SUDOSCAN 2

User guide

Version 3

06/04/2016

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1 Introduction

The SUDOSCAN device is powered by the Windows 7 Embedded SP1 operating system.

1.1 Patent

The SUDOSCAN® device is covered by U.S. Patent No. 8665443 and 8918170, entitled "Electrophysiological analysis system and method". The SUDOSCAN trademark is protected by U.S. Trademark Registration 11/922812, owned by Impeto Medical.

1.2 Use

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

1.3 Principle

SUDOSCAN measures the capacity of the sweat glands to release chloride ions in response to an electric stimulus. It is a dynamic test equivalent to a stress test.

Description:

The SUDOSCAN device consists of the following:

- **A control panel and display**

- **A pair of foot sensor plates**

- **A pair of hand sensor plates**

- **A power cable**

1.4 Installation

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

Complete installation should take no more than 15-20 minutes.

<u>Caution:</u> **Federal law restricts the use of this device to a licensed physician.**

NOTE

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

2 Power on the system

1	On the front of the Master Unit, there are 2 USB ports and a power button.
2	Press and release the power button to power on.

Power
button

Front
USB ports
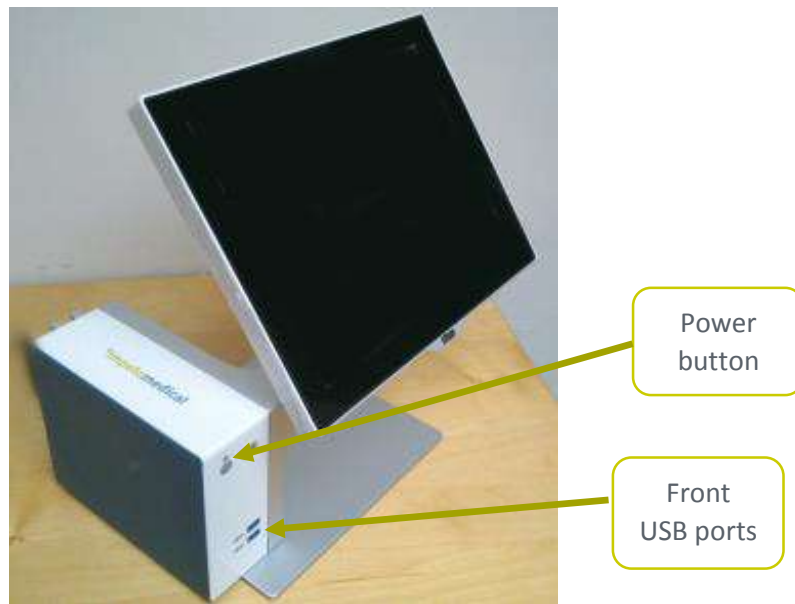
⚠️ WARNING

MODIFICATION OF THE EQUIPMENT IS STRICTLY PROHIBITED.

3 Home page

3.1 List of available functions

Please note that a summary of all functions can be found in the *"How to"* section on *(ref. p62)*.

3.2 Before logging in
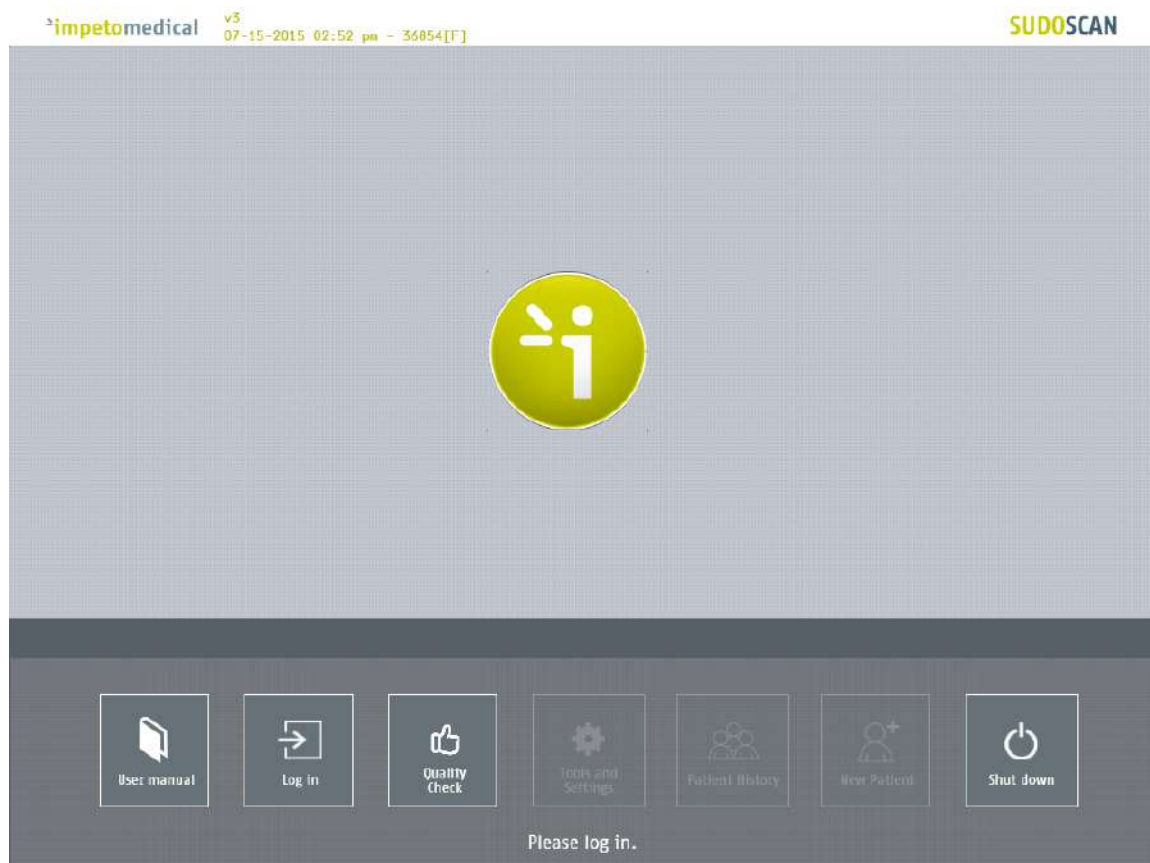
Figure 1 : Home page – no user is logged in

1	Click on the <u>Log in</u> button. The "Log in" screen appears *(ref. p8)*.
2	Click on <u>Quality Check</u> to launch the system "Quality Check" *(ref. p12)*.
3	Click on <u>Shut down</u> to shut down the system.

> ⚠ **WARNING**
>
> **REMOVING THE POWER CORD FROM THE MASTER UNIT OR FROM THE OUTLET BEFORE COMPLETE UNIT SHUT OFF MAY PERMANENTLY CORRUPT DATA ON THE UNIT'S HARD DISK DRIVE.**

| 4 | Click on <u>User manual</u> to display the electronic version of the user manual. |

3.3 For a logged in User
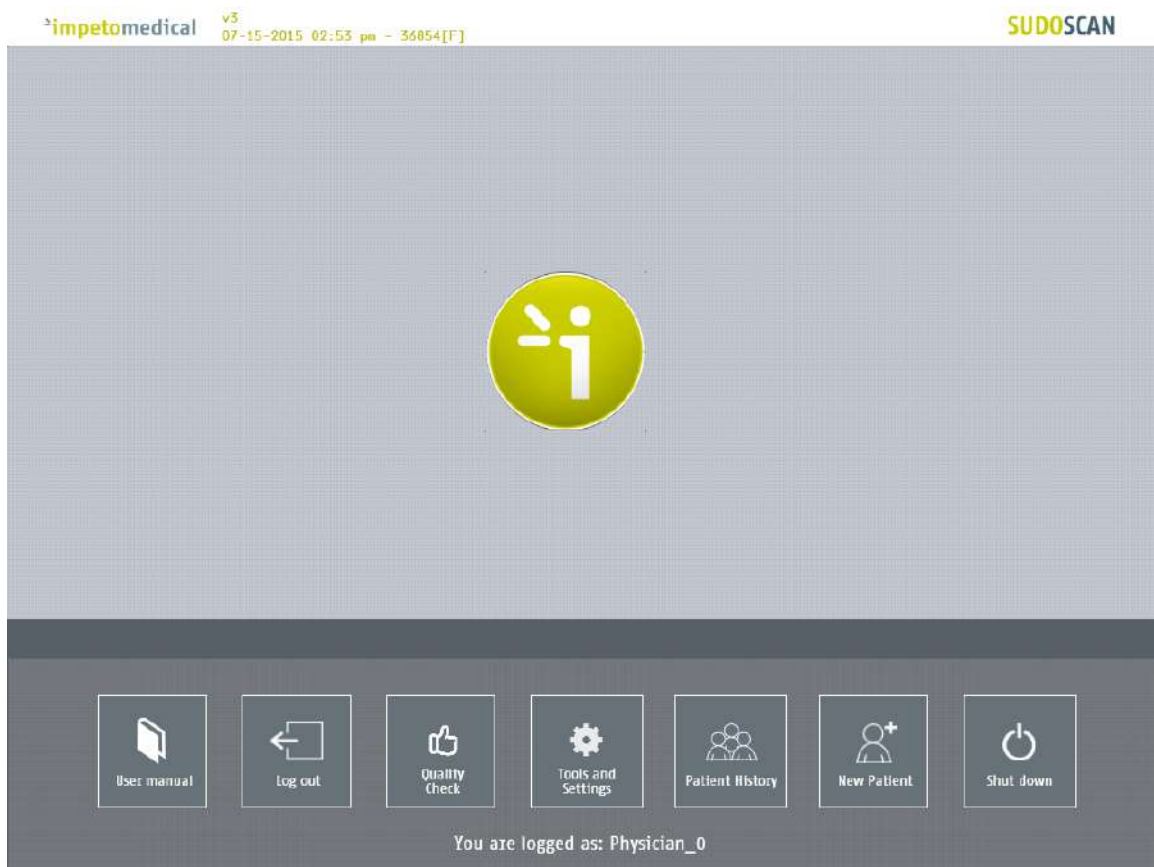
Figure 2 : Home page – User is logged in

1	Click on <u>Log out</u> to log out the current user.
2	Click on <u>Quality Check</u> to launch the system "Quality Check" *(ref. p12)*.
3	Click on <u>Shut down</u> to shut down the system.
4	Click on <u>User manual</u> to display the electronic version of the user manual.
5	Click on <u>Tools & Settings</u> to input specific configuration settings on the two available Tabs *(ref. p17)*.
6	Click on <u>New patient</u> to initiate a scan for a new patient *(ref. p32)*.
7	Click on <u>Patient history</u> to access all completed scans under this specific user account *(ref. p37)*.

4 Log in page

4.1 List of controls

Figure 3 : Log in page

1	Select the physician in the Physician list.
2	Enter your password in the Password field using the on-screen keyboard. The initial password is provided by your system supervisor. Default password: impeto
3	Click on the Log in button to validate the current password for the selected physician *(ref. p9)*.

4.1.1 Other controls

Click on the Home button (🏠) to go to the home page *(ref. p6)*.

Click on the Help button (?) to directly lead you to the specific topic that is displayed on the screen within the User Manual.

Click on Change password if you want to modify your current password *(ref. p10)*.
(NOTE: Current password must be entered in the password field.)

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4.2   Password validation

If the password is correct, the following message appears and the application automatically proceeds to the home screen *(ref. p7)*:

Successfully logged in as Physician1

STANDARD USER
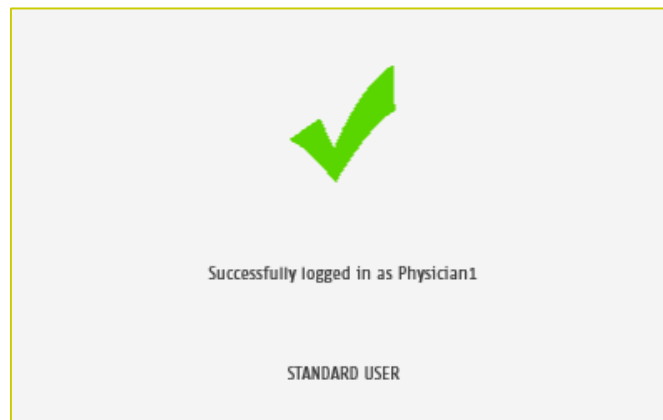
If the password is incorrect, the following message appears and the user has to log in again *(ref. p8)*:

Invalid password
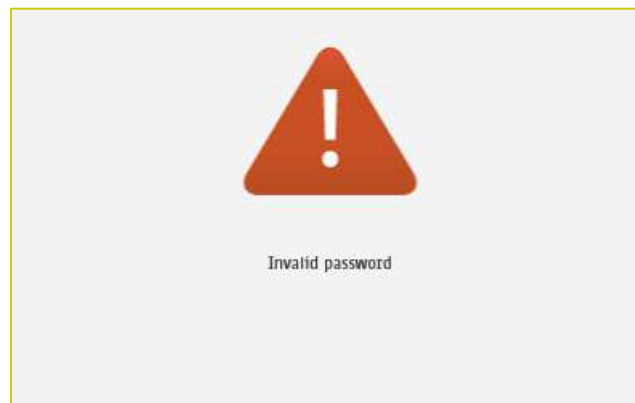
4.3 Password modification

1   **Enter your current password in the <u>Current password</u> field.**

   Click <u>Change password</u> to show the new password fields.

   Enter your new password in the two <u>New password</u> fields, then click on <u>Save password</u>.
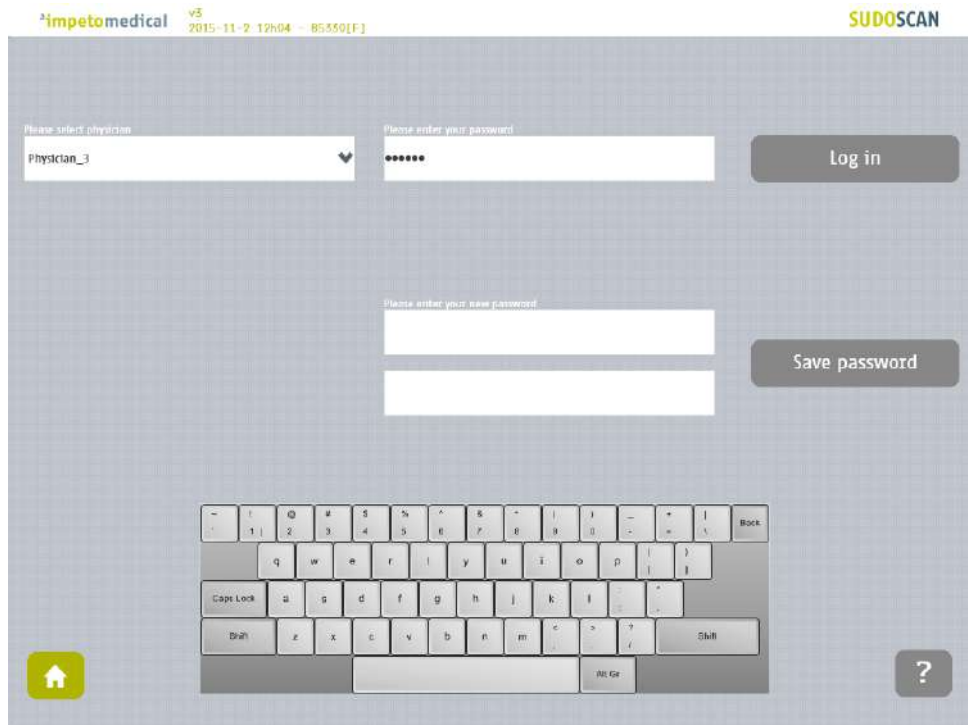
Figure 4 : Log in page – new password fields displayed

Upon selecting the button <u>Save password</u>, a validation check is performed on the different password:

-   If the <u>old password</u> is incorrect, the following message appears:
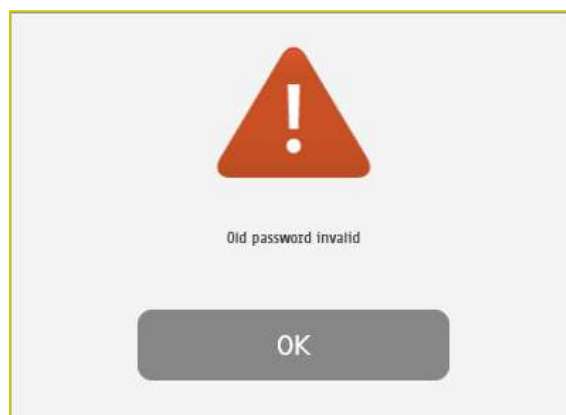
-   If the <u>new passwords</u> are not identical, the following message appears:
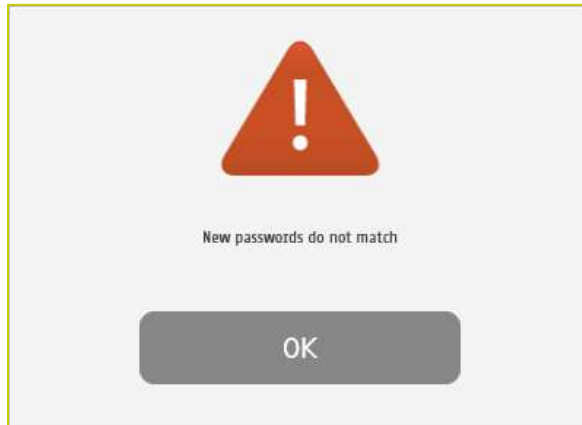
- If the <u>old password</u> is correct and the <u>new passwords</u> are identical, the following message appears and you have successfully changed your password and logged into the system.
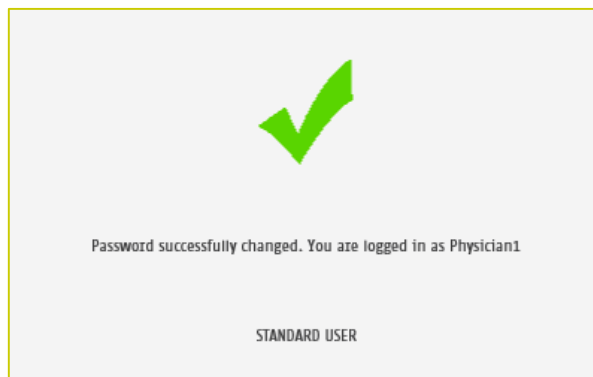
5 Quality Check page

5.1 Overview

The Quality Check allows the operator to test the internal electronic components of the system.

5.2 List of controls
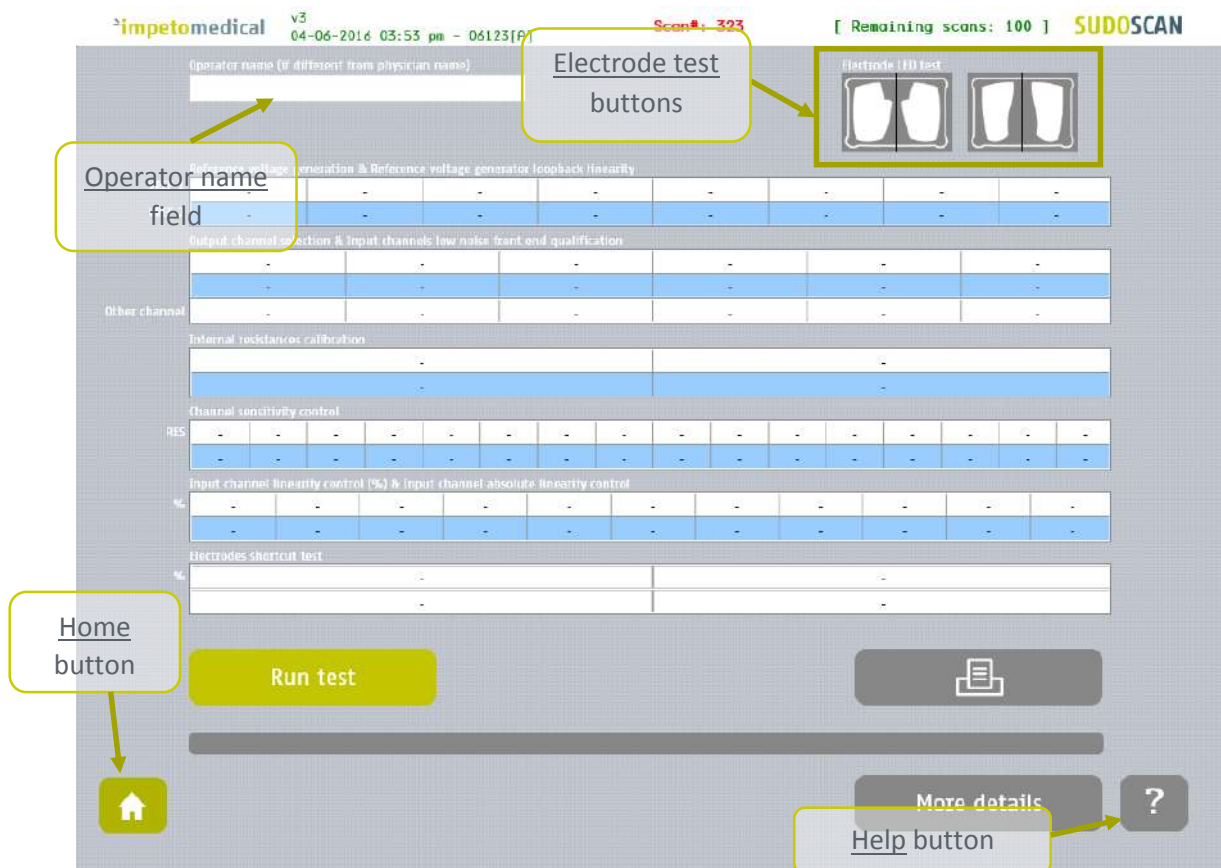
Figure 5 : Quality Check page – Empty

1	Click on the hands (left) and feet (right) Electrode test buttons to check the connectivity of the electrodes. The appropriate electrode LED will light up if the connectivity is Ok.
2	Enter an Operator name to be displayed in the Quality Check report. • *If the Operator name is not set, the Physician's name is displayed in the Quality Check report by default.*
3	Click on the Run test button to launch a full Quality Check sequence *(ref. p14 for Quality Check results interpretation).*

> **NOTE**
>
> **The Quality Check must be performed as a stand-alone test without any contact on the electrodes. .**

5.3 During a Quality Check test
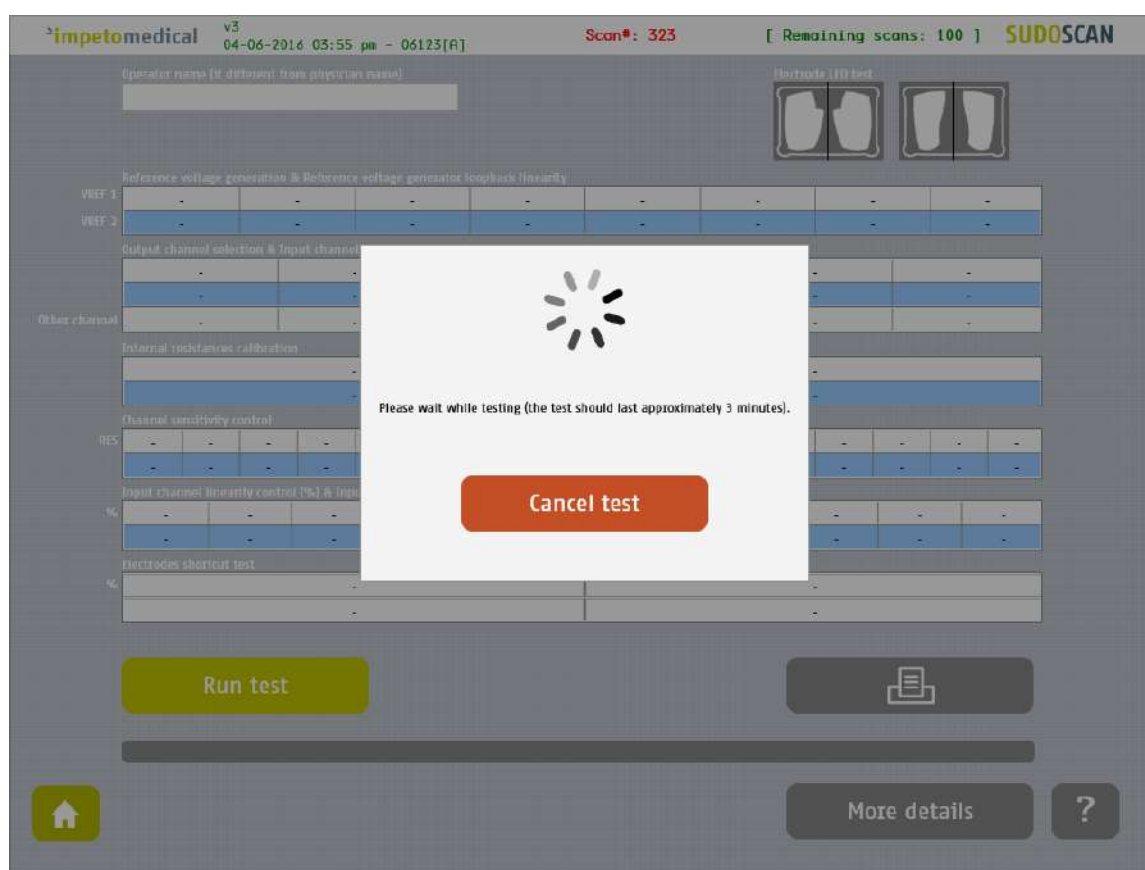
Figure 6: Quality Check page -During the Quality Check

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1   **Click on the** <u>Cancel test</u> **button to stop the Quality Check test.**
          NOTE: It may take several minutes for the test to cancel.

5.4 Quality Check results interpretation

When the Quality Check is complete and no error is observed, green check marks are displayed for every lines as shown below:

Figure 7: Quality Check page - Complete and valid Quality Check

If a problem occurs during the Quality Check, a warning icon appears in place of the green check mark(s). If this occurs, please contact **Impeto Medical** for technical support *(ref. p77)*.

Figure 8 : Quality Check page - Complete and invalid Quality Check

1	Click on the <u>Print</u> button to print or export the Quality Check report.
2	Click on the <u>More details</u> button to display more information on the Quality Check results.

5.5   View more details of the Quality Check results

If an error occurred during the execution of a Quality Check, more information can be displayed by clicking on the More Details button to view the error source.

<table>
<tr><td>NOTE</td></tr>
</table>

Additionnal information is only available for supervisor users.
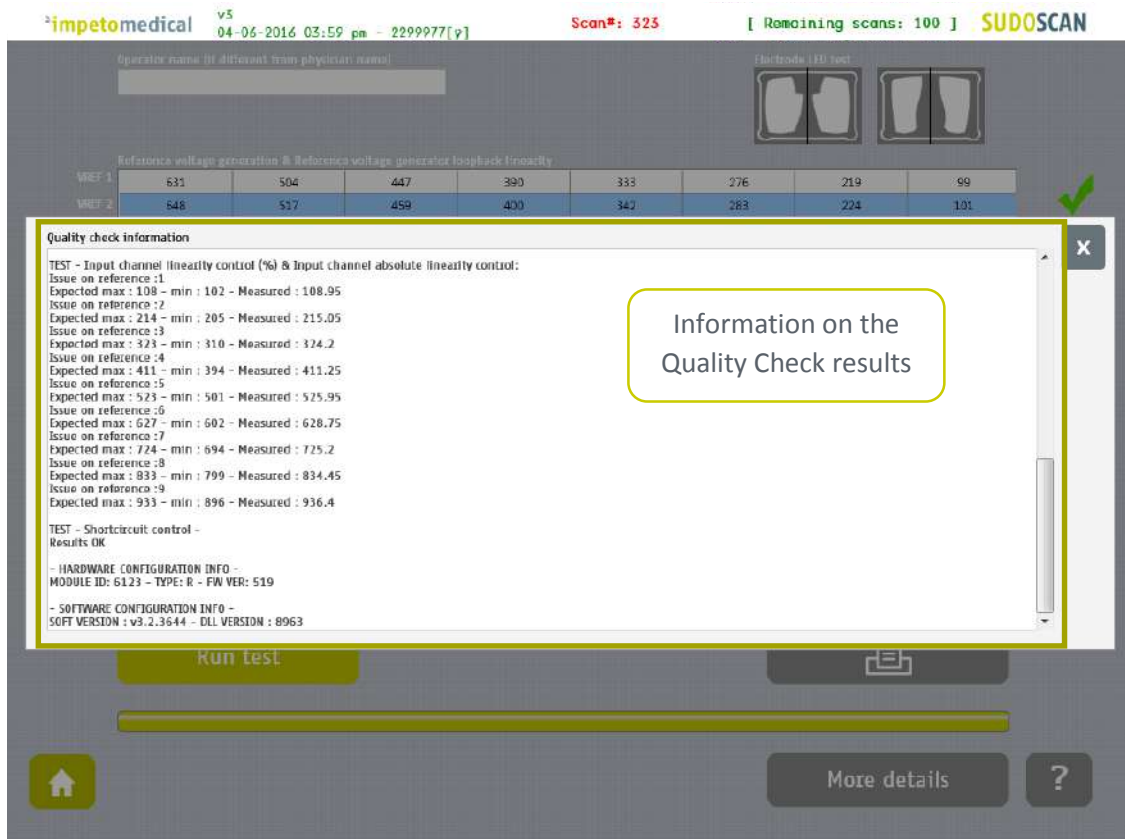
Figure 9: Quality Check page -More details on the Quality Check results

1	Click on the X at the top right corner to close the window.

5.6   Other controls

Click on the Home button (🏠) to go to the home page *(ref. p6).*

Click on the Help button (?) to directly lead you to the specific topic that is displayed on the screen within the User Manual.

6 Tools & Settings page(s)

6.1 Standard users – List of controls

Note: If you are logged in as Supervisor, please refer to p19.

Figure 10 : Configuration page

1	Enter hospital information in the hospital data fields.
2	Enter physician information in the physician data fields.
3	Select the <u>Printer</u> from the dropdown list of pre-installed printers *(ref. p59 to check how to install a printer driver).*

6.1.1 Other controls

	Click on the <u>Configuration (2)</u> tab to access additional settings *(ref. p18).*
	Click on the <u>Home</u> button (🏠) to go to the home page *(ref. p6).*
	Click on the <u>Help</u> button (?) to directly lead you to the specific topic that is displayed on the screen within the User Manual.

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6.2 Standard users – Configuration (2) tab

Figure 11: Standard users - Additional settings

1	**Change your password using the <u>Password management</u> settings.**

2	**Change your print settings:**
	• *Check "Direct print" to display results and automatically print physician and patient reports after a successful scan. (Recommended setting)*
	• *Uncheck "Direct print" to display the results only. End user can print manually from the Physician report or Patient report tabs (ref. p50).*

3	**Change the report settings for the selected physician:**
	• *Activate or deactivate the duplication of comments on both reports.*
	• *Activate or deactivate the display of reports from previous patient scan (if any)*

6.2.1 Other controls

Click on the <u>Home</u> button (home) to go to the home page *(ref. p6).*

Click on the <u>Help</u> button (help) to directly lead you to the specific topic that is displayed on the screen within the User Manual.

6.3   Supervisor user – Additional list of controls

All settings that are available for standard users are also managed by a supervisor.
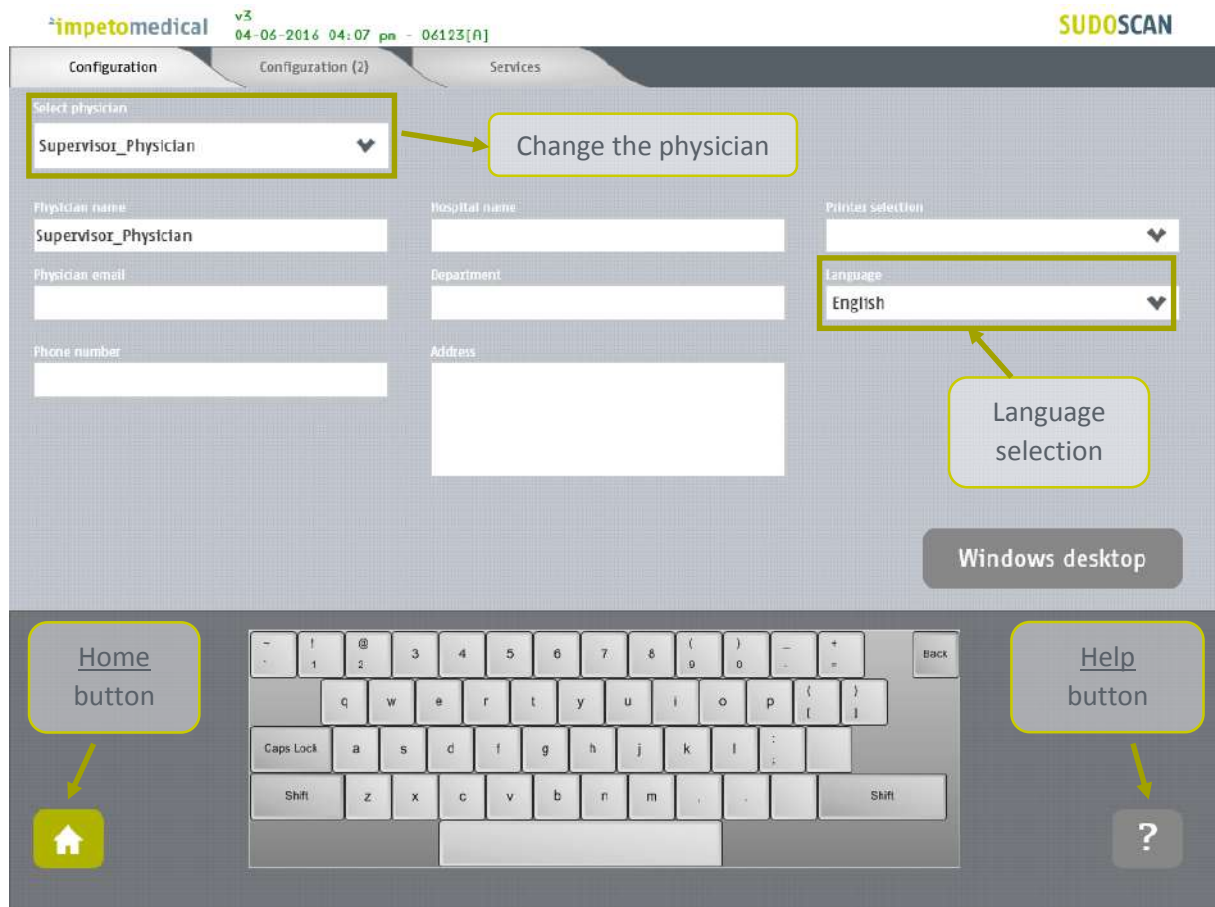
Figure 12: Configuration page - Additional controls for supervisor

1	Select the physician whose settings will be modified.
2	Select the language for the selected physician.
3	Click on Windows Desktop button to close the application and access the Windows OS desktop.

6.3.1   Other controls

	Click on the Configuration (2) tab to access supervisor settings *(ref. p20)*.
	Click on the Services tab to access additional services *(ref. p22)*.
	Click on the Home button (🏠) to go to the home page *(ref. p6)*.
	Click on the Help button (?) to directly lead you to the specific topic that is displayed on the screen within the User Manual.

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6.4 Supervisor user – Configuration (2) tab

Figure 13 : Supervisor users - Configuration (2) page

1	Select the physician whose settings will be modified.
2	Set the password for the selected physician and click on "Save Password".
3	Select the frequency of the Quality Check (a reminder will pop up if no Quality Check is run within the specified time frame).
4	Change the print settings for the selected physician: • *Check "Direct print" to display results and automatically print physician and patient reports after a successful scan (Recommended setting)* • *Uncheck "Direct print" to display the results only. End user can print manually from the Physician report or Patient report tabs (ref. p50).*
5	Change the mouse cursor settings: • *Check the box to hide the mouse cursor* • *Uncheck the box if you want to use a physical mouse.*
6	Change the report settings for the selected physician: • *Activate or deactivate the duplication of comments on both reports.* • *Activate or deactivate the display of reports for the previous scan (if any)*
7	Select the date format to apply for the selected physician. Default mode is MM/DD/YYYY.

8	**Select optional data for the selected physician (all options may not be available)**
	• *When "Date of birth" is not checked, only the patient year of birth is required.*

9	**Select the preferred measurement format (linked to the selected physician).**
	• *kg or lb (weight)*
	• *cm or ft/in (height)*
	• *cm or inches (waist)*
	By default the application displays height in feet/inches (feet/in) and weight in pounds (lb).

6.4.1 Other controls

Click on the <u>Configuration</u> tab to access the standard settings *(ref. p19).*

Click on the <u>Services</u> tab to access additional services *(ref. p22).*

Click on the <u>Home</u> button ( ) to go to the home page *(ref. p6).*

Click on the <u>Help</u> button ( ) to directly lead you to the specific topic that is displayed on the screen within the User Manual.

6.5 Supervisor user – Additional services
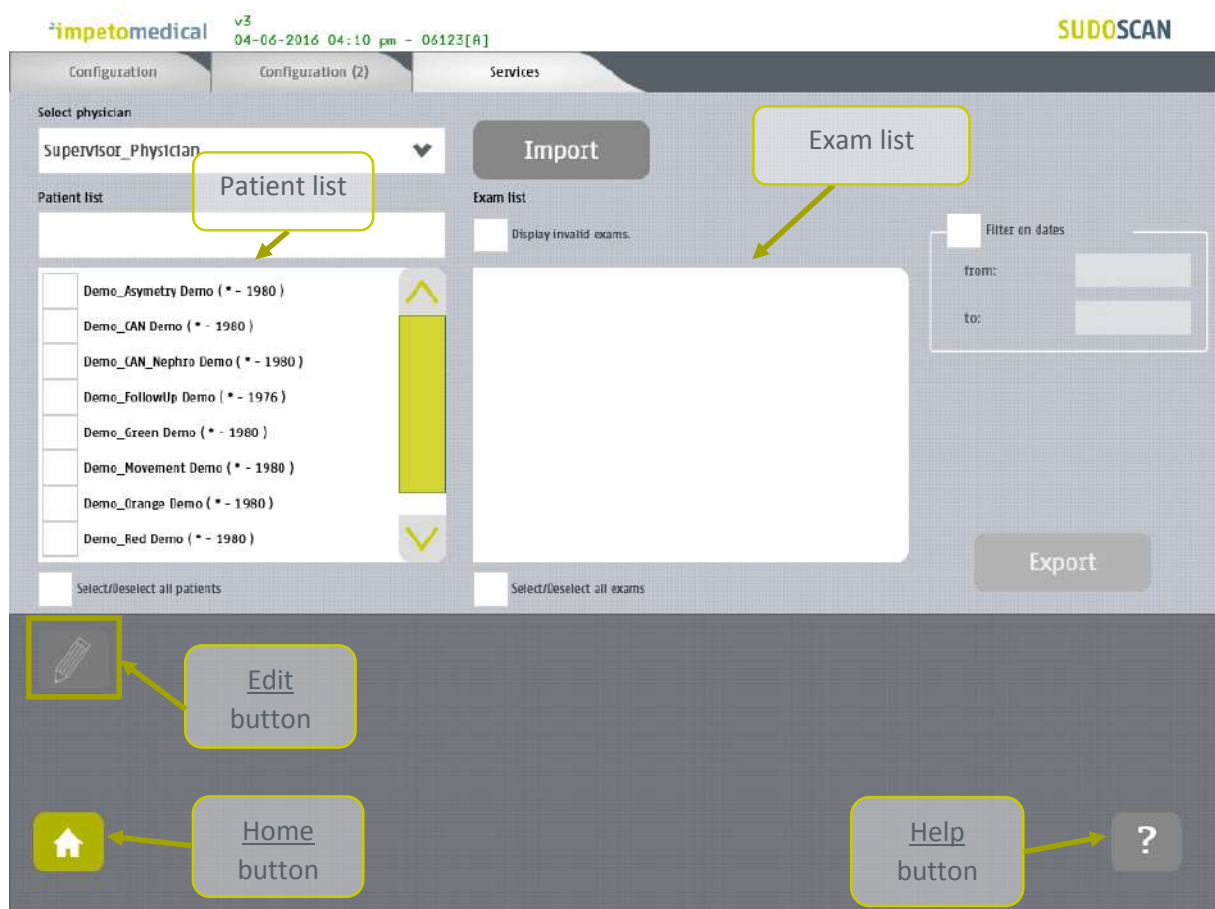
Figure 14 : Services page - Additional supervisor services

1	Select the physician whose patient scans you wish to view.
2	Click on the Import button to import data for the selected physician *(ref. p24).*
3	Select patients from the list. To do so, some tools are available: • *A filter for patient last name, first name, year of birth and patient identifier (PID)* • *A filter for dates ("from" and "to" dates)* • *An option to select/deselect all patients from the list*
4	Select exams from the exam list. To do, some tools are available: • *A filter for dates ("from" and "to" dates)* • *An option to select/unselect all exams from the list*
5	When at least one patient is selected, click on the Edit button to modify the data of the selected patient(s) *(ref. p29).*
6	Click on the Export button to export data attached to the selected patient(s) and exam(s) *(ref. p27).*

6.5.1 Other controls

Click on the <u>**Configuration**</u> **tab to access the standard user settings** *(ref. p19).*

Click on the <u>**Configuration (2)**</u> **tab to access supervisor settings** *(ref. p20).*

Click on the <u>**Home**</u> **button (** **) to go to the home page** *(ref. p6).*
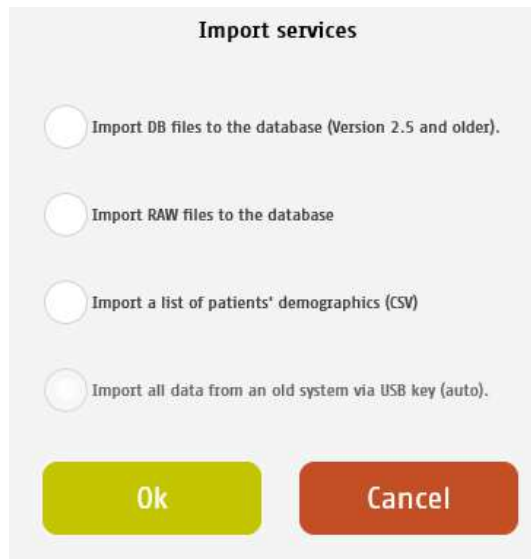
Click on the <u>**Help**</u> **button (** **) to directly lead you to the specific topic that is displayed on the screen within the User Manual.**

6.6 Import data for a selected physician

1 **Insert a virus free USB key containing the data to import.**

2 **Click on the Import button. A popup window appears to select the type of data you want to import:**

You can select several types of data:

- *Import DB files: these are the raw data on older Impeto Medical systems (2.xx version).*
- *Import Raw files: these are the raw data on Impeto Medical systems since 3.1 version.*
- *Import a list of patients from a CSV file use the proposed template to ensure compatibility with the system (ref. p61).*
- *Import all data from an old system via USB key (auto) : Import automatically data from older systems from a USB key. This option is only available if the database from the system is empty.*

3	Verify that the USB key is correctly plugged into the system and select if you want to import files or a complete folder:
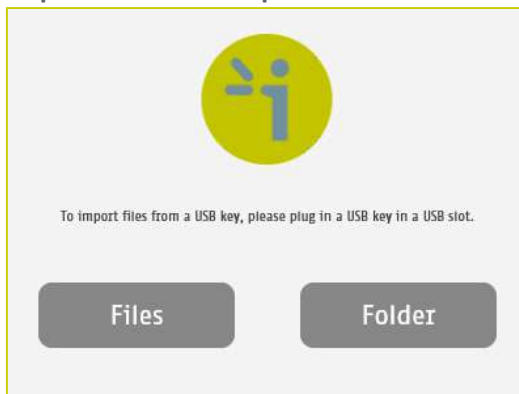
4	Click OK and select files to import:
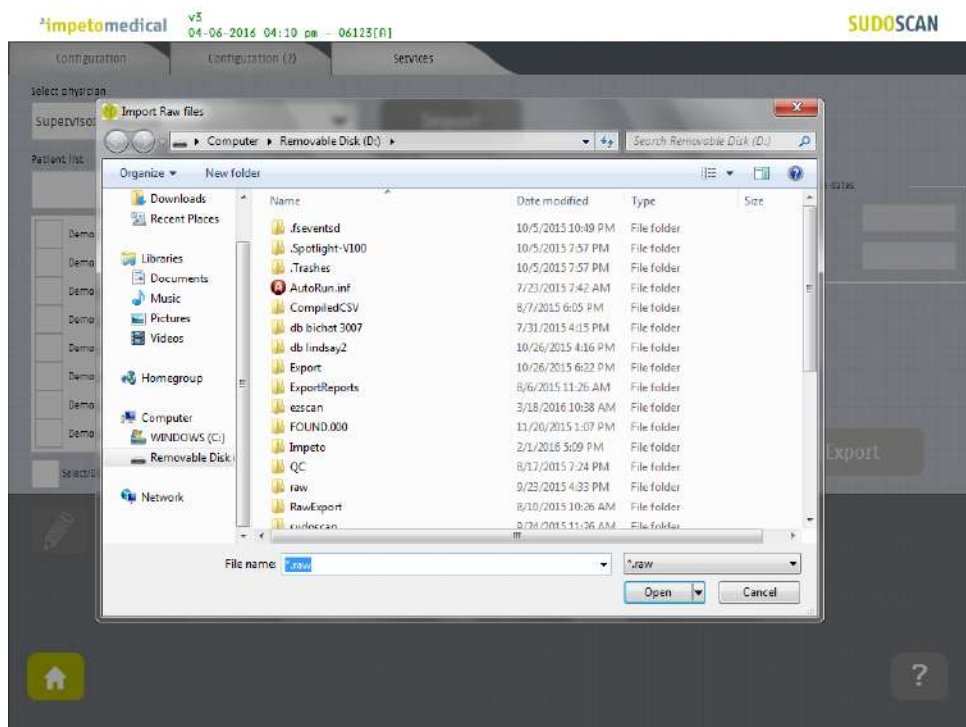
5	The files are importing.

6   **The import is complete.**

Imported successfully

OK
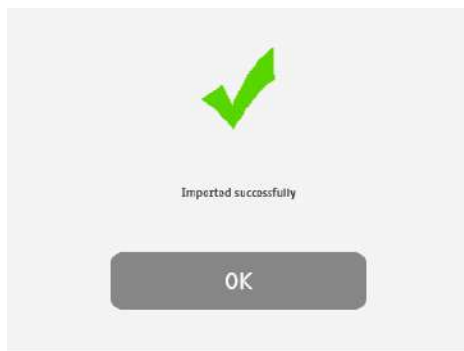
7   **The list of patients is updated with the new data.**
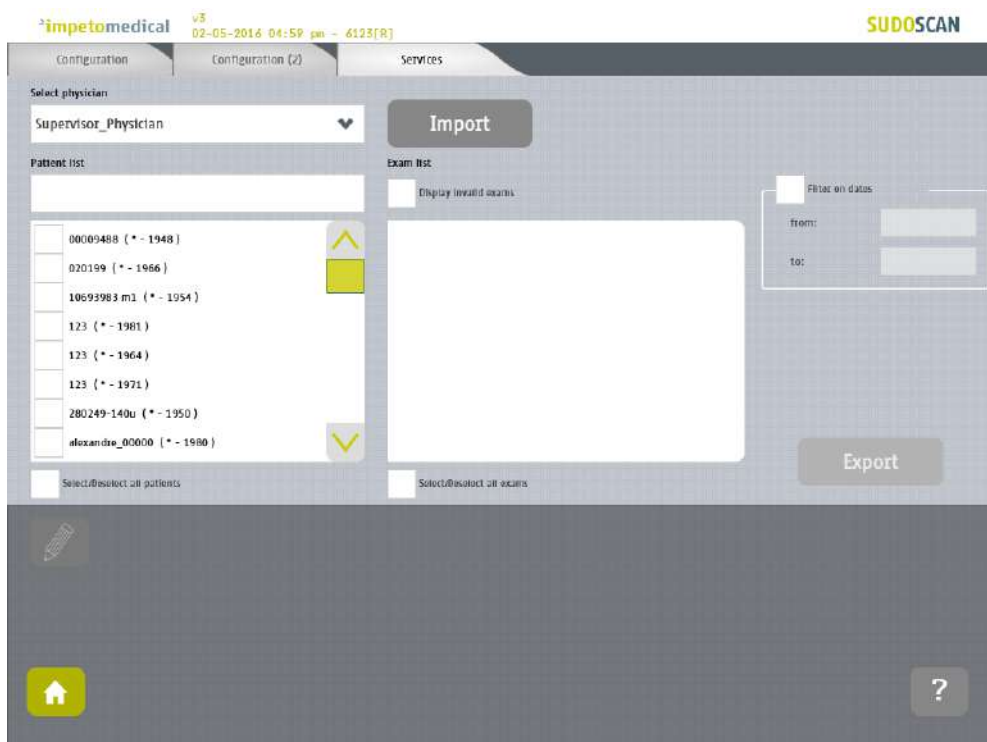
6.7   Export data to a USB key for a selected physician

| **1** | **Insert a virus free USB key with sufficient available space (100 scans ~ 25MB).** |

| **2** | **Select patient(s), exam(s) *(ref. p22)* and click on the <u>Export</u> button. A popup window appears to select the type of data you want to export:** |

You can select several types of data:

- *Compile and export a CSV file: including all data for the selected exams. The encryption of patient names is optional (reversible, irreversible or none).*
  Stored within the /CompiledCSV/ folder on the USB key.
- *Export Raw files: These are the raw data files export, useful when switching from one Impeto system to another.*
  Stored within the /ExportRaw/ folder on the USB key.

3	Click on __OK__ and verify that the USB key is correctly plugged into the system:

Please plug in the USB key on which you wish to export data first and then click OK.

OK

4	Click on __OK__ and the files begin to export:

Exporting data 18/33.

Cancel export
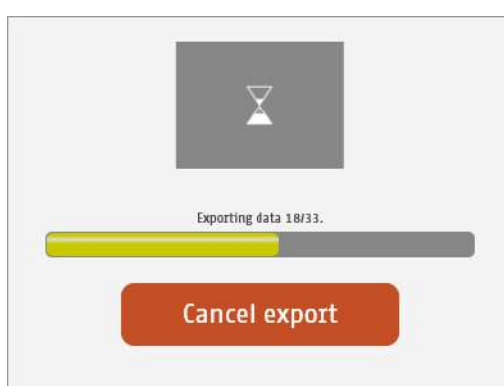
5	The export is complete.

Data successfully exported on USB

OK
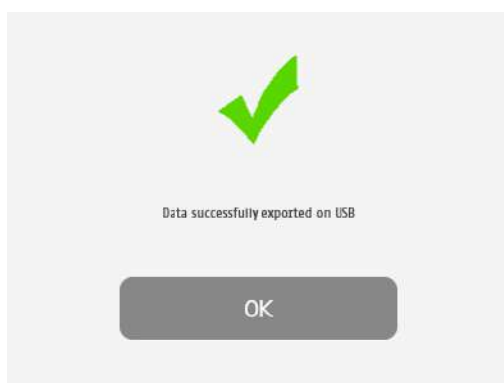
When the export is complete, the data is on the USB key. For the RAW file export process, when a file is missing, a new text file (MissingFiles.txt) is created on the USB key and contains the list of missing files.

Backup data on a regular and frequent basis.

6.8 Patient reconciliation & patient demographic data modification

This feature is also available for standard users when it's been enabled by a supervisor (option "Enable patient modification", ref. p20).

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1 **Select one or several patients** *(ref. p22)* **and click on the** <u>Edit</u> **button.**

---
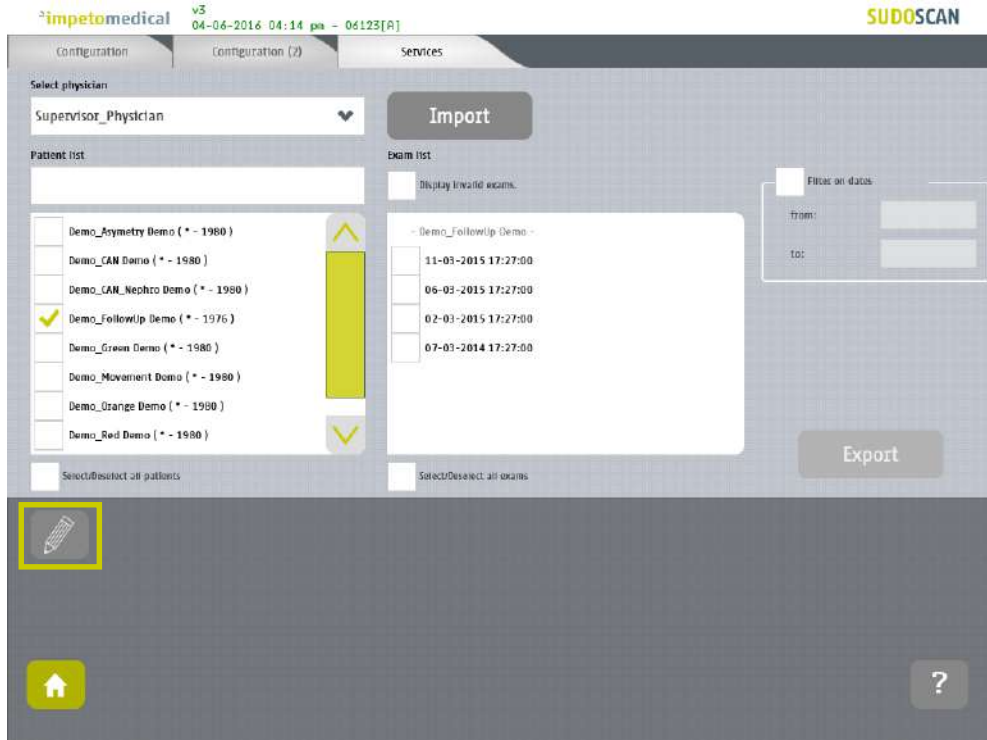
2 **When only one patient is selected, a popup window is displayed to modify the demographic data of the selected patient (last name, first name, date of birth, patient ID and ethnicity):**
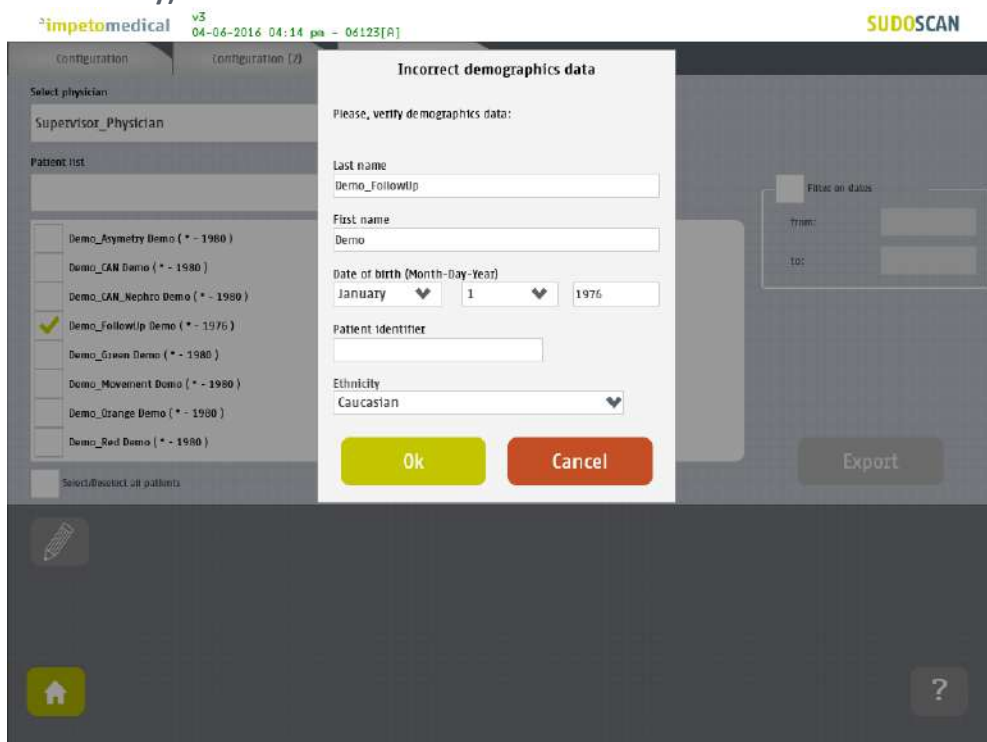
3   When several patients are selected, a popup window is displayed to merge several patients into one patient (exam data):
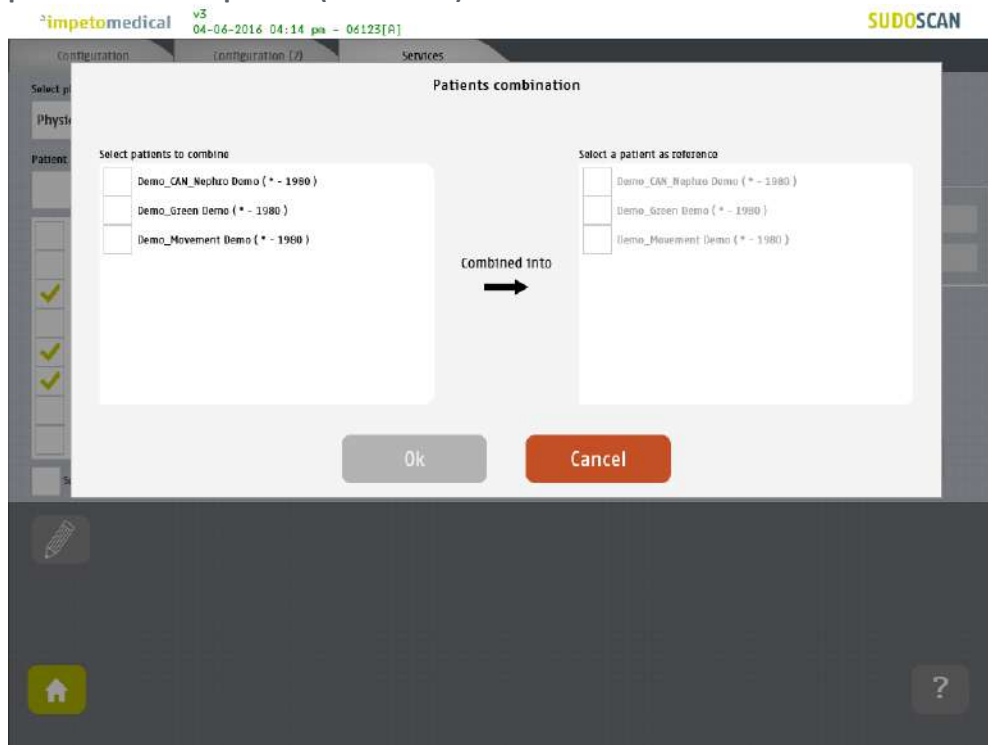
4   Select the patients to merge from the list on the left, and the reference patient from the list on the right:
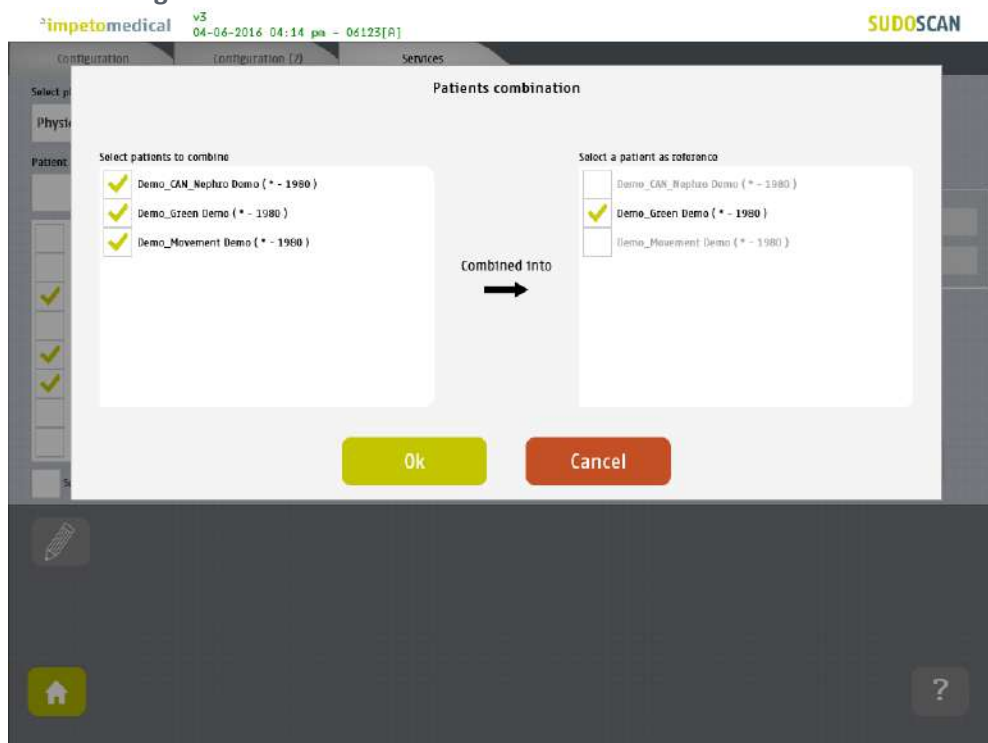
5   **Click on OK to validate: all the data for the selected patients will be combined and updated with demographic data from the reference patient.**
The list of patients is then updated on the Services screen.

7 Scan pages

If a patient does not already exist in the system, then select the New Patient button on the Home screen *(ref. p6)* and fill in demographic data for the patient.

7.1 List of controls

Figure 15 : Patient page

1	After entering the mandatory patient data (indicated by *), the Scan button becomes available and the user can start a scan with a patient firmly situated onto the stainless steel plates *(ref. p33 to setup patient's demographic information and start a scan)*. *Required data are based on enabled options.*
2	Click on Clear patient data to clear all patient data fields.

7.1.1 Other controls

Click on the Home button (🏠) to go to the home page *(ref. p6)*.

Click on the Help button (?) to directly lead you to the specific topic that is displayed on the screen within the User Manual.

7.2   Patient setup & starting a scan

1   Set the patient's demographic information.

Enter data by clicking on the corresponding text box, which will make the on-screen keyboard appear:

- *Last Name and/or Patient ID (IDENTITY CODE)*
- *First name*
- *Age or Date of birth (10 to 109 years). This option can be modified by a supervisor (ref. p20)*
- *Select the appropriate Ethnicity. This option can be enabled by a supervisor (ref. p20)*
- *Select the appropriate Gender*
- *Weight (10 to 199 kg OR 22 to 438 lbs)*
- *Height (100 to 249 cm OR 3 ft 3 ins to 8 ft)*
- *HbA1c (x10, 40 to 199 mmol/mol).*
- *Enter comments in the Additional comments field if necessary*

NOTE

It is also possible to use any standard PC-compatible keyboard when connected to one of the USB ports available on the Master Unit.

NOTE

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.

2   When all required fields have been entered, the scan button turns green as follows:

Scan

If all required fields have not been entered, the scan button is greyed out and cannot be selected:

Scan

⚠ WARNING

The use of USB ports during a scan can lead to a system blocking issue. Please, do not try to plug or unplug USB device on the system during a scan.

3 If required fields are left empty and the <u>Scan</u> button is selected, then all missing fields will be highlighted in red.

Figure 16: Scan page - Highlighting of empty required fields

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3 Click on the <u>Scan</u> button to start the scan *(ref. p32)*.

THE PATIENT MUST NOT TOUCH THE MASTER UNIT.
DO NOT TOUCH THE PATIENT DURING THE SCAN.

7.3 What if the scan cannot be launched

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

- Please check that the sensor plates are correctly inserted within their dock respectively (ref. p56 to see how to insert a sensor plate within a dock). Also, check that the sensor plates were not inverted between hands and feet docks.
- Please check that the dock are correctly plugged on the system and reboot the system.
- If the issue persists, please contact **Impeto Medical** technical services

> **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 Services (ref. p77).

7.4 During the scan

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

> **NOTE**

A Calibration is performed at the beginning of each scan.
The patient is asked to remain still during the scan.
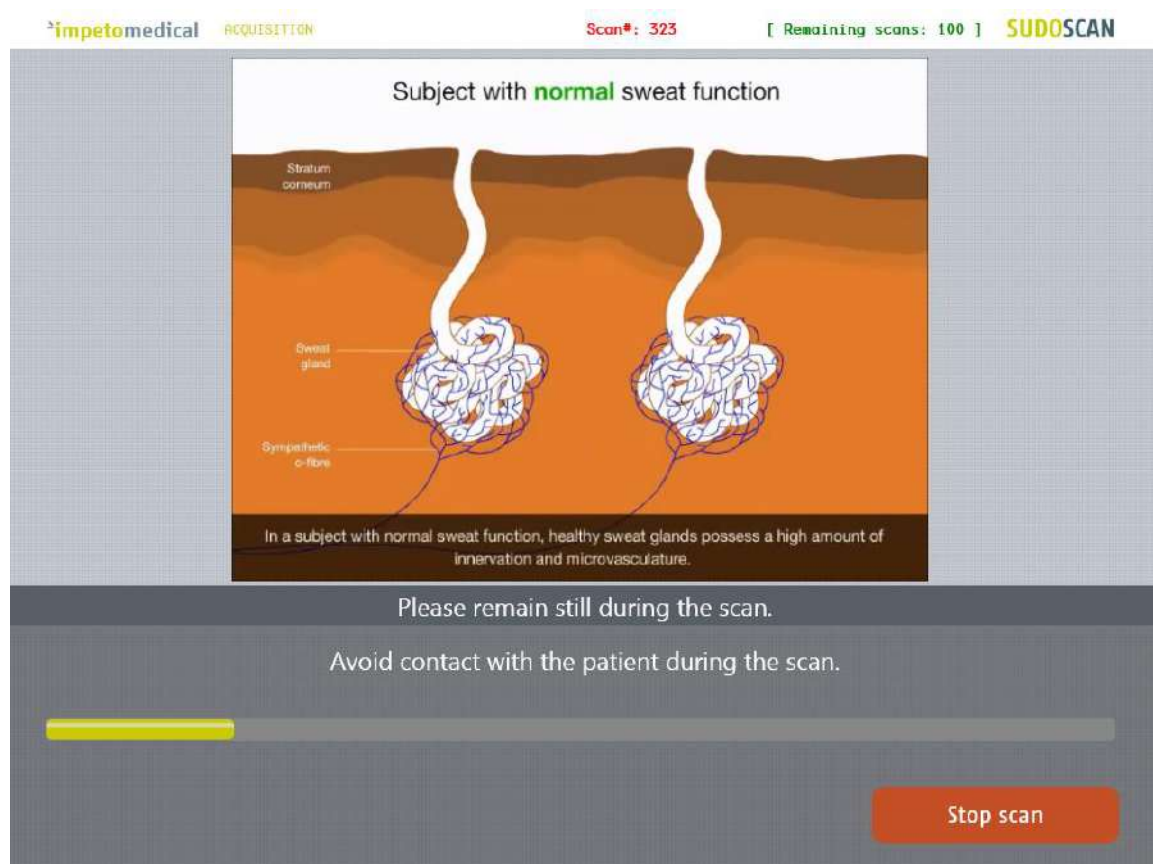
Figure 17: Acquisition

2   **If hand or foot contact on the sensor plates is lost during the calibration, an error message will appear on the screen.**

3   **The scan can be cancelled at any time by selecting the <u>Stop scan</u> button.**

4   **Scan completion is confirmed by a double-bell sound (unless muted).**
- *Upon successful completion of the scan, the scan number (#) will increase by 1 and the remaining scans for the smart electrodes will decrease by 1, as shown in the upper right hand corner of the screen.*
  The results page is displayed once the scan successfully ends (ref. p46).
- *If the scan ends with an issue, the application proceeds to the results page but the remaining scans will not decrease by 1, except if the scan is validated by the user (ref. p47)*

5   **Desinfect the electrodes after each scan with the manufacturer approved cleaning solution and Kim Wipes (KIMTECH Science Brand)*(ref. p53)*.**

8 Patient History page

To retrieve data for exams and patients, click on the <u>Patient History</u> button on the Home screen *(ref. p6)*.

8.1 List of controls
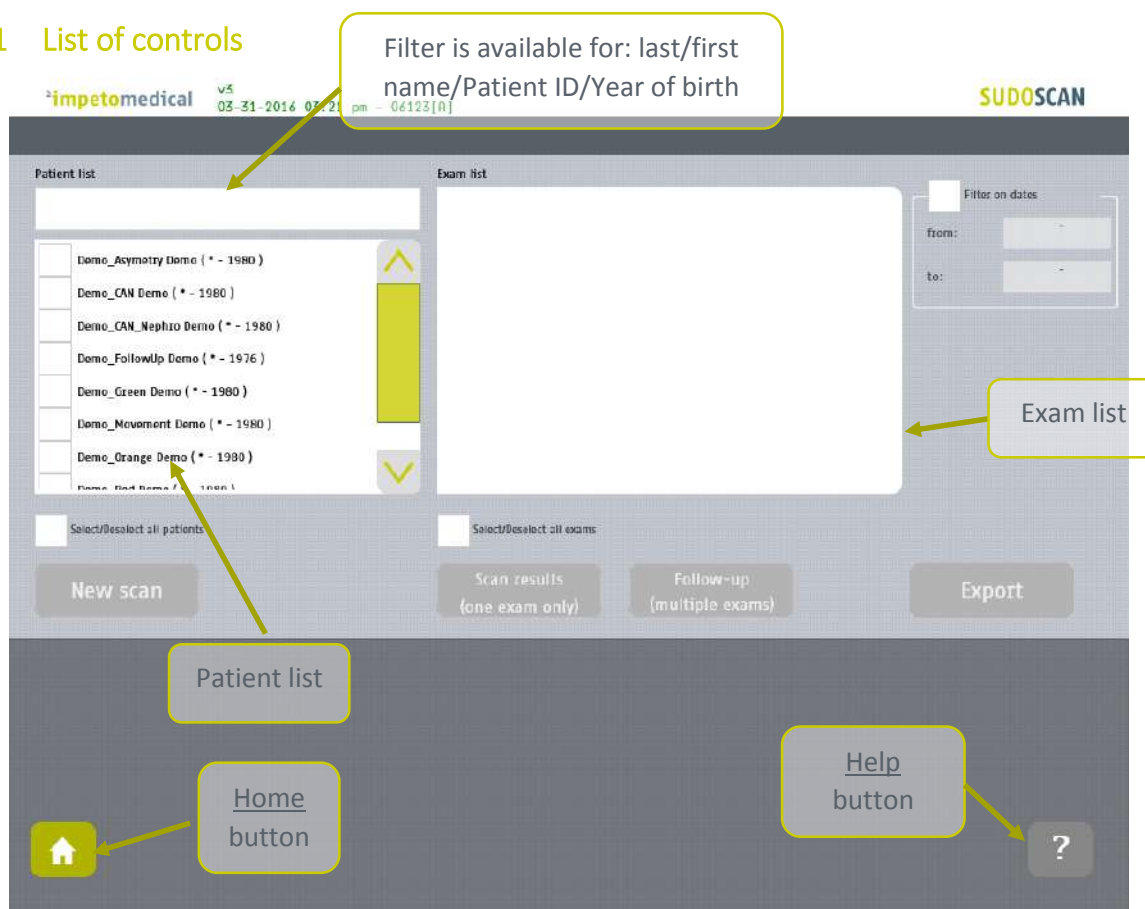
Figure 18 : Patient History page

1	**Select patients from the Patient list and exams from the Exam list** *(ref. p38)*.
2	**Start a <u>new scan</u> for the selected patient** *(ref. p40)*.
3	**Display the <u>results</u> for the selected exam** *(ref. p40)*.
4	**Display the <u>follow-up</u> screen for the selected exams** *(ref. p41)*.
5	**<u>Export</u> or print data and reports for the selected exams** *(ref. p43)*.

8.1.1 Other controls

Click on the <u>Home</u> button (🏠) to go to the home page *(ref. p6)*.

Click on the <u>Help</u> button (?) to directly lead you to the specific topic that is displayed on the screen within the User Manual.

8.2 Selecting patient(s) and exam(s)

To select a patient or an exam, select the corresponding checkbox.

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1   Use the filter to sort through the patient list by last name, first name, year of birth or patient ID.

---
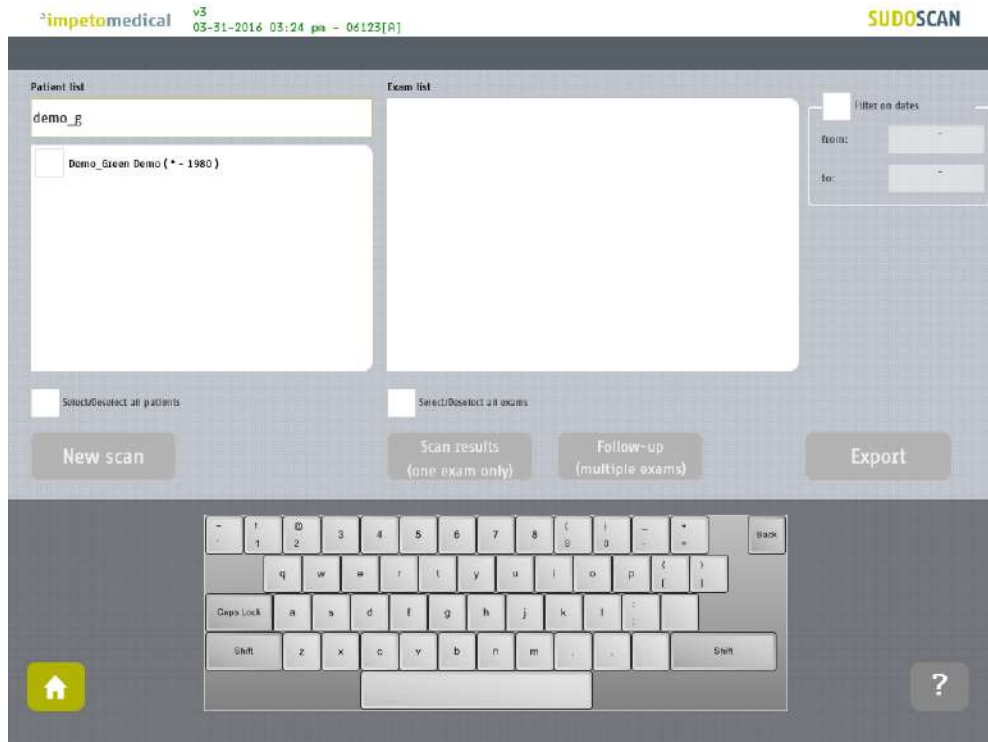
2   Select the patients from the patient list.

3   Use the date filter to display exams for a period of time

The previously selected patients are separated in two categories based on whether or not they have exams corresponding to the date filter ("Filtered patients" or "Selected patients"). Then, the list of exam is updated according to the date filter.

8.3   How to start a new scan for a patient

Select a patient (only one) and click on the **New scan** button *(ref. p32)*:
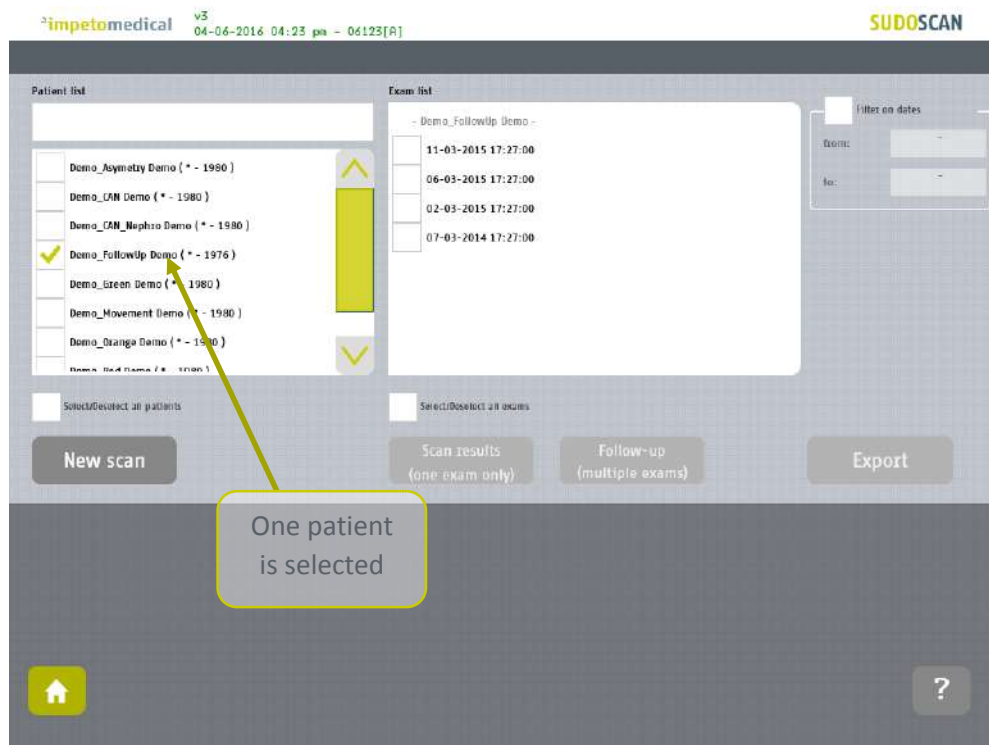
Figure 19: Start a new scan for an existing patient

8.4   How to display results for a single exam

Select a patient and an exam from the exam list and click on **Scan results** button *(ref. p46)*:
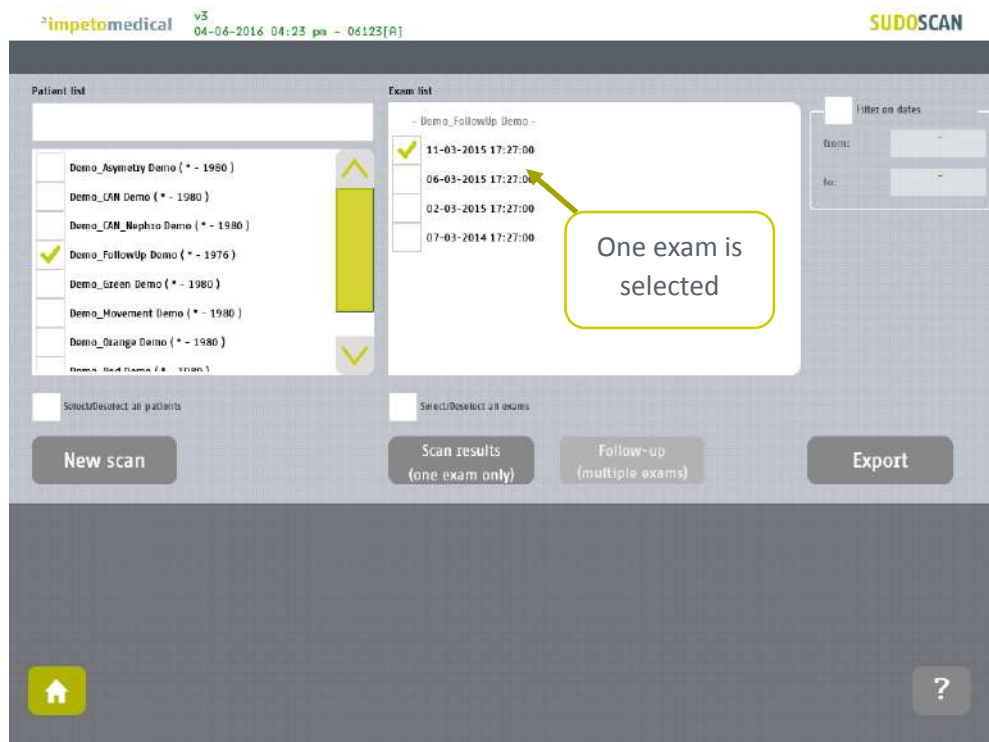
Figure 20: Display results for an exam

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8.5   How to display follow-up for a patient

1   Select several exams for one patient and click on the <u>Follow-up</u> button:
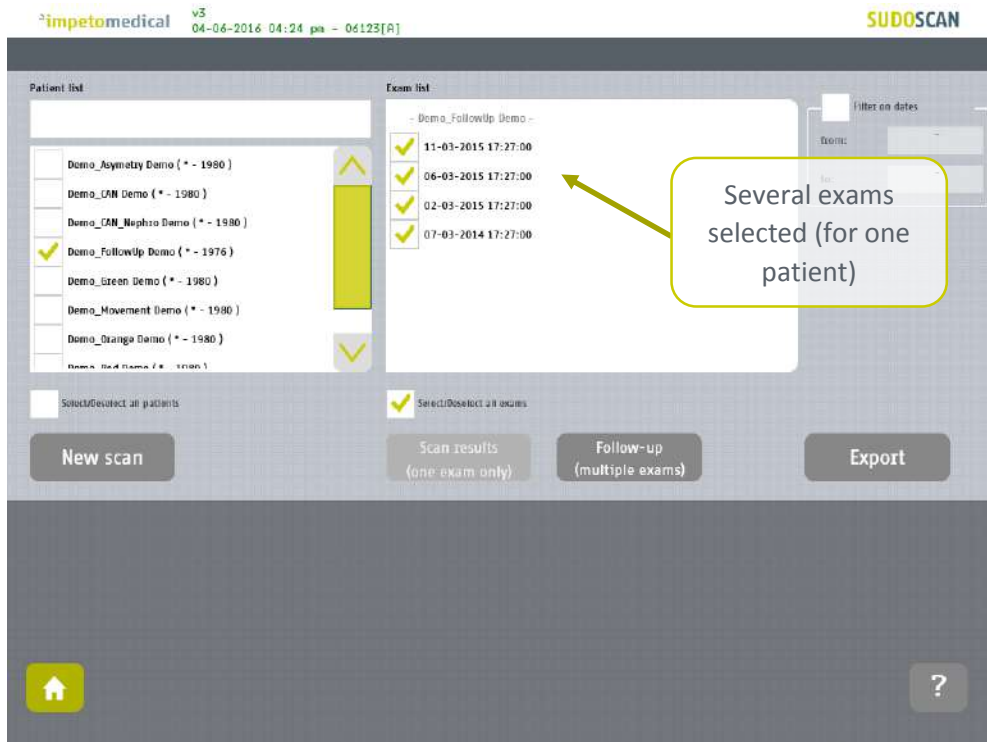
Patient follow-up is displayed when at least 2 exams are selected for the same patient. The device can display up to 15 exams.

2   Click on the <u>follow-up</u> button.
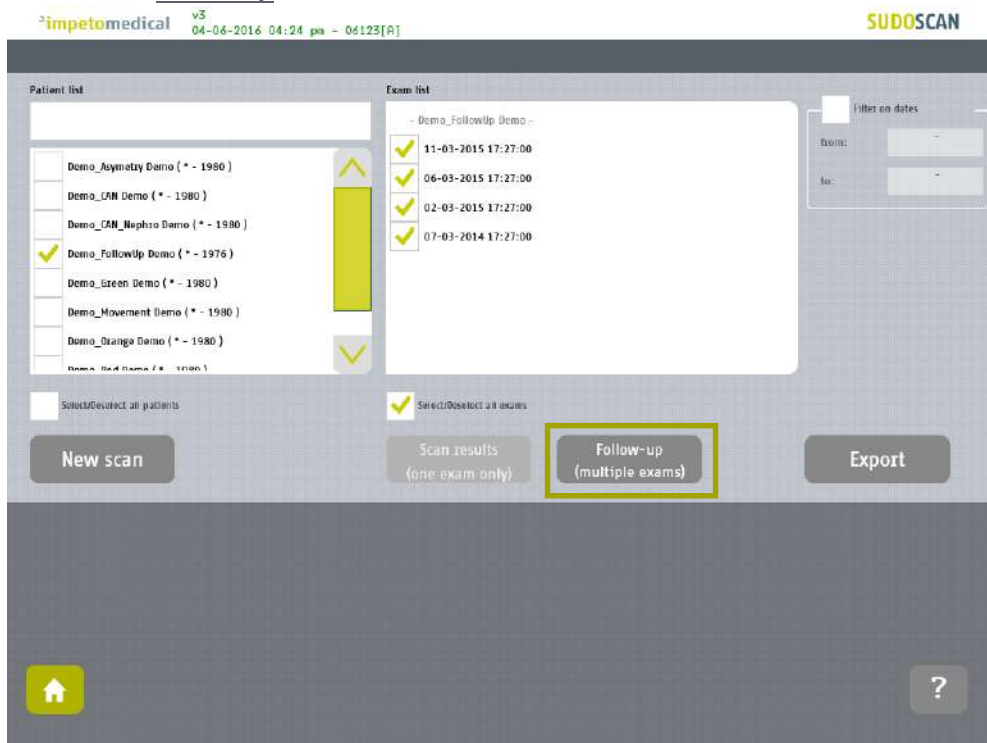
3   **The follow-up screen is displayed.**
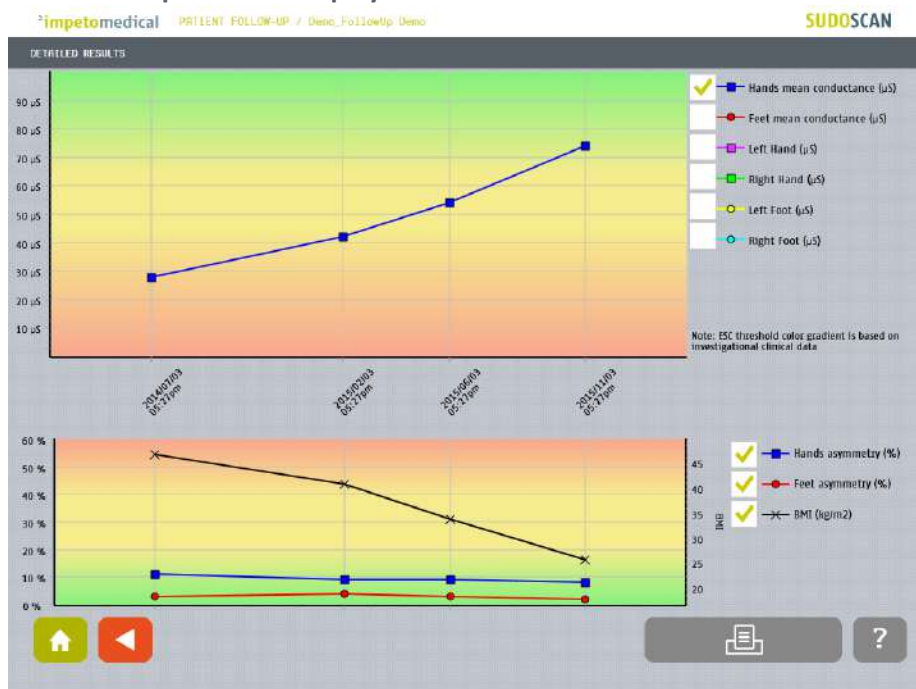
The top graph shows the progression of conductances. It is possible to display the evolution of individual hand and feet (left and right) conductances as well as mean conductances.
The bottom graph shows asymmetry (hands and foot) and the Body Mass Index (BMI).
The user is able to modify how the graphs are depicted by selecting the checkboxes on the right.

4   **Click on the Print button to print the follow-up report:**
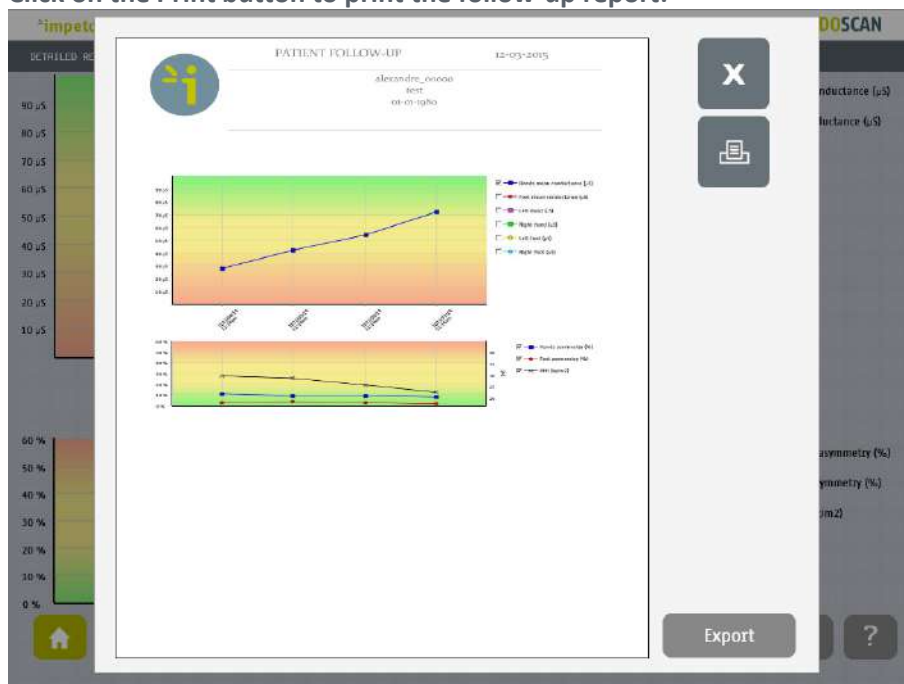
The PDF report is generated and stored within the system. To print the report, select the printer from the list (ref. p17 and 19) and click on the <u>Print</u> *button.*
To export the report to a USB key, click on the <u>Export</u> *button and follow the on-screen instructions.*

8.6   How to export data

1   Select patient(s) and exam(s) and click on the Export button:
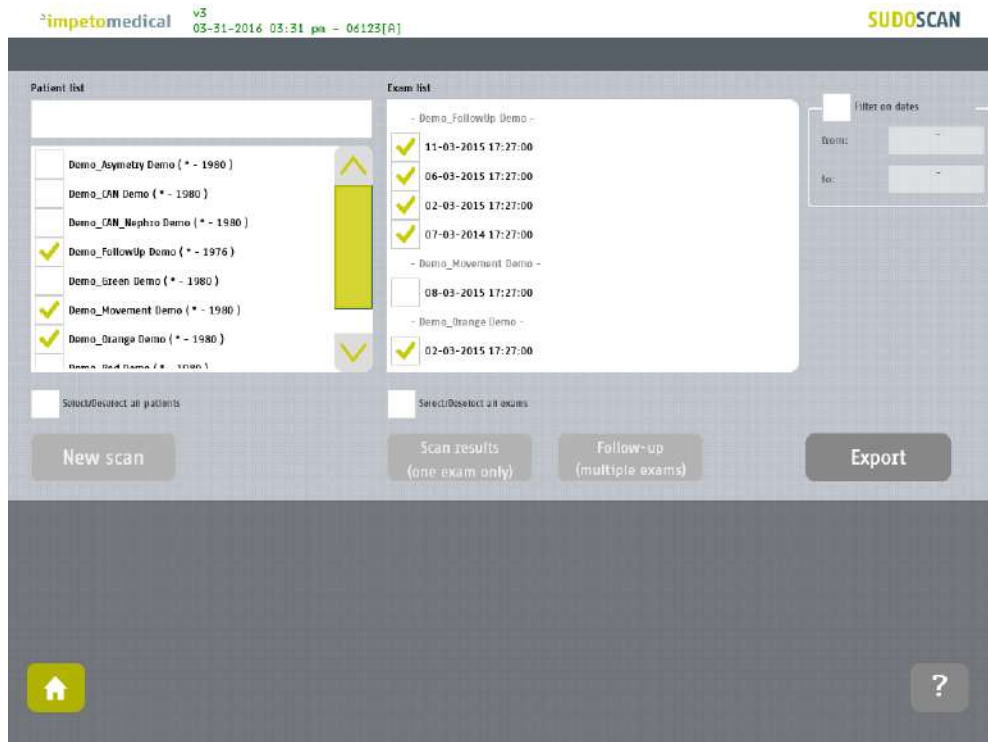
2   Select an option:
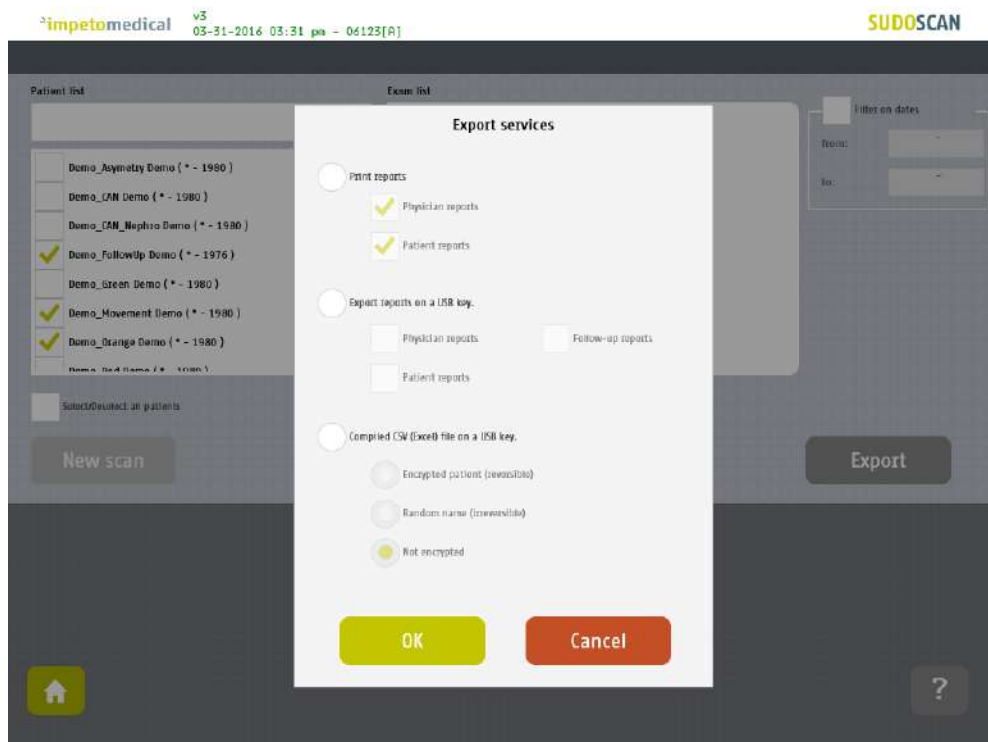
The different options are described as follows:

- *Print reports: Select the type(s) of reports to print e.g. physician and/or patient reports. Then, the reports for the selected exams will be printed if a printer was selected from the settings.*
- *Export the reports to a USB key: The options to export different reports (physician, patient and/or follow-up) for the selected exams to an external USB key.*
  Stored within the /ExportReports/ directory on the USB key.
- *Compile CSV (Excel) file on a USB key: This includes the entire report results for the selected exams. The option to encrypt patient identifiers is available within the following formats: reversible, irreversible or none.*
  Stored within the /CompiledCSV/ directory on the USB key.

| 3 | **Click OK and in the case of export, verify that the USB key is free of viruses and correctly plugged into the system:** |

Please plug in the USB key on which you wish to export data first and then click OK.

OK
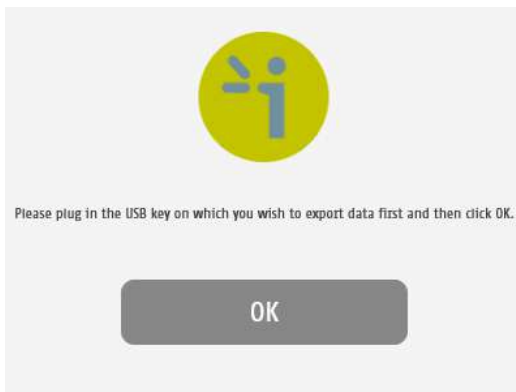
| 4 | **Click Ok and the files begin to export onto the USB.:** |

Exporting data 18/33.

Cancel export

The export is complete.

> **Data successfully exported on USB**
>
> **OK**
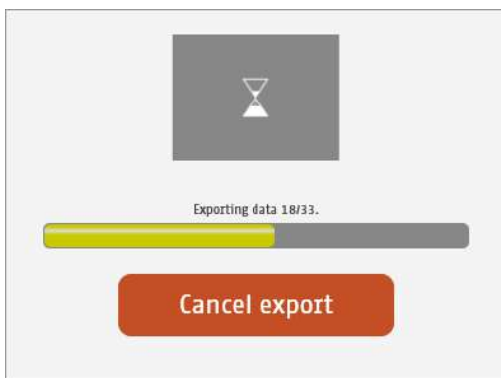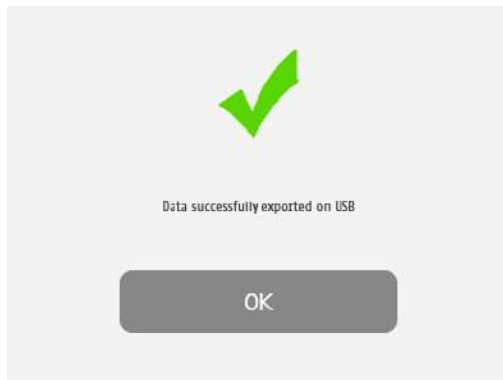
When the export is complete, the data is on the USB key. For the report files export, when a file is missing, a file (MissingFiles.txt) is created on the USB key and contains the list of missing files.

IMPORTANT

Backup data on a regular and frequent basis.

9 Results page

9.1 List of controls

Figure 21: Patient results page

Click on the <u>Patient Results</u> tab to view the on-screen results.

Click on the <u>Physician Report</u> tab to go to the Report page (*ref. p50*).

Click on the <u>Patient Report</u> tab to go to the patient report.


9.1.1 Other controls

Click on the <u>Home</u> button (🏠) to go to the home page *(ref. p6).*

Click on the <u>Help</u> button (?) to directly lead you to the specific topic that is displayed on the screen within the User Manual.
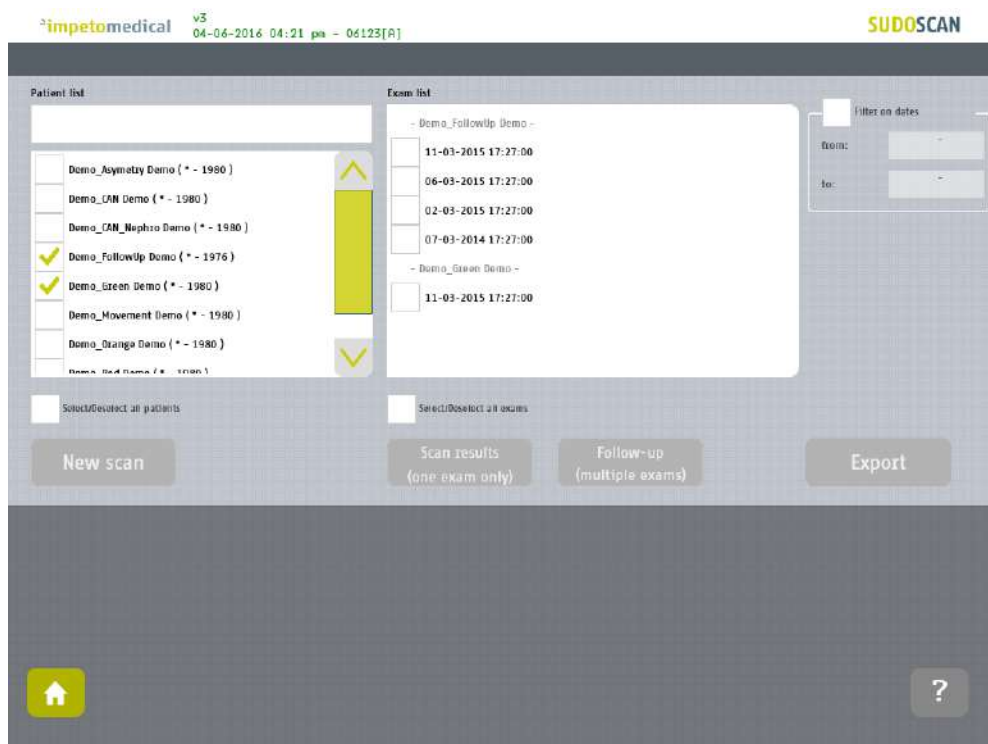

Click on the <u>Go back</u> (◀) button to go back in the application.

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9.2 Results

The SUDOSCAN 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). Results should be interpreted by a physician, taking into account the patient's clinical history.

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

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

9.2.2 Quality of Measure
If the patient moves during the scan, the following message appears on the screen:
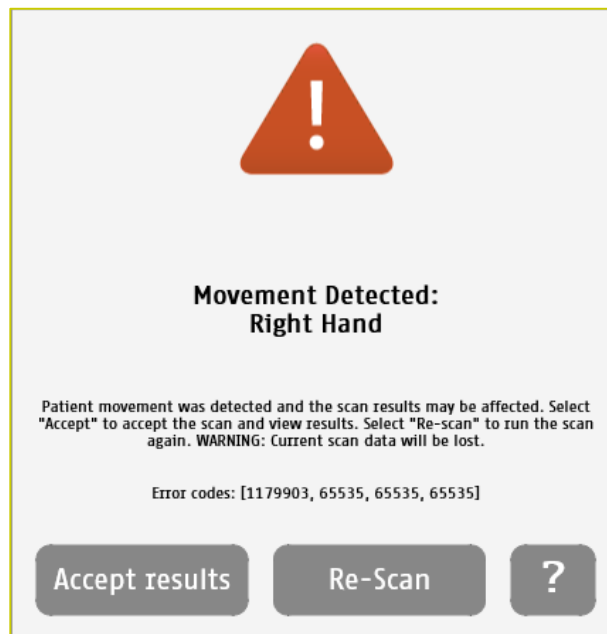
The user is given the opportunity to accept the results or re-scan the patient. Selecting **Accept** will allow the current results to be saved as is within the patient's follow-up. The report will be generated with a note stating that the patient moved during scan and that results may be compromised.

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

NOTE

When performing a Re-Scan, the number of remaining scans will not be decreased unless the user accepts the scan results with the observed error or the scan is performed anew.

NOTE

Electrodes must be disinfected before re-scanning the patient with manufacturer approved disinfectant and Kim Wipes.

During the scan, if the following image is observed, then the patient is either grounded (touched during the scan) or an internal issue may have transpired.
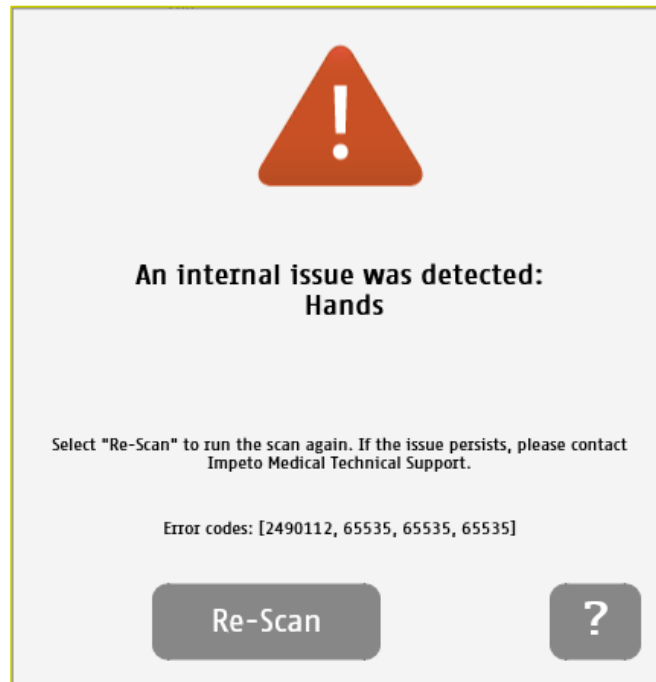
Selecting the **Re-Scan** button will prompt the current scan to be cancelled. The user will be returned to the scan page to start a new scan. If the issue persists, please contact **Impeto Medical** Technical Support *(ref. p77).*

NOTE

When performing a Re-Scan, the number of remaining scans will not be decreased until the user is able to perform a scan without errors.

9.2.3 Note on graphs and ethnicity

An option to indicate the patient ethnicity before the scan can be set by a supervisor (*ref. p20*). Disabling this option may modify the graphs' appearance, but will not affect results.

When Ethnicity is disabled or when set to "Other" on the scan screen, the graphs appear as follows:
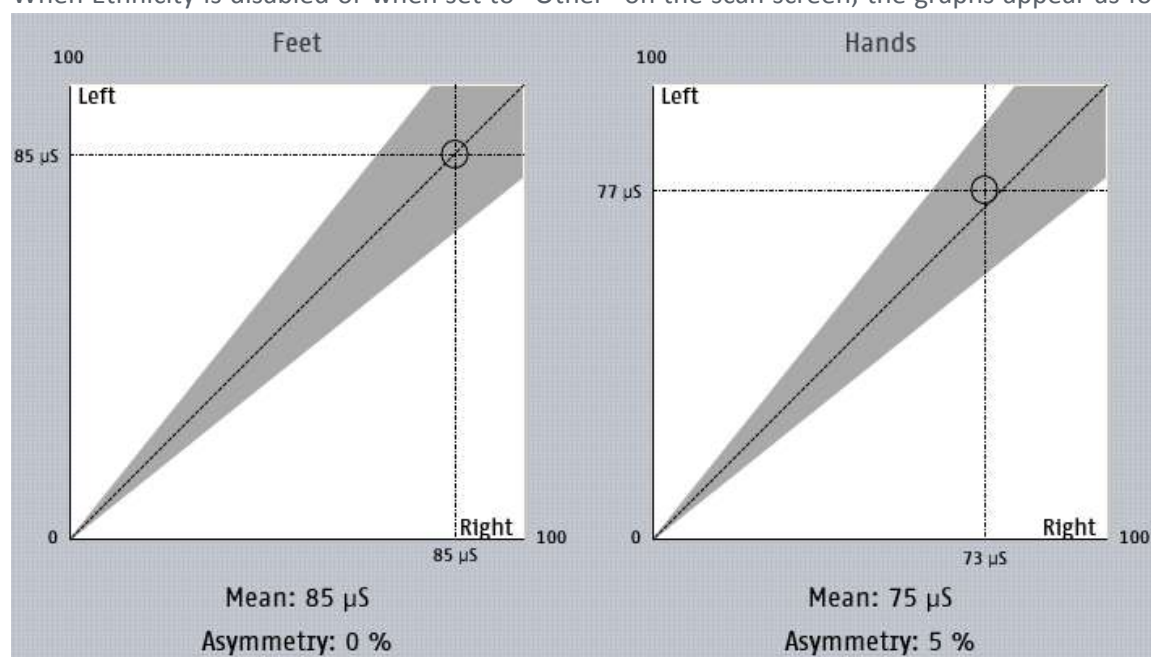
Figure 22: Patient results page - Ethnicity option disabled or set to "Other"

When ethnicity is enabled and not set to "Other", the graphs are displayed as follows:
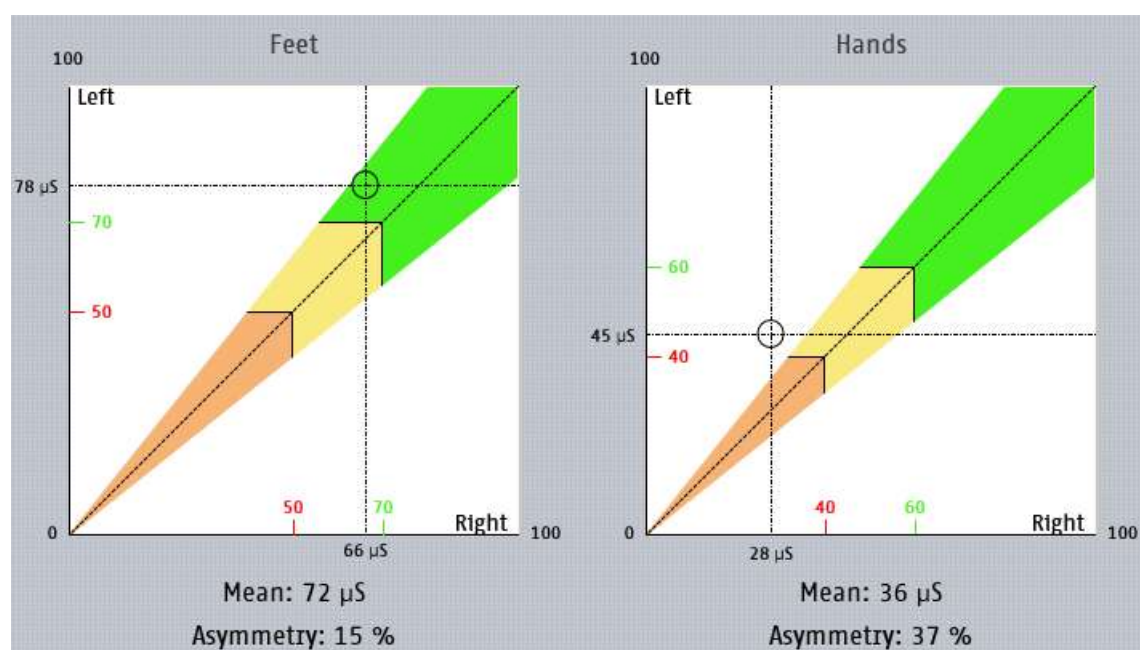
Figure 23: Patient results page - Ethnicity option enabled and not set to "Other"

Thresholds are depicted in different colors and are provided for investigational use only.

10 Physician and Patient Report screens

10.1 Physician report
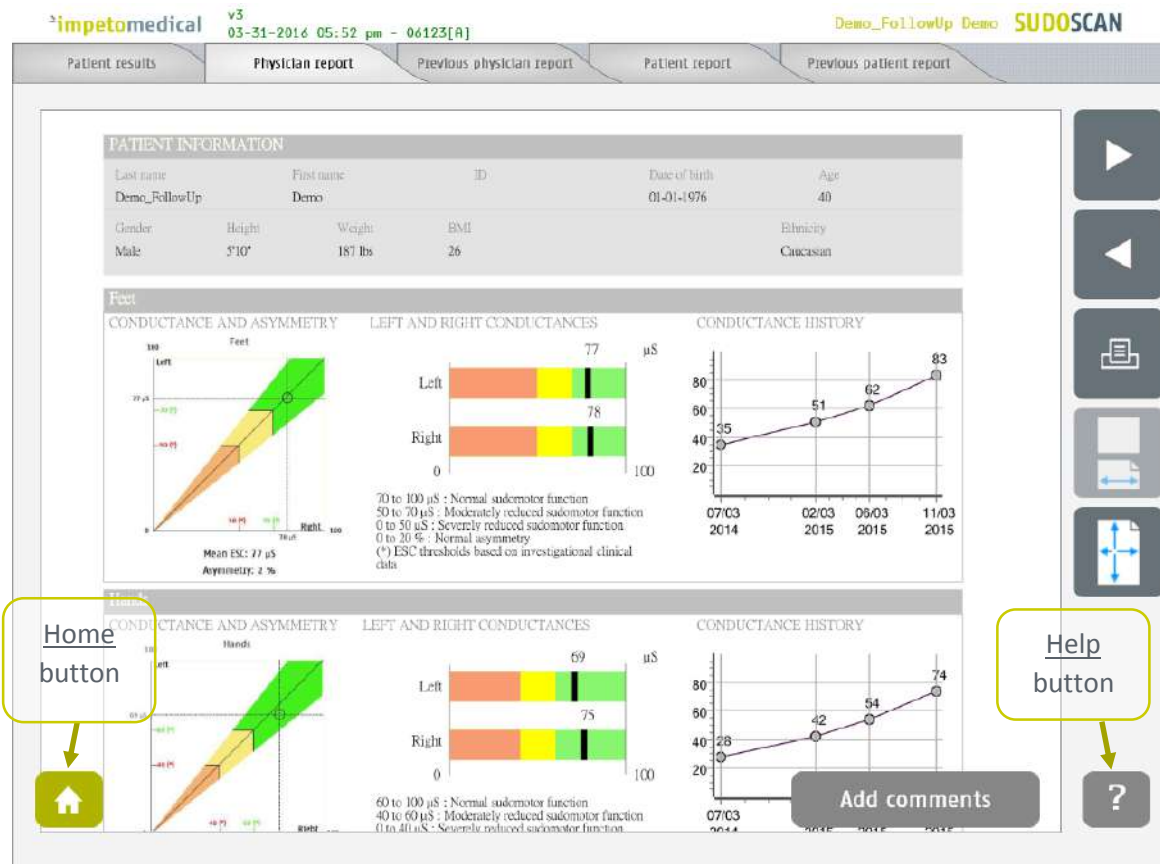
Figure 24 : Physician Report page

1	Click on the <u>Patient Report</u> tab to view the patient report.
2	Click on the <u>Patient Results</u> tab to view the results *(ref. p46)*.
3	To navigate pages within the report (▶ and ◀ buttons)
4	Click on the <u>Print</u> button to print the report.
5	Click on the <u>zoom</u> buttons to display a full-page view or page-width view
6	Click on <u>Add comments</u> button to enter new comments on the physician report.

10.1.1 Other controls

Click on the <u>Home</u> button (🏠) to go to the home page *(ref. p6)*.

Click on the <u>Help</u> button (?) to directly lead you to the specific topic that is displayed on the screen within the User Manual.

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10.2 Patient report

Figure 25: Patient Report page

1	Click on the Physician Report tab to view the physician report.
2	Click on the Patient Results tab to view the results *(ref. p46)*.
3	To navigate pages within the report (▶ and ◀ buttons)
4	Click on the Print button to print the report.
5	Click on the zoom buttons to display a full-page view or page-witdh view
6	Click on the Add comments button to enter new comments on the physician report.

10.2.1 Other controls

Click on the Home button (🏠) to go to the home page *(ref. p6)*.

Click on the Help button (?) to directly lead you to the specific topic that is displayed on the screen within the User Manual.

NOTE

When the option is enabled via additional settings *(ref. p18 and 20)*, the reports from the most recent exams is displayed next to the new ones.

10.3 Add comments to physician and/or patient reports

While the user is visualizing the report, it is possible to add comments and select medication from a list.
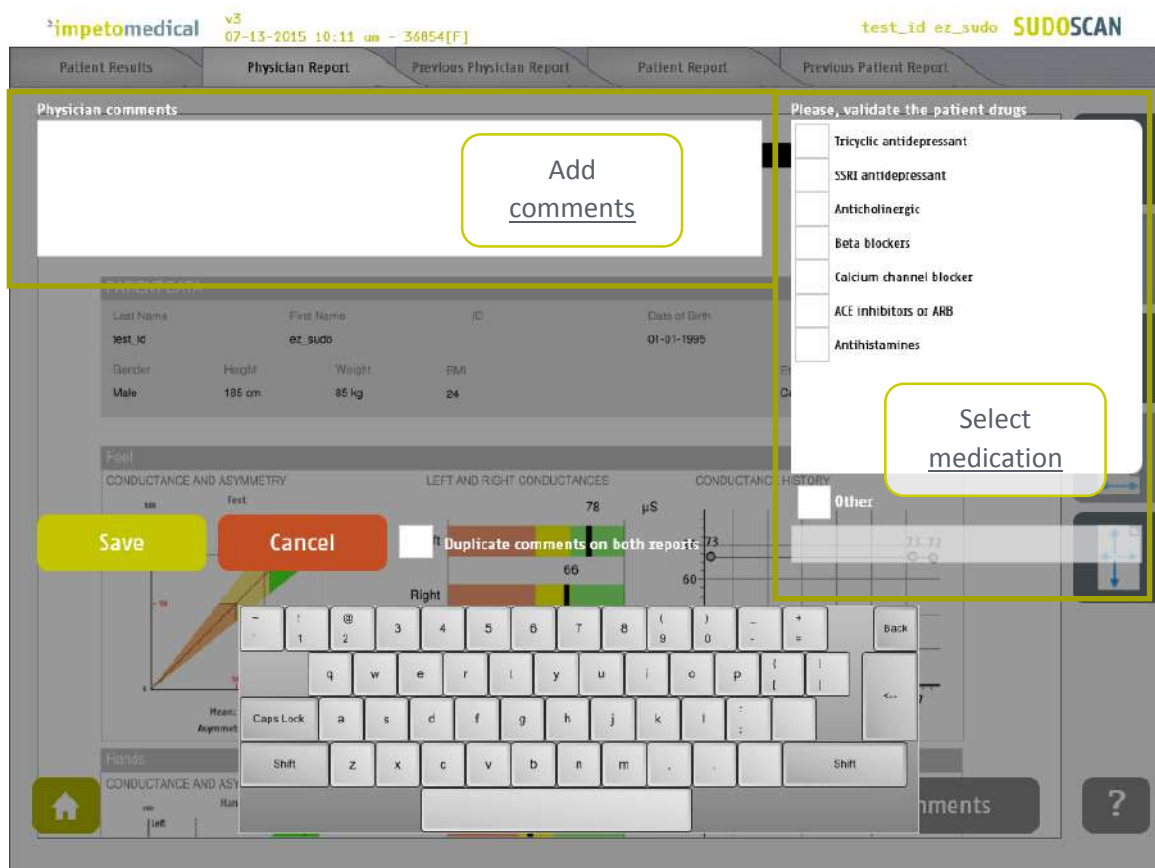
Figure 26: Add comments on reports

1	Add comments to the selected report (physician or patient).
2	Select medications from the list or add medication using the Other text field.
3	The option to duplicate the comments on both the Physician and the Patient reports.
4	Save comments and regenerate the report(s) or cancel the changes and go back to the report.

11 Disinfecting the electrodes

⚠ IMPORTANT

Immediately after each scan, it is important to clean all sensor plates with the manufacturer approved cleaning solution and Kim Wipes (KIMTECH Science Brand).

This will not only disinfect but also neutralize the electrochemical reactions which have taken place on the sensor plates 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 with Kim wipes until dry.

⚠ IMPORTANT

Strictly adhere to the cleaning solution's instructions for use.

12 Replace the electrodes

Before launching a scan *(ref. p32)*, the number of available scans appears on the top right header of the program screen. The scan number (Scan#: XX) will increase by one and the remaining scans (Remaining scans: XX) will decrease by one upon successful completion of a scan.
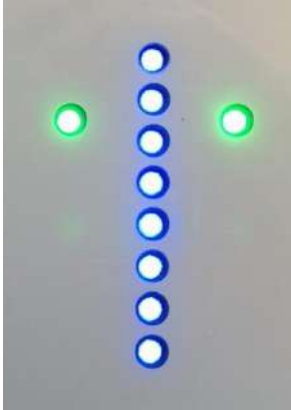
Figure 27: Remaining scans – ample scans are available for this set of electrodes

12.1 Two thresholds

1st Threshold:

A warning appears when the first threshold is reached. The scan text header on the top right identifying the number of scans remaining turns orange in color, as depicted below..
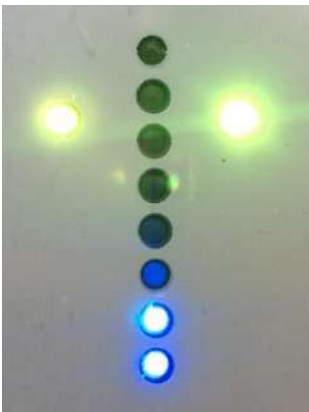
Figure 28: Remaining scans *first warning*

2nd Threshold:

A second warning appears when there are very few scans left. The scan text header on the top right identifying the number of scans remaining turns red in color, as depicted below.

Figure 29: Remaining scans final warning

IMPORTANT

PLEASE PLAN IN ADVANCE WHEN PLACING YOUR REPLACEMENT ELECTRODES ORDERS. 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

NOTE

Be sure to change hand plates and foot plates at the same time.

12.2 How to replace Smart Electrodes

Upon receiving a new Smart Electrode order form, **Impeto Medical** will ship a set of smart electrodes 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 icon reflects "Change Plates" instead of "Scan":

Figure 30: Scan page - Change electrodes.

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

1	Under the electrode dock, loosen the locking screw and hold it down.
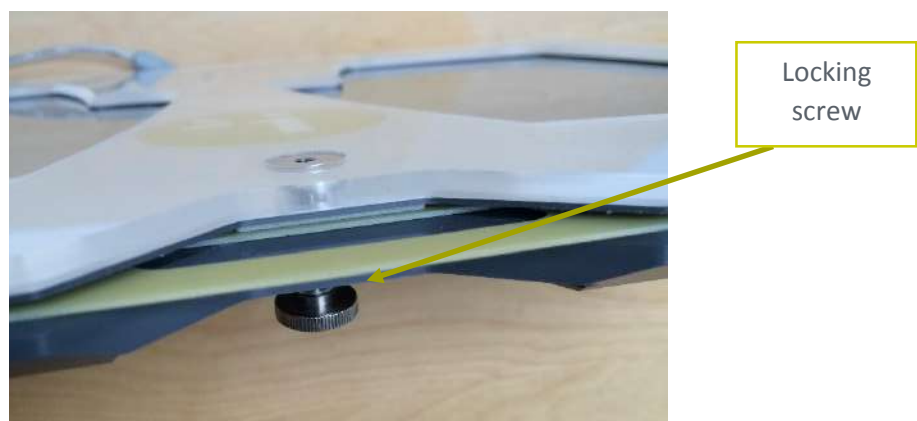
Locking screw

2   **Then remove the electrodes 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.**
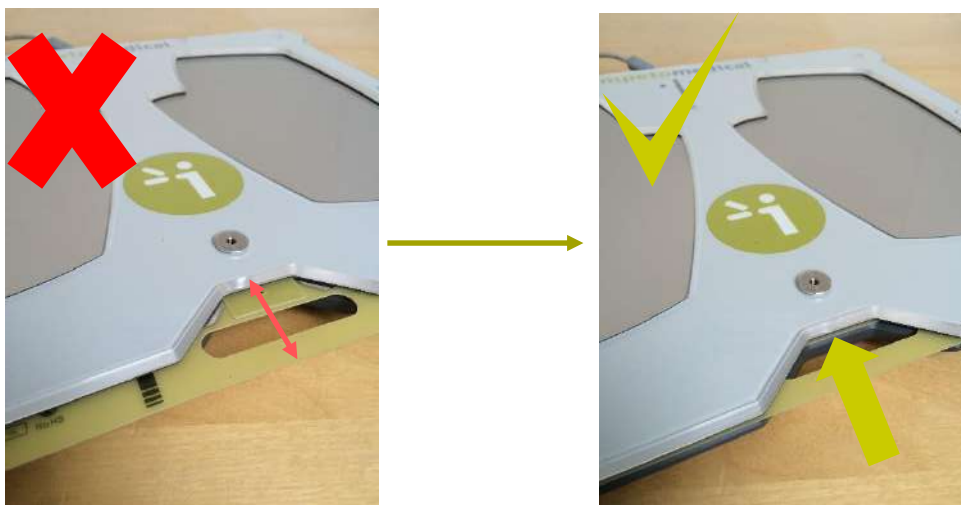
4   **Tighten the locking screw.**

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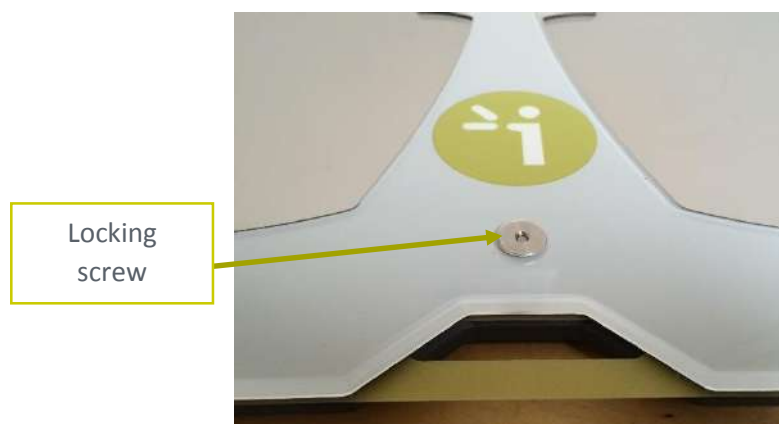
After the change of electrodes, return to the main program screen and then click the New Patient button. The number remaining of scans is updated and displayed on the top right header of the program.

WARNING

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

NOTE

When you replace your SUDOSCAN2 smart electrodes, you can safely dispose of your old smart electrodes at your office or clinic, or recycle them in accordance with your municipality's recycling regulations. However, if you choose, you can contact Impeto Medical at (858) 450-2800 to arrange to return your old electrodes to us.

13 USB printer Driver installation

To install USB Printer drivers, you must be logged in as a Supervisor. In Tools & Settings, access the Windows Desktop *(ref. p20)*.

1	**Ensure your USB key is virus-free.**

⚠️ **IMPORTANT**

DOUBLE CHECK ON ANOTHER COMPUTER THAT THE USB KEY IS VIRUS FREE.

2	**Insert a USB key with the appropriate printer drivers.**
3	**Manufacturer approved printer drivers will be pre-loaded.**
4	**Connect the USB printer to one of the USB ports available on the device.**

5	**On the Windows desktop, open "My Computer" and select the USB key. Locate the printer driver file and follow the instructions to install your printer.**
6	**After the installation is successfully completed, proceed to reboot the system and perform a Quality Check test before logging into the application. *(ref. p12).***

14 Software update installation

In order to provide optimal service, **Impeto Medical** may provide software updates for SUDOSCAN products. Contact **Impeto Medical** to learn how to access updates online.

When an update is available, Impeto Medical will provide instructions with the software update release.

15 Troubleshooting and system maintenance

15.1 USB connection

If the following message appears on top header of the program screen:
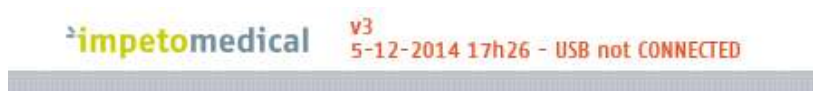
This means that the connection between the application and the hardware has been lost. It will not be possible to perform any scans in this situation.

To troubleshoot the issue:

1	Reboot the system.
2	If the problem persists, then contact your distributor or Impeto Medical Technical Support for further assistance *(ref. p77)*.

15.2 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 *(ref. p12)*.

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. p77)*.

15.3 Issue with the sensor plates

If the sensor plate docks show red LEDs, it means that there is an issue and that the scan cannot be launched.
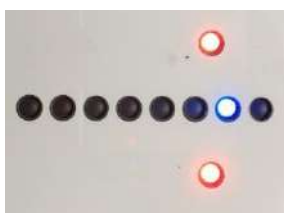
Figure 31: Issue with the sensor plate dock.

In that case, please follow procedure explained p35.

16 Annexes

16.1 Import a patient list via CSV file

The template to follow for the CSV file is the following:

16.1.1 Required data

Name	Firstname	DayOfBirth	MonthOfBirth	YearOfBirth

16.1.2 Optional data

Gender	Age	PID

17 How to

17.1 For a standard user

p5	**Power on the system**
p6	**Shutdown or turn off the system**
p60	**Troubleshoot the system**
	User Log in / Log off
p6	Home page
p8	Log in page
	Test the system hardware (via Quality Check):
p6	Home page
p12	Quality Check page
	Quick start a scan by entering patient demographic data:
p6	Home page
p32	Scan pages
p33	Patient setup & starting a scan
p35	What if the scan cannot be launched
p53	**Disinfect the electrodes**
	Export reports to an USB key:
p6	Home page
p43	How to export data
p54	**Replace the electrodes**
	Configure hospital information:
p6	Home page
p17	Standard users – List of controls
	Select the printer drivers:
p6	Home page
p17	Standard users – List of controls
	Retrieve previous patient data:
p6	Home page
p37	Patient History page
	Change password:
p6	Home page
p10	Password modification
p18	Standard users – Configuration (2) tab

17.2 For a supervisor user only

	Access to the desktop:
p6	Home page
p19	Supervisor user – Additional list of controls
	Install a USB printer:
p6	Home page
p19	Supervisor user – Additional list of controls
p59	USB printer Driver installation
	Upgrade the application software
p6	Home page
p19	Supervisor user – Additional list of controls
p60	Software update installation
	Select a user for configuration purposes
p6	Home page
p19	Supervisor user – Additional list of controls
p20	Supervisor user – Configuration (2) tab
p22	Supervisor user – Additional services
	Metric selection
p6	Home page
p20	Supervisor user – Configuration (2) tab
	Date format selection
p6	Home page
p20	Supervisor user – Configuration (2) tab
	Printing configuration
p6	Home page
p20	Supervisor user – Configuration (2) tab
	Take advantage of additional services
p6	Home page
p19	Supervisor user – Additional list of controls
p20	Supervisor user – Configuration (2) tab
p22	Supervisor user – Additional services
	Set/reset the password of any user
p6	Home page
p20	Supervisor user – Configuration (2) tab
	Select the language for display:
p6	Home page
p19	Supervisor user – Additional list of controls
	Export data to USB key:
p6	Home page
p22	Supervisor user – Additional services
	Import data to USB key:
p6	Home page
p22	Supervisor user – Additional services

18 Precautions for use and technical specifications

Principle of SUDOSCAN device

A low DC voltage is applied to electrodes in contact with the hands and feet, areas with the highest sweat gland density. The electrical current stresses 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 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 from the sweat glands and detected by the electrodes (on the hands and feet).

The SUDOSCAN device is composed of a SUDOSCAN software integrated into a touch-screen Windows 7 PC computer and connected to 4 electrodes placed on the feet, the hands.

General operation of SUDOSCAN

The patient positions his/her bare feet on the feet electrodes, and applies the palms of his/her hands to the hands electrodes.

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

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, and the use of the SUDOSCAN system is strictly reserved for physician use in a healthcare setting.

Precautions of use and maintenance

Transport

If it is necessary to pack, transport or deliver SUDOSCAN after its use, it is recommended to use the original packing box and 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 so as not to damage or weaken them.

The SUDOSCAN box can be stored upright or laid down.
The SUDOSCAN device does not contain any capacitor element.

Recycling

At the end of its lifetime, the SUDOSCAN 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 SUDOSCAN device are free of mercury and of components containing this element.

Protection against moisture

WARNING

Do not use the SUDOSCAN device in a wet or damp environment.
The SUDOSCAN device is not protected from the effects of the discharges of an external defibrillator, nor against high frequency currents or strong electromagnetic disturbances. The use of mobile telephones or wireless fixed telephones can cause signal disturbances.

Electromagnetic compatibility

WARNING

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 handbook.

Maintenance of the device and electrodes

No particular maintenance is necessary.

The external case and the cables of the electrodes can be cleaned using a slightly wet tissue or soaked with 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 electrodes must be cleaned immediately after each patient with an Impeto Medical approved cleaning solution.

WARNING

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 SUDOSCAN 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 oxygen-rich environment, with vapors or inflammable gas
- Keep the device away from any flammable source
- The device is not intended to be sterilized
- Use the device inside
- Use the device in a dry environment
- Maintain a minimum distance of 20 cm around the master unit

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

The following pictograms are affixed on the SUDOSCAN device:

	Indicates that the parts applied of the device are of type BF (IEC 60601-1).
I	Class of electric protection.
	The SUDOSCAN 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

RoHS Restriction of Hazardous Substances directive (Directive 2011/65/UE)

The following pictograms are affixed on the case:

Handle with care

Fragile

Keep dry
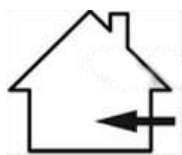
Indoor use only

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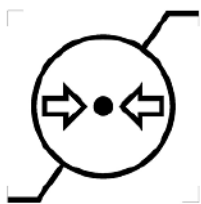
 Indicates the range of atmospheric pressure that the medical device can be safely exposed to

Use of the electrodes

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 electrodes.

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

 WARNING

USE ONLY THE ORIGINAL ELECTRODES PROVIDED BY IMPETO MEDICAL.

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

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

 WARNING

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

Positioning on the electrodes

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

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

Interrupting or stopping the recording

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

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

Recommendations to the operator

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

– Room temperature is between 65 and 95 degrees Fahrenheit,
– Cardiac holter measurements going on can be altered during the 2 minutes time scan.

Contra-indications

 WARNING

The repeated use of the SUDOSCAN 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 SUDOSCAN 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.

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 elements are available for the SUDOSCAN device:

Code	Description
S2MU	SUDOSCAN Master Unit
APH2	Hands plate with two electrodes and its connecting cable
APF2	Feet plate with two electrodes and its connecting cable
DSPHD	Smart Hand Electrodes desk
DSPFD	Smart Foot Electrodes desk
UMS2	Installation manual
ASAFE	Bottle of ANIOS Surfa'Safe spray cleaner
ELOCKS2	Sensor plate locking support
RCPU	Rack Central Processor Unit
PWS2	Medical Power Supply & Power Cable
WBOX	Box of Kim Wipes (KIMTECH Science Brand) for sensor plate cleaning

Technical specifications

• Description

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

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

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

⚠️ WARNING

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

• Characteristics of acquisition

Storage support:	SSD 64 Gb or 128 Gb
Mode:	No compression
Frequency of acquisition:	100 Hz
Resolution:	10 nS (nano Siemens)
Display units:	μS (micro Siemens)
Display precision:	+ or − 1 digit
Accuracy	2%

• Electrical characteristics

Measurement voltage:	1V to 4V DC typical
Frequency:	0 Hz (DC current)
Dynamic resolution:	10 bits
Power requirement of the unit:	100-240 V~ 50/60 Hz 0.4/0.2A

• **Sealing**

Index of protection:
Master Unit	IP20
Electrodes	IP41
Power supply adapter	IP22

• **Mechanical characteristics**

Master Unit alone	9,5 kg
Master Unit dimensions	44,5 x 33,5 x 42,5 cm max
Weight of the Master Unit + sensor plate s: APH2 & APF2:	13,8 kg
Weight of the Master Unit + sensor plate s: DSPHD, DSPFD:	17,4 kg
Weight of the transportation box APH2, APF2	19.0 kg
Weight of the transportation box DSPHD, DSPFD	22.6 kg
Dimensions of the shipping box:	55 x 48 x 41 cm

• **Storage, transport and conditions of use of the apparatus and electrodes**

	Temperature	Moisture (without condensation)	Pressure
Operation	18° to 35°C (65° to 95°F)	20% to 80%	700 to 1060 hPa
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

Table 1

Guidance and manufacturer's declaration – electromagnetic emissions		
The SUDOSCAN device is intended for use in the electromagnetic environment specified below. The customer or the user of SUDOSCAN should ensure that it is used in such an electromagnetic environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	SUDOSCAN 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.
RF emissions CISPR 11	Class B	SUDOSCAN 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 emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 2

Guidance and manufacturer's declaration – electromagnetic immunity			
SUDOSCAN is intended for use in the electromagnetic environment specified below. The customer or the user of the SUDOSCAN should ensure that it is used in such an electromagnetic environment.			
Immunity test	**IEC 60601-1-2 test level**	**Compliance Level**	**Electromagnetic environment guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 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	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV mode differential ±2 kV mode common	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	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	0 Vac during 10 ms 92 Vac during 100 ms 161 Vac during 1 s 0 Vac during 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SUDOSCAN requires continued operation during power mains interruptions, it is recommended that the SUDOSCAN be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m for 50Hz and for 60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level			

Table 3 - for ME equipment and ME systems that are not life-supporting

Guidance and manufacturer's declaration – electromagnetic immunity			
The SUDOSCAN is intended for use in the electromagnetic environment specified below. The customer or the user of the SUDOSCAN should ensure that it is used in such an electromagnetic environment.			
Immunity test	**Immunity test**	**Immunity test**	**Immunity test**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 V rms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the SUDOSCAN, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.17 \sqrt{P}$ $d = 1.17 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.33 \sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (1) should be less than the compliance level in each frequency range. (2) Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

(1) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SUDOSCAN is used exceeds the applicable RF compliance level above, the SUDOSCAN should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the SUDOSCAN.

(2) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [$V1$] V/m.

Table 4 – for ME equipment and ME systems that are not life-supporting

Recommended separation distances between portable and mobile RF communications equipment and the SUDOSCAN			
The SUDOSCAN device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SUDOSCAN can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SUDOSCAN as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d= 1.17\ \sqrt{P}$	80 MHz to 800 MHz $d = 1.17\ \sqrt{P}$	800 MHz to 2,5 GHz $d = 2.33\ \sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.37	0.37	0.74
1	1.16	1.16	2.33
10	3.69	3.69	7.37
100	11.6	11.6	23.3
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Contacts

Impeto Medical

17, rue Campagne Première
75014 PARIS – FRANCE
Tel: +33 (0)1 4320 1640
Fax: +33 (0)1 4335 1833
Mail: info@impeto-medical.com
http://www.impeto-medical.com/fr/

Impeto Medical

Room 107, Building 81,
Stadium Road No.4,
Chaoyang District, Beijing,
China 100027
Mail: info@impeto-medical.com

Impeto Medical, Inc.

8910 University Center Lane, Suite 615
SAN DIEGO, CA 92122 - USA
Tel: (858) 450.2800
Fax: (858) 450.2804
http://www.sudoscan.com/

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