



QUIDEL®

Sofia<sup>®</sup>2



# User Manual

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# General Information

## Quidel Contact Information

Contact Quidel Technical Support from 7:00 a.m. to 5:00 p.m. Pacific Time

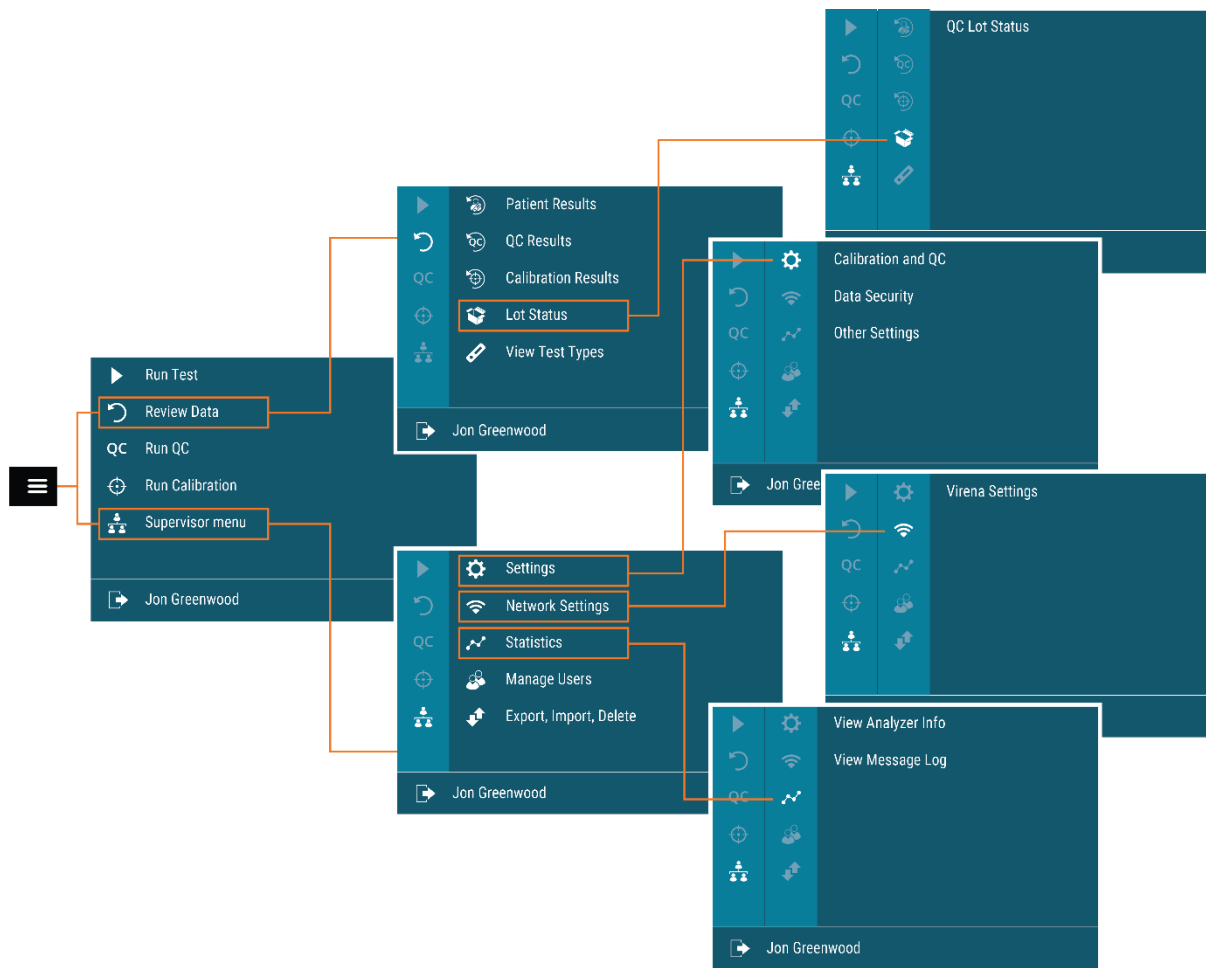
**Tel:** 800.874.1517 (in the U.S.);  
858.552.1100 (outside the U.S.)

**Fax:** 858.552.7905














**Email:** [technicalsupport@quidel.com](mailto:technicalsupport@quidel.com) or contact your local distributor

**Website:** [quidel.com](http://quidel.com)































# Main Menu Structure


























## Labels and Symbols

Label/Symbol	Description
	Manufacturer
	<i>In vitro</i> diagnostic medical device
	Prescription use only
	Consult instructions for use
	Authorized representative in the European Community
	Temperature limitation
	Humidity limitation
	Waste electrical and electronic equipment (WEEE)
	Serial Number
	Catalog Number
	Warning/Caution
	Ultraviolet Radiation
	Potential Biohazard

## Icons

	Menu		OK / Confirm
	Home		Cancel / Delete
	Run Test		Help
	Operator		Add / Create New
	Patient		Edit
	Order Number		Navigate Right
	Read Now Mode		Back / Navigate Left
	Walk Away Mode		Navigate Up
	Positive Result		Navigate Down
	Negative Result		Print
	Control Valid		Deleting
	Control Invalid		Date
	Positive Control		Expiry Date
	Negative Control		Time
	Confirmation		Warning / Error

	Review Data		Battery Level
	Quality Control		Battery Critically Low
	Calibration		Battery Charging / Mains Powered
	Calibration required in 3 days		4G
	Supervisor		USB Device
	Logout		Virena
	Patient Results		Sound off
	QC Results		Sound on
	Calibration Results		
	Test / Test Types		
	Kit Box / Lot		
	Settings		
	Statistics		
	Manage Users		
	Export, Import, Delete		



## Brief Warnings, Precautions and Limitations

- Always operate Sofia 2 on a surface that is level, dry, and not in direct sunlight.
- 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 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.
- To avoid damaging Sofia 2, do not place objects on top of it.
- 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.

## 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.



### 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 counter top operation.
- 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 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 on 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.

# Introduction

## Intended Use

Sofia 2 is a bench top 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.

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 bench top 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. 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.

**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 bench top 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
- QuickStart Guide
- Calibration Cassette

### ***Additional Ancillaries (optional)***

- Dymo Label Printer
- Dymo Vinyl Label Roll
- Dymo Paper Roll
- 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.

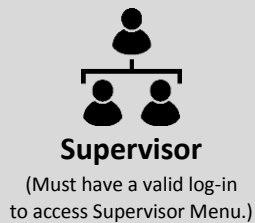
## User Types

**Users** without Supervisor authorization have access to the following functions:



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

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



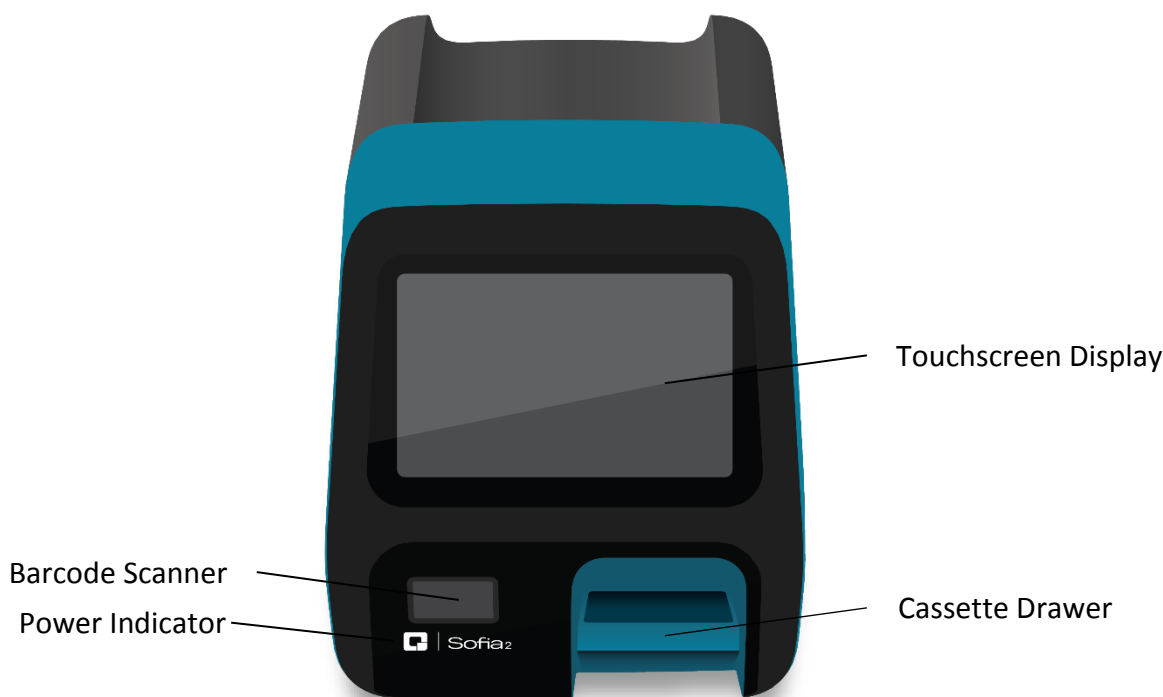
- Add or Delete Users
- Export and Import Settings
- Export Test Records
- Update Sofia 2 Firmware
- View Message Logs
- Review Statistics
- Change Settings

# 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

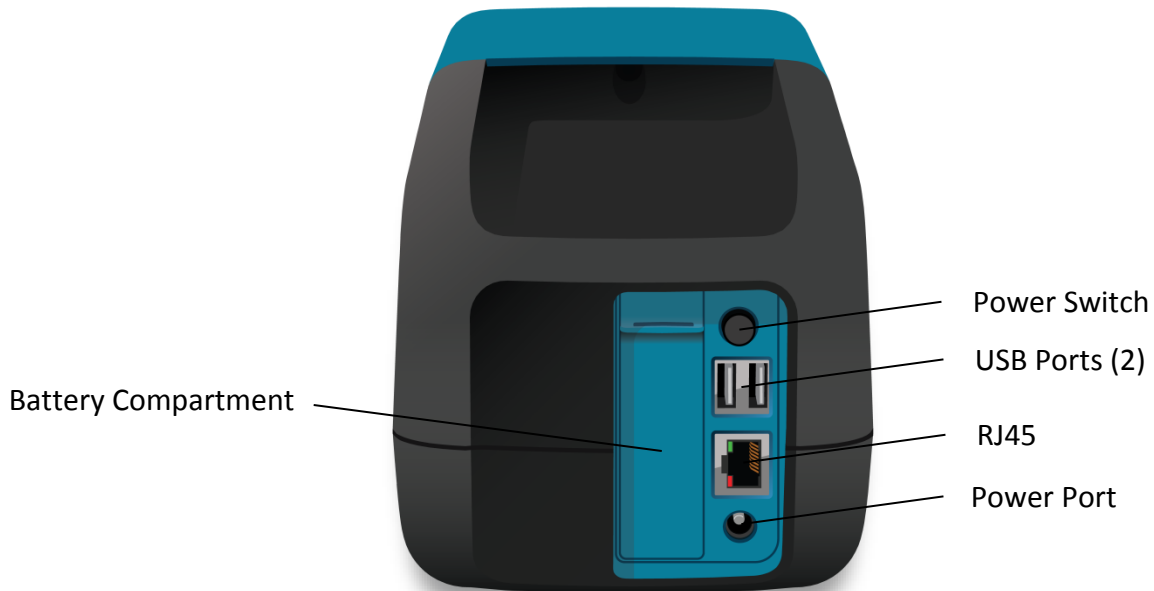
## Sofia 2 Setup

- Place Sofia 2 on the bench top. The unit is portable and can be moved to a suitable location for testing. Ensure counter top is stable, level, dry and free of obstructions. Avoid direct sunlight.
- Ensure the bench provides adequate space for Sofia 2. There must be space to open/close the Sofia 2 drawer and access the connection ports on the back of the unit.
- Plug the Power Adapter into the power port on the back of Sofia 2. Then plug the 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

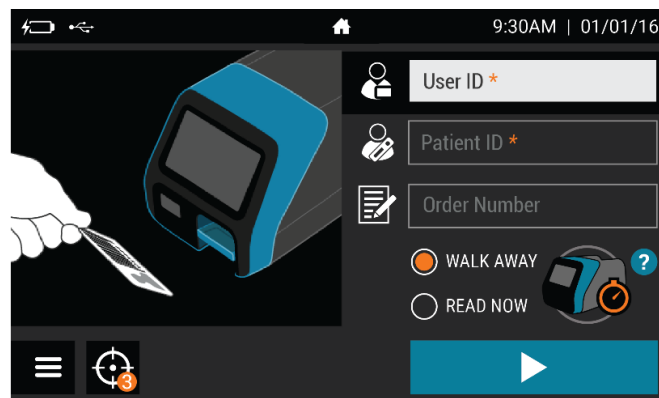
Turn Sofia 2 on using the power switch located on the rear panel (Figure 2).

Figure 2



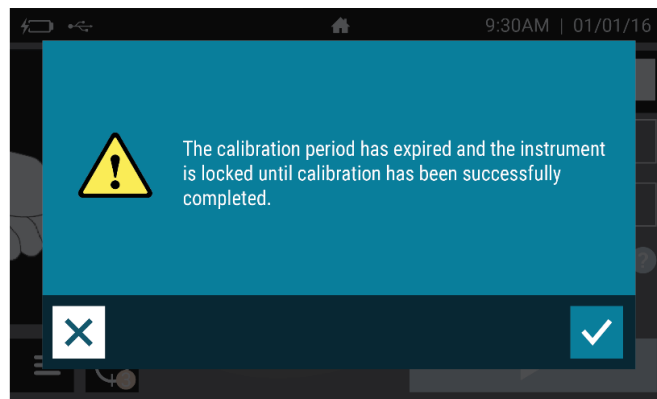
Sofia 2 will display the Power On progress screen and complete a Power On Self-Test. Once the Power On is complete, Sofia 2 will display the Run Test screen (Figure 3) and it is ready for use.

Figure 3

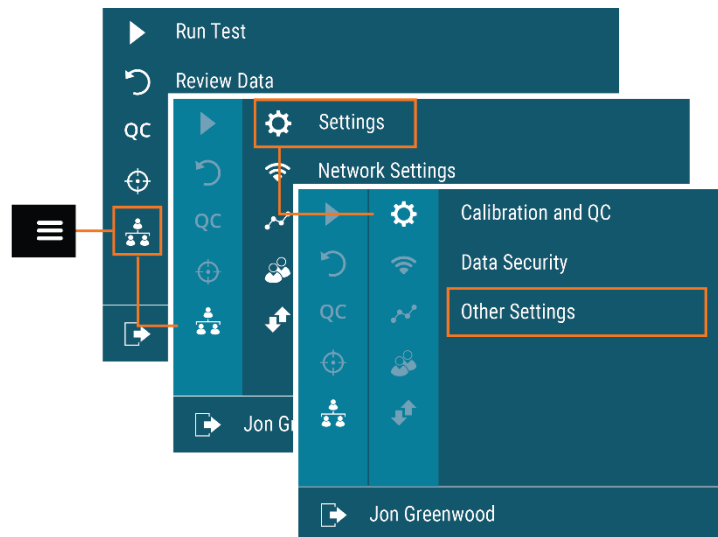


When turning on Sofia 2 for the first time, a calibration check will be required (Figure 4). A calibration check must be performed before using it for the first time. **The default Supervisor ID (1234) will be used for the calibration check.**

Figure 4



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

**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.



## ***Calibration and QC***


### **Calibration Reminder**

Using the touchscreen, enter the number of days for the **Calibration reminder interval** from 2-30. When the selected number of days remain until 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 touchscreen 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. Press  to confirm when changes are complete to return to the Run Test screen.


### ***Other Settings***

#### **Set Site Name**


The Site Name setting sets the name of the clinic, hospital, lab or physician's office where Sofia 2 is being used.

In the field for **Site Name**, use the touchscreen 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.

The Supervisor may also enter the 5-digit ZIP code using the touchscreen keypad.

When the Site Name and ZIP code are complete, continue to set Sound using .

#### **Set Sound**

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 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.

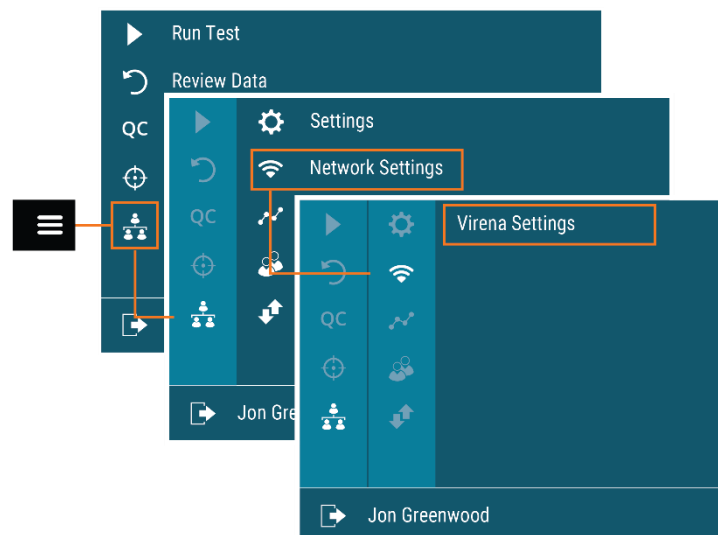
When the 12h format is selected, also select **AM** or **PM**. When the 24h format is selected, the **AM/PM** buttons are non-functional. If an invalid time is added, the field will highlight in red and the confirm button will not be available.

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 confirm button will not be available.

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

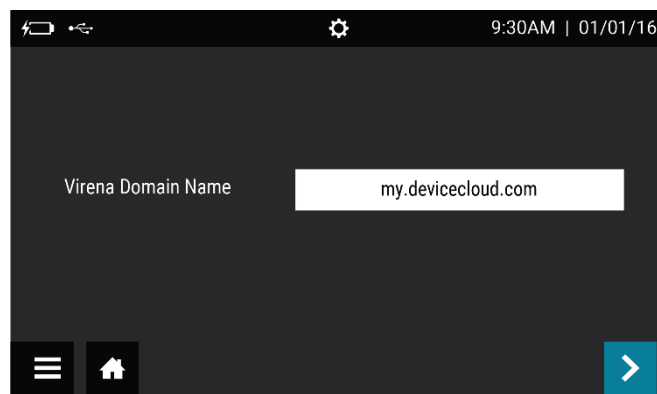
## Network Settings



### ***Virena Settings***

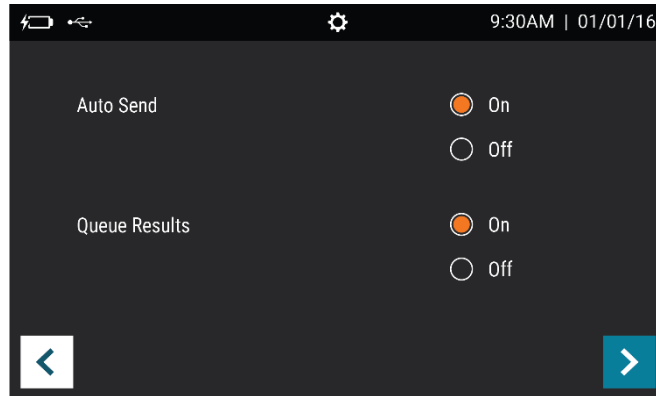
To configure Virena, **Virena Domain Name** is pre-populated and no additional user input is needed (Figure 5).

**Figure 5**



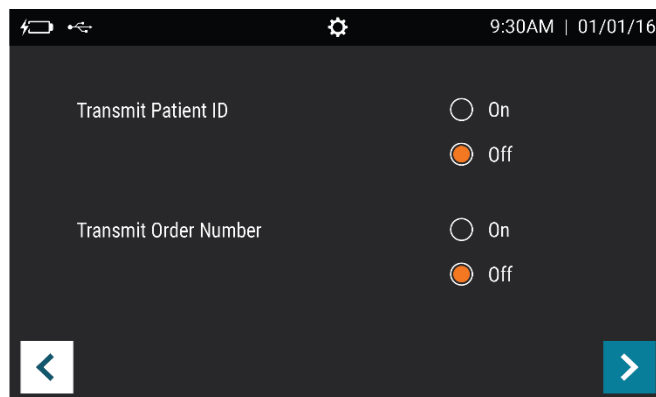
Press > to continue to the next screen. For **Auto Send**, select either **On** or **Off**. For **Queue Results**, select either **On** or **Off** (Figure 6). Both settings must be set to **On** to send results to the Virena cloud daily. Upon activation of Sofia 2's network capabilities, Sofia 2 will 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 6**



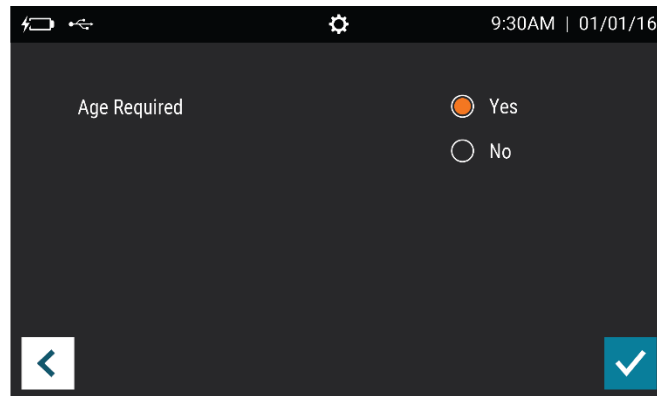
Press > to continue to the next screen. For **Transmit Patient ID**, select either **On** or **Off**. For **Transmit Order Number**, select either **On** or **Off** (Figure 7).


**Figure 7**







Press > to continue to the next screen. For **Age Required**, select either **On** or **Off** (Figure 8). If set to **On**, the User will need to enter the patient's age prior to running each test.

**Figure 8**

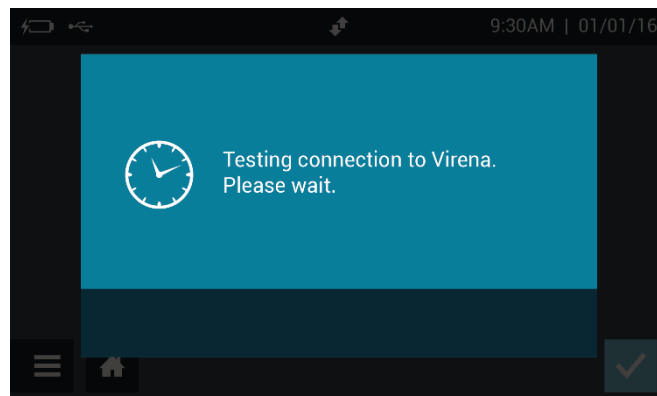


Select  to confirm configuration and return to the Run Test screen.

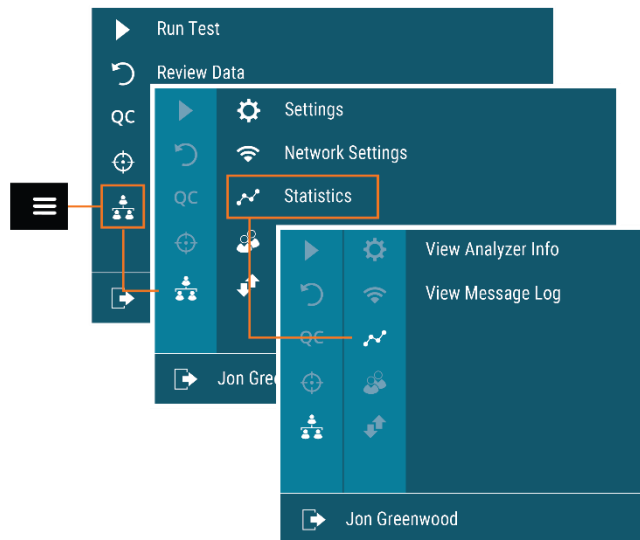
### ***Test Virena Connection***

The final step of Virena configuration is to test the connection. This is accessed through the Export, Import, Delete screen in the Supervisor Menu. To test the connection, use  or  in the first field to select **Test Connection**. Then ensure that  is selected and press  to begin the connection test (Figure 9). 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.

**Figure 9**



## Statistics

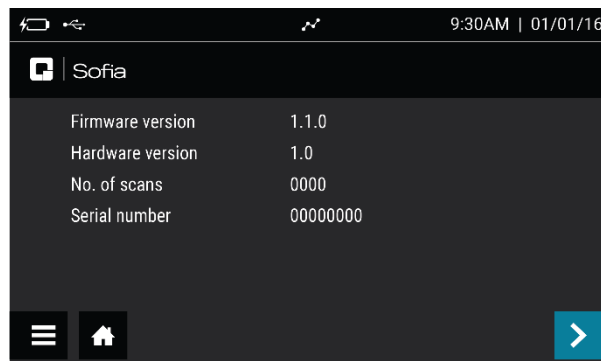


### ***View Analyzer Info***

The first screen of View Analyzer Info displays the **Firmware Version, Hardware Version, No. of scans, and Serial Number** (Figure 10).

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

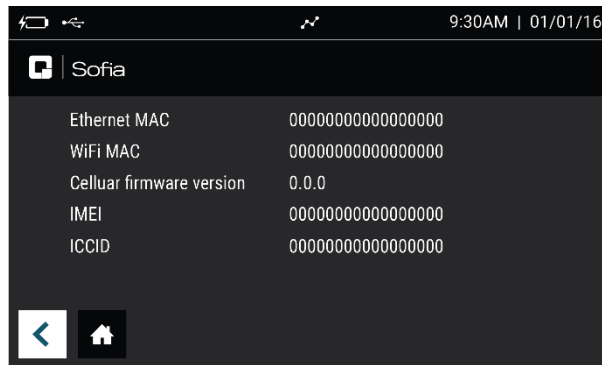
**Figure 10**



The second screen of View Analyzer Info displays the **Ethernet MAC, WiFi MAC, Cellular firmware version, IMEI, and ICCID** (Figure 11).

Select 🏠 to return to the Run Test screen.

Figure 11



### View Message Log

View Message Log displays the Error Code, Date and Time (Figure 12).


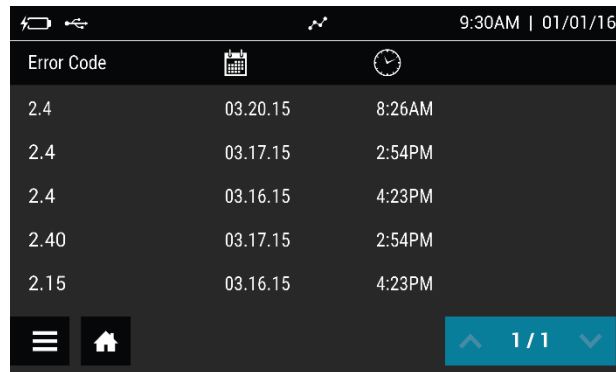
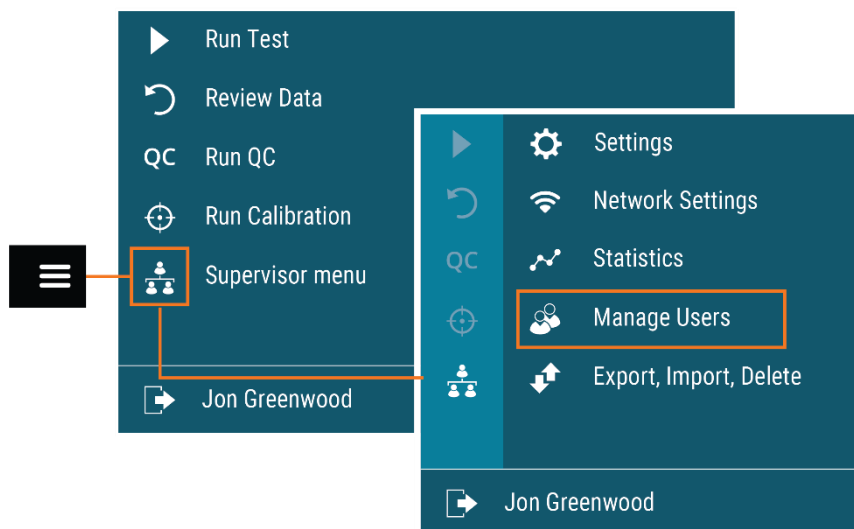
Select  to return to the Run Test screen.

Figure 12



## Managing Users



## Add User

To add a User, Select **+** on the Add User screen (Figure 13).

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

Then choose User Type by selecting Operator or Supervisor.

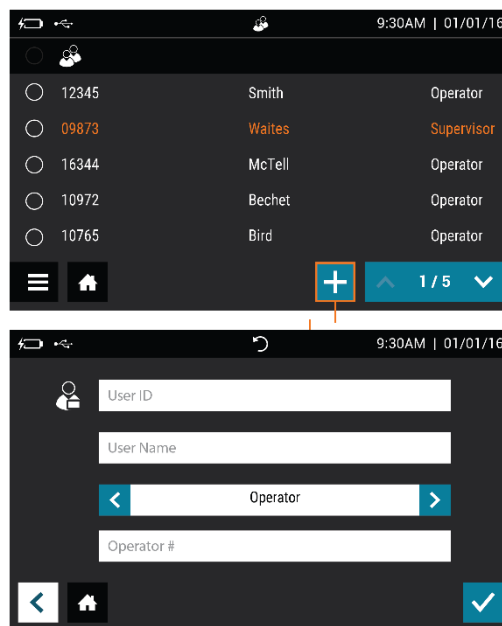
Enter the name for the new user using the on-screen keypad.

To delete a letter, press **←** on the keypad.

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

When the name is complete, press **✓**.

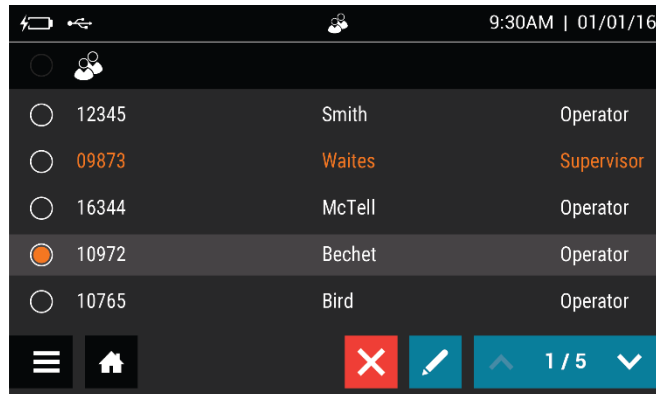
**Figure 13**



## Edit User

Select a User by touching anywhere within the row, then select **✎**. Use the on-screen keypad to edit the User information (Figure 14).

**Figure 14**

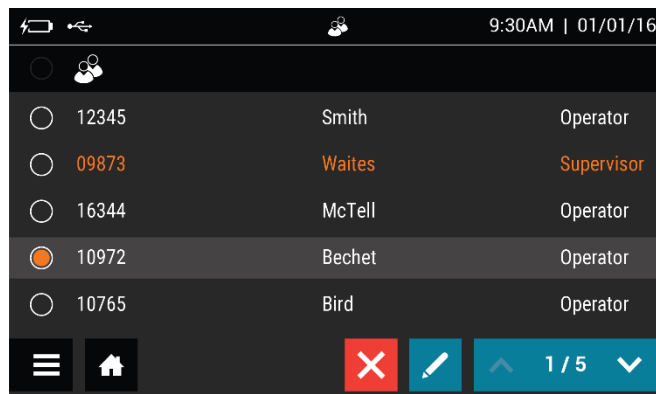


When the information is complete, press ✓.

### **Delete User**

Select a User by touching anywhere within the row, then select ✕ to delete User (Figure 15). This action cannot be undone. If a User is deleted by mistake, re-add the User as described above.

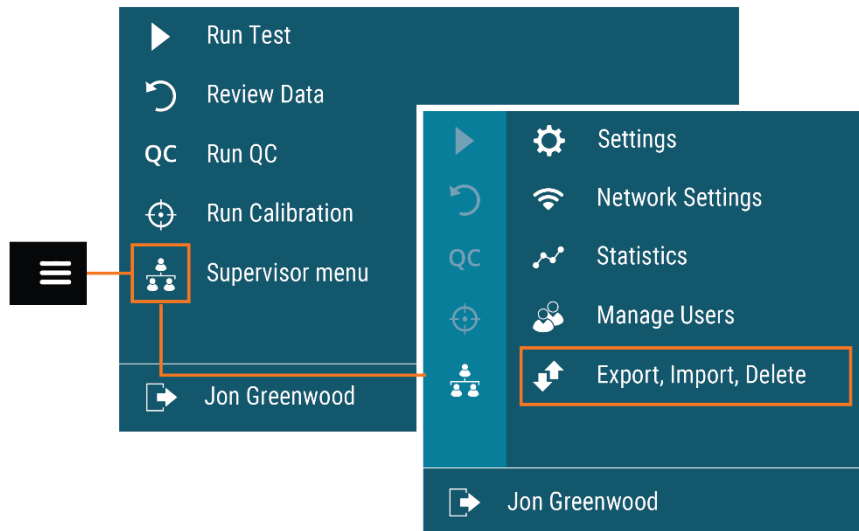
**Figure 15**



**Note:** Maximum number of Users is 100.



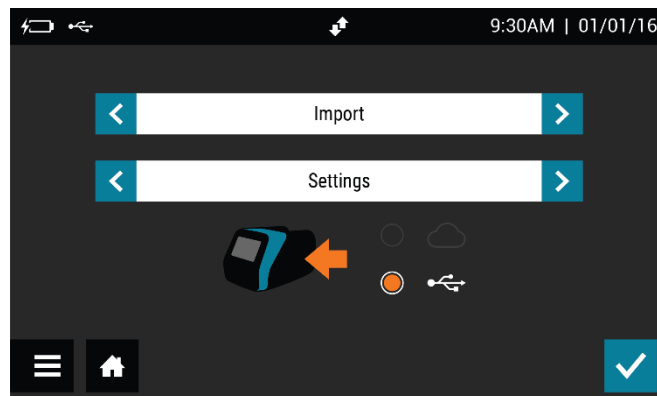
## Export, Import, Delete



### ***Export, Import, or Delete Data Types***

Supervisors may export, import, or delete data to/from either a USB flash drive or the device (Figure 16). Most standard USB flash drives may be used with Sofia 2.

Figure 16





### ***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 settings including Test Type Files 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**.

Select , 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 Test Records & Logs to USB Flash Drive***

Test records may be exported to a desktop computer for back up or analysis.

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

In the next field, use < or > to select **Test Records** or **Logs**.

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

Three “csv” files will be created, one each for patient, QC and Calibration. Each time a patient, QC or Calibration Cassette is run, the result will be appended to the appropriate file on the USB flash drive.

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

### ***Sofia 2 Firmware***



Occasionally, Quidel may release firmware updates to improve functionality of Sofia 2. Users can ensure that their Sofia 2 has the most current firmware by enrolling for an account and registering their Sofia 2 at **myquidel.com**. By following the instructions on the site, Supervisors may install updates from a USB flash drive. Additional detail can be found at **myquidel.com**.

### ***Import Firmware from USB Flash Drive***

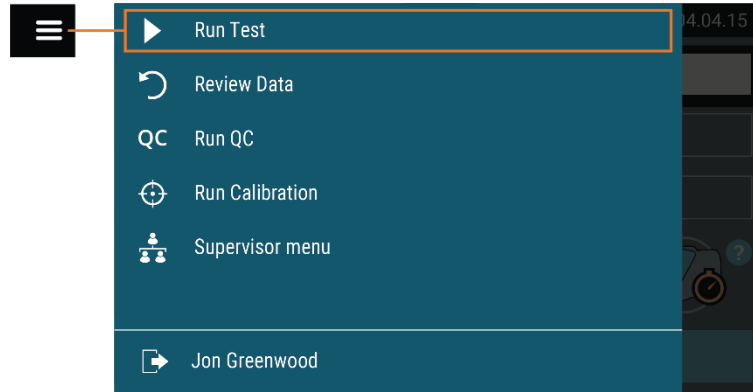
Insert USB flash drive with the firmware to install.


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

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

Select , then select  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.

## Run Test (Patient Specimens)



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

### ***Enter the User ID***

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

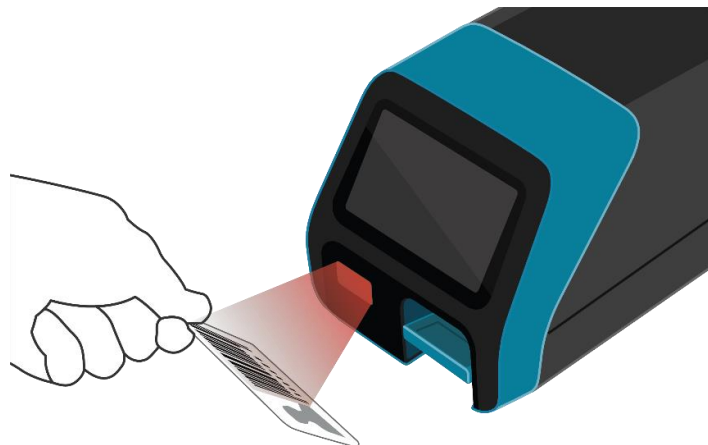
Select the **User ID** field on the Run Test screen. Use the barcode scanner (Figure 17) to scan the barcode from a User's ID Card or manually enter the data using the on-screen keypad on Sofia 2.

### ***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 17) 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 17**



### ***Enter the Order Number, if applicable***

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.

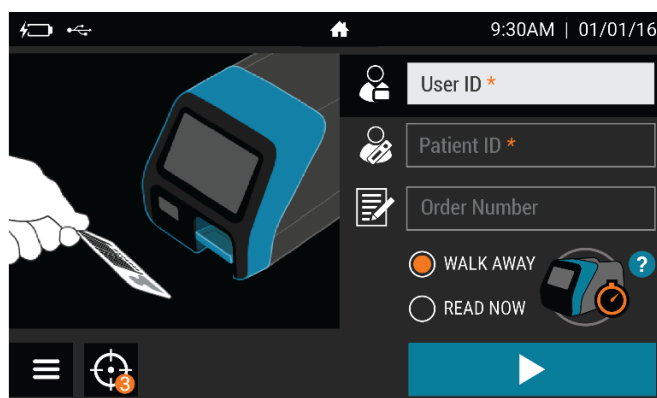
### ***Change Development Mode***

Select the desired Development mode: **WALK AWAY** or **READ NOW** (See description of the WALK AWAY and READ NOW development modes on page 11).

**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 18). If the highlighted mode is the desired mode, no changes are required.

**Figure 18**



### ***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 and development mode are entered, 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.

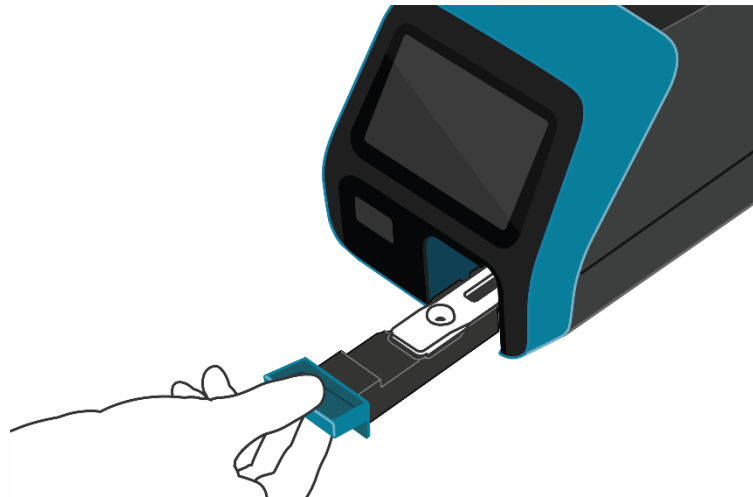
If **Age Required** has been set to **On**, the User will be asked to enter the patient's age before advancing. Refer to the **Virena Settings** section on page 19 for more information.

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 19).

**Figure 19**




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 for 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.

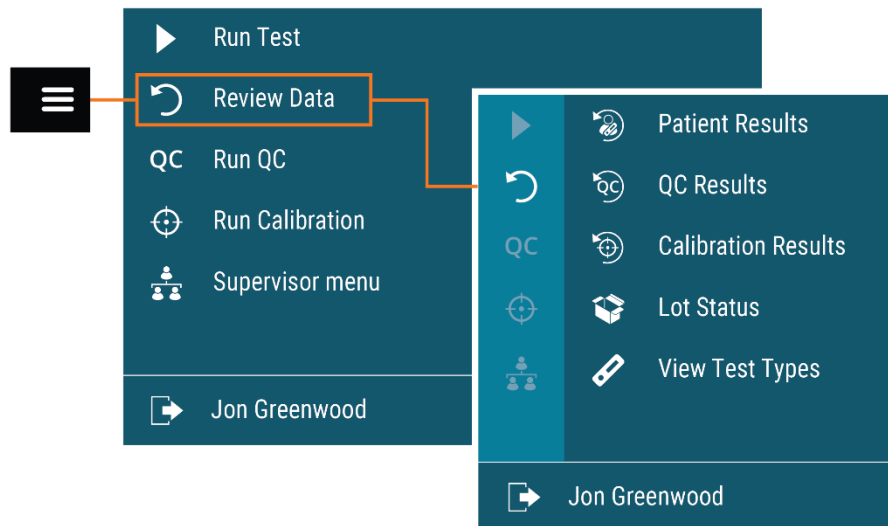
The results may also be printed on an attached printer by selecting .

**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

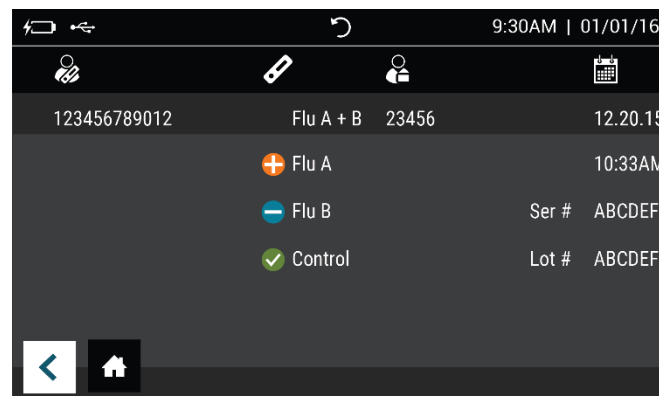



### **Review Patient Results**

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 20).

**Figure 20**



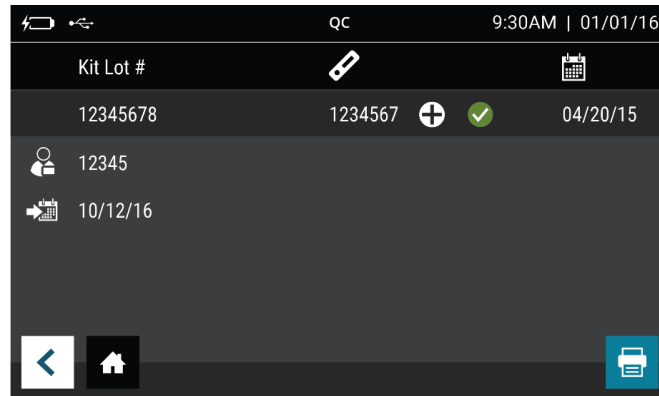
Select  to return to the Run Test screen.


### **Review QC Results**

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

The operator is able to locate QC result details in the same manner as Patient Test Results (Figure 21).

**Figure 21**



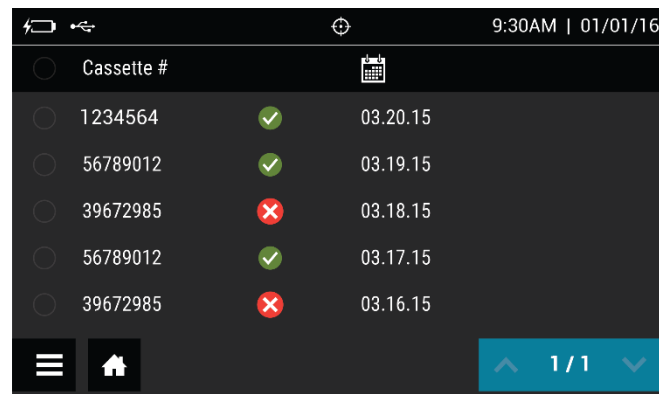
Select  to return to the Run Test screen.


### ***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 22).

**Figure 22**




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.

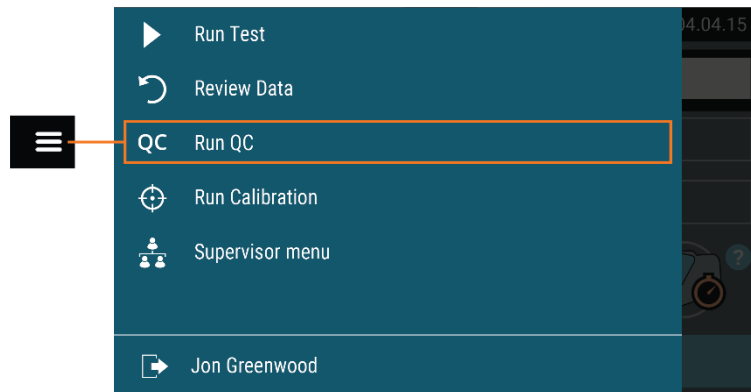
Select  to return to the Run Test screen.

### ***View Test Types***

A list of the installed Test Types and Version number loaded is displayed.

Select  to return to the Run Test screen.

## 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.

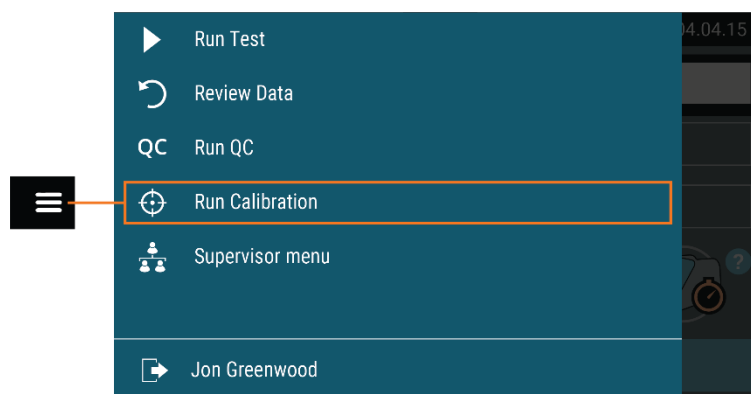
### QC Results

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 Main Menu 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 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 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 30).

**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.

## **Shutdown**

Turn off the unit by holding the power switch in the rear of the unit. 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.

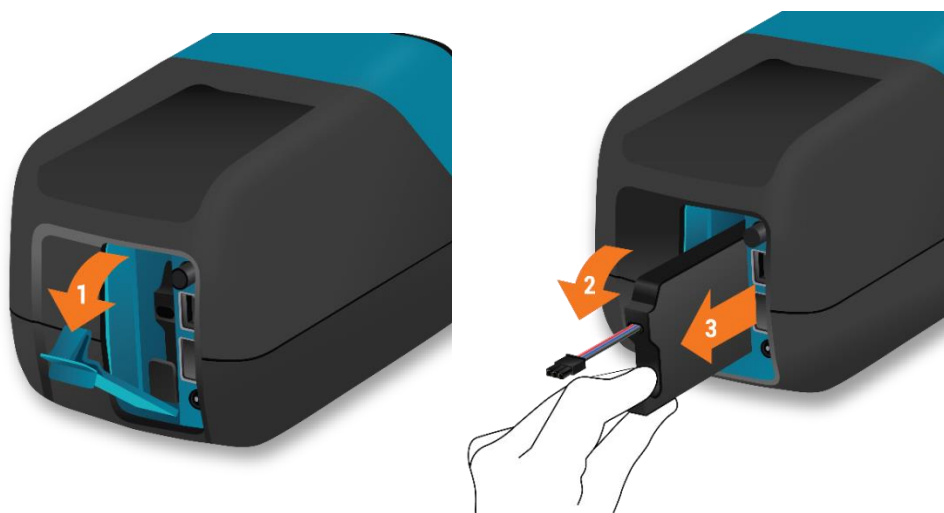
Use only a Quidel-supplied Sofia 2 replacement battery.

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

Prior to 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 23).

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 hazard, do not burn or incinerate the battery. Batteries shall not be disposed of with municipal waste.

**Figure 23**



## **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 prior to 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 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:

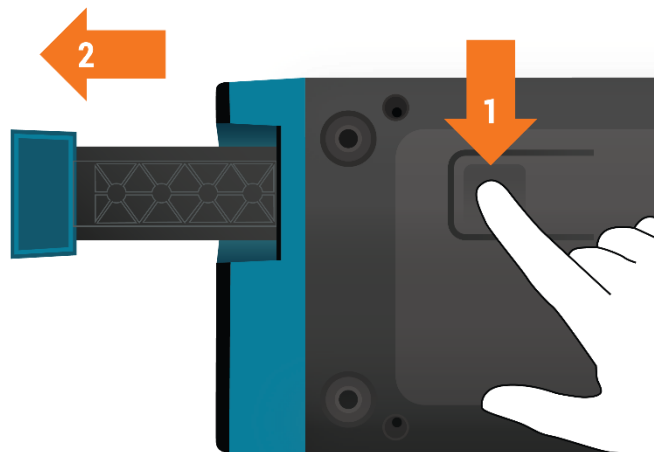
- Clorox Healthcare; Bleach Germicidal Cleaner (EPA Reg #: 56392-7)
- Clorox Commercial Solutions; Clean-Up Disinfectant Cleaner with Bleach 1 (EPA Reg #: 67619-17)
- Clorox Healthcare; Bleach Germicidal Wipes (EPA Reg #: 67619-12)

### Removing the Drawer for Cleaning

Ensure that there is no cassette in the drawer and unplug Sofia 2. Gently pull drawer out until it stops, then lift up Sofia 2 and press the button as shown (Figure 24). The drawer can then be removed.

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

Figure 24



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 25).

**Figure 25**



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*

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

The following barcodes have been configured at time of shipment:

**1D Barcodes:**

- UPC-A
- UPC-E
- EAN – 13 WITH EXTENDED COUPON CODE
- CODABAR
- INTERLEAVED 2 OF 5
- IATA CODE 2 OF 5
- CODE 11
- CODE 39
- CODE 93 AND 93i
- CODE 128
- GS1 DATABAR
- MSI

**2D Barcodes:**

- DATA MATRIX
- AZTEC CODE
- QR CODE

## Appendix B 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.

Error	Description	Action
UNKNOWN_ERROR	Unexpected error.	Contact Technical Support.
USER_ID_MUST_BE_ENTERED	User ID must be entered.	Enter a valid User ID to proceed.
PATIENT_ID_MUST_BE_ENTERED	Patient ID must be entered.	Enter a Patient ID to proceed.
INVALID_USER_ID	Invalid User ID.	Enter a valid User ID to proceed.
NO_REMOVABLE_STORAGE	Removable storage is missing or unwritable.	Install a USB flash drive.
KIT_LOT_ID_MUST_BE_ENTERED	Kit Lot ID must be entered.	Enter the Kit Lot number.
WRITE_FAILED	File write failed.	Replace USB flash drive.
TEMPERATURE_OUT_OF_RANGE	Current temperature out of range of assay or system.	Temperature range allowed is 15°C to 30°C / 59°F to 86°F.
PRINTING_ERROR	Printing failed.	Check connection to printer.

<b>Error</b>	<b>Description</b>	<b>Action</b>
INVALID_QC_CARD_BARCODE	Invalid QC Card Barcode.	Check or rescan QC Card.
PRINTER_NOT_FOUND	Printer not found.	Check connection to printer.
UNREADABLE_CASSETTE	Unreadable cassette barcode.	Ensure Cassette is inserted properly and there are no markings on the barcode.
CASSETTE_NOT_VALID_FOR_CURRENT_TEST	Cassette type not valid for current test.	Retest using a Cassette of the correct device type.
MISSING_ASSAY_METHOD	Method file unavailable for supplied assay type.	Only test with approved Sofia 2 assays.
CASSETTE_PREVIOUSLY_USED	Cassette has previously been used.	Use a Test Cassette that has not been previously run.
DRAWER_OPEN	Cassette drawer is open, unable to read barcode.	Close drawer to proceed with test.
SCANNING_BARCODE	Barcode scanning in progress, cassette availability pending.	Wait until barcode scan is complete.
EXPIRED_BARCODE	Supplied cassette has expired.	Retest with a non-expired Cassette.
CALIBRATION_OVERDUE	The calibration period has expired and the instrument is locked until calibration has been successfully completed.	Calibrate Sofia 2.
CASSETTE_ERROR	The cassette barcode is invalid, missing or unreadable.	Retest using a Cassette with a valid barcode.
DATA_EXPORT_ERROR	Data could not be successfully exported.	Confirm correct USB flash drive was used and inserted correctly.
DATA_IMPORT_ERROR	Data could not be successfully imported.	Confirm correct USB flash drive was used and inserted correctly.
DUPLICATE_USER_ID_ERROR	The User ID already exists.	Choose another User ID.
EXPIRED_QC_CARD	The QC Card is past the expiration date.	Retest with a non-expired QC Card.
FIRMWARE_UPGRADE_ERROR	USB Flash Drive not found or has wrong format.	Confirm correct USB flash drive was used and inserted correctly.
INVALID_USER_NAME	The User Name contains invalid characters.	Enter a User Name containing 20 characters or less.

<b>Error</b>	<b>Description</b>	<b>Action</b>
LOG_FILE_EXPORT_ERROR	Log file could not be successfully exported.	Confirm correct USB flash drive was used and inserted correctly.
LOW_BATTERY_WARNING	Battery is low.	Connect Sofia 2 to AC power or charge battery before running another test.
CALIBRATION_ERROR	Calibration Failed.	Contact Technical Support.
POST_ERROR	Power On Self Test Error.	Clean the drawer, including the two chips located on either side of the drawer, re-boot instrument and retry. If not corrected, discontinue use and contact Technical Support.
SUPERVISOR_ID_ERROR	The supervisor ID should have between 4-12 characters.	Check Supervisor ID and re-enter.
LAST_SUPERVISOR_ERROR	The last supervisor cannot be changed.	Create a replacement Supervisor or set a new default Supervisor before changing User status.
WRONG_VALUE_MEASURED	Stray light or wrong calibration.	Restart Sofia 2 and if issue continues, contact Technical Support.
INVALID_OPERATOR_NUMBER	The operator number is either a duplicate (i.e. another user has the same operator number) or is longer than 20 digits.	Enter a valid Operator number.
CANNOT_DELETE_LOGGED_IN_USER	The logged-in user has attempted to delete themselves.	Log out User and log in as another User before deleting.
CANNOT_DEMOTE_LOGGED_IN_USER	The logged-in user has attempted to demote themselves to an operator.	Log out User before changing User status.
FIRMWARE_UPGRADE_NO_MAINS	No mains power present when performing the upgrade.	Connect Sofia 2 to AC power before upgrading firmware.
FIRMWARE_UPGRADE_NO_FILES	Could not find a valid upgrade file on the USB media.	Ensure that correct firmware upgrade file has been downloaded from <a href="http://myquidel.com">myquidel.com</a> .
FIRMWARE_UPGRADE_FAILED	There was an error during the upgrade (e.g. failed to write upgrade).	Confirm correct USB flash drive was used and inserted correctly.



<b>Error</b>	<b>Description</b>	<b>Action</b>
FIRMWARE_UPGRADE_NO_REMOVABLE_STORAGE	No USB media was present when starting the upgrade process.	Confirm correct USB flash drive was used and inserted correctly.
MATCHING_PIN_AND_OPERATOR_NUMBER	The user has the same value for their PIN and operator number.	Enter a PIN that is different from the operator number.
INSUFFICIENT_USER_RIGHTS	User rights are insufficient to access a function.	Log in as a Supervisor to access this function.
SURVEILLANCE_CONNECTION_ERROR	Surveillance connection failed due to failure of connection to Cellular network or Digi cloud.	Contact Technical Support.
INVALID_AGE	The user has entered an invalid age.	Enter an age between 1-129.
TEST_CONNECTION_ERROR	Test connection error.	Contact Technical Support.
RESET_DEVICE_OR_CONTACT_QUIDEL	Please reset device or contact Quidel Technical Support.	Restart Sofia 2 and if issue continues, contact Technical Support.



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**1317801EN00 (06/17)**