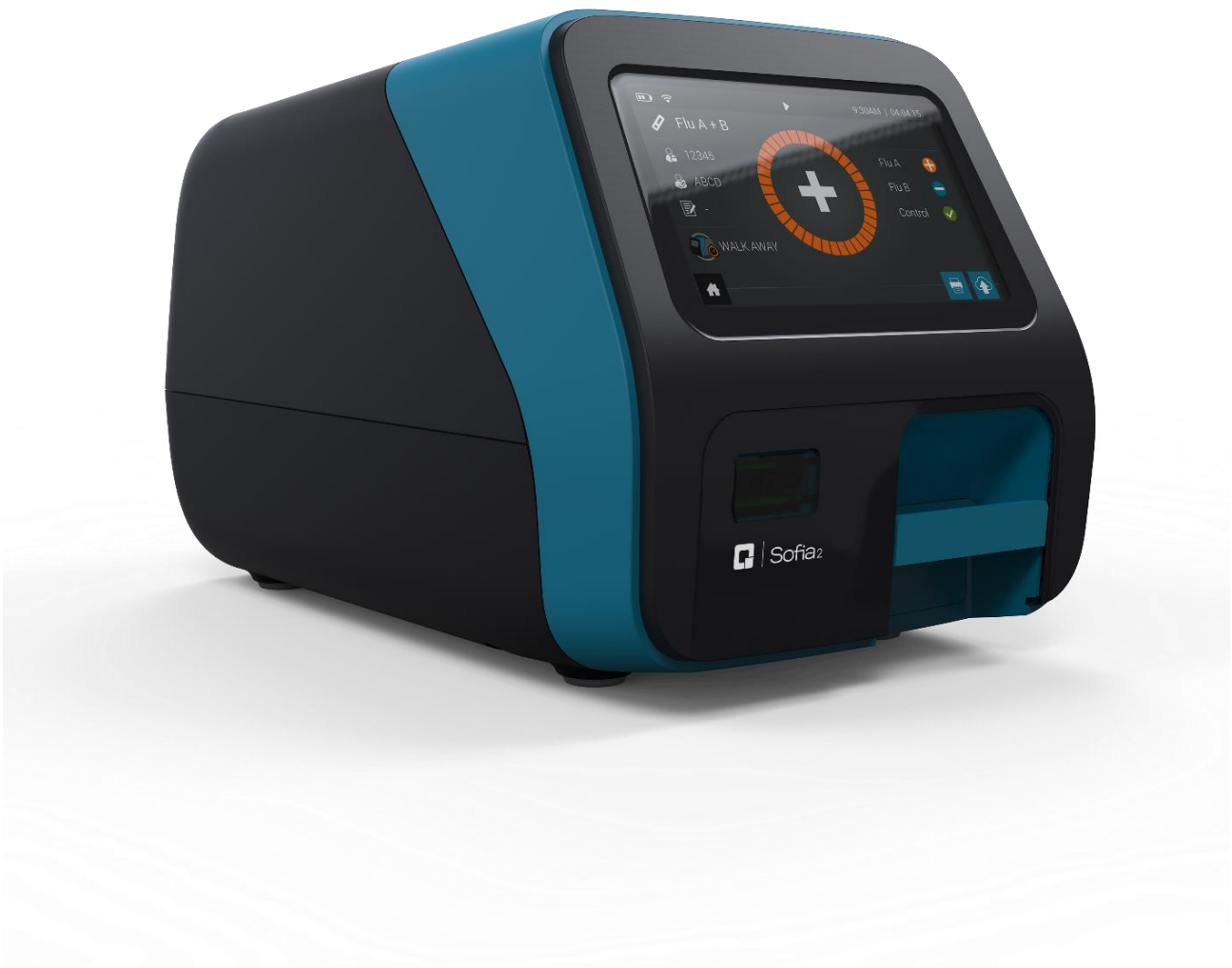
QUIDEL

Sofia®2



User Manual

For *in vitro* diagnostic use
Firmware v.1.12 or higher

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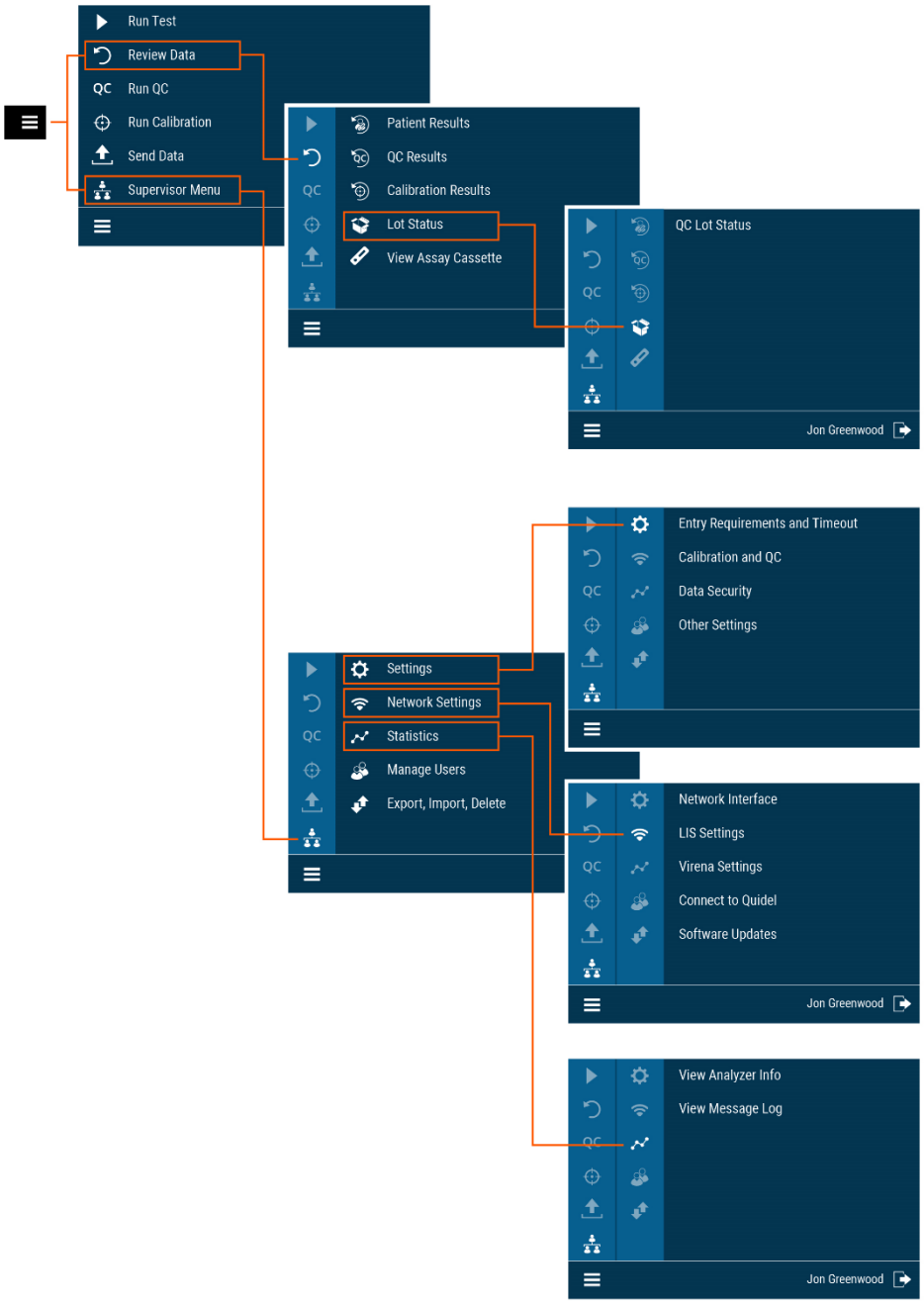
General Information

Assistance

For questions regarding the use of this product, or to report a problem, please contact Quidel Technical Support at 1.800.874.1517 (in the U.S.) or technicalsupport@quidel.com. If outside the U.S., further information can be obtained from your distributor, or directly from Quidel at one of the numbers listed below. Reference **quidel.com** to see more options for Support.

Region	Phone	E-Mail Address
Europe, Middle East and Africa	+353 (91) 412 474 (main) 0 1800 200441 (toll free)	emeatechnicalsupport@quidel.com
Austria	+43 316 231239	
Belgium	+32 (2) 793 0180	
France	0 (805) 371674	
Germany	+49 (0) 7154 1593912	
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@quidel.com
Canada	437.266.1704 (main) 888.415.8764 (toll free)	technicalsupport@quidel.com
China	0400 920 9366 or +86 21 3217 8300	chinatechnicalservice@quidel.com

Main Menu Structure



Labels and Symbols

Label/Symbol	Description
	Manufacturer
IVD	*In vitro* diagnostic medical device
	Consult instructions for use
EC REP	Authorized Representative in the European Community
	Temperature limitation
	Humidity limitation
	Waste electrical and electronic equipment (WEEE)
SN	Serial Number
REF	Catalog Number
	Warning / Caution
	Ultraviolet Radiation
	Potential Biohazard
CE	CE mark of conformity
LOT	Batch code

	Date of manufacture
	Use-by date
	Importer
	Do not re-use
	China RoHS
	Patient number
	Control
	Prescription use only in the United States
	Biological risks
	Device for near patient testing
	Device not for self testing

Icons

Menu

Help

Home

Add / Create New

Run Test

Edit

User/Operator

Navigate Right

Patient

Back / Navigate Left

Order Number

Navigate Up

Read Now Mode

Navigate Down

Walk Away Mode

Skip Control

Positive Result / Positive Control

Control Skipped or cancelled

Negative Result / Negative Control

Print

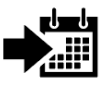
Control Valid

Deleting Data

Control Invalid

Date

Confirmation


Expiry Date

OK / Confirm

Time

Cancel / Delete

Warning / Error

Review Data

Battery Level

Run Quality Control

Battery critically low

Calibration

Battery Charging / Mains Powered

Calibration due in X days

Load data

Supervisor Menu

USB Device Connected

Logout

Virena / Cloud

Patient Results

Sound Off

QC Results

Sound On

Calibration Results

Send to Virena / Check Connection

Test / Test Types

Send to LIS / Check Connection

Kit Box / Lot

WIFI

Settings

WIFI Not Connected

Statistics

Ethernet Enabled

Manage Users

Ethernet Disabled

Export, Import, Delete

Show Password

Barcode Scanner

Hide Password

Brief Warnings, Precautions, and Limitations

- For *in-vitro* diagnostic use.
- For professional and near patient testing.
- For use by healthcare professionals.
- Always operate Sofia 2 on a surface that is level, dry, and not in direct sunlight.
- Do not stack or place objects on top of the Sofia 2. Maintain a 6” minimum clearance around the sides and back of the Sofia 2.
- The Sofia 2 Calibration Cassette is sensitive to light. Store it in the opaque sleeve whenever it is not being used.
- Do not write on the barcode or surface of the Cassette.
- Never move Sofia 2 or open the drawer while there is a test in progress.
- Use only the Power Adapter that was provided with Sofia 2.
- Do not drop Sofia 2 as it could damage the unit.
- Contact Technical Support if the instrument is damaged.
- Sofia 2 has been designed to CISPR 11 Class A. In a domestic environment, it may cause radio interference, in which case you may need to take measures to mitigate the interference.
- Do not immerse the Sofia 2 in water or any liquids.

Safety Precautions

Sofia 2 is designed to provide safe and reliable operation when used according to this User Manual. If Sofia 2 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 in order to avoid unsafe actions that could potentially result in personal injury or damage to the device.

Warning!

To reduce the risk of electrical shock:

- Unplug Sofia 2 before cleaning.
- Plug the device into an approved receptacle.
- Do not immerse in water or cleaning solutions.
- Do not attempt to open the enclosure.

  Note: Significant Electrostatic Discharge (ESD) event(s) may permanently disable ethernet port functionality. If this occurs, please use Wi-Fi or LTE (if available) as alternative methods of communication or contact Customer Service.

To reduce the risk of improper operation:

- Use of any cable or adapter other than those provided by the manufacturer could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment.
- Ensure the device has a minimum separation distance of 12” for Portable RF communications equipment (including peripherals such as antenna cables and external antennas).
- Use of this equipment adjacent to or stacked with other equipment should be avoided.

Ultraviolet Radiation!

To reduce the risk of UV Exposure:

- Do not attempt to open or disassemble Sofia 2.
- Do not attempt to look inside Sofia 2 while operating.

Failure to follow these warnings will invalidate the warranty.

Potential Biohazard!

To reduce the risk of biohazard:

- Dispose of used specimens in accordance with Federal, State, and Local requirements.
- Treat specimens and patient samples as potentially biohazardous material.
- Ensure Sofia 2 is cleaned per the **Maintenance and Cleaning** section.
- Seek specific training or guidance if you are not experienced with specimen collection and handling procedures.
- Use of Nitrile, Latex, or other gloves is recommended when handling patient samples.

Caution!

To reduce the risk of incorrect results:

- Sofia 2 should only be used by trained operators.
- Do not use if Sofia 2 is reporting an error condition that cannot be corrected.
- To obtain accurate results, refer to the assay-specific Package Insert for details on specific tests.
- Use the test kit within the expiration date.

To reduce the risk of Sofia 2 damage:

- Sofia 2 is designed for countertop operation.
- Sofia 2 is not designed to be stacked on top of each other.
- Do not obstruct the flow of air on each side of the unit.

- Maintain 6” minimum clearance on all sides including the back of the device.
- Sofia 2 is not designed to withstand moisture, extreme humidity, or extreme temperatures.
- Sofia 2 is not designed to withstand severe shock or vibration.
- Do not open or disassemble the device.

Failure to follow the precautions mentioned above will invalidate the warranty.

To reduce the risk of environmental contamination:

- Contact Quidel Technical Support at 800.874.1517 for the return or disposal of Sofia 2. See page 3 for additional contact information.
- Clean Sofia 2 per the **Maintenance and Cleaning** section of this User Manual prior to return or disposal.
- Sofia 2 must be disposed of in a safe and compliant manner. Applicable Federal, State, and Local regulatory requirements shall be followed to ensure Sofia 2 is not disposed of as municipal waste. If you are unsure of the proper methods for disposal, contact a certified waste broker for guidance.

Note: Medical equipment that may have come into contact with potentially infectious materials (e.g., patient samples, blood, serum, etc.) must be properly decontaminated prior to disposal or recycling.

Limited Warranty: For warranty information and specific coverage terms, please refer to the contract or other agreement under which the product was purchased, or contact Quidel Technical Support, your local distributor or your Quidel representative for assistance.

Introduction

Intended Use

Sofia 2 is a benchtop analyzer intended to be used with Cassette-based immunofluorescent *in vitro* diagnostic assays manufactured by Quidel Corporation. Sofia 2 is intended for professional and laboratory use.

Rx Only

After the patient sample has been added to the Test Cassette, depending upon the User's choice, the Test Cassette is either placed inside of Sofia 2 for automatically timed development (WALK AWAY Mode) or placed on the counter or benchtop for a manually timed development and then placed into Sofia 2 to be read (READ NOW Mode). Sofia 2 will read the test strip and measure the fluorescent signal by processing the results using method-specific algorithms. Sofia 2 will display the test results.

Refer to assay-specific Package Insert for details on specific tests.

Product Description

Sofia 2 uses a fluorescent tag that is illuminated by an Ultraviolet (UV) light source to generate specific results.

In each test, an internal procedural control line is also read. This ensures that sample flow has occurred within the Test Cassette to permit an accurate reading.

Sofia 2 then displays the test results to the User on the screen and automatically saves them on the device. If configured, the results may also be sent to an attached printer or stored in the cloud using Virena®.

Calibration Check and Quality Control (QC)

Sofia 2 Calibration Check and External Quality Control Tests must be performed on a periodic basis.

- **Sofia 2 Calibration Check:** Calibration Check is a required function that checks the internal Sofia 2 optics and systems. A Calibration Check must be performed every 30 days or less. A special Calibration Cassette is provided with Sofia 2. For replacement Calibration Cassettes, contact Quidel Technical Support.
- **External Quality Controls:** Refer to assay-specific Package Insert for details on specific tests.

Instructions are provided in the **Run Calibration** and **Run QC** sections.

Development Modes

When a patient sample is added to the Test Cassette, it begins to flow through the test strip. The development time required varies by test type. Refer to the assay-specific Package Insert to determine the required development time of each test and the required storage conditions of the test and external controls.

The correct development time is required to get accurate results.

Sofia 2 has been designed to operate in different development modes. The Supervisor and User can identify the mode that works best with their workflow and testing volume.

WALK AWAY Mode may be the most convenient for reading a single patient sample, as the User can walk away during the development period. Sofia 2 has the capability of two different WALK AWAY Modes: User-selected WALK AWAY Mode and LOCKED WALK AWAY Mode.

- User-selected WALK AWAY Mode may be the most convenient for reading a single patient sample, as the User can walk away during the development period. In this mode, the User dispenses the patient sample into the Test Cassette and then immediately inserts the Test Cassette into Sofia 2. Sofia 2 will automatically allow the Test Cassette to develop for the required time period (pre-programmed for each test), read the Test Cassette, analyze and interpret the data, and automatically and objectively display the test result. Depending on the test, Sofia 2 may also read the Test Cassette periodically during the development time and display a positive result prior to the final test time.
- LOCKED WALK AWAY Mode can only be selected while logged in as a Supervisor. In this mode, Sofia 2 has been locked into WALK AWAY development timing for ALL assays run on the analyzer. READ NOW development timing will not be available when this Default Mode has been selected.

READ NOW Mode may be most convenient for high volume situations as Sofia 2 can quickly read multiple patient samples sequentially. The User dispenses the patient sample into the Test Cassette. The User then **manually** times the development period **outside** of Sofia 2. This can be done on the counter or benchtop using a timer. Refer to the assay-specific Package Insert for the required development time. Once the development time is complete, the User inserts the Test Cassette into Sofia 2. Sofia 2 will immediately read and display the test result within 1 minute.

System Components

The following system components are supplied with Sofia 2:

Sofia 2

- Sofia 2 with Rechargeable Battery
- Power Adapter (Meanwell P/N: GSM25B07-P1J or equivalent)
- QuickStart Guide
- Calibration Cassette

Additional Ancillaries (optional)

- Dymo LabelWriter 450 Printer (Part #1752264)

- Dymo LabelWriter 4XL Printer (Part #1755120) *for Firmware 1.13.4 or higher only*
- Dymo Vinyl Label Roll, 2 5/16” x 4” (Part #30256)
- Replacement Battery

Contact Quidel Technical Support for additional supplies at 800.874.1517 (in the U.S.). See page 3 for additional contact information.

Sofia 2 consumable test kits, including Test Cassettes and External Quality Control materials, are supplied separately.

Consult your Quidel representative for a listing of approved Sofia 2 assays.

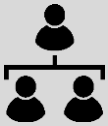
User Types

Users without Supervisor authorization have access to the following functions:

User/Operator

- Power on Sofia 2
- Perform Calibration
- Run QC (External Controls)
- Run Test with Patient Samples
- Review Data (Patient, Calibration, and QC)
- Send Data and Test Connection to Virena

Users with **Supervisor** authorization access can perform all of the following functions:



Supervisor
(Must have a valid log-in to access Supervisor Menu.)

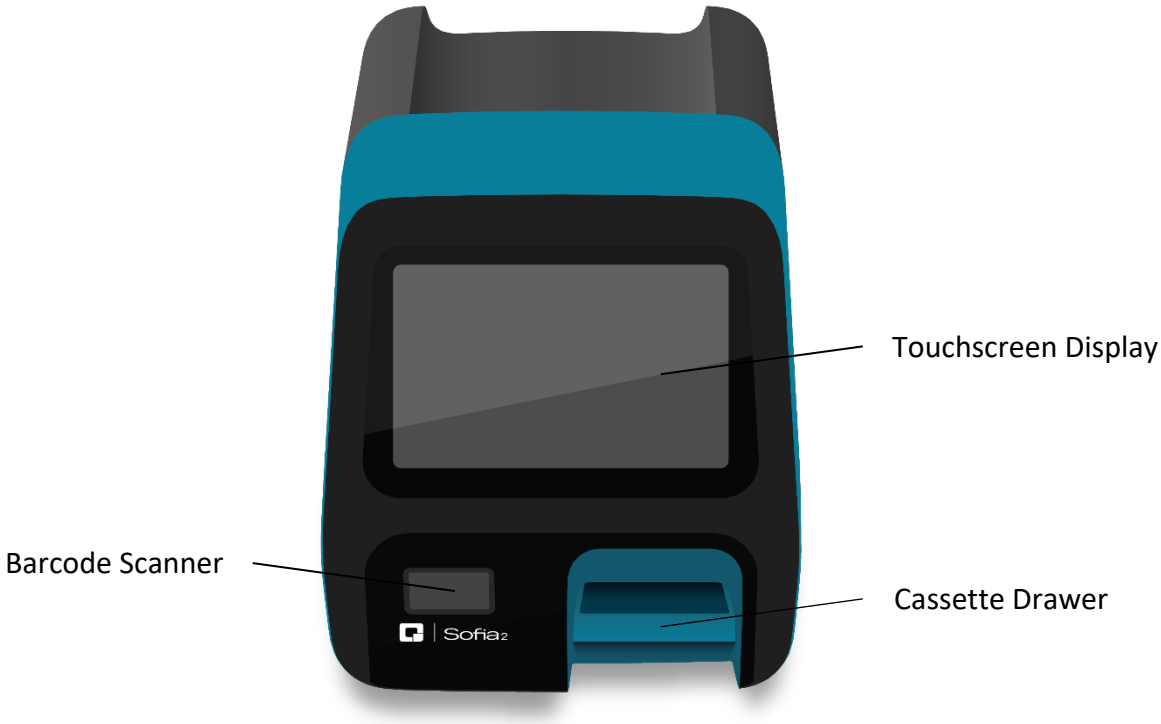
- Import Assay Methods
- Add or Delete Users
- Export and Import Settings
- Update Sofia 2 Firmware
- Import Language Files
- View Message Logs
- Review Statistics
- Change Settings

System Display

System Display

Sofia 2 contains a 4-inch color LCD display for interacting with the user interface (Figure 1).

Figure 1



Installation, Setup, and Operation

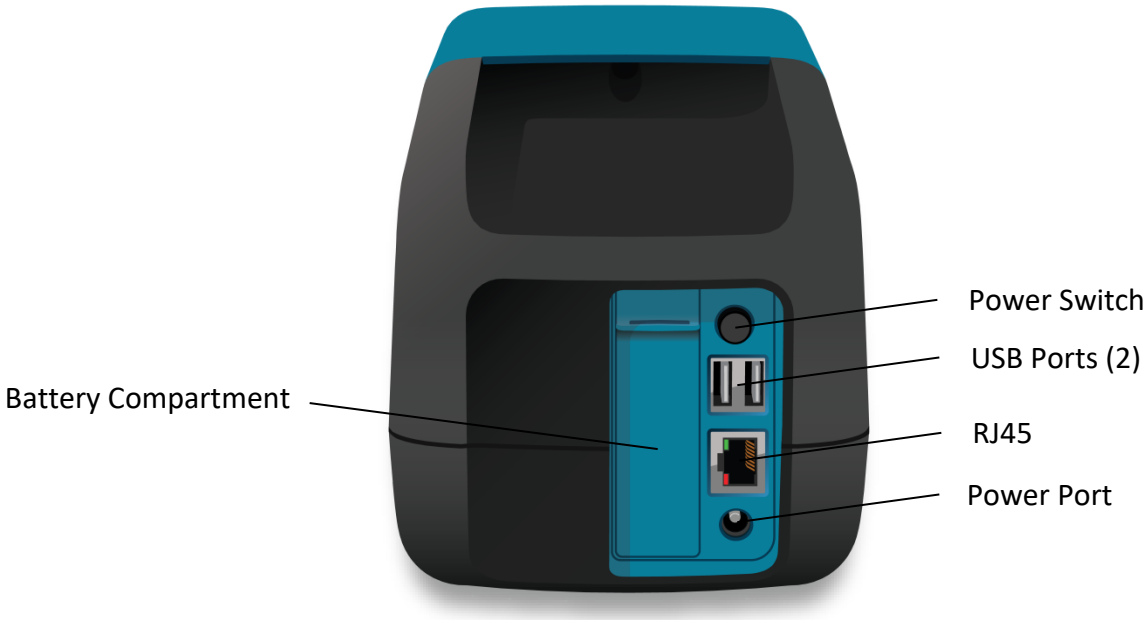
Sofia 2 Setup

- Place Sofia 2 on the benchtop. The unit is portable and can be moved to a suitable location for testing. Ensure the countertop is stable, level, dry, and free of obstructions. Avoid direct sunlight.
- Ensure the bench provides adequate space for Sofia 2 and a 6” minimum clearance around the unit. There must be space to allow adequate ventilation and to open/close the Sofia 2 drawer and access the connection ports on the back of the unit.
- Connect the AC Power Cord to the Power Adapter and ensure the cord is seated into the Power Adapter.
- Plug the Power Adapter with the round plug head into the power port on the back of Sofia 2. Then plug the AC Power Cord attached to the Power Adapter into an available electrical outlet.
- If using the optional Dymo Label Printer, connect to Sofia 2 by plugging into a USB port on the back of the instrument (Figure 2).

Power Up

Turn Sofia 2 on using the power switch located on the rear panel (Figure 2).

Figure 2



Sofia 2 will display the Power On Progress screen and complete a Power On Self-Test. Once the Power On is complete, Sofia 2 will display the Run Test screen (Figure 3) and it is ready for use.

Figure 3

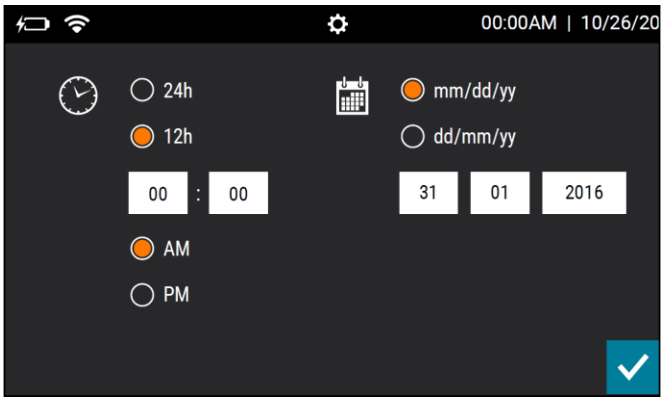
After a Firmware update, or when turning on Sofia 2 for the first time, the User may see several screens upon startup designed to personalize their Sofia 2 settings.

Zip Code:
Sofia 2 will prompt the User to enter the ZIP Code where it is located (Figure 4). Select ✔ to confirm and continue to the next screen.

Figure 4

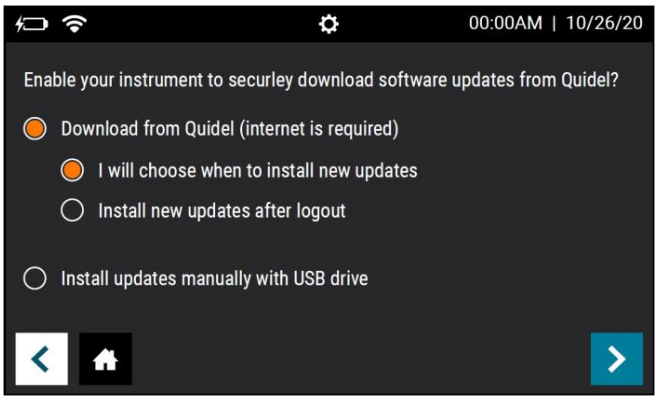
Time and Date:
After a Firmware update, the User will be prompted to verify that the time and date displayed are correct. If they are, press ✔ to confirm the settings (Figure 5). If changes are required, please refer to the **Set Time and Date** section on page 21 of this User Manual for step-by-step instructions detailing how to update the Time and Date settings. Once complete, press ✔ to confirm the settings.

Figure 5



Software Updates:
Sofia 2 will prompt the User to set their software update settings (Figure 6). The "Download from Quidel" options enable Sofia 2 to automatically download software updates directly from the cloud via a Wired Ethernet or Wi-Fi connection.

Figure 6



To Connect to Quidel, Users will select their preferred installation method under "Download from Quidel" and press ›. If the Sofia 2 is already connected to the internet the User will receive confirmation of successful registration and will push › again to advance to the Run Test screen.

If the Sofia 2 is not already connected to the internet, Sofia 2 will prompt the User to set up their network and will take the User to the **Network Interface** screen to do so (page 21).

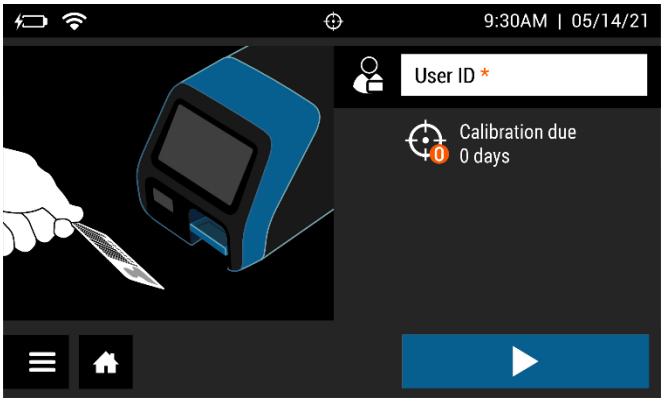
Users also have the option to opt-out of connecting their instrument to Quidel and to continue to download and install updates manually with a USB drive. Those who decide not to Download from Quidel will select "**Install updates manually with a USB drive**", then press › to return to the Run Test screen.

For more information on each option, refer to **Connect to Quidel** on page 25.

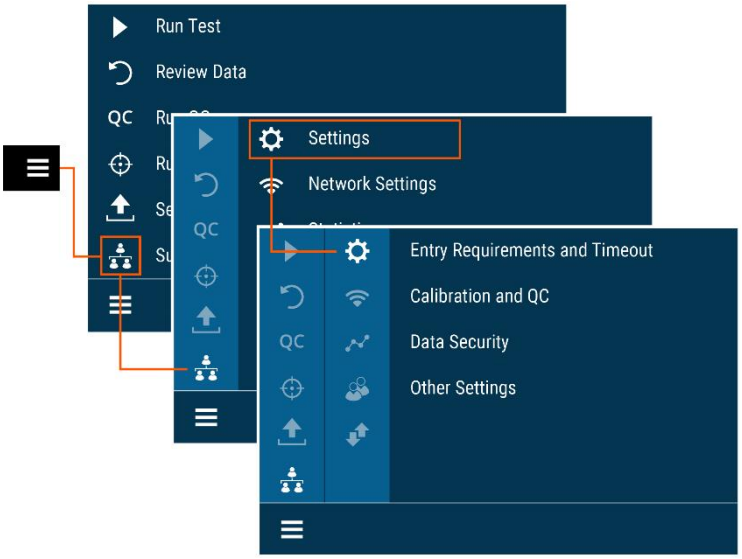
Calibration Check

A Calibration Check must also be performed before using Sofia 2 for the first time (Figure 7). **The default Supervisor ID (1234) will be used for the Calibration Check.**

Figure 7



Supervisor Menu



Logging in as Supervisor

The **Supervisor Menu** allows the Supervisor to access additional functionality and security options depending on the work environment and the location of Sofia 2.

Settings

Entry to the **Settings** menu is accomplished by logging in as the Supervisor. Sofia 2 comes from the manufacturer with a default Supervisor login ID which should be changed when

Note: If the factory default ID is deleted and all other Supervisor codes have been misplaced or forgotten, please call Quidel Technical Support for a 1-day temporary Supervisor ID code that will allow the User to create a new Supervisor ID code. Contact Quidel Technical Support for assistance at 800.874.1517 (in the U.S.). See page 3 for additional contact information.

Sofia 2 is initially installed at the customer site. **The default Supervisor ID is 1234.**

Set Entry Requirements

Setting the Entry Requirements allows the Supervisor to control what information is provided before running a test.

> **Note:** User ID and Order Number can be set to **Required** or **Optional**. Patient ID can be set to **Required**, **Optional** or **Disabled**. When set to **Required**, the fields must be entered for the User to run a patient test.

When the Entry Requirements are complete, continue to Set Default Mode and Timeout using ❯.

Set Default Mode and Timeout

Default Mode

When the Supervisor sets Sofia 2 to a certain default mode, this will be the normal operating mode unless otherwise changed by the Supervisor or Operator.

Select either **WALK AWAY**, **READ NOW,** or **LOCKED WALK AWAY** development mode.

Idle ID Timeout

The Idle ID timeout sets the amount of time that a User ID remains entered and active as a User in running various tests and activities. After the timeout period has expired, the User must re-enter their ID number.

Using the on-screen keypad, enter the number of minutes for the timeout from 1-20. Press ✔ to confirm when changes are complete to return to the Run Test screen.

Calibration and QC

Calibration Reminder

Using the on-screen keypad, enter the number of days for the Calibration reminder interval from 2-30. When the selected number of days remains until the required Calibration, the reminder will appear next to the menu icon on the Run Test screen. Press ✔ to confirm when changes are complete to return to the Run Test screen.

Data Security

The Data Security screen allows the Supervisor to select the number of patient results that remain stored on Sofia 2. The Supervisor may also choose whether patient data is saved along with test data to an attached USB flash drive.

In the **Stored Patient Data** field, use the on-screen keypad to enter the number of patient results saved on the device from 1-1000.

In the **Save Patient Data to USB** field, select **On** or **Off.** If set to **On,** patient data will be saved along with test records when exporting to an attached USB flash drive. A USB flash

drive must be attached prior to beginning a test for that result to be saved. Press ✔ to save the configuration and return to the Run Test screen.

Other Settings

Set Site Name and ZIP Code

The Site Name and ZIP Code settings set the name and location of the clinic, hospital, lab, or physician's office where Sofia 2 is being used.

In the field for **Site Name**, use the on-screen keypad to enter the location name up to 20 characters and/or spaces.

To delete a letter, press ⬅ on the keypad.

Pressing ✖ at any time cancels the changes and returns the Site Name to the previous setting.

In the field for ZIP Code, use the on-screen keypad to enter the 5-digit ZIP Code. The ZIP Code entered for the facility in MyVirena must be used to successfully configure Virena.

When the Site Name and ZIP Code are complete, continue to Set Language and Sound by pressing ❯.

Set Language and Sound

Sofia 2 can be set to display languages that were previously installed from the Export, Import, Delete menu (page 31).

Use ❮ or ❯ to select the appropriate language. This language will be displayed once the User returns to the Run Test screen.

Setting the Sound on Sofia 2 will allow the Supervisor to turn on 🔊 or off 🔇 the beep sound for notifications or when a barcode is scanned.

When the Sound is set, continue to set Barcode and Autoprint using ❯.

Set Barcode Mode and Autoprint Mode

The Barcode Mode option allows for automatic or manual barcode scanning. When set to automatic, the barcode scanner will always be on. When set to manual, the barcode scanner will be off until the barcode scanner icon, , is pressed. This icon will be found on the home screen. Press and the barcode scanner will illuminate for five seconds.

The Autoprint Mode option allows for the automatic printing of Patient, QC, and Calibration results if the optional Dymo Labelwriter 450 is attached.

When the Barcode and Autoprint modes are set, continue to set Time and Date using ❯.

Set Time and Date
The Time option allows for two different time formats to suit specific country requirements.

The User can change the displayed time format to 12h or 24h format.
In the field, select either **12h** or **24h**. Use the on-screen keypad to enter the correct time.

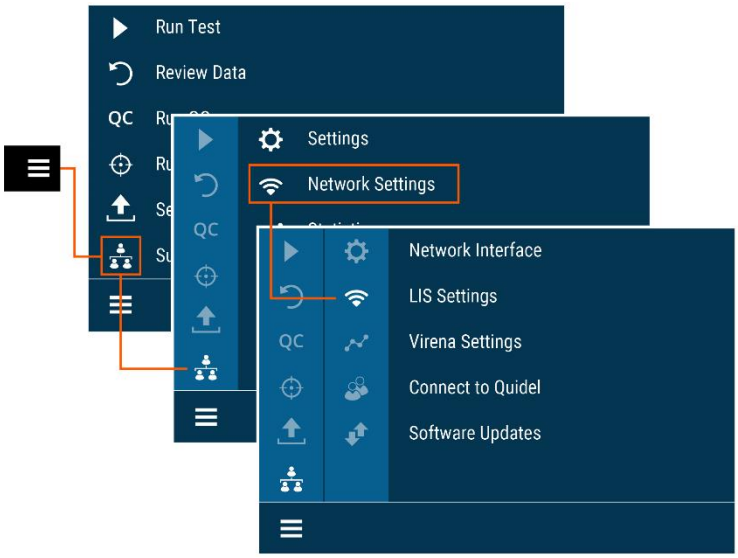
When the 12h format is selected, also select **AM** or **PM**. When the 24h format is selected, the **AM/PM** buttons are non-functional. If an invalid time is added, the field will highlight in red and the ✔ will not be available.

The Date option allows for two different date formats to suit specific country requirements.

In the field, the User can select the date format as either **mm/dd/yy** or **dd/mm/yy** format. Use the on-screen keypad to enter the correct date. If an invalid date is added, the field will highlight in red and the ✔ will not be available.

Press ✔ to confirm when changes are complete to return to the Run Test screen.

Network Settings



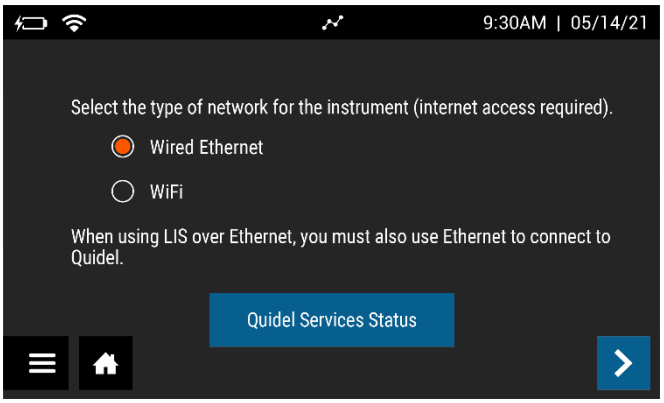
Network Interface

Wired Ethernet: For **Set IP Address**, select **Manual** or **DHCP**. If **DHCP** is selected, select ✔ to test the connection and return to the Run Test screen. If **Manual** is selected, press › to continue to the next screen. Using the on-screen keypad, enter information for **IP Address**, **Subnet Mask**, and **Gateway.** Press › to continue to the next screen. Using the on-screen keypad, enter the information for **Primary DNS** and **Secondary DNS**. Select ✔ to test the connection and return to the Run Test screen.

Wi-Fi: Select your **Wi-Fi network** from the list of available options while considering each network's signal strength. Enter the Wi-Fi Password and press to test the connection. Press ✔ to save the configuration and return to the Run Test screen.

The **Quidel Service Status** button allows the User to check their Network Type, Internet Access, Quidel Service Access, and the progress of any Firmware downloads that are currently in progress. This screen can be helpful for calls with Quidel's Customer Support team (Figure 8).

Figure 8



LIS Settings

Use the on-screen keypad to enter the **LIS IP Address**. **LIS Port** is pre-populated, and no additional user input is needed (Figure 9).

Figure 9

Press > to continue to the next screen. For **Auto Send**, select either **On** or **Off**. If set to **On**, test results will automatically be sent to the LIS as tests are run. If set to **Off**, test results will need to manually be sent to the LIS. See the **Send Data** section on page 40 for additional information. Press > to continue to the next screen and select either **ASTM** or **POCT1-A** as your preferred connection protocol. Press to test the connection. Select ✔ to confirm configuration and return to the Run Test screen.

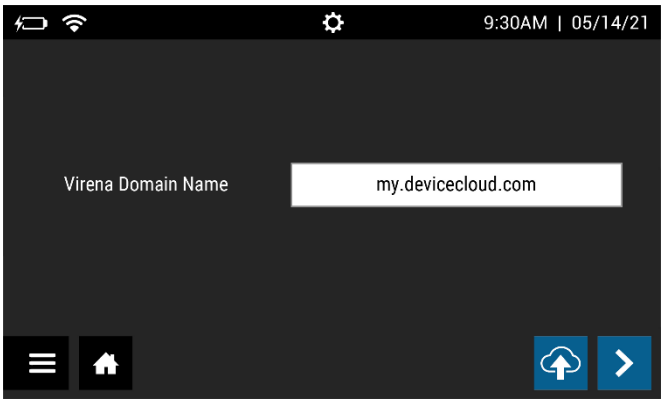
The option to test the connection by pressing on the LIS Settings screen is only available for Sofia 2's that are Connected to Quidel (page 25). Users with a Sofia 2 that is not Connected to Quidel may also refer to the **Send Data** section on page 40 for an alternative way to check their LIS connection.

Virena Settings

Before configuring Virena, ensure that the correct ZIP Code has been entered upon initial startup or in the Other Settings menu. See page 20 for additional information.
On the first Virena Settings screen, **Virena Domain Name** is pre-populated, and no additional user input is needed (Figure 10).

> **Note:** Virena functionality using a wireless cellular connection is currently only available within the US. Presently, outside of the US, Virena must be configured using an Ethernet or WiFi connection.

Figure 10

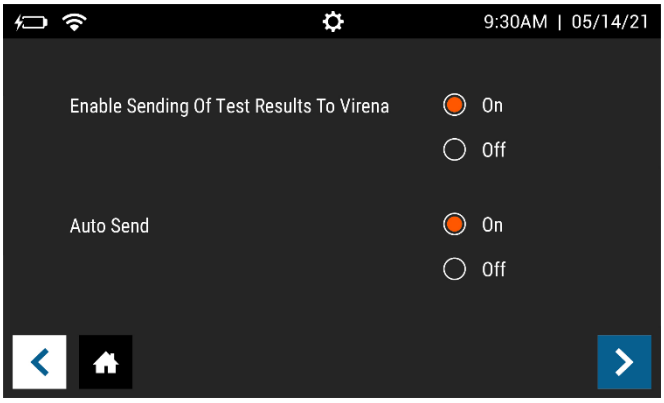


Press > to continue to the next screen.

For **Enable Sending Of Test Results To Virena**, select either **On** or **Off**. For **Auto Send**, select either **On** or **Off** (Figure 11). If Auto Send is set to on, Sofia 2 will send results to Virena when idle. If Auto Send is set to off, the instrument will never send results unless the User manually decides to do so via the **Send Data** screen (page 40). If **Enable Sending Of Test Results To Virena** is set to **Off**, the **Auto Send** options will no longer be selectable because no results can be sent to Virena.

Upon activation of Sofia 2's network capabilities, Sofia 2 will transmit data, de-identified in accordance with 45 C.F.R. § 164.514(b)(1), from the customer's Sofia 2 to Quidel's network of secured, third-party remote hosted servers.

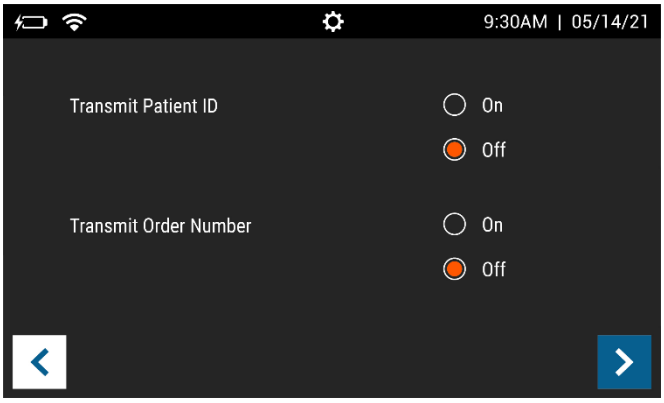
Figure 11



Press > to continue to the next screen.

For **Transmit Patient ID**, select either **On** or **Off**. For **Transmit Order Number**, select either **On** or **Off** (Figure 12). This information is used for study purposes only and this information will not be transmitted regardless of the selection.

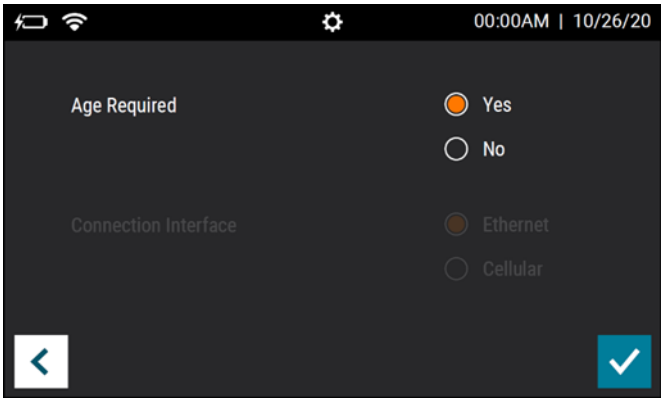
Figure 12



Press > to continue to the next screen.

For **Age Required**, select either **Yes** or **No.** If set to **Yes**, the User will need to enter the patient's age prior to running each test (Figure 13).

Figure 13

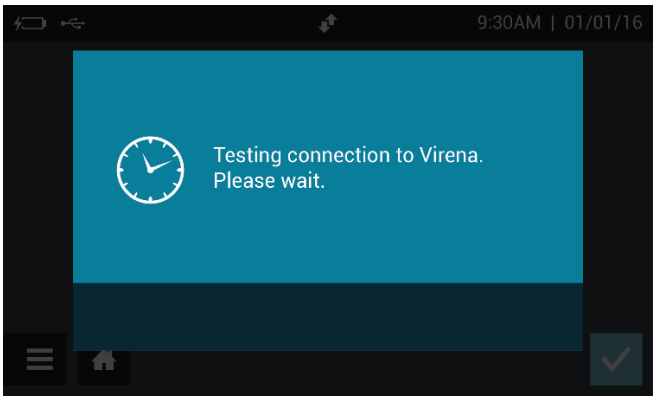


Select ✔ to confirm configuration and return to the Run Test screen.

Test Virena Connection

The final step of Virena configuration is to test the connection. To do this, go to the **Send Data** screen (page 40). Select **Test Connection** and press ☁ to begin the connection test (Figure 14).

Figure 14



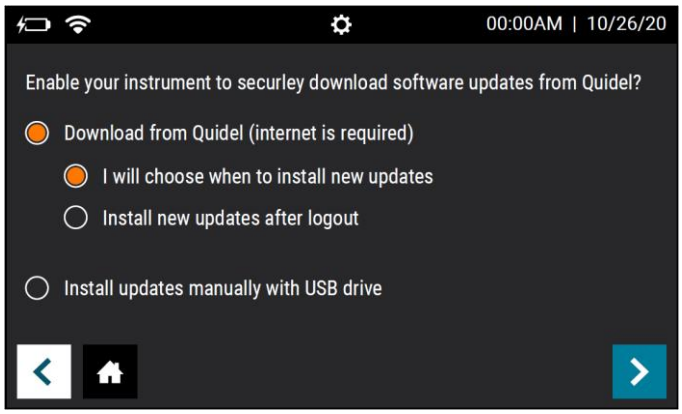
If the Sofia 2 is Connected to Quidel, the User can also test their Virena connection by pressing the icon on the Virena Settings home screen (seen in Figure 10). However, the will only be visible on this screen if the Sofia 2 is Connected to Quidel. Instructions on how to Connect Sofia 2 to Quidel can be found in the next section.

If successful, the on-screen pop-up will display **Test connection success**. If unsuccessful, the on-screen pop-up will display **Test connection error**. If the connection test is unsuccessful after a second attempt, please contact Quidel Technical Support.

Connect to Quidel

The Connect to Quidel screen allows the Supervisor to automatically download Sofia 2 software updates directly to their device from the cloud via a Wired Ethernet or Wi-Fi connection (Figure 15).

Figure 15



To Connect to Quidel, Users will select their preferred installation method under “Download from Quidel”.

- **I will choose when to install new updates** - Users will be alerted by the Load data icon on their home screen when an update is available for installation. At their convenience, the User can navigate to **Software Updates** (page 26) and press “Update Now” to install the update.

- **Install new updates after logout** - Sofia 2 will automatically install software updates at a pre-set time after logout. If the User wishes to modify this pre-set update time, they can do so via the **Software Updates** screen in the section below.

Once the preferred "Download from Quidel" method has been selected, press › to save the configuration and test the Network Connection. If the Sofia 2 is already connected to the internet the User will receive confirmation of successful registration and will push › again to advance to the Run Test screen.

If the Sofia 2 is not already connected to the internet, Sofia 2 will prompt the User to set up their network and will take the User to the **Network Interface** screen to do so (page 21). Users also have the option to not connect their instrument to Quidel and to continue to download and install updates manually with a USB drive. Those who decide not to Download from Quidel will select "**Install updates manually with a USB drive**", then press › to return to the Run Test screen.

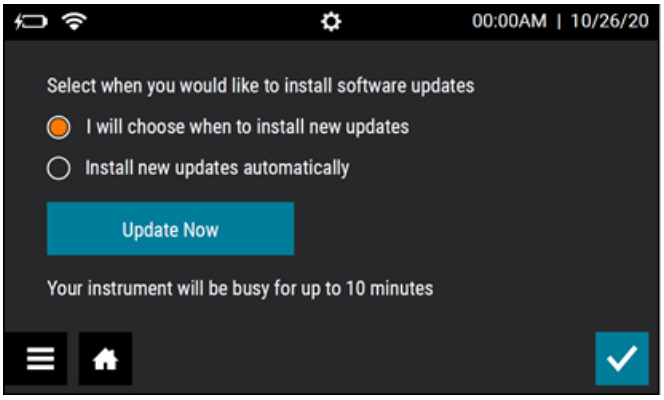
Software Updates

The Software Updates screen is only displayed if the Sofia 2 is Connected to Quidel.

For **"Select when you would like to install software updates"** the User should select the option that best fits their needs.

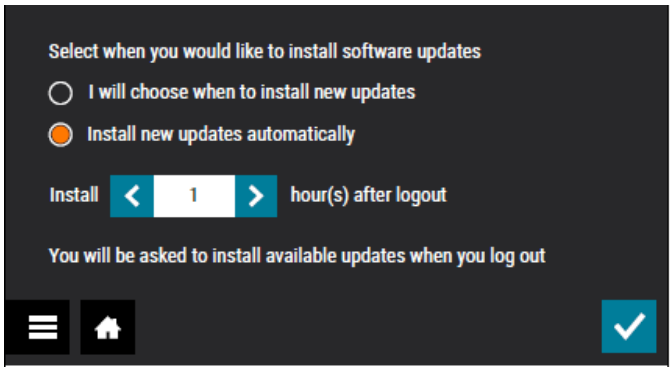
If the User selects "I will choose when to install new updates" they will press ✔ to confirm the selection and return to the Run Test screen. With this option, Sofia 2 will alert the User when a new update is available with the Load data icon ⬇ on the home screen. When the User is ready to install the update, they will revisit this screen and press "Update Now". The "Update Now" button will only appear if a Software Update is available (Figure 16).

Figure 16

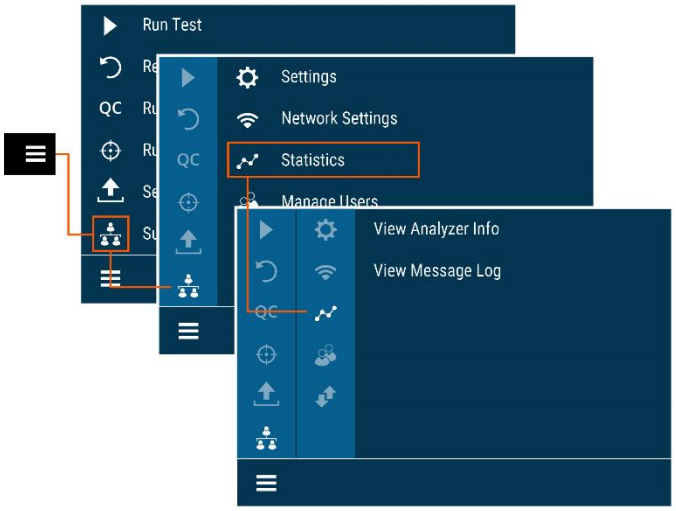


If the User selects "Install new updates automatically" a dropdown menu will appear to allow the User to select how many hours after logout they would like Sofia 2 to wait before the software installation begins (Figure 17). After the selection is made, press ✔ to save the configuration and return to the Run Test screen.

Figure 17



Statistics

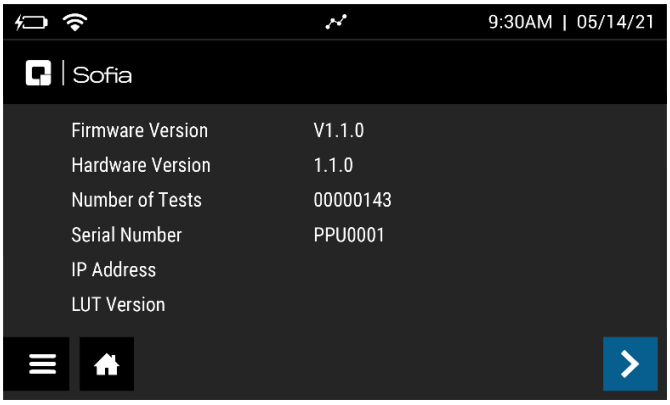


View Analyzer Info

The first screen of View Analyzer Info displays the **Firmware Version**, **Hardware Version**, **Number of Tests**, **Serial Number, IP Address,** and **LUT Version** (Figure 18).

Select > to continue to the next screen or ⌂ to return to the Run Test screen.

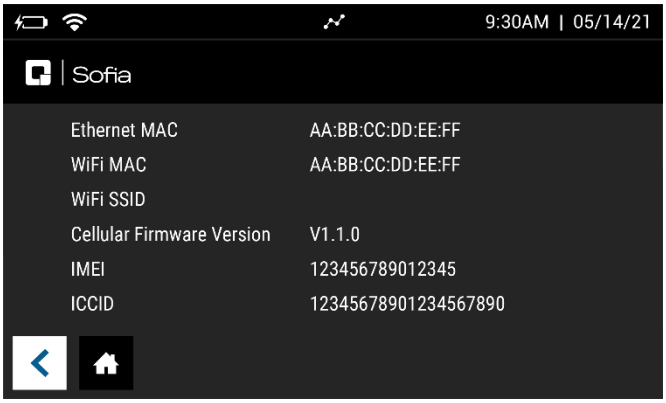
Figure 18



The second screen of View Analyzer Info displays the **Ethernet MAC, Wi-Fi MAC, Wi-Fi SSID, Cellular Firmware Version, IMEI,** and **ICCID** (Figure 19).

Select to return to the Run Test screen.

Figure 19

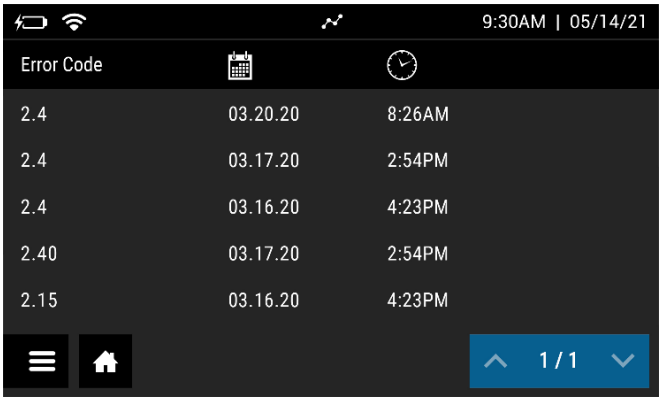


View Message Log

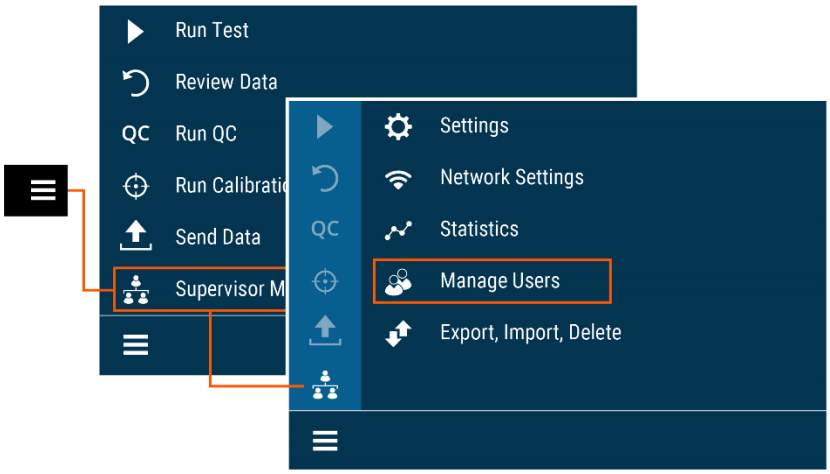
View Message Log displays the Error Code, Date, and Time (Figure 20).

Select to return to the Run Test screen.

Figure 20



Managing Users



Add User

To add a User, select + on the Add User screen (Figure 21).

Use the on-screen keypad or barcode scanner to enter the User ID. User ID must be at least 4 digits.

Choose User Type by selecting Operator or Supervisor.

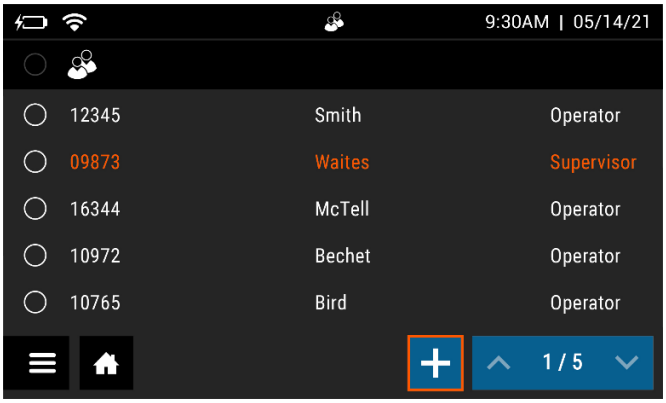
Enter the Name of the new User using the on-screen keypad.

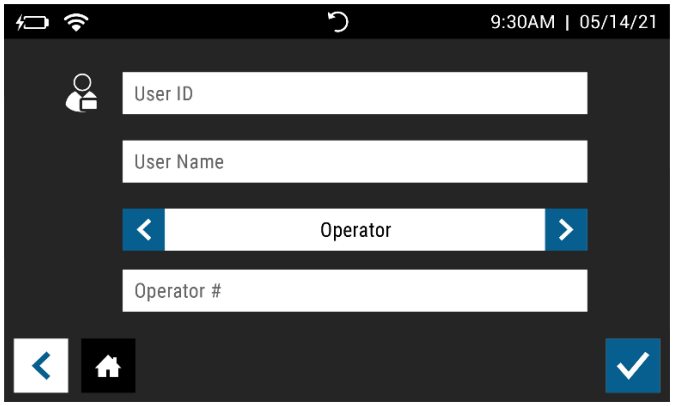
To delete a letter, press ⬅ on the keypad.

Pressing ✕ at any time cancels all previous changes and returns the Name to the previous setting.

When the name is complete, press ✓.

Figure 21

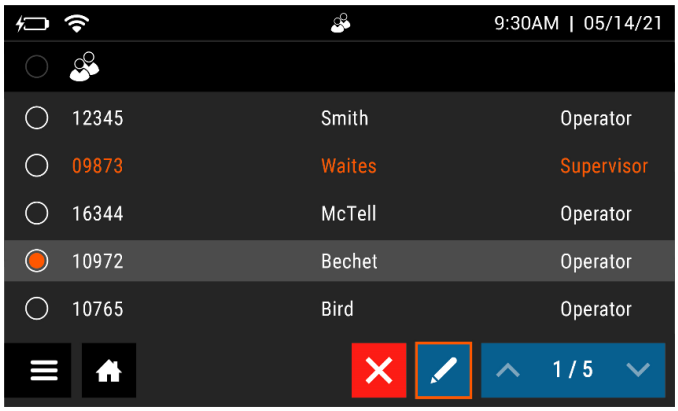




Edit User

Select a User by touching anywhere within the row, then select ✎. Use the on-screen keypad to edit the User information (Figure 22).

Figure 22

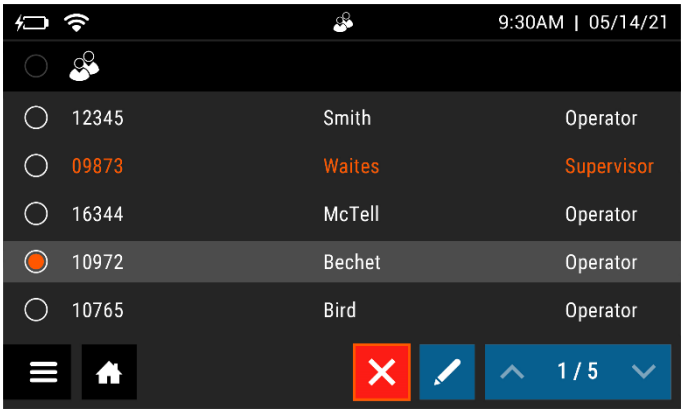


When the information is complete, press ✔.

Delete User

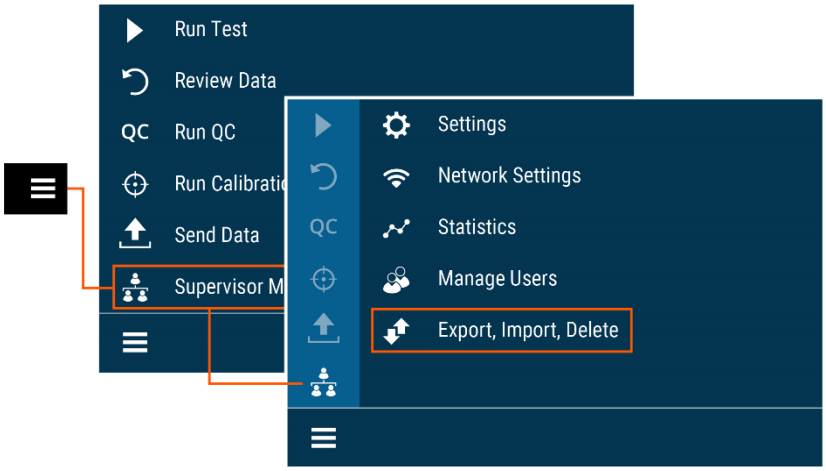
Select a User by touching anywhere within the row, then select ✖ to delete User (Figure 23). This action cannot be undone. If a User is deleted by mistake, re-add the User as described above.

Figure 23



Note: Maximum number of Users is 1000.

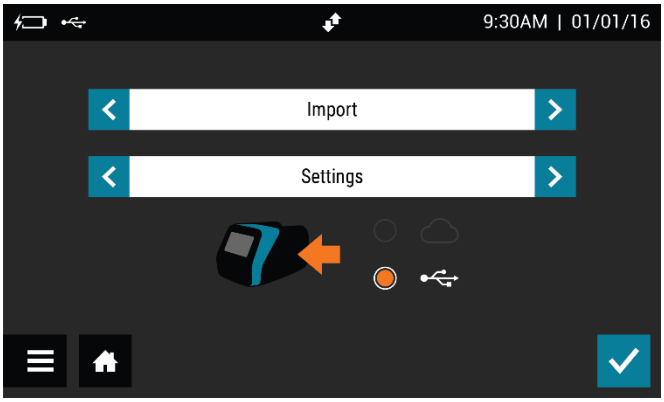
Export, Import, Delete



Export, Import, or Delete Data Types

Supervisors may export, import, or delete data to/from either a USB flash drive or the device (Figure 24). Most standard USB flash drives may be used with Sofia 2.

Figure 24



Export Settings to USB Flash Drive

Supervisors may export the settings of one Sofia 2 to import to another Sofia 2.

Use the < or > in the first field to select **Export**.

In the next field, use < or > to select **Settings**.

Insert a USB flash drive and select , then select ✔ to export Sofia 2 settings data. Once complete, it is safe to remove the USB flash drive.

When cloning Sofia 2, all Users will transfer over. User history, lot status, QC, and test data will not transfer over.

Import Settings from USB Flash Drive

To import the settings of one Sofia 2 onto another Sofia 2, insert the USB flash drive from the "Master" Sofia 2 that has the settings you wish to duplicate.

Use ‹ or › in the first field to select **Import**.

In the next field, use ‹ or › to select **Settings**.

Ensure that •⇠ is selected, then select ✔ to import Sofia 2 settings data. Once complete, it is safe to remove the USB flash drive.

Note: When importing settings from one Sofia 2 to another, patient and QC results on the incoming Sofia 2 will be deleted.

Export Patient Data to USB Flash Drive

Supervisors may export the patient data from Sofia 2 to a USB flash drive.

Use the ‹ or › in the first field to select **Export**.

In the next field, use ‹ or › to select **Patient Data**.

Insert a USB flash drive and select •⇠**,** then select ✔ to export Sofia 2 settings data. Once complete, it is safe to remove the USB flash drive.

Sofia 2 Firmware and Assay Methods

Occasionally, Quidel will release Firmware and Assay Method updates to improve the functionality of Sofia 2. It is recommended that Users ensure that their Sofia 2 has the most current firmware, assay methods, and language files by Connecting their Sofia 2 to Quidel via the **Connect to Quidel** screen on page 25 of this User Manual. If the Sofia 2 is Connected to Quidel the instrument will automatically download these updates.

If the User opts out of Connecting their Sofia 2 to Quidel, they may still get these updates by creating an account and registering their Sofia 2 at **myquidel.com.** After the Sofia 2 is registered at **myquidel.com**, Supervisors may install the updates using a USB flash drive. To do this, follow the instructions on **myquidel.com.**

Import Firmware from USB Flash Drive

Insert USB flash drive with the firmware to install.

Use ‹ or › in the first field to select **Import**.

In the next field, use ‹ or › to select **Firmware**.

Ensure that is selected, then press ✔ to import Sofia 2 firmware. Sofia 2 will complete a self-installation and then power up in the normal startup screen. Once complete, it is safe to remove the USB flash drive.

Import Assay Methods from USB Flash Drive

Insert USB flash drive with the assay method to install.

Use < or > in the first field to select **Import**.

In the next field, use < or > to select **Assay Methods**.

Ensure that is selected, then press ✔ to import Sofia 2 assay methods. Sofia 2 will complete a self-installation and return to the previous screen. Once complete, it is safe to remove the USB flash drive.

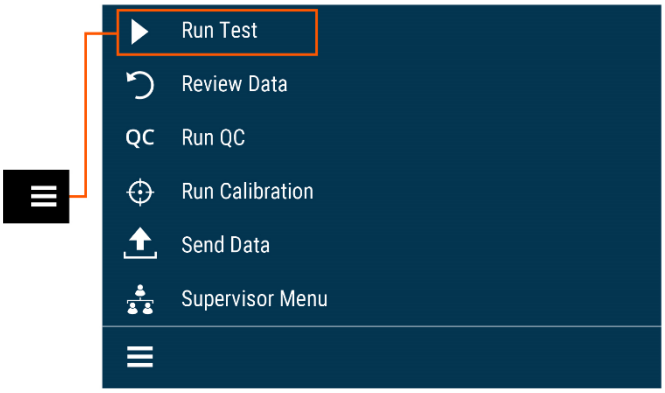
Import Language Files from USB Flash Drive

Insert USB flash drive with the language file to install.
Use < or > in the first field to select **Import**.

In the next field, use < or > to select **Language Files**.

Ensure that is selected, then press ✔ to import Sofia 2 language files. Sofia 2 will complete a self-installation and return to the previous screen. Once complete, it is safe to remove the USB flash drive.

Run Test (Patient Specimens)



The Run Test screen can also be accessed by selecting on most screens.

Enter the User ID

The User ID can be entered using the barcode scanner or manually using the on-screen keypad.

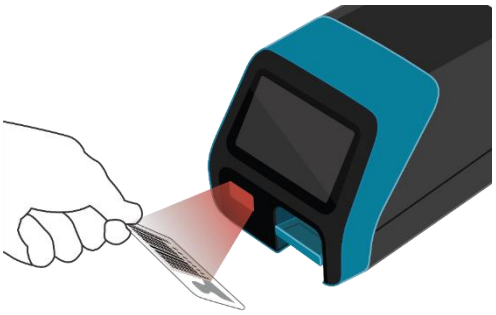
Select the **User ID** field on the Run Test screen. Use the barcode scanner (Figure 25) to scan the barcode from a User's ID Card or manually enter the data using the on-screen keypad on Sofia 2.

Enter the Patient ID

Patient ID can be entered using the barcode or manually using the on-screen keypad.

Select the **Patient ID** field on the Run Test screen. Use the barcode scanner (Figure 25) to scan a Patient ID barcode from a patient chart or other source or manually enter the data using the on-screen keypad on Sofia 2.

Figure 25



Enter the Order Number, if applicable

The Order Number can be entered using the barcode or manually using the on-screen keypad.

Select the **Order Number** field on the Run Test screen. Use the barcode scanner to scan an order number barcode from a patient test requisition or other source or manually enter the data using the on-screen keypad on Sofia 2.

Change Development Mode

Select the desired Development mode: **WALK AWAY** or **READ NOW** (See the description of the WALK AWAY and READ NOW development modes on page 12).

IMPORTANT: Refer to the assay-specific Package Insert for each specific test for instructions on preparing Test Cassettes with patient samples.

The current development mode will be highlighted below the Order Number field (Figure 26). If the highlighted mode is the desired mode, no changes are required.

Figure 26

Test Procedure

In the **WALK AWAY** development mode, proceed directly to the next steps as soon as the patient specimen has been processed and added to the Test Cassette. Do not let the Test Cassette develop outside Sofia 2.

In the **READ NOW** development mode, remember to first manually time the test development of the patient specimen Test Cassette outside of Sofia 2 at room temperature for the required period of time (as defined in the assay-specific Package Insert) **before** proceeding to the next step.

To access additional detail on the two development modes from the Run Test screen select ?. To return to the Run Test screen from the pop-up, select ✔.

Press ▶

After ID information is entered and development mode is selected, press ▶ to advance to the next screen.

If Virena has been configured, the User will advance to the Patient Information screen where additional patient information may be entered.

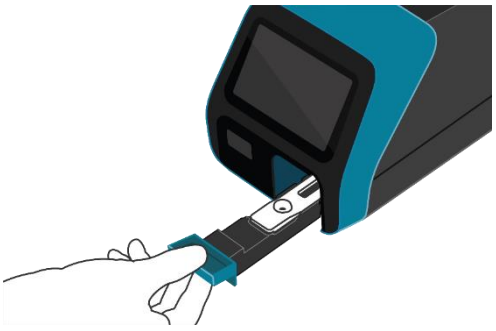
If **Age Required** has been set to **Yes**, the User will be asked to enter the patient's age before advancing. Refer to the **Virena Settings** section on page 23 for more information.

Press ❯ to advance to the next screen and gently pull open the Sofia 2 drawer.

> **Note:** If Virena is not configured, the User will advance directly to the insert cassette screen after pressing ▶.

Insert the Test Cassette into the drawer and gently close the drawer (Figure 27).

Figure 27



Upon closing the drawer, Sofia 2 will start automatically and display the progress on the screen.

Patient Test Results

When the test is complete, the results for both the patient specimen test(s) and the internal procedural control will be displayed on the Sofia 2 screen and automatically saved on the device.

If configured, results may also be stored in the cloud using Virena or transmitted to the LIS.

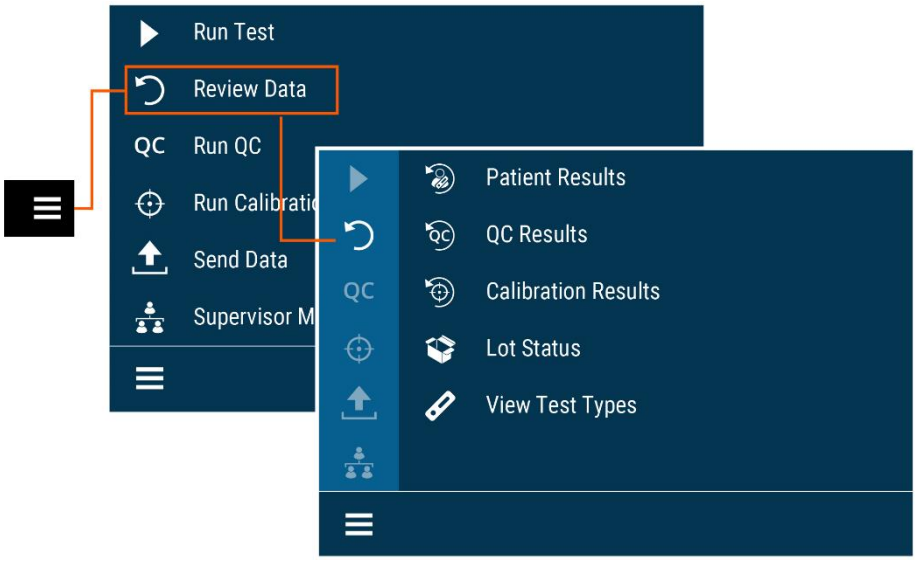
The results may be also be printed on an attached printer by selecting .

Refer to the assay-specific Package Insert for details on how to interpret results for specific tests.

> **Note:** Once results have been generated for an individual Test Cassette, Sofia 2 will no longer accept that Cassette a second time.

If the procedural control is , repeat the test with a new patient sample and a new Test Cassette. To run another patient specimen, select to return to the Run Test screen.

Review Data

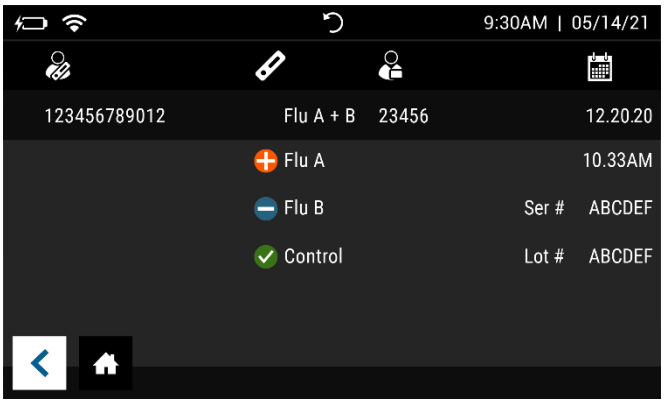


Review Patient Results

Patient Results include the records for previously run patient tests.

In any list of Patient Results, you may show the detailed results by selecting the result to view (Figure 28).

Figure 28



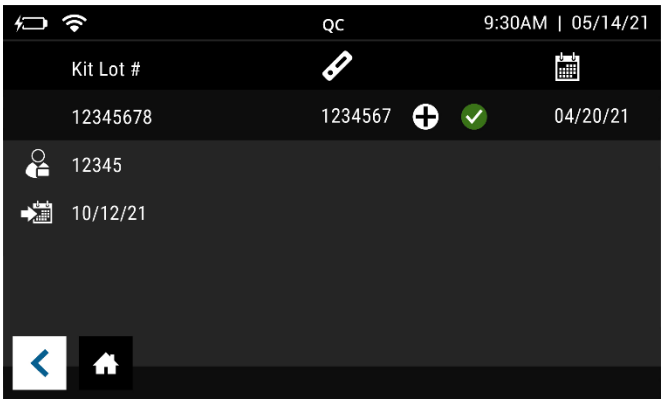
Select to return to the Run Test screen.

Review QC Results

QC Results include the records for previously run QC (Positive and Negative Control) tests.

The operator can locate QC result details in the same manner as Patient Test Results (Figure 29).

Figure 29



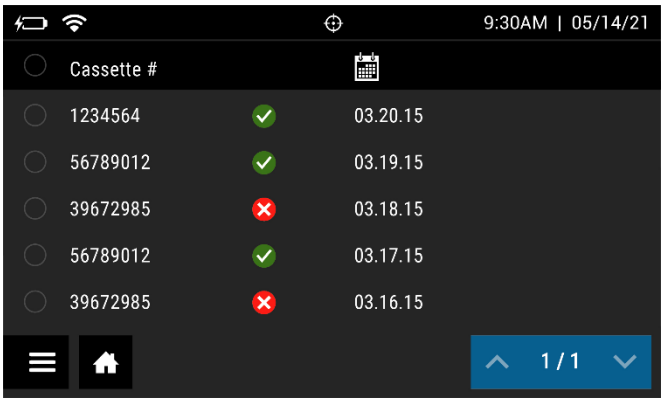
Select to return to the Run Test screen.

Review Calibration Results

Sofia 2 Calibration Results include the records for previously run Calibration tests.

A list of the Calibrations performed will be displayed (Figure 30).

Figure 30



Select to return to the Run Test screen.

View Lot Status

QC Lot Status

QC Lot Status displays the QC Kit/Lots of assays and their expiration dates. This information is captured by Sofia 2 when Quality Controls are run.

A list of the Kit/Lots that have been processed by the QC procedure will be displayed along with the expiration date.

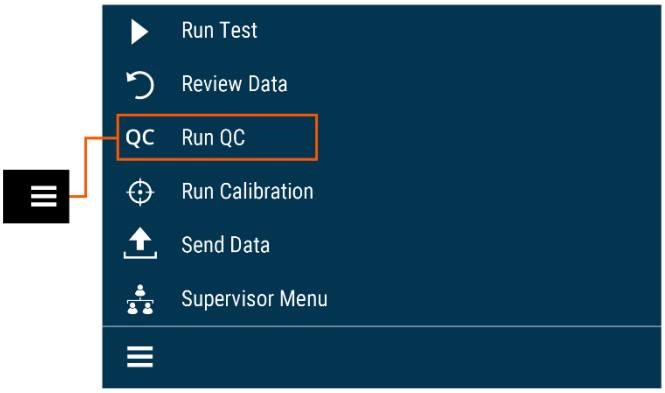
Select to return to the Run Test screen.

View Assay Methods

A list of the installed Assay Methods and Version number loaded is displayed.
Select to return to the Run Test screen.

Note: Results can be reprinted from the Review Data screen by pressing on Sofia 2's with Firmware 1.13.4 or higher.

Run QC



External Quality Control (QC) may be tested to demonstrate that the assay-specific reagents, Test Cassettes, and assay procedures are performing properly.

To run the External Controls, refer to the assay-specific Package Insert for each specific test for step-by-step instructions.

Note: When running Positive and Negative controls with a qualitative test, the Positive Control must be tested first before the Negative Control.

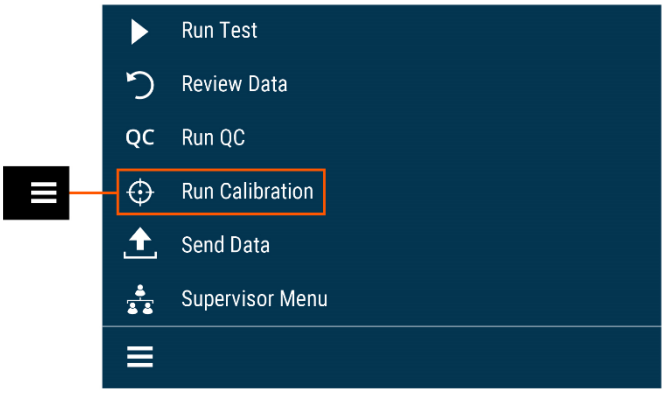
QC Results

Once the QC run is complete, the system will display either a valid result, , or an invalid result, .

Select to complete the QC process and return to the Run Test screen.

If the QC controls do not pass, repeat the external control testing process, or contact the Supervisor or Quidel Technical Support at 800.874.1517 (in the U.S.) for assistance before testing patient specimens. See page 3 for additional contact information.

Run Calibration



Calibration Check is a required function that ensures optimal performance by checking the internal Sofia 2 optics and functions.

IMPORTANT: Calibration Check must be performed within 30 days, prior to testing any patient sample.

Refer to the assay-specific Package Insert for Calibration Check frequency.

Perform Sofia 2 Calibration Check

Use the specific Calibration Cassette included with Sofia 2 for the Calibration Check. For replacement Calibration Cassettes, please contact Quidel Technical Support.

Following the prompts, insert the Calibration Cassette into Sofia 2 and gently close the drawer. Sofia 2 will perform the Calibration Check automatically.

Select to return to the Run Test screen after Calibration is completed.

Caution: Store the Calibration Cassette in the provided storage pouch at room temperature (15°C to 30°C) between uses. Improper storage could damage the Calibration Cassette, which may lead to a failed Sofia 2 Calibration Check. Do not touch the read window of the Calibration Cassette as this may impact the results.

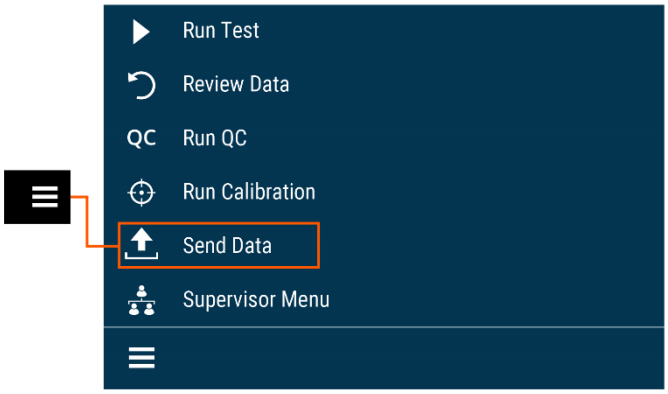
Calibration Results

Sofia 2 displays results as either or indicating that the Calibration Check is completed.

The Calibration results are stored and can be recalled with the **Review Calibration Results** function of Sofia 2 from the **Review Data** menu (page 36).

Note: If Calibration Check does not complete successfully, notify the on-site Supervisor, or contact Quidel Technical Support for assistance at 800.874.1517 (in the U.S.). See page 3 for additional contact information.

Send Data



For **Send Data**, the following options will be displayed on the screen:

- Last Result
- All Results
- Test Connection

To manually send data to Virena, select one of the options above then press . If data was sent successfully, ✔ will appear on the screen. If data was not sent successfully, the message **Send To Virena Error** will appear. Confirm Virena configuration and re-attempt to send data. If unsuccessful after a second attempt, contact Technical Support.

To manually send data to the LIS, select one of the options above then press . If data was sent successfully, ✔ will appear on the screen. If data was not sent successfully, the

message **Send To LIS Error** will appear. Confirm configuration and re-attempt to send data. If unsuccessful after a second attempt, contact Technical Support.

Shutdown

Turn off the unit by holding the power switch in the rear of the unit. The shutdown is complete when the screen goes dark.

Maintenance and Cleaning

Maintenance

Note: Sofia 2 must be sent to Quidel if maintenance is required. The User should not attempt any maintenance except for changing the battery and cleaning the external surfaces and Cassette drawer.

Battery Power

Battery Intended Use

Sofia 2 includes a rechargeable battery. The battery will automatically charge while plugged into AC power. Sofia 2 will automatically switch to battery power when AC power is not available.

Battery Replacement

Sofia 2 is shipped with an internal LiPo rechargeable battery with an expected life of approximately three years.

Use only a Quidel-supplied Sofia 2 replacement battery.

To optimize instrument performance and charging, it is recommended that the battery remain installed in the instrument.

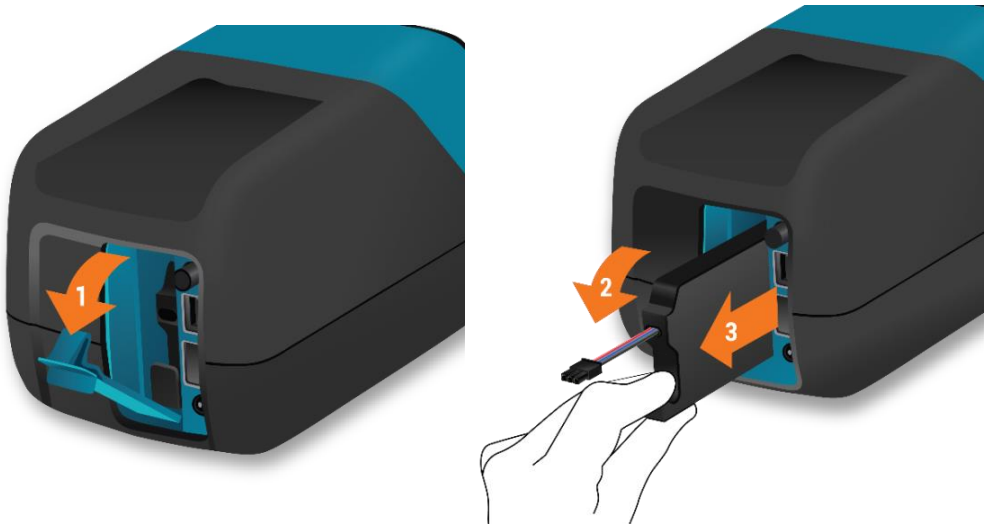
Before replacing the battery, ensure that there is no cassette in Sofia 2. Then power down and unplug Sofia 2. Remove the battery cover on the rear of the instrument. Disconnect the battery cable and carefully slide out the battery (Figure 30).

Attach the new battery and replace the battery cover. Recycle or dispose of the lithium battery in accordance with all Federal, State, and Local laws. To avoid fire and explosion hazards, do not burn or incinerate the battery. Batteries shall not be disposed of with municipal waste.

Sofia 2 Storage

If the Sofia 2 is intended to be stored and/or not used for an extended period of time (> 3 months), unplug the unit from AC power and remove the battery (Figure 31). When ready to use the Sofia 2 again, install the battery and follow the Installation, Setup, and Operation section of this User Manual.

Figure 31



Cleaning

To reduce the risk of electrical shock:

- Do not disassemble Sofia 2. Sofia 2 contains no user-serviceable components.
- Possible electrical shock: Turn off and unplug Sofia 2 before cleaning. Do not clean the ports on the back of the instrument.
- Do not immerse or spray Sofia 2 in liquid.
- Do not clean the underside of the instrument.

Turn off and unplug Sofia 2 before cleaning. Use a soft cloth with 70% alcohol or 0.6% bleach solution to clean the exterior of Sofia 2. Do not use soap or other solutions except those noted below. Wipe the external surfaces and cassette drawer only.

Note: The following disinfectants identified in EPA's list of disinfectants for use against Ebola virus have been found by Quidel to be compatible for use with Sofia 2:

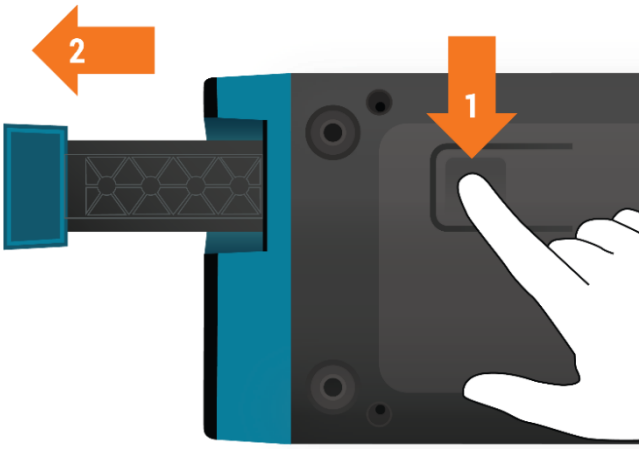
- Clorox Healthcare; Bleach Germicidal Cleaner (EPA Reg #: 56392-7)
- Clorox Commercial Solutions; Clean-Up Disinfectant Cleaner with Bleach 1 (EPA Reg #: 67619-17)
- Clorox Healthcare; Bleach Germicidal Wipes (EPA Reg #: 67619-12)

Removing the Drawer for Cleaning

Ensure that there is no cassette in the drawer and unplug Sofia 2. Gently pull the drawer out until it stops, then lift up Sofia 2 and press the button as shown (Figure 32). The drawer can then be removed.

Note: If resistance is met, do not force. Apply slightly more pressure to release the catch.

Figure 32



Use a soft cloth with 70% alcohol or 0.6% bleach solution to clean the *drawer only*. **DO NOT** *clean the interior of Sofia 2*. **DO NOT** *submerge drawer in cleaning solution*.

After cleaning the drawer, insert it carefully aligning the rails of the drawer into the tracks of Sofia 2 (Figure 33).

Figure 33

Gently slide the drawer until it is latched closed. If resistance is met or the drawer does not slide easily, check the alignment of the rails in the track. Go to the Main Menu and perform Calibration.

Appendices

Appendix A Technical Specifications

Sofia 2

Dimensions	22 cm deep x 12 cm wide x 12 cm high
Weight	2 lbs (1 kg)
Power Supply Input	100-240 VAC, 50/60 Hz, self-switching (U.S./International), 2.93 Amp maximum
Sofia 2 Input	7.5V DC 2.5A
Replaceable Battery	LiPo rechargeable battery
Display	4-inch color LCD touchscreen
LAN Interface	RJ45 connector
Operating Temperature	15°C to 30°C / 59°F to 86°F
Operating Humidity	20% to 85% RH non-condensing
Operating Altitude	2000 m maximum
Shipping and Storage Temperature	–20°C to 55°C
Shipping and Storage Humidity	20% to 85% RH non-condensing
Patient Test Result Storage	1,000 tests maximum
QC Results Storage	200 results maximum
Calibration Results Storage	200 results maximum
User Storage	1000 users maximum

The following barcodes have been configured at the time of shipment:

1D Barcodes:

- **UPC-A**
- **UPC-E**
- **EAN – 13 WITH EXTENDED COUPON CODE**
- **CODABAR**
- **INTERLEAVED 2 OF 5**
- **CODE 39**
- **CODE 93 AND 93i**
- **CODE 128**
- **GS1 DATABAR**

2D Barcodes:

- **DATA MATRIX**
- **AZTEC CODE**
- **QR CODE**

Appendix B Optimizing Analyzer Placement

- Do not stack the analyzers.
- Do not place the analyzer near a heat source.
- Allow for the spacing of a minimum of 6 inches between Sofia 2 analyzers.
- Do not place the analyzer near a wall or other surface that minimizes proper ventilation including the area behind the unit.

Appendix C System Troubleshooting

Error Messages

Note: The chart below describes the error messages that may be displayed while using Sofia 2. If unable to resolve the problem after troubleshooting, please record the error message and contact Quidel Technical Support. The error message will help Technical Support diagnose the problem.

ID	Displayed Text	Action
1	Unexpected error.	Contact Technical Support.
2	User ID must be entered.	Enter a valid User ID to proceed.
3	Patient ID must be entered.	Enter a Patient ID to proceed.
4	Invalid User ID.	Enter a valid User ID to proceed.
5	Removable storage is missing or not writable. Please insert a USB storage device and try again.	Insert a USB flash drive.

ID	Displayed Text	Action
6	Kit Lot ID must be entered.	Enter the Kit Lot number.
7	File write failed.	Replace USB flash drive.
8	Current temperature out of range of assay or system.	The temperature range allowed is 15°C to 30°C / 59°F to 86°F.
9	Printing error.	Check connection to printer.
10	Invalid QC Card barcode.	Check or rescan QC Card.
11	Printer not found.	Check connection to printer.
12	Unreadable Cassette barcode.	Ensure Cassette is inserted properly and there are no markings on the barcode.
13	Cassette not valid for current test.	Retest using a Cassette of the correct device type.
14	Assay Method File unavailable for supplied Cassette.	Only test with approved Sofia 2 assays.
15	Cassette cannot be reused.	Use a Test Cassette that has not been previously run.
16	Cassette drawer is open, unable to read barcode.	Close drawer to proceed with the test.
17	Barcode scanning in progress.	Wait until the barcode scan is complete.
18	Cassette is past the expiration date. Please retest with a non-expired Cassette.	Retest with a non-expired Cassette.
19	Calibration period has expired and the instrument is locked until Calibration has been successfully completed.	Calibrate Sofia 2.
20	Cassette barcode is invalid, missing or unreadable.	Retest using a Cassette with a valid barcode.
21	Data could not be successfully exported.	Confirm correct USB flash drive was used and inserted correctly.
22	Data could not be successfully imported.	Confirm correct USB flash drive was used and inserted correctly.
23	User ID already exists.	Choose another User ID.
24	QC Card is past the expiration date.	Retest with a non-expired QC Card.
25	There was an error performing the upgrade. Please reboot and try again.	Confirm correct USB flash drive was used and inserted correctly.
26	User Name contains invalid characters.	Enter a User Name containing 20 characters or less.
27	Language file could not be successfully loaded.	Confirm correct USB flash drive was used and inserted correctly.
28	Loading Assay Method failed.	Confirm correct USB flash drive was used and inserted correctly.
29	Log file could not be successfully exported.	Confirm correct USB flash drive was used and inserted correctly.

ID	Displayed Text	Action
30	Battery is low. Please plug in to AC power before running another test.	Connect Sofia 2 to AC power or charge battery before running another test.
31	Calibration Failed.	Contact Technical Support.
32	Power On Self-Test error.	Clean the drawer, including the two chips located on either side of the drawer, re-boot the instrument, and retry. If not corrected, discontinue use and contact Technical Support.
33	Supervisor ID should have between 4-12 characters.	Check Supervisor ID and re-enter.
34	Last Supervisor cannot be changed.	Create a replacement Supervisor or set a new default Supervisor before changing User status.
35	Stray light or wrong Calibration.	Restart Sofia 2 and if the issue continues, contact Technical Support.
36	Invalid Operator Number.	Enter a valid Operator number (i.e., is not a duplicate or longer than 20 digits).
37	Logged-in User cannot be deleted.	Log out User and log in as another User before deleting.
38	Logged-in User cannot be changed to an Operator.	Log out User before changing User status.
39	Mains power must be supplied to upgrade. Please plug in to AC power and try again.	Connect Sofia 2 to AC power before upgrading firmware.
40	USB storage device does not contain a valid upgrade file.	Ensure that the correct firmware upgrade file has been downloaded from myquidel.com.
41	There was an error performing the upgrade. Please reboot and try again.	Confirm correct USB flash drive was used and inserted correctly.
42	Removable storage is missing. Please insert a USB storage device with the upgrade file and try again.	Confirm correct USB flash drive was used and inserted correctly.
43	User ID and Operator Number must not match.	Enter a PIN that is different from the Operator Number.
44	User rights are insufficient for this function.	Log in as a Supervisor to access this function.
45	Test connection error.	Contact Technical Support.
46	Unable to apply settings changes, previous values retained.	Return to Settings screen an attempt to apply changes again.
47	Send to Virena error.	Contact Technical Support.
48	Invalid age.	Enter an age between 1-129.

ID	Displayed Text	Action
49	Invalid study code.	Enter a study code containing 1-2 numeric characters.
50	Send to Virena error. Battery is faulty.	Contact Technical Support.
51	Restore factory defaults error.	Contact Technical Support.
52	The operation failed to produce a result.	Contact Technical Support.
53	USB storage device does not contain Assay Methods.	Ensure that the correct Assay Method File has been downloaded from myquidel.com.
54	Some files were not imported successfully.	Ensure that correct files have been downloaded from myquidel.com.

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REF 20299 – Sofia 2 (US)
20300 – Sofia 2 (OUS)

IVD

CE

EC REP

MDSS GmbH
Schiffgraben 41
30175 Hannover,
Germany

Quidel Corporation
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San Diego, CA 92121 USA
quidel.com

For EU only
Quidel Ireland Ltd.
2nd Floor, Merchants Square
Merchants Road
Galway, Ireland H91 ETN2
emeatechnicalsupport@quidel.com

Revision Changes:

- Updated Quidel contact information for customer assistance
- Added label symbols:
  - CE mark of conformity
  - Batch code
  - Date of manufacture
  - Use-by date
  - Importer
  - Do not re-use
  - China RoHS
  - Patient number
  - Control
  - Prescription use only in the United States
  - Biological risks
  - Device for near patient testing
  - Device not for self testing
- Added the following instructions to the Brief Warnings section:
  - For *in-vitro* diagnostic use.
  - For professional and near patient testing.
  - For use by healthcare professionals.
  - Do not immerse the Sofia 2 in water or any liquids.
- Added EU Importer information and address

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