



# Multi-Functional Monitoring System

# **Owner's Manual**



# Dear LifeSmart 2 Plus LS-946C System Owner:

Thank you for purchasing the **LS-946C** Multi-Functional 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.

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) to quantitatively measure the blood glucose,  $\beta$ -ketone, and total cholesterol in whole blood. It is for home use or for healthcare professional use. It should not be used for diagnosis or screening of diseases

The test for hematocrit (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 hematocrit (HCT) is used only to determine whether the blood test sample is within the acceptable range of the Multi-Functional monitoring system. It should not be used for the diagnosis of anaemia or erythrocytosis.

The blood glucose test strip uses fresh capillary whole blood samples from fingertips, and from venous, arterial and neonatal whole blood.

The  $\beta$ -ketone test strip uses fresh capillary whole blood samples from the fingertips, and from venous whole blood.

The total cholesterol test strip uses fresh capillary whole blood samples from the fingertips.

Professionals may use the test strips to test capillary, venous, arterial and neonatal blood sample for blood glucose test or to test capillary only for  $\beta$ -ketone or total cholesterol test; home use is limited to capillary whole blood testing.

# **Test Principle**

Your system measures the amount of glucose/ $\beta$ -ketone/total cholesterol in whole blood. The glucose/ $\beta$ -ketone/total cholesterol testing is based on the measurement of electrical current generated by the reaction of glucose/ $\beta$ -ketone/total cholesterol with the reagent of the strip. The meter measures the current, calculates the glucose/ $\beta$ -ketone/total cholesterol level, and displays the result. The strength of the current produced by the reaction depends on the amount of glucose/ $\beta$ -ketone/total cholesterol in the blood sample.

# IMPORTANT SAFETY INSTRUCTIONS READ BEFORE USE

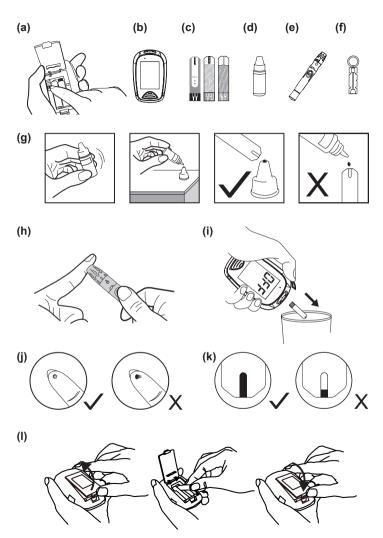
- 1. Use this device **ONLY** for the intended use described in this manual.
- 2. Do **NOT** use accessories which are not specified by the manufacturer.
- 3. Do **NOT** use the device if it is not working properly or if it is damaged.
- This device does **NOT** serve as a cure for any symptoms or diseases.
   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/total cholesterol 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, or 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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# **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, β-ketone, or cholesterol 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, β-ketone, or total cholesterol. Using other substances will lead to incorrect results.
- If you are experiencing symptoms that are inconsistent with your blood glucose, β-ketone, or total cholesterol 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:

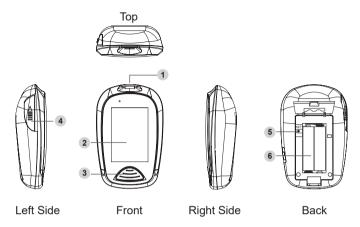
mg/dL	Divided by 18	= mmol/L
mmol/L	Times 18	= mg/dL

### 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



- 1 Test Strip Slot / Strip Port Communication Insert test strip here to turn the meter on for testing. Download test results with a strip port connection cable.
- 2 Display Screen
- Main Button (M)
  Enter the meter memory and silence a reminder alarm.
- Test Strip Ejector
  Eject the used strip by pushing up this button.
- **SET Button (S)** (inside the battery compartment) Enter and confirm the meter settings.
- 6 Battery Compartment

# **Display Screen**

- 1 Ketone Symbol
- 2 Test Result
- 3 Error Warning
- 4 Low Battery Symbol
- 5 Day Average
- 6 Memory Symbol
- 7 Time / Date
- 8 HCT Level
- Measurement Unit
- 4 Auto QC Mode / QC Mode
- Measurement Modes

Gen – any time of day

AC – before meal

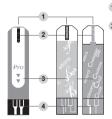
PC - after meal

12 Test Strip Symbol

- Blood Drop Symbol
- 14 Code
- 6 Glucose Symbol
- 6 Alarm Reminder
- 7 Cholesterol Symbol



# **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-946C** monitor should only be used with **LS-946** Blood Glucose, β-ketone, or Total Cholesterol Test Strips. Using other test strips with this meter can produce inaccurate results.

# SETTING THE METER

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

### Entering the Setting Mode (a)

Start with the meter off (no test strip inserted). Press the **S** button (inside the battery compartment).

### 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 the **M** button (the orange button on the front of the device) 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 **S** to skip this step; Or press **M** to select "On", then press **S**.

With the hour/minute flashing in sequence, press M to select the

correct hour/minute. Press 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 backlight

The default setting for meter backlight ("BL") is set to ON. Press **M** to switch between "On" and "OFF".Press **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

# For Blood Glucose Testing

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 " ", "Gen" and "GLU".
- 2. Press M to switch between General, AC, and PC modes.

# For β-Ketone Testing

The meter provides you with one mode for measuring, General. You can start with the meter switched off. Insert a test strip to turn on the meter. The screen will display a flashing " • ", "Gen" and "KETONE".

# For Total Cholesterol Testing

The meter provides you with two modes for measuring, General and QC. You can switch between each mode by:

- 2. Press M to switch between General and QC mode.

# **QUALITY CONTROL TESTING**

# When Should the Control Solution Test be Performed?

- if it is mandatory following the local regulations in your country,
- if you 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 (c), control solutions (d), lancing device (e) or sterile lancets (f) may not be included in the kit (please check the contents on your product box). They can be purchased separately. Please make sure you have those items needed for a test beforehand.

# **Performing a Control Solution Test**

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

- 1. Insert the test strip to turn on your meter
- Wait for the meter to display " ← ", " ♠ ", and "GLU", "KETONE" or "CHOL".
- 2. Press M to mark this test as a control solution test (for the total cholesterol test)

With "QC" displayed, the meter will store your test result in memory under "QC". If you press **M** again, the "QC" will disappear and this test

is no longer a control solution test.

#### WARNING:

When doing the control solution test, you have to mark it so that the test result will **NOT** mix with the **TEST RESULTS** stored in the memory. Failure to do so will mix up the test results with the control solution test results in memory.

### 3. Apply control solution (g)

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:

- Make sure to perform the control solution test in QC mode.
- To avoid contaminating the control solution, do not directly apply control solution onto a strip.

#### 4. 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".

#### NOTE:

- 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 blood glucose,  $\beta$ -ketone, or total cholesterol value obtained. Blood from a site that has not been rubbed exhibits a measurably different glucose,  $\beta$ -ketone, or total cholesterol 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:

- Wash and dry your hands before starting.
- Select the puncture site at fingertips.
- 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.

### • Fingertip testing (h)

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.

#### NOTE:

Choose a different spot each time you test. Repeated punctures at the same spot may cause soreness and calluses.

# Performing a Blood Test

To perform a glucose,  $\beta$ -ketone, or total cholesterol test, you will need: **(b), (c), (e) and (f)**.

### 1. Insert the test strip to turn on the meter

Wait for the meter to display " ← ", " ♠", and "GLU", "KETONE" or "CHOL".

### 2. Select the appropriate measuring mode by pressing M

## 3. Obtaining a blood sample (j)

Use your pre-set lancing device to puncture the desired site. The size of the drop should be at least as big as  $\bullet$  (actual size), which is **1.0** microliter ( $\mu$ L) of volume for both the blood glucose and  $\beta$ -ketone test; 3.0 microliter ( $\mu$ L) of volume for the total cholesterol test. Gently squeeze the punctured area to obtain another drop of blood. Be careful **NOT** to smear the blood sample.

### 4. Apply the sample (k)

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. (Ensure the meter's speaker is on)

#### 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  $\beta$ -ketone/total cholesterol test will appear after the meter counts down to 0. The blood glucose result with HCT levels or the  $\beta$ -ketone/total cholesterol result will be stored in your memory automatically.

### 6. Eject the used test strip (i)

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.

# METER MEMORY

This meter stores the **1000** most recent blood glucose test results along with respective HCT values, dates and times or  $\beta$ -ketone/total cholesterol 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.
- " $\dot{\mathbb{M}}$ " will appear on the display. Press **M** again, and the first reading you see is the last blood glucose result along with HCT value, or the  $\beta$ -ketone/total cholesterol result, date, time and the measuring mode.
- 2. Press M to recall the test results stored in the meter. After the last test result, press M again and the meter will switch off.

# Reviewing Blood Glucose Day Average Results

- 1. Press and release M. When " " appears on the display, keep pressing M for 3 seconds until the flashing " DAY 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 General, AC, and then PC.
- Exit the meter memory. Keep pressing the M and the meter will switch off after displaying the last test result.

#### NOTE:

- 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.

# DOWNLOADING RESULTS ONTO A COMPUTER

#### **Data Transmission Via Cable**

You can use your meter with a strip port cable and the Healthcare Software System to view test results with HCT levels on your personal computer. To learn more about the Healthcare Software System or to obtain a strip port cable separately, please contact the local customer services or place of purchase for assistance.

# 1. Obtaining the required cable and installing the software

To download Healthcare Software System, please visit LifeSmart's website: mylifesmart.net.au.

## 2. Connecting to a personal computer

Connect the strip port cable to a cable port on your computer. With the meter switched off, connect the other end of the strip port cable to the meter data port. "PC" will appear on the meter display, indicating that the meter is in communication mode.

### 3. Data transmission

To transmit data, follow the instructions provided with the software. Results will be transmitted with the date and time. Remove the cable and the meter will automatically switch off.

#### WARNING:

While the meter is connecting to PC, it will be unable to perform a blood glucose/ $\beta$ -ketone/total cholesterol test.

# **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 " graphs of 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 (I)

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.

#### NOTE:

- 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 cloth moistened with tap water or a mild cleaning agent, then dry the device with a soft dry cloth. Do NOT rinse 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), between 10% and 93% 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 2012/19/EU 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), between 10% and 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 blood glucose/β-ketone/total cholesterol 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/β-ketone/total cholesterol 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)
	≥ 13.3 mmol/L (240 mg/dL)
<u> </u>	Ketone Warning: This is shown when your blood glucose result is equal to or higher than 13.3 mmol/L (240 mg/dL).
	What to Do: Check blood ketone if checking ketone is part of your diabetes management program.
Н,	> 38.9 mmol/L (700 mg/dL)

### for β-ketone test

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

## for total cholesterol test

MESSAGE	WHAT IT MEANS
Lo	< 2.5 mmol/L
50	2.5 to 10.3 mmol/L
H,	> 10.3 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.

#### **Cholesterol Test**

The total cholesterol readings deliver plasma equivalent results and are displayed in millimoles of total cholesterol per liter of blood (mmol/L).

### **Total Cholesterol Expected Values**

Total Cholesterol (mmol/L)		
Desirable < 5.1		
Borderline High	5.1 - 6.1	
High	≥ 6.2	

A healthcare professional will discuss values that are specifically appropriate for each patient. At least two measurements of cholesterol in separate occasions should be made before a medical decision is made, since a single reading may not be representative of a patient's usual cholesterol concentration. An elevated cholesterol level is only one risk factor for heart disease. There are many others. A cholesterol less than 5.1 mmol/L (200 mg/dL) is desirable.

Source: National Cholesterol Education Program. ATP III Guidelines At-A-Glance Quick Desk Reference. National Institutes of Health. National Heart, Lung and Blood Institute. NIH Publication No. 01-3305, May 2001.

# **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 shaken.	Shake the control solution vigorously and repeat the test again.
Expired or contaminated control solution.	Check the expiry date of the control solution.
Control solution that is too warm or too cold.	Control solution, meter, and test strips 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 strip.	Please contact customer services.

# DETAILED INFORMATION

The meter provides you with plasma equivalent results.

Time of day	Normal blood glucose range for people without 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. Standards of Medical Care in Diabetes-2018 Jan; 41(Supplement 1): S1-S2.

The  $\beta$ -Ketone test measures Beta-Hydroxybutyrate ( $\beta$ -OHB), the most important of the three  $\beta$ -Ketone bodies in the blood. Normally, levels of  $\beta$ -OHB are expected to be less than 0.6 mmol/L. \*1

 $\beta$  -OHB levels may increase if a person fasts, exercises vigorously or has diabetes and becomes ill. If your  $\beta$ -Ketone result is "Lo", repeat the  $\beta$ -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  $\beta$ -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  $\beta$ -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).

\*1: Wiggam MI, O'Kane MJ, Harper R, Atkinson AB, Hadden Dr, Trimble ER, Bell PM. Treatment of diabetic ketoacidosis using normalization of blood 3-hydroxybutyrate concentration as the endpoint of emergency management. Diabetes Care 1997: 20: 1347-52.

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

# **SYMBOL INFORMATION**

SYMBOL	REFERENT	SYMBOL	REFERENT	
IVD	In vitro diagnostic medical device		Manufacturer	
[]i	Consult instructions for use	EC REP	CE mark	
1	Temperature limit	$\triangle$	Caution	
$\square$	Use-by date	<u></u>	Humidity limitation	
This device does not belong to household waste and must be returned to a collection point for recycling electric and electronic devices according to local laws. If it contains batteries, the batteries should be removed and disposed in accordance with locations for separate collection of spent batteries.	<b>C</b> € <sub>0123</sub>	CE mark		
	RoHS	RoHS compliance		
	REF	Catalogue number		
	contains batteries, the	LOT	Batch code	
	in accordance with locations for separate collection of spent	SN	Serial number	

# **SPECIFICATIONS**

Model No.: LS-946C

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

Power Source: Two 1.5V AAA alkaline batteries

Display: LCD with backlight

Memory: 1000 measurement results with respective date and time

External Output: Strip port cable

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:**  $10^{\circ}\text{C}$  to  $40^{\circ}\text{C}$  ( $50^{\circ}\text{F}$  to  $104^{\circ}\text{F}$ ), between 10%

and 85% R.H. (non-condensing)

Meter Storage / Transportation Conditions: -20°C to 60°C (-4°F to

140°F), between 10% and 93% R.H. (non-condensing)

Strip Storage / Transportation Conditions:  $2^{\circ}$ C to  $30^{\circ}$ C ( $35.6^{\circ}$ F to  $86^{\circ}$ F) and 10% to 85% R.H. for Blood Glucose /  $\beta$ -Ketone / Total

Cholesterol strips

Measurement Units: mmol/L

Measurement Range:

Glucose: 0.56 to 38.89 mmol/L (10 to 700 mg/dL)

β-ketone: 0.1 to 8.0 mmol/L

Total Cholesterol: 2.5 to 10.3mmol/L (100 to 400 mg/dL)

Expected service life: 5 years

Operating Altitude: Up to 2000m, for indoor use

Degree of Pollution: Pollution degree 2

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

# IMPORTANT INFORMATION

Dear user

Thanks for purchasing LifeSmartTM Multi Functional Monitoring System Blood Glucose Plus β-Ketone Monitoring System. This is a connected device. A Non-Bluetooth Lifesmart glucose meter can still send data via a Bluetooth dongle (sold separately). This can send your result data to your smartphone app via Bluetooth technology. The smartphone app is free to download for both Android and iOS platforms, Please search for 'Lifesmart Sugar CheO' for both iOS and Android.

The other advantage is our online cloud platform, BodyLog365TM. Your smartphone app can upload your results data automatically to BodyLog365TM in your unique and secure account. You can see your detailed result (daily, weekly, monthly and yearly) in graphs and figures. You can also generate your medical report and share with your health professional.

You can access BodyLog365TM at: https://smarthealth.mylifesmart.net.au In order to get the full advantage of your device please follow these two steps:

- A. After setting up your smartphone app, please go to 'Settings' and select 'TeleHealth Service'. Please select 'Smarthealth Official Site' and turn on 'Upload automatically'.
- B. Please go to account settings in BodyLog365™ and add the device serial number. You can find the device serial number behind the device.

By following the above simple steps, you can enjoy and monitor your health. Happy monitoring!

Thank you! Team LifeSmart™



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www.mylifesmart.net.au



### TaiDoc Technology Corporation

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For self-testing