Fast PCR Instrument User Manual

For in vitro Diagnostic Use - EN

LABL-000073 Rev. D; July 2026

Autonomous Medical Devices Incorporated

Table of Contents

General Information	p. 3
Available Online	p. 3
Customer Support	p. 3
Intellectual Property	p. 3
Intended Use	p. 4
Testing Environment	p. 4
Limitations of Use	p. 5
Warnings and Precautions	p. 5
Maintenance	p. 6
Symbols	p. 7
Fast PCR Instrument Overview	p. 8
Principles of Operations	p.9
Fast PCR Instrument Set Up	p. 10
Fast PCR App Set Up	p. 13
Test Walkthrough (Optional)	p. 16
Administrator Log-in Information	p. 17
Creating New Operator	p. 17
Log into System Tablet	p. 19
Decontamination Procedure	p. 20
Performance Specifications	p. 21
Emissions	p. 22
Cybersecurity	p. 24

General Information

This document is used solely for the purpose of the Fast PCR Instrument. Always maintain the Instrument in good working order. If the Instrument is used in a manner not specified by Autonomous Medical Devices Incorporated, then protection provided by the equipment may be impaired.

Available Online

Fast PCR Instrument User Manual	www.AMDIFastPCR.com
Fast PCR Instrument Quick Reference Guide (QRG)	www.AMDIFastPCR.com
Fast PCR Mini Respiratory Panel Instructions for Use (IFU)	www.AMDIFastPCR.com
Fast PCR Mini Respiratory Panel Quick Reference Guide (QRG)	www.AMDIFastPCR.com
Fast PCR Cloud Station Operating Manual	www.AMDICloudStation.com
Safety Data Sheet (SDS)	www.AMDIFastPCR.com

Customer Service

If you have any questions regarding the use of this product or if you want to report a test problem, please contact Autonomous Medical Devices Incorporated Customer Service at +1-657-660-6800, customerservice@amdilabs.com or contact your local distributor.

Intellectual Property

© Autonomous Medical Devices Incorporated. All Rights Reserved. AMDI, AMDI Fast PCR, Time of Care and Cloud Station are trademarks of Autonomous Medical Devices Incorporated.

Intended Use

The Fast PCR Instrument is an automated in vitro diagnostic (IVD) device intended for use with compatible Fast PCR Test Discs, which are used in the Fast PCR Mini Respiratory Panel.

Testing Environment

A Certificate of Waiver is required to perform the Fast PCR Mini Respiratory Panel using the Fast PCR Instrument in a CLIA Waived setting. To obtain CLIA waiver information and a Certificate of Waiver, please contact your state health department. Additional CLIA waiver information is available at the Centers for Medicare and Medicaid website at www.cms.hhs.gov/CLIA. Failure to follow the instructions or any modifications to the test will result in the test no longer meeting the requirements for waived classification.

The Fast PCR Mini Respiratory Panel using the Fast PCR Instrument is intended for use by non-laboratory trained healthcare professionals in healthcare facilities operating under a CLIA Certificate of Waiver.

Limitations of Use

- The Fast PCR Instrument is intended to be used in combination with Fast PCR Test Discs.
- Do Not use any consumables not provided by AMDI.
- Do not remove Base Station or Operating Module covers during a test.
- Use only the AMDI supplied cables/peripherals when connecting the Base Station and Operating Modules. Replacements can be orderable directly from AMDI.
- Keep system tablet within 3 meters of Base Station for optimal performance
- Do not attempt to re-use an Fast PCR Test disc associated with an error or invalid result.
- Do not move Base Station or Operating Modules while the System is running. Unplug instrument prior to moving.
- Use of any cables or peripherals not supplied by AMDI may potentially lead to increased electromagnetic emissions and/or decreased electromagnetic immunity and result in improper operation.
- Portable Radio Frequency communications equipment (including peripherals such as antennas) should be no closer then 12 inches (30cm) to any part of the Fast PCR instrument as degradation of performance may occur.
- The Fast PCR Instrument is designed to have stackable Operating Modules (up to 4) on top of the Base Station. Do not stack any additional equipment on the Fast PCR Instrument as it may impact performance.
- Check with your IT policies to ensure that the System Tablet is up-to-date.
- The System Tablet should only be used for the Fast PCR App. Do not use the device for other purposes.
- Do not use near active high frequency surgical equipment, the shielded room of an MRI system or other locations where electromagnetic disturbances are high.
- The instrument contains Class 4 laser inside the enclosure.
- Only authorized AMDI personnel can open the enclosure.

Warnings

- For prescription use only.
- For in vitro diagnostic use.

Precautions

Laboratory Precautions

Handle all samples and waste materials as if they could contain infectious materials

Observe common laboratory safety guidelines

- Clinical and Laboratory Standards Institute (CSLI) protection of Laboratory Workers from Occupational Acquired Infections, Approved Guideline M29m and other appropriate safety guidelines
- Biosafety in Microbiological and Biomedical Laboratories (Centers for Disease Control and Prevention and National Institutes of Health) or other appropriate biosafety procedures

Wear personal protective equipment (PPE) and disposable powder-free gloves while handling samples. Change gloves often and between each test.

NOTE: Test Discs should not be used if dropped or shows signs of breakage. It could contaminate the operating Module and surrounding area.

NOTE: Do not attempt to lift or carry an Operating Module while running or connected to a Base Station.

General PCR Precautions

Wear appropriate PPE when loading Test Discs and refrain from touching one's face while preparing specimens and/or performing the test procedure.

Laboratory area decontamination procedures should be performed daily and PPE should be changed after cleaning.

Maintenance

- No routine maintenance is required for the Fast PCR Instrument beyond the periodic cleaning steps as indicated in the Precautions section, and Decontamination Procedures (page 20).
- Only authorized AMDI personnel should perform service or repairs on the Fast PCR Instrument.

Symbols

Symbol	Description
	Caution: Pay Attention
	Manufacturer
	Date of Manufacture
	Expiration Date (YYYY-MM-DD)
	Keep Away from Water
SN	Serial Number
LOT	Lot Number
30°C 15°C	Temperature Limits (High and Low)
	Do Not Use if Package is Damaged
	Do Not Reuse
REF	Catalog Number
Rx	Prescription Use Only
IVD	In Vitro Diagnostic Medical Device
	Consult Instructions for Use
	USB Cable
LASER 1	Class 1 Laser Product (IEC 60825-1:2014) Wavelength: 445nm Max Output: <39uW Pulse Duration: CW
	Class 4 Laser Product (IEC 60825-1:2014) Wavelength: 445nm Max Output: 2W
	WEEE (Waste Electrical and Electronic Equipment): product should not be disposed of in unsorted municipal waste. Instrument Meets European requirement WEEE Directive 2021/19/EU.

Fast PCR Instrument Overview

The Fast PCR Instrument consists of a System Tablet, a Base Station and up to 4 Operating Modules. Each System Tablet connects via Bluetooth to a single base station.

The Fast PCR Instrument is used with compatible Fast PCR Test Discs to detect multiple nucleic acid targets contained in patient specimens. The Fast PCR Instrument interacts with the test disc to both prep the sample and amplify the targets using polymerase chain reaction (PCR) in a closed system.

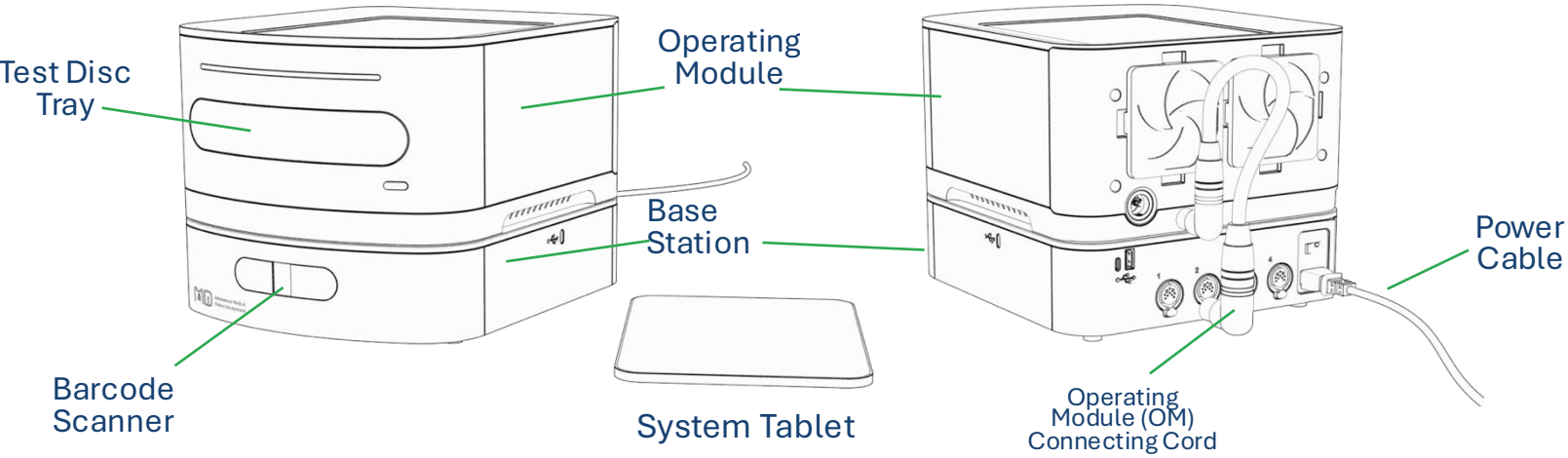
The Fast PCR App includes detailed animations of the workflow to guide the operator through how to load a sample into the test disc and load the test disc into an available Operating Module.

Fast PCR Instrument Set Up

Provided Materials

Hardware:

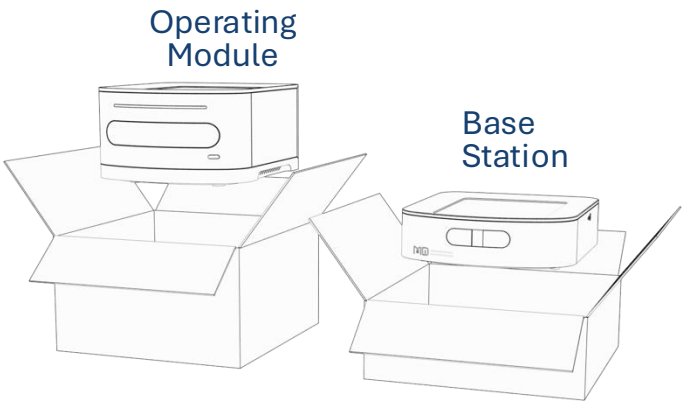
- Fast PCR Base Station
- Fast PCR Operating Module
- OM Connecting Cord
- Power Cable
- System Tablet



Documents: Fast PCR Instrument User Manual; Fast PCR Instrument Quick Reference Guide (QRG)

Unpacking the Instrument

1. Unpack the instrument (Base Station and Operating Module) from the shipping container
   - **Important: Retain the shipping container and packing materials in case you need to return the instrument to AMDI for any reason.**
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 form the sides when lifting.
5. Unpack the Power Cable and Operating Module Connecting Cord

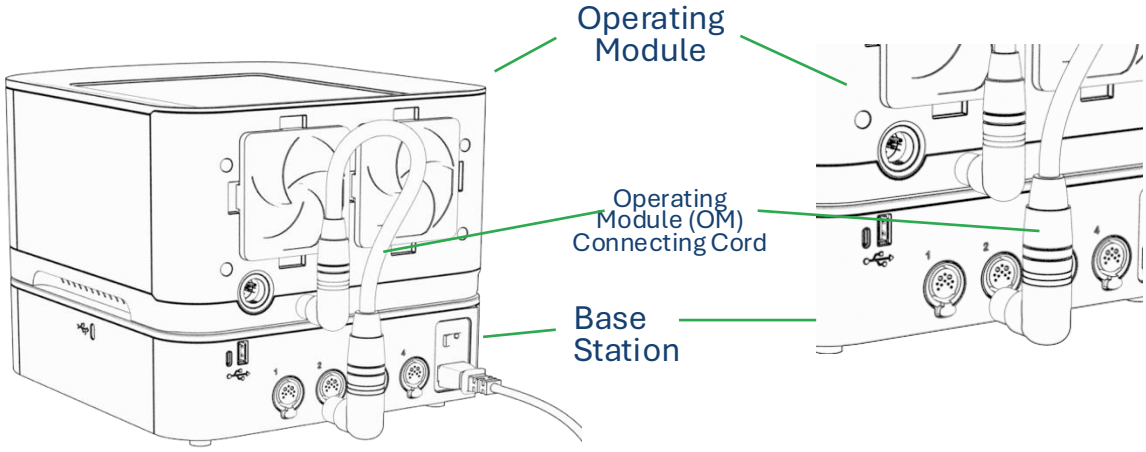


Unpacking the Instrument (Cont.)

6. Inspect the outer cases, front and back panels and rear ports for any damage. Check all the other items for shipping damage. To report any problems, contact Autonomous Medical Devices Incorporated Customer Service at +1-657-660-6800, customerservice@amdilabs.com or contact your local distributor.

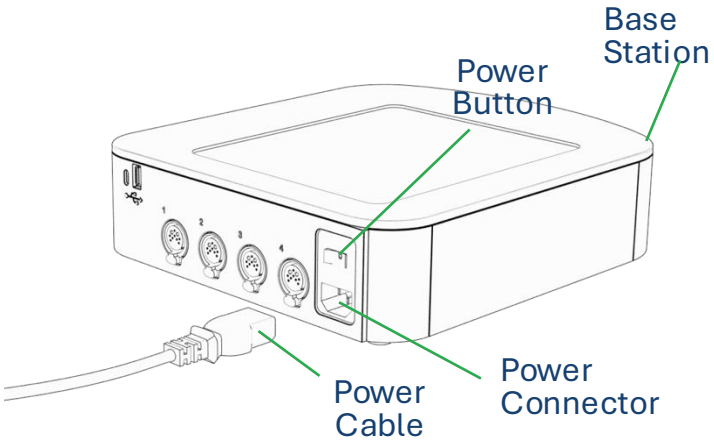
Set up the Instrument

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.
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 Bast 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

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.



- Only use power cable provided with Base Station and connect to a voltage of 100-240V AC, 50-60Hz.
    - **Caution: Using an inappropriate power supply may cause a malfunction.**
- Only use Operating Module Connecting Cord provided to connect Operating Module to Base Station.

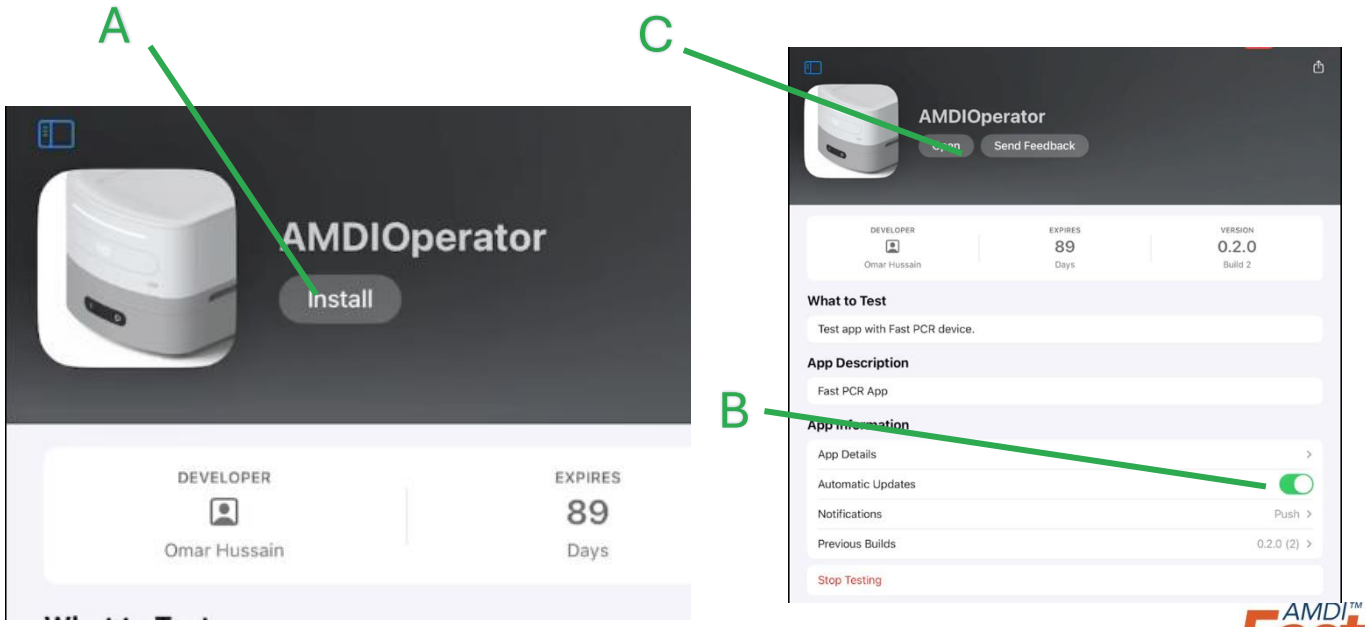
Download the Fast PCR App

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

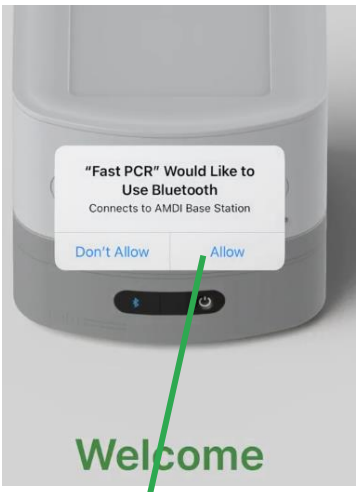
1. Before you download the Fast PCR App, you need to ensure your system tablet has been connected to your local WIFI. Ensure it is a trusted WIFI network prior to connecting. Access Settings on the System Tablet and toggle to the WIFI you would like to use. Once selected, you will be able to use your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

3. Once the AMDIOperator screen opens:

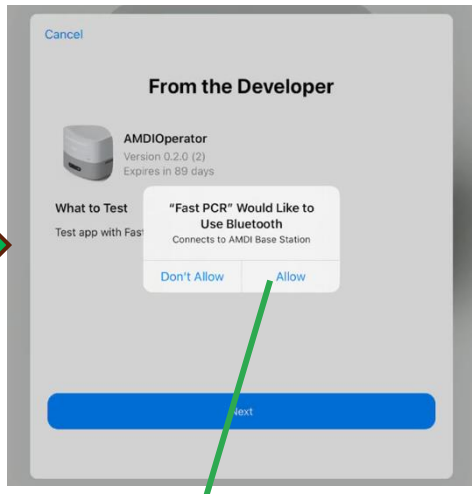
(A) click on the Install button.
(B) once Installed, ensure the Automatic Updates are turned on.
(C) finally, click the Open button to launch the app.



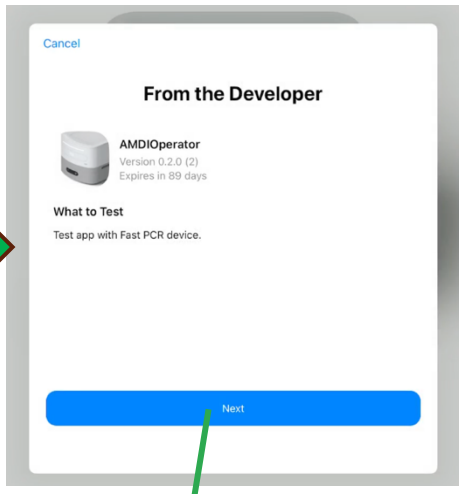
4. Once the Fast PCR App has launched, follow the onscreen prompts to connect the software and Bluetooth. See below:



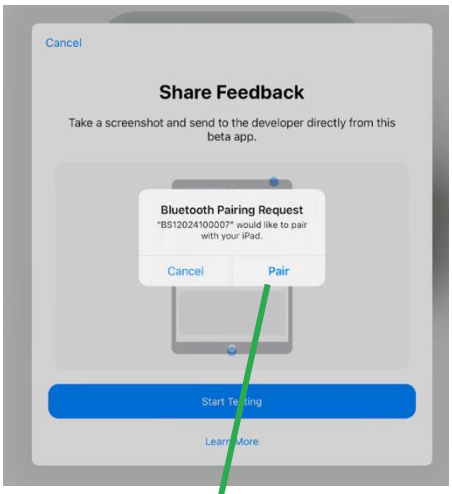
1 Click Allow



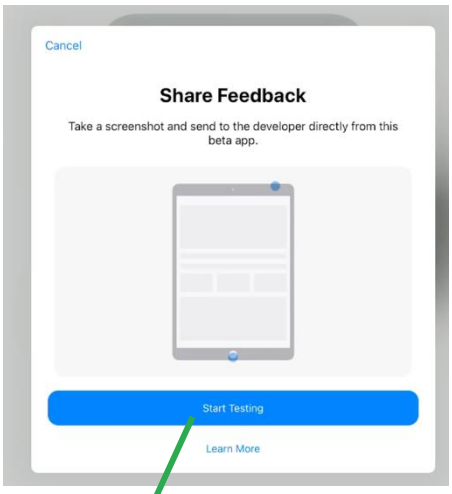
2 Click Allow



3 Click Next



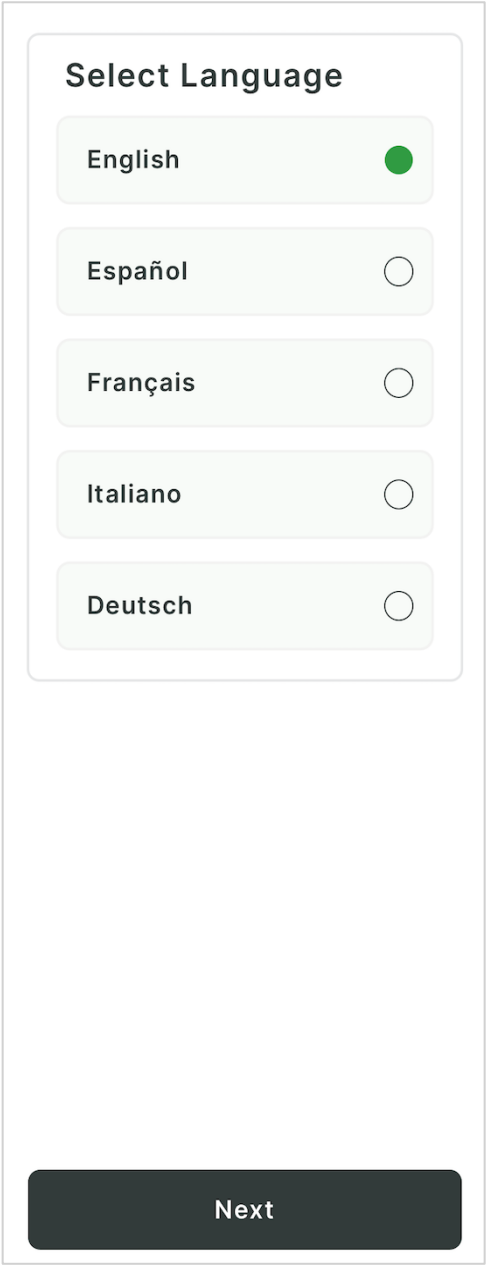
4 Click Pair

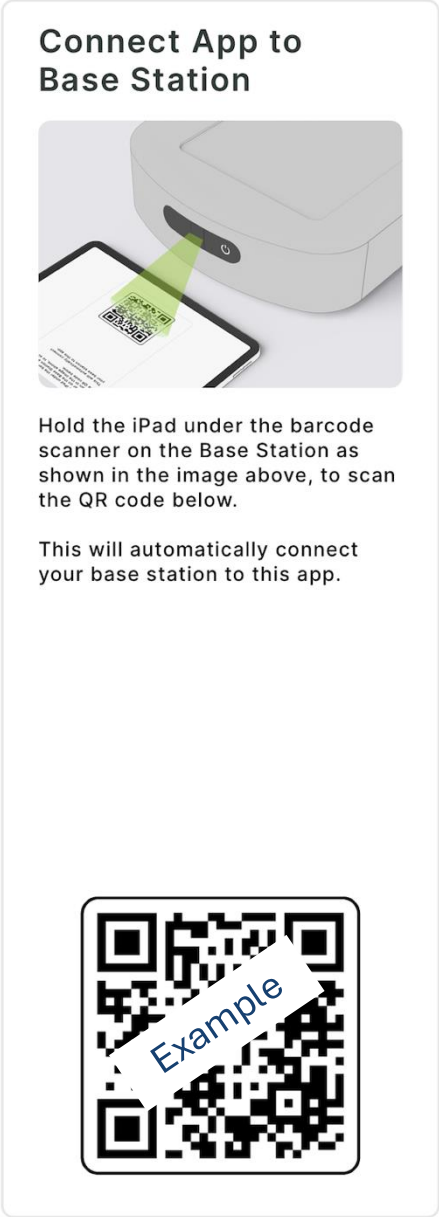


5 Click Start Testing

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.

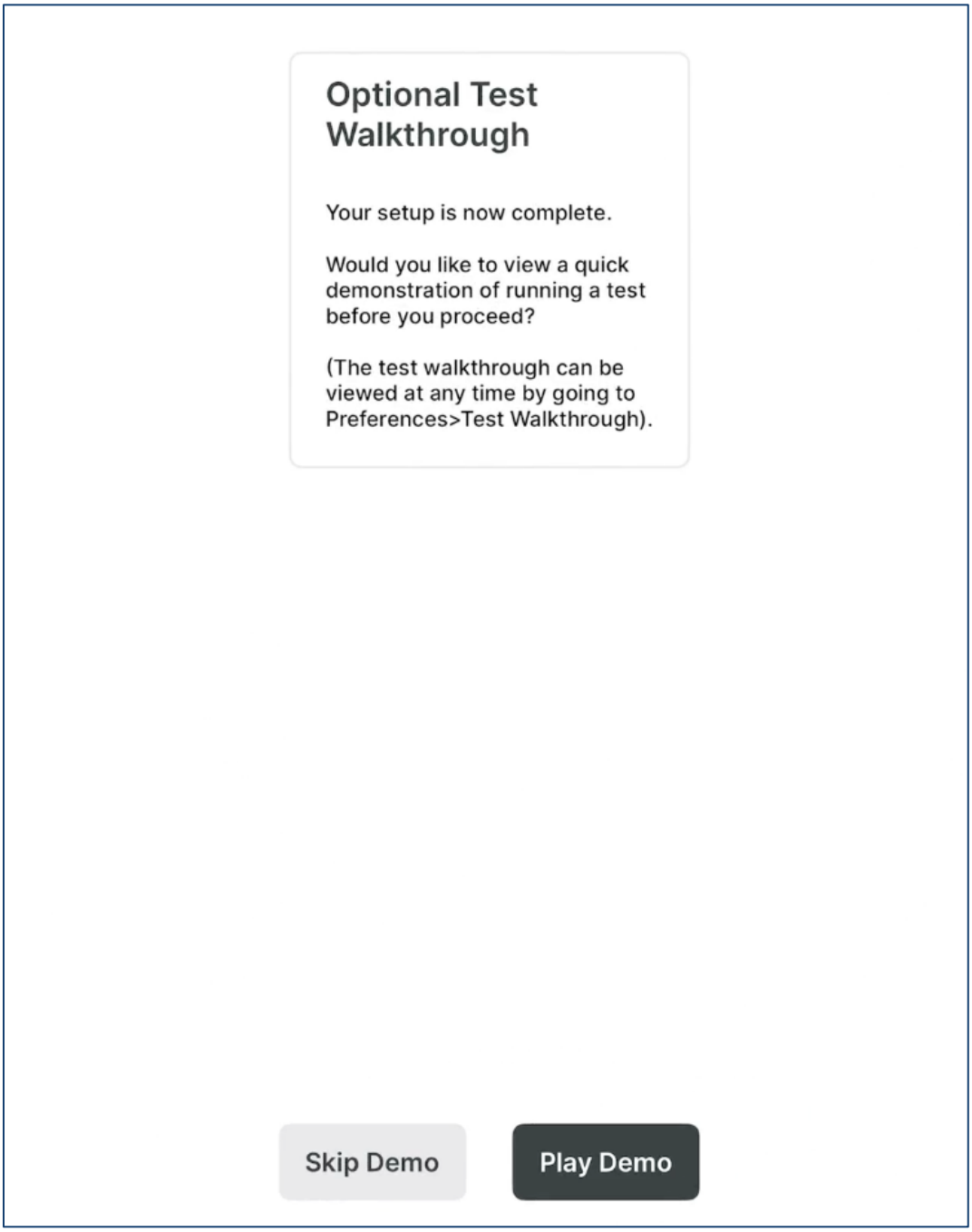




Connect the Fast PCR App to the Base Station by holding the tablet beneath the barcode scanner on the Base Station and scanning the QR code presented on the Fast PCR App screen. This will connect the System Tablet and the Base Station via Bluetooth connection.

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.

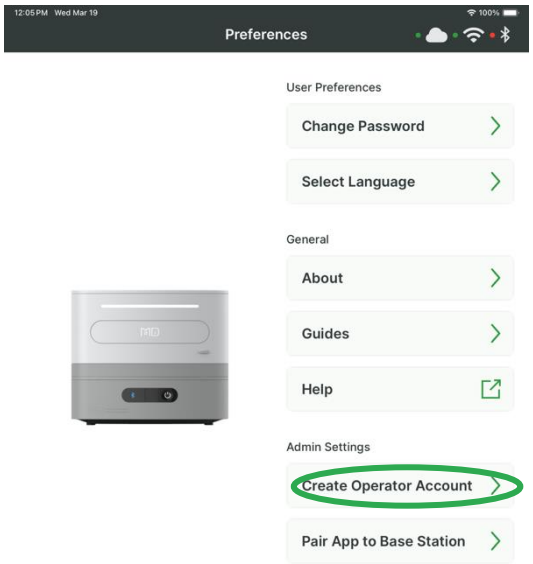


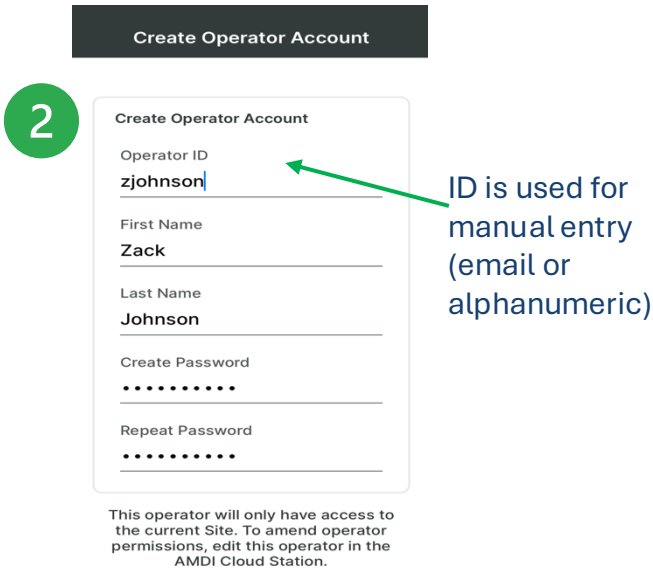
Administrator Log-in Information

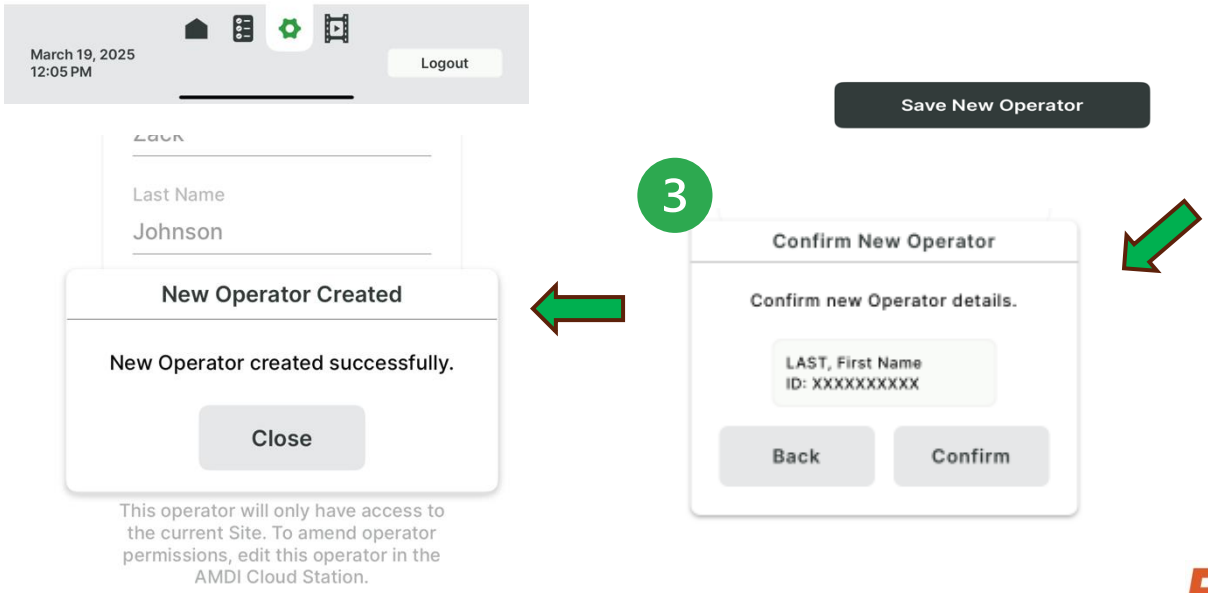
During the ordering process, an organization administrator was identified, and an account was set up (prior to shipment of the Fast PCR System) allowing that designated User administrative privileges.

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.







First Time Log-in for New Operator

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.

1

Login

Create New Password

Create a new password for the account:

Operator Information

JOHNSON, Zack
ID: zjohnson

Password must contain:
- At least 1 numeric character
- At least 1 uppercase character
- At least 1 lowercase character
- At least 1 special character

Create New Password

Enter New Password

Repeat New Password

Enter New Password

Login

2

Operator Information

JOHNSON, Zack
ID: zjohnson

Password must contain:

Password Changed

Password was successfully changed.

Close

Enter New Password

3

Login

Scan Operator ID to Pair Barcode

Scan Operator ID to pair your barcode with your Operator ID.

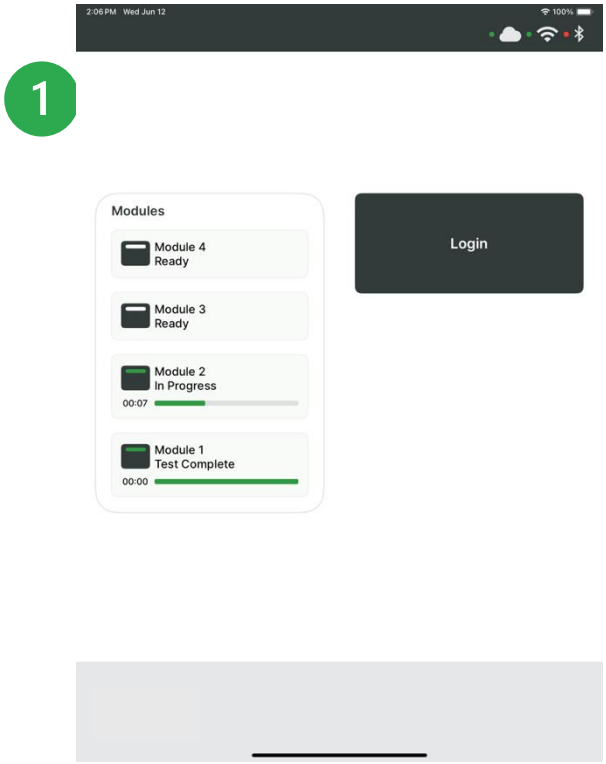
If skipped, this prompt with repeat upon next login.

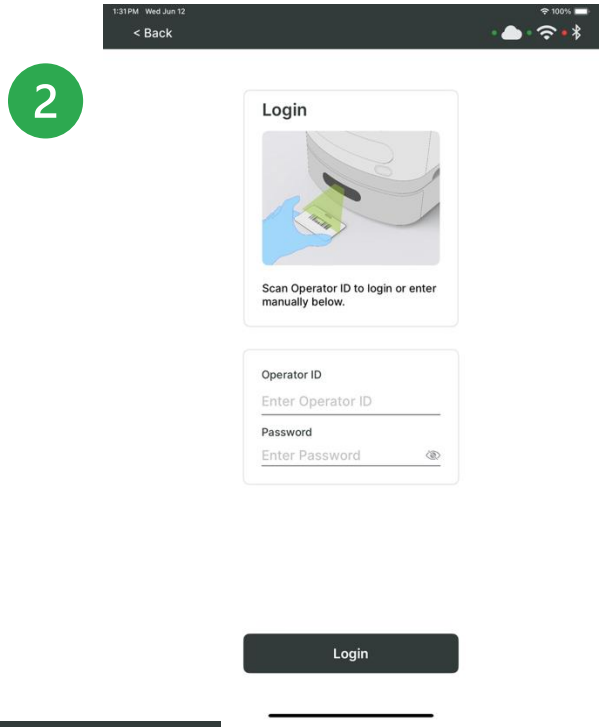
Skip This Step

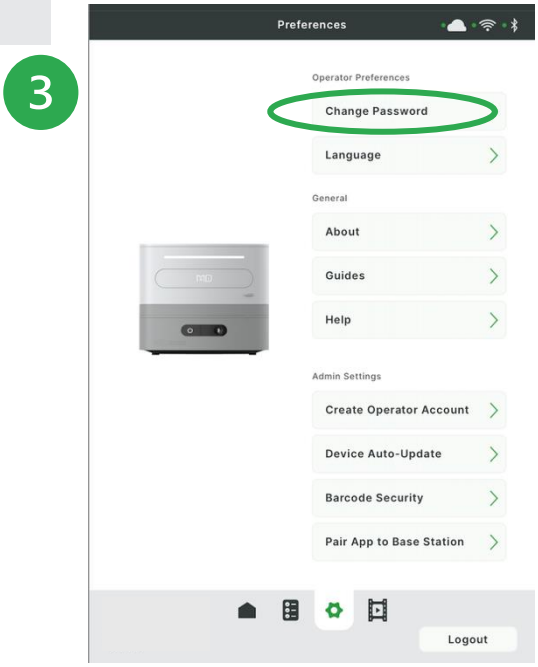
Log on to the System Tablet

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.







Decontamination Procedures

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.

Performance Specifications

Sample Description	One Test Disc per Operating Module (4 Operating Modules max per Base Station)
Test Time	<10 minutes for Mini Respiratory Panel
User Interface	Fast PCR App on System Tablet and barcode scanner
PCR Temperature Control	Temperature Range: 40 deg C to 100 deg C Temperature Accuracy: ±0.25 deg C Temperature Control: 0.1 deg C
Instrument Environmental Specifications	Temperature Range: 15 deg C to 30 deg C Humidity Range: 15% to 80% RH Indoor, Professional Use Only
Electrical Requirements	Input Voltage: 100-240 VAC Input Frequency: 50-60Hz Max Current/Power: 12 A/1200 W
WIFI Requirements	WPA3 secured clinic network with a minimum upload speed of 1Mbps
Pollution Degree	2
Dimensions and Weight	**Base Station (w/o cables):** Width: 27cm (11 in) Depth = 31cm (12 in) Height: 8cm (3 in) **Operating Module (w/o cables):** Width: 27 cm (11 in) Depth = 31cm (12 in) Height: 16 cm (6 in) Weight Base Station: 3.4 kg (7.5 lbs.) Operating Module: 6.6 kg (14.5 lbs.)
Instrument Specifications	Temperature Range: 15C to 30C Humidity Range: 15% to 80% RH
Class 1 Laser Product (IEC 60825 1:2014)	Wavelength: 445nm Max Output: <39uW Pulse Duration: CW
Optical Source	Excitation Type: LED Detection Type: Photodiode Excitation Wavelengths (nm): 470 to 650 Detection Wavelengths (nm): 520 to 720

Performance Specifications (cont.)

Base Station Interfaces	Right Panel: USB-C Back Panel: USB-A & USB-C Wireless: Bluetooth Low Energy (BLE)
Altitude	0 to 2280m (7500 ft)

Emissions

Test	Compliance	Remarks
RF Emissions (CISPR 11)	Group 1, Class A	Suitable for use in professional environments
Harmonic Emissions (IEC 61000-3-2) Class A	Class A	Compliant
Voltage Fluctuations	Compliant	No significant fluctuations observed

EMC Immunity Summary

Test	Test Level	Remarks
Electrostatic Discharge (ESD)	±6 kV contact, ±8 kV air	No degradation of performance
Radiated RF Fields	3 V/m (80 MHz–2.7 GHz)	Maintains essential performance
Conducted RF	3 Vrms (150 kHz–80 MHz)	No effect observed
Electrical Fast Transients (EFT)	±2 kV on power lines	No disruption
Surge	±1 kV differential, ±2 kV common mode	No damage or malfunction
Magnetic Fields	30 A/m at 50/60 Hz	No impact on operation
Voltage Dips/Interruptions	0%, 0%, 70% and 0% dips	Recovers without user intervention

Enclosure Port Immunity to RF Wireless Communication Equipment

Frequency	Modulation	Field Strength	Distance	Remarks
385 MHz	18 Hz pulse	27 V/m	0.3 m	TETRA systems
450 MHz	200 Hz 50% duty	28 V/m	0.3 m	LTE Band 5
710 MHz, 745 MHz, 780 MHz	200 Hz 50% duty	28 V/m	0.3 m	LTE Band 7
810 MHz, 870 MHz, 930 MHz	200 Hz 50% duty	28 V/m	0.3 m	GSM, LTE Band 8
1720 MHz, 1845 MHz, 1970 MHz	200 Hz 50% duty	28 V/m	0.3 m	LTE Band 3
2450 MHz	217 Hz 50% duty	28 V/m	0.3 m	Wi-Fi, Bluetooth
5240 MHz, 5500 MHz, 5785 MHz	217 Hz 50% duty	9 V/m	0.3 m	Wi-Fi 5 GHz

Result: The Fast PCR System maintained essential performance across all tested frequencies.

Proximity Magnetic Field Immunity

Testing simulates magnetic fields from RFID readers and other close-range sources:

Frequency	Field Strength	Distance	Remarks
13.56 MHz	10 A/m	0.1 m	ISO 14443/15693 RFID
134.2 kHz	10 A/m	0.1 m	Animal ID, low-frequency RFID

Result: No disruption to Bluetooth connectivity or system operation observed.

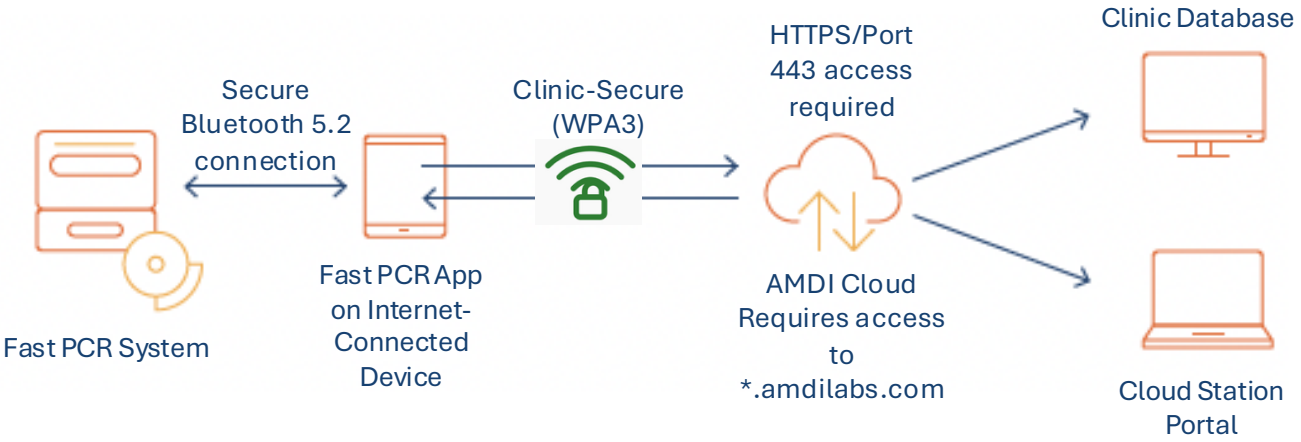
Recommended Separation Distances

Frequency Band	Separation Distance
150 kHz–80 MHz	1.2 m
80 MHz–2.5 GHz	2.3 m

Interface	Purpose	Site Controls (minimum)	Notes
Bluetooth Low Energy (BLE)	App to instrument control/pairing	Pair only the provisioned tablet; keep tablet within ~3m of Base Station; restrict physical access.	Device uses BLE; maintain RF separation from other radios per EMC guidance.
USB-A/ USB-C (Base Station)	For charging purposes only	Use AMDI-supplied cables/peripherals only; prohibit unapproved USB media; control who can plug anything in	Right panel: USB-C Back Panel: USB-A & USB-C Using non-AMDI cables/peripherals can impact performance/compliance
System Tablet WIFI	App download/updates; cloud connectivity via tablet	Connect only to trusted WIFI; follow site mobile-device policies; keep OS/app auto-update On	Manual instructs connecting tablet to trusted WIFI and enabling automatic updates for the Fast PCR App
Cloud Station (web portal)	Fleet/results visibility, admin functions	Access via HTTPS URL with unique credentials & MFA; enforce session policies; admin-only access	Cloud Station requires login & MFA, enforces idle session timeouts, and is admin-restricted

Network & Access Control

- Segment the tablet on a secured clinical network (VLAN/Firewall). WPA3 is recommended with strong WIFI password. Do not use guest/public WIFI for testing workflows.
- Accounts: Create unique operator accounts in the App; Cloud Station access is administrators only with MFA required.
- Session security (Cloud Station): Max session of 8 hrs, inactive sessions auto-timeout (30 minutes). 5 failed attempts locks access.
- RF Hygiene: Keep portable RF gear > 30 cm from instrument; follow the EMC recommended separation distances provided in manual.



Data Handling

- What' stored/where: Instrument/App data (including results) is processed/stored in the AMDI Cloud (daily backups) and displayed in Cloud Station for authorized admins.
- PHI: Results can include patient identifiers and can be viewed in Cloud Station and the Fast PCR App (last 250 results). Handle under your sites HIPAA/PHI policy.

Updates and Change Control

- iOS: Apple notifications for operating system updates. Manage tablet OS updates under your IT change control.
- Fast PCR App (tablet): Software updates notification by AMDI to Admin through Cloud Station notification. Enable Automatic Updates per the manual.
- Cloud Station: Web service with no local installation. AMDI maintains the service. Admins manage access and review audit activity.
- Web Browsers: Notifications provided by individual browser. Manage browser updates under your IT change control.

Logging, Audit and Oversight

- Cloud Station Audit Trail: Admins can search, filter and download audit reports for review. Use this for periodic cybersecurity/audit checks.
- Fast PCR App: AMDI logs all changes made by users. Fast PCR app sends email notification to admin when news users are created.
- Fleet/Results Analytics: Use dashboard analytics (devices, operators, results) to monitor usage trends and anomalies across sites/locations.

Removable Media & Peripherals

- Use AMDI supplied cables/peripherals only. Prohibit third-party installs or altering system settings beyond the manual. Control and malware-scan removeable media per policy site.

Physical Security

- Restrict physical access to the Base Station/Operating Modules and the tablet. Follow handling/placement guidance; do not stack other equipment, keep required clearances.

Decommissioning

- Delete the Fast PCR App from the System Tablet.
- Other data is stored in AMDI cloud and is under AMDI control.

Support & Security Contacts

- Customer Service: +1-657-660-6800; customerservice@amdilabs.com
- Cybersecurity updates and known vulnerabilities are located at www.AMDIFastPCR.com/product-security
- Use these to support suspected cybersecurity incidents or help.

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