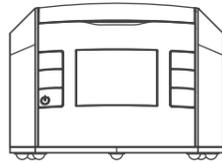


FORA[®] A1C100

Hemoglobin A1c Analyzer

Operation Instruction



Version 2.0
2021/10
541-4611100-021

IMPORTANT INFORMATION

The measurement unit used for indicating the concentration of HbA1c can be either NGSP unit(%), IFCC unit(mmol/mol) or Estimated Average Glucose(mg/dL). The approximate calculation rule for conversion is:

%	10.93 x HbA1c(%) - 23.5	= mmol/mol
%	28.7 x HbA1c(%) - 46.7	= mg/dL

For example;

- 1) 7% x 10.93 - 23.5= 53 mmol/mol
- 2) 7% x 28.7 - 46.7= 154 mg/dL

Source: "National Glycohemoglobin Standardization Program (NGSP)" website <http://www.ngsp.org/bgground.asp>

SAFETY INFORMATION

WARNING!

A warning statement in this manual identifies hazards that could lead to personal injury. These warnings pertain to the entire FORA A1C100 Hemoglobin A1c Analyzer.

CAUTION!

A caution statement in this manual identifies hazards that could lead to product damage or data loss.

IMPORTANT SAFETY INSTRUCTIONS

READ BEFORE USE

1. Use this device **ONLY** for the intended use described in this manual.
2. FORA A1C100 is designed for medical clinician use, only a trained clinician or professional user should use this device.
3. Do **NOT** use accessories which are not specified by the manufacturer.
4. Do **NOT** use the equipment in places where aerosol sprays are being used. Sprays will permanently damage the optical system.
5. Do **NOT** use this device in close proximity to sources of strong electromagnetic radiation, as these may interfere with the accurate operation.
6. Do not let the device or its flexible cord come into contact with surfaces which are too hot to touch.
7. Handle the device with extreme care. Severe mechanical shocks can damage the internal parts.
8. Allow at least 3 cm of air space between the wall and the back of the device in order not to block ventilation, and prevent the power connector from damage.
9. Every six months, replace the fan filter with a new one.
10. Do not open the cover during the measuring process due to the rotation of internal device may cause personal injury or device damaged.
11. Keep the hands away from the inner side of device, do not let any liquid or object get into the inner side of the device.
12. While reloading or replacing the thermal paper, the induction surface of paper roll should be faced up before printing.
13. Always operate the device in an operating temperature range 15°C to 32°C (59°F to 89.6°F), and relative humidity less than 90%.
14. Always store the device in a cool and dry place: temperatures between 10°C to 35°C (50°F to 95°F) relative humidity less than 90%. Avoid direct sunlight.

INTRODUCTION

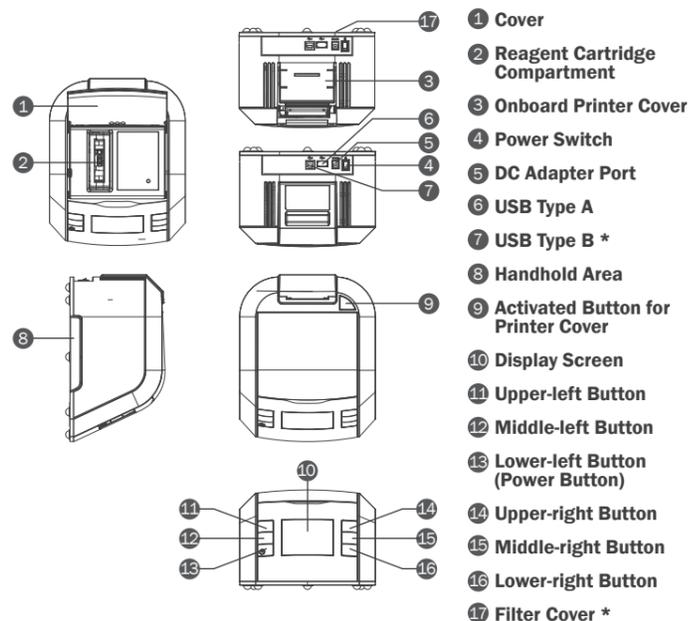
Intended Use

The analyzer is designed to quantitatively measure the percent of glycated hemoglobin (HbA1c %) levels in capillary or venous whole blood samples. Due to its small size and easy operation, it is ideal for professional use in the physician office laboratories and diabetes clinics. Test performed using the HemoglobinA1c Analyzer is intended for in vitro diagnostic use. As with all diagnostic tests, do not base a definitive diagnosis on the results of a single test. A physician should make a diagnosis after all clinical and laboratory findings are evaluated.

Contents of FORA A1C100 System

1. HbA1c Analyzer
2. Power Supply: SINPRO Model No.:MPU31-104, INPUT: 100-240V~47-63Hz, OUTPUT: 10V --- 3A
3. Thermal Paper

Analyzer Overview



NOTE:

- * As to USB Type B, which is without any function for the lay user, but it's required for the manufacturer for internal production use.
- * It is recommended to replace the fan filter on the bottom of analyzer with a new one every six months.

Display Screen

The screen displays several indicators to help you use this analyzer. The seven modes below will display on the main page.

Indicator	Meaning/ You can do this
	Measure Mode: Perform HbA1c tests and edit the current test information, e.g. Operator ID, User ID and Comments.
	QC Mode: Perform control solution tests and edit the current test information, e.g. Operator ID, QC Lot and Test Range for Level 1 and Level 2.
	Record Mode: Review the HbA1c test records in the analyzer and view the records of patient by entering patient ID and date range.
	Setting Mode: Set up the analyzer such as date, time and the unit of measurement.
	Cal Card Mode: Import the lot information for each new box of cartridge by calibration card.
	Training Mode: Video introduce the procedure of HbA1c measurement with both sample preparation and analyzer operation.
	About Mode: Display the serial number, software and hardware version of meter.

BEFORE MEASUREMENT - CONNECTING POWER & STARTING THE SYSTEM

Ensure the power switch is in off position "0". Connect DC adapter power cord to the system and to an appropriate, grounded AC electrical outlet. After the system is properly installed, turn the power switch on the position "I", press the lower-left button to initiate the system. The system performs self-test to verify that the internal mechanical system with time fetch is operating correctly and warm up the system so it is ready for use. If the time fetch errors, a warning with Time error displays on the screen. Press "⌂" to enter Time & Date setting. After operating Time & Date setting, the system completes its initialization and warming up, the main page will display seven modes on the screen and you can start to perform the test.

CAUTION!

Ensure the cover is closed while initiating the system.

WARNING!

Ensure the operating temperature is between 15°C and 32°C (59°F to 89.6°F) in order to get the most accurate test results, or erroneous results may occur.

NOTE:

1. Make sure the cartridge compartment is "Empty" before starting the test.
2. Keep pressing the Lower-left Button (Power Button) for 4 seconds, the analyzer will go to the status of Power Off.
3. Alarm and error message will be showed while the ambient temperature is out of the range 15°C and 32°C (59°F to 89.6°F). Place the analyzer and reagent cartridge in the above temperature range for a period of time. After the balance of temperature, press "return" to re-perform the test; Also, while the analyzer is moved from the surroundings in higher or lower temperature, place the analyzer in the above temperature range for a period of time for the balance of temperature.

Import the lot information for each new box of cartridge by calibration card

1. Press "Enter" to select cal card mode.
2. Open the cover, then insert the calibration card and lean the card against the left side. (Do not move or take out the calibration card during reading.)

NOTE:

1. Do not insert any other metal into the cartridge compartment together with the calibration card.
2. If the error of Incorrect Calibration Data occurred, please contact the local customer service for help.

3. When Lot Information was shown on screen, then take out Calibration Card. Make sure to check the lot number displayed on the screen matches the number on the calibration card.

4. Press "Confirm" to save the lot information.

NOTE:

If the calibration is interrupted or failed, please take out the calibration card first, press "Cancel". Then the system will return to the main page and repeat it again.

5. The analyzer will return to the main page automatically.

PERFORMING THE HBA1C TEST

Opening the Foil Package

Always wear gloves when performing tests.

1. Remove one foil package (containing a reagent cartridge).
2. If the reagent cartridge is removed from refrigerated storage, make sure to warm it up at room temperature for 15 minutes.
3. Open the foil package.

CAUTION!

Do not use scissors to cut open the foil package. Scissors can damage the reagent cartridge, the flexible plastic pull - tab on the cartridge, or the desiccant bag.

4. Remove the reagent cartridge from the foil pouch.

CAUTION!

When handling the reagent cartridge, do not touch or otherwise contaminate the optical window or erroneous test results may occur.

Preparing Patient Samples

1. Clean the finger stick with alcohol swab and let it dry.
2. Prick the finger stick with lancing device.
3. Gently squeeze the finger to assist the flow of blood.
4. Pull up the capillary from the cartridge.
5. Hold the capillary holder at an angle.
6. Touch only the tip of the capillary to the blood drop. Blood will automatically flow into the capillary.

CAUTION!

Too much or less amount of blood, erroneous test results may occur.

7. Less or equal to 0.2 µL of blood is required to fill the capillary.

CAUTION!

When the capillary is filled with the sample, analysis must begin immediately (Avoid blood clotting)

Inserting Capillary Holder into Reagent Cartridge

Carefully insert the capillary holder into the reagent cartridge until the holder gently snaps into place (will hear a click).

CAUTION!

Avoid harsh insertion of the capillary holder. Do not dislodge the sample from the glass capillary or erroneous results may occur.

NOTE:

If the reagent cartridge is damaged or the flexible pull-tab is loose or missing, please discard it and replace with a new one.

Selecting Measure Mode

Inserting the Reagent Cartridge into the System

CAUTION!

Do not pull the tab, before you insert the reagent cartridge into the cartridge compartment or erroneous results may occur.

1. Open the cover at a tilted angle for 120 degree until a click is heard or felt.

The bolts inside the device structure will be fastened to fix the cartridge in the right position while insertion.

NOTE:

If not open the cover for 120 degree, the cover may be closed again or the cartridge may be in malposition while insertion, which may lead to the device damaged in operation. Below warning label is stuck on the device for your information.

WARRANTY CERTIFICATE

YEAR
WARRANTY

Owner's portion

Name of product: _____

Name of owner: _____

Address: _____

Tel No: (Mobile) _____ (H) _____ (O) _____

Email: _____ Age: _____ Gender: M F

Date of Purchase: / /
day month year

Dealer's Stamp:

Serial No.: _____

*NOTE: Please produce this card together with the purchase receipt for warranty service.

WARRANTY REGISTRATION CARD

Dealer's portion

Name of product: _____

Name of owner: _____

Address: _____

Tel No: (Mobile) _____ (H) _____ (O) _____

Email: _____ Age: _____ Gender: M F

Date of Purchase: / /
day month year

Dealer's Stamp:

Serial No.: _____

*IMPORTANT: To qualify for the warranty, please fill in this card and mail to us within 14 days from the date of purchase.

