9. Patients undergoing oxygen therapy may have inaccurate results.
10. Altitude up to 2000 meters above sea level has no effect on readings.
11. Test results may be false if the patient is severely dehydrated or severely hypotensive, in shock, or in hypoglycemic- hyperosmolar state (with or without ketosis). Critically ill patients should not be tested with homeuse 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.

PERFORMANCE CHARACTERISTICS
The performance of the **smartLAB**®*pro* blood glucose test strips is validated both in laboratory and in clinical tests.

PRECISION
Precision of the **smartLAB**® self-monitoring blood glucose system was measured with both venous blood and control solution in the laboratory. The results are shown in the table below:

Within-run	Blood av. mmol/L (mg/dL) 2.3 (42)	SD = 1,9 (CV = 9,8 %)
	Blood av. mmol/L (mg/dL) 4.5 (81)	CV = 4,4%
	Blood av. mmol/L (mg/dL) 6.8 (122)	CV = 3,5%
	Blood av. mmol/L (mg/dL) 11.2 (202)	CV = 3,0%
	Blood av. mmol/L (mg/dL) 19.2 (345)	CV = 2,6%
	Blood av. mmol/L (mg/dL) 31.9 (574)	CV = 2,8%
Total-run	Control av. mmol/L (mg/dL) 2.1 (38)	SD = 3,1 (CV = 7,8%)
	Control av. mmol/L (mg/dL) 6.2 (111)	CV = 3,5%
	Control av. mmol/L (mg/dL) 19.7 (345)	CV = 3,8%

ACCURACY
The accuracy of the **smartLAB**® self-monitoring blood glucose system was assessed by comparison which is also used in laboratories. The results below were obtained by 205 subjects with diabetes at three independent clinics. The regression statistics are derived from a plot of the **smartLAB**® capillary data versus YSI 2300 plasma data. The strips complaz with teh ISO Standrd ISO 15197:2013.

Slope 0.9458
Intercept +0425mmol/L (+7.660 mg/dL)
Correlation coefficient 0.9765
Number of samples 205
Range tested 1.2-35.0 mmol/L or 21-630 mg/dL

REFERENCES

1. Cass, A.E.G. et al., Anal. Chem., 56 (1984), S. 667
2. Tietz, N.: Fundamentals of clinical chemistry, 3. Ausgabe, W.B. Saunders Co., Philadelphia, PA, 1987, S. 427
3. NCCLS Dokument M29-A, Protection of the laboratory worker from instrument biohazards and infectious disease transmitted by blood, bodyfluids, and tissue, 1997.
4. American Diabetes Associations: Standards of Medical Care for Patients with Diabetes Mellitus, Diabetes Care, 25 (2002), S. S37.

LIST OF SYMBOLS

Caution. Please read manual thoroughly.	In-vitro diagnostics only. Not to ingest.
Expiration date	Storage temperature range
This product meets the requirements of directive 98/79 CE for in-vitro diagnostic medical devices.	Control solution
Please read instructions thoroughly.	Opening date of test strip vial.
For <n> measurements	Single use only.
Manufactured by	Lot number
	Catalogue number

NOTE ON **smartLAB**® „NO CODE"-TEST STRIPS
The **smartLAB**®*pro* blood glucose test strips compatible with **smartLAB**® glucose meters need not to 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.

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

D/N D11410-08-02-02_R4_18/02/2017
CE 0537
IVD

NO CODE

INSTRUCTION **smartLAB**®*pro* TEST STRIPS

INTENDED USE
The **smartLAB**®*pro* blood glucose test strips are used with **smartLAB**® glucose meters to measure glucose (ß-D-glucose) in fresh capillary whole blood and plasma calibrated. The **smartLAB**®*pro* blood glucose test strips are only for use outside the body (in vitro diagnostic use only).

IMPORTANT
Please read this insert and the user manual of your **smartLAB**® product thoroughly before using **smartLAB**®*pro* blood glucose test strips. If you have any questions and/or need assistance, please contact the authorized distributors in your country.

MEASUREMENT PRINCIPLE
The **smartLAB**® self-monitoring blood glucose systems have been developed to allow rapid measurement of blood glucose by using an electrochemical detection technique[1]. Thereby they employ a disposable dry reagent strip technology, based on the glucose oxidase method for glucose determination. Each test strip features an electrode containing the enzyme glucose oxidase[2] (Aspergillus niger). A blood sample is applied to the blood collection area at the tip of the strip and is automatically drawn into the reaction zone, where the glucose oxidase catalyzes the oxidation of glucose to produce gluconic 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 the **smartLAB**® glucose meter and displayed on the screen after 5 seconds.

REAGENT COMPOSITION
smartLAB®*pro* blood glucose test strips contain the following reagent:
Glucose oxidase (Aspergillus niger) > 0.6 IU
Potassium ferricyanide > 0.03 mg
Non-reactive ingredients (buffer, mediator, etc.)> 0.06 mg

STORAGE AND HANDLING
1. Do not refrigerate or freeze.
2. Store the test strip at temperature between 2°C to 30°C.
3. Keep away from direct sunlight and heat.
4. Indicate the first opening date on the vial. D
5. Discard test strips and vial 3 months after first opening date.
6. Replace the vial cap immediately after removing a test strip from the vial.
7. Handle the test strip only with dry and clean hands.
8. Store your test strips in their original vial only. Do not transfer them to a new vial or any other container.

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use only. Do not swallow.
2. Do not use the test strip after the expiration date.
3. Do not re-use test strips.
4. Do not cut, bend, scratch, or alter the test strip in any way.
5. When inserting the **smartLAB**®*pro* test strip into your **smartLAB**® blood glucose meter, the message "Code 888" must appear on the display of your meter.

⚠ If "Code 888" DOES NOT appear on the display, test strips and glucose meter are possibly not compatible. In case you did purchase your **smartLAB**® blood glucose prior to 2010 (last 5 gigits of the serial number smaller than 20000), the system needs to be recoded. Please contact your distributor. If you do already have a "no code"-blood glucose meter and "Code 888" still does not appear on display, please contact your distributor, as well.

6. Warning for potential biohazard[3]: 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.
7. If you are experiencing symptoms that are not consistent with your blood glucose test results, and you have followed all instructions described in the **smartLAB**® user manual, contact your healthcare professional.
8. Never make significant changes to your diabetes control program or ignore physical symptoms without consulting your healthcare professional.
9. Operational temperature of **smartLAB**® glucose control solution is between 10°F to 40°F, which is able to avoid occurring error results from test strips.

SUPPLIES FOR TESTING YOUR BLOOD GLUCOSE

smartLAB® blood glucose meter
smartLAB®*pro* blood glucose test strips
smartLAB® user manual of the meter
smartLAB® lancing device, **smartLAB**® lancets, **smartLAB**® Diabetes log-book, **smartLAB**® Control solution (optional with **smartLAB**®*global* and **smartLAB**®*mini*)

SAMPLE COLLECTION AND PREPARATION

The **smartLAB**® self-monitoring blood glucose system is designed and manufactured for use with fresh capillary whole blood. When the capillary blood sample is obtained, it must be used immediately. Blood sample volume required at least 0.6 micro-liters. To obtain a drop of blood, follow these steps:

Step 1: Wash your hands with soap and warm water. Rinse and dry thoroughly.
Step 2: Prepare lancing device according to the user manual.

TESTING YOUR BLOOD GLUCOSE LEVEL

1. Take a test strip from the vial and immediately close the vial cap.

2. Insert the test strip into the slot of the meter, and the meter will turn on automatically. The display will show "Code 888" and the symbol for applying the blood sample. If this is not the case, please contact your distributor. Your glucose meter either needs to be recoded (in case you purchased it prior to 2010. Check if the last 5 digits of the serial number are smaller than 20000) or your glucose test strips are not compatible with this **smartLAB**® glucose meter.

3. Gain a blood sample by using the lancing device on a dry finger. Do not squeeze the finger tip. When the q symbol is displayed, bring your blood sample to the blood collection area on the test strip. The blood is automatically drawn into the reaction zone at the tip of the test strip. The meter will begin reading.

4. Your blood glucose value will be displayed after 5 seconds. Blood glucose results are automatically stored in the meter memory. Remove the test strip and turn the meter off automatically. For detailed information on the test procedure refer to the **smartLAB**® user manual.

QUALITY CONTROL

It is recommended to test the performance of the **smartLAB**® self-monitoring blood glucose system when

1. you begin using a new vial of test strips
2. your blood test results are not consistent with how you feel, or when you think your results are not accurate.
3. Check that the meter and test strips are not working together as a system and that you are performing the test correctly at least once a week.
4. you suspect that the meter or test strips are not working correctly.
5. If you drop the meter.
6. Your test strips have been exposed to temperature outside the storage conditions (2°C to 30°C, 35.6°F to 86°F).

To check the performance of the meter, test strips and your testing technique, run a control solution test by following the instructions detailed in the user manual. The **smartLAB**® glucose control solution can only be used with **smartLAB**® self-monitoring blood glucose systems. Other control solution may provide incorrect results. When **smartLAB**® glucose control solution test results fall within the specified ranges printed on the test strip vial label, it indicates your meter and test strips are working together properly. If your control solution test results are outside the specified range, repeat the control solution test.
Results that fall outside the range may be caused by:
1. Expired or contaminated control solution
2. Error in performing the test
3. Meter malfunction
4. Test strip deterioration

DO NOT use the system to test your blood until you get a control solution test result within the specified range.

TEST RESULTS

The unit of blood glucose test results displayed on the screen is either mmol/L or mg/dL, 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 in 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 in the display, the
monitor has determined that your blood glucose level is higher than 35.0 mmol/L or 630 mg/dL.

Please refer to the User's Manual for instructions on warning messages. When you have any questions or inconsistent test results, check the following items, and then repeat the test.

1. Check if the strips are within the expiration date.
2. Check if "Code 888" appears when inserting a test strip. If this is not the case, please contact your distributor. Your meter needs to be recoded or it is not compatible with the test strips used.
3. Be sure the drop of blood completely filled the reaction zone of the test strip.
4. Check meter performance with the check strip.
5. Check meter and test strip performance with **smartLAB**® glucose control solution.

When test results are still questionable or inconsistent, consult your healthcare professional before making any changes to your diabetes medication program.

The normal fasting glucose range is 3.9 to 6.7 mmol/L (70 to 120 mg/dL). Two hours after meals, normal glucose values should be less than 6.7 mmol/L (120 mg/dL).mg/dL).

CAUTION: If you get unexpected results, low or high blood glucose test results can indicate a potentially serious medical condition. If your blood glucose test result is unusually low or high, or you do not feel the way your test results indicate, repeat the test with a new test strip. If your test result is not consistent with your symptoms or if your blood glucose result is less than 3.3 mmol/L (60 mg/dL) or higher than 13.3 mmol/L (240 mg/dL), you should contact your healthcare professional immediately.

LIMITATIONS

The **smartLAB**®*pro* blood glucose test strips are designed only for use with fresh capillary whole blood sample.
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°F may cause incorrect results.
4. The system is designed to use 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 sodium fluoride-potassium oxalate as a preservative for blood specimens.
7. Hematocrit: the test strip results are not significantly affected by hematocrits in range of 30% to 55%. Hematocrit level 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 below mentioned substances may affect the test results.

* Acetaminophen _ 1.0 mmol/L or 15 mg/dL
* Gentisic Acid _ 0.5 mmol/L or 8 mg/dL
* Levopoda _ 0.5 mmol/L or 10 mg/dL
* Dopamine _ 0.7 mmol/L or 13 mg/dL
* Methyldopa _ 0.12 mmol/L or 2.5 mg/dL
* Uric Acid _ 0.4 mmol/L or 14 mg/dL
* Ascorbic Acid _ 0.17 mmol/L or 3 mg/dL