

LS-946

Blood Glucose Plus ß-Ketone Monitoring System

Owner's Manual



Dear LifeSmart 2 LS-946 System Owner:

Thank you for purchasing the **LS-946** Blood Glucose Plus ß-Ketone Monitoring System. This manual provides important information to help you to use the system properly. Before using this product, please read the following contents thoroughly and carefully.

The System measures both blood glucose and β -ketone. Regular monitoring of your blood glucose and β -ketone levels can help you and your doctor gain better control of your diabetes. Due to its compact size and easy operation, you can use the **LS-946** Blood Glucose Plus \(\mathbb{B}\)-Ketone Monitoring System to easily monitor your blood glucose and β -ketone levels by yourself anywhere, any time.

If you have other questions regarding this product, please contact the local customer service or place of purchase.

Intended Use

This system is intended for use outside the body (*in vitro* diagnostic use) by people with diabetes at home as an aid to monitoring the effectiveness of diabetes control. It is intended to be used for the quantitative measurement of glucose (sugar) in fresh whole blood samples from the finger, and to measure β -hydroxybutyrate (ketone) in fresh whole blood samples from the finger and palm. It should not be used for the diagnosis of or screening for diabetes mellitus.

The test for haematocrit (HCT) as part of the system, is intended for use in the in vitro quantification of packed red blood cell volume fraction in capillary whole blood as an aid in monitoring the status of total volume of red blood cells. The test reading of haematocrit (HCT) is used only to determine whether the blood test sample is within the acceptable range of Blood Glucose Plus \(\mathbb{G}\)-Ketone monitoring system. It should not be used for the diagnosis of anaemia or erythrocytosis.

IMPORTANT SAFTY INSTRUCTIONS READ BEFORE USE

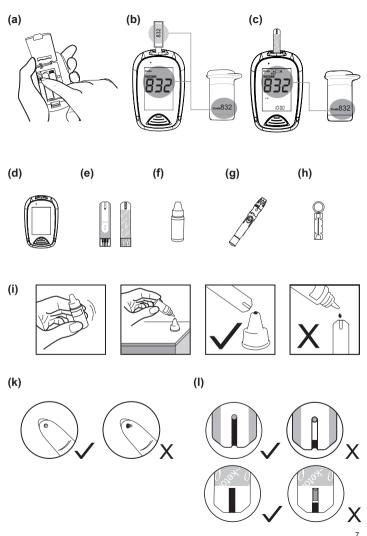
- 1. Use this device **ONLY** for the intended use described in this manual.
- 2. Do **NOT** use accessories which are not specified by the manufacturer.
- 3. Do **NOT** use the device if it is not working properly or if it is damaged.
- This device does **NOT** serve as a cure for any symptoms or diseases.
 The data measured is for reference only. Always consult your doctor to have the results interpreted.
- The blood glucose test strip can be used for the testing of newborns;
 The β-ketone test strip must not be used for the testing of newborns.
- Before using this device to test blood glucose or β-ketone, read all
 instructions thoroughly and practice the test. Carry out all the quality
 control checks as directed.
- Keep the device and testing equipment away from young children. Small items such as the battery cover, batteries, test strips, lancets and vial caps are choking hazards.
- Use of this instrument in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets etc.) may cause damaging static discharges that may cause erroneous results.
- Do NOT use this instrument in close proximity to sources of strong electromagnetic radiation, as these may interfere with accurate operation.
- 10. Proper maintenance and periodic control solution testing are essential to the longevity of your device. If you are concerned about your accuracy of measurement, please contact the local customer service or place of purchase for help.

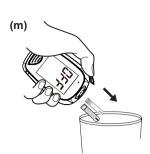
KEEP THESE INSTRUCTIONS IN A SAFE PLACE

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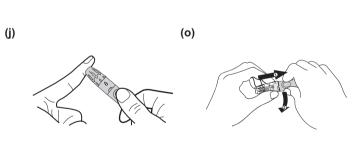
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BEFORE YOU BEGIN

Important Information

- Severe dehydration and excessive water loss may cause readings which are lower than actual values. If you believe you are suffering from severe dehydration, consult a healthcare professional immediately.
- If your blood glucose or β-ketone results are lower or higher than
 usual, and you do not have any symptoms of illness, first repeat the
 test. If you have symptoms or continue to get results which are
 higher or lower than usual, follow the treatment advice of your
 healthcare professional.
- Use only fresh whole blood samples to test your blood glucose or β-ketone. Using other substances will lead to incorrect results.
- If you are experiencing symptoms that are inconsistent with your blood glucose or β-ketone test results and you have followed all the instructions given in this owner's manual, contact your healthcare professional.
- We do not recommend using this product on severely hypotensive individuals or patients in shock. Please consult your healthcare professional before use.
- The measurement unit used for indicating the concentration of blood or plasma glucose will have molarity (mmol/L). The approximate calculation rule for conversion of mmol/L in mg/dL is:

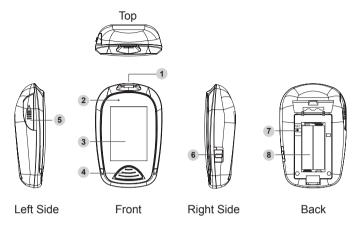
mg/dL	Divided by 18	= mmol/L
mmol/L	Times 18	= mg/dL

For example:

- 1) $120 \text{ mg/dL} \div 18 = 6.6 \text{ mmol/L}$
- 2) 7.2 mmol/L x 18 = 129 mg/dL approximately.
- The HCT is the volume percentage (%) of red blood cells in blood sample.

(Note: Haematocrit =HCT)

Meter Overview



- Test Strip Slot Insert test strip here to turn the meter on for testing.
- 2 Bluetooth Indication Light
- 3 Display Screen
- Main Button (M)
 Enter the meter memory and silence a reminder alarm.
- 5 Test Strip Ejector
 Eject the used strip by pushing up this button.
- Bluetooth Switch
 Activating the Bluetooth function.
- SET Button (S) Enter and confirm the meter settings.
- 8 Battery Compartment

Display Screen

- 1 Ketone Symbol / Ketone Warning 11 Test Strip Symbol
- Glucose Level / Ketone Level
- **Error Warning**
- Low Battery Symbol
- Day Average
- Memory Symbol
- Time / Date
- **HCT Level**
- Glucose / Ketone Measurement Unit
- Measurement Modes

Gen - any time of day

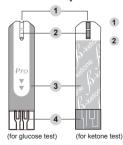
AC - before meal

PC - after meal

- **Blood Drop Symbol**
- 13 Code
- 14 Glucose Symbol
- 15 Alarm reminder



Test Strip



- Absorbent Hole
- 3 Test Strip Handle
- Confirmation Window 4 Contact Bars

ATTENTION:

The front side of test strip should face up when inserting test strip.

Test results may be wrong if the contact bar is not fully inserted into the test slot.

NOTE:

The **LS-946** monitor should only be used with **LS-946** Glucose or β-Ketone Test Strips. Using other test strips with this meter can produce inaccurate results.

SETTING THE METER

Before using your meter for the first time or if you change the meter battery, you should check and update these settings.

Entering the Setting Mode (a)

Start with the meter off (no test strip inserted). Press **S** (Small Orange button Beside Batteries).

1. Setting the date

The sequence of the date setting is: YEAR \rightarrow MONTH \rightarrow DAY. With the YEAR / MONTH / DAY flashing in sequence, press **M** until the correct year/month/day appears. Press **S**.

2. Setting the time format

Press M to select the desired time format --- 12h or 24h. Press S.

3. Setting the time

With the HOUR / MINUTE flashing in sequence, press ${\bf M}$ until the correct hour/minute appears. Press ${\bf S}$.

4. Setting the buzzer

With the buzzer displays, press ${\bf M}$ to switch between "On" and "OFF". Press ${\bf S}$.

5. Deleting the memory

With "dEL" and a " M " on the display, press **M** and select "no" to keep the results in memory then press **S** to skip. To delete all the results, press **M** and select "yes" to delete all the memory records.

6. Setting the reminder alarm

Your meter has four reminder alarms. The meter will display "OFF" and "AL1". If you don't want to set an alarm, press $\bf S$ to skip this step; Or press $\bf M$ to select "On", then press $\bf S$.

With the hour/minute flashing in sequence, press ${\bf M}$ to select the correct hour/minute. Press ${\bf S}$ and go to the next alarm setting.

NOTICE:

When the alarm beeps, press M to switch it off. Otherwise, it will beep for 2 minutes then switch off.

7. Setting the auto send

Press M to select the auto-send On or OFF. Press S.

NOTICE:

This function is referring to the Bluetooth data transmission. If "On" is selected, your result will be transmitted automatically right after the test.

8. Setting the backlight

The default setting for meter backlight ("BL") is set to ON. Press ${\bf M}$ to switch between "On" and "OFF".Press ${\bf S}$.

Congratulations! You have completed all settings!

NOTE:

- These parameters can **ONLY be changed** in the setting mode.
- If the meter is idle for 3 minutes during the setting mode, it will switch off automatically.

THE THREE MEASURING MODES

This meter provides you with three modes for measuring; General, AC, and PC. You can switch between each mode by:

- 1. Start with the meter switched off. Insert a test strip to turn on the meter. The screen will display a flashing "♠" and "Gen".
- 2. Press M to switch between General, AC, and PC modes.

QUALITY CONTROL TESTING

Calibration

You must calibrate the meter every time you begin to use a new vial of β -Ketone test strips by setting the meter with the correct code. Test results may be inaccurate if the code number displayed on the monitor does not match the number printed on the strip vial.

How to Code Your Meter (for β-Ketone test)(b)

1. Insert the code strip when the monitor is off. Wait until the code number appears on the display.

NOTICE:

Make sure the code number on display, code strip, and test strip vial are the same. The code strip should be within the expiry date, otherwise an error message may appear.

2. Remove the code strip, the display will show "OK". This tells you that the meter has finished coding and is ready for β-ketone testing.

Checking the Code Number (c)

You need to make sure that the code number displayed on the meter matches the number on your test strip vial before you proceed. If it matches, you can proceed with your test. If the codes do not match, please stop testing and repeat the calibration procedure. If the problem persists, contact Customer Service for help.

NOTICE:

The codes used in this manual are examples only; your meter may display a different code.

WARNING:

- It is important to make sure that the LCD displayed code is the same as the code on your test strip vial before testing.
 Failure to do so will get inaccurate results.
- The code number for β-Ketone strip is three-digits; please ensure you are using the correct strips for the test.
- If the LCD displayed code is not the same as the code on your test strip vial and the code number cannot be updated, please contact Customer Service for assistance.

When should the control solution test be performed?

- if it is mandatory following the local regulations in your country,
- if yours suspect your meter or test strips are not working properly,
- if your blood glucose or ketone test results are not consistent with how you feel, or if you think the results are not accurate,
- to practice the testing process, or
- if you have dropped or think you may have damaged your meter.

Test strips (e), control solution (f), lancing device (g) or sterile lancets (h) may not be included in the kit (please check the contents in your product box). They can be purchased separately. Please make sure you have all items needed for a blood glucose or ketone test beforehand.

Performing a Control Solution Test

To perform a control solution test, you will need: (d), (e) and (f).

1. Insert the test strip to turn on your meter

Wait for the meter to display " ← " and " ▲ ".

2. Apply control solution (i)

Shake the control solution vial thoroughly before use. Squeeze out the first drop and wipe it off, then squeeze out another drop and place it on the tip of the vial cap. Hold the meter to move the absorbent hole of the test strip to touch the drop. Once the confirmation window fills completely, the meter will begin counting down.

NOTICE:

To avoid contaminating the control solution, do not directly apply control solution onto a strip.

3. Read and compare the result

After counting down to 0, the control solution test result will appear on the display. Compare this result with the range printed on your test strip vial and it should fall within this range. If not, please read the instructions again and repeat the control solution test.

With "QC" displayed, the meter will store your test result in memory under "QC".

- There is no HCT display function while the meter is in QC mode.
- The control solution range printed on the test strip vial is for control solution use only. It is not a recommended range for your blood glucose or ketone level.
- See the MAINTENANCE section for important information about your control solution.

TESTING WITH BLOOD SAMPLE

WARNING:

To reduce the chance of infection:

- · Never share a lancet of the lancing device.
- · Always use a new, sterile lancet. Lancets are for single use only.
- Avoid getting hand lotion, oils, dirt, or debris in or on the lancets and the lancing device.

Preparing the Lancing Device for Blood Testing

Please follow the instructions in the lancing device insert for collecting a blood sample.

Preparing the Puncture Site

Stimulating blood perfusion by rubbing the puncture site before blood extraction has a significant influence on the accuracy of the glucose or $\beta\text{-ketone}$ value obtained. Blood from a site that has not been rubbed exhibits a measurably different glucose or $\beta\text{-ketone}$ concentration than blood from the finger. If the puncture site was rubbed prior to blood extraction, the difference is significantly reduced.

Please follow the suggestions below before obtaining a drop of blood:

- Select the puncture site at fingertips (for glucose test).
- Select the puncture site either at fingertips or palm (please see section 'Alternative Site Testing' [AST]).
- Rub the puncture site for about 20 seconds before penetration.
- Clean the puncture site using cotton moistened with 70% alcohol and let it air dry.
- Use a clear cap (included in the kit) while setting up the lancing device (for β-ketone test).

• Fingertip testing (j)

Press the lancing device's tip firmly against the lower side of your fingertip. Press the release button to prick your finger; a click indicates that the puncture is complete.

Blood from site other than the fingertip (o) (for β-ketone test)
 Replace the lancing device cap with the clear cap for AST. Pull the cocking control back until it clicks. When lancing the palm, avoid lancing the areas with obvious veins because of excessive bleeding.

NOTE:

- Choose a different spot each time you test. Repeated punctures at the same spot may cause soreness and calluses.
- Please consult your health care professional before you begin AST (for β-ketone test).
- It is recommended that you discard the first drop of blood as it may contain tissue fluid, which may affect the test result.

Performing a Blood Glucose or β-Ketone Test

To perform a blood glucose or β -ketone test, you will need: (d), (e), (g) and (h).

1. Insert the test strip to turn on the meter

Wait for the meter to display " ← ¬, " ♠ ", and "GLU" (only in the QC mode) or "KETONE"

2. Select the appropriate measuring mode by pressing M

3. Obtaining a blood sample (k)

Use your pre-set lancing device to puncture the desired site. Wipe off the first drop of blood with a clean cotton swab. The size of the drop should be at least as big as $_{\text{0}}$ (actual size), which is 1.0 microliter (µL) of volume. Gently squeeze the punctured area to obtain another drop of blood. Be careful NOT to smear the blood sample.

4. Apply the sample (I)

Gently apply the drop of blood to the absorbent hole of the test strip at a tilted angle. Confirmation window should be completely filled if enough blood sample has been applied. Do **NOT** remove your finger until you hear a beep sound.

NOTE:

- Do not press the punctured site against your test strip or try to smear the blood
- If you do not apply a blood sample to the test strip within 3 minutes, the
 meter will automatically turn off. You must remove and reinsert the test strip
 to start a new test.
- The confirmation window should be filled with blood before the meter begins to count down. NEVER try to add more blood to the test strip after the drop of blood has moved away. Discard the used test strip and retest with a new one.
- If you have trouble filling the confirmation window, please contact your health care professional or the local customer service for assistance.

5. Read your result

The result of your blood glucose test with HCT levels or the result of your β -ketone test will appear after the meter counts down to 0. The blood glucose result with HCT levels or the β -ketone result will be stored in your memory automatically.

6. Eject the used test strip (m)

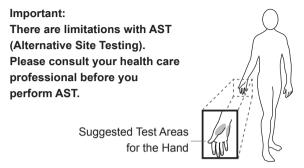
Eject your test strip by pushing the eject button on the side. Use a sharps bin to dispose of used test strips. The meter will switch itself off automatically.

Always follow the instructions in the lancing device insert when removing the lancet.

WARNING:

The used lancet and test strip may be biohazardous. Please discard them carefully according to your local regulations.

Alternative Site Testing (for β-Ketone Test) In addition to using your fingertips, you can test on your palms.



When to use AST?

Food, medication, illness, stress and exercise can affect ketone levels. Capillary blood at the fingertip reflects these changes faster than capillary blood at other sites. Thus, when testing ketone during or immediately after a meal, physical exercise, or any other event, take a blood sample from your finger only.

We strongly recommend that you perform AST **ONLY** at the following times:

- In a pre-meal or fasting state (more than 2 hours since the last meal).
- Two hours or more after taking insulin.
- Two hours or more after exercise.

Do NOT use AST if:

- You think your ketone is low.
- Your AST results do not match the way you feel.
- Your routine ketone results often fluctuate.

METER MEMORY

This meter stores the **1000** most recent blood glucose test results along with respective HCT values, dates and times or β -ketone test results along with respective dates and times in its memory. To enter the meter memory, **start with the meter switched off.**

Reviewing Test Results

- 1. Press and release M.
- " $\dot{\dot{}}$ " will appear on the display. Press **M** again, and the first reading you see is the last blood glucose result along with HCT value, date, time and the measuring mode or you will see the last β-ketone result along with date, time and the measuring mode.
- 2. Press M to recall the test results stored in the meter. After the last glucose or β -ketone test result, press M again and the meter will switch off.

Reviewing Blood Glucose Day Average Results

- Press and release M. When " m appears on the display, keep pressing M for 3 seconds until the flashing " pay appears. Release M and then your 7-day average result measured in general mode will appear on the display.
- **2. Press M to review** 14-, 21-, 28-, 60- and 90- day average results stored in each measuring mode in the order of Gen, AC, then PC.
- Exit the meter memory. Keep pressing the M and the meter will switch off after displaying the last test result.

- Any time you wish to exit the memory, keep pressing M for 5 seconds or leave it without any action for 3 minutes. The meter will switch off automatically.
- Control solution results are NOT included in the day average.

BLUETOOTH PAIRING

Data Transmission Via Bluetooth

You can transmit your data from the meter to your device via Bluetooth. Please contact your local customer service or place of purchase for assistance. Please note that you must complete the pairing between meter and Bluetooth receiver before transmitting data

Pairing with Your Mobile Device

- 1. Turn on the Bluetooth function on your mobile device.
- 2. With the meter off, press and hold the Bluetooth switch for 3 seconds to turn Bluetooth on.
- 3. Follow the instruction of your APP to pair the device. (Ex. Search to find the meter and then add it into app.)
- 4. After successfully pairing the APP with the device, the Bluetooth function of meter shall be on before transmitting the data to your APP.

Bluetooth Indicator on the Blood Glucose Meter:

BLUETOOTH INDICATOR	STATUS
Flashing Blue	The Bluetooth function is on and waiting for connection.
Solid Blue	The Bluetooth connection is established.

- While the meter is in transmission mode, it will be unable to perform a test.
- Make sure your device supporting Bluetooth Smart Technology has turned on Bluetooth before transmitting the data and the meter is within the receiving range. For the requirement of OS version, please find on App Store or Google Play when you download the app.
- The Bluetooth functionality is implemented in different ways by the various mobile device manufacturers, the compatibility issue between your mobile device and the meter maybe occur.

MAINTENANCE

Battery

Your meter comes with two 1.5V AAA size alkaline batteries.

Low Battery Signal

The meter will display one of the messages below to alert you when the meter power is getting low.

- **1. The** " **symbol appears** along with display messages: The meter is functional and the result remains accurate, but it is time to change the batteries.
- **2.** The " **a**" symbol appears with E-b and \triangle : The power is not enough to do a test. Please change the batteries immediately.

Replacing the Battery (n)

To replace the batteries, make sure the meter is turned off.

- **1.** Press the edge of the battery cover and lift it up to remove.
- 2. Remove the old batteries and replace with two 1.5V AAA size alkaline batteries.
- **3.** Close the battery cover. If the batteries are inserted correctly, you will hear a "beep" afterwards.

- Replacing the batteries does not affect the test results stored in the memory.
- As with all small batteries, these batteries should be kept away from children. If swallowed, promptly seek medical assistance.
- Batteries may leak chemicals if unused for a long time. Remove the batteries if you are not going to use the device for an extended period (i.e., 3 months or more).
- Properly dispose of the batteries according to your local environmental regulations.

Caring for Your Meter

Cleaning

- To clean the meter exterior, wipe it with a disinfecting wipe
 (Example:Micro-Kill Plus™) to clean exposed surfaces thoroughly
 and remove any visible dirt, blood or any other body fluid with the
 wipe. Then dry the device with a soft, dry and clean cloth. Do NOT
 rinse the meter with water.
- Do NOT use organic solvents to clean the meter.

Meter Storage

- Storage conditions: -20°C to 60°C (-4°F to 140°F), below 95% relative humidity.
- Always store or transport the meter in its original storage case.
- Avoid dropping and heavy impact.
- · Avoid direct sunlight and high humidity.

Meter Disposal

A used meter should be treated as contaminated and may carry a risk of infection during measurement. The batteries in this used meter should be removed and the meter should be disposed in accordance with local regulations.

The meter falls outside the scope of the European Directive 2002/96/ EC-Directive on waste electrical and electronic equipment (WEEE).

Caring for Your Test Strips

- Storage conditions: 2°C to 30°C (35.6°F to 86°F), below 85% relative humidity. Do NOT freeze.
- Store your blood glucose test strips in their original vial only. Do not transfer to another container.
- Store test strip packages in a cool dry place. Keep away from direct sunlight and heat.

- After removing a glucose test strip from its vial, immediately close the vial cap tightly.
- Touch the glucose and ketone test strips with clean and dry hands.
- Use each test strip immediately after removing it from the vial.
- Write the opening date on the vial label when you first opened it.
 Discard remaining blood glucose or β-ketone test strips after 6 months.
- Do not use test strips beyond their expiry date. This may cause inaccurate results.
- Do not bend, cut, or alter a test strip in any way.
- Keep the strip vial away from children since the cap and the test strip may be a choking hazard. If swallowed, promptly see a doctor for help.

For further information, please refer to the test strip package insert.

Important Control Solution Information

- Use only Our control solution with your meter.
- Do not use the control solution beyond the expiry date or 3 months after first opening. Write the opening date on the control solution vial and discard the remaining solution after 3 months.
- It is recommended that the control solution test be done at room temperature 20°C to 25°C (68°F to 77°F). Make sure your control solution, meter, and test strips are at this specified temperature range before testing.
- Shake the vial before use, discard the first drop of control solution, and wipe off the dispenser tip to ensure a pure sample and an accurate result.
- Store the control solution tightly closed at temperatures between 2°C to 30°C (35.6°F to 86°F). Do NOT freeze.

SYSTEM TROUBLESHOOTING

If you follow the recommended action but the problem persists, please call your local customer service.

Result Readings (for glucose test)

MESSAGE	WHAT IT MEANS	
Lo	< 0.5 mmol/L (10 mg/dL)	
KETONE	≥ 13.3 mmol/L (240 mg/dL)	
Н.	> 38.9 mmol/L (3700 mg/dL)	

Result Readings (for β-ketone test)

MESSAGE	WHAT IT MEANS
Lo	< 0.1 mmol/L
<u>0</u> 5	0.1 to 8.0 mmol/L
Н.	> 8.0 mmol/L

How to interpret blood Ketone results

(Reference: adapted from Information provided in The Balance Guide to Meds & Kit, 2011 - 2012, p15)

Your Ketone reading	Interpretation
Below 0.6mmol/L	This is normal
Between 0.6 and 1.5 mmol/L	You may require medical assistance; contact your Diabetes healthcare team for advice.
Above 1.5mmol/L	Risk of Diabetic ketoacidosis; call your Diabetes healthcare team immediately.

Error Messages

MESSAGE	WHAT IT MEANS	WHAT TO DO
E-b	Appears when the batteries are too low.	Replace the batteries immediately.
E-C	Appears when the wrong code strip is inserted or other coding errors.	Check if the code numbers on the display and the strip vial/ foil packet are the same. If the problem persists, please contact the local customer service for help.
E-2	Expired code strip.	Repeat the test with a new lot of test strip.
E-U	Appears when a used test strip is inserted.	Repeat with a new test strip.
E-t	Appears when ambient temperature is above or below system operation range.	System operation range is 10°C to 40°C (50°F to 104°F). Repeat the test after the meter and test strip are in the above temperature range.
E-0, E-A, E-E	Problem with the meter.	Repeat the test with a new test strip. If the meter still does not work, please contact the local customer service for assistance.
E-F	Appears when test strip is removed while counting down, or insufficient blood volume.	Review the instructions and repeat test with a new strip. If the problem persists, please contact the local customer service for help.

Troubleshooting

1. If the meter does not display a message after inserting a test strip:

POSSIBLE CAUSE	WHAT TO DO
Batteries exhausted.	Replace the batteries.
Test strip inserted upside down or	Insert the test strip with contact bars
incompletely.	end first and facing up.
Defective meter or test strips.	Please contact customer services.

2. If the test does not start after applying the sample:

POSSIBLE CAUSE	WHAT TO DO
Insufficient blood sample.	Repeat the test using a new test strip with larger volume of blood sample.
Defective test strip.	Repeat the test with a new test strip.
Sample applied after automatic switch-off (3 minutes after last user action).	Repeat the test with a new test strip. Apply sample only when flashing " • " appears on the display.
Defective meter.	Please contact customer services.

3. If the control solution testing result is out of range:

POSSIBLE CAUSE	WHAT TO DO
Error in performing the test.	Read instructions thoroughly and
	repeat the test again.
Control solution vial was poorly	Shake the control solution vigorously
shaken.	and repeat the test again.
Expired or contaminated control	Check the expiry date of the control
solution.	solution.
Control solution that is too warm or	Control solution, meter, and test strips
too cold.	should be at room temperature 20°C
	to 25°C (68°F to 77°F) before testing.
Defective test strip.	Repeat the test with a new test strip.
Meter malfunction.	Please contact customer services.
Improper working of meter and test	Please contact customer services.
strip.	

DETAILED INFORMATION

The meter provides you with plasma equivalent results.

	Normal blood glucose range for people witho diabetes (mg/dL)	
Fasting and before meal	< 5.6 mmol/L (100 mg/dL)	
2 hours after meals	< 7.8 mmol/L (140 mg/dL)	

Source: American Diabetes Association (2014). Clinical Practice Recommendations. Diabetes Care, 37 (Supplement 1): S16.

The β -Ketone test measures Beta-Hydroxybutyrate (β -OHB), the most important of the three β -Ketone bodies in the blood. Normally, levels of β -OHB are expected to be less than 0.6 mmol/L.

 $\ensuremath{\mathbb{G}}$ -OHB levels may increase if a person fasts, exercises vigorously or has diabetes and becomes ill. If your β -Ketone result is 0.0 mmol/L, repeat the β -Ketone test with new test strips. If the same message appears again or the result does not reflect how you feel, contact your healthcare professional. Follow your healthcare professional's advice before you make any changes to your diabetes medication programme. If your β -Ketone result is between 0.6 and 1.5 mmol/L, this may indicate development of a problem that could require medical assistance. Follow your healthcare professional's instructions. If your β -Ketone result is higher than 1.5 mmol/L, contact your healthcare professional promptly for advice and assistance. You may be at risk of developing diabetic ketoacidosis (DKA).

Please consult your doctor to determine a target range that works best for you.

SYMBOL INFORMATION

SYMBOL	REFERENT	SYMBOL	
IVD	In vitro diagnostic medical device		Manu
i	Consult instructions for use		Seria
1	Temperature limitation	EC REP	Authorin the
	Use by		Comi
LOT	Batch code	<u> </u>	accoi
2	Humidity limitation	X	Colle and e
C € ₀₁₂₃	CE mark		

SYMBOL	REFERENT	
*	Manufacturer	
SN	Serial number	
EC REP	Authorised representative in the European Community	
<u> </u>	Caution, consult accompanying documents	
X	Collection for electrical and electronic equipment	

SPECIFICATIONS

Model No.: LS-946

Dimension & Weight: 96 (L) x 61 (W) x 26 (H) mm, 67.2 g

Power Source: Two 1.5V AAA alkaline batteries

Display: LCD

Memory: 1000 measurement results with respective date and time

External Output: Bluetooth

Auto electrode insertion detection
Auto sample loading detection
Auto reaction time count-down
Auto switch-off after 3 minutes without action
Temperature Warning

Operating Condition:

10°C to 40°C (50°F to 104°F), below 85% R.H. (non-condensing)

Meter Storage / Transportation Conditions:

-20°C to 60°C (-4°F to 140°F), below 95% R.H.

Strip Storage / Transportation Conditions:

2°C to 30°C (35.6°F to 86°F), below 85% R.H.

Measurement Units: fixed mmol/L for glucose test and β-ketone test **Measurement Range:** 0.56 to 38.89 mmol/L (10 to 700 mg/dL) for

glucose test and 0.1~8.0 mmol/L for β-ketone test

Expected service life: 5 years

This device has been tested to meet the electrical and safety requirements of: IEC/EN 61010-1, IEC/EN 61010-2-101, EN 61326-1, IEC/EN 61326-2-6.

NOTE

NOTE

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