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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
Labels and Symbols

<table>
<thead>
<tr>
<th>Label</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>![ manufacturer icon ]</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>![ in vitro diagnostic medical device icon ]</td>
<td>In vitro diagnostic medical device</td>
</tr>
<tr>
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<td>Consult instructions for use</td>
</tr>
<tr>
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<td>Authorized representative in the European Community</td>
</tr>
<tr>
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<td>Temperature limitation</td>
</tr>
<tr>
<td>![ SD Card icon ]</td>
<td>SD Card</td>
</tr>
<tr>
<td>![ catalog number icon ]</td>
<td>Catalog Number</td>
</tr>
</tbody>
</table>

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.
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., Positive, Negative, or Invalid) on the screen. The results can also be automatically printed on an integrated printer if this option is selected, saved on a SD card and sent to a 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 mode. 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 instrument. 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
  - 4x LR6-AA + 6V, \( \approx \) 4.16 A
  - AC Power Cord
  - DC Power Cord
  - Specific Country Adapter(s)

**Installation Pack**

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

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

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.
System Display and Keypad

User Types

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

- 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:

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

Table 1

<table>
<thead>
<tr>
<th>Button Icon</th>
<th>Button Name</th>
<th>Function</th>
<th>Example of Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Numeric Keypad</td>
<td>Enter numeric data</td>
<td>Entering a date and time or ID's</td>
</tr>
<tr>
<td></td>
<td>Backspace</td>
<td>Backspace to delete data</td>
<td>Delete the character to the left of the cursor</td>
</tr>
<tr>
<td></td>
<td>Decimal Point</td>
<td>Decimal Point</td>
<td>IP Addresses</td>
</tr>
<tr>
<td></td>
<td>Up/Down/Left/Right Arrows</td>
<td>Navigate the User interface</td>
<td>Selecting a field</td>
</tr>
<tr>
<td></td>
<td>Eject</td>
<td>Eject a Cassette</td>
<td>Interrupting testing</td>
</tr>
<tr>
<td></td>
<td>Soft Keys</td>
<td>Select menu options shown on the screen above each key</td>
<td>Selecting OK on the “Enter or Scan” screen</td>
</tr>
<tr>
<td></td>
<td>Paper Feed</td>
<td>Paper Feed</td>
<td>Loading paper into Sofia</td>
</tr>
<tr>
<td></td>
<td>Print</td>
<td>Manual print</td>
<td>Printing previous results</td>
</tr>
</tbody>
</table>
### System User Interface

<table>
<thead>
<tr>
<th>Screen Icon</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Walk Away Mode" /></td>
<td>Indicates Sofia is in the <strong>WALK AWAY Mode</strong>.</td>
</tr>
<tr>
<td><img src="image" alt="SD Card" /></td>
<td>There is an SD Card inserted in the slot.</td>
</tr>
<tr>
<td><img src="image" alt="Read Now Mode" /></td>
<td>Indicates Sofia is in the <strong>READ NOW Mode</strong>.</td>
</tr>
<tr>
<td><img src="image" alt="Supervisor" /></td>
<td>Indicates the <strong>Supervisor</strong> is currently logged into Sofia.</td>
</tr>
</tbody>
</table>

### 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 counter top 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).
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).

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.

*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.*

**Note:** The paper does not need to be fed through the roller.
When turning on Sofia for the first time, the Calibration Overdue screen will display (Figure 7). It is recommended to setup Sofia before running a Calibration Check.

Figure 7

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 9).

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 9

Cassette Drawers
Sofia has two cassette drawers available for testing the different assays. Below are the two versions of cassette drawers (Figure 8) provided to Sofia users. The image on the left depicts the standard drawer and compatible cassette design. The image on the right depicts the Hybrid Drawer and compatible cassette designs. For more information, please contact Quidel Technical Support at 800.874.1517, (in the U.S.). For additional contact information (page 3).

Figure 8

Standard Drawer (Gray)
- Accepts standard Quidel Cassette formats

Hybrid Drawer (Blue)
- Accepts multiple Quidel Cassette formats
Load Test Type File

Select LOAD TEST TYPES from the Supervisor menu.
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. Press OK to acknowledge.

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 10).

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 Supervisor Menu.

Delete User
Select the Options key in the Manage Users screen to view the pop-up menu. Highlight the User ID to be removed, then select Delete User to delete a User from the device.
Press BACK to return to the Supervisor Menu.
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.). For additional contact information see (page 3).

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.

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 ID Required
In the **Set Entry Requirements and Timeout** menu, using the Up/Down arrows, select **ORDER 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.

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 "Yes" or "No." If set to "Yes," User must scan the QC barcode every time a QC test is run.

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 20 characters, and/or spaces.
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 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 is automatically default to English, and if another language is required, you may upload another language. 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 Setting 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.

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 “Hide Options” 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 to print results. Select the BACK button to return to results.

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**

View Lot Status displays the 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 Review Data screen.

**View Test Type**

A list of the installed Test Types and Version numbered loaded is displayed. Select the BACK button 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 or invalid results performed by the selected user. Select the BACK button 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.
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, 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.

Load Analyzer Software
Occasionally, Quidel may release software updates to improve functionality of Sofia.
Insert the SD Card with the software to install.
Choose Load Analyzer Software to load new Sofia software. Sofia reads the new software version on the SD Card that is being installed and displays a Load Analyzer Software confirmation screen.
Select OK to confirm installation.
Sofia will complete a self-installation and then power up in the normal startup screen.

Note: During the software installation time, do not unplug or power off Sofia.

Load Language File
Sofia is capable of displaying several languages. Only two languages maybe stored at one time.
Select Load Language File 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.
Calibration Check

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

**IMPORTANT:** Calibration Check must not exceed 30 days prior to testing any patient sample.

**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 27).

**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.). For additional contact information (page 3).

Run QC

External Positive and Negative Quality Controls (QC) may be tested to demonstrate that the assay-specific reagents, cassettes and assay procedures are performing properly.

Refer to assay-specific package insert for details on specific tests.

Quidel recommends that External Positive and Negative Controls be run:

- Once for each untrained operator, and once for each specific type of analyte.
- Once for each new shipment of kits provided that each different lot received in the shipment is tested.
- As deemed additionally necessary by your internal quality control procedures, and in accordance with local, state and federal regulations or accreditation requirements.

**Run QC: External Positive and Negative Controls**

To run the External Positive and Negative Controls for the specific test, refer to the assay-specific Package Insert for each specific test for preparing the test cassettes with QC controls.

**Note:** The Positive Control must be tested first before testing the Negative Control.

When prompted, use the Barcode Scanner to scan the QC Card specific for the test and kit lot to be evaluated. This card provides Sofia with specific information, including the kit lot number and expiration date.
**Set Development Mode and Start QC**

Select the desired development mode: WALK AWAY or READ NOW (see Development Modes section) by using the Left/Right arrows to highlight the desired mode (Figure 12).

Press **START QC** to proceed. Sofia will then prompt the User to run the External Controls.

Prepare a Positive Control Cassette using the Positive Control and the test procedure instructions in the Package Insert. Follow the screen instructions to insert the Positive Control Cassette and gently close the drawer.

When the Positive Control is completed, the drawer will open automatically. Remove the Positive Control Cassette.

Prepare a Negative Control Cassette using the Negative Control and the test procedure instructions in the Package Insert. Follow the screen instructions to insert the Negative Control Cassette and gently close the drawer.

When the Negative Control is completed, the drawer will open automatically. Remove the Negative Control Cassette. When the QC test is complete, the results will be displayed.

**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. For additional contact information (page 3).

---

**Run Patient Specimens**

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 10).

- 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.

- 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.

---

**Figure 12**

**Figure 13**
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 key pad. 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 key pad on Sofia.

![Figure 14](image1.png)

Enter the Patient ID

Patient ID can be entered using the barcode or manually using the key pad. 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 key pad on Sofia.

![Figure 15](image2.png)

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 key pad on Sofia.

Test Procedure

In the WALK AWAY development mode, proceed directly to the next step 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). 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.

Using the WALK AWAY and READ NOW Modes with Patient Specimens

WALK AWAY Mode

Use the WALK AWAY Mode for automatically timing the test development before scanning and displaying the test result, as the user can walk away during the development mode.

First select the WALK AWAY 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.

Refer to the assay-specific package insert for sample collection and preparation procedures.

If required, input or scan the User ID, patient ID and order #. Then press Start Test, and Sofia drawer will automatically open.

After the user adds the patient sample and inserts the Cassette into Sofia, Sofia will automatically time the test development, scan, and display the test result.

READ NOW Mode

Use the READ NOW Mode to allow more efficient throughput of multiple tests which have been set up and developed on the benchtop prior to reading.

First select the READ NOW 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.

Refer to the assay-specific package insert for sample collection and preparation procedures. Additionally, each assay may have unique sample stability requirements which can provide workflow options. Adhere to the extraction procedure for specific specimen extraction.

When ready to test, prepare cassettes to receive the specimen immediately before use.

Note: Cassettes should not sit open in ambient conditions unless you are ready to label and use them.

Label the cassettes accordingly and place them in order in the work area.

Once you have extracted the specimens, you should proceed to the testing step (Figure 16).

Add extracted specimen #1 to cassette #1, then immediately set your timer to the designated development time as indicated in the assay-specific package insert.

1 minute later, add specimen #2 to cassette #2.

Note: Spacing samples apart by 1 minute accounts for the time it takes to analyze the cassette and report the result. More time may be required in between each test if data entry is required.
Continue adding the appropriate extracted specimen to its appropriate cassette 1 minute after each until all cassettes have been charged with specimen.

When the timer goes off for cassette #1, if required, input or scan the User ID, patient ID and order # into Sofia for cassette #1. Then insert cassette #1 into Sofia, Sofia will display the result in approximately 1 minute. The tray will then open. Sofia screen will display the identifier information and results (Figure 17).

Remove cassette #1. Press Start New Test and input the required identifier information, e.g., User ID, Patient ID and order # for cassette #2.

Place cassette #2 into the tray and then gently close the drawer. Sofia will now automatically run test when the drawer is closed. Proceed in the same fashion until all cassettes have been tested.

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

For the IP (internet provider) 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 18). Select OK to save changes and exit.
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 19).

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**.
Surveillance Mode

**Note:** Before setting up Sofia to Sofia Surveillance Mode, please set up other features on Sofia, particularly the Location Name for surveillance purposes.

**Sofia and Virena Router Connection Installation**

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

**Set Network Configuration**

Refer to the Network Configuration section (page 41).

Scroll to Set IP Address and ensure Manual is checked, see Figure 20. 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 20. If it does not match, please enter the correct numbers. Then select OK.

**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.

Under Set SURV Parameters, select the following using the Left/Right/Up/Down arrows:

- Age Required: ✔ Yes
- Transmit Patient ID: ✔ Off
- Auto Send: ✔ On
- Queue Results: ✔ On

When completed, screen will display as Figure 21.

Press OK to return to the Settings screen.

**Figure 20**

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

**Figure 21**
**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 44 to confirm all settings and connections.

If unsuccessful in configuring Router or network connections, contact Quidel Technical Support. For additional contact information (page 3).

**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](image)

**Note:** Fields #1-4 allow for additional demographics data not currently defined in Sofia.

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

Remove old batteries and replace properly according to positive or negative polarity diagrammed on Sofia. Replace the battery cover and power 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.

**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.

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 by aligning the rails of the drawer into the tracks of Sofia (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.
## Appendix A Technical Specifications

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimensions</td>
<td>24 cm deep x 16 cm wide x 10 cm high</td>
</tr>
<tr>
<td>Weight</td>
<td>3 lbs</td>
</tr>
<tr>
<td>Power Supply Input</td>
<td>100-240 VAC, 47-63 Hz, self-switching (U.S./International), 0.9-0.34 Amps max</td>
</tr>
<tr>
<td>Sofia Input</td>
<td>6V DC 4.16A max</td>
</tr>
<tr>
<td>Replaceable Batteries</td>
<td>4x LR6-AA + 6V 4.16A max</td>
</tr>
<tr>
<td>Keypad</td>
<td>Numeric</td>
</tr>
<tr>
<td>Display</td>
<td>3.5 inch diagonal</td>
</tr>
<tr>
<td>LAN Interface</td>
<td>RJ45 connector</td>
</tr>
<tr>
<td>Operating Temperature</td>
<td>15°C to 30°C / 59°F to 86°F</td>
</tr>
<tr>
<td>Operating Humidity</td>
<td>20%-85% non condensing</td>
</tr>
<tr>
<td>Shipping and Storage Temperature</td>
<td>-20°C to +55°C</td>
</tr>
<tr>
<td>Shipping and Storage Humidity</td>
<td>20%-85% non condensing</td>
</tr>
<tr>
<td>Patient Test Result Storage</td>
<td>500 tests maximum</td>
</tr>
<tr>
<td>QC Results Storage</td>
<td>200 results maximum</td>
</tr>
<tr>
<td>Calibration Results Storage</td>
<td>200 results maximum</td>
</tr>
</tbody>
</table>
Barcode Scanner

The Opticon barcode scanner (Model OPR-2001) is shipped in the correct configuration and is ready for use after connecting to 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.). For additional contact information (page 3).

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 DATABAR OMNIDIRECTIONAL
- GS1 DATABAR EXPANDED

Appendix B System Troubleshooting

<table>
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<th>Symptom</th>
<th>Cause</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paper out error</td>
<td>Sofia detects a printer error or that the printer is out of paper</td>
<td>Check the printer paper and install a new roll if needed.</td>
</tr>
<tr>
<td>SD Card error</td>
<td>The system detects that the SD Card is missing or inserted incorrectly.</td>
<td>Check the SD Card slot in the back of the unit. Install SD Card if needed.</td>
</tr>
<tr>
<td>SD Card full</td>
<td>The system detects the SD Card is full.</td>
<td>Replace SD Card in the back of the unit.</td>
</tr>
<tr>
<td>Barcode Scanner does not scan or enter data-power</td>
<td>The Barcode Scanner may be unplugged.</td>
<td>Check to ensure the Barcode Scanner is connected to the back of the unit.</td>
</tr>
<tr>
<td>Barcode Scanner does not scan or enter data-Bar code Scanner</td>
<td>The Barcode Scanner may be improperly programmed.</td>
<td>Contact Quidel Technical Support at 800.874.1517 for barcode reprogramming or to obtain a replacement Barcode Scanner. For additional contact information (page 3).</td>
</tr>
<tr>
<td>Sofia Calibration Check failed</td>
<td>Calibration Cassette stored outside of provided light-protecting pouch.</td>
<td>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. For additional contact information (page 3).</td>
</tr>
<tr>
<td>Drawer Blocked Error</td>
<td>Anything on bench top in way of drawer opening.</td>
<td>Unblock drawer and press EJECT button. If error continues, contact Quidel Technical Support at 800.874.1517. For additional contact information (page 3).</td>
</tr>
</tbody>
</table>
**Error Messages**

**Note:** The chart below describes some of 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.

<table>
<thead>
<tr>
<th>Error</th>
<th>Description</th>
<th>Action</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sofia Calibration Error</td>
<td>Sofia Calibration Failed.</td>
<td>Please contact Technical Support.</td>
<td>###.061.032</td>
</tr>
<tr>
<td>Barcode Reader Error</td>
<td>The barcode scan is invalid or the Barcode Scanner may be improperly programmed or defective.</td>
<td>Ensure barcode is complete and not damaged and rescann. If error continues, please contact Technical Support.</td>
<td>###.061.010</td>
</tr>
<tr>
<td>Calibration Overdue</td>
<td>Instrument locked.</td>
<td>Please calibrate Sofia.</td>
<td>###.061.060</td>
</tr>
<tr>
<td>Cassette Error</td>
<td>The Cassette barcode is invalid, missing or unreadable.</td>
<td>Please retest using a Cassette with a valid barcode.</td>
<td>###.061.042</td>
</tr>
<tr>
<td>Cassette Reuse Error</td>
<td>Sofia has recognized this Cassette has already been used.</td>
<td>Please use a cassette that has not been previously run.</td>
<td>###.061.002</td>
</tr>
<tr>
<td>Data Export Error</td>
<td>Data could not be successfully exported.</td>
<td>Please confirm correct SD Card was used and inserted correctly.</td>
<td>###.061.036</td>
</tr>
<tr>
<td>Data Import Error</td>
<td>Data could not be successfully imported.</td>
<td>Please confirm correct SD Card was used and inserted correctly.</td>
<td>###.061.033</td>
</tr>
<tr>
<td>Device Type Error</td>
<td>The device type is incorrect.</td>
<td>Please retest using a Cassette of the correct device type.</td>
<td>###.061.044</td>
</tr>
<tr>
<td>Drawer Blocked</td>
<td>Please unblock drawer, and press Eject key once more.</td>
<td>If the failure occurs repeatedly please call Technical Support.</td>
<td>###.061.006</td>
</tr>
<tr>
<td>Duplicated User ID Error</td>
<td>The User ID already exists.</td>
<td>Please choose another User ID.</td>
<td>###.061.040</td>
</tr>
<tr>
<td>Expired Cassette</td>
<td>The Cassette is past the expiration date.</td>
<td>Please retest with a non-expired Cassette.</td>
<td>###.061.043</td>
</tr>
<tr>
<td>Expired QC Card</td>
<td>The QC Card is past the expiration date.</td>
<td>Please retest with a non-expired QC Card.</td>
<td>###.061.046</td>
</tr>
<tr>
<td>Firmware Upgrade Error</td>
<td>SD Card not found or has wrong format.</td>
<td>Please confirm correct SD Card was used and inserted correctly.</td>
<td>###.061.068</td>
</tr>
<tr>
<td>ID Warning</td>
<td>Entered ID is invalid.</td>
<td>Please type in a valid User ID to proceed.</td>
<td>###.061.006</td>
</tr>
<tr>
<td>Invalid User Name</td>
<td>The User Name contains invalid characters.</td>
<td>Please enter only letters and numbers.</td>
<td>###.061.041</td>
</tr>
<tr>
<td>Language File Import Error</td>
<td>Language file could not be successfully loaded.</td>
<td>Please confirm correct SD Card was used and inserted correctly.</td>
<td>###.061.034</td>
</tr>
<tr>
<td>Loading Test Type Error</td>
<td>Loading Test Types failed.</td>
<td>Please confirm correct SD Card was used and inserted correctly.</td>
<td>###.061.039</td>
</tr>
<tr>
<td>Log File Export Error</td>
<td>Log file could not be successfully exported.</td>
<td>Please confirm correct SD Card was used and inserted correctly.</td>
<td>###.061.035</td>
</tr>
<tr>
<td>Low Battery Warning</td>
<td>Batteries are low.</td>
<td>Connect Sofia to AC power or replace batteries before running another test.</td>
<td></td>
</tr>
<tr>
<td>Missing User ID Error</td>
<td>The User ID is missing. A User ID is mandatory for adding or editing a User.</td>
<td>Please type in a valid User ID to proceed.</td>
<td>###.061.013</td>
</tr>
<tr>
<td>SD Card Error</td>
<td>SD Card has wrong format or file not found.</td>
<td>Remove the SD Card and insert an approved SD Card from Quidel.</td>
<td>###.061.003</td>
</tr>
<tr>
<td>SD Card Missing or Full</td>
<td>Please insert a SD Card with enough free space on it.</td>
<td>Check the SD Card slot in the back of the unit. Install SD Card if needed.</td>
<td></td>
</tr>
<tr>
<td>SD Card Read Error</td>
<td>Read failure from SD Card.</td>
<td>Remove the SD Card and insert an approved SD Card from Quidel.</td>
<td>###.061.005</td>
</tr>
<tr>
<td>SD Card Write Error</td>
<td>Write failure on SD Card.</td>
<td>Remove the SD Card and ensure that the &quot;write lock&quot; switch on the SD Card is not activated. Once you have ensured the SD Card is unlocked, insert the SD Card and press OK.</td>
<td>###.073.054</td>
</tr>
<tr>
<td>Self Test Failed</td>
<td>Power On Self Test Error.</td>
<td>Discontinue use and contact Technical Support.</td>
<td>###.044.001</td>
</tr>
<tr>
<td>Supervisor ID Error</td>
<td>The supervisor ID should have between 4-12 characters.</td>
<td>Please check Supervisor ID and re-enter.</td>
<td>###.061.012</td>
</tr>
<tr>
<td>Temperature Warning</td>
<td>Temperature is out of range.</td>
<td>Temperature range allowed is 15.0°C to 30.0°C/ 59°F to 86°F.</td>
<td>###.061.018</td>
</tr>
<tr>
<td>Unknown Test Type</td>
<td>The required Test Type is not installed.</td>
<td>Refer to page 20 to see instructions for installing Test Type files.</td>
<td>###.061.031</td>
</tr>
<tr>
<td>User Type Cannot Be Changed</td>
<td>This is the last supervisor. Its type cannot be changed.</td>
<td>Create a replacement Supervisor or set a new default Supervisor before changing User status to Operator.</td>
<td>###.061.054</td>
</tr>
<tr>
<td>Wrong Value Measured</td>
<td>Stray light or wrong calibration.</td>
<td>Restart Sofia, and if issue continues, contact Technical Support.</td>
<td>###.071.021</td>
</tr>
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30175 Hannover, Germany

20221-Sofia Software Version 1.0.0 or higher

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