



Unio™  
Cara



User guide  
Blood glucose monitoring system

mg/dL



More freedom. More confidence. With mylife™.

**YPSOMED**  
SELFCARE SOLUTIONS

## Preface

Thank you for choosing the mylife™ Unio™ Cara blood glucose monitoring system. Please read this user guide thoroughly before testing your blood glucose. It provides all information you need to use the product. The mylife™ Unio™ Cara blood glucose meter must only be used with mylife™ Unio™ test strips and mylife™ ControlGDH control solution. The use of other test strips or control solutions may lead to incorrect test results.

It is recommended that the blood glucose level should be monitored regularly. The mylife™ Unio™ Cara blood glucose monitoring system is accurate and easy-to-use, and is therefore your reliable diabetes management assistant.

The mylife™ AutoLance™ lancing device and mylife™ Lancets are intended for patient self-monitoring by an individual. They must not be used on more than one person due to the risk of cross-contamination.

The mylife™ Unio™ Cara blood glucose monitoring system is manufactured by Bionime Corporation and distributed by Ypsomed Distribution AG.

If you have any questions or concerns, please contact your local Ypsomed customer service (see page 72).

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## Intended use

The mylife™ Unio™ Cara blood glucose monitoring system is intended for in-vitro (outside the body) diagnostic use for self-testing. The coding of the test strips is automatically detected. The test result is plasma equivalent and achieved by using (a) fresh capillary whole blood that may be drawn from the fingertip, palm or forearm, (b) venous whole blood samples and (c) arterial whole blood samples.

You may consult your healthcare professional for instructions on how to use the system correctly. Our customer support staff are available to assist you. Healthcare professionals may use the mylife™ Unio™ Cara blood glucose monitoring system for surveillance of the blood glucose levels of patients in medical facilities.

For a better understanding of this user guide, the mylife™ Unio™ Cara blood glucose monitoring system will be referred to as BGMS; the mylife™ Unio™ Cara blood glucose meter as meter; the mylife™ SoftCase as SoftCase; the mylife™ Unio™ test strips as test strips; the mylife™ AutoLance™ lancing device as lancing device; the mylife™ Lancets as lancets; the mylife™ ControlGDH control solution as control solution; the mylife™ App as app and the smartphone or personal computer as mobile device.

## mylife™ Unio™ Cara package contents



1



2



3



4

- 1 mylife™ SoftCase
- 2 mylife™ Unio™ Cara blood glucose meter (with 2 CR2032, 3 volt batteries installed)
- 3 Vial with mylife™ Unio™ test strips (10 pcs.)
- 4 mylife™ AutoLance™ lancing device
- 5 Disposable mylife™ Lancets (10 pcs.)
- 6 mylife™ Unio™ Cara user guide
- 7 mylife™ Unio™ Cara quick start guide
- 8 Diabetes diary



5



6



7



8

## **Bluetooth® wireless technology**

Bluetooth® wireless technology is used by most smartphones and many other devices. Your mylife™ Unio™ Cara meter uses Bluetooth® wireless technology to pair and to transmit your glucose results to compatible wireless devices (such as PCs and smartphones).

The mylife™ Unio™ Cara meter is designed to work with the mylife™ App.

Visit [www.mylife-diabetescare.com/software](http://www.mylife-diabetescare.com/software) for information on which wireless devices are compatible with your mylife™ Unio™ Cara meter, and where/how to download the mylife™ App and mylife™ Software on your compatible device.



**WARNING:** The Bluetooth® feature on your meter transmits test results to your compatible wireless device. To prevent other people's results from being sent to your compatible wireless device, do not let anyone else use your meter to test their blood glucose. This meter is for single patient use only.

**WARNING:** In locations where cell phone use is not permitted, such as hospitals, some healthcare professionals' offices and airplanes, you should turn the Bluetooth® feature off (flight mode). See page 20 for more information.

### **Bluetooth® trademark**

The Bluetooth® word mark and logos are owned by Bluetooth® SIG, Inc. and any use of such marks by Ypsomed Distribution AG is under license. Other trademarks and trade names are those of their respective owners.

## mylife™ Unio™ Cara blood glucose meter





## Display and symbol overview



	Indicates that Bluetooth® is configured and not in flight mode	<b>mg/dL</b>	Unit of the test result
	Indicates the pre-meal marker		Indicates the post-meal marker
	Indicates the exercise marker		Indicates the fasting marker
	Indicates the illness marker		Indicates when to apply the blood sample
	Indicates the average testing result		Indicates the test result stored in the memory
	Appears after test strip insertion into the meter	<b>AM PM</b>	Indicates the time format is 12H
	Indicates a control solution test result		Warns when the operational temperature limit is exceeded during testing
<b>888</b>	Test result		Current date under time mode or testing date under memory mode
<b>88:88</b>	Displays current time under time mode or testing time under memory mode		Warns when the battery is low or must be replaced
	The blood glucose result is within the target range		The blood glucose result is above the target range The blood glucose result is below the target range

## Menu guidance

To **turn on the meter**: press the main  button for 0.5 seconds or insert a test strip.

To **turn off the meter manually**: press and hold the main  button for 3 seconds.

To **turn off the meter automatically**: the meter will power off automatically after 30 seconds if no buttons are pressed or no strip is inserted.

To navigate in the menu of the meter use the following buttons:

 **To scroll down in the menu (F8 – F1)**

 **To scroll up in the menu (F1 – F8)**

## On the backside of the mylife™ Unio™ Cara meter the following short cuts are shown:

---

 +  2 sec → F1–F8 Press the down  and up  buttons simultaneously for 2 seconds to access the setting function mode.

---

 +  1 sec → /✂ Press the main  and up  buttons simultaneously for 1 second to turn on/off the flight mode.

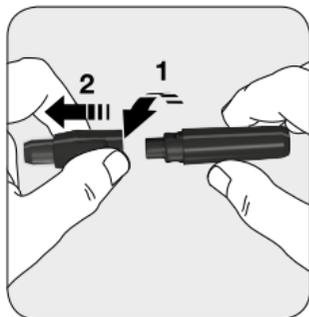
---

 +  1 sec →  Press the down  and main  buttons simultaneously for 1 second to set the alarms.

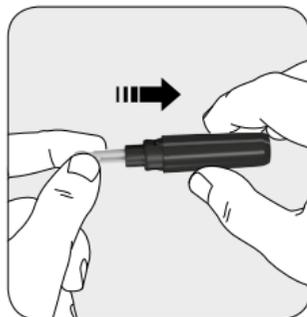
---

Short cuts are only applicable when the meter is on and no test strip is inserted.

## How to perform a blood glucose measurement



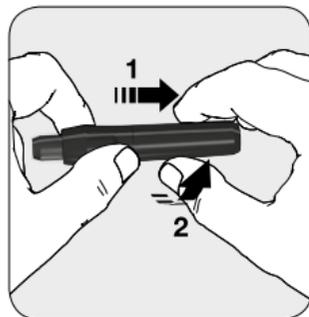
Take off the depth-adjustable cap by turning both parts smoothly in opposite directions.



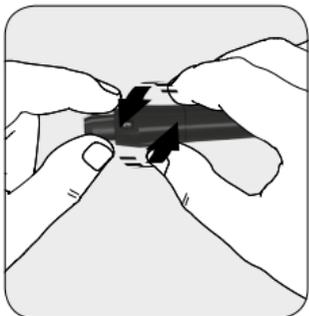
Insert a new disposable lancet firmly into the lancet carrier.



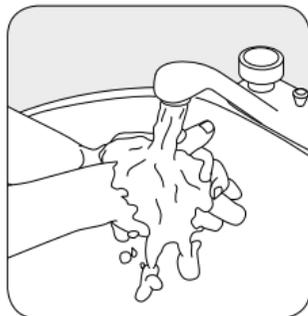
Twist off and set aside the protective cap of the disposable lancet.



Close the depth-adjustable cap by smoothly turning both parts into lock position.



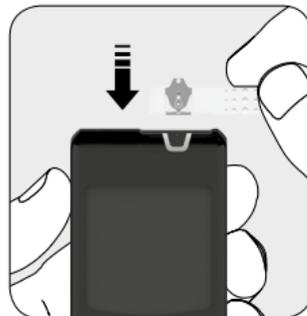
Choose the penetration depth by turning the cap. 1–3 for soft or thin skin; 4–5 for average skin; 6–7 for thick or calloused skin.



Wash and dry your hands.



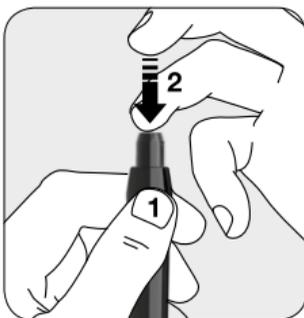
Take one test strip from the vial and close the cap of the vial immediately.



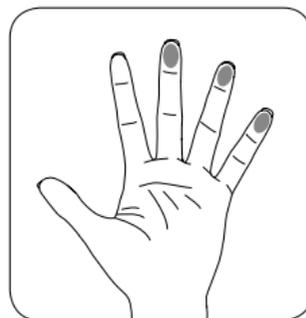
Insert the test strip into the test strip port on the meter. The meter will automatically activate.



Once the strip is inserted, the meter turns on, all symbols will appear on the meter display accompanied by a beep signal (if volume is turned on).



- 1 Press the security button to unlock the lancing device (keep pressing until finger is pricked).
- 2 Place the finger against the lancing device and press the finger on the cap. The lancing device has an automatic load and release function → no priming necessary.



Recommended sites for obtaining blood.



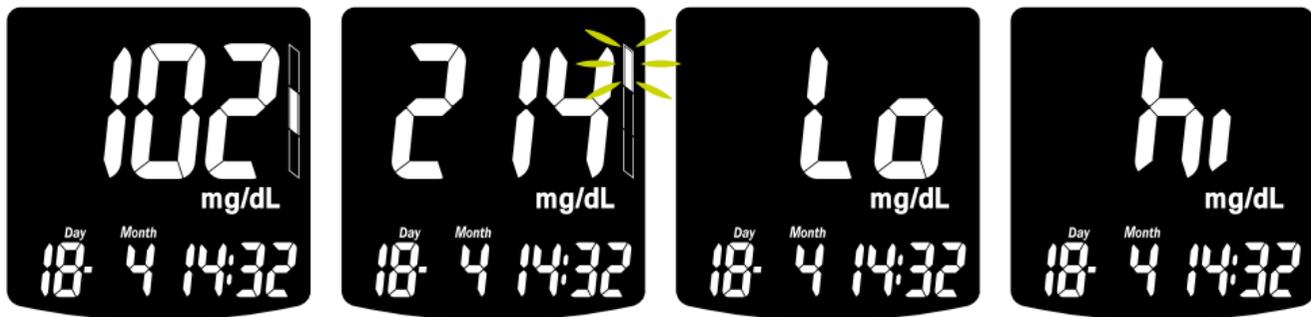
Gently squeeze your fingertip to get a drop of blood. Apply the blood drop to the edge of the test strip. When the viewing window is completely filled with blood, you will hear a beep (if the volume of the meter is switched on) and the measurement process starts.

If the view window of the test strip is not completely filled with blood, the measurement will not be performed. Discard the test strip and repeat the test with a new one.



The countdown mode will begin on the display window. After 5 seconds, the test result will appear.

**To upload data onto the mobile device, please refer to pages 20, 24 and 26.**



Beside the blood glucose result, you will also get an indication if your measurement is within, above or below the target range. This is indicated by a bar on the right side of the display (provided you have defined the blood glucose target range. See page 30).

The limit bar in the middle appears when your blood glucose is within your defined range.

The upper limit bar blinks twice if your measurement is above the defined target range. The lower limit bar blinks twice when your measurement is below the defined target range.

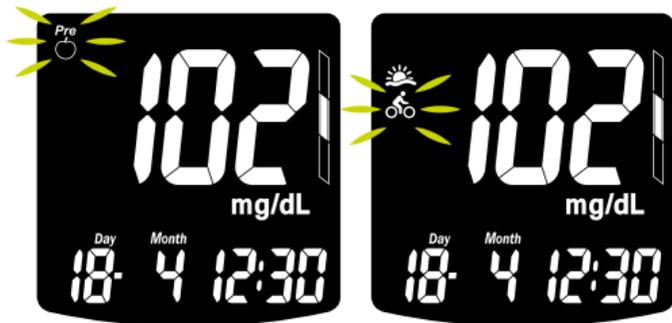
For further information about your test result, please consult your healthcare professional.

If your test result is below 10 mg/dL, "Lo" will appear on the screen. If your test result is above 600 mg/dL, "Hi" will appear on the screen. Please repeat your test with a new strip. If you still get a "Lo" or "Hi" result, you should immediately contact your healthcare professional.

## Markers

Markers have to be set after measurement within 10 seconds. They cannot be edited after confirmation. For every measurement, up to four markers can be set.

- Pre**  
 Before meal/pre-prandial.  
Set this marker before you eat.
- Post**  
 After meal.  
Set this marker after you have eaten.
-  Fasting.  
Set this marker after you woke up.
-  Sport.  
Set this marker when you are doing sports.
-  Ill.  
Set this marker when you are sick.



After performing a measurement, the pre-prandial symbol  will flash on the screen. You can set up to four markers per measurement. Select the markers by using the down  or up  button. To confirm a marker, press the main  button (short press), if you do not want confirm a marker, use the down  or up  button. In both cases the next marker will blink. If you don't want to set any marker or leave the marker setting, press the main  button for 1 second (long press) or remove the test strip. You will return to the home screen.

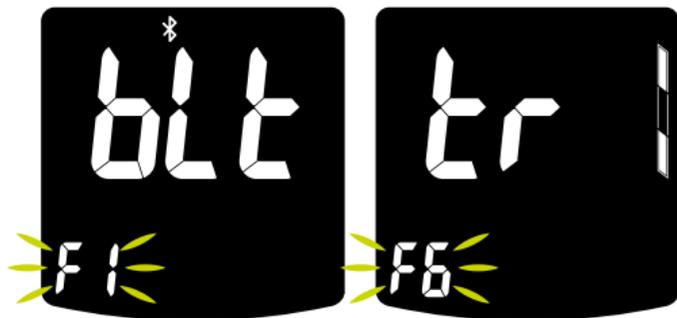
Remove the test strip from the meter. Dispose of the used test strip properly in compliance with local regulations.

## Settings: how to access the setting function mode

You can enter the setting function mode (F1 – F8) by pressing the down  and up  buttons for 2 seconds.

### There are 8 possible setting modes:

- F1 → Flight mode on/off
- F2 → Alarm
- F3 → Pairing
- F4 → Remove a paired device
- F5 → Date and time
- F6 → Blood glucose target range
- F7 → Volume on/off
- F8 → Control measurement



When entering the setting function mode, the setting function number blinks in the lower left corner. You can select the different setting functions by using the down  or up  button. When selecting a setting function confirm it with the main  button. You are then able to change the respective setting. The setting process of the selected setting function is completed after going through the setting flow. To confirm a setting function press the main  button (short press). If you wish to leave the setting function mode press the main  button for 1 second (long press). In both cases you will return to the home screen.

## Settings: Bluetooth® flight mode on/off

Before you can turn on/off flight mode, you first need to configure Bluetooth® by pairing at least one device (please refer to page 24).

When the meter is configured with a mobile device, the Bluetooth® symbol  is shown statically on the display (Bluetooth® is in sleep mode). After a measurement, Bluetooth® activates automatically. If Bluetooth® is in sleep mode and you are not performing a measurement but want to synchronise data with the app, you can activate Bluetooth® on the home screen by pressing the the main  and up  buttons simultaneously for 2 seconds.



If you wish to **turn off Bluetooth® flight mode** temporarily, press the main  and up  buttons simultaneously for 1 second. The Bluetooth® symbol  will appear.



If you wish to **turn on Bluetooth® flight mode** temporarily, press the main  and up  buttons simultaneously for 1 second. The Bluetooth® symbol  will disappear.



For more information about how to work with Bluetooth®, please refer to pages 24 and 26.

To set the **Bluetooth® flight mode via the setting function mode**, press the down  and up  buttons simultaneously for 2 seconds. Press the main  button to confirm **F1**.

Bluetooth® flight mode can be switched on or off. Scroll down  or up  to select on or off and confirm the settings with the main  button.

blt off = flight mode on

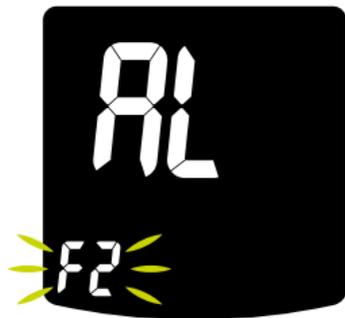
blt on = flight mode off

## Settings: set an alarm

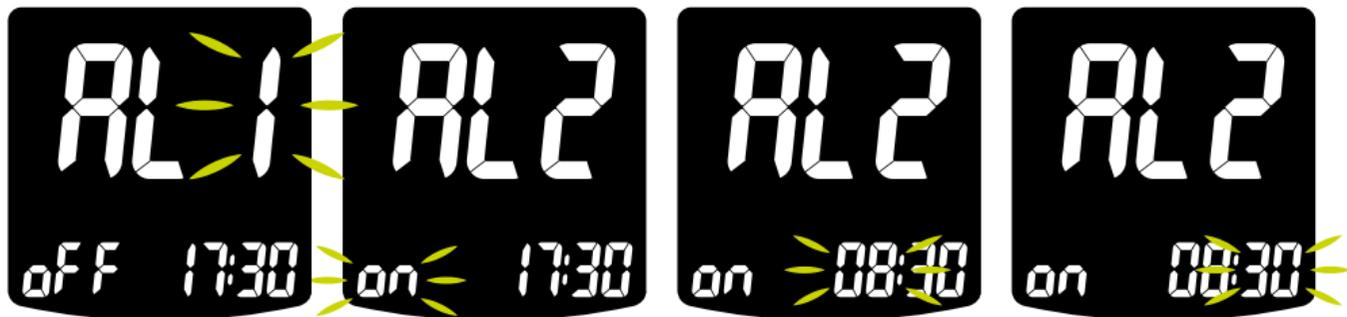
This feature reminds the user when to perform a test. There are 4 sets of alarms available.

When an alarm is turned on, the meter will beep for 30 seconds. To turn off the alarm, insert a test strip or press any button.

To set a daily alarm you can press the down  and main  buttons simultaneously for 1 second and you enter directly into the alarm mode (please see next page).



To enter the alarm function via the setting mode, press the down  and up  buttons simultaneously for 2 seconds. Scroll with the down  or up  button until you see **F2**. Confirm by pressing the main  button.



You can **set 4 alarms** from "AL 1" to "AL 4". Choose the number by pressing the down  or up  buttons. Confirm by pressing the main  button.

**Turn "on" or "off" the alarm** by pressing the down  or up  button. Confirm by pressing the main  button.

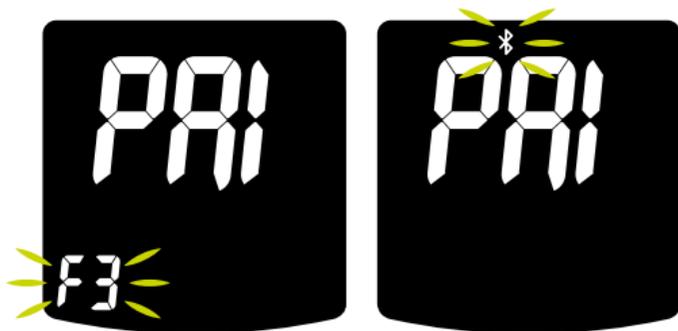
**Set the hour** by pressing the down  or up  button. Confirm by pressing the main  button.

**Set the minutes** by pressing the down  or up  button. Confirm by pressing the main  button.

## Settings: pairing/deleting a device

The mylife™ Unio™ Cara is equipped with Bluetooth® technology for wireless data transmission between the meter and a mobile device. Bluetooth® is turned off (deactivated) by default.

If you wish to use this wireless connectivity, you first need to establish a connection between the meter and a mobile device by going through the following pairing procedure:



Enter the pairing setting function by pressing the down  and up  buttons simultaneously for 2 seconds. Scroll with the down  or up  button until you see **F3**. Confirm by pressing the main  button.

The display shows “PAI” (for pairing) and the Bluetooth® symbol  will light up indicating that the procedure for pairing will be performed now. Make sure that Bluetooth® is turned on on your mobile device and that the app is activated.



As soon as a connection with a mobile device is established, a 6 digit passkey code is shown in the display. Enter the code into the app on your mobile device. This code must be entered within 30 seconds. If the time is exceeded or a wrong identification code is entered, the Er8 **Er8** and Bluetooth® **✕** symbols will blink. Repeat the procedure.



After having entered the code into the mylife™ App, the meter and mobile device are paired successfully by indicating the device no. d1, d2 or d3. Subsequently the home screen incl. Bluetooth® symbol **✕** will be shown.



- Up to 3 mobile devices can be paired with mylife™ Unio™ Cara.
- A device identifier (d1, d2 and d3) is provided by the meter. Note the name of your mobile device to every identifier d1 – d3 for example in the quick start guide in order to allocate each pairing to the corresponding mobile device.

	Bluetooth® is configured (= sleep mode), requires min. 1 paired device → The Bluetooth® symbol  is statically visible on the home screen
	Bluetooth® is activated and the meter is ready to connect with a mobile device → The Bluetooth® symbol  is flashing until a connection to the app is available (for max. 2 hours)
<b>No Bluetooth® symbol</b>	Bluetooth® is not configured because of no paired device OR Bluetooth® is configured and temporarily in flight mode → No Bluetooth® symbol visible

- Once your mylife™ Unio™ Cara is paired with at least one device, Bluetooth® is configured (in sleep mode). The Bluetooth® symbol  is statically visible on the screen.
- If a connection to a mobile device is available after a measurement, data will be automatically transmitted to the app.
- For battery lifetime reasons, Bluetooth® deactivates after data transmission to the app (Bluetooth® goes into sleep mode, not to be mistaken with flight mode).
- If no connection to a mobile device is available after a measurement, the meter remains connectable for a mobile device for 2 hours during which data can be polled by the app. The Bluetooth® symbol  is flashing during that time.
- If Bluetooth® is in sleep mode and you are not performing a measurement but want to synchronise data with the app, you can activate Bluetooth® on the home screen by pressing the main  and up  buttons simultaneously for 2 seconds.



To **delete a device from your meter** press the down  and up  buttons simultaneously for 2 seconds. You will get to the setting function mode. Press the down  or up  button until you see **F4**. Confirm with the main  button.

In the lower right corner "d1" blinks to prompt to select the device to be removed. Use the down  or up  button to select between all paired devices.

After having selected the appropriate device (d1, d2 or d3) to be removed, confirm the removal with the main  button.

## Settings: set date and time



You can enter the date/time setting mode by pressing the down  and up  buttons simultaneously for 2 seconds. Scroll with the down  or up  button until you see **F5**. Confirm by pressing the main  button.



With the year format blinking, press the down  or up  button until you see the current **year**. Confirm by pressing the main  button.



Once the year is confirmed, the **month** setting will appear. Press the down  or up  button until you see the current month. Confirm by pressing the main  button.



Once the month is confirmed, the **day** setting will appear. Press the down  or up  button until you see the current day. Confirm by pressing the main  button.



Once the day is confirmed, the **time format** selection will appear. With the time format blinking, press the down  or up  button to switch between 12H and 24H. Confirm by pressing the main  button.

Once the time format is confirmed, the **hour** setting will appear. Press the down  or up  button until you see the current hour. Confirm by pressing the main  button.

Once the hour is confirmed, the **minute** setting will appear. Press the down  or up  button until you see the current minute. Confirm by pressing the main  button.

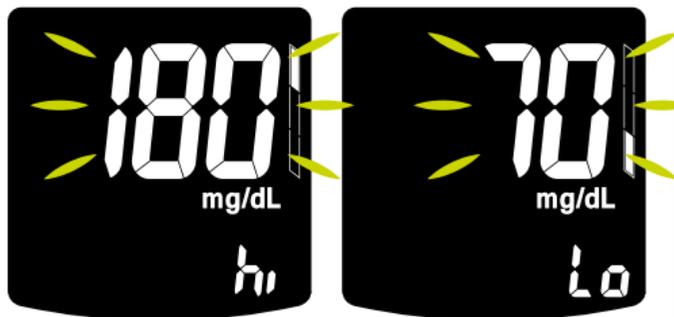
## Settings: set blood glucose target range



You can enter the blood glucose target range setting by pressing the down  and up  buttons simultaneously for 2 seconds. Scroll with the down  or up  button until you see **F6**. Confirm by pressing the main .

The target range function can be switched on or off (standard setting is off). Scroll down  or up  to select on or off and confirm the settings with the main .

When turning the blood glucose target range on, please define the target range limits as following:



The **upper limit** bar will appear and the blood glucose value will blink. Press the down or up button to adjust the value. Press the main button to confirm.

The **lower limit** bar will appear and the blood glucose value will blink. Press the down or up button to adjust the value. Press the main button to confirm.



The adjustable target range for the lower and upper limit is the same for both and lies between 60 mg/dL and 300 mg/dL. The lower limit cannot be higher than the upper limit and vice versa. Both limits cannot have the same value. Please discuss the blood glucose target range with your physician.

## Settings: volume on/off



You can enter the volume setting mode by pressing the down  and up  buttons simultaneously for 2 seconds. Scroll with the down  or up  button until you see **F7**. Confirm by pressing the main  button.

With the volume blinking, press the down  or up  button to turn the volume on or off. Confirm by pressing the main  button.

## Records: recall test results

The meter stores 1000 test results with time, date, marker and target range automatically.

If your meter has stored 1000 results, which is the maximum memory capacity, the oldest one will be deleted and the newest result will be stored. To recall your measured records, power on the meter without inserting a test strip by pressing the main  button.



Press any button to switch from the home screen to the memory mode. The memory symbol  in the upper left corner will be displayed. The latest test result will appear with the number "1" in the lower right corner.



Use the down  and up  button to review all previous results with date and time (and marker). Results are displayed from the most recent to the oldest.

## Averages: recall average test results



The meter is able to calculate averages. To recall the average of the measured test results, you have the option to choose between 1 day, 7 days, 14 days, 30 days, 60 days and 90 days.

The average will not be calculated with the results from the control solution test.

To recall your average test results, power on the meter without inserting a test strip by pressing the main  button. Press again 2 times the main  button.

On the top line the average symbol  is displayed.



To navigate from one average result to the other, use the down  and up  buttons.

The large number with the mg/dL specification indicates the calculated average of the measurements during the selected period (which is shown on the bottom line on the left). The number shown in the lower right corner indicates how many test results have been considered for the calculation.



On the bottom line on the right the number of calculated test results during the period is displayed.



The average function is related to the time setting. Time and date must be set correctly on your meter to enable correct average calculations.

The quantity of the measurements within the chosen days must be > 0. For example, the 14-day average will show no figure if no measurements have been performed during this time.

The “Lo” and “Hi” results, control solution test results and test results under abnormal temperature <math>< 6^{\circ}\text{C}</math> or <math>> 44^{\circ}\text{C}</math> will be excluded from average calculations.

## Quality control test with mylife™ ControlGDH control solution

A quality control test should be performed whenever you want to check if your BGMS is working properly or whenever you want to practise and check the correct the testing procedure.

Only use a control solution tested with the BGMS under control solution mode. If the test result is within the control solution range printed on the label of the test strip vial, the BGMS passes the quality control test. That means your BGMS is working correctly.

There are two different types of control solutions available: normal and high.

Control solution range	mg/dL	mmol/L
Normal	83 – 113	4.6 – 6.3
High	237 – 321	13.2 – 17.8

Example of control solution range printed on your test strip vial label.



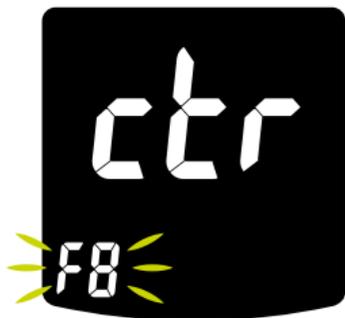


Example of opening date.

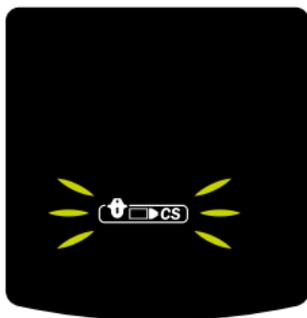


**Each time you open a new bottle of control solution, write the date of opening on the label. The control solution is usable for up to 3 months after opening the bottle, or until the expiry date printed on the label, whichever comes first.**

**Control solution test results do not represent your blood glucose level.**



Enter the control measurement by pressing the down  and up  buttons simultaneously for 2 seconds. Scroll with the down  or up  buttons until you see **F8**. Confirm by pressing the main  button.



A flashing control solution symbol  **CS** with the test strip  symbol appear.



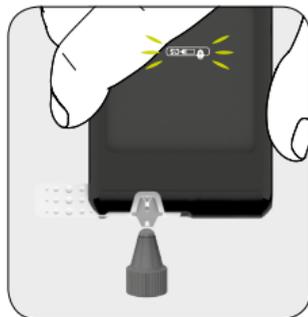
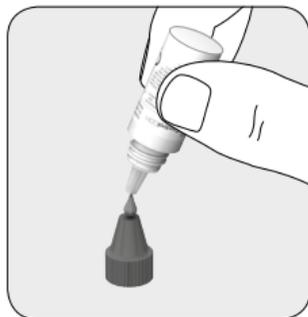
Take one test strip from the test strip vial and recap it immediately.



Insert the test strip into the test strip port.



As soon as the control solution symbol  CS with the test strip symbol  are stable, a flashing blood drop  prompts to apply the corresponding control solution.



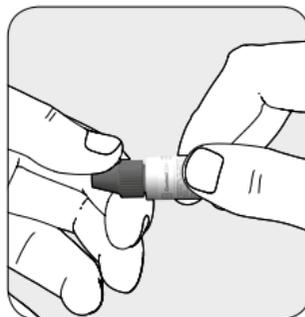
Before opening the cap of the control solution, shake the bottle well. Open the bottle and place the cap upright on the table. Drip a drop of control solution on the top of the cap. Gently place the sample entry of the test strip onto the drop of control solution on the top of the cap.



When you hear a beep (if volume is switched on) please wait for the test result. You will see the countdown mode on the screen.



After five seconds, the test result of the control solution test appears. The result will automatically be marked with the control solution marker (CS). Compare your quality control test result to the control solution range printed on the test strip vial label. This result will not be used for the average calculations of your meter.



Clean the top of the cap and close the cap on the control solution bottle.

If control solution results are out of range, your BGMS may not be working properly. Repeat the quality control test. If your control solution results are still out of range, do not use the BGMS.

Contact your local Ypsomed customer service (see page 72).

Possible reasons why your control solution results are out of range:

- Your control solution has expired or has been opened more than 3 months ago.
- Your test strips have expired or have been opened more than 12 months ago.
- Your control solution is diluted.
- The cap of the test strip vial or the control solution has been left open for a long time.
- The test procedure was not performed correctly.
- Malfunction of the meter or the test strip.
- Your control solution test has been performed out of normal temperature range (< 6 or > 44 °C).
- The surface of the cap of the control solution was not clean.



- Your control solution test results will not be included in the average calculations, but can still be recalled. The control solution test result will be marked with the “CS” symbol  CS on the screen.
- The suggested temperature range for the control solution test is 6–44 °C.
- Do not drip the control solution directly from the bottle onto the sample entry of the test strip. The reagent on the test strip could be sucked into the bottle of control solution and could cause the solution to degenerate. Doing so could potentially contaminate the meter via the test strip port.
- Do not touch the nozzle of the control solution bottle. If you have touched it, please clean it carefully with water.

## Data management

In addition to data management via Bluetooth® by the mylife™ App on a mobile device, the mylife™ Unio™ Cara meter lets you transfer data from the meter to a compatible PC-based software, such as the mylife™ Software, by means of a conventional micro-USB cable. Data transfer from the mylife™ Unio™ Cara to the mylife™ Software can also be carried out by using the Bluetooth® interface of the meter in combination with a specific dongle for the PC. To do this, the mylife™ Unio™ Cara initially needs to be paired with the PC. Please follow the instructions for pairing the meter and PC software as described in the section Settings: pairing/deleting a device on page 24.



**A micro-USB data cable or a Bluetooth® dongle for your PC can be ordered at your local Ypsomed customer service (see page 72).**

The mylife™ Software is a therapy management solution designed to cover the needs of people with diabetes and healthcare professionals for a thorough diabetes management. It has an intuitive and user-friendly design for ease of use, trend reports and useful statistics for a better therapy overview. The mylife™ Software is compatible with all mylife™ Diabetescare devices, such

as mylife™ Unio™, mylife™ Unio™ Neva, mylife™ Unio™ Cara, mylife™ Pura®, mylife™ Pura®X and mylife™ YpsoPump®, and a wide range of other devices for a complete therapy picture. Get more information about the mylife™ Software at

[www.mylife-diabetescare.com/software](http://www.mylife-diabetescare.com/software)



## Battery change

Your meter is delivered with 2 CR2032, 3 volt batteries installed. Two new batteries will provide power to perform about 1000 tests under normal circumstances. To insert the batteries, proceed as follows:



To insert/change the batteries of your meter, use a pen point to press the bottom-right spot on the cover, at the same time slide up the cover.

Remove the old batteries and insert the new ones. Be sure to insert the batteries in the correct direction (polarity (+) facing up).



Slide the battery cover back until it snaps into place.



The mylife™ Unio™ Cara meter will enter into the self-testing mode automatically when replacing the batteries (all symbols will appear on the screen). Press any button to exit the self-test and enter into the setting mode.



You must set the time and date when replacing the batteries. Please refer to page 28.

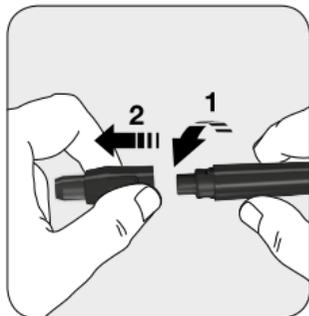


**Date and time need to be set again after each battery replacement. Measurements, target range, volume and pairing information will not be deleted when changing batteries.**

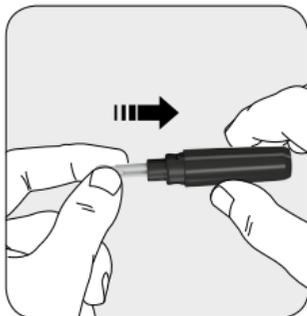
## mylife™ AutoLance™ overview



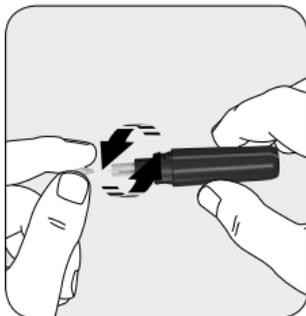
## Handling of mylife™ AutoLance™



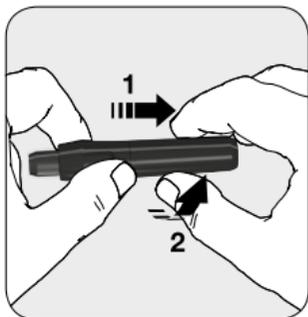
Take off the depth-adjustable cap by turning both parts smoothly in opposite directions.



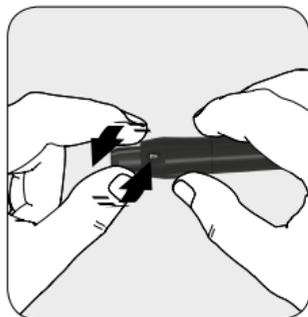
Insert a new disposable lancet firmly into the lancet carrier.



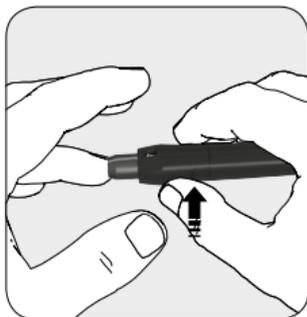
Twist off and set aside the protective cover of the disposable lancet.



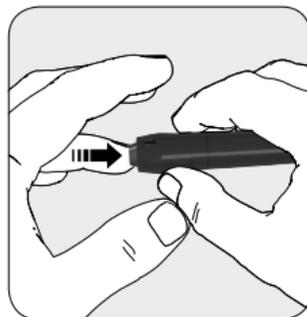
Close the depth-adjustable cap by smoothly turning it into lock position.



Choose the penetration depth by turning the cap. 1–3 for soft or thin skin; 4–5 for average skin; 6–7 for thick or calloused skin.

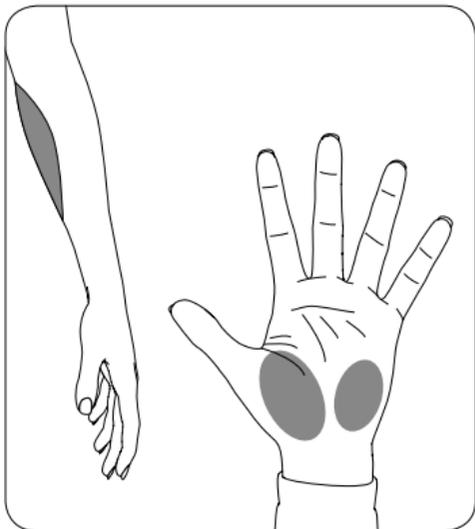


Place the finger against the lancing device and press the safety button.



While pressing the safety button, press your finger smoothly on the cap. The lancing device loads and releases automatically. No priming necessary.

## Alternative site testing (AST)

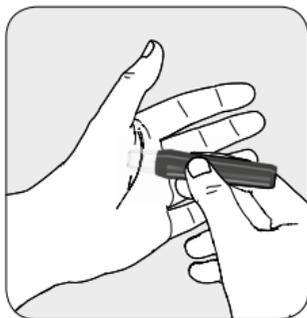
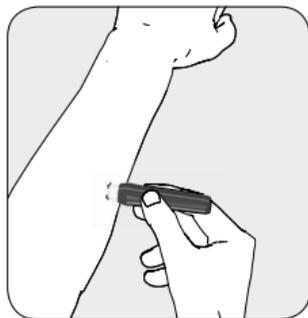
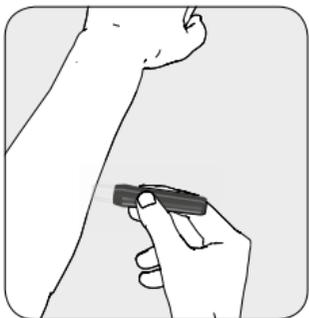


The AST function can enable you to test the blood glucose level on sites other than the fingertips and helps you to avoid repeatedly pricking the fingertips and thus reducing pain.



Select the clear AST cap to perform a measurement on an alternative site.

**The AST cap can be ordered at your local Ypsomed customer service (see page 72).**



Massage the puncture area of the palm or forearm for a few seconds and immediately after massaging the puncture area, press and release the lancing device with the clear cap against it.

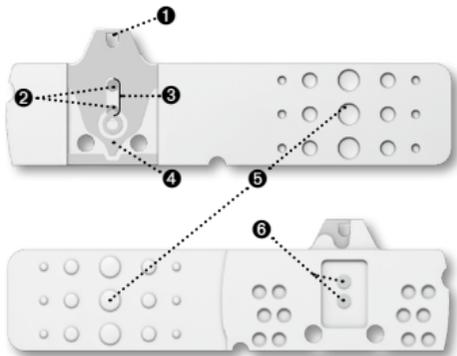
Continue holding the lancing device against the puncture site, and gradually increase pressure for a few seconds until the blood sample size is sufficient.



- The blood glucose test results of blood samples taken from different sites may vary in certain conditions; rapid changes in glucose levels following a drink or a meal, an insulin dose or exercise may be seen. In these cases, only the fingertip should be used.
- DO NOT test on the palm or forearm if you are testing for hypoglycaemia (low blood glucose) or hypoglycaemia perceptual disorder.
- Fingertip samples can show rapid changes of glucose faster than palm or forearm samples.
- As the blood flow taken from the forearm or palm is slower than from the fingertip, we recommend using the lancing device with clear cap (AST cap) for testing at sites other than the fingertip.

## mylife™ Unio™ test strips

The meter must only be used with mylife™ Unio™ test strips. The use of other test strips may lead to incorrect test results.



### ❶ Sample entry

Apply a drop of blood or control solution here. The test requires only 0.7 µL of blood.

### ❷ Gold electrodes

Electrochemical sensor with GDH-FAD enzyme.

### ❸ Viewing window

This window is yellow before applying blood sample. It gradually turns red as it fills with blood.

### ❹ Indication symbol

Insert test strip with indication symbol up front and down towards meter.

### ❺ Handle bar

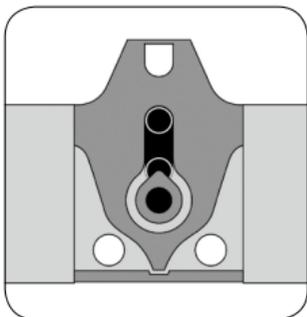
Grip here to insert test strip into meter.

### ❻ Electrode contacts

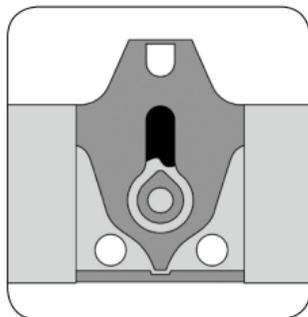
Sensing signal output terminals.



- Close the test strip vial immediately after taking out the test strip.
- Do not reuse test strips. Test strips are intended to be used only once.
- Do not use expired test strips.
- Record the date of opening a new test strip vial for the first time. Discard the vial of test strips 12 months after the first opening.
- Store the test strips in a cool (4–30 °C) and dry location (<90 % relative humidity). Do not expose to heat or direct sunlight.
- If the meter and test strips are exposed to considerable temperature variation, please wait 30 minutes before measurement.



Make sure your blood sample covers the whole area of the viewing window to get an accurate test result.



An insufficient blood sample can result in an error message (see page 65). If this occurs, repeat the test with a new test strip.

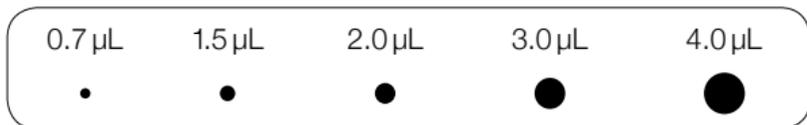


- Check the expiry date printed on the test strip vial every time you use a test strip. Do not use expired test strips.
- Use each test strip immediately after removing it from the vial.
- Fill the blood drop only to the sample entry of the test strip.
- Please do not drip or inject the blood sample directly onto the sample entry of the test strip using a syringe. Doing so may contaminate the meter or cause damage.

## Precautions

- Before using the BGMS to test your blood glucose, please read the user guide carefully.
- The meter must only be used with mylife™ Unio™ test strips and mylife™ ControlGDH control solution. The use of other strips or control solutions may lead to incorrect results.
- If the meters and test strips are exposed to considerable temperature variation, please wait 30 minutes before performing the measurement.
- Dispose of used batteries properly in compliance with local regulations.
- Please note that the BGMS contains small parts (e.g. test strips) which are a potential choking hazard for children.
- Do not allow water to enter the meter. Never immerse the meter or hold it under running water.

- The minimum blood sample size for testing is 0.7  $\mu\text{L}$ .



- Please use a minimum of 0.7  $\mu\text{L}$  to perform the test with the BGMS. A blood sample size above 3.0  $\mu\text{L}$  might contaminate the test strip port and the meter. Make sure your blood sample covers the whole area of the view window to get an accurate test result. A sample size below 0.7  $\mu\text{L}$  may lead to an error message (see page 65). If this occurs, repeat the test with a new test strip.

## Limitations of the mylife™ Unio™ Cara meter

- For capillary, venous and arterial whole blood testing only. The BGMS is not intended for serum or plasma testing.
- Inaccurate test results may be obtained at an altitude of more than 3048 meters (10000 feet).
- Severe dehydration may cause inaccurately low results.
- The glucose test may be invalid if abnormally high concentrations of the following are present: ascorbic acid  $\geq 5$  mg/dL, xylose  $\geq 20$  mg/dL, uric acid  $\geq 20$  mg/dL.
- If the mylife™ Unio™ Cara meter and mylife™ Unio™ test strips are exposed to considerable variation in temperature, please wait 30 minutes before measurement.
- Do not test the blood sample from palm or forearm when glucose is changing rapidly (scenarios: after drinking, after meal, after exercise).
- Do not test on the palm or forearm if you are testing for insulin dose calculations or hypoglycaemia (low blood glucose).
- The blood sample from palm or forearm should not be tested when testing for hypoglycaemia (low blood glucose).
- To avoid potential electromagnetic or other interference, keep meter away from electromagnetic radiation sources such as X-rays or MRI.

## Maintenance, cleaning and disinfection

- Keep your meter and test strip free of dust, water or any other liquid. If the meter is dropped or damaged, perform a quality control test (see page 37) before performing a blood glucose test to ensure that the meter is still functioning correctly.
- Clean and disinfect the outside of the device only. Do not remove the battery cover when cleaning and disinfecting.
- Clean the outside of the meter with a damp cloth and mild soap or detergent. Do not wet the test strip port.
- Always keep the metal contact points of the test strip entry port clean. If any dust or impurities appear, please clean with a small soft brush, otherwise the meter may not work correctly when you insert a test strip.
- Users should wash their hands thoroughly with soap and water after handling the meter, lancing device or test strips.
- Please examine your LCD screen, test strip port, buttons and surface of your meter and lancing device after cleaning and disinfecting. Stop using the meter and/or lancing device if any of the following occur:
  - Thin, sliver streaks appear on the screen.
  - The screen becomes cracked, soft, dissolved, brittle or swollen.
  - You are unable to turn on/off your meter, operate the up/down button, the lancing device release button or depth-adjustable cap.
  - You are unable to enter meter settings, function modes or recall your testing results.

## Clean and disinfect the meter



To **clean the meter** thoroughly wipe the entire surface of the meter with disinfecting wipes to remove any possible dirt, dust, blood and other body fluids.

### To **disinfect the meter**:

1. Take another disinfecting wipe and wipe the meter thoroughly (note: all blood and body fluids should be cleaned from surface before disinfection).
2. Allow the surface to remain wet for 1 minute.
3. Allow to air-dry.

## Clean and disinfect the lancing device



To **clean the lancing device** thoroughly wipe the entire surface of the lancing device with disinfecting wipes to remove any possible dirt, dust, blood and other body fluids.



To **disinfect the lancing device**:

1. Take another disinfecting wipe and wipe the lancing device thoroughly (note: all blood and body fluids should be cleaned from surface before disinfection).
2. Allow the surface to remain wet for 1 minute.
3. Allow to air-dry.

## Error messages and troubleshooting



### Error 0: Strip damage

The inserted test strip has been used or damaged.

Please use a new test strip.



### Error 1: Battery

The battery symbol  and Er1 symbol **Er 1** appear and the meter will not function when the battery is low.

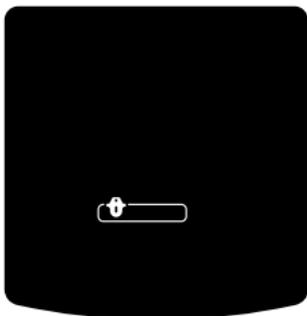
Please change the batteries immediately (see page 46).



### Error 2: Sampling

Do not apply the blood to the sample port of the test strip before the sample symbol  is displayed.

Please discard the test strip if the meter shows the Er2 symbol **Er2** and repeat the test with a new test strip.



### **Error 3: Strip insertion**

When the test strip is inserted incorrectly, the meter will beep 4 times while the strip symbol  flashes. Do not apply a sample on the test strip.

Please reinsert the unused test strip correctly. If, after performing the required steps, the strip symbol  and flashing Er3 symbol **Er3** appear on the screen, the test strip has been inserted incorrectly more than twice. Please reinsert the unused test strip again after reviewing the steps on how to insert a test strip correctly on page 13 or call your local Ypsomed customer service for support (see page 72). This error message can also indicate that you may have used the wrong test strips. Please check the test strip vial to ensure you are using mylife™ Unio™ test strips.



### **Error 4: Meter malfunction 1**

The meter has malfunctioned.

Please perform a quality control test or reinstall the battery to check if the meter works properly.



#### **Error 5: Signal**

The signal transmission is disrupted.

Please repeat the test by using a new test strip.



#### **Error 6: Blood sample**

The blood sample volume is insufficient.

Please repeat the test by using a new test strip.



#### **Error 7: Calibration**

A calibrating error occurred. Please follow the steps below:

1. Remove the test strip from the meter.
2. Turn off the meter (press and hold the main  button for 3 seconds).
3. Press the main  button to turn on the meter.

If **Er7** is not shown after turning on the meter, your meter is functioning properly and is able to perform a test. If the meter still does not work, please contact your local Ypsomed customer service (see page 72).



#### **Error 8: Bluetooth®**

Timeout during pairing procedure.

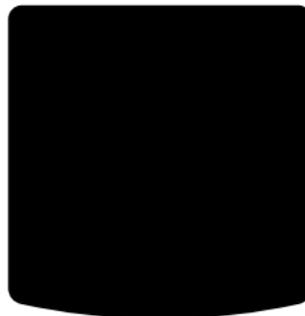
1. No connection. Make sure a) the app is installed, started and in pairing mode, b) Bluetooth® is enabled and c) the mobile device is close enough (max. 10 m).
2. Passcode not entered in time: repeat the pairing process and make sure that the passcode provided by the meter is entered immediately on the mobile device.



#### **Error 9: Max. devices**

A maximum of 3 mobile devices have already been paired to the meter.

To add a new device, delete one first. Confirm the warning with the main  button (see page 24).



#### **Error 10: Meter malfunction 2**

If the meter will not turn on, please follow the steps below:

1. Open the battery cover and remove the battery.
2. Wait for 5 minutes and reinsert the battery as instructed on page 46.

If the meter still does not work, please contact your local Ypsomed customer service (see page 72).



#### **Error 11: Temperature**

In order to get accurate test results, please test at a temperature between 6–44 °C. When the temperature is below 6 °C or above 44 °C, the meter will not function. The temperature symbol  and Er11 symbol **Er11** are displayed.

If the meter and test strips are exposed to a substantial change in temperature, please wait 30 minutes before the measurement.



**A blood sample should only be applied to the test strip after the test strip has been inserted correctly and the meter's screen is showing the image of the test strip and a flashing blood drop symbol. If the flashing blood drop symbol is not showing on the screen, do not apply a sample to the test strip. Please reinsert the unused test strip correctly. The screen must show the image of the test strip accompanied by the flashing blood drop symbol (this symbol takes 3 seconds to show after correctly inserting the test strip) in order for a sample to be applied. For instruction please consult your user manual and/or contact your local Ypsomed customer service (see page 72).**

## Technical specifications

Measurement technology	Electrochemical sensor GDH-FAD
Reference device	Olympus AU400
Measurement calibration	Plasma
Sample	Capillary, venous and arterial whole blood
Minimum sample volume	0.7 $\mu$ L
Coding	Autocoding (no user interaction required)
Measuring range	10–600 mg/dL
Test time	5 seconds
Memory capacity	1 000 measurements
Power saving	On
Operating temperature	6–44 °C
Operating relative humidity	10–90 %
Haematocrit	20–70 % when blood glucose $\leq$ 200 mg/dL 20–60 % when blood glucose $>$ 200 mg/dL

Power supply	2 CR2032 batteries
Meter battery life	1 000 measurements
Meter dimension	82 × 50 × 15.5 mm
Meter weight	59 ± 5 g
Monitor	LCD display
Meter storage conditions	-10–60 °C
Test strip storage conditions	4–30 °C, < 90 % relative humidity
Data interface	Option A: wireless via Bluetooth® (transmission range 10 m) Option B: micro-USB port (micro-USB/USB-A-type cable)
Data management	Data can be transferred to the mylife™ App and to a PC-based software, such as the mylife™ Software. SiDiary, Diabass® and diasend® conformity to be reconfirmed. Please contact your local customer service (see page 72).

## Disposing of the mylife™ Unio™ Cara meter, mylife™ Unio™ test strips, mylife™ AutoLance™ and mylife™ Lancets



- During blood glucose measurement, the meter may come into contact with blood. Used meters therefore carry a risk of contamination. Please dispose of your used meter after removing the batteries in compliance with local regulations. For information about correct disposal, please contact your local authority.
- Used test strips and lancets are potentially infected. Please dispose of the used test strip and/or the puncture-proof or biohazard container for your used lancets in compliance with local regulations.

## Warranty

- The manufacturer warrants that your mylife™ Unio™ Cara blood glucose monitoring system will be free from defects in materials and workmanship for five years from the date of purchase.
- This warranty does not apply to the performance of a mylife™ Unio™ Cara blood glucose monitoring system that has been altered, misused, tampered with or abused in any way.
- This warranty applies only to the original purchaser of the mylife™ Unio™ Cara meter.
- This warranty does not apply for any damage caused by the use of other test strips than mylife™ Unio™ test strips.

## Customer service

We are keen to provide a comprehensive service to our customers. Please review all the instructions to ensure that you are performing all measurement steps correctly. If you have any questions, or in the event of any problems with mylife™ Unio™ products, please contact your local Ypsomed customer service:

- AT** Ypsomed GmbH, Am Euro Platz 2, AT – 1120 Wien  
Kostenlose Service-Hotline: 00800 55 00 00 00  
info@ypsomed.at, www.mylife-diabetescare.at
- BE** Ypsomed BVBA, Researchdreef 12, BE – 1070 Brussel  
Ypsomed SPRL, Allée de la Recherche 12, BE – 1070 Bruxelles  
Klantenservice/Service clientèle: 0800 -294 15, info@ypsomed.be, www.mylife-diabetescare.be
- CH** Ypsomed AG, Brunnmattstrasse 6, CH – 3401 Burgdorf  
Kostenlose Service-Hotline/numéro gratuit/numero verde: 0800 44 11 44  
info@ypsomed.ch, www.mylife-diabetescare.ch
- DE** Ypsomed GmbH, Höchster Straße 70, DE – 65835 Liederbach  
Kostenlose Service-Hotline: 0800 9776633, info@ypsomed.de, www.mylife-diabetescare.de
- DK** Ypsomed ApS, Smedeland 7, DK – 2600 Glostrup  
Tel: +45 48 24 00 45, info@ypsomed.dk, www.mylife-diabetescare.dk
- ES** Ypsomed Diabetes, SLU, Avda. Madrid 95, 5° 1ª, ES – 08.028 Barcelona  
Atención al cliente: 900373955, info@ypsomed.es, www.mylife-diabetescare.es

- FI** Ypsomed Oy, Eteläinen Salmitie 1, FI-02430 Masala  
Asiakaspalvelu: +358 (0)9 250 1350, info@ypsomed.fi, www.mylife-diabetescare.fi
- FR** Ypsomed S.A.S, 44 rue Lafayette, FR-75009 Paris  
Service clientèle: 0800 883058, info@ypsomed.fr, www.mylife-diabetescare.fr
- IN** Ypsomed India Pvt Ltd., 10/61/1-F, Kirti Nagar Industrial Area, IN-New Delhi-11015  
Customer care: 099999 75157, info@ypsomed.co.in, www.mylife-diabetescare.co.in
- NL** Ypsomed BV, Postbus 1190, NL-3430 BD Nieuwegein  
Klantenservice: 0800-9776633, info@ypsomed.nl, www.mylife-diabetescare.nl
- NO** Ypsomed AS, Papirbredden, Grønland 58, NO-3045 Drammen  
Tel: +47 22 20 93 00, info@ypsomed.no, www.mylife-diabetescare.no
- SE** Ypsomed AB, Adolfsbergsvägen 31, SE-168 67 Bromma  
Kundtjänst: 08 601 25 50, info@ypsomed.se, www.mylife-diabetescare.se
- UK** Ypsomed Ltd., 1 Park Court, Riccall Road, North Yorkshire, Escrick, UK - YO19 6ED  
Customer care: 0344 856 7820, info@ypsomed.co.uk, www.mylife-diabetescare.co.uk

## Description of symbols used

 Manufacturer	 EU Representative
 For in-vitro diagnostic use	 For single use only
 Use by	 Storage temperature limitations
 Sterilised using irradiation	 Caution (consult instructions for use and warnings)
 CE Mark	 CE Mark with number of Notified Body
 Consult instructions for use	 Lot number
 Reference number	 Serial number
 Separate collection of electrical and electronic equipment	 Biological risks
 Global Trade Item number (international and unique identifier for trade items)	

## Manufacturer

### **mylife™ Unio™ Cara meter, mylife™ Unio™ test strips, mylife™ ControlGDH control solution**

Manufacturer: Bionime Corporation

No. 100, Sec. 2, Daqing St., South Dist., Taichung City 40242, Taiwan

The products comply with In-Vitro Diagnostic Directive 98/79/EC (CE 0197).

EU Representative: Bionime GmbH, Tramstrasse 16, 9442 Berneck, Switzerland

### **mylife™ AutoLance™ lancing device**

Manufacturer: Bionime Corporation

No. 100, Sec. 2, Daqing St., South Dist., Taichung City 40242, Taiwan

The product complies with Medical Device Directive 93/42/EEC (CE).

EU Representative: Bionime GmbH, Tramstrasse 16, 9442 Berneck, Switzerland

### **Disposable mylife™ Lancets**

Manufacturer: SteriLance Medical (Suzhou) Inc.

No. 68 Litanghe Road, Xiangcheng, Suzhou, 215133, China

The product complies with Medical Device Directive 93/42/EEC (CE 0197).

EU Representative: Emergo Europe, Prinsessegracht 20, 2514 AP, The Hague, The Netherlands



**Diabetescare**



Bionime Corporation  
No. 100, Sec. 2  
Daqing St., South Dist.  
40242 Taichung City  
Taiwan



Bionime GmbH  
Tramstrasse 16  
9442 Berneck  
Switzerland  
info@bionime.ch

Manufactured for  
Ypsomed Distribution AG  
3401 Burgdorf  
Switzerland  
www.mylife-diabetescare.com

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