SQA-iO

User Manual

Version: Nov 2024
Catalog #: IO-ML-01677-00

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SECTION 1: Intended Use, System Specifications and Requirements

Intended Use

The SQA-iO Sperm Quality Analyzer is an automated point-of-care in vitro use only medical device for semen analysis performed by healthcare professionals (trained lab technicians). The SQA-iO does not provide a comprehensive evaluation of a male's fertility status.

The SQA-iO provides direct and calculated quantitative measurements for the following parameters:

SQA-iO Reported Semen Parameters	
Directly Measured Semen Parameters	**Calculated Semen Parameters**
Sperm Concentration (Conc) M/mL	Total Motility (PR + NP), %
Motile Sperm Concentration (MSC), M/mL	Progressive Motility (PR), % (combines Rapidly and Slowly Progressive Motility, %)
Progressively Motile Sperm Concentration (PMSC), M/mL (combines Rapid and Slow PMSC, millions/mL)	Non-Progressive Motility (NP), %
Normal Forms (Normal Morphology), %	Immotile (IM), %
	Functional Sperm Concentration (FSC), millions/mL

System Specifications and Requirements

Device Front Panel: Measurement Compartment (insert testing capillary to begin testing as shown below)

Rear Panel: Utilizes a USB male connection cable (plug-in to connect device)

Specifications

- Dimensions: 8 X 9.5 X 10.5 cm / Weight: 0.350 Kg
- Analysis Time: 75 seconds
- Power supply: 5V DC (USB)
- Noise level: 0 [dBA]
- Device power consumption: 1.7 [BTU/hour] = 0.5 [Watts]
- Sources of radiant energy: Two LEDs (motility and concentration channels)
- Detector system: Two photo detectors (Motility and Optical Density)
- Software: Resides on flash memory and on a secure server on the Cloud
- Motility channel input signal: Analog, up to 5V

SQA-iO Minimum Requirements

- PC: Intel Core i5 M520 2.4GHz or equivalent
- RAM: 4GB
- Monitor Screen: Color, Wide screen – minimum resolution 1024 x 768
- Operating system compatibility: Windows 7 Professional or above
- Communication Ports: one USB port
- Internet Access: 5mb/second

Operation temperature

- Operates in ambient temperature (15-38ºC)

Quality Control/Calibration

- Internal: Electronic Self-Test/Auto-Calibration runs @ start-up. Reference values verified prior to each test.

Sample Testing

- Calibrated to test samples at room temperature 20-25ºC (68-77ºF) within one hour of sample collection.
- Test only liquefied human semen samples. QwikCheck Liquefaction vials (available from MES and sold separately) can be used to liquify semen sample prior to aspiration in the capillary, if needed.

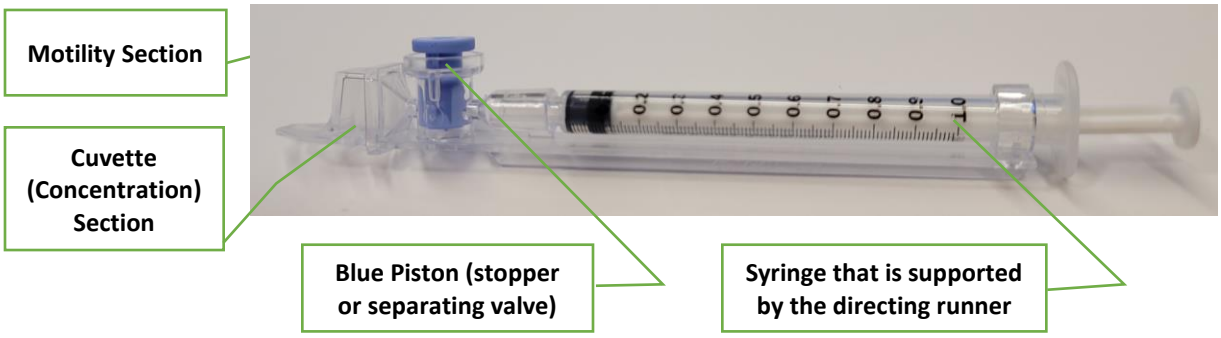
SECTION 2: System Overview and Reportable Range

The SQA-iO is a high-performance PC-based analytical medical device that tests semen samples. The device works with a computer application that covers the device, sample processing, test results, and patient and facility information.

After collection and preparation, a semen sample is drawn into an SQA testing capillary and the capillary is inserted into the SQA-iO where testing is performed. Test results are processed utilizing proprietary technology and algorithms. Test results are available in approximately 75 seconds. Reportable ranges for all parameters evaluated by the SQA-iO are listed below.

SQA-iO Reportable Range	
Parameter	**Range**
Sperm Concentration M/ml	<2-400
Total Motility %	0-100
Progressive Motility %	0-100
Rapidly Progressive Motility %	0-100
Slowly Progressive Motility %	0-100
Non-progressive Motility %	0-100
Immotile %	0-100
Normal Forms %	2-30
MSC M/ml	0-400
PMSC M/ml	0-400
Rapid PMSC M/ml	0-400
Slow PMSC M/ml	0-400
FSC M/ml	0-120

SECTION 3: Technology



Testing Capillary

- Disposable, plastic, testing capillary. Requires 600 µl of sample for normal volume testing.
- Insert into the measurement compartment of the SQA-iO
- Designed to collect and test samples in a biologically safe manner. Use only manufacturers' certified testing capillaries.

Cuvette Section (Concentration assessment)

- Millions of sperm cells are analyzed in the 'tall' cuvette section of the testing capillary based on spectrophotometry analysis of the semen sample and application of proprietary algorithms.

Motility Section (Motility parameter assessment)

- Tens of thousands of sperm cells are analyzed in the 'thin' motility section of the testing capillary as they move through a light beam in the device.

- Light disturbances are then converted into analog signals and analyzed by proprietary algorithms.

Inserting the Testing Capillary into the SQA-iO

- After filling the testing capillary (see Appendix Section for guidelines), insert the SQA testing capillary all the way into the SQA-iO measurement chamber with the BLUE PISTON facing down.

SECTION 4: Getting Started

First time connecting: Follow the **SQA-iO Quick Start Guide** instructions or directly download the software from www.sqa-io.com and register your account, following the on-screen instructions. This is the time to set all preferred testing and your facility defaults and to load test credits.

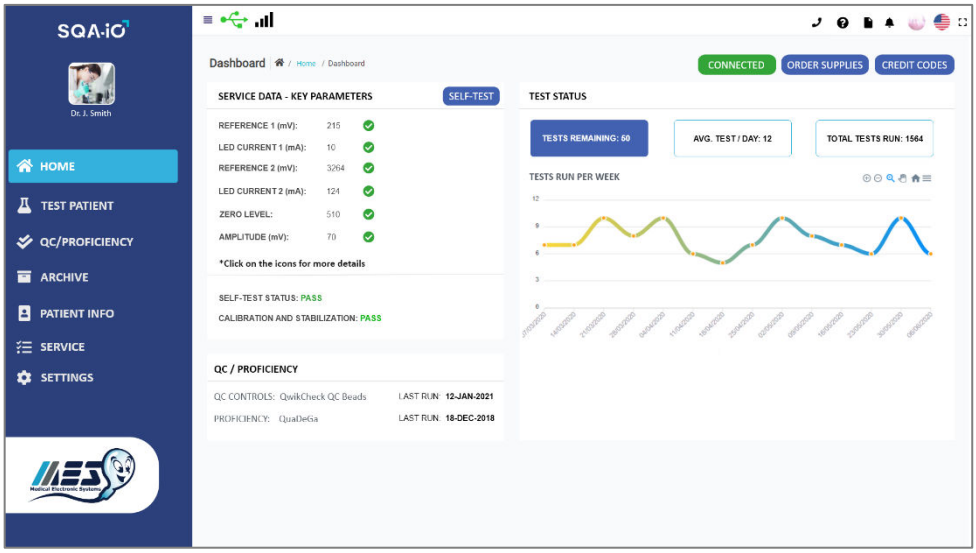
Connecting to the SQA-iO for testing:

- Connect the SQA-iO to the computer using the supplied USB cable.
- Go to: www.sqa-io.com or click on the desktop icon to activate the SQA-iO interface.
- Enter the unique 8-digit registration number located inside your device kit.
- If you are asked to authorize the download of a driver required to run the SQA-iO app, please accept.
- Log into the SQA-iO using your username and password.
- The SQA-iO will now go through a calibration check, wait until it finishes.
- The device is now ready for sperm testing.

SECTION 5: SQA-iO Navigation and Testing

The SQA-iO navigation is simple to use. Just click on one of the six options on the navigation bar on the left side of the screen to select where you want to go. The navigation screen is always visible when using the application. After 15 minutes of SQA-iO inactivity, the security mechanism of the SQA-iO application will warn the user that it will timeout. If the user does not use the SQA-iO application within 5 minutes, it will automatically shut down and the user will be required to log back in to use the device.

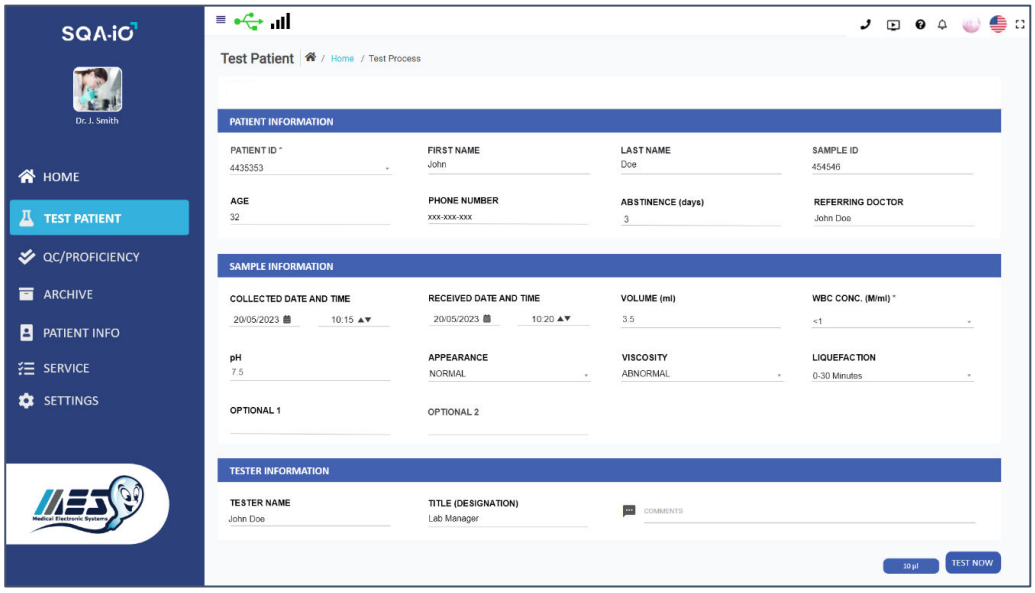
Home Screen:



The Home Screen provides the following information:

- The device is connected when this icon is **GREEN** if it is red the connection has been lost.
- **Service Data – Key Parameters:** Displays the calibration and self-test parameters of the SQA-iO and indicates if they are within normal limits (**green** checkmark); borderline (**yellow** checkmark) or out of range (**red** checkmark). Click on the checkmark for detailed information for what to do. Click on the REPORT button to run a calibration report for your records.
- **Test Status:** Since the SQA-iO will not operate without test credits, the status of the remaining test credits as well as a graph of tests run per week is displayed.

Test Patient



Enter patient and sample data in the TEST PATIENT screen seen above. Mandatory fields are indicated by an asterisk * and an error message will appear if they are empty. PLEASE NOTE: Although sample volume is not a mandatory field, some semen parameters that are related to sample volume will not be presented if volume is not entered.

Use the OPTIONAL 1 and OPTIONAL 2 'open' fields to input any information desired.

After entering patient data, select: Test now (please see the appendix section for capillary filling instructions)

Samples need to be completely liquefied and run within one hour of collection as motility parameters can decline over time. QwikCheck Liquefaction vials can be used to liquify semen sample prior to aspiration in the capillary, if needed.

Sample Volume Measurement:

When to measure: After sample liquefaction and before testing, measure the sample volume according to the laboratory procedures. Enter sample volume in the "patient testing" screen of the SQA-iO, as instructed above.

Do not heat the samples – maintain them at room temperature as excessive heat and/or cold may shock sperm cells and could affect motility.

See Appendix section for guidelines about semen sample collection and for instructions on how to fill the testing capillary and insert it into the SQA-iO.

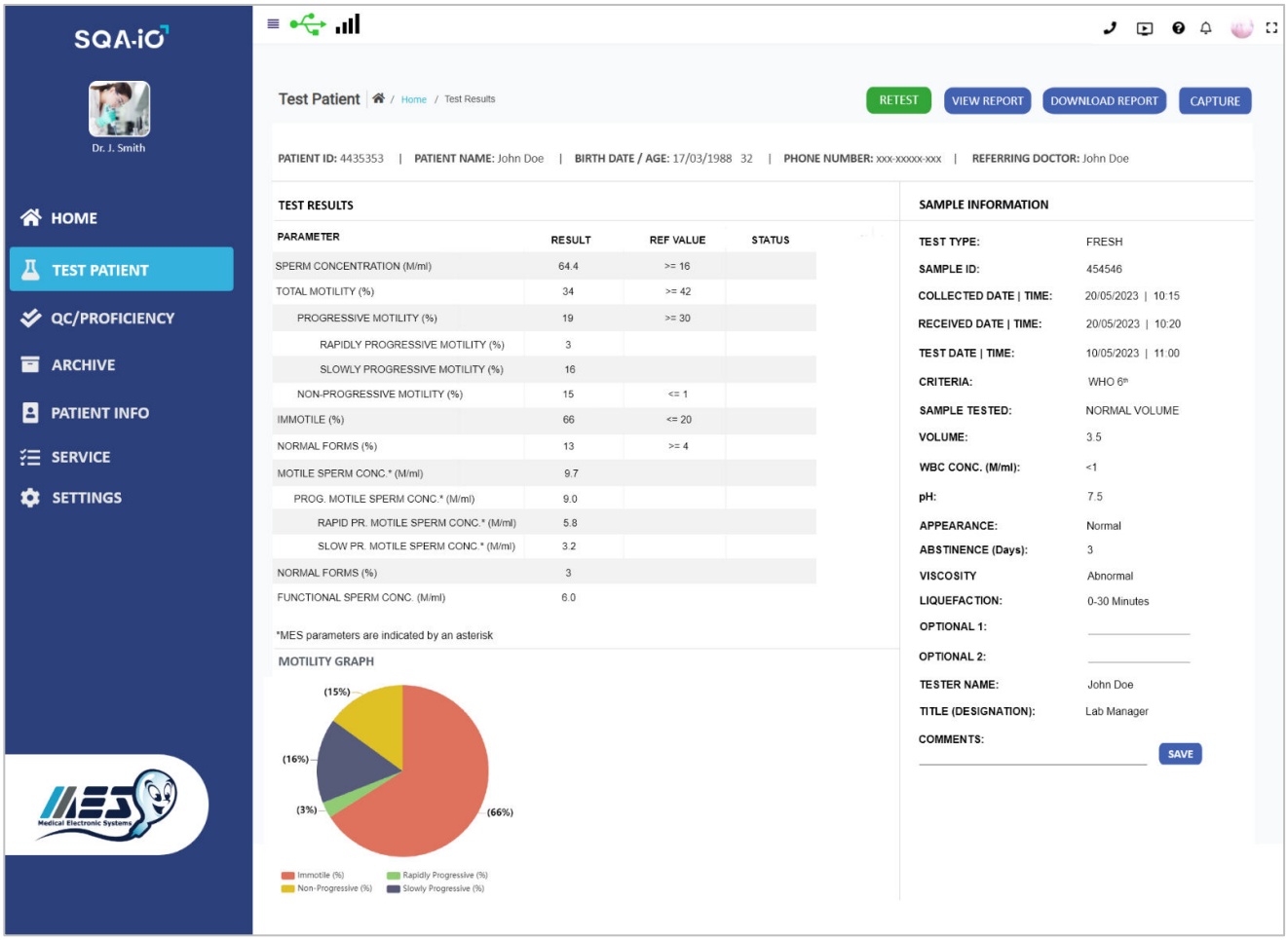
Test Patient – Test Results

After approximately 75 seconds, the patient's test results will be displayed, along with the SAMPLE INFORMATION. All sperm testing parameter values will be shown along with the REFERENCE VALUES (if available) and an indicator arrow only if the results are high or low based on the laboratory's approved reference values and protocols for results interpretation. If there is no arrow, the test results are either in the normal range or there is no reference value for the parameter set by the laboratory. REFERENCE VALUE defaults are provided by the manufacturer based on WHO/MES guidelines. Go to SETTINGS to set the laboratory's own reference value defaults.

Three navigation options are available from the TEST RESULTS screen:

- **RETEST:** Select to run a second test on the same patient if desired.
- **VIEW REPORT:** Click to view and print the patient's report
- **SAVE:** Click to save the test results to the patient archive.

PATIENT TEST RESULTS SCREEN



Test Patient – Semen Analysis Report

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Medical Electronic Systems

5000 West Street LA.
CA 90000 University Laboratory

PHONE: 837-6029-686
EMAIL: MES@gmail.com
SITE: www.mes-global.com

SQA-iO AUTOMATED SEMEN ANALYSIS RESULTS

SQA-iO MES - Signal Processing Technology

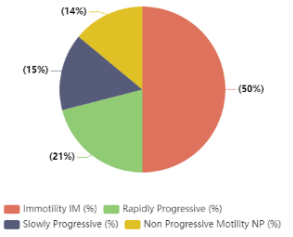
PATIENT INFORMATION

FIRST NAME:	John	LAST NAME:	Doe
PATIENT ID:	4435353	AGE:	32
REFERRING DOCTOR:	John Doe	PHONE NUMBER:	xxx-xxx-xxx

SAMPLE INFORMATION

SAMPLE ID:	454546	ph:	7.5
TEST TYPE:	FRESH	APPEARANCE:	NORMAL
COLLECTED DATE / TIME:	20/05/2020 | 10:15	VISCOSITY:	ABNORMAL
RECEIVED DATE / TIME:	20/05/2020 | 10:20	LIQUEFACTION:	0-30 Minutes
TEST DATE / TIME:	20/05/2020 | 11:00	ABSTINENCE (days):	3
CRITERIA:	WHO 6TH	SAMPLE TESTED:	NORMAL VOLUME
VOLUME:	3.5	OPTIONAL 1:	
WBC CONC. (M/ml):	<=1	OPTIONAL 2:	

PARAMETER	RESULT	UNITS	REF.VALUE		MOTILITY GRAPH
CONCENTRATION	6.0	M/ml	>=16	↓	
TOTAL MOTILITY	50	%	>=42	↓	
PROGRESSIVE	36	%	>=30	↓	
RAPIDLY PROGRESSIVE	21	%			
SLOWLY PROGRESSIVE	15	%			
NON-PROGRESSIVE	14	%	<=1		
IMMOTILE	50	%	<=20	↓	
NORMAL FORMS	3	%	>=4		
MOTILE SPERM CONC.*	9.7	M/ml			
PROG. MOTILE SPERM CONC.*	9.0	M/ml			
RAPID PR. MOTILE SPERM CONC.*	5.8	M/ml			
SLOW PR. MOTILE SPERM CONC.*	3.2	M/ml			
FUNCTIONAL SPERM CONC.* (M/ml)	6.0	M/ml			



*MES parameters are indicated by an asterisk

COMMENTS: Very clear seminal plasma

Signature: _____ Tester Name: John Doe Title (Designation): Lab Manager

FAC ID#: Z9XQWR | SN#: 10111 | [MC] | Conc. Standard 1 | 20/05/2020 11:30:01 | AVG 55.81 | AW 15427 | CNT 330 | OD 1.126

The semen analysis report can be customized in the SETTINGS section. It displays the information on the testing facility, all the test results, a motility graph and patient and physician information as well as comments.

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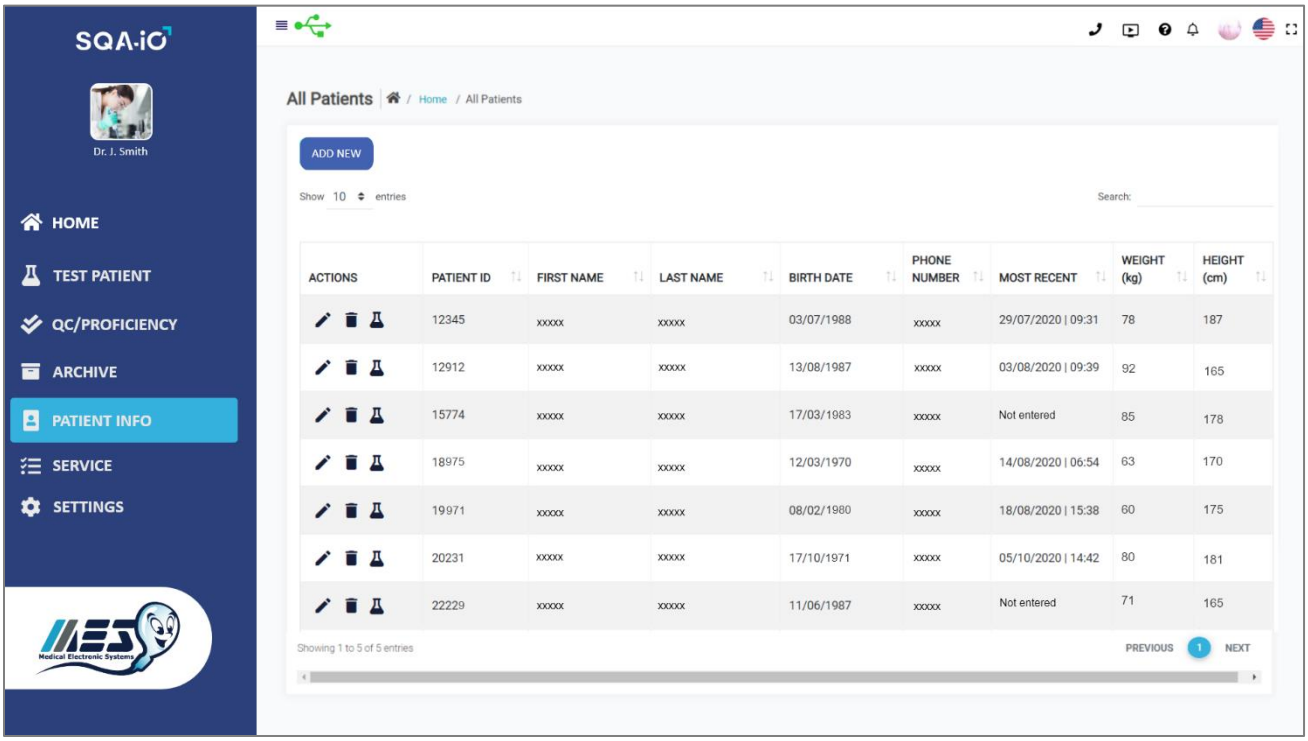
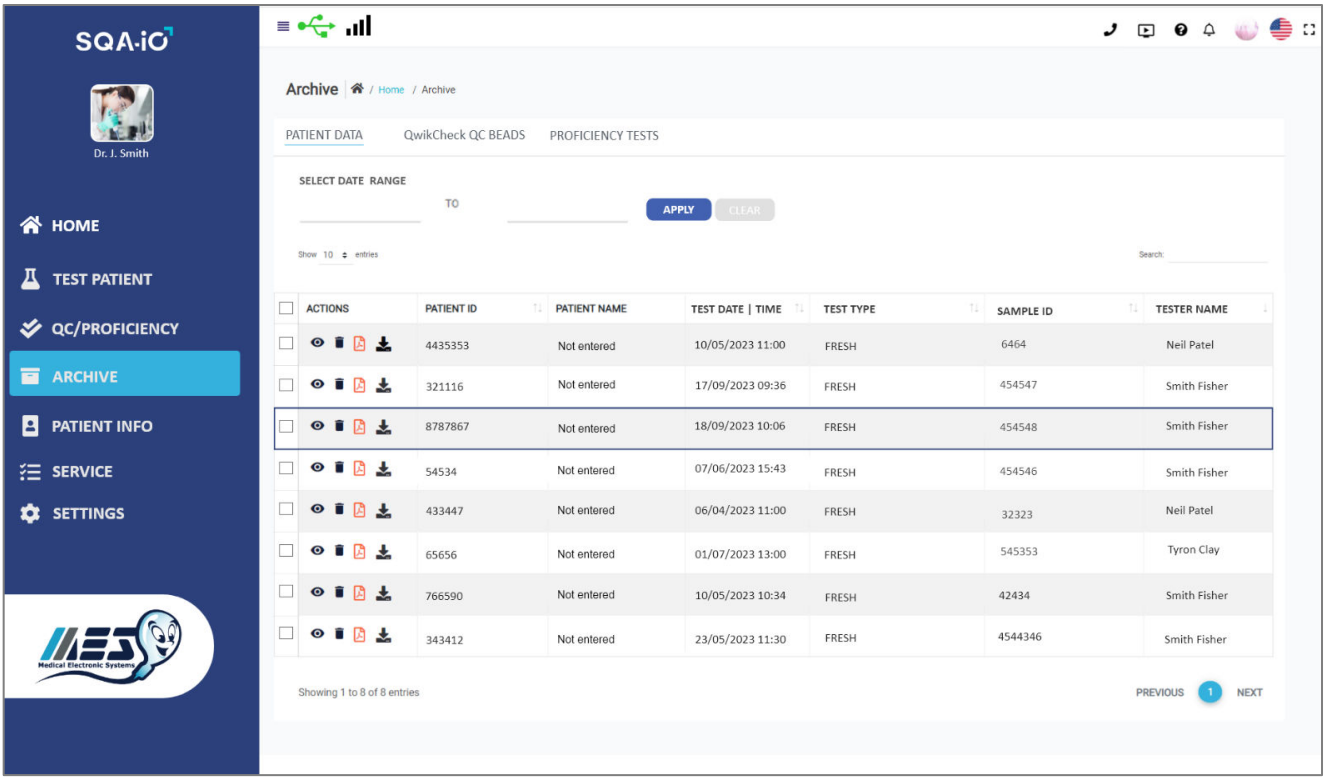
Patient Info



The PATIENT INFORMATION screen is for managing detailed patient information. New patients can be added by clicking on ADD NEW. Patient information can be edited or deleted by clicking on the icons under ACTION. Click on the column header to sort patient data.

Archive



Click on ARCHIVE to see a complete list of the patient's test results. Sort by date range. View, delete or run reports by selecting the patient with a click and then clicking on the desired ACTION button.

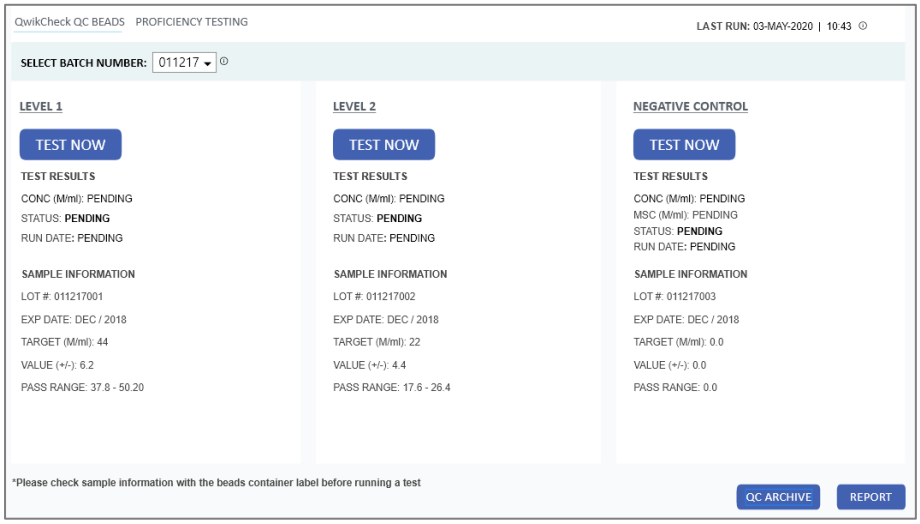
SECTION 6: QC / Running CONTROLS

Select QC/Controls from the navigation panel to run three levels of QwikCheck Beads quality control samples. When running QwikCheck Beads controls please follow the instructions in the package insert. Also, be sure to:

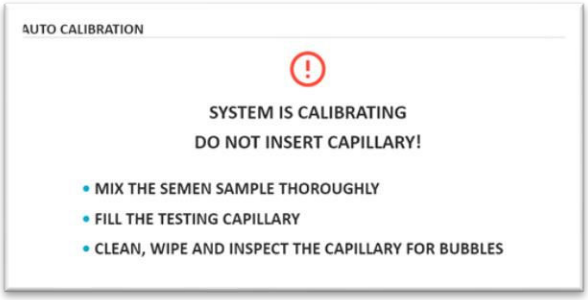
- Use a separate, new capillary for each level of beads – mixing beads will produce inaccurate results.
- Mix the samples gently before aspirating into the testing capillary.
- Do not return beads solution to the container after testing – this will contaminate the samples AND beads adhere to the capillary walls so the concentration of the beads will be altered.

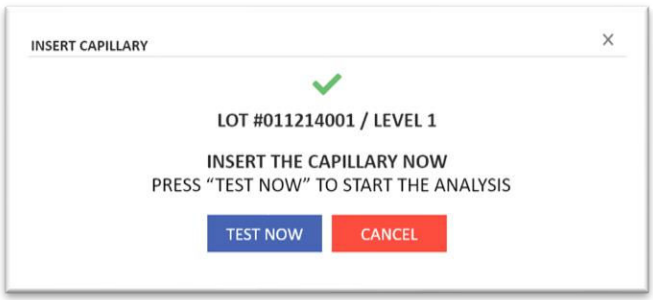
Testing QC Controls

- The screen below will be activated when entering QC Controls from the navigation panel. If controls have never been run, all TEST RESULTS and SAMPLE INFORMATION will be shown as PENDING.
- **SELECT BATCH NUMBER:** From the drop-down menu, find the batch number that corresponds to the batch number on the outside label of the QwikCheck beads box that will be tested.
- **SAMPLE INFORMATION:** All three beads' levels will automatically be filled when the batch is selected.
- **LAST RUN:** If previous tests have been run, a notification of the last date and time is shown.
- **TEST NOW:** Select TEST NOW when ready to run the beads level with the corresponding capillary.



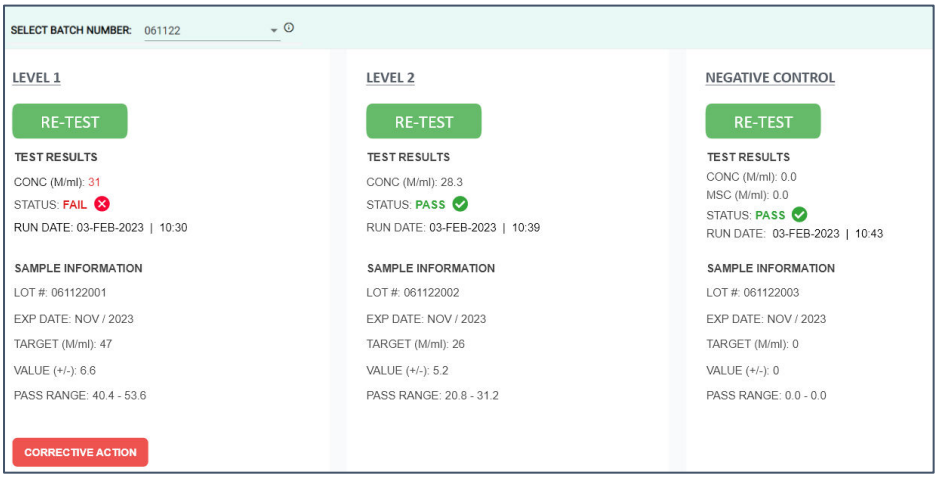
Follow the on-screen instructions for capillary preparation and insertion.



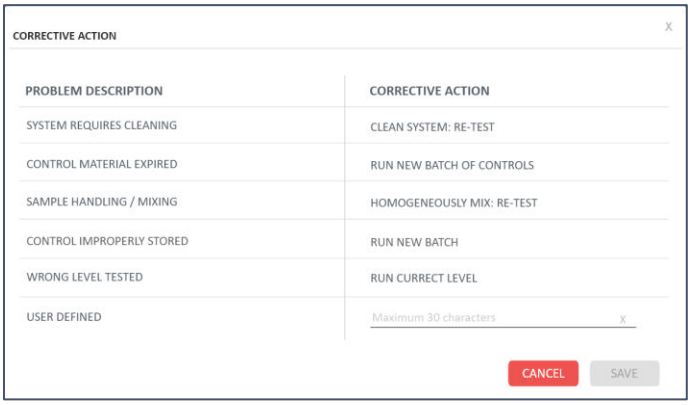


Results and Corrective Action:

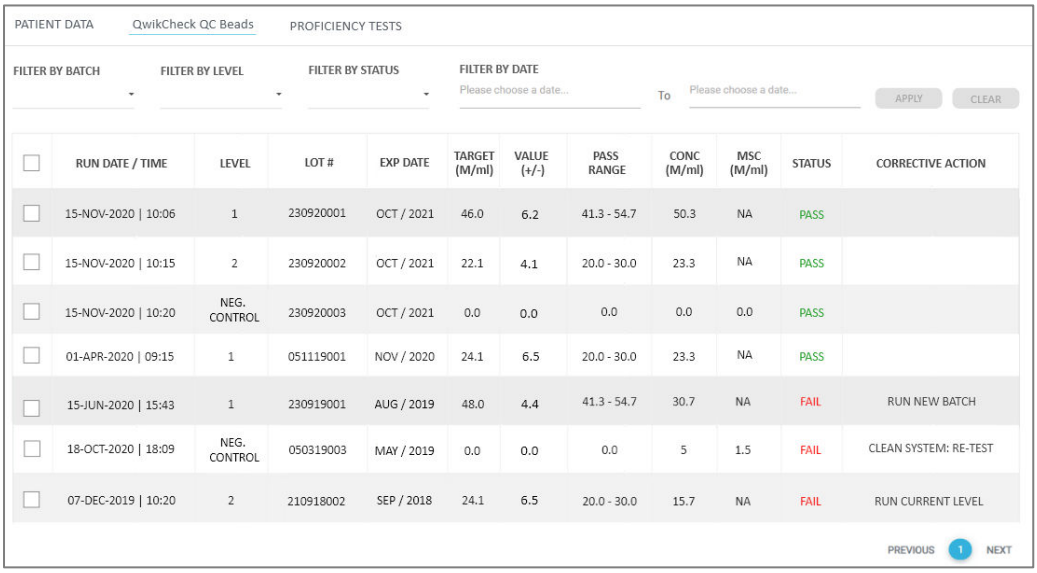
- **RESULTS:** Control testing takes about 20 seconds per test. Results are displayed automatically and, if out of range, a CORRECTIVE ACTION alert will be shown. Select the CORRECTIVE ACTION button to identify what caused the out-of-range results.



- **CORRECTIVE ACTIONS** are listed below and, once selected, will appear on the QC Report and will be saved in the QC archive. Use the USER DEFINED option if none of the actions listed describe the problem.



QC ARCHIVE: Select this option from the TESTING or ARCHIVE screen to view all QC tests. Many options for selecting and presenting results are available from this screen and results can be exported for record keeping.



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QC/Controls Test Report: After completing a test, select the REPORT button to run a QC report showing the results and graphed results.

MES Fertility Center
5000 West Street LA, CA 90000

PHONE: 837-6029-686
EMAIL: MES@gmail.com
WEBSITE: Johndoe@gmail.com

QUALITY CONTROL REPORT - QwikCheck QC BEADS

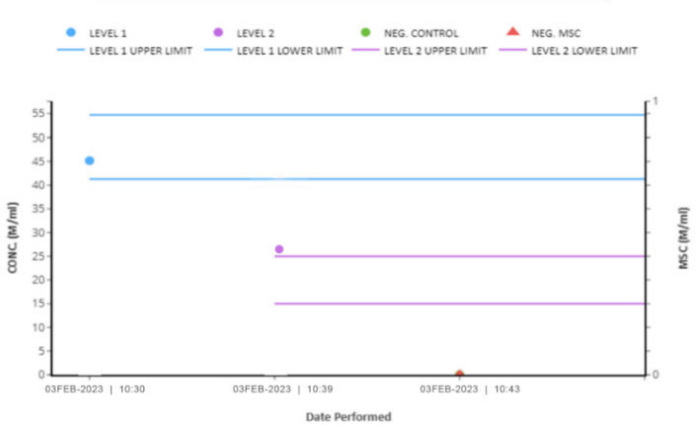
SQA-iO MES - Signal Processing Technology

QUALITY CONTROL INFORMATION

QC TYPE:	QwikCheck Beads	REPORT DATE / TIME:	03-FEB-2023 | 11:00
RUN DATE:	03-FEB-2023		

RUN DATE / TIME	LEVEL	LOT #	EXP DATE	TARGET (M/ml)	PASS RANGE	RESULTS (M/ml)	STATUS	CORRECTIVE ACTION
03-FEB-2023 | 10:30	1	061122001	NOV / 2023	47	40.4 - 53.6	46	✓	
03-FEB-2023 | 10:39	2	061122002	NOV / 2023	26	20.8 - 31.2	28.2	✓	
03-FEB-2023 | 10:43	NEG. CONTROL	061122003	NOV / 2023	0	0.0-0.0 CONC.MSC	0.0	✓	

QUALITY CONTROL GRAPH



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SECTION 7: SQA-iO Test Kit and Test Credits

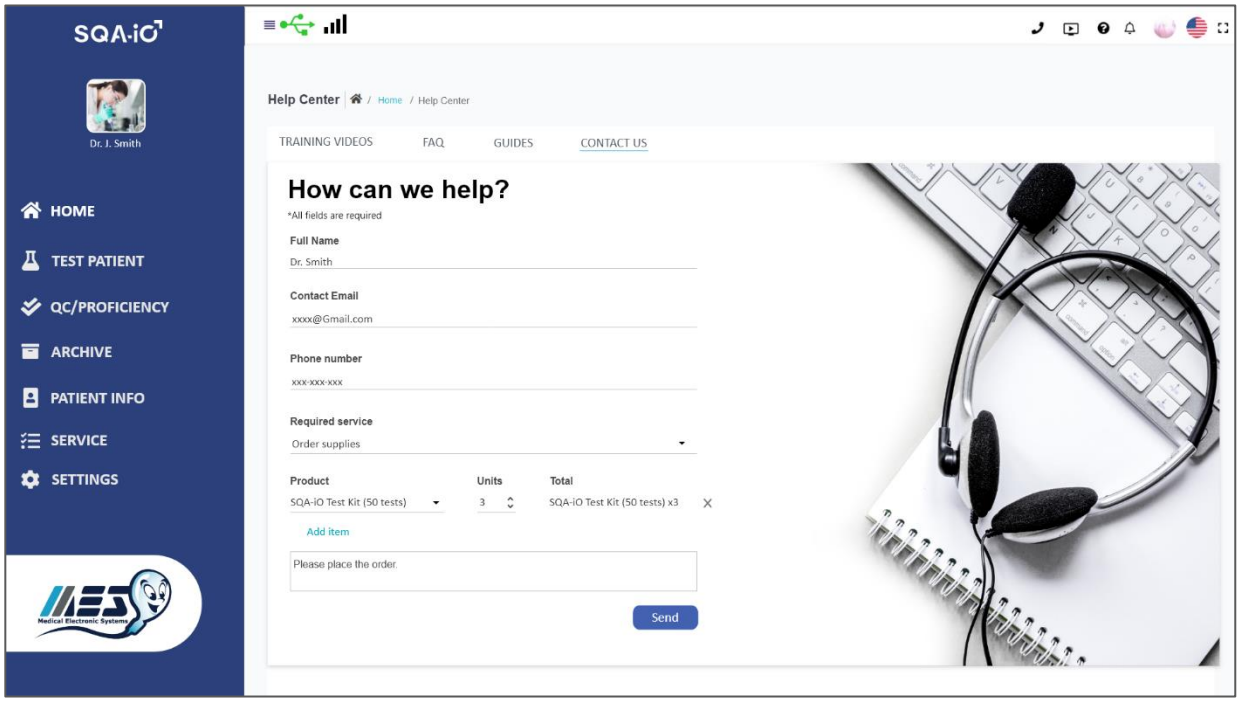
The SQA-iO Test Kit contains all the supplies necessary to run a semen sample on the device:

- 50 SQA Testing Capillaries
- Cleaning supplies
- Unique Credit Code for loading test credits
- Full instructions for use of supplies

The SQA-iO cannot operate without test credits. Each new test kit is a unique randomly generated TEST CREDIT CODE. When you receive a new test kit, enter this code into the SQA-iO when a pop-up screen is displayed. The SQA-iO will know when there are few or no test credits remaining and will send a warning message. From the pop-up SELECT:

- **ORDER KIT** to purchase a new kit from your distributor or
- **ENTER CREDIT CODE** if you have a new test kit and need to load the test credit code

Test kits can also be ordered through **CONTACT US**. Go to the drop-down menu and select the first option: "REORDER NEW TEST KITS"



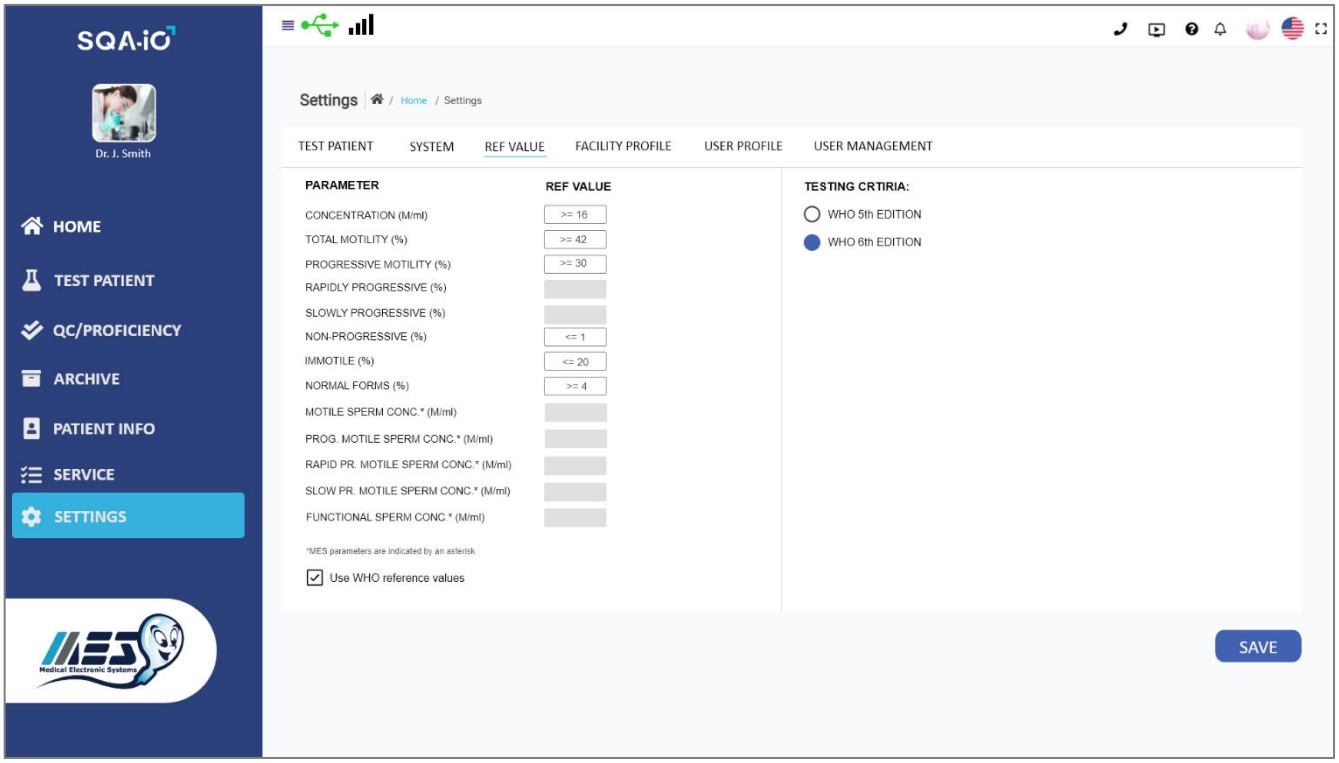
SECTION 8: Set-up the SQA-iO Defaults Settings

The following options are available in SETTINGS depending on the user permission status.
FACILITY PROFILE: Facility admins can select this option to set up the test report and SQA-iO with personal information and a logo.

USER MANAGEMENT: Facility admins can select this option to view users of their facility and add, remove, and edit users.

In addition, the option to **Include Debris Assessment** can be selected as a default to enable a visual assessment of the sample to assess for debris. To do this, prepare a standard slide with a 22X22 coverslip and a drop of semen. View the slide under a laboratory microscope. Select the level of debris based on the options presented. The automated analysis will now compensate for debris.

REF. VALUE: Users with Editor permission can select either WHO 5th or 6th edition testing criteria for reference values. The manufacturer's factory defaults are pre-set to WHO 6th criteria. Uncheck "Use WHO reference values" to set custom reference values.

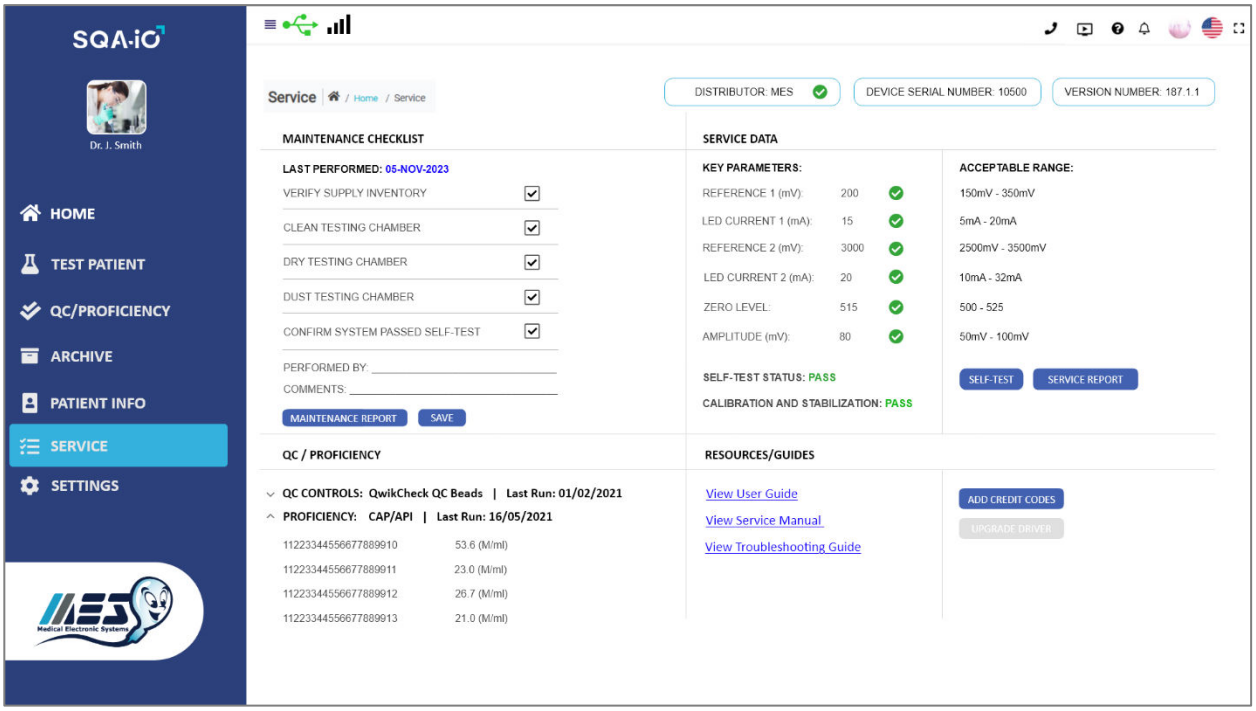


USER PROFILE: Any user can select this option to view their current profile information, change their password, set-up the test report with a signature and upload a personal profile picture.

SECTION 9: Service

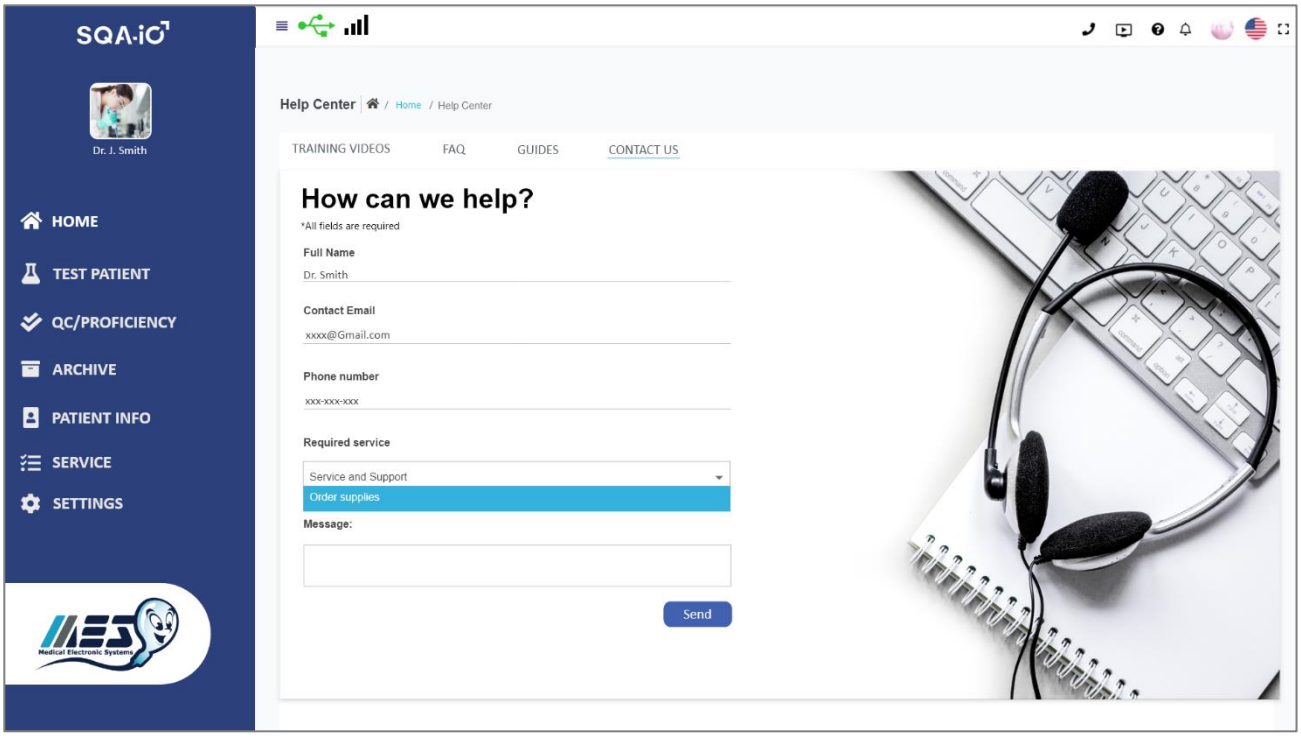
Enter this screen to view/access the:

- Maintenance Checklist: A useful option to assist the user to document and track the device maintenance and cleaning schedule. Use of the table is optional and will not impact the testing of samples or device operation.
- SERVICE DATA / KEY parameters: Check to confirm that the SQA-iO device is ready for testing.
- User Guide, Service Manual and Troubleshooting Guide: Click on the links provided.

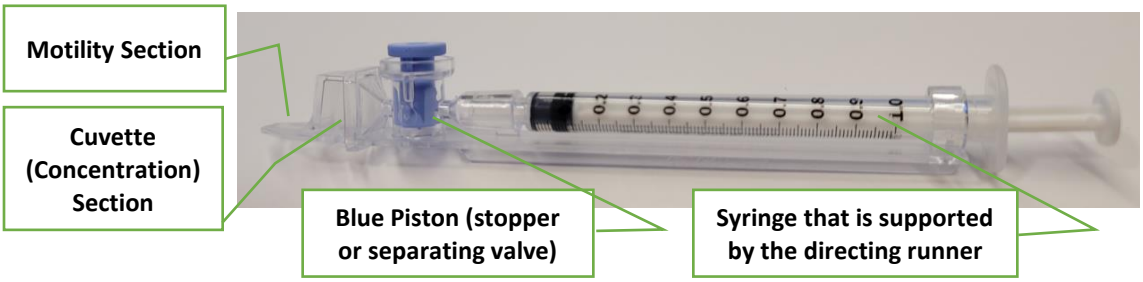


Contact Us

Contact Us is available by clicking the phone icon at the top right of the screen. To order new test kits or request support, use the drop-down menu and message box to contact your local distributor.



APPENDIX 1: Filling the Testing Capillary with a Semen Sample



Sample size, collection and preparation instructions:

1. A minimum of 0.6 ml. of semen is required.
2. Samples should be self-collected without using lubricants or other cremes.
3. Maintain the sample at room temperature (do not heat or refrigerate).
4. Measure sample volume according to laboratory protocols.
5. Enter the sample volume into the TEST PATIENT screen of the SQA-iO.
6. Test the sample after liquefaction and within 1 hour of collection for optimal results.
7. Before filling the capillary, the semen sample must be **completely** liquified and gently mixed by rotating the sample collection container.
8. *WARNING:* ***Do not shake or use a pipette to mix the sample otherwise air bubbles will form and test results will be inaccurate.***
9. Carefully check that the liquefied, fully mixed semen is **free** of air bubbles.

Filling the capillary… Ready to test:

1. Push the syringe pump fully into the syringe and then place only thin part of the capillary into the bottom of the sample (Fig 1).
2. Pull the syringe pump back slowly while keeping the tip of the capillary well below the sample level and below any surface bubbles. Continue to aspirate the sample until it appears in the Luer adaptor (Fig. 1 & 2).
3. Check the capillary after filling (Fig. 2) to visually confirm that the sample has completely filled the cuvette and thin section of the capillary (without a meniscus). Tap on the syringe to make sure there are no air bubbles in the sample. If air bubbles still appear below the Luer adaptor, fill again with a small quantity of semen to draw the air bubbles into the syringe.
4. Wipe the tip of the capillary with a Kimwipe quickly (to avoid wicking) (Fig. 3). Also wipe the exterior of the capillary if any spillage occurs, in order to keep the SQA-iO clean. Visually confirm that the capillary chambers are still full after cleaning. If not, slightly push in the piston of the syringe to re-fill the capillary section.
5. Slowly push-in the blue separating valve until it is level with the plastic (Fig. 4).
6. Insert the testing capillary into the SQA-iO all the way with the blue valve down (Fig 5)


Fig. 1: Filling


Fig. 2: Inspect for bubbles


Fig. 3: Wipe the tip


Fig. 4: Push-in the blue valve

Fig. 5: Insert capillary into SQA-iO

APPENDIX 2: Cleaning the SQA-iO

When to clean: WEEKLY

- Or if SELF-TEST or any other failure occurs
- Or if System becomes contaminated with semen

Cleaning kit components:

Long cleaning brush (provided in the SQA-iO device kit)

Fibrous material cleaning paddles (single use)

Sponge-tipped drying paddles (single use)

Cleaning fluid (single drop dispenser)

Fig.1 Long Cleaning Brush

Fig. 2 Clean the chamber

CLEANING: STEP 1

- Insert the long brush supplied in your device kit (bristle side down) into the chamber of the SQA-iO in the same way a testing capillary would be inserted (Fig 1 and 2).
- Pull the brush out, applying downward pressure to sweep or '**dust off'** the optics (you will feel a 'shelf' in the back/top section of the chamber) – (Fig 2 and 3)

Fig. 3 "Dust off"

CLEANING: STEP 2

1. Use a **Fibrous material** cleaning paddle (Fig 4) supplied in your TEST KIT.
   - Moisten with only ONE drop of cleaning fluid.
   - Shake off excess fluid.
   - Insert into the measurement compartment fibrous material facing **down** and move the cleaning paddle in and out 5 times (Fig 5).
   - Then, insert into the measurement compartment fibrous material facing **up** and move the cleaning paddle in and out 5 times (Fig 5).
2. Dry the testing chamber using a sponge-tipped drying paddle that is supplied in your TEST KIT.
   - Insert it into the testing chamber and leave it for 10 – 15 seconds (Fig 6).
   - Leave the drying paddle in place, DO NOT move it in and out.

Fig. 4 Fibrous cleaning paddle

Fig. 5 Insert cleaning paddle down and up

Fig. 6 Dry the testing chamber with sponge

APPENDIX 3: Reference Values of Semen Parameters

Reference Values for Semen Parameters					
SEMEN PARAMETER	**REFERENCE RANGE***	**SOURCE**	**SEMEN PARAMETER**	**REFERENCE RANGE***	**SOURCE**
CONCENTRATION (M/ml)	≥ 15	WHO 5th Edition	CONCENTRATION (M/ml)	≥ 16	WHO 6th Edition
TOTAL MOTILE PR + NP (%)	≥ 40		TOTAL MOTILITY RP+SP+NP (%)	≥ 42	
PROGRESSIVE PR (%)	≥ 32		PROGRESSIVE MOTILITY (%) (RAPIDLY PROGRESSIVE + SLOWLY PROGRESSIVE MOTILITY)	≥ 30	
NON-PROGRESSIVE (%)	≤ 1		NON-PROGRESSIVE (%)	≤1	
IMMOTILE IM (%)	≤ 18		IMMOTILE (%)	≤ 20	
MOTILE SPERM CONC. (M/ml)	≥ 6.0		MOTILE SPERM CONC. (M/ml)	≥ 7.0	
PROG. MOTILE SPERM CONC. (M/ml)	≥ 5.0		PROGRESSIVELY MOTILE SPERM CONC (M/ml)	≥ 5.0	
			RAPID PR. MOTILE SPERM CONC. (M/ml)	≥ 1.8	
			SLOW PR. MOTILE SPERM CONC. (M/ml)	≥ 3.2	
NORMAL FORMS (%)	≥ 4		NORMAL FORMS (%)	≥ 4	
FUNCTIONAL SPERM CONC. (M/ml)			FUNCTIONAL SPERM CONC. (M/ml)	≥ 0.2	

* The reference values established above are based on WHO 5th and 6th edition guidance and reference tables.

APPENDIX 4: Product Performance Data and Claims

Clinical studies were performed at three sites where site operators (total n = 12) tested native human semen samples by the SQA-iO, and matched samples were tested by trained operators with the SQA-V comparative method. The data set included a total of 165 matched results, and the performance across all parameters is shown in Table 1 below.

Table 1: SQA-iO vs. SQA-V (n = 165)

Parameter	Intercept	CI	Slope	CI	Correlation	CI
CONCENTRATION, M/ml	-1.5	-2.0 to -0.7	1.0	1.0 to 1.0	1.0	0.98 to 0.99
MOTILITY, %	-3.0	-3.1 to -1.7	1.0	1.0 to 1.0	1.0	0.95 to 0.97
PROGRESSIVE MOTILITY, %	-0.8	-1.0 to 0.0	0.9	0.9 to 1.0	1.0	0.97 to 0.98
RAPIDLY PROGRESSIVE, %	0.1	0.0 to 0.3	1.0	0.9 to 1.0	0.9	0.90 to 0.94
SLOWLY PROGRESSIVE, %	-0.8	-1.0 to 0.0	1.0	0.9 to 1.0	0.9	0.86 to 0.93
NON-PROGRESSIVE, %	-1.9	-3.0 to -1.0	1.2	1.0 to 1.3	0.8	0.71 to 0.83
IMMOTILE, %	3.0	1.0 to 5.0	1.0	1.0 to 1.0	1.0	0.95 to 0.97
MSC, M/ml	-0.9	-1.7 to -0.6	1.0	1.0 to 1.0	1.0	0.98 to 0.99
PMSC, M/ml	-0.4	-0.7 to -0.3	1.0	0.9 to 1.0	1.0	0.99 to 1.00
RAPID PMSC, M/ml	0.0	-0.1 to 0.0	1.0	1.0 to 1.0	1.0	0.96 to 0.98
SLOW PMSC, M/ml	-0.1	-0.4 to -0.1	1.0	0.9 to 1.0	1.0	0.98 to 0.99
MORPHOLOGY, %	0.0	0.0 to 0.1	1.0	0.9 to 1.0	1.0	0.96 to 0.98
FSC, M/ml	-0.1	-0.1 to 0.0	0.9	0.9 to 1.0	1.0	0.97 to 0.99

The data presented in Table 1 demonstrates slopes between 0.9 and 1.2, and a correlation coefficients ("r") ≥0.8.

Appendix 5: SQA-iO Warranty

Warranty Sperm Quality Analyzer SQA-iO

Medical Electronic Systems ("MES") warrants that the SQA-iO Sperm Quality Analyzer will be free from defects in workmanship and materials for a period of twelve (12) months from date of the first, initial installation. If a device is resold or re-installed after the first, initial installation, the warranty will continue (or expire) based on the first, initial installation date.

If, during the one-year warranty period, the device is shown to MES's reasonable satisfaction to be defective, MES shall, at its option, replace or repair such a device without charge for parts or labor. The foregoing remedy shall be purchaser's sole and exclusive remedy under this warranty.

The warranty is subject to the following conditions:

- Proper cleaning is followed based on the manufacturer's guidance AND evidence of such scheduled cleaning (weekly) and proper maintenance of the device per the manufacturer's guidelines is provided from the system records.
- No modifications or alterations are made to the SQA-iO device or related testing supplies.
- The SQA-iO is not used, operated, or opened by anyone other than the purchaser.
- The SQA-iO is not serviced by anyone or any other entity other than MES or its designee.
- The SQA-iO is used, as labeled for human semen testing only, transported in its original box, stored in the proper temperature range and only manufacturer supplied testing supplies are used for testing, service and maintenance.

If the above conditions are not met or proper maintenance/cleaning records are not provided, this warranty shall be void and of no further force or effect. EXCEPT FOR THE FOREGOING WARRANTIES, THE PRODUCTS ARE SOLD AS-IS AND WITHOUT ANY OTHER WARRANTY OF ANY NATURE WHATSOEVER. MES HAS NOT MADE AND DOES NOT MAKE ANY OTHER REPRESENTATION, WARRANTY, GUARANTY, OR COVENANT, EXPRESS OR IMPLIED, WITH RESPECT TO THE DESIGN, CONDITION, DURABILITY, SUITABILITY, FITNESS FOR USE, FITNESS FOR A PARTICULAR PURPOSE, OR MERCHANTABILITY OF THE SQA IN ANY RESPECT. UNDER NO CIRCUMSTANCES AND IN NO EVENT, WHETHER AS A RESULT OF BREACH OF CONTRACT OR WARRANTY, TORT (INCLUDING NEGLIGENCE AND STRICT LIABILITY) OR OTHERWISE, INCLUDING BUT NOT LIMITED TO INACCURATE RESULTS OR OPERATOR ERROR, SHALL MES BE LIABLE FOR ANY SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES. IN NO EVENT SHALL MES'S LIABILITY WITH RESPECT TO THE PRODUCT EXCEED THE PURCHASE PRICE FOR SUCH PRODUCT.

Appendix 6: Warnings and Regulatory Information

Warnings and Precautions:

- Maintenance Schedule: Clean the measurement compartment weekly using ONLY manufacturer's cleaning supplies provided in the test kit.
- Semen is considered a biologically hazardous material and is subject to laboratory protocols for handling and disposing of such materials in specially marked hazardous waste containers.
- Indoor Use

Cybersecurity Controls:

- Operate the SQA-iO software interface in a controlled environment of the laboratory, accessible to trusted, authorized personnel only.
- Carefully read the entire SQA-iO IFU before initial use to ensure optimal results.
- The SQA-iO USB port is intended to connect the SQA-iO device only. Do not connect any USB devices such as a mouse or a keyboard to the USB port of the SQA-iO.

EMC Related Information

- Intended Use: the SQA-iO is designed and tested to comply with applicable Electromagnetic Compatibility (EMC) standards for use in the electromagnetic environment specified below.
- EMC Compliance: the SQA-iO complies with the requirements of IEC 60601-1-2 general requirements for basic safety and essential performance related with electromagnetic compatibility of Medical Devices. Compliance has been verified through testing under specific conditions. To maintain compliance, follow the guidelines provided in this Instruction for Use.
- No SQA-iO deviations were found from the reference standard or allowances during the SQA-iO EMC testing.
- Electromagnetic Environment: The SQA-iO is intended for use in an indoor environment where radiated RF disturbances are controlled. The intended user of the SQA-iO device should ensure that it is used in such an environment.
- Operate the device away from any source of vibrations such as a centrifuge.
- Use of Accessories: Only use accessories and cables provided or approved by the manufacturer. The use of unauthorized accessories may result in increased emissions or decreased immunity of the device. Specifications of the accessories (PC) required for the safe performance of the SQA-iO are included in Section 1 of the Instruction for Use.
- Interference Caution and Reporting: The user should be aware that electromagnetic emissions from nearby equipment or devices may affect the proper operation of the SQA-iO.
- If electromagnetic interference is suspected to impact the performance of the SQA-iO, report the issue to the manufacturer through CONTACT US, and to the relevant regulatory authority (such as US FCC- Federal Communication Committee). Provide details of the interference, equipment involved, and operating conditions.
- The SQA-iO complies with both emission and immunity requirements.
- The SQA-iO device communicates with the user's PC via a single USB port. There are no RF wireless functions applied by the SQA-iO device.
- Maintenance instructions to ensure that the SQA-iO remains safe and performs to EM disturbances as intended: Disconnect the device if not in use for an extended period of time.

- FCC warning: The SQA-iO operator is required to cease operating the device if the Commission or its representative find that the device is causing harmful interference. Operation cannot resume until the condition causing the harmful interference has been corrected.
- NOTE: "Harmful interference" is defined in 47 CFR §2.122 by the FCC as follows: Interference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the [ITU] Radio Regulations.

Symbols:

CE mark

IVD Symbol for **"IN VITRO DIAGNOSTIC MEDICAL DEVICE"**

℞ Symbol for **"The intended use of a prescription IVD product"**

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