i·sens

Owner's Booklet

KetoSens™

Blood β-Ketone Monitoring System

- β-Ketone Measurement
- 2.5" Large, Backlit Display
- Strip Ejector for Easy Ejection of Used Test Strips

KETONE | 2.5 | ☀ | 📥

0.3
mmol/L KETONE
09:24   12:37 PM

◄ S ►

KETONE

Welcome to the KetoSens
Blood *β*-Ketone Monitoring System

Thank you for choosing the KetoSens Blood *β*-Ketone Monitoring System. The system provides you with rapid and convenient blood *β*-Ketone *in vitro* (i.e., outside the body) diagnostic monitoring. You can obtain accurate results in just 8 seconds with a small (0.5 µL) blood sample.

Table of Contents

Important Information: Read This First!

For optimum safety and benefits, please read the entire manual contents before using the system. Please note the following instructions:

> Intended use:
> KetoSens Blood β-Ketone Monitoring System is used for the quantitative measurement of the β-Ketone level in capillary/venous whole blood as an aid in monitoring diabetic ketoacidosis management effectively at home or in clinical settings.
> Fresh venous whole blood may be used only if drawn by healthcare professionals.
> KetoSens Blood β-Ketone Monitoring System should be used only for self-testing outside the body (*in vitro* diagnostic use only). Test blood β-Ketone in fresh capillary/venous whole blood samples from the traditional fingertip testing.

Meaning of Symbols Used:

IVD	For *in vitro* diagnostic use
CE	This product fulfills the requirements for Directive 98/79/EC on *in vitro* diagnostic medical devices
⚠	Cautions for safety and optimum product use
⧗	Use by
⌧	Do not discard this product with other household-type waste
⊗	Do not reuse
📖	Consult instruction for use
🌡	Temperature limitations
EC REP	Authorised representative

LOT	Batch code
🏭	Manufacturer
SN	Serial number

- The KetoSens Blood β-Ketone Monitoring System is intended for self-testing outside the body (*in vitro* diagnostic use).
- β-Ketone in blood samples reacts with the chemical in the test strip to produce a small electrical current. The KetoSens meter detects this electrical current and measures the amount of β-Ketone in the blood sample.
- The KetoSens Blood β-Ketone Meter is designed to minimise code related errors in monitoring by using the no-coding function.
- The KetoSens Blood β-Ketone Meter should be used only with the KetoSens Test Strips.
- An abnormally high or low red blood cell count (hematocrit level over 60 % or below 30 %) may produce inaccurate results.
- Critically ill patients should not be tested with blood β-Ketone meters.

If you need assistance, please contact your authorised i-SENS sales representative or visit www.i-sens.com for more information.

Specifications

Product specifications

Measurement range	0.1–8.0 mmol/L
Sample size	Minimum 0.5 μL
Test time	8 seconds
Sample type	• Fresh capillary whole blood • Fresh venous whole blood (healthcare professionals only)
Assay method	Electrochemical
Battery life	3,000 tests
Power	Two 3.0 V lithium batteries (disposable, type CR2032)
Memory	1,000 test results
Size	106 x 58 x 17 (mm)
Weight	71.8 g (with batteries)

Operating ranges

Temperature	15–30 ˚C (59–86 ˚F)
Relative humidity	10–90 %
Hematocrit	30–60 %

Storage/transport conditions

Temperature	Meter (with batteries)	0–50 ˚C (32–122 ˚F)
	Test Strip	4–30 ˚C (39–86 ˚F)
	Control solution	8–30 ˚C (46–86 ˚F)
Relative humidity	Test strip	10-90 %

KetoSens Blood $β$-Ketone Monitoring System

KetoSens BKM System includes the following items:
* KetoSens Blood $β$-Ketone Meter
* Owner's Booklet
* Batteries

Optional items:
* KetoSens Blood $β$-Ketone Test Strips
* Lancets
* Lancing Device
* Logbook
* Carrying Case
* Quick Reference Guide

• Check all the components after opening the KetoSens blood $β$-Ketone monitoring system package. The exact contents are listed on the main box.

• The cable for data management software can be ordered separately. Please contact your authorised i-SENS sales representative.

Inserting or Replacing the Batteries

The KetoSens Meter uses two 3.0 V lithium batteries.
Before using the meter, check the battery compartment and insert batteries if empty.
When the ▬▬ symbol appears on the display while the meter is in use, the batteries should be replaced as soon as possible. The test results may not be saved if the batteries run out.
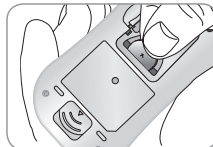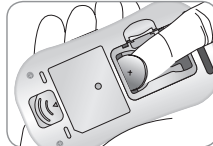
Step 1

Make sure the meter is turned off. Push the cover in the direction of the arrow to open the battery compartment.

Step 2

Remove the used batteries one at a time. Slip your index finger under the battery to lift and pull out as shown. Insert two new batteries with the + side facing upwards and make sure the batteries are inserted firmly.

Step 3

Place the cover on the battery compartment. Push down until you hear the tab click into place.

Note: Removing the meter batteries will not affect your stored results. However, you may need to reset your meter settings. See pages 14–19.

Caring for Your System

Use a soft cloth or tissue to wipe the meter exterior. If necessary, dip the soft cloth or tissue in a small amount of alcohol.

Do not use organic solvents such as benzene or acetone, or household and industrial cleaners that may cause irreparable damage to the meter.
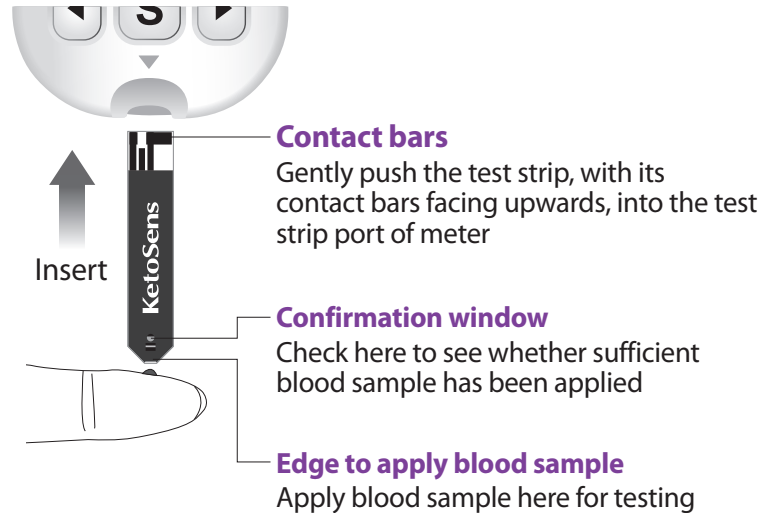
Caution:

- Do not expose the meter to direct sunlight, heat, or excessive humidity for an extended period of time.
- Do not let dirt, dust, blood, or water enter into the meter's test strip port.
- Do not drop the meter or submit it to strong shock.
- Do not try to fix or alter the meter in any way.
- Strong electromagnetic radiation may interfere with the proper operation of this device. Keep the device away from sources of strong electromagnetic radiation, especially when measuring your blood β-ketone.
- Store all the meter components in the portable case to prevent loss and help keep the meter clean.

Disposal of the meter

If you need to throw your meter away, you should follow existing policies and procedures of your own country or region. For information about correct disposal, please contact your local council or authority. If you need assistance, contact your authorised i-SENS sales representative or visit _www.i-sens.com._

KetoSens Blood *β*-Ketone Test Strip

The KetoSens Blood *β*-Ketone Monitoring System measures blood *β*-Ketone quickly and accurately. It automatically absorbs the small blood sample applied to the narrow edge of the strip.

Insert

Contact bars
Gently push the test strip, with its contact bars facing upwards, into the test strip port of meter

Confirmation window
Check here to see whether sufficient blood sample has been applied

Edge to apply blood sample
Apply blood sample here for testing

Warning!

- The KetoSens Blood β-Ketone Test Strips should be used with fresh capillary whole blood samples, or with fresh venous whole blood samples if drawn by healthcare professionals.
- Do not reuse test strips.
- Do not use test strips past the expiration date.
- Test strips in new, unopened test strip box can be used up until the expiration date printed on the foil packet if the test strips are used and stored according to its storage and handling methods.
- Store test strips in a cool and dry place at a temperature between 4–30 ˚C (39–86 ˚F).
- Keep test strips away from direct sunlight or heat and do not freeze.
- Store test strips only in their original box.
- Open the foil test strip packet to take out a test strip for testing and use the test strip immediately. Do not use the test strip if the foil is damaged or torn.
- Handle test strips only with clean and dry hands.
- Do not bend, cut, or alter test strips in any way.
- For detailed storage and usage information, refer to the KetoSens test strip package insert.

Caution:
- Keep the meter and testing supplies away from young children.
- The test strips and foil packet may be choking hazards.

KetoSens Blood β-Ketone Meter

Data Port
Used to transfer data
from the meter to a
computer with
a cable

Display
Shows results
and messages

S Button
Turns the
meter on/off,
confirms menu
selections,
and changes
information

◀ , ▶ Button
Turns the meter
on, selects
or changes
information

Test Strip Port
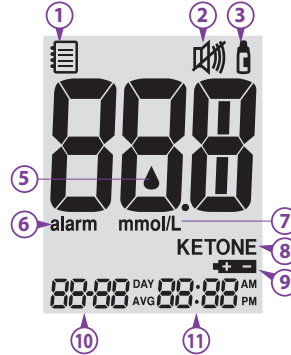Insert test strip
here

Test Strip Ejector
Slide down to
discard the used
strips

Note:
• The cable for data management software can be ordered
  separately. Please contact your authorised i-SENS sales
  representative.
• The unit of measurement is fixed and it cannot be changed by
  the user.

KetoSens Blood β-Ketone Meter Display

① **Memory recall mode:** appears
   when test results stored in the
   memory are displayed
② **Mute symbol:** appears only when
   the sound is set to OFF
③ **Control solution flag:** appears
   when the control solution test
   results are saved or displayed
④ **Test results**
⑤ **Blood insertion symbol:** indicates
   meter is ready for the application of
   a drop of blood or control solution
⑥ **alarm:** appears when the time alarm has been set
⑦ **mmol/L:** unit for measurinig blood β-Ketone
⑧ **KETONE:** appears when the KetoSens strip is inserted, and
   when the test results are saved or displayed
⑨ **Battery symbol:** indicated meter battery is running low and
   needs to be replaced
⑩ **Date**
⑪ **Time**

Note: It is recommended to check if the display screen on the
meter matches the illustration above every time the meter
turns on. Do not use the meter if the display screen does not
exactly match the illustration as the meter may show incorrect
results.

Setting Up Your System

Press and hold the **S** button for 3 seconds to enter SET mode. After all settings are finished, press and hold the **S** button for 3 seconds to turn off the meter.
Press the ◀ or ▶ button to change values. Press and hold the ◀ or ▶ button to scroll faster.

## Adjusting the Date and Time

Step 1 Entering SET Mode

Press and hold the **S** button for 3 seconds to enter SET mode. After all the segments flash across the screen, the 'SET' will show up. Press the ◀ or ▶ button to select 'YES' and press the **S** button to go to the next step.
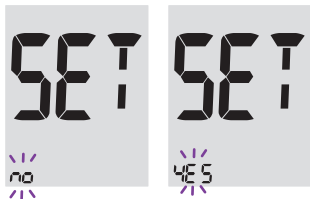
Step 2 Setting the Year

Press the ◀ or ▶ button to adjust until the correct year appears. When the present year appears, press the **S** button to confirm your selection and to go to the next step.
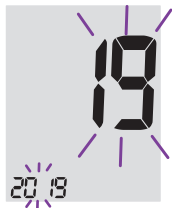
Step 3 Setting the Month

A number indicating the month will blink on the screen.
Press the ◀ or ▶ button until the correct month appears. Press the **S** button to confirm your selection and to go to the next step.

Step 4 Setting the Date

Press the ◀ or ▶ button until the screen displays the correct date. Press the **S** button to confirm the date and to go to the next step.

Step 5 Setting the Time Format

The meter can be set in the AM/PM 12-hour or the 24-hour clock format.
Press the ◀ or ▶ button to select a format. The AM•PM symbol is not displayed in the 24-hour format. After selecting the format, press the **S** button to go to the next step.

Step 6 Setting the Hour

Press the ◀ or ▶ button until the correct hour appears.
After the hour is set, press the **S** button to go to the next step.

Step 7 Setting the Minute

Press the ◀ or ▶ button until the correct minute appears. After setting the minute, press the **S** button to go to the next step.

Setting the Sound On/OFF

Step 8

On pressing the ◀ or ▶ button the screen will display 'On' or 'OFF'. Press the **S** button to confirm the selection.

The meter will beep in the following instances if the sound is set to On:
- When you press a button to turn on the meter,
- When the test strip is inserted in the meter,
- When the blood sample is absorbed into the test strip and the test starts,
- When the test result is displayed,
- When it is time for a pre-set blood glucose test.

If the sound is set to OFF, none of the sound functions will work.
After setting the sound, press the **S** button to go to the next step.

Note:
The 🔇 symbol is displayed only when the sound is set to OFF.

Turning on the Strip Expiration Date Indicator

Step 9

This setting allows you to turn the strip expiration date indicator on or off. This setting turns the function on or off only. See page 20 to set the strip expiration date.
When 'EP' appears on the screen, press the ◄ or ► button. The screen will display 'On' or 'OFF'. Press the **S** button to confirm the setting. If you do not want to set the indicator, press the **S** button while the screen displays 'OFF'.
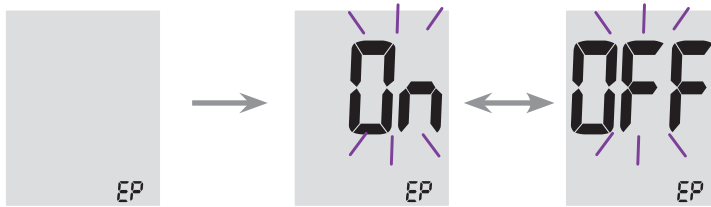
Note:
If the pre-set expiration date is reached, the meter will display 'EP' when the test strip is inserted and when the test result is displayed right after the test.
If the expiration date is set to October of 2021, the meter will display 'EP' at the beginning of November, 2021.

Step 1 Entering the Expiration Date Setting

Press and hold the ◄ and ► buttons at the same time for 3 seconds to enter the expiration date settings. After all segments flash across the screen, 'EP' will show up.

Note:
The strip expiration date is printed on the test strip box.

Step 2 Setting the Year

A number indicating the year will blink at the bottom left corner of the screen. Press the ◄ or ► button until the correct year appears. Press the **S** button to confirm the year and set the month.

Step 3 Setting the Month

A number indicating the month will blink at the bottom of the screen. Press the ◄ or ► button until the correct month appears. Press and hold the **S** button for 3 seconds to confirm the month and turn off the meter.

Checking the System

You may check your meter and test strips using the KetoSens Control Solutions(control L and/or M). The KetoSens Control Solution contains a known amount of β-Ketone and is used to check that the meter and the test strips are working properly. KetoSens Control Solution ranges are printed on the KetoSens test strip box. Compare the result displayed on the meter to the KetoSens Control Solution range printed on the test strip box.

Before using a new meter or a new box of test strips, you may conduct a control solution test following the procedure on pages 21–22.

Notes:
- Use only the KetoSens Control Solution (available for purchase separately).
- Check the expiration date printed on the bottle. When you first open a control solution bottle, record the discard date (date opened plus three (3) months) in the space provided on the label.
- Make sure your meter, test strips, and control solution are at room temperature before testing. Control solution tests must be done at room temperature (20–25 ˚C, 68–77 ˚F).
- Before using the control solution, shake the bottle, discard the first drop and wipe the tip clean.
- Close the control solution bottle tightly and store at a temperature between 8–30 ˚C (46–86 ˚F).

You may do a control solution test:
- When you want to practice the test procedure using the control solution instead of blood,
- When using the meter for the first time,
- Whenever you open a new box of test strips,
- If the meter or test strips do not function properly,
- If your symptoms are inconsistent with the blood β-Ketone test results and you feel that the meter or test strips are not working properly,
- If you drop or damage the meter.

Control Solution Testing

Step 1

Insert a test strip into the meter's test strip port, with the contact bars facing upwards.
Gently push the test strip into the port until the meter beeps. Be careful not to bend the strip while pushing it in.
The symbol will show up.
Press ▶ for 3 seconds till the ' ' appears on the display.

Step 2

Shake the KetoSens Control Solution bottle well before each test.
Remove the cap and squeeze the bottle to discard the first drop.
Then wipe the tip with a clean tissue or cloth. Dispense a drop of control solution onto a clean non-absorbent surface. It helps to squeeze a drop onto the top of the cap as shown. After the symbol appears on the display, apply the solution to the narrow edge of the test strip until the meter beeps. Make sure the confirmation window fills completely.
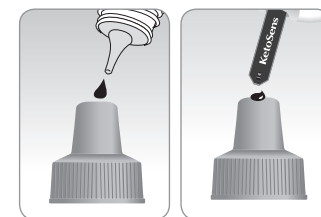
Step 3

A test result will appear after the meter counts down from 8 to 1.
When flagged, the result is stored in the meter's memory but it is not included in the averages.

0.6
mmol/L
KETONE
09.24 12:37 PM

Step 4

Compare the result displayed on the meter to the range printed on the test strip box. The result should fall within that range. Used strips should be discarded safely in appropriate containers.

Control Solution Range
Control L : 0.4–1.0 mmol/L
Control M : 1.9–2.9 mmol/L

Caution:
The range printed on the test strip box is for the KetoSens Control Solution only. It has nothing to do with your blood β-Ketone level.

Note:
The Control Solution can be purchased separately. Please contact your authorised i-SENS sales representative.

Comparing the Control Solution Test Results

The test result of each control solution should be within the range printed on the label of the test strip box. Repeat the control solution test if the test result falls outside of this range. Out of range results may occur in the following situations:
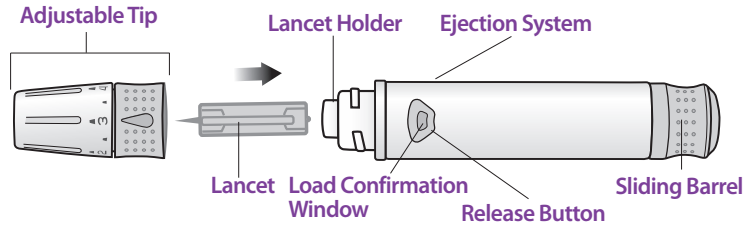
Situations	Do This
• When the control solution bottle was not shaken well, • When the meter, test strip, or the control solution were exposed to high or low temperatures, • When the first drop of the control solution was not discarded or the tip of the bottle was not wiped clean, • When the meter is not functioning properly.	Repeat the control solution test by referring to the 'Notes' on page 20.
• When the control solution is past the expiration date printed on the bottle, • When the control solution is past its discard date (the date the bottle was opened plus three (3) months), • When the control solution is contaminated.	Discard the used control solution and repeat the test using a new bottle of control solution.

If results continue to fall outside the range printed on the test strip box, the KetoSens Test Strip and Meter may not be working properly. Do not use your system and contact your authorised i-SENS sales representative.

Using the Lancing Device

You will need a lancing device in order to collect a blood sample.
You may use the lancing device that is included in the KetoSens Blood β-Ketone Monitoring System or any other medically approved lancing device.

Adjustable Tip **Lancet Holder** **Ejection System**

Lancet **Load Confirmation Window** **Release Button** **Sliding Barrel**

- The lancing device is for use by a single user only and should not be shared with anyone.
- Use a soft cloth or tissue to wipe the lancing device. If necessary, a small amount of alcohol on a soft cloth or tissue may be used.

Caution: To avoid infection when drawing a sample, do not use a lancet more than once,
- Do not use a lancet that has been used by others.
- Always use a new sterile lancet.
- Keep the lancing device clean.

Note: Repeated puncturing at the same sample site may cause pain or skin calluses (thick hard skin). Choose a different site each time you test.

Preparing the Lancing Device

Step 1

Wash hands and sample site with soap and warm water. Rinse and dry thoroughly.
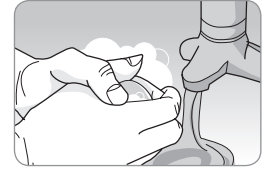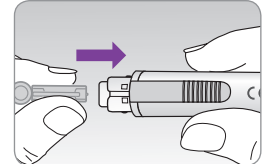
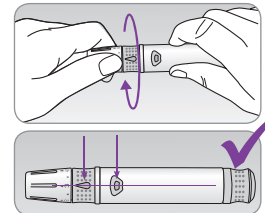### Step 2

Unscrew and remove the lancing device tip.
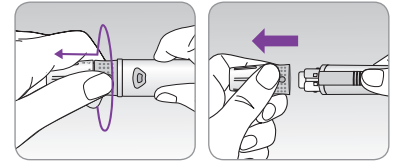
Step3

Firmly insert a new lancet into the lancet holder. Hold the lancet firmly. Gently twist to pull off protective disk. Save disk to recap lancet after use. Replace lancing device tip.

Step4

Turn the adjustable tip until it is aligned with the load confirmation window and release button as shown in the diagram.

Step 5

The lancing device has six puncture depth settings, numbered 0 through 5 (0 for a shallow puncture, 5 for a deeper puncture).
Choose a depth by rotating the top portion of the adjustable tip until the desired number aligns with the arrow.
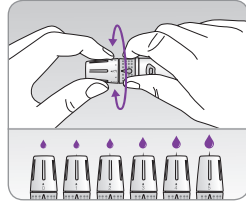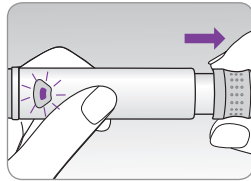
Note:
0 = a shallow puncture for softer skin
5 = a deeper puncture for thick or calloused skin

Step 6

To cock the lancing device, hold the body of lancing device in one hand and pull the sliding barrel with the other hand. The device is loaded when you feel a click and the load confirmation window turns red.

Note: The skin depth to get blood samples will vary for various people at different sample sites. The lancing device's adjustable tip allows the best depth of skin penetration to get an adequate sample size.

## Preparing the Meter and Test Strip

Step 7

Insert a test strip with the contact bars facing upwards into the meter's test strip port. Push the strip in gently until the meter beeps. Be careful not to bend the test strip. The 🔺 symbol will appear on the screen.
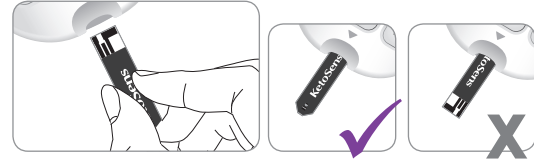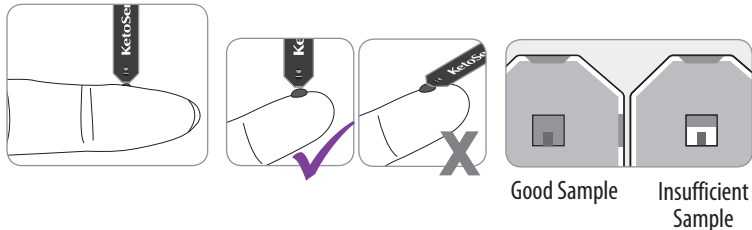
Applying Blood Sample

Step 9

Obtain a blood sample using the lancing device. Place the device against the pad of the finger as shown in the diagram. Press the release button. Remove the device from the finger. Wait a few seconds for a blood drop to form. A minimum volume of 0.5 microliter is needed to fill the confirmation window. (Actual size of 0.5 μL : ●)
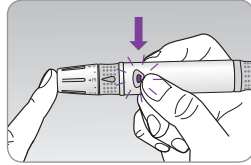
Step 10

After the ▲ symbol appears on the screen, apply the blood sample to the narrow end of the test strip till the meter beeps. If the confirmation window is not filled in time because of abnormal viscosity (thickness and stickiness) or insufficient volume, the Er4 message may appear.

It is recommended to place the test strip vertically into the blood sample site as shown below.

Good Sample   Insufficient Sample

Note: The meter may switch off if the blood sample is not applied within 2 minutes of the ▲ symbol appearing on the screen. If the meter turns off, remove the strip and reinsert it and apply blood sample after ▲ symbol appears on the screen.

Step 11

The test result will appear after the meter counts down from 8 to 1. The result will be automatically stored in the meter's memory.
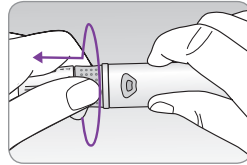
If the test strip is removed after the test result is displayed, the meter will automatically switch off after 3 seconds. Discard used test strips safely in appropriate containers.
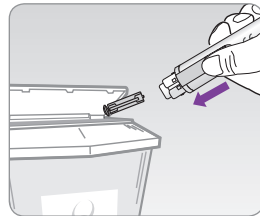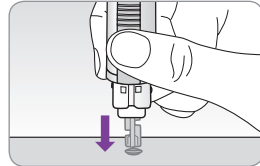
Discarding Used Lancets

Step 1

Unscrew lancing device tip.

Step 2

Stick the lancet into the saved protective disk.
Push the lancet ejector forward with the thumb to dispose of the used lancet in a proper biohazard container.
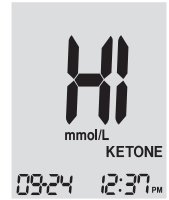

Caution: The lancet is for single use only. Never share or reuse a lancet. Always dispose of lancets properly.

HI Message

The meter displays results between 0.1–8.0 mmol/L 'HI' appears when the blood β-Ketone level is greater than 8.0 mmol/L.

If 'HI' is displayed again upon retesting, please contact your healthcare professional immediately.

Note: In case of blood β-ketone test, 0.0 mmol/L appears when a test result is less than 0.1 mmol/L.

Meter Memory

The KetoSens meter can save up to 1,000 β-Ketone test results with time and date. If the memory is full, the oldest test result will be deleted and the latest test result will be stored.
The KetoSens meter calculates and displays the averages of total test results from the last 1, 7, 14, 30 and 90 days.
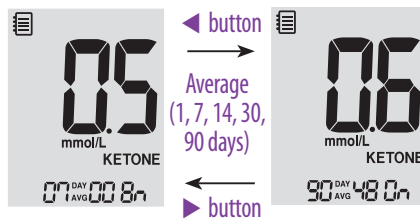
Viewing Averages Stored in Memory

Step 1

Press any button to turn the meter on. The current date and time will be displayed at the bottom of the screen followed by the 1 day average value and the number of the test results saved within the current day.

The number of tests within the current day
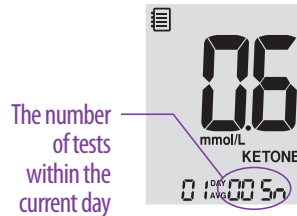
Step 2

Press the ◀ button to view 7, 14, 30 and 90-day average values and the number of tests performed for the last test period.

◀ button

Average (1, 7, 14, 30, 90 days)

▶ button

Step 3

Use the ▶ button to scroll back through the averages seen previously.
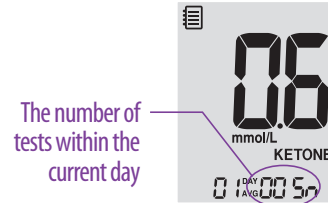Press the **S** button to turn off the meter.

Note: The control solution test results saved with ' 🜊 ' are not included in the averages.

Viewing Test Results Stored in Memory

Step 1

Press any button to turn the meter on. The current date and time will be displayed on the bottom of the screen followed by the 1 day average value and the number of the test results saved within the current day.

The number of tests within the current day

mmol/L
KETONE
01 DAY AVG 00 5n

Step 2

Use the ▶ button to scroll through the test results, starting from the most recent and ending with the oldest. Press the ◀ button to return to the result seen previously. After checking the stored test results, press the S button to turn off the meter.

03
mmol/L
KETONE
08:03 DAY 12:03 PM

◀ button
→
←
▶ button

06
mmol/L
KETONE
11:22 DAY AVG 08:30 PM
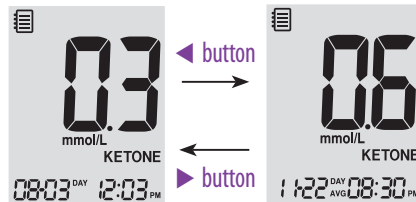
Note: The control solution test results saved with 🔖 will be displayed with 🔖 when you review the stored test results.

Three types of alarms can be set in the KetoSens Meter. The alarms ring for 15 seconds and can be silenced by pressing any button or by inserting a test strip.

Setting the Time Alarms (alarm 1–3)

Step 1

Without inserting a test strip, press the ◀ and **S** buttons simultaneously for 3 seconds to enter the time alarm setting. 'alarm 1' will be displayed while 'OFF' blinks on the screen.

alarm
OFF 12:00 PM

Step 2

On pressing the ▶ button, 'alarm 1' is set and 'On' is displayed on the screen. Press the ▶ button again to cancel 'alarm 1'. 'OFF' will blink on the screen.
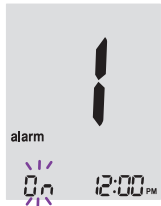
alarm
On 12:00 PM

Step 3

Press the ◀ button while 'On' blinks to adjust the time of 'alarm 1'. A number indicating the hour will blink on the screen. Press the ▶ button to set the hour.
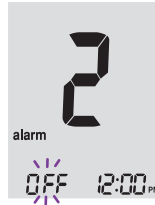
alarm
On 04:00 PM

Step 4

On pressing the ◀ button, the number indicating the minute will start blinking. Press the ▶ button to set the minute.

alarm

On 04:20 PM

Step 5

Press the **S** button to finish and to go to 'alarm 2' mode.
Repeat steps 2 to 4 to set the remaining time alarms (alarm 2–3).

alarm

OFF 12:00 PM

Step 6

Press the **S** button for 3 seconds to finish and turn the meter off.

Message	What It Means	What To Do
Er 1	A used test strip was inserted.	Repeat the test with a new test strip.
Er 2	The blood or control solution sample was applied before the ▲ symbol appeared.	Repeat the test with a new test strip and wait until the ▲ symbol appears before applying the blood or control solution sample.
Er 3	The temperature during the test was above or below the operating range.	Move to an area where the temperature is within the operating range 15–30 °C (59–86 °F) and repeat the test after the meter and test strips have reached a temperature within the operating range.

Message	What It Means	What To Do
Er4	The blood sample has abnormally high viscosity or insufficient volume.	Repeat the test after inserting a new test strip.
Er5	This error message may appear when the wrong blood $β$-Ketone test strip is used instead of the KetoSens Blood $β$-Ketone test strip.	Repeat the test after inserting a KetoSens test strip.
Er6	There is a problem with the meter.	Do not use the meter. Contact your authorised i-SENS sales representative.
Er8	An electronic error occurred during the test.	Repeat the test with a new test strip. If the error message persists, contact your authorised i-SENS sales representative.

Note: If the error messages persist, contact your authorised i-SENS sales representative.

Problem	Troubleshooting
The display is blank even after inserting a test strip.	• Check whether the test strip is inserted with the contact bars facing upwards. Check if the strip has been inserted completely into the test strip port. • Check if the appropriate test strip was used. • Check whether the batteries are inserted with the + side facing upwards. • Replace the batteries.
The test does not start even after applying the blood sample on the strip.	• Check if the confirmation window is filled completely. • Repeat the test with a new test strip.
The test result doesn't match the way you feel.	• Repeat the test with a new test strip. • Check the expiration date of the test strip. • Perform control solution test.

Note: If the problem is not resolved, please contact your authorised i-SENS sales representative.

Performance Characteristics

The performance of KetoSens Blood β-Ketone Monitoring System has been evaluated in laboratory and in clinical tests.

Accuracy: The accuracy of the KetoSens BKM System (Model GM01GAA) was assessed by comparing blood β-Ketone results obtained by patients with those obtained using a Randox Monaco a laboratory instrument. The following results were obtained by diabetic patients at clinic centers.

Slope	0.9821
Y-intercept	0.0094 mmol/L
Correlation coefficient (r)	0.9969
Number of sample	100
Range tested	0.03–7.86 mmol/L

Precision: Precision studies were performed in a laboratory using the KetoSens Brand of BKM Systems.

Within Run Precision		
Blood avg.	0.4 mmol/L	SD = 0.027 mmol/L
Blood avg.	1.1 mmol/L	SD = 0.056 mmol/L
Blood avg.	3.4 mmol/L	CV = 3.7 %
Blood avg.	5.2 mmol/L	CV = 3.5 %
Blood avg.	6.9 mmol/L	CV = 3.6 %

Total Precision		
Control avg.	0.6 mmol/L	SD = 0.049 mmol/L
Control avg.	2.3 mmol/L	CV = 3.8 %
Control avg.	3.9 mmol/L	CV = 4.3 %

This study shows that there could be a variation of up to 4.3 %.

Warranty Information

Manufacturer's Warranty

i-SENS, Inc. warrants that the KetoSens Meter shall be free of defects in material and workmanship in normal use for a period of five (5) years. The meter must have been subjected to normal use. The warranty does not cover improper handling, tampering, use, or service of the meter. Any claim must be made within the warranty period.

i-SENS will, at its discretion, repair or replace a defective meter or meter part that is covered by this warranty. As a matter of warranty policy, i-SENS will not reimburse the consumer's purchase price.

Obtaining Warranty Service

To obtain warranty service, you must return the defective meter or meter part along with proof of purchase to your nearest i-SENS sales or customer service representative.

MEMO