

# VitaPCR™

User Manual

REF PCRAC0101



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

Please contact Trentron Biomedical Ltd. for any further questions.

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## 1. Warning and Safe Use

- 1.1 For the safety concern, please use the power cord designed for VitaPCR™ and choose a power supply according to your region.
- 1.2 Please DO NOT put fingers or other objects in the test wells to avoid any damage
- 1.3 Please place VitaPCR™ on a clean, stable and flat surface. Avoid poor air flow or direct sunlight.
- 1.4 Please DO NOT move VitaPCR™ during test.
- 1.5 Please DO NOT drop VitaPCR™.
- 1.6 Please follow the regulations of "Operation Directions Governing Management of Infectious Biological Materials" and wear proper protective clothing
- 1.7 DO NOT use in damp places to avoid leakage and electric shock.
- 1.8 There is no repair tool or related material in the VitaPCR™ package. If there is any problem, please contact Trenton Biomedical Ltd. immediately for assistance. Any damages not caused by Trenton Biomedical Ltd. is out of warranty.
- 1.9 The VitaPCR™ and the accessories are restricted for uses described in this manual. Efficacy and user safety can only be guaranteed under manual instruction. Please follow the instruction in this manual to proceed all the steps.
- 1.10 Please keep clean and empty in the back of the VitaPCR™, where the power Jack and ports are located.
- 1.11 If there is any damage on the package upon receiving the VitaPCR™, please DO NOT use it and contact Trenton Biomedical Ltd. immediately for assistance.
- 1.12 All the connection ports are restricted to the devices provided with the VitaPCR™ package. Any use or function not covered by this manual is out of warranty.
- 1.13 Due to the high sensitivity of VitaPCR™ detection kits, contamination caused by incomplete cleaning may result in false-positive report. Please read Section 4: Maintenance and Troubleshooting for more details.

## 2. Machine Specifications

### 2.1 Intended Use

The VitaPCR™ Instrument is a rapid molecular *in vitro* diagnostic test utilizing a real-time reverse transcription polymerase chain reaction (RT-PCR) amplification technology for the processing and analysis of VitaPCR™ tests.

This document describes the whole procedures of the VitaPCR™ Instrument, which utilizes technology for qualitative detection and discrimination of infectious diseases. It is NOT intended to guide or monitor treatment for these diseases.

The VitaPCR™ Instrument is intended for use by all healthcare professionals.

### 2.2 Product Description

The VitaPCR™ serial assays performed on the VitaPCR™ Instrument is a rapid molecular *in vitro* diagnostic test utilizing a polymerase chain reaction (PCR) amplification technology for the qualitative detection of target. The sample is loaded into the supplied Reagent Tube and tested by the VitaPCR™, 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 ONLY adaptor provided by Trenton Biomedical Ltd. or adaptors meet the above specifications and CE requirements (e.g.: EN 60950) in order to avoid inaccurate examination or 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 on a location where the air vents located at the rear and sides 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 manufacturer or local distributor. Allow your device to equilibrate to room temperature for at least 30 minutes.

## 2.5 Components

### 2.5.1 Front & Back View



- 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.

## 2.5.2 Accessories

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



- Rack for test procedure  
tube



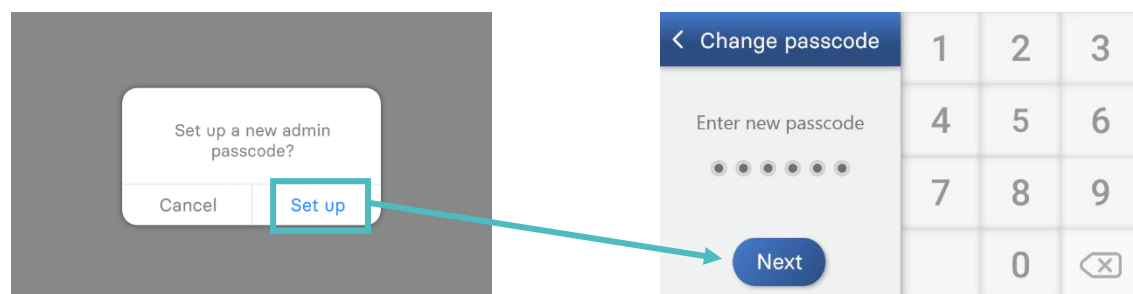
- Quick Reference Guide of VitaPCR™ Instrument

## 3. Getting Started

### 3.1 Initial Setup

**Connect** the adaptor to your device. Plug the appropriate, region specific adaptor into an appropriate electrical outlet.

**Power On:** Once the power is connected, press the Power Button in the front side of your device to power on and start it. Once your device is running, you will be prompted to change the Admin's Passcode.

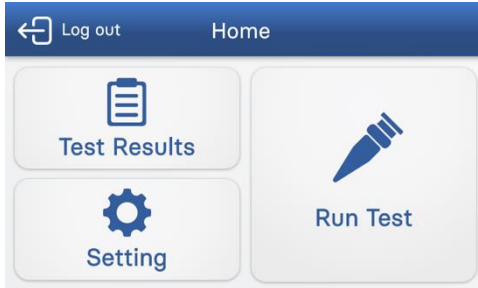




## 3.2 User Interface

### 3.2.1 Home Screen

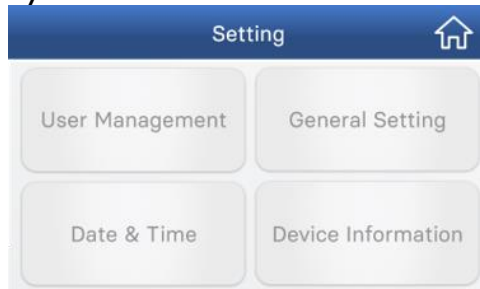
Displays buttons for access to:



- Run Test
- Test Results
- Setting

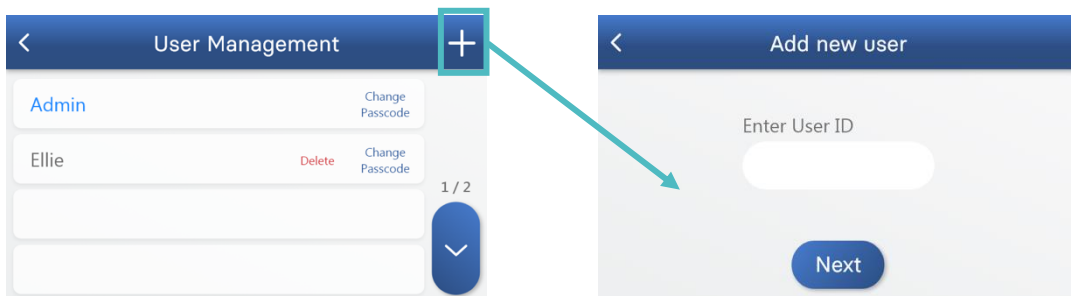
### 3.2.2 Setting

Displays buttons for access to



- User Management
- General Setting
- Set Date & Time
- Device Information

### 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.*

## 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 “+”.

## Set Date & Time:



To adjust the date and time, select each number and press “-” and “+” to change it.

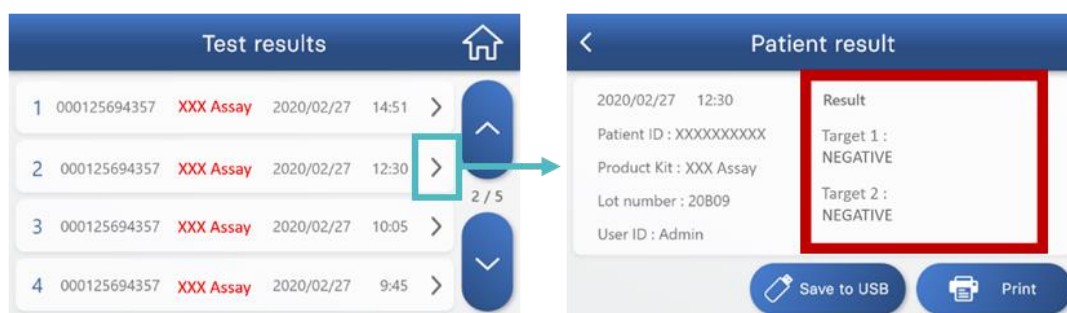
To save the date and time settings, press “Save”. Press “<” on the top to go back to the previous menu.

## Device Information:



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

### 3.2.3. Test History



The page of test results provides the access to all the test history arranged by date. To view the details of a specific test, press “>” on the right.

**Depending on different assays, the result section (red box) will show the corresponding results.**

Press “Save to USB” in order to save the specific test result to the USB (ensure the USB is correctly plugged in).

Press ‘Print’ to print the specific test result (printer not provided).

### 3.3 Running a 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.

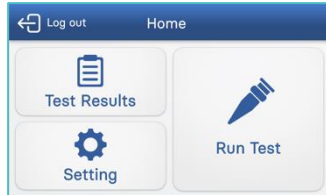
*Note:*

- *To obtain raw data for technical support, plug USB into USB flash drive port at the back of instrument before start the test. The file name of raw data is “XXXXXXXX\_RAW.csv”*
- *If USB is plugged after the test is done, only the simple results as showed on the test history page can be exported.*



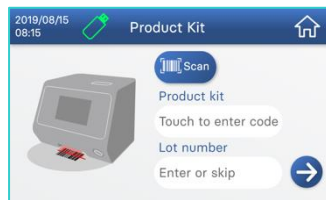
1. Place the VitaPCR™ instrument on a flat surface.

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

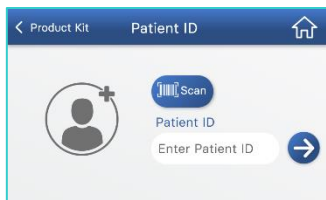


2. Select User ID.  
Enter User Passcode.

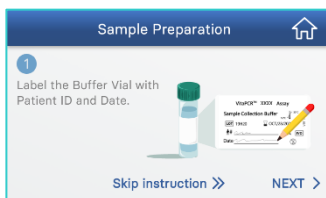
3. Press the “Run Test”.



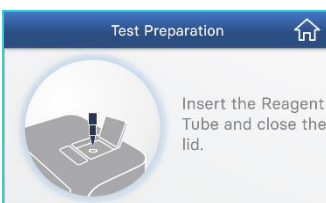
4. Scan the barcode on the reagent package by the built-in barcode scanner in the lower front side of VitaPCR™ instrument.



5. Scan or key in Patient ID.  
Confirm the Product Kit type and Patient ID.

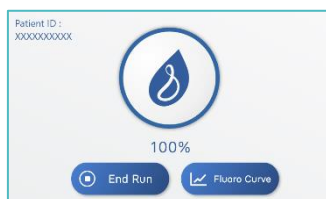


6. Follow the on-screen and Quick Start Guide instructions to prepare your sample.



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.

## 4. Maintenance and Trouble-shooting

### 4.1 Cleaning

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

#### Cleaning Procedure:

1. Unplug the power cord from the wall outlet and VitaPCR™.
2. Close the lid.
3. Using 70% ethanol or a germicidal disposable wipe, gently wipe the outer surfaces of VitaPCR™, removing any dust.

***NOTE: Do not press the wipe against the open vents of VitaPCR™ Instrument.***

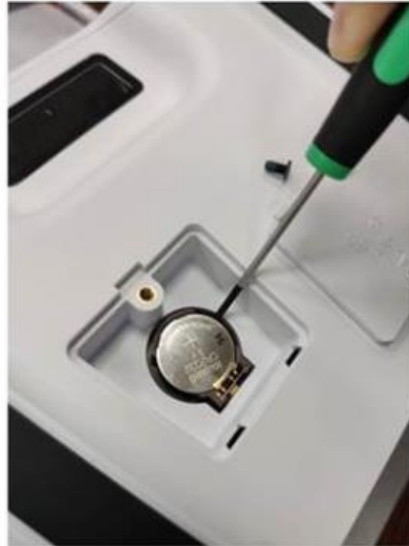
4. Using a new cloth, wipe the front of VitaPCR™ twice top to bottom, then twice left to right. Follow this step for the back, top and bottom of VitaPCR™.
5. Do not let liquid gather around any opening. Make sure no liquid enters your device.
6. Allow the unit to dry for at least 10 minutes and check it's all dry before re-connecting the power cord for the AC Adapter.

## 4.2 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>




















### 4.3 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.



## 5. Additional Information

### 5.1 Symbol Description

	Do Not Re-Use		Manufacturer
	Consult Instructions for Use		Positive Control
	Caution		Negative Control
	Temperature Limit		Catalogue Number
	Use-By Date		Contains sufficient for <n> tests
	Batch Code		Patient Number
	<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		



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