DRW
Diagnostics for the Real World

SAMBA III Tablet Module

Software User Guide

C19-0123-EN, Version 6.0

REF I19-0007-TM

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Safety

Read these operating instructions carefully and fully before use.

The following symbols are used in this document, the associated equipment and packaging.

In Vitro Diagnostic medical device

Catalogue number

Serial number

Caution

Consult instructions for use

Manufacturer

Authorised representative in the European Community

Do not dispose of instrument with regular waste

Device for near-patient testing

Consult the tablet and printer manufacturers User Guides for further safety information

Warnings & Precautions

- Always wear gloves when using the SAMBA III Instrument System. In addition, it is recommended that the operator wears safety glasses and a laboratory gown.

- Do not expose the SAMBA III Tablet Module or Printer to direct heat, water, or chemicals. Always use the Tablet with the protective case fitted.

- Do not operate any SAMBA III Tablet Module or Printer or conduct any tests without proper training.

- Do not upgrade the operating system for the tablet.

- Do not download or install any other applications on the Tablet.

- Do not use these instruments in close proximity to sources of strong electromagnetic radiation, as it may interfere with proper operation.

- Use of these instruments in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets etc.), may cause damaging static discharges.

- Do not change any of the Tablet settings. The Tablet is supplied set up and ready to use. Changing settings could affect communication with the Assay Module and effective transmission of the results via Bluetooth connection

- If the Tablet and Printer are not used in a manner specified by the manufacturers, the protection provided with the equipment may be impaired. Refer to the Tablet and Printer manufacturers' User Guides for more information.

NOTE	In the event of any serious incident that occurs in relation to the TM, please report to Diagnostics for the Real World (Europe) Ltd, Authorised Representative and the Competent Authority of the Member State in which the user and/or the patient is established.

Intended Purpose

The SAMBA III Instrument system (SAMBA III Assay Module and SAMBA III Tablet Module) is an automated sample extraction, nucleic acid amplification (isothermal or polymerase chain reaction) and real-time fluorescence nucleic acid detection system. The SAMBA III Instrument system is used solely in combination with SAMBA III Reagent kits for qualitative, quantitative, or semi-quantitative reporting of test results. The SAMBA III Instrument system is intended for use by trained laboratory staff within either centralised hospital laboratories or near-patient environments.

Product description and principle of operation

The SAMBA III Instrument system consists of the SAMBA III Assay Module and the SAMBA III Tablet Module. Each SAMBA III Assay Module (AM) is a small automated robotic machine that processes a set of single-use SAMBA III cartridges which hold all the reagents and materials required to process the input sample. The SAMBA III cartridges are designed to be fully disposable and single use and thus contain all components needed, e.g. reagents and pipette tips. The AM consists of various motor-driven axes of movement, a syringe pump and a number of temperature-controlled zones including thermo-cycling zones for the PCR process. A positive PCR product is detected by an optical module using fluorescence emitted by fluorescent tags linked to specific target probes.

The SAMBA III Tablet Module is the user interface for running of the SAMBA test in the Assay Module and can control up to eight (8) Assay Module units. The Tablet Module has the capability to connect to a Bluetooth printer and an option for connectivity to the institution's Laboratory Information Management System (LIMS) as well as data management system.

DISCLAIMER

A manual record of the test results must be maintained against the patient records in accordance with the established protocols of the organisation or institution.

Diagnostics for the Real World (Europe) Ltd is not liable for any loss of data or any failure to maintain records as deemed by the organisation or institution

Refer to the tablet and printer manufacturers User Guides for servicing requirements of the tablet, printer, and their chargers.

Installation

Refer to the Tablet and printer manufacturers' User Guides for details on unpacking, charging and basic operation on storage and shipping. The TM software is designed to run on a Zebra ET-40 tablet device. The User Interface is optimised for this device's screen size and has been fully tested to ensure Bluetooth (BLE) connections work as required.

The installable software comes as an .apk file and will be named:

`samba3_tablet_app_vA.B.C.apk`

Where A.B C is the version number of the software.

To install the software on the tablet, copy the installable file onto a suitable USB stick (i.e. with a USB C connector) and plug this into the tablet's USB port. Navigate to the **Files** app on the tablet's Android OS and locate the USB stick. Tap the installable file in the list of files on the stick and follow the instructions and prompts to install the file.

When installed, the SAMBA III Software App should appear as an icon (SAMBA III) on the main page of the tablet. For convenience, move this to the tablet's Home screen if desired.

Tap the app's icon to start the software.

First Use

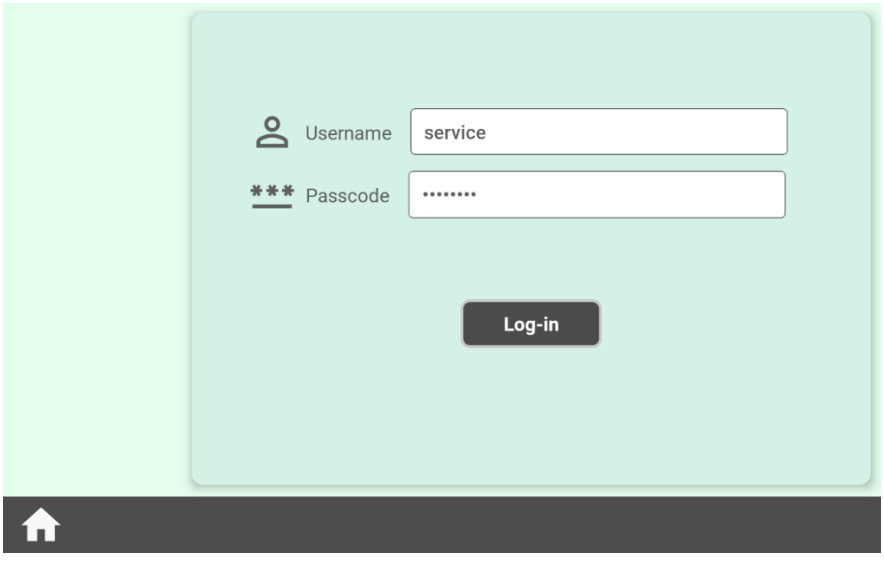
When the app starts, the Welcome screen will be presented:

Tap anywhere on this screen to proceed.

Logging-in

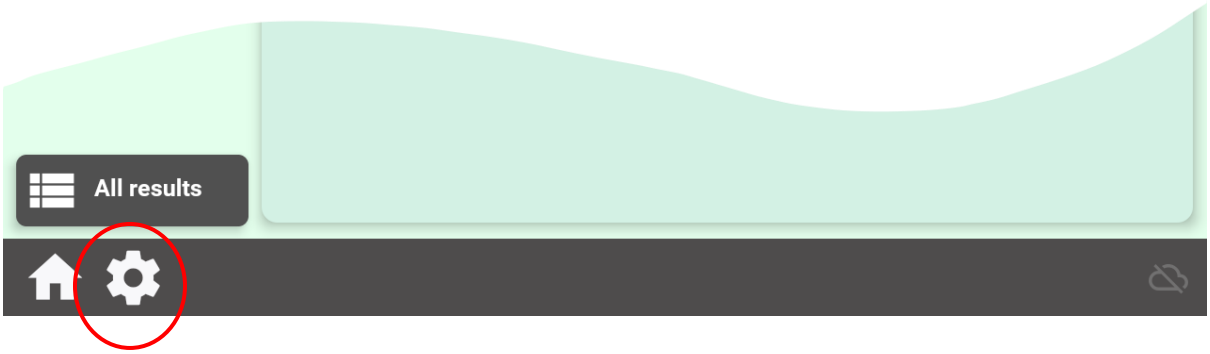
On a new tablet that is being used for the first time, it will be necessary to log-in as a Service Operator to configure the initial settings and to create some basic user accounts or connect to a SAMBA III Assay Modules.

On the Log-in screen:



Enter the username: **service** and password: **d4xt36;P** then tap the ***Log-in*** button.

When logged-in, navigate to the **Settings** screens by tapping the 'gear' icon in the bottom left of the screen:



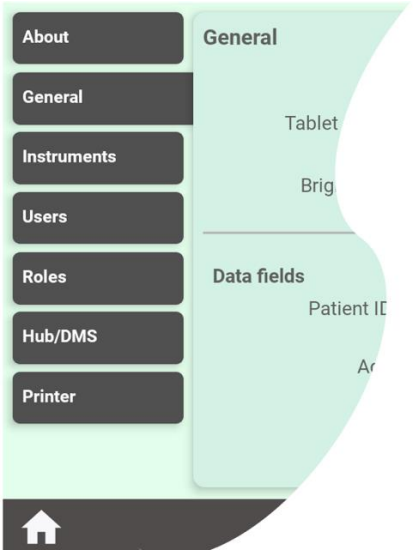
For a full description of all settings, pleases refer to the Settings sections below. As a minimum, it is advisable to configure the following:

- Tablet name (**Settings** > ***General***)
- Required Data Fields (**Settings** > ***General***)
- Connected Instruments (**Settings** > ***Instruments***)
- User Accounts (**Settings** > ***Users***)

NOTE: The default credentials "service" and "d4xt36;P" should only be used for initial setup, as there will be restrictions in place for this user account. After initial log-in, navigate to the "User Accounts" settings as above to setup new users.

Settings

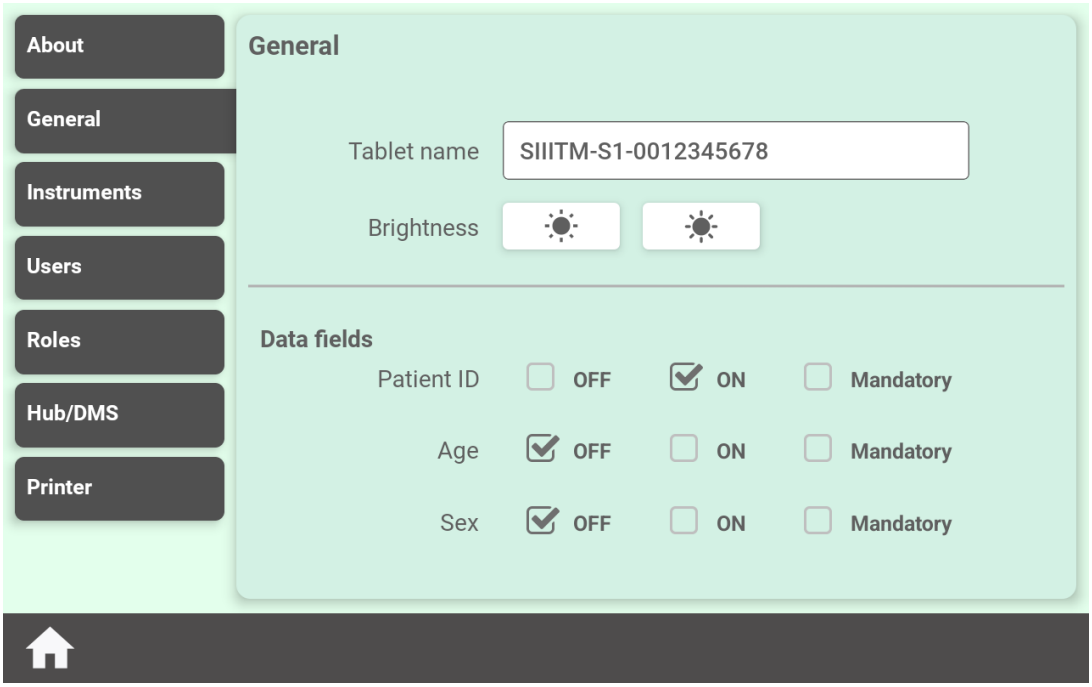
To access the **Settings** screens, tap the 'gear' icon at the bottom left of the **Main** screen. This will show the ***General*** settings screen, with the other settings screens available by tapping the tab buttons down the left-hand side.



The function of each Settings tab is described below.

General

This ***General*** tab is used to give a name to the tablet, to adjust the screen brightness and to configure which patient data fields are in use.



Tablet name

The tablet name is entered into a freeform text field. Any changes to this field are automatically saved when you leave this screen.

Brightness

Adjust the screen brightness using the brightness buttons. Permission may be required for these adjustments upon the initial implementation of any changes.

Data Fields

When using the tablet in 'stand-alone' mode (i.e. without a Hub/DMS connected and configured to use the DMS data field configuration), the scrollable list of fields that can be used for patient data entry and result display is shown.

Each field can either be **OFF**, **ON** or **Mandatory**. When **Mandatory** is set, an assay will not be allowed to start until the associated data field is populated with data during the test setup.

Additionally, it is possible to enable/disable the display of Ct value and Constituent Targets. When either of these is **Enabled**, a ***Show Details*** button will appear on all results screens, and when pressed, it will reveal the Ct values and/or Constituent Targets as appropriate. The constituent targets apply to test targets which have more than one constituent target constituting a result, for example SARS-CoV-2 has two separate gene targets, both feeding into a single result, with gene targets being visible when the Constituents target field is enabled.

Roles

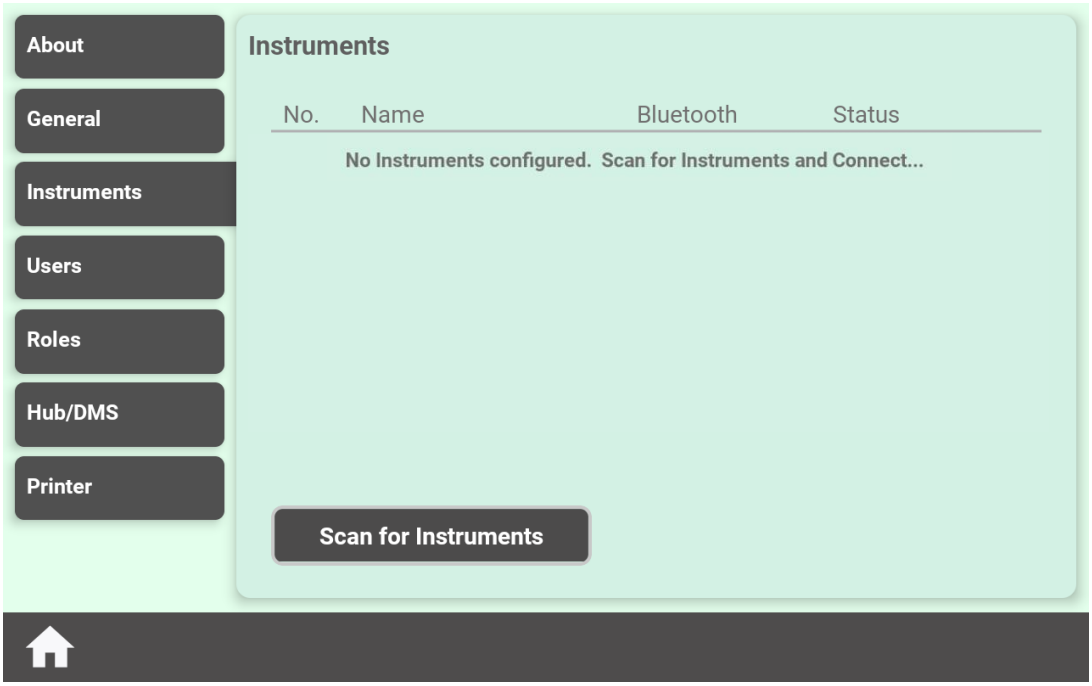
The ***Roles*** settings tab is where user roles (Clinician or Admin) can be defined. Each field can be defined as permissions granted to either the Clinician or Admin role. The fields defined for each role will define what permissions each user type will have access to.

Hub/DMS

The ***Hub/DMS*** settings tab is where (if applicable) the connection address to the Hub/DMS can be input, allowing the tablet module to communicate with the Hub/DMS. Each of the settings fields can be set to **OFF** or **ON**, which will determine if the feature is enabled or not.

Instruments

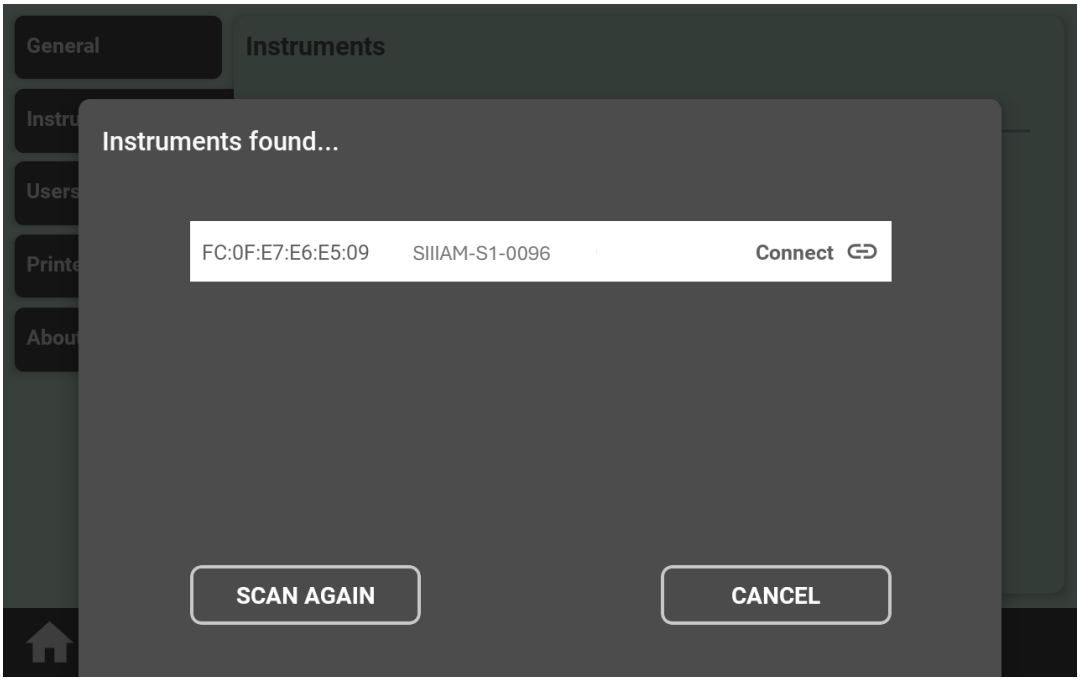
The ***Instruments*** settings tab is where all Assay Module connections are configured and managed. Initially there will be no known Assay Modules, so available Instruments will need to be scanned for, selected, paired, and connected.



Scan and Connect

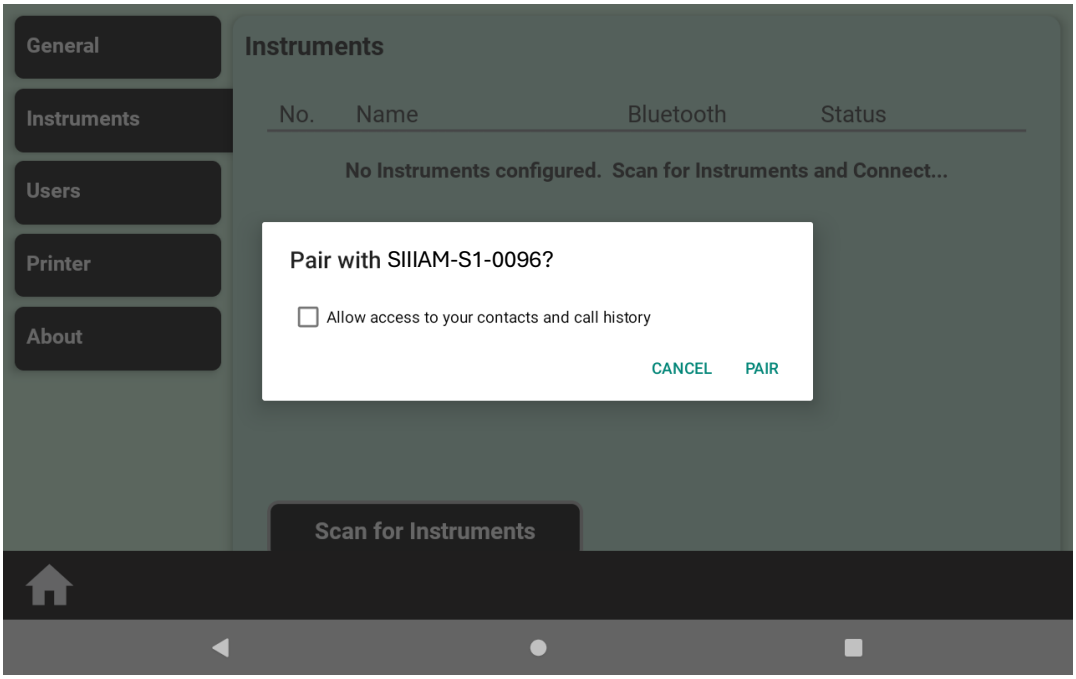
The first step to connect Assay Modules to the tablet is to scan and find nearby Instruments. Ensure that the instruments intended for connection are powered on, then tap the ***Scan for Instruments*** button.

After a few seconds, available instruments should be listed on the tablet screen



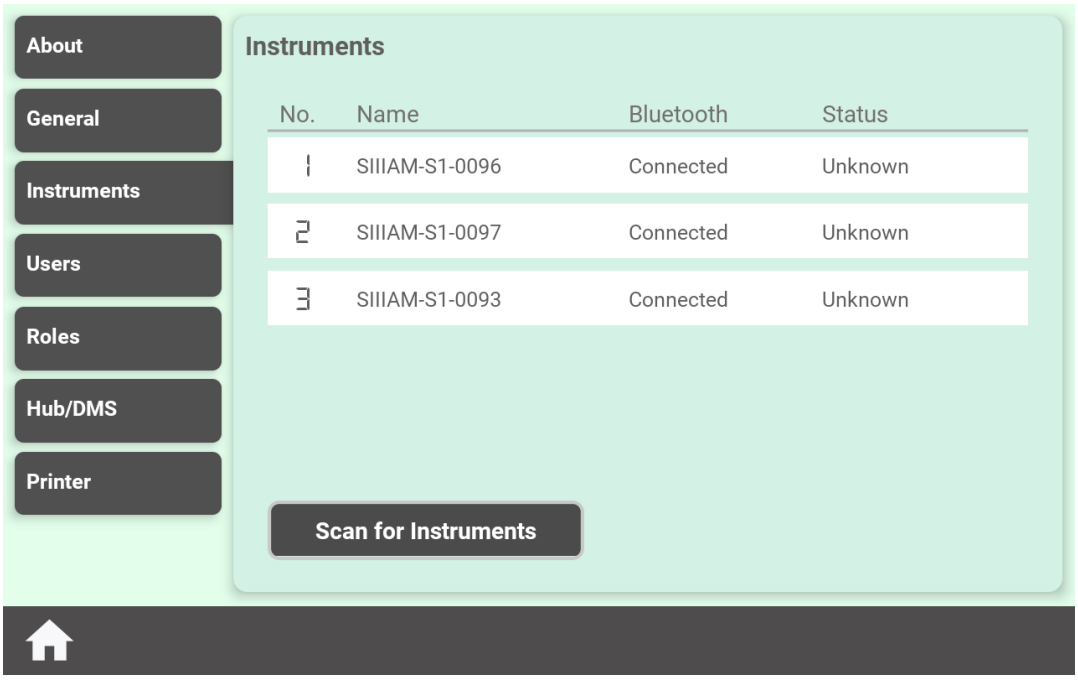
If the expected Instruments don't appear in the list, make sure they are powered-on then tap the ***Scan Again*** button.

When the required Instrument is found, tap its row in the list to initiate the connection process. A prompt to 'pair' will appear as part of the Bluetooth bonding process.



Tap the ***Pair*** button to confirm the connection.

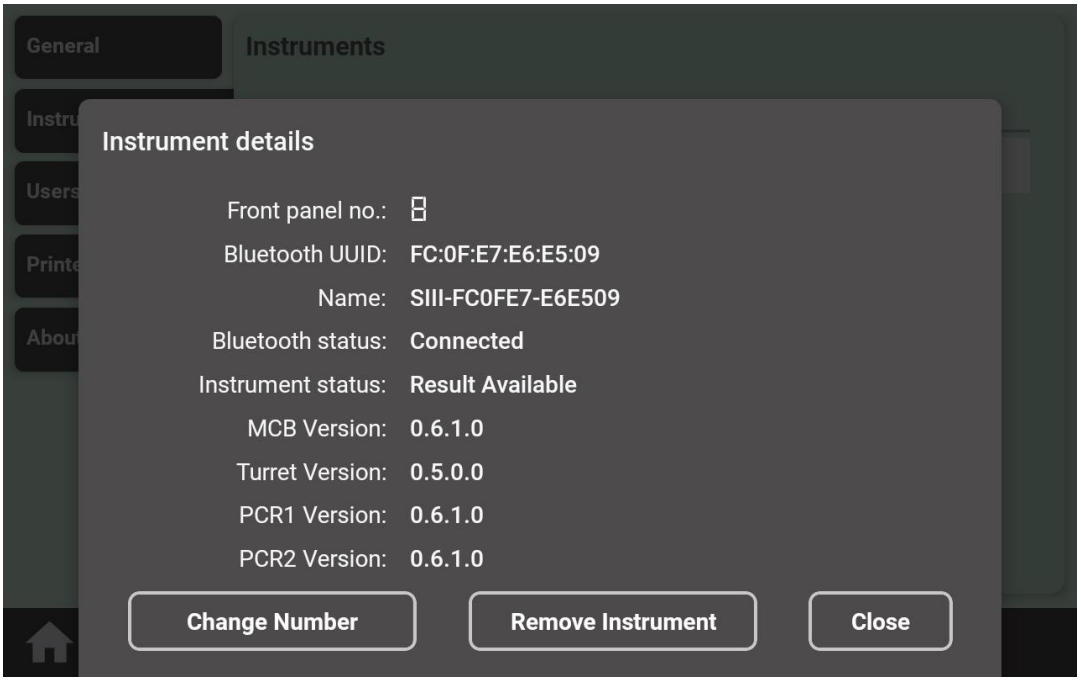
When the Instrument is successfully connected, it will appear in the list of known instruments.



The Instrument's Name, Bluetooth condition and Status will be displayed along with its Front Panel number. In the screen shown above, an Instrument with Front Panel number 8 is connected, and it currently has an assay result available.

Instrument Details

Full instrument details can be viewed by tapping an instrument row in the list.

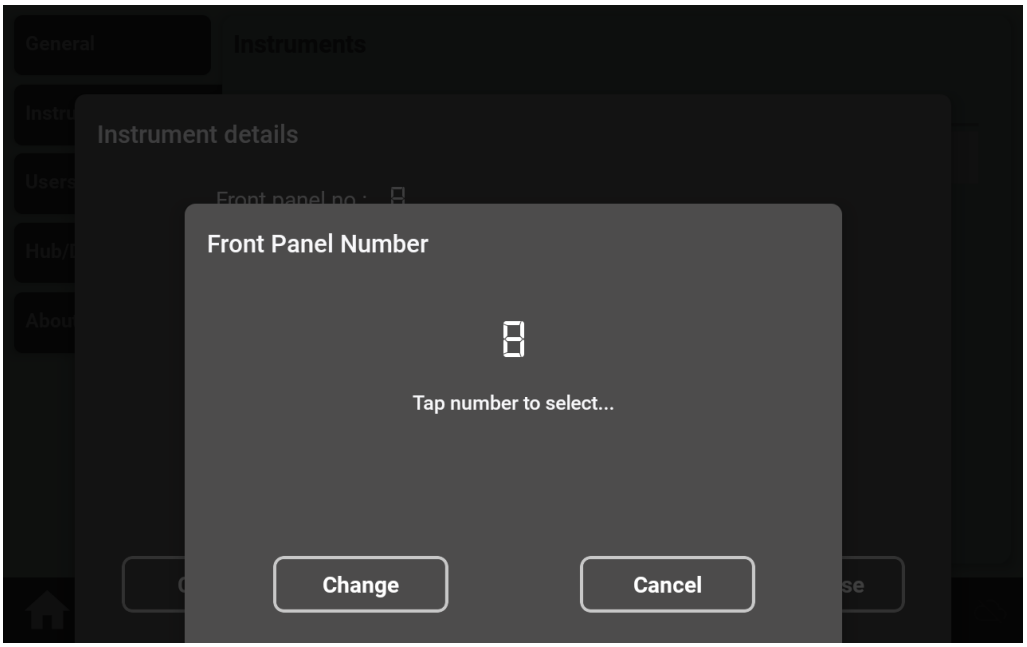


This will show the Instrument 'Details pop-up' with all known details about the instrument, including:

- Front panel number
- Bluetooth ID
- Instrument name
- Bluetooth status
- Instrument status
- MCB Firmware version

Change front panel number

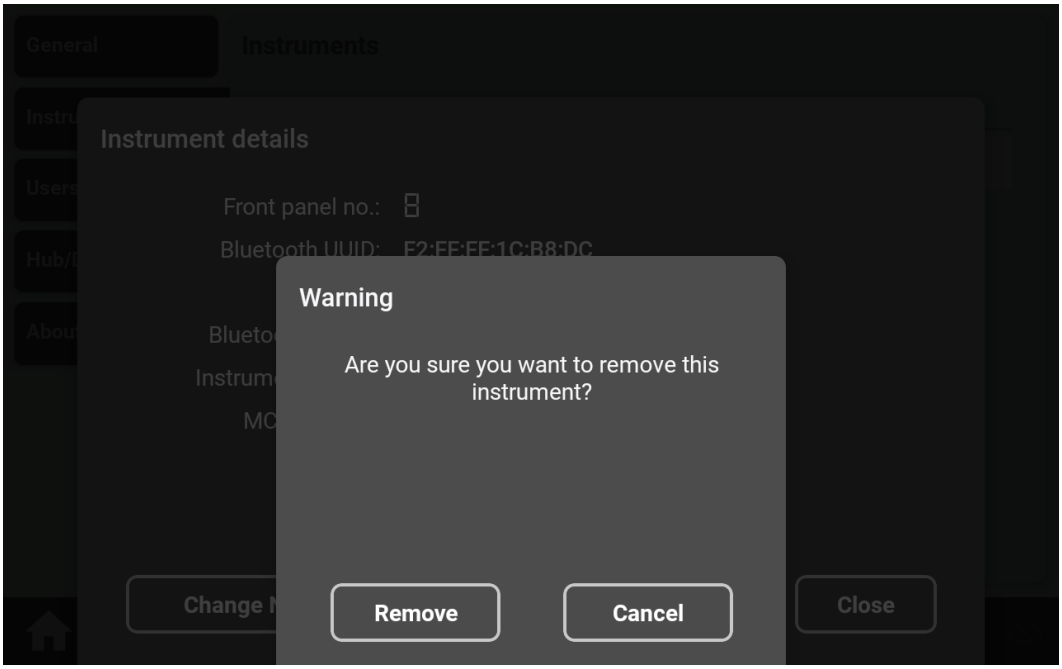
From the 'Instrument Details pop-up', tap the ***Change Number*** button to show the pop-up for changing the instrument's front panel number.



Tap the current number (***8***) to show the list of available numbers (1 – 19) and tap one of them to select. Tap the ***Change*** button to confirm the change and to send the new front panel number to the instrument.

Remove Instrument

To remove an instrument from the list of known Assay Modules, bring up the 'Instrument Details pop-up' (by tapping the required instrument row in the list of instruments) and then tap the ***Remove Instrument*** button.



Confirm the removal by tapping the ***Remove*** button. The Instrument will be removed from the list of known instruments and the tablet will no longer try to connect to it.

Users

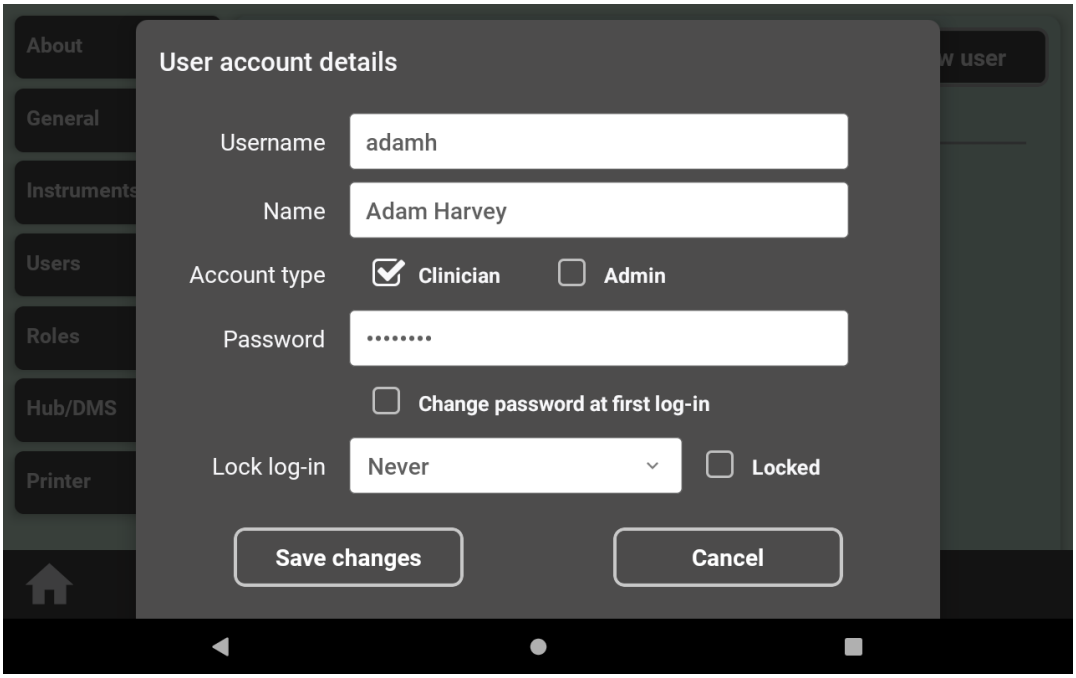
To create, modify, and delete user accounts on the Tablet Module, go to the ***Users*** settings tab.

Note: The Tablet Module's user accounts are only used when the tablet is in 'stand-alone' mode (i.e. without a Hub/DMS connected and configured to use the Operator Login option).

Initially the tablet will have no User Accounts defined.

Create User Account

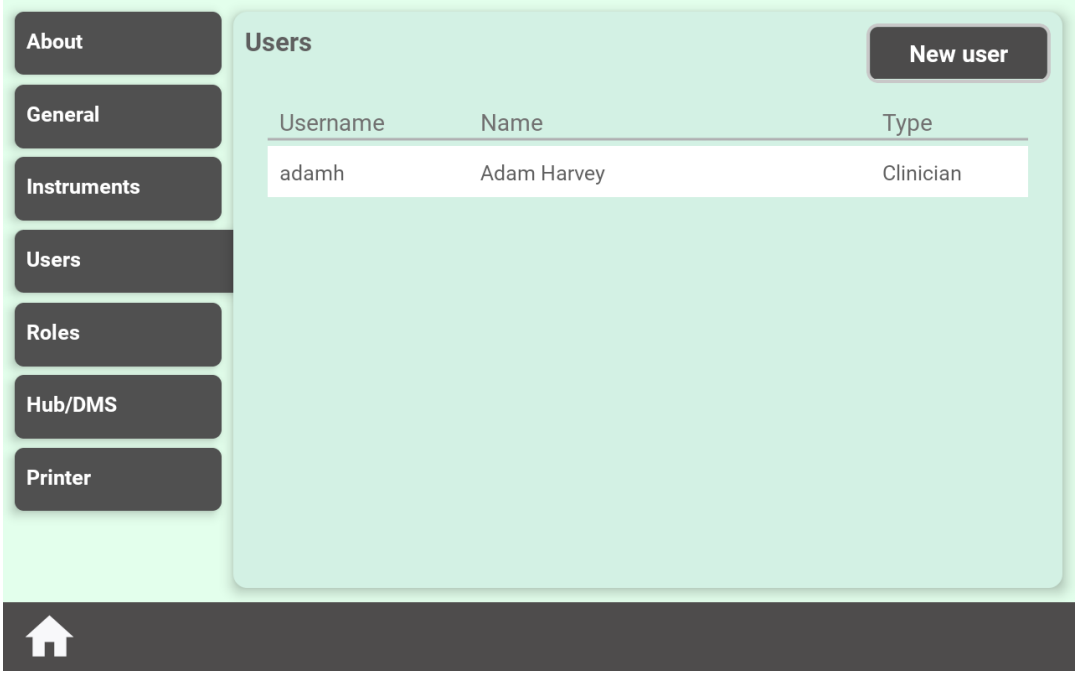
To create a new user account, tap the ***New user*** button and fill-in the required details in the pop-up that is shown.



The data fields are as follows:

- **Username** – to be used as input when logging-in.
- **Name** – the full name of the user.
- **Account type**
  - **Clinician** provides basic access to run assays and view results.
  - **Admin** provides full access to all settings and configuration options.
- **Password** – (optional) the password to be used when logging-in. This can be left blank if only a username is required for log-in.

To confirm and save the new account, tap the ***Save changes*** button. It will appear in the list of all User Accounts.



Modify User Account

To modify an existing User Account, tap the row in the list of user accounts. The account details pop-up will be shown and allow any changes to be made. Tap the ***Save changes*** button to confirm and save the modified patient details.

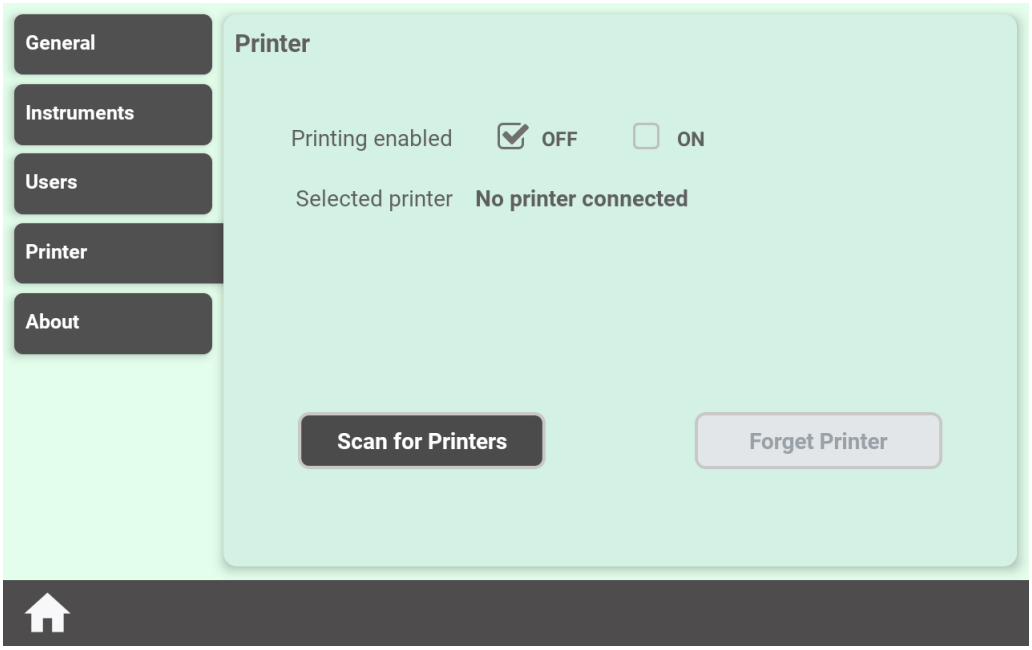
Delete User Account

To delete an existing User Account, tap the row in the list of user accounts. The account details pop-up will be shown. Tap the ***Delete User*** button, and when the confirmation pop-up is shown, tap ***Delete User*** again.

The account will be deleted from the tablet and the user will no longer be able to log-in.

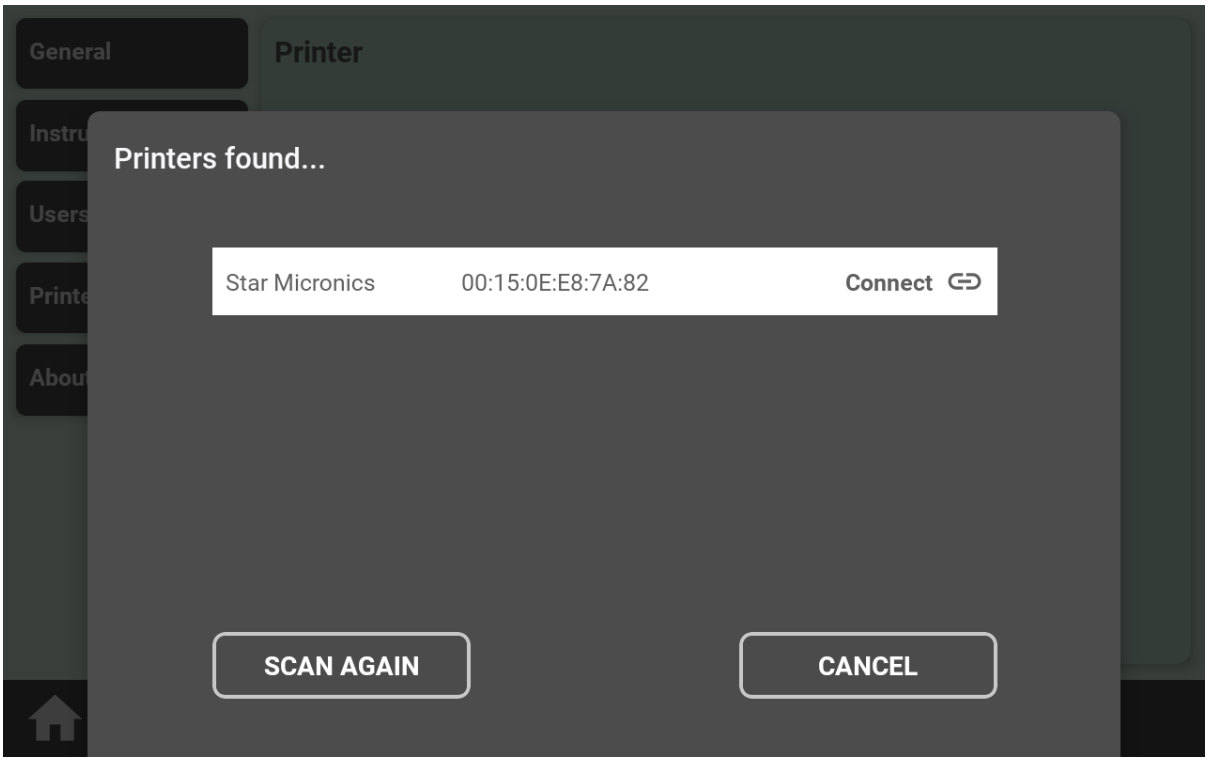
Printer

To configure a Bluetooth printer, go to the ***Printer*** tab.

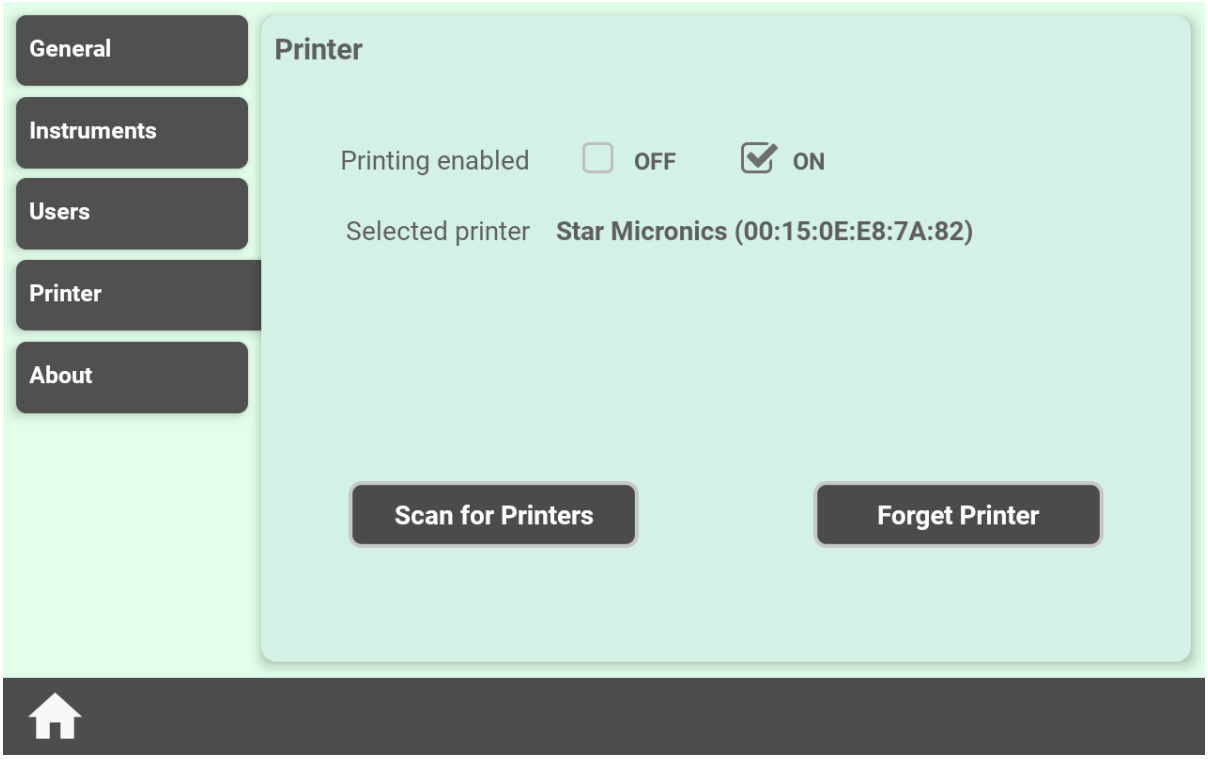


The SAMBA III Tablet is designed to operate with a Star Micronics SM-230i Bluetooth printer. To configure the printer, follows these steps:

1. Ensure the printer is powered-on.
2. Tap the ***Scan for Printers*** button to initiate a search for available printers. Note this may take 30 seconds or so.

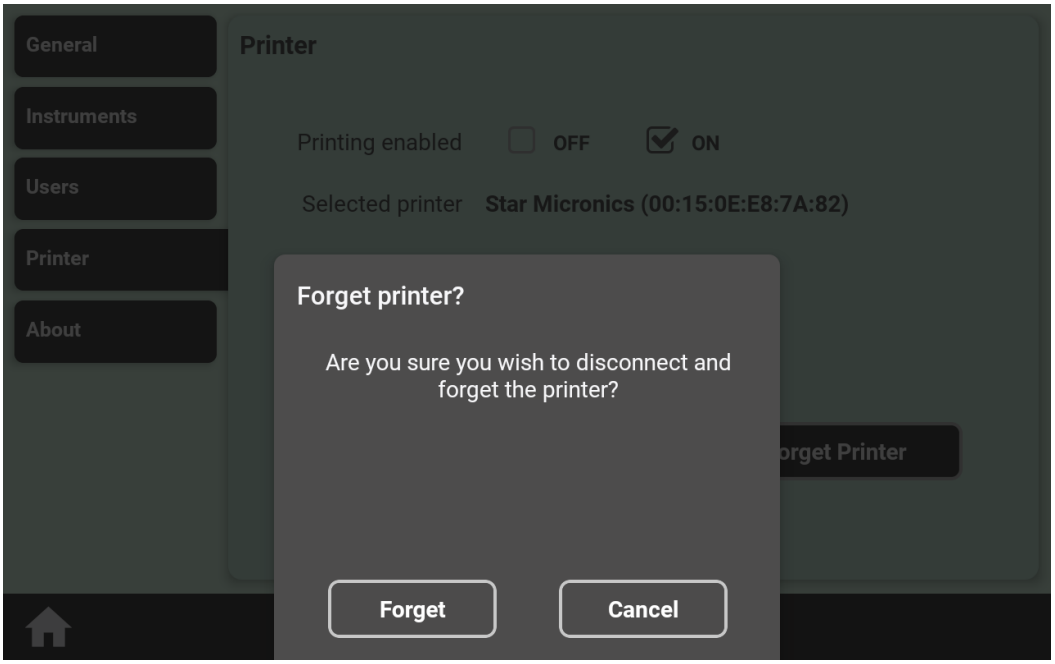


3. When your printer is found, tap it on the screen to select it.



4. Ensure **Printing Enabled** is set to **ON.**
5. Your printer is now configured and ready, and a ***PRINT*** button should appear on all result screens.

To remove the printer configuration, go to the Printer settings tab and tap the ***Forget Printer*** button, then confirm that you wish to forget it.



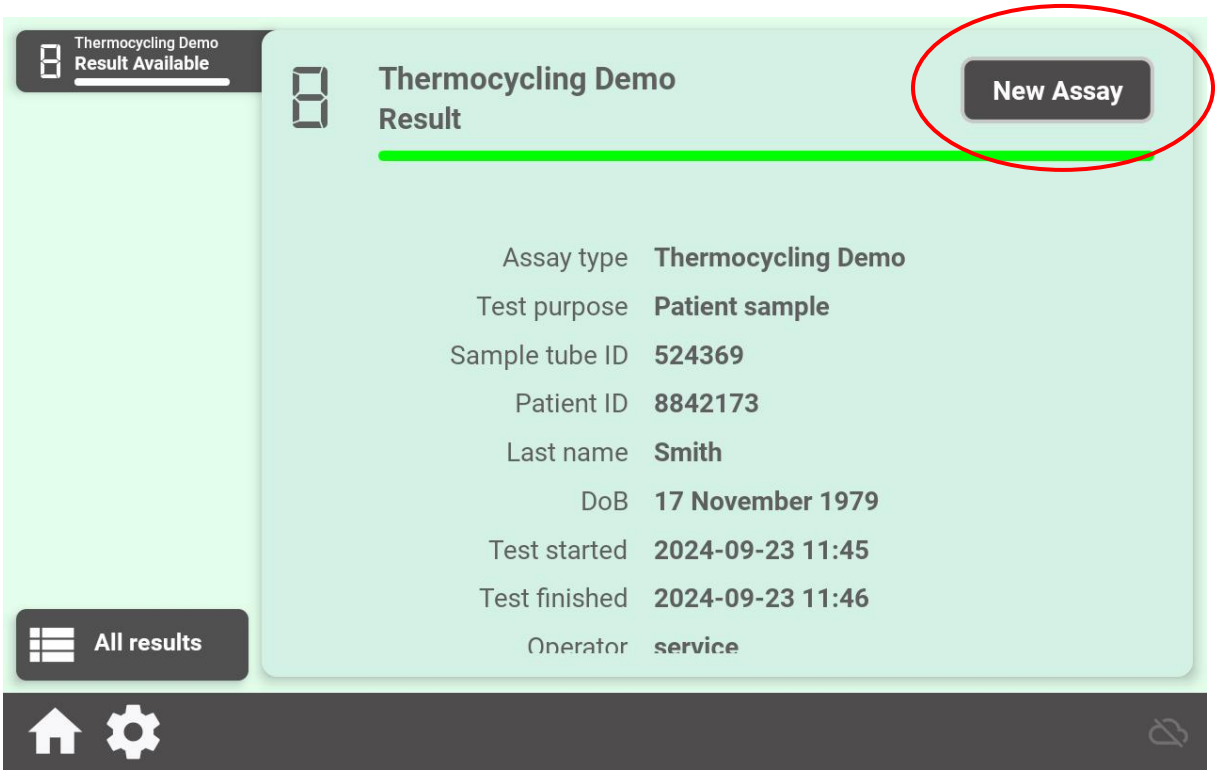
About

The ***About*** settings tab displays information including the Tablet Module part number, the current software version number, the tablet name as entered in the General settings tab, and various address and contact information for DRW. It also displays CE and UKCA regulatory marks.

Running an Assay

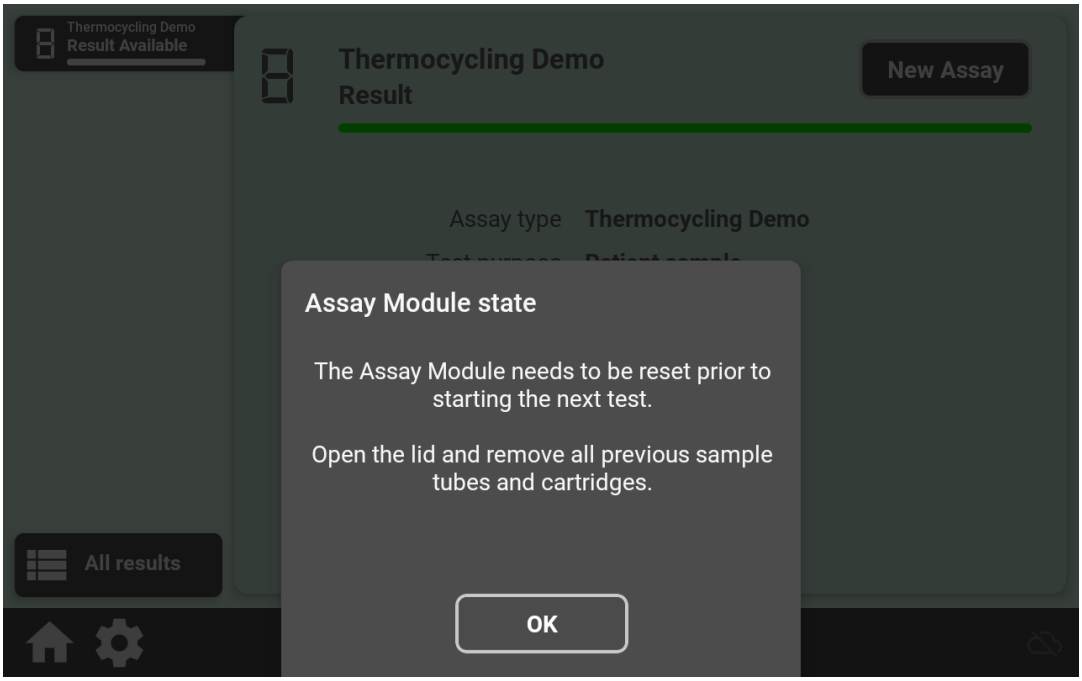
Test Setup

When an Assay Module is available to run new test, it will either be in the Idle or Result Available state. Select the required Assay Module by tapping its tab on the **Main Screen**.

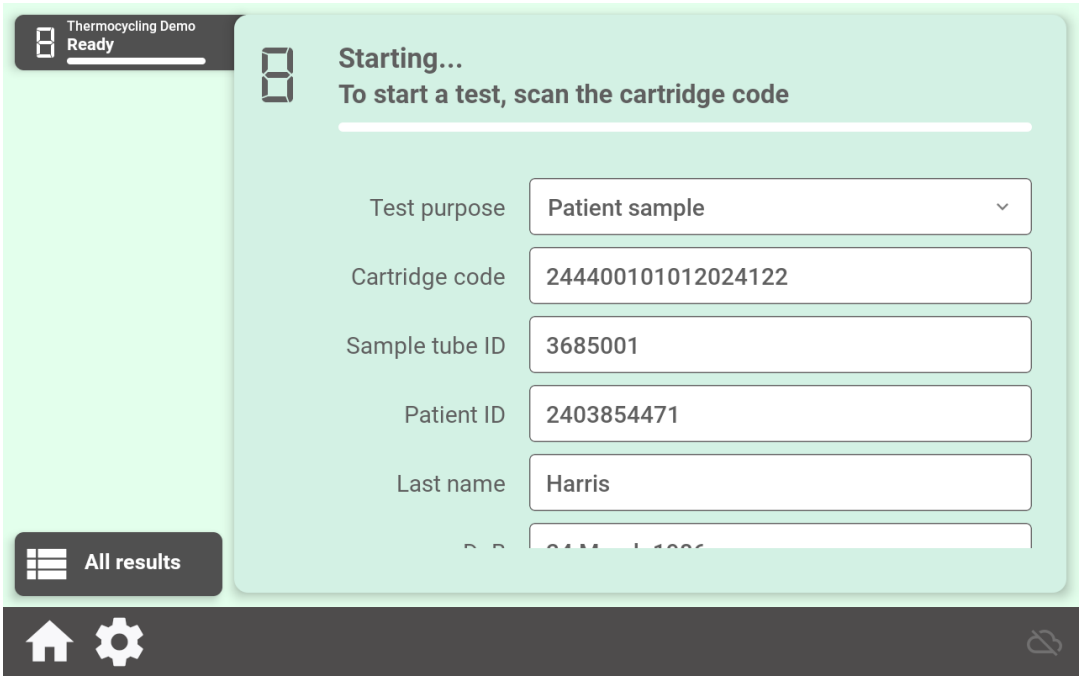


If the previous result is showing, tap the ***New Assay*** button at the top.

If the Assay Module is unable to start a new test, for example, it may still contain the cartridges and sample from the previous test, a warning message may be displayed, prompting to open the Instrument lid and remove the cartridges and sample.



When this has been done, tap the ***New Assay*** button again to proceed to the test setup screen:



1. Select the Test Purpose. This can be one of:

    - Patient Sample
    - QC
    - Training

2. Scan the cartridge QR code using the barcode scanner. With the barcode on the cartridge bag facing the Tablet, move the bag to position the barcode within camera proximity so the barcode can be read. Try moving it closer and further away to determine the best position for scanning.

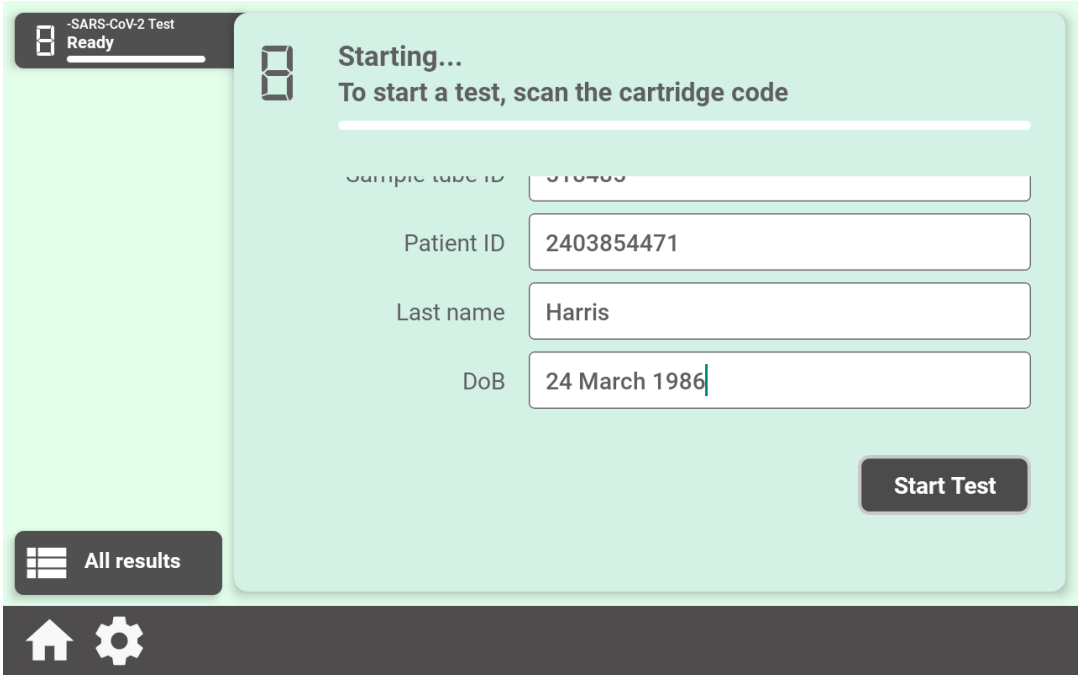
    2.1 If the scanned code is not recognised or the cartridge has expired, a warning message will be displayed.

    2.2 When the Barcode is successfully registered, proceed to next step.

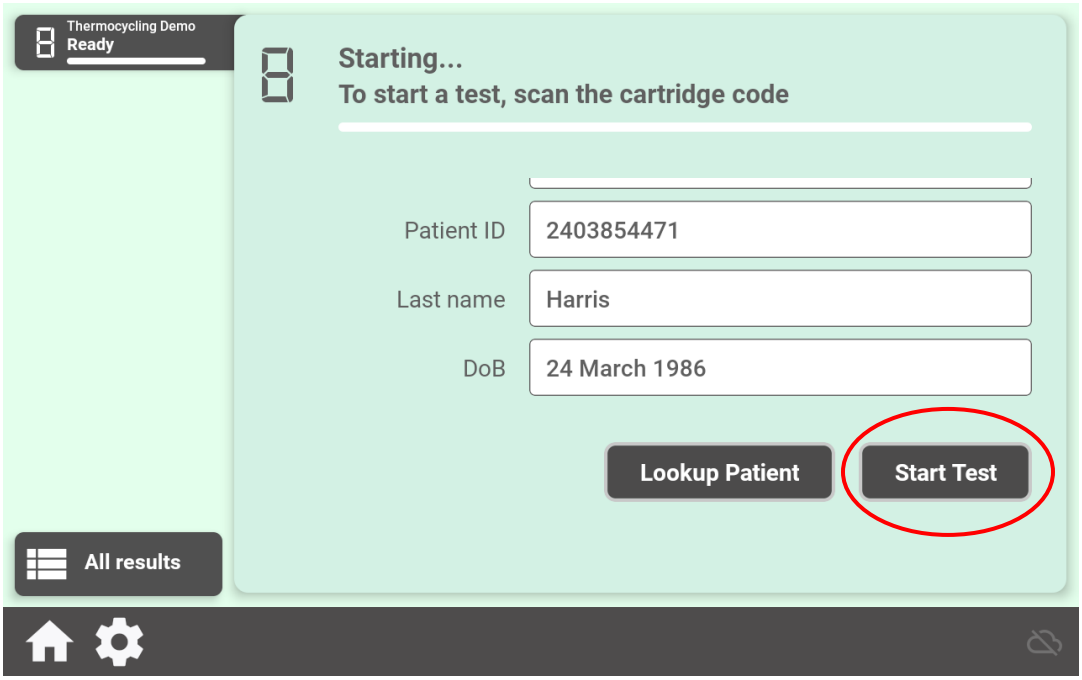
3. Scan the datamatrix code on the front of the sample tube using the barcode scanner on the tablet.

4. Enter the remaining patient details.

    4.1 If any fields have been designated as mandatory in the settings, a message will appear to indicate that all mandatory fields before progressing.



5. When the sample tube and cartridges are loaded, close the lid. The start button will now be available.

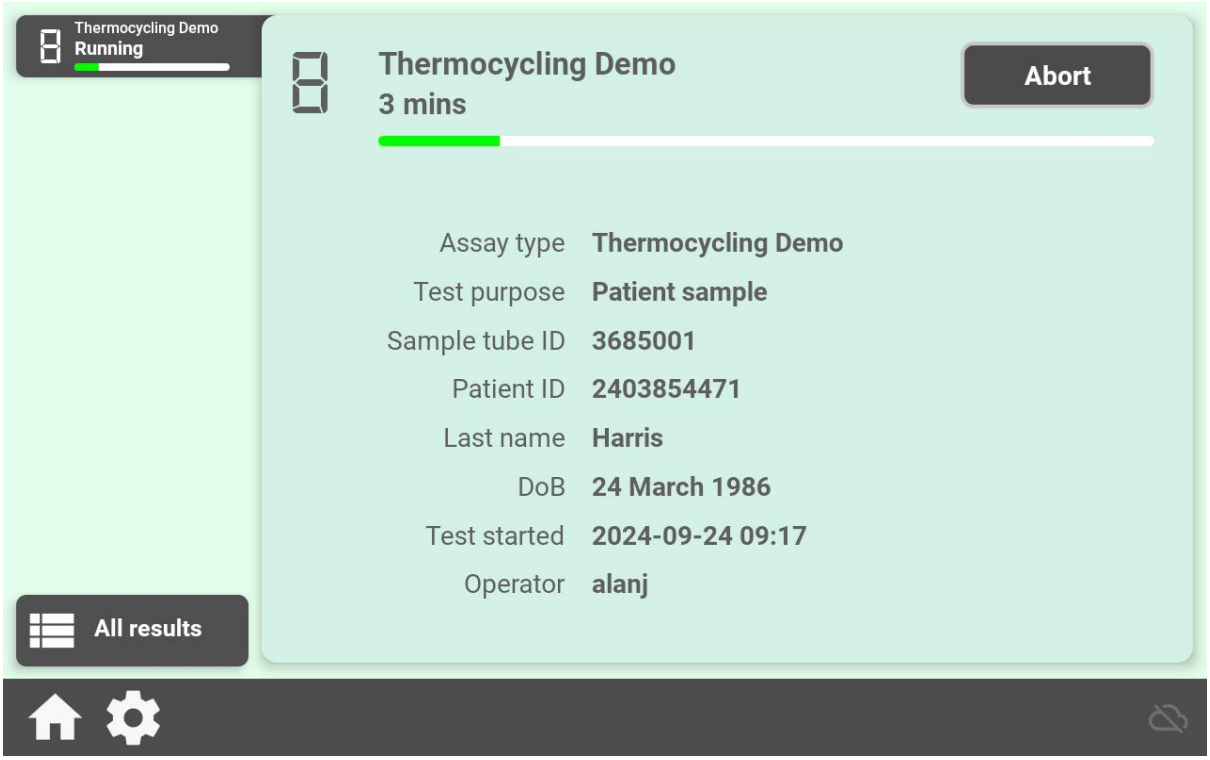


6. Tap the ***Start Test*** button to begin the test.

Note: The ***Start Test*** button will be disabled if the cartridge code is invalid, expired, or unrecognised, if any patient data is invalid or if any Mandatory fields are empty.

Test Progress

When the test is running, the instrument tabs will give a summary of progress, and the main screen will give details progress information for the selected instrument.

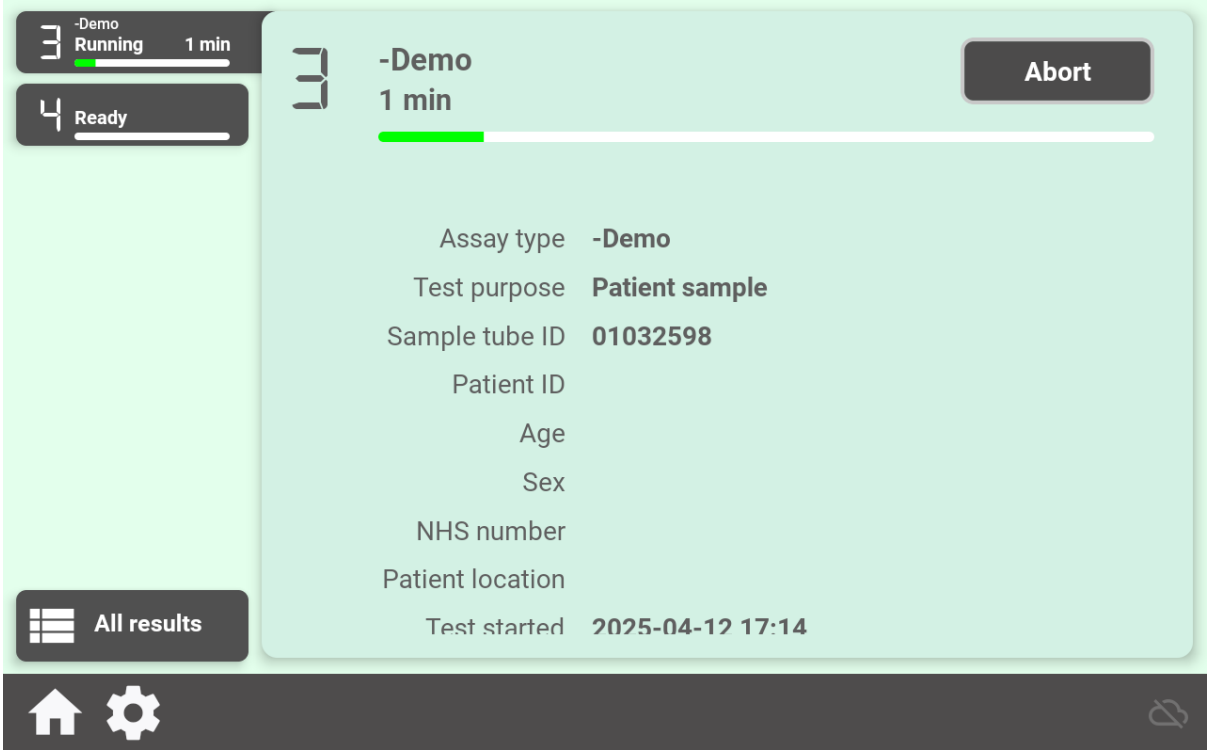


The running assay name will be shown at the top of the screen, progress will be shown as a horizontal bar indicating the percentage complete and the estimated number of minutes to completion will be shown.

The patient details, test start time, and operator name will also be shown.

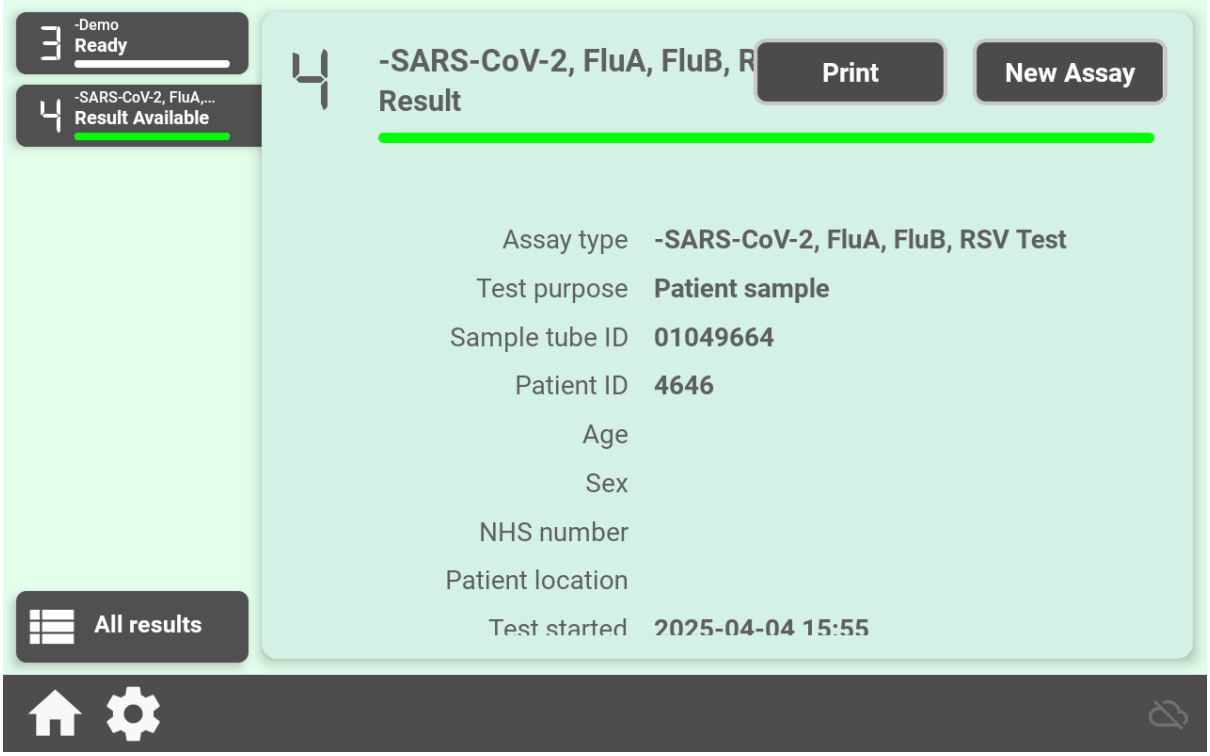
While the test is running, other tests may be started on any available Assay Module(s). To do this, tap the Home button to return to the Main Application Screen.

The Main Application screen shows progress for each test. A new test can be started by tapping the **Ready** button for another Assay Module.

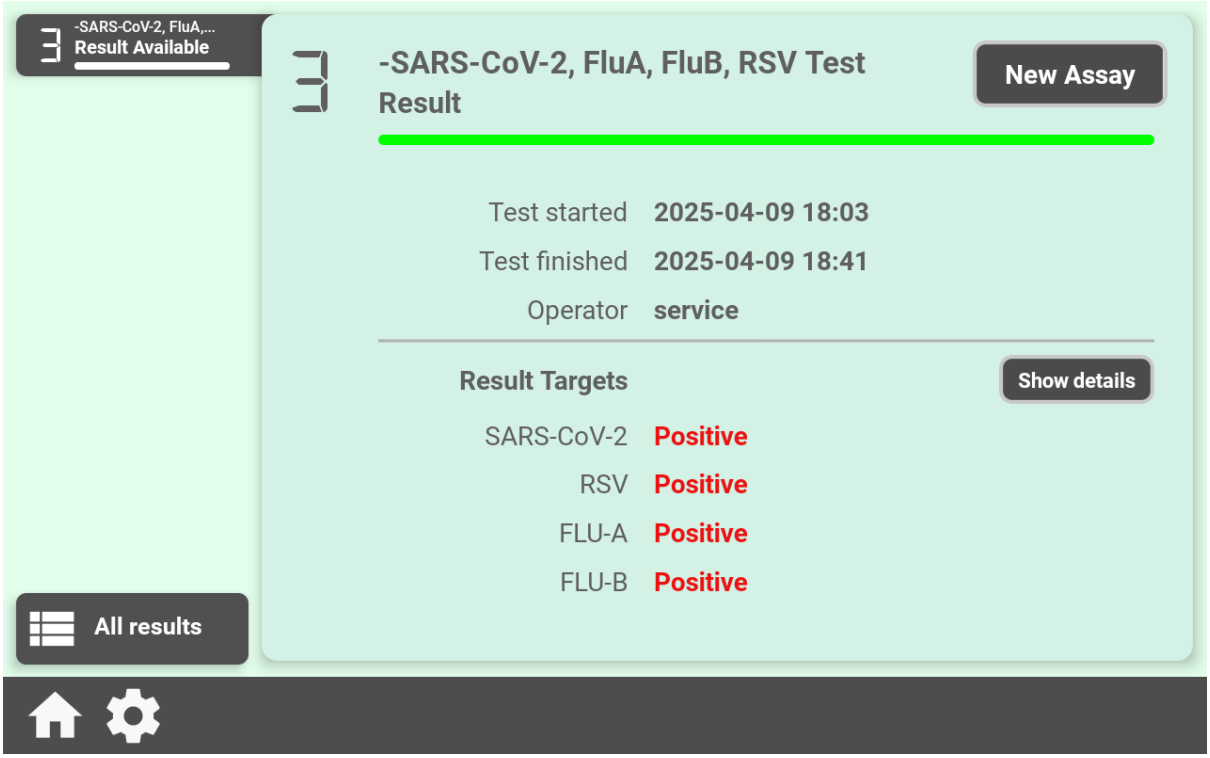


Test Result

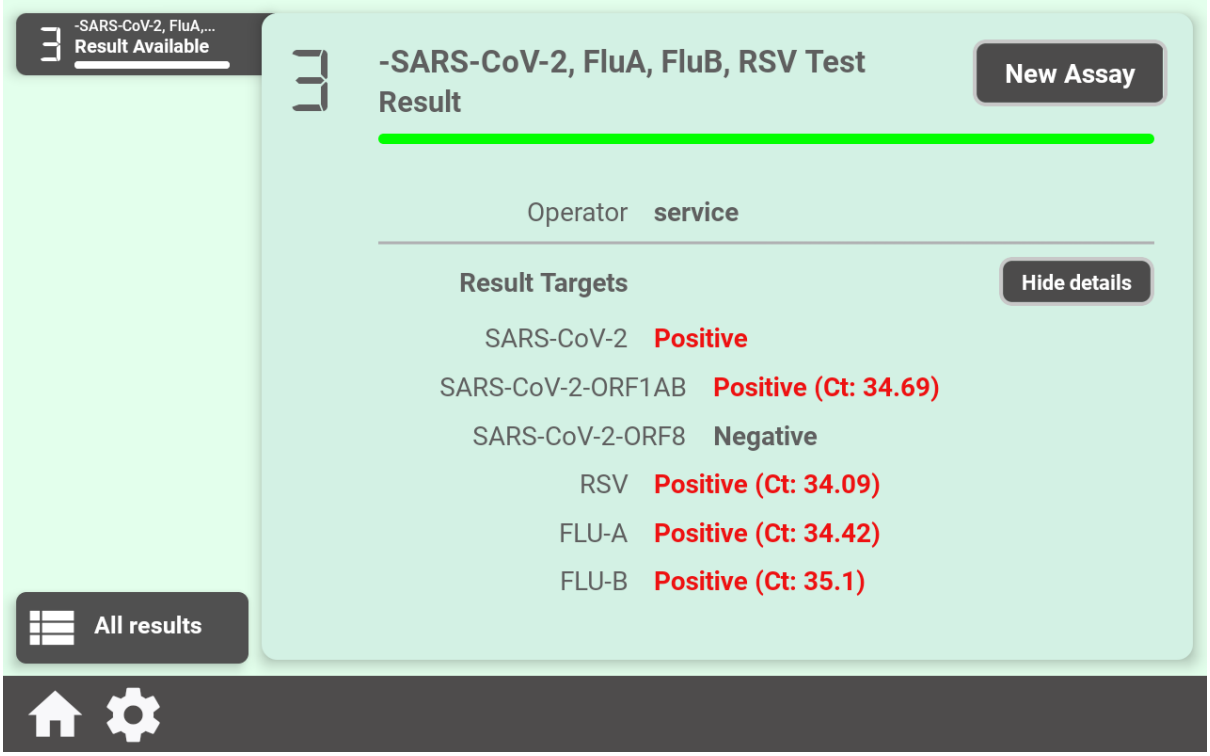
When the assay is complete, the instrument's status will change to Result Available, and the details of the result will be shown.



At the end of the test, a summary of the test details and results are displayed on the Test Result screen. For interpretation of results, refer to Instructions for Use for the corresponding test e.g. SAMBA III SCoV-2/Flu/RSV Test, STI Ulcer Panel etc.



For detailed results (if Ct values and/or constituent results are enabled) press the ***SHOW DETAILS*** button.



NOTE	An **"Invalid"** result indicates that the test needs to be repeated using a fresh sample and cartridges.
	A **"Halted"** result indicates that the test has failed and needs to be aborted and repeated using a fresh sample and cartridges.
	A **"No Result"** result indicates that the instrument has been turned off or lost power and needs to be repeated using a fresh sample and cartridges.
	An **"Aborted"** result indicates that the user Aborted the test by pressing and holding the Abort button.
	An **"Aborted – Lid**" opened during assay. Please retest following the IFU" result indicates that the lid was opened while one of the motors in the machine was running so the test was Halted for safety reasons and subsequently Aborted by the user. The test needs to be repeated using a fresh sample and cartridges.

The Test Result screen also has two buttons - ***PRINT*** and ***START NEW ASSAY***

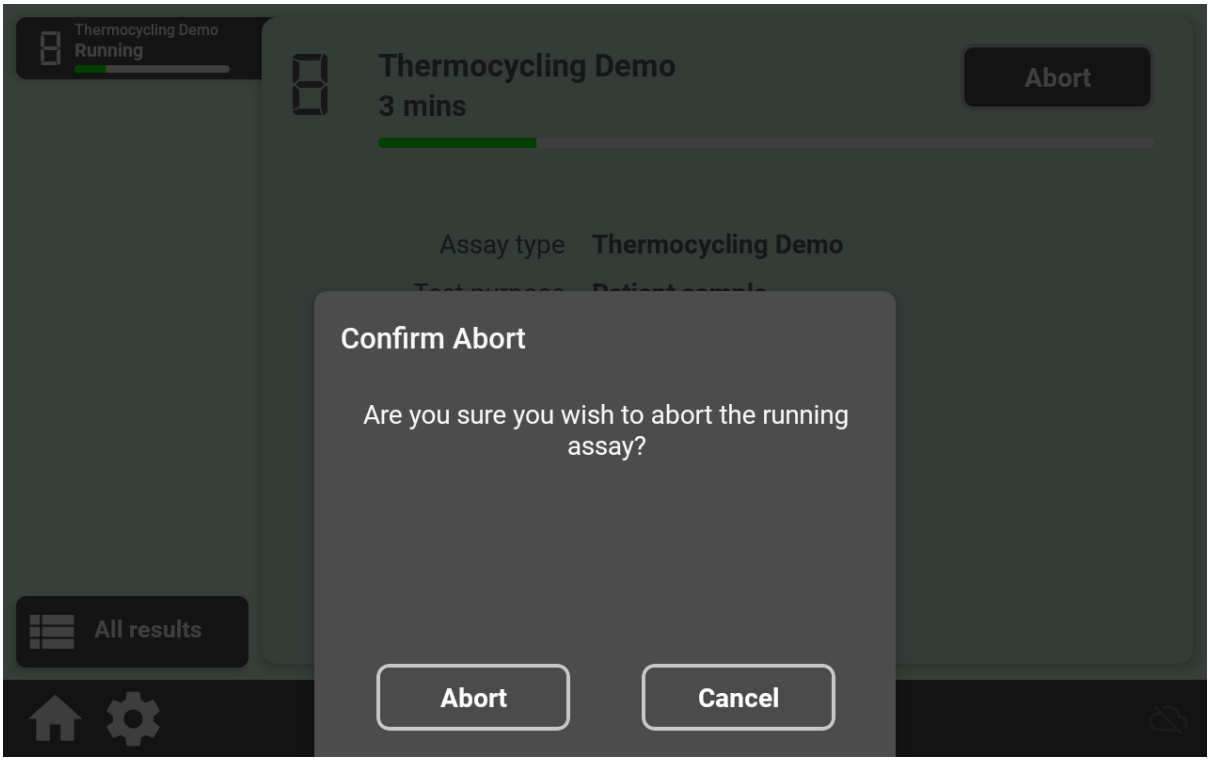
The **PRINT** function will send the results to the Bluetooth printer supplied. The result should be sent/recorded/entered into the patient record system utilized by the organization or institution.

START NEW ASSAY- A new test may be started on the same Assay Module when this button is visible. Select ***START NEW ASSAY*** button or tap the Back button on the Tablet to return to the Main Application screen. An available Assay Module can then be selected to start a new test. Once selected, **SCAN CARTRIDGE** will appear.

To begin another test, tap the ***New Assay*** button in the top right of the screen.

Aborting a test

A test can be aborted at any time or when a fault is identified.
If it becomes necessary to abort a test, user must navigate to the Test Progress screen. The ***Abort*** button in the top right of the screen should be pressed and held for 3 seconds. The user must confirm the test is to be aborted.



Tap ***Abort*** again to confirm, and the running assay will begin the abort process.

In the event of an instrument malfunction the test may be aborted by opening the Assay Module lid. If this method is used, the User must still navigate to the Test Progress screen on the Tablet and select Abort after closing the lid.

When the Assay Module aborts, it will attempt to unlock any cartridge parts that are engaged. Once the instrument returns the cartridge parts, the stripe on the Assay Module will turn white, and the lid may now be opened safely. Carefully remove all cartridge parts and dispose of them. Ensure any parts still attached to the instrument head are removed as well. See the SAMBA III Assay Module User Guide (Doc No. C19-0122-EN) for further details.

NOTE	If a problem occurs during the test, the stripe on the front of the Assay Module will change to red. The test should be aborted (refer to page 23 'Aborting a test' for more information).

⚠	Aborting a test and opening the lid exposes the user to potentially hazardous materials. Appropriate care should be taken when removing and disposing of the cartridge parts.

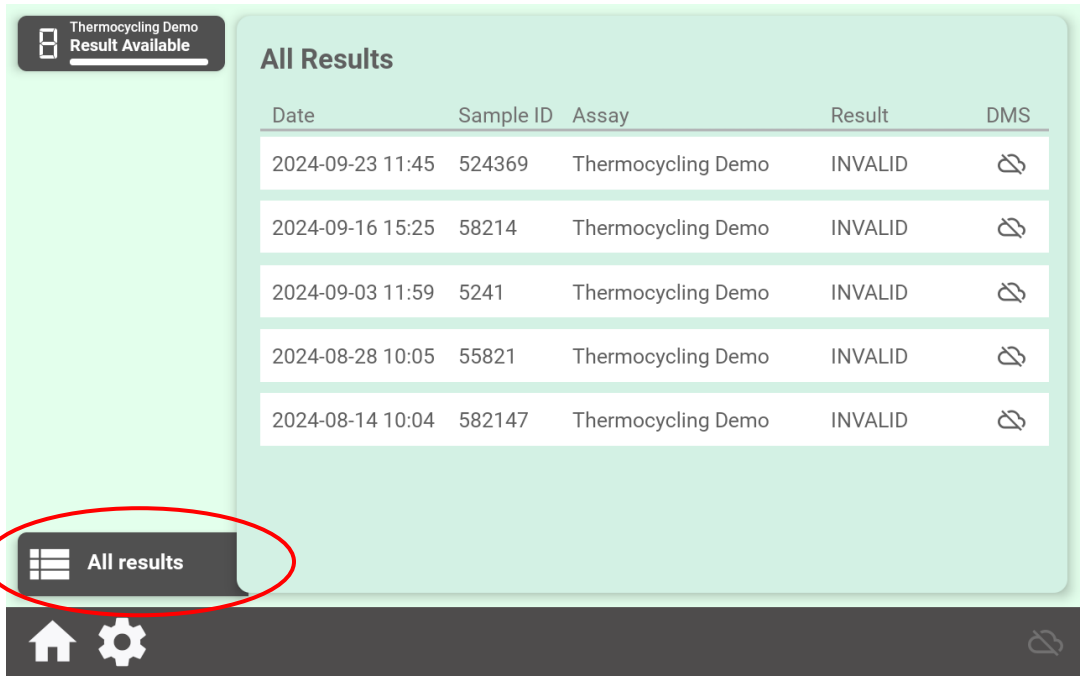
⚠	If any parts are still locked onto the instrument head, restart the Assay Module by closing the lid and switching the instrument off. Turn the Assay Module back on and wait for the instrument to unlock all parts so that they can be safely removed.

⚠	Cartridges from an aborted test cannot be reused if either the test cartridge seals and/or the patient sample tube cap have been pierced. In this case, the cartridges and sample tube should be removed from the Assay Module and disposed of in accordance with established biohazard procedures. If the sample tube cap has not been pierced, the sample can be reused.

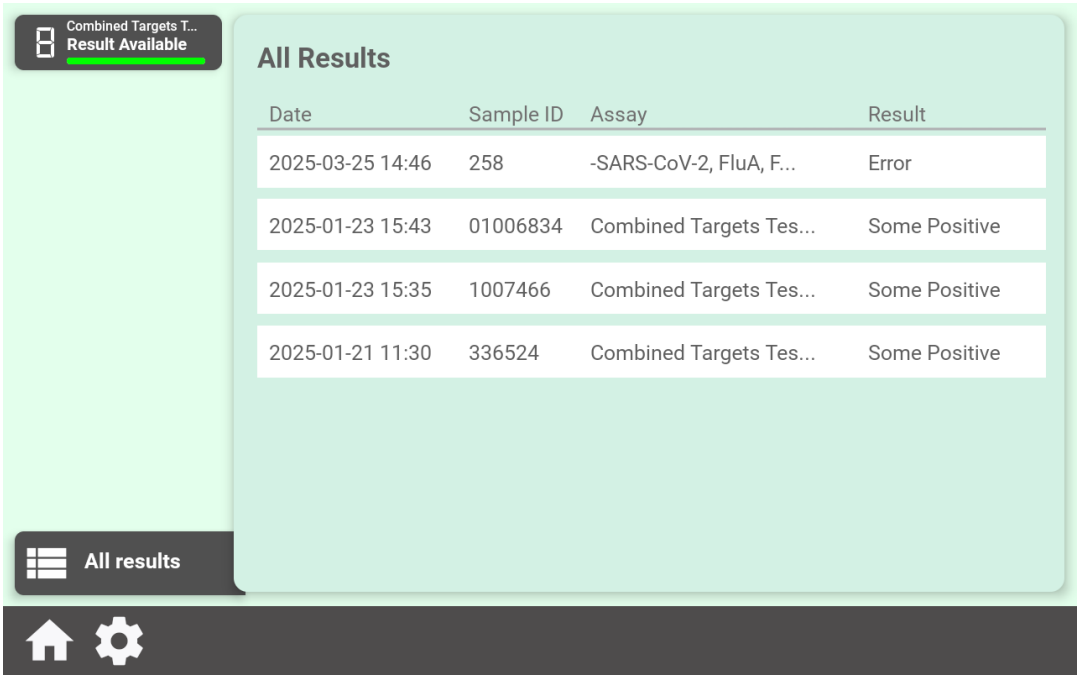
Accessing Previous Results

When the Tablet Module is operating, any test results retrieved from Assay Modules will be stored in the tablet.

To view a summary of these results, tap the ***All Results*** tab, which is placed below the Assay Module tabs on the main screen.



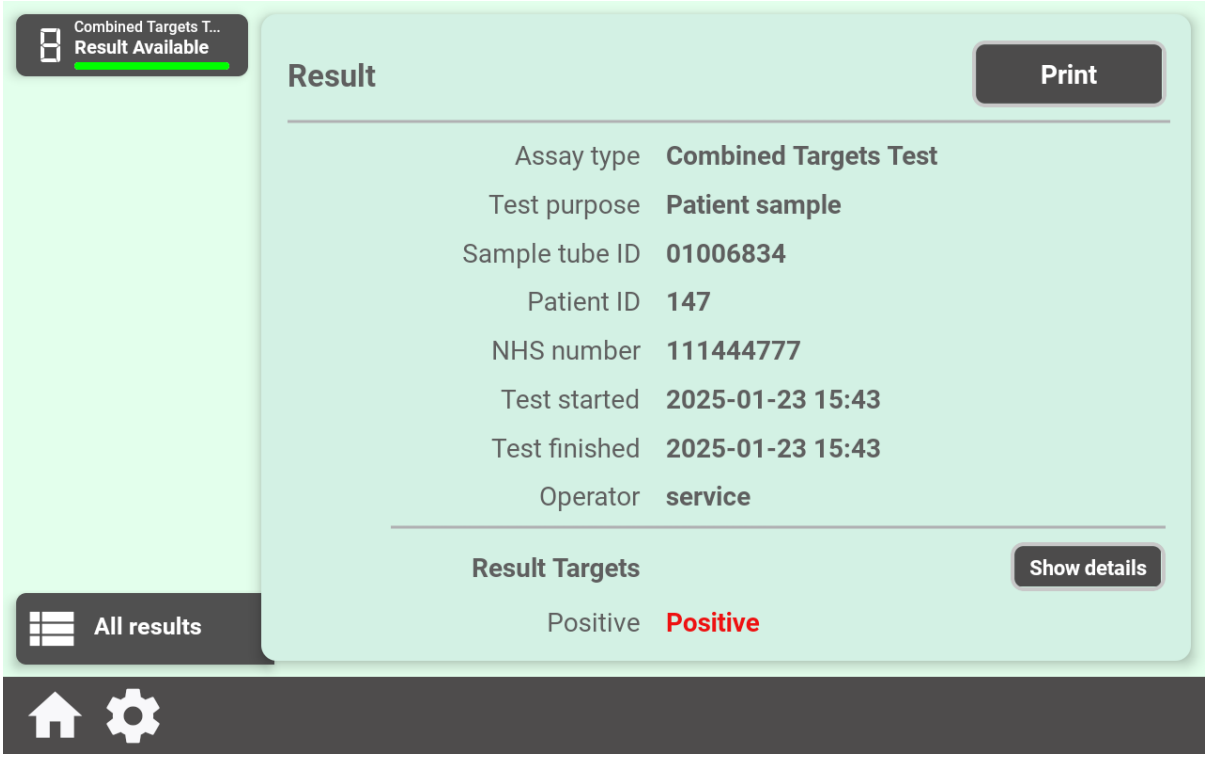
The results are listed in reverse chronological order. If the list is longer than the screen swipe up and down to view the complete list.



All results shows the following information for each result:

- **Date** – the date and time that the test was started
- **Sample ID** – the ID number on the sample tube
- **Assay** – the assay type
- **Result** – a summary of the result

Tap any row containing the result summary information to view more details. Depending on the fields used it might be necessary to swipe up and down to view all of the result.



Tap the ***Show details*** button to view results for all targets.

Tap the **Home** button to return to the home screen.

Maintenance

Refer to the Tablet manufacturer's User Guide for cleaning and maintenance instructions.

Spillages
If samples are spilled onto the Tablet, then it should be cleaned with a clean wipe wetted with a solution of one part household bleach to nine parts water followed by a wipe-down with wipe wetted with clean water. Wipe dry using a lint-free cloth.

Specifications

Tablet
Refer to the Tablet manufacturer's User Guide for specifications.

Printer
Refer to the Printer manufacturer's User Guide for specifications.

SAMBA III App
The SAMBA III App is designed to run on a Zebra ET-40 tablet device. For further details, select the **Settings** icon in the top right-hand corner of the Main Application screen and select:

About
The About screen lists the DRW serial number of the tablet (listed as SIIITM…), the version of the SAMBA III App software, and contact details for DRW.

Technical Support

Tablet
For Technical Support on the tablet contact the manufacturer (refer to the tablet manufacturer's User Manual for contact details).

Printer
For Technical Support on the printer contact the manufacturer (refer to the printer manufacturer's User Manual for contact details).

Tablet App and SAMBA III System
For technical support on the SAMBA III App or the SAMBA III Instrument System contact Diagnostics for the Real World Ltd Customer Service:

UK: Tel +44 1223 785330 Email: service@drw-ltd.com
USA: Tel +1 888 773 1550 Email: service@drw-ltd.com
Feedback for the SAMBA III Tablet can be submitted by contacting DRW Customer Service using the contacts listed above.

Revision history:

Version no.	Date approved	Brief description of changes
1.0	06 Nov 24	Initial release
2.0	19 Nov 24	Updated User Guide throughout to correct minor typos, grammatical errors and formatting. Updates made for clarity and completeness; thus, risk is low.
3.0	10 Apr 25	Added references to Combined Targets functionality and Bluetooth printing. Removed all references to the Hub/DMS. Added CE and UKCA mark. Updated images throughout. Updates made for clarity and completeness; thus, risk is low.
4.0	11 Jun 25	Added Contents table on page 3 as an improvement. Updated the Intended Use to align consistently in technical documentation. Updates made for improvement and completeness; thus, risk is low.
5.0	23 Aug 25	Updated the symbols section to include symbol for near-patient testing. Updated intended purpose to include near-patient environments. Updated EU rep symbol. Updates made for clarity and completeness; thus, risk is low.
6.0	29 Oct 25	Updated to include settings for “Roles” and “Hub/DMS”. Updates are made for completeness, thus risk is low.

EU REP

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