SUDOSCAN

User guide

Version 3

POM.06_EN

Rev.2

Powered by SUDOtest

TABLE OF CONTENTS

1 Introduction

1.1 Patents

Submission number	Country/Region
0601239	FR
200680026807.6	CH
11/922.812	USA
06763845.2	EUROPE, DE, FR, UK
14/613.952	USA
0753461	FR
EP2008/052211	PCT (International)
08717066.8	EUROPE, FR
1258037	FR

1.2 Use

The product is a medical device for Galvanic Skin Response assessment to aid in the evaluation of sudomotor function. The device is indicated for use in the general adult population.

1.3 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 pair of foot sensor plates**
- **A pair of hand sensor plates**
- **A software application**

1.4 Installation

Carefully follow instructions in the corresponding manual to ensure correct installation.

Complete installation should take no more than 25-30 minutes.

Caution for the USA: Federal law restricts this device to sell on order of a physician or licensed practitioner.

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

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 exam.

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 DELAY 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.** Notes : - 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 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 ELECTRODES BEFORE STARTING A SCAN, WITH THEIR BARE FEET ON THE FEET SENSOR PLATES AND APPLYING THE PALMS OF THEIR HANDS TO THE HANDS SENSOR PLATES.

2	During the acquisition, the scan can be stopped at all time.

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 USB DEVICE ON THE SYSTEM DURING A SCAN.

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

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

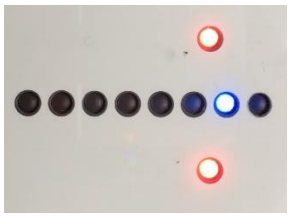
2.4 What if the scan cannot be started?

If you filled in all 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. p12 to see how to insert a smart electrode within a dock).** **Also, check that the smart electrodes were not swapped between the hands and feet smart docks.**
2	**Please check that the docks are correctly plugged in the system and reboot the system.**
3	**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. Try to reboot the system.
4	**If the issue persists, please contact Impeto Medical Technical Support (ref. p28).**

Note:

Red LEDS on the docks indicates that the scan cannot be launched.



If the issue persists after you followed the procedure above, please contact **Impeto Medical** Technical Support (ref. p28).

2.5 Results interpretation

The device immediately populates results after a scan. The measured conductances are displayed on the screen. Test results provide a measure 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 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:

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

2.5.2 Quality of Measure

If the patient moves slightly during the scan, a message appears to inform the user.

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 (ie. 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. p28).*

Notes:

- **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.**

3 Actions to perform

3.1 After each scan: Disinfecting the electrodes (all 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 neutralize the electrochemical reactions which have taken place on the electrodes during the scan. Additionally, this stops the corrosion process which would otherwise quickly damage the 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.

Please refer to the website www.sudoscan.com/for-physicians/cleaning-products/.

3.2 On system request: Testing the hardware

The Quality Check test verifies that the device is functioning optimally. 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. p28)*.

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

4 Replace the electrodes

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

4.1 How to replace Smart Electrodes

Please plan in advance when placing your replacement electrodes orders.
For USA only: It can take 5-7 business days for the order to be processed and delivered. You will need to determine how soon to order replacement electrodes based upon your usage

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

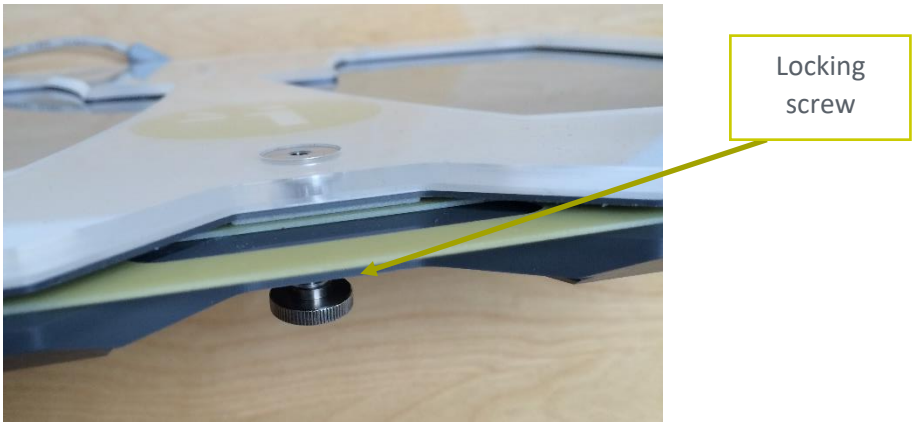
When there are no scans left, the system prevents the user from starting a scan and the Scan button shows “Change Plates” and turns red instead of showing “Scan” and being green:

Note :

- **Be sure to change hand plates and foot plates at the same time.**
- **Do not disconnect electrode docks from the master unit to replace electrodes.**

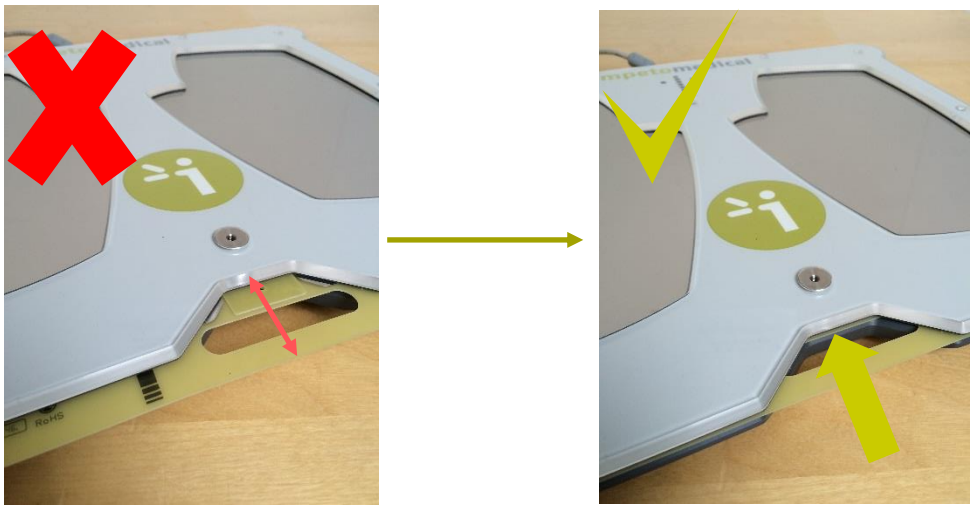
Once you have received a new set of smart electrodes, follow the instructions to replace them:

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

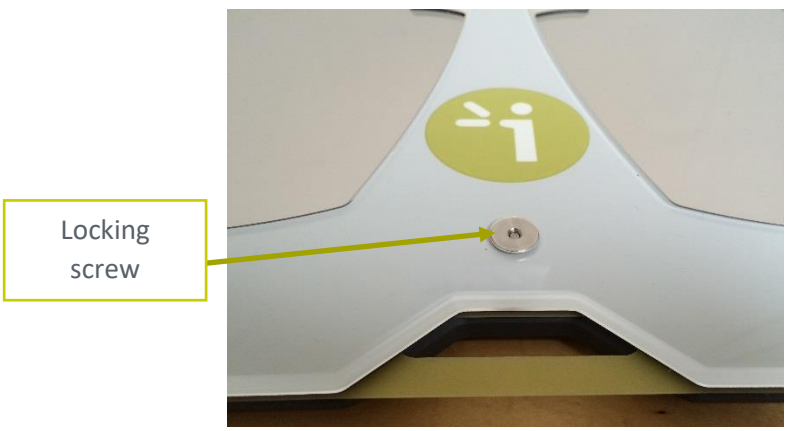


2 **Then remove the electrode to be replaced by pulling it out gently.**

3 **Insert the new electrode into the dock by gently sliding it in until the electrode is firmly aligned within the dock base.**



4 **Tighten the locking screw.**



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

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

WHEN PLUGGING THE ELECTRODES IN OR OUT OF THE SYSTEM, ENSURE THAT THE PLUGS ARE CORRECTLY INSERTED IN THEIR SOCKET AND REMEMBER TO PULL THEM GENTLY.

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

For USA only: However, if you choose, you can contact Impeto Medical *(ref. p28)* to arrange to return your old electrodes to us.

5 Precautions for use and technical specifications

Principle of the device

Low voltage is applied to sensor plates 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 sensor plates. 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 sensor plates (on the hands and feet).

The device is composed of a software connected to 4 sensor plates placed on the feet, the hands.

General operation of the device

The patient positions their bare feet on the feet sensor plates, applies the palms of their hands to the hands sensor plates.

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 sensor plate and will measure the current passing through the sensor plates.

Several successive cycles of measurements are carried out in an automatic way and all the measured values are recorded on the hard disk. Data-processing is then performed to compute the conductance on each sensor plate.

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 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, to transport or deliver the device after its use, it is recommended to arrange all its elements in their housing and position of origin.

Pay particular attention to carefully arrange the sensor plate cables in the locations especially designed for them in the protection foams, not to damage or weaken them.

The box can be stored upright or laid down.
The device does not comprise any accumulator.

Recycling

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

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

Protection against electricals chocks

CONNECT THE DEVICE ONLY TO AN HOST SAFE PC COMPUTER, CONFORM AT MINIMA OF IEC/UL - 60950-1 STANDARD (Information Technology Equipment - Safety - Part 1: General Requirements), CLASS I OR CLASS II
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 out of IEC 60601-1-2 Edition 4 requirements. The use near of mobile telephones or wireless fixed telephones can cause signal disturbances.

The use of portable and mobile RF communication devices (for example: cellular 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 ionizing radiations (x-rays, gamma rays …) 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 and sensor plates

No particular maintenance is necessary.

The external case and the cables of the sensor plates 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 feet and hands sensor plates must be cleaned immediately after each patient with an Impeto Medical approved cleaning solution.

ONLY PERSONEL AUTHORIZED BY IMPETO MEDICAL IS 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 unauthorized person. Warranty will hold only against manufacturing defects and certainly not for any mechanical damage due to mishandlings or misuse. Refer to manual for proper use of the equipment.

Use and storage conditions:

- Do not block the vents
- Do not use the device in a dusty environment
- Do not use the device in an environment rich in oxygen, with vapors or inflammable gases
- Keep the device away from all inflammable sources
- The device is not meant to be sterilized
- Use the device inside
- Keep the device in a dry environment
- Maintain a minimum distance of 20cm (about 8 inches) around the device

Description of the pictograms affixed on the device and on the case

<u>The following pictograms are affixed on the device:</u>

Indicates that the parts applied of the device are of type BF (IEC 60601-1).

I

Class of electric protection.

Indoor use only

CE

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

Warning

Registered Trademark

REF

Indicates the manufacturer catalogue reference

LOT

Indicates the manufacturer lot code

SN

Indicates the serial number

Tells the user the need to consult the instructions for use

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

RF Non-ionized radiation

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

The following pictograms are affixed on the case:

Handle with care

Fragile

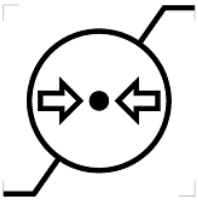
Keep dry

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 sensor plates

Information about the use of the sensor plates are provided as guidance only.

To ensure high quality recordings, particular care must be taken to the preparation of the skin of the patient and to the installation of the sensor plates.

It is also advisable to verify the sensor plate cable connectors are well inserted into the corresponding sockets at the rear of the Master Unit.

Clean the patient's skin to ensure a good contact between the skin and the sensor plates.

USE ONLY THE ORIGINAL SENSOR PLATES PROVIDED BY IMPETO MEDICAL.
USE ONLY THE ORIGINAL USB CABLE PROVIDED BY IMPETO MEDICAL.
CONNECT USB CABLE DIRECTLY AT THE HOST PC, DON'T UTILISE A USB HUB
BEFORE POWERUP THE HOST PC CONNECT USB CABLE, FOOT DOCK CABLE AND MOUNT LOCKING SUPPORT CONNECTORS

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

Impeto Medical cannot guarantee correct working with USB cable issued from other manufacturers or if USB cable is connected at one USB HUB.

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

THE MAXIMUM WEIGHT ACCEPTED BY THE SENSOR PLATES IS 199KG OR 438LBS.

Positioning on the sensor plates

The patient must position the sole of their bare feet in the center of the feet sensor plates and firmly apply their hands flat in the center of the hands sensor plates.

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

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 going on can be altered during the 2 minutes time scan.

Contra-indications

The repeated use of the device does not create any side effect. 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 sensor plate,
- 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 sensor plate 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
UMA	Installation guide
ADSPHD	Hand Smart Electrodes Dock Bluetooth® RFID
DSPFD	Foot Smart Electrodes Dock Bluetooth® RFID
ASAFE	Cleaning product
ELOCKA	Locking support connectors
PH1	Screwdriver
DSP	Smart Electrodes RFID
USBA	USB cable, length 820mm (2.69 ft)
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.

- **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

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 performances of the device does not affect basic safety or the essential performances. The device doesn't 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. – **Home Healthcare environment,** **except**, trains, planes, helicopters – **Professional Healthcare facility environment,** **except** 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: – Use 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 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 a.c. 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 or a battery.
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 apply 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

Contacts

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Legal Manufacturer

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SudoScan, Inc.
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Email: sales_us@impeto-medical.com
http://www.sudoscan.us

Beijing Impeto Medical

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