Thank you for your purchase of the STANDARD LipidoCare Analyzer!

This User Manual contains all of the information needed to use the Analyzer. Please read this User Manual carefully before using the Analyzer. Familiarize yourself with the required preparations and the measurement procedure before performing the first measurement. Also read the package insert of the lipid test strips to be used for the planned test.

If you cannot reach SD Biosensor Customer Care Service, please contact your healthcare professional or local distributor. You can also visit www.sdbiosensor.com for product demonstrations. Thank you again for choosing the STANDARD LipidoCare Analyzer.

Abbreviations

ТС	Total Cholesterol
TG	Triglycerides
HDL	High Density Lipoprotein cholesterol
LDL	Low Density Lipoprotein cholesterol

The packaging materials, labels and instruction of use for STANDARD LipidoCare Analyzer may contain the following symbols or abbreviations which are listed below with their meaning:

	Please consult instructions for use	LOT	Batch code
	Caution, consult accompanying documents		To discard it separately from other household waste
ĺÌ	Consult instructions for use	1	To indicate the temperature limitations in which the transport package has to be kept and handled
IVD	In Vitro diagnostic use	\sum	Use by / Expiry date
	Manufacturer	EC REP	Authorized Representative in the European Community
REF	Reference number	$\sum_{i=1}^{n}$	Contains Sufficient for <n>Tests</n>
\sim	Date of manufacture	SN	Serial number of the analyzer
(Do not reuse		



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CHAPTER 1. Understanding New Analyzer

1. Indication for Use; Purpose of the Analyzer

The STANDARD LipidoCare Analyzer is designed to measure the quantitative measurement of the blood parameters: Total Cholesterol('TC'), Triglycerides('TG'), High-Density Lipoprotein Cholesterol('HDL'), calculated 'LDL', 'LDL/HDL', 'non-HDL' and glucose. This system is intended for in vitro diagnostic use to test fresh capillary whole blood, venous whole blood plasma or serum. The STANDARD LipidoCare Lipid Test system should be only used with the STANDARD LipidoCare Lipid Test Strip and either the STANDARD LipidoCare Blood Glucose Test Strip or the SD Codefree Blood Glucose Test strip. The system is suitable for professional use as well as for self-testing, and is a valuable tool in monitoring diabetes and cholesterol levels, but it is not intended to diagnose diabetes or cholesterolrelated cases.

2. Test principle

LIPID

By means of a codechip, the Analyzer reads the lot-specific characteristics of the lipid test strips currently in use. Then an unused test strip is inserted into the Analyzer. While inserted, the application area of the test strip is illuminated by an LED (light-emitting diode) from below. Before the actual measurement is performed, the reflection behaviour of the test strip is determined by means of the light which is reflected (from the application area). The blood sample is then applied to the application area and the measurement chamber flap is closed. The constituent to be determined in the applied sample undergoes an enzymatic reaction with formation of a dye. The amount of dye formed increases with the concentration of the substance to be determined. After a certain period of time, the colour intensity is measured by illuminating the application area again from below using the LED. The intensity of the reflected light is measured with a detector (reflectance photometry). The measured value is determined in the agal strength of the reflected light, with the previously measured blank value and the real to-specific information (codechip) also being considered. Finally, the result is displayed and simultaneously stored in the memory.

GLUCOSE

The glucose test strip is designed with an electrode that measures glucose levels. Glucose in the blood sample mixes with reagent on the test strip that causes a small electric current. The amount of current that is created depends on how much glucose is in the blood. The STANDARD LipidoCare Analyzer measures the current that is created and converts the measurement to the amount of glucose that is in the blood. The blood glucose result is displayed on the LCD display. By touching a drop of blood to the tip of the glucose test strip, the strip's reaction chamber automatically draws the blood into the strip through capillary action. When the chamber is full, the STANDARD LipidoCare Analyzer starts to measure the blood glucose level.

3. Before You Start Testing



Carefully read and follow the instructions in the measuring and package inserts for the lipid test strips and control solutions. It is very important to follow the instructions in order to prevent an incorrect result or improper treatment.

Samples

Lipid

The STANDARD LipidoCare Analyzer for lipid testing is designed for measuring fresh capillary whole blood or venous blood (venous whole blood, serum or plasma) sample.

* Professional use only for venous blood.

Glucose

The STANDARD LipidoCare Analyzer for glucose is designed for testing fresh capillary whole blood samples (for example, blood from your fingertip, palm, upper arm, or forearm). Do not use the STANDARD LipidoCare Analyzer for glucose of serum or plasma or arterial, venous whole blood.

Refer to the Safety Information

There is a potential risk of infection. We recommend that healthcare professionals using the STANDARD LipidoCare Analyzer to perform measurements for more than one patient use gloves and follow all other locally applicable health and safety regulations.

Operating conditions

To ensure proper function of your STANDARD LipidoCare Analyzer, observe the following guidelines:

Operate the analyzer only with the acceptable environmental conditions; temperature: 5°C to 45°C, humidity: maximum relative humidity 80 % for



temperatures up to 31°C decreasing linearly to 39% relative humidity at 45°C, altitude: up to 3,776m.

- In order to perform a measurement, place the Analyzer on a level surface or hold it in your hand.
- Strong electromagnetic fields may impair the function of the Analyzer. Do not use the Analyzer close to sources of strong electromagnetic radiation.

4. The STANDARD LipidoCare Analyzer

The Analyzer includes:

- * STANDARD LipidoCare Analyzer
- * STANDARD Lipid Check Strip
- * STANDARD Glucose Check Strip
- * User Manual
- * Quick Guide
- * 4 AAA 1.5 V batteries

STANDARD LipidoCare Analyzer



		Battery compartment lid Provide access to the battery compartment (4 AAA 1.5 V alkaline manganese batteries).
	Н	Codechip Slot Insert a codechip for lipid test strip.
K K	I	Measurement chamber cover You can remove this cover to clean the test strip guide.
H	J	Data port Download test results to a personal computer if you have the software. (SD LMS)
	K	Printer port Print test results to external thermal printer.
	L	SET/PRT Button SET/PRT Press to set the Analyzer or print the test result.

Display of STANDARD LipidoCare Analyzer



The symbols in the display have the following meaning.

CODE	Indicate Codechip sign		Warning when the battery is low or must be replaced
	Indicate printing	n	Indicate index number of memory
888	Codechip number or memory number stored in memory	Ø	Indicate during the analyzer setting
X	Indicate blood checking	1	Indicate beep setting
	Indicate if environmental temperature is exceeded during testing	M	Indicate the Lipid Profile and TC-HDL strip
	Indicate open or close flap	mg/dL mmol/L	Unit of the test result
888	Test result	=	Indicate a test result stored in memory (Single parameter mode)
DAY	Indicate the average result	Ā	Indicate a test result stored in memory (All parameter mode)
SE BL	Indicate the blood sample type. BL: Capillary or Venous whole blood SE: Serum or plasma	Ċ	Indicate a control solution test result
6	Indicate blood checking	\odot	Indicate beep setting



	Glucose test strip	•	Lipid test strip
EXP	Indicate if the lipid test strip is exceeded the expiration date	88-88	Date Indicate the Bluetooth ('bt') only for 02LA20G
88:88	Indicate Measurement time	TG	Indicate Triglycerides
TC	Indicate Total cholesterol	LDL	Indicate LDL cholesterol
HDL	Indicate HDL cholesterol	non-HDL	Indicate non-HDL cholesterol
GLU	Indicate glucose	LDL/HDL	Indicate LDL/HDL

5. Power supply

To save power, the Analyzer turns itself off after 5 minutes unless a button is pressed or a new test strip is inserted. When the Analyzer turns itself off, all test results obtained so far remain in the memory. Battery life is expected at approximately 1000 measurements. When the battery warning is displayed for the first time, approximately 50 measurements can still be performed. In this case, replace the batteries as soon as possible.

When replacing the new batteries, you must re-enter the date and time. Use only AAA alkaline manganese batteries.

Measurement results including the related measurement date and time as well as all other Analyzer settings, remain stored even when no batteries are inserted. Please respect the environment and dispose of used batteries according to your local regulations and laws.

Do not throw batteries onto an open fire. There is a risk of explosion.

Lipid Profile Item TC TG Color Blue Red Yellow Glucose strip Lipid Check Strip Glucose Check Strip Glucose Flectrode Arming Knob 0 t Strip

6. Test Strips

- Lipid strip -

7. Accessories

Optional Accessories

STANDARD Micropipette 35µl
STANDARD Micropipette 10µl
STANDARD Ezi Tube+ 35µl
STANDARD Ezi Tube + 10µl
STANDARD Lancets (30G)
STANDARD Lancing Device
STANDARD Safety Lancets (23G)
STANDARD Alchol Swab
STANDARD Thermal Printer (model: MPT-700)
STANDARD Thermal Printer (model: SPP-R200)
STANDARD Thermal Printer Cable
STANDARD Thermal Printer Paper (Nomal type)
STANDARD Thermal Printer Paper (Label type)
STANDARD Lipid Manegement Software
Universal Mini USB Cable

CHAPTER 2. Testing the STANDARD LipidoCare Analyzer

1. Operating the Analyzer

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

STEP 1. Insert batteries.

- 1. Ensure the Analyzer is switched off and turn it over.
- 2. Open the battery compartment lid by slightly pressing the tab towards the centre of the Analyzer.
- 3. Lift the lid upwards to remove it from the Analyzer.



 Insert four batteries into the compartment according to the illustrations. Please note the orientation of the "+" (battery head) and "-" terminals (flat end). Use only alkaline manganese batteries (1.5 V, AAA).







- 5. Close the battery compartment lid.
- 6. Turn the Analyzer on to test the function of the new batteries.
- 7. Check the display is functioning correctly to prevent misinterpretations due to defective display elements.
 - If you think the display screen does not appear for long enough, you can hold down the other button (the next time you switch on the Analyzer). The display screen is then shown for the time the button is pressed.



- After inserting or replacing batteries, confirm that the time and date are set correctly. If they are not, reset the Analyzer before testing.
- Always replace all four batteries at the same time because batteries with different capacities may impair the function of the Analyzer. Do not use rechargeable batteries.

STEP 2. Set the Analyzer

Brief overview of the Analyzer settings

The following table provides an overview of the available settings.

Stage	Setting	Options
1	Веер	On, Off
2	Year	үүүү
3	Date Format	m-d, d-m
4	Date	mm-dd, dd-mm
5	Time Format	12h, 24h
6	Time	hh:mm
7	Sample. Type (for Lipid)	SE, BL
8	Unit of the Test Result	mg/dL, mmol/L
9	Auto Printing	On, Off
10	Printing Page	P-1, P-2
11	Hypo warning (for glucose)	Off, 60, 70, 80
12	Alarm	Off, 4 Alarms
13	Bluetooth with PC*	On, Off
14	Bluetooth with Printer*	On, Off
15	Repairing Printer*	On, Off

* Only for 02LA20G

Stage 0) Entering set mode

- Turn on the meter and then press and hold the SET/PRT () button (on the top side of the Analyzer) for 3 seconds to enter set mode. If you want to leave the set mode, press the SET/PRT () button.
- Press the e pi button to change the currently flashing setting. You can
 press the e pi button as many times as needed (or keep it pressed) until
 the desired setting (value) is reached.



Press the obstant press by the current setting and go to the next setting.





You can only move forward through the settings. Returning to the previous setting is not allowed. Corrections can only be made by repeating the settings. The setting procedure can be terminated at any time by pressing the setting. () button. The settings made up to that point will be stored.

4. Once the setting is completed, the Analyzer will be automatically turned off.

Stage 1) Setting - Beep

At the first stage, you set the Beep function.

 When you enter the set mode, the display for setting the beep will be the first step of the setting mode.



 Set the beep mode on or off by pressing either of button and then select the preferred feature by pressing the button. If you select the beep on feature, a 'beep' sound is made at the same time; otherwise, if you select the beep off feature, no sound is made.



Stage 2) Setting – Year

In the second stage, you set the Year in Date & Time setting.

 After setting the Beep funtion, the display for setting the Year will appear. Set the correct year by pressing or button and then select the correct year by pressing the button.



Stage 3) Setting – Date Format

In stage 3, you set the Date Format in Date & Time setting.

 Next will appear the setting display for Date Format. The Analyzer can display either a Month-Day (m-d) format or a Day-Month (d-m) format. Set the preferred format on the screen by pressing either or button and select by pressing the button.

BL

Stage 4) Setting – Date In stage 4, you set the date



L - Capillary or Venous Whole Blood



Ex) 1-1



LipidoCare

STANDARD



2. Set the **Printing Page** mode, -'P-1'(1 copy) or 'P-2'(2 copies) - by pressing either of or button and then select the preferred feature by pressing the button.



Stage 11) Setting – Hypo Warning

In stage 11, you set the Hypo Warning function.

3. After the Printing Page setting, the display for setting the Hypo Warning will appear.



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*Only for 02LA20G

STANDARD[®]



You can set the Analyzer to let you know when your glucose result indicates possible low blood glucose (hypoglycemia). You can also select what blood glucose level you want this indicator to have - 60, 70 or 80 mg/dL.
 If your glucose results are lower than the selected hypo result, the hypo symbol will appear on the LCD with a 'beep' sound. It

GLU

is very important to manage your hypoglycemia.

Stage 12) Setting – Alarm

In stage 12, you set the Alarm function. You can set a maximum of 4 alarms to remind you to test your glucose.

- 1. After the Hypo Warning setting, the display for setting the **Alarm** will appear.
- Set the first Alarm function, 'On' or 'Off', by pressing either the or button and then select the preferred feature by pressing the button. If you select the Alarm 'Off' feature, the Analyzer automatically powers off.
- If you select the Alarm 'on' feature in first alarm mode, the clock will blink. Set the desired hour and minute for the alarm by pressing either the either by button and then select the preferred time by pressing the either button.
- 4. The 2nd Alarm setting mode appears next. Set the Alarm in the same way as above. [2, 3]







- 5. You can set the third and fourth Alarm modes in the same way as above. [2, 3]
- 6. When you finish setting the last alarm, the Analyzer automatically power off.

Stage 13) Setting – Bluetooth with PC

You can set Bluetooth communication with your PC. If the analyzer is paired with a PC, the test results are transferred automatically via Bluetooth.

- 1. After the alarm setting, the display for bluetooth with PC function will appear on the screen.
- Select ON or OFF by pressing the left or right button and then save it by pressing the ON/OFF button.



Stage 14) Setting – Bluetooth with Printer

You can set Bluetooth communication with a printer.

- After the setting of Bluetooth with a PC, the display for bluetooth with printer function will appear on the screen.
- 2. Select ON or OFF by pressing the left or right button and then save it by pressing the ON/OFF button.



*Only for 02LA20G



If you set both auto-printing and Bluetooth with Printer as ON, you can get the test results printed automatically via Bluetooth communication.

Stage 15) Setting – Re-Pairing Printer

You can set the analyzer to be automatically paired with the previously paired printer whenever the printer is near the analyzer.

- 1. After the Bluetooth with printer setting, the display for re-pairing printer function will appear on the screen.
- Select ON or OFF by pressing the left or right button and then save it by pressing the ON/OFF button.



STEP 3. Insert a codechip

Lipid Test Strip

Coding

The codechip provides the Analyzer with important information on the production-specific characteristic of the respective lipid test strip to measure your results accurately. The codechip is required when a new Lipid test strip package is opened. Before you use your Analyzer with a new box of lipid test strips, you should set the Analyzer to "match" the lipid test strips. The number on the codechip should match the number on the outer box and the test strip foils.



Code Setting

- 1. Make sure the Analyzer is turned off. Remove the old codechip if one is installed.
- 2. Insert a new codechip until it clicks into place.



3. Turn the Analyzer ON. The 3-digit code number of the inserted codechip and the appropriate parameter name appears with the flashing lipid test strip



symbol. This number and parameter name must match the codechip. If it does not, repeat the steps above (1-2).
Lipid Profile
TC TG



A codechip is included in each test strip package. Store the lipid test strips together with the codechip in the package.

Glucose Test Strip



A codechip is not necessary for glucose testing.

2. Preparing for measurement

Lipid Test System - components required:

- STANDARD LipidoCare Analyzer
- Lipid test strips for the desired parameter with the related codechip
- Lancets and Lancing device
- Tool for collecting the blood such as the STANDARD Ezi tube+ or micropipette



Only use STANDARD LipidoCare Lipid Test Strip and either STANDARD LipidoCare Blood Glucose Test Strip or SD Codefree Blood Glucose test strip.

Precaution

Do

- Read the test strip package insert.
- Operate the Analyzer at the acceptable test-specific temperatures.
 - For Lipid testing 18-32 °C (64-90°F)
 - For Glucose testing 10-45 °C (50-113°F)
- Place the Analyzer on a level surface or hold it steady in your hand.
- Keep the guidelines for cleaning.
- Make sure that all display elements are displayed.
- Keep the STANDARD Lipid Check Strip away from sunlight.

Do not

- Use lipid test strips beyond the expiration date, this may cause inaccurate results.
- Touch or remove the test strip during actual measurement.
- Subject the Analyzer to sudden movements during a measurement.

- Reuse the test strip.
- Store the Analyzer and strips at extreme temperatures.
- Store the Analyzer and lipid test strips under humid or damp conditions without suitable protection.
- Open the chamber flap during the measurment.



Not following these precautions can lead to inaccurate results.

Getting a Drop of Blood

Sample type

- For Lipid testing : Only use fresh capillary whole blood or venous blood in heparin or an EDTA treated vacuum tube. The venous blood sample should be used within 6 hours after collection.
 - Fresh Capillary Whole Blood
 - Venous Whole Blood
 - Venous Blood Serum
 - Venous Blood Plasma



Only professional use for venous blood.

For Glucose testing : Only use fresh capillary whole blood.

Capillary Whole Blood

- 1. Wash your hands in warm, soapy water. Rinse well and dry completely. Warming fingers can increase blood flow.
- Turn the lancet insert cap counterclockwise to remove it, insert the lancet into the lancing device holder and push down firmly until it is fully seated. Twist the lancet protective disk until it separates from the lancet.
- Replace the cap and turn it clockwise, until it is snug. Adjust the puncture depth setting by turning the comfort dial. The dial has 1 to 5 steps, and the higher the step number, the stronger the blood sampling pressure on the puncture site.

The comport tip offers 5 different levels of skin penetration.

- 1-2: for soft or thin skin
- 3: for average skin
- 4-5: for thick or callused skin
- After cocking the lancing device back, hold the lancing device firmly against the side of finger and then press the release button.













How to use STANDARD Ezi Tube+

- Touch the tip of a STANDARD Ezi Tube+ to the edge of the blood drop. Blood will automatically be drawn up the tube by capillary action. Keep the tube in contact with the blood until it is filled to the black line. You should squeeze your finger if you need more blood.
- 2. Transfer the collected sample to the sample well on the test strip by gently squeezing the bulb of the STANDARD Ezi Tube+.
- 3. Close the flap to start the test.





Used STANDARD Ezi Tube+ can cause infection. Please discard the used STANDARD Ezi Tube+ according to local regulations.

Collect the blood sample carefully to try and avoid air bubbles.

How to use the micropipette



Place the tip securely on the micropipette.



Slowly release the pluger and check the blood is drawn into the tip.



Push the plunger down and hold it in this position.



Open the flap and apply the blood sample.

*Only for lipid testing



Touch the tip to the blood drop.



Remove the tip from the micropipette and dispose of the tip in a biohazardous waste container.

3. Running a test - Lipid

Test Procedure

Check the following before performing a measurement:

- 1. Are date and time correct?
- 2. Does the battery symbol appear? If it appears, only a few more measurements can be performed. Replace the batteries as soon as possible.
- 3. Check the expiration date of the lipid test strip. Always use lipid test strips which are not expired.
- 4. Check the code number on the analyzer. Ensure it matches the code number on the codechip.
- With lipid and glucose test strips, check the reaction area for discolouration before starting measurement. If you detect discolouration, this test strip is unusable.
- Remove a lipid test strip from the foil pouch and hold it by the black handle with your thumb and index finger so that the horizontal lines and triangle are facing upwards.
- Open the Measurement Chamber Flap and insert the lipid test strip into the 'Lipid Test Strip Slot ' of the Analyzer. Make sure it is fully inserted - you will know when it is fully inserted as the meter will beep and the display will instruct you to close the Measurement Chamber Flap.
- Close the Measurement Chamber Flap and then re-open it when instructed to do so on the display. When the Chamber Flap is opened, the blood drop icon will flash on the screen.
- Apply the blood sample from the pipette or capillary tube to the sample application area of the lipid test strip. Do not touch the application area.

 When sufficient blood has been added, the display will instruct you to close the Measurement Chamber Flap. Once the flap is closed, the meter will start counting down from 3 minutes.















 When the countdown reaches 0, your result appears on the screen. If using a lipid profile test strip, use the left and right arrows to view the results for the different parameters.



- When the test is complete, pull out the used test strip and discard in a biohazardous waste container. The Analyzer shuts off automatically 3 seconds after you remove the test strip.
 - Do not open the Measurment chamber flap during the test.
 - If you do not close the measurement chamber flap immediately after applying blood, the analyzer display flashes the close flap icon with countdown and beep.





If you do not close the flap within 20 seconds of applying the blood, the Analyzer displays the 'E-7' message.



The blood drop must fill the entire blood application hole.



4. Running a test - Glucose

Test Procedure

- Remove a new glucose test strip from its container. Be sure to tightly replace the container cap immediately after removing a glucose test strip.
- Insert the glucose test strip into the 'Glucose Test Strip Slot' of the Analyzer. The Analyzer will automatically enter the glucose testing mode.
- 3. When the blood drop symbol flashes, you are ready to perform a glucose test.



4. Obtain a blood sample using the lancet and lancing device.

- Hold your finger to the tip of the glucose strip until the yellow window is completely filled with blood. Do not place the blood drop on top of the glucose strip.
- 6. The blood will be drawn into the glucose strip automatically. If the beeper is turned on, the Analyzer will beep to let you know the glucose test is beginning.
- 7. When blood is applied to the glucose strip, the display counts down from 5 to 1 and your result appears on the display in just 5 seconds.
- 8. When the test is done, pull out the used glucose test strip. The Analyzer shuts off automatically 3 seconds after you remove the test strip.





5. Running a test - Lipid/Glucose

Test Procedure

- 1. Open the Measurement Chamber Flap and insert the lipid test strip into the 'Lipid Test Strip Slot ' of the Analyzer. Make sure it is fully inserted you will know when it is fully inserted as the meter will beep and the display will instruct you to close the Measurement Chamber Flap.
- 2. Insert a glucose test strip into the 'Glucose Test Strip Slot' of the Analyzer.



Either lipid or glucose test strip can be inserted first.

3. The icons for glucose and lipid parameters will be displayed together on the screen. You should test your glucose first.



When the 'GLU' icon flashes in Lipid/Glucose mode, you should not apply blood sample to the LIPID test strip.

- Glucose Testing -

- 4. Obtain a blood sample using the lancet and lancing device.
- Hold your finger to the tip of the glucose test strip until the yellow window is completely filled with blood. Do not place the blood drop on top of the glucose test strip.
- The blood will be drawn into the glucose test strip automatically. If the beeper is turned on, the Analyzer will beep to let you know the test is beginning.
- 7. When blood is applied to the glucose test strip, the screen counts down from 5 to 1 and your result appears on the display in 5 seconds.
- 8. The LCD display will then switch to lipid test mode after 3 seconds.

- Lipid Testing -

- 9. Open the Measurement Chamber Flap.
- 10. Apply the blood directly from the pipette or capillary tube to the sample application area of the lipid test strip. Do not touch the application area.
- 11. When sufficient blood has been added, the display will instruct you to close the Measurement Chamber Flap. You must close the flap within 20 seconds or E-7 will appear. Once the flap is closed, the meter will start counting down from 3 minutes.
- 12. When the countdown reaches 0, your result appears on the screen. If using a lipid profile test strip, use the left and right arrows to view the results for the different parameters.
- 13. When the test is complete, pull out the used test strip and discard in a biohazardous waste container. The Analyzer shuts off automatically 3 seconds after you remove the test strip.



If the auto print function is turned on, then the test result will be printed automatically after finishing the test.

6. Understanding Your Results

Understanding lipid Results

Your Lipid Results

Single Test Results





Measuring range

Measuring range		For results outside the measuring range, the STANDARD LipidoCare displays :			
	mg/dL(mmol/L)	Low	High		
TC	100~450 (2.59~11.64)	<100mg/dL (<2.59mmol/L)	>450mg/dL (>11.64mmol/L)		
TG	45~650 (0.51~7.34)	<45mg/dL (<0.51mmol/L)	>650mg/dL (>7.34mmol/L)		
HDL	25~95 (0.65~2.46)	<25mg/dL (<0.65mmol/L)	>95mg/dL (>2.46mmol/L)		



If the results are out of the measuring range, the analyzer displays "N/A" for the calculated parameters related to the measurement parameters.

Expected Value

The National Heart, Lung and Blood Institute issued the 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) in May 2011. The ATP III report presented the NCEP's updated clinical quidelines for cholesterol testing and management and described the following classifications for cholesterol and triglyceride testing:



	mg/dL	mmol/L	Classification		mg/dL	mmol/L	Classification
LDL	<100	<2.59	Optimal	HDL	<40	<1.03	Low
	100~129	2.59~3.34	Near optimal/		≥60	≥1.55	High
			above optimal	Triglycerides	<150	<1.69	Normal
	130~159	3.36~4.11	Borderline high		150~199	1.69~2.25	Borderline high
	160~189	4.14~4.89	High		200~499	2.26~5.64	High
	≥190	≥4.91	Very high		≥500	≥5.65	Very high
Total	<200	<5.18	Desirable				
Cholesterol	200~239	5.18~6.19	Borderline high				
	≥240	≥6.22	High				

The ATP III identified HDL levels below 40 mg/dL (1.03 mmol/L) as associated with increased risk of coronary heart disease (CHD) in men and women. A high HDL level greater than or equal to 60 mg/dL (1.55 mmol/L) is protective and decreases CHD risk.

HDL

HDL is valid only if Triglyceride level is below 650 mg/dL (7.34 mmol/L).

non-HDL

ATP III identifies non-HDL (total cholesterol minus HDL) as a secondary target of therapy in persons with high triglycerides (\geq 200 mg/dL). The goal for non-HDL in persons with high serum triglycerides can be set at 30 mg/dL higher than that for LDL on the premise that a VLDL level \leq 30 mg/dL is normal. non-HDL can be calculated using the equation below.

*non-HDL(calculated) = Total Cholesterol - HDL

<u>LDL</u>

LDL can be calculated using the equation below. Calculated LDL is an estimation of LDL and valid only if Triglyceride level is 400 mg/dL (4.52 mmol/L) or below.

*LDL (calculated) = Total Cholesterol - HDL - (Triglycerides/5) (mg/dL) *LDL (calculated) = Total Cholesterol - HDL - (Triglycerides/2.17) (mmol/L)

• If Triglyceride level is above 400mg/dL (4.52mmol/L), the analyzer displays "N/A" for LDL and LDL/HDL.

- If Triglyceride level is "Hi", the analyzer displays "N/A" for HDL, LDL, LDL/HDL and non-HDL.
- If HDL level is "Lo", the analyzer displays "N/A" for HDL, LDL, LDL/HDL and non-HDL.



Understanding Glucose Results

The STANDARD LipidoCare Analyzer is plasma-equivalent for glucose testing. Your Analyzer glucose results may be different from clinical lab results. This is due to normal variation. To compare your Analyzer with lab results, follow the guidelines below.

Your glucose results

1. 5 seconds after applying blood to a glucose strip, you will receive a test result between 10mg/dL and 600mg/dL (0.6mmol/L and 33.3mmol/L)



If your blood glucose is above 600 mg/dL (33.3mmol/L), you will receive a "HI" and if below 10 mg/dL(0.6mmol/L), you will receive "Lo". In these cases, repeat the test with a new glucose test strip. If these messages are displayed again, contact your healthcare professional immediately.



Range of Expected Values

Self-testing may help to monitor your blood glucose levels. Consult with your physician to determine the best range of expected blood glucose values for you.

- Expected blood glucose values for non-diabetic adults are as follows:
 - » Before eating < 100 mg/dL (5.6 mmol/L)
 - » One to Two hours after meals < 140 mg/dL (7.8 mmol/L)

These test strips deliver results that correspond to blood glucose concentrations in plasma as per the recommendation of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). Therefore, the STANDARD LipidoCare analyzer displays blood glucose concentrations that refer to plasma although whole blood is always applied to the test strip.

What This Means For You

Frequent blood glucose testing is the best means to track how well you are doing with your diabetes management. It helps you track the effects of medications, diet, exercise, and stress management. Test results can also tell you if your diabetes is changing. This may alert you to adjust your treatment plan. Always consult your healthcare professional before making any adjustments.

Frequency of Testing

Work with your healthcare professional to decide when and how often to test. This will depend on such things as age, type of diabetes, and medications. It is important to make testing part of your daily routine.

CHAPTER 3. Using the Analyzer Memory

1. Analyzer Memory

The STANDARD LipidoCare Analyzer has 7 memory modes, each of which can be used to store up to 500 results, together with date, time and flags, letting you review them in order from the most recent to the oldest. If the memory is full and a new result is added, the Analyzer deletes the oldest result. The STANDARD LipidoCare Analyzer also has the function to review the averages for glucose results.



- ALL mode
- Lipid/Glucose mode : 7 sub-parameters: 1)TC, 2)TG, 3)HDL, 4)LDL, 5)LDL/HDL, 6)non-HDL, 7)Glucose
- TC·HDL mode : 3 sub-parameters: 1)TC, 2)HDL, 3)non-HDL
- TC mode
- TG mode
- HDL mode
- Glucose mode

LCD Symbol of Memory

Symbol	Details
	Indicates you are in memory mode.
Ā	Indicates you are in ALL memory mode.



Each Parameter title flashes when you are in ' Lipid/Glucose ' and ' TC-HDL ' mode. When you enter' ALL ' mode, the initial ' A ' appears in the center of the memory symbol.

2. Displaying stored results

All mode

- Switch on the Analyzer, then press the or button to enter memory mode.
- press 🧹 : You can check the latest test result.
 - press 🗾 : You can check the oldest test result.





The date and time on the display indicates the time the measurement was performed, not the current time.

Mode change

Memory Parameter Chain



1. Press the SET/PRT (💭) button to change the memory mode.



2. Each time you press the SET/PRT (💯) button, the last stored value of each memory mode is displayed.



3. Press the 💽 button to show the next most recent result in that specific memory mode.

4. You can exit memory mode by pressing the or button in any memory display.

Lipid/Glucose Mode

Press the 🗹 or 🔊 button to switch between the memory areas of the seven different parameters when in Lipid/Glucose mode.







If the memory is empty, three dashes (---) will appear on the display.



3. Displaying Glucose Averages

The Analyzer calculates 7, 15 and 30-day averages of glucose test results stored in the memory. HI/Lo results (results outside of the reading range) and results with control solution symbol are not included in averages.

Searching Glucose Averages

- 1. Switch on the Analyzer and press the 💽 or 💟 button to enter "All" memory mode.
- 2. Press the SET/PRT (🗭) button until you enter glucose mode.
- 3. Press the button to review three kinds of 7, 15 and 30 day averages of glucose test results stored in the memory in sequence. You can also review the number of glucose results at each average in the bottom right of the LCD window. If you Press the arrow button once more after displaying the 30 day average, the 7-day average result will appear again.

If there aren't any stored 7, 15 and 30-day averages, the following display will appear on the LCD.





4.

You cannot search the stored results or average of results in the Analyzer if a glucose test strip is inserted in the Analyzer. After removing the strip from the Analyzer, you can search the results and average of results stored in the memory by pressing the strip button.

4. Delete Memory

Delete Individual Memory

- 1. Switch on the Analyzer and press the 💽 or 💽 button to enter memory mode.
- Find the stored result you want to delete and then press and hold the and arrow buttons together for 3 seconds, whilst the result you want to delete is displayed.



3. 'dEL' will now appear on the screen. Press and hold the 'SET/PRT' button for 3 seconds to confirm the deletion of the result.



Delete Total Memory

- 1. Switch on the Analyzer and then press the < or 🕥 button to enter memory mode.
- 2. Press and hold the sutton, button and set/PRT (🐼) button together for 3 seconds.
- 3. 'All' and 'dEL' will now appear on the screen. Press and hold the SET/PRT (🌮) button for 3 seconds to confirm you want to blank the meter memory.

CHAPTER 4. Printing

How to Print

Auto Printing

If you set Auto Printing function to "ON" in the setting mode, the Analyzer will not display the "Printing" symbol.

Manual Printing

If you press SET/PRT (🕸) button in any memory mode, the printer will print that result and display the "Printing" symbol.





If you select 'P-1' in setting mode, the Analyzer prints only one copy in printing mode. If you select 'P-2', the Analyzer automatically prints two copies.







Print two copies function

If you have the 02LA20G model, you can print via Bluetooth or by using a mini USB cable. If you do not have the Bluetooth model, you will need a mini USB cable to be able to print.

CHAPTER 5. Data transfer

Please contact your local distributor for more information on downloading results.



You can download LMS Software at www.sdbiosensor.com.

CHAPTER 6. Bluetooth communication



Only the 02LA20G model can be used to transfer data from an analyzer through Bluetooth. The model number is indicated on the label of the analyzer.

1. Data Trasfer

The data measured by the analyzer can be transferred to a PC via Bluetooth (02LA20G model only).



If you want the analyzer to be paired with a PC, the pairing step is necessary. And the STANDARD Lipid Management Software (LMS) should be installed on the PC. To start the pairing step, follow the steps below;

Pairing

 At the strip stand-by state for either a lipid or glucose, press the ON/OFF button for 2 seconds. Then, 'bt' icon will appear on the left side of the screen with the setting icon which means pairing is ready. When you run the device for the first time, press the setup button and execute BT ON in the BT setup step.



 Open the STANDARD Lipid Management Software (LMS) installed on the PC. Click'Setting'menu on the left side and then, check the bluetooth equipment at the check box.



 Click 'Pairing' button on the screen to look for the device for pairing. It will start to search the STANDARD LipidoCare Home analyzer near.



 After finishing searching, the available analyzer will be listed up on the screen. Select the available analyzer by clicking the address of the analyzer.



5) When the pairing is done, 'Pairing is done' message will appear on the screen.

At the same time, the analyzer will display 'OK' message on the screen. If you receive the both messages on the PC and the analyzer, pairing is done successfuly.





6) After pairing processes are done, the analyzer is now ready for testing.

2. Technical Information



Hereby, SD Biosensor declares that STANDARD LipidoCare Analyzer is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC. You can view your product's Declaration of Conformity(DoC) to Directive 1995/5/EC(R&TTE) at www. sdbiosensor.com.



Changes or modifications made to this equipment not expressly approved by SD Biosensor, Inc. for compliance could void the user's authority to operate the equipment.





This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to ETSI EN 301 489-1 and 17. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Rotate or relocate the receiving antenna.
- Increase the distance between the equipment and receiver.
- · Connect the equipment into an outlet on a different circuit to which the receiver is connected.
- Consult your local distributor or an experienced radio/TV technician for help.

CHAPTER 7. Control Solution Test

1. Control Solution Test

It is important to perform Control Solution Tests with more than one level of Control Solution to assure your System is working properly. Control Solution is used to check that the Analyzer and the test strips are working together as a system and that you are performing the test correctly. It is very important that you do this simple check routinely to make sure you get an accurate result.

When to use STANDARD Lipid & Glucose Control Solution

- Before using your Analyzer for the first time.
- · When you open a new vial or pouch of strips.
- Whenever your result does not agree with the way you feel.
- When replacing the batteries or cleaning the Analyzer.



- Use only the specified Control Solution.
- Check the expiration date on the control solution container. Do not use STANDARD Glucose Control Solution after expiration or the discard date (date opened plus three months), whichever comes first.
- Do not swallow control solution; it is not for human consumption.
- Do not apply control solution to the skin or eyes as it may cause irritation.

2. Control Solution Test for Lipid (recommended for medical professionals only)

What you need:

- STANDARD LipidoCare Analyzer
- · Lipid test strips for the desired measurements with the related codechip
- SDB Lipid Control Solution Level 1 , Level 2

Performing a SDB Lipid Control Solution Test

- 1. Prepare the test strip for the desired measurement (e.g. measurement of Lipid Profile).
- 2. Insert a test strip into the Analyzer.
- 3. Make sure the number on the display matches the codechip and the test strip package and that the test strip is inserted correctly.
- 4. 'OPE' will appear on the screen, indicating that you should open the chamber flap.
- 5. Leave the chamber flap open and press and hold the 💽 button for 3 seconds to enter control solution mode. If you don't want to perform a lipid control solution check, press the 🥑 button.
- 6. Gently mix the lipid control solution and apply the exact volume for the particular parameter by using a micropipette or capillary tube.

7. After 3 minutes, the test result will appear on the screen.



 Compare the result to the range printed on the control solution insert. If the results are not within the lipid control range printed on the insert, then the Analyzer and test strip may not be working properly. Repeat the control test.

If the control solution result is still not acceptable, please call your local customer support and service center.

- 9. Remove the used test strip from the Analyzer and discard it.
 - This solution is made by human and animal source materials. Treat as potentially infectious.
 - The human source material used to produce this product has been tested by using FDA- accepted methods and found nonreactive for hepatitis B surface antigen (HBsAg), and for antibodies to hepatitis C(HCV) and human immunodeficiency viruses(HIV-1 and HIV-2). Because no test can offer complete assurance that infectious agents are not present, this product should be considered potentially infectious and handled with the same precautions used with patient specimens.
- Â
- Store upright and refrigerated at 2-8°C(36-46°F). Stored under this condition, SDB Lipid Control Solution can be expected to give stable results through the expiration date printed on the label. Minimize exposure to bright light.
- Do not use SDB Lipid Control Solution:
 - If it is cloudy or has an odour.
 - If it has been shipped or stored improperly.

3. Control Solution Test for Glucose

Performing a Glucose Control Solution Test

- 1. Remove a new glucose test strip from the test strip container. Be sure to tightly replace the container cap after removing a glucose test strip.
- 2. Insert a glucose test strip (yellow window printed arrow symbol facing up)into the glucose test strip slot. The Analyzer turns on automatically.
- Press the constraints of a second stocheck the testing system using a STANDARD Glucose control solution. If you don't want to perform a glucose control solution check, press the constraints of a second stocheck.



- 4. Shake the STANDARD Glucose control solution container and then remove the cap. Gently squeeze the container to form one small drop. Bring the drop to the edge of the glucose strip, and allow the glucose strip to automatically draw the STANDARD Glucose control solution into the yellow window. When STANDARD Glucose control solution is applied to the glucose test strip, the Analyzer counts down from 5 to 1 on the screen.
- 5. The STANDARD Glucose control solution result appears on the screen in just 5 seconds.





- 6. Compare the glucose control solution result to the range printed on the glucose test strip container. If the results are not within the glucose control range printed on the glucose test strip container, then the Analyzer and glucose strips may not be working properly. Repeat the STANDARD Glucose control solution test. If the control solution result is still not acceptable, please call your local customer support and service center.
- 7. Remove the used glucose test strip from the Analyzer and discard it.



- The STANDARD Glucose Control Solution range printed on the glucose test strip container is for STANDARD Glucose Control Solution only. It is not a recommended range for your blood glucose level.
- Store STANDARD Glucose Control Solution tightly closed at temperatures between 8-30°C (46-86°F). Do Not refrigerate.
- STANDARD Glucose Control Solution should be tested at room temperature 18-30°C (64-86°F).

4. Troubleshooting control solution

Check	Action
Did you do the test in control solution mode? Did you see "control solution container icon" on the screen with the result?	If not, insert a glucose test strip, press the 🧹 or 🕥 button for 3 seconds to display a control solution container icon.
Have the glucose test strips and/or glucose control solution expired?	Make sure that the glucose test strips and STANDARD Glucose Control Solutions are not beyond their expiration dates. This date is shown on the container/bottle. Make sure the containers have not been open for longer than the specified period (6 months for the test strips and 3 months for the control solution).
Were STANDARD glucose control solutions at room temperature (18-30°C, 64-86°F) when used?	lf not, warm up/cool down to room temperature (18-30°C, 64-86°F) and retest.
Did you insert a lipid or glucose test strip firmly into the Analyzer?	Make sure a lipid or glucose test strip is inserted into the lipid or glucose test strip slot until it will go no further.
Did you follow the procedure correctly?	Read the instruction for use again and retest.
Were the lipid or glucose test strips stored correctly?	If not, retest with a new lipid or glucose test strip.
Is the Analyzer damaged? Does it show an error code?	If yes, please call your local customer support and service center.
Is the control solution result outside the appropriate acceptable range?	Repeat the test. If you get the same results, do not use your Analyzer and test strips until you solve the problem. If you cannot solve the problem, please call your local customer support and service center.

CHAPTER 8. Check Strip Test

A Check Strip test is used to check that the Analyzer is working well.

When to use the STANDARD Lipid & Glucose check strips?

- When you want to easily check the function of the Analyzer.
- Before using your Analyzer for the first time.
- Whenever your result does not agree with the level you feel.
- If you have repeated a test and the blood glucose result is still lower or higher than expected.



The Check Strip test does not replace a Control Solution test.

1. How to Use a STANDARD Lipid Check Strip

1. For entering the "Checking" mode of lipid, turn on the meter and press and hold the 💽 and 💽 buttons for 3 seconds, until 'CHE' appears on the screen.

- 2. Insert the STANDARD Lipid Check Strip.
- 3. The check result will appear on the screen in just 10 seconds. If there is no problem with the Analyzer, 'OK' will appear on the screen; if there is a problem with the analyzer, 'EEE' will appear on the screen and you should contact your local distributor.





2. How to Use the STANDARD Glucose Check Strip

- 1. Insert the STANDARD Glucose Check Strip (with the words 'check strip' facing upwards) into the glucose test strip slot. The Analyzer will turn on automatically.
- 2. The check result will appear on the screen in 5 seconds. If there is no problem with the Analyzer, 'OK' will appear on the screen; if there is a problem with the analyzer, 'EEE' will appear on the screen and you should contact your local distributor.





CHAPTER 9. Maintenance and Troubleshooting

1. Cleaning your Analyzer

Caring for the STANDARD LipidoCare Analyzer is easy. If you need to clean it, follow these guidelines carefully to help you get the best performance possible;

To prevent malfunction of the Analyzer, keep the test strip slot free of blood, moisture, dirt, or dust. Use a lint-free cloth dampened with water to clean the Analyzer. Ensure the cloth is damp, and not wet. Do not use an abrasive cloth or antiseptic solution, as these may damage the display screen.

A clean optical measuring system is a basic prerequisite for determining precise measured values. Therefore clean the Analyzer regularly and immediately after it becomes dirty. Always switch off the Analyzer before cleaning it. Use only the following items for cleaning:

- Ordinary lint-free cotton buds
- Ordinary lint-free tissues
- Ordinary disinfecting tissues

Do not use any disinfectant sprays or tissues or cotton buds which are dripping wet as the liquid may enter the Analyzer and damage it.



Cleaning the outer Analyzer components

- Ensure the Analyzer is switched off.
- Wipe the outside of the Analyzer with a lightly moistened, lint-free cotton cloth.

Cleaning the inner Analyzer components

- 1. Open the measurement chamber flap.
- Remove the measurement chamber cover (including the lipid test strip guide) by slightly pushing it to the center of the Analyzer and then pulling it upwards.

 In case of significant dirt, you can rinse the measurement chamber cover (separately from the Analyzer) under warm running water. Dry the measurement chamber cover with a fresh cloth.





Cleaning the optical measuring system

 Clean the easily accessible areas of the optical measuring system with a lint-free pad or a moistened cotton swab. Make sure that no liquid enters the Analyzer. Do not insert any objects into the Analyzer.





- 2. Allow the Analyzer to dry thoroughly.
- Do not fit the measurement chamber cover into the Analyzer until it is completely dry. Press the front end of the measurement chamber cover slightly downwards until you feel it click into place.

2. Maintenance, Testing and Transportation

Analyzer

- 1. Keep the test strip slots free of dust.
- 2. Protect the internal Analyzer from humidity.
- 3. If the analyzer is stored with the batteries inserted, it is best to keep it in a low humidity environment to prevent defects.

Test Strips

- Lipid and glucose test strips should be stored between 2-32°C(36-90°F). Lipid test strips may be stored in the refrigerator between 2-8°C(36-46°F), but
 must be brought to room temperature for 30 minutes before using.
- 2. Keep away from heat and direct sunlight.
- 3. Keep the codechip either in the analyzer or stored in the lipid test strip package.
- 4. Keep the glucose test strip container closed tightly.
- 5. Use test strip immediately after opening the pouch for lipid or taken from the container of glucose.
- 6. Keep the STANDARD Lipid Check Strip away from direct sunlight. The STANDARD Lipid Check Strip can become discoloured if it is exposed to sunlight.

Control solution

- 1. Do not use STANDARD Glucose/Lipid Control Solution beyond the expiration date.
- 2. For STANDARD Glucose Control Solution, store between 8-30°C(46-86°F) but not refrigerate or freeze.
- For SDB Lipid Control Solution, store upright and refrigerated at 2-8°C(36-46°F). Stored under this condition, SDB Lipid Control Solution can be expected to give stable results through the expiration date printed on the label.
- The STANDARD Glucose Control Solution can be used for 3 months after opening the container. Write the opened date on the STANDARD Glucose Control Solution container when you first open it.
- 5. Wipe the container tip clean and reseal the container tightly after each use.

CHAPTER 10. Screen Messages and Troubleshooting

1. Warning message

Indication	Warning description
	Warning : Hypo Warning Message If you set a Hypo warning, then this message will appear if your blood glucose level falls below the set value.

Indication	Warning description
	Warning Your test result is higher than the measuring range. *This indication is for Glucose.

		LipidoCare
Indication	Warning description	
	Warning Your test result is lower than the measuring range. *This indication is for Glucose.	

Indication	Warning description
<u>نا 20</u> میں	Warning: Low Battery
مربع	At this time, battery is getting low but you can still perform about 50 tests.

Indication	Warning description
	Warning: Replace Battery Battery power is low. If the battery is empty and you press the power button, the battery icon will flash for 10 seconds and then the analyzer will turn off automatically.

2. Error message

Indication	Error description
In case of lipid test strip	Error: Strip Error The lipid or glucose test strip is dirty, used, damaged or inserted improperly.
In case of glucose test strip	Solution Discard this test strip and test again using a new test strip.

Indication	Error description
In case of lipid test strip	Error: blood sample Error An insufficient amount of blood was applied.
In case of glucose test strip	Solution Discard this test strip and test again using a new test strip with a larger sample.

Indication	Error description
	Error: Expired strip (Only for a Lipid test strip) The Lipid test strips are expired.
	Solution Discard this test strip and test again using a new lipid test strip that has not expired. If the strips are not expired and you still get E-3 then this means the year and/or date are not set correctly. Please refer to the section on setting the Analyzer.

Indication	Error description
E - 4	Error: Temperature Error If the environmental temperature is above or below the operation range of the Analyzer, a thermo Analyzer icon will appear on the display.
	Solution Move to an area between 18-32°C(64-90°F) for lipid or 10-45°C (50-113°F) for glucose, wait for 30 minutes, and perform a test. Do not artificially heat or cool the Analyzer.

Indication	Error description
8-5	Error: Communication Error The communication between Analyzer and computer or printer is failed.
8-5	Solution Connect the Analyzer and external device again. If the error message persists, please contact your local distributor.

Indication	Error description
собе Б - Б © ПП	Error: Code mismatching Error The inserted test strip and codechip do not match.
	Solution Change the appropriate test strip or codechip.

Indication	Error description
	Error: Flap Open The chamber flap of the Analyzer is open during measurement.
	Solution Close the chamber flap and do not touch or open the flap during measurement.

Indication	Error description
E - 8	Error: Blood Error Measurement chamber flap is closed for testing without blood sample.
	Solution Re-test with sufficient blood sample.

Indication	Error description
	Error: Communication Error with codechip The Analyzer cannot communicate with the inserted codechip.
	Solution Re-insert the codechip. If the error message persists, please contact your local distributor.

Indication	Error description
	Error: Internal Error There is an internal error of the analyzer.
	Solution Turn the Analyzer off and then back on again. If the error message persists, please contact your local distributor.

CHAPTER 11. Warnings, Precautions and Limitations

- Discard test strip after using. Strips are to be read once. Never insert or read a used test strip.
- Do not ingest.
- Discard the used test strip according to local regulations.
- Store and transport analyzer at -20~50°C (-4~122°F) and 10%-93%RH.

1. Test Strip for Lipid

- 1. Make sure the codechip number matches the lipid test strip code number. Never use a codechip from a different lot.
- 2. Out-of-date or expired strips cannot be used in your test system. Check the expiration date in the package or pouch.
- Add all of the blood to the lipid test strip at one time. If you do not get all of the blood on the strip, do not add more blood to the same strip. Test again with a new test strip and fresh blood sample.
- 4. Venous whole blood, serum and plasma is only for professional use.

2. Test Strip for Glucose

- 1. Use only fresh capillary blood. Do not use serum or plasma or venous whole blood.
- The STANDARD LipidoCare System is not designed to be a substitute for pathology laboratory equipment and should not be used for the diagnosis of diabetes.
- Extremes in hematocrit may affect test results. Hematocrit levels less than 20% may cause falsely high readings. Hematocrit levels greater than 60% may cause falsely low readings.
- 4. Not intended for screening or diagnosis or for use on neonates.
- 5. Never make significant changes to your diabetes control program or ignore physical symptoms without consulting with your healthcare professional.
- Severe dehydration (excessive water loss) may cause false low results. If you believe you are suffering from dehydration, consult your healthcare
 professional right away.
- Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate low results may occur for individuals experiencing a hyperglycemichyperosmolar state, with or without ketosis. Critically ill patients should not be tested with the Analyzer.

CHAPTER 12. Product Technical Information

1. Analyzer Specifications

Battery Operation	4 AAA 1.5 V, Alkaline batteries
Battery Life	Around 1,000 tests
Display	LCD
Controls	4 Buttons (SET/PRT, ON/OFF, arrow: >/<)
Memory	500 results
Automatic Shutoff	1 minute after last user action without inserting test strip into the Analyzer 5 minutes after last user action when inserting test strip into the Analyzer



2. Test strip for Lipid

Measuring Range	TC: 100 - 450 mg/dL (2.59 - 11.64 mmol/L) TG: 45 - 650mg/dL (0.51 - 7.34 mmol/L) HDL: 25 - 95 mg/dL (0.65 - 2.46 mmol/L)
Sample	Fresh capillary whole blood or venous whole blood, serum or plasma
Sample Size	10 μl(Single) / 35 μl (Lipid Profile)
Test Time	3 minutes
Test Strip Storage Temperature	2 - 32°C (36 - 90°F)
Hematocrit	TC and TG parameter: 30 - 50% HDL parameter: 30-52%
Testing Temperature	18 - 32°C (64 - 90°F)

3. Test strip for Glucose

Measuring Range	10 - 600 mg/dL (0.6 - 33.3 mmol/L)
Sample	Fresh capillary whole blood
Sample Size	0.9 µl
Test Time	5 seconds
Test Strip Storage Temperature	2 - 32°C (36 - 90°F)
Hematocrit	20 - 60%
Testing Temperature	10 - 45°C (50 - 113°F)
Altitude	Up to 3,776m(12,388 ft)
Calibration	Plasma-equivalent

4. Electromagnetic Compatibility

This Analyzer meets the electromagnetic immunity requirements as per EN ISO 15197 Annex A. The chosen basis for electrostatic discharge immunity testing was basic standard IEC 61000-4-2. In addition, it meets the electro -magnetic emissions requirements as per EN 61326. Its electromagnetic emission is thus low. Interference from other electrically driven equipment is not to be anticipated.

Appendix 1: Information for Healthcare Professionals

Protection against infections

There is a potential risk of infection. Medical staff using the STANDARD LipidoCare Analyzer to perform measurements for more than one patient must be aware that any object coming into contact with human blood is a potential source of infection.

- Use gloves.
- Apply blood outside the Analyzer. When measuring glucose in several persons clean and disinfect the Analyzer before each measurement as blood
 cannot be applied using capillary pipettes.
- When measuring cholesterol and triglycerides in several persons, always use capillary pipettes to apply blood outside the Analyzer.
- Dispose of used capillary pipettes and lipid test strips in a clinical waste bin.
- Follow all other locally applicable guidelines and regulations on health and safety.

Appendix 2: References

- 1. American Diabetes Association: Standards of Medical Care in Diabetes-2013, Diabetes Care, Volume 36, Supplement 1, January 2013, S11-S66.
- Siedel J, Hagele EO, Ziegenhorm J, Wahlefeld AW. Reagent for the enzymatic determination of serum total cholesterol with improved lipolytic efficiency. Clin Chem 1983;29:1075-80.
- Expert Panel on Detection, Evaluation, and Treatment of High Cholesterol in Adults. Executive summary of the Third Report of the National Cholesterol Education Program(NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Cholesterol in Adults(Adult Treatment Panel III). JAMA 2001;285:2486-97.

Return

You should contact SD Biosensor Customer Service before returning your Analyzer. You will be instructed how to return the Analyzer to SD Biosensor, Inc. Returned Analyzers without this authorization will not be accepted.





