



FINDER 1.5 Instrument

User Guide



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The FINDER 1.5 Instrument is only for use with the FINDER SARS CoV-2 Test. The FINDER 1.5 Instrument and FINDER SARS-COV-2 Test are distributed together as a system. Validation of the instrument and test system has not been reviewed by FDA. Review under the EUA program is pending. Distributed in accordance with the guidance on Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency, Section IV.C.2.

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1. General Information

1.1. Intended Use

The FINDER 1.5 Instrument is an automated analyzer designed to perform *in vitro* diagnostic tests on clinical specimens using only the FINDER SARS-CoV-2 Test.

The FINDER 1.5 Instrument is for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high complexity tests.

Validation of the instrument and test system has not been reviewed by FDA. Review under the EUA program is pending. Distributed in accordance with the guidance on Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency, Section IV.C.2.”

1.2. Compliance

1.2.1. Safety and EMC/EMI Standards Compliance

The FINDER 1.5 Instrument meets the following applicable standard: EN 61326-2-6:2012 - Electrical equipment for measurement, control, and laboratory use – EMC requirements – Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment.

1.2.2. Accessory compliance

The printer accessory is in conformity with the protection requirements of EU Council Low Voltage Directive 73//23/EEC and Electromagnetic Compatibility Directive 89/336/ECC on the approximation of the laws of the member states of the EEC Commission.

The printer has been tested and found to comply with the limits for Class A Information Technology Equipment according to CISPR 22/European Standard EN 55022. In a domestic environment, this product may cause radio interference in which case the user may be required to take adequate measures.

The following are EMI and Safety Standards applied to the printer: EMI – EN55022 Class A; EMS – EN61000-3-2, EN61000-3-3, EN50082-1; Safety Standard EN60950; EMI – FCC Part#15 Class A; Safety Standards UL(1950), c-UL (No.950).

1.2.3. Quality Management System

Baebies, Inc. is an ISO 13485:2016 certified company in the design, manufacture, installation, and servicing of in-vitro diagnostic analyzers, reagents, and test kits.

1.3. Warnings

WARNING: The FINDER 1.5 Instrument is intended for use by healthcare professionals only.

WARNING: The FINDER 1.5 Instrument is indicated for IVD use only and should only be used with approved FINDER cartridges.

WARNING: DO NOT use bleach or any other disinfectants that contain bleach to clean the instrument or the area used for sample preparation, as toxic gases may be formed.

WARNING: If the FINDER 1.5 Instrument is used in any way other than described in this manual, the Instrument may not operate as intended, may produce inaccurate or no results, and/or may pose a safety hazard.

WARNING: The FINDER 1.5 Instrument must not be used in the presence of explosive gases as doing so could pose a safety hazard.

WARNING: Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of the FINDER 1.5 Instrument could result in increased electromagnetic emissions or decreased electromagnetic immunity of the device and result in improper operation.

WARNING: Portable RF communications equipment can affect the FINDER 1.5 Instrument and should be used in accordance with the EMC information provided in this manual. Otherwise, degradation of the performance of the device could result.

WARNING: The use of other cables or accessories not provided or recommended with the FINDER system results in non-compliance and may pose a safety hazard, cause the instrument to not operate as intended, or negatively affect EMC performance.

WARNING: Use of the instrument adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING: Use of an incompatible power receptacle may produce electrical shock and fire hazards.

WARNING:

1. Power Rating: The instrument's power cord must be connected to a power receptacle that provides voltage and current within the specified rating for the system. The use of an incompatible power receptacle may produce electrical shock and fire hazards.

2. Electrical Grounding: The instrument must be connected to a three-prong receptacle with a functional ground. Do not use a two-prong plug adapter to connect primary power to the external power supply. The use of a two-prong adapter disconnects the utility ground, creating a severe shock hazard.

WARNING Hot Surface: The instrument's cartridge deck may be hot during instrument tests and operation.

WARNING Biohazard: Used cartridges contain human samples and must be disposed of within the facility's standard biohazard waste stream.

WARNING Biohazard: Use appropriate Personal Protective Equipment (PPE) when handling samples or used cartridges, in addition to observing your organization's approved procedures. The FINDER Tablet screen is capable of being operated while wearing latex, nitrile, and vinyl gloves.

1.4. Operating Precautions

- Use the instrument within the environmental conditions specified.
- Use the power cord provided with the instrument.
- Precautions, adherences, and installation according to the Electromagnetic Compatibility (EMC) guideline information provided in this manual, and verification of all medical devices in simultaneous operation are required to ensure the electromagnetic compatibility and co-existence of all other medical devices prior to use of the FINDER 1.5 Instrument.
- The emissions characteristics of this device make it suitable for use in industrial areas and hospitals (CISPR 11 class A). The device is not intended to be used in a residential environment. If it is used in a residential environment (for which CISPR 11 class B is normally required), the device might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the device.
- Do not use this instrument in close proximity to sources of strong electromagnetic radiation or mobile RF communications equipment, as these may interfere with the proper operation.
- Treat all physiological samples and used cartridges as biohazards in accordance with your organization's approved procedures.
- Operate the instrument on a flat surface, away from excessive humidity and direct sunlight.
- Operate the instrument in a clean area free of dust.
- Do not operate the instrument if the internal components have been exposed to fluids.
- Use only unexpired cartridges.

CAUTION: If the instrument must be returned for any reason after the initial installation, the user must properly decontaminate and package the instrument properly for shipment. See Section 6.9 for decontamination instructions.

CAUTION: The instrument is sensitive to environmental conditions. Avoid the conditions described below.

Humidity: The Instrument is designed to be operated in a humidity of 27% -80%. Operation of the instrument outside of this range may compromise performance.

Heat: The Instrument is designed to be operated in an environment with ambient temperature ranging from 15°C to 30°C. Performance has not been established outside of this range.

Altitude: The Instrument is designed to operate at elevations of up to 3000 m above mean sea level. Performance of the Instrument has not been established outside of this range.

Dust: Avoid operation of the instrument in environments with excessive dust.

CAUTION: The internal components of the FINDER 1.5 Instrument are not user-serviceable. The instrument must be serviced only by authorized personnel. The case must not be opened by the user as doing so may void the instrument warranty.

CAUTION: Never use a dropped cartridge as it may compromise the performance of the system.

CAUTION: Inspect the foil pouch prior to opening and inspect the cartridge after removal from the foil pouch. Do not use a cartridge that has been damaged or has a damaged pouch.

CAUTION: Over rotating the FINDER feet can result in them detaching from the instrument. If this occurs, the feet can be reinserted into the instrument.

CAUTION: If the cartridge fails the cartridge integrity checks, firmly close the cartridge sample lid prior to removal of the cartridge. Failure to do so can lead to contamination of the FINDER instrument.

CAUTION: Improper sample loading may result in test failures and a loss of sample. In case of incomplete sample loading, do not attempt to load more sample into the cartridge.

CAUTION: Failure to close the sample lid may lead to contamination of the FINDER instrument during cartridge removal. Always be sure to securely close the cartridge sample lid prior to the test starting.

CAUTION: Do not attempt to autoclave the used cartridge.

CAUTION: Always remove the cartridge from the instrument at the conclusion of a test.

CAUTION: Do not turn off the instrument during a software update.

CAUTION: Use of the FINDER 1.5 instrument with the tablet undocked is currently not supported.

2. FINDER Overview

2.1. System Description

The FINDER 1.5 Instrument is a diagnostic test system for use by health care professionals to rapidly analyze samples in a clinical laboratory.

The FINDER 1.5 Instrument consists of an instrument connected to an 8-inch tablet, with a tablet application for instrument control. To perform a test, the operator prepares the sample, inserts an assay-specific single-use cartridge into the instrument, and then loads the sample using a fixed-volume pipette. After the test is complete, the software computes test results which are then displayed to the user and optionally printed.

The FINDER 1.5 Instrument performs fully automated test sequences on a single-use cartridge using digital microfluidic technology. Once the test has been initiated, no user intervention is required.

2.2. Physical and Environmental Operating Specifications

Table 1 - Operating Specifications

Instrument Operation	
Dimensions	Height: 10.6 in (26.87 cm)
	Width: 8.9 in (22.56 cm)
	Length: 12.3 in (31.34 cm)
Weight	15 lb (6.80kg)
Temperature	15°C – 30°C (59°F – 86°F)
Relative humidity	27% – 80%, non-condensing
Altitude	Elevations of up to 3000 m above mean sea level (Up to 9842 ft)
Location	Indoor use. Dry, clean, horizontal surface. Avoid direct sunlight.
Pollution degree of the intended environment	2
Storage and transport (in the original packaging)	
Temperature	-10°C – 35°C (14°F – 95°F)
Relative humidity	27% – 80%, non-condensing
Power Supply	
Input	120 VAC
Frequency	60Hz
Input current	<1.0 A
Mains supply voltage fluctuations	Up to ±10% of the nominal voltage
Overtoltage category	II

2.3. Instrument Components

The FINDER 1.5 Instrument contains a tablet computer, detectors, electrowetting hardware, and a motorized platform that interfaces with the reagent cartridge. The user interacts with the instrument through an application on the tablet. Figure 1, Figure 2, and Figure 3 illustrate the instrument front view, cartridge loading area, and rear view, respectively.

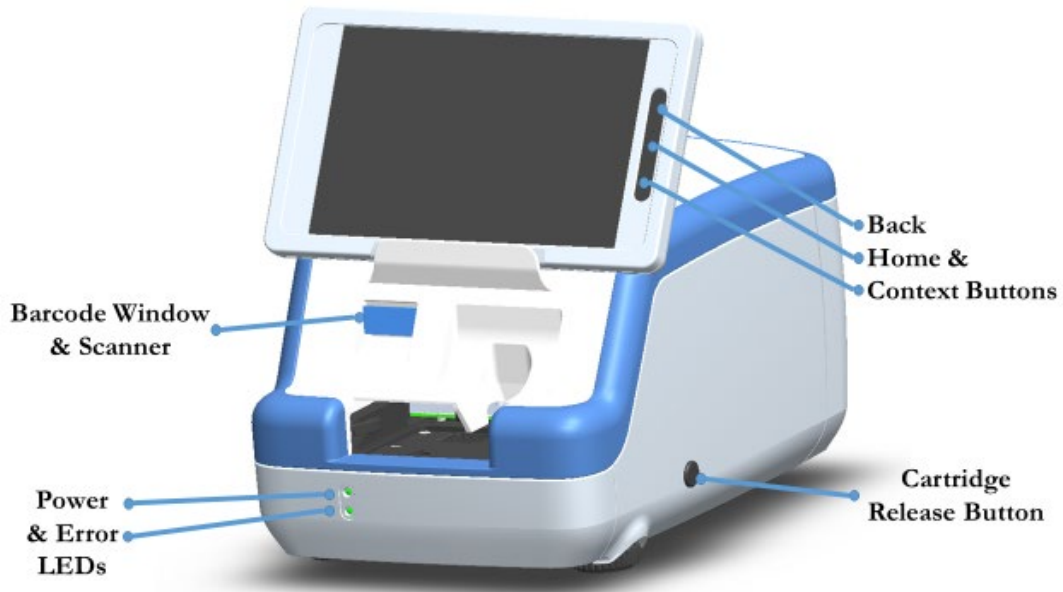


Figure 1 – FINDER 1.5 Instrument - Front View

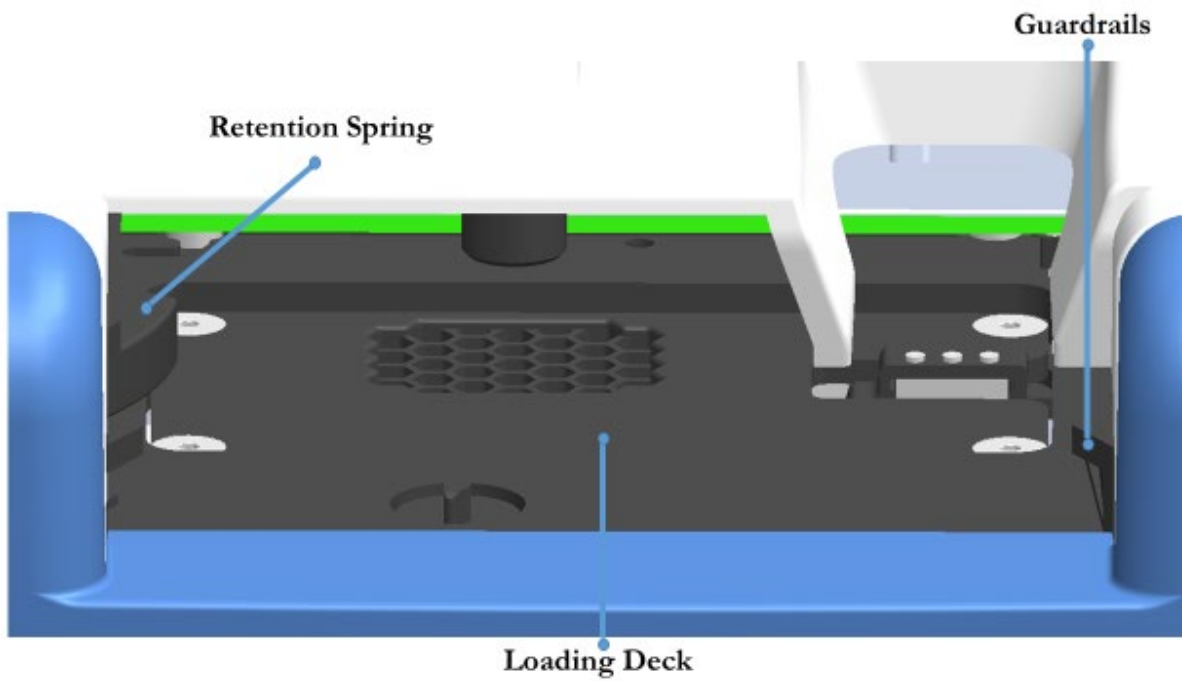


Figure 2 - FINDER 1.5 Instrument - Cartridge Loading Area



Figure 3 - FINDER 1.5 Instrument - Rear View

2.4. FINDER Cartridge

Each single-use cartridge is self-contained and contains assay-specific reagents. On cartridge, assay steps are performed automatically without the need for user intervention. Figure 4 shows a diagram of a FINDER cartridge.

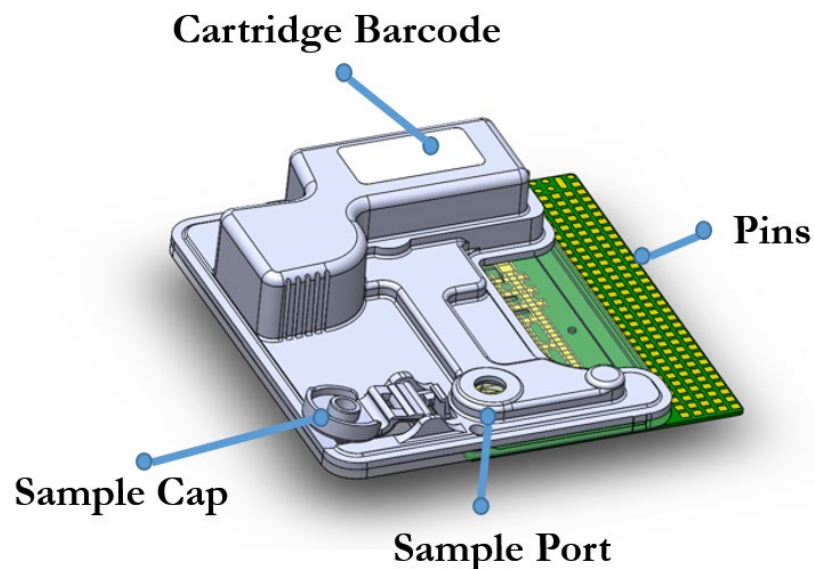


Figure 4 – FINDER Cartridge Diagram

3. Installation of Instrument, Software, and Printer

3.1. Receipt of the Instrument

If you suspect that the instrument has been mishandled during shipping, notify the carrier and Baebies. Look for evidence of shock, scratches, marring, and cracked or broken components and enclosures. In the case of suspected damage, keep the instrument and packing materials undisturbed for carrier inspection. The instrument should be stored in an environment as described in section 2.2 – “Physical and Environmental Operating Specifications” until the instrument is installed.

3.2. Instrument Installation

1. Refer to the provided installation checklist from FINDER Technical Support to install both the instrument and the optional printer.

3.3. Turning the Instrument and Tablet Power On/Off

1. Power on the instrument tablet by pressing and holding down the Power button located on the top of the tablet for approximately three (3) seconds.
2. Power on the instrument by moving the power switch located on the back of the instrument base to the ON position. The Power LED should immediately light up green. The FINDER application should automatically open on the tablet after approximately 10 seconds.

Note: If the Power LED on the FINDER Instrument does not light up immediately, turn the instrument off, unplug it, and contact FINDER Technical Support.

Note: Power off the instrument by moving the power switch to the OFF position located on the back of the instrument base & unplug the power cord of the instrument to disconnect the device from AC power.

3.4. VIEWER Application

The VIEWER Application was preinstalled on the tablet, which utilizes an Android operating system.

3.4.1. VIEWER Login and Setup

After instrument installation, a series of instrument checks are automatically performed and an initial Administrator account must be created to continue.

Full instrument configuration is detailed in the Instrument Configuration section.

1. Create the Administrator user account by scanning or manually entering an Identity Code and Display Name (Figure 5). A typical identity code for single individual accounts would be a person's badge number or another personnel identifier. This is illustrated.

Note: The initial account created will automatically be given the Administrator permission level. Refer to the User Management section for a description on the permission level access controls given to user accounts.

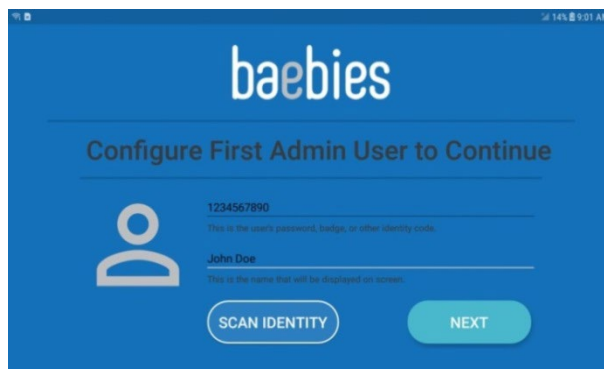


Figure 5 - First Admin User Setup

- If the instrument is not level, the initial user setup cannot proceed. In this case, the VIEWER Application will prompt the user to level the instrument before continuing (Figure 6). The “Front-to-Back” and “Side-to-Side” numbers reflect the unbalance. Adjust the leveling feet of the FINDER 1.5 Instrument by turning them clockwise or counter-clockwise to raise or lower the feet and balance the instrument. When the “Front-to-Back” and “Side-to-Side” measurements are within the instrument defined limits, the “OK” button will become active. If you are not able to level the deck, contact FINDER Technical Support for assistance.

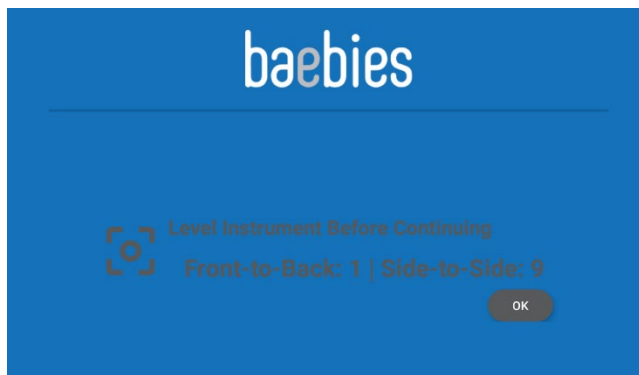


Figure 6 - Instrument Level Display

Note: Tests cannot be performed with the instrument out of level. Once level, do not move the instrument.

Caution: Do not over-rotate the instrument feet, as this can result in them falling out of the instrument. If this occurs, the feet can be reinserted back into the instrument.

- From the Completed Test Runs screen (Figure 7), inspect the **NEW RUN** button to view the current instrument status. Verify that the **NEW RUN** button is blue and the text “NEW RUN” is displayed as shown below.

Note: If the button is orange and the text “WARNING” or “ERROR” is displayed, select “NEW RUN” to view the error message and contact FINDER Technical Support.

Run ID	Assays Performed	Time Performed
19	Main Protocol	2019-08-12_16:37:48
18	Main Protocol	2019-08-12_15:37:29
17	[0149]: Cartridge contamination suspected.	2019-08-12_15:32:11
16	Main Protocol	2019-08-12_15:13:01
15	Main Protocol	2019-08-12_14:51:29
14	Main Protocol	2019

Figure 7 - Completed Test Runs Screen

4. Instrument Configuration

Instrument configuration options are found in the navigation menu (Figure 8). The navigation menu can be accessed by pressing the three horizontal lines on the top left corner of the tablet screen (☰)

The instrument configuration screen is composed of four categories: Device Setup (Table 2), Barcode Scanner (Table 3), User Management (sections 4.3 and 4.4), and Test Configuration (Table 5). Select any category to display specific configuration fields. A user can also print or export the audit log from the Configuration menu as well as update the device software. The instrument configuration categories are described in sections 4.1 through 4.5.

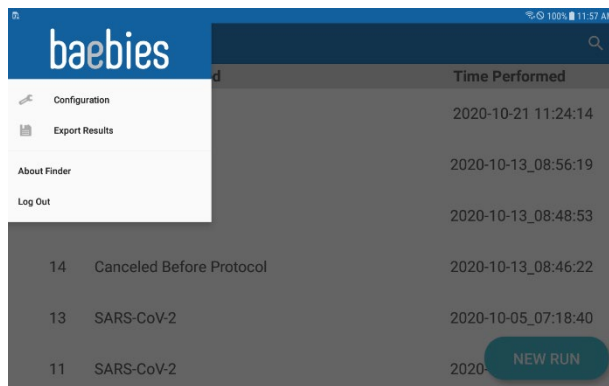


Figure 8 - Navigation Menu

4.1. Device Setup

Table 2 - Device Setup Options

Field	Description
Device Setup	Subsection containing instrument information
Instrument Up Time	Display of total time instrument has been operational. Updates upon tapping.
Instrument Accelerometer	Displays the status of the instrument level.
Printer Settings	Subsection containing printer configuration options
Printer Enabled	Option to disable/enable the printer. If disabled, the Print button will not appear as an on-screen option.
Automatically Print Results	Select whether or not a result is printed automatically after a completed test.
Print Test Page	Sends a test page to the printer to verify successful printer setup.

4.2. Barcode Scanner

Table 3 - Barcode Scanner Options

Field	Description
Test Scanner Configuration	Subsection containing triggers for testing the scanner settings
Test Sample Settings	Triggers a sample barcode scan, allowing testing of sample barcode settings
Test Operator Settings	Triggers a user barcode scan, allowing testing of user barcode settings
Scanner Setup	Subsection containing scanner configuration options
Scanner timeout	The amount of time that the barcode scanner will stay on when no barcodes are recognized. (Time in seconds – default: 30 s)
Code 39 Full ASCII	Enable to configure the expected format of Code 39 barcode to expect Full ASCII (default: alphanumeric)
Code 39 Check Digit	Enable to configure the expected format of Code 39 barcode to expect a check digit
Interlaced 2 of 5 Check Digit	Enable to configure the expected format of Interlaced 2 of 5 barcodes (Disabled, Standard, German Parcel, DHL, Daimler Chrysler, Bosch, Italian Post)
Barcode Settings	Subsection containing the individual options to trim barcode prefixes/suffixes
Trim First Digits from Sample Barcode	Configure sample scans to ignore the first 1 to 5 digits of a barcode
Trim Final Digits from Sample Barcode	Configure sample scans to ignore the last 1 to 5 digits of a barcode
Trim First Digits from Identity Barcode	Configure user scans to ignore the first 1 to 5 digits of a barcode
Trim Final Digits from Identity Barcode	Configure user scans to ignore the last 1 to 5 digits of a barcode

4.3. User Management Introduction

Access control to the FINDER 1.5 Instrument is provided using configured user accounts. Each User Account is required to have an identity code, a display name, and a permission level. An expiration date is optional.

4.3.1. Identity Code

The identity code is the unique identifier for the account being created. This identity code is used to identify whether the person attempting to use the device is authorized to do so and the code is required to unlock the instrument. An identity code may be set up for individuals or groups of individuals. A typical identity code for single individual accounts would be a person's badge number or another personnel identifier.

Identity codes can contain any alphanumeric character.

Identity codes are not displayed or included with test results. A user's identity code should not be shared with individuals not authorized to use the FINDER 1.5 Instrument.

4.3.2. Display Name

The display name is the identifier displayed on FINDER 1.5 Instrument screens and included with test results and reports. A common display name for single-user identity codes would include the user's name. A common display name for a multi-user identity code may include "Building 3 – Floor 2" or "NICU", for example.

Display names can contain any alphanumeric character.

Display names can be a maximum of 32 characters long.

4.3.3. Permission Levels

User accounts are classified as described in Table 4. User permission levels can be modified by Admin accounts.

Table 4 - User Account Permissions

Permission Level	Description
Locked	The user has an account but is not allowed to log into the VIEWER application. Expired accounts have their permission level automatically set to Locked.
View Results	Users are only able to view results for tests previously performed on the instrument.
Run Tests	Users can view results and perform tests on the instrument, but cannot change instrument configuration settings.
Admin	Admin accounts are capable of performing all actions required to perform a test or view results. An Admin account is required to perform any configuration of the instrument including updates of system software and adjustments of user permissions.

4.3.4. User Account Expiration Date

An expiration date can be set for each user account. Expiration dates are included to help support lab or hospital training protocols. An account is prevented from accessing the instrument, viewing results, or initiating a new test if the expiration date has been reached. Expired Administrator accounts are still able to change all instrument configuration settings. An Administrator account is required to reset or change the expiration date for an account.

4.4. User Management Procedure

4.4.1. Reviewing Users

To review the current user accounts configured on the instrument, navigate to the Configuration setting, and then select User Management (Figure 9). A list of the current user accounts configured on the instrument is displayed.

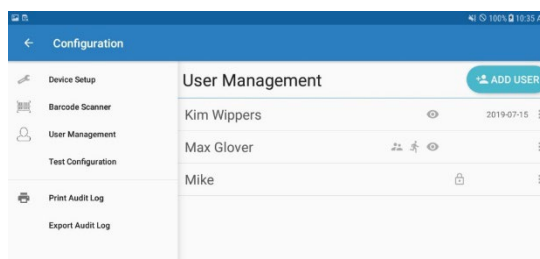


Figure 9 - User Management

4.4.2. Adding Users

To add a new user to the instrument, select the **Add User** button to navigate to the Create New User screen (Figure 10). Select the **Scan Identity** button to turn on the barcode scanner. Present a barcode to the barcode scanner to scan in an Identity Code. Alternatively, an identity code can be manually inputted on the tablet keyboard by pressing on the Identity Code field. The Display Name is added by pressing the field and manually entering the information.

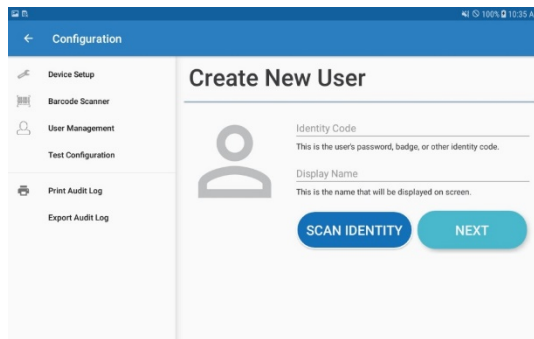


Figure 10 - Create New User Screen

4.4.3. Editing Users

Editing an existing user account is accomplished by selecting the user account on the User Management screen and manually editing the information (Figure 11). An Identity Code and Display Name can be changed by manual entry. Additionally, the Identity Code can be scanned by pressing the 'Scan' button. Permission levels are set by pressing the highest appropriate permission level. An expiration date can be modified by pressing the 'Change' button, which opens a calendar for date selection.

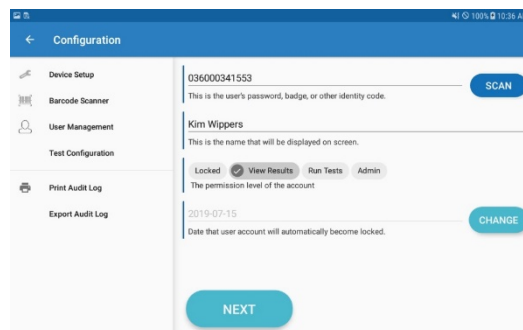


Figure 11 - Edit User Dialog

4.5. Test Configuration

Table 5 - Test Configuration Options

Field	Description
Test Screen Timeout	The amount of time with no user interaction that can pass before the tablet screen moves to a lock screen. This can be set in minutes and seconds. By default, the display does not timeout to the lock screen after any amount of time.
Default Tests	The tests which are checked by default at the start of a run can be edited here.

5. Instrument Operation

5.1. Required Materials

The following materials are required for setting up, maintaining, and performing tests on the FINDER 1.5 Instrument.

5.1.1. Materials provided with the FINDER Instrument:

1. FINDER 1.5 Instrument including the following items:
 - a. Instrument power cord (NEMA 5-15P to IEC 320-C13, 6ft long)
 - b. Deck actuation tool (7/64" size, T-handle)
 - c. FINDER Tablet with VIEWER Application pre-programmed on the tablet
 - d. FINDER 1.5 Instrument User Guide
 - e. USB Drive
2. *(Optional) Printer (OMNIPrint, Catalog #OM5200U-BI) including:*
 - a. *Printer paper, 1 roll (Thermal paper, 2.25" wide, 2.25" max diameter)*
 - b. *Printer power cord (AC/DC Wall Mount Adapter 7.5V 15W)*
 - c. *Printer USB cable (USB Type A to Type B)*

5.1.2. Materials required but not provided with the FINDER Instrument:

1. FINDER Cartridge (assay-specific)
2. Controls – See FINDER assay-specific Instructions for Use for information regarding controls
3. 70% Isopropanol (IPA)
4. FINDER Cleaning Accessory (Baebies P/N: 4076)
5. Other materials may be required based on the specific assay panel; see the assay Instructions for Use (IFU) for additional details

5.2. Instrument Preparation

1. Login to the instrument by scanning or manually entering your Identity Code.
2. Ensure that the instrument is ready to test by verifying the **New Run** button is blue and the text "New Run" is displayed.

*Note: The **New Run** button will be red or yellow and the text will read "ERROR" or "WARNING" respectively if the instrument is not fully operational. See the Instrument Integrity Check section for troubleshooting issues that may prevent a run from being performed.*

5.3. Test Setup

Refer to the FINDER Cartridge assay-specific Test Instructions for Use for workflow instruction

5.4. Test and Results

1. Once the test is started, a progress screen with a countdown will be displayed. The user can cancel the test at any time by pressing the back button on the screen and scanning their identity code. If no errors are encountered, the test will continue the countdown.

Refer to FINDER Cartridge Instructions for Use for the expected time to result.

If an error that would invalidate the test is encountered while the test is in progress, the test will immediately end. See the Flags section for additional details.

2. When the test is complete, the instrument will display the test results screen or display error flags that may have been generated. An error code and description of failure will be displayed in place of a result if a flag was identified to invalidate a test. In the case of an invalid result, the analyzed specimen should be repeated.
3. The results of the test will be automatically printed if a printer is connected and the instrument is configured to auto-print. Otherwise, the result can be manually printed by pressing **Print Results** on the results screen. The result can also be reviewed and printed on the instrument by selecting the run on the **Completed Test Run** screen.
4. Press the back button to return to the default, **Completed Test Run** screen.
5. Remove the cartridge from the instrument by pulling on the cartridge grips.
6. Dispose of the used cartridge in a biohazard waste bag.

CAUTION: Do not attempt to autoclave the used cartridge.

CAUTION: Always remove the cartridge from the instrument after a test. Failure to remove the cartridge after an extended period of time can lead to minor filler fluid leaks and contamination of the FINDER 1.5 Instrument.

5.5. Canceling a Run

At any point during the test procedure, the user can cancel the process and return to the run list. This is achieved by performing the following.

1. Press the back icon in the top left of the screen or the tablet's back button on the right side of the tablet.
2. When a cancellation is initiated, a popup appears. To complete the cancellation, the user must press **SCAN** and scan their ID (not necessarily the ID of the user initiating the test). Alternatively, the user can press **RESUME** to close the cancellation popup with no effect.

If an error is encountered during setup, there will be an additional button, labeled "END TEST", which will also generate this popup.

5.6. Analyzing a Control

Analyzing quality control materials on the FINDER 1.5 Instrument should be performed following the standard workflow. Please refer to the assay-specific Instructions for Use for information about the use of controls.

5.7. Review a Previous Test Result

Results are stored on the FINDER 1.5 Instrument and can be reviewed at any time. Previous results are displayed on the **Completed Test Runs** screen. The **Completed Test Runs** screen can be accessed after run completion and is used to navigate to other VIEWER features including but not limited to **Export Results, Configuration, and New Run**

Results are displayed chronologically with the newest results listed at the top. To search for a specific sample/patient ID, press the **Search** icon in the top right corner and enter the sample or patient ID that you wish to review.

6. Servicing and Maintenance

6.1. Servicing

CAUTION: The internal components of the FINDER 1.5 Instrument are not user-serviceable. The instrument must be serviced only by authorized personnel. The case must not be opened by the user as doing so may void the instrument warranty.

WARNING: Internal Voltage: Turn the instrument power off and unplug the power cord from the AC outlet before servicing the instrument. Failure to do so may create an electrical shock hazard.

6.2. Preventive Maintenance

No preventive maintenance is required for the FINDER 1.5 Instrument. General cleaning is outlined below.

6.3. Instrument Cleaning

6.3.1. Routine Cleaning

The exterior of the FINDER 1.5 Instrument should be cleaned on an as-needed basis or as dictated by local requirements. Wipe down the outer surfaces of the instrument using a low-lint cloth or tissue moistened with 70% isopropyl alcohol.

WARNING: DO NOT use bleach or any other disinfectants that contain bleach to clean the instrument or the area used for sample preparation, as toxic gases may be formed.

Excess dust in the cartridge loading area can lead to an increased rate of cartridge failures.

CAUTION: Follow all instructions provided by FINDER Technical Support to minimize excess moisture being introduced within the FINDER deck.

6.3.2. Filler Fluid Spills

The FINDER Cartridge contains an inert filler fluid medium that is intended to be fully contained within the reagent cartridge. In the unlikely event of filler fluid escaping the reagent cartridge, the instrument should be powered off and FINDER Technical Support should be contacted.

If the amount of escaped filler fluid is minor, testing can continue on the instrument. Tests performed with filler fluid contamination may lead to an increased failure rate during cartridge integrity checks or during a test. FINDER Technical Support can help evaluate the nature of the filler fluid contamination.

6.4. Replacing the Fuse

Power entry module fuses may be replaced by the operator. To change the fuse, first, turn the instrument off and unplug the power cord from the AC outlet. Next, remove the fuse holder from the power inlet located on the back of the device using a No. 1 or smaller screwdriver or equivalent. Remove both fuses and replace them with an equivalent fuse. The fuses for the device are 1.0 Amp, 250 Volt, Slow Blow fuses, and measure 5mm x 20mm.

6.5. Replacing the Printer Paper (Optional)

Replace the printer paper as-needed.

1. To open the paper cover push the latch located on the left of the printer (Figure 12).
2. Open the cover fully and remove the old paper roll core.
3. Please make sure no objects are dropped inside and avoid touching any internal parts of the printer including the rubber roller with any sharp object.
4. Make sure the paper roll is positioned as shown.
5. Pull the paper so that the leading edge of the roll goes at least two inches beyond the printer tear bar (Figure 13).
6. Gently close the printer paper cover and make sure it is closed tightly.
7. Press the FEED button to make sure the roll is properly loaded. If you notice any wrinkles or creases on the edges of the paper try loading the paper again.
8. Tear the excess paper against the serrated edge.



Figure 12 - Printer Paper Cover Latch



Figure 13 - Printer Internal Components

6.6. Software Lost Credentials

A user will be locked out of the instrument if their account expiration date has passed or if the user has lost or forgotten their Identity Code. If this occurs any Administrator account can be used to restore the user's access either by resetting the user's expiration date or Identity Code.

If all Administrator accounts are no longer able to access the instrument, contact FINDER Technical Support.

6.7. Software Updates

Software updates to the FINDER 1.5 Instrument tablet are provided by Baebies on a USB drive. FINDER customers will be informed when a FINDER software update is made available. To upgrade the FINDER 1.5 Instrument software the following steps should be performed.

1. Ensure the instrument is powered on
2. Plug the USB drive containing the software update into the USB port on the back of the FINDER 1.5 Instrument.
3. Press the navigation menu in the VIEWER application and select "Configuration". Next, press **Update Software**.
4. The FINDER 1.5 Instrument will scan the USB drive for software updates and prompt the user to confirm the installation. If no new software is found on the USB drive the instrument will return a message stating that no new updates were found.

5. Confirm the software update to begin the installation. After installation, the system will automatically restart.

CAUTION: Do not turn off the instrument during a software update.

6.8. Exporting Information

FINDER results and audit logs may be exported from the FINDER 1.5 Instrument to a USB drive to further support lab or hospital workflows. Before accessing the export functions, insert the provided USB drive into the USB port on the back of the FINDER 1.5 Instrument.

USB drives must be in the FAT32 format for FINDER to export data.

- Results: The **Export Results** command is found under the navigation menu. Results on the instrument can be exported in bulk to support additional data result workflows. When **Export Results** is selected all results and device logs on the instrument are copied to the attached USB drive. Results are not deleted from the instrument as part of the export process.
- Audit Logs: The **Export Audit Log** command is found under the navigation menu -> Configuration. Audit logs can be exported from the FINDER 1.5 Instrument to support hospital or lab electronic medical record security guidelines. The FINDER audit log contains all user account management activities performed on the system such as account creations, removals, or role changes.

6.9. Returning Instruments to Baebies

Customers returning a FINDER 1.5 Instrument to Baebies should contact FINDER Technical Support to facilitate the return. The device should be decontaminated before the instrument is returned.

6.10. Device Decontamination

The instrument must be decontaminated if there is a spill of potentially hazardous biological material on the instrument, or when the instrument will be returned to Baebies.

Users performing the decontamination procedure must be familiar with the basic setup and operation of the instrument. Baebies recommends the use of 70% isopropyl alcohol for the decontamination of infectious agents and human samples.

WARNING: DO NOT use bleach or any other disinfectants that contain bleach to clean the instrument or the area used for sample preparation, as toxic gases may be formed.

1. Do not immerse the instrument in liquid.
2. Wear protective gloves and safety glasses when handling contaminated instruments or performing this decontamination procedure.
3. A face shield is recommended whenever there is a possibility of aerosol contamination.

Required Materials

1. 70% Isopropyl alcohol
2. Deionized or distilled water
3. Paper towels or lint-free cotton cloths
4. Lab coat
5. Protective gloves
6. Safety glasses
7. Face shield (recommended)

Decontamination Procedure

1. Turn the instrument off and disconnect it from the power supply.
2. Remove any cartridge from the deck and dispose of the cartridge in a biohazard waste bag.
3. Moisten a paper towel or cloth with 70% isopropyl alcohol. **Do not soak.**
4. Wipe all of the instrument's exposed surfaces.
5. Wait 20 minutes to allow the alcohol to dry. **Do not wipe dry.**
6. After the alcohol has dried, moisten a paper towel or cloth with deionized or distilled water and wipe all surfaces that were cleaned with alcohol.
7. Use a paper towel or cloth to dry all the surfaces.
8. Discard used cleaning materials in a biohazard waste bag.

7. Integrity Checks

7.1. Instrument Integrity Check (Continuous)

The FINDER 1.5 Instrument continuously monitors critical subsystems within the instrument for ready status and error conditions. The **New Run** button will be red when the instrument is not ready for testing. Pressing the red **Error** button will display the condition that is preventing the instrument from proceeding.

Any test in progress will be canceled if the instrument integrity status encounters a system error. The **New Run** button will turn red and display "ERROR" if an error is present. New tests cannot be initiated when an instrument integrity error is present.

7.2. Cartridge Checks

The integrity of the reagent cartridge is automatically verified on every test before sample introduction.

If a cartridge setup check fails, the test will be canceled and the user will be presented with a flag and suggested user action.

See the Flags section for additional detail on user actions.

7.3. Run Checks

The instrument performs a series of quality checks throughout the assay to ensure the validity of the final result. Run checks include monitoring activities such as fluidic operations, detector signal levels, reagent efficacy, and sample quality. If a Run flag is generated, the user will be presented with a flag and suggested user action at the end of the test. Run flags may prevent a result from being displayed.

See the Flags section for additional detail on user actions.

8. Flags

Flags are generated as part of the Baebies automated quality control process throughout the entirety of the test. For each workflow step, flag measurements are made, and events which may compromise the run will be displayed to the user. If a run compromising event is detected, the instrument will generate a Flag and may immediately cancel the test. Results will not be displayed if the instrument has determined that the flag would compromise the validity of the result. All potential flags are listed in Table 6.

Table 6 - Flag Descriptions

Flag Range	Error Message	User Action
0100 – 0108	Cartridge not detected	Remove reagent cartridge and fully reinsert it. If problem persists, discard cartridge.
0109 - 1000	Cartridge connection failure	Remove reagent cartridge, clean according to instructions in the user manual, and reinsert cartridge. If problem persists, discard cartridge.
1000 - 1999	Cartridge initialization failure	Securely close the cartridge sample well cap and discard the cartridge. Insert a new cartridge and try again.
4000 - 4999	Cartridge protocol failure	Test results were not able to be calculated due to suspected system failure. Discard cartridge, insert a new cartridge, and retest sample.
5000	Internal control failure	The internal control did not amplify. Retest the sample.
10000 - 10999	System error	Test results were not able to be calculated due to suspected system error. Discard cartridge. Restart instrument before retesting sample.




















9. Troubleshooting

Issue	Description / Solution
Fuse Replacement	<p>If the instrument does not power on after a system reset, the fuses likely need to be replaced.</p> <ol style="list-style-type: none"> 1. Power down the FINDER 1.5 Instrument by flipping the switch to the off position. 2. Remove the power cable. 3. Remove the fuse holder using a number 1 or smaller screwdriver underneath the red piece. 4. When in place, pull the screwdriver toward you and the fuse module will slide out. 5. To replace the fuses, place the screwdriver gently underneath the end of each fuse and gently push up. Repeat on the other fuse. Place the replacement fuses into the slots by gently pushing down at the ends. 6. Reinsert power entry module. 7. Insert the power cable and flip the power switch to the on position.
The reagent cartridge is stuck in the deck	<p>If the deck motor failed to disengage the New Run button will display a warning stating the deck is closed.</p> <ol style="list-style-type: none"> 1. Do NOT attempt to pull a cartridge out of the instrument. 2. Using the deck actuation tool, insert the tip of the tool into the cartridge release button on the side of the instrument. 3. After turning the tool 180 degrees, the deck should open. 4. Remove the reagent cartridge using the grips.
The New Run icon blinks between blue and red or the Error button selection reads instrument not level	<p>Select the New Run button when it displays an error. If the instrument is found to be unlevel, relevel the instrument.</p> <ol style="list-style-type: none"> 1. Reset the application by pressing the menu icon and swiping left to terminate the VIEWER application. 2. Open the app by swiping up on the android home screen, and select the VIEWER Application. 3. Relevel the instrument by adjusting the three feet until the application allows you to continue.
"Cartridge Connection Failure" message	<p>If the following error "Cartridge Connection Failure" is displayed after initialization, remove the cartridge and cancel the run. Press "NEW RUN" and follow the onscreen instructions to retry initialization.</p> <p>If the "Cartridge Connection Failure" appears after retesting, the instrument deck should be cleaned using the cleaning accessory.</p> <ol style="list-style-type: none"> 1. Remove the FINDER SARS-CoV-2 Cartridge from the instrument. 2. Acquire the cleaning accessory (P/N: 4076) and an IPA spray bottle 3. Lightly saturate the Velcro portion of the Cleaning Accessory with isopropyl alcohol (IPA). 4. Insert and remove the FINDER Cleaning Accessory into the instrument three (3) times to clean the pins. 5. Wait 1 minute and put the accessory back in the resealable pouch. 6. Press "NEW RUN" and follow the onscreen instructions to retry initialization on the original cartridge.

Issue	Description / Solution
	<p>7. If the issue persists, discard the cartridge and retry initialization with a new cartridge.</p> <p>Note: the FINDER 1.5 Cleaning Accessory should be replaced weekly; following one week of use, the Cleaning Accessory should be discarded and a new one should be used.</p>
Software Process Error	<p>If the Export Results, Software Upgrade, or Instrument Syncing process take unusual amounts of time (>15 min), contact FINDER Technical Support.</p>
Barcode Scanner does not turn on	<ol style="list-style-type: none"> 1. Power cycle the device 2. Ensure the tablet is locked in place using the key 3. Terminate the FINDER Viewer Application by pressing the "Context" button followed by swiping left 4. Reopen the FINDER Viewer Application by pressing the app from the Android home screen
Barcodes Fail to Scan	<p>CLSI compliant specimen barcodes and 2D cartridge barcodes may be easily scanned by the instrument. User barcodes that are significantly larger or smaller than specimen barcodes may have difficulty scanning. If barcodes are difficult to scan, the following actions should be performed:</p> <ol style="list-style-type: none"> 1. Ensure the barcode is being held perpendicular to the barcode scanner. 2. Gently wipe down the barcode window using a lint-free cloth and 70% Isopropyl alcohol 3. If the issue persists, contact FINDER Technical Support.

10. Symbols and Abbreviations

The following symbols/abbreviations may appear on the instrument, product labels, and in this document:

Symbol	Description
	Caution, hot surface
	Potential hazard
	Warning or Caution
	<i>In vitro</i> diagnostic medical device
	Reference item number
	Manufacturer name and/or physical location
	Date of manufacture
	Date of expiration, use-by date
	Lot number
	Serial number
	Storage or transit temperature limits
	Humidity limitations
	Total number of tests that can be performed with the IVD
	Single-use only, do not re-use
	Consult instructions for use
	Keep away from sunlight
	Alternating current (AC)
	Rated power input, alternating current
	Fuse specifications
RX only	Prescription device only
QTY	Quantity of contents