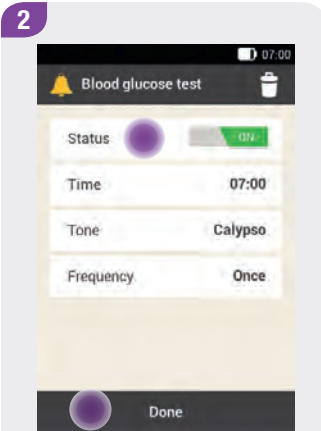


12.2.4 Reminder: Blood Glucose Test After Meal

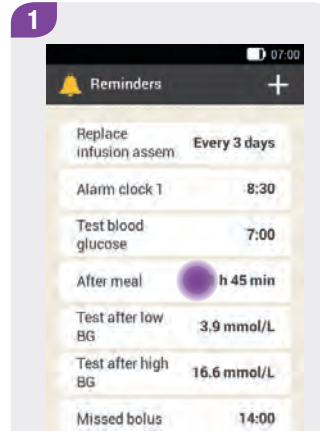


Tap the **Status** switch so that it is in the **ON** position. Tap **Time**, **Tone** or **Frequency** to make the desired settings.

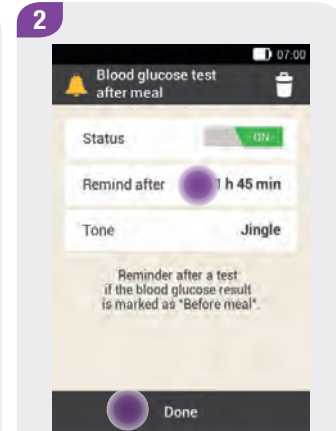
Once you have made all settings, tap **Done**.

Note

The reminder appears following a previous entry (BG test, bolus advice) that was marked as **Before meal**.



Tap **After meal**.

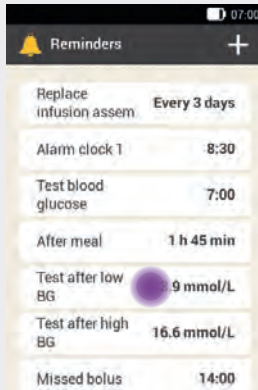


Tap **Remind after**.

Once you have made all settings, tap **Done**.

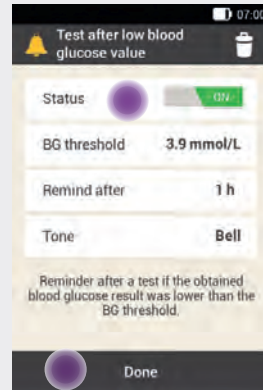
12.2.5 Reminder: Test After Low BG

1



Tap the **Test after low BG** entry.

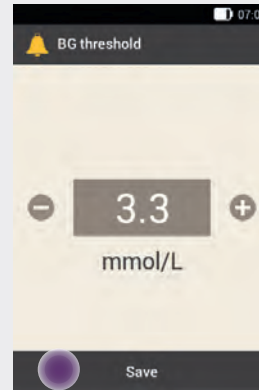
2



Tap the **Status** switch so that it is in the **ON** position. Tap **BG threshold**, **Remind after** or **Tone** to make the desired settings.

Once you have made all settings, tap **Done**.

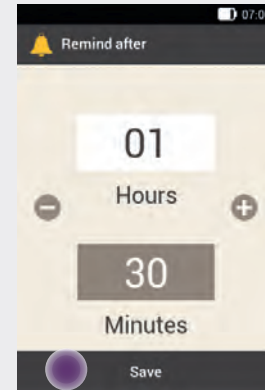
3



Use **-** and **+** to set the lower **BG threshold** that should be used to remind you to test your blood glucose again.

Tap **Save**.

4

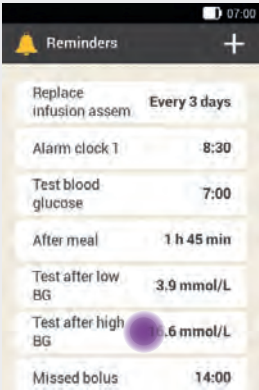


Use **-** and **+** to set the hours and minutes for the time span after which you want to test your blood glucose again.

Tap **Save**.

12.2.6 Reminder: Test After High BG

1

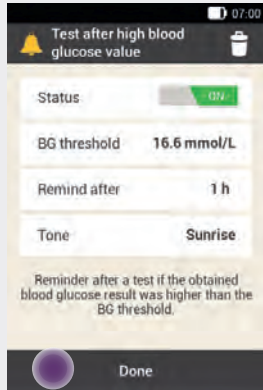


Reminders

- Replace infusion assem. Every 3 days
- Alarm clock 1 8:30
- Test blood glucose 7:00
- After meal 1 h 45 min
- Test after low BG 3.9 mmol/L
- Test after high BG 15.6 mmol/L
- Missed bolus 14:00

Tap the **Test after high BG** entry.

2



Test after high blood glucose value

Status ON

BG threshold 15.6 mmol/L

Remind after 1 h

Tone Sunrise


Reminder after a test if the obtained blood glucose result was higher than the BG threshold.

Done

Tap the **Status** switch so that it is in the **ON** position. Tap **BG threshold**, **Remind after** or **Tone** to make the desired settings.

Once you have made all settings, tap **Done**.

3



BG threshold

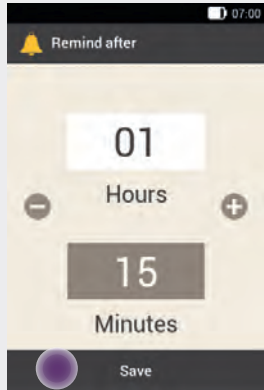
15.0 mmol/L

Save

Use **-** and **+** to set the upper **BG threshold** that should be used to remind you to test your blood glucose again.

Tap **Save**.

4



Remind after

01 Hours

15 Minutes

Save

Use **-** and **+** to set the hours and minutes for the time span after which you want to test your blood glucose again.

Tap **Save**.

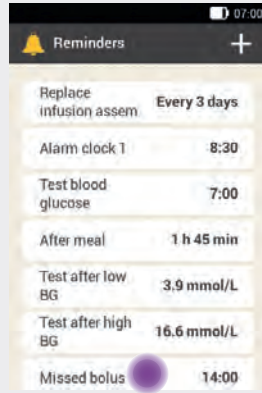
12.2.7 Reminder: Missed Bolus

This reminder occurs if no bolus was delivered within 2 hours prior to the programmed time. You can program up to 5 reminders of the **Missed bolus** type.

Example

The missed bolus reminder is programmed for 13:00. If no bolus is delivered between 11:00 and 13:00, the previously programmed reminder will occur at 13:00. If a bolus was delivered between 11:00 and 12:59, no reminder will occur.

1

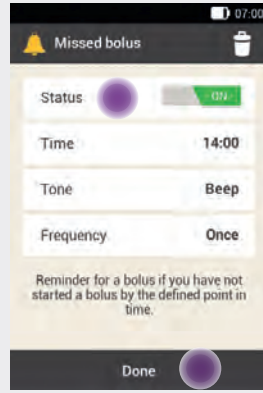


Reminders

- Replace infusion assem. Every 3 days
- Alarm clock 1 8:30
- Test blood glucose 7:00
- After meal 1 h 45 min
- Test after low BG 3.9 mmol/L
- Test after high BG 16.6 mmol/L
- Missed bolus 14:00

Tap the **Missed bolus** entry.

2



Missed bolus

- Status ON
- Time 14:00
- Tone Beep
- Frequency Once

Reminder for a bolus if you have not started a bolus by the defined point in time.

Done

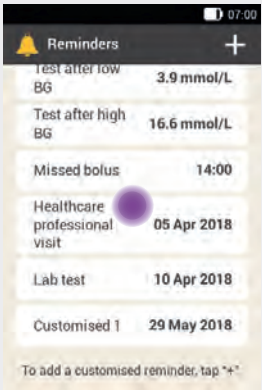
Tap the **Status** switch so that it is in the **ON** position. Tap the **Time**, **Tone** or **Frequency** elements to make the desired settings.

Once you have made all settings, tap **Done**.

12.2.8 Appointment Reminders: Healthcare Professional Visit, Lab Test, Customised

Appointment reminders are a helpful way of reminding you of an upcoming healthcare professional visit or lab test. In addition, you can set customised appointment reminders. These reminders are displayed when you turn on the diabetes manager on the specified reminder date.

1



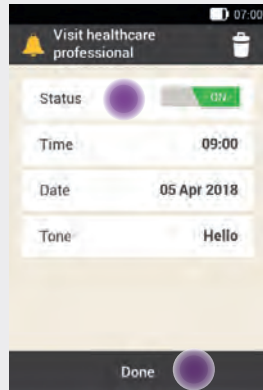
Reminders

Test after low BG	3.9 mmol/L
Test after high BG	16.6 mmol/L
Missed bolus	14:00
Healthcare professional visit	05 Apr 2018
Lab test	10 Apr 2018
Customised 1	29 May 2018

To add a customised reminder, tap "+"

Tap **Healthcare professional visit**.

2



Visit healthcare professional

Status ON

Time 09:00

Date 05 Apr 2018

Tone Hello

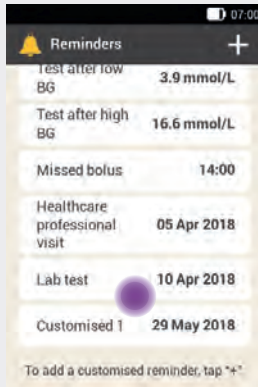
Done

Tap the **Status** switch so that it is in the **ON** position. Tap **Time**, **Date** or **Tone** to make the desired settings.

Once you have made all settings, tap **Done**.

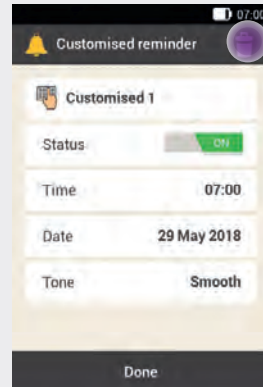
12.3 Deleting Reminders


1



Tap the reminder you want to delete, for example, **Customised 1**.

2



Tap the  symbol to delete the reminder.

3



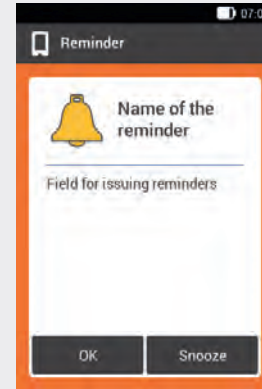
Tap **Yes** if you want to permanently delete the reminder now.

12.4 Issuing Reminders

If the diabetes manager is turned off, it will turn on at the specified time and show the respective reminder. The diabetes manager vibrates and the respective reminder is accompanied by the selected tone. The volume corresponds to the set signal mode (see chapter *Changing Settings*, section *Tone and Vibration*).

You now have the option of confirming the reminder or of being reminded again. If you want to be reminded again later, the reminder will be issued again after 15 minutes.

Example



Reminder: Replace infusion assembly

Tap **OK** to confirm the reminder. The reminder will no longer be displayed.

Tap **Snooze** if you want to be reminded again at a later point in time. The reminder will be issued again in 15 minutes.

13 Injection Therapy Mode

If you do not want to use your micropump for a while, you can switch to injection therapy mode. This could be the case, for example, if you want to temporarily or permanently go without your insulin pump during your holiday.

When you switch to injection therapy, your diabetes manager supports you as follows:

- ▶ Bolus advice results are rounded to the increment of your pen.
- ▶ You can note down your basal injections in the detailed test result and in the logbook entries of the diabetes manager.
- ▶ A reminder is available that you can use to be reminded about basal insulin injections.



WARNING

Discuss pausing your pump therapy with your healthcare team. Switch to alternative therapies only after consultation.

Note

- ▶ If bolus advice is used, carry out the injections in a timely fashion and using the suggested dosage. If you inject a different insulin amount, you should adjust the respective logbook entry.
- ▶ Manually enter all occasional insulin amounts delivered (without bolus advice) in the electronic logbook of the diabetes manager.
- ▶ Ensure suitable storage conditions for the pump when micropump usage is temporarily discontinued.

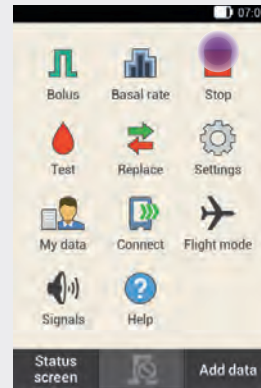
13.1 Removing the Micropump Temporarily

When you do water sports or take a bath or shower, you must remove the micropump from the infusion assembly. Also remove the micropump before entering rooms with high temperatures (such as a sauna or sunbed) and before taking a ride on a roller coaster.

Stop the micropump before removing it; otherwise the pump will unnecessarily continue to deliver insulin. However, you should take into account for how long you stop or remove the micropump as this interrupts the insulin supply to your body.

Removing the micropump

1



In the Main menu, tap **Stop** to interrupt insulin delivery.

2



Press the flap of the infusion assembly to detach the micropump. Remove the pump from the infusion assembly.

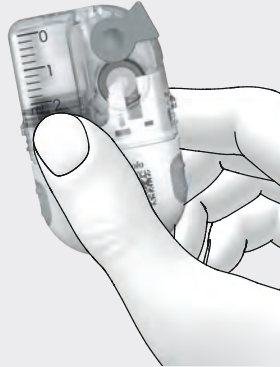
Replacing the protective caps

3



Place the yellow protective cap supplied onto the cannula support of the infusion assembly.

4

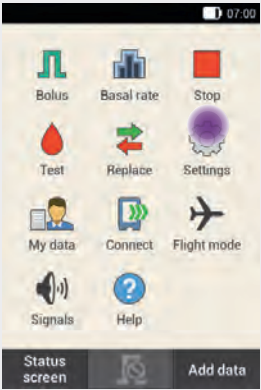


Insert the grey protective cap supplied into the opening near the reservoir needle.

Keep the micropump in a safe place.

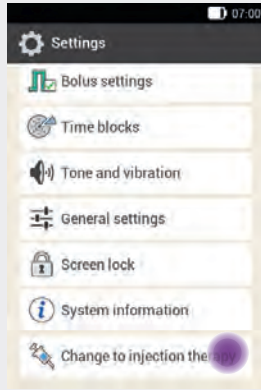
13.1.1 Activating Injection Therapy Mode

1



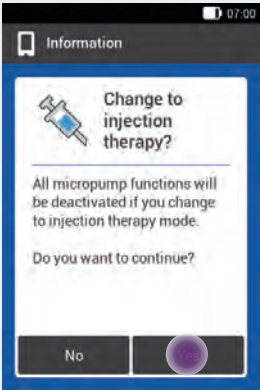
In the Main menu, tap the **Settings** menu.

2



Tap the **Change to injection therapy** entry.


3



If you want to switch to injection therapy, tap **Yes**.

The functions for controlling the micropump will be turned off.

4



Tap the desired insulin increment for the pen.

Tap **Save**.

5



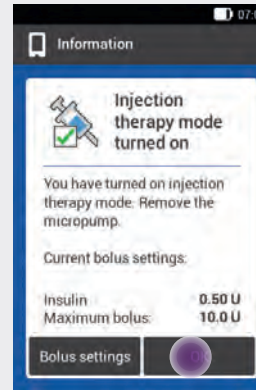
Use **-** and **+** to set the maximum bolus amount you want to deliver with the pen/syringe.

Tap **Save**.

Note

While in injection mode, the insulin amount for bolus advice is rounded for the pen according to the set insulin increment.

6

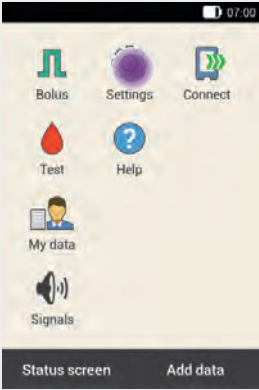


The display informs you that injection therapy mode is turned on. The current bolus settings are displayed.

Tap **OK** if you want to continue using these settings.

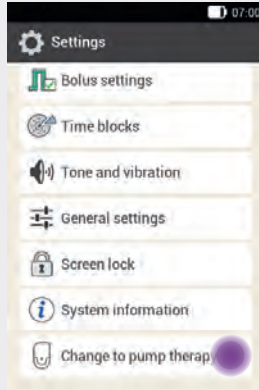
13.1.2 Deactivating Injection Therapy Mode

1



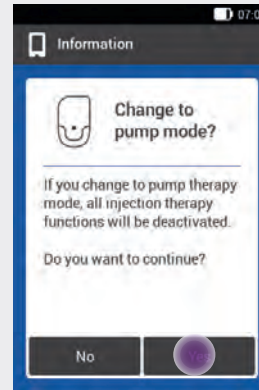
In the Main menu, tap the **Settings** menu.

2



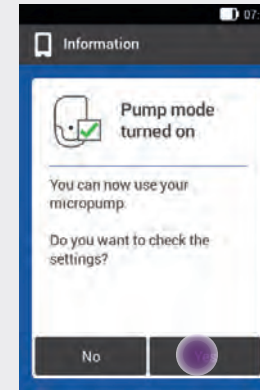
Tap the **Change to pump therapy** entry.

3



Tap **Yes**.

4



If you want to use the micropump with the settings last saved, tap **No**.

If you want to check the pump therapy settings, tap **Yes**.

Note

If you tap **No** on the **Pump mode turned on** information display, a connection to the micropump last used is established and the Status screen appears on the diabetes manager.


If you tap **Yes** on the **Pump mode turned on** information display, you are directed to the current pump therapy settings. You should check the settings for basal rate and bolus advice when using the injection mode for a longer period of time.

If there is no reservoir on the pump base, no data connection to the micropump can be established.

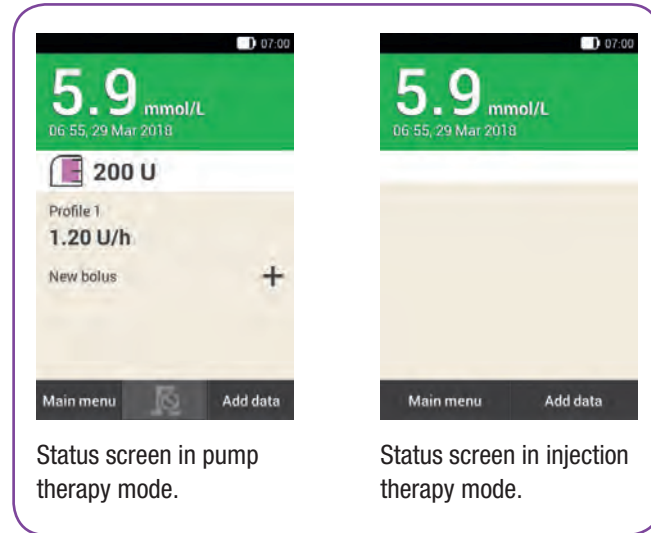
If you have filled a new reservoir and connected it to the pump base, the micropump is in Stop mode. In this case, you must activate the process for replacing the reservoir and infusion assembly and enter the correct reservoir fill amount in the diabetes manager.

13.2 Injection Therapy Displays

Once you turn on injection therapy mode, some of the displays and menus on the diabetes manager change. The displays necessary for pump therapy are no longer available on the Status screen. In the Main menu, some of the menus are omitted from the menu selection.

The  button to cancel an ongoing bolus is omitted in injection therapy mode.

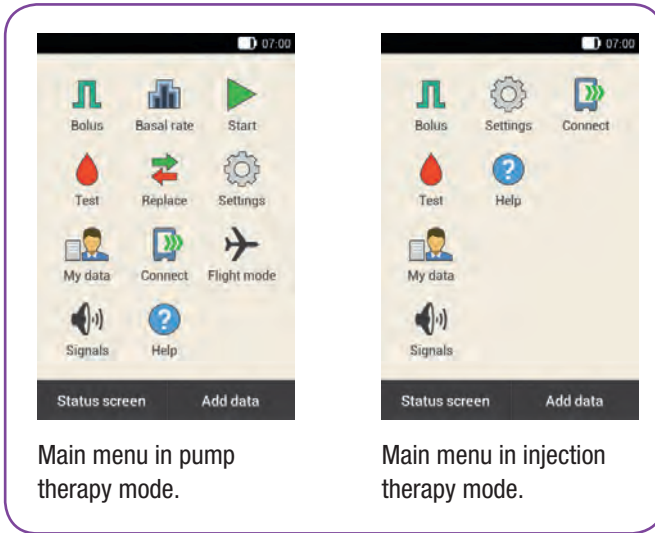
Display elements omitted on the Status screen



Status screen in pump therapy mode.

Status screen in injection therapy mode.

Symbols omitted in the Main menu



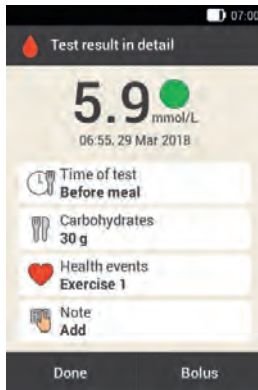
Main menu in pump therapy mode.

Main menu in injection therapy mode.

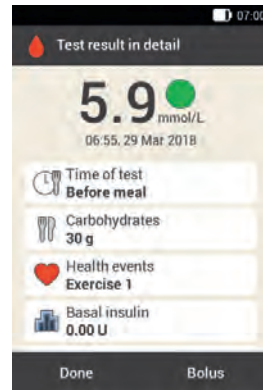
Display element	Status screen for injection therapy
	Reservoir symbol is omitted
Basal Rate Profile 1 0.50 U/h	Basal rate information omitted
Standard 6.50 U	Ongoing bolus information omitted

Menu icon	Main menu for injection therapy
	Start and Stop menu is omitted
	Basal rate menu is omitted
	Replace menu is omitted
	Flight mode menu is omitted

Test result in detail



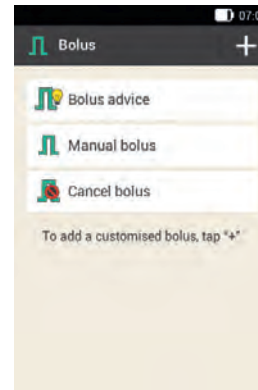
Test result in detail display in pump therapy mode.



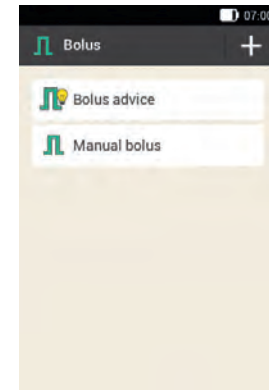
Test result in detail display in injection therapy mode.

You will also see the entry field for basal insulin.

Bolus



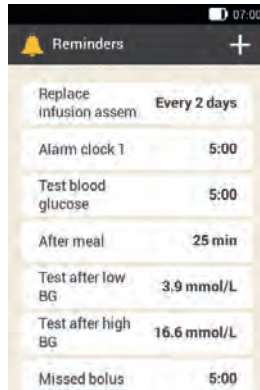
Bolus display in pump therapy mode.



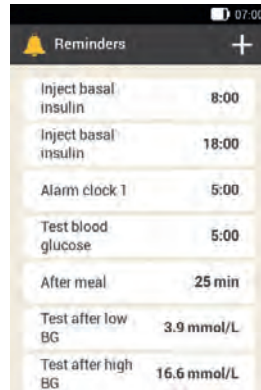
Bolus display in injection therapy mode.

The *Cancel bolus* element is omitted. You cannot create any customised boluses.

Reminders



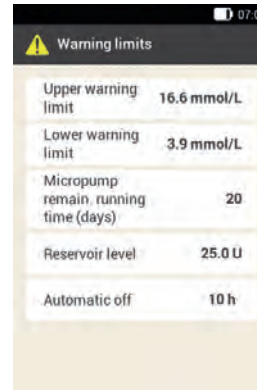
Reminders display in pump therapy mode.



Reminders display in injection therapy mode.

Instead of the **Replace infusion assembly** reminder, the **Inject basal insulin** reminder appears.

Warning limits



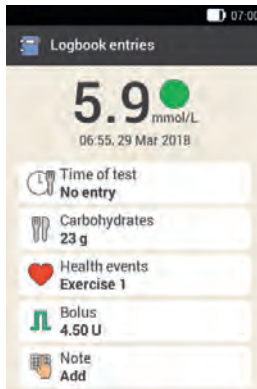
Warning limits display in pump therapy mode.



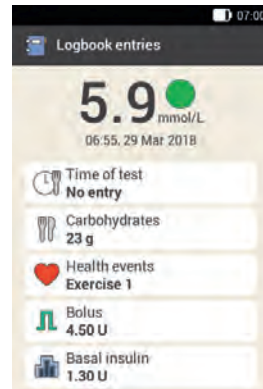
Warning limits display in injection therapy mode.

The **Micropump remain, running time (days)** and **Reservoir level** elements are omitted.

My data



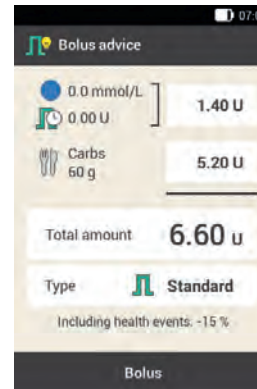
Logbook entries display in pump therapy mode.



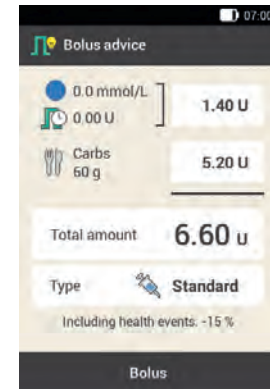
Logbook entries display in injection therapy mode.

You can enter or change the amount of basal insulin delivered in the Basal insulin entry.

Bolus advice



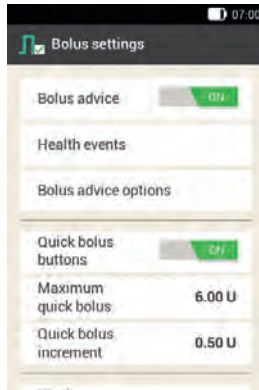
Bolus advice display in pump therapy mode.



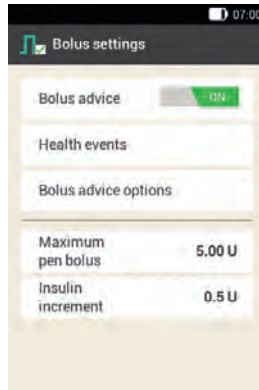
Bolus advice display in injection therapy mode.

The Type entry provides only the Pen option.

Bolus settings



Bolus settings display in pump therapy mode.

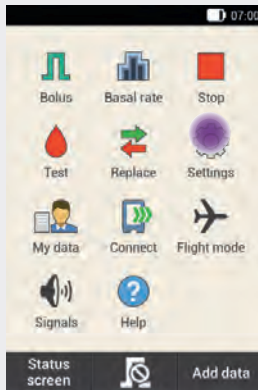


Bolus settings display in injection therapy mode.

Instead of the quick bolus elements, the elements for setting the insulin increment and the maximum bolus amount appear.

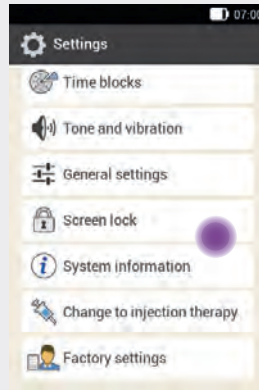
13.3 Injection Therapy Settings

1



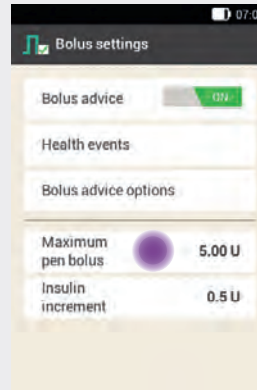
In the **Main menu**, tap the **Settings** menu.

2



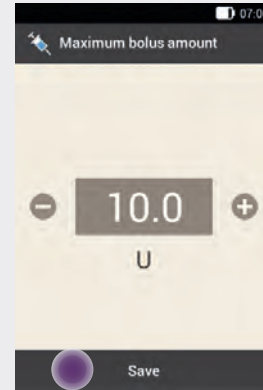
Tap the **Bolus settings** entry.

3



Tap **Maximum pen bolus**.

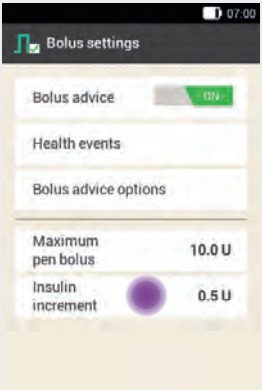
4



Use **-** and **+** to set the maximum bolus amount you want to deliver with the pen/syringe.


Tap **Save**.

5



Tap **Insulin increment**.

6



Tap the desired insulin increment for the pen.

Tap **Save**.

14 Care and Maintenance

This chapter provides information on how to care for and maintain the micropump system. In the *Control Tests* section, you will learn how to check whether the micropump system is working properly.

If a problem cannot be solved or if you have any questions about caring for and maintaining the micropump system, contact your Customer Support and Service Centre. Do not attempt to repair the diabetes manager or micropump yourself.

14.1 Cleaning the Micropump System

Clean the micropump and diabetes manager as described on the following pages. To clean the micropump system, use only a cloth dampened with distilled water or 70 % isopropanol.

Clean the finger pricker according to the instructions in the respective instructions for use.

WARNING

To clean the micropump system, use only distilled water or 70 % isopropanol. Other cleaning agents could damage the micropump system or impair its function.

Replace the consumables of the micropump system, if they are soiled.

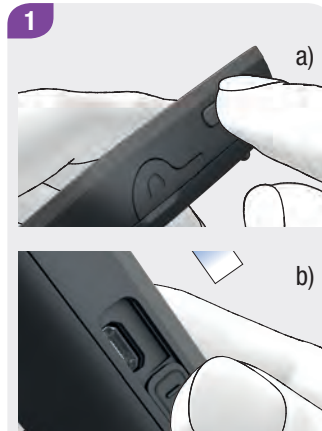
Note

- ▶ Avoid liquid or moisture entering the openings in the diabetes manager.
- ▶ Do not spray a cleaning solution directly onto the diabetes manager or micropump.
- ▶ Do not immerse the diabetes manager or micropump in liquids.

14.1.1 Cleaning the Diabetes Manager

It is advisable to always keep the diabetes manager clean and clean it at regular intervals.

When you clean the diabetes manager, adhere to the following guidelines to ensure optimum performance. Use only the specified cleaning agents. Do not use any abrasive substances as they may cause the screen to become scratched. If the screen of the diabetes manager is scratched, it may be difficult to read under certain circumstances. In this case, the diabetes manager must be replaced.



- a) Turn off the diabetes manager.
b) Close the cover of the USB socket.

Cleaning the casing



Remove any large contaminants with a clean cloth.

Wipe the surface of the diabetes manager and the area around the test strip slot carefully with a another clean, soft and slightly dampened cloth.

Cleaning the screen



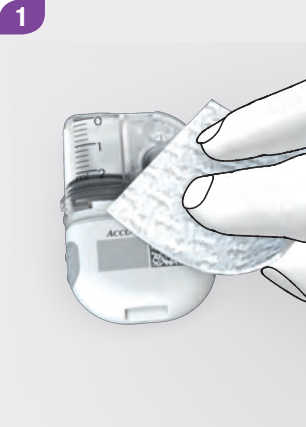
Wipe the screen of the diabetes manager carefully with a soft and slightly dampened cloth.

Remove any remaining lint. Dry the wiped areas thoroughly.

14.1.2 Cleaning the Micropump

Clean your micropump before reservoir replacement is due. Clean the micropump only with the reservoir attached. Replace the reservoir afterwards.

Use a soft and slightly dampened cloth to clean the micropump surface. Use only the specified cleaning agents. Use neither soap nor abrasive cleaning agents as they may cause the pump casing to become scratched, discoloured or otherwise damaged. Do not try to clean parts inside the device. Replace the micropump immediately if the casing shows chipped areas or cracks.



Remove any large contaminants with a clean cloth.

Wipe the surface of the micropump carefully.

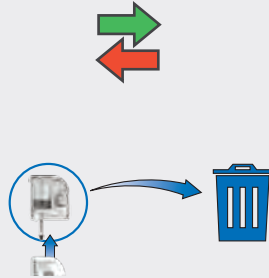


Wipe the pump shield and the ventilation opening of the pump base.

Check whether the ventilation opening is clean and clear.

Note

Cleaning the ventilation opening is important for the zinc-air battery in the reservoir to work properly.

3

Replace the used reservoir with a new one (see the chapter *Replacing System Components*).

14.2 Control Tests

You can check whether the diabetes manager is delivering correct test results by performing a control test. Perform a control test using control solution whenever

- ▶ you open a new test strip box.
- ▶ you have left the test strip container open.
- ▶ you think the test strips might be damaged.
- ▶ the test strips were exposed to extreme temperatures or humidity.
- ▶ you want to check the diabetes manager and test strips.
- ▶ the diabetes manager has fallen on the floor.
- ▶ your test result does not match how you feel.
- ▶ you want to check if you are performing the test correctly.

Instead of applying blood to the test strip, you apply glucose control solution for this control test. The diabetes manager is able to detect that glucose control solution was used and shows whether the control result falls within the correct range. The control results are not displayed in the logbook.

14.2.1 Information on the Control Solution

The available control solutions differ, depending on the country. The control solutions have different information printed on the labels.

- ▶ Close the control solution bottle tightly after use.
- ▶ Write the date you opened the control solution bottle on the bottle label. The control solution is good for 3 months from the date you opened the bottle as long as the use by date on the bottle label is not exceeded.
- ▶ Do not use control solution that is past the use by date.
- ▶ The control solution can stain your clothes. If you have spilled control solution on your clothes, wash them with water and soap.

Note

Use only the Accu-Chek Aviva control solutions: Control 1 with low glucose concentration or Control 2 with high glucose concentration.


14.2.2 Preparing a Control Test

A control test works the same way as a blood glucose test. Instead of blood, you apply control solution to the test strip.

To perform a control test, you need the following items:

- ▶ Diabetes manager
- ▶ Accu-Chek Aviva test strips
- ▶ Accu-Chek Aviva control solution Control 1 or Control 2
- ▶ A clean, dry paper towel

Note

- ▶ If a control test delivers results that are outside the specified concentration range, you cannot be sure that the diabetes manager and test strips are functioning properly. Blood glucose tests may then deliver incorrect test results. Incorrect test results may cause the wrong therapy recommendation to be made and thus result in serious adverse health effects.
- ▶ If a test strip error occurs, remove and dispose of the test strip, and repeat the test with a new test strip.
- ▶ When a test strip is in the diabetes manager, the touchscreen and the buttons, including the power button, are deactivated. The buttons are activated again when you remove the test strip or the test is complete.
- ▶ Another way to start a control test is from the Main menu. In the **Main menu**, tap the **Test**  menu.
- ▶ Do not apply control solution to the test strip before you have inserted the test strip into the test strip slot.

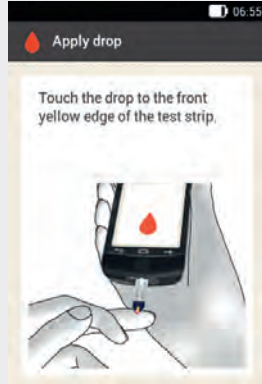
14.2.3 Performing a Control Test

1



Check the use by date that is indicated on the test strip container next to the  symbol. Use only test strips that are not past the use by date.

2



Insert the test strip into the test strip slot of the diabetes manager, in the direction of the arrow. The **Apply drop** display appears.

3



Select the control solution to test.

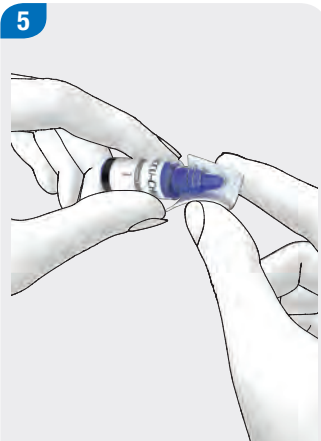
Use the *Control 1* control solution with low glucose concentration for the hypoglycaemic range. Use the *Control 2* control solution with high glucose concentration for the hyperglycaemic range.

4



Place the diabetes manager on a flat surface, such as a table.

Applying a drop



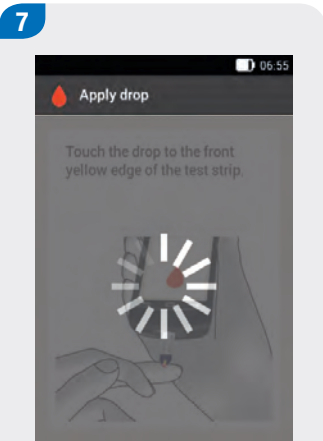
5

Remove the bottle cap. Wipe the tip of the bottle with a paper towel.



6

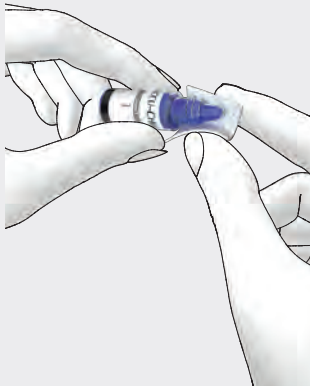
Squeeze the bottle until a tiny drop forms at the tip. Touch the drop to the **front edge** of the yellow window of the test strip. Do not put control solution on top of the test strip.



7

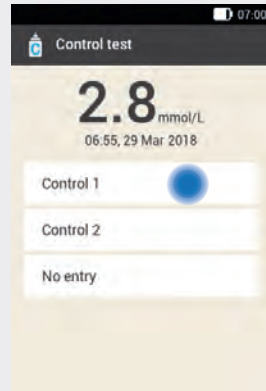
Testing starts when there is enough control solution in the test strip.

8



Wipe the tip of the bottle with a paper towel. Cap the bottle tightly.

9



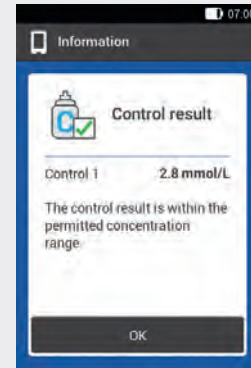
The control result is displayed.

Tap the control solution you used (for example, [Control 1](#)).

Note

If you choose [No entry](#), the control test display shown in the next step will not appear. The control result will not be analysed. Continue with Step 12.

10

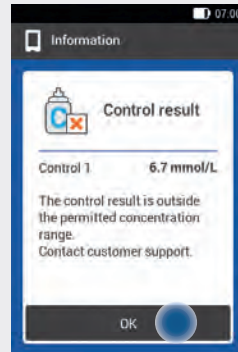


If the control result is within the permitted concentration range, the diabetes manager and test strips are working properly.

Tap [OK](#).

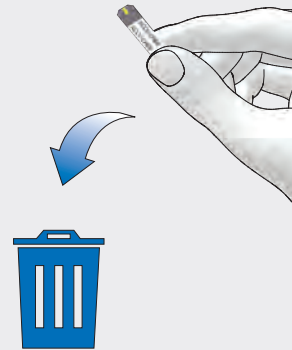
Note

Outside the permitted concentration range, LO or HI means that the control result is outside the permitted range. Note the information in the section *Causes of Control Tests with Errors* in this chapter.

11

The table in the following section lists the causes of a control result outside the permitted concentration range or of the LO and HI displays.

Tap **OK**.

12

Remove the test strip from the diabetes manager. Dispose of the used test strip according to local regulations.

14.2.4 Causes of Control Tests with Errors

If the control result is outside the concentration range, check the information in this section to help solve the problem: If you cannot answer the questions in the table with Yes, correct the respective item and repeat the test. For details on the correct temperature range and storage conditions, see the chapter *Technical Data*. If you have observed all these items and are still experiencing implausible control results or error messages, contact your Customer Support and Service Centre.

Question
Did you perform the control test as instructed in the User's Manual?
Did you use a new test strip?
Did you wipe the tip of the dropper on the bottle before applying the control solution to the test strip?
Did you apply a hanging drop of control solution?
Did you apply only one drop of control solution?

Question
Was the drop free from any air bubbles?
Did you apply control solution only after the signal sounded and the Apply drop display appeared?
The test strip must not be moved before or during the test. Did you comply with this?
Was the test strip straight (not bent)?
Did you perform the test within the correct temperature range?
Did you select the control solution on the Control test display that corresponds to the control solution you used?
Is the test strip slot clean?
Has the control solution been open for less than 3 months? Control solutions are only good for 3 months after they have been opened. After that time control solutions must not be used any more.
Did you observe the section <i>Control solution storage and handling</i> in the control solution package insert?

Question

Did you observe the storage conditions for the diabetes manager, test strips and control solutions?

Has either the use by date of the test strips or the control solution expired?

You can find the use by date on the label of the test strip container and on the label of the bottle next to the ⏳ symbol.

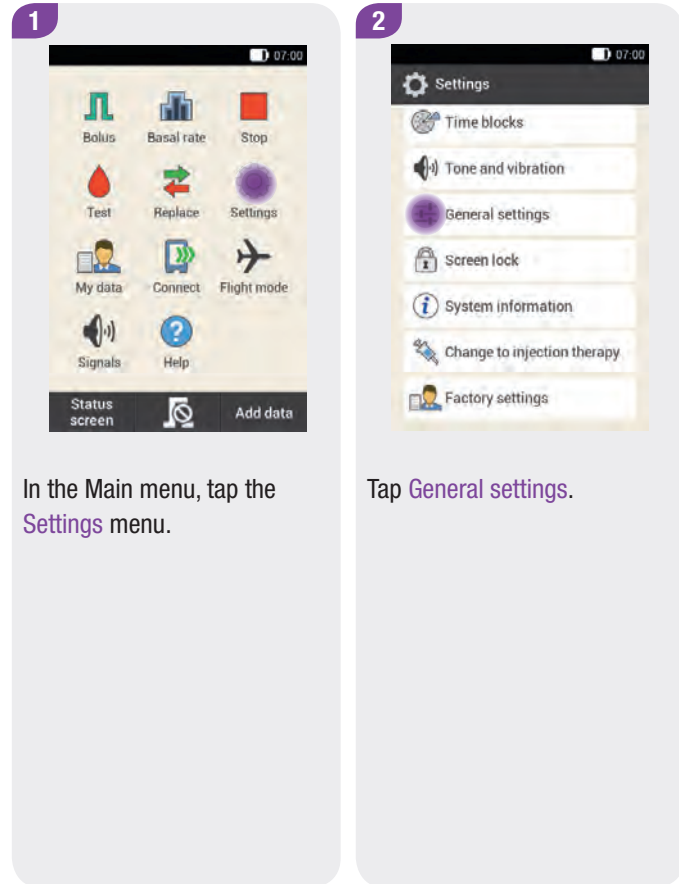
14.3 Checking the System Functions

If you cannot feel or hear the vibrations and signals of the diabetes manager or suspect that there might be other defects, you can perform a system function test. This test checks whether the screen, vibration and signal features are working properly.

If the diabetes manager does not work as described in the explanations of the system function test, contact your Customer Support and Service Centre.

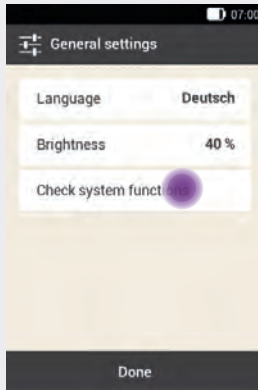
WARNING

The system must be working perfectly for all system messages (warnings and information, maintenance and error messages) to be issued correctly.



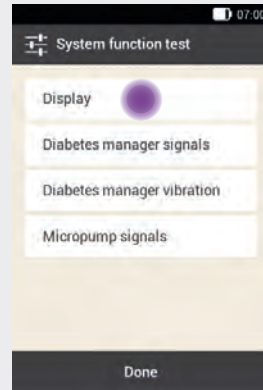
Checking the screen

3



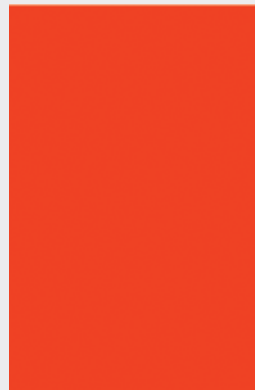
Tap **Check system functions**.

4



Tap **Screen**.

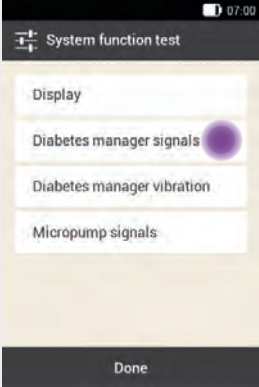
5



The screen shows a sequence of colours (red, blue, green and white) in quick succession.

Diabetes manager signals

6



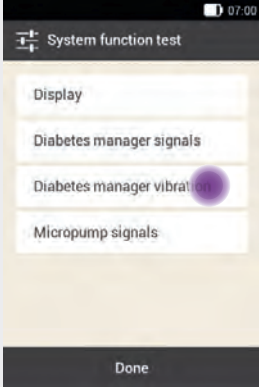
The screenshot shows a mobile application interface titled 'System function test'. It features a list of four items: 'Display', 'Diabetes manager signals', 'Diabetes manager vibration', and 'Micropump signals'. The 'Diabetes manager signals' item is highlighted with a purple circle. At the bottom of the screen is a black bar with the word 'Done' in white.

Tap **Diabetes manager signals**.

The diabetes manager emits signals.

Diabetes manager vibration

7



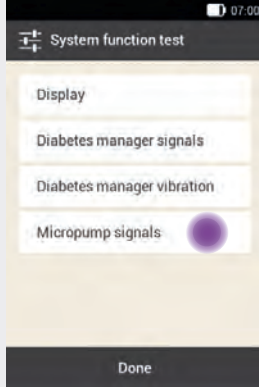
The screenshot shows the same 'System function test' screen. The 'Diabetes manager vibration' item is highlighted with a purple circle. At the bottom of the screen is a black bar with the word 'Done' in white.

Tap **Diabetes manager vibration**.

The diabetes manager vibrates.

Micropump signals

8



The screenshot shows the same 'System function test' screen. The 'Micropump signals' item is highlighted with a purple circle. At the bottom of the screen is a black bar with the word 'Done' in white.

Tap **Micropump signals**.

The micropump emits signals.

Note

If you are using injection therapy mode, the **Micropump signals** entry will be deactivated and greyed out.

15 Messages and Troubleshooting

There are different types of messages that the micropump system uses to inform you about the status of the micropump system, problems or errors.

These messages are:

- ▶ information messages
- ▶ warnings
- ▶ maintenance messages
- ▶ error messages

All messages are described on the following pages. It is very important that you pay attention to the messages and act according to the information and instructions given on the displays.

The diabetes manager can show messages on the screen and bring them to your attention by means of the signal LED as well as by tones and vibration. The LED of the diabetes manager lights up to signal warnings, maintenance messages and error messages. The micropump can signal messages by emitting tones.

When messages appear on the screen, you must confirm them. Some error and maintenance messages require your immediate attention. Perform the measures displayed on the respective screens or described in this chapter. If you are unable to take care of the error or maintenance message immediately, you can temporarily mute some of these messages. Tones and vibration are then stopped for a certain time period. In this case, the message remains visible on the screen and the LED lights up.

If you are unsure whether the micropump system is working properly, switch to alternative therapies according to the instructions of your healthcare professional. If the problem cannot be resolved using the suggested solutions, contact your Customer Support and Service Centre.

Messages are displayed with selection or confirmation buttons in the lower part of the screen. The buttons are briefly deactivated so that you cannot inadvertently confirm a message before you have read it.



WARNING

If you ignore or do not notice the messages of the micropump system, there is a risk of hypoglycaemia.

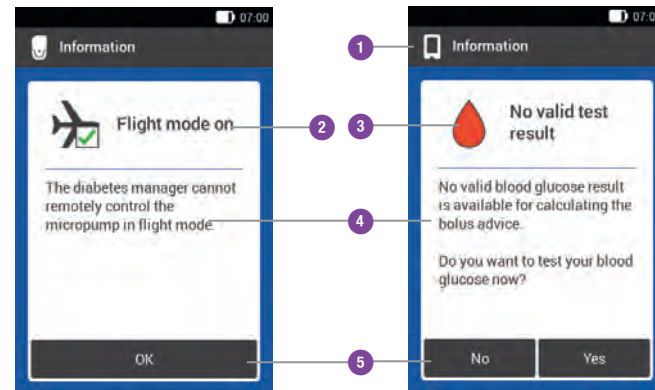
Note



Check regularly for messages of the micropump system on the screen.

15.1 Information Messages

There are messages that inform you about a particular status of the micropump system or an event. You must confirm these messages with **OK**. In addition, there are messages that include a question to be answered with **Yes** or **No**, for example, after you have entered a blood glucose result.

Examples of information messages:



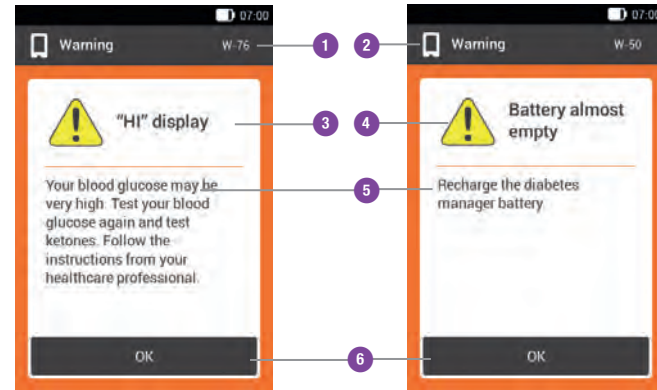
1	<ul style="list-style-type: none">  Information on the micropump  Information on the diabetes manager
2	Title of information message
3	Information message symbol
4	Information or explanation
5	Buttons (OK , No , Yes)

15.2 Warning Messages

Warnings inform you about the status of the micropump system or about therapy or health risks. Some warnings appear before maintenance messages occur to bring to your attention at an early stage that you will have to intervene in the near future. At the time the warning is issued, the micropump system is fully functional.

When a warning is displayed, a tone specific to warnings sounds and the diabetes manager vibrates. The tone for a warning also sounds when the [Turn off signals](#) feature is turned on.

Examples of warnings:



1	Warning code
2	Warning refers to the micropump Warning refers to the diabetes manager
3	Title of warning
4	“Warning” symbol
5	Explanation of warning or corrective measure
6	Button for confirming the warning (OK)

Code	Title of warning	Information/possible cause	Information/possible solution
Warnings triggered by the micropump			
W-25	Running time of the pump will end soon	The period of use of the pump base will end soon.	Ensure that you have a new pump base at hand as a replacement. Replace the pump base after the remaining time that is displayed.
W-31	Low level of insulin in the reservoir	There is only a small amount of insulin in the reservoir.	Be prepared to replace the reservoir soon.
W-32	Battery almost empty	The battery level is low.	Replace the reservoir.
W-35	Limited battery power	The openings on the micropump intended for reservoir battery ventilation are covered, which means that the zinc-air battery is only delivering limited energy to the micropump.	Ensure that there is an unrestricted air supply to the reservoir and pump base.
W-36	TBR cancelled	An active Temporary Basal Rate was cancelled.	Program a new Temporary Basal Rate.

Messages and Troubleshooting

Code	Title of warning	Information/possible cause	Information/possible solution
W-37	Low amount delivered	The micropump cannot deliver the insulin amount that is programmed for the basal rate or bolus in the specified time.	At present, the micropump can only deliver a programmed insulin amount at reduced speed. Check whether the delivered insulin amounts are sufficient for your insulin needs. Test your blood glucose more frequently.
W-38	Bolus cancelled	An active bolus was cancelled.	
W-40	Replace reservoir	The operating life of the reservoir will soon come to an end.	Replace your reservoir in the near future.
W-41	Micropump stopped	The micropump has been in Stop mode for at least an hour and is not delivering any insulin.	Start the micropump if you want to continue with insulin delivery.
Warnings triggered by the diabetes manager			
W-50	Battery almost empty	The rechargeable battery level is low.	Recharge the battery of your diabetes manager.

Code	Title of warning	Information/possible cause	Information/possible solution
W-71	Connection interrupted	No current data from the micropump is available. The data for calculating bolus advice may not be up to date.	Ensure that the micropump and diabetes manager are no more than 2 metres apart and that there are no obstacles between them.
W-73	No connection to the micropump	No current data from the micropump is available. The displayed data may not be complete.	The data is updated when the connection between the diabetes manager and the micropump is re-established.
W-75	Warning limit exceeded	High blood glucose value	Test ketones and your blood glucose. Check insulin delivery. Follow the instructions of your healthcare professional.
W-76	“HI” display	Your blood glucose is very high.	Test your blood glucose again and test ketones. Follow the instructions of your healthcare professional.
W-80	Hypoglycaemia	Blood glucose has fallen below the hypo warning limit.	Eat or drink fast acting carbohydrates. Then test your blood glucose.

Messages and Troubleshooting

Code	Title of warning	Information/possible cause	Information/possible solution
W-81	“LO” display	Your blood glucose result may be very low.	Eat or drink fast acting carbohydrates. Test your blood glucose again immediately and then again within the next half hour. If hypoglycaemia persists, test your blood glucose and consult your healthcare professional.
W-82	<i>Bluetooth</i> connection deactivated	The <i>Bluetooth</i> connection to the micropump was deactivated because the rechargeable battery of the diabetes manager is almost empty.	Recharge the battery of your diabetes manager.
W-84	Testing not possible	You cannot test your blood glucose while the diabetes manager is connected to a USB cable.	Remove the USB cable from the diabetes manager.
W-85	Missing data	Internal clock error or error in existing bolus data. The saved data can no longer be used to calculate bolus advice.	

Code	Title of warning	Information/possible cause	Information/possible solution
W-86	Flight mode on	Data cannot be synchronised between the diabetes manager and micropump because flight mode is turned on. Therefore, the entries saved for bolus advice may not be up to date. Bolus advice can currently only make recommendations based on the entries saved on the device.	You can still use the bolus advice feature. Note, however, that the diabetes manager is not receiving any information (for example, errors) from the micropump. When flight mode is turned off and the diabetes manager and micropump are within communication range, the data will be synchronised. The data for bolus advice will then be up to date again.
W-88	Flight mode on	The saved logbook entries may not be up to date.	When flight mode is turned off and the diabetes manager and micropump are within communication range, the logbook entries will be synchronised.

Messages and Troubleshooting

Code	Title of warning	Information/possible cause	Information/possible solution
W-89	Check logbook entries	A quick bolus selected in bolus advice was not confirmed by the pump and set to zero. The reason for this is that the last quick bolus was not delivered within the 15-minute timeframe after bolus advice.	The allocation to correction bolus and meal bolus as well as the entered health events may not be correct. This may affect the next bolus advice calculations. Correct the logbook entries as required.
W-90	Time synchronised with micropump	A time difference between the diabetes manager and the micropump was corrected.	Check the time on the diabetes manager.
W-92	TBR without insulin delivery	Due to the set TBR, the amount to be delivered in the current time block is so low that it falls below the smallest output (delivery amount) the pump can technically deliver.	Check whether it is acceptable for you for no insulin to be delivered in this time period. The insulin amount that was not delivered will be delivered later on during the next time blocks.

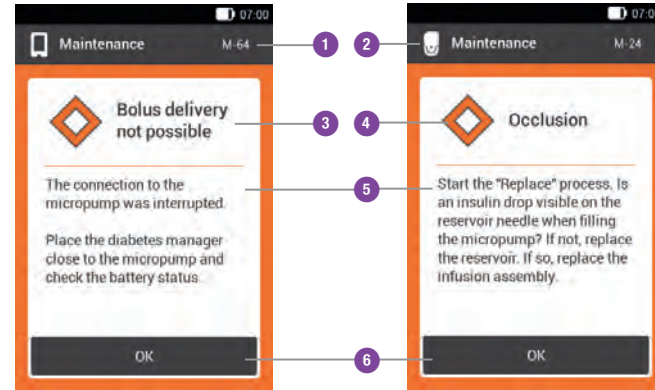
Code	Title of warning	Information/possible cause	Information/possible solution
W-93	Fill reservoir needle	The micropump must NOT have been inserted in the micropump holder.	The micropump must NOT have been inserted in the micropump holder while it is being filled. Remove the micropump from the micropump holder before filling it.
W-99	No connection to the micropump	The rechargeable battery of the diabetes manager is empty, therefore no data can be exchanged with the micropump. The data for calculating bolus advice may not be up to date.	The diabetes manager can currently only give bolus advice based on the entries saved in the diabetes manager.



15.3 Maintenance Messages

Maintenance messages inform you about a temporary loss of certain features of the micropump system. Maintenance messages require you to intervene in order to solve the problem. The micropump switches to Stop mode and does not deliver any insulin. Once the cause of the maintenance message has been eliminated, you can use all features of the micropump system again.

When a maintenance message is displayed, a tone specific to maintenance messages sounds and the diabetes manager vibrates. The tone for maintenance messages also sounds when the **Turn off signals** feature is turned on.

Examples of maintenance messages:



1	Code of maintenance message
2	 Maintenance activity refers to the micropump  Maintenance activity refers to the diabetes manager
3	Title of maintenance message
4	“Maintenance” symbol
5	Explanation of maintenance message or corrective measure
6	Button to confirm (OK) or postpone the maintenance message (Snooze)

Code	Title of maintenance message	Possible cause/consequences	Further information
Maintenance messages triggered by the micropump			
M-18	Replace micropump	The operating life of your micropump has come to an end.	Replace your micropump base and the reservoir now.
M-19	Discrepancy in reservoir level	The entered insulin amount does not correspond to the measured reservoir level.	Replace the reservoir, if required, with a new reservoir.
M-21	Reservoir empty	The insulin in the reservoir has been used up.	Select the Replace menu and replace the reservoir with a new one.
M-22	Micropump battery empty	The micropump battery, which is located in the reservoir, is empty	Select the Replace menu and replace the reservoir with a new one.
M-23	Automatic off	The automatic off feature has stopped insulin delivery. The micropump is in Stop mode.	Start the micropump to resume insulin delivery.
M-24	Occlusion	An occlusion was detected which means that insulin delivery is not working at all or is restricted.	Remove the micropump from the infusion assembly and start filling the reservoir using the <i>Replace</i> menu. If no drop is visible at the reservoir needle, replace the reservoir. If a drop is visible, replace the infusion assembly.

Messages and Troubleshooting

Code	Title of maintenance message	Possible cause/consequences	Further information
M-26	Fill reservoir needle	The reservoir needle must be refilled after replacing the reservoir.	Remove the micropump from the infusion assembly. Tap the Replace menu, select Reservoir and follow the instructions for filling the reservoir.
M-27	No data connection	The micropump system setup was interrupted.	Hold the diabetes manager close to the micropump to ensure that data is exchanged between the pump and the diabetes manager. Resume setting up the micropump system when the connection has been re-established. Replace the pump if the problem persists.
Maintenance messages triggered by the diabetes manager			
M-51	Test strip error	The test strip is used, damaged or not completely inserted into the test strip slot.	Use a new test strip or re-insert the test strip into the test strip slot.
M-53	Test failed	The blood glucose test did not work properly.	Repeat the blood glucose test with a new test strip.
M-54	Drop too small	The amount of blood or control solution is not sufficient to perform a test.	Repeat the test with a new test strip. Make sure the blood drop or drop of control solution is large enough.

Code	Title of maintenance message	Possible cause/consequences	Further information
M-56	Drop applied too early	The drop was drawn into the test strip before Apply drop appeared on the screen.	Repeat the test with a new test strip and a fresh blood drop or drop of control solution.
M-58	Temperature too high or too low	The ambient temperature for testing blood glucose or performing a control test is outside the permitted range.	Make sure the ambient temperature is within the permitted range. Wait 5 minutes before testing your blood glucose again or performing a control test.
M-59	Battery almost empty	The rechargeable battery level is very low.	Recharge the battery of your diabetes manager.
M-60	Clock error	A discrepancy in the micropump's internal clocks was detected.	Set the current time and the current date on the diabetes manager.
M-62	Connection failed	The pairing code was not scanned successfully. This may be the case, for example, if it is too dark or the code or camera lens is dirty and the code cannot be read correctly.	Try rescanning the pairing code on the micropump.

Messages and Troubleshooting

Code	Title of maintenance message	Possible cause/consequences	Further information
M-64	Bolus delivery not possible	The connection between the diabetes manager and micropump was lost.	Hold the diabetes manager close to the micropump and ensure that data communication is not disrupted. You can deliver a quick bolus straight from the micropump.
M-65	Bolus delivery not possible	The micropump is currently in Stop mode.	If you want to deliver a bolus, start the micropump first.
M-67	Bolus delivery failed	There is no connection to the micropump.	Hold the diabetes manager close to the micropump. You can deliver a quick bolus straight from the micropump.
M-77	Operation failed	The requested operation failed. Try again.	
M-78	Outside of temperature range	The temperature of the diabetes manager is too high or too low.	Wait for 5 minutes until the diabetes manager has adjusted to this temperature.
M-84	Temperature is at limit of range	The ambient temperature is at the edge of the range permitted for blood glucose tests.	Ensure the ambient temperature is within the permitted range before you test your blood glucose.
M-85	Micropump incompatible	You tried to pair the diabetes manager with a micropump base that is incompatible.	Contact your Customer Support and Service Centre.

Code	Title of maintenance message	Possible cause/consequences	Further information
M-86	Micropump not started	The micropump cannot be started because ongoing processes have not finished yet.	Check whether you need to react to prior error messages or maintenance messages. Example: The prior message was <i>Reservoir empty (M-21)</i> . Only after replacing the reservoir, will you be able to start the micropump.
M-87	Micropump not stopped	The micropump cannot be stopped.	Try to stop the micropump again. Remove the micropump from the pump base if you want to interrupt insulin delivery.
M-88	Flight mode turned off	The micropump and the diabetes manager are not within communication range. Flight mode could not be turned on on the micropump.	Hold the diabetes manager close to the micropump.
M-94	Connection failed	There is a communication problem between the micropump and the diabetes manager.	Hold the diabetes manager close to the micropump and ensure that data communication is not disrupted. Check the micropump.
M-95	No micropump located	A connection to the micropump could not be established.	Check whether the micropump is too far away.

Messages and Troubleshooting

Code	Title of maintenance message	Possible cause/consequences	Further information
M-96	USB connection failed	The USB connection between the diabetes manager and the software on the computer failed.	Check whether the software is correctly installed on the computer.

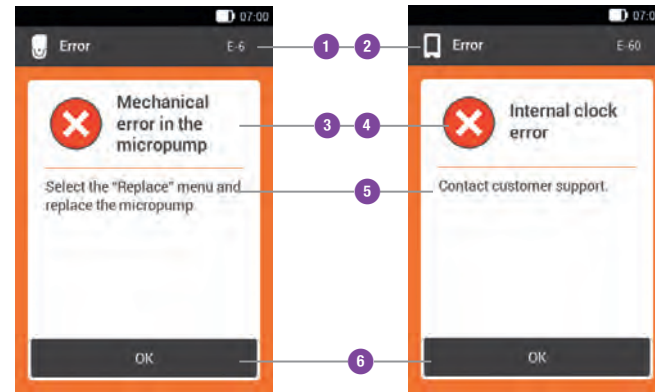
15.4 Error Messages



When an error message is displayed, a tone specific to these messages sounds and the diabetes manager vibrates. The tone for error messages also sounds when the **Turn off signals** feature is turned on. The vibration feature cannot be turned off.

Error messages are displayed when significant malfunctions of the micropump system are registered. The micropump switches to Stop mode. The micropump system can only be used again when the problem has been solved.

For most problems, the diabetes manager displays a message with a short description of the problem and a proposed solution. This section goes into more detail describing the problem with the possible cause and suggesting possible solutions. If the problem cannot be resolved using the suggested solutions, contact your Customer Support and Service Centre.

Examples of error messages:



1	Code of error message
2	 Error refers to the micropump  Error refers to the diabetes manager
3	Title of error message
4	“Error” symbol
5	Explanation of error message
6	Button to confirm (OK) or postpone the error message (Snooze)

Code	Title of error	Possible cause/consequences	Possible solutions
Error messages triggered by the micropump			
E-6	Mechanical error in the micropump	The micropump switches to Stop mode and does not deliver any insulin.	Select the <i>Replace</i> menu and replace the micropump and the reservoir.
E-7	Electronic error	Communication between the micropump and diabetes manager is not possible. The micropump does not deliver any insulin.	Select the <i>Replace</i> menu and replace the micropump and the reservoir.
E-8	Micropump battery error	The energy supply is defective. The micropump switches to Stop mode and does not deliver any insulin. After 10 seconds the pump turns off.	Select the <i>Replace</i> menu and replace the reservoir with a new one.
Error messages triggered by the diabetes manager			
E-57	Electronic error	The electronic components of the diabetes manager are not behaving as expected.	Remove the rechargeable battery from the diabetes manager and reinsert it. If the error message is displayed again, contact your Customer Support and Service Centre.
E-60	Internal clock error	Internal clock error in the diabetes manager	Contact your Customer Support and Service Centre.

15.5 Troubleshooting

For most problems, the diabetes manager displays a message with a short description of the problem and a proposed solution. This chapter goes into more detail describing the problem with the possible cause and suggesting possible solutions. If the problem cannot be resolved using the suggested solutions, contact your Customer Support and Service Centre.

Messages and Troubleshooting

Problem	Possible cause	Possible solutions
The screen is blank or the diabetes manager cannot be turned on.	The rechargeable battery is low.	Charge the battery. For more information, see the chapter <i>Setting Up the Micropump System</i> .
	The rechargeable battery may be damaged.	Replace the rechargeable battery if the diabetes manager cannot be charged.
	An electronic error has occurred in the diabetes manager.	Reset the diabetes manager by pressing and holding the power button for at least 5 seconds.
	The ambient temperature is higher or lower than the operating temperature recommended for the diabetes manager.	Move the diabetes manager to an area with the suitable temperature. Wait 5 minutes before turning on the diabetes manager. Do not heat or cool the diabetes manager using any aids.
	The screen is damaged or the diabetes manager is defective.	Contact your Customer Support and Service Centre.
The battery is not being charged while the diabetes manager is connected to a PC via a USB cable.	The USB port on the PC is not supplying any charging current.	Recharge the battery with a charger using a wall socket.

Problem	Possible cause	Possible solutions
The battery must be charged more often than at the beginning.	The number of charge cycles for the rechargeable battery is limited. If this number is exceeded, the charge capacity is reduced and the battery must be recharged more frequently.	Replace the battery.
The screen freezes or does not respond.	An electronic error has occurred in the diabetes manager.	<ul style="list-style-type: none"> ▶ Reset the diabetes manager by pressing and holding the power button for at least 5 seconds until the screen turns off. ▶ Remove the rechargeable battery from the diabetes manager and reinsert it.
The screen is defective or the colours are not represented correctly.		Perform a diabetes manager function test. For more information, see the section <i>Checking the System Functions</i> in the chapter <i>Care and Maintenance</i> of this User's Manual. If the system function test of the screen shows a problem, contact your Customer Support and Service Centre.

Problem	Possible cause	Possible solutions
<p>The sound is faulty. You cannot hear the signals.</p>	<p>The sound feature is turned off or the volume is set too low.</p>	<ul style="list-style-type: none"> ▶ Check to see if the signal modes (Normal, Vibration, Quiet, Loud) have sound activated and if the volume is set at a level that is audible. For more information, see the section <i>Tone and Vibration</i> in the chapter <i>Changing Settings</i> of this User's Manual. ▶ Check to see if the <i>Turn off signals</i> option is on and active. The <i>Turn off signals</i> option may need to be turned off or its settings adjusted. For more information, see the section <i>Turning Off Signals</i> in the chapter <i>Changing Settings</i> of this User's Manual. ▶ Perform the system function test for the diabetes manager. For more information, see the section <i>Checking the System Functions</i> in the chapter <i>Care and Maintenance</i> of this User's Manual. If the system function test shows a problem with the signals of the diabetes manager or micropump, contact your Customer Support and Service Centre.
<p>Start time: The start time for the first time block cannot be changed.</p>	<p>Initial setup is already complete and, therefore, the start time for the first time block cannot be changed any more.</p>	<p>To change the start time for the first time block, select the <i>Reset</i> option on the <i>Time Blocks</i> display. After resetting the time blocks, you must re-enter all time block information.</p>

Problem	Possible cause	Possible solutions
You cannot feel any vibrations when a signal is emitted.	The vibration feature is turned off.	Check the settings on the <i>Tone and vibration</i> display. The diabetes manager only vibrates if the active signal mode (Normal, Vibration, Quiet, Loud) includes vibration. Check the touchscreen settings (Tone; Vibration; Tone and vibration; No tone, no vibration).
The occlusion alarm of the micropump was triggered.	The micropump was exposed to a temperature that was too low.	Make sure the ambient temperature is suitable. Perform the recommended maintenance measure (see maintenance message M-24) and continue the therapy.

16 Technical Data

16.1 Micropump System

Technical data of the micropump system

Permitted insulin types	Rapid-acting U100 insulin types: Humalog®, NovoLog/NovoRapid®, Apidra®, Insuman® Infusat
Electromagnetic compatibility	The micropump system meets the EMC requirements for home healthcare environments. Classified in accordance with CISPR 11, group 1, class B (residential).
Safety	The safety concept is based on a control system that consists of two microprocessors and a supervisor microprocessor (supervising system). The control system has a dual channel software architecture that performs all safety-relevant functions twice. Whenever a defect or fault occurs in the control system, it is identified by the supervisor microprocessor and vice versa. The control and supervising systems signalise errors by means of acoustic signals and messages on the diabetes manager screen.

16.2 Diabetes Manager

Technical data of the diabetes manager	
Device type	Accu-Chek Aviva Solo diabetes manager, model # The Accu-Chek Aviva Solo diabetes manager is suitable for continuous operation.
Access control	PIN-based protection
Dimensions	124 x 64 x 17 mm (L x W x H)
Weight	140 g
Signal reproduction	Graphical user interface, status LED, loudspeaker, vibration alarm
Screen	Capacitive colour LCD multi-touch screen with backlight
Screen size	3.5 "
Screen resolution	320 x 480 pixels
Video format	MPEG-4 at a frame rate of 30 frames/second
Audio format	mp3
Screen brightness	#
Screen orientation	Portrait (standard) or landscape
Screen timeout	30 sec. (screen goes dark after 15 sec., plus 15 sec. until screen times out)
Camera	2 megapixels for scanning the pairing code (2D data matrix code) at a minimum of 300 lx up to a maximum of 20,000 lx.

Technical data of the diabetes manager

Data transfer between the micropump and the diabetes manager	Bluetooth Low Energy (BLE) wireless technology
Transmission frequency	2402–2480 MHz
Transmission power	Maximum 1 mW / 0 dBm Channels: 37*FHSS + 3*DSSS advertising channels Modulation: GFSK Bandwidth: 1 MHz “single hop frequency”
Communication range	> 1.5 m (line of sight)
Admissible temperature range	During operation: +5 °C to +40 °C Storage between periods of use, without packaging: -25 °C to +70 °C Storage and transport, with packaging: -20 °C to +50 °C
Admissible humidity range	During operation: 15 % to 93 % Storage between periods of use, without packaging: 5 % to 93 % Storage and transport, with packaging: 5 % to 85 %
Atmospheric pressure	During operation: 70 to 106 kPa During charging: 80 to 106 kPa Storage between periods of use, without packaging: 54.9 to 106 kPa Storage and transport, with packaging: 54.9 to 106 kPa
Operating height	Up to 3,000 m above sea level
Alarm types	Visual, acoustic, vibration
Sound pressure of the alarm signal	> 45 dB (A) at a distance of 1 m

Technical Data

Technical data of the diabetes manager	
Frequency	1–3 kHz
Interface to PC	USB 2.0 (micro-B)
Memory capacity	5,000 blood glucose tests, 5,000 logbook entries, 5,000 pump events
Power supply	Rechargeable lithium-ion battery
Battery voltage	3.7 V
Battery capacity	1,530 mAh
Charging voltage via USB	5 V
Socket adapter	PHIHONG switching power supply, model PSC03R-050
IP rating	IP20
Protection class	II in battery mode with internal power supply
Bolus calculator	Accu-Chek Bolus Advisor
Blood glucose meter	Accu-Chek Aviva
Test strip slot	Illuminated test strip slot for Accu-Chek Aviva test strips
Measuring range	0.6–33.3 mmol/L (10–600 mg/dL)
Test principle	Refer to the test strip package insert
Test time	Refer to the test strip package insert
Blood sample	Refer to the test strip package insert
Sample type	Refer to the test strip package insert

16.3 Micropump

Technical data of the micropump	
Dimensions	Approx. 68 × 40 × 15 mm
Weight	Micropump without reservoir: approx. 18 g Micropump with filled reservoir and infusion assembly: approx. 32 g
Pump casing	Impact and scratch-resistant plastic (polycarbonate)
Quick bolus buttons	Silicone buttons for delivering quick boluses and turning flight mode on/off
Admissible temperature range*	During operation: +5 °C to +40 °C Storage between periods of use, without packaging: -25 °C to +70 °C Storage and transport, with packaging: -20 °C to +50 °C
Admissible humidity range	During operation: 15 % to 93 % Storage between periods of use, without packaging: 15 % to 93 % Storage and transport, with packaging: 20 % to 85 %
Atmospheric pressure	During operation: 70 to 106 kPa (700 to 1060 mbar) Storage without packaging: 54.9 to 106 kPa (549 to 1060 mbar) Storage and transport, with packaging: 54.9 to 106 kPa (549 to 1060 mbar)
Motor type	Stepper motor
Power supply	1.2 V zinc-air battery for internal power supply
Life expectancy of the battery	If used in a typical usage pattern (50 U/day using U100 insulin; room temperature: 23 °C ±2 °C), the battery life is approximately 96 hours.

* For information on the admissible temperature range for usage, storage and transport of the insulin used, see the instructions for use of the insulin manufacturer.

Technical Data

Technical data of the micropump	
Basal rate	Minimum: 0.1 U/h Maximum: 25.0 U/h
Basal rate, increments	0.1 U up to under 5.0 U: increments of 0.01 units 5.0 U up to under 25.0 U: increments of 0.1 units
Basal rate delivery accuracy	±15 % or better at 0.1 U to 1.0 U ±5 % or better at 1.0 U to the maximum
Basal rate profiles	Up to 5 customised profiles
Temporary Basal Rate (TBR)	0–90 % for basal rate reductions and 110–250 % for basal rate increases in increments of 10 % The duration is adjustable in 15-minute increments for a time period of up to 24 hours.
Bolus types	Standard bolus, quick bolus, extended bolus, multiwave bolus
Bolus amount	Minimum: 0.2 U Maximum: 50 U
Bolus delivery accuracy	±30 % or better at 0.2 U up to under 1.0 U ±17 % or better at 1.0 U up to under 6.0 U ±8.5 % or better at 50.0 U

Technical data of the micropump	
Bolus amount, increments	0.2 U up to under 2.0 U: increments of 0.05 units 2.0 U up to under 5.0 U: increments of 0.1 units 5.0 U up to under 10.0 U: increments of 0.2 units 10.0 U up to under 20.0 U: increments of 0.5 units 20.0 U up to 50.0 U: increments of 1.0 units The duration of an extended bolus or a multiwave bolus is adjustable in 15-minute increments for a time period of up to 24 hours.
Delivery lag time	Adjustable in 15-minute increments from 0 to 60 minutes
Quick bolus – increments	0.2 U / 0.5 U / 1.0 U and 2.0 U
Bolus delivery speed	1.0–2.5 U/min.
Sound pressure of the alarm signal	> 45 dB at a distance of 1 m
Occlusion alarm	Rotation detector
Maximum duration until message “Maintenance M24: OCCLUSION”*** is displayed	50 hours
Maximum insulin amount until message “Maintenance M24: OCCLUSION” is displayed	5.0 U
Maximum limit value for the system warning in the event of an occlusion	330 kPa (3.3 bar)

Technical Data

Technical data of the micropump	
Maximum pressure	150 kPa (1.5 bar)
Reservoir	Fillable insulin container
Reservoir fill amount	Maximum: 200 U Minimum: 80 U (± 12 U)
Maximum overdelivery in the event of an error	0.4 U
Remote control and data transfer	<i>Bluetooth</i> Low Energy, ISM 2.4 GHz communication channel
Communication range	> 1.5 m (line of sight)
IP rating	IP22

16.4 Infusion Assembly

Technical data of the infusion assembly	
Micropump holder	Dimensions: Approx. 68 × 40 × 1.65 mm
Cannula	Orange, 6 mm 90° Teflon® soft cannula Blue, 9 mm 90° Teflon® soft cannula
Cannula fill amount	0.2 U
Maximum period of use	72 hours
Sterility	Sterilized using ethylene oxide for single use according to ISO 11135-1
Protective caps	Silicone caps for the reservoir and the infusion assembly

16.5 Technical Data of the Insertion Device

Technical data of the insertion device	







Declaration of conformity







Roche hereby declares that the radio equipment type Accu-Chek Solo micropump system conforms with the Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following Internet address: <http://declarations.accu-chek.com>

17 Symbols, Abbreviations, Signals




17.1 Symbols









The following symbols appear on the packaging and on the components of the micropump system:






Symbol	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

Symbol	Meaning
	Sterilized using ethylene oxide
	Manufacturer
	Date of manufacture
	Catalogue number
	Batch code
	Serial number

Symbols, Abbreviations, Signals

Symbol	Meaning
	Global Trade Item Number
	This product fulfils the requirements of the European Directive 93/42/EEC on medical devices.
	This product also fulfils the requirements of the following directives: <ul style="list-style-type: none"> ▶ European Directive 2014/53/EU on the provision of radio equipment (RED). ▶ European Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).
FCC ID	The FCC ID (Federal Communications Commission Identification) indicates that the radio frequency equipment has passed the equipment authorization process for the United States of America.
IC ID	The IC ID (Industry Canada Identification) indicates that the radio frequency equipment has passed the equipment authorization process for Canada.

Symbol	Meaning
	The compliance mark indicates that the product complies with the applicable standard and establishes a traceable link between the equipment and the manufacturer, importer or their agent responsible for compliance and for placing it on the Australian and New Zealand market.
	Keep away from sunlight
	Keep dry
	Do not use if package is damaged
	Admissible humidity range
	Admissible air pressure range
	Do not throw away
	<i>Bluetooth</i> [®] wireless technology

Symbol	Meaning
	Electronic device of type BF according to the standard IEC 60601-1.
	Non-ionizing radiation
Rx only	Federal law (USA) restricts this device to sale by or on the order of a physician
IP20	Protected against solid foreign objects with a diameter of at least 12.5 mm Protected against access with a finger
IP22	Protected against solid foreign objects with a diameter of at least 12.5 mm Protected against access with a finger Protected against dripping water when the casing is tilted by up to 15°
	Warning against device use in electromagnetic or high electrical fields or environments
	Device of protection class II
	Suitable for indoor use only

17.2 Abbreviations

Abbreviation	Meaning
am	Ante meridiem: Before midday (12-hour clock notation for times before 12 noon)
BE	Broteinheit (bread equivalent)
BG	Blood Glucose
°C	Degrees Celsius (or Centigrade)
CC	Carbohydrate Choice
DM	Diabetes manager
°F	Degrees Fahrenheit
FCC	Federal Communications Commission (United States)
g	Gram
h	Hour(s)
IC	Industry Canada (Canadian telecommunications authority)
IEC	International Electrotechnical Commission

Abbreviation	Meaning
ISO	International Organization for Standardization
KE	Kohlenhydrateinheit (carbohydrate unit)
LCD	Liquid Crystal Display
mg/dL	Milligrams per decilitre
mmol/L	Millimoles per litre
kPa	Kilopascal
PC	Personal Computer
PIN	Personal Identification Number (secret code)
pm	Post meridiem: After midday (12-hour clock notation for times after 12 noon)
SD	Standard Deviation
sec.	Seconds
TBR	Temporary Basal Rate

Abbreviation	Meaning
U	Unit (<i>International Unit</i> , also <i>IU</i>) Unit of measurement for the amount of a biologically active substance, for example insulin, referring to the biological activity.
U/h	Insulin amount delivered in units per hour
U100	Insulin concentration. Each millilitre of liquid contains 100 units of insulin.
USB	Universal Serial Bus

17.3 Signals

Many features of the micropump system are accompanied by acoustic signals. Tones and melodies are generated for this purpose.

Tone	Function/Meaning

18 Appendix

18.1 Guarantee

The statutory provisions on rights in consumer goods sales in the country of purchase shall apply.

Any changes or modifications to the micropump system not expressly approved by Roche could render your operating guarantee for the Accu-Chek Solo micropump system invalid.

18.2 Licence Information

Licence agreement for open source software:
This product contains open source software components. For more information on open source software, see the *System information* item in the *Settings* menu of the diabetes manager.

18.3 Customer Support and Service Centre

If you encounter problems, have questions regarding operation or need additional information about the Accu-Chek Solo micropump system, contact your Customer Support and Service Centre.

For contact details of the responsible customer support and service centre, see below.

Do not attempt to repair or modify the components of the micropump system yourself. Our staff will help solve any problems you might be experiencing with the micropump system from Roche.

Australia

Accu-Chek Enquiry Line: 1800 251 816
Pump Support: 1800 633 457
www.accu-chek.com.au

Distributed in the United Kingdom by:

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

¹⁾ calls may be recorded for training purposes

Some mobile operators may charge for calls to these numbers.
burgesshill.insulinpumps@roche.com
www.accu-chek.co.uk
www.accu-chek.ie

18.4 Supplies and Accessories

For information on the availability of additional Accu-Chek products and accessories in your country, contact the responsible Accu-Chek Customer Support and Service Centre.

Note

Use only supplies and accessories from Roche. Otherwise, you risk malfunctions of the micropump system, incorrect test results and over- or under-delivery of insulin.

Supplies for the micropump system

- ▶ Accu-Chek Solo reservoir assembly
- ▶ Accu-Chek Solo cannula assembly and micropump holder
- ▶ Accu-Chek Solo micropump
- ▶ Accu-Chek Solo insertion device

Supplies for the blood glucose test

- ▶ Accu-Chek Aviva test strips
- ▶ Accu-Chek Aviva control solutions
- ▶ Accu-Chek FastClix finger pricker
- ▶ Accu-Chek FastClix lancet drums

Accessories

- ▶ Charging cradle for the diabetes manager
- ▶ Carry case/belt pouch
(Accu-Chek carry case/Accu-Chek belt pouch)
- ▶ Rechargeable battery for the diabetes manager
- ▶ Battery door for the diabetes manager
- ▶ Charger for the diabetes manager
- ▶ USB cable

If you need to replace defective system components or need another User's Manual for the micropump system, contact your Customer Support and Service Centre.

18.5 Disposing of the Micropump System

 **WARNING**

All objects which can come into contact with human bodily fluids carry a potential risk of infection. There is a risk that the objects may transmit infections. Dispose of used micropump system components because using them more than once may result in infections being transmitted.

Since your micropump system may come into contact with blood during use, it carries a risk of infection. Therefore, it falls outside the scope of the European Directive 2012/19/EU (directive on waste electrical and electronic equipment) and cannot be disposed of with other electronic devices.

Dispose of the used micropump system components according to local regulations.

Rechargeable battery of the diabetes manager

Dispose of the battery correctly and recycle it according to local regulations.