

04

INTRO

SAFETY INFORMATION
GENERAL INFORMATION

12

THE LUX SYSTEM

GETTING TO KNOW THE SYSTEM
SETTING THE SYSTEM

30

TESTING

PREANALYTICAL PHASE
CHECKINGS
RUNNING THE TEST
ALTERNATIVE SITES

60

MEMORY

FUNCTIONS
REVIEWING
DELETION

68

TROUBLESHOOTING

ERROR MESSAGES
MAINTENANCE

72

TECHNICAL INFORMATION

TECHNICAL SPECIFICATIONS
REFERENCES
SYMBOLS
WARRANTY



INTRO

04 ***SAFETY INFORMATION***

09 ***GENERAL INFORMATION***

INTRO

SAFETY INFORMATION



PROTECTION AGAINST INFECTION

All people using the LUX meter to perform measurements on more than one patient must be aware that anything coming into contact with human blood is a potential source of infection. Therefore:

- 1. Use gloves.*
- 2. Discard any used test strips in a safe container.*
- 3. Follow all the locally applicable health and safety regulations.*
- 4. Use either a professional or a disposable lancing device to prevent cross contamination when performing measurements on more than one patient.*

4

OPERATING CONDITIONS

To ensure a correct operation of the LUX meter, please observe the following guidelines:

1. Use the device only within the allowed temperature range: 10°C -40°C (50°F-104°F).
2. Use the meter only at a relative humidity of 85% or even less.
3. When performing a measurement, please place the meter on a flat surface or hold it in your hand.



ELECTROMAGNETIC INTERFERENCE PROTECTION

Strong electromagnetic fields may impair the function of the device. Do not use the meter close to sources of strong electromagnetic radiations.

SUNLIGHT INTERFERENCE

Strong sunlight fields may impair the function of the device. Do not use the instrument if exposed to direct sunlight.

INTEGRATED CONTROL FUNCTIONS

The LUX meter has several control functions integrated and available, including the followings:

- An automatic check of the electronic components and of the functions when the device is powered on.
- An automatic check of the room temperature before and during the measurement.
- An automatic check of the test strip to make sure that the coding information necessary for the measurement is in the memory.
- A check of the optical system and the overall function by means of control solutions.

For further information, please refer to the quality control section of this user manual (pagxxx).

CAUTIONS

Glucose test strip

- Unless indicated by a healthcare professional, the therapeutic program should not be changed or the results which may highlight a problem be ignored.
- A severe dehydration could affect the results. In that case, please contact a healthcare professional immediately.
- The hematocrit (HCT) level may affect the results. In case of a hematocrit level less than 20%, the results may be overestimated with respect to the real blood glucose level; if the hematocrit level is higher than 60%, the results may be underestimated.
- Wrong results may be obtained in case of hypotension or shock.
- The LUX meter must not be used to diagnose diabetes.
- Use only fresh capillary blood with glucose test strips.
- This device cannot be used to diagnose or test neonatal diabetes.

Lipid and hemoglobin test strips

- Before performing a measurement, please make sure that you are using the correct code chip for the test strip you are testing. Using the wrong code chip inaccurate results may be obtained.
- Do not use expired test strips. The expiration date is printed on the outside of each strip vial.
- Please use sufficient blood to perform a test. If you do not apply enough blood onto the test strip, the meter will not function properly.
- Dispose of all the used test strips and other accessories safely and in accordance with all the current laws.
- Do not insert a used test strip into the meter.
- Venous blood samples must be taken only by a healthcare professional. If you are performing a self-test, please use capillary blood samples.
- To open a test strip vial, press down on the cap and twist it. After taking a strip out, close the cap securely. Once opened, a test strip vial can be stored for three months.
- Please store the test strips at 8°C-30°C.
- For getting accurate results, the correct code chip must be used.
- Do not swallow a test strip or any other LUX meter accessory.

INTENDED OF USE

The LUX meter is used for the quantitative measurement of 5 haematic parameters: Glucose, Total Cholesterol, Triglycerides, HDL Cholesterol, LDL Cholesterol (calculated) and Hemoglobin. Furthermore the system is capable of calculating the CHOL/HDL and LDL/HDL ratios.

The meter is suitable for professional use as well as for self-test. Please read carefully the instructions for use and the guidelines.

- Types of blood samples
 - Lipid and hemoglobin: Please use fresh capillary blood or venous blood. Please note that any tests using venous blood should be carried out by a healthcare professional, and it should not be used for self-test.
 - Glycaemia: Please use fresh capillary blood. Any tests using arterial or venous blood must be carried out by a healthcare professional. This type of blood is not suitable for a blood glucose test.
- The LUX meter can be used only with the test strips designed to measure lipids, total cholesterol (CHOL), triglycerides (TG), high-density lipoproteins (HDL), the CHOL/HDL ratio, the low-density lipoproteins (LDL)/HDL ratio, hemoglobin (Hb), and blood glucose (GLU).
- Please check the operating condition and the expiry date of the test strips before using them with the LUX meter. If damaged or expired strips are used, inaccurate results may be obtained.
- The LUX glucose test is plasma-calibrated to allow you to compare the results with those of a laboratory test.
- The LUX meter for self-test is used for monitoring an existing disease; the patient should perform the treatment only when he has received an appropriate training from a healthcare professional before using the system.

TEST PRINCIPLE

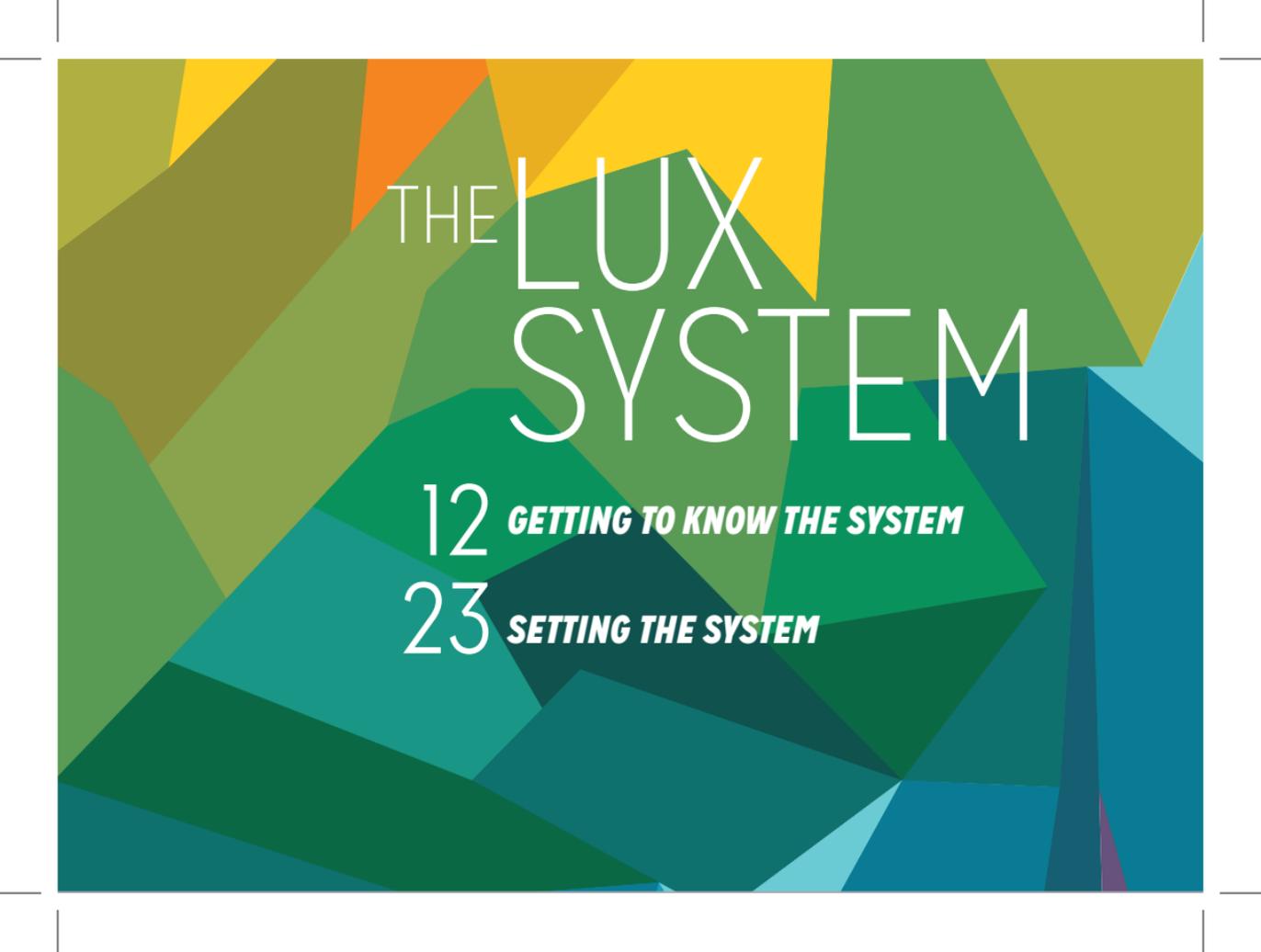
CHOL/TG/HDL/Hb

By means of a code chip, the meter can read the lot-specific characteristics of the test strips currently in use (only the glucose test strips have not a code chip). In each box of the test strips there is a code chip which must be inserted in the meter to perform the measurement. To run a test, please take out a new test strip from the vial and insert it into the device. Once inserted, the application area of the test strip is illuminated by a LED (light-emitting diode). Before applying the sample, the meter reads the reflectance value of the test strip (blank value). When the display shows the icon of the blinking droplet, apply with the pipette a blood sample volume of 15 μ L when using the LIPID test strips and a blood sample volume of 7 μ L when using the HEMOGLOBIN test strips. The analyte to measure in the sample undergoes an enzymatic reaction with the formation of a dye. The amount of the dye developed in the reaction increases with the concentration of the parameter to determine. After a certain period of time (depending on the parameter to test), the colour intensity is measured by the device by means of lighting the sample application area again from below using the LED. The intensity of the reflected light is measured with a detector (reflectometric measurement). The measured value is determined from the signal strength of the reflected light, using the previously measured blank value and the lot-specific information stored in the code chip. Finally, the result will be displayed and simultaneously stored in the memory.

Glucose

The glucose contained in the blood sample will react with the electrodes of the glucose test strip, producing an electric current which will stimulate a chemical reaction.





THE LUX SYSTEM

12 *GETTING TO KNOW THE SYSTEM*

23 *SETTING THE SYSTEM*

THE LUX SYSTEM

GETTING TO KNOW THE SYSTEM

PACKAGE CONTENTS



LUX METER



1.5 V AAA ALKALINE BATTERIES (3 EA)

USER MANUAL (1 EA)

HARDCASE

**15 μ L PIPETTE TO BE USED
WITH THE LIPID TEST STRIPS**

THE LUX SYSTEM

GETTING TO KNOW THE SYSTEM

SYSTEM COMPONENTS SOLD SEPARATELY



AVAILABLE TESTS

GLUCOSE TEST STRIPS

LIPID TEST STRIPS

(1 STRIP VIAL + 1 CODE CHIP + 10 PIPETTE TIPS)

HEMOGLOBIN TEST STRIPS

(1 STRIP VIAL + 1 CODE CHIP + 10 PIPETTE TIPS)

.....

ACCESSORIES

**7 μ L PIPETTE TO BE USED WITH THE
HEMOGLOBIN TEST STRIPS**

DATA READING

THE LIX SYSTEM

GETTING TO KNOW THE SYSTEM

CONTROLS

GLUCOSE CHECK STRIP

LIPID CHECK STRIP

HEMOGLOBIN CHECK STRIP

GLUCOSE CONTROL SOLUTIONS

.....
CHOLESTEROL CONTROL SOLUTIONS

.....
HDL CONTROL SOLUTIONS

.....
TRIGLYCERIDES CONTROL SOLUTIONS

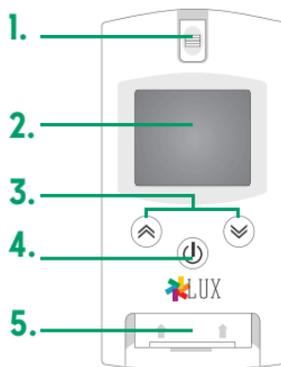
.....
HEMOGLOBIN CONTROL SOLUTIONS

THE LUX SYSTEM

GETTING TO KNOW THE SYSTEM IL SISTEMA

DESCRIPTION

FRONT



1. HOUSING FOR THE GLUCOSE TEST STRIP AND EJECTOR BUTTON OF THE TEST STRIP

The glucose test strip is inserted here. By pressing this button, it is possible to eject the strip after performing a measurement.

2. DISPLAY

It is possible to view the test results, the information, the symbols and all the stored test results.

3. UP/DOWN BUTTON

By pressing this button, it is possible to visualize all the stored values and together with the power button, it is possible to change the meter settings.

4. POWER BUTTON AND SETTINGS MENU, PRESS THIS BUTTON TO:

- Switch on/off the meter
- Enter the different meter settings which are changed using the up/down buttons ▼ or ▲
- Switch between the different test parameters
- Show the currently stored code numbers (before performing the measurement)
- Review the results (when in memory mode)

5. HOUSING FOR THE CHOL, TG, HDL STRIPS AND COVER OF THE HOUSING

When the strip is inserted, the cover is made to slide and it is locked by the test strip

THE LUX SYSTEM

GETTING TO KNOW THE SYSTEM

16



6. BATTERY COMPARTMENT COVER

7. HOUSING FOR THE CODE CHIP

It is possible to insert here the code chip of each parameter in order to perform the tests

THE LIIX SYSTEM

GETTING TO KNOW THE SYSTEM

DISPLAY



Every time the instrument is powered on, the display shows temporarily all the symbols that can be visualized. Check regularly that all the display symbols are operating correctly to prevent misinterpretations due to a defective display. The symbols shown on the display have the following meanings:

SIMBOLS



DESCRIPTION

LIPID AND HEMOGLOBIN TEST STRIP

APPLY THE BLOOD

BLOOD GLUCOSE TEST STRIP

CHECK STRIP

TEMPERATURE HIGHER OR LOWER THAN THE OPTIMAL RANGE FOR MEASUREMENTS

LOW BATTERY ALARM, PLEASE REPLACE THE DEAD BATTERY

CONTROL SOLUTION TEST RESULT

AFTER-MEAL TEST RESULT

AFTER-DRUG TREATMENT TEST RESULT

TEST RESULT

THE LIX SYSTEM

GETTING TO KNOW THE SYSTEM

18

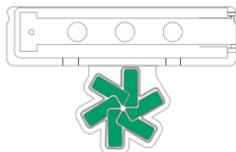
SYMBOLS	DESCRIPTION	SYMBOLS	DESCRIPTION
m/d	MONTH/DAY	mg/dL	UNIT OF MEASUREMENT FOR LIPIDS AND BLOOD GLUCOSE
mem	MEMORY	mmol/L	
	APPLY BLOOD	GLU	GLUCOSE
Code	CODE CHIP	CHOL	TOTAL CHOLESTEROL
	ACOUSTIC ALERT ON/OFF	Hb	HEMOGLOBIN
88/88	DATE (MONTH/DAY)	CHOL HDL	CHOLESTEROL/HDL RATIO
DAY/ AVG	AVERAGE OF THE TEST RESULTS	HDL	HDL CHOLESTEROL (HIGH DENSITY LIPOPROTEINS)
88:88	MEASUREMENT TIME	TG	TRIGLYCERIDES
AM PM	MEASUREMENT TIME (AM/PM)	LDL	LDL CHOLESTEROL (LOW DENSITY LIPOPROTEINS)
g/dL	UNIT OF MEASUREMENT FOR HEMOGLOBIN	HDL LDL	LDL/HDL RATIO

THE LUX SYSTEM

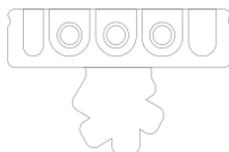
GETTING TO KNOW THE SYSTEM IL SISTEMA

TEST STRIPS AND CODE CHIPS

LIPID TEST STRIP



FRONT

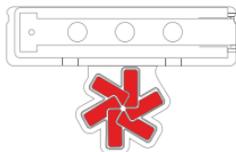


REAR

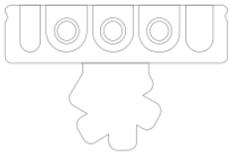


CHIP

HEMOGLOBIN TEST STRIP



FRONT



REAR



CHIP

THE LIX SYSTEM

GETTING TO KNOW THE SYSTEM

POWER SUPPLY

The meter switches off automatically after 3 minutes. All the results are stored in the memory. With a new set of batteries, it is possible usually to perform approximately 1,000 measurements. When the low battery icon is displayed, the batteries should be replaced.

When replacing the batteries, the date and time settings are not affected because the meter features a separate realtime clock and clock battery. Use only 1.5V AAA alkaline batteries.

The test results, including the related measurement date and time, as well as all the meter settings, remain stored even when the batteries are removed.

Please respect the environment and discard used batteries according to the applicable regulations and local laws.



- .. Do not touch the buttons when replacing the batteries. There is a risk of system error.
- .. Do not throw batteries onto an open fire. There is a risk of explosion.

THE LIIX SYSTEM

GETTING TO KNOW THE SYSTEM

INSERTING THE BATTERIES

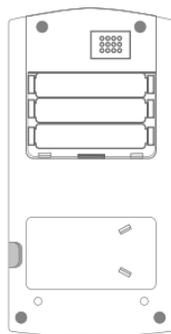
1. Please make sure that the meter is switched off.
2. Open the battery compartment by gently pressing the tab towards the midst of the meter. Slide the cover upwards to remove it from the device.



THE LUX SYSTEM

GETTING TO KNOW THE SYSTEM

3. Insert 3 batteries into the compartment as shown in the figure. Please note the orientation of the "+" (battery head) and "-" terminals (flat end). Use only alkaline batteries (1.5V, AAA).
4. Close the battery cover, place it on the guide rail and slide it down.



NOTE:

REPLACE ALWAYS ALL THREE BATTERIES AT THE SAME TIME BECAUSE BATTERIES WITH DIFFERENT CAPACITIES MAY IMPAIR THE FUNCTION OF THE METER. DO NOT USE RECHARGEABLE BATTERIES.

THE LUX SYSTEM

SETTING THE SYSTEM

SETTINGS TABLE

The following table provides an overview of the available settings.

Settings	Options	Default settings*
YEAR	20xx	YEAR SHIPPING
DATE	m/d (month/day), 00/00	M/D, 1/01
TIME FORMAT	24-hour format (24h), 12-hour format (12h) with AM/PM	12H
TIME	hour → minute	12:00 AM
BEEPER	on or off	ON
DAY/AVG	average value of glucose for..... days (1-90 days)	14 DAY/AVG
UNIT OF MEASUREMENT	mg/dL, mmol/L	THE UNIT OF MEASUREMENT IS SETTABLE (MG/DL OR MMOL/L)

* "Default settings" refers to the meter settings at the shipping time

THE LIX SYSTEM

SETTING THE SYSTEM

SETTING THE SYSTEM

Use the power, ▼ or ▲ buttons as described below to change the settings. The meter must be switched off before activating the setting mode.

1. Press and hold the power button for 3 seconds until you hear a beep. The message **SET** will be displayed on the LCD screen.



24

2. *Setting the year*

Press the ▼ or ▲ button to set the year, then press the power button to save. After setting the year, there is no need to repeat this step.

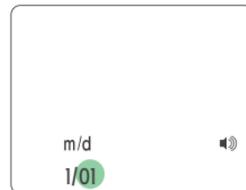
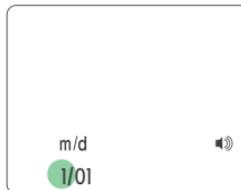


THE LUX SYSTEM

SETTING THE SYSTEM

3. *Setting the date*

Press the ▼ or ▲ button to set the month and the day, then press the power button to save. After setting the month and the day, there is no need to repeat this step.



Setting the time format

4. Press the ▼ or ▲ button to set either 12h or 24h, then press the power button to save. After setting the 12h or 24h time format, there is no need to repeat this step.

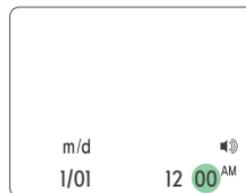
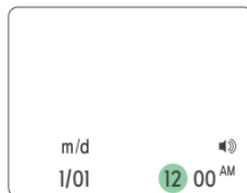


THE LIX SYSTEM

SETTING THE SYSTEM

5. *Setting the time*

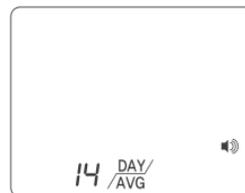
Press the ▼ or ▲ button to set the time, then press the power button to save. After setting the time, there is no need to repeat this step.



26

6. *Setting the DAY/AVG (only for glucose)*

Press the ▼ or ▲ button to set the desired days (1 DAY ~ 90 DAYS), then press the power button to save. After setting the DAY/AVG, there is no need to repeat this step

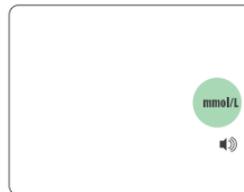


THE LUX SYSTEM

SETTING THE SYSTEM

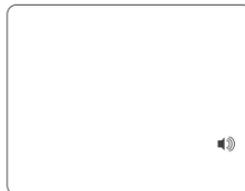
7. *Setting the unit of measurement*

Press the ▼ or ▲ button for 3 seconds to set the desired unit of measurement (mg/dL or mmol/L), then press the power button to save. After setting the unit of measurement, there is no need to repeat this step.



8. *Setting the beeper*

Press the ▼ or ▲ button to set the beeper, then press the power button to save. After setting the beeper, there is no need to repeat this step.





TESTING

30 *PREANALYTICAL PHASE*

36 *CHECKINGS*

44 *RUNNING THE TEST*

55 *ALTERNATIVE SITES*

TESTING

PREANALYTICAL PHASE

Before testing the followings should be prepared:

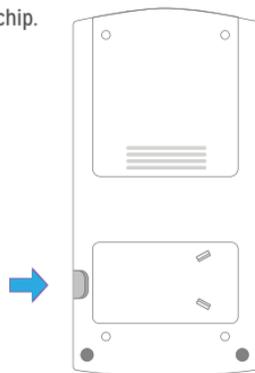
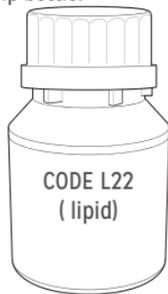
- *LUX meter*
- *The desired test strips with the related code chips for LUX lipid test strips and LUX hemoglobin test strips*
- *Mini pipette (15 μ L for lipids and 7 μ L for hemoglobin) for collecting the blood sample and loading it onto the test strip*
- *Lancing device together with lancets or disposable lancets (for healthcare professionals, a device suitable for use on several patients must be used)*
- *Disinfectant wipes for disinfection, after puncture*

QUICK SETTINGS

Before using the meter for the first time, perform the following steps:

- Insert the batteries.
- Set date, time and beeper.
- Insert the code chip (this can also be done directly before performing the measurement).

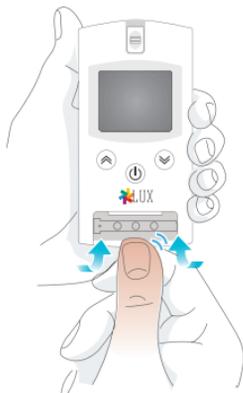
1. Make sure that the code chip number matches the code number printed on the label of the test strip bottle.
2. Insert the code chip.



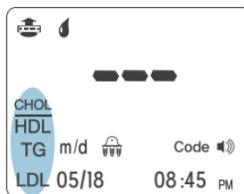
TESTING

PREANALYTICAL PHASE

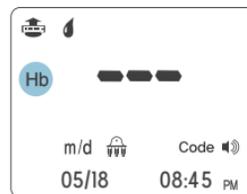
3. Insert the test strip into the housing locking it at the top.
4. Press the power button and check the code number.



5. Check the name of the analyte shown on the display.



LIPID



HEMOGLOBIN

NOTE:

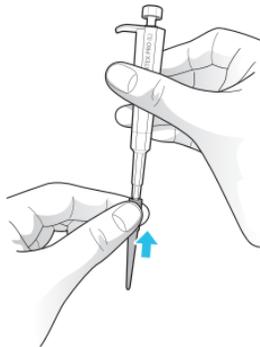
IF THE CODE CHIP AND THE TEST STRIP DO NOT MATCH, THE ERROR MESSAGE "E5" WILL BE DISPLAYED ON THE LCD SCREEN.

PREANALYTICAL PHASE

1. Wash the hands thoroughly with soap and warm water, rinse and dry them well. If the fingers are warm, it will be easier to get a blood sample.
2. Sit and keep the arm along the body for at least one minute.
3. Choose the puncture site neither too close to the nail nor too much at the center of the fingertip.

PREPARING THE MINIPIPETTE

1. Insert the pipette tip into the pipette as shown in the figure.
2. Push down on the top button of the pipette as shown in the figure, and hold it.



TESTING

PREANALYTICAL PHASE

SAMPLING

1. Perform the fingerpricking using a lancing device together with a sterile lancet for professional use or a disposable lancet.
2. Discard the first blood droplet and press gently to get a second blood droplet.
3. Hold the pipette so that the tip touches the blood sample on the fingertip as shown in the figure, avoiding pressing the tip on the skin.
4. Release the top button of the minipipette slowly to draw the blood into the tip. If the button is released too quickly, you may not collect enough blood.

34



TESTING

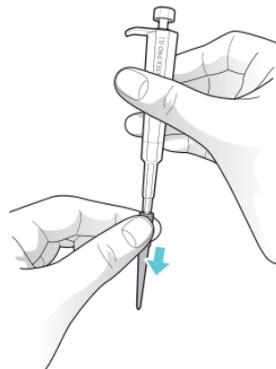
PREANALYTICAL PHASE

APPLYING THE SAMPLE

1. After collecting a sufficient blood sample, place the pipette tip on the strip well. Press the top button of the pipette to transfer the blood to the strip.



2. After applying the blood sample onto the test strip, remove the pipette tip and safely dispose of it.



NOTE:

LANCETS ARE DISPOSABLE DEVICES. TO REDUCE THE RISK OF INFECTION, DO NOT SHARE WITH OTHERS THE LANCETS. DISPOSE OF THE LANCETS IN A SAFE PLACE IN ACCORDANCE WITH LAWS AND REGULATIONS IN FORCE.

TESTING

CHECKINGS

MEASURING WITH THE CONTROL SOLUTIONS

The control solution test allows you to know if the meter and the test strips are working properly. Check the meter periodically to ensure that the readings are accurate.

It is possible to perform a control solution test in the following cases:

- When you open a new test strip bottle
- When you suspect that a test strip is damaged (i.e., if the lipid test strips were exposed to the air for a long period of time after opening the bottle, or if the test strip bottle was left open for a long period of time)
- When a test strip has been stored in conditions different from those specified (i.e. above or below the advised temperature or humidity conditions)
- When the meter or the test strips operate abnormally
- When the meter is dropped
- When the test results do not match your feelings
- When the batteries of the meter are replaced, or if the meter is cleaned

Before performing the test with the control solution

Before testing with the control solution it is necessary to use the control solutions:

- Lipids: LUX TC control solution, LUX TG control solution, LUX HDL control solution,
 - Hemoglobin: LUX hemoglobin control solution
 - Glucose : LUX glucose control solution.
- Please check the expiration dates of the test strips and control solution. Do not use expired test strips or control solutions.
 - Do not allow the control solutions to come into contact with skin or eyes. This may cause irritation.

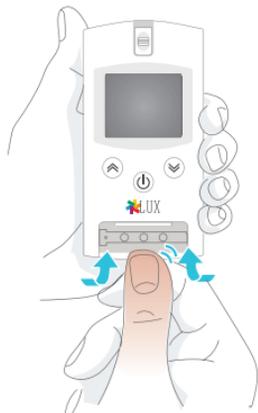
DO NOT SWALLOW OR INJECT THE CONTROL SOLUTIONS.

CAUTION

MEASURING WITH THE CONTROL SOLUTIONS

Procedure for lipids and hemoglobin

1. Insert the control solution code chip and the test strip into its housing locking it at the top.



2. Turn on the meter

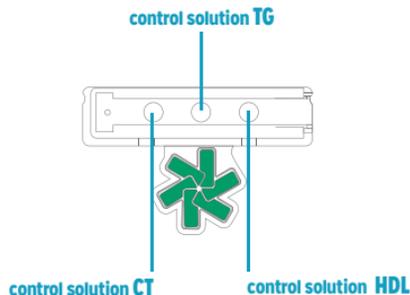


3. Shake the control solution bottle. Gently press the bottle until a drop of control solution forms. Discard the first drop and press again until a new drop of control solution forms.

TESTING

CHECKINGS

4. Apply the control solution with the pipette (15 μ L for lipids and 7 μ L for hemoglobin) onto the corresponding well of the test strip. Then the measurement will begin. After applying the control solution to the test strip, please make sure that the control solution bottle cap is securely closed.



THE LIPID TEST STRIPS NEED THREE TYPES OF CONTROL SOLUTIONS (TC, TG, HDL), ONE FOR EACH WELL.

CAUTION

5. When the test result is shown on the LCD screen, press the ▲ button for 3 seconds.

TESTING CHECKINGS

6. The control solution symbol will be displayed on the LCD screen.

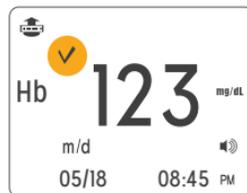
TESTING WITH THE LIPID CONTROL SOLUTIONS



-Press the power button. The test results will be stored in the memory of the meter.

-If the test result falls outside of the range printed on the label of the strip bottle, there may be a problem. Please repeat the test.

TESTING WITH THE HEMOGLOBIN CONTROL SOLUTIONS



-Press the power button. The test results will be stored in the memory of the meter.

-If the test result falls outside of the range printed on the label of the strip bottle, there may be a problem. Please repeat the test.

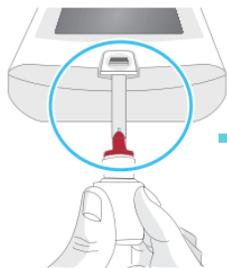
TESTING

CHECKINGS

MEASURING WITH THE CONTROL SOLUTIONS

Procedure for blood glucose

1. Insert a glucose test strip into its housing and push it until it stops. A beep will sound.
2. Apply a drop of control solution onto the front edge of the test strip.



- THE CONTROL SOLUTION RANGE PRINTED ON THE STRIP BOTTLE IS APPLIED ONLY TO THE LUX SYSTEM. (LIPID, HEMOGLOBIN, GLUCOSE)
- STORE THE CONTROL SOLUTIONS AT THE SPECIFIED TEMPERATURE (LIPID: 2-8°C, GLUCOSE: 8-30°C). HOWEVER, THE LIPID CONTROL SOLUTIONS SHOULD BE LEFT AT ROOM TEMPERATURE FOR 30 MINUTES BEFORE USE.
- DO NOT USE EXPIRED LIPID OR GLUCOSE CONTROL SOLUTIONS.
- THE LIPID, HEMOGLOBIN AND GLUCOSE CONTROL SOLUTIONS CAN BE USED FOR 3 MONTHS AFTER OPENING.
- IT IS NOT NECESSARY TO PREPARE SEPARATELY OR TO DILUTE THE CONTROL SOLUTIONS.
- AFTER USING THE CONTROL SOLUTIONS, CLEAN THE TIP BEFORE CLOSING THE CAP TIGHTLY.

CAUTION

CHECK STRIPS

It is possible to perform a test with the check strips in the following situations:

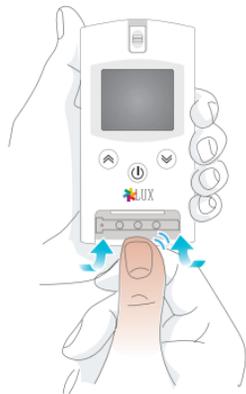
- Whenever you want to test the functioning of the meter
- Before the first use of the meter
- When the test results do not match your feelings
- When repeated test results are higher or lower than the expected results

THE CHECKING USING THE CHECK STRIPS DOES NOT REPLACE THE CONTROL SOLUTION TEST.

CAUTION

LIPID AND HEMOGLOBIN CHECK STRIPS

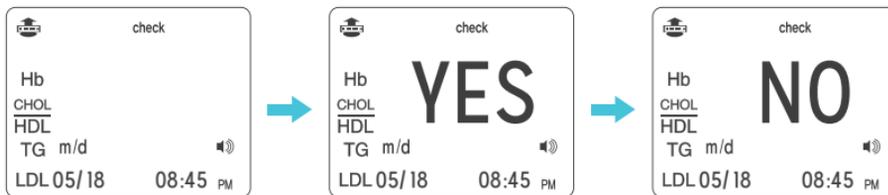
1. Insert the check strip into the housing and turn the meter on.



TESTING

CHECKINGS

- The message “**check**” will appear on the LCD screen, followed by the test result.
- If the strip is okay, the message **YES** will appear. If it is not okay, the message **NO** will be shown on the display.



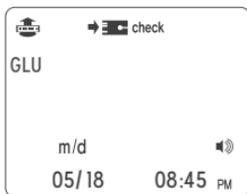
42

PLEASE NOTE THAT IF THE LIPID OR HEMOGLOBIN TEST STRIPS HAVE BEEN EXPOSED TO DIRECT SUNLIGHT, THIS MAY CAUSE FADING AND INACCURATE TEST RESULTS.

CAUTION

GLUCOSE CHECK STRIPS

1. Insert the check strip into the housing for the blood glucose test strip.
2. The message "**check**" will appear on the LCD screen, followed by the test result.
3. If the strip is okay, the message **YES** will appear. If it is not okay, the message **NO** will be shown on the display. If the strip cannot be checked for some reason, the message **NO** will be displayed. If so, please repeat the test.

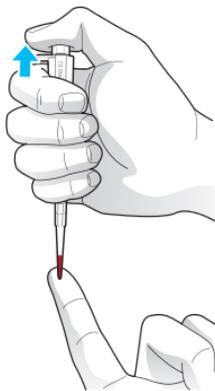


TESTING

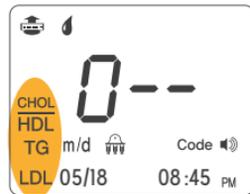
RUNNING THE TEST

LIPID TESTING

1. Insert a lipid test strip into the housing until you hear a click and turn on the meter.
2. Collect the first blood sample using the minipipette (15 μ L).



3. After collecting a sufficient blood sample, place the pipette tip on the first well of the strip. Press the top button of the pipette to transfer the blood to the strip. The test will start when a beep will sound.



TESTING

RUNNING THE TEST

4. Collect the second blood sample using the minipipette and transfer it to the second well of the strip.



5. Collect the third blood sample using the minipipette and transfer it to the third well of the strip.



NOTE:

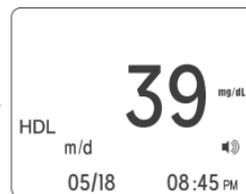
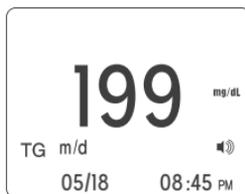
IT TAKES ABOUT 3 MINUTES TO COMPLETE THE TEST.

TESTING

RUNNING THE TEST

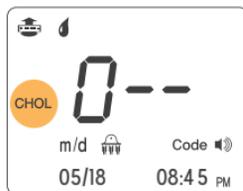
6. The results will be displayed in the following order:

CHOL → TG → HDL → LDL → CHOL/HDL → LDL/HDL

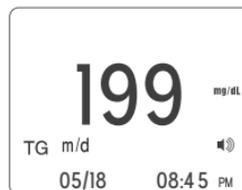


VIEWING RESULTS

VIEWING CHOLESTEROL RESULTS



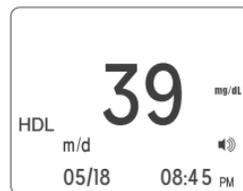
VIEWING TRIGLYCERIDES RESULTS



TESTING

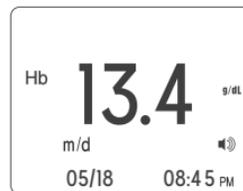
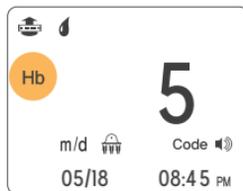
RUNNING THE TEST

VIEWING HDL CHOLESTEROL RESULTS



48

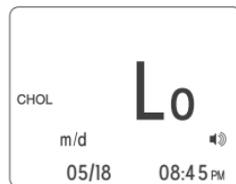
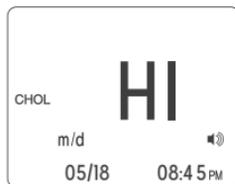
VIEWING HEMOGLOBIN RESULTS



LIMITATION

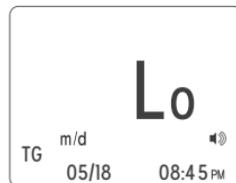
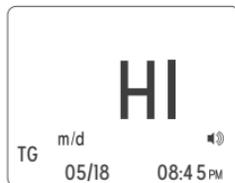
LIMITS OF READING FOR CHOLESTEROL

If the test result is higher than 400 mg/dL, the HI message will be displayed. If the test result is lower than or equal to 100 mg/dL, the Lo message will be shown on the LCD screen. If you get HI or Lo, repeat the test using a new test strip. If the result is still the same, please contact your physician.



LIMITS OF READING FOR TRIGLYCERIDES

If the test result is higher than 600 mg/dL, the HI message will be displayed. If the test result is lower than or equal to 50 mg/dL, the Lo message will be shown on the LCD screen. If you get HI or Lo, repeat the test using a new test strip. If the result is still the same, please contact your physician.

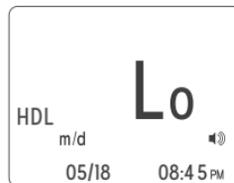
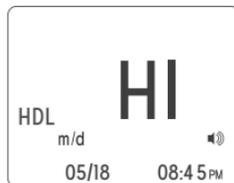


TESTING

ESECUZIONE DEI TESTS

LIMITS OF READING FOR HDL

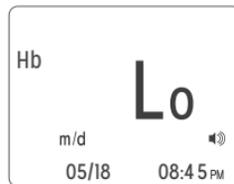
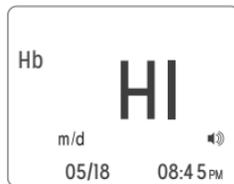
If the test result is higher than 80 mg/dL, the HI message will be displayed. If the test result is lower than or equal to 20 mg/dL, the Lo message will be shown on the LCD screen. If you get HI or Lo, repeat the test using a new test strip. If the result is still the same, please contact your physician.



50

LIMITS OF READING FOR HEMOGLOBIN

If the test result is higher than 25 g/dL, the HI message will be displayed. If the test result is lower than or equal to 5 g/dL, the Lo message will be shown on the LCD screen. If you get HI or Lo, repeat the test using a new test strip. If the result is still the same, please contact your physician.



BLOOD GLUCOSE TESTING

Blood glucose testing does not require any code chip. If you insert a blood glucose test strip into the device when it is off, the device will turn on automatically and it will switch to the blood glucose measurement mode.

1. Insert a glucose test strip into its housing and push it until it stops. The blood glucose measurement mode will start up automatically. The device will beep and the blood glucose test icon (a blood drop) will appear on the LCD screen and begin to blink.
2. Before testing, wash your hands thoroughly with soap and water, and rinse and dry them completely. Perform the fingerpricking. Press the finger gently to facilitate the blood flow.



TESTING

RUNNING THE TEST

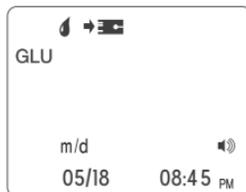
3. Bring the blood droplet near the test strip and let the test strip aspirate the blood as shown in the picture. Do not let the blood fall on the strip.



TESTING

RUNNING THE TEST

4. After 5 seconds, the blood glucose result will be displayed on the LCD screen. It will be used the unit of measurement selected in the settings.



TESTING

RUNNING THE TEST

5. When loading a control solution sample, or taking a blood sample after a meal or after taking drugs, it is necessary to enter this information into the meter using the special icons. After loading the blood sample and the result being displayed, do not remove the test strip; instead, press the ▼ button to display the special icons. To select one of the icons, press again the ▼ button. It is possible to select  "sample taken after a meal", or  "sample taken after a dose of medication".



ALTERNATIVE SITE TESTING (AST)

Please contact your healthcare professional before using any of these alternative sites to test your blood glucose.

Alternative site results may differ from fingertip results when blood glucose levels are changing quickly (e.g., after a meal, after taking insulin, during or after exercise).

Do not take a sample from an alternative site to test (or re-test) your blood glucose level if any of the following conditions apply:

- When you think your blood glucose is low (hypoglycemia)
- When you are not aware of the symptoms when experiencing hypoglycemia
- When the alternative site results do not agree with your feelings
- After a meal
- After exercise
- During sickness
- During times of stress

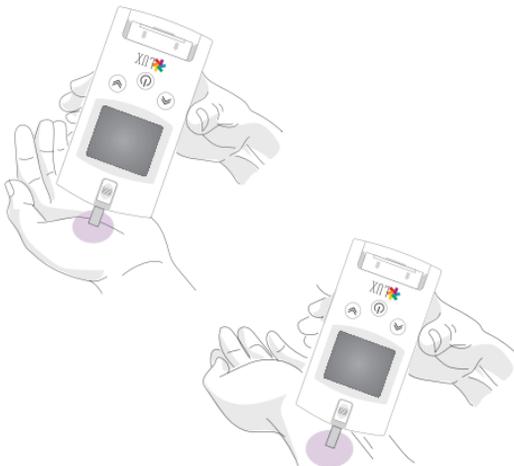
TESTING

ALTERNATIVE SITES

1. Insert a glucose test strip into its housing, the meter will beep.



2. Load the sample onto the strip bringing the blood droplet near the test strip and letting the test strip aspirate the blood. When the meter beeps, the measurement will start.



WARNINGS

Make sure to use an alternative site for the blood glucose test two hours or more after taking insulin, after a meal, or after exercise.

Do not use alternative sites if you are pregnant, if you are aware that your blood glucose level is not as stable as usual, if you think you have hypoglycemia (low level of sugar in the blood) or hyperglycemia (high level of sugar in the blood), or when you think your blood glucose may be rising or falling quickly.

Do not use an alternative site if alternative site results do not agree with your feelings.



MEMORY

60 *FUNCTIONS*

61 *REVIEWING*

63 *DELETION*

MEMORY FUNCTIONS

MEMORY FUNCIONS

The LUX meter is able to measure and calculate 5 different haematic parameters, including lipids, hemoglobin and glucose. The device can store up to 1.000 readings in its memory; if the meter runs out of memory, it is necessary to delete some of the old readings.

- Blood glucose test strip
- Hemoglobin test strip
- Lipid test strip: CHOL, TG, HDL, LDL, CHOL/HDL, LDL/HDL

REVIEWING MEMORIES

1. To view the most recent test results, press the power button or the button ▼ or ▲ when the strip is not inserted. It is possible to scroll the item by pressing the ▼ or ▲ button.

GLU → (CHOL, TG, HDL, LDL, CHOL/HDL, LDL/HDL) → Hb → TC → TG → HDL



MEMORY

REVIEWING

2. After selecting the desired item, press the power button.

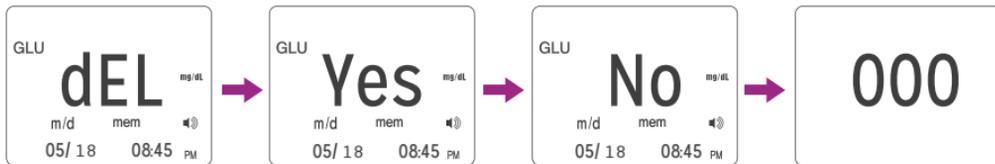
It is possible to search the test results of the desired item by pressing the ▼ or ▲ button.

3. To turn off the meter after checking the stored readings, just press the power button.

MEMORY DELETION

DELETING MEMORIES

To delete all the test results, enter the stored readings and then press the ▼ and ▲ buttons simultaneously for 3 seconds. All the stored test results will be deleted.





TROUBLESHOOTING

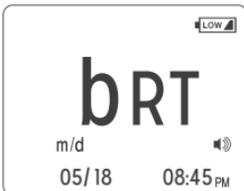
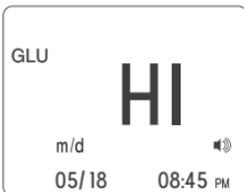
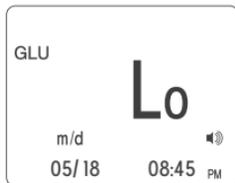
66 *ERROR MESSAGES*

69 *MAINTENANCE*

TROUBLESHOOTING

ERROR MESSAGES

DISPLAY



MESSAGE

Too low value

This screen appears when the test results are below the allowed range of measurement. If this message is shown, run the test again using a new test strip. If you obtain again the same result, please contact your physician immediately.

(Display: blood glucose concentration \leq 20mg/dL → 'Lo')

Too high value

This screen appears when the test results are above the allowed range of measurement. If this message is shown, run the test again using a new test strip. If you obtain again the same result, please contact your physician immediately.

(Display: blood glucose concentration \geq 600mg/dL → 'Hi')

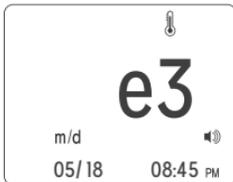
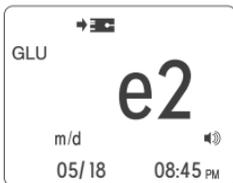
Low battery

Please replace the batteries immediately. If the battery is low and you press the power button, the battery icon will blink and the meter will turn off automatically after 10 seconds.

TROUBLESHOOTING

ERROR MESSAGES

DISPLAY



MESSAGE

Strip error

The strip is damaged, used, or has been inserted wrongly. Dispose of the test strip and perform the measurement using a new test strip.

Glucose test strip: low amount of blood

The amount of blood applied to the test strip is not sufficient. Dispose of this test strip and repeat the test using a new test strip, taking care of applying enough blood.

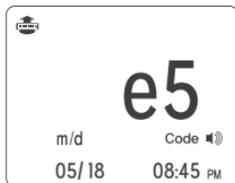
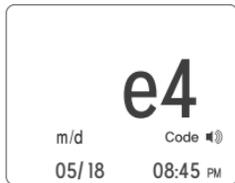
Temperature error

This message appears when the room temperature is lower or higher than the operating temperature range. Leave the meter in a place with a temperature between 10-40°C for 30 minutes and repeat the measurement. Do not heat up or cool down the meter artificially.

TROUBLESHOOTING

ERROR MESSAGES

DISPLAY



MESSAGE

Missing code chip error

This message appears when there is no code chip inserted in the meter. Insert the correct code chip and repeat the test. If this error message appears again, please contact the customer service for assistance.

Code chip and test strip mismatch error.

This message appears when the code chip inserted in the meter is not the correct one for the test strip being measured, or when performing a measurement with the lipid test strip in the normal measuring mode. Check the chip inserted in the meter and the testing mode, then repeat the test.

Problem with the test strip

This message appears when a test strip is removed after a measurement has started. Repeat the test. Insert the test strip properly into the meter. Do not move or remove the test strip.

TROUBLESHOOTING MAINTENANCE

MAINTENANCE

Cleaning

If dust or moisture gets into the strip housing of the meter, this can cause the device to malfunction. Please take care when cleaning the meter. Wipe the meter with a slightly damp soft cloth. Do not use an abrasive cloth or disinfectant, because they may damage the LCD screen.

It is very important to keep the screen clean. Clean the meter regularly.

- **Cleaning the lipid and hemoglobin test strips housing**
-
- Dampen a clean cloth.
- Slide the housing cover up and wipe inside with the damp cloth. Wipe away any debris, dirt or stains.
- After cleaning, run a test with the control solution to ensure that the meter operates properly.
-

PLEASE MAKE SURE THAT THE DEVICE IS TURNED OFF BEFORE CLEANING IT.

CAUTION

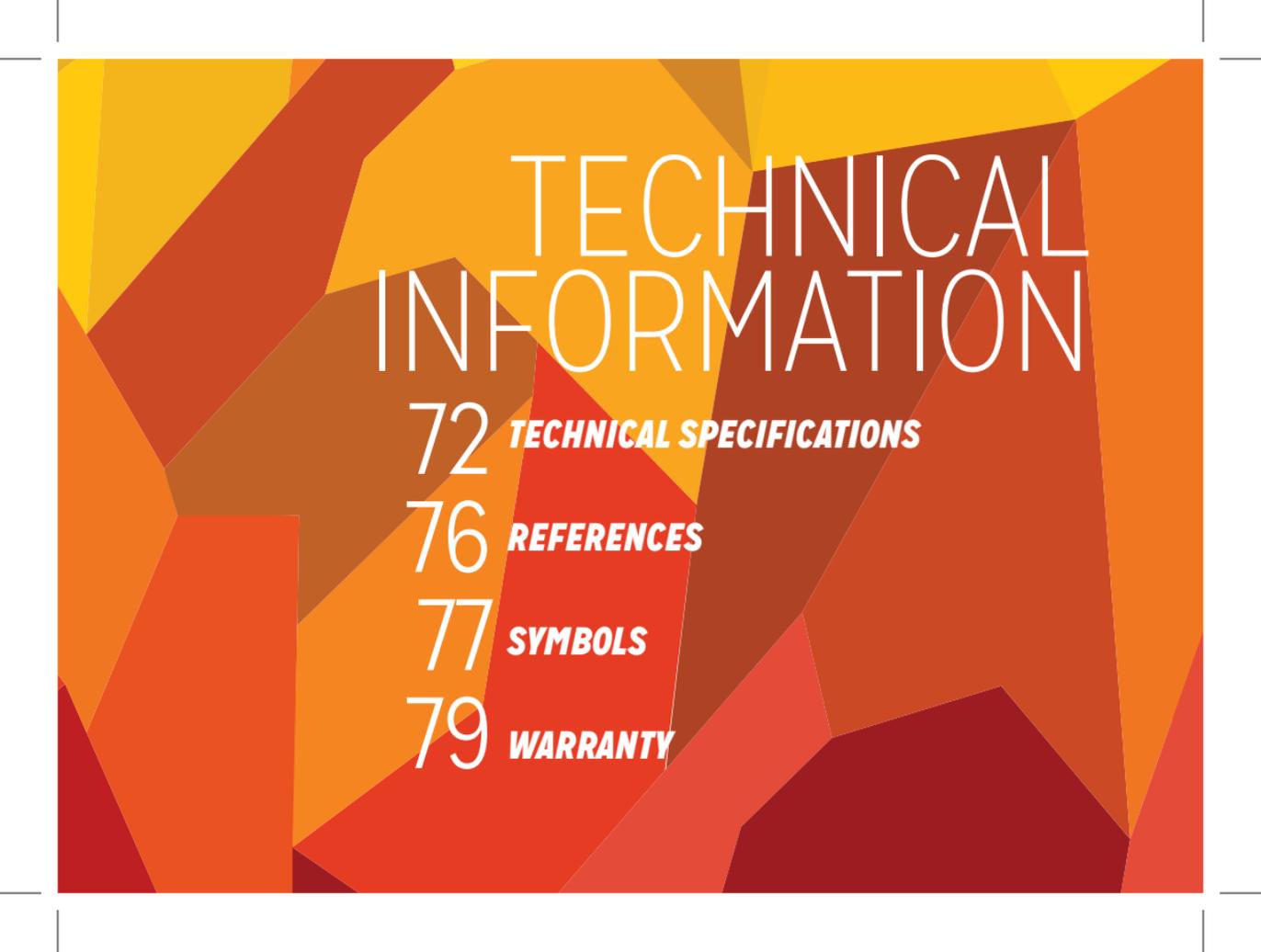
69

Meter

- Protect the strip housing from dust.
- Do not store the meter in a wet place.
- Store the meter at a temperature between 10-40°C.
- If the batteries are installed in the meter, the device must be kept in a low-humidity environment.

- **Lipid and hemoglobin test strips and blood glucose test strips**
- Store all the test strips at the specified temperature (8-30°C).
- If the test strips are stored at a temperature lower than 8°C or higher than 30°C, please allow them to warm or cool to room temperature before using.
- Keep the test strips away from direct sunlight. If the lipid and hemoglobin test strips are exposed to direct sunlight, they may change colour and they may not give accurate results.
- The code chips to measure lipids and hemoglobin must be stored either in the meter or together with the strip bottle.
- Please close the lid of the test strip bottle tightly after use.
-
-
-
-





TECHNICAL INFORMATION

72 ***TECHNICAL SPECIFICATIONS***

76 ***REFERENCES***

77 ***SYMBOLS***

79 ***WARRANTY***

TECHNICAL INFORMATION

TECHNICAL SPECIFICATIONS

METER

POWER SOURCE	3 X AAA 1.5V alkaline manganese batteries
NUMBER OF MEASUREMENTS	More than 500 measurements (lipids: 500, Glucose/ Hemoglobin: 1.000) (with new batteries)
METHOD OF MEASUREMENT	Lipid and hemoglobin: reflectometric method, Glucose: electrochemical method
DISPLAY	LCD (LED Backlight)
OPERATION BUTTONS	3 buttons: a power switch (ON/OFF button), a up button and a down button
MEMORY CAPACITY	1.000 readings
FUNCTIONS	Average of the glucose measurements (1-90 days)

TECHNICAL INFORMATION

TECHNICAL SPECIFICATIONS

STRIPS

LIPID AND HEMOGLOBIN TEST STRIPS

MEASUREMENT RANGE	Total cholesterol: 100-400 mg/dL (2.59-10.36 mmol/L), Triglycerides: 50-600 mg/dL (0.57-6.78 mmol/L) , HDL: 20-80 mg/dL (0.52-2.07 mmol/L), Hemoglobin: 5-25 g/dL (3.1-15.51 mmol/L)
SAMPLE	Fresh capillary blood for self-testing and professional use. Venous blood samples must be taken by a healthcare professional.
SAMPLE VOLUME	15uL (Cholesterol, Triglycerides, HDL for each test), 7uL (Hemoglobin)
MEASURING TIME	Lipids: within 3 minutes; Hemoglobin: 5 seconds
STORAGE TEMPERATURE	8-30°C
HEMATOCRIT	Total cholesterol, Triglycerides: 30-50%; HDL: 35-50%
MEASURING TEMPERATURE	10-40°C

TECHNICAL INFORMATION

TECHNICAL SPECIFICATIONS

BLOOD GLUCOSE TEST STRIPS

MEASUREMENT RANGE

20-600 mg/dL (1.1-33.3 mmol/L)

SAMPLE

Fresh capillary blood

SAMPLE VOLUME

0.5 μ L

MEASURING TIME

5 seconds

STORAGE TEMPERATURE

2-30°C

HEMATOCRIT

20-60%

MEASURING TEMPERATURE

10-40°C

MEASURING METHOD

Electrochemical method

CALIBRATING METHOD

Plasma calibration

TECHNICAL INFORMATION

TECHNICAL SPECIFICATIONS

PRODUCT LIST

LIST OF THE AVAILABLE PRODUCTS

Kit	Meter LUX + Instructions for use + 3 X AAA 1.5V batteries + 1X15 μ L pipette for lipids + 1 hardcase
Strips	LUX lipid test strips (10 T) + 1 code chip + 10 pipette tips LUX hemoglobin test strips (10 T) + 1 code chip + 10 pipette tips LUX blood glucose test strips (50 T) LUX blood glucose test strips (25 T)
Quality control	LUX total cholesterol control solutions LUX triglycerides control solutions LUX HDL control solutions LUX hemoglobin control solutions LUX glucose control solutions LUX lipid check strips LUX hemoglobin check strips LUX glucose check strip
Accessories	7 μ L minipipette for hemoglobin Data reading

TECHNICAL INFORMATION

REFERENCES

REFERENCES

1. National Cholesterol Education Panel. Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) Final Report. *Circulation* 2002; 106: 3413-21.
2. Grundy SM, Cleeman JI, Merz CNB, et al. Implications of recent clinical trials for the National Cholesterol Education Program Adult Treatment Panel III guidelines. *Circulation* 2004; 110: 227-39.
3. Siedel J, Hagele EO, Ziegenhorm J, Wahlefeld AW. Reagent for the enzymatic determination of serum total cholesterol with improved lypolitic efficiency. *ClinChem* 1983; 29: 1075-80.

TECHNICAL INFORMATION

SYMBOLS

SYMBOLS	DESCRIPTION	SYMBOLS	DESCRIPTION
	CONSULT INSTRUCTIONS FOR USE		BATCH NUMBER
	CAUTION! REFER TO THE ATTACHED DOCUMENTS AND TO THE SAFETY-RELATED NOTES OF THE MANUAL ACCOMPANYING THIS METER.		IN VITRO DIAGNOSTIC MEDICAL DEVICE
	TEMPERATURE LIMITATION		SERIAL NUMBER
	USE BY...		SINGLE USE
	MANUFACTURER		WEEE DIRECTIVE
			THIS PRODUCT FULFILLS THE REQUIREMENTS OF THE EUROPEAN DIRECTIVE 98/79/EC ON IN VITRO DIAGNOSTIC MEDICAL DEVICES.

TECHNICAL INFORMATION

SYMBOLS

Disposal of used electrical and electronic equipments



This symbol on the product, its accessories or packaging indicates that it should not be treated as household waste. Please dispose of this equipment at your local collection point for recycling electrical and electronic equipments. If you live in Europe, there are separate collection services for electrical and electronic waste. By ensuring the correct disposal of this product, you will help prevent potential hazards to the environment and to human health which could otherwise result from improper disposal of this equipment. Recycling materials also helps conserve our natural resources. Therefore please do not dispose of old electrical or electronic equipment with your household waste. For more detailed information about recycling this product or its accessories, please contact your local city office, your household waste disposal service, or the seller from whom you purchased this product.

TECHNICAL INFORMATION

WARRANTY

WARRANTY

Manufacturer's warranty:

Biochemical Systems International S.r.l. warrants to the original purchaser that this device will be free from defects for 1 year starting from the date of original purchase.

Warranty limitations:

This warranty is subject to the following exceptions and limitations:

1. Biochemical Systems International S.r.l. shall not be required to replace any unit which is damaged or malfunctions due to abuse, accidents, alteration, neglect, misuse, maintenance by someone other than Biochemical Systems International S.r.l. or failure to operate in accordance with the instructions.
2. Biochemical Systems International S.r.l. reserves the right to make changes in design without obligation to incorporate such changes into previously manufactured devices.
3. Biochemical Systems International S.r.l. has no knowledge of the performance of the device when a test strip is altered or modified in any way.

EMC TEST RESULTS

This equipment complies with EN 61326:2006 Class B requirements. The emissions of the energy used are low and not likely to cause interference in nearby electronic equipment. The equipment has been tested for immunity to electrostatic discharge at test levels of $\pm 2\text{kV}$, $\pm 4\text{kV}$ and $\pm 8\text{kV}$ of air discharge. The equipment has been tested for immunity to radio frequencies interference at the frequency of 80MHz to 2.7GHz and test level of 3V/m.



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