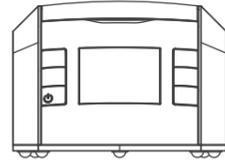


Part no.	311-4611100-XXX
Product name	機器說明書/U-RIGHT /英文
Spec	L297*W420mm/銅版紙/100P/雙面/黑/3折
Designer	Emily
Color	 K:90  K:15

Glucorx U-Right HbA1c Analyser

(Model TD-4611)



Version 1.0
2017-03
541-4611100-XXX

Operation Instruction

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 Glucorx U-Right HbA1c Analyser.

CAUTION!

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

Please cut off this 'Dealer's portion' of the Warranty Registration Card, insert it in an envelope and post to:

Glucorx Ltd
4 Wintonlea, Monument Way West,
Woking, Surrey, GU21 5EN, UK

TERMS & CONDITIONS OF WARRANTY

1. Glucorx warrants 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 send it with the Warranty Certificate to our office for warranty service. Glucorx will then repair or replace defective parts, or exchange the whole product as Glucorx may choose, with no additional charge to the original owner. After such repair, replacement or exchange, the product will be warranted for the remaining time of the warranty period.
3. This warranty is valid only if the Warranty Certificate and Warranty Registration Card are duly completed with date of obtaining product, serial number and if the Warranty Registration Card is sent to our office (or you register on our website www.glucorx.co.uk) no later than 6 months from the date obtained.
4. This warranty is void if this product has been repaired or serviced by an unauthorised 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, Glucorx disclaim all other warranties, including those of merchantability of fitness for a particular purpose with respect to the use of this product. Glucorx shall not be liable for any direct, consequential or incidental damages arising out of the use or inability to use this product.

Glucorx
Quality Diabetic Care

IMPORTANT SAFETY INSTRUCTIONS

READ BEFORE USE

1. Use this device **ONLY** for the intended use described in this manual.
2. This device 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; the rotation of the internal device may cause personal injury or damage the device.
11. Keep hands away from the inner side of the 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 facing 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

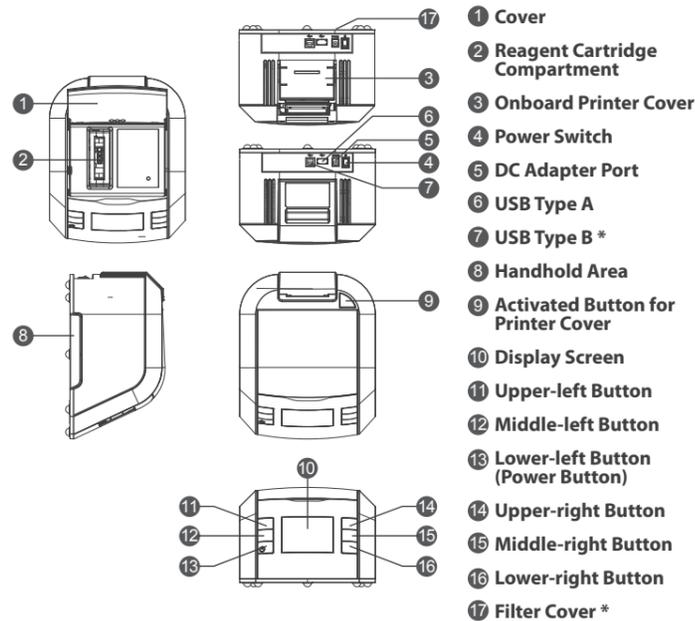
Intended Use

This analyser is designed to quantitatively measure the percent of glycated haemoglobin (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. Tests performed using the Glucorx U-Right HbA1c Analyser 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 this System

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

Analyser Overview



NOTE:

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

Display Screen

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

Indicator	Meaning / Instruction
	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 analyser and view the records of patient by entering patient ID and date range.
	Setting Mode: Set up the analyser 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 analyser 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 "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 initialisation 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 analyser will go to the status of Power Off.
3. Alarm and error message will show while the ambient temperature is out of the range 15°C and 32°C (59°F to 89.6°F). Place the analyser 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 analyser is moved from the surroundings in higher or lower temperature, place the analyser 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 Glucorx Customer care for help.

3. When Lot Information is shown on screen, 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 analyser 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 10 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. Hand wash your puncture site with warm water and let it dry.
2. Prick the finger 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 (120 degrees) 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 you do not open the cover at a 120 degree angle, the cover may close again or the cartridge may be in malposition while insertion, which may lead to the device being damaged in operation. Below warning label is stuck on the device for your information.

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; the rotation of internal device may cause personal injury or damage the device. The operation of device will be suspended immediately once the cover is open, then the measuring will be forced to stop.

NOTE:
Make sure you DO NOT OPEN THE 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 is 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 analyser 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 analyser will return to the main page automatically.

NOTE:
If the control solution test result is out of the range, please contact GlucoRx Customer care 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 search 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 search result will display. Select the result you want to review

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

5. Press “Delete” to delete the test 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.

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 analysers at the same time as 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 you do not need to use the inner data 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 from 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 is 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 show 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 go back to main page.

MAINTENANCE

Caring for Your Analyser

· 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 analyser exterior and accessories. Wipe it with a soft dry cloth. Do NOT rinse with water.

Analyser Storage

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

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

· Avoid dropping and heavy impact.

· Avoid direct sunlight and high humidity.

SYMBOL INFORMATION

Symbol	Referent	Symbol	Referent
	Manufacturer		Authorised representative in the European Community
	<i>In vitro</i> diagnostic medical device		Type B Equipment
	Consult instructions for use		Collection for electrical and electronic equipment
	Serial number		Caution, consult accompanying documents
	CE mark		Temperature limitation

SPECIFICATIONS

Overview

Model no.	TD-4611
System Description	Point-of-care immunoassay analyser
Quantitative Tests	Haemoglobin 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

Test Handling

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
External Output:	USB or Bluetooth

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.

Distributed by GlucoRx Ltd. 4 Wintonlea, Monument Way West, Woking, Surrey, GU21 5EN, UK Website: www.glucoRx.co.uk Customer careline: 01483 755133	 TaiDoc Technology Corporation B1-7F, No. 127, Wugong 2nd Rd., Wugu Dist., 24888 New Taipei City, Taiwan www.taidoc.com
 MedNet GmbH Borkstraße 10, 48163 Münster, Germany	



[Dealer's Portion]

WARRANTY REGISTRATION CARD



Product Name:

Owner's Name:

Address:

Tel No: (M) (H) (W)

Email:

Date of Birth: Gender: M F

Blood glucose testing frequency:

Insulin dependent?

Date obtained: / / Serial No:

Day Month Year

GP Surgery name and Address:

*IMPORTANT: To qualify for the warranty, please fill in this card and mail to us within 6 months from date product obtained.

 [Owner's Portion]

WARRANTY CERTIFICATE



Product Name:

Owner's Name:

Address:

Tel No: (M) (H) (W)

Email:

Date of Birth: Gender: M F

Blood glucose testing frequency:

Insulin dependent?

Date obtained: / / Serial No:

Day Month Year

GP Surgery name and Address:

*NOTE: Please produce this card for warranty service.