

**WARNING**

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

Note

- ▶ Do not use the insertion device without first inserting the cannula assembly. Before storing the insertion device, ensure that there is **no** cannula assembly in the insertion device.
- ▶ Never store the insertion device in a primed state. Storing the insertion device incorrectly may weaken the spring tension, which will impair the operation of the insertion device.
- ▶ Check at regular intervals whether the micropump system has visible or tangible signs of damage. This applies in particular if the system components were dropped or were exposed to particular mechanical stress.

4.3.2 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 the insulin in compliance with the manufacturer's 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.
- ▶ During filling, make sure you remove any air bubbles from the reservoir.

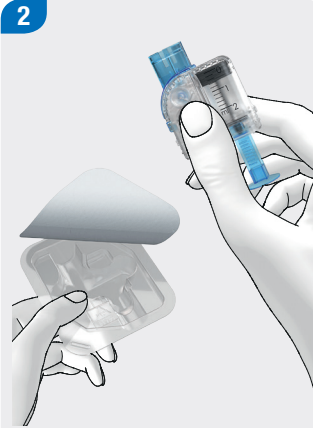


WARNING

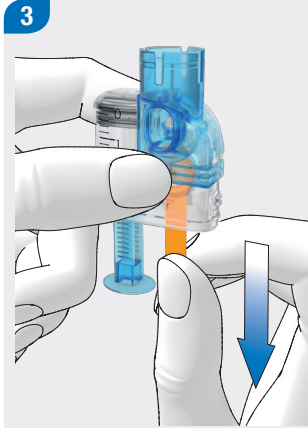
- ▶ Only use the micropump to deliver rapid-acting U100 insulin.
- ▶ If you connect an empty reservoir to the micropump (for example, for training purposes), insulin delivery (basal rate and bolus delivery) is nevertheless displayed, although no insulin is delivered because of the empty reservoir.



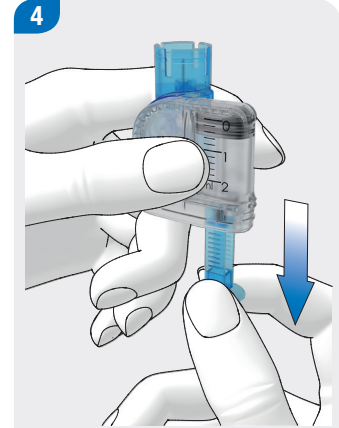
1
Disinfect the top of the insulin vial with a sterile alcohol wipe. Allow the disinfected top of the insulin vial to dry.



2
Remove the new reservoir assembly from the packaging.



3
Carefully pull out the battery's protective film downwards in the direction of the arrow to activate the battery.



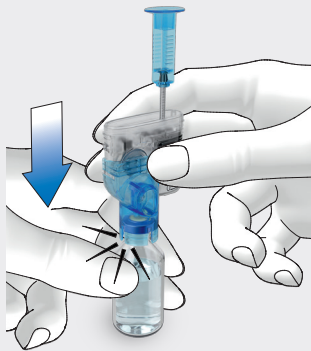
4
Hold the round part of the handle firmly and pull it downwards in the direction of the arrow in order to fill the reservoir with air.

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

Note

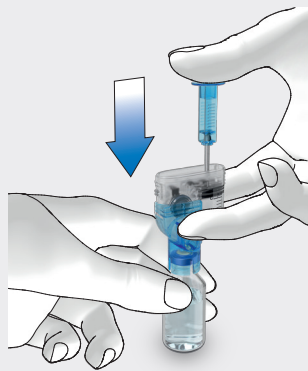
- ▶ The reservoir must be filled with at least 80 U.
- ▶ The reservoir has a maximum holding capacity of 200 U (2.0 ml).
- ▶ Take care not to touch the reservoir needle. You might injure yourself.

5



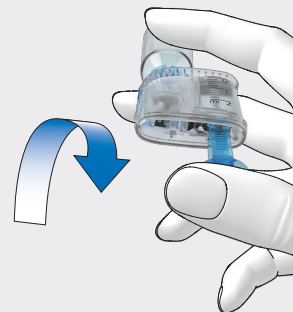
Place the insulin vial on a flat and solid surface (for example, a table top) and hold it firmly. Place the filling aid onto the vial. Push the filling aid downwards until you hear it click into place.

6



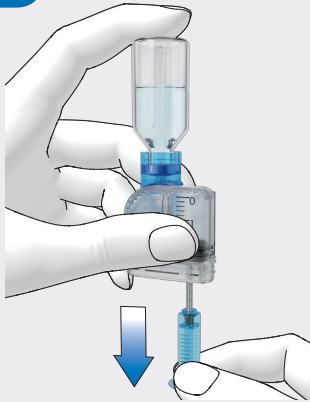
Press the handle all the way down in the direction of the arrow to fill the insulin vial with air.

7



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

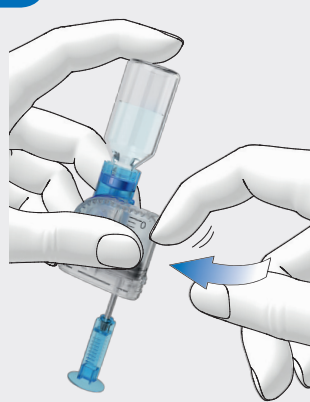
8



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.

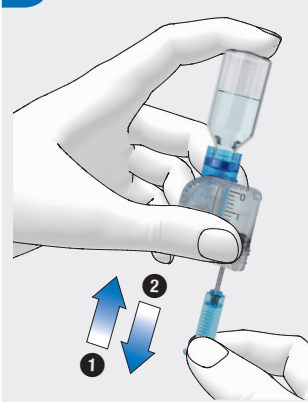
9



To release air bubbles from the reservoir, hold the reservoir at an angle.

Gently flick your finger against the reservoir several times.

10



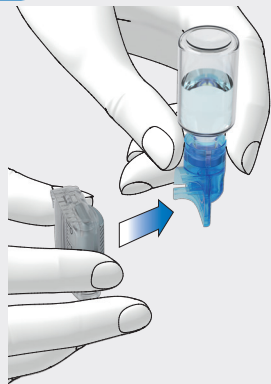
Slowly push the handle upwards in the direction of the arrow ① to remove air bubbles from the reservoir.

Slowly pull the handle downwards in the direction of the arrow ② until the reservoir is filled with the required amount of insulin again.

Note

Check the reservoir from several angles to make sure that there are no air bubbles in the reservoir.

11



Remove the filling aid from the reservoir by pulling it off laterally in the direction of the arrow.

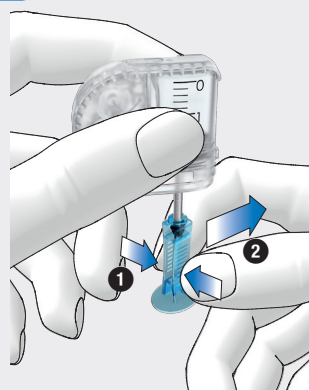
Contact your local waste management authority for guidance on how to recycle or dispose of the filling aid in an environmentally responsible manner.



WARNING

During disposal, ensure that no third party could injure themselves.

12



Compress the handle on the ribbed surface **1** and then remove the handle laterally from the piston rod **2**.

Dispose of the handle.

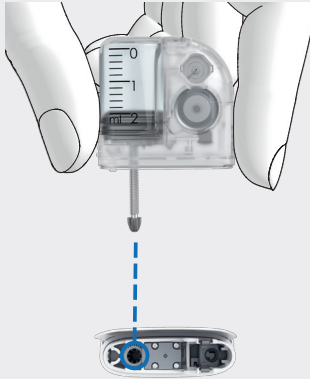
13



To connect the reservoir to the pump base in the next step, you first have to remove the reservoir cap.

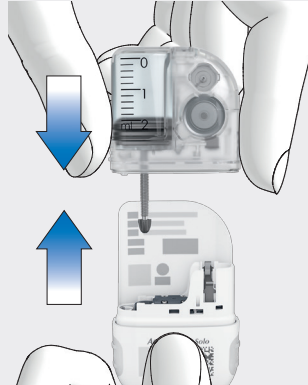
4.3.3 Connecting the Reservoir to the Pump Base

1



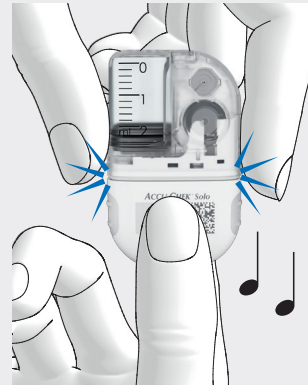
Align the piston rod of the filled reservoir such that you can insert it into the piston rod opening of the pump base.

2



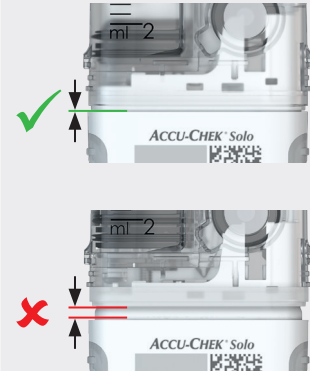
Push the filled reservoir onto the pump base until both parts are tightly connected.

3



When both components are connected to each other correctly and the battery is activated, the micropump issues the “Start” signal sequence. If this sequence of signals is not issued, check whether the battery is activated and repeat Steps 1 to 3.

4



Make sure that there is no gap between the reservoir and the pump base.

The pump base and the reservoir are only connected correctly when the “Start” signal sequence is issued **and** when the pump base and the reservoir are seamlessly connected.

Note

- ▶ Do not exert too much force when connecting the pump base to the reservoir.
- ▶ Make sure that the opening for ventilation of the micropump is always clear so that the battery is fully functional.
- ▶ For more information on the sequences of signals, see chapter 17.3 *Signals*.

5



Read the reservoir level using the reservoir scale.

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

6



Use **-** and **+** to set the number of 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**.

4.3.5 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.

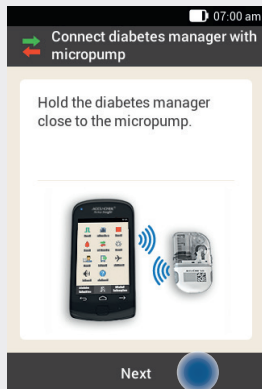
You can simply use the camera on the back of the diabetes manager and the pairing code (2D-Barcode) on the pump base to pair the devices. If this is not possible, you can enter the pump key into the diabetes manager. If several micropumps are within the communication range of the diabetes manager, you must select the micropump serial number from a list that is displayed.



Note

Each pump base can only be paired once with a 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. If this is the case, you have to use a new pump base.

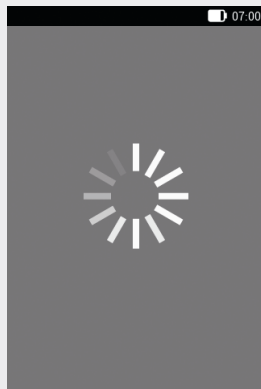
1



After you have connected the reservoir to the pump base, hold the diabetes manager close to the micropump to establish the radio connection.

Tap [Next](#).

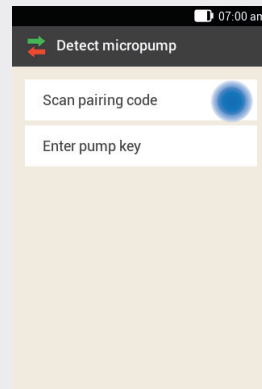
2



The diabetes manager establishes the radio connection to the micropump.

Wait a moment.

3



Tap [Scan pairing code](#).

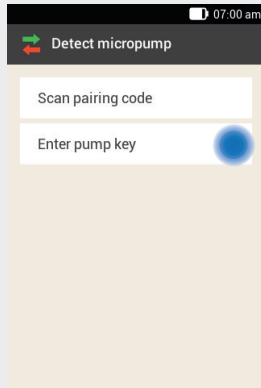
4



Point the camera of the diabetes manager at the pairing code on the pump base. Hold the diabetes manager in such a way that the pairing code can be read in full. A signal sounds if the pairing code was detected, and a prompt to fill the reservoir needle is displayed.

Entering the pump key manually

1

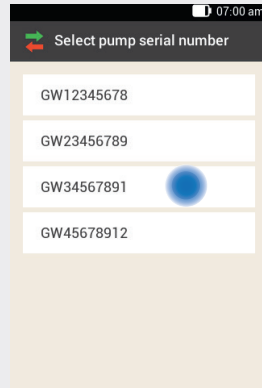


If no signal sounds, the pairing code was not detected.

Tap  to return to the [Detect micropump](#) display.

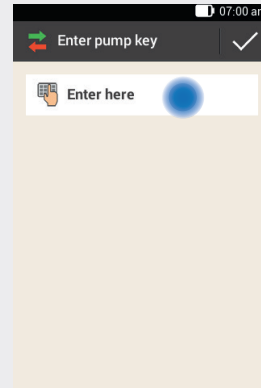
Tap [Enter pump key](#).

2



If there are several micropumps within range, tap the pump serial number of your micropump.

3



Tap [Enter here](#) and enter the pump key using the keyboard.

If pairing was successful, a signal sounds.

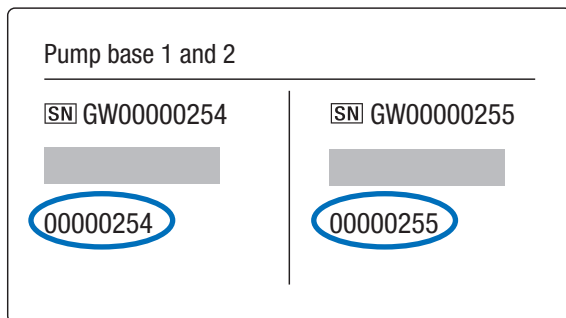
Tap [Done](#).

Note

You will find the pump key(s) in the envelope in the bottom drawer of the micropump system packaging (system kit).

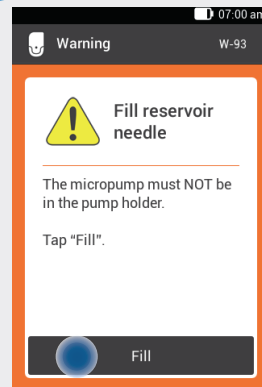
The pump serial number of the micropump is on the pump shield label and on the packaging label next to the **SN** symbol.

Pump key example:



4.3.6 Filling the Reservoir Needle

1



The micropump is now ready to fill the reservoir needle and displays a message to this effect.

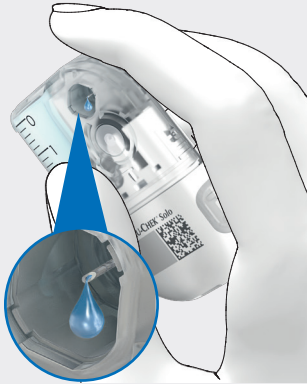
Tap **Fill**.



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.

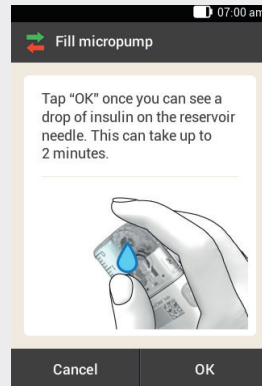
2



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.

3



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

If you **cannot** see a drop of insulin at the tip of the needle, tap **Cancel**.

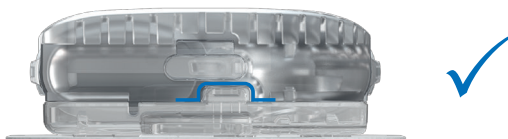
Note

- ▶ If you do not see a drop of insulin at the tip of the needle after a maximum of 2 minutes, there is still too much air in the reservoir. If no insulin drop is visible even after refilling, you must use a new reservoir.
- ▶ If you tap **Cancel** or do not enter any data, an information message is displayed after 2 minutes saying that filling failed. You can then replace the reservoir or restart filling.
- ▶ The  button is deactivated during filling.

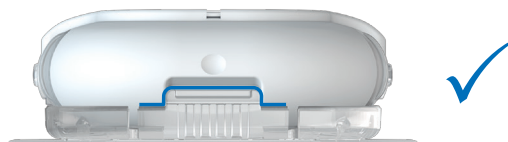
4.3.7 Attaching the Micropump

To properly attach the micropump to the pump holder, the recesses for attaching the micropump need to be clicked onto the hooks on the pump holder.

Hook on the top of the reservoir



Hook on the bottom of the pump base



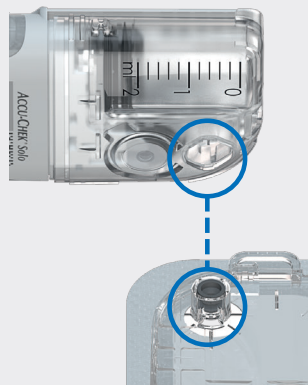
WARNING

Check the micropump and the pump holder for damage before you attach the micropump to the pump holder. Deformations or cracks can cause the micropump system to become leaky. This can lead to hyperglycemia.

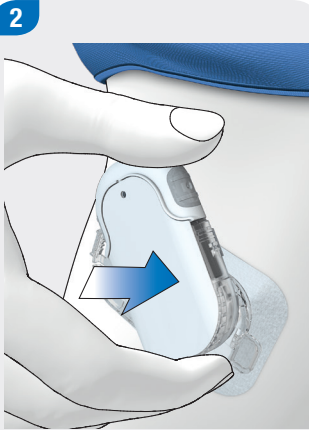
Note

- ▶ Check the site on your body with the adhesive pad of the infusion assembly at least once a day.
- ▶ If you insert the micropump into the infusion assembly (pump holder and cannula) frequently or incorrectly, the micropump system can become leaky.

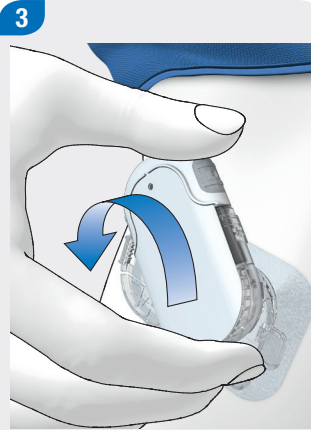
1



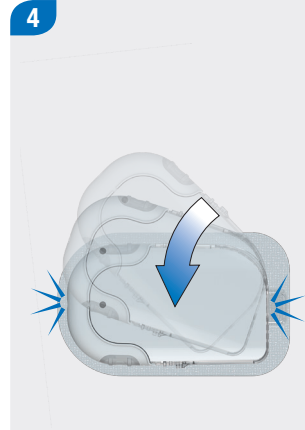
Hold the micropump in a position so that the reservoir needle is above the grey cannula head of the pump holder.



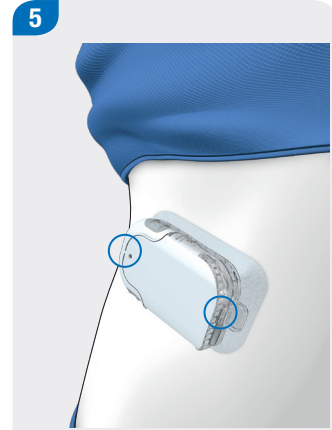
Place the reservoir needle of the micropump on the gray cannula head of the pump holder.



Turn the micropump carefully in place. You may apply light pressure on the pump shield to make sure the reservoir needle stays inside the cannula head of the pump holder.



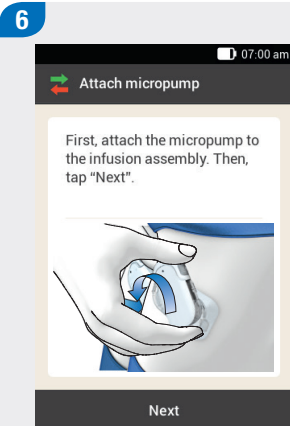
After one eighth turn (approx. 45 degrees), the micropump clicks into the front and rear hooks on the pump holder.



Examine the front and back hooks of the pump holder to make sure the micropump properly clicked in place.

The micropump is now ready for insulin delivery.

4.3.8 Activating the Basal Rate Profile



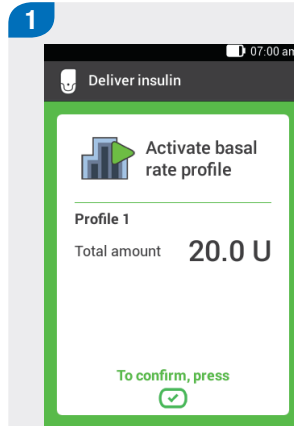
Tap **Next**.

A small amount of insulin is delivered in order to fill the soft Teflon® cannula.

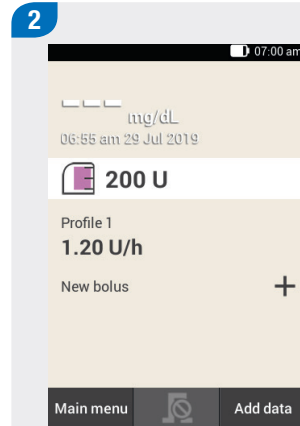
After having completed all preparatory steps for using the micropump for the first time, you can activate the set basal rate profile.

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 settings for basal rate profiles you agreed on with your healthcare professional. For more information, see chapter 8 *Basal Rate Profiles and Temporary Basal Rates*.



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



The Status screen displays the activated basal rate profile.

4.4 Stopping and Starting the Micropump

The **Stop**  and **Start**  items in the Main menu enable you to interrupt or restart insulin delivery.

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 professional.

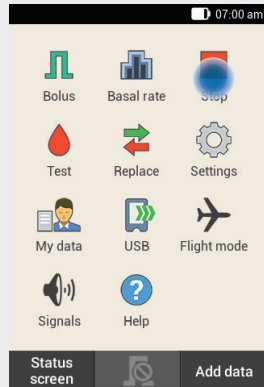
Note

If insulin delivery is interrupted, check your blood glucose level. If needed, 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.

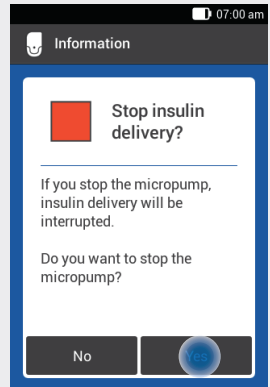
Stopping insulin delivery

1



Tap **Stop** .

2



Tap **Yes**.