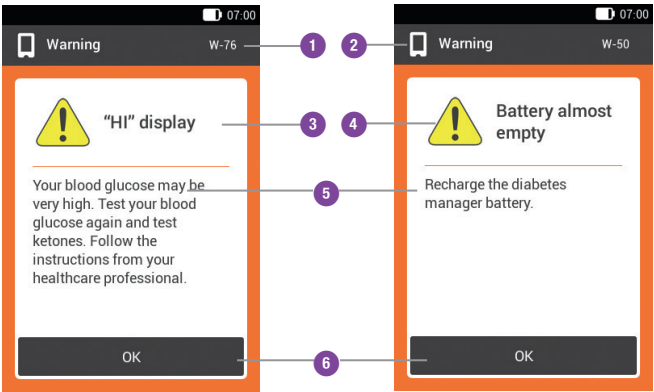


## 15.2 Warnings

Warnings inform you about relevant technical states of the micropump system or about possible risks for your therapy or health. Warnings signalize an imminent maintenance message. You are thus notified at an early stage that you will have to intervene in the short term to ensure the complete functionality of the micropump system.

When a warning is displayed, the diabetes manager issues the “Warning” signal sequence and vibrates. For more information on the sequences of signals, see chapter 17.3 *Signals*.

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
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 **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 opening that is intended for battery ventilation is covered; this means that the energy supplied by the battery is restricted.	Make sure that there is an unrestricted air supply to the opening for ventilation on the micropump.
W-36	TBR canceled	An active temporary basal rate was canceled.	Make sure that the cancellation was intentional. Program a new temporary basal rate if required.

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 cannot deliver a programmed insulin amount within the time specified. Check whether the delivered insulin amounts are sufficient for your insulin needs. Test your blood glucose at shorter intervals.
W-38	Bolus canceled	An ongoing bolus was canceled.	Make sure that the cancellation was intentional. Note the insulin amount already delivered, and program a new bolus if necessary.
W-40	Replace reservoir	The operating life of the reservoir will soon come to an end.	Replace the reservoir as soon as possible.
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.

Code	Title of warning	Information/possible cause	Information/possible solution
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 **Warnings triggered by the diabetes manager.**

W-50	Battery almost empty	The rechargeable battery level is low.	Recharge the battery of your diabetes manager.
W-71	Connection interrupted	No current data from the micropump is available. The data for calculating the bolus advice may not be up to date.	Ensure that the micropump and diabetes manager are no more than 6.5 feet 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 data for calculating the bolus advice may not be up to date.	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 the insulin delivery. Follow the instructions of your healthcare professional.
W-76	“HI” display	Your blood glucose may be very high.	Test ketones and your blood glucose. Check the insulin delivery. Follow the instructions of your healthcare professional.

Code	Title of warning	Information/possible cause	Information/possible solution
W-80	Hypoglycemia	Blood glucose has fallen below the hypo warning limit.	Eat or drink fast-acting carbohydrates. Then test your blood glucose. If hypoglycemia persists, consult your healthcare professional.
W-81	“LO” display	Your blood glucose result may be very low.	Eat or drink fast-acting carbohydrates. Test your blood glucose again and then again within the next half hour. If hypoglycemia persists, consult your healthcare professional.
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	Bolus data missing	A problem was encountered when determining active insulin. The current value may not be correct.	—

Code	Title of warning	Information/possible cause	Information/possible solution
W-86	Flight mode on	Data cannot be synchronized between the diabetes manager and the micropump because flight mode is turned on. Therefore, the entries saved for the 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.	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 synchronized. 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 synchronized.
W-89	Check logbook entries	It was not possible to assign a bolus delivered by the micropump to a bolus confirmed in the bolus advice function.	Correct the logbook entries as required.
W-90	Time synchronized with micropump	The time difference between the diabetes manager and the micropump was corrected.	Check the time on the diabetes manager.

Code	Title of warning	Information/possible cause	Information/possible solution
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 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.

## 15.3 Maintenance Messages

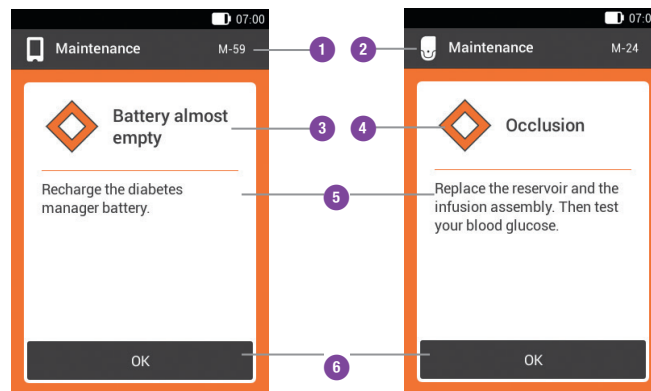
Maintenance messages inform you about a temporary loss of certain features of the micropump system. Maintenance messages require you to intervene in order to solve the problem. Once the cause of the maintenance message has been eliminated, you can use all features of the micropump system again.



When a maintenance message is displayed, the diabetes manager issues a “Maintenance” signal sequence and vibrates. The signal sequence also sounds when the [Turn off signals](#) feature is turned on. For more information on the sequences of signals, see chapter *17.3 Signals*.

### WARNING

If you do not correct the cause of the occlusion message M-24, insulin delivery may not function or may function only to a limited extent. This can lead to hyperglycemia.



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
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 **Maintenance messages triggered by the micropump.**

M-18	Replace micropump	The operating life of your micropump has come to an end.	Replace your pump 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 <b>Replace</b>  menu and replace the reservoir.
M-22	Micropump battery empty	The micropump battery, which is located in the reservoir, is empty	Select the <b>Replace</b>  menu and replace the reservoir.
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.

Code	Title of maintenance message	Possible cause/consequences	Further information
M-24	Occlusion	An occlusion was detected which means that insulin delivery is not working at all or is restricted.	Replace the reservoir and the infusion assembly. Then test your blood glucose. If the message is displayed repeatedly, contact the Accu-Chek Customer Care Service Center.
M-26	Fill reservoir needle	The reservoir needle must be refilled after replacing the reservoir.	Remove the micropump from the infusion assembly. Select the <b>Replace</b>  menu and replace the reservoir. After that, 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. If the message is displayed repeatedly, replace the pump base.

Code	Title of maintenance message	Possible cause/consequences	Further information
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 **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.
M-56	Drop applied too early	The drop was drawn into the test strip before <b>Apply drop</b> 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.

Code	Title of maintenance message	Possible cause/consequences	Further information
M-59	Battery almost empty	The level of the rechargeable battery is very low.	The diabetes manager automatically deactivates communication via <i>Bluetooth</i> wireless technology to save power. As a result, communication with the micropump is interrupted. Recharge the battery of your diabetes manager.
M-60	Clock error	A discrepancy in the internal clocks of the micropump system 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 if the code or camera lens is dirty and the code cannot be read correctly.	Try rescanning the pairing code on the micropump. Alternatively, you can enter the pump key manually.
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 in STOP mode.	If you want to deliver a bolus, start the micropump first.

Code	Title of maintenance message	Possible cause/consequences	Further information
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 or contact the Accu-Chek Customer Care Service Center.
M-78	Outside of temperature range	The temperature of the diabetes manager is too high or too low.	Make sure the ambient temperature is within the permitted range. Wait 5 minutes until the diabetes manager has adapted itself to this temperature.
M-85	Micropump incompatible	You tried to pair the diabetes manager with a pump base that is incompatible.	Contact the Accu-Chek Customer Care Service Center.
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 <b>Reservoir empty (M-21)</b> . Only after replacing the reservoir, will you be able to start the micropump.

Code	Title of maintenance message	Possible cause/consequences	Further information
M-87	Micropump not stopped	The micropump cannot be stopped.	Try to stop the micropump again. If the pump does not stop, remove the micropump from your body, switch to an alternative therapy method and contact the Accu-Chek Customer Care Service Center.
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 and restart the locating process.
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.

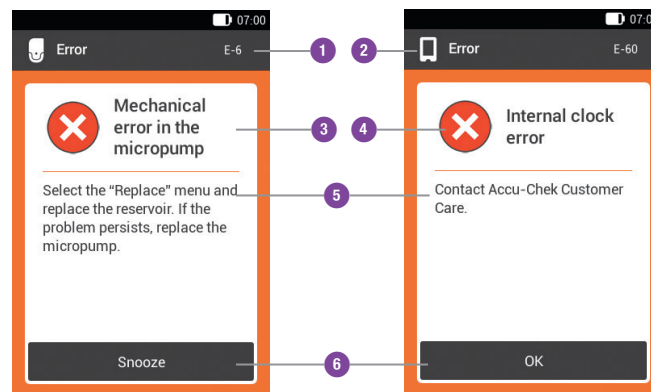
## 15.4 Error Messages

Error messages inform you about important malfunctions of the micropump system. The micropump switches to STOP mode and does not deliver any insulin. Once the cause of the error message has been eliminated, you can use all features of the micropump system again.

When an error message is displayed, the diabetes manager issues the “Error” signal sequence and vibrates. The signal sequence also sounds when the [Turn off signals](#) feature is turned on. The vibration feature cannot be turned off. For more information on the sequences of signals, see chapter [17.3 Signals](#).

For most problems, the diabetes manager displays a message with a short description of the problem and a proposed solution. If the problem cannot be resolved using the suggested solutions, switch to alternative therapy methods and contact the Accu-Chek Customer Care Service Center.




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
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 **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 <b>Replace</b>  menu and replace the reservoir. If the problem persists, replace the micropump.
E-7	Electronic error	Communication between the micropump and diabetes manager is not possible. The micropump switches to STOP mode and does not deliver any insulin.	Select the <b>Replace</b>  menu and replace the reservoir. Wait at least 30 seconds after removing the used reservoir before connecting a new reservoir to the pump base. If the problem persists, replace the micropump.
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 <b>Replace</b>  menu and replace the reservoir.

Code	Title of error	Possible cause/consequences	Possible solutions
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 **Error messages triggered by the diabetes manager.**

E-57	Electronic error	The diabetes manager was restarted due to an electronic error.	If the problem recurs, contact the Accu-Chek Customer Care Service Center.
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## 15.5 General Troubleshooting


This chapter deals with general error situations that do not necessarily result in a message on the micropump system.



If the problem cannot be resolved using the suggested solutions, contact the Accu-Chek Customer Care Service Center.

Problem	Possible cause	Possible solutions
The screen is blank or the diabetes manager cannot be turned on.	The level of the rechargeable battery is low.	Recharge the battery. For more information, see chapter 3 <i>Putting the Diabetes Manager into Operation</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 the Accu-Chek Customer Care Service Center.

Problem	Possible cause	Possible solutions
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.
The screen freezes or does not respond.	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 until the screen turns off.
		Remove the rechargeable battery from the diabetes manager and reinsert it.
The screen is defective or the colors are not represented correctly.	The screen is damaged or the diabetes manager is defective.	Perform the system function test for the diabetes manager screen. For more information, see chapter <i>14.3 Checking the System Functions</i> . If the system function test of the screen shows a problem, contact the Accu-Chek Customer Care Service Center.

Problem	Possible cause	Possible solutions
The sound is faulty. You cannot hear the signals.	The feature <b>Turn off signals</b> is activated or the volume is set too low.	Check whether the <b>Turn off signals</b> option is turned on. For more information, see chapter <i>11.5 Turning Off Signals Temporarily</i> . Check whether the signal modes ( <b>Normal</b> , <b>Vibration</b> , <b>Quiet</b> , <b>Loud</b> ) have sound activated and whether the volume is set to a level that is audible. For more information, see chapter <i>11.4 Tone and Vibration</i> .
	The speakers are damaged or the diabetes manager is defective.	Perform the system function test for the diabetes manager. For more information, see chapter <i>14.3 Checking the System Functions</i> . If the system function test shows a problem with the signals of the diabetes manager or micropump, contact the Accu-Chek Customer Care Service Center.
The start time for the first time block cannot be changed.	Initial setup is already complete and, therefore, the start time for the first time block cannot be changed any more.	To change the start time for the first time block, select the <b>Reset</b> option on the <b>Time blocks</b> display. After resetting the time blocks, you have to re-enter all time block settings.
You cannot feel any vibrations from the diabetes manager.	The active signal mode does not include a vibration signal.	Check the settings on the <b>Tone and vibration</b> display. The diabetes manager only vibrates if the active signal mode ( <b>Normal</b> , <b>Vibration</b> , <b>Quiet</b> , <b>Loud</b> ) includes vibration.
	The vibration feature is turned off.	Check the touchscreen feedback settings ( <b>Tone</b> , <b>Vibration</b> , <b>Tone and vibr.</b> , <b>Off</b> ).

Problem	Possible cause	Possible solutions
The occlusion message of the micropump was triggered.	The micropump was exposed to a temperature that was too low.	Make sure the ambient temperature is suitable. Replace the reservoir and the infusion assembly. Then test your blood glucose. Contact the Accu-Chek Customer Care Service Center if the message is displayed repeatedly.
The micropump does not issue a message and the diabetes manager displays the  symbol even though the diabetes manager and micropump are within communication range.	The micropump is in flight mode.	Turn off flight mode on the micropump. For more information, see chapter 11.9.2 <i>Turning Off Flight Mode</i> .
	The micropump was turned off by the automatic off feature.	Check the settings for the automatic off feature. For more information, see chapter 11.1 <i>Warning Limits</i> .
	The micropump turned off without prior notice due to an electronic defect.	<p>Check whether the micropump is turned off. To do this, with the quick bolus feature activated, press and hold both quick bolus buttons simultaneously for approximately 3 seconds.</p> <ul style="list-style-type: none"> <li>▶ If you hear the sequence of signals for the quick bolus, wait 5 seconds without pressing the quick bolus buttons in order to cancel the quick bolus. Check whether the connection between the diabetes manager and the micropump is being disturbed by other electronic devices.</li> <li>▶ If you do <b>not</b> hear the signal sequence for the quick bolus, replace the pump base and the reservoir. For more information, see chapter 9 <i>Replacing System Components</i>.</li> </ul>

Problem	Possible cause	Possible solutions
The micropump issues the “Error” signal sequence and the diabetes manager displays the  symbol even though the diabetes manager and micropump are within communication range.	The micropump turned off due to an electronic defect (E-7).	Select the <b>Replace</b>  menu and replace the reservoir. Wait at least 30 seconds after removing the used reservoir before connecting a new reservoir to the pump base. If the problem persists, replace the micropump. For more information, see chapter 9 <i>Replacing System Components</i> .



# 16 Technical Data

## 16.1 Micropump System

Technical data of the micropump system	
<b>Permitted insulin types</b>	U100 insulins: Humalog®, NovoLog®, NovoRapid®, Apidra®, Insuman® Infusat, Fiasp®
<b>Electromagnetic compatibility</b>	The micropump system meets the EMC requirements for home healthcare environments in accordance with IEC 60601-1-2.
<b>Electromagnetic emission</b>	Classified in accordance with CISPR 11, group 1, class B (residential).
<b>Safety</b>	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 signalize errors by means of acoustic signals and messages on the diabetes manager screen.
<b>Communication between micropump and diabetes manager</b>	<i>Bluetooth</i> Low Energy (BLE) wireless technology
<b>Transmission frequency</b>	2402–2480 MHz

**Technical data of the micropump system**

<b>Transmission power</b>	1 mW / 0 dBm Channels: 37*FHSS + 3*DSSS advertising channels Modulation: GFSK Bandwidth: 1 MHz “single hop frequency”
<b>Communication range</b>	2.2 yards (the range may be impaired by obstacles)

## 16.2 Diabetes Manager

Technical data of the diabetes manager	
<b>Device type</b>	Accu-Chek Guide Solo diabetes manager The Accu-Chek Guide Solo diabetes manager is suitable for continuous operation.
<b>Expected Service Life</b>	4 years
<b>Access control</b>	PIN-based protection
<b>Dimensions</b>	4.9 × 2.5 × 0.7 in (L × W × H)
<b>Weight</b>	4.94 oz
<b>Signal reproduction</b>	Graphical user interface, status LED, speakers, vibration alarm
<b>Screen</b>	Capacitive color LCD multi-touch screen with backlight
<b>Screen size</b>	3.5"
<b>Screen resolution</b>	320 × 480 pixels
<b>Screen timeout</b>	After 2 minutes of no activity
<b>Camera</b>	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	
<b>Admissible temperature range</b>	<p>Storage and transport, with packaging: -4 °F to +122 °F</p> <p>During operation: +41 °F to +104 °F</p> <p>Storage between periods of use: -13 °F to +158 °F</p> <p>Cooling-down time from maximum storage temperature between periods of use to operating temperature, at an ambient temperature of 68 °F: 15 minutes <sup>1</sup></p> <p>Warming-up time from minimum storage temperature between periods of use to operating temperature, at an ambient temperature of 68 °F: 15 minutes <sup>2</sup></p>
<b>Admissible humidity range</b>	<p>Storage and transport, with packaging: 5% to 85%</p> <p>During operation: 15% to 90%</p>
<b>Atmospheric pressure</b>	<p>Storage and transport, with packaging: 54.9 kPa to 106 kPa (549 mbar to 1060 mbar)</p> <p>During operation: 70 kPa to 106 kPa (700 mbar to 1060 mbar)</p> <p>During charging: 80 kPa to 106 kPa (800 mbar to 1060 mbar)</p> <p>Storage between periods of use: 54.9 kPa to 106 kPa (549 mbar to 1060 mbar)</p>
<b>Operating height</b>	<p>Up to 9842 ft above sea level (diabetes manager)</p> <p>Up to 6561 ft above sea level (charger)</p>
<b>Signal types</b>	Visual, acoustic, vibration
<b>Sound pressure level of the signal</b>	≥ 45 dBA at a distance of 3.3 ft
<b>Frequency of the signals</b>	1–3 kHz
<b>Interface to PC</b>	USB 2.0 (micro-B)
<b>Memory capacity</b>	5,000 blood glucose tests, 5,000 logbook entries, 5,000 pump events

<sup>1,2</sup> according to IEC 60601-1-11:2015

Technical data of the diabetes manager	
<b>Power supply</b>	Rechargeable lithium polymer battery model: Nugen
<b>Battery voltage</b>	3.7 V
<b>Battery capacity</b>	1,530 mAh
<b>Charging voltage via USB</b>	5 V
<b>Max. charging current</b>	700 mA
<b>USB charger</b>	Technics switch-mode power supply, model TS051X110-0502R
<b>IP rating</b>	IP20
<b>Bolus calculator</b>	Accu-Chek Bolus Advisor
<b>Test strip slot</b>	Illuminated test strip slot for Accu-Chek Guide test strips
<b>Measuring range</b>	10–600 mg/dL
<b>Test principle</b>	Refer to the test strip package insert
<b>Test time</b>	Refer to the test strip package insert
<b>Blood sample</b>	Refer to the test strip package insert
<b>Sample type</b>	Refer to the test strip package insert

## 16.3 Micropump

Technical data of the micropump	
<b>Dimensions</b>	Approx. 2.5 × 1.5 × 0.6 in
<b>Weight</b>	Micropump with filled reservoir < 1.02 oz
<b>Pump casing</b>	Impact and scratch-resistant plastic (polycarbonate)
<b>Quick bolus buttons</b>	Silicone buttons for delivering quick boluses, turning flight mode on/off and muting messages temporarily
<b>Admissible temperature range<sup>3</sup></b>	<p>Storage and transport, with packaging (pump base): -4 °F to +122 °F</p> <p>Storage and transport, with packaging (reservoir): +50 °F to +86 °F</p> <p>During operation and storage between uses: +41 °F to +104 °F</p> <p>Cooling-down time from maximum storage temperature between periods of use to operating temperature, at an ambient temperature of 68 °F: 10 minutes<sup>4</sup></p> <p>Warming-up time from minimum storage temperature between periods of use to operating temperature, at an ambient temperature of 68 °F: 10 minutes<sup>5</sup></p>
<b>Admissible humidity range</b>	<p>Storage and transport, with packaging (pump base): 5% to 85%</p> <p>Storage and transport, with packaging (reservoir): 20% to 80%</p> <p>During operation and storage between uses: 15% to 90%</p>
<b>Atmospheric pressure</b>	<p>Storage and transport, with packaging: 54.9 kPa to 106 kPa (549 mbar to 1060 mbar)</p> <p>During operation: 70 kPa to 106 kPa (700 mbar to 1060 mbar)</p> <p>Storage between periods of use: 54.9 kPa to 106 kPa (549 mbar to 1060 mbar)</p>

<sup>3</sup> 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.

<sup>4,5</sup> according to IEC 60601-1-11:2015

Technical data of the micropump	
<b>Motor type</b>	Stepper motor
<b>Power supply</b>	1.4 V zinc-air battery for internal power supply
<b>Life expectancy of the battery</b>	If used in a typical usage pattern (50 U/day using U100 insulin; room temperature: 73.4 °F $\pm$ 3.6 °F), life expectancy of the battery is up to 4 days.
<b>Basal rate</b>	Minimum: 0.1 U/h Maximum: 25.0 U/h
<b>Basal rate delivery accuracy</b>	$\pm$ 16% or better at 0.1 U/h $\pm$ 5% or better at 1.0 U/h
<b>Basal rate, increments</b>	0.1 U/h up to under 5.0 U/h: increments of 0.01 U/h 5.0 U/h up to under 25.0 U/h: increments of 0.1 U/h
<b>Basal rate profiles</b>	Up to 5 customized profiles
<b>Temporary Basal Rate (TBR)</b>	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. Up to 5 individual TBRs can be programmed.
<b>Bolus types</b>	Standard bolus, quick bolus, extended bolus, multiwave bolus
<b>Bolus amount</b>	Minimum: 0.2 U Maximum: 35 U

Technical data of the micropump	
<b>Bolus delivery accuracy</b>	±30% or better at 0.2 U ±5% or better at 50.0 U
<b>Bolus amount, increments</b>	0.2 U up to under 2.0 U: increments of 0.05 U 2.0 U up to under 5.0 U: increments of 0.1 U 5.0 U up to under 10.0 U: increments of 0.2 U 10.0 U up to under 20.0 U: increments of 0.5 U 20.0 U up to 50.0 U: increments of 1.0 U 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.
<b>Delivery lag time</b>	Adjustable in 15-minute increments from 0 to 60 minutes
<b>Quick bolus increment</b>	0.2 U / 0.5 U / 1.0 U and 2.0 U
<b>Delivery speed</b>	Boluses: 1.0–2.5 U/min. Filling the reservoir needle: 1.0–2.5 U/min.
<b>Sound pressure level of the signal</b>	≥ 45 dBA at a distance of 1 m
<b>Occlusion detection</b>	Rotation detector
<b>Maximum amount of time until occlusion message M-24</b>	50 hours at a basal rate of 0.1 U/h 5 hours at a basal rate of 1 U/h
<b>Maximum insulin amount until occlusion message M-24</b>	5.0 U
<b>Maximum pressure</b>	150 kPa (1.5 bar)

Technical data of the micropump	
<b>Reservoir fill amount</b>	Maximum: 200 U Minimum: 80 U
<b>Maximum overdelivery in the event of an error</b>	0.4 U
<b>IP rating</b>	IP22

## 16.4 Infusion Assembly

Technical data of the infusion assembly	
<b>Pump holder</b>	Dimensions: Approx. $2.6 \times 1.3 \times 0.3$ in
<b>Adhesive pad</b>	Dimensions: Approx. $3.3 \times 2$ in
<b>Cannula</b>	Orange: 6 mm, soft Teflon® catheter, 90° insertion angle Blue: 9 mm, soft Teflon® catheter, 90° insertion angle
<b>Cannula fill amount</b>	0.7 U
<b>Maximum period of use</b>	up to 3 days
<b>Sterility</b>	Sterilized using ethylene oxide for single use according to EN ISO 11135

## 16.5 Insertion Device

Technical data of the insertion device	
<b>Dimensions</b>	3.2 × 2.1 × 1.9 in
<b>Weight</b>	3 oz
<b>Period of use</b>	<p>Approx. 1 year</p> <p>You can program a reminder in the diabetes manager to remind you to replace the insertion device before the end of the period of use.</p>

## 16.6 Delivery Rate Accuracy

It is the responsibility of the healthcare professional to decide whether the accuracy of the delivery rate is adequate for the patient in question. The delivery accuracy does not depend on the length of the cannula used.

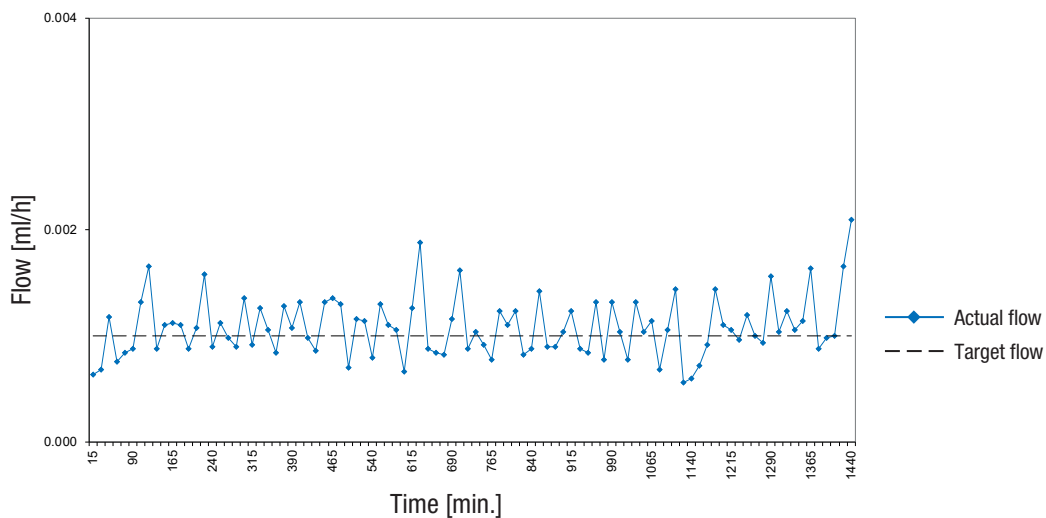
The measurements were carried out according to IEC 60601-2-24 under the following conditions:

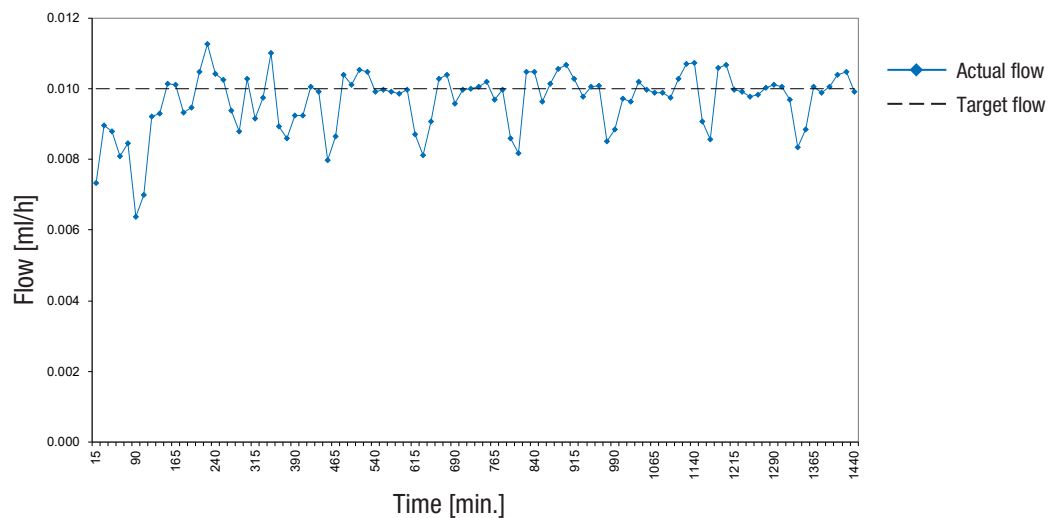
Description	Value	Unit
Temperature	69.8 $\pm$ 42.8	°F
Relative humidity	50 $\pm$ 30	%
Atmospheric pressure	1013 $\pm$ 50	mbar

## 16.6.1 Startup Chart

The startup chart shows changes in the delivery rate over the stabilization period.

### 0.1 U/h, 6 mm cannula

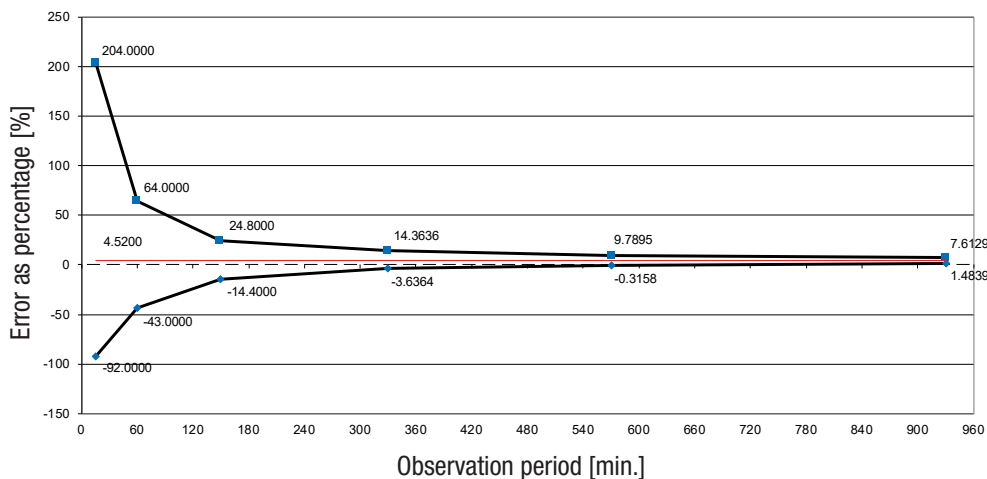


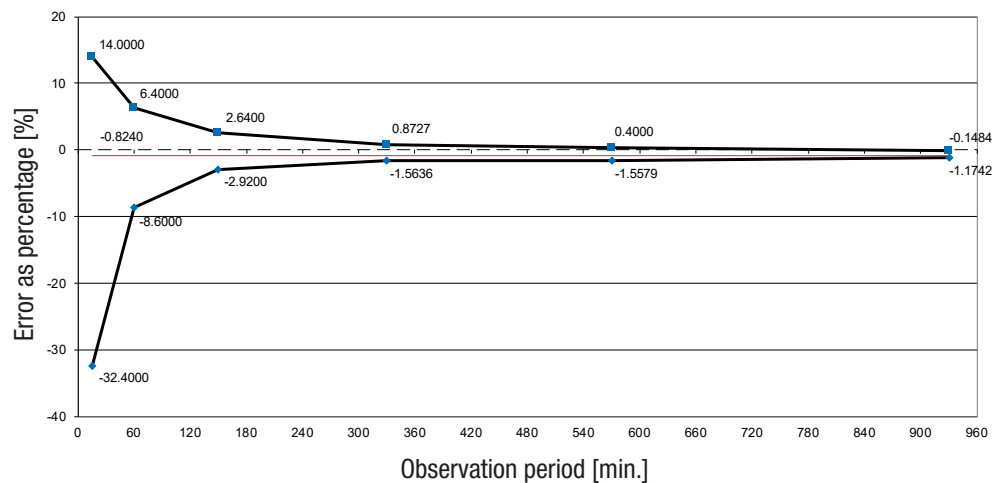
**1 U/h, 9 mm cannula**

## 16.6.2 Trumpet Curve

The trumpet curve shows the delivery rate accuracy during the observation period.

### 0.1 U/h, 6 mm cannula















**1 U/h, 9 mm cannula**




# 17 Symbols, Abbreviations, Signals









## 17.1 Symbols

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




Symbol	Meaning
	Consult instructions for use or consult electronic instructions for use
	Caution, refer to safety-related notes in the instructions for use accompanying this product.
	Follow instructions for use
	Temperature limit
	Use only once
	Use by

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

Symbol	Meaning
	Global Trade Item Number
	This product fulfills the requirements of the European Regulation 2017/745 on medical devices.
	This product also fulfills the requirements of the following directives: <ul style="list-style-type: none"> <li>▶ European Directive 2014/53/EU on the provision of radio equipment (RED).</li> <li>▶ European Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).</li> </ul>
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
	Keep away from sunlight
	Keep dry
	Do not use if package is damaged and consult instructions for use
	Humidity limitation
	Atmospheric pressure limitation
	Do not throw away
	<i>Bluetooth</i> ® wireless technology
	Applied part of type BF according to the standard IEC 60601-1. Classifies the degree of protection against electrical shock offered by the device.*
<b>Rx only</b>	Federal law (USA) restricts this device to sale by or on the order of a physician

\* The micropump is an applied part BF. The diabetes manager is not an applied part.

Symbol	Meaning
<b>IP20</b>	Device is protected against access to hazardous parts with a finger.
<b>IP22</b>	Device is protected against access to hazardous parts with a finger and protected against the effects of dripping water when the casing is tilted at an angle of 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
°F	Degrees Fahrenheit
FCC	Federal Communications Commission (United States)
g	Gram
h	Hour(s)
IC	Industry Canada (Canadian telecommunications authority)
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization

Abbreviation	Meaning
KE	Kohlenhydrateinheit (carbohydrate unit)
LCD	Liquid Crystal Display
mg/dL	Milligrams per deciliter
min.	Minutes
mmol/L	Millimoles per liter
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 milliliter of liquid contains 100 units of insulin.
USB	Universal Serial Bus

## 17.3 Signals

Both the diabetes manager and the micropump can issue signals.

### 17.3.1 Signals of the Diabetes Manager

The diabetes manager can issue the following sequences of signals:

Designation	Occurrence
Start	▶ Turning on the diabetes manager
Error	▶ Issuing error messages
Maintenance	▶ Issuing maintenance messages
Warning	▶ Issuing warnings
Connect USB	▶ Establishing a USB connection between the diabetes manager and a PC
Disconnect USB	▶ Disconnecting the USB connection between the diabetes manager and a PC

### 17.3.2 Signals of the Micropump

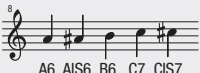
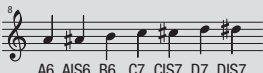


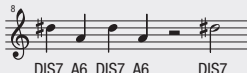
The micropump's acoustic signals are based on the C-major scale.

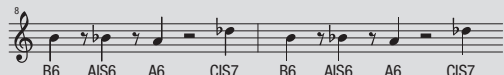
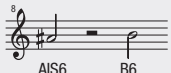
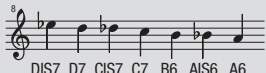

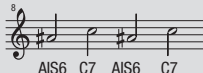


The micropump uses the following frequencies:

Tone	Frequency ( $\pm 2.5\%$ )
A6	1 760 Hz
AIS6	1 864 Hz
B6	1 975 Hz
C7	2 093 Hz
CIS7	2 217 Hz
D7	2 349 Hz
DIS7	2 489 Hz

The micropump can issue the following sequences of signals:

Designation	Occurrence	Notes representation
<b>Start</b>	▶ Connecting the pump base and reservoir	 <p>A6 AIS6 B6 C7 CIS7</p> <p>5 short, ascending tones</p>
<b>Quick bolus</b>	▶ Start of programming a quick bolus	 <p>A6 AIS6 B6 C7 CIS7 D7 DIS7</p> <p>7 short, ascending tones</p>
<b>Quick bolus increment</b>	▶ Acoustic feedback of the programmed quick bolus increments	 <p>A6</p> <p>A long, deep tone</p>
<b>Execute</b>	▶ Start of the quick bolus delivery ▶ End of insulin delivery	 <p>A6 AIS6 B6 C7 CIS7</p> <p>5 long, ascending tones. The last tone is longer.</p>
<b>Cancel</b>	▶ Timeout while programming a quick bolus ▶ Programming of a quick bolus not possible ▶ Stopping the micropump	 <p>DIS7 A6 DIS7 A6 DIS7</p> <p>4 short tones alternating high/low, followed by 1 pause and 1 long tone</p>

Designation	Occurrence	Notes representation
<b>Maintenance Error</b>	<ul style="list-style-type: none"> <li>▶ Issuing error messages</li> <li>▶ Issuing maintenance messages</li> <li>▶ Energy storage after battery error</li> </ul>	 <p>3 short tones followed by 1 pause and 1 high tone. The sequence of signals is repeated every 5 seconds.</p>
<b>Warning</b>	<ul style="list-style-type: none"> <li>▶ Issuing warnings</li> </ul>	 <p>1 long tone followed by 1 pause and 1 higher tone. The sequence of signals is repeated every 30 seconds.</p>
<b>Flight mode off</b>	<ul style="list-style-type: none"> <li>▶ Deactivating flight mode on the micropump</li> </ul>	 <p>7 short, descending tones</p>
<b>Beep</b>	<ul style="list-style-type: none"> <li>▶ Starting a bolus</li> <li>▶ Starting a basal rate</li> <li>▶ Starting a TBR</li> </ul>	 <p>A long, high tone</p>
<b>Invalid selection</b>	<ul style="list-style-type: none"> <li>▶ Exceeding the maximum insulin amount for a bolus</li> </ul>	 <p>4 long tones alternating low/high</p>

# 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.

### **Limited Express Warranty, Disclaimer, and Limitation of Remedies for the Accu-Chek® Guide Solo Diabetes Manager, Accu-Chek® Solo Pump Base, and Accu-Chek® Solo Insertion Device**

LIMITED EXPRESS WARRANTY, DISCLAIMER OF IMPLIED WARRANTIES AND LIMITATION OF REMEDIES FOR THE ACCU-CHEK GUIDE SOLO DIABETES MANAGER, ACCU-CHEK (United States of America)

LIMITED EXPRESS WARRANTY COVERAGE

#### Limited Warranty Coverage for the Accu-Chek Guide Solo Diabetes Manager

Subject to the terms and conditions stated herein ("Limited Express Warranty"), Roche Diabetes Care, Inc. ("Roche")

warrants to you, the original purchaser of the Accu-Chek Guide Solo Diabetes Manager ("Diabetes Manager"), that, if Roche, at its sole discretion, determines, during the period of four (4) years from the date of purchase, that the Diabetes Manager manifests a defect in material or workmanship while utilized under normal use and conditions, Roche will replace the Diabetes Manager. Proof of purchase date may be required.

This four-year (4) warranty period applies only to new Diabetes Managers and, in the event the Diabetes Manager is replaced, the warranty period shall not be extended or reset. Replacement of a Diabetes Manager will not extend the original 4-year warranty, which will continue to apply.

From time-to-time, Roche may offer software updates for your Diabetes Manager to help to ensure the up-to-date functionality of your pump. Roche reserves the right to offer those updates, if any, in its sole discretion either at no charge or for an additional fee to be determined at a future date. Any future software updates will be subject to your acceptance of other terms and conditions that may be applicable at that time, including additional terms that may modify or limit the terms of this Warranty.

#### Limited Warranty Coverage for the Accu-Chek Solo Pump Base

Subject to this Limited Express Warranty, Roche warrants to you, the original purchaser of the Accu-Chek Solo Pump Base (“Pump Base”), that, if Roche, at its sole discretion, determines that an unexpired Pump Base manifests a defect in material or workmanship while utilized under normal use and conditions during the period of eighteen (18) months from the date of manufacture and six (6) months from the time of activation, both of which constitute the “Pump Base Warranty Period”, Roche will replace the Pump Base. To be eligible for replacement, the activation of the Pump Base must fall within both of the time periods within the Pump Base Warranty Period (i.e. occur on or before the expiration date printed on the label and on or before a time no more than six (6) months before you notify Roche of the claim).

This Pump Base Warranty Period applies only to new Pump Bases and, in the event a Pump Base is replaced, the warranty period shall not be extended or reset. Replacement of a Pump Base will not extend the original Pump Base Warranty Period, which will continue to apply.

#### Limited Warranty Coverage for the Accu-Chek Solo Insertion Device

Subject to this Limited Express Warranty, Roche warrants to you, the original purchaser of the Accu-Chek Solo Insertion Device (“Insertion Device”), that, if Roche, at its sole discretion, determines, during the period of one (1) year from the date of

manufacture that an unexpired Insertion Device manifests a defect in material or workmanship while utilized under normal use and conditions, Roche will replace the Insertion Device. Replacement of an Insertion Device does not extend the original one (1) year warranty.

#### LIMITED EXPRESS WARRANTY TERMS AND CONDITIONS

##### Claim Procedure

To be eligible for this Limited Express Warranty, you must notify Roche of the claimed defect with the Diabetes Manager, Pump Base or the Insertion Device within the applicable warranty periods outlined above by calling the Accu-Chek Customer Care Service Center toll free at 1-800-280-7801. For a claim involving a Diabetes Manager, Pump Base or an Insertion Device, you must provide the Diabetes Manager, Pump Base or Insertion Device serial number and a description of the claimed defect. The serial number for the Diabetes Manager, Pump Base, and Insertion Device is located on the product packaging and on the device. You may also be required to verify the date of purchase of the Diabetes Manager, Pump Base, and/or the Insertion Device, the expiration date of the Diabetes Manager, the expiration date and activation date of the Pump Base, and/or the expiration date of the Insertion Device. The expiration date for the Diabetes Manager, Pump Base, and Insertion Device is located on the product packaging. You should retain the Diabetes Manager, Pump Base, and Insertion Device packaging after opening. Your

failure to follow any of the above steps may result in the denial of coverage under this Limited Express Warranty. The Diabetes Manager, Pump Base or Insertion Device must be properly packaged and returned to Roche according to the instructions provided in the Return Merchandise Authorization, or RMA Kit provided by the Accu-Chek Customer Care Center. With a prior authorization, Roche will pay all reasonable freight and transportation charges, where applicable, incurred in shipping the Diabetes Manager, Pump Base or Insertion Device to Roche under this Limited Express Warranty. For the avoidance of doubt, this Limited Express Warranty does not cover replacements provided by any person or entity other than Roche.

### Proof of Purchase

In order to verify the date of purchase, the date of expiration, or the time of activation and to determine if the claim under this Limited Express Warranty is within the applicable warranty periods, Roche may require that you provide a valid proof of purchase, expiration or activation. Your failure to provide a valid proof of purchase, expiration or activation, as determined by Roche, may result in the denial of coverage under this Limited Express Warranty.

### Exclusions

This Limited Express Warranty covers only the original purchaser and cannot be transferred or assigned with the sale, rental or other transfer of the Diabetes Manager, Pump Base or the Insertion Device to any other person or entity. Any sale, rental, or

other transfer or use of the Diabetes Manager, Pump Base or the Insertion Device covered by this Limited Express Warranty to or by a person or entity other than the original purchaser shall cause this warranty to immediately terminate.

This Limited Express Warranty will apply only if the Diabetes Manager, Pump Base or the Insertion Device at issue has been used in accordance with the Accu-Chek Solo Micropump System User's Manual and/or other written instructions provided by Roche.

This Limited Express Warranty will apply only if the Pump Base has been used with the Accu-Chek Guide Solo Diabetes Manager for use with the Pump Base by the federal Food and Drug Administration. This Limited Express Warranty is void where the Pump Base has been used with any unapproved or unauthorized diabetes controller and/or diabetes controller mobile application, including any associated software updates of that unapproved or unauthorized application.

THIS LIMITED EXPRESS WARRANTY DOES NOT APPLY IF THE DIABETES MANAGER, PUMP BASE OR THE INSERTION DEVICE HAVE BEEN:

- ▶ Altered, changed or modified by any person or entity other than Roche;
- ▶ Opened, serviced or repaired by any person or entity other than Roche;
- ▶ Damaged by an act of God or other "force majeure" like event beyond the control of Roche;

- ▶ Damaged by misuse, abuse, negligence, accident, unreasonable use, or improper handling, care or storage;
- ▶ Damaged by routine wear and tear, causes unrelated to defective materials or workmanship or other circumstances outside of the reasonable control of Roche.

This Limited Express Warranty does not apply to supplies and accessories, including but not limited to, reservoirs, pump holders, cannula assemblies, batteries or other accessories, or related products provided by third parties (e.g., data management tools).

This Limited Express Warranty does not extend to design defects (i.e. claims that the Diabetes Manager, Pump Base, or the Insertion Device should have been designed in a different way).

#### **DISCLAIMER OF IMPLIED WARRANTIES AND LIMITATION OF REMEDIES**

REPLACEMENT AS PROVIDED UNDER THE ABOVE LIMITED EXPRESS WARRANTY OF THE DIABETES MANAGER, PUMP BASE OR THE INSERTION DEVICE IS YOUR EXCLUSIVE REMEDY AND THE ENTIRE OBLIGATION OF ROCHE. THIS EXCLUSIVE REMEDY SHALL NOT BE DEEMED TO HAVE FAILED ITS ESSENTIAL PURPOSE SO LONG AS ROCHE IS WILLING AND ABLE TO REPLACE A DIABETES MANAGER, PUMP BASE OR AN INSERTION DEVICE WITH DEFECTS IN MATERIALS OR WORKMANSHIP IN THE MANNER DESCRIBED BY THE ABOVE LIMITED EXPRESS WARRANTY.

ANY IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE EXPRESSLY DISCLAIMED.

IN NO EVENT SHALL ROCHE, ITS SUPPLIERS, DISTRIBUTORS, SERVICE PROVIDERS, AND/OR AGENTS BE LIABLE FOR INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES ARISING FROM OR IN ANY WAY CONNECTED WITH THE PURCHASE OR USE OF THE DIABETES MANAGER, PUMP BASE OR INSERTION DEVICE OR BY A BREACH OF THE ABOVE LIMITED EXPRESS WARRANTY, WHETHER SUCH CLAIM IS BASED IN WARRANTY, CONTRACT, TORT OR OTHERWISE.

#### Important Additional Provisions

ROCHE DOES NOT WARRANT THE SUITABILITY OF THE DIABETES MANAGER, PUMP BASE OR THE INSERTION DEVICE FOR ANY SPECIFIC PERSON AS HEALTH CARE AND TREATMENT ARE COMPLEX SUBJECTS REQUIRING THE SERVICES OF QUALIFIED HEALTH CARE PROVIDERS.

The above Limited Express Warranty gives you specific legal rights, and you may also have other rights, which vary by jurisdiction. The above Limited Express Warranty applies only to the Diabetes Managers, Pump Bases and the Insertion Devices that were originally sold for use in the United States of America.

Note that some jurisdictions do not allow the exclusion of implied warranties or the limitation of indirect, special, incidental, or consequential damages, so the above exclusions or limitations

may not apply to you. ROCHE'S LIABILITY IN SUCH JURISDICTIONS SHALL BE LIMITED TO THE MAXIMUM EXTENT PERMITTED BY LAW. SUCH LIMITATIONS SHALL INCLUDE BUT ARE NOT LIMITED TO THE FOLLOWING: ANY IMPLIED WARRANTIES THAT CANNOT BE DISCLAIMED UNDER THE LAW OF A PARTICULAR JURISDICTION ARE LIMITED, TO THE EXTENT ALLOWED BY LAW, TO THE TIME PERIOD COVERED BY THE ABOVE LIMITED EXPRESS WARRANTY, OR TO THE APPLICABLE TIME PERIOD PROVIDED BY LAW, WHICHEVER PERIOD IS SHORTER.

#### No Other Warranty or Agreement

Unless modified in writing and signed by both Roche and you, the foregoing Limited Express Warranty is understood to be the complete and exclusive understanding between Roche and you, superseding all prior warranties and agreements, oral or written, and all other communications relating to any defect in, failure or other malfunction in a Diabetes Manager, Pump Base or an Insertion Device. No employee, agent or other representative of Roche or any other party is authorized to make any product warranty or agreement applicable to a Diabetes Manager, Pump Base or an Insertion Device in addition to those made in the foregoing.

## 18.2 License Information

License 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 Declaration of Conformity, Radio Equipment Directive

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 may be found at: [declarations.accu-chek.com](http://declarations.accu-chek.com)

## 18.4 Connecting Non-System Devices

Additional equipment connected to the diabetes manager must demonstrably comply with the relevant IEC or ISO standards (for example, IEC 60950 or IEC 62368 for data processing equipment). Moreover, all configurations must comply with the normative requirements for medical systems (see section 16 of the latest edition of IEC 60601-1). Anyone who connects additional equipment to medical electrical equipment is deemed to be the system configurer, and is therefore responsible for the system being compliant with the normative requirements for systems. If you have any questions, contact the Accu-Chek Customer Care Service Center.

## 18.5 Accu-Chek Customer Care Service Center

If you encounter problems, have questions regarding operation or need additional information about the Accu-Chek Solo micropump system, visit [accu-chek.com/support](http://accu-chek.com/support) or contact the Accu-Chek Customer Care Service Center toll-free at 1-800-688-4578.

We offer assistance in many languages. You can also visit [accu-chek.com](http://accu-chek.com) for diabetes information, self-care tools, product support and demonstrations..

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.

Accu-Chek Customer Care Service Center:

**In US, distributed by:**

Roche Diabetes Care, Inc.

Indianapolis, IN 46256, **USA**

Toll Free: 1-800-280-688-4578

[accu-chek.com](http://accu-chek.com)

## 18.6 Supplies and Accessories

For information on the availability of additional Accu-Chek products and accessories contact the Accu-Chek Customer Care Service Center.

### **WARNING**

- ▶ Use only the supplied charger and the associated USB cable, or a certified USB charger (for example, a laptop certified according to IEC 60950 or an equivalent safety standard).
- ▶ Use only the rechargeable battery supplied.
- ▶ Use only supplies and accessories from Roche and do not modify them. Otherwise, you risk malfunctions of the micropump system, incorrect test results and over-delivery or under-delivery of insulin.

### **Supplies for the micropump system**

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

### **Supplies for the blood glucose test**

- ▶ Accu-Chek Guide test strips
- ▶ Accu-Chek Guide control solutions
- ▶ Accu-Chek lancing device
- ▶ Accu-Chek lancets

### **Accessories/replacement components**

- ▶ Charging cradle for the diabetes manager
- ▶ Carry case/belt pouch for the diabetes manager (Accu-Chek carry case)
- ▶ 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 the Accu-Chek Customer Care Service Center.

## 18.7 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 some components, such as cannulas, cannula assemblies, and lancets may come into contact with human bodily fluids during use, carry a potential risk of infection. Do not use such components more than once, and when removed, dispose of in accordance with guidance found in the next section.

### Rechargeable battery of the diabetes manager

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

### 18.7.1 Disposal Guideline

Used components, such as cannulas, cannula assemblies, and lancets, that come into contact with blood or bodily fluids carry a risk of infection transmission. Place used cannulas, cannula assemblies, and lancets in an approved sharps disposal container or other strong plastic container immediately after use. When the container is 3/4 full, put the lid on, seal it with tape and put a “Do not recycle” label on the container. Do not overfill.

Never throw used cannulas, cannula assemblies, or lancets into the toilet. Do not recycle cannulas, cannula assemblies, or lancets. Do not put sharps containers in the household trash unless allowed in your community. Discard the container according to local regulations. Customers in the United States may use their zip code to find local information about sharps disposal regulations. Refer to website named SafeNeedleDisposal.org (<https://safeneedledisposal.org/>).

Roche is committed to waste avoidance and proper waste management including recycling, environmental sustainability, and product stewardship. Roche strives to design products and packaging that minimizes waste impacts at the end-of-life. All used components which can come into contact with human blood carry a potential risk of infection. We strongly encourage our customers to comply with all applicable laws or ordinances relating to the proper disposal of sharps and/or contaminated

products. Please contact your local waste management authority for the appropriate handling and disposal of used micropump system components, used lancets, and used batteries.

Please consider the following points when discarding a used diabetes manager, associated testing supplies, and device batteries:

- ▶ Unused and expired components must be disposed of in an environmentally sound manner.
- ▶ The diabetes manager is considered an e-waste due to batteries and electronics contained within. Under conditions of normal handling and use the materials do not pose any immediate threat. Improperly handled e-waste and batteries may leach toxins into the soil and water and emit toxins into the atmosphere. Therefore, contact your local waste management authority for guidance on how to recycle or dispose of e-waste in an environmentally responsible manner. Many towns and/or counties have collection facilities or periodic household hazardous waste collection events, where e-waste may be collected for disposal.

## 18.7.2 Component Recycling and Disposal

### List of Solo Pump System Components for Recycling and Disposal Guidance

#### Pump Holder

Generally, can be discarded with household trash. However, contact your local waste management authority for guidance on how to recycle or dispose of in an environmentally responsible manner.

#### Cannula Assembly

Do not recycle cannulas, cannula assemblies, or lancets. Used components, such as cannulas, cannula assemblies, and lancets, that come into contact with blood or bodily fluids carry a risk of infection transmission. Place used cannulas, cannula assemblies, and lancets in an approved sharps disposal container.

#### Insertion Device

Generally, can be discarded with household trash. However, contact your local waste management authority for guidance on how to recycle or dispose of in an environmentally responsible manner.

#### Diabetes Manager

**Batteries** - The diabetes manager is considered an e-waste due to batteries and electronics contained within. Contact your local waste management authority for guidance on how to recycle or dispose of the rechargeable battery and e-waste in an environmentally responsible manner.

### Pump Base

The pump base is considered an e-waste due to electronics contained within. Contact your local waste management authority for guidance on how to recycle or dispose of e-waste in an environmentally responsible manner

### Reservoir Assembly

**Reservoir Filling Aid** – Generally, can be discarded with household trash. However, contact your local waste management authority for guidance on how to recycle or dispose of in an environmentally responsible manner

**Handle for Piston Rod** – Generally, can be discarded with household trash. However, contact your local waste management authority for guidance on how to recycle or dispose of in an environmentally responsible manner

**Batteries** – The Reservoir contains a zinc-air battery and is considered an e-waste due to batteries and electronics contained within. Contact your local waste management authority for guidance on how to recycle or dispose of the rechargeable battery in an environmentally responsible manner.

**Protective film for battery** – Generally, can be discarded with

household trash. However, contact your local waste management authority for guidance on how to recycle or dispose of in an environmentally responsible manner


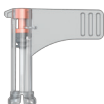




### Potential risk of infection







- ▶ Cannula
- ▶ Cannula assemblies
- ▶ Lancets

### Explanation of Colors

- = Household trash
- = Potential risk of infection
- = Batteries
- = e-Waste

## Solo Component Recycling and Disposal Overview

Disposable Parts		
		
Pump holder	Cannula	Reservoir
		
Period of use		
up to 3 days	up to 3 days	up to 4 days
Can be discarded with household trash. Contact your local waste management authority for guidance on how to recycle or dispose of in an environmentally responsible manner.	Do not recycle cannulas, cannula assemblies, or lancets. These components come into contact with blood or bodily fluids carry a risk of infection transmission. Place used cannulas, cannula assemblies, and lancets in an approved sharps disposal container.	Can be discarded with household trash. The Reservoir contains a zinc-air battery and is considered an e-waste due to batteries and electronics contained within. Contact your local waste management authority for guidance on how to recycle or dispose of in an environmentally responsible manner.

Reusable Parts		
		
Insertion device	Diabetes manager	Pump base
		
Period of use		
up to 3 days	up to 3 days	up to 4 days
Can be discarded with household trash. Contact your local waste management authority for guidance on how to recycle or dispose of in an environmentally responsible manner.	Do not recycle cannulas, cannula assemblies, or lancets. These components come into contact with blood or bodily fluids carry a risk of infection transmission. Place used cannulas, cannula assemblies, and lancets in an approved sharps disposal container.	Can be discarded with household trash. The Reservoir contains a zinc-air battery and is considered an e-waste due to batteries and electronics contained within. Contact your local waste management authority for guidance on how to recycle or dispose of in an environmentally responsible manner.

## 18.8 Bolus Calculation

The bolus that is recommended by the bolus advice feature consists of two components: a recommendation for a meal bolus that covers your intake of food and a recommendation for a correction bolus to adjust your blood glucose level. The correction bolus may be positive if your current blood glucose level is above your target BG, or negative, if it falls below your target BG.

### 18.8.1 Meal Bolus

A meal bolus is the amount of insulin that needs to be delivered to compensate for the amount of carbohydrates you are planning to eat. It is calculated as follows:

**Meal bolus = carbohydrate amount × carbohydrate ratio**

The following applies here:

Carbohydrate ratio = insulin : carbohydrates

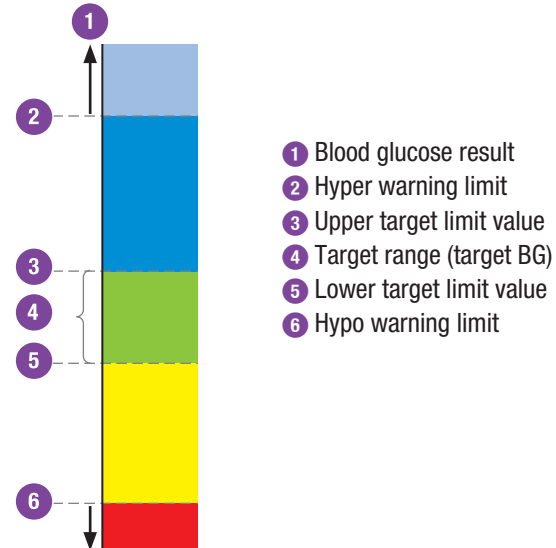
### 18.8.2 Correction Bolus

If your current blood glucose level is not within your target range, a correction bolus is suggested.

The following applies here:

Insulin sensitivity = insulin : change in blood glucose

#### BG thresholds



The calculation of the proposed correction bolus is based on your current blood glucose result, your insulin sensitivity in the current time block, your target range and on whether you plan a meal. The target BG is calculated as the mean value from the lower and upper target limit value.

### Examples of bolus advice calculations

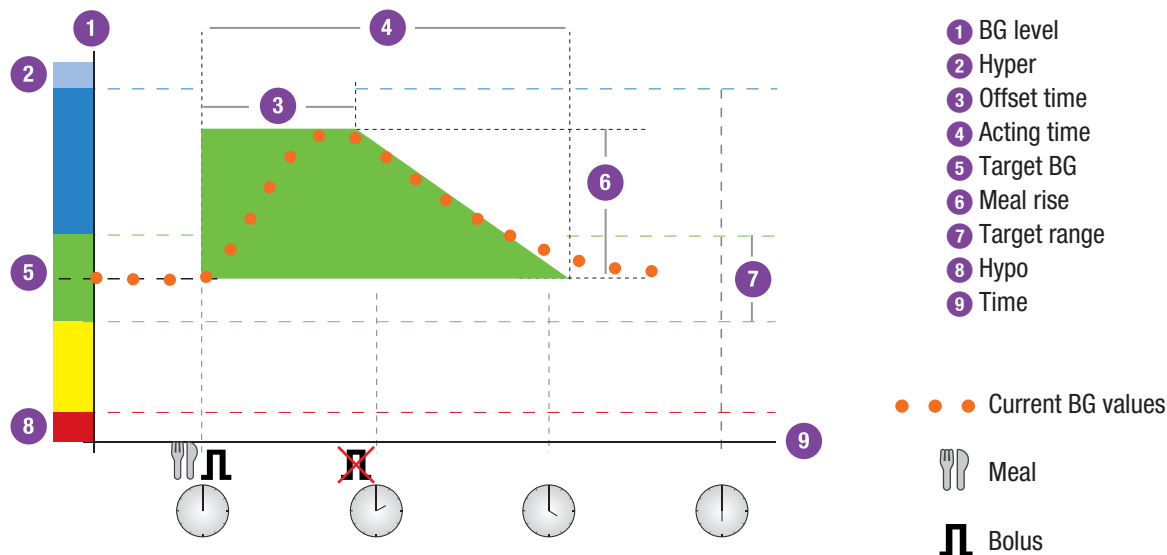
Blood glucose level	Without food intake/carbohydrates	Before a meal
Above the upper target limit value	$(\text{Current BG} - \text{target BG}) \times \text{insulin sensitivity}$	$(\text{Current BG} - \text{target BG}) \times \text{insulin sensitivity} + \text{meal bolus}$
Within target range	No correction bolus necessary.	$(\text{Current BG} - \text{target BG}) \times \text{insulin sensitivity} + \text{meal bolus}$ . The correction bolus can be negative.
Between lower target limit value and hypo warning limit	No bolus recommended. The correction bolus is negative.	$(\text{Current BG} - \text{target BG}) \times \text{insulin sensitivity} + \text{meal bolus}$ . The correction bolus is negative.
Below hypo warning limit	A hypo warning is displayed. You receive the advice to eat fast-acting carbohydrates.  No bolus advice available.	A hypo warning is displayed. You receive the advice to eat fast-acting carbohydrates.  No bolus advice available.

### 18.8.3 Subsequent Meal Boluses

If you intend to eat several meals or snacks within a short time period, you should deliver a meal bolus for each meal.

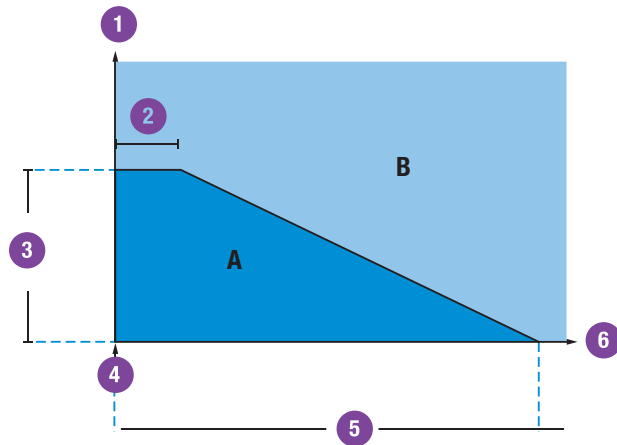
### 18.8.4 Correction Bolus After a Meal

After a meal, it is normal for your blood glucose level to increase even if you delivered the correct meal bolus. The allowed increase in the blood glucose level is called “meal rise”. After a certain period of time, the so-called offset time, the blood glucose level drops from the peak value until it reaches the target level again. The period of time from the start of the blood glucose increase until the blood glucose level returns to the target level is defined as the acting time. During this time, a correction bolus is only recommended if your blood glucose level exceeds the allowed value after a meal. The allowed value depends on the blood glucose target value and the “meal rise”.



The dotted line shows how your blood glucose level may change after a meal bolus. Bolus advice tolerates an increase in your blood glucose level within the allowed range for the meal rise (green) without calculating an additional correction bolus. If you enter a carbohydrate amount that is greater than the snack size, the set meal rise is added to the current blood glucose target value. The shape of the meal rise (the width of the green area) is determined by the offset time and the acting time.

The difference between your current blood glucose level and your blood glucose target value is called delta BG value. A correction bolus that was delivered according to the conditions mentioned above covers this difference. When the correction bolus starts to act, your current blood glucose level should drop, and the respective delta BG value decreases after the offset time. At the end of the acting time, your blood glucose level should have reached the target range again. You will only receive a recommendation for an additional correction bolus if your current blood glucose result is higher than the current delta BG value.



- 1 Blood glucose result
- 2 Offset time
- 3 Delta BG
- 4 Correction bolus
- 5 Acting time
- 6 Time

If your blood glucose result is within range A of the graph, no correction bolus will be recommended. If your blood glucose result is within range B of the graph, a correction bolus will be recommended.

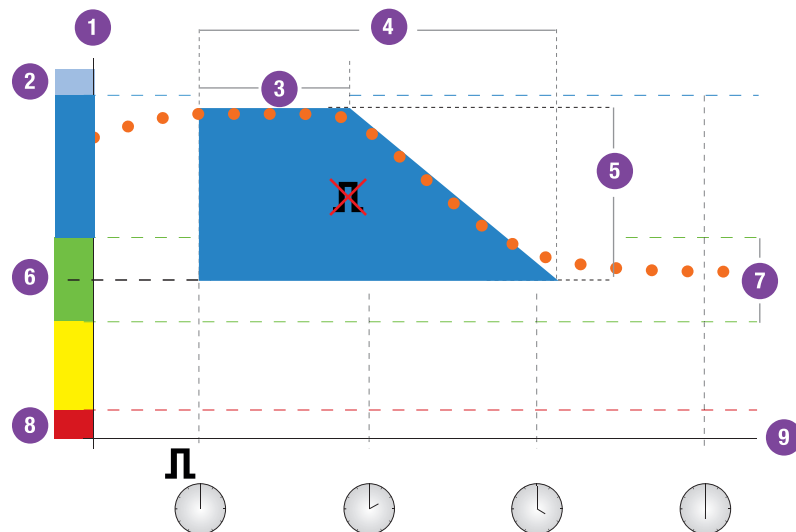
### 18.8.6 Examples

The following charts show various examples of how bolus advice takes different factors into account for the calculations.

The currently allowed blood glucose value considers the following factors:

- ▶ Target BG
- ▶ Meal rise
- ▶ Delta BG

## After a correction bolus



- 1 BG level
- 2 Hyper
- 3 Offset time
- 4 Acting time
- 5 Delta BG
- 6 Target BG
- 7 Target range
- 8 Hypo
- 9 Time

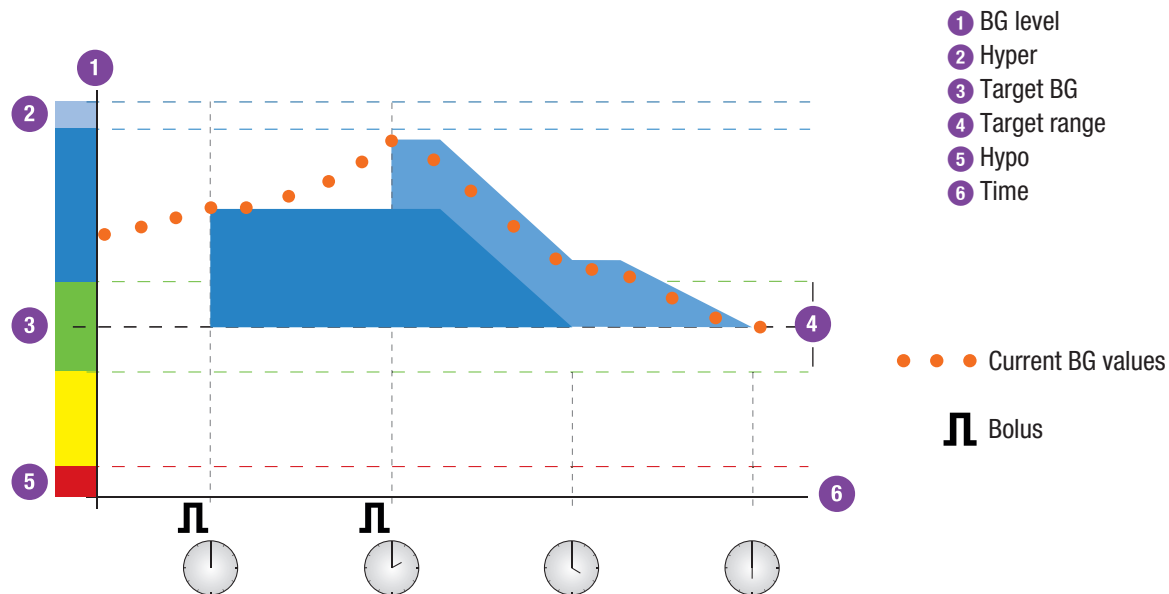
● ● ● Current BG values

⌋ Bolus

~~⌋~~ No bolus required

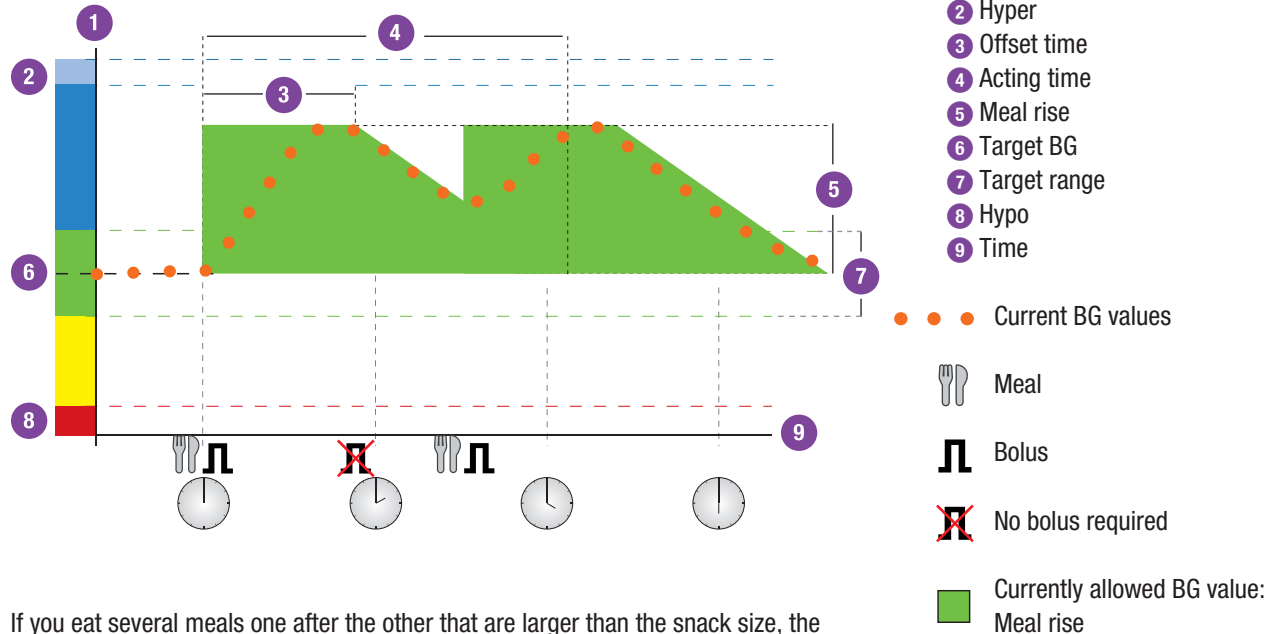
■ Currently allowed BG value:  
Corrected BG

The first correction bolus at 12:00 noon remains active during the acting time (width of the blue area). If the blood glucose value at 14:00 drops below the currently allowed blood glucose value (upper edge of the blue area), no additional correction bolus will be calculated.



If a blood glucose result is above the currently allowed blood glucose value, a bolus will be calculated (light blue) that considers only the difference between the current blood glucose value (orange dots) and the currently allowed blood glucose value (upper edge of the dark blue area).

## Subsequent Meals



If you eat several meals one after the other that are larger than the snack size, the meal rise is newly started for each meal bolus. Even if you eat several meals in succession, the allowed meal rise is not greater than for one meal alone.

# 19

## Glossary

Term	Definition
Acting time	The acting time is the period of time from the start of bolus delivery until the blood glucose level is expected to return to the target value.
Active insulin	A calculated value representing the amount of insulin currently in the body that still has a lowering effect on the blood glucose level after a correction bolus. This value does not include any insulin amounts that were delivered to compensate for carbohydrate intake.
Automatic off	The automatic off function is a feature for emergency situations. If you have not touched any buttons on your micropump and not operated the diabetes manager for the specified number of hours, the micropump stops insulin delivery.
Basal rate	The basal rate is the insulin amount delivered per hour to cover your meal-independent insulin needs. In insulin pump therapy, your basal rate is determined together with your healthcare professional and can be adjusted to meet your individual physiological needs that can change as the day progresses.
Basal rate profile	A basal rate profile consists of up to 24 time blocks. An individual basal rate can be programmed for each time block. The Accu-Chek Solo micropump offers you up to 5 different basal rate profiles in order to easily adjust insulin delivery to meet your changing insulin needs (for example, during the week compared to at the weekend).

Term	Definition
BG threshold	A limit value that triggers a test reminder when the blood glucose level is above or below this value. The BG thresholds do not affect the target ranges or the warning limits.
Blood glucose (BG)	The blood glucose level
Blood glucose result	Result of a blood glucose test
<i>Bluetooth</i> wireless technology	Wireless transfer technology that digital devices use to exchange data
Bolus	The insulin amount required to cover the intake of food or correct an elevated blood glucose level. The bolus type and bolus amount are determined by your healthcare professional's guidelines, your blood glucose level, the food you ate, your current state of health or your physical activity.
Bolus advice options	Settings that are independent of the time of day and affect exclusively bolus advice calculation. These settings include meal rise, snack size, acting time and offset time. Bolus advice calculation is also affected by the parameters target range, insulin sensitivity and carbohydrate ratio, which are dependent of the time of day and can be saved in the respective time blocks.
Bolus advice	A feature that provides the user with suggestions as to how much insulin should be delivered for a meal or to correct the blood glucose level
Broteinheit (Bread Equivalent) (BE)	One of the 4 units for the carbohydrate amount that you can select when setting up the micropump system. 1 BE = 12 grams of carbohydrates
Carbohydrate Choice (CC)	One of the 4 units for the carbohydrate amount that you can select when setting up the micropump system. 1 CC = 15 grams of carbohydrates
Carbohydrate ratio	The carbohydrate ratio defines the insulin amount necessary to compensate for a certain amount of carbohydrates consumed.

Term	Definition
Carbohydrate unit (KE)	One of the 4 units for the carbohydrate amount that you can select when setting up the micropump system. 1 KE = 10 grams of carbohydrates
Carbohydrates	Carbohydrates are nutrients that are broken down into glucose during digestion and increase blood glucose. Carbohydrates are generally counted to calculate a bolus insulin dose.
Control result	The value displayed on the diabetes manager after a control test. If the control result is within the range shown on the label of the test strip container, the test strips and the integrated meter of the diabetes manager are working properly.
Control test	A meter test using control solution that lets you know whether the integrated meter of the diabetes manager and the test strips are working properly.
Current time	The time you set via the <i>Settings</i> menu on the <i>Time and date</i> display.
Delivery lag time	Period of time before delivery of a programmed bolus begins.
End time	Time at which a time block ends
Error	Error messages are displayed when relevant malfunctions of the micropump system are registered. In case of micropump errors, the micropump switches to STOP mode. The micropump system can only be used again once the problem has been solved.
Extended Bolus	The extended bolus does not deliver the bolus insulin all at once, but over a programmable period of time.
Factory settings	The initial settings on the micropump system before you change or customize them.

Term	Definition
Flight mode	Setting that deactivates all wireless communication of the micropump system. Activate flight mode when you are in an airplane or when other situations require the <i>Bluetooth</i> wireless technology feature to be deactivated. Exchanging data between the diabetes manager and the micropump is not possible in flight mode.
Gram	One of the 4 units for the carbohydrate amount that you can select when setting up the micropump system.
Health event	Information on your current state of health or your activities. Each health event stands for a certain percentage according to your settings and is used to adjust bolus advice recommendations. Up to 4 health events can be selected and stored with a blood glucose result.
HI	Appears on the screen when the test result is above the diabetes manager's measurement range. HI stands for high.
Hyper	Hyperglycemia
Hypo	Hypoglycemia
Immediate amount	Insulin amount that is delivered at the beginning of a multiwave bolus and corresponds to a standard bolus.
Infusion site	Site at which the cannula is inserted into the subcutaneous tissue for insulin delivery.
Insulin	Insulin is a hormone that is necessary to process glucose. Insulin is produced in the beta cells of the pancreas.

Term	Definition
Insulin increment	The amount in units (U) by which your insulin dose is adjusted when programming a bolus or when making a manual logbook entry.
Insulin sensitivity	The insulin sensitivity (U : mg/dL) defines the insulin amount required to lower your blood glucose level by a certain value.
Limit value	The upper limit value and lower limit value together define the blood glucose target range. For bolus calculation, the mean value from the upper limit value and lower limit value is used as the blood glucose target value.
LO	Appears on the screen when the test result is below the diabetes manager's measurement range. LO stands for low.
Maintenance	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. Maintenance messages of the micropump switch the micropump to STOP mode.
Meal rise	The initially allowed increase in blood glucose level after a meal bolus.
Multiwave Bolus	A multiwave bolus combines a standard bolus with an extended bolus. A part of the bolus amount is delivered immediately, whereas the other part is delivered over a programmable period of time.
Occlusion	An occlusion prevents the insulin from flowing correctly from the micropump into your body.
Offset time	The offset time is the time period after which the insulin is expected to start lowering an elevated blood glucose level significantly and to start returning to the original blood glucose level after a meal.

Term	Definition
Paired	The diabetes manager and the micropump communicate with each other and transfer information to each other when they are paired.
Pen/syringe bolus	A bolus delivered using an insulin pen or syringe.
Quick bolus	Bolus that is programmed and delivered using the quick bolus buttons on the micropump.
Regular insulin	Insulin that has the same chemical structure as insulin produced by the human pancreas. Regular insulin usually needs 30 to 45 minutes to take effect.
Reminder	A feature the diabetes manager can use to remind you of an event, a task or a planned activity.
Settings	Settings are individually adjustable values and parameters that define the way the micropump system works.
Snack size	The snack size defines a carbohydrate threshold; when this is exceeded, a meal rise should be taken into account for bolus advice. Thus, the snack size indicates the carbohydrate amounts up to which no increase in the blood glucose level is to be tolerated after a meal.
Snooze	Reschedules a reminder or message to reoccur after a preset period of time (for example, after 15 minutes).
Standard Bolus	The standard bolus delivers the programmed insulin dose all at once.
Standard deviation (SD)	The standard deviation indicates how the values are scattered around the average. A high standard deviation means that the values are scattered away from the average.

Term	Definition
Start time	The start time of a time block.
STOP mode	When your micropump is in STOP mode, it does not deliver any insulin. Insulin delivery is only stopped if you switch to STOP mode, change the basal rate profile, make settings using a PC or when error messages or maintenance messages are issued. Ongoing boluses or temporary basal rates are interrupted when the micropump switches to STOP mode.
Target range	The target range describes which blood glucose values are considered acceptable before a meal or when fasting. The target range is specified by the lower and upper BG thresholds.
Temporary Basal Rate (TBR)	Temporary increase or decrease in your basal rate profile to match changing insulin needs due to increased or decreased activity level, illness or stress.
Time block	Time blocks help you to set the target range and the parameters insulin sensitivity and carbohydrate ratio for bolus advice for specific times of day. You can set up a maximum of 8 time blocks.
Time of test	Information on the point in time when a blood glucose result was obtained. The information can be stored together with a blood glucose result. When the results are subsequently analysed, either all test results can be displayed or only the test results for a specific time of test.
Total daily dose	The total amount of insulin (basal rate plus boluses) delivered in a 24-hour period, beginning at midnight.
U100	U100 indicates the insulin concentration. Each milliliter of liquid contains 100 units of insulin
Unit (U)	Unit of measurement for insulin

Term	Definition
Warning	Warnings inform you about situations that require your attention or draw your attention to a possible hazardous situation. The micropump system triggers a warning message if an action of your part is required in the near future.
Warning limit	When your blood glucose result is above or below the hyper or hypo warning limit, a warning is displayed. You should set the hyper and hypo warning limits together with your healthcare professional. In case of blood glucose results below the lower warning limit, no bolus advice will be calculated.

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