



SUDOSCAN

User guide

Version 3

POM.01_EN

Rev.2



Powered by SUDOtest

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1 Introduction

1.1 Use

The device is a digital chrono-amperometric analyser used for early identification and follow-up of peripheral autonomic neuropathies.

1.2 Principle

The device measures the capacity of the sweat glands to release chloride ions in response to an electric stimulus. It is a dynamic test for the sweat glands equivalent to cardiac stress test for the heart.

NOTE

All options are not available in every region, please check with your distributor to see which product is available in your region.

The device consists of the following:

- A feet smart dock and smart electrodes
- A hands smart dock and smart electrodes
- A SudoScan software application installed in a Host PC



NO MODIFICATION OF THIS DEVICE IS ALLOWED.

1.3 Installation

To ensure correct installation, carefully follow the instructions in the installation guides for this device and the Host PC. Complete installation should take no more than 15-20 minutes.

Impeto Medical is able to provide a printed version of this user guide within 7 business days following the receipt of the request.

1.4 Power up the system

Refer to the Install Guide.



REMOVING THE POWER CORD FROM THE HOST PC OR FROM THE OUTLET BEFORE COMPLETE SHUTDOWN MAY IRREMEDIABLY CORRUPT DATA ON THE STORAGE DEVICE.

1.5 Quality check

The Quality Check allows the operator to test the internal electronic circuitry of the device. We recommend to perform a QC once a month.

If an error occurs during normal use of the device, try to launch a Quality Check. If the test fails and you still encounter issues, please contact your distributor or **Impeto Medical** (cf. p26).



The quality check must be performed without the patient (nobody in contact with the electrodes).

2 Start a scan

When starting a scan, the first step is to determine if the patient is already in the database of the system, or if it is their first examination.

NOTE

For any additional help, please press the Help button  (bottom right corner).

2.1 Log in

- 1 To start a scan, you need to be connected to your account. When you are connected, an indication of the account used is displayed at the bottom of the screen.
If you are not connected, click on the Log In button, select your account and enter your password.



AFTER THE PERIOD OF INACTIVITY, THE SYSTEM LOCKS ITSELF AND THE PHYSICIAN IS LOGGED OUT OF THE SYSTEM.

2.2 Start a scan

2.2.1 Start a scan for a new patient

1 Once you are connected on the system, click on New Patient on the Home screen.

2 Set patient's demographic information.

NOTE

- It is also possible to use any standard PC-compatible keyboard when connected to one of the USB ports available on the Host PC.
- Verify the data with your patient. Invalid (out of acceptable ranges) or missing data will be highlighted with a RED background, and patient data should be re-entered.



IF THE PATIENT OR A HOMONYMOUS ALREADY EXISTS IN THE SYSTEM, THE USER WILL BE INFORMED BEFORE STARTING THE SCAN.

PLEASE ENSURE THAT DEMOGRAPHIC DATA ARE DISPLAYED WITH THE RIGHT UNITS FOR YOUR REGION (WEIGHTS IN KG OR POUNDS, HEIGHTS IN CM OR FEET/INCHES).

2.2.2 Start a scan for a patient that already exists in the system

1 Once you are connected on the system, click on Patient History on the Home screen.

2 Using filters, select the patient from the patient list.

3 Click on the New Scan button.

4 The patient's demographic information shall already be set. Verify with the patient that they are correct and modify them if needed.

2.3 During the scan

- 1 Click on the Scan button.



ENSURE THAT THE PATIENT IS CORRECTLY POSITIONED ONTO THE SMART ELECTRODES BEFORE STARTING A SCAN, WITH THEIR BARE FEET ON THE FEET SMART ELECTRODES AND APPLYING THE PALMS OF THEIR HANDS TO THE HANDS SMART ELECTRODES.

- 2 During the acquisition, the scan can be stopped at any time by selecting the Stop scan button.

The application displays a video and a progress bar during the scan. The scan progression is also described by the LEDs that are lit progressively, from bottom to top, on each smart dock (hands and feet).

NOTE

A calibration is performed at the beginning of each scan.

The patient is requested to remain still during the scan.

If hands or feet contact with the smart electrodes is lost during the calibration, then an error message will appear on the screen.



THE PATIENT MUST NOT TOUCH THE HOST PC.

DO NOT TOUCH THE PATIENT DURING THE SCAN.

THE USE OF USB PORTS DURING A SCAN CAN FREEZE THE PROGRAM APPLICATION. PLEASE DO NOT PLUG OR UNPLUG THE USB DEVICE ON THE HOST PC DURING A SCAN.

- 3 Once the acquisition is complete the results are displayed and the reports can be printed
-

NOTE

Export data on a USB key:

Insert a virus-free USB key containing enough free space (100 scans ~ 25MB) in a free USB port of the Host PC.

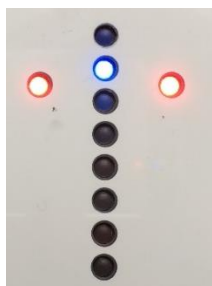


THE DEVICE IS NOT A STORAGE MANAGEMENT SYSTEM AND DATA ON THE HOST PC SHALL BE BACKED UP ON A REGULAR AND FREQUENT BASIS.

2.4 What if the scan cannot be started?

NOTE

Red LEDs on the top of the smart docks indicates that the scan cannot be launched.



If you filled in all the information about the patient but the scan still cannot be started:

- | | |
|---|--|
| 1 | Please check that the smart electrodes are correctly inserted within their smart docks (ref. to p11 to see how to insert a smart electrodes within a dock). Also, check that the smart electrodes were not swapped between the hands and feet smart docks. |
| 2 | Please check that the feet smart dock cable connector is well inserted into the corresponding socket at the rear of the hands smart dock and the USB cable is well connected between the sockets of the hands smart dock and the USB port of the Host PC. Tighten locking support connectors. Then, reboot the system. |
| 3 | Please check the Bluetooth connection is activated on the Host PC. |
| 4 | Check if the following message appears on the top header of the program screen. |



This means that the connection between the application and the hardware has been lost. Please check the USB connection between the hands smart dock and the Host PC. Then, reboot the system.

- | | |
|---|---|
| 5 | If the issue persists, please contact Impeto Medical Technical Support (ref. pErreur ! Signet non défini.). |
|---|---|

2.5 Results interpretation

The device immediately populates results after a scan. The measured conductances are displayed on the screen. Test results provide a measurement of Galvanic Skin Response for each extremity, and a measure of sudomotor function. Results are expressed as skin conductances measured in micro-Siemens (μS). The system has to be used by healthcare professionals for a correct interpretation of the results and correct follow-up of the recommendations given according to the results of the test.

2.5.1 Asymmetry

Asymmetry for hands and feet is computed using the following formula:

$$\text{Asymmetry} = \frac{(\text{Left Electrode Conductance} - \text{Right Electrode Conductance})}{\max(\text{Left Electrode Conductance}, \text{Right Electrode Conductance})}$$

2.5.2 Quality of Measurement

If the patient moves slightly during the scan, a message appears to inform the user: “Movement Detected”.

Then the user is given the opportunity to accept the results or re-scan the patient. Selecting **Accept** will allow the current results to be saved within the patient’s follow-up. The report will be generated with a note stating that the patient moved during scan and that results may be compromised.

Selecting **Re-Scan** will return the user to the scan page to start a new scan.

If the patient is either electrically grounded (i.e. touched during the scan) or an internal issue may have occurred during the scan, a message appears to inform the user that the results are compromised and cannot be used

Selecting the **Re-Scan** button will prompt the current scan to be cancelled. The user will be returned to the scan page to start a new scan. If the issue persists, please contact **Impeto Medical** Technical Support (*ref. pErreur ! Signet non défini.*).

NOTE

- When performing a Re-Scan, the number of remaining scans will not be decreased unless the user accepts the scan results with the observed error or the scan is performed anew.
- Smart electrodes must be cleaned before re-scanning the patient with manufacturer-approved cleaning solution.

3 Actions to perform

3.1 After each scan: Disinfecting the smart electrodes (all smart electrodes)



IMMEDIATELY AFTER EACH SCAN, IT IS IMPORTANT TO CLEAN ALL SMART ELECTRODES WITH THE MANUFACTURER-APPROVED CLEANING SOLUTION.

This will not only disinfect but also neutralise the electrochemical reactions that have taken place on the smart electrodes during the scan. Additionally, this stops the corrosion process, which would otherwise quickly damage the smart electrodes' surface.



1 Deposit only a small quantity of cleaning product on each electrode.

2 Wipe the electrodes until dry with Soft Tissue Wipes



STRICTLY ADHERE TO THE CLEANING SOLUTION'S INSTRUCTIONS FOR USE AND PRECAUTION.
Please refer to the website www.impeto-medical.com/en/cleaning-products.

3.2 On system request: Testing the hardware

The Quality Check test verifies that the device is functioning optimally. The Quality check should be done on a regular and frequent basis and on system request.

Note: If an error occurs during normal use of the device, perform a Quality Check test. If the test indicates that the device passed and you are still encountering issues, please contact your distributor or **Impeto Medical** Technical support (*ref. pErreur ! Signet non défini.*).

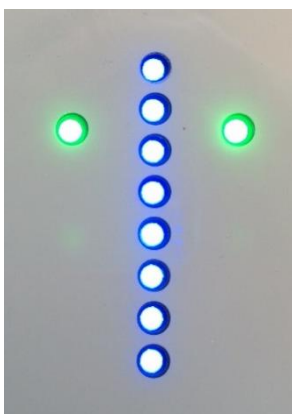


It is important that no one stands on the smart electrodes while performing a Quality Check.

4 Replace the smart electrodes

All options are not available in every region, please check with your distributor which product is available in your region.

Before launching a scan, the number of available scans appears on the top right corner of the screen. The scan number (#) will increase by one and the number of remaining scans will decrease by one upon successful completion of a scan.



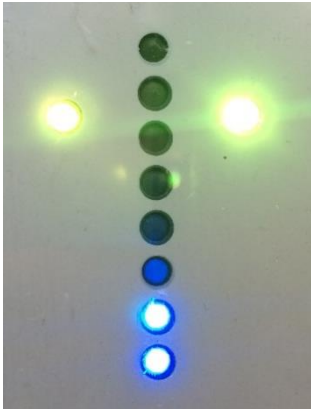
Remaining scans – ok

4.1 Thresholds

Thresholds 1:

The first warning appears when the first threshold is reached. The number of remaining scans turns orange.

 v3 2015-24-2 13h47 - 85330[F]	Scan#: 69 [Remaining scans: ] SUDOSCAN
--	---

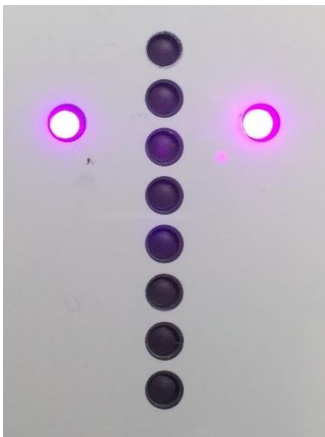


Remaining scans first warning

Threshold 2:

The second warning appears when there are very few scans left. The number of remaining scans turns red.

 v3 2015-24-2 13h50 - 85330[F]	Scan#: 69 [Remaining scans: ] SUDOSCAN
--	---



Remaining scans last warning

4.2 How to replace Smart Electrodes

Please plan in advance when placing your replacement smart electrodes set orders.

Upon receiving a new order, a set of smart electrodes will be shipped to replace existing used smart electrodes once all scans have been used.

When there are no scans left, the system prevents the user from starting a scan “[No scan left]” and the scan button shows “Change Plates” and turns red instead of showing “Scan” and being green:

Change plates

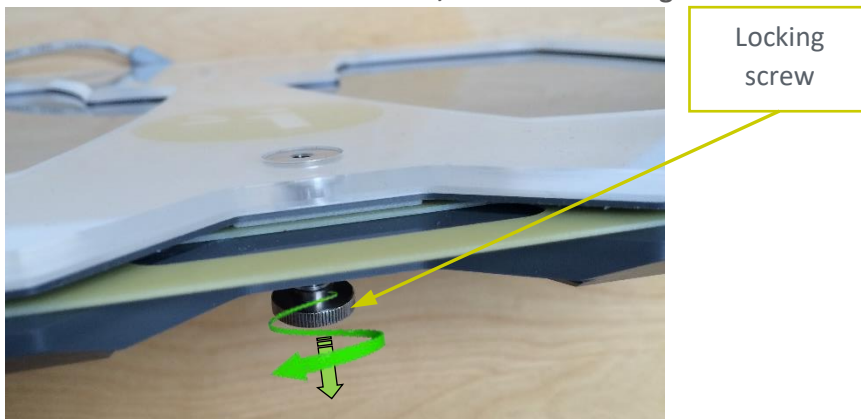
NOTE

Be sure to change hands smart electrodes and feet smart electrodes at the same time.

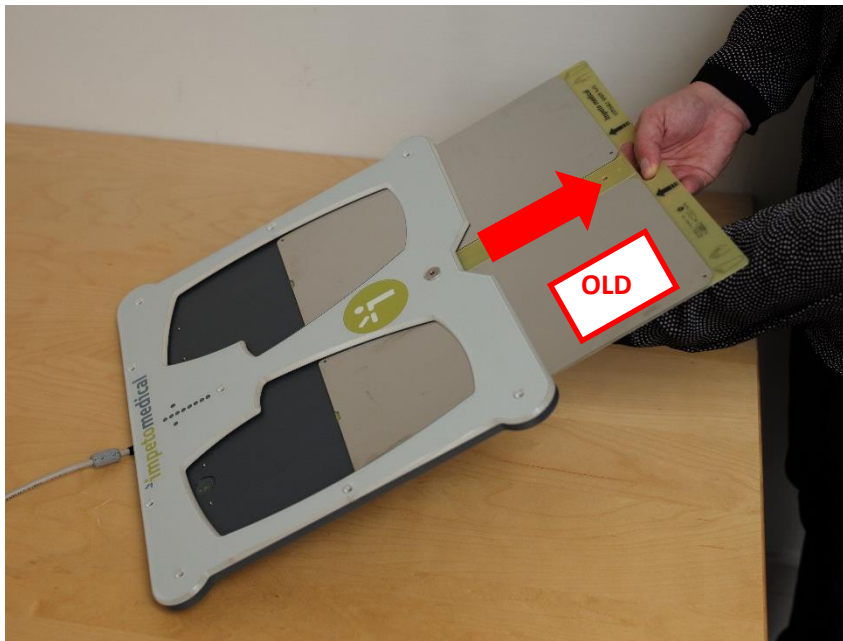
Do not disconnect the feet smart dock cable or USB cable to replace electrodes.

Once you have received a new set of smart electrodes, follow the instructions to replace them:

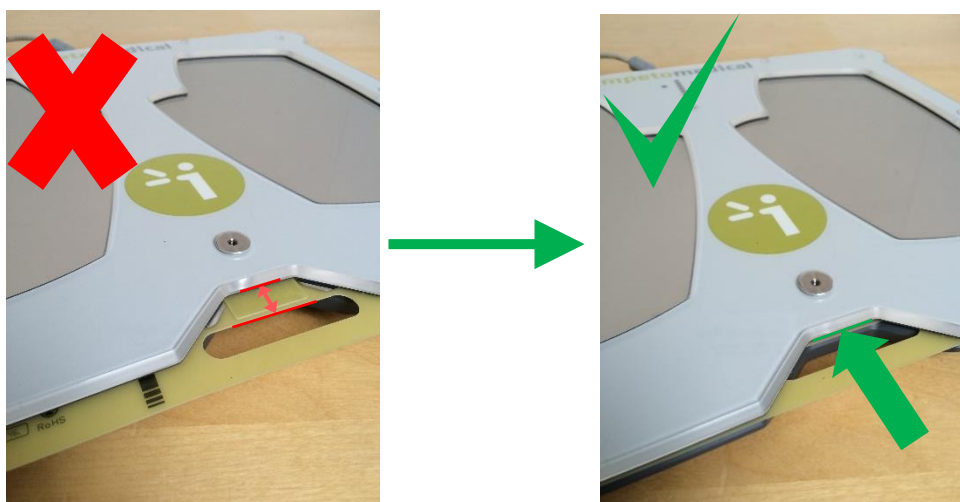
- 1 On the underside of the smart dock, loosen the locking screw and hold it down.**



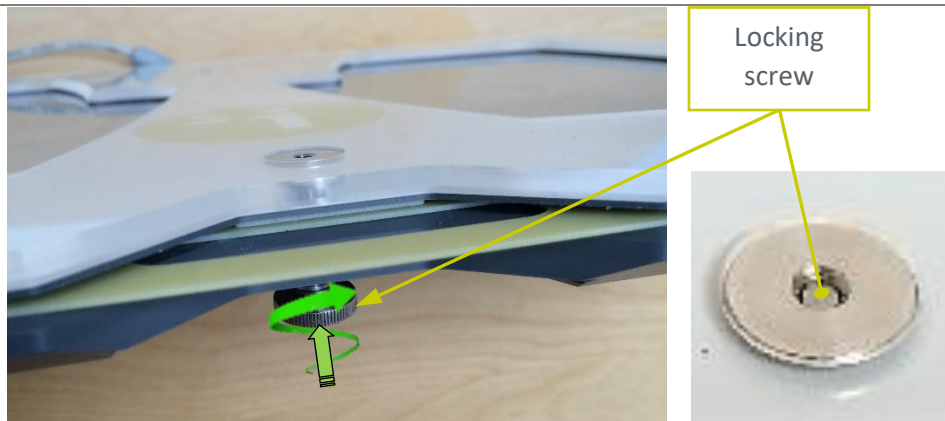
-
- 2 Then remove the smart electrodes to be replaced by pulling it out gently.



-
- 3 Insert the new smart electrodes into the smart dock by gently sliding it in until the smart electrodes are firmly aligned within the dock base.



-
- 4 Tighten the locking screw.
-



After the change of smart electrodes, return to the main program screen and then click the New Patient button. The number of remaining of scans will be updated and displayed on the top right header of the program.



IF SMART DOCKS HAVE BEEN DISCONNECTED FROM THE SYSTEM, PLEASE PLUG THEM IN AGAIN AND RESTART THE SYSTEM. SMART ELECTRODES REPLACEMENT DOES NOT REQUIRE THE SMART DOCKS TO BE DISCONNECTED FROM THE SYSTEM. RESTARTING THE SYSTEM AFTER INSTALLATION OF THE NEW SMART ELECTRODES IS NOT REQUIRED.

**WHEN PLUGGING THE SMART ELECTRODES INTO OR OUT OF THE SYSTEM, ENSURE THAT THE FEET SMART DOCK CABLE CONNECTOR IS WELL INSERTED INTO THE CORRESPONDING SOCKET AT THE REAR OF THE HANDS SMART DOCK AND THE USB CABLE IS WELL CONNECTED BETWEEN THE SOCKETS OF THE HANDS SMART DOCK AND THE USB PORT OF THE HOST PC.
PLEASE MOUNT AND TIGHTEN LOCKING SUPPORT CONNECTORS.**

NOTE

After changing the smart electrodes, The first scan pairs the smart electrodes with the smart dock in which it has been inserted. It is then no longer possible to use the smart electrodes with another smart dock. Smart electrodes must be replaced after all the scans have been used.

When you replace your smart electrodes, you can safely dispose of your old smart electrodes or recycle them in accordance with your local regulations and/or recycling process.

5 Precautions for use and technical specifications

Principle of the device

Low voltage is applied to smart electrodes in contact with the hands and feet, areas with the highest sweat gland density. The electric current stimulates the sweat glands, which, in response, release chloride ions (Cl⁻).

At low voltage, the stratum corneum acts as a capacitor and only the sweat ducts allow the transmission of ions from the skin to the smart electrodes. This ensures that the measurements taken correspond solely to the sweat gland function.

There is an observable electrochemical reaction between the Cl⁻ ions and the anode.

The device records the electrochemical conductance related to the concentration of the chloride ions released from the sweat glands and detected by the smart electrodes (on the hands and feet).

The device is composed of software running on a Windows Host PC* connected to two smart electrodes.

*: complies as a minimum with the Low Voltage Directive 2014/35/UE, IEC/UL 60950-1 Standard, Electromagnetic Compatibility Directive 2014/30/UE, CISPR 32 Class A, CISPR 35 standards

General operation of the device

The patient positions their bare feet on the feet smart electrodes, applies the palms of their hands to the hands smart electrodes.

After entering the patient demographic information (last name, first name, age, gender, height, weight), the operator will initiate the software and activate the electronic circuitry of the device, which will then apply DC voltage to the smart electrodes and will measure the current passing through the smart electrodes.

Several successive cycles of measurements are carried out in an automatic way and all the measured values are recorded on the storage device. Data processing is then performed to compute the conductance on each smart electrode.

At the end of the measurement cycle, which lasts approximately 3 minutes, the user can see the displayed patient report on the screen and also has the option of printing out a hard copy of the report. No control is accessible to the patient. The device has to be used by healthcare professionals for a correct interpretation of the results and correct follow-up of the recommendations given according to the results of the test.

Precautions of use and maintenance

Transport

If it is necessary to pack, transport or deliver the device after its use, it is recommended to arrange all its elements in their housing and original position.

Pay particular attention to carefully arranging the feet smart docks cable in the locations especially designed for them in the protection foams, and not to damage or weaken them.

The box can be stored upright or laid down.

The device embeds a very low power lithium accumulator whose lifespan is strictly greater than 5 years.

The users cannot access these accumulators and only Impeto personnel can replace them.



Recycling

At the end of its lifetime, the device can be returned to **Impeto Medical**'s authorised distributor, which will return it to **Impeto Medical** in order to ensure the recycling of certain components.

The device's components and the accessories are free of mercury and of components containing this element.

Protection against electrical shocks



CONNECT THE DEVICE ONLY TO A SAFE HOST PC, COMPLYING AS A MINIMUM WITH IEC/UL -60950-1 STANDARD (Information Technology Equipment - Safety - Part 1: General Requirements), CLASS I OR CLASS II.

TO USE AT AN ALTITUDE HIGHER THAN 2,000 M, AND UP TO 3,000 M, USE EXCLUSIVELY A SAFE HOST PC CERTIFIED TO OPERATE UP TO 3,000 M.

THE PATIENT MUST NOT TOUCH THE HOST PC OR OTHER EQUIPMENT.

Protection against moisture



DO NOT USE THE DEVICE IN A WET OR DAMP ENVIRONMENT.

Electromagnetic compatibility (see Table 1 and Table 2)



The device is not protected from the effects of the discharges of an external defibrillator, nor against high frequency currents or strong electromagnetic disturbances outside IEC 60601-1-2 Edition 4 requirements. Use near mobile telephones or wireless fixed telephones can cause signal disturbances.

The use of portable and mobile RF communication devices (for example: mobile telephones) can influence the analysis carried out during the recording, as the recorded signals can be disturbed by electromagnetic interferences.

The device should not be used in the presence of ionising radiations (x-rays, gamma rays, etc.) because those could erase the internal storage.

For the tables concerning the electromagnetic emissions and the immunity of the recorder, see the appendices of this user guide.

Maintenance of the device

No particular maintenance is necessary.

The external case and the cables of the smart docks can be cleaned using a slightly wet tissue or with a very small amount of soapy water. Do NOT use any detergent product, alcohol or acetone.

To avoid corrosion and ensure the best conditions of hygiene, the hands and feet smart electrodes must be cleaned immediately after each patient with an Impeto Medical-approved cleaning solution.



ONLY PERSONEL AUTHORISED BY IMPETO MEDICAL ARE ALLOWED TO PERFORM ANY REPAIRS OR MAINTENANCE ON THE DEVICE (MAINTENANCE, CALIBRATION, ETC.).

All the technical documents (component part lists, descriptions, calibration instructions) are kept by **Impeto Medical**.

The warranty is null and void if the device was opened and repaired by any unauthorised person. The warranty only applies to manufacturing defects and certainly not for any mechanical damage due to mishandling or misuse. Refer to the manual for proper use of the equipment.

Use and storage conditions



Do not cover or block the vents of the Host PC in operation

- Maintain a minimum distance of 20 cm (8 inches) around the Host PC and the electrode docks
- Do not use the device in a dusty environment
- Do not use the device in an oxygen-rich environment, with vapours or flammable gas, near or with flammable products (flammable anaesthetics...)
- Keep the device away from any flammable source
- The device is not intended to be sterilised
- Do not use the device outside
- Use the device in a dry environment
- Please ensure a stable and secured positioning of the hand dock to avoid injury or system deterioration in case of fall

Description of the pictograms affixed to the device and to the box

The following pictograms are affixed to the device:



Indicates that the parts supplied with the device are of type BF (IEC 60601-1)



Indoor use only



The SUDOtest device is in conformity with European Directive 93/42/EEC



Warning



Registered Trademark



Indicates the manufacturer catalogue reference



Indicates the manufacturer lot code



Indicates the serial number



Tells the user the need to consult the instructions for use



The product must be disposed of in an appropriate structure for recovery and recycling



RF Non-ionised radiation

RoHS

Restriction of Hazardous Substances (Directive 2011/65/UE + 2015/863/UE)

The following pictograms are affixed to the box:



Handle with care



Fragile



Keep dry



Keep upright



Recyclable



Indicates the temperature limit that the medical device can be safely exposed to



Indicates the range of moisture that the medical device can be safely exposed to



Indicates the range of atmospheric pressure that the medical device can be safely exposed to

Use of the smart electrodes

To ensure high quality recordings, particular care must be taken with the preparation of the patient's skin and with the installation of the smart electrodes.

It is also advisable to verify the feet smart dock cable connector is well inserted into the corresponding socket at the rear of the hands smart dock and the USB cable between the sockets of the hands smart dock and the USB port of the Host PC. Tighten the locking support connectors.

Clean the patient's skin to ensure a good contact between the skin and the smart electrodes.



USE ONLY THE ORIGINAL SMART ELECTRODES PROVIDED BY IMPETO MEDICAL.

USE ONLY THE ORIGINAL USB CABLE PROVIDED BY IMPETO MEDICAL.

CONNECT THE USB CABLE DIRECTLY TO THE HOST PC, DO NOT USE A USB HUB.

BEFORE POWERING UP THE HOST PC: CONNECT THE USB CABLE, FEET DOCK CABLE, MOUNT AND TIGHTEN LOCKING SUPPORT CONNECTORS.

Impeto Medical cannot guarantee the results of measurements carried out with smart electrodes issued from other manufacturers.

Impeto Medical cannot guarantee correct operation with a USB cable issued from other manufacturers or if a USB cable is connected to a USB HUB.

Impeto Medical cannot guarantee the correct operation of the **CLASS I** Host PC **without the power supply connected to protective earth.**

When it is not in use, the device can be stored without disconnecting the smart docks cables.



THE MAXIMUM WEIGHT ACCEPTED BY THE SMART DOCKS IS 199KG (438LBS).

Positioning on the smart electrodes

The patients must position the sole of their bare feet in the centre of the feet smart electrodes and firmly apply their hands flat in the centre of the hands smart electrodes.

Except in the event of a significantly overweight patient, all scans will be performed with the patient standing upright on the feet smart electrodes.

Interrupting or stopping the recording

The test will automatically stop at the end of the measurements cycle, after approximately 3 minutes.

To stop the test **BEFORE** the end of the measurements cycle, select the Cancel button during the scan.

Recommendations to the operator

As for any medical examination, it is recommended to check the environmental conditions and the condition of the patient before carrying out a measurement:

- Room temperature is between 18 and 35 degrees Celsius (65 and 95 degrees Fahrenheit)
- Cardiac holter measurements in progress can be altered during the 2-minute time scan.

Contra-indications



The repeated use of the device does not create any side effects. However, it is advised not to proceed with measurements on the following patients:

- People with any open or bleeding wounds that would come into contact with the surface of the smart electrodes,
- People with missing limbs,
- Pregnant women or women who are uncertain about a possible pregnancy.

Calibration

The device auto-calibrates at the beginning of each test. The auto-calibration ensures that each smart electrode has enough contacts to proceed with the measurements, therefore it is not necessary to calibrate the device before use.

If the calibration is interrupted, the operator is informed by an audible bell sound and/or an error message.

Accessories and disposable parts

The following items are available:

Description Code

Code	Description
UMSA	Installation guide
ADSPHD	Hand Smart Electrodes Dock Bluetooth® RFID
DSPFD	Foot Smart Electrodes Dock Bluetooth® RFID
ASAFE	Cleaning product
ELOCKSA	Locking support connectors
PH1	Screwdriver
DSP	Smart Electrodes RFID
USBA	USB cable
WBOX	Box of dry wipes box by Kim Wipes (KIMTECH Science brand) for cleaning the electrodes

Technical specifications

• Description

The device is capable of measuring galvanic skin responses and is designed for the medical professional.

The device is a class IIa medical device (according to the EEC directive 93/42) and a class II medical device (according to FDA 21CFR 882.1540).

The device complies with IEC 60601-1 Edition 2 and Edition 3.1 (Medical Electrical Equipment, Part 1: General requirements for safety) and IEC 60601-1-2 Edition 3 and Edition 4 (Electromagnetic compatibility – Requirements and tests / General requirements for basic safety and essential performance).

CB Test Certificate, tested for the national deviations below:

AE – AR – AT – AU – BE – BG – BH – BR – BY – CA – CH – CN – CO – CZ – DE – DK – ES – FI – FR – GB – GR – HU – HR – ID – IE – IL – IN – IT – JP – KE – KR – LY – MY – MX – NL – NO – NZ – PK – PL – PT – RO – RS – RU – SA – SE – SG – SI – SK – TH – TR – UA – US – ZA

The device complies with ANSI/AAMI PC69:2007: Active implantable medical devices —Electromagnetic compatibility— EMC test protocols for implantable cardiac pacemakers. People with implantable cardiac pacemakers may be safely tested with the device, provided the device remains at least 30 cm (12 inches) away from the implanted device, as laboratory tests have demonstrated that the device should not influence the function of implantable cardiac pacemakers due to Electromagnetic Interference at this distance.



STOP USE OF THE DEVICE IF THE PATIENT EXPERIENCES DIZZINESS OR BRADYCARDIA AS THESE COULD BE INDICATIVE OF INTERFERENCE WITH AN IMPLANTABLE CARDIAC PACEMAKER.

• Acquisition characteristics

Mode:	No compression
Frequency of acquisition:	100 Hz
Resolution:	10 nS (nano Siemens)
Display units:	μS (micro Siemens)
Display precision:	+ or – 1 digit
Accuracy:	2%

• Electrical characteristics

Measurement voltage:	1V to 4V DC typical
Frequency:	0 Hz (DC current)
Dynamic resolution:	10 bits

Power and I/O interface requirement: 5V DC – 500mA
 Powered from Host PC by one High Power USB 2.0/3.0 and
 > port, type A, Full Speed
 Insulation: 5KVac/1min (Type BF)
 USB isolated interface on Hands Smart Electrodes Dock

• RF characteristics

Bluetooth® v2.1 + EDR, 2.402 ~ 2.480 GHz, FHSS/GFSK modulation, 79 channels at 1MHz
 intervals (Class 2 radio): ERP ≤ 4dBm

RFID 13.56 MHz: ERP 2dBμA/m @ 3m

• Sealing

Protection index:
 Smart docks IP41

• Mechanical characteristics


Weight of Hand Smart Electrodes Dock + DSP: 4.4 kg (9.7 lbs)
 Hand Smart Electrodes Dock dimensions: 41.1 x 34.2 x 4.7 cm (16.18 x 13.46 x 1.85
 (inches)
 Weight of Foot Smart Electrodes Dock + DSP: 3.5 kg (7.7 lbs)
 Foot Smart Electrodes Dock dimensions: 41.1 x 34.2 x 2.3 cm (16.18 x 13.46 x 0.91
 (inches)
 Weight of the shipping box 10.9 kg (24 lbs)
 Dimensions of the shipping box: 49.5 x 45 x 13 cm (19.49 x 17.72 x 5.12
 inches)

• Storage, transport and conditions of use

	Temperature	Moisture (without condensation)	Pressure
Operation	18° to 35°C (65° to 95°F)	20% to 80%	800 to 1,060 hPa or 700 to 1,060 hPa exclusively with one Host PC certified to operate up to 3,000 m of altitude
Storage	5° to 45°C (41° to 113°F)	10% to 85%	500 to 1,060 hPa

Transport	-5° to 50°C (23° to 122°F)	10% to 90%	500 to 1,060 hPa
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Table 1

IEC 60601-1-2: Edition 4.0 2014-02 General requirements for basic safety and essential performance Electromagnetic disturbances Tests, Guidance and Manufacturer's Declaration		
Basic Safety and Essential Performance The degradation of the performance of the device does not affect basic safety or the essential performance. The device does not present essential performance characteristics according to the risk assessment. If a defect is observed following an electromagnetic transient disturbance, the system recovers nominal functionalities after reboot		
Electromagnetic environment The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure that it is used in such an electromagnetic environment. <ul style="list-style-type: none"> – Home Healthcare environment, <u>except</u> trains, planes, helicopters – Professional Healthcare facility environment, <u>except</u> hospital environment near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high 		
Interference may occur in the vicinity of equipment marked with the following symbol:		
WARNING: <ul style="list-style-type: none"> – Use of the device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the device and the other equipment should be observed to verify that they are operating normally. – Use of accessories and cables other than those specified or provided by IMPETO MEDICAL for the device could result in increased electromagnetic emissions or decreased electromagnetic immunity of the device and result in improper operation. – 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 device, including cables. Otherwise, degradation of the performance of the device could result. 		
Emissions test	Compliance	Guidance
Conducted and radiated RF emissions CISPR 11 Ed 5.1 2010-05	Group 1	the device uses RF energy for its internal function only. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
	Class B	the device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic current emissions IEC 61000-3-2 Ed 3.2 2009-04	Complies	/
Voltage fluctuations and flicker emissions IEC 61000-3-3 Ed 3.0 2013-05	Complies	/

Immunity test	IEC 60601-1-2 test level	Compliance level	Guidance
Electrostatic discharge (ESD) IEC 61000-4-2 Ed 2.0 2008-12	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4 Ed 3.0 2012-04	5/50ns, 0.75 ms/100Khz ±2 kV for power supply lines	5/50ns, 0,75 ms/100Khz ±2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5 Ed 2.0 2005-11	1,2/50 µs U, 8/20 µs I ±1 kV line to line ±2 kV lines to earth	1,2/50 µs U, 8/20 µs I ±1 kV line to line ±2 kV lines to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 Ed 2.0 2004-03 NOTE: Ut is the AC mains voltage prior to application of the test level	0 % Ut for 0.5 cycle (1 phase) 0 % Ut for 1 cycle 70 % Ut for 25/30 cycles (50/60 Hz) 0 % Ut for 250/300 cycles (50/60 Hz)	0 % Ut for 0.5 cycle (1 phase) 0 % Ut for 1 cycle 70 % Ut for 25/30 cycles (50/60 Hz) 0 % Ut for 250/300 cycles (50/60 Hz)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 Ed 2.0 2009-09	30 A/m	30 A/m 50 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Immunity for ME equipment and ME systems that are not life-supporting			
Immunity test	IEC 60601-1-2 test level	Compliance level	Guidance
Conducted RF IEC 61000-4-6 Ed 4.0 2013-10	150 kHz – 80 MHz 3 V ISM Bands 6V AM 80% @ 1 KHz	150 kHz – 10.56 MHz 6 V 16.56 MHz – 80 MHz 6 V NOTE: the device integrates aSUD RFID transmitter 13.56 MHz, the exclusion band 13.56 MHz +/- 3MHz should be applied according to ETSI EN 301 489-3 V1.6.1 for receiver category 2. ISM and Amateur Radio bands exclusion: – 13.553 MHz to 13.567 MHz – 14 MHz to 14.2 MHz	See WARNING Table 1
Radiated RF electromagnetic field IEC 61000-4-3 Ed 3.2 2010-04	80 MHz – 2.7 GHz 10V/m AM 80% @ 1 KHz	80 MHz – 2.7 GHz 10V/m AM 80% @ 1 KHz	See WARNING Table 1
Radiated RF proximity fields from RF Wireless communications equipment IEC 61000-4-3 Ed 3.2 2010-04	Band 380 - 390 MHz 27 V/m, PM 50% @ 18 Hz Band 430 - 470 MHz 28 V/m, (FM ±5 kHz, 1 kHz sinus) or PM @ 18 Hz Band 704 - 787 MHz 9 V/m, PM 50% @ 217 Hz Band 800 - 960 MHz 28 V/m, PM 50% @ 18 Hz Band 1700 - 1990 MHz 28 V/m, PM 50% @ 217 Hz Band 2400 - 2570 MHz 28 V/m, PM 50% @ 217 Hz Band 5100 - 5800 MHz 9 V/m, PM 50% @ 217 Hz	Band 380 - 390 MHz 27 V/m, PM 50% @ 18 Hz Band 430 - 470 MHz 28 V/m, (FM ±5 kHz, 1 kHz sinus) or PM @ 18 Hz Band 704 - 787 MHz 9 V/m, PM 50% @ 217 Hz Band 800 - 960 MHz 28 V/m, PM 50% @ 18 Hz Band 1700 - 1990 MHz 28 V/m, PM 50% @ 217 Hz Band 2400 - 2570 MHz 28 V/m, PM 50% @ 217 Hz Band 5100 - 5800 MHz 9 V/m, PM 50% @ 217 Hz	See WARNING Table 1

Table 2

Electromagnetic compatibility RADIO tests		
Standard	Transmitter	Compliance
ETSI EN 302 291-1 V1.1.1 ETSI EN 302 291-2 V1.1.1 ERC Recommendation 70-03	RFID 13.56 MHz	Complies Transmitter carrier output levels Transmitter spurious emissions
FCC 47 CFR PART 15, SUBPART C, 15.225	RFID 13.56 MHz	Complies Conducted emissions and Spurious emissions (Radiated): FCC Part 15 CLASS B Field strength within and outside of the bands 13,110 -14,010 MHz : FCC part 15 subpart C
ETSI EN 300 328 V1.8.1 ERC Recommendation 70-03. Recommendation N° 1999/519/CE	Bluetooth®	Complies RF output power Transmitter spurious emissions
FCC 47 CFR PART 15, SUBPART C, 15.247	Bluetooth®	Complies Conducted emissions and Spurious emissions (Radiated): FCC Part 15 CLASS B
USA FCC ID	Bluetooth®	T9J-RN42
CANADA	Bluetooth®	IC RSS-210 low power comm. device
Certification Number	Bluetooth®	6514A-RN42

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