P

Diabetes Management Technology

CLOVER® A1c®
Analyzer

INSTRUCTION FOR USE

For measuring Hemoglobin A1c

CE IVD

NGSP

IFCC International Federation of Clinical Chemistry and Laboratory Medicine

OSANG Healthcare

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TABLE OF CONTENTS

1. INTENDED USE

The ***CLOVER A1c***® analyzer is an IVD(In Vitro Diagnostic Device) device for measuring Hemoglobin A1c by the well established method of boronate affinity. It is able to analyze both capillary whole blood and venous blood. Anticoagulants may be used, such as EDTA(ethylenediaminetetraacetic acid) and heparin etc. This ***CLOVER A1c***® system is designed to help controlling diabetes and it is intended to be used by professionals in laboratories, clinics and hospitals. Same as all diagnostic tests, do not make a definitive diagnosis of diabetes based on the result of
a single test. A physician should make a diagnosis after all clinical and laboratory findings are evaluated.

2. General Information

The ***CLOVER A1c***® Analyzer uses the reflectance spectrophotometer for measuring the Hemoglobin A1c. It is easily validated with the Check Cartridge provided with the Analyzer kit for quality assurance.

The Analyzer also includes a DC 9 V, 2A adapter. Using other adapters may affect the analyzer and give inaccurate test results.

Calibration

The ***CLOVER A1c***® Analyzer has been programmed to produce results that are standardized to DCCT (Diabetes Control and Complications Trial).

The DCCT is a landmark multi-center trial which conclusively linked elevated HbA1c level to the complications associated with Diabetes.
The DCCT showed the importance of improved glycemic control in reducing the risk and progression of the complications of diabetes. Glycemic control was determined by the measurement of Hemoglobin A1c. The ADA (American Diabetes Association) recommends measurement of the Hemoglobin A1c levels of two to four times per user, with less frequency in patients with stable control, and more frequency in patients with unstable control.

3. Principles of Operation

3.1 Reflectance Spectrophotometry

The ***CLOVER A1c***® system is a fully automated boronate affinity assay for the determination of the percentage of Hemoglobin A1c(HbA1c%) in whole blood.
The ***CLOVER A1c***® system Test Cartrideg includes a cartridge and reagent pack.

The reagent pack is pre-filled with reagent solution and rinsing solution. The reagent solution contains agents that lyse erthrocytes and boronate bead that binds cis-diols of glycated hemoglobin.

The blood sample (4μL) is collected at the sampling area of the reagent pack.
The reagent pack is then inserted into the cartridge, where the blood is instantly lysed releasing the hemoglobin and the boronate resin binding the glycated hemoglobin.

The blood sample mixture is rotated to the measurement zone of the cartridge, where the amount of total hemoglobin in the blood sample is measured by the reflectance of the photo sensor, which consists of LED (Light Emitting Diode) and PD (Photo Diode).

The cartridge is then rotated so that the rinsing solution washes out non-glycated hemoglobin from the blood sample, thus the amount of glycated hemoglobin can be photometrically measured.

The ratio of glycated hemoglobin with respect to total hemoglobin in the blood sample is calculated.

3.2 calculation of Results

$$\text{HbA1c\%} = A \times \left[\frac{\text{HbA1c}}{\text{Total Hemoglobin}} \times 100 \right] + B$$

'A' and 'B' are the slope and intercept factor to correct the value for DCCT calibration.

4. CLOVER A1c® Contents

Upon receipt of the product, carefully inspect for any obvious physical damage.If any damage is evident to the ***CLOVER A1c®*** Analyzer, please consult our authorizedrepresentative in your area.

Contents

1. ***CLOVER A1c®*** Analyzer
2. Instructions for Use
3. Exclusive Power Adapter
4. Fan Filters
5. Daily Check Cartridge
6. Monthly Check Cartridge

5. Storage Instructions

The ***CLOVER A1c®*** Analyzer must be stored at temperatures between 10°C~35°C (50~95°F). Test Cartridges must be stored between 2~32°C (36-90 °F) and at a relative humidity between 10% to 90%.

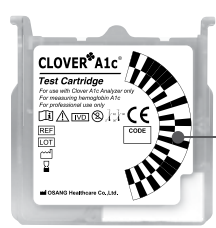
WARNING:
Do not modify this equipment without authorization of the manufacturer.

6. Device Description

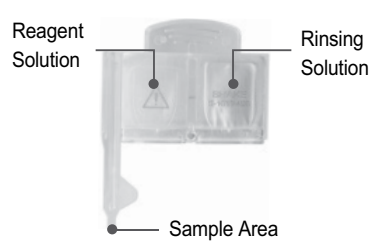
6.1 Analyzer

6.2 Test Cartridge

[Cartridge]

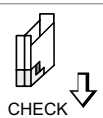
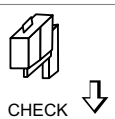
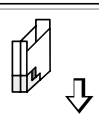
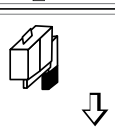


[Reagent Pack]

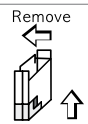


CAUTION:
Do not touch the cartridge code area. Fingerprints and scratches may affect the recognition of cartridge barcode.

7. LIST OF ICONS

Icon	Name	Function
Warming up	Warming up	It is displayed on the analyzer LCD once it is powered on.
	Open the lid	Open the lid of the analyzer.
	Insert Check Cartridge	Analyzer is under 'Check Mode'. Insert Check Cartridge into the analyzer.
	Insert Check Reagent Pack	Insert Check reagent pack into the analyzer.
	Insert Test Cartridge	Insert Test Cartridge into the analyzer.
	Apply sample to sample area	Apply sample to sample area of reagent pack.
	Insert Reagent Pack	Insert reagent pack with sample into the analyzer.

7. LIST OF ICONS

Icon	Name	Function
	Close the lid	Close the lid of the analyzer.
	Remove cartridge	Remove the cartridge from the analyzer.
	PC Connection	Indicates that the analyzer is connected to a PC.
	Printer	Indicates that the thermal printer use is active.
	Memory	Select this icon to view the test results in memory.
	Set up	Select this icon to set up the analyzer.

8. INSTALLATION

Overview

This section provides detailed installation instructions for the ***CLOVER A1c®***.
You must follow the installation steps correctly to ensure proper installation, operation, and service.

CAUTION
Do not drop or handle the system roughly. This can disturb internal calibrated optics and electronics or cause other damages.
Always handle the system with care. The ***CLOVER A1c®*** Self is a precision system and must be handled accordingly.

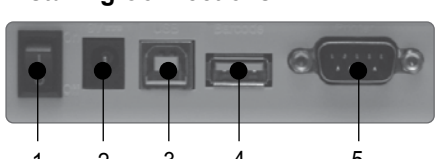
Place the system where it will not be subjected to extreme temperature variations. Avoid proximity to open windows, direct sunlight, ovens, hot plates, open burners, radiators and dry ice baths.

Do not place the ***CLOVER A1c®*** on the same bench with a source of vibration.

Provide bench space large enough to allow free air circulation around the system - 8cm (3 inches) on all sides.

Your ***CLOVER A1c®*** is delivered in 1 shipping carton.
1. Carefully remove the contents of the shipping carton.
2. Inspect the carton and system for visible signs of damage.
3. If damage to the system exists, immediately file a complaint with the carrier.
4. Make sure all items are included with your system, and keep them for future use.

Installing Connections



System Connections:
1. Power Button
2. DC 9V adapter port
3. USB port (PC connection port)
4. Barcode Scanner port
5. Thermal Printer port (Serial port RS 232)

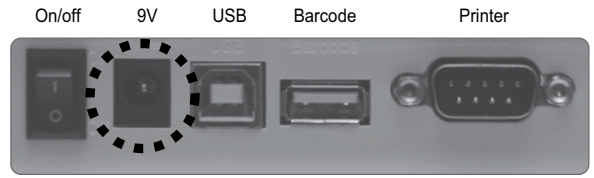
Connect the System Power

1. Ensure that the system power button is in the off position.
2.Connect the power code of the system to appropiately grounded AC electrical outlet.

9. OPERATION

9.1 Power On

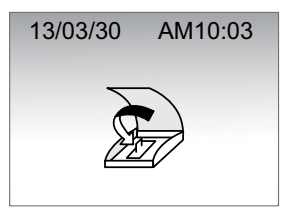
Connect the DC 9V adapter to the power port on the back side of the analyzer.



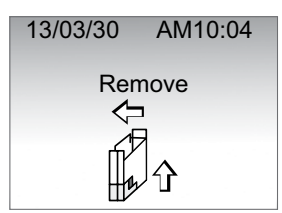
Make sure that the lid is closed before connecting the adapter.

After the system is properly installed, you can start the ***CLOVER A1c®***.

To start the ***CLOVER A1c®***, turn the power switch to the 'ON' position.



If the lid is open, the icon of "Close the lid " will be displayed.
Close the lid, and the warming up will start.



If the cartridge is inserted, the icon of "Remove the cartridge" will be displayed.
Remove the cartridge and close the lid.
Warming up will start.

9. OPERATION

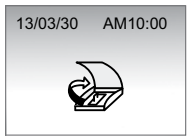
9.2 Warming up

When the power is connected, the displays shows 'Warming up' until the device is ready for test.
Warming up will take approximately 5 minutes depending on the ambient temperature.

While warming up, the ***CLOVER A1c***® performs hardware functionality test to verify that the internal optics and the mechanical system are operating correctly.

9.3 Stand-by

After warming up, the analyzer goes into 'Stand-by' mode.



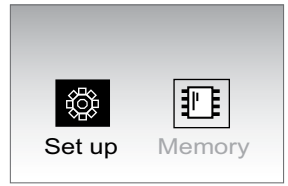
Note: The analyzer will automatically go into 'stand-by' mode after a test.

9.4 Power Save

After 30 minutes in 'stand-by' mode, without any action, the Analyzer goes into 'Power Save' mode.
To Return to 'Stand-by' mode, press ⏻ shortly, or just open the lid for testing.

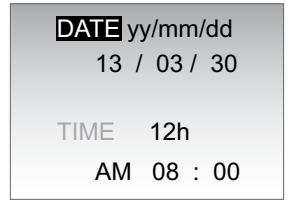
10. SETTING THE ANALYZER

Getting into set up mode



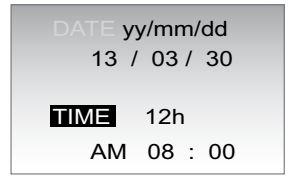
In stand-by mode, press the ⏻ button and hold for 3 seconds. Choose between set up and memory mode by pressing ▲ or ▼ buttons. Then, press ⏻ button to select.

Date



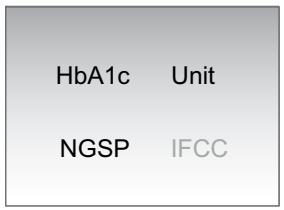
Select the date format ('yy/mm/dd' or 'mm/dd/yy' or 'dd/mm/yy') by pressing the ▲ or ▼, then press ⏻ Next, set the date by pressing the ▲ or ▼ bottens. You may hold the arrow keys to scroll through the dates faster.

Time



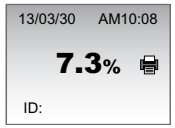
Select the time format by pressing the ▲ or ▼ buttons, then press ⏻. 12h for standard time / 24h for military time

HbA1c test result unit

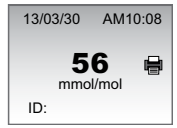


Select the desired HbA1c test unit by pressing the ▲ or ▼, then press ⏻.

[NGSP]



[IFCC]



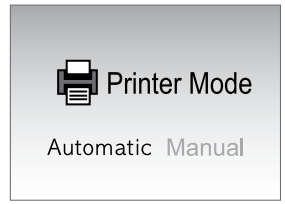
Barcode use

Select whether or not to use the barcode system by pressing ▲ or ▼, then press ⏻

Printer use

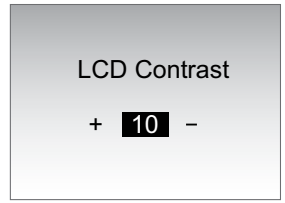
Select whether or not to use the printer by pressing ▲ or ▼, then press ⏻.
If 'Use' is selected, Printer mode option is displayed.
If 'Not Use' is selected, LCD contrast control is displayed.

Printer mode



Once the printer option is selected, choose either 'Automatic' or 'Manual' by pressing the ▲ and ▼ arrows.
• Automatic: Result is printed automatically after each test.
• Manual: Result will only be printed when the print button is pressed.

LCD contrast control



Set up the contrast desired, by pressing the ▲ or ▼, then press ⏻.

PROCEDURE

The ***CLOVER A1c***® test can be performed on capillary blood sample or on venous whole blood collected using K_2·K_3 EDTA, lithium heparin, sodium citrate or sodium fluoride/ oxalate as an anticoagulant.

Test Procedure

IMPORTANT : Please read through and familiarize yourself with the contents of this instruction manual and the ***CLOVER A1c***® System operation before using the system for the first time.

STEP 1.

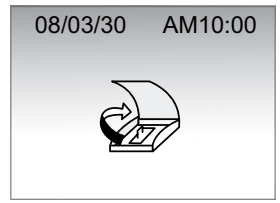
When the power is connected, the display will show 'Warming up' until the device is ready for use. This will approximately 5 minutes depending on the ambient temperature.

While warming up, the ***CLOVER A1c***® performs hardware funtionality test to verify that the internal optics and the mechanical system are operating correctly.

IMPORTANT : Do not move the analyzer during the 'Warming up'.

STEP 2.

Open the lid of the ***CLOVER A1c***® analyzer, when the analyzer is in 'Stand-by' mode, displaying the 'Open the lid' icon.

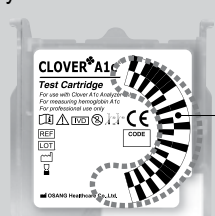


STEP 3.

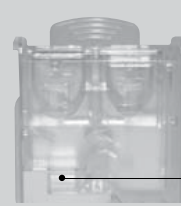
Open the Test Cartridge pouch by tearing the pouch on the side with serrated edge.
DO NOT use scissors to open the pouch
Scissors can damage the reagent pack.

Use the test cartridge within 2 minutes of opening.

CAUTION
When handling the Reagent pack and Cartridge, do not touch the cartridge code area on the front or the bead window at the back. Any contamination of these area may cause of erroneous values.



Cartridge Code Area

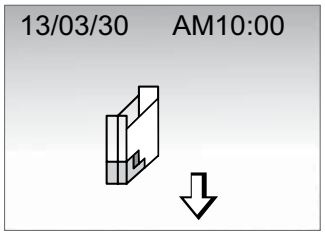


Bead Window

STEP 4.

Gently insert the cartridge into the cartridge compartment when 'Insert Test Cartridge' is shown. Hold the cartridge with barcode facing left.

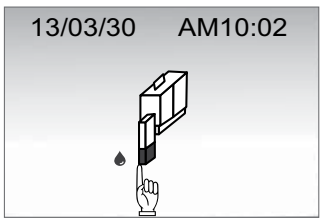
Ensure a gentle snap is either heard or felt to confirm proper placement.

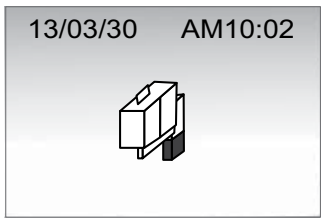


NOTE : Do not force the cartridge into the analyzer. The cartridge is designed to fit only in one way.

STEP 5.

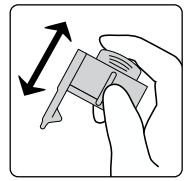
The display will show the ''Apply sample to sample area" and 'Insert Reagent Pack' icon.





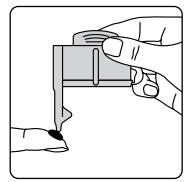
STEP 5-1.

Gently mix the reagent pack 5 ~ 6 times before applying blood sample.



CAUTION : Do not mix too vigorously, it may cause air bubbles. If bubbles are present wait until they disappear before testing.

STEP 5-2.



Apply the blood sample by gently touching the drop of blood with the tip of the sampling area.
Ensure that the sampling area is completely filled.

IMPORTANT : Once the reagent pack is filled with the blood sample, analysis must begin immediately.

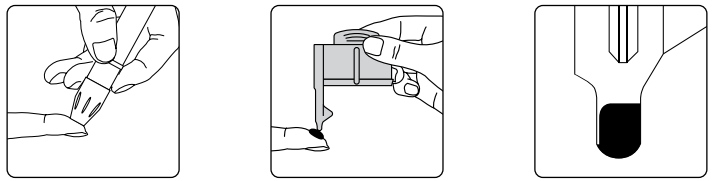
11. TESTING HbA1c

Sample Collection and Handling.

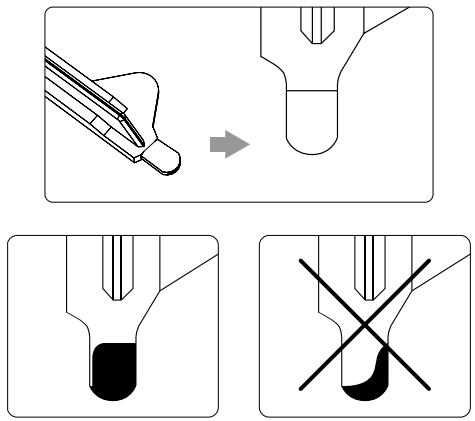
Capillary whole blood obtained from a fingertip can be used for HbA1c test.
A 4uL blood sample is needed for the HbA1c.

- Capillary Blood Process

Prick the fingertip of the patient to get a minimum of 4uL of capillary blood sample, and touch softly the blood sample with the capillary tip of the Reagent Pack. The blood is automatically drawn up. Make sure that the sample area is completely filled.



Sample Collecting Area of Reagent Pack

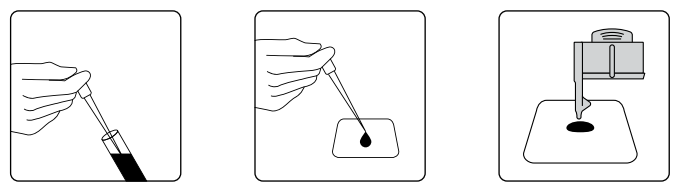


IMPORTANT : Once the reagent pack is filled with the blood sample, analysis must begin immediately.

11. TESTING HbA1c

- Venous Blood Process

Venous whole blood collected in tubes with $K_2 \cdot K_3$ EDTA, lithium heparin, sodium citrate or sodium fluoride/ oxalate as anticoagulants can be used.
Venous whole blood can be stored at 2~8℃ (36~46°F) for 7 days with unbroken seal (only 3 days when seal is broken) and at 20~25 ℃ (68~77°F) for 3 days.
Allow blood samples to reach room temperature. Anti-coagulated blood should be mixed well prior to testing. Remove the stopper from the holder and take out a drop of blood sample on a clean container. Softly touch the sampling area of the reagent pack on the blood sample, and wait until the sampling area is completely filled.



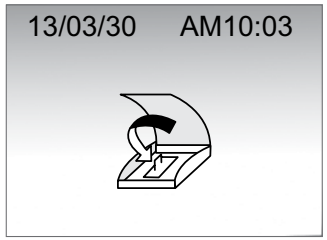
NOTE : Do not wipe off excess blood outside the sampling area.
Do not touch the open end of the sampling area.

CAUTION : There is a potential risk of biological hazard.
All part of the ***CLOVER A1c®*** system should be considered potentially infectious.

- Use gloves.
- Dispose of used test cartridges in a sturdy container with lid.
- Follow all hygiene and safety regulations in force locally.

STEP 6.

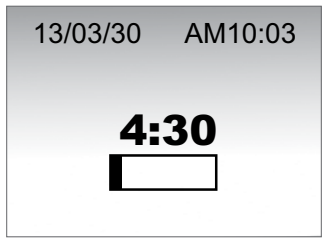
Insert the reagent pack into the cartridge in the analyzer. The 'close the lid' icon will be displayed.



NOTE : Do not force the reagent pack into the cartridge, it will only fit one way.

STEP 7.

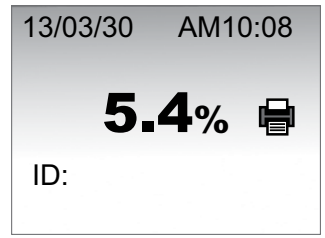
The test starts automatically when the lid is closed.



IMPORTANT : Do not open the lid during test.
Do not vibrate or move the analyzer during test.

STEP 8.

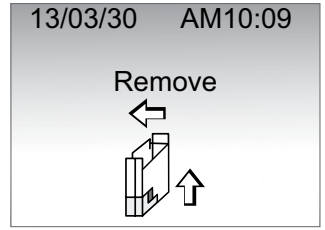
The measuring time is 5 minutes and the test result will be displayed (in % or mmol/mol).

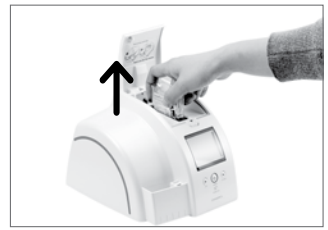


NOTE : If the results ">14%" or "<4%" are displayed, repeat testing to confirm result. If the second result also is outside the range, contact your local distributor.

STEP 9.

After the test is completed, open the analyzer lid. 'Remove cartridge' will be shown. Remove the test cartridge from the analyzer by gently pushing it to the left and pulling it out.

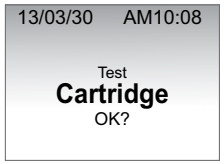




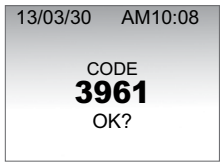
CAUTION : Do not force the cartridge to remove it from the analyzer. Dispose all waste in accordance with applicable national and/or local regulations.

Code confirmation display after the test

In the event of an error in the process of recongnizing the cartridge code, the analyzer asks for the type and code of the cartridge.



1. It asks to confirm if the cartridge is a test cartridge or a check cartridge. Take out the cartridge, and use the ▲ ▼ to match the type of cartridge, and press ⏻ to confirm.



2. After selecting the type of cartridge, use the ▲ ▼ to match the code number of the cartridge, then press ⏻ to confirm, and the test result is displayed.

Expected values

Expected values
The American Diabetes Association's (ADA's) 2012 Clinical Practice Recommendation for diabetes specifies a treatment goal of less than 7% HbA1c.*

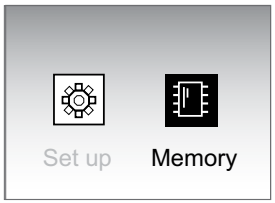
Limitation of Procedure

The ***CLOVER A1c***® assay gives accurate and precise results over a range of total Hemoglobin of 7 to 20 g/dL. Most patients will have hemoglobin concentrations within this range.
However, patients with severe anemia may have Hemoglobin concentrations lower than 7 g/dL, and patients with polycythemia may have Hemoglobin concentrations above 20 g/dL. Patients known to have these condition should be tested with another method for HbA1c determination.

12. REVIEWING RESULTS

STEP 1.

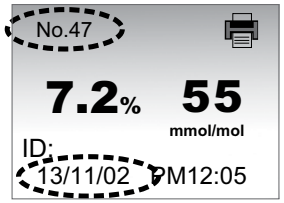
In stand-by mode, press the ⏻ button for 3 seconds for ⚙ or 🧠.
Press either the ▲ or ▼ button to select 'memory', then press ⏻.

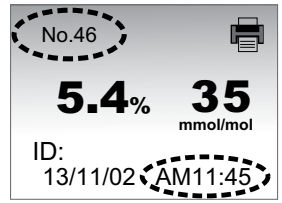


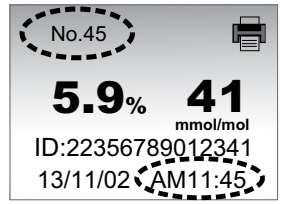
12. REVIEWING RESULTS

STEP 2.

The test results will appear chronologically starting with the most recent date.
Press the ▲ and ▼ buttons to scroll through.







13. CHECKING THE SYSTEM

QUALITY CONTROL

The ***CLOVER A1c***® Check Cartridge checks that the optical and operating systems of the analyzer.

Type of Check Cartridges

- ***CLOVER A1c***® Daily Check Cartridges
- ***CLOVER A1c***® Monthly Check Cartridges

Storage Instruction

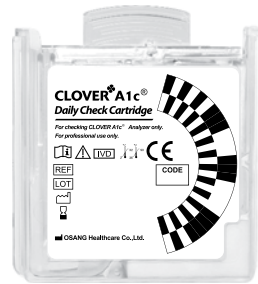
- The Check Cartridge must be protected from sunlight during storage.
- Store the Check Cartridge at temperature 2-32℃ (36-90°F).
- Store the Check Cartridge at humidity < 90%.
- Always store the Check Cartridge in its protective packaging to prevent scratches which may affect the result.
- If refrigerated allow Check Cartridge reach room temperature for at least 1 hour before use.

Precautions/ Warnings

- For In Vitro Diagnostic use.
- Do not use the Check Cartridge beyond the expiration date printed on the Check Cartridge Label and Pouch.
- Do not use the Check Cartridge if stored incorrectly or if it is dirty, scratched or damaged.

13. CHECKING THE SYSTEM

13.1 Daily Check Cartridge

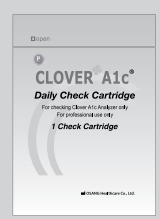


When to Use the Daily Check Cartridge

- Once a day before samples are tested.
- After the analyzer has been moved.
- After an error message. (Er 1 or Er 3)

The Daily Check Cartridge, used to check the analyzer, is composed of a cartridge in a pouch, without a reagent pack.
Life-time : Up to the expiry date on the cartridge label.

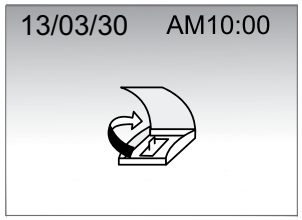
NOTE : Be careful in maintaining the Daily Check Cartridge by keeping in the provided blue color pouch when not in use.



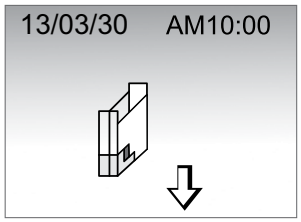
* The Daily Check Cartridge can be purchased from local distributors。

How to use the Daily Check Cartridge

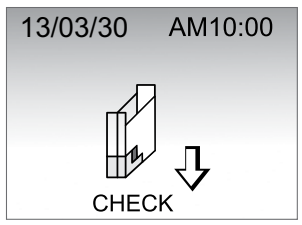
1) Open the lid ***CLOVER A1c***® Analyzer



2) Press ▼ for 3 seconds to enter into the 'Daily Check' mode.

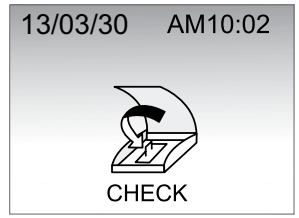


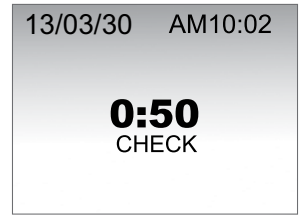
3) Insert the Daily Check Cartridge while 'Daily' and 'CHECK' are blinking.



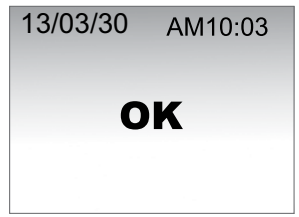
NOTE : To leave the 'Daily Check' mode, press ▼ for 3 seconds.

4) Close the lid. The test starts automatically.

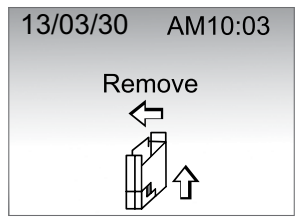




5) After 1 mimute 'OK' or error message will be displayed.



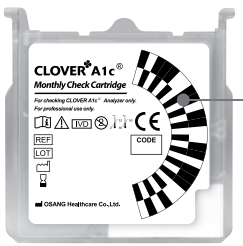
6) Press (⏻) and remove the Daily Check Cartridge when the test is completed.



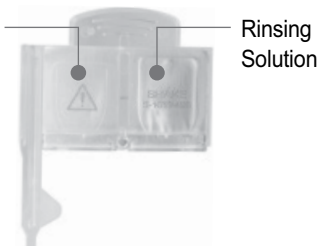
NOTE : If an error message is displayed, repeat the test. If it still displays error message, do not use the analyzer.
Please contact your local representative for customer support.

13.2 Monthly Check Cartridge

[Monthly Check Cartridge]



[Monthly Check Reagent Pack]



When to Use the Monthly Check Cartridge

- When there is a concern that the test result may be incorrect.
- After an error message. (Er 4 or Er 5)
- Once a month before samples are tested.

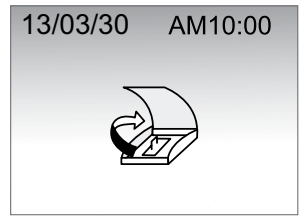
The Monthly Check Cartridge, used to check the analyzer, is composed of a reagent pack, just like the Test Cartridge, but without the sampling area.

CAUTION
- Do not use the Monthly Check Cartridge after the expiry date.
- The Monthly Check Cartridge can be purchased from local representative.
- Do not reuse.

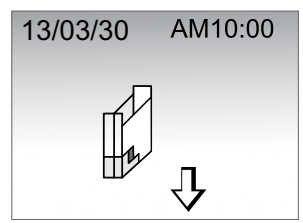
NOTE
- If Monthly Check Cartridge be reused, analyzer show up ‘Do not reuse!’.
- The Monthly Check Cartridge can be purchased from local distributors.

How to use the Monthly Check Cartridge

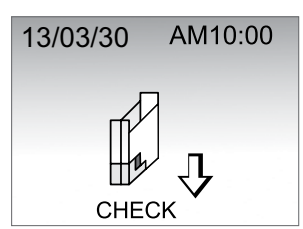
1) Open the lid ***CLOVER A1c***® Analyzer



2) Press ▲ for 3 seconds to enter into the 'Monthly Check' mode.

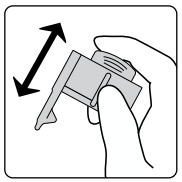


3) Insert the Monthly Check Cartridge while ‘Monthly’ and ‘CHECK’ are blinking.



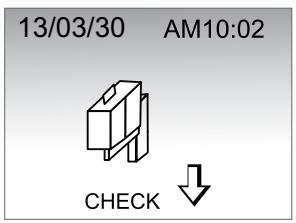
NOTE : To leave the 'Monthly Check' mode, press ▲ for 3 seconds.

4) Gently mix the Check Reagent Pack before use.

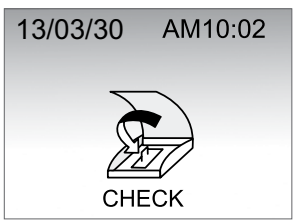


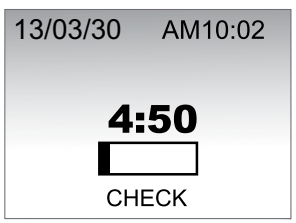
CAUTION : Do not mix too vigorously, it may cause air bubbles.
If bubbles are present wait until they disappear.

5) Insert the Check Reagent Pack, when the 'Insert Check Reagent Pack' icon is displayed, Insert it respectively.

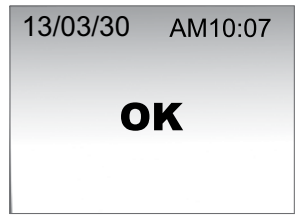


6) Close the lid. The test starts automatically.

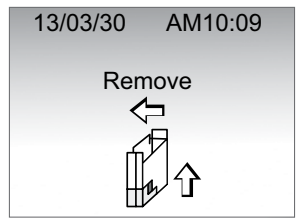




7) After 5 minutes 'OK' or error message will be displayed.



8) Press (⏻) and remove the Monthly Check Cartridge when the test is completed.



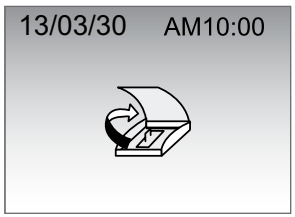
NOTE : If an error message is displayed, repeat the test again. If it still displays error message, do not use the analyzer. Please contact your local representative for customer support.

13.3 HbA1c Control Solution

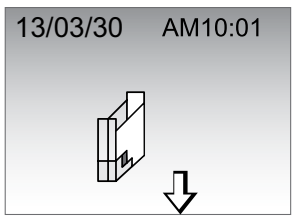
If external quality control testing is desired, commercial controls from other vendors may be purchased.
Controls of human whole blood only can be used with the ***CLOVER A1c®.***
Please contact your local representative for technical support.

How to test with the Control Solution

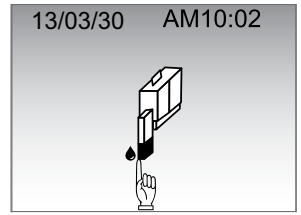
1) Open the lid of the ***CLOVER A1c®*** analyzer.

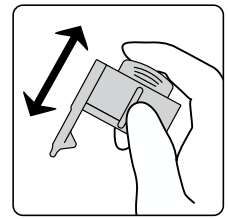


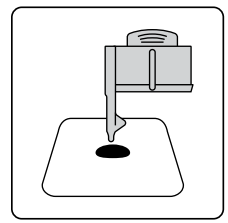
2) Insert the cartridge when the 'Insert Test Cartridge' icon displayed.

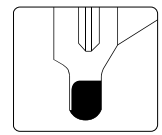


3) Mix the reagent pack gently 5~6 times and touch softly the control solution with the tip of sampling area, so that the control solution is automatically drawn up into the sampling area. Wait until the sampling area is completely filled with the control solution.

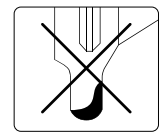






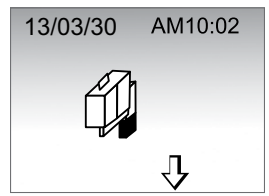


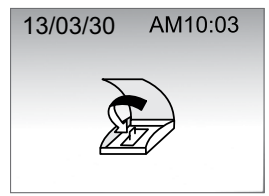
[adequate]



[inadequate]

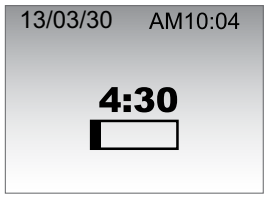
4) Insert the reagent pack into the cartridge compartment of the analyzer and close the lid.

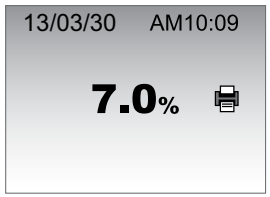




13. CHECKING THE SYSTEM

5) Close the lid. The test starts automatically.





The test result should be within the range specified on the manual of the respective control solution.

If the control results fall outside the designated range, the following sources of error may have occurred:

- Deterioration of the cartridge due to high humidity, heat, or over exposure to light.
- Deterioration of the control solution.

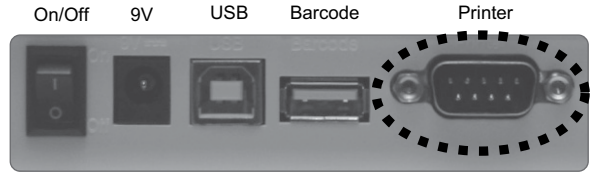
Corrective action

- Always repeat the QC test using a fresh cartridge from a new box or new lot.
  If the repeat test falls out of range a second time, proceed to the next possible cause.
- Repeat the quality control procedure with a fresh bottle of control solution.
- Contact your local representative for customer support.

14. OPTIONS

14.1 Printing Test Results with the Thermal Printer

Connect the thermal printer to the analyzer with the interface cable(RS-232C).
The analyzer should be in stand-by mode.



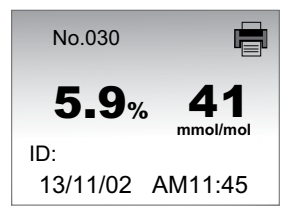
The printer is already pre-set to either manual or automatic printing.
Please refer to page 15.

- **Automatic :** Prints automatically after every test.
- **Manual :** Prints only when printer button pressed.

NOTE : Refer to the printer manual for details of printer setting.

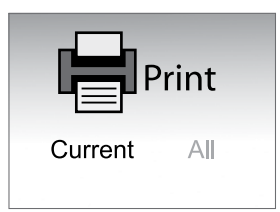
Printer in manual mode

STEP 1. Press the printer button after the result is displyed.



STEP 2. LCD will displayed ‘Current’ and ‘ALL’

STEP 3. Press ▲ or ▼ to select one or the other and or press ⏻ .



- **Current :** Only that result will print.
- **ALL :** Every result in memory will print.

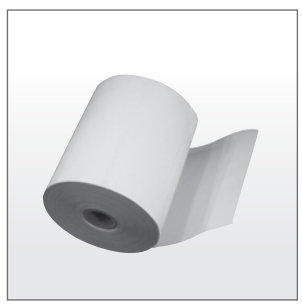
Unpacking

The below pictures show the items which should be included for the standard of STP-103Ⅲ Package. If any items are damaged or missing, please contact with our local representatives for technical assistance.

STP-103Ⅲ

AC-DC adaptor

Interface cable(RS-232C)



Paper Roll

14.2 Using Barcode Scanner

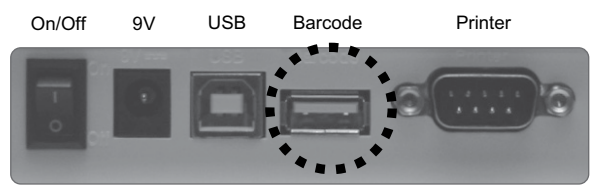
***CLOVER A1c®* accepts data input from the following barcode symbologies**

Code 93 standard includes check digit
Code 39 with optional check digit required
Code 128 standard includes check digit
CodaBar without check digit

The analyzer is pre-set to use the barcoding system appropriately during the set-up process. Please refer to page 20 .

The barcode scanner can be used to scan the patients' ID. All the patients' information is stored in the analyzer for future reference. Connect the barcode scanner to the analyzer.

A maximum of 14 characters can be displayed, stored, and transmitted by system. Barcode information field can read numbers and upper case, lower case. Remove excess characters as leading or trailing characters.

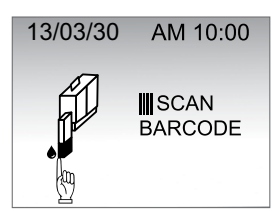


When performing test using barcode system

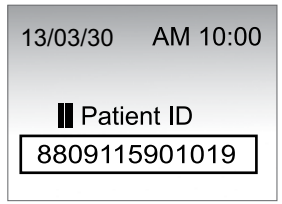
STEP 1. Open the lid of ***CLOVER A1c®*** analyzer.

STEP 2. Insert the cartridge when the 'Insert cartridge' icon is displayed.

STEP 3. The LCD display will prompt you to 'scan barcode'.



STEP 4. Scan the desired barcode until the Patient ID is displayed on the LCD.



NOTE
It is important that the labels be printed to the required specifications.
Reading errors may occur if any of the following conditions exist :

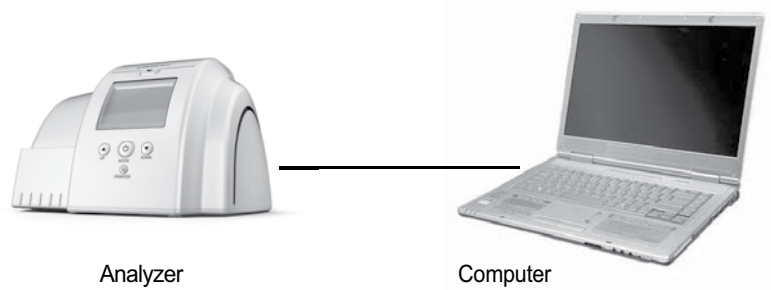
- The width of the barcode is too narrow
- The barcode length is too long
- The height is too low
- The reader is held too far from the label
- The background reflection is too high or low

If the reader is not able to consistently read your labels, apply a test label of the format being used to a new specimen tube and perform the barcode test.

If the reader is able to read the test label, the quality of your labels may be inadequate. If the test label cannot be read, the reader itself could be the problem.

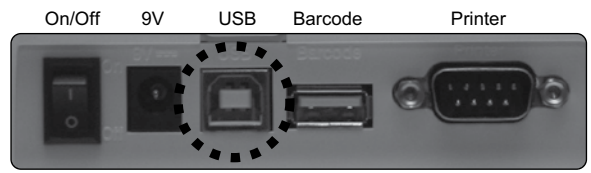
Contact with our local representatives for technical assistance.

14.3 Transfer Test Results to a Computer



Analyzer Computer

STEP 1. Connect the USB Cable from the analyzer to the PC while in stand-by mode.



STEP 2. Once connected the analyzer will display ‘PC’.

STEP 3. Download the PC application program.

STEP 4. Once the program is downloaded, click the ‘Date Transfer’ icon on your PC. The results from the analyzer will be transferred over.

NOTE
For more information, please refer to the user’s guide. You can find user’s guide if you are installed window program.

CAUTION
- To view the User's Guide, you need Adobe Reader Version 3 or higher.
- If this is not already installed on your computer, you can download it free at (http://www.adobe.com/products/acrobat/readstep2.html)
- You can purchase the computer communication cable separately from a local representative.
  Please use the exclusive USB cable provided by OSANG Healthcare

15. TROUBLESHOOTING

GENERAL INFORMATION

If an operational or system problem occurs, an error code may display on the system screen with an explanation of the problem. This section of the guide lists the various errors and messages, along with a description and corrective actions. If the problem persists, record the error code and contact your local representative for technical support provider for assistance.

ERROR CODE	DESCRIPTION	CORRECTIVE ACTION
Er 1 (Er 1-1 ~1-8)	Problem with the analyzer system	Please power switch off and on again. If the problem persists contact your local representative.
Er 2 (Er 2-1 ~2-5)	Check Cartridge error	Check cartridge may be damaged (bar code label, reagent pack, surface of cartridge etc.) or alien substance was inserted into the check cartridge.
Er 3	Problem with reading bar code of test cartridge	Press the ⏻ button, remove the cartridge and then insert again. Use the Daily Check Cartridge to confirm the analyzer performance. If the error persists, contact your local representative.
Er 4	Test Cartridge error	Reagent may be left in Test Cartridge. Please press ⏻ button and remove the cartridge. Insert a new test cartridge and perform the test again.
Er 5	Problem with reagent pack of the test cartridge	The analyzer is unable to recognize the solutions (within the reagent pack). The reagent pack may be damaged and leak reagent solution. Please press ⏻ button and remove the cartridge. Insert a new test cartridge and perform the test again.

15. TROUBLESHOOTING

ERROR CODE	DESCRIPTION	CORRECTIVE ACTION
Er 6	The cartridge is left in the analyzer for an extended period of time or the lid is left open	Please press ⏻ button and remove the cartridge. Insert a new Test Cartridge and perform the test again.
Er 7	Open the lid during the test	Please press ⏻ button and remove the cartridge. Insert a new test or check cartridge and perform again.
Lo ℃ Operating Temp : 17-32℃ Current : XX.X℃	The ambient temperature is too low	Please make sure the equipment is within normal operating temperatures for at least 10 minutes and re-test.
Hi ℃ Operating Temp : 17-32℃ Current : XX.X℃	The ambient temperature is too high	Please make sure the equipment is within normal operating temperatures for at least 10 minutes and re-test
<4 %	The HbA1c test tesult is lower than 4.0% (20mmol/mol)	Please use the check cartridge to validate the analyzer and re-test the blood sample.

15. TROUBLESHOOTING

ERROR CODE	DESCRIPTION	CORRECTIVE ACTION
>14%	The HbA1c test result is higher than 14.0% (130 mmol/mol)	Please use the check cartridge to validate the analyzer and re-test the blood sample.
Do not Reuse	Problem with reusing the cartridge. (Test or Monthly Check Cartridge)	Please press mode button and remove the cartridge. Check whether the cartridge is reused or not. Insert a new cartridge and perform the test again. If the problem persists contact your local representative.
The Analyzer does not power on	There is a problem with the power adaptor or the analyzer itself	Unplug the power adaptor and reconnect. If the problem still persists, contact your local representative.

16. SPECIFICATION

SampleType	Capillary whole blood, Venous blood with anticoagulant
Sample Volume	4 uL
Test Range	4.0~14.0%
Reading Time	5 minutes
Memory Capacity	200 test results
Wavelength	415 nm (normal)
Power Required	DC 9 V-2 A
Dimensions/Weight	200*198*139(mm) / 1.4kg
Storage Temperature	10 ~ 35 ℃ (50 ~ 95 ˚F)
Operating Temperature	17 ~ 32 ℃ (63 ~ 90 ˚F)
Relative Humidity Range	10% ~ 90%
Option	PC Connection Cable Thermal Printer Barcode Scanner

Recommended maintenance routine

1) Cleaning the exterior
2) Changing the fan filter
3) Cleaning the cartridge compartment

Cleaning the analyzer

1) Disconnect the analyzer before cleaning.
2) Dust the Analyzer by wiping with a soft, clean cloth.
3) Do not use liquid or aerosol cleaners.
4) If necessary, alcohol swab can be used to wipe out dirt, but other chemical solutions should not be used. Cleaning solutions may cause damage to the analyzer surface.

Cleaning the cartridge compartment

STEP 1. Turn the power off and disconnect the power cord before cleaning.

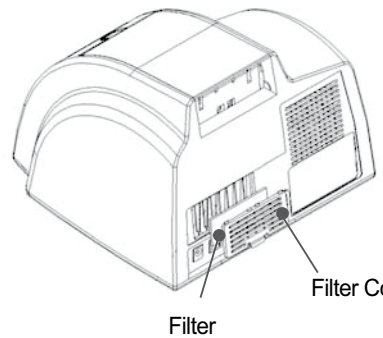
STEP 2. When the lid is opened, press the two black knobs to rotate the cartridge compartment forward.

STEP 3. Dampen a sponge swap with water or ethanol.

STEP 4. Gently wipe the cartridge compartment. Be careful not to drip any liquids into the system.

Replacing the Fan Fileter :

Check the fan filters located on the backside of the analyzer regularly. Replace the fan filter if it is clogged by dust. Extra filters come with your system.



STEP 1. Remove the fan filter cover.

STEP 2. Remove the used fan filter and replace with a new one carefully.

STEP 3. Close the fan filter cover.

NOTE
Additional Fan Filter can be purchased from our representatives, nearest in your area.

18. SAFETY

The analyzer has been fully tested according to the Electrical Safety Regulations (EN 61010-1).

SAFETY TIPS

1) Do not disassemble the Analyzer.
2) Do not place the analyzer in places with high humidity.
3) Do not place the analyzer in polluted or dusted areas.
4) Do not expose the analyzer to any impact, shock, or vibration.
5) Do not place the analyzer next to any chemical products.
6) Keep away from direct sun light.
7) Do not cover the ventilation openings on the back with any materials.
8) Do not touch the analyzer with any metallic or inflammable materials.
9) Keep away from strong electromagnetic fields.
10) Do not install near any potential electromagnetic sources.

19. DISPOSAL

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

The Waste Electrical and Electronic Equipment (WEEE) Regulations implement provisions of the European Parliament and Council Directive 2012/19/EU aimed to reducing the amount of EEE waste going for final disposal.

OSANG Healthcare Co., Ltd. as the manufacturer, has specific instructions for the recovery of the analyzer. Please contact our representatives in your area for the respective instructions before disposing.

20. PRECAUTION

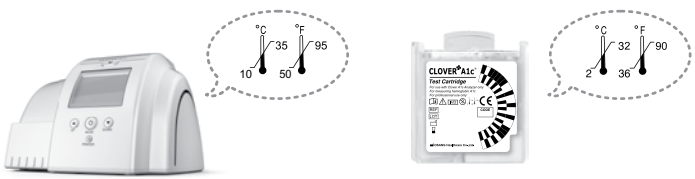
1. Analyzer should be located on the flat table.

2. ***CLOVER A1c®*** system is a precise optical equipment. So, it should be installed in a stable place without vibration.

3. Electric power should be stable.

4. Analyzer and Cartridge should not be exposed to the direct sunlight.

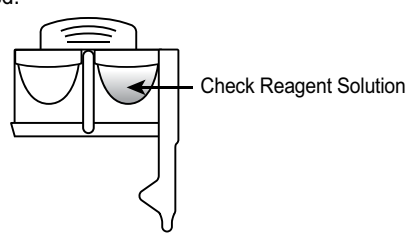
5. Users should carefully follow the indicated analyzer operating temperature and cartridge storage temperature.



6. Allow the test cartridge and analyzer to reach room temperature (ambient temperature) 30 minutes before use.
   Use the test cartridge within 2 minutes after opening pouch.

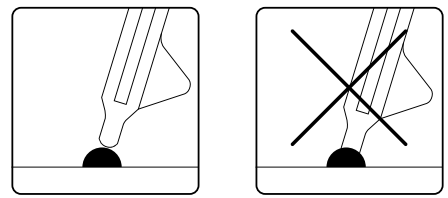
7. Do not move or give any kind of impact while the analyzer is under testing.

8. The bead inside the Reagent Solution of the Reagent Pack, might sink and coagulate. Gently mix the Reagent Pack before testing, and visually check that the beads are not coagulated.



20. PRECAUTION

9. When collecting blood, touch the end of the capillary tip (sampling area) to the blood sample, do not put the tip deep into the blood sample to avoid excess blood.



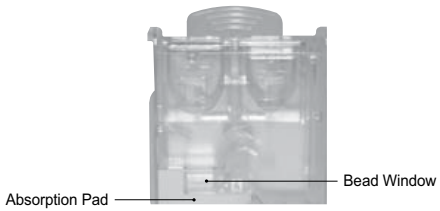
10. Do not apply too much pressure to the Reagent Pack when inserting it into the Cartridge. Insert the Reagent Pack gently. Much pressure may cause the mixture of the two reagents resulting in bad result.

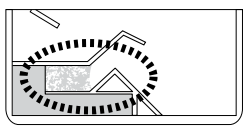
11. Firmly combine a reagent pack into cartridge with a mild pressure until 'Tick' sound from the cartridge.

12. If there is some material inside cartridge holder, a cartridge cannot be firmly positioned into the analyzer. In such case, check the cartridge holder.

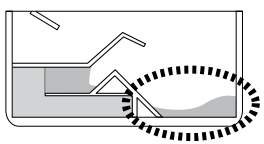
20. PRECAUTION

13. . After test completion and removal of cartridge, inspect the cartridge for symptoms. If any of the following symptoms occur, repeat the test to confirm validity of the result.

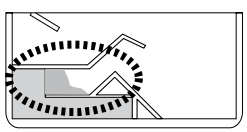




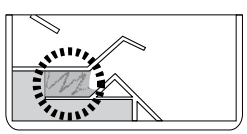
1) If the bead window is not colored uniformly.



2) If Reagent is left in the cartridge not be absorbed fully into absorption pad.



3) If bead is not accumulated fully in the bead window. If the bead is accumulated just like half sized an so on.



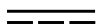
4) If the cartridge has residue or some scratch on the bead window.

14. Besides, when any kind of errors happen as specified in the manual, refer to the troubleshooting instructions from the analyzer instruction for use.

21. SYMBOL & DESCRIPTION

Symbol	Description
CE	This prodect fulfills the requirements of Directive 98/79/EC on in vitro diagnostic medical devices
	Consult instructions for use.
	Used by
	Caution, consult accompanying documents
EC REP	Authorised representative in the European Community.
IVD	*In vitro* diagnostic medical device.
LOT	*Batch code*
REF	Catalog number
SN	Serial number
	Manufacturer

21. SYMBOL & DESCRIPTION

Symbol	Description
	Do not reuse
	Date of Manufacturer
	Keep away from sunlight
	Direct Current
	Waste Electrical and Electronic Equipment
	Biohazard

MEMO

MEMO

CLOVER A1c®

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