smartLAB® genie+

Self-Monitoring Blood Glucose Meter with wireless data transfer

User Manual

Please read this manual thoroughly before first using this device

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HMM Diagnostics GmbH
D-69221 Dossenheim, Germany
www.hmm.info

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I. Introduction

Thank you for using the **smartLAB**®*genie*+ 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**®*genie*+ glucose meter 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**®*genie*+ 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.

With its integrated ANT module, all measurement results can be transferred wirelessly to an accordant receiver device (laptop, PC, hFon or hFon Collect)*, where they can be further processed and analyzed.

** More information about the hFon , hFon Collect or hLine Terminal on* ***www.hline.eu***

Measuring principle

The **smartLAB**®*genie*+ 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 glucose oxidase method for glucose determination.

Each test strip features an electrode containing the glucose oxidase from aspergillus niger. A capillary blood sample is applied to the collecting area of the strip, and is automatically drawn into the reaction zone, where the glucose oxidase catalyzes the oxidation of glucose to produce glyconic acid. 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. The glucose concentration is measured by your **smartLAB**®*genie*+ meter and displayed on the screen after 5 seconds.

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 (B-D-glucose) value from capillary whole blood. It is used outside the body only (In-vitro diagnostic use). The meter should be used only **smartLAB**®*pro* blood glucose test strips. Testing is not valid on neonatal blood specimen.

Important information

- 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.

- 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. The meter, test strips and lancing device should be kept away from children or pets.

- Please refer to the limitations of the procedure before testing.

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

- Store the meter, test strips and control solution in a dry place with temperature range between 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. D Discard all unused strips immediately after 90 days from open date. The strips are for single use only.

- 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 viral disease.

- You can download the test results from the meter memory to a computer for more in-depth analysis. (Requires according software and a Bluetooth module)

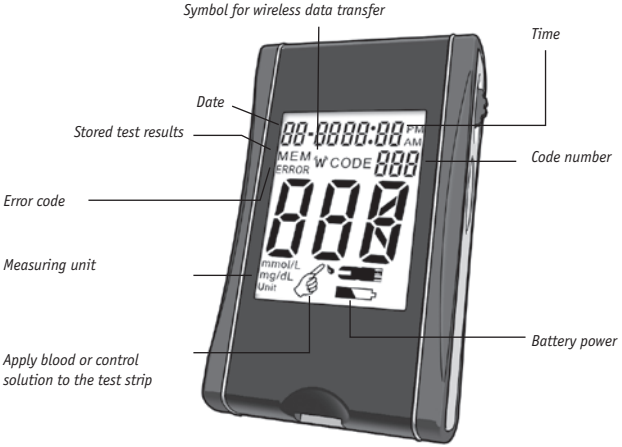
⚠ Do not touch the test strip with wet hands

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

⚠ Do not bend, cut or twist the strip

II. Your smartLAB® *genie+*

Display & functions



Specifications

1. *Type:* smartLAB® *genie+*
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:* 360 values, 100 insulin units
6. *Operating temperature:* 10°C~40°C (50°F~104°F)
7. *Relative humidity:* RH ≤90%
8. *Blood sample:* ≥ 0,6 µL capillary whole blood
9. *Calibration:* Plasma equivalent
10. *Hematocrit (Hct):* 30-55%
11. *Battery type:* 2 CR 3V Lithium batteries
12. *Battery life:* over 2000 measurements
13. *Display-size:* 40 x 32 mm
14. *Meter dimensions:* 85 x 51 x 20 mm
15. *Weight:* 50g (without batteries)
16. *Data transfer/ communication*: ANT wireless

Test strip insertion slot *(rear side): insert test- or check strip here*

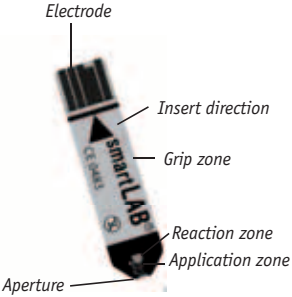
Scroll Wheel
Scroll function within menus (e.g. selection to set date, time, alarm); scroll through stored test results; setting time,

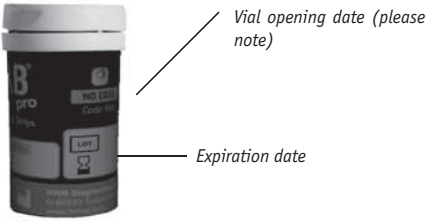
Functions:

Turn = selection / scrolling
Push = store / select

S-Button
Switching on the meter, entering the setup mode, entering ANT mode, exit menus, turning off the meter

The smartLAB® *pro* test strips





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

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

- Use only with **smartLAB®** blood glucose self-monitoring systems.
- Keep the test strips in their original vial.
- Close the vial tightly right after you take out a test strip. This keeps the test strips dry.
- Use the test strip within three minutes after you have taken it out of the vial.
- The strip is for single use only. Do not reuse it.
- Record the date you first open the test strip vial. Be sure to check the "Expiration Date" on the test strip vial. The test strip is durable for three months from the date the vial is opened or until the expiration date on the vial, whichever comes first.
- Store the test strip vial and your meter in a cool dry place
- Store the test strips below 30°C (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.

Note on smartLAB® „NO CODE“-test strips

The **smartLAB**®*pro* blood glucose test strips compatible with **smartLAB**® glucose meters need not to be coded, any more. Thus, when inserting a test strip, the display will read „Code 888“. That is because all test strip charges only use this code. This will make it easier for you to use your **smartLAB**® product free from errors. (Avoidance of coding errors)

If „Code 888“ DOES NOT appear while inserting a test strip, your meter either needs to be recoded or your glucose meter is not compatible with these **smartLAB**®*pro* blood glucose test strips. In either case, please contact your distributor.

Explanation of symbols

	Please refer to the manual
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®*genie+* blood glucose meter
1 User manual
1 carrying bag
2 CR 2032 3V batteries
1 smartLAB® lancing device
1 AST Cap
1 smartLAB® Check Strip
1 smartLAB® Quick Start instruction
10 smartLAB® lancets
10 smartLAB®*pro* blood glucose test strips
1 smartLAB® control soultion

III. Setup & functions

Inserting batteries

The meter uses two CR 2032 3V Lithium batteries. Batteries will normally last for over 2000 tests. Other types of CR 3V Lithium batteries are also acceptable, yet the capacity of test times may differ. Insert the batteries 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 case on the back side of your **smartLAB**® *genie+* meter and insert batteries with plus sign to the top. First insert the battery on the right side and then press the left side down until it clicks. Close the battery case.

battery change symbol

Note:
1. Remove the batteries when you will not be using the meter for one month or longer.
2. Values won't be deleted when the batteries are replaced.

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**® 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.

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

Switching the meter on/off

When a test- or check strip is inserted into the strip slot, the meter turns on automatically. You can also switch on the meter manually by pressing the S-button longer than 3 seconds.
The meter will operate a quick self check (all characters and symbols appear in LCD display) and continue with the start-up mode.

In first line of the display you will see month, day, time and code 888 appear on the LCD display. In the middle three dashes will flash („- - -„) and in the bottom line the unit of measurement (mg/dL or mmol/L) and a flashing test strip symbol will be visible. At this stage you can:

- enter the memory mode „MEM“ by turning the scroll wheel, to show or delete stored test results
- enter the ANT mode by pushing the S-button longer than 3 seconds
- enter the general setting mode by pushing the S-button at least for 6 seconds
- power off the meter by pressing the S-button once.

Setting date, time and alarms

Setting the current time and date in your meter is important if you use the meter memory or if you want to download your results to a computer. Display of current time and date can be helpful when copying your obtained results to log book by hand. Date and time have to be set up before first-time use and after changing batteries.

The meter has a function to setup the data automatically (Heart Beat). When you use the device for the first time or after changing the batterie and you have an ANT receiver in reach, the meter will be set automatically. If indicated data is wrong or you want to make any changes manually, please proceed as follows:

Enter the setting mode

With the meter switched on (Start-up Mode „- - -„ and „Test strip symbol“ flashing), press and hold the S-button for at least 6 seconds to enter setting mode. The last two digits of the current year flash in the middle of the LCD display.

Note: If indicated date / month / day / hour / minute and unit are correct you can save settings by pressing the S-button once.

If you want to change the current value, turn the scroll wheel to either increase or decrease the numbers and store by pressing the scroll wheel. You can leave the setting mode at any point by pushing the S-button.

Setting date & time

Turn the scroll wheel up or down until the digits of the current year are shown on the display. By pushing the scroll wheel you store the year and continue with the month settings. Just like before, you can choose the current month by turning the wheel and finally save it by pushing it. Concludingly, do the same for setting the current day.

Choosing time mode

After setting the day, the colon between hour and minute will start flashing. Here you can choose between 12-hour- and/or 24-hour-display.

12-hour display:

Next to the minute display, AM appears for the time between 00:01 - 11:59 o'clock; PM appears for the time between 12:00 – 23:59 o'clock,

24-hour display:

The area next to the minute display stays empty (00:00 - 23:59). Confirm the desired display by pushing the scroll wheel.

Setting time

You can set the time (hours & minutes) by turning and pushing the scroll wheel, just as explained before. After that, you will enter the signal tone mode (if a Bluetooth module is installed, the automatic Bluetooth transfer setting will come first).

Setting signal tone

If the signal tone is activated, your meter will beep after every measured glucose value. To switch the tone on or off, enter the menu. In the upper display row you can see „bE-bE“ and the setting alternatives:

OFF = signal tone is switched off
ON = signal tone is switched off

Choose the desired setting by turning the scroll wheel and confirm by pressing the wheel. You will enter the LCD backlight setting mode after that.

Switching LCD backlight on/off

The meter has an LCD backlight as well as an illuminated test strip slot. When entering the menu, you see „bL“ in the upper display row and the setting alternatives:

OFF = backlight switched off
ON = backlight switched on

Choose the desired setting by turning the scroll wheel and confirm by pressing the wheel. You will enter the LCD measuring unit setting mode after that.

Changing the measuring unit

The display shows „SCL" and the current measuring unit mg/dL or mmol/L. If you want to change it, keep the scroll wheel pushed for longer than 10 seconds. A double signal tone indicates that the unit has been changed.

Exiting the setting mode

By continually pushing the scroll wheel you can check the settings again or alternatively leave the setting mode by pushing the S-button. You are now in the start up mode.

Further possible steps

- By inserting a test strip, the meter will be ready for running a blood glucose test
- By turning the scroll wheel you enter the test memory
- By shortly pressing the S-button, you can switch off the meter

Note: After choosing another measuring unit, all stored values will be automatically converted. The long time of 10 seconds for changing the unit is necessary to avoid accidential changes.

The meter switches off automatically after 2 minutes, if no test strip is inserted or the S-button or scroll wheel is used.

Setting up the wireless data transfer

Your **smartLAB**®*genie+* blood glucose monitor has an integrated ANT+ module with which you can transfer measurement values to a PC, laptop or mobile phone (e.g. the HMM hFon)*. There, they can be stored, analyzed and processed with the accordant telemedicine software.

What is ANT?
ANT is a wireless transmission standard for your measured values. You need a module for your transmitter as well as for your receiver to use this technology.

To enter the setting mode for wirless data transfer („ANT mode"), keep the S-button pushed longer than 3 and less than 6 seconds with the meter turned on. You can enter the following options in this menu:

- *Manual data transfer of measured values not sent yet (dc)*
- *Manual data transfer of all values stored on the device (dc A)*
- *Automatic data transfer of values not sent yet and Heart Beat (Hb)*
- *Automatic data transfer after each measurement (1A U)*

By turning the scroll wheel you enter the according submenu. Choose a mode by keeping the scroll wheel pushed for a second. You return to the ANT mode by pushing the „S-button".

** More information about the hFon or hLine Terminal on **www.hline.eu***

Manual data transfer of measured values not sent yet (dc):
After you have entered the ANT mode, the display will show the setting mode for the last measured value (see image 1).

image 1

You can start the data transfer of measured values not sent yet by pushing the scroll wheel. The symbol for wireless data transfer will start to flash. When the data was transferred successfully, the display will show „image 1a“. In case the value could not be transmitted, the display will read „image 1b“. If all measured values have been sent already, „image 1c“ will appear.

image 1a

image 1b

image 1c

Manual data transfer of all values stored on the device (dc A):
In this mode („image 2“) you can have all values stored on the meter transferred to a receiver device. To start the transfer process, push the scroll wheel.(Not recomended to use more often)

image 2

After having started data transfer of all stored values, the symbol for wireless data transfer W will start to flash.
When the data was transferred successfully, the display will show „image 2a“. In case the value could not be transmitted, the display will read „image 2b“. If there is no measurement result stored on the meter which could be transferred, „image 2c“ will appear.

image 2a

image 2b

image 2c

Automatic data transfer of values not sent yet and Hear Beat (Hb default is „ON“):

In this mode you can set that your **smartLAB**®*genie*+ automatically transfers all values not sent yet to a receiver device. Every 10 minutes, the meter will initiate a data transfer. At the same time the Heart Beat will be sent to a receiver to indicate the battery status and also to set up the meter automatically.

Note: When you first time use the meter or after changing the battery the Heart Beat will try to connect every minute until it has been set up by the receiver. After that the Heart Beat will show every 10 minutes.

On the display below you can see this data transfer mode whether it is turned on or off. If the mode is activated, the display will show „image 3a“. If it is not activated, it will read „image 3b“. You can change the settings by shortly pushing the scroll wheel and then turning it. The display will change accordingly. Confirm your selection by pushing the scroll wheel. You return to the ANT mode by pushing the „S-button“.

image 3a

image 3b

Automatic data transfer after each measurement (1A U default is „ON“):

In this mode you can set, that your **smartLAB**®*genie*+ will automatically transfer the blood glucose result to a receiver device in its vicinity, after each measurement.

Shown on the display below you can see the data transfer mode whether it is turned on or off. If the mode is activated, the display will show „image 4a“. If it is not activated, it will show „image 4b“. You can change the settings by shortly pushing the scroll wheel and then turning it. The display will change accordingly. Confirm your selection by pushing the scroll wheel. You return to the ANT mode by pushing the „S-button“.

image 4a

image 4b

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**® *genie*+ meter, the **smartLAB**® *pro* 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. „Code 888“ appears on the display and afterwards the symbol for applying blood.

⚠ In case „Code 888“ DOES NOT appear on the display, please contact your supplier (see chapter „Note on **smartLAB**® „NO CODE“ test strips“)

3. Collecting a blood sample

When the blood drop flashes on the display, gently 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 device.

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 results

Test results are automatically stored on the internal memory with date and time. If the maximum storage capacity of 360 values is reached, the oldest value will be deleted. When a corresponding data transfer mode is turned on, the device will try to connect to a predefined device. You can choose, whether you want the device to send the data every 10 minutes or after each measurement. Also, you can transfer single data or the complete data memory manually. (also read chapter „Setting up the wireless data transfer“).

Note: The test strips are for single use only and must not be re-used. If you insert an already used strip, „Err“ will appear on the display.

6. Discarding the test strip

Write down the test result in your diabetes log book if you like and remove the test strip from the insertion slot. The meter will then turn off. If you don't remove the strip, the meter will power off after 5 minutes, automatically.

7. Discarding used lancets

- Remove the end cap of the lancet and carefully pull out the lancet from the holder.
- Dispose of the used lancet according to local regulations

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:

Alternate Blood Collection Sites

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

- 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**® *pro* blood glucose test strips are whole-blood referenced. Your meter is plasma-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. If „LO“ appears on the display, the monitor has determined that your blood glucose level is lower than 1.1 mmol/L or 20 mg/dL. If „HI“ appears on the display, the monitor has determined that your blood glucose level is higher than 35 mmol/L or 630 mg/dL. Please refer to the User Manual for instructions on warning messages.

Expected results for non-diabetic adults:
The normal fasting glucose range is 70 to 110 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).

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 **smartLAB**® check strips are within the expiration date or were stored too long in cold, warm or moist environment. Be sure that the drop of blood completely filled the reaction zone of the test strip. Only take out the strips directly before use, to avoid any damage from environmental influence.
2. Do a function control test with the **smartLAB**® check strips.

3. *Optional:* Performance check of meter and test strips:
   Check meter and test strip performance with the **smartLAB**® control solution. When test results are outside the acceptable range imprinted on the strip vial, please repeate the performance check with a new check strip from a new vial. When the result now is in the acceptable range, you can repeat the measurement. The **smartLAB**® control solution is available from your test strip supplier.

4. Repeating the blood sugar measurement:

If the repeated test results still are questionable or inconsistent and do not match your physical condition, consult your healthcare professional before making any changes to your diabetes medication program.

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) that is either very high (above 55%) or very low (below 30%) may not provide accurate 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. 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 as LO or HI 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:
In order to compare the results of your **smartLAB**®*genie*+ meter with a laboratory meter, it must be guaranteed that both use the same measuring method (whole blood measurement). Your **smartLAB**®*genie*+ is a plasma calibrated meter. This makes it easier to compare its results to lab devices.

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. Take your meter to the doctor's office, and test yourself by fingertip within five minutes of having blood drawn from your arm by a healthcare professional. Keep in mind that the lab uses different technology than the meter, and that blood glucose meters for self testing generally read somewhat lower or higher than the lab result.

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**®*genie*+ 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® control solution:

- **smartLAB**® control solution is for in vitro diagnostic use only.
- **smartLAB**® control solution is not intended for human consumption or injection.
- Use only with **smartLAB**®*pro* test strips.
- Shake the **smartLAB**® control solution well before each use.
- Write the date you first opened the bottle on the bottle label.
- The **smartLAB**® 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**® control solution that is past the expiration date

- The **smartLAB**® 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**® control solution at room temperature, below 30°C (86°F). Do not freeze nor refrigerate.

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**®*genie*+ meter, a **smartLAB**®*pro* test strip, and **smartLAB**® 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. „Code 888“ appears on the display and afterwards the symbol for applying blood.

⚠ In case „Code 888“, DOES NOT appear on the display, please contact your supplier (see chapter „Note on **smartLAB**® „NO CODE“ test strips“)

2. Running the control solution test

When the symbol for applying blood appears, shortly shake the bottle with the **smartLAB**® 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.) and

close 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. 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**® 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?	*This will humidify strips inside. Replace the test strips.*
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.*

Storing, displaying and deleting test results

Your meter automatically saves up to 360 glucose test results with date and time. You can display these results at any time. The values are saved chronologically, beginning with the latest value. Thus, it is important that date and time are set correctly in your **smartLAB**® *genie*+ meter.

Note:

1. Never change your diabetes therapy due to one single saved result.
2. Stored memory won't get lost when you replace the batteries. However, please check if date and time are still set correctly.
3. If the memory is full and a new result is saved, the oldest result on the memory (no. 360) will be deleted.

Displaying test results:

- Press the S-button to power on the meter and wait until it is in start up mode.
- You can display the stored results by either turning the scroll wheel up or down. It starts with the latest value. By turning the wheel, you can scroll through the results on the memory.

Deleting test results:

- To delete a stored result, press the scroll wheel and keep it pushed (at least 3 seconds), until „dEL“ and then „OK“ appears on the display. The test result has been deleted succesfully.

Displaying average values

- Push the scroll wheel and then release it to display the average glucose values of the last 7 days.
- By turning the scroll wheel, you can then switch to the average results of the last 14, 28 or 90 days.
- Press the scroll wheel to go back to the memory mode.
- Press the S-button if you want to exit memory mode and go back to start up mode.

IV. Miscellaneous

Maintenance

Your **smartLAB**® *genie*+ blood glucose meter 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: Do gently wipe the meter's surface with a soft cloth. Do not get any moisture in the test strip slot.

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 “
Solution: Replace with new batteries.

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

Memory error
Display: „MEM Err“
Solution: Replace batteries first. If “Err” reoccurs, 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.

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

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.

Limitations of the measurement procedure

1. DO NOT use serum or plasma sample.
2. DO NOT use neonate blood sample.
3. Extreme humidity may affect the results. A relative humidity greater than 90% may cause incorrect results.
4. 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.
5. DO NOT reuse the test strips. The test strips are intended for single use only.
6. DO NOT use iodoacetic acid, fluoride or sodium fluoride/oxalate as a preservative for blood specimens.
7. 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.
8. Interfering substances depend on the concentration. The substances below may affect the test results:
   - Acetaminophen > 15 mg/dL or 1.0 mmol/L
   - Geneticist Acid > 8 mg/dL or 0.5 mmol/L
   - Levodopa > 10 mg/dL or 0.5 mmol/L
   - Dopamine > 13 mg/dL or 0.7 mmol/L
   - Methyldopa > 2.5 mg/dL or 0.12 mmoll/L
   - Uric Acid >14 mg/dL or 0.4 mmol/L

9. Patients undergoing oxygen therapy may have inaccurate results.

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

11. 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.

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

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

14. Grossly lipemic (fatty) samples may interfere with some methodologies. To be aware of such interferences, patients under the supervision of their physician should have baseline glucose values established by a clinical laboratory method prior to starting home glucose monitoring. These baseline values should be checked periodically thereafter.

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.

Wear parts, batteries etc. are excluded from warranty.

Manufacturer:

HMM Diagnostics GmbH
Friedrichstr. 89
D-69221 Dossenheim, Germany

mail: info@hmm.info
www.hmm.info

Weitere Informationen zu den smartLAB® Produkten /
More information on our smartLAB® products:

www.smartlab.org