

Distribution France

Ypsomed S.A.S
18/20 Rue Soleillet
FR-75020 Paris
Tél.: +33 (0)015870 2000
Fax: +33 (0)015870 2001
Numéro gratuit: 0800 883058
info@ypsomed.fr
www.mylife-diabetescare.fr

Distribution UK

Ypsomed Ltd
Blackwood Hall Business Park
North Duffield
Selby, North Yorkshire
YO8 5DD
Customer Care: +44 844 856 7820
Fax: +44 844 5070 443
Email: info@ypsomed.co.uk
www.mylife-diabetescare.co.uk

**BIONIME CORPORATION**

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

EC	REP
----	-----

Bionime GmbH

Tramstrasse 16,
CH-9442 Berneck / Switzerland
E-mail: info@bionime.ch

Manufactured for
Ypsomed Distribution AG
CH-3401 Burgdorf
Switzerland



0197

101-3GM550-353

FR+EN

**Pura™**

Système de mesure de la glycémie
Blood glucose monitoring system

**Manuel de l'utilisateur
User manual**

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

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

The mylife™ Softlance lancing device and the mylife™ Lancets 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-infection.

The mylife™ Pura™ blood glucose monitoring system is manufactured by Bionime Corporation and supported by Ypsomed Distribution AG. If you have any question or concerns, please contact your local Ypsomed customer service (see page 48).

The mylife™ Pura™ blood glucose monitoring system is intended for in vitro (outside the body) diagnostic use for self testing. Coding is automatically detected. The test result is achieved using fresh capillary whole blood samples from the fingertip, palm or forearm. You may consult your healthcare professional for instructions on how to use the system correctly. Our customer support staff is of course also available to assist you.

Healthcare professionals may use the BGMS for surveillance of the blood glucose levels of patients in medical facilities in the UK.

Hereinafter the mylife™ Pura™ blood glucose monitoring system will be referred to as BGMS; the mylife™ Pura™ blood glucose meter as meter; the mylife™ Pura™ blood glucose test strips as test strips; the mylife™ Softlance lancing device as lancing device; the mylife™ Lancets as lancets; and the mylife™ Control / Pura™ control solution as control solution, for short.

Table of contents

About mylife™ Pura™ BGMS	
Package of mylife™ Pura™ BGMS	6
mylife™ Pura™ meter	8
Precautions for mylife™ Pura™ BGMS	12
mylife™ Pura™ test strip	14
Preparing for test	
Meter activation and battery change	16
Setting up your meter – Setting the date, time and volume	18
Switching the mylife™ Pura™ meter on/off	22
Switching the backlight on/off	23
Testing procedure	
Performing a blood glucose test with mylife™ Pura™ BGMS	24
Alternative site testing (AST)	28
View window appearance	30

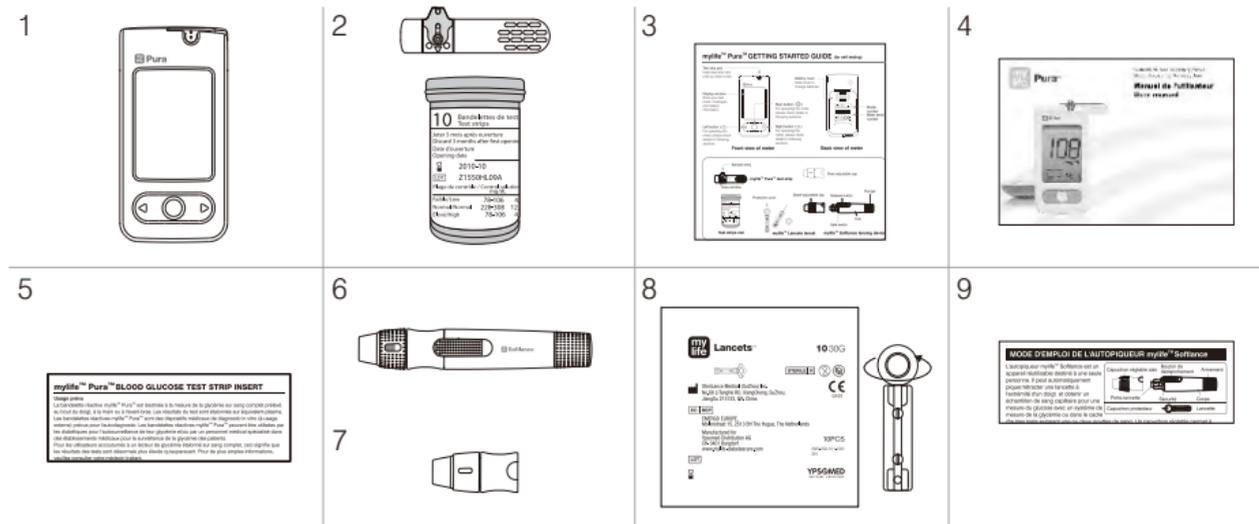
Table of contents

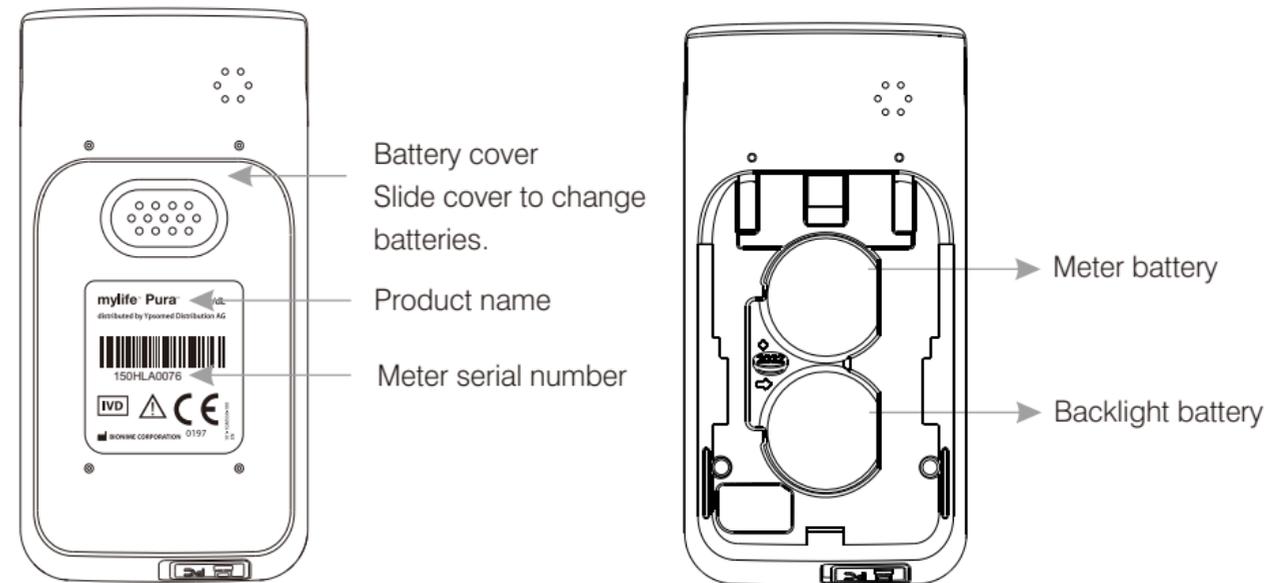
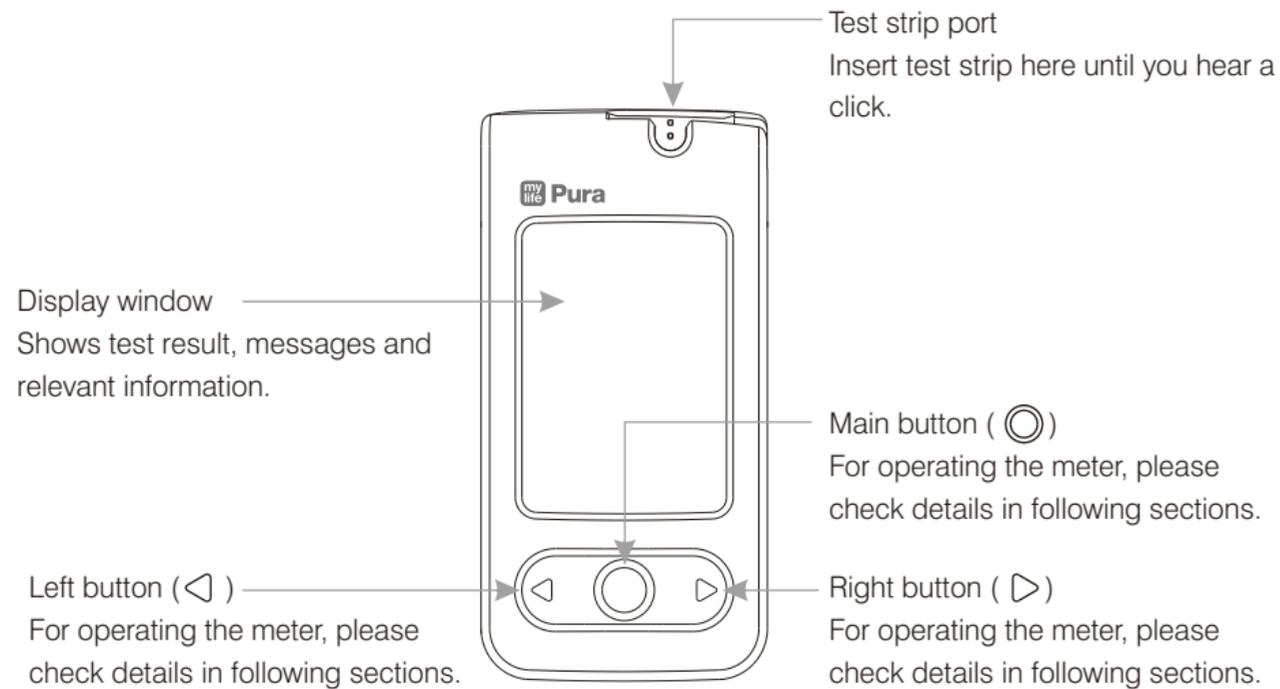
Quality control	
"Lo" and "Hi" readings of mylife™ Pura™ meter	31
Quality control test with mylife™ Control / Pura™ control solution	32
Review your test memory	
Performing a quality control test	34
Recalling test results and averages	37
Error messages and trouble shooting	
Specification of mylife™ Pura™ meter	44
Limitations of mylife™ Pura™ meter	46
Meter data transmission management (optional)	47
Customer service	48
Description of used symbols	48
Warranty	49
Disposing of the mylife™ Pura™ meter, test strips and lancets	49
Main parts	50

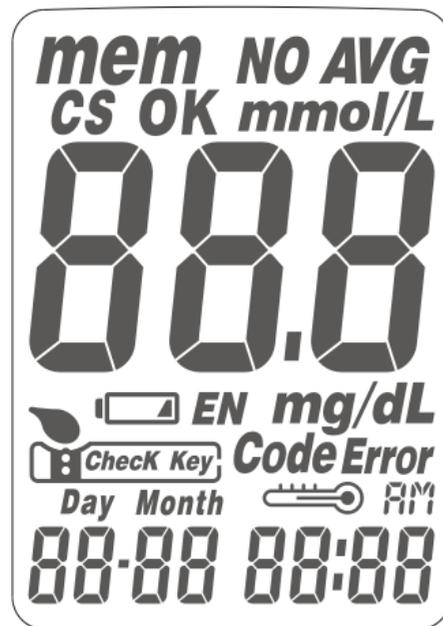
Package of mylife™ Pura™ BGMS

1. mylife™ Pura™ meter (with 2 CR2032 batteries installed)
2. mylife™ Pura™ test strips (10 pcs)
3. mylife™ Pura™ getting started guide
4. mylife™ Pura™ BGMS user manual
5. mylife™ Pura™ blood glucose test strip insert
6. mylife™ Softlance lancing device
7. mylife™ Pura™ clear adjustable cap ("AST")
8. Disposable mylife™ Lancets lancets (10 pcs)
9. Instructions for the mylife™ Softlance lancing device
10. mylife™ Pura™ warranty card
11. mylife™ Pura™ carrying case

Package of mylife™ Pura™ BGMS







mem	Indicates a test result stored in meter memory (memory mode)		Indicates when to apply the blood sample
NO AVG	Indicates a test result which is not included in the average function of this meter		Test strip (internal calibration and autocoding)
AVG	Indicates the average result (average mode)	Code Error	Warns if test strip is not inserted correctly or wrong test strip has been used
CS	Indicates a control solution test result	Day Month 	Current date (time mode) or testing date (memory mode)
mmol/L mg/dL	Unit of test result according to presetting		Indicates if environmental temperature parameters are exceeded during testing
888	Test result	AM	Indicates the time in 12h format
	Warns when the battery is low or must be replaced	88:88	Current time (time mode) or testing time (memory mode)
OK EN Check Key Manufacturing use only			

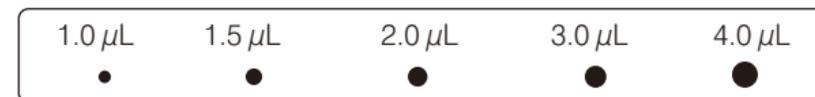
Precautions for mylife™ Pura™ BGMS

- Before using the BGMS to test your blood glucose, please read the instructions for use carefully.
- The meter must only be used with mylife™ Pura™ test strips and mylife™ Control / Pura™ control solution. The use of other test strips or control solutions may lead to incorrect results.
- The BGMS has not been validated for use on neonates. It should not be used on neonates.
- The BGMS is not intended for arterial blood glucose testing.
- If the meters and test strips are exposed to a considerable temperature variation, please wait 30 minutes before measurement.
- Dispose of used batteries properly.
- Please note 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.

Precautions for mylife™ Pura™ BGMS

- The minimum blood sample size for testing is 1.0 μL (●).

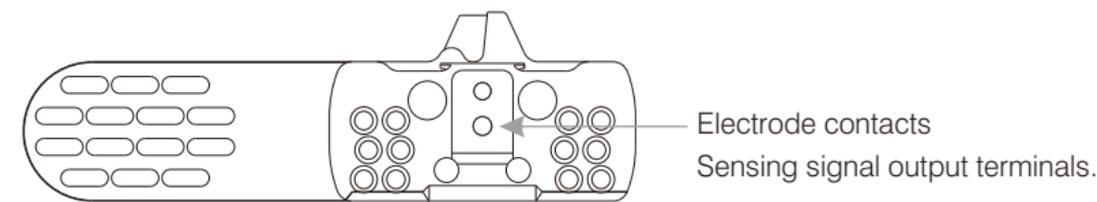
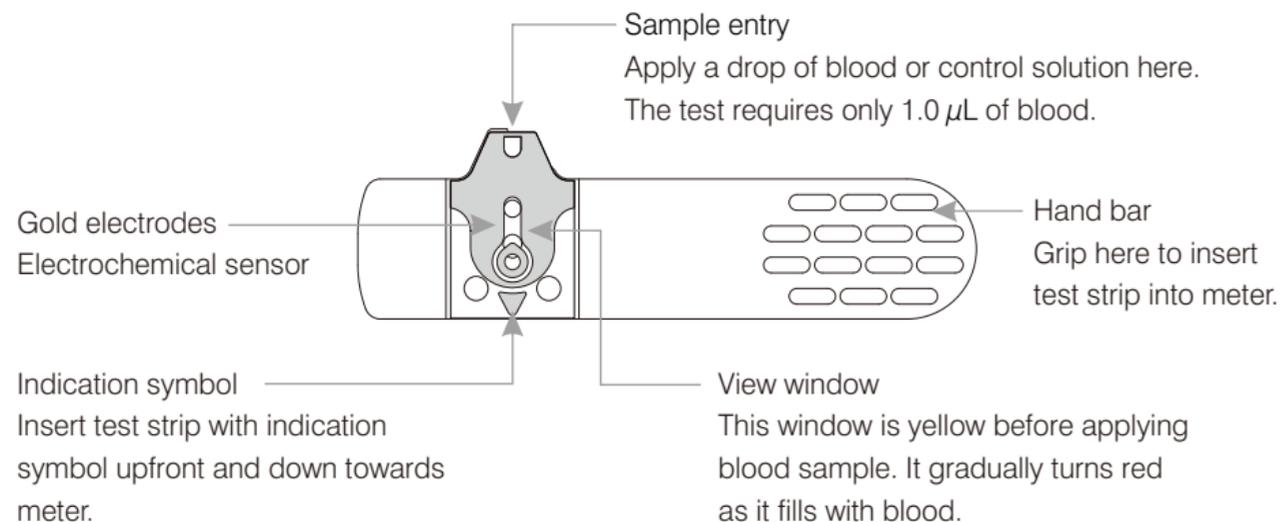
Sample size example



Please take a minimum of 1.0 μL to do the test on the BGMS. A blood sample size above 3.0 μL 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 1.0 μL may lead to an error message "Error 4". (see page 40). If this occurs, repeat the test with a new test strip.

The meter must only be used with mylife™ Pura™ test strips and mylife™ Control / Pura™ control solution.

The use of other test strips or control solutions may lead to incorrect results.



PRECAUTION

- Recap the test strip vial immediately after taking out a 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 6 months after first opening.
- Store the test strips in a cool (4-30°C resp. 39-86°F) and dry location (<90% relative humidity). Do not expose to heat or direct sunlight.
- For detailed information, please refer to the mylife™ Pura™ test strips package insert.
- If the meter and test strips are exposed to considerable temperature variation, please wait 30 minutes before measurement.

Meter activation and battery change

Your meter comes with two CR2032, 3 volt, batteries installed. Two new batteries will provide power to perform about 1,000 tests under normal use. Press the main button or insert a test strip to activate your meter.



NOTE

- When the meter backlight ceases to function, please change your backlight battery.
- When the backlight battery runs out of power the meter will still work properly, but without backlight illumination.

Meter activation and battery change



1. Turn the meter over. Press and push battery cover to open.



2. Install the battery. Be sure to put battery in correct way with the "+" symbol up.



3. Slide the battery cover back until it snaps into place.

4. The meter performs a self test.

5. Press any button to exit the self test and enter setting mode.

6. Set the time and date after the batteries are replaced. See chapter "Setting up your meter – Setting the date, time and volume". Test results are still retained in the memory.



PRECAUTION

- Please follow local regulations and discard used battery properly.

Setting up your meter – Setting the date, time and volume

You can enter setting mode in two ways:

1. Reload meter battery

After removing the meter battery, press the main button several times until the screen is blank, then follow the battery installation steps to load batteries. The meter will perform a self test. Press the main button to exit the self test and enter setting mode.

2. With battery inserted

First press the main button to switch on the meter. Then press the main button again for a further 7 seconds until you hear a beep, indicating that you have successfully entered setting mode. The display screen will show setting data.



NOTE

- After pressing the main button for 2 seconds, the screen backlight is activated. Press the main button for another 2 seconds and the backlight and display switch off.
- Continued pressure on the main button for a further 3 seconds elicits a beep, and the meter enters setting mode.
- A quick press of the main button allows setting changes. However, if you want to return to the time mode, you must go through all the settings first by repeated pressing of the main button.

Setting up your meter – Setting the date, time and volume

1. Year setting

With the year format flashing, press the left or right button to adjust it. Then press the main button to confirm it. It will then shift to next digit for setting. Repeat the above action until the year setting is completed and it will move to month setting.



2. Month setting

With the month flashing, press the left or right button until the current month appears. Then press the main button to confirm it and it will move to day setting.



3. Day setting

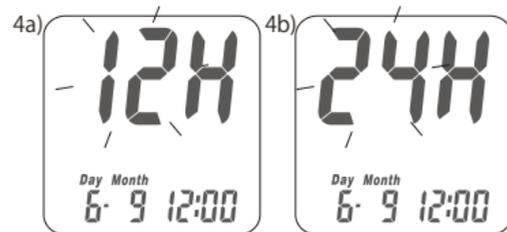
With the day flashing, press the left or right button until the current day appears. Then press the main button to confirm it and it will move to time format setting.



Setting up your meter – Setting the date, time and volume

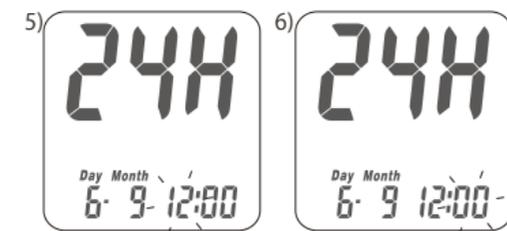
4. Time format 12/24h selection

With the time format flashing, press the left or right button to adjust it. Then press the main button to confirm it and it will move to hours setting.



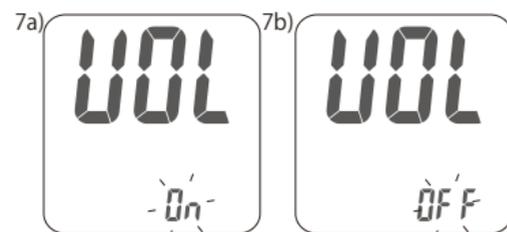
5. Hour setting

With the hour flashing, press the left or right button until the current hour appears. Then press the main button to confirm it and it will move to minute setting.



6. Minute setting

With the minute flashing, press the left or right button to adjust it. Then press the main button to confirm it. Then it will move to volume setting.



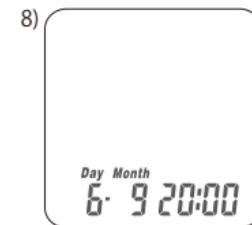
7. Volume setting

With the volume flashing, press the left or right button to switch it on or off. Then press the main button to confirm and finish the settings.

Setting up your meter – Setting the date, time and volume

8. Finishing setting up

After volume settings, you will hear a confirmation beep (if volume is switched on). All the settings are saved, and the display will return to time mode (if volume is switched off, the display will return to time screen without the beep).



NOTE

- Your meter is now ready for use. The meter default will depend upon the units of measurement normally used in your country.
- If the meter is unused for more than 2 minutes, it will automatically exit setting mode and switch off.

Switching the mylife™ Pura™ meter on/off

1. How to switch on the meter

Press the main button or insert a test strip.

2. Manual power off

Press the main button for 4 seconds.

3. Auto power off

If the meter is unused for more than 2 minutes, it will automatically switch off.

Switching the backlight on/off

1. How to switch on the backlight

Press the main button for 2 seconds after power is on.

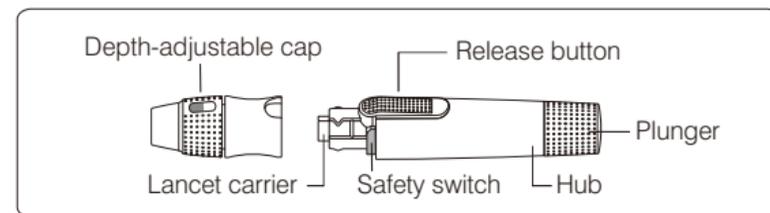
2. Manual backlight off

Press the main button for another 2 seconds.

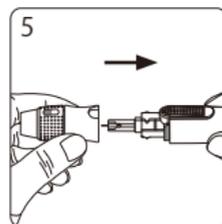
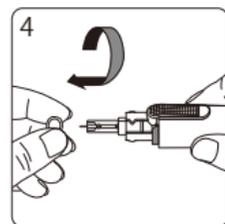
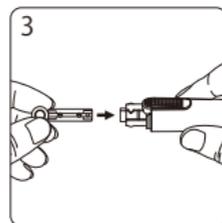
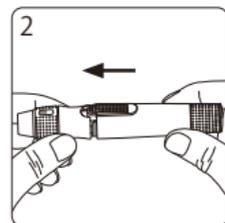
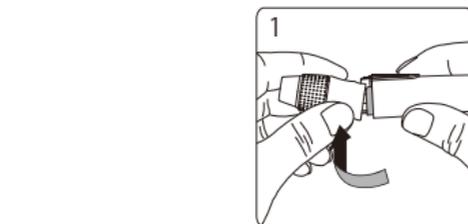
3. Auto backlight off

The meter backlight will automatically switch off if the meter is unused for more than 10 seconds.

Performing a blood glucose test with mylife™ Pura™ BGMS

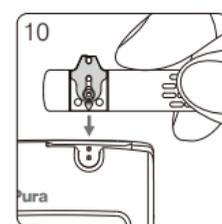
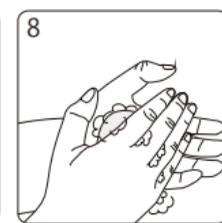
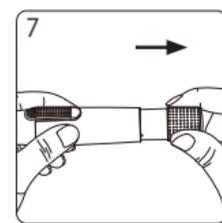
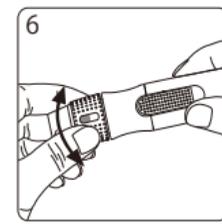


1. Hold the depth-adjustable cap in one hand and hold the hub in the other hand. Bend the cap to one side.
2. Pull off the depth-adjustable cap.
3. Insert a new disposable lancet firmly into lancet carrier.
4. Twist off and set aside the protective cover of the disposable lancet.
5. Replace the depth-adjustable cap.



Performing a blood glucose test with mylife™ Pura™ BGMS

6. Choose penetration depth by rotating the top portion of the depth-adjustable cap until the required setting depth is indicated in the window. Settings are based on skin type "▣▣▣" for soft or thin skin; "▣▣▣▣" for average skin; "▣▣▣▣▣" for thick or calloused skin.
7. Hold the hub in one hand and pull on the plunger with the other hand. This cocks the lancing device. Release the plunger, which will automatically move back to its original position against the hub. The device is now ready to use.
8. Wash your hands with warm soapy water and dry thoroughly.
9. Take one test strip from the vial. Recap the vial immediately.
10. Insert the test strip into the test strip port of the meter with the indication symbol facing down. The meter confirms the insertion of the test strip with a beep (if volume is switched on).

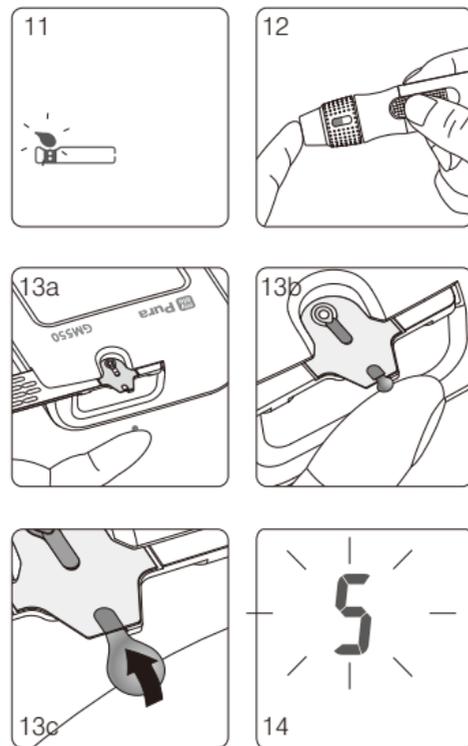


NOTE

The meter will automatically detect the code number on the test strip.

Performing a blood glucose test with mylife™ Pura™ BGMS

11. A blood drop symbol appears and is accompanied by a further beep (if volume is switched on). The blood sample must then be applied within the next two minutes.
12. Place the lancing device against your fingertip and press the release button.
13. Touch and hold the drop on the edge of sample entry until you hear a beep (if volume is switched on) and the view window is totally filled with blood. If the view window is not completely filled, or the test does not start, please discard the test strip and repeat the test with a new test strip.
14. You will see the countdown mode on the screen. After 5 seconds, the test result will appear.

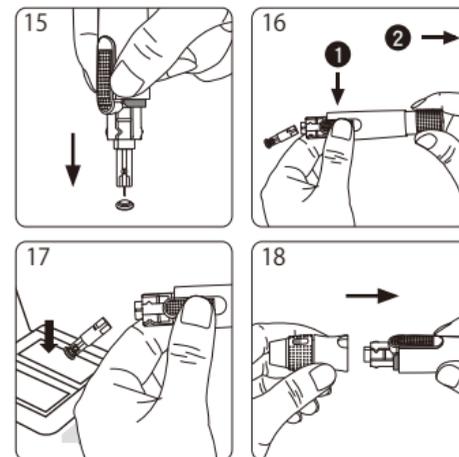


NOTE

Please dispose of the used test strip and/or the puncture-proof or biohazard container for your used lancets according to your local regulations.

Performing a blood glucose test with mylife™ Pura™ BGMS

15. Pull off the depth-adjustable cap of the lancing device. Without touching the used disposable lancet, stick the lancet tip into its protective cover.
16. Pressing the release button with one hand (see figure 16, step 1) and pulling on the plunger with the other hand (see figure 16, step 2) will safely eject the used lancet.
17. Dispose the used lancet into an appropriate puncture-proof or biohazard container.
18. Replace the depth-adjustable cap after finishing the test.



⚠ PRECAUTION

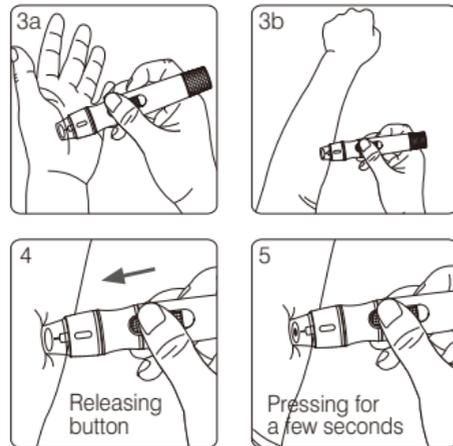
- Do not present your blood drop to the sample entry on the test strip until you see the "☹" appear. The meter is performing an internal test and will display "☹" and "Error" if you apply blood too soon. If this occurs, repeat the test with a new test strip.
- Record the date of first opening of a new test strip vial. Discard the test strip vial 6 months after first opening.
- Always keep the metal contact points of the test strip entry point clean. If any dust or impurities are present, please clean with a small soft brush, otherwise the meter may not work correctly when you insert a test strip.

10 Bandolette de test Test strips	
Jeter 3 mois après ouverture Discard 3 months after first opening	
Date d'ouverture Opening date	
2010-10	
LOT Z1550HL09A	
Plage de contrôle / Control solution range	
Faible/Low	78-106 4
Normal/Normal	228-308 12
Elevé/High	78-106 4

Alternative site testing (AST)

Alternative site testing: Palm or forearm blood sampling

1. Select clear cap ("AST") and follow steps 1 to 11 on pages 24 to 26.
2. Massage the puncture area of palm or forearm for a few seconds.
3. Immediately after massaging the puncture area, press and hold the lancing device with the clear cap against it.
4. Press the release button.
5. Continue holding the lancing device against the puncture site, and gradually increase pressure for a few seconds until the blood sample size is sufficient.
6. Follow steps 13 to 14 on page 26 to complete the test.
7. Follow steps 15 to 18 on page 27 to discard the used disposable lancet.



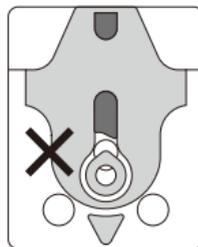
Alternative site testing (AST)

PRECAUTION

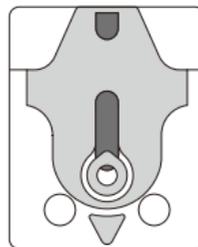
- The blood glucose test results of blood samples taken from different sites might vary in certain conditions, such as rapid changes in glucose levels following a drink or a meal, an insulin dose, or exercise. In these cases, only the fingertip should be used.
- DO NOT test on the palm or forearm if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

View window appearance

Make sure your blood sample covers the whole area of the view window to get an accurate test result. An insufficient blood sample can result in an error message ("Er4"). If this occurs, repeat the test with a new test strip.



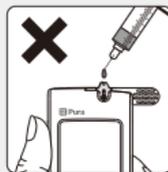
Insufficient blood sample



Sufficient blood sample

PRECAUTION

- 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 from the vial.
- Do not reuse test strips.
- If the meters and test strips are exposed to a considerable temperature variation, please wait 30 minutes before measurement.
- Present 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 test strip using a syringe. Doing so may contaminate the meter or cause damage, and is not recommended.



"Lo" and "Hi" readings of mylife™ Pura™ meter

The meter displays results between 10 and 600 mg/dL. If your test result is below 10 mg/dL, "Lo" will appear on the screen. Please repeat your test using a new test strip. If you still get a "Lo" result, you should immediately contact your healthcare professional or follow their instruction for therapy.

If your test result is above the high end of the BGMS detection range (above 600 mg/dL), "Hi" will appear on the screen. Please repeat your test using a new test strip. If you still get a "Hi" result, you should immediately contact your healthcare professional or follow their instruction for therapy.



NOTE

- If your blood glucose result is unusually high or low, or if you question your testing results, repeat the test using a new test strip function. You can also run a quality control test (see page 32) to check your meter and test strip. If the test result remains unusually high or low, contact your healthcare professional immediately or follow their instruction for therapy.
- If you are experiencing symptoms that are not consistent with your blood glucose test results and you have followed all instructions in this manual, contact your healthcare professional immediately or follow their instruction for therapy.

Quality control test with mylife™ Control control solution

When should a quality control test be performed?

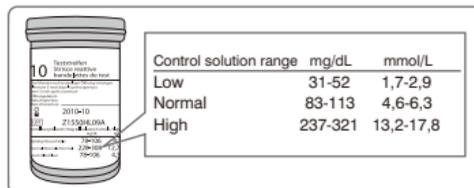
Whenever you want to check whether or not your BGMS is working properly.

Whenever you want to practice testing and check correct procedure.

Please use control solution tested with BGMS under control solution mode. If the test result is within the control solution range printed on the strip vial label, the BGMS passes the quality control test.

That means your BGMS is working correctly.

Control solution range:



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

Quality control test with mylife™ Control control solution

Possible reasons your control solution results are out of range:

- Your control solution has expired or has been opened for more than 3 months.
- Your test strip has expired or has been opened for more than 6 months.
- 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 (<10°C and >40°C resp. <50°F and >104°F).

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 outside the range, do not use the BGMS. Contact your local Ypsomed customer service (see page 48).

⚠ PRECAUTION

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

📎 NOTE

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

Example of expiry date:



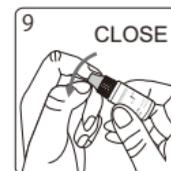
Performing a quality control test

1. Take one test strip from vial and recap immediately.
2. Insert the test strip with indication symbol upfront and down into test strip port.
3. While the blood drop symbol is flashing, press and hold the main button for more than 3 seconds until the "CS" symbol appears.
4. You will see flashing "☉" and "CS" symbols on the screen, prompting you to apply the control solution.
5. Before opening the cap, shake the bottle of control solution well. Open the bottle and place the cap upright on the table.
6. Drip a drop of control solution on the top of the cap.
7. Gently touch the sample entry of the test strip onto the drop of control solution on top of the cap.
8. 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 5 seconds, the test result will appear.



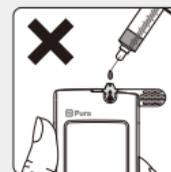
Performing a quality control test

9. Clean the top of the cap and tightly replace the cap on the control solution bottle.
10. The control solution result appears. Compare your quality control test result to the control solution range printed on the test strip vial label.



PRECAUTION

- Your control solution test results will not be included in average reading calculations, but can still be recalled. The control solution test result will be shown with the "CS" symbol on the screen.
- Our suggested temperature range for the control solution test is 15~40°C (59~104°F).
- Before "☉" and "CS" appear, please do not present the control solution to the sample entry on test strip because the meter is still performing an internal check. If you do so, the meter will show "☉" and "Error", accompanied by beeps (if volume is switched on).
- 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's degeneration. Doing this 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.



Performing a quality control test

Maintenance

Keep your meter and test strip free of dust, water or any other liquid. Store the meter in the carrying case when not in use. If the meter is dropped or damaged, perform a quality control test before doing a blood glucose test, to insure that the meter is still functioning correctly.

Cleaning the meter

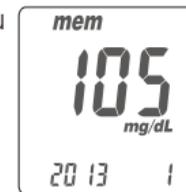
Clean the outside of the meter with a damp cloth and mild soap or detergent. Do not wet the test strip port.

Always keep the metal contact points of the test strip entry point clean. If any dust or impurities are present, please clean with a small soft brush, otherwise the meter may not work correctly when you insert a test strip.

Recalling test results and averages

The meter is able to store 500 test results with time and date automatically. If your meter has stored 500 results, which is the maximum memory, the newest test result will replace the oldest one. To recall your test memory, switch on the meter without a test strip inserted.

1. Press the main button to switch from the time mode to the memory mode. First you will see the "mem" symbol in the upper left corner of the display. When you press the right hand button, the latest result is displayed. By pressing the right hand button continually previous test results will be shown in date order. You will see the sequence number in the lower right corner and the year in the lower left corner of the display, followed by date and time of the measurement.



NOTE

The right hand button is for reviewing the tests in ascending order, and the left hand button is for reviewing in descending order. The number "1" is the latest test result, while the number "500" is the oldest test result.

2. To end review of tests in memory, press main button again, and you will enter the averages mode. Press the right hand button and the display shows "AVG" in the upper right corner and the average value for the day. By continually pressing the right hand button you will get to the 1-day, 7-day, 14-day, 30-day and 90-day averages of your blood glucose values. You will see the number of calculated days in the lower left corner and the number of calculated readings in the lower right corner.

Recalling test results and averages



3. Non-averaging set and canceled:

You may select the unwanted or doubtful test results and exclude them from the average calculation, after each test. After measurement, as long as the test strip is clicked in the meter it is called "test mode". After removing the test strip it is called "memory mode". After finishing your test in the "test mode", you can exclude an unwanted result by pressing the right hand button until you see the symbol "NO AVG" in the top right hand corner of the screen. Keep the right hand button pressed and press the main button simultaneously to confirm the value as "non-average". After removing the test strip from the meter the measured test result will be stored in memory mode and cannot be amended. This value will now remain flagged by the "NO AVG" symbol.

If you want to cancel this non-average setting, stay in the "test mode". Press the right hand button until the "NO AVG" symbol changes to "AVG" in the upper right hand corner of the screen. To confirm this original status you again simultaneously press the main button. The value will now be stored as a regular value and included in the average values.



NOTE

- The average function is related to the time setting. Time and date must be set correctly to

Recalling test results and averages

enable averages to show. For example, the 14-day average will show no figure if there have been no tests recorded in the 14 days prior to, and including, the current date.

- The non-averaging/re-averaging function only works in the "test mode" and when you have a result. In the memory mode ("mem"), this action cannot be performed.

4. Quick searching: If you want to see all values automatically displayed in sequence, first enter the memory mode. Then press the right or left button for 2 seconds. The right hand button is for scrolling the most recent to oldest results; the left hand button scrolls from the oldest to the most recent. Anytime you want to stop, just release the button. The current value will be displayed. Any particular reading can thus be checked.
5. Reading immediately after test: If you have just finished a test, press the main button to enter the "mem" (memory) mode and review this latest test result.



NOTE

Your control solution test results will be automatically non-averaged, but may still be recalled. They will appear under the "CS" symbol in the memory mode.

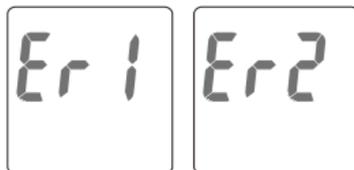


PRECAUTION

- Time and date must be set in order to activate the average function.
- "Lo" and "Hi" results, control solution results and test results recorded out of normal temperature range (<10°C and >40°C resp. <50°F and >104°F). are not included in the averages calculations.

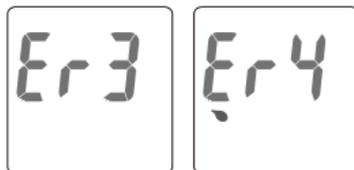
Error messages and trouble shooting

Er1 - The inserted test strip has been used or is damaged. Please use a new test strip from vial.



Er2 - Meter has malfunctioned. Perform a quality control test with control solution, or reinstall the batteries to check if the meter works properly. Check once more meter function.

Er3 - Signal transmission is disrupted; repeat the test with a new test strip.



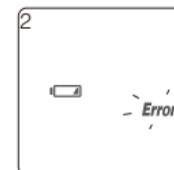
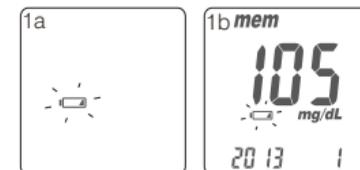
Er4 - Applied blood volume is insufficient, please repeat the test with a new test strip.

If the error screen still appears, contact your local Ypsomed customer service (see page 48).

Error messages and trouble shooting

Battery error

1. The "  " symbol flashes when battery power is low. Change meter battery as soon as possible. The test may still be performed.
2. The "  " and "Error" symbols are flashing when the battery power is too low. The meter cannot perform the test. Please change the battery immediately.



NOTE

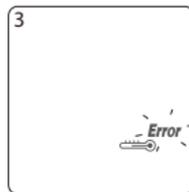
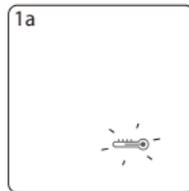
- When the meter backlight doesn't function, please change your backlight battery.
- When the backlight battery runs out of power, the meter will still work properly, but without backlight illumination.

Error messages and trouble shooting

Temperature error

In order to ensure accurate test results, perform testing between 10~40°C (50~104°F).

1. When the ambient temperature is 0~9°C (32~48°F) or 41~50°C (106~122°F) the "☹" warning symbol flashes (1a); you still can perform the test, but the result is only for reference, because within these temperature ranges it may not be correct. In the memory mode this value will be flagged with the "☹" symbol (1b); repeat the test in an area within the normal temperature operating range.
2. If the meters and test strips are exposed to a considerable temperature variation, please wait 30 minutes before measurement.
3. When the temperature is below 0°C (32°F) or over 50°C (122°F), the meter cannot perform the test and the "Error" symbol will flash together with thermometer symbol showing "☹" on screen. Please move the BGMS to environment within the normal temperature operating range and repeat the test after 30 minutes.



Error messages and trouble shooting

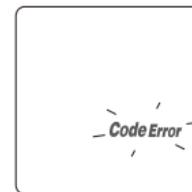
Sampling error

Please do not present the blood drop to the sample entry of the test strip before the meter displays "☹". If you do so, the meter will display "Error" and "☹" accompanied by beeps (if volume is switched on). Please discard the test strip and repeat the test with a new one.



Code error

The test strip is not inserted correctly. Please reinsert the test strip following the instructions of use. If "Code Error" reappears, it could mean you are using the wrong test strip. After making sure you are using the right test strip and the test strip is inserted correctly, "Code Error" still appears, please contact your local Ypsomed customer service (see page 48).



Meter malfunction

If the meter cannot be started, please follow the steps below:

1. Open the battery cover, remove the batteries.
2. Wait for 5 minutes or press the main button several times until the screen is blank and insert the batteries as described in "Meter activation and battery change" on pages 16 to 17.

The meter should be working normally after completing the above steps. If not, please contact your local Ypsomed customer service (see page 48).

Specification of mylife™ Pura™ meter

Measurement technology	Oxidase electrochemical sensor
Measurement calibration	Plasma
Sample	Capillary whole blood
Minimum sample volume	1.0 microliter
Coding	Autocoding
Measuring range	10-600 mg/dL
Test time	5 seconds
Memory capacity	500 blood glucose test results with date and time
Power saving	Automatic shutdown 2 minutes after last user action. Press the main button "  " for 4 seconds.
Operating temperature	10~40°C (50~104°F)
Operating relative humidity	10-90%

Specification of mylife™ Pura™ meter

Hematocrit	30-60%
Power supply	2 CR2032 batteries
Meter battery life	About 1,000 tests
Meter dimension	90.6 mm x 46.0 mm x 16.5 mm (H x W x D)
Meter weight	53.0 g ± 5.0 g with batteries
Monitor	LCD display
Display area	47.0 mm x 33.5 mm (H x W)
Meter storage conditions	-10~60°C (14~140°F)
Test strip storage conditions	4~30°C (39~86°F), <90% relative humidity
Meter data transmission management	Meter data can be transmitted to a computer with the PC-Link adapter. The data being managed by the DIABASS software.

Limitations of mylife™ Pura™ meter

- The BGMS is not intended for serum or plasma testing (for capillary whole blood testing only).
- Inaccurate test results may be obtained at altitude of more than about 3,048 meters (10,000 feet).
- Severe dehydration may cause inaccurately low results.
- The BGMS has not been validated for use on neonates.
- The glucose test may be invalid in the presence of abnormally high concentrations of uric acid >16.0 mg/dL.



NOTE

- Do not use this meter close to strong electromagnetic radiation sources, in order to avoid interference with normal operation.
- Keep the meter free of dust, water or any liquid.

Meter data transmission management (optional)

The meter data can be managed by the mylife™ Pura™ PC-Link system. The mylife™ Pura™ PC-Link system includes mylife™ Pura™ PC-Link adapter and a software CD (with USB driver and DIABASS updated driver). Meter data can be transmitted to the computer with mylife™ Pura™ PC-Link adapter. The data must be managed by DIABASS software (sold separately). Please read the instructions of mylife™ Pura™ PC-Link system before attempting meter data transmission. The mylife™ Pura™ PC-Link system is optional and may be sold independently. If you have any questions or concerns, please contact your local Ypsomed customer service (see page 48).

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

Distribution France

Ypsomed S.A.S
18/20 Rue Soleillet
FR-75020 Paris
Tél.: +33 (0)015870 2000
Fax: +33 (0)015870 2001
Numéro gratuit: 0800 883058
info@ypsomed.fr
www.mylife-diabetescare.fr

Distribution UK

Ypsomed Ltd
Blackwood Hall Business Park
North Duffield
Selby, North Yorkshire
YO8 5DD
Customer Care: +44 844 856 7820
Fax: +44 844 5070 443
Email: info@ypsomed.co.uk
www.mylife-diabetescare.co.uk

Description of used symbols

	Manufacturer		EU Representative		Consult instructions for use
	For in vitro diagnostic use		For single use only		Reference number
	Use by		Temperature limitations		Lot number
	Sterilized using irradiation		Caution (consult instructions for use and warnings)		Serial number
	CE Mark		CE Mark with number of Notified Body		

The manufacturer warrants that your mylife™ Pura™ meter will be free from defects in materials and workmanship for four years from the date of purchase.

This warranty does not apply to the performance of a mylife™ Pura™ meter that has been altered, misused, tampered with or abused in any way.

This warranty applies only to the original purchaser of the mylife™ Pura™ meter.

Please complete and return the enclosed warranty card to your local Ypsomed affiliate.

This warranty does not apply for any damage caused by the use of other test strips than mylife™ Pura™ test strips.

If the mylife™ Pura™ meters and test strips are exposed to a considerable variation in temperature, please wait 30 minutes before measurement.

Disposing of the mylife™ Pura™ meter, test strips and lancets



NOTE

- During blood glucose measurement, the meter may come into contact with blood. Used meters therefore carry a risk of infection. Please dispose of your used meter after removing the batteries – following the disposal regulations applicable in your country. 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 according to your local regulations.

Main parts

mylife™ Pura™ meter, mylife™ Pura™ test strip, mylife™ Control 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 (CE0197).

EU Representative: Bionime GmbH, Tramstrasse 16, CH-9442 Berneck / Switzerland

mylife™ Softlance 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/EC.

EU Representative: Bionime GmbH, Tramstrasse 16, CH-9442 Berneck / Switzerland

Disposable mylife™ Lancets lancets

Manufacturer: SteriLance Medical Inc.,

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

EU Representative: Emergo Europe

Molenstraat 15 2513 BH the Hague, The Netherlands

The Product complied with Medical Device Directive 93/42/EEC (CE0197)

Version: August 2013