



iCareDx PSS-1 RT-PCR Testing System

User Manual, V:A01

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Revision history

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1. INTENDED USE

The PSS-1 platform is a qualitative RT-PCR test intended to detect the RNAs from SARS-CoV-2 virus that causes COVID-19 from saliva specimens of symptomatic individuals. The PSS-1 platform is for prescription use only, and it tests symptomatic individuals who are suspected of COVID-19 by a healthcare provider.

2. SYMBOLS USED IN THIS INSTRUCTION MANUAL

The following advisory symbols are used in this manual.

Table 1 Advisory Symbol Meanings

 DANGER	Indicates a Risk of Electric Shock which could, if not avoided, result in serve injury or death.
 DANGER	Indicates a Burn Hazard which could, if not avoided, result in serve injury or death.
 WARNING	Indicates a hazardous situation which could, if not avoided, result in serve injury or death; or severely damage the unit.
 CAUTION	Indicates a hazardous situation which could, if not avoided, result in minor or moderate injury; or degrade or impair the functionality of the unit.
 CAUTION	Indicates a Risk of Crush hazard due to moving parts which could, if not avoided, result in minor or moderate injury.
	Advisory note or other useful information.
	Refer to "Section NN" for more details.
	In Vitro Diagnostics
	Serial Number
	Biological Hazard
	Manufacturer
	Consult instructions for use

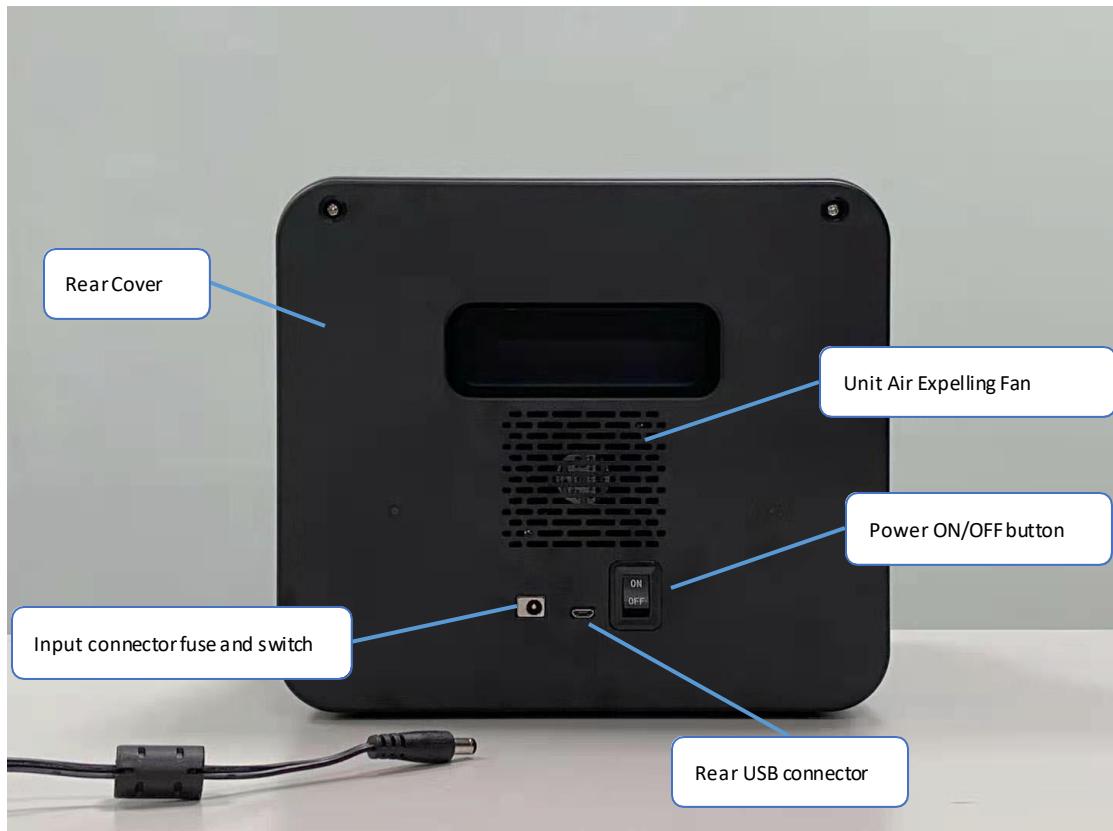
3. UNIT DESCRIPTION

The PSS-1 Real-Time Thermal cycler provides a safe and controlled method heating and cooling the test samples placed within the PSS-1.

To protect the samples from evaporation and contamination during the heating and cooling of a PCR process the PSS-1 are sealed using a clear Disk.

The PSS-1 unit has the following external features:





The PSS-1 unit is designed to be used with accessories some of which are listed below:



The other specialist accessories may be available at request. Please contact your distributor for details.

4. TECHNICAL SPECIFICATION

Model Type

Model Name	PSS-1
------------	-------

Physical Unit Properties

Dimensions (W x D x H)	230 mm x 200 mm x 210 mm
Weight	2.2kg

Console

DC Power Input	12VDC $\pm 5\%$
ARM base CPU	Qualcomm MSM8909 Platform
Memory	1GB LPDDR3 / 8GB EMMC
Color LCM display	6.5 inch TFT color display
Touch Panel	Capacitive touch panel
Camera	5M Pixel for electrophoresis , 2M Pixel for barcode scan
LED	Blue LED for electrophoresis
Audio	0.5W Speaker/Mic
USB port	USB 2.0 for administrator maintenance only
Wifi radio	802.11 b/g/n

Power Adaptor

Brand name	SOY Technology Co., Ltd
Model	SOY-1200400-327
Power Cord Rating	IEC C13, 3-Core, 10A max
Inlet Module Type	IEC C14
Supply Voltage	100-240 VAC $\pm 10\%$
Supply Frequency Range	50 /60Hz $\pm 5\%$
Output Power	12VDC $\pm 5\%$, 48W max
Fuse Ratings and Sizes	T3.15A 250V $\Phi 3.6*10$ mm
Mains Supply capability	The power for this unit must come from a stable mains supply. Do not power from inverters, frequency convertors, or generators.

Operating Environment

Temperature Range	+22 to +28 °C (Ambient temperatures above 25°C can reduce the rate of cooling)
Relative Humidity Range	45% to 75% non-condensing
Maximum Operating Altitude	2000 m above sea-level

Storage and Transportation

Temperature Range	-10 to +40 °C
Relative Humidity Range	5% to 95% non-condensing

PCR Performance

Thermal Ramp Rate	Pre Heater Maximum Ramp Rate 1.1°C per second
Thermal Uniformity	1. Cup Holder Heater (23->98°C): Uniformity achieved after 1.5~5 minutes Maximum $\pm 0.1^\circ\text{C}$ steady-state error 2. Disk High Voltage Heater (50->99°C): Uniformity achieved after 24~33 seconds Maximum $\pm 1.2^\circ\text{C}$ steady-state error 3. Disk Low Voltage Heater (50->59°C): Uniformity achieved after 18~27 seconds Maximum $\pm 1.0^\circ\text{C}$ steady-state error
Fluorescence Detection	LED illumination Compact camera module for image capture

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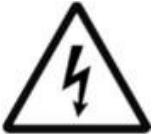
5. SAFETY PRECAUTIONS AND LIMITATIONS OF USE

It is essential that all users of this equipment have fully read and understood the following safety precautions and limitations of use before installing or operating the PSS-1 unit.

IMPORTANT	
 WARNING	<p>The protection provided by this equipment may be impaired if it is not used in a manner described in this manual.</p>
 WARNING	<p>It is essential that the user of this equipment is aware of the potential hazards associated with the unit and its accessories.</p> <p>All operators should be familiar with the safety precautions and warnings given in these instructions before attempting to operate the unit.</p> <p>Improper use of this unit or its accessories may impair their functionality and invalidate the manufacturer's warranty.</p>

Unit Handling Precautions	
 CAUTION	<p>Care should be taken not to drop the unit or subject it to rough physical handling, both during normal use and during transportation and storage.</p>
 WARNING	<p>The unit should be supported using the base of the unit when being lifted or moved. Do not lift the unit by any other part of the casework.</p> <p>Care should be taken when lifting the unit due to its weight.</p>

 CAUTION	<p>Care should be taken not to knock the LCD display. Do not use excessive force when touching the touch screen or operating the buttons.</p>
---	---

Unit Installation and Operating Environment	
 DANGER  WARNING	<p>The PSS-1 unit is designed for indoor laboratory use only. The acceptable operating temperature range is 22°C to 28°C, with a relative humidity of 45% to 75% non-condensing, at a maximum altitude of 2000m above sea level.</p> <p>If the unit is stored in conditions outside of these ranges, it must be left to stand unpowered until it has acclimatised to within these environmental limits before being powered.</p>
 DANGER	<p>Use only the AC mains power cord provided with the unit or as specified Section 4. The unit must be connected to a suitably earthed mains supply, with appropriate earth-leakage and over-current protection.</p>
 WARNING	<p>Always ensure that the mains power connector is securely inserted into the rear of the unit, and any excess power cord does not pose a potential trip or pull hazard.</p>
 WARNING	<p>The power for this unit must come from a stable mains supply. Do not power from inverters, frequency convertors, or generators. This unit requires a power supply with both a stable voltage and stable frequency. Inverters, frequency convertors, and generators do not provide acceptable stability and the unit can perform outside its specification, or fail to perform, or be damaged by the use of these forms of power supply.</p>

 CAUTION	<p>There is a possible finger crush hazard due to the moving parts of the door. Care should be taken when closing the door.</p>
 WARNING	<p>The unit must be installed and operated on a solid, stable and level working surface; ensuring that the ventilation holes under the unit and at the rear of the unit are not obstructed.</p>

General Operating Precautions	
 DANGER	<p>Ensure that the power is switched off at both the AC mains supply outlet and at the back of the unit before inserting or removing the mains power cord.</p>
 DANGER	<p>The PSS-1 can reach temperatures of over 98°C and can remain hot for a time after the PSS-1 system is turned off.</p> <p>If conditions are set such that the experiment is finished with the plate at a high temperature it will exit the unit with the potential to burn the operator and care should be taken.</p>

Unit Maintenance and Serviceability	
 DANGER  WARNING	<p>There are no user or operator serviceable parts inside the unit.</p> <p>Do not remove the unit casework.</p> <p>Removal of the unit's casework will void the manufacturer's warranty and may expose the user to a Risk of Electric Shock resulting in serious injury or death.</p>
 DANGER	<p>Always switch off the unit and disconnect the power cord before performing any cleaning or decontamination procedure.</p> <p>If liquid is spilt into or over the unit, switch off and disconnect the power from the AC mains outlet before attempting to deal with the spillage.</p>
 DANGER	<p>Ensure that the PSS-1 unit has cooled down to room temperature before performing any cleaning operation and before moving or storing the unit.</p>
 WARNING	<p>The use of harsh chemicals and cleaning agents may damage the unit and degrade its performance.</p> <p>Always follow the cleaning and decontamination procedures specified in Sections 8.1 and 8.2 of this instruction manual.</p>
 WARNING	<p>Do not autoclave any part of the unit or its accessories.</p>

6. UNIT INSTALLATION

Before installing the PSS-1 unit, please check that the delivery is complete and that the unit and any accessory parts are intact and free from any signs of transportation damage. Also ensure that all external and internal packaging has been removed from the unit before installation.



Please retain all packaging for future transportation and storage of the unit and its accessories.

The PSS-1 unit should be installed in a location which meets the following requirements:

- Safe and suitable operating environment (see Section 5)
- Solid, stable, level working surface
- At least 10cm clearance around the unit to adjacent objects and walls
- Earthed AC mains power connection (see Section 4)



WARNING

Please also observe and abide by the Unit Installation and Operating Environment safety precautions and preconditions listed in Section 5.



WARNING

The power for this unit must come from a stable mains supply that matches the specification on the back panel of the unit. Do not power from inverters, frequency convertors, or generators (see Section 5).



WARNING

Ensure that the correct fuse type has been fitted in the mains inlet fuse holder as detailed on the back of the unit. See Section 4 for details.



WARNING

If the unit has been stored in a cool environment, it must be left to stand unplugged until it has acclimatised to the new room temperature before being powered.

Install and test the PSS-1 unit using the following procedure:

- 1) Place the unit on the suitably selected working surface (as specified above), ensuring that the ventilation holes underneath and on the rear of the unit are not obstructed.
- 2) Connect the unit to the AC mains power outlet using the mains power cord supplied or as specified in Section 4.

3) Switch the mains power on at supply outlet first, and then switch the unit on using the power switch located at the rear of the unit.

This can take 30seconds as the unit initializes the system and runs a basic-settings.

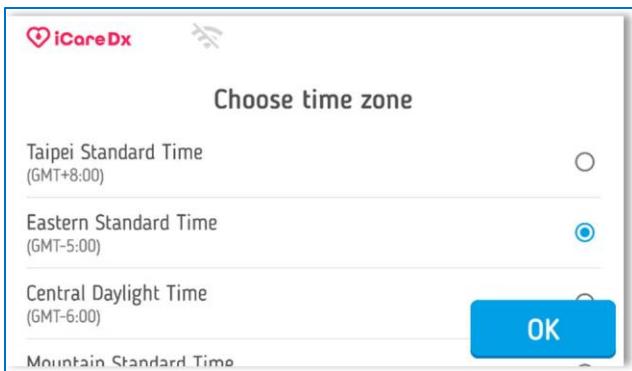
4) Start-up is complete when this screen is shown.

6.1 Basic settings when first time use the system

For the first time to use this system, please follow the step to finish the basic setting:

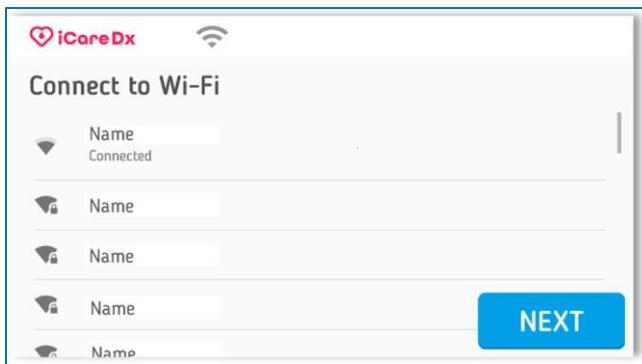
1. Select Time Zone

Scroll the screen to choose the time zone. Four time zones support here



2. Setup Wi-Fi connection

This system required to work with Wi-Fi connection. Select an available AP to connect.

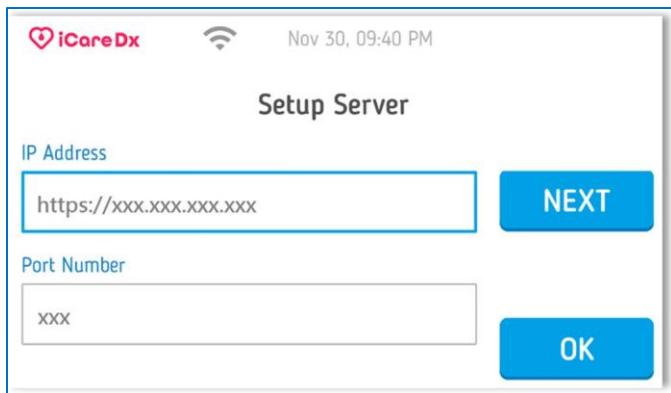


3. Setup Server

Input the Server IP address and Port number

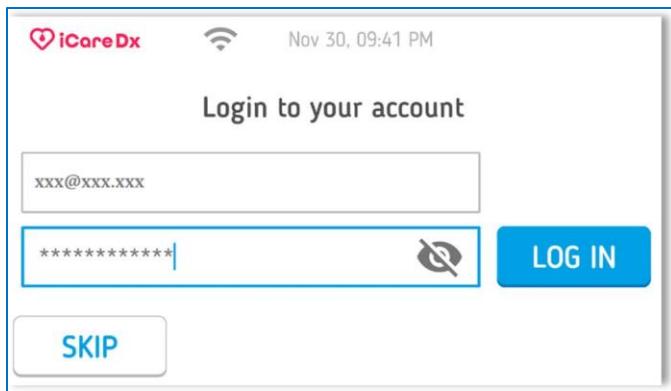
Server IP : <https://192.168.1.200>

Port number : 443



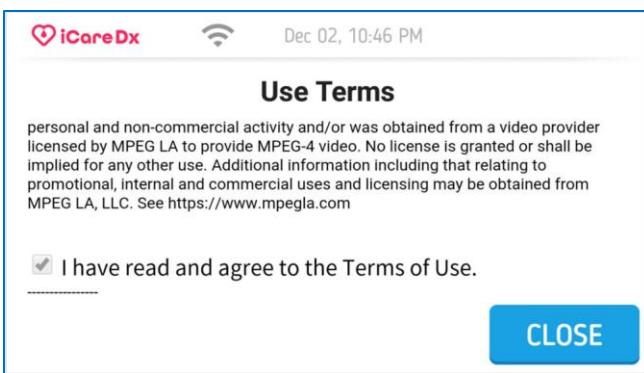
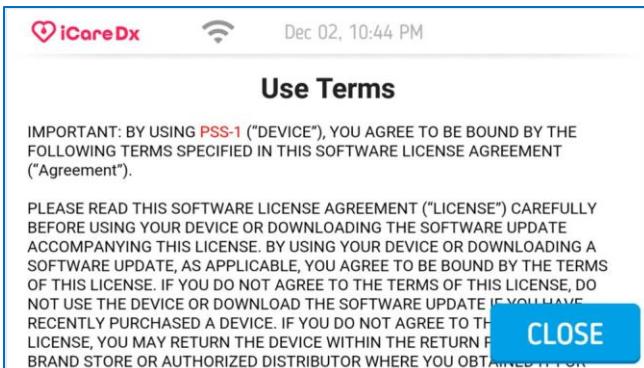
4. Login to operator account

Login with your account and test result will be saved to Cloud automatically when finish test



5. Use Terms

Go through the use terms page and check the agreement. Tap Done to finish the setup process



7. UNIT OPERATION



Please ensure that you have read and fully understood all of the Safety Precautions and Limitations of Use listed in Section 5 before attempting to operate the PSS-1 unit.

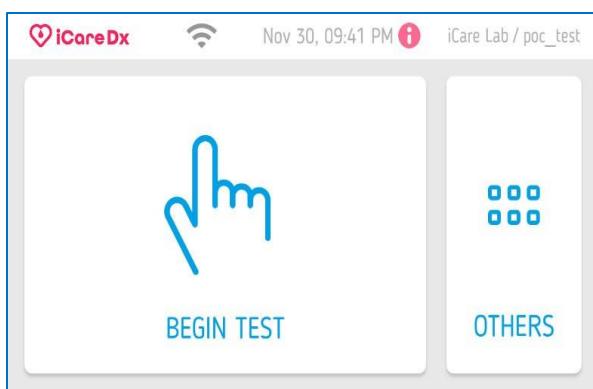
7.1 User Touch Screen Display and Controls

The unit's user interface consists of a large high definition color LCD display which has an integrated touch screen that will support multi-finger gestures. (The touch screen is designed to operate when wearing standard laboratory gloves.)

The unit is controlled through an application that runs on the PSS-1 unit that has been designed to match the operation of the Real-Time PCR Thermal Cycler to the normal experimental procedures used by Biotechnologist's so that it is intuitive and so easy to use.

7.2 Operation of the PSS-1 RT-PCR system

7.2.1 Turning on PSS-1



Before connecting PSS-1 to the mains electrical connection make sure that the voltage and frequency detailed on the label at the rear of the unit matches the supply voltage.

- Connect the supply using the cable provided with the unit. Turn the power on at the wall (if switched) then turn the power button On. PSS-1 will wake up, and initialize its systems. Once a screen like the one in Figure 1 is visible the PSS-1 is ready to use. This is the HOME screen and can always be returned to by touching the QUIT at the bottom left of the other screens.

From the HOME screen user can create a new experiment by touch <BEGIN TEST>. For each of the operations PSS-1 will guide the user through the steps required.

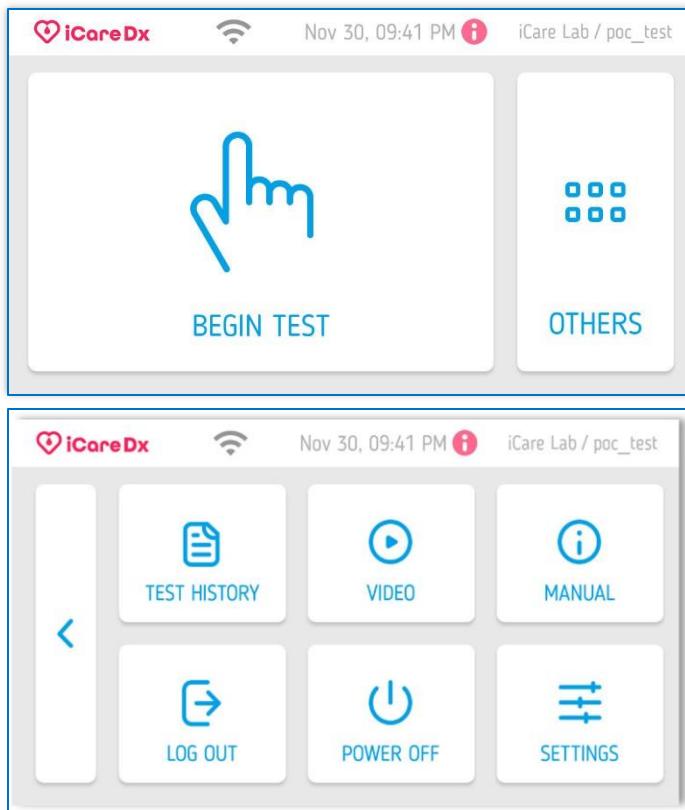


Figure 1

- To check the version of the software running on PSS-1, from the HOME screen touch the OTHERS > SETTINGS > ABOUT in the bottom left of the screen. A pop-up information window will appear listing the version (See Figure 2).

Close the screen by touching the CLOSE button in the bottom right corner of the screen.

The next sections of this manual will guide the user through the regular operations that can be completed using PSS-1.

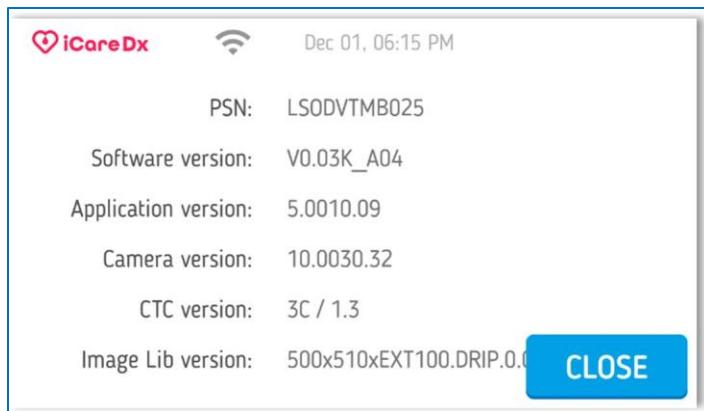


Figure 2

7.2.2 Running the Experiment

- To create a new experiment touch the BEGIN TEST square or tile on the screen (PSS-1 is fitted with a touch screen, it is quite sensitive and doesn't need high force to operate).

iCareDx provides clear step-by-step instruction and also video instruction. Please follow the steps to test.

Step 1: Open Disk door and insert Disk

Step 1-1. Slide Disk door down.



Step 1-2. Remove Disk from packaging. Pull tape off of Disk.



Step 1-3. Insert Disk until it locks and you hear the bell.



Step 1-4. Turn the Disk latch until lock full.

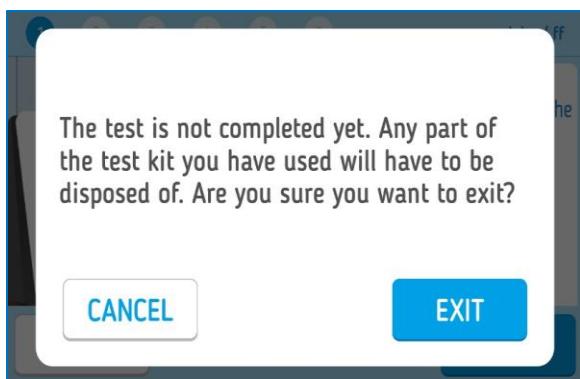


Step 1-5. Slide the Disk door up.



Notice: If you select QUIT the test process in any step, the test kit you have used must be disposed of.

Please refer to [Test finish and test kit recycle](#).



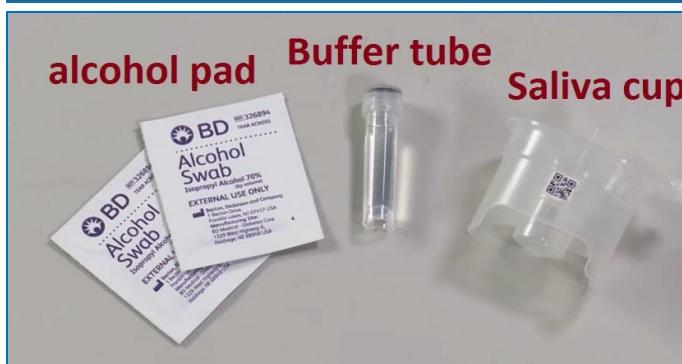
Step 2: Prepare Saliva and put Saliva cup into Red holder

Step 2-1. Please confirm the saliva sample has ready or not.



If the answer is "No", please remove Saliva cup, Buffer tube and the alcohol pad from packaging.

If the answer is "Yes", please just remove Buffer tube and the alcohol pad from packaging. Use front facing camera to scan the QR code on Saliva cup.



Point the label towards camera, see it shown in the central of the screen.

Hold steadily and slightly move back and forth until reading success.

Notice:

If Saliva sample has not been collected, please follow [Collect the Saliva to collect the sample.](#)

If Saliva sample is ready, please skip [Collect the Saliva](#) and jump to [3. Clean Red holder with the alcohol pad](#)

COLLECT THE SALIVA

- **Begin drooling into cup:**

Drool saliva to the indicated line, any air bubbles should be above the line. Collected saliva should be clear. There should not be phlegm, food particles, or any visible impurities.

- **Saliva sample check**



If saliva does not look like these, redo collection by emptying Saliva cup and clicking BACK

- **Notice: Important!! Before collecting saliva:**

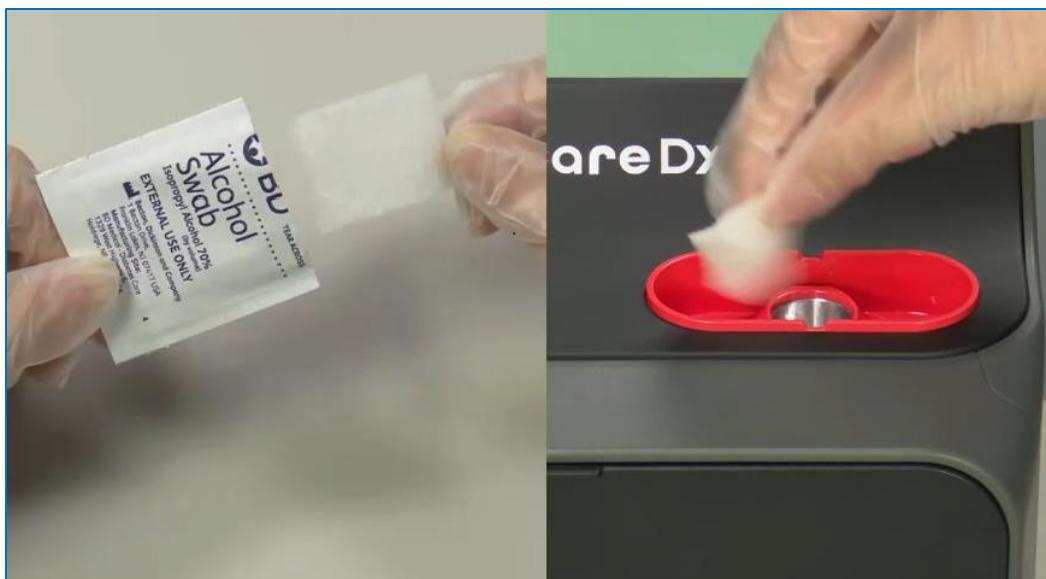
Use fingers to lightly massage saliva glands. There should be increase in salivation. Please do not use spitting method. Massage until saliva pools at bottom of mouth, tilt head forward and prepare saliva to slowly drool out.



Only when collecting saliva, the saliva cup is in contact with mouth and duration should not more than 1 minute.



Step 2-2. Clean Red holder with the alcohol pad.



Step 2-3. Insert the Saliva cup into the Red holder until you hear the bell.

Step 3: Heating and cooling process

Sample inactivation, heating and cooling down saliva

 Do not touch the Saliva cup when Saliva + Buffer solution is heating.



The Saliva is cooling down.

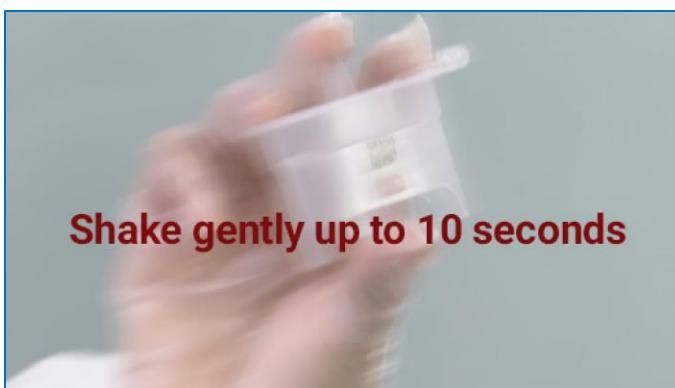
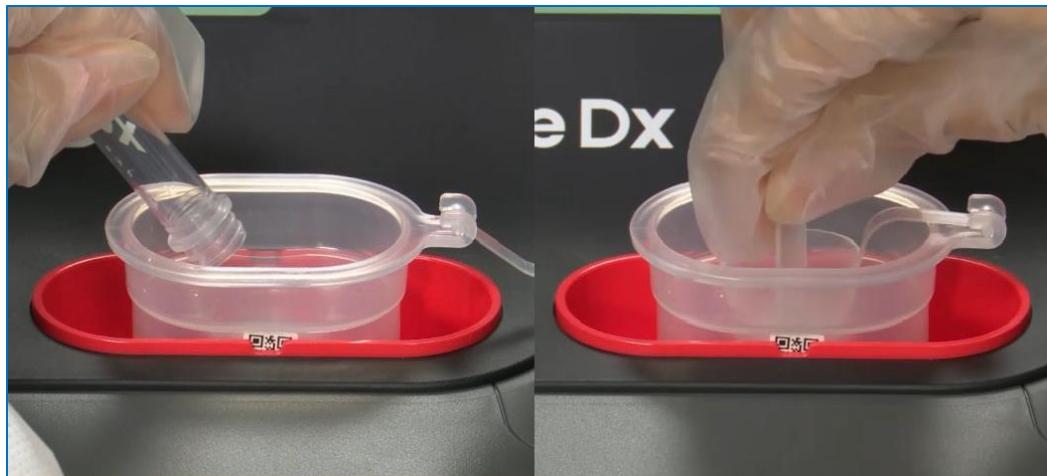


Please wait for heating and cooling process finish then tap Next to next process.

Step 4: Mixing the Buffer and Saliva

Step 4-1. Open lid on Saliva cup.

Remove the Buffer tube cap and empty contents into the Saliva cup. Cover the cup with lid.



Step 4-2.

Remove the Saliva cup from the Red holder and shake gently up to **10** seconds

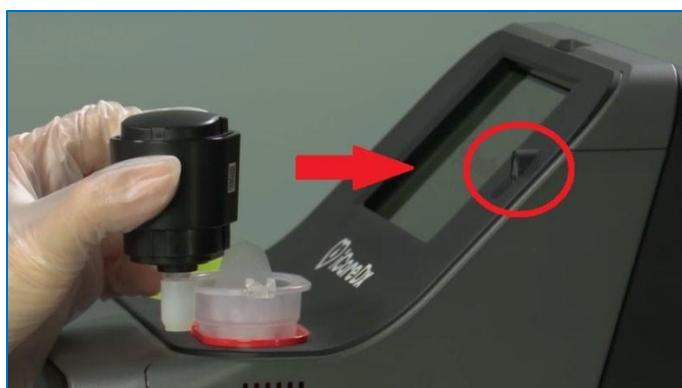
Step 4-3. Insert Saliva cup back into the Red holder until you hear the bell.

Step 4-4. Tap the screen to start heating process.

Step 5: Mixing the reagent with the Saliva and Buffer for PCR process

Step 5-1. Open lid on Saliva cup.

Step 5-2. Clean Green holder with the alcohol pad

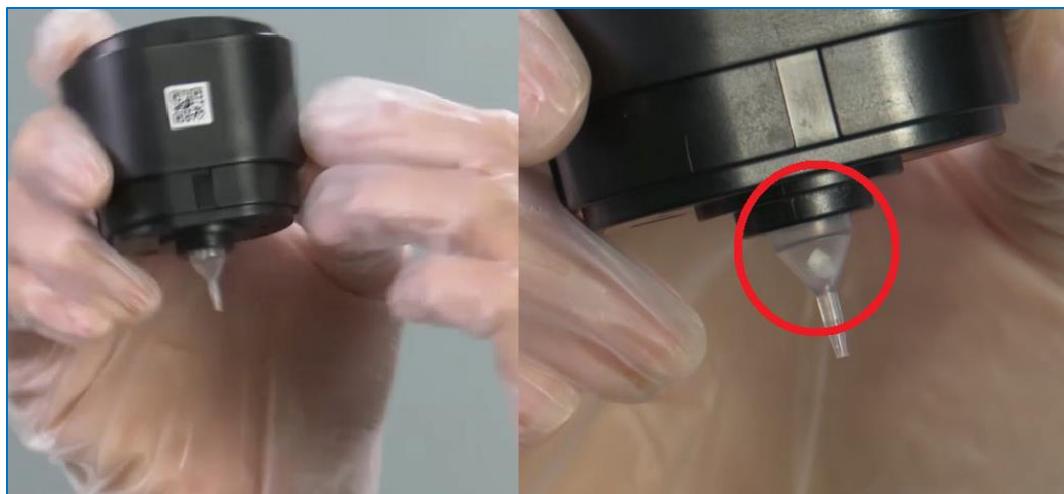


Step 5-3 Remove Cartridge from packaging. Use front facing camera to scan QR code on Cartridge.

Step 5-4. Remove the stopper on Cartridge.



Notice: Make sure reagent ball is at the bottom of the Cartridge tip. If not, lightly tap or knock on the side of Cartridge.





Step 5-5.

Place Cartridge onto Saliva cup. Firmly press Cartridge for 3 second with both hands, then release.



Step 5-6.

Transfer Cartridge onto Green holder. Make sure Cartridge is fully inserted into the holder.



Step 5-7.

Keep Cartridge on Green holder and wait for the countdown to finish.
Tap NEXT and wait 30 second countdown. (The reagent is mixing Saliva and Buffer solution)

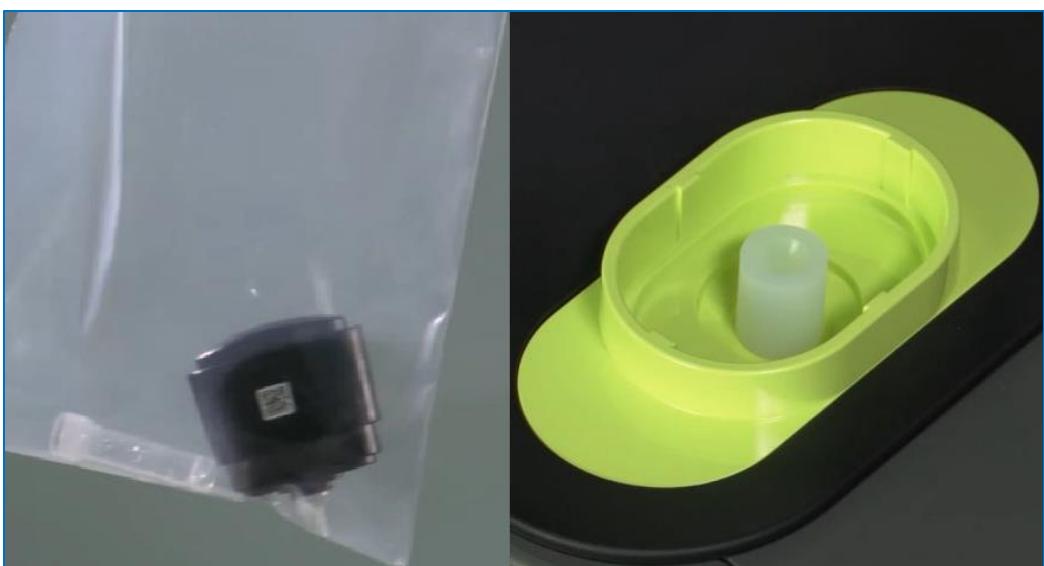
Step 5-8.

Firmly press for 3 seconds with both hands, then while maintaining the pressing position, take out Cartridge and release it.



Step 5-9.

Return Cartridge into the ziplock bag. Insert the stopper of Cartridge into the hole of Green holder.



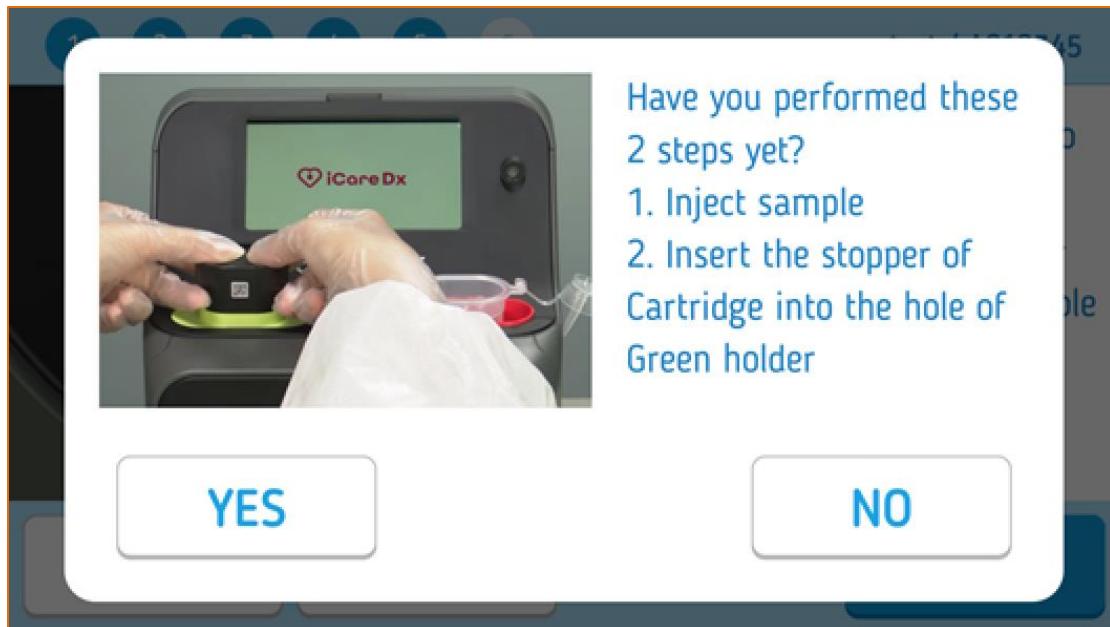
Step 5-10. Press NEXT to begin PCR.

Step 6: PCR Process

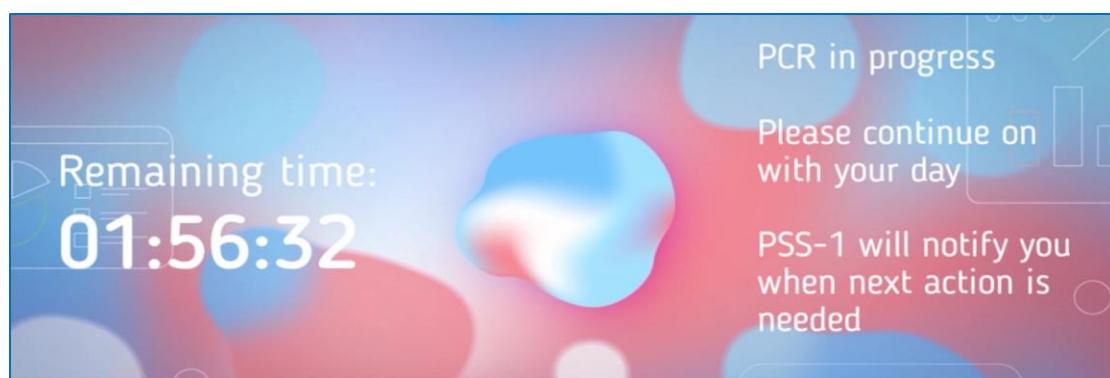
Notice:

A dialog “Have you performed this step yet?” will be popped up when enters PCR process.

Please confirm you have done Step 5-8 and Step 5-9 or you have to finish these steps before PCR.

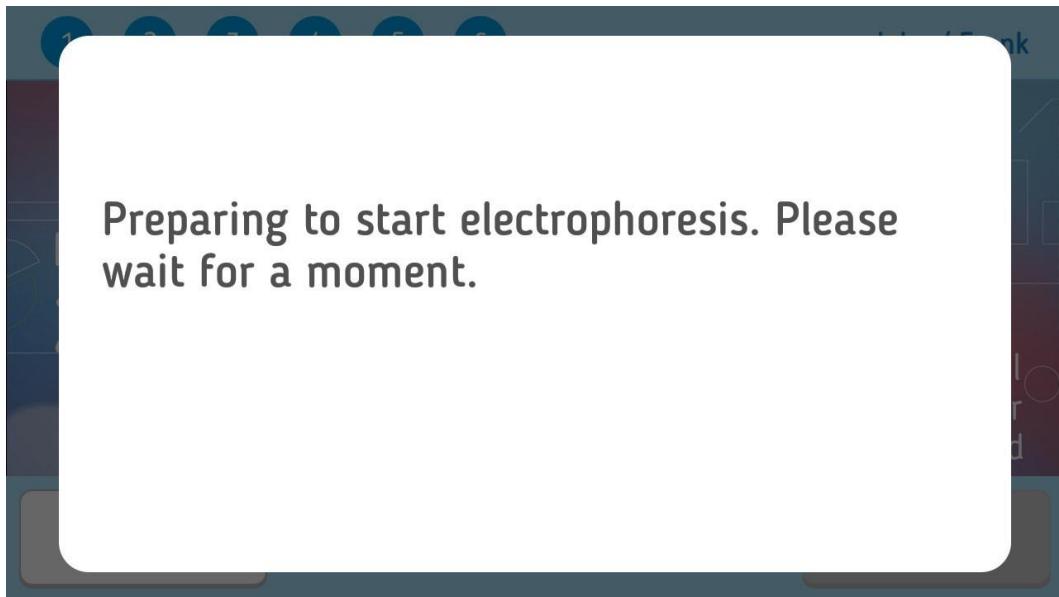


When PCR process, do not touch the device. It takes times to finish and please be patient to wait.

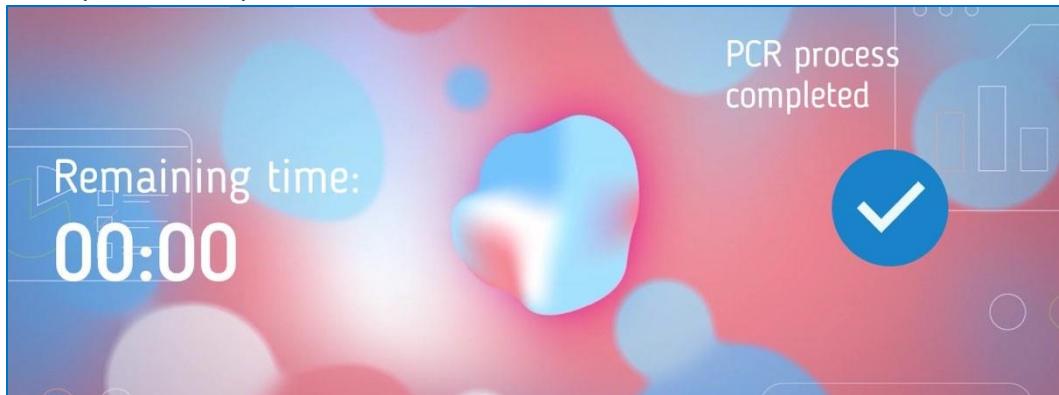


Notice:

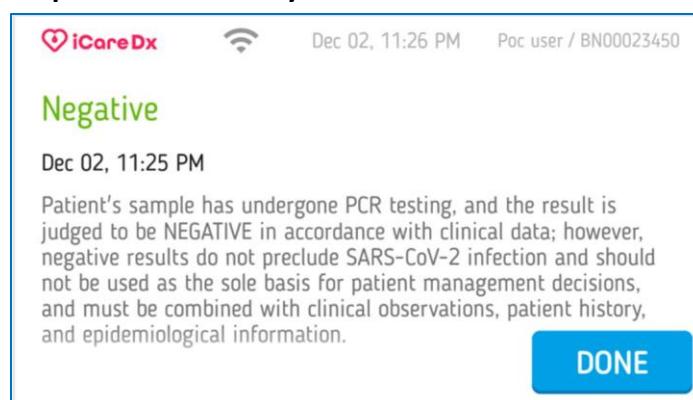
A warning dialog will pop-up in about 30 minutes of remaining time.



PCR process completed



Step 7: Result identify



When PCR process finish, you can check the result after result identify.

Test result and test record will be uploaded to the server in the local network when Wi-Fi connection is available.

Note:

Cleaning Frequency: one time per month.

Step 8: Test finish and test kit recycle

Please take out all kits and dispose them into the ziplock bag.

If locked, please tap UNLOCK. Any placemat used can also be placed into the ziplock bag accordingly.



If you are going to perform a new test run, back to Home screen and tap BEGIN TEST.

If you have finished all of the test, remember to log out your account before leave.

7.2.3 Experiment Results

All	Positive	Negative	
Date/Time	Cup ID	Result	Upload
Jan 25, 05:46 PM	0N62N01807	Negative	Yes
Jan 25, 05:41 PM	0N62N01807	Invalid	Yes
Jan 25, 05:38 PM	0N62N01801	Invalid	CLOSE

At the end of an experiment the results are displayed as shown in Figure 3. Depending on the time of experiment different parameters are shown.

In Home screen , tap OTHERS > TEST HISTORY can check all the test result under the user log-in account. Tap single test result can check the result detail.

Negative
POC_user
Dec 02, 10:43 PM
Uploaded
Patient's sample has undergone PCR testing, and the result is judged to be NEGATIVE in accordance with clinical data; however, negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management and must be combined with clinical observations. CLOSE

Figure 3.

8. MAINTENANCE AND SERVICING

Although the PSS-1 unit does not require any scheduled maintenance or servicing, the operator should regularly clean and inspect the unit for any defects, as described in Section 8.1 below.

	<p>Please observe and comply with all of the Unit Maintenance and Serviceability precautions listed in Section 8.</p> <p>Never removed the unit casework. There are no user or operator serviceable parts inside the unit.</p> <p>Always switch off and unplug the unit before performing any cleaning or disinfecting tasks.</p>
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For technical and service related enquiries, please contact your distributor or iCareDx at the address given on Page 2 of this manual.

8.1 Decontamination Procedure

The unit and accessories should be decontaminated using the following procedure before being stored or transported.

Decontamination Procedure

Thoroughly clean all outside surfaces of the product (including any accessories, power cords, manuals, packaging, etc) with a damp cloth soaked with suitable disinfectant solution.

8.2 Transportation and Storage

The PSS-1 unit and its accessories should be thoroughly decontaminated using the procedure detailed in Section 8.1 before being placed in its original packaging for transportation or storage.

	<p>Refer to Section 4 for the acceptable range of Storage and Transportation environmental conditions. Always ensure that the unit and accessories are completely dry and free of any condensation before being packed.</p>
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9. WARRANTY AND RETURNS

Warranty

Limited 15 Months Warranty

iCare Diagnostics, Inc Ltd. warrants the PSS-1 product, when purchased new and installed and operated in accordance with the instructions of this manual, to be free from defects in materials and workmanship, and will repair or replace, at their discretion, any unit or accessory which exhibits such defects.

In no event will iCare Diagnostics, Inc be liable for any indirect, incidental or consequential damages resulting from any defect or warranty claim.

 NOTE	Unspecified use or unauthorized modification of any part of the PSS-1 unit or its accessories or the use or attachment of any adaptor or peripheral not supplied, specified or sanctioned by iCare Diagnostics, Inc will invalidate this warranty.
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The PSS-1 At-Home RT-PCR Testing System and its associated accessories are covered by a standard iCare Diagnostic, Inc warranty. Contact your local iCare Diagnostic, Inc office for the details of the warranty.

Under the terms of this warranty, the product must be returned in its original packaging, transportation prepaid by the sender, with a copy of the Proof of Purchase and a detailed description of the problem.

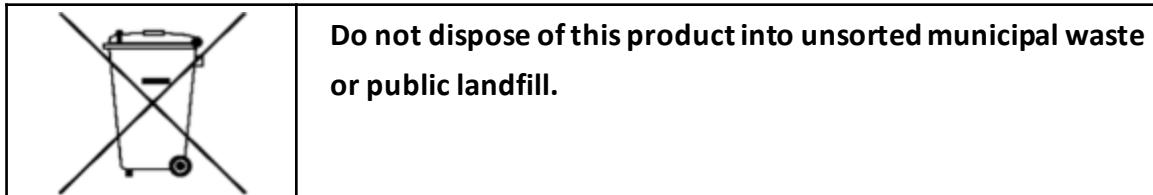
 WARNING	The product must be decontaminated using the procedure detailed in Section 8.2 and a Certificate of Decontamination supplied with any return. If the product is considered too hazardous to be shipped, please contact iCare Diagnostics, Inc on the number given on Page 2 of this manual for further instructions.
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Please contact your distributor (or iCare Diagnostics, Inc on the number given on Page 2 of this manual) to assess the defect and arrange the return the product if necessary.

10. PRODUCT DISPOSAL

At end-of-life, this product must be disposed of in accordance with your local authority regulations for the disposal of potentially hazardous waste and electronic equipment.

The unit and its accessories should be decontaminated using the procedure detailed in Section 8.2 before disposal or shipping.



Please contact your distributor (or iCare Diagnostics, Inc at the address on Page 2 of this manual) for details of how to correctly dispose of this product.

11. CERTIFICATION INFORMATION

FCC DECLARATION OF CONFORMANCE

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment.

This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

Any changes or modifications not expressly approved by the party responsible for compliance could void the authority to operate equipment.

This device and its antenna must not be co-located or operating in conjunction with any other antenna or transmitter.

For body worn operation, this device has been tested and meets FCC RF exposure guidelines. When used with an accessory that contains metal may not ensure compliance with FCC RF exposure guidelines.

For product available in the USA/Canada market, only channel 1~11 can be operated. Selection of other channels is not possible

E-Label of REGULATORY INFORMATION

For Regulatory Information and Compliance mark (E-Label). Please refer to your device via the following step: OTHERS > SETTINGS > About