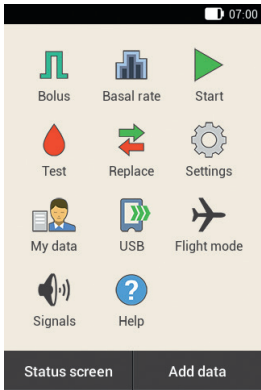
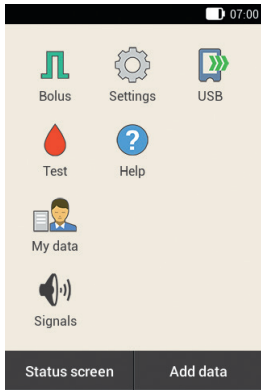


Symbols omitted in the Main menu



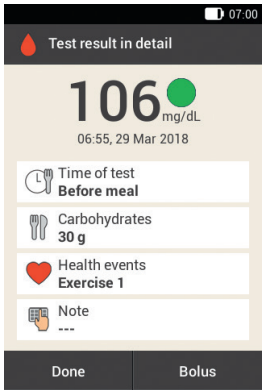
Main menu in pump therapy mode.



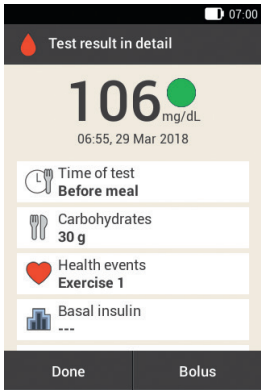
Main menu in injection therapy mode.

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



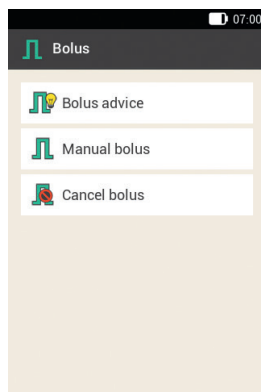
Test result in detail display in pump therapy mode.



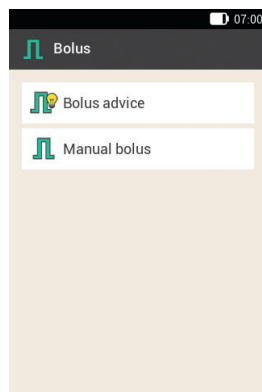
Test result in detail display in injection therapy mode.

You will also see the entry field for basal insulin.

Bolus



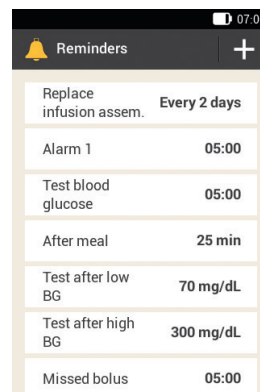
Bolus display in pump therapy mode.



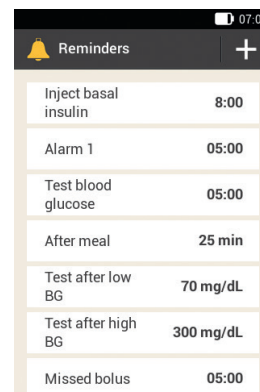
Bolus display in injection therapy mode.

The **Cancel bolus** element is omitted.

Reminders



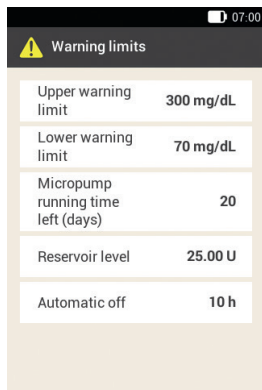
Reminders display in pump therapy mode.



Reminders display in injection therapy mode.

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

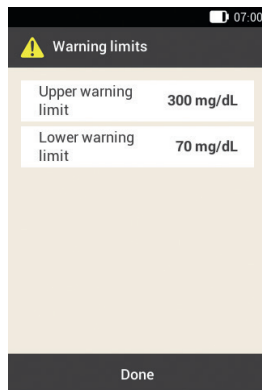
Warning limits



Warning limits display in pump therapy mode. The screen shows a yellow warning icon and the title 'Warning limits'. Below the title, there are five rows of settings: Upper warning limit (300 mg/dL), Lower warning limit (70 mg/dL), Micropump running time left (days) (20), Reservoir level (25.00 U), and Automatic off (10 h).

Warning limits	
Upper warning limit	300 mg/dL
Lower warning limit	70 mg/dL
Micropump running time left (days)	20
Reservoir level	25.00 U
Automatic off	10 h

Warning limits display in pump therapy mode.



Warning limits display in injection therapy mode. The screen shows a yellow warning icon and the title 'Warning limits'. Below the title, there are two rows of settings: Upper warning limit (300 mg/dL) and Lower warning limit (70 mg/dL). The rest of the screen is empty, and there is a 'Done' button at the bottom.

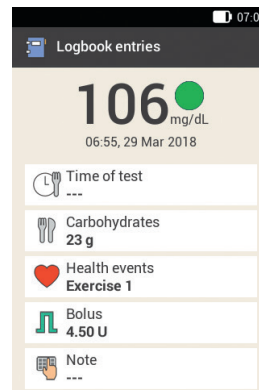
Warning limits	
Upper warning limit	300 mg/dL
Lower warning limit	70 mg/dL

Done

Warning limits display in injection therapy mode.

The Micropump remain, running time (days), Reservoir level and Automatic off options are omitted.

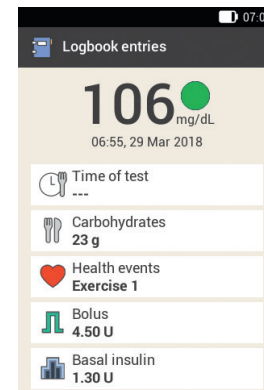
My data



Logbook entries display in pump therapy mode. The screen shows a blue logbook icon and the title 'Logbook entries'. Below the title, there is a large display of the current glucose level (106 mg/dL) with a green trend arrow. Below this, there are five rows of data: Time of test (---), Carbohydrates (23 g), Health events (Exercise 1), Bolus (4.50 U), and Note (---).

Logbook entries	
106 mg/dL 06:55, 29 Mar 2018	
Time of test	---
Carbohydrates	23 g
Health events	Exercise 1
Bolus	4.50 U
Note	---

Logbook entries display in pump therapy mode.



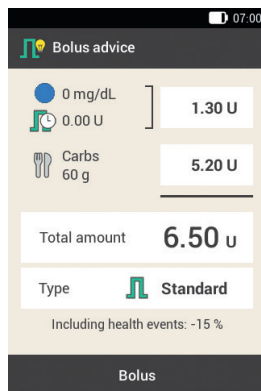
Logbook entries display in injection therapy mode. The screen shows a blue logbook icon and the title 'Logbook entries'. Below the title, there is a large display of the current glucose level (106 mg/dL) with a green trend arrow. Below this, there are five rows of data: Time of test (---), Carbohydrates (23 g), Health events (Exercise 1), Bolus (4.50 U), and Basal insulin (1.30 U).

Logbook entries	
106 mg/dL 06:55, 29 Mar 2018	
Time of test	---
Carbohydrates	23 g
Health events	Exercise 1
Bolus	4.50 U
Basal insulin	1.30 U

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

0 mg/dL
0.00 U] **1.30 U**

Carbs
60 g **5.20 U**

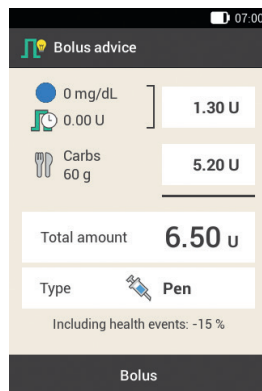
Total amount **6.50 U**

Type **Standard**

Including health events: -15 %

Bolus

Bolus advice display in pump therapy mode.



Bolus advice

0 mg/dL
0.00 U] **1.30 U**

Carbs
60 g **5.20 U**

Total amount **6.50 U**

Type **Pen**

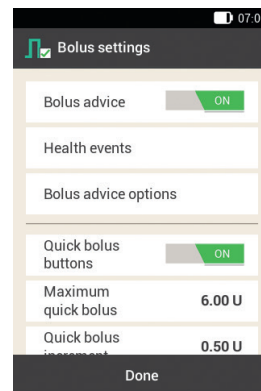
Including health events: -15 %

Bolus

Bolus advice display in injection therapy mode.

The **Type** entry provides only the **Pen** option.

Bolus settings



Bolus settings

Bolus advice **ON**

Health events

Bolus advice options

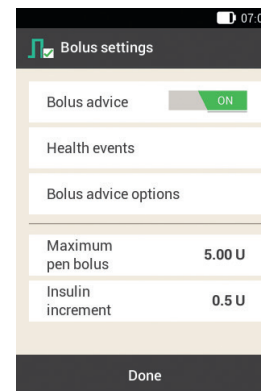
Quick bolus buttons **ON**

Maximum quick bolus **6.00 U**

Quick bolus increment **0.50 U**

Done

Bolus settings display in pump therapy mode.



Bolus settings

Bolus advice **ON**

Health events

Bolus advice options

Maximum pen bolus **5.00 U**

Insulin increment **0.5 U**

Done

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.

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 the Accu-Chek Customer Care Service Center. Do not attempt to repair the diabetes manager or micropump yourself.

Clean the lancing device according to the instructions in the respective instructions for use.

Replace the consumables for the micropump system if they are soiled or damaged.

14.1 Cleaning and Disinfecting the Micropump System

What is the difference between cleaning and disinfecting?

- ▶ Cleaning is the removal of dirt from the micropump, diabetes manager and insertion device.
- ▶ Disinfecting is the removal of most, but not all, disease-causing and other types of microorganisms (bloodborne pathogens) from the micropump, diabetes manager and insertion device.

Note

For technical assistance or questions on cleaning and disinfecting, contact the Accu-Chek Customer Care Service Center at 1-800-688-4578.

Approved Cleaning and Disinfecting Product

Always use Super Sani-Cloth Germicidal Disposable Wipes to clean and disinfect the micropump system. The effect of using more than one product interchangeably to clean and disinfect the micropump system has not been tested. Using solutions other than the Super Sani-Cloth could result in damage to the micropump system.

The following active ingredients have been approved for cleaning and disinfecting the component: A mixture of alkyl dimethyl ethylbenzyl ammonium chloride (0.25%), alkyl dimethyl benzyl ammonium chloride (0.25%) and up to 55% isopropyl alcohol.

Super Sani-Cloth contains the approved active ingredients and is licensed for use in the US and Canada.

Super Sani-Cloth can be purchased from Amazon.com, Officedepot.com, and Walmart.com.

For US: EPA Reg. No. 9480-4 for SUPER SANI-CLOTH

Roche has tested the approved components of the micropump system as follows:

Diabetes Manager

Up to 208 cleaning/disinfection cycles. One cycle means 1× cleaning and 1× disinfection. One cycle per week. Expected lifetime: 4 years

Micropump

Up to 120 cleaning/disinfection cycles, with respect to an operational time of 120 days, one cycle per day. One cycle means 1× cleaning and 1× disinfection.

Insertion device

Up to 180 cleaning/disinfection cycles, with respect to an operation time of 12 months, one cycle every other day. One cycle means 1× cleaning and 1× disinfection.

For more information see:

- ▶ FDA Public Health Notification: Use of Fingertick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens; Initial Communication, (2010).
<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm> (accessed January 17, 2018)
- ▶ CDC website on “Infection Prevention during Blood Glucose Monitoring and Insulin Administration”.
<http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html> (accessed January 17, 2018)

**WARNING****Micropump system**

- ▶ Always use Super Sani-Cloth for both cleaning and disinfecting.
- ▶ Failure to follow the cleaning and disinfection instructions will damage the micropump system and stop it from working properly.
- ▶ Do not get any moisture in slots or openings.
- ▶ Do not spray anything onto the micropump system.
- ▶ Do not immerse the micropump system in liquid.

Cleaning and Disinfecting the micropump system

The procedure described in this chapter applies for the following components of the micropump system:

- ▶ Diabetes manager
- ▶ Micropump
- ▶ Insertion device

Note

You need at least 3 Super Sani-Cloth wipes.

- ▶ one wipe for cleaning
- ▶ two wipes for disinfecting



14.1.1 How to clean and disinfect the micropump system

Failure to follow these instructions will damage the devices and stop them from working properly.

DO NOT get any moisture in slots or openings.



DO NOT spray anything onto the devices.



DO NOT immerse the devices in liquid.



14.1.2 Cleaning and disinfecting the diabetes manager



WARNING

- ▶ Switch off the diabetes manager for cleaning or disinfection.
- ▶ Do not clean or disinfect the diabetes manager while performing a blood glucose or control test.

Use only Super Sani-Cloth wipes for cleaning and disinfecting.

What to Clean and Disinfect

The following parts of the diabetes manager should be cleaned and disinfected:

- The area around slots and openings
(do not get any moisture in slots or openings)
- The diabetes manager display
- All of the diabetes manager's surfaces.
This includes the top, the bottom and the sides of the device.

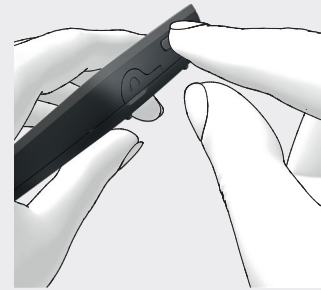
Follow steps 1-7 to clean and disinfect the diabetes manager.

1



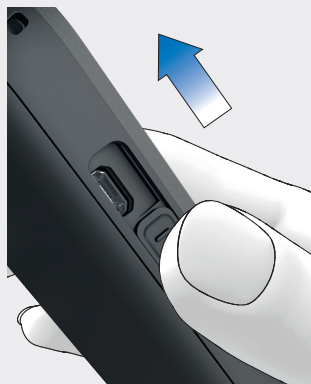
Wash hands with soap and water and dry thoroughly.

2



Turn off the diabetes manager by pressing and holding the power button until the Turn Off screen appears. Tap the *Turn Off* button.

3



Close the cover of the USB port.

Note

Be careful not to wipe any dirt into the openings of the diabetes manager.

Make sure that no liquid enters any slot or opening.

Clean the diabetes manager until all visible contamination is removed.

4



Cleaning

Wipe all surfaces of the diabetes manager with a Super Sani-Cloth wipe. Remove any visible contaminants. Carefully wipe around the test strip slot and other openings.

5



Disinfection

For disinfecting the diabetes manager, get a new Super Sani-Cloth wipe. Wipe all surfaces thoroughly.

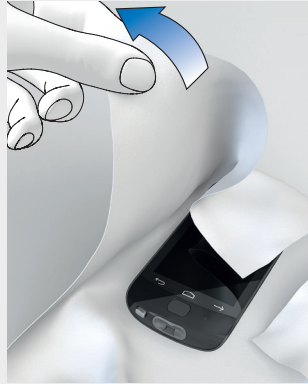
6



Wrap the diabetes manager in a new Super Sani-Cloth wipe. Allow treated surfaces to remain moist for at least 2 minutes.

You might need multiple wipes to completely wrap the diabetes manager.

7



Unwrap the diabetes manager.

Allow the diabetes manager to air dry.

14.1.3 Cleaning and disinfecting the micropump

WARNING

- ▶ Clean and disinfect the micropump only with the reservoir attached.
- ▶ Set the micropump into stop mode for cleaning or disinfection.

Use only Super Sani-Cloth wipes for cleaning and disinfecting.

What to Clean and Disinfect

- All micropump surfaces
- The quick bolus buttons
- The pump shield
- The area around the openings for ventilation (do not get any moisture in the opening)

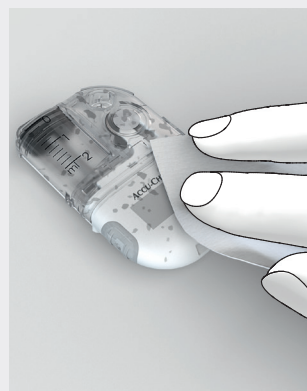
Follow steps 1-5 to clean and disinfect the micropump.

1



Wash hands with soap and water and dry thoroughly.

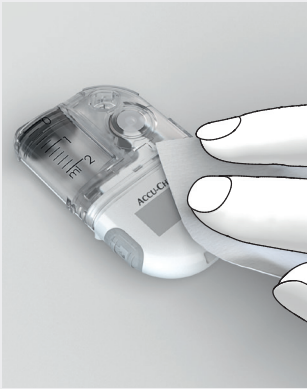
2



Cleaning

Wipe all surfaces of the micropump with a Super Sani-Cloth wipe. Remove any visible contaminants. Be careful not to wipe any dirt into the openings on the micropump.

3

**Disinfection**

For disinfecting the micropump, get a new Super Sani-Cloth wipe. Wipe all surfaces thoroughly.

Pay special attention to hard-to-reach places, for example, around the openings.

4



Wrap the micropump in a new Super Sani-Cloth wipe. Allow treated surfaces to remain moist for at least 2 minutes.

You might need multiple wipes to completely wrap the micropump.

5



Unwrap the micropump.

Allow the micropump to air dry.

Note

- ▶ Cleaning the opening for ventilation is important for the battery in the reservoir to work properly.
- ▶ Clean the micropump until all visible contamination is removed.

14.1.4 Cleaning and disinfecting the insertion device

WARNING

Clean and disinfect the insertion device only if no cannula assembly is inserted.

Use only Super Sani-Cloth wipes for cleaning and disinfecting.

Before cleaning the insertion device, make sure that the insertion device is not primed and that there is **no** cannula assembly in the insertion device.

What to Clean and Disinfect

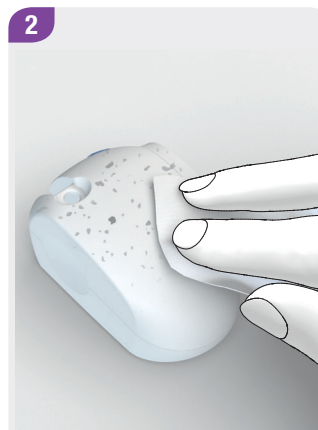
The following parts of the insertion device should be cleaned and disinfected:

- ▶ All of the insertion device surfaces
- ▶ The detach button, release button and priming handle
- ▶ The cannula assembly slot
- ▶ The safety release and the lock
- ▶ The area around the cannula opening

Follow steps 1-5 to clean and disinfect the insertion device.



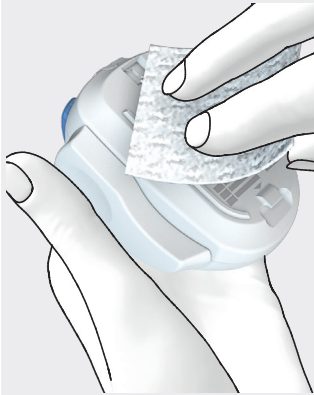
Wash hands with soap and water and dry thoroughly.



Cleaning

Wipe all surfaces of the insertion device with a Super Sani-Cloth wipe, including the top, bottom, and sides. Remove visible contaminants. Be careful not to wipe any dirt into the openings on the insertion device.

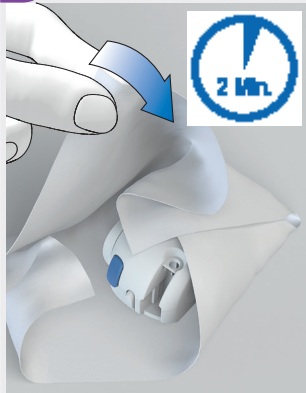
3

**Disinfection**

For disinfecting the insertion device, get a new Super Sani-Cloth wipe. Wipe all surfaces thoroughly.

Pay special attention to hard-to-reach places, for example, around the openings.

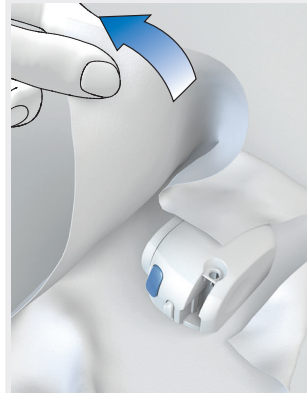
4



Wrap the insertion device in a new Super Sani-Cloth wipe. Allow treated surfaces to remain moist for at least 2 minutes.

You might need multiple wipes to completely wrap the insertion device.

5



Unwrap the insertion device.

Allow the insertion device to air dry.

Note

- ▶ Take particular care to thoroughly clean and disinfect hard-to-reach places, e.g. around openings.
- ▶ Clean the insertion device until all visible contamination is removed.

14.2 Control Test of the Diabetes Manager

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.

Observe the package insert for the control solution.

Note

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

14.2.1 Preparing a Control Test

A control test works the same way as a blood glucose test.

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

- ▶ Diabetes manager
- ▶ Accu-Chek Guide test strips
- ▶ Accu-Chek Guide 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.
- ▶ 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.

14.2.2 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.

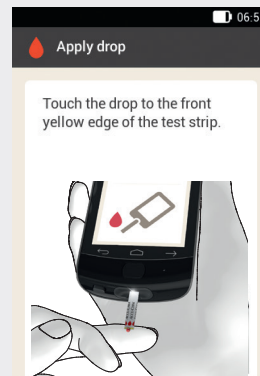
Note

- ▶ If the diabetes manager is completely turned off (not in standby mode), turn it on. Press and hold the power button on the top of the diabetes manager until the diabetes manager turns on.



- ▶ Do not insert the test strip into the test strip slot until the diabetes manager has turned on and the status screen appears.

2



Insert the test strip into the test strip slot of the diabetes manager in the direction of the arrow. The device turns on automatically and the LED at the test strip slot lights up. If the tone for blood glucose tests is turned on, a signal sounds.

3



Select the control solution to test.

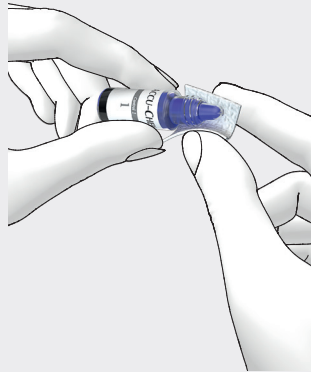
Applying a drop

4



Place the diabetes manager on a flat and solid surface (for example, a table top).

5



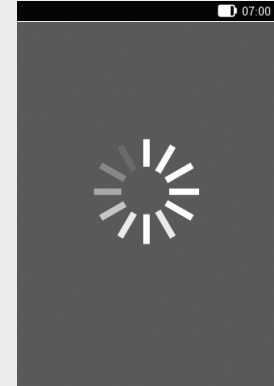
Remove the bottle cap. Wipe the tip of the bottle with a paper towel.

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.

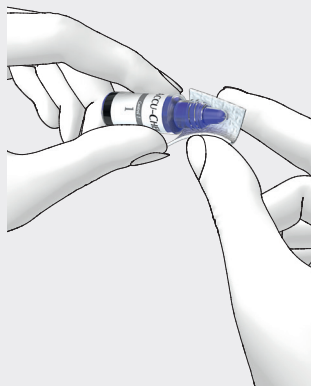
7



Remove the bottle from the test strip when the progress circle screen appears.

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

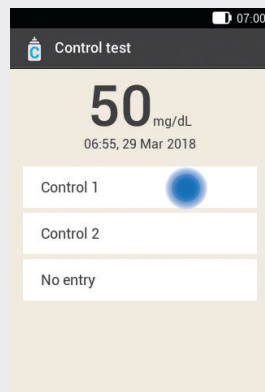
8



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

Displaying the control result

9



The control result is displayed.

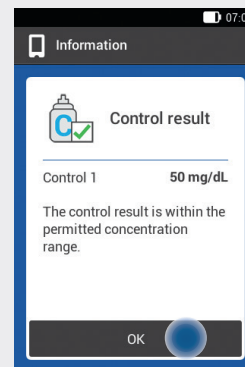
Tap the control solution you used (for example, [Control 1](#)).

Note

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

Continue with Step 12.

10



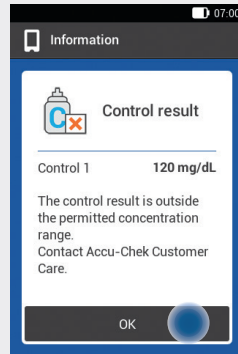
If the control result is within the permitted concentration range, the diabetes manager and test strips are working properly.

Tap [OK](#).

Note

Outside the permitted concentration range, LO or HI means that the control result is outside the permitted range. For more information, see chapter 14.2.3 *Causes of Control Tests with Errors*.

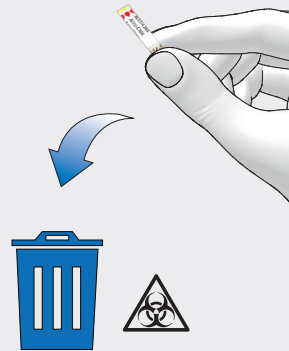
11



The listing 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 and discard the used test strip.

Contact your local waste management authority for guidance on how to recycle or dispose of used test strips in an environmentally responsible manner.

14.2.3 Causes of Control Tests with Errors

If the control result is outside the concentration range, check the items listed below. If you cannot answer the questions with Yes, correct the respective item and repeat the test.

- ▶ 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 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?
- ▶ Was the drop free from any air bubbles?
- ▶ Did you apply control solution only after the signal sounded and the **Apply drop** display appeared?
- ▶ Was the test strip kept still before and during the test?
- ▶ Was the test strip straight (not bent)?
- ▶ Did you perform the control 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 bottle been open for less than 3 months?
- ▶ Did you observe the information and instructions in the control solution package insert?

- ▶ Did you observe the storage conditions for the diabetes manager, test strips and control solutions?
- ▶ Did you pay attention to the use by date of the test strips and the control solution?

For details on the correct temperature range and storage conditions, see chapter *16 Technical Data*.

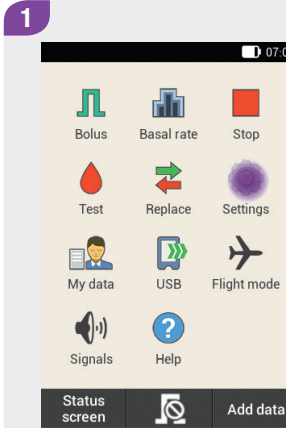
If you have observed all these items and the control result is still outside the concentration range, contact the Accu-Chek Customer Care Service Center.

14.3 Checking the System Functions

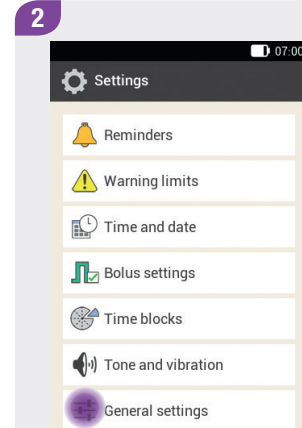
The micropump system must be working perfectly for all system messages (information messages and warnings, maintenance and error messages) to be issued correctly.

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 the Accu-Chek Customer Care Service Center.

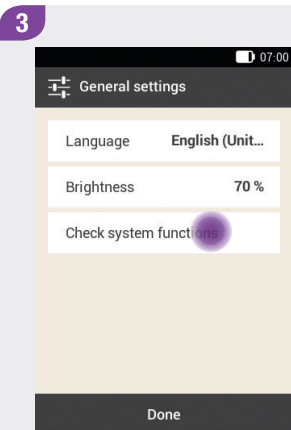


In the Main menu, tap the **Settings** menu.

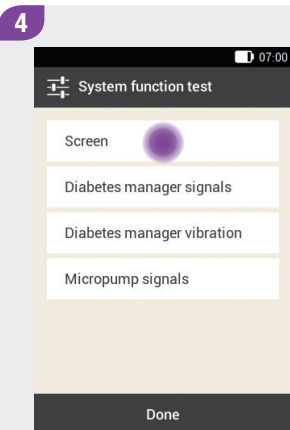


Tap **General settings**.

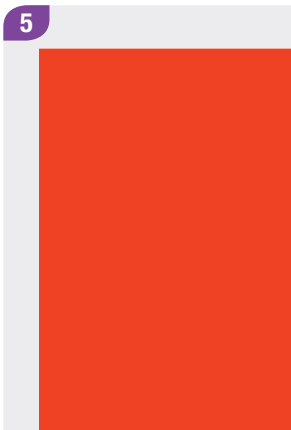
Checking the screen



Tap **Check system functions**.

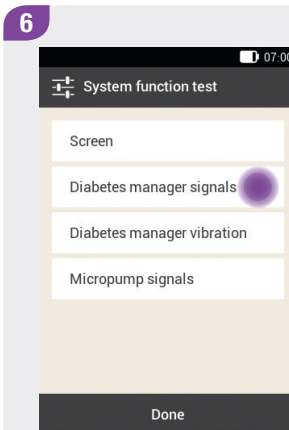


Tap **Screen**.



The screen shows different colors (red, green, blue and white) in quick succession. In addition, the diabetes manager vibrates whenever the display changes.

Diabetes manager signals

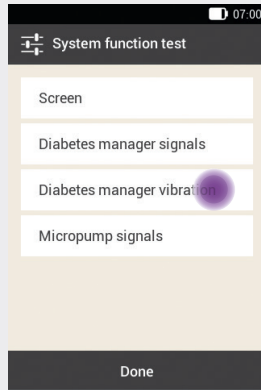


Tap **Diabetes manager signals**.

The diabetes manager sounds 1 signal.

Diabetes manager vibration

7

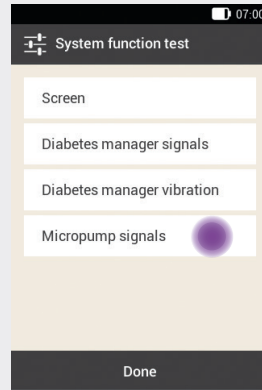


Tap **Diabetes manager vibration**.

The diabetes manager vibrates.

Micropump signals

8



Tap **Micropump signals**.

The micropump sounds 1 signal.

Note

If you are using injection therapy mode, the **Micropump signals** entry will be deactivated and grayed 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:

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

The diabetes manager issues messages on the screen and can emit tones, vibration signals or both, depending on the setting. In addition, the LED of the diabetes manager lights up to signal warnings, maintenance messages and error messages.

When the diabetes manager is turned off or in standby mode (screen is turned off), the micropump issues messages through signals. The micropump does not signal any warnings if it is connected to the diabetes manager and the diabetes manager is active (screen is turned on).



WARNING

If you ignore or do not notice the messages from the micropump system, there is a risk of hypoglycemia or hyperglycemia, which may culminate in ketoacidosis.

When a message is displayed, pick up the diabetes manager to receive further information and be able to react to the message. In the lower part of the display, selection or confirmation buttons are displayed. The buttons are briefly deactivated so that you cannot inadvertently confirm the message before you have read it.

Error and maintenance messages are repeated every 5 seconds and cannot be muted. The cause of the error or maintenance message must be confirmed and corrected.

Warnings and reminders are repeated every 30 seconds and can be muted as often as desired for 5 minutes. Tones and vibration signals are stopped for a certain time period. In this case, the message remains visible on the screen and the LED lights up.

All micropump system messages are stored in the event data. To access a past message, drag the information screen down from the top of the screen and tap the message. Event data is retained even if power to the diabetes manager is interrupted (for example, when changing the battery).

If you are unsure whether the micropump system is working properly, switch to alternative therapies according to the instructions given by your healthcare professional and check the system functions according to the instructions provided in chapter 14.3 *Checking the System Functions*. If the problem cannot be resolved using the suggested solutions, contact the Accu-Chek Customer Care Service Center.

Note

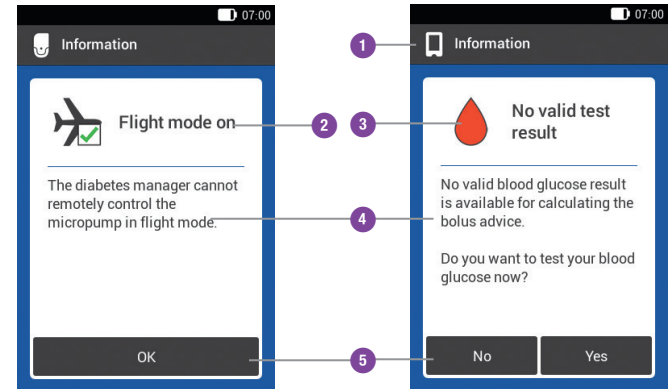
- ▶ If the micropump signals a maintenance or error message and you do not have the diabetes manager at hand, you can mute the message for 5 minutes using the quick bolus buttons on the micropump. Note that you cannot use the quick bolus buttons to deliver a quick bolus before you have muted the message.
- ▶ If the micropump issues the “Error” signal sequence and the diabetes manager does **not** display any error messages even though the diabetes manager and micropump are in communication range, the micropump might have turned off due to an electronic defect (E-7). For more information, see chapter 15.4 *Error Messages*.

15.1 Information

Information messages inform you about a particular state or event.

Confirm the information messages with **OK** or, if it is a question, answer it with **Yes** or **No**.

Examples of information messages:



1	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)