

# Fast PCR Instrument Quick Reference Guide

CLIA Complexity: Waived

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

IVD

REF FP-001



If you have any questions regarding the use of this product or if you want to report a problem, please contact Autonomous Medical Devices Technical Support at: +1-657-660-6818 or [customerservice@amdilabs.com](mailto:customerservice@amdilabs.com) or contact your local distributor.

## 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.

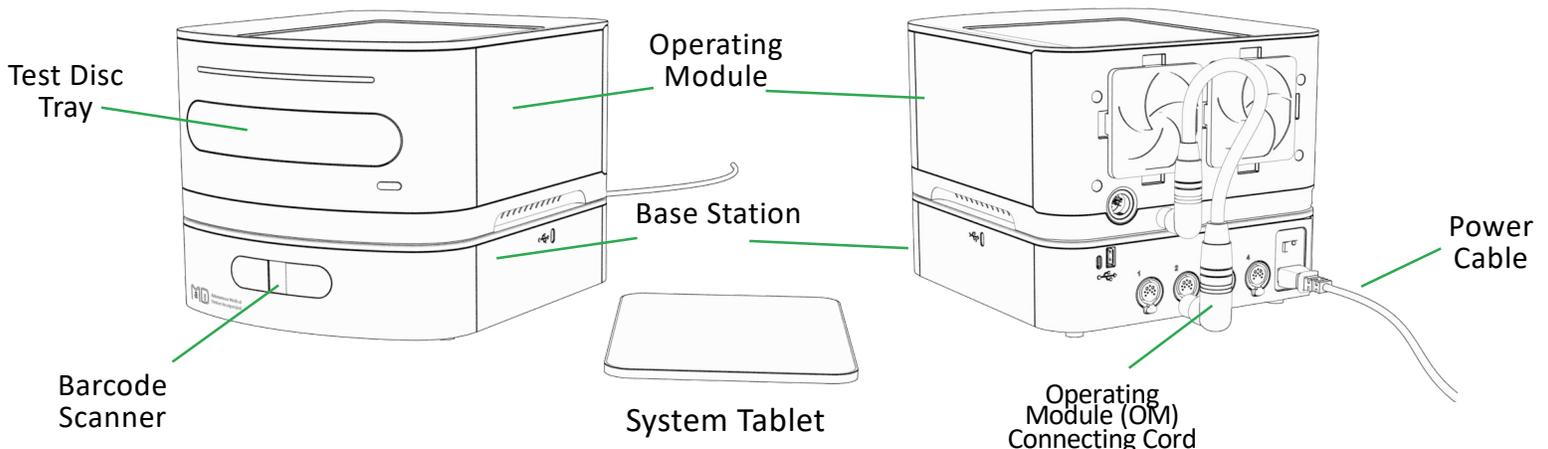
## Provided Materials

### Hardware:

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

### Documentation:

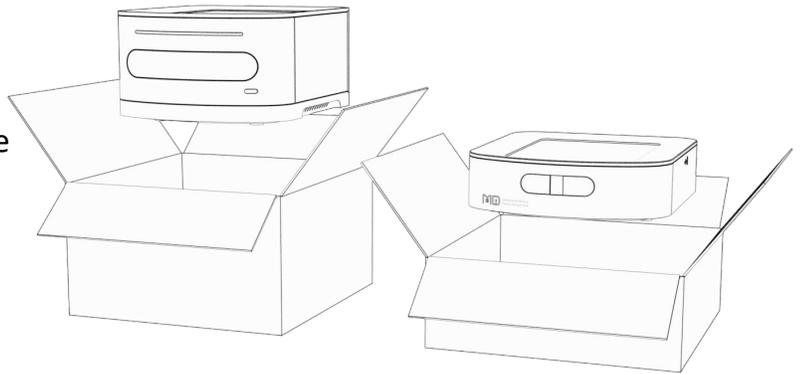
Fast PCR Instrument Quick Reference Guide



# Unpacking the Instrument

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

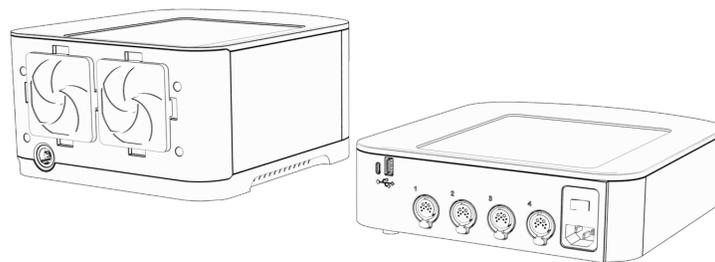
1. Unpack the instrument (Base Station and Operating Module) from the shipping container.
2. Do not apply any force to the tray, barcode scanner window or the tops of the units.
3. Do not hold or lift the Operating Module using the tray.
4. Handle with care. Use both hands to support the Base Station 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 Technical Support at: +1-657-660-6818 or [customerservice@amdilabs.com](mailto:customerservice@amdilabs.com) or contact your local distributor.



# Set up the Instrument

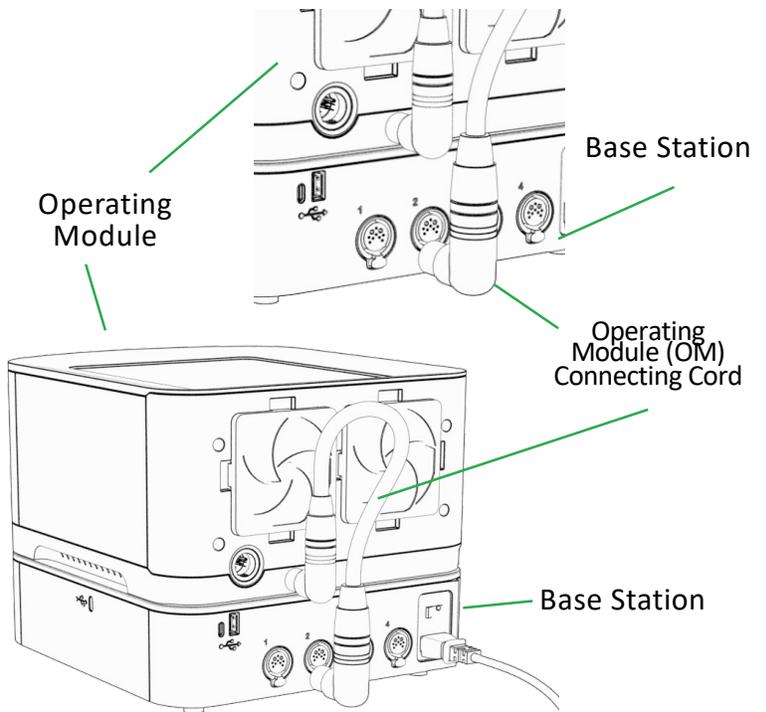
Instrument location and operating environment

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  $\leq$  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 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.



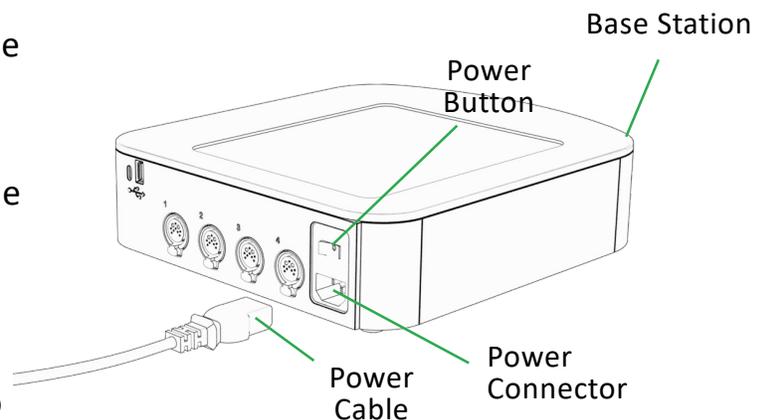
## Connect the Power Supply

**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.



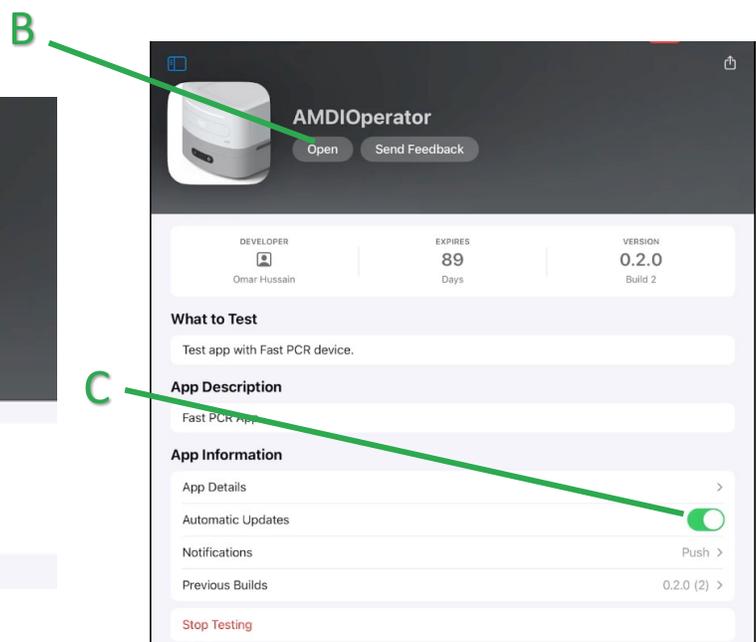
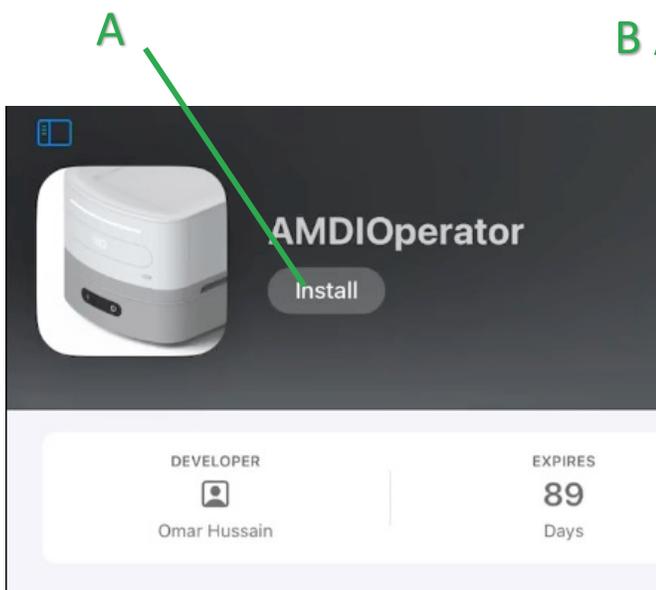
# Download Fast PCR App

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. 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.



3. Once the AMDIOperator screen opens:
  - (A) click on the Install button.
  - (B) once Installed, ensure the Automatic Updates are turned on.
  - (C) finally, click the Open button to launch the app.



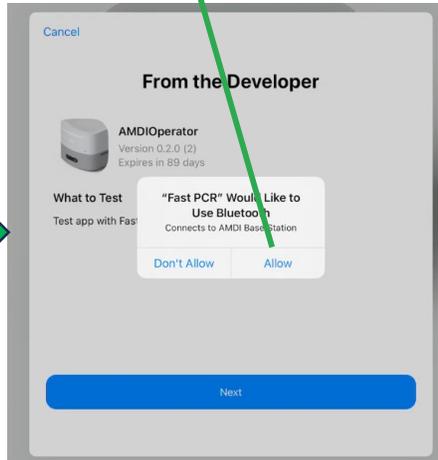
# Download Fast PCR App (cont.)

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

1 Click Allow



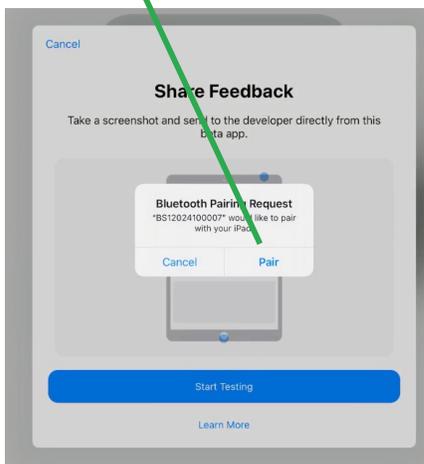
2 Click Allow



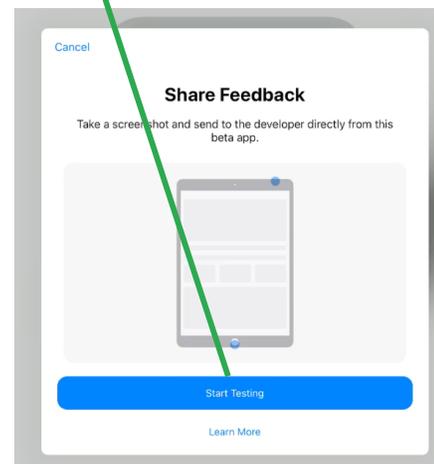
3 Click Next



4 Click Pair



5 Click Start Testing



# 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.



Welcome

Next

Select Language

- English
- Español
- Français
- Italiano
- Deutsch

Next

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.

## Connect App to Base Station



Hold the iPad under the barcode scanner on the Base Station as shown in the image above, to scan the QR code below.

This will automatically connect your base station to this app.



# 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. This Test Walkthrough can be skipped at this step and can be accessed within the preferences section of the Fast PCR App at any time.

## Optional Test Walkthrough

Your setup is now complete.

Would you like to view a quick demonstration of running a test before you proceed?

(The test walkthrough can be viewed at any time by going to Preferences>Test Walkthrough).

Skip Demo

Play Demo

# 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

Create a new Operator is under **Preferences** and you must be logged in with Admin privileges. The password created by Admin is temporary.

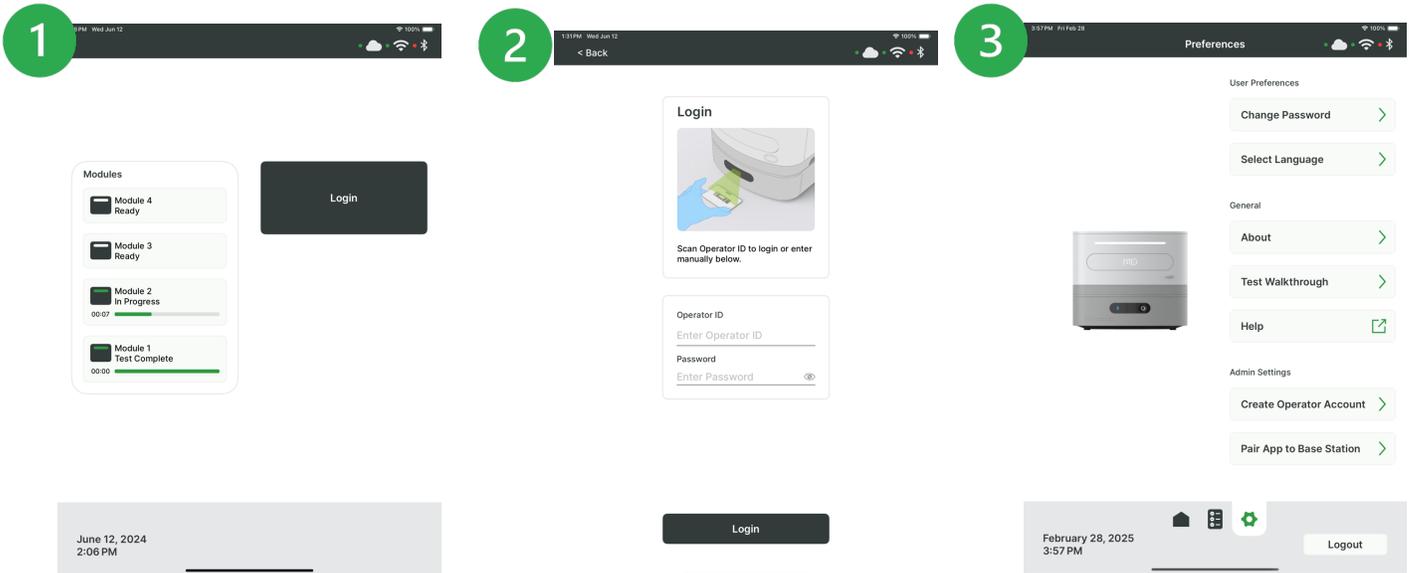
The screenshot shows the 'Preferences' menu with 'Create Operator Account' circled in green. Step 1 points to this menu item. Step 2 shows the 'Create Operator Account' form with fields for Operator ID (zjohnson), First Name (Zack), Last Name (Johnson), Create Password, and Repeat Password. A green arrow points to the Operator ID field with the text 'ID is used for manual entry (email or alphanumeric)'. Step 3 shows the 'Confirm New Operator' dialog with 'LAST, First Name ID: XXXXXXXXXXXX' and 'Back'/'Confirm' buttons. Below this is a 'New Operator Created' notification: 'New Operator created successfully.' with a 'Close' button. A 'Save New Operator' button is also visible at the bottom of the form area.

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

The screenshot shows the login process in three steps. Step 1: 'Create New Password' screen with fields for 'Enter New Password' and 'Repeat New Password'. Step 2: 'Password Changed' notification: 'Password was successfully changed.' with a 'Close' button. Step 3: 'Scan Operator ID to Pair Barcode' screen with a barcode scanner image and text: 'Scan Operator ID to pair your barcode with your Operator ID. If skipped, this prompt will repeat upon next login.' There are 'Login' buttons at the bottom left and 'Skip This Step' at the bottom right.

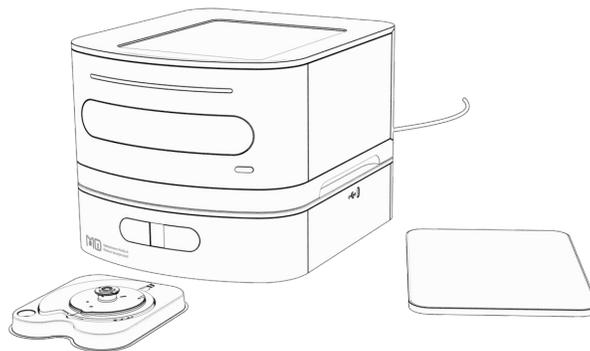
# Log on to the System Tablet

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 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, no less than daily when in use.

1. Unplug the power cord from the wall outlet and the instrument.
2. Carefully wipe down both the outside and beneath the lid where the Test Disc sits with either a) water, b) 10% v/v household bleach diluted with water, or c) 70% v/v alcohol (ethanol or isopropanol) diluted with water.



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