

# VitaPCR™

User Manual

REF PCRAC0101



## Trentron Biomedical Ltd

(Building D) 15F, No. 93, Sec. 1, Xintai 5th Rd.,  
Xizhi Dist., New Taipei City 22175, Taiwan (R.O.C.)

Office: +886-2-2697-2728

Fax: +886-2-2697-1876

E-mail: [service@credodxbiomed.com](mailto:service@credodxbiomed.com)

Before using the VitaPCR™ Instrument, please read this user manual carefully. Having a clear understanding of the correct operating procedure, machine setup and other additional functions is required to carry out proper diagnostic steps.

Please contact Credo Diagnostics Biomedical Pte. Ltd. or local distributors for any further questions.

# Table of Content

<b>1. Warning and Safe Use</b> .....	3
<b>2. Machine Specifications</b> .....	4
<b>2.1 Intended Use</b> .....	4
<b>2.2 Product Description</b> .....	4
<b>2.3 Device Specifications</b> .....	5
<b>2.4 Unpacking</b> .....	6
<b>3. Components</b> .....	7
<b>3.1 VitaPCR™ Instrument</b> .....	7
<b>3.2 Accessories</b> .....	7
<b>4. Initial Setup</b> .....	8
<b>5. User Interface</b> .....	8
<b>6. Setting</b> .....	9
<b>6.1 User Management</b> .....	9
<b>6.2 General Setting</b> .....	10
<b>6.3 Date &amp; Time</b> .....	10
<b>6.4 Device information</b> .....	11
<b>7. Run Test</b> .....	11
<b>8. Data Extraction</b> .....	13
<b>9. Maintenance and Troubleshooting</b> .....	14
<b>9.1 Cleaning</b> .....	14
<b>9.2 Errors and Warnings</b> .....	15
<b>9.3 Button Cell Battery (CR2032)</b> .....	16
<b>10. Symbol Description</b> .....	17
<b>11. Revision History</b> .....	18

## 1. Warning and Safe Use

- For the safety precautions, please use the power cord designed for VitaPCR™ Instrument and choose a power supply according to your region. To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- DO NOT expose this VitaPCR™ Instrument to strong electric or electromagnetic fields, as they may interfere with proper operations
- DO NOT put fingers or other objects in the test wells to avoid any damage.
- Please place VitaPCR™ Instrument on a clean, stable and flat surface. Avoid poor air flow or direct sunlight. DO NOT use it in damp places to avoid leakage and electric shock.
- Please DO NOT move VitaPCR™ Instrument during the test.
- Please DO NOT drop VitaPCR™ Instrument.
- Please follow the "Operation Directions Governing Management of Infectious Biological Materials" regulation and wear proper protective equipment (PPE).
- The VitaPCR™ Instrument and the accessories are restricted for uses described in this manual. Efficacy and user safety can only be guaranteed under normal usage conditions. Please follow the instruction in this manual to proceed all the steps.
- Please keep the back and side (where the fans, power jack, and ports are located) of the VitaPCR™ Instrument clean and clear.
- All the connection ports are restricted to the devices provided with the VitaPCR™ Instrument package. Any usage condition not in accordance with the instruction for the intended purpose might void the warranty.
- There is no repair tool or related material in the VitaPCR™ Instrument package. If you encounter any problem, please contact Credo Diagnostics Biomedical Pte. Ltd. or local distributors immediately for assistance. Any unauthorized repair may void the warranty.
- If there is any damage on the package upon receiving the VitaPCR™ Instrument, please DO NOT use it and contact Credo Diagnostics Biomedical Pte. Ltd. or local distributors immediately for assistance.

## **2. Machine Specifications**

### **2.1 Intended Use**

The VitaPCR™ Instrument is a rapid molecular *in vitro* diagnostic device utilizing a real-time polymerase chain reaction (Real-Time PCR) amplification technology to process and analyze VitaPCR™ tests.

The VitaPCR™ Instrument utilizes technology for qualitative detection and discrimination of infectious diseases. It is NOT intended to guide or monitor treatment for these diseases.

### **2.2 Product Description**

The VitaPCR™ serial assays performed on the VitaPCR™ Instrument is a rapid molecular *in vitro* diagnostic test utilizing a real-time polymerase chain reaction (Real-Time PCR) amplification technology for the qualitative detection of target. The sample is loaded into the supplied Reagent Tube and tested by the VitaPCR™ Instrument, which automatically completes and displays the result on the touchscreen. It is intended as an aid in the *in vitro* diagnosis.

Results do not exclude any other possibilities and should not be used as the sole basis for diagnosis, treatment or other patient management decisions.

## 2.3 Device Specifications

<b>Dimensions</b>	15.5 x 16.5 x 20.5 cm (H*W*D)
<b>Weight</b>	1.2kg
<b>Power Supply</b>	12V, 5A
<b>Color Touch Screen</b>	4" capacitive touch LCD display
<b>Fluorescence Detection</b>	450 to 750 nm
<b>Fluorescence Channel</b>	4 channels
<b>Sample Well</b>	one
<b>Storage Environment</b>	15-40°C
<b>Operating Environment</b>	10-38°C ; 10-80%RH
<b>Power Adaptor</b>	INPUT: AC 100-240V~2.0A Max, 50-60Hz OUTPUT: DC 12V = 5A <i>Note: We strongly recommend using the adaptor provided by Credo Diagnostics Biomedical Pte. Ltd. or adaptors that meet the above specifications and CE requirements (e.g.: EN 60950) in order to avoid any risk.</i>

## 2.4 Unpacking

Unpack the VitaPCR™ Instrument and place on a clean, flat, and stable surface within reach of an electrical outlet. Place your device in a location where the air vents at the back of the instrument will not be blocked. Avoid your device from direct sunlight.

Inspect for any obvious signs of damage. Report any damage immediately to Credo Diagnostics Biomedical Pte. Ltd. or local distributor. Allow your device to equilibrate to room temperature for at least 30 minutes.

### 3. Components

#### 3.1 VitaPCR™ Instrument



- ① Lid (Test Reaction Well is inside.)
- ② Button of the lid.
- ③ Touch Screen Display.
- ④ Power Button.
- ⑤ RS232 Port : For printer connection.
- ⑥ USB Flash Drive Port : For datalogging including data, time, and result.  
(Compatible with USB 3.0 flash drives in FAT32 format only.)
- ⑦ Power Jack.
- ⑧ Scanner

#### 3.2 Accessories

- Power Adaptor  
(INPUT: AC 100-240V,  
2.0A Max, 50-60Hz.  
OUTPUT: DC 12V, 5A)



- Rack for test procedure tube



- Quick Reference Guide of VitaPCR™ Instrument

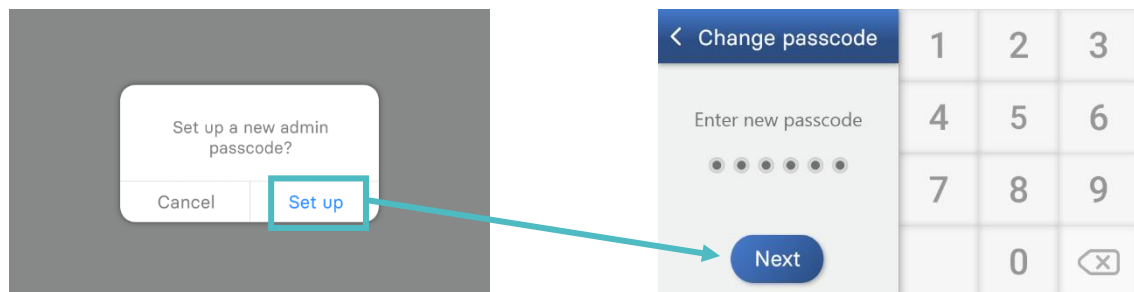


## 4. Initial Setup

**Connect** the adaptor to your device. Then, plug the appropriate, region-specific adaptor into a proper electrical outlet.

**Power On:** Once the power is connected, press the Power Button on your device's front side to power on and start it. Once your device is running, it will go through instrument function check.

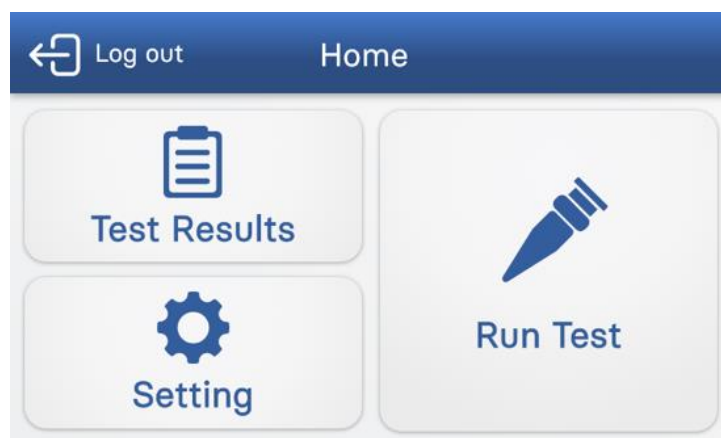
**Set up admin passcode:** Once the Instrument Function Check is finished, you will be prompted to change the admin passcode.



## 5. User Interface

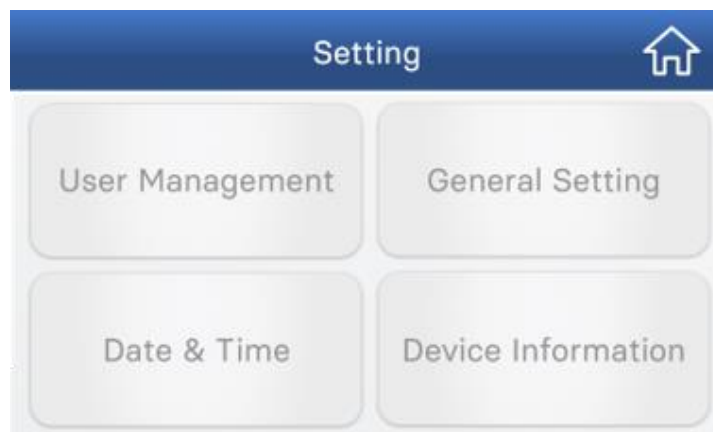
### Home Screen

Displays the access to **"Run Test"**, **"Test Results"**, and **"Setting"**.



## 6. Setting

- On the "Setting" page, there are four subpages - "User Management", "General Setting", "Date & Time", and "Device Information".



### 6.1 User Management

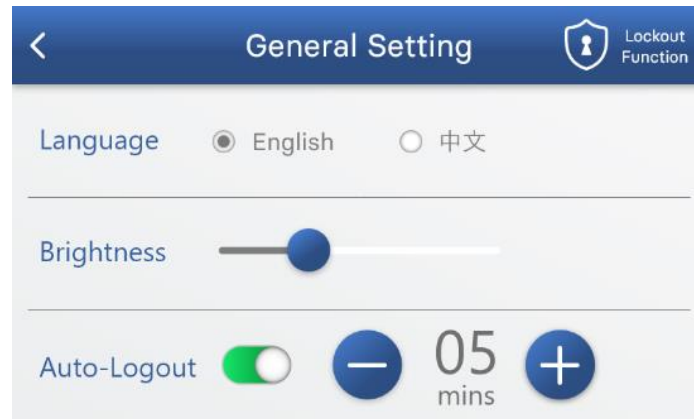


- To create a new user profile, press "+". The new user must type in their User ID and Passcode.
- User ID is composed of alphabets and digits, up to 14 characters. Please note that Passcodes must be 6 digits.
- You will be asked to enter the password again for confirmation. Press 'Next' to advance.

NOTE: If the Admin password is forgotten, the Admin must contact the manufacturer or local distributor.

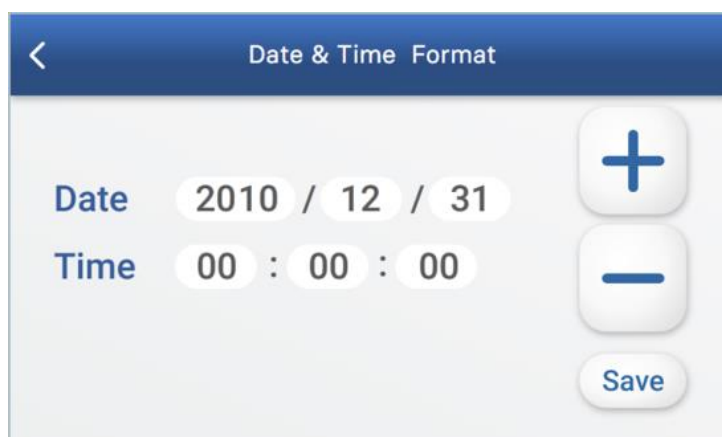
## 6.2 General Setting

- Select the language by directly pressing.
- Move the bar to set the screen brightness
- Press the 'Auto-Logout' switch to enable or disable the auto-logout function. When the Auto-Logout is enabled (green), select the timer by pressing “-”and “+”.



## 6.3 Date & Time

- To adjust the date and time, select each number and press “-” and “+” to change it.
- To save the date and time settings, press “Save”. Press “<” on the top to go back to the previous menu.



## 6.4 Device information

- The device information contains device's Serial Number, Module Number, Main board Version, Firmware Version and GUI Version information.



## 7. Run Test

Before running a test with the VitaPCR™ Instrument, please make sure you follow the sample preparation procedure as per the corresponding test kit package insert.

Note: It is highly recommended to connect to VitaDataLink™\* or insert a USB flash drive before starting any test in order to collect complete data.

Note: Only the USB flash drive with a 3.0 flash drive in FAT 32 format is compatible.

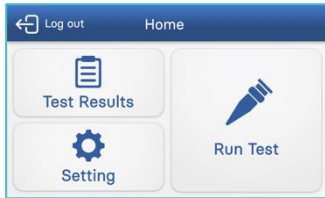
Note: Only User/Result data shown on the test history page will be exported if the USB flash drive is plugged in or the VitaDataLink™ is connected after the test is done.

\*VitaDataLink™ is a connectivity software designed for database management of VitaPCR™ system and featured with automatic transfer of HL7 messages across disparate healthcare systems. Contact your local distributor for details.

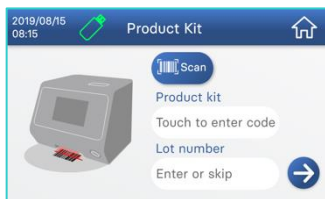


1. Place the VitaPCR™ Instrument on a flat surface.

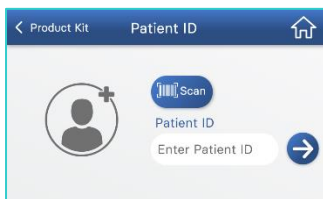
Turn on the VitaPCR™ Instrument by pressing the power button in the front side of the device.



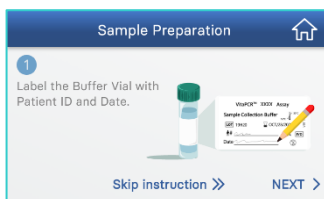
2. Select User ID.  
Enter User Passcode.
3. Press the “Run Test”.



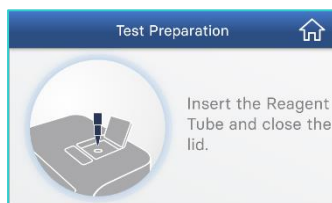
4. Scan the barcode on the reagent package by the built-in barcode scanner in the lower front side of VitaPCR™ Instrument. If you have difficulty in scanning barcode, type the product key manually instead.  
Confirm the Product Kit type.



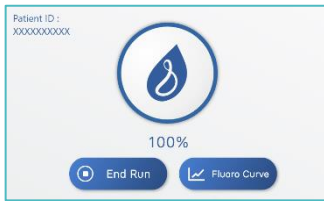
5. Scan or key in Patient ID.  
Confirm the Product Kit type and Patient ID.  
When entering Patient ID, please follow local regulations and do not include any personal information that may allow the individual to be identified.



6. Follow the on-screen and Quick Start Guide instructions to prepare your sample.



7. Press the button to open the lid.  
Insert the Reagent Tube and close the lid.  
Press “RUN” to start the reaction.



8. Verify the process percentage on VitaPCR™ screen increasing Circular progress bar turns blue while test is ongoing.
9. Read the Results on the screen.

## 8. Data Extraction

If the VitaDataLink™ is connected, the data will be automatically transferred to the software database. For further information, please refer to the VitaDataLink™ manual.

If the USB flash drive is attached, the data will be automatically exported after each testing run. And the data will be organized into two independent folders.

- **RawData Folder:** *Encrypted Raw Data*

Each test will generate one *Encrypted Raw Data* excel file located in the **RawData Folder**. The *Encrypted Raw Data* is solely for troubleshooting and software data input purposes.

- **Result Folder:** *Encrypted & Non-Encrypted User/Result Data*

All the *Data* of the tests run on the same day will be included in two files named by the date. The one in .csv file is encrypted while another one in .txt file can be opened through the Excel software. The *User/Result Data* contains information shown on the test history page and are located in the **Result Folder**.

Note: To read the Non-Encrypted User/Result Data, please first enter the Excel software. Click the “FILE” button and choose “Open”. Use the “Browse” function to select and open the Non-Encrypted User/Result Data in txt file type. The Non-Encrypted User/Result Data is NOT readable if opening it directly.

## 9. Maintenance and Troubleshooting

### 9.1 Cleaning

We recommend cleaning the VitaPCR™ Instrument each day after use.

- Cleaning Procedure:

1. Unplug the power cord from the wall outlet and VitaPCR™ Instrument.
2. Close the lid.
3. Using 70% ethanol or a germicidal disposable wipe, gently wipe the outer surfaces of VitaPCR™ Instrument, removing any dust.  
**\* Do not press the wipe against the open vents of VitaPCR™ Instrument.**
4. Using a new cloth, wipe the front of VitaPCR™ Instrument twice top to bottom, then twice left to right. Follow this step for the back, top and bottom of VitaPCR™ Instrument.
5. Please ensure the openings are kept dry.
6. Allow the unit to dry for at least 10 minutes and check it's all dry before re-connecting the power cord for the AC Adapter.

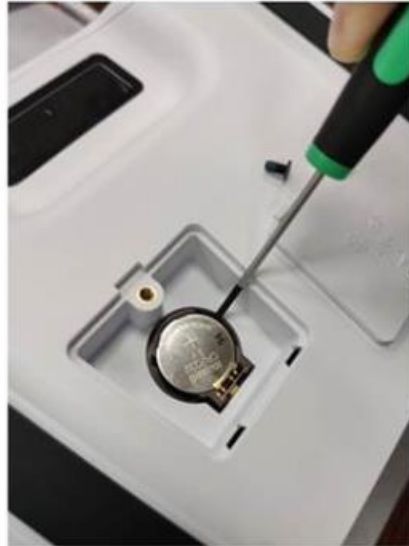
## 9.2 Errors and Warnings

<b>Messages</b>	<b>Description and Recommendation</b>
Error: E1	The heating function is malfunctioning, please reboot your device. If this error still remains, please contact the manufacturer or local distributor for your service.
Error: E2	The Optical function is malfunctioning, please reboot your device. If this error still remains, please contact the manufacturer or local distributor for your service.
Error: E3	The battery is dead. Please replace the battery.
Error: E4	The reagent is expired. Please use a new reagent kit.
Error: E5	The lid was opened during the test process. Stop the test and discard the used reagent.
Error: E6	The printer is not connected, please try to connect the printer again.
Error: E7	Data transmission failure. Please check the USB is connected correctly.
Error: E8	The barcode scanner is malfunctioning, please reboot your device. If this error still remains, please manually enter the barcode information and contact the manufacturer or local distributor for your service.
Error: E9	<p>The volume of liquid in the reagent tube is not correct.</p> <ol style="list-style-type: none"><li>1. Please swing the tube three times and make sure no bubble exists. Insert the reagent tube back to the testing well and continue to run the test.</li><li>2. If the liquid volume is still not enough, please getting a new kit. Prepare the reagent tube with sample-collected buffer and the new kit.</li></ol>
















### 9.3 Button Cell Battery (CR2032)

CR2032 battery for storing the date and time is equipped at the bottom of the instrument. Replace the battery with 3mm-cross screwdriver when Error: E3 shows in the screen of the instrument.



## 10. Symbol Description

	Do Not Re-Use		Manufacturer
	Consult Instructions for Use		Catalogue Number
	Caution		Temperature Limit
	<i>In vitro</i> diagnostic medical device		Keep away from sunlight
	Do not use if package is damaged		Keep Dry
	CE mark		Authorized Representative in the European Community
	WEEE - Electronic equipment marked with this symbol are subject to European Union Directive 2012/19/EU (WEEE), and cannot be disposed of in the municipal waste system		



### Trenton Biomedical Ltd.

(Building D) 15F, No. 93, Sec. 1, Xintai 5th Rd.,  
Xizhi Dist., New Taipei City 22175, Taiwan (R.O.C.)

Office: +886-2-2697-2728

Fax: +886-2-2697-1876

E-mail: [service@credodxbiomed.com](mailto:service@credodxbiomed.com)



MedNet EC-REP GmbH  
Borkstrasse 10,  
48163 Muenster,  
Germany

## 11. Revision History

**Version Changes:** Version 6.0 to 7.0

<b>Document Version</b>	<b>Date</b>	<b>Revision</b>
6.0	July 2022	1. Intended Use wording 2. Format and section adjustment 3. Removal of not relevant symbols 4. Warning and safe use
7.0	July 2023	Change of address