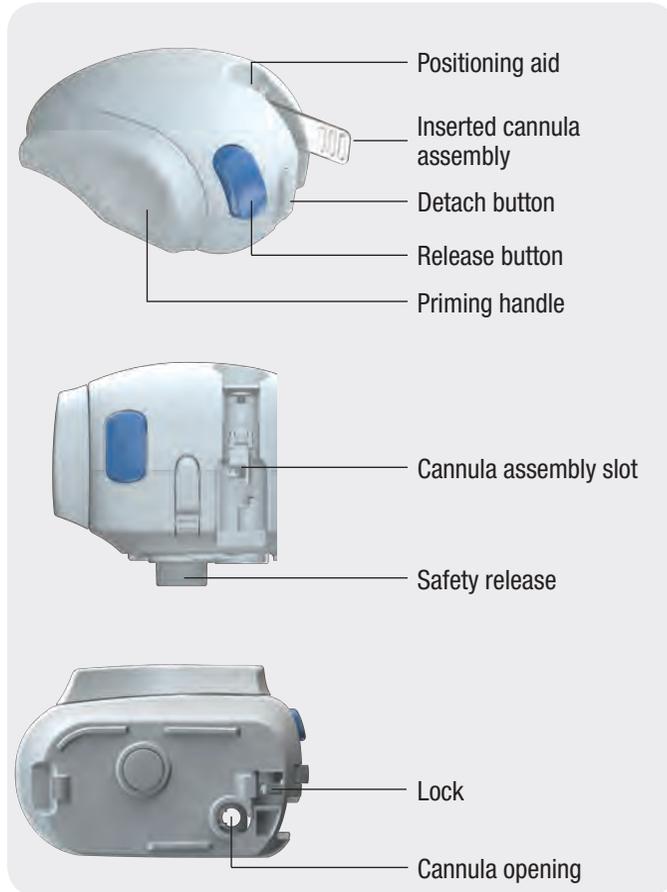
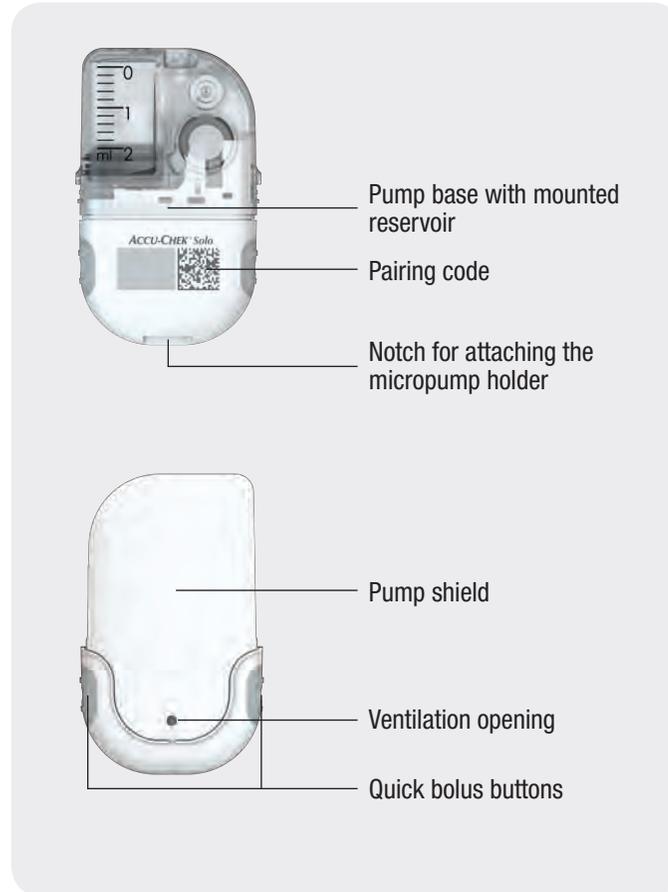


**Insertion device**



**Micropump**



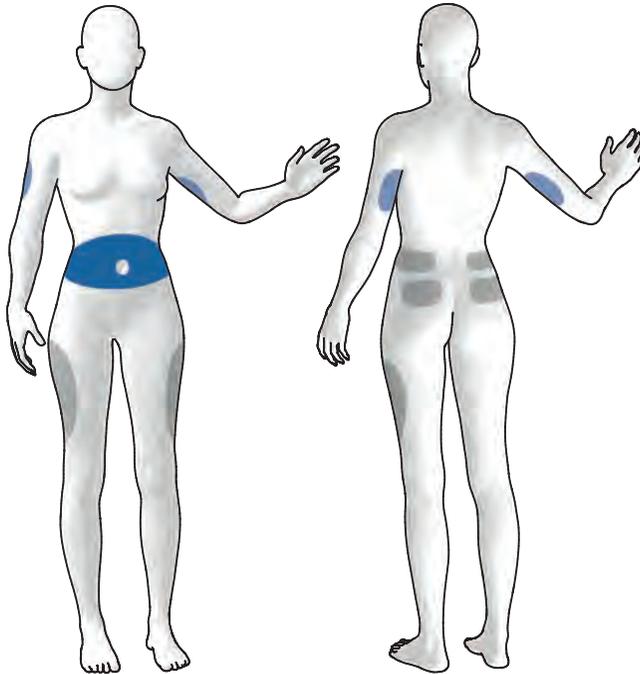
### **WARNING**

- ▶ The reservoir, cannula and micropump holder are intended for single use and are sterile packaged. They must not be used if their sterile packaging was previously opened or damaged or if the use by date has expired.
- ▶ Check at regular intervals that the micropump holder and cannula are tightly connected to each other. Make sure that the micropump holder does not detach itself from the infusion site and that the adhesive pad is not wet. Insulin delivery may be interrupted by a loose fitting or displaced cannula.
- ▶ Check your blood glucose level at least four times a day and once within a period of 1 to 3 hours if the micropump was exposed to any mechanical impact.

### **Note**

- ▶ The micropump holder must not be attached to sites on the body with scars, birthmarks and moles, tattoos, injuries, bruises or rashes.
- ▶ Before you attach the micropump holder to the body, the infusion site must be completely dry.
- ▶ A new infusion site must be at least 5 cm away from the last infusion site.
- ▶ If the micropump holder frequently becomes detached from the skin, consult your healthcare team to find a method that may improve adhesion to the skin.
- ▶ If the infusion site becomes inflamed, replace the infusion assembly immediately and choose a new infusion site.
- ▶ Check the micropump system for possible damage or leaks regularly.
- ▶ Check your blood glucose level after changing the infusion assembly once within 1 to 3 hours.
- ▶ Check the micropump system for damage or leaks if you can smell insulin.

## 4.2 Recommended Infusion Sites



Blue areas: Recommended infusion sites

Grey areas: Possible infusion sites

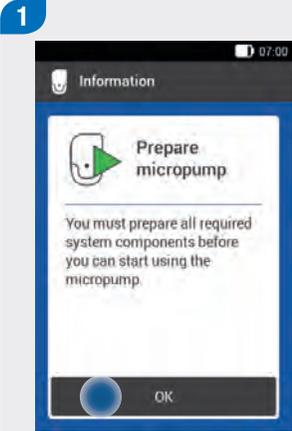
Choose a suitable infusion site before inserting a new infusion assembly. Consult your healthcare team for advice. Sites with sufficient subcutaneous tissue are the most suitable. For example:

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

### Note

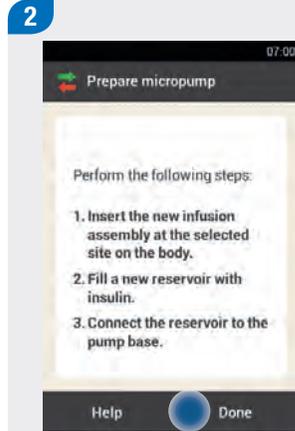
If the infusion site becomes inflamed, replace the infusion assembly immediately and choose a new infusion site.

## 4.2.1 Attaching the Infusion Assembly



After setting up the diabetes manager (see Chapter 3), the [Prepare micropump](#) display appears.

Tap [OK](#).



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

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

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

### WARNING

Before using the insertion device for the first time or if it has been stored for a longer period, before inserting the cannula, you must push down the safety release on the insertion device and press the release button on the insertion device to check that it does not contain a cannula. There is a risk that the cannula may not be inserted under the skin correctly due to insufficient spring tension in the insertion device.

### Note

If there is an unexplained rise in your blood glucose level or an occlusion alarm occurs, check the micropump and the infusion assembly for occlusions and leaks. If you are unsure whether the infusion assembly is working properly, replace it immediately.

### 4.2.2 Step 1: Attaching the Infusion Assembly to the Body

1



Wash your hands with warm water and soap and dry them thoroughly.

2



Select a suitable site on the body.

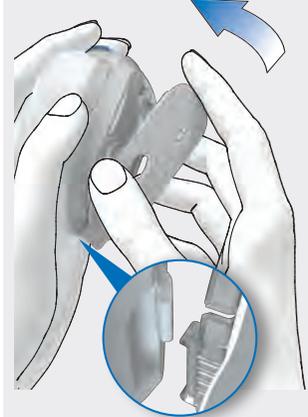
Disinfect the site on the body by wiping it with an alcohol wipe, for example. Then let the skin dry completely.

3



Remove the micropump holder from the packaging.

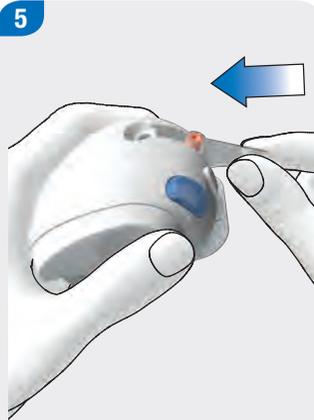
4



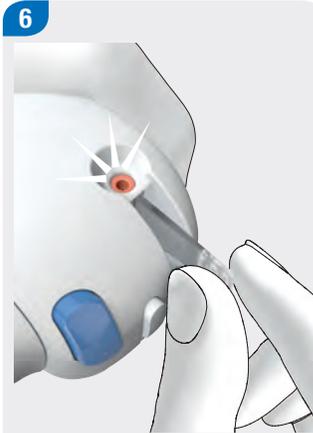
Attach the hook of the micropump holder to the bottom of the insertion device.

Press on the micropump holder lightly until it engages with the lock at the front of the insertion device.

## Putting the Micropump Into Operation



5  
Insert the cannula assembly diagonally into the cannula assembly slot.

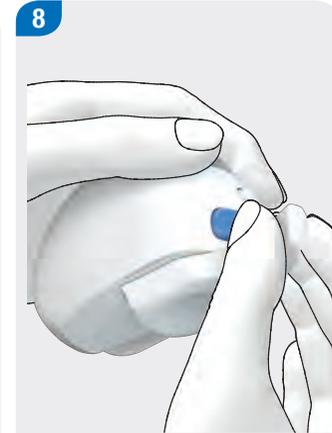


6  
Push the cannula assembly into the slot until you hear it click into place.

Use the positioning aid to check whether the cannula assembly has the correct position.

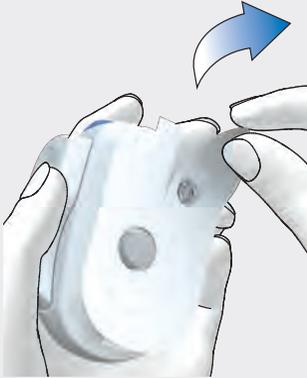


7  
Prime the insertion device by rotating the priming handle clockwise in the direction of the arrow by approximately half a turn.



8  
When the insertion device is fully primed, you will hear a click.

9



Remove both parts of the protective film from the adhesive pad.

Do not touch the adhesive surface of the adhesive pad. This could impair the adhesive properties.

10



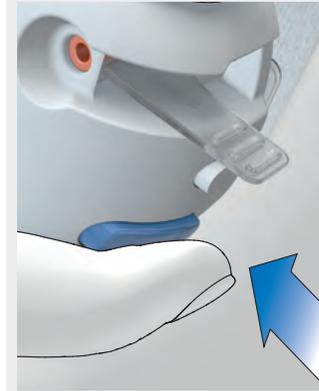
Press the insertion device firmly against the selected site on the body so that the adhesive pad is applied evenly to the skin. Make sure the surface of the skin is taut.

11



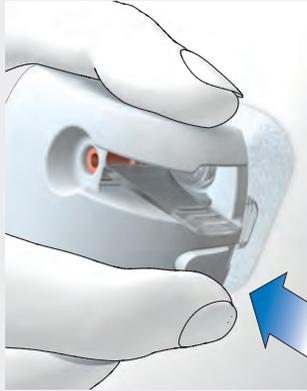
Smooth over the adhesive pad around the infusion assembly so that the infusion assembly is in good contact with the skin.

12



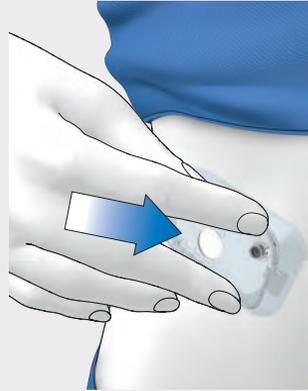
Press the blue release button to insert the cannula under the skin.

13



Press the detach button and detach the insertion device from the infusion assembly.

14



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

The infusion assembly is now safely attached to the site on the body.

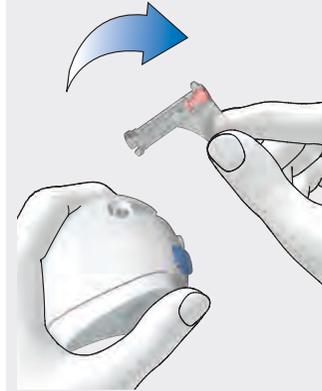
15



Check whether the grey cannula head is visible in the opening of the cannula support and is flush with the cannula support.

If the grey cannula head is not visible, the cannula was not inserted. Remove the micropump holder and repeat Steps 2 to 15.

16



Remove the used cannula casing from the insertion device.

17



Dispose of the used cannula casing according to local regulations.

**WARNING**

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

### 4.2.3 Step 2: Filling the Reservoir with Insulin

In addition to the reservoir assembly, you need an insulin vial with U100 insulin and a form of disinfectant, such as a sterile alcohol wipe.

- ▶ Use and store insulin in compliance with the manufacturer specifications and pay attention to the use by date.
- ▶ Make sure that the insulin is at room temperature before using it in the micropump. Use the reservoir immediately after filling it.
- ▶ Occlusions may occur if the temperature of the insulin or micropump system is too low.
- ▶ You can also use a 3 ml pen cartridge to fill the reservoir. To do so, place the top of the cartridge onto the filling aid and press the seal stopper of the cartridge down with a pen or similar device.
- ▶ During filling, make sure you remove any air bubbles from the reservoir.



#### WARNING

- ▶ Use only permitted U100 insulin types to fill the reservoir.
- ▶ If you connect an empty reservoir to the micropump (for example, for training purposes), insulin delivery (basal rate and bolus delivery) is nevertheless displayed, although no insulin is delivered because of the empty reservoir.
- ▶ Never fill the micropump while it is connected to an infusion assembly attached to your body. There is a risk of uncontrolled insulin delivery.

**Filling a new reservoir with insulin**

1



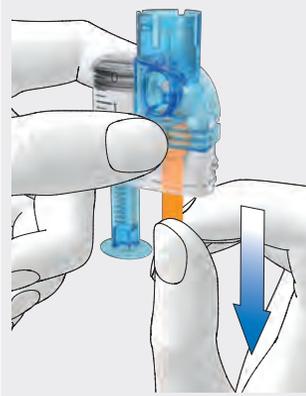
Disinfect the top of the insulin vial with a sterile alcohol wipe. Allow the disinfected top of the vial to dry.

2



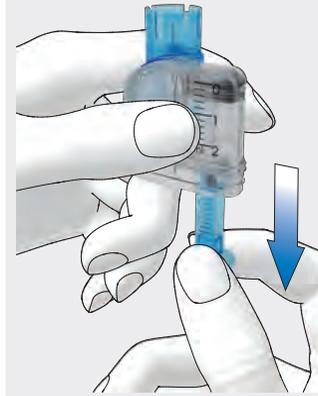
Remove the new reservoir from the packaging.

3



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

4



Hold the round part of the handle firmly and pull it downwards in the direction of the arrow.

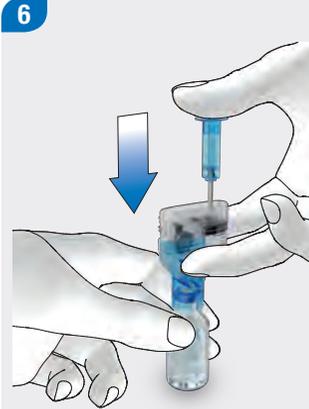
Fill the reservoir with the volume of air that you later want to fill with insulin.

**Note**

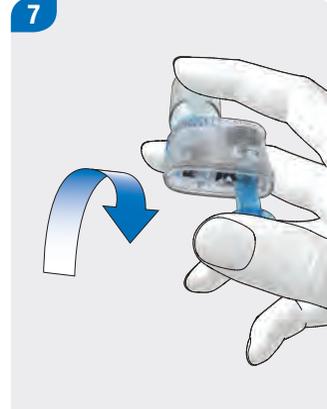
- ▶ The reservoir must always be filled with a minimum of 80 U for the electronics to detect that the reservoir is filled.
- ▶ The reservoir has a maximum holding capacity of 200 U (2.0 ml).
- ▶ Take care not to touch the reservoir needle. You might injure yourself.



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



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



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

8



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

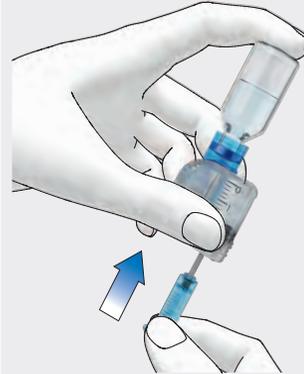
Try to ensure that no air bubbles form in the reservoir.

9



Gently flick your finger against the reservoir to release any air bubbles from the reservoir.

10



Push the handle upwards slightly in the direction of the arrow to push air bubbles out of the reservoir.

Then pull the handle downwards again to fill the reservoir with the desired amount of insulin.

11



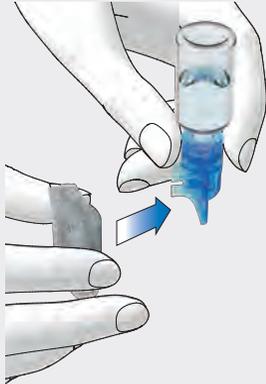
Compress the corrugated part of the handle such that the upper end of the handle opens.

Remove the handle from the piston rod to the side.

Dispose of the handle.

### 4.2.4 Step 3: Connecting the Reservoir to the Pump Base

12



Detach the filling aid from the reservoir by removing it sideways in the direction of the arrow.

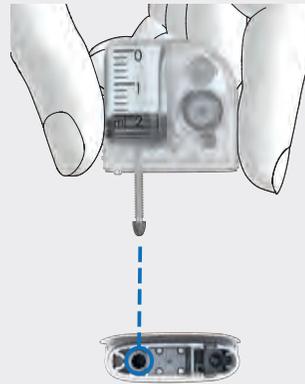
Dispose of the filling aid.

1



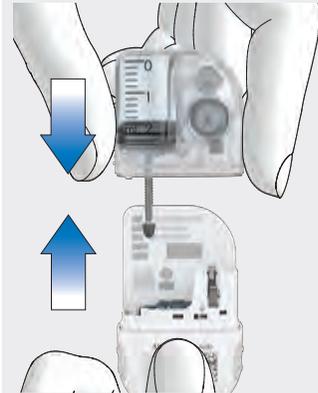
Remove the blue reservoir cap from the pump base.

2



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

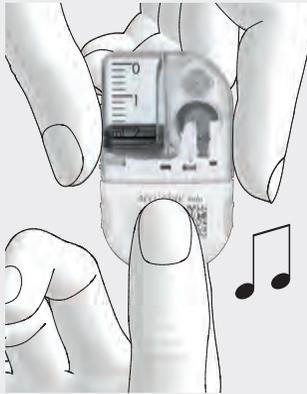
3



Hold the pump base with one hand and the reservoir with the other.

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

4



Pay attention to whether a rising sequence of tones is issued after connecting the reservoir and pump base. The sequence of tones confirms that the system components are connected to each other correctly and that the battery has been activated.

### Note

- ▶ Make sure that there is no gap between the reservoir and the pump base.
- ▶ Do not exert too much force when connecting the pump base to the reservoir.
- ▶ Make sure that the ventilation opening of the micropump is always clear so that the battery is fully functional.

## Setting the reservoir fill amount

1



Read the reservoir level using the reservoir scale.

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

2



Use  $-$  and  $+$  to set the insulin units with which you filled the reservoir.

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

Tap [Save](#).

#### 4.2.5 Step 4: Pairing the Diabetes Manager and Micropump

To be able to operate the micropump using the diabetes manager, you must pair the devices.

Once the diabetes manager and the pump have been paired, the pairing settings are stored in both devices so that you do not have to repeat this process.

If radio connection between the diabetes manager and the micropump is stopped or interrupted, it will automatically be restored once the devices are within an appropriate range of each other.

You can simply use the camera on the back of the diabetes manager and the pairing code on the pump base to pair the devices. If this is not possible, you can enter the pump key into the diabetes manager. If several micropumps are within the communication range of the diabetes manager, you must select the micropump serial number from a list that is displayed.



**Note**  
Once a pump base is paired with a diabetes manager, it cannot be paired with a different diabetes manager. So if you are using a different diabetes manager than before, for example, a replacement device, it cannot be paired with the micropump that has been in operation so far. In this case, you must use a new pump base.

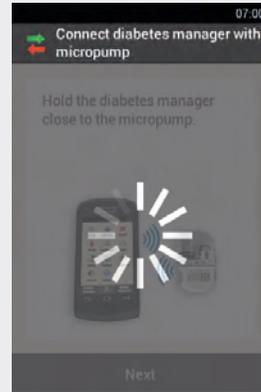
1



Hold the diabetes manager close to the micropump to establish the radio connection.

Tap **Next**.

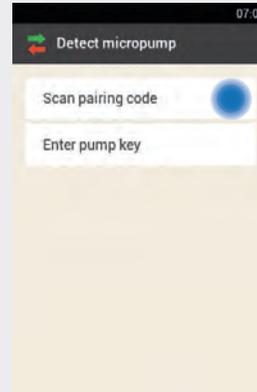
2



The diabetes manager establishes the radio connection to the micropump.

Wait a moment.

3



Tap **Scan pairing code**.

4



Point the camera of the diabetes manager at the pairing code on the pump base. Hold the diabetes manager such that the pairing code appears in the middle of the screen.

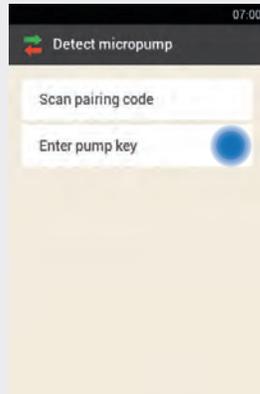
5



If the pairing code has been successfully scanned and registered, a signal is issued shortly afterwards.

The micropump and the diabetes manager are now paired with each other.

6



If the pairing code cannot be successfully scanned, you can enter the pump key manually.

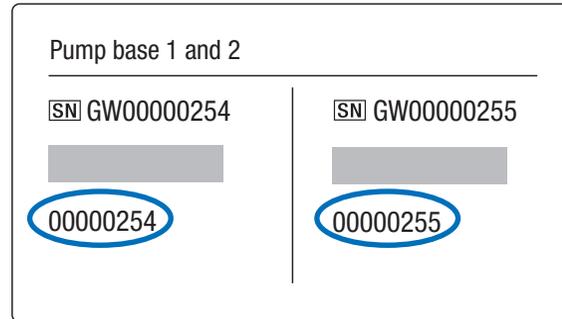
Tap **Enter pump key**.

**Note**

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

The pump serial number of the micropump is on the pump shield label and the packaging label next to the **SN** symbol.

Pump key example:



7



If several micropumps are within communication range: Tap the **pump serial number** of your micropump.

8



Enter the **pump key** using the keyboard.

If pairing was successful, a signal is issued.

Tap **Done**.

#### 4.2.6 Step 5: Filling the Reservoir Needle

##### WARNING

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

## Putting the Micropump Into Operation

1



The micropump is now ready to fill the reservoir needle and issues a signal.

Tap **Fill**.

2



The reservoir needle is filled.  
Wait a moment.

3



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

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

4

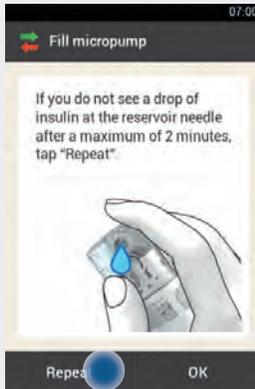


If you can see a drop of insulin at the tip of the needle, tap **OK**.

Continue with Step 1 of the next section.

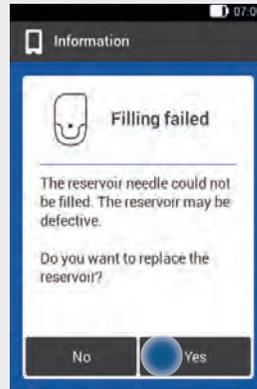
The  button is deactivated.

5



If you **cannot** see a drop of insulin at the tip of the needle, tap **Repeat**. The **Repeat** button is only activated after approx. 2 minutes.

6



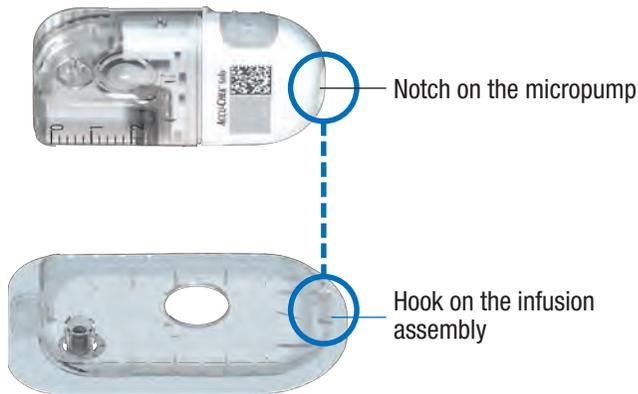
Tap **Yes** and follow the instructions on the displays that follow.

### Note

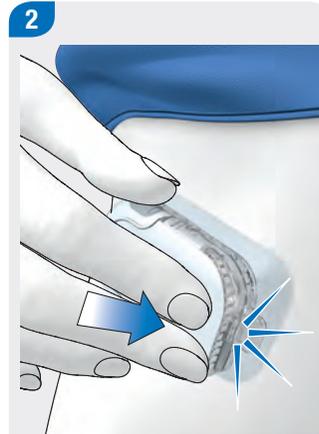
If you do not see a drop of insulin at the needle tip after a maximum of two minutes, there is still too much air in the reservoir. If no insulin drop is visible even after refilling the reservoir, you must use a new reservoir.

### 4.2.7 Step 6: Attaching the Micropump

To attach the micropump correctly to the infusion assembly, you must engage the notch on the micropump with the hook on the infusion assembly.



First place the pump onto the infusion assembly using slight pressure.



Exert some pressure on the pump shield so that the micropump engages with the hook at the front of the infusion assembly.

When the micropump is correctly attached to the infusion assembly, you hear a click sound.

3



Check whether the micropump is securely attached to the infusion assembly.

The micropump is now ready for insulin delivery.

4



Tap **Next**.

A small amount of insulin is delivered to fill the micropump system.

### **WARNING**

- ▶ Check the site on the body with the adhesive pad of the infusion assembly at least once a day.
- ▶ Inserting the sensor under the skin or wearing the adhesive pad can cause the site to become irritated or inflamed. Symptoms include, amongst other things, redness, swelling, pain, heat sensation or weeping. Remove the infusion assembly if signs of inflammation or contamination are visible. Place a new infusion assembly on a different suitable site on the body.

### **Note**

- ▶ Check at regular intervals whether the adhesive pad with the infusion assembly is securely attached to the body. A loose infusion assembly may interrupt insulin delivery.
- ▶ If there is an unexplained rise in your blood glucose level or an occlusion alarm occurs, check the micropump and the infusion assembly for occlusions and leaks. Replace your infusion assembly if you are not sure whether it is working properly.

## 4.2.8 Activating the Basal Rate Profile

After having completed all preparatory steps for using the micropump for the first time, you can activate the set basal rate profile.

Once you have activated the basal rate profile, the micropump system setup is complete. The basal rate is delivered and you can use other system features.

Follow the setting for basal rate profiles you agreed on with your healthcare professional. For more information on basal rate profiles, see the chapter *Basal Rate Profiles and Temporary Basal Rates*.

1



The image shows a smartphone screen with a dark header bar containing a white insulin icon and the text "Deliver insulin". The main content area has a white background with a green border. At the top, there is a blue bar with a white arrow icon and the text "Activate basal rate profile". Below this, it says "Profile 1" and "Total amount 20.0 U". At the bottom, there is a green bar with the text "To confirm, press" and a green checkmark icon in a circle.

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

2



The image shows a smartphone screen with a light beige background. At the top, there is a status bar with signal strength, battery, and time (07:00). Below that, there is a glucose level indicator showing "200 U" and a date "06:55, 29 Mai 2018". The main content area shows "Profile 1" and "1.20 U/h". Below that, there is a "New bolus" button with a plus sign. At the bottom, there are three buttons: "Main menu", a home button icon, and "Add data".

The Status screen displays the activated basal rate profile.

## 4.2.9 Stopping and Starting the Micropump

With the **Stop**  and **Start**  items in the Main menu, you can interrupt or start insulin delivery again.

Discuss with your healthcare professional when and for how long insulin delivery may be interrupted.

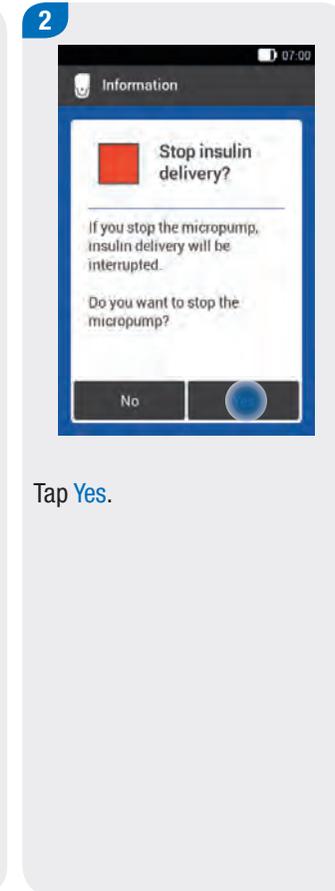
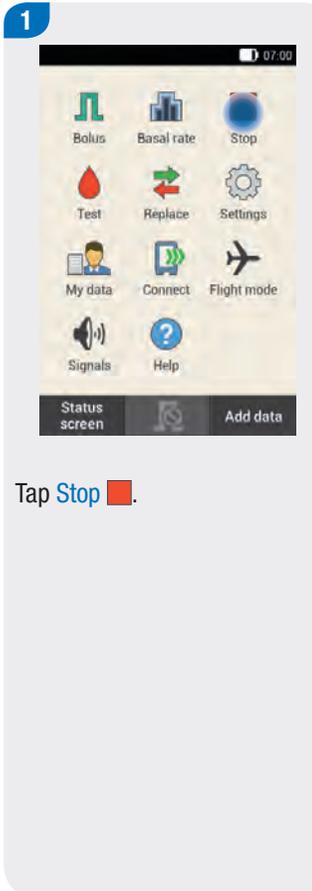
If necessary, use a syringe or insulin pen to deliver insulin according to the instructions of your healthcare team.

### Note

If your insulin delivery is interrupted for any reason, check your blood glucose level and deliver the missing insulin using a syringe or pen, for example, when:

- ▶ You stop or remove the pump for a longer period of time.
- ▶ There is a technical problem with the pump.
- ▶ There is an occlusion in the cannula/infusion assembly.
- ▶ The reservoir or infusion assembly is leaking.
- ▶ The infusion assembly has come loose at the infusion site.

### Stopping insulin delivery



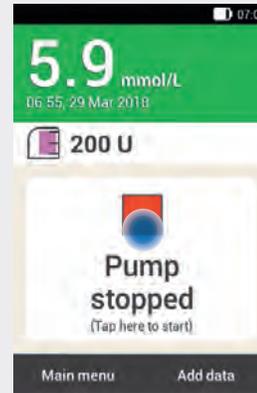
## Putting the Micropump Into Operation

While the micropump is in Stop mode, it emits a signal every hour to remind you that no insulin is being delivered.

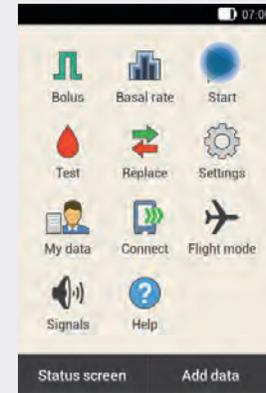
### Note

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

## Starting or stopping insulin delivery



or

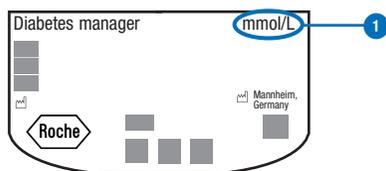


On the Status screen, tap the  symbol to restart the micropump.

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

# 5 Testing Your Blood Glucose

## 5.1 Checking the Unit of Measurement



Blood glucose results can be specified in two different units of measurement (mg/dL and mmol/L). As a result, two versions of the same diabetes manager are available. Check whether the diabetes manager displays the unit of measurement familiar to you. The unit of measurement your diabetes manager displays is shown on the back of your diabetes manager ❶. If you do not know which unit of measurement is correct for you, contact your healthcare team.

### WARNING

The unit of measurement that your diabetes manager displays cannot be changed. Contact your Customer Support and Service Centre if the wrong unit of measurement is printed on the back. A wrong unit of measurement may lead to incorrect interpretation of blood glucose results and therefore to wrong therapy recommendations being made, thus resulting in serious adverse health effects.

- ▶ You need the diabetes manager, a test strip, a finger pricker and a lancet drum.
- ▶ Set up the diabetes manager before testing your blood glucose for the first time.
- ▶ Read the test strip package insert. In the package insert, you will find further important information on storage and possible causes of incorrect test results.

## 5.2 Performing a Blood Glucose Test

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

### WARNING

- ▶ A blood glucose test that was performed incorrectly can lead to incorrect test results and thus to wrong therapy recommendations being made, which can result in serious adverse health effects. Therefore, follow the notes on how to perform blood glucose tests correctly, carefully.
- ▶ A contaminated puncture site may lead to incorrect test results. Wash your hands and the puncture site with warm water and soap and rinse them well.
- ▶ Test your blood glucose regularly, at least 4 times a day.
- ▶ The micropump system is only intended for blood glucose testing with fresh capillary blood from the fingertip.

### Note

- ▶ When the diabetes manager prompts you to apply a drop, you have approximately 2 minutes to apply blood to the test strip. If you do not apply any blood during this time, the diabetes manager turns itself off.
- ▶ Visually impaired persons must always be supported by a sighted person when applying the blood drop.
- ▶ The micropump system is not suitable for testing blood from alternative sites.

### Prior to the test



1 Wash your hands with warm water and soap and rinse them well. Dry your hands thoroughly with a clean towel before obtaining blood.