SensoCard
SensoCard Plus

Blood Glucose Meter

CE 0197

IVD In vitro Diagnostic Medical Device

Human Voice Data Telling

Instructions for Use

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⚠️ IMPORTANT – READ THIS BEFORE USING THE EQUIPMENT

Before testing your blood with **SensoCard** or **SensoCard Plus** Blood Glucose Monitoring System, please read this user manual carefully.

For the safe and easy operation, studying of the Instructions For Use of the meter and accessories (finger pricker, test strip) is necessary. Should you miss studying this manual, you will not be familiar with the proper use of the system.

Always consult with your diabetes healthcare professional. This advice applies to all blood glucose monitoring systems. Always use the equipment only for the purpose described in this manual.

Never use accessories which are not supplied or recommended by the manufacturer or distributor.

Never use the equipment if it is not working properly.

Ship and store the meter at -20 - 60°C (-4 - 140°F).

⬚ IVD ⬚ **INTRODUCTION**

Thank you for choosing **SensoCard** blood glucose monitoring system. It has been carefully designed to enable you to easily, reliably and accurately monitor your blood glucose level. This meter meets the International Standards belong to the applicable EMC emission, electrostatic discharge, radio frequency radiation.

This manual belongs to both **SensoCard** and **SensoCard Plus** meters. The only difference between them is the talking ability of **SensoCard Plus**. So if it is not specially indicated, all instructions are relevant to both meters.

⚠ **Note!** In this manual if "**SensoCard**" is written, it refers to both **SensoCard** and **SensoCard Plus** meters.

To get the best from your **SensoCard** meter, please take the time to become familiar with. Read and understand the instructions in this manual before using your meter. Follow the instructions included in the "**Maintenance**" section to prolong life and accuracy of your meter.

This guide should tell you everything you need to know about operating **SensoCard** meter, however it is recommended that you visit your medical doctor, specializing in diabetes treatment if you need further advice.

Keep this manual in a safe place so that you can find and consult it any time. If you have any technical questions not included in this manual, please contact your local distributor.

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INTRODUCTION

Content of **SensoCard** kit:
- **SensoCard** blood glucose meter (D45-8001-x)
- Instruction For Use (D45-9201-x)
- Instruction For Use in pictures (D45-9202-x)
- Lancing device (ALT-4451-x)
- 8 pcs. Disposable, microbiologically sterile lancets (ALT-4414-x)
- 1 pce. Check-strip (D45-4001-x)

Content of **SensoCard Plus** kit:
- **SensoCard Plus** blood glucose meter (D46-8001-x)
- Instruction For Use (D45-9201-x)
- Instruction For Use in pictures (D46-9202-x)
- Lancing device (ALT-4451-x)
- 8 pcs. Disposable, microbiologically sterile lancets (ALT-4414-x)
- 1 pce. Check-strip (D45-4001-x)

All parts are microbiologically clean.

ⓘ SENSOCARD METER EXPLAINED

SensoCard indicates blood glucose concentration by checking the reaction between chemical reagents and the blood drop on the test strip. The reaction triggers, the generation of a current in the test strip's reagent zone and this current is conducted to the meter. The current is in correlation with blood glucose concentration. Therefore the meter can determine blood glucose concentration by measuring the extent of current flow.

The whole measuring process is controlled by a microprocessor inside the **SensoCard** meter. The microprocessor also controls the internal calibration of the device and if any failure is detected in the operation, a relevant error message is displayed (see section "**Error messages and Troubleshooting**").

SensoCard automatically stores measured data together with the current date and time. The memory capacity is large enough to store the data of the last 500 tests. Stored data can also be uploaded to a host computer via IR interface with the help of an additional device named **LiteLink** (shipped separately upon request).

UNIQUE FEATURE OF SENSOCARD PLUS

This feature is a great help for those people who may have problems with reading displayed characters from the screen. By using the speaking function of the device, possibility of misreadings caused by poor sight can be reduced significantly.

All the important instructions and values that are displayed on the screen are also told by **SensoCard Plus**. Clear and simple sentences of the device make **SensoCard Plus** a very easily usable blood glucose meter. There is no need for further explanation of the sentences told by the device as they are self explaining sentences. Just follow the instructions as you hear them and you will use **SensoCard Plus** without any difficulty.

Data telling is available in two languages by default: English and German.

⚠️ **Note**: **SensoCard Plus** always gives a typical beeping voice when switching off.

FOR USERS HAVING PLASMA EQUIVALENT CALIBRATED METER

⚠️ **This section refers only to users who have plasma equivalent calibrated meter. If your meter is plasma equivalent calibrated, than "Plasma equivalent calibrated" is written on the label at the back side of your meter.**

Laboratory blood glucose measurements can be made either from whole blood samples or from plasma samples (liquid portion of blood without red blood cells). Both methods are widely used, neither is more accurate than the other. However, there is a slight difference between the results obtained from the two samples. Values of plasma measurements are usually 10% to 15% higher than their whole blood equivalents. So if plasma result is 221 mg/dl, you may have your whole blood reading within the range of 190 mg/dl to 200 mg/dl. Because of the slight difference, result values obtained from the different methods cannot be simply compared.

Plasma calibrated **SensoCard** meter displays the result of blood glucose measurement as it had been obtained from the plasma reading. So the glucose content that is displayed by the meter is the glucose content that would be in the plasma. Therefore results of the measurements can be easily compared with the results obtained from a laboratory using plasma for readings.

⚠ **Important!**
It is important to know, that Plasma calibrated **SensoCard** uses only whole blood for reading. To get plasma result, Plasma calibrated **SensoCard** converts the result of the whole blood measurement to plasma glucose value.*

* Paul D'Orazio, Robert W. Burnett, Niels Fogh-Andersen: Approved IFCC Recommendation on Reporting Results for Blood Glucose, IFCC-SD, WG-SEPOCT Document Stage 1, Draft 9, September 2003

⚠ IMPORTANT PRECAUTIONS

Always operate **SensoCard** blood glucose meter according to the instructions described hereafter. If the equipment is used in a manner not recommended by this manual, the warranty provided by the manufacturer may be lost.

**It is essential to read and follow the information below :**

- **SensoCard** is designed to be used ONLY with **SensoCard Test** strip and no other strips. Always check if the 3-digit code on the vial of strips you are using matches the 3-digit code appearing on the meter's screen. If it does not, then enter the code into the meter (see the "**Strip code setting**" section).

- **SensoCard** meter is calibrated to be used only with fresh capillary blood. No venous blood or plasma is suitable for accurate monitoring of glucose level.

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TECHNICAL DATA

	SensoCard	SensoCard Plus
Batteries:	1 pce. 3V, type: CR2032	2 pcs. 3V, type: CR2032
Battery lifetime:	1 year or 1500 measurements	1 year or 1000 measurements
Calibrated for:	SensoCard Test Strip	
Average test time:	5 sec	
Sample volume needed:	min 0.5 μl capillary blood	
Measuring range:	1.1 – 33.3 mmol/l (20 - 600 mg/dl)	
Display:	under 1.1 mmol/l: **Lo**, above 33.3 mmol/l: **Hi**	
Memory capacity:	last 500 results with time and date	
Strip-code range:	1-UU6 (alphanumerical)	
Coding system:	internal with Code-card	
Automatic switch on:	upon insertion of test strip	
Automatic switch off:	in 2 minutes after the last button activation	
Operating temperature:	10 - 40°C	
Relative humidity:	< 90% RH	
Size:	45 x 90 x 7 mm	55 x 90 x 15 mm
Weight (with batteries):	64 g	96 g

PARTS OF SENSOCARD AND SENSOCARD PLUS METERS

1. OK button
2. Up button
3. Down button
4. Display
5. Strip holder slot

6. Code-card slot
7. Battery holder
8. IR data output interface
9. Loud-speaker (only in **SensoCard Plus**)
10. Strip ejector button

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ABOUT TEST STRIP

1. Flat wire conductor

3. Reagent window

2. Reagent zone
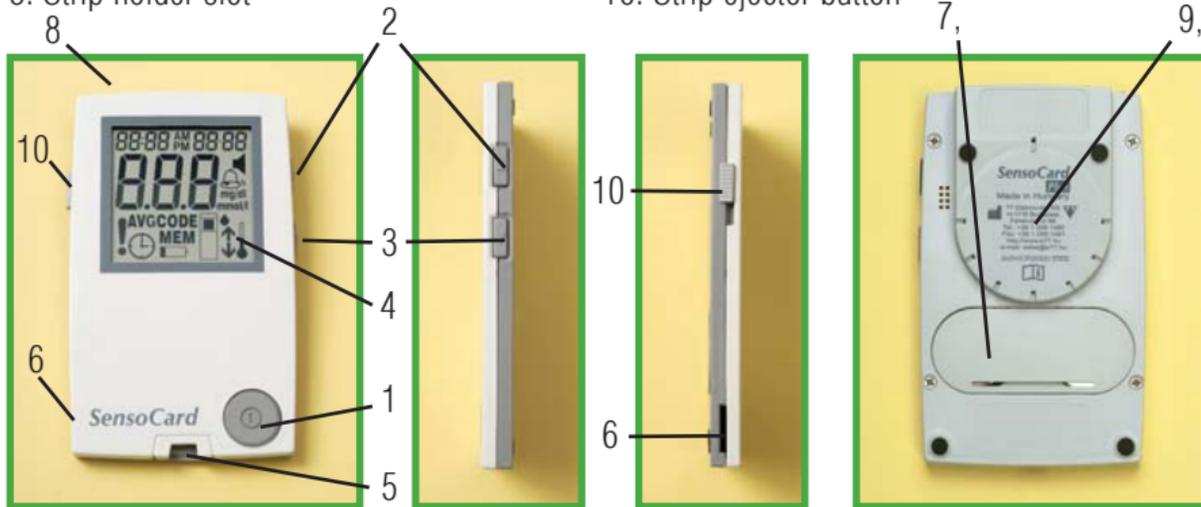
SensoCard is designed ONLY for in vitro use with **SensoCard Test** strip.
No other strips will give you an accurate result.
Always check if the 3-digit code on the bottle of strips you are using, matches the 3-digit code you have entered in your meter. If they are not the same your measuring result will be incorrect (see section "**Strip-code setting**" later).
Each vial of strips is labeled also with a date of expiry. Always use the strips within three months from the date of opening and never use the strips if they are expired.
Before testing always make sure both meter and strips are at room temperature.

Note: **SensoCard Test** strip reacts with blood glucose forming a current. The intensity of the current is proportional to blood glucose concentration. **SensoCard** meter detects generated micro-current and calculates glucose concentration.

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SensoCard Test strips are sensitive to heat and mechanical damage – do not use strips if you suspect such danger may occur. Always keep the strips in their original package, close the vial each time when you removed a strip.

Do not expose the vial of strips to direct sunlight or store it near any heating device (radiator, etc). Unused strips which are stored in the original capped vial under the circumstances described in this chapter, remain stable until the expiration date (indicated on bottle-label). Test strip must be shipped and stored at 8 - 30°C (46 - 86 F). Avoid both freeze and extreme heat.

⚠️ Important!

- Read the Instructions for use of **SensoCard Test** strip before you start to use it!
- Always note the date of the first opening of the vial of strips and use the strips within three months from that date.
- Use the removed strip immediately and always close the vial carefully.
- If the strips were stored below or above room temperature, wait at least 30 minutes before opening the vial.

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Strip insertion and use

The strip must be inserted into meter's strip holder with the black side facing upwards and with the squared end pointing towards the device. The meter will turn on automatically by inserting the test strip. Always ensure that the strip is fully and securely inserted into the centre of the strip holder. Make sure that enough blood – $0.5\,\mu l$ – is applied to reagent area, located at the tip of the arrowhead end of the strip. The little reagent window at the end of the strip should fill up completely if sufficient amount of blood is applied.
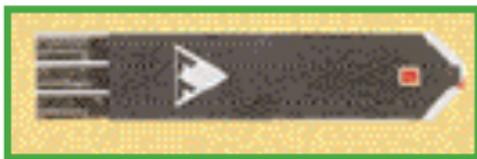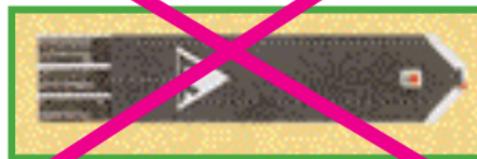
sufficient amount of blood   insufficient amount of blood

⚠ **Note**: On insertion of test strip meter will turn on automatically.

BEFORE STARTING MEASUREMENT

Readings might be effected by:

■ Skin contaminants: Always wash and dry your hands thoroughly before taking your blood sample and using **SensoCard**. Wash your hands with warm water, this also stimulates blood-stream. If you have difficulties in obtaining your blood sample, try hanging your arm down before pricking your finger. It helps to increase the blood flow.

■ Severe dehydration may lead to low measurement results.

■ Abnormally high concentration of Vitamin C (Ascorbic Acid) may lead to high results.

■ Hematocrit (red blood cells volume) level in blood also has an influence on measurement result. If the hematocrit level is over 55% ($>55\%$) the measurement results may be too low, if however, the hematocrit level is below 30% ($<30\%$) the meter may yield unusually high results.

■ In case of dialysis the hematocrit level of blood may vary. This may influence the displayed glucose level.

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BLOOD SAMPLING

It is recommended to use the lancing device and disposable lancets packed together with the meter to prick your finger. If you use them, please read the following instructions too:

Before using them, please make sure to wash your hands thoroughly with warm water and then dry them before pricking.(Thereby you stimulate the blood stream!)

Use the side of the finger-tip for pricking, however alternatively every other part of your palm can be pricked also.

Wipe off the blood that disperses first after pricking and then collect one drop without pressing your finger too hard.

Pressing your finger pad from the lower part up will help you to produce a blood drop.

⚠ **Warning!**

- Excessive rubbing may influence measurement results.
- Read the lancing device's instructions for use before you start to use it.
- Dirt or contaminants on finger, or insufficient amount of blood may lead to inaccurate measurement results.

STRIP-CODE SETTING

Your **SensoCard** meter and **SensoCard Test** strip form together an accurate measuring system. To assure that the meter and the strips work together properly, the **SensoCard** meter must be coded to the strips what are used actually. Coding the meter means entering the code value which is assigned individually to each vial of strips. The code is a three-digit alphanumerical number affixed to the strips' vial which influences the accuracy of the meter while it calculates glucose concentration.

There are two ways how you can enter strip-code
- by using Code-card (included for every vial of strips), or
- by setting the code value manually - which is printed onto the label of the strips' vial.

⚠ Important!

- Verify that the code displayed on LCD matches the code number on the vial of test strips each time you use your meter. The code needs to be entered only once for each vial of test strips. The meter will memorise the code until you change it.
- If your Code-card is broken or missing, please follow instructions for "**Setting strip-code manually**" in this chapter!

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Setting strip-code with Code-card

1. *Switch the meter on* (with the **OK** button or by inserting a **SensoCard Test** strip into the strip holder). After the initial full screen, the actual code value will appear on the LCD. A large 3-digit alpha-numerical value, "**CODE**" caption and a strip icon with a flashing arrow will be displayed. The code value displayed on the screen must be compared to the code value printed onto the label of the **SensoCard Test** strips' vial. If they are not the same, go on with the code setting process.


Important to set code!

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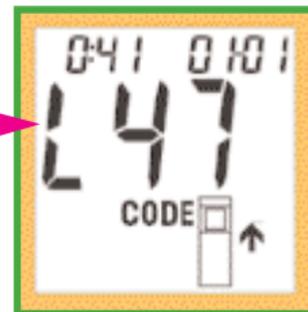
2. *Press the* **Down** *button on the right side of meter to enter the* *"**code setting**" function.* A simple animation displayed on the screen will request the Code-card to be inserted into its slot on the left bottom side of the meter.
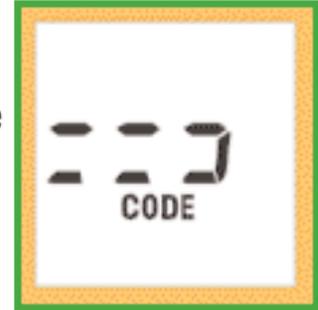

3. *Insert and remove Code-card in Code-card slot with one expressed move without interruption.*
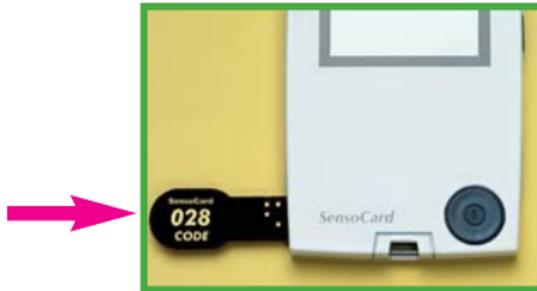
4. The meter returns automatically to the test screen where the recently set code value is displayed, showing that it has been stored in **SensoCard**. Now the meter is ready to perform the blood glucose test with the new code value.

Ready for measurement!

⚠ Warning!

SensoCard waits for the insertion of the Code-card for 60 seconds. If the Code-card is not inserted within 60 seconds the meter displays an **E-C** error message and the actual code value remains the same as before. In this case please repeat the coding process again.

Setting strip-code manually

When the Code-card is missing or it is damaged, you may want to set the strip code manually. The range of the available code values covers 1 – UU6. Digits that can be set vary between 0-U (18 unique values each : 0, 1, 2, 3, 4, 5, 6, 7, 8, 9, A, C, E, F, H, L, P, U). The value of the third digit can vary between 0-6, only if the first two digits' values are "U". In order to set the code manually follow the instructions below.

Press the **Down** button on the right side of meter and when the code requesting animation is displayed press the **Down** button again. A large 3-digit alphanumerical code value will appear on the screen with flashing first digit.

Code value can be adjusted digit by digit. After entering this menu function modify the value of the first digit with the **Up** and **Down** buttons. By pressing the **OK** button, the first digit will be set and the second digit will be flashing, indicating that now its value can be modified. Use the **Up** and **Down** buttons to adjust the value of the second digit similarly to what you did with the first one and then press **OK** when you are ready. Now the last digit should be flashing. After you have set the value of the last digit as well, store the new code by pressing **OK**. The meter will return to the test screen where the new code value will be displayed. Compare this code value with the code value affixed to the strips' vial label. If they are the same you are ready to perform blood glucose test, if not repeat the code setting procedure again.

⚠ **Note**: If no buttons are pressed for 2 minutes, the meter automatically turns off and the actual code value remains the same as before.

MEASURING WITH THE METER

Before you start the test make sure you have everything ready you might need: meter, test strip, finger pricking device, some tissues. Now, put your meter on a clean flat surface. Wash your hands thoroughly.


1. Switch **SensoCard** on either by inserting test strip into its strip holder or by pressing the **OK** button. By pressing the **OK** button test screen appears on the display. Compare the displayed code value with the code value indicated on the strips' vial label. It is recommended to check the strips' expiration date as well.

In the lower right side of the screen a strip icon and a flashing arrow will instruct you to insert the test strip. Take a test strip and holding it by its arrow head shaped end, insert it firmly into the middle of the strip holder. The black side of strip must be face up and it must be inserted all the way into the holder so that the manufacturer's logo will be seen at the entrance of the strip holder.

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If the strip is in its right place the screen changes: instead of the flashing arrow a flashing blood drop icon appears on the LCD, indicating that the meter is waiting for blood dropping.

⚠ **Note**: **SensoCard** can be switched on by inserting test strip as well.
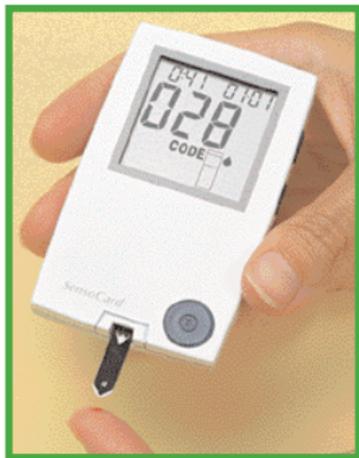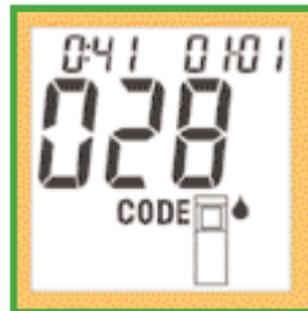
2. Prick your finger and gently squeeze out a small droplet of blood (0.5μl is enough). Apply the blood droplet to the tip of the arrow head shaped end of test strip laterally. Blood should fill up the reagent zone completely (see picture in the "**Strip insertion and use**" paragraph of the chapter "**About Test Strip**"). Insufficient amount of blood might result significant inaccuracy or the failure of the test.

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3. Flashing blood drop icon disappears from the screen after the blood droplet reaches the strip. Flashing clock icon shows that the meter is performing the test. Do not move or touch strip during measuring time.

4. On the average measurements take 5 seconds, after the result is displayed on the screen.

SensoCard Plus not only displays but also tells the result in human voice. If **Up** button is pressed the meter tells you the result again.

Meter will display "**Lo**" if the measured value is under 1.1 mmol/l (20 mg/dl) and "**Hi**" if the value is above 33.3 mmol/l (600 mg/dl).

5. When the result has appeared, it is possible to mark it with the **Down** button. If **Down** button is pressed again, the mark disappears. Marked results will be neglected in case of average glucose level calculation of the last 7-14-28 days tests' results. For more information see chapter **Memory/ Storing** data.
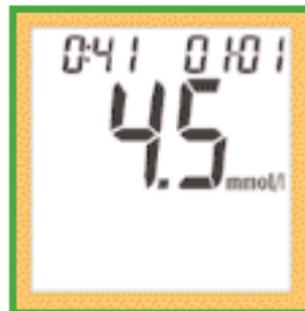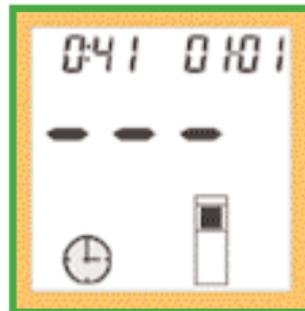
Note: Marks can only be added or removed right after the measurement. They cannot be changed when recalling them from memory.

6. After completing the measurement, test strip can be removed from the meter. Push the ejector button downwards on the left side of the meter to eject the strip.

Test result can be seen on the screen for 2 minutes or until the strip is removed or the meter is switched off. Meter will automatically store the result in the memory together with actual date and time. However, it is recommended always to record the test result in a diabetes diary before turning meter off.

Used strip and lancet are contaminated with blood. Be careful, follow the relevant, local instructions when you throw used strip and lancet away.

In case of any error message refer chapter "**Error messages and Troubleshooting**"

⚠ **Warning!**

■ High or low results which are incorrect may have serious medical consequences. If your blood glucose is unusually high (greater than 16 mmol/) or low (lower than 3 mmol/l), or if you question your results, repeat the test more carefully with a new strip. Consult your healthcare professional before making significant changes to your diabetes medication program. Do not ignore physical symptoms.

■ Electromagnetic interference and electrostatic discharge may interfere with meter. Do not use near highly radiant devices, eg.: mobile phone, microwave oven.

■ Do not perform test with damaged test strip.

■ Make sure that the test strip is inserted properly. Improper position of test strip will cause inaccurate test result.

■ Do not move or remove test strip during measurements.

■ Do not perform test at extreme conditions. Different external temperature from the specified operating temperature range or too high humidity (eg.:humid bathroom) might effect the accuracy of test result!

■ When the meter was stored in a too cold or warm place, wait for at least 30 minutes until meter and strip reach room temperature.

MEMORY

SensoCard is able to store up to 500 measurements with related times and dates.

Storing data

SensoCard meter automatically stores each test result when it switches off. If memory is full, the oldest result will be lost while the new result will be added.

False or control measurement's result can be marked, thus not to be calculated in the average glucose level of the last 7-14-28 day long time periods.

Results can be marked after measurements only by pressing the **Down** button.

An exclamation mark will also appear on the display's lower left side when recalling marked results from memory.
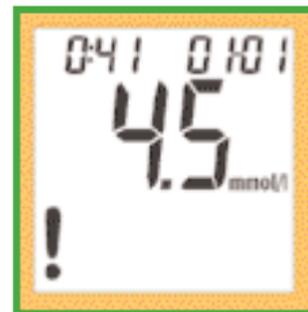
Recalling data from memory

Stored data can be retrieved from memory by selecting **MEMORY** mode. Press the **Up** button on the right side of **SensoCard** after switching the meter on to enter **MEMORY** mode. Result of the last measurement will appear on the screen. Date and time of the measurement will be displayed in the upper line of the display.
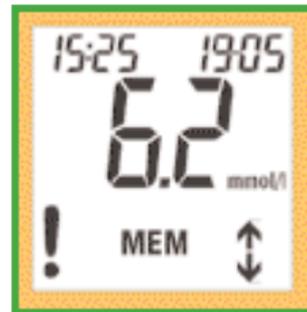
Scroll among stored memory records with the help of the **Up** and **Down** buttons. When you reach the earliest memory record, meter stops scrolling. Those results that were marked after measurement will be displayed with exclamation mark (**!**) when recalled.

By pressing the **OK** button, meter will enter the "**Average calculation**" mode. Press the **OK** button again to return to test mode.

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Average calculation

SensoCard is able to calculate the average glucose level of the last 7-14-28 days tests' results. Calculated average contains all test results from the selected 7, 14 or 28 day long time periods, except the marked ones. However, this function only operates accurately if date and time are precisely set.

To study the average value of your glucose level enter first the **MEMORY** menu by pressing the **Up** button after switching on the device. In the **MEMORY** menu press the **OK** button to display the average glucose level of the last 7 day period. Use the **Up** and **Down** buttons to switch between the average of the last 7, 14 and 28 day long time periods. By pressing the **OK** button you will return to test screen.

Note: If there is no test result in the memory – after memory deletion or before the first test of a new device –, no average value will be displayed.

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OVERVIEW OF FUNCTION MENUS

By keeping the **OK** button pressed after switching on, meter will offer alternatively six functional modes: calibration screen "**CAL**", data download screen "**PC**", time set screen "**SEt**", memory data delete screen "**dEL**", measurement unit selection screen "**SEt**" and switching to speaking function screen "**SEt**" in case of **SensoCard Plus** meter. These function modes will follow each other as you keep pressed the **OK** button in the same order as they were mentioned above. To enter one of the function modes, release the **OK** button when the desired function's tag is displayed.

SETTING DATE AND TIME

SensoCard meter is used world-wide, therefore it works both with a 12 and a 24 hour system. It is not able to recognise "leap" years.
Time is displayed in the upper left corner, while date appears in the upper right corner of screen.

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Switch meter on with the **OK** button and keep it pressed. Select the time setting menu by releasing the **OK** button when "**SEt**" time appears on the screen.
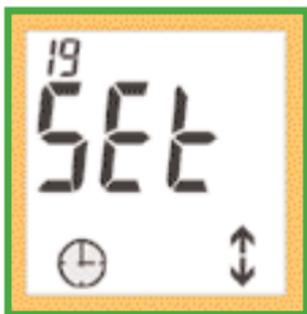
After entering the time setting menu, only hours will be displayed in the upper left corner of the screen. Hours can be modified with the help of the **Up** and **Down** buttons. By pressing and holding down the buttons, hours can be set in fast mode. As you scroll hours, clock mode changes at each rolling over between 12 hour clock mode and 24 hour clock mode. After setting the hours press the **OK** button to switch to minutes setting function and use the **Up** and **Down** buttons for adjusting here as well.

When time is set press the **OK** button again to go on to date setting. In the upper right corner first month then day will be displayed. They can be adjusted with the **Up** and **Down** buttons and set with the **OK** button similarly to time setting.

After time and date are set, the meter can be switched off by pressing the **OK** button. Changes will be stored automatically.

⚠️ **Note**: meter switches off automatically in 2 minutes if you do not press any key.

PC MODE

In "**PC**" mode data stored in meter's memory can be downloaded to PC based computer. To download data, an additional adapter – called **LiteLink IR** adapter – is needed to establish data communication connection between PC and **SensoCard** meter. **LiteLink** adapter together with data communication control program is shipped separately upon buyer's request. Data management program on PC side and manuals containing all information on data downloading, installation, operational settings are attached on CD.

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Switch the meter on with the **OK** button and keep it pressed until "**PC**" mode appears. Release the button.

Target **LiteLink** adapter's IR interface with **SensoCard** meter's IR output. To start data transfer press the **Up** or **Down** button on **SensoCard**.

When data transfer is finished, meter will switch off automatically.

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SELECTING MEASUREMENT UNIT (mmol/l – mg/dl)

SensoCard meter is able to display measured results in two measurement system units: mmol/l or mg/dl. Contact your healthcare professional to check which unit is preferred in your country.

⚠️ **Note:** Changing of measurement unit doesn't effect test results, only the way it is displayed. 1 mmol/l equals to about 18 mg/dl. So for the same blood glucose level 5.4 mmol/l or 97 mg/dl will be displayed depending on which measurement unit is selected.

To choose between the two measurement units, after switching on the meter keep pressed the **OK** button until "**SEt**" and mmol/l with mg/dl is displayed on the screen.

After entering this menu only the recently active unit will appear on the screen. Switch between the two possible units (mmol/l and mg/dl) with the help of the **Up** and **Down** buttons. When the desired unit is selected, store your setting by pressing the **OK** button. Meter will switch off automatically.

DELETING DATA STORED IN MEMORY

All data in memory can be deleted in "**dEL**" mode. After deletion default data setting will be restored (set by Manufacturer: ! 5.4 mmol/l).

Switch meter on with the **OK** button and keep it pressed until "**dEL**" appears on the screen, then release the button.
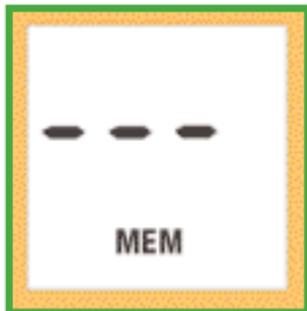
To avoid data loss by mistake, memory deletion will only be executed if after entering this menu first **Down** button and right after **Up** button is pressed. After deletion meter switches off automatically.

⚠ Important!

It is possible to exit from the memory delete mode without loosing data by pressing the **OK** button or by pressing the buttons in any order other than first **Down** button then **Up** button. Data will not be lost either if meter switches off automatically after 2 minutes.

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SWITCHING TO SPEAKING FUNCTION

SensoCard Plus meter can speak in two different languages by default: English and German. To switch between these two languages or to switch loud-speaker off enter loud-speaker switching menu. To enter this menu, after turning on the device keep pressed the **OK** button until "**SEt**" and the sign of a loud-speaker is displayed on screen. Then release **OK** button.

Select "**GEr**" to set German language or select "**EnG**" to set English with the help of the **Up** and **Down** buttons. Choose "**OFF**" to switch off loud-speaker. Always the actual setting is displayed on the screen. Store your setting by pressing **OK** button. Meter will switch off.

⚠ **Note**: If speaking function is switched on, the sign of loud-speaker will be displayed on the screen all the time.

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BATTERY REPLACEMENT

SensoCard meter is powered by 1 pce, while **SensoCard Plus** 2 pcs of round cell batteries, type CR2032. Other types of batteries are not allowed to be used under the guarantee terms and conditions!

When the batteries are getting low, a battery icon is displayed on the screen. It indicates that batteries are needed to be replaced soon. When battery icon is displayed the meter is still operating accurately, but replacement of batteries should be done not later than finishing the next 10 test measurements. Find inside two batteries in **SensoCard Plus**, but only one battery in **SensoCard**.

After battery icon is displayed, **SensoCard Plus** tells you every time you witch off the meter to replace batteries.

If 10 test measurements are done after the first appearance of the battery icon, the error message "E-6" will be displayed on the screen when the meter is switched on. It means that it is not allowed to perform any more tests until the batteries are changed.

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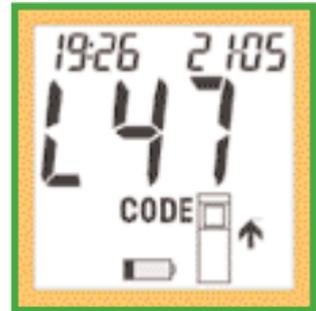
⚠ **Important!**   Keep meter switched off while replacing batteries.

The battery holder is located on the back side of the meter. The battery cover can be opened by pushing the narrow isolated part of the cover upwards. Replace the old, discharged batteries with new ones. Make sure the "**+**" and "**–**" poles are properly positioned. Click the battery cover back into its place, then check the equipment's ability to operate by switching the meter on.

SensoCard

SensoCard Plus

⚠️ **Important!**

■ If the instrument does not work after battery replacement: replace the batteries again, press and hold the **OK** button down for about 15-20 seconds, then replace batteries.

■ If batteries are replaced in 60 seconds, date and time are not needed to be reset. After 60 seconds, date and time should be reset.

■ Code number and test data are stored and they will not be lost due to battery replacement. They will be available after battery replacement as well.

■ Electrostatic discharge may interfere with the meter. In the case of unusual effects (turn off, reset, errors) follow the instructions in the "**Error messages and Troubleshooting**" chapter.

MAINTENANCE

If **SensoCard** is used according to this Instructions For Use, only minimal maintenance is necessary. However, to always have accurate test results, we recommend you to perform the following operations:

■ If necessary, use a wet cloth for cleaning the whole surface of instrument.

■ After maintenance check functionality. For more details see chapter "**SensoCard system checking**".

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⚠️ **Warning!**

- ■ Protect the inside of the meter from water!
- ■ Never immerse the meter or hold it under running water!
- ■ Avoid disassembling the meter, repairs should be done exclusively by authorised service.
- ■ Keep in touch with your local distributor's technical service, if you need assistance contact them.

SENSOCARD SYSTEM CHECKING

Checking the measuring accuracy of the meter is recommended after every maintenance. Check test of **SensoCard** can be carried out by supplied **Check-strip** or with **CareSens** control solution. **CareSens** control solution can be obtained from Manufacturer upon user's request for additional charge (see exact address and phone number of manufacturer at the end of this manual).

To perform system checking, please follow the steps of one of the checking possibilities below.

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Checking with Check-strip

Press **OK** button and keep it pressed until "**CAL**" appears on the screen, then release it.

Strip icon will be displayed together with flashing arrow icon, indicating that the meter is waiting for strip insertion.

Insert **Check-strip** – which is included in **SensoCard** package – into strip holder with the "**Check**" label facing upwards. Meter will perform the measurement and display the result of the check.

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If the displayed value is within the given range – that is indicated on the label affixed to the **Check-strip** holding pocket –, the meter is operating perfectly. Remove **Check-strip**, and switch the meter off.

If the result of the self test is not in the given value range, perform the self test again. If test result's value is still out of given range, contact your local distributor and ask for help.

⚠ **Important!**

- Do not apply blood on the **Check-strip**!
- Protect **Check-strips** against physical damage and keep them in a safe place. If **Check-strip** is damaged or lost, contact your local distributor for advice.

Checking with CareSens control solution

Press **OK** button and keep it pressed until "**CAL**" appears on the screen, then release it.

Strip icon will be displayed together with flashing arrow icon, indicating that the meter is waiting for strip insertion. Compare displayed code value with code value written on the vial of **SensoCard Test** strips. If code values are not the same please set the correct code value before continuing see "**Strip code setting**" chapter for details.

Insert the **SensoCard Test** strip and push it gently until the end position. The black side with the manufacturer's logo should be facing upwards.

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Shake control solution bottle well before use. Drop **CareSens** control solution to the reagent area of test strip, which is at the tip of the arrowhead-shaped end of the test strip. Meter will perform measurement and display the result in the active unit (mmol/l or mg/dl).

Check if displayed result is within the range of L1 or L2 value indicated on the label of **SensoCard Test** strip's vial. If the result is within the range, your meter works perfectly.
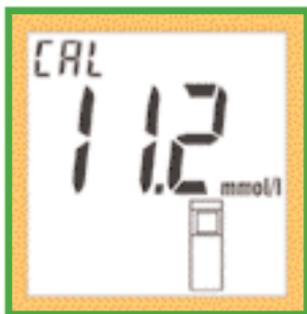
If the result of self test is not in the given value range:

- ■ perform self test again.
- ■ check if the code value displayed on LCD is the same as the code value written on **SensoCard Test** strip's vial.
- ■ check meter with **Check-strip** as well.
- ■ see chapter "**Maintenance**" and/or "**Error messages and troubleshooting**" for further advice.

If test result value is still out of the given range, contact your local distributor and ask for help.

ERROR MESSAGES AND TROUBLESHOOTING

When using **SensoCard** meter, some error messages consisting of a letter "**E**" followed by a number or letter might appear on the display. The cause of these errors may be that you are not doing something correctly or that there is a problem with the meter. In case of an error message pressing any button, the meter will switch off automatically.

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⚠️ **Important!** Do not continue test if an error message is displayed!

This chapter lists error messages, explains their means and possible reasons causing malfunctioning.

1. Instrument is not working
- ■ Batteries are discharged and need to be replaced.
- ■ If the batteries are not low, remove them and keep the **OK** button pressed for about 15-20 seconds then place the batteries back.
- ■ Check that the battery poles are correctly positioned and that the battery cover is closed properly.

2. Meter is very cold or too warm.
- ■ Allow meter to gradually reach room temperature.

3. **E-0 error message**

- If this error message remains on screen after turning meter on, the meter has got damaged. Please remove the batteries and keep the OK button pressed about 15-20 seconds the batteries and turn on the meter. If E-0 appears again, please contact your local distributor.

4. **E-2 error message**

- Strip has been removed from the instrument during measurement.

5. **E-3 error message**

- Used strip is inserted. Repeat measurement with new test strip!
- **Check-strip** is inserted instead of test strip. Replace it with a test strip.
- Strip is not correctly inserted.
- Blood was applied before strip insertion. Repeat measurement with new test strip!

6. **E-5 error message**

- Strong electromagnetic field (e.g.: mobile phone) or high intensity electrostatic discharge interfere with the meter. Repeat the measurement.

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- Meter is damaged. Check the meter with **Check-strip**, see "**SensoCard system checking**" chapter.

7. **E-6** **error message**
- Batteries are low. Replace the batteries.
- High intensity electrostatic discharge may influence the meter. Please remove the batteries and keep the **OK** button pressed about 15-20 seconds. Replace the batteries and turn on the meter. If **E-6** appears again, please change the batteries.

8. **E-7** **error message**
- Insufficient amount of blood was applied on strip. Repeat test with bigger drop of blood.
- High intensity electrostatic discharge may influence the meter. Please repeat the measurement.

9. **E-8** **error message**
- Test wasn't performed properly. Repeat test with new test strip and be more careful when performing each step.

10. E-9 **error message**

- External temperature is too high or low (out of the range 10-40 °C). Wait at least 30 minutes before using the device, until it completely reaches room temperature. **SensoCard** is able to check external temperature. If it detects values not conforming to its operational requirements, the following error messages will be displayed:
- An arrow icon directed downward and the **E-9** error message together indicate low temperature (below 10 °C).
- An arrow icon directed upward and the **E-9** error message together indicate high temperature (above 40 °C).

11. E-C **error message**

This error message may appear during using Code-card. There might be one of the following problems:

- Code-card is damaged. Please check the integrity of Code-card. If you can find any mechanical damage on Code-card, contact your local distributor.
- Code-card insertion or removal was not continuous. Insert and remove Code-card with a bit quicker expressed move.

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- Code-card insertion or removal was too slow. Repeat Code-card insertion without interruption.

12. Flashing result
- If temperature gradient is too high, **SensoCard** still keeps on operating, but the displayed result will be flashing, indicating the abnormal operational circumstances. Be cautious with these test results, they might be inaccurate.

13. Instrument shows Lo constantly
- Code setting is not correct. Check and set the proper code value.
- Insufficient amount of blood was applied on the strip. Repeat test with a bigger drop of blood.

14. Instrument shows Hi constantly
- Code setting is not correct. Check and set the proper code value.

15. Battery symbol appears on display
- Batteries are low. Replace batteries.

If error messages cannot be eliminated by applying the recommendations above, please contact your local distributor for advice. Thank you for your confidence in purchasing our product.

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MANUFACTURER'S WARRANTY

77 Elektronika Kft. warrants **SensoCard** blood glucose meter against defects in materials and workmanship for a period of three years from the date of purchase. The warranty is lost if the instrument is misused, poorly maintained or is tampered with. Liability under this warranty is limited to the repair of defective parts or – at the discretion of 77 Elektronika Kft. – to the replacement of the instrument. The right to rescind the purchase agreement exists only if the replacement is also found to be defective. Claims other than these will not be dealt with.

The warranty is not valid if the damage results from misuse, maltreatment, tampering, human error and the use of extreme.

This warranty is valid only if the date, the stamp and the signature of the dealer are recorded on the warranty card on the date of purchase.

The warranty period is not to be extended by any claim made under this warranty.

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SYMBOLS

 0197   98/79/EEC IVD directive, **SensoCard** meter

 0120   93/42/EEC MDD directive, lancet

    In vitro diagnosticum

    Information inside

    Warning !

    Manufacturer

    Temperature range

    Biological risk

    Expiry date

Manufacturer:
77 ELEKTRONIKA Kft.
1116 Budapest, Fehérvári út 98.
HUNGARY
Tel: + 36 1 206 - 1480
Fax: + 36 1 206 - 1481
E-mail: sales@e77.hu
www.e77.hu

Your local distributor:

Meter serial number:

Service records: