

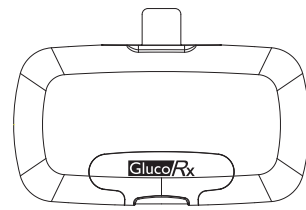
|              |  |
|--------------|--|
| Part no.     | 311-4140100-XXX                                  |
| Product name | 機器說明書/GlucoRx HCT Connect i/EN含保證卡/GlucoRx(DIME) |
| Spec         | L297*W420mm/銅版紙/100P/雙面/黑/4折/無處理                 |
| Designer     | JF   |
| Color        | ■ K:100    ■ K:75    ■ K:30    ■ K:20            |



311-4140100-000  
Version 1.0  
2019/04

## HCT Connect i

INTEGRATED MULTI-PARAMETER  
MONITORING SYSTEM  
(TD-4140B)



### Operation Instruction

#### Dear GlucoRx HCT Connect i System Owner:

Thank you for choosing the GlucoRx HCT Connect i Integrated Multi-Parameter Monitoring System. This manual provides important information to help you use the system properly. Before using this product, please read the following contents thoroughly and carefully.

If you have other questions regarding this product, please contact GlucoRx Customer care on 01483 755133.

#### Intended Use

This system is intended for use outside the body (in vitro diagnostic use) to quantitatively measure the blood glucose or  $\beta$ -ketone levels in whole blood. It is for home use or for healthcare professional use. It should not be used for diagnosis or screening of diseases.

Professionals may use the test strips to test capillary, venous, arterial and neonatal blood sample; home use is limited to capillary whole blood testing.

The blood glucose test strip uses fresh capillary whole blood samples from the fingertips, and from venous, arterial and neonatal whole blood. The blood glucose test strip can be used on neonates.

The  $\beta$ -ketone test strip uses fresh capillary whole blood samples from the fingertips, and from venous whole blood.

The test for haematocrit (HCT) as part of the system, is intended for use in the in vitro quantification of packed red blood cell volume fraction in capillary whole blood as an aid in monitoring the status of total volume of red blood cells. The test reading of haematocrit (HCT) is used only to determine whether the blood test sample is within the acceptable range of blood glucose system. It should not be used for the diagnosis of anaemia or erythrocytosis.

### IMPORTANT SAFETY INSTRUCTIONS

#### Read Before Use

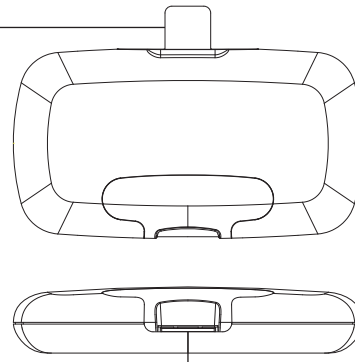
1. Use this device ONLY for the intended use described in this manual.
2. Do NOT use accessories which are not specified by the manufacturer.
3. Do NOT use the device if it is not working properly or if it is damaged.
4. The blood glucose test strip can be used for the testing of newborns.
5. This device does NOT serve as a cure for any symptoms or diseases. The data measured is for reference only. Always consult your doctor to have the results interpreted.
6. Before using this device to test blood glucose or  $\beta$ -ketone, read all instructions thoroughly and practice the test. Carry out all the quality control checks as directed.
7. Keep the device and testing equipment away from young children. Small items such as the test strips, lancets and vial caps are choking hazards.
8. Use of this instrument in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets etc.) may cause damaging static discharges that may cause erroneous results.
9. Do NOT use this instrument in close proximity to sources of strong electromagnetic radiation, as this may interfere with the accurate operation.
10. Proper maintenance and periodically control solution test are essential to the longevity of your device. If you are concerned about your accuracy of measurement, please contact your local customer service or place of purchase for help.
11. Do NOT use the monitoring system on a jailbroken or rooted device.

KEEP THESE INSTRUCTIONS IN A SAFE PLACE

### GETTING STARTED

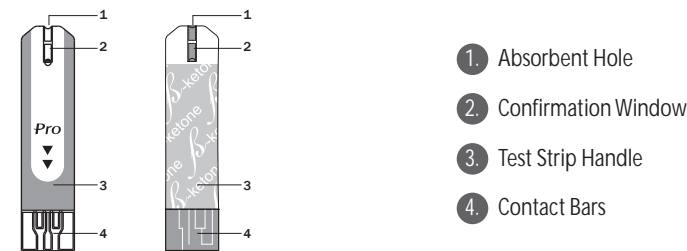
#### About the GlucoRx HCT Connect i Integrated Multi-Parameter Monitoring System

Lightning Connector



Test Strip Slot

#### GlucoRx HCT Connect Test Strips



#### NOTE

The GlucoRx HCT Connect i monitor should only be used with GlucoRx HCT Connect i Glucose or Ketone Test Strips. Using other test strips with this meter can produce inaccurate results.

#### How to Install and Update the GlucoRx HCT APP

GlucoRx HCT Connect i is designed to be used in conjunction with the GlucoRx HCT APP, available on the APP Store for free download. You must connect to the internet to download the APP. The APP Store can be accessed by tapping the APP Store icon on your mobile iOS devices.

GlucoRx HCT APP is designed to assist you in easy testing, recording, tracking and monitoring of blood glucose and/or  $\beta$ -ketone.

It is simple and intuitive to use, for better understanding of your current condition and to achieve better diabetes control.

#### System Requirement

For the required mobile OS version, please find on APP Store when you download the app.

#### Updating

When new features are added to the GlucoRx HCT APP, the APP Store will notify you automatically. Please perform the updates accordingly to provide you with the latest features that we have developed in your best interest.

### QUALITY CONTROL TESTING

#### When Should a Quality Control Test be Performed?

- if you suspect the meter or test strips are not working properly,
- if your blood test results are not consistent with how you feel, or if you think the results are not accurate,
- to practice the testing process, or
- if you have dropped or think you may have damaged the meter.

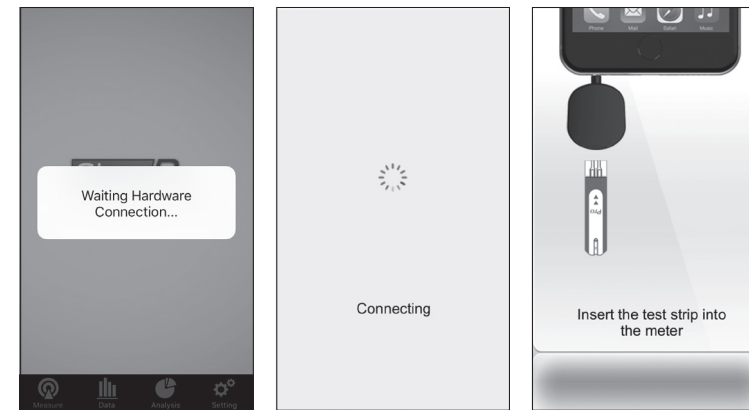
Test strips, control solution, control key, lancing device or sterile lancets may not be included in the kit (please check the contents on your product box). They can be obtained separately. Please make sure you have all items needed for a blood test beforehand.

#### How to Perform a Quality Control Test

To perform a quality control test, you will need: meter, appropriate test strip, blood glucose control solution or ketone control key. Please make sure you have the correct control solution or control key corresponding to your test strip.

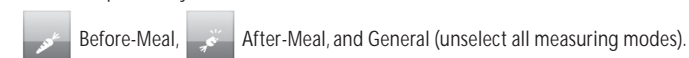
#### 1. Plug in GlucoRx HCT Connect i

Tap GlucoRx HCT icon to enter this app on home page, connect GlucoRx HCT Connect i with your device, a "Waiting Hardware Connection" message will appear on the screen. Then a "connecting" message will appear followed by the message "Insert the test strip into the meter". Please follow the instruction and insert the glucose test strip or ketone strip into GlucoRx HCT Connect i.



#### 2. The Measuring Modes

The meter provides you with three measurement modes:



#### NOTE

If blood glucose test strip or  $\beta$ -ketone control key is inserted for control testing, no need to select any measuring modes, your meter will automatically identify this measurement as QC test; please move to next step.

#### 3. Apply Blood Glucose Control Solution or Insert Ketone Control Key

3.1 for Blood Glucose test

Shake the control solution vial thoroughly before use.

Squeeze out a drop and wipe it off, then squeeze out another drop and place it on the tip of the vial cap. Hold the meter to move the absorbent hole of the test strip to touch the drop. Once the confirmation window fills completely, the "Processing" message will appear on the screen. Your device will tag this measurement as QC test automatically. To avoid contaminating the control solution, do not directly apply control solution onto a strip.

3.2 for  $\beta$ -ketone control test

Insert the ketone control key into your device. A "Waiting Optimisation" message will then appear on the screen. Turn on the switch on the front side of the ketone control key after the message of "take blood samples" appears on the screen; the "processing" message will appear on your Smart phone screen. Your device will tag this measurement as QC test automatically.

#### 4. Read and Compare the Result

After "Processing" message appears, the quality control test result will then show on the display. Compare this result with the range printed on the test strip vial and it should fall within this range. If not, please read the instructions again and repeat the quality control test. With the  $\beta$ -ketone control test, make sure you turn off the switch on the front side of the ketone control key after removing it from your device.

With "QC" displayed, the meter will store the control solution test result in memory.

#### NOTE

- The control solution range printed on the test strip vial is for control solution use only. It is not a recommended range for your blood glucose level.
- See the 'Caring for Your Meter' section for important information about your control solution.

### IMPORTANT INFORMATION ABOUT TESTING YOUR BLOOD GLUCOSE/ $\beta$ -KETONE LEVEL

#### Preparing the Lancing Device for Blood Testing

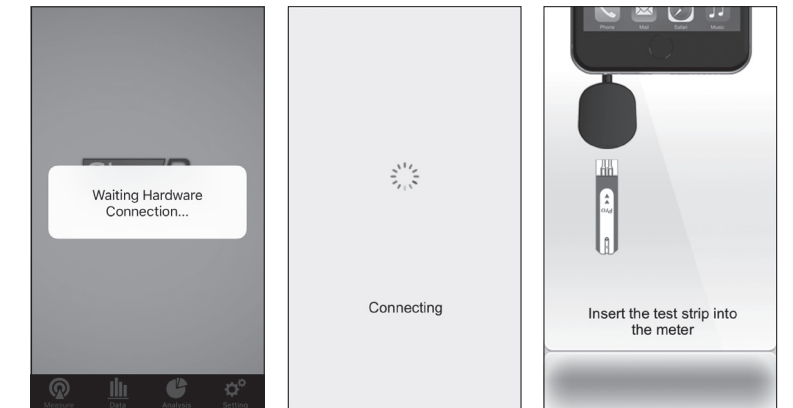
Please refer to the manufacturer's instructions for the lancing device to collect a blood sample.

#### Performing a Blood Glucose/ $\beta$ -ketone Test

To perform a blood glucose/  $\beta$ -ketone test, you will need meter, blood glucose/  $\beta$ -ketone test strip, sterile lancet and lancing device.

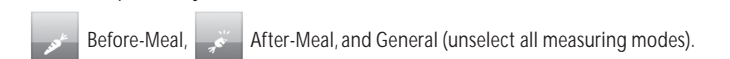
#### 1. Insert the test strip into the meter

Tap GlucoRx HCT icon to enter this app on home page, connect GlucoRx HCT Connect i with your device, a "Waiting Hardware Connection" message will appear on the screen. And then a "connecting" message will appear followed by the message "Insert the test strip into the meter". Please follow the instruction and insert the test strip into GlucoRx HCT Connect i.



#### 2. Select the appropriate measuring mode by touching the screen. (for blood glucose tests)

The meter provides you with three measurement modes:



#### NOTE

If a  $\beta$ -ketone test strip is inserted, no need to select any measuring modes; please move to next step.

#### 3. Obtaining a blood sample

Use the pre-set lancing device to puncture the desired site. The size of the drop should be at least as big as  $\blacklozenge$  (actual size), which is 1.0 microliter ( $\mu$ L) of volume for a blood glucose test or 1.0 microliter ( $\mu$ L) of volume for a  $\beta$ -ketone test. Gently squeeze the punctured area to obtain another drop of blood. Be careful **NOT** to smear the blood sample.

#### NOTE

- Choose a different spot each time you test. Repeated punctures at the same spot may cause soreness and calluses.
- It is recommended that you discard\* the first drop of blood as it may contain tissue fluid, which may affect the test result.
- \* WHO Guidelines on drawing blood: best practices in phlebotomy, 2010 -Section 7.2.2.

#### 4. Apply the sample

Gently apply the drop of blood to the absorbent hole of the test strip at a tilted angle. Confirmation window should be completely filled if enough blood sample has been applied. Do **NOT** remove your finger until the "processing" message appears on the screen.

#### 5. Read your result

The result of your test will appear after the meter shows the "Processing" message. This result will automatically be stored in the memory.



[ 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: .....

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 ]

YEAR WARRANTY

### 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: .....

GP Surgery name and Address: .....

\*NOTE: Please produce this card for warranty service.

## 6. Pull out the used test strip

Pull out the used test strip. Use a sharps bin to dispose of used test strips.

### WARNING

- Always follow the instructions in the lancing device package insert when removing the lancet.
- The used lancet and test strip may be biohazardous. Please discard them carefully according to your local regulations.**

### NOTE

- Do not press the punctured site against the test strip or try to smear the blood.
- The confirmation window should be filled with blood. Do **NOT** remove your finger until the "processing" message appears on the screen.
- NEVER** try to add more blood to the test strip after the drop of blood has moved away. **Discard the used test strip and retest with a new one.**
- If you have trouble filling the confirmation window, please contact your health care professional or GlucoRx Customer care on 01483 755133 for assistance.

## INTRODUCTION ON GIUCORx HCT APP

### Data

The device stores your blood glucose with HCT and  $\beta$ -ketone test results, along with respective dates and times.

- To review the data in your mobile device, press Data on the main menu bar. The first page you see is the total records for all test results. You can also tap the buttons on the top of the screen which are divided into three categories: All, BG and Ketone to view the data respectively. Next you can see previous data by swiping upwards.

### NOTE

Only a blood glucose test will show the corresponding haematocrit value.

- Tap the record on the Data page to recall individual results; a pop-up window will appear. Next you can type in a personal note to add new results for that individual measurement. You also can edit anytime by tapping the existing notes.

### Analysis

The analysis feature is designed to let you understand your blood glucose/  $\beta$ -ketone reading distribution in percentage appear with 7D, 14D, 1M, 2M and 3M analysis, average analysis and highest and lowest value.

The analysis feature is designed to let you understand your latest test result through a piechart or diagram display, to have an overview or a 7-14-30- day average analysis.

- To review the analysis on your smart phone, press Analysis on the main menu bar; the first page you will see is your latest blood glucose or ketone test result. Next you can type in a personal note to add new results for that individual measurement.
- Tap the readings on the test result page; an overview page will appear with 7 Days, 14 Days and 30 Days analysis. You can select 7 Days, 14 Days or 30 Days button on the top to switch between 7-14-30 days view. You will see the current 7-14-30 day of glucose control average percentage.
- Next you can see the trend graph by swiping upwards. The first page you will see is the 7-day data record, displayed by day-average test result with a colour dot. You can swipe right or left to review the testing trend. You also can select the 7/14/30 button on the top side to switch between 7-14-30 days view. Then tap the Return key on the upper-left side to go back to the latest test result page.
- An additional item is available only with blood glucose test results. You can view your average reading compared with estimated HbA1c value for the past 3 months to better understand the effectiveness of your diabetes control. Tap the HbA1c Estimate to enter the comparison page, and then tap the Input Measured HbA1c button on the bottom to input the recorded percentage.

### Setting

Select Setting on the main menu bar. You can set up to automatically upload your test results to TeleHealth Service. Through this service, the healthcare provider can easily view and manage your data record synchronically. Tap TeleHealth Service and Bluetooth Smart Meter sections to enter the data upload setting.

You also can set up your personal profile data and target range in Profile and Health Target sections.

## MAINTENANCE

### Caring for Your Meter

#### Cleaning

- To clean the meter exterior, wipe it with a cloth moistened with tap water or a mild cleaning agent, then dry the device with a soft dry cloth. Do NOT rinse with water.
- Do **NOT** use organic solvents to clean the meter.

#### Meter Storage

- Storage conditions: -20°C to 60°C (-4°F to 140°F), between 10% and 93% relative humidity.
- Always store or transport the meter in its original storage case.
- Avoid dropping and heavy impact.
- Avoid direct sunlight and high humidity.

#### Meter Disposal

The used meter should be treated as contaminated and may carry a risk of infection during measurement. The meter should be disposed in accordance with local regulations.

The meter falls outside the scope of the European Directive 2002/96/EC-Directive on waste electrical and electronic equipment (WEEE).

## DISPLAY MESSAGES AND PROBLEM-SOLVING GUIDE

The following is a summary of display messages. If your app displays an error message, please follow the actions for the error message as described in the table below. If the problem persists, please contact GlucoRx for help.

### For blood glucose test

| MESSAGE   | WHAT IT MEANS |
|-----------|---------------|
| <b>Lo</b> | < 0.5 mmol/L  |
| <b>Hi</b> | > 38.9 mmol/L |

### For $\beta$ -ketone test

| MESSAGE   | WHAT IT MEANS |
|-----------|---------------|
| <b>Lo</b> | < 0.1 mmol/L  |
| <b>Hi</b> | > 8.0 mmol/L  |

### NOTE

The user can set up their glucose/ketone target range in the setting mode according to his/her own current status after consulting their doctor to get better control.

| Error Type  | Error Code | Error Message Display                           | How To Do   |
|-------------|------------|---|---|
| Accessory   | Err.23     | Hardware error                                  | Please contact GlucoRx Customer Care on 01483 755133 for assistance.  |
|             | Err.41     |   |   |
| Temperature | Err.25     | Temperature is too low                          | System operation range is 10°C to 40°C (50°F to 104°F). Repeat the test after the meter and test strip are in the above temperature range.    |
|             | Err.26     | Temperature is too high                         |   |
| Strip       | Err.24     | Strip has been used                             | Repeat with a new test strip.   |
|             | Err.29     | Please re-insert the strip or use another strip | Repeat the test with a new test strip. If the meter still does not work, please contact GlucoRx Customer Care on 01483 755133 for assistance. |
|             | Err.30     | Please re-insert the strip or use another strip |   |
| Measurement | Err.40     | Strip is removed during measurement             | Repeat the test with a new test strip.  |
|             | Err.45     | Operation error                                 |   |
|             | Err.51     | HCT error                                       |   |

## DETAILED INFORMATION

### Blood Glucose Test

The blood glucose readings deliver plasma equivalent results and are displayed in millimoles of glucose per liter of blood (mmol/L).

| Time of day             | Normal plasma glucose range for people without diabetes |
|-------------------------|---|
| Fasting and before meal | < 5.6 mmol/L  |
| 2 hours after meals     | < 7.8 mmol/L  |

Source: American Diabetes Association. Standards of medical care in diabetes- 2018 Jan; 41(Supplement 1): S1-S2.

### $\beta$ -Ketone Test














The  $\beta$ -Ketone readings deliver plasma equivalent results and is displayed in millimoles of ketone per liter of blood (mmol/L).

|                              |             |
|------------------------------|-------------|
| $\beta$ -Ketone <sup>1</sup> | <0.1 mmol/L |
|------------------------------|-------------|

<sup>1</sup> Wu AHB. Tietz clinical guide to laboratory tests. 4th ed. St. Louis, Mo: Saunders/Elsevier; 2006.

**Please consult your doctor to determine a target range that works best for you.**

## SYMBOL

| Symbol  | Referent  | Symbol  | Referent  |
|---|---|---|---|
|  | <i>In vitro</i> diagnostic medical device   |  | Manufacturer  |
|  | Consult instructions for use  |  | Serial number                                       |
|  | Caution   |  | Authorised representative in the European Community |
|  | Temperature limit   |  | Batch code  |
|  | CE mark   |  | Humidity limitation                                 |
|  | This device does not belong to household waste and must be returned to a collection point for recycling electric and electronic devices according to local laws. If it contains batteries, the batteries should be removed and disposed in accordance with local regulations for separate collection of used batteries. |  | Use-by date   |
|   |   |  | Catalogue number                                    |

## SPECIFICATIONS

**Model No.:** TD-4140B

**Dimensions:** 51 (L) x 24 (W) x 8.8 (H) mm

**Weight:** 9.0 g

**Power Source:** iOS device

**Memory:** Unlimited results on GlucoRx HCT APP

**External output:** Lightning connector

Auto electrode insertion detection

Auto sample loading detection

Temperature Warning

#### Operating Condition:

10°C to 50°C (41°F to 104°F), between 10% and 85% R.H. (non-condensing)

#### Meter Storage/Transportation Conditions:

-20°C to 60°C (-4°F to 140°F), between 10% and 93% R.H. (non-condensing)

#### Strip Storage / Transportation Conditions:

2°C to 30°C (35.6°F to 86°F) and between 10% and 85% R.H. (non-condensing) for blood glucose/ $\beta$ -ketone test strips

**Measurement Units:** mmol/L

#### Measurement Range:

0.5 to 38.9 mmol/L for glucose test; 0.1-8.0 mmol/L for  $\beta$ -ketone test

**Expected service life:** 5 years


**Operating Altitude:** Up to 2000m, for indoor use





**Degree of Pollution:** Pollution degree 2

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.  
Unit 1C Henley Business Park, Pirbright Road, Guildford, Surrey, GU3 2DX, 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

For self-testing.  
     
TD-4140B

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

**GlucoRx Ltd**  
**Unit 1C Henley Business Park, Pirbright**  
**Road, Guildford, Surrey, GU3 2DX, UK**

### TERMS & CONDITIONS OF WARRANTY

 **Quality Diabetes Care**

- GlucoRx warrants this product to be free of defects in workmanship and materials within the said warranty period on the Warranty Certificate.
- 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.
- 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.
- 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.
- 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.