QUIDEL | Sofia®

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. PST.

Tel: 800.874.1517 (in the U.S.);

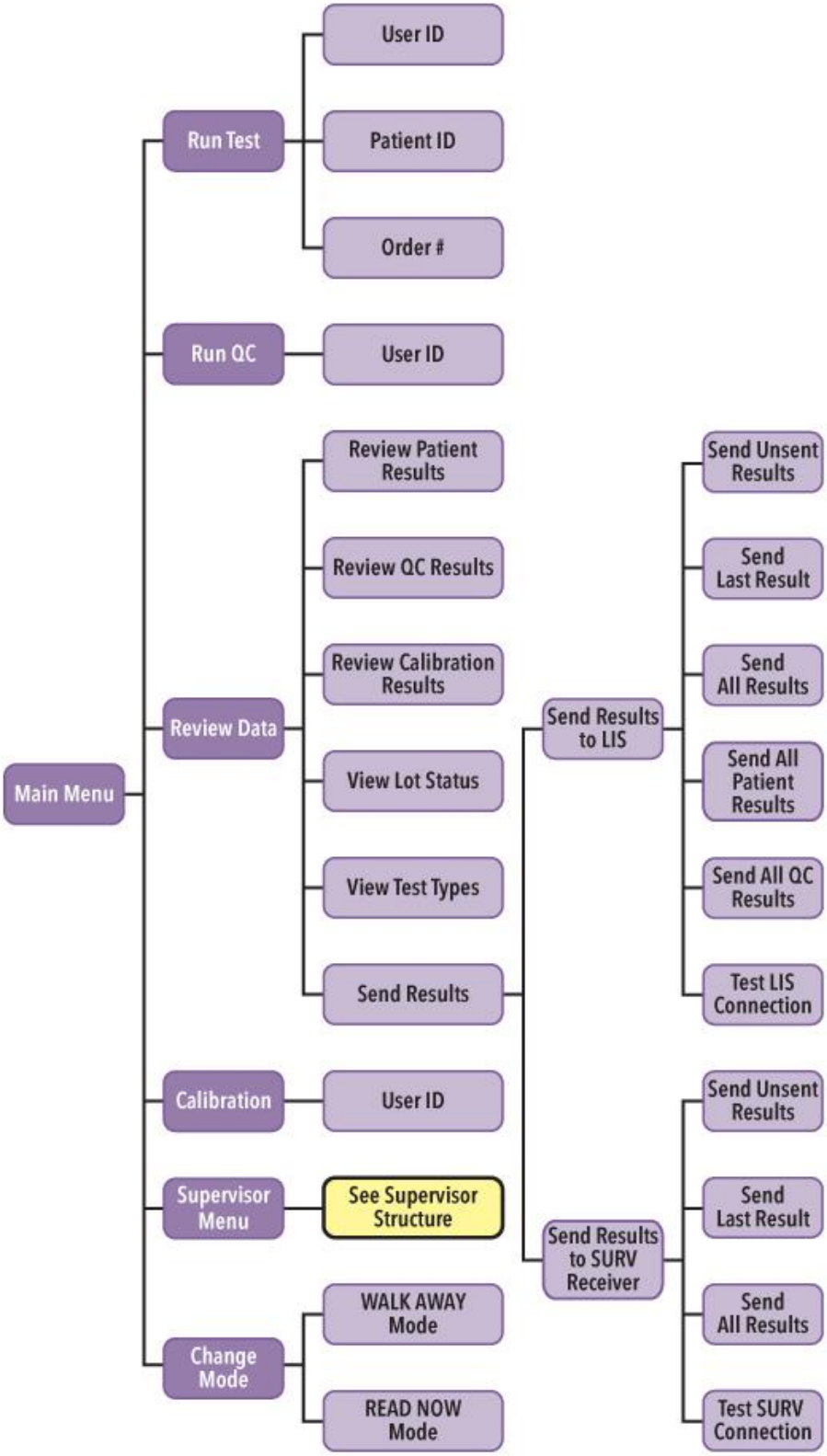
858.552.1100 (outside the U.S.);

Fax: 858.552.7905

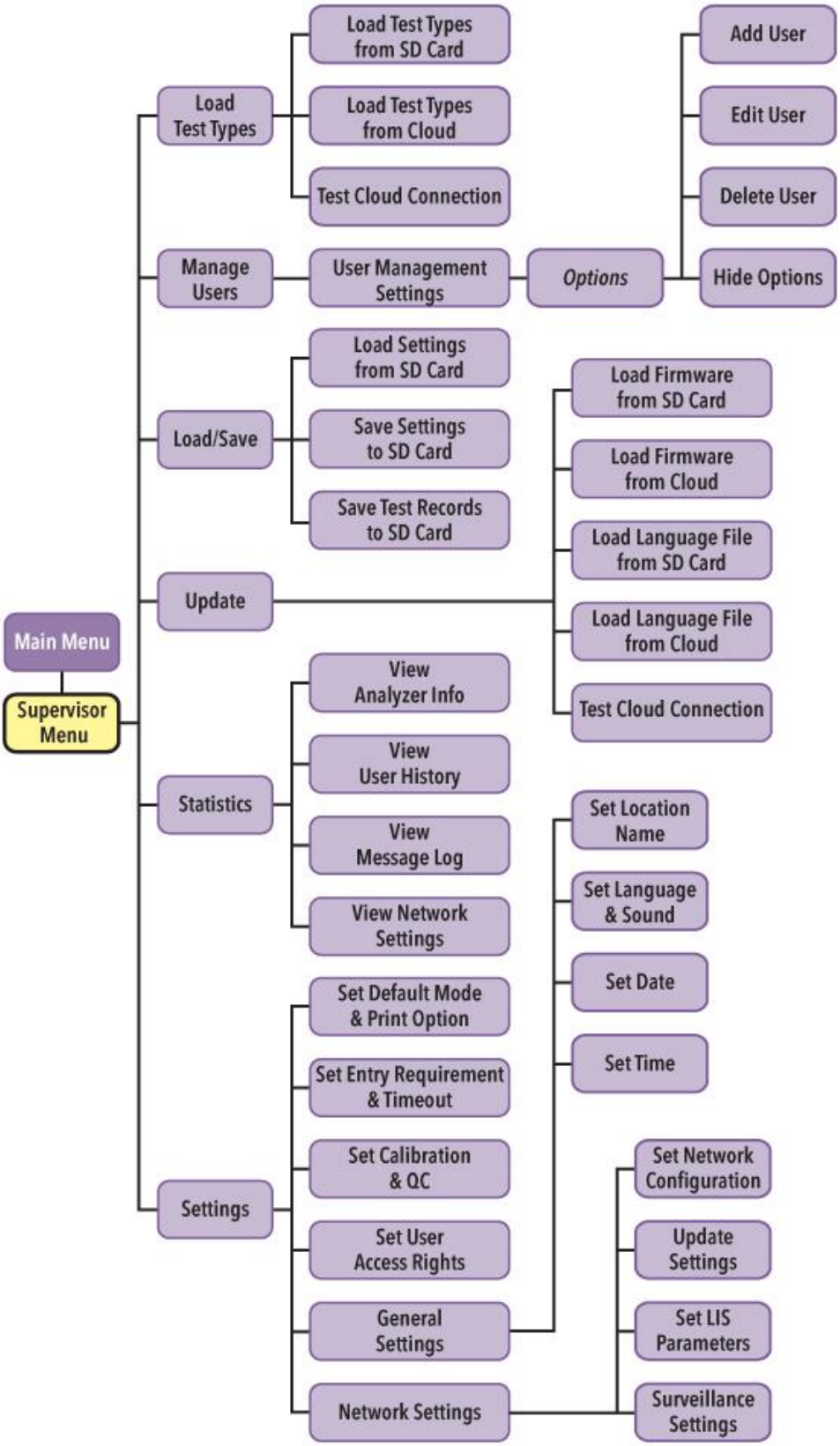
E-mail: technicalsupport@quidel.com or contact your local distributor

Website: quidel.com

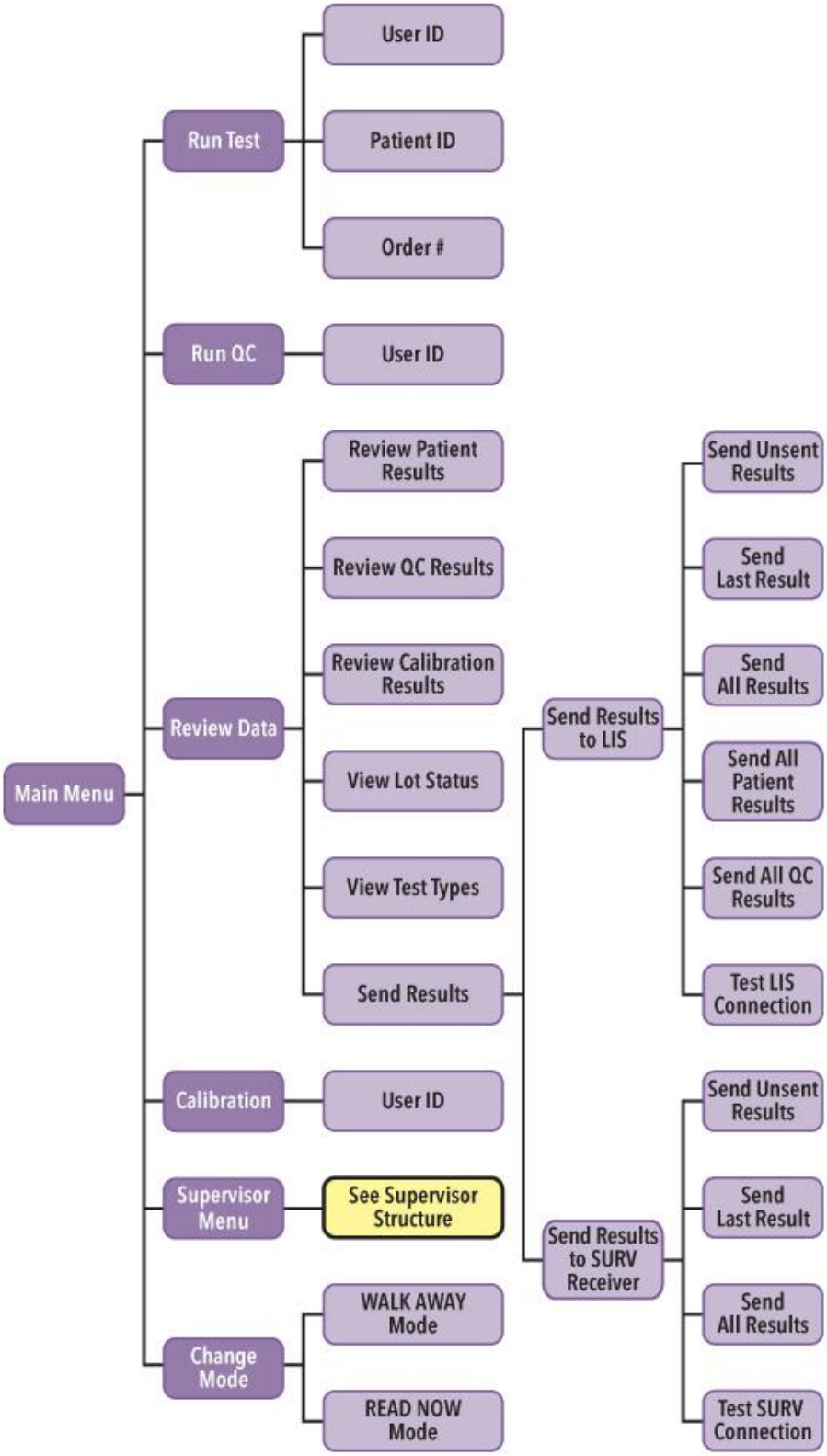
Main Menu Structure – v.2.0 or higher



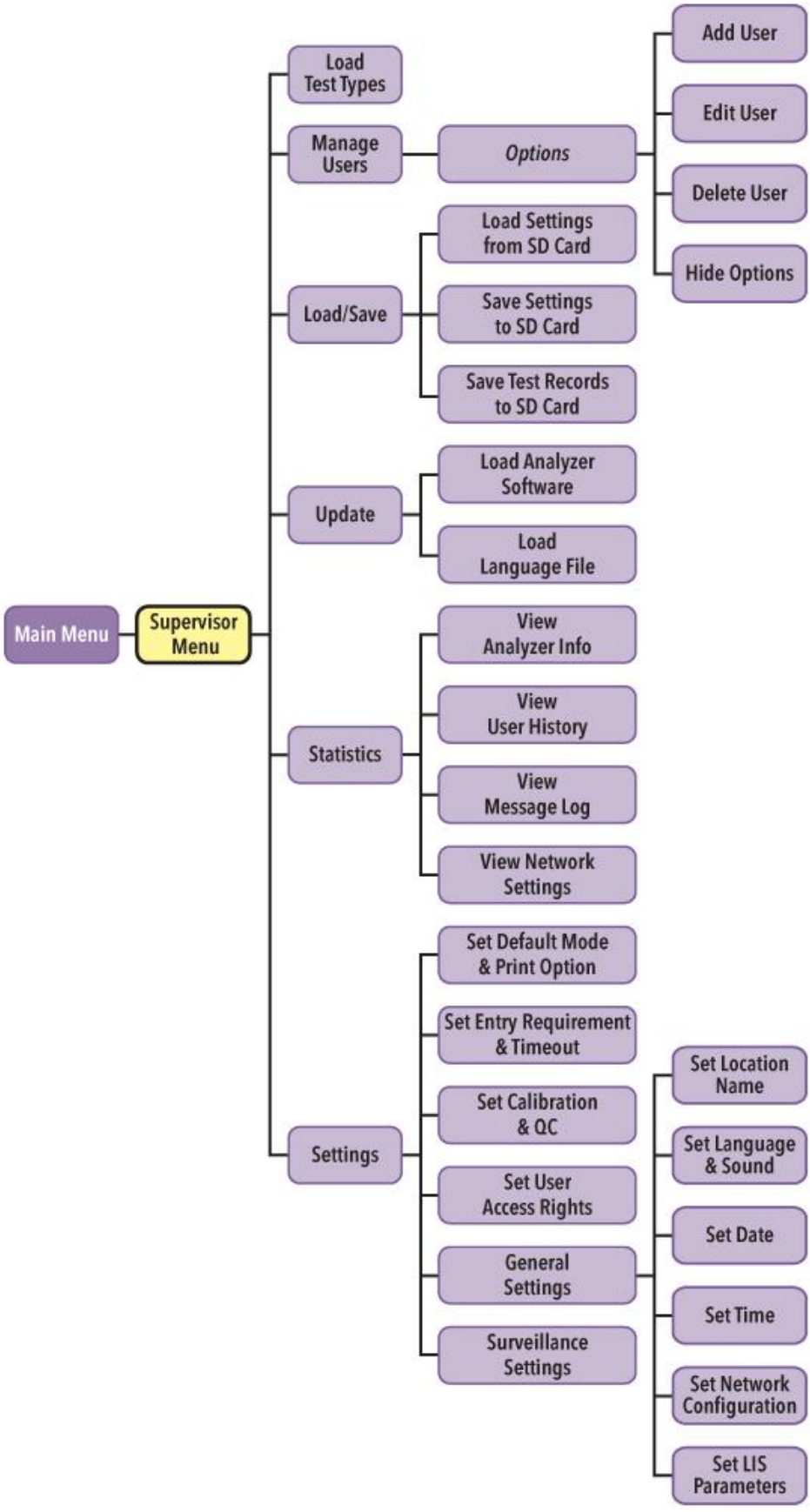
Supervisor Menu Structure – v.2.0 or higher



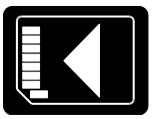
Main Menu Structure – previous to v.2.0



Supervisor Menu Structure – previous to v.2.0



Labels and Symbols

Label	Description
	Manufacturer
	In vitro diagnostic medical device
	Prescription use only
	Consult instructions for use
	Authorized representative in the European Community
	Temperature limitation
	Directive 2002/06/EC on waste electrical and electronic equipment (WEEE)
	SD Card
	Serial Number
	Catalog Number

Symbol	Description
	Warning! Indicates a hazardous situation, which if not avoided, could result in injury to the Operator or a bystander (e.g., electrical shock or UV exposure).
	Potential Biohazard! An agent of biological origin that has the capacity to produce deleterious effects on humans, i.e. microorganisms, toxins, and allergens derived from those organisms; and allergens and toxins derived from higher plants and animals.

	Caution! Indicates a situation, which if not avoided could result in damage to the device or incorrect results.
	Laser Radiation! Do not stare into beam.

Brief Warnings, Precautions and Limitations

- Always operate Sofia on a surface that is level and dry and not in direct sunlight.
- The Sofia Calibration Cassette is sensitive to light. Store it in the opaque sleeve it was shipped in whenever it is not being used.
- Never move Sofia while there is a test in progress.
- Use only the power adapter that was provided with Sofia.
- Do not drop Sofia as it could damage the unit.
- To avoid damaging Sofia, never place objects on top of it.

Safety Precautions

Sofia is designed to provide safe and reliable operation when used according to this User Manual. If Sofia 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 before cleaning.
- Plug the device into an approved receptacle.
- Do not immerse in water or cleaning solutions.
- Do not attempt to open the enclosure.
- Use the appropriate power cord for the region.

Laser Radiation!

To reduce the risk of UV Exposure:

- Do not attempt to open or disassemble Sofia.

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 is cleaned per the **Maintenance and Cleaning** section prior to storage, transport or disposal.
- Seek specific training or guidance if you are not experienced with specimen collection and handling procedures.
- Use of Nitrile, Latex, or other gloves is recommended when handling patient samples.

Caution!

To reduce the risk of incorrect results:

- Sofia should only be used by trained operators.
- Do not use if Sofia 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 dating.

To reduce the risk of Sofia damage:

- Sofia is designed for counter-top operation under laboratory conditions.
- Sofia is not designed to withstand moisture, extreme humidity, or extreme temperatures.
- Sofia 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. See page 4 for additional contact information.
- Clean Sofia per the **Maintenance and Cleaning** section of this User Manual prior to return or disposal.

Note: Always dispose of Sofia and accessories in accordance with Federal, State and Local requirements.

Introduction

Intended Use

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

After the patient sample has been added to the Test Cassette, depending upon the assay and/or the user's choice, the Cassette is either placed inside of Sofia 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 to be scanned (READ NOW Mode). Sofia will scan the test strip and measure the fluorescent signal by processing the results using method-specific algorithms. Sofia will display the test results.

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

Product Description

Sofia 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 scanned. This ensures that sample flow has occurred within the Cassette to permit an accurate reading.

Sofia then displays the test results to the User (e.g., Quantitative, Qualitative, or Invalid) on the screen. The results can also be automatically printed on an integrated printer if this option is selected, saved on an SD Card and sent to an LIS if connected.

Calibration Check and Quality Control (QC)

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

- **Sofia Calibration Check:** Calibration Check is a required function that checks the internal Sofia optics and systems. A Calibration Check must be performed every 30 days or less, as set by the supervisor. A special Calibration Cassette is provided with the Installation Pack.
- **External Quality Controls:** Refer to assay-specific Package Insert for details on specific tests.

Instructions are provided in the **Calibration Check** 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 has been designed to operate in different development modes. The Supervisor and User can identify the mode that works best with the 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 has the capability of three different WALK AWAY Modes: User selected WALK AWAY Mode, Locked WALK AWAY Mode and Forced WALK AWAY Mode.

- User Selected **WALK AWAY Mode** may be 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 Cassette and then immediately inserts the Cassette into Sofia. Sofia will automatically allow the Cassette to develop for the required time period (pre-programmed for each test), scan the Cassette, analyze and interpret the data, and automatically and objectively display the test result.
- **Locked WALK AWAY Mode** can only be selected while logged in as a Supervisor. In this mode Sofia 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.
- **Forced WALK AWAY Mode** is used with certain Sofia assays. Please refer to appropriate assay-specific Package Insert for information regarding this mode. In this mode Sofia will automatically develop the Cassette for the required time period (pre-programmed for each test), scan the Cassette, and display the test result when completed. READ NOW development timing will **not** be available for some assays that require Forced WALK AWAY Mode.

READ NOW Mode may be most convenient for high volume situations as Sofia can quickly read multiple patient samples sequentially. The User dispenses the patient sample into the Cassette. The User then **manually** times the development period **outside** of Sofia. 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 Cassette into Sofia. Sofia will immediately scan and display the test result within 1 minute.

System Components

Inspect the shipping container for obvious shipping damage prior to opening. Unpack the shipping container and inspect the unit and components for damage.

The following system components are supplied with the purchase of each Sofia:

Sofia

- Sofia with integrated printer
- Printer Paper
- Batteries 4x LR6-AA + 6V, ⎓4.26 A
- AC Power Cord
- DC Power Cord
- Specific Country Adapter(s)

Installation Pack

- User Manual
- QuickStart Guide
- Warranty Card
- Barcode Scanner
- Barcode Scanner Stand
- SD Card(s) – Test Type Files (Blue), Language Files (Yellow),* and Blank SD Card
- Calibration Cassette

For components supplied with Virena®, refer to the Sofia Surveillance Mode Installation Instructions.

Contact Quidel Technical Support for additional supplies at 800.874.1517 (in the U.S.). See page 4 for additional contact information.

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

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

**Language Files (Yellow) may not be provided in the Installation Pack. If needed, contact Quidel Technical Support.*

User Types

Users/Operators without Supervisor authorization have access to the following functions:

User/ Operator

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

Instructions for these basic User functions are provided in the Basic User Instructions section.

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

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

- Load Test Types
- Add or Delete Users
- Load and Save Settings
- Save Test Records
- Update Sofia Firmware
- Load Languages
- View User History
- View Message Logs
- Review Patient Results
- Review Statistics
- Change Settings

System Display and Keypad

System Display

The Sofia contains a 3.5-inch diagonal color LCD display for interacting with the user interface.

System Keypad

The User Interface includes a numeric keypad and other function specific buttons (Table 1 and Figure 1).

Table 1
Keypad Description

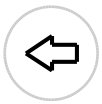
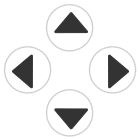
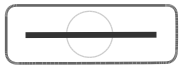
Button Icon	Button Name	Function	Example of Use
	Numeric Keypad	Enter numeric data	Entering a date and time or IDs
	Backspace	Backspace to delete data	Delete the character to the left of the cursor
	Decimal Point	Decimal Point	IP Addresses
	Up/Down/Left/Right	Navigate the User Interface	Selecting a field
	Eject	Eject a Cassette	Interrupting testing
	Soft Keys	Select menu options shown on the screen above each key	Select OK on the “Enter or Scan” screen
	Paper Feed	Paper Feed	Loading paper into Sofia
	Print	Manual print	Printing previous results

Figure 1

System User Interface

Screen Icon	Description
	Indicates Sofia is in the **WALK AWAY Mode.**
	There is an SD Card inserted in the slot.
	Indicates Sofia is in the **READ NOW Mode.**
	Indicates the **Supervisor** is currently logged into Sofia.

Installation, Setup and Operation

Sofia Setup

Sofia Setup

- Place Sofia on the bench top within reach of an electrical outlet. The unit is portable and can be moved to a suitable location for testing. Ensure countertop is stable, flat and dry. Avoid direct sunlight.
- Ensure the bench provides adequate space for Sofia and barcode scanner stand. There must be space to open/close Sofia drawer and access the connection ports on the back of the unit.
- Plug the DC power cord into the power port in the back of Sofia. Plug the country specific AC adapter power cord into the DC power cord and an available electrical outlet.
- Plug the Barcode Scanner into the PS2 port in the back of Sofia (Figure 2).

Figure 2

Note: For Virena Router set-up, please refer to the Sofia Surveillance Mode Installation Instructions that are supplied in the separate Virena Router package.

- SD Card – Proper insertion should follow the diagram label on Sofia. The SD Card should be inserted with the copper contact points facing away from the power switch with the notched corner facing down as shown (Figure 3).

Figure 3

Loading Paper

Load paper into the integrated printer of Sofia (Figure 4).

- Lift black handle to remove paper cover.
- Place paper roll in Sofia with the paper tail coming from under the roll towards the operator.
- Holding the paper tail towards the operator, replace the paper cover and snap in place.

Note: The paper does not need to be fed through the roller bar.

Note: If the roller bar disconnects from paper cover, snap into place with gear on the left (Figure 4).

Figure 4

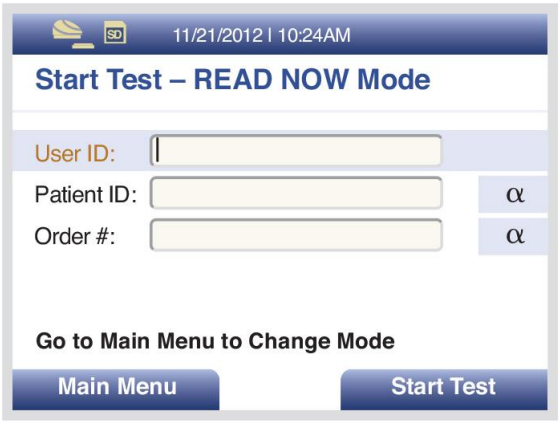
Power Up

Turn Sofia on using the power switch located on the rear panel (Figure 5). Hold the toggle switch down for 1-2 seconds until the screen illuminates.

Figure 5

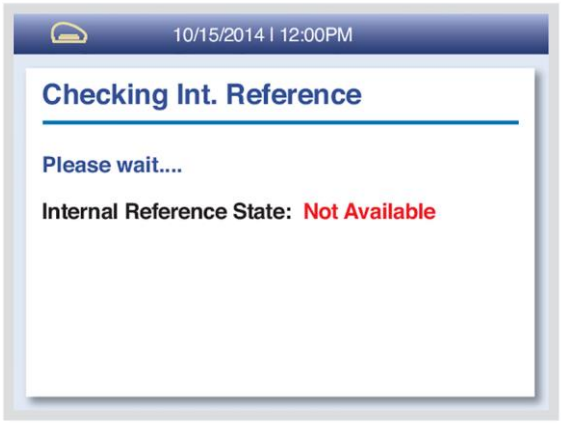
Sofia will display the Power On progress screen and complete a Power On Self-Test. The Barcode Scanner will chirp upon powering up. Once the Power On is complete, Sofia will display the Start Test screen (Figure 6) and Sofia is ready for use.

Figure 6



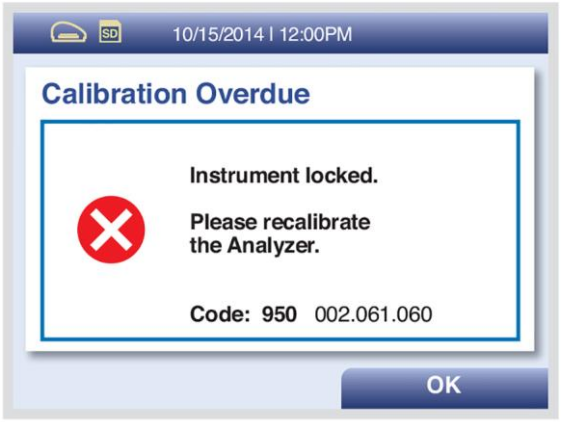
When turning on Sofia for the first time, the **Checking Internal Reference** screen will display (Figure 7). Depending on which drawer is installed, the Internal Reference State may not be available. If this is the case, it is acceptable to continue testing.

Figure 7



Following the internal reference check, Sofia will require a calibration check (Figure 8). A calibration check must be performed before using it for the first time.

Figure 8



Cassette Drawers

Sofia has three cassette drawers available for testing the different assays. Below are the three versions of cassette drawers and compatible cassette designs provided to Sofia users (Figure 9). For more information, please contact Quidel Technical Support at 800.874.1517 (in the U.S.). See page 4 for additional contact information.

Figure 9

Standard Drawer (Gray)

- Accepts standard Quidel Cassette formats

Hybrid Drawer (Blue)

- Accepts multiple Quidel Cassette formats

Hybrid Drawer (Orange)

- Required for Quantitative Assays

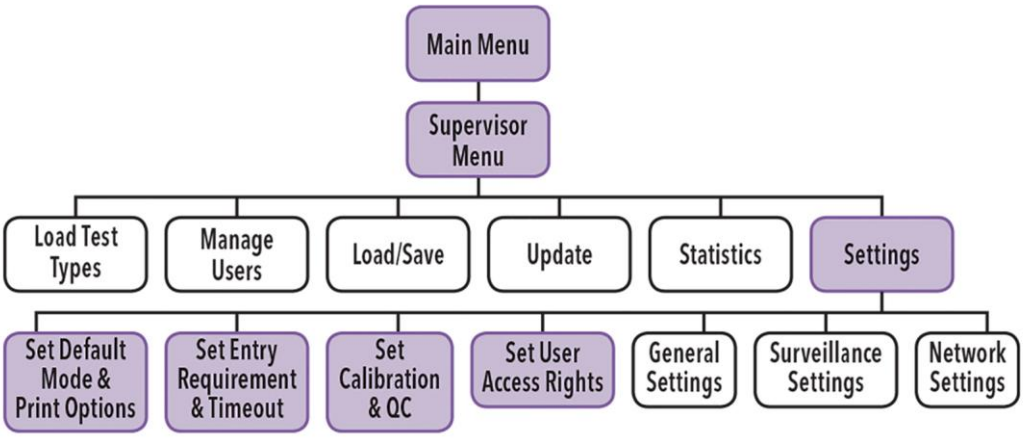
Navigating the Menu Settings

Use the Up/Down arrows in the circle just below the screen to highlight the desired options on the menu (Figure 10).

Use the keys to the right and left of the circle just below the screen for SELECT, BACK, OK, CANCEL and MAIN MENU options.

Figure 10

System Settings



Logging in as Supervisor

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

Entry to the **SETTINGS** menu is accomplished by logging in as the Supervisor. Sofia comes from the manufacturer with a default Supervisor login ID which should be changed when Sofia 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 4 for additional contact information.

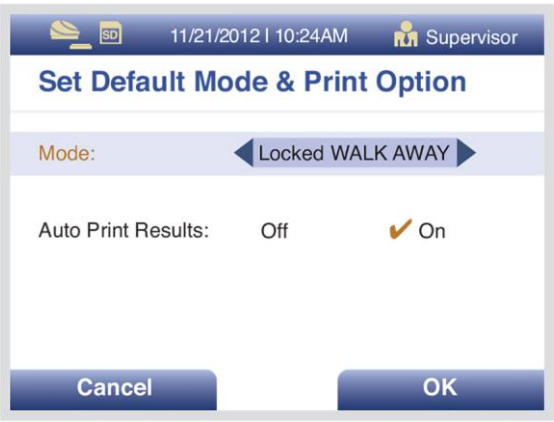
Set Default Mode and Print Options

Default Mode

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

Using the Up/Down arrows, select **Mode**. Using the Left/Right arrows, select **either WALK AWAY, READ NOW** or **Locked WALK AWAY** development mode (Figure 11). Select the **OK** button to confirm.

Figure 11



Print Options
Using the Up/Down arrows, select **Auto Print Results**.

Using the Left/Right arrows, select **ON** or **OFF**. **Auto Print Results ON** forces the printer to automatically print every patient test, calibration and QC result at the end of each procedure.

Select the **OK** button to confirm and return to the Settings screen.

Set Entry Requirement and Timeout

Setting the Entry Requirement allows the supervisor to control what information is provided before running a test.

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

User ID Required
Using the Up/Down arrows, select **USER ID**. With the Left/Right arrows, select **Required** or **Optional**.

Use the Down arrow to highlight the next option. Press **OK** to confirm when changes are complete and return to the Settings screen.

Patient ID Required
In the **Set Entry Requirements and Timeout** menu, using the Up/Down arrows, select **PATIENT ID**. With the Left/Right arrows, select **Required** or **Optional**.

Use the Down arrow to highlight the next option. Press **OK** to confirm when changes are complete and return to the Settings screen.

Order # Required
In the **Set Entry Requirements and Timeout** menu, using the Up/Down arrows, select **ORDER #**. With the Left/Right arrows, select **Required** or **Optional**.

Use the Down arrow to highlight the next option. Press **OK** to confirm when changes are complete and return to the Settings screen.

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 Up/Down arrows, select **Idle ID TIMEOUT**. With the keypad, enter the number of minutes for the timeout from 1-20. Press **OK** to confirm when changes are completed.

> **Note**: If multiple users will be sharing frequent use for Sofia testing, a shorter idle time is recommended.

Set Calibration and QC

Calibration Reminder
Using the keypad, enter the number of days for the reminder interval from 2-30 days.

Once employed, Sofia will provide an on-screen reminder to run calibration.

IMPORTANT: Once the reminder has popped up, no tests can be run until calibration has been successfully completed.

QC Barcode Requirement
The QC Barcode Requirement option requires the capture of the lot number and expiration date of assay kit.

Using the Up/Down arrows, select **Require QC Barcode**. Using the Left/Right arrows, select **ON** or **OFF.** If set to **ON,** User must scan the QC barcode every time a QC test is run. Press **OK** to confirm when changes are complete and return to the Settings screen.

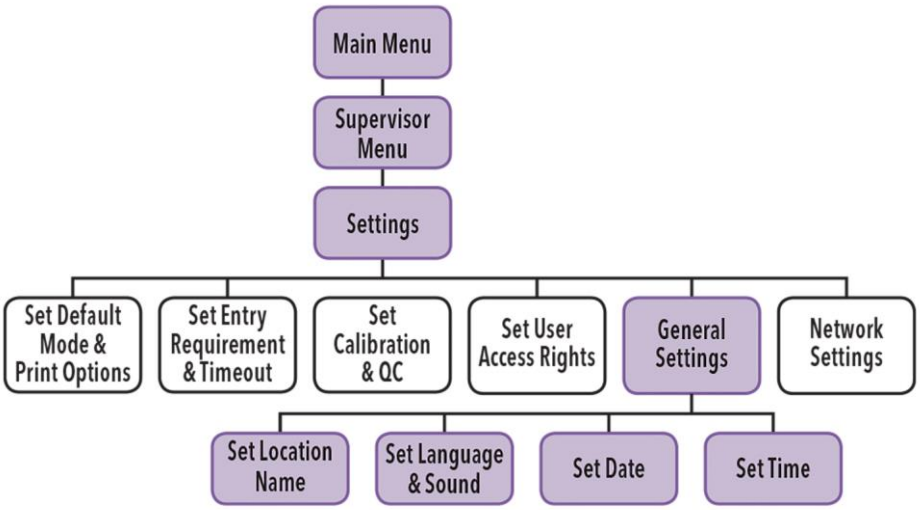
Set User Access Rights

The User Access Rights option allows Supervisor to determine if Operators have access to Patient Data.

Access Patient Data
When enabled, this allows a non-Supervisor User to view and print past patient test results as long as they have entered a valid User ID. When disabled, it prevents a non-Supervisor user from accessing patient related data.

Using the Left/Right arrows, select **ON** or **OFF** and press **OK** to confirm and exit.

General Sofia Settings



Set Location Name

The Location Name setting sets the name of the clinic, hospital, lab or physician's office that will appear on all of the printouts.

Select **SET LOCATION NAME** in the General Settings.

Using the Left/Right/Up/Down arrows, select one letter at a time and press **OK** to construct the name of up to 15 characters, and/or spaces.

To delete a letter, press the **BACKSPACE** button ⇦ the keypad.

To delete entire entry, select **Clear All** and press **OK**.

When the name is complete, select **Done** and press **OK** to return to the General Settings Menu.

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

Set Language and Sound

Default Language
Sofia allows for two languages to be programmed at all times. The first language automatically defaults to English, and if another language is required, you may upload another language using an SD Card or through the Cloud. Refer to the **Update** section for instructions. This setting is used to select which language Sofia displays.

Using the Left/Right arrows, select English OR the other installed language (if installed) and press the Down arrow to select **SET SOUND**.

Set Sound
Setting the sound of Sofia will allow the Supervisor to turn ON or OFF the beep sound when the keypad is pressed.

Using the Left/Right arrows, select **ON** or **OFF.** Press **OK** to confirm and return to the General Settings Menu.

Set Date

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

From the General Settings Menu, select **SET DATE** to update the current day, month and year. The User can change the displayed date format as MM/DD/YYYY or dd.mm.yyyy format.

Using the Up/Down arrows, select the parameter to change.

For the format fields, use the Left/Right arrows.

For the **SET DATE** fields, use the Up/Down arrows to select the desired field and then use the numeric keypad to enter the correct numbers. Note that the Left arrow backspaces and deletes existing characters.

Select **OK** to confirm all changes and return to the General Settings Menu or CANCEL to exit with no changes.

Set Time

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

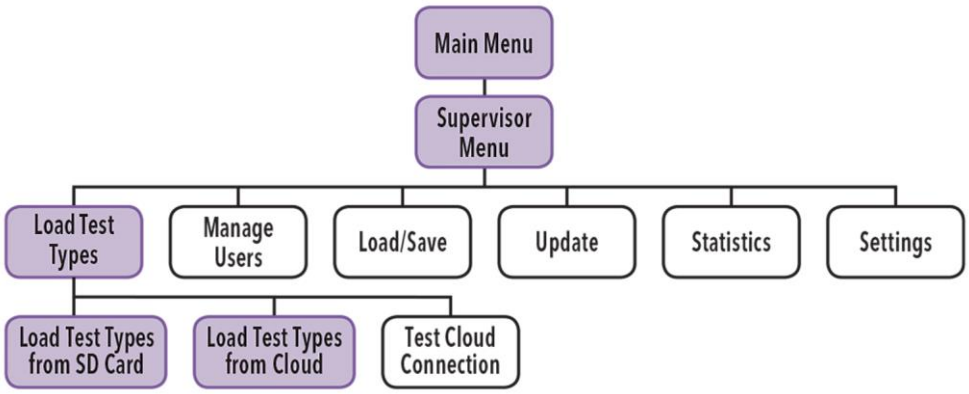
The User can change the displayed time format as 12h or 24h format.

In the **SET TIME** fields, use the Left/Right arrows to select 12h or 24h. Then use the Up/Down arrows to select the hours and minutes. Then use the numeric keypad to enter the correct time.

When the 12h format is chosen, use the Left/Right arrows to select **AM** or **PM**. When the 24h format is chosen, the time must be entered in that format.

Select **OK** to confirm all changes and return to the General Settings Menu or CANCEL to exit with no changes.

Load Test Types



A new test type file is needed for each new assay or test. These test type files can be installed from an SD Card or from the Cloud. In order to download test type files from the Cloud, Sofia must currently have Firmware 2.0 or higher.

Select **LOAD TEST TYPES** from the Supervisor Menu.

Load Test Types from SD Card

Choose ***Load Test Types from SD Card*** to load new Sofia test type files. Insert the SD Card with the test type files (blue) to be installed and select **OK**. Sofia will load the test types that are on the SD Card if they are not already in Sofia.

Sofia will display the test types that are newly installed. If the same version of a test type file has already been installed, status will show as “old.” Press **OK** to confirm installation.

Load Test Types From Cloud

Choose ***Load Test Types from Cloud*** to load new test type files. Select **OK** to connect to Cloud. After installation, press **BACK** to exit. Sofia reads the new test type files on the Cloud that are being installed and displays the test types files that are newly installed.

Note: When loading Test Type Files from the Cloud, do not unplug or power off Sofia.

If unable to load the Test Type Files from the Cloud successfully, refer to the Update Setting section on page 40 for details on the IP Address and Port Number.

Test Cloud Connection

Note: Test Cloud Connection option is not required for every update or installation. It is used to troubleshoot when Sofia is not installing the updates properly.

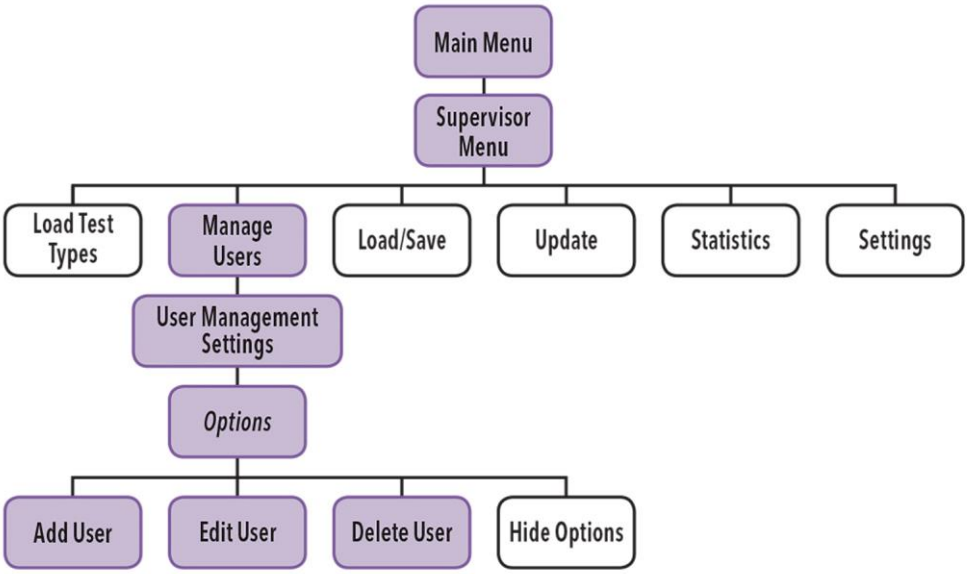
Select **Test Cloud Connection** to verify router connection.

If Cloud Connection is established, screen displays "The Analyzer can be connected to Cloud." Then press **OK**; Sofia is now connected to the Cloud.

If Cloud Connection is not established, screen displays "The Analyzer cannot be connected to Cloud." Review **Sofia and Virena Router Connection Installation** and **Set Network Configuration** sections to confirm all settings and connections.

If unsuccessful in configuring Router or Cloud connections, contact Quidel Technical Support. See page 4 for additional contact information.

Managing Users



Add User

Select the Options key in the Manage Users screen to view the pop-up menu. Use the Up/Down arrows to select **Add User**.

Use the numeric keypad or barcode scanner to enter the ID number. User ID must be numeric and at least 4 digits.

Then use the Up/Down arrows to select User Type and Left/Right arrows to select between Operator and Supervisor.

Press the **Save & Next** button when both fields are complete.

Using the Left/Right/Up/Down arrows, select a letter at a time and press **OK** to construct the name (Figure 12).

Figure 12

To delete a letter, press the **BACKSPACE** button on the keypad.

To delete entire entry, select **Clear All** and press **OK**.

When the name is complete, select **Done** and press **OK**.

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

Edit User

Select the Options key in the Manage Users screen to view the pop-up menu. Select **Edit User** to edit the name of a user.

Use the numeric keys or barcode scanner to enter the ID number.

Edit the User Name using the Up/Down/Left/Right arrows. To save edits select **Done** and press **OK**.

Press **BACK** to return to the User Management Settings.

Press **CANCEL** to return to the Supervisor Menu.

Delete User

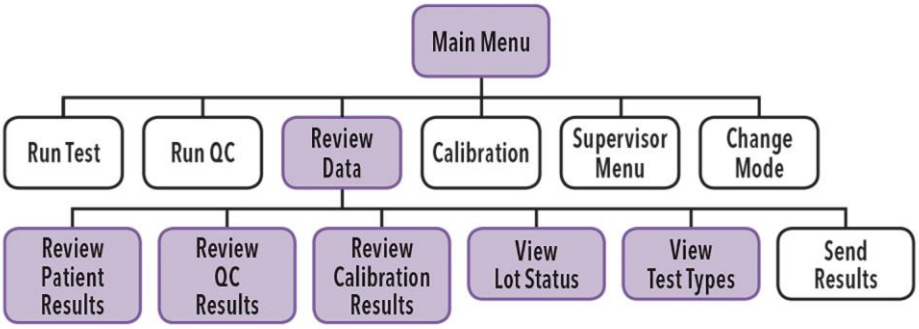
Highlight the User ID to be removed. Select the Options key in the Manage Users screen to view the pop-up menu, then select **Delete User** to delete a User from the device.

Press **BACK** to return to the User Management Settings.

Press **CANCEL** to return to the Supervisor Menu.

Note: Maximum number of users is 400.

Review Data



Review Patient Results

Patient Results include the records for previously run patient tests. The results can be searched to locate specific results, and Operators will only have access if the Supervisor has enabled the Access Patient Data function.

To find specific results, select **OPTIONS** then **SEARCH**.

The search Patient Results screen provides the User the ability to search or filter by:

- Patient ID
- User ID
- Test Type
- Result

Select the filter criteria using the Left/Right/Up/Down arrows. Select **SEARCH** to filter the results.

A reduced set of results is displayed as **Filtered Patient Results**.

Select **Options** and **All Results** to display all Results.

In any list of Patient Results, you may show the detailed results by highlighting the result to view, selecting **OPTIONS** and **DETAILS**.

This display is essentially the same as the original results screen when the test was originally run and displayed.

Select Print button print results. Select the **BACK** button to return to results. Select the **BACK** button again to return to the Review Data screen.

Review QC Results

QC Results include the records for previously run QC (Positive and Negative Control) tests. The results can be searched to locate specific results.

The **OPTIONS** button enables search function to locate QC result details in the same manner as Patient Test Results. Select the **BACK** button to return to the Review Data screen.

Review Calibration Results

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

A list of the calibrations performed will be displayed.

Select the **BACK** button to return to the Review Data 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 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 the **BACK** button to return to the View Lot Status screen. Select the **BACK** button again to return to the Review Data Section.

Calibrator Lot Status

When an assay requires the use of a calibrator, a list of kit/lots that have been processed by the QC procedure will be displayed along with the expiration date.

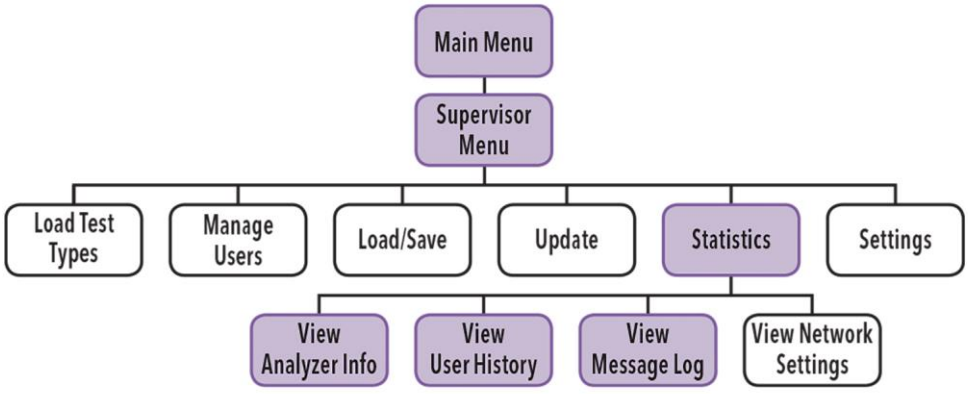
Select the **BACK** button to return to the **Review Data** screen.

View Test Types

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

Select the **BACK** button to return to the View Lot Status screen. Select the **BACK** button again to return to the Review Data screen.

Sofia Statistics



View Analyzer Info

View Analyzer Info displays the Firmware Version, Bootware Version, Hardware Version, Number of Scans and Sofia Serial Number.

Select the **BACK** button to return to the Statistics screen.

View User History

View User History allows Supervisors to view the User ID, Name and User Type information.

Using the Up/Down arrows highlight the User to view and select **DETAILS**.

Under **DETAILS**, Supervisor can view the different Test Type and the number of positive, negative, quant or invalid results performed by the selected user.

Select the **BACK** button to return to the User History screen. Select the **BACK** button again to return to the Statistics screen.

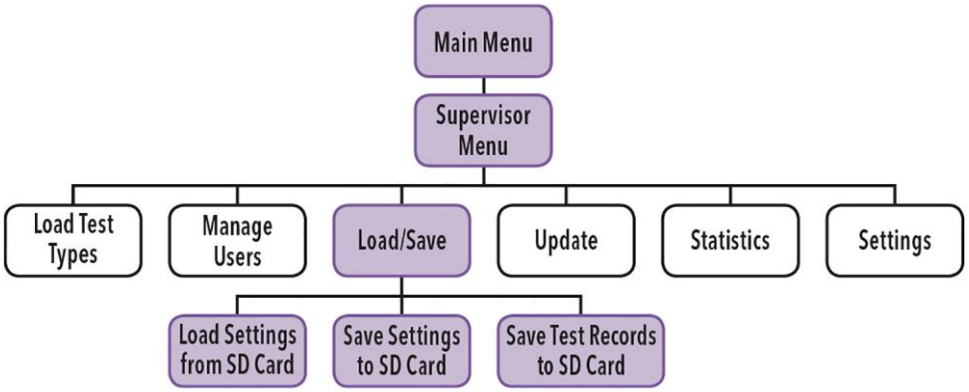
View Message Log

View Message Log displays the Message Code with the Date and Time.

Select the **BACK** button to return to the Statistics screen.

Note: Both User History and the Message Log can be printed using the Print button.

Load/Save



Save Settings to SD Card

To save the settings of one Sofia onto another Sofia you may clone the settings of the first and duplicate onto additional Sofia.

Select **Save Settings to SD Card** from the Load/Save menu.

Insert a blank formatted SD Card and select **OK** to Save Sofia settings data. When the Save is complete, remove the SD Card and press **OK**.

When cloning Sofia, all settings including Test Type Files will transfer over. User history, lot status, QC and test data will not transfer over.

Load Settings From SD Card

Select **Load Settings from SD Card** from the Load/Save menu.

To load the settings of Sofia onto another Sofia insert the SD Card from the "Master" Sofia that has the settings you wish to duplicate. Select **OK**.

When the screen prompts that data has loaded successfully, remove the SD Card and select **OK**.

Save Test Records to SD Card

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

If a blank SD Card is inserted prior to Sofia use, then 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 SD card.

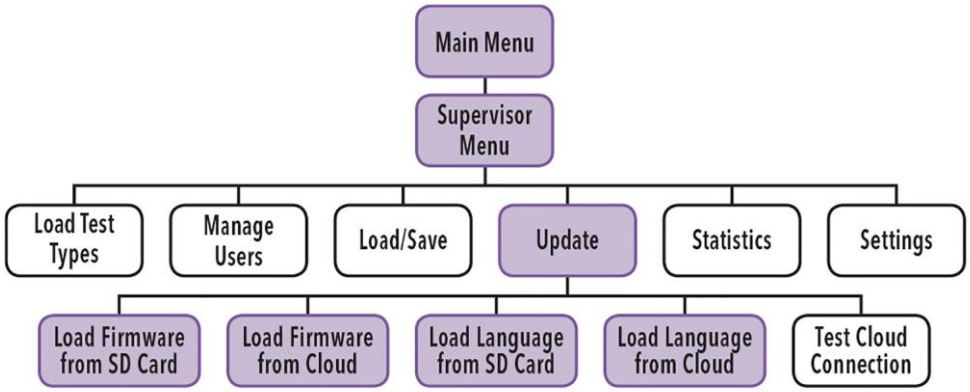
Select **Save Test Records to SD Card** from the Load/Save menu.

Insert a blank formatted SD Card and select **OK** to Save the Sofia record.

When complete, remove the SD Card and select **OK**.

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

Update



Load Sofia Firmware

Occasionally, Quidel may release firmware updates to improve functionality of Sofia. These updates can be installed from an SD Card or from the Cloud. In order to download the latest firmware from the Cloud, Sofia must currently have Firmware 2.0 or higher

Load Firmware from SD Card

Insert SD Card with the firmware to install.

Choose ***Load Firmware from SD Card*** to load new Sofia firmware. Sofia reads the new firmware version on the SD Card that is being installed and displays a Load Analyzer Firmware confirmation screen.

Select **OK** to confirm installation.

Sofia will complete a self-installation and then power up in the normal startup screen.

Load Firmware from Cloud

Choose ***Load Firmware from Cloud*** to load new Sofia firmware. Sofia reads the new firmware version on the Cloud that is being installed and displays a Load Analyzer Firmware confirmation screen.

Select **OK** to confirm installation.

Sofia will complete a self-installation and then power up.

> Note: During the firmware installation time, do not unplug or power off Sofia. The firmware update might take up to 15 minutes.

If unable to load the Firmware from the Cloud successfully, refer to the Update Settings section on page 40 for details on the IP Address and Port Number.

Test Cloud Connection

> **Note: Test Cloud Connection** option is not required for every update or installation. It is used to troubleshoot when Sofia is not installing the updates properly.

Select **Test Cloud Connection** to verify router connection.

If Cloud Connection is established, screen displays “The Analyzer can be connected to Cloud.” Then press **OK** to return to the Main Menu; Sofia is now connected to the Cloud.

If Cloud Connection is not established, screen displays “The Analyzer cannot be connected to Cloud.” Then press **OK** to return to the Main Menu. Review **Sofia and Virena Router Connection Installation** and **Set Network Configuration** sections to confirm all settings and connections.

If unsuccessful in configuring Router or Cloud connections, contact Quidel Technical Support. See page 4 for additional contact information.

Load Language File

Sofia is capable of displaying several languages. Only two languages may be stored at one time. Language files can be installed from an SD Card or from the Cloud. In order to download the latest language file from the Cloud, Sofia must currently have Firmware 2.0 or higher.

Load Language File from SD Card

Select **Load Language File** from SD Card to load a new language file.

Insert the correct SD card with the language file on it (yellow label) and select **OK**. Wait for the language file to be read, then select **OK** to confirm installation. When language is loaded correctly, remove the SD Card and select **OK** to return to the Supervisor Menu. The menu will now be in the newly installed language.

Load Language File from Cloud

Select **Load Language File from Cloud** to load a new language file.

Wait for the language file to be read then select **OK** to confirm installation. When language is loaded correctly, select **OK** to return to the Supervisor Menu. The menu will now be in the newly installed language.

> **Note:** When loading Language Files from Cloud, do not unplug or power off Sofia.

If unable to load the Language File from the Cloud successfully, refer to the Update Settings section on page 40 for details on the IP Address and Port Number.

Test Cloud Connection

> **Note:** Test Cloud Connection option is not required for every update or installation. It is used to troubleshoot when Sofia is not installing the updates properly.

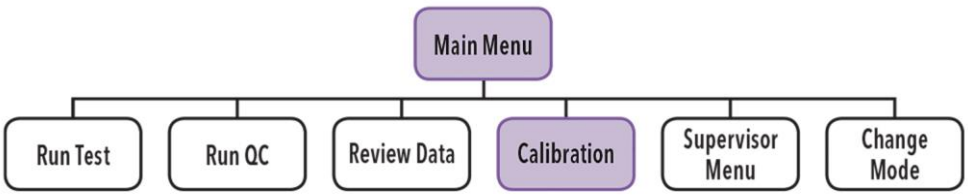
Select **Test Cloud Connection** to verify router connection.

If Cloud Connection is established, screen displays “The Analyzer can be connected to Cloud.” Then press **OK** to return to the Main Menu; Sofia is now connected to the Cloud.

If Cloud Connection is not established, screen displays “The Analyzer cannot be connected to Cloud.” Then press **OK** to return to the Main Menu. Review **Sofia and Virena Router Connection Installation** and **Set Network Configuration** sections to confirm all settings and connections.

If unsuccessful in configuring Router or Cloud connections, contact Quidel Technical Support. See page 4 for additional contact information.

Calibration Check



Calibration Check is a required function that ensures optimal performance by checking the internal Sofia 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 Calibration Check

Use the specific Calibration Cassette included with Sofia for the Calibration Check.

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

The Calibration Cassette will automatically eject when calibration is complete.

Select **OK** 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 Calibration Check.

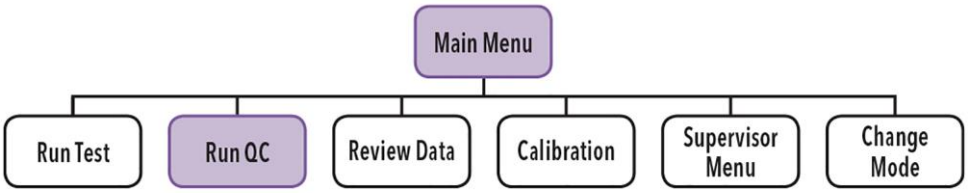
Calibration Results

Sofia displays "Calibration Results" indicating that Calibration Check is completed. The results will be either "Passed" or "Failed."

The calibration results are stored and can be recalled with the **Review Calibration Results** function of Sofia from the **Review Data** menu (page 29).

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 4 for additional contact information.

Run QC



External Quality Controls (QC) may be tested to demonstrate that the assay-specific reagents, 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.

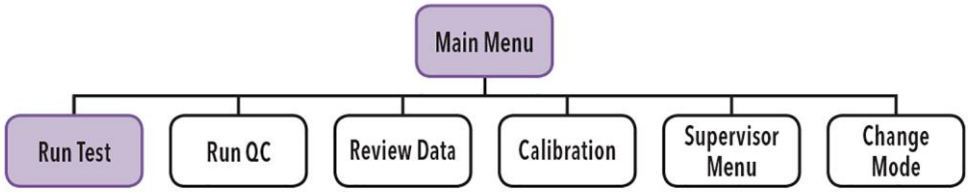
QC Results

The displayed results are stored and can be recalled with the **Review QC Results** function in the **Review Data** menu.

Select **OK** to complete the QC process and return to the Main Menu.

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 4 for additional contact information.

Run Patient Specimens



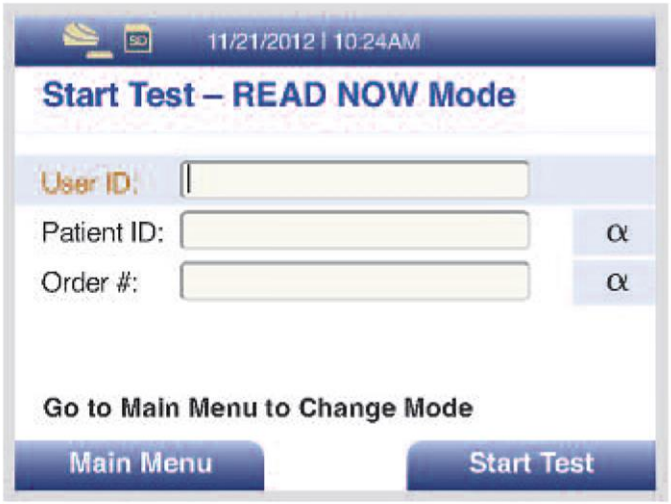
IMPORTANT: Refer to the assay-specific Package Insert for each specific test for instructions on preparing Test Cassettes with patient samples.

In the **Main Menu**, select **RUN TEST** to get back to the **Start Test** screen.

Before entering any User ID or specimen information:

- Select the desired Development mode: **WALK AWAY** or **READ NOW** (See description of the WALK AWAY and READ NOW development modes on page 13).
- The current (or default) development mode will be shown at the top of the Start Test screen (Figure 13). If the default mode is the desired mode, no changes are required.

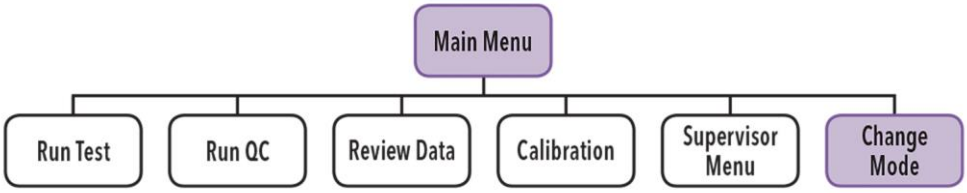
Figure 13



- If the Supervisor has set the default mode to **Locked WALK AWAY** mode, then User will only be allowed to test in the **WALK AWAY** mode.

- Depending on the assay, Sofia may automatically run the test in **Forced WALK AWAY** mode. In this case, no changes need to be made to the work mode.

Change Development Mode



Select the desired development mode by using the Up/Down arrows. Then select **OK** to confirm.

Sofia will then return to the **Start Test** screen displaying the newly selected development mode.

Enter the User ID

User ID can be entered using the barcode or manually using the keypad.

Use the arrows to highlight the **User ID** field on the **Start Test** screen. Use the barcode scanner (Figure 14) to scan the barcode from a User's ID Card or manually enter the data using the numeric keypad on Sofia.

Enter the Patient ID

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

Use the arrows to highlight the **Patient ID** field on the **Start Test** screen. Use the barcode scanner to scan a Patient ID barcode from a patient chart or other source or manually enter the data by selecting the alpha entry **α** option and using the numeric keypad on Sofia.

Figure 14

Enter the Order #, if applicable

Use the arrows to highlight the Order # field on the Start 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 by selecting the alpha entry **α** option and using the numeric keypad on Sofia.

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 into the Test Cassette. Do not let the Cassette develop outside Sofia.

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

Press START Test

Sofia drawer will automatically open.

Insert the Test Cassette into the drawer and gently close the drawer (Figure 15).

Figure 15

Upon closing the drawer, Sofia 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 screen.

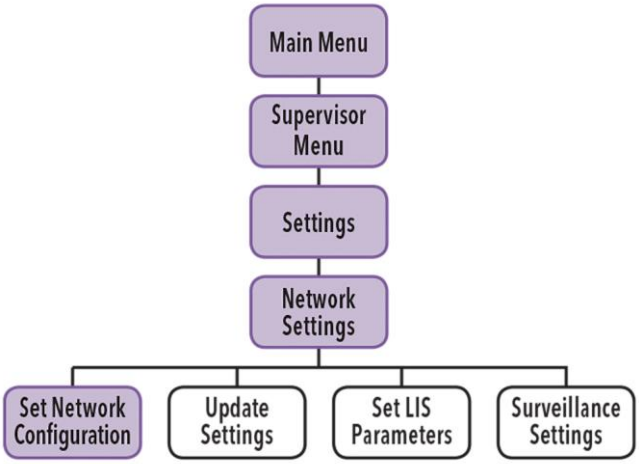
The results will be automatically printed on the integrated printer if the **Auto Print** option has been selected as the default setting. The results can also be printed by pushing the PRINT button on Sofia.

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 will no longer accept that Cassette a second time.

If the procedural control is “Invalid,” repeat the test with a new patient sample and a new Cassette. To run another patient specimen, select Start New Test.

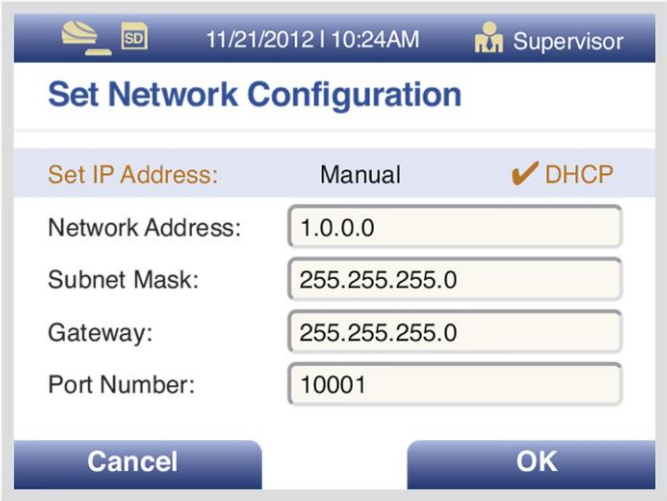
Network Configuration



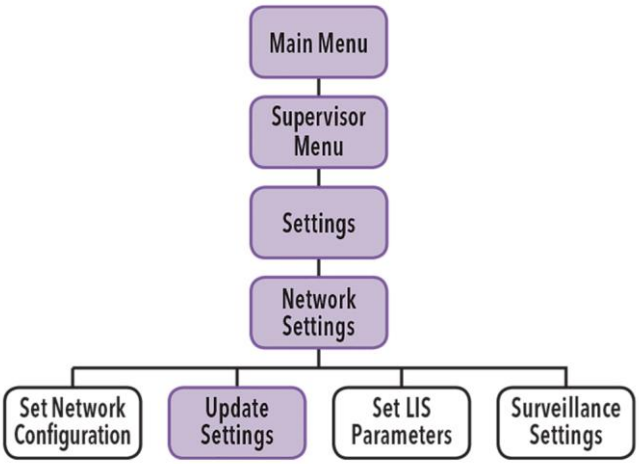
For the Network Configuration, use the Up/Down arrows to select the field to modify.

For the IP (internet protocol) Address, use Left/Right arrows to select “Manual” or “DHCP.” Use the numeric keypad to enter address and numbers for the Network Address, Subnet Mask, Gateway and Port Number (Figure 16). Select **OK** to save changes and exit.

Figure 16



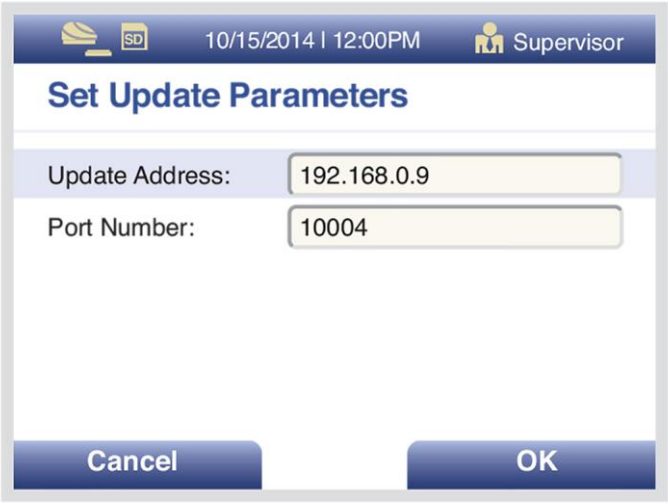
Update Settings



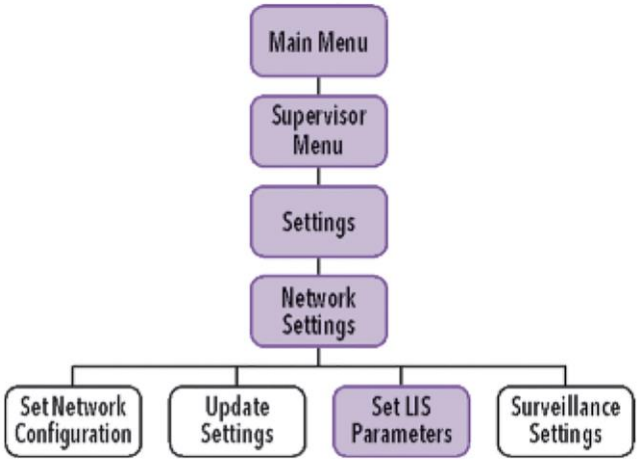
In order to download Test Type Files, Language Files or Firmware via the Cloud, Sofia must be set up to a specific IP Address and Port Number.

Sofia's default IP Address and Port Number (Figure 17) are set up to be compatible with the Virena Router when the Router is wired directly to Sofia. For other configurations, contact Quidel Technical Support.

Figure 17



Laboratory Information System (LIS)

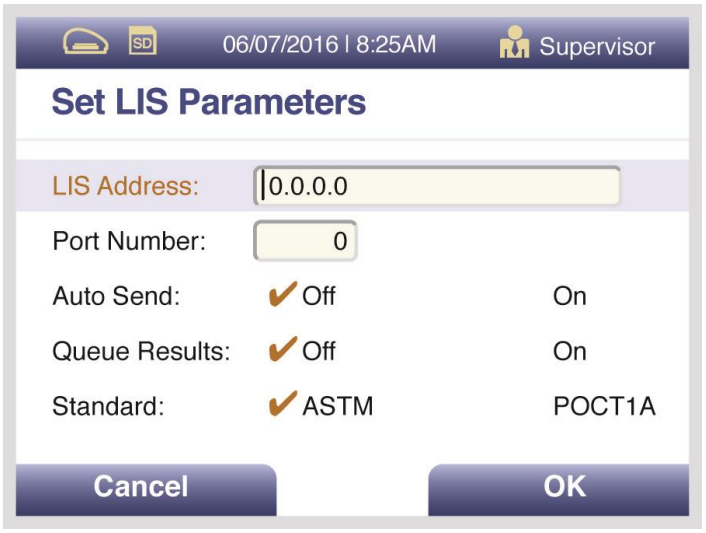


LIS Parameters and Settings

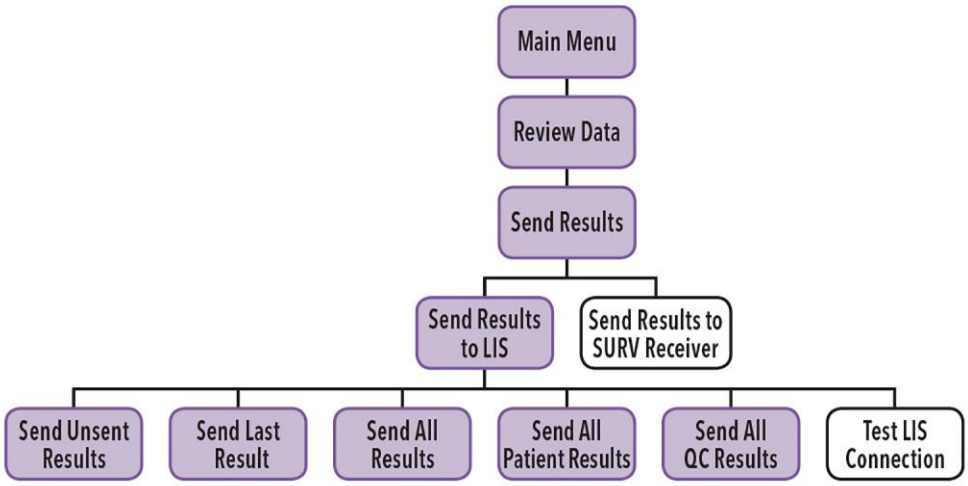
Select **Set LIS Parameters**, use the numeric keypad to enter the **LIS Address** in the form. Use the Up/Down arrows to select **Port Number**, then use the numeric keypad to enter number.

For the **Auto Send** and **Queue Results** options, use the Left/Right/Up/Down arrows to select **Off** or **On** option. Select **OK** to save changes and exit (Figure 18).

Figure 18



Send Results to LIS



When **Send Results to LIS** is selected, the following options will be displayed on the screen:

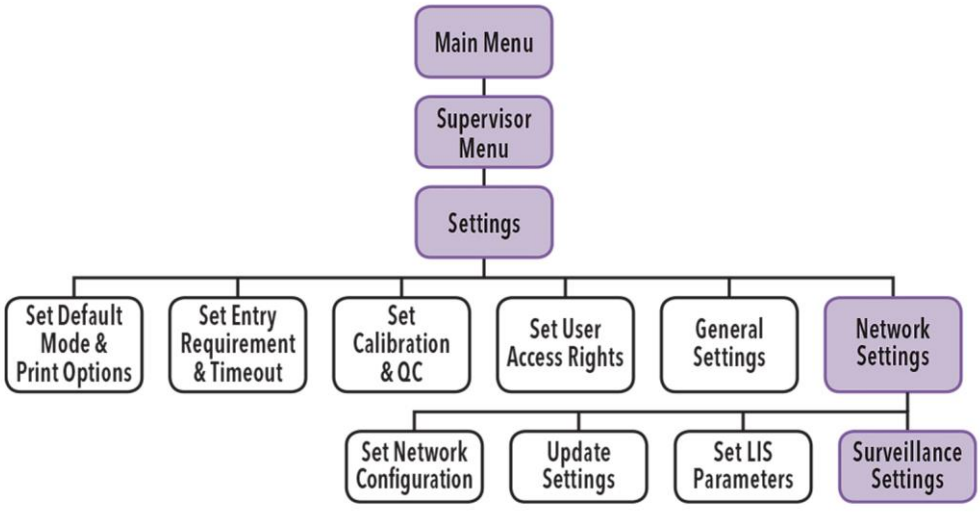
- Send Unsent Results
- Send Last Result
- Send All Results
- Send All Patient Results
- Send All QC Results
- Test LIS Connection

When selecting to send results, you will see **Sending to LIS – Please Wait**.

If data was sent successfully, the screen will display **Data were transmitted successfully.**

Note: If the auto send function for LIS or SURV is turned ON, and results are not transmitted successfully, then Sofia will keep retrying every 5 minutes of inactivity until a connection with the router or server is established.

Surveillance Mode



Sofia and Virena Router Connection Installation

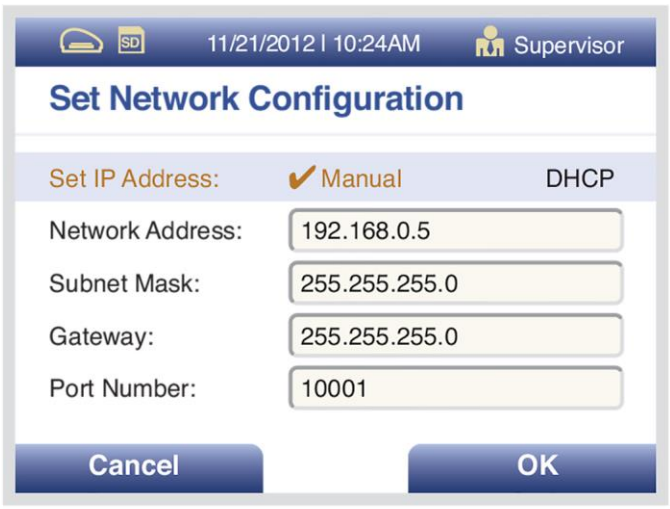
Please refer to the **Sofia Surveillance Mode Installation Instructions** that are supplied in the separate Virena Router package.

Set Network Configuration

Refer to the **Network Configuration** section (page 39).

Scroll to **Set IP Address** and ensure **Manual** is checked, see Figure 19. Scroll to Network Address and enter IP network address to 192.168.0.5. Verify that all configurations on Sofia including: Subnet Mask, Gateway and Port Number match what is shown in Figure 19. If it does not match, please enter the correct numbers. Then select **OK**.

Figure 19



Wait 1 minute, then go to **View Network Settings** under Statistics and ensure that you have a valid IP address.

Surveillance Mode Set Up

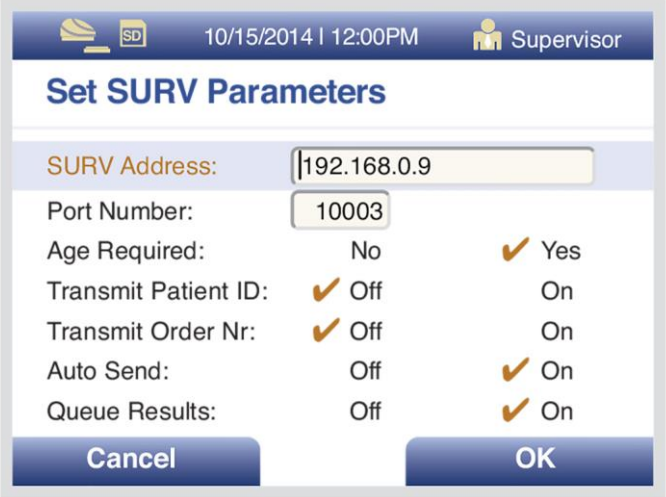
> **Note:** If Sofia does not show Surveillance Settings as an option, Sofia will require an upgrade to Firmware 1.3.1 or above.

Go to Surveillance Settings, then under **Set SURV Parameters**, select the following using the Left/Right/Up/Down arrows:

Age Required: ✓ Yes
Transmit Patient ID: ✓ Off
Transmit Order Nr: ✓ Off
Auto Send: ✓ On
Queue Results: ✓ On

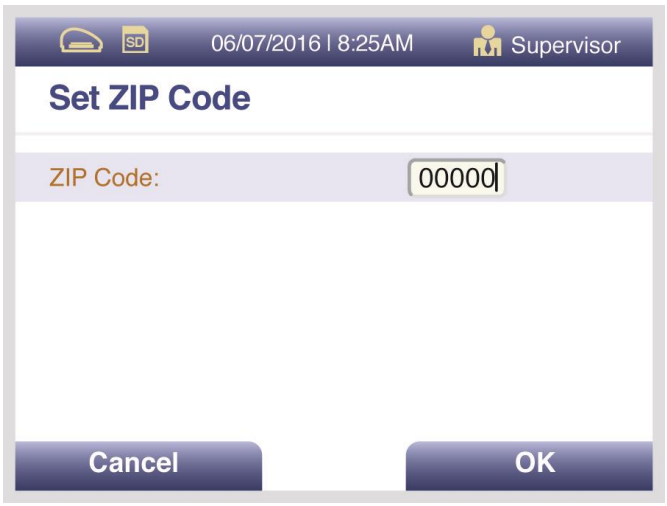
When completed, screen will display as Figure 20.

Figure 20



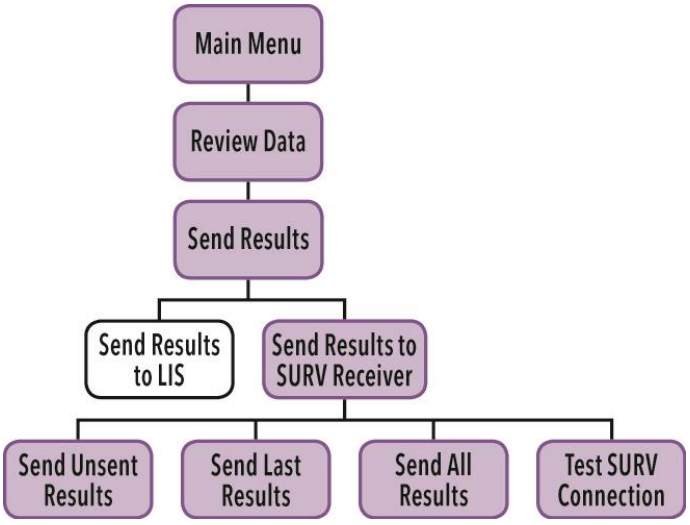
Press **OK** to go to the **Set Zip Code** screen (Figure 21).

Figure 21



Press **OK** to return to the **Surveillance Settings** screen.

Virena Router Connection Verification



Select **Test SURV Connection** in the **Send Results to SURV Receiver** menu to verify router connection.

If connection is established, screen displays **"The Analyzer can be connected to SURV."**

Then press **OK** to return to the Main Menu; Sofia is now ready to be run in the **Surveillance Mode**.

If connection is not established, screen displays **"The Analyzer cannot be connected to SURV."**

Then press **OK** to return to the Main Menu. Review **Sofia and Virena Router Connection Installation** and **Set Network Configuration** on page 43 to confirm all settings and connections.

If unsuccessful in configuring Router or network connections, contact Quidel Technical Support. See page 4 for additional contact information.

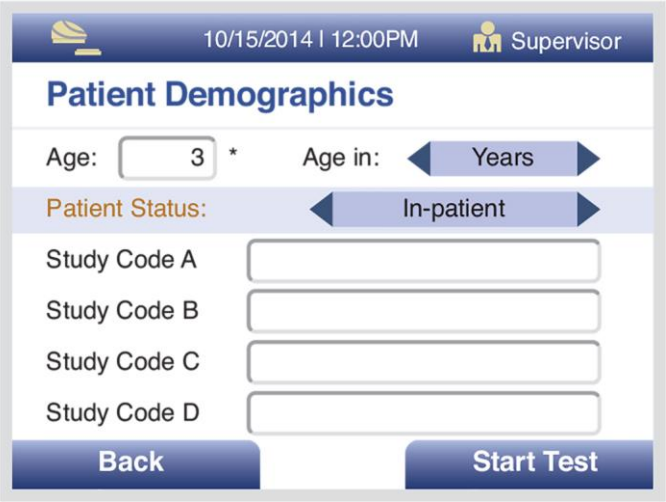
Performing Tests in Surveillance Mode

Go to the **Main Menu** and select **Run Test**.

Enter (User ID, Patient ID and Order #) if required, then press Start Test.

Patient Demographics screen (Figure 22).

Figure 22



Note: Study Code A-B allows for additional demographics data not currently defined in Sofia with a limit of two (2) numeric characters.

Enter numeric value for Age (select appropriate units of Years, Months, or Weeks) by using the Right arrow.

Press the Down arrow and select Patient Status (select In-patient, Out-patient, or Proficiency) by using the Right arrow. Then press Start Test.

Send Results to SURV Receiver

When **Send Results to SURV Receiver** is selected, the following options will be displayed on the screen:

- Send Unsent Results
- Send Last Result
- Send All Results
- Test SURV Connection

When selecting to send results, you will see **Sending to SURV**.

If data was sent successfully, the screen will display **Data were transmitted.**

> **Note:** If the auto send function for LIS or SURV is turned ON, and results are not transmitted successfully, then Sofia will keep retrying every 5 minutes of inactivity until a connection with the router or server is established.

Shutdown

Turn off the unit using the power switch in the rear of the unit. The “Shutting Down the system” screen will be displayed. Shutdown is complete when the screen goes dark.

Maintenance and Cleaning

Turn off the unit using the power switch in the rear of the unit. The “Shutting Down the system” screen will be displayed. Shutdown is complete when the screen goes dark.

Maintenance

> **Note:** Sofia must be sent to Quidel if maintenance is required. The User should not attempt any maintenance except for replacing paper, changing batteries, and cleaning the external surfaces and Cassette drawer only.

Battery Power

Battery Intended Use

The batteries provide an optional alternative source of power if wall power is unavailable. Sofia does not automatically switch to batteries in the event of a power failure. However, unplugging the external power supply from the back of Sofia switches Sofia to batteries.

Battery Installation

Four (4) LR6-AA batteries are supplied with the purchase of Sofia.

Before powering on Sofia, gently place Sofia face down.

Remove the battery cover and place the LR6-AA batteries properly according to positive or negative polarity diagrammed on Sofia.

Replace the battery cover and power on Sofia.

Changing Batteries
Ensure that there is no Cassette in the Sofia.

Once Sofia is properly powered off, gently place Sofia face down and remove the battery cover (Figure 23).

Figure 23

Remove old batteries and replace properly according to positive or negative polarity diagrammed on Sofia.

Note: The batteries only act as an alternative power source with limited capacity. It is not a stand-by power source. The external power supply must be unplugged from Sofia for batteries to work.

Replace the battery cover and power on Sofia.

Cleaning

To reduce the risk of electrical shock:

- Do not disassemble Sofia. Sofia contains no operator serviceable components and warranty will be voided if disassembled.
- Possible electrical shock: Turn off and unplug Sofia prior to cleaning.
- Do not immerse or spray Sofia in liquid.

Turn off and unplug Sofia before cleaning. Use a soft cloth with 70% alcohol or 0.6% bleach solution to clean exterior of Sofia. Wipe the external surfaces and Cassette drawer only.

Note: Do NOT clean with soap or other solutions except 70% alcohol or 0.6% bleach.

Removing the Drawer for Cleaning
Power on Sofia.

Press the eject button located on Sofia keypad.

Gently pull drawer out until it stops, then lift up Sofia as shown (Figure 24).

As shown in Figure 24, there is a "V" shaped slot on the underside of the drawer. Gently press this catch release with your thumb while slowly sliding the drawer out.

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 Cassette drawer only. **Do NOT** clean the interior of Sofia. **Do NOT** submerge drawer in cleaning solution.

After cleaning the Cassette drawer, insert it carefully aligning the rails of the drawer into the tracks of Sofia (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 main menu and perform Calibration.

Appendices

Appendix A Technical Specifications

Sofia

Dimensions	24 cm deep x 16 cm wide x 12 cm high
Weight	3 lbs
Power Supply Input	100-240 VAC, 47-63 Hz, self-switching (U.S./International), 0.9-0.34 Amps max
Sofia Input	6V DC 4.16A max
Replaceable Batteries	4x LR6-AA + 6V ⎓ 4.16 A
Keypad	Numeric
Display	3.5-inch diagonal
LAN Interface	RJ45 connector
Operating Temperature	15°C to 30°C / 59°F to 86°F
Operating Humidity	20%-85% non-condensing
Shipping and Storage Temperature	–20C to +55C
Shipping and Storage Humidity	20%-85% non-condensing
Patient Test Result Storage	500 tests maximum
QC Results Storage	200 results maximum
Calibration Results Storage	200 results maximum

Barcode Scanner

The Opticon barcode scanner (Model OPR-2001) is shipped in the correct configuration and is ready for use after connecting to the Sofia via the PS2 port. Additional information may be obtained at **opticonUSA.com** or by contacting Opticon technical support at **1.800.636.0090 x 2127**.

Contact Quidel Technical Support for assistance at 800.874.1517, (in the U.S.). See page 4 for additional contact information.

The following barcodes have been configured at time of shipment:

- UPC-A
- UPC-E
- EAN – 13 (WITHOUT ISBN TRANSLATION
- CODABAR (NOT ENCODED)
- INTERLEAVED 2 of 5
- IATA
- TELEPEN NUMERIC
- CODE 128
- CODE 93
- GS1 DATABAR LIMITED
- GS1 DATABAR TRUNCATED
- IEAN-8
- CODE 39 REG
- CODE 39 ITALIAN (ENCODED WITHOUT TRANSMIT ST/SP)
- INDUSTRIAL 2 of 5
- S-CODE
- MSI/PLESSEY (NOT ENCODED)
- UK/PLESSEY (ENCODED)
- EAN-128
- GS1 DATA AR OMNIDIRECTIONAL
- GS1 DATABAR EXPANDED

Appendix B System Troubleshooting

Symptom	Cause	Action
Paper out error	Sofia detects a printer error or that the printer is out of paper	Check the printer paper and install a new roll if needed.
SD Card error	The system detects that the SD Card is missing or inserted incorrectly.	Check the SD Card slot in the back of the unit. Install SD Card if needed.
SD Card full	The system detects the SD Card is full.	Replace SC Card in the back of the unit.
Barcode Scanner does not scan or enter data – power	The Barcode Scanner may be unplugged.	Check to ensure the Barcode Scanner is connected to the back of the unit.
Barcode Scanner does not scan or enter data – Barcode Scanner	The Barcode Scanner may be improperly programmed.	Contact Quidel Technical Support at 800.874.1517 for barcode reprogramming or to obtain a replacement Barcode Scanner. See page 4 for additional contact information.
Sofia Calibration Check failed	Calibration Cassette stored outside of provided light-protecting pouch.	Test the Calibration Cassette. If the calibration check does not pass or is invalid, contact Quidel Technical Support at 800.874.1517 to obtain a replacement Calibration Cassette. See page 4 for additional contact information.

Symptom	Cause	Action
Drawer Blocked Error	Anything on bench top in way of drawer opening.	Unblock drawer and press EJECT button. If error continues, contact Quidel Technical Support at 800.874.1517. See page 4 for additional contact information.

Error Messages

Note: The chart below describes the error codes that may be displayed while using Sofia. If unable to resolve the problem after troubleshooting, please record the last six digits of the error code and contact Quidel Technical Support. The six digits will help Technical Support diagnose the problem.

Error	Description	Action	Code
Sofia Calibration Error	Sofia Calibration Failed.	Please contact Technical Support.	###.###.061.032
Barcode Reader Error	The barcode scan is invalid or the Barcode Scanner may be improperly programmed or defective.	Ensure barcode is complete and not damaged and rescan. If error continues, please contact Technical Support.	###.###.061.010
Calibration Overdue	Instrument locked.	Please calibrate Sofia.	###.###.061.060
Cassette Error	The Cassette barcode is invalid, missing or unreadable.	Please retest using a Cassette with a valid barcode.	###.###.061.042
Cassette Reuse Error	Sofia has recognized this Cassette has already been used.	Please use a Cassette that has not been previously run.	###.###.061.002
Data Export Error	Data could not be successfully exported.	Please confirm correct SD Card was used and inserted correctly.	###.###.061.036
Data Import Error	Data could not be successfully imported.	Please confirm correct SD Card was used and inserted correctly.	###.###.061.033
Device Type Error	The device type is incorrect.	Please retest using a Cassette of the correct device type.	###.###.061.044
Drawer Blocked	Please unblock drawer, and press Eject key once more.	If the failure occurs repeatedly please call Technical Support.	###.###.060.006
Duplicated User ID Error	The User ID already exists.	Please choose another User ID.	###.###.061.040
Expired Cassette	The Cassette is past the expiration date.	Please retest with a non-expired Cassette.	###.###.061.043

Error	Description	Action	Code
Expired QC Card	The QC Card is past the expiration date.	Please retest with a non-expired QC Card.	###.###.061.046
Firmware Upgrade Error	SD Card not found or has wrong format.	Please confirm correct SD Card was used and inserted correctly.	###.###.061.068
ID Warning	Entered ID is invalid.	Please type in a valid User ID to proceed.	###.###.061.006
Invalid User Name	The User Name contains invalid characters.	Please enter only letters and numbers.	###.###.061.041
Language File Import Error	Language file could not be successfully loaded.	Please confirm correct SD Card was used and inserted correctly.	###.###.061.034
Loading Test Type Error	Loading Test Types failed.	Please confirm correct SD Card was used and inserted correctly.	###.###.061.039
Log File Export Error	Log file could not be successfully exported.	Please confirm correct SD Card was used and inserted correctly.	###.###.061.035
Low Battery Warning	Batteries are low	Connect Sofia to AC power or replace batteries before running another test.	###.###.061.051
Missing User ID Error	The User ID is missing. A User ID is mandatory for adding or editing a User.	Please type in a valid User ID to proceed.	###.###.061.013
SD Card File Error	SD Card has wrong format or file not found.	Remove the SD Card and insert an approved SD Card from Quidel.	###.###.061.003
SD Card Missing or Full	Please insert a SD Card with enough free space on it.	Check the SD Card slot in the back of the unit. Install SD Card if needed.	###.###.061.007
SD Card Read Error	Read failure from SD Card.	Remove the SD Card and insert an approved SD Card from Quidel.	###.###.061.005
SD Card Write Error	Write failure on SD Card.	Remove the SD Card and ensure that the "write lock" switch on the SD Card is not activated. Once you have ensured the SD Card is unlocked, insert the SD Card and press **OK**.	###.###.073.054
Self-Test Failed	Power On Self Test Error.	Discontinue use and contact Technical Support.	###.###.044.001

Error	Description	Action	Code
Supervisor ID Error	The supervisor ID should have between 4-12 characters.	Please check Supervisor ID and re-enter.	###.###.061.012
Temperature Warning	Temperature is out of range.	Temperature range allowed is 15°C to 30°C/ 59°F to 86°F.	###.###.061.018
Unknown Test Type Error	The required Test Type is not installed.	Refer to page 26 to see instructions for installing Test Type files.	###.###.061.031
User Type Cannot Be Changed	This is the last supervisor. Its type cannot be changed.	Create a replacement Supervisor or set a new default Supervisor before changing User status to Operator.	###.###.061.054
Wrong Value Measured	Stray light or wrong calibration.	Restart the Sofia, and if issue continues, contact Technical Support.	###.###.071.021

REF 20221 – Sofia
Software Version 2.0 or higher

IVD

CE

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