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IMH12-008 Rev.2011-12-01

SELF-TESTING

IVD CE 0123

Diabetes Management Technology

CLOVER® A1c™ Self
Test Analyzer

INSTRUCTION FOR USE



REF INFH01AS

For measuring Hemoglobin A1c

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1. INTENDED USE

The ***CLOVER A1c Self*** analyzer is an IVD(In Vitro Diagnostic Device) device for measuringHemoglobin A1c by the well established method of boronate affinity. It is able to analyze bothcapillary whole blood and venous blood. Anticoagulants may be used, such asEDTA(ethylenediaminetetraacetic acid) and heparin etc. This ***CLOVER A1c Self*** system is designedto help controlling diabetes and it is intended to be used by patients and professionals at home,laboratories, clinics and hospitals. Same as all diagnositc tests, do not make a definitivediagnosis of diabetes based on the result of a single test. A physician should make a diagnosisafter all clinical and laboratory findings are evaluated.

IMPORTANT : Please read through and familiarize yourself with the contents of this operation manual before using the system for the first time.

2. INTRODUCTION

The ***CLOVER A1c Self*** system is a small, portable and fully automated point-of-care system forHbA1c test. The system delivers rapid tests of HbA1c.

The ***CLOVER A1c™ Self*** System may be used as a basic test system where the user purchases the Analyzer and manually records the results, or as an advanced system where a suite of accessories enable automatic printing of results, input of patient and operator identification numbers, and full connectivity to a PC. In this manner, the system is highly versatile and can be tailored to specific user needs.

This manual contains all the information needed to operate and maintain the ***CLOVER A1c™ Self*** Analyzer.

3. PRINCIPLES OF OPERATION

The ***CLOVER A1c™ Self*** system is a fully automated boronate affinity assay for the determination of the percentage of Hemoglobin A1c (HbA1c %) in whole blood(capillary and venous).

The Test Cartridge is composed of a cartirdge and a reagent pack containing the reagents necessary for the determination of hemoglobin A1c.

A cartridge should be inserted into the analyzer cartridge holder first and later assembled with areagent pack which was applied with 4ul blood sample at the sample collecting area. A reagentpack is composed of reaction solution and washing solution. The reaction solution containshemolyzing agent which lyses the red blood cells, and boronate resin which binds to the cis-diolsof glycated hemoglobin. The washing solution cleans the non-specific glycated hemoglobin(except HbA1c)

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

The assembled cartridge is inserted into the ***CLOVER A1c™ Self*** Analyzer and rotated so that the sample mixture is placed at the measurement zone of the cartridge, where the amount of total hemoglobin in the blood sample is photometrically the diffused reflectance of the optical sensor composed with LED(Lgiht Emitting Diode) andPD(Photo Diode)

Then, the assembled cartirdge is rotated so that the washing 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.

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

Where ‘HbA1c’ and ‘Total Hemoglobin’ are the signal obtained from the ***CLOVER A1c™ Self*** system, ‘A’ and ‘B’ are the slope and intercept factor to correct the value for DCCT(Diabetes Control and Complication Trial) calibration.

4. CLOVER A1c™ Self Contents

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

Contents

1. ***CLOVER A1c Self*** Analyzer
2. Instruction Manual
3. Exclusive Power Adapter
4. Fan Filters
5. Daily Check Cartridge
6. Monthly Check Cartridge





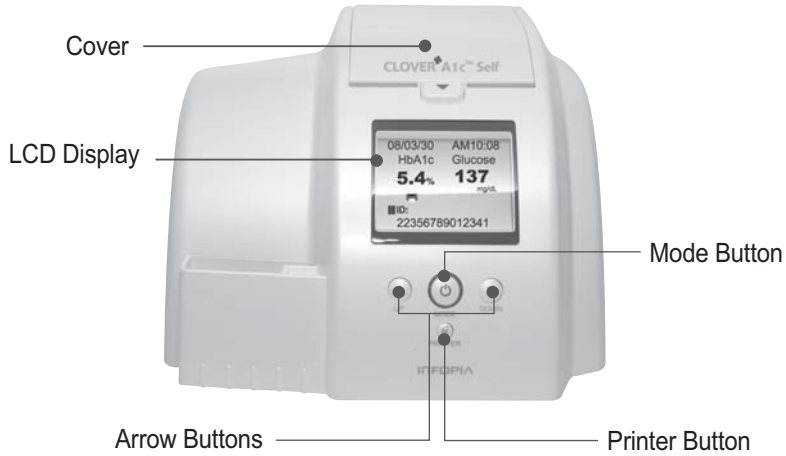
5. Storage Instructions

The ***CLOVER A1c™Self*** analyzer must be stored at 10°C~35°C. Test Cartridges must be stored at 2°C~32°C(36°F-90°F) and 10%~90% R.H(Relative Humidity)

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

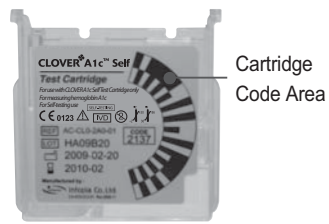
6. Device Description

6.1 Analyzer

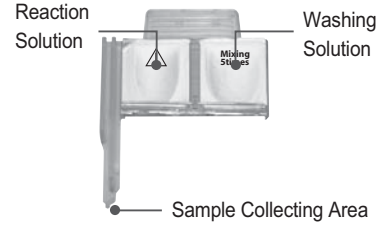


6.2 Cartridge

[Test Cartridge]

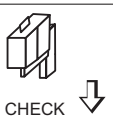
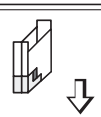
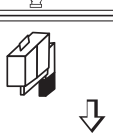


[Reagent Pack]

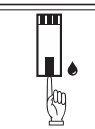
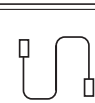
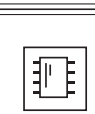
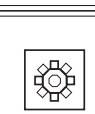


• **Caution:** Be careful not to touch or contaminate the cartridge code area in any way. Any stain on the testcartridge code may cuase incorrect test result.

7. LIST OF ICONS

Icon	Name	Function
Warming up	Warming up	It is displayed on the analyzer LCD once it is powered on.
CLOVER A1c™ Self	Power Save mode	Analyzer is under 'Power Save Mode'
	Open the cover	Open the cover of the analyzer.
	Insert Check Cartridge	Analyzer is under “Check Mode”. Insert daily check cartridge or monthly check cartridge into the analyzer.
	Insert Check Reagent Pack	Insert monthly check reagent pack into the analyzer. In case of daily check cartridge, the iconwill not be shown up.
	Insert Test Cartridge	Insert Test Cartridge into the analyzer.
	Apply sample to capillary tip	Apply blood sample to sample collecting area.
	Insert Reagent Pack	Insert reagent pack with blood sample into the analyzer.

7. LIST OF ICONS

Icon	Name	Function
	Close the cover	Close the cover of the analyzer.
	Remove cartridge	Remove the cartridge from the analyzer.
	Insert strip	Insert the blood glucose test strip into the glucose module.
	Apply sample to glucose test strip	Apply blood sample to the blood glucose test strip.
	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™ Self***. You must follow the installation steps correctly to ensure proper installation, operation, and service.

CAUTION
Do not drop or handle the system roughly. The calibrated optics, electronics orother internal parts can be disrupted or damaged. Always handle the system with care. The ***CLOVER A1c™ Self*** ia s precise system and must be handle carefully.

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

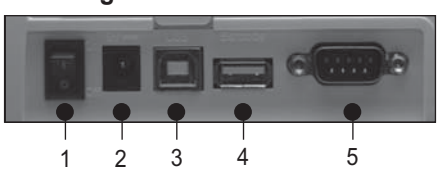
Do not place the ***CLOVER A1c™ Self*** on the same place with a source of vibration

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

Unpacking the System

Your ***CLOVER A1c™ Self*** is delivered in 1 shipping carton.
1.Carefully take out the contents of the shipping carton.
2.Please check physical damage on the carton and system
3.If the system is damaged, please contact to your representative in your area.
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 9 V
3. USB port
4. Barcode Scanner port
5. Thermal Printer port (Serial port RS 232)

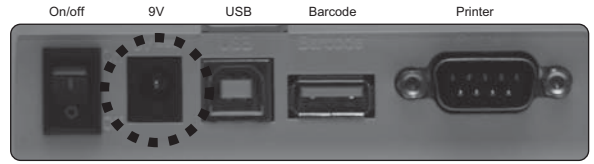
Connect the System Power

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 cover is closed before connecting the adapter.

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

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





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



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

9. OPERATION

9.2 Warming up

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



While warming up, the ***CLOVER A1c™ Self*** performs hardware function test to check internal opticsand the mechanical system.

9.3 Stand-by

After warming up, the analyzer goes into 'Stand-by' mode. Two different 'Stand-by' icons will be displayed when glucose module is used.



• Glucose Module Inactive



• Glucose Module Active

Note: The analyzer will automatically go into 'stand-by' mode after a test.
The cartridge has to be pulled out and the cover closed.

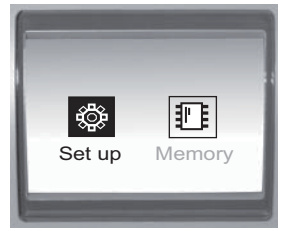
9.4 Power Save

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

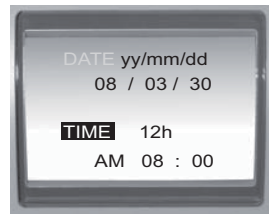
Date



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



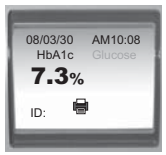
Select the time format by pressing the ▲ or ▼ buttons, then press ⏻ .
12h for standard time / 24h for military time

HbA1c test result unit



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

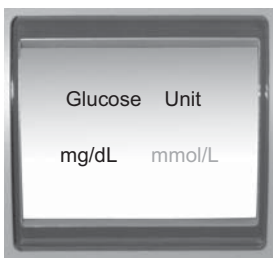
[NGSP]



[IFCC]



Glucose test result unit



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

[mg/dL]



[mmol/L]



Barcode use



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

10. SETTING THE ANALYZER

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™ Self* test may be performed on capillary blood taken from a fingerstick or on venous blood collected using EDTA, heparin, oxalate as an anticoagulant.

Test Procedure

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

STEP 1.

When the power is connected, the LCD will display 'Warming up' until the device gets ready for the test.
Approximately 5 minutes depending on the environment temperature.

While warming up, the ***CLOVER A1c™ Self*** 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 cover of the CLOVER A1c™ Self analyzer, when the analyzer is in 'Stand-by' mode, displaying the 'Open the cover' icon.





IMPORTANT : Details on analyzer functionality, please refer the analyzer instruction for use.

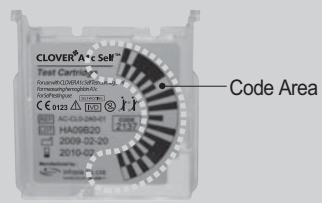
STEP 3.

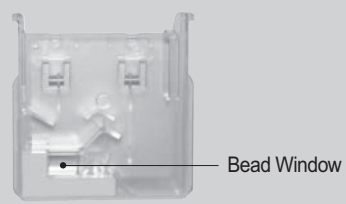
Remove one pouch from storage.
Tear the pouch open on the side with the serrated edge.
DO NOT use scissors to cut open pouch.
Scissors can damage the reagent pack.



Please use the test cartridge within 30 minutes after tearing the pouch.

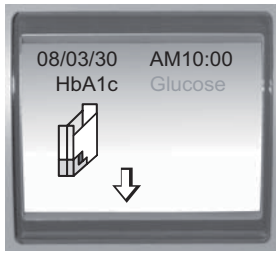
CAUTION: When handling the reagent pack and cartridge, be careful not to touch the Code Area of the front side, nor the bead window at the back side. Any dirt or contamination of both areas, may cause erroneous test values.





STEP 4.

Carefully insert the cartridge into the cartridge compartment once the 'cartridge insert' icon is displayed. Hold the cartridge so that the barcode faces to the left.
Make sure a gentle snap is either heard or felt to ensure proper placement.



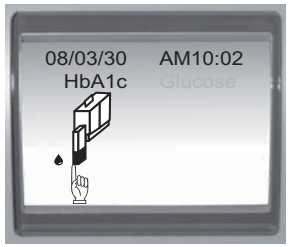


NOTE : Do not force the cartridge into the system. The cartridge is designed to fit only in one way.
Environmental influences(e.g. air humidity and light) on the test cartridge may cause damage to the test cartridges and lead to false measurements or error messages.

STEP 5.

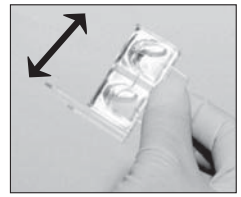
The LCD will then display the 'Reagent Pack' and 'Applying sample' icon.





STEP 5-1.

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



CAUTION : Do not mix it too violently. It may make some bubbles. If you drop the test cartridge and the bubble is arisen in the test cartridge, please wait until the bubble sinks.

STEP 5-2.



Place the blood sample up to the sample collecting area by softly touching the blood sample.
make sure that the sample area is completely filled.

IMPORTANT : After the capillary tip is filled with sample, analysis must begin within 5 minutes.

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.

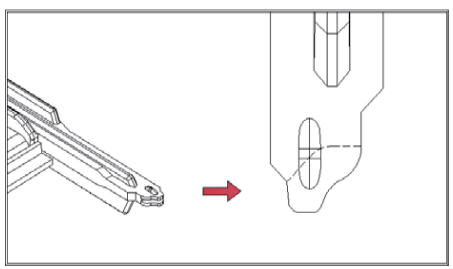
- Capillary Blood Process

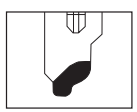
Prick the fingertip of the patient to get a minimum of 4uL of capillary blood sample, and touch softly the blood sample with the capillary tip of the Reagent Pack. The blood is automatically drawn up. Make sure that the sample area is completely filled.

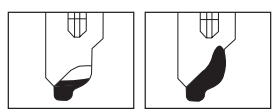




Sample Collecting Area of Reagent Pack




[adequate]

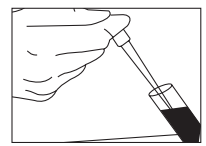
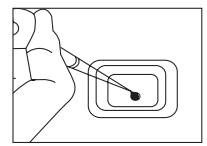
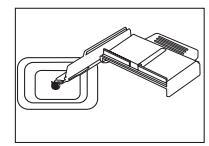

[inadequate]

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

11. TESTING HbA1c

- Venous Blood Process

For venous whole blood samples, acceptable Anti-coagulants are EDTA, heparin and these blood samples may be stored at -70°C to 5°C(-94°F to 41°F) for two weeks, or up to 25°C(77°F) for one week.
Stored blood should be whole blood, not as hemolysate. Allow blood samples to reach room temperature, 20~25°C(68-77ºF).
Anticoagulated 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 sample collection area of the Reagent Pack on the blood sample, and wait until the sample area is completely filled.

NOTE : If blood is stained outside the sample area, carefully wipe the stain out with a tissue. Do not allow the wiping tissue to touch the open end of the sample area of the capillary tip.

CAUTION : There is a potential risk of infection. Medical staff and other persons using the *CLOVER A1c™ Self* analyzer to perform measurements for more than on patient must be aware that any object coming into contact with human blood is a potential source of infection.

- 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 cover' icon will be displayed.





NOTE : Do not force the reagent pack into the system. The reagent pack is designed to fit only in one way.

STEP 7.

The test starts automatically once the cover is closed.

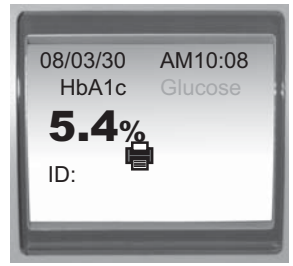




IMPORTANT : Do not open the analyzer during the test.
Do not vibrate or move the analyzer during the test.

STEP 8.

The timer will countdown from 5 minutes until the HbA1c% is displayed.



NOTE : If you see ">14.0%" or "<4.0%" displayed, HbA1c% level may be above 14.0% or below 4.0%, repeat testing. If the second result is again outside this range, please contact your local customer support and service center.

STEP 9.

After the test is done, open the cover of the analyzer. The display will show the 'cartridge remove' icon. Take out the cartridge from the analyzer by gently pushing to the left and pulling out.





CAUTION : Do not give strong impact to cartridge. 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

Mean blood glucose results are 10.0-15.0% lower.
Non-Diabetic Range is 4.0~6.0% and the ADA most recent Clinical Practice Recommendation for diabetes specifies a treatment goal of less than 7%.

[Reference]

The Diabetes Control and Complications Trial (DCCT) :
a five-year progress report. Clin Chem 47 :1985–1992, 2001.
Defining the relationship between plasma glucose and HbA1c: analysis of glucose profiles and HbA1c in the Diabetes Control and Complications Trial. Diabetes Carel 25: 275-278, 2002

HbA1c standard test results

	Approximate Mean Plasma Glucose*		
GHB(%)	*mg/dL*	*mmol/L*	*Interpretation*
4	65	3.5	Non-Diabetic Range
5	100	5.5	
6	135	7.5	
7	170	9.5	ADA Target
8	205	11.5	Action Suggested
9	240	13.5	
10	275	15.5	
11	310	17.5	
12	345	19.5	

*Perform the A1C test at least two times a year in patients who are meeting treatment goals (and who have stable glycemic control).
*Perform the A1C test quarterly in patients whose therapy has changed or who are not meting glycemic goals.

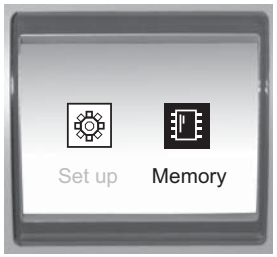
Limitation of Procedure

The *CLOVER A1c™ Self* 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 those values. However, patients with severe anemias may have Hemoglobin concentrations ower than 7 g/dL, and patients with polycythemia may have Hemoglobin concentrations above 24 g/dL. Patients known to have these condition should be assayed by a test employing a different assay principle if their Hemoglobin concentrations are outside of the acceptable range.

CAUTION : Discard cartridge in proper container, according to your standard laboratory procedures.

STEP 1.

In stand-by mode, press the button for 3 seconds for or .
Press either t he or button to select 'memory', then press .



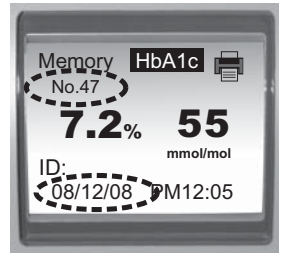
STEP 2.

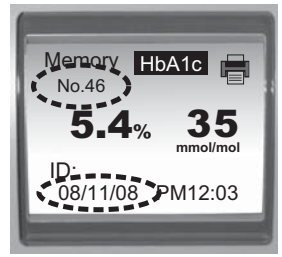
Press either the or button to select between 'HbA1c' and 'Glucose', then press .

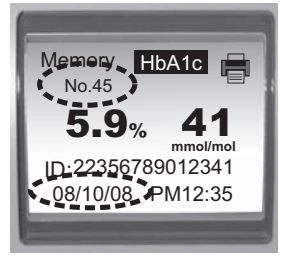


STEP 3.

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







QUALITY CONTROL

The *CLOVER A1c™ Self* Check Cartridge checks that the optical and operating systems of the Analyzer are working correctly.

IMPORTANT : Please read through and familiarize yourself with the contents of theCLOVER A1c™Self Analyzer Operation Manual before using the system for the first time.

- Check Cartridge

- *CLOVER A1c™ Self* Daily Check Cartridge
- *CLOVER A1c™ Self* Monthly Check Cartridge

Storage Instruction

- The Check Cartridge must be protected from sunlight during storage; do not leave the check cartridge in direct sunlight for long periods of time.
- Store the Check Cartridge at 2 ~ 32°C (36 ~90°F)
- Store the Check Cartridge at a Humidity < 90%
- Always store the Check Cartridge in its protective packaging to prevent scratchs that may affect the test result.
- If the Check Catridge is stored in the refrigerator, it must be allowed for an hour to reach the room temperature before use.

Precautions/Warings

- 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 it has been stored incorrectly, or if it is dirty, scratched, or damaged in any way.

Daily check cartridge



When to Use the Daily check cartridge

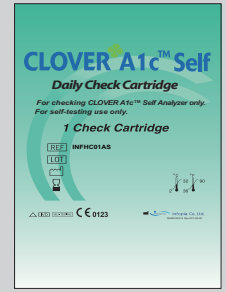
- Once a day before samples are tested.
- After the analyzer has been moved.
- After an error message. (Er 1-7 or Er 7 or Er 3)

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 green color pouch when not in use.
- The Daily check cartridge can be purchased from local distributors.



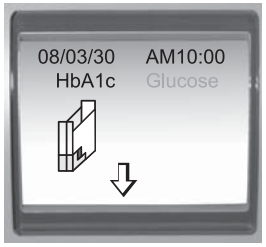
How to use the Daily check cartridge

1) Open the Cover of *CLOVER A1c™ Self* Analyzer.



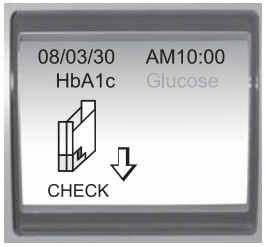


2) Press ▼ for 3 seconds to enter into the Daily check cartridge mode.





3) Insert the Daily check cartridge while 'Daily' and 'CHECK' are blinking.





NOTE : To leave the Daily check cartridge mode, press ▼ for 3 seconds.

13. CHECKING THE SYSTEM

4) Close the cover. The test starts automatically.





5) After 1 mimute 'OK' or 'Er 2' will be displayed.



'OK' : When the analyzer is ready to be used.

'Er 2' : When the analyzer is not ready to be used.

6) After the test is complete. Take out the cartridge.





NOTE : If an errer message is displayed, repeat the test. If is still displays Er 2 message 'Do Not use the analyzer'.
Please contact your local representative for customer support.

Monthly check cartridge



When to Use the Monthly check cartridge

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

The Monthly check cartridge, used to check the Analyzer, is composed of a cartridge and a regent pack, just like the test cartridge, but without the capillary rod.

CAUTION
- Do not reuse.
- Do not use the Monthly Check Cartridge after the expiry date.

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

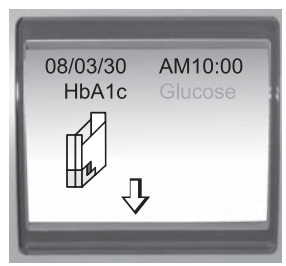
How to use the Monthly check cartridge

1) Open the Cover of *CLOVER A1c™ Self* Analyzer.





2) Press ▲ to enter into the Monthly Check Cartridge mode.





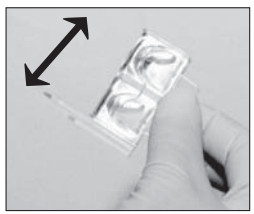
3) Insert the Monthly Check Cartridge while 'Monthly' and 'CHECK'.





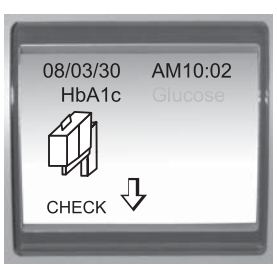
NOTE : To leave the Monthly check cartridge mode, press ▲ for 3 seconds.

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



CAUTION : Do not mix it too violently. It may make some bubbles.
If you drop the test cartridge and the bubble is arisen in the test cartridge, please wait until the bubble sinks.

5) Insert the Monthly Check Reagent Pack, when the 'insert check reagent pack' icon is displayed. Insert it respectively.





NOTE : Do not contaminate sample collecting area(Capillary tip) of reagent pack.

6) Close the cover. The test starts automatically.





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

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



8) After the test is complete. Take out the cartridge.





NOTE : If an error message is displayed, repeat the check again. If it still displays error message 'Do Not use the analyzer'.
Please contact your local representative for customer support.

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™ Self*.
Please contact your local representative for technical support.

When to run a control test

1) With each new shipment of test cartridges, even if the cartridge are from the same lot as previously received.
2) With each new lot of test cartridges.
3) If there is concern that test result may be incorrect

WARNING
Use only *CLOVER A1c™ Self* HbA1c Control Solution with the *CLOVER A1c™ Self* system.

How to test with the Control Solution

1) Open the Cover of *CLOVER A1c™ Self* Analyzer.



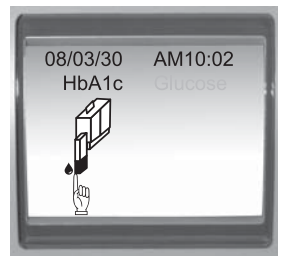


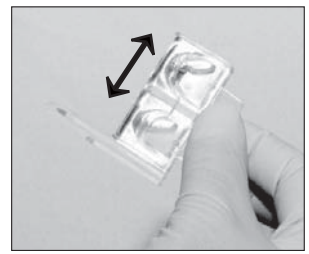
2) Insert the cartridge when the 'Cartridge insert' icon displayed.





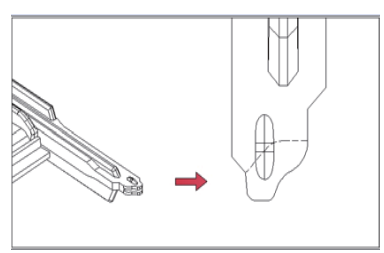
3) Gently mix the reagent pack 5~6 times and touch softly the control solution with the capillary tip, so that the control solution is automatically drawn up into the sample area. Wait until the sample area is completely filled with control solution.

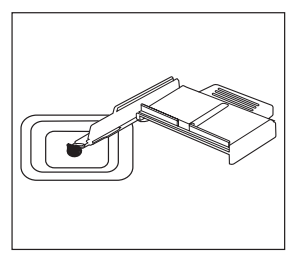


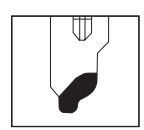


CAUTION : Do not mix it too violently. It may make some bubbles.
If you drop the test cartridge and the bubble is arise in the test cartridge, please wait until the bubble sinks.

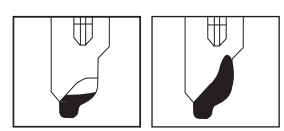
Reagent pack sample area







[adequate]

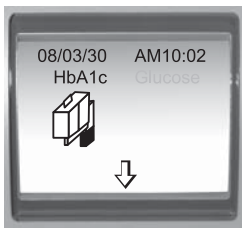


[inadequate]

IMPORTANT : Once the reagent pack is filled with the control solution, analysis must begin immediately.

13. CHECKING THE SYSTEM

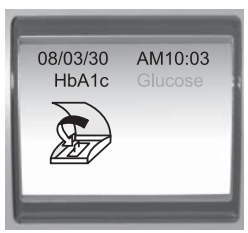
4) Insert the reagent pack into the cartridge and close the cover to the analyzer.





NOTE : Do not contaminate sample collecting area(Capillary tip) of reagent pack.

5) Close the cover. The test starts automatically.

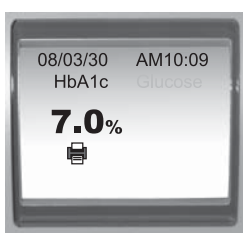






IMPORTANT
- Do not open the analyzer during the test.
- Do not vibrate or move the analyzer during the test.

6) The HbA1c% is displayed after 5 minutes.



NOTE :
The test result should be within the range speccified on the manual of the respective control solution.

13. CHECKING THE SYSTEM

7) After the test is complete. Take out the cartridge.





NOTE : If an error message is displayed, repeat the check again. If it still displays error message 'Do Not use the analyzer'.

If the control test 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.

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

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Medical Supplies since 1953

14.1 Blood Glucose Test

The *CLOVER A1c™ Self* can test the blood glucose by simply connecting the glucose module.

STEP 1. Prepare the test item for measuring glucose level using the module.



(3Sec glucose module)

or



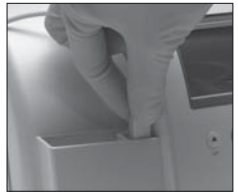
(5Sec glucose module)

CAUTION

1. Yellow Glucose Module is for 3 Seconds product and the glucose test strip should be ELEMENT™ test strip.
1. Green Glucose Module is for 5 Seconds product and the glucose test strip should be GlucoLab Auto-coding™ test strip

STEP 2. Connect the blood glucose Module to the port located in the front side of the Analyzer.





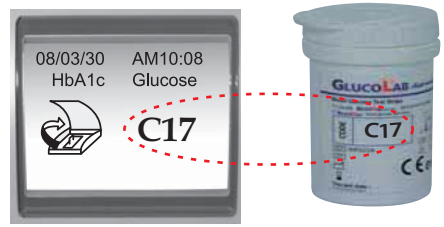
STEP 3. Once the strip icon display on the *CLOVER A1c™ Self* analyzer LCD, insert the blood glucose test strip into the blood glucose module.







STEP 4. Check the same code number between strip vial and *CLOVER A1c™ Self* anlayzer LCD.



or



STEP 5. Check the applying sample blood icon on the *CLOVER A1c™ Self* anlayzerLCD.



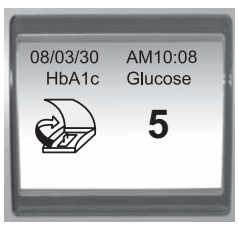
STEP 6. Collect the sample blood using the lancing device and apply it on the glucose test strip.

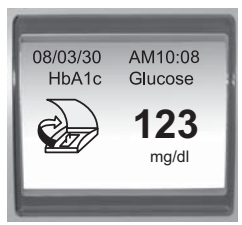



STEP 7. The analyzer will display the blood glucose test result..



or





STEP 8. Once the test is complete, slide the ejector button forward to remove the glucose test strip from the glucose test module.
You don't want more glucose test, disconnect the glucose test module from the *CLOVER A1c™ Self* analyzer.




14.2 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.



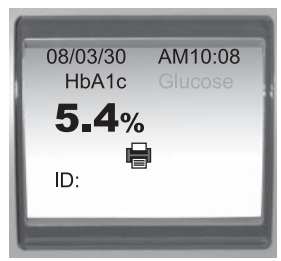
The printer is already pre-set to either manual or automatic printing.
Please refer to page 15.

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

When printer is 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 SRP-III Package. If any items are damaged or missing, please contact with our local representatives for technical assistance.



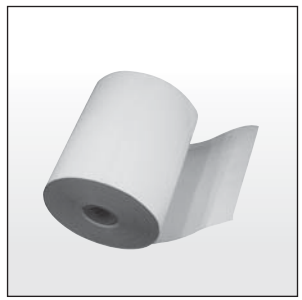
SPR-III



AC-DC adaptor(9V, 2A)



Interface cable(RS-232C)



Paper Roll

Installation



STEP 1.

Push both cover latches and open the cover.



STEP 3.

Insert a paper roll and close the cover.

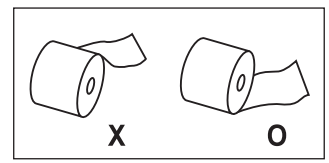


STEP 3.

After closing the cover cut the paper.

CAUTION

- Don't touch the print head. It can be very hot after printing continuously for a long time.
- Make sure that the paper direction is correct.



Specification

Specification	SRP-III
Print Method	Horizontal Direct Thermal
Resolution	8dots/mm(384dots)
Number of Column	42 columnas (9x17) 32 columnas (12x4)
Character set	95 Alphanumeric, UPCA, UPCE, JAN8(EAN), CODE39, CODE93, COLE128, ITF, CODABAR
Character Per Inch	16CPI
Interface	RS-232C/Parallel
Data biffer	4Kbytes or 45bytes
Print speed	35mm/sec (Max.)
Power	9V DC ± 10%
Power consumption	Approx 2.0A(mean)
Dimensions(mm)	136(M) x 202(L) x 89(H)
Weight	500 g

Design, Specifications are subject to change without notice. Ask factory for technical specifications before purchase and/or use. Whenever a doubt arises form this products, please inform us immediately for technical cosultation without fail.

14.3 Scanner

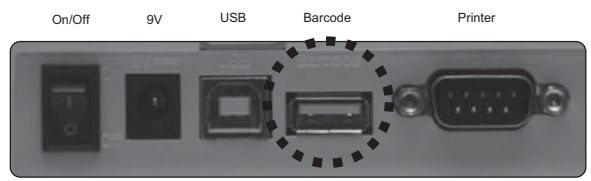
***CLOVER A1c™ Self* accepts data input from the following barcode symbologies**

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 14.

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.

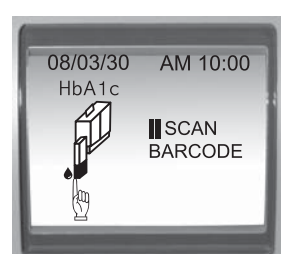


When performing your test with the barcode system

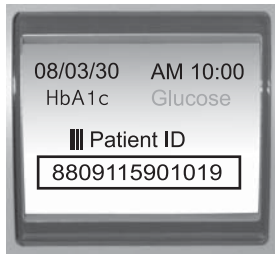
STEP 1. Open the cover of *CLOVER A1c™ Self* analyzer

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

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



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 :

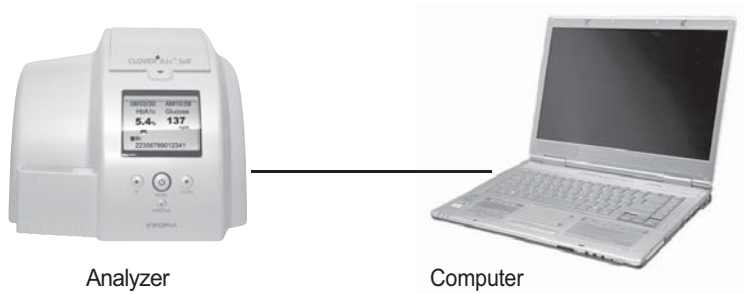
- The narrow bar width is too small
- The barcode length is too great
- The height is too small
- The reader is held too far from the label
- The background reflection is too high or low

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.

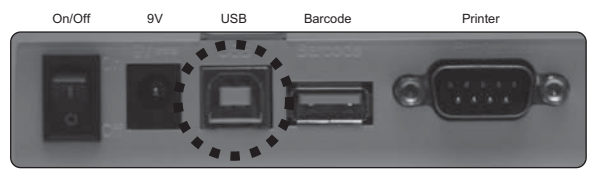
Contact with our local representatives for technical assistance.

14.4 Transfer Test Results to a Computer



Analyzer Computer

STEP 1. Connect the RS-232 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.

15. PRODUCT LIST

COMPONENTS

ITEM	CONTENTS	PRODUCT CODE
CLOVER A1c™ Self **Analyzer**	1 Analyzer 1 Instruction for use 1 Exclusive Power Adapter 5 Fan Filters 1 Daily Check Cartridge 1 Monthly Check Cartridge	**INFH01AS**
>>> Optional Products		
CLOVER A1c™ Self **Test Cartridge**	10 Test cartridges 1 Instruction for use	**INFHS01AS**
CLOVER A1c™ Self **Check Cartridge**	10 Monthly check cartridge	**INFHMC01AS**
CLOVER A1c™ Self **Check Cartridge**	1 Daily check cartridge	**INFHDC01AS**
CLOVER A1c™ Self **Glucose Test Modules (3Sec)**	1 Glucose Test Module (3Sec) 1 Instruction for use	**AC-CL0-1A1-02**
CLOVER A1c™ Self **Glucose Test Modules (5Sec)**	1 Glucose Test Module (5Sec) 1 Instruction for use	**AC-CL0-1A1-02**
Thermal Printer	1 Thermal printer 1 Instruction for use	**AC-CLO-1B0-01**
Barcode Scanner	1 Barcode scanner 1 Instruction for use	**AC-CLO-1C0-01**
PC Cable	1 PC Cable	**AC-CLO-1D0-01**
CLOVER A1c™ Self **Fan Filter**	1 Fan fileter	**AC-CL0-1A2-01**

16. 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	Problem with the analyzer system	Please power switch off and on again. If the problem persists contact your local representative.
Er 2	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 test cartridge and then insert again. If the 'reagent pack' icon is displayed, you can start the test. If the error persists, contact your local representative.
Er 4	Test Cartridge error	Test cartridge may be damaged or has residue on the outside (coding area). 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.

16. TROUBLESHOOTING

ERROR CODE	DESCRIPTION	CORRECTIVE ACTION
Er 6	The cartridge is left in the analyzer for an extended period of time or the cover is left open	Please press button and remove the cartridge. Insert a new test cartridge and perform the test again.
Er 7	Opening the cover while test or check is in progress	Please press button and remove the cartridge. Insert a new test or check cartridge and perform again.
Er 8	Problem with the glucose module connection	Please re-connect the cable again. If problem persist, contact your local representative.
Er 9	Damaged glucose test strip	Please insert a new test strip and perform the test agaim. If the problem paersists, open a new bottle and repeat test.
Er 10	Problem with the auto-coding label	Please insert a new test strip and perform the test again. If the problem persist, contact your local representa-tive.

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ERROR CODE	DESCRIPTION	CORRECTIVE ACTION
Er 11	Test strip is damaged	Please insert a new test strip and perform test again.
Er 12	The sample was inse rted too soon	Please wait for the LCD to display ‘Apply bood sample’ icon before applying the sample for the test.
Lo ℃	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 ℃	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.

16. TROUBLESHOOTING

ERROR CODE	DESCRIPTION	CORRECTIVE ACTION
>14%	The HbA1c test result is higher than 14.0% (130mmol/mol)	Please use the check cartridge to validate the analyzer and re-test the blood sample.
Lo mg/dl ou Lo mmol/L	The blood glucose test result is lower than 10mg/dl or 0.6mmol/L	Please double check the accuracy of the test strip by performing a control solution test and re-test with blood sample.
Hi mg/dl ou Hi mmol/L	The blood glucose test result is higher than 600mg/dl or 33.3mmol/L	Please double check the accuracy of the test strip by performing control solution test and re-test with a fresh blood sample.
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.

17. SPECIFICATION

Sample Type	Capillary whole blood, Venous blood with anticoagulant
Sample Volume	4 μl
Test Range	4.0~14.0%
Reading Time	5 minutes
Memory Capacity	200 test results
Wavelength	415 nm (normal)
Power Required	DC 9 V-1.5 A
Dimensions/Weight	200*200*139(mm) / 1.4kg
Storage Temperature	10 ~ 35 ℃ (50 ~ 95 °F)
Operating Temperature	17 ~ 32 ℃ (63 ~ 90 °F)
Relative Humidity Range	10% ~ 90%

Option	Glucose Test Module PC Connection Cable Thermal Printer Barcode Scanner

Recommended maintenance routine

1) Cleaning the exterior
2) Changing the air 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. Rotate the cartridge compartment forward with the compartment door open.

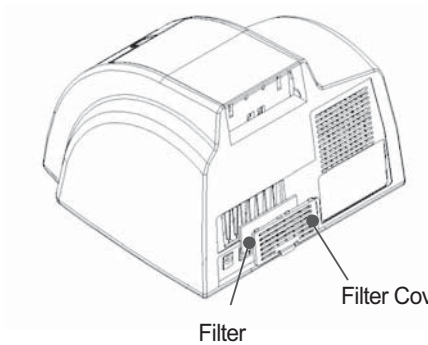


STEP 3. Dampen a sponge swap with water or ethanol.

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. Take out 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.

19. 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.

20. DISPOSAL

The Analyzer must be disposed accoding 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 ailmed to reducing the amount of EEE waste going for final disposal.

infopia 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.

21. PRECAUTION

1. Analyzer should be located on the flat table.

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

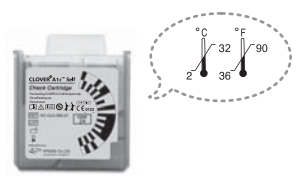
3. Electric power should be stable.

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



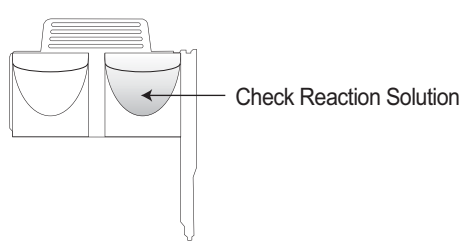
5. Users should carefully follow the indicated Analyzer operating temperature and Cartridge storage temperature.





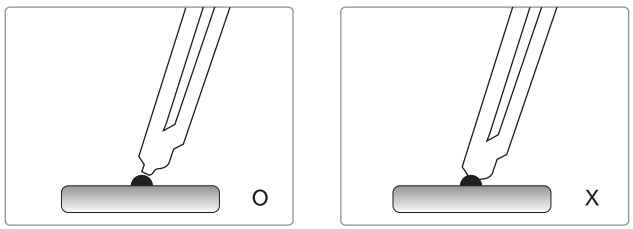
6. Do not move or give any kind of impact while the Analyzer is under testing.

7. The bead inside the Reaction Solution of the Reagent Pack, might sink and be coagulated after some period of time. So, users should shake the Reagent Pack before testing, and visually check if the beads are not coagulated.



8. Cartridge should be kept at the same test environment beside the Analyzer at least 30 minutes before test.

9. While collecting blood, users should contact the end of capillary tip slightly to the blood sample not putting the tip deep into the blood sample.
Putting the capillary tip deep into the blood sample may cause high results due to excessive blood sample.



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.

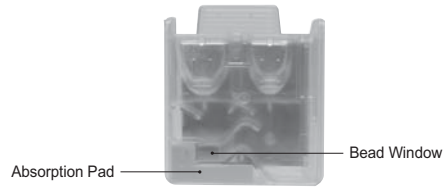
11. Firmly combine a reagent pack into cartridge with a mild pressure until 'Tick' sound from the cartridge.

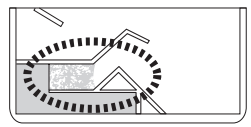


12. If there is some material inside cartridge holder, a cartridge cannot be firmly positioned into the analyzer. In such case, check the cartridge holder.

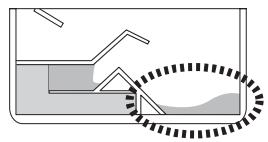


13. When test is done, after removing cartridge, if users find the below symptoms in inspecting the cartridge, users should test again because the test result may not be orrect.

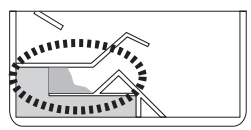




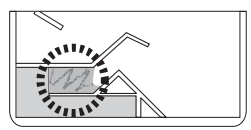
1) If the bead window is not colored uniformly.



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.

5) If unusual sounds comes while operating.

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

22. SYMBOL & DESCRIPTION

Symbol	Description
CE 0123	This symbol indicates that the product complies with the applicable directives of the European Union.
	Consult instruction 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

22. SYMBOL & DESCRIPTION

Symbol	Description
	This symbol indicates the position of inserting the reagent pack.
	This symbol indicates a temperature hazard.
	Temperature Limitation
	Do not reuse
	Date of Manufacturer
	Keep away from sunlight
	Direct Current
	Waste Electrical and Electronic Equipment
	This symbol indicates that the system is type A equipment, which provides a particular degree of protection against electric shock.

MEMO

MEMO

