ACCU-CHEK® Spirit Combo

Roche

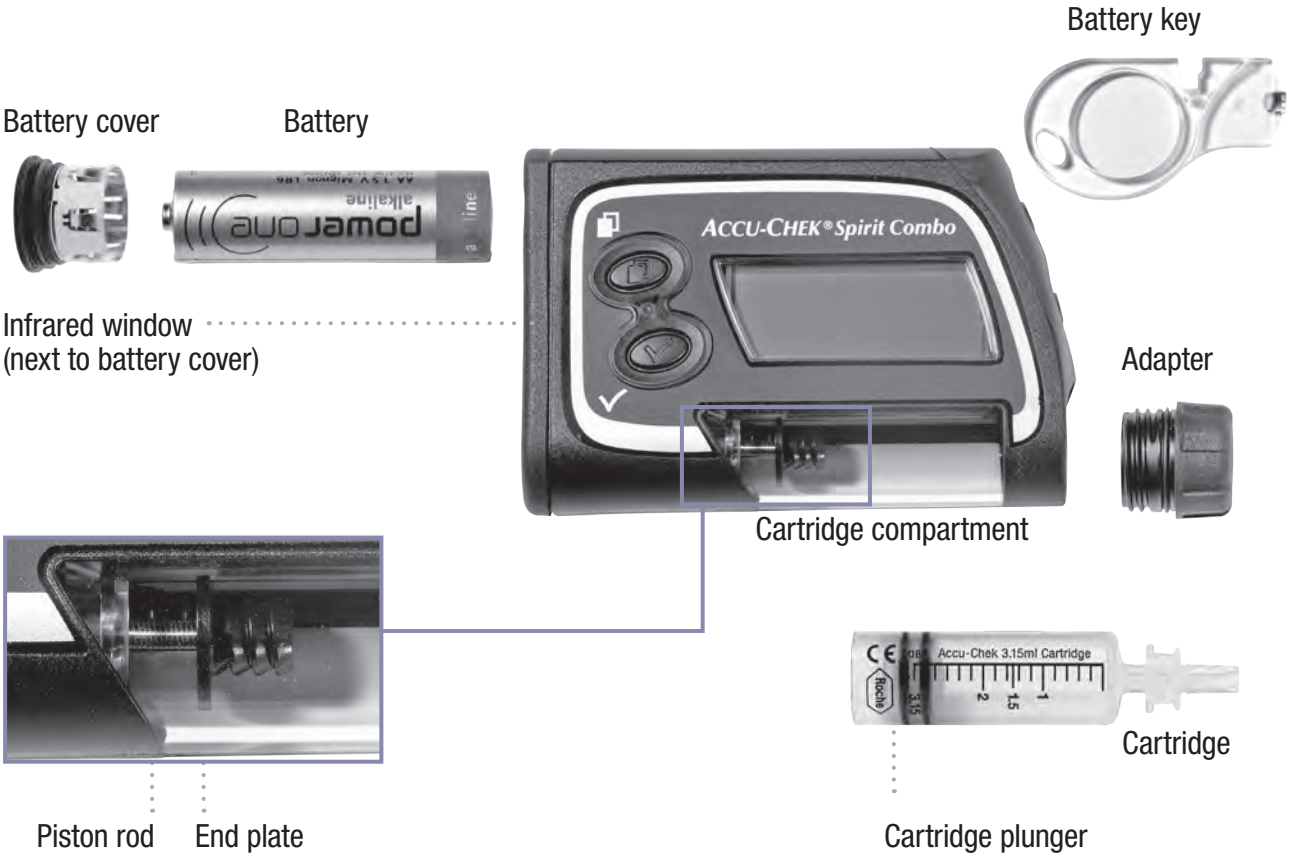
User's Manual

Accu-Chek® Spirit Combo Insulin pump

ACCU-CHEK®

Your insulin pump

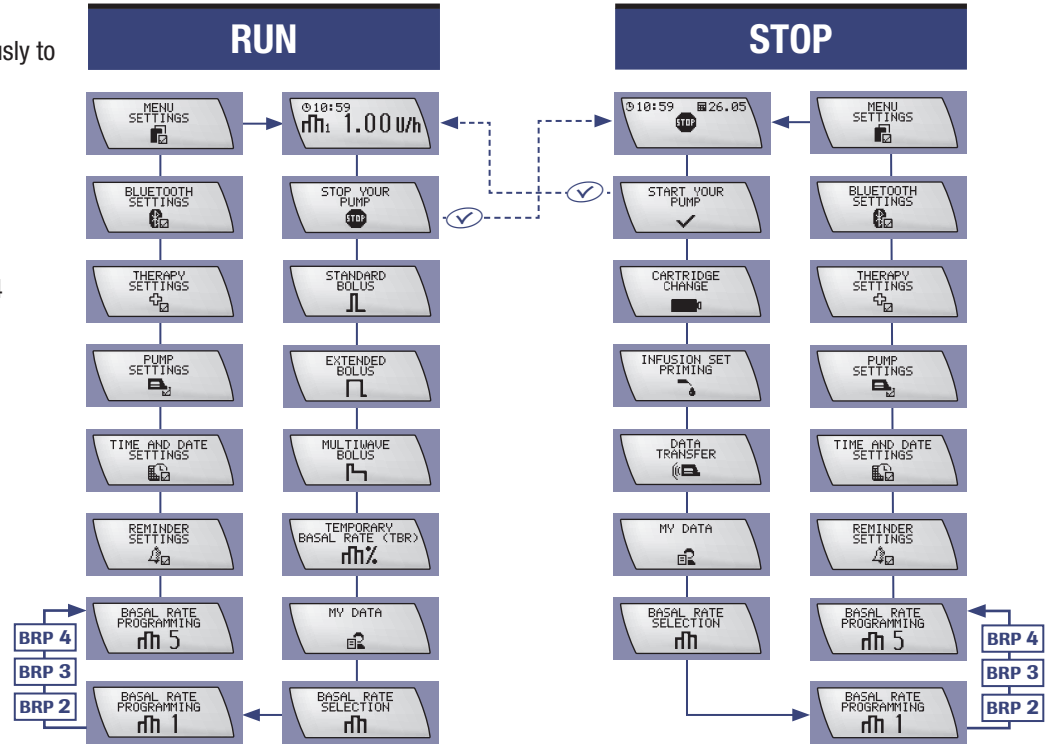
Pump details and accessories



Overview of the ADVANCED user menu

- Press ⊕ to move forwards
- Press ⊕ + ⊕ simultaneously to move backwards
- Press ✓ to select or save
- Press ⊕ to go up
- Press ⊕ to go down

BRP = Basal Rate Profile 2–4

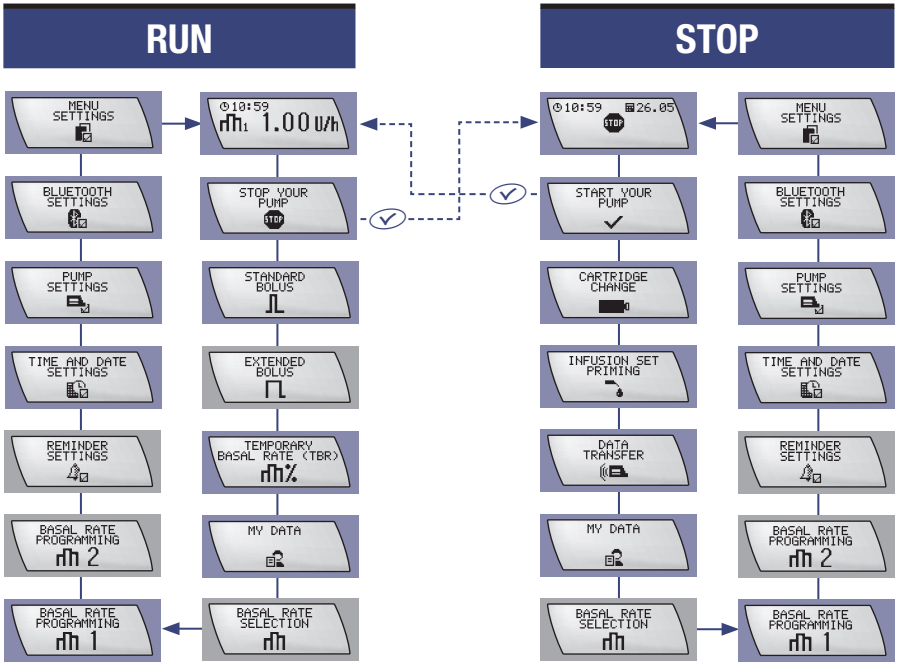


Overview of the STANDARD and CUSTOM user menus

Accessible menus in the CUSTOM user menu can be selected using the appropriate Accu-Chek PC software (sold separately).

- Press ⧉ to move forwards
- Press ⧉ + ⏶ simultaneously to move backwards
- Press ✓ to select or save
- Press ⏶ for up
- Press ⏷ for down

= not accessible in the STANDARD user menu



Dear user of the Accu-Chek Spirit Combo insulin pump,

This User's Manual is provided for you, as a person with diabetes, and for healthcare professionals. It contains all the necessary information for the safe and efficient use of your Accu-Chek Spirit Combo insulin pump. Regardless of your level of experience with pump therapy, please read this User's Manual carefully before beginning insulin pump therapy. Always refer to this User's Manual first, when you have questions about or have problems using your insulin pump. If you cannot find the solution to your problem in this document, we recommend that you contact your local pump support. You will find the address on the inside back cover of this manual.

Your Accu-Chek Spirit Combo insulin pump has been developed exclusively for the continuous subcutaneous delivery of U100 short-acting insulin or fast-acting insulin analogue. **Whether insulin pump therapy is the appropriate way of treating your diabetes must be decided by your healthcare professional.** The correct insulin type for the treatment of your insulin-dependent diabetes mellitus will be prescribed by your doctor or healthcare team. *You should not begin pump therapy unless you have attended the appropriate training course.*

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 for use coming with your insulin, infusion set, and additional devices used for your insulin therapy.

Your Accu-Chek Spirit Combo insulin pump is a valuable medical device. We strongly encourage you to add your insulin pump to your home contents insurance policy to protect you in case of accidental damage or loss. Ask your insurance agent for details.

About this User's Manual

To ensure the safe and convenient use of your new Accu-Chek Spirit Combo insulin pump, some information in this User's Manual requires particular attention. This information is presented as "WARNING", "CAUTION" or "Note".

- A "WARNING" informs you about risks to your health. Neglecting this information may even lead to life-threatening situations in some cases.
- A "CAUTION" informs you about risks to your device. Malfunction or damage may result if you do not follow these instructions.
- A "Note" contains important information relating to the efficient and smooth operation of your new Accu-Chek Spirit Combo insulin pump.

1 Understanding your new system 1

1.1 Overview 1
1.2 Display and sounds 3
1.3 Keys and key combinations 9
1.4 Accessories and disposables 13
1.5 Emergency kit 16
1.6 General safety information 17

2 Getting started 19

2.1 Before you begin 19
2.2 Inserting the battery 19
2.3 Start-up process 23
2.4 Setting the time and date 26
2.5 Your basal rate profile 29
2.6 Connecting the cartridge, adapter and infusion set 36
2.7 Inserting the cartridge 38
2.8 Priming the infusion set 43
2.9 Positioning the infusion set 46
2.10 Starting insulin delivery 50
2.11 Stopping insulin delivery 51
2.12 General safety information 52

3 Using your pump in daily life 55

3.1 Wearing your pump 55
3.2 Interruption of insulin pump therapy 58
3.3 Your insulin pump and water 61
3.4 Changing the infusion set 63
3.5 Changing the cartridge and infusion set 67
3.6 General safety information 70

4 Boluses and Temporary Basal Rates 71

4.1 Understanding boluses 71
4.2 Programming a Standard Bolus 72
4.3 Programming an Extended Bolus 78
4.4 Programming a Multiwave Bolus 83
4.5 Programming a Temporary Basal Rate (TBR) 87
4.6 General safety information 92

5 Personalizing your pump 93

5.1 Introduction 93
5.2 Selecting a user menu 95
5.3 STANDARD user menu 97
5.4 Viewing your pump data 99
5.5 Transferring your data to a computer 105
5.6 Pump settings 107
5.7 ADVANCED user menu 114
5.8 Basal rate profiles 115
5.9 Setting a reminder 118
5.10 Therapy settings 120
5.11 CUSTOM user menu 124

6 Using the Accu-Chek Spirit Combo insulin pump with the meter 127

6.1 Meter 127
6.2 Switching *Bluetooth*® wireless technology ON and OFF 129
6.3 Pairing your pump with the meter 130
6.4 Troubleshooting the *Bluetooth*® connection 133

7 Care and Maintenance 137

7.1 Inspecting your pump 137
7.2 Damage to your pump 139
7.3 Your insulin pump and water 140
7.4 Repair of your pump 142
7.5 Maintaining your pump 143
7.6 Storing your pump 144
7.7 Disposing of your pump 144

8 Warnings and errors 145

8.1 Confirming a warning or error 146
8.2 List of warnings 147
8.3 List of errors 153
8.4 List of reminders 164

9 Troubleshooting 165

9.1 Therapy-related issues 166

Appendix A: Technical data 169
Appendix B: Configuration parameters 185
Appendix C: Sterile products and accessories 188
Appendix D: Abbreviations 191
Appendix E: Beeps and melodies 192
Appendix F: Symbols 198
Appendix G: Warranty and Declaration of Conformity 204
Index 205
Glossary 209
Quick reference table for errors, warnings and reminders 214
Reminder 216
Bluetooth® registration 217

1 Understanding your new system

1.1 Overview

Your Accu-Chek Spirit Combo insulin pump has many helpful features that help to ensure safe and efficient pump therapy.

Note *In this User's Manual the term "meter" always refers to your Accu-Chek diabetes management device, which is compatible with your Accu-Chek Spirit Combo insulin pump.*

1.1.1 Summary of features

Interaction with the meter
Your Accu-Chek Spirit Combo insulin pump has been designed for use with the meter. This intelligent blood glucose meter enables you to communicate with the pump using *Bluetooth*® wireless technology.

Three user menus
Your Accu-Chek Spirit Combo insulin pump has been designed to adapt to your level of experience in pump therapy – whether you are a beginner or an experienced pump user. Your pump "grows" with you!
You can use one of 3 menus – STANDARD, ADVANCED or CUSTOM – to access the functions and settings you will need from day to day.

STANDARD	This is the most basic menu – designed for simplicity and comfort.
ADVANCED	This menu helps you to adjust your therapy to a wider range of situations.
CUSTOM	The CUSTOM menu enables you to fine-tune your pump according to your personal needs and skill level.

See chapter *5 Personalizing your pump.*

Five basal rate profiles
You can choose from 5 basal rate profiles in line with your different daily routines.

Three bolus types
Your Accu-Chek Spirit Combo insulin pump enables you to program 3 bolus types, each corresponding to different situations you may encounter, and this provides you with a lot of flexibility.

Quick Bolus
You can program a Quick Bolus without looking at the display screen and check that it is correctly programmed by counting the beeps and vibrations. This is particularly useful when you want to program the bolus discreetly in public.

Warnings and errors signalled in two ways
For your safety, warnings and errors are signalled using both audible beeps and vibration of the pump. In addition, the beep tones are fully adjustable – from silent to loud.

Data transfer
The built-in infrared interface on the bottom of your Accu-Chek Spirit Combo insulin pump enables you to transfer data between your pump and a personal computer.

Rotating display
Your pump's display can be rotated by 180 degrees, and you can also adjust its contrast. Combined with the backlight, these features make the display easier to read.

Reminder
As well as warnings and errors, your pump can signal reminders. This works like an electronic alarm clock.

Choice of batteries
Your Accu-Chek Spirit Combo insulin pump can be powered by either disposable or rechargeable batteries. (If you decide to use rechargeable batteries, you will need a battery charger recommended by the battery manufacturer).

Key Lock
The Key Lock feature allows you to lock all 4 keys on your Accu-Chek Spirit Combo insulin pump. This function prevents you from accidentally activating your pump. For example, you can use Key Lock while you are asleep or when playing sports.

1.2 Display and sounds

Your Accu-Chek Spirit Combo insulin pump has a Liquid Crystal Display (LCD) screen. This display, together with the 4 keys, enables you to program the pump. It also shows important information about the status of your pump.

WARNING

Changes in the status of your pump can be life-threatening. If for any reason you cannot hear the audible signals or feel the vibrations of your pump, looking at the display is the only way that you will notice changes or malfunctions in your pump.

1.2.1 Backlight

The backlight helps you to read the information on the display in poorly-lit areas. You can turn on the backlight while in RUN or STOP mode, or when navigating through the menus, by pressing ⊂▲⊃.

The backlight turns on automatically when a reminder, warning or error message is displayed, and turns off automatically after 10 seconds if no keys are pressed.

Tip: In poorly-lit areas, begin programming with the ⊂▲⊃.

1.2.2 Rotating display

Your pump's display can be rotated by 180 degrees. See section *5.6.4 Display orientation.*
Note that when you rotate the display, the ⊂▼⊃ and ⊂▲⊃ key functions will be reversed.

CAUTION

If incomplete characters, numbers or symbols appear on the display, put your pump into STOP mode and remove the battery for a few seconds. When you reinsert the battery, the pump will perform a system check. If this does not resolve the problem, put your pump into STOP mode and contact your local pump support. For details see inside the back cover.

1.2.3 Display screens

The screens displayed by your pump relate to one of the following modes:

- RUN
- STOP
- QUICK INFO

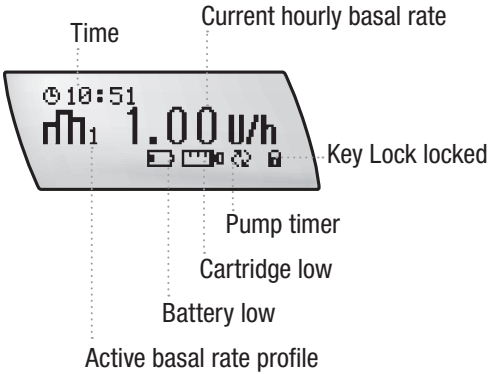
The following screens are all accessed from the user menus (see section *5.2 Selecting a user menu*):

- Information
- Function
- Set-up

Note *To save battery life, the screen of your Accu-Chek Spirit Combo insulin pump goes blank if you do not press any key for more than 20 seconds. When your pump shows a blank screen, you have to press a key before any other operation can be performed.*

RUN screen

The screen is blank by default to save energy. The screen goes blank again after 20 seconds if no key is pressed. By pressing any key, the RUN screen is displayed when the pump is in RUN mode. This means that insulin is being delivered to your body according to the basal rate you have programmed.



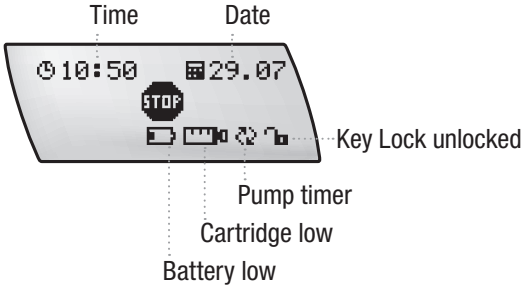
The above screen shows all the possible symbols, including the current time, the current basal rate profile, and the current hourly basal rate in units per hour.

The RUN screen also displays reminder information (such as “cartridge low”) and special functions (such as Key Lock – locked or unlocked) in the form of symbols (see *Appendix F: Symbols*)

Note *After you program or review information, the pump returns to the RUN screen.*

STOP screen

The STOP screen is displayed when the pump is in STOP mode. This means that insulin is no longer being delivered to your body. The STOP screen shows the current time and date, and the STOP symbol.



The STOP screen also displays reminder information (such as “battery low”) and special functions (such as Key Lock – locked or unlocked) in the form of symbols.

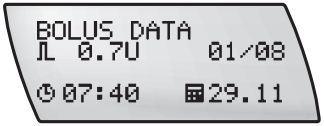
Your pump must be in STOP mode in the following situations: You are

- programming specific functions
- changing the cartridge and/or the infusion set
- priming the infusion set
- transferring data to or from the pump
- changing the battery

QUICK INFO screen

You display the QUICK INFO screen by pressing the ✓ key while in RUN or STOP mode. The QUICK INFO screen shows the remaining insulin content of the cartridge in units.

By pressing ✓ again you enter the BOLUS DATA function. You can view the last 30 boluses by pressing ▲ or ▼.



You can leave the QUICK INFO screen either pressing ✓ again or pressing no key for 20 seconds.

Information, Function and Set-up screens

You access these screens when you program the pump, perform a function, change a setting, or store or transfer information. You can reach these screens from either the RUN or STOP screen.

1.2.4 Navigating through the screens

The following procedure explains how to navigate through the screens. Think of these screens as menu choices. See section *1.2.3 Display screens*.

1. Press the key to select a screen of your choice.
2. Press the key again to see the next available choice in the menu. (After you reach the last menu choice, you will return to the first menu choice.)
3. When you reach the screen of your choice, press the ✓ key. The next set of screens are called Function screens, and all relate to the choice you have just made. There may be one or several Function screens.
4. Press the ▼ or ▲ key to increase or decrease the displayed value, or press the key again to move to the next Function screen to make further changes. (After you reach the last Function screen, you will return to the first Function screen.)
5. Press the ✓ key to save your changes.

You can move backwards through the main menu screens by pressing the key and key simultaneously.
In any submenu the same key combination will move you back to the main menu screen.

Note *Changes that you made in the submenu will not be saved.*

1.2.5 Status messages and alarm signals

Your Accu-Chek Spirit Combo insulin pump informs you of the status of your pump using audible beeps, vibrations and displayed messages. It is vital that you be able to hear and/or feel the beeps and vibrations. Be aware that some carrying pouches may hinder the perceptibility of the signals.

You can turn off either beeps or vibrations, but for your safety you cannot turn off both at the same time for the initial alarm signal.

See chapter *8 Warnings and errors* for a description of the full range of warnings and errors.

STOP warning
The STOP warning is triggered when your pump switches from RUN mode to STOP mode, or when a battery is inserted. The pump emits 2 beeps and vibrates once every minute. This warns you that insulin delivery has been interrupted.

To turn off the STOP warning, press either ⊕ or ⊖ for 3 seconds. You then hear a melody, confirming that the STOP warning has been turned off. If you press the key too briefly, the STOP warning will not be turned off.

Note *For your safety, the volume of the STOP warning cannot be changed. It is independent of the programmed beep volume.*

1.3 Keys and key combinations

You use the 4 keys on the Accu-Chek Spirit Combo insulin pump to program functions, access information, and set up the pump. Each time you press a key the pump will beep, unless the beep tone is set OFF.

Note *Avoid pressing the keys with your fingernails or other pointed objects. These can damage the rubber coating of the keys, which can lead to consequential damage.*

The following table lists the keys and their functions.

Key	Name	Function
	Menu	▶ Move through menus, function screens and information screens
	OK	▶ Select a menu ▶ Save changes and exit the function and information screens ▶ View the QUICK INFO screen
	Up	▶ Move forward in the information screens ▶ Increase a setting ▶ Turn on the backlight ▶ Program a Quick Bolus ▶ Cancel a Quick Bolus ▶ Turn off the STOP warning (press and hold 3 sec. until you hear a melody)

Key	Name	Function
	Down	▶ Move backward in the information screens ▶ Decrease a setting ▶ Program a Quick Bolus ▶ Cancel a Quick Bolus ▶ Turn off the STOP warning (press and hold 3 sec. until you hear a melody)

CAUTION

Do not press the keys with a sharp or pointed item such as the tip of your fingernail, as this could damage the casing of your Accu-Chek Spirit Combo insulin pump. Instead, use the pad of your fingertip to avoid puncturing the keys.

1.3.1 Combining keys

You can obtain additional functions by pressing 2 keys simultaneously. In the following table, a plus symbol (+) indicates that both keys must be pressed at the same time.

Combination	Function
⧉ + △	▸ Exits menus, function screens and information screens without saving your changes. ▸ Moves you to a previous menu.
⧉ + ▽	▸ Unlocks the keys. Press and hold both keys until you hear 3 short beeps (RUN mode) or 3 long beeps (STOP mode).
△ + ▽	▸ Copies an hourly basal rate to the following hour.

⚠ WARNING

If the keys on your pump are not functioning properly, disconnect your pump and contact your local pump support (see inside back cover).

1.3.2 Scrolling

To enter larger or smaller values, the ⊕ and ⊖ keys must sometimes be pressed several times until the desired value is shown, with each press of the key changing the figure by a small increment. However, you can also press and hold the key (scrolling function) to change the value faster. When programming boluses and hourly basal rates the increment of the value change increases if you keep the ⊕ or ⊖ key pressed.

When you begin scrolling, the pump beeps once.

1.3.3 Locking the keys

The Key Lock feature allows you to lock all 4 keys on your Accu-Chek Spirit Combo insulin pump. This function prevents you from accidentally activating your pump. For example, you can use Key Lock while you are asleep or when playing sports.

You turn on the Key Lock function in the PUMP SETTINGS – See section *5.6 Pump settings*.

1.4 Accessories and disposables

High-quality sterile disposables and accessories are a vital part of the Accu-Chek Spirit Combo insulin pump system, and help to ensure safe pump therapy. The infusion set is the applied part. Always follow the instructions provided by your doctor or healthcare team – as well as the printed instructions included with the product – relating to the use of these items.

Note *Use your insulin pump, sterile disposables and accessories for the first time in the presence of your doctor or healthcare team.*

1.4.1 Sterile disposables

Each sterile disposable, such as a cartridge or infusion set, should be used only once, as re-using these products could lead to infection or could damage your pump. Do not use a sterile product if the package has been damaged or opened.

WARNING

Your pump has been designed for use with U100 insulin. Only use sterile disposables and accessories that are designed for use with your Accu-Chek Spirit Combo insulin pump. The correct functioning of your pump can only be guaranteed if you use sterile products with the Accu-Chek brand and genuine Accu-Chek Spirit Combo insulin pump accessories.

1.4.2 Adapter

The adapter connects the cartridge to the infusion set, and also keeps the cartridge compartment watertight with 2 seals, one inside and one outside the adapter. It holds the cartridge in place and prevents the entry of air bubbles. The 2 small vents on the adapter allow air pressure to be equalized inside and outside the cartridge compartment. The adapter will not work properly if the vents are blocked or dirty, or if the seals are missing.

Note *It is essential to change the adapter at least every 2 months. You must also change the adapter if the seals become worn, are lost, or if the vents are blocked.*

1.4.3 Battery

Your pump requires a 1.5 V AA alkaline (LR6) or lithium (FR6) battery that has a mimimum capacity of 2500 mAh.

- Alkaline batteries: Only use high-quality alkaline LR6 batteries that comply with IEC 60086-1. The Accu-Chek Spirit Combo insulin pump was successfully tested with a Varta Power One alkaline LR06, AA, 1.5 V battery which complies with IEC 60086-1.

- Lithium batteries: Only use lithium batteries that comply with IEC 60086-4. The Accu-Chek Spirit Combo insulin pump was successfully tested with an Energizer Ultimate Lithium FR06, AA, 1.5 V battery which complies with IEC 60086-4.

Do not use carbon zinc or nickel cadmium (NiCd) batteries.

If you prefer, you can use rechargeable batteries – in this case, we recommend a Varta Rechargeable Accu *Ready to Use* NiMH, HR06, AA, 1.2 V battery that complies with IEC 62133 and has a mimium capacity of 2600 mAh. Only use a battery charger officially recommended by the battery manufacturer. See *Appendix A: Technical Data, p. 170.*

Contact your local pump support if you intend to use a different type of battery to the one recommended.

CAUTION

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

Note *Always remember to remove the battery if your Accu-Chek Spirit Combo insulin pump is not going to be used for a long period, in order to conserve the battery.*

Battery cover

The battery cover seals the battery compartment, and must be changed at least every 2 months. You must remove and replace the battery cover using the battery key – do not use knives, screwdrivers or other sharp objects, as these may damage your pump.

Battery key

The battery key tightens and loosens the battery cover. It is also designed to loosen the luer-lock connection between the infusion set and adapter if it cannot be loosened by hand, by using the notch on the side. However, never use the battery key to attach or tighten an infusion set. Using the battery key prevents possible damage to the battery cover.

If you lose the battery key, or if it becomes cracked or worn, order a replacement immediately, rather than using makeshift tools.

For a list of recommended accessories and disposables, see Appendix C.

1.5 Emergency kit

It is highly recommended to keep accessories and disposables with you in case of an emergency. This enables you to change these items if necessary.

Consult the instructions for use coming with your medical devices (e.g. lancing device), accessories and disposables.

Such an emergency kit should contain:

- An Accu-Chek infusion set
- A new AA alkaline or lithium battery
- An Accu-Chek Spirit 3.15 ml cartridge system
- An insulin pen or syringe for alternative therapy
- A vial of insulin
- Treatment for low blood glucose levels
- Blood glucose monitoring equipment (such as an Accu-Chek blood glucose meter)
- A disinfectant for skin
- A battery key
- A battery cover
- An adapter

WARNING

Make sure that you have an alternative therapy plan, provided by your healthcare professional. Use this plan whenever you need to interrupt pump therapy.

1.6 General safety information

WARNING

Always make sure to accurately program your personal settings to avoid inappropriate insulin delivery. This phrase means that either too much or too little insulin is delivered. Too much insulin can lead to severe hypoglycaemia. Too little insulin can lead to a life-threatening ketoacidosis.

CAUTION

If you should drop your pump, immediately inspect it carefully for damage. Do not use your Accu-Chek Spirit Combo insulin pump if cracks or chips are visible – these may allow water, dust, insulin or other foreign substances to enter the pump and lead to malfunction.

WARNING

Your insulin pump has not been tested with cardiac pacemakers. For information about the safe use of your Accu-Chek Spirit Combo insulin pump with a cardiac pacemaker, contact the pacemaker manufacturer. For reference see *Appendix A: Tables 201–205*.

2 Getting started

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

2.1 Before you begin

Successful insulin pump therapy requires you to check your blood glucose levels frequently. It is therefore recommended that you use an Accu-Chek blood glucose meter as often as directed by your doctor or healthcare team (at least 4 times a day).
Your Accu-Chek Spirit Combo insulin pump has been designed for use with the meter. This intelligent blood glucose meter enables you to communicate with the pump using *Bluetooth*® wireless technology.

WARNING

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

2.2 Inserting the battery

Your Accu-Chek Spirit Combo insulin pump turns on as soon as you insert the battery. When you remove the battery, your pump keeps track of the time and date for about one hour. If the power is interrupted for a longer period of time (after more than 1 hour), your pump will revert to the factory settings for the date and time. Your insulin pump settings (such as the hourly basal rates, bolus increment and active user menu) and the event memory (bolus and alarm history, history of daily insulin totals and Temporary Basal Rates) are always saved, regardless of battery condition or the amount of time your pump has been without a battery. See section *1.4.3 Battery* for information on batteries (both disposable and rechargeable types).

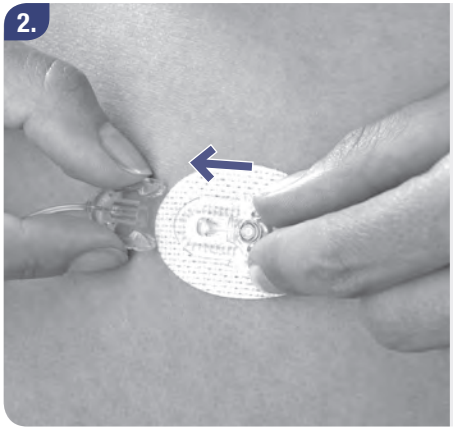
Procedure for inserting and changing the battery

1.

Press to move to the STOP YOUR PUMP screen.

Press to select. Your pump is now in STOP mode and insulin delivery stops.

2.



Remove or disconnect your infusion set from the infusion site, to ensure that there is no risk of accidental insulin delivery.

3.

Remove the battery cover.

Use the battery key to turn the battery cover anticlockwise. Make sure that the opening of the battery compartment and the seal are clean and undamaged. Where appropriate, remove the old battery.

4.

Insert the battery, negative (–) end first, positive (+) end up, into the battery compartment.

5.

Place the cover on the positive end and gently push the battery in, while turning the cover clockwise to partially tighten it.

6.

Use the battery key to fully tighten the battery cover. You can verify that the battery cover is correctly tightened by checking that it is in line with the pump casing. Do not over-tighten.

After inserting the battery, the pump begins its start-up process (see section below).
If the pump does not begin the start-up process after inserting the battery, make sure that the battery is inserted correctly (negative end first).

CAUTION

If your pump reverts to the factory settings for the date and time immediately after the power supply is interrupted for a short amount of time, please contact your customer support to report this issue as it may be due to a component failure.

CAUTION

To prevent water from entering the pump casing, only insert or change the battery in a dry environment. Make sure that the battery cover seal is not worn or missing, and that the battery is correctly inserted.

Note *If your pump was in RUN mode before you removed the battery, the error E8: POWER INTERRUPT will occur when the new battery is inserted. Press ✓ twice to confirm and snooze the error. Check the time and date and correct them if necessary. Then put your pump into RUN mode.* See section *2.4 Setting the time and date.*

WARNING

It is important that you always check that the date and time are set up correctly before you put your pump into RUN mode after a battery change. Otherwise there is a risk that too much or not enough insulin will be delivered because of a shift of basal rate time blocks. Basal rates that are delivered at the wrong time can lead to hyper- or hypoglycaemia.

2.3 Start-up process

Your pump runs a start-up process when you insert a battery or when you change the cartridge. During this process, your pump performs a series of internal tests.

When you …	Then …
change the battery	the whole start-up process is performed.

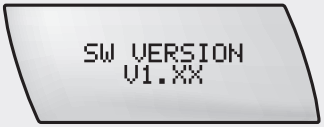
When you …	Then …
change only the cartridge	the start-up process begins at the SELF-TEST screen.

WARNING

Do not interrupt the start-up process by pressing keys or otherwise handling the insulin pump. Interruption of the process may lead to malfunction of your pump.

Start-up process sequence

1.



The software version screen appears.

2.

The Accu-Chek logo appears.

3.

The SELF-TEST screen appears.

4.

The BEEP TEST screen appears and your pump beeps.

Listen for the beeps.

⚠ WARNING

If you cannot hear the beeps from your Accu-Chek Spirit Combo insulin pump, you may not be notified of changes within the pump in time to take action. If you do not hear the beeps, stop using the pump and contact your local pump support. (See inside back cover)

5.

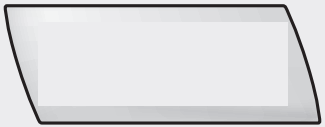
The VIBRATION TEST screen appears and your pump vibrates.

Check the vibrations.

⚠ WARNING

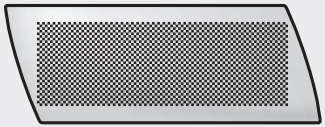
If you cannot feel the vibrations, you may not be notified of changes within the pump in time to take action. If you do not feel the vibrations, stop using the pump and contact your local pump support. (See inside back cover)

6.



The display then goes blank. Check that the display is empty. (The backlight turns on during this step.)

7.



The display then shows a pattern. Check that the pattern is even.

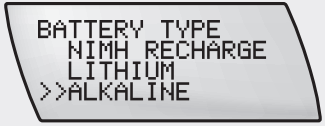
8.

The display turns black. Check that the display is completely black.

9.

If your pump detects a warning or an error during the start-up process, it signals the error or warning at this point. See section *8.3 List of errors*.

10.



After the self-test, press ⊕ or ⊖ to select the type of battery you inserted.

Press ✓ to save and exit.

11.

The end of the start-up process is signalled by a melody, and the pump displays the STOP screen.

The STOP warning occurs every minute. To turn the STOP warning off, press ⊕ or ⊖ until you hear a melody and/or feel a vibration.
When you use your pump for the first time or have not used it for a longer time, you will be guided automatically to the TIME AND DATE SETTINGS option after step 10 (see next page).

CAUTION

Make sure that you choose the correct battery type. Otherwise you may not be informed about a low battery in time.

2.4 Setting the time and date

It is essential to set the time and date correctly, because basal rates and history information are stored on the basis of the time and date set in the pump. When you travel across time zones, make sure that the time and date are re-set correctly.
You can choose between American or European/Military time.

American	European/Military
12-hour clock	24-hour clock
month.day.year	day.month.year

WARNING

- Incorrect setting of the time and date can lead to incorrect basal insulin delivery. Make sure that the time and date of your pump are set correctly, to ensure correct delivery and data memory. Do not make therapy decisions based on a single result in the pump's memory.
- If the power is interrupted for a longer period of time (after more than 1 hour), your pump will revert to the factory settings for the date and time.
- In addition, if you, your doctor, or healthcare team are reviewing your data electronically, it is essential that you synchronize the time and date of your pump with those of your blood glucose meter, your personal computer or handheld device. Otherwise, the resulting data might not be meaningful. Check these devices regularly to ensure that the settings remain synchronized.

Procedure for setting the time and date

1.

Press to move to the TIME AND DATE SETTINGS screen.

Press to select.

2.

The HOUR screen is displayed.

Press or to set the hour.

3.

Press to move to the MINUTE screen.

Press or to set the minute.

4.

Press to move to the YEAR screen.

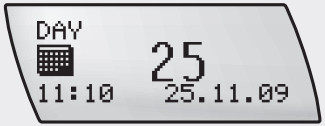
Press or to set the year.

5.

Press to move to the MONTH screen.

Press or to set the month.

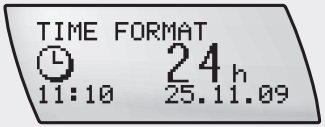
6.



Press to move to the DAY screen.

Press or to set the day.

7.



Press to move to the TIME FORMAT screen.

Press or to set the time format.

8.

Press to move to the DATE FORMAT screen.

Press or to set the date format.

Press to save and exit.

2.5 Your basal rate profile

Your Accu-Chek Spirit Combo insulin pump must be programmed with your personal settings before you begin pump therapy. Your doctor or healthcare team can help you to understand how to use the pump.

2.5.1 Programming your basal rate profile

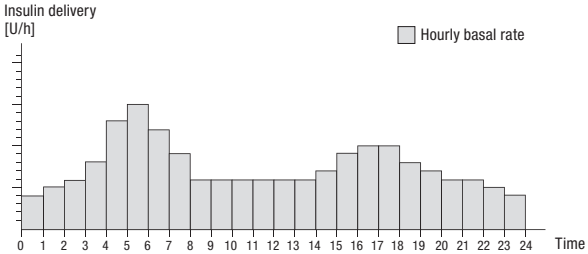
Your Accu-Chek Spirit Combo insulin pump delivers insulin according to the programmed hourly basal rate, 24 hours a day. This flow of insulin, measured in international units per hour (U/h), is called the basal rate profile and is calculated to meet your basic insulin needs.

The pump can store up to 5 different basal rate profiles to match your changing insulin needs – for example: Monday to Friday, Exercise Day or Sleeping Late Day.

Note *For your safety and convenience during programming, your Accu-Chek Spirit Combo insulin pump switches to RUN or STOP screen if no key is pressed within 20 seconds. Any changes you have made before this "time-out" occurs will not be saved.*

An Accu-Chek Spirit Combo basal rate profile consists of up to 24 different hourly basal rates. Each hourly rate may be changed independently. The total of all 24 basal rates in one basal rate profile is called the (daily) basal rate total.

Example: Basal rate profile for 18 U/24 hours



Your basal rate profile should be reviewed:

- After any programming changes are made to your pump
- After a new battery is inserted
- After confirming the error E7: ELECTRONIC ERROR.

Note *Insulin delivery does not stop or pause during basal rate programming.*

Procedure for programming your basal rate profile

1.

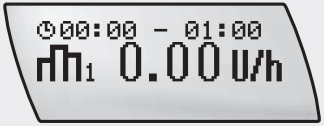
Press to move to the BASAL RATE PROGRAMMING 1 (2, 3, 4 or 5 accordingly) screen.

2.

Press to select.

The daily BASAL RATE TOTAL is displayed.

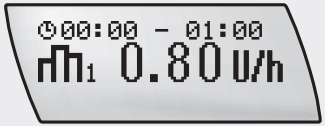
3.



Press to move to the first hour.

This is always 00:00–01:00 (12 AM–01 AM if the American time format is used).

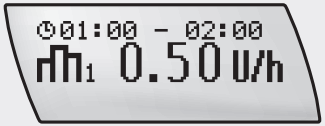
4.



Press ⊕ or ⊖ or scroll to set the hourly basal rate given by your doctor or healthcare team.

Note *The increments shown depend on the programmed basal rate: it will be*
0.01 U from 0.05 U to 1.00 U,
0.05 U from 1.00 U to 10.0 U and
0.1 U from 10.0 U to 50.0 U

5.



Press ⊡ to move to the next hour.

6.

Continue using ⊡ and ⊕ or ⊖ to set the hourly basal rates for the remaining hours. This allows you to program your individual basal rate profile on an hour-by-hour basis. Continue until all 24 hours are programmed.

7.

Press ✓ to confirm.

The new daily BASAL RATE TOTAL is displayed.

Press ✓ to save the profile and exit.

Copying an hourly basal rate

If your basal rate is the same for multiple hours in a row, you can save time by copying an hourly basal rate to one or more hours.

1.

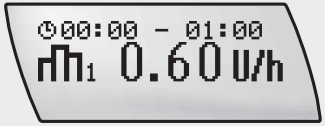
Press to move to the BASAL RATE PROGRAMMING 1 (2, 3, 4 or 5 accordingly) screen.

2.

Press to select.

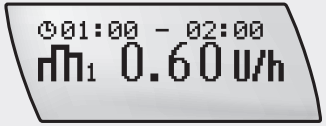
The daily BASAL RATE TOTAL is displayed.

3.



Press to move to the hourly basal rate you want to copy.

4.



Press and simultaneously.
A special beep confirms that you are pressing the keys correctly. The same hourly basal rate is copied to the next hour.

5.

If you want to copy the rate to multiple hours, press and repeatedly or press and hold and (scroll).

6.

Press ✓ to confirm.

Check the new daily BASAL RATE TOTAL.

Press ✓ to save and exit.

Note *At any point in the programming of your basal rate, you have the following options to exit.*

If you want to …	*Then …*
save the changes	▸ *Press ✓ and check the new daily basal rate total.* ▸ *Press ✓ again. Your pump returns to the RUN or STOP screen.*
undo the changes	▸ *Wait for your Accu-Chek Spirit Combo insulin pump to return to the RUN or STOP screen, or* ▸ *Press ⧉ and ▲ simultaneously (exit feature) to exit the Function screen.*

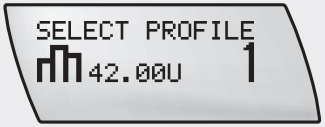
Selecting a basal rate profile

When you have programmed more than one basal rate profile (ADVANCED or CUSTOM MENU), you can select the required profile.

1.

Press ⊕ to move to the BASAL RATE SELECTION screen.

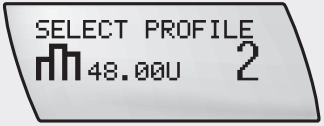
2.



Press ✓ to select.

The SELECT PROFILE for the current basal rate profile is displayed.

3.



Press ▲ or ▼ to select a basal rate profile.

The SELECT PROFILE screen and its daily basal rate total appear accordingly.

4.

Press ✓ to select the displayed profile. The new basal rate profile is active immediately.

⚠ WARNING

Make sure that you select an appropriately programmed basal rate profile. Otherwise there could be inappropriate insulin delivery.

Note *When you change your user menu for example from ADVANCED to STANDARD, your current basal rate profile may not appear.*

If the basal rate profile number(s) you want does not appear:

- *Select the ADVANCED user menu, or*
- *Assign the basal rate profile to an available basal rate profile number*

A running Temporary Basal Rate increase or decrease stays active, even if you change the basal rate profile on your pump.

Basal rate and bolus

During normal use, your pump is in RUN mode and insulin is continuously delivered to your body, according to the basal rate profile you have programmed.

A bolus can be programmed as required. A bolus is 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 and depends on your blood glucose level, your food intake, and your activity level, as well as stress and illness. See section *4.1 Understanding boluses*.

2.6 Connecting the cartridge, adapter and infusion set

Before you change the cartridge, adapter or infusion set, check that your pump is in good working order. See section *7.1.1 Checklist*.

Insulin can flow uncontrolled from the cartridge or infusion set if the cartridge plunger and the piston rod are not properly connected and the pump is positioned at a higher level than the infusion site. Prevent leakage of insulin by correctly inserting the cartridge: move the piston rod to the correct position and twist the adapter until the cartridge plunger is aligned with the end plate of the piston rod. (See section *3.5 Changing the cartridge and infusion set*).

Have the following materials ready:

- A filled Accu-Chek Spirit 3.15 ml cartridge system with a luer-lock connection (for filling instructions see the instructions for use provided with this product)
- An Accu-Chek Spirit Combo insulin pump adapter
- A new Accu-Chek infusion set

WARNING

Ensure that the cartridge is at room temperature before use to prevent from air bubbles.

Procedure to connect the cartridge, adapter and infusion set

1.

Remove the protective cap from the cartridge. (Do not touch the cartridge tip.)

2.

Push the adapter onto the cartridge tip all the way until it stops.

3.

Carefully prepare a new Accu-Chek infusion set, following the instructions supplied for use.

4.

Hold the adapter and twist the infusion set luer-lock connection by hand, clockwise into the adapter. Do not over-tighten.

WARNING

To avoid leakage, tightly attach the infusion set to the adapter. Turn the infusion set luer-lock connector until it stops. Do not over-tighten or use any auxiliary tools, as this may crack the infusion set luer-lock connector and result in leakage of insulin.

2.7 Inserting the cartridge

Have the following materials ready:

- A filled Accu-Chek Spirit 3.15 ml cartridge system with a connected Accu-Chek Spirit Combo insulin pump adapter
- A new Accu-Chek infusion set

WARNING

Do not use your pump for the delivery of medication other than U100 short-acting regular human insulin or rapid-acting insulin analogue.

Procedure for inserting the cartridge

1.

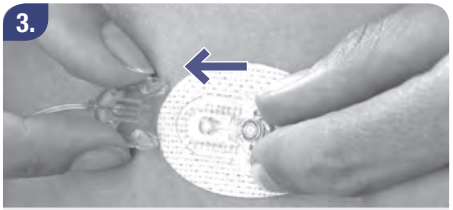
Press to move to the STOP YOUR PUMP screen.

2.

Press to select.

The pump displays the STOP screen, and insulin delivery stops.

3.



Disconnect the transfer set from the headset to ensure that there is no risk of accidental insulin delivery.

4.

Remove the cartridge, if necessary. Unscrew carefully. Do not pull the cartridge out until it is completely unscrewed.

5.

Press ⊕ to move to the CARTRIDGE CHANGE screen.

Press ✓ to select.

6.

Make sure your infusion set is disconnected and the cartridge has been removed.

Press and hold ✓ for 3 seconds, until you hear a melody.

7.

The piston rod begins to return. Do not touch or otherwise disturb the piston rod while it is rewinding, as this could result in damage to your pump.

8.

When the piston rod has returned completely, the CARTRIDGE VOLUME screen displays the maximum volume, 315 U.

CAUTION

Do not change the cartridge if the cartridge compartment is not completely dry. When the piston rod is rewinding, insulin solution could enter your pump and lead to malfunction. If necessary, use a soft cloth to dry the cartridge compartment.

9.

Hold your pump upright. Hold the new filled cartridge so that the connected adapter and infusion set points upwards, parallel, and close to the cartridge compartment.

10.

Make sure that the top edge of the threaded part of the adapter is level with the top of the cartridge compartment.

11.

Press ⊕ or ⊖ to move the piston rod forward until the end plate of the piston rod is level with the bottom of the cartridge plunger.

12.

The CARTRIDGE VOLUME decreases accordingly on the display.

Tip: To prevent air bubbles move the piston rod to at least 310 U.

13.

Position your insulin pump with the opening of the cartridge compartment pointing downwards. Insert the cartridge into the cartridge compartment.

14.

Do **not** insert the cartridge into your insulin pump without first connecting the infusion set tubing.

Do **not** hold your pump in an upright position when inserting the cartridge.

15.

Screw (do not push) the adapter closed in a clockwise direction, until it is correctly seated against the cartridge compartment.

It is not necessary to apply pressure. Do not over-tighten the adapter, otherwise it will be difficult to remove the cartridge, adapter and cartridge plunger, and you could cause damage to your pump.

16.

The cartridge is correctly inserted when the end plate of the piston rod is correctly seated against the cartridge plunger.

17.

If the end plate of the piston rod is not correctly aligned with the cartridge plunger, remove the cartridge from the cartridge compartment and repeat steps 9 to 14.

18.

Check that the infusion set luer-lock connector is still correctly connected to the adapter. Tighten the infusion set by hand by screwing it in a clockwise direction, until it sits tightly in the adapter.

19.

Press ✓ after correctly inserting the cartridge.

Your pump performs a self-test. See section *2.3 Start-up process*.

20.

When the self-test process is finished, the INFUSION SET PRIMING screen is displayed.

See section *2.8 Priming the infusion set*. Start from step 4 in the *Procedure for priming the infusion set*.

CAUTION

If an empty cartridge is inserted into the pump (e.g. 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.

2.8 Priming the infusion set

WARNING

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

The Accu-Chek Spirit Combo insulin pump stops priming at 25 units of insulin. If no insulin emerges from the needle or there are air bubbles in the tubing after priming, repeat the priming function until the infusion set is bubble-free and completely filled with insulin. When insulin appears at the tip of the needle, press ✓ to stop priming. The amount of insulin used for priming is not added to the pump's history of daily insulin totals.

Your pump should be upright during priming, with the adapter pointing upwards to help let air bubbles out of the cartridge and infusion set.

WARNING

Air bubbles in the cartridge and infusion set may result in the infusion of air instead of insulin. If this happens, your body will not receive the required amount of insulin. Remove bubbles while filling the cartridge and priming the infusion set, and without having the infusion set connected to your body.

Procedure for priming the infusion set

1.

Press ⊕ to move to the STOP YOUR PUMP screen.

Press ✓ to select.

2.

The pump displays the STOP screen, and insulin delivery stops.

3.

Prepare the tubing or cannula for priming according to the infusion set's instructions for use.

4.

Press ⊕ to move to the INFUSION SET PRIMING screen.

Press ✓ to select. The priming amount of 25 units of insulin is shown on the display.

5.

Make sure your infusion set is disconnected.

Press and hold ✓ for 3 seconds, until you hear a melody. The priming process begins.

6.

To ensure that any air bubbles are removed always hold your pump upright, and gently tap it with the bottom in the palm of your hand.

7.

A count-up is shown on the display. Your pump stops priming after 25 units.

You can stop the priming process at any time by pressing ✓.

The infusion set is properly primed when there are no air bubbles visible in the tubing and a drop of insulin has come out of the needle. When the priming process is complete, your pump returns to STOP.

2.9 Positioning the infusion set

Always follow the instructions given to you by your doctor or healthcare team and the instructions for the infusion set you are using.

Change your infusion set as frequently as recommended by the manufacturer.

2.9.1 Preparing the infusion site

Infusion site selection
Your doctor or healthcare team will help you choose your infusion site areas according to a planned rotation pattern. Avoid your waistline, bones, scar tissue, recent infusion sites, bruises and sores. Choose an infusion site at least one inch (2.5 cm) away from the navel and previous infusion sites.

Infusion site preparation
It is important to prepare the infusion site properly to reduce the risks of infection. Your doctor or healthcare team will provide you with infusion site preparation guidelines.

Have the following materials ready:
- Your Accu-Chek Spirit Combo insulin pump
- A disinfectant for your skin
- A new Accu-Chek infusion set

2.9.2 Inserting the cannula

1.

Make sure that your pump is properly connected (including cartridge, adapter and infusion set) and correctly programmed with your personal settings.

2.

Make sure your pump is in STOP mode.

3.

Wash your hands thoroughly.

4.

Disinfect the infusion site and let it dry completely.

5.

Insert the cannula of your Accu-Chek infusion set according to the instructions.

Note *If you use an infusion set with a soft cannula, you must proceed with a bolus to fill the air space in the cannula and headset, according to the instructions for the infusion set you are using. Failure to do so could result in missed insulin dosing. See section 4.2 Programming a Standard Bolus.*

WARNING

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

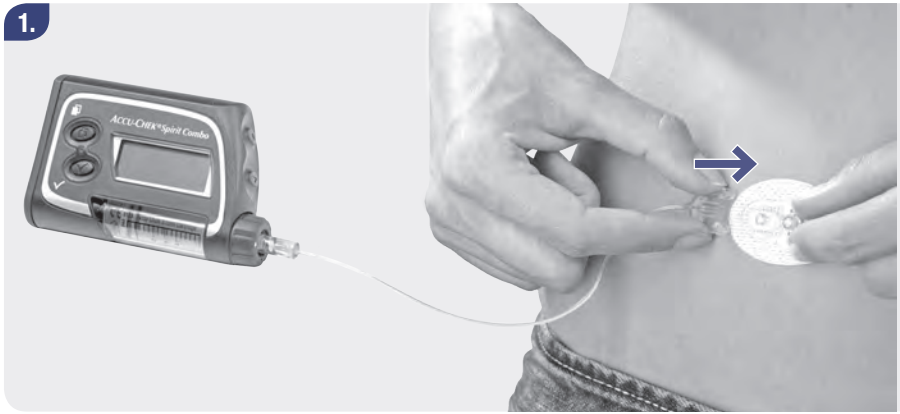
If you have read and followed all instructions, cautions, warnings and notes found in this chapter, you should now be ready to deliver insulin to your body using your Accu-Chek Spirit Combo insulin pump.

2.9.3 Connecting the insulin pump

WARNING

Pay attention to the tubing of the infusion set connected to your body. There is a risk of strangulation if the tubing becomes wrapped around your neck. In case of doubt, use the shortest tubing length to minimise the risk of strangulation.

1.



Attach the infusion set to the insulin pump and start insulin delivery. See section *2.10 Starting insulin delivery*.

2.10 Starting insulin delivery

Procedure for starting insulin delivery

1.

Your pump is in STOP mode.

2.

Press to move to the START YOUR PUMP screen.

3.

Press to select. Your pump shows the RUN screen.

Insulin delivery begins within 3 minutes.

2.11 Stopping insulin delivery

For your safety, you must only perform certain functions and actions when the pump is in STOP mode. These functions and actions include:

- changing the cartridge
- connecting and disconnecting the adapter and/or infusion set
- priming the infusion set
- data transfer

CAUTION

When your Accu-Chek Spirit Combo insulin pump is in STOP mode, no insulin is delivered to your body. You must put your pump into RUN mode to continue insulin delivery.

Procedure to stop insulin delivery

1.

Press ⊕ to move to the STOP YOUR PUMP screen.

2.

Press ✓ to select. Your pump returns to the STOP screen.

Your pump is now in STOP mode.
No insulin is being delivered.

STOP warning

The STOP warning is triggered when your pump switches from RUN mode to STOP mode, or when a battery is inserted. The pump emits 2 short beeps and vibrates once every minute. This warns you that insulin delivery has been interrupted.

To turn off the STOP warning, press either ⊕ or ⊖ for 3 seconds. You then hear a melody and/or feel a vibration, confirming that the STOP warning has been turned off.

If you press the key too briefly, the STOP warning will not be turned off.

Note *For your safety, the volume of the STOP warning cannot be changed. It is independent of the programmed beep volume.*

2.12 General safety information

⚠ WARNING

The cartridge and infusion set are sterile products intended for single use only. Sterility is guaranteed for unopened packaging up to the indicated expiry date. Do not use sterile products if the packaging is damaged.
Do not re-use single-use materials because this might lead to a malfunction of your Accu-Chek Spirit Combo insulin pump, incorrect insulin delivery and/or infection. Always handle these items with clean hands. Avoid any contact of the infusion set and the connecting parts of your insulin pump with antiseptics, antibiotic creams, soaps, perfumes, deodorants, body lotions, or any other cosmetics. They may contaminate these parts.

WARNING

Always check your personal settings before using your new pump, in order to avoid incorrect insulin delivery. Record your personal settings from your current insulin pump, and ensure that they are correctly programmed into your new Accu-Chek Spirit Combo insulin pump. Incorrect programming of your pump may cause incorrect insulin delivery.
Do not use the pump without knowing your personal settings. If you are not sure about your settings or you are inexperienced, ask your doctor or healthcare team to set or check them. Only change your settings after consulting your doctor or healthcare team.

WARNING

The support of a doctor or healthcare team is vital when training on and using your Accu-Chek Spirit Combo insulin pump. Regular visits to your doctor or healthcare team are also essential during insulin pump therapy. Always carefully follow instructions from the medical professionals responsible for your care.

Note *When an Extended Bolus, a Multiwave Bolus and/or a Temporary Basal Rate (TBR) is/are active and you put your pump into STOP mode, the warning W6: TBR CANCELLED and/or the warning W8: BOLUS CANCELLED occur(s). Press ✓ twice for each warning to confirm and turn them off. See section 8.2 List of warnings.*

Note *Your pump cannot detect infusion set leakage. If you detect any loss of insulin and all parts are correctly tightened, immediately replace the leaking component. Because insulin delivery has been interrupted, check your blood glucose level and take appropriate action according to your doctor's or healthcare team's instructions.*

Note *If the battery is too low, the start-up process may not be able to complete. In this case, the pump beeps five tones and keeps restarting the process until you remove the battery or until it is empty.*

Note *Check the amount of insulin remaining in the cartridge at least once a day. If you press ✓ from the RUN or STOP screen, your pump displays the remaining cartridge content in units.*

Before going to sleep, make sure that:

- the cartridge contains enough insulin to last through the night
- the time and date are set correctly

3 Using your pump in daily life

This chapter provides important guidelines on how to use your pump safely from day to day.

3.1 Wearing your pump

Attach your pump safely to your body or clothes to prevent damage. You can use one of our special carrying systems that enable you to carry your pump on or under your clothes. Wear your pump under your clothes or directly on your body to protect it from hot, cold or wet weather.

CAUTION

When wearing your pump, prevent any contact with objects that could damage it or accidentally press its keys (e.g. key chains, keys, pocket knives or coins).

3.1.1 When not to wear your pump

Electromagnetic fields and hazardous areas

WARNING

Do **not** use your pump near strong electromagnetic fields. Otherwise insulin delivery may stop and the error E7: ELECTRONIC ERROR may occur. Follow the instructions below before you enter areas with electromagnetic fields:

- Stop and remove your pump.
- Leave your pump outside these areas.

Strong electromagnetic fields such as radar or antenna installations, high-voltage sources, X-Ray sources, computer tomography, MRI, CAT scan and all other sources of electrical current, may cause your pump to fail. See *Appendix A: Technical data* for more information about electromagnetic fields. If the error E7: ELECTRONIC ERROR occurs near areas with electromagnetic fields, contact your local pump support.

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 normally affect the functioning of your pump.

Because there are so many devices, such as cellular phones, that emit electromagnetic radiation, the effect of such devices on your pump cannot be ruled out. It is therefore recommended to keep your pump at least 4 inches (10 cm) away from these devices while they are active.

Do not use your pump in hyperbaric chambers or in hazardous areas, such as areas where flammable gases or vapours could be present. This could cause an explosion.

Always stop and remove your pump before you enter these areas. If you have questions, contact your local pump support (see inside back cover).

Your pump is designed to work in normal barometric conditions (calculation based on standard atmosphere). During operation you can use your pump at a barometric pressure from 50 to 106 kPa (500 to 1060 mbar). These conditions also apply to transport and storage in its shipping case. This equals an altitude of approx. –300 to +5400 m. At sea level (0 m of height) the standard atmosphere is defined with a barometric pressure of 101.325 kPa.

3.1.2 Sport and exercise

Exercise is an important part of diabetes management. Your Accu-Chek Spirit Combo insulin pump is designed to enable you to safely perform a range of sporting activities while wearing your pump. It is important that you protect your pump before you begin exercise or sporting activities. Do not wear your pump for sports that involve body contact such as boxing, football or hockey, since rough contact could damage your pump.
Consult our sterile product brochures and accessories catalogue for more information about carrying systems or contact your local pump support (see inside back cover) for more information.

Note *Rapid and extreme changes in air pressure, for example in an airplane that is taking off or when practising sports like hang-gliding, can influence insulin delivery, especially if there are air bubbles in the cartridge or tubing. This also applies to rapid and extreme changes in temperature; for example, when leaving a heated room and going outside in cold weather.*

We therefore recommend that you wear your pump close to your body, remove any air bubbles from the cartridge and tubing and also measure your blood glucose more frequently in such situations.

3.1.3 Travelling with your pump

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

When you travel across time zones, make sure that the time and date on your pump are set correctly to the local time.

If you have questions, contact your local pump support (see inside back cover).

WARNING

You must ensure that the *Bluetooth®* wireless technology is switched off before boarding an aircraft, as emissions from your pump or the meter could interfere with the electronics systems of the aircraft. See section *6.2 Switching Bluetooth® ON and OFF.*

3.2 Interruption of insulin pump therapy

Consult with your doctor or healthcare team about when and for how long your insulin pump therapy can be interrupted.

Measure your blood glucose level regularly during any insulin delivery interruption. Use a syringe or insulin pen to inject insulin according to the instructions of your doctor or healthcare team.

WARNING

Because only fast- or rapid-acting insulin is used for insulin pump therapy, only a small amount of insulin is stored in the body. If insulin delivery is interrupted for any reason – such as:

- If you stop the pump
- There is a technical problem with the pump
- The cartridge is leaking and/or the infusion set is leaking
- There is an occlusion in the infusion set or in the headset
- The cannula has slipped out of the infusion site –

you must replace the missing insulin immediately.

3.2.1 Short interruptions

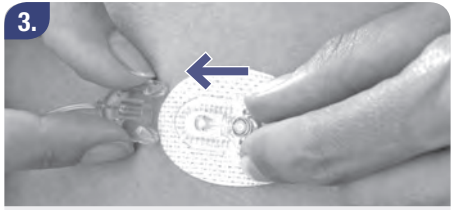
1.

Press ⊕ to move to the STOP YOUR PUMP screen.

2.

Press ✓ to put your pump in STOP mode.

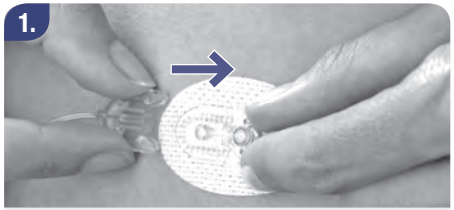
3.



Remove the infusion set or, when using a disconnectable infusion set, disconnect the transfer set from the headset and use the protective covers that came with it.

Resuming insulin delivery

1.



Reconnect your infusion set or insert a new one and put your pump into RUN mode.

Where appropriate, attach a new Accu-Chek infusion set. (See section *3.4 Changing the infusion set*).

Measure your blood glucose level within 2 hours of restarting pump therapy to check the function of the system and to ensure insulin delivery.

3.2.2 Long interruptions

When you need to interrupt your pump therapy for more than one day, use the following procedure.

1.

Put your pump into STOP mode.

2.

Remove the cartridge, adapter, and infusion set.

3.

Reinsert the adapter.

4.

Remove the battery and reinsert the battery cover.

Store your pump properly.
See section *7.6 Storing your pump*.

3.3 Your insulin pump and water

CAUTION

Before any contact with water, disconnect and take off your Accu-Chek Spirit Combo insulin pump. Check your pump daily to ensure that it is not chipped, cracked or damaged in any way, and that the battery cover and the adapter are correctly closed. Otherwise water, dust, insulin, or other substances may enter your pump and lead to malfunction.

Disconnect and remove your pump before taking a bath, or going into a whirlpool, shower or swimming pool. Avoid exposing your pump to high humidity, such as in a sauna, as this could result in damage. To make it easy to remove your pump, use disconnectable Accu-Chek infusion sets.

3.3.1 Accidental contact with water

Your Accu-Chek Spirit Combo insulin pump is protected against brief accidental contact with water. Examples of accidental water contact include:

- Rain
- Water splashes while you are cycling, jogging or hiking
- Accidental immersion in the sink, washbasin or bath

What to do after any water contact

Put your pump into STOP mode, disconnect the pump from your body, and inspect it. Use a soft cloth to dry the outside of the pump, and check the battery compartment and the cartridge compartment for water. If the battery compartment or cartridge compartment are wet, 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 to dry the pump, as this could damage the pump's housing. Do not reinsert the battery or the cartridge until the compartments are completely dry. See section *7.5.1 Cleaning your pump*.

Other liquids

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

- Cleaning solutions
- Beverages
- Oil or fat

See section *7.5.1 Cleaning your pump*.

CAUTION

Avoid any contact between your Accu-Chek Spirit Combo insulin pump, the infusion set, and the connecting parts of your insulin pump with health and beauty products (for example: antiseptics, antibiotic creams, soaps, perfumes, deodorants, body lotions, or other cosmetics). These substances could discolour your pump or fog the display.

3.4 Changing the infusion set

When you change the infusion set, keep the following information in mind:

- Infusion sets are sterile products intended for single use only. Sterility is guaranteed for unopened packaging up to the indicated expiry date. Do not use sterile products if the package is damaged.
- Correctly tighten the infusion set onto the adapter to avoid leakage. Turn the infusion set luer-lock connector until it stops. Do not turn it any further and do not use auxiliary tools, as this may crack the infusion set luer-lock connector and result in leakage.
- Your pump cannot detect infusion set leakage. You should inspect all parts of your infusion set regularly during the day and before you go to sleep. If there seems to be any loss of insulin and all parts are correctly tightened, look for and immediately replace a leaking component. Check your blood glucose level immediately, as insulin delivery has been interrupted. Take appropriate action according to your doctor's or healthcare team's instructions.
- Always disconnect your infusion set before changing a cartridge or priming the infusion set. Otherwise, you risk uncontrolled insulin delivery into your body. Always follow the instructions for the infusion set and cartridge system you are using.

Procedure for changing the infusion set

Have the following materials ready:

- Your Accu-Chek Spirit Combo insulin pump
- A disinfectant for your skin
- A new Accu-Chek infusion set

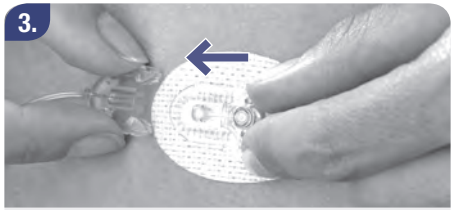
1.

Make sure your pump is in STOP mode.

2.

Wash your hands thoroughly.

3.



Disconnect the transfer set from the headset.

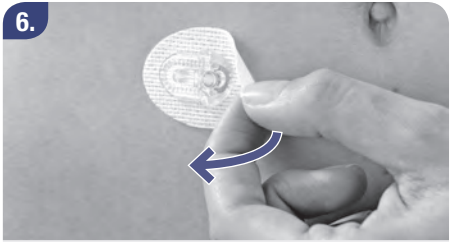
4.

Remove the infusion set from the adapter and dispose of it correctly.

5.

Tip: The battery key has a notch that fits all Accu-Chek infusion set luer-lock connectors. You can use this to loosen the luer-lock connector from the adapter if it cannot be loosened by hand.

6.



Remove the used infusion headset and dispose of it correctly.

7.

Carefully prepare a new Accu-Chek infusion set for use.

8.

Screw the Accu-Chek infusion set clockwise into the adapter.
Carefully tighten the luer-lock connector by hand.

9.

Prime the infusion set following the instructions found in section *2.8 Priming the infusion set.*

10.

Prepare the infusion site and insert a new infusion set following the instructions in section *2.9 Positioning the infusion set.*

11.

Put the pump in RUN mode. See section *2.10 Starting insulin delivery.*

Note *If you use an infusion set with a soft cannula, you must begin with a bolus to fill the air space in the cannula and headset, according to the instructions for use for the infusion set you are using. Failure to do so could result in inadequate insulin dosing. See section 4.2 Programming a Standard Bolus.*

WARNING

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

3.5 Changing the cartridge and infusion set

Have the following materials ready:

- Your Accu-Chek Spirit Combo insulin pump
- A disinfectant for your skin
- A new Accu-Chek infusion set
- A filled Accu-Chek Spirit 3.15 ml cartridge system
- A new adapter (this must be changed at least every 2 months)

Never reuse the Accu-Chek Spirit 3.15 ml cartridge system. This can cause infections and blockages or occlusions. The cartridge should be changed:

- Before it is completely empty
- If you believe the quality of the insulin is damaged or compromised
- In accordance with insulin manufacturers recommendations if using the pre-filled Sanofi-Aventis Insuman Infusat glass cartridges
- Or at least every 6 days when using the Accu-Chek Spirit 3.15 ml cartridge system

Procedure for changing the cartridge and infusion set

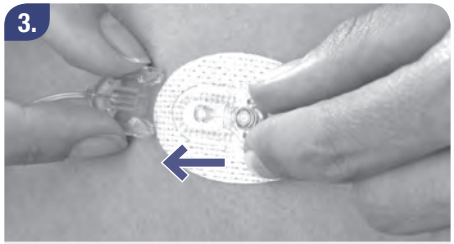
1.

Make sure your pump is in STOP mode.

2.

Wash your hands thoroughly.

3.



Remove the transfer set from the headset.

4.

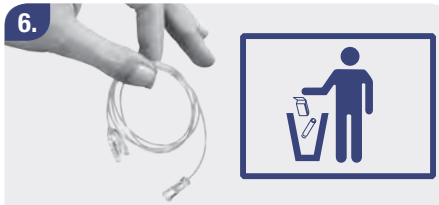
Hold your Accu-Chek Spirit Combo insulin pump with the adapter pointing downwards.

5.

Remove the adapter and cartridge from your pump by unscrewing the adapter from the pump casing.

Note *Pulling the adapter from the pump casing without completely unscrewing it may result in the plunger staying attached to the piston rod. If this should happen, please call your local pump support (see inside back cover).*

6.



Remove the transfer set from the adapter and dispose of it correctly.

Tip: The battery key has a notch that fits all Accu-Chek infusion set luer-lock connectors. You can use the battery key to loosen the luer-lock connector between your infusion set and adapter.

7.

Remove the cartridge from the adapter and dispose of the cartridge properly.

8.

Hold the adapter to the light to check for signs of wear or dirt (especially on the seals inside and outside of the adapter).

9.

If necessary, clean the adapter using water and dry it. If it shows signs of wear or dirt, replace it immediately.

10.

Insert a new cartridge and a new infusion set. See section *2.7 Inserting the cartridge.*

3.6 General safety information

WARNING

Always carry spare sterile products and accessories (infusion set, insulin cartridge, batteries), an insulin pen/syringe, and insulin. Without insulin, diabetic ketoacidosis may develop and may require in-patient hospital treatment.

CAUTION

Do not place your insulin pump in direct sunlight. Overheating of the insulin and the pump must be avoided. Protect your insulin pump from direct exposure to cold wind and temperatures over 104 °F (40 °C) and below 41 °F (5 °C). These conditions may damage the insulin and the housing of your insulin pump, and could also cause a malfunction of the battery. See the instructions for the insulin you are using to determine the acceptable temperature range.

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

- *The cartridge contains enough insulin to last through the night*
- *The battery level is OK*
- *The time and date are set correctly*

4 Boluses and Temporary Basal Rates

4.1 Understanding boluses

A bolus is 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 type and amount is determined by your doctor or healthcare team's guidelines, your blood glucose level, your food intake, your health condition, and your activity level. Discuss the timing, the amount and type of bolus you need with your doctor or healthcare team.

Your pump can deliver 3 types of bolus:

Standard Bolus	fast delivery
Extended Bolus	delivery over a programmed period of time
Multiwave Bolus	combines fast delivery with delivery over a programmed period of time

Note *If the connection between your pump and the meter is interrupted while a bolus delivery is running note the following:*

- *Standard Bolus: The whole bolus will be delivered. In case you do not manually stop the bolus delivery on your pump.*
- *Extended Bolus: The whole extended bolus will be delivered during the programmed period of time. In case you do not manually stop the bolus delivery on your pump.*
- *Multiwave Bolus: The whole bolus of fast delivered insulin (Standard Bolus) and the whole bolus delivery for the programmed period of time (Extended Bolus) will be delivered. In case you do not manually stop the bolus delivery on your pump.*

4.2 Programming a Standard Bolus

There are 2 ways to program a Standard Bolus:

Quick Bolus	Using ⊕ and ⊖ on your insulin pump, with bolus increments determined by the user
Using Standard Bolus menu	Using ⊕ and ✓ to enter the menu and then ⊕ and ⊖ to program the amount

The bolus amount per delivery is limited to 50 units using U100 insulin.
After you program a Standard Bolus, there is a delay of 5 seconds before bolus delivery starts. This delay allows you to cancel the bolus by pressing the ⊕ or ⊖ key. The warning W8: BOLUS CANCELLED is displayed. Press ✓ twice to confirm and turn off the warning. See chapter *8 Warning W8: BOLUS CANCELLED*.

Note *You can not program a new Standard Bolus as long as one Standard Bolus, Quick Bolus or the immediate part of a Multiwave Bolus is running.*

4.2.1 Programming a Quick Bolus

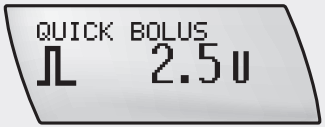
The following process uses only the ⊕ and ⊖ keys. You can start with either key. The recommended steps below are those described with the first key appearing without round brackets, such as ⊕. For the alternative step, press the key in the parenthesis, such as (⊖).
Because your pump beeps and vibrates to guide you through the programming steps, you can program the Quick Bolus without looking at the pump screen. After the bolus is programmed, you can count the beeps and vibrations of your pump to check the correct programming. For safety reason, you should also check the display as long as you are less experienced with the pump. The factory setting for the increment of the Quick Bolus is 0.5 units.

Procedure for programming a Quick Bolus

1.

From the RUN screen, press and hold ⊖ (⊕) until you hear a sequence of beeps and feel a vibration.
This activates the Quick Bolus function.

2.



Press ⊕ (⊖) once for each increment until the required bolus amount is reached. You must not use the key you pressed first.

3.

With each pressing of the key, your pump beeps and vibrates simultaneously; once for each programmed bolus increment.

4.

5 seconds after last pressing ⊕ (⊖), your pump confirms the total bolus amount with one beep and vibration for each bolus increment programmed.

5.

The Standard Bolus symbol blinks for 5 seconds (the bolus delivery start delay).

6.

After the bolus delivery start delay, the pump beeps 3 times and vibrates and then begins to deliver the total bolus amount programmed. A countdown of the remaining bolus amount appears on the display.

⚠ WARNING

The bolus increment that can be programmed into your Accu-Chek Spirit Combo insulin pump determines the Quick Bolus amount using the ⊕ and ⊖ keys of your insulin pump.
Incorrect programming of the bolus increment may cause inappropriate insulin delivery.
See section *5.10.1 Adjusting the bolus increment*.

4.2.2 Cancelling a Quick Bolus

During programming (the bolus amount blinks)	Press the ⊖ or ⊕ key you used to enter the Quick Bolus programming option. This will reset the bolus amount to 0.0 units. You hear a melody. If no new bolus is programmed, your pump returns to the RUN screen and beeps 3 times and vibrates after 5 seconds.	No bolus is delivered.
During confirmation (when the beeps and vibrations occur), or **During start delay** (Standard Bolus symbol blinks)	Press ⊖ or ⊕. You hear a melody. Your pump returns to the RUN screen. A warning W8: BOLUS CANCELLED occurs. Press ✓ twice to confirm and turn off the alert. See chapter *8 Warning W8: BOLUS CANCELLED*.	No bolus is delivered.
During bolus delivery (countdown of bolus amount)	Press and hold ⊖ or ⊕ for 3 seconds until you hear a melody. A warning W8: BOLUS CANCELLED is displayed. Press ✓ twice to confirm and turn off the alert. See chapter *8 Warning W8: BOLUS CANCELLED*. You can view the actual bolus amount delivered prior to the cancellation by looking at the bolus history. See section *5.4.1 Viewing your bolus history.*	Bolus delivery is interrupted.

Note *Make sure that the cancellation was deliberate, and then program a new bolus, if required.*

4.2.3 Programming a Standard Bolus using Standard bolus menu

Independent of the bolus increment setting, the bolus increments for the menu-guided Standard Bolus are fixed at 0.1 unit. You can program this bolus in the STANDARD BOLUS screen by holding the ⊕ or ⊖ key (scrolling) until the bolus amount is displayed.

1.

Press ⊡ to move to the STANDARD BOLUS screen.

2.

Press ✓ to select. The BOLUS AMOUNT screen appears.

3.

Press or scroll ⊕ to increase or ⊖ to decrease the bolus amount.

4.

Press ✓ to confirm the bolus amount. The Standard Bolus symbol blinks for 5 seconds (the bolus delivery start delay).

After this bolus delivery start delay, your pump beeps 3 times and vibrates and begins to deliver the total bolus amount programmed. The countdown of the remaining bolus amount appears on the display.

4.2.4 Cancelling a Standard Bolus

During programming (the bolus amount blinks)	You have 3 options for cancelling during programming: ▸ If you do not press any key for 20 seconds after programming the bolus amount, your pump returns to the RUN screen. ▸ Return to the Standard Bolus screen by pressing ⧉ + ⌃ simultaneously. ▸ Set the bolus amount to 0.0 units. Press ✓ to exit.	No bolus is delivered.
During the start delay (Standard Bolus symbol blinks)	Press ⧉ + ⌃, ⌄ or ⌃. You hear a melody. Your pump returns to the RUN screen. A warning W8: BOLUS CANCELLED occurs. Press ✓ twice to confirm and turn off the alert. See chapter *8 Warning W8: BOLUS CANCELLED*.	No bolus is delivered.
During bolus delivery (countdown of bolus amount)	Press and hold ⌄ or ⌃ for 3 seconds until you hear a melody. You can view the actual bolus amount delivered prior to the cancellation by looking at the bolus history. See section *5.4.1 Viewing your bolus history*.	Bolus delivery is interrupted.

Cancellation during the start delay and during the bolus delivery will cause a *WARNING W8: BOLUS CANCELLED*. Press ✓ twice to confirm and snooze the warning. See chapter *8 Warnings and errors*.

Check to see if any insulin was delivered: It is possible that a small amount of insulin may have been delivered during the cancel bolus process. In pump mode, press ▶ twice on the meter to view the BOLUS DATA screen. If more insulin was delivered than required for your therapy, you must eat carbohydrates to compensate for that insulin. If you program a new bolus you have to take into account any amount of insulin already delivered during the cancel bolus process.

Note *Make sure that the cancellation was deliberate and program a new bolus, if needed.*

4.3 Programming an Extended Bolus

The Extended Bolus option enables you to program a bolus to be delivered over a period of time. This function is helpful during long meals, dinners, or receptions, or when you have meals that are digested slowly. The Extended Bolus may also be appropriate for people who have gastroparesis (delayed digestion).

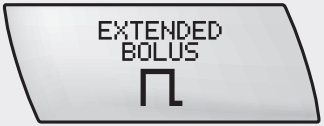
The duration of bolus delivery can be programmed in 15-minute intervals up to 12 hours and begins immediately after confirmation. Throughout the bolus delivery, the remaining time and amount of the Extended Bolus and the current hourly basal rate are displayed in the RUN screen.

Tip: You can add a Standard or Quick Bolus to an ongoing Extended Bolus. If you cancel the Standard Bolus, the Extended Bolus continues to run.
During the delivery of an Extended Bolus, the programming of another Extended Bolus or a Multiwave Bolus is blocked. If you try to do this, you will receive the error message: “Bolus currently running”. The error message only appears on your meter.

If you want to program a different Extended Bolus, put the pump in STOP mode to cancel the current bolus and to program a new one.

Procedure for programming an Extended Bolus

1.



Press to move to the EXTENDED BOLUS screen.

2.

Press to select. The BOLUS AMOUNT screen appears.

3.

Press to increase or to decrease the bolus amount.

The duration of the last Extended Bolus delivered appears.

4.

Press to move to the BOLUS DURATION screen.

Press to increase or to decrease the bolus duration.

Tip: Press to switch between programming the bolus amount and bolus duration.

5.

Press to confirm the bolus amount and duration. The pump returns to the RUN screen. The bolus delivery begins within the next 3 minutes.

Note *If a Temporary Basal Rate is active at the same time as the Extended Bolus, the remaining time and amount of the bolus and the amount of the increased or decreased hourly basal rate are displayed in the RUN screen.*

4.3.1 Cancelling an Extended Bolus

During programming (the bolus amount or bolus duration blinks)	You can either: ▸ wait for your pump to return to the RUN screen. ▸ press ⧉ and ⌃ simultaneously to exit the Function screen. ▸ set the bolus amount to 0.0 units and press ✓.	No bolus is delivered.
During bolus delivery	▸ If the Extended Bolus delivery has begun, it can be cancelled by putting your pump into STOP mode. This cancels the bolus delivery and the warning W8: BOLUS CANCELLED is displayed. Press ✓ twice to confirm and turn off the alert. See chapter *8 Warning W8: BOLUS CANCELLED*. The bolus amount delivered up to the cancellation can be reviewed in the BOLUS HISTORY screen. See section *5.4.1 Viewing your bolus history*.	Bolus delivery is interrupted.

Note *If a Temporary Basal Rate is active at the same time, it is also cancelled when your pump is put into STOP mode. The warning W8: BOLUS CANCELLED and the warning W6: TBR CANCELLED are displayed. Press ✓ twice to confirm and turn off the first warning. The second alert appears on the display. Press ✓ twice to confirm and turn off the second warning. Both alerts are recorded in the warnings history.*

See chapter *8 Warning W6: TBR CANCELLED* and *Warning W8: BOLUS CANCELLED*. Make sure that the cancellation was deliberate and then program a new Extended Bolus (and/or Temporary Basal Rate) if needed.

4.4 Programming a Multiwave Bolus

The Multiwave Bolus option is available in the ADVANCED user menu. It is designed to better simulate the body's insulin delivery, and combines an immediate bolus delivery followed by an Extended Bolus delivery. This option can be helpful when you have meals that include both rapidly and slowly absorbed carbohydrates.
The duration of bolus delivery can be programmed in 15-minute intervals for up to 12 hours.

Note

- *The Multiwave Bolus is available only in the ADVANCED user menu.*
- *You can add a Standard Bolus to an ongoing Multiwave Bolus. If you cancel the Standard Bolus, the Multiwave Bolus remains running.*
- *During the delivery of a Multiwave Bolus, the programming of a second Multiwave Bolus or an Extended Bolus is blocked. If you need a different Multiwave Bolus, put your pump in STOP mode to cancel the current bolus and program a new one.*

When programming a Multiwave Bolus, make sure that you are using the ADVANCED user menu and your pump is in RUN mode.

Procedure for programming a Multiwave Bolus

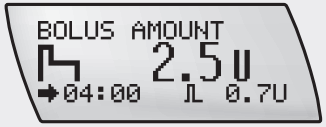
1.

Press to move to the MULTIWAVE BOLUS screen.

2.

Press to select. The BOLUS AMOUNT screen appears.

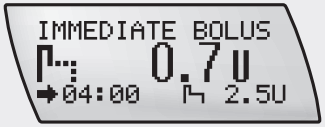
3.



Press or to increase or decrease the total bolus amount.

Note *The first time you press , the bolus duration of the last Multiwave Bolus and a default immediate bolus amount appear. The latter increases or decreases proportionally as you increase or decrease the total bolus amount.*

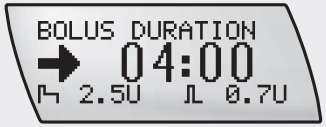
4.



Press to move to the IMMEDIATE BOLUS screen.

Press or to correct and set the immediate bolus amount.

5.

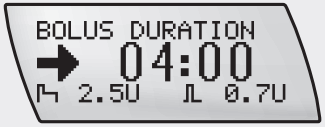


Press to move to the BOLUS DURATION screen.

Press or to correct and set the Extended Bolus duration in increments of 15 minutes for up to 12 hours.

Tip: Press to loop between programming the total BOLUS AMOUNT, IMMEDIATE BOLUS and BOLUS DURATION.

6.



Check the total and immediate bolus amounts and the Extended Bolus duration programmed on the screens.

7.

Press to confirm both bolus amounts and the bolus duration. The Multiwave Bolus symbol blinks for 5 seconds (bolus delivery start delay).

8.

The pump beeps 3 times and vibrates. The immediate bolus delivery begins. The countdown of the remaining bolus continues to appear on the display.

Note *If a Temporary Basal Rate is active at the same time, the remaining time and amount of the bolus and the amount of the increased or decreased hourly basal rate are displayed on the RUN screen.*

4.4.1 Cancelling a Multiwave Bolus

During programming (the bolus amount blinks)	There are 3 ways to cancel a Multiwave Bolus during programming: ▸ Do not press any key for 20 seconds. The pump returns to the RUN screen. ▸ Return to the Multiwave Bolus screen by pressing ⧉ + ⌃ simultaneously. ▸ Set the total bolus amount to 0.0 units and press ✓.	No bolus is delivered.
During the start delay (Multiwave symbol blinks)	▸ Press ⧉ + ⌃, ⌄ or ⌃. The pump beeps and vibrates. The pump returns to the RUN screen.	No bolus is delivered.
During immediate bolus delivery	▸ You can cancel immediate delivery by pressing and holding ⌄ or ⌃ for 3 seconds until you hear a melody. This cancels the whole bolus (immediate and Extended Bolus delivery).	Bolus delivery is interrupted.
During extended delivery	▸ You can cancel the extended delivery by putting the pump in STOP mode. This cancels the Extended Bolus.	Bolus delivery is interrupted.

Cancellation of the bolus during start delay, immediate bolus delivery or extended delivery will cause the warning W8: BOLUS CANCELLED. Press ✓ twice to confirm and turn off the alert. See chapter *8 Warning W8: BOLUS CANCELLED*.

You can review the actual bolus amount delivered before the cancellation by looking at the bolus history. See section *5.4.1 Viewing your bolus history*.

Note *If a Temporary Basal Rate is active at the same time, it is also cancelled when your pump is put in STOP mode. The warning W8: BOLUS CANCELLED and the warning W6: TBR CANCELLED are displayed.*
Press ✓ twice to confirm and turn off the first warning. The second warning appears on the display. Press ✓ twice to confirm and turn off the second warning. Both warnings are recorded in the alarm history. See chapter 8 Warning W6: TBR CANCELLED and Warning W8: BOLUS CANCELLED. Make sure the cancellation was intended and then program a new Multiwave Bolus (and/or Temporary Basal Rate), if needed.

4.5 Programming a Temporary Basal Rate (TBR)

Your pump allows you to temporarily increase or decrease your basal rate. This enables you to match your changing insulin needs due to increased or decreased activity level, illness, or stress.

Typically, a basal rate is set to 100 %, but you can:

- Increase it to 250 % for up to 24 hours
- Decrease it to 0 % for up to 24 hours

When you increase or decrease your basal rate, each hourly basal rate for the duration you program is increased or decreased. The characteristic shape of your basal rate profile remains and does not become a flat curve, if the change is larger than 0 %. For 0 % the basal rate profile becomes a flat line and no insulin (except boluses) is delivered during the programmed duration.

Discuss programming a Temporary Basal Rate with your doctor or healthcare team.

Note *A running Temporary Basal Rate increase or decrease remains active, even if you have changed the basal rate profile.*

You can only program a Temporary Basal Rate when your pump is in RUN mode.

Procedure for programming a Temporary Basal Rate

1.

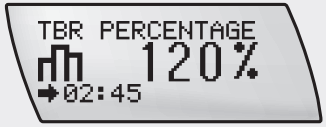
Press ⊕ to move to the TEMPORARY BASAL RATE (TBR) screen.

2.

Press ✓ to select. The TBR PERCENTAGE screen appears.

Note *If no Temporary Basal Rate is currently active, the percentage is set to 100 %. If a Temporary Basal Rate is active, its duration and percentage appear on the RUN screen.*

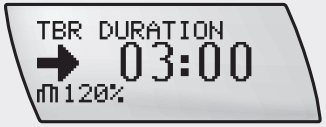
3.



Press ⊕ or ⊖ to increase or decrease the basal rate.

Tip: When you increase (or decrease) the Temporary Basal Rate, the duration of your previous Temporary Basal Rate increase (or decrease) appears. However, when you use your pump for the first time, a default value appears.

4.



Press ⊕ to move to the TBR DURATION screen.

Press ⊕ or ⊖ to correct and set the duration.

Tip: You can switch between programming the basal rate percentage and duration by pressing ⊕.

5.

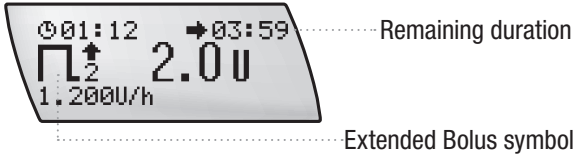
Press ✓ to save and exit.

The new Temporary Basal Rate is immediately activated.

When a Temporary Basal Rate is active, the pump emits a beep once every hour.

Note *During Temporary Basal Rate delivery, the increase or decrease in percentage, the increased or decreased hourly basal rate (hourly basal rate plus TBR percentage), and the remaining time are displayed in the RUN screen. An arrow pointing upwards symbolizes a Temporary Basal Rate increase; an arrow pointing downwards symbolizes a Temporary Basal Rate decrease.*

Note *If an Extended Bolus or a Multiwave Bolus is active at the same time, the remaining time and amount of the bolus and the amount of the increased or decreased hourly basal rate are displayed in the RUN screen.*
Example: Extended Bolus running



TBR OVER Alert

At the end of a Temporary Basal Rate, the warning W7: TBR OVER is displayed. Press ✓ twice to confirm and turn off the warning. See chapter *8 Warning W7: TBR OVER*.

4.5.1 Cancelling a Temporary Basal Rate

During programming	There are 3 ways to cancel a Temporary Basal Rate during programming: ▶ Do not press any key for 20 seconds. The pump returns to the RUN screen. ▶ Exit the Temporary Basal Rate (TBR) screen by pressing ⧉ + ⌃ simultaneously. ▶ Set the TBR percentage to 100 %. Press ✓ to save and exit.	Pump continues to deliver normal basal rate.
During delivery	There are 2 ways to cancel a Temporary Basal Rate during delivery: ▶ Set the TBR percentage to 100 %. Press ✓ to save and exit. The warning W6: TBR CANCELLED is displayed. ▶ Or you can put your pump in STOP mode. The Temporary Basal Rate delivery is cancelled, as well as any Extended or Multiwave Bolus that is currently running. The warning W6: TBR CANCELLED is displayed. Press ✓ twice to confirm and turn off the alert.	Pump returns to normal basal rate.

Note *If an Extended Bolus or a Multiwave Bolus is active at the same time, it is also cancelled when your pump is put into STOP mode. The warning W8: BOLUS CANCELLED and the warning W6: TBR CANCELLED are displayed.*
Press ✓ twice to confirm and turn off the first alert. The second alert appears on the display. Press ✓ twice to confirm and turn off the second alert. Both alerts are recorded in the alarm history. See chapter 8 Warning W6: TBR CANCELLED and Warning W8: BOLUS CANCELLED. Make sure that the cancellation was intended and then program a new Temporary Basal Rate (and/or an Extended or Multiwave Bolus), if needed.

4.6 General safety information

WARNING

- Incorrect programming of your insulin pump may cause inappropriate insulin delivery.
- Your insulin pump must be programmed with your personal settings before starting insulin pump therapy.
- Do not operate your insulin pump without knowing your personal settings.
- If you are not sure about your personal settings, or you are less experienced, ask your doctor or healthcare team to check your personal settings.
- Work with your doctor or healthcare team to determine the timing, amount, and type of bolus you need to deliver.
- Make sure you know your personal carbohydrate-to-insulin ratio and your correction factor.

WARNING

When your pump is in STOP mode it does not deliver insulin. Put the pump in RUN mode to continue insulin delivery.

5 Personalizing your pump

This chapter explains how to use the available menu options, and to personalize your pump to match your level of experience with insulin pump therapy.

5.1 Introduction

Using the 4 keys on the pump, and their combinations, you can access the menu options and their relevant screens. This enables you to, for example:

- Program the pump
- Perform a function
- Change a setting
- Store information

Note *Your Accu-Chek Spirit Combo insulin pump has been designed for use with the meter. This is intelligent blood glucose meter that enables you to control your insulin pump using Bluetooth® wireless technology.*

5.1.1 User menus

Your Accu-Chek Spirit Combo insulin pump has been designed to adapt to your level of experience in pump therapy – whether you are a beginner or an experienced pump user. Your Accu-Chek Spirit Combo insulin pump “grows” with you!
You can use one of 3 menus – STANDARD, ADVANCED or CUSTOM – to access the functions and settings you will need from day to day.

STANDARD	This menu provides all the basic functions you need for successful pump therapy. If you are new to pump therapy, we recommend that you start with this menu. As you become more experienced, you may wish to change to the ADVANCED user menu.
ADVANCED	This menu provides the complete range of the Accu-Chek Spirit Combo insulin pump functions. It includes all the functions from the STANDARD user menu, plus a wide range of functions for the more experienced user.
CUSTOM	Because the Accu-Chek Spirit Combo insulin pump has so many features, you may want to decide which screens are displayed when you scroll through the menu choices. Using appropriate PC software, this menu enables you to hide screens of the ADVANCED user menu and thereby customize your pump.

At the beginning of this User's Manual, you will find fold-out diagrams of the STANDARD, CUSTOM and ADVANCED user menus.

Note *For your safety and convenience during programming, your Accu-Chek Spirit Combo insulin pump returns to the RUN or STOP screen if no key is pressed within 20 seconds. The changes you made before your pump timed out will not be saved.*

5.2 Selecting a user menu

Note *For guidance in choosing the most suitable user menu, see section 5.1.1 User menus. If you are still not sure which menu to choose, discuss this with your doctor or healthcare provider.*

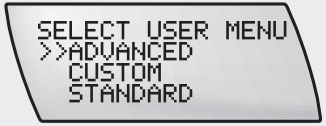
Procedure for selecting a user menu

1.

Press to move to the MENU SETTINGS screen.

Press to select.

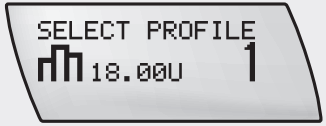
2.



The SELECT USER MENU screen is displayed.

Press or to select a user menu.

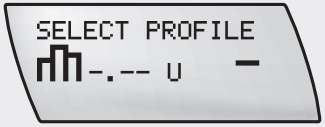
3.



Press to confirm.

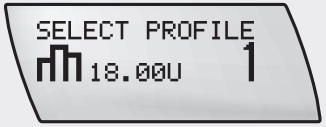
The selected basal rate profile and its daily insulin total appear, or …

4.



… if the previous basal rate profile is not available from the selected user menu, dashes appear instead.

5.



Press ⊕ or ⊖ to select a basal rate profile, if required.
Check the (new) basal rate profile and its daily insulin total.

Press ✓ to save and exit.

The new user menu and basal rate profile are active immediately.

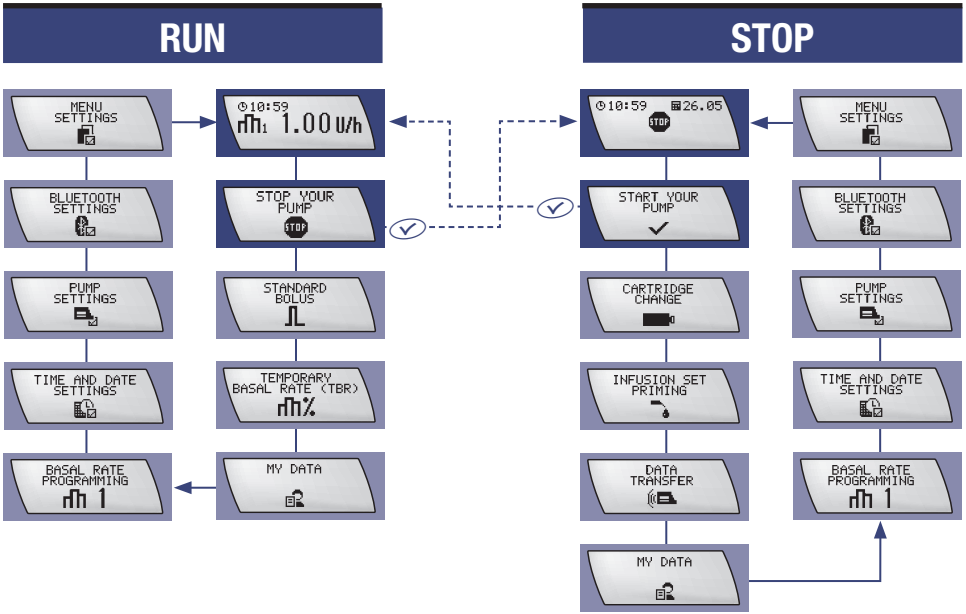
CAUTION

A running increased or decreased Temporary Basal Rate will remain active, even if you change the basal rate profile. The Temporary Basal Rate is based on the new basal rate.

5.3 STANDARD user menu

The following is a list of menu options from the STANDARD user menu. To view the order in which they appear on the display, refer to the menu diagram below:

- Press ⊕ to move forwards
- Press ⊕ + ⊖ simultaneously to move backwards



Some of the functions have already been described elsewhere in this User's Manual, as listed below. The remaining functions are described following the list.

TIME AND DATE SETTINGS

- See section *2.4 Setting the time and date*.

BASAL RATE PROGRAMMING

- See section *2.5.1 Programming your basal rate profile*.

CARTRIDGE CHANGE

- See section *2.7 Inserting the cartridge*.

INFUSION SET PRIMING

- See section *2.8 Priming the infusion set*.

START YOUR PUMP

- See section *2.10 Starting insulin delivery*.

STOP YOUR PUMP

- See section *2.11 Stopping insulin delivery*.

QUICK BOLUS

- See section *4.2.1 Programming a Quick Bolus*.

STANDARD BOLUS

- See section *4.2 Programming a Standard Bolus*.

EXTENDED BOLUS

- See section *4.3 Programming an Extended Bolus*.

TEMPORARY BASAL RATE (TBR)

- See section *4.5 Programming a Temporary Basal Rate (TBR)*.

MENU SETTINGS

- See section *5.2 Selecting a user menu* earlier in this chapter.

BLUETOOTH SETTINGS

- See chapter *6 Using the Accu-Chek Spirit Combo insulin pump with the meter*.

5.4 Viewing your pump data

The memory of your Accu-Chek Spirit Combo insulin pump stores all the events (warnings and errors, programming operations and insulin delivery records), up to 4500 events. This data corresponds to about the last 90 days of use, and can be accessed on a personal computer using the Accu-Chek software products.

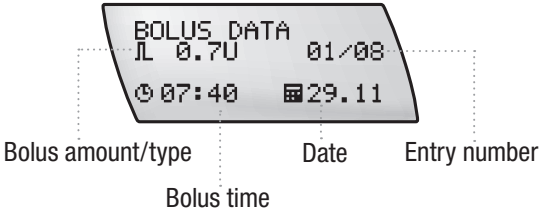
The following data can be reviewed directly on your Accu-Chek Spirit Combo insulin pump:

Bolus history	last 30 boluses
Alarm history	last 30 warnings and errors
History of daily insulin totals	last 30 daily totals of insulin delivered
Temporary Basal Rate history	last 30 increases and decreases in basal rate
Pump timer	remaining time in days until the pump timer expires

Note *Once 30 history entries are in memory (e.g. bolus history, alarm history), adding a new entry deletes the oldest entry.*

5.4.1 Viewing your bolus history

The BOLUS DATA screen allows you to view up to the last 30 bolus deliveries, starting with the most recent entry.



Each BOLUS DATA screen displays:

- Bolus type (Standard, Extended or Multiwave Bolus)
- Bolus duration (only displayed for an Extended or Multiwave Bolus)
- Time
- Date
- Entry number (01 is the most recent) of total entries (example 01/30) of a delivered bolus

Tip: You can enter the BOLUS DATA screen also from the QUICK INFO screen. See section *1.2.3 Display screens.*

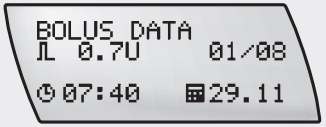
Procedure for viewing the bolus history

1.

Press to move to the MY DATA screen.

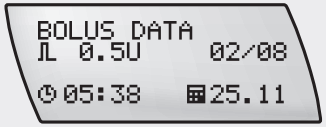
Press to select.

2.



The BOLUS DATA screen appears, showing the most recent bolus information.

3.



Press or to view the entries.

Press to exit.

5.4.2 Viewing the error and warning history

The ERROR DATA menu allows you to view up to the last 30 warnings and errors, starting with the most recent entry.

Each ERROR DATA screen displays:

- Number and type of the warning or error (for example, W6)
- Warning or error (for example, TBR CANCELLED)
- Time
- Date
- Entry number (01 is the most recent) of total entries (example 01/30) of a warning or error

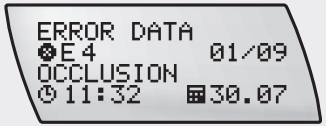
Procedure for viewing the error data history

1.

Press ⊕ to move to the MY DATA screen.

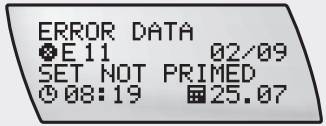
Press ✓ to select.

2.



Press ⊕ to move to the ERROR DATA screen.

3.



Press ▲ or ▼ to view the entries.

Press ✓ to exit.

5.4.3 Viewing the history of daily insulin totals

This function allows you to view up to the last 30 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
- Date
- Entry number (01 is the most recent) of total entries (example 01/04) of a daily insulin total

Procedure for viewing the daily insulin totals

1.

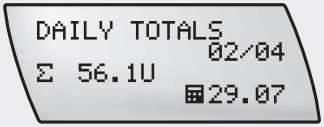
Press to move to the MY DATA screen.

Press to select.

2.

Press to move to the DAILY TOTALS screen.

3.



Press or to view the entries.

Press to exit.

5.4.4 Viewing the Temporary Basal Rate history

This option allows you to view up to the last 30 Temporary Basal Rate (TBR) increases or decreases, starting with the most recent entry.

Each TBR DATA screen displays:

- TBR increase or decrease in percentage
- TBR duration
- Time
- Date
- Entry number (01 is the most recent) of total entries (example 01/30) of a delivered Temporary Basal Rate

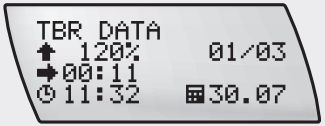
Procedure for viewing the Temporary Basal Rate history

1.

Press to move to the MY DATA screen.

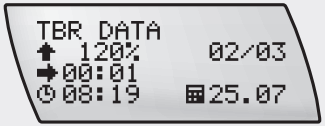
Press to select.

2.



Press to move to the TBR DATA screen.

3.



Press or to view the entries.

Press to exit.

5.4.5 Viewing the time remaining (pump timer)

The pump timer function only occurs on a backup or loan pump.

Your backup pump has been provided for contingency use only. It has a pre-set operating time of 180 days. When you first start your backup or loan pump, it will begin to count down the remaining days. Before the operating time expires, you will be prompted with the warning W5: PUMP TIMER or W9: LOANTIME WARNING message, and the pump timer symbol will be displayed in the RUN and STOP screen. When the operating time has expired, you will be prompted with the error E5 or E9: END OF OPERATION, and the pump will turn to STOP mode.

After the error E5 or E9, the pump cannot be switched to RUN mode again.

See chapter *8: Warning W5: PUMP TIMER, W9: LOANTIME WARNING* and *Error E5, E9: END OF OPERATION*

Procedure for viewing the time remaining

1.

Press ⊕ to move to the MY DATA screen.

Press ✓ to select.

2.

Press ⊕ to move to the PUMP TIMER screen.
The number of days remaining until the pump timer expires is shown.

Press ✓ to exit.

Note *This setting is country-specific and may not be visible on your pump.*

5.5 Transferring your data to a computer

The built-in infrared interface on the bottom of your Accu-Chek Spirit Combo insulin pump enables you to transfer data between your pump and a personal computer.

The memory of your Accu-Chek Spirit Combo insulin pump stores all the events (warnings and errors, programming operations and insulin delivery records) up to a total of 4500 events. This data corresponds to about the last 90 days of use, and can be accessed on a personal computer using the Accu-Chek information management products (for details see the user information provided with the software).
For availability of the appropriate software see Appendix C.

Procedure for transferring your data

1.

Put your pump in STOP mode.

2.

Press to move to the DATA TRANSFER screen.

Press to select.

3.

Press . A melody signals that your pump is ready to transfer data.

4.

When the data transfer is complete, press ✓ to return to the STOP screen.

Set up your pump with a cartridge, adapter, and a new infusion set, and put it in RUN mode if necessary.

Note *Your pump will return to STOP mode 15 minutes after the last data transfer when the DATA TRANSFER screen is selected. You can press twice ⊡ + ▲ to exit while data is being transferred. The data transfer is interrupted, and the error E12: DATA INTERRUPTED occurs. See chapter 8.*

5.6 Pump settings

These settings relate to the practical use of the pump. For settings relating to your therapy, see *5.10 Therapy settings* later in this chapter.

5.6.1 Turning Key Lock on and off

The Key Lock function allows you to lock the 4 keys of your Accu-Chek Spirit Combo insulin pump. This function prevents you from accidentally activating your pump. For example, you can use Key Lock while you are asleep or when playing sports.

If the Key Lock is turned on and no key is pressed for 10 seconds after your pump has returned to the RUN screen or STOP screen, all 4 keys are locked.

Procedure for turning the Key Lock on or off

1.

Press ⊕ to move to the PUMP SETTINGS screen.

Press ✓ to select.

2.

The current Key Lock status (ON or OFF) appears.

3.

Press ▲ or ▼ to turn the Key Lock ON or OFF.

Press ✓ to save and exit.

Procedure for unlocking the Key Lock

If you press any key while the screen is blank, the Key Lock symbol indicates that the keys are locked.

Note *The Key Lock remains unlocked during fast bolus delivery of Standard or Multiwave Bolus.*

1.

From the blank screen, press and hold + for 3 seconds.
You hear 3 beeps in RUN or STOP mode when you press the keys and again after 3 seconds to confirm that the Key Lock is unlocked.

2.

If no key is pressed for 10 seconds after your pump has returned to the RUN or STOP screen, all 4 keys are automatically locked.

5.6.2 Adjusting the sound volume

Your pump emits different acoustic signals in different handling situations to facilitate handling e.g. for blind or partially-sighted users. For details on the meaning of the sound patterns, see the *Appendix E: Beeps and melodies*. You can adjust the volume of the beeps according to your personal preference. There are 5 volume levels available: off, low, medium, high and maximum.

Note *The volume of the STOP warning is independent of the programmed beep volume – it always sounds at the maximum level. If the beeps are turned off, and a warning or error occurs, the beeps become active again to ensure that you are aware of the warning or error. If the warning or error is not cancelled, the beeps gradually increase in volume until the maximum level is reached.*

Procedure for adjusting the sound volume

1.

Press ⊕ to move to the PUMP SETTINGS screen.

Press ✓ to select.

2.

Press ⊕ to move to the SOUND VOLUME screen.

Press ▲ or ▼ to adjust the sound volume.

Press ✓ to save and exit.

5.6.3 Changing signal settings

The Accu-Chek Spirit Combo insulin pump enables you to choose how you want your pump to alert you when a warning or error occurs.
You have 3 options:

Beep only	
Vibrate only	
Beep and vibrate	

For your safety, if you do not respond to the vibration, the pump starts beeping after one minute.

Procedure for changing the signal settings

1.

Press to move to the PUMP SETTINGS screen.

Press to select.

2.

Press to move to the SIGNAL SETTINGS screen.

Press or to set the signals.

Press to save and exit.

5.6.4 Display orientation

Your pump allows you to turn the display by 180°, so that you can view it more easily, depending on how you are wearing the pump.

Note *If you turn the display orientation of your pump by 180°, the functions of the ⊕ and ⊖ keys are also reversed. The functions of the ⊡ and ✓ keys remains the same, whichever screen orientation you choose.*

Procedure for setting the display orientation

1.

Press ⊡ to move to the PUMP SETTINGS screen.

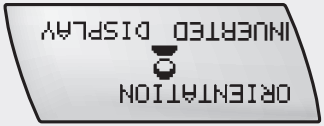
Press ✓ to select.

2.

Press ⊡ to move to the ORIENTATION screen.

The current orientation is displayed.

3.



Press ⊕ or ⊖ to select the display orientation.

Press ✓ to save and exit.

5.6.5 Setting the display contrast

Your pump allows you to adjust the display contrast to suit your preferences.

Procedure for setting the display contrast

1.

Press to move to the PUMP SETTINGS screen.

Press to select.

2.

Press to move to the DISPLAY CONTRAST screen.

Press or to select the desired contrast level.

Press to save and exit.

5.6.6 Selecting the language

Your pump can display the information in several languages.
You can chose the language according to your preferences.

Procedure for setting the language

1.

Press ⊕ to move to the PUMP SETTINGS screen.

Press ✓ to select.

2.

Press ⊕ to move to the LANGUAGE screen.

Press ▲ or ▼ to select a language.

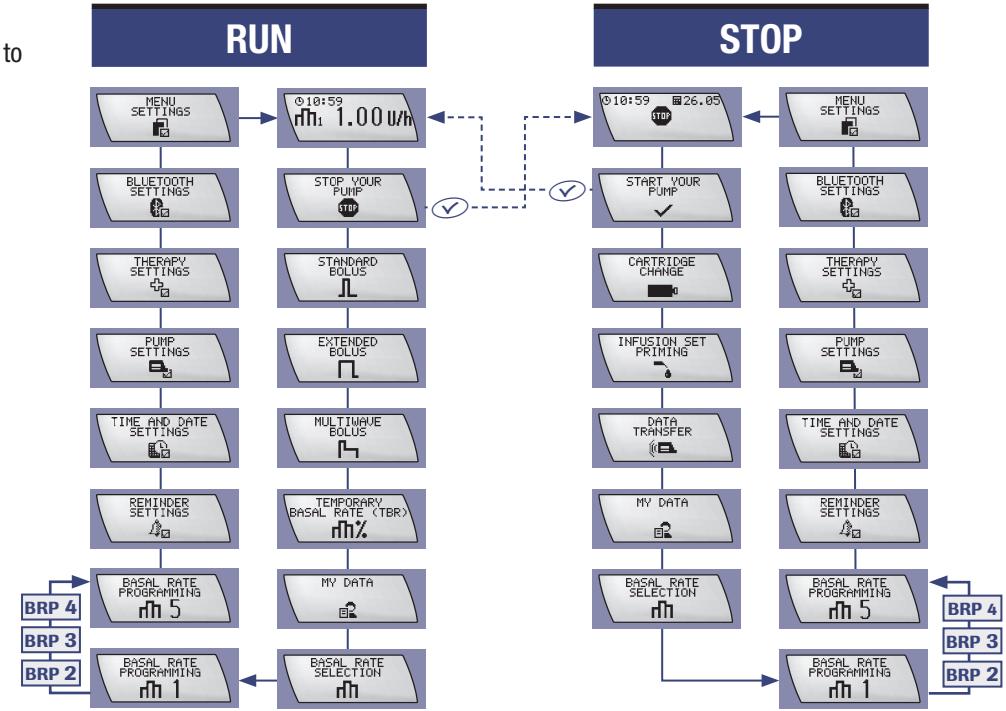
Press ✓ to save and exit.

5.7 ADVANCED user menu

The following is a list of additional menu options available in the ADVANCED user menu. To view the order in which they appear on the display, refer to the menu diagram below:

- Press ⊡ to move forwards
- Press ⊡ + ⊡ simultaneously to move backwards

BRP = Basal Rate profile 2–4



Note *The ADVANCED user menu contains all the options from the STANDARD user menu.*
Some of the functions are described elsewhere in this User's Manual, as listed below. The remaining functions are described in this chapter following the list.

MULTIWAVE BOLUS

- See section *4.4 Programming a Multiwave Bolus*.

5.8 Basal rate profiles

Your pump has 5 different basal rate profiles to match your changing insulin needs (for example, Monday to Friday or Exercise Day or Sleeping Late Day).
Discuss additional basal rate profiles with your doctor or healthcare team. Also, consult with your doctor or healthcare team before changing basal rate profiles, as this may affect how you use your pump.

5.8.1 Programming additional basal rate profiles

WARNING

Your Accu-Chek Spirit Combo insulin pump must be programmed with your personal settings prior to starting insulin pump therapy. Do not operate your pump without knowing your personal settings. If you are not sure about your personal settings or you are inexperienced, ask your healthcare provider to check your personal settings.

Procedure for Programming additional basal rate profiles

1.

Press ⊕ to move to the BASAL RATE PROGRAMMING (2, 3, 4, 5) screen you wish to program.

Press ✓ to select.

2.

The hourly basal rates for each additional basal rate profile are set in the same way as for basal rate profile 1.

See section *2.5.1 Programming your basal rate profile*.

Note *Only basal rate profiles that are accessible in your current user menu are available. If the basal rate profile number(s) do(es) not appear, select the ADVANCED user menu, or program the basal rate profile to an available basal rate profile number.*

5.8.2 Selecting a basal rate profile

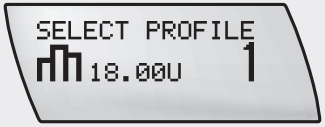
Procedure for selecting a basal rate profile

1.

Press to move to the BASAL RATE SELECTION screen.

Press to enter.

2.



Press or to select a basal rate profile. The selected basal rate profile and its daily insulin total appear.

Press to select.

The new basal rate profile is active immediately.

Note *Only basal rate profiles that are accessible in your current user menu are available.*
A running Temporary Basal Rate increase or decrease stays active, even if you change the basal rate profile on your pump.

5.9 Setting a reminder

You can set both single and multiple reminders on your pump. Multiple reminders are repeated at a set time every day. You can use this feature to remind you, for example, when you need to test your blood glucose.

Procedure for setting single or multiple reminders

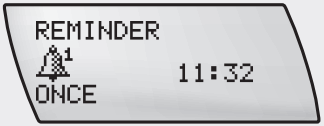
1.

Press to move to the REMINDER SETTINGS screen.

2.

Press to select. The current REMINDER status and alarm time appear.

3.



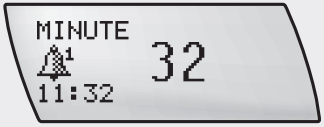
Press or to change the REMINDER setting to OFF, ONCE or EVERY DAY.

4.

Press ⊕ to move to the HOUR screen.

Press ⊕ or ⊕ to set the hour.

5.



Press ⊕ to move to the MINUTE screen.

Press ⊕ or ⊕ to set the minute.

Press ⊕ to save and exit.

Turning off the reminder

When the reminder sounds, the reminder screen is displayed.

Press ⊕ twice to snooze and confirm and return to RUN or STOP mode (See also chapter *8.4 Reminder R1*).

5.10 Therapy settings

These settings relate to the therapeutic use of the pump. For settings relating to the practical use of the pump, see pump settings earlier in this chapter.

5.10.1 Adjusting the bolus increment

Designed for those patients who may need large or small amounts of insulin, the bolus increment for the Quick Bolus of your Accu-Chek Spirit Combo insulin pump is adjustable. It is initially set to 0.5 units per key-press, but it can be changed to 0.1, 0.2, 0.5, 1.0 or 2.0 units.

WARNING

The bolus increment determines the Quick Bolus amount per key press using the ⊕ and ⊖ keys. Incorrect programming of the bolus increment may cause inappropriate insulin delivery.

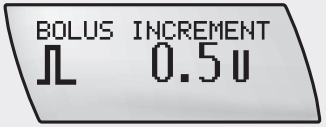
Procedure for adjusting the bolus increment

1.

Press ⊕ to move to the THERAPY SETTINGS screen.

Press ✓ to select.

2.



Press ⊕ to move to the BOLUS INCREMENT screen.

Press ⊕ or ⊖ to select a bolus increment.

Press ✓ to save and exit.

5.10.2 Adjusting the prime amount

The prime amount needed to fill an infusion set depends on the length of the infusion set tubing. The shorter your infusion set tubing, the less insulin will be required to prime the infusion set. The default setting for the prime amount is 25 units of U100 insulin.

Note *The amount of insulin used for the priming is not added to the history of daily insulin totals.*

Procedure for adjusting the prime amount

1.

Press to move to the THERAPY SETTINGS screen.

Press to select.

2.

Press to move to the PRIME AMOUNT screen.

Press or to select a prime quantity between 0.0 and 50.0 units.

Press to save and exit.

5.10.3 Locking basal rate profiles

Your Accu-Chek Spirit Combo insulin pump allows you to adapt your hourly basal rate profile as needed. You can then lock your basal rate profiles to provide additional protection against accidentally changing a basal rate during normal operation. If the basal rate lock is set to ON, programming of the basal rate profiles 1, 2, 3, 4 and 5 is blocked.

If you try to program a basal rate while the BASAL RATE LOCK is turned ON, the key symbol in the BASAL RATE TOTAL screen indicates that basal rate programming is locked.
The ⊕ and ⊖ functions are blocked.
However, you can still change between the different basal rate profiles 1 to 5.

Procedure for locking the basal rate profiles

1.

Press ⊡ to move to the THERAPY SETTINGS screen.

Press ✓ to select.

2.

Press ⊡ to move to the BASAL RATE LOCK screen.

Press ⊕ or ⊖ to turn the basal rate lock ON or OFF.

Press ✓ to save and exit.

5.10.4 Automatic Off

Automatic Off is a safety feature that stops insulin delivery and triggers error E3: AUTOMATIC OFF if no keys are pressed within a programmed time period in RUN mode. This feature can either be set to OFF or programmed up to 24 hours in 1-hour intervals. The factory setting is OFF.
Discuss using the Automatic off function with your doctor or healthcare team.

Procedure for using Automatic Off

1.

Press to move to the THERAPY SETTINGS screen.

Press to select.

2.

Press to move to the AUTOMATIC OFF screen.

Press or scroll to increase or to decrease the duration for the Automatic off in 1-hour intervals.

3.

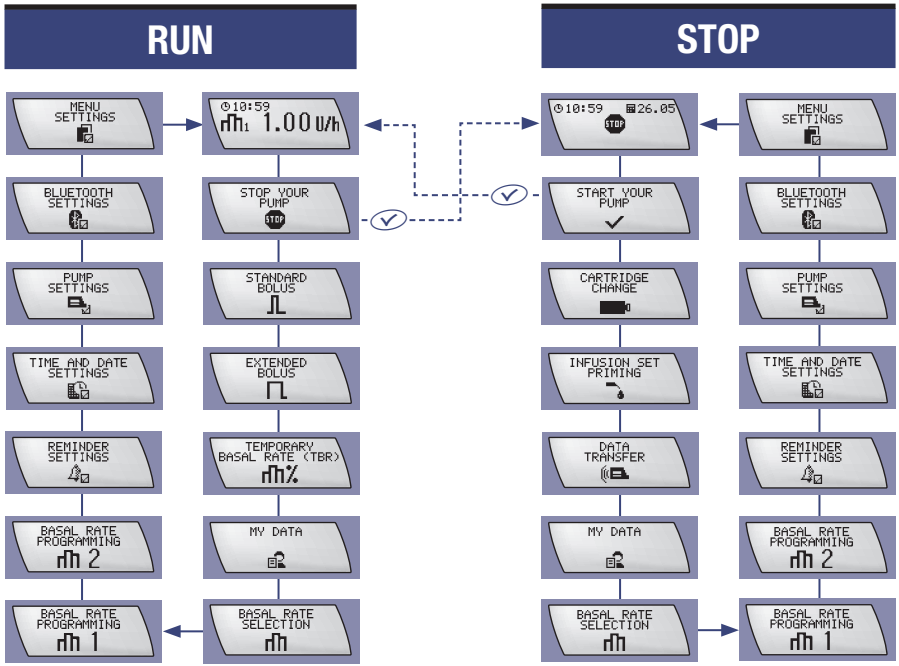
If you would like to set the Automatic Off function to off, press until “0 h” and OFF appear on the display.

Press to save and exit.

5.11 CUSTOM user menu

The CUSTOM user menu is designed to adapt your pump to your special requirements and preferences. It allows you or your healthcare provider to display or hide screens and thereby customize the individual user menus.

- Press ⊕ to move forwards
- Press ⊕ + ⊕ simultaneously to move backwards



Note *By default, the CUSTOM user menu contains all of the functions available except the following:*

- *Multiwave Bolus*
- *Basal rate profiles 3, 4 and 5*
- *Therapy Settings*

To change the CUSTOM user menu, you, your doctor, or your healthcare provider must use the Accu-Chek 360° configuration software.

6 Using the Accu-Chek Spirit Combo insulin pump with the meter

This chapter describes how the Accu-Chek Spirit Combo insulin pump works with the meter, and explains how to pair the 2 devices using *Bluetooth*® wireless technology.

Note *In this User's Manual the term "meter" always refers to your Accu-Chek diabetes management device, which is compatible with your Accu-Chek Spirit Combo insulin pump.*

"Pairing" means to set up a connection between the 2 devices using *Bluetooth*® wireless technology. This is a secure connection, and there is no risk of your pump receiving signals from any other device.

Note *The pump cannot communicate with the meter using Bluetooth® wireless technology when the devices are more than 2 meters apart.*

6.1 Meter

The meter – available separately – is both a blood glucose meter and a remote-control device for your Accu-Chek Spirit Combo insulin pump. Using the meter, you can program your pump without handling it, and also receive bolus advice and review history information.

Note *Do not leave your meter unattended as long as it is connected to your pump. Otherwise your pump could be manipulated remotely without your control (for example: children playing with the meter).*

6.1.1 Tasks that must be performed on the pump

The following tasks cannot be performed remotely using the meter:

- Changing the cartridge
- Priming the infusion set
- Data transfer
- *Bluetooth*® settings
- Display settings

All the other functions available on the Accu-Chek Spirit Combo insulin pump can be performed using the meter.

Before using your pump together with the meter you must read the documentation (*User's Manual*) provided with this product.

6.2 Switching *Bluetooth*® wireless technology ON and OFF

WARNING

You must ensure that *Bluetooth*® wireless technology is switched off on both devices before boarding an aircraft, as emissions from your pump or the meter could interfere with the electronics systems of the aircraft.

To prolong the battery life and avoid accidental changes on your pump, you should switch off *Bluetooth*® wireless technology, if the meter is lost, stolen or, you plan not to carry it with you for a longer period of time.

Procedure for switching *Bluetooth*® wireless technology ON and OFF

1.

Press ⊕ to move to the BLUETOOTH SETTINGS screen.

2.

Press ✓ to move to the ON/OFF screen.

Press ▲ or ▼ to switch the *Bluetooth*® wireless technology on or off.

Press ✓ to save and exit.

6.3 Pairing your pump with the meter

If you have already acquired the meter together with the Accu-Chek Spirit Combo insulin pump, the 2 devices will already have been paired.
When pairing your Accu-Chek Spirit Combo insulin pump with the meter, place both devices on a table or desk, so that you can see the displays of both devices clearly.

You should not perform the pairing process in crowded areas, since the emissions of other electronic devices could interfere with the connection.

Procedure for Pairing

1.

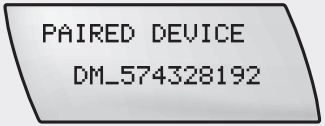
Press to move to the BLUETOOTH SETTINGS screen.

2.

Press to move to the ON/OFF screen.

Press or to switch the *Bluetooth*® wireless technology on.

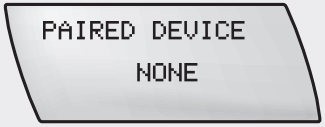
3.



Press to move to the PAIRED DEVICE screen.

Note *When Bluetooth® is turned off, you cannot access the Paired Device menu.*

4.



Pump screen

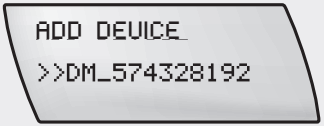
meter screen

If the pump screen indicates that no paired device is available, turn on the meter in pairing mode by holding down ☼ and simultaneously pressing ⓘ.

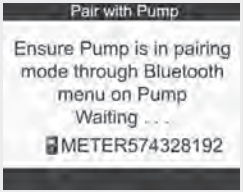
5.

Press the ⊡ key on the pump to see the ADD DEVICE screen, and press ✓ to initiate pairing.

6.



Pump screen



meter screen

The pump begins searching and detects the meter, displaying its serial number (This process may take several minutes).

Press ⌃ or ⌄ to select the number, which is also shown on your meter screen.

Press ✓ on the pump to confirm that you want to pair the meter.

7.

Pump screen

meter screen

The pump begins the pairing process and shows a 10-digit code. Enter the code on the meter display, using ⬭, △ and ▽ and then ⬭ to move to the next digit. Confirm the complete code with ⬭.

8.

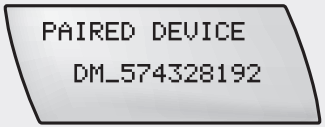
meter screen

After the pairing is completed press ⓘ to turn off the meter.

9.

The pump now shows the DEVICE PAIRED screen. Press ✓ to confirm the pairing.

10.



The pump displays the PAIRED DEVICE screen. You can return to the RUN screen by pressing ✓.

If the pairing is not successful in a first attempt, wait a few minutes before you repeat the procedure in a safe or less crowded environment.

6.4 Troubleshooting the *Bluetooth*® connection

In case of problems with the *Bluetooth*® connection or after the appearance of the warning W10: BLUETOOTH FAULT, you have to repeat the pairing procedure described in section *6.3 Pairing your pump with the meter*.
Since only one meter at a time can be paired with your pump, you must delete the pairing before you can pair your pump with a new meter.

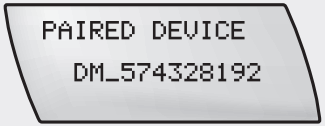
1.

Press to move to the BLUETOOTH SETTINGS screen.

2.

Press to move to the BLUETOOTH ON/OFF screen.

3.



Press to move to the PAIRED DEVICE screen.

4.

Press ⊕ to move to the DELETE DEVICE screen.

Press ✓ once to delete the pairing and a second time to confirm.

Then repeat the pairing procedure described in section *6.3 Pairing your pump with the meter.*

If the pairing is still not successful, contact local pump support (details on inside back cover).

6.4.1 Handling warnings and errors

The Accu-Chek Spirit Combo insulin pump and meter behave in the following ways when warnings and errors occur.

- If both devices are switched on and paired you can enter the meter's pump menu and snooze and confirm the warning or error through the meter.
- If the meter is switched off, and you switch it on in response to a warning, error or reminder on the pump, the meter switches immediately to the pump menu. All the functions available on the pump are performed from the pump menu of the meter.

Note *The above points do not apply in the case of E7: ELECTRONIC ERROR.*

6.4.2 Use in aircraft

WARNING

You must ensure that *Bluetooth*® wireless technology is switched off on both devices before boarding an aircraft, as emissions from your pump or the meter could interfere with the electronics systems of the aircraft.

7 Care and Maintenance

This chapter explains how to take care of your pump and keep it properly maintained.

CAUTION

Do not perform any servicing or repair on your Accu-Chek Spirit Combo insulin pump as this may void the guarantee. For further information, contact your local pump support (see inside back cover).

7.1 Inspecting your pump

Your pump must be properly maintained to guarantee accurate insulin delivery.
Check the pump display regularly during the day and before you go to sleep, and especially if for any reason you might not be able to hear the beeps or feel the vibrations.

Accessories
Use only sterile products and accessories with the Accu-Chek brand designed to be used with your pump. Replace and discard these items according to your doctor's or healthcare team's recommendations and the instructions that come with these items.

7.1.1 Checklist

Check your pump daily, and make sure that:

- The pump casing, the display, and the cartridge are not chipped or cracked and that the display does not show incomplete or abnormal letters or symbols.
- You carefully inspect the cartridge. Make sure that the actual amount of insulin in the cartridge equals the displayed cartridge amount on the QUICK INFO screen.
- You inspect all parts of your pump and infusion set regularly during the day and before you go to sleep. If you detect any loss of insulin, immediately replace the leaking component.
- The battery cover is correctly tightened and positioned, in line with the pump casing.
- The adapter is correctly attached.
- Your infusion set is primed, free of air bubbles, and tightly connected to the adapter.
- Your infusion set is inserted according to the instructions for its use.
- Your infusion site is secure, comfortable, and free of irritation or infection.
- The cartridge is free of air bubbles.
- Your pump is in RUN mode.
- The basal rates are set correctly according to your doctor's or healthcare team's recommendations.
- The time and date are set correctly.
- The Temporary Basal Rate changes are set according to your doctor's or healthcare team's recommendations.
- The beeps and/or vibrations are set.
- You have your personal emergency kit with you. (See section *1.5 Emergency kit*)

7.2 Damage to your pump

7.2.1 What to do if you drop your pump

If the pump is dropped it could be damaged, as well as the seal that protects it against water. So be careful not to drop your pump! Use the specially designed pump carrying system to help avoid dropping your pump. See Roche sterile products and accessories catalogues and brochures for more information, or contact your local pump support (details on inside back cover).

If you drop your pump:

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

Put your pump in STOP mode, and take out and reinsert the battery, so that the self-test is started.

Note *If a Temporary Basal Rate, an Extended Bolus or a Multiwave Bolus is active at the same time, it is cancelled when your pump is put into STOP mode. The warning W8: BOLUS CANCELLED or the warning W6: TBR CANCELLED is displayed.*

Press ✓ twice to confirm and turn off the alert. The alerts are recorded in the alarm history.

See chapter 8 Warning W6: TBR CANCELLED and Warning W8: BOLUS CANCELLED.

Make sure that the cancellation was deliberate and then program a new Temporary Basal Rate (and/or an Extended or Multiwave Bolus), if needed.

CAUTION

Immediately inspect your pump if it is dropped. Do not use your Accu-Chek Spirit Combo insulin pump if chips, cracks or other damages are visible. Otherwise water, dust, insulin or other foreign substances may enter your pump and could result in a malfunction.

If you have questions or are not sure whether your pump has been damaged, contact your local pump support (details on inside back cover).

7.3 Your insulin pump and water

CAUTION

Avoid contact with water. Check daily that your Accu-Chek Spirit Combo insulin pump is not chipped, cracked or damaged in any way, and that the battery cover and the adapter are correctly closed. If the pump is chipped or cracked, water, dust, insulin, or other substances may enter your pump and lead to malfunction. Before any contact with water, disconnect and take off your pump.

Disconnect and remove your pump before taking a bath, or going into a whirlpool, shower, or swimming pool. Avoid exposing your pump to high humidity, such as in a sauna, as this could result in damage. To make it easy to remove your pump, use disconnectable Accu-Chek infusion sets.

7.3.1 Accidental contact with water

Your Accu-Chek Spirit Combo insulin pump is IPX8 waterproof when leaving the factory site. However hair-line cracks could appear during use. Therefore we may only guarantee protection against brief accidental water contact such as:

- Rain
- Water splashes while you are cycling, jogging or hiking
- Accidental immersion in the sink, washbasin or bath

What to do after any water contact

Put your pump into STOP mode, disconnect the pump from your body, and inspect it. Use a soft dry cloth to dry the outside of the pump, and check the battery compartment and the cartridge compartment for water. If the battery compartment or cartridge compartment are wet, turn your pump upside down to let the water run out and let it air dry. Do not use warm air such as a hair dryer to dry the pump, as this could damage the pump's housing. Do not reinsert the battery or the cartridge until the compartments are completely dry. See section *7.5.1 Cleaning your pump*.

Other liquids

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

- Cleaning solutions
- Beverages
- Oil or Fat

In case of contact with these substances, clean your pump immediately. See section *7.5.1 Cleaning your pump*.

CAUTION

Avoid any contact between your Accu-Chek Spirit Combo insulin pump, the infusion set, and the connecting parts of your insulin pump with health and beauty items (for example: antiseptics, antibiotic creams, soaps, perfumes, deodorants, body lotions, or any other cosmetics). These substances could discolour your pump or fog the display.

7.4 Repair of your pump

CAUTION

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

If you have problems with your pump, contact your local pump support (details on inside back cover). Your local pump support can answer many questions and resolve many problems over the telephone. You may be requested to return your pump to Roche for investigation. For example, you may need to return your pump if a warning or error could not be cleared by following the procedures described in chapter *8 Warnings and errors*.

If you have to ship your pump, carefully pack the pump and the used cartridge, battery, battery cover, adapter, and infusion set to avoid damage during transportation. Place your pump back in the shipping case and put the case in a package that will not rip or tear. It is recommended to ship your pump using a company that tracks the shipment for you.

When you return your pump, include the following:

- a description of the reason for returning your pump
- your name and address
- your daytime phone number
- the serial number of your pump
- any RMA (Return Material Authorization) number received from your local pump support.

By returning your pump to Roche, you authorize Roche to undertake any testing on your infusion pump that is needed for a proper inspection, and understand that your pump may not be returned to you.
(For the address, see inside the back cover.)

7.5 Maintaining your pump

7.5.1 Cleaning your pump

The best time to clean your pump is when you change the cartridge. Use a soft cloth to clean the outside of the pump. If necessary, use a clean cloth with alcohol (isopropanol or ethanol). If these measures are not successful, contact your local pump support (details on inside back cover) for more instructions. Also see section *7.3.1 Accidental contact with water.*

CAUTION

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

7.5.2 Batteries

It is important to change your battery regularly and to keep spare batteries available. The life of any battery is affected by how you use your Accu-Chek Spirit Combo insulin pump, your personal settings, delivery rates, temperature, and other factors.
For details see Appendix A for lifetime of battery.
See section *1.4 Accessories and disposables* or Appendix C for more information on recommended batteries.
See section *2.2 Inserting the battery* for instructions on how to change your battery.

7.6 Storing your pump

CAUTION

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

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

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

Storage conditions

Temperature	41 °F to 113 °F (+5 °C to +45 °C)
Air humidity	5 to 85 % relative air humidity
Barometric pressure	500 to 1060 mbar

7.7 Disposing of your pump

Since your Accu-Chek Spirit Combo insulin pump may come into contact with blood during use, it may carry a risk of infection. Therefore it 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 Accu-Chek Spirit Combo insulin pump, return it to Roche (address inside the back cover) for professional disposal.

Battery

Correctly dispose of empty batteries, recycling them wherever possible.

Cartridge, Infusion set, Adapter, and Accessories

Dispose of the cartridge, infusion set, adapter, and accessories, according to the instructions that came with the respective product and according to local regulations.

8 Warnings and errors

A safety system monitors and controls the function of your Accu-Chek Spirit Combo insulin pump. This safety system performs more than 9 million safety checks every day. If it detects a change from the pump's normal state, it will trigger a warning or an error message. Beeps, vibrations, and messages on the pump screen indicate the cause of a warning or error. Warnings and errors are the only way you can be quickly notified of any changes in your pump.

CAUTION

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

Your pump signals warnings and errors 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.

If you do not confirm the warning or error within 60 seconds, it will be signalled again. Even when the beep is turned off or programmed at lower than maximum volume, the beep volume will rise to the loudest volume level if not confirmed. Both the beep and vibration will then continue at this level until confirmed.

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

Note

- *The volume of the STOP warning is separate from the programmed beep volume and cannot be changed. It always occurs at the maximum level.*
- *Key Lock is unlocked by the system each time a warning or error occurs.*

8.1 Confirming a warning or error

When you confirm:
W1: CARTRIDGE LOW
E1: CARTRIDGE EMPTY
W2: BATTERY LOW
E2: BATTERY EMPTY
W5: PUMP TIMER
E5: END OF OPERATION,
the symbol for that warning or error stays in the RUN screen or STOP screen as a reminder.

Battery low symbol
Pump timer symbol
Cartridge low symbol
Key Lock symbol

For other warnings or errors, alarm information is cleared from the display but stays in the alarm history and the event memory.

When a warning or an error occurs:

- Press ✓ to turn off the beeps and vibrations. The warning or error code stays on the display.

- As soon as you understand the reason for the warning or error, confirm by pressing ✓ again.
- Take appropriate action, as necessary.
- If more than one warning and/or error occurs simultaneously, press ✓ twice for each warning or error to confirm them and turn them off.
- After a warning or error, make sure that you switch your pump back to RUN mode where appropriate.

Note *When you use your pump together with the meter you can also snooze and confirm an incoming warning or error with the meter. For further information see the meter user information.*

8.2 List of warnings

WARNING

After a warning occurs, your Accu-Chek Spirit Combo insulin pump may be in STOP mode and insulin delivery may be interrupted. In order to maintain insulin delivery, you must act immediately according to the instructions given for each error code, or put your Accu-Chek Spirit Combo insulin pump in RUN mode to continue the insulin delivery.

Warning W1: CARTRIDGE LOW

The content of the insulin cartridge has dropped to 20 units of insulin. Be prepared to replace the cartridge as soon as possible. The “cartridge low” symbol appears in the RUN or STOP screen as a reminder until you change the cartridge.

- Press ✓ twice to snooze and to confirm the warning. Change the cartridge before it is empty.

- If necessary, put your pump in RUN mode.

See section *3.5 Changing the cartridge and infusion set*.

Warning W2: BATTERY LOW

The battery power is low. Be prepared for a battery change as soon as possible. The battery low symbol appears in the RUN or STOP screen as a reminder until you change the battery.

- Press ✓ twice to snooze and to confirm the warning.

- Replace the battery as soon as possible. Failure to change the battery within a few hours of receiving the warning could result in additional error messages.
- If necessary, put your pump in RUN mode.

See section *1.4 Accessories and disposables* on recommended batteries. See section *2.2 Inserting the battery* for instructions on how to change the battery.

Warning W3: REVIEW TIME

The pump settings and history data are saved in memory regardless of power loss. However, it may be necessary to set the time and date again.

- Press ✓ twice to snooze and to confirm the warning.

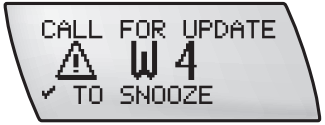
- Review the time and date and correct them, if they are wrong.
- If necessary, put your pump in RUN mode.

See section *2.4 Setting the time and date*.

Warning W4: CALL FOR UPDATE

Your pump has been in use for 6 years now. It is recommendable to think about a new pump soon.

- Press ✓ twice to snooze and to confirm the warning.



- Put your pump in RUN mode if necessary.

If, after the warning W4: CALL FOR UPDATE an E6 or E7 error message appears, your pump is no longer able to operate. Contact your local pump support in both situations (see inside back cover).

Warning W5: PUMP TIMER (backup pumps only)

Your pump's operating time will expire soon. When the warning W5: PUMP TIMER occurs, your pump has a remaining operating time of 30 days.

- Press ✓ twice to snooze and to confirm the warning.

- Put your pump in RUN mode.
- Go to the MY DATA menu on your pump.

- Move to the PUMP TIMER screen. The days until the pump timer expires are shown.

When the PUMP TIMER reaches zero, the pump will change to STOP mode and will no longer operate. The error, E5: END OF OPERATION, will appear on the display. Contact your local pump support (details on inside back cover) to discuss the options for further use of your Accu-Chek Spirit Combo insulin pump.

Note *The warning W5: PUMP TIMER and the error E5: END OF OPERATION are based on running time (the total time the pump is in RUN mode), and not on calendar years. See section 5.4.5 Viewing the time remaining.*

Warning W6: TBR CANCELLED (Temporary Basal Rate Cancelled)

A temporary increase or decrease in the basal rate has been cancelled.

- Press ✓ twice to snooze and to confirm the warning.

- If necessary, put your pump in RUN mode.
- Make sure that the cancellation was intended and then program a new Temporary Basal Rate if necessary.

Warning W7: TBR OVER (Temporary Basal Rate Over)
A Temporary Basal Rate has ended. The original basal rate (100 %) will resume automatically once the warning has occurred.

- Press ✓ twice to snooze and to confirm the warning.

- Decide whether a further Temporary Basal Rate change is required. If necessary, program a new Temporary Basal Rate.

Warning W8: BOLUS CANCELLED
A bolus was cancelled during the start delay or after delivery began.

- Press ✓ twice to snooze and to confirm the warning.

- If necessary, put your pump in RUN mode.
- Make sure that the cancellation was intended and then program a new bolus if needed.

Note *The actual bolus amount that was delivered before the cancellation can be reviewed in the bolus history. See section 5.4.1 Viewing your bolus history.*

Warning W9: LOANTIME WARNING (loan pumps only)
The pump is coming to the end of its loan period. In the MY DATA menu, check the remaining loan time in the PUMP TIMER menu. Make sure that you arrange for the replacement of the pump within the scheduled loan time.

- Press ✓ twice to snooze and to confirm the warning.

- Put your pump in RUN mode if necessary.
- Go to the MY DATA menu on your pump.
- Move to the PUMP TIMER screen. The days until the loantime expires are shown.

Note *This setting is country-specific and may not be visible on your pump.*

Warning W10: BLUETOOTH FAULT
You need to re-do the pairing procedure for the Accu-Chek Spirit Combo insulin pump and meter.
See section *6.3 Pairing your pump with the meter.*

- Press ✓ twice to snooze and to confirm the warning.

- Put your pump in RUN mode if necessary.

8.3 List of errors

WARNING

After the occurrence of an error, your Accu-Chek Spirit Combo insulin pump is in STOP mode and insulin delivery is interrupted. In order to maintain insulin delivery, you must act immediately according to the instructions given for each error.

Error E1: CARTRIDGE EMPTY

The insulin cartridge is empty. You must change it immediately.

- Press ✓ twice to snooze and to confirm the error.

- Disconnect or remove the infusion set from the infusion site.
- Change the cartridge and prime the infusion set.
- Reconnect the infusion set or insert a new one.
- Put your pump in RUN mode.

See section *3.5 Changing the cartridge and infusion set.*

Error E2: BATTERY EMPTY

The battery is empty. You must replace it immediately.

WARNING

After inserting a new battery, always check that the time and date of your Accu-Chek Spirit Combo insulin pump are set correctly. Incorrect programming of the time and/or date may cause incorrect insulin delivery. If you, your doctor or healthcare team store and analyse your therapy data electronically and the time and date of the devices used are not set identically, the resulting data might not be meaningful.

- Press ✓ twice to snooze and to confirm the error.

- Replace the battery.
- Put your pump in RUN mode.

Note *Your pump stores the settings you saved before the battery power ran out. If your pump is without power for more than one hour, check that the time and date are still correct. See section 1.4 Accessories and disposables on recommended batteries. See section 2.2 Inserting the battery for instructions on how to change your battery.*

Error E3: AUTOMATIC OFF

Automatic Off is a safety feature that stops insulin delivery and triggers the error E3: AUTOMATIC OFF if no keys are pressed within a programmed time period in RUN mode.

- Press ✓ twice to snooze and to confirm the error.

- Put your pump in RUN mode.

Error E4: OCCLUSION

> **WARNING**
>
> If the error E4: OCCLUSION occurs, immediately check your blood glucose level, and then check again about 2 hours later, as insulin delivery has been interrupted. If your blood glucose level is high, take appropriate action according to your doctor's or healthcare team's instructions.

Insulin was not delivered. This may be due to:

- a blocked infusion set
- a damaged cartridge
- a dirty or damaged piston rod

If the error E4: OCCLUSION (blockage) occurs, follow the steps listed below:

- Press ✓ twice to turn off and to confirm the error.

- Disconnect or remove the infusion set from your infusion site.
- Change the infusion set and prime it, as explained in chapter *2*.
- Put your pump in RUN mode.

In rare cases, the cartridge itself can be the cause of the occlusion. If the error E4: OCCLUSION occurs again, you must change the cartridge. Follow the steps listed below:

- Press ✓ twice to turn off and to confirm the error.
- Disconnect or remove the infusion set from your infusion site.
- Change the cartridge and prime the infusion set, as explained in chapter *2*.
- Reconnect or insert a new infusion set at your infusion site.
- Put your pump in RUN mode.

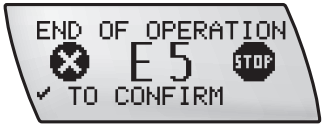
If the error E4: OCCLUSION occurs again, prime your infusion set without a new cartridge. Follow the steps listed below:

- Press ✓ twice to turn off and to confirm the error.
- Disconnect or remove the infusion set from your infusion site.
- Remove the cartridge, adapter and infusion set from your pump.
- Carry out the INFUSION SET PRIMING function (See section *2.8 Priming the infusion set*) **without** the cartridge, adapter, and infusion set inserted.
- Rewind the piston rod.
- Insert a new cartridge with the adapter and infusion set connected.
- Prime the infusion set.
- Reconnect or insert a new infusion set at your infusion site.
- Put your pump in RUN mode.

If the error E4: OCCLUSION continues to occur, use the alternative therapy plan provided by your doctor or healthcare team. Contact your local pump support (details on inside back cover) for more assistance.

Error E5: END OF OPERATION (backup pumps only)
The pump timer of your Backup pump has reached zero. The pump changes to STOP mode and will no longer operate. The error E5: END OF OPERATION appears on the display. Before this error occurs, the warning W5: PUMP TIMER will remind you to replace your pump soon. If necessary, use the alternative therapy plan provided by your doctor or healthcare team.

- Press ✓ twice to snooze and to confirm the error.



- Contact your local pump support (see inside back cover) to discuss the options for further use of the Accu-Chek Spirit Combo insulin pump.

Note *The warning W5: PUMP TIMER and the error E5: END OF OPERATION are based on running time (the total time the pump is in RUN mode) and not on calendar years.*

Error E6: MECHANICAL ERROR

A mechanical error has been discovered during a routine automatic system check and insulin delivery has stopped.

- Press ✓ twice to snooze and to confirm the error.

- Remove or disconnect the infusion set from your infusion site.
- Remove the cartridge, adapter, infusion set, and battery from your pump. Insert a new battery.
- It is essential that you rewind the piston rod. Install a new cartridge and infusion set. (See section *2.7 Inserting the cartridge*). Prime the infusion set (See section *2.8 Priming the infusion set*).
- Reconnect the infusion set at your infusion site.
- Put your pump in RUN mode.

If the error E6: MECHANICAL ERROR occurs again, use the alternative therapy plan provided by your doctor or healthcare team. Contact your local pump support (details on inside back cover) for more assistance.

Error E7: ELECTRONIC ERROR

An electronic error has been discovered during a routine automatic system check and insulin delivery has stopped.

Note *You cannot turn off and confirm the error E7: ELECTRONIC ERROR by pressing ✓. You must remove the battery instead.*

- Remove or disconnect the infusion set from your infusion site.

- Replace the battery in the pump (See section *2.2 Inserting the battery*).
- Prime the infusion set.
- Reconnect the infusion set at your infusion site.
- Put your pump in RUN mode.

After the error E7: ELECTRONIC ERROR always check your settings like e.g. basal rate profile, time and date.
If the error E7: ELECTRONIC ERROR occurs again, contact your local pump support (details on inside back cover) for assistance. Use the alternative therapy plan provided by your doctor or healthcare team.

Error E8: POWER INTERRUPT

A power interrupt error occurs when you insert a new battery without first placing the pump in STOP mode. See section *2.2 Inserting the battery* for instructions on how to change the battery. The error can also occur if the pump has been dropped. In this case, see section *7.2.1 What to do if you drop your pump*.

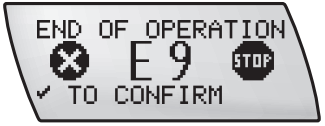
- Press ✓ twice to snooze and to confirm the error.

- Your pump goes into STOP mode.
- Check the time and date and correct them if they are wrong. See section *2.4 Setting the time and date*.
- Put your pump in RUN mode. Program a new bolus and/or Temporary Basal Rate if necessary. See chapter *4 Boluses and Temporary Basal Rates.*

If the error E8: POWER INTERRUPT occurs during programming, check your settings.

Error E9: END OF OPERATION (loan pumps only)
The pump timer of your Loaner pump has reached zero. The pump changes to STOP mode and will no longer operate. The error E9: END OF OPERATION appears on the display. Before this error occurs, the warning W9: LOANTIME WARNING will remind you to replace your pump soon. If necessary, use the alternative therapy plan provided by your doctor or healthcare team.

- Press ✓ twice to snooze and to confirm the error.



- Contact your local pump support (details on inside back cover) to discuss the options for further use of the Accu-Chek Spirit Combo insulin pump.

Note *This setting is country-specific and may not be visible on your pump.*
The warning W9: LOANTIME WARNING and the error E9: END OF OPERATION are based on running time (the total time the pump is in RUN mode) and not on calendar years.

Error E10: CARTRIDGE ERROR
The cartridge change function was not correctly performed.

- Press ✓ twice to snooze and to confirm the error.

- Remove or disconnect the infusion set from your infusion site.
- Remove the cartridge.
- Reinsert the cartridge. (See section *2.7 Inserting the cartridge*)

- Prime the infusion set.
- Reconnect the infusion set at your infusion site.
- Put your pump into RUN mode.
- If the error E10: CARTRIDGE ERROR occurs during the rewinding of the piston rod, insert a new battery in the pump and repeat the procedure.

Error E11: SET NOT PRIMED

The cartridge has been changed but the infusion set has not been primed. The error will be displayed when you try to put your pump in RUN mode.

- Press ✓ twice to snooze and to confirm the error.

- Remove or disconnect the infusion set from your infusion site.
- Prime the infusion set (See section *2.8 Priming the infusion set*).
- Reconnect the infusion set at your infusion site.
- Put your pump in RUN mode.

See sections *3.5 Changing the cartridge and infusion set* and *2.8 Priming the infusion set*.

WARNING

Never prime an infusion set that is connected to your body. You risk uncontrolled insulin delivery into your body. Always follow the instructions provided with your infusion set.

Error E12: DATA INTERRUPTED

CAUTION

If infrared data transfer between your pump and a compatible device is disrupted in any way, the configuration may be incomplete and the error E12: DATA INTERRUPTED will occur. The data transfer must be successfully completed before you can put your Accu-Chek Spirit Combo insulin pump into RUN mode.

Data transfer between your pump and the PC was interrupted before it was completed.

- Press ✓ twice to snooze and to confirm the error.

- Restart the data transfer.

Before you can put your pump in RUN mode, the data transfer must have been successfully performed.

See section *5.5 Transferring your data to a computer*.

Error E13: LANGUAGE ERROR
The language setting needs to be checked.

- Press ✓ twice to snooze and to confirm the error.

- Follow the steps in section *5.6 Pump settings* to change the language.
- Put your pump in RUN mode.

8.4 List of reminders

Reminder R1: REMINDER
A reminder has been programmed on the pump.

- Press ✓ twice to snooze and to confirm the reminder.

- If necessary, put your pump in RUN mode.

Note *If you have set the reminder occurrence to EVERY DAY, the same reminder occurs every 24 hours. Turn the reminder function OFF if you do not want the alarm to go off again at that same time every day. See section 5.9 Setting a reminder.*

Reminder R2: END OF WARRANTY
The 4-year warranty covering your insulin pump has expired. For any questions and concerns about the warranty, contact your local pump support (see inside back cover).

- Press ✓ twice to snooze and to confirm the reminder.

- Put your pump in RUN mode if necessary.

9 Troubleshooting

This chapter describes problems that may occur when using your Accu-Chek Spirit Combo insulin pump. Any problems that generate a warning or error are described in chapter *8*.

Note *The solutions provided in this chapter will normally enable you to resolve the problem and continue with your pump therapy. However, if the recommended action does not resolve the problem, or if you have any concerns, do not hesitate to contact your doctor or healthcare team.*

Note *Troubleshooting information relating to the Bluetooth® connection between the meter and the Accu-Chek Spirit Combo insulin pump is included in chapter 6 Using the Accu-Chek Spirit Combo insulin pump with the meter. Also refer to the documentation (User's Manual) coming with the meter.*

Although your pump has an internal security check system, it cannot, for example, detect if your infusion set is leaking, if an empty cartridge has been inserted instead of a filled cartridge or if the insulin you are using has lost its efficacy. These problems can result in a rapid rise in your blood glucose level. Therefore, it is essential to check your pump and blood glucose level during the day.

9.1 Therapy-related issues

Many factors – such as alcohol consumption, medication, decreased activity, illness and stress – can affect your blood glucose level. Contact your doctor or healthcare team for advice on how to manage these, or any other, therapy-related issues.

Problem	Recommended Action
Individual characters, numbers, or symbols on the display are shown incompletely or not at all.	Contact your local pump support (details on inside back cover).
Your Accu-Chek Spirit Combo insulin pump does not beep or vibrate.	Check that the beep volume and alarm signals are turned on. Check the battery and change it if necessary. If the pump still does not beep or vibrate, contact your local pump support (details on inside back cover).
The self-test is not completed correctly (after an error E7: ELECTRONIC ERROR).	Remove the battery, wait a few seconds, and insert it again. If the self-test is still not completed correctly, contact your local pump support (details on inside back cover).
Insulin delivery is incorrect due to inaccurate time setting.	If the time setting is inaccurate, the correct hourly basal rate cannot be delivered. Check and reset the time if necessary. Perform the same check whenever you change the battery.
Insulin delivery is incorrect due to incorrect basal rate programming.	Review any changes that you have made to your basal rate programming, to ensure that you are using the correct basal rate profile.

Problem	Recommended Action
There are air bubbles in the cartridge and/or infusion set.	Check your blood glucose level. In the cartridge: Disconnect the infusion set from the headset and re-prime the infusion set. If the air bubbles remain, replace the cartridge. Always fill the cartridge with insulin that is at room temperature. In the infusion set: Disconnect from the headset and prime your infusion set. Reconnect the headset and ensure that all connections are tight and secure.
The cartridge is empty.	Replace the cartridge. (Cartridges are for single use only.)
The infusion set is disconnected or dislodged.	Check your blood glucose level. Make sure that all the connections are tight. Inspect the connections for leaking insulin. Change your infusion set and infusion site.

Problem	Recommended Action
There is a leak in the system.	Check your blood glucose level. Check for leaking insulin at all the connection points and on the skin. Change the infusion set, the infusion site, the cartridge and the adapter.
There is an occlusion (blockage) in the system.	Check your blood glucose level. Follow the instructions in chapter *8 Error E4: OCCLUSION*.
Priming was not completed (E11 or air bubbles in infusion set).	Disconnect from the headset and re-prime the infusion set. Always prime until a bubble-free insulin flow emerges from the tip of the needle. Ensure that the tubing is free of air. Reconnect to the headset.

Appendix A: Technical data

General Technical Data	
HVIN	Accu-Chek Spirit Combo
Maximum dimensions (without adapter)	Approx. 82.5 × 56 × 21 mm (3.2 × 2.2 × 0.8 inches)
Weight	▸ empty insulin pump: approx. 80 g (2.8 ounces) ▸ insulin pump including battery, full plastic cartridge and infusion set: approx. 110 g (3.9 ounces)
Pump casing	Shock- and scratch-resistant plastic, resistant to pharmaceuticals, all edges rounded
Temperature ranges*	During operation: +5 to +40 °C (+41 to +104 °F) During storage in its shipping case: +5 to +45 °C (+41 to +113 °F) During transport: -20 to +50 °C (-4 to +122 °F)
Air humidity	During operation: 20 to 90 % relative humidity During storage in its shipping case: 5 to 85 % relative humidity During transport: 5 to 95 % relative humidity
Barometric pressure (simplified calculation based on standard atmosphere)	Altitude: approx. –300 to +5400 m During operation: 50 to 106 kPa (500 to 1060 mbar) During transport or storage in its shipping case: 50 to 106 kPa (500 to 1060 mbar)

General Technical Data	
Power supply	One 1.5 V AA Alkaline (LR6) or Lithium (FR6) battery or one 1.2 V rechargeable NiMH AA (HR6) battery. Batteries should have a minimum capacity of 2500 mAh. Do not use alkaline batteries that do not comply with IEC 60086-1. Do not use lithium batteries that do not comply with IEC 60086-4. Do not use carbon zinc or nickel cadmium (NiCd) batteries. Rechargeable batteries should have a minimum capacity of 2600 mAh. Only use a battery charger officially recommended by the battery manufacturer. Do not use rechargeable batteries that do not comply with IEC 62133. Contact your local pump support if you intend to use a different type of battery or rechargeable battery to the one recommended.
Lifetime of battery	If used in a typical usage pattern (50 U/day using U100 insulin; operating temperature 23 °C ±2 °C [73 °F ±4 °F] at minimum/intermediate/maximum basal rate), the battery life is approximately: Alkaline: 70 days with *Bluetooth*® off; 30 days with *Bluetooth*® on Lithium: 200 days with *Bluetooth*® off; 80 days with *Bluetooth*® on NiMH: 100 days with *Bluetooth*® off; 40 days with *Bluetooth*® on
Lifetime of insulin pump	6 years
Data storage time	The time and date are safely stored in the memory for about 1 hour after the battery has been removed. Other insulin pump settings (the hourly basal rates, remaining cartridge content, bolus increments, active user menu and alarm settings) and the event memory (bolus history, history of daily insulin totals, Temporary Basal Rate history and alarm history) are saved, regardless of battery voltage and the time your insulin pump has been without a battery.

General Technical Data	
Delivery	Your Accu-Chek Spirit Combo insulin pump delivers insulin according to the programmed hourly basal rate, 24 hours a day. ▸ Minimum dose: 1/20 of the hourly basal rate, delivered a maximum of 20 times per hour. ▸ Test interval: every 3 minutes.
Basal rate	Min. 0.05 U/h, max. 50 U/h. There are 24 hourly basal rates adjustable in increments of 0.01 U/h (up to 1.00 U/h), 0.05 U/h (up to 10.0 U/h) and 0.1 U/h (up to 50.0 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 U/h, 0.2 U/h, 0.5 U/h, 1.0 U/h and 2.0 U/h. For the Standard Bolus, Extended Bolus and Multiwave Bolus, the amount is adjustable in fixed increments of 0.1 U/h. The duration of the Extended Bolus and the Multiwave Bolus is adjustable in intervals of 15 minutes (15 minutes up to 12 hours).
Temporary Basal Rate	Adjustable in 10 % increments, 0–90 % for decreases, 110–250 % for increases. The duration is adjustable in 15 minute intervals, up to a maximum of 24 hours. The last programmed duration is used by default for the next Temporary Basal Rate change.
Bolus delivery speed	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.

General Technical Data	
Maximum time before the error E4: OCCLUSION** occurs	Plastic cartridges: ▶ at medium basal rate 1.0 U/h: ≤ 2 h ▶ at minimum basal rate 0.05 U/h: ≤ 24 h Sanofi-Aventis Insuman Infusat glass cartridges***: ▶ at medium basal rate 1.0 U/h: ≤ 8 h ▶ at minimum basal rate 0.05 U/h: ≤ 120 h
Maximum missing volume before the error E4: OCCLUSION** occurs	Plastic cartridges: ≤ 2.0 U Sanofi-Aventis Insuman Infusat glass cartridges***: ≤ 8.0 U
Maximum system occlusion alarm threshold	< 400 kPa (4.0 bar)
Maximum alarm threshold	< 400 kPa (4.0 bar)
Maximum pressure	400 kPa (4.0 bar), for plastic and Sanofi-Aventis Insuman Infusat glass cartridges*** and infusion sets.
Flow (delivery rate)	During infusion set priming and bolus: 0.2 U/sec.
Maximum quantity delivered at a single fault condition	≤ 1.0 U
Cartridge	The Accu-Chek Spirit 3.15 ml cartridge system and the Accu-Chek 3.15 ml plastic cartridge with a luer-lock connection. Sanofi-Aventis Insuman Infusat cartridges*** have been evaluated and approved for use with the Accu-Chek Spirit Combo insulin pump.

General Technical Data	
Infusion sets	The Accu-Chek infusion sets with a luer-lock connector.
Data transfer between pump and a PC	Infrared interface
Safety system	The safety concept is based on a control system which consists of two microprocessors (1 main processor and 1 supervisor processor). Whenever a defect or fault occurs in the main processor, it is identified by the supervisor processor. If, for example, overdelivery occurs, the motor is immediately switched off and the error E7: ELECTRONIC ERROR occurs. The main processor and supervising processor signal the error E7 with beeps and vibrations. In addtion, the main processor shows the specific error E7 number on the pump display. Conversely, the main processor can also determine at any time whether the supervisor processor is working correctly.
IPX8	Protected against the effects of temporary immersion in water under standardized conditions (up to 60 minutes and 2.5 meters [8 feet]).
Electric shock protection	The Accu-Chek Spirit Combo insulin pump and the Accu-Chek infusion sets are applied parts of the type BF.

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

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

*** Insuman® Infusat produced by Sanofi-Aventis Deutschland GmbH is a registered trademark of the Sanofi group.

Technical standards

Table 201: Electromagnetic emission

Guidance and manufacturer's declaration – electromagnetic emissions		
The Accu-Chek Spirit Combo insulin pump is intended for use in the electromagnetic environment specified below. The customer or the user of the Accu-Chek Spirit Combo 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 Spirit Combo insulin pump must emit electro-magnetic 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 Spirit Combo 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 Spirit Combo insulin pump is intended for use in the electromagnetic environment specified below. The customer or the user of Accu-Chek Spirit Combo 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	

Immunity test standard	IEC 60601 test level *	Compliance level	Electromagnetic environment – guidance
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	< 5 % UT (0.5 cycle) 40 % UT (5 cycles) 70 % UT (25 cycles) < 5 % UT for 5s	Not applicable	

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

Immunity test standard	IEC 60601 test level *	Compliance level **	Electromagnetic environment – guidance
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m 30 A/m	3 A/m 30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

* Test levels acc. to IEC/EN 60601-1-2:2007 and IEC 60601-1-2:2014
** Successfully tested by the manufacturer with 400 A/m

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

Guidance and manufacturer's declaration – electromagnetic immunity				
The Accu-Chek Spirit Combo insulin pump is intended for use in the electromagnetic environment specified below. The customer or the user of the Accu-Chek Spirit Combo 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 Spirit Combo 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 MHz 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	$da = 11.7 \sqrt{P}$ $db = 2.3 \sqrt{P}$	2.3 GHz to 2.5 GHz 800 MHz to 2.3 GHz and 2.5 GHz to 2.7 GHz

Guidance and manufacturer's declaration – electromagnetic immunity

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

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

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

a) 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 Spirit Combo insulin pump is used exceeds the applicable RF compliance level above, the Accu-Chek Spirit Combo 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 Spirit Combo.

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 Spirit Combo insulin pump.				
The Accu-Chek Spirit Combo insulin pump is intended for use in electromagnetic environments in which radiated RF disturbances are controlled. The customer or the user of the Accu-Chek Spirit Combo insulin pump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Accu-Chek Spirit Combo 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 $db = 2.3\sqrt{P}$	2.3 GHz to 2.5 GHz $da = 11.7\sqrt{P}$
0.01	12 cm	12 cm	23 cm	118 cm
0.1	38 cm	38 cm	73 cm	373 cm
1	1.2 m	1.2 m	2.3 m	11.8 m
10	3.8 m	3.8 m	7.3 m	37.3 m
100	12 m	12 m	23 m	118 m
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.				

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

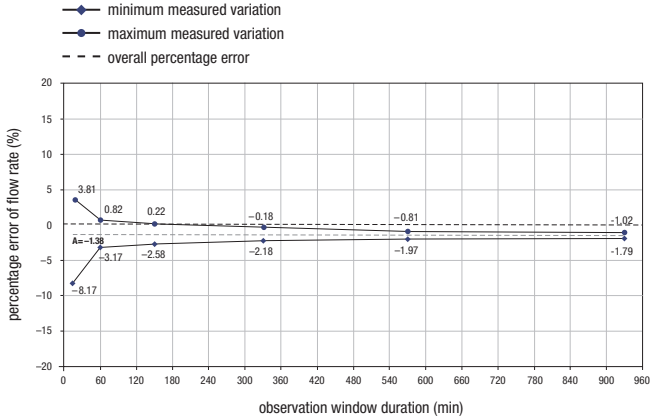
Note *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*

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

Accuracy of flow rate for the Accu-Chek 3.15 ml plastic cartridges and the Accu-Chek Spirit 3.15 ml cartridge system

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

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

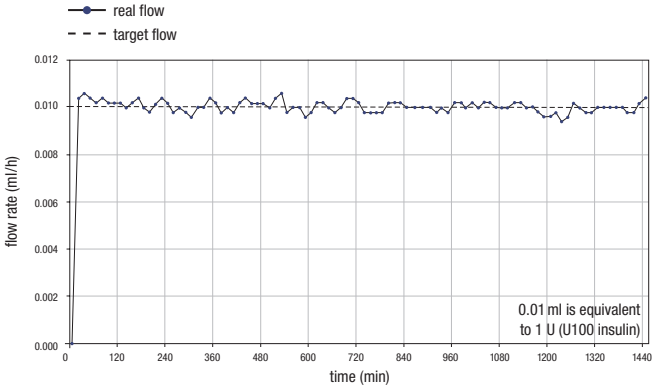


The maximum deviation of the delivered amount (overall mean percentage error of flow rate) for U100 insulin is ≤ ±5 %*, where your Accu-Chek Spirit Combo insulin pump is located ≤ 1 m (3.3 feet) above / below the infusion site.

* The measurements were made at a medium basal rate of 1.0 U/h according to IEC 60601-2-24:2012 with an Accu-Chek TenderLink infusion set 17/110 at room temperature.

Start-up graph over the stabilization period

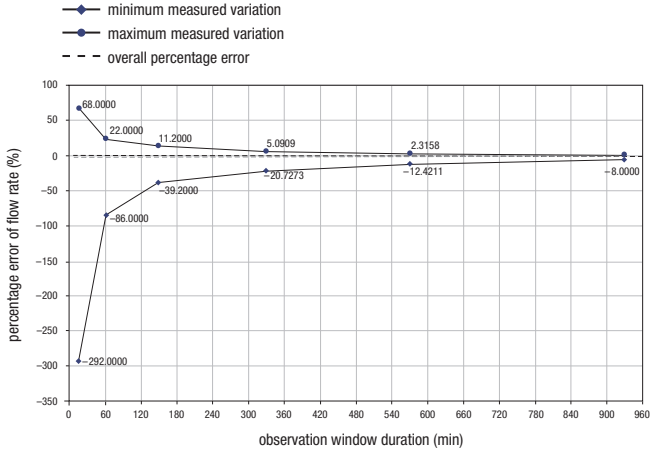
The start-up graph shows changes in the flow rate over the stabilization time.



Accuracy of flow rate for the Accu-Chek 3.15 ml plastic cartridges and the Accu-Chek Spirit 3.15 ml cartridge system at minimum hourly basal rate of 0.05 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.



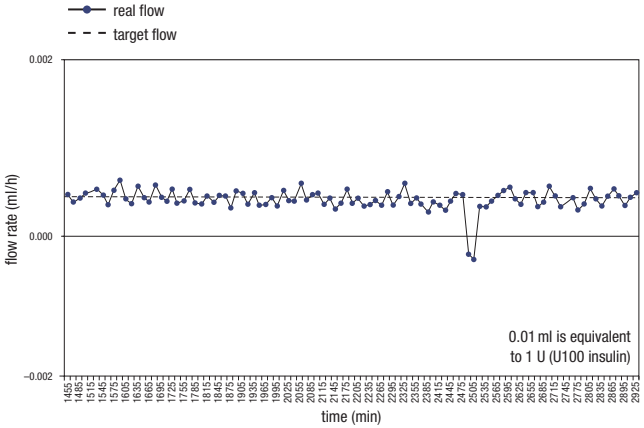
The maximum deviation of the delivered amount (overall mean percentage error of flow rate) for U100 insulin is ≤ 30%*.

It is in the responsibility of the health care professional to decide whether the accuracy of the flow rate is sufficient for the according patient.

* The measurements were made at the minimum rate of 0.05U/h according to IEC 60601-2-24:2012 with an Accu-Chek TenderLink Infusion set 17/110 at room temperature.

Start-up graph over the stabilization period

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



Bolus

For U100 insulin the maximum deviation of
a maximum bolus (25 U and 50 U) is ≤ ±5 % and
the maximum deviation of a minimum bolus (0.1 U) is ≤ ±30 %*.

* The measurements were made according to IEC 60601-2-24:2012 with an Accu-Chek Rapid-D Link infusion set 12/100 at room temperature.

Appendix B: Configuration parameters

	Typical range available on the pump and standard parameter settings*	Maximum parameter range adjustable with the Accu-Chek 360° configuration software
Basal rate Hourly basal rate + max. TBR (hourly basal rate combined with temporary basal rate, max. increase)	62.5 U/h	max. amount: 0–250.0 U/h
Default basal rate	0 U/h	0–50 U/h
Hourly basal rate increment	0.01 U/h (up to 1.00 U/h), 0.05 U/h (up to 10.0 U/h) and 0.1 U/h (up to 50.0 U/h)	0.0 U/h, 0.05–50.0 U/h
Hourly basal rates	25.0 U/h	max. amount: 0–50.0 U/h
Temporary Basal Rate TBR increases or decrease in increments of TBR duration TBR duration increments	0–250 % 10 % max. 24 h 15 min	0–500 % 10 % 15 min–50 h 15 min, 30 min, 1 h
Basal rate profiles available Basal rate lock	5 off	1–5 on or off

* Note: These factory settings may vary in some countries and depend on the changes you, your doctor or healthcare team make using your insulin pump or pump programming software for healthcare professionals.

	Typical range available on the pump and standard parameter settings*	Maximum parameter range adjustable with the Accu-Chek 360° configuration software
Bolus Bolus amount per bolus delivery	25.0 U	max. amount: 0–50.0 U
bolus amount increments for Quick Bolus bolus amount increments for Standard Bolus bolus duration (Extended Bolus, Multiwave Bolus) bolus duration increments	0.5 U 0.1 U max. 12 h 15 min	0.1 U, 0.2 U, 0.5 U, 1.0 U or 2.0 U 15 min–50 h 15 min, 30 min, 1 h
Prime volume	25.0 U	max. amount: 0–50.0 U
Display orientation	standard or inverted	
Display contrast	7 steps	
User menus	3 (STANDARD, ADVANCED or CUSTOM)	
Volumes (for beeps)	off, 4 steps	
Alarm signals turned on	beeps, vibrations or both	

* Note: These factory settings may vary in some countries and depend on the changes you, your doctor or healthcare team make using your insulin pump or pump programming software for healthcare professionals.

	Typical range available on the pump and standard parameter settings*	Maximum parameter range adjustable with the Accu-Chek 360° configuration software
Battery type	AA (LR6) ALKALINE, AA (FR6) LITHIUM or AA (HR6) NiMH rechargeable battery	
Key Lock	On or Off	
Automatic off	On (1–24 h) or Off (0 h)	
Reminder	On or Off If On: occurs once or every day	
Time format	European (24 h) or American (12 h, am/pm)	
Date format	European (dd.mm.yy) or American (mm.dd.yy)	
Bluetooth®	On or Off	

* Note: These factory settings may vary in some countries and depend on the changes you, your doctor or healthcare team make using your insulin pump or pump programming software for healthcare professionals.

Appendix C: Sterile products and accessories

Cartridges

Name	Comments
Accu-Chek Spirit 3.15 ml cartridge system Accu-Chek 3.15 ml plastic cartridge Sanofi-Aventis Insuman Infusat Prefilled 3.15 ml Glass Cartridges* (U100)	Plastic cartridges are single-use items only. Do not re-use cartridges. Refer to the instructions for use of the insulin you are using for information on the acceptable temperature range for storage and handling.

* Insuman® Infusat produced by Sanofi-Aventis Deutschland GmbH is a registered trademark of the Sanofi group.

Accu-Chek infusion sets

Name	Comments
Accu-Chek Rapid-D Accu-Chek Rapid-D Link Accu-Chek Tender Accu-Chek TenderLink Accu-Chek FlexLink Accu-Chek Ultraflex	All Accu-Chek infusion sets are available with various tubing and cannula lengths. All infusion sets listed on the left are compatible with the Accu-Chek Spirit Combo insulin pump. Discuss with your doctor and/or healthcare team to find the infusion set that fits you best. For recommendations on how long you may use the same infusion set see the information material provided with this product.

Accessories

Name	Comments
Adapter Battery cover	Adapter and battery cover are part of the Accu-Chek Spirit Combo service pack and the Accu-Chek Spirit Combo service pack small. Replace your adapter and battery cover every 2 months.
Batteries	One 1.5 V, AA alkaline (LR6) battery compliant with IEC 60086-1 or one lithium (FR6) battery compliant with IEC 60086-4. The Accu-Chek Spirit Combo insulin pump was successfully tested with a Varta Power One alkaline LR6, AA, 1.5 V battery which complies with IEC 60086-1 and with an Energizer Ultimate Lithium FR6, AA, 1.5 V battery which complies with IEC 60086-4. The battery should have a minimum capacity of 2500 mAh. For battery lifetime see p. 170 *Lifetime of battery*

Name	Comments
Rechargeable batteries	Rechargeable batteries are not provided by Roche. Only use a battery charger officially recommended by the battery manufacturer. One 1.5 V, AA alkaline (LR06) battery compliant with IEC 60086-1 or one lithium (FR06) battery compliant with IEC 60086-4. The Accu-Chek Spirit Combo insulin pump was successfully tested with a Varta Power One alkaline LR06, AA, 1.5 V battery which complies with IEC 60086-1 and with an Energizer Ultimate Lithium FR06, AA, 1.5 V battery which complies with IEC 60086-4. The battery should have a minimum capacity of 2500 mAh. For battery lifetime see p. 170 *Lifetime of battery*

Name	Comments
Carrying systems	All Accu-Chek Spirit Combo and Accu-Chek Spirit carrying systems are compatible with the Accu-Chek Spirit Combo insulin pump. Roche offers a wide range of carrying system solutions to best fit your lifestyle.
Accu-Chek 360° configuration software	Check with your local pump support for the availability of appropriate pump programming software.
Accu-Chek Spirit Combo quick reference guide	This is a convenient pocket size reference that you may take with you to assist with your insulin pump questions.

Appendix D: Abbreviations

Abbreviation	Meaning
approx.	Approximately
BRP	Basal rate profile
h	Hour(s)
IEC	International Electrotechnical Commission
IR	Infrared
kPa	Kilopascal
LCD	Liquid Crystal Display
NiMH	Nickel Metal Hydrid (used with rechargeable batteries)
PC	Personal Computer
sec.	Seconds

Abbreviation	Meaning
TBR	Temporary Basal Rate
U	International Units in context with biological effectiveness of a certain insulin amount
U/h	Amount of International Units of insulin delivered per hour
U100	This is the insulin concentration. Each millilitre of liquid contains 100 International Units of insulin
dd.mm.yy	European date format: day.month.year
mm.dd.yy	American date format: month.day.year

Appendix E: Beeps and melodies

Acoustic Signals

All of the functions of the Accu-Chek Spirit Combo insulin pump are supported by acoustic signals. The acoustic signals are beeps.

- Duration for very short sound = 31.25 ms ±20 %
- Duration for short sound = 62.5 ms ±20 %
- Duration for medium sound = 93.75 ms ±20 %
- Duration for long sound = 125.0 ms ±20 %
- Duration for short pause = 125.0 ms ±20 %
- Duration for medium pause = 218.75 ms ±20 %
- Duration for long pause = 500.0 ms ±20 %

Sound	Function
	UP KEY Frequency: 3131 Hz ±5 % Duration: Short sound
	DOWN KEY Frequency: 2486 Hz ±5 % Duration: Short sound

Sound	Function
	MENU KEY Frequency: 2820 Hz ±5 % Duration: Short sound
	NAVIGATION BACKWARDS (MENU + UP KEY) Frequency: 2763 Hz ±5 % Duration: Short sound
	EXECUTE FUNCTION (OK KEY) Frequency: 2090 Hz ±5 %, 2486 Hz ±5 % Duration: 2 × short sound
	CANCEL FUNCTION Frequency: 2486 Hz ±5 %, 2090 Hz ±5 % Duration: 2 × short sound

Sound	Function
	BASE STATE RUN (KEYS UNLOCKED) Frequency: 2789 Hz ±5 % Duration: Short sound, short pause, short sound, short pause, short sound
	BASE STATE RUN (KEYS LOCKED) Frequency: 2763 Hz ±5 % Duration: Short sound, short pause, short sound, short pause, short sound
	BASE STATE STOP (KEYS UNLOCKED) Frequency: 2789 Hz ±5 % Duration: Long sound, short pause, long sound, short pause, long sound
	BASE STATE STOP (KEYS LOCKED) Frequency: 2763 Hz ±5 % Duration: Long sound, short pause, long sound, short pause, long sound

Sound	Function
+	CARTRIDGE CONTENT ≤20 U Frequency: f1 = 2090 Hz ±5 %, f2 = 2486 Hz ±5 %, f3 = 2789 Hz ±5 % Duration: f1 short sound, f2 short sound, long pause, f3 medium sound, short pause, f3 medium sound, short pause, f3 medium sound
+	20 U < CARTRIDGE CONTENT ≤50 U Frequency: f1 = 2090 Hz ±5 %, f2 = 2486 Hz ±5 %, f3 = 2789 Hz ±5 % Duration: f1 short sound, f2 short sound, long pause, f3 medium sound, short pause, f3 medium sound

Sound	Function
	50 U < CARTRIDGE CONTENT ≤100 U Frequency: f1 = 2090 Hz ±5 %, f2 = 2486 Hz ±5 %, f3 = 2789 Hz ±5 % Duration: f1 short sound, f2 short sound, long pause, f3 medium sound
	100 U < CARTRIDGE CONTENT Frequency: f1 = 2090 Hz ±5 %, f2 = 2486 Hz ±5 %, f3 = 2789 Hz ±5 % Duration: f1 short sound, f2 short sound, long pause, f3 long sound
	SYSTEM TEST SUCCESSFUL Frequency: 1043 Hz ±5 %, 1314 Hz ±5 %, 1563 Hz ±5 %, 2090 Hz ±5 % Duration: 4 × long sound

Sound	Function
	COPY BASAL RATE Frequency: 2486 Hz ±5 %, 3131 Hz ±5 %, 2486 Hz ±5 % Duration: 3 × short sound
	TEMPORARY BASAL RATE ACTIVE Frequency: 2789 Hz ±5 % Duration: Short sound, short pause, short sound
	STOP WARNING Frequency: 2789 Hz ±5 % Duration: Long sound, short pause, long sound

Sound	Function
	Reminder (REPEATING SEQUENCE) Frequency: f1 = 1043 Hz ±5 %, f2 = 1850 Hz ±5 % Duration: f1 medium sound, short pause, f2 medium sound, short pause, f1 medium sound, medium pause, f2 medium sound Repeating Interval: 3000.0 ms ±20 %
	WARNING (REPEATING SEQUENCE) Frequency: f1 = 1043 Hz ±5 %, f2 = 1850 Hz ±5 % Duration: f1 medium sound, short pause, f2 medium sound, short pause, f1 medium sound, medium pause, f2 medium sound, short pause, f2 medium sound Repeating Interval: 3000.0 ms ±20 %

Sound	Function
	ERROR (REPEATING SEQUENCE) Frequency: f1 = 1043 Hz ±5 %, f2 = 1850 Hz ±5 % Duration: f1 medium sound, short pause, f2 medium sound, short pause, f1 medium sound, medium pause, f2 medium sound, short pause, f2 medium sound, short pause, f2 medium sound Repeating Interval: 3000.0 ms ±20 %
	UPPER LIMIT REACHED Frequency: 2486 Hz ±5 %, 3131 Hz ±5 %, 2486 Hz ±5 %, 3131 Hz ±5 % Duration: 4 × short sound
	LOWER LIMIT REACHED Frequency: 2090 Hz ±5 %, 2486 Hz ±5 %, 2090 Hz ±5 %, 2486 Hz ±5 % Duration: 4 × short sound

Sound	Function
	OK KEY PRESSED Frequency: 2789 Hz ±5 % Duration: Short sound
+	CHANGED TO BASE STATE RUN BY OK KEY (KEYS UNLOCKED) Sequence: A12, long pause, A14
+	CHANGED TO BASE STATE RUN BY OK KEY (KEYS LOCKED) Sequence: A12, long pause, A15
+	CHANGED TO BASE STATE STOP BY OK KEY (KEYS UNLOCKED) Sequence: A12, long pause, A16
+	CHANGED TO BASE STATE STOP BY OK KEY (KEYS LOCKED) Sequence: A12, long pause, A17
+	CHANGED TO BASE STATE STOP BY CANCELLATION OF FUNCTION Sequence: A13, long pause, A16

Sound	Function
	INITIAL POINT (SUBMENU, VALUE) Frequency: 2820 Hz ±5 % Duration: Short sound, short pause, short sound
	SUPERVISOR SEQUENCE (GENERATED BY SUPERVISOR) Frequency: 2630 Hz ±10 %, 95 ms ±10 % Pause: 95 ms ±10 % Frequency: 2630 Hz ±10 %, 95 ms ±10 % Pause: 95 ms ±10 % Frequency: 2630 Hz ±10 %, 95 ms ±10 % Pause: 200 ms ±10 % Frequency: 2630 Hz ±10 %, 95 ms ±10 % Pause: 95 ms ±10 % Frequency: 2630 Hz ±10 %, 95 ms ±10 %

Tactile Signals

Dedicated functions of the Accu-Chek Spirit Combo insulin pump are supported by tactile signals additionally. The tactile signals are vibrations which are generated by a vibra motor.

Signal	Function
K	SHORT VIBRATION Duration short vibration = 109.375 ms ±5 %
M	MEDIUM VIBRATION Duration medium vibration = 203.125 ms ±5 %
L	LONG VIBRATION Duration long vibration = 281.25 ms ±5 %

Signal	Function
Alarm	WARNING AND REMINDER (REPEATING SEQUENCE) Duration vibration = 1062.5 ms ±5 % Duration pause = 2125.0 ms ±5 % (Repeating interval = 3187.5 ms ±5 %)
Error	ERROR (REPEATING SEQUENCE) Duration vibration = 531.25 ms ±5 % Duration pause = 1062.5 ms ±5 % (Repeating interval = 1593.75 ms ±5 %)

Appendix F: Symbols

Display Symbols

Icon	Meaning
	Basal Lock OFF
	Basal Lock ON
	Basal Rate
	Basal Rate Total
	Battery Empty
	Battery Low
	Beep Volume
	Bluetooth® OFF

Icon	Meaning
	Bluetooth® ON
	Bluetooth® Settings
	Bluetooth® in Remote control mode
	Beep Test
	Cartridge Empty
	Cartridge Full
	Cartridge Low
	OK

Icon	Meaning
	Clock
	Data Transfer menu
	Data Transfer (to start screen)
	Data Transfer running
	Date
EU	Date Format EU
US	Date Format US
	Display contrast
	Extended Bolus
	Key Lock OFF

Icon	Meaning
	Key Lock ON
	Pump timer (Call for update)
	Menu Settings
	Multiwave Bolus
	Multiwave Bolus Immediate
	My Data
	Pairing Failed
	Pairing Successful
	Priming
	Progress Bar

Icon	Meaning
	Pump Settings
	Reminder
	Reminder Every Day
	Reminder OFF
	Reminder Settings
	Reminder Single
	Display orientation
	Beep
	Beep and Vibration
	Standard Bolus

Icon	Meaning
STOP	Stop
Σ	Total
	Temporary Basal Rate
	Therapy Settings
	Time and Date Settings
U	Units
U/h	Units per hour
	Vibrations
	Error
	Warning

General Symbols

Icon	Meaning
	Consult instructions for use
	Caution, refer to safety-related notes in the instructions for use accompanying this product.
	Follow instructions for use
	Temperature limitation (store at)
	Use only once
	Use by
STERILE EO	Sterilized using ethylene oxide
STERILE R	Sterilized using irradiation

Icon	Meaning
	Manufacturer
	Date of manufacture
REF	Catalogue number
LOT	Batch code
SN	Serial number
GTIN	Global Trade Item Number
CE 0088	This product fulfils the requirements of the European Directive 93/42/EEC on medical devices.

Icon	Meaning
	This product also fulfils the requirements of: ▶ European Directive 1999/5/EC on radio and telecommunications terminal equipment (R&TTE). ▶ European Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS II).
LR6 (AA) +	Recommended battery
	Keep away from sunlight
	Keep dry
	Do not use if package is damaged
	Recycling

Icon	Meaning
	Do not throw away
	Admissible humidity range
	Admissible air pressure range
	Fragile – handle with care!
	Bluetooth® wireless technology
	Electronic device of type BF according to the standard IEC 60601-1. Protection against electrical shock.
	Non-ionizing radiation

Icon	Meaning
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.
	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.
Rx only	Federal law (USA) restricts this device to sale by or on the order of a physician.

Icon	Meaning
IPX8	Symbol for protection against the effect of temporary immersion in water (up to 60 minutes and 2.5 meters [8 feet]), according to IEC 60529.
MR CT US X-Ray	Warning against device use in electromagnetic or high electrical field or environments

Appendix G: Warranty and Declaration of Conformity

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

Declaration of Conformity
Roche hereby declares that the Accu-Chek Spirit Combo insulin pump conforms with the basic requirements and other relevant regulations of the European Directive 2014/53/EU. The currently valid conformity declaration may be found at the following website: 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 Spirit Combo insulin pump: 20 mW

Index

A

Abbreviations 191
Accessories 13
Adapter. 14, 144, 189
ADVANCED user menu 94, 114
Air bubbles 14, 36, 40, 43, 44, 167
Alarm signals 8, 110, 166
Automatic Off 123, 154

B

Basal rate profile 115, 125, 185, 191
Battery 14, 20, 148, 170, 187, 189, 198
Battery cover 15, 20, 60, 189
Battery key 20
Beeps and melodies 192
Beep volume. 9, 52, 109, 145, 166
Blood glucose levels 16, 19, 35, 71
Bluetooth® wireless technology 129, 130, 165
Bolus 71
Bolus history. 75, 77, 86, 100, 151, 170
Bolus increment 120

C

Cartridge 38
Cleaning your pump 143
Configuration parameters 185
Contact with water 61, 140, 141
CUSTOM user menu 124, 125

D

Damage to your pump 39, 41
Display contrast 112
Display orientation 111
Display screens
- Function screens 7
- Information screens 7, 10, 11
- navigating through 4
- QUICK INFO screen. 6, 100
- RUN screen 5
- STOP screen 6

Disposing of your pump 144

E
Electromagnetic immunity 177
Electromagnetic radiation 56
Emergency kit. 16, 138
Exercise 29, 56, 115
Extended Bolus. 71, 78, 79, 81, 82, 92, 171, 186, 199

F
Features 1, 2, 94

H
History of daily insulin totals 19, 43, 102, 121, 170
Hourly basal rate. 5, 11, 31, 32, 166, 185, 210

I
Infection 13, 46, 48, 52, 66, 138, 144
Infusion set. 6, 42, 43, 44, 46, 51, 63
Inspecting your pump 137
Insulin delivery
  starting 98
  stopping. 51, 98

K
Keylock. 3, 12, 107, 108, 187
Keys
  combining 11

L
Language
  selecting 95, 113
Leakage 36, 37, 54, 63
Luer-lock connector 37, 42, 63, 64, 65, 68, 173

M
Meter
  interaction with 1
  pairing your pump 130
Multiwave Bolus 71, 83, 84, 86, 92, 115, 171, 186, 199

P
Personalizing your pump. 2, 93
Personal settings 17, 29, 47, 53, 92, 115, 143
Prime amount. 121
Priming. 43, 44, 121, 128, 168, 199
Pump settings. 107
Pump therapy
  interruption of 58

Q
Quick Bolus 2, 10, 72, 73, 74, 75, 79, 120, 171, 186

R
Reminders
list of 164, 216
Reminder Settings 118, 200
Repair of your pump 142
Rotating display 2, 4

S
Safety system 145
Scrolling 12, 76
Sport 56
Standard Bolus . . . 71, 72, 74, 75, 76, 77, 79, 83, 171, 186, 200
Status messages 8
Status of your pump 3, 8
Sterile disposables 13
Sterile products 13, 52, 63, 70, 137, 139
STOP-warning
confirming 9, 30, 52
turning off 52
Storing your pump 144
Swimming 61, 140
Symbols
Display Symbols 198
General Symbols 201

T
Tactile signals 197
Technical Data 169
Temporary Basal Rate . . . 87, 88, 89, 90, 91, 92, 150, 151, 171, 185, 191, 200, 215
Temporary Basal Rate history
viewing 103
Therapy settings 120
Time and Date
Settings 27
Time remaining (pump timer) 104
Transferring Data 6, 105
Travelling 57
Troubleshooting
therapy-related issues 166

U
Unlocking Keylock 108

W
Warning history
viewing 101
Warnings
list of 147

Warnings and errors 145
confirming 146
handling. 134
Warranty. 15, 204
Wearing your pump
carrying systems 55, 56, 190
in hazardous areas. 56

Glossary

Adapter
The adapter connects the cartridge and infusion set. It has 2 seals and forms an efficient seal for the cartridge compartment of your Accu-Chek Spirit Combo insulin pump. The 2 small vents on the adapter allow the equalization air pressure.

Automatic Off
Automatic Off is a safety feature that stops insulin delivery and triggers an error if no keys are pressed within a programmed time period in RUN mode. See the entry in chapter 5 *Personalizing your pump.*

Basal rate
This is the amount of insulin delivered per hour that is required to cover your basic 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 Accu-Chek Spirit Combo insulin pump according to the curve of your personal basal rate profile or profiles.

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

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

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

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 are specially designed to suit your individual needs while wearing your Accu-Chek Spirit Combo insulin pump.

Cartridge
The insulin reservoir of your Accu-Chek Spirit Combo insulin pump. It holds 3.15 ml (315 U) of short-acting insulin or fast-acting insulin analogue.

Cartridge compartment
The chamber in your Accu-Chek Spirit Combo insulin pump for the cartridge.

Daily insulin total
The total amount of insulin delivered (basal rate plus boluses) delivered in a 24-hour day, beginning at midnight. This amount does not include any insulin needed for the priming of infusion sets.

Diabetes manager
This is an intelligent diabetes management device that enables you to measure your blood glucose level, manage your blood glucose data, and get bolus advice. It also enables remote control of your Accu-Chek Spirit Combo insulin pump, using *Bluetooth*® wireless technology.

Factory settings
Your Accu-Chek Spirit Combo insulin pump is provided by Roche with a standard configuration (factory settings). These settings can be adapted to your individual needs directly on your Accu-Chek Spirit Combo insulin pump or by using the Accu-Chek 360° configuration software.

Hourly basal rate
An hourly basal rate is the amount of insulin delivered by your Accu-Chek Spirit Combo insulin pump for each hour.

Infusion set
Infusion sets connect your Accu-Chek Spirit Combo insulin pump to your body. The insulin is delivered from the cartridge through the infusion set tubing and cannula or needle into your subcutaneous tissue. Infusion sets can be disconnectable or non-disconnectable.

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 offset time of insulin analogue is shorter than the offset time of regular insulin.

Insulin, regular (short-acting or fast-acting)
Insulin that has the same chemical structure as insulin produced by the human pancreas. The offset 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 standardized conditions (maximal 60 minutes a day and 2.5 meters [8 feet]).

Luer-lock connector
A standardized fitting at the end of the infusion set which allows to tightly connect the infusion set and cartridge through the adapter.

Meter
See *Diabetes manager*.

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

Priming
Process of filling the tubing with insulin and pushing any air bubbles out.

Personal settings
Your Accu-Chek Spirit Combo insulin pump must be programmed with your personal settings prior to starting insulin pump therapy. Personal settings include the basal rate profile(s), the correct time and date and all other variable values which can be tailored to your individual needs on your Accu-Chek Spirit Combo insulin pump. Your personal settings can also be programmed using the Accu-Chek 360° configuration software.

Rapid-acting insulin analogue
See Insulin analogue (rapid acting).

Regular insulin (short-acting or fast-acting)
See Insulin, regular (short-acting or fast-acting).

RUN
During normal use, your Accu-Chek Spirit Combo insulin pump is in RUN mode and insulin is continuously delivered. Boluses, Temporary Basal Rates and almost all functions can be programmed from RUN mode.

RUN screen
The RUN screen is the starting point for all functions which can be accessed while your Accu-Chek Spirit Combo insulin pump delivers insulin. Your Accu-Chek Spirit Combo insulin pump displays the RUN screen during normal use when no programming is being performed. The time, current hourly basal rate, selected basal rate profile and all currently activated functions appear on the RUN screen.

Settings
Settings are individually programmable values and parameters that affect the way your Accu-Chek Spirit Combo insulin pump works.

Scrolling
Scrolling allows a fast and easy programming of a range of values.

STOP
When your Accu-Chek Spirit Combo insulin pump is in STOP, it does not deliver any insulin. The insulin delivery is only stopped if an error occurs or if your Accu-Chek Spirit Combo insulin pump is put into a necessary STOP, (e.g. when changing the cartridge, adapter or infusion set or for data transfer). Functions such as Extended Bolus or Temporary Basal Rate are interrupted by putting your Accu-Chek Spirit Combo insulin pump into STOP.

STOP screen
The STOP screen is the starting point for all functions that require that your Accu-Chek Spirit Combo insulin pump does not deliver insulin.

Temporary Basal Rate
Temporary increase or decrease of your basal rate profile in percentages (from 0–500 %) 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 insulin or rapid-acting insulin analogue.

Quick reference table for errors, warnings and reminders

Errors

No	Error	What you have to do
E1	CARTRIDGE EMPTY	Change the cartridge.
E2	BATTERY EMPTY	Change the battery.
E3	AUTOMATIC OFF	Put your Accu-Chek Spirit Combo insulin pump into RUN if necessary.
E4	OCCLUSION	Change the cartridge and infusion set. See section *2.6* to *2.9*.
E5	END OF OPERATION	Arrange for immediate replacement of your Accu-Chek Spirit Combo insulin pump. Contact your healthcare professional for alternative insulin therapy options.

No	Error	What you have to do
E6	MECHANICAL ERROR	See chapter *8*.
E7	ELECTRONIC ERROR	See chapter *8*.
E8	POWER INTERRUPT	See chapter *8*.
E9	END OF OPERATION	Arrange for immediate replacement of your Accu-Chek Spirit Combo insulin pump. Contact your healthcare professional for alternative insulin therapy options.
E10	CARTRIDGE ERROR	See chapter *8*.
E11	SET NOT PRIMED	Prime your infusion set.
E12	DATA INTERRUPTED	Restart the data transfer.
E13	LANGUAGE ERROR	See chapter *8*.

Warnings

No	Warning	What you have to do
W1	CARTRIDGE LOW	Change cartridge before it is completely empty.
W2	BATTERY LOW	Replace the battery as soon as possible.
W3	REVIEW TIME	Set the time and date.
W4	CALL FOR UPDATE	Contact your local pump support.
W5	PUMP TIMER	In the MY DATA menu check for the remaining operation time under the menu PUMP TIMER. Arrange for replacement of pump within the scheduled pump operation time.

No	Warning	What you have to do
W6	TBR CANCELLED	Put your Accu-Chek Spirit Combo insulin pump into RUN if necessary. Ensure the cancellation was intended and program a new Temporary Basal Rate if necessary.
W7	TBR OVER	Decide whether a further Temporary Basal Rate change is appropriate and program one if necessary.
W8	BOLUS CANCELLED	Put your Accu-Chek Spirit Combo insulin pump into RUN if necessary. Ensure that the cancellation was intended and program a new bolus if necessary.

No	Warning	What you have to do
W9	LOANTIME WARNING	In the MY DATA menu, check for the remaining insulin pump loan time under the menu PUMP TIMER. Arrange for replacement of pump within the scheduled pump loan time.
W10	BLUETOOTH FAULT	Re-do pairing procedure for insulin pump and meter. See section *6.4 Troubleshooting the Bluetooth® connection* in the User's Manual for detailed information.

Reminder

No	Reminder	What you have to do
	Reminder	Put your Accu-Chek Spirit Combo insulin pump into RUN if necessary.
	END OF WARRANTY	Contact your local pump support.

Some reminders and warnings are country specific and may never occur on your pump.

Bluetooth® registration

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

FCC ID VWI-17

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

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

Your contact for assistance with and/or additional information about your Accu-Chek Spirit Combo insulin pump:

CE 0088

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