



Solana User Manual

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A symbols glossary can be found at quidelortho.com/global/en/resources/symbol-glossary.

General Information















QuidelOrtho Contact Information

Website quidelortho.com

If you have any questions regarding the use of this product, please contact QuidelOrtho Technical Support at 1.800.874.1517, option 2 (in the U.S.) or technicalsupport@quidelortho.com. If outside the U.S., further information can be obtained from your distributor, or directly from QuidelOrtho at one of the numbers listed below. Reference **quidelortho.com** to see more options for Support.

Country	Phone	E-Mail Address
Europe, Middle East, and Africa	+353 (91) 412 474 (main) 1800 200441 (toll free)	
Austria	+43 316 231239	
Belgium	+32 (2) 793 0180	
France	0 (805) 371674	
Germany	+49 (0) 7154 1593912	emeatechnicalsupport@quidelortho.com
Netherlands	0 800 0224198	
Switzerland	0 800 554864	
United Kingdom	0 800 3688248	
Ireland	+353 (91) 412 474	
Italy	+39 (800) 620 549	
North America, Asia-Pacific, Latin America	858 552 1100	technicalsupport@quidelortho.com
Canada	437 266 1704 (main) 888 415 8764 (toll free)	technicalsupport@quidelortho.com
China	0400 821 3535	TSC_China@quidelortho.com

Labels and Symbols

Label	Description
	Manufacturer
	<i>In vitro</i> diagnostics
	CE mark of conformity (Conformité Européenne)
	Consult instructions for use
	Authorized representative in the European Community
	Temperature limitation
	Directive 2002/96/EC on waste electrical and electronic equipment (WEEE)
	Serial number
	Catalog number
	Part number
	Information of particular importance
	Warning! Indicates a hazardous situation, which if not avoided, could result in injury to the Operator or a bystander (e.g., electrical shock or UV exposure).
	Potential Biohazard! An agent of biological origin that has the capacity to produce deleterious effects on humans, i.e. microorganisms, toxins, and allergens derived from those organisms; and allergens and toxins derived from higher plants and animals.
	Caution! Indicates a situation, which if not avoided could result in damage to the device or incorrect results.

Brief Warnings, Precautions and Limitations

NOTE: Within this document, text in **bolded, purple-colored font** indicates hyperlinks in the electronic document. The word “Solana” is interchangeable with the word “instrument” or “device” throughout this manual.

- Always operate Solana on a surface that is level, dry, and stable, away from direct intense lighting.
- Operation of Solana should occur at room temperatures between 15°C to 35°C.
- Highly intense light and vibrations may influence results and must be avoided.
- Never move Solana while in operation or in the unlocked position.
- Do not expose Solana to strong electromagnetic radiation.
- Do not use a power adapter other than the adapter provided with Solana.
- Do not drop Solana as it could damage the unit.
- Never place objects on top of Solana.
- Never start testing without reaction tubes inserted.
- Do not re-open/open the lid of the reaction tube once it has been closed.
- Pouring liquids into testing wells can damage Solana. Avoid spilling bleach in the well as this can cause corrosion of the internal parts, which can cause failure of the instrument.
- Maintenance and decontamination of workspace and equipment should follow and be performed according to established laboratory protocols and schedules. QuidelOrtho does not require preventative maintenance for the instrument as a requirement.
- Turn off Solana when not in use.

Safety Precautions

Solana is designed to provide safe and reliable operation when used in accordance with instructions in this User Manual. If Solana is used in a manner not specified in the User Manual, the protection provided by the equipment may be impaired.

All warnings and precautions should be followed to minimize personal injury or damage to the device.



Warning!

To reduce the risk of electrical shock:

- Unplug Solana before cleaning. Should the Solana instrument need to be moved for bench-top cleaning, please engage the transport lock prior to doing so. **See Transport Lock** section for details.
- Plug the device into an approved, properly installed receptacle or Universal Power Supply.
- Do not immerse in water or cleaning solutions.
- Do not open instrument housing or disassemble the device.
- Use the appropriate power cord for the region.

Failure to follow these warnings invalidates the warranty.



Potential Biohazard!

To reduce the risk of biohazard:

- Treat specimens as potentially biohazardous material.
- Dispose of used specimens in accordance with applicable local, regional, and national requirements.
- Clean Solana per the **Maintenance and Cleaning** section prior to storage, transport, or disposal.
- Seek specific training or guidance if you are not experienced with specimen collection and handling procedures.
- Use well-fitting nitrile, latex, or other impermeable disposable gloves when handling patient specimens or known positive samples.



Caution!

To reduce the risk of incorrect results:

- Trained and qualified operators should operate Solana.
- Refer to the assay-specific package insert for details on specific tests.
- Use the assay kit before the expiration date.

To reduce the risk of Solana cybersecurity vulnerability exploit:

- Due to known cybersecurity vulnerabilities with Solana (CUPS vulnerabilities), it is recommended to keep Solana disconnected from networks unless precautions are taken, such as segregated local area network (LAN) and designated IP connections.
 - Disable the CUPS Interface, which allows access to the CUPS Printing Interface, required for Network Printing.
 - *System > Security Settings > CUPS Interface > OFF*
 - If you are currently using the Network Printing option, switch to use of a directly connected DYMO printer. Contact Technical Support for more information.
 - Disable Network (SSH), which allows remote login access to the Solana Instrument.
 - *System > Security Settings > Network (SSH) > OFF*

To reduce the risk of Solana damage:

- Solana is designed for countertop operation under normal laboratory conditions.
- Solana is not designed to withstand moisture, extreme humidity, or extreme temperatures.
- Solana is not designed to withstand severe shock or vibration.
- Do not open instrument housing or disassemble the device.
- Do not use bleach on the tube holder.

Failure to follow the precautions mentioned above invalidates the warranty.

To reduce the risk of environmental contamination:

- If the inside of the Solana is contaminated, please contact QuidelOrtho Technical Support.
- Clean Solana per the **Maintenance and Cleaning** section prior to return or disposal.
- Dispose of Solana and accessories in accordance with local, regional, and national requirements.

Cybersecurity:

■ **Due to known cybersecurity vulnerabilities with Solana (CUPS vulnerabilities), it is recommended to keep Solana disconnected from networks unless precautions are taken, such as segregated local area network (LAN) and designated IP connections.**

- Disable the CUPS Interface, which allows access to the CUPS Printing Interface, required for Network Printing.
 - *System > Security Settings > CUPS Interface > OFF*
 - If you are currently using the Network Printing option, switch to use of a directly connected DYMO printer. Contact Technical Support for more information.
- Disable Network (SSH), which allows remote login access to the Solana Instrument.
 - *System > Security Settings > Network (SSH) > OFF*
- If a cybersecurity compromise of the Solana is suspected, make sure it is disconnected from any network and immediately contact your institution IT support for next steps. Possible restoration will require QuidelOrtho technical support at telephone: 800.874.1517 (in the U.S.), 858.552.1100 (outside U.S.), or technicalsupport@quidelortho.com.

- **Change the default Admin password immediately.** A temporary (valid for 24 hours) Administrator-level password can be obtained by contacting QuidelOrtho Technical Support and supplying the instrument serial number, located on bottom of instrument.
- Use strong passwords. The Administrator should assign passwords with minimum length (8 recommended minimum), upper/lowercase, and special characters. Do not share passwords, each user should have a unique password. Passwords should be changed and managed in accordance with your organization's procedures. Entry of passwords are obscured on the display.
- Users and their passwords are assigned only by the Administrator.
- Anti-malware prevention by design only allows the software in the product to execute (from allow/deny listing). Other software cannot be installed on the device. All device software is essential. No unused or unneeded services are allowed.
- Currently Solana should not be connected to networks without extreme caution. Data in transit encryption with SSL/TLS is supported at current recommended strength from standards. LIS connections with HL7 are not encrypted and are intended for use on a customer secure network behind a firewall.
- Data at rest is not encrypted, including passwords.
- USB ports are used for described export/import of settings and data backup, or updates only. Otherwise, they are inactive and cannot be used for bootup (disabled) or for uploading other software.

- Software updates are installed by the customer Administrator as described and are available for registered users from myquidel.com. Solana software has security measures that disallow improperly modified or malware.
- Secure and appropriate data disposal is available for Savanna. Please contact QuidelOrtho Technical Support.
- *Solana* is portable and may be located in a secure area with restricted access. Please take precautions to prevent theft.
- With potential sensitive data loss or exposure, Solana customers are recommended to ensure data is backed up regularly. See instructions to export data to USB, or LIS can serve as remote storage. Data to be backed up include logs, user lists, and database of test information.

Limited Warranty

For specific warranty coverage and limitations, please refer to the applicable contract under which the product was purchased, QuidelOrtho's standard warranty terms at quidelortho.com/terms-of-sale or contact your distributor or QuidelOrtho representative for assistance.

Intended Use

Solana is a stand-alone instrument which is able to run up to 12 tubes of Solana diagnostic assays.

It should only be used according to the safety precautions outlined in the **Brief Warnings, Precautions and Limitations** section. Solana is only compatible with QuidelOrtho Solana assays run by trained qualified personnel.

Product Description

Solana uses isothermal, helicase-dependent amplification and fluorescent, probe-based detection that is illuminated by an ultraviolet (UV) and visible light source to generate specific results.

Each reaction tube contains an internal process control that is also read via fluorescence. This ensures that amplification has occurred within the reaction tube to permit an accurate reading.

Solana then displays the test results to the user (e.g., Positive, Negative, Invalid) on the screen. These results can be printed on an integrated or networked printer, label printer, saved on a USB flash drive, and/or sent to a Laboratory Information System (LIS).

System Components

The following system components are included:

- Solana instrument
- Power supply and cords
- Ethernet cord
- DYMO® LabelWriter® 4XL printer
- DYMO LabelWriter 4XL printer labels

- Stylus
- Workflow tray
- Transport rack

To place an order, please contact or fax QuidelOrtho Customer Service.

Solana consumable assay reagent kits and External Quality Control materials are provided separately.

Contact QuidelOrtho Customer Service or visit the Quidel website for a list of approved Solana assays.

System Display

Solana has a 6 inch × 3.5-inch color touchscreen user interface.

Functional Description

Hardware

Figure 1, Figure 2, and Figure 3 identify the components of the Solana instrument.

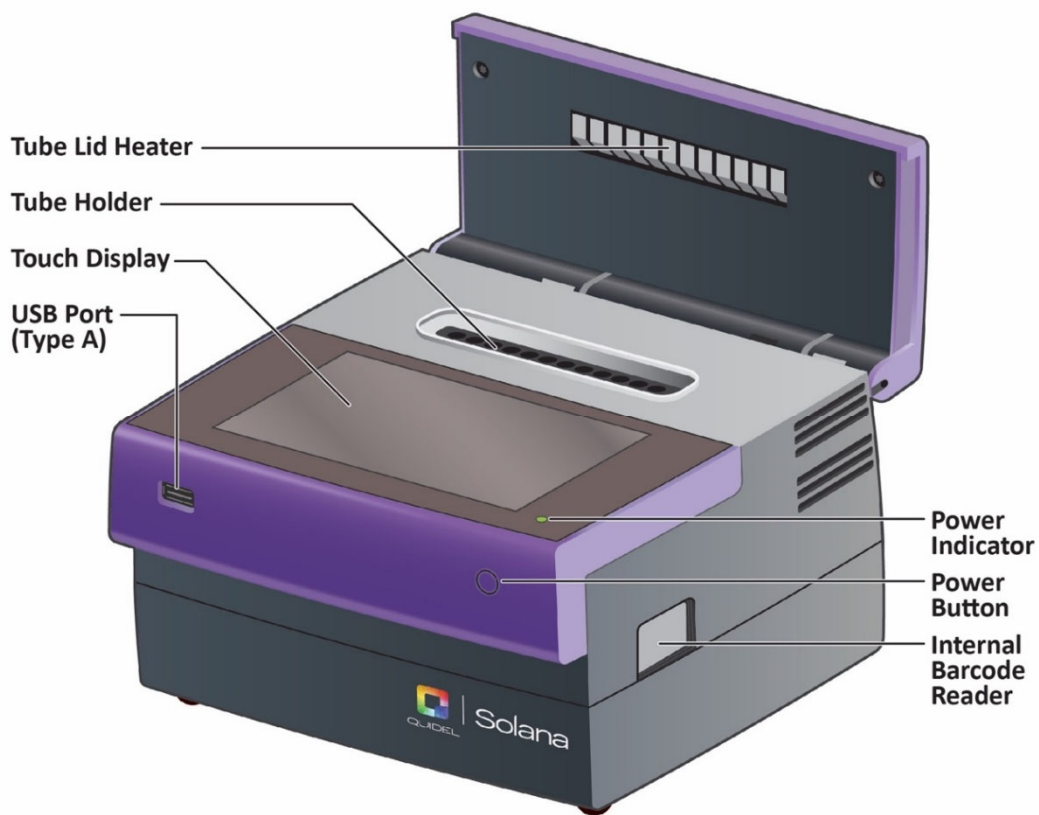


Figure 1

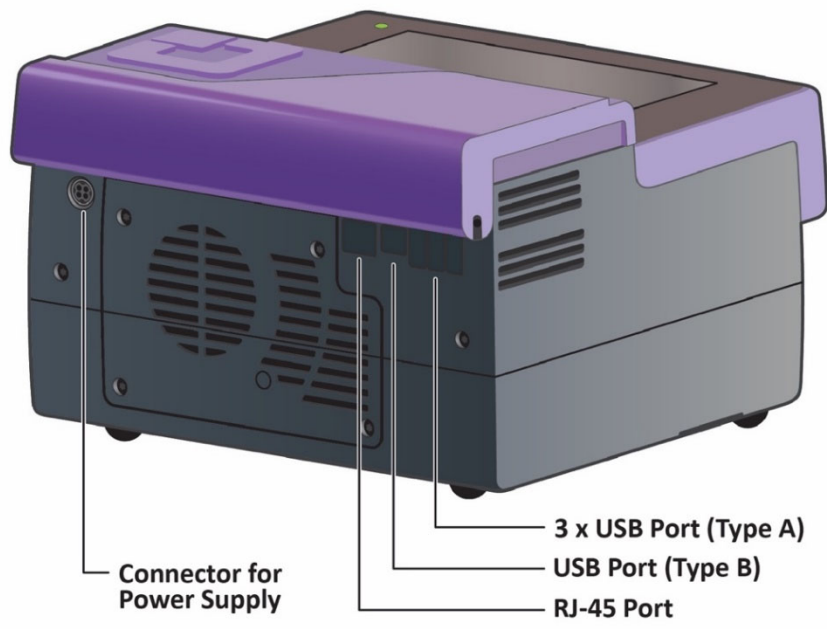


Figure 2

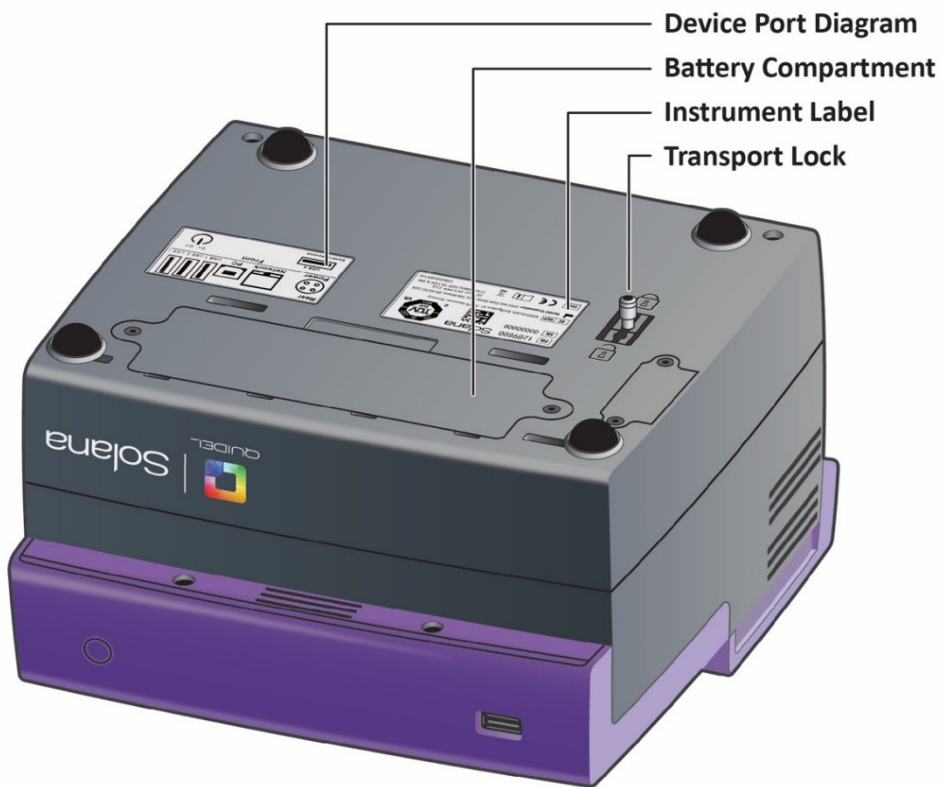


Figure 3

Set-up and Connection Procedures


Unpacking of Solana

Inspect the shipping container for obvious damage prior to opening. Unpack the contents, placing Solana upright on a dry, stable, and level surface. Carefully examine the Solana for damage. Check that all other system components are provided (see **System Components** section) and are in good condition.

In case of damage or any missing parts, contact QuidelOrtho Technical Support.

Placement of Solana

The Solana is portable and can be moved to a suitable secure location for testing or storage with transport locked properly. Solana is intended for use in a secure location safe from unauthorized removal or theft and prevent sensitive data loss or exposure.


 When moving the instrument, lock the mechanical transport lock. See the **Locking and Unlocking Solana** section for instructions on locking and unlocking the instrument and shutting down.


The Solana must be placed on a dry, stable, and level surface and within the operating conditions specified in the **Technical Specifications** section. The location needs to be within reach of an appropriate wall electrical outlet and other wired connections (e.g., DYMO printer). In addition, it should be placed with enough surrounding space to perform the following functions:


- Easily open and close the tube lid heater to insert or remove the reaction tubes
- Easy access to all connection ports on the back of the unit should be considered during placement of instrument, such as the connector for the power supply, in case of emergency or under abnormal operating conditions

The measured signal may change due to following:

- Changes in ambient light levels
- Contamination of the optical parts (Ex. Corrosion from bleach and sample leakage)
- Electromagnetic interference
- Temperature changes (Ex. Placing under air vents and direct sunlight.)
- Mechanical movements (vibrations). (Ex. Centrifuges and large machines.)

 Do not place Solana in a location that is subject to vibrations, such as near machines that vibrate, shake, or spin. Solana is a highly sensitive and precise optical instrument.

 Do not place Solana in a location that will subject it to sources of direct airflow, such as an overhead air vent or an adjacent instrument with a fan vent. Direct airflow can affect Solana Instrument's ability to maintain proper temperature.

 Do not place Solana near sources of intense light (e.g., direct sunlight). Solana has internal correction for normal levels of ambient light, but highly intense light falling into the tube holder port may cause significant interference with the measurement.

 Do not place Solana directly next to a microwave or source of electromagnetic interference.



Do not expose Solana to ambient temperatures outside 15°C to 35°C.

AC Power Connection

- Solana operates at: 100–240 VAC, 0.5 A, 50–60 Hz.
- Use the provided power supply only. Use of a temporary power cord (e.g., extension cords, power strips) is to be avoided. A Universal Power supply can be used.
- Connect Solana to a properly installed electrical outlet or Universal Power Supply.

Plugging and Unplugging Solana

- With the flat side of the instrument connector facing down, hold firmly to the connector and plug into the power port in the back of Solana (**Figure 4**).
- Plug the outlet connector to a properly installed electrical outlet.

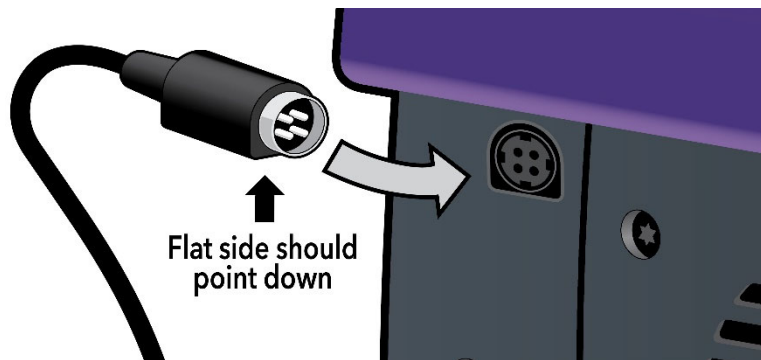


Figure 4

- To unplug the unit, hold firmly to the instrument connector (**Figure 5**) and unplug from the instrument port. Do not unplug by pulling on the cord. Pulling on the cord will cause the instrument connector to loosen and not connect to the instrument correctly.

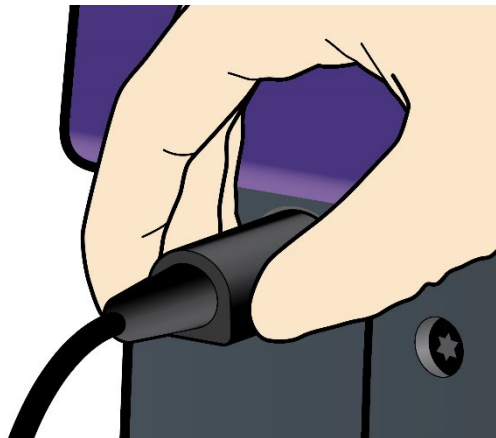



Figure 5

Locking and Unlocking Solana

Transport Lock

The Transport Lock feature is used to lock and shutdown the instrument before moving or shipping.

 Upon initial shipment from the manufacturer, the Solana Transport lock will be engaged.

To disengage the Transport Lock upon initial setup and when properly set for relocation:

- Power up the Solana (see [Startup Solana](#)).
- When the message to unlock the transport lock is displayed ([Figure 6](#)) place Solana on a stable surface. Facing the front of the instrument, tilt the instrument to stand on its left side.
- Unlock the unit by sliding the lever to the unlocked position (see [Figure 7](#)).

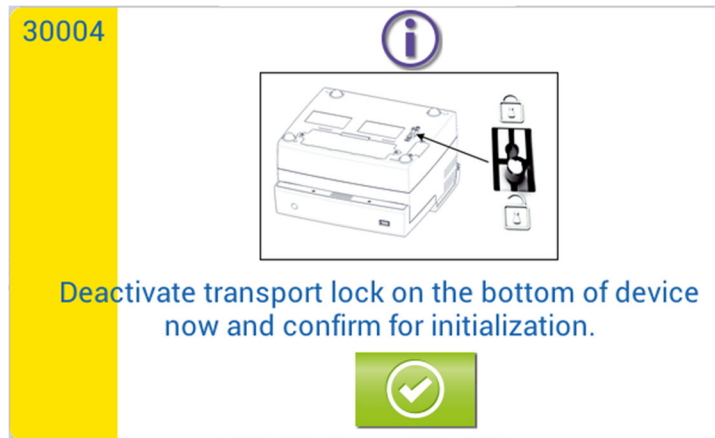


Figure 6

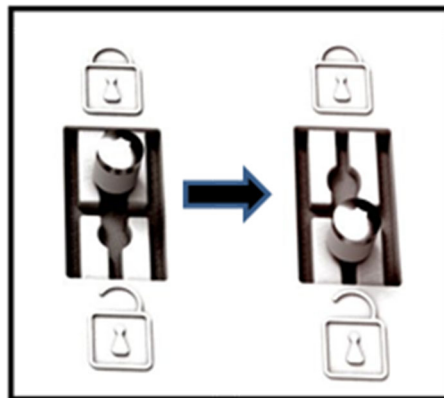




Figure 7

- Touch the  button after confirming the instrument is unlocked. **Note:** This message does not appear if the unit was powered down using normal shutdown procedures (shutdown without activating the onboard transport lock or locking the instrument manually).

To engage the Transport Lock for relocation or shipment:

- Proceed to System ► Maintenance ► Transport Lock.
- Touch the **Transport Lock** button.
- Touch the  button to confirm lock and shutdown.
- The message below (**Figure 8**) appears briefly while the instrument prepares for lock.

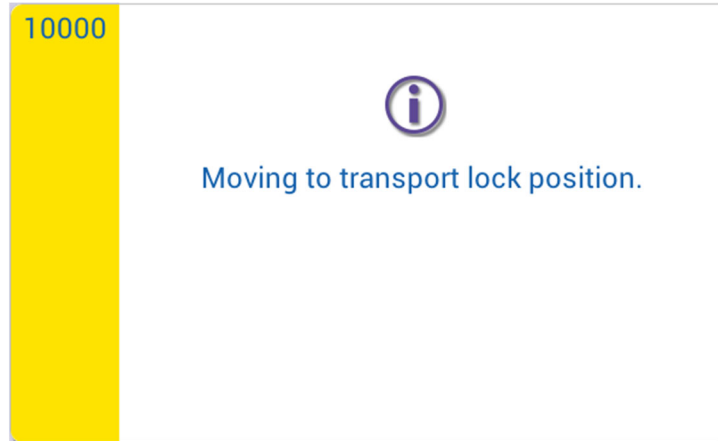


Figure 8

- A new message instructs the user to set the transport lock (**Figure 9**)

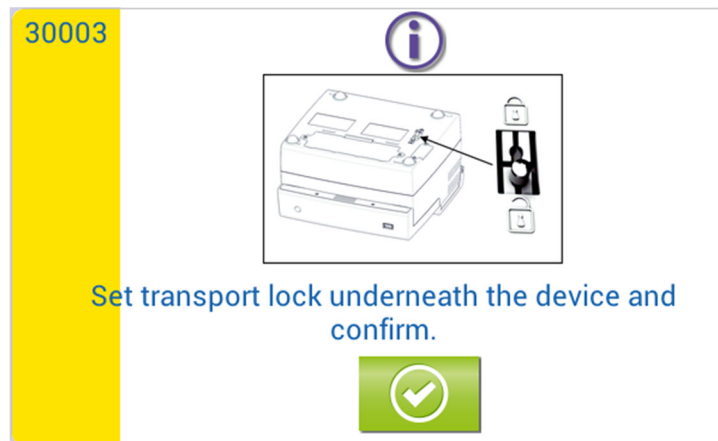



Figure 9

- Lock the device.
 - Keeping Solana on a stable surface, tilt the unit left to sit on its left face.
 - Move the transport lock lever into the locked position.
 - Return the unit to the upright position.
- Touch the  button to confirm the instrument is locked.

The instrument automatically shuts down.

Startup Solana

Power Up


- Press and hold the **power button**  (Figure 1) for approximately 2 seconds. The display screen lights up with the Quidel logo (Figure 10). The instrument initializes, and the power indicator light turns green.



Figure 10

- During initialization, Solana displays a self-check screen (Figure 11). An internal self-check is performed to ensure that values from internal reference standards are within a defined range. Solana compares internal settings with an internal solid fluorescence standard.
- While the Solana remains On, an internal self-check will automatically occur every 15 hours.
- In case of a Self-check failure, please refer to the [Troubleshooting](#) section or contact Technical Support.








Figure 11

General Operation

Procedural Notes

The default user ID and password for the Administrator is “**Admin**” and “**admin**”, respectively. **Change the default Admin password immediately.** Passwords should be changed periodically and managed in accordance with your organization’s procedures. A temporary (valid for 24 hours) Administrator-level password can be obtained by contacting QuidelOrtho Technical Support and supplying the instrument serial number, located on bottom of instrument. Use strong passwords: The Administrator should assign passwords with minimum length (8 recommended minimum), upper/lowercase, and special characters. Do not share passwords, each user should have a unique password.

Solana has a touchscreen display. Touch an icon to select the desired action. To type information, touch the entry field to activate the touchscreen keypad and touch the keys on the screen.

- Touch the **green checkmark**  button to confirm/save changes, selections, or actions on most screens.
- Touch the **red stop**  button to exit menus, cancel changes, selections, or processing on most screens.
- Touch the **blue stop**  button to delete selections, field information, Method Files, and test runs.
- Touch the **Home** button  to go to the **Main Menu**.
- Buttons that are grayed out represent actions that are not available. For example, the network button  is grayed out because Solana is not connected to the network.
- Solana goes to sleep after 20 minutes of inactivity while in **Sleep Mode** and completely shuts down after 2 hours. Press the power button to activate Solana.
 - If **Sleep Mode** has been turned **Off**, Solana will always remain on and active.



User Login

If **User Access Control** is turned **On**, the login screen is displayed (**Figure 12**) and the user must enter the **User ID** and **Password** to proceed to the **Main Menu**. If **User Access Control** is turned **Off**, login is not required and the **Main Menu** appears. See **User Logout** section below. Refer to the **User Access Control** section for details on modifying this feature.





Figure 12

If **User Access Control** is **On**, each user should log out after use.

- Touch the logout icon  in the **Main Menu** (**Figure 14**).
- Touch the  button to confirm logout (**Figure 13**).
- Type in the **User ID** and **Password** information.
- Alternatively, scan a barcode with user ID.
- Touch the **Enter** (return) key to enter the settings.
- The **Main Menu** (**Figure 14**) appears if the login information entered is correct regardless of internal calibration pass/fail status, the Main Menu will always appear.

User Logout

If **User Access Control** is **On**, each user should log out after use.

- Touch the logout icon  in the **Main Menu** (Figure 14).
- Touch the  button to confirm logout (Figure 13).

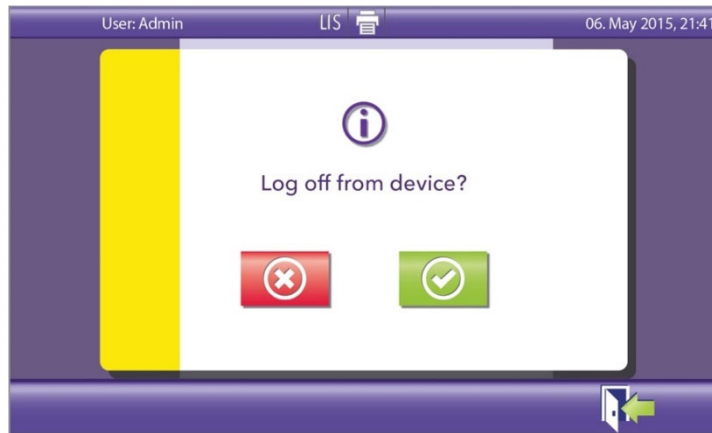


Figure 13

Main Menu

The following choices are available on the **Main Menu** (Figure 14).

- **New Test:** to start a new test
- **Review Results:** to show the results of completed tests
- **System:** to change the workflow and instrument settings, access maintenance features, and retrieve instrument information
- **LIS Orders** (if LIS server connection is **On**): to view LIS orders received
- **User Log-out** (if **User Access Control** is **On**): to logout of the instrument or change users

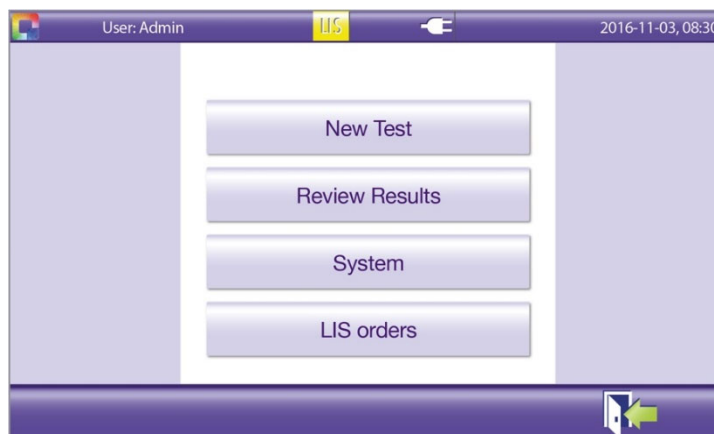


Figure 14

The options are described in separate sections below.

System

There are 3 choices on the **System** menu (Figure 15).

- Settings
- Maintenance
- Info

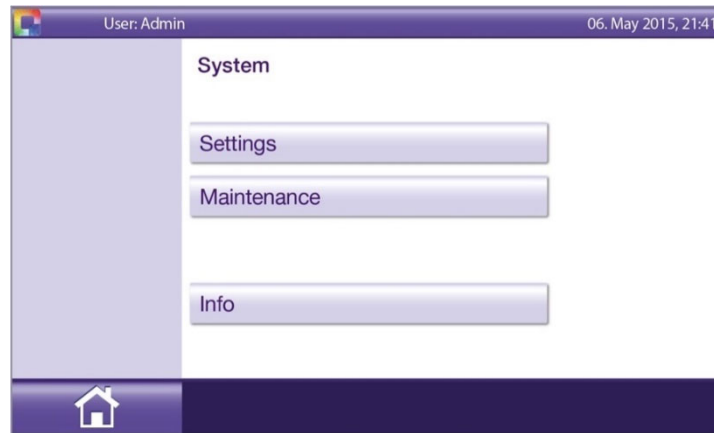


Figure 15

The **Info** option displays the instrument software version, Linux version, instrument serial number, MAC-Address, and build number.

NOTE: Changes to **Settings** and **Maintenance** are saved and applied to subsequent uses of the instrument. It is suggested to review **System: Settings** prior to using Solana the first time.

Settings

There are three types of **Settings** (Figure 16):

- Security settings
- Workflow settings
- Device settings

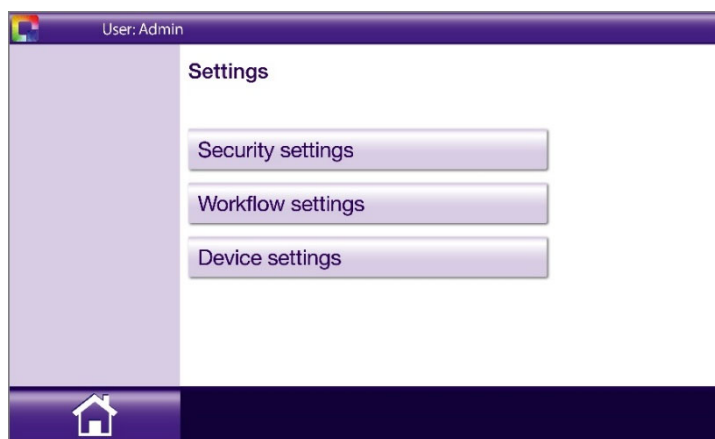


Figure 16

Security Settings

Currently Solana should not be connected to networks and follow cybersecurity protections described below. Within Security Settings, the following is displayed (Figure 17):

- CUPS Interface
- USB
- Network (SSH)

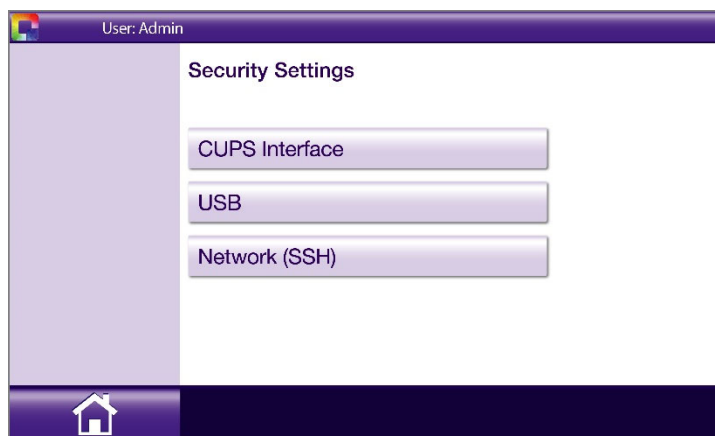


Figure 17

CUPS Interface OFF (default) – QuidelOrtho strongly recommends that the CUPS Interface remains in the OFF position to mitigate a potential cybersecurity vulnerability. Network printing will be unavailable when set to OFF, however local printing to the Dymo LabelWriter 450, 4XL, or 550 printer model is still possible. Contact your local QuidelOrtho representative for instructions on how to obtain a compatible Dymo LabelWriter printer from QuidelOrtho.

USB ON (default) – This option allows the Solana Instrument to recognize docked USB devices.

Network (SSH) OFF (default) – QuidelOrtho strongly recommends that the Network (SSH) remains in the OFF position to mitigate a potential cybersecurity vulnerability. Remote login access to the Solana Instrument will be unavailable when set to OFF.

Workflow Settings

Within **Workflow Settings**, the following can be configured (**Figure 18**):

- **Order settings**
- **Result handling**

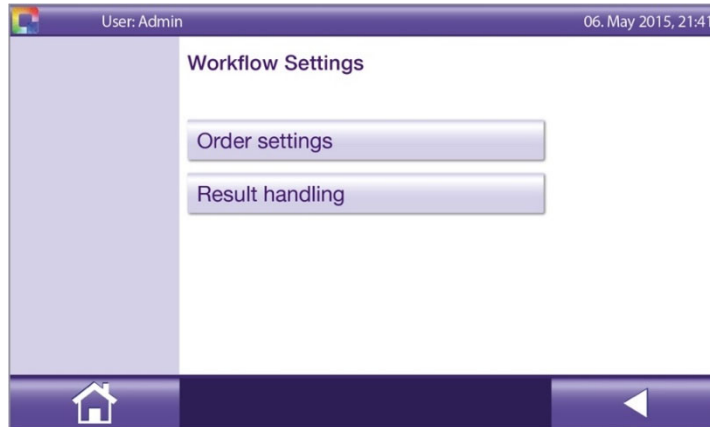


Figure 18

Order settings

Within **Order settings**, the following can be configured (**Figure 19**).

- **Test selection auto fill**
- **Sample ordering auto sample order**

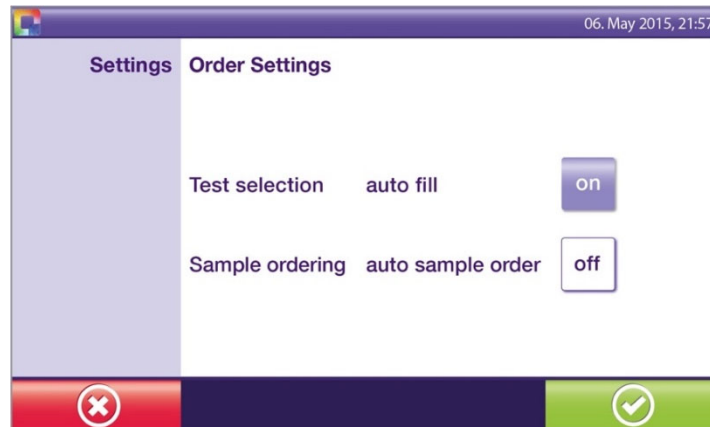



Figure 19

Test selection: The default **auto fill** setting is **Off**. See **Start New Test** sections for more information on test selection.

Auto fill Off – This option allows the user to **select the test method first**, then assign the selected test to individual sample tubes, in any order. Selection of a test does not need to be repeated for each tube.

Auto fill On – This option allows the user to **select the tubes first**, then assign the test method by selecting the test one time.

- To change the displayed setting, touch the **On/Off** icon.  (When highlighted purple the test option is on.)


- Touch the  button to confirm the selection.

Sample ordering: The default **auto sample order** is **Off**. See **Assigning Sample Type and ID** section for more information on sample ordering.

Auto sample order Off – This option allows the user to assign a single sample ID to multiple tubes. The sample ID entry does not need to be repeated for each tube.

Auto sample order On – This option allows the user to automatically assign a sample ID to the next available tube. This setting is helpful when scanning in barcodes for patient specimens in sequential order.

- To change the displayed setting, touch the **On/Off** icon.  (When highlighted purple the test option is on.)

- Touch the  button to confirm the selection.

Result Handling

Within **Result Handling**, the following can be set (**Figure 20**).

- **Overwrite oldest results if memory full?**
- **Autoprint results**

Overwrite Off (default) – This option does not allow the oldest results to be overwritten with the newest results. When Solana memory is full, a warning appears and the user cannot start a new test (the **Start New Test** button is not available on the **Main Menu**). Results must be manually deleted to free up memory.

Overwrite On – This option allows the oldest results to be overwritten with the newest results when Solana memory is full.

Autoprint Off (default) – Manual selection of the print option is required.

Autoprint On – Solana will automatically print every test run result. An instrument printer must be connected.

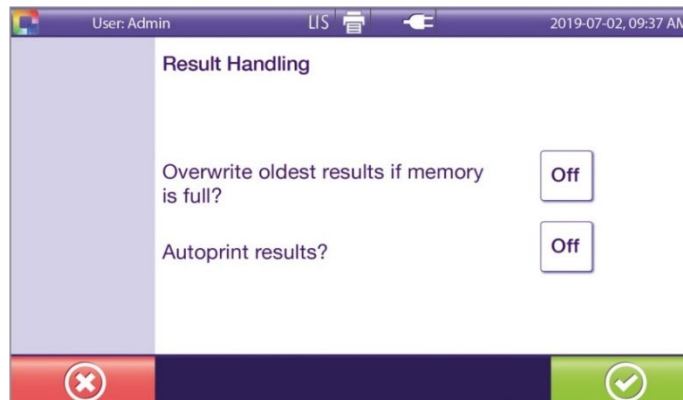




Figure 20

- To change the displayed setting, touch the **On/Off** icon.  (When highlighted purple the test option is on.)
- Touch the  button to confirm the selection.

Device Settings

Within **Device Settings**, the following parameters can be configured (**Figure 21**):

- **Date & Time**
- **Language**
- **User access control**
- **Network configuration**
- **Brightness & Sleep Mode**
- **Delete Patient Info in All Records**






Figure 21

Date and Time

Within **Date and Time** settings, the date and time and formats can be set (**Figure 22**).



Figure 22

- **Date** – To change the date, touch the left  or right  arrow to arrive at the appropriate year, month, or day.
- **Date format** – To change the date format, touch the drop-down arrow to see the selections (**dd. MM yyyy**, **yyyy-MM-dd**, or **MM/dd/yyyy**). Touch the desired date format.
- **Time** – To change the time, touch the left or right arrow to arrive at the appropriate hour or minute.
- **Time format** – To change the time format, touch the drop-down arrow to see the selections. A **12-hour** or **24-hour** format is available. Touch the desired time format.
- Touch the  button to confirm the selection(s).

Language

Within **Language** settings, the preferred language (if available) can be set. The language can also be set for the keyboard (if available). The default language is **English**.

User Access Control

The **User Access Control** menu can be accessed by the Administrator only (**Figure 23**). The default **User Access Control** setting is **Off**.

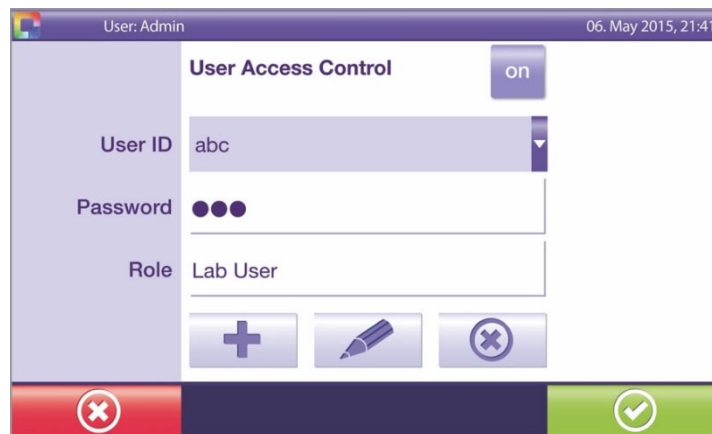


Figure 23

User Access Control Off – This option does not have user roles assigned to any user and does not require user login.

User Access Control On – This option has Administrator or Lab User roles assigned to users and requires user login.

- To change the displayed setting, touch the **On/Off** icon.  See below for functions that can be performed by a Lab User and Administrator.


There are two types of user access levels or roles: **Administrator** and **Lab User**, each user in the laboratory can be assigned as an **Administrator** or a **Lab User**. Both Administrators and Lab Users can perform all functions related to performing a test. All users can also view, print and export results to a USB flash drive.

Administrators have access that Lab Users do not. Administrators can add or delete users and passwords, change roles of users, and can delete results. The administrator cannot change assigned rights of user specific roles.

Functions or menus that are not accessible for a role are not visible on the graphical user interface after the user logs on. The table below outlines the functions available to Administrators and Lab Users with regards to instrument settings and system management.

Function	Lab User	Administrator
Changing Instrument Settings		
Test selection auto fill on/off		X
Auto sample ordering on/off		X
Auto Result Handling on/off		X
Adjust Date, Date Format, Time, Time Format		X
Change Language		X
Change Keyboard		X
Switch on/off		X
Add a New User		X
Delete User		X
Edit an Existing User		X
Edit Network Configuration		X
Activate LIS		X
Edit LIS Network configuration		X
Activate Virena®		X
Edit Virena Network Settings		X
Activate Result Transfer	X	X
Activate SW Network updates		X
Adjust Volume and Brightness	X	X

Managing and Maintenance of the System		
View Virena status	X	X
Virena – Send last result, send all results, send unsent results		X
Review LIS orders	X	X
View new incoming LIS orders	X	X
Delete LIS orders		X
Install SW update		X
Install methods		X
Delete methods		X
Import new report template		X
View event log	X	X
Export events to USB	X	X
Delete events in event log		X
Activate Transport Lock for shipment		X

When **User Access Control** is **On**  (Figure 23), the following options are available to Administrators on the **User Access Control** menu:



Add a New User






Edit an Existing User




Delete a User

■ To **Add a New User**, touch the appropriate icon (see above) and type the information for the **User ID**, **Password**, and **Role** fields.

■ Touch the  button to confirm the entries.

- To **Edit an Existing User**, select the user from the User ID drop-down list.
- Touch the appropriate icon (see above).
- Modify the **User ID**, **Password**, and **Role** fields, as needed.
- Touch the  button to confirm the changes.
- To **Delete a User**, select the user from the User ID drop-down list.
- Touch the delete icon. 
- Touch the  button to confirm the permanent deletion of the selected user.

To exit the **User Access Control** screen, hit the left  (back) button.

Network Settings

Due to known cybersecurity vulnerabilities with Solana (CUPS vulnerabilities), it is recommended to keep Solana disconnected from networks unless precautions are taken, such as segregated local area network (LAN) and designated IP connections.

LAN, and LIS Server can be programmed (Figure 24). Virena Settings is set to default OFF.

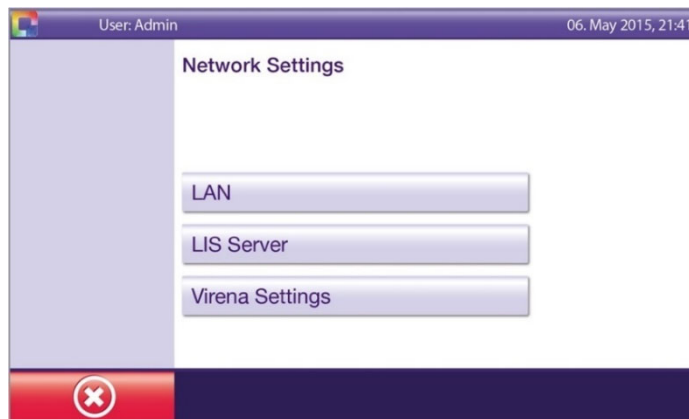



Figure 24

LAN

- To add **LAN** network settings, touch the **LAN** button.
- Select either a **Static IP** or a **Dynamic IP** (Figure 25).
- Type in the **IP address**, **Subnet mask**, and **Default gateway** into the applicable fields (may be provided by your network administrator).
- Touch the  button to confirm the entries.

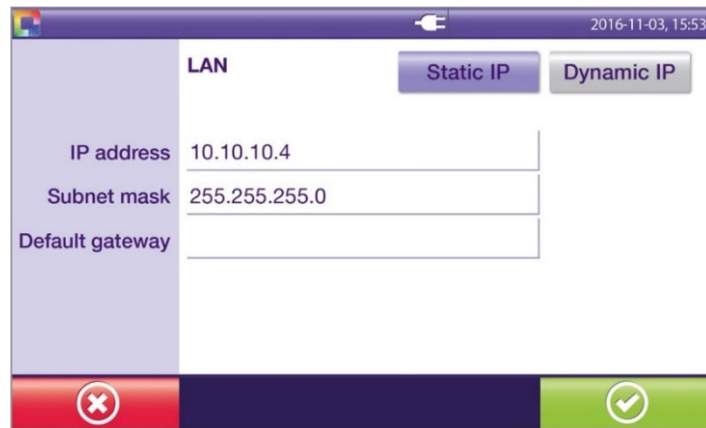


Figure 25

LIS Server

Turning the **LIS Server On** allows the user to view **LIS Orders** from the **Main Menu**. The default setting is **Off**.

Due to known cybersecurity vulnerabilities with Solana (CUPS vulnerabilities), it is recommended to keep Solana disconnected from networks unless precautions are taken, such as segregated local area network (LAN) and designated IP connections. LIS connections with HL7 are not encrypted and are intended for use on a customer secure network behind a firewall.


- To modify **LIS Server** settings, touch the **LIS Server** button (Figure 24).
- To change the displayed setting, touch the **On/Off** icon on off (Figure 26).
- If the **LIS Server** is **On**, type in the **Server IP**, **Server Port**, and **Listener Port** information (can be provided by your lab's LIS coordinator).
- **Auto Order Nbr** is an option that may be turned **On/Off**. on off When **Auto Order Nbr** is **On**, Solana will automatically generate and assign Order numbers in the absence of selected or entered Order numbers.
- Touch the button to confirm the entries.
- When the **LIS Server** is connected, the symbol  is visible.
- To test the **LIS Server** connection, touch the **Test** button. A pop-up window will provide information on the LIS Test status.
- Touch the button to acknowledge the Test status.




Figure 26

Virena® Settings

Virena is a Global Wireless Surveillance and Remote Instrument Data Management System that provides a near real-time de-identified database. When **Virena** is activated, de-identified results from patient samples can be forwarded to **Virena**. The default setting is **Off**. For detailed instructions on activating **Virena**, refer to the Solana Virena Instructions for Use included with the Virena router package.

- To modify **Virena Settings**, touch the **Virena Settings** button (Figure 24).

- To change the displayed setting, touch the **On/Off** icon  (Figure 27).

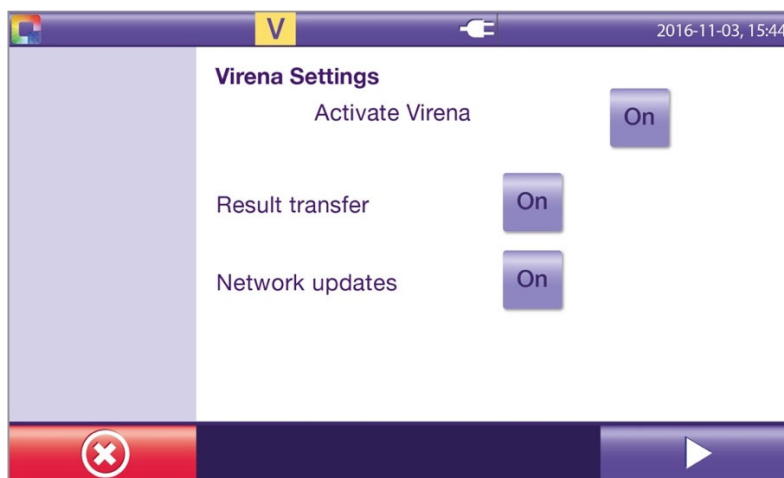





Figure 27

- If **Activate Virena** is **On**, set **Result transfer** and **Network updates** settings **On/Off**.  
 - **Result transfer** refers to sending the results to the Virena. If this feature is turned **On**, the results are automatically sent to the Virena once the test is completed. If turned **Off**, the results are not automatically sent.
 - **Network updates** This feature is currently unavailable. Please contact Technical Support for information on the availability of software upgrades or visit the Customer Portal at myquidel.com for more information.
- Touch the right arrow (next)  button at the bottom of the screen to advance to the next screen.

- Type in **Virena IP address** (Figure 28).

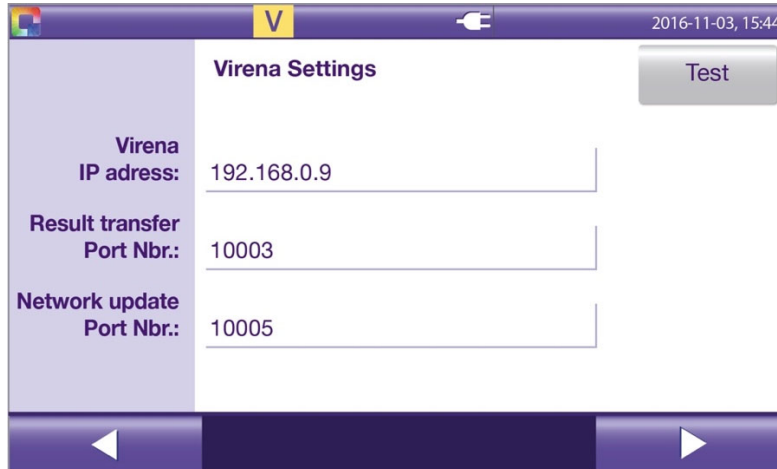




Figure 28

- If applicable, type **Result transfer Port Nbr. (Number)** and **Network update Port Nbr.**
- If desired, touch the **Test** button to test the Virena connection. A pop-up window will provide information on the Virena Test status. **Note:** When Virena is activated and Solana has unsent results, a “V” highlighted in yellow  is displayed in the top banner (Figure 28).
- Touch the  button to acknowledge the Test status.
- Touch the right arrow (next) button at the bottom of the screen to advance to the next screen.
- Type in the **Zip Code** (Figure 29).

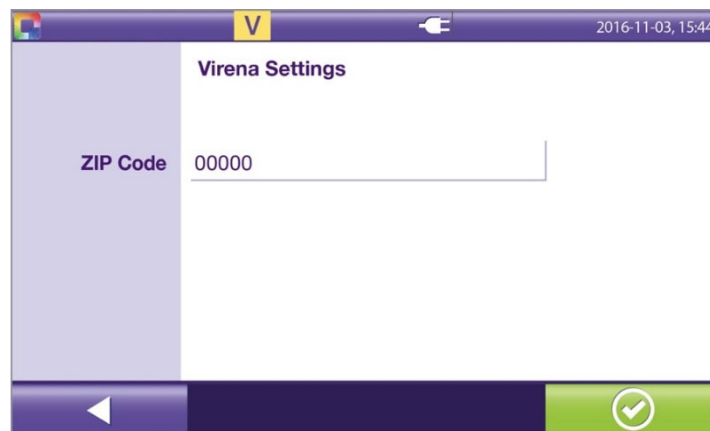




Figure 29


Touch the  button to save and confirm the selections and entries or touch the left (back) arrow button  to cancel edits and return to previous screens.

Brightness & Sleep Mode

Within **Brightness & Sleep Mode** settings, the following can be adjusted (Figure 30).

Brightness

The default setting is at maximum brightness.

- Touch left (-) or right (+) of the current setting to decrease or increase the brightness, respectively.
- Touch the  button to confirm the selection.

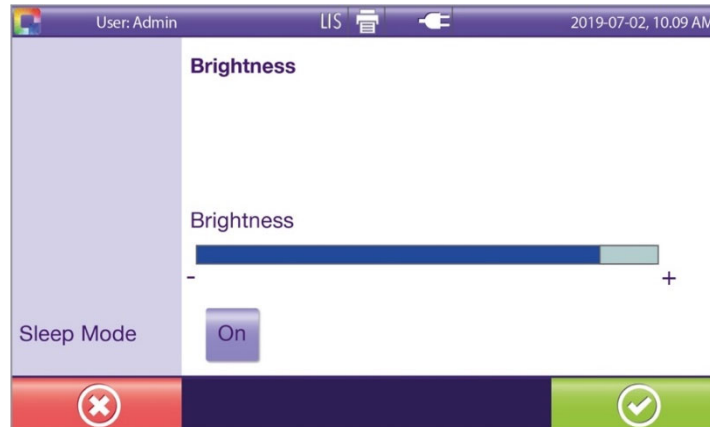



Figure 30

Sleep Mode

Solana users have the option to turn **Sleep Mode Off**. When **Sleep Mode** is activated, the Solana instrument will enter low-power Sleep Mode after a period of inactivity. Press and hold the Solana power button to exit this mode.

Delete Patient Info in All Records

The **Delete Patient Info in All Records** setting deletes all patient identifiers or LIS order numbers at one time, if activated. This feature would be used when returning instruments to QuidelOrtho. **Note:** This does not delete results, but rather, deletes any potential personal identifying information. If there are Unsent LIS Results pending, these must be manually deleted. See [LIS Status](#) section for details.

- If desired, touch the **Delete Patient Info in All Records** button to activate this feature.
- Touch the  button to confirm the selection.

Maintenance

The following options are available in the **Maintenance** settings:

- Virena Status
- LIS Status
- Software/Test methods/ Report Template
- Event Log
- Transport Lock (see Transport Lock for details)

Virena Status

If Virena is activated, the **Virena Status** screen shows if results have been transmitted through Virena and allows the user to send unsent results. Please refer to the **Solana Virena Mode Installation Instructions for Virena WR11 Router**, available on QuidelOrtho.com or contact QuidelOrtho Technical Support.

Touch the **Virena Status** button.

- View any displayed messages (**Figure 31**).

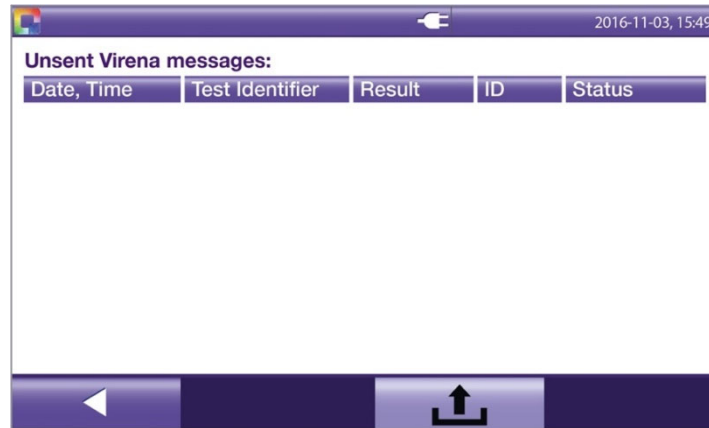







Figure 31

- If needed, touch the **Upload**  button.
- View the status at the bottom of the screen.
- If results should be sent, touch the  button next to the appropriate option(s) (**Send Unsent Results**, **Send Last Result**, **Send All Results in DB** [database]).
 - For example, if unsent results are available, touch the  button next to **Send Unsent Results**.
- If information was sent, a message is displayed on the status of the export (e.g., "Result export started").
- Touch the  button to confirm.
- Touch the **left arrow (back)**  button to return to previous screens.

LIS Status

If **LIS Server** is connected and confirmed, the **LIS Status** screen shows the status of LIS Results that have not been sent (**Figure 32**).

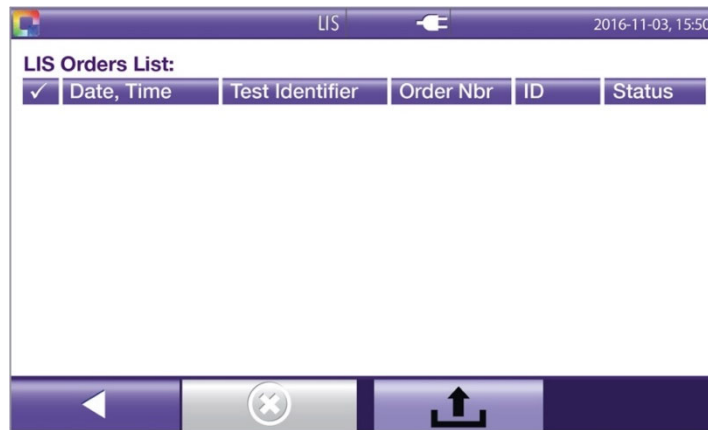






Figure 32

- Touch the **LIS Status** button.
- View any displayed LIS results.
- Select the result that requires action by touching the first column of the row with the relevant result. A checkmark appears next to the selected LIS result.
- If needed, touch the **Upload** button.
- View the status at the bottom of the screen.
- If results should be sent, touch the  button next to the appropriate option(s) (**Send Unsent Results**, **Send Last Result**, **Send All Results in DB** [database]).
 - For example, if unsent results are available, touch the  button next to **Send Unsent Results**.
- If information was sent, a message is displayed on the status of the export (e.g., “Result export started”).
- Touch the  button to confirm.
- Touch the **left arrow (back)** button  to return to previous screens.

Software / Test methods / Report Template

This menu allows for, the installation of software updates, updating and deleting of test methods, management of printing, and selection of available languages (Figure 33).





Figure 33

Manage Languages

The **Manage Languages** option is used to select preferred languages from the available options.

Install software update

The **Install software update** option is used to update software by downloading from a USB flash drive.

- Insert the USB flash drive.
- Touch the **Install Software Update** button.
- Select the source of the update by touching the **USB flash drive** icon (**Figure 34**).
- Touch the  button to confirm installation.
- A pop-up message will appear requesting that Solana be rebooted to continue the installation process.
- Press the  button and the Solana will then automatically shut down and reboot.
- During the reboot, a message will appear to indicate that the update is in progress—do not switch the Solana off.
- Once the installation is complete, Solana will automatically reboot again.
- After this final reboot, the installation process is complete.

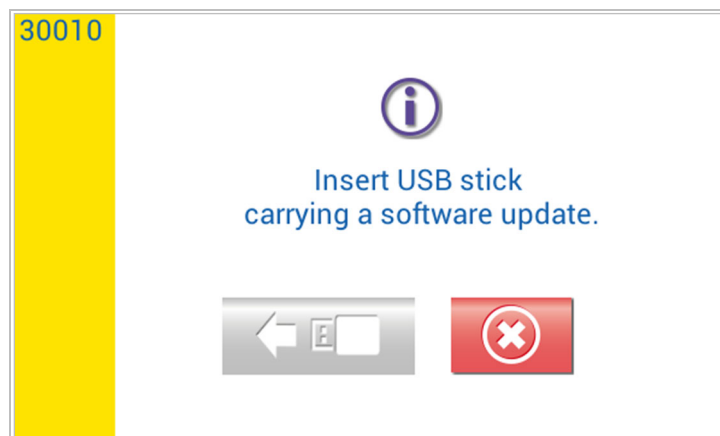


Figure 34

Manage methods

Manage methods is used to import new test methods or delete existing methods. Method files cannot be overwritten. To install a new version of an existing method, the older version must be deleted first.

Installing a New Method File

- Touch the **Manage Methods** button.
- To add a new method, insert the USB flash drive.

Note: If Updating a Method File, you must delete the previous file (see below) prior to installing the New Method File.

- Touch the **USB flash drive** button.

- Select the method files by touching the box next to the method or touch the check mark at the top of the list to select all methods.

- Touch the  button to confirm installation.

Deleting a Method File


- To delete a method, select the test method from the displayed list.

- Touch the **delete** button. 

- Touch the  button to confirm deletion.

Report template

Report template is used to import new printer templates provided by QuidelOrtho.





- Touch the **Report template** button.
- Insert the USB flash drive.
- Touch the  button to confirm installation.

Event Log

The **Event Log** (Figure 35) is used to review recent Solana software events, such as login data, self-check logs, and instrument error messages.



Figure 35

- To view information on another page, touch the **scroll bar** on the right side of the screen.
- To view detailed information, touch the **respective row** on the screen.
- To change the date sorting order, touch the **up or down arrow**   in the **Date**  column header.
- Touch the **left arrow (back)**  button to return to the previous screen.


Start New Test

Starting New Test (Test Selection: Autofill Mode Off)

To start tests based on **LIS Orders**, please also see **LIS Order Assignment** section.

With the **auto fill Off**, the test method is selected first, then the test is assigned to the applicable tubes. Refer to the **Order Settings** section for setting the **Test Selection Autofill** mode.

Note: The **New Test** button does not appear if the instrument did not pass internal calibration. Reboot the instrument or contact QuidelOrtho Technical Support.

- From the **Main Menu**, touch the **New Test** button  to start a new test.
- The test method selection screen appears (**Figure 36**).

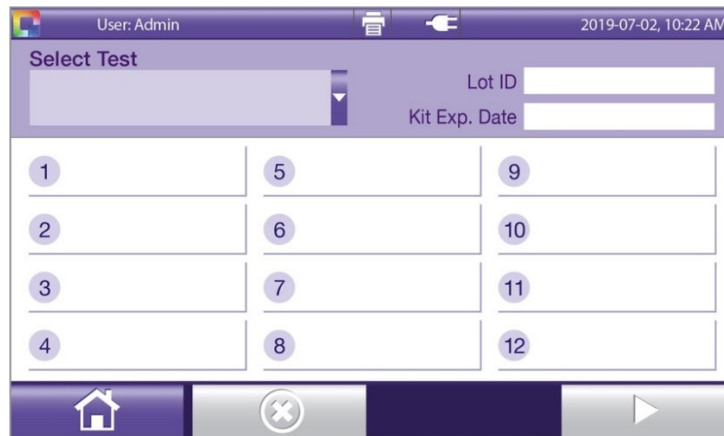




Figure 36

- Touch the **Select Test** drop-down list to select the test method (**Figure 33**).
- Type the **Lot ID**, then touch the **Enter** key .
- Type the **Kit Exp. Date** using MM/DD/YYYY date format (**Figure 37**). For example, if the date is June 23, 2019, type "06/23/2019." Touch the **Enter** key  to confirm the entries.

Note: Scanning the assay barcode which is included with each Solana Assay kit will automatically populate the test method, Lot ID and Kit Exp. Date.

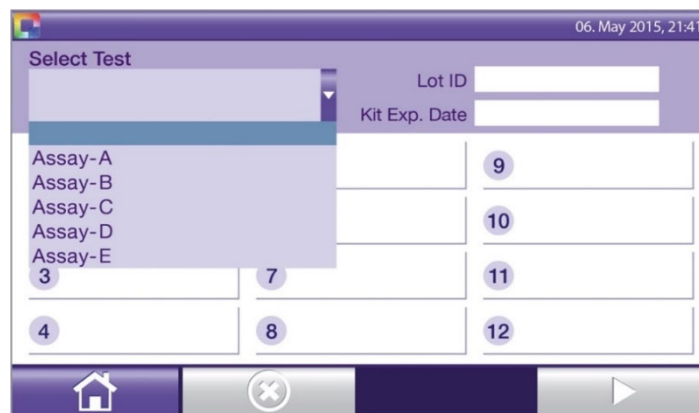


Figure 37

- Select the tubes you want to test (**Figure 38**).

Note: Selections can be reversed (undone) by touching the tube selected in error and then touching the delete button. For example, if tube 1 was selected in error, touch tube 1 to highlight, then touch the

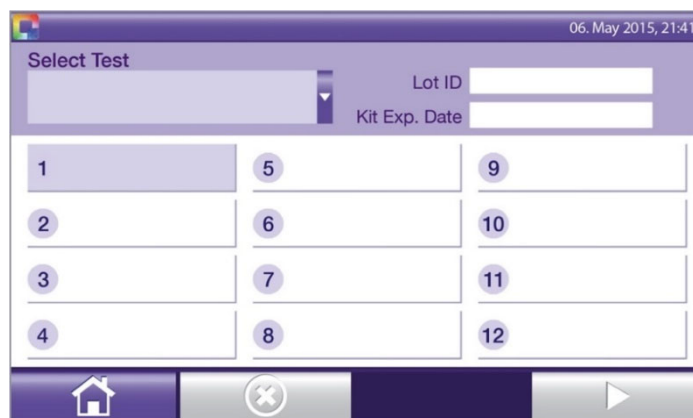
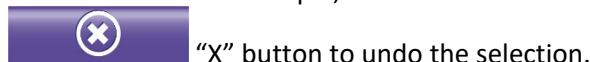



Figure 38

It is possible to assign multiple test methods in one run if the method files are compatible. After assignment of the first test, the instrument drop-down menu offers only the tests that are compatible.

- To add a test with a compatible method file, select or scan the test information and assign tube locations as described above.
- Touch the **right arrow (next)** button  to advance to the sample ordering screen. See **Assigning Sample Type and ID** section for further instructions.

Starting New Test (Test Selection: Autofill Mode On)

To start tests based on **LIS Orders**, please also see **LIS Order Assignment** section.

With the **auto fill On**, the tubes are selected first, then the user assigns the test method by selecting the test one time. Refer to the **Order Settings** section for setting the **Test selection auto fill** mode.

A run consists of up to 12 tubes tested together in the same batch. Instructions for performing 1 test in a single run and for performing multiple tests in a single run are described below.

One Test Method Per Run

- From the **Main Menu**, touch the **New Test** button to start a new test.
- The test method selection screen appears (**Figure 39**). The first tube is highlighted.

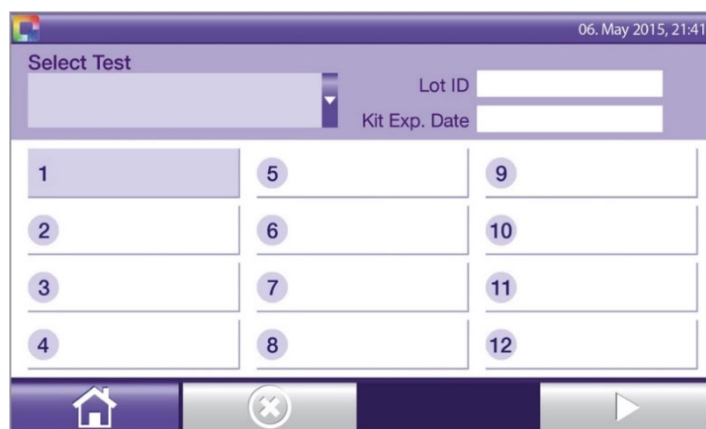


Figure 39

- Touch the last tube position needed to select all tubes between tube 1 and the last selected tube. See the example in [Figure 40](#). Tube 4 was chosen as the last tube, therefore tubes 1 through 4 are selected.

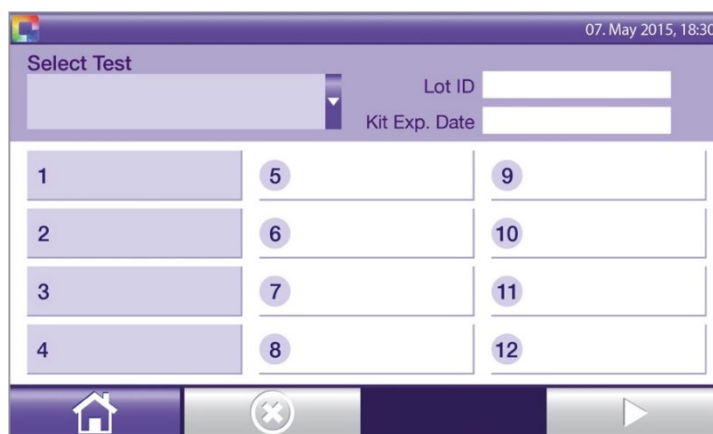



Figure 40

- Type the **Lot ID**, then touch the **Enter** key. 
- Type the **Kit Exp. Date** using MM/DD/YYYY date format. For example, if the date is June 23, 2019, type "06/23/2019." Touch the **Enter** key to confirm the entries.
- Touch the **Select Test** drop-down list to select the test method ([Figure 41](#)).

Note: Scanning the assay barcode which is included with each Solana Assay kit will automatically populate the test method, Lot ID and Kit Exp. Date once the test tubes are selected.

- Touch the **right arrow (next)** button  to advance to the sample ordering screen. See [Assigning Sample Type and ID](#) section for further instructions.

Procedure to Run Different Test Methods in the Same Batch

It is possible to assign multiple test methods in one run if the method files are compatible. After assignment of the first test, the instrument drop-down menu offers only the tests that are compatible.


- Follow instructions for **One Test Method Per Run** section to select tubes and tests for the first set of tubes to be tested with one test **except DO NOT** touch the **right arrow (next)** button .
- For the second test, the first available tube is highlighted (**Figure 41**). In the example in **Figure 41**, tubes 1 through 4 are tested with the first test. Tube 5 is highlighted and available for the second test.




Figure 41


- Touch the last tube position for the second test to select all tubes in between. In the example in **Figure 42**, tube 8 was chosen as the last tube, so tubes 5 through 8 were selected.



Figure 42

- Type the **Lot ID**, then touch the **Enter** key. 
- Type the **Kit Exp. Date** using MM/DD/YYYY date format. For example, if the date is June 23, 2019, type "06/23/2019." Touch the **Enter** key to confirm the entries.
- Touch the **Select Test** drop-down list to select the test name.

Note: Scanning the assay barcode which is included with each Solana Assay kit will automatically populate the test method, Lot ID and Kit Exp. Date once the test tubes are selected.

- Touch the **right arrow (next)** button  to advance to the sample ordering screen. See **Assigning Sample Type and ID** section for further instructions.

Assigning Sample Type and ID

The **Sample Type** and **ID** are set from the sample ordering screen (Figure 43). The default **Sample Type** is **Patient**. The default **ID** is blank.



Figure 43

Auto Sample Order Off

This option allows the user to assign the same sample ID to multiple tubes. The sample ID entry does not need to be repeated for each applicable tube.

QC Samples

- Select **QC** from the **Sample Type** drop-down list (Figure 43).
- An instruction to scan the QC barcode is displayed (Figure 44).

Note: QC sample IDs are entered using a barcode scanner only.

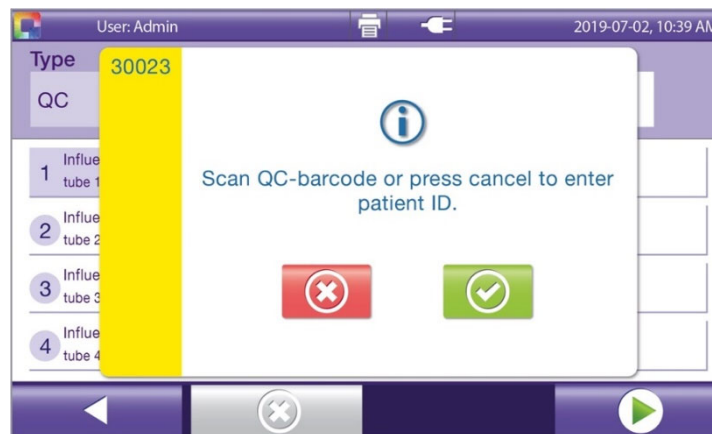






Figure 44

- To enter the **ID** of the QC sample, touch the  button to confirm the selection of a QC sample.
 - If QC sample type was entered in error, touch the exit button. The **Sample Type** reverts to **Patient**. See instructions above for **Patient Samples**.

Note: QC samples identified as patient samples have result treated as patient samples, which impacts Virena reporting, if applicable.

- Scan the QC sample's barcode.
 - If a barcode is scanned that is not a recognized ID for a QC sample, an error message is displayed.
- Touch the applicable tube(s) to assign the ID to the QC tube.
- Repeat as needed for additional QC samples.

Manual Entry of Patient Samples

- If needed, select **Patient** from the **Sample Type** drop-down list.
- Touch the **ID** field and enter sample information (**Figure 43**).
- Touch the Enter key, then touch the applicable tube(s) to assign the displayed sample information.
- To enter additional sample information:
 - Touch the **ID** field
 - Delete the currently displayed ID using the Back button 
 - Repeat the procedure as described above.
- Touch the **Play**  button to start the tests.
- Touch the  button to confirm all tubes are loaded and to start the run (**Figure 45**).

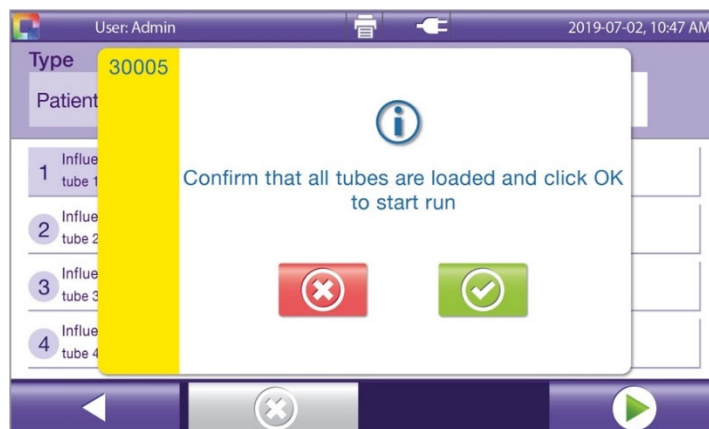





Figure 45

Barcode Entry of Patient Samples

- If needed, select **Patient** from the **Sample Type** drop-down list.
- Touch the **ID** field and scan sample barcode.
- Touch the applicable tube(s) to assign the displayed sample information.
- To enter additional sample information, repeat the steps above.
- Touch the **Play**  button to start the tests.

- Touch the  button to confirm all tubes are loaded and to start the run.


Correcting an Erroneous Sample ID Entry

- Touch the tube that contains an entry error.
- Touch the **Delete** button  to clear the information.
- Re-enter the corrected sample information as described above.




Auto Sample Order On

This option allows the user to automatically assign a sample ID to the next tube. This setting is helpful when scanning in barcodes for patient specimens in sequential order.



QC Samples

- If needed, select the appropriate tube.
- Select **QC** from the **Sample Type** drop-down list.
- An instruction to scan the QC barcode is displayed (**Figure 44**). **Note:** QC sample IDs are entered using a barcode scanner only.
- To enter the **ID** of the QC sample, touch the  button to confirm the selection of a QC sample.
 - If QC sample type was entered in error, touch the exit button. The **sample type** reverts to **Patient**. See instructions above for **Patient Samples**.
 - **Note:** QC samples identified as patient samples have result treated as patient samples
- Scan the QC sample's barcode.
 - If a barcode is scanned that is not a recognized ID for a QC sample, an error message is displayed.
- Assign the ID to the QC tube.
- Repeat as needed for additional QC samples.


Manual Entry of Patient Samples

- If needed, select the appropriate tube.
- If needed, select **Patient** from the **Sample Type** drop-down list.
- If Virena is not activated touch the **ID** field and enter sample information.
- Touch the **Enter key**.  The ID will automatically populate the next available tube.
- To enter additional sample information, repeat the steps above.
- Touch the **Play**  button to start the tests.
- Touch the  button to confirm all tubes are loaded and to start the run.


Barcode Entry of Patient Samples

- If needed, select the appropriate tube.
- If needed, select **Patient** from the **Sample Type** drop-down list.
- Touch the **ID** field and scan sample barcode. The **ID** will automatically populate the next available tube.
- To enter additional sample information, scan the next sample barcode. The **ID** will automatically populate the next available tube.
- Touch the **Play**  button to start the tests.
- Touch the  button to confirm all tubes are loaded and to start the run.

Correcting an Erroneous Manual Sample ID Entry



- Touch the tube that contains an entry error.
- Enter corrected sample information in the ID field.
- Touch the **Enter** button .

Correcting an Erroneous Barcoded Sample ID Entry

- Touch the tube that contains an entry error.
- Touch the **Delete** button  to clear the information.
- Scan the corrected sample barcode. The corrected ID will automatically populate.

Test in Progress

Once testing has started, the *Test in Progress* bar will display the test percent completion, and a countdown timer at the top of the menu will indicate overall test progression (**Figure 46**).

- If needed, to abort the test touch the abort  button.
- Touch the  button to confirm termination of the run.
- Discard the tubes after aborting the test(s).


 If the aborted run needs to be repeated, please refer to the individual Solana Assay Product Insert to ensure the original samples are within storage specifications.



Figure 46

When the test is complete, the results are displayed (**Figure 47**).



Figure 47

Note: It is not possible to edit the lot specific information or sample information after testing is completed.

Sample Assignment or Editing Sample ID During the Run


It is possible to edit sample names or numbers during the test run (**Figure 48**).

! **QC Sample Type** is not accessible for this function. QC information must be added prior to the start of the run.

- On the *Test in Progress* screen, touch the edit  button to edit the information (**Figure 46**).
- Add or edit sample information as needed. See **Assigning Sample Type and ID** section for details.



Figure 48

- Touch the **Play**  button to save edits and return to the *Test in Progress* screen.

LIS Orders


The **LIS Orders** option is available on the **Main Menu** (Figure 15) if **LIS Server** settings are configured and the LIS is connected. Touch **LIS Orders** to view LIS orders received (Figure 49).



Figure 49

LIS Order Assignment

To send a result from Solana to an LIS system, an LIS Order must be assigned to a tube.

- To assign an order to a test, touch the **New Test** button  on the **Main Menu**.
- Assign test methods according to the instructions in the **Start New Test** section (Figure 50).

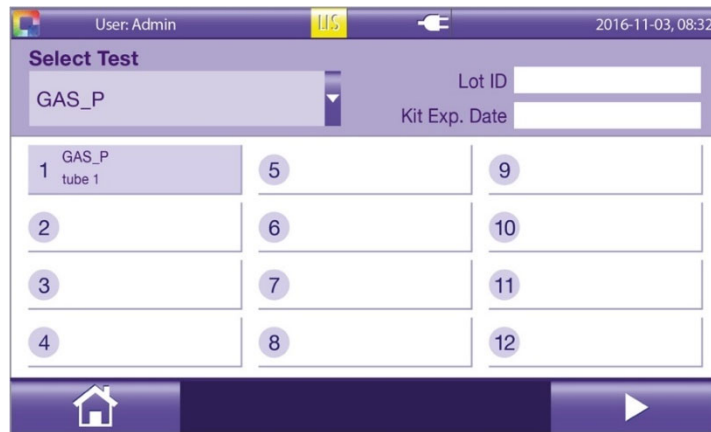




Figure 50

- Touch the **right arrow (next)** button  to advance to the sample ordering screen.
- Assign sample information according to the instructions in the **Assigning Sample Type and ID** section.
- Touch the **right arrow (next)** button  to advance to the **Order Number** screen.

- Enter an Order Number into the Order Number field manually, using the barcode scanner or by touching the **LIS Orderlist** button to the right of the **Order Number** field (**Figure 51**).



Figure 51

- Touch the first column of the row with the relevant order (**Figure 52**). A checkmark appears next to the selected LIS order.

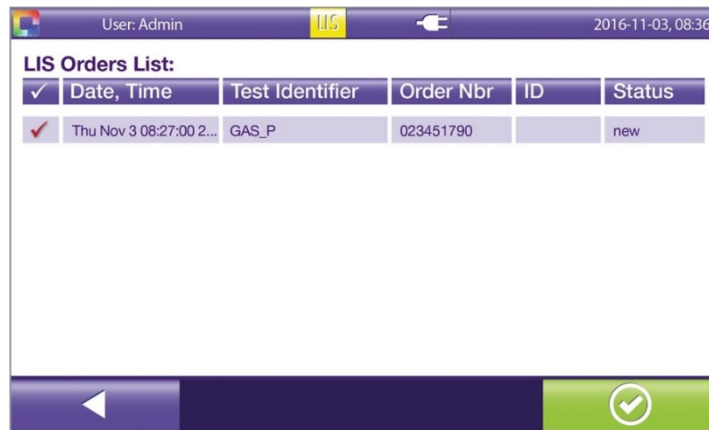


Figure 52


- Touch the  button to confirm the selection. The LIS **Order Number** is now displayed.
- Touch the appropriate tube(s) to assign the **Order Number**. The **Order Number** appears with the corresponding tube (**Figure 53**).



Figure 53



- Touch the **Play**  button to start the test.
- Touch the  button to confirm all tubes are loaded and to start the run.
- After testing is complete (**Figure 54**), results automatically transmit for each tube that has a LIS order assigned.



Figure 54

Review and Managing Results

The **Review Results** menu is used to view and manage results from completed tests.

View Results

- Touch **Review Results** button on the **Main Menu** (Figure 14).
- A list of runs showing **Date** and **Run ID** is displayed with the most recent results displayed at the top (Figure 55). Five runs per page will be displayed.



Figure 55

- If needed, scroll through the list of runs by touching the reverse or forward buttons.
- To view individual sample results in a run, touch the **Date** **Date** or **Run ID** **Run ID** of the relevant run.
 - Results are displayed (Figure 56) one page at a time.
 - Scroll through the results by touching the **reverse** **<<** or **forward** **>>** buttons, if needed.

- Refer to the Solana assay package insert for result interpretation.

✓	Tube	Sample Type	Sample ID	Method	Result
	1	Patient	test1	GAS	Invalid
	2	Patient	test2	GAS	Invalid
	3	Patient	test3	GAS	Invalid

Figure 56

Managing Results

Run data can be printed, exported to a USB flash drive, or deleted.

Note: Official records of all test results are displayed and/or printed. Saved data (results) are for convenience only and are to be managed by the Administrator.


- From the **Results** screen, select the relevant run(s) (Figure 57).

✓	Date	Run ID
✓	2016-10-06 09:42:51	162
	2016-09-07 12:35:42	151
	2016-08-29 15:27:01	145
	2016-08-29 14:50:26	144
	2016-08-25 11:31:00	141


Figure 57

- Touch the **Delete** , **Print** , or **Export**  button at the bottom of the screen, as appropriate.
 - If exporting to a USB flash drive, instructions to insert a USB drive appears.

Note: Data is exported as a CSV file.

- If needed, insert the USB drive.
- Touch the  button to confirm the USB drive is inserted.



Individual tube results can be printed if Solana is connected to a printer.

- From the **Sample Results** screen (**Figure 54**), select the tube(s).
- Touch the **Print** button at the bottom of the screen.
- Once the activity is completed, the user is notified. Touch the  button to acknowledge.

For more information, refer to **Troubleshooting** section.

Shutdown

Note: If the instrument will be shut down for transport, refer to the **Locking and Unlocking Solana** section for appropriate instructions. If the instrument is transported without engaging the **Transport Lock**, damage may occur and impair Solana functionality.

- Press the **power button**  for at least 4 seconds.
- A message appears asking for confirmation of shutdown.
- Touch the  button to confirm shutdown.

Shutdown is complete when the screen is dark and power indicator light is off.

Maintenance and Cleaning



The safety information must be read thoroughly and understood before starting maintenance and servicing work.

Solana should be cleaned regularly. Maintenance and decontamination of workspace and equipment should follow and be performed according to established laboratory protocols and schedules.


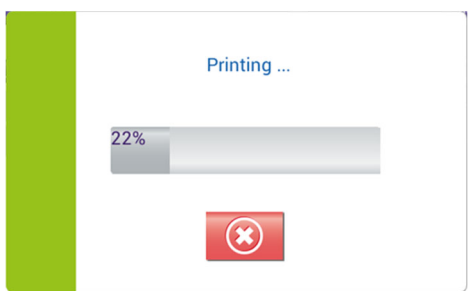
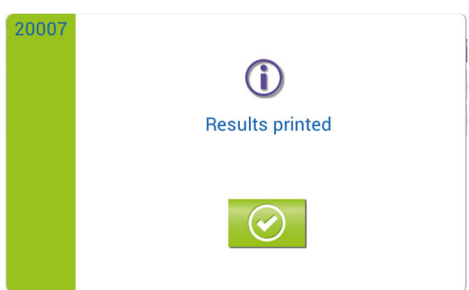
Do not use aggressive cleaning agents such as acetone or bleach on the tube holder. Care should be taken to avoid application of any liquids to the inside of the Solana via the open tube holes, the edges of the display screen, or the rear connectors. If the inside of the Solana is contaminated, please contact QuidelOrtho Technical Support.

Troubleshooting

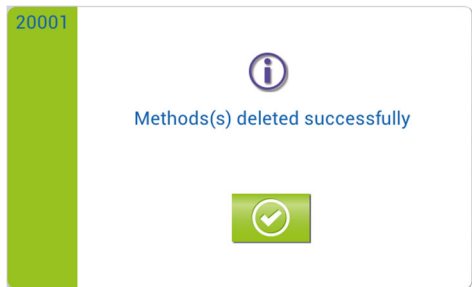
The information provided by the graphical user interface of Solana can be divided into three different levels:

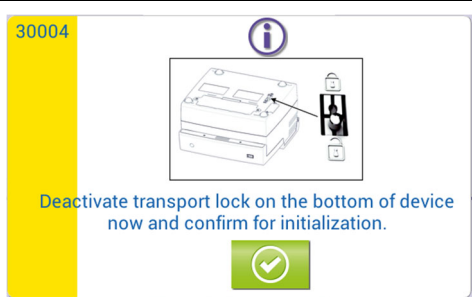
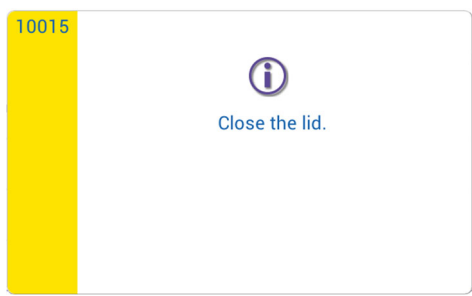
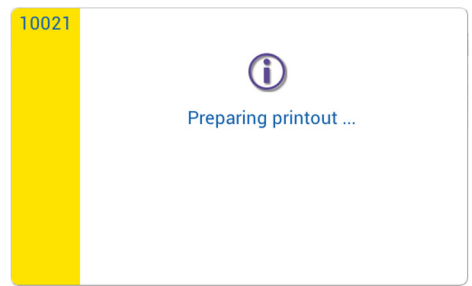
- **For information only:** no action is required, and the pop-up window is automatically dismissed, or the user confirms or acknowledges actions by touching the green checkmark button. These pop-up windows are marked with green color.
- **User interaction is required:** the user is prompted to provide the information, confirmation or rejection via the touch screen. These pop-up windows are marked with yellow color.
- **Critical information:** the user must undertake the corrective actions to avoid any further damage. These pop-up windows are marked with red color.

The table below shows common messages along with the cause and solution. **Note:** The pop-up messages displayed in the table below serve as examples of messages that might be encountered; message wording in the examples may differ from the actual messages displayed on the current version of Solana.

For Information Only (green)		
Pop-up message	Cause	Solution
	User selected Info option.	Acknowledge the message by touching the green button.
	Print in progress.	No action required.
	Print job complete.	Acknowledge the message by touching the green button.

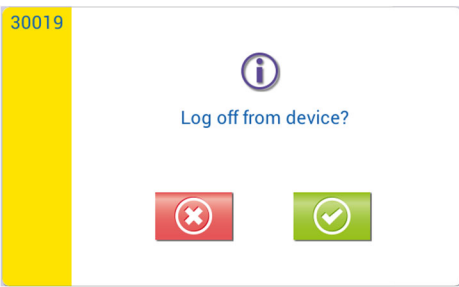
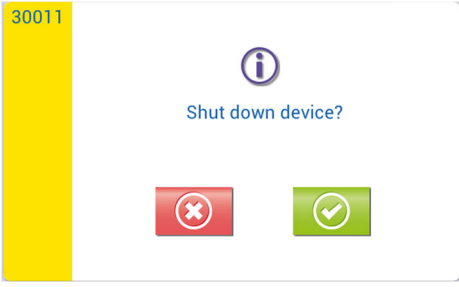
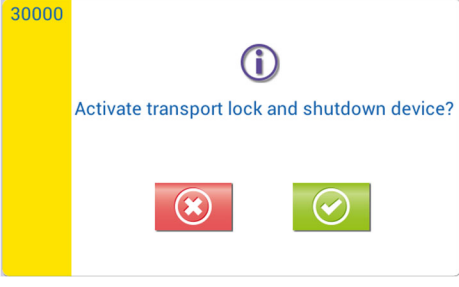
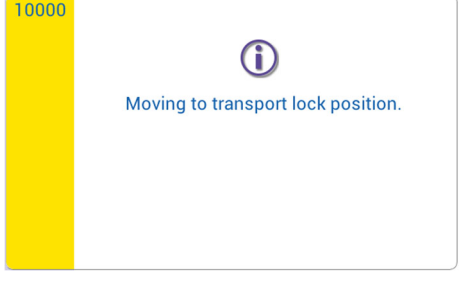

For Information Only (green)		
Pop-up message	Cause	Solution
<p>20008</p> 	User deleted test results.	Acknowledge the message by touching the green button.
	Export of data to USB flash drive in progress.	No action required or cancel by touching red button.
<p>20003</p> 	Data export to USB flash drive successful.	Acknowledge the message by touching the green button.
	User installed software updated software.	Continue by touching the  button.
<p>20011</p> 	Report (printer) template import successful.	Acknowledge the message by touching the green button.

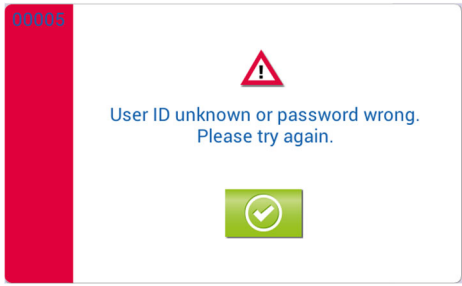
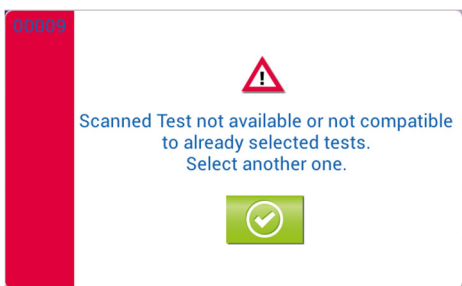



For Information Only (green)		
Pop-up message	Cause	Solution
<p>20001</p> 	Test method deletion successful.	Acknowledge the message by touching the green button.

User Interaction Required (yellow)		
Pop-up message	Cause	Solution
<p>30004</p> 	Instrument was turned on after shutdown with the transport lock activated.	Ensure transport lock is unlocked and confirm by touching the green button.
<p>10015</p> 	Tube lid heater is open.	Close tube lid to continue.
<p>10021</p> 	User selected print option.	No action required.

User Interaction Required (yellow)		
Pop-up message	Cause	Solution
<p>30010</p> 	User selected to install software update.	Insert USB flash drive (USB stick) with software update and touch the USB drive button, or cancel by touching the red button.
<p>30001</p> 	User selected to add a new Report (printer) Template.	Insert USB flash drive (USB stick) with new printer template and confirm by touching green button or cancel by touching red button.
<p>30013</p> 	User selected data export to USB flash drive (USB stick).	Insert the USB flash drive (USB stick) and confirm by touching the green button or cancel by touching the red button.
<p>30009</p> 	User selected to add a new test method and chose USB flash drive as source of update.	Insert USB flash drive with new methods and confirm by touching the green button or cancel by touching the red button.
<p>30018</p> 	User selected to delete results.	Confirm by touching green button or cancel by touching red button.






User Interaction Required (yellow)		
Pop-up message	Cause	Solution
<p>30006</p>  <p>Discard all changes and exit menu?</p>	User started new test and attempted to exit.	Confirm by touching green button or cancel by touching red button.
<p>30007</p>  <p>Abort current run?</p>	User aborted run.	Confirm by touching green button or cancel by touching red button.
<p>30016</p>  <p>Permanently delete selected user?</p>	Administrator selected to delete a user.	Confirm by touching green button or cancel by touching red button.
<p>30014</p>  <p>Do you really want to delete event log data?</p>	User selected to clear the event log.	Confirm by touching green button or cancel by touching red button.
<p>30012</p>  <p>Do you really want to delete selected methods?</p>	User selected to delete test method.	Confirm by touching green button or cancel by touching red button.

User Interaction Required (yellow)		
Pop-up message	Cause	Solution
<p>30019</p>  <p>Log off from device?</p>	User selected to log off.	Confirm by touching green button or cancel by touching red button.
<p>30011</p>  <p>Shut down device?</p>	User pressed the power button to shut down.	Confirm by touching green button or cancel by touching red button.
<p>30000</p>  <p>Activate transport lock and shutdown device?</p>	User selected to active transport lock.	Confirm by touching green button or cancel by touching red button.
<p>10000</p>  <p>Moving to transport lock position.</p>	Instrument is preparing for transport lock.	No action required.
<p>30003</p>  <p>Set transport lock underneath the device and confirm.</p>	User confirmed the activation of transport lock.	Set the transport lock to the locked position and confirm by touching green button.

Critical Information (red)		
Pop-up message	Cause	Solution
	Login information is incorrect or does not exist.	Acknowledge the message by touching the green button and re-enter User ID and Password
	User scanned in a test method barcode that was invalid. User may have selected 2 methods that are not compatible.	Acknowledge the message by touching the green button. Ensure the correct barcode was scanned and the test method is installed. Ensure that the selected tests are compatible.
	User scanned in a QC sample barcode that was invalid.	Acknowledge the message by touching the green button. Scan in a barcode in the appropriate format or enter information for a patient sample.
	An error occurred.	Contact Technical Support. Acknowledge the message by touching the green button.
	Memory is full and overwriting of old results is off.	If needed, transfer data to another storage device and delete data on Solana to free up memory. Acknowledge the message by touching the green button. Or, cancel by touching the red button; however, user will not be able to run new tests.

Critical Information (red)		
Pop-up message	Cause	Solution
<p>A red vertical bar is on the left. The message box contains a red warning triangle icon, the text "Transfer failed!", and a green checkmark button.</p>	Data transfer failed.	Contact Technical Support. Acknowledge the message by touching the green button.
<p>A red vertical bar is on the left. The message box contains a red warning triangle icon, the text "Error during print, see event log.", and a green checkmark button.</p>	Printing error.	Acknowledge the message by touching the green button. View event log.
<p>A red vertical bar is on the left. The message box contains a red warning triangle icon, the text "All tubes assigned.", and a green checkmark button.</p>	User attempted to assign more than 12 tubes.	Acknowledge the message by touching the green button. Review tube assignments.
<p>A red vertical bar is on the left. The message box contains a red warning triangle icon, the text "Installation of method failed, check error log!", and a green checkmark button.</p>	Installation of new method failed.	Acknowledge the message by touching the green button. View event log.
<p>A red vertical bar is on the left. The message box contains a red warning triangle icon, the text "Installation of print template failed, check error log!", and a green checkmark button.</p>	Installation of new print template failed.	Acknowledge the message by touching the green button. View event log.

These additional symbols may appear:

	Disk full (please delete data)		Local DYMO printer is connected
	Caution: Disk is almost full		Device is connected to a permanent power supply.
	LIS is activated. If new LIS orders exist, this icon is yellow.		

Technical Specifications

Feature	Specifications
Dimensions	Height: 150 mm (5.9 in.) Width: 240 mm (9.4 in.) Depth: 240 mm (9.4 in.)
Weight	Approx. 4000 g (8.8 lb.)
Operating Conditions	Only for indoor use
	Temperature between +15°C and +35°C
	Elevation up to 2000 m high
	Highest relative humidity 80% for temperatures up to 31°C
Transport Conditions	Temperature between -20°C up to +70°C (20 to 80% rH)
Safety	Power Supply Class I
	Instrument Class III
Protection Degree	IP20
Pollution Degree	2
Standards	EN 61010-1

Mechanical Data and Hardware Features

Feature	Specifications
Tubes	Up to 12 PCR tubes (50 µL)
Data entry	Interactive 17.8 cm (7 in) touchscreen
Heating/cooling system	Peltier heating/cooling unit with 2 independent temperature sensors (NTC) 15°C to 95°C (59°F to 203°F) with ±0.5°C; ramp ±0.5°C/s
Cover Heater	5°C offset to heater unit (to avoid condensation)

Feature	Specifications
Temperature accuracy	$\pm 0.5^{\circ}\text{C}$ (between 35°C and 50°C), $\pm 1^{\circ}\text{C}$ (outside this range), $\pm 2^{\circ}\text{C}$ (above 80°C)
Noise	<12,000 Hz and maximum noise <55 dB(A)
Connections	4 x USB and Ethernet
Communications Interfaces	USB (5V) Ethernet RJ-45 (3.3V)
Full standalone operation	<ul style="list-style-type: none"> ▪ Data entry via touchscreen, barcode ▪ Multiple assays per run ▪ User access control ▪ Full traceability of results

Optics

Feature	Specifications
Signal detection	Multiple wavelengths for up to 4 dyes per tube
Wavelength combinations excitation/emission (nm)	365/460, 470/520, 560/625, and 625/680
Dyes	Coumarin, FAM™, ROX™, CY®5, etc.
Scan interval 12 tubes	10 seconds (for one wavelength channel)
Performance	1 raw data acquisition cycle for maximum 12 tubes with up to 4 colors (on 2 detectors) within 35 seconds
Sensitivity	10 to 12 mol/L fluorescein sodium in 0.1 N sodium hydroxide (measured with excitation at 470 nm and detection at 520 nm)
Surveillance	Internal check among solid standards

Power Requirements of the Instrument

Feature	Specifications
External Power Supply	Input: 100-240V ~ 1.5-0.7A 47 – 63Hz Output: 24V 3A
Installation/Overvoltage Category	Power Supply Class I

Accessories

Feature	Specifications
External printer	DYMO LabelWriter 4XL printer
Internal Barcode scanner	<ul style="list-style-type: none"> ▪ Maximum current 500 mA (USB 2.0 specification) ▪ Control characters are CR/LF (carriage return line feed)

REF 20278 – Solana Instrument
1523700 - Printer

IVD



EC REP

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