Fast PCR Instrument Quick Reference Guide

Laboratories with a Certificate of Waiver may use the Fast PCR Mini Respiratory Panel using the Fast PCR Instrument.

Laboratories with a Certificate of Waiver must follow the manufacturer's instructions for performing the test.

IVD **Rx Only**

If you have any questions regarding the use of this product or if you want to report a problem, please contact Autonomous Medical Devices Customer Service at: +1-657-660-6800, customerservice@amdilabs.com or contact your local distributor. For additional information, please find the full Fast PCR Instrument User Manual at www.AMDIFastPCR.com.

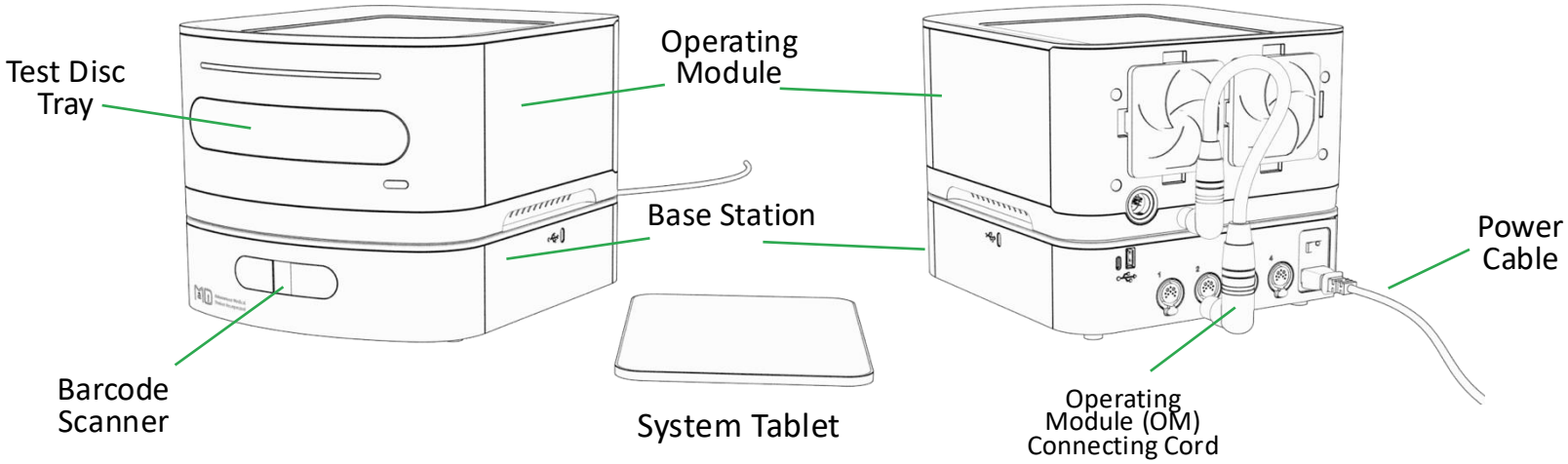
Before You Begin

Important: Read the Fast PCR Instrument Quick Reference Guide and the Fast PCR Mini Respiratory Panel Quick Reference Guide prior to running a test.

Provided Materials

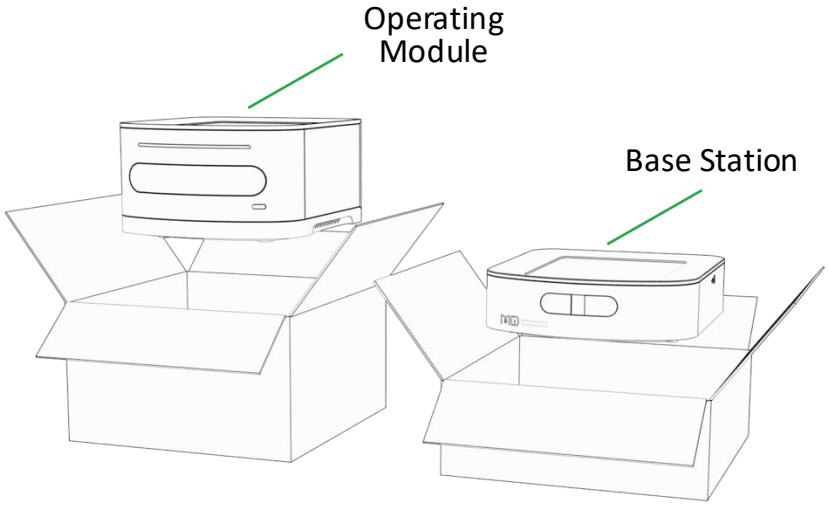
Hardware:
Fast PCR Base Station
Fast PCR Operating Module
OM Connecting Cord
Power Cable
System Tablet

Documentation:
Fast PCR Instrument Quick Reference Guide
Fast PCR Instrument User Manual



Unpacking the Instrument

Important: Retain the shipping container and packing materials in case you need to return the instrument to AMDI for any reason.

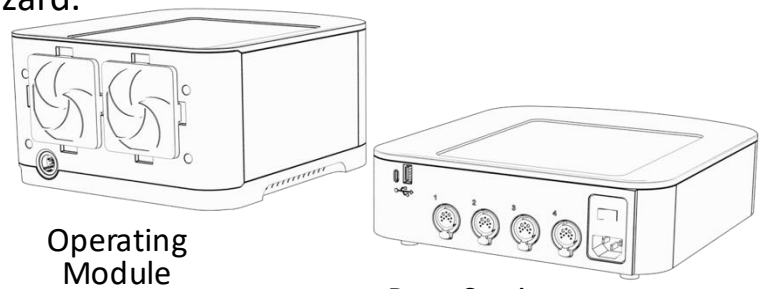


1. Unpack the instrument (Base Station and Operating Module) from the shipping container.
2. Do not apply any force to the tray, barcode scanner window or the tops of the units.
3. Do not hold or lift the Operating Module using the tray.
4. Handle with care. Use both hands to support the Base Station and the Operating Module from the sides when lifting.
5. Unpack the Power Cable and Operating Module Connecting Cord.
6. Inspect the outer cases, front and back panels and rear ports for any damage. Check all other items for shipping damage. To report any problems, contact Autonomous Medical Devices Customer Service at: +1-657-660-6800, customerservice@amdilabs.com or contact your local distributor.

Set up the Instrument

Instrument location and operating environment.

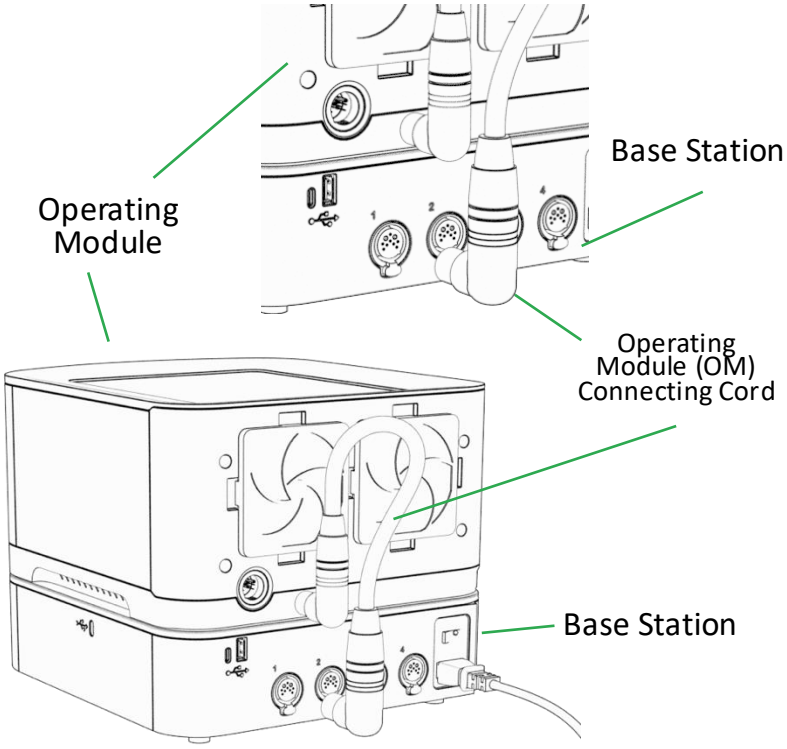
1. Place on a level, vibration-free surface away from direct sunlight.
2. Allow at least 10 cm (4 inch) rear clearance for ventilation and at least 10 cm (4 inch) front clearance for barcode scanning.
3. Operating temperature is between (15°C to 30°C) and relative humidity ≤ 75% with an operating altitude up to 7500 feet above sea level.
4. Locate the instrument near a grounded outlet to avoid power cable from becoming a trip hazard.



Set up the Instrument (cont.)

5. With Base Station on the bottom, stack Operating Module on top, ensuring each Operating Module fits securely and lines up with the front of the Base Station. You can stack up to 4 Operating Modules for each Base Station.

6. Connect the Operating Module Connecting Cord from the base station to each Operating Operating Module. You will hear an audible click when connected. They should be connected in order from 1 to 4 starting with #1 corresponding to the Operating Module closest to the Base Station so Fast PCR App can accurately display Operating Module placements.



Connect the Power Supply

Caution: Using an inappropriate power supply may cause a malfunction.

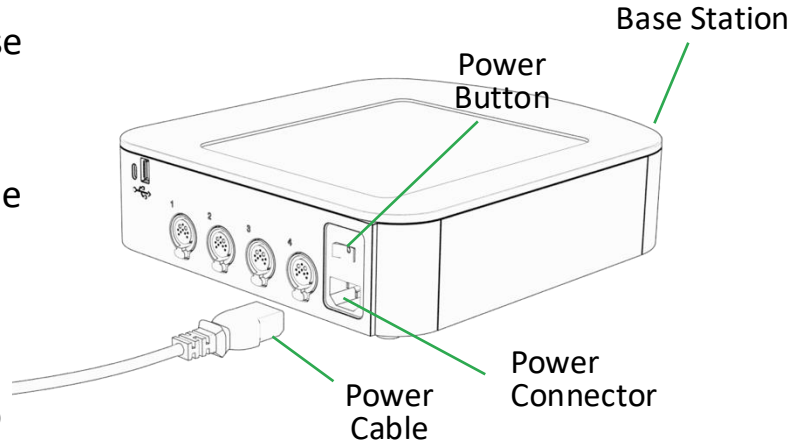
Only use power cable provided with Base Station and connect to a voltage of 100-240V AC, 50-60Hz.

Only use Operating Module Connecting Cord provided to connect Operating Module to Base Station.

1. Insert power cable into the Base Station power connector located in the rear of the unit.

2. Connect the power cable to the properly grounded power outlet.

3. Once plugged in, flip the Power button to the ON position.



Download Fast PCR App

The Fast PCR instrument must be used with the Fast PCR App downloaded onto a mobile smart device such as the provided system tablet.

1. Before you download the Fast PCR App, you need to ensure your system tablet has been connected to your local WIFI. Ensure it is a trusted WIFI network prior to connecting. Access Settings on the System Tablet and toggle to the WIFI you would like to use. Once selected, you will be able to use your system tablet as intended.

2. Using the iPad Camera, download the Fast PCR App using the below QR code.

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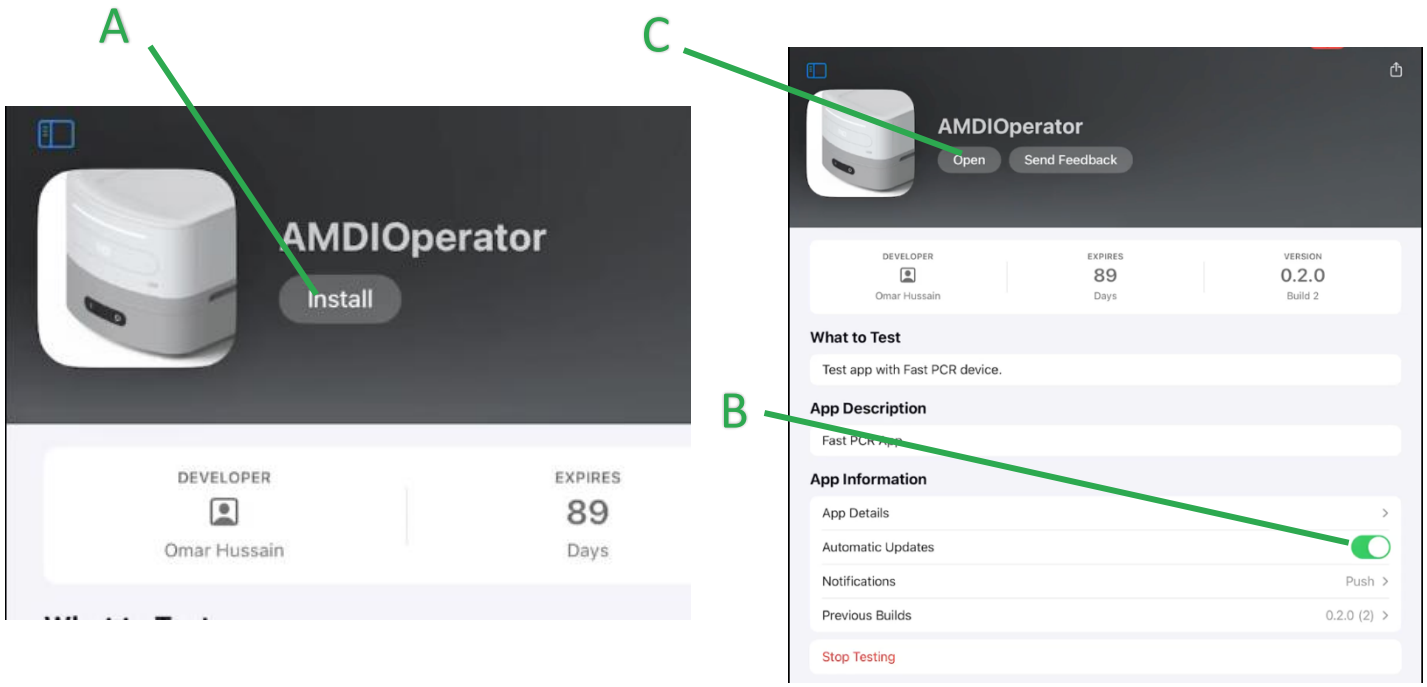
3. Once the AMDIOperator screen opens:

(A) click on the Install button.

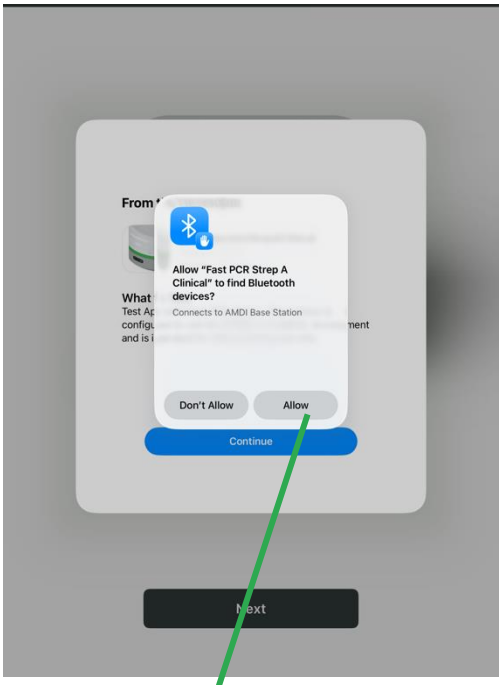
(B) once Installed, ensure the Automatic Updates is turned on.

(C) finally, click the Open button to launch the app.

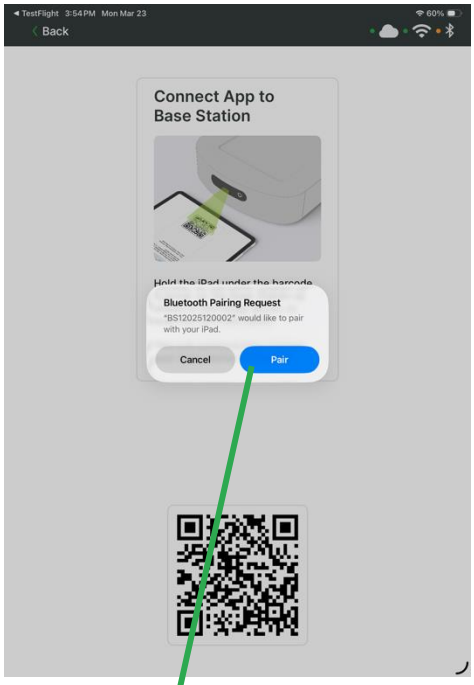


Download Fast PCR App (cont.)

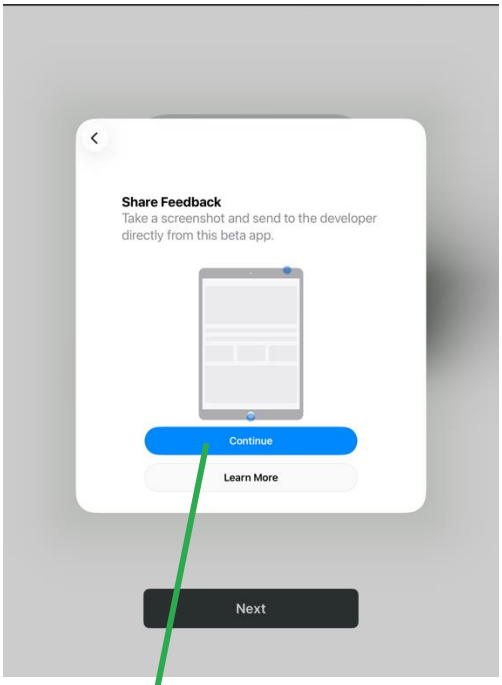
4. Once the Fast PCR App has launched, follow the onscreen prompts to connect the software and Bluetooth. See below:



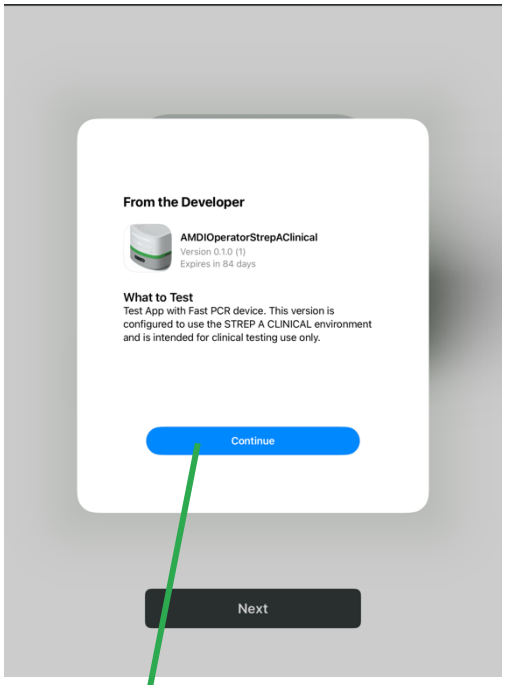
1 Click Allow



2 Click Pair



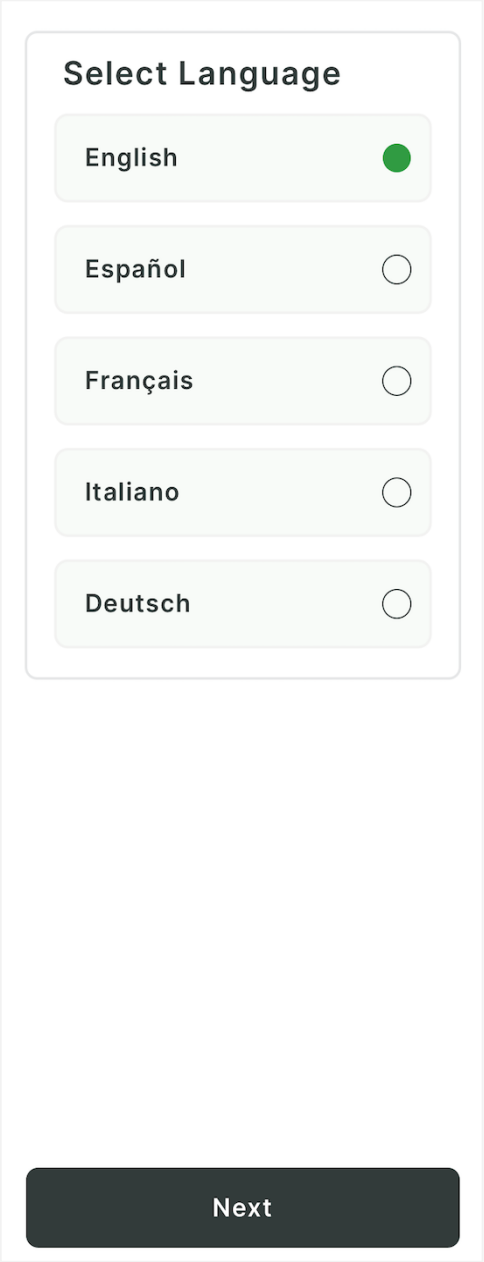
3 Click Continue

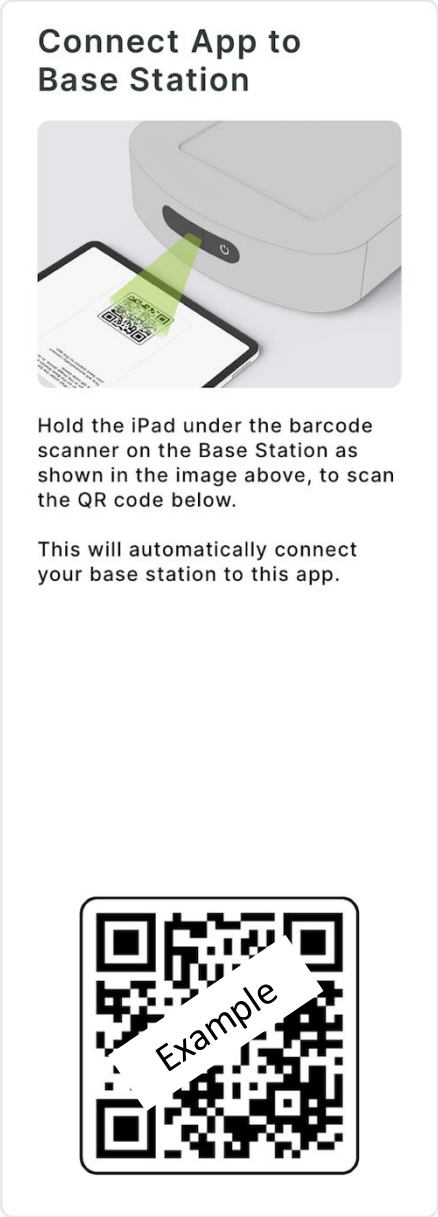


4 Click Continue

Connect the System Tablet to the Instrument

From the Welcome Screen, follow the on-screen prompts to select your preferred language and to finish setting up the Fast PCR App by connecting the System Tablet to the Instrument.

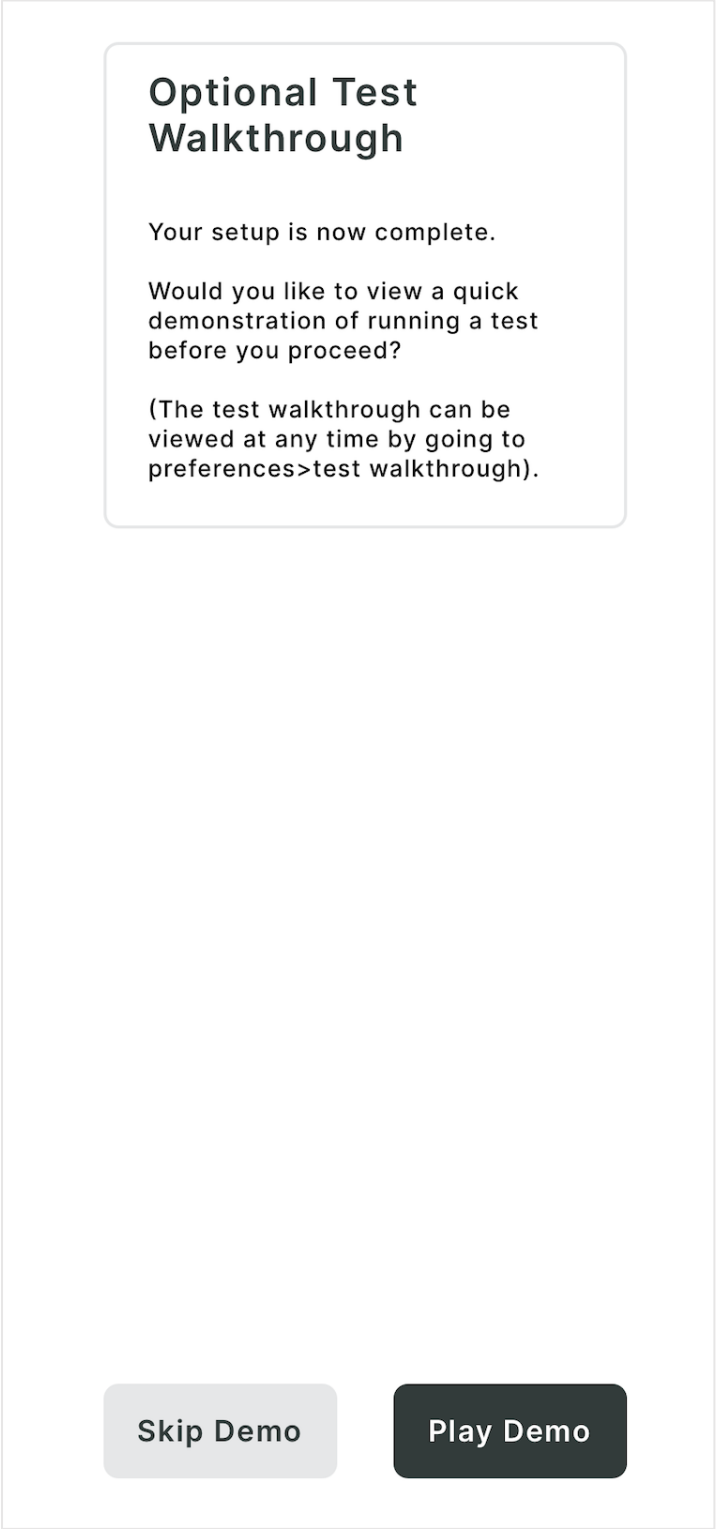




Connect the Fast PCR App to the Base Station by holding the tablet beneath the barcode scanner on the Base Station and scanning the QR code presented on the Fast PCR App screen. This will connect the System Tablet and the Base Station via Bluetooth connection.

Test Walkthrough (optional)

1. Once the Set Up has been completed, the Fast PCR App will provide the option of an Optional Test Walkthrough that will allow the User to View the test workflow and animations prior to performing a test. The images and the animations for the walkthrough are the identical animations that are presented during the actual Test Workflow.
2. The Test Walkthrough can be skipped at this step and can be accessed within the Guides part of the preferences section of the Fast PCR App at any time.



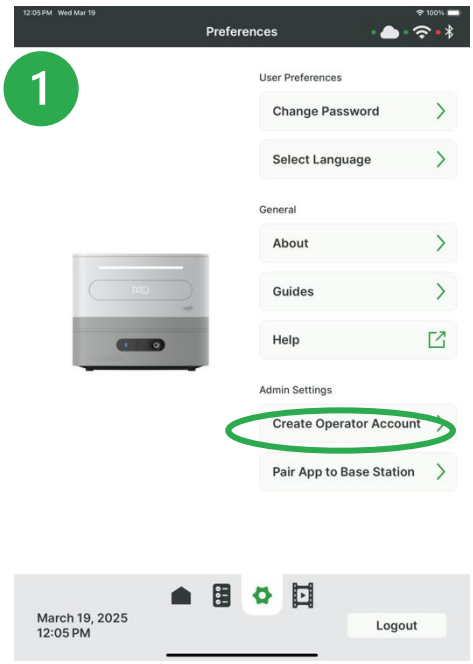
Administrator Log-in information

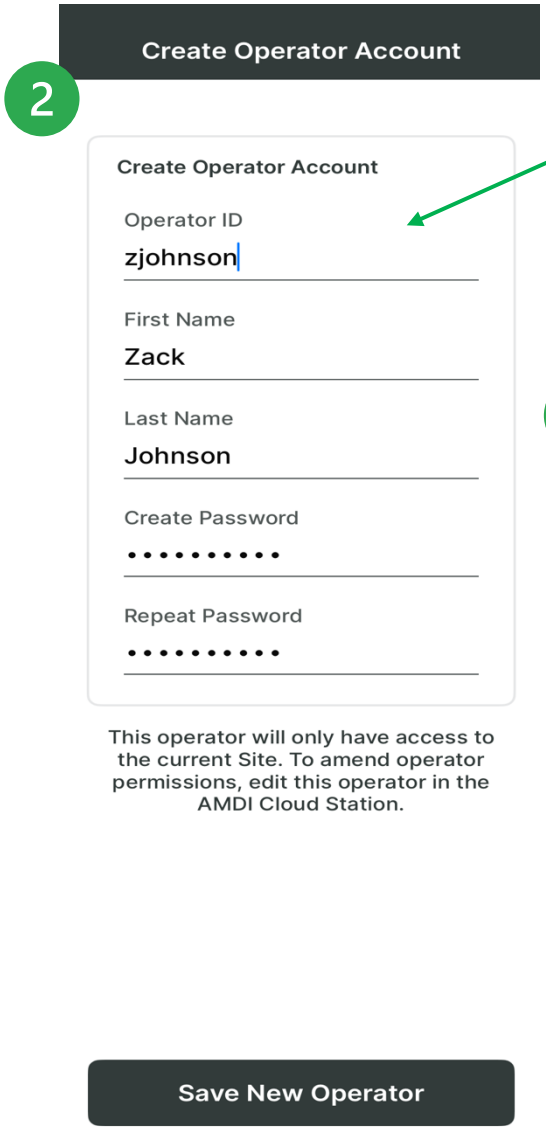
During the ordering process, an organization administrator was identified, and an account was set up (prior to shipment of the Fast PCR System) allowing that designated User administrative privileges.

Creating New Operator

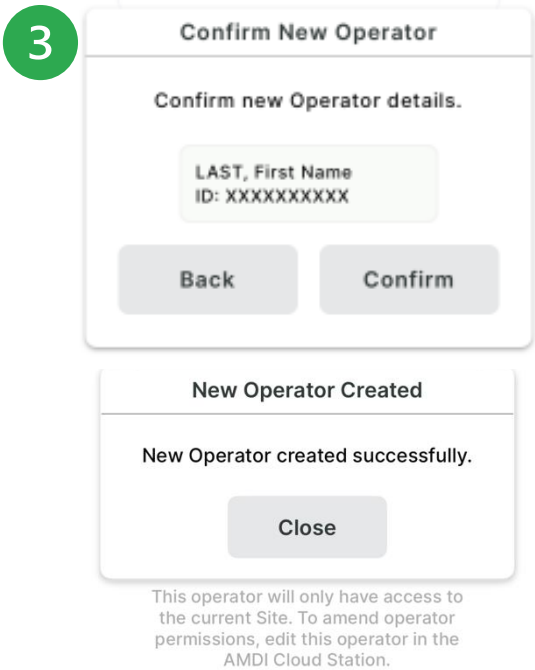
To create a new Operator, you must be logged in with Admin privileges. Select “Create Operator Account” under **Preferences.** The password created by Admin is temporary.

- Operator ID must be at least 12 characters long
- Password must be at least 10 characters long and include at least:
  - 1 numeric character
  - 1 uppercase character
  - 1 lower case character
  - 1 special character





ID is used for manual entry (email or alphanumeric)

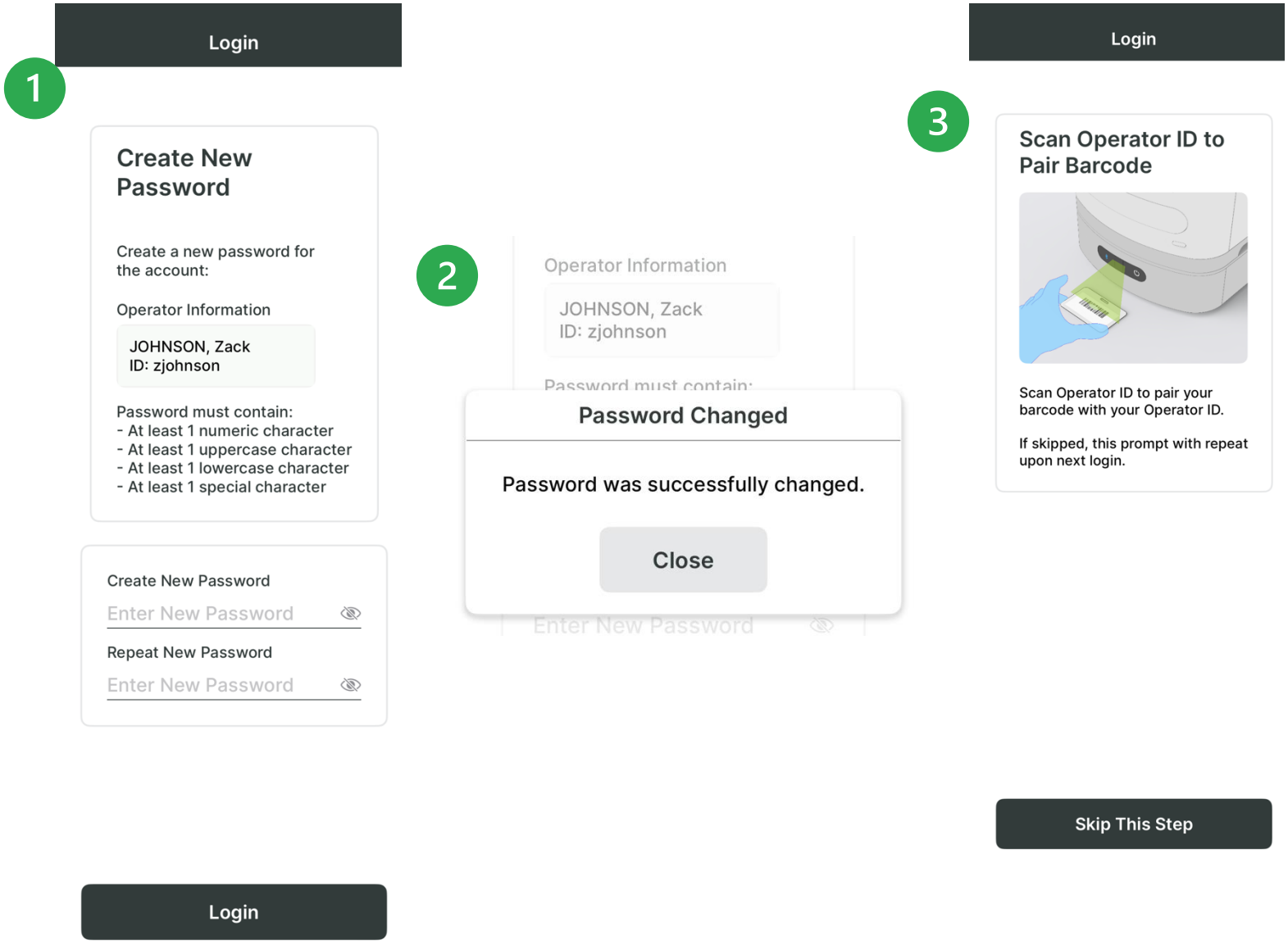


Creating New Operator (cont.)

First time log in for new Operator will prompt change of temporary password created by Admin. It will also prompt the new User to Scan barcode to associate with their account.

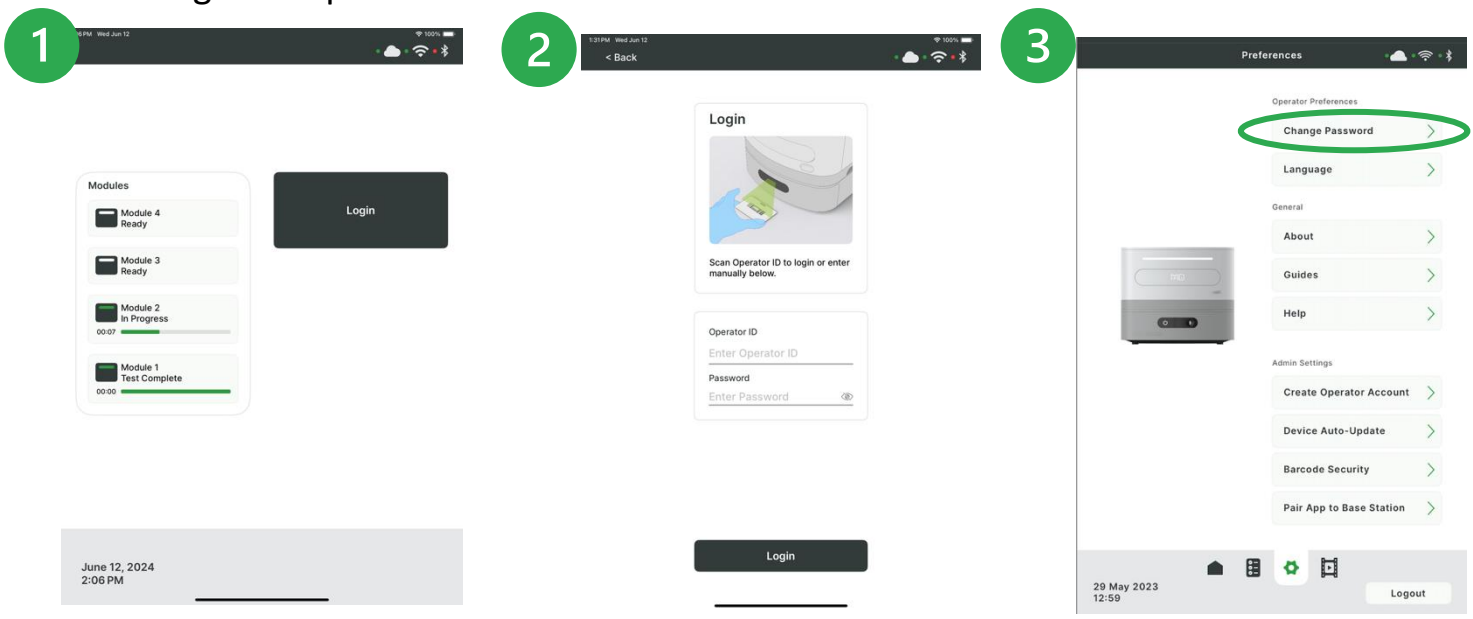
Password must be at least 10 characters long and include at least:

- 1 numeric character
- 1 uppercase character
- 1 lower case character
- 1 special character



Log on to the System Tablet

1. Launch the Fast PCR App and click on the Login button on the main screen.
2. Log into the system using your Operator ID and Passcode set up by the System Administrator.
   - Once you have logged onto the system, you will be prompted to set up a new password if you have not already done so as well as to connect your Operator Badge ID.
   - Connecting your Operator Badge ID will allow you to login without entering ID and password.
3. Once logged into the system, Users can navigate to the Preferences section and change their password.



Run a Test Disc

1. Refer to the Fast PCR Mini Respiratory Panel QRG for instructions on running a Test Disc.

Cleaning and Disinfection

Cleaning of the exterior surfaces of the Fast PCR instrument and the immediate work area should be performed as necessary, including at least daily when in use.

1. Put on clean PPE, such as a lab coat and gloves.
2. Unplug the power cord from the wall outlet and the instrument.
3. Carefully wipe down both the outside and beneath the lid where the Test Disc sits with either a) 10% v/v household bleach diluted with water, or b) 70% v/v alcohol (ethanol or isopropanol) diluted with water.

NOTE: Do not spray cleaning solution directly on the instrument.

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