USER MANUAL

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2019/06

Be sure to read the manual before use and follow the instructions.

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Symbols

Date of manufacturing

Manufacturer

Catalogue number

Serial number

Alternative current

Protective earth

Supplementary fuse

Caution, consult instructions for use

WEEE symbol

This product is manufactured in compliance with the European Union's Waste Electrical & Electronic Equipment (WEEE) Directive 2012/19/EU. Please follow your institutional requirements for disposal of the accessories.

Section 1. Introduction

The **POCKIT™ Central** Nucleic Acid Analyzer (**POCKIT™ Central)** is a bench top sample-in-answer-out molecular detection system. It integrates magnetic bead-based nucleic acid extraction, fluorescence-based insulated isothermal PCR (iiPCR) (ref. 1-3) amplification/detection, and liquid handling technologies to offer a walk-away protocol for nucleic acid detection. Results are displayed on the monitor in less than 1.5 hours; the data is automatically stored in an internal storage space and can be exported via a USB flash drive.

The user-friendly interface and ready-to-use cartridge-based consumables allow users to drastically reduce hands-on time and simplify laboratory workflow.

1.1 Intended Use

POCKIT™ Central is intended to provide qualitative detection of nucleic acid targets using fluorescence-based iiPCR reagents for research use only. Intended users are properly trained laboratory technicians familiar with molecular biology techniques, and those who want to perform iiPCR using reagents developed by GeneReach.

Note: The test results should be used as an aid in diagnosis, not to be used as the sole basis for treatment or other patient management decisions.

1.2 Product Description

The **POCKIT™ Central** is intended to be used with the **POCKIT™ Central** Premix Reagents and **POCKIT™ Central** Cartridge Set.

Section 2. General Information

2.1 Product Components

- **POCKIT™ Central** Nucleic Acid Analyzer × 1 unit
- User manual × 1 copy
- Setup Tray × 1 piece
- Warranty card × 1 copy
- Transfer Cartridge × 2 pieces (for transportation protection purpose)

2.2 Specifications

- Dimensions: 310 mm (W) × 480 mm (D) × 400 mm (H)
- Net weight: 21 kg
- Power supply: 100-120/200-240 V AC, 50/60 Hz, 2A
- Fuses: 2A, 250V AC, ϕ 5 × 20 mm fast-acting, low breaking capacity glass tube fuses
- Storage condition: 10 ~ 40˚C, 55±25% RH

2.3 Testing Capacity

- Number of samples: 1 - 8 reactions per run, per instrument
- Sample input volume: 200 µl per reaction

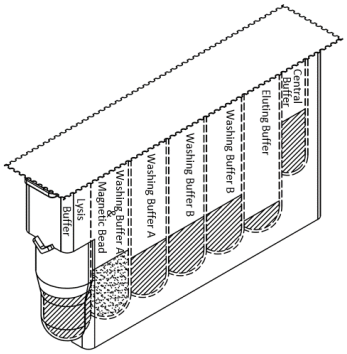
2.4 Equipment and Materials Required But Not Provided

- **POCKIT™ Central** Premix Reagent
- **POCKIT™ Central** Cartridge Set (including Extraction Cartridges and Transfer Cartridges)
- 1000-µl micropipette and filter tips
- Disposable gloves
- Uninterrupted power system
- Biological safety cabinet or hood (optional)

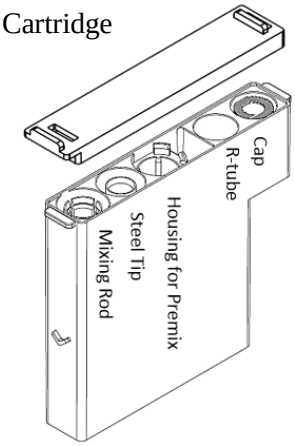
Note: The components of **POCKIT™** Cartridge Set are listed below, please refer to the respective user manual for details.

1) Extraction Cartridge: Preloaded with all extraction solutions, elution buffer, and iiPCR buffer.
2) Transfer Cartridge: Comprising a receiving hole for the reaction Premix Reagent (lyophilized pellet) and all accessories for liquid transfer and iiPCR.
3) Premix Reagent

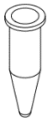
1) Extraction Cartridge



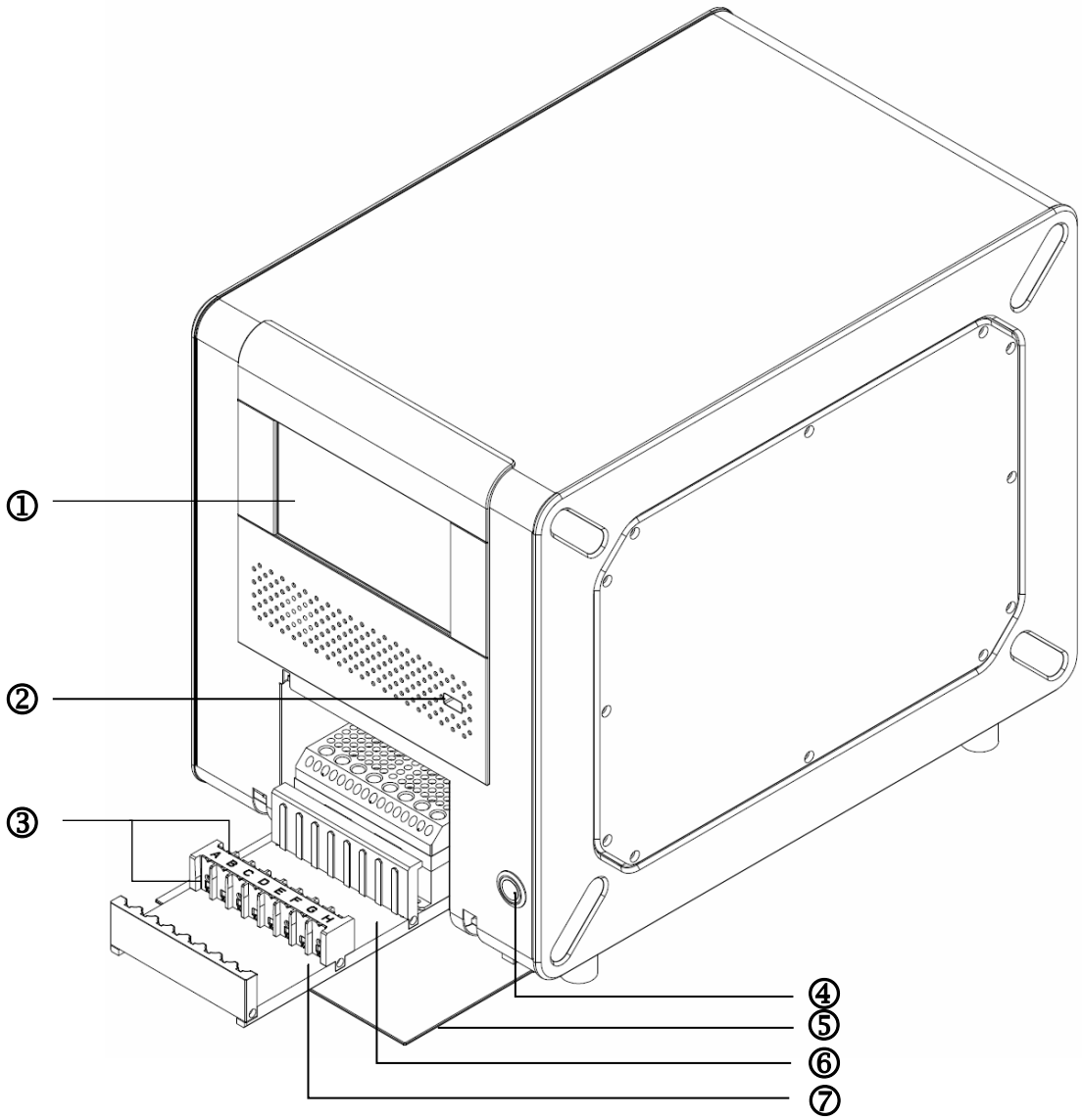
2) Transfer Cartridge



3) Premix Reagent



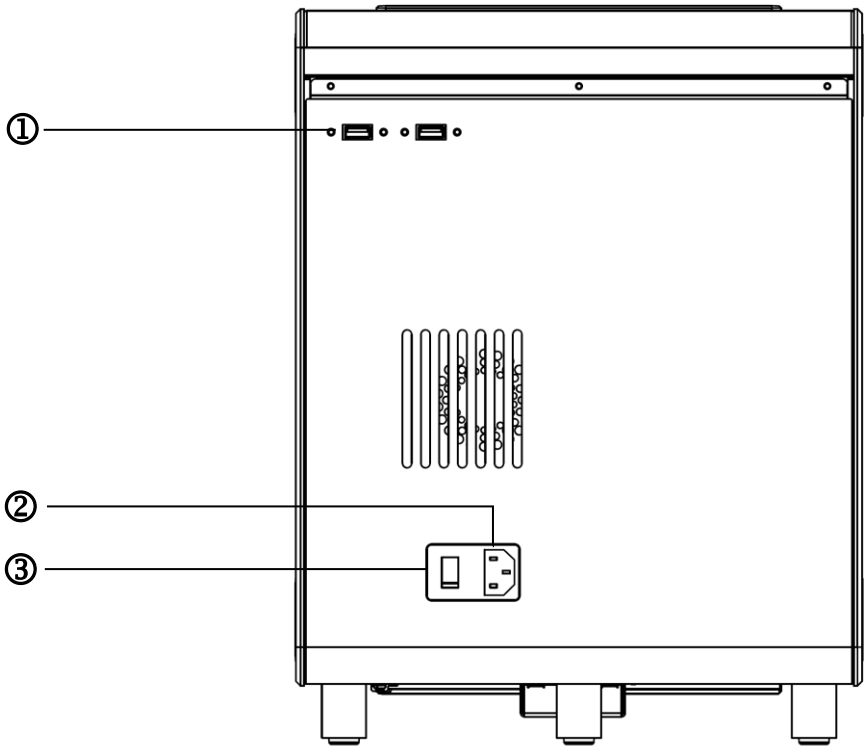
2.5 Front View



No.	Item	Description
1	Control panel	A touchscreen where users key in the operation commands and view the results.
2	USB port	A slot where users insert the USB flash drive for data acquisition and transfer.
3	Tray sensor	Sensors for monitoring cartridges.
4	Wake/Sleep button*	Pressing the button to enter sleep mode or wake up the system.
5	Door	To protect interior mechanical components and operators.
6	Reaction slot	Housing for the Transfer Cartridge.
7	Extraction slot	Housing for the Extraction Cartridge.

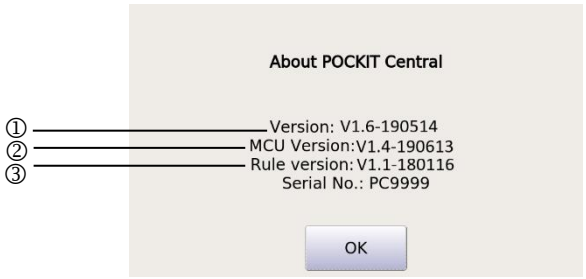
***Note: Wake/Sleep button is disabled during operation.**

2.6 Rear View



No.	Item	Description
1	USB ports	Two slots where users insert the USB flash drive for data acquisition.
2	Main switch	To turn on/off the main power.
3	Socket	To connect to a 18 AWG power cord (300 V, 3×0.824 mm^2, 1.8 M)

2.7 Software Version



No	Item	Description
1	Software Version	Software version on **POCKIT™ Central** system.
2	MCU Version	Firmware version on **POCKIT™ Central** system.
3	Rule Version	Algorithm version on **POCKIT™ Central** system.

2.8 Unpacking

Note:

1. **Inspect the shipping container for obvious shipping damage prior to opening. Report any damage immediately to local distributor or GeneReach with a photo(s).**
2. **Keep the packaging boxes and accessories provided for future transportation.**
3. **Set the POCKIT™ Central on a flat, level and stable surface. Avoid setting the device at locations with exposure to direct or reflected sunlight, or to infrared light emitted by electrical devices (such as infrared halogen lamp).**

The **POCKIT™ Central** will be packed in double boxing, i.e. a carton box and honeycomb board packaging. Unpack the **POCKIT™ Central** instrument and place it on a clean, flat, level and stable surface within reach of an electrical outlet. When handling the instrument, hold both sides of the instrument to move it and avoid touching the door. Two person lifting is highly suggested.

Place the instrument in a location where the air vent and main switch in the back of instrument will not be blocked.

Section 3. Warnings and Precautions

Check the device upon receiving. If any item is missing or damaged, please contact your local distributor or GeneReach immediately for replacement. Do not use any damaged items as they may lead to poor performance of the test or harm the user.

	Not following the instructions may cause personal injury or device failure.

- **Safety information**
  - Please read these warnings, precautions and safety/operating instructions carefully before operating this product.
  - Do not touch any plugs and electricity switches with wet hands.
  - Switch off and unplug the device before moving it.
  - Hold the plug while pulling the power cord out from the electrical outlet. Do not pull it by the cord directly.
  - Do not place the power cord on any hot surfaces.
  - Do not disassemble **POCKIT™ Central**. This will void the warranty.

- **Operation**
  - When handling infectious materials, always wear a lab coat, disposable gloves and protective goggles. Follow local biosafety regulations and guidelines to deal with potentially infectious materials.
  - The working area should be set away from post PCR amplification area.
  - Make sure the ambient temperatures during reaction are kept at 15-35°C.
  - Inclusion of the internal control in the reaction is recommended.
  - Make sure all the equipment provided by users have been calibrated according to the SOP provided by the manufacturers before the test.
  - Residual nucleic acids on waste materials, such as gloves, cartridges, and used consumables, may lead to contamination of subsequent tests. Please dispose them immediately according to your local regulations.
  - Do not reuse consumables. Reuse the consumables will lead to incorrect results.

- **Shipping and transportation**
  - Pack the device carefully before transportation (***See section 7.3***).
  - Users should perform a performance qualification test after the device has been moved.

- **Limitation of use**
  - Only use consumables and accessories provided from GeneReach.

Section 4. Getting Started

4.1 Initial Setup

Note: Set the POCKIT™ Central on a flat, level, stable surface. Avoid placing heavy objects on top of the machine.

1) Plug the power cord into the socket in the back of **POCKIT™ Central** and to an available electric outlet.

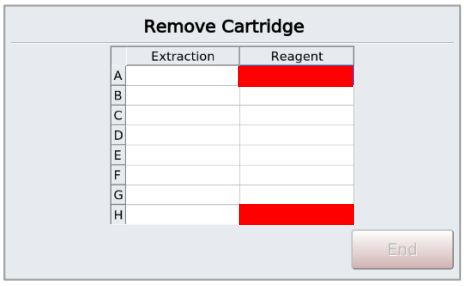
   Note:

   1. **Make sure the plug is connected to a grounded receptacle to prevent electrical shock or fire.**
   2. **To avoid power failure during a run, connecting POCKIT™ Central to an uninterrupted power system (UPS) and/or voltage regulator is highly recommended.**

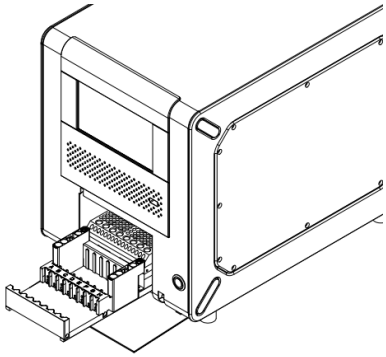
2) Once the power is connected, turn on the main power switch on the back of the instrument.

3) Remove the Transfer Cartridges (for transportation protection purpose).

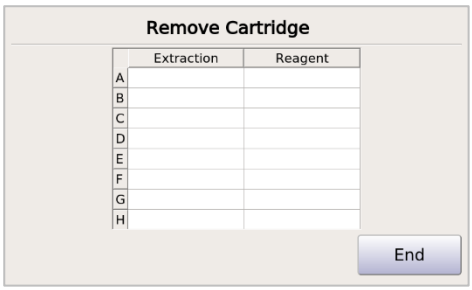
Once the device is powered up, the **Door Opening** notice will be shown on the screen. Make sure nothing blocks the door. Press **OK** to open.



The **Remove Cartridges** instruction will be displayed on the monitor.



Remove the Transfer Cartridges on slot A and H.



Press **End** to return to Home screen.

4.2 Main Menu

The buttons of **Main Menu** are for access to the following functions:

- Start: Run test
- Search Archive
- Cleaning/Shipping Setup
- UV: Turn on/off UV Lamp
- Basic Settings

4.3 Onscreen Keyboard

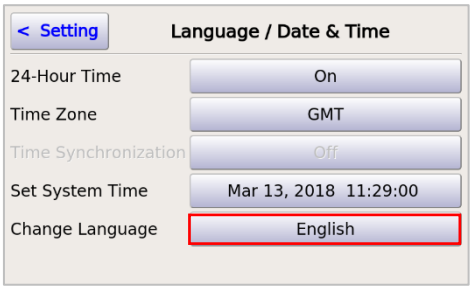
The onscreen keyboard enables users to input information into the **POCKIT™ Central** instrument. Press **ABC** or **123** to switch between text and number entries.

4.4 Setting Language, Date and Time

Users are able to set **Language**, **Date & Time**, and select the format in which the date and the time are displayed.

Go to **Home** > **Basic Settings** > **Language / Date & Time**

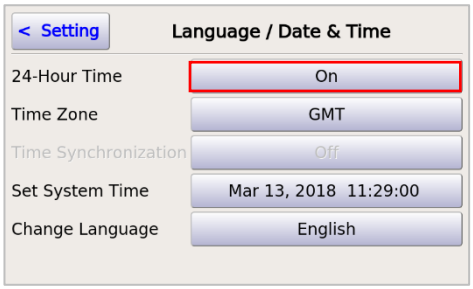
1) Language



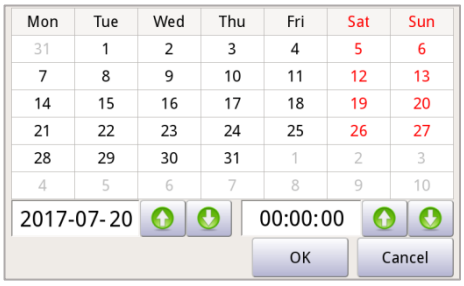
Select **English/简体中文** to change language preference if needed.

Select **OK** to complete language setting.

2) Date & Time



Press **On/Off** to choose between 12-hour or 24-hour mode.

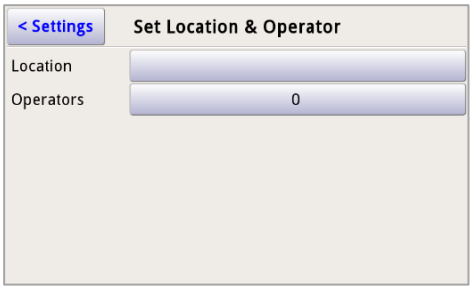


Set the **Date & Time** by pressing the up and down arrow keys on the touch screen to move between day/month/year or hour/minute/second settings. Users can also press the numbers on the calender to set the date.

4.5 Setting Basic Information

1) Location & Operator

Go to **Home** > **Basic Settings** > **Set Up Location & Operator**



Touch the blank bar to enter/edit location and operator information.

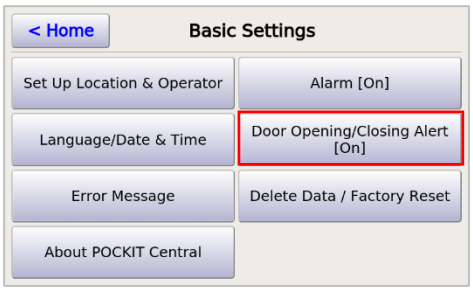
Press **+** icon to create a new Operator.

Touch the blank to activate the onscreen keyboard to enter the operator name. Press **Save** button and go back to **Home** screen.

Note: To delete an Operator, choose the Operator from previous screen and press Delete Account on this screen.

2) Door Opening/Closing Alert

Go to **Home** > **Basic Settings** > **Door Opening/Closing Alert**



To activate or inactivate the alert screen for Door Opening/Closing.

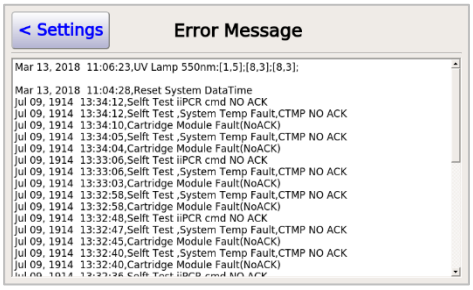
3) About POCKIT™ Central

Go to **Home** > **Basic Settings** > **About POCKIT Central**

The screen displays information of this device.

4) Error message

Go to **Home** > **Basic Settings** > **Error Message**

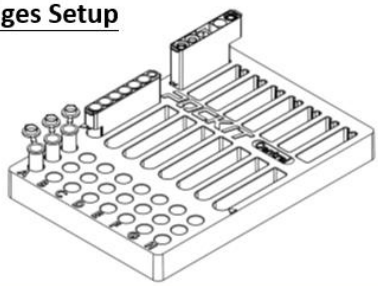


Read-only field showing system error summary.

Section 5. Performing A Test

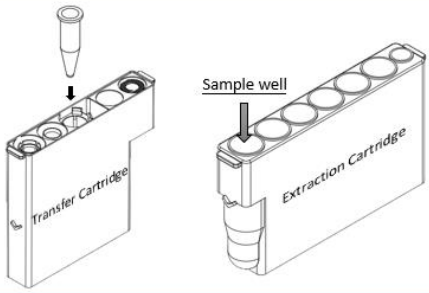
5.1 Quick Guide

Cartridges Setup 1



1.Prepare Extraction, Transfer Cartridges, Premix, samples and IC (optional) according to respective POCKIT Central reagent manual.
2.Place them on the Setup Tray.

2

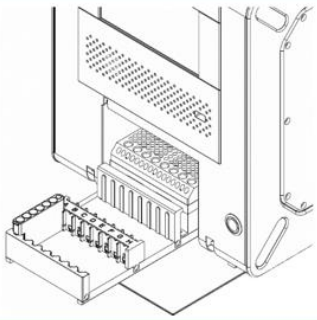


1.Remove Transfer Cartridge Cap. Insert one Premix into the well #3 of the Transfer Cartridge.
⚠Cut excessive film and plastics outside the rim of Premix.
2.Peel off the aluminum film and add 200 µl sample to the sample well of Extraction Cartridge.
⚠Remove any residual film from the Extraction Cartridge surface.

Inserting cartridges & Initiating tests 1

Enter Sample ID & Extraction Lot No. using the onscreen keyboard of POCKIT Central.

2

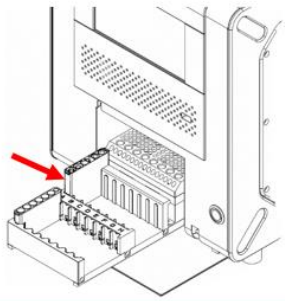


Insert the sample-loaded Extraction Cartridge.

3

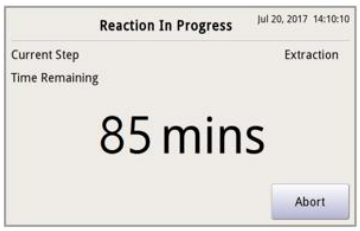
Enter Reagent Lot No. using the onscreen keyboard of POCKIT Central.

4



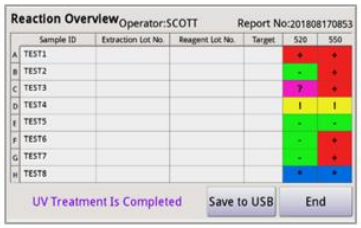
Insert the loaded-Transfer Cartridge.

5



Press Confirm and Run to start reaction. Reaction completes in 85 minutes.

6



- View results.
- Please refer to respective user manual for data interpretation.

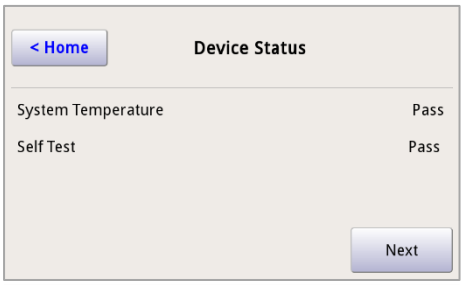
5.2 Running Tests

Before the instrument is used for the first time, **Operator** info and **Date & Time** settings must be set up before a test can be performed. For further details, please refer to ***Section 4 Getting Started***.

Go to **Home** > **Start**

1) From **Home** screen, select **Start**.

Press **Start** from **Home** screen.



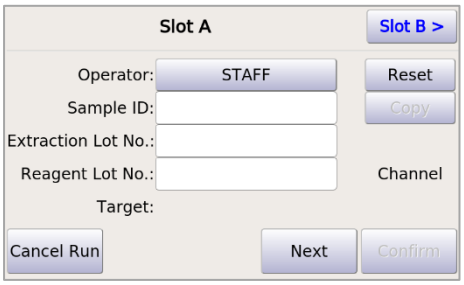
The instrument will perform a self test automatically. Press **Next** to continue once self test is passed.

Press **OK** to proceed.

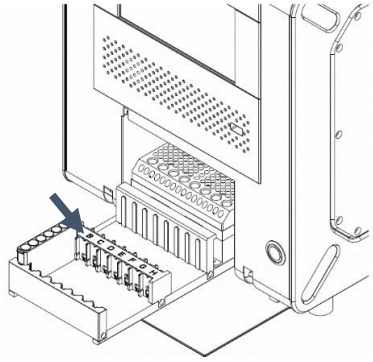
Note:

1. **Make sure nothing blocks the door.**
2. **Skip this step if the Door Opening/Closing Alert alert is off.**

2) Entering **Sample ID**, **Extraction Lot No.** and **Reagent Lot No.**



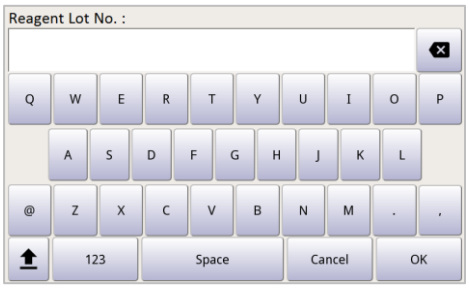
Select the desired slot, and enter the **Sample ID** and **Extraction Lot No.** (stated on the product label).



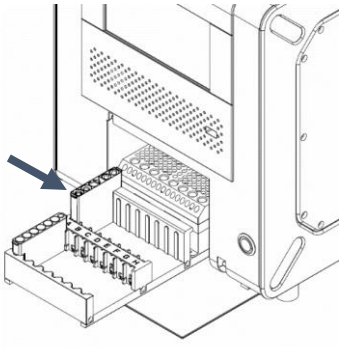
Insert the respective sample-loaded Extraction Cartridge.

Note:

1. **Make sure to remove any residual film from the Extraction Cartridge surface.**
2. **Please refer to user manual of respective POCKIT™ Central reagent for sample loading instruction.**
3. **Make sure the indicator light of the slot is off after loading the cartridge.**



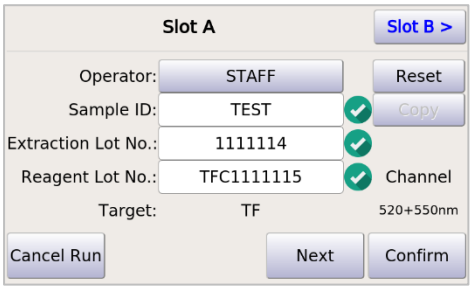
Enter the **Reagent Lot Number** (stated on the product label). Press **OK** when completed.



Insert the loaded Transfer Cartridge.

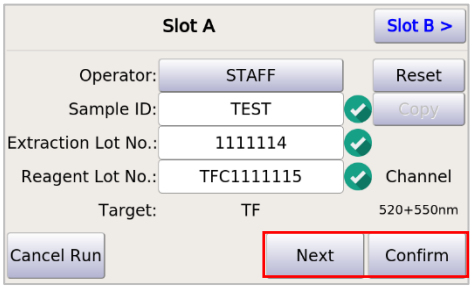
Note:

1. **Make sure to cut excessive film and plastics outside the rim of Premix.**
2. **Make sure the indicator light of the slot is off after loading the cartridge.**



Once the **Reagent Lot No**. is entered, the system will automatically bring in the channel and target information.

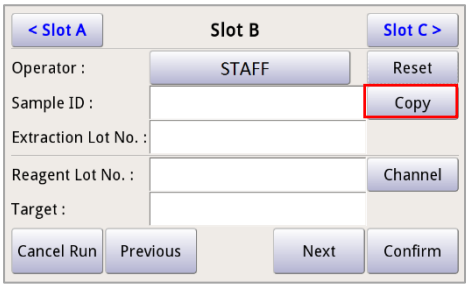
Note: Please refer to respective user manual of the POCKIT™ Central reagent to confirm channel information.



Press **Next** or **Slot B >** to proceed to next slot if you have more than one sample.

Or press **Confirm** to proceed to **Run Overview**.

3) Copying sample information from previous slot (optional).

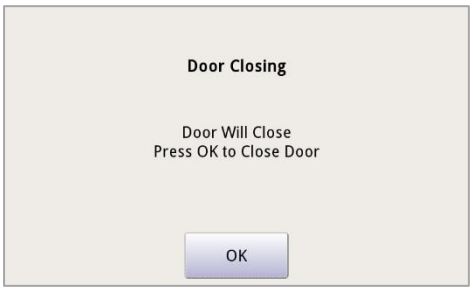


Press **Copy** to duplicate the sample information from the previous slot. Modify the input information if needed.

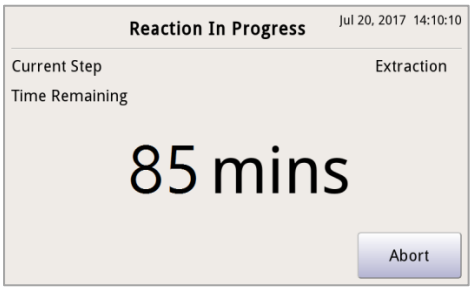
4) Confirming test information (Reaction Overview).

Check if all the information is correct, press **Run** to initiate the run. Or **Edit** to go back to the previous screen to revise.

If you wish to abort this run at this step, press **Cancel Run**.

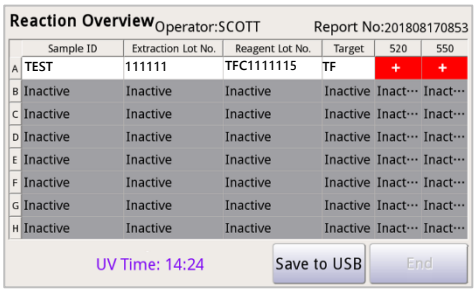


After pressing **Run**, a **Door Closing** notice will show up on the screen. Press **OK** to initiate the run.



Reaction in progress. The screen will display the remaining time and instrument status.

5) Reaction complete.

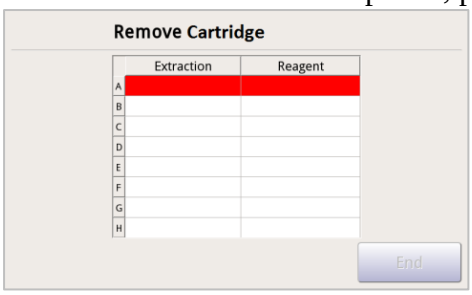


Test results are displayed directly on the screen, and UV lamp will automatically be turned on for 15 minutes.

Note: Do not abort UV irradiation process.

Data are stored in **Data Archive** automatically. If users wish to export the data, insert an USB and press **Save to USB** button.

6) When UV irradiation is completed, please remove cartridges.



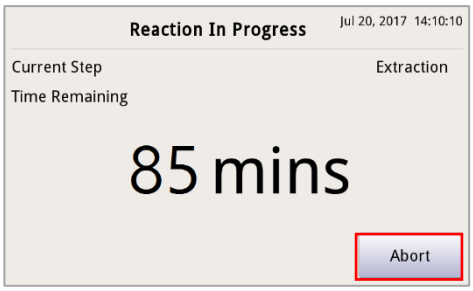
Remove all used catridges. Press **End** to go back to **Home** screen.

Note:

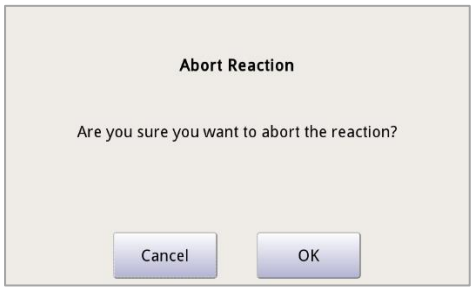
1. **Please make sure all the consumables are in the corresponding position (refer to the illustration in Troubleshooting). If not, please contact your local distributor of GeneReach for assistance.**
2. **If special disposal handling are required for Steel Tips due to local regulation, soad used Steel Tips with bleach prior to disposal.**
3. **Used consumables and waste products should be discarded following local regulation once reaction is finished. Cap the Transfer Cartridges prior to disposal.**

5.3 Aborting Reaction

To stop the run while the reaction is in progress.

1) 

Press **Abort**.

2) 

Press **OK** to abort or **Cancel** to continue the run.

Note: Do not abort UV irradiation process.

The system will initiate resetting.

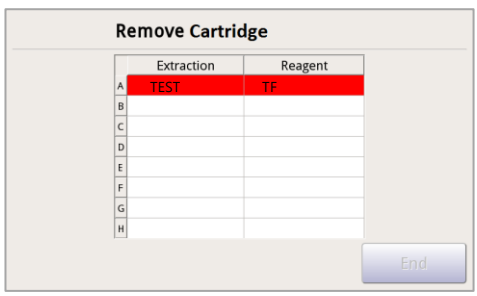
3)

The UV lamp will be automatically turned on for 15 minutes. The remaining time will be shown on the screen.

Note: Do not abort UV irradiation process.

4)

Press **OK** to proceed.

5) 

Remove the cartridges. Press **End** to go back to **Home**.

Note:

1. **Please make sure all the consumables are in the corresponding position (refer to the illustration in Troubleshooting). If not, please contact your local distributor of GeneReach for assistance.**
2. **If special disposal handling are required for Steel Tips due to local regulation, soad used Steel Tips with bleach prior to disposal.**
3. **Used consumables and waste products should be discarded following local regulation once reaction is finished. Cap the Transfer Cartridges prior to disposal.**

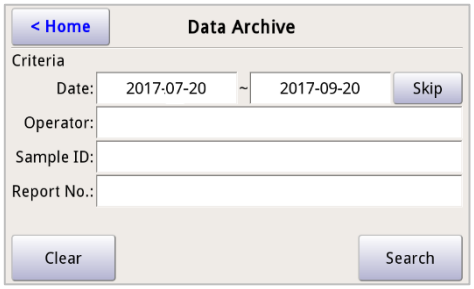
Section 6. Data Review

6.1 Accessing Test Results

This allows users to access and export test results saved in the **Data Archive**.

Go to **Home** > **Search Archive**

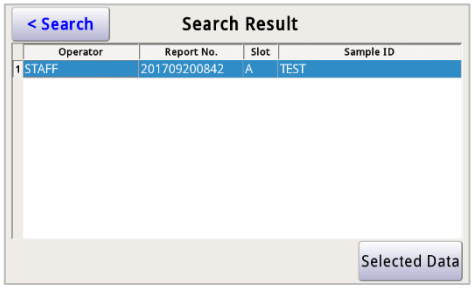
1)



Enter search criteria, such as date, operator, sample ID or report number.

Press **Search** button when complete.

2)



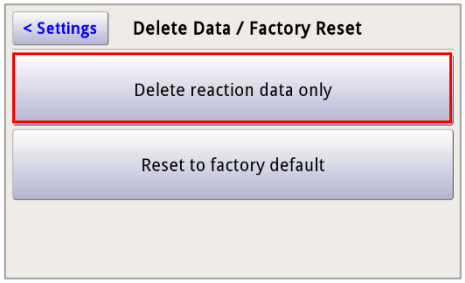
Select the desired entry, and press **Selected Data**.

6.2 Deleting All Data/Resetting to Factory Default

1) **Delete Data** can be acessed through **Basic Settings** and allows users to delete all historical data.

Note: It is recommended to export all data before executing this function.

Go to **Home** > **Basic Settings** > **Delete Data / Factory Reset**

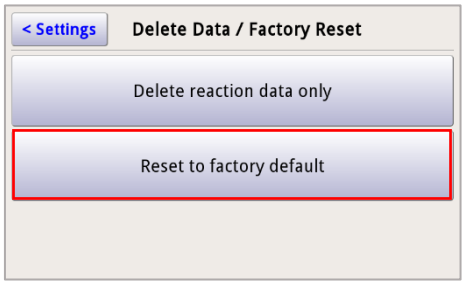


Select **Delete reaction data only** to delete all historical data.

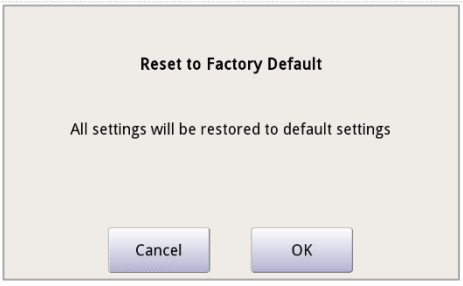
Press **OK** to delete all archived data.

2) **Reset to factory default** can be acessed through **Basic Settings** screen and allows users to restore the instrument to factory default setting.

Note: This will delete data of all operator information and test results from the instrument. It is recommended to export all data before executing this function.



Select **Reset to factory default**.



Press **OK** to reset the instrument to default setting.

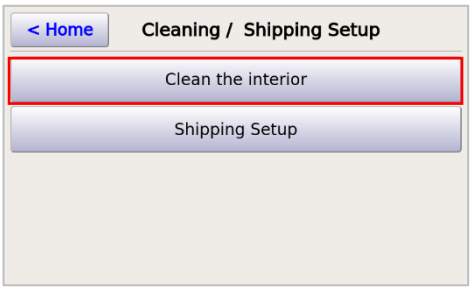
Section 7. Cleaning and Shipping POCKIT™ Central

7.1 Cleaning and Maintenance

In case of spills and leakage of liquid, cleaning mode can be accessed from **Cleaning / Shipping Setup** screen.

Note: Do not disassemble POCKIT™ Central for cleaning. This will void the warranty.

Go to **Home** > **Cleaning / Shipping Setup**

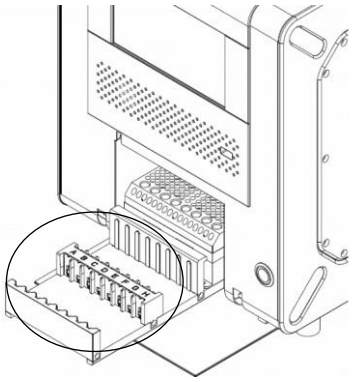


Select **Cleaning / Shipping Setup** on **Home** screen, and press **Clean the interior** button.

Select **OK** to open the door.

Note:

1. **Make sure nothing blocks the door.**
2. **Skip this step if the Door Opening/Closing Alert alert is off.**



Use **dry or damp** lint-free cloth/wipes to clean the tray (circled area). Do not leave any solutions on the tray as the electronic parts may be damaged. Wipe off any visible stain on the sensors immediately.

Note: Not regularly cleaning the instrument may decrease instrument reliability.

7.2 Turning on UV Lamp

UV lamp can be turned on manually through **UV** screen.

Go to **Home** > **UV**

Select **UV** from **Home** screen. Press **OK** to activate UV lamp.

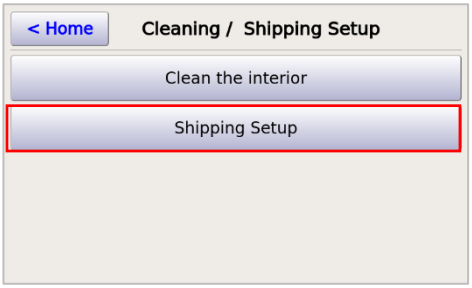
The remaining time is displayed on the screen.

7.3 Getting the Instrument Ready for Shipping

Before transporting the instrument, use the original packaging boxes to pack the instrument to ensure that no damage will occur to the instrument during transportation. Follow instructions below for shipping setup and repacking.

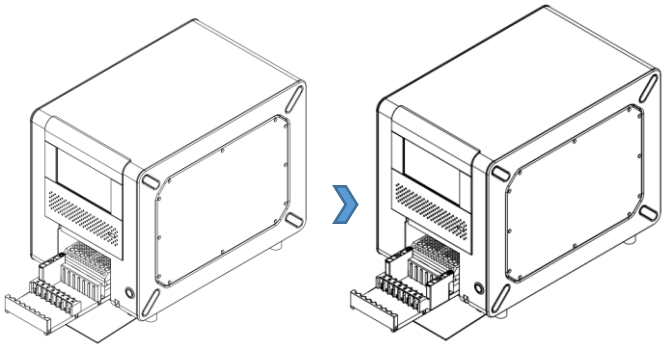
Note: If the original packaging boxes are lost or damaged, contact local distributor or GeneReach for replacement packaging boxes.

Go to **Home** > **Cleaning / Shipping Setup**



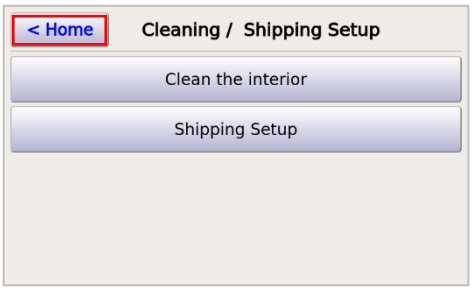
Select **Cleaning / Shipping Setup** on **Home** screen, and press **Shipping Setup** button.

Select **OK** to open the door.



Place the Transfer Cartridges (for transportation protection purpose) in reaction slots A and H. Once the cartridges are set, the door will be closed automatically. The robotic arms will rest on the cartridges.

Note: If the Transfer Cartridges are not available, contact distributor or GeneReach.

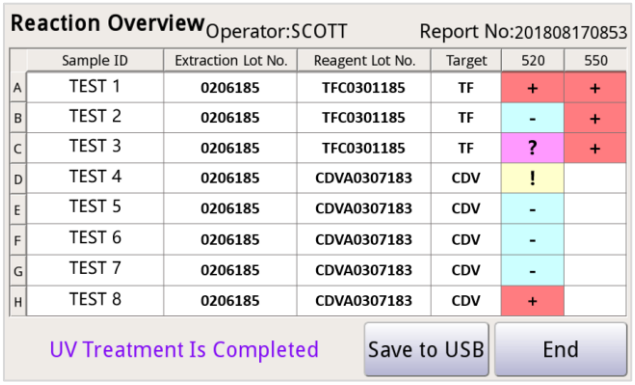


Press **Home** to go back to Main menu, switch off the main power in the back of instrument and pull off the power cord before packing.

Section 8. Display the Result

8.1 Result Interpretation

An example of results displayed on the monitor



	Sample ID	Extraction Lot No.	Reagent Lot No.	Target	520	550
A	TEST 1	0206185	TFC0301185	TF	+	+
B	TEST 2	0206185	TFC0301185	TF	-	+
C	TEST 3	0206185	TFC0301185	TF	?	+
D	TEST 4	0206185	CDVA0307183	CDV	!	
E	TEST 5	0206185	CDVA0307183	CDV	-	
F	TEST 6	0206185	CDVA0307183	CDV	-	
G	TEST 7	0206185	CDVA0307183	CDV	-	
H	TEST 8	0206185	CDVA0307183	CDV	+	

- Description of the results:

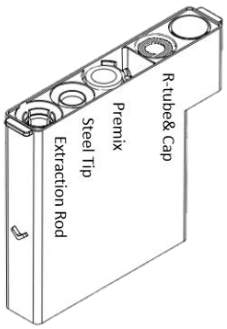
Results	Description
+	Positive
-	Negative
?	Undetermined
!	Warning
*	Abnormal, signals outside detection range

***Note: Interpret the results according to the user manual of the reagent used.**
***Note: When you see a " ！" or "＊", please check if an R-tube is in the corresponding position (refer to the illustration in Troubleshooting). Contact your local distributors or GeneReach for their assistance.**

8.2 Reviewing Raw Data

1) Data could be exported to a USB flash drive in Excel and PDF formats right after a run or through Search Archive screen.
2) Insert a USB on a PC or Mac. Find the report file in the folder; files are named after report numbers.
3) Please refer to the **POCKIT™ Central** reagent manual for data interpretation.

Troubleshooting

Problems	**Possible causes**	**Solutions**
" ! " or " ∗ " symbol shown after the run	Fluorescence signals are abnormal	● Check if an R-tube is in the corresponding position after reaction (see illustration below.)  ● Contact **GeneReach** or local distributor for technical support.
Liquid spills	Liquid spills	● Please refer to ***Section 7 Cleaning/Shipping Setup*** to deal with liquid spills. Use new cartridges to repeat if needed. ● If tubes are broken and liquid leaks are found, contact GeneReach or local distributor for technical support.
Door cannot be opened	The door is blocked	Clear any objects that may block the door from opening.
Door cannot be closed：“Remove Cartridges” notice is shown on screen	Cartridges are not removed	Clear all cartridges and press “**End**” to close door and go back to Home screen.
	Stain on tray sensor	Clean the tray sensor using a dry cotton swab.
	Other failures	Long-press the **Wake up/Sleep** button for 5 seconds to close the door. Contact **GeneReach** or local distributor for technical support.
USB not working	USB mulfunction	● Try other USB drives.
	USB port failure	● Try the other USB ports. ● Restart the **POCKIT™ Central** to recheck. ● Contact **GeneReach** or local distributor for technical support.
Error mode	Environment temperatures are out of range	● Ensure environment temperatures are within 15-35˚C. Restart the **POCKIT™ Central** again. ● Contact **GeneReach** or local distributor for technical support.
	Self-test failure	● Restart the **POCKIT™ Central** to recheck. ● Contact **GeneReach** or local distributor for technical support.
	System failure	● Restart the **POCKIT™ Central** to recheck. ● Contact **GeneReach** or local distributor for technical support.

	Lot number error	• Check if the entered lot number matches with the product lot number. • Contact **GeneReach** or local distributor for technical support.
Test is aborted due to power outage	Unstable power source	• Check if the power voltage matches with the power supply of the **POCKIT™ Central**. • Connect the **POCKIT™ Central** to an UPS system.
Tray sensor error	Over illumination	• Avoid setting the device at locations with exposure to direct or reflected sunlight, or to infrared light emitted by electrical devices (such as infrared halogen lamp).

Reference

1. Chang, H. G., Tsai, Y., Tsai, C., Lin, C., Lee, P., Teng, P., *et al*. (2012). A thermally baffled device for highly stabilized convective PCR. *Biotechnology Journal*, 7(5), 662-666. doi: 10.1002/ biot.201100453.
2. Tsai, Y., Wang, H. T., Chang, H. G., Tsai, C., Lin, C., Teng, P., *et al*. (2012). Development of TaqMan Probe-Based Insulated Isothermal PCR (iiPCR) for Sensitive and Specific On-Site Pathogen Detection. *PLoS ONE*, 7(9), e45278. doi:10.1371/journal.pone.0045278.
3. Tsai, Y., Lin, Y., Chou, P., Teng, P., Lee, P., *et al*. (2012). Detection of white spot syndrome virus by polymerase chain reaction performed under insulated isothermal conditions. *J. Virol. Methods* 181:134-137.