SUDOSCAN

User guide

Version 3

10/11/2015

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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.

In addition, the SUDOSCAN is an adjunctive tool in the diagnosis of distal symmetric peripheral neuropathy (DSPN) in the adult population.

1.3 Principle

SUDOSCAN measures the capacity of the sweat glands to release chlorides ions in response to an electrochemical activation. 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.

Caution: Federal law restricts this device to sale by or on the order of a physician or licensed practitioner.

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.**

WARNING

NO MODIFICATION OF THIS EQUIPMENT IS ALLOWED.

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. p67)*.

3.2 Before logging in

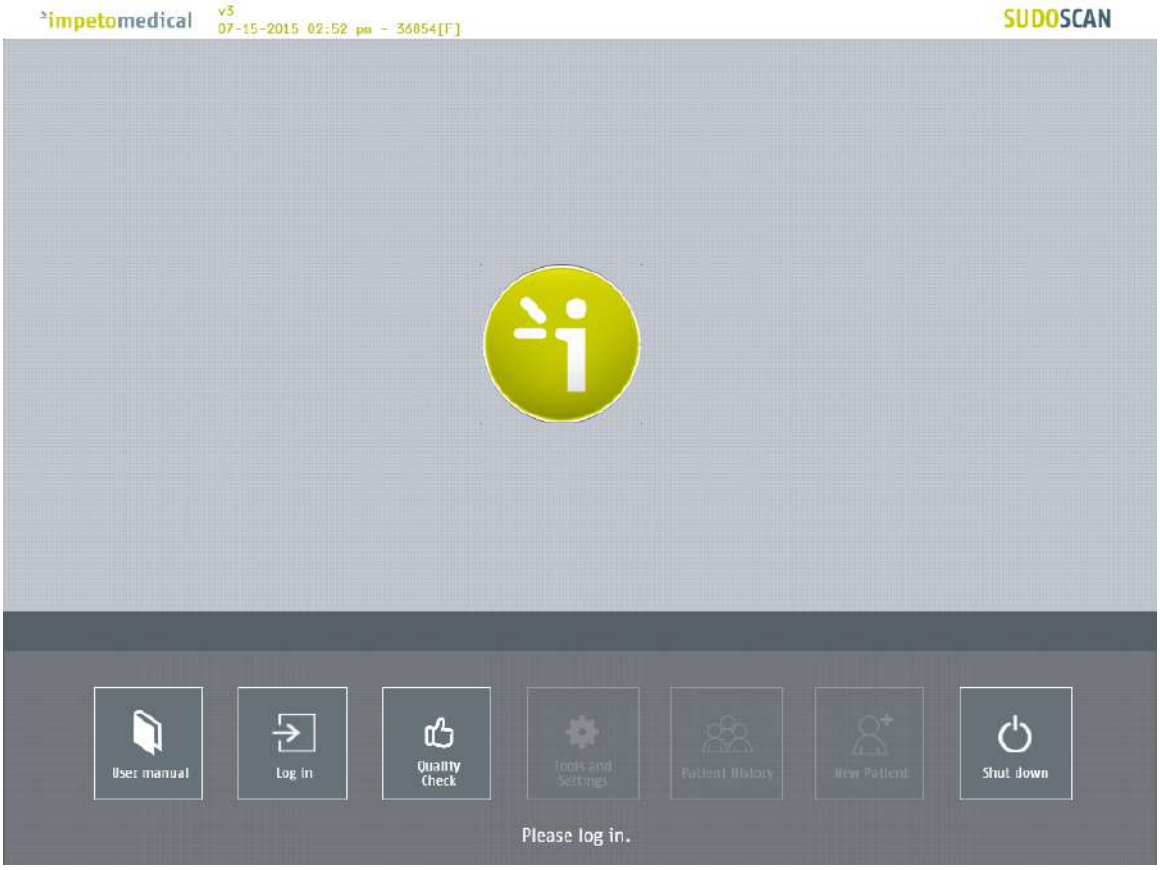


Figure 1 : Home page – no user logged in

1	**Click on the Log in button. The "Log in" panel appears *(ref. p9)*.**
2	**Click on Quality Check to execute the system "Quality Check" *(ref. p13).***
3	**Click on Shut down 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 User manual to display the electronic version of the user manual.**

3.3 For a logged in User

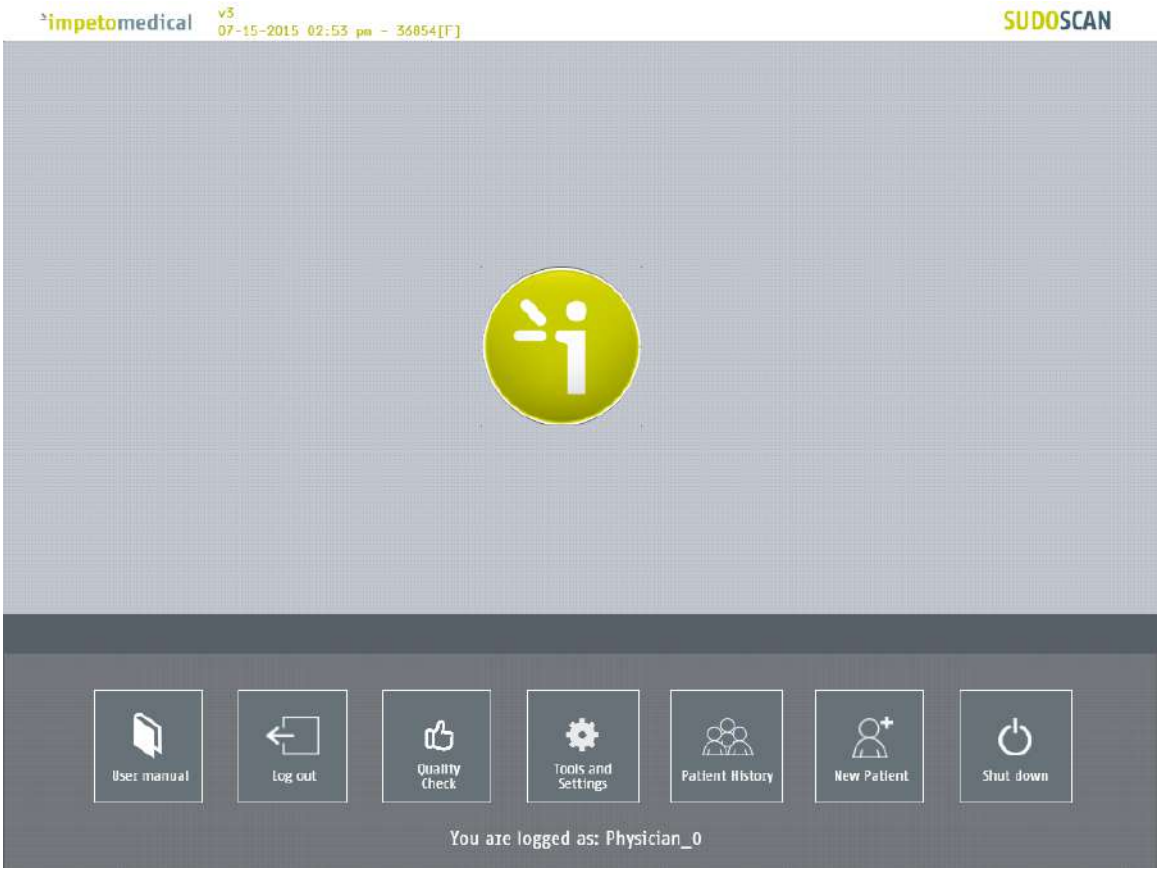


Figure 2 : Home page – User logged in

1	**Click on Log out to log out the current user.**
2	**Click on Quality Check to execute the system "Quality Check" *(ref. p13)*.**
3	**Click on Shut down to shut down the system.**
4	**Click on User manual to display the electronic version of the user manual.**
5	**Click on Tools & Settings to enter the configuration page(s) *(ref. p18)*.**
6	**Click on New patient to initiate a scan for a new patient *(ref. p33)*.**
7	**Click on Patient history to access to the patient history *(ref. p38)*.**

4 Log in page

4.1 List of controls

Figure 3 : Log in page

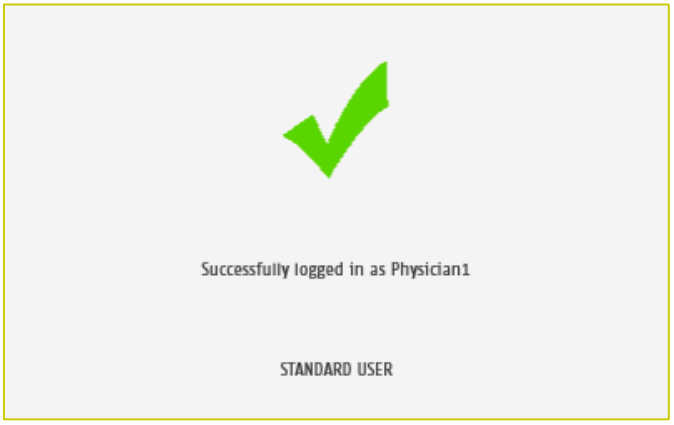
1	**Select the physician in the Physician list.**
2	**Enter your password in the Password field using the on-screen keyboard. The initial password is provided by your system supervisor. Default password: impeto.**
3	**Click on the Log in button to validate the current password for the selected physician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

4.1.1 Other controls

	Click on the Home button ( ) to reach the home page *(ref. p7).*
	Click on the Help button (?) to reach contextual help.
	Click on Change password if you want to modify your current password *(ref. p11).* (NOTE: Current password must be entered in the password field.)

4.2 Password validation

If the password is correct, the following message appears and the application automatically proceeds to the home screen *(ref. p8)*:



If 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 Current password field.** **Click Change password to show the new password fields.** **Enter your new password in the two New password fields, then click on Save password.**

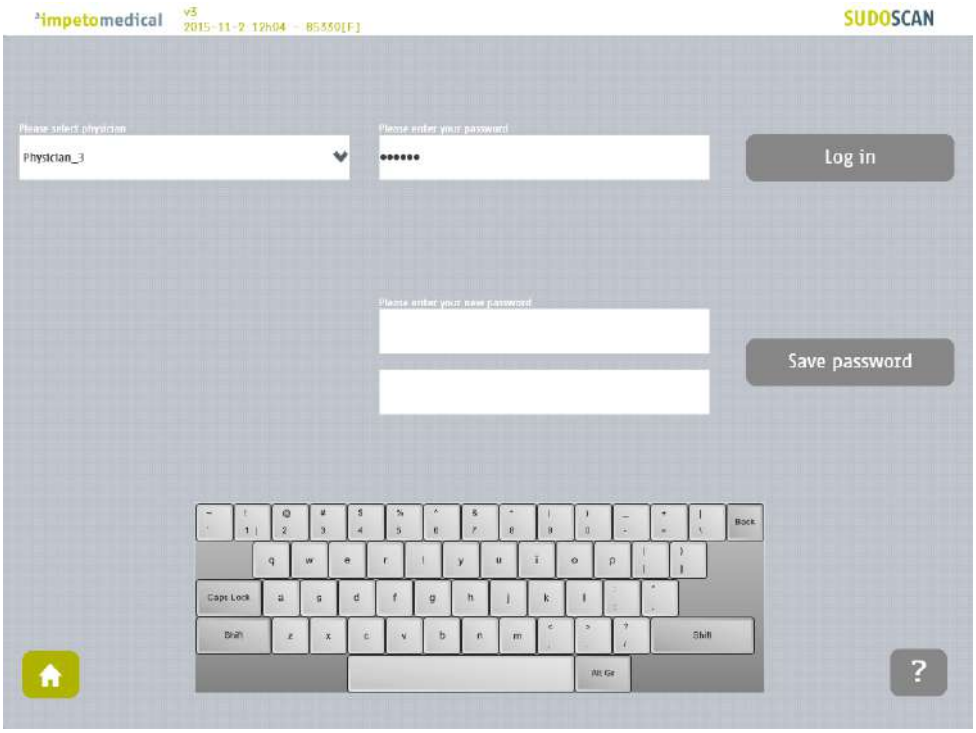
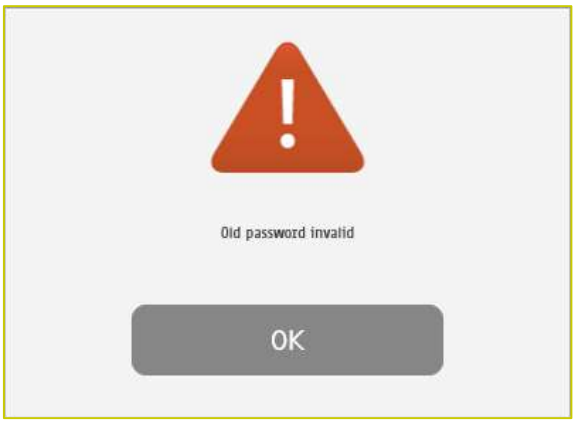


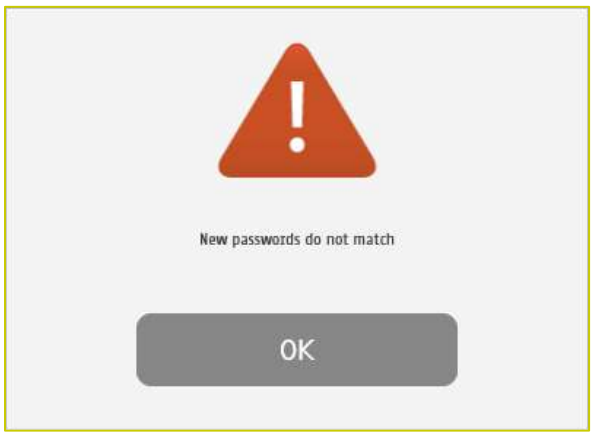
Figure 4 : Log in page – new password fields displayed

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

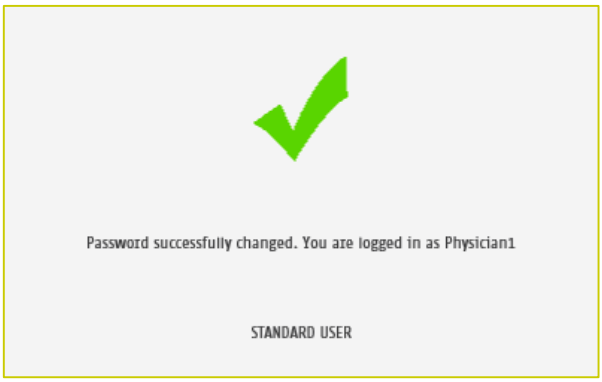
- If the old password is not correct, the following message appears:



- If the new passwords are not identical, the following message appears:



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



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 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 execute a full Quality Check sequence *(ref. p15 for Quality Check results interpretation)*.**

NOTE

The Quality Check must be conducted free of contact with the electrodes.

5.3 During a Quality Check test

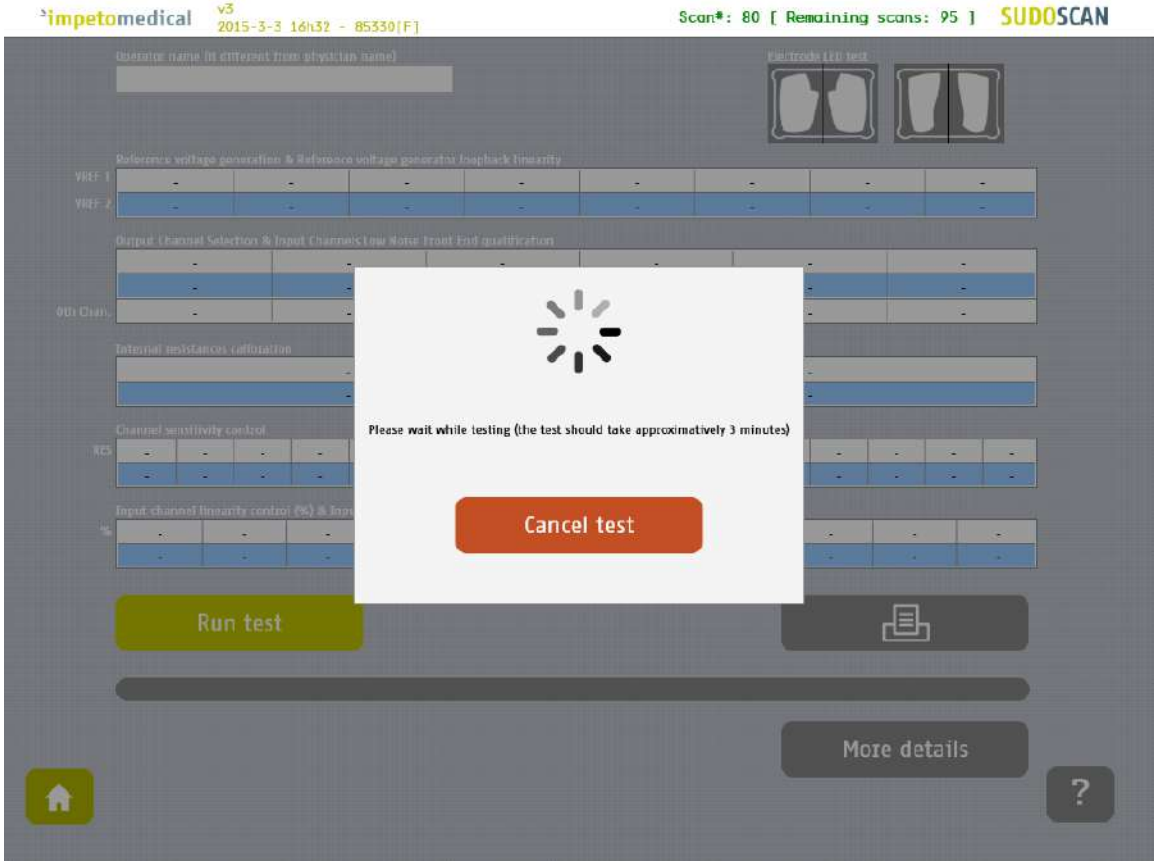


Figure 6: Quality Check page -During the Quality Check

1	**Click on the Cancel test 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 errors were found, green checks are displayed for every lines as follows:

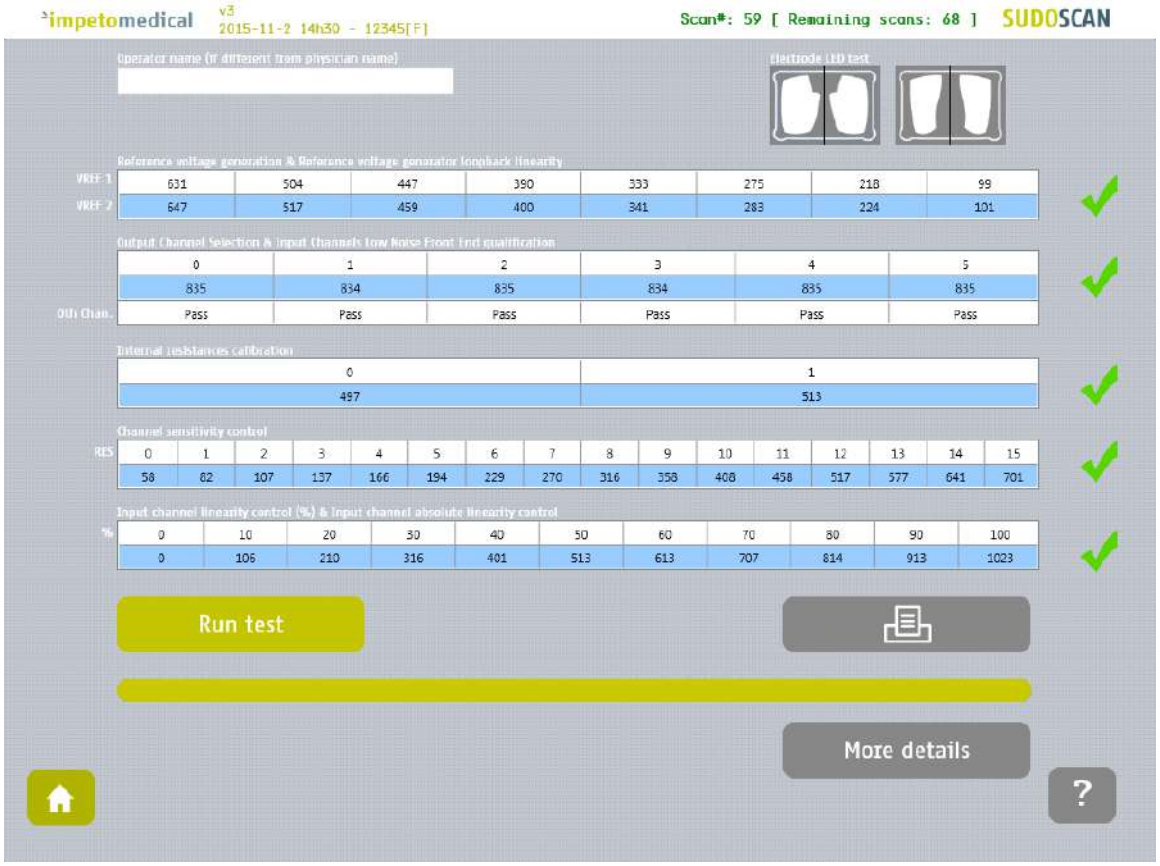


Figure 7: Quality Check page - Complete and valid Quality Check

If a problem occurs during the Quality Check, warning icons appear in place of the green checks. In that case, please contact **Impeto Medical** for technical support *(ref. p82)*.

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

1	**Click on the Print button to print and export the Quality Check report.**
2	**Click on the More details 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, you can display more information by clicking on the More Details button to view the error source.

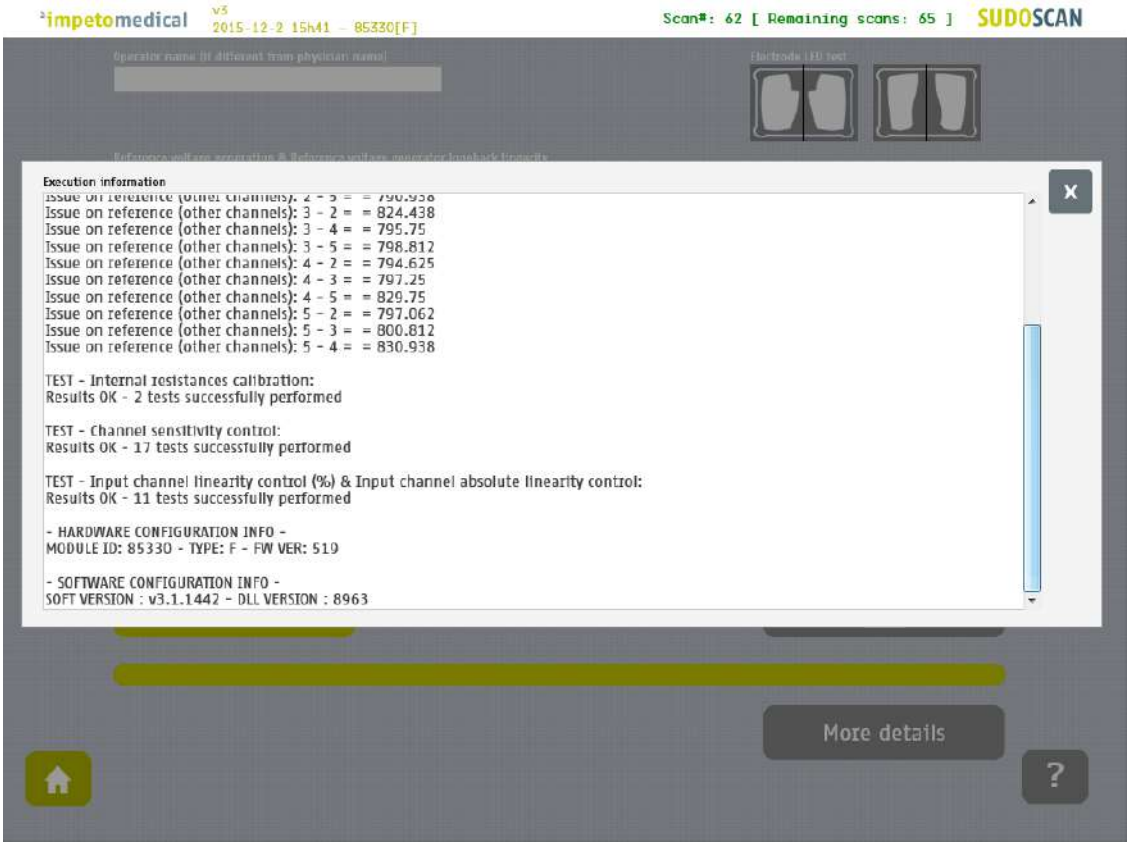


Figure 9: Quality Check page -More details on the Quality Check results

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 (?) to reach contextual help.

6 Tools & Settings page(s)

6.1 Standard users – List of controls

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

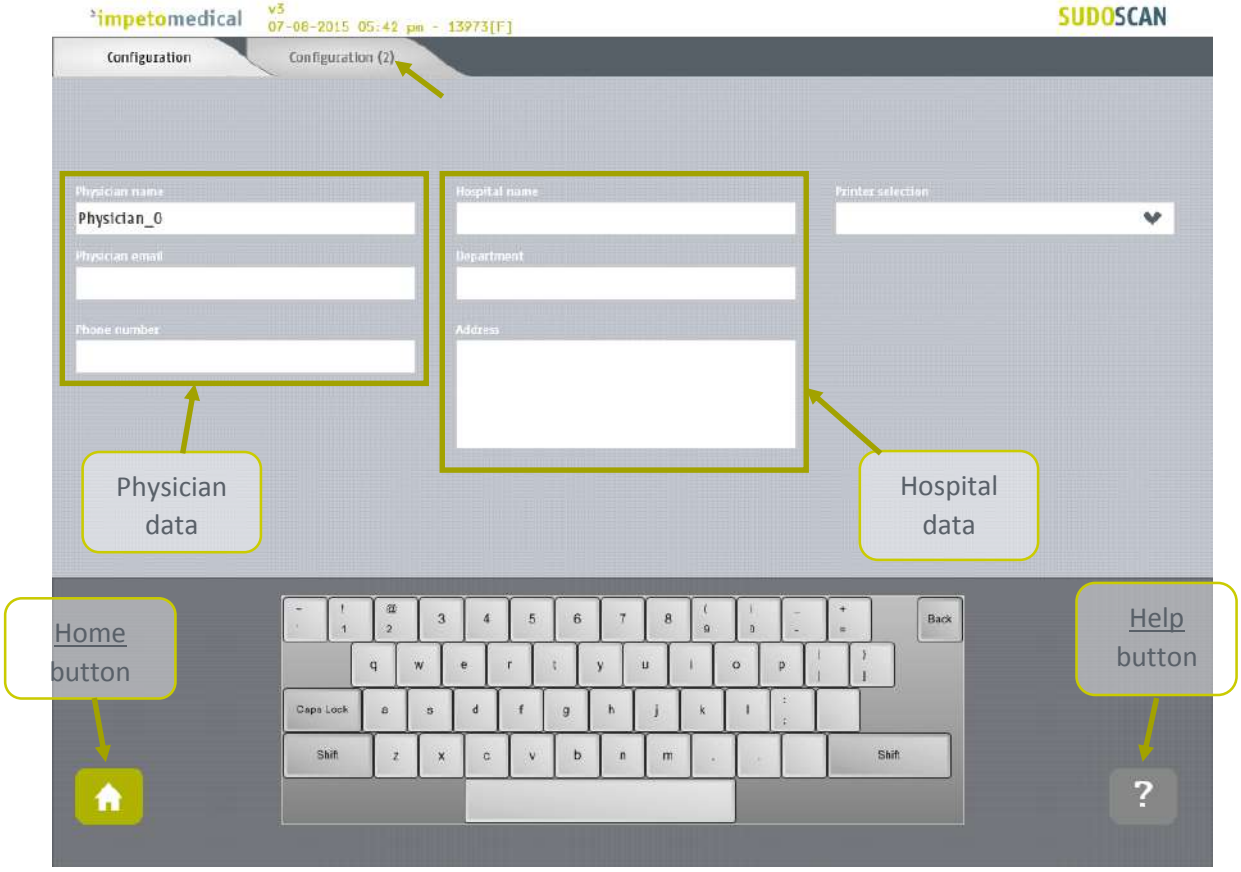


Figure 10 : Configuration page

1	**Enter hospital information in the hospital data fields.**
2	**Enter physician information in the physician data field.**
3	**Select the Printer from the dropdown list of installed printers *(ref. p62 to check how to install a printer driver).***

6.1.1 Other controls

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

6.2 Standard users – Configuration (2) tab

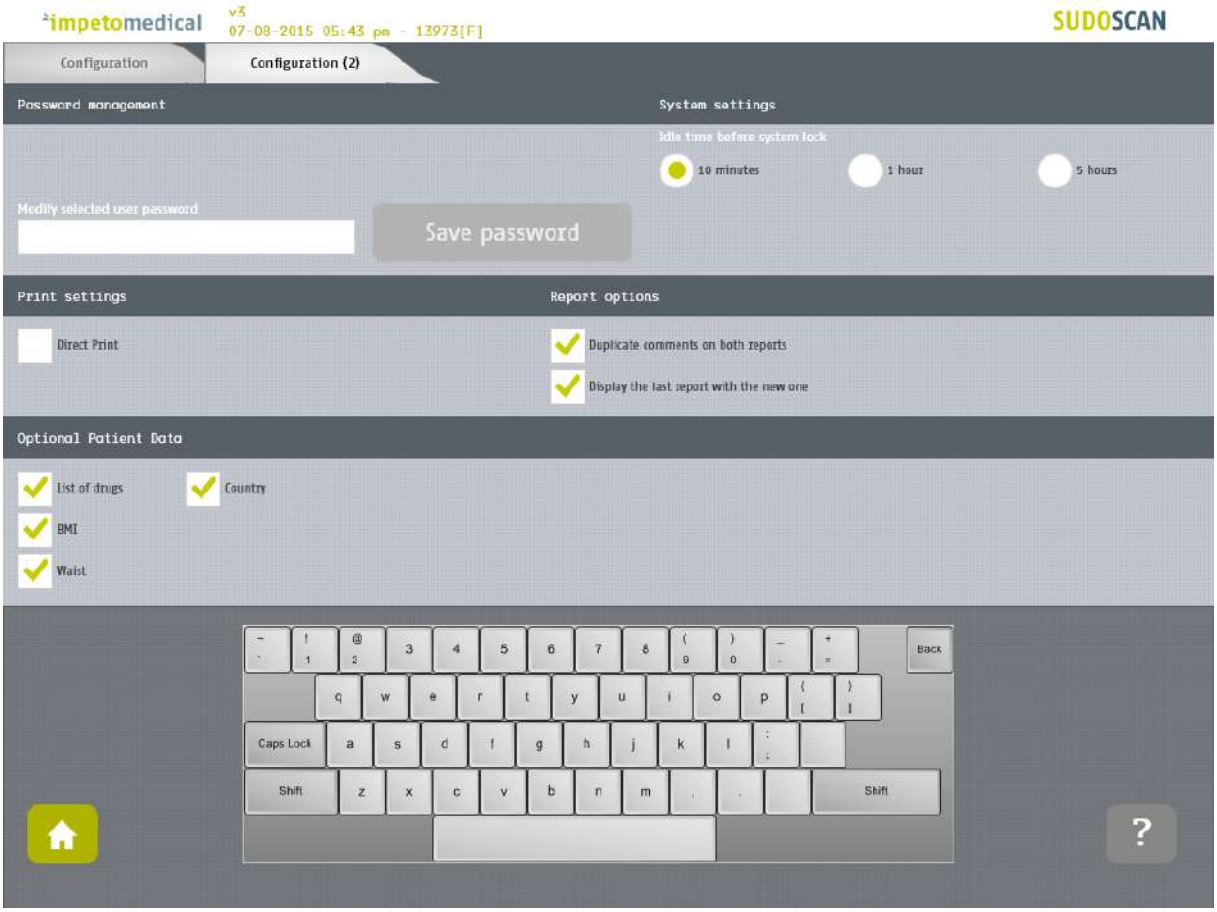


Figure 11: Standard users - Additional settings

1	**Change your password using the Password management settings.**
2	**Select the time delay before the system locks itself and you are logged out the application.**
3	**Change your print settings:** • *Check "Direct print" to display results and automatically print physician and patient reports after a successful scan. (Suggested setting)* • *Uncheck "Direct print" to display the results only. End user can print manually from the Physician report or Patient report tabs (ref. p51).*
4	**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)*
5	**Select optional data (all options may not be available).**

6.2.1 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.

6.3 Supervisor users – Additional list of controls

All settings that are available for standard users are also manageable by a supervisor.

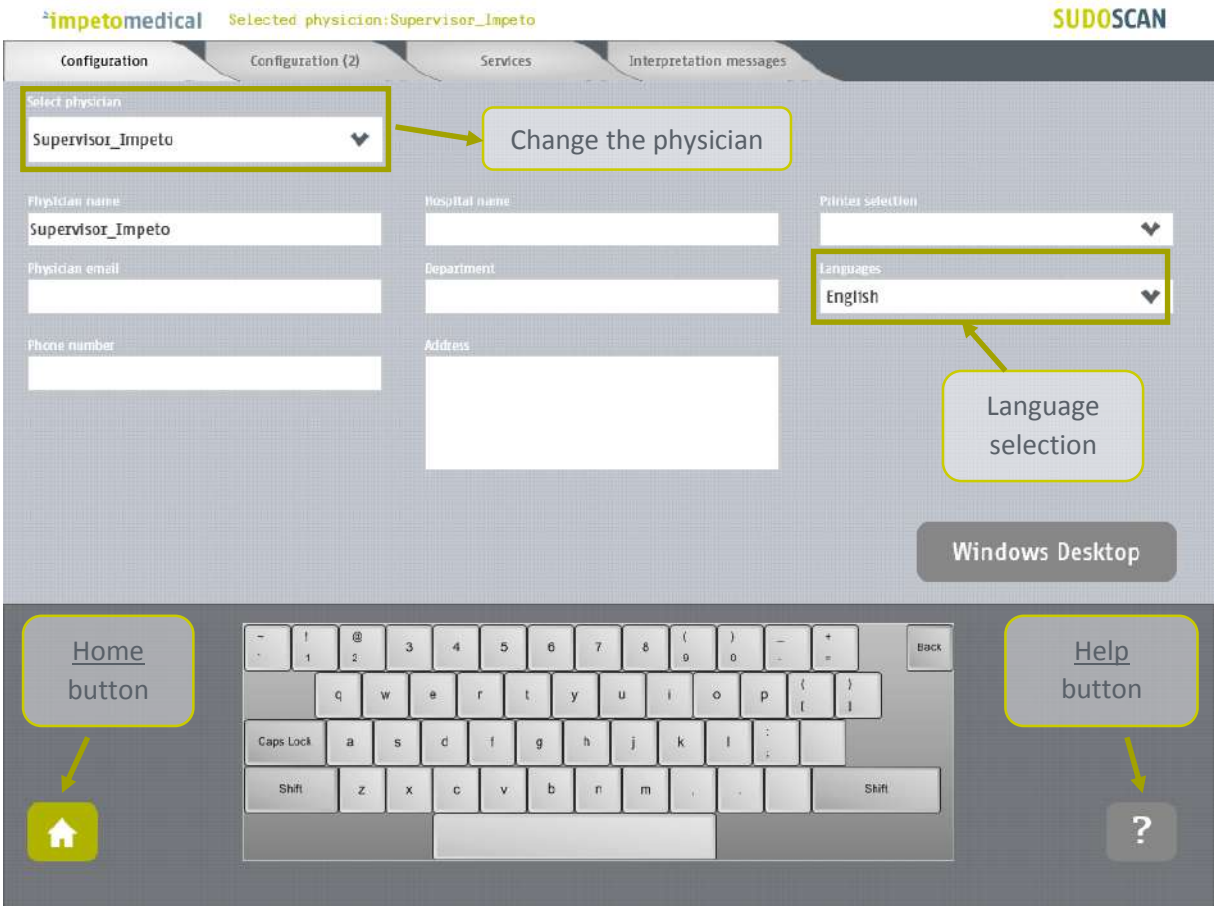


Figure 12: Configuration page - Additional controls for supervisor

1	**Select the physician 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 Configuration (2) tab to access supervisor settings *(ref. p21)*.
	Click on Services tab to access additional services *(ref. p23)*.
	Click on the Home button ( ) to reach the home page *(ref. p7)*.
	Click on the Help button ( ) to reach contextual help.

6.4 Supervisor users – Configuration (2) tab

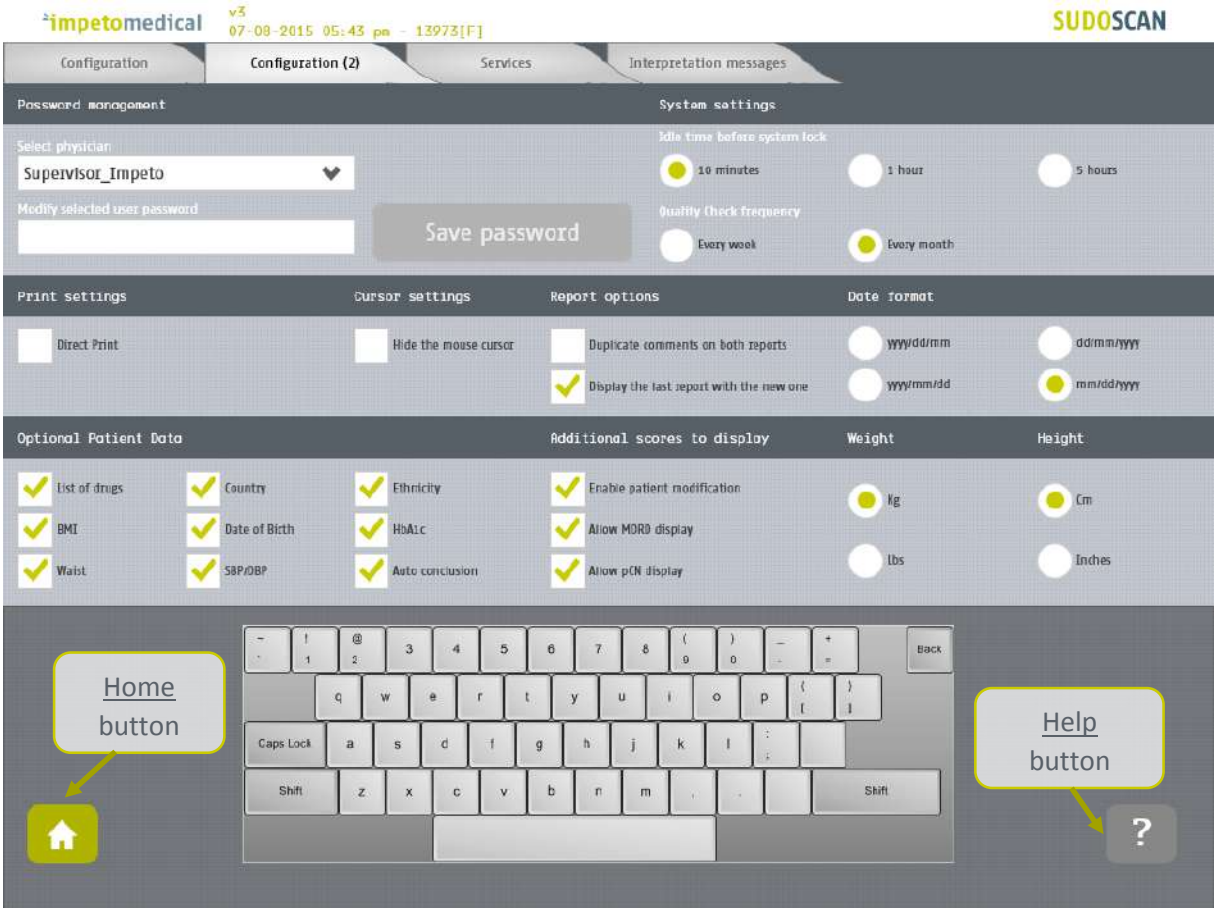


Figure 13 : Supervisor users - Configuration (2) page

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 you are logged out the application.**
4	**Select the frequency of the Quality Check (a remainder 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 (Suggested setting)* • *Uncheck "Direct print" to display the results only. End user can print manually from the Physician report or Patient report tabs (ref. p51).*
6	**Change the mouse cursor settings:** • *Check the box to hide the mouse cursor* • *Uncheck the box if 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 scan (if any)*

8	**Select the date format to apply for the selected physician.** Default mode is MM/DD/YYYY.
9	**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.*
10	**Change data management settings:** • *Check "Enable the patient modification" to allow standard users to modify patient demographic data.* • *Check "Enable the display of MDRD" and/or "pCN" 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 (lb).

6.4.1 Other controls

Click on the Configuration tab to access the standard settings *(ref. p20).*
Click on the Services tab to access additional services *(ref. p23).*
Click on the Home button ( ) to reach the home page *(ref. p7).*
Click on the Help button ( ) to reach contextual help.

6.5 Supervisor users – Additional services

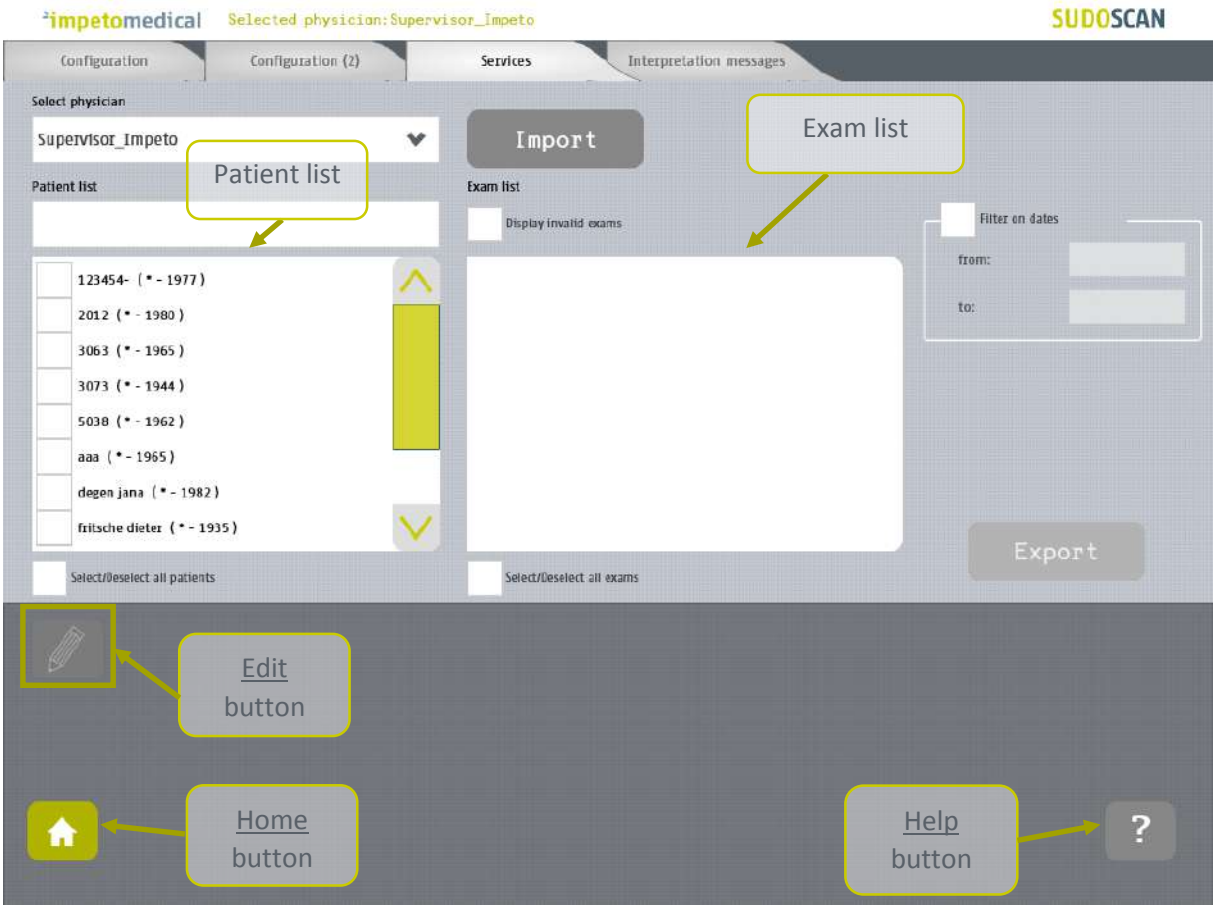


Figure 14 : Services page - Additional supervisor services

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. p25).***
3	**Select patients from the list. To do so, some tools are available:** • *A filter for patients' name, first name, year of birth and patient identifier (PID)* • *A filter for dates ("from" and "to" dates)* • *A control to select/deselect 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 control 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 attached to the selected patient(s) *(ref. p30).***
6	**Click on the Export button to export data attached to the selected patient(s) and exam(s) *(ref. p*Erreur ! Signet non défini.*).***

6.5.1 Other controls

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

Click on the Configuration (2) tab to access supervisor settings *(ref. p21)*.

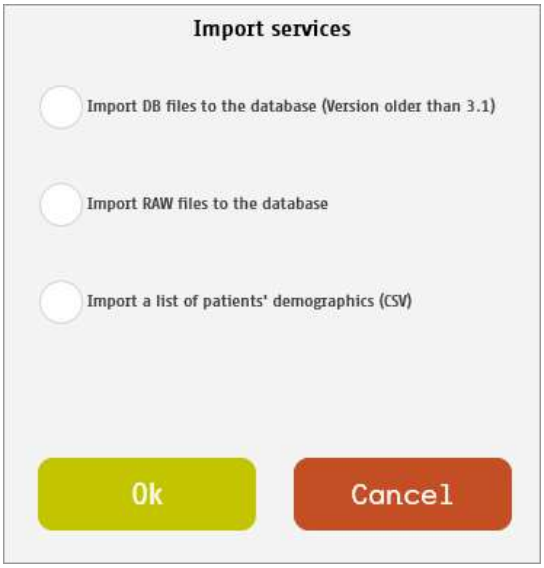
Click on the Home button ( ) to reach the home page *(ref. p7)*.

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

6.6 Import data for a selected physician

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

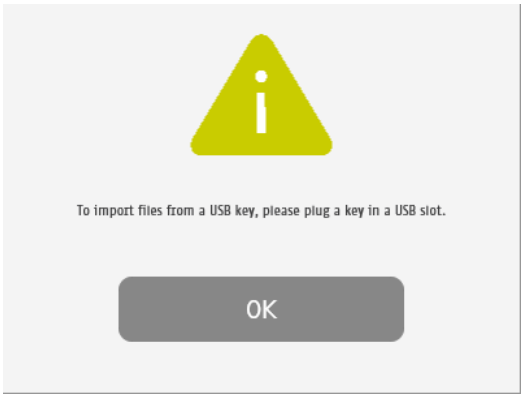
2 **Click on the Import button. A popup window appear to select the type of data you want to import:**



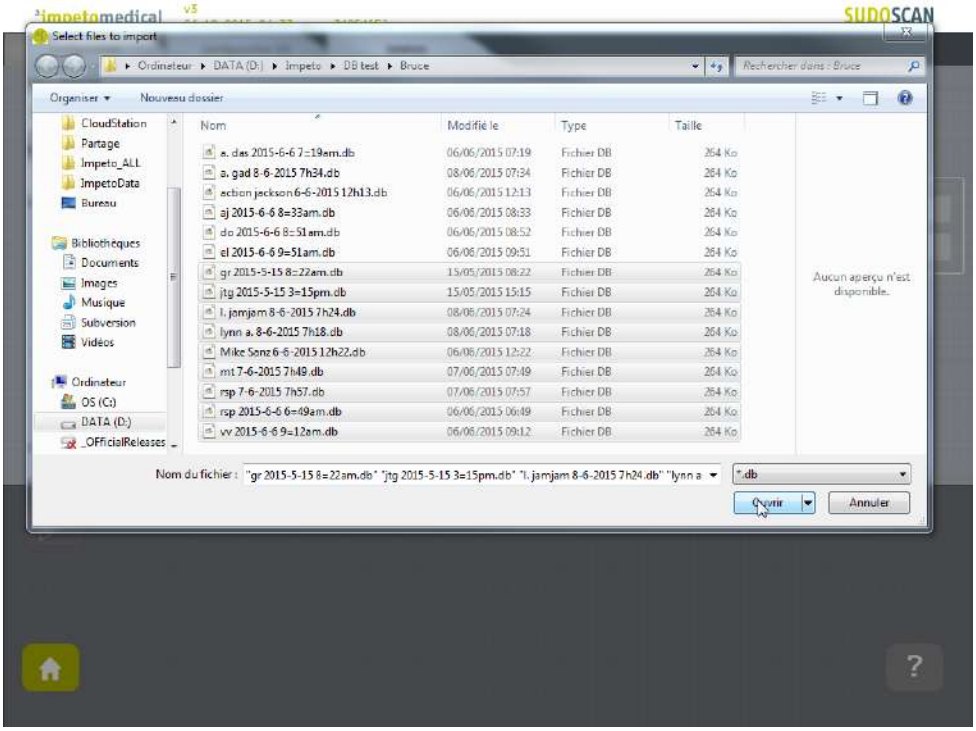
You can select several type of data:

- *Import DB files: these are the raw data on old Impeto systems (2.xx version).*
- *Import Raw files: these are the raw data on Impeto 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. p66).*

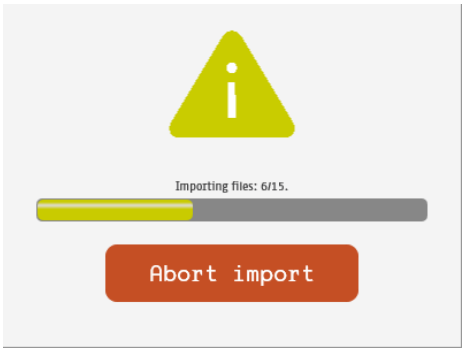
3 **Validate and verify that the USB key is correctly plugged into the system:**



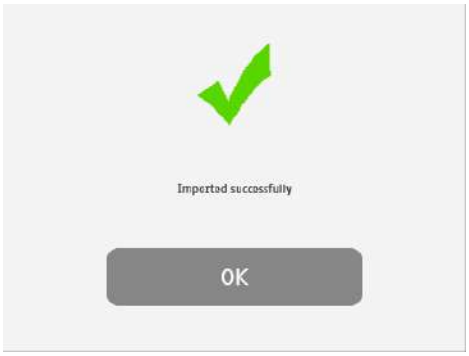
4 **Validate and select files to import:**



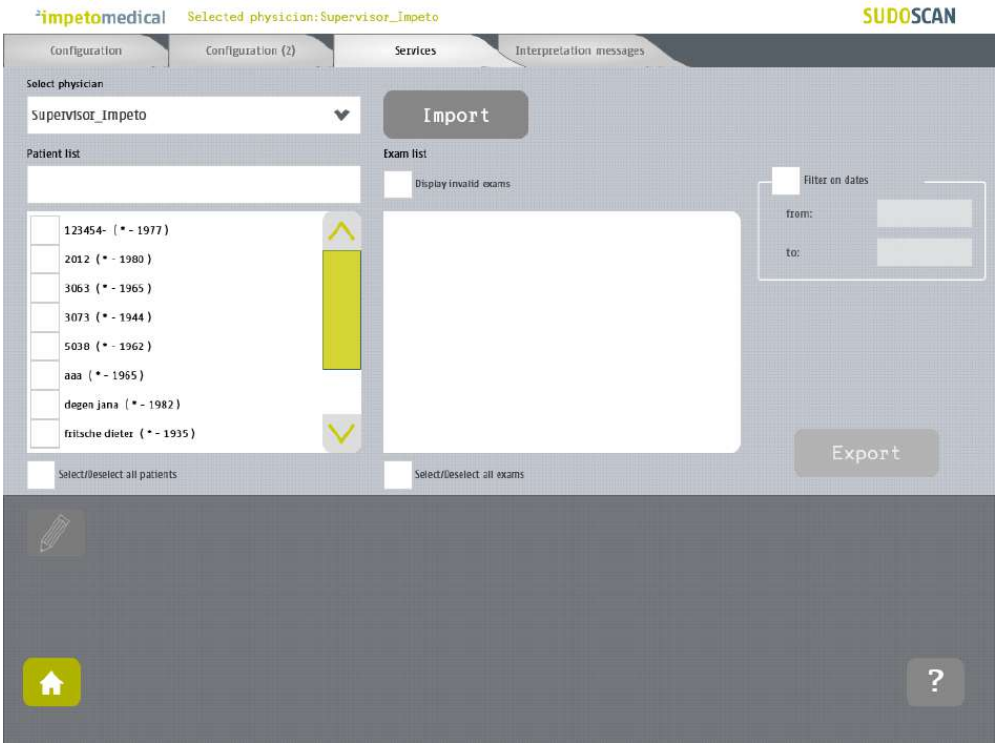
5 **The files are imported.**



6 **The import is complete.**



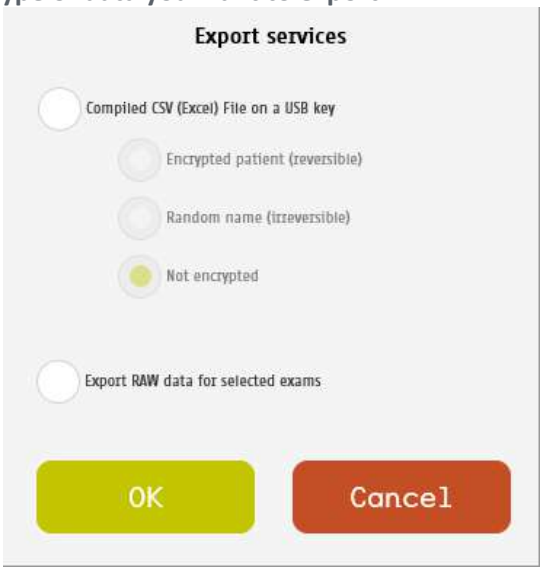
7 **The list of patients is updated with the new data.**



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).**

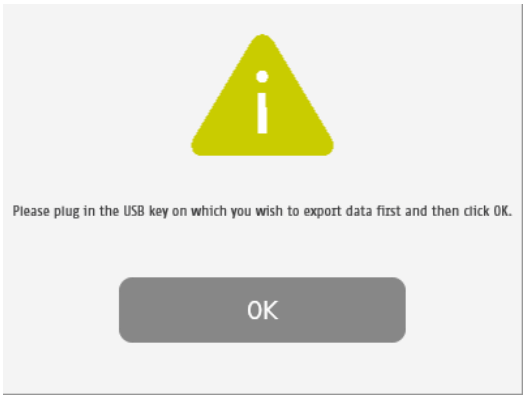
2 **Select patient(s), exam(s) *(ref. p23)* and click on the Export button. A popup window appears to select the type of data you want to export:**



You can select several types of data:

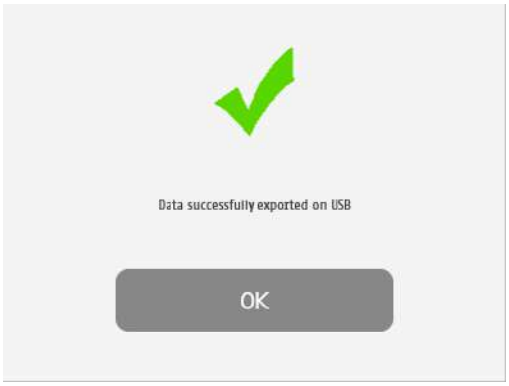
- *Compile and export a CSV file: including all data for the selected exams. Exported data are detailed within annexes (ref. p64). The encryption of patients' names and first names is optional (reversible, irreversible or none).*
  Stored within a /CompiledCSV/ directory.
- *Export Raw files: These are the raw data, useful to switch from one Impeto system to another.*
  Stored within a /ExportRaw/ directory.

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



4	**Click on Ok and the files are then exported:**

5	**The export is complete.**



NOTE

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

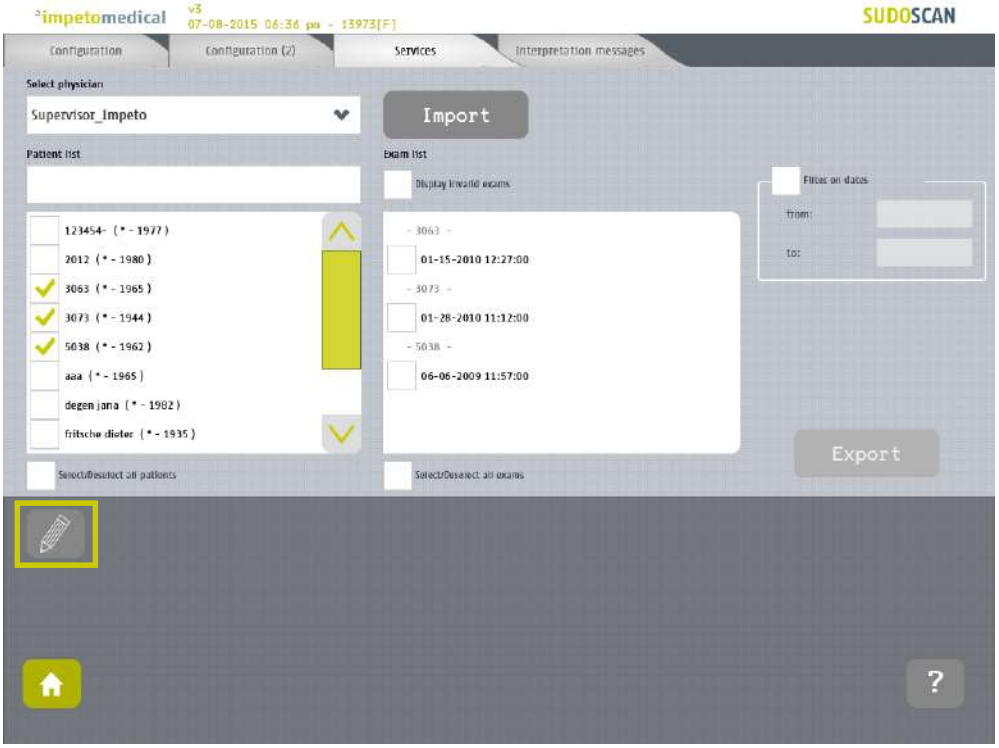
IMPORTANT

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

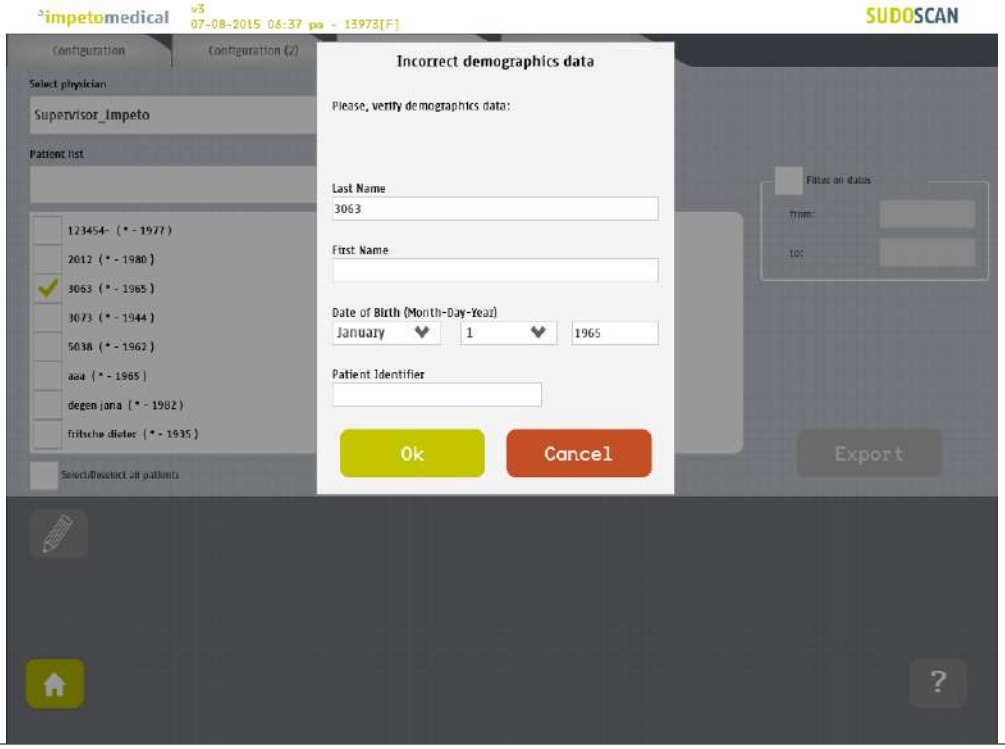
6.8 Patient reconciliation & patient demographic data modification

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

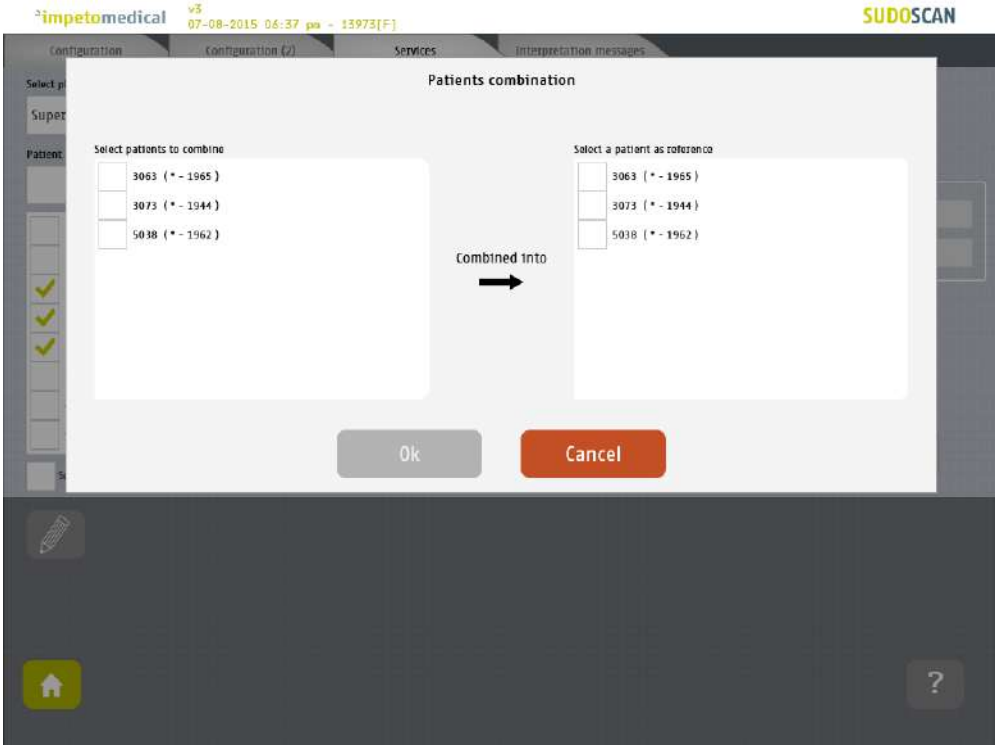
1 **Select one or several patients *(ref. p23)* and click on the Edit button.**



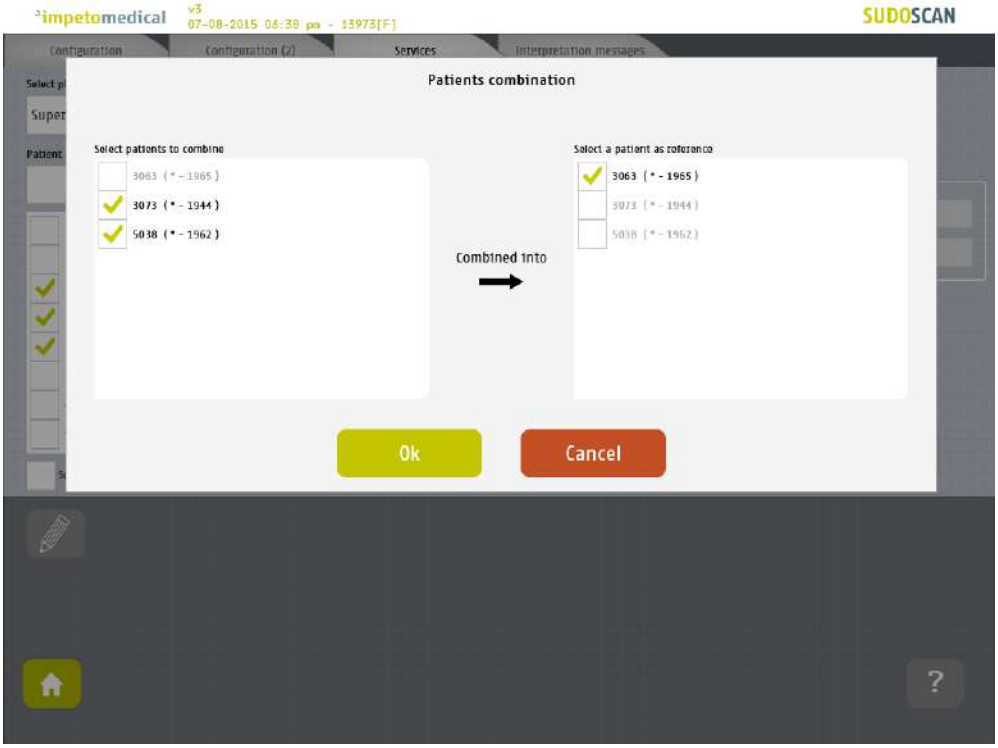
2 **When only one patient is selected, a popup window is displayed to modify the demographic data of the selected patient (last name, first name, date of birth and patient ID):**



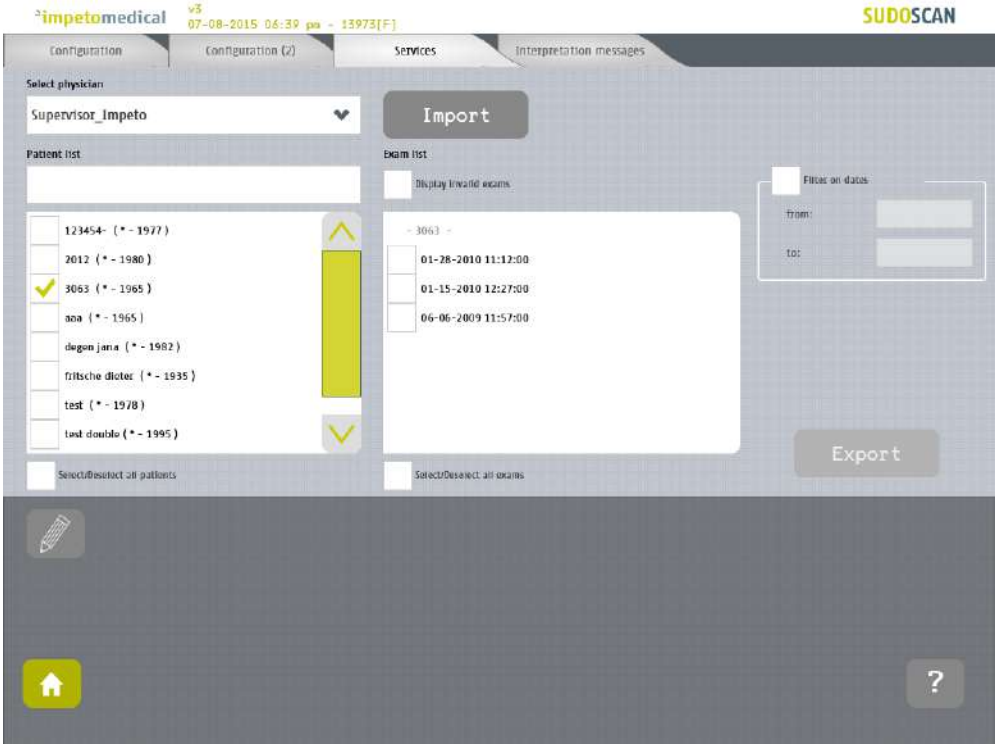
3 **When several patients are selected, a popup window is displayed to merge several patients into one:**



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. p7)* and fill in demographic data for the patient.

7.1 List of controls

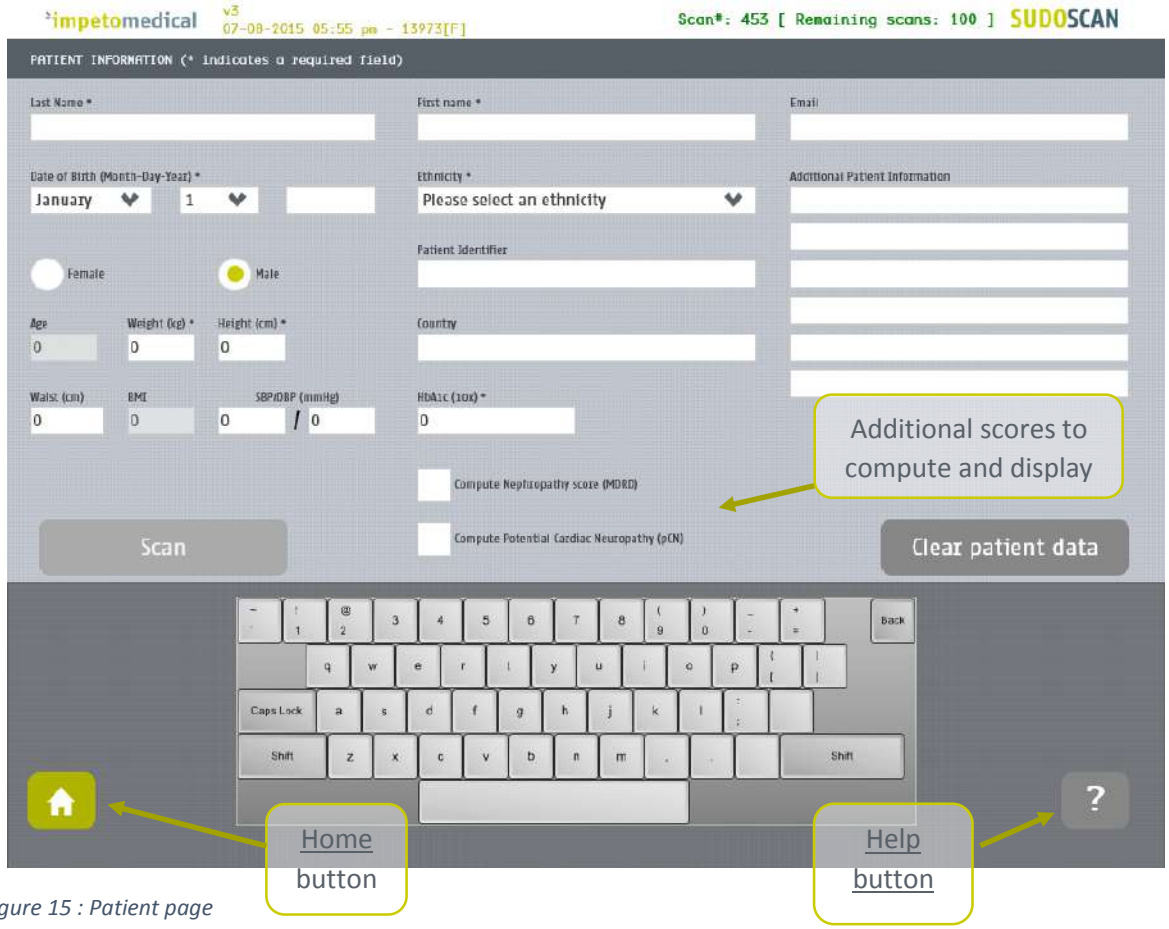


Figure 15 : Patient page

1	**After entering the mandatory patient data (indicated by *), the Scan button becomes available and the user can start a scan *(ref. p34 to setup patient's demographic information and start a scan)*.** ***Required data are depending on enabled options.***
2	**If 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 (?) to reach contextual help.

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. p21)*
- *Select the appropriate Ethnicity. 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). This parameter is mandatory if the computation of pCN is enabled*
- *Enter comments in the Additional comments field if necessary*

NOTE

It is also possible to use any standard PC-compatible keyboard 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:

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

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 Scan button is selected, then any missing fields will be highlighted in red.**

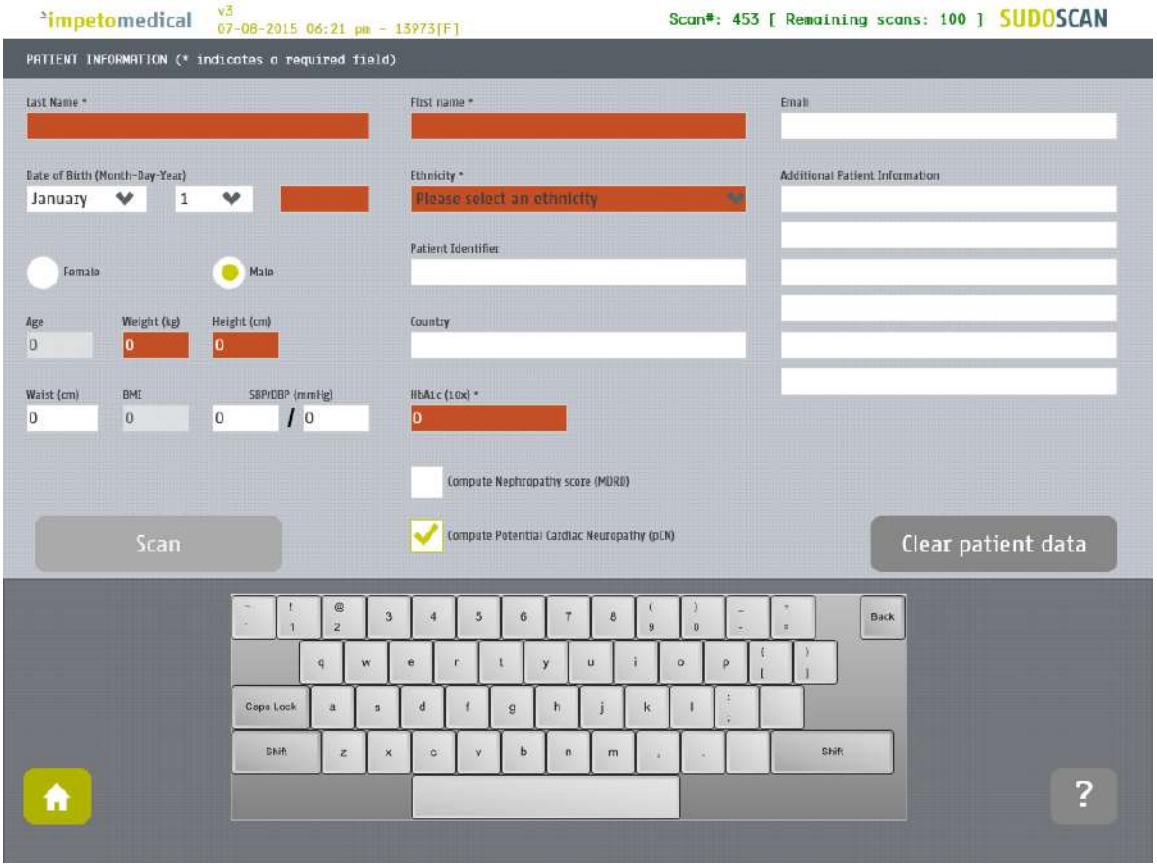


***Figure 16**: Scan page - Highlighting of empty required fields*

3 **Click on the Scan button to start the scan *(ref. p33)*.**

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.

NOTE

A calibration is performed at the beginning of each scan.
The patient is asked to remain still during the scan.

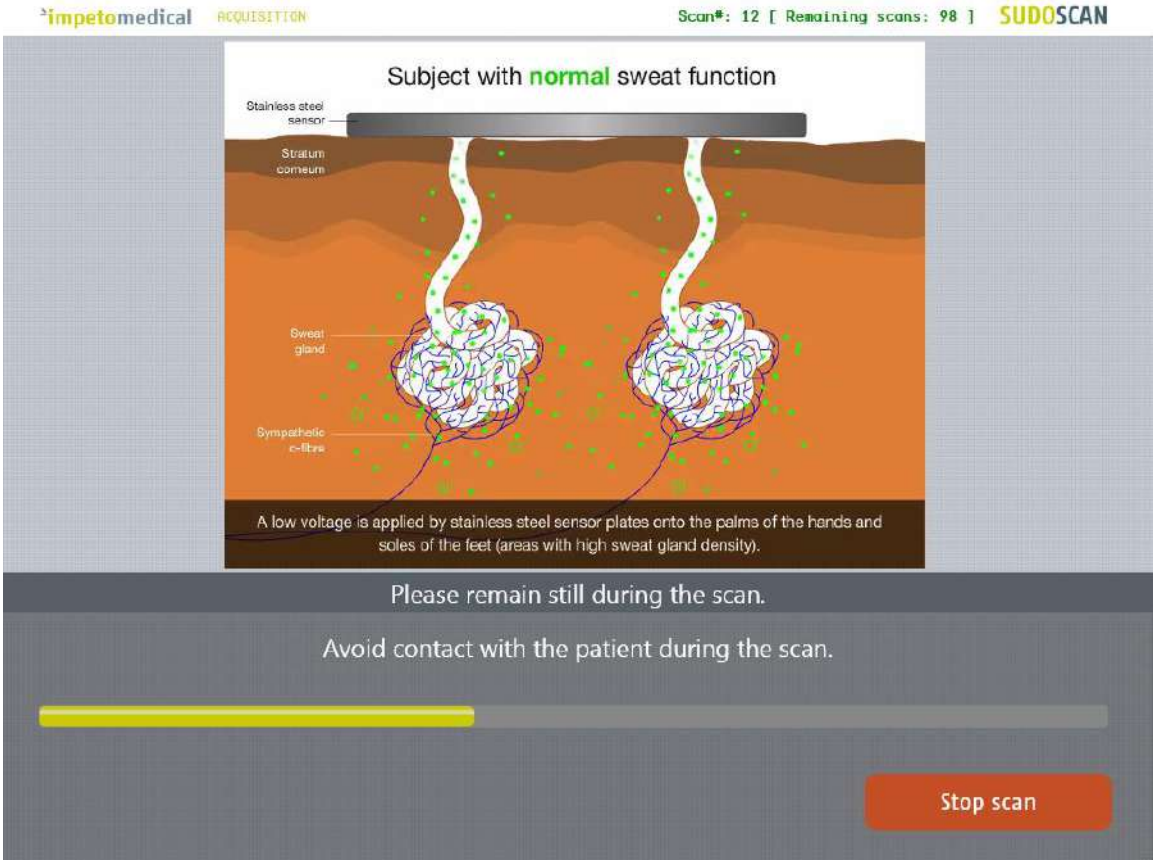


***Figure 17**: Acquisition*

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

3	**The scan can be cancelled at any time by selecting the Stop scan 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 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. p47).* • *When 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. p48)*
5	**Clean the electrodes after each scan with the manufacturer-approved cleaning solution *(ref. p54)*.**

8 Patient History page

To retrieve data for exams and patients, click on the Patient History button on the Home screen *(ref. p7)*.

8.1 List of controls

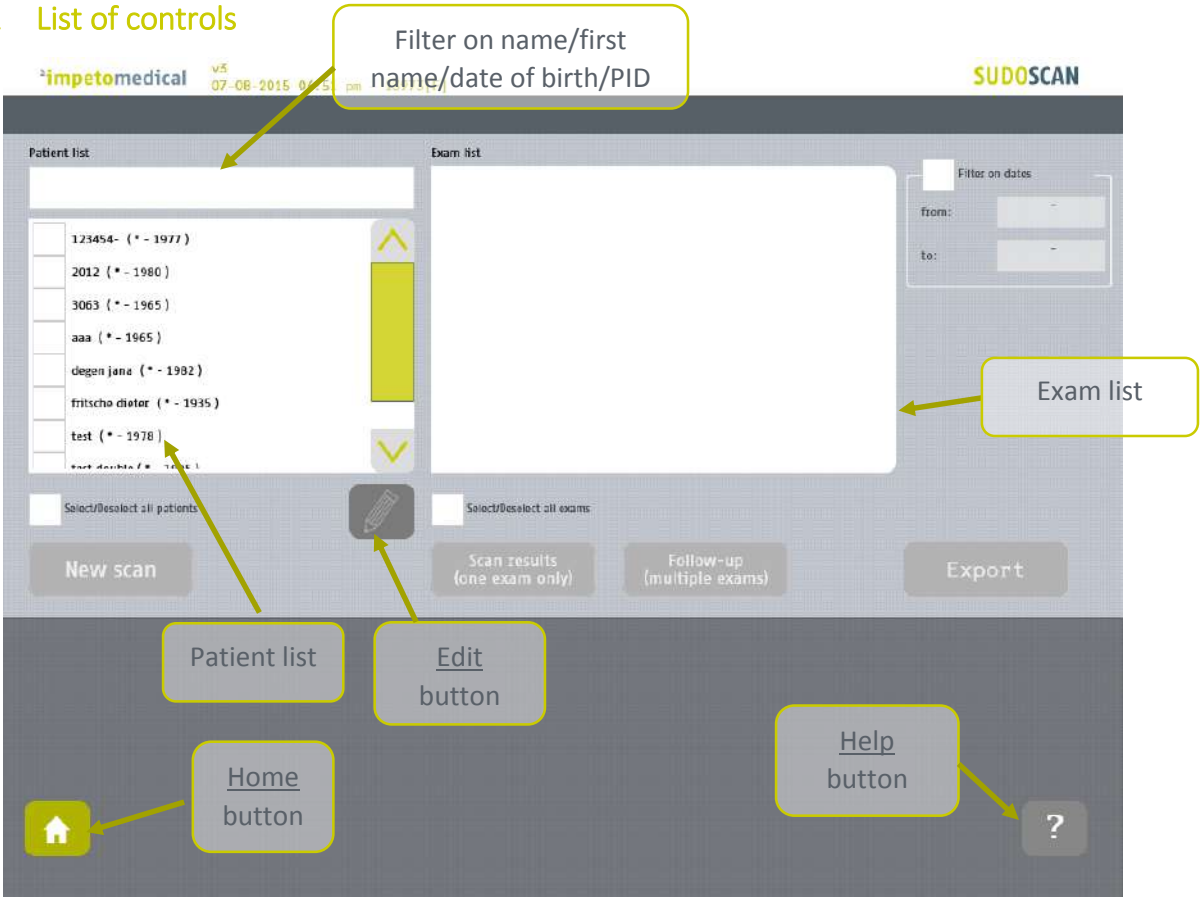


Figure 18 : Patient History page

1	**Select patients from the Patient list and exams from the Exam list *(ref. p39)*.**
2	**When available, modify patient demographic data or reconcile data from several patients by clicking on the Edit button.** This option is available for supervisor users *(ref. p30)*.
3	**Start a new scan for the selected patient *(ref. p41)*.**
4	**Display the results for the selected exam *(ref. p41)*.**
5	**Display the follow-up screen for the selected exams *(ref. p42)*.**
6	**Export or print data and reports for the selected exams *(ref. p44)*.**

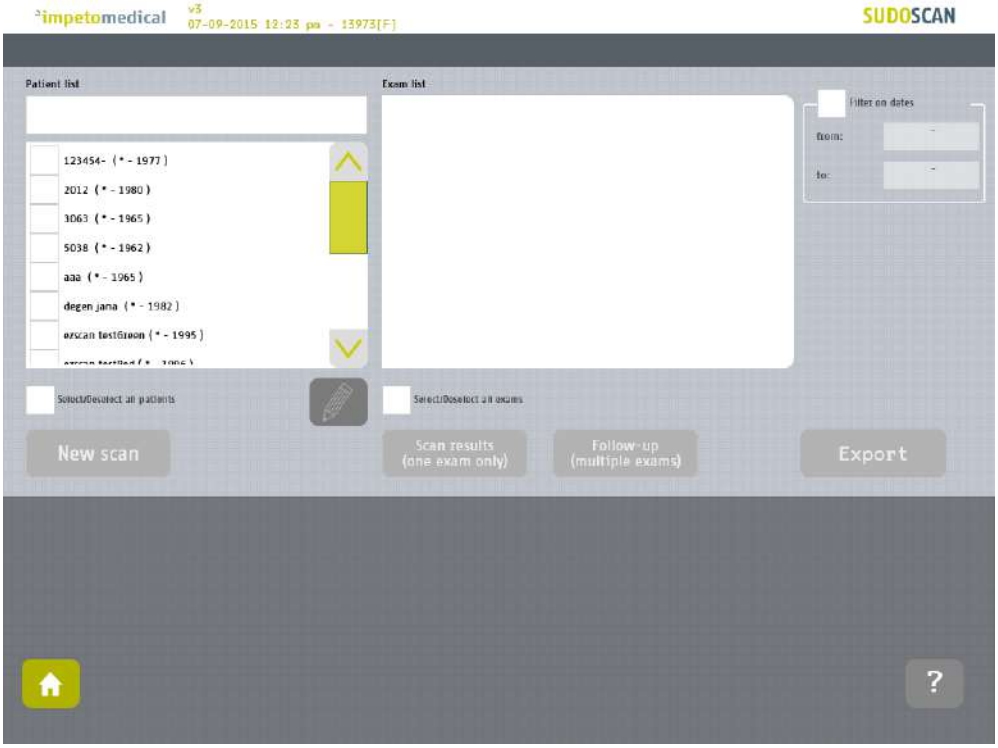
8.1.1 Other controls

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

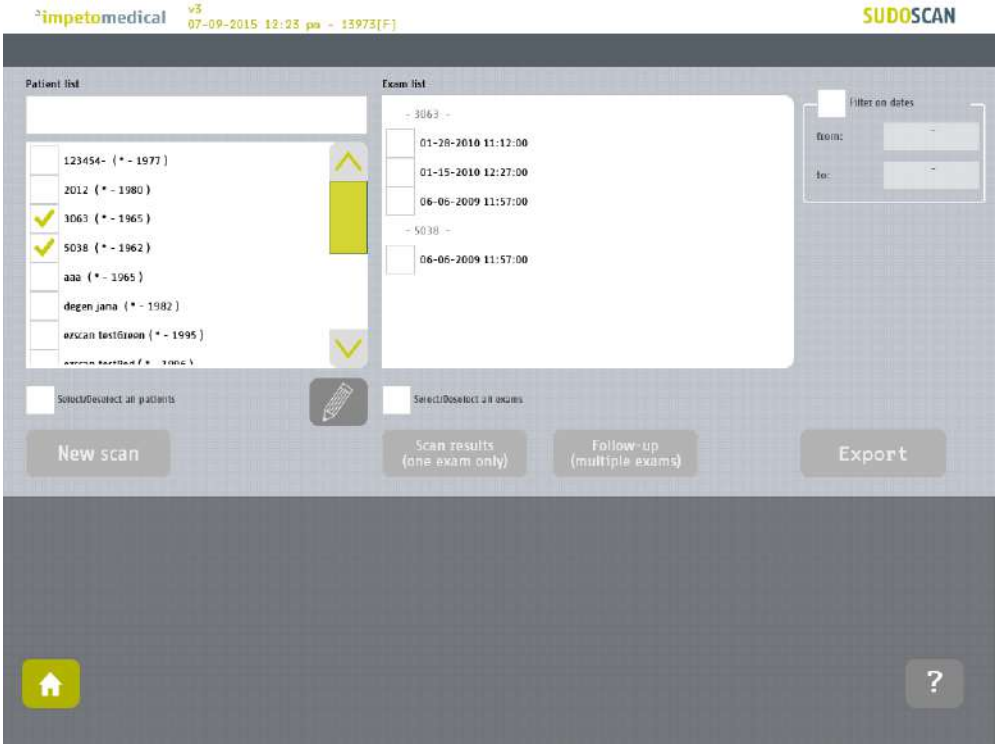
8.2 Selecting patient(s) and exam(s)

To select a patient or an exam, select the checkbox that corresponds to the desired entry.

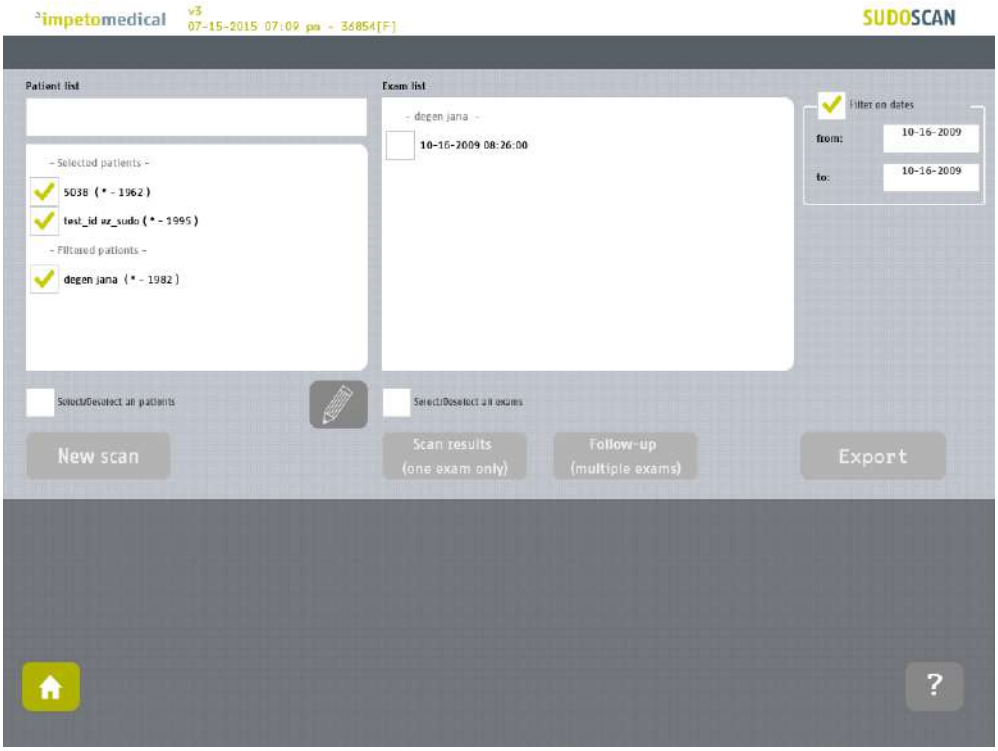
Use the patient filter to filter the patient list by last name, first name, year of birth or patient ID.



Select the patients from the patient list.



Use the date filter to display exams for a precise date



The patients that were selected are still selected but separated in two categories based on whether they have exams corresponding to the date filter ("Filtered patients") or not ("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. p33)*:

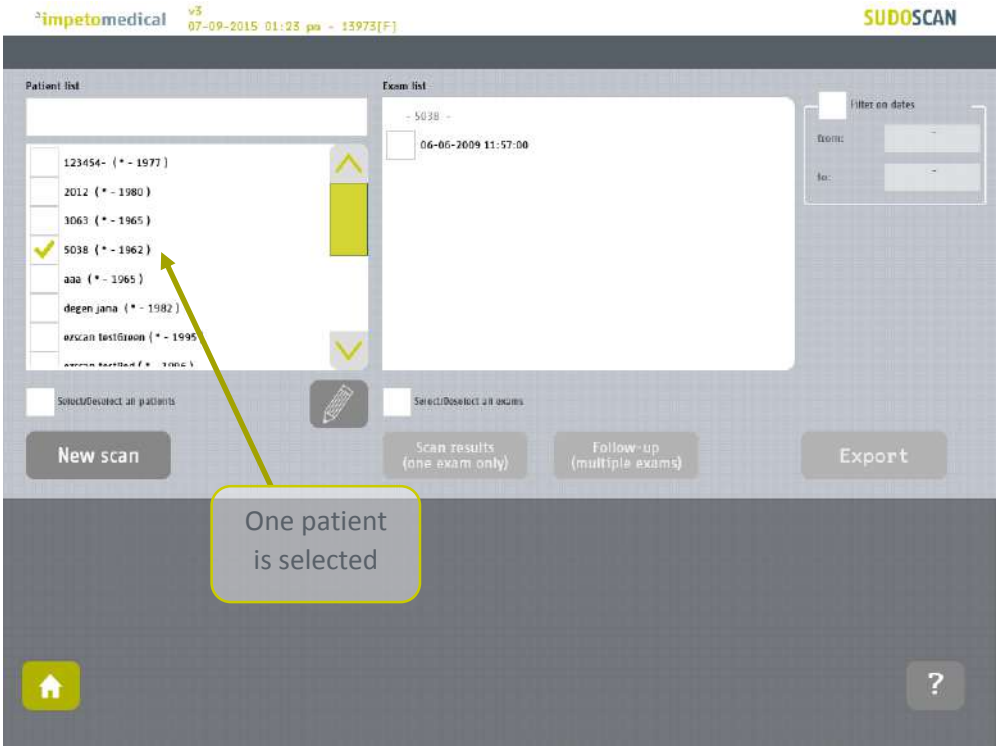


Figure 19: Start a new scan for an existing patient

8.4 How to display results for an exam

Select an exam (only one) from the exam list and click on Scan results button *(ref. p47)*:

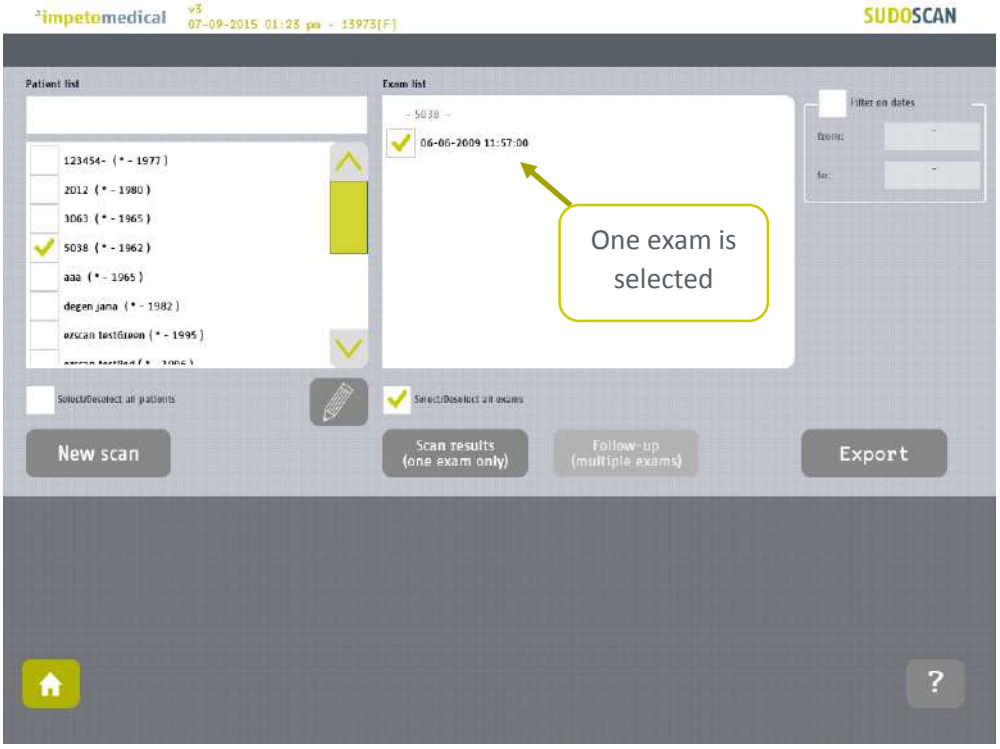
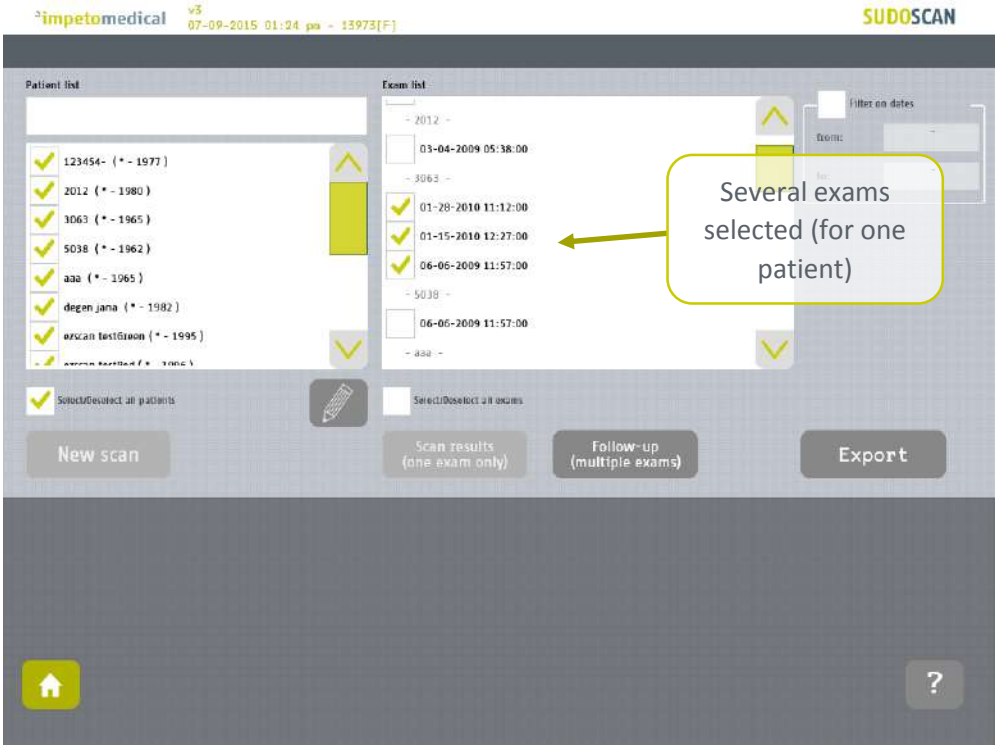


Figure 20: Display results for an exam

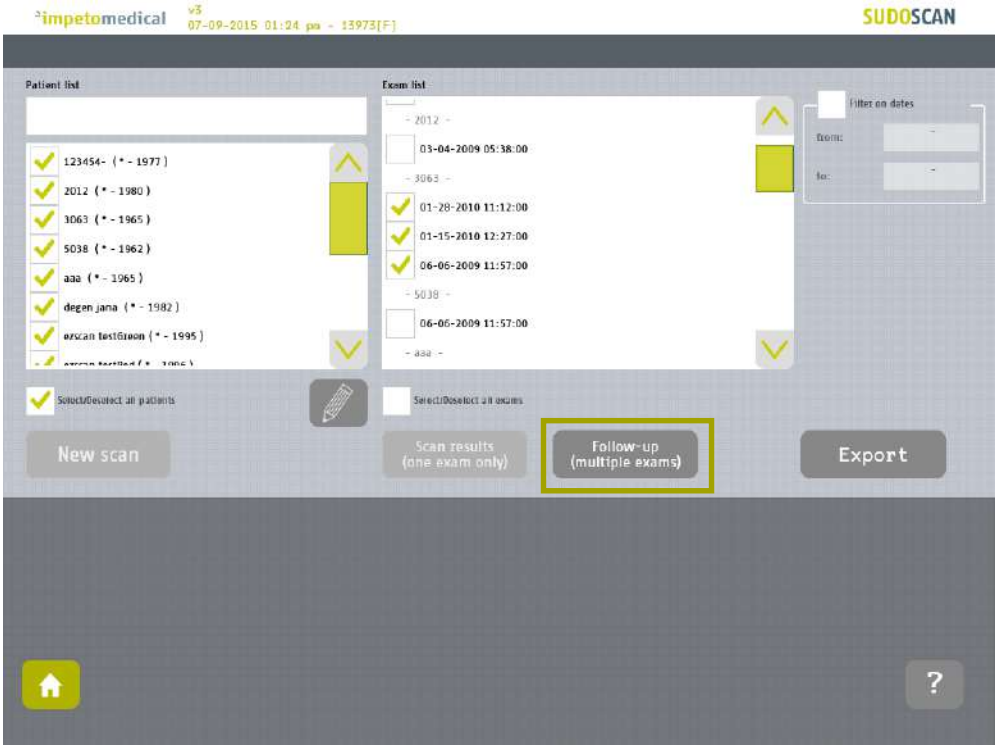
8.5 How to display the follow-up for a patient

Select several exams for a 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.

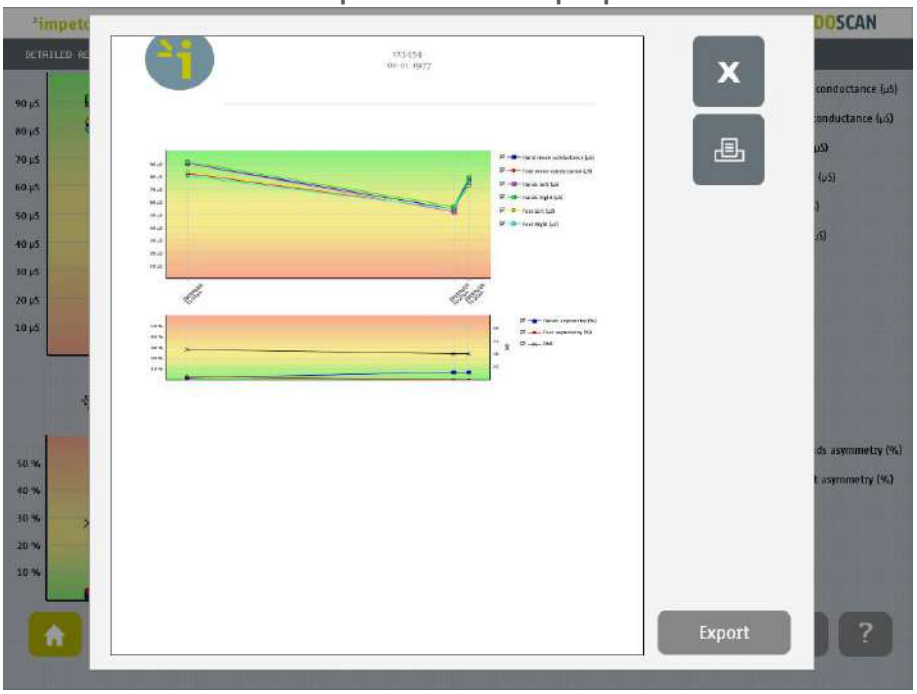
Click on the follow-up button.



The follow-up screen is displayed.

The top graph charts the progression of conductances. It is possible to display the evolution of hands and foot (left and right) conductances as well as means conductances.
The bottom graph charts asymmetries (hand and foot) and the Body Mass Index (BMI).
The different plots are enabled/disabled by clicking on their checkboxes on the right.

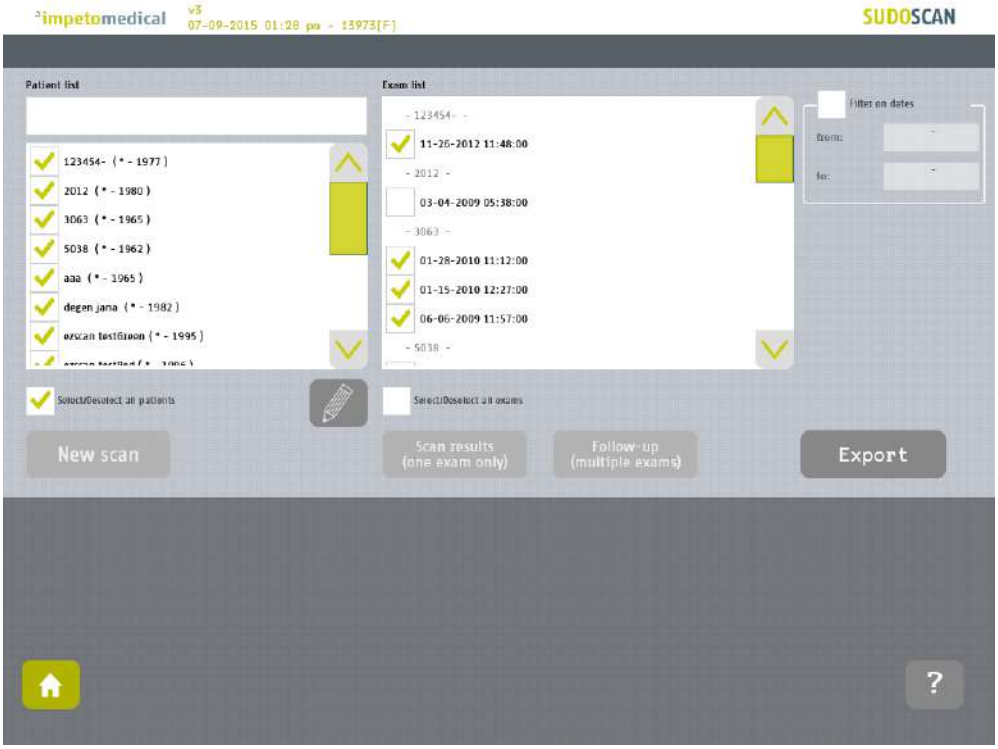
Click on the Print button to print the follow-up report:



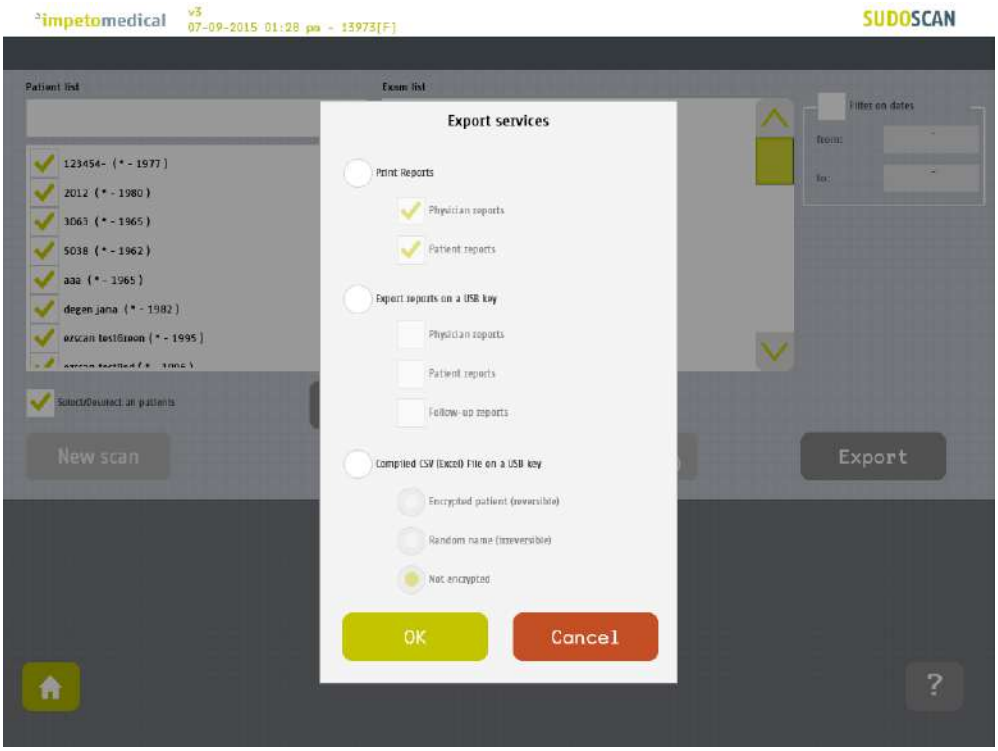
The PDF report is generated and stored within the system. To print the report physically, ensure that a printer has been selected and click on the Print button.
To export the report to a USB key, click on the Export button and follow the instructions on the screen.

8.6 How to export data

Select patient(s) and exam(s) and click on the Export button:



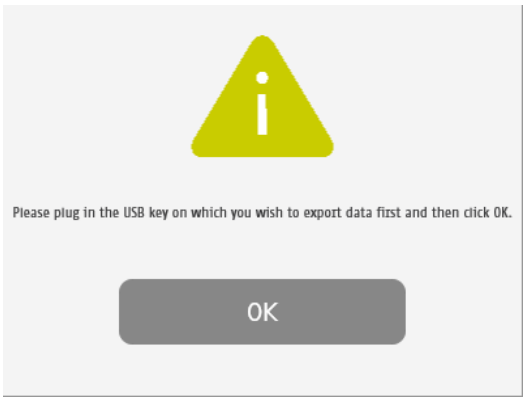
Select an option:



The different options are:

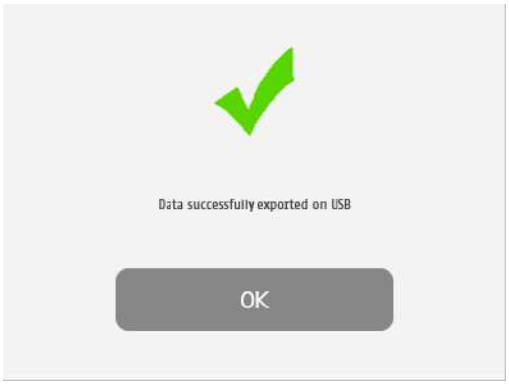
- *Print reports: Select the type(s) of reports to print e.g. physician and/or patient reports. Then, if a printer is selected, the reports for the selected exams will be physically printed.*
- *Export the reports to a USB key: You can export the different reports (physician, patient and/or follow-up) for the selected exams to a USB key.*
  Stored within the /ExportReports/ directory.
- *Compile CSV (Excel) file on a USB key: Including relevant data for the selected exams. Exported data are detailed within annexes (ref. p64). The encryption of patients' last names and first names is optional (reversible, irreversible or none).*
  Stored within the /CompiledCSV/ directory.

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



Click Ok and the files are exported:

The export is complete.



NOTE

When the export is complete, the data is 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

It is highly recommended to back up your data on a regularly basis.

9 Results page

9.1 List of controls

Figure 21: Patient result page

Click on the Patient Results tab to view the on-screen results.

Click on the Physician Report tab to reach the Report page (*ref. p51*).

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 ( ) to reach contextual help.

Click on the Go back ( ) button to go back in the application.

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 taking into account the patient's clinical history.

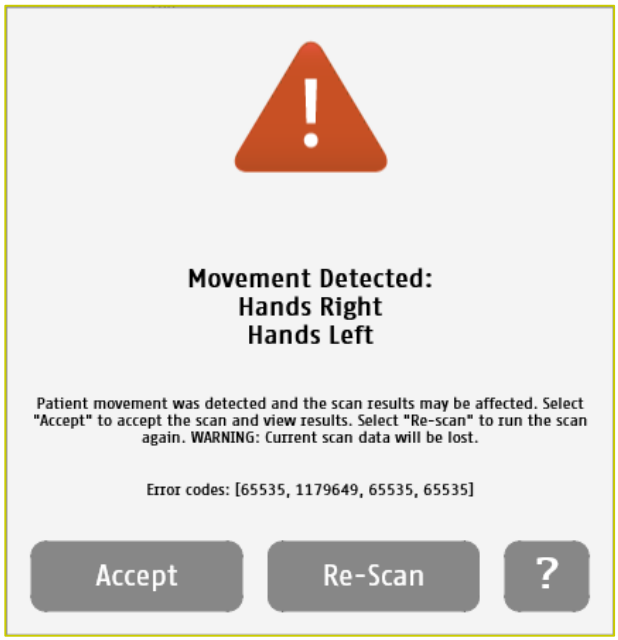
9.2.1 Asymmetry

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 include the current results in the patient's follow-up. The reports will be generated with a note 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.

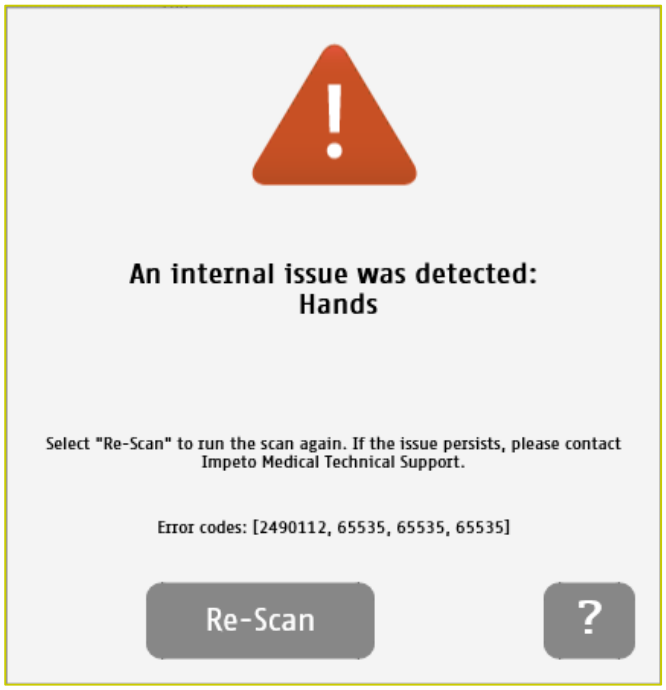
NOTE

When performing a Re-Scan, the number of remaining scans will not be decreased until the user accepts the scan results or the scan is performed without error.

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 Medical** Technical Support *(ref. p82).*

NOTE

When performing a Re-Scan, the number of remaining scans will not be decreased until the user accepts the scan results or the scan is performed without error.

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. p21*). 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:

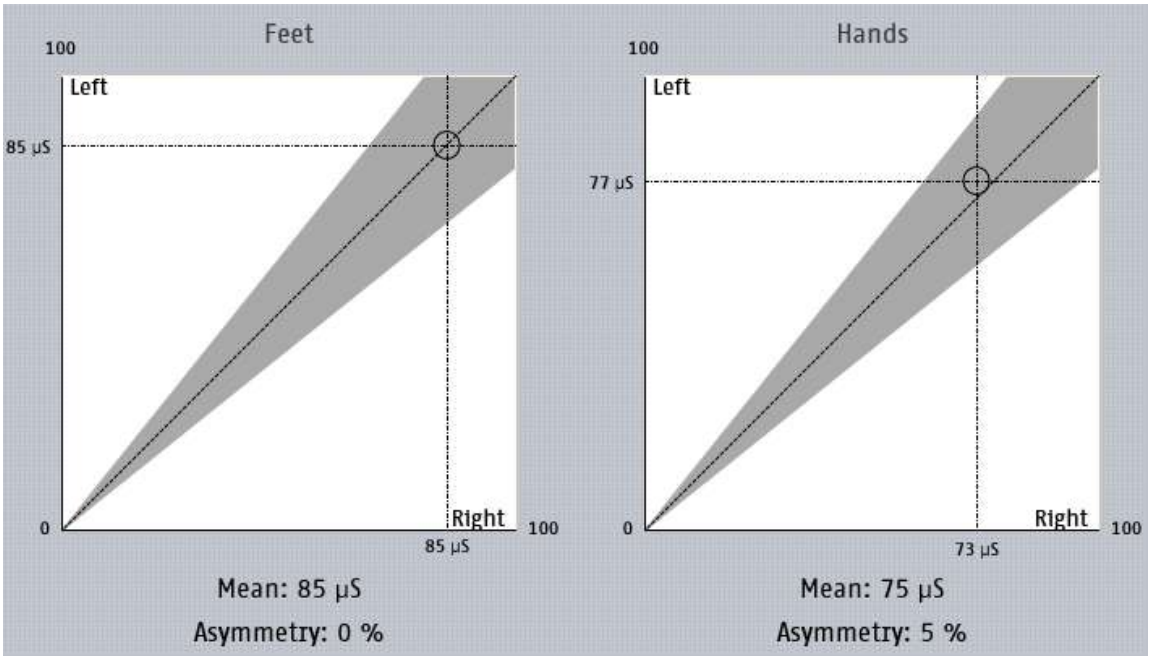


Figure 22: Patient results page - Ethnicity option disabled or set to "Other"

When ethnicity is enabled and not set to "Other", the graphs are displayed as follows:

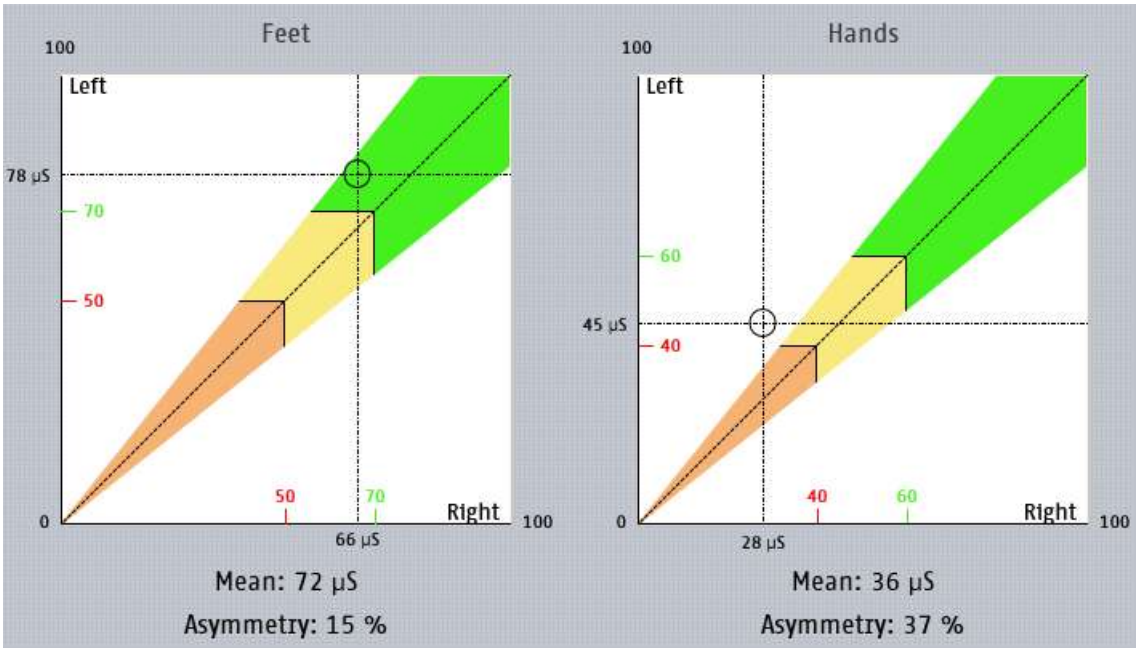


Figure 23: Patient results page - Ethnicity option enabled and not set to "Other"

10 Physician and Patient Report screens

10.1 Physician report

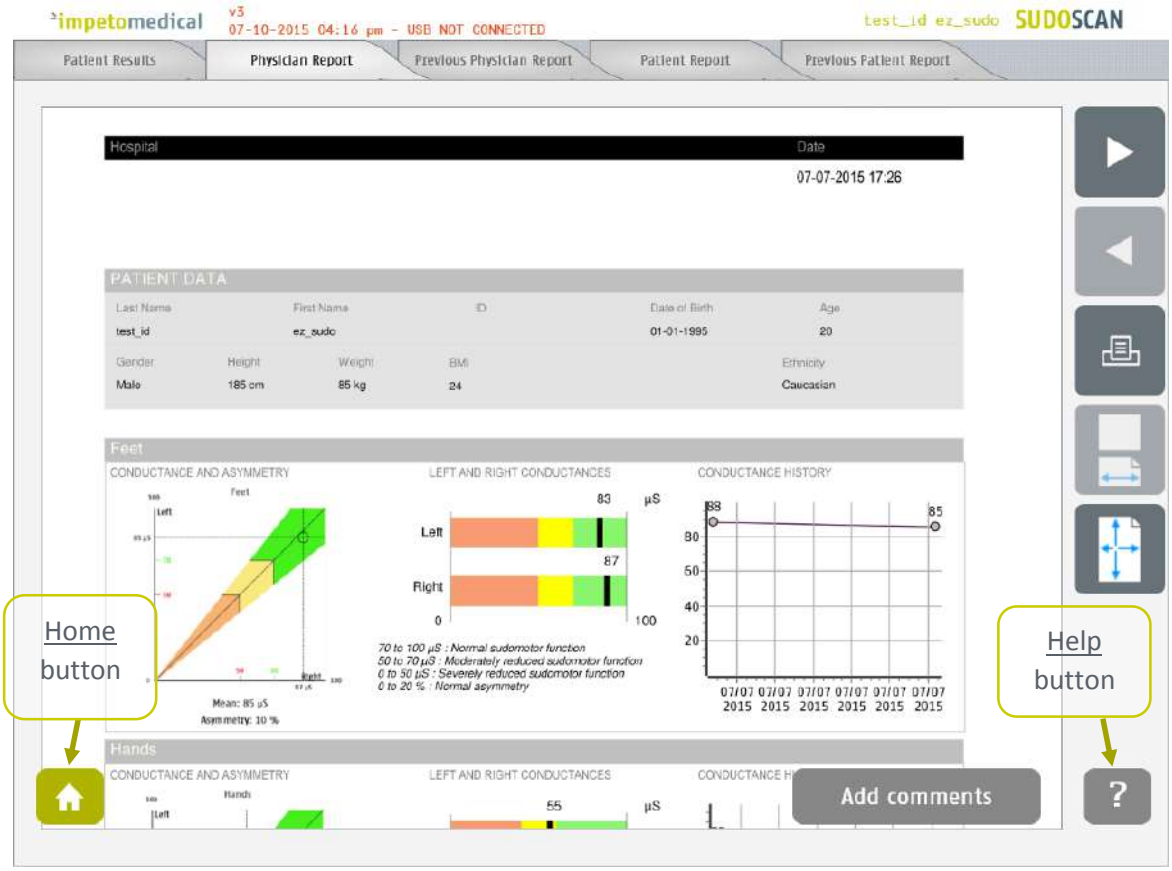


Figure 24 : Physician Report page

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. p47)*.**
3	**Navigate pages within 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-page view or page-width 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 ( ) to reach contextual help.

10.2 Patient report

Figure 25: Patient Report page

1	**Click on the Physician Report tab to view the physician version of the report.**
2	**Click on the Patient Results tab to view the results *(ref. p47)*.**
3	**Navigate pages within 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-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 reach the home page *(ref. p7)*.
	Click on the Help button ( ) button to reach the contextual help.

NOTE

When the option is enabled in additional supervisor settings *(ref. p)*, 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.

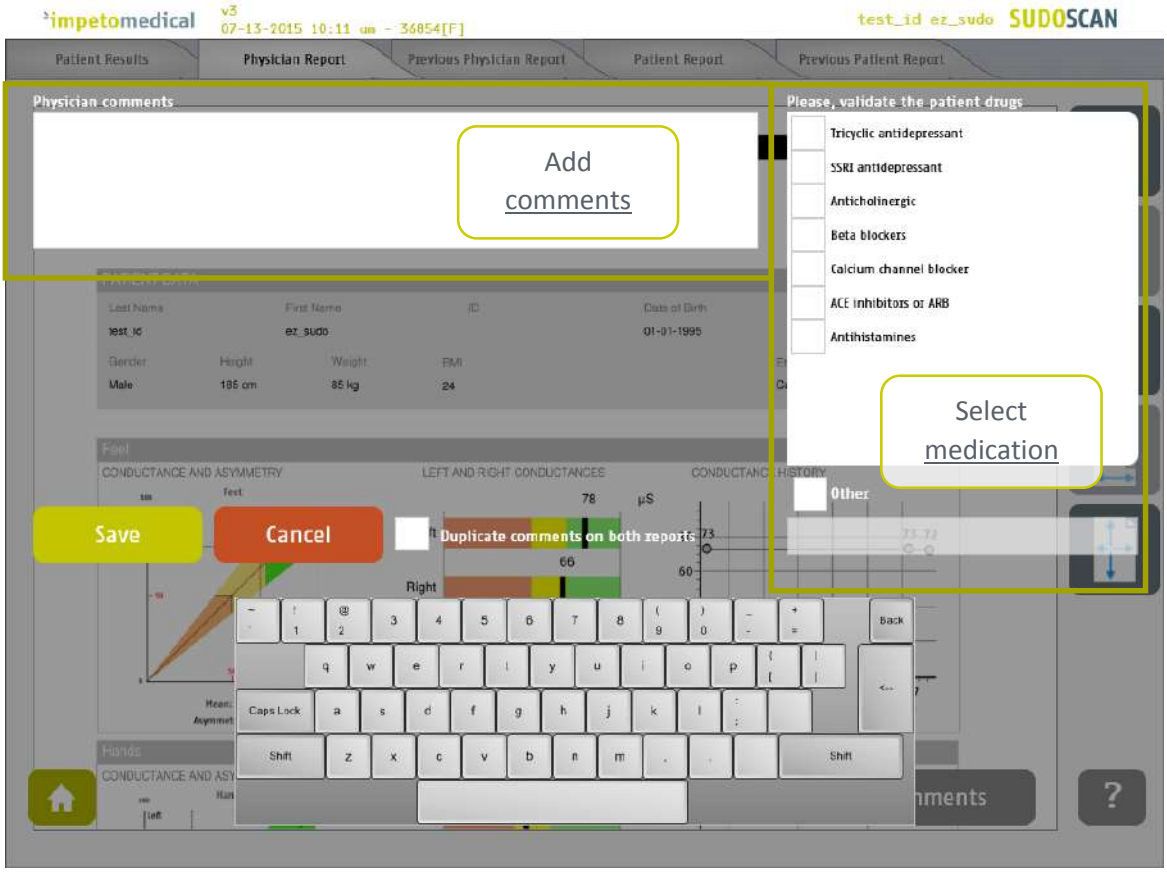


Figure 26: Add comments on reports

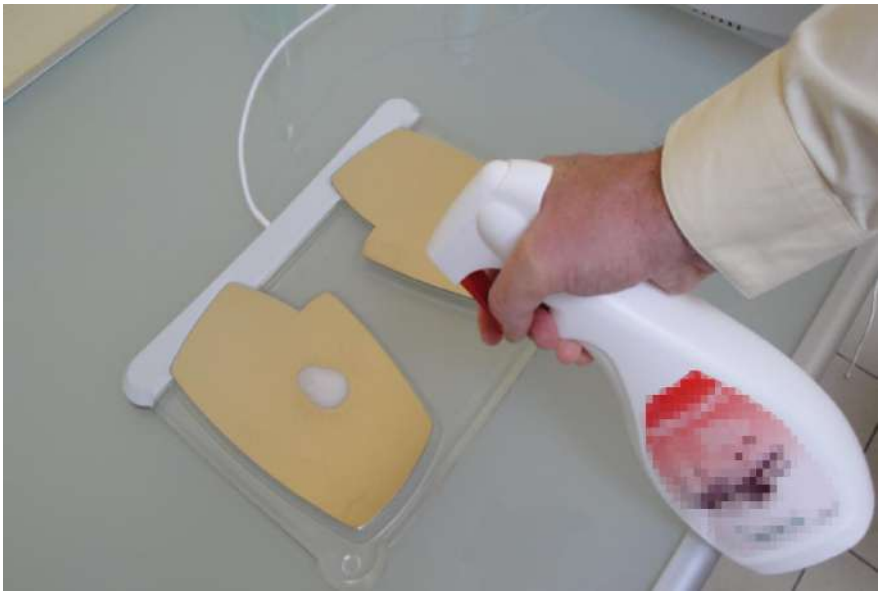
1	**Add comments to the selected report (physician or patient).**
2	**Select medications from the list or add medication using the Other field.**
3	**Duplicate the comments on the other report or not.**
4	**Save comments and regenerate the report(s) or cancel the changes and go back to the report.**

11 Cleaning the sensor plates

IMPORTANT

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

This will not only disinfect but 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 the sensor plates with Kimtech Science wipes until dry.** ***Use a new sheet for each sensor plate.***

IMPORTANT

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

12 Replace the electrodes

Before launching a scan *(ref. p33)*, the number of available scans appears on the top right corner of the screen. The scan number (#) will increase by one and the remaining scans will decrease by one upon successful completion of a scan.

Figure 27: Remaining scans – ok

12.1 Thresholds

Thresholds 1:

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

***Figure 28**: Remaining scans first warning*

Threshold 2:

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

Figure 29: Remaining scans last warning

IMPORTANT

PLEASE PLAN IN ADVANCE WHEN PLACING YOUR 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 BASED UPON YOUR USAGE.

12.2 How to replace Sensor Plates

Impeto Medical will ship a set of sensor plates and an activation code that will be used to replace the sensor plates once all scans have been used.

When there are no scans left, the system prevents the user from starting a scans:

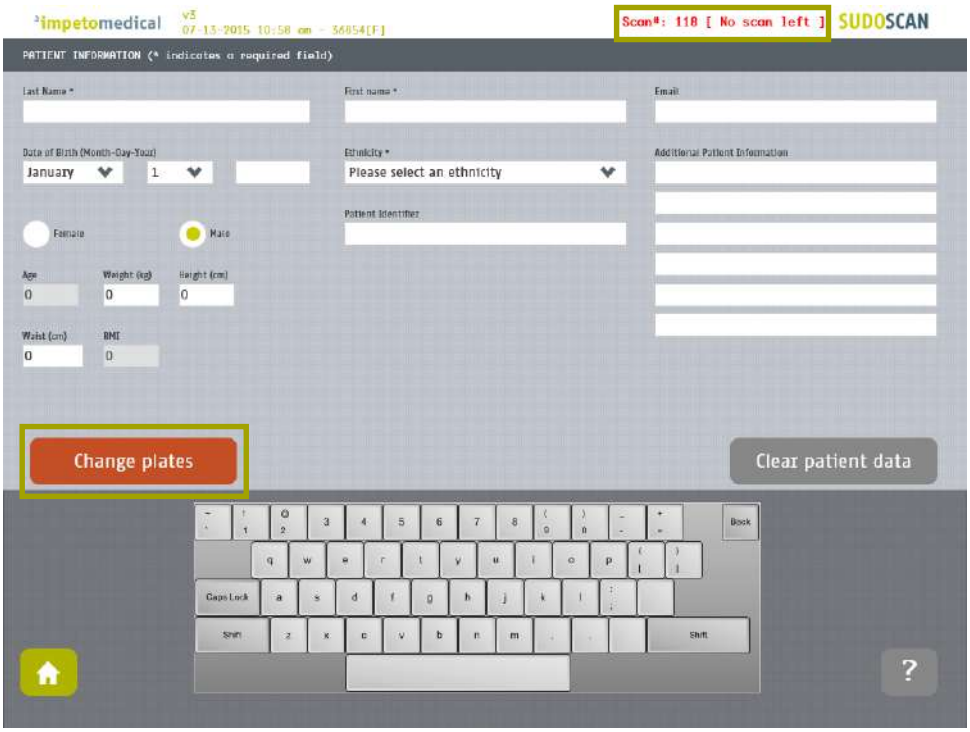


Figure 30: Scan page - Change sensor plates.

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

1	**Press the Change plates button. A disclaimer* appears on the screen. Read it and press the Accept button.**

***----DISCLAIMER----**
BY CLICKING "ACCEPT" YOU AKNOWLEDGE AND AGREE THAT EACH NUMERIC KEY CODE ENTITLES YOU TO A NUMBER OF SCANS PER ELECTRODE PAIR PURCHASED TO COINCIDE WITH THE LIMIT OF THE RECOMMENDED SERVICE CYCLE OF THE ELECTRODE. USE OF REUSABLE ELECTRODES IN ACCORDANCE WITH THE RECOMMENDED REPLACEMENT SCHEDULE WILL HELP YOU TO ENSURE OPTIMAL TEST PERFORMANCE AND ACCURATE TEST RESULTS. EXPIRED ELECTRODES MUST BE PROMPTLY RETURNED TO IMPETO MEDICAL FOR PROPER DISPOSITION USING THE PRE-PAID RETURN PACKAGING PROVIDED WITH YOUR SHIPMENT. IMPETO MEDICAL RESERVES THE RIGHT TO ASSESS A REPLACEMENT CHARGE IN THE EVENT A NUMERIC KEY CODE IS TAMPERED WITH, MISPLACED OR LOST.

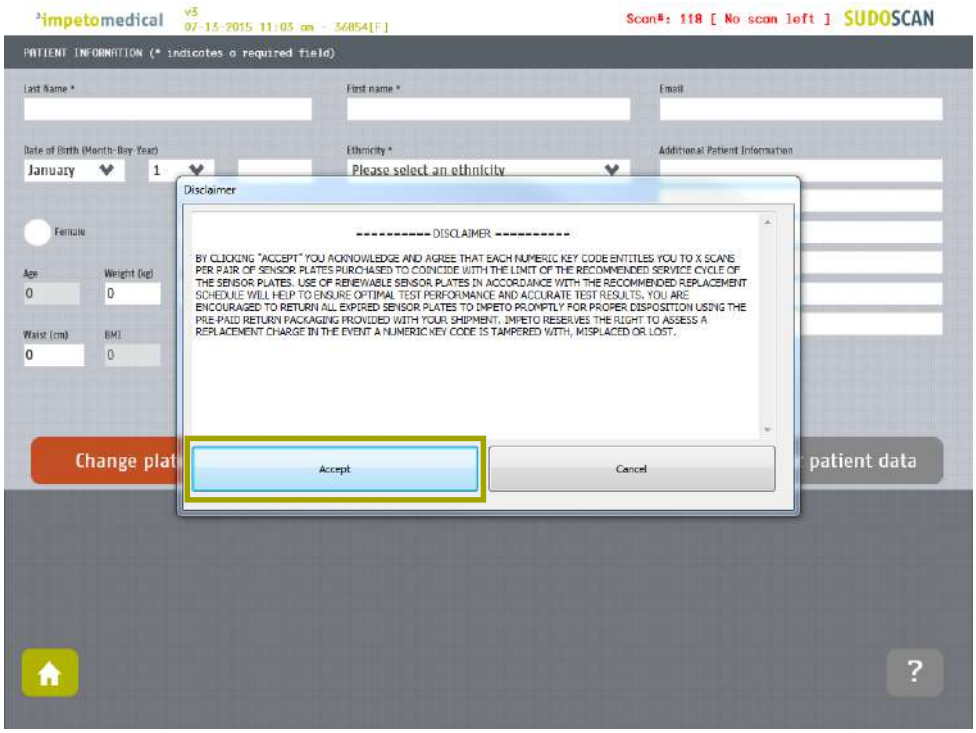


Figure 31: Scan page - Disclaimer

2 **A step by step procedure to replace the sensor plates appears. All the checkboxes must be checked. Once the procedure is completed, press the "DONE" button.**

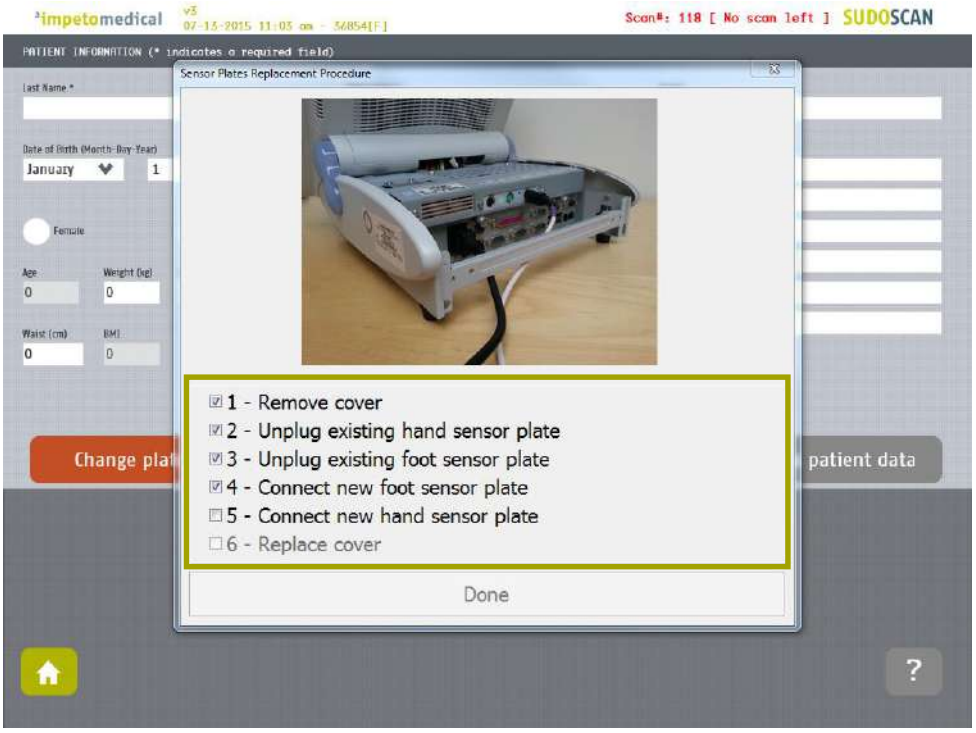


Figure 32: Step-by-step procedure to change sensor plates

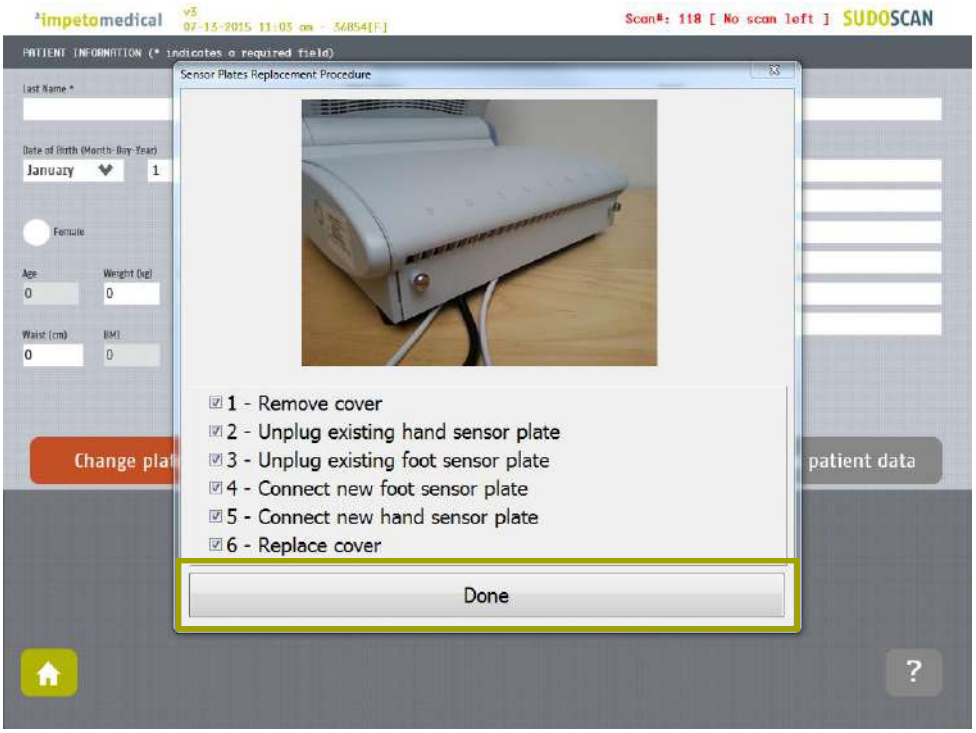


Figure 33: Completed step-by-step procedure to change sensor plates

3 **A numeric keypad appears.**

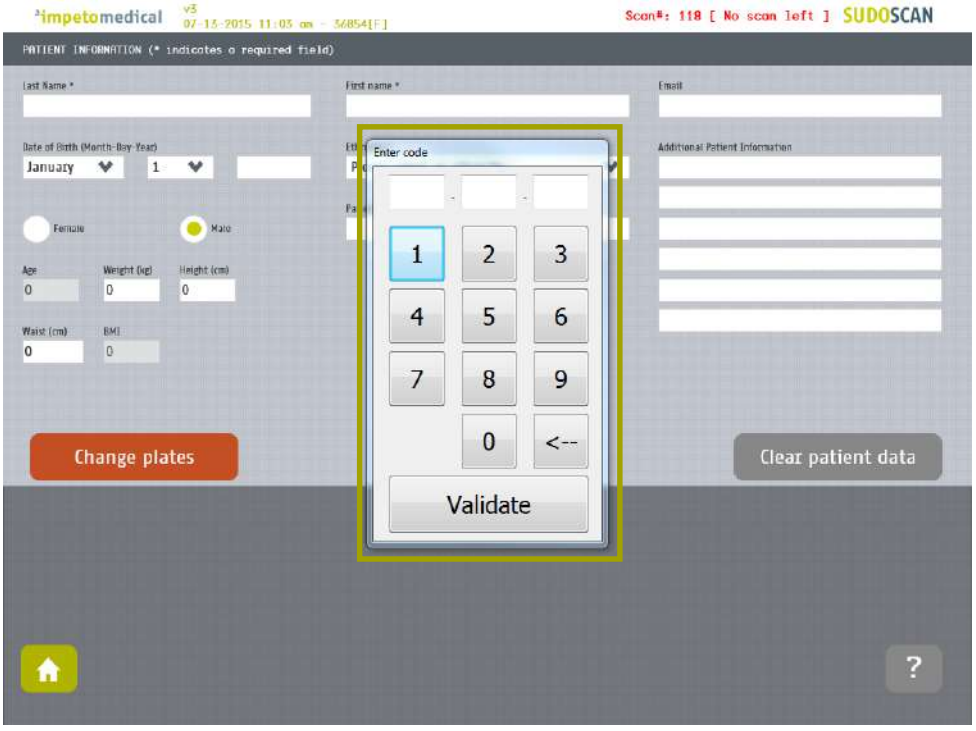


Figure 34: Enter the activation code provided

4 **Enter the 9 digit code and press the Validate button.**

Remaining scan counter will be reloaded with the corresponding number of scans.

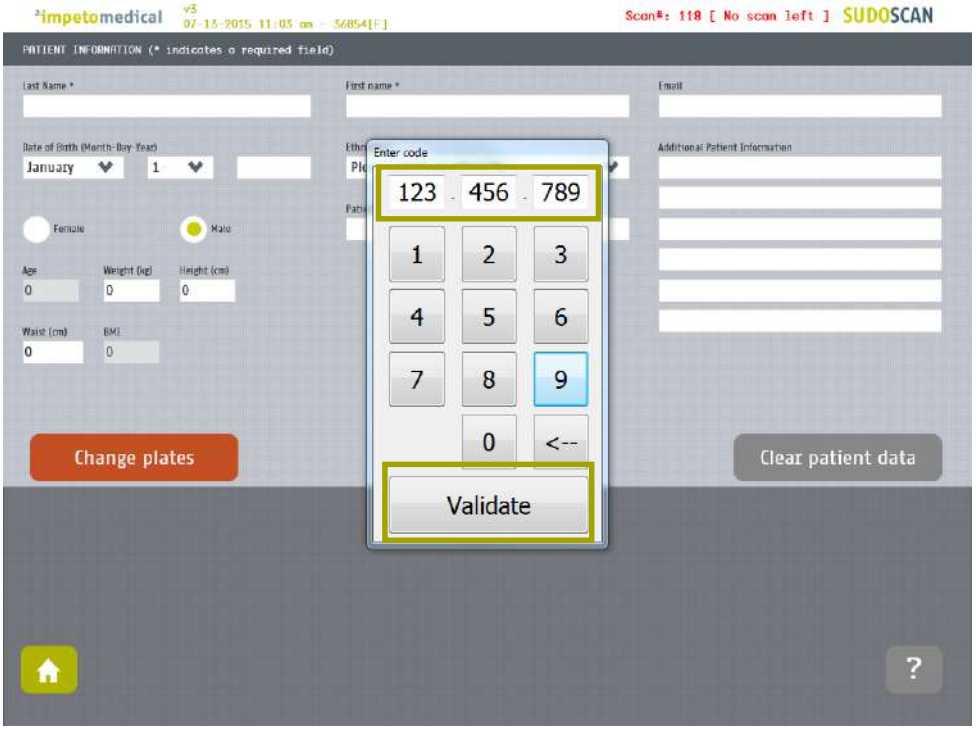
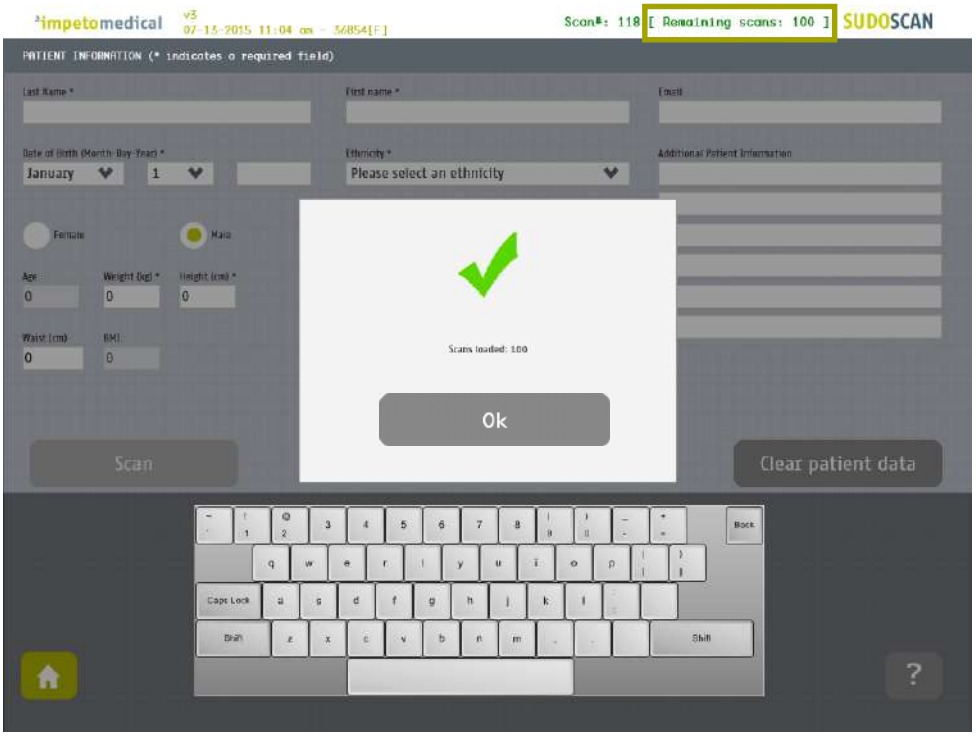


Figure 35: Validate the activation code

Upon completion, the following message will be displayed confirming scans have been successfully added:



IMPORTANT

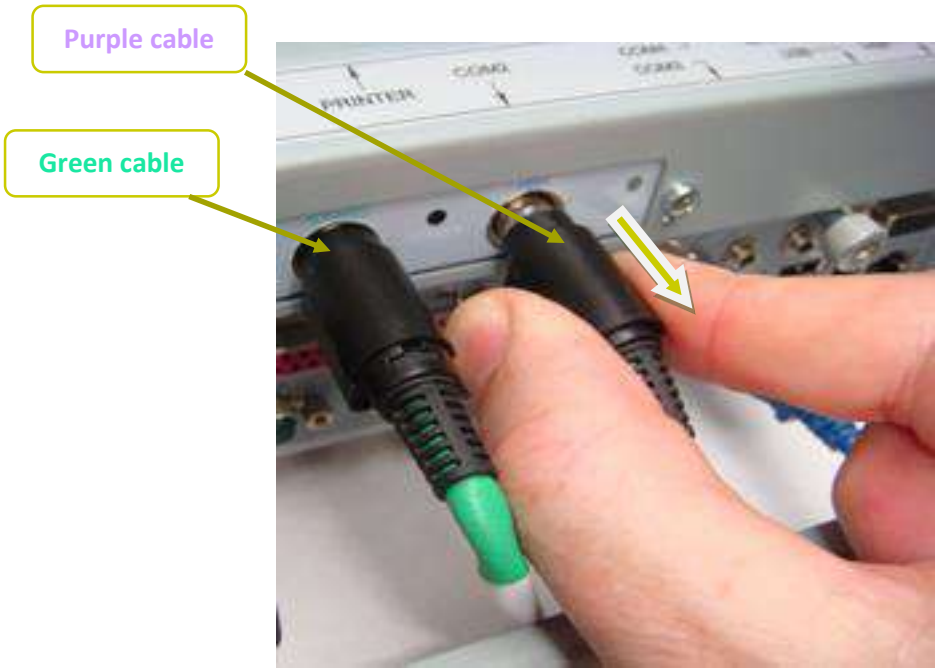
PACK UP YOUR USED SET OF SENSOR PLATES. USE THE COMPRESSION BOX PROVIDED WITH THE NEW SET OF SENSOR PLATES AND IMMEDIATELY SEND THE USED SET BACK TO IMPETO MEDICAL INC. USING THE PRE-PAID FEDEX LABEL PROVIDED.

NOTE

The code can only be used one time to activate one specific set of sensor plates. Once it has been entered in a system, it can no longer be used. Sensor plates must be replaced after all the scans have been used.

12.3 Disconnect the sensor plates

1	Open the back cover by loosening the screws.
2	Unscrew the sensor plates cable retention bracket, if installed.
3	Grab the large black plastic casing 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 port, Purple cable in the Purple Feet port



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. p21).*

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	**After the installation successfully completes, reboot the system and start a Quality Check via the software *(ref. p13)*.**

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 Troubleshoot the system

15.1 USB connection

The following message may 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 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 *(cf. p82)*.**

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** Technical support *(cf. p82)*.

16 Annexes

16.1 Data export in CSV files (Excel compatible)

16.1.1 Data in compiled CSV from a standard user account

- Name: Patient's last name
- Firstname: Patient's first name
- Gender: Patient's gender
- Age: Patient's age
- DoB: Patient's date of birth
- PID: Patient's identifier
- Email
- Country
- Ethnicity
- Date: Date of exam
- Time: Time of exam
- R_Hand: Hand resistance
- R_Foot: Foot resistance
- Comment: Pre-scan comments
- Comment1: Pre-scan comments
- Comment2: Pre-scan comments
- Comment3: Pre-scan comments
- Comment4: Pre-scan comments
- Comment5: Pre-scan comments
- QoM: Quality of Measure (0 if issues were observed, 1 else)
- QoM_Accepted: When QoM is 0, QoM_Accepted is 0 if the exam was discarded, 1 else
- Medication
- ReportDoctorComment: Comments on doctor reports
- ReportPatientComment: Comments on patient reports
- Height
- Weight
- SBP: Systolic Blood Pressure
- DBP: Diastolic Blood Pressure
- HB1AC: Glycated hemoglobin
- Waist
- MDZ: Right hand conductance
- MGZ: Left hand conductance
- PDZ: Right feet conductance
- PGZ: Left feet conductance
- Nephro Sc.: Modification of Diet in Renal Disease
- Hands_Asym: Hands asymmetry
- Feet_Asym: Feet asymmetry
- CAN Sc.: Probability of Cardiac Neuropathy

16.1.2 Data in compiled CSV (from Advanced Configuration)

- Name: Patient's name
- Firstname: Patient's first name
- Gender: Patient's gender
- Age: Patient's age
- DoB: Patient's date of birth
- PID: Patient's identifier
- Email
- Country
- Ethnicity
- Date: Date of exam
- Time: Time of exam
- R_Hand: Hand resistance
- R_Foot: Foot resistance
- Comment: Pre-scan comments
- Comment1: Pre-scan comments
- Comment2: Pre-scan comments
- Comment3: Pre-scan comments
- Comment4: Pre-scan comments
- Comment5: Pre-scan comments
- QoM: Quality of Measure (0 if issues were observed, 1 else)
- QoM_Hand_Left: Code for the QoM on Left Hand
- QoM_Hand_Right: Code for the QoM on Right Hand
- QoM_Foot_Left: Code for the QoM on Left Foot

- QoM_Foot_Right: Code for the QoM on Right Foot
- QoM_Accepted: When QoM is 0, QoM_Accepted is 0 if the exam was discarded, 1 else
- Medication
- Medication_Other
- Hands_Esc_Goal
- Feet_Esc_Goal
- RawFile
- RawFile_SHA256
- CalibRawFile
- CalibRawFile_SHA256
- ReportDoctorComment: Comments on doctor reports
- ReportPatientComment: Comments on patient reports
- Height
- Weight
- SBP: Systolic Blood Pressure
- DBP: Diastolic Blood Pressure
- HB1AC: Glycated hemoglobin
- Waist
- Keywords
- MDA_Offset
- MDA_CB
- MDA_CBN
- MDA_Threshold
- MDA_Coeff
- MDA_CH
- MDA_CHN
- MGA_Offset
- MGA _CB
- MGA _CBN
- MGA _Threshold
- MGA _Coeff
- MGA _CH
- MGA _CHN
- PDA_Offset
- PDA _CB
- PDA _CBN
- PDA _Threshold
- PDA _Coeff
- PDA _CH
- PDA _CHN
- PGA_Offset
- PGA _CB
- PGA _CBN
- PGA _Threshold
- PGA _Coeff
- PGA _CH
- PGA _CHN
- MDC_Offset
- MDC_CB
- MDC_CBN
- MDC_Threshold
- MDC_Coeff
- MDC_CH
- MDC_CHN
- MGC_Offset
- MGC _CB
- MGC _CBN
- MGC _Threshold
- MGC _Coeff
- MGC _CH
- MGC _CHN
- PDC_Offset
- PDC _CB
- PDC _CBN
- PDC _Threshold
- PDC _Coeff
- PDC _CH
- PDC _CHN
- PGC_Offset
- PGC _CB
- PGC _CBN
- PGC _Threshold
- PGC _Coeff
- PGC _CH
- PGC _CHN
- MDZ: Right hand conductance
- MGZ: Left hand conductance
- PDZ: Right feet conductance
- PGZ: Left feet conductance
- pIGT: Probability of Impaired Glucose Intolerence
- pIR: Probability of Insulin Resistance
- pDC: Probability of Diabetes Complication
- Color: Color of the ellipse for EzScan

- Bargraph: EzScan score value
- MDRD: Modification of Diet in Renal Disease
- Hands_Asym: Hands asymmetry
- Feet_Asym: Feet asymmetry
- pCN: Probability of Cardiac Neuropathy
- HW Module ID
- SW Version

Where

- MDA: Right Hand as Anode
- MGA: Left Hand as Anode
- PDA: Right Feet as Anode
- PGA: Left Feet as Anode
- MDC: Right Hand as Cathode
- MGC: Left Hand as Cathode
- PDC: Right Feet as Cathode
- PGC: Left Feet as Cathode
- Offset: Offset for detachment
- CB: Low conductance
- CBN: Normalized low conductance
- Threshold: Threshold for detachment
- Coeff: Coefficient for detachment
- CH: High conductance
- CHN: Normalized high conductance

16.2 Import a patient list via CSV file

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

16.2.1 Required data

Name	Firstname	DayOfBirth	MonthOfBirth	YearOfBirth

16.2.2 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**
p63	**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 by entering patient demographic data:
p7	Home page
p33	Scan pages
p34	Patient setup & starting a scan
p54	**Clean the sensor plates**
	Export reports to USB key:
p7	Home page
p44	How to export data
p55	**Replace the sensor plates**
	Configure hospital information:
p7	Home page
p18	Standard users – List of controls
	Select the printer drivers:
p7	Home page
p18	Standard users – List of controls
	Retrieve previous patient data:
p7	Home page
p38	Patient History page
	Change password:
p7	Home page
p11	Password modification
p19	Standard 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 a USB printer:
p7	Home page
p20	Supervisor users – Additional list of controls
p62	USB printer drivers installation
	Upgrade the application software
p7	Home page
p20	Supervisor users – Additional list of controls
p63	Software update installation
	Select a 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
	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
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
	Set/reset the password of any user
p7	Home page
p21	Supervisor users – Configuration (2) tab
	Select the language for display:
p7	Home page
p20	Supervisor users – Additional list of controls
	Export data to USB key:
p7	Home page
p23	Supervisor users – Additional services
	Import data to USB key:
p7	Home page
p23	Supervisor users – Additional services

18 Precautions for use and technical specifications

Principle of the 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 patient sweat gland function.

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

The device records the electrochemical skin conductance based on the concentration of chloride ions from the sweat glands as detected by the sensor plates (on the hands and feet).

The SUDOSCAN device is composed of SUDOSCAN software integrated into a touch-screen Windows 7 PC computer and connected to 4 sensor plates for the hands and feet.

General operation of SUDOSCAN

The patient places their bare feet on the feet sensor plates and applies the palms of their hands to the hands sensor plates.

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

Several successive cycles of measurements are carried out automatically and all the measured values are recorded. 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. The use of the SUDOSCAN device is strictly reserved for physician use in a healthcare setting.

Precautions for use and maintenance

Transport

The SUDOSCAN device is delivered under the packing conditions described previously.

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

Take particular care to carefully arrange the sensor plate cables in the locations especially designed for them in the protective foams, so as 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 life cycle, the SUDOSCAN device must be returned to **Impeto Medical**'s authorized distributor, which will return it to **Impeto Medical**, in order to ensure proper 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 radiation (x-rays, gamma rays, etc.) because those could erase the internal storage.
For the tables concerning electromagnetic emissions and the immunity of the recorder, see the appendices of this handbook.

Maintenance of the device and sensor plates

No special maintenance is necessary.

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

To avoid corrosion and to ensure best hygiene conditions, 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 ARE ALLOWED TO PERFORM ANY REPAIRS OR MAINTENANCE ON THE DEVICE (MAINTENANCE, CALIBRATION, ETC.).

All the technical documents (component part lists, descriptions, calibration instructions) are kept by **Impeto Medical**.
The warranty is null and void if the SUDOSCAN device is opened and repaired by any unauthorized person. Warranty applies to manufacturing defects and not for any mechanical damage due to mishandlings and/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

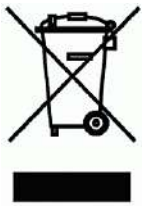
Class of electric protection.

CE

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

Warning

Registered Trademark

	Indicates the manufacturer catalogue reference
	Indicates the manufacturer lot code
	Indicates the serial number
	Tells the user the need to consult the instructions for use
	The product must be disposed 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

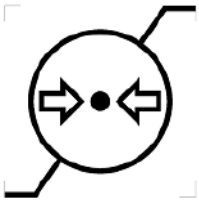
Keep dry

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 with the preparation of the skin of the patient and the installation and maintenance 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 soles 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. Scans are performed with patent standing upright.

A patient may be instructed to perform a scan while seated if they have either exceeded the maximum weight capacity or are unable to remain standing for the duration of the scan..

Interrupting or stopping the scan

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 with 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.

Contraindications

WARNING

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

- People with any open or bleeding wounds that would come into contact with the surface of the 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 OR IMPLANTABLE CARDIOVERTER DEFIBRILLATOR.

• Characteristics of acquisition

Storage support:	320 Gb Hard disk
Mode:	No compression
Frequency of acquisition:	100 Hz
Resolution:	1 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

• **Physical 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

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">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.</td></tr>
<tr><th>Immunity test</th><th>Immunity test</th><th>Immunity test</th><th>Immunity test</th></tr>
<tr><td></td><td></td><td></td><td>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.</td></tr>
<tr><td>Conducted RF

IEC 61000-4-6</td><td>3 Vrms

150 kHz to 80 MHz</td><td>3 V rms

3 V/m</td><td>Recommended separation distance

$d = 1.17\ \sqrt{P}$</td></tr>
<tr><td>Radiated RF

IEC 61000-4-3</td><td>3 V/m
80 MHz to 2,5 GHz</td><td></td><td>$d = 1.17\ \sqrt{P}$ 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:

 </td></tr>
<tr><td colspan="4">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.</td></tr>
</table>

(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 [*V*1] 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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CE 0120

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Cleared in 2010