CLOVER® A1c® *Plus*

Instructions for Use

· For use with CLOVER A1c® Plus Test Cartridge only
· For measuring hemoglobin A1c
· For professional use only

OSANG Healthcare infopia

IVD

Table of Contents

1. Intended Use

The CLOVER A1c® Plus Analyzer is an IVD(In Vitro Diagnostic Device) device for measuring Hemoglobin A1c using the well established method of boronate affinity. Capillary whole blood or venous blood treated with anticoagulant (K2EDTA, lithium heparin, sodium citrate, or sodium fluoride/Potassium oxalate). This CLOVER A1c® Plus Analyzer is designed to help controlling diabetes and it is intended to be used by professionals at laboratories, clinics and hospitals.

2. Principles of Operation

The reagent solution contains reagent that lyse erthrocytes and boronate bead that binds cis-diols of glycated hemoglobin. Inserting the Reagent Pack into the Cartridge is instantly lysed releasing the Hemoglobin and the boronate bead binding the glycated hemoglobin. firstly, 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 photo sensor. next, The washing solution washes out non-glycated Hemoglobin from the blood sample, thus the amount of glycated hemoglobin can be measured. Finally, The ratio of glycated hemoglobin with respect to total Hemoglobin in the blood sample is calculated.

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

The CLOVER A1c® Plus Analyzer has been programmed to produce results that are standardized to DCCT (Diabetes Control and Complications Trial).
'A' and 'B' are the slope and intercept factor to correct the value for DCCT calibration.

3. Preparation prior to Operation

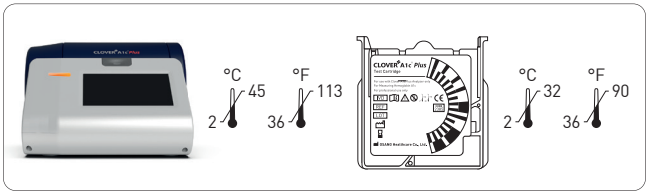
3.1 Installation

- CLOVER A1c® Plus Analyzer is a precise optical equipment. So, it should be installed in a flat and stable place without vibration. (If the Analyzer is placed in an excessively tilted state, a caution icon is displayed.)
- Electric power should be stable.
- Must be use the power adaptor and AC cord supplied with analyzer.
- Analyzer and Cartridge should not be exposed to the direct sunlight.
- Provide bench space large enough to allow free air circulation around the system - 8cm(3 inches) on all sides.

3.2 Environment

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

- The CLOVER A1c® Plus Analyzer has a storage temperature between 2°C~45°C (36~113°F) and operating temperature between 10~40°C (50~104°F) .
- Test Cartridges must be stored between 2~32°C (36-90 °F) and at a relative humidity between 10% to 90%.



- 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.

4. CLOVER A1c® Plus Contents

After receipt, carefully inspect the product for physical damage. If any damage is found, contact your local distributor.

Contents

1ea
CLOVER A1c® Plus Analyzer

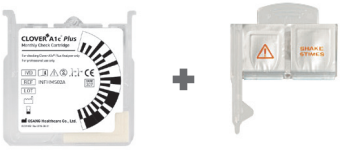
1ea
Instructions for Use

1ea
Exclusive Power Adapter

1ea
AC Cord

5ea
Fan Filters

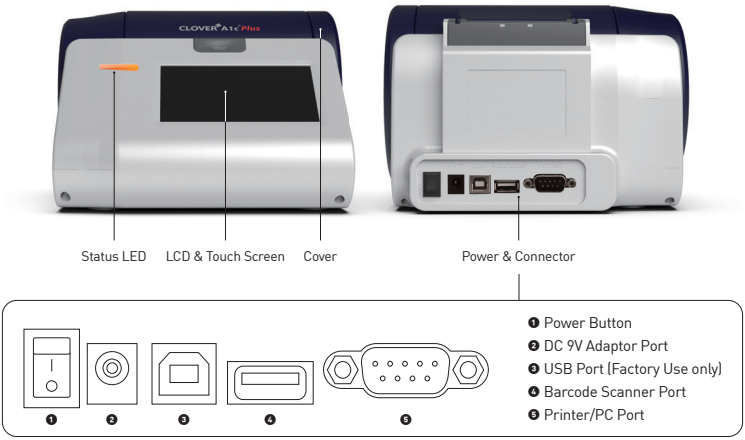
1ea
Daily(Blue) Check Cartridge



1ea
Monthly(Blank) Check Cartridge

5. Device Description

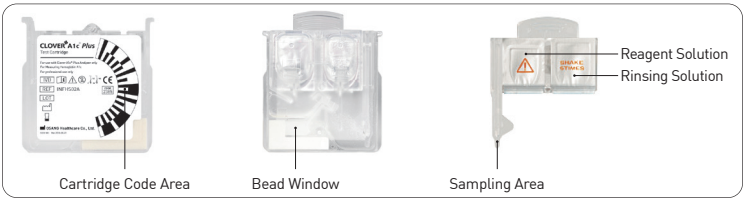
5.1 Analyzer



The USB port is exclusively used by the manufacturer. If this port is used for other than the intended use, the analyzer may have a problem.

5.2 Test Cartridge

When handling 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.



5.3 List of Icons

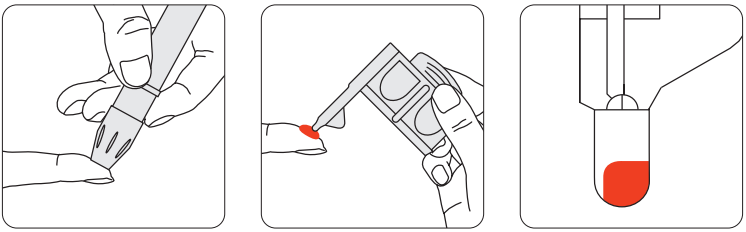
Icon	Name	Function
	Home	Return to the Stand-by Mode
	Setting	Set up the analyzer.
	Check Mode	Check Cartridge test Mode
	Daily Check Mode	Daily Cartridge test Mode
	Monthly Check Mode	Monthly Cartridge test Mode
	Memory Mode	View Saved test results
	Print	Print the test results
	Keyboard	Enter the Patient ID or operator ID.
	Caution	Abnormal condition of the analyzer

6. Sample Collection and Handling

Capillary whole blood from fingertip and venous whole blood can be used for HbA1c testing. 4μL blood sample is needed.

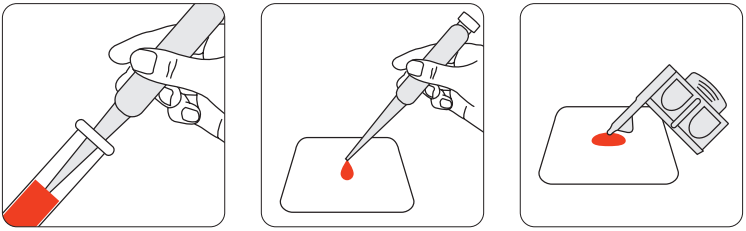
6.1 Capillary Blood Sampling

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 Sampling Area is completely filled.



6.2 Venous Blood Sampling

Venous whole blood collected using K2·K3EDTA, lithium heparin, sodium citrate or sodium fluoride/ oxalate as an anticoagulant can be used.

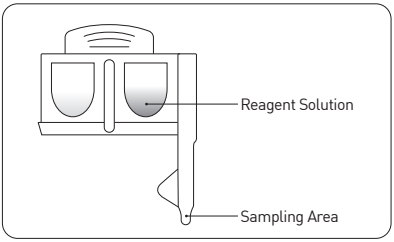


Venous whole blood can be stored at 2~8°C (36~46°F) for 7 days with unbroken seal (only 3 days when seal is broken) and at 20~25°C (68~77°F) for 3 days. If longterm storage needs, sample can be stored at -72 ~ -68 °C(-98 ~ -90°F) for 20 days, but do not freeze and thaw repeatedly.

Allow blood samples to reach room temperature(Frozen sample should be totally thawed). Anti-coagulated blood should be mixed well prior to testing. Remove the rubber stopper from the tube and take out a drop of blood sample from the tube. The blood sample taken out from tube should be placed on a clean surface.
Softly touch the sampling area of the Reagent Pack on the blood sample, and wait until the sampling area is completely filled.

CAUTION: There is a potential risk of biological hazard. All part of the CLOVER A1c® Plus should be considered as potentially infectious.
· Use gloves.
· Discard the used test cartridges in a solid container with a lid.
· Comply with all local hygiene and safety regulations.

6.3 Check the Reagent Pack and Sample Collecting Area

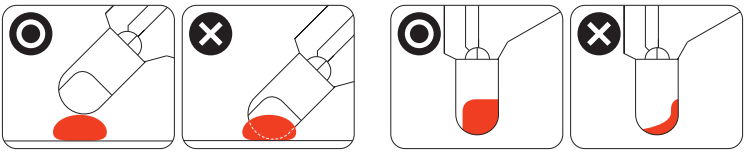


Reagent Solution
The beads inside the Reagent Solution might sink and stack tightly. Gently shake the reagent pack to make the beads in the reagent solution are uniformly spread.

CAUTION: Do not mix it too vigorously to avoid air bubbles. If the air bubbles are formed, wait until they disappear before testing.

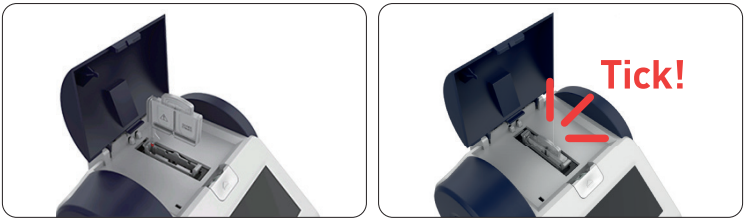
Sampling with Capillary tip

- To collect a blood, touch the blood sample with the end of the capillary tip.
- Do not immerse the tip deep into the blood sample.
- Do not touch the open end of the sampling area
- Check the cavity whether it is fully filled with the blood. An unoccupied space or an air bubbles lead to wrong results.



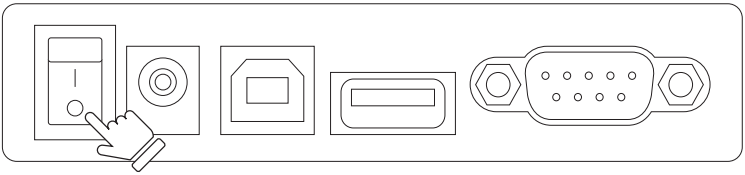
Insert the Reagent Pack

- Insert the Reagent Cartridge gently. Too much force and rapid insertion may lead to abnormal results.
- Insert the Reagent Pack into the cartridge until you hear a 'Tick' sound.



7. Operation

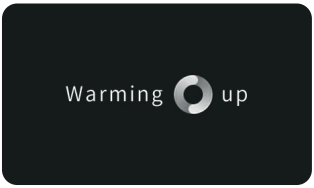
7.1 Power On



Connect the DC 9V adaptor provided in the system package to the power port. To start the CLOVER A1c® Plus , turn the power switch to the 'ON' position.

7.2 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® Plus performs hardware functionality test to verify that the internal optics and the mechanical system are operating correctly. Lid must be kept closed while 'Warming up'.



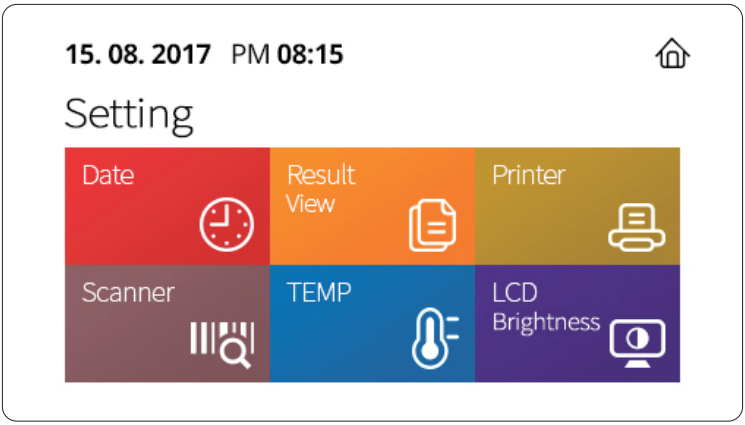
7.3 Stand-by

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

7.4 Power Save

If there is no action for 30 minutes, the analyzer turns into 'Power Save' mode. To return to 'Stan-by' mode, open the lid or touch the LCD Screen.

8. Setting the Analyzer

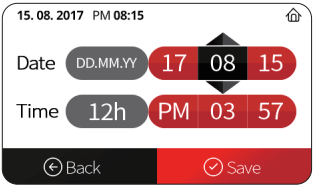


To enter the setting mode, touch the icon in the standby mode.
Touch the icon to return the Standby mode.
Touch the Save button to save the displayed setting value.
If you do not want to save the displayed value, touch the Back button.

Date	Set the Date and Time
Result View	Set the unit of results
Printer	Set the Print
Scanner	Set the Barcode scanner
TEMP	Set the unit of temperature
LCD Brightness	Set the LCD Brightness

8.1 Date

Touch the item you want to change and use the ▲ and ▼ buttons to change the value. When using the analyzer for the first time, set the time. It is important to manage the result value.



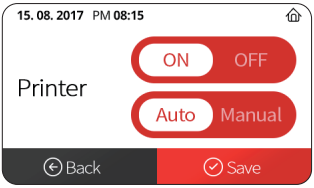
8.2 Result Unit

The unit of the result value can be changed. NGSP, IFCC, eAg, etc. can be selected single or in combination.

8.3 Printer

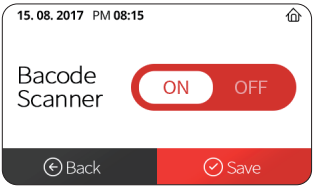
Select printer ON OFF or ON OFF to activate connected printer. When printer is ON OFF , select Auto Manual or Auto Manual for printing option.

Automatic: Result is printed automatically after testing
Manual: Result is printed by pressing Icon



8.4 Barcode Scanner

Select ON OFF or ON OFF to activate connected barcode scanner.



8.5 Temperature Unit

Select Temperature unit to be displayed.

8.6 LCD Brightness

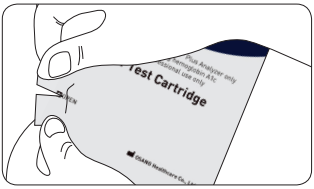
LCD brightness can be adjusted in 10 steps.
(Darkest: '0' ~ '10': Brightest)

9. Testing HbA1c

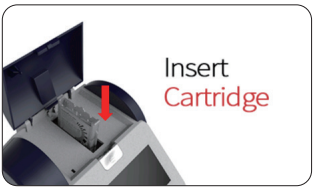
Importance: The CLOVER A1c® Plus Analyzer setup is described in the CLOVER A1c® Plus Analyzer Instruction for Use.
Please read through and familiarize yourself with the contents of both this manual and the CLOVER A1c® Plus System Instructions for Use before using the system.
Follow the procedure displayed on the LCD screen for each step.

Step 1.
Open the lid of the CLOVER A1c® Plus Analyzer.

Step 2.
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.



Step 3.
Insert the Cartridge
- Gently insert the cartridge into the cartridge compartment when 'Cartridge insert' is shown. Hold the cartridge barcode facing left.
- Do not force the cartridge into the analyzer. The cartridge is designed to fit only in one way.



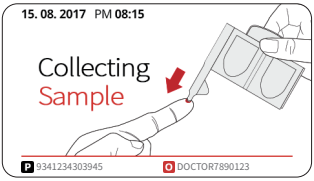
Step 4.

Gently shake the reagent pack to make the beads in the reagent solution uniformly spread.

Step 5.

Collect the sample(Blood, Control solution, etc.).

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



Step 6.

Insert the Regent Pack.

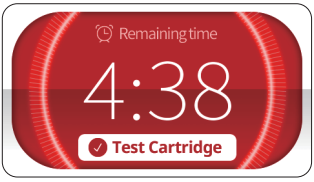
Caution: Close the lid immediately after inserting the reagent pack. Delay may lead to inaccurate measurements.

Step 7.

Closing the Lid will start the test automatically.

The remaining test time will be displayed.

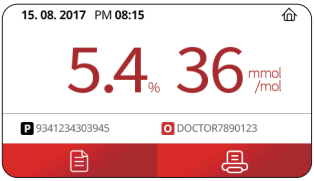
- Do not open the analyzer during test.



Step 8.

Result displays after measuring.

Important: When the printer function is set to Auto Manual, press the icon when you want to print the displayed result value to the printer.



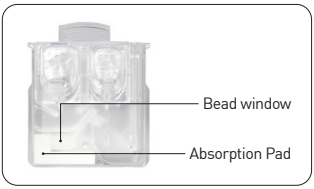
Step 9.

Remove the test cartridge from the analyzer by gently pushing it towards the left and pulling it out simultaneously.

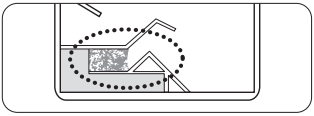
Caution: Do not forcedly pull out the cartridge from the analyzer.

Step 10.

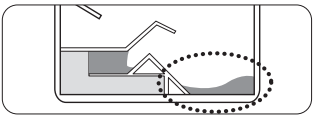
Inspect the used cartridge for symptoms. If any of the following symptoms are observed, repeat the test in order to verify validity of the result.



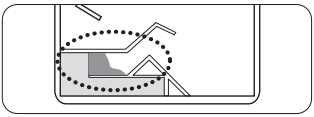
- If the bead window is not colored uniformly.



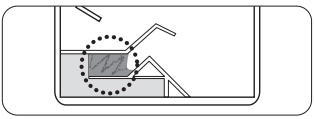
- If there is remaining Reagent solution in the cartridge.



- If bead window is not fully occupied with bead.



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

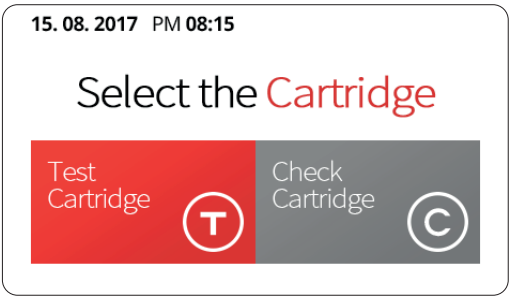


Besides, when any kind of errors appears, refer to the troubleshooting on the Analyzer instruction for use.

Code confirmation display after the test

When error shows up in the process of recognizing the cartridge code, the analyzer will asks for the type and code of the cartridge.

Analyzer will ask to confirm the cartridge is a test cartridge or a check cartridge. Take out the cartridge, and select the  or  to match the type of cartridge.



After selecting the type of cartridge, tap the up and down icon  to match the code number of the cartridge, then press  to confirm, and the test result is displayed.

Expected values

The American Diabetes Association's (ADA's) 2014 Clinical Practice Recommendation

for diabetes specifies a treatment goal of less than 6.5% HbA1c.*

Limitation of Procedure

The CLOVER A1c® Plus assay gives accurate and precise results in the range of 7~20 g/dL of total hemoglobin. Most patients have hemoglobin concentrations within this range.

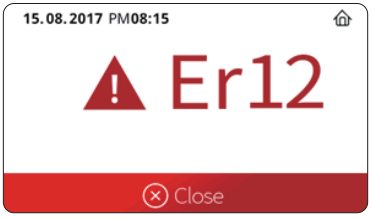
However, patients with severe anemia may have Hemoglobin concentrations lower than 7 g/dL, and patients with polycythemia may have Hemoglobin concentrations above 20 g/dL. Patients known as these condition should be tested with another method for HbA1c determination.

Warning after test when movement (slope) occurs before test, mark Er12 when movement (slope) occurs during test, and stop test.

If the ' CLOVER A1c® Plus' detects movement (slope) before cartridge insertion, the screen shows a caution Icon ⚠ and does not move on to the next step.

If motion is detected during the test, Error 12 is displayed on the screen and the test is terminated.

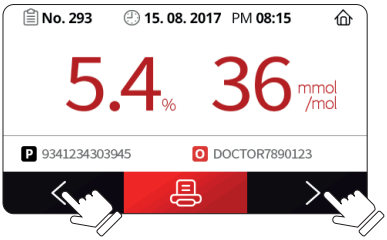
If the test is stopped by Error 12, remove the cartridge and re-measure the analyzer in a stable, flat, vibration-free place.



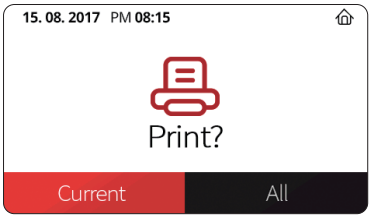
10. Reviewing Results

It shows the test results up to 1000 that have been measured

In the Stand-by mode, select the icon.



Select the , icon to view the measurement results.
When the icon is selected, the currently displayed result value is Printed.
Display of the result depends on the type of In the setting mode.

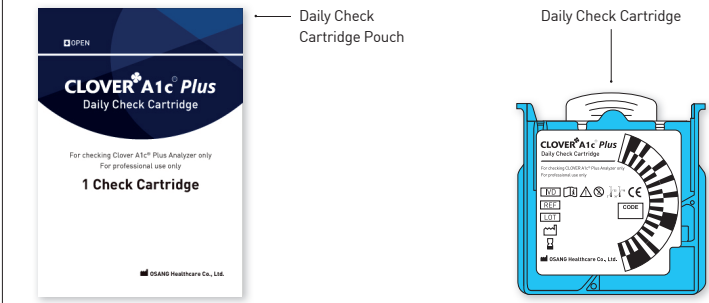


When the printer function is set to , press the icon when you want to print the displayed result value to the printer.
Current – Only the currently displayed result value is output.
All – All results stored in memory are output at once.

11. Quality Control

11.1 Daily Check

The Daily Check is intended to check for abnormal operation of the Analyzer.



When to use the Daily Check Cartridge

- Daily inspection
- Power is turn on again
- Re-verify errors in occur during use (Er1, Er3, Er7, etc.)

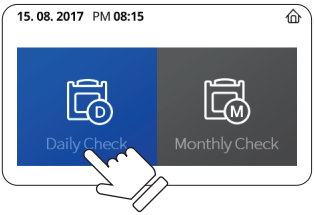
After use, be sure to store the Daily Check Cartridge in a dedicated pouch. (Reusable)

Step 1.

In standby mode, touch icon.

Step 2.

On the check mode selection screen, touch the icon on the left.



Step 3.

When the cartridge is inserted and the lid is closed, the test starts automatically.

- Gently insert the cartridge into the cartridge compartment when 'Cartridge insert' is shown. Hold the cartridge barcode facing left.
- Do not force the cartridge into the analyzer. The cartridge is designed to fit only in one way.
- Do not open the analyzer during test.

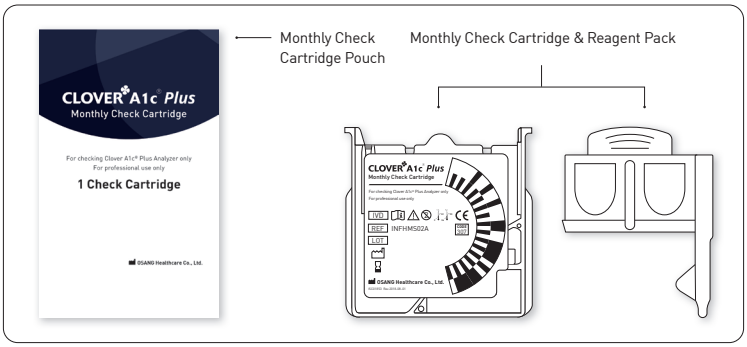
Step 4.

After one minute, 'OK' or an error message is displayed.

OK: there is no abnormality in the Analyzer
Error: Test again. (Refer to Trouble shooting page for the type of error.) If fail is repeated, please contact your local representative for customer support.

11.2 Monthly Check

The Monthly Check is intended to check for abnormal operation of the Analyzer. (Not reusable)



When to use the Monthly Check Cartridge

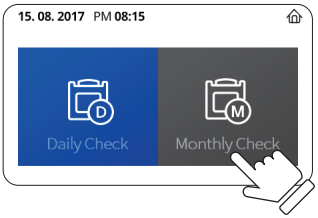
- Monthly inspection
- When there is a concern that the test result may be incorrect
- Recheck the errors that occurred during use. (Er2, etc)

Step 1.

In standby mode, touch icon.

Step 2.

On the check mode selection screen, touch the icon on the Right.



Step 3.

Insert the cartridge of monthly check cartridge.

- Gently insert the cartridge into the cartridge compartment when 'Cartridge insert' is shown. Hold the cartridge barcode facing left.
- Do not force the cartridge into the analyzer. The cartridge is designed to fit only in one way.

Step 4.

Shake the reagent pack gently and press until the 'tick' sound to fully insert it into the cartridge.

Step 5.

Close the Lid and test starts automatically. The remaining test time is displayed.

Step 6.

After five minutes, 'OK' or an error message is displayed.

OK: there is no abnormality in the Analyzer.
Error: Test again. (Refer to Trouble shooting page for the type of error.) If fail is repeated, please contact your local representative for customer support.

11.3 HbA1c Control Solution

The quality control materials are intended to check for the degradation of the cartridges or problem of whole system. If external quality control testing is desired, commercial controls from other vendors can be used. Please contact your local representative to inquire about the materials.

When use the quality control materials

- On suspicion that test results may be incorrect.
- On suspicion that performance degradation of test cartridges
- After an error message

Verifying and Correction the Results

The results should be within the acceptable range for the control. If the values using the control material have deviations over the limit, check several point in below. The problems appear repeatedly in spite of the correction, consult your local representative for customer support.

- Expire dates of test cartridges and control materials.
- Storage condition
  : Do the test materials have been stored properly, according to the recommendations?
- Sample collecting procedure
  : Is the cavity fully occupied with the sample? Or isn't the sample excess?
- Contamination of the test materials
- Quality control using check cartridges: Correction of abnormality of analyzer

12. Options (Sold separately)

12.1 Printer

To use the printer, the printer function must be set to ON OFF in setting mode. Refer to item 8.3 on page 14.

Components

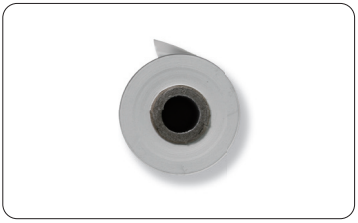
The below pictures show the items which should be included for the standard of STP-103III Package.

If any items are damaged or missing, please contact with our local representatives for technical assistance.

Printer

Adapter & cord

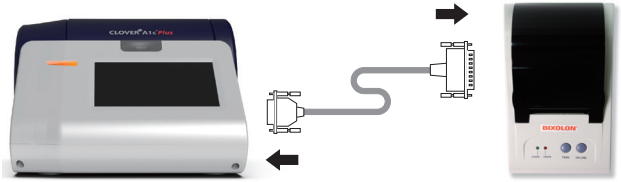
Data Cable

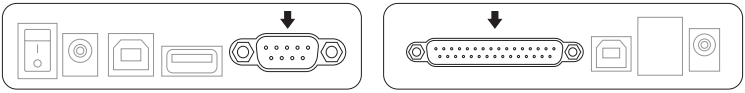


Paper Roll

Connection

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

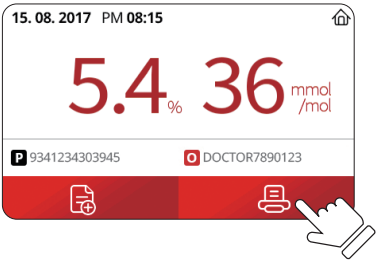


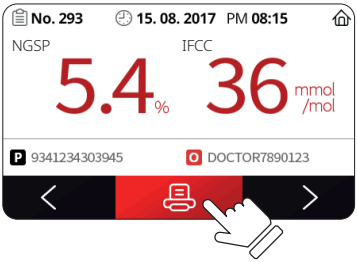


Printing Test Result

Operating type of printer is already pre-set to either manual or automatic printing in analyzer.

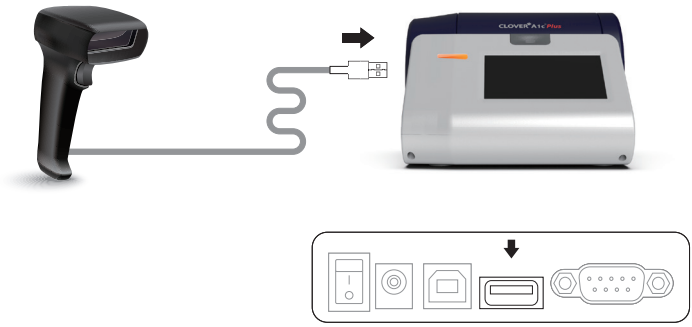
Automatic setting: Result is printed automatically after testing
Manual setting: Result is printed by pressing Icon





12.2 Barcode Scanner

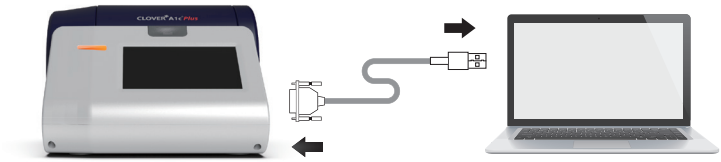
Patient information and user information can be entered using a barcode scanner before sample measurement.
To use the barcode scanner, the barcode scanner status must be set to ON in the setting mode. Please refer to section 8.4 on page 14 of the manual.
Only TechScan Korea 'TSK-750-32IV (USB Type)' can be used for barcode scanner.



Connect the Barcode Scanner to the USB Port of the analyzer.

The icon is displayed while the reagent pack is being inserted. You can enter the patient ID and operator ID directly by selecting the icon.

12.3 Dedicated cable for communication (Send the Results to PC)



1. If the CLOVER A1c® Plus Management Program is installed on the PC, the measured result can be managed on the PC.
2. Connect the PC to the analyzer with the interface cable(RS-232C). The analyzer should be in stand-by mode.
3. Analyzer and PC are connected properly, the "PC Connection" message will be displayed on the screen.

4. Run a CLOVER A1C® Plus Management Program on a PC.
5. When you click the "Data Transfer" icon in the CLOVER A1c(R) Plus Management Program, the results stored in the analyzer are transferred to the PC.

CLOVER A1c® Plus Management Program can be downloaded from the homepage.
www.osanghc.com

13. Troubleshooting

General Information

If an operational or system problem occurs, an error code may display on the system screen. This section provides explanations and corrective actions with errors and messages.

If the problem persists, record the error code and contact your local representative for technical support provider for assistance.

Message	Reason		Solution
Er1	1	Motor error (warming-up)	Please power switch off and on again. If the problem persists contact your local representative.
	2	Analyzer system fault	
	3	Temperature error of sensor space	
	4	Cartridge recognition Sensor error	
	5	Measurement error of measuring sensor	
	6	Error of constant temperature	
	7	Motor error (test)	After daily check mode, please use again.
Er2	Check Cartridge		Check the contamination of the check cartridge, foreign matter, scratches, etc., and measure again.
Er3	Problem with reading bar code of test cartridge		Perform daily check mode. If there is no problem, insert a new test cartridge and perform the test again.
Er4	Measurement error in test cartridge		Insert a new test cartridge and perform the test again.
Er5	Problem with Reagent Pack of the test cartridge		The reagent pack may be damaged and leak reagent solution. Please remove the cartridge. Insert a new test cartridge and perform the test again.
Er6	problem when the cartridge (reagent pack inserted) is left in the analyzer for an extended period of time or when the lid is left open.		Discard cartridges that have been left unused for a long time. Insert a new test cartridge and perform the test again.
Er7	Open the lid during the test		Discard used cartridge. Insert a new test cartridge and perform the test again.
Er8	The cartridge is Expired		Check the expiration date of the cartridge label.
Er9	Reagent Pack error		Before the collecting sample, please use to shake the Reagent Pack.

Message	Reason	Solution
Er10	Problem with less blood on Reagent Pack, Low hemoglobin capacity	Please correctly insert blood to Reagent Pack (See '6.3 Check the reagent pack and sample collecting area' on pages 9, 10), Do check for hemoglobin in the blood.
Er11	Problem with excess blood on Reagent Pack, High hemoglobin capacity	
Er12	Motion (slope) of the analyzer during the test	Ensure that the analyzer installation is in a flat, vibration-free location. Do not move the analyzer when inserting cartridge and reagent pack. Re-measurement with a new cartridge.
Do Not Reuse	Problem with reusing the cartridge. (Test or Monthly Check 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.
<4%	The HbA1c test result is lower than 4.0% (NGSP) or 20mmol/mol(IFCC)	If the measured value is abnormally low, please use the Monthly check cartridge validate the analyzer and re-test the blood sample.
>14%	The HbA1c test result is higher than 14.0% (NGSP) or 130mmol/mol(IFCC)	If the measured value is abnormally High, please use the Monthly check cartridge validate the analyzer and re-test the blood sample.
Lo ℃	The ambient temperature is lower than 10 ℃ (50℉)	Please make sure the equipment is within normal operating temperatures for at least 10 minutes and re-test.
Hi ℃	The ambient temperature is Higher than 40 ℃ (104℉)	Please make sure the equipment is within normal operating temperatures for at least 10 minutes and re-test.

14. Specification

Sample Type	Capillary whole blood, Venous with anticoagulant
Sample Volume	4㎕
Test Range	4.0~14.0% (NGSP)
Measurement Time	5 minutes
Memory Capacity	1000 test results
Power Required	DC 9 V-2 A
Dimensions/Weight	190*210*133 ± 1mm / 1.4kg (±0.1kg)
Storage Temperature	2 ~ 45 ℃ (36~113℉)
Operating Temperature	10 ~ 40 ℃ (50 ~ 104℉)
Relative Humidity	10% ~ 90%
Option	Management Program (PC), Thermal Printer, Bar-code Scanner

15. Maintenance

15.1 Cleaning the surface of the analyzer

- Turn off the power and remove the power adopter before cleaning.
- Wipe out the dust using soft clean cloth.
- Do not use liquid or gaseous detergent.
- If necessary, clean the contaminated area with an alcohol with a soft sponge. Do not use other chemicals. The surface of the analyzer may be damaged.

15.2 To clean cartridge holder

- Turn off the power and remove the power adopter before cleaning.
- Open the lid, check there is no dust in the cartridge inserting part.
- Wipe off alcohol with a soft sponge.
- Remove dust inside using air blower.
- Be careful not to leave any liquid or dust inside cartridge holder.

15.3 Replacing the Fan Filter

Five fan filters are provided with the analyzer.
Periodically check the fan filter on the side of the analyzer.
Replace fan filter if it is clogged with dust.
Additional fan filters can be purchased from our representatives or resellers.

1. Open the fan filter cover.
2. Remove the used fan filter.
3. Carefully replace with a new one.
4. Close the fan filter cover.

16. Warranty

Please confirm the enclosed warranty card with analyzer.

17. Safety

The analyzer has been fully tested according to the Electrical Safety Regulations (EN 61010-2-101).

Safety tips

· Do not disassemble the analyzer.
· Do not expose analyzer to high humidity.
· Do not expose analyzer to pollution or dust.
· Do not expose analyzer to any impact, shock, or vibration.
· Do not place analyzer next to chemical products.
· Keep away from direct sun light.
· Do not cover ventilation openings on the side of the analyzer.
· Do not touch the analyzer with any metallic or inflammable materials.
· Do not install analyzer near any potential electromagnetic sources.
· Keep away from strong electromagnetic fields.
· 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® Plus is a precision system and must be handled accordingly.

18. 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.

19. Symbols & Descriptions

Icon	Function	Icon	Function
	Consult instructions for use.		Manufacturer
	Used by date		Temperature limitation
	Caution, consult accompanying documents		Do not reuse
	In vitro diagnostic medical device.		Date of Manufacturer
	Batch code		Keep away from sunlight
	Catalog number		Direct Current
	Serial number		Waste Electrical and Electronic Equipment

CLOVER A1c® Plus

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