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General Information

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     858.552.1100 (outside the United States);
Fax: 740.592.9820
E-mail: customerservice@quidel.com
### Labels and Symbols

<table>
<thead>
<tr>
<th>Label</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Manufacturer" /></td>
<td>Manufacturer</td>
</tr>
<tr>
<td><img src="image" alt="IVD" /></td>
<td>In vitro diagnostics</td>
</tr>
<tr>
<td><img src="image" alt="CE mark" /></td>
<td>CE mark of conformity (Conformité Européenne)</td>
</tr>
<tr>
<td><img src="image" alt="i" /></td>
<td>Consult instructions for use</td>
</tr>
<tr>
<td><img src="image" alt="EC REP" /></td>
<td>Authorized representative in the European Community</td>
</tr>
<tr>
<td><img src="image" alt="Temperature limitation" /></td>
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<tr>
<td><img src="image" alt="WEEE" /></td>
<td>Directive 2002/96/EC on waste electrical and electronic equipment (WEEE)</td>
</tr>
<tr>
<td><img src="image" alt="SN" /></td>
<td>Serial number</td>
</tr>
<tr>
<td><img src="image" alt="REF" /></td>
<td>Catalog number</td>
</tr>
<tr>
<td><img src="image" alt="i" /></td>
<td>Information of particular importance</td>
</tr>
<tr>
<td><img src="image" alt="Warning" /></td>
<td><strong>Warning!</strong> 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).</td>
</tr>
<tr>
<td><img src="image" alt="Biohazard" /></td>
<td><strong>Potential Biohazard!</strong> 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.</td>
</tr>
<tr>
<td><img src="image" alt="Caution" /></td>
<td><strong>Caution!</strong> Indicates a situation, which if not avoided could result in damage to the device or incorrect results.</td>
</tr>
</tbody>
</table>
Brief Warnings, Precautions and Limitations

- Always operate Solana on a surface that is level, dry, and stable, and away from direct intense lighting.
- 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.
- Maintenance and decontamination of workspace and equipment should follow and be performed according to established laboratory protocols and schedules.
- 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.
- Plug the device into an approved, properly installed receptacle.
- 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 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 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 Quidel 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.

Intended Use

Solana is a standalone 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 Quidel 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, saved on a USB flash drive, and/or sent to a LIS.

**System Components**

The following system components are supplied by Quidel:

- Solana instrument
- Power supply and cords
- Ethernet cord
- Dymo LabelWriter 450 printer
- Dymo LabelWriter 450 printer labels
- Stylus

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

Solana consumable assay reagent kits and External Quality Control materials are provided separately. Contact Quidel 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
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 Quidel Technical Support.

Placement of Solana
The Solana is portable and can be moved to a suitable location for testing or storage.

⚠️ When moving the instrument, lock the mechanical transport lock. See the Transport Lock section for instructions on locking the unit 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
- Access all connection ports on the back of the unit, 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
- Electromagnetic interference
- Temperature changes
- Mechanical movements (vibrations)

⚠️ 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 device.

⚠️ 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 above 35°C.
Unlocking Solana

Before powering up Solana, ensure the mechanical transport is unlocked. See Figure 3 for the location of the transport lock.

To access the transport lock, place Solana on a stable surface. Facing the front of the device, tilt the device to stand on its left side. Unlock the unit by sliding the lever to the unlocked position (see Figure 4).

AC Power Connection

- Solana operates at: 100–240 V<sub>AC</sub>, 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.
- Connect Solana to a properly installed electrical outlet.

Plugging and Unplugging Solana

- With the flat side of the instrument connector facing down, plug the instrument connector into the power port in the back of Solana (see Figure 5).
- Plug the outlet connector to a properly installed electrical outlet.
To unplug the unit, hold the instrument connector (Figure 6) and unplug from the instrument port. Do not unplug by pulling on the cord.

Figure 6

General Operation

Procedural Notes

Within this document, text in bolded, purple-colored font indicates hyperlinks in the electronic document.

The default user ID and password for the Administrator is “Admin” and “admin”, respectively. Passwords should be changed and managed in accordance with your organization’s procedures. A temporary (valid for 24 hours) Administrator-level password can be obtained by contacting Quidel Technical Support.

Solana has a touchscreen display. Touch the icon to select the option. 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 cancel/exit changes, selections, or processing on most screens.

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 in idle mode. Press and hold the power button to activate Solana. After 2 hours in idle mode, Solana turns off.
Startup Solana

Power Up

⚠️ Before powering up, make sure the mechanical transport lock is **unlocked** (see Unlocking Solana section).

- Press and hold the power button (**Figure 1**) for approximately 2 seconds.

The display screen lights up with the Quidel logo. The system boots up and the power indicator light turns green.

- If a message to unlock the transport lock is displayed (**Figure 7**), touch the button after confirming the unit is unlocked. **Note:** This message does not appear if the unit was powered down using normal shutdown procedures (shutdown without locking the device).

![Figure 7](image)

**Deactivate transport lock on the bottom of device now and confirm for initialization.**

During bootup, Solana displays a self-check screen (**Figure 8**). An internal 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. In case of a failure, please refer to the Troubleshooting section.
User Login

If User Access Control is turned On, the login screen is displayed (Figure 9) 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 Main Menu section below. Refer to the User Access Control section for details on modifying this feature.

- 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 10) appears if the login information entered is correct and the instrument passes internal calibration.
Main Menu

The following choices are available on the Main Menu (Figure 10).

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

![Main Menu Image](image)

**Figure 10**

The options are described in separate sections below.

User Logout

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

- Touch the logout icon in the Main Menu (Figure 10).
- Touch the button to confirm logout (Figure 11).
System

There are 3 choices on the System menu (Figure 12).

- Settings
- Maintenance
- Info

The Info option displays the instrument software version, Linux version, device serial number and build.

Changes to Settings and Maintenance are saved and applied to subsequent uses of the device. It is suggested to review System: Settings prior to using Solana the first time.
Settings
There are two types of settings (Figure 13):

- Workflow Settings
- Device Settings

![Figure 13](image)

Workflow Settings
Within Workflow Settings, the following can be configured (Figure 14):

- Order Settings
- Result Handling

![Figure 14](image)
Order Settings

Within Order Settings, the following can be configured (Figure 15).

- Test Selection Autofill
- Sample Ordering Auto Sample Order

![Order Settings](image)

Figure 15

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

**Autofill 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.

**Autofill 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.
- 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 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.
- Touch the button to confirm the selection.
**Result Handling**

Within **Result Handling**, overwriting of older results can be set (**Figure 16**). The default **Overwrite** setting is **Off**.

**Overwrite Off** - 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.

- To change the displayed setting, touch the **On/Off** icon.
- Touch the **button to confirm the selection.**

![Figure 16](image)

**Device Settings**

Within **Device Settings**, the following parameters can be configured (**Figure 17**):

- **Date & Time**
- **Language**
- **User Access Control**
- **Network Configuration**
- **Brightness**
- **Delete Patient Info in All Records**
Date and Time settings, the date and time and formats can be set (Figure 18).

- **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. MMM yyyy, yyyy-MM-dd, or MMM/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** can be set. The language can also be set for the **Keyboard**. The default language is **English**.

**User Access Control**

The **User Access Control** menu can be accessed by the Administrator only (Figure 19). The default **User Access Control** setting is **Off**.

![Figure 19](image)

**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 three types of user access levels or roles: Administrator, Lab User, and Technical Specialist. 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. The Technical Specialist role is for Quidel Technical Support personnel or Field Application Specialists. 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 and view amplification curves. 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.
<table>
<thead>
<tr>
<th>Function</th>
<th>Lab User</th>
<th>Administrator</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Changing Instrument Settings</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test Selection autofill on/off</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Auto Sample ordering on/off</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Auto Result Deletion on/off</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Adjust Date, Time, Time Format</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Change Language</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Change Keyboard</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Switch on/off</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Add new user</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Delete user</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Edit user</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Edit Network Configuration</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Activate LIS</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Edit LIS Network configuration</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Activate Virena</td>
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<tr>
<td>Edit Virena Network Settings</td>
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<tr>
<td>Activate Result Transfer</td>
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<td>X</td>
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<td>Activate SW Network updates</td>
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<td>X</td>
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<tr>
<td>Adjust Volume and Brightness</td>
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<tr>
<td><strong>Managing and Maintenance of the System</strong></td>
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<tr>
<td>View Virena status</td>
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<td>X</td>
</tr>
<tr>
<td>Virena – Send last result, send all results, send unsent results</td>
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<td>X</td>
</tr>
<tr>
<td>Review LIS orders</td>
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<tr>
<td>Function</td>
<td>Lab User</td>
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<td>---------------</td>
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<td>View new incoming LIS orders</td>
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<td>Install SW update</td>
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<td>Install methods</td>
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<td>Delete methods</td>
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<tr>
<td>Import new report template</td>
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<tr>
<td>View event log</td>
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<td>Export events to USB</td>
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<td>Delete events in event log</td>
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<td>X</td>
</tr>
<tr>
<td>Activate Transport Lock for shipment</td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

When **User Access Control** is **On (Figure 19)**, the following options are available to Administrators on the **User Access Control** menu:

- **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.

- **Edit an Existing User**
  - Select the user from the User ID drop-down list.
  - Touch the edit button.
  - 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 button.

- 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**

LAN, LIS Server, and Virena network settings can be programmed (**Figure 20**).

![Figure 20](image)

**LAN Settings**

- To add **LAN** network settings, touch the **LAN** button.
  - Select either a **Static IP** or a **Dynamic IP** (**Figure 21**).
  - Type in the **IP Address**, **Subnet Mask**, and **Default Gateway** into the applicable fields.

- Touch the button to confirm the entries.
LIS Settings

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

- To modify **LIS Server** network settings, touch the **LIS Server** button (Figure 20).
- To change the displayed setting, touch the **On/Off** icon (Figure 22).
- 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).

- 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.
**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** network settings, touch the **Virena** button (**Figure 20**).
- To change the displayed setting, touch the **On/Off** icon (**Figure 23**).

**Figure 23**

- If **Activate Virena** is **On**, set **Result Transfer** and **Network Updates** settings **On/Off**.
  - **Result Transfer** refers to sending the results to the Virena Cloud. If this feature is turned **On**, the results are automatically sent to the Virena Cloud once the test is completed. If turned **Off**, the results are not automatically sent.
  - **Network Updates** refers to software update notifications and ability to download from the Virena device. If this feature is turned **On**, a message in the top banner of the Solana display indicates when software updates are available. If turned **Off**, the availability of updates is not displayed.

- Touch the right arrow (next) button at the bottom of the screen to advance to the next screen.
- Type in **Virena IP address** (**Figure 24**).
If applicable, type **Result Transfer Port Number** and **Network Update Port Number**.

If desired, touch the **Test** button to test the Virena connection. **Note:** When Virena is activated but not connected, a “V” highlighted in yellow is displayed in the top banner (Figure 24).

Touch the right arrow (next) button at the bottom of the screen to advance to the next screen.

Type in the **Zip Code** (Figure 25).

Touch the **button** to confirm the selections and entries, or touch the left (back) arrow button to return previous screens.

**Brightness**

Within **Brightness** settings, the brightness of the display can be adjusted (Figure 26). The default setting is at maximum brightness.

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

![Brightness Image]

**Figure 26**

*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 Quidel. **Note**: This does not delete results, but rather, deletes any potential personal identifying information.

- 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

*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.

- Touch the **Virena Status** button.
- View any displayed messages *(Figure 27).*
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 received LIS orders (Figure 28).
- Touch the **LIS Status** button.
- View any displayed LIS orders.
- Select the order that requires action by touching the first column of the row with the relevant order. A checkmark appears next to the selected LIS order.
- 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, and management of raw data (**Figure 29**).

**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 30**).

- 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.

**Manage Methods**

*Manage Methods* is used to import new test methods (new Solana assay), 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 loading a Method File Update, 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 Quidel.

- Touch the **Report Template** button.
- If needed, insert the USB flash drive.
- Touch the button to confirm installation.

**Note:** Test results can be printed on a network printer. To do so, the following are required:

- Network printer IP address and make/model
- PC (personal computer) with administrator rights to modify network settings
- Connect Solana to LAN (see **Network Settings** section).
  - LAN settings set to Dynamic IP
  - If Solana is connected to Virena, contact Technical Support to setup simultaneous Virena and network printing.
- Upload print template to Solana (see **Report Template** section).
- Connect PC to LAN
- Configure printer driver on the PC

Please see separate instructions for Network Printer Set-up for Solana for details. Contact Technical Support or access the Quidel website to obtain these instructions.

**Event Log**

The **Event Log** is used to review recent Solana software events, such as login data and errors.

- 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.

**Transport Lock**

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

- Touch the **Transport Lock** button.
- Touch the button to confirm lock and shutdown.
- The message below (Figure 31) appears briefly while the instrument prepares for lock.
A new message instructs the user to set the transport lock (Figure 32).

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 device is locked.

The instrument automatically starts shutting down.

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 **Autofill 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 Quidel Technical Support.

- From the **Main Menu**, touch the **New Test** button to start a new test.
- The sample ordering screen appears (**Figure 33**).

![Figure 33](image)

- If needed, type the **Lot ID** and **Kit Exp. Date** using MM/DD/YYYY date format (**Figure 33**). For example, if the date is June 23, 2015, type “06/23/2015.” Touch the **Enter** key to confirm the entries. **Note:** Scanning the barcode enters the test method, Lot ID and Kit Exp. Date.
- Touch the **Select Test** drop-down list to select the test method (**Figure 34**) or scan the barcode of the assay packaging.

![Figure 34](image)

- Select the tubes you want to test (**Figure 35**).
Selections can be reversed (undone) by touching the tube selected in error. For example, if tube 1 was selected in error, touch tube 1 to undo the selection.

![Select Test](image)

**Figure 35**

- Touch the right arrow (next) button. Sample Type and Sample ID can be entered at this point or later during the run. See Assigning Sample Type and ID section for further instructions.

- Touch the Play button to start the test.

If desired, to add a test with a compatible method file, select or scan the test information and assign tube locations as described above. **Note:** It is possible to assign different tests 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.

**Starting New Test (Test Selection: Autofill Mode On)**

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

With the Autofill 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 Autofill 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 Per Run**

- From the Main Menu, touch the New Test button to start a new test.

- The sample ordering screen appears (Figure 36). The first tube is highlighted.
■ Touch the last tube position to select all tubes between tube 1 and the last selected tube. See the example in Figure 37. Tube 4 was chosen as the last tube, therefore tubes 1 through 4 are selected.

![Figure 36](image)

![Figure 37](image)

■ Selections can be reversed (undone) by touching the tube(s) that is out of range. For example, if tube 4 is out of range, touch tube 4. Individual tubes within the range cannot be unselected individually.

■ If needed, type the **Lot ID** and **Kit Exp. Date** using MM/DD/YYYY date format. For example, if the date is June 23, 2015, type “06/23/2015.” Touch the **Enter** key to confirm the entries. **Note:** Scanning the barcode enters the test method, Lot ID and Kit Exp. Date.

■ Touch the **Select Test** drop-down list to select the test method (Figure 34) or scan the barcode of the assay packaging.

■ Touch the right arrow (next) button. **Sample Type** and **Sample ID** can be entered at this point or later during the run. See **Assigning Sample Type and ID** section for further instructions.

■ Touch the **Play** button to start the test.
Procedure to Run Different Assays in the Same Batch

It is possible to assign different tests in one run if the method files are compatible (e.g., Solana Trichomonas assay and Solana GAS assay). After assignment of the first test, the instrument drop-down menu offers only the tests that are compatible.

- Follow instructions for One Test 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 Play button.

- For the second test, the first available tube is highlighted (Figure 38). In the example in Figure 38, tubes 1 through 4 are tested with the first test. Tube 5 is highlighted and available for the second test.

- Touch the last tube position for the second test to select all tubes in between. In the example in Figure 39, tube 8 was chosen as the last tube, so tubes 5 through 8 were selected.
If needed, type the **Lot ID** and **Kit Exp. Date** using MM/DD/YYYY date format. For example, if the date is June 23, 2015, type “06/23/2015.” Touch the **Enter** key to confirm the entries. **Note:** Scanning the barcode enters the test method, Lot ID and Kit Exp. Date.

- Touch the **Select Test** drop-down list to select the test name or scan the barcode of the assay packaging.

- Touch the right arrow (next) button. **Sample Type** and **Sample ID** can be entered at this point or later during the run. See **Assigning Sample Type and ID** section for further instructions.

- Touch the **Play** button to start the tests.

## Assigning Sample Type and ID

The **Sample Type** and **ID** are set from the sample ordering screen (**Figure 40**). The default **Sample Type** is **Patient**. The default **ID** is blank.

![Figure 40](image)

### 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.

### Patient Samples

- If needed, select **Patient** from the **Sample Type** drop-down list.

- Touch the **ID** field to enter sample information.
  
  - If Virena is not activated, type in the ID or scan the barcode (**Figure 40**).
  
  - If Virena is activated, type the sample **ID** or scan the barcode (**Figure 41**). Type **Age** (in years, using whole numbers) and **Status** (In-Patient, Out-Patient, or Proficiency). **Note:** Sample ID, Age, and Status are required for Virena. If not entered, an error message is generated after the run is complete.
If needed, enter **Study Fields** by touching the **Open** button. **Note:** This feature is optional and may be helpful for tracking samples in research studies.

- Enter 2-digit numeric values for up to 4 **Study Fields**.
- Touch the **Enter** key when information is complete.
- Touch the **button** to confirm the **Study Fields** entries.

Touch the **Enter** key (**Figure 41**).

Touch the **button** to confirm the **ID** entries.

The entered Sample Type and Sample ID are displayed.

Touch the applicable tube(s) to assign the displayed sample information.

To enter additional sample information, touch the **ID** field to enter sample information as described above.

The Sample Type and Sample ID are displayed.

Touch the applicable tube(s) to assign the displayed sample information.

**QC Samples**

- Select **QC** from the **Sample Type** drop-down list (**Figure 40**).
- An instruction to scan the QC barcode is displayed (**Figure 42**). **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, 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.

**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.

**Patient Samples**

- If needed, select the appropriate tube.
- If needed, select Patient from the Sample Type drop-down list.
- Touch the ID field to enter sample information.
  - If Virena is not activated, type in the ID or scan the barcode (Figure 40).
  - If Virena is activated, type the sample ID or scan the barcode (Figure 41). Type Age (in years, using whole numbers) and Status (In-Patient, Out-Patient, or Proficiency). Note: Sample ID, Age, and Status are required for Virena. If not entered, an error message is generated after the run is complete.
- If needed, enter Study Fields by touching the Open button. Note: This feature is optional and may be helpful for tracking samples in research studies.
  - Enter 2-digit numeric values for up to 4 Study Fields.
- Touch the **Enter** key when information is complete.

- Touch the **✓** button to confirm the **Study Fields** entries.

- Touch the **Enter** key (**Figure 41**). 

- Touch the **✓** button to confirm the **ID** entries for the sample.

- Repeat steps above for other patient samples.

**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 43**). **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, 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.

- Assign the ID to the QC tube.

- Repeat as needed for additional QC samples.

**Test in Progress**

Once testing has started, a value showing the percentage complete and a countdown timer at the top of the menu indicate test progression (**Figure 44**).
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 resuming testing after initially aborting a run, be certain that the specimen meets the specifications of the specific assay.

During testing, the status of all samples is “pending.” After the run, the results are displayed (Figure 45).

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.

- On the Sample Ordering screen, touch the edit button to edit the information (Figure 44).
- Enter the information, select one or more tubes, and touch the Enter key button. See Assigning Sample Type and ID section for details.
LIS Orders

The LIS Orders option is available on the Main Menu (Figure 10) if LIS Server settings are configured and the LIS is connected. Touch LIS Orders to view LIS orders received (Figure 46).

<table>
<thead>
<tr>
<th>Date, Time</th>
<th>Test Identifier</th>
<th>Order Nbr</th>
<th>ID</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thu Nov 3 08:27:00 2...</td>
<td>GAS_P</td>
<td>023451790</td>
<td></td>
<td>new</td>
</tr>
</tbody>
</table>

LIS Order Assignment

To send an order from Solana to a LIS system, a 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 tubes to a test per instructions in the Start New Test section.
- Select the tube(s) (Figure 47).

- Touch the right arrow (next) button to advance to the next screen.
- Touch the LIS button at the bottom of the screen (Figure 48).
To touch the **LIS Orderlist** to the right of the **Order Number** (Figure 49).

Touch the first column of the row with the relevant order (Figure 50). A checkmark appears next to the selected LIS order.
Touch the button to confirm the selection. The tube now displays the LIS Order Number (Figure 51).

Touch the tube to assign the Order Number to the tube. The Order Number appears with the corresponding tube (Figure 52).
Touch the Play button to start the test.

Touch the button to confirm all tubes are loaded and to start the run (Figure 53).

After testing is complete (Figure 54), results automatically transmit for each tube that has a LIS order assigned.
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 10).
- A list of runs showing Date and Run ID is displayed with the most recent results displayed at the top (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 or 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.

![Sample Results Table]

<table>
<thead>
<tr>
<th>Tube</th>
<th>Sample Type</th>
<th>Sample ID</th>
<th>Method</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Patient</td>
<td>test1</td>
<td>GAS</td>
<td>Invalid</td>
</tr>
<tr>
<td>2</td>
<td>Patient</td>
<td>test2</td>
<td>GAS</td>
<td>Invalid</td>
</tr>
<tr>
<td>3</td>
<td>Patient</td>
<td>test3</td>
<td>GAS</td>
<td>Invalid</td>
</tr>
</tbody>
</table>

**Figure 56**

An amplification curve of the target nucleic acids for each test can also be viewed by an Administrator.

**Note:** The curve is presented for information only and should not be used to override the result (Positive, Negative, or Invalid) generated by the software.

- From the Sample Results screen (**Figure 56**), touch the row with the relevant sample.
- The real-time curve of the selected tube is shown in a separate window (**Figure 57**).
- Move up and down the page using the scroll bar.

**Figure 57**

**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 58).

<table>
<thead>
<tr>
<th>Date</th>
<th>Run ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016-10-06 09:42:51</td>
<td>162</td>
</tr>
<tr>
<td>2016-09-07 12:35:42</td>
<td>151</td>
</tr>
<tr>
<td>2016-08-29 15:27:01</td>
<td>145</td>
</tr>
<tr>
<td>2016-08-29 14:50:26</td>
<td>144</td>
</tr>
<tr>
<td>2016-08-25 11:31:00</td>
<td>141</td>
</tr>
</tbody>
</table>

Figure 58

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.
- If needed, insert the USB drive.
- Select the run by touching the box next to the run, or touch the check mark at the top of the list to select all displayed runs.
- Touch the button to confirm the USB drive is inserted.

Note: Data is exported as a CSV file.

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

- From the Sample Results screen (Figure 56), select the tube(s).
- Touch the print button at the bottom of the screen.

Real-time curves can be printed if Solana is connected to a printer.

- From the Test Result screen with the real-time curve (Figure 57), touch the print button at the bottom of the screen.

Once the activity is completed, the user is notified. For more information, refer to Troubleshooting section.

Shutdown

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

- 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. If the inside of the Solana is contaminated, please contact Quidel 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)

<table>
<thead>
<tr>
<th>Pop-up message</th>
<th>Cause</th>
<th>Solution</th>
</tr>
</thead>
</table>
| Instrument Software: 2.0.2  
Linux Version: 090912202015#17  
Serial Number: 15020012  
Build: 11726 | User selected Info option. | Acknowledge the message by touching the green button. |
| Printing ... | Print in progress. | No action required. |
| 20007  
Results printed | Print job complete. | Acknowledge the message by touching the green button. |
| 20008  
Data deleted | User deleted test results. | Acknowledge the message by touching the green button. |
<p>| Exporting ... | Export of data to USB flash drive in progress. | No action required, or cancel by touching red button. |</p>
<table>
<thead>
<tr>
<th>Pop-up message</th>
<th>Cause</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>20009</td>
<td>Data export to USB flash drive successful.</td>
<td>Acknowledge the message by touching the green button.</td>
</tr>
<tr>
<td></td>
<td>Result export successful.</td>
<td></td>
</tr>
<tr>
<td>20011</td>
<td>User installed software updated.</td>
<td>Continue by touching the button.</td>
</tr>
<tr>
<td></td>
<td>Restart to continue installation.</td>
<td></td>
</tr>
<tr>
<td>20011</td>
<td>Report (printer) template import successful.</td>
<td>Acknowledge the message by touching the green button.</td>
</tr>
<tr>
<td></td>
<td>Template successfully imported.</td>
<td></td>
</tr>
<tr>
<td>20001</td>
<td>Test method deletion successful.</td>
<td>Acknowledge the message by touching the green button.</td>
</tr>
<tr>
<td></td>
<td>Methods(s) deleted successfully</td>
<td></td>
</tr>
<tr>
<td>Pop-up message</td>
<td>Cause</td>
<td>Solution</td>
</tr>
<tr>
<td>----------------</td>
<td>-------</td>
<td>----------</td>
</tr>
<tr>
<td>30004 Instrument was turned on after shutdown with the transport lock activated.</td>
<td>Ensure transport lock is unlocked and confirm by touching the green button.</td>
<td></td>
</tr>
<tr>
<td>10016 Tube lid heater is open.</td>
<td>Close tube lid to continue.</td>
<td></td>
</tr>
<tr>
<td>10021 User selected print option.</td>
<td>No action required.</td>
<td></td>
</tr>
<tr>
<td>30010 User selected to install software update.</td>
<td>Insert USB flash drive (USB stick) with software update and touch the USB drive button, or cancel by touching the red button.</td>
<td></td>
</tr>
<tr>
<td>30001 User selected to add a new Report (printer) Template.</td>
<td>Insert USB flash drive (USB stick) with new printer template and confirm by touching green button, or cancel by touching red button.</td>
<td></td>
</tr>
<tr>
<td>Pop-up message</td>
<td>Cause</td>
<td>Solution</td>
</tr>
<tr>
<td>----------------</td>
<td>-------</td>
<td>----------</td>
</tr>
<tr>
<td><strong>30013</strong></td>
<td>User selected data export to USB flash drive (USB stick).</td>
<td>Insert the USB flash drive (USB stick) and confirm by touching the green button, or cancel by touching the red button.</td>
</tr>
<tr>
<td><strong>30009</strong></td>
<td>User selected to add a new test method and chose USB flash drive as source of update.</td>
<td>Insert USB flash drive with new methods and confirm by touching the green button, or cancel by touching the red button.</td>
</tr>
<tr>
<td><strong>30018</strong></td>
<td>User selected to delete results.</td>
<td>Confirm by touching green button or cancel by touching red button.</td>
</tr>
<tr>
<td><strong>30006</strong></td>
<td>User started new test and attempted to exit.</td>
<td>Confirm by touching green button or cancel by touching red button.</td>
</tr>
<tr>
<td><strong>30007</strong></td>
<td>User aborted run.</td>
<td>Confirm by touching green button or cancel by touching red button.</td>
</tr>
<tr>
<td>Pop-up message</td>
<td>Cause</td>
<td>Solution</td>
</tr>
<tr>
<td>----------------------------------------------------</td>
<td>-----------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------</td>
</tr>
<tr>
<td>30016</td>
<td>Administrator selected to delete a user.</td>
<td>Confirm by touching green button or cancel by touching red button.</td>
</tr>
<tr>
<td>![User Interaction Required (yellow)]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>30014</td>
<td>User selected to clear the event log.</td>
<td>Confirm by touching green button or cancel by touching red button.</td>
</tr>
<tr>
<td>![User Interaction Required (yellow)]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>30012</td>
<td>User selected to delete test method.</td>
<td>Confirm by touching green button or cancel by touching red button.</td>
</tr>
<tr>
<td>![User Interaction Required (yellow)]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>30019</td>
<td>User selected to log off.</td>
<td>Confirm by touching green button or cancel by touching red button.</td>
</tr>
<tr>
<td>![User Interaction Required (yellow)]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>30011</td>
<td>User pressed the power button to shut down.</td>
<td>Confirm by touching green button or cancel by touching red button.</td>
</tr>
<tr>
<td>![User Interaction Required (yellow)]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### User Interaction Required (yellow)

<table>
<thead>
<tr>
<th>Pop-up message</th>
<th>Cause</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="User selected to active transport lock." /></td>
<td>User selected to active transport lock.</td>
<td>Confirm by touching green button or cancel by touching red button.</td>
</tr>
<tr>
<td><img src="image" alt="Instrument is preparing for transport lock." /></td>
<td>Instrument is preparing for transport lock.</td>
<td>No action required.</td>
</tr>
<tr>
<td><img src="image" alt="Set transport lock underneath the device and confirm." /></td>
<td>User confirmed the activation of transport lock.</td>
<td>Set the transport lock to the locked position and confirm by touching green button.</td>
</tr>
</tbody>
</table>

### Critical Information (red)

<table>
<thead>
<tr>
<th>Pop-up message</th>
<th>Cause</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="User ID unknown or password wrong. Please try again." /></td>
<td>Login information is incorrect or does not exist.</td>
<td>Acknowledge the message by touching the green button and re-enter User ID and Password</td>
</tr>
<tr>
<td>Pop-up message</td>
<td>Cause</td>
<td>Solution</td>
</tr>
<tr>
<td>----------------</td>
<td>-------</td>
<td>----------</td>
</tr>
<tr>
<td><img src="image" alt="Scan Test Not Available" /></td>
<td>User scanned in a test method barcode that was invalid. User may have selected 2 methods that are not compatible.</td>
<td>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.</td>
</tr>
<tr>
<td><img src="image" alt="Barcode Invalid" /></td>
<td>User scanned in a QC sample barcode that was invalid.</td>
<td>Acknowledge the message by touching the green button. Scan in a barcode in the appropriate format or enter information for a patient sample.</td>
</tr>
<tr>
<td><img src="image" alt="Restart Device or Contact Quidel Technical Support" /></td>
<td>An error occurred.</td>
<td>Contact Technical Support. Acknowledge the message by touching the green button.</td>
</tr>
<tr>
<td><img src="image" alt="Memory Full" /></td>
<td>Memory is full and overwriting of old results is off.</td>
<td>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.</td>
</tr>
<tr>
<td><img src="image" alt="Data Transfer Failed" /></td>
<td>Data transfer failed.</td>
<td>Contact Technical Support. Acknowledge the message by touching the green button.</td>
</tr>
<tr>
<td>Pop-up message</td>
<td>Cause</td>
<td>Solution</td>
</tr>
<tr>
<td>-----------------------------------------------------------------------------</td>
<td>---------------------------------------------------------</td>
<td>-------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Printing error.</td>
<td>Acknowledge the message by touching the green button.</td>
<td>View event log.</td>
</tr>
<tr>
<td>User attempted to assign more than 12 tubes.</td>
<td>Acknowledge the message by touching the green button.</td>
<td>Review tube assignments.</td>
</tr>
<tr>
<td>Installation of new method failed.</td>
<td>Acknowledge the message by touching the green button.</td>
<td>View event log.</td>
</tr>
<tr>
<td>Installation of new print template failed.</td>
<td>Acknowledge the message by touching the green button.</td>
<td>View event log.</td>
</tr>
</tbody>
</table>

These additional symbols may appear:

- **Disk full (please delete data)**
- **Caution: Disk is almost full**
- **LIS is activated. If new LIS orders exist, this icon is yellow.**
Local Dymo printer is connected or a network printer is configured.

Device is connected to a permanent power supply.

Virena warning sign indicating a connection error.

**Technical Specifications**

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

**Mechanical Data and Hardware Features**

<table>
<thead>
<tr>
<th>Feature</th>
<th>Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tubes</td>
<td>Up to 12 PCR tubes (50 μL)</td>
</tr>
<tr>
<td>Data entry</td>
<td>Interactive 17.8 cm (7 in) touchscreen</td>
</tr>
<tr>
<td>Heating/cooling system</td>
<td>Peltier heating/cooling unit with 2 independent temperature sensors (NTC)</td>
</tr>
<tr>
<td></td>
<td>15°C to 95°C (59°F to 203°F) with ±0.5°C; ramp ±0.5°C/s</td>
</tr>
<tr>
<td>Cover Heater</td>
<td>5°C offset to heater unit (to avoid condensation)</td>
</tr>
<tr>
<td>Temperature accuracy</td>
<td>±0.5°C (between 35°C and 50°C), ±1°C (outside this range), ±2°C (above 80°C)</td>
</tr>
<tr>
<td>Noise</td>
<td>&lt;12,000 Hz and maximum noise &lt;55 dB(A)</td>
</tr>
<tr>
<td>Connections</td>
<td>4 x USB and Ethernet</td>
</tr>
<tr>
<td>Feature</td>
<td>Specifications</td>
</tr>
<tr>
<td>---------</td>
<td>----------------</td>
</tr>
<tr>
<td>Full standalone operation</td>
<td></td>
</tr>
<tr>
<td>▪ Data entry via touchscreen, barcode</td>
<td></td>
</tr>
<tr>
<td>▪ Multiple assays per run</td>
<td></td>
</tr>
<tr>
<td>▪ User access control</td>
<td></td>
</tr>
<tr>
<td>▪ Full traceability of results</td>
<td></td>
</tr>
</tbody>
</table>

**Optics**

<table>
<thead>
<tr>
<th>Feature</th>
<th>Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signal detection</td>
<td>Multiple wavelengths for up to 4 dyes per tube</td>
</tr>
<tr>
<td>Wavelength combinations excitation/emission (nm)</td>
<td>470/520, 560/625, 520/570 and 625/680</td>
</tr>
<tr>
<td>Dyes</td>
<td>FAM™, ROX™, HEX™, CY®5, Coumarin, TAMRA™, etc.</td>
</tr>
<tr>
<td>Scan interval 12 tubes</td>
<td>10 seconds (for one wavelength channel)</td>
</tr>
<tr>
<td>Performance</td>
<td>1 raw data acquisition cycle for maximum 12 tubes with up to 4 colors (on 2 detectors) within 35 seconds</td>
</tr>
<tr>
<td>Sensitivity</td>
<td>10 to 12 mol/L fluorescein sodium in 0.1 N sodium hydroxide (measured with excitation at 470 nm and detection at 520 nm)</td>
</tr>
<tr>
<td>Surveillance</td>
<td>Internal check among solid standards</td>
</tr>
</tbody>
</table>

**Power Requirements of the Instrument**

<table>
<thead>
<tr>
<th>Feature</th>
<th>Specifications</th>
</tr>
</thead>
</table>
| External Power Supply | Input: 100-240V ~ 1.5-0.7A 47 – 63Hz  
Output: 24V 2.5A |
| Battery Pack (optional) | Lithium Battery 5 S2P 18.5 VDC 4.5 Ah |
| Installation/Overvoltage Category | Power Supply Class I |

**Accessories**

<table>
<thead>
<tr>
<th>Feature</th>
<th>Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>External printer</td>
<td>Dymo 450 printer</td>
</tr>
</tbody>
</table>
| Internal Barcode scanner | Maximum current 500 mA (USB 2.0 specification)  
Control characters are CR/LF (carriage return line feed) |

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