User Manual
ImmuView® Reader

SSI Diagnostica A/S

Version 1.0.3

Reference no. 18344

Contents

1 General Information

1.1 Warnings & Limitations

⚠ **Warning:** Only use the approved and listed peripheral accessories with the ImmuView® Reader.

⚠ **Warning:** Do not use the ImmuView® Reader in close proximity to sources of strong electromagnetic radiation (e.g., unshielded intentional RF sources), as these may interfere with the proper operation.

⚠ **Warning:** Maximum current supplied by all USB peripherals should not exceed 1.1A (2 High power Loads and 1 Low power Load).

⚠ **Warning:** This Instrument is designed to operate only with the provided power supply plug pack; This module forms part of the system. Do not operate the system with a different power supply module. The correct power supply is required to maintain the safety and electromagnetic compatibility of the system.

⚠ **Warning:** Risk of electrical shock. Do not operate the Instrument or the power supply plug pack if it has been opened, damaged, or exposed to moisture, condensation, or rain. The external power supply plug pack is sealed with no user serviceable parts. Do not operate this module with any damaged or exposed parts.

⚠ **Warning:** Do not open or attempt to repair the Instrument or other accessories as there is a risk of damage to the Instrument. This Instrument does not contain serviceable parts and should be returned to SSI Diagnostica A/S for repair. Opening the Instrument will also void the warranty. Real time clock coin battery included in the equipment will run for the operational life and is not a user replaceable item.

⚠ **Warning:** Only operate the Instrument for its intended purpose and in accordance with this user manual and warnings. Protection provided by the equipment may be impaired if the equipment is operated in a manner contradictory to the above. This Instrument (including power supply) is designed to operate within the manufacturers specifications. Do not exceed the manufacturer's specifications when in use.

⚠ **Warning:** Any changes or modifications not expressively approved by SSI Diagnostica A/S could void the product compliance with safety, electrical, EMC and other applicable requirements and the user's authority to operate the equipment.

⚠ **Warning:** Position the instrument with clear access to connectors. Keep connected cables clear of work areas such that tripping or catching will not pull the instrument off its workbench. The mains socket outlet intended to use with ImmuView® Reader external power pack should be located near the equipment and should be readily accessible. It is recommended that the user unplug the ImmuView® Reader when not in use.

⚠ **Warning:** USB and Ethernet Interfaces: Please ensure that interfaces of such equipment are separated from mains by double reinforced insulation and present no risk of electrical shock if intended for connection to external equipment.

NOTE 1. Failure to follow these warnings will void the ImmuView® Reader warranty.

1.2 Safety Information

The ImmuView® Reader is intended to provide safe and reliable operation when used in accordance with this User Manual. If the instrument is used in a manner that is not specified in the User Manual, the protections provided by the equipment may be impaired.
The ImmuView® Reader is designed to operate safely under these conditions:

- Indoor use (protected from water).
- Altitude up to 2000m.
- Temperature 15ºC to 35ºC.
- Relative humidity 10% to 70% non-condensing.
- Mains supply voltage fluctuations not to exceed ±10% of the nominal voltage.
- Installation Categories (Overvoltage categories) II.
- Pollution Category 2.
- Use with specified and supplied external AC/DC power adaptor only.
- Mains socket for AC/DC power pack should be readily accessible.
- Set up instrument on a stable, level bench, in an office or laboratory environment.
- The ImmuView® Reader is not intended to be used as a handheld instrument; only operate the instrument on a flat and level surface.
- Install the ImmuView® Reader at least 100mm minimum from any edges.
- Install cables to prevent risk of tripping or pull that may cause instrument or personal injury.
- The ImmuView® Reader is a non-serviceable part, opening the instrument will void the instrument warranty.
- Ensure ferrites are fitted to USB peripheral accessories before operation with the ImmuView® Reader.

Personal safety
For personal protection and biological waste procedures, please refer to issued in-house safety procedures regarding personal protection wear when handling human infectious and non-infectious biological materials.

1.3 Copyright

2 Introduction

This manual describes setup, configuration, and operation of the ImmuView® Reader — also referred to as "the instrument".
This manual is provided as an operational guide to describe the use of the instrument. This document does not describe operation of the specific diagnostic test or provide any input to the requirements, safety or processing of any diagnostic test which is outside the scope of SSI Diagnostica A/S.

The ImmuView® Reader is a portable, easy to use rapid testing instrument platform designed to provide qualitative results for visible colorimetric lateral flow tests. Key features of the ImmuView® Reader include multiplexing support, automated workflow management, colour touch screen, networking, and communication options.

The ImmuView® Reader is intended to be developed as part of a larger diagnostic system including an assay and specific test instructions and therefore should not be considered in isolation. If the intended patient care carries risks of injury or death additional tests or indicators must be considered. The ImmuView® Reader uses an image sensor to control and acquire images from the image sensor in full RAW mode, with control of exposure and sensor gain.
The ImmuView® Reader complies with the emission and immunity requirements described in IEC61326-2-6 and IEC61326-1 (Industrial Locations).

NOTE 2. Contact manufacturer for CE Declaration

This equipment has been tested and found compliant with emissions limits required by CISPR11 Class B equipment. This instrument complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this instrument may not cause harmful interference, and (2) this instrument must accept any interference received, including interference that may cause undesired operation. These limits are designed to provide protection against harmful interference in a residential installation. This equipment generates, uses, and radiates radio frequency energy and if not installed and used in accordance with the instructions, may cause harmful interference to radio communications.

Where SSI Diagnostica A/S is the importer and distributer, the product has WEEE registration for the UK and specific other countries as required.

NOTE 3. Contact manufacturer for WEEE Directive Declaration

NOTE 4. Contact manufacturer for RoHS Declaration

SSI Diagnostica A/S advises the user to assess the electromagnetic environment of the intended operational environment of the instrument prior to use.

This product is compliant with following standards and directives:

EU Regulation 2017/746 on In Vitro Diagnostic Medical Devices	IVDR
EU Directive 2011/65 on restriction of the use of certain hazardous substances in electrical and electronic equipment	RoHS
EU Regulation 2006/1907 on Registration, Evaluation, Authorisation and Restriction of Chemicals	REACH
EU Directive 2012/19 on waste electrical and electronic equipment	WEEE
FDA Cyber Security Compliance	

FDA CFR Title 21 Part 820
ISO 13485
ISO 61010-1
ISO 61010-2-101
ISO 62366-1:2015
ISO 62304

2.1 Intended Use

The ImmuView® Reader is an adjunctive instrument for automated reading and interpretation of results for ImmuView® lateral flow immunochromatographic in vitro diagnostics test strips.

2.2 Package Contents

The following contents are supplied with the ImmuView® Reader:

- ImmuView® Reader
- 1 x Instrument check
- 2 x Strip-carriers
- Power supply (With adaptors for US, EU, UK, Canada, and AUS)
- 1 x Ferrite key
- 3 x Ferrites (clip on for accessories only)
- 1 x Quick guide
- 1 x Certificate of Analysis (CoA)

2.3 Contact Information

SSI Diagnostica A/S
Herredsvejen 2
3400 Hillerød
Denmark

T: (+45) 48 29 91 00
EAN: 5790 002327452
VAT: 37294535

info@ssidiagnostica.com

www.immuview.com

2.4 Symbols

SYMBOL	DESCRIPTION
	USB Port for connection on of a USB flash memory key
	Network Port: to connect the instrument to a network.
	Power Cable Port: to connect the SSI Diagnostica A/S power supply to the ImmuView® Reader
	Security lock slot: to connect a security lock to the ImmuView® Reader
	Power Button: to power on the ImmuView® Reader

2.5 Conventions

SYMBOL	DESCRIPTION
⚠	**Warning:** Indicative of a situation which if not avoided could result in injury of the user and/or damage of the Instrument
NOTE	**Information:** Critical information relating to procedures or use of the Instrument.

2.6 Labels

The following image illustrates the Rating Label used on the ImmuView® Reader. The definitions of each logo are listed in the table below.

SYMBOL	DESCRIPTION
	Product Branding
	Catalogue Number
	Caution
	CE Mark
	WEEE Directive Compliance
	Refer to Instructions for Use
	Manufacturer
	For IVD performance evaluation only
	*In vitro* diagnostic medical device
	Instrument Serial Number

3 Instrument Overview

Figure 1 ImmuView® Reader Front View

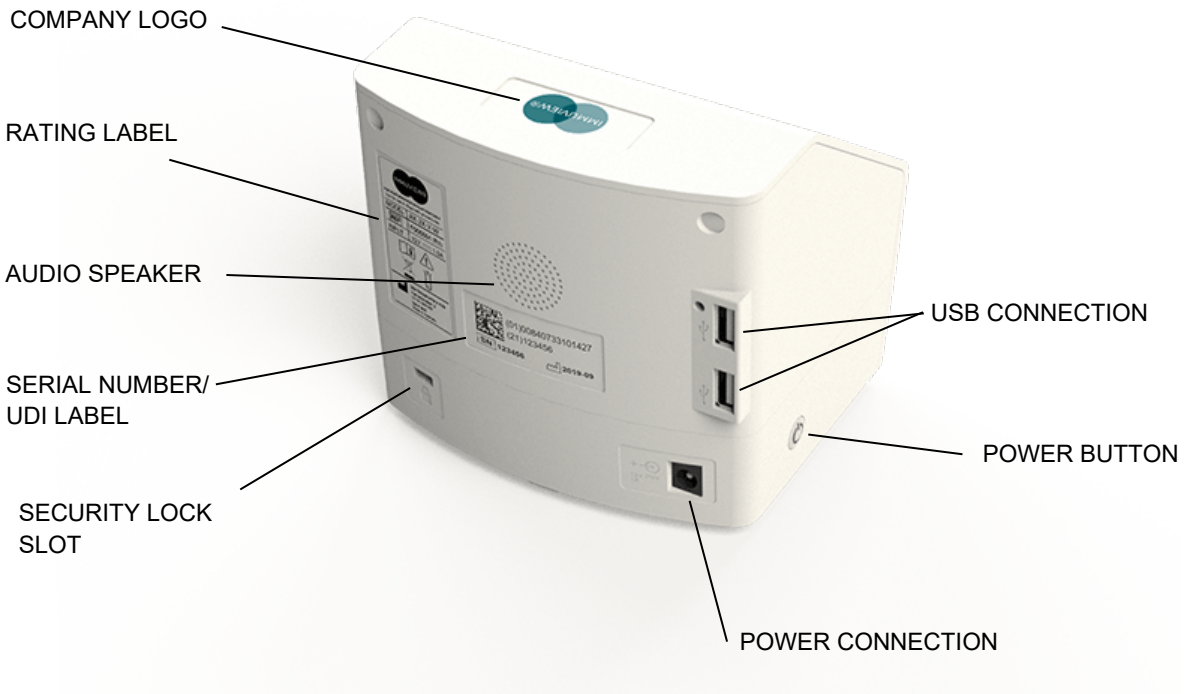


Figure 2 ImmuView® Reader - Rear View

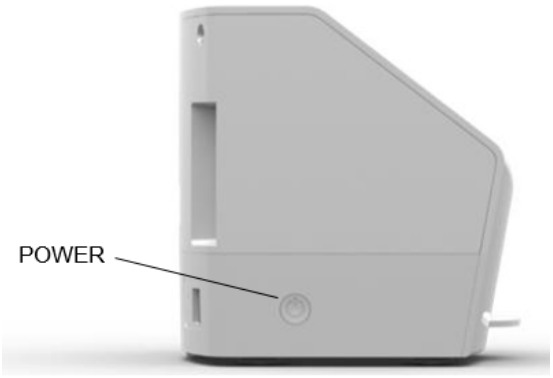


Figure 3 ImmuView® Reader Left View

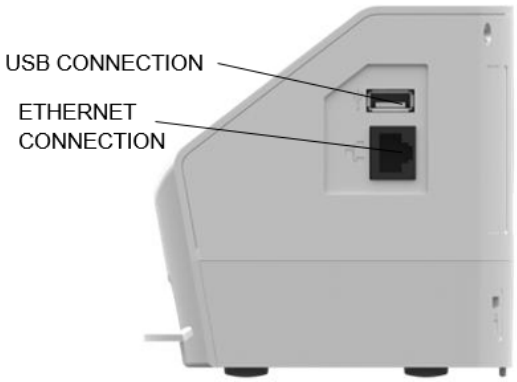


Figure 4 ImmuView® Reader Right View

3.1 LED Status Indicator

Rapid flash:	Initial power connection registered.
Slow flash:	Power connected but the instrument is shutdown.
Solid:	Instrument on.

3.2 Power Button

Powered off: When no power supply is connected the ImmuView® Reader is powered off.
Standby: To place the ImmuView® Reader into standby mode, connect the supplied power adapter to the instrument; you will notice that the status indicator on the front face of the instrument will flash rapidly to indicate that power has been connected, the instrument status indicator will then begin to flash slowly to indicate the ImmuView® Reader is in standby mode.
Start-up: Holding down the power button for 2-3 seconds will initiate the ImmuView® Reader start up sequence. Wait for the boot up sequence to complete, this should take approximately 3 minutes, then the ImmuView® Reader application home screen is displayed.
Shut-down: Once the ImmuView® Reader is powered on and the application is displayed, the instrument will shut-down if the power button is pressed and held for 2-3 seconds. The shutdown status bar is displayed and the instrument powers off.

3.3 Application States

On/active: The application is fully operational, displaying screens at the user set brightness level and is receiving user inputs via the touch screen.
Screen saver: The application screen dims to 40% Brightness after 3 minutes of inactivity to preserve the display. Touching the display returns the display to full brightness.

NOTE 5. The screen brightness level will not dim to 40% if the instrument Brightness settings are already set to 40% or less.

Auto logoff: The application logs off from the current user setting after 30 min from either the time the last test completed or the time the touch screen was last touched. The application screen goes blank until touched.

3.4 Performance

The ImmuView® Reader performance data is depended on the ImmuView® kit that is being tested. For in-depth performance data please refer to the kit specific ImmuView® Instructions for use (IFU).
The overall ImmuView® kit performance with the reader is:

- The ImmuView® Reader is validated and set up to be as close to an experienced operator as possible or slightly better (≥95% agreement with the visual output).
- <4% Coefficient of Variation (%CV) between ImmuView® Readers inter lot and intra lot variation.
- The sensitivity (analytical and clinical) is equal or not significantly different than visual reading.
- The specificity (analytical and clinical) is equal or not significantly different than visual reading.

The ImmuView® Reader uses a decision algorithm to determine the outcome of the inserted strip in the carrier. The algorithm processes images taken with green and red light for maximum exposure of the colored lines.

3.5 Limitations

For test specific limitations please refer to the kit specific ImmuView® Instructions for use (IFU). General test related limitations observed with the reader:

- The reader may report 'Positive' for an analyte if there are 'White lines' near/on the test line.
- The reader may report 'Boil & Re-Test Sample' if the strip is put in the carrier reversed (text name oriented to be put in the carrier first).
- Discrepancy between the operator eye and the reader output may occur especially in borderline samples.
- The reader may report 'Invalid' if the strip is not placed behind the 'arrow' in the strip-carrier during reading.
- The reader may report 'Invalid' if the strip has dots, membrane errors and/or other strip related errors.

4 Test Consumables

The following table summarises the test consumable types compatible with the SSI Diagnostica ImmuView® Reader.

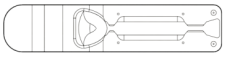
Ref.: 10322: Strip Carrier, ImmuView® Reader, SSI Diagnostica

Ref.: 10323: Instrument check, Cartridge, IC-W, ImmuView® Reader

Warning: Do not apply excessive force when inserting a strip carrier. Excessive force could damage the instrument.

Warning: Strip Carrier usage. Make sure that the small arrow is always visible after an ImmuView® strip has been inserted. If not inserted correctly the reader will report **Invalid.**

5 Materials needed and Setup requirements.

UNPACK		**Instrument:** Unpack the ImmuView® Reader and set it up on a stable, level bench, in a clean office or lab type environment.
POWER UP		**Power Supply:** Configure the power supply for your region. Connect the 12V power supply to the instrument.
CONNECT		**Ethernet Cable (Not supplied):** Required to connect the ImmuView® Reader to a network. Used for connectivity to Desktop Software, network printing and remote access to test results. Connect the network cable prior to powering on the instrument.
TEST		**Consumable:** Insert a strip carrier or IC cartridge into the slot to trigger lateral flow testing.
EXPORT		**Test results on USB Key:** Use a FAT32 formatted USB key to export test results and instrument data from the ImmuView® Reader.
SOFTWARE UPDATE		**Software Update on USB Key:** Use a FAT32 formatted USB key loaded with a software update to install the latest software onto the ImmuView® Reader. Refer to Section 6 Software Update.
POWER DOWN		**Power Off/Standby:** It is recommended that the ImmuView® Reader is powered down when not in use. However, the instrument will go into a screen saver mode when left on and not in use.
FITTING FERRITES		**Ferrites must be fitted to approved USB accessories, USB cables:** Refer to section 13.1 Fitting Ferrites 1. Retrieve ferrite core from zip lock bag inside packaging. 2. Place USB peripheral cable inside the ferrite core, distance from ferrite core to USB connector base should be 29±2mm. 3. Lock the cable in place by pushing the cable down. 4. Close the ferrite core once the cable is in correct position

6 Software Update

Installing instrument software updates does not remove any calibration settings, unless specifically noted by the update documentation.
A software update does not clear instrument calibration, instrument normalisation or the instrument factory settings. With the exception of - major software updates where the above may need to be cleared to ensure compatibility with corresponding software architecture changes. Settings that may be cleared by an update are to be stored in a separate file to ensure the protection of these settings. The software update is capable of applying a firmware update for the baseboard and/or tray board firmware.

⚠ **Warning:** Stored test data may be at risk of being deleted during the software update process! It is highly recommended that the test result stored on the ImmuView® Reader is archived to an external formatted, USB Key prior to performing a software update.

⚠ **Warning:** DO NOT REMOVE USB KEY DURING SOFTWARE UPDATE. USB Flash memory instrument can be removed from the ImmuView® Reader once the software update is complete.

Update Sequence:

1) *Prior to software update, export test results and users list stored on the ImmuView® Reader.*
2) *Attach USB key with the required software to the instrument USB port, located on the right-hand side of the ImmuView® Reader.*
3) *Turn the instrument off by pressing and holding the power button for 3 seconds or longer.*
4) *Power up the ImmuView® Reader by holding down the power button until the instrument begins the start-up sequence.*
5) *Touch the screen to confirm the update process when a confirmation request is displayed onscreen.*
6) *Remove the USB Key when prompted that the update is complete. The instrument will then reboot.*
7) *The instrument will power up as normal. Observe the version number displayed during start up to confirm that the software update was applied.*
8) *Check the Settings/About screen to see that correct software version has been applied.*

NOTE 6. *The first time a self test is run following a software update a fault or warning result may be given. Please make special note of the information given on the Self Test screen as to what other functions may need to be conducted following a software update, such as normalisation. Please run the self test for a second time from the admin menu.*

7 User Types

7.1 Standard User

The standard user has access to the home menu, testing, result review and basic settings.

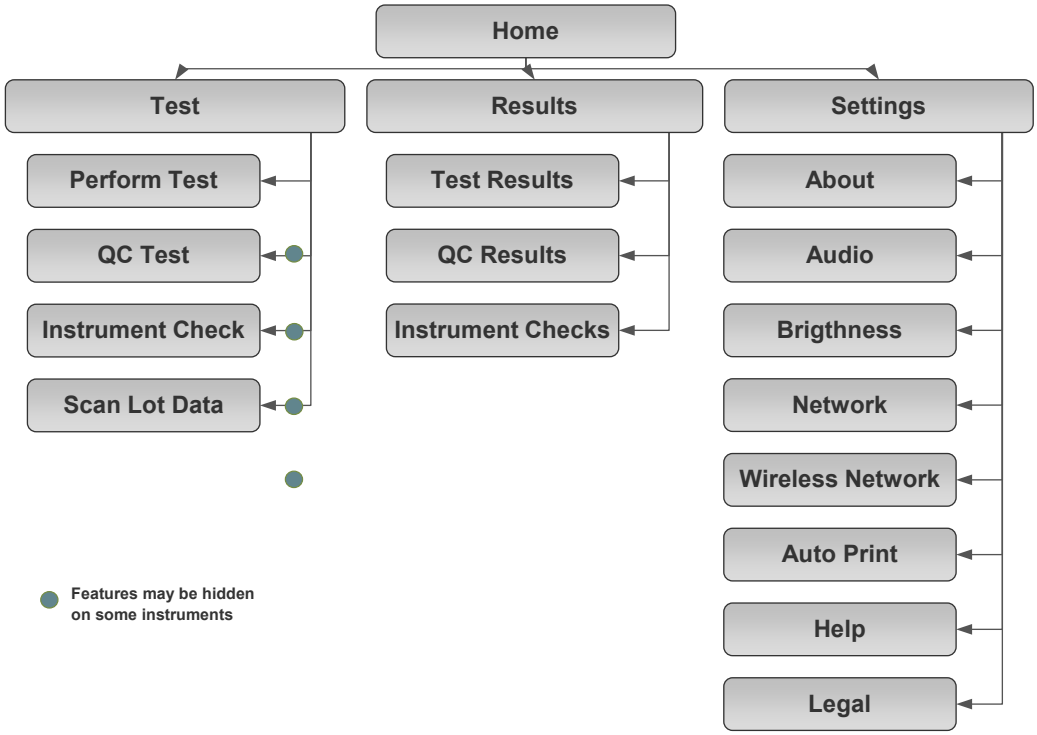


Figure 5 Standard User Menu Structure

The standard user can:

- Run a test.
- Run a QC test and update the QC status*.
- Review the QC status*.
- Run an instrument check test*.
- Run Scan Lot data*.
- Review results.
- Print a single test result.
- Export a single test result to an attached USB key.
- Can view the instrument "About" information.
- Adjust the instruments audio settings.
- Configure the LCD screen brightness level.
- Configure the LAN connection.
- Configure the Wireless Network.
- Configure the auto print settings.
- Can review the instrument "Help" information.
- Can review the instrument "Legal" information.

*NOTE 7. *Some features may be disabled by the Admin user of the instrument; these features may not be available on your instrument.*

7.2 Admin User

There is one admin user role on the ImmuView® Reader. The admin user has access to the all the same functionality as the standard user as well as access to the "Admin Settings" screens.

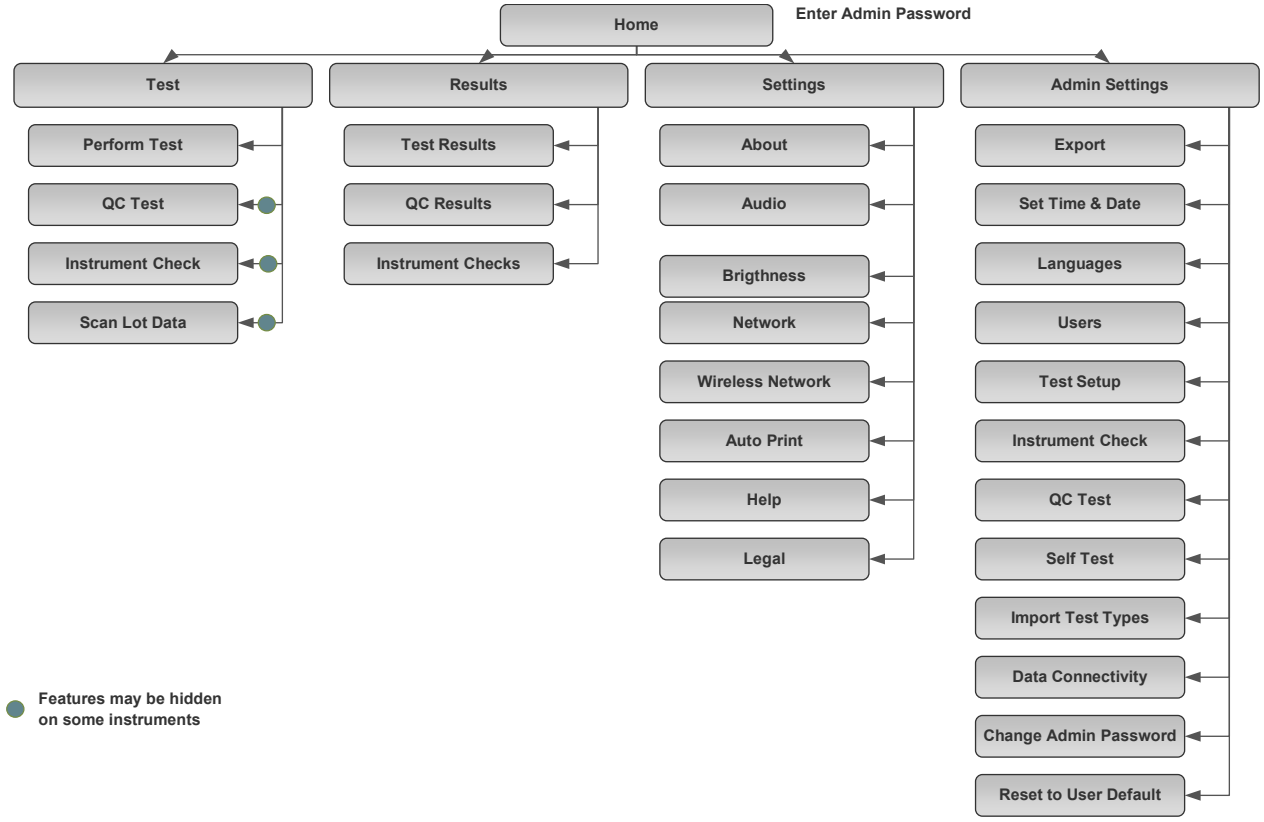


Figure 6 Admin User Menu Structure

*NOTE 8. *Some features may be disabled; these features may not be available on your instrument.*

The admin user can:

- Export test results, test result summary files and log files.
- Change time and date.
- Set the language on the device.
- Export or import a list of users, using a USB key.
- Add, edit, and delete up to 99 users on the device.
- Require that only authorised users can login to the device.
- Configure Save Diagnostics.
- Configure the warning and lockout of the instrument check, or turn instrument check off*.
- Require the instrument check to run on a schedule*.
- Configure the warning and lockout of the QC tests or turn QC testing off*.
- Require the QC tests to run on a schedule*.
- Run a self test as required.
- Require the self test to run on a schedule.
- Import test types onto the device.
- Edit test type list.

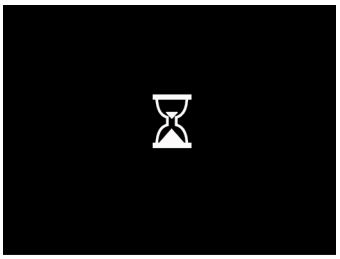
- Configure Data Connectivity options.
- Change the admin password.
- Return the device to user default settings.

8 User Instructions

This section contains basic instructions for Users (non Admin) after the system has been installed and set up by the Administrator. See the Administrator section of this user manual for more detailed instructions on instrument installation and configuration.

8.1 Boot up

Once the user has powered on the instrument, the instrument begins the boot up sequence. The Bootloader booting sequence displays a white hourglass icon. The Kernel loading sequence displays a white hourglass icon.



The loading sequence displays a white hourglass icon.
Upon instrument application start up:

1. Hourglass icon appears
2. Screen goes black periodically
3. Loading bar appears and begins to load till full
4. "ImmuView®" logo is displayed with indication of start-up progress.

The start-up process takes around 3 minutes.

8.2 Self Test at Start Up

Self Test is an automated instrument test that is run to verify correct internal system functionality of key areas of the ImmuView® Reader. Self test occurs during the instrument boot up sequence, as required, or as scheduled by the admin user.

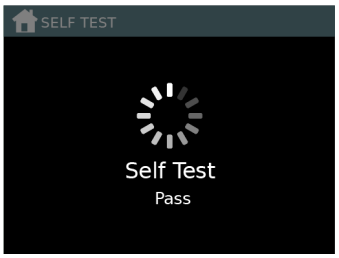
Each failed Self Test is assigned a level of severity:

- **Warning:** Self test indicates a warning but testing is not locked out.
- **Fault:** Self test fails because of a fault and testing is locked out.
- **Critical Failure:** Self test fails and the instrument cannot be used.

8.2.1 Self Test Results

After Self Test the following Self Test Status screens will apply for the following severities:

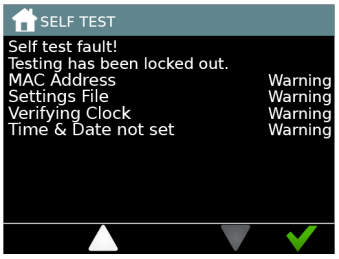
Pass: In the case of a boot up self test the instrument then advances to the login screen. Where a self test has been run manually by an admin the instrument automatically returns to the previous application screen.



Example of a self test Pass result

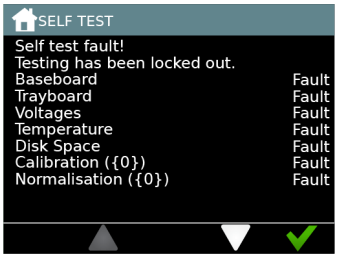
Warning: "Self Test Warning!" is displayed. The tests that caused the warning are displayed. Tests that passed are not displayed. In the case of a boot up self test the user confirms the warning and then advances to the login screen. Testing is not locked out.

Where a self test has been run manually by an admin user, the user confirms the warning and the application then returns to previous screen. Testing is not locked out.



Example of a self test Warning result

Fault: "Self Test Fault! Testing has been locked out" is displayed. The tests that caused the fault or warning are displayed. The Self Tests that are in the warning category that failed are displayed. Tests that passed are not displayed. In case of Boot up Self test: user confirms and advances login screen. Testing is locked out. As requested, or scheduled by the admin user: user confirms then returns to previous application screen. Patient and QC testing is locked out.

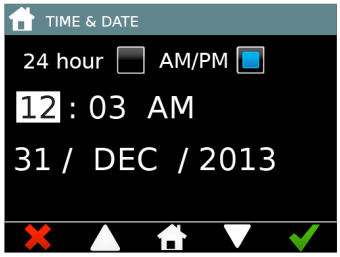


Example of a self test Fault result

The current Self Test Result is available in the Instrument Information Screen and the last passed Self Test is shown in the printed report output.

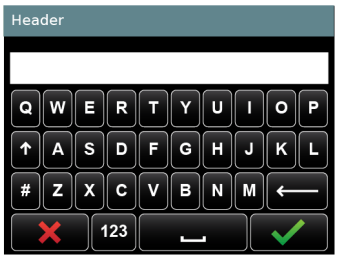
8.2.2 Self Test Protocols.

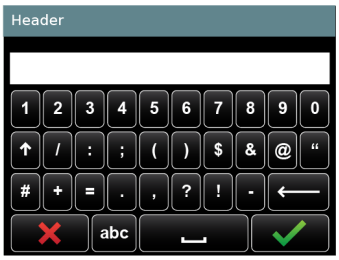
SELF TEST	DESCRIPTION	TYPE
1. Tests for communication with the baseboard micro controller.	Tests communication with the baseboard micro controller.	Fault
2. Tests for communication with the tray-board micro controller.	Tests communication with the tray-board micro controller.	Fault
3. Tests the internal voltages, ensures they are within a limit.	Checks system voltages are within expected ranges.	Fault
4. Checks Instrument internal temperature.	The software checks the presence of the temperature sensor inside the instrument and ensures that the temperature is greater than 0°C and less than 50°C.	Fault
5. Checks the network controller	Checks the network controller and that the MAC address is valid.	Warning
6. Checks the presence of SD card.	If the SD card is absent or has a connection problem, then the instrument stops the self test and assigns the critical failure status. The instrument cannot run without the SD card and after confirmation will reboot itself until an SD card is present.	Critical Failure
7. Disk Space Check	The software checks the SD Card for low disk space (<100MB remaining). The disk space on the internal NAND flash is also checked to ensure that at least 10MB of free space is remaining. Either condition will cause a self test fault state. The software is designed such that this error should not occur in normal use. The storage of results is size limited in order to leave at least this amount of disk space free on both the SD card and the internal NAND flash.	Fault
8. Checks the integrity of the Settings File	Checks the integrity of the settings file (corrupted, regenerated, or unexpectedly changed by other agents). If the settings file is corrupted, then a default setting file will be generated. Instrument settings will have returned to their default state.	Warning
9. Check Calibration	If the instrument is not exposure calibrated, then the instrument will record a fault. Every time Self Test is run, the software checks to ensure the instrument is calibrated. If this fault occurs, then the user needs to run the exposure calibration operation in order to be able to run a test.	Fault
10. Check Normalisation	If the instrument is not normalised, then the instrument will record a fault. Every time Self Test is run, the software checks to ensure the instrument is normalised. If this fault occurs, then the user needs to run the normalisation operation in order to be able to run a test.	Fault

SELF TEST	DESCRIPTION	TYPE
11. Check RTC Check Time and Date	Every time the ImmuView® Reader runs a Self Test the software checks the Real Time Clock (RTC): 1) Checks that the instrument can communicate with the RTC hardware. 2) Checks if the RTC has been set to a valid time since the battery was installed. If time and date check fail, then the application requires the user set it prior to login. 	Fault

8.3 System Keyboard and Keypad

The onscreen QWERTY keyboard and numeric keypad enables the user to type text input into the ImmuView® Reader.



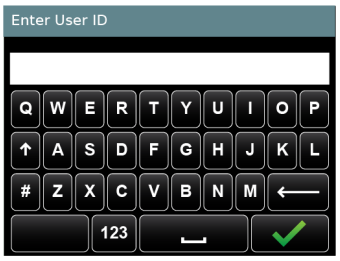


NOTE 9. The instrument produces an audible 'click' when the touch screen is pressed (the click, and the volume is configurable in Settings/Audio).

NOTE 10. A USB connected barcode wand can also be used to input data read from a barcode into the onscreen keyboard/keypad screens.

8.4 User Login

The Login Method can be toggled to: 'Username', 'Password', or 'None'. If the Login Method is set to "Username", The user is required to enter a valid User ID at the login screen to gain access to the ImmuView® Reader.
If the Login Method is set to "Password" the user can log onto the instrument, given they enter a valid User ID input using the onscreen keyboard and the correct associated password.
If the Login Method is set to "None" there will be no prompt to input a username or password. While set to "None" User ID fields will read "Default User".



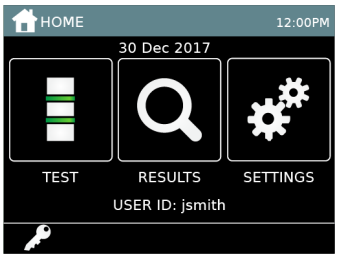
The User ID entered can be between 1 and 20 characters in length.

NOTE 11. Refer to section 9.4.3 Login Method for configuring Instrument login requirements.

8.5 Main Menu

The Home Menu screen provides the following options:

- TEST, for running a test.
- RESULTS, for reviewing previously run test results.
- SETTINGS, for configuring the instrument.



Pressing the key icon logs out from the current user ID and navigates to the login screen.

NOTE 12. The time and date are displayed to the user on the main screen.

NOTE 13. By default, startup sequence, user login is 'Default User'

8.6 Toolbar Indicators

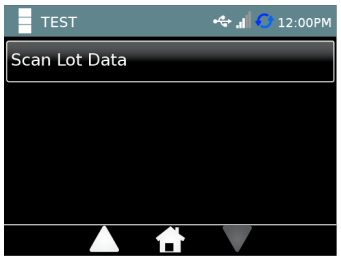
The toolbar displays the application screen icon and title as well as the current time. Icons appear in the application task bar to indicate the following:

	A USB key is detected by the instrument and is ready for use.
	When WiFi is set to [On] and the instrument is connected to WiFi the signal strength is displayed. The icon indicates 5 varying levels of WiFi signal strength.
	When WiFi is set to [On] but no WiFi connection is available the WiFi disconnected icon is displayed. When WiFi is set to [Off], no WiFi icon is displayed in the toolbar header.
	Active: Results are currently being sent; icon rotates when sync is in progress. LIS connection -> pending.
	Completed: All test results have been successfully sent to the server. LIS connection -> successful.
	Error: Where sync is enabled, and the instrument has a sync error. LIS connection -> failed.
	Idle: Indicates that sync is enabled and there are unsent results to be sent to the server. When LIS is set to [Off], no sync icon is displayed in the toolbar header.

8.7 Test Menu

The Test menu shows a list of the different types of tests that can be run on the ImmuView® Reader:

- Perform Test
- QC Test *, for running an Assay QC test for the test types available.
- Instrument Check*, for running an instrument quality check, independently of the assay.
- Scan Lot Data*



*NOTE 14. *These options may not be available, dependant on the Administrator settings applied.*

NOTE 15. Running a Test, an Assay QC Test or an Instrument Check Test is not interrupted by other instrument functions such as Self Test or auto logout.

NOTE 16. In the event that the test cannot be completed due to instrument failure or unexpected power loss, a test result will be saved that indicates the test did not complete. The user interface will distinguish incomplete from complete test results.

NOTE 17. A memory nearly full warning may be displayed prior to running a test if instrument result storage capacity is less than 25 remaining tests, the user is warned that memory is low prior to commencing a test. The instrument is capable of storing 999 test results. If the user runs a test when the memory is full, then the oldest test result is deleted as the newest one is saved. A warning is displayed every time the user runs a test with full or nearly full memory.

8.8 Setup Lot Data

The ImmuView® Reader can store Lot Data for each test type loaded on the instrument. The user can enable or disable the use of Lot Data through the Test Setup settings menu.

NOTE 18. Refer to: Section 9.5.5 Scan Lot Data

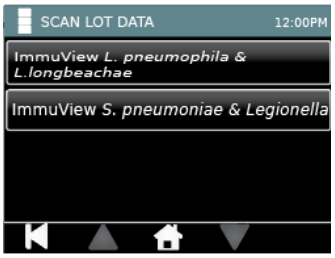
If the user wishes Lot Data to be captured in the test workflow, then they should set up Lot Data prior to running tests.

Step 1. Select Scan Lot Data

If the [Scan Lot Data] has been set to [ON] in the Test Setup settings, then the user can select Scan Lot Data from the Test Menu.

Step 2. Choose Test Type

A list of test types loaded on the instrument is displayed. The user can select a test type to add new Lot Data or view previously saved Lot Data.



Step 3. Scan New Test Lot

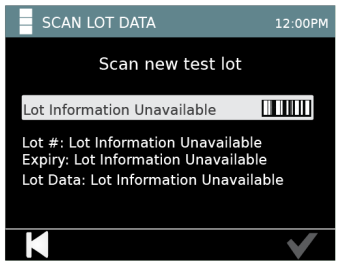
If no Lot Data is saved the fields: Lot #, Expiry and Lot Data contain “Lot Information Unavailable”. When “Lot Information Unavailable” is shown the cancel button is not displayed and the save button is displayed in the disabled stated.

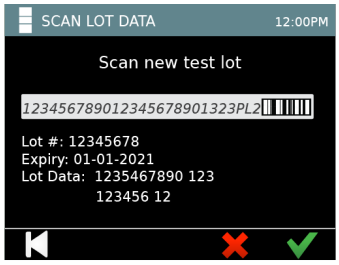
To add Lot Data the user must use a Barcode Scanner peripheral device to scan an appropriate Barcode then click the tick button (✓) to save results.

NOTE 19. Refer to Section 13.4 Barcode Scanner

If Lot Data has previously been saved for the test type, then all fields will be filled.

The user can delete the Lot Data for a test type by selecting the red (X) button.





8.9 Run a Sample Test

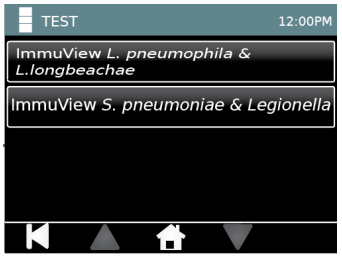
The ImmuView® Reader is capable of running qualitative tests. Up to 100 test types can be installed on the ImmuView® Reader.

NOTE 20. The user is not able to run a test if the instrument is in any of the following states:

- *Self Test (ST) is in the "Fault" state.*
- *the instrument has not passed the Assay QC test for the selected test type (if Assay QC is required)*
- *the instrument has not passed Instrument Check (if Instrument Check is required)*
- *the instrument has not been exposure calibrated*
- *the instrument has not been normalised*

8.9.1 Example Sample Test

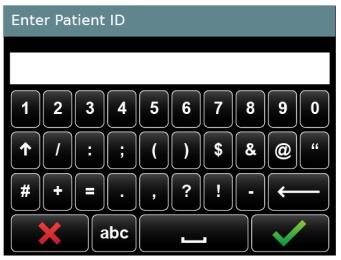
Step 1. Choose Test Type



Select the test type of interest from the displayed test list prior to running a test.

NOTE 21. Admin user can configure the test types imported onto the ImmuView® Reader. Refer to Section 9.9 Import Test Types

Step 2. Patient ID

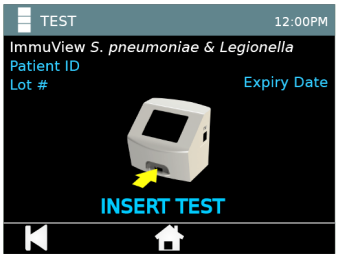


Enter a unique Patient ID using the onscreen keyboard. Select [✓] to save text input. Selecting [X] cancels the test and test data is not saved.

NOTE 22. The Patient ID should be between 1 to 20 characters. If the Patient ID entered is too long or too short, then the instrument displays an invalid input notification.

NOTE 23. If [Patient ID] is set to [Off] in the Admin Settings/Test Setup menu, then Step 2 is skipped and the Test number (T001 for example) is assigned as the Patient ID.

Step 3. Insert Test



The instrument prompts the user to insert the test consumable, and displays the lot information (if applicable) and the Patient ID.

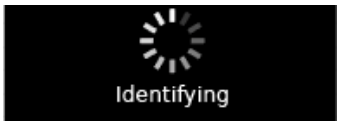
The test begins when the cartridge/strip carrier insertion is detected by the ImmuView® Reader. NB. Be careful that the ImmuView strip do not bounce back when inserting the cartridge. If so, this might cause an invalid test result due to misplacement of the strip in the cartridge.

Selecting [Back] or [Home] cancels the test and test data is not saved.

Step 4. Identifying

During the identifying step, the instrument detects test consumable insertion and performs additional checks if applicable.

Step 5. Identifying and Acquiring Image

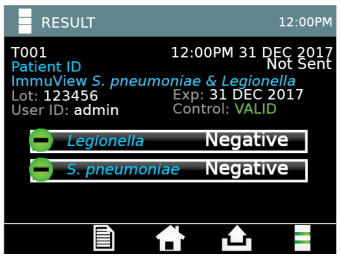


The identifying and acquiring image step in the workflow is where the instrument illuminates the test bay area and captures the image for processing. The test consumable must be left inserted in the test bay during this phase of analysis

Step 6. Analysing and Saving

The instrument performs the analysis on the captured image, at which point the user has the option to remove the cartridge from the instrument test bay if desired. The instrument will continue to analyse the data to produce a result.

Step 7. Result



The result screen displays:

- Test number
- Patient ID
- Test type
- LIS status
- Test time and date (when the test consumable was detected)
- Lot number (if applicable)
- Expiry date (if applicable)
- User ID
- Control line result
- **Final test result**

A result bar can be shown for each test line analysed.
The result can be printed to a connected printer.
The result can be exported to an attached USB Key or LIS (if configured).
The [New Test] icon enables the user to run a new test. Note that this icon will be greyed out when the result is initially displayed – this occurs while the instrument is saving the result to internal memory.

NOTE 24. If the ImmuView® Reader is in "Rapid Test" mode (set in Admin Settings/Test Setup/ Rapid Test [On]) then the instrument remembers the test type run and restarts a new test. This is to enable the user to run a series of the same tests more rapidly.

In the case of a test error: "Error: ##" is displayed as the test result. The error code can be looked up in section 17.1 In-Test Error Dialogues of this user manual.

8.10 Run QC Test

If the instrument and assay produce the same expected result, then it is confirmation that the assay and instrument are working correctly.

NOTE 25. A maximum of 100 test types can be imported onto the ImmuView® Reader.

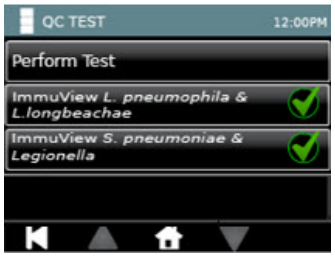
NOTE 26. The user is not able to run an Assay QC test if the instrument is in any of the following states:

- *Self Test (ST) is in the "Fault" state*
- *has not passed Instrument Check (if Instrument Check is required)*
- *has not been successfully exposure calibrated by the Factory user*
- *has not been successfully normalised by the Factory user*

8.10.1 Performing an Assay QC Test

The QC test function allows the user to test if the assay is performing as intended by running the positive and negative control available in the kit.

Step 1. QC Test Menu

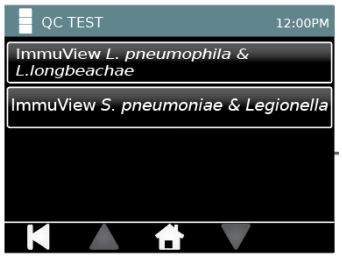


The QC test menu shows a list of the QC test methods that can be run on the ImmuView® Reader:

- Run a QC test.

This screen also displays a list of the QC test Status' for all the Test Types with associated Assay QC tests.

Step 2. Choose Test Type



If different ImmuView® tests are loaded on the instrument, then select from the displayed test list prior to running a test. If one test is loaded the instrument will navigate directly to perform test screen.

NOTE 27. Admin user can configure the list of displayed test types.

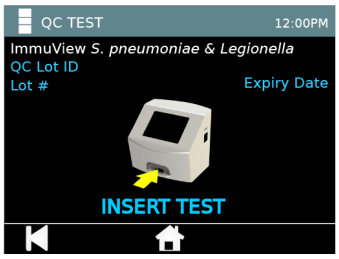
Step 3. Enter QC Lot ID

Enter a unique QC Lot ID using the onscreen keyboard. Select [OK] to save text input.
Selecting [Back] cancels the test and test data is not saved.

NOTE 28. The QC Lot ID should be between 1 to 20 characters. If the QC Lot ID entered is too long or too short, then the instrument displays and invalid input notification.

NOTE 29. If [QC Lot ID] is set to [Off] in the Admin Settings/Test Setup menu, then Step 2 is skipped and the Test number (T001 for example) is assigned as the QC Lot ID.

Step 4. Insert Test



The instrument prompts the user to insert test consumable, and displays the Test Type, the QC Lot ID, the lot information (if applicable) and the Expiry Date.

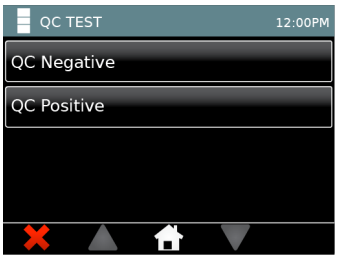
The test begins when the test consumable insertion is detected by ImmuView® Reader. NB. Be careful that the ImmuView strip do not bounce back when inserting the cartridge. If so, this might cause an invalid test result due to misplacement of the strip in the cartridge.

Selecting [Back] or [Home] then [OK] to confirm cancels the test and test data is not saved.

Step 5. Identifying

During the identifying step the instrument detects test consumable insertion and performs additional checks if applicable.

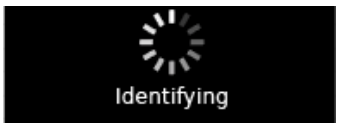
Step 6. Select QC test expected outcome.



The user must select the associated QC test with a known outcome they wish to run for the inserted test.

Selecting [Cancel] or [Home] cancels the test and test data is not saved.

Step 7. Identifying and Acquiring Image

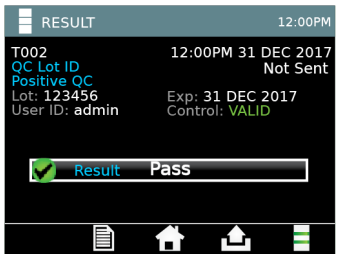


The identifying and acquiring image step in the workflow is where the instrument illuminates the test bay area and captures the image for processing. The test consumable must be left inserted in the test bay during this phase of analysis.

Step 8. Analysing

The instrument then performs the analysis on the captured image, at which point the user has the option to remove the test consumable from the instrument test bay if desired. The instrument will continue to analyse the data to produce a result.

Step 9. Result



The result screen displays:

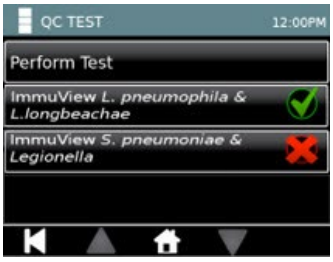
- Test number
- QC Lot ID
- QC Test outcome type
- LIS status
- Test time and date (when the test consumable was detected)
- Lot number (if applicable)
- Expiry date (if applicable)
- User ID
- Control line result
- **Result**

The result can be printed to a connected printer.
The result can be exported to an attached USB Key or LIS (if configured).
[New Test] enables the user to navigate to the test menu in order to start a new test. Note that this icon will be greyed out when the result is initially displayed – this occurs while the instrument is saving the result to internal memory.

In the case of a test error: "Error: ##" is displayed as the test result. The error code can be looked up in section 17.1 In-Test Error Dialogues of this user manual.

8.10.2 QC Status

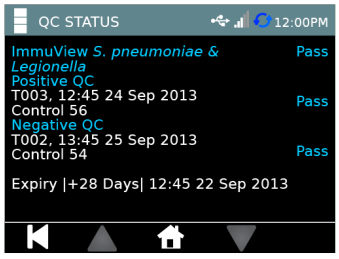
The QC status of tests can be selected from the menu to view more detailed information. The QC status screen shows the test status of each QC test that is associated to the Test type and the date which the QC status was run.



The QC test menu* shows a list of the QC tests that can be run on the ImmuView® Reader and QC test status'.
*Options provided may not be available in some locations, dependant on the Administrator settings applied.
The QC status for each Test Type is indicated by an icon.

Fail	Fail is shown where one or more of the associated QC tests have failed.
Due	Due is shown where one or more of the associated QC tests are due.
Pass	Pass is shown when all associated QC tests have passed.

The QC status screen displays the latest result of all the associated QC tests and the overall QC status for the selected test type. The user can scroll [Up] and [Down] through the screens if there are more than 2 associated QC test types.



Each test (with defined QC test types) has a pass, fail or overdue status based on the last result of each of the associated Assay QC tests.

- If one or more results have failed: the QC Status is Fail.

- If one or more result is overdue and no results have failed: QC status is due.
- If all QC results are pass and none are due: the QC status is pass.

An Assay QC status is set to overdue following:

- A new Test Types Package being loaded onto the instrument.
- The instrument being "Reset to Factory Default".
- The instrument current time is past the Assay QC validity period timestamp.

8.11 Run an Instrument Check Test

This section describes the Instrument Check (IC) test functionality and its associated settings. The IC test is configured to run using a supplied printed strip reference standard and returns a pass or fail result based on analysis of the IC cartridge inserted. The instrument check function reads the test lines of the printed strip and confirms that they fall within the acceptable range. This process provides a reliable confirmation that the instrument is operating correctly.

SSI Diagnostica A/S recommends the use of an Instrument Check in the case that an Assay QC Control test is repeatedly failing, and the user wishes to confirm that the instrument is capable of performing a test analysis independently from the assay.

The Instrument Check (IC) function can be configured, enabled, or disabled in the instrument Admin settings.

The Instrument Check (IC) includes a scheduler to remind users to perform the instrument check test at specific intervals. This check has the advantage that it is independent of any Assay and Assay controls and specifically checks the instrument reading capability using an external cartridge/strip carrier and printed strip standard.

If the Instrument fails the IC test, the instrument can be configured to prevent the user from running any tests. Alternatively, it can be set to provide a warning or to apply no action, depending on the Admin settings.

There can only be one Instrument Check test type loaded on the instrument.

8.11.1 Instrument Check Status

There are three Instrument Check status possibilities:

- Pass: Where the last Instrument Check test has passed.
- Fail: Where the last Instrument Check test has failed.
- Overdue: Where the Instrument Check Pass Status validity period has ended, or when an Instrument Check test has not previously been run.

The instrument check status is updated at the completion of each instrument check test.

The Instrument Check status is set to fail when instrument check fails.

The Instrument Check status is set to overdue at the end of the validity period.

The instrument application does not permit an instrument check to be conducted with an expired test consumable.

The default Instrument Check test includes a focus test and checks that the validation marks are present and within limits.

8.11.2 Running an Instrument Check Test

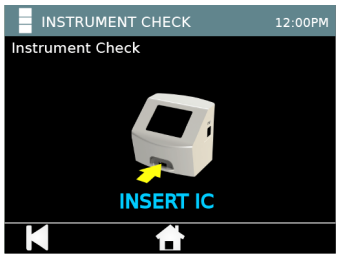
The instrument check cartridge should be kept dark in the pouch when not in use.

Step 1. Insert Test Consumable

The instrument displays the Test Type and asks the user to insert the IC cartridge.

The test begins when the cartridge is inserted.

Selecting [Back] cancels the test.



Step 2. Identifying

The identifying step in the workflow is where the instrument illuminates the test bay area and captures the image for processing. The test consumable must be left inserted in the test bay during this phase of analysis.

Step 3. Analysing and Saving

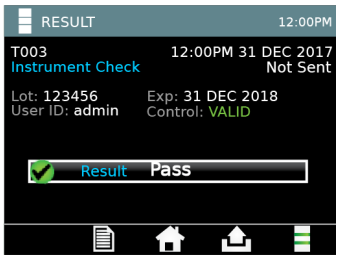
The instrument then performs the analysis on the captured image, at which point the user has the option to remove the test consumable from the instrument test bay if desired. The instrument will continue to analyse the data to produce a result.

Step 4. Result

The Instrument Check result screen displays:

- Test Number
- Time and Date of Test
- LIS status
- User ID
- Result
- Control line result

The result can be printed to a connected printer or exported to an attached USB key by selecting icons in the footer bar.
Selecting the [New Test] icon allows the user to run a new test.
Note that this icon will be greyed out when the result is initially displayed – this occurs while the instrument is saving the result to internal memory.

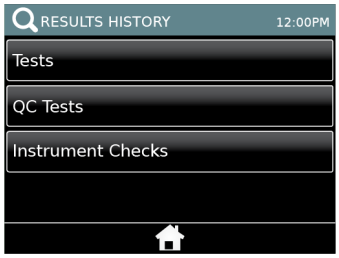


8.12 Results History

The Results History menu contains the following results:

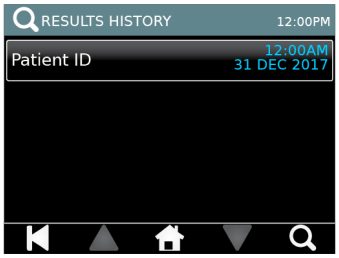
- Test results
- QC test results*
- Instrument Check results*

NOTE 30. * Some options may not be available in this menu; dependant on whether QC and IC testing is enabled.



NOTE 31. The ImmuView® Reader is able to store the results of 999 Standard Test and IC Tests, and a separate 99 Assay QC tests in the instrument memory. If the user runs a test with the memory full, then the oldest result is deleted as the newest one is saved. A warning is displayed to the user prior to running a test in this case.

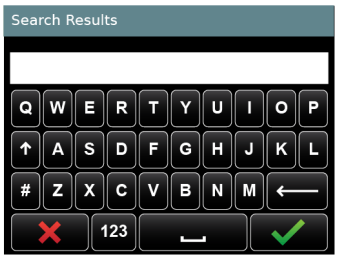
8.12.1 Test Results



If "Tests" is selected from the results history menu, then a summary list of all tests saved in the instrument memory is shown in order of newest to oldest. The following information is displayed:

- Patient ID (as entered by the user at the time of running the test)
- Test Date and Time

The results summary screen can be navigated through using the [Up] and [Down] navigation arrows.
The user can select [Back] to return to the "Results" menu screen.
The user can select [Home] to return to the "Home" screen.
The user can select [Search] to filter the list of results.
The user can filter the summary list by entering a search term.
The test result summary list filters down and only display results where the search term is contained within the:



- Test Number
- Patient ID
- Time and Date of Test
- Test Type
- Lot Number
- Expiry Date
- User ID

The user can select the result from the results summary screen to see the individual result.
The patient result displays:

- Test Number
- Patient ID
- Time and Date of Test
- Test Type
- LIS status
- Lot Number (if available)
- Expiry Date (if available)
- User ID
- Control line result
- Result

The result can be printed to a connected printer.

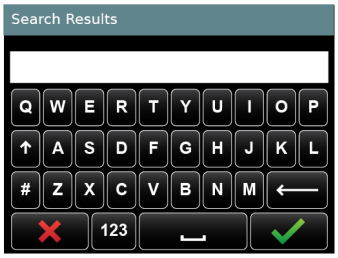
The result can be exported to an attached USB Key and/or to LIS (if configured).

8.12.2 QC Test Results

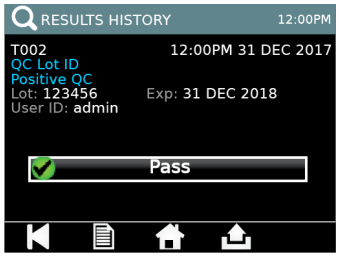
A summary list of all QC tests saved in the instrument memory is shown in order of newest to oldest. The following information is displayed:

- QC Test Type
- Test Date and Time

The QC results summary screen can be navigated through using the [Up] and [Down] navigation arrows.
The user can select [Back] to return to the “Results” menu screen.
The user can select [Home] to return to the “Home“ screen.
The user can select [Search] to filter the list of results.
The user can filter the summary list by entering a search term.
The test result summary list filters down and only display results where the search term is contained within:



- Test Number
- QC Lot ID
- Time and Date of test
- Test Type
- LIS status
- Lot Number
- Expiry Date
- User ID

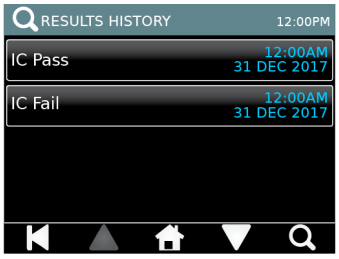


The user can select the result from the results summary screen to see the individual result.
The Control result displays:

- Test Number
- QC Lot ID
- Time and Date of test
- Test Type
- LIS status
- Lot Number (if available)
- Expiry Date (if available)
- User ID
- Control line result
- Result

The result can be printed to a connected printer or exported to an attached USB Key by selecting icons in the footer bar.

8.12.3 Instrument Check Results



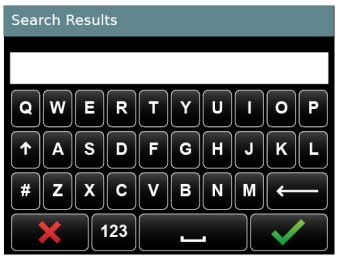
A summary list of all IC tests saved in the instrument memory is shown in order of newest to oldest. The following information is displayed:

- Instrument Check result
- Test Date and Time

The IC results summary screen can be navigated through using the [Up] and [Down] navigation arrows.
The user can select [Back] to return to the “Results” menu screen.
The user can select [Home] to return to the “Home” screen.
The user can select [Search] to filter the list of results.

The user can filter the summary list by entering a search term.
The test result summary list filters down and only display results where the search term is contained within:

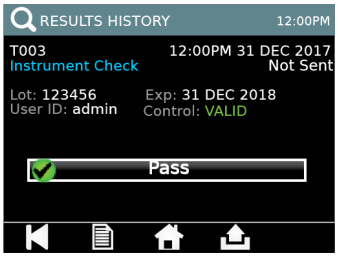
- Test Number
- Time and Date of test
- User ID



The user can select the result from the results summary screen to see the individual result.
The result displays:

- Test Number
- Time and Date of test
- Test Type
- User ID
- Result

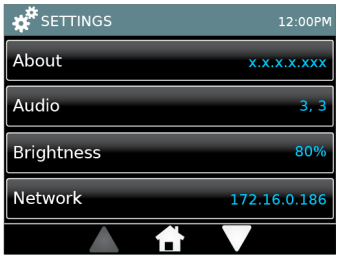
The result can be printed to a connected printer or exported to an attached USB Key by selecting icons in the footer bar.

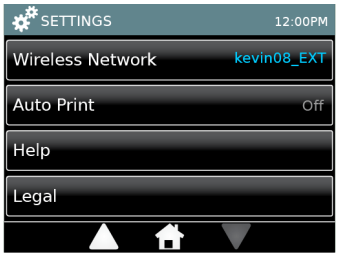


8.13 Settings

The “Settings” screen is accessed from the Home menu and allows a user to configure the ImmuView® Reader.
Use the settings screen to find out information about the ImmuView® Reader or change/update the instrument settings, including:

- About Information
- Audio Settings
- Brightness Control
- Network Setup
- Wireless Network Setup
- Auto Print Control
- Help Information
- Legal Information





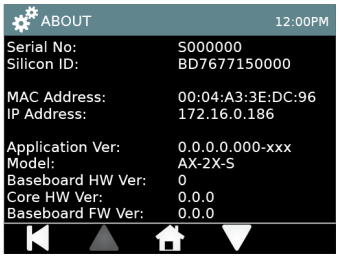
8.13.1 About

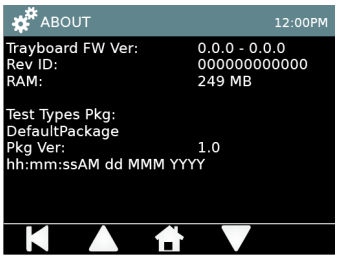
The Info screen displays the following information:

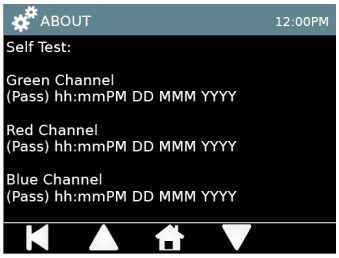
- Serial No, the manufacturers ID
- Silicon ID, a unique ID read from the Instrument.
- MAC Address, unique identifier assigned to the network interface.
- IP Address, an Internet Protocol address, a numerical label assigned to each instrument.
- Application Version: the application version number and a build number.
- Model Number: identifying the ImmuView® Reader model type.
- Baseboard Hardware Version
- Core board Hardware Version
- Baseboard Firmware Version
- Trayboard Firmware Application and Bootloader Versions.
- Rev ID, mercurial version
- RAM (MB)
- Test Types Package: name and version of the test type package loaded and the timestamp when it was loaded.
- Self Test: timestamp and result <Pass>, <Warning> or <Fault>
- Instrument Check: timestamp and status <Pass> or <Due>
- Exposure Calibration: exposure, gain and timestamp.

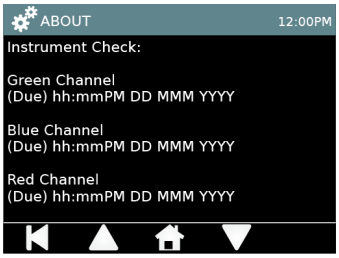
The about screen can be navigated through using the [Up] and [Down] navigation arrows.
The user can select [Back] to return to the results menu screen.
The user can select [Home] to return to the Home menu.

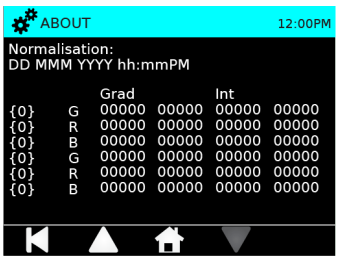
NOTE 32. A record of these identifying fields can assist SSI Diagnostica A/S in providing support and assistance.







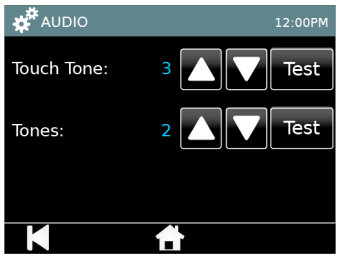




8.13.2 Audio

The ImmuView® Reader sound volume can be edited on this screen. The volume can be adjusted from 0 (no sound) to 5 (highest volume). The test icon allows the user to hear what the current settings are.
The ImmuView® Reader uses sound for the following functions:

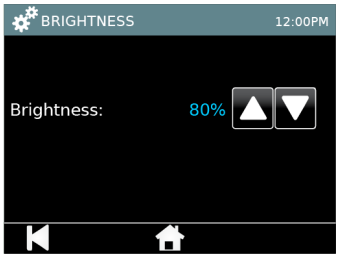
- Screen click when the touch screen is touched (Touch Tone).
- Process tones for end of test, alerts, and warnings (Tones).



Settings apply immediately.
Select [Return] to return to the settings menu.
Select [Home] to return to the home menu.

8.13.3 Brightness

The screen brightness may be adjusted using the up and down arrows. The default and recommended setting are 50%.



Settings apply immediately.
Select [Back] to return to the settings menu.
Select [Home] to return to the home menu.

8.13.4 Network

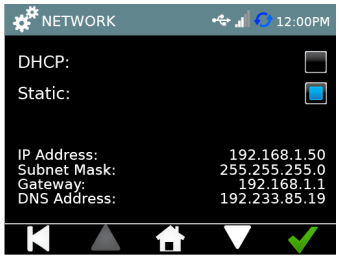
The “Network Setup” screen allows a user to configure the Ethernet connection to the Instrument.

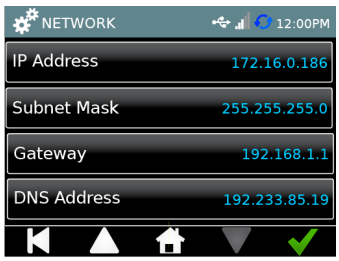
On this screen the user is able to enable DHCP protocol (for automatic IP address assignment), or manual IP address configuration. DHCP requires the presence of a DHCP server on the network.

The default is DHCP. To switch to static IP, an IP address and subnet mask must be entered manually.

DHCP (Router): The ImmuView® Reader supports the use of a typical network with DHCP enabled. Plug the instrument into a network port on the router, then power the Instrument on.

Using Static: IP Addressing is a method of setting up a network where the IP address is assigned manually. The benefit of a static address is IP addresses can be assigned carefully so that each instrument has its own address—with no overlap and the IP address is fixed. This does mean however that when you connect an ImmuView® Reader to a new network, you would have to select the "manual" configuration option and enter in.

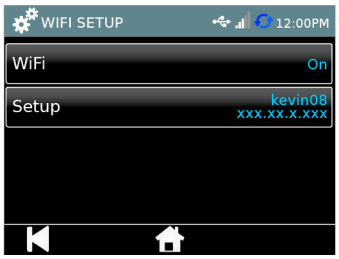




8.13.5 Wireless Network

NOTE 33. A WiFi Dongle must be connected to the ImmuView® Reader to use the features described in this section refer to section 14.5 WiFi Dongle.

The software is able to configure the WiFi Dongle and establish connection to a WiFi Network. WiFi connection status is indicated by an icon in the toolbar at the top of the screen; *refer to section 8.6 Toolbar Indicators.*



Touching the WiFi button toggles between [On] and [Off] which enables and disables WiFi connectivity.

Additionally, the WiFi status is shown by the Connection button on the WIFI SETUP menu, e.g. Not Connected, Connecting, or Connected with Network Name and IP address.

When the WiFi button is toggled to [On], clicking the Setup button will navigate to the WiFi connection menu.

The names of available WiFi Networks are listed.

The connected WiFi Network is indicated by a tick (✓).

Click on connected WiFi Network to edit WiFi IP addresses or forget the Network.

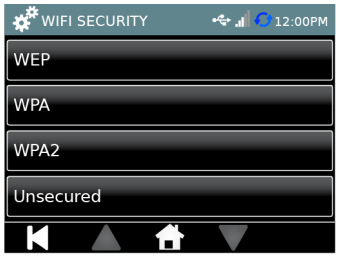
Click on the name of the WiFi network you want to connect to.

If the WiFi Network you want to connect to isn't listed in the Connection Menu, click on the Manual Connection button.

A password is required the first time you connect to a secure WiFi Network.

Upon selecting a WiFi network an enter password screen is displayed. Enter the WiFi Network Security Key or Password then click the tick button (✓) to confirm.

If 'Manual Configuration' is selected an 'Enter SSID' keyboard screen is displayed.

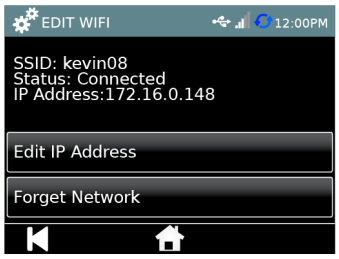


Enter the SSID (service set identifier, i.e., name) of the WiFi Network then click the tick button (✓) to confirm.

Select the Network's Security Type.

Enter the WiFi Network Security Key or Password then click the tick button (✓) to confirm.

Once successfully joined the user is taken to the Edit WiFi screen.



Click on the Edit IP Address button to set the instrument's IP address for this WiFi network.

Click Forget Network to forget the saved Password and IP address for this WiFi Network.

Click the Back button to return to the Connection Menu.

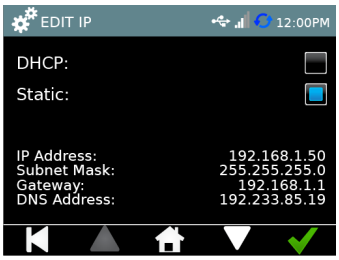
On this screen the user is able to enable DHCP protocol (for automatic IP address assignment), or static IP address configuration. DHCP requires the presence of a DHCP server on the network.

The default is DHCP. To switch to static IP, an IP Address, Subnet Mask, Gateway, and DNS settings must be entered manually.

Click the down navigation arrow then select IP Address, Subnet Mask, Gateway, or DNS to manually enter details.

Click tick button (✓) to refresh the instrument's WiFi IP Address.

NOTE 34. The IP Address is for this WiFi Network only and does not relate to the Ethernet Network Settings included in section 7.12.4



8.13.6 Auto Print

The Auto Print function allows the user to configure the auto printing on to automatically print on completion of a test run, or set off, requiring the user to manually trigger the report to be printed.

The Auto Print function can be turned to [On] or [Off]

8.13.7 Help

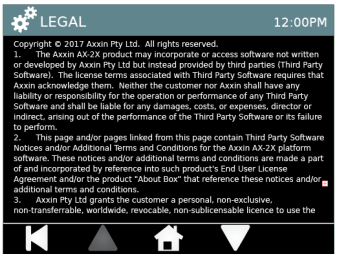
The “Help” screen displays the company contact information and ImmuView® Reader copyright information. Direct any queries to the company via the website.

Select [Back] to view the “Settings Menu”.

Select [Home] to go to the "Home Menu”.

8.13.8 Legal

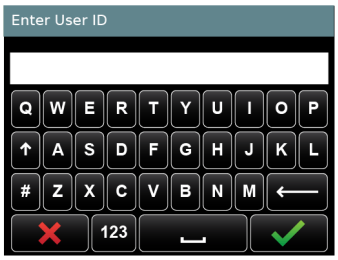
The Legal page contains the software licensing and legal information.



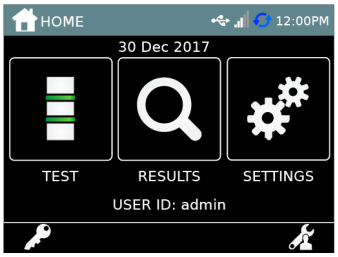
9 Administrator User Instructions

To access administrator functions described in this section you need to login using the admin user ID.
The default admin login is present when the instrument is first received from SSI Diagnostica A/S.

The default admin login is: admin
The default admin password: admin

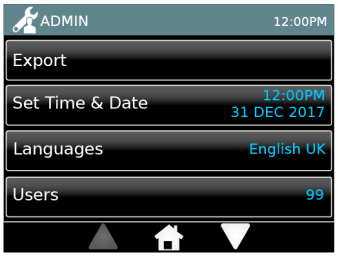


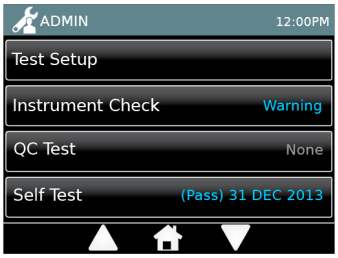
The admin user sees the same Home menu as a Standard User with the addition of the admin user settings icon in the footer bar, on the bottom right.

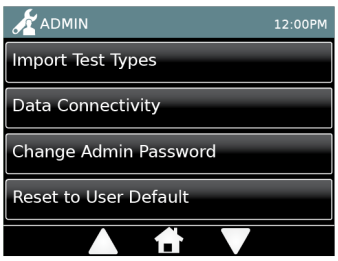


Use the administrator settings screen to change or update instrument configuration, including:

- Export Result and Log files
- Time & Date
- Languages
- Users
- Test Setup
- Instrument Check
- QC Test
- Self Test
- Import Test Types
- Data Connectivity
- Change Admin Password
- Reset to User Default







NOTE 35. The "Import Test Types" button is disabled if a USB key is not detected. A USB key icon ( ) is displayed in the header and the button(s) enabled when a USB key is detected.

9.1 Export

The “Export” settings screen allows an Admin User to Export instrument results, summary files and logs onto an attached USB Key.
The summary file is a list of all test results stored on the instrument.
Ensure a USB key is attached then select one of the summary file types available:

1. Export .CSV File, summary file exported as a *.CSV file.

   This setting enables the admin user to export data where each field value is separated from the next by a "," comma (e.g., ‘2,56’). In this case, 2 and 56 will be placed in separate columns.

2. Export .TSV File, summary file exported as a *.TSV file

   This setting enables the admin user to export data where each field value is separated from the next by a “tab” stop character (e.g., ‘2 56’). In this case, 2 and 56 will be placed in separate columns.

3. Export Test Diagnostics

   This setting enables the Admin user to export test diagnostics to a USB key. If support is needed this can be asked for by SSI Diagnostica A/S.

4. Export Logs

   This setting enables the Admin user to export instrument logs to a USB key. If support is needed this can be asked for by SSI Diagnostica A/S.

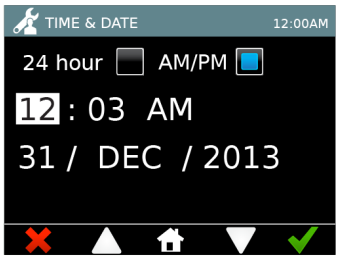
When summary files have exported successfully, the software provides the opportunity to delete all test results. Make sure you do not accept until the necessary files have been exported.
The exported summary files from the ImmuView® Reader can be viewed using external software applications (e.g., Microsoft Excel)

NOTE 36. The user will only be able to export result and log files when a USB key is detected. A USB key icon ( ) is displayed in the header and the buttons are enabled when a USB key is detected.

NOTE 37. If the results memory file is approaching its maximum limit, then the user is advised to export the test results. If the maximum storage limit is reached the ImmuView® Reader deletes the oldest test result to make room for the newest and the Test Numbers begin to increment past T999.

9.2 Set Time & Date

The "Time & Date" screen allows the admin user to set the correct time and date.
Use the up and down arrow keys and touch screen to change the time and choose between a 12 Hour or 24-Hour display.
Use the up and down arrow keys and the touch screen to change the date and move between day, month, and year.



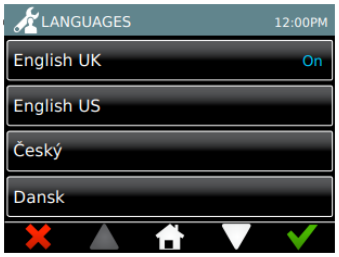
Press [OK] to save the settings and return to the admin menu.

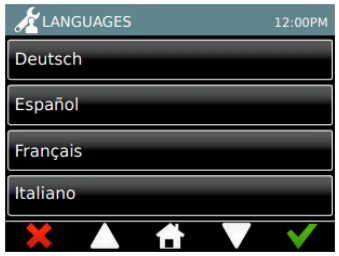
NOTE 38. The time and date are displayed to the user on the main screen. Time and date are confirmed by the user.

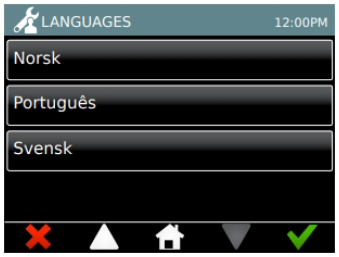
NOTE 39. The ImmuView® Reader Real Time Clock (RTC) maintains the instrument set time whilst the instrument power down.

9.3 Languages

The “Language” settings screen allows an admin user to configure the Language set on the ImmuView® Reader.
All text strings on the ImmuView® Reader will be displayed in the Language selected. Text strings that are input in test type packages are independent of language settings.







Languages available include:

- English UK
- English US
- Czech
- Danish
- French
- German
- Italian
- Norwegian
- Portuguese
- Spanish
- Swedish

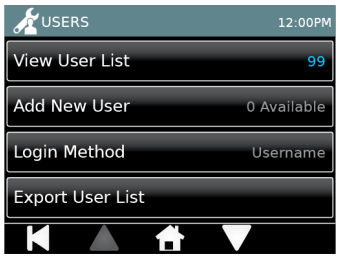
NOTE 40. Messages displayed during system boot-up and the software update processes are displayed in English UK only.

NOTE 41. The same onscreen keyboard will be used for data entry across all languages using Standard English keyboard characters.

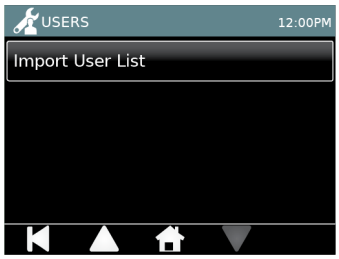
9.4 Users Settings

The User Menu allows the Admin to add, delete and edit the list of instrument users. Functions include:

- View User List
- Add New User
- Login Method selection
- Export User List
- Import User List



NOTE 42. The import and export buttons are disabled if a USB key is not detected. A USB key icon ( ) is displayed in the header and the buttons are enabled when a USB key is detected.



9.4.1 View User List, Edit/Delete User

The User List shows all Standard User profiles authorised to use the instrument.

Select a User from the list to edit User details or to delete the User.

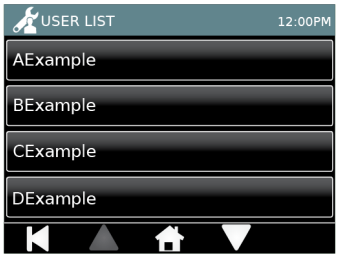
To delete a current User, press delete. A warning will be displayed confirming to delete user.

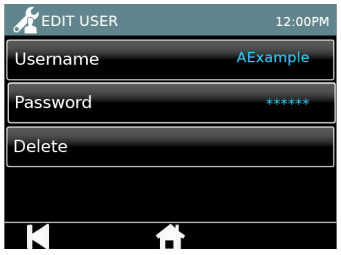
Press [OK] to delete User and return to the Setup Users screen.

Press [Cancel] to return to the Users screen without deleting the user.

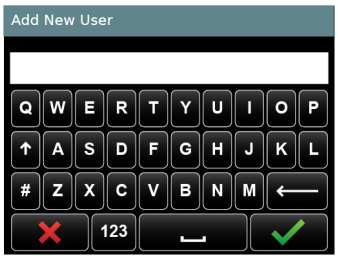
NOTE 43. Deleting a User is permanent. Once deleted, the User profile will be lost.

NOTE 44. Test results performed by this user that are already stored in the instrument performed will not be affected.





9.4.2 Add New User



To add a new user, the instrument prompts the user with the following steps:

1. Enter a new User ID
   Using the on-screen keyboard or an electronic barcode, enter a new User ID. Press [OK] to proceed.
   The User ID must be 2 to 20 characters, alphanumeric, and cannot contain spaces or special characters. User IDs are not case sensitive.

2. Enter a new Password
   Using the on-screen keyboard, enter a new password and press [OK] to proceed.
   The Password must be between 1 to 20 characters long.
   .
3. Confirm new Password.
   Re-enter the new password to complete the process.

NOTE 45. The user will be prompted to re-enter the password if mismatch is detected.

NOTE 46. Up to 100 users can be created.

NOTE 47. A unique User ID is required for each user. If a duplicate User ID is entered, the instrument will prompt to use a different ID.

NOTE 48. The following user IDs are reserved in the ImmuView® Reader software application: admin, factory and axxin. You will receive an error notification if you try to add these to the user list.

9.4.3 Login Method

The Login Method can be toggled to: ‘Username’, ‘Password’, or ‘None’.

If the Login Method is set to “Username”, users may enter any user ID and will not be asked for a password.

If the Login Method is set to “Password” then a user can log onto the instrument, given they enter a valid User ID input using the onscreen keyboard and the correct associated password.

If the Login Method is set to “None” there will be no prompt to input a username or password. While set to “None” User ID fields will read “Default User”.

9.4.4 Export User List

Export all configured users to a USB drive connected to the instrument. This user list can then be imported to another ImmuView® Reader or to the same instrument following a software upgrades. This permits 'cloning' of user accounts across a number of instruments.

NOTE 49. The export button disabled if a USB key is not detected. A USB key icon ( ) is displayed in the header and the button is enabled when a USB key is detected.

9.4.5 Import User List

Import a complete user list that has been exported from an ImmuView® Reader, using a USB drive connected to the instrument. This permits 'cloning' of user accounts across a number of instruments.
Press [OK] to return to the User screen.

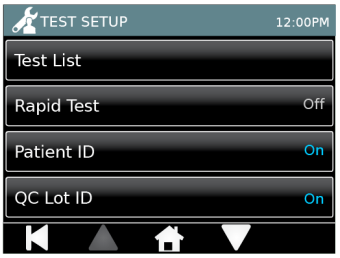
NOTE 50. Only Users exported from an ImmuView® Reader of compatible software can be imported.

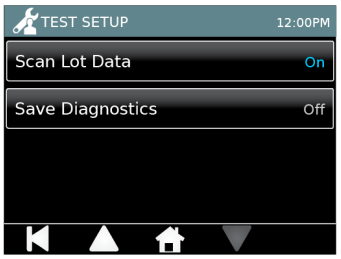
NOTE 51. The import button is disabled if a USB key is not detected. A USB key icon ( ) is displayed in the header and the button is enabled when a USB key is detected.

9.5 Test Setup Settings

The Test Setup Menu allows the Admin to edit the settings for the following functions:

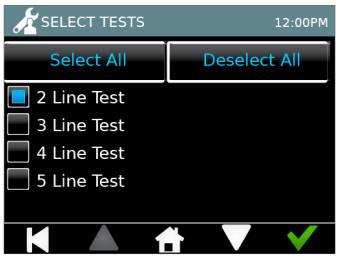
- Test List
- Rapid Test
- Patient ID
- QC Lot ID
- Scan Lot Data
- Save Diagnostics





9.5.1 Test List

The test list displays a list of test types that have been imported onto the instrument. From this list, the admin user can select which test types to display in the test menu. Only the selected test types will be available for running from the test menu.



9.5.2 Rapid Test

The Rapid Test mode can be turned [On] and [Off].

When [On] is selected the instrument remembers the selected test type and the testing method to enable more rapid testing capability. Allowing for multiple tests without going to the Test selection page between the test results.

When [Off] is selected the instrument does not remember the selected test type and the testing method, the user needs to select the test type each time.

NOTE 52. The user is still required to enter a Patient ID if Patient ID entry is required.

9.5.3 Patient ID

The Patient ID can be turned [On] and [Off].

When [On] is selected, the instrument prompts the user to enter a Patient ID at the start of a test.

When [Off] is selected, the instrument does not prompt the user to enter a Patient ID.

9.5.4 QC Lot ID

The QC Lot ID can be turned [On] and [Off].

When [On] is selected, the instrument prompts the user to enter a QC Lot ID at the start of a test.

When [Off] is selected, the instrument does not prompt the user to enter a QC Lot ID.

9.5.5 Scan Lot Data

The Scan Lot Data test function can be turned [On] and [Off].

When [On] is selected, the Scan Lot Data test function is visible in the test menu.

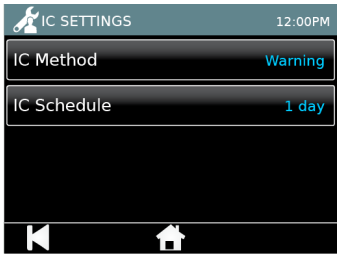
When [Off] is selected, the Scan Lot Data test function is hidden in the test menu.

9.5.6 Save Diagnostics

Save Diagnostics increases the file size of the .bin file results to contain more detailed information, useful for diagnostic and troubleshooting purposes. This feature can be asked upon if comprehensive sample/test result support is needed from SSI Diagnostica A/S.

NOTE 53. Turning Save Diagnostics on greatly slows the ImmuView® Reader cycle time (due to longer results saving time). The results export operation will also be slowed considerably. You should select this option if you are supplying an .bin file to SSI Diagnostica A/S for support.

9.6 Instrument Check Settings



The Admin user can configure the instrument check method and schedule. The method can be configured between:

- None: Where the instrument check functionality is hidden from the testing and results screens and no instrument check status is applied. *
- Warning: Where a warning is displayed to the user prior to running a QC test or test when the instrument check status is set to fail or due.
- Lockout: Where the user is prevented from running a QC test or test when the instrument check status is set to fail or due.

*NOTE 54. *The results button will only be hidden when there are no instrument check results in the instrument memory.*

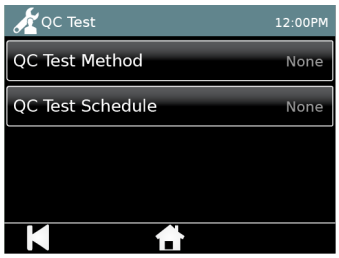
The schedule can be configured between:

- 1 day or 7 days

After the number of days has elapsed since the IC status for a test type has been set to pass, the IC test status is set to due.

NOTE 55. Some options listed here may not be available in some menus; depending on the configuration of the ImmuView® Reader.

9.7 QC Test Settings



The Admin user can configure the QC test method and schedule:
The method can be configured between:

- None: Where the QC test functionality is hidden from the testing and results, no QC test status is applied. *
- Warning: Where a warning is displayed to the user prior to running a test when the QC status for that test type is set to fail or due.
- Lockout: Where the user is prevented from running a test when the QC status for that test type is set to fail or due.

*NOTE 56. *The results button will only be hidden when there are no QC test results in the instrument memory.*

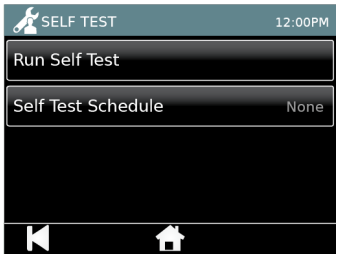
The schedule can be configured between:

- None: where no schedule is applied
- or 1 day, 7 days, 28 days, 30 days

After the number of days has elapsed since the QC status for a test type has been set to pass, the QC test status is set to due.

NOTE 57. Some options listed here may not be available in some menus; depending on the configuration of the ImmuView® Reader.

9.8 Self Test Settings



The admin user can run a self test as desired and set up a schedule to automatically run a self test after a set amount of time.

The schedule can be configured between:

- None: where no schedule is applied
- or 1 day, 7 days, 28 days, 30 days

After the number of days has elapsed since the last self test was run, the self test is run again.

NOTE 58. A scheduled self test does not interrupt testing.

9.9 Import Test Types

The ImmuView® Reader is supplied by the manufacturer with a default set of test types loaded onto the instrument. The admin user can then import new test types onto the ImmuView® Reader from this screen, if the appropriate file type is found on an attached USB key.

NOTE 59. Ensure that the USB key is connected to the instrument before attempting import.

NOTE 60. Importing new a new test types.ax2pkg profile will replace all test types previously loaded onto the instrument.

NOTE 61. All test types will be imported and displayed on the instrument. To configure which test types to display, refer to section 9.5.1Test List

If the test type file was successfully imported the instrument displays a conformation message to the user. The ImmuView® Reader then reboots.

Additionally, if the user inserts a USB key containing a valid test package before powering on the ImmuView® Reader, and no custom test package has been imported before, then the ImmuView® Reader will automatically initiate a Test Package import process upon application boot up.

The new test type package is available when the user runs a test. Information about the test type package, including name, version number and timestamp of import is viewable in the ImmuView® Reader "About" screen.

NOTE 62. The number of test types that can be saved and loaded in one Workspace Package is 100.

NOTE 63. The Workspace test types package must be the in USB flash memory key root directory folder for the ImmuView® Reader to find the test type package file.

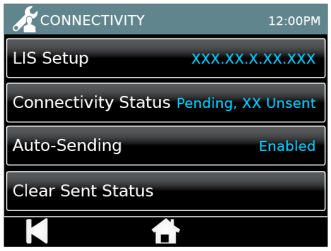
NOTE 64. The import button is disabled if a USB key is not detected. A USB key icon ( ) is displayed in the header and the button is enabled when a USB key is detected.

NOTE 65. Uploading a new set of test definitions does not affect results already held in the test results store.

9.10 Data Connectivity

Data connectivity refers to the ability to connect to a laboratory information system (LIS) and send assay results for storage in that system.

The ImmuView® Reader communicates with an LIS Server using the HL7 standard. This standard defines TCP/IP data exchange and protocol frames used for communication between a LIS server and an instrument.



NOTE 66. Only unidirectional communications are possible using the LIS transmission feature from the ImmuView® Reader to the LIS Server.

9.10.1 Packet Format

Results to be sent to the LIS are packaged as an ASCII formatted data packet. The packet is divided broadly into several categories/sections each of which contain fields appropriate for certain types of information.

As an example, a data packet may contain the following categories:

- Message Header - Information used to parse the message.
- Specimen Segment - Information about the specimens tested.
- Observation Request Segment - Information about the Type of test requested (1 to many).
- Observation Results Segments - Information about the result of the tests.

The categories above are defined in the HL7 standard.

9.10.2 Setup LIS Connection

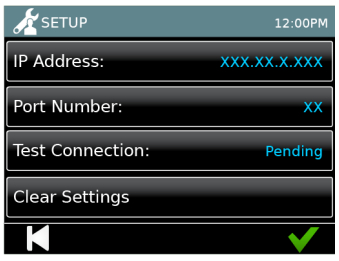
The following section demonstrates the steps for Setting up the ImmuView® Reader for LIS communications:

Navigate to LIS Setup Menu

The first step is to Set the LIS Server IP address and Port Number settings in the ImmuView® Reader to establish communications on the same network.

Select the 'LIS Setup' option.

Set LIS Server IP Address

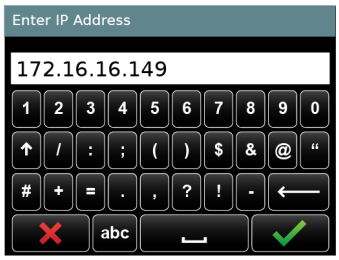


Setting up communications to the LIS Server requires knowledge of the server credentials. Contact your IT provider to acquire the IP Address & Port Number details of the LIS Server to be used.

Select the "IP Address" option.

Enter the IP Address of the LIS server into the field provided, with each unique ID number separated by a full stop '.'

E.g., "XXX.XXX.XXX.XXX"



Set LIS Server Port Number

Setting up communications to the LIS Server requires knowledge of the server credentials. Contact your IT provider to acquire the IP Address & Port Number details of the LIS Server to be used.

Select the "Port Number" option.
Enter the Port Number of the LIS Server into the field provided.

The default value is provided is 51112. However, this number will be specific to the LIS Server you are using.

The number must lie between the following range: 49152 - 65535

Test LIS Server Connection
To Test the connection between the ImmuView® Reader & the LIS Server, run the 'Test Connection' option.

Select "Test Connection"
One of three states will be displayed:

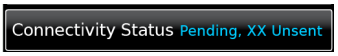
Pending: Test Connection not yet run
Success: ImmuView® Reader successfully connects to LIS
Failed: ImmuView® Reader failed connection with LIS

Touch the ✓ icon to apply confirm the applied IP & Port Number settings of the LIS Server.

Clear Settings
Use the 'Clear Settings' option, to quickly clear all configured options within the LIS Setup menu.

9.10.3 Check Connectivity Status

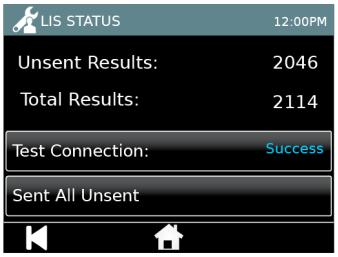
Connectivity Status



The user may access the Status screen to view transmission data statistics with the LIS Server.

To do this, navigate to the Data Connectivity menu under the Admin settings, then select the 'Connectivity Status' option.

LIS Status



Under the LIS Status menu, the user can review the transmission stats with the LIS Server.
The categories shown are:

- Unsent Results (results not yet sent to LIS)
- Total Results (total number of results in instrument memory)

Test Connection

The first user option shown is a repeat command also found under the LIS Setup menu.
The user can run the 'Test Connection' option from the LIS Status screen as well for convenience.

Send All Unsent

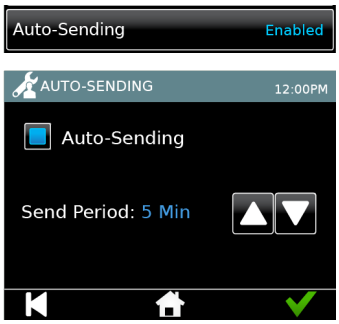
The 'Send All Unsent' option performs an immediate transmission of all unsent test results to the LIS.
Refer to Section 7.3 Toolbar Indicators, to understand the Transmission Status shown by the ImmuView® Reader.

When sending the results, the unsent result count will reset to 0 as all previously unsent results have been sent to the LIS server.
During transmission of the results, a stop button (✘) will appear on the bottom right corner of the screen. This will allow the use to stop the current transmission and leave the remaining results as unsent.

9.10.4 Auto Sending

Auto-Sending

The user can set the ImmuView® Reader to automatically send results to the LIS Server at regular periods. When the period elapses, all of the unsent results will be sent to the LIS Server.



Auto send can be configured by selecting on the "Auto Send" option from the Data Connectivity menu within the Admin Settings.

Home → Admin Settings → Data Connectivity → Auto Send.

Toggle the Auto Send ON / OFF button , to enable the Auto Send Period

Adjust the Auto Send period by using the Up/Down arrows. .

The available periods are:

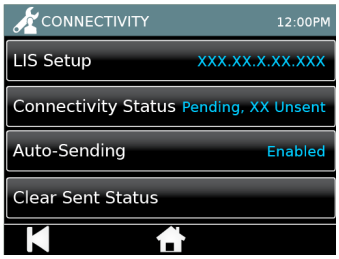
- 5 Minutes
- 15 Minutes
- 30 Minutes
- 1 Hour
- 1 Day

Touch the ✓ icon to confirm the applied settings.

9.10.5 Clear Sent Status

Clear Sent Status

The user can clear the sent status of the number of transmissions sent to the LIS Server.
This may be useful if the user exports all test results off the instrument and clears the memory and wishes to track one for one any new test results.



9.10.6 Send Single Result to LIS Server

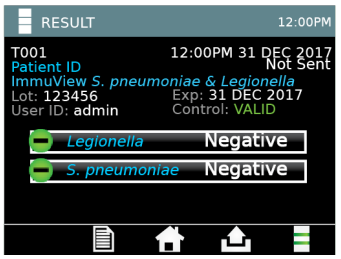
Manual Send

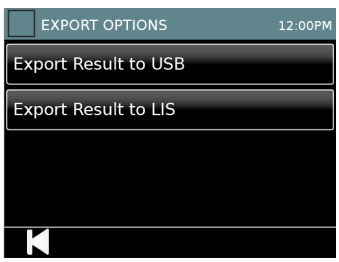
There are two methods to send a single result to the LIS Server:

- At the end of running a live test,
- Via the results menu

At the end of running a test select the Export icon to open the result export options.

When viewing the Result page select the Export icon to open the result export options.





Select the "Send to LIS" button to transmit the currently viewed result to the LIS server; regardless of its previous sent/unsent status.

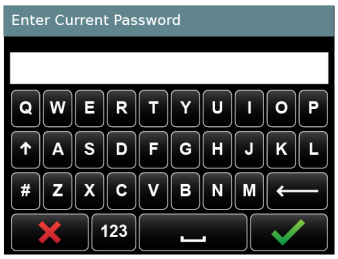
NOTE 67. LIS must be configured before the user is able to Export Result to LIS

NOTE 68. The export button is disabled from result screens if LIS is not configured, and no USB is detected

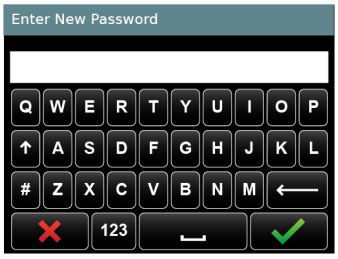
9.11 Change Admin Password

The admin user may wish to change the Administrator password for security reasons. To do so select the “Change Admin Password” option from the “Admin Settings” menu.

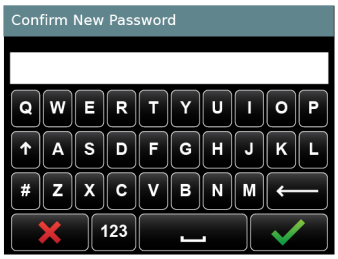
Enter Current Password: The admin user must enter the current Administrator Password to prove they have authorisation to change the Administrator Password.



Enter New Password: The admin user must enter a new password.



Confirm New Password: The new password must be re-entered to verify that the New Password was entered correctly and is remembered.



NOTE 69. Please ensure that the admin user password is kept safe to prevent locking yourself out from these settings.

NOTE 70. A reset to user default will reset the admin password see section 9.12

9.12 Reset to User Default

NOTE 71. This cannot be undone. Please ensure that any important data such as User Lists and Test Results are exported to a USB Memory Key prior to performing Reset to User Default.

Select “Reset to User Default” to perform the following:

- Remove all users accounts.
- Reset Admin password to its software default (“admin”).
- Remove all Test Results.
- Reset the test number to T001
- Return to user default flag is set, such that a time and date set shall run at the next power up.
- Instrument check status set to (Due).
- Assay QC status set to (Due).
- Set User Settings:
    - Audio: both set to level 3
    - Brightness 80%
    - LAN Network, set to DHCP
    - WiFi Network, set to Off
    - Auto Print, set to Off
- Set Admin Settings:
    - Save Diagnostics, set to Off
    - Assay QC method set to warning
    - Assay QC schedule set to none
    - Instrument Check, set to warning (7 Days)
    - Instrument Check schedule set to none
    - Self Test schedule set to 1 day
    - Language set to English UK
    - Time set to 24hr
    - Login Method set to Username
    - LIS Setup not set auto-sending set to On
    - Admin password reset to default (“**admin**”)
    - No standard users configured, 99 users available
    - Test Setup: Rapid Test set to Off
    - Test Setup: Patient ID set to On
    - Test Setup: QC Lot ID set to On
    - Test Setup: Scan Lot Data set to On
    - Test Setup: Save Diagnostics set to Off
    - SSI Diagnostica Default Test Types Package loaded

The ImmuView® Reader requires on screen confirmation: “Are you sure you want to reset your ImmuView® Reader to user default?” Once completed the ImmuView® Reader will reboot.

10 Data Export and Archive

A user can export the following file types from the ImmuView® Reader to a USB key.

- Test result report image for a single test result
- Test Results .bin (encrypted data, images and detailed results. For support and troubleshooting instrument and ImmuView test)
- Test Results .CSV or .TSV (for import to Microsoft excel)
- Log Files (for support and troubleshooting instrument)

Test Results and Data Archive Recommendation: It is highly recommended that a tests results "Archive" is made to an external USB Key and is stored separate to the instrument as a backup.

10.1 Single Test Result Image/Printed Test Report

A single test result can be exported to a USB or printed to a connected printer at the completion of a test or when viewing a single test result in the instrument results screens.

The report has a common format for all test types and where a field is not used it is left blank.

REPORT TYPE	DESCRIPTION
Compact USB Printer Seiko Smart Label Printer 620	Printed on a Shipping label W: 54mm (2 1/8 in) H: 101.6 (4 in)
Export to USB Key	Exported to an attached USB Flash Memory Key as an image viewable on a standard PC.

10.2 Test Result .bin Files

The application automatically saves test results to a location in the ImmuView® Reader memory. The test results are .bin files that can be exported, printed and viewed in special software (not provided).

The .bin file contains a database of all test data (test results and test type information etc.). Separate .bin files are created for patient tests, QC tests and IC tests. The .bin file format requires special software (not provided) to display its contents and is not directly readable. The instruments silicon ID and the Software Update version number are saved in each test result record. After a test result has been saved on the instrument after test completion, there will be no user ability to edit or annotate anything in the test result record on the instrument. All test definition information used to run the test will be included in the test result. No dynamic link is maintained between a test result and a test definition as the test definition may be changed after the test is run. Each test result file contains a GUID to uniquely identify the test run. The exposure calibration and normalisation values used for a test are stored in the test result.

10.3 Test Results.CSV or .TSV

A .CSV or .TSV file summary "spreadsheet" of the Instrument Details and all test results is also available from the "Export" options.

The contents of the exported .CSV/.TSV results summary file are listed below.

10.4 Log Files

The log files are in text format and are provided for system diagnostics and are intended for use by support staff at SSI Diagnostica A/S.

11 ImmuView® Reader Specifications

ITEM	DESCRIPTION
Test Bay Configuration	Wide single slot, configured for SSI Diagnostica strip carrier format. Holds one test consumable only per test.
Multiple Assay Types	Supports multiple assay types and test protocols
Multiplex Capability	The instrument can be configured to read multiple test and control lines
Modes	• Instrument stand-alone – Manual read
Measurement Technology	Advanced image acquisition and analysis
Illumination Type	• Green LED – 520nm • Red LED – 622nm • Blue LED – 470nm
Colour Touch Screen	3.5” diagonal capacitive TFT LCD
Communications	• Ethernet • USB • WiFi (USB connected peripheral) • LIS-HL7
Data Storage	• High capacity on board storage for up to 999 test results. • History Records allow search and retrieval. • Archive or export via USB
Power	• 12 V DC from external AC/DC supplied plug pack. • DC Voltage fluctuation ±10% • DC Current consumption: 0.2A DC typical, 1A max @ 12V DC
Dimensions	165 mm W x 140 mm H x 175 mm D
Weight	Approx. 650 g
Wireless support (Not provided)	• USB attached Buffalo Airstation N150 Wireless USB Adapter
Barcode scan support (Not provided)	• USB attached Datalogic QuickScan QD2430 2D with stand
Printer Support (Not provided)	• USB attached Seiko SLP-620 label printer
Keyboard Support (Not provided)	• USB attached Generic keyboard, English QWERTY

Operating Environment	• Indoor Use • 15°C to 35°C. • 10% to 70% RH (non-condensing). • 0 to 2000m altitude. • Pollution degree: 2
Storage Environment	• 2°C to 45°C, • 10% to 70% RH (non-condensing) for at least 7 days.
Peripherals	• USB Key (FAT32 formatted) • USB connected WiFi Dongle • USB connected Label Printer • USB connected Barcode Scanner

12 12V Power Supply Adaptor Specifications

The ImmuView® Reader is operated using only the specified and supplied AC/DC power adaptor to ensure both the EMC and safety compliance of the product.

The SSI Diagnostica A/S supplied Power adapter, 12V DC, 1.25A:

Part No: P004831

Description: Power adapter input 100-240VAC~50/60Hz 0.5A. Output DC 12V, 1.25A Approval UL, CUL, GS, CE, RCM, UK, FCC, ISED, NRCan, Energy efficiency Level VI, DoE, CoC Tier 2. Interchangeable AC mains plugs, 4 types to fit regions: AU (Australia), UK, US and EU (Europe).

Rated input voltage	100-240VAC
Rated input frequency	50/60Hz +/- 3Hz
Rated input current	0.5A max.
Operating Environment	0ºC to 40ºC. 10% to 90% RH (non-condensing).
Storage Environment	-20ºC to 80ºC. 10% to 90% RH (non-condensing).
Output voltage	12 V
Output current:	1.25 Amps

13 Accessories (not provided)

Accessories that can be used with the ImmuView® Reader are available separately and include:

- A USB key
- A Label printer, the Seiko SPL620
- A Barcode scanner, Datalogic QuickScan Barcode Wand QD2430 with stand
- A WiFi Dongle
- A generic keyboard English QWERTY

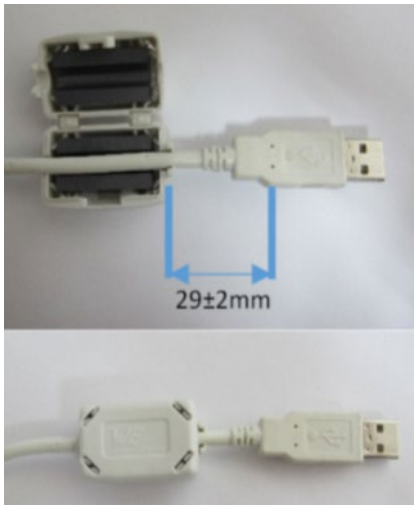
13.1 Fitting Ferrites (provided)

Three ferrite cores are supplied with the ImmuView® Reader. Ferrites must be fitted to the following accessories prior to use in the operation of the ImmuView® Reader:

- Label printer, the Seiko SPL620
- Barcode scanner, the Datalogic QuickScan Barcode Wand QD2430

Fitting ferrites:

- Retrieve ferrite core from zip lock bag inside packaging.
- Place USB peripheral cable inside the ferrite core, distance from ferrite core to USB connector base should be 29±2mm.
- Lock the cable in place by pushing the cable down.
- Close the ferrite core once the cable is in correct position



13.2 USB key

The SanDisk, Cruzer Blade key is an example of a typical USB key proven to work with the instrument.

- Formatted for FAT32, min 1GB with only 1 partition.
- The USB Key doesn't perform CD-ROM emulation.
- The USB Key does not have propitiatory software loaded to run it.
- There is only one USB Key present during a software update process.

A USB key may take a few seconds to be detected by the ImmuView® Reader drivers. A USB icon [ ] is displayed in the task bar when a USB key has been successfully detected.

13.3 Label printer

Seiko Smart Label Printer – SLP 620
The Seiko Smart Label printer type SLP 620 is approved for operation with the ImmuView® Reader. The printer will print the ImmuView® Reader Test report on a receipt or adhesive shipping label.
Operation Summary

- Plug in the SLP 620 AC Adapter cord to the mains outlet.
- Connect output cord to ImmuView® Reader, and power up the Instrument.
- Connect the SLP USB cord to the ImmuView® Reader.
- Turn on SLP by pressing the power button. Ensure green status light is shown, indicating the printer is online. Press the button once to toggle between online and offline modes.
- Prepare and load a roll of labels into the spindle holder under the label cover and adjust the label guide to fit the labels.
- Insert free end of the roll into the slot, until the SLP automatically feeds the labels through. If this doesn't occur, press the form feed button to advance the labels through the slot. Close the label cover.
- If you want to have automatic printing of test results, on the ImmuView® Reader, go to Settings -> Printer Setup to toggle Auto Printing on. If not, the option to print will need to be selected after the completion of a test.
- With the SLP turned on, run test on the ImmuView® Reader.
- Press and hold for 2 seconds to turn SLP off.

Model No. SLP 620

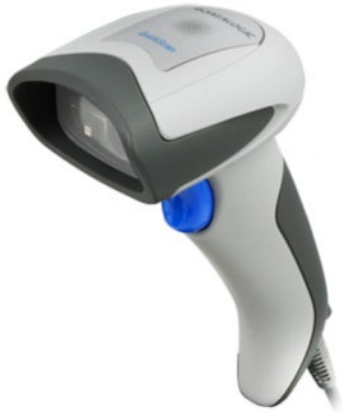
Specifications Summary

- Weight 490 g
- Dimensions 113.8 mm W 172.0 mm D 148.0 mm H
- Max. Print Speed (70mm/second)
- Resolution 8 dots per mm
- Label Shipping Label
- SLP-SRL or SLP-SRLB (Bulk)
- Following Components Included:
- Smart Label Printer (SLP 620, SLP 650 or SLP 650SE)
- Quick Start Guide
- CD-ROM containing software and printer drivers
- USB cable
- Serial cable (SLP 650SE only)
- AC adapter
- Roll of Smart Labels
- Specification SLP620 SLP650 & SLP650SE

Warning: ImmuView® Reader Power Rating Specifications
12V DC, DC Voltage fluctuation ±10%.
DC Current consumption 0.2A DC typical @ 12 V DC.

13.4 Barcode Scanner

Datalogic QuickScan Barcode Wand, QD2430



ImmuView® Reader can accept input from a standard USB connected barcode wand, where the barcode wand operates in “keyboard mode”. In “keyboard mode” the wand will supply a character string that appears in the text box as if it was typed on the onscreen keyboard.

Both the “contact” type barcode wand and CCD or laser “non-contact” type barcode readers can be used. The ImmuView® Reader is configured to automatically accept barcode reader inputs for all text fields with the exception of password inputs.

Plug the cable into the reader then connect it to the Instrument via USB.
For a complete setup and operating procedure refer the Datalogic QuickScan™ QD2430 user manual.

SPECIFICATIONS SUMMARY	
Light Source	LED
Roll (Tilt) Tolerance	Up to $\pm 360°$
Pitch Tolerance	$\pm 65°$
Skew (Yaw) Tolerance	$\pm 60°$
Print Contrast Minimum	25% minimum reflectance
Operating Temperature	$0°$ to $50°$C ($32°$F to $122°$F)
Storage Temperature	$-40°$ to $70°$C ($-40°$F to $158°$F)
Humidity	0% to 95% relative humidity, non-condensing
Drop test	Scanner withstands 18 drops from 1.5m (5ft)
Ambient Light Immunity	Up to 86,000 Lux
ESD Level	16 KV
Supply Voltage	4.5-14.0 V (DC)
Operating Current	140mA (typical) 380mA (max)
Idle/Standby	50mA (typical)
Dimension	Height: 163mm (6.4”) Length: 91mm (3.6”) Width: 41mm (1.6”)
Weight	~145g (~5.1oz) without cable
Types	Code 39, EAN, PDF-417, DataMatrix, QR Code
Interface	RS232, Keyboard Wedge, USB Com Std., USB Keyboard, USB OEM

More information is available at: http://www.datalogic.com/eng/products/automatic-data-capture/general-purpose-handhelds/quickscan-qd2400-pd-612.html

13.5 WiFi Dongle

Buffalo NTechnology Wireless-N Ultra-Compact USB 2.0 Adapter WLI-UC-GNM

Buffalo's NTechnology Wireless-N Ultra-Compact USB 2.0 Adapter offers a portable solution for applying a wireless network connection to the ImmuView® Reader.

NOTE 72. Refer to section 8.13.5 Wireless Network

Features and Benefits

- Ultra compact design minimizes physical impact and fits into any USB port.
- Designed to meet 802.11n specifications.
- WiFi Certified™ to ensure compatibility with other certified devices.
- Faster speed and greater range than standard 802.11g
- Backward compatible with 802.11g and 802.11b
- Push-button setup with AirStation One-Touch Secure System (AOSS)
- Supports WPA2, WPA-PSK (AES, TKIP), and 128/64-bit WEP security.
- USB 2.0 support

Specifications

- Wireless LAN Interface
- Access Mode Infrastructure Mode, Ad-hoc Mode
- Antenna (Tx x Rx) 1 x 1
- Interface USB 2.0
- Wireless Security WPA2, WPA-PSK (AES, TKIP), 128/64-bit WEP

Other

- Dimensions (WxHxD) 0.6 x 0.76 x 0.32 in.
- Weight 4 grams

More information is available at: http://www.buffalotech.com/content/files/products/wli-uc-gnm_DS.pdf

14 Default Test Types Packages

The software installs with a set of default test types.

The Default Test Types package is generated automatically every time when the software detects no test type package on the ImmuView® Reader and is loaded as a factory default.

NOTE 73. The ImmuView® Reader automatically initiates a Test Package import process upon application boot up if default test type is the current configuration.

15 Cleaning & Decontamination

WARNING: The isopropyl alcohol used in this procedure is flammable.

Ensure the ImmuView® Reader is not powered.

Do not use isopropyl alcohol within 3m of open flames or sources of ignition.

Avoid contact with skin.

WARNING: Instrument may be contaminated.

Avoid contact with skin.

Wash hands with hand wash after completing decontamination.

Suggested materials:

- **Gloves:** Disposable laboratory gloves
- **Wipes:** Lint free wipes
- **Swabs:** Foam Tipped Swab

Name: Chemtronics, Foamtips™ #140
Product No.: CF4050
Swab Length: 2.87" (7.3 cm)
Head Material: 100 ppi Open Cell Foam
Head W/L: 0.19" x 0.50" (4.8 x 12.7 mm)

- **Isopropyl Alcohol:** 99% Isopropyl Alcohol in a spray dispenser
- **Hand wash:** Disinfectant hand wash

The ImmuView® Reader can be cleaned using a lint free wipe, damp with Isopropyl Alcohol (IPA). SSI Diagnostica A/S does not recommend using free liquids to clean the instrument.

Dip the lint free wipe into the Isopropyl Alcohol and allow any excess fluid to flow off. If any lint or dust remains on the wipe, dispose of wipe and use a new one.

1. **Inspect:** Inspect for damage or visible contamination.
2. **Dispose:** Dispose of any materials left on the instrument such as test parts.
3. **Wipe surfaces:** Wipe all surfaces of the instrument with wipes wetted with isopropyl alcohol.
   Use sufficient alcohol such that the surfaces are clearly wetted by the cleaning process.
   Surfaces include the LCD display and touch screen.
4. **Dispose:** Dispose of all used materials and gloves.
5. **Wash hands:** Wash hands with the disinfectant hand wash.

16 Service & Maintenance

16.1 Software Issue Reporting

If you have an issue with the operation of the ImmuView® Reader software, then you should contact support.

SSI Diagnostica A/S recommends e-mailing SSI Diagnostica A/S support via info@ssidiagnostica.com
with the following information:

- Customer details – Name and contact details.
- ImmuView® Reader details – Model, serial number, instrument application version, test type package (About screen)
- Description of fault
- Pictures of errors, tests, and samples
- Instrument log file export as an attachment
- .csv export as an attachment
- Test Diagnostics export as an attachment (if to large use OneDrive, WeTransfer, google drive or other cloud based services)
- If asked sending sample of interest to SSI Diagnostica A/S for further evaluation

Some things to consider when reporting a software defect or bug:

1. Make sure your software is up to date and that you are using the intended version.
2. Take note of what steps you performed to cause the defect to occur. Steps to reproduce are the **most important part** of any defect report. If SSI Diagnostica A/S is able to reproduce the defect, the defect can be investigated. If the steps are unclear, it might not even be possible for SSI Diagnostica A/S to replicate the issue that you have found.
3. What where you expecting to see "*expected result*" and what happened instead "*actual result*"?
4. If you are seeing an Error or Warning dialogue, please let us know the Error Code number "0000" which can be found on the top line of the dialogue screen.
5. Take note of how many instruments are affected.
6. Take note of how frequently you are seeing the defect.
7. Take note of what hardware is connected to the instrument such as printers, barcode scanners, USB keys or to a desktop computer via a network connection.
8. If you believe you are seeing multiple defects on the same instrument, please fill separate support forms per defect, rather than by instrument.

16.2 Service & Repair Procedure

SSI Diagnostica A/S recommends the following customer procedure for assessing instrument for return to service.

1. Use the ImmuView® Reader User Manual for information on instrument operation, troubleshooting, error codes and self test as an initial step in resolving the issue.
2. If problem is not resolved, then SSI Diagnostica A/S recommends contacting info@ssidiagnostica.com for further guidance.
3. If problem is not resolved or the ImmuView® Reader fails to operate correctly, fails self test, or hardware is deemed to be faulty then contact info@ssidiagnostica.com for further guidance.
4. SSI Diagnostica A/S will acknowledge the receipt of Return for Service Request within 5 business days.
5. Ship the decontaminated ImmuView® Reader to SSI Diagnostica A/S with the Return for Service Request marked to:
   - *SSi Diagnostica A/S*
     Attn. Commercial depart.
     Herredsvejen 2
     3400 Hilleroed
     Denmark

NOTE 74. The decontamination procedure recommended by SSI Diagnostica A/S can be found in section 15 Cleaning & Decontamination.

16.3 Transport and storage conditions

The ImmuView® Reader is to be transported in its original packaging carton (H 180mm, W 190mm, D 180mm). The original packaging consists of:

- White cardboard carton (H 180mm, W 190mm, D 180mm) UDI label and serial no. Label.
- Sealable plastic bag with desiccant sachet.
- 2 x Foam inserts.
- Power supply carton with power supply and adaptor inserts.
- Sealable plastic bag with 3 x ferrite core and 1x ferrite safety key.
- Sealable plastic bag with Strip carriers and note.
- Aluminium Foil pouch with Instrument check consumable.
- Certificate of Analysis
- Quick guide

Shipping

Shipping cartons are to be lined with bubble wrap and or other box fillings to protect the instrument cartons during shipping.
Shipping labels are to be placed on the same face of the shipping carton:

- Shipping label is placed on the top left-hand corner.
- Courier shipping paperwork will be placed on the top face.
- 2°c to 45°c,
- 10% to 70% relative humidity (non-condensing)

Storage environment (dry conditions)

2°c to 45°c,
10% to 70% relative humidity (non-condensing)

16.4 Return for Service Request

The customer must complete and provide the Return for Service form (at the end of this section) with any ImmuView® Reader returned for service. The completed form may be supplied electronically via email or shipped with the instrument.
SSI Diagnostica A/S must receive a completed form before any work, inspection or service of the ImmuView® Reader can begin.
The ImmuView® Reader should be packed securely in the original packing materials before returning to SSI Diagnostica A/S.
Return for Service Checklist:

- ✓ Return form completed and provided via email or shipped with the ImmuView® Reader.
- ✓ Copy of the return form retained if required.
- ✓ Instrument serial number noted on shipping documents.
- ✓ Instrument cleared of risks and free of contamination for servicing.
  (refer to Section 15 Cleaning & Decontamination for instructions)
- ✓ All data on the Instrument is copied and retained in archive.
- ✓ Instrument is packed in original packaging for shipping.

NOTE 75. Data may be erased from the instrument during service.

NOTE 76. Instruments not cleaned for return to service may be returned or an additional fee incurred.

NOTE 77. Warranty is voided if the SSI Diagnostica A/S Warrant Void label has been removed. An additional fee may be incurred to review this unit.

NOTE 78. Instrument is to be shipped in original packaging or equivalent packaging. Instrument may incur damage if not shipped with appropriate packaging material. Please contact support@immuview.com if further advice is required on return packaging.

NOTE 79. No new accessories are supplied with the repaired Instrument. If Instrument is returned without original cable or original power supply as an example, then the Instrument is returned without these.

NOTE 80. If SSI Diagnostica A/S Quote is not accepted, then instrument will be returned as supplied and an inspection fee charged.

Return for Service Form			
Instrument Serial No.		Instrument Software Version	
Contact Name			
Contact Phone No.			
Contact Email			
Return Address for Shipping			
Company Name			
Street Address			
State/Province			
Country		Zip/Postal Code	
Courier Information	Name	Account Number	
Service Information			
All instrument data copied and archived?	☐ YES	☐ NO	
Instrument cleaned and decontaminated, safe for service?	☐ YES	☐ NO	
Is this a warranty repair?	☐ YES	☐ NO	
Did the instrument suffer damage?	☐ YES	☐ NO	
Description of fault:			
Are you authorized to request this repair and authorize payment for service and shipping charges?	☐ YES		

NAME	SIGNATURE	DATE (dd month yyyy)

17 Errors, Warnings, and Information

This section provides troubleshooting steps for specific errors and warning codes and explains information messages. Once the steps listed below are executed, if the error or warning persists, contact: support@immuview.com. Alternatively, please contact SSI Diagnostica A/S directly.

SSI Diagnostica A/S
Herredsvejen 2
3400 Hilleroed
Denmark

T: (+45) 48 29 91 00
F: (+45) 48 29 91 79
EAN: 5790 002327452
VAT: 37294535

support@immuview.com
www.immuview.com

Warning: The software uses a standard Warning screen. A Warning screen will be displayed where a user has made a selection that is not reversible, and a confirmation is required.
Error: If the ImmuView® Reader receives a request or performs an action outside the normal operating parameters for that user/test/function, an error message will be displayed, explaining what error has occurred and requiring the user to confirm the error has been noted before the ImmuView® Reader returns to normal operation. In some cases, it may cancel a current test and/or require an Instrument reboot.
Information: An information screen supplies the user with important information. There are no [OK] or [Cancel] input required from the user so once the user has finished reading the message [OK] will exit the screen.

17.1 In-Test Error Dialogues

CODE	DESCRIPTION	ACTION
Error: 2	Could Not Identify Cartridge This can occur only if the overall image average grey level is below a defined limit.	Possible cause: the strip is not present in the strip carrier. Check that the strip is in the cartridge/strip carrier. Check for contaminants. Attempt to rerun test
		Possible cause: the camera or LED's have failed, and the image is black. Run a self test on the instrument. If the self test fails, contact SSI Diagnostica A/S
		Possible cause: exposure calibration is not correct – re-execute the exposure calibration. Run a self test on the instrument. If the instrument needs to be calibrated, then contact SSI Diagnostica A/S
Error: 5	Could Not Locate Strip The device could not locate the cartridge/ strip carrier in the acquired image.	Check that strip is correctly inserted in the cartridge/strip carrier. Change it to check for contaminants on the strip carrier/cartridge fiducial marks. Attempt to rerun test. Try another strip carrier/cartridge. If error continues contact SSI Diagnostica A/S. "Acquire image" of the instrument internals and check the image quality is adequate.

17.1 In-Test Error Dialogues		
CODE	**DESCRIPTION**	**ACTION**
Error: 20	Could not normalise	The signal from the strip could not be 'normalised' during the test. Typically, this occurs when the cartridge/carrier is located in the wrong position in the image. Ensure that your cartridge is being inserted correctly and repeat the test. If this error occurs repeatedly contact SSI Diagnostica A/S.
Error: 35	Cannot locate fiducials on the strip carrier. The device fiducial features on the cartridge/strip could not be found. The test was unable to proceed.	Check that the correct cartridge/strip carrier is being used with the instrument. Check that cartridge/strip carrier was inserted correctly into the instrument. Check for contaminants. Check that the selected test matches the cartridge/carrier used. Attempt to rerun test using a new cartridge/strip carrier. If error continues contact SSI Diagnostica A/S.
Error: 36	Cartridge/Carrier Could Not Be Correctly Found - Scale The device fiducial features on the cartridge/strip carrier found but scale is out of range.	Check that the correct cartridge/strip carrier is being used with the instrument. Check that cartridge/strip carrier was inserted correctly into the instrument. Check for contaminants. Check that the selected test matches the cartridge/carrier used. Attempt to rerun test using a new cartridge/strip carrier. If error continues contact SSI Diagnostica A/S.
Error: 37	Cartridge/Carrier Could Not Be Correctly Found - Position The device fiducial features on the cartridge/strip carrier found but position is out of range.	Check that the correct cartridge/strip carrier is being used with the instrument. Check that cartridge/strip carrier was inserted correctly into the instrument. Check for contaminants. Check that the selected test matches the cartridge/carrier used. Attempt to rerun test using a new cartridge/strip carrier. If error continues contact SSI Diagnostica A/S.
Error: 38	Failed to locate the strip cartridge/carrier. The device fiducial features on the cartridge/strip could not be found. The test was unable to proceed.	Check that the correct cartridge/strip carrier is being used with the instrument. Check that cartridge/strip carrier was inserted correctly into the instrument. Check for contaminants. Check that the selected test matches the cartridge/carrier used. Attempt to rerun test using a new cartridge/strip carrier. If error continues contact SSI Diagnostica A/S.

17.1 In-Test Error Dialogues		
CODE	**DESCRIPTION**	**ACTION**
Error: 41	Cartridge/Carrier Could Not Be Correctly Found - Rotation The analysis software was able to locate the cartridge/strip carrier; however, the rotation angle found was outside the acceptable limits.	Check that the correct cartridge/strip carrier is being used with the instrument. Check that cartridge/strip carrier was inserted correctly into the instrument. Check for contaminants. Check that the selected test matches the cartridge/carrier used. Attempt to rerun test using a new cartridge/strip carrier. If error continues contact SSI Diagnostica A/S.
Error: 43	Could not locate the control line, Multiple Candidates The instrument was unable to determine the location of the control line with sufficient confidence. The algorithm found more than one control line. This error may occur when no control line is present on the strip.	Check that strip is correctly inserted in the cartridge/strip carrier. Check for control line being present. Check the position of the lines on the strip to ensure that it is within manufacturing specifications/tolerances. Check that a test line is not within the search region for the control line. Check for contaminants on the strip. Attempt to rerun test. If error continues contact SSI Diagnostica A/S. SSI Diagnostica A/S to review test type package.
Error: 44	Strip Analyser Could Not Locate Control Line, No Line Found The device has found no control lines within the control line search region.	Check that strip is correctly inserted in the cartridge/strip carrier. Check for control line. Check the position of the lines on the strip to ensure that it is within manufacturing specifications/tolerances. Check for contaminants on the strip. Attempt to rerun test. If error continues contact SSI Diagnostica A/S. SSI Diagnostica A/S to review test type package.
Error: 45	Strip Analyser Could Not Locate Line, Line Width Validation Failed A line has been found, but the line width score is outside the acceptable limit defined in the test type. Either the test strip/cartridge is invalid, or the test type is incorrectly defined.	Check that strip is correctly inserted in the cartridge/strip carrier. Check the test line. Check for contaminants on the strip. Attempt to rerun test. If error continues contact SSI Diagnostica A/S. SSI Diagnostica A/S to review test type package.
Error: 46	Strip Analyser Could Not Locate Line, Line Peak Validation Failed A line has been found, but the peak score is outside the acceptable limit defined in the test type. Either the test strip/cartridge is invalid, or the test type is incorrectly defined.	Check that strip is correctly inserted in the cartridge/strip carrier. Check the test line. Check for contaminants on the strip. Attempt to rerun test. If error continues contact SSI Diagnostica A/S. SSI Diagnostica A/S to review test type package.

17.1 In-Test Error Dialogues		
CODE	**DESCRIPTION**	**ACTION**
Error: 47	Strip Analyser Could Not Locate Line, Line Area Validation Failed A line has been found, but the area score is outside the acceptable limit defined in the test type. Either the test strip/cartridge is invalid, or the test type is incorrectly defined.	Check that strip is correctly inserted in the cartridge/strip carrier. Check the test line. Check for contaminants on the strip. Attempt to rerun test. If error continues contact SSI Diagnostica A/S. SSI Diagnostica A/S to review test type package.
Error: 48	Strip Analyser Could Not Locate Line, Line Position Validation Failed A line has been found, but the position score is outside the acceptable limit defined in the test type. Either the test strip/cartridge is invalid, or the test type is incorrectly defined.	Check that strip is correctly inserted in the cartridge/strip carrier. Check the test line. Check for contaminants on the strip. Attempt to rerun test. If error continues contact SSI Diagnostica A/S. SSI Diagnostica A/S to review test type package.
Error: 49	Focus Out of Range The focus of the camera is outside of limits. This error will only occur if the test has the 'Run Focus Check' option enabled in kinetic.	Re-power the instrument. Attempt to run a self test. SSI Diagnostica A/S to acquire image and ensure that the internal validation marks are clearly visible and not obscured by debris or other materials.
Error: 50	Analyser Exception	A general analysis error. Re-power the instrument. Attempt to run a self test. If error continues contact SSI Diagnostica A/S. "Acquire image" of the instrument internals and check the image quality is adequate.
Error: 52	No Image Acquired	Camera failed to return an image. Re-power the instrument. Attempt to run a self test. If error continues contact SSI Diagnostica A/S. "Acquire image" of the instrument internals and check the image quality is adequate.
Error: 64	Could Not Make Decision, Unknown Exception The decision module in the test type encounters an error.	This is most likely due to an error in the logic of the decision algorithm definition in the test package. Other Possible causes are: The test package is not correctly installed – try importing again. An incorrect test package is being used with the software version installed on the instrument. Check test package release details. Contact SSI Diagnostica A/S. SSI Diagnostica A/S to review test type package.

17.1 In-Test Error Dialogues		
CODE	**DESCRIPTION**	**ACTION**
Error: 65	Could Not Make Decision, Audio Tone Not Set This is most likely due to an error in the logic of the decision algorithm definition in the test package. The Audio Tone is not being set by the algorithm and is required.	Possible causes are: The test package is not correctly installed – try importing again. An incorrect test package is being used with the software version installed on the instrument. Check test package release details. Contact SSI Diagnostica A/S. SSI Diagnostica A/S to review test type package to ensure that the audio tone is set correctly by the algorithm.
Error: 66	Could Not Make Decision, Detailed Message Not Set This is most likely due to an error in the logic of the decision algorithm definition in the test package. The required 'Detailed Message' Fields are not set by the algorithm.	Possible causes are: The test package is not correctly installed – try importing again. An incorrect test package is being used with the software version installed on the instrument. Check test package release details. Contact SSI Diagnostica A/S. SSI Diagnostica A/S to review test type package to ensure that the Detailed Message fields are set correctly by the algorithm.
Error: 67	Could Not Make Decision, Icon Not Set This is most likely due to an error in the logic of the decision algorithm definition in the test package. The required 'Icon' fields are not set by the algorithm. (RESULT_DECISION_ICON_X)	Possible causes are: The test package is not correctly installed – try importing again. An incorrect test package is being used with the software version installed on the instrument. Check test package release details. Contact SSI Diagnostica A/S. SSI Diagnostica A/S to review test type package to ensure that the result Icons are set correctly by the algorithm.
Error: 68	Could Not Make Decision, Message Not Set This is most likely due to an error in the logic of the decision algorithm definition in the test package. The required 'Message' fields are not set by the algorithm. (RESULT_DECISION_MESSAGE_X)	Possible causes are: The test package is not correctly installed – try importing again. An incorrect test package is being used with the software version installed on the instrument. Check test package release details. Contact SSI Diagnostica A/S. SSI Diagnostica A/S to review test type package to ensure that the result messages are set correctly by the algorithm.
Error: 69	Could Not Make Decision, Title Not Set This is most likely due to an error in the logic of the decision algorithm definition in the test package. The required 'Title' fields are not set by the algorithm (RESULT_DECISION_TITLE_X)	Possible causes are: The test package is not correctly installed – try importing again. An incorrect test package is being used with the software version installed on the instrument. Check test package release details. Contact SSI Diagnostica A/S. SSI Diagnostica A/S to review test type package to ensure that the result 'Title' fields are set correctly by the algorithm

17.1 In-Test Error Dialogues		
CODE	**DESCRIPTION**	**ACTION**
Error: 70	Could Not Make Decision, Set UI Type Not in Allowed List This is most likely due to an error in the logic of the decision algorithm definition in the test package. The required 'Type' field is not set to a valid value by the algorithm.	Possible causes are: The test package is not correctly installed – try importing again. An incorrect test package is being used with the software version installed on the instrument. Check test package release details. Contact SSI Diagnostica A/S. SSI Diagnostica A/S to review test type package to ensure that the UI type for the result is set correctly by the algorithm.
Error: 71	Could Not Make Decision, UI Type Not Set This is most likely due to an error in the logic of the decision algorithm definition in the test package. The required 'Type' field is not set by the algorithm.	Possible causes are: The test package is not correctly installed – try importing again. An incorrect test package is being used with the software version installed on the instrument. Check test package release details. Contact SSI Diagnostica A/S. SSI Diagnostica A/S to review test type package to ensure that the UI Type is set correctly by the algorithm.
Error: 72	Could Not Make Decision, Unknown Type This is most likely due to an error in the logic of the decision algorithm definition in the test package. The required 'Type' field is set to an invalid type for the application.	Possible causes are: The test package is not correctly installed – try importing again. An incorrect test package is being used with the software version installed on the instrument. Check test package release details. Contact SSI Diagnostica A/S. SSI Diagnostica A/S to review test type package to ensure that the UI Type is set correctly by the algorithm.
Error: 73	Could Not Make Decision, Valid Flag Not Set This is most likely due to an error in the logic of the decision algorithm definition in the test package. The required 'Valid' field is not set to true by the algorithm.	Possible causes are: The test package is not correctly installed – try importing again. An incorrect test package is being used with the software version installed on the instrument. Check test package release details. Contact SSI Diagnostica A/S. SSI Diagnostica A/S to review test type package to ensure that the UI Type is set correctly by the algorithm.
Error: 74	Could Not Make Decision, Ratio Title Not Set This is most likely due to an error in the logic of the decision algorithm definition in the test package. The required 'Ratio Title' field is not set by the algorithm.	Possible causes are: The test package is not correctly installed – try importing again. An incorrect test package is being used with the software version installed on the instrument. Check test package release details. Contact SSI Diagnostica A/S. SSI Diagnostica A/S to review test type package to ensure that the required number of ratio output fields are defined correctly.

17.1 In-Test Error Dialogues		
CODE	**DESCRIPTION**	**ACTION**
Error: 75	Could Not Make Decision, Ratio Output Not Set This is most likely due to an error in the logic of the decision algorithm definition in the test package. The required 'Ratio Output' fields are not set by the algorithm	Possible causes are: The test package is not correctly installed – try importing again. An incorrect test package is being used with the software version installed on the instrument. Check test package release details. Contact SSI Diagnostica A/S. SSI Diagnostica A/S to review test type package to ensure that the required ratio outputs are set correctly.
Error: 76	Could Not Make Decision, QC Result Not Set Correctly This is most likely due to an error in the logic of the decision algorithm definition in the test package. The required 'QC Result' output is not set by the algorithm correctly.	Possible causes are: The test package is not correctly installed – try importing again. An incorrect test package is being used with the software version installed on the instrument. Check test package release details. Contact SSI Diagnostica A/S. SSI Diagnostica A/S to review test type package to ensure that the QC result flag is set correctly.
Error: 80	Could Not Make Decision, Quant Title Not Set This is most likely due to an error in the logic of the decision algorithm definition in the test package. The required 'Quantitative Title' output fields are not set correctly.	Possible causes are: The test package is not correctly installed – try importing again. An incorrect test package is being used with the software version installed on the instrument. Check test package release details. Contact SSI Diagnostica A/S. SSI Diagnostica A/S to review test type package to ensure that the quantitative output fields are set correctly.
Error: 81	Could Not Make Decision, Quant Output Not Set This is most likely due to an error in the logic of the decision algorithm definition in the test package. The required 'Quantitative Output' fields are not set correctly.	Possible causes are: The test package is not correctly installed – try importing again. An incorrect test package is being used with the software version installed on the instrument. Check test package release details. Contact SSI Diagnostica A/S. SSI Diagnostica A/S to review test type package to ensure that the quantitative output fields are set correctly.
Error: 82	Strip Analyser Could Not Locate Control Line, No Peak Candidates The strip analyser could not locate any trace of a control line in the expected control line region.	Check the control line. Check for contaminants on the strip. Attempt to rerun test. If error continues contact SSI Diagnostica A/S. SSI Diagnostica A/S to review test type package, ensure that the control line search region is sufficiently wide enough to enclose the control line.

17.1 In-Test Error Dialogues		
CODE	**DESCRIPTION**	**ACTION**
Error: 83	Strip Analyser Could Not Locate Test Line, No Peak Candidates The strip analyser could not locate any trace of a test line in the expected test line region.	Attempt to rerun test. If error continues contact SSI Diagnostica A/S. SSI Diagnostica A/S to review test type package, ensure that the test line search region is sufficiently wide enough to enclose the test lines.
Error: 86	Normalisation Exception	The normalisation failed to complete. Re-attempt normalisation. Contact SSI Diagnostica A/S.
Error: 96	Could Not Complete Exposure Calibration, Not Scale Calibration	Could not complete exposure calibration, the exposure calibration algorithm is not able to complete the primary scale calibration. Check that the strip is in the cartridge/strip carrier. Check that the cartridge has fiducials markings that are visible and not damaged. Check for contaminants. Attempt to re-run test.
Error: 145	Strip Analyser Scale Rotate Factor Out Of Range	Could not analyse, the image scale and rotation are out of range. The instrument requires re-calibration.
Error: 200	Could Not Locate Cartridge, No Edges	Could not locate the cartridge window in the expected location. Check that cartridge is inserted correctly into the slot. Check for damage or contaminants on cartridge. Attempt to re-run test.
Error: 201	Could Not Locate Cartridge, No Label	Could not locate the cartridge printed label in the correct locations. Check that cartridge is inserted correctly into the slot. Check for damage or contaminants on cartridge. Attempt to re-run test.
Error: 300	Image Level Out Of Range	The camera returned a dark or light image that is out of range. Re-power the instrument. Attempt to run a self test. If error continues contact supplier. "Acquire image" of the instrument internals and check the image quality is adequate.
Error: 301	Voltage Out Of Range	Per-test self test failed. The system voltages are out of range. Re-power the instrument. Attempt to run a self test. If error continues contact SSI Diagnostica A/S. Ensure correct power supply is being used.

17.1 In-Test Error Dialogues		
CODE	**DESCRIPTION**	**ACTION**
Error: 302	Temperature Out Of Range	Per-test self test failed. The instrument temperature is out of range. Re-power the instrument. Attempt to run a self test. The ambient air temperature is out of the acceptable range. If error continues contact SSI Diagnostica A/S.
Error: 310	Consumable Removed	The consumable was removed during image acquisition.
Error: 312	Image out of Balance	Check that the test cartridge isn't damaged and there are no obstructions to the instrument cartridge slot. Check that the cartridge is inserted correctly into the slot. Attempt to rerun test. If error continues contact SSI Diagnostica A/S.
Error: 313	Image too Dark	Check that the test cartridge isn't damaged and there are no obstructions to the instrument cartridge slot. Check that the cartridge is inserted correctly into the slot. Attempt to rerun test. If error continues contact SSI Diagnostica A/S.
Error: 320	Barcode Not Found	The barcode could not be found in the image. Ensure that the correct cartridge is being used. Check that cartridge is inserted correctly into the slot. Check for damage or contaminants on cartridge. Attempt to re-run test.
Error: 321	Barcode Has Expired	The barcode on the cartridge has expired. Discard cartridge.
Error: 322	Barcode Does Not Match Selected Test	The barcode on the cartridge does not match the selected test type. Attempt to re-run test with the correct test type selected.
Error: 323	Barcode Check Digit Not Correct	The barcode check digit is incorrectly formatted. Check that cartridge is inserted correctly into the slot. Check for damage or contaminants on cartridge. Attempt to re-run test. Discard cartridge if error continues.
Error: 324	Barcode In Incorrect Location	The barcode was read, but the cartridge is not in the correct location for the test. Check that cartridge is inserted correctly into the slot. Attempt to re-run test
Error: 325	Barcode Format Error	The format of the barcode is incorrect. Check that cartridge is inserted correctly into the slot. Change for damage or contaminants on cartridge. Attempt to re-run test. Discard cartridge if error continues.

17.1 In-Test Error Dialogues

CODE	DESCRIPTION	ACTION
Error: 326	Barcode Found But Damaged	The barcode has been found but is damaged. Check that cartridge is inserted correctly into the slot. Change for damage or contaminants on cartridge. Attempt to re-run test. Discard cartridge if error continues.

17.2 Warning Dialogue

CODE	DESCRIPTION	ACTION
0001	Are you sure you want to delete user {0}? This cannot be undone.	The instrument requires confirmation that the user does intend to delete the user ID. This step once confirmed cannot be undone.
0002	Delete lot data for {0}?	The instrument requires confirmation that the user does intend to delete the selected lot data. This step once confirmed cannot be undone.
0003	Are you sure you wish to change the Admin password?	The instrument requires confirmation that the admin user wishes to change the Admin password
0004	{0} selected. Proceed?	The instrument requires user confirmation that the test type selected by an internal barcode read is the intended test type for the carrier/cartridge.
0005	Do you wish to change the time to: {0}? This may affect the status of the device schedulers.	The instrument requires confirmation that the user wishes to change the instrument time. This is required because changing the instrument time will affect the self test, instrument check and QC test schedules.
0007	The QC status for this test has failed or is overdue!Do you wish to proceed?	The instrument is warning the user that the instrument either; failed its last QC test for that test type or it is due to for another QC test. The user may proceed with the test, but the test result may be compromised.
0008	Instrument check has failed or is overdue! Do you wish to proceed?	The instrument is warning the user that the instrument either; failed its last instrument check test or it is due to for another instrument check test. The user may proceed with the test, but the test result may be compromised.
0010	Device memory is almost full! Please export and delete result data.	This dialogue notifies the user that the ImmuView® Reader memory is almost full and needs to clear in the near future. Attach a USB flash memory key to the instrument and perform Test Result export and confirm the request to wipe instrument memory. This dialogue will appear until the memory is cleared or the memory is full.
0011	Device memory is full! {0} shall be deleted if you wish to proceed.	This dialogue notifies the user that the ImmuView® Reader memory is full and needs to clear before further testing can be performed. If you proceed a result will be deleted from the test memory to make room for the new test result. This cannot be undone. Attach a USB flash memory key to the instrument and perform Test Result export and confirm the request to wipe instrument memory.

17.2 Warning Dialogue

CODE	DESCRIPTION	ACTION
0013	Delete all test results from the device memory?This cannot be undone.	The instrument requests the user to confirm that they would like to delete all test results from the instrument. This cannot be undone
0014	Cancel changes? Changes made will be lost.	This is an instrument warning, advising the users that any changes made on the current GUI screen will be lost by navigating away without saving changes.
0015	Cancel test? Test data will be lost.	This is an instrument warning, advising the users that cancelling the current test will lose the current test data. This cannot be undone.
0017	Import list of {0} users? Imported user list will replace existing user list. This cannot be undone.	The instrument informs the user that importing a new user list will replace the user list on the instrument. Please make sure this is what you want to do before proceeding with the import request.
0023	Save diagnostics substantially increases memory use!Do you wish to proceed? It will automatically disable after 20 tests. Do you wish to proceed?	The Save diagnostics function on the instrument uses more memory than a standard test result. Only use this function for troubleshooting purposes. The instrument warns you before you turn this function on.
0029	Cancelling will lose the normalisation progress made! Are you sure you want to cancel?	This is an instrument warning, advising the users that cancelling the current normalisation progress will lose the current data. This cannot be undone.
0032	Reset device settings to user default? All current settings and data will be lost.	The instrument requires confirmation that the admin user wishes to reset the instrument to a user default state. This cannot be undone.
0033	Not all test results have been copied to the server. Do you wish to proceed with deleting all files?	This is an instrument warning, advising the users that not all test results have been copied to the server. The instrument requests the user to confirm if they wish to proceed with the deletion of all files from the instrument. This cannot be undone.
0035	Are you sure you wish to change the password?	The instrument requires confirmation that user wishes to change the user password.
0036	Are you sure you want to clear the LIS settings?	The instrument requires confirmation that the user wishes to clear the current LIS settings.
0038	Import Test Types Package: {0} Version = {1} Import shall replace existing Test Types. Do you wish to proceed?	The instrument informs the user that importing a new test type package will replace the current test type package on the instrument. Please make sure this is what you want to do before proceeding with the import request.

17.3 Errors Dialogue

CODE	DESCRIPTION	ACTION
0512	A critical error has occurred! Please refer to user manual. Reboot required.	The ImmuView® Reader has suffered a critical error. The instrument will not boot up. Arrange return of the instrument.

17.3 Errors Dialogue

CODE	DESCRIPTION	ACTION
0513	RTC failure! Please refer to user manual.	The ImmuView® Reader real time clock battery has failed. Arrange return of the instrument.
0514	User ID not recognised! Please try again.	The user ID entered does not match an ID entered in the instrument user ID list. Please re-attempt user ID entry. IF you have forgotten your user ID, please contact the administrator.
0515	User ID input invalid! Entry should be between 1 and 20 characters.	The text input by the user does not meet the requirements of being between 1 and 20 alphanumeric characters.
0516	Invalid input! Entry should be between 1 and 20 characters.	The text input by the user does not meet the requirements of being between 1 and 20 alphanumeric characters.
0517	User ID already exists! Please enter a different ID.	The user ID entered already exists on the instrument, please either: a) Enter a different User ID b) delete current user ID c) edit current user ID *NOTE 81. The following user IDs are not available on the instrument "admin", "factory" or "axxin".*
0518	Lot Expired.	If an expired Lot is detected, then the instrument will not permit the activation of the Test Lot.
0520	Barcode does not match test selection.	If an internally read barcode test selection does not match a known test type on the instrument the instrument will not permit the test to proceed.
0522	Passwords do not match! Please re-enter password.	The password entered does not match the password saved on the instrument. Please try to attempt entering the password again. If you have forgotten your password, please contact the administrator.
0523	Import of user list failed! Please try again.	The import of the user list failed. Please check the USB key is correctly connected to the instrument and re-attempt import.
0524	Export of user list failed! Please try again.	The export of the user list failed. Please check the USB key is correctly connected to the instrument and re-attempt export.
0525	Barcode could not be read.	The instrument was unable to read an internal barcode from a carrier/cartridge. The instrument will not permit the test to proceed.
0526	Import failed! Multiple test type packages detected. Please check USB key and try again.	The instrument has detected that there is more than one test type package available for import on the attached USB key. Remove one of the test type packages from the USB key then re-attempt import.
0527	No test type package found! Please check USB key contents and try again.	If no Test types are loaded onto the instrument, then a Test Type Package must be imported onto the instrument from an attached USB Flash memory key.

17.3 Errors Dialogue

CODE	DESCRIPTION	ACTION
0528	A maximum of 50 test types can be imported onto the device! Please edit the test type package.	The test types package the user is attempting to import is too large. Please contact supplier. Supplier must ensure that test type package provided to the end user contains less than 50 tests.
0529	Test type package import failed! Default test type package loaded.	The instrument was unable to import the Test Types from an attached USB Flash memory key. Please ensure that the file is placed correctly in the main file directory and the file name correct. Ensure that only a single test type package is located on the USB key.
0530	SD card not found! The device will reboot. Please refer to user manual.	The ImmuView® Reader cannot find the external SD memory card. The instrument will not boot up. Arrange return of the instrument.
0531	Barcode does not contain valid. Test Type.	An internally read barcode does not contain a valid test type or the test type read does not include internal barcode reading. The instrument will not permit the test to proceed
0532	QC status has failed! Please update the control status.	The QC status for the selected test type has failed. Please run a new QC test for that test type to update the QC status to pass.
0533	Exposure calibration failed! Please try again.	The attempt made to calibrate the ImmuView® Reader has failed. Please re-attempt calibration. If this does not correct the issue, then contact SSI Diagnostica A/S.
0534	Normalisation failed! Please try again.	The attempt made to normalise the ImmuView® Reader has failed. Please re-attempt normalisation. If the problem persists, replace the normalisation strip. If this does not correct the issue, then contact SSI Diagnostica A/S.
0535	Instrument check has failed! Please run a new instrument check.	The user may not* be able to run a test until instrument check test has passed. Run a new instrument check to update the instrument check status to Pass. *Instrument check functionality is configurable, and settings may vary.
0536	Self test has failed! Testing is locked out. Please refer to user manual.	The instrument self test has failed, and testing has been locked out. Run a new self test to confirm the result, then refer to failure the self test has recorded to identify what the issue is.
0539	{0} instrument exposure calibration has not been completed. Please refer to user manual.	{0} displays either Visual or Fluorescent. The instrument has not been exposure calibrated yet. Please contact the administrator to complete the exposure calibration process.
0546	Input invalid. Input must be between 1 and 20 characters.	The text input by the user does not meet the requirements of being between 1 and 20 alphanumeric characters.
0547	Print set to {1} failed! Please check printer status.	Ensure the correct printer has been connected (SLP620). Reinsert printer and re-power. If this does not correct the issue, then contact SSI Diagnostica A/S.

17.3 Errors Dialogue

CODE	DESCRIPTION	ACTION
0548	No USB device found! Please check USB device connection and try again.	If the user attempts to perform a task on the instrument that required a USB flash memory key attached, the instrument will look for the attached USB instrument. If the instrument cannot be found, then an error message is displayed. Check that the USB Flash memory key is correctly attached and reattempt task.
0553	Image acquisition failed! Please try again.	If you attempt to run a test the instrument cannot take an image, then the image acquisition will have failed. Please attempt to run a self test to confirm that the instrument is operating correctly.
0554	Network settings not applied! Please try again.	The system was unable to apply the selected network settings. Check network connection and try again. If the problem persists, restart the unit, and try again.
0557	Test expired! Please discard the test.	If a cartridge/strip carrier is inserted into the instrument with and expired, expiry date then the instrument will not permit the test to proceed.
0559	QC status is overdue! Please update the control status.	The QC status for the selected test type is overdue. Please run a new QC test for that test type to update the QC status to pass.
0560	Instrument check is overdue! Please run a new instrument check.	The instrument check test status is overdue. To reset the instrument check status to pass, please run a new instrument check test.
0561	Test type not available! Please discard the test.	If the user attempts to run a test that is not available on the instrument, the instrument notifies the user that the test type is not available. Please discard the test.
0562	Export failed! Please try again.	The instrument was unable to export to an attached USB Flash memory key. This could be due to the following reasons: a) A USB Flash memory key was not correctly inserted into the instrument's USB serial port at the point of export. b) The USB Flash memory key was not formatted correctly and cannot be recognized by the ImmuView® Reader. See USB requirements.
0563	Results data has been corrupted! Please refer to user manual.	A results corruption has occurred, please attempt to export results. Please contact SSI Diagnostica A/S.
0564	The test has timed out! Please discard the test.	The next test step was not completed in the allotted time. The test has timed out. Please discard the test.
0565	Password not recognised! Please try again.	The password entered is not recognised by the instrument, please enter the correct password. If you have forgotten the admin password, please contact SSI Diagnostica A/S.
0566	IP address {0} is invalid! Please enter a valid IP address.	An incorrect or invalid IP address has been entered. Please check what was entered then try again.
0567	Subnet mask {0} is invalid! Please enter a valid subnet mask.	An incorrect or invalid subnet mask has been entered. Please check what was entered then try again.

17.3 Errors Dialogue

CODE	DESCRIPTION	ACTION
0569	Printer not found! Please check printer connection and try again.	If the user attempts to print a test report before setting up the instrument printer connections this error will be displayed. a) Try connecting the USB report printer to the instrument. If the printer is not found after connecting, try to reboot the instrument. b) Set up a network connected printer.
0570	Device is not normalised! Testing is locked out. Please refer to user manual.	If the instrument is not successfully normalised prior to testing, test results may be incorrect. This instrument requires normalisation to be complete before the ImmuView® Reader can perform testing.
0572	Maximum of 99 users reached! Please delete an existing user ID before adding a new user.	The instrument is notifying the user that the user list is full. No more users can be added until some are cleared from the instrument memory. Please delete a user to be able to add a new user.
0591	Cannot proceed! There are no test types available in the test type package for this category of test.	User is unable to proceed with the test selection category as there are no test types available. If this occurs, contact SSI Diagnostica A/S as the test category may not be part of the supplied test type package file.
0593	Invalid Password. Passwords must be between 8 and 64 characters in length	An incorrect or invalid password has been entered. Please check what was entered then try again.
0594	Return to user default request failed! Please try again.	The instrument has not successfully been returned to user default. Re-attempt the request. If request continues to fail, run a self test. Contact SSI Diagnostica A/S.
0595	Port Number Invalid. Please enter a valid Port number.	An incorrect or invalid port number has been entered. Please check what was entered then try again.
0597	Could not obtain IP Address. Please check network connection and try again.	The IP Address was unable to be obtained from the network. Ensure the instrument is connected to a valid network and try again.
0600	An error has occurred! Changes were not saved.	An error occurred writing the changes to the instrument SD card. Reboot instrument and try again. If error continues to occur, run a self test. Contact SSI Diagnostica A/S.
0765	Invalid barcode found.	The barcode scanned is not recognised by the instrument. Please try again or use the keyboard to enter the details.

17.4 Information Dialogue

CODE	DESCRIPTION	ACTION
0256	User deletion completed successfully!	The delete user function has completed successfully.
0257	Lot data deleted successfully.	The delete Lot data function has completed successfully.
0258	{0} users imported successfully!	User import function has completed successfully.
0259	Exported {0} users successfully to USB device!	User export function has completed successfully.
0260	No user ID list found! Please check USB key and try again.	If the user is attempting to import a user list and the instrument cannot find the user list on the attached USB key, then the user should check the USB key contacts to ensure that the file is in the correct location and in the correct format.
0261	No user ID list found on device! Please enter users.	If there is no user IDs entered on the instrument, the instrument informs the user. The admin user should add users to the instrument then reattempt request.
0262	Test types imported successfully! Device shall reboot.	The instrument has successfully imported Test Types. The instrument informs the user that an instrument reboot is required prior to testing with the newly imported Test Types.
0264	Calibration completed successfully!	Calibration attempt on ImmuView® Reader has been completed successfully.
0265	Normalisation completed successfully!	Normalization attempt on ImmuView® Reader has been completed successfully.
0268	Report has been successfully sent to printer: {0}	A dialogue to inform the user that the instrument successfully sent the report to the printer. If the report does not print the issue is most likely to be with the printer.
0269	The current operation was cancelled successfully! Press OK to continue.	If the user cancels an operation, this dialogue informs the user that the operation was successfully cancelled.
0270	Exported successfully to USB device!	The instrument successfully exported to an attached USB flash memory drive.
0272	No test results found in device memory!	An attempt was made to export test results when the memory was empty. Run a test and retry the export function.
0273	Image: {0} acquired successfully!	The instrument has successfully acquired an image and saved it to the attached USB key.
0276	Result deletion completed successfully!	Results deletion function has completed successfully. All results have been deleted.
0277	Changes made were saved.	Changes made were saved successfully.
0278	User ID successfully changed!	User ID was successfully changed.
0279	Password changed successfully!	Admin password wad successfully changed.
0280	No results found containing {0}! Please enter different search term.	If the text in the search field entered by a user in the Test Results search function return no results, then an information dialogue box informs the user.
0281	Device time has not been set! Please set the device time.	Attempt to reset time.

17.4 Information Dialogue

CODE	DESCRIPTION	ACTION
0288	User default settings restored successfully! Device shall reboot.	Upon successful restoration of the user default settings, the instrument must reboot.
0289	New user created successfully.	New user was successfully created.
0290	The USB device has insufficient storage space. Please check USB device and try again.	Check USB device and try again.
0337	Time and date set successfully. Instrument will reboot.	Time and date were successfully created, and instrument must reboot.
0510	Lot successfully created.	New test lot was successfully activated

18 Warranty & End User License Agreement

The ImmuView® Reader product is warranted against defects in materials and workmanship for a period of one (1) year. For specific warranty information, contact the SSI Diagnostica A/S or distributor in your country. If any defects should occur during the warranty period, SSI Diagnostica A/S will replace the defective parts without charge. However, the following defects are specifically excluded:

- Defects caused by improper operation or by improper packaging of returned goods.
- Repair or modifications done by anyone other than SSI Diagnostica A/S
- Materials not specified by SSI Diagnostica A/S
- Deliberate or accidental misuse.
- Damage caused by disaster.
- Damage due to use of improper solvent or sample.

The warranty does not apply to fuses.

For enquiry or request for repair service, contact SSI Diagnostica A/S after confirming the model and serial number of your Instrument.

18.1 Design Life and Updates

The ImmuView® Reader is intended for desktop research only and has a design life of five years or 20,000 reads, whichever is achieved earlier. After this period, the equipment must be decommissioned and not used, or specifically evaluated for any further application or extension of life and support.
SSI Diagnostica A/S reserves the right to issue a “change notice” relating to the construction, software, or use of the ImmuView® Reader at any time. The ImmuView® Reader must be quarantined from use immediately after a change notice is issued and until the update is completed.

18.2 Instrument Failure and Errors

The ImmuView® Reader and its associated software are constructed using standard components and methods. The ImmuView® Reader and the software can fail or provide incorrect readings or result in error.

These risks should be considered by the intended user and where applicable mitigated by other methods independent of the SSI Diagnostica A/S supplied equipment, such as:

- Warnings
- Use of other indicators or readings.
- Secondary, independent, testing or measurement.

18.3 Disposal of the ImmuView® Reader

If the ImmuView® Reader is to be decommissioned. The ImmuView® Reader is to be returned to SSI Diagnostica A/S (see section 2.3 for contact information, section 15 for decontamination and section 16 for the procedure).