Bluetooth®
SMART

ANT+

smart**LAB**®
global W nG

Self-Monitoring Blood Glucose System with wireless data transfer

User Manual

⚠ *Please read this manual thoroughly before first using this device*

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I. Introduction

Thank you for using the **smartLAB**®*global W nG* Self-Monitoring Blood Glucose System. This system was produced in close association with diabetes health care professionals, hospitals and, most importantly, people with diabetes. The measuring results can help you determine the effects of food, exercise and diabetes medications.

Your **smartLAB**®*global W nG* glucose system was designed to be dependable, easy-to use, compact, lightweight and portable to assist you in monitoring your blood glucose on a regular basis. Please read this manual thoroughly before you begin testing. It provides you and your diabetes care team with important information and step-by-step direction to use meter correctly. Although your **smartLAB**®*global W nG* System is easy to use, you should consult your healthcare professional (this may be your doctor, diabetes nurse educator or pharmacist) for instructions on how to use the system. The only way to obtain accurate results from any system is to make sure you correctly use it. If you have any concerns, please call your authorized distributor in your country during business hours.

The **smartLAB**®*global W nG* System is an ANT+ and *Bluetooth*® Smart device. It supports the ANT+ device profile (V. 2.1) and is kompatible with receiving devices (such as PC and Smartphones) that support the ANT+ weight scale device profile. With the integrated *Bluetooth*® Smart the **smartLAB**®*global W nG* System can also sent data via BLE to a corresponding receiver. You can then transmitt your values wireless to these receiving devices.

Measuring principle

The **smartLAB**®*global W nG* Self-Monitoring Blood Glucose System is designed to allow rapid measurement of blood glucose by using an electrochemical biosensor technology. This system employs a disposable dry reagent strip technology, based on the FAD-binding glucose dehydrogenase.

Each test strip features an electrode containing FAD-binding glucose dehydrogenase. A capillary blood sample is applied to the collecting area of the strip, and is automatically drawn into the reaction zone, where the FAD-binding glucose dehydrogenase catalyzes the glucose dehydrogenation. It will produce gluconolactone.
During the reaction, a mediator transfers electrons to the electrode surface and generates a current. The amount of the current is proportional to the amount of glucose present in the blood sample. After 5 seconds, the **smartLAB**®*global W nG* will show glucose concentration on the screen

Intended use

This blood glucose meter is a self-test IVD medical equipment and intended for both home testing and for professional use to monitor the blood glucose value from capillary whole blood and venous whole blood. It is used outside the body only (In-vitro diagnostic use). The meter should be used only with **smartLAB**®*nG* blood glucose test strips.

Important information

- The **smartLAB**® *global W nG* blood glucose meter is designed and approved for testing venous whole blood or fresh capillary whole blood samples from your fingertips, palm and forearm. The meter is for in vitro diagnostic use ONLY (for testing outside the body). It should not be used to diagnose diabetes.

- The **smartLAB**® *global W nG* blood glucose meter can only be used with **smartLAB**®*nG* Blood Glucose Test Strips. Other test strips will give inaccurate results.

- Severe impact may cause the meter to malfunction. Do not disassemble the meter as it may damage components inside and cause an incorrect reading. The warranty will be void if the meter has been disassembled.

- Testing is not valid for neonatal blood specimens.

- Incorrect results may occur when performing the test. If you believe you are not feeling well, please contact your healthcare professional immediately.

- Always keep the meter clean and store it in a safe place. Protect from direct sunlight to ensure a longer lifespan.

- The strip slot should be kept free from dirt, dust, blood stains, and water stains.

- Do not store the meter and test strips in a car, a bathroom or a refrigerator. And the meter, strips and lancing device should be kept away from children or pets.

- Remove batteries if the meter will not be used for one month or more.

- Store the kits in a dry place with temperature range is 2 to 30°C (35.6 to 86 °F). Keep away from direct sunlight and heat.

- Store your test strips in their original vial only. Do not transfer them to a new vial or any other container.

- Indicate the date you open the vial. $\boxed{D}$ Discard all unused strips immediately after 90 days from open date. The strips are for single use only.

- You should not test critically ill patients with home-use blood glucose meters.

- Warning for potential biohazard: Healthcare professionals using this system on multiple patients should be aware that all products or objects that come in contact with human blood, even after cleaning, should be handled as if capable of transmitting a viral disease.

- Please dispose device according to the local rule of the disposition of electronic device/ accessory waste.

- If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

⚠ Do not touch the test strip with wet hands

⚠ Do not use expired test strips
   (see expiration date on the strip vial)

⚠ Do not bend, cut or twist the strip

⚠️   Consult with your healthcare professional before testing on your palm or forearm.

⚠️   Altitude up to 3,048 meters above sea level has no effect on readings.

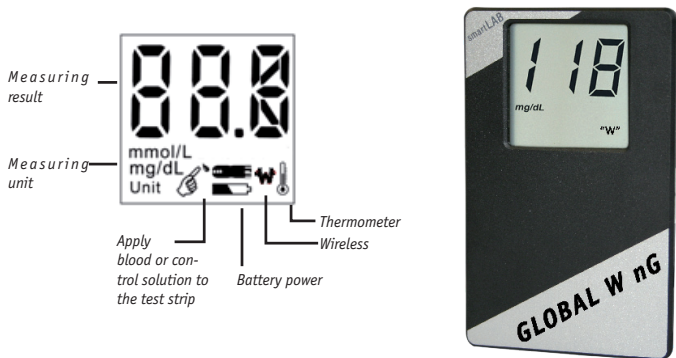*Health-Related Information*

- If you are experiencing dehydration, frequent urination, low blood pressure, shock or hyperosmolar hyperglycemic nonketotic coma (HHNKC), you may get a test result that is lower than what your blood glucose really is. If you think you are dehydrated, call your healthcare professional right away.
- If you have followed the steps in the user's manual, but still have symptoms that do not seem to match your test results, or if you have questions, please contact your healthcare professional.
- Please read your test strip instructions carefully for additional health-related information
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Note on smartLAB® *nG* „NO CODE"-test strips

The **smartLAB**® *nG* blood glucose test strips compatible with **smartLAB**® *nG* glucose systems need not to be coded, any more.
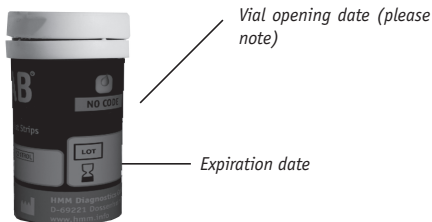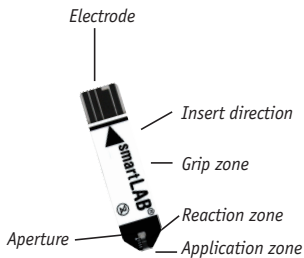
II. Your smartLAB®*global W nG*

Display & functions

Measuring result

Measuring unit

mmol/L
mg/dL
Unit

Apply blood or control solution to the test strip

Battery power

Wireless

Thermometer

118
mg/dL
"W"

GLOBAL W nG

Specifications

1. *Type:* smartLAB®*global W nG*
2. *Measuring range:* 20~630 mg/dL (1.1~35.0 mmol/L)
3. *Measuring duration:* 5 seconds
4. *Time mode:* AM/PM - 24 hours
5. *Memory:* 480 values
6. *Operating temperature:* 10°C~40°C (50°F~104°F)
7. *Storage Temperature*: -20°C ~50°C (-4°F~122°F)
8. *Relative humidity:* RH ≤90%
9. *Blood sample:* ≥ 0,6 µL capillary whole blood

10. *Calibration:* Plasma equivalent
11. *Hematocrit (Hct):* 30-55%
12. *Battery type:* 2 CR 3V Lithium batteries
13. *Battery life:* approx. 500 measurements
14. *Display-size:* 30 x 30 mm
15. *Meter dimensions:* 80 x 50 x 5 mm
16. *Weight:* 30g (without batteries)
17. *Data transfer:* wireless through integrated ANT and BLE module
18. *Transportation temperature:* -20°C ~50°C (-4°F~122°F)
19. *Transportation humidity:* RH ≤90%

The smartLAB®*nG* test strips

Electrode

Insert direction

Grip zone

Reaction zone

Aperture

Application zone

Vial opening date (please note)

Expiration date

Note: You can find the test strip expiration date on the vial label next to the ⧗ symbol.

Explanation of symbols

Symbol	Description
⚠	*Caution*
CE	*This product meets the requirements of Directive 98/79/CE for in vitro diagnostic medical devices.*
LOT	*Lot number*
⧖	*Expiration date*
IVD	*For in vitro diagnostic use only*
CR2032 3V	*Use Lithium battery CR 2032 3V*
⊗	*Single use only*
⌐	*Storage temperature*
▲	*Manufacturer*
📖	*Before use, read manual first*
REF	*Catalogue number*
SN	*Serial number*
CONTROL	*Control solution*
D	*Opening date of test strip vial*

Set contents

1 smartLAB®*global W nG* blood glucose meter
1 User manual
1 hard box
2 CR 2032 3V batteries
1 smartLAB® lancing device
1 smartLAB® Check Strip
1 smartLAB® Quick Start instruction
10 smartLAB® lancets
10 smartLAB®*nG* blood glucose test strips
1 smartLAB®*nG* blood glucose test strip instruction

III. Setup & Operating procedures

Installing batteries

The meter uses 2 CR 2032 3V Lithium batteries. Batteries will normally last for aprox. 500 tests. Other types of CR 3V lithium batteries are also acceptable, yet the capacity of test times may differ.

Low battery symbol

Install the batteries, by removing the plastic protection when you first use the meter or replace with new batteries when the "LP" message and the low battery symbol appear on the LCD display. Open the battery lid on the back side of the **smartLAB**°*global W nG* meter and insert batteries with plus sign to top. First insert the battery on the right side and then press the left side down until it clicks. Close the battery lid. The display will light up and all symbol will blink for around 10 seconds. Afterwards you can use the device.

Note:

1. Remove the batteries when not using the meter for one month or longer.

2. Values won't be deleted when the batteries are replaced.

3. The device needs to be set again after battery change. Please make sure that the device is close to a corresponding receiving device for settings.

4. The device will try to contact the gateway within the first 10 minutes after inserting batteries. If no connection is possible, "ERR 002" will show on the display. The device will now try to connect to gateway in a certain interval in the background.

Meter, batteries, lancets, test strips etc. must be disposed of according to local regulations at the end of their usage.

Function check

You can carry out a function check with the Check Strip which is included in your meter set. You do not have to do the function check before every measurement. It helps you to control if your **smartLAB**®*nG* meter works properly, from time to time, though.

1. Insert check strip into the meter:
Make sure your check strip is inserted with writing to top. The meter will turn on automatically and the display will show „CHK".

2. Check message in LCD display:
The function check will take approx. 3 seconds. The check can produce the following messages on the display:

• „OK" - your meter works properly

• „FAL"- change batteries and check again. If the message still appears, please refer to your local supplier.

After showing "OK" the device will start to send measured data. If device has not been set yet by the system it will be set now. Afterwards the data will be shown on the screen.

3. Remove check strip:
The meter will turn off automatically after removing the check strip. Please keep the check strip in the soft case of the meter.

Wireless Data transfer

You can connect your **smartLAB**®*global W nG* with a partner device which fulfills the standard protocol of ANT+ or BLE wireless data transfer. You can transfer measured blood glucose values automatically and wireless to the device. Partner devices could be laptops, smartphones, tablets or any other ANT+ or BLE-capable device. The communication will be enabled by a gateway* which can be installed on PC, Smartphone or Tablet.

To allow a data transfer to a portal your **smartLAB**®*global W nG* needs to be set by the system. When using the device for the first time and removing the battery protection the display will blink for 5 seconds which indicates that the device is trying to communicate with the gateway to set the device.

After each measurement the device will send the data to the gateway. Saved Data will be transfered automatically every 30 minutes or together with a new Mesaurment. You can also manually transfer measured data. Please go to Chaper "Manually transfer not sent data".

When transfering data, the wireless symbol "W" will flash on the display.

Note: The BLE or ANT+ installation on the according partner device varies and can not be explained in every detail, here. Please read the partner device's user manual thoroughly on how to activate BLE or ANT and how to connect the device to your **smartLAB**®*global W nG*.

Manually transfer not sent data

You can initialize a manual data tranfer by following these steps:

- Insert the Check Strip into the test strip slot. "Chk" and "OK" should show.
- On the display the wireless symbol will flash afterwards; the device is now trying to communicate with gateway and send all data, which have not been send yet.
- The last 20 measured values will show display. The results will be shown chronologically on the display, the first for 3 seconds, the values afterwards for 1 second.
- The device will turn off when removing the Check Strip.

Notes on using smartLAB® *nG* blood glucose test strips

- Use only with **smartLAB**®*nG* Blood Glucose Meters.
- Run a control solution test every time you open a new box of test strips
- Keep the test strips in their original bottle.
- After you take a test strip out of the bottle, tightly close the bottle immediately. This keeps the test strips dry.
- Use the test strip within three minutes after taking it out of the bottle.
- The strip is for single use only. Do not reuse it.
- Record the date you open the test strip bottle. Be sure to check the expiration date on the test strip bottle. The test strip is good for 6 months from the date the bottle is opened or until the expiration date on the bottle, whichever comes first.
- Store the test strip bottle and your meter in a cool dry place.
- Store the test strips between 2°C ~30°C (36°F - 86°F). Do not freeze.
- Do not apply blood or control solution to the test strip before you insert it into the meter.
- Do not touch the test strip with wet hands. Do not bend, cut, or twist the test strips.

Running a blood glucose test

1. Preparations
Before running a blood glucose test, make
yourself acquaint with the test strips and the
lancing device. Keep all required materials
ready for use: your **smartLAB**®*global W nG*
meter, the **smartLAB**®*nG* test strips and the
smartLAB® lancing device including lancets.
Wash your hands thoroughly with warm water
before collecting the blood sample. Rinse your hands thoroughly.

2. Switch on the meter
Take a strip out of the vial and immediately close it. Insert the strip
into the meter in the direction of the arrow on the strip. The meter
turns on automatically. The symbol for applying blood will appear
on the display.

Note: If the device could not be set by the gateway
after changing the batteries you can still run a blood
glucose test. When inserting a test strip the display will
show „nod". After that the symbol for applying blood
will appear on the display.

3. Collecting a blood sample
When the blood drop flashes on the display, gen-
tly massage the part of your finger tip which you
obtain a drop of blood from using the lancing
device. Place the lancing device against the pad
of your finger. Press the trigger button to activate the lancing de-
vice.

4. Blood glucose measurement

Hold the application zone of the test strip vertically onto the blood sample. The blood is automatically sucked in the reaction zone of the test strip. Be sure to get enough blood on the strip's reaction zone, otherwise, an inaccurate reading may result. The signal tone indicates that enough blood entered the reaction zone. The meter will now start with the measurement which will last 5 seconds. The LCD display shows the remaining time of measurement in seconds. Afterwards the note „OK" indicates a correct measurement. The measurement is finished with another signal beep and the measured value is shown on the display.

5. Storing memories

The displayed result is automatically stored in the memory of the meter. If more than 480 results are reached, the oldest one is deleted.

After every measurement the meter tries to connect to another pre-installed ANT or BLE partner (please refer to the chapter "Wireless data transfer" in this manual to learn how to connect your device with a ANT or BLE partner). The Wireless-sign will start flashing. If a connection can be established, the result will be transferred automatically. In case no connection was found, "ERR" and the Wireless-sign appears on the display. Please make sure that you set up your wireless connection correctly according to the instructions in the manual of your partner device.

Note: If the glucose value could not be transmitted via ANT or BLE, it will still be saved on the internal memory of your **smartLAB**®*global W nG*.

Once the connection can be established the next time, all values that have been measured in the meantime will be transferred to the partner device.

6. Discarding used test strips and lancets

Write down the measured result in your personal diabetic log book and take the test strip off the strip slot. The meter turns off. If you don't take off the test strip, the meter will turn off automatically after 5 minutes.

In order to discard lancets from the **smartLAB**® lancing device, remove the end cap and carefully pull the used lancet out of the holder. Dispose the lancet according to local regulations, in order to avoid hurting other people.
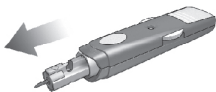
Reading stored test results from memory

You can read the last 20 test results on the internal memory of your **smartLAB**®*global W nG* meter by inserting the check strip. The results will be shown chronologically on the display. Further results can be seen in the corresponding portal.

Alternate Site Testing (AST) with the transparent cap

You can also gain the blood sample from other parts of the body than the finger tip. If you want to use Alternate Site Testing, please use the transparent cap for your lancing device. Carry out the following steps:

• Gently massage the desired punctuation site on your arm or hand for a few seconds. This will improve the blood circulation.

Alternate Blood Collection Sites

• Push the lancing device with the transparent cap against the desired blood collection site and push the trigger button to gain a sample.

• Exercise a constant pressure until you see through the transparent cap, that enough blood is gained. After that you can carry out the blood glucose test, as usual.

Understanding your test results

The **smartLAB**®*nG* blood glucose test strips are plasma referenced and calibrated for easier comparison to lab results. The unit of blood glucose test results displayed on the screen is either mg/dL or mmol/L, depending on which unit of measurement you have selected. The mmol/L results will always include a decimal point; mg/dL results do not include a decimal point.

Expected results for non-diabetic adults:
The normal fasting glucose range is 70 to 100 mg/dL (3.9 to 6.1 mmol/L). Two hours after meals, normal glucose values should be less than 120 mg/dL (6.7 mmol/L).

Expected results for diabetic adults:
The normal fasting blood glucose range for an adult with diabetes is 70-130 mg/dL (3.9~7.2 mmol/L)*. Two hours after meals, the blood glucose range for an adult with diabetes is less than 180 mg/dL (10.0 mmol/L). For further queries about diabetes: please consult your healthcare professional for the blood glucose range appropriate for you.

Unusual test results:
If your blood glucose result doesn't match the way you feel, follow these steps, and then repeat the test:

1. Check if the strips are within the expiration date.

2. Be sure that the drop of blood completely filled the reaction zone of the test strip

3. Do a function control test with the **smartLAB**® check strip

4. *Optional:* Check meter and test strip performance with the **smartLAB**®*nG* control solution. When test results are still questionable or inconsistent, consult your healthcare professional before making any changes to your diabetes medication program.

5. Repeat the Measurement:
If the values of the repeated measurements are however questionable and do not match the way you feel, please contact your health care professional before you change your medication.

Note:
1. Extremely high humidity may affect the test results. A relative humidity greater than 90% may cause inaccurate results.
2. A red blood cell count (Hematocrit) below 30% may cause higher results. Hematocrit above 55% may cause lower results.
3. Some studies have shown that electromagnetic fields may affect results. Do not test near an operating microwave oven.

Symptoms of high or low blood glucose:
Being aware of the symptoms of high or low blood glucose can help you understand your test results and decide what to do if they seem unusual. A high blood glucose would be greater than 240 mg/dL (13.33 mmol/L). A low blood glucose would be below 60 mg/dL (3.33 mmol/L). Here are the most common symptoms:

High blood glucose (hyperglycemia): fatigue, increased appetite or

thirst, frequent urination, blurred vision, headache, general aching, or vomiting.

Low blood glucose (hypoglycemia): sweating, trembling, blurred vision, rapid heartbeat, tingling, or numbness around mouth or fingertips. If you are experiencing any of these symptoms, test your blood glucose. If your blood glucose result is displayed greater than 240 mg/dL (13.33 mmol/L) or below 60 mg/dL (3.33 mmol/L) and you have symptoms of low or high blood glucose, contact your doctor immediately. If your blood glucose result does not match how you feel, follow the steps under „Unusual Test Results."

Comparing your meter's result to a lab result:
A common question is how the blood glucose results on your meter compare to the lab results. Your blood glucose can change quickly, especially after eating, taking medication, or exercising. If you test yourself in the morning, then go to the doctor's office for a blood glucose test. The results will probably not match, even if you are fasting. This is typically not a problem with your meter, it just means that time has elapsed and your blood glucose has changed.

If you want to compare your meter result to the lab result, you must be fasting. Bring your meter to the doctor's office, and test yourself by fingertips within five minutes of having blood drawn from your arm by a healthcare professional. Keep in mind that the lab could use different technology than **smartLAB**®*global W nG* blood glucose meter, and that blood glucose meters for self testing generally read somewhat lower or higher than the lab result. For accuracy and precision data and for important information on limitations, see the instructions that come with your test strips.

Optional: Control Solution Testing

Running a control test lets you know that your meter and test strips are working properly to give reliable results. You should run a control test when:

- You use the **smartLAB**®*global W nG* blood glucose meter for the first time.
- You open a new vial of test strips.
- You think the meter or test strips might be working incorrectly.
- You drop the meter.
- You have repeated a test and the test results are still lower or higher than expected.
- You are practicing the test procedure.

Note: Professional users are instructed to follow federal, state, and local guidelines concerning QC practices.

About the smartLAB®*nG* control solution
- **smartLAB**®*nG* control solution is not intended for human consumption or injection.
- Use only with **smartLAB**®*nG* test strips.
- Write the date you first opened the bottle on the bottle label.
- The **smartLAB**®*nG* control solution is durable for three months from the date the vial is opened or until the „Expiration Date" on the bottle, whichever comes first.
- Do not use **smartLAB**®*nG* control solution that is past the „Expiration Date"
- The **smartLAB**®*nG* control solution can stain clothing. If you spill it, wash your clothes with soap and water.

- Close the bottle tightly after use.
- Left over control solution should not be added back into the control bottle.
- Store the bottle of **smartLAB**®*nG* control solution at room temperature, below 30°C (86°F). Do not freeze nor refrigerate.
- If you would like to purchase **smartLAB**®*nG* control solutions, please contact your local dealer.

Running a smartLAB® control solution test

Please make sure you have all necessary items at hand when running a control solution test. You need the **smartLAB**®*global W nG* meter, a **smartLAB**®*nG* test strip, and **smartLAB**®*nG* control solution.

1. Switch on the meter

Take a strip out of the vial and immediately close it. Insert the strip into the meter in the direction of the arrow on the strip. The meter turns on automatically and the symbol for applying blood.

2. Running the control solution test

When the symbol for applying blood appears, shortly shake the bottle with the **smartLAB**®*nG* control solution. Open the bottle and wipe the tip of the bottle with a tissue. Squeeze a little drop of control solution on a clean, not adsorbing surface (plastic, glass, etc.) andclose the bottle immediately. Hold the application/reaction zone of the test strip vertically onto the drop of control solution. The control solution is automatically sucked in the reaction zone of the test strip. The signal tone indicates that enough blood entered the reaction zone. The meter will now start with the measurement

which will last 5 seconds. The LCD display shows the remaining time of measurement in seconds. Afterwards the note „OK" indicates a correct measurement. The measurement is finished with another beep signal and the measured value is shown on the display. Leave the test strip in its slot.

3. Comparing the results / acceptable range

Compare the result with the acceptable range indicated on the test strip vial. CONTROL The acceptable range is indicated in both units (mg/dL and mmol/L). Please pay attention on comparing the results with corresponding units.

4. Understanding control test results

The label on your test strip vial shows the acceptable ranges for the **smartLAB**®*nG* control solutions. The result you get should be inside this range. Make sure you compare the result to the correct level of control. When the control result is inside the range on the test strip vial, your test strips and your meter are working properly. If your control result is not inside the acceptable range (printed on your test strip vial), here are some things you can do to solve the problem:

Problem	Solution
Was the test strip exposed to open air for a long period of time?	*Repeat the control test with properly stored strips.*
Was the test strip vial capped tightly? Or was test strip cap left open?	*If the cap was not tight, or the bottle was left uncapped, open a new bottle of test strips. Do not reuse the strips from the affected bottle.*
Does the meter work properly?	*You can use the check strip to verify the meter's functions.*
Is the control solution expired or contaminated?	*Replace with new control solution to check the performance of your glucose meter.*
Were test strips and control solution stored in a cool and dry place?	*Repeat the control test with properly stored strips or control solutions.*
Did you follow the testing steps properly?	*Read Chapter "Control Solution Testing" again and retest.*

IV. Miscellaneous

Maintenance

Your **smartLAB**®*global W nG* Blood Glucose System does not require
any special cleaning. Just keep the meter free of dirt, dust, blood-
and water stains. Following these guidelines carefully will help you
getting the best performance possible: Gently wipe the meter's sur-
face with a soft cloth Do not get any moisture in the test strip slot.

⚠️   Please do not spray any cleaning solution directly onto
the system.

⚠️   Do not pour liquid into the system or put the system under
water or liquid

To clean the lancing device, use a mild dishwashing liquid and a soft
cloth. DO NOT place the entire device under water.

⚠️   Please make sure that no liquids enter the meter's
apertures.

Troubleshooting

Note: If you are not sure how to react on error codes, please contact your local supplier.

Battery empty
Display: „LP" & „Battery symbol $\square$"
Solution: Replace with new batteries.

Not enough blood in test strip
Display: „Err" and test strip with hand
If not enough blood is in the test strip, this error will show.
Solution: Use a new test strip and restart the measurement procedure.

No Wireless connection
Display: "Err" and Wireless-sign
After measurement, the meter tries to transfer the value to the gateway but a connection cannot be established.
Solution: Make sure meter and partner device are in close communication proximity. If necessary, set up the Wireless connection again.

System error
Display: „001 Error "
Solution: Replace batteries first. If the error still occurs, please contact your local supplier.

Memory error
Display: „005 Error"
Solution: Replace batteries first. If "Err"still occurs, please contact your local supplier.

Test strip already used or wet
Display: „Err" & „Test strip symbol"
Solution: Use a new test strip.

Test result is higher than 630 mg/dL (35.0 mmol/L)
Display: „HI"
Solution: Test again. If the result is still too high, please contact your doctor immediately.

Test result is under 20 mg/dL (1.1 mmol/L)
Display: „LO"
Solution: Test again. If the result is still too low, please contact your doctor immediately.

Temperature too high
Display: „Ht" & „Thermometer symbol"
The operating temperature is too high (above the required temperature range from 10°C - 40°C (50°F - 104°F)). The error is a warning that a continuation under these conditions might lead to wrong blood glucose readings.
Solution: Take the meter to a location with appropriate working temperature and wait for the next measurement until the error does not occur again.

Temperature too low
Display: „Lt" & „Thermometer symbol"
The operating temperature is too low (below the required temperature range from 10°C - 40°C (50°F - 104°F)). The error is a warning that a continuation under these conditions might lead to wrong blood glucose readings.
Solution: Take the meter to a location with appropriate working temperature and wait for the next measurement until the error does not occur again.

System error
Display: „FAL"
Solution: Re-insert the check strip (with writing to top). If „FAL" still occurs, please contact your local supplier.

Error 002
Display: „ERR 002"
Solution: Device was not set by gateway. When inserting batteries again, please be close to a gateway. Device will anyhow try to connect with gateway in certain interval.

Limitations of the measurement procedure

1. DO NOT use serum or plasma sample.

2. DO NOT use neonate blood sample.

3. DO NOT use anticoagulant NaF or potassium oxalate for venous sample preparation.

4. Extreme humidity may affect the results. A relative humidity greater than 90% may cause incorrect results.

5. The system is designed to be used at temperatures between 10°C and 40°C (50°F and 104°F). Outside this range, the system may yield erroneous results.

6. DO NOT reuse the test strips. The test strips are intended for single use only.

7. DO NOT use iodoacetic acid, fluoride or sodium fluoride/oxalate as a preservative for blood specimens.

8. Hematocrit:
   Test strip results are not significantly affected by hematocrits in range of 30% to 55%. Hematocrit levels less than 30% may cause incorrect high readings and hematocrit levels greater than 55% may cause incorrect low readings. If you do not know your hematocrit level, consult your healthcare professional.

9. Critically ill patients should not be tested with **smartLAB**®*nG* blood glucose meters.

10. DO NOT use during xylose absorption testing. Xylose in the blood will interfere Self-Monitoring Blood Glucose System.

11. Patients undergoing oxygen therapy may have inaccurate results.

12. Altitude up to 3050 meters above sea level has no effect on readings.

13. Test results may be false if the patient is severely dehydrated or severely hypertensive, in shock, or in hypoglycemic-hyperosmolar state (with or without ketosis). Critically ill patients should not be tested with home-use blood glucose meter.

14. Elevated cholesterol and triglyceride levels may interfere with the way light is reflected producing erroneous meter results.

15. Recent studies have shown that EMI can cause electronic medical device performance degradation and could lead to inappropriate therapy.

16. Lipemic samples: Cholesterol level up to 500 mg/dL (12.92 mmol/L) and triglycerides up to 3,000 mg/dL (33.6mmol/L) do not affect the results. Grossly lipemic patient samples have not been tested and are not recommended for testing with **smartLAB**®*global W nG* Blood Glucose Meter.

17. Interfering Substances depend on the concentration. The below substances up to the test concentration will not affect the test results:

Concentrations of the interferance tested	Bias		Glucose Level 80 mg/dL (4.4 mmol/L)	250 mg/dL (13.9 mmol/L)	500 mg/dL (27.8 mmol/L)
Ascorbic Acid	4 mg/dL	(0.26 mmol/L)	10.89%	-1.76%	4.55%
Ibuprofen	50 mg/dL	(2.43 mmol/L)	3.10%	2.88%	4.62%
L-Dopa	1.8 mg/dL	(0.09 mmol/L)	10.59%	7.91%	4.90%
Sodium Salicylate	50 mg/dL	(3.12 mmol/L)	-2.59%	9.42%	-0.84%
Tetracycline	1.5 mg/dL	(0.03 mmol/L)	-5.32%	3.81%	3.20%
Tolbutamide	100 mg/dL	(3.70 mmol/L)	-2.60%	12.30%	0.89%
Bilirubin-unconjugated	2.4 mg/dL	(0.04 mmol/L)	-2.52%	4.05%	-0.23%
Uric acid	8 mg/dL	(0.48 mmol/L)	2.71%	9.55%	-1.75%
Xylose	4 mg/dL	(0.27 mmol/L)	-5.12%	-1.64%	-4.44%

Regularity and Safety Notice

CE

Declaration of Conformity
This product is compliant with the EC Directives: -1999/5/EC

Safety Statement
This product has been verified to conform to the safety certification in accordance with the specification of EN Standards: EN 60950-1:2006 + A11:2009 + A1:2010 + A12:2011

WEEE note

The WEEE (Waste Electrical and Electronic Equipment) Directive, that came into effect as European law on 13th February 2003, led to a major change in the disposal of electrical equipment.

The primarily purpose of this directive is to prevent electronic waste (WEEE), while encouraging for reuse, recycling and other forms of reprocessing to reduce waste.

The WEEE logo on the product and the packaging indicates that it is not allowed to dispose of the product in the ordinary household waste. It is your responsibility to deliver all the disused electrical and electronic equipment to the respective collection points. A separate collection and proper recycling of electronic waste helps dealing economically with natural resources. Furthermore, the recycling of electrical waste is a contribution to the conservation of our environment and thus the health of all people. More information concerning the disposal of electrical and electronic devices, reprocessing and the collection points you can get from the local authorities, waste disposal companies, from retailers and manufacturers of the device.

Warranty

HMM Diagnostics GmbH products need to fulfill high quality requirements.
Because of this reason, HMM Diagnostics GmbH gives a 2-year warranty by purchasing this **smartLAB**® product. You can even extend the warranty from 2 to 5 years without extra pay when you register your product. Please register online under following website: www.hmm.info/en/registration.

Wear parts, batteries etc. are excluded from warranty.

Hersteller/ Manufacturer:

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