



## AutoSense AutoSense Voice

Blood Glucose Meter  
Instruction for Use



# **AutoSense** **AutoSense Voice**

Blood Glucose Meter  
Instructions for Use

# CONTENTS

READ THIS BEFORE USING THE EQUIPMENT	4
INTRODUCTION	5
CONTENTS OF AutoSense AND AutoSense VOICE KIT	6
AutoSense METER EXPLAINED	7
UNIQUE FEATURE OF AutoSense VOICE	8
FOR USERS OF PLASMA-EQUIVALENT CALIBRATED METERS	9
PRECAUTIONS	11
TECHNICAL DATA	12
PARTS OF THE METER	13
ABOUT THE TEST STRIP	14
Strip insertion and use	16
BEFORE TAKING MEASUREMENTS	17
BLOOD SAMPLING	18
STRIP-AUTOCODING	20
MEASURING WITH THE METER	22
Flagging and marking test results	27

MEMORY	29
Storing data	29
Recalling data from memory	30
Average calculation	31
OVERVIEW OF FUNCTION MENUS	32
PC mode	32
Setting date and time	33
Alarm settings	35
Switching to speaking function	36
Deleting stored data	37
Selecting unit of measurement	38
Setting hypoglycemic limit	39
BATTERY REPLACEMENT	40
MAINTENANCE	44
AutoSense SYSTEM CHECKING	45
Checking with Check-strip	45
Checking with CareSens control solution	47
ERROR MESSAGES AND TROUBLESHOOTING	49
MANUFACTURER'S WARRANTY	56
SYMBOLS	57

## READ THIS BEFORE USING THE EQUIPMENT

### **IMPORTANT!**

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

For safe and easy operation, close study of the Instructions for Use of the meter and its accessories (lancing device, test strip) is necessary. Should you neglect to study this manual, you will not be familiar with the proper use of the equipment.

Always consult 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.

Do not use accessories that are not supplied or recommended by the manufacturer or distributor.

Do not use the equipment if it does not function properly.

Ship and store the meter at  $-20^{\circ}\text{C}$  to  $50^{\circ}\text{C}$  ( $-4^{\circ}\text{F}$  to  $122^{\circ}\text{F}$ ).

# INTRODUCTION

Thank you for choosing the **AutoSense** Blood Glucose Monitoring System. It has been carefully designed for easy, reliable, and accurate monitoring of your blood glucose level.

This blood glucose meter meets international standards for the applicable EMC (Electromagnetic Compatibility)- emission, electrostatic discharge, and radio frequency radiation.

This manual is for both **AutoSense** and **AutoSense Voice** meters. The only difference between them is the speaking ability of **AutoSense Voice**. Therefore, if not specifically indicated, all instructions are relevant to both meters.



## Note:

In this manual, if “**AutoSense**” is cited, it refers to both **AutoSense** and **AutoSense Voice** meters.

To get the best from your **AutoSense** meter, please take the time to become familiar with it.

Please read and understand the instructions in this manual before using your

meter. Follow the instructions provided in “**Maintenance**” to prolong the lifespan and accuracy of your meter.

This manual should tell you everything you need to know about operating your **AutoSense** meter; however, it is recommended that you visit a medical doctor specializing in diabetes treatment if you require more advice.

Keep this manual in a safe place so that you can access and refer to it any time. Please contact your local distributor if you have any technical questions not addressed in this manual.

## CONTENTS OF AutoSense AND AutoSense VOICE KIT

- AutoSense or AutoSense Voice Blood Glucose Meter
- Instructions for Use
- Illustrated Instructions for Use
- Lancing device
- Disposable, microbiologically sterile lancets (8 pcs.)
- Check-strip (1 pc.)

All parts are microbiologically clean.

## AutoSense METER EXPLAINED

**AutoSense** 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 correlates with the blood glucose concentration. Therefore, the meter determines blood glucose concentration by measuring the extent of current flow.

The entire measuring process is controlled by a microprocessor inside the **AutoSense** meter.

The microprocessor also controls the internal calibration of the device, and if any failure is detected during operation, a relevant error message is displayed (see "**Error messages and Troubleshooting**").

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



## UNIQUE FEATURE OF AutoSense VOICE

This feature is a great help for people who may have problems reading the characters displayed on the screen. By using the speaking function of **AutoSense Voice**, the possibility of misreading caused by poor sight can be reduced significantly.

**AutoSense Voice** also vocalizes the important instructions and values displayed on the screen. The clear and simple sentences spoken by the device make **AutoSense Voice** an extremely easy-to-use blood glucose meter. No further explanation of the information vocalized by the device is required, as it is self-explanatory. Just follow the instructions as you hear them, and you will use **AutoSense Voice** without any difficulty. Audio data is available in 2 languages by default: English and German.



**Note:**

**AutoSense Voice** always emits a typical beeping sound when switching off.

## FOR USERS OF PLASMA- EQUIVALENT CALIBRATED METERS

This section refers only to users with a plasma-equivalent calibrated meter. If your meter is plasma-equivalent calibrated, then **“Plasma-equivalent calibrated”** is printed on the label on the back of your meter.

Blood glucose measurements can be made either from whole blood or from plasma (the liquid portion of blood without red blood cells).

Both methods are widely used, although neither is more accurate than the other is. However, there is a slight difference between the results obtained from the 2 samples. Plasma measurement values are generally 10%–15% higher than their whole blood equivalents. Thus, if a plasma result is 221 mg/dl, the whole-blood reading may be within the 190 mg/dl to 200 mg/dl range. Due to the slight difference, the resulting values obtained from the different methods cannot be compared simply.

The plasma-calibrated **AutoSense** meter displays the blood glucose measurement as obtained from plasma. Therefore, the glucose content displayed by the meter is the glucose content that would be in the plasma. Thus, the measurement can be easily compared with the results obtained from a laboratory that uses plasma for readings.



### **IMPORTANT!**

The plasma-calibrated **AutoSense** meter uses only whole blood for reading. To obtain a result for plasma, the plasma-calibrated **AutoSense** meter 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

## PRECAUTIONS

Always operate your **AutoSense** Blood Glucose Meter according to the instructions provided hereafter. If the equipment is used in a manner not recommended by this manual, the warranty provided by the manufacturer may be voided.

It is essential to read and follow the information below:

- **AutoSense** is designed to be used **ONLY** with an **AutoSense Test** strip and no other strips.
- When inserting a new strip, always check if the code on the vial of strips you are using matches the code that appears on the display. If it does not, **DO NOT** use the strip to measure your blood glucose value (see **“Strip Autocoding”**).
- Your **AutoSense** meter is calibrated to be used only with fresh capillary blood. Venous blood or plasma is not suitable for accurate monitoring of glucose levels.

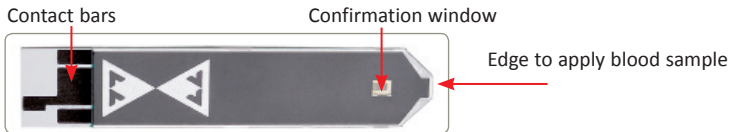
## TECHNICAL DATA AutoSense / AutoSense Voice

Batteries:	1 pc. 3 V, type: CR2032/(2 pcs. 3 V, type: CR2032)
Battery life:	1 year or 1500 measurements/(1 year or 1000 measurements)
Calibrated for:	<b>AutoSense Test</b> strip
Average test time:	5 seconds
Required sample volume:	Min. 0.5 µl capillary blood
Measuring range:	1.1–33.3 mmol/l (20–600 mg/dl)
Display:	Below 1.1 mmol/l: Lo, above 33.3 mmol/l: Hi
Memory capacity:	Last 500 results with time and date
Strip autocode range:	1–15
Coding system:	Autocoding
Automatic switch on:	Upon insertion of test strip
Automatic switch off:	In 2 minutes after the last button activation
Operating temperature:	10°C–40°C
Relative humidity:	<90%
Size:	55 mm × 100 mm × 21 mm
Weight:	60 g/ (90 g) with batterie(s)

# PARTS OF THE METERS



## ABOUT THE TEST STRIP



Your AutoSense meter is designed **ONLY** for in vitro use with an **AutoSense Test** strip.

Other strips will not provide an accurate result.

When inserting a new strip, always check if the code on the vial of strips you are using matches the code that appears on the display. The code does not match that on the vial, **DO NOT** use the strip to measure your blood glucose value. If the code numbers do not match, your measured result will be incorrect (see “**Strip Autocoding**”).

Each vial of strips is also labeled with an expiry date. Always use the strips within 3 months from the date of opening and never use the strips if they have expired.

Before testing, always ensure that both the meter and the strips are at room temperature.



**Note:**

The **AutoSense Test** strip reacts with blood glucose, generating a current. The intensity of the current is proportional to the blood glucose concentration. The **AutoSense** meter detects the generated microcurrent and calculates the glucose concentration.

**AutoSense Test** strips are sensitive to heat and mechanical damage—do not use the strips if you suspect that such damage may have occurred. Always keep the strips in their original package, and close the vial each time after removing a strip.

Do not expose the strips to direct sunlight or store them near any heating device (radiator, etc.). Unused strips that are stored in the original capped vial under the circumstances described in this section will remain stable until the expiration date (indicated on vial label).

The test strips must be shipped and stored at 1°C–30°C (34°F–86°F). Avoid both freezing and extreme heat.



**IMPORTANT!**

- Read the **AutoSense Test** strip Instructions for Use before using them.
- Always note the date when the vial is first opened, and use the strips within 3 months from that date.
- Use the removed strip immediately and always close the vial carefully immediately after removing a strip.
- If the strips are stored below or above room temperature, wait at least 30 minutes before opening the vial.

***Strip insertion and use***

The strip must be inserted into the meter's strip holder with the black side facing upwards and the square end pointing towards the device. The meter will switch on automatically upon the insertion of the test strip.

Always ensure that the strip is completely and securely inserted into the center of the strip holder.

Ensure that enough blood (0.5  $\mu$ l) is applied to the reagent area located at the tip of the arrowhead-shaped end of the strip. The reagent window

at the end of the strip should be filled up completely if a sufficient amount of blood has been applied (see pictures):



Sufficient amount of blood



Insufficient amount of blood



**Note:** The meter will switch on automatically upon insertion of the test strip.

## BEFORE TAKING MEASUREMENTS

Readings might be affected by:

- Skin contaminants: Always wash and dry your hands thoroughly before taking your blood sample and using **AutoSense** meter. Wash your hands with warm water, as this stimulates blood flow. If you have difficulties obtaining your blood sample, try dangling your arm downwards before pricking your finger. This helps to increase blood flow.

- Severe dehydration may lead to low measurement values.
- An abnormally high concentration of vitamin C (ascorbic acid) may lead to high measurement values.
- The hematocrit (red blood cell volume) level in the blood may influence the measured results. If the hematocrit level exceeds 55% (>55%), the measurement results may be too low; however, if the hematocrit level is below 30% (<30%), the meter may display unusually high results.
- In case of dialysis the hematocrit level may vary. This may influence the displayed glucose level.

## 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:

- Before using them, wash your hands thoroughly with warm water and dry them before pricking (thereby stimulating the blood flow).
- Prick the side of your fingertip. However, any other part of your palm or forearm may be pricked.
- Wipe off the blood that emerges initially after pricking, and then collect one drop without pressing your finger too hard. Pressing your finger pad from the lower part upwards will help you to produce a blood drop.

**WARNING!**

- Excessive rubbing may influence the measurement results.
- Read the Instructions for Use for the lancing device before using it.
- Dirt or contaminants on the finger or an insufficient amount of blood may lead to inaccurate results.

## STRIP AUTOCODING

Together, your **AutoSense** meter and **AutoSense Test** strip form an accurate measuring system.

The **AutoSense** meter has an autocoding system to ensure that the meter and the strips work together properly. The meter automatically reads the code on the back of the strip after a strip is inserted (the code is assigned individually to each vial of strips). Manual coding of the meter is not needed. When inserting a new strip, always check if the code on the vial of strips that you are using matches the code that appears on the display (it influences the accuracy of the meter while it calculates glucose concentration). The code number can be any number from 1 to 15. If the code numbers do not match, **DO NOT** use the strip to measure your blood glucose value.

In case you have an **AutoSense Voice** meter, the meter can also read out the code if the speaking function is switched on.



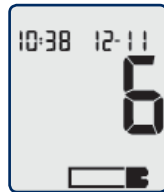
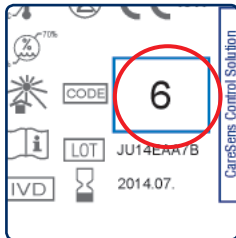
### IMPORTANT!

- Verify that the code displayed matches the code number on the vial of test strips each time you use your meter. The meter will autocode each strip. The code number can be any number from 1 to 15.
- If the code displayed upon insertion of a new strip does not match the code printed on the vial, **DO NOT** use the strip to measure your blood glucose value.



### WARNING!

After strip insertion **AutoSense** meter displays the strip's code number until a sample droplet is applied. Verify that the code displayed matches the code number on the vial of test strips each time you use your meter.



## MEASURING WITH THE METER

Before you start the test, check that everything you might need is ready: meter, test strip, lancing device, some tissues. Now, put your meter on a clean, flat surface. Wash your hands thoroughly.

**1.** Switch **AutoSense** meter on either by inserting a test strip into the strip holder or by pressing the **OK** button. Upon insertion of a test strip, a code number will appear on the display. Compare the displayed code with the code printed on the vial label. It is also recommended to check the strips' expiration date.

If the meter is switched on by pressing the **OK** button, on the lower right side of the display, a strip icon will instruct you to insert the test strip. Take a test strip, and holding it by its arrowhead-shaped end, insert it firmly



into the middle of the strip holder. The black side of strip must face up and it must be inserted all the way into the holder so that the manufacturer's logo is visible at the entrance of the strip holder.

If the strip has been inserted correctly, the display changes: a code number appears on the display until a blood droplet is applied to the strip. After that, a flashing blood drop icon will appear on the display, indicating that the meter is waiting for the blood sample.



**Note:**

The insertion of a test strip will switch on the **AutoSense** automatically

**2.** Prick your finger and gently squeeze out a small droplet of blood (0.5  $\mu$ l is sufficient). Apply the blood droplet laterally to the tip of the arrowhead-shaped end of the test strip. The blood should fill up the reagent zone



completely (see picture in “**Strip insertion and use**” paragraph in “**About Test Strip**”). An insufficient amount of blood might result in significant inaccuracy or failure of the test.

**3.** The flashing blood drop icon will stop flashing when the blood droplet touches the strip. A flashing horizontal bar in the middle of the display indicates that the meter is performing the test. The measurement is performed automatically. Do not move or touch the strip during this time.

**4.** On average measurements are made 5 seconds, after which the result is automatically displayed. **AutoSense Voice** not only displays but also vocalizes the result in a human voice. **The meter will display “Lo” if the measured value is below 1.1 mmol/l (20 mg/dl) and “Hi” if the value exceeds 33.3 mmol/l (600 mg/dl).**



**5.** When the result is displayed, you may mark (!) and/or flag it with the **SET** button. If the **SET** button is pressed again, the next marking/flagging combination appears. For more information, refer to “**Flagging and marking test results**”.

Marked results will be neglected in case of average glucose level calculation from the last 7-14-30-60-90 days' test results. For more information, refer to "**Memory/ Storing**" data.



**Note:** Marks can only be added or removed immediately after a measurement. They cannot be changed when recalling from the memory.

**6.** After completing the measurement, the test strip can be removed from the meter. Press the ejector button on the top of the meter to eject the strip.

The test result will be displayed for 2 minutes, until the strip is removed, or the meter switched off. The meter will automatically store the result together with the actual test date and time. However, it is recommended that you always record the test result in a diabetes diary before switching the meter off.





The used strip and lancet are contaminated with blood. Be careful and follow the relevant local instructions when you discard the used strip and lancet. If an error message appears, refer to **“Error messages and Troubleshooting.”**



### **WARNING!**

- **If “Lo” is displayed as a result after testing it means that the measured value is too low, it is out of measuring range! Contact your healthcare professional immediately.**
- **If “Hi” is displayed as a result after testing it means that the measured value is too high, it is out of measuring range! Contact your healthcare professional immediately.**
- Incorrect high or low results may have serious medical consequences. If your blood glucose is unusually high (greater than 16 mmol/l) 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 the meter. Do not use it near highly radiant devices, e.g., mobile phones, microwave ovens.
- Do not perform the test with a damaged test strip.
- Ensure that the test strip is inserted properly. Improper positioning of the test strip will lead to an inaccurate test result.
- Do not move or remove test strip during measurement.
- Do not perform the test in extreme conditions. External temperatures that differ from the specified operating temperature range or too high humidity (e.g., a humid bathroom) might affect the accuracy of the test result!
- If the meter has been stored in a place that is too cold or too warm, wait at least 30 minutes before use to ensure the meter and strip have reached room temperature.

### ***Flagging and marking test results***

At the end of each measurement, special flags and marks can be set to add information to each measurement. The SET button can define 11 different flag and marking combinations. By pushing the SET button, the following combinations can be set one in sequence: Mark, Premeal,

Mark & Premeal, Postmeal, Mark & Postmeal, Sport activity, Mark & Sport activity, Premeal & Sport activity, Postmeal & Sport activity, Mark & Postmeal & Sport activity. The last status is the unmarked or unflagged state. After selecting one flag and/or marking combination, it can be saved in the meter memory by pressing the **OK** button. After the **OK** button is pressed, the meter will switch off automatically.



Premeal value



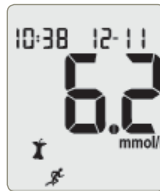
Postmeal value



After sport activity



Premeal &amp; Sport activity



Postmeal &amp; Sport activity

# MEMORY

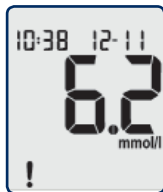
**AutoSense** is able to store 500 measurements with time and date data.

## *Storing data*

Your **AutoSense** meter automatically stores each test result when it switches off. If the memory is full, the oldest result will be discarded, while the new result will be added.

False or control measurement results can be marked, thus are not calculated in the average glucose level of the last 7/14/30/60/90-day periods.

Results can be marked after measurements by pressing the **SET** button. An exclamation mark (!) will appear on the lower left corner of the display when recalling saved marked results.



### Recalling data from memory

Stored data can be retrieved from the memory by selecting **"MEMORY"** mode. Press the **SET** button after switching the meter on to enter **"MEMORY"** mode. The result of the last measurement will be displayed. The date and time of the measurement will be displayed on the upper line of the display.



Scroll through the stored memory records with the **SET** button. The meter stops scrolling when you reach the earliest saved record. Results that have been marked after measurement will be displayed with an exclamation mark (!) when recalled.

By pressing the **OK** button, meter will enter the **"Average calculation"** mode. Pressing the **OK** button will return you to the test screen.

## Average calculation

**AutoSense** is able to calculate the average glucose level of the last 7/14/30/60/90-days' test results. The calculated average contains all test results from the selected periods except those that have been marked. However, this function operates accurately only if the date and time have been set precisely.

To study the average value of your glucose level, first enter the **"MEMORY"** menu by pressing the **SET** 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 **SET** button to switch between the averages of the different periods. Pressing the **OK** button will return you to the test screen.



### Note:

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



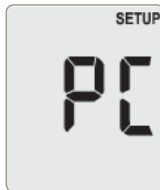
## OVERVIEW OF FUNCTION MENUS

By keeping the **OK** button pressed after switching on, the meter will display the 8 alternative function modes: check “**CHK**,” data download “**PC**,” time set “**SEt**,” alarm settings “**Alr**,” speaking function “**SEt**” for **AutoSense Voice** meter, memory data delete “**dEL**,” measurement unit selection “**SEt**,” and hypoglycemic limit setting “**Hyp**.”

These modes will appear in the listed sequence as you keep the **OK** button depressed. To enter a function mode, release the **OK** button when the desired function tag is displayed.

### *PC mode*

In “**PC**” mode, stored data can be downloaded to a PC. To download data, an additional adapter—a **LiteLink IR** adapter—is needed to establish a data communication connection between your PC and the **AutoSense** meter. The **LiteLink** adapter and data communication control program is shipped separately upon the buyer’s request.



The PC-side data management program and manuals containing all information on data downloading, installation, and operational settings are provided on CD.

- Switch the meter on with the **OK** button and keep it pressed until “**PC**” appears, and release the **OK** button.
- Target **LiteLink's IR** interface with the **AutoSense** meter IR output.
- Press the **SET** button to start the data transfer.

The meter will switch off automatically when the data transfer is completed.

### ***Setting date and time***

Your **AutoSense** meter is used worldwide, therefore, it works with both a 12- and a 24- hour system.

The time is displayed in the upper left corner, while the date appears in the upper right corner of the screen.

Switch the meter on with the **OK** button and keep it pressed.

Select the time setting menu by releasing the **OK** button when “**SET**” time is displayed.



After entering the time setting menu, the year will be displayed in the upper left corner of the screen. This can be modified with the **SET** button. By pressing and holding down the button, years can be set in fast mode. After setting the year, press the **OK** button to proceed to hour setting.

You can set hours in the same manner the year. As you scroll the hours, the clock mode changes at each rollover between 12- and 24-hour clock modes. After setting the hours, press the **OK** button to switch to the minute-setting function, and use the **SET** button to modify the displayed minute value.

When time is set press the **OK** button again to proceed to date setting. In the upper right corner, the month, then day will be displayed. Similar to time setting, these can be adjusted with the **SET** button and set with the **OK** button.

After the time and date are set, switch the meter off by pressing the **OK** button. The changes will be stored automatically.

**Note:**

The meter switches off automatically in 2 minutes if you do not press any key.

**Alarm settings**

The **AutoSense** and **AutoSense Voice** meters are able to alert the user with the alarm function, featuring a flashing screen and sound effect, if a blood glucose measurement has to be made.



Three different dates can be set by entering the **“Alr”** menu. To enter this menu, keep the **OK** button pressed after switching on the device until **“Alr”** is displayed.

The first **“Alr1”** can be switched **ON** and **OFF** by pushing the **SET** button.

- If **“Alr1” “ON”** has been activated, press the **OK** button first before setting the hours with the **SET** button. Press the **OK** button to proceed to minute setting and set the minute(s) with the **SET** button. After setting the date for **“Alr1”** press **OK** to access **“Alr2”**.

- If “**Alr1**” “**OFF**” has been activated, press the **OK** button to proceed to “**Alr 2**” which can be set in the same way as “**Alr1**”.

The same steps can be applied for “**Alr3.**” After setting “**Alr3,**” switch off the meter by pressing the **OK** button. The changes will be stored automatically.



**Note:**

The meter switches off automatically in 2 minutes if you do not press any key.

### *Switching to speaking function*

Your **AutoSense Voice** meter speaks in 3 different languages by default: English, German, and Turkish. To switch between languages, or to switch off the speaker, enter the loudspeaker switching menu. Keep the **OK** button pressed after switching on the device until “**SET**” and a loudspeaker icon is displayed. Then, release the **OK** button. Using the **SET** button, select “**EnG**” for English, “**GEr**” for German, or “**Tr**” for Turkish. Select “**OFF**” to switch off the loudspeaker. The actual setting is always displayed. Press the **OK** button to store the setting, after which meter will switch off.



**Note:**

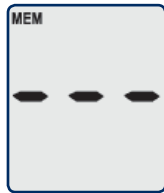
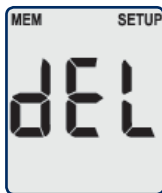
If the speaking function is switched on, the loudspeaker icon will be displayed all the time.

**Deleting stored data**

All stored data can be deleted in “dEL” mode.

Switch the meter on with the **OK** button and keep it pressed until “dEL” is displayed, and then release the **OK** button.

To avoid data loss by mistake, press **SET** first, and press the **OK** button immediately after to delete the meter memory. The meter switches off automatically after memory deletion.

**IMPORTANT!**

You can exit the memory delete mode without data loss by pressing the **OK** button or by pressing the buttons in any order other than **SET** then

**OK.** Data will not be lost either if the meter switches off automatically after 2 minutes.

In case the memory contains no data, a display with horizontal bars is displayed when switching to average calculation mode.

### **Selecting unit measurement** (mmol/l – mg/dl)

Your **AutoSense** meter can display the measured results in 2 units of measurement: mmol/l or mg/dl. Contact your healthcare professional to check which unit is preferred in your country.



**Note:** Changing the unit of measurement will not affect your test results, only the way they are displayed. For example, 1 mmol/l is equivalent to approximately 18 mg/dl. Thus, depending on which measurement unit you select, 5.4 mmol/l or 97 mg/dl will be displayed for the same blood glucose level.



To choose between the units of measurement, keep the **OK** button pressed after switching on the meter until “**SET**” and mmol/l with mg/dl

is displayed. Only the most recent active unit will be displayed after you enter this menu. Switch between the 2 units (mmol/l and mg/dl) with the **SET** button. When the desired unit has been selected, store your setting by pressing the **OK** button. The meter will switch off automatically.

### **Setting hypoglycemic limit**

Your **AutoSense** meter is able to alert the user by displaying an **“unhappy”** face if a measured blood glucose level exceeds a specified limit. To enter this menu, keep the OK button pressed after switching on the device until **“Hyp”** is displayed.

After entering this menu, different limits can be set using the **SET** button. In sequence, these limits are: OFF, 3, 3.4, 3.8, 4.2 mmol/l.

After selecting the desired limit value, store your setting by pressing the **OK** button. The meter will switch off automatically.





## BATTERY REPLACEMENT

Your **AutoSense** meter is powered by a CR2032 round-cell battery (1 pc.), while **AutoSense Voice** is powered by 2 CR2032 batteries. The use of other types of batteries is not permitted under the guarantee terms and conditions!

When the batteries run low, a battery icon is displayed. It indicates that the batteries need to be replaced soon.

The meter will still operate accurately when the battery icon is displayed, but batteries should be replaced no later than the end of the next 10 test measurements.

After the battery icon is displayed, **AutoSense Voice** will remind you to replace the batteries each time you switch off the meter.

If 10 test measurements are made after the battery icon first appears, the error message “E-6” will be



displayed when the meter is switched on. It means that you may not perform more tests until the batteries have been replaced.



### **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 part of the cover upwards. Replace the old, discharged batteries with new ones. Ensure that the “+” and “-” poles are properly positioned. Click the battery cover back into place, and then check the equipment by switching on the meter.



AutoSense



AutoSense Voice

**IMPORTANT!**

If the meter does not function after battery replacement, remove batteries again, press and hold the **OK** button for 15–20 seconds, and then replace batteries again.

If batteries are replaced in 60 seconds, the date and time need not be reset. The date and time should be reset if the batteries are replaced after 60 seconds.

Test data are stored and will not be lost due to battery replacement.

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

## MAINTENANCE

If **AutoSense** is used according to the Instructions for Use, only minimal maintenance is necessary. However, to obtain always-accurate test results, we recommend performing the following actions:

- If necessary, use a wet cloth to clean the surface of the meter.
- After maintenance, check the functionality of the device. For more details, refer to ***“AutoSense system checking.”***



### **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 carried out exclusively by authorized service personnel.
- Keep in touch with your local distributor's technical service; contact them if you require assistance

# AutoSense SYSTEM CHECKING

Checking the measuring accuracy of the meter is recommended after every maintenance operation.

A check test of your **AutoSense** can be carried out with the supplied **Check-strip** or with **CareSens** control solution. The **CareSens** control solution can be obtained from the manufacturer upon request; an additional charge applies (for the manufacturer address and phone number, refer to the end of this manual). To perform system checking, follow the steps of one of the checking options below.

## *Checking with Check-strip*

Press the **OK** button and keep it pressed until “**CHK**” is displayed, then release the **OK** button.

A flashing strip icon will be displayed, indicating that the meter is waiting for strip insertion.



Insert the **Check-strip** included in your **AutoSense** package into the strip holder with the **“Check”** label facing upwards. The meter will perform the measurement and display the result of the check.

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

If the result of the self-test is outside the stated value range, perform the self-test again. If test result value is still outside the stated range, contact your local distributor and request assistance.





## IMPORTANT!

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

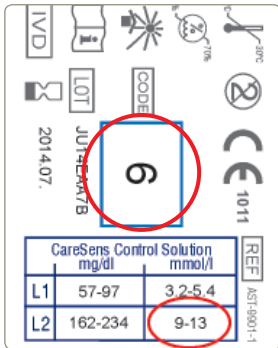
### *Checking with CareSens control solution*

Press the **OK** button and keep it pressed until **“CHK”** is displayed, then release the **OK** button.

A flashing strip icon will be displayed, indicating that the meter is waiting for strip insertion. Insert an **AutoSense Test** strip and push it gently into the end position. Compare the displayed code with code printed on the vial that held the strip. If the codes differ, insert another strip.







The black side with the manufacturer's logo should face upwards.

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

Check if the displayed result is within the range of **L1** or **L2** values indicated on the label of the **AutoSense Test** strip vial. If the result is within the range, your meter is functioning properly.

If the result of the self-test is outside the given value range:

- Perform self test again.
- Check if the code displayed is the same as the code on the **AutoSense Test** strip vial.

- Check the meter with **Check-strip** as well.
- See chapter *“Maintenance”* and/or *“Error messages and troubleshooting”* for further advice.

If the test result value is still outside the given range, contact your local distributor and request assistance.

## ERROR MESSAGES AND TROUBLESHOOTING

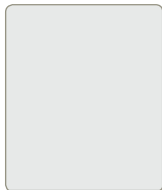
When using your **AutoSense** meter, error messages consisting of the letter *“E,”* followed by a number or letter, might appear on the display. The cause of these errors may be incorrect use of the meter or a problem with the meter. In case of an error message generated by pressing any button, the meter will switch off automatically.



### **IMPORTANT!**

Do not continue a test if an error message is displayed.

This section lists error messages, explains their meanings, and the possible reasons for a malfunction.



### Instrument is not working

- Batteries are discharged and must be replaced.
- If the batteries are not running low, remove them and keep the **OK** button pressed for 15–20 seconds, and then replace the batteries.
- Check that the battery poles are correctly positioned and that the battery cover is closed properly.

### Screen is too dim or screen persistence occurs

- If screen cannot be seen properly because it is dim or all graphics are displayed simultaneously, the meter is very cold or too warm.
- Allow meter to reach room temperature gradually.

### E-O error message

- If this error message remains on screen after turning meter on, the meter has become damaged. Remove the batteries and keep the **OK** button pressed for 15–20 seconds, replace the batteries, and switch on the meter. If “E-0” appears again, please contact your local distributor.



### E-1 error message

- Code error. Please ensure that the proper **AutoSense** test strip is used with the meter.



### E-3 error message

- Used strip is inserted. Repeat measurement with new test strip.
- **Check-strip** has been inserted, replace it with a test strip.
- Strip was inserted incorrectly.
- Blood was applied before strip insertion. Repeat measurement with a new test strip.



### E-4 error message

- Strong external light. Do not expose the meter to direct sunlight.



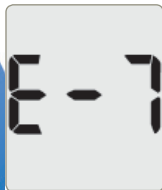
### E-5 error message

- Strong electromagnetic field (e.g.: mobile phone) or high-intensity electrostatic discharge is interfering with the meter. Repeat the measurement.
- Meter is damaged. Check the meter with **Check-strip**, refer to *"AutoSense system checking"*.



### E-6 error message

- Batteries are running low. Replace the batteries.
- High-intensity electrostatic discharge may be affecting the meter. Remove the batteries and keep the **OK** button pressed for 15–20 seconds. Replace the batteries and switch on the meter. If *"E-6"* appears again, change the batteries.



### E-7 error message

- Insufficient amount of blood was applied to the strip. Repeat test with a bigger drop of blood.
- High-intensity electrostatic discharge may be affecting the meter. Repeat the measurement.
- Hematocrit level of sample is too high or too low. Repeat test with a fresh drop of blood.
- Test strip is damaged. Repeat test with another strip.



### E-8 error message

- Test was not performed properly. Repeat test with a new test strip and be more careful when performing each step.



### E-9 error message

- External temperature is too high or low (outside the 10°C–40°C range). Wait at least 30 minutes before using the device, until it fully reaches room temperature.

**AutoSense** is able to detect the external temperature. If it detects values that differ from its operational requirements, the following error messages will be displayed:

- A downward-pointing arrow icon and the “E-9” error message indicate low temperature (below 10°C).
- An upward-pointing arrow icon and the “E-9” error message indicate high temperature (above 40°C)



### Flashing result with "!" and "thermometer" mark

- **AutoSense** keeps operating if external temperature is close to the operating limits (10-10.5°C or 39.5-40°C), but the displayed result will flash, indicating close-to-abnormal operational circumstances. Be cautious with these test results, as they might be inaccurate.



### Flashing result with "☹️" mark

- Result flashes and a sad face is displayed on screen if the result is below the set hypoglycemic limit



### Instrument constantly displays "Lo"

- Code is not correct, repeat test with a new strip and check autocode.
- Insufficient amount of blood was applied on the strip. Repeat test with a bigger drop of blood.

**Warning!** 

**If "Lo" is displayed as a result after testing it means that the measured value is too low, it is out of measuring range! Contact your healthcare professional immediately.**



### Instrument constantly displays “Hi”

- Code is not correct, repeat test with a new strip and check autocode.

**Warning!** 

**If “Hi” is displayed as a result after testing it means that the measured value is too high, it is out of measuring range! Contact your healthcare professional immediately.**



### Battery icon is displayed

- Batteries are running 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.



## MANUFACTURER'S WARRANTY













**77 Elektronika Kft.** provides warranty for the **AutoSense Blood Glucose Meter** against defects in materials and workmanship for a period of 5 years from the date of purchase. The warranty is void 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.**, 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 entertained.

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

This warranty is valid only if the date, stamp, and 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.

# SYMBOLS

	In vitro diagnostic medical device
	98/79/EEC IVD directive, AutoSense meter
	0120 93/42/EEC MDD directive, lancing device and lancets
	Manufacturer
	Consult instructions for use
	Warning!
	Serial number
	Direct current
	Storage temperature limitation
	Biological risk
	Use by date: for lancing device and lancets
	Date of manufacture

# AutoSense & AutoSense Voice

Notes:

58

Notes:



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](mailto:sales@e77.hu)  
Website: [www.e77.hu](http://www.e77.hu)

Your local distributor:

Meter serial number:

Service records:



**77 Elektronika Kft.**

HUNGARY


1116 Budapest, Fehérvári út 98.

Tel.: +36 1 206-1480

Fax: +36 1 206-1481

E-mail: [sales@e77.hu](mailto:sales@e77.hu)

[www.e77.hu](http://www.e77.hu)

 1011 Applied to AutoSense

 In vitro Diagnostic Medical Device