MEDEIA QBIOSCAN/SODOCHECK (HW4)
STEP BY STEP INSTRUCTIONS

- Sudomotor sympathetic skin potential (SudoCheck)
- Quantitative Sudomotor Axon Reflex Test (QSART)
- Sympathetic Skin Response (SSR)
- Bioelectrical Impedance Analysis (BIA) and Body Composition Analyze
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DESCRIPTION OF THE DEVICE

The SudoCheck system is a programmable electro medical system including:

- Electronic device box
- Disposable electrodes
- Reusable electrode plates
- Reusable cables
- USB Communication cable
- Software installed on a computer.

Through the 6 tactile electrodes, a weak current with a very low frequency is sending alternatively between 2 electrodes with a sequence and the SudoCheck system is recording the electrical conductivity of 11 pathways of the human body.

In accordance with the 21 CFR 882.1540, the SudoCheck system is a galvanic/sympathetic skin response device that provides skin conductance measurements on the PC screen.

DEVICE SETUP INSTRUCTIONS

WHAT IS IN THE PACKAGE

1) Device Box

2) Reusable USB Communication cable: USB 2.0 Cable Male A/B 6Ft

3) Two Electrode Metal Plates, One plate for the two hands and one plate for the two feet

4) 5 two leads cables

5) PC Laptop with QBioscan/Sodocheck software
DEVICE SETUP

Hand 2 Yellow (L) to small plate left side
Red (R) to small plate right side
Feet 2 Yellow (L) to small plate left side
Red (R) to small plate right side

Forehead – Not used

Hand 1 Yellow (L) to large plate left side
Red (R) to large plate right side
Feet 2 Yellow (L) to large plate left side
Red (R) to large plate right side

Yellow is always for the left panel
Red is always for the panel on the right

Large pad is for the fingers
Small pad is for the palm

Yellow (L) is always the left side
Red (R) is always the right side

Suggest running wire leads from connection snap to QBioscan box going toward the top. This keeps wire leads out of the way of the patient

Yellow is always for the left panel
Red is always for the panel on the right

Foot 2 goes to the small pad
Foot 1 goes to the large pad

For a FREE Demonstration Call:
+1 800 433 4609
sales@medea.com
When you connect the cables to the metal plates, make sure you follow the Left (L-Yellow) and Right (R-Red) on each cable to the plate.

OPTIONAL USE OF BIOIMPEDANCE ELECTRODES

Instead using metal plates for hands and feed the QBioscan device can also be used with disposable Bioimpedance electrodes for SudoCheck and SSR test.

**WARNING: DANGER!!!: DO NOT** use disposable bioimpedance electrode with combination with QSART test. Disposable bioimpedance electrode are only compatible with SudoCheck and SSR test.

When you connect the cables to the Disposable bioimpedance electrode follow the same, make sure you follow the Left (L-Yellow) and Right (R-Red) on each cable to the plate.

Follow the picture above fore electrode on the feet. The same placement is for the electrode on the hands as on the feet.
PC SOFTWARE SETUP

1) At the PC software home screen menu click “SETTINGS” (you may click on the tab or on the setting box).

![Image of PC Software Menu]

2) Under the “HARDWARE” tab make sure “HW4” is chosen as the “Hardware Type” option.

3) Make sure you connect the device cables properly.
   - Connect USB cable at the back on the device box to one of the laptop USB ports.

4) Press “Check Connection” button. A pop-up will appear if the connection to the device is good.

5) Press “Save” button at the top right corner.

You are now ready to hook the patient and start a new measurement.

If you use QBioscan (HW4) device with combination with HW10 device. You can select HW10 as a primary device and as a secondary device you can select HW4. In that way you can use the both devices at the same time.

![Image of PC Software Settings]
SAFETY INFORMATION

BASIC SAFETY RULES

ATTENTION! Handling the device
Please take note of the information included in these instructions for use.
• Keep the instructions for use in a safe place.

DANGER! Danger of explosion
Do not use the device in an environment enriched with one of the following gases:
- Oxygen
- Flammable anesthetics
- Other flammable substances/air mixtures

CAUTION! Patient hazard, damage to device
• Additional devices that are connected to medical electrical devices must be demonstrably in accordance with their corresponding IEC or ISO standards (e.g. IEC 60950 for data processing devices). Furthermore, all configurations must correspond to the normative requirements for medical systems (see IEC 60601-1-1 or section 16 of the 3rd edition of IEC 60601-1, respectively). The person who connects additional devices to medical electrical devices is the system configurator and is therefore responsible for ensuring that the system matches the nonnative requirements for systems. We would like to point out that local laws regarding normative requirements take precedence. Please direct any queries to your local specialist dealer or Technical Service.
• Please have maintenance, recalibration and BIA measuring technology checks performed every two years.
• The device does not contain any parts to be maintained by the user. Please only have maintenance, technical checks and repairs performed by an authorized service partner. You can find service partners in your area at www.medeia-inc.com or by sending an e-mail to service@medeia-inc.com.
• Only use original Medeia accessories and spare parts. Otherwise, Medeia will not grant any warranty.

CAUTION! Patient hazard, malfunction
• Keep other medical devices, e.g. high-frequency surgical devices, at a minimum distance of approx. 1 meter to prevent incorrect measurement or faults with wireless transmission.
• Keep HF devices such as cell phones at a minimum distance of approx. 1 meter to prevent incorrect measurement or faults with wireless transmission.

WARNING! Preventing electric shock
• Never touch the power supply with wet hands.
• Do not use an extension cable and multiple outlets. This also applies for the USB connection on the touchscreen display.
• Make sure that the power cable is not cramped and cannot be damaged by sharp edges.
• Do not operate the device above a height of 3000 m.

WARNING! Patient hazard, Preventing injuries and infections
• Prepare the device hygienically after each measurement.
• Ensure that the patient does not have any contagious diseases.
• Ensure that the patient does not have any wounds on the palms or the soles of their feet.
• Ensure that the positioning of the device is steady and even.
• The device is not designed to be a stand assist. Assist people with limited mobility, e.g. when they are sitting up from a wheelchair.
• Ensure that the weighing platform is dry before the patient steps onto it.
• Ensure that the patient has dry feet before they step onto the weighing platform.
• Ensure that the patient does not step directly onto the edges of the weighing platform.
• Ensure that the patient steps onto the weighing platform slowly and safely.
• Route the network and power cable such that no one can trip over them.

ATTENTION! Preventing device damage
• Make sure that fluids never get inside the device. These can destroy the electronics.
• Switch off the device before you disconnect the power pack from the power supply.
• If device is not be used for a longer period of time, disconnect the power pack from the power supply. Only then is the device out of operation.
• Do not let the device fall.
• Do not subject the device to heavy jolts or vibrations.
• Do not place the device in direct sunlight and make sure that it is not placed in direct proximity of a heat source. High temperatures could damage the electronics.
• Avoid rapid temperature fluctuations. If the device is transported where a temperature difference of more than 20°C occurs, the device must be left alone for two hours before it is switched back on. Otherwise, condensate may form; this can damage the electronics.
• Strong cleaning agents can ruin the scale's surfaces. Use only a soft cloth that you can dip in ethyl alcohol, if necessary.

WARNING! Patient hazard, Use of measured results
The QBioscan is not a diagnostic device. The device assists the attending physician with creating a diagnosis.
• For the creation of a precise diagnosis and for the initiation of therapies, in addition to the use of the QBioscan, careful examinations must be conducted by the attending physician and the results of these taken into consideration.
• The responsibility for diagnoses and the therapies derived from them lies with the attending physician.

ATTENTION! Data Loss
• Before you save and re-use values measured with the QBioscan (e.g. in the PC software QBioscan or in a hospital information system), make sure that the measured values are plausible.
• If measured values have been transmitted from the software QBioscan to the PC software QBioscan or to a hospital information system, make sure before re-use that the measured values are plausible and assigned to the correct patient.

WARNING! Handling packaging material, Danger of suffocation
Packaging material made of plastic film (bags) presents a danger of suffocation.
• Store packaging material out of the reach of children.
• If the original packaging material is no longer available, only use plastic bags with safety holes in order to reduce the danger of suffocation.

NOTE:
Store the original packaging material for future use (e.g. returning for maintenance).

CONTRAINDICATIONS

Impedance measurements cannot be carried out on patients with:
• Electronic Implants, e.g. cardiac pacemaker
• Active prostheses

Impedance measurements cannot be carried out on patients who are connected either to:
• Life-support electronic systems, e.g. artificial heart, artificial lungs, or
• Portable electronic medical devices, e.g. ECG
The electrodes’ conductivity values will vary and results will not be accurate, if
The patient shows signs of excessive perspiration
Dermatological lesions come in contact with the electrodes

Warning: The QBioscan should not be used together with, or in the presence of any implanted electronic devices, for example defibrillators or cardiac pacemakers. The same applies for patients connected to electronic life support devices, as the current and voltage that is applied to the patient could cause injury.

Results won’t be accurate or conductivity values will vary in patients who cannot be held seated.
The calibration of the device was designed for performance on patients in sitting positions. Other positions will result in inaccurate and false measures.

Conductivity values will be inaccurate and results will be changed in patients with
• A prostheses or metal pins on the level of the joints or extremities
• A absence of one or more limbs

As the effects on the fetus are unknown, and the accuracy of readings are not confirmed yet, this device should not be used on pregnant women.

The device should not be used under the following conditions and in the environments listed below:

On a floor with synthetic material - Synthetic material will boost the Electrostatic discharge and as a result, the equipment might short. A message will appear on the display and the measurement process will stop (see troubleshooting).

Once the device is in an environment with a relative humidity lower than 30%, the electrostatic discharge is increased and the equipment might short. A message will appear on the display and the measurement process will stop (see troubleshooting).

In the presence of an MRI or MR or CT scan, the electromagnetic environment might short the device. A message will appear on the display and the measurement process will stop (see troubleshooting).

**GENERAL CONTRA INDICATIONS**

- The QBioscan cannot be used in the presence or in association with cardiac pacemakers or defibrillators, or any other implanted electronic devices
- Measures cannot be performed on patients connected to electronic life support devices
- Prostheses or metal pins on joints or extremities
- Dermatological lesions in contact with the electrodes
- Patients who are unable to be held upright or seated
- An absence of one or more limbs.
- Excessive perspiration (hyperhidrosis)
- This device cannot be used on pregnant women, as the effects on the fetus is unknown and the accuracy of the readings are unclear.
- The environment in which the system performs: The floor (synthetic material) and a relative humidity of less than 30% can prevent precise measurements. Due to its low voltage generation, the QBioscan system is sensitive to geopathic electromagnetic discharges.
HYGIENIC PREPARATION

WARNING! Electric shock
The device has not been put out of operation if the on/standby button is pressed and the touchscreen display goes out. The use of fluids on the device can lead to electric shock.
- Before each hygienic treatment, remove the mains cable to ensure that the device is out of operation.

CLEANING
Clean the surfaces of the device with a soft cloth as required, dipped in ethyl alcohol if necessary.

DISINFECTION
The device must be disinfected at regular intervals using commercially-available disinfectants. Observe the instructions for use of the disinfectant.
Observe the following intervals:
- Before each measurement:
  - Weighing platform and foot electrodes
  - Standing aid and pair of hand electrodes
- After each use:
  - Weighing platform and foot electrodes
  - Standing aid and pair of hand electrodes

MAINTENANCE

On leaving the factory, your Medeia device has an accuracy of ± 0.15 % or better. To preserve this level of accuracy, the product must be set up with care and maintained on a regular basis.
The device’s measurement technology for bioelectric impedance analysis (BIA) must be checked every two years. We recommend performing maintenance of the whole device as part of this check.

ATTENTION!
Incorrect measurements may be taken as the result of improper maintenance
- Please only have maintenance and repairs performed by an authorized service partner.
- You can find service partners in your area at www.medeia.com or by sending an e-mail to service@medeia.com.

RECALIBRATION

We recommend having your device maintained prior to recalibration.
The device’s measurement technology for bioelectric impedance analysis (BIA) must be checked every two years.

ATTENTION!
Incorrect measurements may be taken as the result of improper maintenance
- Please only have maintenance and repairs performed by an authorized service partner.
- You can find service partners in your area at www.medeia-inc.com or by sending an e-mail to service@medeia-inc.com.
Recalibration is necessary where one or more calibration seals are damaged or the contents of the calibration counter no longer match the number on the valid calibration counter sticker.
SUDOMOTOR ASSESSMENT

TEST DESCRIPTION

There are 3 type of test for sudomotor assessment:

**Sudomotor sympathetic response (SudoCheck):**
It is Sudomotor Sympathetic Skin Response (SSR) test with bioelectrical stimulation.
The total test time is: 3 minutes (45 sec per each hand and each foot)

**Sympathetic Skin Response (SSR) - Breathing Stimulation**
It is basic Sympathetic Skin Response test with 10sec Deep Breathing Stimulation.
The total test time is: 4 minutes (60 sec per each hand and each foot)

**Sudomotor Axon Reflex Test (QSART)**
The total test time is: 12 minutes (3 minutes per each hand and each foot)

There is also a combine test between SudoCheck and QSART
The total test time is: 9 minutes
3 minutes (45 sec per each hand and each foot) for SudoCheck
6 minutes (3 minutes for one hand and one foot)

PREPARATION BEFORE A TEST SESSION

While waiting for this procedure to begin patients should be asked to relax.
The person undergoing the procedure should be seated in a comfortable chair, preferably with arm rests but
without wheels or rollers, throughout the entire procedure;
The procedure candidate may be asked to empty his/her bladder prior to testing;

Before the electrodes are attached, the skin of the examined person must be sanitized using standard alcohol
wipes.
A poor signal quality may result if the electro-conductivity between the electrodes and the skin is not secure. In
such cases, the electrodes should be replaced with new ones (use only standardized and recommended electrodes
to guarantee signal integrity).

**WARNING:** Changing the patient’s position (e.g. supine, sitting, stretching, talking, sudden movements, etc.) during
the test unless indicated by test protocol may affect the accuracy of the QHRV measurements.

**WARNING:** For best recording results, electrical noise should be minimized by placing the patient away from
electrical equipment or other sources of electromagnetic interference.

The recording must be performed in a comfortable, relaxed sitting position with limiting body movements.
If patient feels tired after coming to the examination room, allow him/her to have a 10- to 15-minute rest before
beginning the testing.

It is important to eliminate any factors that can cause emotional stress. There is no need to provide specific
training to patients on how to be tested. However, it is important to brief the patient on what is entailed in the
test and how the test will unfold. This will help to lower any anxiety felt by the patient and his/her alertness levels,
and establish a good rapport with the test administrator.
QSART TEST WARNING:

During the QSART test, the HW4 will produce a small electrical stimulation with 1mA of current for 30 seconds to stimulate sweat output. Patients with high conductivity might find this to be very uncomfortable. If that is the case, stop the test immediately. Do not try to complete the test.

Always tell the patient before the test starts that the test will produce an electrical current that is safe, but that some people find it too uncomfortable and that they should tell you if that is the case and you will stop the test.

Place only hands and feet on the plates. Do not conduct the test using other body parts.

Make sure the lead wires are correctly connected to the plates before starting the test.

This test is not to be done on patients with any electronic implants. Examples include pacemakers, defibrillators, cochlear implants, spinal stimulators, and insulin pumps. This test is not to be done on patients with a prosthesis. This test is not to be done if the patient has had surgery and they have put in surgical plates or pins.

This test should not be done if a woman is pregnant. This test is not suitable for infants.
START A NEW MEASUREMENT

Select “New Measurement” from the menu or from the big Icon.

Select “Sudomotor Assessment”. Press “OK” Button to continue.

Select the desired assessment type. Press “Continue” Button.
Fill the patient questioner if applicable and press “Continue” Button.

Select Existing patient from the list or create a new one.

Fill the patient Profile. First Name, Last Name, Gender, Birthdate, Weight and Height are mandatory fields.
Make sure the signal is good for all 4 pathways: RW-RH (Right hand), RW-RF (Right foot), RW-LF (left foot), RW-LH (left hand).

Press Start Button when all 4 pathways have good signal quality.

During the test procedure, the person being tested should avoid any speaking or physical body movements that are not related to the procedure; Otherwise the test results can be compromised.

Follow the test instruction on the screen.
PRINT PATIENT REPORT

The QBioscan software provides the download of examination results from the QBioscan and explanatory patient data; it permits for added clinician interpretation and comments and saves and prints patient examination reports.

WARNING: Only trained personnel, familiar with the manufacturer supplied labeling and the manual, shall operate the QBioscan and QBioscan software.

WARNING: The QBioscan software does not provide an examination results analysis. Before further procedures are carried out, patient results should be considering with patient history.

CAUTION: Run regular virus checking software and system diagnostics to ensure proper operation of the user supplied external hardware.

CAUTION: As with all electronic devices, back up the system frequently to ensure integrity of data on the user supplied external hardware.

Follow the instructions on the screen.