



SUDOSCAN[®]

POWERED BY WITHINGS

User guide

SUDOSCAN

software SUDOSCAN 2 & EZSCAN 2 (Optional)

version 4

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1. General Information

1.1. Important notice

Before using SUDOSCAN, review the information in this user guide that describes how to use SUDOSCAN, and gives additional regulatory information on this product. Retain this documentation for future reference.

Installation instructions are available within the Install Guide provided with the device.

Please contact Impeto Medical when in need of assistance, setting up, using or maintaining the device or to report unexpected operations or events. Any serious incident occurring in relation to SUDOSCAN should be reported to Impeto Medical and the competent authorities in your country of residence.

All User Guides are available online at : <https://www.sudoscan.com/resources/user-manuals/>

PAPER VERSION OF THE INSTRUCTION FOR USE

The user can, upon request, obtain a **free-of-charge** paper copy of these User Guides. This paper copy will be provided no later than **seven (7) calendar days** following receipt of your request. To ensure that the correct version is provided, please clearly state the specific **SUDOSCAN's software option used** and the **Serial Number (SN)** when submitting your request.

Please submit your request to the Manufacturer using the following contact details: contact@impeto-medical.com

DISCLAIMER

Information in this guide may change without notice.

1.2. Device description

1.2.1. Device Name and Identification

Product name : SUDOSCAN

Product Code : SUDO2

1.2.2. Components

SUDOSCAN hardware components consist of :

- Two Docks (1 Hand, 1 Feet) intended to receive electrodes
- Two Smart Electrodes: One electrode for the hand dock and the other one for the feet dock.
- Non-Medical HOST computer
- Accessories: one USB cable to connect the device to the HOST computer.

SUDOSCAN operates with two possible softwares:

- Sudoscan 2 software
- EZscan 2 software



- **EZSCAN 2 SOFTWARE IS NOT AVAILABLE IN EVERY REGION, PLEASE CHECK WITH YOUR DISTRIBUTOR TO SEE IF IT IS AVAILABLE IN YOUR REGION.**
- **NO MODIFICATION OF THIS DEVICE IS ALLOWED.**

1.2.3. Intended Use and indications

The device is a digital chrono-amperometric analyzer that measures electrochemical skin conductance for two indications depending on the software:

- **Sudoscan 2 software:** Assessment of sudomotor function for the early identification and follow-up of peripheral autonomic neuropathies
- **Ezscan 2 software :** Assessment of sudomotor function for the early detection of peripheral autonomic neuropathies in order to identify people at increased risk of diabetes (pre-diabetes included). This is a method to optimize the screening of prediabetes and diabetes risk

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

1.2.4. Intended patient population

The device is intended for use in patients older than 2 years.

For Sudoscan 2 software:

- Patients with various peripheral neurological conditions, including: hereditary, metabolic, autoimmune, toxic
- Patients with diabetes
- Patients treated by chemotherapies
- Patients with amyloid diseases
- Patients with Fabry diseases
- Patients with Parkinson and Multiple System Atrophy diseases

For Ezscan 2 software (excluded patients with neurological conditions) :

- General population of patients >2 years old for screening of diabetes risk

1.2.5. Intended User profile

SUDOSCAN is intended to be used by Healthcare Professionals in hospitals, Healthcare Professional's offices or Pharmacy.

1.2.6. Principle of operations

Low voltage is applied to smart electrodes in contact with the hands and feet, which are the 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 through 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 and the Electromagnetic Compatibility Directive 2014/30/UE.

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 a cardiac stress test for the heart.

1-The patients place their bare feet on the feet smart electrodes and the palms of their hands on the hands smart electrodes.

2-After filling in the patient demographic information (last name, first name, age, gender, height, weight), the operator can initiate the software scan and activate the electronic circuit of the device.

3-A DC voltage is then applied to the smart electrodes, and the generated current is measured. Several successive cycles of measurements are carried out automatically, and the measured values are recorded. Data processing is then performed to calculate the conductance on each smart electrode.

4-At the end of the scan, 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.

No control is accessible to the patient. The device must be used by healthcare professionals for a correct interpretation of the results and correct follow-up of the recommendations given according to the test results.

1.2.7. Performance characteristics

1.2.7.1. Clinical performance

The clinical performance of SUDOSCAN has been established through extensive clinical studies and literature reviews, demonstrating its effectiveness in assessing sudomotor function as a marker for diabetic peripheral neuropathy (DPN) and risks associated with diabetes.

1. Detection of Diabetic Peripheral Neuropathy (DPN)

SUDOSCAN provides a reliable and objective assessment of small nerve fiber function. Compared to gold-standard diagnostic methods:

- Sensitivity: 87.5%
- Specificity: 76.2%
- Correlation: Strong correlation with reference composite scores in addition to the gold standard tests: quantitative sudomotor axon reflex test (QSART) and skin biopsy

2. Diabetes and Prediabetes Screening

The Electrochemical Skin Conductance (ESC) measured by SUDOSCAN, combined with the diabetes-risk index (Ezscan software), is an accurate tool for early screening of metabolic dysregulation:

- Sensitivity: Ranges from 72% to 97%.
- Specificity: Ranges from 31% to 90.5%.
- Accuracy: Comparable to standard screening methods for diabetes and prediabetes (such as Fasting Plasma Glucose, HbA1c, and OGTT).

3. Reproducibility and Reliability

SUDOSCAN measurements are highly reproducible and operator-independent:

- Reproducibility: Correlation coefficient of 0.85 (hands) and 0.93 (feet).
- Reliability: Variation is lower than or comparable to traditional assessment methods for small and large fiber neuropathy.
- Clinical Utility: The speed, non-invasiveness, and high reproducibility make SUDOSCAN suitable for patient follow-up and as a reliable endpoint in multi-center clinical trials.

1.2.7.2. Clinical benefit

SUDOSCAN provides significant clinical benefits for the management of patients at risk of sudomotor dysfunction.

- **Favorable clinical performance:** The device ensures high sensitivity and specificity for the evaluation of diabetic peripheral neuropathy (DPN) and metabolic disorders associated with diabetes. These performances have been validated through clinical investigations comparing SUDOSCAN results with diagnostic gold standards.
- **Meaningful clinical improvement for patients:** Regardless of condition severity, the device allows for the early identification of small fiber nerve damage, which is potentially reversible in its early stages. This early detection enables clinical actions that can prevent serious complications, such as foot ulcers and amputations. Furthermore, it provides an objective way to monitor disease progression or treatment efficacy through the tracking of nerve fiber degeneration and regeneration.

- **Effectiveness and practicality compared to alternative methods:** SUDOSCAN offers a favorable impact on patient care by providing a quick (approx. 1 minute), non-invasive, and painless screening alternative. Unlike invasive methods such as skin biopsies, it requires no specialized clinical infrastructure, improving both the ease of use and the availability of sudomotor function assessment.

1.2.8. Precautions

1.2.8.1. Contraindications

- People with any open or bleeding wounds at any electrode contact surface location,
- People with missing leg(s) or hand(s),
- Pregnant women or women who are uncertain about a possible pregnancy

1.2.8.2. Undesirable side-effects

In rare cases, dizziness, discomfort or mild tingling may occur when using SUDOSCAN.

1.2.8.3. Residual Risks

SUDOSCAN undergoes regular risk analysis and clinical evaluation as part of our continuous product safety monitoring.

Through this proactive management process, certain residual risks associated with the use of the device have been identified. However, it has been formally concluded that:

- All identified risks have been reduced as far as possible through rigorous design and mitigation measures.
- No individual risk remains at an unacceptable level.
- All residual risks are considered insignificant when compared to the established clinical benefits of the device.

To ensure safe and optimal operation, users should strictly follow the instructions provided in this manual, particularly regarding patient positioning and the interpretation of results in conjunction with other clinical findings.

1.2.8.4. Warnings

- The data provided by this device is intended for informational use only, and is not intended to replace traditional methods of definitive diagnosis or treatment.
- Do not use this device for any purpose other than the intended use.
- For patients with implantable cardiac pacemakers: the device should remain at least 30 cm (12 inches) away from the implanted device.
- Stop use of the device immediately if the patient experiences dizziness or bradycardia as these could be indicative of interference with an implantable cardiac pacemaker.
- Do not use the device in an environment rich in oxygen, with vapors or inflammable gases.
- Keep the device away from all inflammable sources.
- Only personnel authorized by Impeto Medical are allowed to perform any repairs or maintenance on the device (maintenance, calibration, etc...)
- The maximum weight accepted by the sensor plates is 199kg.

1.2.8.5. General Precautions

- Use only the original sensor plates provided by Impeto Medical.
- Before powerup, connect hand and foot dock cable and mount locking support connectors.
- Do not position the device where it is difficult to operate the On/Off switch or disconnect the USB cable.
- Do not interconnect this equipment with other equipment or use accessories, detachable parts, or materials not described in the instructions for use.
- Use of parts and components other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment 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.
- 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.
- Do not move during the measurement.
- Do not use the device or any components if they are damaged.
- Do not try to repair or modify this device yourself.
- Do not perform any service or maintenance (including cleaning) while the device is in use with a patient.
- Do not use a wireless mouse or keyboard.
- Do not subject the unit to violent shocks or vibrations, do not shake or drop it.
- Clean all smart electrodes with the manufacturer approved cleaning solution.
- The device is not meant to be sterilized.
- Do not submerge the device in water or liquids.
- Use the device indoors.
- Keep the device in a dry environment.
- Do not operate the device in a severe environment of extreme temperature, humidity, or direct sunshine.
- Follow operation and storage conditions as described in the technical specifications section of this guide. Otherwise, measurement results may be impacted.
- Do not use the device in a dusty environment.
- Exposing the device to prolonged lint or dust might damage the device or reduce its life.
- Do not block the vents.
- Maintain a minimum distance of 20 cm (about 8 inches) around the device.

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 cell whose lifespan is strictly greater than 5 years.
- The users cannot access these accumulators and only Impeto personnel can replace them.

Protection against electrical shocks



- **CONNECT THE DEVICE ONLY TO A SAFE HOST PC, COMPLYING AS A MINIMUM WITH IEC 62368-1 -STANDARD (Audio/video, information and communication technology equipment Part 1: Safety requirements), CLASS I OR CLASS II.**
- **TO USE AT AN ALTITUDE HIGHER THAN 2000 M, AND UP TO 3000 M, USE EXCLUSIVELY**
- **A SAFE HOST PC CERTIFIED TO OPERATE UP TO 3000 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 4.1 REQUIREMENTS.**
- **USE NEAR MOBILE TELEPHONES OR WIRELESS FIXED TELEPHONES CAN CAUSE SIGNAL DISTURBANCES.**

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 ADVISABLE TO VERIFY IF THE CONNECTOR OF THE SMART FEET DOCK CABLE IS WELL INSERTED INTO THE CORRESPONDING PURPLE SOCKET AT THE BELOW OF THE SMART HANDS DOCK. THE USB CABLE BETWEEN THE SOCKETS OF THE SMART HANDSDOCK AND FOR THE USB PORT SPECIFIED IN THE INSTALLATION GUIDE OF THE HOST PC MUST BE ALSO VERIFIED. TIGHTEN THEN THE LOCKING SUPPORT CONNECTORS.**

- **MAKE SURE THE PATIENT'S SKIN IS CLEAN TO ENSURE A GOOD CONTACT BETWEEN THE SKIN AND THE SMART ELECTRODES ARE DRY BEFORE USE**
- **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.**
- **THE MAXIMUM WEIGHT ACCEPTED BY THE SMART DOCKS IS 199KG (438LBS)**

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

💡 Impeto Medical cannot guarantee correct operation with a USB cable issued from any 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 if the power supply is not connected to the ground.

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

Positioning on the smart electrodes

- The patients must position the sole of their bare feet in the centre middle of the feet smart electrodes and firmly apply their hands flat in the centre middle of the hands smart electrodes.
- It is recommended that the patient stand up during the test, except if the weight of the patients is over 199 kgs


Interrupting or stopping the recording

- The test will automatically stop at the end of the measurements cycle test, after approximately 3 minutes.
- To stop the test BEFORE the end of the measurements cycle, press on Cancel button

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.

 Contact your physician in case of symptoms, doubt and questions.

1.2.9. Requirements for operations

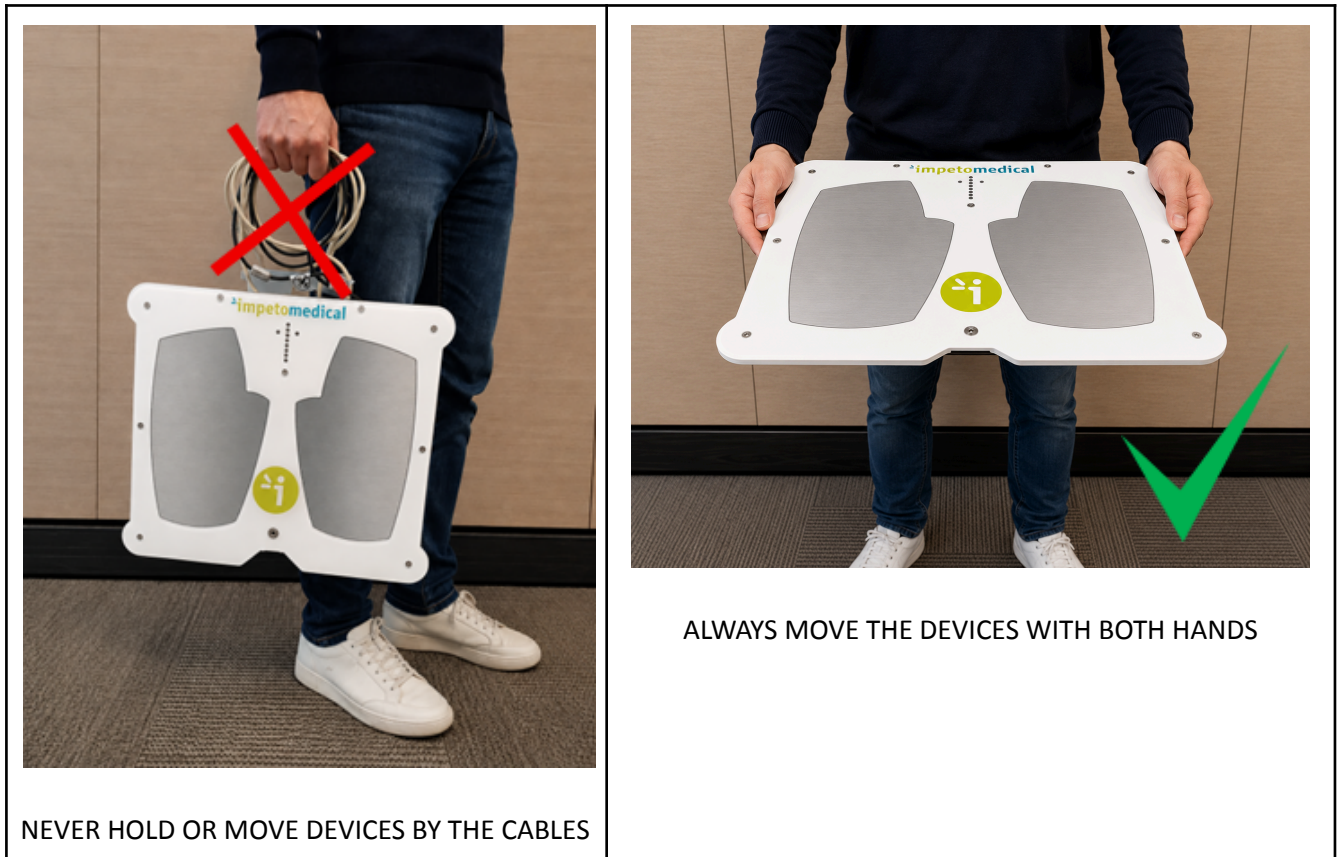
As for any medical examination, it is recommended to check the environmental conditions and the condition of the patient before carrying out a measurement:

- Room temperature is between 18 and 35 degrees Celsius (65 and 95 degrees Fahrenheit)
- Cardiac holter measurements in progress can be altered during the 3-minute time scan.

2. Installation and Preparation

2.1. Installation

For proper installation, carefully follow the instructions in the SUDOSCAN and host computer installation guide below. The complete installation takes about 15 to 20 minutes.



Feet Smart Dock:

- Verify that the smart electrodes are correctly inserted and locked

Hands Smart Dock:

- Verify that the smart electrodes are correctly inserted and locked.
- Verify that the Feet Smart Dock cable is correctly connected to the purple connector located on the underside of the dock.
- Verify that the USB cable is correctly connected to the grey "host computer" port located under the Hand Smart Dock. .
- Verify that the ElockSA bracket locks both cables in place.

Host PC:

- Verify that the USB-A cable is correctly inserted into the USB ADSPHD port located on the back of the host computer.
- Verify that the Wi-Fi/Bluetooth dongle is present on the back of the host computer

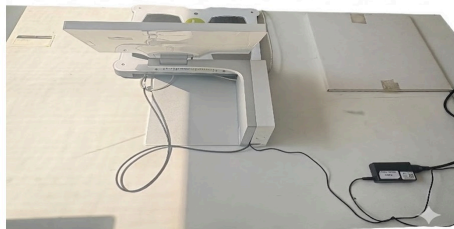
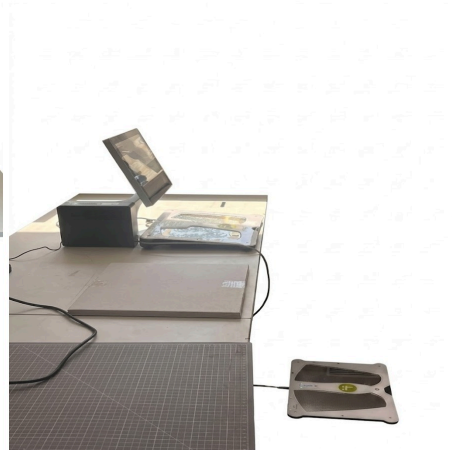
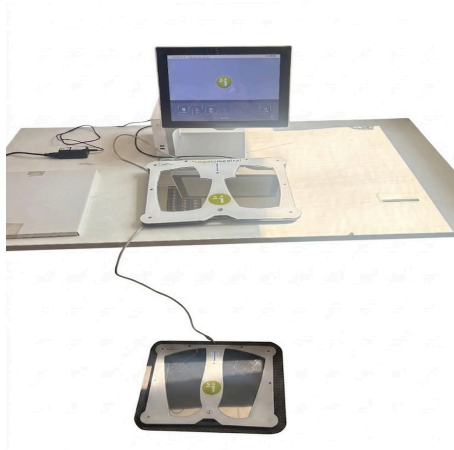


DO NOT UNPLUG THE DONGLE !!! IT IS FORBIDDEN

- Verify that the power adapter is properly inserted into the power connector on the back of the host computer.
- Verify that the power cord is properly connected to the power adapter.



the following photos show examples of correct SUDOSCAN installations :





2.2. 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 IRREDEMIABLY CORRUPT DATA ON THE STORAGE DEVICE.

2.3. 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.

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.



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



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 refer to the **troubleshooting section (refer to page n°28)**.



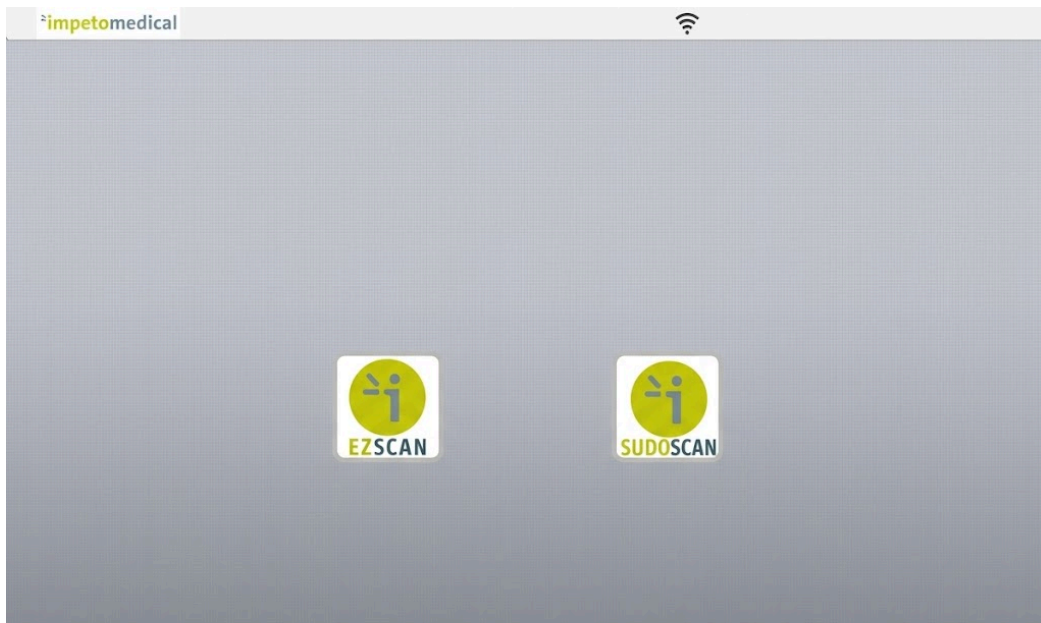
THE QUALITY CHECK MUST BE PERFORMED WITHOUT THE PATIENT (NOBODY IN CONTACT WITH THE ELECTRODES).

3. Operations and Test Execution

3.1. Software

Upon launching the application, the software selection screen is displayed. This screen allows the operator to choose between two available applications: **SUDOSCAN** or **EZSCAN**.

 This selection screen only appears if the EZSCAN option has been activated on the device.



3.2. Log in

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.

3.3. Start a scan

3.3.1. Start a scan for a new patient

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

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.

2- Set patient's demographic information.

💡 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 NAMESAKE 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)

3.3.2. 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.

3.4. During the scan

1 - Patient position

Correct positioning for the test :

- To ensure an accurate scan, please verify that the patient is correctly positioned on the smart electrodes before starting:
- Feet: Both feet must be bare and placed flat on the foot electrodes.
- Hands: Adjust the height of the smart hands dock according to the patient's height. Both hands must be placed flat so that the entire palm is in contact with the hand electrodes, applying gentle pressure.
- Posture: The patient must be in a standing position. The patient should be slightly leaning forward.
- Stability: The patient must remain still and not move throughout the duration of the test.
- Jewelry: It is recommended to remove all jewelry before starting the scan.
- Operator: The operator must not touch the patient during the test.



2- Click on the Scan button.

During the acquisition, the scan can be stopped at any time by selecting the Stop scan button. The application displays a video (You can personalize the media displays while the scan is in progress) 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).

💡 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.

💡 To personalize media displays during the scan, go to Tools > Settings. Available options: Video, Clinical Questionnaire, Slideshow.



THE PATIENT MUST NOT TOUCH THE HOST PC. DO NOT TOUCH THE PATIENT DURING THE SCAN.



USING USB PORTS DURING A SCAN MAY CAUSE THE APPLICATION TO FREEZE. DO NOT PLUG OR UNPLUG ANY USB DEVICES FROM THE HOST PC WHILE A SCAN IS IN PROGRESS.

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



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.

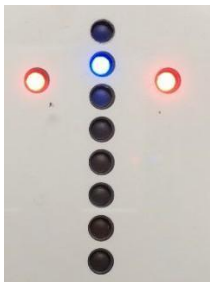


THE DEVICE IS NOT A STORAGE MANAGEMENT SYSTEM AND DATA ON THE HOST PC SHALL BE BACKED UP ON A REGULAR AND FREQUENT BASIS.

3.5. What if the scan cannot be started?



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 p 31) to see how to insert 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 (refer to page 30).

3.6. 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.

3.6.1. Asymmetry

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

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

3.6.2. 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 (refer to p25)

💡 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.

3.7. Patient's Data Deletion

Patient data can be deleted either for selected patients or for all patients simultaneously.

To delete data for specific patients, select the patients in the Patient History interface and click the "Delete Patients" button.

To delete all patient data, log in as a Supervisor Impeto User and click the "Clear Database" button in the Service interface

4. Maintenance and Servicing

4.1. General Care



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 (1 press) of cleaning product on each electrode.
- 2- Wipe the electrodes until dry with Soft Tissue Wipes



CLEANING SOLUTION DISCLAIMER AND INSTRUCTIONS:

- **PLEASE NOTE THAT WHILE THE MANUFACTURER RECOMMENDS SPECIFIC COMPATIBLE SOLUTIONS, WE ARE NOT THE MANUFACTURER OF THESE CLEANING PRODUCTS.**
- **TO ENSURE SAFETY AND EFFECTIVENESS, USERS MUST STRICTLY ADHERE TO THE CLEANING SOLUTION MANUFACTURER'S INSTRUCTIONS AND SAFETY PRECAUTIONS. THIS INCLUDES:**
 - **PERSONAL PROTECTIVE EQUIPMENT (PPE): MANDATORY USE OF APPROPRIATE EQUIPMENT, SUCH AS GLOVES AND MASKS, AS SPECIFIED BY THE SOLUTION PROVIDER.**
 - **APPLICATION: COMPLIANCE WITH THE RECOMMENDED PRODUCT QUANTITY AND THE REQUIRED CONTACT TIME TO ENSURE PROPER DISINFECTION.**

For a list of recommended compatible products, please visit our website at: <https://www.sudoscan.com/resources/>

4.2. 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, an error message will be displayed.

4.3. Maintenance



ONLY AUTHORIZED PERSONS BY IMPETO MEDICAL ARE ALLOWED TO PERFORM ANY REPAIRS OR MAINTENANCE ON THE DEVICE.

All the technical documents (accessories list, descriptions, calibration instructions) are prepared by Impeto Medical.

The warranty is not valid if the device was opened and repaired by any unauthorized person. The warranty is only valid on manufacturing defects and will not be valid for any mechanical damage due to mishandling or misuse. Refer to the manual for proper use of the equipment.

4.3.1. Hardware maintenance

No particular maintenance is necessary.

Occasionally, the 2 contacts under each electrode of a smart electrodes and smart docks can be cleaned with a wet tissue.



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

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

4.3.2. Software Maintenance and updates

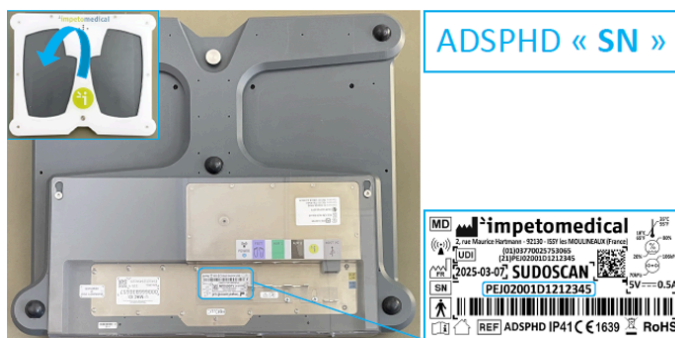
4.3.2.1. Obtaining Software Updates

Updates of software applications are released periodically. To obtain the latest approved software version contact the Manufacturer directly via :

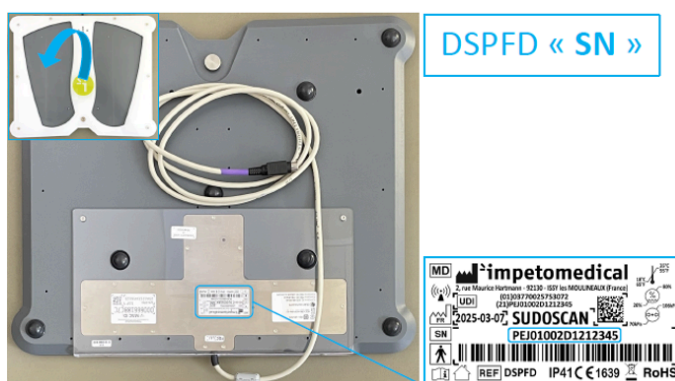
Email: support@impeto-medical.com

Please provide the device's Serial Number (SN) and the current Software Version Number when requesting an update. (for the most recent version : Hand dock (ADSPH): PEJ 02001DXXXXXXX and Feet dock (DSPFD) : PEJ01002DXXXXXX)

HAND DOCK (ADSPHD):



FEET DOCK (DSPFD):



4.3.2.2. Manual Installation procedure

If a manual installation is required, please follow these steps:

- Before making any changes to the system, make sure to check for and install all available windows updates, during this step don't force the shutdown or the reboot of the device.
- After the updates have finished installing, please restart your computer to apply the changes.

- Receive software's Upgrade The update file will be provided via [Specify method, e.g., secure download link or physical media].
- Before upgrade, make sure to exit and close all running programs
- Ask Admin Authorisation: contact Impeto Medical to receive the Administrator account password to be able to run the installer.
- Verification: After upgrade, launch the software and navigate "About" or "Information" menu to verify that the Version Number of displayed Software is matching the upgraded version.
- Restart System: Restart the device

4.3.2.3. Data Backup procedure

Before making any major software update, you must back up all patient data and configuration files to prevent data loss.

Backup Data: To export data, open the patients history menu on the home page "on the software to a secure external storage device (e.g., USB key or network server).

1- Select patients from the Patient list and exams from the Exam list

2- When available, modify patient demographic data or reconcile data from several patients by clicking on the Modify button. The option is available for supervisor users and standard users when enabled.

3- Start a new scan for the selected patient.


4- Display the results for the selected exam.

5- Display the follow-up screen for the selected exams.

6- Export or print data and reports for the selected exams.

Other controls

 Click on the Home button to reach the home page.

 Click on the Help button to reach the contextual help.


Verify Backup: Confirm that the copied files are accessible and intact before proceeding with the update.



THE MANUFACTURER IS NOT RESPONSIBLE FOR DATA LOSS DUE TO FAILURE TO FOLLOW THE MANDATORY BACKUP PROCEDURE.

4.3.2.4. 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.

 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 (refer to page 30).



IT IS IMPORTANT THAT NO ONE STANDS ON THE SMART ELECTRODES WHILE PERFORMING A QUALITY CHECK.

4.4. Troubleshooting

Problems	Causes	Actions
The machine does not turn on	<ul style="list-style-type: none"> -Power supply issue -Power adapter is defective -Bad connection between components 	<ul style="list-style-type: none"> -Check that the machine is correctly connected to the mains power supply -Check that the green indicator light on the power supply is lit -Check the connections of the power cord / connector
QC fails	<ul style="list-style-type: none"> -Incorrect electrode (hands/feet) connections with Elock(SA) -Play or looseness between electrode connectors and the machine, the Elock(SA) loose or misaligned or not present -Someone is standing on the hands/feet plates electrodes -Plates are wet -Plates are placed in an environment causing electromagnetic interference -Faulty interface board -Microsoft Security Essentials / Windows Defender enabled 	<ul style="list-style-type: none"> -Ensure color codes are respected (green for hands and purple for feet) and fix the with Elock(SA) -Check that the Elock(SA), locking clamp is properly installed -Make sure no one is touching the plates electrodes during QC -Ensure the plates are completely dry, if not wipe them -Check the interference level in "Manual Test" mode under the Quality Control tab while logged in as Supervisor -Check if QC Passes without the plates electrodes connected to the system -Disable Microsoft Security Essentials/ Windows Defender realtime protection
WARNING CPU HIGH USAGE	<ul style="list-style-type: none"> -CBS log files too large on the hard drive -Microsoft Security Essentials enabled/ Windows Defender 	<ul style="list-style-type: none"> -Contact Impeto Medical Customer Service -Disable Microsoft Security Essentials/ Windows Defender realtime protection
USB NOT CONNECTED error message	<ul style="list-style-type: none"> -Cable plugged in incorrectly or not plugged in at all -Internal machine issue 	<ul style="list-style-type: none"> -Check the connections according to the install guide -Contact Impeto Medical Customer Service
Error message Electrodes comm. error	<ul style="list-style-type: none"> -Bluetooth board issue -Pairing issue -Disabling the Bluetooth feature on Windows. -Enabling Airplane Mode on Windows -Dongle Bluetooth not present on the host PC -Plates placed in an environment with electromagnetic interference 	<ul style="list-style-type: none"> -Contact Impeto Medical Customer Service -Contact Impeto Medical Customer Service -Enabling the Bluetooth feature on Windows -Disable Airplane Mode on Windows -Check the presence of the Dongle Bluetooth on the correct USB port -Place the plates on a nonmetallic surface or put an insulating material underneath (cardboard, wood, plastic, etc.)
Unable to find my patient history	<ul style="list-style-type: none"> - Machine moved, BIOS battery issue 	<ul style="list-style-type: none"> -Reset the machine's OS time and date

Cannot connect the machine to WiFi	<ul style="list-style-type: none"> -Invalid password -Secured network -Bad network -Bad connection 	<ul style="list-style-type: none"> -Verify the password provided by the ISP -Contact the ISP to authorize internet access for Sudoscan -Check signal strength in Windows taskbar -Contact the ISP to improve internet access
The machine does not complete a scan	<ul style="list-style-type: none"> -Microsoft Security Essentials enabled/ Windows Defender -Other applications installed on the machine -Device not installed properly -Presence of a printer monitoring software -Device in a disturbance environment -Another antivirus installed on the machine 	<ul style="list-style-type: none"> -Disable Microsoft Security Essentials/ Windows Defender realtime protection -Uninstall applications or contact Impeto Medical Customer Service -Check the connections according to the installation guide -Uninstall the printer monitoring software -Check the installation and the environment around the device -Contact Impeto Medical Customer Service
The machine is slow	<ul style="list-style-type: none"> -Corrupted RFID tag -Device not installed properly -Presence of a printer monitoring software -Other applications installed on the machine -Machine not connected to a secure network -Microsoft Security Essentials/ Windows Defender "Realtime Protection" enabled 	<ul style="list-style-type: none"> -Contact Impeto Medical Customer Service -Check the connections according to the installation guide -Uninstall the printer monitoring software -Contact Impeto Medical Customer Service -Check with the IT service regarding MAC or IP address filtering and address configuration settings. -Disable Microsoft Security Essentials/ Windows/ Windows Defender realtime protection in windows
Unable to print a report	<ul style="list-style-type: none"> -Printer powered off -Printer not connected to Sudoscan -Print spooler full -Printer incorrectly configured in Windows -Printer not configured in the application -Printer ink jet used 	<ul style="list-style-type: none"> -Verify printer is powered on -Ensure the printer is connected via USB or WiFi to Sudoscan -Cleaning / Restart -Check that the settings are configured using the TCP/IP method -Ensure printer is selected under "Tools and Settings" -Use a lazer printer or contact Impeto Medical Customer Service
My printer is not recognized by the system	<ul style="list-style-type: none"> -Missing driver on the system -Printer too old -Printer powered off -Printer incorrectly configured on OS -Printer not compatible -Printer incorrectly configured in Windows 	<ul style="list-style-type: none"> -Contact Impeto Medical Customer Service -Contact Impeto Medical Customer Service -Verify printer is powered on -Contact Impeto Medical Customer Service -Contact Impeto Medical Customer Service -Contact Impeto Medical Customer Service

The machine turns on but the screen remains black	-USB key plugged into the system	-Check that no USB key is connected to the system
	-Antivirus installed on the machine	-Contact Impeto Medical Customer Service
	-Touchscreen connector not properly connected	-Check if touchscreen connector is correctly inserted and not crooked
	-Windows update in progress	-Wait a few minutes.

MY ISSUE IS NOT LISTED : PLEASE CONTACT THE CUSTOMER SUPPORT SERVICE (<https://www.sudoscan.com/who-we-are/contact-us/>)

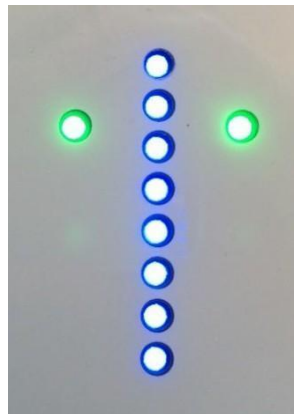
4.5. Consumable management : smart electrodes

4.5.1. 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.

impetomedical v3 25-02-2026 21:16 - 00384[R] Scan#: 0 Remaining scans: 1 SUDOSCAN



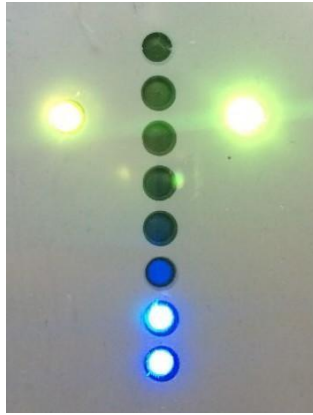
Remaining scans – ok

4.5.1.1. Thresholds

Thresholds 1:

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

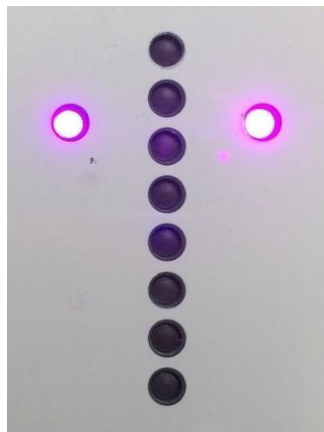
impetomedical v3 25-02-2026 21:16 - 00384[R] Scan#: 0 [Remaining scans: 1] SUDOSCAN



Remaining scans first warning

Threshold 2:

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



Remaining scans last warning

4.5.1.2. 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:



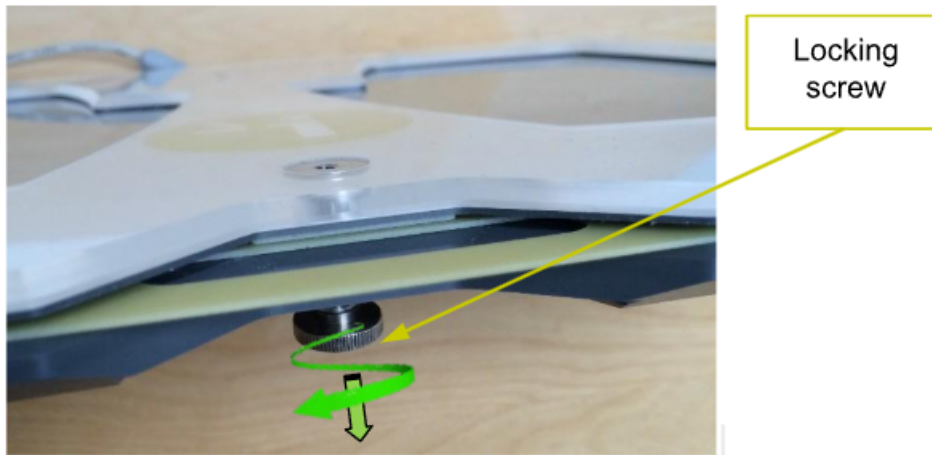
💡 Be sure to change hands smart electrodes and feet smart electrodes at the same time. Do not disconnect the feet smart dock cable or USB cable to replace electrodes.

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



SHUTDOWN THE DEVICE BEFORE DO ANYTHING

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



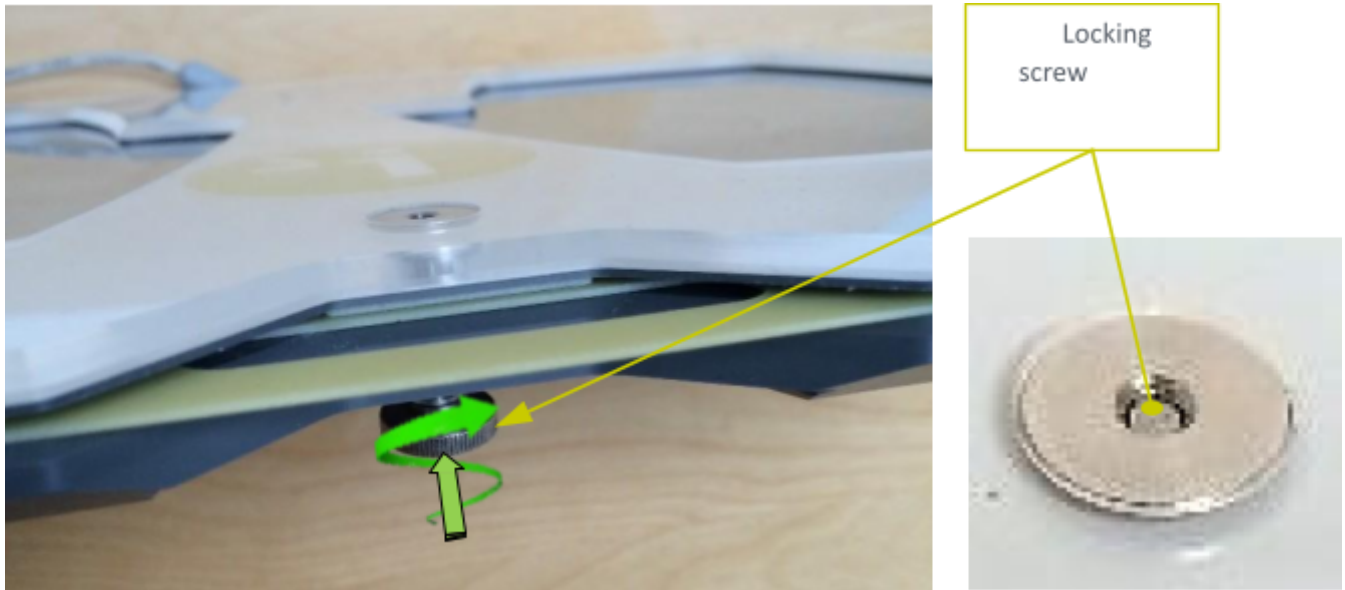
2- Then remove the smart electrodes to be replaced by pulling it out gently.



3- While keeping the electrode dock elevated so that the screw does not scratch the electrode, 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 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. RESTART THE SYSTEM AFTER INSTALLATION OF THE NEW SMART ELECTRODES.**
- **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 ASSEMBLE AND SCREW THE CONNECTOR LOCKING BRACKET AND POLYCARBONATE PROTECTIVE PLATE.**

💡 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. Technical Specifications

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

Acquisition characteristics

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

Electrical characteristics

Measurement voltage:	1 V to 4 V DC typical
Frequency:	0 Hz (DC current)
Dynamic resolution:	10 bits
Power and I/O interface requirement	5 V DC – 500 mA Powered from Host PC by one High Power USB 2.0/3.0 >
port, type A, Full Speed Insulation:	4,8 KVac/1min USB isolated interface on Hands Smart
Applied Parts type:	BF

RF characteristics

RFID 13.56 MHz, Class 1, ASK modulation, 1 channel:	Transmitter H-field \leq -10 dB μ A/m @10m
Bluetooth® v2.1 + EDR, 2,402 ~ 2,480 GHz, FHSS/GFSK modulation, 79 channels at 1MHz intervals (Class 2 radio):	EIRP \leq -11 dBm, RF Transmit Power 4 dBm typ.

Protection index

Smart docks	IP41
Smart electrodes	IP41

Mechanical characteristics

Weight of Hand Smart Electrodes Dock + DSP:	4,1 kg (9,0 lbs)
Hand Smart Electrodes Dock dimensions:	41,1 x 34,4 x 5,2 cm (16,18 x 13,54 x 2,04) (inches)
Weight of Foot Smart Electrodes Dock + DSP:	3,4 kg (7,5 lbs)
Foot Smart Electrodes Dock dimensions:	41,1 x 34,4 x 2,8 cm (16,18 x 13,54 x 1,10) (inches)
Weight of the shipping box	10,5 kg (23,0 lbs)
Dimensions of the shipping box:	47,5 x 26,0 x 40,0 cm (18,70 x 10,23 x 15,75) (inches)
Expected minimum product life	5 years

Clinical benefit/performance

The device used in conjunction with the clinician evaluation helps the physical examination of the patient.

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 1060 hPa or 700 to 1060 hPa exclusively with one Host PC certified to operate up to 3000 m of altitude
Storage	5° to 45°C (41° to 113°F)	10 % to 85 %	500 to 1060 hPa
Transport	-5° to 50°C (23° to 122°F)	10 % to 90 %	500 to 1060 hPa

6. Safety and performance

The device complies with IEC 60601-1 Edition 3.2 (Medical Electrical Equipment, Part 1: General requirements for safety and essential performance), EN 60601-1-2 of 2014 + AMD1 : 2020 (Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance)

CB test certificate, valid for countries listed 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

National differences for Europe, United States of America, Canada and Japan have been evaluated.



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

Table 1

<p>IEC 60601-1-2 Edition 4.1: 2014 + AMD1: 2020 Part 1-2: General requirements for basic safety and essential performance Collateral Standard: Electromagnetic disturbances Tests Guidance and Manufacturer's Declaration</p>	
<p>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 Scan restart or Host PC reboot</p>	
<p>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</p>	
<p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>	

WARNING:

- 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 6.2: 2015 + A1: 2016 + A2: 2019	Complies 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.
	Complies 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 5.0: 2018	Complies Class A	For information: Test performed at 50 Hz (Host PC AC power supply)
Voltage fluctuations and flicker IEC 61000-3-3 Ed 3.2: 2013 + A1: 2017 + A2: 2021	Complies	For information: Test performed at 50 Hz (Host PC AC power supply)

Immunity test	IEC 60601-1-2 test level	Compliance	Guidance
Electrostatic discharge (ESD) IEC 61000-4-2 Ed 2.0: 2008	±8 kV contact ±15 kV air Test performed at 60 Hz (Host PC AC power supply)	Complies	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	5/50ns, 0.75 ms/100 KHz ±2 kV for power supply lines Test performed at 60 Hz (Host PC AC power supply)	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5 Ed 3.1: 2014 + A1: 2017	1,2/50 µs U, 8/20 µs I ±1 kV line to line ±2 kV lines to earth Test performed at 60 Hz (Host PC AC power supply)	Complies	Mains power quality should be that of a typical commercial or hospital environment.

Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 Ed 2.0: 2009	30 A/m @ 50 Hz and 60 Hz, Test time 10 s Test performed at 60 Hz (Host PC AC power supply)	Complies	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines (Host PC) IEC 61000-4-11 Ed 3.0: 2020 NOTE: Ut is the AC mains voltage prior to application of the test level	0 % Ut for 0,5 cycle 0 % Ut for 1 cycle 70 % Ut for 25/30 cycles 0 % Ut for 250/300 cycles Ut: 240 V 50 Hz and 100 V 60 Hz	Complies	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.
Radiated fields in close Proximity: Magnetic field IEC 61000-4-39 Ed 1.0: 2017	30 kHz 8 A/m, CW Modulation, Dwell time 3 s 134,2 kHz 65 A/m, Pulse modulation 2,1 kHz, Dwell time 3 s 13,56 MHz 7,5 A/m, Pulse modulation 50 kHz, Dwell time 3 s	Complies	See WARNING Table 1
Immunity test RF	IEC 60601-1-2 test level	Compliance	Guidance
Radiated RF electromagnetic field IEC 61000-4-3 Ed 4.0: 2020	80 MHz – 2.7 GHz 10 V/m, AM 80% @ 1 KHz, Dwell time 2 s	Complies	See WARNING Table 1
Radiated RF proximity fields from RF Wireless communications equipment IEC 61000-4-3 Ed 4.0: 2020	Band 380 - 390 MHz 27 V/m, PM 50% @ 18 Hz, Dwell time 3 s Band 430 - 470 MHz 28 V/m, (FM ±5 kHz, 1 kHz sinus), Dwell time 3 s Band 704 - 787 MHz 9 V/m, PM 50% @ 217 Hz, Dwell time 3 s Band 800 - 960 MHz 28 V/m, PM 50% @ 18 Hz, Dwell time 3 s Band 1700 - 1990 MHz 28 V/m, PM 50% @ 217 Hz, Dwell time 3 s Band 2400 - 2570 MHz 28 V/m,	Complies	See WARNING Table 1

	PM 50% @ 217 Hz, Dwell time 3 s Band 5100 - 5800 MHz 9 V/m, PM 50% @ 217 Hz, Dwell time 3 s		
Conducted disturbances, induced by radio-frequency fields IEC 61000-4-6 Ed 4.0: 2013	150 kHz – 80 MHz 3 V ISM and Amateur radio bands 6 V AM 80% @ 1 KHz, Step size 1 %	Complies	See WARNING Table 1

Table 2 (report date : 06/06/2024)

Electromagnetic compatibility and RADIO tests RFID and Bluetooth			
Standard	Transmitter	Compliance	
EMC: ETSI EN 301 489-1 V2.2.3 ETSI EN 301 489-3 V2.2.0	RFID 13.56 MHz	Complies	
RADIO: ETSI EN 300 330 V2.1.1	RFID 13.56 MHz	Complies Radiated Spurious emissions	
EMC: ETSI EN 301 489-1 V2.2.3 ETSI EN 301 489-17 V3.2.4	Bluetooth®	Complies	
RADIO: ETSI EN 300 328 V2.2.2	Bluetooth®	Complies Radiated Spurious emissions	
47 CFR Part 15 Radio Frequency Devices; Subpart C Intentional Radiators	RFID 13.56 MHz Bluetooth®	Complies 47 CFR Part 15C Section 15.209 radiated emissions 47 CFR Part 15C Section 15.207 conducted emissions	
FCC IDENTIFIER	RFID 13.56 MHz	2ADI8-SL03SER	
FCC IDENTIFIER	Bluetooth®	T9J-RN42	
Electromagnetic compatibility - Radiated Electric and Magnetic field Active implantable medical devices: cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices			
Standard	Applied Limits	Compliance	Guidance and Information
ISO 14117 Ed 2: 2019	ISO 14117 Ed 2: Annex M Magnetic field 1 kHz : 135,5 dBuA/m 3 kHz : 140,8 dBuA/m 3 kHz – 180 kHz : 140,8 dBuA/m 180 kHz : 140,8 dBuA/m 1 MHz : 129,5 dBuA/m 1 MHz – 10 MHz : 129,5 dBuA/m 10 MHz : 129,5 dBuA/m 30 MHz : 120 dBuA/m	Complies	STOP USE OF THE DEVICE IF THE PATIENT EXPERIENCES DIZZINESS OR BRADYCARDIA AS THESE COULD BE INDICATIVE OF INTERFERENCE WITH AN IMPLANTABLE CARDIAC PACEMAKER.

	ANSI/AAMI PC69: Annex M Electric field 30 MHz : 154 dBuV/m 100 MHz : 143,5 dBuV/m 300 MHz : 134 dBuV/m	Complies	Additional frequency band from 10 MHz up to 300 MHz measured in order to cover also former ANSI/AAMI PC 69 standard Annex M limits
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Table 3 : Accessories and disposable parts

The following items are available:

<u>Code</u>	<u>Description</u>
SUDO2	Hand smart electrode dock + Feet smart electrode dock + DSPx2
HOST PC - SANGO	Host Computer
ADSPHD	Hand Smart Dock
DSPFD	Feet Smart Dock
DSPx2	Smart Electrodes SET
UMSA	Installation guide + Host PC User Manual Guide + Safety Test + Quality Check report
ELOCKSA	Cable Locking support
PPPHD	Protective Polycarbonate plate for Hand Smart Dock
PH1	Screwdriver
PWS	Power Supply
USBA	USB cable

7. Disposal, warranty and security

7.1. Disposal

At the end of its useful life, this device must not be disposed of with household or municipal waste. The symbol of the crossed-out wheeled bin on the device or its packaging indicates its classification as Waste Electrical and Electronic Equipment (WEEE).

To prevent potential negative impacts on the environment and human health, it is the user's responsibility to ensure the device is disposed of through designated collection points or authorized recycling facilities. In all cases, users must comply with the local, regional, and national environmental regulations in force.

We strictly recommend contacting your local authorized Impeto Medical distributor for specific guidance on the take-back and disposal procedures applicable in your region.

In the European Union, the device may also be returned to your distributor when purchasing an equivalent replacement. Please be aware that improper disposal may be subject to administrative sanctions according to local legislation. The device and its accessories are mercury-free.



7.2. Warranty

The device is covered by a standard limited warranty for a period of one (1) year from the date of purchase. Please note that this warranty period and its specific terms may vary according to the local legislation or the terms of your individual sales agreement.

For full details regarding coverage, limitations, and warranty service procedures, please refer to the specific terms and conditions provided by your authorized distributor or included in your sales contract.

7.3. Security

This medical device has been designed in accordance with current cybersecurity best practices to ensure safe and secure operation in a clinical environment. The device includes multiple layers of protection to prevent unauthorized access, data manipulation, and service interruption.

The software has been designed to operate securely within a healthcare environment and includes several built-in cybersecurity controls to protect patient data and prevent unauthorized access:

- It enforces strong, unique passwords that expire every 180 days, and automatically locks after inactivity.

- It runs under a standard Windows user account without admin rights, minimizing system-level risks.
- All external communications are encrypted using Encrypted Protocols (TLS, HTTPS)
- The internal database is fully encrypted, ensuring protection of patient data and configuration information.
- Following Firewall PORTS have been blocked for inbound and outbound traffic: 3306, 1234, 5040, 5357, 135, 10500

8. Security Maintenance

Users must maintain a secure environment by always keeping Windows updated, restricting access to authorized personnel, and installing the software only on a secured network.

Users must update the installed Microsoft Defender antivirus regularly through Windows Update. A new antivirus software can be installed on the machine but the Software folder “C:\Program Files\IMPETO” must be excluded from the Antivirus real time protection and scan.

8.1. Device Communication, Risks and Mitigations

The device communicates using the following interfaces:

- Ethernet: (optional) for connecting to hospital/local domain network
 - Risk associated : Unauthorized access if network is compromised; data interception; malware propagation.
 - Mitigation : The Ethernet Connection must be authorized by System Administrator and configured by the local IT department to ensure secure network access.
- Wi-Fi: (optional) for wireless connection
 - Risk associated : Eavesdropping, unauthorized access, weak encryption attacks, rogue access points.
 - Mitigation : The Wifi Connection must be authorized by System Administrator and configured by the local IT department to ensure secure network access.
- USB: for data export
 - Risk associated : Introduction of malware; unauthorized data copying or modification.
 - Mitigation : User must login with strong password to operate the device, antivirus check.
- HTTPS/Web API: (optional) for Cloud services
 - Risk associated : Man-in-the-middle attacks if certificates are invalid; data leakage if endpoints are compromised.
 - Mitigation : TLS encryption, certificate verification
- Bluetooth: to communicate with the electrodes
 - Risk associated : Unauthorized pairing; interception of data.
 - Mitigation : Pairing must be authorized by System Administrator, encrypted communication
- HL7 (optional): if activated, to instantaneously include and share patient data with the HIS (Hospital Information System)
 - Risk associated : Unintended exposure of patient data; unauthorized access if HIS is not secure.
 - Mitigation : HL7 communication is configured and authorized only by the System Administrator.

8.2. Emergency

In the event of a cybersecurity incident, users must be able to quickly contact the manufacturer. The device provides the following emergency contact details:

- See “Contacts” chapter at the end of the document and/or Impeto Support: support@impeto-medical.com

The Users should follow these steps if a cybersecurity threat is suspected or detected:

1. As Supervisor Account, go to the Configuration interface and click on the Windows Desktop Button.
2. Disconnect the machine from the internet from Wifi or Ethernet connections.
3. Immediately report the incident using the above provided contact methods.
4. Contact your local IT provider
5. Note all actions taken, user accounts in use and any suspicious behavior.

Equipment Symbol Description

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 SUDOSCAN device is in conformity with European Directive 93/42/EEC



Warning



Registered Trademark



Indicates Medical Device



Indicates Unique Device Identifier



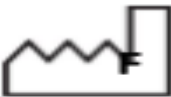
Indicates the manufacturer catalogue reference



Indicates the serial number



Indicates the manufacturer



R

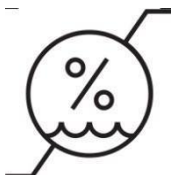
Indicates the country of manufacturing and date of manufacture



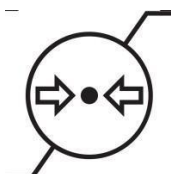
Indicates direct current



Indicates the maximum and minimum temperature limits at which the medical device shall be used



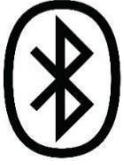
Indicates the maximum and minimum humidity limits at which the device shall be used



Indicates the maximum and minimum atmospheric pressure limits at which the device shall be used



Indicates RF Non-ionised radiation



Indicates Bluetooth device



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

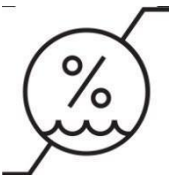
RoHS

Restriction of Hazardous Substances (Directive 2015/863/UE)

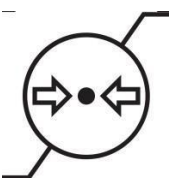
The following pictograms are affixed to the packaging box:



Indicates the maximum and minimum temperature limits at which the medical device shall be stored



Indicates humidity limit : to indicate the maximum and minimum humidity limits at which the device shall be stored



Indicates atmospheric pressure limit : to indicate the maximum and minimum atmospheric pressure limits at which the device shall be stored