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To access the latest version of the User Manual, visit http://quidel.link/SofiaQ or scan the QR Code with your smart phone.

A symbols glossary can be found at quidel.com/glossary.

Sofia Q is a small analyzer intended to be used with Sofia Cassette-based immunofluorescent *in vitro* diagnostic assays manufactured by Quidel Corporation and software (Quidel App) residing on an Apple iPhone manufactured by Apple. Procedural operation of the Sofia Q and test interpretation is performed by the App.

Sofia Q is intended for professional and laboratory use.

Connection of Sofia Q to a micro-USB compliant power source powers on the Sofia Q, rendering it both functional and discoverable via Bluetooth, the latter allowing pairing of the Sofia Q with the smartphone. The MAC address needed for pairing can be retrieved from the label barcode at the bottom of the Sofia Q.

Once the Sofia Q and the phone are paired via Bluetooth, the App can control the various functions necessary to perform a test as described below. The App provides instructions for the collection and manipulation of a biological sample with a swab, as well as the application to an immunofluorescent Assay (IFA) cassette. In addition, the temperature is read by an internal sensor to ensure that it is in the appropriate range (15°C to 30°C).

Upon proper insertion of a test cassette into the Sofia Q, a sensor triggers the assay countdown timer on the phone.

Once the countdown timer on the app reaches zero, images of the test strip are transferred to the iPhone where they are analyzed for QC metrics to determine whether the test is valid or invalid. If valid, the status of the test is determined, and a Positive or Negative test result is displayed on the screen of the phone. If invalid, an Invalid test result is displayed.

The image, the test raw data, and result can be uploaded in a dedicated server using the WIFI functionality of the phone, or maintained in the phone, within the App.

A multi-color indicator light is used to produce a visual cue that signifies the status of the Sofia Q.

The color and pattern combination and their meaning are as shown in Table 1 below:

Table 1. Sofia Q status light colors and meanings	
Status Light	*Sofia Q State*
Blinking Blue	Sofia Q is plugged in
Solid Blue	Sofia Q has been paired with the smart phone
Blinking Red	Sofia Q is ready to receive the cassette containing sample to test
Blinking Purple	The test is in progress (timer is counting down time to test completion)
Solid Purple	The test is complete, test results have been delivered to the App

Refer to assay-specific Package Insert or QRI for details regarding specific tests.

SYSTEM COMPONENTS
The following system components are supplied with Sofia Q:
- Sofia Q
- USB cable

MATERIALS REQUIRED BUT NOT PROVIDED
- An adapter (5 V AC/DC) that meets IEC 60601-1-2:2014 requirements.
- Apple iPhone (Apple iPhone 8 and newer models, running OS 13 or later versions of the operating system).

Sofia Q consumable test kits, including Test Cassettes are sold separately.

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

INSTALLATION, SETUP AND OPERATION
Brief Warnings and Precautions
- Always operate Sofia Q on a surface that is level, dry, and not in direct sunlight.
- Do not write on the barcode or surface of the Test Cassette.
- Never move Sofia Q while there is a test in progress.
- Use only the USB cable that was provided with Sofia Q.
- Do not drop Sofia Q as it could damage the unit.
- Contact Technical Support if the instrument is damaged.
- Do not place Sofia Q instruments near a heat source.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation.

Setting Up the Sofia Q
- Place Sofia Q on counter or bench top. Sofia Q is portable and can be moved to a suitable location for testing. Avoid direct sunlight
- Connect the USB cable with an adapter (5 V AC/DC) that meets IEC 60601-1-2:2014 requirement.
- To power down, unplug the Sofia Q.

Installing the Sofia Q App
In order to begin using the Sofia Q system, you will need to download the Sofia Q app. To download the app, search the name in the Apple App store, download and install. The application is currently compatible with iOS 13 and above for use on Apple iPhone 8 and later.

Using the Sofia Q device
The Sofia Q can be set in two different modes (WALK AWAY mode and READ NOW mode). The procedures for each mode are described below.

WALK AWAY Mode
In WALK AWAY Mode, the user immediately inserts the Test Cassette into the Sofia Q device. Positive and negative test results will be displayed at 15 minutes.
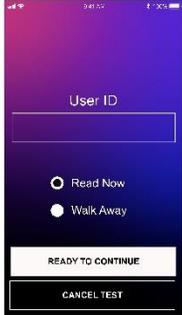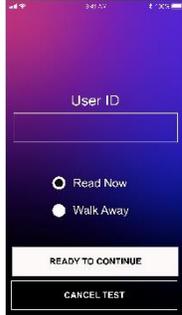
READ NOW Mode
Allow the test to develop for the full 15 minutes before placing in the Sofia Q device.

The user first places the Test Cassette onto the counter or bench top for 15 minutes (outside of Sofia Q). The user manually times this development step. The Test Cassette MUST remain on the bench for 15 minutes to get an accurate result. Then, the user inserts the Test Cassette into Sofia Q. In READ NOW Mode, Sofia Q will scan and display the test result within 1 minute.

Warning: Results must not be interpreted past 30 minutes after inoculation. Using Sofia Q past this time may result in false results.

Run Test

1. Once the App is installed, tap the Sofia Q App icon to start the App. Press Run Test when ready.	2. Input the User ID by tapping the field and using the onscreen keyboard. The field can only accept letters and numbers and no spaces.	3. Select the preferred mode, READ NOW, or WALK AWAY. The selection will be retained for subsequent runs	4. Input the Serial Code by tapping the camera icon and scanning the label on the bottom of the Sofia Q. The pairing will be retained for subsequent runs.

5. The Sofia Q App will then pair with **Sofia Q** and alert the user when the process is successful. Tap continue when ready.	**6.** The on-screen instructions will then prompt the user to remove the Test Cassette from its wrapper.	**7.** Scan the barcode located on the Test Cassette using the camera.	**8.** The on-screen instructions will guide the user for the remainder of the test. Insert Test Cassette when instructed to do so.

SOFIA Q INTERPRETATION OF RESULTS

When the test is complete, the results will be displayed on the iPhone screen. Test Lines will not be visible to the naked eye.

The three possible results screens and their interpretation are displayed below:

Reader Display	Interpretation
	Positive Test for SARS (SARS antigen present)
	Negative Test for SARS (no SARS antigen detected)

	Result Invalid

MAINTENANCE AND CLEANING

Sofia Q should be cleaned regularly. Use a soft cloth with 70% alcohol or 0.6% bleach solution to clean exterior surface of Sofia Q. Do not clean with soap or other solutions. Wipe external surfaces only.

TECHNICAL SPECIFICATIONS

Dimensions	6.15 cm wide x 7.92 cm high
Weight	~190 grams
Power Supply Input	Standard 5V AC/DC Adapter
Operating Temperature	15°C to 30°C / 59°F to 86°F
Operating Humidity	20% to 85% RH non-condensing
Operating Altitude	2000 m maximum
Shipping and Storage Temperature	−20°C to 55°C
Shipping and Storage Humidity	20% to 85% RH non-condensing

SAFETY PRECAUTIONS

Sofia Q is manufactured to allow safe performance when is operated according to this User Manual.

All warnings and precautions must be followed to prevent personal injury or damage to the instrument.
- This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
- This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:
  - Reorient or relocate the receiving antenna.
  - Increase the separation between the equipment and receiver.
  - Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

■ Consult the dealer or an experienced radio/TV technician for help.

 Warning!

To reduce the risk of electrical shock:
■ Unplug Sofia Q before cleaning.
■ Do not immerse in water or cleaning solutions.
■ Do not attempt to open.
■ Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
■ The customer should use an adapter (5 V AC/DC) that meets IEC 60601-1-2:2014 requirements.
■ Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Sofia Q".

Ultraviolet Radiation!

To reduce the risk of UV Exposure:
■ Do not attempt to open or disassemble Sofia Q.

TROUBLESHOOTING
■ Sofia Q function may be affected by RF, you may need to take measures to mitigate the RF and restore Sofia Q performance. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Sofia Q"
■ If the system does not detect the cassette upon insertion, remove the cassette fully and reinsert gently.
■ If the system does not pair during the App workflow and no errors arise, close the app, and restart it to try again.

Contact Quidel Technical Support from 7:00 a.m. to 5:00 p.m. Pacific Time
Tel: 800.874.1517 (in the U.S.)
858.552.1100 (outside the U.S.)
Fax: 858.552.7905
E-mail: technicalsupport@quidel.com or contact your local distributor
Website: quidel.com

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