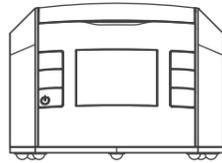


# FORA<sup>®</sup> A1C100

## 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

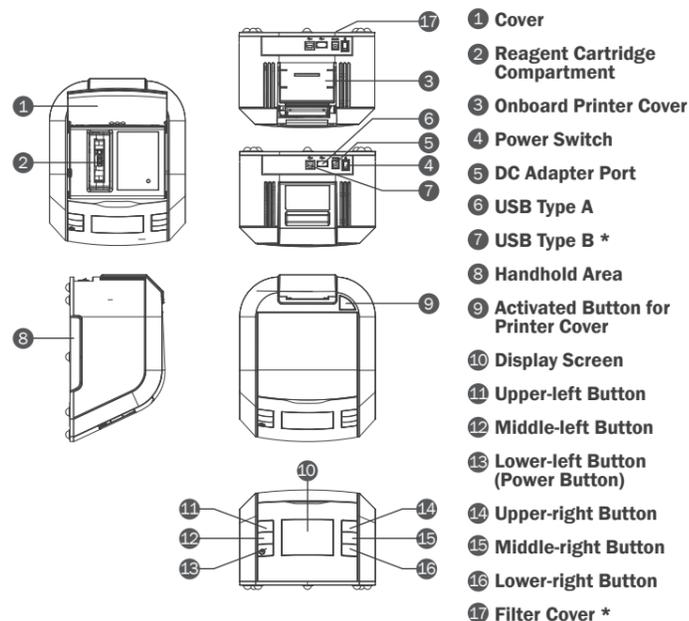
#### Intended Use

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
	<b>Measure Mode:</b> Perform HbA1c tests and edit the current test information, e.g. Operator ID, User ID and Comments.
	<b>QC Mode:</b> 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.
	<b>Record Mode:</b> Review the HbA1c test records in the analyzer and view the records of patient by entering patient ID and date range.
	<b>Setting Mode:</b> Set up the analyzer such as date, time and the unit of measurement.
	<b>Cal Card Mode:</b> Import the lot information for each new box of cartridge by calibration card.
	<b>Training Mode:</b> Video introduce the procedure of HbA1c measurement with both sample preparation and analyzer operation.
	<b>About Mode:</b> 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 "O". 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.

2. Hold the reagent cartridge with the label facing left.

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

3. Insert the reagent cartridge into the cartridge compartment until a gentle snap is heard or felt.

4. Using a smooth, slow, continuous motion, pull the flexible pull - tab completely out of the reagent cartridge.

**NOTE:**  
Make sure the blood sample in capillary holder is inserted and pull the flexible pull-tab.

5.  Press “Enter” to select measure mode.

6.  Press “Confirm” to confirm cartridge insertion.

7. Close the cover, then start measuring.

**NOTE:**  
 During mesurement, you can press “return” to stop the measurement and return to previous page.

**WARNING!**  
Do not open the cover during the measuring process due to the rotation of internal device may cause personal injury or device damaged. The operation of device will be suspended immediately once the cover is open, then the measuring will be forced to stop.

**NOTE:**  
Make sure DO NOT OPEN COVER while in the following conditions:

- Initiating the system
- In measuring process
- In operation process

## Enter Patient ID & Operator ID information

During measuring, the system will show the percentage of completion Patient information can only be entered during measurement. Entering the information will not interrupt the processing. Both letters and numbers can be entered.

1.  Enter Patient ID & Operator ID information by pressing “Edit”.

2. Edit HbA1c information: Patient ID, Operator ID, Comments.

 Move keyboard current position to left direction.

 Move keyboard current position to down direction.

 Confirm the current input character.

 Save information.

 Back to edit HbA1C information view. You can also use a barcode reader or keyboard to enter the information.

3. When the test was finished, the test result will display, and the result will be automatically recorded.

4. You can press “Print” to print a copy of measurement.

5. The measurement unit can be switched by pressing either “%” or “mmol/mol”.

6. You can press “PCL” to transmit data via bluetooth dongle.

7. Remove the used cartridge and the analyzer will return to the main page automatically.

## Selecting QC Mode

1. Press “Enter” to select QC mode.

2. See the label on the current control solution vial to select Level 1 or Level 2. An animation for control solution test plays automatically on the screen.

3. Follow the instructions in the control solution insert to perform the control solution test correctly.

4. During testing, the system will show the percentage of completion. Entering the information of Operator ID, QC Lot and Test Range will not interrupt the processing. Both letters and numbers can be entered.

**NOTE:**  
See the label on the current control solution vial to enter the Test Range.

5. When the test was finished, the QC test result will display, and the result will be automatically recorded.

6. Remove the used cartridge and the analyzer will return to the main page automatically.

**NOTE:**  
If the control solution testing result is out of the range, please contact the local customer service for assistance.

## Selecting Record Mode

**How to do**

 Press “Enter” to select record mode.

Five modes can be selected:

Last 10, All, Patient ID, Date Range and QC.

### “Last 10” and “All”

1. Enter “Last 10” or “All”.

2. Select the result you want to review.

3. Press “Print” to print a copy of the patient test result if necessary.

4. Press “Delete” to delete the patient test result if necessary.

### Patient ID

1. Select Patient ID.

2. Enter the patient ID you want to review.

3. Press “Search”. The searching result will display. Select the result you want to review.

4. Press “Print” to print a copy of the patient test result if necessary.

5. Press “Delete” to delete the patient test result if necessary.

### Date Range

1. Select “Date Range”

2. Enter the time period you want to review

3. Press “Search”. The searching result will display. Select the result you want to review

4. Press “Print” to print a copy of the testing result if necessary

5. Press “Delete” to delete the testing result if necessary.

6. “No record” will appear, indicating that there are no test results in the memory.

## QC

1. Select “QC”.

2. Select the result you want to review.

3. Press “Print” to print a copy of the QC test result if necessary.

4. Press “Delete” to delete the QC test result if necessary.

## Selecting Setting Mode

**How to do**

 Press enter to select setting mode.

Setting the Date & Time

1. Use the Right/Down arrows to select the Year, Month, Day, Hour and the Minutes.

2. Use the + and - arrows to change the Year, Month, Day, Hour and the Minutes.

3. Time & Date format:

- YYYY/MM/DD
- Hour : Min

4. Press “Return” to save the setting, then return to setting mode.

**NOTE:**  
To keep the date and time settings:

- Always connect the power cord to the analyzer and plug it into a functioning wall outlet.
- Always keep the power switch on (1).

Setting the HbA1c Unit

1. Use the down arrows to select % or mmol/mol.

2. Press “Return” to save the setting, then return to setting mode.

Setting the Export Data

1. Use the down arrows to select “USB Flash” or “Bluetooth”.

**NOTE:**  
The inner existing data will be overwritten while exporting data by the storage device. It is important to complete the data export and import in sequence. Meanwhile, do not export data from several analyzers at the same time due to the latter data will overwrite the former one.

2. Insert a storage device into the USB port if “USB Flash” is selected, and then select “Confirm”.

3. “Data Export Success” will appear, indicating that the data is transmitted well.

4. Insert a bluetooth dongle if “Bluetooth” is selected, and then select “Confirm”.

5. “PCL” will appear, indicating that the data will be transmitted to the host.

Setting the Import Data

1. Use the down arrows to select “Replace” or “Append”.

**NOTE:**  
Before selecting “Replace”, make sure the inner data is no need to use or the data has exported for backup.

2. Insert a storage device into the USB port, and then select “Confirm”.

3. “Data Import Success” will appear, indicating that the data is transmitted well.

4. Remove the storage device form the USB port.

Setting the Reset

1. Select “Reset” in the setting menu.

2. “Please confirm that you want to reset” will appear, select “Confirm” to reset.

Setting the QC Test Interval

1. Select “QC Test Interval” in the setting menu.

2. Select the interval you want to perform: Never, 1 week, 1 month, 3 months or Other.

3. If Other selected, you can adjust the desired range from 1 week to 52 weeks.

Setting the Report Headers

1. Select Line1 or Line2. The Line1/2 screen displays.

2. Use keyboard to edit

3. Select Return. (The printer report header information will be saved.)

Setting the Report Headers

1. Select Line1 or Line2. The Line1/2 screen displays.

2. Use keyboard to edit.

3. Press “Save” to confirm the setting, then return to setting mode.

## Selecting Training Mode

**How to do**

 Press “Enter” to select training mode.

Animation will be showed repeatedly to help you use the device properly.

Press “Return” to back to main page.

## Selecting About Mode

**How to do**

 Press “Enter” to select about mode.

Meter SN, software and hardware version will be showed on the display.

Press “Return” to back to main page.

## MAINTENANCE

### Caring for Your Analyzer

· Turn the power switch off and disconnect the electrical plug to replace the fan filter.

· Turn the power switch off and disconnect the electrical plug to clean the analyzer exterior and accessories, wipe it with a soft dry cloth. Do NOT rinse with water.

### Analyzer Storage

· Storage conditions: 10 °C to 35 °C (50 °F to 95 °F), 10% to 90% relative humidity.

· Always store or transport the analyzer in its original storage case.

· Avoid dropping and heavy impact.

· Avoid direct sunlight and high humidity.

## SYMBOL INFORMATION

Symbol	Referent	Symbol	Referent
	Manufacturer		Type B Equipment
	<i>In vitro</i> diagnostic medical device		Collection for electrical and electronic equipment
	Consult instructions for use		Caution, consult accompanying documents
	Serial number		Temperature limitation
	CE mark		Model number
	RoHS Compliance		Keep away from sunlight
	Storage / transport temperature limitation		Storage / transport humidity limitation
	Authorised representative in the European Union		

## SPECIFICATIONS

Overview	
Model no.	FORA A1C100
System Description	Point-of-care immunoassay analyzer
Quantitative Tests	Hemoglobin A1c (whole blood): Range: 4% to 16%
Test Format	Self-contained immunoassay cartridges
Test Measurement	Automatic, optional transmission
Test Method	HbA1c - monoclonal antibody agglutination reaction
Time to Test Results	HbA1c ≤6 minutes

General	
Dimensions	5.28 (H) x 7.56 (W) x 9.25 (D) inch 13.4 (H) x 19.2 (W) x 23.5 (D) cm
Weight	3.8 kg (8.38 lbs)
Power Requirements	100 to 240 VAC; 50/60 Hz
Maximum Power Input	30 watts
Output	10 VDC, 3A
Operating Pressure Range	800 hPa to 1060 hPa
Operating Altitude	Up to 2000 meters (6000 feet)
Operating Temperature	15 °C to 32 °C (59 °F to 89.6 °F) - HbA1c
Storage Temperature	10 °C to 35 °C (50 °F to 95 °F) - HbA1c
Operating Humidity	10% to 90%, non-condensing, actively controlled
Storage Humidity	10% to 90%, non-condensing, actively controlled

Sample Volume	HbA1c - ≤ 0.2 µL whole blood
Sample Preparation	No pretreatment; no pipetting required
Patient ID/Operator ID Entry	switch buttons, barcode reader (optional), keyboard (optional)

## Computer/ Peripheral Interfaces

AC to 10V DC Power Adapter	DC Power Jack
Memory	10,000 results
Onboard Printer	Thermal printer, 57 mm (2.28 inch) width x 50mm diameter paper reel
	USB or Bluetooth

External Output

This device has been tested to meet the electrical and safety requirements of: IEC/EN 61010-1, IEC/EN 61010-2-101, EN 61326-1, IEC/EN 61326-2-6.

 <b>FornCare Suisse AG</b> Neugasse 55, CH9000, St. Gallen, Switzerland www.foracare.ch	 <b>MedNet EC-REP GmbH</b> Borkstraße 10, 48163 Münster, Germany	 FORA A1C100		
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### TERMS & CONDITIONS OF WARRANTY

1. We warrant this product to be free of defects in workmanship and materials within the said warranty period on the warranty certificate.
2. During the warranty period, if this product is found to be defective, you may bring it, together with the purchase receipt and Warranty Certificate, on a carry-in basis to our office during normal business hours for warranty service. We will then repair or replace defective parts or exchanging the whole product as we may choose, at no charge to the original owner. After such repair, replacement or exchange, the product will be warranted for up to the remainder of the warranty period.
- 3.This warranty is valid only if the Warranty Certificate and Warranty Registration Card are duly completed with date of purchase, serial number and dealer’s stamp, and if the Warranty Registration Card is sent to our office not later than 14 days from the date of purchase.
4. This warranty is void if this product has been repaired or serviced by unauthorized person. This warranty does not cover defects caused by misuse, abuse, accident, tampering, lack of reasonable care, fire or any other acts beyond human control.
5. Except as stated in the above paragraphs, we disclaim all other warranties, implied or expressed, including the warranties of merchantability or fitness for a particular purpose with respect to the use of this product. We shall not be liable for any direct, consequential or incidental damages arising out of the use or inability to use this product.



PLEASE  
AFFIX  
STAMP

## DEALER’S INFORMATION