User Manual
ImmuView® Reader 2.0

SSI Diagnostica A/S

Reference no. 213414

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1 General Information

1.1 Warnings & Limitations

⚠ **Warning:** Only use SSID A/S approved assays with the ImmuView® Reader 2.0

⚠ **Warning:** Only use the recommended and listed optional items with the ImmuView® Reader 2.0

⚠ **Warning:** Do not use the ImmuView® Reader 2.0 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 peripherals as there is a risk of damage. This Instrument does not contain serviceable parts and should be returned to SSI Diagnostica A/S for repair. Opening the Instrument voids the warranty. The real time clock battery included in the Instrument 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. Protection provided by the Instrument may be impaired if the Instrument is operated in a manner contradictory to these instructions.

⚠ **Warning:** Any changes or modifications not expressively recommended 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 Instrument

⚠ **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 the workbench. The mains socket outlet should be located near the Instrument and should be readily accessible. It is recommended that the user unplug the ImmuView® Reader 2.0 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

⚠ **Warning:** Ferrites must be fitted to the cables of attached USB peripherals to prevent electromagnetic interference.

⚠ **Warning:** In the event of suspected malicious code or a cybersecurity attack immediately unplug the instrument from both the network port and the power mains and discontinue use. Contact SSI Diagnostica A/S to report the suspicious event(s).

NOTE 1. Failure to follow these warnings will void the ImmuView® Reader 2.0 warranty

1.2 Safety Information

The ImmuView® Reader 2.0 is intended to operate safely and reliably when used in accordance with this User Manual and under the following conditions:

- Indoor use (protected from water)
- Altitude up to 2000 m
- Temperature 15°C to 35°C
- Relative humidity 10% to 70% non-condensing
- Mains supply voltage fluctuations not to exceed ±10% of the nominal voltage
- Overvoltage Category II
- Pollution Category 2
- Use with specified and supplied external AC/DC power adaptor only
- Set up instrument on a stable, level surface, in a laboratory environment.
- Operate the instrument on a stable, flat and level surface, at least 100 mm minimum from any edges
- Position cables to prevent risk of tripping or pulling to prevent instrument or personal injury
- The ImmuView® Reader 2.0 is non-serviceable. Opening the instrument will void the warranty
- Ensure ferrites are fitted to USB peripherals before connecting to the ImmuView® Reader 2.0

Personal safety

Refer to in-house safety procedures for biological waste and personal protective equipment (PPE) use when handling human biological materials.

2 Introduction

This User Manual describes setup, configuration, and operation of the ImmuView® Reader 2.0 – also referred to as "the Instrument". This document is provided as an operational summary to describe the use of the Instrument. This document does not describe operation or use of any specific diagnostic test – that information is outside the scope of this document and is described in the specific Instructions for Use and Quick Guides for those tests.

The ImmuView® Reader 2.0 is a portable *in vitro* diagnostic (IVD) instrument designed to provide qualitative results for rapid IVD tests. The ImmuView® Reader 2.0 can be used with SSI Diagnostica A/S approved immunochromatographic *in vitro* diagnostics tests. Key features of the ImmuView® Reader 2.0 include multiplex test support, automated workflow management, colour touch screen, networking, data archiving, and communication options.

The ImmuView® Reader 2.0 contains LEDs that can be enabled independently as required for illumination of the test.

The ImmuView® Reader 2.0 software contains instrument application software, which is the main application running on the instrument touch screen user interface. It controls the instrument in order to perform qualitative analysis of the tests.

Operation is subject to the following two conditions: (1) this instrument may not cause harmful electromagnetic or radio frequency interference, and (2) this instrument must accept any electromagnetic or radio frequency interference received, including interference that may cause undesired operation. These limits are designed to provide protection against harmful interference. This instrument 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.

SSI Diagnostica A/S recommends user assessment of the potential for electromagnetic interference in the intended operational environment of the instrument prior to use per standard institutional practices.

The ImmuView® Reader 2.0 complies with the emission and immunity requirements described in IEC 61326-2-6 and IEC 61326-1 (Industrial Locations).

This Instrument has been tested and found compliant with emissions limits required by CISPR 11 Class B equipment.

This instrument complies with Part 15 of the FCC Rules.

NOTE 2. Screen images shown in the User Manual are for illustrative purposes only. Test availability varies depending on the instrument and software version – tests shown on the example screen images may not be available in all markets.

2.1 Intended Purpose

The ImmuView® Reader 2.0 is an adjunctive instrument for automated reading and interpretation of results for immunochromatographic *in vitro* diagnostics tests.

The instrument is to be used by laboratory professionals or health care professionals only.

2.2 Package Contents

The following contents are supplied with the ImmuView® Reader 2.0:

- ImmuView® Reader 2.0 instrument
- Power supply (with adaptors for US/Canada, EU, UK, and AUS)
- 1 x Ferrite key
- 3 x Ferrites (clip on for USB peripherals only)
- 1 x Reader Quick Guide
- 1 x Technical Data Sheet

Note: ImmuView® Reader 2.0 Configuration Model specific contents will be added and described in the Technical Data sheet.

In addition to the above items, a Cartridge Drawer and Instrument Check Cartridge are supplied with the ImmuView® Reader 2.0. Strip carriers (for use with ImmuView® lateral flow tests) are also provided with some instrument configurations. Additional Strip Carriers and Instrument Check Cartridges are available for purchase.

2.3 Legal Manufacturer and Authorised Representative Contact Information

Legal Manufacturer

SSI Diagnostica A/S
Herredsvejen 2
3400 Hillerød
Denmark
T: (+45) 48 29 91 00

info-dk@ssid.com
www.ssid.com

UK Representative (UKRP)

Emergo Consulting (UK) Limited
c/o Cr360 – UL International
Compass House, Vision Park Histon
Cambridge CB24 9BZ
United Kingdom

Swiss Representative

CH REP

MedEnvoy Switzerland
Gotthardstrasse 28
6302 Zug
Switzerland

2.4 Symbols

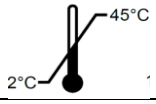
SYMBOL	DESCRIPTION
	USB Port: for connection of a USB flash memory key
	Network Port: to connect the instrument to a network
	Power Cable Port: to connect the SSI Diagnostica A/S power supply to the ImmuView® Reader 2.0
	Security lock slot: to connect a security lock to the ImmuView® Reader 2.0
	Power Button: to power on the ImmuView® Reader 2.0

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 labels used on the ImmuView® Reader 2.0. The definitions of each logo are listed in the table below.

SYMBOL	DESCRIPTION
	Product Branding
	Catalogue Number / Reference number
	Caution is necessary when operating the device, or situational awareness is required by the operator to avoid undesirable consequences.
	CE Mark indicating that the instrument has been assessed as meeting the IVDR (EU 2017/746) requirements
	Indicates temperature limits to which device can be safely exposed.
	Electrical and electronic equipment (EEE) contains materials, components and substances that may be hazardous and present a risk to human health and the environment when waste electrical and electronic equipment (WEEE) is not handled correctly.
	Consult Instructions for use or consult electronic instructions for use.
	Date of manufacture (if no expiry date)
	Manufacturer
	*In vitro* diagnostic medical device
	Instrument Serial Number
	Not for near patient testing
	Not for self-testing

3 Instrument Overview

Figure 1. ImmuView® Reader 2.0 Front View

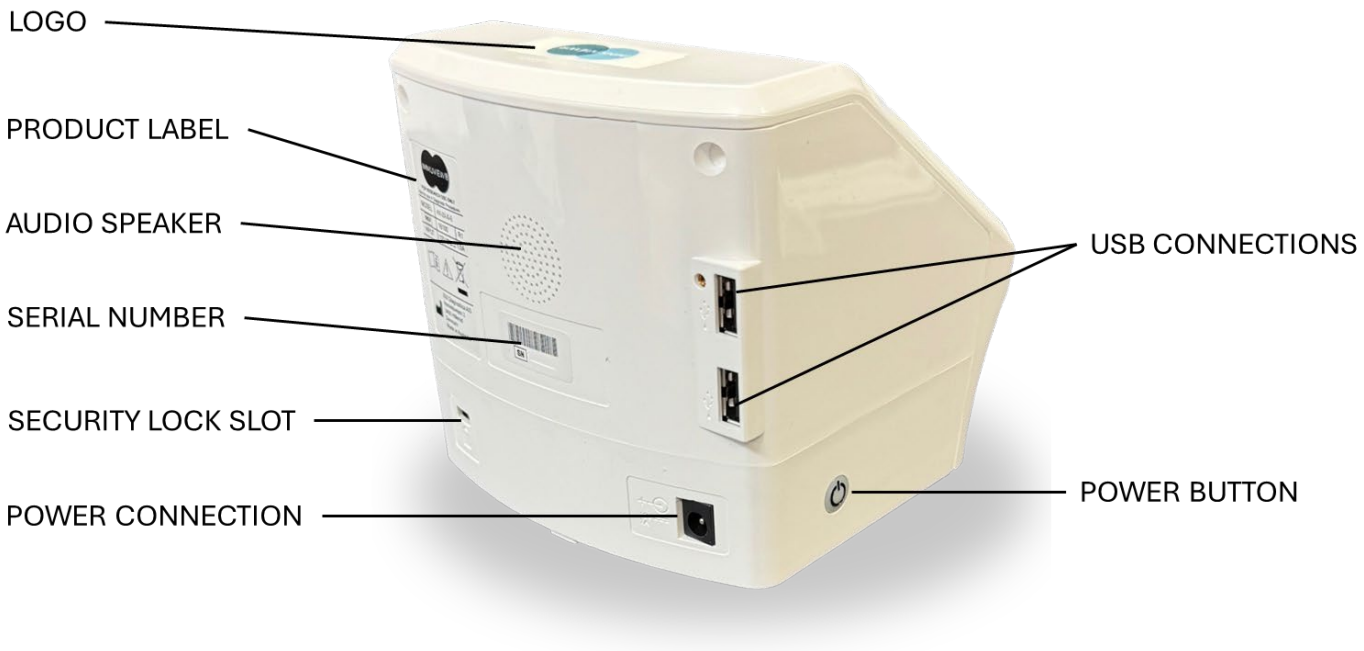


Figure 2. ImmuView® Reader 2.0 - Rear View

Figure 3. ImmuView® Reader 2.0 Left View

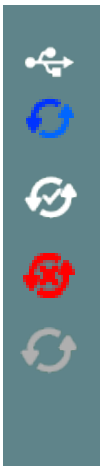
Figure 4. ImmuView® Reader 2.0 Right View

3.1 LED Status Indicator

Rapid flashing white light: Initial power connection registered
Slow flashing white light: Power connected but the instrument is shutdown
Solid flashing white light: Instrument on

3.2 Toolbar Indicators and Navigation Bar Icons

The toolbar at the top of the screen shows the menu title and the current time. Additional icons that may be shown in the toolbar are listed below.



A USB key is detected by the instrument and is ready for use

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

The Navigation Bar located at the bottom of the screen is used to interact with the on-screen menus and perform other functions. The icons that appear in the Navigation Bar vary depending upon the screen. Icons that may appear in the Navigation Bar are listed below.

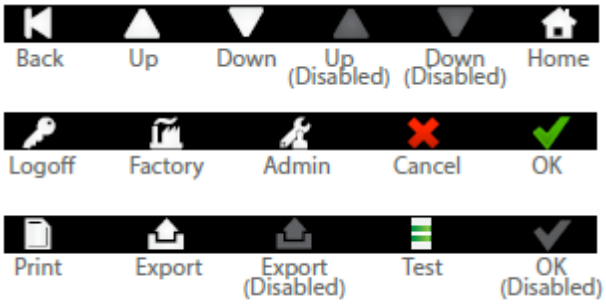


Figure 5. ImmuView® Reader 2.0 Navigation Bar

3.3 Limitations and Precautions

For test specific limitations and precautions refer to the Instructions for use (IFU) provided with the assay. General limitations and precautions are listed below:

- Use only tests that are approved for use on the ImmuView® Reader 2.0.
- Do not use a test past its expiration date.
- When testing a patient or QC sample, verify that the test type selected from the Test Menu matches the type of test performed.
- Discrepancies between the operator eye and the ImmuView® Reader 2.0 output may occur, especially in borderline samples (analyte concentration near the test's limit of detection).
- The ImmuView® Reader 2.0 may report 'Invalid' if the test is not correctly positioned in the Cartridge Drawer.
- The ImmuView® Reader 2.0 may report 'Positive' or 'Invalid' if there is splatter, tears and/or other aberrations present on the membrane. Inspect tests for splatter, tears, and other aberrations before placing in the Cartridge Drawer to avoid incorrect or invalid results.
- If an 'Invalid' result is obtained read the test again, or retest the sample.
- Be attentive to the overall test time when performing a test, so that the instrument is ready to read the test results at the end of the incubation period.

4 Setup Guide

UNPACK		**Instrument:** Unpack and visually inspect the ImmuView® Reader 2.0 instrument and provided items for damage. Verify that all items listed on the Technical Data Sheet are included in the box. Contact SSI Diagnostica A/S or local distributor for replacement of any damaged or missing items. Set up the instrument on a stable, level surface, in a laboratory environment.
POWER UP		**Power Supply:** Configure the power supply for your region. Connect the 12V power supply to the instrument
CONNECT		**Ethernet Cable (Not provided):** Required if the ImmuView® Reader 2.0 will be connected to a network for LIS access. Connect the network cable prior to powering on the instrument
EXPORT		**Test results on USB Key:** Use a FAT32 formatted USB key (not provided) to export test results and instrument data from the ImmuView® Reader 2.0
SOFTWARE UPDATE		**Software Update on USB Key:** A FAT32 formatted USB key containing a software update is used to install software updates onto the ImmuView® Reader 2.0 (refer to Section 13)
POWER DOWN		**Power Off/Standby:** It is recommended that the ImmuView® Reader 2.0 is powered down when not in use. However, the instrument will go into a screen saver mode when left on and not in use
FERRITES		**Ferrites:** Three ferrites are supplied with the ImmuView® Reader 2.0. *A ferrite must be fitted to the cable of each of the following USB peripherals to prevent electromagnetic interference:* • Label printer (Seiko SPL620) • Barcode scanner (Datalogic QuickScan Barcode Wand QD2430) To install ferrites: 1. Retrieve ferrite from zip lock bag inside packaging. 2. Place USB peripheral cable inside the ferrite: the distance from the ferrite to USB connector base should be 29±2mm. 3. Lock the cable in place by pushing the cable down. 4. Close the ferrite once the cable is in correct position

5 User Types

5.1 Standard User

The standard user has access to the home menu, testing, result review and basic settings of the ImmuView® Reader 2.0.

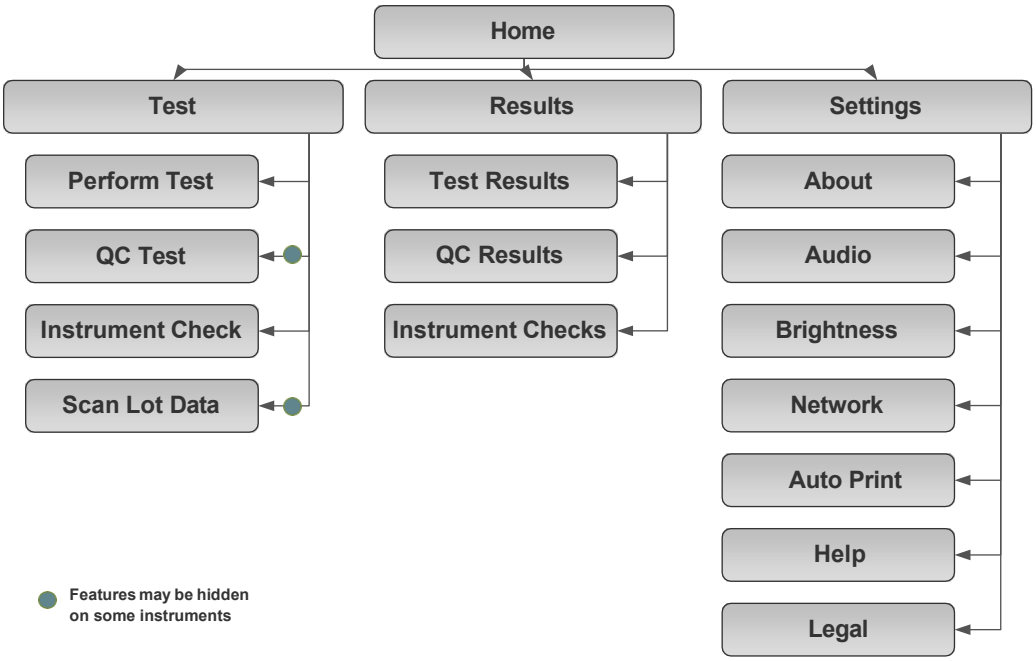


Figure 6. Standard User Menu Structure

5.2 Admin User

There is a single Admin User role on the ImmuView® Reader 2.0. The Admin User has access to all Standard User settings and functions, plus the additional "Admin Settings" screens.

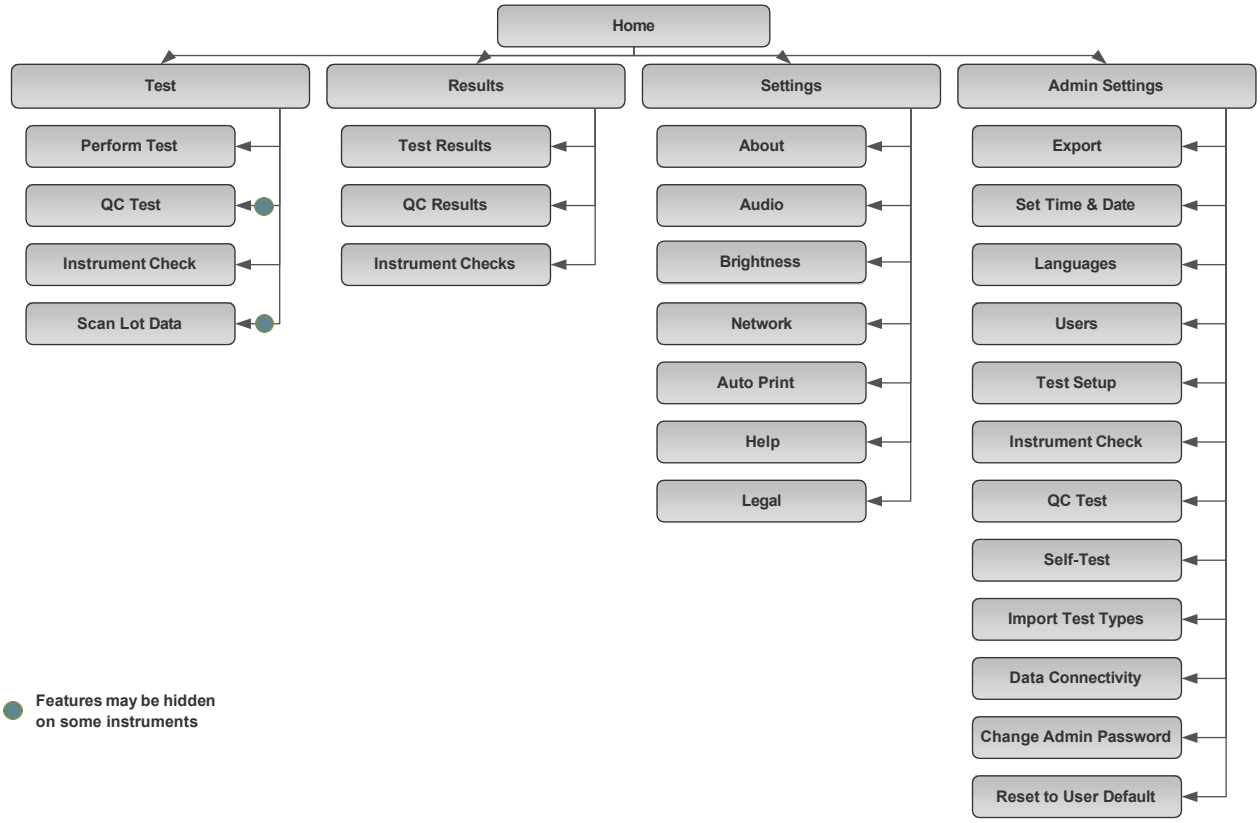


Figure 7. Admin User Menu Structure

6 Standard User Instructions

This section contains basic instructions for Standard Users after the system has been installed and set up by the Administrator ("Admin User"). See the Administrator User section of this user manual (Section 7) for more detailed instructions on instrument installation and configuration.

6.1 Powering On/Off and Application States

Standby: To place the ImmuView® Reader 2.0 into standby mode, connect the supplied power adapter to the instrument: the instrument is in standby mode.

Start-up: Holding down the power button for 2-3 seconds will initiate the ImmuView® Reader 2.0 start up sequence. The start-up sequence takes a few minutes and includes an automated self-test to verify proper internal system functionality of the instrument. The application home screen is displayed when the startup sequence is completed.

Shut-down: To shut down the instrument, press and hold down the power button for 2-3 seconds. The shutdown status bar is displayed and the instrument powers off.

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.

Auto log off: The application logs off from the current user setting 30 minutes from either the time the last test completed or the time the touch screen was last touched. The application screen remains blank until touched.

6.2 Self-Test at Start Up

The instrument Self-Test is an automated procedure that runs to verify proper functionality of key instrument systems and components. Self-test occurs during the instrument start up sequence, and as scheduled by the Admin User.

Following completion of the Self-Test process, a screen summarizing the Self-Test results is displayed.

Pass: In the case of a passing Self-Test the instrument progresses to the login screen. When a Self-Test has been run manually by an Admin user, the instrument automatically returns to the previous application screen upon completion of a passing Self-Test.

Warning: "Self-Test Warning!" is displayed. The test(s) that caused the warning are listed. In the case of a boot up Self-Test: the user confirms the warning to advance to the login screen. Testing is not locked out. In the case of Self-Test has been run manually by an Admin User: the user confirms the warning, and the application returns to previous screen. Testing is not locked out.

Fault: "Self-Test Fault! Testing has been locked out" is displayed. The test(s) that caused the fault are listed (any test that caused a warning is also listed). In the case of Boot up Self-test: the user confirms the fault to advance to the login screen. Testing is locked out. In case of Self-Test has been run manually by an Admin User: the user confirms the fault, and the application returns to previous screen. Testing is locked out.

Critical Failure: "Critical Failure!" is displayed. The instrument cannot be used.

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.

6.3 System Keyboard and Keypad

The onscreen QWERTY keyboard and numeric keypad are used to enter text input.

NOTE 3. The instrument produces an audible 'click' when the touch screen is pressed (the volume is configurable in Settings/Audio)

NOTE 4. A USB connected barcode scanner can also be used to input data read from a barcode into the onscreen keyboard/keypad screens (see Section 12.3)

NOTE 5. A connected generic USB keyboard (English QWERTY) can also be used to enter text into the onscreen keyboard/keypad screens (see Section 12).

6.4 User Login

The Login Method is set by the Admin User:

- If the Login Method is set to "Password" the user is required to enter both a valid User ID and password.
- If the Login Method is set to "Username" the user is required to enter a valid User ID at the login screen.
- If the Login Method is set to "None" there is no prompt to input a username or password. When the Login Method is set to "None" the User ID field will read "Default User".

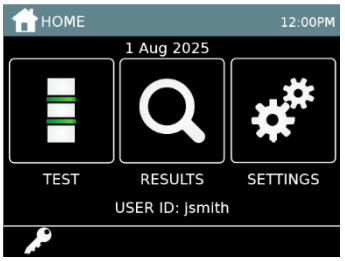
User IDs must be between 1 and 20 characters in length.

NOTE 6. Refer to Section 7 for configuring Instrument login requirements

6.5 Home Menu

The following options are available on the Home Menu screen:

- **TEST** – run a patient sample, a QC test, or an Instrument Check test
- **RESULTS** – review results from previously run tests
- **SETTINGS** – configure the instrument settings



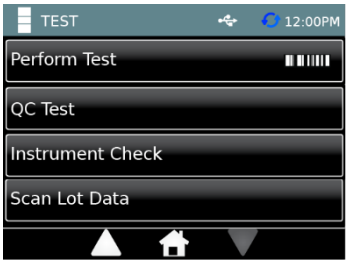
Pressing the Key icon logs out the current user ID and navigates to the login screen.

NOTE 7. The time and date are displayed to the user on the main screen

6.6 Test Menu

The Test menu provides access to the following options for running tests and entering lot information:

- Perform Test – for testing a patient sample. Pressing this selection displays the test list.
- QC Test* – for running an QC test. Pressing this selection displays a list of the QC tests that can be run and the QC Test Status for each Test Type.
- Instrument Check – for running an instrument quality check test using the Instrument Check Cartridge, independent of the test
- Scan Lot Data* – for entering lot data for a specific test type



*NOTE 8. *These options may not be available, depending on the instrument configuration or Administrator settings applied.*

NOTE 9. If External Select Scan is (On) users can also scan the barcode on the assay kit box to select a test. Refer to 7 Administrator User Instructions.

NOTE 10. 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.

NOTE 11. A memory nearly full warning (warning code 0010, Section 16.2) will be displayed prior to running a test if the result storage capacity is less than 25 remaining tests. The instrument storage capacity is 999 test results. If a test is run when the memory is full 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.

6.7 Scan Lot Data

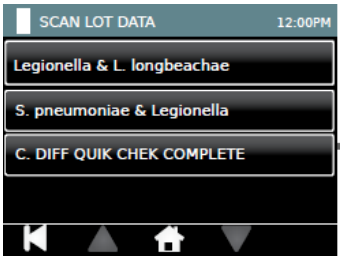
The ImmuView® Reader 2.0 can store Lot Data for each test type loaded on the instrument. The Admin User can enable or disable the use of Scan Lot Data in the Admin User Test Setup menu.

If the user wishes for Lot Data of the test kit to be automatically captured in the test workflow, Lot Data should be chosen prior to running any tests. Alternatively, if the Admin User has set (Scan Lot Data) to (Per Test) in the Test Setup settings the user will be prompted to enter Lot Data each time a test is run.

Step 1. Select Scan Lot Data

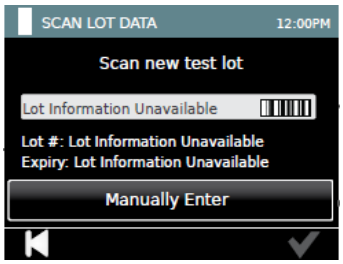
If (Scan Lot Data) has been set to (ON) by the Admin User in the Test Setup settings, then 'Scan Lot Data' can be selected from the Test Menu.

Step 2. Choose Test Type



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

Step 3. Scan New Test Lot



"Lot Information Unavailable" is displayed if Lot Data has not been entered and saved.

To add Lot Data a Barcode Scanner peripheral device can be used to scan an appropriate Barcode, then click the √ (Accept) button to save results. Lot Data may also be entered manually using the on-screen keypad by selecting the "Manually Enter" option.

NOTE 12. Refer to Section 12.3 Barcode Scanner

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

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

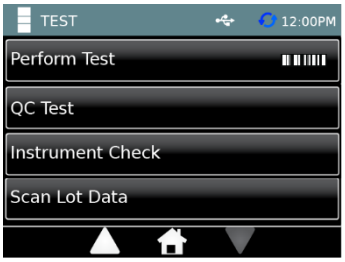
6.8 Run a Patient Sample Test

Refer to the IFU and Quick Guide provided with the assay for instructions on how to perform the assay specific test.

Refer to the Quick Guide for the assay type being performed for information on which Cartridge Drawer is required. Verify that the correct Cartridge Drawer is installed in the ImmuView® Reader 2.0 instrument before proceeding.

NOTE 13. 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 QC test for the selected test type (if QC test is required)*
- *The instrument has not passed an Instrument Check test within the required period*

Step 1. Select 'Perform Test' from the Test Menu.



Step 2. Choose Test Type

Select the test type from the test list

NOTE 14. The Admin User can configure the test types imported onto the ImmuView® Reader 2.0 instrument. Refer to Section 7.

NOTE 15. Verify that the test type selected matches the type of test performed.

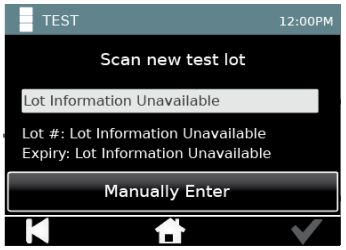
Step 3. Scan New Test Lot

If (Scan Lot Data) is set to (Per Test) the instrument will prompt for kit lot information to be entered. To input Test Lot information a Barcode Scanner can be used to scan an appropriate Barcode, then click the √ (OK) button to save results.

Lot Number can also be entered manually by pressing the "Manually Enter" button and entering Lot information using the onscreen keyboard. Select √ to save text input. Selecting ✖ (Cancel) will go back to the previous screen.

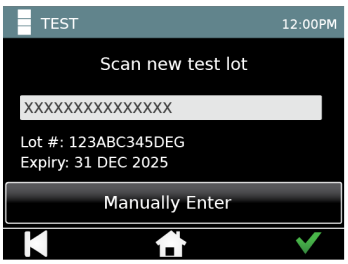
Enter the Lot Expiry date using the onscreen keyboard in the DD/MM/YYYY format

Select √ to save. Selecting ✖ will go back to the previous screen. The (Home) button will cancel the test.

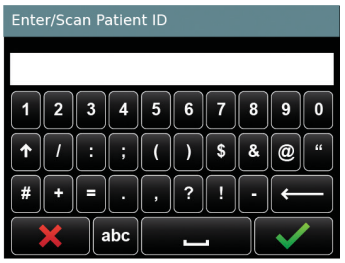


When completed, the "Scan New Test Lot" screen contains all required information.

Select √ to save and go to the next screen.



Step 4. Enter Patient ID Information



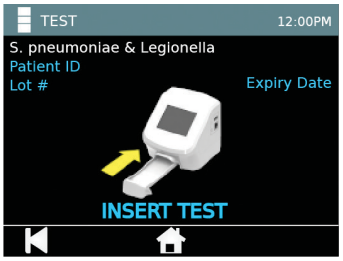
Enter a unique Patient ID using the onscreen keyboard or by scanning a barcode containing the Patient ID. Click √ to save the text input. Selecting ✖ cancels the test and test data is not saved.

Warning: To ensure patient privacy the patient name or any easily identifiable patient information should not be used as the ID.

NOTE 16. The Patient ID must 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 17. If (Patient ID) is set to (Off) in the Admin User Settings/Test Setup menu, then this step is skipped and a default test number (e.g. T001) is automatically assigned as the Patient ID

Step 5 Insert Test



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

Pull out the Cartridge Drawer and place the test into the appropriate recess (refer to the Quick Guide for the assay specific test being performed for additional details).

The test is read immediately when the Cartridge Drawer is closed.

Selecting (Back) or (Home) cancels the test and test data is not saved.

Step 6. Identifying and Acquiring Image

During the identifying and acquiring image step the instrument illuminates the test bay area and captures the image for processing.

NOTE 18. The Cartridge Drawer must remain closed during this phase of analysis.

Step 7. Analysing and Saving

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

Step 8. Result

The ImmuView® Reader 2.0 produces an audible tone to indicate that the analysis is finished. Test results are displayed on the screen when the analysis is complete. In the case of an "Invalid" result, read the test again, or retest the sample.

The result screen displays:

- Test number
- Patient ID
- Test type
- LIS status*
- Test time and date
- Lot number (if applicable)
- Expiry date (if applicable)
- User ID
- Control line result
- Show Results Image
- Final Test Results

The results can be printed using a connected printer by pressing the icon.

The result can be exported to an attached USB Key or LIS (if configured) by pressing the icon.

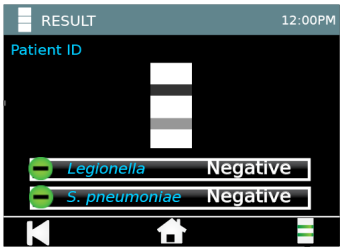
NOTE 19. Test results image is not exported.

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 20. If "Rapid Test" mode has been enabled by the Admin User the same test type will automatically be selected when the (New Test) icon is pressed.

Step 9. Show Results Image

If Show Results Image is set to (ON) by the Admin User, then the Show Results Image screen can be accessed by selecting the "Show Results Image" icon on the results screen.



In the case of a test error: "Error: ##" is displayed as the test result. Information on error codes can be found in Section 16 of this User Manual.

6.9 Run QC Test

QC testing is performed to confirm proper functionality of both the instrument and the test assay. Refer to the IFU and Quick Guide provided with the test specific assay for instructions on how to perform the test.

NOTE 21. 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*
- *The instrument has not passed an Instrument Check test within the required period*

6.9.1 Performing an Assay QC Test

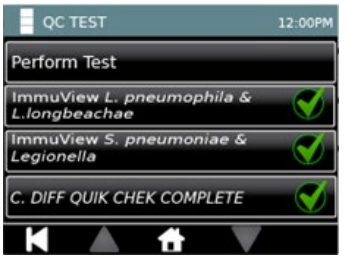
The QC test function allows the user to determine if the test is performing as intended by running the positive and negative control available in the Assay kit.

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 2.0.

This screen also displays the QC Test Status for each Test Type with associated QC tests (see Section 6.10.2 for more information on QC Test Status)

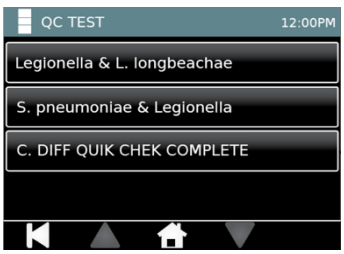
Select (Perform Test) to run a new QC Test.



Step 2. Choose QC Test Type

If multiple QC Test Types are loaded on the instrument, select the desired QC Test from the list. If only one QC Test Type is loaded it will automatically be selected.

NOTE 22. The Admin User can configure the list of displayed test types. The test types available varies based on the instrument model and configuration.



Step 3. Enter QC Lot ID

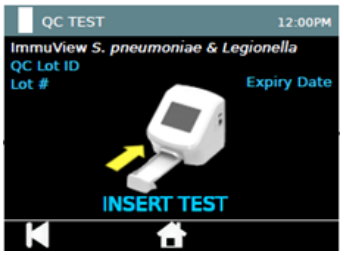
Enter a unique QC Lot ID using the onscreen keyboard. Select (OK) to save text input.

Selecting (Back) cancels the test and test data is not saved.

NOTE 23. The QC Lot ID must be between 1 to 20 characters.

NOTE 24. If (QC Lot ID) is set to (Off) by the Admin User this step is skipped and a default test number (e.g. T001) is automatically assigned as the QC Lot ID

Step 4. Insert Test



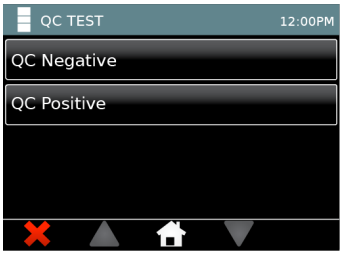
The instrument prompts the user to insert test, and displays the Test Type, the QC Lot ID, the lot information (if applicable) and the Expiry Date.

Pull out the Cartridge Drawer and place the test into the appropriate recess (refer to the Quick Guide for the assay specific test being performed for additional details).

Test analysis begins immediately when the Cartridge Drawer is closed.

Selecting (Back) or (Home) cancels the test and data is not saved.

Step 5. Select QC test expected outcome.



Select the known outcome for the associated QC test.

Selecting (Cancel) or (Home) cancels the test and data is not saved.

Step 6. Identifying and Acquiring Image

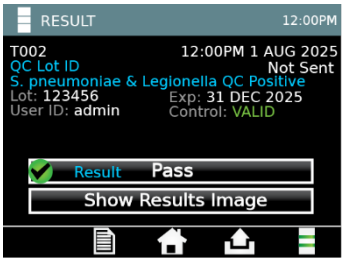
During the identifying and acquiring image step in the workflow the instrument illuminates the test bay area and captures the image for processing.

NOTE 25. The Cartridge Drawer must remain closed during this phase of analysis.

Step 7. Analysing

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

Step 8. Result



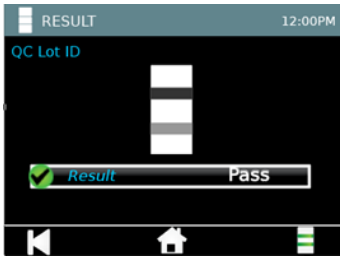
QC Test results are displayed on the screen when the analysis is complete.

The results can be printed using a connected printer by pressing the icon.

The result can be exported to an attached USB Key or LIS (if configured) by pressing the icon.

Pressing the (New Test) icon navigates to the Test Menu. 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.

Step 9. Show Results Image

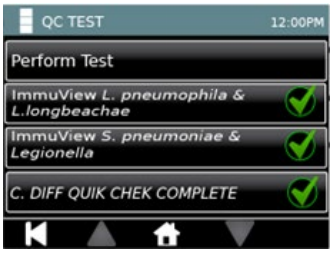


If Show Results Image is set to (ON) by the Admin User, then the Show Results Image screen can be accessed by selecting the "Show Results Image" icon on the results screen.

NOTE 26. Test results image is not exported.

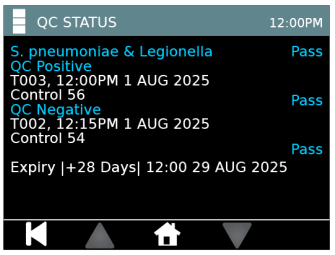
In the case of a test error: "Error: ##" is displayed as the test result. The error code can be looked up in Section 16 of this User Manual.

6.9.2 QC Test Status



The QC Test status for each associated Test Type is indicated by an icon. Select the test from the menu to view more detailed information (some options may not be available, depending on the Admin User settings and instrument model configurations).

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 overdue
Pass	Pass is shown when all associated QC tests have passed



The QC status screen shows the status of the QC Test, the date the most recent QC Test was performed, and the most recent QC Test results. 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 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 have passed and none are due: the QC status is pass

QC status is set to overdue due to any of the following reasons:

- Importing a new Test Types Package (see Section 7)
- The instrument being "Reset to Factory Default"
- The instrument current date and time is past the QC test validity period timestamp

6.10 Run an Instrument Check Test

This section describes the Instrument Check test functionality and its associated settings. The Instrument Check test uses an Instrument Check Cartridge – a printed strip reference standard – and returns a pass or fail result based on analysis of the Instrument Check Cartridge. The Instrument Check function reads the test lines of the printed strip and confirms that they fall within the acceptable range.

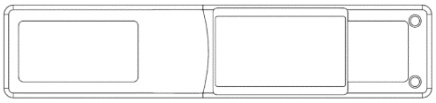
The Instrument Check test provides a reliable confirmation that the instrument is operating correctly and therefore must be performed at a minimum of once every seven (7) days.

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

The Instrument Check function includes a scheduler (configured in the Admin User settings) to remind users to perform Instrument Check tests at specific intervals. The Instrument Check function is independent of any test and test controls and specifically checks the instrument reading capability using an external cartridge and strip standard.

6.10.1 Instrument Check Cartridge

The Instrument Check Cartridge is provided separately. When removing the Instrument Check Cartridge from the supplied pouch/packaging, grasp the cartridge by its sides to minimise touching and damage to the strip in the cartridge.



NOTE 27. SSI Diagnostica A/S recommends storing the Instrument Check Cartridge in its original pouch packaging to minimise light exposure. The Instrument Check Cartridge in its supplied packaging is suitable for extended storage within the temperature range 2°C to 30°C and humidity 10% to 80% RH.

In the event an instrument check test fails, re-run the Instrument Check test using another Instrument Check Cartridge (SSI Diagnostica recommends having a second Instrument Check cartridge available for this purpose). If the Instrument Check test subsequently passes, the Instrument Check Cartridge may require replacement. Contact SSI Diagnostica A/S for Instrument Check Cartridge replacement options (see Section 2.3 for contact information).

6.10.2 Instrument Check Status

There are three Instrument Check status possibilities:

- Pass: The last Instrument Check test has passed
- Fail: The last Instrument Check test has failed
- Overdue: The Instrument Check Pass Status validity period has ended, or an Instrument Check test has not been performed

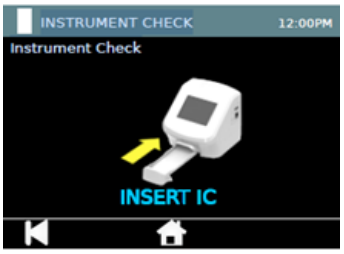
The Instrument Check status is updated at the completion of each Instrument Check test.

NOTE 28. Visual and fluorescent controls must pass in order to run the corresponding test methodology.

NOTE 29. The instrument application does not permit an Instrument Check test to be conducted with an expired Instrument Check Cartridge.

6.10.3 Running an Instrument Check Test

Step 1. Insert Instrument Check Cartridge



The instrument prompts the user to insert the Instrument Check Cartridge.

Pull out the Cartridge Drawer and place the Instrument Check Cartridge into the appropriate recess in the Cartridge Drawer, with the arrow on the Instrument Check Cartridge facing up and pointed toward the instrument.

Instrument Check test analysis begins immediately when the Cartridge Drawer is closed.

Selecting (Back) or (Home) cancels the test.

Step 2. Identifying and Acquiring Image

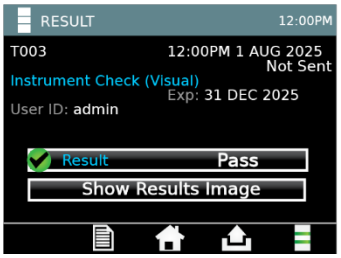
During the identifying step in the workflow the instrument illuminates the test bay area and captures the image for processing.

NOTE 30. The Cartridge Drawer must remain closed during this phase of analysis.

Step 3. Analysing and Saving

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

Step 4. Result



Instrument Check test results are displayed on the screen when the analysis is complete.

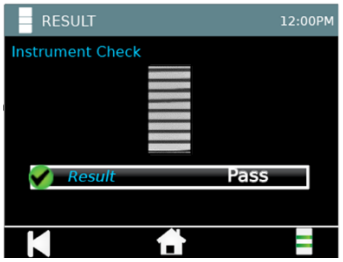
The results can be printed using a connected printer by pressing the icon.

The result can be exported to an attached USB Key or LIS (if configured) by pressing the icon.

NOTE 31. Show Results Image cannot be exported to an attached USB Key, printer or LIS.

Pressing the (New Test) icon navigates to the Test Menu. 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.

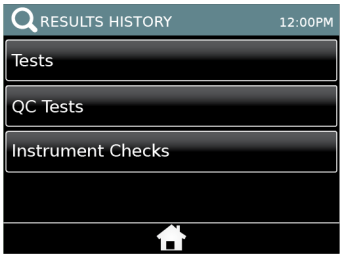
Step 5. Show Results Image



If Show Results Image is set to (ON) by the Admin User then the Show Results Image screen can be accessed by selecting the "Show Results Image" icon on the results screen.

In the case of a test error: "Error: ##" is displayed as the test result. The error code can be looked up in Section 16 of this User Manual.

6.11 Results History

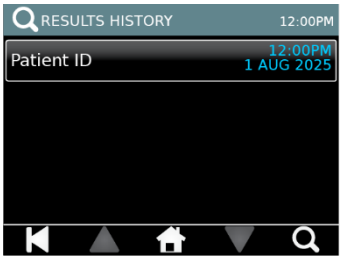


The Results History menu contains the following results:

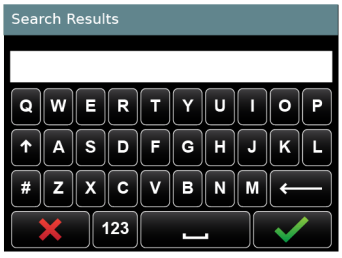
- Test results
- QC test results*
- Instrument Check results

NOTE 32. * Some options may not be available in this menu, dependent on whether QC testing is enabled

NOTE 33. The ImmuView® Reader 2.0 is able to store the results of 999 Standard and Instrument Check Tests, and a separate 99 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



Selecting "Tests," "QC Tests," or "Instrument Checks" from the results history menu displays a list of all saved test results in that category, shown in order of newest to oldest. The (Up) and (Down) navigation arrows can be used to scroll through the displayed results.



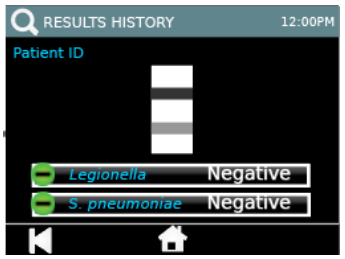
Clicking the (Search) icon opens the keyboard screen. Entering a search term filters the results list to show only results containing the search term (all results fields are searched, including date, lot number, and User ID).

Select a result from the list to review the individual test result.

The result can be printed using a connected printer by pressing the icon.

The result can be exported to an attached USB Key or LIS (if configured) by pressing the icon.

The results image can be accessed by selecting the "Show Results Image" icon on the results screen.



6.12 Standard User Settings

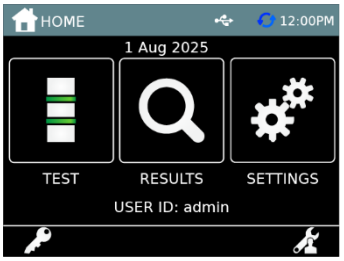
The **"Settings"** screen is accessed from the Home menu and allows the Standard User to view and configure the standard ImmuView® Reader 2.0 information and settings.

- About: Displays ImmuView® Reader 2.0 information such as Serial Number, Model Number, and Software Version. Information from the "About" screen may be requested when contacting SSI Diagnostica A/S for technical support.
- Audio: View and adjust the screen click and alert tone volume levels
- Brightness: View and adjust the screen brightness level (the recommended default setting is 80%)
- Network: View and configure the Ethernet connection settings. Both DHCP and static IP configurations are supported.
- Auto Print: Enable or disable the auto printing feature (only applicable when the instrument is connected to a printer). When set to (On), test results are automatically printed upon completion of a test. When set to (Off), the user must manually print each test result from the Test Results screen.
- Help: Provides contact information and ImmuView® Reader 2.0 copyright information. Queries should be directed via the website at www.ssid.com
- Legal: Contains software licensing and legal information

7 Administrator User Instructions

To access administrator functions described in this section you must first login using the Admin User ID.

The default Admin login is: admin



The Admin User Home screen is the same as a Standard User, with the addition of the Admin User settings icon in the footer bar, on the bottom right. Access the Admin User menu to view and configure advanced instrument settings.

- Export: Export test results, test diagnostics files, and log files to a USB Key.
  - Test results files contain all test results stored on the instrument. Test results files can be exported in either .CSV or .TSV format.
  - When test results files have been exported successfully, the software provides the opportunity to delete all test results. There is no warning and this action cannot be undone, therefore it is recommended to not delete test results unless all required results have been successfully exported.
  - Exporting results to a LIS is covered separately in Section 8.
  - Test diagnostics and log files may be requested when contacting SSI Diagnostica A/S for technical support.

  NOTE 34. 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 oldest test result is deleted to make room for the newest and the Test Numbers begin to increment past T999.

- Set Time & Date: Use the up and down arrow keys and touch screen to set the time and date, and choose between a 12-Hour or 24-Hour time display format. The ImmuView® Reader 2.0 Real Time Clock (RTC) maintains the time and date when the instrument is powered off.

  NOTE 35. Changing the time or date will cause the reader to reboot and may affect the status of the Self-Test, Instrument Check, and QC Test schedules.

- Languages: Select the language. Available languages are:
  - English UK
  - English US
  - Czech
  - Danish
  - French
  - German
  - Italian
  - Norwegian
  - Portuguese
  - Spanish
  - Swedish

  NOTE 36. Messages displayed during system boot-up and the software update processes are displayed in English UK only

  NOTE 37. The same onscreen keyboard will be used for data entry across all languages using Standard English keyboard characters

- Users Settings: Manage the user list (add, delete and edit), select the login method, and export or import the user list
  - View User List: Select a user from the list to edit the username or password, or delete the user

    NOTE 38. Deleting a User is permanent. Once deleted, the User profile will be lost; however, stored results from tests performed by a deleted user will not be affected.

  - Add New User: Create a User ID and password (if required) for new users

    NOTE 39. Up to 99 users can be created.

    NOTE 40. 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 41. The following user IDs are reserved in the ImmuView® Reader 2.0 software application: admin, factory and Axxin. An error notification will be displayed if these user IDs are typed into the user list.

  - Login Method: Set the login method required for Standard Users.

        - (Username): Users may enter any user ID and will not be asked for a password.
        - (Password): A valid username and password (configured in Users Settings) is required to login and use the instrument.
        - (None): There is no prompt to enter a username or password. When set to "None" the User ID field will read "Default User".
    - Export User List: Export the user list to a USB drive. This user list can then be imported to another ImmuView® Reader 2.0 (or to the same instrument after a reset to factory settings or major software upgrade). This permits 'cloning' of user accounts across a number of instruments.
    - Import User List: Import a complete user list from a USB drive (user list that was exported from another instrument).
- Test Setup: View and configure settings and options related to running patient and QC tests.
    - Test List: Select which test types are displayed in the Test Menu. Standard Users are only able to see and run the selected test types.
    - Rapid Test: Turn Rapid Test mode (On) or (Off). Rapid Test mode allows for multiple tests of the same test type to be performed in succession without going to the Test selection page each time a test is run.
    - Patient ID: When (On) is selected, the user is prompted to enter a Patient ID at the start of a test. When (Off) is selected a consecutive alphanumeric test number (e.g. T001) is automatically assigned as the Patient ID.
    - QC Lot ID: When (On) is selected, the user is prompted to enter a QC Lot ID at the start of a QC test. When (Off) is selected a consecutive alphanumeric test number (e.g. T001) is automatically assigned as the QC Lot ID.
    - Scan Lot Data: The Scan Lot Data test function can be set to (On), (Off), or (Per Test).
        - (On): Scan Lot Data test function is visible in the test menu
        - (Off): Scan Lot Data test function is hidden in the test menu
        - (Per Test): The user is prompted to enter lot information each time a test is run
    - Save Diagnostics: When the Save Diagnostics function is enabled, more detailed information is stored (useful for diagnostic and troubleshooting purposes) which increases the size of the .bin file. Since this feature significantly increases the test cycle time and results export time, it should only be enabled if requested by SSI Diagnostica A/S Technical Support.
    - Show Results Image: When (On) is selected, the Show Results Image icon is visible on the results screen. When (Off) is selected, the Show Results Image icon is hidden. When enabled analysis time is increased by ≈10 seconds per test.
    - External Select Scan: When (On) is selected, the user will be able to select a test from the Test Menu by using a barcode scanner to scan the QR code on the test kit box.
- IC (Instrument Check) Settings: Set the minimum frequency requirement for performing Instrument Check tests. The schedule can be toggled between 1 day and 7 days. After the selected number of days has elapsed since the Instrument Check test has passed, the Instrument Check test status is set to due. The user is prevented from running a patient or QC test when the Instrument Check status is due or has failed.
- QC Test Settings: Configure the QC Test Method and QC Test Schedule.
    - QC Test Method Settings:
        - (None): QC test functionality is hidden from the testing and results menus; no QC test status is applied*.
        - (Warning): A warning is displayed to the user prior to running a test when the QC status for that test type is due or has failed.
        - (Lockout): The user is prevented from running a test when the QC status for that test type is due or has failed.
    - QC Test Schedule Settings:
        - None: no schedule is applied
        - 1 day, 7 days, 28 days, 30 days

- Self-Test Settings: The Admin User can manually run a Self-Test or set a schedule for Self-Tests to be run automatically. Self-Tests can be scheduled to be run with the following frequencies:
    - None (no schedule is applied)
    - 1 day, 7 days, 28 days, 30 days

  After the set number of days has elapsed since the last Self-Test was run, the Self-Test will run again. Scheduled Self-Test does not interrupt testing.
- Import Test Types: The ImmuView® Reader 2.0 is supplied with a default set of Test Types loaded. The Admin User can import new Test Types from this screen by inserting a USB key containing a Test Type Package (TTP) file.

  NOTE 42. Ensure that the USB key containing the new TTP is connected to the instrument before starting the import process.

  NOTE 43. A USB key icon ( ) is displayed in the header when a USB key is detected. An error message will be displayed if "Import Test Types" is selected and a USB key is not detected.

  NOTE 44. Importing a new TTP file will replace all Test Types previously loaded onto the instrument

  NOTE 45. All imported Test Types will be displayed on the instrument. To configure which Test Types to display, refer to "Test List" above.

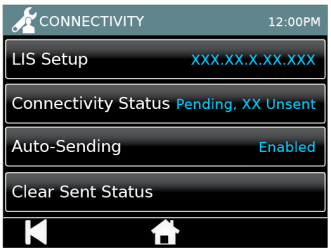
  NOTE 46. Uploading a new set of Test Types does not affect results already held in the test results memory storage

  If the TTP was successfully imported the instrument displays a confirmation message, then reboots.

  The new imported TTP is immediately available. Information about the TTP, including name, version number and timestamp of import is viewable in the ImmuView® Reader 2.0 "About" screen.
- Data Connectivity: The ImmuView® Reader 2.0 has the ability to communicate with an LIS Server using the HL7 standard. Refer to Section 8 for more information on LIS connectivity.
- Change Admin User Password: The current Admin User password must be entered before a new password can be set. A reset to user default (see below) will also reset the Admin User password.
- Reset to User Default: Reset the ImmuView® Reader 2.0 to the manufacturer's default settings. This action cannot be undone - ensure that any important data such as User Lists and Test Results are exported to a USB key prior to performing a Reset to User Default. Performing a Reset to User Default removes all user accounts, resets the Admin User password, restores the default TTP, and deletes all stored test results and lot data. Confirmation is required to perform a Reset to User Default ("Are you sure you want to reset to user default?"). Once confirmed the instrument will reboot.

8 Data Connectivity

The ImmuView® Reader 2.0 has the ability to communicate with a laboratory information system (LIS) Server using the HL7 standard protocol. Only unidirectional communications (ImmuView® Reader 2.0 → LIS Server) are possible between the ImmuView® Reader 2.0 and the LIS Server.



8.1 Packet Format

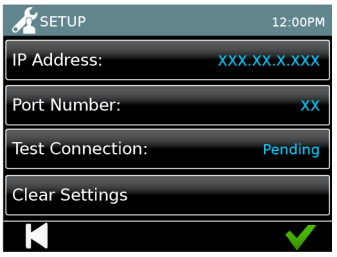
Results sent to the LIS are packaged as an ASCII formatted data packet. The packet is divided into several categories/sections, each of which contain fields appropriate for certain types of information.

A data packet may contain the following categories, as defined in the HL7 standard:

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

8.2 Setup LIS Connection

This section describes the steps for Setting up the ImmuView® Reader 2.0 for LIS communications:



Navigate to LIS Setup Menu

Configure the LIS Server IP address and Port Number settings to establish network communications.

Set LIS Server IP Address

Contact your IT department or contractor for the LIS Server IP Address.

Enter the IP Address of the LIS server into the field provided, with each unique number separated by a full stop (.) - e.g., "XXX.XXX.XXX.XXX"

Set LIS Server Port Number

Contact your IT department or contractor for the LIS Server Port Number information.

Enter the Port Number of the LIS Server into the field provided. The default value provided is 51112. However, this number will be specific to the LIS Server you are using. The Port Number must be within the following range: 49152 – 65535.

NOTE 47. Upon installation of software updates the LIS configuration might have to be set up again.

Test LIS Server Connection

Use this function to test the connection between the ImmuView® Reader 2.0 and the LIS Server.

Select "Test Connection"

One of three states will be displayed:

- Pending: Test Connection not yet run
- Success: ImmuView® Reader 2.0 successfully connected to LIS
- Failed: ImmuView® Reader 2.0 failed to connect to the LIS

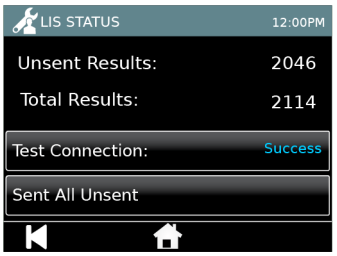
Press the ✓ icon to confirm and apply the IP & Port Number settings of the LIS Server.

Clear Settings

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

8.3 Check Connectivity Status

Connectivity Status



Select 'Connectivity Status' to view the LIS Server transmission data statistics.

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 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.

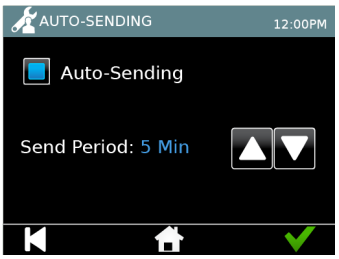
Refer to Section 3.2 "Toolbar Indicators and Navigation Icons" to understand the Transmission Status shown by the ImmuView® Reader 2.0.

When sending the results, the unsent result count will reset to 0 as all previously unsent results are 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 stop the current transmission and leave the remaining results as unsent.

8.4 Auto-Sending

Auto-Sending



The user can set the ImmuView® Reader 2.0 to automatically send results to the LIS Server at regular periods. All unsent results will be sent to the LIS Server at the defined time intervals.

Set the Auto-Sending period by using the Up/Down arrows. Available choices are 5 Minutes, 15 Minutes, 30 Minutes, 1 Hour, and 1 Day. Press the ✓ icon to confirm and apply the settings.

8.5 Clear Sent Status

Clear Sent Status

The user can clear the sent status of results sent to the LIS Server. This may be useful if all test results have been exported and the test memory cleared.

8.6 Send Single Result to LIS Server

Manual Send

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

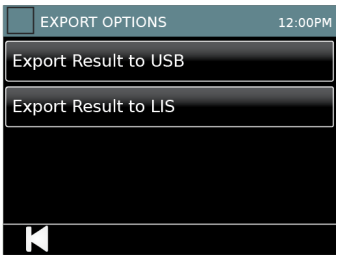
- Immediately after running a test
- When reviewing saved results from the 'Results' menu

From the Test Result screen select the Export icon to open the result export options.

Select "Export Result to LIS" to transmit the currently viewed result to the LIS server, regardless of its previous sent/unsent status.

NOTE 48. LIS must be configured before the user is able to Export Result to LIS.

NOTE 49. The export button is disabled from result screens if LIS is not configured, and no USB is detected.



9 Data Export and Archive

The Admin User can export the following file types from the ImmuView® Reader 2.0 to a USB key:

- Test result report for a single test result
- Test Results .bin (encrypted data, images and detailed results, used for troubleshooting and support)
- Test Results .CSV or .TSV (for import to Microsoft Excel or other spreadsheet software)
- Log Files (for support and troubleshooting)

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 from the instrument on a regular basis as a backup.

9.1 Single Test Result Export or Printed Test Report

A single test result can be exported to a USB key or printed to a connected printer at the completion of a test, or when viewing a single test result from the Results screens.

The report has a common format for all test types. Any unused fields are left blank.

REPORT TYPE	DESCRIPTION
Compact USB Printer Seiko Smart Label Printer 620	Printed on a Shipping label W: 54 mm (2 1/8 in) H: 101 mm (4 in)
Export to USB Key	Exported to an attached USB Flash Memory Key as an image viewable on a standard PC

9.2 Test Diagnostics Files

Test Diagnostics results are exported as .bin files, an encrypted format that can only be viewed or printed using special software (not provided). A .bin file export may be requested by SSI Diagnostica A/S Technical Support when troubleshooting instrument issues.

9.3 Test Results (.CSV or .TSV)

A .CSV or .TSV file summary "spreadsheet" export contains all test results plus instrument details.
The contents of the exported .CSV/.TSV file includes (but is not limited to) the following information:

- Test information (Test Number, Test Date, Test ID, Assay ID, Test Type...)
- Configuration Details (No Timer, Lot Number, Expiry Date, User ID...)
- Results and decisions (Result Code, Decision QC result, Decision Title, Decision Message...)
- Status Information (Self-Test Status, Instrument Check Status, QC Status, Factory Mode ...)
- Device Information (Device Serial Number, Application Version, Package Name, Package Version, Temperature...)

9.4 Log Files

The log files are exported in text format and contain system diagnostics information for use by SSI Diagnostica A/S Technical Support.

10 ImmuView® Reader 2.0 Specifications

ITEM	DESCRIPTION
Test Bay Configuration	• Changeable Cartridge Drawer with customised insert for compatible test formats
Measurement Technology	• Advanced image acquisition and analysis
Illumination	• Green LED – 520nm • Red LED – 622nm • Blue LED – 470nm
Colour Touch Screen	• 3.5" diagonal capacitive TFT LCD
Communications	• Ethernet • USB • LIS-HL7
Data Storage	• 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	• 124 mm W x 118 mm H x 142 mm D
Weight	• ≈ 700 g
Barcode Scanner Support (not provided)	• USB attached Datalogic QuickScan QD2430 2D
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 2000 m altitude. • Pollution degree: 2
Storage Environment	• 2°C to 45°C • 10% to 80% RH (non-condensing)
Peripherals	• USB Key (FAT32 formatted) • USB connected Label Printer • USB connected Barcode Scanner • General keyboard

11 12V Power Supply Adaptor Specifications

The ImmuView® Reader 2.0 must be operated using only the specified and supplied AC/DC power adaptor to ensure both the EMC and safety compliance of the product.

- SSI Diagnostica A/S supplied Power adapter, 12V DC, 1.25A: Part No: P004831
- Approval: UL, CUL, GS, CE, RCM, UK, FCC, ISED, NRCan, Energy efficiency Level VI, DoE, CoC Tier 2
- Four (4) interchangeable region-specific AC mains plug: (Australia), UK, US, and EU (Europe).

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

12 Optional Items (not provided with ImmuView® Reader 2.0)

Optional items that can be used with the ImmuView® Reader 2.0 are available separately and include:

- USB key
- Ethernet cable
- Label printer, the Seiko SPL620
- Barcode scanner (Datalogic QuickScan Barcode Wand QD2430 with stand)
- Generic keyboard (English QWERTY)

Contact SSI Diagnostica A/S for more information on the availability of optional items.

12.1 USB Key

The ImmuView® Reader 2.0 is compatible with USB keys with the following specifications:

- 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 is required to import or export user lists, or to export test results for manual archiving. It may take a few seconds for an inserted USB key to be detected by the ImmuView® Reader 2.0. A USB icon ( ) is displayed in the task bar when a USB key has been successfully detected.

12.2 Label Printer

Seiko Smart Label Printer – SLP 620

The Seiko Smart Label printer type SLP 620 is recommended for use with the ImmuView® Reader 2.0. The printer will print Test Reports 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 2.0, and power up the Instrument
- Connect the SLP USB cord to the ImmuView® Reader 2.0
- 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 2.0, go to Settings à Auto Print 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 2.0.
- Press and hold for 2 seconds to turn SLP off.

12.3 Barcode Scanner

The ImmuView® Reader 2.0 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 "contact" type barcode wand and CCD or laser "non-contact" type barcode readers can be used. The ImmuView® Reader 2.0 is configured to automatically accept barcode reader inputs for all text fields with the exception of passwords.

Connect the barcode reader to an available USB port on the ImmuView® Reader 2.0.

The Datalogic QuickScan Barcode Wand, QD2430 is a barcode reader that is recommended for use with the ImmuView® Reader 2.0. For a complete setup and operating procedure refer the Datalogic QuickScan™ QD2430 user manual.

13 Software Update

Instructions for installing software updates will be provided with the software updates as required.

14 Cleaning & Decontamination

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

Ensure the ImmuView® Reader 2.0 is powered off and unplugged before cleaning.

Do not use isopropyl alcohol within 3 m 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:

- Disposable laboratory gloves
- Lint-free wipes
- Foam Tipped Swab
- Disinfecting Solution: Isopropanol (≥ 99%) or 10% household bleach solution

The ImmuView® Reader 2.0 (including the Cartridge Drawer, drawer slot, and Strip Carriers) can be cleaned using a lint-free wipe dampened (but not dripping) with one of the Disinfecting Solutions listed above. SSI Diagnostica A/S does not recommend applying disinfecting solution directly to the instrument.

Wet the lint-free wipe with the Disinfecting Solution 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 dampened with Disinfecting Solution
   Use sufficient Disinfecting Solution such that the surfaces are clearly wetted by the cleaning process. Surfaces include the LCD display and touch screen.
   When using 10% bleach as the Disinfection Solution: following decontamination, remove residual bleach solution with a lint-free wipe dampened with water, then dry with a clean lint-free wipe.
4. **Dispose:** Dispose of all used materials and gloves
5. **Wash hands:** Wash hands using a disinfecting hand wash

15 Service & Maintenance

15.1 Software Issue Reporting

Contact SSI Diagnostica A/S Technical Support if you experience an issue with the ImmuView® Reader 2.0 software.

⚠ **Warning:** In the event of suspected malicious code or a cybersecurity attack immediately unplug the instrument from both the network port and the power mains and discontinue use. Contact SSI Diagnostica A/S to report the suspicious event(s).

E-mail the following information to SSI Diagnostica A/S Technical Support at info-dk@ssid.com:

- Customer details – Name and contact information
- ImmuView® Reader 2.0 details – Model, serial number, instrument application version, test type package (from the "About" screen)
- Description of fault or error
- Pictures of errors, tests, and samples
- Information on any sample(s) causing an error (e.g. type, consistency, colour). Samples should be saved in case they need to be shipped to SSI Diagnostica A/S for further evaluation.
- Instrument log file export as an attachment
- .csv export as an attachment
- Test Diagnostics export as an attachment (if too large use OneDrive, WeTransfer, google drive or other cloud-based services)

Consider the following when reporting a software defect or bug:

1. Take note of what steps you performed to cause the defect to occur. Steps required to reproduce the error are an important part of any defect report.
2. What were you expecting to see (expected result) and what happened instead (actual result)?
3. If you are seeing an Error or Warning dialogue, please record the Error Code number "0000" which can be found on the top line of the dialogue screen.
4. How many instruments are affected?
5. How frequently you are seeing the defect or error?
6. What hardware is connected to the instrument (e.g. printer, barcode scanner, USB key)?
7. If you believe you are seeing multiple issues on the same instrument, please complete a separate support form per issue.

15.2 Return for Service Request

Complete the Return for Service form (provided by SSID Diagnostica A/S) for any ImmuView® Reader 2.0 instrument 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 can begin. SSI Diagnostica A/S will acknowledge receipt of Return for Service Requests within 2 business days.

The ImmuView® Reader 2.0 should be packed securely in the original packaging or equivalent before returning to SSI Diagnostica A/S. Shipping cartons should be lined with bubble wrap and or other packing material to protect the instrument cartons during shipping.

Contact SSID Diagnostica A/S or your local representative for instructions on returning the instrument for service:

NOTE 50. Data may be erased from the instrument during service.

NOTE 51. Instruments not cleaned prior to return for service may be returned or an additional fee incurred.

NOTE 52. Warranty is voided if the "Warranty Void" label has been removed or tampered with. An additional fee may be incurred.

NOTE 53. 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 54. If SSI Diagnostica A/S Quote is not accepted, then instrument will be returned as supplied and an inspection fee charged.

15.3 Transport and storage conditions

Shipping cartons should be lined with bubble wrap and or other packing material to protect the instrument cartons during shipping:

- 2°C to 45°C
- 10% to 80% relative humidity (non-condensing)

Storage environment:

- 2°C to 45°C
- 10% to 80% relative humidity (non-condensing)

16 Errors, Warnings, and Information

This section provides information and troubleshooting steps for specific errors and warning codes. If the error or warning persists, contact Info-dk@ssid.com for assistance. Alternatively, contact SSI Diagnostica A/S directly via email or telephone.

SSI Diagnostica A/S
Herredsvejen 2
3400 Hillerød, Denmark

Info-dk@ssid.com
www.ssid.com
T: (+45) 48 29 91 00

Warning: 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 2.0 receives a request or performs an action outside the normal operating parameters for that user/test/function, an error message will be displayed. The error message describes what error has occurred and requires the user to confirm the error has been noted before the instrument returns to normal operation. In some cases, it may cancel a current test and/or require an instrument reboot.

Information: An information screen provides the user with important information. There is no specific input required from the user – pressing (OK) will exit the screen.

16.1 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 LEDs 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. 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. 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.

16.1 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 cartridge/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: 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.

16.1 In-Test Error Dialogues		
CODE	**DESCRIPTION**	**ACTION**

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 that the cartridge/strip carrier is placed correctly in the Cartridge Drawer. Check for control line being present. Check for contaminants on the strip. Attempt to rerun test. If error continues contact SSI Diagnostica A/S.
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 that the cartridge/strip carrier is placed correctly in the Cartridge Drawer. Check for control line. Check for contaminants on the strip. Attempt to rerun test. If error continues contact SSI Diagnostica A/S.
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 that the cartridge/strip carrier is placed correctly in the Cartridge Drawer. Check the test line. Check for contaminants on the strip. Attempt to rerun test. If error continues contact SSI Diagnostica A/S.
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 that the cartridge/strip carrier is placed correctly in the Cartridge Drawer. Check the test line. Check for contaminants on the strip. Attempt to rerun test. If error continues contact SSI Diagnostica A/S.
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 that the cartridge/strip carrier is placed correctly in the Cartridge Drawer. 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.

16.1 In-Test Error Dialogues		
CODE	**DESCRIPTION**	**ACTION**

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 that the cartridge/strip carrier is placed correctly in the Cartridge Drawer. Check the test line. Check for contaminants on the strip. Attempt to rerun test. If error continues contact SSI Diagnostica A/S.
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.
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.
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. If error continues contact SSI Diagnostica A/S.SSI Diagnostica A/S to review test type package.
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. If error continues 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.

16.1 In-Test Error Dialogues		
CODE	**DESCRIPTION**	**ACTION**
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. If error continues 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. If error continues 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. If error continues 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. If error continues 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
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. If error continues 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. If error continues 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.

16.1 In-Test Error Dialogues		
CODE	**DESCRIPTION**	**ACTION**
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. If error continues 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. If error continues 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. If error continues 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.
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. If error continues 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. If error continues 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. If error continues contact SSI Diagnostica A/S.SSI Diagnostica A/S to review test type package to ensure that the quantitative output fields are set correctly.

16.1 In-Test Error Dialogues		
CODE	**DESCRIPTION**	**ACTION**
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. If error continues 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.
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: 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 for contaminants. Attempt to re-run test. If error continues contact SSI Diagnostica A/S.
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. If error continues contact SSI Diagnostica A/S.
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. If error continues contact SSI Diagnostica A/S.
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. If error continues contact SSI Diagnostica A/S.
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 SSI Diagnostica A/S.

16.1 In-Test Error Dialogues		
CODE	**DESCRIPTION**	**ACTION**
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.
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. If error continues contact SSI Diagnostica A/S.
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. If error continues contact SSI Diagnostica A/S.
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 If error continues contact SSI Diagnostica A/S.

16.1 In-Test Error Dialogues		
CODE	**DESCRIPTION**	**ACTION**
Error: 325	Barcode Format Error	The format of the barcode is incorrect. 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: 326	Barcode Found But Damaged	The barcode has been found but is damaged. 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.

16.2 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 User 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 2.0 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.

16.2 Warning Dialogue		
CODE	**DESCRIPTION**	**ACTION**
0011	Device memory is full! {0} shall be deleted if you wish to proceed.	This dialogue notifies the user that the ImmuView® Reader 2.0 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.
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 user 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 user 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.

16.3 Errors Dialogue		
CODE	**DESCRIPTION**	**ACTION**
0512	A critical error has occurred! Please refer to user manual. Reboot required.	The ImmuView® Reader 2.0 has suffered a critical error. The instrument will not boot up. Arrange return of the instrument.
0513	RTC failure! Please refer to user manual.	The ImmuView® Reader 2.0 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 55. 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.

16.3 Errors Dialogue		
CODE	**DESCRIPTION**	**ACTION**
0528	A maximum of 100 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 SSI Diagnostica A/S or local distributor to ensure that test type package contains less than 100 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 2.0 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 2.0 has failed. 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.
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.
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 key. If the USB key 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.

16.3 Errors Dialogue		
CODE	**DESCRIPTION**	**ACTION**
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 an 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 recognised by the ImmuView® Reader 2.0. See USB requirements.
0563	Results data has been corrupted! Please refer to user manual.	A results corruption has occurred, please attempt to export results.
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 User 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.
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 2.0 can perform testing.

16.3 Errors Dialogue		
CODE	**DESCRIPTION**	**ACTION**
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.
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
0765	Invalid barcode found.	The barcode scanned is not recognised by the instrument. Please try again or use the keyboard to enter the details.

16.4 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 are no user IDs entered on the instrument, the instrument informs the user. The Admin User should add users to the instrument then reattempt request.

16.4 Information Dialogue		
CODE	**DESCRIPTION**	**ACTION**
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.
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 User 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.
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

17 Warranty & End User License Agreement

The ImmuView® Reader 2.0 is warrantied to materially conform to applicable product specifications for a period of one (1) year from the date of delivery. If any defect is determined during the Warranty period, SSI Diagnostica A/S will, at its election, repair or replace the non-conforming instrument without charge. However, the following damage and defects are specifically excluded:

- Defects or damage caused by improper operation of the instrument
- Damage incurred due to improper packaging of returned goods
- Repair or modifications done by anyone other than SSI Diagnostica A/S
- Use of materials not specified by SSI Diagnostica A/S
- Deliberate or accidental misuse of the instrument
- Damage caused by disaster
- Damage due to use of improper cleaning solution or sample

Fuses are also excluded from the warranty.

For enquiry or request for repair service, contact SSI Diagnostica A/S (please have the instrument model and serial number ready).

17.1 Updates

SSI Diagnostica A/S reserves the right to issue a "change notice" relating to the construction, software, or use of the ImmuView® Reader 2.0 at any time. The ImmuView® Reader 2.0 must be quarantined from use immediately after a change notice is issued and until the update is completed.

17.2 Instrument Failure and Errors

The ImmuView® Reader 2.0 and its associated software are constructed using standard components and methods. The ImmuView® Reader 2.0 and the software can fail or provide incorrect readings or results 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.

17.3 Disposal of the ImmuView® Reader 2.0

Abide by local, regional, and national regulations for electrical waste when disposing of the ImmuView® Reader 2.0.

18 Incident reporting

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the member state in which the user and/or patient is established.

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Quality Certification
SSI Diagnostica A/S ensures that the development, production, and distribution of in vitro diagnostics comply with EN ISO 13485 standard.