change your battery cover if it looks used or dirty and at least every 6 months.

Removing the battery

If you remove the battery while your pump is delivering insulin (RUN mode), the insulin delivery pauses automatically (PAUSE mode). The pump will emit a beep every 8 seconds for as long as the battery is removed while the pump is in PAUSE mode.

When you remove the battery, your pump stores the time and date for about 10 hours.

If you insert a new battery within 15 minutes, Temporary Basal Rates and boluses that were running before the pump went in PAUSE mode will continue. Furthermore, the basal rate missed while the pump was in PAUSE mode will be delivered on top of the ongoing basal rate once the pump is back in RUN mode.

If the pump has been without a battery for more than 15 minutes, the pump stops completely (STOP mode) and cancels Temporary Basal Rates and boluses. Once you have replaced the battery, you have to restart the pump from the main Menu screen and program any Temporary Basal Rates and boluses again. See chapter 3.2, page 34.

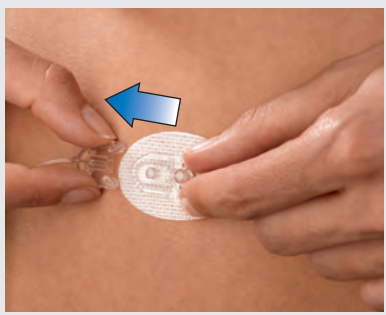
Your insulin pump settings (such as the basal rates, remaining cartridge content, bolus increment, active user profile, or alarm settings) and event memory (bolus and alarm history, history of daily insulin totals and Temporary Basal Rates) are always saved, regardless of the battery

condition or the amount of time your pump has been without power.

Inserting the battery

Ensure that no dirt or dust can enter the battery compartment while changing the battery. When you start your pump for the first time, begin with step 6.

1



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

2

Turn the adapter anti-clockwise to a 90° position.

3

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

4

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 outwards.

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.

Once you have inserted the battery, the pump begins its start-up process. If the pump does not begin the start-up process after the battery has been 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 a battery for more than 10 hours, the setup wizard

launches to help you program your pump's initial settings, such as the time and date.

2.3 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 10 hours
- Insert a new battery while the pump is in PAUSE mode

You will learn more about this in the following chapter.

Note

- If you are in the status screen and you

do not press the ●, ▲ or ▼ key for more than 10 seconds, these keys will be locked. The key lock does not lock the quick bolus keys. See chapter 8.3.3, page 72.

- If you suspect the pump is damaged, for example, when it has been dropped, you can take out and reinsert the battery to start the self-test. See chapter 9.4, page 86.

Self-test sequence

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

The display turns red.

1

Make sure that the area is completely red.

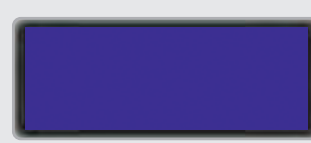
The display turns green.

2

Make sure that the area is completely green.

The display turns blue.

3



Make sure that the area is completely blue.

The display turns black.

4

Make sure that the area is completely black.

The Vibration test screen appears and the pump vibrates.

5

Make sure you can feel the vibration.

The Sound test screen appears and the pump emits a series of beeps.

6

Make sure you can hear them.

If this is the first time you have started your pump, or if it has been without power for over 10 hours, the setup wizard guides you through the time and date setting steps. Otherwise, the start-up process continues with step 6 on page 23.

Set the time, date and battery type

⚠ WARNING

It is vital that you set the correct time and date on your pump including a.m. and p.m. for the 12-hour time format. Otherwise, you might not get the correct amount of insulin at the correct time.

The Set hour screen appears.

1

Press ▲ or ▼ to set the hour.

Press ● to go to Set minute.

The Set minute screen appears.

2

Press ▲ or ▼ to set the minutes.

Press ● to go to Set year.

The Set year screen appears.

3

Press ▲ or ▼ to set the year.

Press ● to go to Set month.

The Set month screen appears.

4

Press ▲ or ▼ to set the month.

Press ● to go to Set day.

The Set day screen appears.

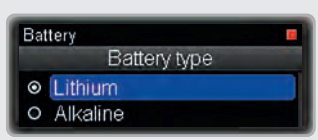
5

Press ▲ or ▼ to set the day.

Press ● to confirm.

The Battery type screen appears.

6



Press ▲ or ▼ to move to the battery type of the inserted battery.

Press ● to select.

⚠ WARNING

Always make sure that the correct battery type is selected after changing the battery.

The Start insulin delivery? screen appears.

7

Press ●● to select no.

The Pump stopped screen appears.

Before using your pump, you must program at least one basal profile. Continue with programming basal profile 1. See chapter 2.4, page 24.

If there is already a programmed basal profile you can simply select yes.

2.4 Program Basal Profile 1

Your pump delivers a continuous stream of insulin to cover your basic insulin need. This is called your basal rate profile. You can program it in time blocks with different hourly basal rates to cover your varying basal insulin requirement throughout the day. By default your pump shows 24 time blocks, one for each hour of the day. By changing the End time you can program a varying number of time blocks (1 to 24) with a minimum duration of 15 minutes and a maximum duration of 24 hours, if needed.

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.

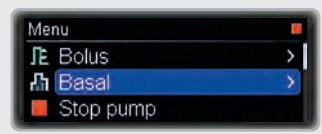
Your personal settings for the basal profile should be provided by your healthcare professional.

1

From the status screen, press ●.

The main Menu appears.

2

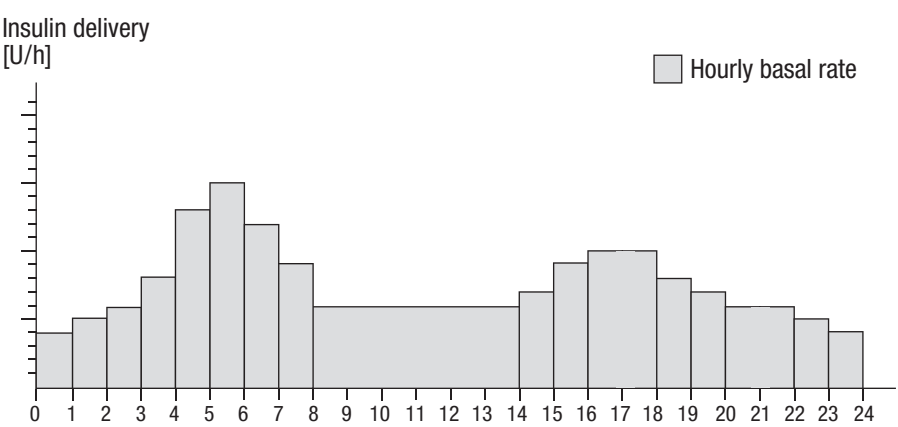


Press ▼ to move to Basal.

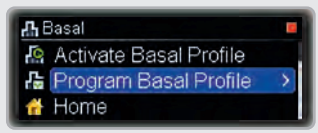
Press ● to select.

The Basal menu appears.

Example: Basal rate profile for 18 U/24 hours



3

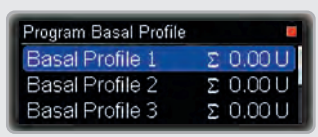


Press ▼ to move to Program Basal Profile.

Press ● to select.

The Program Basal Profile screen appears.

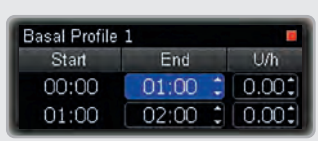
4



Press ● to select Basal Profile 1.

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

5



Press ▲ or ▼ to set the time.

Press ●.

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

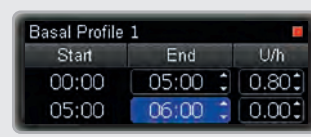
6

Press ▲ or ▼ to set the hourly basal rate.

Press ●.

The End time of the second time block is highlighted.

7



Continue programming the End time and hourly basal rate for the total of 24 hours.

8

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.

9

Make sure the daily total matches your therapy requirement.

Press ● to confirm.

The Pump stopped screen appears.

10

The next step is to insert the cartridge.
See chapter 2.5, page 26.

Note

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

2.5 Changing the Cartridge and Transfer Set

Change the cartridge and transfer set in the following situations:

- When the cartridge is empty and your pump displays Maintenance M21: Cartridge empty
- When your pump displays Maintenance M24: Occlusion
- If you think that there might be an occlusion in the tubing (even without an alarm)
- When the infusion site shows signs of irritation or infection
- When there seems to be a loss of insulin due to a leaking component

⚠ 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 secretion at the insertion site. 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.

Changing the cartridge

Have the following materials ready:

- A new cartridge
- A new Accu-Chek Insight infusion set

Note

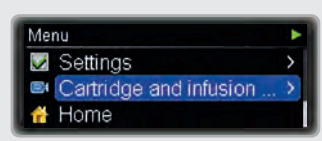
Ensure the cartridge and insulin are at room temperature.

1

From the status screen, press ●.

The main Menu appears.

2

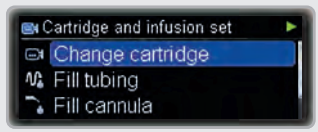


Press ▼ to move to Cartridge and infusion set.

Press ● to select.

The Cartridge and infusion set menu appears.

3



Press ● to select Change cartridge.

The Change cartridge screen appears.

4

Hold the pump in an upright position. Turn the adapter with the tubing anti-clockwise.

5

When you reach an angle of 120°, remove the adapter with the cartridge. The pump starts rewinding the piston rod.

6

Disconnect the infusion set from your body.

Press ● to confirm.

⚠ WARNING

Always disconnect the infusion set from your body when changing the cartridge.

Wait until the pump finishes rewinding the piston rod. If the piston rod is already fully rewound, this screen is not displayed. If the piston rod does not rewind, contact your local pump support.

Insert a cartridge only if the Insert new cartridge and connect adapter screen appears.

⚠ WARNING

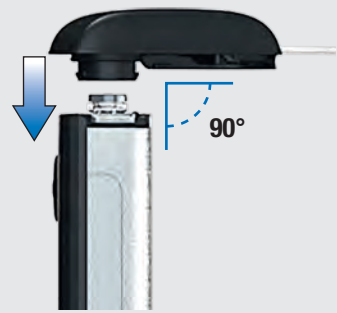
- Before inserting the cartridge into the insulin pump, check every cartridge for cracks or damages.
- Never use a cartridge that has been dropped, even if it seems to be undamaged.

7

Make sure you hold the pump in an upright position.

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

8



Place a **new adapter** on the bayonet socket of the cartridge compartment. Make sure you insert the nose of the adapter into the notches of the pump's housing at a right angle (90°). Otherwise the needle could bend.

CORRECT

INCORRECT

⚠ WARNING

- Always use a new adapter when changing the cartridge.
- A needle is located at the centre of the adapter nose. Insulin delivery is only guaranteed if the needle is fitted onto the cartridge centrally in a perpendicular manner (see step 8).

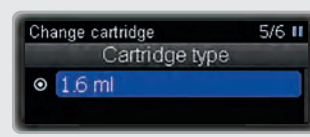
9

Turn the adapter clockwise all the way until it stops. The adapter is correctly positioned when it is aligned with the pump's housing.

Then press ● to confirm.

The Cartridge type screen appears.

10



Press ● to confirm.

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

The pump then performs a self-test. See chapter 2.3, page 21.

After the self-test, the Fill tubing? screen appears.

11

Press ● to fill the infusion set tubing with insulin.

⚠ WARNING

If an empty cartridge is inserted into the pump (for example for training purposes), the pump displays the programmed insulin deliveries (infusion set priming, basal rate and bolus deliveries), even though no insulin is being delivered due to the empty cartridge.

Changing the transfer set (adapter and tubing)

After you have connected a new adapter, it is essential that you fill the transfer set and cannula with insulin. The amount of insulin used for filling is not added to the pump's history of daily insulin totals.

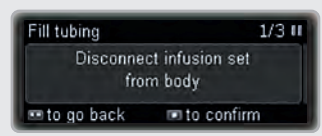
Hold your pump upright during filling so that the adapter points upwards to help release any remaining air bubbles from the cartridge and tubing. If no insulin emerges from the connector, or if there are air bubbles in the tubing after filling, repeat the filling process until the infusion set is bubble-free and completely filled with insulin.

⚠ 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 air bubbles when you fill the cartridge and infusion set, with the tubing disconnected from your body.

The Fill tubing screen appears.

12



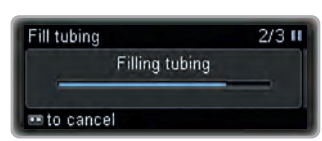
Make sure the infusion set is not connected to your body.

Press ● to confirm.

⚠ WARNING

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

The pump automatically starts to fill the tubing.



13

You can stop the filling process at any time by pressing ●●.

Filling is complete, when the pump has stopped. Check if insulin drips from the tubing.

If no insulin drips from the tubing, press ◀◀ to go back.

Start a second filling process:

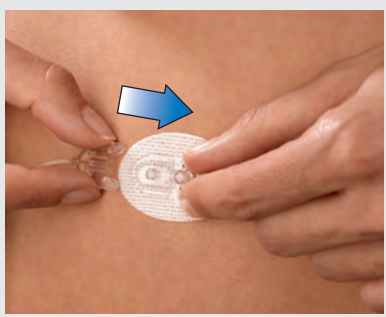
Press ▲ or ▼ to move to Fill tubing.

Press ● to select.

As soon as insulin starts to drip from the tubing, press ◀◀ to stop the filling process.

When filling is complete, you are prompted to connect the infusion set to your body.

14

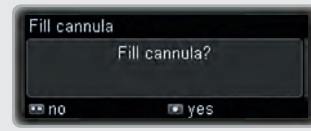


You can now insert the cannula into your body. Read and follow the instructions that came with your infusion set carefully.

Attach the connector of the tubing to the head set and press ● to confirm.

The Fill cannula? screen appears.

15



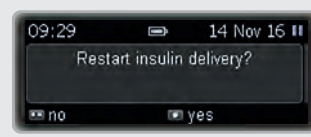
Press ● to fill the infusion set cannula with insulin.

The pump automatically starts to fill the cannula.

The default fill amount for the cannula is 0.7 U. See chapter 8.4.3, page 81.

When filling is complete, the Restart insulin delivery? screen appears.

16



Press ● to select yes or ◀◀ to select no.

2 STARTING YOUR PUMP

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 underdelivery or overdelivery of insulin.

Note

When wearing your pump, prevent any contact with objects in your pockets, such as key chains, keys 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

⚠ 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 pump displays Error E7: Electronic error.

Always stop your pump, remove it from your body, and leave it outside these areas. See Appendix A: Technical Data, page 98 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 vapours 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 page).

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 take-off
- when practising 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 practising sports that involve high-impact body contact such as boxing or rugby. 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 page).

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 page).

3.2 Stopping and Starting Your Pump

You should discuss with your doctor or healthcare team when and for how long insulin delivery may be interrupted.

Check your blood glucose level regularly any time insulin delivery is interrupted. 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
- The cannula has slipped out of the infusion site

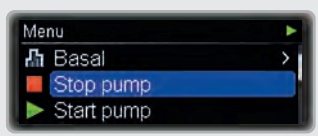
Stop your pump

1

From the status screen, press ●.

The main Menu screen appears.

2



Press ▼ to move to Stop pump.

Press ● to select.

The Pump stopped screen appears.

You can now disconnect the infusion set from your body and take off 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.

Note

You can suppress this STOP warning by pressing and holding ●● for 3 seconds.

Start your pump

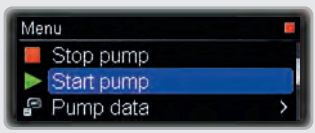
Make sure your infusion set is completely filled with insulin and free of air bubbles. Connect the infusion set to your body according to the instructions that came with it.

1

From the Pump stopped screen, press ●.

The main Menu screen appears.

2



Press ▼ to move to Start pump.

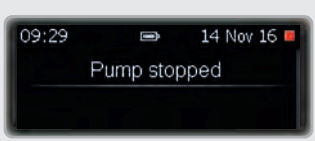
Press ● to select.

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.

1



Switch your pump to STOP mode. See chapter 3.2, page 34.

Disconnect the infusion set from your body.

2

Hold the pump in an upright position. Remove the adapter, cartridge and battery from the pump. See chapter 2, page 17.

Make sure you store your pump properly. See chapter 9.6, page 87.

3.3 Your Insulin Pump and Water

Your pump is waterproof according to the IPX8 standard. However, since the adapter of the infusion set is not watertight, water may enter the cartridge compartment. If water does enter the pump, follow the instructions in this chapter.

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. See chapter 9.4, page 86.

When water has entered the cartridge or battery compartment

Water may enter into the cartridge compartment through the adapter if the pump has been immersed 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 compartments are completely dry before reinserting the cartridge or battery. 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
- Drinks
- Oil or fat

Avoid any contact between the pump or infusion set and 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 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 message or warning message)
- Current time and date

1

From the status screen, press ▼.

The Cartridge and battery screen appears.

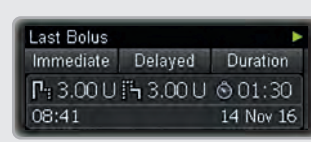
2

Press ▼.

Press ▲ if you want to go back.

The Last Bolus screen appears.

3



Press ▼.

Press ▲ if you want to go back.

The Total daily dose screen appears.

4

Press ▼.

Press ▲ if you want to go back.

The Last message screen appears.

5

Press ▼.

Press ▲ if you want to go back.

The Time and date screen appears.

6

Press ▼ to return to the status screen.

Press ▲ if you want to go back.

4 Administering Boluses

4.1 Standard Bolus

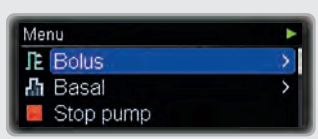
The standard bolus delivers the programmed insulin dose all at once. This bolus can be helpful for foods that are digested quickly, such as cake or bread. The standard bolus is also the best option for correcting high blood glucose levels. If necessary, you can adjust the speed of the bolus delivery. See chapter 8.4.2, page 77.

1

From the status screen, press ●.

The main Menu screen appears.

2



Press ● to select Bolus.

The Bolus menu appears.

3

Press ● to select Standard Bolus.

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

4

Press ▲ or ▼ to set the immediate bolus amount.

Press ● to confirm.

The Bolus to deliver screen appears for 5 seconds.

If necessary, you can press ●● and program a new bolus amount.

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 and holding ⊂⊃ 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. This bolus type lets you discreetly deliver a bolus while your pump is hidden in your clothing.

This bolus is suitable for meals that contain mainly carbohydrates that are digested quickly, as well as for the correction of high blood glucose levels.

The quick bolus function is deactivated by default. You can activate or deactivate the quick bolus function with the Accu-Chek 360° configuration software or in the Therapy settings on your pump. See chapter 8.4.2, page 77. 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 or 2.0 units in the Therapy settings on your pump.

⚠ WARNING

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

If necessary, you can adjust the speed of the bolus delivery. See chapter 8.4.2, page 77.

Program a quick bolus

1

In RUN mode press one of the ⊂⊃ keys and release it. **Immediately** afterwards, press and hold the same key for at least 3 seconds until you hear a beep tone and feel the pump vibrate.

The Quick Bolus screen appears with the bolus amount highlighted.

2

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.

If necessary, press the key you used in step 1 to set the amount to 0.

3

To confirm the bolus amount, press and hold the same key for at least 3 seconds. Your pump beeps once and vibrates twice.

Your pump confirms the bolus amount with one beep and vibration for each bolus increment programmed.

Note

You can cancel a quick bolus while the confirmation screen is displayed or during delivery by pressing and holding for 3 seconds.

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

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

4.3 Cancelling a Bolus

4.3.1 Cancelling a Bolus During Programming

Standard, extended and multiwave bolus

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

Quick bolus

You can cancel a quick bolus while the confirmation screen is displayed or during delivery by pressing and holding for 3 seconds.

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

4.3.2 Cancelling a Bolus During Delivery

During delivery of a standard, quick or the immediate part of a multiwave bolus press and hold for 3 seconds to cancel the bolus.

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

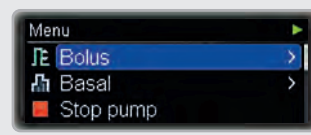
4.3.3 Cancelling a Bolus Using the Cancel Bolus Menu

1

From the status screen, press .

The main Menu screen appears.

2



Press to select Bolus.

The Bolus menu appears.

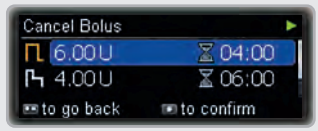
3

Press ▼ to move to Cancel Bolus.

Press to select.

The Cancel Bolus screen appears.

4



If more than one bolus is being delivered, press ▲ or ▼ to move to the bolus you want to cancel.

Press ● to confirm.

The pump displays Warning W38.

5

Press ● to mute the warning.

Press ● again to confirm.

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 digested slowly, 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 in-progress extended bolus and one additional extended or multiwave bolus.

Example

Ian is planning to eat a pizza. He knows it contains few fast-acting carbohydrates and a lot of fat and carbohydrates that are digested slowly. Therefore, he programs an extended bolus for his pizza.

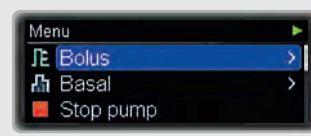
Program an extended bolus

1

From the status screen, press ●.

The main Menu screen appears.

2



Press ● to select Bolus.

The Bolus menu appears.

3

Press ▼ to move to Extended Bolus.

Press ● to select.

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

4

Press ▲ or ▼ to set the delayed bolus amount.

Press ●.

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

5

Press ▲ or ▼ to set the duration.

Press ● to confirm.

Your pump returns to the status screen showing a progress bar of the remaining bolus amount and duration, in addition to the hourly basal rate.

Note

To cancel an extended bolus, use the Cancel Bolus menu. See chapter 4.3.1, page 41.

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 carbohydrates that can be digested both rapidly and slowly, or long meals with several courses. You can also use this bolus type when you are planning to eat carbohydrates that are digested slowly but have an elevated blood glucose level before the meal. You program the immediate part of the bolus to correct the blood glucose level and the delayed 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 in-progress multiwave bolus, and one additional extended or multiwave bolus.

Example

Ian is invited to dinner. He will have pastries as a starter and steak with potatoes as his main course. In addition, his blood glucose level is slightly outside 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.

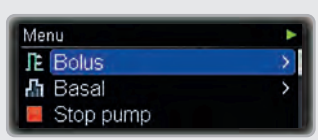
Program a multiwave bolus

1

From the status screen, press ●.

The main Menu screen appears.

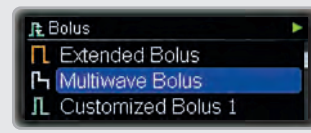
2



Press ● to select Bolus.

The Bolus menu appears.

3



Press ▼ to move to Multiwave Bolus.

Press ● to select.

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

4

Press ▲ or ▼ to set the immediate bolus amount.

Press ●.

The delayed bolus amount is highlighted.

5

Press ▲ or ▼ to set the delayed bolus amount.

Press ●.

The duration of the delayed bolus is highlighted. The duration of your last multiwave bolus is given as a default.

6

Press ▲ or ▼ to set the duration.

Press ● to confirm.

The screen showing the bolus to be delivered appears.

If necessary, you can press ●● and program the bolus anew.

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

To cancel a multiwave bolus, press and hold ●● for 3 seconds during delivery of the immediate part, or use the Cancel Bolus menu during delivery of the delayed part. See chapter 4.3.1, page 41.

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 you 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

Ian 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.

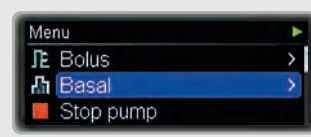
Program a TBR

1

From the status screen, press ●.

The main Menu screen appears.

2



Press ▼ to move to Basal.

Press ● to select.

The Basal menu appears.

3

Press ● to select Temporary Basal Rate.

The Temporary Basal Rate menu appears.

4

Press ● to select Basic TBR.

The Basic TBR screen appears with the TBR percentage highlighted.

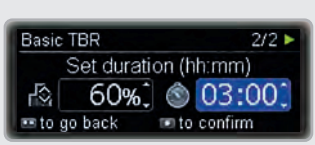
5

Press ▲ or ▼ to set the TBR percentage.

Press ●.

The TBR duration is highlighted.

6



Press ▲ or ▼ to set the duration.

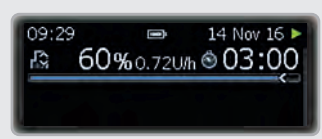
Press ● to confirm.

The status screen appears, showing the percentage and the remaining duration of the TBR in addition to the modified hourly basal rate.

When the duration of the TBR has expired, your pump displays Reminder R7: TBR completed.

Cancel a TBR

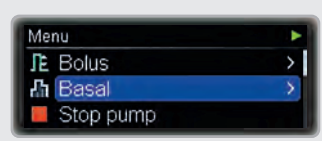
1



From the status screen, press ●.

The main Menu screen appears.

2



Press ▼ to move to Basal.

Press ● to select.

The Basal menu appears.

3

Press ● to select Temporary Basal Rate.

The Temporary Basal Rate menu appears.

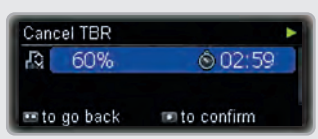
4

Press ▼ to move to Cancel TBR.

Press ● to select.

The Cancel TBR screen appears.

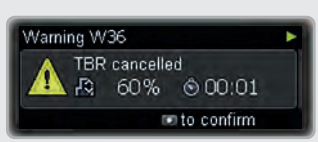
5



Press ● to confirm.

The pump displays Warning W36: TBR cancelled to confirm the cancellation was intended.

6



Press ● twice to mute and confirm the warning.

5.2 Additional Basal Profiles

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

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

Example

Ian is a construction worker and from Monday to Friday he is on his feet from early morning until the end of the day. At the weekend, he likes to sleep in late and read books for hours. After discussing his varying daily routines with his doctor, Ian 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)

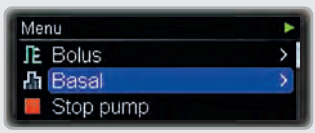
1

From the status screen, press ●.

The main Menu screen appears.

5 BASAL PROFILE OPTIONS

2

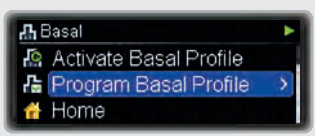


Press ▼ to move to Basal.

Press ● to select.

The Basal menu appears.

3



Press ▼ to move to Program Basal Profile.

Press ● to select.

The Program Basal Profile screen appears.

4

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.

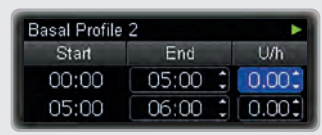
5

Press ▲ or ▼ to set the time.

Press ●.

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

6



Press ▲ or ▼ to set the hourly basal rate.

Press ●.

The End time of the second time block is highlighted.

7

Continue programming the End times and hourly basal rates for all time blocks. After you have programmed an hourly basal rate for all 24 hours press ●.

The Basal Profile daily total screen for the Basal Profile 2 (3, 4, or 5) appears.

8

Make sure the daily total matches your therapy requirement.

Press ● to confirm.

The status screen appears.

Note

You can now activate this basal profile using the Activate Basal Profile menu.

5.3 Activating a Basal Profile

Example

Ian is planning a lazy weekend, 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)

1

From the status screen, press ●.

The main Menu screen appears.

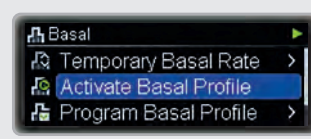
2

Press ▼ to move to Basal.

Press ● to select.

The Basal menu appears.

3

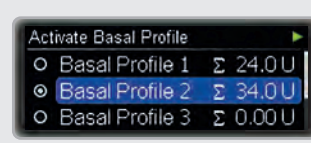


Press ▼ to move to Activate Basal Profile.

Press ● to select.

The Activate Basal Profile screen appears.

4



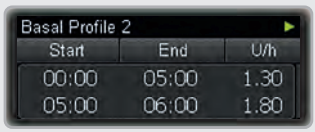
Press ▲ or ▼ to move to Basal Profile 2 (1, 3, 4, or 5).

Press ● to select.

5 BASAL PROFILE OPTIONS

The Basal Profile 2 (1, 3, 4, or 5) summary screen appears.

5



Make sure you selected the correct profile.

Press ●.

The status screen appears. The new basal profile is active immediately.

6 Viewing Your Data

Your insulin pump stores up to 9000 pump events (maintenance messages, warnings and errors, programming operations and insulin delivery records). This data corresponds to approximately 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 maintenance messages, 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.

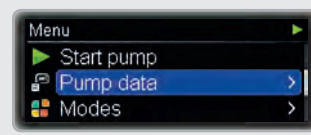
Viewing your data

1

From the status screen, press .

The main Menu screen appears.

2

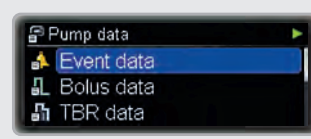


Press ▼ to move to Pump data.

Press to select.

The Pump data menu appears.

3



Press ▲ or ▼ to move to Event data, Bolus data, TBR data, Daily totals, Pump timer or Version as needed.

Press to select.

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

4

Press ▼ to view previous entries.

Press ▲ to move back to more recent results.

Press ∞ to go back to the Pump data menu screen or press ∞ twice to return to the status screen.

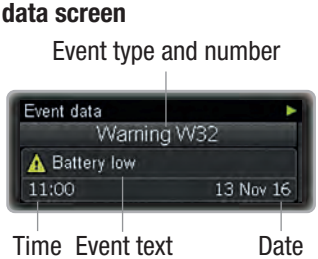
6.1 Event Data

The Event data screen allows you to view up to the last 90 maintenance messages, warnings and errors, starting with the most recent entry.

Each event data screen displays:

- Type and number of the maintenance message, warning, or error (for example, Warning W32)
- The text of the maintenance message, warning or error (for example, Battery low)
- Time
- Date

Event data screen



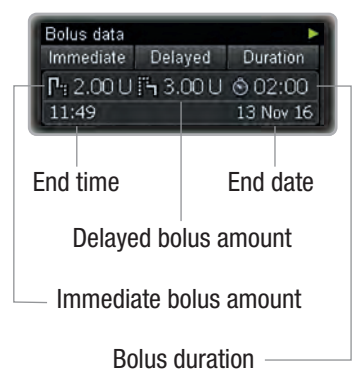
6.2 Bolus Data

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)
- End time
- End date

Bolus data screen



6.3 TBR Data

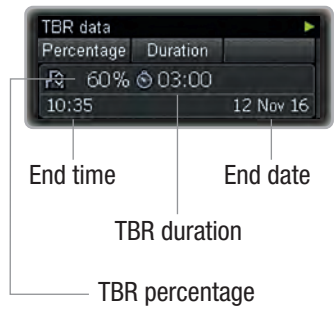
The TBR data screen allows you to view up to the last 90 Temporary Basal Rates (TBR), starting with the most recent entry.

Each TBR data screen displays:

- TBR in percentage
- TBR duration

- End time
- End date

TBR data screen



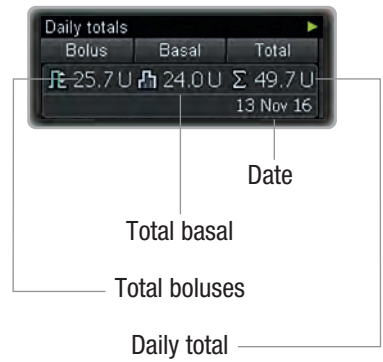
6.4 Daily Totals

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

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, the pump displays Warning W39: Loantime warning to 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, your pump displays Maintenance M25: Loantime over 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.

6

7 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. See chapter 8.3.1, page 68.

You will learn how to program a mode to best suit your preferences in the chapter about settings.

You have 4 different signal modes:

Normal	Set the signal that you prefer in most of your everyday 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* wireless technology of your pump. You need this mode when you travel by airplane, where you are not allowed to use *Bluetooth* wireless technology.

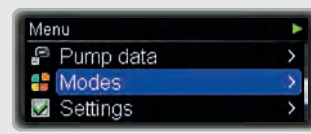
Change the signal mode

1

From the status screen, press ●.

The main Menu screen appears.

2

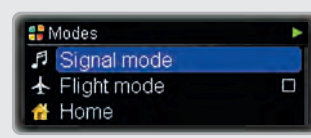


Press ▼ to move to Modes.

Press ● to select.

The Modes menu appears.

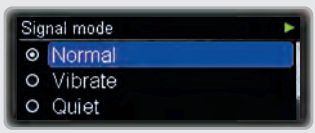
3



Press ● to select Signal mode.

The Signal mode screen appears.

4



Press ▲ or ▼ to move to Normal, Vibrate, Quiet or Loud.

Press ● to select.

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 68.

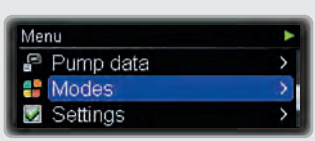
Switch the flight mode on or off

1

From the status screen, press ●.

The main Menu screen appears.

2



Press ▼ to move to Modes.

Press ● to select.

The Modes menu appears.

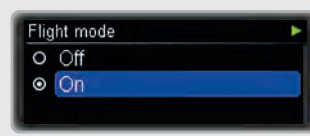
3

Press ▼ to move to Flight mode.

Press ● to select.

The Flight mode screen appears.

4



Press ▲ or ▼ to move to On or Off as needed.

Press ● to select.

The pump returns to the status screen. The flight mode is active immediately and *Bluetooth* wireless technology 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 communication between your pump and 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 adjust your pump to your personal therapy requirements.
Time and date	Help to ensure that your insulin is delivered at the right time.

Enter the settings menu

1

From the status screen, press ●.

The main Menu screen appears.

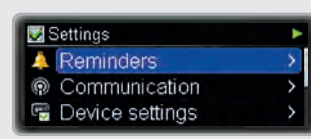
2

Press ▼ to move to Settings.

Press ● to select.

The Settings menu appears.

3



Press ▲ or ▼ to move to Reminders, Communication, Device settings, Therapy settings or Time and date as needed.

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

1

In the Settings menu press ● to select Reminders.

The Reminders menu appears.

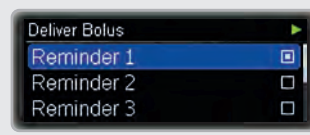
2

Press ▲ or ▼ to move to Deliver Bolus, Missed Bolus or Alarm clock as needed.

Press ● to select.

The Deliver Bolus, Missed Bolus or Alarm clock screen appears.

3

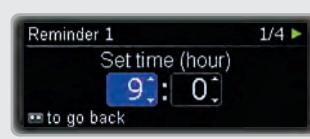


Press ▲ or ▼ to move to Reminder 1 (2, 3, 4, or 5).

Press ● to select.

The Reminder 1 (2, 3, 4, or 5) screen appears with the hours highlighted.

4



Press ▲ or ▼ to set the hour.

Press ●.

The minutes are highlighted.

5

Press ▲ or ▼ to set the minutes.

Press ●.

The Reminder 1 (2, 3, 4, or 5) Tone screen appears.

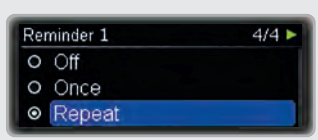
6

Press ▲ or ▼ to move to Tone 1 to 10 as needed.

Press ●.

The Reminder 1 (2, 3, 4, or 5) status screen appears.

7



Press ▲ or ▼ to move to Off, Once or Repeat as needed.

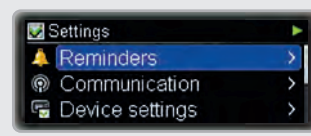
Press ● to select.

Note

When the reminder goes off, press ● twice to mute and confirm. If the key lock is active, you must unlock the keys before you can confirm the reminder. See chapter 8.3.3, page 72.

Set the infusion set change reminder

1



In the Settings menu press ▲ or ▼ to move to Reminders.

Press ● to select.

The Reminders menu appears.

2

Press ▼ to move to Infusion set change.

Press ● to select.

The Infusion set change screen appears with the days highlighted.

3

Press ▲ or ▼ to set the number of days after which the reminder sounds.

Press ●.

The hours are highlighted.

4

Press ▲ or ▼ to set the hour.

Press ●.

The minutes are highlighted.

5

Press ▲ or ▼ to set the minutes.

Press ●.

The Infusion set change Tone screen appears.

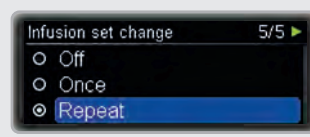
6

Press ▲ or ▼ to move to Tone 1 to 10 as needed.

Press ●.

The Infusion set change screen appears.

7



Press ▲ or ▼ to move to Off, Once or Repeat as needed.

Press ● to select.

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 the Accu-Chek software.

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, the pump and the device can exchange data with each other using a stable and secure connection via *Bluetooth* wireless technology.

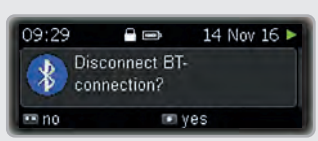
Your pump can be paired with up to 5 other devices in total. If you want to pair another device when 5 devices are already paired with your pump, you have to delete the pairing of one of the paired devices first.

In this chapter you will learn how to:

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

Note

You can control your pump from another Accu-Chek device via *Bluetooth* wireless technology only if the display of the pump is off. If you unlock the keys of your pump while *Bluetooth* wireless technology is active, you will be asked if you would like to interrupt communication via *Bluetooth* wireless technology.



Select yes to operate your insulin pump from the display again. Select no to continue operating your pump from another Accu-Chek device.

8.2.1 Switching *Bluetooth* wireless technology On and Off

There are 2 ways to switch the communication via *Bluetooth* wireless technology on and off:

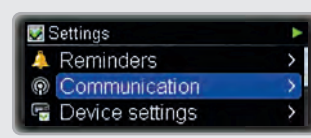
- You can use Flight mode. When Flight mode is on, *Bluetooth* wireless technology is switched off.
- You can switch *Bluetooth* wireless technology on or off in the Communication menu.

When *Bluetooth* wireless technology is turned off, the airplane icon appears on the status screen.

Note

Switching off *Bluetooth* wireless technology increases the battery lifetime.

1

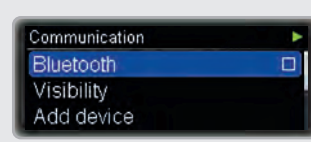


In the Settings menu press ▼ to move to Communication.

Press ● to select.

The Communication menu appears.

2



Press ● to select *Bluetooth*.

The *Bluetooth* screen appears.

3

Press ▲ or ▼ to move to Off or On as needed.

Press ● to select.

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* wireless technology is switched on before switching Visibility on.

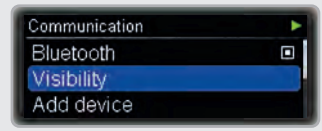
1

In the Settings menu press ▼ to move to Communication.

Press ● to select.

The Communication menu appears.

2



Press ▼ to move to Visibility.

Press ● to select.

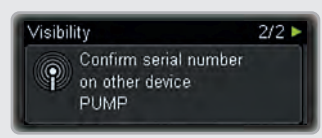
The Visibility screen appears.

3

Press ● to confirm.

The other device displays the serial number of the pump.

4



Continue according to the instructions of the other device.

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.

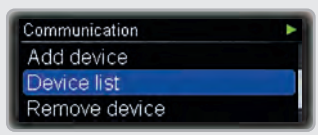
1

In the Settings menu press ▼ to move to Communication.

Press ● to select.

The Communication menu appears.

2

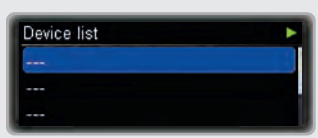


Press ▼ to move to Device list.

Press ● to select.

The Device list screen appears.

3



Press ▼ to view the complete list.

Press ● to return to the status screen.

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 communication via *Bluetooth* wireless technology 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* wireless technology 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 software used.

1

In the Settings menu press ▼ to move to Communication.

Press ● to select.

The Communication menu appears.

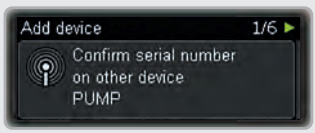
2

Press ▼ to move to Add device.

Press ● to select.

The pump shows the Confirm serial number screen.

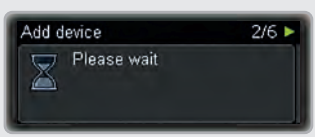
3



Confirm the pump's serial number on the other device as soon as it appears on its screen.

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

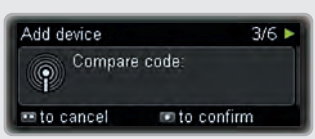
4



Please wait ...

Both devices will then display a code.

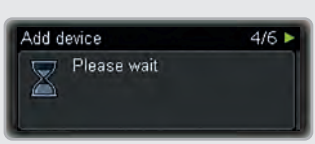
5



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

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

6



Please wait ...

The pump shows the Pairing successful screen.

7

Press ● to confirm.

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

8

Press ● to confirm.

Note

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

Try again, preferably in a less crowded environment.

Make sure that the device you want to pair with the pump is not already paired. If this is the case, you need to remove the device from the list of paired devices before you start pairing. See chapter 8.2.5, page 67.

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 pair the pump with the device again, as described earlier in this chapter. See chapter 8.2.4, page 65.

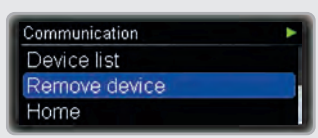
1

In the Settings menu press ▼ to move to Communication.

Press ● to select.

The Communication menu appears.

2

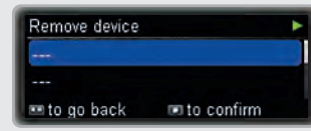


Press ▼ to move to Remove device.

Press ● to select.

The Remove device screen appears.

3



Press ▲ or ▼ to move to the device you want to remove from the list.

Press ● to confirm.

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 or Diminished.
Key lock	When using the key lock, the keys on the front of your pump are disabled so that they cannot be pressed accidentally. Select the key lock timeout.
Language	Select your preferred language.
Display	Personalise the display design.

8.3.1 Personalising Your Mode Settings

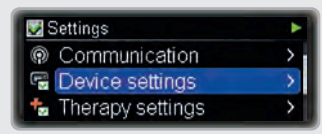
For all signal modes you can adjust the sound volume and select whether you want your pump to sound, vibrate or both at the same time as an event (warning, reminder, error, maintenance message) occurs.

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

However, since errors and maintenance messages 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

1

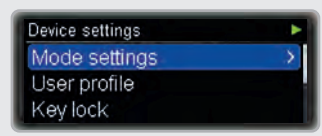


In the Settings menu press ▼ to move to Device settings.

Press ● to select.

The Device settings menu appears.

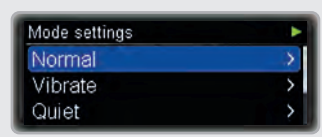
2



Press ● to select Mode settings.

The Mode settings menu appears.

3

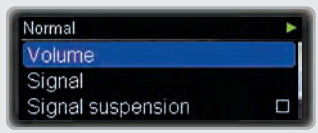


Press ▲ or ▼ to move to Normal, Quiet, Vibrate or Loud as needed.

Press ● to select.

The Normal, Quiet, Vibrate or Loud screen appears.

4



Press ● to select Volume.

The Volume screen appears.

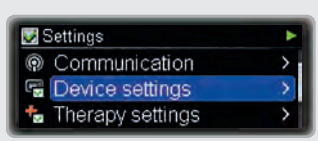
5

Press ▲ or ▼ to select the volume as needed.

Press ● to confirm.

Select the signal for reminder, warning, maintenance message, error

1

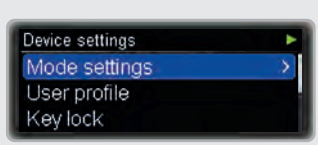


In the Settings menu press ▼ to move to Device settings.

Press ● to select.

The Device settings menu appears.

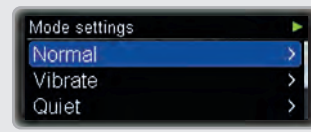
2



Press ● to select Mode settings.

The Mode settings screen appears.

3

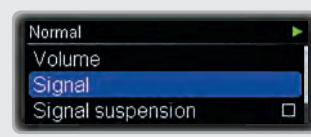


Press ▲ or ▼ to move to Normal, Quiet, Vibrate or Loud as needed.

Press ● to select.

The Normal, Quiet, Vibrate or Loud screen appears.

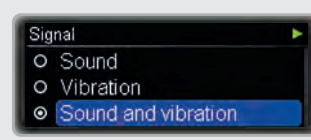
4



Press ▼ to move to Signal.

The Signal screen appears.

5



Press ▲ or ▼ to move to Sound, Vibration, or Sound and vibration as needed.

Press ● to select.

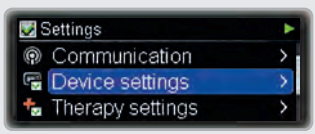
Set the signal suspension

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

However, since errors and maintenance messages require your immediate attention, you cannot suspend these event signals.

Also, the reminders you programmed will not be silenced.

1

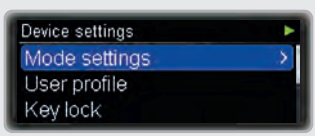


In the Settings menu press ▼ to move to Device settings.

Press ● to select.

The Device settings menu appears.

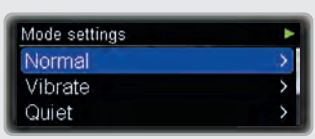
2



Press ● to select Mode settings.

The Mode settings screen appears.

3

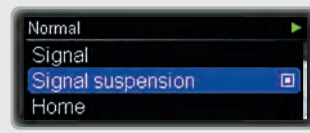


Press ▲ or ▼ to move to Normal, Quiet, Vibrate or Loud as needed.

Press ● to select.

The Normal, Quiet, Vibrate or Loud screen appears.

4



Press ▼ to move to Signal suspension.

Press ● to select.

The Signal suspension screen appears with the start time highlighted.

5

Press ▲ or ▼ to set the start time.

Press ●.

The end time is highlighted.

6

Press ▲ or ▼ to set the end time.

Press ●.

The Signal suspension status screen appears.

7

Press ▲ or ▼ to move to Off, Once, or Repeat as needed.

Press ● to select.

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

Each user profile defines different behaviours and increments for programming values. In the user profile Expressive the scrolling functions of the pump are disabled 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. This may be helpful if you have impaired eyesight. For more information, contact your local pump support (see inside back cover page).

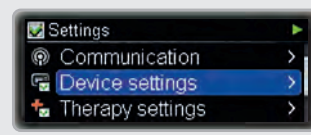
In the user profile Diminished all acoustic signals will sound one octave lower. This may be helpful if you have impaired hearing.

Increments:

Standard	0.05 increments (0–2 U) 0.1 increments (2–5 U) 0.2 increments (5–10 U) 0.5 increments (10–20 U) 1.0 increments (20 U)
Expressive	0.5 increments
Diminished	same increments as Standard profile

Select the User profile

1

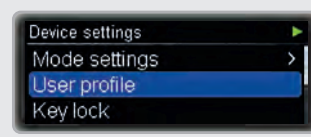


In the Settings menu press ▼ to move to Device settings.

Press ● to select.

The Device settings menu appears.

2



Press ▼ to move to User profile.

Press ● to select.

The User profile screen appears.

3

Press ▲ or ▼ to move to Standard, Expressive, or Diminished as needed.

Press ● to select.

8.3.3 Key Lock

The key lock function automatically locks the ●, ▲ and ▼ keys on the front of the pump if you do not press any of them for a specified amount of time. This helps you to avoid accidental operation of the pump.

The key lock is activated by default. **The key lock does not lock the quick bolus keys ◎◎.** The quick bolus keys ◎◎ still work even if the key lock for the front keys is active.

Ensure that the keys on the front of the pump and the quick bolus keys cannot be pressed accidentally, in particular when you carry your pump in a pocket or wear it under clothing. You may carry your pump in a protective case.

Parents, legal guardians and caregivers should advise children in their care **not** to play around with the pump keys, to avoid unintentional operation of the pump.

Unlocking the keys

To unlock the front keys, press the following keys in the order given below, within 1 second:

1 One of the ◎◎ keys
2 The ▲ key
3 The ▼ key

Or:

1 One of the ◎◎ keys
2 The ▼ key
3 The ▲ key

⚠ WARNING

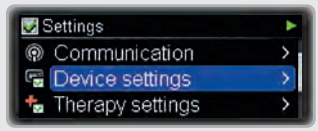
Unperceived deactivation of the key lock or activation of the quick bolus function may lead to unintended actions of the pump. This could lead to underdelivery or overdelivery of insulin and may result in severe consequences for your health, such as hyperglycaemia or hypoglycaemia.

Adjusting the key lock

In this section you will learn how to set the length of time before the keys automatically lock. From the Device settings menu it is possible to set a time between 4 and 60 seconds. The minimum timeout interval of 4 seconds is recommended for children.

If the length of time is set to more than 10 seconds, there is a higher risk of the pump being operated accidentally. The countdown to the timeout starts as soon as the pump returns to the status screen.

1

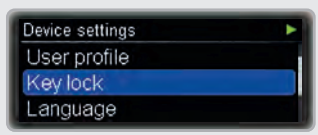


In the Settings menu press ▼ to move to Device settings.

Press ● to select.

The Device settings menu appears.

2

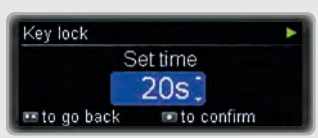


Press ▼ to move to Key lock.

Press ● to select.

The Key lock screen appears.

3

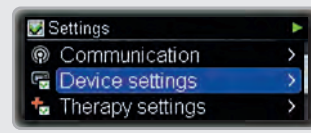


Press ▲ or ▼ to change from the current value to the desired number of seconds.

Press ● to confirm.

8.3.4 Select the Language

1

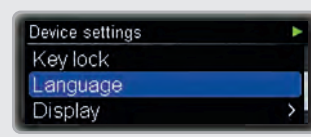


In the Settings menu press ▼ to move to Device settings.

Press ● to select.

The Device settings menu appears.

2

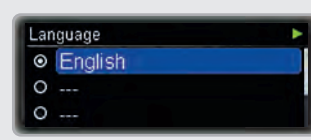


Press ▼ to move to Language.

Press ● to select.

The Language screen appears.

3



Press ▲ or ▼ to move to the desired language.

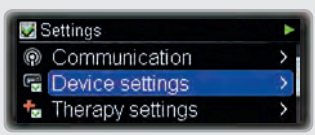
Press ● to select.

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

1

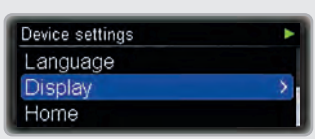


In the Settings menu press ▼ to move to Device settings.

Press ● to select.

The Device settings menu appears.

2

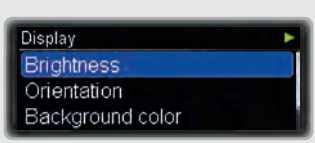


Press ▼ to move to Display.

Press ● to select.

The Display menu appears.

3



Press ● to select Brightness.

The Brightness screen appears.

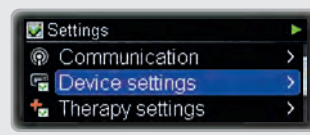
4

Press ▲ or ▼ to adjust the brightness as needed.

Press ● to confirm.

Change the orientation

1

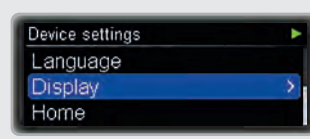


In the Settings menu press ▼ to move to Device settings.

Press ● to select.

The Device settings menu appears.

2



Press ▼ to move to Display.

Press ● to select.

The Display menu appears.

3

Press ▼ to move to Orientation.

Press ● to select.

The Orientation screen appears.

4

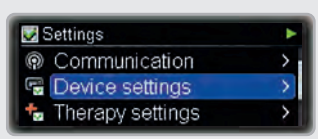
Press ▲ or ▼ to move to Standard or Rotated as needed.

Press ● to select.

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

Change the background colour

1

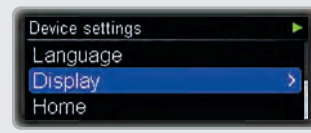


In the Settings menu press ▼ to move to Device settings.

Press ● to select.

The Device settings menu appears.

2



Press ▼ to move to Display.

Press ● to select.

The Display menu appears.

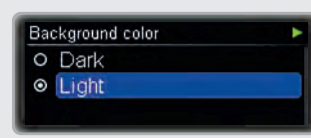
3

Press ▼ to move to Background color.

Press ● to select.

The Background color screen appears.

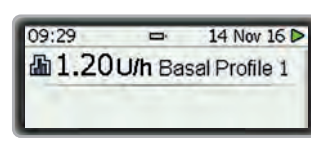
4



Press ▲ or ▼ to move to Dark or Light as needed.

Press ● to select.

The status screen appears in the changed 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, the wrong amount of insulin may be delivered, leading to a risk of hypoglycaemia or hyperglycaemia. The therapy settings should be provided by your healthcare professionals and you should discuss these with them before making any changes.

You can adjust the:

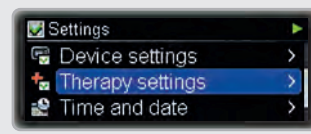
Automatic off	Set the time for Maintenance M23: Automatic off.
Bolus settings	Activate or deactivate the quick bolus function. Set the increment for the quick bolus, the delivery speed, the maximum bolus amount and the lag setting.
Infusion set settings	Set the filling amount for the infusion set tubing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

8.4.1 Adjusting the Automatic Off Function

The Automatic off function is a safety feature for emergency situations. The pump displays Maintenance M23: Automatic off and stops the insulin flow if you do not touch any key on your pump or communicate with your pump using *Bluetooth* wireless technology for the selected number of hours.

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

1

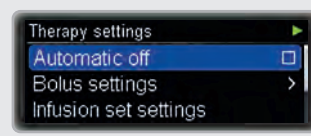


In the Settings menu press ▼ to move to Therapy settings.

Press ● to select.

The Therapy settings menu appears.

2



Press ● to select Automatic off.

The Automatic off screen appears.

3

Press ▲ or ▼ to switch from the current value to the desired number of hours.

4

Press ● to confirm.

Respond to the maintenance message M23: Automatic off

1

When the maintenance message occurs, press ● to mute the maintenance message.

2

Unlock the key lock if the keys are locked. See chapter 8.3.3, page 72.

Press ● again to confirm. Then restart insulin delivery or take other appropriate action.

Note

It is highly recommended to check your blood glucose level after the pump displayed 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 activate or deactivate the quick bolus function.

Furthermore, you can adjust:

- The quick bolus increment
- The delivery speed
- The maximum bolus amount
- The lag setting

⚠ WARNING

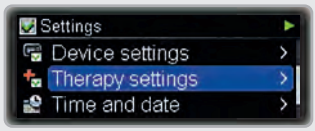
It is vital that you use the correct quick bolus increment. Otherwise, this could lead to underdelivery or overdelivery of insulin and may result in severe consequences for your health, such as hyperglycaemia or hypoglycaemia.

Activate the quick bolus function

The quick bolus function is deactivated by default. When you activate the quick bolus function, you can administer boluses using the quick bolus keys ●● of your pump. See chapter 4.2, page 40.

Note that the key lock does not lock the quick bolus keys ●●. The quick bolus keys ●● still work even if the key lock for the front keys is active.

1

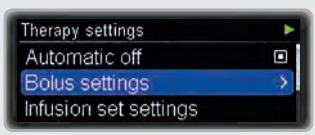


In the Settings menu press ▼ to move to Therapy settings.

Press ● to select.

The Therapy settings menu appears.

2

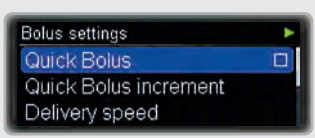


Press ▼ to move to Bolus settings.

Press ● to select.

The Bolus settings menu appears.

3

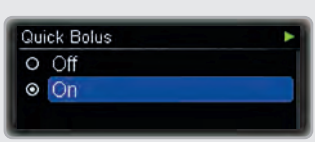


Press ▼ to move to Quick Bolus.

Press ● to select.

The Quick Bolus screen appears.

4



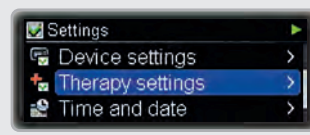
Press ▲ or ▼ to move to On or Off as needed.

Press ● to select.

Adjust the quick bolus increment

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 or 2.0 units per key press. See chapter 4.2, page 40.

1

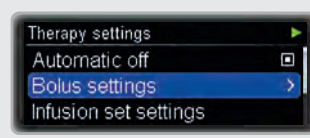


In the Settings menu press ▼ to move to Therapy settings.

Press ● to select.

The Therapy settings menu appears.

2

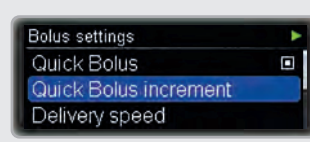


Press ▼ to move to Bolus settings.

Press ● to select.

The Bolus settings menu appears.

3



Press ▼ to move to Quick Bolus increment.

Press ● to select.

The Quick Bolus increment screen appears.

4

Press ▲ or ▼ to set the desired increment.

Press ● to confirm.

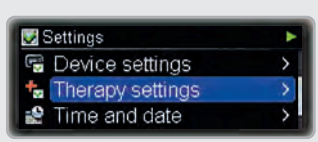
Adjust the delivery speed

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)

1

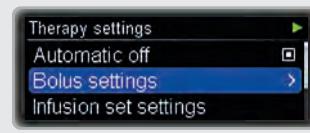


In the Settings menu press ▼ to move to Therapy settings.

Press ● to select.

The Therapy settings menu appears.

2



Press ▼ to move to Bolus settings.

Press ● to select.

The Bolus settings menu appears.

3

Press ▼ to move to Delivery speed.

Press ● to select.

The Delivery speed screen appears.

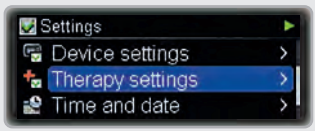
4

Press ▲ or ▼ to move to Very slow, Slow, Moderate or Standard as needed.

Press ● to select.

Adjust the maximum bolus amount

1

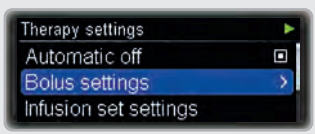


In the Settings menu press ▼ to move to Therapy settings.

Press ● to select.

The Therapy settings menu appears.

2

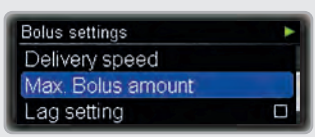


Press ▼ to move to Bolus settings.

Press ● to select.

The Bolus settings menu appears.

3



Press ▼ to move to Max. Bolus amount.

Press ● to select.

The Max. Bolus amount screen appears.

4

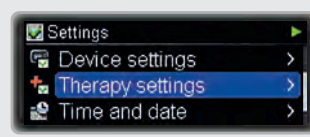
Press ▲ or ▼ to set the maximum bolus amount as needed.

Press ● to confirm.

Adjust the lag setting

In some situation (e.g. 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.

1

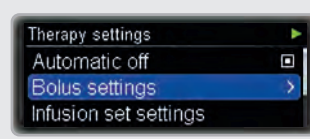


In the Settings menu press ▼ to move to Therapy settings.

Press ● to select.

The Therapy settings menu appears.

2



Press ▼ to move to Bolus settings.

Press ● to select.

The Bolus settings menu appears.

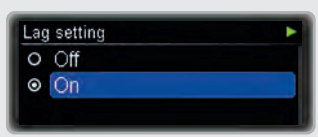
3

Press ▼ to move to Lag setting.

Press ● to select.

The Lag setting screen appears.

4



Press ▲ or ▼ to move to On or Off as needed.

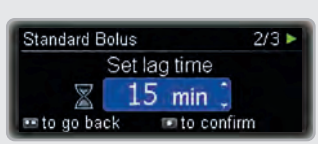
Press ● to select.

Note

How to set the lag time

With the 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.

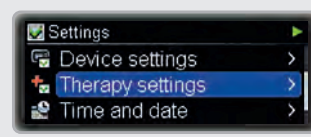
The bolus delivery will start after the lag time has expired.

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.

1

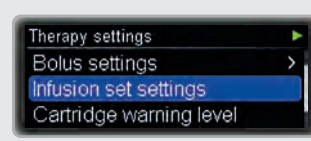


In the Settings menu press ▼ to move to Therapy settings.

Press ● to select.

The Therapy settings menu appears.

2



Press ▼ to move to Infusion set settings.

Press ● to select.

The Set tubing fill amount screen appears.

3

Press ▲ or ▼ to set the tubing fill amount.

Press ●.

The Set cannula fill amount screen appears.

4

Press ▲ or ▼ to set the cannula fill amount.

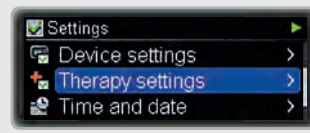
Press ● to confirm.

8.4.4 Adjusting the Cartridge Warning Level

When the insulin amount in your pump's cartridge is low your pump displays 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.

1



In the Settings menu press ▼ to move to Therapy settings.

Press ● to select.

The Therapy settings menu appears.

2

Press ▼ to move to Cartridge warning level.

Press ● to select.

The Cartridge warning level screen appears.

3

Press ▲ or ▼ to set the warning amount as needed.

Press ● to confirm.

8.5 Setting the Time and Date

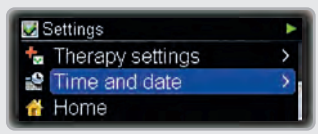
⚠ WARNING

It is vital that you set the correct time and date on your pump including a.m. and

p.m. for the 12-hour time format. Otherwise, you might not get the correct amount of insulin at the correct time.

Set the time

1

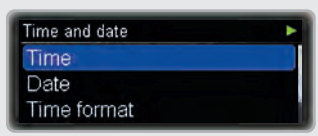


In the Settings menu press ▼ to move to Time and date.

Press ● to select.

The Time and date screen appears.

2



Press ● to select Time.

The Time screen appears with the hours field highlighted.

3

Press ▲ or ▼ to set the hours.

Press ●.

The minutes field is highlighted.

4

Press ▲ or ▼ to set the minutes.

Press ● to confirm.

Set the date

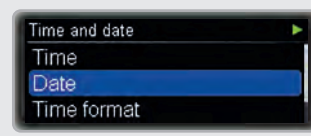
1

In the Settings menu press ▼ to move to Time and date.

Press ● to select.

The Time and date screen appears.

2



Press ▼ to move to Date.

Press ● to select.

The Date screen appears with the year field highlighted.

3

Press ▲ or ▼ to set the year.

Press ●.

The month field is highlighted.

4

Press ▲ or ▼ to set the month.

Press ●.

The day field is highlighted.

5

Press ▲ or ▼ to set the day.

Press ● to confirm.

Adjust the time format

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

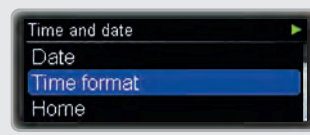
1

In the Settings menu press ▼ to move to Time and date.

Press ● to select.

The Time and date screen appears.

2



Press ▼ to move to Time format.

Press ● to select.

The Time format screen appears.

3

Press ▲ or ▼ to move to 24 h or 12 h as needed.

Press ● to select.

9 Maintaining Your Pump

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

9.1 General Safety Information

⚠ WARNING

Do not place your insulin pump in direct sunlight. The insulin and the pump must not become overheated. Protect your insulin pump from direct exposure to cold wind and temperatures over 40 °C (104 °F) and below 5 °C (41 °F). These conditions may damage the insulin and could 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 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

9.2 Inspecting Your Pump

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

Accessories

Only use the Accu-Chek Insight sterile products and accessories, which are designed to be used with your pump. You will find a list of sterile products and accessories in Appendix G: List of Accessories, page 124.

Replace and discard these items according to your doctor's or healthcare team's recommendations, and follow the instructions that come with these items.

9.3 Maintaining Your Pump

9.3.1 Cleaning Your Pump

Before cleaning your pump, put your pump in STOP mode. Always disconnect the infusion set from your body. Use a soft cloth to clean the outside of the pump. Avoid pressing the keys of your pump during cleaning, as this may accidentally put your pump back in RUN mode. If necessary, use a clean cotton cloth dampened with alcohol (70 % Isopropanol or 50 % Propanol). Do not use solvents, strong detergents, bleaching agents, scouring pads or sharp instruments for cleaning, as they may damage the pump. Make sure that no liquid enters the pump.

9.3.2 Replacing the Battery Cover

Replace the battery cover when it looks used or dirty and at least every 6 months.

9.4 Damage to Your Pump

⚠ WARNING

Check at regular intervals whether the pump has visible or tangible signs of damage. This applies in particular if the pump was dropped or was exposed to particular mechanical stress.

Dropping the pump could damage it. 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 page).

If you drop your pump, check **all** of the following items:

1. Infusion set
2. Pump and accessories (see "Appendix G: List of Accessories")
3. Cartridge
4. Battery cover
5. Self-test

1. Infusion set

What to check
Check that all connections within the infusion set are still closed.

What to do if check is not okay
Reconnect open connections and tighten loose ones.

2. Pump, sterile products and accessories

What to check
Check your pump and its sterile products and accessories for chips and cracks.

What to do if check is not okay
In case of damage or if you suspect a damage, contact your local pump support (see inside back cover page).

3. Cartridge

What to check
Remove the cartridge. Check that the cartridge is not damaged (e.g. microcracks, deformations, scratches). Be aware that the cartridge could be defective even if you cannot see any damages (e.g. microcracks). Make sure that no insulin is leaking from the cartridge.
If insulin is leaking from the cartridge, clean the cartridge compartment. Change the cartridge and transfer set. See chapter 2.5.

What to do if check is not okay
If the cartridge is damaged, discard it.

4. Battery cover

What to check
Remove the battery cover and battery. Check battery cover for cracks or loose parts.

What to do if check is not okay
Replace a damaged battery cover with a new battery cover.

What to check
Insert the battery. Place the battery cover on top of the battery. Push the battery cover all the way into the battery compartment until you hear the release click.
What to do if check is not okay
If you cannot insert the battery cover correctly, change the battery cover.

5. Self-test

After you insert the battery, your pump performs a self-test. Check that the self-test runs error-free. See chapter 2.3.
What to do if check is not okay
If the self-test does not run as described, change the battery and, if available, change the battery cover.
If the problem persists, contact your local pump support (see inside back cover page).
If the self-test ran error-free, select Change cartridge from the Cartridge and infusion set menu. See chapter 2.5.

9.5 Repairing Your Pump

Do not carry out a service on your pump or make repairs to it. Do not use any lubricants on the pump mechanism. If you have questions, contact your local pump support (see inside back cover page).

9.6 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 (see chapter 3.2, page 34), then:

1. Remove the battery to preserve the battery life.
2. Remove the cartridge.
3. Insert the battery cover.
4. 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)

9.7 Disposal

Insulin pump

Since your insulin pump may come into contact with blood during use, it can carry a risk of infection. The insulin pump falls outside the scope of the European Directive 2012/19/EU (Directive on waste electrical and electronic equipment (WEEE)). If you need to dispose of your insulin pump, return it to Roche (see inside back cover page) 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 respective 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, your pump displays Warning W31: Cartridge low. Warnings will not stop insulin delivery.
Maintenance messages	A maintenance message will be triggered when the pump requires your immediate action to maintain its functionality. For example, when the cartridge is empty your pump displays Maintenance M21: Cartridge empty. After a maintenance message 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.

All messages fall into the low-priority category according to EN 60601-1-8:2006.

10 RESPONDING TO A PUMP MESSAGE

Respond to a reminder, warning, maintenance message or error

1

When the message occurs, press ● to mute the signals.

2

Unlock the key lock if the keys are locked. See chapter 8.3.3, page 72.

Press ● again to confirm.

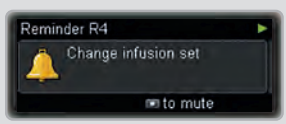
Then take appropriate action.

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

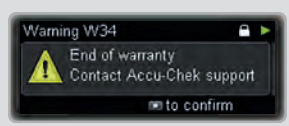
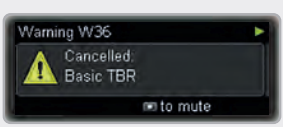
You can learn how to use and program reminders in the chapter about settings. See chapter 8.1, page 59.

If the key lock is active, you must unlock the keys before you can confirm the reminder. See chapter 8.3.3, page 72.

Press to mute	Press to confirm	Reminder
		Deliver Bolus Reminder (1 to 5): Remember to deliver a bolus as appropriate.
		Missed Bolus Reminder (1 to 5): Check whether you missed delivering a necessary bolus.
		Alarm clock (1 to 5): Wake up!
		Change infusion set Reminder: Change your infusion set as appropriate.
		TBR completed Reminder: The time of a programmed Temporary Basal Rate has expired. Check if you need to program a new one.

10.2 List of Warnings

If the key lock is active, you must unlock the keys before you can confirm the warning. See chapter 8.3.3, page 72.

Press to mute	Press to confirm	Warning
		W31 Cartridge low: The cartridge in your pump is nearly empty. Ensure that you have a full cartridge ready.
		W32 Battery low: The battery in your pump is nearly dead. Ensure that you have a new battery ready.
		W33 Invalid time/date: When the pump has been out of power for more than one hour, the time and date may no longer be correct. Set the correct time and date. See chapter 8.5, page 82.
		W34 End of warranty: The guarantee period for your pump has expired. Contact your local pump support (see inside back cover page) to discuss appropriate action.
		W36 TBR cancelled: A Temporary Basal Rate has been cancelled. Make sure that the cancellation was intended. Program a new TBR if appropriate.

Press to mute	Press to confirm	Warning
		W38 Bolus cancelled: A bolus has been cancelled. Make sure that the cancellation was intended. Program a new bolus if appropriate.
		W39 Loantime warning (loan pumps only): The loan time for your pump will expire soon. Contact your local pump support (see inside back cover page) to discuss appropriate action.

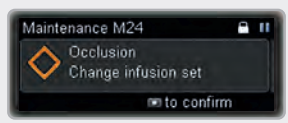
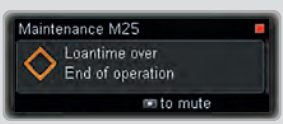
10.3 List of Maintenance Messages

After a maintenance message 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.

If the key lock is active, you must unlock the keys before you can confirm the maintenance message. See chapter 8.3.3, page 72.

Press to mute	Press to confirm	Maintenance message
		M20 Cartridge not inserted: Insert a cartridge.
		M21 Cartridge empty: There is no insulin left in the cartridge. Insert a new cartridge.
		M22 Battery empty: The battery in your pump is dead. Insert a new battery.

10 RESPONDING TO A PUMP MESSAGE

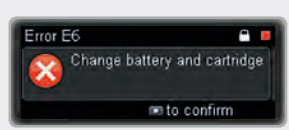
Press to mute	Press to confirm	Maintenance message
		M23 Automatic off: You did not press any pump key during the period specified for Automatic off. See chapter 8.4.1, page 76. After this maintenance message the pump will be in STOP mode.
		M24 Occlusion: The insulin cannot flow freely. Change the complete infusion set. If the maintenance message occurs again, change the cartridge as well.
		M25 Loantime over (loan pumps only): The loan time of your pump has expired. Contact your local pump support (see inside back cover page) to discuss appropriate action. After this maintenance message the pump will be in STOP mode.
		M26 Cartridge change not completed: The cartridge change process was interrupted. Repeat the cartridge change.
		M27 Data download failed: The data transfer to a computer has been interrupted. Restart the data download.

Press to mute	Press to confirm	Maintenance message
		M28 Pause mode timeout: Your pump has been in PAUSE mode for more than 15 minutes and has switched to STOP. TBR and boluses have been cancelled. Restart insulin delivery and reprogram TBR and boluses as appropriate.
		M29 Battery type not set: The battery type was not set during the start-up process. Set the correct battery type.
		M30 Cartridge type not set: The cartridge type was not set during the Change cartridge or start-up process. Set the correct cartridge type.

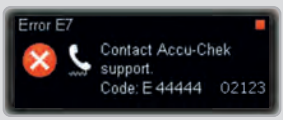
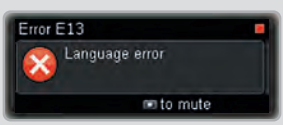
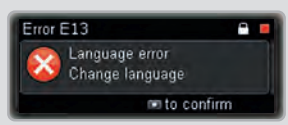
10.4 List of Errors

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 page) for advice and change to alternative insulin therapy if necessary.

If the key lock is active, you must unlock the keys before you can confirm the error message. See chapter 8.3.3, page 72.

Press to mute	Press to confirm	Error
		E6 Mechanical error: The mechanical system of the pump does not work properly. Change the battery and the cartridge.

10 RESPONDING TO A PUMP MESSAGE

Press to mute	Press to confirm	Error
		E7 Electronic error: When this message occurs, change the battery. If the message still occurs, you cannot resolve the problem yourself. Call your local pump support (see inside back cover page) for advice. Change to an alternative insulin therapy.
		E10 Rewind error: The piston rod has not rewound correctly during the cartridge insertion. Change the battery and repeat the cartridge change.
		E13 Language error: The pump can no longer show the selected language. Change to another language. If you cannot select your language and cannot read another available language, then contact your local pump support (see inside back cover page).

Appendices

Appendix A: Technical Data

General Technical Data	
Maximum dimensions (with adapter)	Approx. 84 × 52 × 19 mm (3.3 × 2.0 × 0.7 inches)
Weight	An empty insulin pump: approximately 99 g (3.5 ounces) Pump including cartridge, battery and infusion set: approximately 122 g (4.3 ounces)
Pump casing	Shock- and scratch-resistant plastic, resistant to pharmaceuticals, all edges rounded
Temperature ranges[1]	During operation: +5 °C to +40 °C (+41 °F to +104 °F) During storage: +5 °C to +45 °C (+41 °F to +113 °F) During transport: –20 °C to +50 °C (–4 °F to +122 °F) Time to cool down from max. storage temperature to operating temperature[2]: 15 min
Air humidity	During operation: 20 % to 90 % relative humidity During storage: 20 % to 85 % relative humidity During transport: 20 % to 95 % relative humidity
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. Do not use lithium batteries that do not comply with IEC 60086-4. Batteries should have a minimum capacity of 1200 mAh. Do not use carbon zinc or rechargeable (NiCd/NiMH) batteries.

[1] See the instructions for use of the insulin you are using for information on the acceptable temperature range for operation, storage and transport.

[2] according to IEC 60601-1-11:2015

General Technical Data	
Lifetime of battery	If used in a typical usage pattern (50 U/day using U100 insulin, ambient temperature +23 °C ±2 °C [+73 °F ±4 °F] at minimum/intermediate/maximum basal rate), the battery life is approximately: Lithium (1200 mAh): at least 21 days with *Bluetooth* wireless technology switched off Lithium (1200 mAh): at least 20 days with *Bluetooth* wireless technology switched on Alkaline (1200 mAh): at least 6 days with *Bluetooth* wireless technology switched off Alkaline (1200 mAh): at least 5 days with *Bluetooth* wireless technology switched on If you use your pump with third-party products, the actual battery life may vary from the battery life specified in this User's Manual.
Expected Service Life	5 years
Data storage time	The time and date are safely stored in the memory for about 10 hours after the battery has been removed. Other insulin pump settings (for example, the hourly basal rates, remaining cartridge content, bolus increments, active user profile and alarm settings) 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.
Basal rate	Min. 0.02 U/h, max. 25 U/h.
Bolus	The maximum 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 and 2.0 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.

General Technical Data		
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	
Priming speed	12 U/min	
Sound pressure	In addition to tactile notification the pump generates on average a sound pressure of at least 45 dB.	
Message Maintenance M24: Occlusion		Maximum time between occlusion and message
	Cartridge type	1.6 ml
	Basal rate 1.0 U/h	3:10 h
	Basal rate 0.02 U/h*	280 h
Maximum occlusion volume before the message Maintenance M24: Occlusion** occurs	1.6 ml cartridge: 2.0 U	
Maximum system occlusion alarm threshold	330 kPa (3.3 bar)	
Maximum pressure	350 kPa (3.5 bar)	
Minimum opening pressure adapter vent	0.65 bar	
Flow (delivery rate)	Variable	

* The maximum time will be indicated with 144 h as this is the recommended interval for changing infusion sets.

** Determined using measurement methods according to IEC 60601-2-24:2012.

General Technical Data	
Maximum quantity delivered at a single fault condition	≤0.8 U
Cartridge	You can use the following pre-filled cartridges with your Accu-Chek Insight insulin pump: ■ NovoRapid® PumpCart® (prefilled cartridge containing 1.6 ml solution for injection) ■ Fiasp®, PumpCart® (prefilled cartridge containing 1.6 ml solution for injection) Check the availability in your country or ask your local pump support.
Infusion sets	Applied part: the 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 twice. Whenever a defect or fault occurs in the control system, it is identified by the supervising microprocessor and vice versa. For example, if overdelivery occurs, the motor is immediately switched off and the pump displays Error E7: Electronic error. The control system and supervising system signalize the error acoustically (beeps) and in a tactile way (vibrations). Additionally the control system shows the specific error 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 (1.3 m for 60 minutes).

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 1	The Accu-Chek Insight insulin pump must emit electromagnetic energy in order to perform its intended function. In rare cases, nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	The Accu-Chek 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 that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

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 the Accu-Chek Insight insulin pump should ensure 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 5 s	Not applicable	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 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.

* Test levels according to IEC 60601-1-2:2014

Note:

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

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[a)]
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 kHz to 800 MHz
Radiated RF IEC 61000-4-3	10 V/m 800 MHz to 2.5 GHz	[b)]E2a = 2 V/m for 2.3 GHz to 2.5 GHz [c)]E2b = 10 V/m for 800 MHz to 2.3 GHz and 2.5 GHz to 2.7 GHz	$da = 11.7\sqrt{P}$ 2.3 GHz to 2.5 GHz $db = 2.3\sqrt{P}$ 800 MHz to 2.3 GHz and 2.5 GHz to 2.7 GHz

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 meter (m).
Field strengths from fixed RF transmitters as determined by an electromagnetic site survey,[d)] should be less than the compliance level in each frequency range.[e)]
Interference may occur in the vicinity of equipment marked with the following symbol: 

a) Possible shorter distances outside ISM bands are not considered to have a better applicability of this table.

b) Exclusion band for *Bluetooth* ISM 2.4 GHz communication channel

c) Compliance band for the system equipment

d) 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.

e) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

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 (W)	Separation distance according to frequency of transmitter (m)			
	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 2.5 GHz to 2.7 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 meter (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.

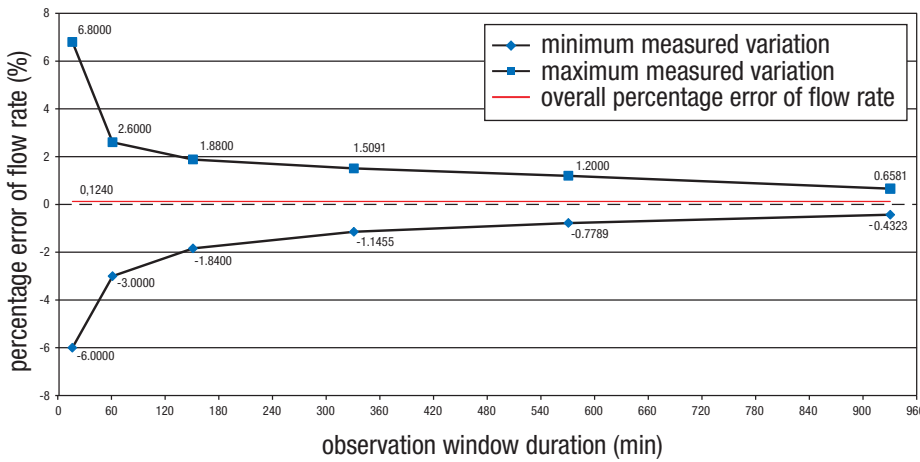
Note:

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

Accuracy of Flow Rate

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. This trumpet curve is an example that refers to all compatible infusion sets. See Appendix G: List of Accessories, page 124 for more information on compatible infusion sets. The maximum deviation of the delivered amount (overall mean percentage error of flow rate) for U100 insulin is ≤ ±5 %*.



* The measurements were made at a medium basal rate of 1.0 U/h according to IEC 60601-2-24:2012 with the Accu-Chek Insight Flex and Accu-Chek Insight Tender infusion sets with 100 cm tubing at room temperature. The measurement refers to the maximum deviation of the delivered amount. More than 18 tests performed. All within specification.

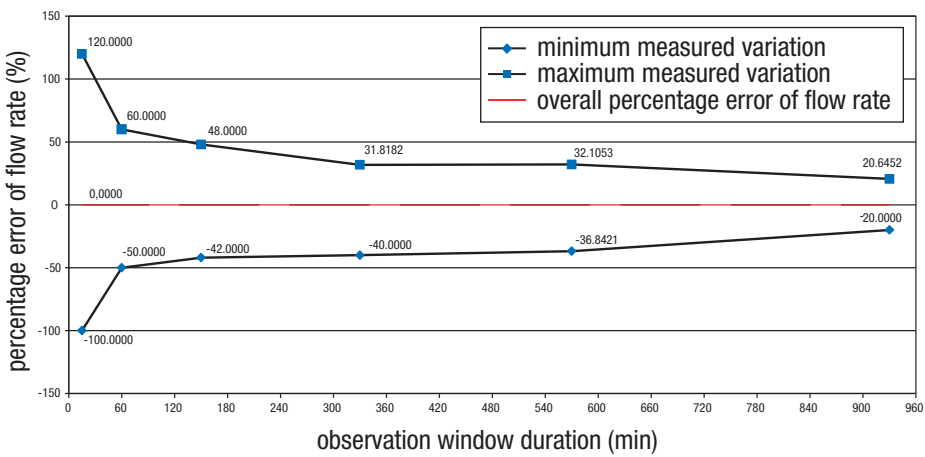
Accuracy of flow rate at minimum hourly basal rate of 0.02 U/h

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. This trumpet curve is an example that refers to all compatible infusion sets. See Appendix G: List of Accessories, page 124 for more information on compatible infusion sets.

The maximum deviation of the delivered amount (overall mean percentage error of flow rate) for U100 insulin is ≤ ±60 %*.

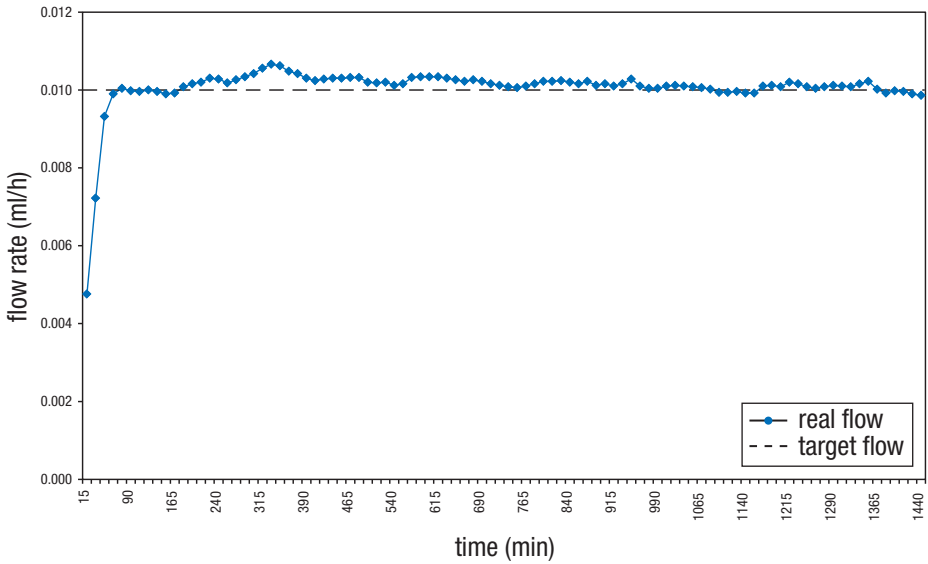
It is the responsibility of the healthcare professional to decide whether the accuracy of the flow rate is sufficient for the patient.



* The measurements were made at the minimum rate of 0.02 U/h according to IEC 60601-2-24:2012 with the Accu-Chek Insight Flex and Accu-Chek Insight Tender infusion sets with 100 cm tubing at room temperature. The measurement refers to the maximum deviation of the delivered amount.

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 error of flow rate) for 25 U of U100 insulin is ≤ ±5 %* where your Accu-Chek Insight insulin pump is located ≤ 0.8 m (2.62 feet) above/below the infusion site.

Bolus

For U100 insulin the maximum deviation of a maximum bolus is ≤ ±5 % and the maximum deviation of a minimum bolus is ≤ ±50 %.**

* The measurements were made at a medium basal rate of 1.0 U/h according to IEC 60601-2-24:2012 with the Accu-Chek Insight Flex and Accu-Chek Insight Tender infusion sets with 100 cm tubing at room temperature.

** The measurements were made according to IEC 60601-2-24:2012 with the Accu-Chek Insight Flex and Accu-Chek Insight Tender infusion sets with 100 cm tubing at room temperature.

Appendix B: Configuration Parameters

Parameter	Standard parameter settings	Available value or range on the pump
Maximum basal delivery (maximum hourly basal rate combined with maximum temporary basal rate)	62.5 U/h	62.5 U/h
Default basal rate	0	0–25 U/h
Hourly basal rates increment	0.01 (from 0.02 U/h to 5.00 U/h) and 0.1 (from 5.00 U/h to 25.0 U/h)	
Hourly basal rates	0, 0.02–25.0 U/h	0, 0.02–25.0 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	0–25.0 U	0–50.0 U
Bolus amount increments for quick bolus	0.5 U	0.1, 0.2, 0.5, 1.0, 2.0 U
Bolus amount increments for standard bolus, extended bolus and multiwave bolus	0.05 U (0–2 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)	4 h	15 min to max. 24 h
Bolus duration increments	15 min	

Parameter	Standard parameter settings	Available value or range on the pump
Bolus delivery speed	Standard: 12 U/min	Standard: 12 U/min Moderate: 9 U/min Slow: 6 U/min Very slow: 3 U/min
Maximum bolus	25 U	1–50.0 U
Lag time	Off	Off or On If On: 0 to 60 min in 15 min increments
Infusion set fill amount	14.0 U	0–25.0 U
Cannula fill amount	0.7 U	0.0–2.0 U
Display orientation	Standard	Standard or rotated
Display brightness	2	0–5 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 = silent)
Signal	Acoustic and tactile	Acoustic, tactile or acoustic and tactile
Modes	Normal: Volume 3 / sound & vibration Vibrate: Volume 0 / vibration Quiet: Volume 1 / vibration Loud: Volume 4 / sound & vibration	Normal: Volume 0–5 / sound & vibration Vibrate: Volume 0–5 / vibration Quiet: Volume 0–5 / vibration Loud: Volume 0–5 / sound & vibration

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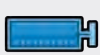
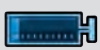
Parameter	Standard parameter settings	Available value or range on the pump
Battery type	AAA (FR03) LITHIUM 1.5 V	AAA (FR03) LITHIUM 1.5 V or AAA (LR03) ALKALINE 1.5 V
Key lock timeout	10 sec.	4–60 sec.
Automatic off	Off	On (1–24 h) or Off (0 h)
Reminder	Off	Deliver Bolus, Missed Bolus, Alarm Clock, Infusion set change off, once or repeatedly
Time format	24 h	24 h or 12 h am/pm
Bluetooth	Off (if delivered with another *Bluetooth* wireless technology device the standard parameter is on)	Off or On
Cartridge warning level	25 U	0–100 U
User profile	Standard	Standard, Expressive, Diminished
Quick bolus	Off	Off or On

Appendix C: Abbreviations

Abbreviation	Meaning
approx.	Approximately
h	Hour(s)
IEC	International Electrotechnical Commission
kPa	Kilopascal
sec.	Seconds
TBR	Temporary Basal Rate
U	International Units in context with biological effectiveness of certain insulin amount
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
	RUN mode (pump running)
	STOP mode (pump stopped)
	PAUSE mode (pump paused)
	Operation successful
	Connection failed
	Battery full
	Battery low
	Battery empty
	Cartridge full
	Cartridge low
	Cartridge empty
	Key lock activated

Icon	Meaning
	OK key
	Quick bolus key
	Up key
	Down key
	Cartridge and infusion set menu
	Change cartridge menu
	Fill cannula menu
	Fill tubing menu
	Bolus
	Bolus data
	Cancel bolus

Icon	Meaning
	Standard bolus
	Extended bolus
	Multiwave bolus
	Immediate amount multiwave bolus
	Delayed amount multiwave bolus
	Basal rate
	Activate basal profile
	Temporary Basal Rate
	TBR data
	Program basal profile
	Modes
	Signal mode
	Reminder

Icon	Meaning
	Event data
	Settings
	Therapy settings
	Device settings
	Pump data
	Pump timer
	Flight mode
	Home
	Duration
	Please wait/lag time
	Total icon
	Daily totals
	Time and date settings

Icon	Meaning
	Software version
	Maintenance
	Warning
	*Bluetooth* wireless technology
	Error
	Error support
	Communication
	Radio button selected
	Radio button not selected
	Icon on
	Icon off

General Symbols

Symbol	Meaning
	Caution, refer to safety-related notes in the instructions for use accompanying this product.
	Follow instructions for use
	Consult instructions for use
	Sterilized using ethylene oxide
	Sterilized using irradiation
	Global Trade Item Number
	Batch code
	Catalogue number
	Serial number
	Use by
	Manufacturer
	Date of manufacture

Symbol	Meaning
	Temperature limitation (store at)
	Admissible humidity range
	Admissible air pressure range
	Use only once
	Do not use if package is damaged
	Fragile – handle with care!
	Keep dry
	Keep away from sunlight
	Recycling
	Do not throw away
	Flammable
	*Bluetooth* wireless technology
	Non-ionizing radiation

Symbol	Meaning
	Electronic device of type BF according to the standard IEC 60601-1. Protection against electrical shock.
IPX8	Symbol for protection against the effect of temporary immersion in water (up to 60 minutes and 1.3 meters [4.3 feet]), according to IEC 60529.
	Complies with the provisions of the applicable EU Legislation
FCC ID	The FCC ID (Federal Communications Commission Identification) indicates that the radio frequency equipment has passed the equipment authorization process for the United States of America.
IC ID	The IC ID (Industry Canada Identification) indicates that the radio frequency equipment has passed the equipment authorization process for Canada.

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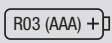
Symbol	Meaning
	The compliance mark indicates that the product complies with the applicable standard and establishes a traceable link between the equipment and the manufacturer, importer or their agent responsible for compliance and for placing it on the Australian and New Zealand market.
	Recommended battery
Rx only	Federal law (USA) restricts this device to sale by or on the order of a physician
	Warning against device use in electromagnetic or high electrical fields or environments

Appendix E: Warranty and Declaration of Conformity

Warranty

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

Declaration of Conformity

Roche hereby declares that the radio equipment type Accu-Chek Insight insulin pump is in compliance with Directive 2014/53/EU.

The full text of the EU declaration of conformity may be found at the following Internet address:
http://declarations.accu-chek.com

Radio Frequency Connectivity

Bluetooth wireless technology operating in the frequency band of 2.400 GHz to 2.4835 GHz.

Maximum Transmitted Power

Accu-Chek Insight insulin pump: 20 mW

Appendix F: Details on User Profiles

In addition to the display and the vibrations, your pump uses a sophisticated sound pattern to provide you with information on the pump's current status and give you feedback on values you programmed. With the user profiles the pump offers special support that may be helpful for people with impaired hearing or impaired eyesight. In the chapter about setting you can learn how to select a user profile. See chapter 8.3.2, page 71.

Diminished

When Diminished is selected, all sounds of the pump will be issued one octave lower than in the user profile Standard. This may be helpful for users with impaired hearing. Discuss using this user profile with your healthcare professional if you have hearing problems. Additionally, it is highly recommended that you pay special attention to the vibrations and watch the pump's display frequently.

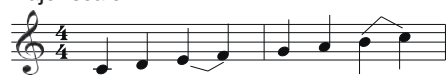
Expressive

Discuss using the Expressive user profile with your caregiver and healthcare professional. With some training and experience this user profile may help you to operate the pump if you have impaired eyesight.

When Expressive is selected

- The Scrolling function for all numeric value settings is switched off
- Numeric values in many screens are additionally signalled using acoustic feedback
- For pump messages (errors, maintenance messages, warnings, reminders) the pump can provide the corresponding numeric code using acoustic feedback in addition to the standard signal

The acoustic signals are designed using a C major scale:



Tone	Frequency (Hz, ± 5 %)
DO2	528
RE2	594
MI2	660
FA2	704
SO2	792
LA2	880
TI2	990
DO3	1056
RE3	1188
MI3	1329
FA3	1408

Tone	Frequency (Hz, ± 5 %)
SO3	1584
LA3	1760
TI3	1980
DO4	2112
RE4	2376
MI4	2640
FA4	2816
SO4	3168
LA4	3520

Scrolling function

Switching off the scrolling function enables you to count the number of increments programmed. The increment for bolus amounts is 0.5 U by default for all bolus amounts. You can program to other increments using compatible Accu-Chek software.

Numeric values

Additional acoustic feedback for numeric values is provided for

- Bolus amounts (3 sec. after last increment programmed)
- Bolus durations (3 sec. after last increment programmed)
- Lag time (3 sec. after last increment programmed)
- TBR percentages (3 sec. after last increment programmed)
- TBR durations (3 sec. after last increment programmed)
- Basal profile total daily dose (when screen is displayed)
- Quick info screen: Time, last bolus amount, total daily dose, cartridge content, battery percentage (when screen is displayed)

Each digit in a numeric value is allocated an acoustic signal

Digit	Acoustic code
0	DO3-LA2
1	DO3
2	DO3-RE3
3	DO3-RE3-MI3
4	DO3-RE3-MI3-FA3
5	DO3-RE3-MI3-FA3-SO3
6	DO3-RE3-MI3-FA3-SO3-LA3
7	DO3-RE3-MI3-FA3-SO3-LA3-TI3
8	DO3-RE3-MI3-FA3-SO3-LA3-TI3-DO4
9	DO3-RE3-MI3-FA3-SO3-LA3-TI3-DO4-RE4

For numbers with more than one digit, there will be a small pause between the signals for each digit. Dots or colons between digits are indicated by a very short DO.

Examples:

Quick info screen – time 9:29

From status screen press ▲ to move to quick info. Wait for the acoustic signal.

Digit	Acoustic code
9	DO3-RE3-MI3-FA3-SO3-LA3-TI3-DO4-RE4
:	DO
2	DO3-RE3
9	DO3-RE3-MI3-FA3-SO3-LA3-TI3-DO4-RE4

Program extended bolus screen – bolus amount 6.00 U, bolus duration 2:00 h

Digit	Acoustic code
6	DO3-RE3-MI3-FA3-SO3-LA3
.	DO
0	DO2-LA2
0	DO2-LA2

Digit	Acoustic code
2	DO2-RE3
:	DO
0	DO2-LA2
0	DO2-LA2

Pump messages

For each type of pump message there is a specific standard acoustic code and the message number is signalled as described for numeric values.

Message type	Acoustic code
Error	LA4-DO3-SO3-DO3 pause DO3-RE3-MI3-FA3
Maintenance	LA4-DO3-SO3-DO3 pause DO3-RE3-MI3
Warning	LA4-DO3-SO3-DO3 pause DO3-RE3
Reminder	The signal can be selected during programming the according reminder

Example:

Maintenance M21: Cartridge empty

When the message occurs, the standard signal for the corresponding message sounds.

Content	Acoustic code
Maintenance	LA4-DO3-SO3-DO3 pause DO3-RE3-MI3

Press ● to mute.

Then press ▲ to hear the specific message code including the message number:

Content/ Digit	Acoustic code
Maintenance	LA4-DO3-SO3-DO3 pause DO3-RE3-MI3
2	DO3-RE3
1	DO3

Appendix G: List of Accessories

Cartridge	You can use the following pre-filled cartridges with your Accu-Chek Insight insulin pump: ■ NovoRapid® PumpCart® (prefilled cartridge containing 1.6 ml solution for injection) ■ Fiasp®, PumpCart® (prefilled cartridge containing 1.6 ml solution for injection) Check the availability in your country or ask your local pump support.
Battery cover	Accu-Chek Insight insulin pump battery cover Accu-Chek Insight service pack
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 Accu-Chek Insight Tender infusion set Accu-Chek Insight Rapid infusion set Accu-Chek Insight Adapter & Tubing* *Required for connecting the infusion set to the pump.
Compatibility	You can pair the following devices via *Bluetooth* wireless technology with your Accu-Chek Insight insulin pump: ■ a mobile device with mySugr® pump control installed ■ Accu-Chek Smart Pix diabetes management system Only 1 device can actively control the insulin pump at a time. See chapter 8.2.4, page 65 for more information about pairing the pump with other devices.

⚠ WARNING

- The correct functioning of your Accu-Chek Insight insulin pump can only be guaranteed if you use accessories, including software and apps **available in your country**, designated for use with your insulin pump by Roche.
- Do not use infusion sets or other accessories that are not designated for use with your Accu-Chek Insight insulin pump by Roche as this could lead to leakage or malfunction of the pump and underdelivery or overdelivery of insulin.

Note

For additional Accu-Chek products and accessories 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 message if no keys are pressed within a programmed time period in RUN mode. See chapter 8.4.1, page 76.
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**	*Bluetooth* technology is the global wireless standard for simple, secure connectivity. This technology is common in many portable devices, such as, PCs or 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 determined by your doctor or healthcare team's guidelines, your blood glucose level, your food intake and your activity level.
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.
Cartridge	The insulin reservoir of your insulin pump.
Cartridge compartment	The chamber in your insulin pump for the cartridge.

Daily insulin total	The total amount of insulin (basal rate plus boluses) delivered in a 24-hour period, 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 in STOP mode.
Flight mode	Activate the flight mode when airborne or in other situations where it is required to switch off *Bluetooth* wireless technology. 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.
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 site	The place where the infusion set cannula or needle is inserted into your subcutaneous tissue to deliver insulin.
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).
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.
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.
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 60 minutes a day and 1.3 meters [4.3 feet]).

Lag Time	With the lag time you can specify a delay between programming a bolus and the actual beginning of the bolus delivery.
Maintenance	A maintenance message will be triggered when the pump requires your immediate action to maintain its functionality. After a maintenance message 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 maintenance messages, your pump switches to PAUSE mode and interrupts the insulin delivery. However, if you close the adapter within 15 minutes, 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.
Status screen	The status screen indicates if your pump is in RUN, PAUSE or STOP mode. 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 maintenance messages 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 (TBR)	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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Your contact for assistance with and additional information about your Accu-Chek Insight insulin pump*:

Distributed in the United Kingdom by:
Roche Diabetes Care Limited
Charles Avenue, Burgess Hill
West Sussex, RH15 9RY, **United Kingdom**
Accu-Chek Pump Careline [1]:
UK Freephone number: 0800 731 22 91
ROI Freephone number: 1 800 88 23 51

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

burgesshill.insulinpumps@roche.com
www.accu-chek.co.uk
www.accu-chek.ie

Roche Diabetes Care South Africa (Pty) Ltd.
Hertford Office Park, 90 Bekker Road
Vorna Valley, Midrand
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1686
Email: info@accu-chek.co.za
Call Toll Free: 080-34-22-38-37 (SA only); +254 20 523 0560 (Kenya only);
+27 (11) 504 4677 (Other countries)

* Note that the local pump support in your country of residence may only provide support in the corresponding official language(s).

CE 0123

Approved/listed/registered under the product name: Accu-Chek Insight insulin pump

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www.accu-chek.com

ACCU-CHEK®

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