Q-Sweat

Quantitative Sweat Measurement System

Rev. 05/01/24
Instructions for Use

P/N 5192

Q-Sweat Patent No. 6.269.265.

For more information, contact:

WR MEDICAL ELECTRONICS CO.
1700 Gervais Avenue
Maplewood, MN 55109 USA

- *Phone:* **651-604-8400**
- *Phone toll-free within the United States:* **800-635-1312**
- *FAX:* **651-604-8499**
- *E-mail:* **neuro@wrmed.com**
- *Web site:* **www.wrmed.com**

Comments or Questions?

We would appreciate receiving any suggestions, comments, or questions that would help us to improve this manual. Please forward comments to the address above.

EU Authorized Representative:

EC REP

Medical Device Safety Service (MDSS)
GmbHSchiffgraben 41
30175 Hannover
Germany

Contents

PRODUCT DESCRIPTION

The Q-Sweat quantitative sweat measurement system, along with the WR Testworks software, can be used as a standalone device to support the acquisition of trans epidermal water loss (TEWL) measurements on patients. Based off original QSART measurement devices, the Q-Sweat uses unique design elements to gather its data. The device supports measurement rates of nL/minute and totalizing volumes in mL from moisture emitted by skin through use of room air dried by desiccant. This allows for accurate measurement of sweat rates via differential humidity comparisons pre and post skin contact in standardized, quantitative, and easy to perform tests. The Q-Sweat is not designed for vital signs monitoring or self-monitoring of patients.

INTENDED USE, INDICATIONS AND CONTRAINDICATIONS

Intended Use:

The Q-Sweat Quantitative Sweat Measurement System is designed to measure the sweat output of the skin of humans. The Q-Sweat examines the integrity of the postganglionic sympathetic sudomotor axon, assisting in the diagnosis of small fiber neuropathies. This device is intended to be used as a screening test for autonomic disorders, including adrenergic, cardiovagal and post ganglionic sudomotor failure, small fiber neuropathy and peripheral neuropathy. This device does not make a diagnosis or indicate by itself that any disease state exists; it only documents sweat output.

Indications for Use:

Along with testing for autonomic disorders, this device can also be used in scientific studies of the anatomy, physiology, and biochemistry of the skin and associated structures. All tests are non-invasive, standardized, quantitative, and easy to perform. The Q-Sweat Quantitative Sweat Measurement Lab provides physicians with several useful tools, including:

- Measurements of rate in nL/minute and totalized volume in mL.
- Two different ways to test sweat utilizing up to 4 body sites simultaneously.
- Resting Sweat test - a measurement of the body's resting sweat rate.
- Evoked Sweat test - a measurement of the body's response to stimuli (QSART).
- Accuracy down to 0.1 nL, with traceable history of output that is standardized and repeatable.

This equipment is intended for use by trained medical technicians, nurses, and physicians in a clinical, hospital, or professional setting. Testing is intended for a patient population of adolescents and adults who are suspected of or having an autonomic or sweating based disorder.

Intended Users:

- Trained medical technicians
- Nurses
- Physicians

Intended Patient Population:

- Age: Adolescent and adult
- Health: Suspected of, or having, autonomic disorders.
- Patient State: Not relevant

Usage Environment

The equipment is intended for use in an indoors clinic, hospital, or professional healthcare facility. Refer to the Instruction for Use for the Operating Environment temperature and humidity conditions.

Contraindications:

- Do not conduct this testing on fragile or damaged skin.
- Do not conduct this testing on wounds.
- Do not conduct this testing on internal tissues.
- Do not conduct this testing over tattoos or scars.
- Do not conduct this testing while on certain sweat-altering medications.
- Do not conduct this testing with lotions or creams or other on-skin media.

WARNINGS AND CAUTIONS

Cautions:

- This device is restricted to sale by or on the order of a physician.
- This device is to be operated only by trained personnel under the direction of a physician.
- Subjects to be tested must be examined by a physician before testing.
- Do not use the device on any person when any covers of any equipment have been removed.
- This device is to be serviced only by WR Medical Electronics Co. If servicing is done by any party other than WR Medical Electronics Co., the product warranty and/or safety or quality certifications could become invalid. Contact themanufacturer for repair advice before attempting to repair.

Warnings:

- None. See Contraindications.

ELECTROMAGNETIC COMPATIBILITY

The system has been independently tested and found to comply with IEC 60601-1-2:2001 + A1:2004, Class B for Emissions, Immunity for Non Life-Supporting Equipment IEC 61000-3-2:2006 and IEC 61000-3-3:1995 +A1:2001 +A2:2006.

CAUTION: MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANING DOCUMENTS.

CAUTION: 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 HRV, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

No.	Test/Standard	Port (enclosure, AC, DC, I/O)	Emissions Class and Group / Immunity Test Level
1	CISPR 11, Radiated and Conducted Emissions	Enclosure	Class B
2	IEC 61000-3-2:2006	AC	50-2000Hz, Class A
3	IEC 61000-3-3:1995 +A1:2001 +A2:2006	AC	Pst, Plt, 120 minutes
4	IEC 61000-4-2 Electrostatic Discharge Immunity	Enclosure	±2kV, ±4kV, ±6kV contact, ±2kV, ±4kV, ±6kV, ±8kV air
5	IEC 61000-4-3 Radiated RF Immunity	Enclosure	3V/m, 80-1000MHz, 1-2.5GHz, 80% 1kHz AM
6	IEC 61000-4-4 Burst Immunity	AC	2kV, 5kHz repetition rate
7	IEC 61000-4-5 Surge Immunity	AC	±1kV Line-to-Line, ±2kV Line-to-Ground
8	IEC 61000-4-6 Conducted RF Immunity	AC	3V, 0.15-80MHz, 80% 1kHz AM
9	IEC 61000-4-8 Rated Power-Frequency Field Immunity	Enclosure	30A/m, 50/60Hz
10	IEC 61000-4-11 Voltage Dips	AC	0% (100% reduction), 0.5 cycle; 0% (100% reduction), 1 cycle; 70% (30% reduction) UT, 0.5 sec
11	IEC 61000-4-11 Voltage Interruptions	AC	0% (100% reduction), 5 sec

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Cleaning Instructions

Before cleaning, ALWAYS ensure that the unit is powered off and that the power cord is disconnected. NEVER immerse the unit or any components. NEVER apply cleaning solutions or moisture to the unit directly, instead apply to the cloth and then useit to clean the requisite components. ALWAYS ensure that the unit is clean and dried completely before reconnecting power and resuming testing.

Main Unit

- The main unit may be cleaned with a dry, lint-free clean cloth.
- If the main unit or desiccant housing becomes visibly soiled, they may be cleaned using a damp, lint-free cloth, enzymatic cleaner, quaternary ammo nium compound, or bleach wipes.
- Isopropyl alcohol (70%) may be used as an alternative but may overtime strip ink from printed labels and printed materials on the surfaceof the unit or desiccant housing.
- The parking fixture and hose connectors may be cleaned with a damp cloth, enzymatic cleaner, or bleach wipes. These pieces may also be cleaned with 70% isopropyl alcohol.
- Rubber gasket seals may deteriorate over time. Replacements may be acquired locally or purchased from WR Medical Electronics.

Measurement hoses and capsules

- Hose exteriors may be cleaned with a damp cloth, enzymatic cleaner, 70% isopropyl alcohol, or bleach wipes.
- Hose interiors may acquire a buildup of material over time. If visible buildup has occurred and cannot be removed, replacement hoses may be purchased from WR Medical Electronics.
- If material buildup in the hoses has reached the hose connectors, themain unit hosing may be contaminated as well. End users may carefully remove the cover of the main unit and visually inspect the hosing.If internal hosing is affected, the unit should be sent to WR Medical Electronics for cleaning and any possible repair.

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SAFETY INFORMATION

System Classification (IEC601-1/EN60601-1)

- Type of protection against electric shock: Type BF
- Degree of protection against electric shock: Class I
- Degree of protection against moisture ingress (IEC529): Ordinary IPX0
- Degree of protection in the presence of a flammable anesthetic mixture with air or with oxygen or with nitrous oxide: Not protected (unsuitable)
- Mode of operation: Continuous
- Sterilization/disinfections: Not suitable

After exposure to transport and storage extremes, allow the system to acclimatize before operating. The system should not be subject to transport and storageextremes for longer than 15 weeks.

Safety and Information Symbols

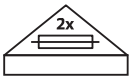
Symbols that appear on the equipment have the following meanings:

Attention, consult accompanying documents

Type BF Applied Part – F Type patient contact part isolated from other parts of the equipment such that patient leakage currents cannot exceed allowed limits in NORMAL and SINGLE FAULT CONDITION

On – Power connection to supply mains

Off – Power disconnection for supply mains



250V F.8A 5x20mm

Replace fuselinks as marked

Consult Operating Manual

ETL CLASSIFIED

C ETL LISTED US

Intertek

CE 0413

SYSTEM DESCRIPTION

BACKGROUND

The Q-Sweat quantitative sweat measurement system accurately measures moisture from the skin. Results are given in nanoliters/minute (rate) and microliters (total volume).

Dr. Phillip Low of Rochester, Minnesota has published several papers on sweat measurement in humans. In his articles are normative values based on age and gender.

SUGGESTED READINGS & REFERENCES

Laboratory Evaluation of Autonomic Function, Clinical Autonomic Disorders, 2nd Edition, 1997 Lippincott-Raven Publishers, Philadelphia, Chapter 15, pages 179-209

Low, Phillip A,; Mathias, Christopher J. "Quantitation of Autonomic Impairment", Peripheral Neuropathy, 4th Edition, Dyck, PJ; Thomas, PK, editors, Elsevier Saunders Inc, Chapter 44, pgs 1103-1133:2005

Low, Phillip A. "Laboratory Evaluation of Autonomic Function", Clinical Autonomic Disorders: Evaluation and Management, 2nd Edition, Low, PA, editor, Lippincott-Raven, Chapter 15, pgs 179-209:1997

Low, Phillip A.; Zimmerman, IR, "Development of an Autonomic Laboratory", Clinical Autonomic Disorders: Evaluation and Management, 2nd Edition, Low, PA, editor, Lippincott-Raven, Chapter 29, pgs 383-390:1997

American Academy of Neurology, "Assessment: Clinical Autonomic Testing", Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology, Published in Neurology, 1996;46:873-880

PARTS of the DEVICE

The Q-Sweat and its supporting parts are regarded as Class I.

Part Number	Description	Intended Use
5189b	Four Evoked Capsules. Cable length 2.6 meters each.	Picks up moisture from patients' skin.
5193	Desiccant Cylinder with desiccant	Drying medium used during the testing process.
5196	Four Silicone straps	Holds the capsules firmly to the patients' skin.
5552	USB cable. Cable length 1.8 meters.	Data connection, Case IV to computer.
5192	Instructions for Use	Safety and Operating instructions.
0309	Power cord. Cable length 2.4 meters.	IEC320 Hospital grade.

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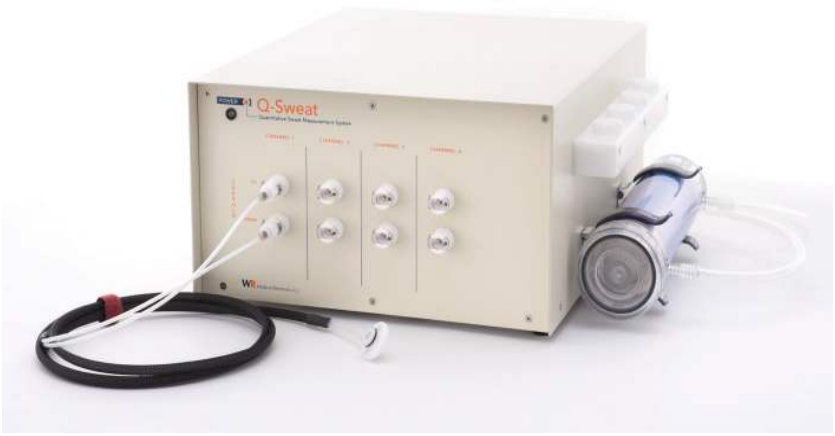
OVERVIEW

The Q-Sweat uses room air drawn across a desiccant to pick up moisture from the skin. This moisture is evaporated inside a measurement capsule where it is transported by airflow to temperature and humidity sensors, and a measurement of moisture is made.

4-Channel Q-Sweat Main unit

The Q-Sweat main unit contains an internal power supply, air pump, airflow regulator, voltage-sensitive proportioning orifice valve (VSO), mass air flow sensors, output air connections, input air connections, and a USB interface. The Q-Sweat Main Unit communicates through the interface to a computer withWR Testworks software.



Measurement capsules

Measurement capsules are provided in 2 sizes:

- Evoked (0.787 sq cm. measurement area)
- Resting (5.06 sq cm. measurement area)

The capsule is a component of a hose assembly, which consists of the measurement capsule (patient interface end), an 8' long hose, and connectors which attach to the front of the Q-Sweat Main Unit.

The Measurement capsules attach to patients' skin with silicone straps.

Measurement Capsules

WR Testworks Application software

WR Testworks consists of a main framework with application submodules. The available submodules include software for the following acquisition devices:

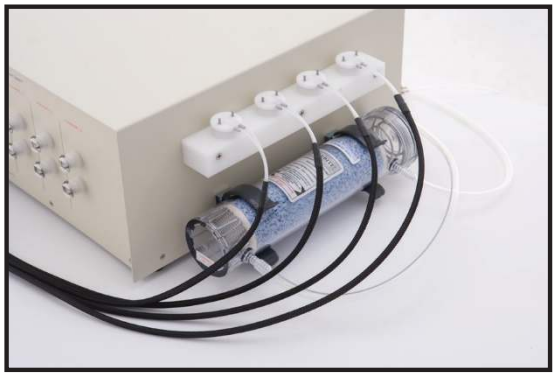
- Q-Sweat Main Unit
- CASE IV QST System
- HRV Acquire

The WR Testworks main framework includes the patient database, tests performed, patient demographics, report generation options, user and study set up, and several other features which are described in detail in the WR Testworks Software User Guide.

Optional: WR Medical recommends CNSystems CNAP BP Monitor for use with WR Testworks.

Parking Fixture

The Parking Fixture is located along the side of the Q-Sweat Main Unit. When not in use the measurement capsules should be placed on the parking fixture. This keeps the measurement capsules dry by limiting their exposure to room air.



When the measurement capsules are on the parking chamber and the hoses are connected to the front panel of the Main Unit, air will be flowing through the hoses and desiccant as long as the Main Unit is turned on. If any of the connections are broken the air supply will be shut off.

Power Light

A bicolor LED on the front panel of the Q-Sweat main unit gives information as to the operational status of the system.

Steady green	unit is running and is in use
Flashing green	unit is ready for patient testing
Steady amber	warming up
Flashing amber	POST error (contact WR Medical)
Light off	Main Unit is not running or powered off

SYSTEM OPERATION

Basic Test Procedure

1. Perform a visual check of your equipment. If damage is found, do not use the device. Contact WR Medical Electronics Co. for service and repair instructions.
    - Examine your desiccant source to be sure it is fresh, indicated by a blue color. Desiccant that is pink is used. Replace desiccant if necessary.

2. Turn the unit on at least 15 minutes prior to patient testing.

3. Enter the patient demographics into the software. Select the sweat test as indicated by the water drop icon.

4. Choose the recording site and prepare patient skin according to protocol. Do not use on broken or inflamed skin. Typical recording sites are:
    - the medial forearm (75 percent of the distance from the ulnar epicondyle to the piciform bone),
    - the proximal leg (lateral aspect, 5 cm. distal to the fibular head),
    - the distal leg (medial aspect, 5 cm. proximal to the medial malleolus),
    - the proximal foot (on a flat surface over the extensor digitorum brevis muscle).

5. Attach the recording capsules to the selected skin locations and start a recording.

6. Once the recording is complete, stop the recording and remove the measurement chambers from the patient and place them back on the parking chamber.

7. Follow the steps in the WR Testworks Software User's Guide for saving, discarding, or analyzing the data.

Skin capsule affixed to arm

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External Desiccant Cylinder Refill Instructions

A refillable desiccant cylinder is used to dry room air.

Replacement desiccant, in a convenient 5 lb glass jar, can be purchased directly from WR Medical Electronics Co. Use P/N 5598 when ordering.

The Q-Sweat device has a built-in sensor that indicates when desiccant needs to be replaced. A warning in WR Testworks software will alert you to replace the desiccant. The life of the desiccant can be extended by running the unit only during its 15-minute warmup period and during patient testing. Do not leave the unit running overnight. Note that desiccant is blue when it is new and turns pink as it becomes used (humidified).

Step One:
Remove the desiccant cylinder from the Q-Sweat device, and assemble the items for refilling the cylinder; replacement desiccant, a marker, a funnel, the black plastic wrench, and a plastic bag for disposal.

Step Two:
Using a permanent marker pen, mark the current upper and lower limit of the desiccant contained within the cylinder. This gives you a guideline for refilling the desiccant and prevents over filling or under filling.

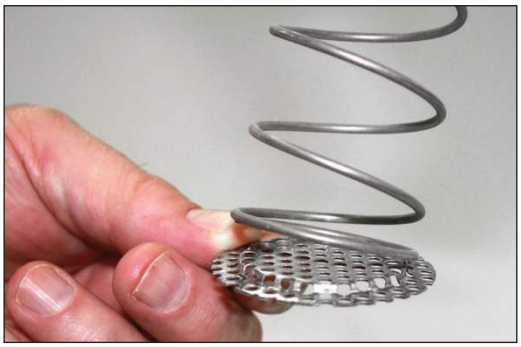
Step Three:
Unscrew the plastic end cap. It can be removed by hand or with the black plastic wrench that was included with the system.

Step Four:
Note how the components of the cylinder were assembled, and keep the parts at hand. Note that the white felt disk is always the first layer in contact with the desiccant.

Step Five:
Dispose of the used desiccant properly. If the metal screen and white felt disk fall from the cylinder, replace them carefully and make sure they are flat within the cylinder.

Step Six:
A small funnel may help with the transfer of new (blue) desiccant into the cylinder. Fill only up to the line made earlier indicating the proper fill level.

Step Seven:
Insert the white felt disk.



Step Eight:
Insert the metal screen with the 'bump' on top.

Step Nine:
Insert the metal spring.

Step Ten:
Re-attach the plastic cap. Hand tighten only, do not use the black wrench to tighten the plastic cap.

VERIFICATION OF CALIBRATION AND MAINTENANCE

VERIFICATION OF CALIBRATION

At the WR Medical manufacturing facility, each individual sensor is calibrated to a physical standard using a traceable measurement system (temperature, flow in and out, and fractional RH). The Q-Sweat™ device and its matched sensors can be verified for accuracy using a 5-microliter test with a calibrated Hamilton micro-pipette or equivalent.

For verification at a facilities site, a known quantity of water may be placed in the parking fixture and then evaporated and totalized by the system. The totalized amount should be compared to the known quantity placed in the fixture capsule. For a 5-microliter sample, accuracy is +/- 5%.

MAINTENANCE

The Q-Sweat does not require regular maintenance. Visually examine the main unit, hose connectors on the front and rear panels, and the capsule assemblies including the connectors. Look for damage or changes in appearance. Hose assemblies should also be examined for nicks, cuts, or other sources of potential leaks.

RESPONSIBILITY OF THE SUPPLIER

WR Medical Electronics Co. accepts responsibility for the effects of safety, reliability, and performance of the equipment only if:

- Assembly operations, extensions, readjustments, modifications, or repairs are carried out by persons authorized by WR Medical Electronics Co.
- The electrical installation of the room complies with local regulations.
- The equipment is used in accordance with the system manual.

SERVICE AND TECHNICAL SUPPORT

CAUTION:

- This device is to be serviced only by WR Medical Electronics Co. If servicing is done by any party other than WR Medical Electronics Co., the product warranty and/or safety or quality certifications could become invalid. Contact WR for advice before returning for repair.
- No readjustments or modifications are to be made by anyone other than persons authorized by WR Medical Electronics.

Prior to returning the Q-sweat unit for repair, please contact the Technical Support/ Help Desk for a Return Authorization Number.

Technical Support/Help Desk
WR Medical Electronics Co., 1700 Gervais Avenue, Maplewood, MN 55109 USA
Phone: 651-604-8483 or toll-free: 800-635-1312)
Fax: 651-604-8499
E-mail: helpdesk@wrmed.com
Web: www.wrmed.com

Please have your serial number available.

The Help Desk staff is available during normal business hours (8:00 am to 4:30 pm, Monday - Friday, Central Standard Time).

WARRANTY

WR Medical standard 1-year warranty from date of purchase for main device. Cords and Cables are 90-days. If additional warranty is needed, please contact the sales department for additional information.

DISPOSAL

WEEE Directive 2012/19/EU - Do not dispose of WEEE products in general waste. At the end of life of the product, contact WR Medical Electronics Co.'s Customer Service for return instruction.
Disposal of devices or consumables must be done in accordance with local, state, and federal laws and regulations.

SALES SPECIFICATION SHEET- Q-SWEAT®

WR Medical Electronics Co.
1700 Gervais Avenue
Maplewood, MN 55109
www.wrmed.com | 651-604-8400

PHYSICAL DIMENSIONS

Height:	7.6 in. (19.3 cm.)
Width:	14.5. in. (36.8 cm.)
Depth:	16.0 in. (40.6 cm.)
Weight:	16.0 lbs. (7.3 kg.)

POWER REQUIREMENTS

Power:	100 - 240 VAC, 50/60 Hz
Max Power Draw:	80VA
Protection:	2 x F0.8A (5x20mm IEC127)

ENVIRONMENT

	OPERATING	TRANSPORT AND STORAGE
Temperature:	20 - 25.6 degrees C	0 - 40 degrees C
Relative Humidity:	30 - 85% (non condensing)	0 - 80% (non condensing)
Atmospheric Pressure:	N/A	300 hPa – 1060 hPa

SWEAT MEASUREMENT OUTPUT

Number of Channels:	4
Measurement Method:	direct vapor pressure calculation
Measurement Area:	(two chambers provided): 0.787 and 5.06 square cm.
Dry air flow rate:	60.0 SCCM
Sweat Rate Measurement:	
Range:	0–1700 nanoliters
Accuracy:	± 5 percent
Repeatability:	± 5 percent
Sensitivity:	0.1 nanoliters

SOFTWARE REQUIREMENTS

Application Software:	WR Testworks®

REGULATORY

FDA MDL Number:	D009009
FDA 510K:	K992874
Health Canada License Number:	64196
Device Directive 93/42/EEC for Medical Devices	
Certificate No.:	41314493-02
EC Class:	I, Measuring

ETL CLASSIFIED
C ETL US LISTED
Intertek
CE 0413