SD LipidoCare® Professional
System

CODE 011

TC

162 mg/dL

11:28 9:26

Lipid Profile

Glucose

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Important Safety Instructions

Before using the SD LipidoCare Professional Analyzer, please read the following information.

Important Safety Instructions

The lancing device are for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients!

All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

The Food and Drug Administration and the Center for Disease Control have issued warnings and notifications regarding the risk of bloodborne pathogen transmission when more than one individual uses a blood glucose monitoring system. For important instructions for disinfecting your meter and lancing device, please read the following references:

- U.S. Food and Drug Administration. FDA Public Health Notification: Use of Fingerstick Devices on More Than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication. (2010).
  http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm
- Centers for Disease Control and Prevention. CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Blood Borne Pathogens. (2010).
  http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html

Special Information for Healthcare Providers and Caregivers

- Do not use this analyzer to measure the cholesterol and glucose in people who are experiencing cardiovascular collapse (severe shock) or decreased peripheral blood flow.
- Hematocrit: Extremes in hematocrit may affect test results. The following hematocrit ranges for each parameter will not affect the accuracy of the measurements:
    - TC, TG: 30 – 55%
    - HDL: 30 – 52%
    - Glucose: 20 – 60%

CHAPTER 1. UNDERSTANDING THE NEW ANALYZER

1. Indication for use; purpose of the analyzer

The SD LipidoCare Professional Analyzer is intended to be used by individuals in the Professional to measure total cholesterol (TC), triglycerides (TG), HDL cholesterol (HDL), and glucose in capillary whole blood with the SD LipidoCare Professional Lipid Profile Test Strips and SD LipidoCare Professional Blood Glucose Test Strips; it is also intended to calculate low density lipoprotein (LDL), the LDL/HDL ratio, and non-HDL. This analyzer is to be used outside the body (in vitro diagnostic).

The SD LipidoCare Professional Lipid Profile Test Strips are intended to be used by medical professionals to measure total cholesterol (TC), triglycerides (TG), and HDL cholesterol (HDL) in capillary whole blood and venous blood on an SD LipidoCare Professional Analyzer. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases. Triglyceride measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism, or various endocrine disorders. Calculated LDL-cholesterol values are reported only when triglycerides are ≤400mg/dL; when triglycerides are >400 mg/dL, the calculated LDL-cholesterol and LDL/HDL (LDL-cholesterol and HDL-cholesterol ratio) are not reported.

The SD LipidoCare Professional Blood Glucose Test Strips are intended to be used by medical professionals to measure glucose in capillary whole blood on an SD LipidoCare Professional Analyzer. Glucose measurement is for the quantitative measurement of the concentration of glucose in capillary whole blood that can be taken from the fingertip, palm, upper arm, and/or forearm as an aid in the management of diabetes. Glucose measurement is not to be used for the diagnosis of or screening for diabetes or neonatal use. Alternate site testing should be done during steady-state times, when glucose is not changing rapidly.

The SD Lipid Control Solution and SD Glucose Control Solution are used as quality control materials for the SD LipidoCare Professional System.

2. Test principle

LIPID

The SD LipidoCare Professional System combines enzymatic methodology and solid-phase technology to measure total cholesterol (TC), HDL cholesterol (HDL), and triglycerides (TG). Blood sample used for testing is whole blood from a fingerstick. The sample is applied to an SD LipidoCare Professional Test Strip. The test strip is then placed into the SD LipidoCare Professional Analyzer, where a unique system on the test strip separates the plasma from the blood cells. A portion of the sample flows to the bottom layer of the test strip and is transferred to the total cholesterol, triglyceride, and HDL cholesterol (HDL) reaction pads. The SD LipidoCare Professional Analyzer measures TC, TG, and HDL by an enzymatic method based on the method formulation of Allain et al.[6] and Roeschlau.[7] To measure TC, TG, and HDL in the blood, the following formulations are used:

Total cholesterol (TC)

Cholesterol ester $\xrightarrow{\text{cholesterol esterase}}$ Cholesterol + Fatty acid

Cholesterol + O_2 $\xrightarrow{\text{cholesterol oxidase}}$ Cholesterol-3-one + H_2O

$2H_2O_2$ + 4-AAP + Coupler (Toluidine) $\xrightarrow{\text{Peroxidase}}$ Quinoneimine + $4H_2O$ (Colored-dye)

HDL cholesterol

Total cholesterol specimen (VLDL, LDL, HDL) $\xrightarrow{}$ VLDL, LDL depleted specimen

Cholesterol Esters $\xrightarrow{\text{cholesterol esterase}}$ Cholesterol + Fatty acid

Cholesterol + O_2 $\xrightarrow{\text{cholesterol oxidase}}$ Cholesterol-3-one + H_2O

$2H_2O_2$ + 4-APP + Coupler (Toluidine) $\xrightarrow{\text{Peroxidase}}$ Quinoneimine + $4H_2O$ (Colored-dye)

Triglycerides (TG)

Triglycerides $\xrightarrow{\text{Lipoprotein lipase(LPL)}}$ Glycerol + Fatty Acids

Glycerol + ATP $\xrightarrow{\text{Glycerol kinase (GK)}}$ Glycerol-1-phosphate + ADP

Glycerol-1-Phosphate + O_2 $\xrightarrow{\text{Glycerophosphate oxidase(GPO)}}$ 3-dihydroxyactone-PO_4 + H_2O_2

H_2O_2 + 4-AAP + Coupler (Toluidine) $\xrightarrow{\text{Peroxidase}}$ Quinoneimine + HCL + $2H_2O$ (Colered-dye)

GLUCOSE

The SD LipidoCare Professional Blood Glucose test strip is designed with an electrode that measures glucose levels. Glucose in the blood mixes with the reagent on the test strip and causes a small electric current. The amount of current created depends on how much glucose is in the blood. The SD LipidoCare Professional Analyzer measures the current created and converts it to the amount of glucose. The blood glucose result is displayed on the LCD display. Once a drop of blood touches 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 SD LipidoCare Professional Analyzer starts to measure the blood glucose level.

3. Before you start a test

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

Samples

For measuring lipid (cholesterol)
The SD LipidoCare Professional Analyzer for lipid testing is designed for testing a fresh capillary whole blood sample from the fingertip.

For measuring glucose
The SD LipidoCare Professional Analyzer for glucose is designed for testing a fresh capillary whole blood sample from the fingertip, palm, upper arm, or forearm.

Refer to the Safety Information
There is a potential risk of infection. To clean and disinfect this analyzer, please refer to the Chapter 6 Maintenance and Troubleshooting section.

Operating conditions
To ensure proper function of the SD LipidoCare Analyzer, observe the following guidelines:
- Operate the analyzer within the acceptable temperature and the humidity range. This range is test-dependent:
  - ✓ For Lipid Testing : 64–90°F (18–32°C), 10–90%RH
  - ✓ For Glucose Testing: 50–113°F (10–45°C), 10–90%RH
- To perform a measurement, place the analyzer on a level surface or hold it in your hand.

4. The SD LipidoCare Professional Analyzer

The Analyzer package includes following:
- SD LipidoCare Professional Analyzer
- SD Lipid Check Strip
- SD Glucose Check Strip
- User Manual
- Quick Guide
- 4 AAA 1.5 V batteries

> **NOTE:**
> The SD LipidoCare Professional Lipid Profile Test Strips, SD LipidoCare Professional Blood Glucose Test Strips, SD Lipid Control Solution, and SD Glucose Control Solution are required, but not included, and must be purchased separately.
> If you want to purchase these products, please contact our customer service center at 855-486-2888.

Appearance

A	Display	Shows a test result, messages, and stored values in the memory
B	Arrow Buttons	Used for setting and review of the memory
C	On/Off Button	Press to turn Analyzer on or off
D	Lipid Test Strip Slot	Insert a lipid test strip here
E	Door	Block the light for an accurate test result
F	Glucose Test Strip Slot	Insert a glucose test strip here.
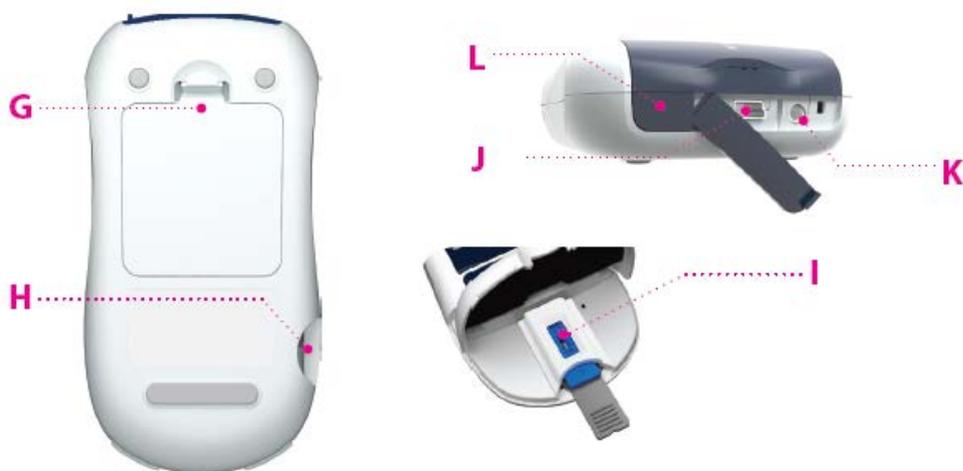
G	**Battery compartment lid**	Provides access to the battery compartment (4 AAA 1.5 V alkaline batteries)
H	**Codechip slot**	Insert a codechip for lipid testing
I	**Optic cover**	Holds the inserted test strip to prevent the movement of the test strip when you are testing
J	**Data port**	Download test results to a personal computer
K	**Printer port**	Print test results on an external thermal printer
L	**SET/PRT Button**	Press to set the analyzer or print the test results

Display of the SD LipidoCare Professional Analyzer
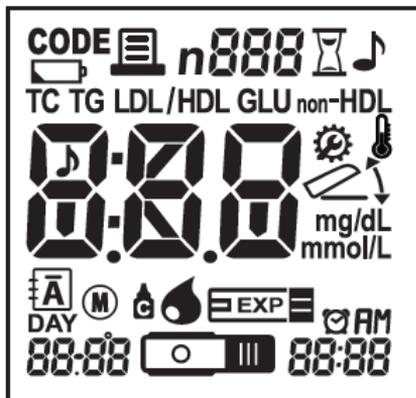
The symbols in the display have the following meanings:

CODE	Indicates a codechip sign		Warning when the battery is low
	Indicates printing	**n**	Indicates the index number of the memory
888	Codechip number or memory number stored in the memory		Appears during setting mode
	Indicates measurement being performed	♪	Indicates beep sound setting
	Indicates the operating temperature is out of the range	**(M)**	Indicates Lipid Profile test strip
	Open or close the flap	mg/dL mmol/L	Units of test results
8.8.8	Test Result		Indicates a test result stored in the memory (all parameters)
DAY	Indicates the days of the calculated average result		Indicates alarm setting
	Indicates application of the sample		Indicates a control solution test result
	Glucose test strip	**88:88**	Date
EXP	Indicates an expired test strip		Lipid test strip

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88:88 AM	Indicates the testing time	LDL	Low Density Lipoprotein
TC	Total Cholesterol	TG	Triglycerides
HDL	High Density Lipoprotein	GLU	Glucose
LDL/HDL	LDL to HDL ratio	non-HDL	non-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 are stored in the memory. Battery life is expected to last for approximately 1,000 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 reset the date and time. Use only AAA alkaline manganese batteries. The stored test results, including the testing date and time as well as all other analyzer settings, will remain, even when no batteries are inserted. Do not throw batteries into a fire. There is a risk of explosion!

6. Test strips

SD LipidoCare Professional Lipid Profile Test Strip	SD LipidoCare Professional Blood GlucoseTest Strip

Lipid Check Strip	Glucose Check Strip

CHAPTER 2. USING THE SD LIPIDOCARE PROFESSIONAL ANALYZER

1. Changing the batteries

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

1) Ensure the analyzer is switched off, and turn it over.
2) Open the battery compartment lid by slightly pressing the tab toward the center of the analyzer.
3) Lift the lid upward to remove it from the analyzer.

4) Insert four batteries into the compartment. 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 functionality of the new batteries.
7) Check to ensure that the display is functioning correctly to prevent misinterpretations due to defective display elements.

> **NOTE:**
> - After inserting or replacing the batteries, confirm that the time and date are set correctly. If they are incorrect, reset the analyzer before using.
> - Always replace all four batteries at the same time. Do not use rechargeable batteries.

2. Setting the analyzer

The following table provides an overview of the available settings.

Stage	Setting	Options	Default Setting
1	Beep	On, Off	On
2	Year	YYYY	2015
3	Date Format	m-d, d-m	m-d
4	Date	mm-dd, dd-mm	1- 1
5	Time Format	12h, 24h	12h
6	Time	hh:mm	12:00 AM
7	Units of the Test Result	mg/dL, mmol/L	mg/dL
8	Auto Printing	On, Off	On
9	Printing Page	P-1, P-2	P-1
10	Hypo warning (for glucose)	Off, 60,70,80	Off
11	Alarm	Off, 4 Alarms	Off
12	Bluetooth (PC)*	On, Off	Off
13	Bluetooth (Printer) *	On, Off	Off
14	Bluetooth Repairing(Printer) *	On, Off	Off

These functions are only for the 02LA20G with Bluetooth module.

STAGE 0) Entering the setting mode

1) Press the SET/PRT button (on the top of the analyzer) for three seconds to enter the setting mode after turning the analyzer on or in the standby state. If you want to leave the setting mode during any of the steps, press the SET/PRT button quickly.

2) Press the left or right button to change the current flashing setting. You can press the left or right button as many times as needed (or keep it pressed) until the desired setting (value) is reached.

3) Press the ON/OFF button to store the selected setting and go to the next setting. If you want to quit the setting stage, press the SET/PRT button.
4) If the settings are completed, the analyzer will be automatically turned off.

CAUTION
You can only move forward through the settings. Corrections can only be made by repeating the settings. The setting procedure can be terminated at any time by pressing the SET/PRT button.

Stage 1) Setting – Beep

In the 1st stage, you can set the beep function.
1) If you enter the setting mode, the first step of the setting mode will appear.

2) Turn the beep sound on or off by pressing either the left or right button and then save the preferred feature by pressing the ON/OFF button. If you select the *beep sound on* feature, a "beep" sound will be made at the same time. Otherwise, if you select the *beep off* feature, no sound will be made.
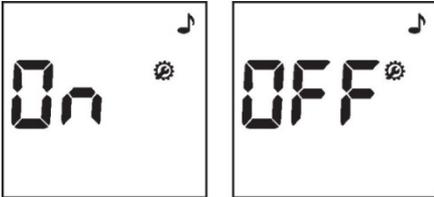
Stage 2) Setting – Year

In the 2nd stage, you can set the year. After setting the beep, the display for setting the year will appear. Select the correct year by pressing the left or right button, and then save it by pressing the ON/OFF button.

Stage 3) Setting – Date Format

In the 3rd stage, you can set the date format.

1) The analyzer can display the month and day in either Month-Day (m-d) format or Day-Month (d-m) format. Select the preferred format by pressing either the left or right button, and then save it by pressing the ON/OFF button.
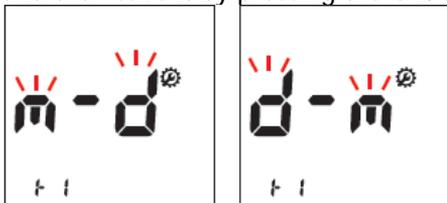
Stage 4) Setting – Date

In the 4th stage, you can set the date.

1) After setting the date format, select the actual date by pressing either the left or right button, and then save it by pressing the ON/OFF button.
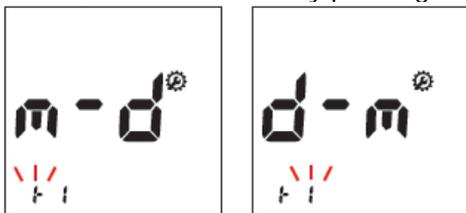
Stage 5) Setting – Time Format

In the 5th stage, you can set the time format.

1) The analyzer can display the time in either the 12h format or the 24h format. Select the preferred format by pressing either the left or right button, and then save it by pressing the ON/OFF button.
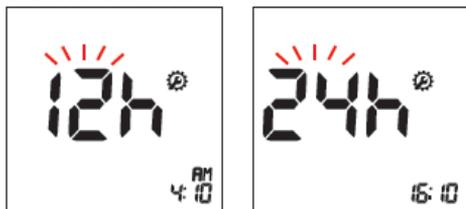
Stage 6) Setting – Time

In the 6th stage, you can set the time, the current hour, and the minutes. Select the hour and minute by pressing either the left or right button and then save them by pressing the ON/OFF button.

  a) 12h Format:
     Sub-step 1) Set AM or PM.
     Sub-step 2) Set hour (1 to 12).
     Sub-step 3) Set minute (1 to 59).

  b) 24h Format:
     Sub-step 1) Set hour (1 to 24).
     Sub-step 2) Set minute (1 to 59).

Stage 7) Setting – Unit of the Test Result

In the 7th stage, you can set the units for the test results.
1) The unit of the test result stage will appear.
2) You can select the preferred units by pressing the left or right button, and then you can save your selection by pressing the ON/OFF button.
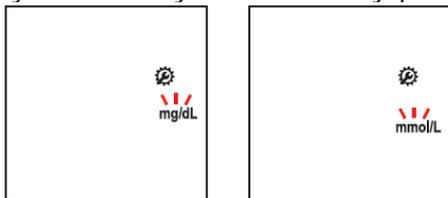
Stage 8) Setting – Auto Printing

In the 8th stage, you can set the auto printing function.
1) Following the test unit setting, the display for the auto printing function will appear.
2) Turn the auto printing function on or off by pressing either the left or right button, and then save your selection by pressing the ON/OFF button.
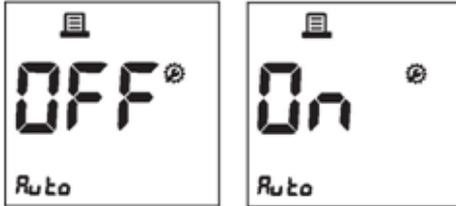
NOTE:
The Auto Printing function allows a person to print the results automatically, right after testing.

Stage 9) Setting – Simplex/Duplex Printing

In the 9th stage, you can set either single-sided or double-sided printing options.
1) After the auto printing function is set, the display for setting single-sided or double-sided printing will appear.
2) Set the preferred feature by pressing the left or right button, and then save it by pressing the ON/OFF button.
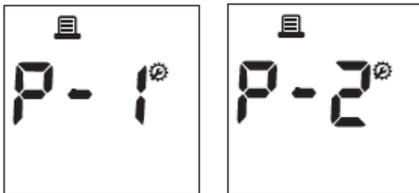
NOTE:
If you select the P-1, it will be set to print the test results in simplex (on one side of paper).
If you select the P-2, it will be set to print the test results in duplex (on both sides of the paper).

Stage 10) Setting – Hypo warning for glucose

In the 10th stage, you can set the hypo warning function for the glucose testing only.

1) After the printing setting, the display for setting the hypo warning will appear.
2) You can turn the hypo warning off or select the hypo level as 60, 70, or 80 mg/dL by pressing the left or right button. Then save it by pressing the ON/OFF button.
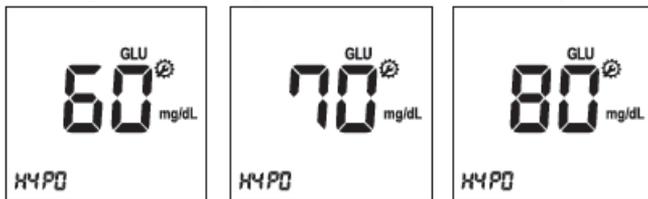
NOTE:
- Please consult your healthcare provider for an appropriate hypo level, from among 60, 70, or 80mg/dL, to be set for you.
- If your glucose results are lower than a selected hypo result, the hypo symbol will appear on the screen with a beep sound. It is very important to manage your hypoglycemia. Contact your healthcare provider immediately.

Stage 11) Setting – Alarm

In the 11th stage, you can set up to four alarms to remind yourself to do a glucose test.

1) After the hypo warning setting, the display for setting the alarm will appear.
2) Turn the first alarm on or off by pressing the left or right button, and then save it by pressing the ON/OFF button. If you select *Off*, the analyzer will automatically turn off. For the model 02LA20G, additional setting stages remain. Please refer to the next page for the additional setting steps.
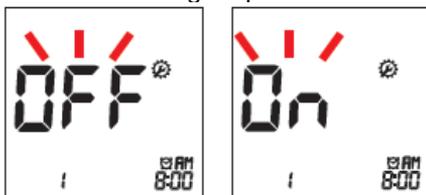
3) If you select ON for the first alarm, the clock icon will blink. Select the desired time for the alarm by pressing the left or right button, and then save it by pressing the ON/OFF button.
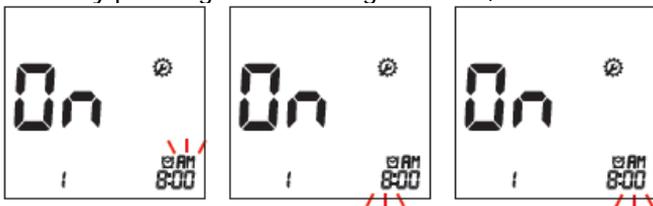
4) Next, the second alarm setting mode will appear. Set the second alarm by following steps 2 and 3 above.
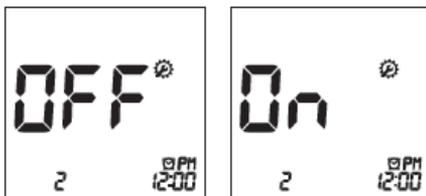
5) You can set the third and the fourth alarm modes in the same way, by following steps 2 and 3 above.

Stage 12) Setting – Bluetooth with PC, only for 02LA20G

In the 12th stage, you can set the Bluetooth communication with your PC or smartphone. If the analyzer is paired with the PC or smartphone, the test results are transferred automatically, via Bluetooth.

1) After the alarm setting, the Bluetooth setting will appear on the screen.
2) Turn it on or off by pressing the left or right button, and then save it by pressing the ON/OFF button.

Stage 13) Setting – Bluetooth with Printer, only for 02LA20G

In the 14th stage, you can set the Bluetooth communication with a printer.

1) After setting the Bluetooth with a PC, the Bluetooth and printer icons will appear on the screen.
2) Turn the selection on or off by pressing the left or right button, and then save it by pressing the ON/OFF button.
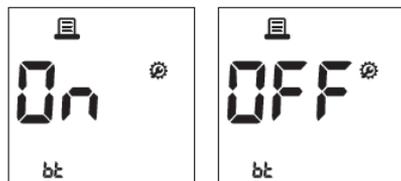
NOTE: If you set both auto-printing and Bluetooth with printer to ON, you can get the test results printed automatically, via the Bluetooth communication.

Stage 14) Setting – Repairing the Printer, only for 02LA20G

In the 14th stage, you can set the analyzer to be automatically paired with the previous paired printer, whenever the printer is near the analyzer.

1) After the Bluetooth with printer setting, the repairing setting will appear on the screen.
2) Turn it on or off by pressing the left or right button, and then save it by pressing the ON/OFF button.
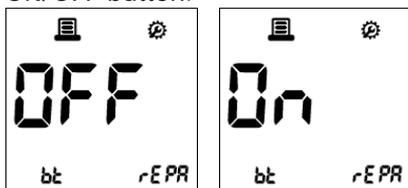
STEP 4. Insert a code chip
For measuring cholesterol (Lipid)
Coding

The code chip is included in the test strip package. The code chip provides the analyzer with important information on the production-specific properties of the SD LipidoCare Professional Lipid Profile Test Strip in order to measure your results accurately. Before you use the SD LipidoCare Professional Analyzer with a new test strip for the first time, you should check that the code numbers on the analyzer and the test kit are the same.


Lipid Profile
Blue Case

Code Setting

1) Make sure that the analyzer is turned off. Remove the old (or inserted) code chip from the analyzer.
2) Insert a new code chip until it snaps into place. Then turn the analyzer on.

3) The 3-digit code number of the inserted code chip will appear with a flashing lipid test strip symbol. This number must match the information provided in the lipid test strip package or pouch. If it doesn't match, repeat steps 1 and 2 above.
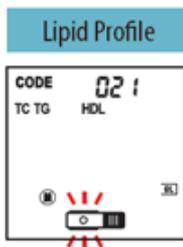
> **CAUTION:**
> The SD LipidoCare Professional Lipid test strip package includes a code chip with test strips.

For measuring glucose
The blood glucose testing requires no coding. Therefore, a code chip is not needed for glucose testing.

3. Pairing, only for 02LA20G

If you want the analyzer to be paired with a PC, the pairing step is necessary, and the lipid management software (LMS) should be installed on the PC. To start the pairing process, follow the steps below:

1) At the strip standby state for either a lipid or glucose, press the ON/OFF button and hold it for 2 seconds. Then, the bt icon will appear on the left side of the screen with the setting icon, which means pairing is ready.
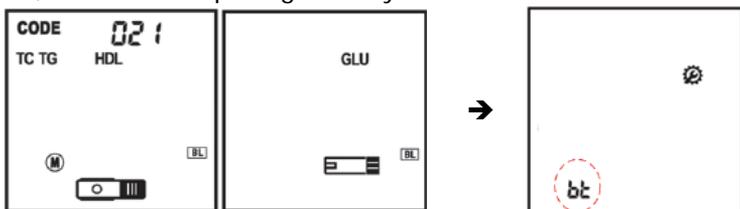

2) Open the Lipid Management Software (LMS), installed on the PC. Click the Setting menu on the left side, and then check the bluetooth equipment at the check box.

3) Click the Pairing button on the screen to look for the device for pairing. It will start to search the SD LipidoCare Professional Analyzer nearby.

4) After the search is complete, the available analyzer will be listed on the screen. Select the available analyzer by clicking the address of the analyzer.
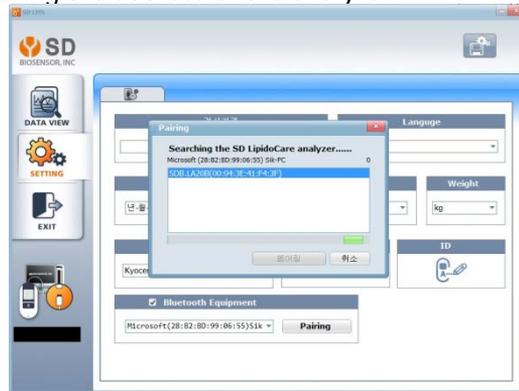
5) When complete, the Pairing Is Done message will appear on the screen.

At the same time, the analyzer will display the OK message on the screen. If you receive both messages on the PC and the analyzer, pairing was done successfully.
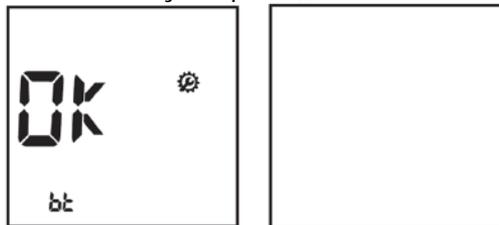
6) After the pairing processes are complete, the analyzer is now ready for testing.
   NOTE: You can download the LMD program from our website: www.sdbiosensor.com.
   This program is free of charge.

4. Analyzer Memory

The SD LipidoCare Professional Analyzer can store the test results of up to 500 data with testing dates and times, and it can assign a number to let you review the test results 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.

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

The SD LipidoCare Professional Analyzer has a function that shows the averages for only the glucose parameter.

LCD Symbol of Memory

Symbol	Details
	Indicates that it displays the test results stored in the memory, only for the mode you selected (just one mode at a time)
	Indicates that it displays the test results stored in the memory of all the parameters.

NOTE:
The data will display with the corresponding parameter symbol, such as *Lipid* or *Glucose*. When you enter the ALL mode, the initial *A* will appear at the center of the memory symbol.

Mode change

You can change the mode by pressing the SET/PRT button at the memory mode. The order of the memory mode is as follows:

- Press the SET/PRT button quickly to change the memory mode.
- Each time you press the SET/PRT button, the latest result of the mode will be displayed.
- Press the left button to view the next result in the specific memory mode.
- If you press the right button, the oldest stored result will appear on the screen.
- You can exit memory mode by pressing the ON/OFF button in any memory mode.

5. Reviewing stored test results
All modes

Turn the analyzer on, then press the left or right button at the strip standby state to enter memory mode. The All mode is the first memory mode with the icon displayed when you enter the memory mode. In the All mode, the icon is displayed all the time. You can review all the stored glucose and lipid test results in the memory according to the order of the testing time.


When entering the All mode of the memory, the latest result with the largest index number will display first. If you press the left button, the second latest result will appear on the screen. If you press the right button, the oldest result will appear on the screen.

NOTE:
The date and time on the screen indicate the testing date and time, not the current date and time.

NOTE:
- If the memory is empty, three dashes (---) will appear on the screen.
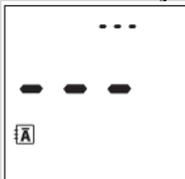
- If you want to quit the memory mode, press the ON/OFF button; then the analyzer will turn off.

Lipid Mode

If you want to review the lipid results only, you can review them in the Lipid mode. After entering the Memory mode, the All mode will appear. Press the SET/PRT button quickly to enter the Lipid mode.

When you perform a lipid profile test using the SD LipidoCare Professional Lipid Profile Test strip, you will get six parameter results in total, at once. The index number is assigned to all the parameter results from a test. You can review them all by pressing the left or right button.

The following picture describes the parameter, in sequence. On the screen, both the and icons appear in the Lipid mode.

How to review the data

When 500 results are stored in the memory, the first displayed result is the TC value of the 500th result.

If you press the left button at the TC value, the TC value of the index 499 will appear. Use the left button at the TC value to go to the previous index test results.

If you press the right button, TG, HDL, LDL, LDL/HDL, and non-HDL will appear, in order. After TC, you can use the left button to view the results of the previous parameter.
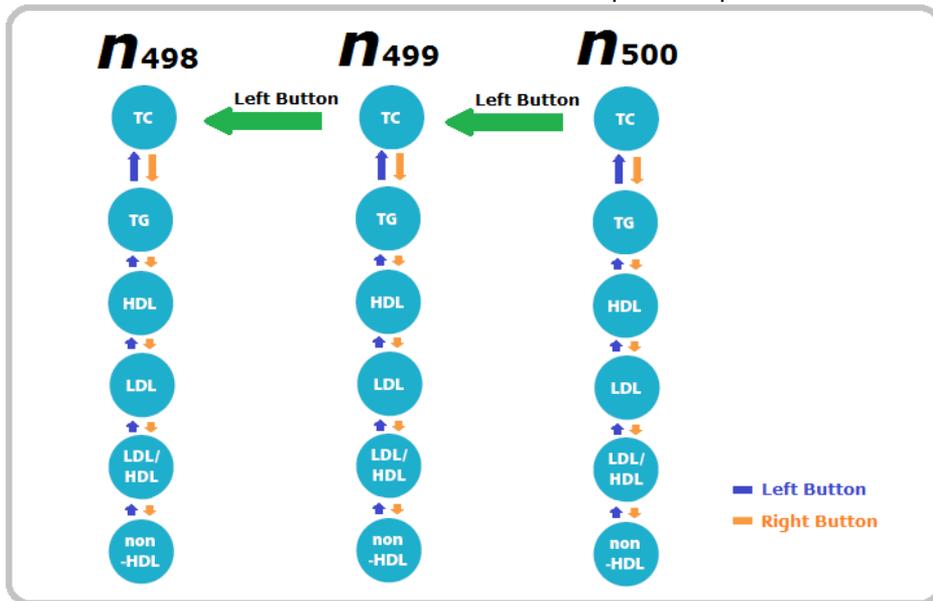
Ex)

Glucose Mode

If you want to review only the glucose results, you can review them in the glucose mode. After entering the Memory mode of the memory, press the SET/PRT button 2 times, quickly, to change the glucose mode. On the screen, both **GLU** and the 🗂 icon will appear in the glucose mode.

At first, the latest stored glucose result among all of the stored glucose results will appear on the screen.

After displaying the latest glucose result on the screen, press the left button to review the second latest stored glucose result.

When displaying the latest stored glucose result on the screen, you can press the right button to review the oldest stored glucose result in the analyzer.

6. **Displaying the average of glucose test results**

The analyzer can calculate 7-, 15-, and 30-day averages of glucose test results stored in memory. The HI/Lo result (results outside of the reading range) and control solution test results are not included in the averages.

Searching Glucose Averages
1) Switch the analyzer on, then press the left or right button to enter the All memory mode.
2) Press the SET/PRT button to enter the Glucose mode.
3) Press the right button to review the three kinds of averages, which are 7-, 15-, and 30-day averages of the glucose test results stored in memory, in sequence. You can also check the number of glucose results used for calculating the average in the right bottom of the LCD window. If you press the left button once more after displaying the 30-day average, the 7-day average result appears again.
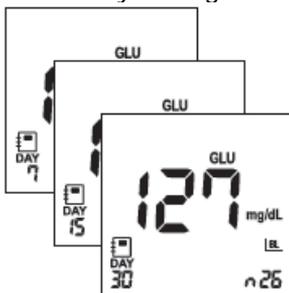
4) If there are not any stored glucose test results, the following display will appear on the screen:
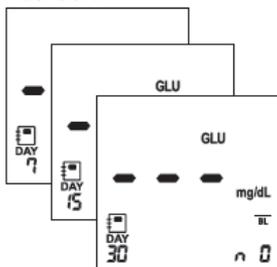
### 7. Deleting test data

1) Switch the analyzer on and then press the left or right button in order to enter the Memory mode at the test strip (lipid or glucose) standby state.
2) Navigate through to identify the result you want to delete. Press the left and right button together, and hold for 3 seconds.

3) The dEL message will appear on the screen. Press the SET/PRT button, and hold it for 3 seconds.
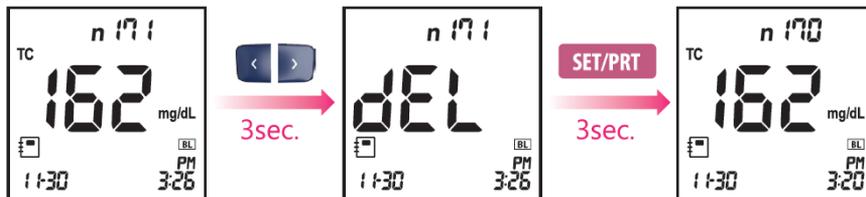
8. Printing

Material required, but not provided

• SD Thermal printer (Model Number: 90TPRT10)
• SD USB cable

If you want to purchase the accessories listed above, please contact our customer service center at 1-855-486-2888.

How to print

Auto Print

If you have turned the auto printing function on in the Setting mode, the analyzer will not display the Printing symbol. When a test is done, the test result sheet is automatically printed, without any action.

Manual Printing

If you press the SET/PRT button in the Memory mode, the Printing symbol will appear on the screen and the test result sheet will be printed with the result.
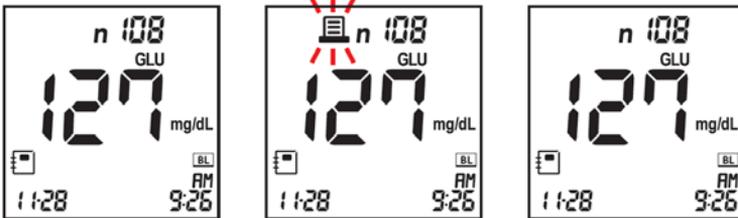
NOTE:
• If you have selected P-1 in the setting mode, it will print the test results in simplex (on one side of paper).
• If you have selected P-2 in the setting mode, it will print the test results in duplex (on both sides of the paper).
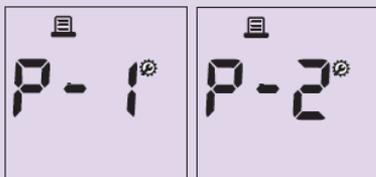

# CHAPTER 3. COLLECTING BLOOD SAMPLES

CAUTION
- When collecting the capillary blood from the fingerstick, palm, forearm, or upper arm, there is the possibility of a bloodborne pathogen transmission.
- Users should wash hands thoroughly with soap and water after handling the meter, lancing device, or test strips.
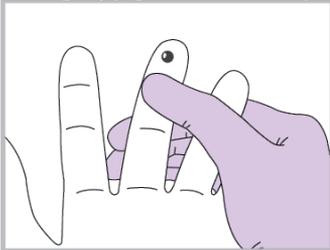
1. Getting a blood sample from fingersticks

1) Twist off the protective lancet cap.
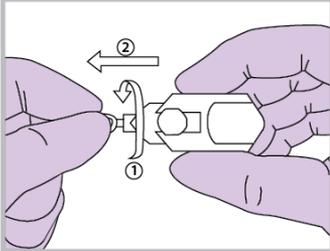
2) Position the lancet and press it firmly against the puncture site.
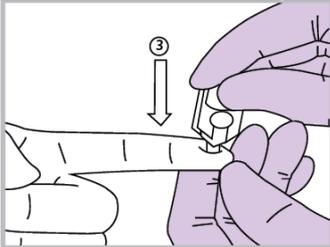
3) Gently apply intermittent pressure to the puncture site to obtain sufficient blood.

CAUTION:
- A lancet should be used only once. Do not share used lancets with another person. To prevent possible infection, a used lancet should not be touched by another person.
- Dispose of used lancets in a biohazardous waste container with lid.

2. Getting a blood sample from alternative sites
Important Information About AST

Sites other than fingertips may have fewer nerve endings, so obtaining a blood sample from these sites may be less painful. The technique for alternative site testing is different from fingertip testing. However, blood glucose results from sites other than your fingertip could be significantly different, because blood glucose levels change rapidly after a meal, insulin, or exercise. Consult with your healthcare provider prior to testing from a site other than your fingertip. Rapidly changing results are likely to occur after eating. Insulin dosing and physical activity are shown in the fingertip more quickly than in an alternative sites. The AST results should never be used to calibrate CGMs or for insulin dose calculations.

AST Precautions
- AST testing should not be done within 2 hours of a meal, exercise, or medication.
- Results from AST testing should not be used to calibrate continuous glucose monitors (CGMs).
- Results from AST testing should not be used for insulin dosing calculations.
- AST testing should not be done if your AST results do not match the way you feel.
- AST should only be done at times when the patient's blood glucose is not rising or falling rapidly.

Things to Know When using alternative sites

Please read the following before testing at alternative sites (palm, forearm, and upper arm). The capillary whole blood of the fingertips reflects changes in glucose levels more rapidly than in alternative sites. The test results from the fingertip testing and AST may differ, due to factors such as lifestyle and ingested food, which affect glucose levels.

| Use Alternative Site Testing only When	Use Fingertip Testing
• Testing before a meal • You are in a fasting state • Two hours have passed since a meal • Two hours have passed since insulin dosing • Two hours have passed since physical activity	• Within two hours after a meal • Within two hours after insulin dosing • Within two hours after physical activity • If you have a history of hypoglycemia, are experiencing low-blood glucose, or suffer from hypoglycemic unawareness (you cannot tell when you have low blood glucose) • During times of stress or illness

NOTE:
- Results from alternative site and fingertip samples may differ from each other, as there is a time lag for the glucose levels to reach the same value. Use a fingertip sample if you suffer from hypoglycemia or have experienced hypoglycemic shock or symptoms.
- If the sample drop of blood runs or spreads due to contact with hair or with lines on your palm, do not use that sample. Try puncturing again in a smoother area.

Sampling for the AST Procedure

1) Select a soft, fleshy area on the palm, forearm, or upper arm free of visible veins, moles, and hair and away from bone.
2) Press and vigorously rub the selected area for 10 seconds until it starts to feel warm to the touch.
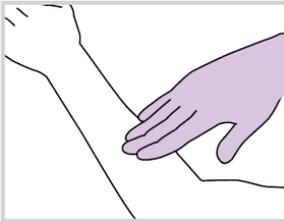
3) Wash the area with warm, soapy water. Rinse and dry completely. If you use alcohol wipes to cleanse the site, make sure that the area is dry before lancing the site.
4) Twist off the protective lancing device cap.
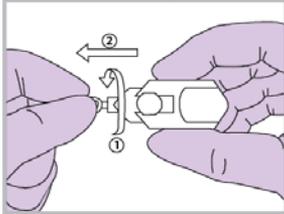
5) Position the lancing device and press it firmly against the puncture site.
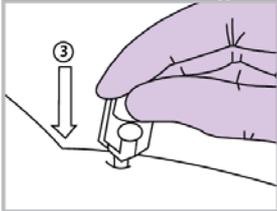
6) Lift the disposable lancing device straight up.
7) Touch and hold a drop of blood to the edge of the test strip until the yellow window is completely filled with blood. The blood is drawn into the strip automatically.
8) The meter counts down from 5 to 1 second with beep sound.
9) The blood test result appears in just 5 seconds and is displayed in mg/dL.
10) Remove and discard the used test strip. The meter automatically shuts off in 5 seconds after removing the test strip.

NOTE:
- Repeat the blood draw if the fluid is clear.
- It is recommended to use the lancing device with the clear end cap when testing alternative sites. Please call 855-486-2888 to order an AST lancing kit containing the lancing device, lancets, and the clear end cap.

CHAPTER 4. PERFORMING A TEST FOR LIPID OR GLUCOSE

1. Before testing for lipid or glucose

1) Before Testing

Make sure you have all the necessary components.

SD LipidoCare Professional system
- SD LipidoCare Professional Analyzer
- SD LipidoCare Professional Lipid Profile Test Strip
- SD LipidoCare Professional Blood Glucose Test Strip
- Sample collection tool, such as a reusable lancing device, lancets, and a capillary tube (optional)

If you want to purchase sample collection tools, please contact the SD Biosensor customer service center at 1-855-486-2888.

<Precaution>
Do
- Read the test strip package insert.
- Operate the analyzer at the acceptable test-conditions:
  - For lipid testing : 64–90°F (18–32°C), 10–90% RH
  - For glucose testing: 50–113°F (10–45°C), 10–90% RH
- Place the analyzer on a level surface or hold it steady in your hand.
- Keep the guidelines for cleaning and disinfecting.
- Make sure that all display elements are displayed.

Do not
- Use lipid test strips beyond the expiration date, as 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 test strips at extreme temperatures or humidity.
- Open the door during the measurement.

CAUTION: Not following these precautions can lead to inaccurate results.

2. **Test Procedure for cholesterol (lipid) only**

1) Prepare a lipid test strip for the measurement.
2) Hold the lipid test strip with thumb and index finger so that the lipid test strip is facing upward.

3) Insert the lipid test strip into the lipid test strip slot of the analyzer. When the lipid test strip reaches the correct position, you will hear a beep.
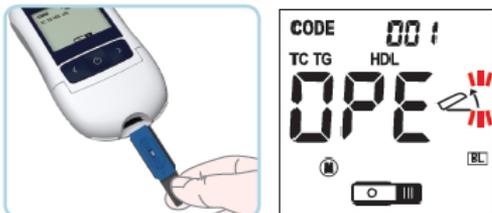
4) After the display appears, open the door by lifting it. Then, the display below will appear.
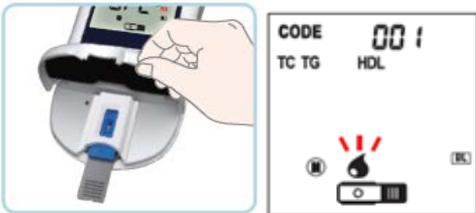
5) Prepare the blood samples collected from your fingerstick.

NOTE:
- For the procedure to collect the capillary whole blood from your fingerstick, please refer to Chapter 3. Collecting Blood Samples.
- To measure the lipid, the capillary whole blood from your fingerstick is the only option. Do not use a blood sample from an alternative site.

6) Apply the collected sample to the sample application area of the lipid test strip.

7) The message "CLo" will appear for 5 seconds. After closing the door, it performs the measurement for 3 minutes.
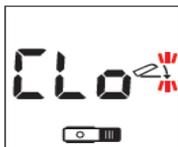
8) Your result appears on the screen after 3 minutes. When the test is done, pull out the used test strip and discard it. The analyzer shuts off automatically, 3 seconds after the used test strip has been removed.


NOTE:

The (M) icon will be displayed on the screen with the test reult. Please press the left or right button to see the other parameter results. The order of the display is as noted below:
- Pressing the right button: TC ➔ TG ➔ HDL ➔ LDL ➔ LDL/HDL ➔ non-HDL of the same index number
- Pressing the left button: TC ➔ non-HDL ➔ LDL/HDL ➔ LDL ➔ HDL ➔ TG ➔ TC

- Do not open the door during the test.
- If you do not close the door after applying the blood sample to the test strip, the Close Door message will appear on the screen, accompanied by warning beeps.
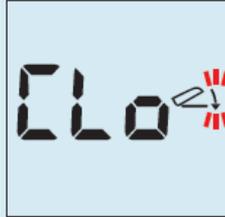
- If you do not close the door within 20 seconds after the blood sample is applied, the analyzer will display the E-7 error message.
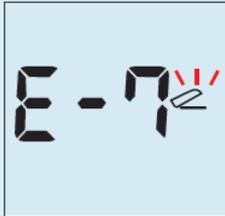
- The entire blood application area must be filled with blood drop.

Example of not enough blood

Example of enough blood
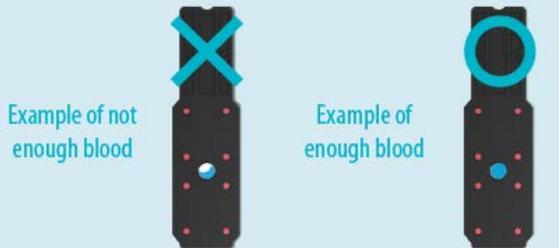
3. **Procedure for glucose**

1) Take a glucose test strip from a container. Make sure to tightly close the container cap after taking a glucose test strip.
2) Insert a 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 next to the glucose strip symbol, you are ready to perform a glucose test.
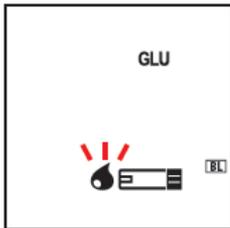
4) Obtain a drop of blood sample from your fingerstick or alternative site, using a lancet and lancing device.

NOTE: Refer to Chapter 3, Collecting Blood Samples, for instructions on how to collect the blood sample from your fingerstick or alternative site**.**

5) Touch the top edge of the test strip to the blood on your finger. Do not take off your finger until the yellow window is completely filled with blood. Do not drop the blood from above.
6) The blood will be drawn into the glucose strip automatically.
7) The analyzer display counts down from 5 to 1 (seconds), and your result will appear on the display after 5 seconds.
8) When the test is done, pull out the used glucose test strip. The Analyzer will shut off automatically in 3 seconds.

4. Understanding Your Results

	Measuring Range, mg/dL(mmol/L)	For results outside the measuring range, the SD LipidoCare analyzer displays	
		Low(Lo)	High(HI)
TC	100–450 (2.59–11.64)	< 100 (2.59)	> 450 (11.64)
TG	45–650 (0.51–7.34)	< 45 (0.51)	> 650 (7.34)
HDL	25–95 (0.65–2.46)	< 25 (0.65)	> 95 (2.46)
Glucose	20–600 (1.2–33.3)	< 20 (1.2)	> 600 (33.3)

• For Lipid
  After finishing the test, you can review test results by pressing the left or right button;
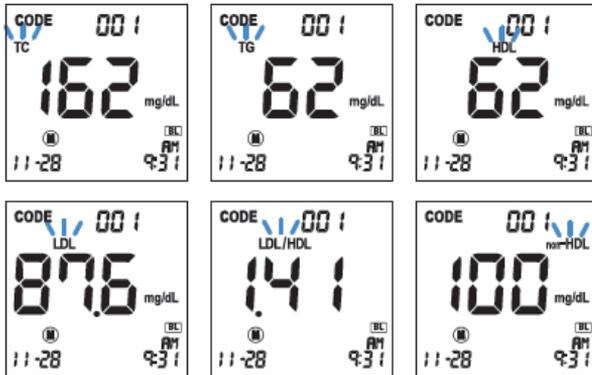
the total cholesterol (TC), Triglycerides (TG), and high density lipoprotein (HDL) appear on the screen, in order. They are the measured results. The low-density lipoprotein (LDL), LDL/HDL, and non-HDL appear on the screen, in order. They are the calculated results.

Expected Value for lipid

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 guidelines for cholesterol testing and management and described the following classifications for cholesterol and triglyceride testing:

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

Non-HDL

ATP III identifies non-HDL (total cholesterol minus HDL) as a secondary target of therapy in persons with high triglycerides (≥200mg/dL). The goal for non-HDL in persons with high serum triglycerides can be set at 30mg/dL higher than that for LDL cholesterol, on the premise that a VLDL level ≤30mg/dL is normal.[1] Non-HDL can be calculated using the equation below.

non-HDL (calculated) = Total Cholesterol - HDL

LDL

LDL can be calculated using the equation below. Calculated LDL is an estimation of LDL and is valid only if the triglyceride level is 400mg/dL (4.55mmol/L) or below.[3]

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

TC/HDL Ratio

The ATP III report does not comment on the use of the ratio of total to HDL cholesterol. Various authors have suggested that the TC/HDL ratio is the strongest lipid risk factor and can be a useful summary of CHD risk.[4, 5] A ratio of 4.5 or less is desirable. A ratio greater than 6.0 suggests a high risk of CHD.[4]

Expected Value for Glucose

- **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[10]:**
  Before eating <100 mg/dL (5.6 mmol/L)
  One to two hours after meals <140 mg/dL (7.8 mmol/L)
  Reference:
  American Diabetes Association: Diabetes Care, 2015;38(Suppl. 1):S8-S16

Your glucose results

1) After 5 seconds from applying blood to the glucose strip, you should receive a test result between 20–600mg/dL.

2) If your blood glucose result is above 600mg/dL, you will receive *HI*. If your blood glucose result is below 10mg/dL, you will receive *Lo*. In these cases, repeat the test with a new glucose test strip. If these messages appear again, please contact your healthcare provider immediately.
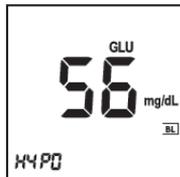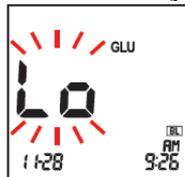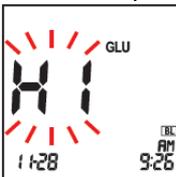
CHAPTER 5. CONTROL SOLUTION TEST

1. Control Solution Test

It is important to perform a control solution test with more than one level of the control solution. The control solution is used to check that the analyzer and the test strips are working together, as a system, properly. It is very important that you do this simple check routinely to make sure you get an accurate result.

When to use Lipid or Glucose Control Solution
- Before using your analyzer for the first time
- When you open a new strip vial, pouch, or packaging
- Whenever your result does not agree with your symptoms

CAUTION
- Use only the specified control solution.
  - ✓ SD Lipid Control Solution
  - ✓ SD Glucose Control Solution
- Check the expiration date on the control solution container. Do not use the control solution after the expiration or discard date.
- Do not swallow the control solution; it is not for human consumption.
- Do not apply the control solution to the skin or eyes, as it may cause irritation.


What you need:
- SD LipidoCare Professional Analyzer
- SD LipidoCare Professional Lipid Profile Test Strips
- SD LipidoCare Professional Blood Glucose Test Strips
- The codechip
- SD Lipid Control Solution - Level 1 , Level 2
  OR
  SD Glucose Control Solution – Level M, Level H

2. Procedure for the lipid control solution

1) Prepare the lipid test strip and the code chip.
2) Make sure the code chip matches the code number of the test strip package.
3) Insert a test strip into the analyzer.
4) When the OPE message is displayed on the screen, open the door. Press the left button and hold it for 3 seconds, then check to ensure that the control solution icon appears on the screen. If you don't want to do a control solution test, press the left or right button one time to exit.
5) Gently shake the lipid control solution and apply a drop to the test strip, using a capillary tube.
6) After 3 minutes, the test result will appear on the screen.
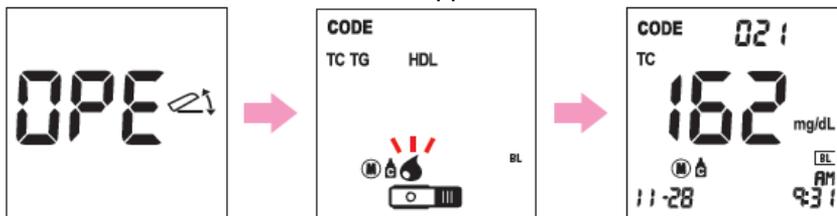
7) Compare the result to the range printed on the control solution insert. If the results are not within the lipid control range printed on the insert, the analyzer and the test strip may not be working properly. Repeat the control test. If the control solution result is still not acceptable, please contact our customer service center at 1-855-486-2888.
8) Remove the used test strip from the analyzer and discard it.

CAUTION:
- Store upright and refrigerate SD Lipid Control Solution at 36–46°F. It can be expected to give stable results through the expiration date printed on the label. Minimize exposure to strong light.
- The SD Lipid Control Solution should be tested at room temperature, 64–90°F (10–90% RH).
- Do not use the SD Lipid Control Solution if it is
  - ✓ cloudy
  - ✓ has an odor
  - ✓ shipped or stored improperly
- The acceptable range printed on the lipid control solution insert is for the SD Lipid Control Solution only. It is not a recommended range for your lipid profile levels.

3. Procedure for the glucose control solution

1) Take a new glucose test strip from the test strip container. Be sure to tightly replace the container cap after taking a glucose test strip.
2) Insert a glucose test strip (yellow window with a printed arrow symbol facing up) into the glucose test strip slot. The analyzer turns on automatically.
3) Press the left button and hold it for 3 seconds, then check to ensure that the control solution icon appears on the screen. If you don't want to perform a control solution test, press the left or right button one time to exit.
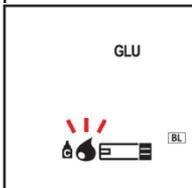
4) Shake the SD Glucose Control Solution bottle and gently squeeze the container to form one small drop. Bring the drop to the edge of the glucose strip and allow the glucose strip to automatically draw the SD Glucose Control Solution into the yellow window. When the SD Glucose Control Solution is applied to the glucose test strip, the Analyzer counts down from 5 to 1 (seconds) on the screen.
5) The SD 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 SD Glucose Control Solution test. If the control solution result is still not acceptable, please contact our customer service center at 1-855-486-2888.
7) Remove the used glucose test strip from the analyzer and discard it.

CAUTION
- The acceptable range printed on the glucose test strip container is for the SD Glucose Control Solution only. It is not a recommended range for your blood glucose level.
- Store the SD Glucose Control Solution, after closing the cap tightly, at temperatures between 46–86°F (8–30°C). Do not refrigerate.
- The SD Glucose Control Solution should be tested at room temperature, 64–86°F (10–90% RH).
- If a glucose control solution test is still not acceptable, please contact our customer service center at 1-855-486-2888.

4. Troubleshooting the control solution

Check	Action
Have the test strips and/or control solutions expired?	Make sure that the test strips and the control solutions are not past the expiration date. Once opened, they are good only for a limited time period: - Glucose test strip : 6 months - SD Glucose Control Solution : 3 months - SD Lipid Control Solution : 1 month
Were SD glucose control solutions at room temperature (18–30°C, 64–86°F) when used?	If not, warm up/cool down to the room temperature (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 goes no further.
Did you follow the procedure correctly?	Read the user manual again and retest.
Was a lipid or glucose test strip 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, contact our customer service center at 1-855-486-2888.
Is the control solution result outside the acceptable range?	Repeat the test. If you get the same result, do not use your analyzer and test strip, and call our customer service center at 1-855-486-2888.

CHAPTER 6. CHECK STRIP TEST

1. **Check Strip Test**
   The check strip test is used to check that the analyzer is working well.

2. **When to use the Lipid and Glucose check strip**
   - Whenever you suspect the meter does not function properly
   - Before using your analyzer for the first time
   - If you have dropped the analyzer
   - If the analyzer has not been used for a long time

   CAUTION: The check strip test does not replace the control solution test.

3. **How to Use the SD Lipid Check Strip**
   1) To enter the Checking mode of the lipid check strip, press both the left and right buttons together at the strip standby mode, and hold for 3 seconds. Then, the CHE message will appear on the screen.

   2) Insert the SD Lipid Check Strip into the lipid strip slot of the analyzer.

   3) The check strip result appears on the screen after 10 seconds. If there is no problem with the analyzer, the OK message will appear on the screen. Otherwise, if there is a problem with the analyzer, the EEE error message will appear on the screen.

   NOTE: If you get the EEE error message, please try to perform a check strip test again. If it keeps displaying the EEE error message, please contact our customer service center at 1-855-486-2888.

4. How to use the SD Glucose check strip

1) Insert the SD Glucose Check Strip with the *check strip* print facing up into the glucose test strip slot. Then the analyzer starts the glucose check strip testing automatically.

> **NOTE:** There is no special mode to enter for this glucose check strip testing. If the SD Glucose Check Strip is inserted into the analyzer, the analyzer starts the check strip test automatically.

2) The check strip test result will appear on the screen after 5 seconds. If there is no problem with the analyzer, the OK message with the GLU icon will appear on the screen. If there is a problem with the analyzer, the EEE error message will appear on the screen.
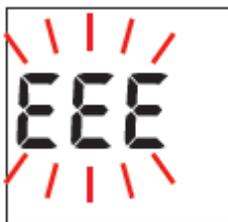
CHAPTER 7. MAINTENANCE AND TROUBLESHOOTING

1. Cleaning and Disinfection

The SD Biosensor recommends that the following practices and procedures be followed when using the SD LipidoCare Professional Analyzer to minimize the risk or transmission of bloodborne pathogens. This analyzer is at high risk of becoming contaminated with bloodborne pathogens, such as the Hepatitis B Virus (HBV). Transmission of this virus has been documented, due to contaminated analyzers.

> **NOTE:**
> FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010)
> *http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm*
> CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010)
> *http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html*

Cleaning is the general removal of debris such as food, feces, urine, blood, saliva, or other body secretions, but cleaning does not kill germs effectively.

Disinfection is the process of killing disease-causing microbes (bacteria and viruses) that may be on the surface of your analyzer. Disinfection is the only way to reduce your exposure to disease

Cleaning & Disinfecting Materials

The SD Biosensor tested a commercially available wipe, the Discide Ultra Disinfecting towelette, manufactured by Palmero Health Care, on the SD LipidoCare Professional Analyzer, and the wipe is shown to be safe and effective on our analyzer.

Product: Discide Ultra Disinfecting towelettes
EPA Reg#: 10492-4
EPA Est. #: 56952-WI-001
Registrant: Palmero Health Care

For purchasing Discide Ultra Disinfecting towelettes, please visit
http://www.palmerohealth.com or http://www.amazon.com

When you clean and disinfect the analyzer, please use the Discide Ultra Disinfecting towelettes only. It could shorten the use-life or affect the performance of the SD LipidoCare Professional Analyzer if you use other wipes.

When to clean and disinfect the analyzer

We recommend that you clean and disinfect the analyzer once a week. The cleaning and disinfection instructions were validated for 10,950 cleaning and disinfection cycles (10,950 cleaning wipes and 10,950 disinfecting wipes) on the analyzer which supports cleaning and disinfection after each patient, up to 10 patients per day, for the 3 year use life of the analyzer.

Please examine the LCD, test strip port, buttons, and surface of your analyzer after the cleaning and disinfecting cycles. Stop using the analyzer and contact our customer service (1-855-486-2888) immediately if you find the following:

- Thin silver streaks appear, become cracked, soft, dissolved, brittle, or swollen; clouding of LCD display
- You are unable to turn on/off your meter or operate left/right button
- You are unable to enter the meter settings or function modes, or you are unable to recall your testing results
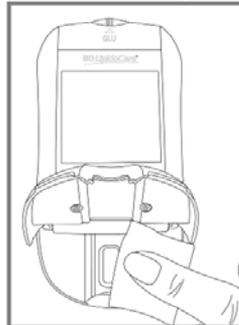
Cleaning STEPS

STEP 1- Dispose of used test strip.
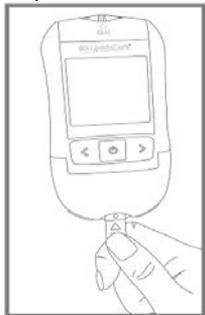
STEP 2 - Take a wipe from the package or container. If the wipe is very wet, wring it slightly to discard excess liquid.

STEP 3 - Wipe each side of your analyser, according to the following method:

<Appearance of analyser>   <Inside and under the door>
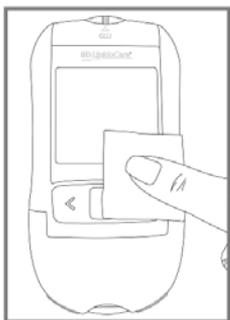
1) Wipe the outside of the analyzer up and down 4 times.
2) Wipe the outside of the analyzer left and right 4 times.
3) Open the door, and then repeat steps 1 and 2 for the inside and under the door.

STEP 4 - Allow the analyzer to air dry. Dispose of the wipe.

Disinfecting STEP

STEP 1   Take another wipe and then wipe the analyzer thoroughly.
The analyzer should be cleaned prior to the disinfection step.
- Wipe the outside of the analyzer up and down 4 times.
- Wipe the outside of the analyzer left and right 4 times.
- Open the door and then repeat steps 1 and 2 for the inside and under the door.

STEP 2   Allow the surface to remain wet for 1 minute.

STEP 3   Allow to air dry.

STEP 4   After handling the analyzer or test strips for cleaning and disinfection, wash your hands thoroughly with soap and water.

CAUTION
- Do not get water inside the analyzer. Never immerse the analyzer or hold it under running water, because it will damage the analyzer.
- Do not spray directly into the strip slot! Moisture in the strip slot may lead to incorrect results. If you suspect that moisture may have entered the strip slot, perform a lipid or glucose control solution test.
- Do not wrap the meter in a wipe; take extreme care not to get liquid in the test strip slot or cable port of the analyzer.
- After disinfection, users' gloves should be removed and hands should be thoroughly washed with soap and water before proceeding to the next patient.

If you have any questions, please contact our customer service center at 1-855-486-2888.

2. Maintenance, Testing, and Transportation

Analyzer
1) Keep the test strip slots free of dust.
2) If the analyzer is stored with batteries inserted, it is best to keep it in a low humidity environment to prevent defects.
3) Keep the analyzer dry, and avoid exposing it to extremes in temperature and humidity.
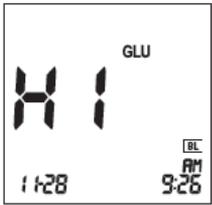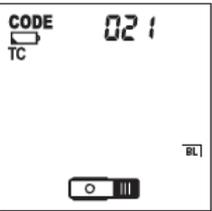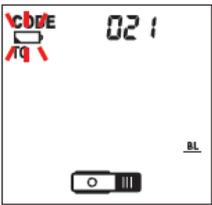4) Do not take apart the analyzer.

Test Strip
1) Lipid and glucose test strips should be stored at 36–90°F (10–90% RH). Lipid test strips may be stored in the refrigerator at a temperature of 36–46°F (2–8°C). However, the lipid test strips must be brought to room temperature for 30 minutes before using.
2) Keep away from heat and direct sunlight.
3) Either keep the lipid code chip in the analyzer or store it in the lipid test strip package.
4) Keep the glucose test strip container closed tightly.
5) Use test strips immediately after taking them from the container.
6) Keep the lipid check strip away from direct sunlight. It can be discolored if the lipid check strip is exposed to sunlight.
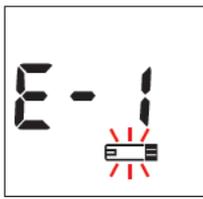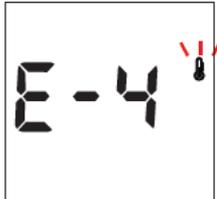
Control solution
1) Do not use any SD Glucose or Lipid Control Solution that has passed the expiration date.
2) For the SD Glucose Control Solution, keep the environment at 8–30°C (46–86°F) and do not refrigerate or freeze.
3) For the SD Lipid Control Solution, store it at the refrigerated temperature of 36–46°F (2–8°C). If the SD lipid control solution is stored in this condition, the SD Lipid Control Solution can be expected to give stable results through the expiration date printed on the label.
4) The SD Glucose Control Solution can be used for 3 months after opening the container. The SD Lipid Control Solution can be used for 1 month after the first opening. Write the date on the bottle of the control solution when you first open it.
5) Wipe the top of the bottle to clean, and reseal the cover of the bottle tightly after each use.
6) Store each control solution at the following temperatures:
   - ✓ For Lipid control solution: 36–46°F (2–8°C)
     SD Lipid Control solution should be stored in the refrigerator.
   - ✓ For Glucose control solution: 48–86°F (8–30°C)

CHAPTER 8. SCREEN MESSAGE AND TROUBLESHOOTING

1. Warning message

Indication	Description
GLU **60** mg/dL BL AM 9:26 HYPO	**Hypo Warning Message** When your glucose result is equal to or less than the Hypo setting value, the HYPO icon will appear.
GLU **HI** BL 11:28 AM 9:26	**Warning** Your test result is higher than the measuring range of the parameter.
GLU **Lo** BL 11:28 AM 9:26	**Warning** Your test result is lower than the measuring range of the parameter.
CODE 021 TC BL	**Warning: Low Battery** At this time, the battery is getting low, but you can still perform about 50 tests.
CODE 021 TC BL	**Warning: Replace Battery** The battery power is low. If you press the button after the battery runs out, the battery icon will flash, and then, after 10 seconds, the analyzer will turn off automatically.

2. Error message

Indication		Description
Lipid Test Strip	**Glucose Test Strip**	**Strip Error** The lipid or glucose test strip is damaged or inserted improperly. **Solution** Discard the test strip and perform the test again, using a new test strip.
Lipid Test Strip	**Glucose Test Strip**	**Blood Sample Error** Insufficient amount of blood has been applied. **Solution** Discard the test strip and perform the test again, using a new test strip with a sufficient blood sample.
		Expired strip (Only for a lipid test strip) The lipid test strips are expired. **Solution** Discard the inserted lipid test strip and perform the test again, using a new lipid test strip.
		Temperature Error If the environmental temperature is above or below the acceptable operation range, a thermo icon will appear on the display. **Solution** Move to an area at 64–90°F for lipid or 50–113°F for glucose, then wait for 30 minutes. After stabilization, perform a test. Do not artificially heat or cool the analyzer.
For PC	**For Printer**	**Communication Error** The communication between the analyzer and a computer or a printer has failed. **Solution** Try to connect again, and if the error message still appears, please contact our customer service center at 1-855-486-2888.

Indication	Description
CODE E-6 ◻▥	**Codechip Error** A code chip of other manfuacutrers or other products made by SD Biosensor is inserted. **Solution** Check to ensure that the code chip is from the package of the test strip inserted. Insert the correct one.
E-7	**Flap Open Error** The door of the analyzer is open during the measurement. **Solution** Close the door and do not touch or open the door during the measurement.
E-8 ◻▥	**Blood Error** The door is closed for testing without a blood sample. **Solution** Re-test with a blood sample.
CODE E-9	**Communication Error with Code Chip** The analyzer cannot communicate with the inserted code chip. **Solution** Re-insert the code chip. If the error message still appears, please contact our customer service center at 1-855-486-2888.
EEE	**Internal Error** An internal error of the analyzer has occurred. **Solution** Turn off the analyzer, and then turn it on again. If the error message still appears, please contact our customer service center at 1-855-486-2888.
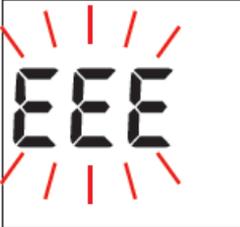
CHAPTER 9.　WARNINGS, PRECAUTIONS, AND LIMITATIONS

- Discard test strip after using. Strips are to be used once. Never re-use a test strip.
- Do not ingest.

1. Test Strip for Lipid

1) Make sure the code chip number matches the number indicated on the lipid test strip package. Never use a code chip from a different lot.
2) Out-of-date or expired strips cannot be used in your test system. Check the expiration date on the package or pouch.
3) Add the blood sample to the lipid test strip at once. Do not add blood to the same strip. Test again with a new test strip and fresh blood sample.
4) Not intended for screening or diagnosis, or for use on neonates.
5) Never make significant changes to your healthcare program or ignore physical symptoms without consulting with your healthcare provider.
6) The following hematocrit range does not affect the test result of each parameter:
   - TC, TG: 30–55%
   - HDL: 30–52%

2. Test Strip for Glucose

1) The SD LipidoCare Professional System is not designed to be a substitute for pathology laboratory equipment, and it should not be used for the diagnosis of diabetes.
2) 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.
3) Not intended for screening or diagnosis, or for use on neonates.
4) Never make significant changes to your diabetes control program or ignore physical symptoms without consulting with your healthcare provider.
5) Severe dehydration (excessive water loss) may cause false low results. If you believe you are suffering from dehydration, consult your healthcare professional right away.
6) Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate results may occur for individuals experiencing a hyperglycemic hyperosmolar state, with or without ketosis.
7) This device has not been evaluated in critically ill patients

CHAPTER 10. 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 shut-off	• 1 minute after last user action without a test strip inserted into the analyzer • 5 minutes after last user action with a test strip inserted into the analyzer

2. Test Strips

Measuring Range	• TC: 100–450 mg/dL (2.59–11.64 mmol/L) • TG: 45–650 mg/dL (0.51–7.34 mmol/L) • HDL: 25–95 mg/dL (0.65–2.46 mmol/L) • Glucose: 20–600 mg/dL (1.2–33.3 mmol/L)	
Sample	**Lipid**	Fresh capillary whole blood from the fingertip, Venous whole blood, or Serum or plasma
	Glucose	Fresh capillary whole blood from the fingertip, palm, forearm, or upper arm
Sample Size	**Lipid**	35uL
	Glucose	0.9uL
Test Time	**Lipid**	3 minutes
	Glucose	5 seconds
Storage Temperature	36–90°F (10–90% RH) for both lipid and glucose test strip	
Hematocrit	• TC, TG: 30–55% • HDL: 30–52% • Glucose: 20–60%	
Operating Condition	**Lipid**	64–90°F(10–90% RH)
	Glucose	50–113°F(10–90% RH)
Altitude	Up to 3,776m (12,388 ft) only for glucose	

Appendix 1: References

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4. 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.
5. 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.
6. IDF Clinical Guidelines Task Force. Global guideline for Type 2 diabetes. Brussels; International Diabetes Federation, 2005.
7. Definition and diagnosis of diabetes mellitus and intermediate hyperglycemia: report of a WHO/IDF consultation. WHO, Geneva 2006 (ISBN 92 4 159493 4, ISBN 978 98 4 159793 6).
8. D'Orazio et al.: "Approved IFCC Recommendation of Reporting Results for Blood Glucose (Abbreviated);" Clinical Chemistry 51:9 1573-1576-(2005).
9. American Diabetes Association, Position Statement, Diagnosis and Classification of Diabetes Mellitus, Diabetes Care 35:S4-S10, 2012.
10. American Diabetes Association: Clinical Practice Recommendations (2013) Diabetes Care, Vol 36, Supplement 1, p. S1-S100

Appendix 2: Warning

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:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help

CAUTION

Any changes or modifications to this device not explicitly approved by manufacturer could void your authority to operate this equipment.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This device complies with RF exposure requirement.

For further information on

SD LipidoCare®

please contact your
SD Biosensor, Inc.
Representative

Catalogue no. : 02LA10G/02LA20G
FCCID: RPJ02LA10G/RPJ02LA20G

Manufacturer

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