SUDOSCAN

User guide

Version 3

13/01/2017

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1 Introduction

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

1.1 Patent

The SUDOCAN® device is covered by following patents : "Electrophysiological analysis system and method" (Patent 1 898 783 and 2 124 736), and "Procédé d'analyse physiologique par stabilisation d'une surtension" (PCT2014/069479)..

1.2 Use

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

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.

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 up the system

1	Open the hinged cover located below the screen at the front of the Master Unit.
	Inside on the right there are 2 USB ports and power button.
2	Press and release the power button to power on.

Power button

Front USB ports

⚠️ WARNING

NO MODIFICATION OF THIS EQUIPMENT IS ALLOWED.

3 Home page

3.1 List of available functionalities

Please note that a summary of all functions is in the *"How to"* section on *(ref. p61)*.

3.2 For User not logged in
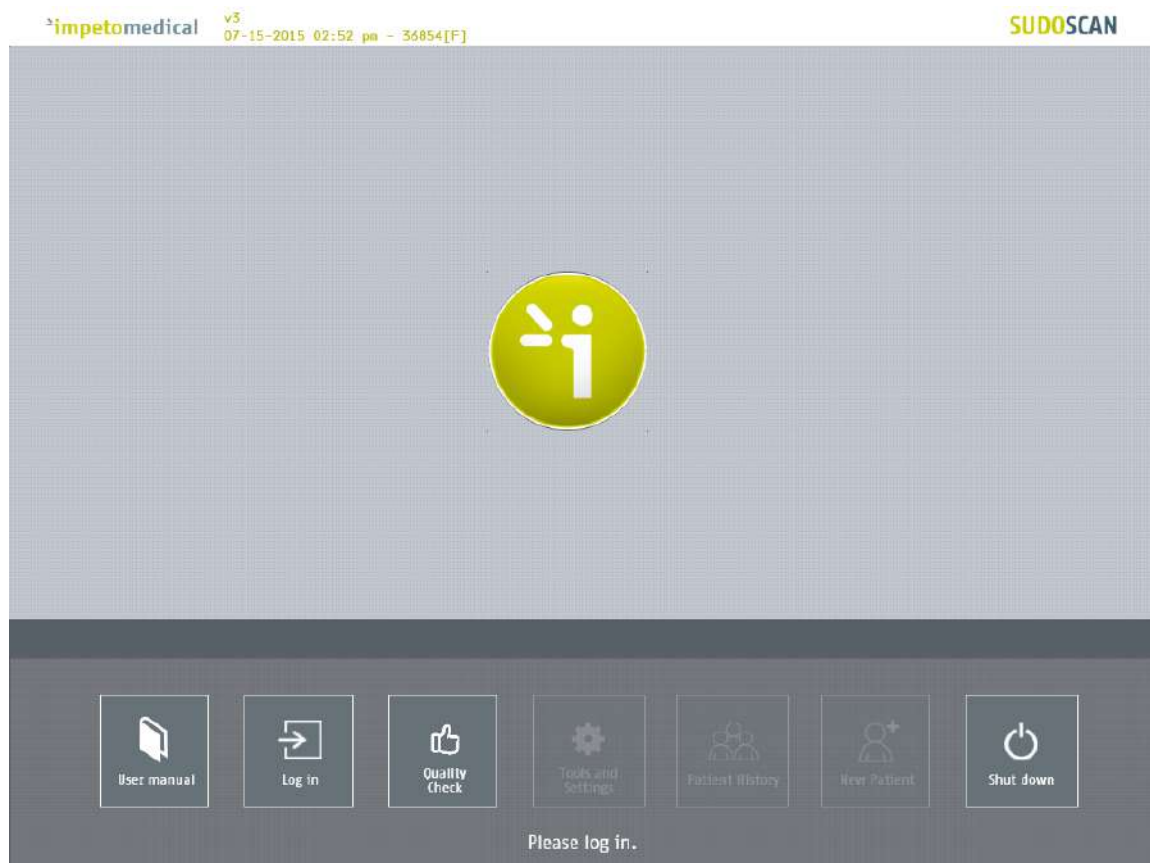
Figure 1 : Home page – no user logged in

1	Click on the <u>Log in</u> button. The "Log in" panel appears *(ref. p9)*.
2	Click on <u>Quality Check</u> to launch the system "Quality check" *(ref. p13)*.
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 IRREMEDIABLY 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
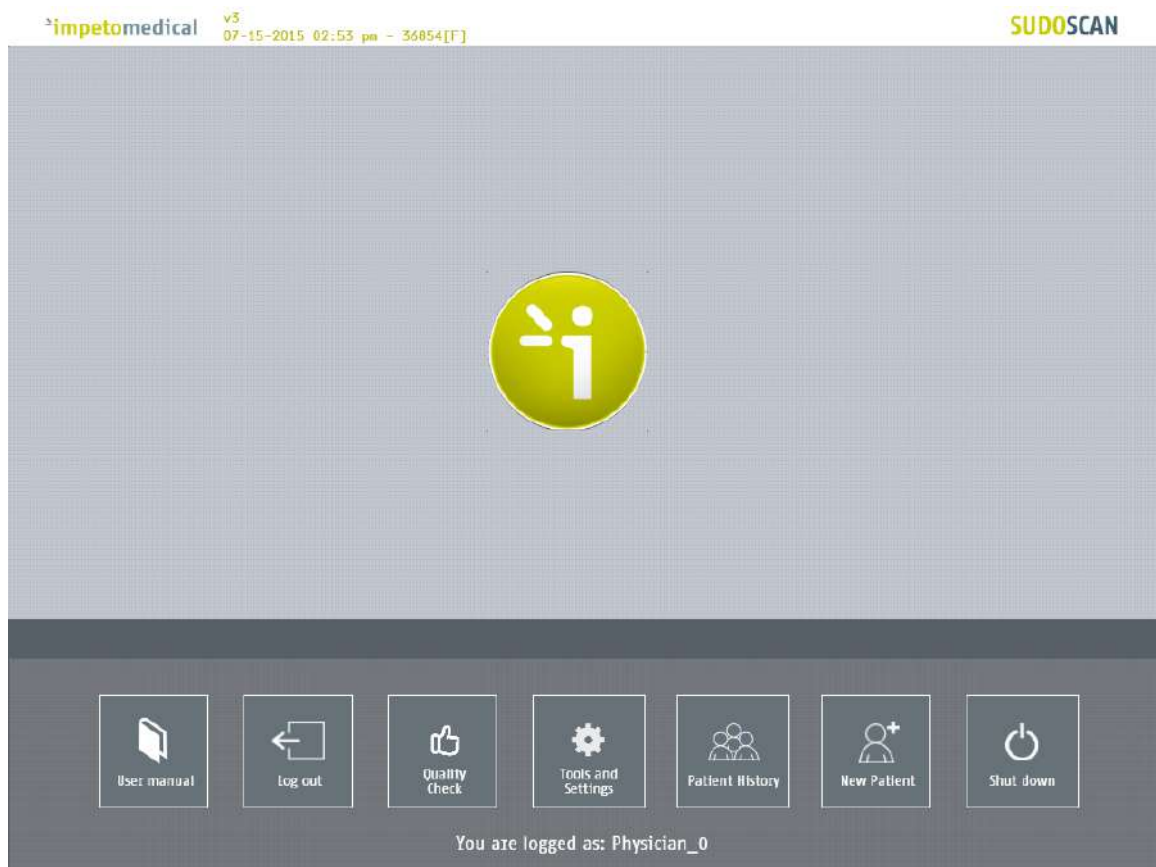
Figure 2 : Home page –user logged in

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. p13).*
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 enter the configuration page(s)** *(ref. p18).*
6	**Click on** <u>New patient</u> **to initiate a scan for a new patient** *(ref. p34).*
7	**Click on** <u>Patient history</u> **to access to the patient history** *(ref. p39).*

4 Log in page

4.1 List of controls

Figure 3 : Log in page

1	Select the physician in the <u>Physician list.</u>
2	Enter your password in the <u>Password field</u> using the <u>on-screen keyboard</u>. The initial password is provided by your system supervisor. Default password: impeto.
3	Click on <u>Log in</u> button to validate the current password for the selected physician *(ref. p10).*

4.1.1 Other controls

Click on the <u>Home</u> button (🏠) to reach the home page *(ref. p7).*
Click on the <u>Help</u> button (?) button to reach the contextual help.
Click on <u>Change password</u> if you want to modify your current password *(ref. p11).* After the current password is entered in the password field.

4.2 Password validation

When the password is correct, the following message appears and the application automatically proceeds to the home screen *(ref. p8)*:
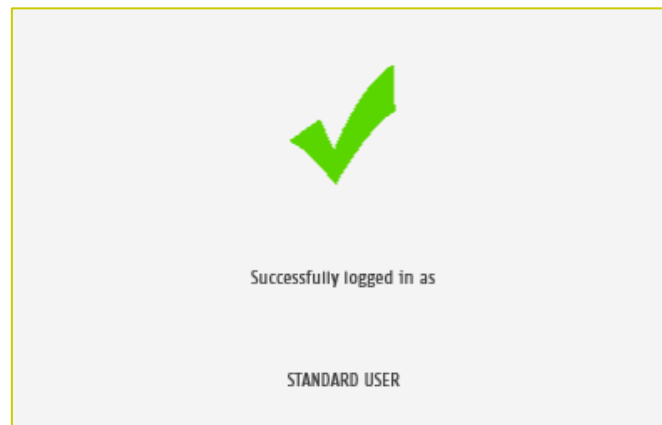
When the password is not correct, the following message appears and the user has to log in again *(ref. p9)*:
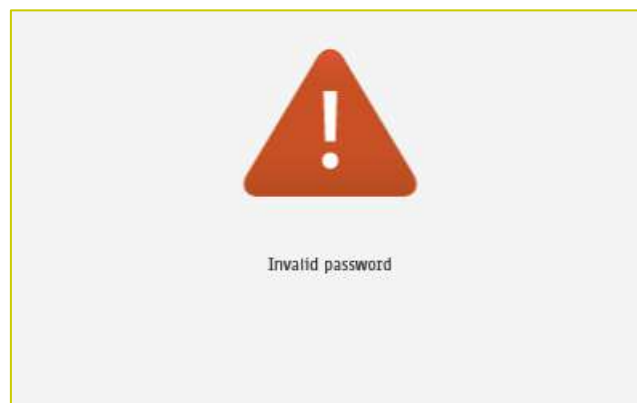
4.3   Password modification

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

Click Change password to show the new password fields.

Fill the two new password fields with the same new password then click on <u>Save password</u>.
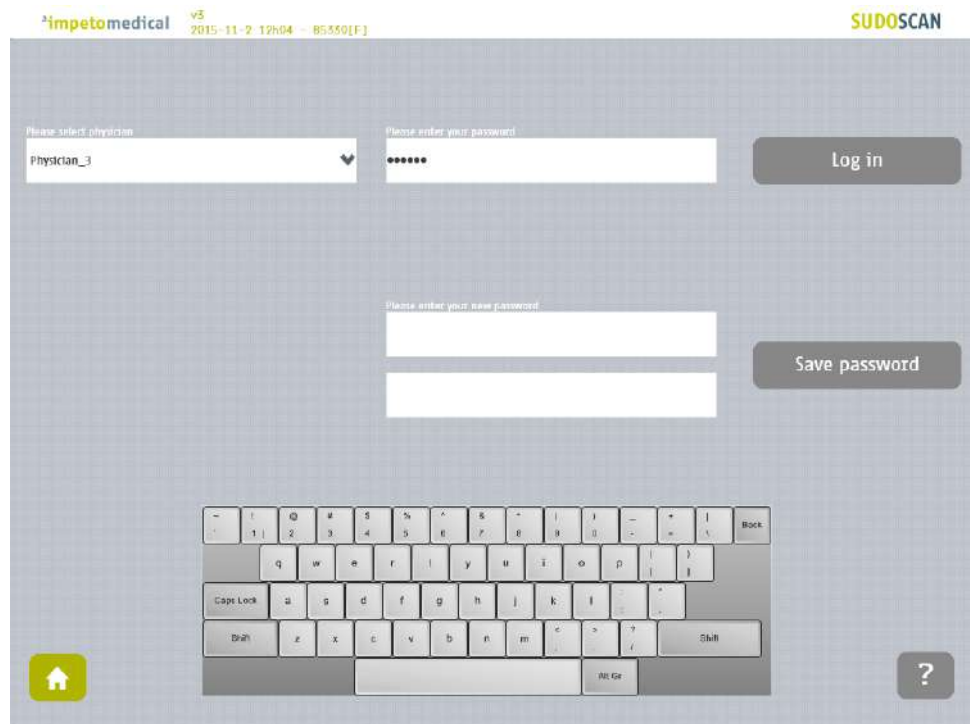
Figure 4 : Log in page – new password fields displayed

When the button <u>Save password</u> is clicked, a check is performed on the different passwords. Then,

-   If the <u>old password</u> is not correct, the following message appears:

- If the <u>new passwords</u> are not identical, the following message appears:

New passwords do not match

OK

- If the <u>old password</u> is correct and the <u>new passwords</u> are identical, the following message appears and you are automatically logged in.

Password successfully changed. You are logged in as

STANDARD USER
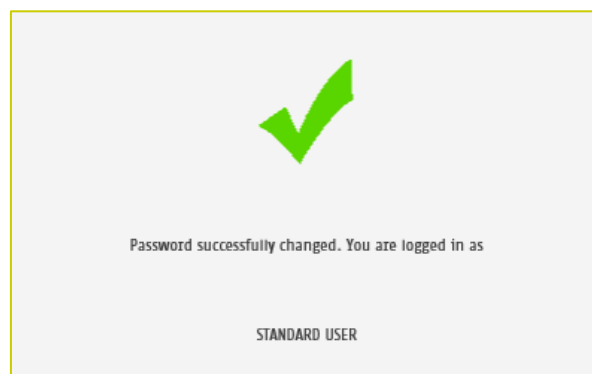
5 Quality check page

5.1 Overview

The Quality Check allows the operator to test the internal electronic circuitry 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 with 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 instead*
3	**Click on the Run test button to launch a full Quality Check sequence** *(ref. p15 for Quality Check results interpretation).*

NOTE

The electrodes must be carried out without patient (nobody on contact with the electrodes).

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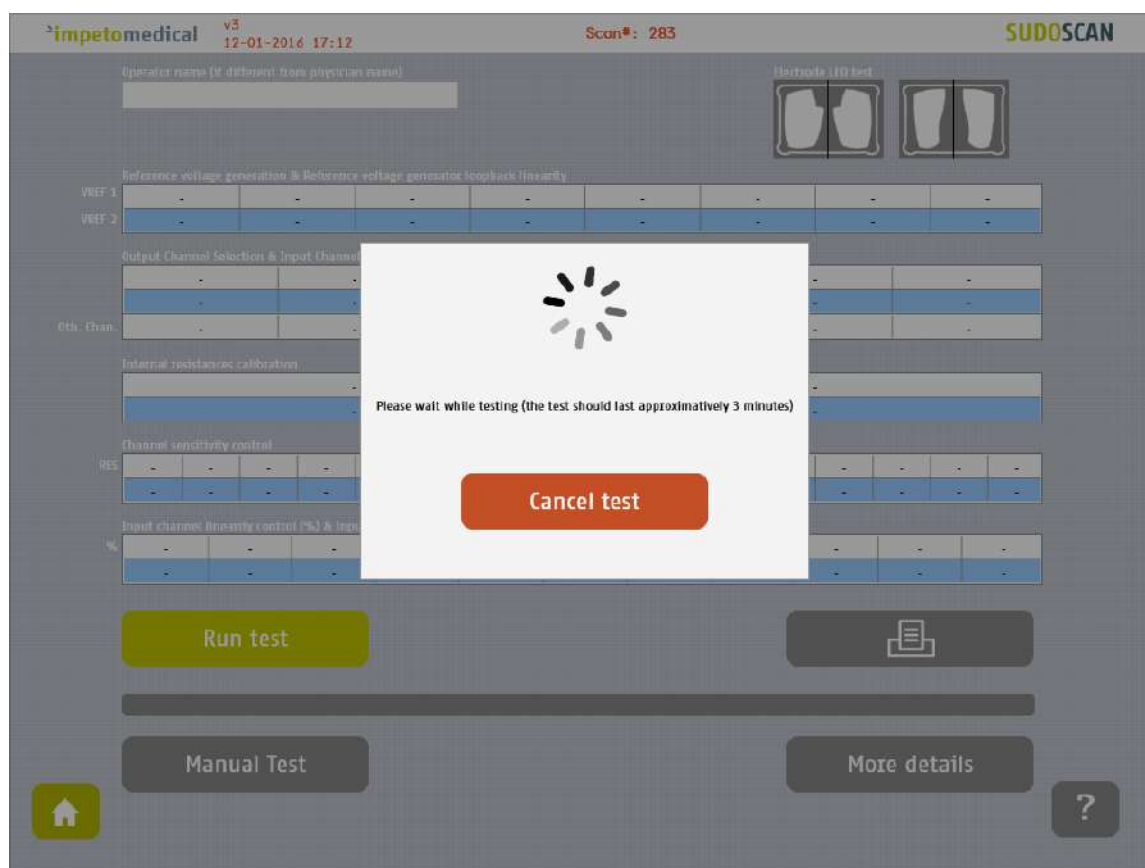
Figure 6: Quality Check page -During the Quality Check

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

5.4 Quality Check result interpretation

When the Quality Check is complete and no error occurred, green checkmarks are displayed for every lines as follows:

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

If a problem occurs during the Quality Check, some warning icons appear in place of the green checks. In that case, please contact **Impeto** technical support *(ref. p76)*.

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 regarding to the Quality Check results.

5.5 To have more details on the Quality Check results

When an error occurred during the execution of a Quality Check, you can display more information by clicking on the More Details button to know the error source.
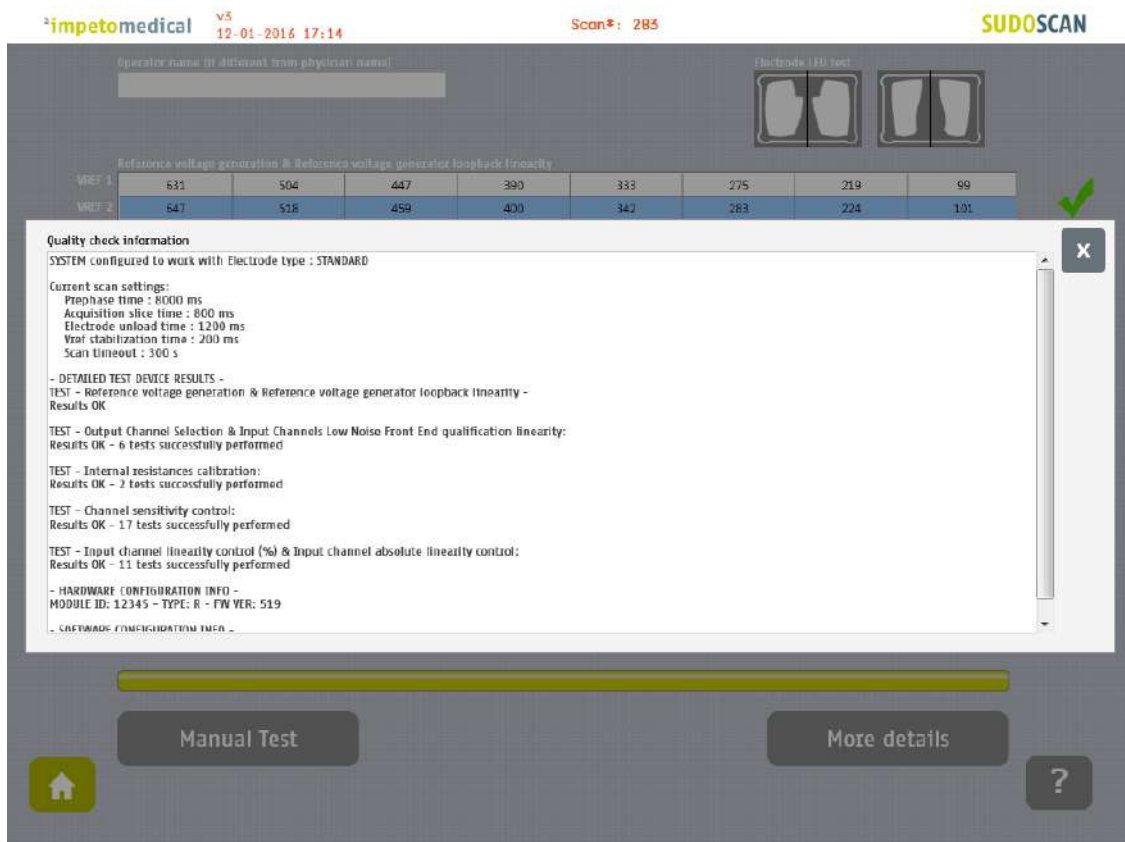
Figure 9: Quality Check page -More details on the Quality check results

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

5.6 Other controls

	Click on the Home button (🏠) to reach the home page *(ref. p7).*
	Click on the Help button (?) button to reach the contextual help.

6 Tools & Settings page(s)

6.1 Standard user – List of controls

If you are logged in as Supervisor, please see p20.

Figure 10 : Configuration page

1	Enter hospital information in the hospital data fields.
2	Enter the physician information in the physician data field
3	Select the <u>printer</u> from the dropdown list of installed printers *(ref. p58 to check how to install a printer driver).*

6.1.1 Other controls

	Click on the <u>Configuration (2)</u> tab to access to additional settings *(ref. p19).*
	Click on the <u>Home</u> button ( ) to reach the home page *(ref. p7).*
	Click on the <u>Help</u> button ( ) button to reach the contextual help.

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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. (Preferred setting)*
- *Uncheck "Direct print" to display the results only. End user can select manual print from the Physician report or Patient report tabs (ref. p53).*

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 for the previous exams (when existing)*

4	Select optional data (all options may not be available).

6.2.1   Other controls

Click on the <u>Home</u> button ( ) to reach the home page *(ref. p7).*

Click on the <u>Help</u> button ( ) button to reach the contextual help.

6.3   Supervisor users – Additional list of controls

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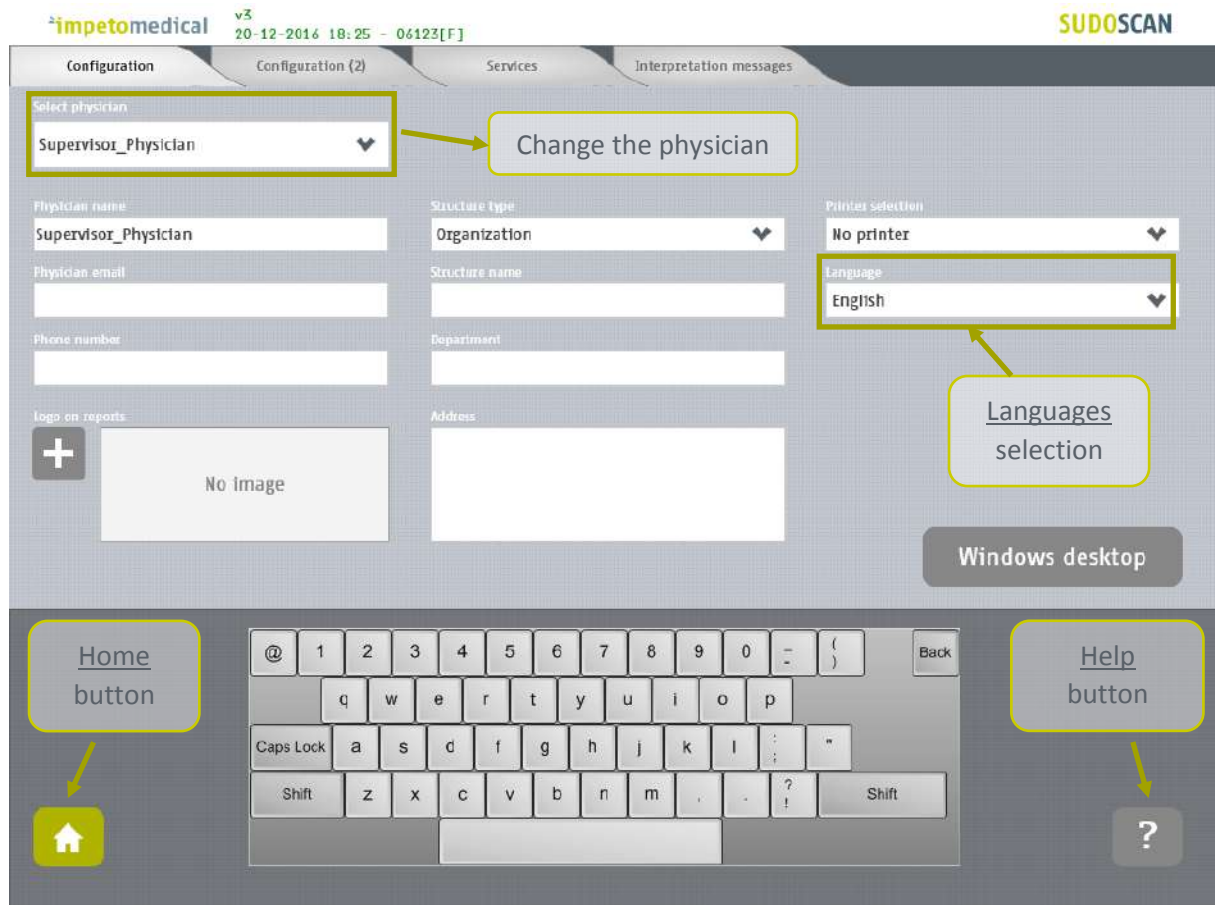
Figure 12: Configuration page - Additional controls for supervisor

1	Select the physician you want to modify the settings of.
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 to supervisor settings *(ref. p21)*.
Click on the Services tab to access to additional services *(ref. p23)*.
Click on the Interpretation messages to modify messages that appear as interpretation on the Results screen and on the reports. *(ref. p25)*
Click on the Home button (🏠) to reach the home page *(ref. p7)*.
Click on the Help button (?) button to reach the contextual help.

6.4   Supervisor users – 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 time delay before the system locks itself and the physician is logged out the application.
4	Select the frequency of the Quality Check (a reminder will pop up if no Quality Check is run in the time specified).
5	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. (Preferred setting)*
- *Uncheck "Direct print" to display the results only. End user can select manual print from the Physician report or Patient report tabs (ref. p53).*

6	Change the mouse cursor settings:

- *Check the box to hide the mouse cursor*
- *Uncheck the box in case you want to use a physical mouse.*

7	**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 exams (when existing)*
8	**Select the date format to apply for the selected physician.** Default mode is DD/MM/YYYY.
9	**Select optional data for the selected physician (all options may not be available)**
	• *When "Date of birth" is not checked, only the Year of birth is required.*
10	**Change data management settings:**
	• *Enable the patient modification to allow standard users to modify demographic data for their patients.* • *Enable the display of the CAN and/or Nephropathy scores to allow standard users to enable their computation for patients.*
11	**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 (lbs).**

6.4.1 Other controls

Click on Configuration tab to access to the standard settings *(ref. p20).*
Click on Services tab to access to additional services *(ref. p23).*
Click on Interpretation messages to modify messages that appear as interpretation on the Results screen and on the reports. *(ref. p25)*
Click on the Home button (🏠) to reach the home page *(ref. p7).*
Click on the Help button (?) button to reach the contextual help.

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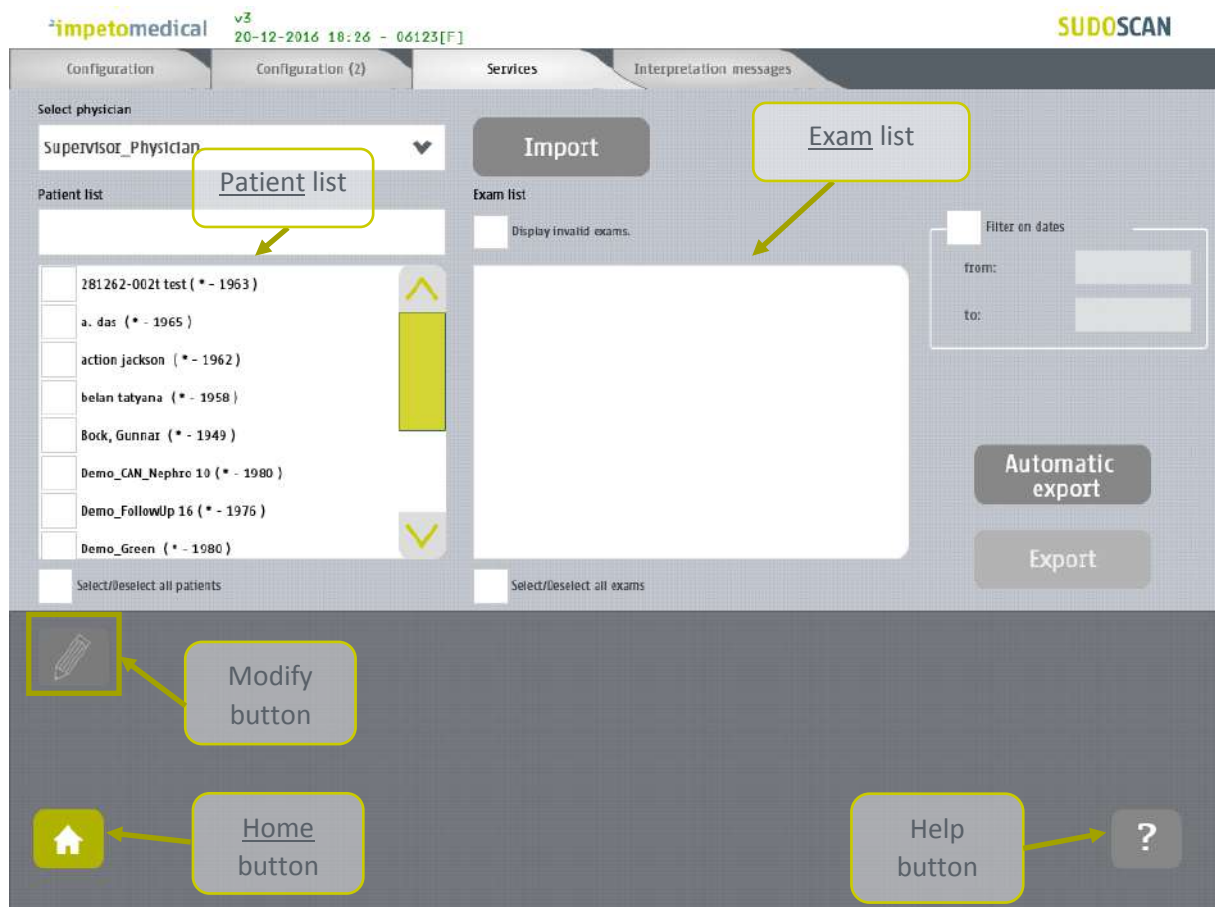
Figure 14 : Services page - Additional supervisor services

1	Select the physician whose settings will be modified.
2	Click on <u>Import</u> button to import data for the selected physician *(ref. p26)*.
3	Select patients from the list. To do so, some tools are available: • *A filter on patients' last name, first name, year of birth and patient identifier (PID)* • *A filter on dates ("from" and "to" dates)* • *A control to select/unselect all patients from the list*
4	Select exams from the exam list. To do so, some tools are available: • *A filter on dates ("from" and "to" dates)* • *A checkbox to select/unselect all exams from the list*
5	When at least one patient is selected, click on Modify button to modify the data of the selected patient(s) *(ref. p31).*
6	Click on Export button to export data of the selected patient(s) and exam(s) *(ref. p29).*

6.5.1 Other controls

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

Click on <u>Configuration (2)</u> tab to access to supervisor settings *(ref. p21).*

Click on Interpretation messages to modify messages that appear as interpretation on the Results screen and on the reports. *(ref. p25)*

Click on the <u>Home</u> button ( ) to reach the home page *(ref. p7).*

Click on the <u>Help</u> button ( ) button to reach the contextual help.

6.6   Supervisor users – Interpretation messages

When the option to display <u>Interpretation messages</u> is checked (option "Auto conclusion" from supervisor settings *ref. p21*), a message is displayed on the results screen and within reports regarding to the exam results. Supervisor users can modify the content of these messages for each user.
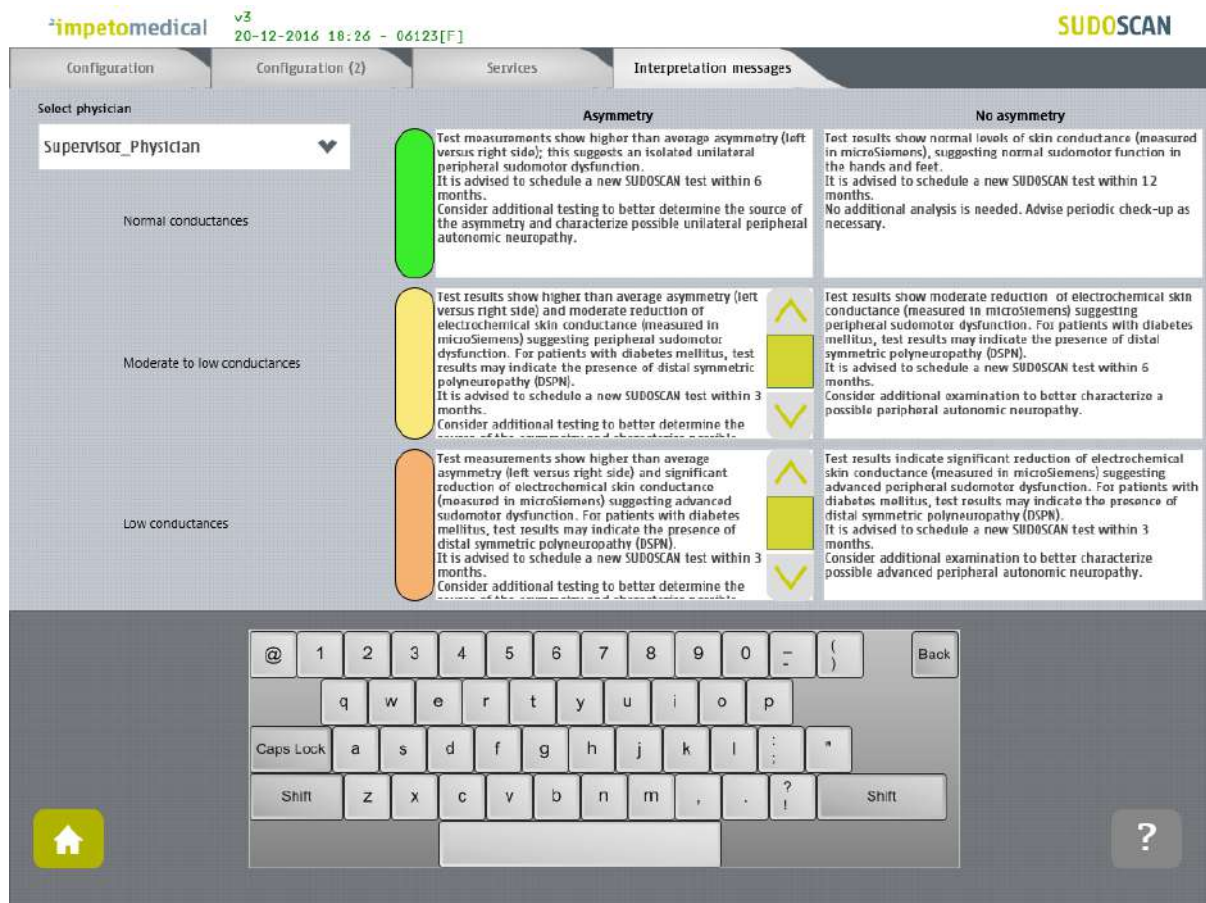
Figure 15: Modify Interpretation messages

1	Select the physician whose settings will be modified.
2	Select the type of message you want to modify and modify the content. The new content is saved automatically.

6.6.1   Other controls

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

Click on <u>Configuration (2)</u> tab to access to supervisor settings *(ref. p21)*.

Click on <u>Services</u> tab to access to additional services *(ref. p23)*.

Click on the <u>Home</u> button (🏠) to reach the home page *(ref. p7)*.

Click on the <u>Help</u> button (?) button to reach the contextual help.

6.7   Import data for a selected physician

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

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

You can select several type 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 files use the proposed template to ensure compatibility with the system (ref. p60).*
- *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:

To import files from a USB key, please plug in a USB key in a USB slot.

Files   Folder
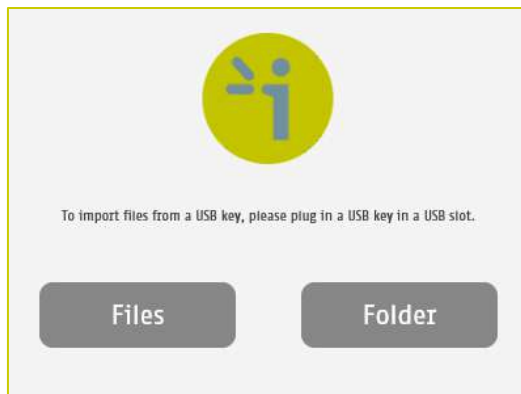
4	Click OK and select files to import:

5	The files are imported.

Importing files: 7/77.

Cancel import
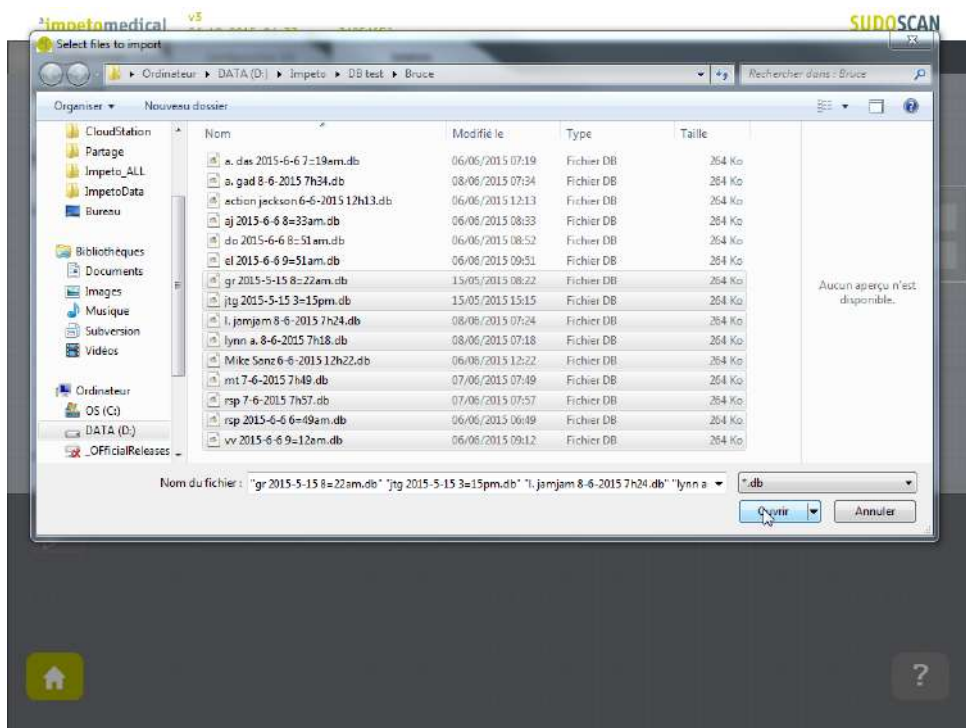
6   The import is complete.
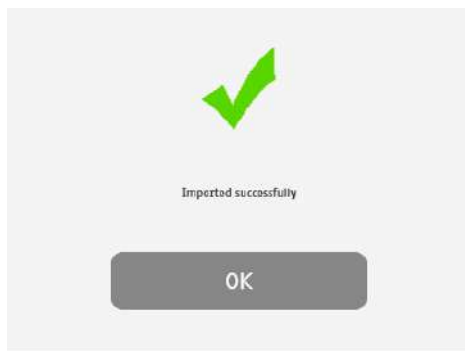
7   The list of patients is updated with the new data.
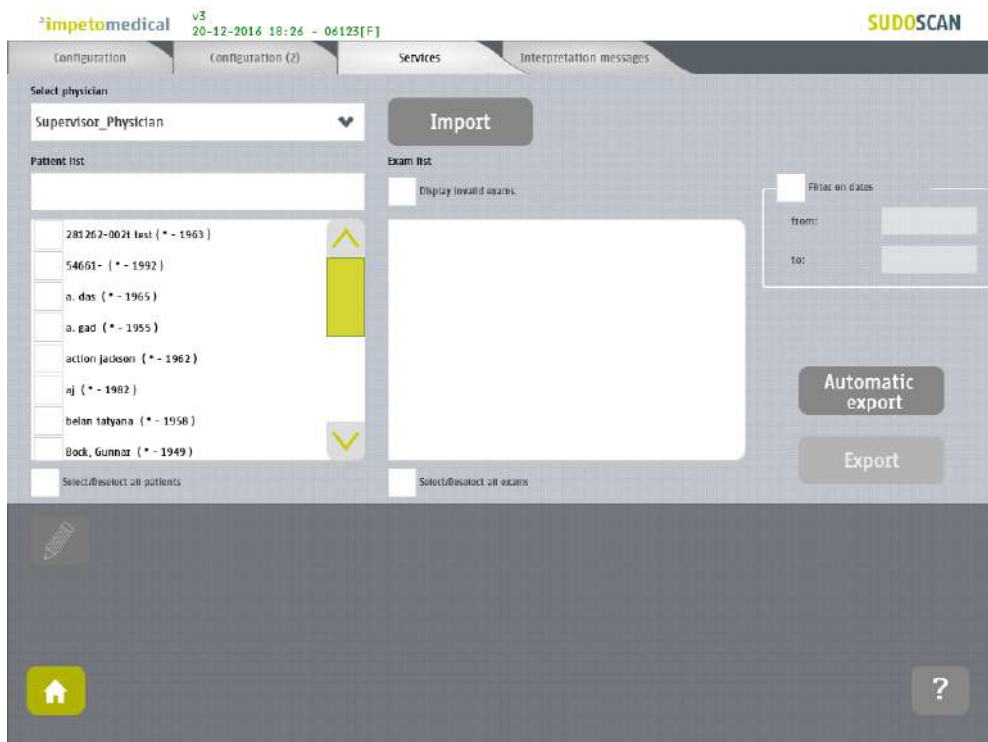
6.8   Export data on a USB key for a selected physician

1   **Insert a virus free USB key containing enough free space (100 scans ~ 25MB).**

2   **Select patient(s), exam(s)** *(ref. p23)* **and click on** Export **button. A popup window appears to precise the type of data you want to export:**

You can select several type of data:

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

3	Click OK and verify that the USB key is correctly plugged into the system:
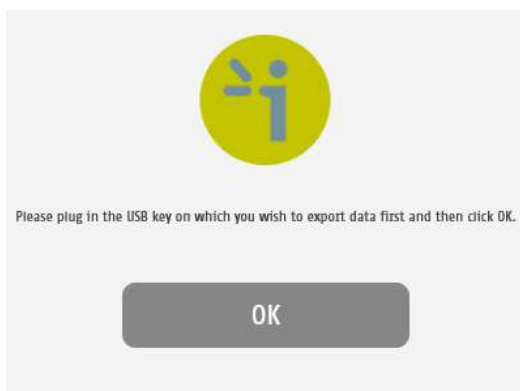
Please plug in the USB key on which you wish to export data first and then click OK.

OK

4	Click OK and the files are exported:

Exporting data 19/47.

Cancel export

5	The export is complete.

Data successfully exported on USB

OK
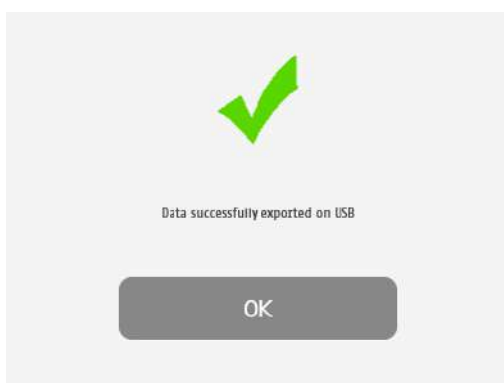
NOTE

When the export is complete, the data are on the USB key. For the RAW 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

We strongly recommend to back up your data on a regularly basis.

6.9 Patient reconciliation & Patient demographic data modification

This feature is also available for standard users when it has been enabled by a supervisor (option "Enable patient modification", ref. p21).

| 1 | Select one or several patients *(ref. p23)* and click on the Modify button. |

| 2 | When only one patient is selected, a popup window is displayed to modify demographic data of the selected patient (name, first name, date of birth and patient ID): |

3   When several patients are selected, a popup window is displayed to gather several patients under one:
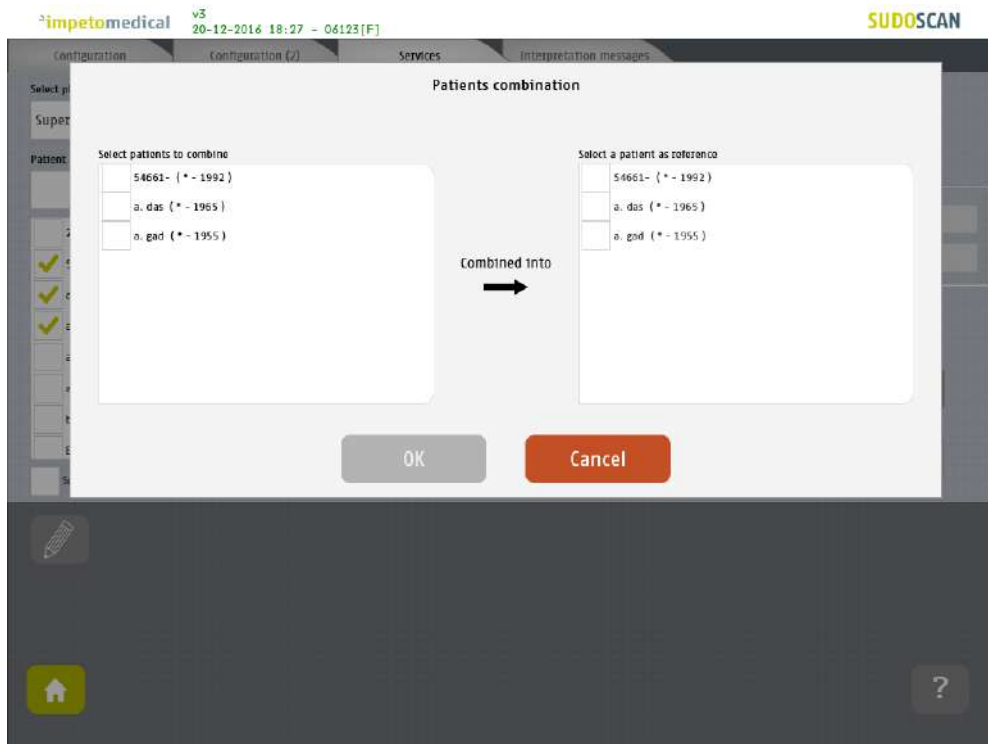
4   Select the patients to gather from the list on the left, and the referent patient from the list on the right:
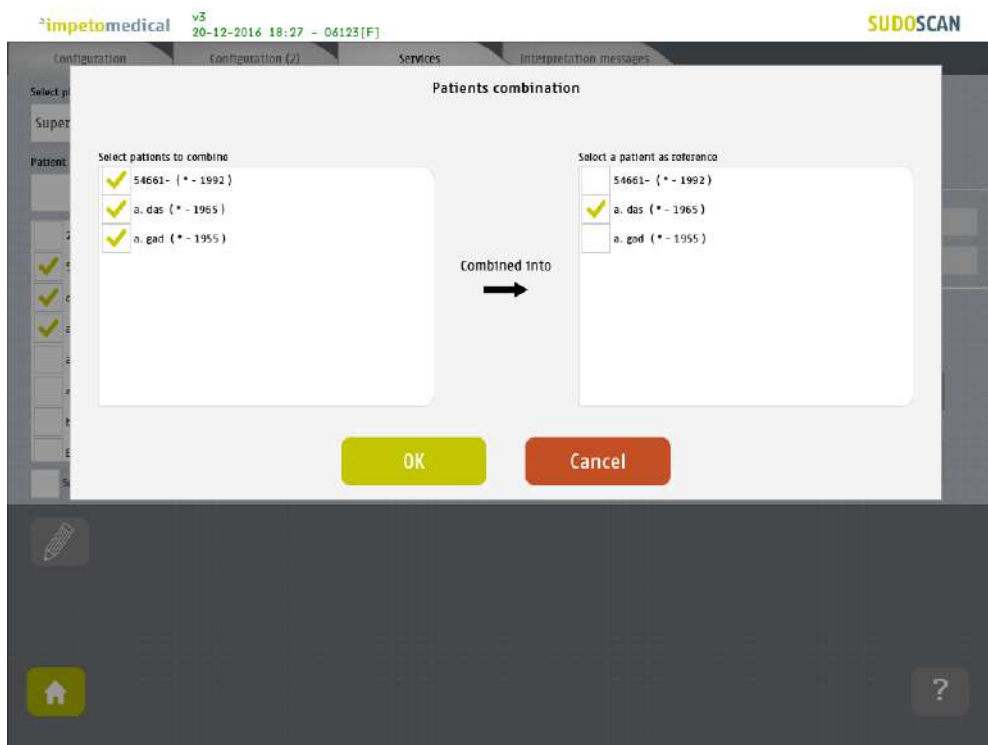
5 **Click on Ok to validate, and all the data for the patients to gather will be combined and updated with demographic data from the referent patient.**

The list of patient is then updated on the Services screen.

7 Scan pages

When a patient does not exist already on the system, select New Patient button on the Home screen *(ref. p7)* and fill in demographic data for the patient.

7.1 List of controls

Figure 16 : Patient page

1	**After entering the mandatory patient data indicated by an *, the Scan button becomes available and the user can start a scan** *(ref. p35 to setup patient's demographic information and start a scan).*
	Required data are depending on enabled options.
2	**When available, select additional scores to compute during the scan.**
3	**Click on Clear patient data to clear all patient data fields.**

7.1.1 Other controls

Click on the Home button (🏠) to reach the home page *(ref. p7).*

Click on the Help button (?) button to reach the contextual help.

7.2 Patient setup & start a scan

1 Set the patient's demographic information.

Enter data by clicking on the corresponding text boxes, 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. p21)*
- *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-type keyboard connected to one of the USB connections available on the Master Unit.**

> **NOTE**
>
> **Verify the data with your patient. Invalid (out of acceptable range) or missing data will be flagged with a RED background and patient data should be re-entered.**

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

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

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

3 If all required fields have not been entered and the <u>Scan</u> button is selected, then any missing fields will be highlighted in red.

Figure 17: Scan page - Highlighting of empty required fields

4 Click on the <u>Scan</u> button to start the scan *(ref. p34)*.

  WARNING

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

7.3 During the scan

1 The application displays a video and a progress bar during the scan.

A calibration is performed at the beginning of each scan.
The patient is requested to remain still during the scan.
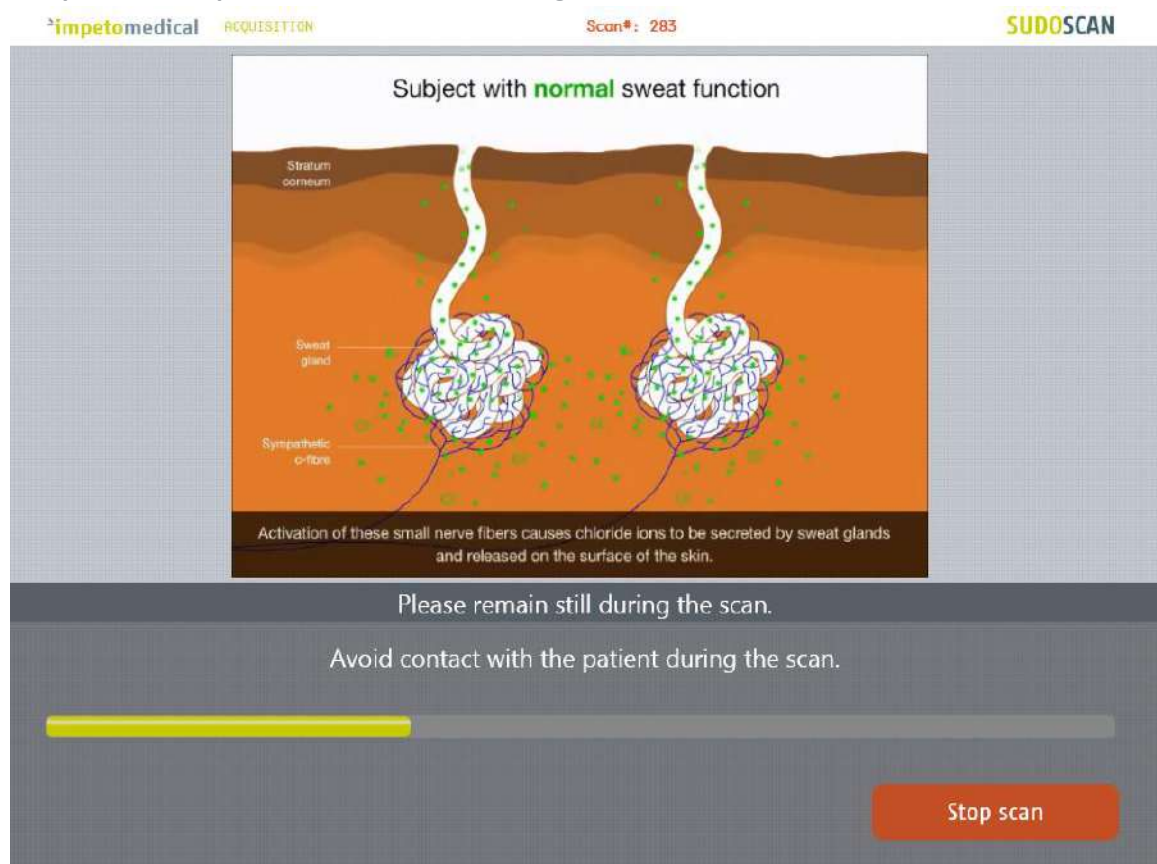
Figure 18: Acquisition

2 If hand or foot contact on the sensor plates is lost during the calibration, then 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. The result page is displayed once the scan successfully ends (ref. p48).*

- *When the scan ends with an issue, the application process to the result page but the reports are not generated, except if the scan is validated by the user (ref. p49)*

5	**Cleanup the electrodes after each scan with manufacturer approved cleaning solution *(ref. p56).***

8 Patient History page

To retrieve data for exams and patients, click on the Patient History button from the Home screen *(ref. p39)*.

8.1 List of controls
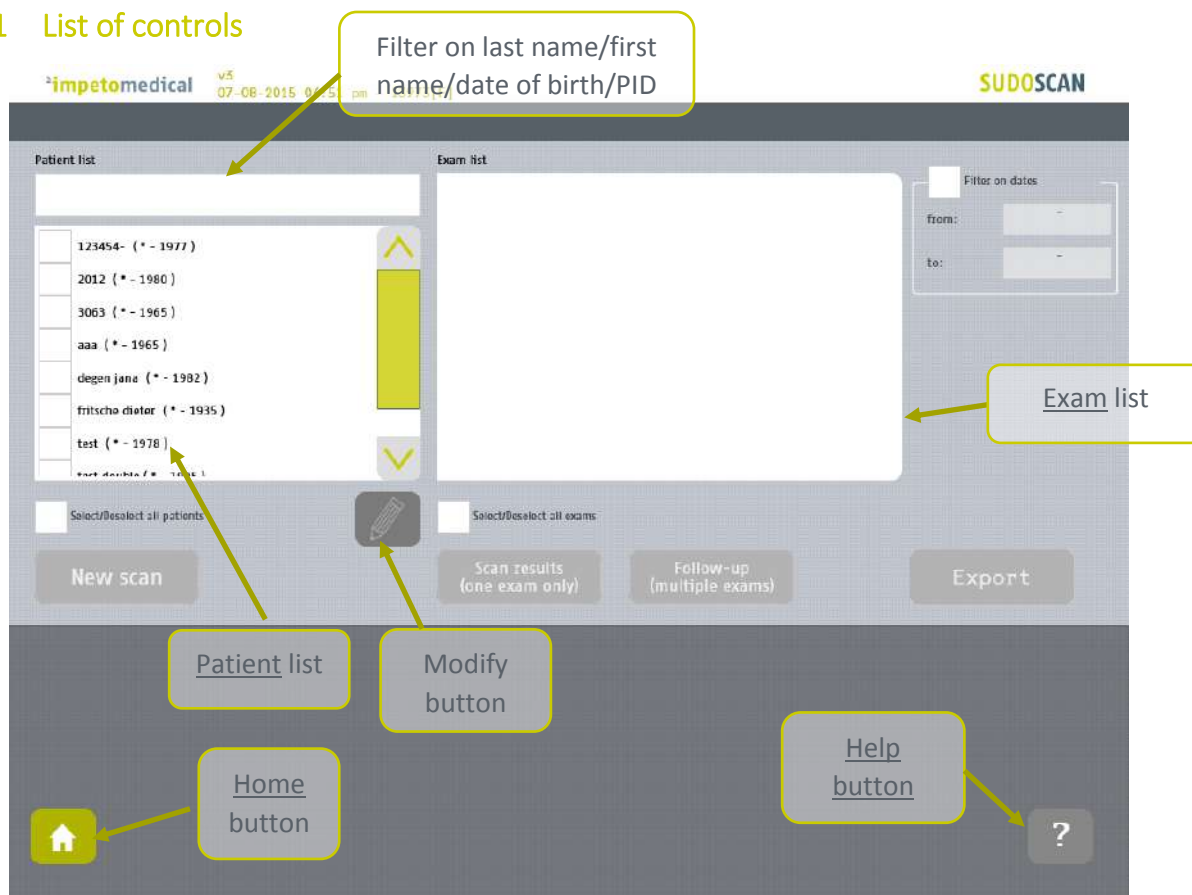
Figure 19 : Patient History page

1	Select patients from the **Patient list** and exams from the **Exam list** *(ref. p40)*.
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 for standard users when enabled *(ref. p31)*.
3	Start a **new scan** for the selected patient *(ref. p40)*.
4	Display the **results** for the selected exam *(ref. p42)*.
5	Display the **follow-up** screen for the selected exams *(ref. p43)*.
6	**Export** or **print** data and reports for the selected exams *(ref. p45)*.

8.1.1 Other controls

Click on the **Home** button (🏠) to reach the home page *(ref. p7)*.

Click on the **Help** button (?) button to reach the contextual help.

8.2   Selection of patient(s) and exam(s)

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

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 exam list 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. p34):
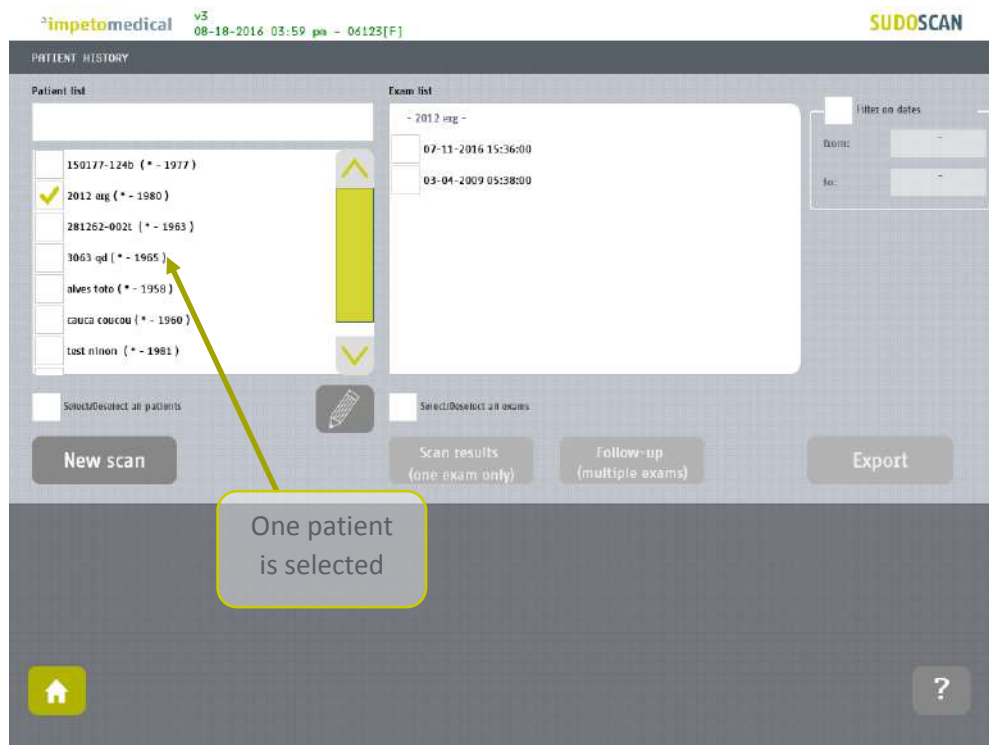
Figure 20: Start a new scan for an existing patient

8.4   How to display results for a single exam

Select a patient and an exam from the exam list and click on the Scan results button *(ref. p48)***:**
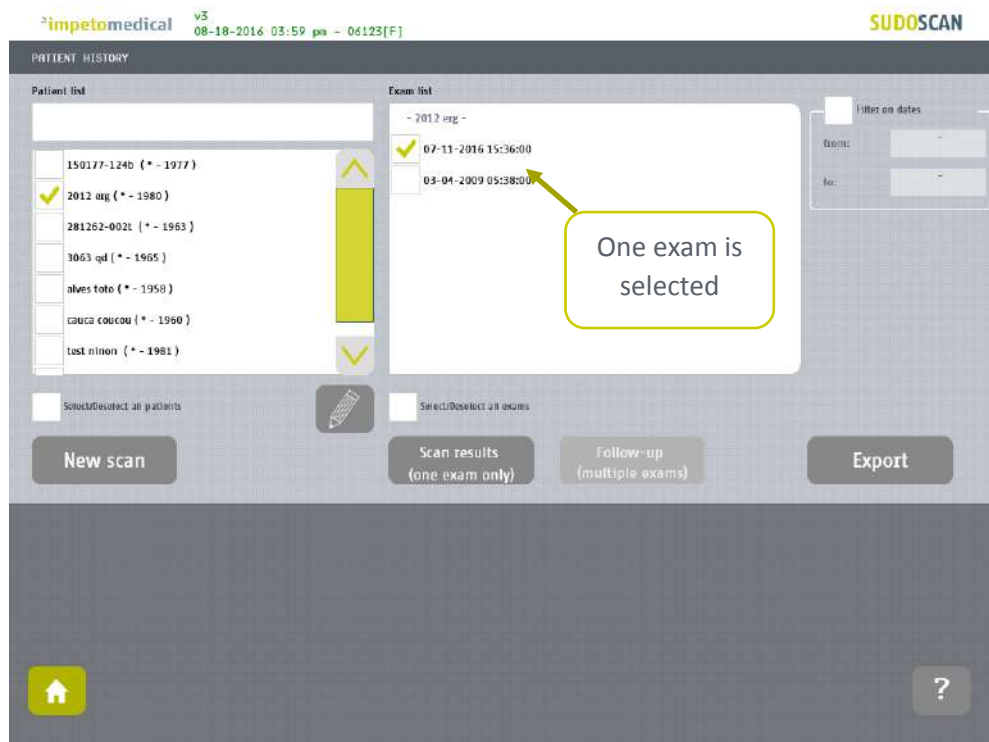
Figure 21: Display results for an exam

8.5 How to display follow-up for a patient

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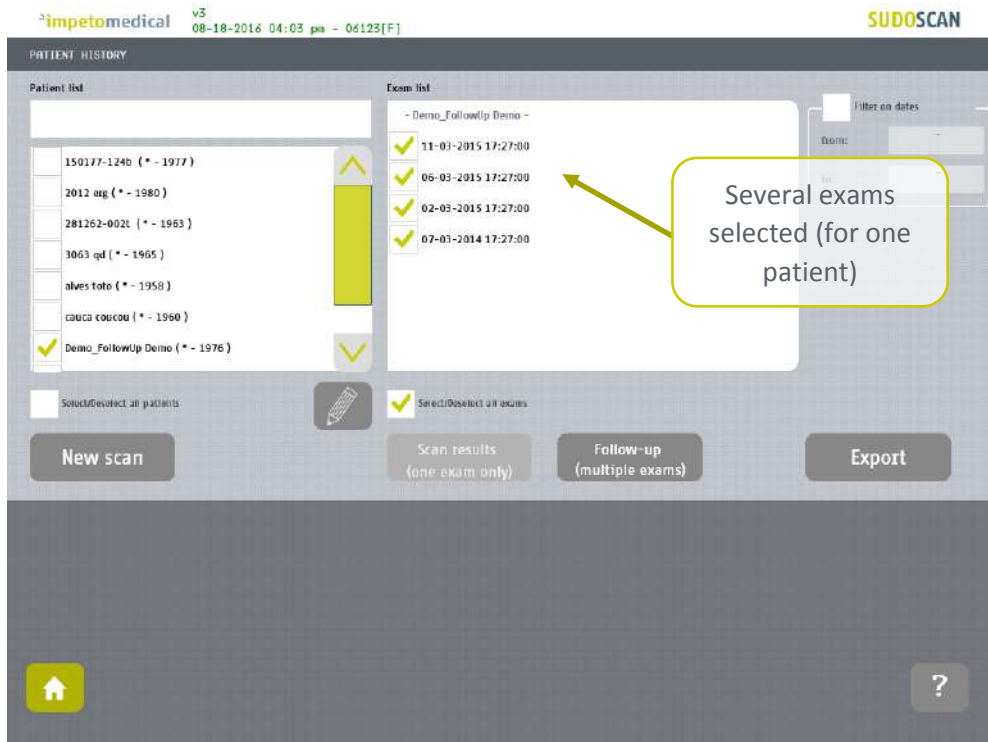
Patient follow-up is displayed when at least 2 exams are selected for the same patient. The device can display up to 15 exams.

2 Click on the **follow-up** button.
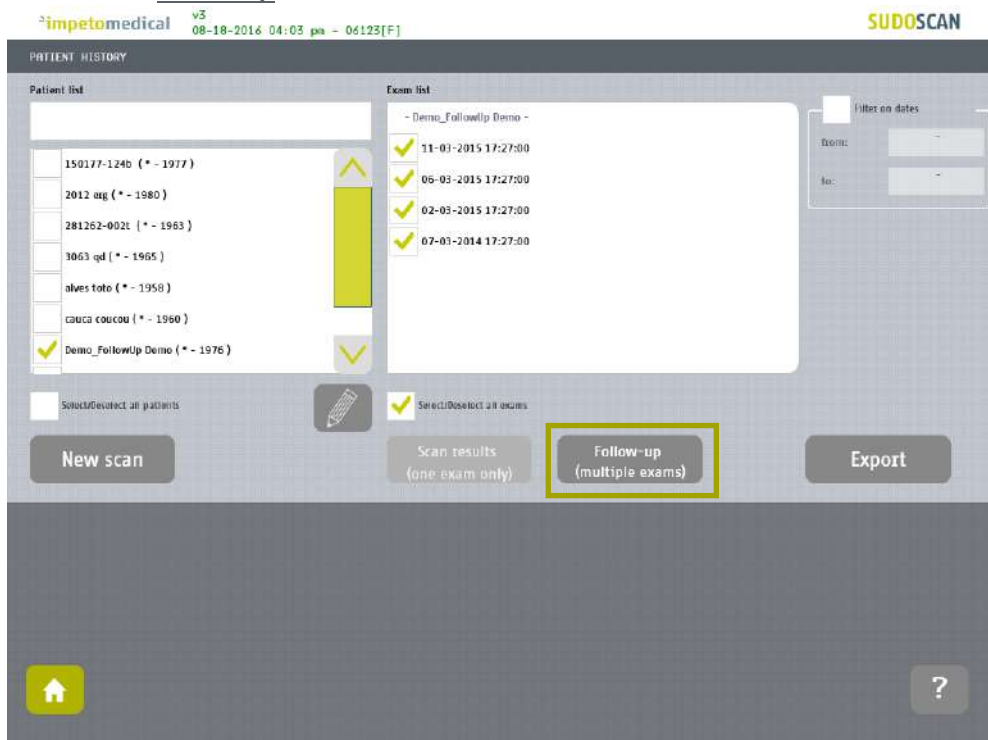
3   **The follow-up screen is displayed.**

The top graph shows the progression of conductances. It is possible to display the evolution of individual hand and foot (left and right) conductances as well as mean conductances.
The bottom graph shows asymmetry (hands and feet) and Body Mass Index (BMI).
The user is able to modify which graphs are depicted by selecting the checkboxes on the right.

4   **Click on the Print button to print the follow-up report:**
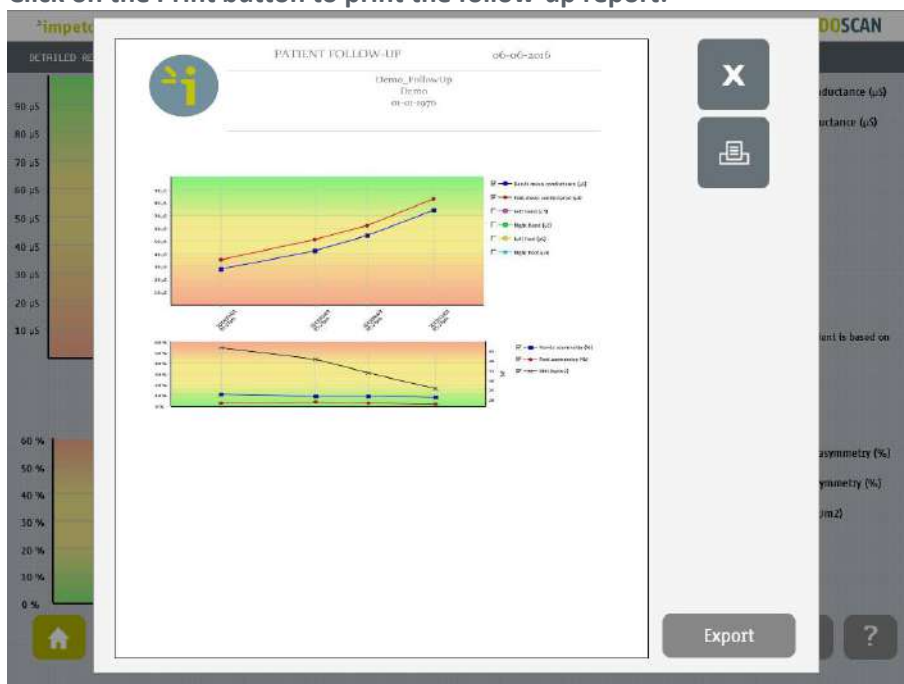
The PDF report is generated and stored within the system. To print the report, select the printer from the list (ref. p18 and 20) and click on the Print button.
To export the report to a USB key, click on the Export button and follow the on-screen instructions.

8.6 How to export data

1   **Select patient(s) and exam(s) and click on the <u>Export</u> button:**
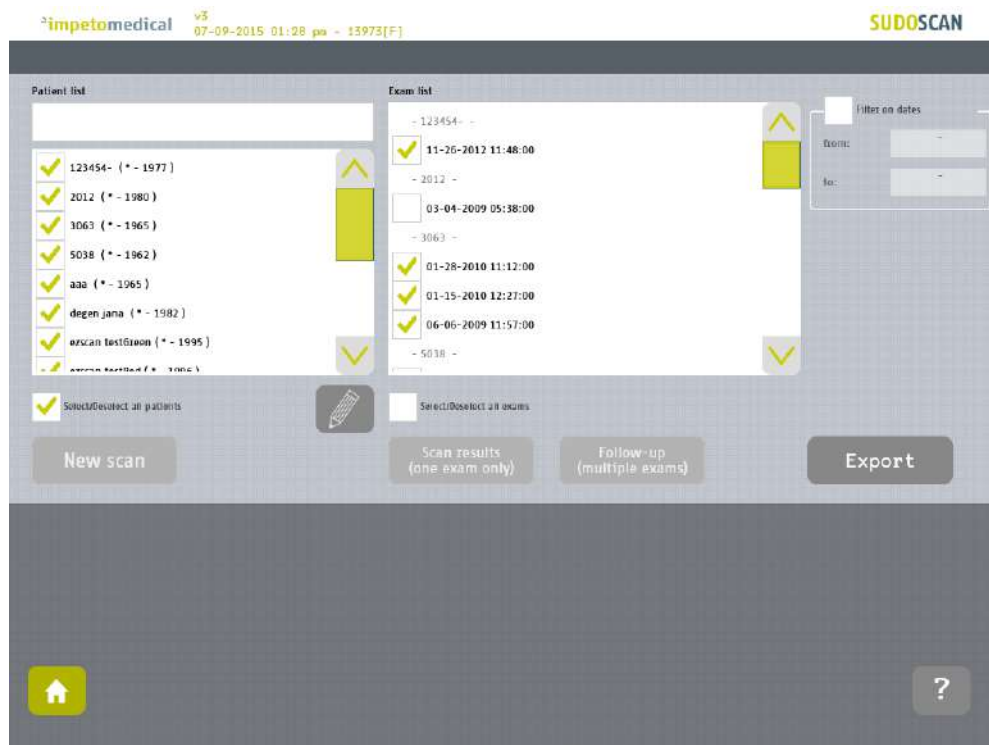
2   **Select an option:**
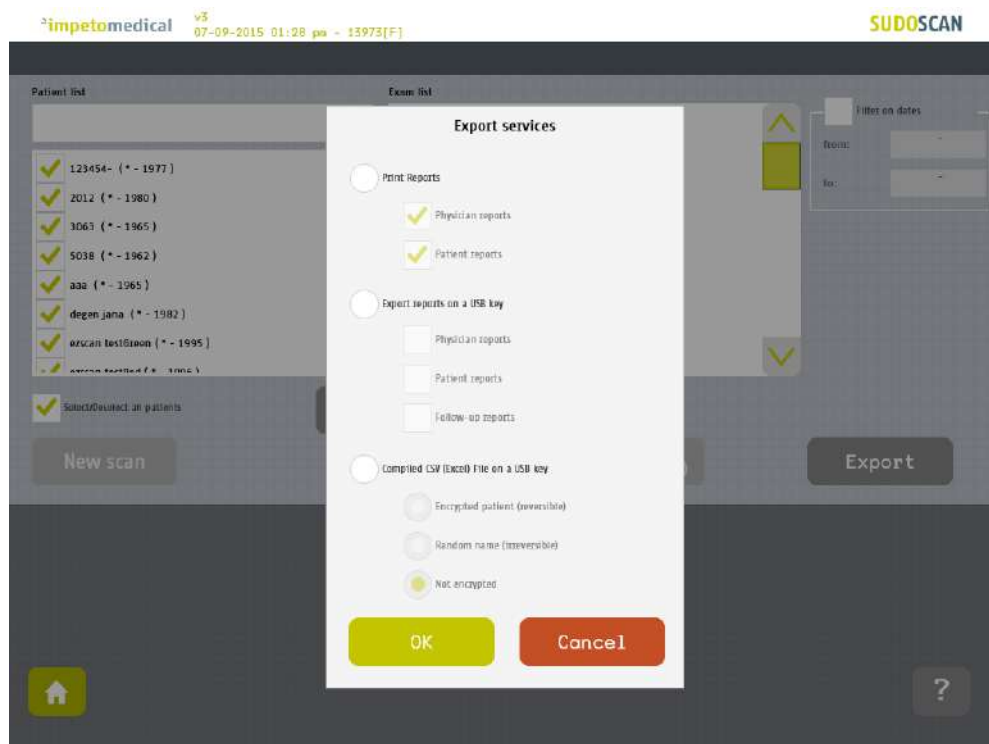
The different options are:

- *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: 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 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 are exported:**

Exporting data 19/47.

Cancel export

---
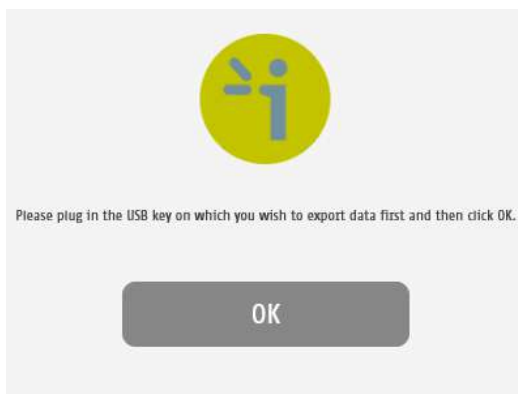
5   **The export is complete.**
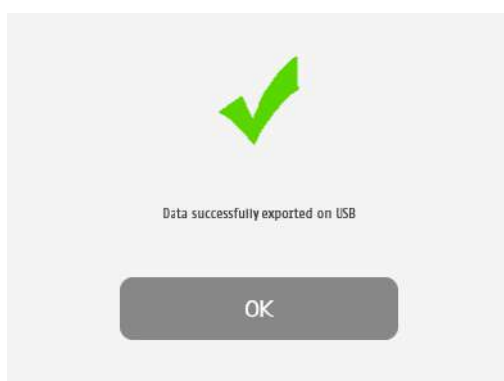
NOTE

When the export is complete, the data are on the USB key. For the reports export, when a file is missing, a file (MissingFiles.txt) is created on the USB key and contains the list of missing files.

IMPORTANT

We strongly recommend to back up your data on a regularly basis.

9 Result page

9.1 List of controls

Figure 22: Patient results page

1	Click on the Patient Results tab to view the on-screen results.
2	When available, click on Previous Physician report tab to visualize the last generated report for the selected patient. *This option can be enabled in Tools and Settings (ref. p19).*
3	Click on the Physician Report tab to reach the Report page (*ref. p53*). For more information on the results interpretation, go to p51.
4	When available, click on Previous Patient report tab to visualize the last generated report for the selected patient. *This option can be enabled in Tools and Settings (ref. p19).*
5	Click on the Patient Report tab to reach the patient version of the report.

9.1.1 Other controls

Click on the Home button (🏠) to reach the home page *(ref. p7)*.

Click on the Help button (?) button to reach the contextual help.

Click on the Go back (◀) 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 and take 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:
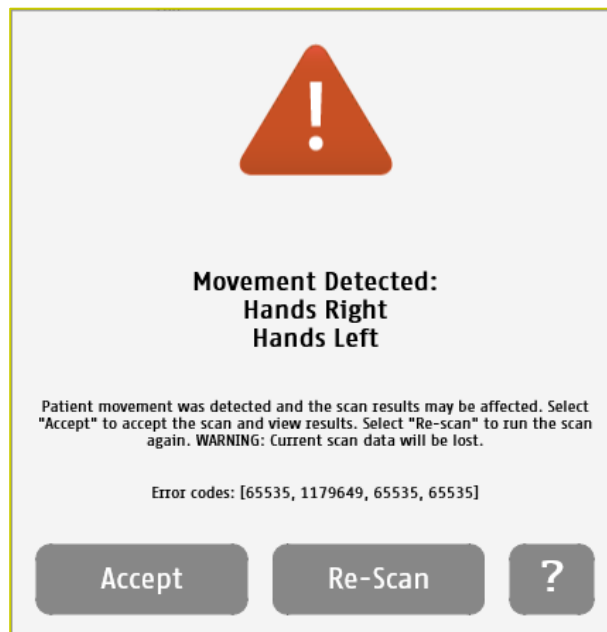
The user is given the opportunity to accept the results or re-scan the patient. Selecting **Accept** will include the current results in the patient's follow-up. The reports will be generated with a mention that the patient moved during scan and that results may be affected.

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

NOTE

Electrodes must be cleaned before re-scanning the patient with manufacturer approved cleaning solution.

During the scan, if the patient is either grounded (touched during the scan), or if an internal issue occurs, the following message will appear:
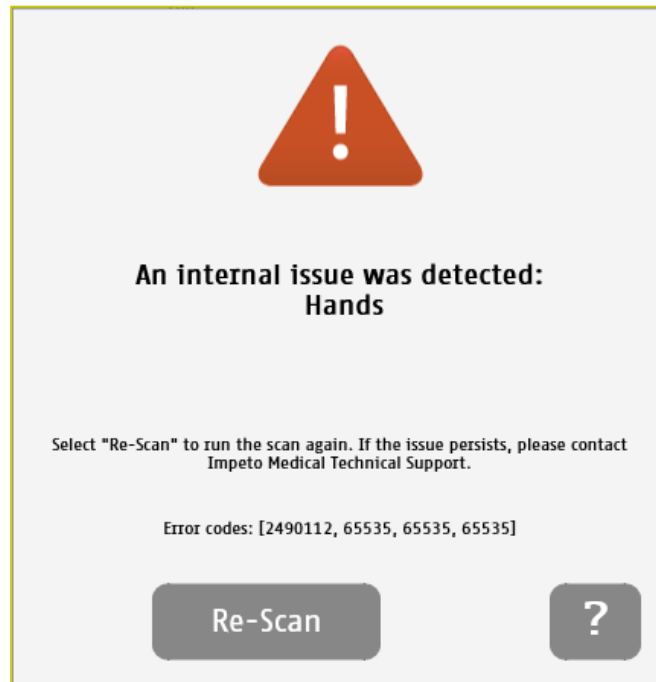
After selecting the **Re-Scan** button, the current scan will be cancelled. The user will return to the scan page to start a new scan. If the issue persists, please contact **Impeto** Technical Support *(ref. p76).*

9.3 Quick interpretation of the results

9.3.1 Disclaimer

Information for user regarding Autonomic Function Testing: Indications for use and utilization guidelines are provided as suggestions only. Physicians should ensure that the billing and coding complies not only with carrier guidelines, but also with applicable laws, rules and regulations. It is incumbent upon the physician to determine the medical necessity and utilization for any test on individual patients. This information is not intended to be and should not be construed as legal or regulatory advice.

9.3.2 Patient with no sudomotor dysfunction
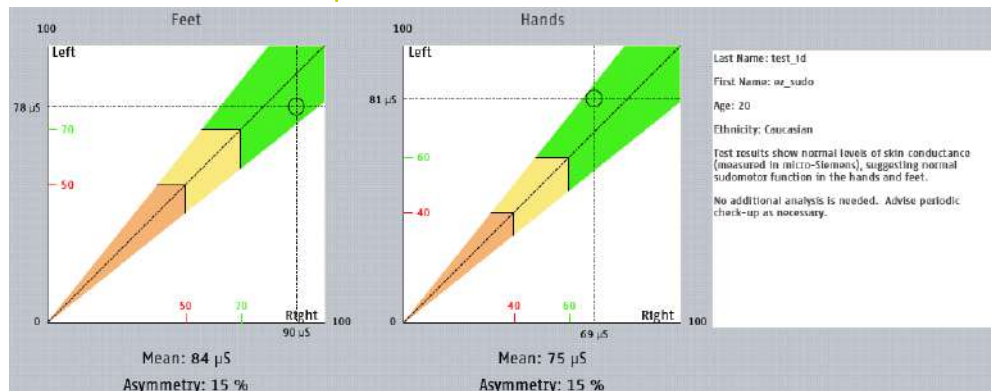
The subject has high hands and feet conductances, which suggests no sudomotor dysfunction.

9.3.3 Patient with intermediate sudomotor dysfunction
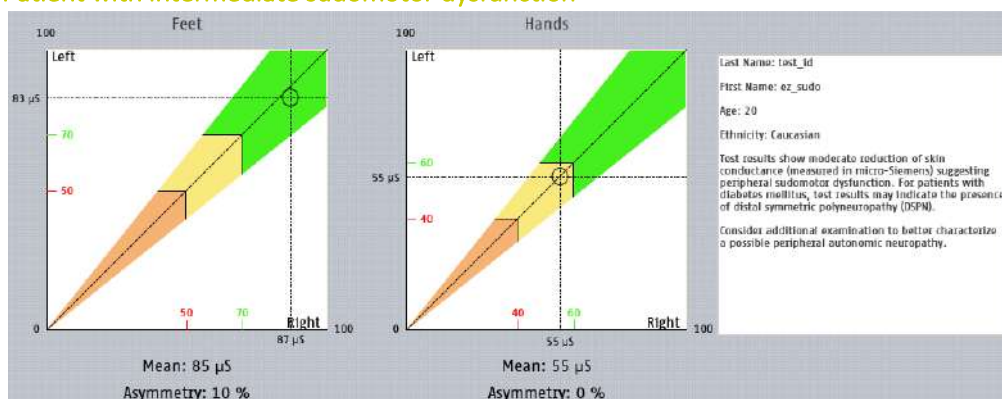
Test results show modest reduction of skin conductance suggesting possible early signs of sudomotor dysfunction.

9.3.4 Patient with high sudomotor dysfunction
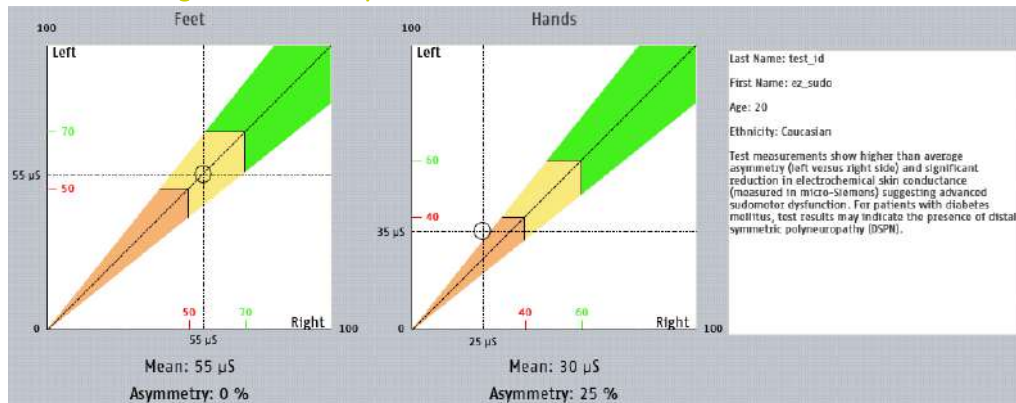
The patient has very low skin conductances on the hands and feet. This suggests advanced sudomotor dysfunction.

10 Physician and Patient Report screens

10.1 Physician report
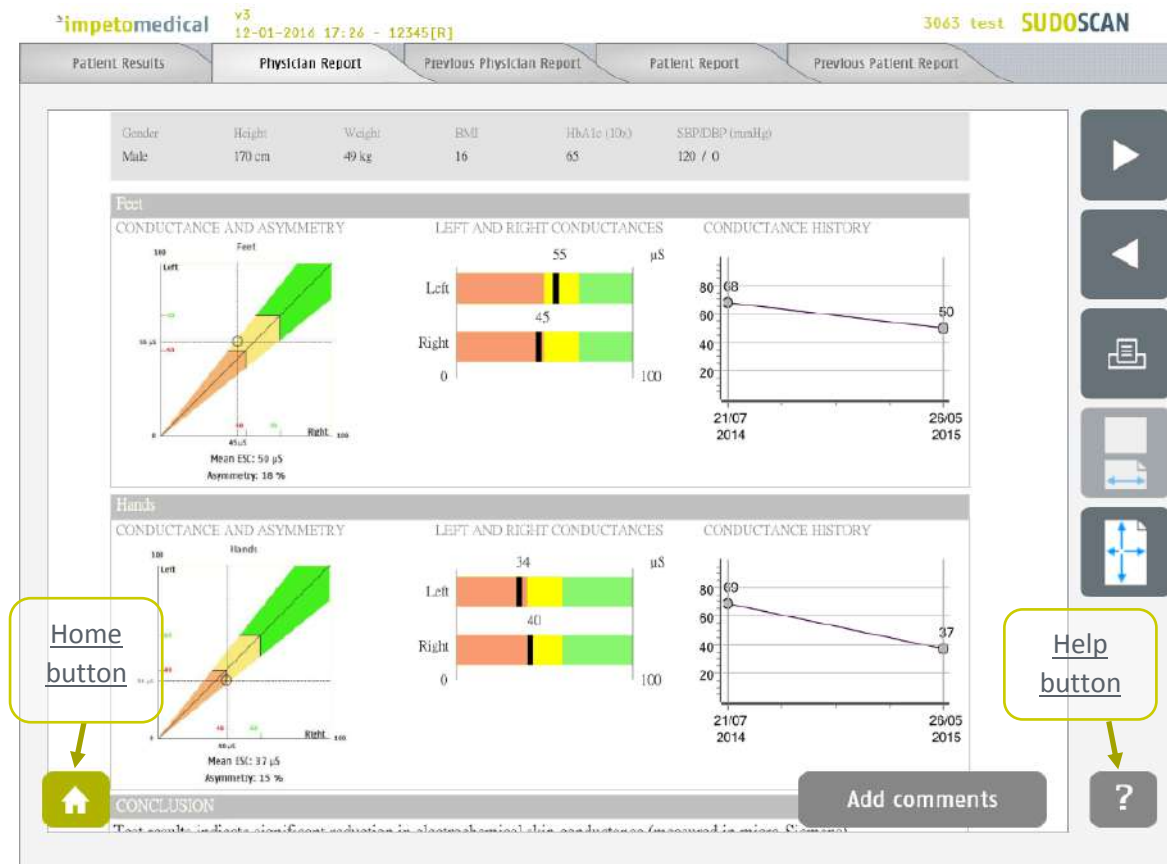
Figure 23 : Physician Report page

1	Click on the Patient Report tab to view the patient version of the report.
2	Click on the Patient Results tab to view the results *(ref. p48)*.
3	Navigate in the report (▶ and ◀ buttons)
4	Click on the Print button to physically print the report.
5	Click on the zoom buttons to display a full sheet view or wide-sheet view
6	Click on Add comments button to enter new comments on the physician report.

10.1.1 Other controls

Click on the Home button (🏠) to reach the home page *(ref. p7)*.

Click on the Help button (?) button to reach the contextual help.

10.2 Patient report
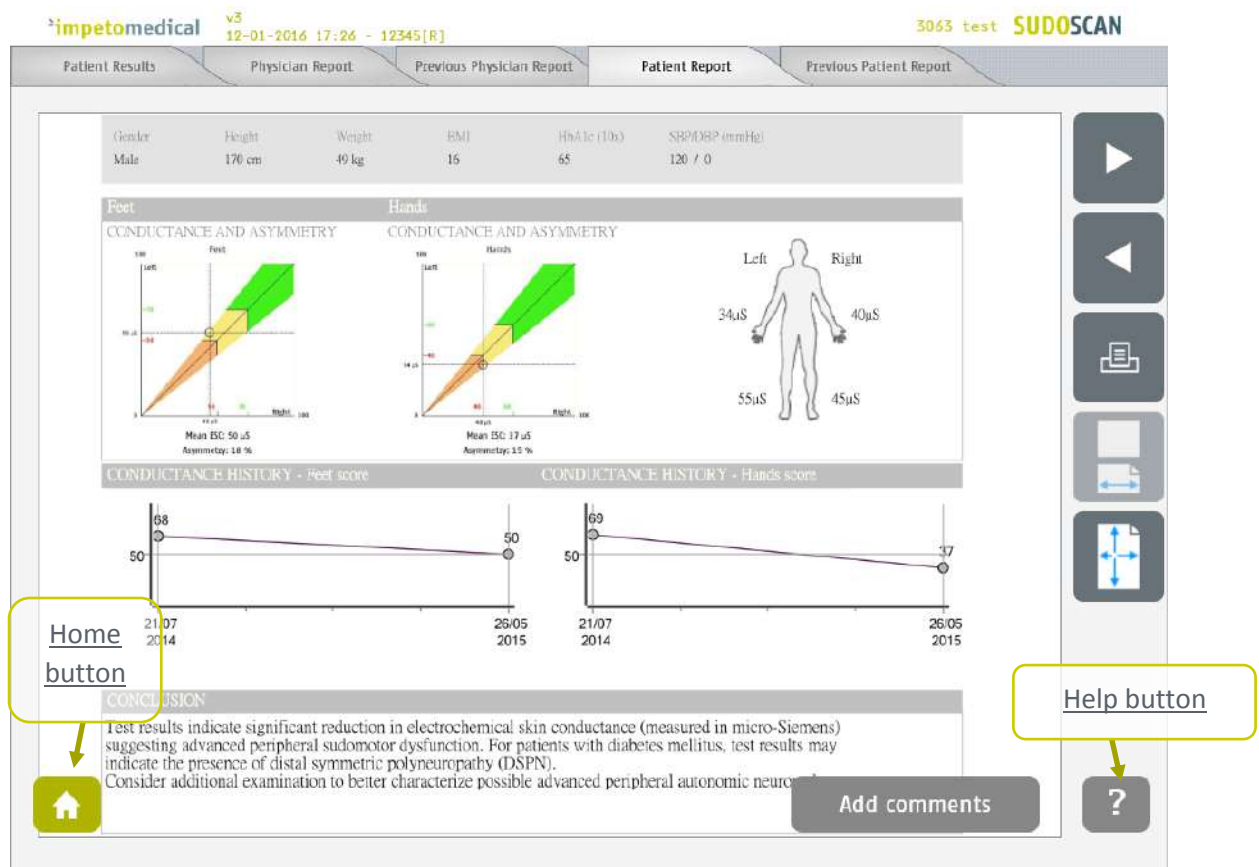
Figure 24: Patient Report page

1	**Click on the** <u>**Physician Report**</u> **tab to view the physician version of the report.**
2	**Click on the** <u>**Patient Results**</u> **tab to view the results** *(ref. p48).*
3	**Navigate in the report (** ▶ **and** ◀ **buttons)**
4	**Click on the** <u>**Print**</u> **button to physically print the report.**
5	**Click on the** <u>**zoom**</u> **buttons to display a full sheet view or wide-sheet view**
6	**Click on** <u>**Add comments**</u> **button to enter new comments on the physician report.**

10.2.1 Other controls

Click on the <u>**Home**</u> **button (** 🏠 **) to reach the home page** *(ref. p7).*

Click on the <u>**Help**</u> **button (** ❓ **) button to reach the contextual help.**

> **NOTE**

When the option is enabled from additional settings *(ref. p19 and 21),* **the reports for the penultimate exams is displayed next to the new ones.**

10.3 Add comments on physician and/or patient reports

While the user is visualizing the report, it is possible to add comments and select medication from a list.
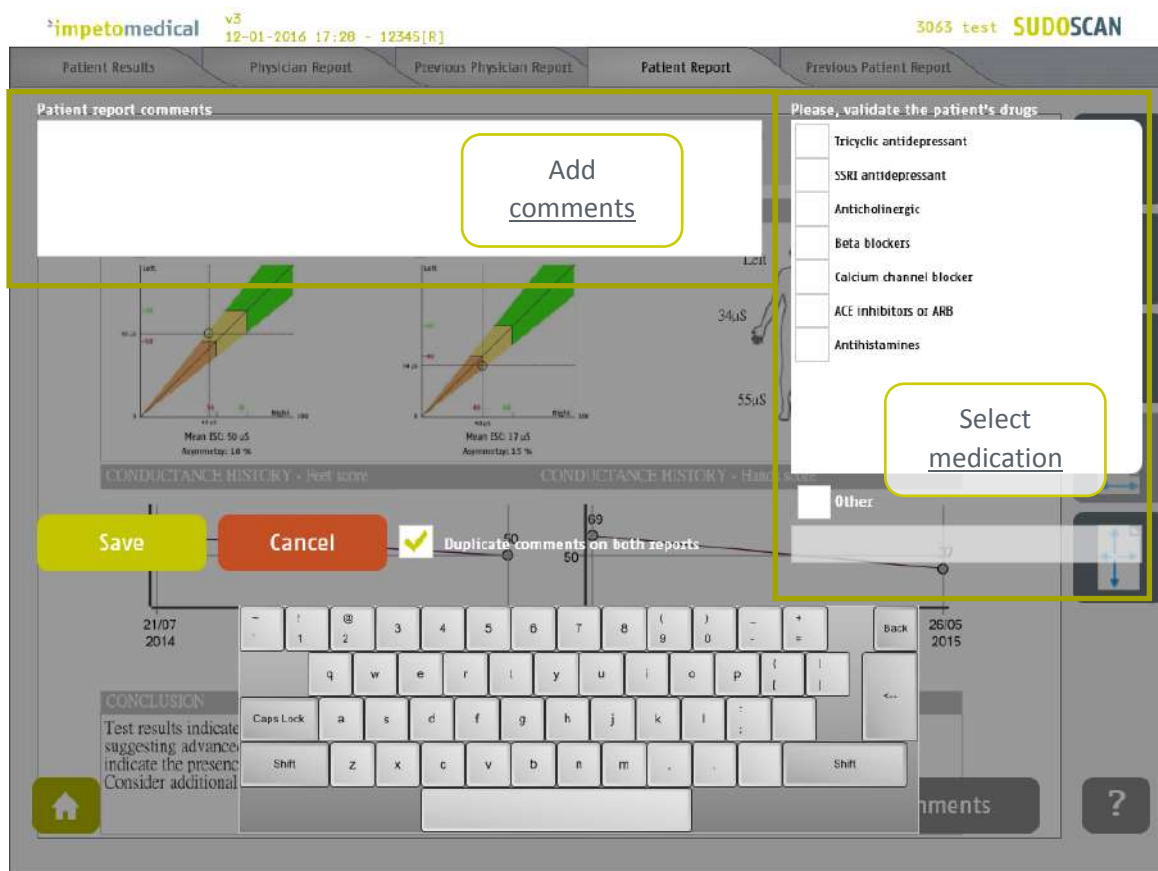
Figure 25: Add comments on reports

1	Add <u>comments</u> for the selected report (physician or patient).
2	Select <u>medications</u> from the list or add medication using the <u>Other</u> field.
3	Duplicate the comments on the other report or not.
4	<u>Save</u> the comments and regenerate the report(s) or <u>cancel</u> the changes and go back to the report.

11 Cleaning the sensor plates

⚠ IMPORTANT

Immediately after each scan, it is important to clean all sensor plates with the manufacturer approved cleaning solution.

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 sensor plates' surface.
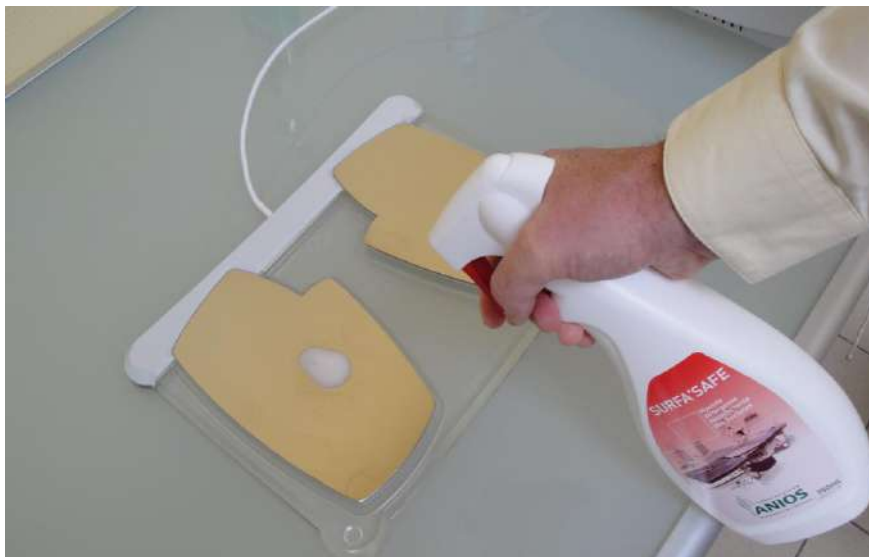
1	**Deposit only a small quantity of cleaning product on each sensor plate.**
2	**Wipe sensor plates until dry.**
	Use a new sheet for each sensor plate.

⚠ IMPORTANT

Strictly adhere to cleaning product instructions for use and precaution.

12 Replace the electrodes

When the sensor plates have to be replaced, please follow these instructions to unplug the old sensor plates and plug the new ones:

1	Open the back cover by loosening the screws.
2	Unscrew the sensor plates' cable retention bracket, if installed.
3	Grab the larger part of each plug and gently pull it backwards.
4	When installing a new set of sensor plates, please ensure the plugs are correctly seated in the socket to ensure a proper connection. Green cable in the Green Hands plug, Purple cable in the Purple Feet plug

Purple cable

Green cable
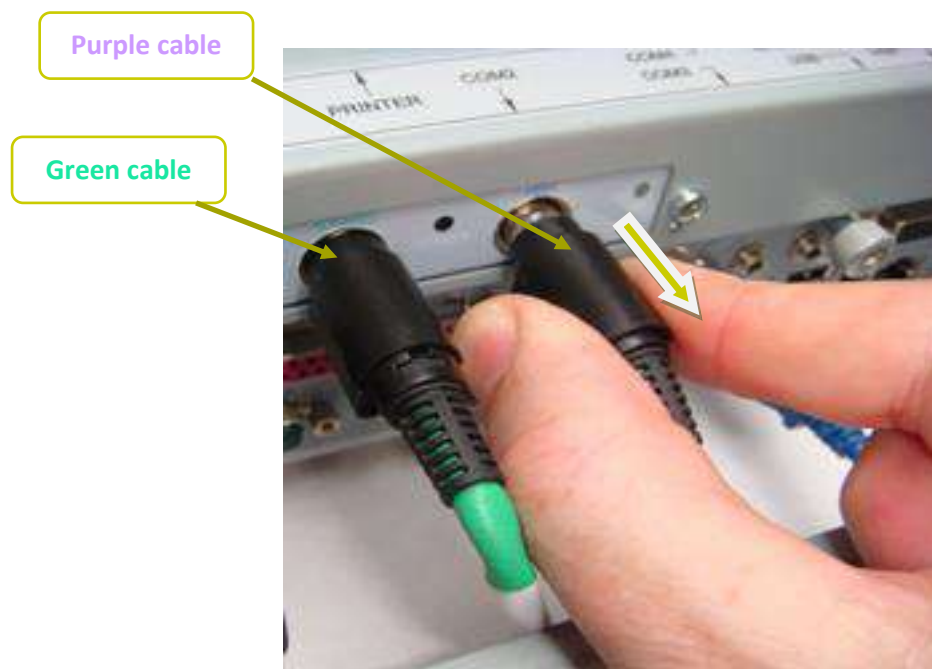
13 USB printer drivers installation

To install USB Printer drivers, you must be logged in as a Supervisor. In Tools & Settings, access the Windows Desktop *(ref. p62).*

1	**Ensure your USB key is free of viruses.**

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

2	**Insert a USB key with the appropriate printer drivers.**
3	**Follow the standard Windows procedure to install the new printer drivers and configure the printer default options.**
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 and follow instructions to install your printer.**
6	**After the installation successfully ends, reboot the system and start a Quality Check via the software *(ref. p13).***

14 Install software updates

Impeto Medical will occasionally provide software updates to ensure continuous enhancement of SUDOSCAN products. Check with your distributor or contact **Impeto Medical** to learn how to access updates online.

When an update is available, Impeto Medical will provide adequate procedure alog with the software update release.

15 Troubleshoot the system

15.1 USB connection

The following message can appear on top of the screen:
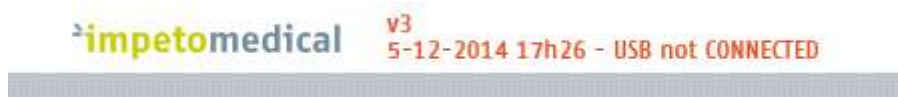
This means that the connection between the application and the hardware has been lost. It will not be possible to perform any scan in that situation.

To solve the issue:

1	**Reboot the system.**
2	**If the problem is not solved, contact your distributor or Impeto Medical** *(cf. p76)*.

15.2 Test the hardware

The Quality Check controls the proper functioning of the device. It should be done regularly *(cf. p13)*.

If an error occurs during normal use of the device, try to launch a Quality Check. If the test is negative and you still encounter issues, please contact your distributor or **Impeto Medical** *(cf. p76)*.

16 Annexes

16.1 Import a patient list via a 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

p6	**Power up the system**
p7	**Shutdown or turn off the system**
p59	**Troubleshoot the system**
	User Log in / Log off
p7	Home page
p9	Log in page
	Test the system hardware (via Quality Check):
p7	Home page
p13	Quality check page
	Quick start a scan via entering demographical patient data:
p7	Home page
p34	Scan pages
p35	Patient setup & start a scan
p56	**Clean up the sensor plates**
	Export reports to USB key:
p7	Home page
p42	How to export data
p23	Supervisor users – Additional services
p57	**Replace the sensor plates**
	Configure the hospital information:
p7	Home page
p18	Standard user – List of controls
p20	Supervisor users – Additional list of controls
	Select the printer driver:
p7	Home page
p18	Standard user – List of controls
p20	Supervisor users – Additional list of controls
	Select the language for display:
p7	Home page
p20	Supervisor users – Additional list of controls
	Retrieve previous patient data:
p7	Home page
p39	Patient History page
	Change password:
p7	Home page
p11	Password modification
p19	Standard users – Configuration (2) tab
P21	Supervisor users – Configuration (2) tab

17.2 For a supervisor user only

	Access to the desktop:
p7	Home page
p20	Supervisor users – Additional list of controls

	Install an USB printer:
p7	Home page
p20	Supervisor users – Additional list of controls
p58	USB printer drivers installation

	Upgrade the application software
p7	Home page
p20	Supervisor users – Additional list of controls
p59	Install software updates

	Select the user for configuration purposes
p7	Home page
p20	Supervisor users – Additional list of controls
p21	Supervisor users – Configuration (2) tab
p23	Supervisor users – Additional services
p25	Supervisor users – Interpretation messages

	Metric selection
p7	Home page
p21	Supervisor users – Configuration (2) tab

	Date format selection
p7	Home page
p21	Supervisor users – Configuration (2) tab

	Printing configuration
p7	Home page
p19	Standard users – Configuration (2) tab
p21	Supervisor users – Configuration (2) tab

	Take advantage of additional services
p7	Home page
p20	Supervisor users – Additional list of controls
p21	Supervisor users – Configuration (2) tab
p23	Supervisor users – Additional services
p25	Supervisor users – Interpretation messages

	Set/reset the password of any user
p7	Home page
p21	Supervisor users – Configuration (2) tab

18 Precaution of use and technical specifications

Principle of SUDOSCAN device

Low voltage is applied to sensor plates 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 sensor plates. This ensures that the measurements taken correspond solely to the sweat gland function.

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

The device records the electrochemical conductance related to the concentration of the chloride ions from the sweat glands and detected by the sensor plates (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 sensor plates placed on the feet, the hands.

General operation of SUDOSCAN

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

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

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

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

Precautions of use and maintenance

Transport

If it is necessary to pack, to transport or deliver SUDOSCAN after its use, it is recommended to arrange all its elements in their housing and position of origin.

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

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

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 sensor plates

No particular maintenance is necessary.

The external case and the cables of the sensor plates can be cleaned using a slightly wet tissue or soaked with soapy water. Do NOT use any detergent product, alcohol or acetone.

To avoid corrosion and ensuring the best conditions of hygiene, the feet and hands sensor plates must be cleaned immediately after each patient with an Impeto Medical approved cleaning solution.

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
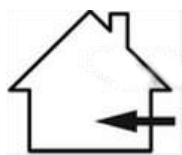
Indoor use only

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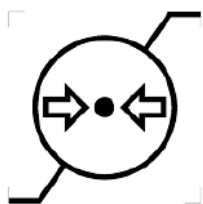
Indicates the range of atmospheric pressure that the medical device can be safely exposed to

Use of the sensor plates

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

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

⚠ WARNING

USE ONLY THE ORIGINAL SENSOR PLATES PROVIDED BY IMPETO MEDICAL.

Impeto Medical cannot guarantee the results of measurements carried out with sensor plates 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 SENSOR PLATES IS 199KG OR 438LBS.

Positioning on the sensor plates

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

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

Interrupting or stopping the recording

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

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

Recommendations to the operator

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

- Room temperature is between 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
SuMU	SUDOSCAN Master Unit
APH2	Hands plate with two sensor plates and its connecting cable
APF2	Feet plate with two sensor plates and its connecting cable
UMSu	Installation manual
ASAFE	Bottle of ANIOS Surfa'Safe spray cleaner
ELOCK	Sensor plate locking support
RCPU	Rack Central Processor Unit
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.

• Characteristics of acquisition

Storage support:	320 Gb Hard disk
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 - 127V AC at 50 - 60Hz 2,5A
	220-240V AC at 50 Hz 1,5A

- **Sealing**

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

- **Mechanical characteristics**

Master Unit alone	10,5 kg
Master Unit dimensions	38 x 38 x 30 cm
Weight of the Master Unit + sensor plates:	14,5 kg
Weight of the transportation box:	17,5 kg
Dimensions of the shipping box:	56 x 51 x 45 cm

- **Storage, transport and conditions of use of the apparatus and sensor plates**

	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.			

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