

Thank you for your purchase of the SD MultiCare™ analyzer!

This User Manual contains all the information needed to use the analyzer and keep it ready to operate. 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 inserts of the test strips to be used for the planned test.

If you cannot reach SD 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 SD MultiCare™ analyzer.

The packaging materials, labels and instruction for use for SD MultiCare™ analyzer may contain the following symbols or abbreviations which are listed below with their meaning:

Symbols



NOTE

Please consult instructions for use.



Caution, consult accompanying documents



Consult instructions for use



In vitro diagnostic medical device
This system is intended to use outside the body (in vitro diagnostic use).



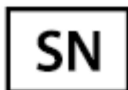
Manufacturer



Catalogue number



Date of manufacture:
To indicate the date of manufacture for this analyzer



Serial number for this analyzer.



To indicates that the product is fragile and you need to handle it with care



Batch code:
To indicate the lot number for this system



Crossed out wheeled bin: To discard it separately from other household waste



To indicate the temperature limitations in which the transport package has to be kept and handled



Use by / Expiry date



To use for 3 months after first opening the container.



Do not reuse:
To warn the user of a piece of equipment that it is for single use only and that it must not therefore be used more than once



Contains Sufficient for <n> Tests



This product fulfills the requirements of Directive 98/79/EC on in vitro diagnostic medical devices



To indicates that you should keep the product dry

Abbreviations

HbA1c	Hemoglobin A1c
CRP	C-reactive Protein
u-ALB	Micro-Albumin
CRT	Creatinine
ACR	Albumin to Creatinine Ratio
Vit-D	Vitamin D
SDB	SD biosensor, Inc.

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CHAPTER 1. Understanding Your New Analyzer

1. Indication for Use; Purpose of the analyzer

The SD MultiCare™ analyzer work to measure the quantitative measurement of blood parameter: **HbA1c, CRP, u-ALB, CRT**. The analyzer is indicated for monitoring the blood parameter in fresh capillary whole blood samples or venous blood. The SD MultiCare™ analyzer should be used with the SD MultiCare™ test strip. Testing is done outside the body (in vitro diagnostic use). This analyzer is indicated in clinical settings by healthcare professionals. The SD MultiCare™ analyzer be only used the SD MultiCare™ test strip for the appropriate parameter.

2. Test principle

By means of a code chip, the analyzer reads the lot-specific characteristics of the 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 while scanning. 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. 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 motor and LED. The intensity of the reflected light is measured with a detector (reflectance photometry). The measured value is determined from the signal strength of the reflected light, with the previously measured blank value and the read lot-specific information (code chip) also being considered. Finally, the result is displayed and simultaneously stored in the memory.

3. Before You Start Testing

Carefully read and follow the instructions in the User's Manual and Package Inserts for the test strips and control solutions. It is very important to follow the instructions in order to prevent an incorrect result or improper treatment.

Samples

The SD MultiCare™ analyzer for each parameter testing is designed for monitoring fresh capillary whole blood samples, venous blood, or serum/plasma. Each sample is different from test strip's type

Safety Information

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

Operating conditions

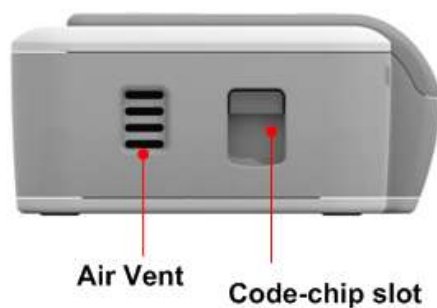
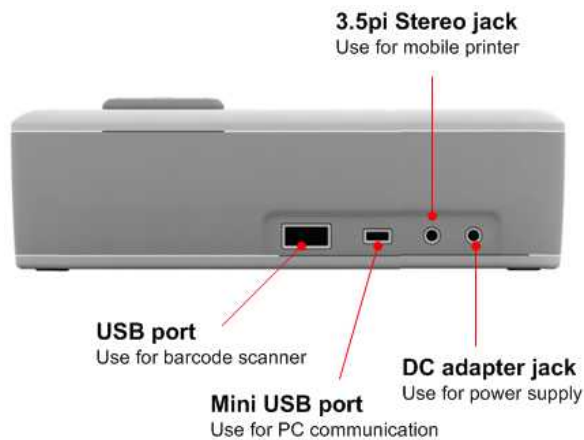
To ensure proper function of your SD MultiCare™ analyzer, observe the following guidelines:

- The SD MultiCare™ analyzer is only for interior use.
- The SD MultiCare™ analyzer is only for use within altitude 2,000M and humidity 85%
- Operate the analyzer only within the acceptable temperature range. This range is test-dependent:
 - For HbA1c 18-32 °C, Please refer to the test strip's package
- 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.
- The analyzer's air vents must be free for air (Do not cover the air vents)
- If the analyzer cause a sudden malfunction, unplug the AC adapter from the outlet.

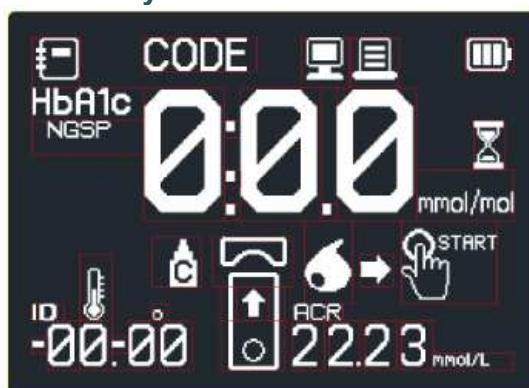
4. The SD MultiCare™ analyzer

Cat. No.	03MA10 -HbA1c
Analyzer	SD MultiCare™ analyzer
Check Strip	SD MultiCare Check Strip
Control Solution	SD MultiCare Control Solution
Battery	Four batteries (1.5 V, AA)
DC Power supply	Input: AC100~240V, 50/60Hz (Voltage tolerance ±10%) Output: DC5V/1A
Power consumption	Max 2W
Over Voltage Category	II
Pollution Degree	II
Lancing Device	Lancing Device
Pipette	5µℓ Mini Pipette
Printer (Optional)	SD Printer SD Printer Cable SD PC Communication Cable
Labeling	User's Manual Quick Guide




















Overview of SD MultiCare™ Analyzer

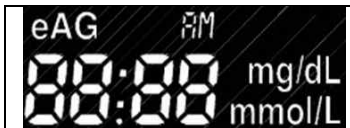


Display of SD MultiCare™ Analyzer



Every time you insert new batteries, you can only check the display. Otherwise, the analyzer displays standby state after power on. The symbols in the display have the following meaning:

	Set mode		Bluetooth connection
	Code		PC connection
	Printing		AC adapter connected
	AC Adapter connected		Memory Index
	<ul style="list-style-type: none"> • HbA1c value (% or mg/dL or mmol/mol) • Code digit • Testing time count • OK • m-d or d-m • Memory Index number 		Processing
	Out of Temperature range		Sound
	Test with control solution		Pull Strip out
	Insert Strip		Blood
	HbA1c Calibration select		Press Start button
	<ul style="list-style-type: none"> • Date • ID number 		

	<ul style="list-style-type: none"> • Time • eAG value (mg/dL or mmol/L) 		
---	---	--	--

5. Power supply

5V/2A DC power adapter or 4 AA alkaline batteries can be used.

When using batteries, to save power, the analyzer turns itself off after 2 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. With a set of fresh batteries, you will normally be able to perform at least 200 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.

Please respect the environment and dispose of used batteries according to your local regulations and laws.

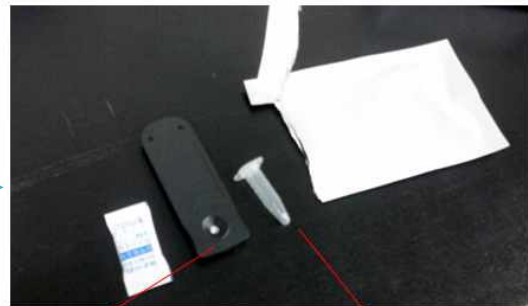
Do not throw batteries onto an open fire. There is a risk of explosion!

6. SD MultiCare™ Test Strip

SD MultiCare™ Test strip



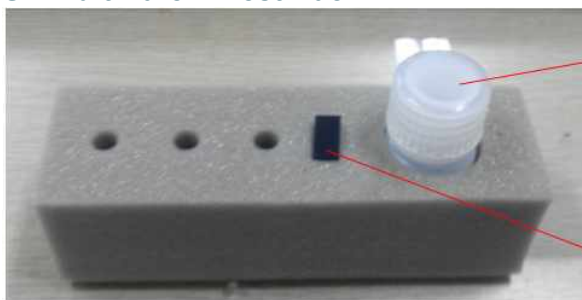
SD MultiCare™ Test strip with pouch



A1cCare™ Strip

A1cCare™ Regent Tube

SD MultiCare™ Test Rack



A1cCare™ Buffer Bottle

Code Chip

7. SD MultiCare™ Accessories

5µl Mini Pipette



200µl Mini Pipette

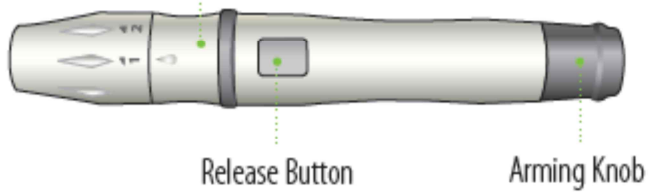


Check Strip



Lancing device (with a white cap for fingertip testing and a clear cap for Alternative Site Testing)

Cap & Comfort dial with puncture depth selection



AST Cap



Cap & Comfort dial with puncture depth selection

SD Control solution



SD MultiCare Analyzer DC adapter



Optional Accessories

- * **SD Biosensor Pinter**
- * **SD Biosensor Printer cable**
- * **SD Biosensor Barcode Scanner**
- * **SD Biosensor PC communication cable**

CHAPTER 2. Testing the SD MultiCare™ Analyzer

1. Operating the analyzer

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

STEP 1. Insert batteries or Connect DC adapter jack



STEP 2. Set the analyzer.

STEP 3. Insert a code chip.

**You can also be done directly before performing the measurement.*



STEP 1-1. 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.
4. Insert four batteries into the compartment according to the illustrations. Please note the orientation of the “+” (battery head) and “-” terminals (fl at end). Use only alkaline manganese batteries (1.5 V, AA).

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.

5. Close the battery compartment lid.
6. Turn the analyzer on to test the function of the new batteries.
7. Check that the display is functioning correctly to prevent misinterpretations due to defective display elements.

Note.

- If you think the display screen does not appear for long enough, you can hold down the Enter 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.

STEP 1-2. Connect DC adapter jack

1. Ensure the DC adapter jack is provided by SD Biosensor, inc. (DC adapter jack is 4 mm external-diameter and 1.7 mm internal-diameter, and output is 5V/2A.)
2. Connect DC adapter jack to the dc jack port in the back of analyzer

Note.

- If the batteries are already inserted and if DC adapter jack is connect, the analyzer use a power only from dc jack

STEP 2. Set the analyzer

Brief overview of the analyzer settings

The following table provides an overview of the available settings.

Stage	Setting	03MA10 (HbA1c)	Default Setting*
1	Beep	On, off	On
2	Year	YYYY	2012
3	Date Format	m-d, d-m	m-d
4	Month-Day	mm-dd	01- 28
5	Time Format	12h, 24h	12h
6	Time	hh:mm	02:30pm
7	Auto Printing	On, off	Off
8	Printing Page	P-1, P-2	P-1
9	HbA1c Calibration	NGSP, IFCC, mono-S, JDS	NGSP
10	eAG unit	mg/dL, mmol/L	mg/dL
11	CRT unit	mg/dL, mmol/L	mg/dL
12	ACR unit	mg/g, mg/mmol	mg/g
13	Bluetooth with PC	On, Off	Off
14	Bluetooth with printer	On, Off	Off
15	Bluetooth Printer re- pair	On, Off	Off

* "Default setting" describes the analyzer setting at the time of shipping.

* Stage 13,14,15 is only for 03MA20

Stage 0) Entering set mode

***03MA10**

1. Press the **SET/PRT** button (on the top side of the analyzer) during 3 seconds to enter set mode after turn on and standby state. If you want to leave the set mode instead (this is only possible if a date and time setting is made) in any set mode, press the **SET/PRT** button.
2. If the displayed setting is, you can continue directly to the next setting by pressing the **Enter** button.
3. Press the ◀ or ▶ button to change the currently flashing setting. You can press the ◀ or ▶ button as many times as needed (or keep it pressed) until the desired setting (value) is reached.
4. Press the **Enter** button again to confirm (store) the current setting and go to the next setting. You can only move forward through the settings. Moving backwards is not possible. Corrections can only be made by repeating the settings. The setting procedure can be terminated at any time by pressing the Enter button. The settings made up to that point will be stored.
If you want to exit the setting mode without changing, press the set button

Stage 1) Setting - Beep

* 03MA10

In 1st stage, you set the **Beep** function.

1. If you enter the set mode, the display for setting the beep will appear the first step of the setting mode.



■ **Default Setting: On**

2. Set the beep mode on or off by pressing either ◀ or ▶ button and then selecting the preferred feature by pressing the **Enter 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

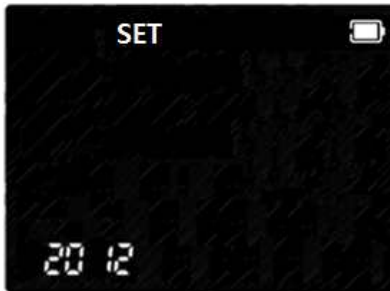


Stage 2) Setting – Year

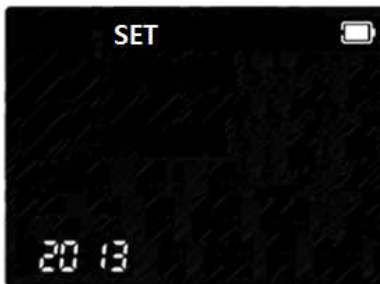
*03MA10

In 2nd stage, you set the Year in Date & Time setting.

1. After setting **Beep**, the display for setting Date & Time will appear. Set the correct year by pressing ◀ or ▶ button and then select the correct year by pressing the **Enter** button.



■ Default Setting: 2012



Stage 3) Setting – Date Format

***03MA10**

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

1. Next will appear the setting display for **Date Format**. The analyzer can display the month and day in either a Month-Day (m-d) format or a Day-Month (d-m) format. Set the preferred format on the display by pressing either ◀ or ▶ button and select by pressing the **Enter button**.



■ Default Setting: m-d



Stage 4) Setting – Month-Day

***03MA10**

In 4th stage, you set the **Month-Day** in Date & Time setting.

1. After setting Date Format, set the correct month or day on the display by pressing either ◀ or ▶ button and select by pressing the Enter button.



■ Default Setting: 01-31



Stage 5) Setting – Time Format

***03MA10**

In 5th stage, you set the **Time Format** in Date & Time setting.

1. Next will appear the display for setting the **Time Format**, 12 or 24 Hour clock format. The analyzer can display the time in either the 12h format or the 24h format. Set the preferred format on the display by pressing either ◀ or ▶ button and select by pressing the **Enter button**.



■ **Default Setting: 12h**



Stage 6) Setting – Time

*** 03MA10**

In 6th stage, you set the **Time**, the current hour and minutes, in Date & Time setting.

1. Next will appear the display for setting the current **Time**, hour and minute. Set the hour and minute on the display by pressing either ◀ or ▶ button and select by pressing the **Enter button**.

a. 12h Format

sub-step1) set AM or PM, sub-step 2) ⇒ set hour(1 to 12), sub-step 3) minute(1 to 59)



b. 24h Format

sub-step1) set hour(1 to 24), sub-step 2) minute(1 to 59)



Stage 7) Setting – Auto Printing

***03MA10**

In 7th stage, you set the **Auto Printing** function.

1. After Result unit setting, the display for setting **Auto Printing** function will appear.



■ **Default Setting: Off**

2. Set **Auto Printing** function, 'On' or 'Off', by pressing either ◀ or ▶ button and then select the preferred feature by pressing the **Enter button**.



Stage 8) Setting – Printing Page

***03MA10**

In 8th stage, you set the **Printing Page** mode.

1. After **Auto Printing** function setting, the display for setting **Printing Page** mode will appear.



■ **Default Setting: P-1**

2. Set **Printing Page** mode, 'P-1' or 'P-2', by pressing either >> or << button and then select the preferred feature by pressing the **Enter** button.



Stage 9) Setting – Calibration Type

*03MA10

In 9th stage, you set the **Result calibration unit** for HbA1c test.

1. Next will appear the display for setting the **result unit - % or mg/dL or mmol/mol**. Set the each unit by pressing either ◀ or ▶ button and select by pressing the **Enter button**



■ **Default Setting: NGSP(%)**

Stage 10) Setting – eAG unit

*03MA10

In 10th stage, you set the **Result unit** for HbA1c test.

1. Next will appear the display for setting the **result unit - % or mg/dL or mmol/L**. Set the each unit by pressing either ◀ or ▶ button and select by pressing the **Enter button**



■ **Default Setting: mg/dL**

Stage 11) Setting – Creatinine unit

***03MA10**

In 11th stage, you set the **Result unit** for Creatinine test.

1. Next will appear the display for setting the **result unit - mg/dL or mmol/L**. Set the each unit by pressing either ◀ or ▶ button and select by pressing the **Enter button**



■ **Default Setting: mg/dL**

Stage 12) Setting – ACR unit

***03MA10**

In 12th stage, you set the **Result unit** for u-ALB and Creatinine test.

1. Next will appear the display for setting the **result unit - mg/g or mg/mmol**. Set the each unit by pressing either ◀ or ▶ button and select by pressing the **Enter button**



■ **Default Setting: mg/g**

Stage 13) Setting – Bluetooth communication with PC

*03MA20

In 13th stage, you set the only for 03MA20

1. Next will appear the display for setting - **On or Off**. Change the set by pressing either ◀ or ▶ button and select by pressing the **Enter button**



■ **Default Setting: Off**

Stage 14) Setting – Bluetooth communication with Printer

*03MA20

In 13th stage, you set the only for 03MA20

1. Next will appear the display for setting - **On or Off**. Change the set by pressing either ◀ or ▶ button and select by pressing the **Enter button**



■ **Default Setting: Off**

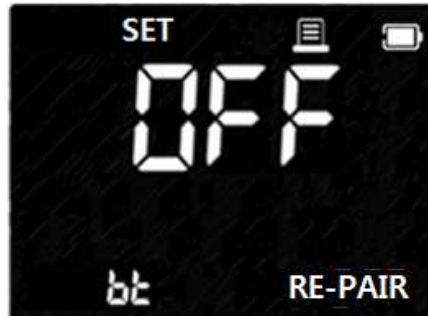
Stage 15) Setting – Bluetooth re-pair enabling with Printer

***03MA20**

In 13th stage, you set the only for 03MA20

When the set is On, the analyzer always search for the new mobile printer.

1. Next will appear the display for setting - **On or Off**. Change the set by pressing either ◀ or ▶ button and select by pressing the **Enter button**



■ **Default Setting: Off**



European Union Directive Conformance Statement

Hereby, SD Biosensor declares that SD MultiCare 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 Directives 1995/5/EC(R&TTE) Directive at www.sdbiosensor.com.




WARNING: 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 Part 15 of the FCC Rules. 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:

- 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.

 NOTE	<p>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:</p> <ul style="list-style-type: none"> • 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 <p>Caution: Any changes or modifications to this device not explicitly approved by manufacturer could void your authority to operate this equipment.</p> <p>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.</p> <p>This equipment should be installed and operated with minimum 20 cm between the radiator and your body.</p>
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STEP 3. Insert a code chip

HbA1c Test Strip

***03MA10**

Coding

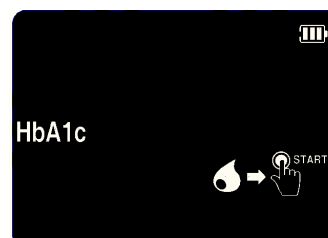
The code chip provides the analyzer with important information on the production-specific properties of the respective test strip to measure your results accurately. The code chip is required at least when a new test strip kit is opened. Before you use your analyzer with a new of test strips for the first time, you should set the analyzer to “match” the strips.

If the code chip is not matched with the test strip, E-9 error is displayed.



Code Setting

1. Make sure the analyzer is turned off. Remove old code chip if one is installed.
2. Insert a new code chip until it snaps into place.
3. Turn the analyzer ON. A 3-digit code number of inserted code chip and the appropriate parameter name appear with flashing test strip symbol. This number and parameter name must match the information provided in test strip kit. If it does not, repeat steps the above 1~2.



- Do not forget to have the code chip, which is supplied with each new test strip external packaging before performing the first measurement.
- Each code chip belongs to one particular test strip external packaging. If possible, store the test strip together with the code strip in the external packaging.

2. Preparing a measurement

SD MultiCare™ testing system

- SD MultiCare™ analyzer
- Test strips for the desired measurements with the related code chip:
 - SD MultiCare™ HbA1c
- Lancets and Lancing device
- 5uL & 200uL mini pipette(only for HbA1c)
- Alcohol swab, if required

Only use SD MultiCare™ test strips. Using other test strips with this analyzer can cause inaccurate results.

Precaution

Always ...

- Read the test strip package insert.
- Operate the analyzer at the acceptable test-specific temperatures 18~32°C
- Place the analyzer on a level surface.
- Keep the guideline for clean
- Make sure that all display elements are displayed

Never ...

- Use test strips beyond the expiration imprinted on kit because they may cause inaccurate results.
- Touch or remove the test strip during actual measurement (although this is possible before starting the measurement when blood is applied outside the analyzer).
- Subject the analyzer to sudden movements during a measurement.
- Reuse the test strip applied either blood or control solution.
- Store the analyzer and strips at extreme temperatures
- Store the analyzer and test strips under humid or damp conditions without suitable protection

CAUTION

Not following these precautions can lead to inaccurate results.

Getting a Drop of Blood

Sample material

***03MA10**

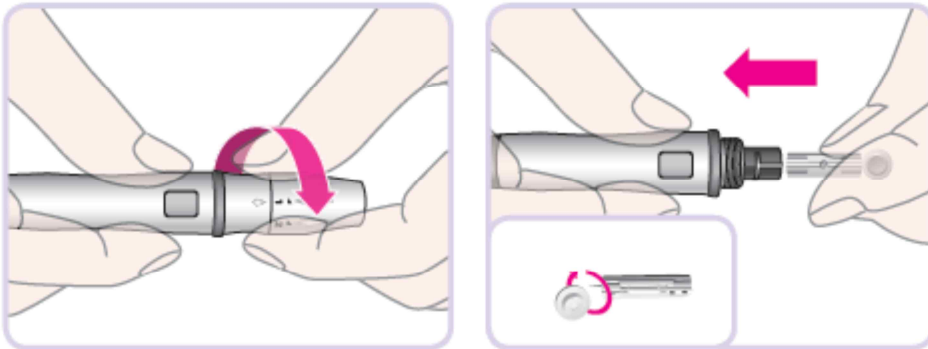
Fresh capillary blood or venous blood drawn in heparin tube is used as sample material. You need a free hanging blood drop for measurement.

For more information on sample material and use of heparinised blood, please refer to the related test strip package insert.

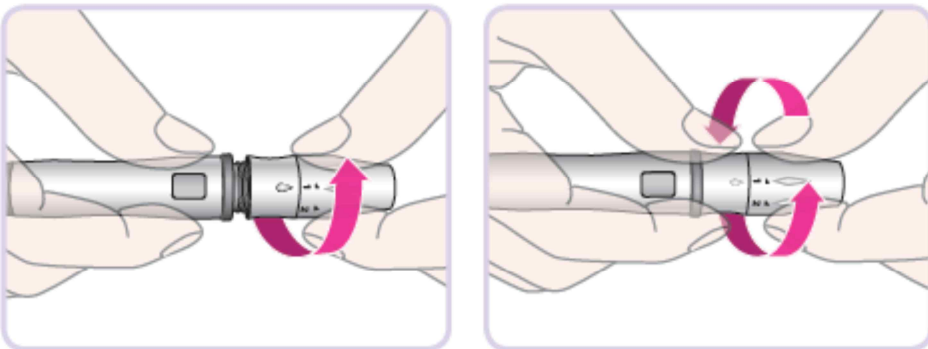
Capillary Whole Blood

***03MA10**

1. Wash your hands in warm, soapy water. Rinse well and dry completely. Warming fingers can increase blood flow.
2. 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.



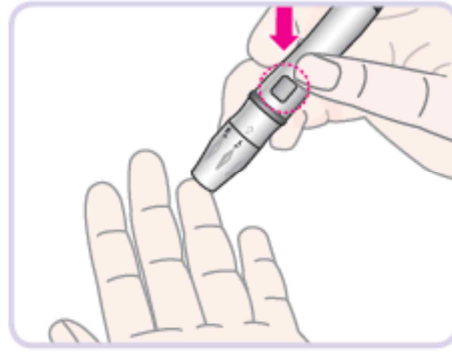
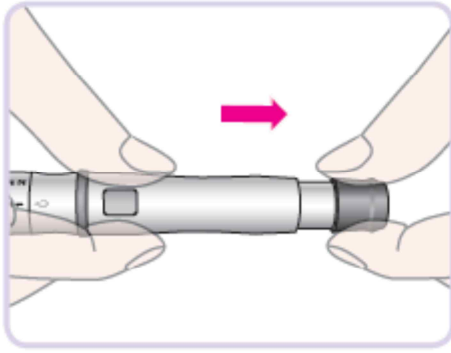
3. Replace the cap and turn it clockwise, until it is snug. Adjust the puncture depth setting by turning the comfort dial. The dial has 1 to 5 steps, and the higher the step number, the stronger the blood sampling pressure on the puncture site.



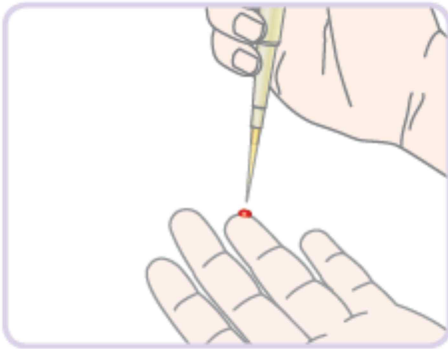
The comfort tip offers 5 different levels of skin penetration.

- 1-2: for soft or thin skin
- 3: for average skin
- 4-5: for thick or callused skin

3. After cocking the lancing device back, hold the lancing device firmly against the side of finger and then press the release button.



4. Get blood sample by using the micropipette.



5. Performing a HbA1c Test

Testing for HbA1c

Switching on the analyzer

1. Place the analyzer on a level surface. Switch on the analyzer by pressing the **Enter button** or insert a HbA1c test strip.
2. In case of the analyzer has had a code chip for the specific HbA1c after power on, it will enter the appropriate testing mode for the inserted code chip. Otherwise, for 03MA10 it will display the following warning message, but for 03MA10G it will automatically enter the glucose testing mode.



Performing a measurement

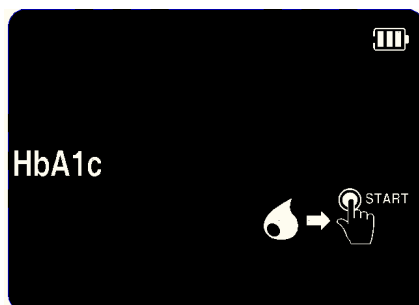
Check the following displays before performing the measurement:

- 1 Are date and time correct?
- 2 Does the battery symbol or DC plug symbol appear?
- 3 With HbA1c test strips, check the reaction area for discolouration before starting measurement. If you detect discolouration, this test strip is unusable. For detailed information, see the insert of the respective test strip.

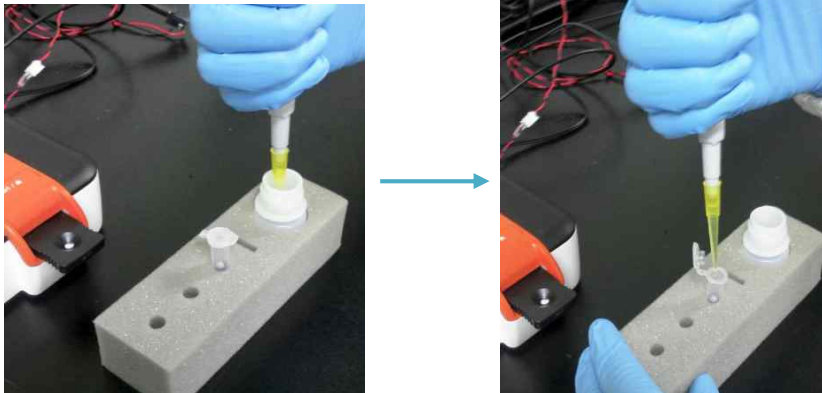
1. Prepare a test strip for the required measurement. Check the expiry date of the test strip. Always use test strips before their expiry date has passed.
2. Hold the test strip with thumb and index finger so that blood apply part is facing upwards.



3. Insert the test strip into the HbA1c Test Strip Slot of the analyzer. When the test strip reaches the correct position, Strip is automatically inserted deeper to the analyzer. If the strip is normal for test, the blood and **START** button icon displays. This is blood waiting state.



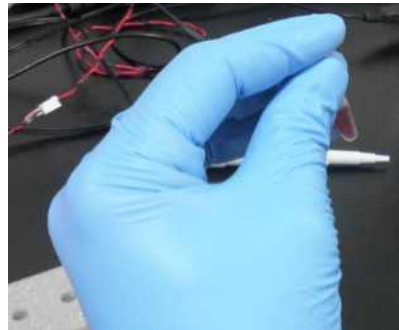
4. With using 200uL mini-pipette, apply the buffer solution from the buffer bottle to the reagent tube



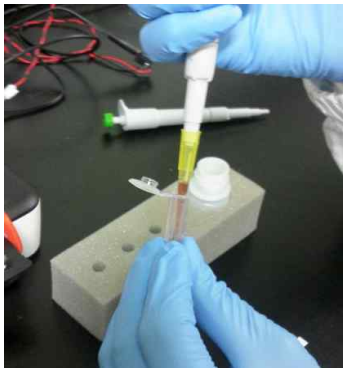
5. Prepare capillary blood with using lancet or venous blood. And with using 5uL mini-pipette, apply the blood to the reagent tube.



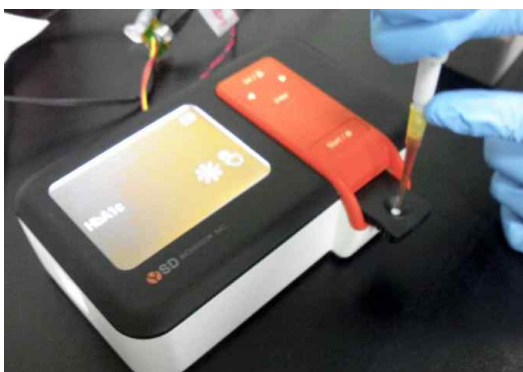
- Put a lid on the reagent tube, and shake well 6~8 times to mix the blood and reagent with the buffer



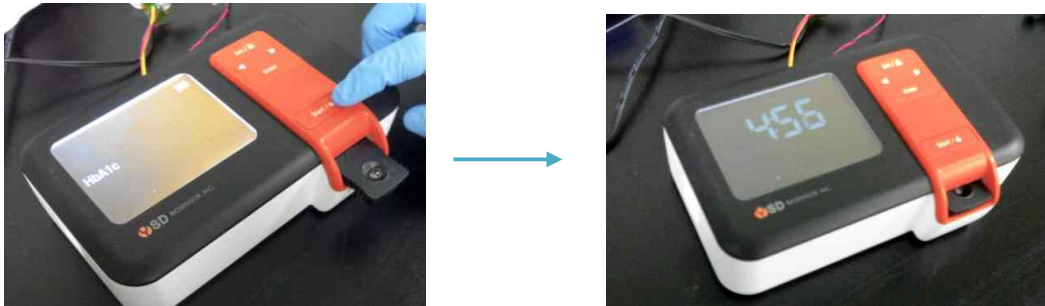
- With using 200uL mini-pipette, collect 200uL solution from the reagent tube



- Apply 200uL solution to the strip



9. Push the **START** button



10. Your result appears on the display in 3~5 minutes.



When the test is done, pull out the used test strip. The analyzer shuts off automatically after you remove the test strip.

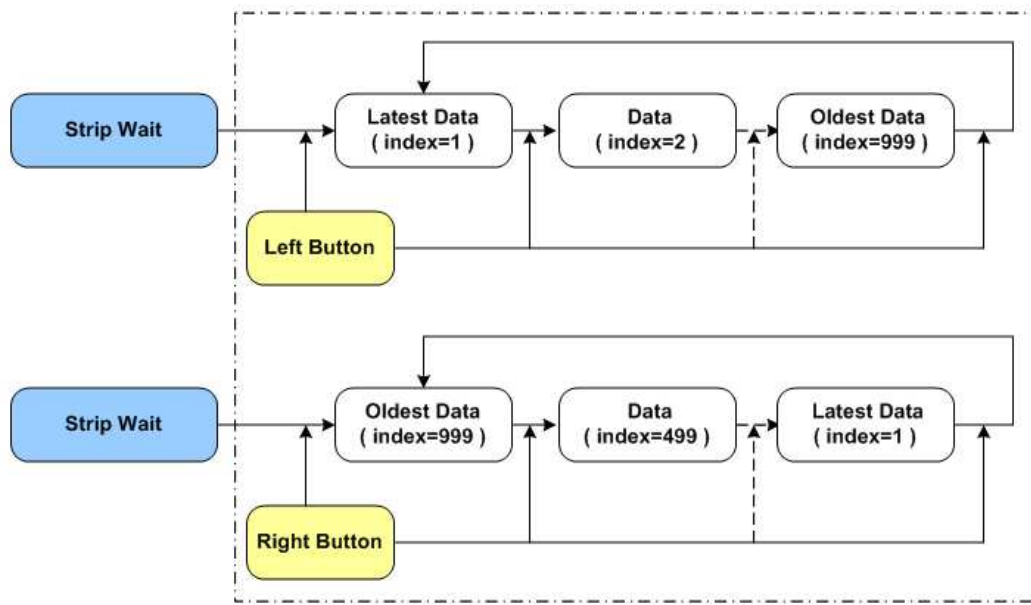
CAUTION

Discard the used test strips in proper container, according to your standard laboratory procedures.

CHAPTER 3. Using the Analyzer Memory

1. Memory Map

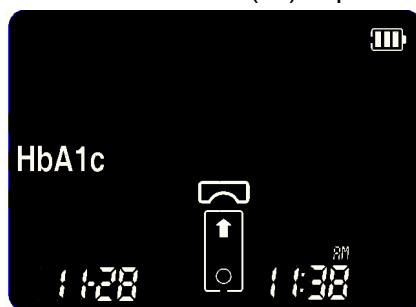
The SD MultiCare™ analyzer has 1000 measured values together with date, time and flags letting your review them in order from the most recent to the oldest. If the memory is full and a new result is added, the analyzer deletes the oldest result.



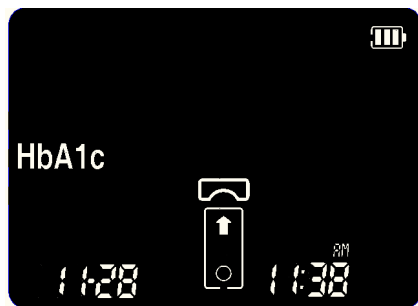
2. Displaying stored measured values

1. Switch on the analyzer, then press ◀ or ▶ button in display mode flashing HbA1c test strip symbol to enter memory mode.

(1) When **Left Button** (◀) is pushed, the latest data shows



(2) When **Right** Button (▶) is pushed, the oldest data shows



(if total number of test is 999)



3. Delete Memory

You can delete each data in memory review

To delete the displayed data, press **Enter button** during 2 seconds.

Then the delete confirm message show, and press **Enter button**.

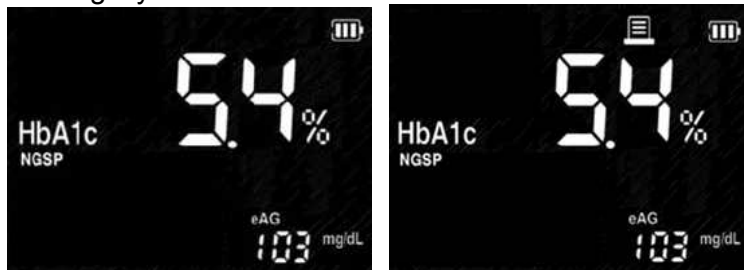
If you don't want to delete the data in message show state, press **Left** or **Right button**



CHAPTER 4. Printing

How to Print

1. If you press **SET/PRT** button in any memory mode, then print the results with flashing 'Printing' symbol.



2. If you set Auto Printing function in setting mode, always display flashing 'Printing' symbol.



3. If you select one copy function in setting mode, the analyzer prints only one copy in printing mode. If you select two copy, the analyzer automatically print two copies.



Print one copy function



Print two copy function

CHAPTER 5. Data transfer

Results can be downloaded from memory via USB interface.

For more information on downloading results to a suitable system (such as a PC), please call your local customer support and service centre.

The analyzer displays the following during data transfer.



CHAPTER 6. Control Solution Test

1. Control Solution Test

It is important to perform Control Tests with more than one level of Control to assure your System is working properly and your testing technique is good.

Why you should do a control solution test;

- SD 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 SD control solution

- If you leave the cap off the container of test strips.
- Before using your analyzer for the first time.
- To check the test strips when you open a new strips vial or packaging.
- If you drop the analyzer.
- Whenever your result does not agree with the way you feel.
- If you have repeated a test, and the result is still lower or higher than expected.
- When you want to check the performance of a analyzer and test strip.

Before you begin;

- Use only SD Control Solution.
- Check the expiration date on the control solution container. Record the opening date on the container label. Do Not use after expiration or discard date (date opened plus three months), whichever comes first.
- Shake the container, discard the first drop of control solution, and wipe off the tip to ensure a proper sample and an accurate result.

CAUTION:

- 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 HbA1c strip

To ensure that the analyzer is functioning properly, you should regularly use control solution for a control check. Make a habit of carrying out a control check in the following situations:

- When you open a new test strip packaging.
- After replacing the batteries.
- After cleaning the analyzer.
- When you doubt that the measured values are correct.

A control check is performed in the same way as a regular measurement with the difference that control solutions are used instead of blood.

What you need:

- Your SD MultiCare™ analyzer
- Test strips for the desired measurements with the related code strip:
- Control solutions for the respective test parameter
 - SD MultiCare™ HbA1c Control

Preparing to perform a control check

1. Prepare the test strip container for the HbA1c measurement
2. Make sure the code strip belonging to these test strips is at hand (unless the analyzer has already been coded for this test strip container).
3. Prepare the control solution matching the test strips. The following description assumes that the analyzer has already been coded for the test strips used here.

3. 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, do the test again. Insert a test strip; Press the ► button for 3 seconds to display a control solution container icon.
Have the test strips and/or control solution expired?	Make sure that test strips and control solutions are not past expiration date. This date is shown the container/bottle. Make sure containers have not been open for more than 3 months.
Were glucose control solutions at room temperature (18-32°C, 64-88°F) when used?	If not, retest with new bottle of glucose control solution, or warm up/cool down to room temperature. (18-32°C, 64-88°F)
Did you insert test strip firmly into analyzer?	Make sure test strip is inserted into the test strip slot until it will go on further.
Did you follow the procedure correctly?	Read the instruction for use again and retest.
Were test strips stored correctly?	If not, retest with a new test strips.
Is the analyzer damaged? Does it show an error code?	If yes, contact SD Customer Care Service Center Tel: at 82-80-977-9700
Is the control result outside the appropriate acceptable range?	Repeat the test. If you get the same results, do not use your analyzer and test strip until you solve the problem. If you still have problem, call the SD Customer care service center at 82-80-977-9700

CHAPTER 7. Performing a SD Check Strip Test

When should I check my analyzer using a SD Check Strip?

- When you want to easily check the performance 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.

CAUTION:

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

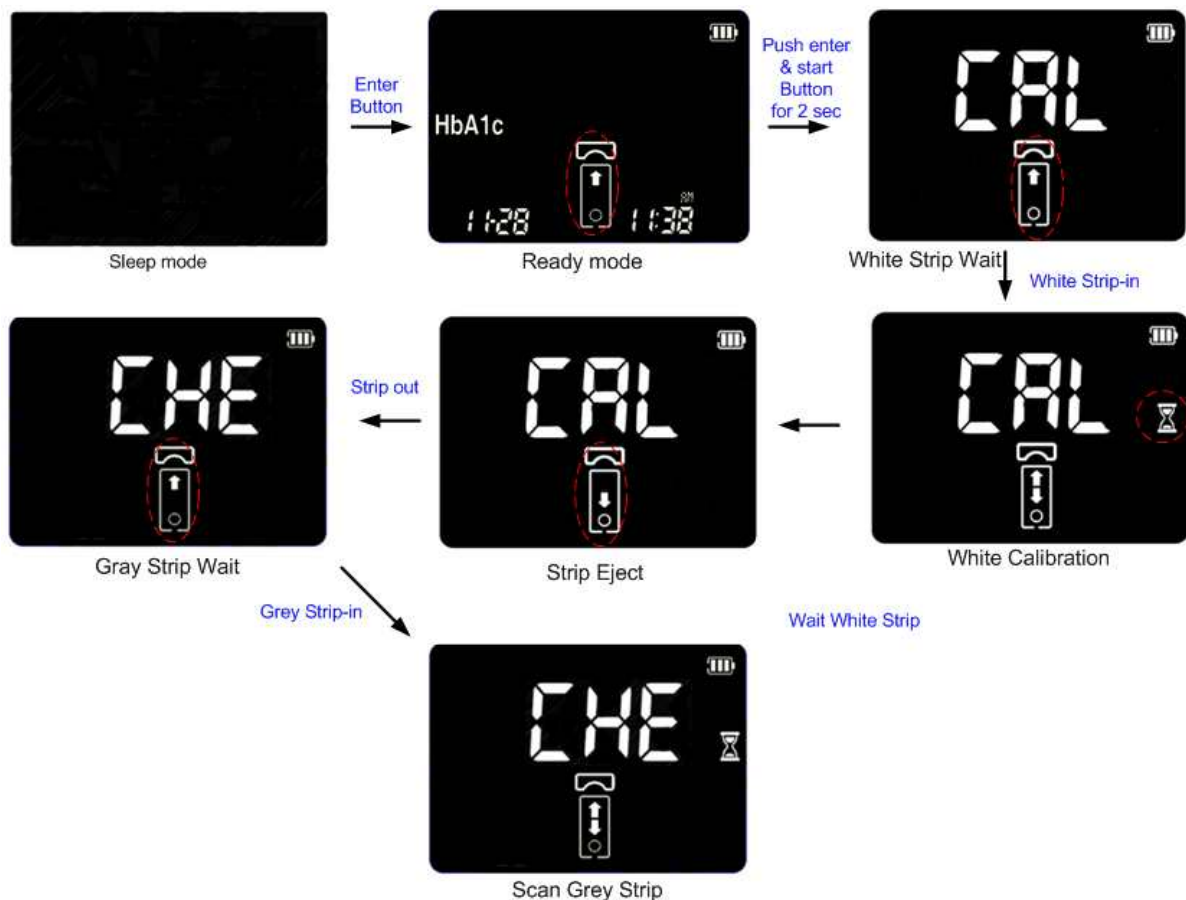
1. How to Use the SD HbA1c Check Strip

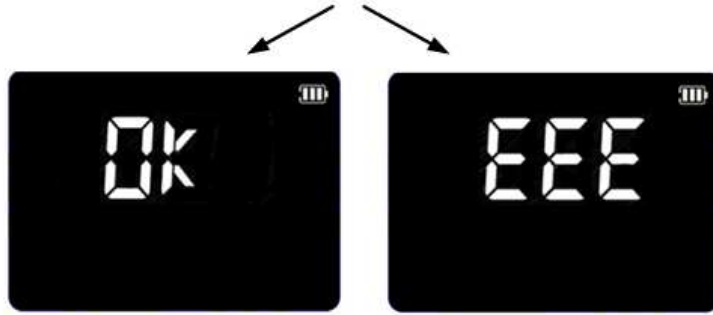
Before you insert the SD check strip to the analyzer, you have to press the **Enter** and **Start button** at the same time during 3 seconds in blood wait state.

Then 'CHE(Check)' is displayed, you can insert the check strip to the analyzer.

SD HbA1c check strip test take 15 seconds.

If the analyzer displays 'EEE', the analyzer has a problem. Call the SD Customer care service center at 82-80-977-9700





If measured value is within a range, OK

If measured value is not within a range, EEE

CHAPTER 8. Maintenance and Troubleshooting

1. Cleaning your Analyzer

Caring for the SD MultiCare™ analyzer is easy. Just keep it free of dust. If you need to clean it, follow these guideline carefully to help you get the best performance possible;

To prevent malfunction of the analyzer, keep the test strip port free of blood, moisture, dirt, or dust. Use a lint-free cloth dampened with water to clean analyzer. Thoroughly wring out cloth before use. 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

Mild soap suds as well as 70 % ethanol or isopropyl alcohol are suitable for cleaning.

When used in the professional sector (e.g. doctor's surgeries), a mixture consisting of 1-propanol, 2-propanol and glutaraldehyde (brand name "Bacillol plus") is recommended.

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. In the professional sector, the outside of the analyzer can be cleaned with "Bacillol plus".

2. Maintenance, Testing and Transportation

The analyzer needs little or no maintenance with normal use. It automatically tests its own systems every time you turn it on and lets you know if something is wrong. If you drop the analyzer or think it is not giving accurate results, make sure that your test strips and control solution haven't expired, and then run a control test.

Analyzer

1. Keep the test strip slots free of dust.
2. Protect the internal analyzer from humidity.
3. The carrying case is designed to let you store a variety of supplies you may need and helps to protect your analyzer.
4. The temperature and humidity of the analyzer during transport and storage are -4-140°F (-20-60°C) and 15%-95% RH, non-condensing.
5. If you keep the analyzer with the battery inserted, then keep it in a low humidity environment.

Test Strip

1. Store at room temperature of 20~30°C (68~86°F) for HbA1c test strip package and 2~32°C (36~90°F) for glucose.

2. Strips may be stored in a refrigerator at 2~8 °C (35~46 °F), but must be brought to room temperature before using. Do not freeze.
3. Keep away from heat and direct sunlight.
4. Keep the code chip either in the analyzer or stored with other strips and do not store the code chip in the HbA1c test strip package.
5. The glucose test strip container closes tightly and can protect the glucose test strips, so you should keep the unused glucose test strips in the container in which they came.
6. Use test strip as soon as you have removed it.

Lancet and Lancing device


1. The needle of lancet is sharp, keep the lancet away from children.
2. Keep the lancet and lancing device dry and do not store in direct sunlight, or high heat and humidity locations.
3. A lancet should not use for the other intended use except sampling blood.
4. A lancet is for single use only. Do not reuse.
5. A lancet provided with the SD MultiCare™ Blood glucose analyzer is able to use every lancing devices manufactured by other company. But if at all possible, use the lancing device manufactured by Standard Diagnostics, Inc.
6. Before using, check a packaging condition, if there is any problem, you should not use it.
7. If a lancet protective disk is loosed or needle of a lancet is exposed, you should not use it.
8. To reduce the chance of infection for the used lancet, discard it.


Control solution

1. Do not use SD Control Solution that has passed the expiration date.
2. Keep the SD Glucose Control Solution in 46-86°F (8-30°C) environments.
3. Do not refrigerate or freeze.
4. The SD glucose Control Solution can be used for 3 months after opening the container. Write the opened date on the SD Control Solution container when you first opened.
5. No reconstitution or dilution is necessary.
6. Wipe the container tip clean and reseal the container tightly after each use.

CHAPTER 8. Screen Messages and Troubleshooting

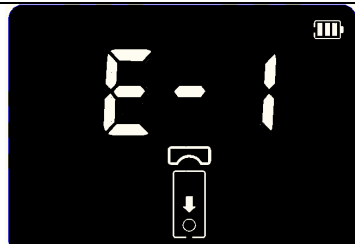
1. Warning messages

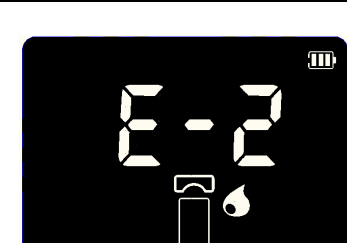
Indication	Warning description
	<p>Warning: Low Battery At this time, battery is getting low but you can still perform about 10 tests.</p>
	<p>Solution Replace the battery soon.</p>

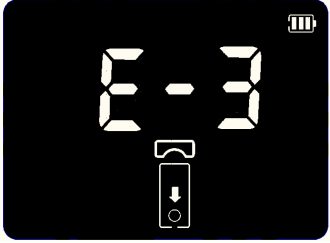
Indication	Warning description
	<p>Warning: Replace Battery Battery power is low. If you press the Enter button after discharging of the battery, the battery icon will flash and then after ten seconds the analyzer will turn off automatically.</p>
	<p>Solution Replace the battery immediately.</p>


2. Error messages

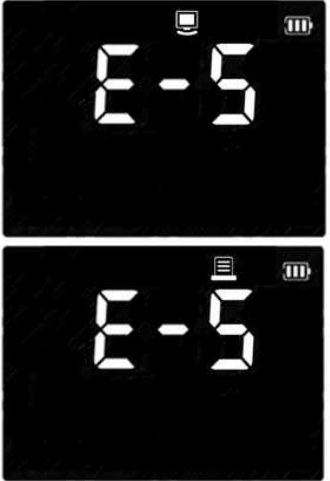
In certain circumstances error messages may appear on your display. Generally, you should first try the solutions suggested for the respective error. If the problem persists, please contact your local customer support and service centre.

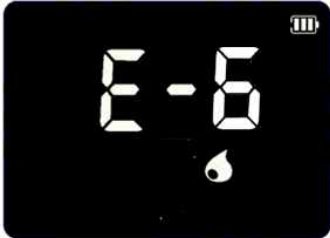
Indication	Error description
	<p>Error: Strip Error Defective test strip or the test strip is damaged or inserted improperly.</p>
	<p>Solution Discard this test strip and test again using a new test strip.</p>

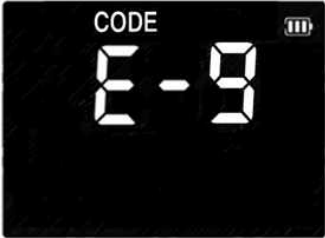
Indication	Error description
	<p>Error: blood sample Error An insufficient amount of blood was applied.</p>
	<p>Solution Discard this test strip and test again using a new test strip with a larger sample, making sure blood is placed to the narrow channel in the top edge of the test strip.</p>


Indication	Error description
	<p>Error: Expired strip The test strips are expired.</p> <p>Solution Discard this test strip and test again using a new test strip does not past expiration date.</p>

Indication	Error description
	<p>Error: Temperature Error Unknown barcode If the environmental temperature is above or below the operating range of a analyzer, a thermo analyzer icon will appear on the display.</p> <p>Solution Move to an area at 68-88°F (18-32°C), and perform a test. Do not artificially heat or cool the analyzer.</p>

Indication	Error description
	<p>Error: Communication Error The communication between analyzer and computer or printer is failed.</p> <p>Solution Connect again between analyzer and external device. If the error continues turn off an analyzer. Then turn on the analyzer again. If there is still error message, please contact STANDARD DIAGNOSTICS, INC. TEL: 1-877-882-3695.</p>

Indication	Error description
	<p>Error: Extremely low Total hemoglobin If the measured total hemoglobin is under 7g/dL,</p>
	<p>Solution Connect again between analyzer and external device. If the error continues turn off an analyzer. Then turn on the analyzer again. If there is still error message, please contact STANDARD DIAGNOSTICS, INC. TEL: 1-877-882-3695.</p>

Indication	Error description
	<p>Error: Communication Error with code chip The analyzer cannot communicate to the inserted code chip. And the code chip is not matched with proper test strip.</p>
	<p>Solution Re-insert the code chip. If there is still error message, please contact STANDARD DIAGNOSTICS, INC. TEL: 1-877-882-3695.</p>

Indication	Error description
	<p>Error: Internal Error Message for a analyzer It happens to internal error not to work.</p>
	<p>Solution Turn off and then turn on the analyzer again. If there is still error message, please contact SD Biosensor, inc. TEL: 82-80-977-9700.</p>

CHAPTER 9. Warnings, Precautions and Limitations

1. Test Strip

- Make sure the Code Chip and test strip lot numbers match. Never use a Code Chip from a different lot than the test strip.
- Out-of-date or expired strips cannot be used in your test system. Check package for expiration date.
- Add all of the blood the test strip at one time. If you do not get all of the blood on the strip, do not add blood to the same strip. Test again with a new unused test strip and fresh blood sample.
- Discard test strip after using. Strips are to be read once. Never insert or read a used test strip.
- Discard the used test strips in proper container, according to your standard laboratory procedures
- Do not ingest.

CHAPTER 10. Product Technical Information

1. Analyzer Specifications

ON/OFF Source	Four batteries (1.5 V, AA)
Battery Life	Around 200 tests
Display	LCD (240x160 dots)
Controls	5 Buttons(SET/PRT, Enter, Arrow: ◀/▶, Start/Eject)
Memory	999
Automatic Shutoff	<ul style="list-style-type: none">• 1 minutes 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 HbA1c

Result Range	4.0~ 14.0%
Sample	Fresh capillary whole blood or venous blood
Sample Size	5uL
Test Time	3~5 minutes
Test Strip Storage Temperature	°C – °C (68°F – 86°F)

* CRP, u-ALB, and CRT's information is referred to the test strip package

3. 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.

Annex 1: Information for Healthcare Professionals

Protection against infections

***03MA10**

There is a potential risk of infection. Medical staff using the SD MultiCare™ 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 test strips in a clinical waste bin.
- Follow all other locally applicable guidelines and regulations on health and safety.

Annex 2: References

1. American Diabetes Association, Clinical Practice Recommendation Guidelines 2003, Diabetes care, Vol. 26. Supplement 1. p.22
2. Stedman, TL. Stedman's Medical Dictionary, 27th Edition, 1999, p. 2082.
3. Ellen T. Chen, James H. Nichols, Show-Hong Duh, Glen Hortin, MD: Diabetes Technology & Therapeutics, Performance Evaluation of Blood Glucose Monitoring Devices, Oct 2003, Vol. 5, No. 5: 749 -768

Annex 2: Supplies and Accessories

The following supplies and accessories are available from SD Biosensor, Inc. or the distributor.

ITEM	Details
Analyzer	SD MultiCare™ Analyzer (without Glucose Module)
Strip	SD MultiCare™ test strip (25T x individual pouch)
Control Solution	SD MultiCare Control Solution
Lancet	Lancets (100ea x 1 box)

Warranty

You are a valued customer of Standard Diagnostics, Inc. It is important to us that you are completely satisfied with your SD MultiCare™ Analyzer. Standard Diagnostics, Inc. warrants your SD MultiCare™ Analyzer will be free from defects in materials and workmanship for a period of three years from the date of original purchase. If during this time the analyzer does not work properly because of a defect in materials or workmanship, Standard Diagnostics, Inc. agree to replace or repair, free of charge any and all parts proven to be defective and subject to warranty. This warranty is in lieu of all other warranties, expressed or implied, including any implied warranty of merchantability of fitness for any purpose, other than stated herein. This warranty does not apply to the performance of the SD MultiCare™ analyzer that has been damaged by accident or has been altered, misused, tampered with, or abused in any way. This warranty only applied to the original purchaser of the analyzer and/or its agents.

Return

You must contact SD Biosensor Customer Service at 82-80-977-9700 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.

Disposal

The Analyzer must be disposed according to the local regulations concerning the disposal of electrical and electronic equipment.

The Waste Electrical and Electronic Equipment (WEEE) regulation implement provisions of the European Parliament and Council Directive 2002/96/EC aimed to reducing the amount of EEE waste going for final disposal.

Please contact our representatives in your area for the respective instructions before disposing.

Manufactured by

SD Biosensor, Inc.

C-4th&5th, 16, Deogyong-daero, 1556 beon-gil,
Yeongtong-gu, Suwon-si, Gyeonggi-do, 443-813,
Republic of Korea

www.sdbiosensor.com