



EZSCAN

User guide

Version 3

24/11/2015



TABLE OF CONTENTS

1	INTRODUCTION.....	5
1.1	PATENT	5
1.2	USE	5
1.3	PRINCIPLE	5
1.4	INSTALLATION.....	5
2	POWER UP THE SYSTEM	6
3	HOME PAGE.....	7
3.1	LIST OF AVAILABLE FUNCTIONALITIES	7
3.2	FOR USER NOT LOGGED IN.....	7
3.3	FOR A LOGGED IN USER.....	8
4	LOG IN PAGE	9
4.1	LIST OF CONTROLS.....	9
4.1.1	OTHER CONTROLS	9
4.2	PASSWORD VALIDATION	10
4.3	PASSWORD MODIFICATION	11
5	QUALITY CHECK PAGE.....	13
5.1	OVERVIEW	13
5.2	LIST OF CONTROLS.....	13
5.3	DURING A QUALITY CHECK TEST	14
5.4	QUALITY CHECK RESULT INTERPRETATION.....	15
5.5	TO HAVE MORE DETAILS ON THE QUALITY CHECK RESULTS	17
5.6	OTHER CONTROLS	17
6	TOOLS & SETTINGS PAGE(S)	18
6.1	STANDARD USER – LIST OF CONTROLS.....	18
6.1.1	OTHER CONTROLS	18
6.2	STANDARD USERS – CONFIGURATION (2) TAB.....	19
6.2.1	OTHER CONTROLS	19
6.3	SUPERVISOR USERS – ADDITIONAL LIST OF CONTROLS.....	20
6.3.1	OTHER CONTROLS	20
6.4	SUPERVISOR USERS – CONFIGURATION (2) TAB.....	21
6.4.1	OTHER CONTROLS	22
6.5	SUPERVISOR USERS – ADDITIONAL SERVICES	23
6.5.1	OTHER CONTROLS	24
6.6	SUPERVISOR USERS – INTERPRETATION MESSAGES.....	25
6.6.1	OTHER CONTROLS	25
6.7	IMPORT DATA FOR A SELECTED PHYSICIAN	26
6.8	EXPORT DATA ON A USB KEY FOR A SELECTED PHYSICIAN	29
6.9	PATIENT RECONCILIATION & PATIENT DEMOGRAPHIC DATA MODIFICATION.....	31
7	SCAN PAGES.....	34
7.1	LIST OF CONTROLS.....	34

7.1.1	OTHER CONTROLS	34
7.2	PATIENT SETUP & START A SCAN	35
7.3	DURING THE SCAN	37
8	PATIENT HISTORY PAGE	39
8.1	LIST OF CONTROLS	39
8.1.1	OTHER CONTROLS	39
8.2	SELECTION OF PATIENT(S) AND EXAM(S)	40
8.3	HOW TO START A NEW SCAN FOR A PATIENT	42
8.4	HOW TO DISPLAY RESULTS FOR AN EXAM	42
8.5	HOW TO DISPLAY THE FOLLOW-UP FOR A PATIENT	43
8.6	HOW TO EXPORT DATA	45
9	RESULT PAGE	48
9.1	LIST OF CONTROLS	48
9.1.1	OTHER CONTROLS	48
9.2	RESULTS	49
9.2.1	QUALITY OF MEASURE	49
9.3	QUICK INTERPRETATION OF THE RESULTS	51
9.3.1	DISCLAIMER	51
9.3.2	LOW RISK OF DIABETES	51
9.3.3	MODERATE RISK OF DIABETES	52
9.3.4	HIGH RISK OF DIABETES	54
9.3.5	VERY HIGH RISK OF DIABETES	54
10	REPORT PAGE	56
10.1	EZSCAN REPORT	56
10.1.1	OTHER CONTROLS	56
10.2	ADD COMMENTS ON REPORTS	57
11	CLEANING THE SENSOR PLATES	58
12	REPLACE THE ELECTRODES	59
13	USB PRINTER DRIVERS INSTALLATION	60
14	INSTALL SOFTWARE UPDATES	61
15	TROUBLESHOOT THE SYSTEM	61
15.1	USB CONNECTION	61
15.2	TEST THE HARDWARE	61
16	ANNEXES	62
16.1	DATA EXPORT WITHIN CSV FILES (EXCEL COMPATIBLE)	62
16.1.1	DATA IN COMPILED CSV FROM A STANDARD USER ACCOUNT	62
16.1.2	DATA IN COMPILED CSV (FROM ADVANCED CONFIGURATION)	62
16.2	IMPORT A PATIENT LIST VIA A CSV FILE	64
16.2.1	REQUIRED DATA	64
16.2.2	OPTIONAL DATA	64
17	HOW TO	65
17.1	FOR A STANDARD USER	65
17.2	FOR A SUPERVISOR USER ONLY	66

18 PRECAUTION OF USE AND TECHNICAL SPECIFICATIONS	67
CONTACTS	80

1 Introduction

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

1.1 Patent

The eZscan® 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 eZscan device is a medical device used for the early detection of cardiometabolic risk.

1.3 Principle

The eZscan device 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. The information is then used to determine peripheral sudomotor dysfunction.

Description:

The eZscan 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 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 functionalities

Please note that a summary of all functions is in the “How to” section (*ref. p65*).

3.2 For User not logged in

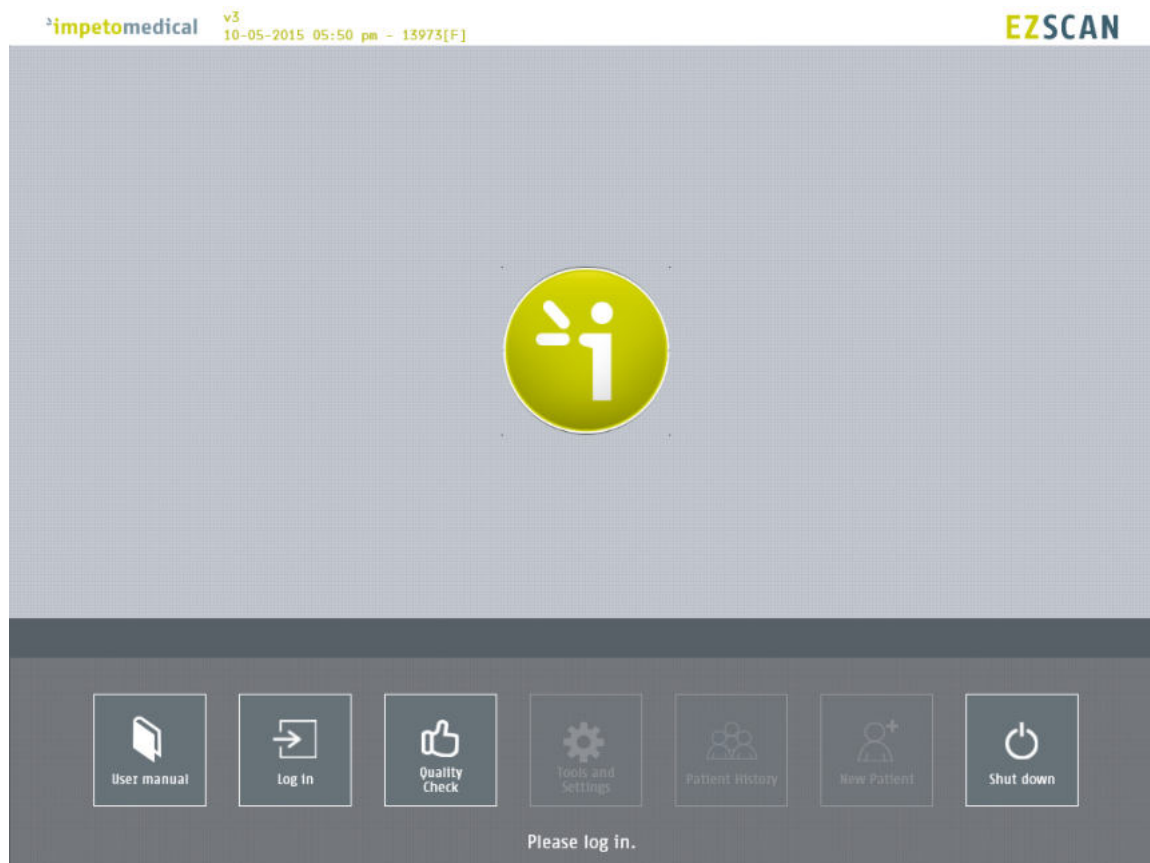


Figure 1 : Home page – no user logged in

- 1 Click on the Log in button. The “Log in” panel appears (*ref. p9*).
- 2 Click on Quality Check to launch 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 IRREDEMIABLY 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

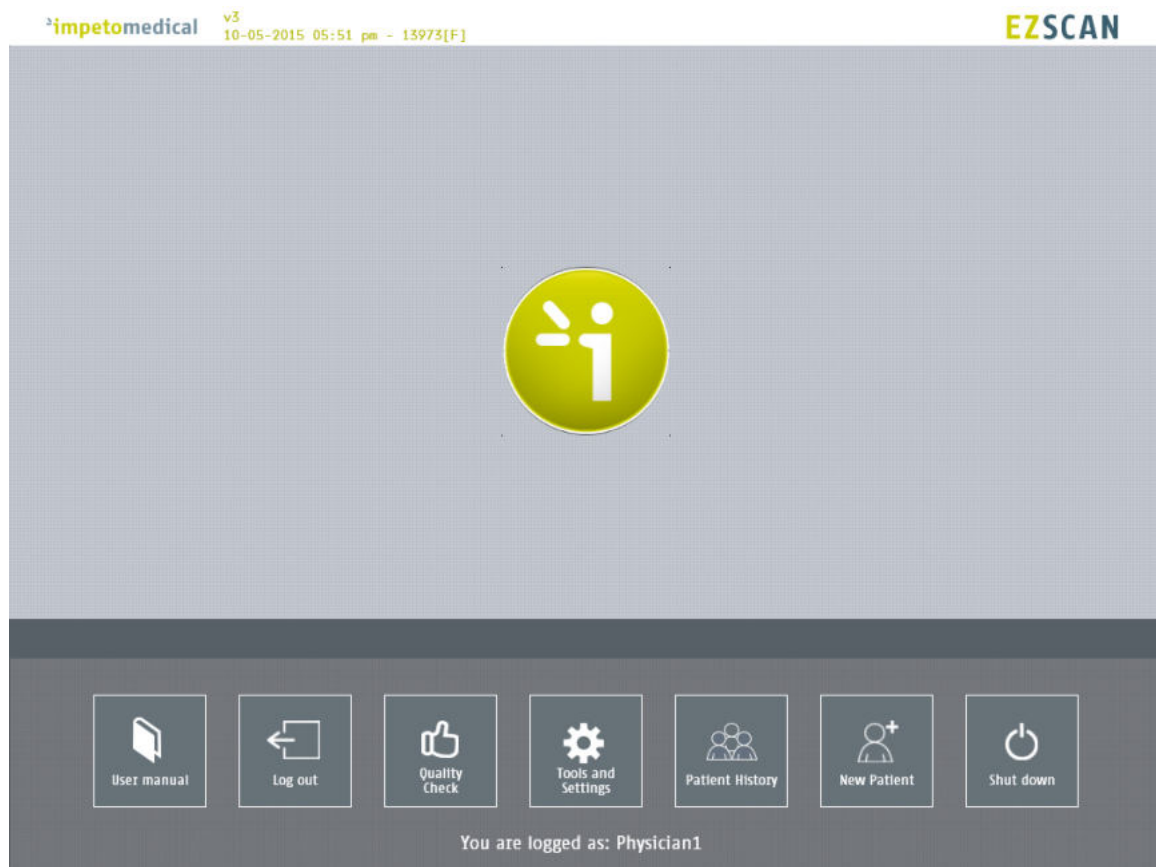


Figure 2 : Home page –user logged in

- 1 Click on Log out to log out the current user.
- 2 Click on Quality Check to launch 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. p34).
- 7 Click on Patient history to access the patient history (ref. p39).

4 Log in page

4.1 List of controls

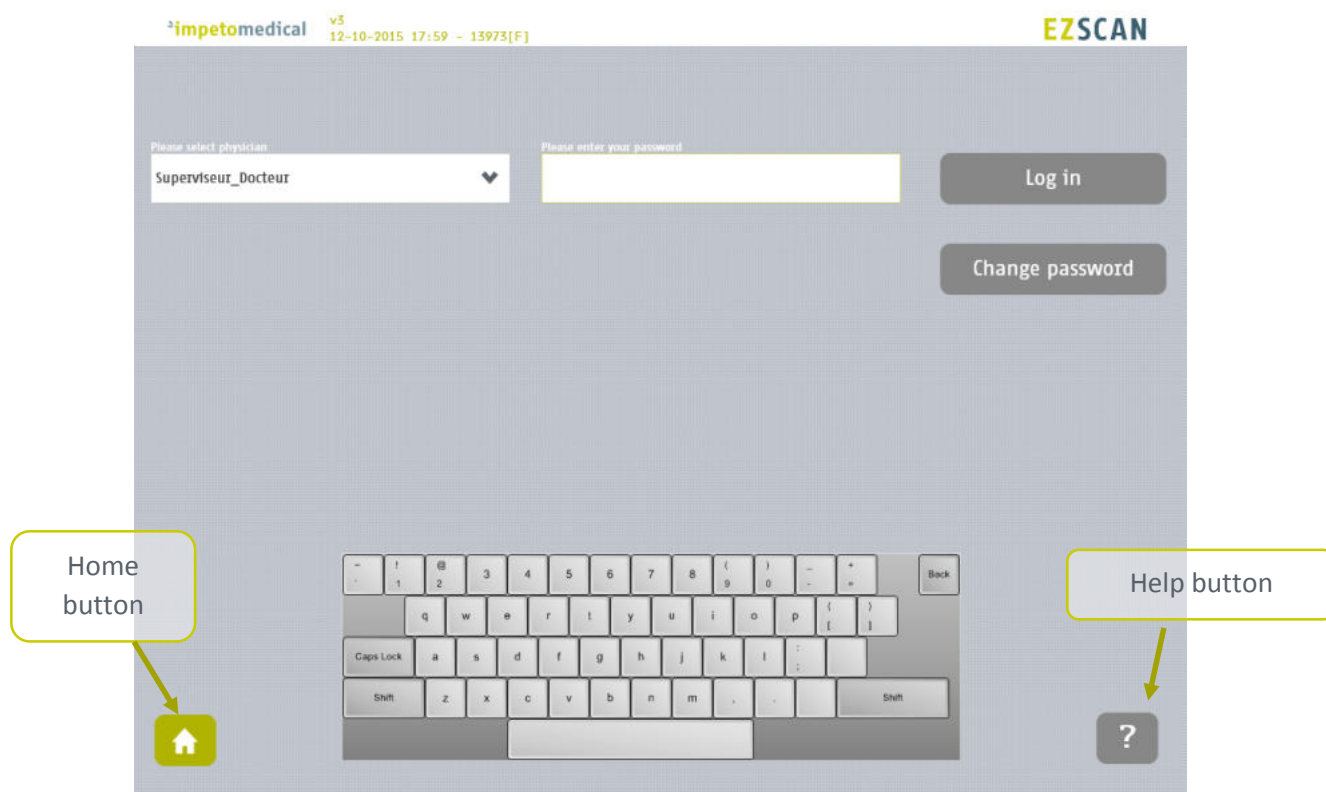



Figure 3 : Log in page

- 1 Select the physician in the 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 Log in button to validate the current password for the selected physician (*ref. p8*).

4.1.1 Other controls

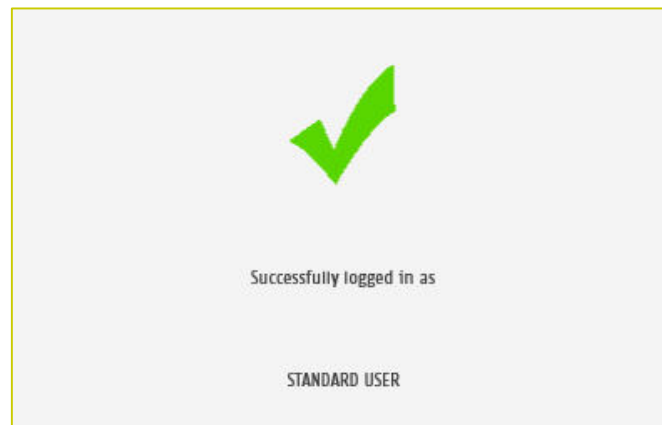
Click on the Home button () to access the home page (*ref. p8*).

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

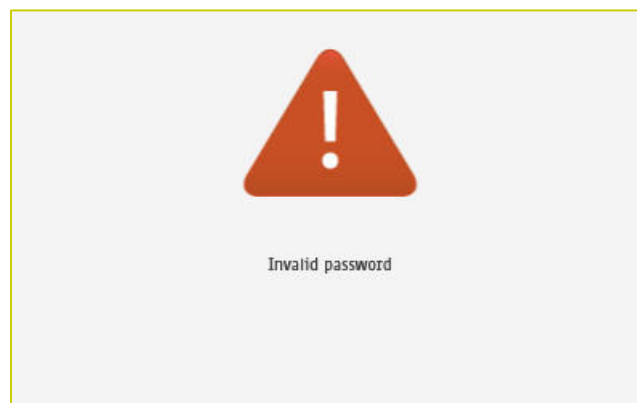
Click on Change password if you want to modify your current password (*ref. p11*).
After the current password is entered in the password field.

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 Current password field.
Click Change password to show the new password fields.
Fill the two new password fields with the same new password then click on Save password.

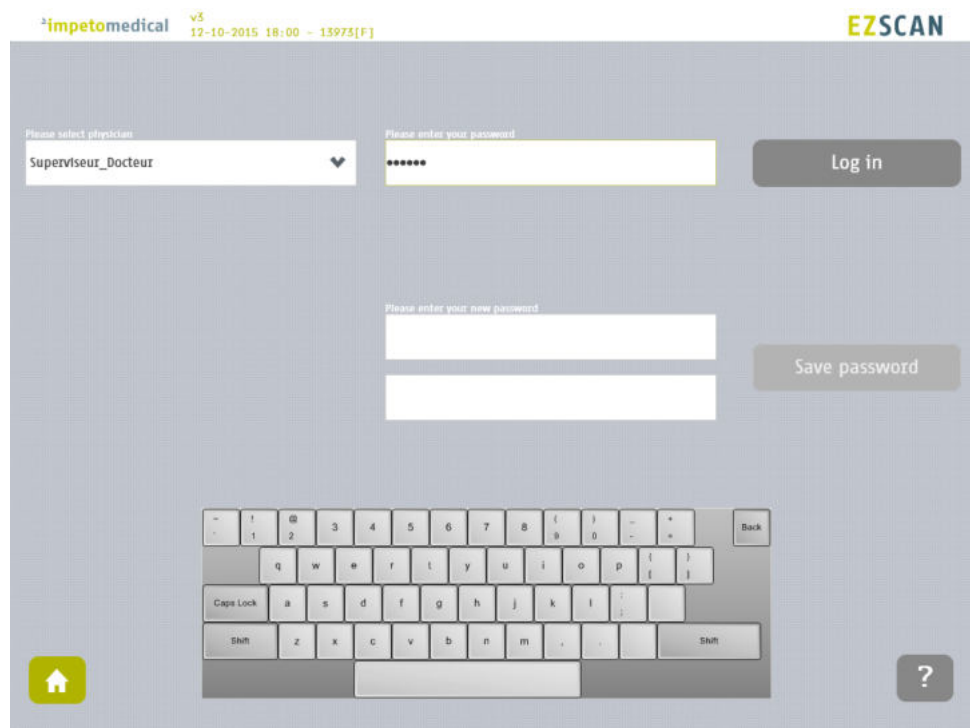
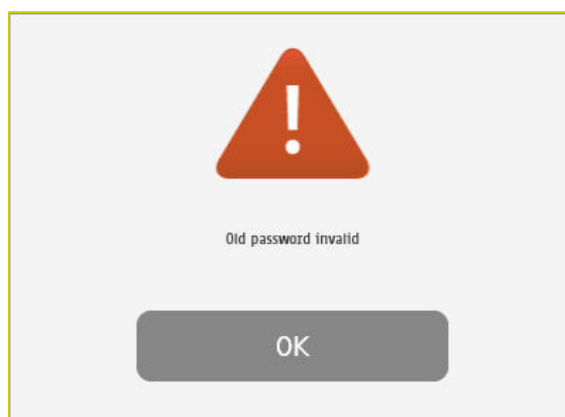


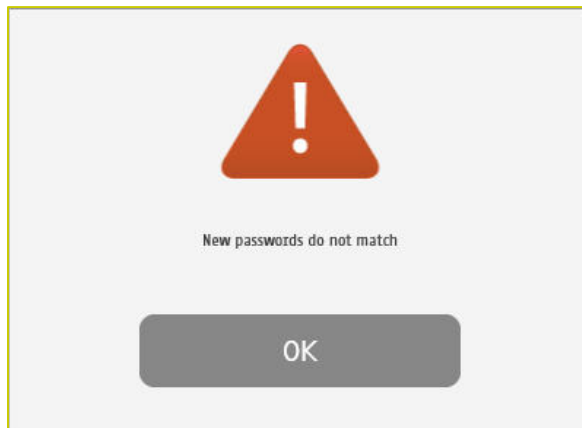
Figure 4 : Log in page – new password fields displayed

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

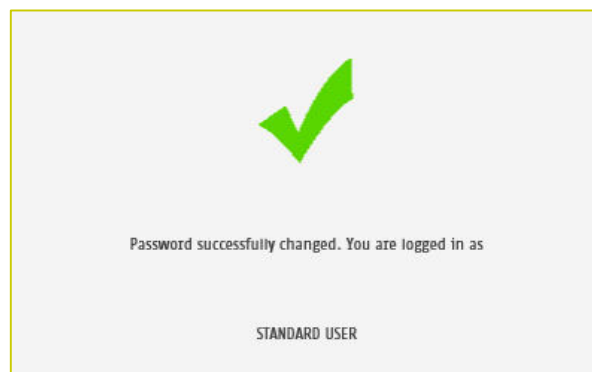
- If the old password is not correct, the following message appears:



- 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

The screenshot shows the EZSCAN Quality Check interface. At the top, it displays 'impetomedical v3', a timestamp '12-10-2015 17:56 - 13975[F]', and 'Scan#: 774 EZSCAN'. The main area contains several sections: 'Operator name (if different from physician name)' with a text input field; 'Electrode test buttons' showing two pairs of hand/foot icons; 'Reference voltage generation & Reference voltage generator loopback linearity' with a table of dashes; 'Subject Channel Selection & Input Channels Low Noise Front End qualification' with a table; '0th. Chan.' with a table; 'Internal resistances calibration' with a table; 'Channel sensitivity control' with a table; and 'Input channel linearity control (%) & Input channel absolute linearity control' with a table. At the bottom, there is a 'Run test' button, a 'More details' button, a 'Home button' (represented by a house icon), and a 'Help button' (represented by a question mark icon). Annotations with yellow boxes and arrows point to the 'Operator name field', 'Electrode test buttons', 'Home button', and 'Help button'.

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 execute 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

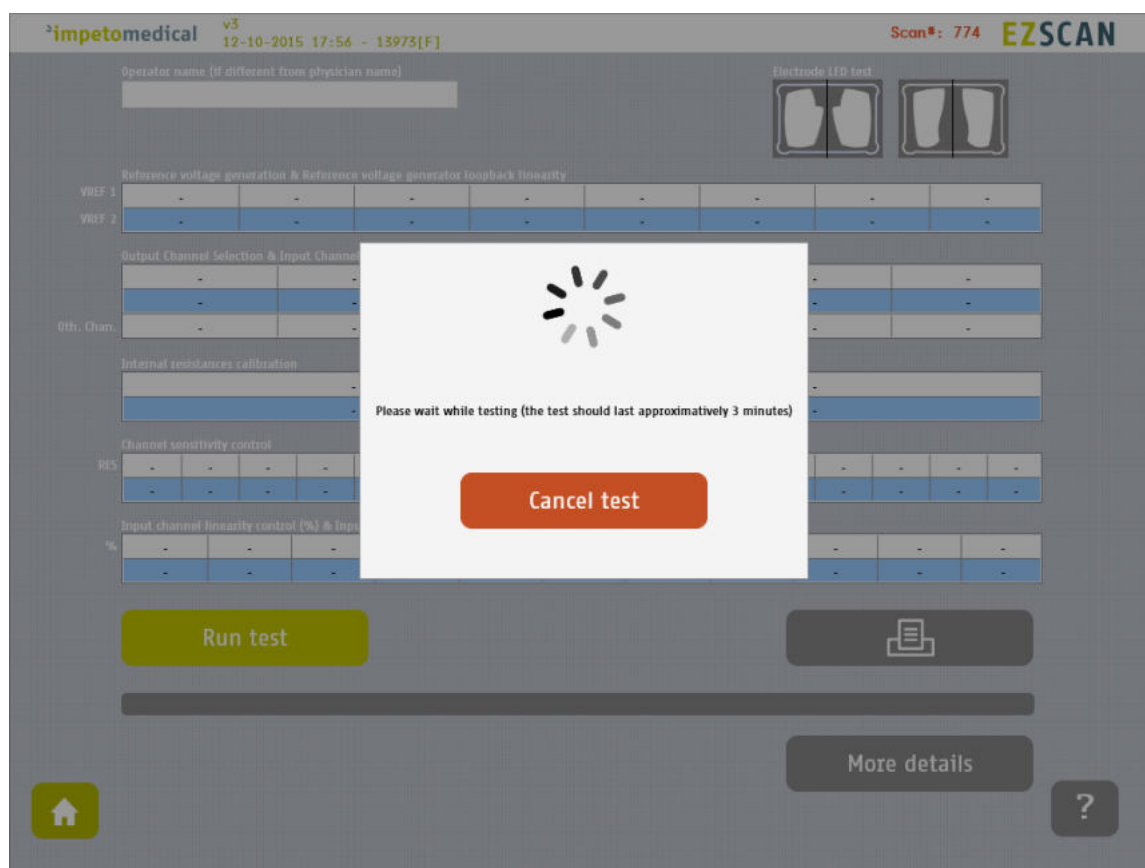


Figure 6: Quality Check page -During the Quality Check

- 1 Click on the Cancel test 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 checks are displayed for every lines as follows:

impetomedical v3 12-10-2015 18:17 - 13973[F] Scan#: 774 **EZSCAN**

Operator name (if different from physician name)

Electrode LED test

Reference voltage generation & Reference voltage generator loopback linearity								
VREF 1	630	504	447	390	333	275	219	99
VREF 2	647	517	459	400	342	283	224	101

Output Channel Selection & Input Channels Low Noise Front End qualification						
	0	1	2	3	4	5
	835	834	835	834	835	835
0th. Chan.	Pass	Pass	Pass	Pass	Pass	Pass

Internal resistances calibration	
0	1
505	520

Channel sensitivity control																
RES	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
	59	83	108	139	169	197	233	275	320	363	414	465	525	585	651	711

Input channel linearity control (%) & Input channel absolute linearity control											
%	0	10	20	30	40	50	60	70	80	90	100
	0	108	213	321	407	520	622	718	826	927	1023

Run test

More details

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. p80*).

12-10-2017 17:59 - 15793[P]

Operator name (if different from physician name)

Electrode IED test

Reference voltage generation & Reference voltage generator loopback linearity

VREF 1	631	504	447	390	333	275	219	99
VREF 2	647	518	459	400	342	283	225	101

Output Channel Selection & Input Channels Low Noise Front End qualification

	0	1	2	3	4	5
	835	834	835	834	835	835
0th. Chan.	Pass	Pass	Pass	Pass	Pass	Pass

Internal resistances calibration

0	1
512(*)	528(*)

Channel sensitivity control

RES	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
	60(*)	84(*)	110	141(*)	171(*)	200(*)	237(*)	279(*)	325(*)	368(*)	420(*)	472(*)	532(*)	594(*)	661(*)	722(*)

Input channel linearity control (%) & Input channel absolute linearity control

%	0	10	20	30	40	50	60	70	80	90	100
	0	109(*)	216(*)	326(*)	413(*)	528(*)	632(*)	729(*)	839(*)	941(*)	1023

Run test

Problem observed during the test

More details

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

- | | |
|---|---|
| 1 | Click on the <u>Print</u> button to print and 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.

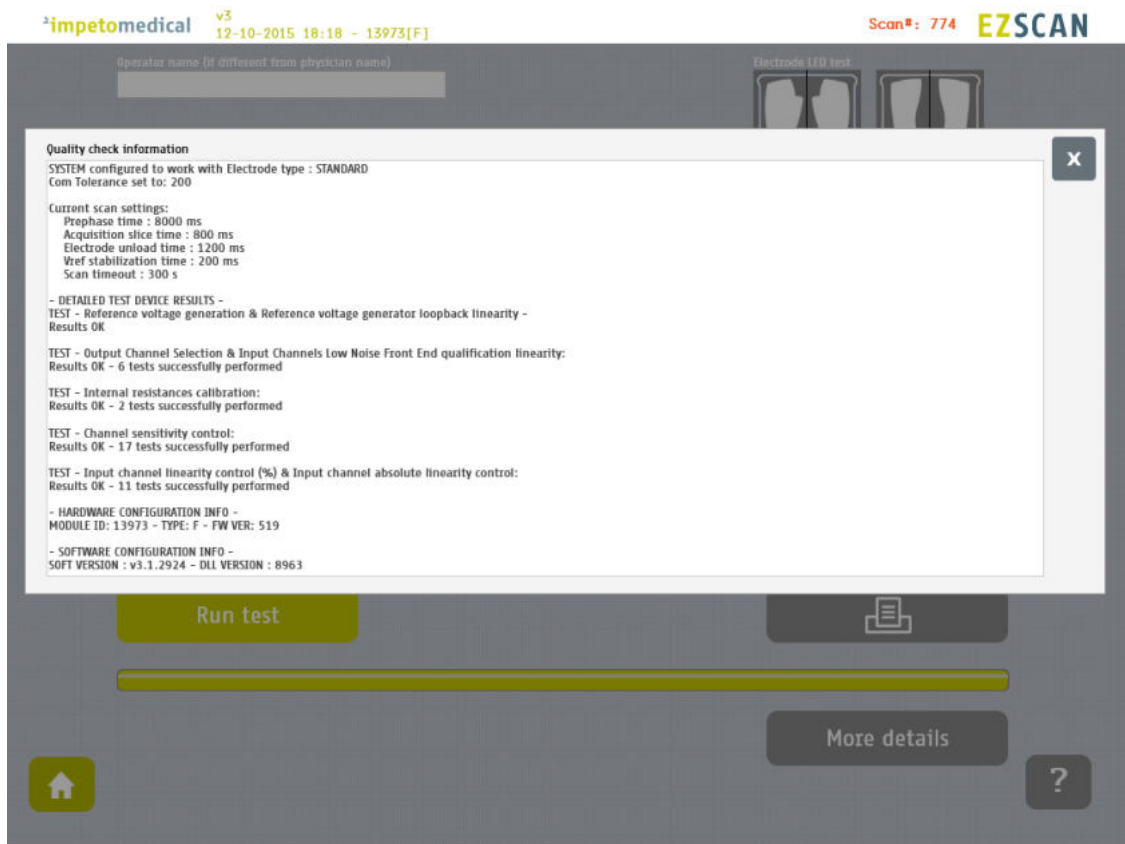


Figure 9: Quality Check page -More details on the Quality check results

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

5.6 Other controls

Click on the Home button () to access the home page (ref. p8).

Click on the Help button () button to access 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.

impetomedical v3 10-50-2015 03:42 pm - 13973[F] EZSCAN

Configuration Configuration (2)

Physician name
Physician1
Physician email
Phone number

Hospital name
Department
Address

Printer selection

Physician data

Hospital data

Home button


Help button

Figure 10 : Configuration page

- 1 Enter the physician information in the physician data fields.
- 2 Enter hospital information in the hospital data fields.
- 3 Select the printer from the dropdown list of installed printers (*ref. p60 to see how to install a printer driver*).

6.1.1 Other controls

Click on Configuration (2) tab to access to additional settings (*ref. p19*).

Click on the Home button () to access the home page (*ref. p8*).

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

6.2 Standard users – Configuration (2) tab

The screenshot shows the 'Configuration (2)' tab in the EZSCAN application. At the top, there's a header with 'impetomedical v3', a timestamp '10-30-2015 03:42 pm - 13973[F]', and the 'EZSCAN' logo. Below the header, the 'Configuration (2)' tab is active, showing several sections:


- Password management:** Includes a 'Modify selected user password' field and a 'Save password' button.
- System settings:** Features 'Idle time before system lock' with three radio buttons: '10 minutes' (selected), '1 hour', and '5 hours'.
- Print settings:** Includes a 'Direct Print' checkbox.
- Report options:** Includes a checkbox for 'Display the last report with the new one'.
- Optional Patient Data:** Includes checkboxes for 'List of drugs', 'BMI', and 'Waist', all of which are checked. There is also a 'Country' dropdown menu.
- Additional scores to display:** Includes a checkbox for 'Display mean conductances', which is checked.

At the bottom of the screen, there is a keyboard overlay with a 'Home' button (house icon) on the left and a 'Help' button (question mark icon) on the right.

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. (Preferred setting)
 - Uncheck “Direct print” to display the results only. End user can select manual print from the report screen (ref. p56) or from patients’ history (ref. p39).
- 4 **Change the report settings for the selected physician:**
 - Activate or deactivate the display of reports for the previous exams (when existing)
- 5 **Select optional data (all options may not be available).**
- 6 **Enable the display of extra scores (only available for eZscan)**

6.2.1 Other controls

Click on the Home button () to reach the home page (ref. p8).

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.

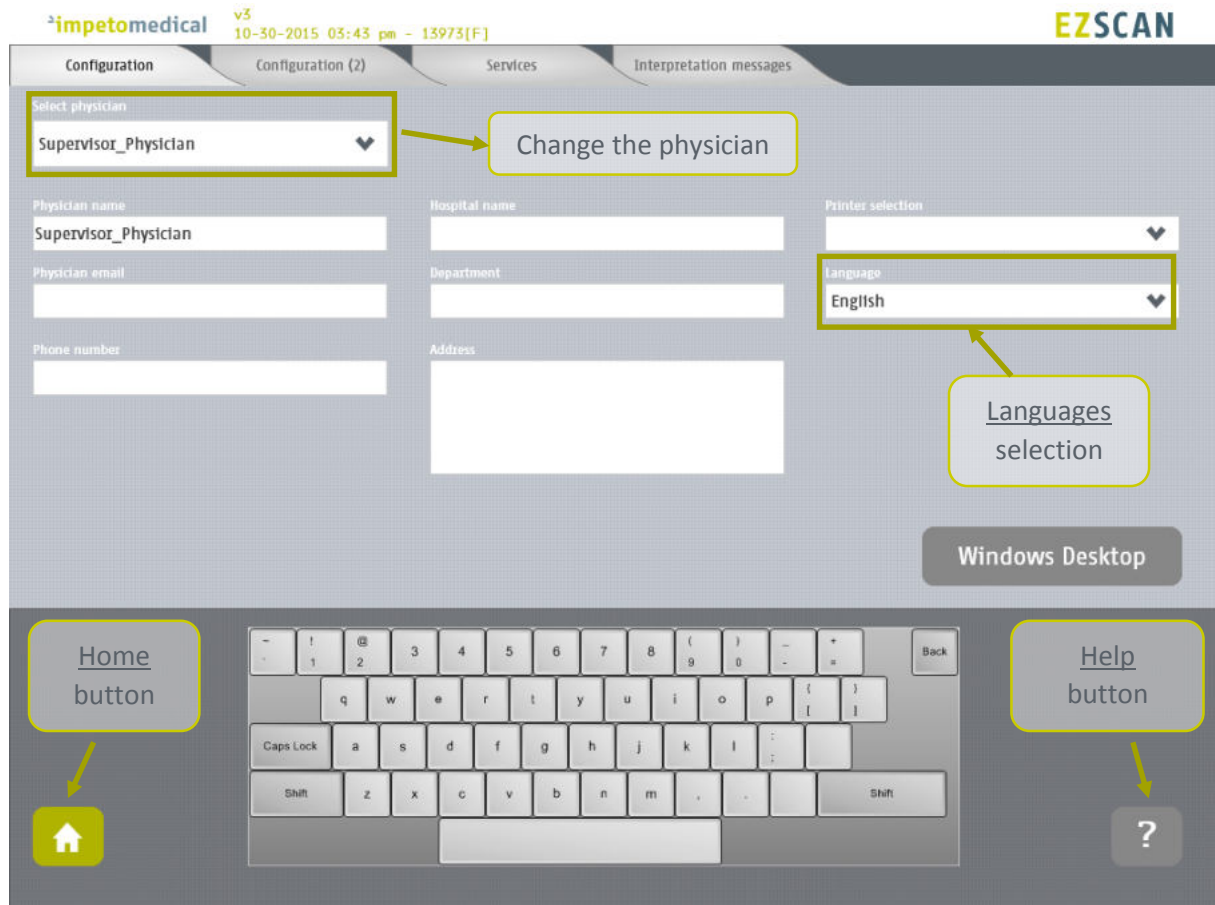


Figure 12: Configuration page - Additional controls for supervisor


- 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 to supervisor settings (*ref. p21*).

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. p8*).

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

6.4 Supervisor users – Configuration (2) tab

impetomedical v3 10-30-2015 03:44 pm - 13973[F] **EZSCAN**

Configuration Configuration (2) Services Interpretation messages

Password management

Select physician: Supervisor_Physician

Modify selected user password:

Save password

System settings

Idle time before system lock: 10 minutes (selected), 1 hour, 5 hours

Quality Check frequency: Every week, Every month (selected)

Print settings

Direct Print: ☐

Cursor settings

Hide the mouse cursor: ☒

Report options

Display the last report with the new one: ☒

Date format

yyyymmdd/mm (selected), dd/mm/yyyy, mm/dd/yyyy

Optional Patient Data

List of drugs: ☒ Country: ☐ Ethnicity: ☒ BMI: ☒ Date of Birth: ☒ HbA1c: ☐ Waist: ☒ SBP/DBP: ☒

Additional scores to display

Display mean conductances: ☒ Enable patient modification: ☒

Weight

Kg (selected), lbs

Height

Cm (selected), In

Home button:



Help button:

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 for 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 the reports after a successful scan. (Preferred setting)
 - Uncheck “Direct print” to display the results only. End user can select manual print from the report screen (ref. p56) or fro patients’ history (ref. p39).
- 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 display of reports for the previous exams (when existing)

8	<p>Select the date format to apply for the selected physician.</p> <p>Default mode is DD/MM/YYYY.</p>
9	<p>Select optional data for the selected physician (all options may not be available)</p> <ul style="list-style-type: none"> • <i>When “Date of birth” is not checked, only the Year of birth is required.</i>
10	<p>Change data management settings:</p> <ul style="list-style-type: none"> • <i>Enable the patient modification to allow standard users to modify demographic data for their patients.</i> • <i>Enable the display of extra scores (via bargraphs) on reports and results screen.</i>
11	<p>Select the preferred measurement format (linked to the selected physician).</p> <ul style="list-style-type: none"> • <i>kg or lb (weight)</i> • <i>cm or ft/in (height)</i> • <i>cm or inches (waist)</i> <p>By default the application displays height in centimeters (cm) and weight in kilograms (kg).</p>

6.4.1 Other controls

<p>Click on <u>Configuration</u> tab to access to the standard settings (<i>ref. p20</i>).</p>
<p>Click on <u>Services</u> tab to access to additional services (<i>ref. p23</i>).</p>
<p>Click on Interpretation messages to modify messages that appear as interpretation on the Results screen and on the reports. (<i>ref. p25</i>)</p>
<p>Click on the <u>Home</u> button () to reach the home page (<i>ref. p8</i>).</p>
<p>Click on the <u>Help</u> button () button to reach the contextual help.</p>

6.5 Supervisor users – Additional services

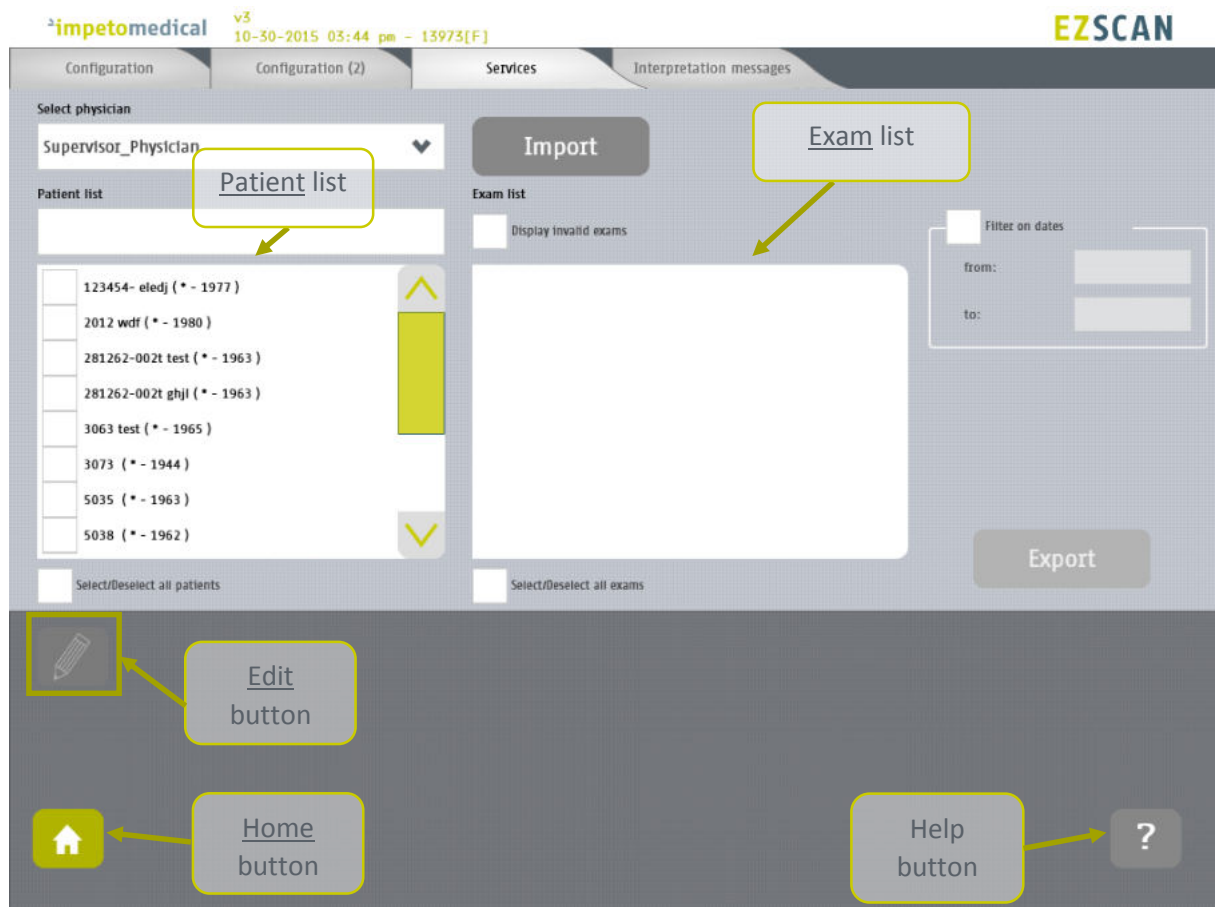


Figure 14 : Services page - Additional supervisor services

- 1 Select the physician whose settings will be modified.
- 2 Click on Import 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' 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 control to select/unselect all exams from the list
- 5 When at least one patient is selected, click on Edit button to modify the data attached to the selected patient(s) (*ref. p31*).
- 6 Click on Export button to export data attached to the selected patient(s) and exam(s) (*ref. p29*).

6.5.1 Other controls

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

Click on Configuration (2) 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 Home button () to reach the home page (*ref. p8*).

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

6.6 Supervisor users – Interpretation messages

The eZscan software is used to detect potential risk of diabetes. The computed scores are used to display the level of the potential risk and some explanation about the situation. The messages that are used in each situation can be modified by any user with supervisor privileges.

²impetomedical v3 10-30-2015 03:45 pm - 13973[F] **EZSCAN**

Configuration Configuration (2) Services Interpretation messages

Select physician
Supervisor_Physician

	CONCLUSION	EXPLANATIONS	RECOMMENDATION
Low eZscan score	NORMAL RESULT: You have a high probability of not having an abnormality in your glucose metabolism and with this, not an increased diabetes risk.	There is a low risk of becoming IGT and T2DM. It hints you have a high probability of normal glucose metabolism. It is only a reference for screening of diabetes. A clinical diagnosis must be made by the physician in the context of all available information.	Plan a new eZscan test in 12 months.
Moderate eZscan score	INTERMEDIATE RESULT: You have a low probability of having an abnormality in your glucose metabolism but an increased risk in getting diabetes in the following years.	There is a moderate risk of becoming IGT and T2DM. It hints you have a probability of having an abnormality in your glucose metabolism (IGT or T2DM), or easily becoming IGT and T2DM. It is only a reference for screening of diabetes. A clinical diagnosis must be made by the physician.	Suggest to do OGTT to confirm if there is abnormal glucose metabolism. Plan a new eZscan test in 6 months. Some lifestyle change can be advised.
High eZscan score	ABNORMAL RESULT: You have a high probability to become impaired glucose tolerant or diabetic in the next few months.	There is a high risk of becoming IGT and T2DM. It hints you have a high probability of having an abnormality in your glucose metabolism (IGT, T2DM) or complication, or easily becoming IGT or T2DM. It is only a reference for screening of diabetes. A clinical diagnosis must be made by the physician.	Suggest to do OGTT and another test to diagnose abnormal glucose metabolism, diabetes or diabetic complication. A new eZscan test is to be planned in 3 months.
Very high eZscan score	CLEARLY ABNORMAL RESULT!	There is a very high risk of becoming IGT and T2DM. It hints you have a very high probability of having an abnormality in your glucose metabolism (IGT, T2DM) or complication. It is only a reference for screening of diabetes. A clinical diagnosis must be made by the physician in the	Consult a physician and have a complete set of tests done with emphasis on diabetes and complication. A new eZscan test is to be planned in 1 month.

Home ?

Figure 15: Modify interpretation messages

- 1 Select the physician whose settings will be modified from Configuration (ref. p20), Configuration (2) (ref. p21), or Services (ref. p23).
- 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 Configuration tab to access to the standard user settings (ref. p20).

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

Click on Services tab to access to additional services (ref. p23).

Click on the Home button () to reach the home page (ref. p8).

Click on the Help 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:

Import services

☐ Import DB files to the database (Version 2.5 and older)

☐ Import RAW files to the database

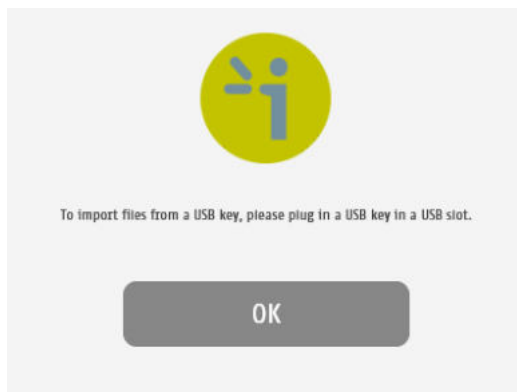
☐ Import a list of patients' demographics (CSV)

Ok **Cancel**

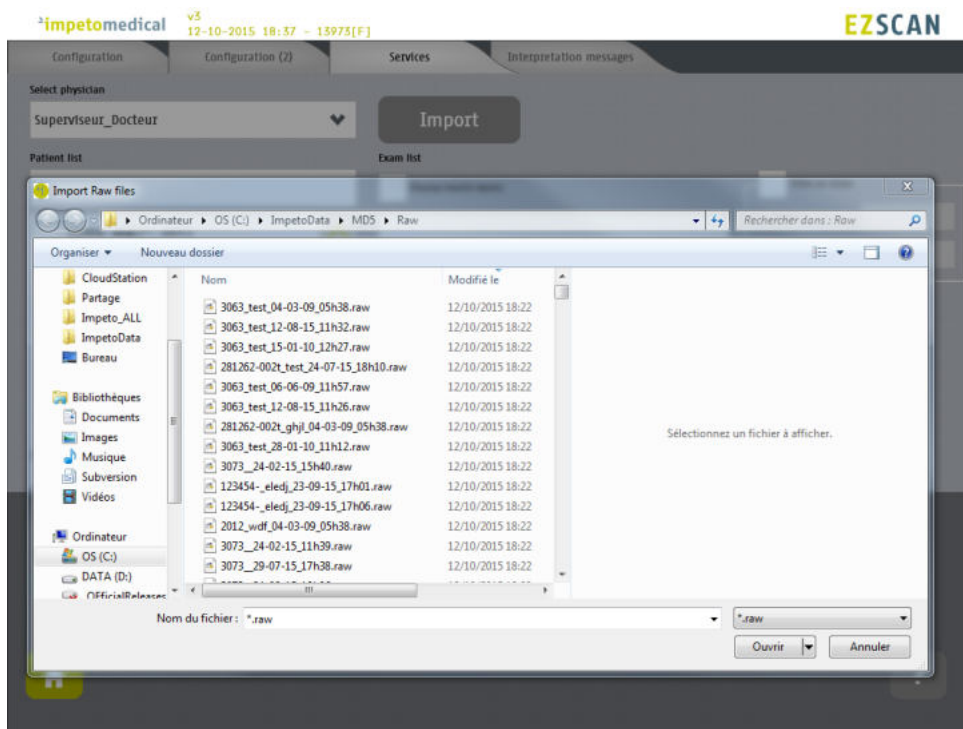
You can select several type of data:

- 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 files use the proposed template to ensure compatibility with the system (ref. p64).
-

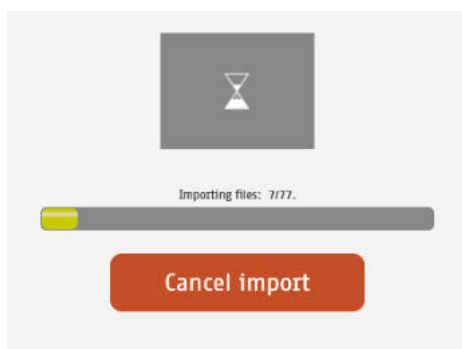
3 **Validate and verify that the USB key is correctly plugged into the system:**



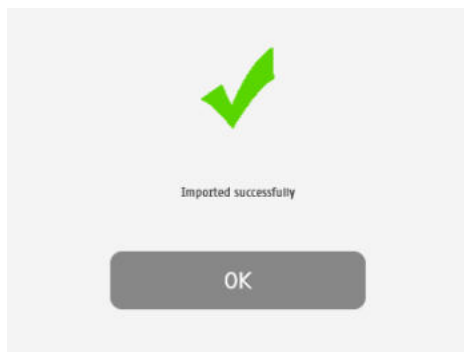
4 **Validate and select files to import:**



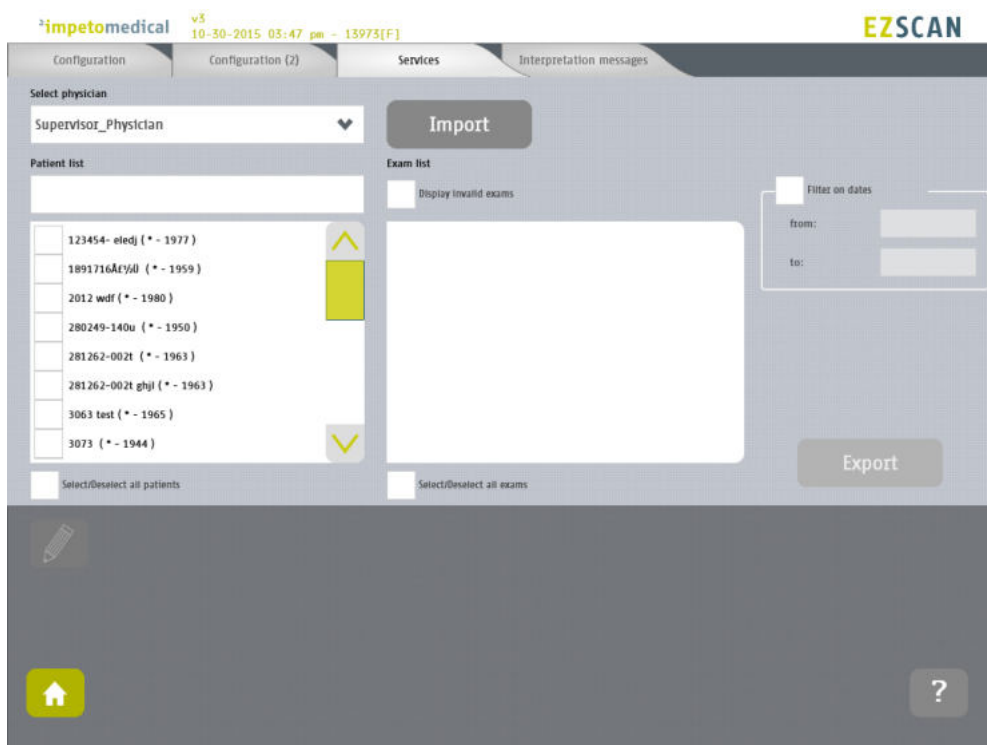
5 **The files are imported.**



6 The import is complete.



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



6.8 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. p40) and click on Export button. A popup window appears to precise the type of data you want to export:

Export services

☐ Compiled CSV (Excel) File on a USB key

☐ Encrypted patient (reversible)

☐ Random name (irreversible)

☒ Not encrypted

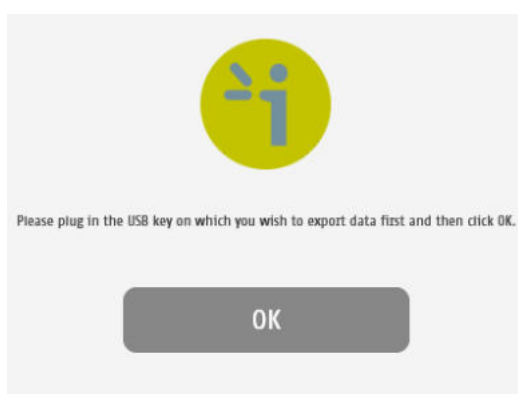
☐ Export RAW data for selected exams

OK **Cancel**

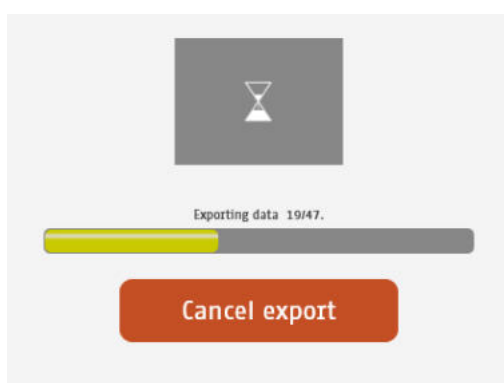
You can select several type of data:

- Compile and export a CSV file: including all data for the selected exams. Exported data are detailed within annexes (ref. p62). The encryption of patients' names and first names is optional (reversible, irreversible or none).
Stored within /CompiledCSV/ directory.
- Export Raw files: These are the raw data, useful to switch from one Impeto system to another.
Stored within /ExportRaw/ directory.

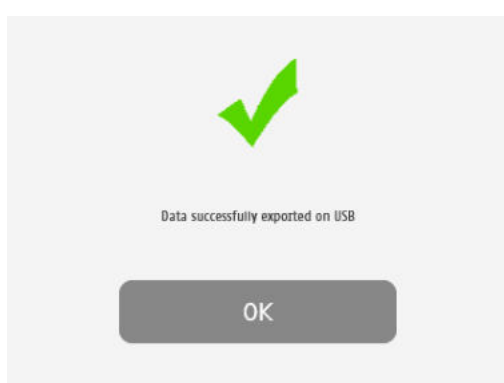
3 **Validate and verify that the USB key is correctly plugged into the system:**



4 **Validate and the files are exported:**



5 **The export is complete.**



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 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. p19).

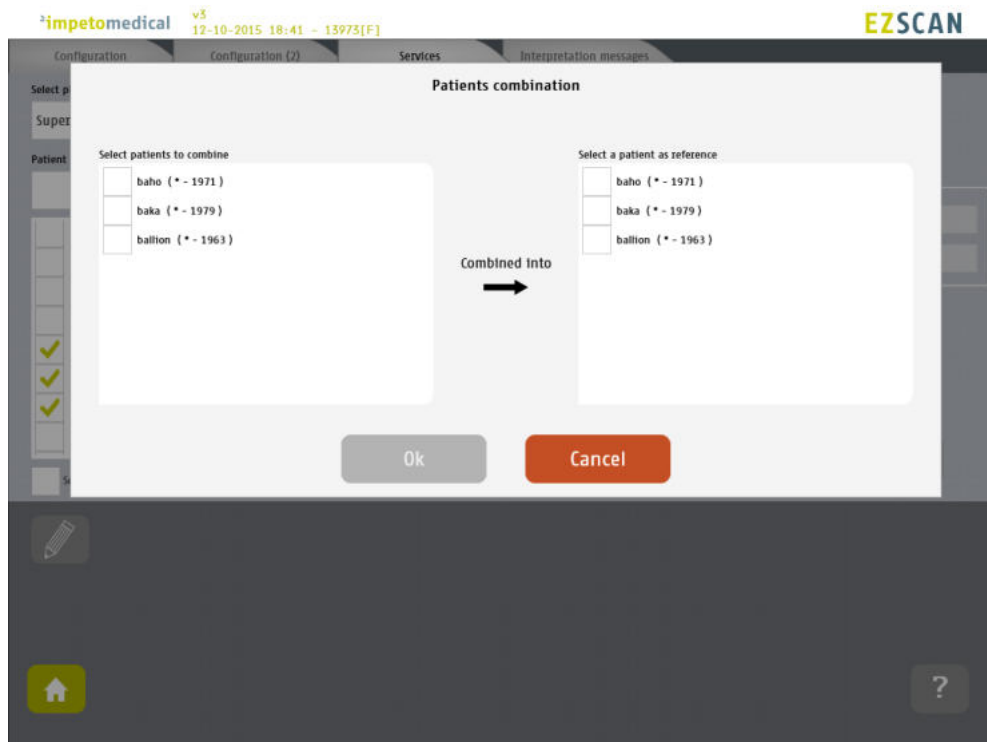
- 1 Select one or several patients (*ref. p40*) and click on the Edit button.

The screenshot shows the EZSCAN interface with the 'Services' tab selected. The 'Patient list' on the left contains several entries, with 'baho (* - 1971)', 'baka (* - 1979)', and 'ballion (* - 1963)' marked with green checkmarks. The 'Exam list' on the right shows exams for 'baho' and 'ballion'. A yellow box highlights the 'Edit' button (pencil icon) at the bottom left of the patient list. The 'Import' and 'Export' buttons are visible at the top right.

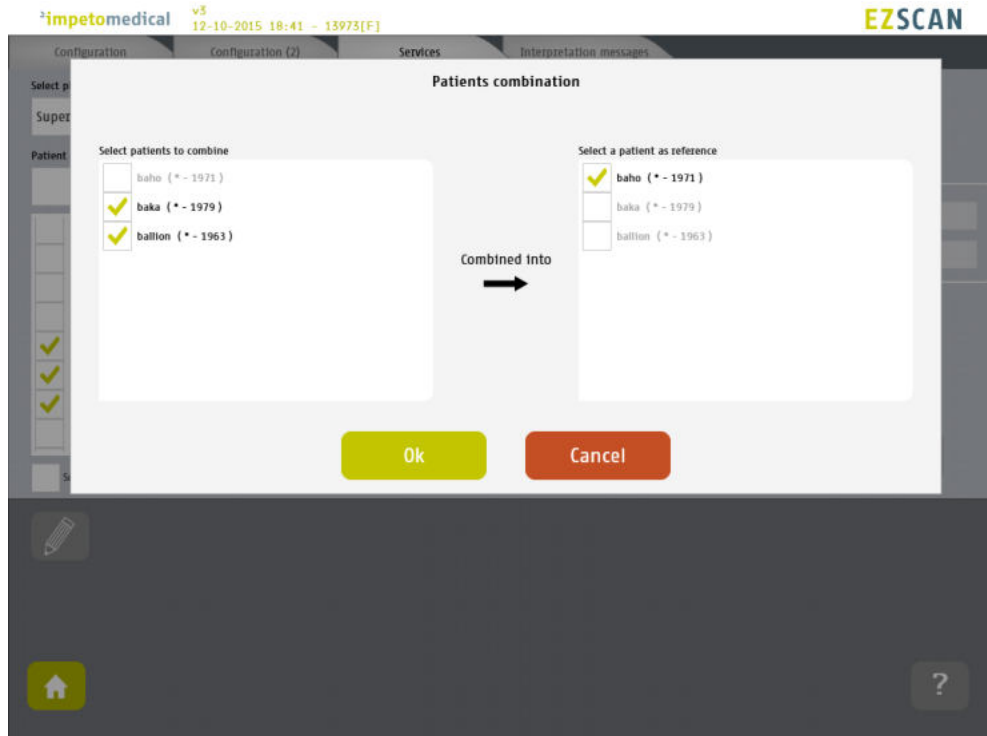
- 2 When only one patient is selected, a popup window is displayed to modify demographic data of the selected patient (name, first name, date of birth, patient ID, ethnicity):

The screenshot shows the EZSCAN interface with the 'Incorrect demographics data' popup window displayed. The popup contains the following fields: 'Last Name' (baho), 'First Name' (empty), 'Date of Birth (Day-Month-Year)' (1 January 1971), and 'Patient Identifier' (empty). The 'Ok' button is highlighted in yellow. The background shows the same patient list as the previous screenshot, with 'baho (* - 1971)' selected.

-
- 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.

impetomedical v5 12-10-2015 18:41 - 13973[F] **EZSCAN**

Configuration Configuration (2) **Services** Interpretation messages

Select physician
Superviseur_Docteur

Import

Patient list

<input type="checkbox"/>	3073 (* - 1944)
<input type="checkbox"/>	5035 (* - 1963)
<input type="checkbox"/>	5038 (* - 1962)
<input type="checkbox"/>	54661- (* - 1992)
<input checked="" type="checkbox"/>	baho (* - 1971)
<input type="checkbox"/>	ballion (* - 1964)
<input type="checkbox"/>	bance (* - 1954)
<input type="checkbox"/>	test test (* - 1995)

Select/deselect all patients

Exam list

☐ Display invalid exams




- baho -

<input type="checkbox"/>	01-06-2015 09:06:00
<input type="checkbox"/>	27-02-2015 13:55:00
<input type="checkbox"/>	01-07-2014 14:34:00

Select/deselect all exams

Export

Filter on dates
from:
to:

7 Scan pages

When a patient does not exist already on the system, select New Patient button on the Home screen (ref. p8) and fill in demographic data for the patient.

7.1 List of controls

impetomedical v3 12-10-2015 18:47 - 13973[F] Scan#: 774 EZSCAN

PATIENT INFORMATION (* indicates a required field)

Last Name * First name * Email

Date of Birth (Day-Month-Year) * 1 January

Female Male

Age Weight (kg) * Height (cm) *

0 0 0

Waist (cm) BMI SBP/DBP (mmHg) * HbA1c (10x)

0 0 120 / 0 0

Scan Clear patient data

Home button Help button


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 changes according to enabled options.

- 2 Click on Clear patient data to clear all patient data fields.

7.1.1 Other controls

Click on the Home button () to access the home page (ref. p8).

Click on the Help button () button to access 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 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).
- SBP/DBP (8 to 400 mmHg). **This option can be changed by a supervisor (ref. p21).**
- 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.

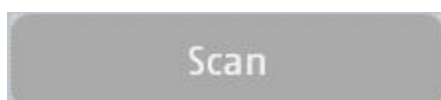
NOTE

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

The screenshot shows the 'PATIENT INFORMATION' form on the EZSCAN interface. At the top, it displays 'impetomedical v3', the date and time '12-10-2015 18:48 - 13973[F]', and the scan number 'Scan#: 774 EZSCAN'. The form includes fields for 'Last Name *', 'First name *', 'Email', 'Date of Birth (Day-Month-Year) *', 'Patient Identifier', 'Age', 'Weight (kg) *', 'Height (cm) *', 'Waist (cm)', 'BMI', 'SBP/DBP (mmHg) *', and 'HbA1c (10x)'. Several fields are highlighted in red, indicating they are empty and required. These include 'Last Name *', 'First name *', 'Date of Birth (Day-Month-Year) *' (specifically the day and month dropdowns), 'Weight (kg) *', 'Height (cm) *', 'Waist (cm)', 'BMI', and 'HbA1c (10x)'. There are also radio buttons for 'Female' and 'Male', and a 'Patient Identifier' field. To the right of the main form is a section for 'Additional Patient Information' with five empty text input fields. At the bottom of the form are two buttons: 'Scan' and 'Clear patient data'. Below the form is a virtual keyboard with a home button on the left and a question mark button on the right.

Figure 17: Scan page - Highlighting of empty required fields

-
- 3 Click on the Scan button to start the scan (ref. p37).



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 requested to remain still during the scan.

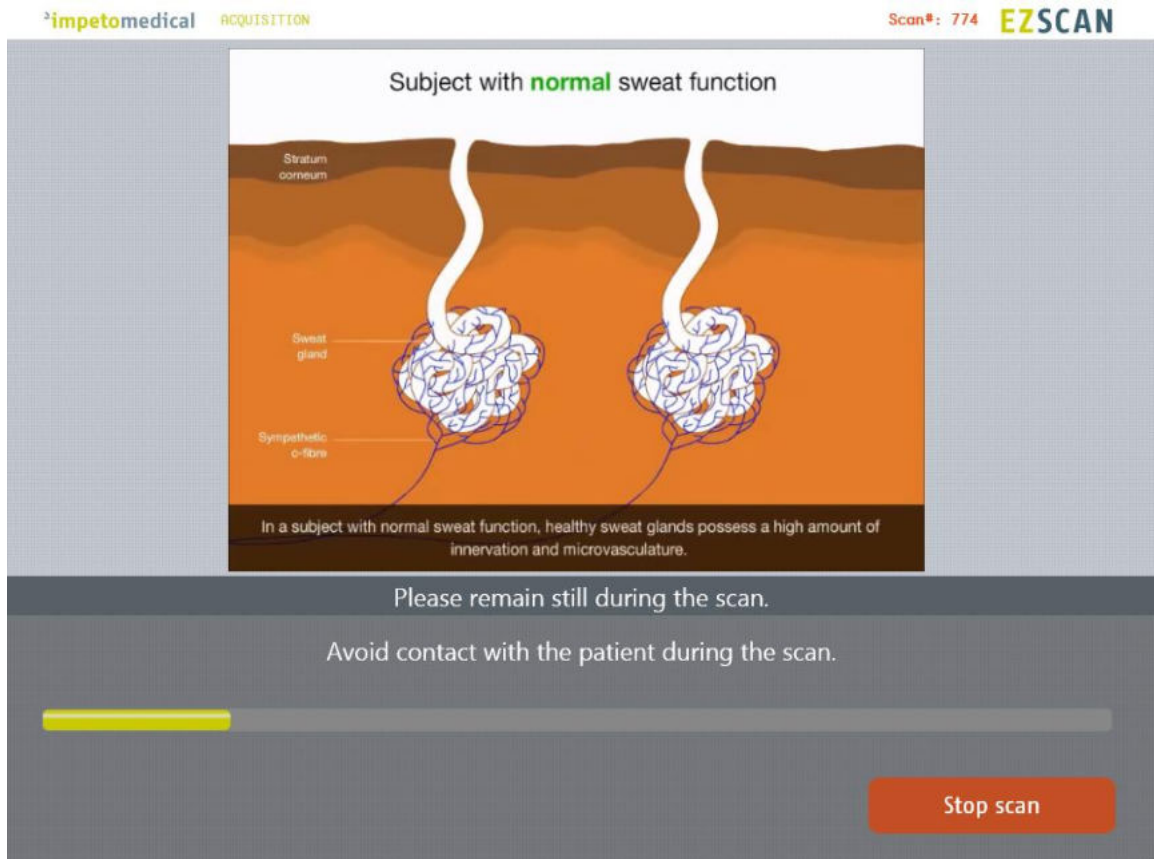
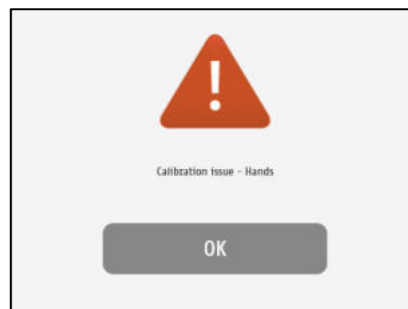


Figure 18: Acquisition

- 2 If hand or foot contact on the sensor plates is lost during calibration, then 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 . The result page is displayed once the scan successfully ends (ref. p48).*
- *When the scan ends with an issue, the application processes to the result page but the reports are not generated, except if the scan is validated by the user (ref. p49)*

5 Clean the electrodes after each scan with manufacturer approved cleaning solution (ref. p58).

8 Patient History page

To retrieve data for exams and patients, click on the [Patient History](#) button from the Home screen (ref. p8).

8.1 List of controls

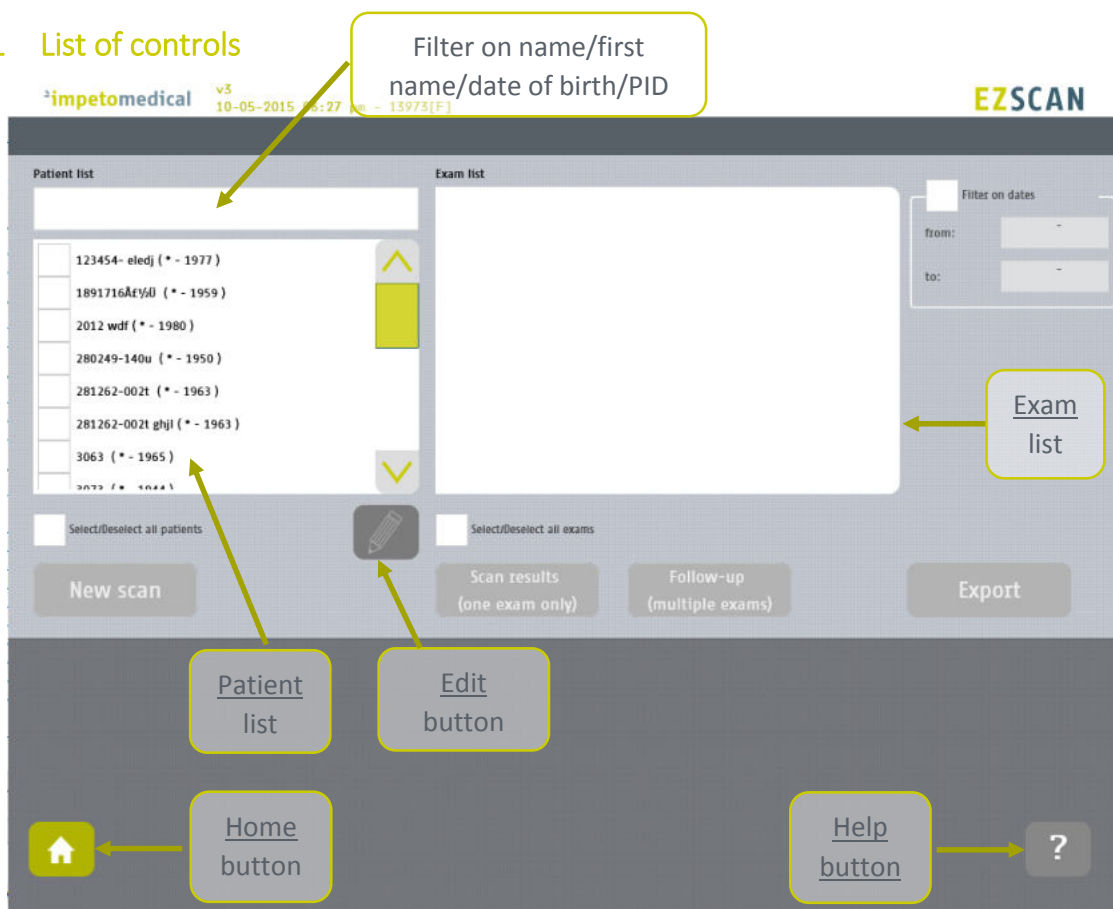



Figure 19 : Patient History page

- 1 Select patients from the [Patient list](#) and exams from the [Exam list](#) (ref. p40).
- 2 When available, edit patient demographic data or combine data from several patients by clicking on the [Edit button](#). The option can be enabled by supervisor users (ref. p21).
- 3 Start a [New scan](#) for the selected patient (ref. p34).
- 4 Display the [results](#) for the selected exam (ref. p48).
- 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 access the home page (ref. p8).

Click on the [Help](#) button () button to access the contextual help.

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

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

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

The screenshot shows the EZSCAN software interface. At the top, there is a header with 'impetomedical v3' and a timestamp '10-05-2015 06:27 pm - 13973[F]'. The main area is divided into two columns: 'Patient list' and 'Exam list'. The 'Patient list' contains a table with patient information, including ID, name, and year of birth. The 'Exam list' is currently empty. To the right of the 'Exam list' is a 'Filter on dates' section with 'from:' and 'to:' fields. Below the lists are buttons for 'New scan', 'Scan results (one exam only)', 'Follow-up (multiple exams)', and 'Export'. At the bottom, there is a home button and a help button.

Patient list	
<input type="checkbox"/>	123454- elndj (* - 1977)
<input type="checkbox"/>	1891716Aeydl (* - 1959)
<input type="checkbox"/>	2012 wdf (* - 1980)
<input type="checkbox"/>	280249-140u (* - 1950)
<input type="checkbox"/>	281262-002t (* - 1963)
<input type="checkbox"/>	281262-002t ghjl (* - 1963)
<input type="checkbox"/>	3063 (* - 1965)
<input type="checkbox"/>	3072 (* - 1965)

Exam list	
-----------	--

Select the patient(s) from the patient list.

The screenshot shows the EZSCAN software interface with selections. In the 'Patient list', the checkboxes for '2012 wdf (* - 1980)' and '281262-002t (* - 1963)' are checked. In the 'Exam list', there are two entries: '2012 wdf' and '281262-002t'. The '2012 wdf' entry has a checkbox that is checked, and the '281262-002t' entry has a checkbox that is unchecked. The 'Filter on dates' section is still present on the right. The buttons at the bottom are the same as in the previous screenshot.

Patient list	
<input type="checkbox"/>	123454- elndj (* - 1977)
<input type="checkbox"/>	1891716Aeydl (* - 1959)
<input checked="" type="checkbox"/>	2012 wdf (* - 1980)
<input type="checkbox"/>	280249-140u (* - 1950)
<input checked="" type="checkbox"/>	281262-002t (* - 1963)
<input type="checkbox"/>	281262-002t ghjl (* - 1963)
<input type="checkbox"/>	3063 (* - 1965)
<input type="checkbox"/>	3072 (* - 1965)

Exam list	
<input checked="" type="checkbox"/>	2012 wdf - 03-04-2009 05:38:00
<input type="checkbox"/>	281262-002t - 07-24-2015 18:10:00 09-18-2013 11:40:00 03-29-2010 12:55:00 (Not validated yet) 03-04-2009 05:38:00

Use the filter on dates to display exams for a precise date (here September 18th, 2013)

The screenshot shows the EZSCAN software interface. At the top, the logo 'impetomedical' is on the left, 'v3' is in the center, and 'EZSCAN' is on the right. Below the logo, a status bar displays '10-05-2015 06:30 pm - 13973[F]'. The main interface is divided into two columns: 'Patient list' on the left and 'Exam list' on the right. The 'Patient list' column has a search bar at the top. Below it, there are two sections: 'Selected patients' and 'Filtered patients'. The 'Selected patients' section contains one entry: '2012 wdf (* - 1980)' with a green checkmark. The 'Filtered patients' section contains one entry: '281262-002t (* - 1963)' with a green checkmark. Below these sections are two checkboxes: 'Select/Deselect all patients' and 'Select/Deselect all exams'. The 'Exam list' column has a search bar at the top. Below it, there is one entry: '09-18-2013 11:40:00'. To the right of the 'Exam list' column is a date filter section. It has a checkbox labeled 'Filter on dates' which is checked. Below it are two date pickers: 'from: 09-18-2013' and 'to: 09-18-2013'. At the bottom of the interface, there are four buttons: 'New scan', 'Scan results (one exam only)', 'Follow-up (multiple exams)', and 'Export'. In the bottom left corner, there is a home icon. In the bottom right corner, there is a question mark icon.

The patients that were selected are still selected but separated in two categories 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. p34*):

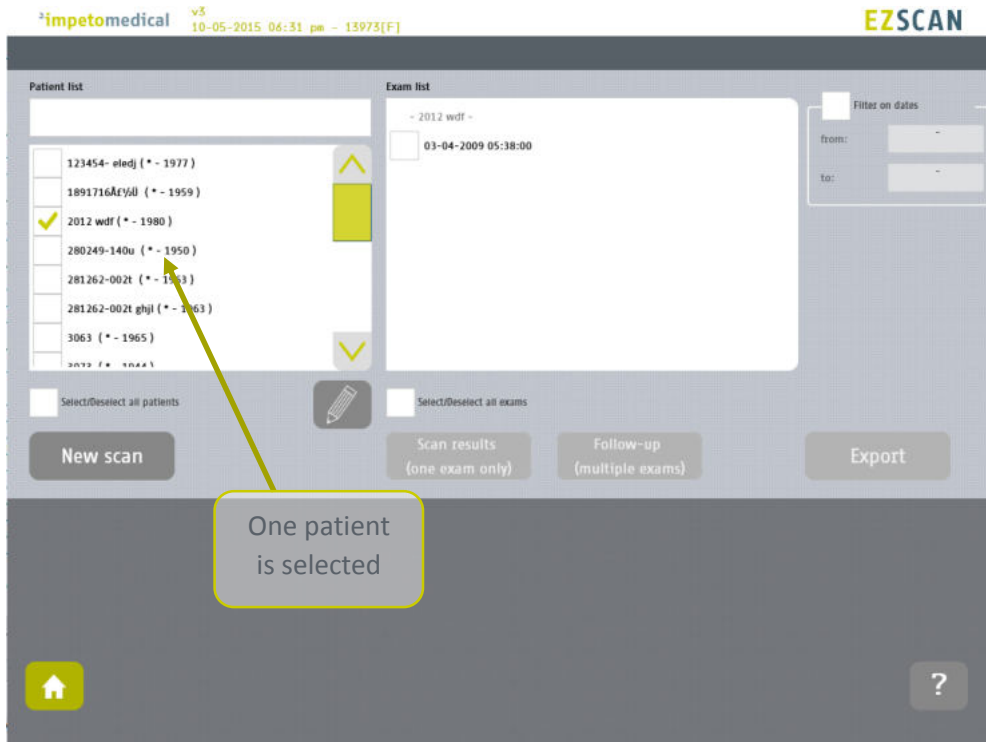


Figure 20: Start a new scan for an existing patient

8.4 How to display results for an exam

Select an exam (only one) from the list of exams and click on the Scan results button (*ref. p48*):

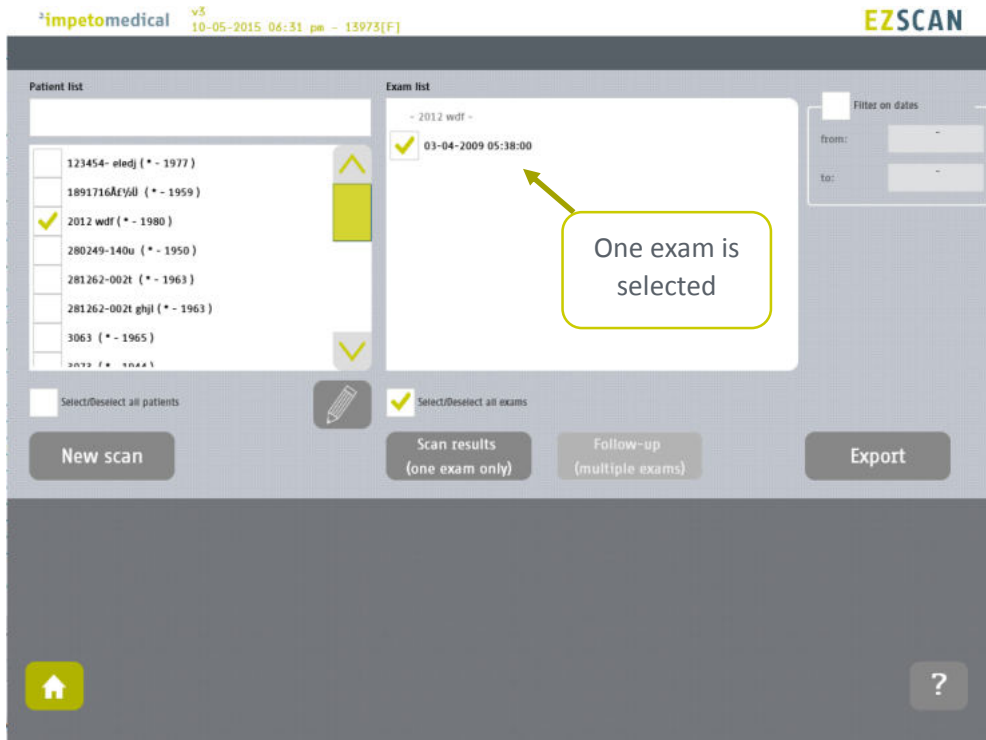
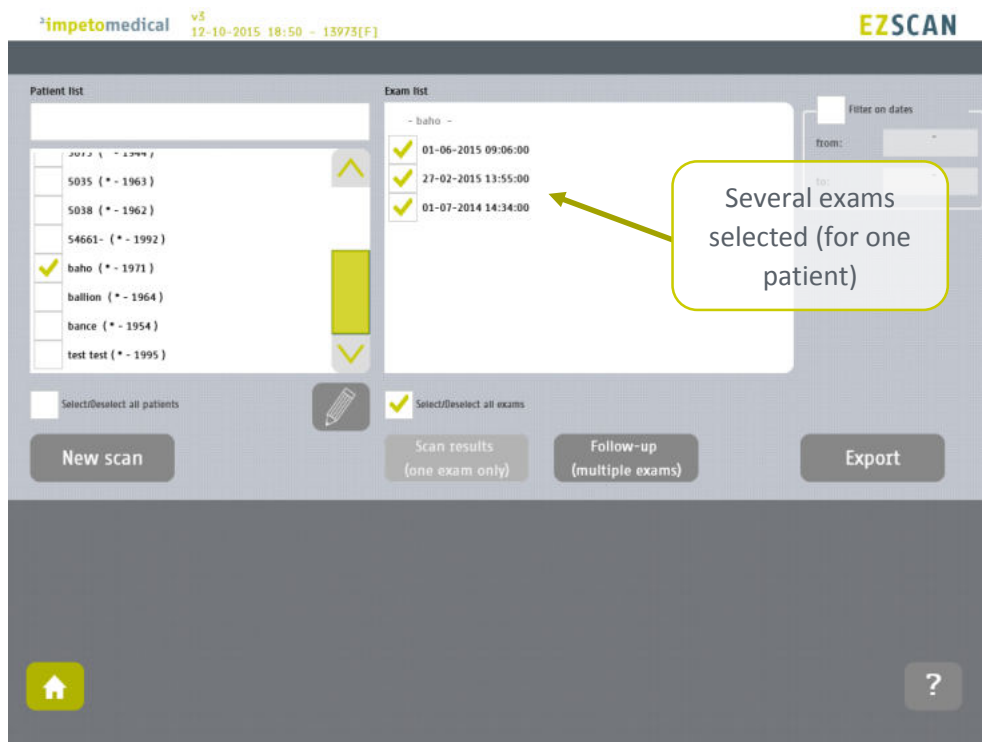


Figure 21: Display results for an exam

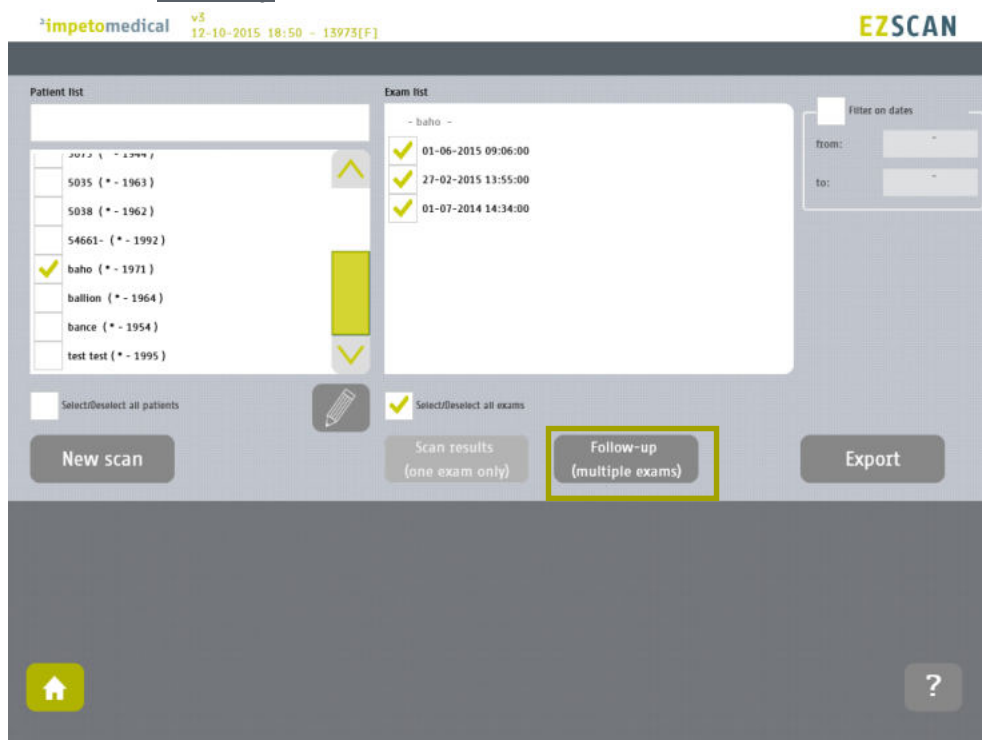
8.5 How to display the follow-up for a patient

Select several exams for a patient and click on Follow-up button:

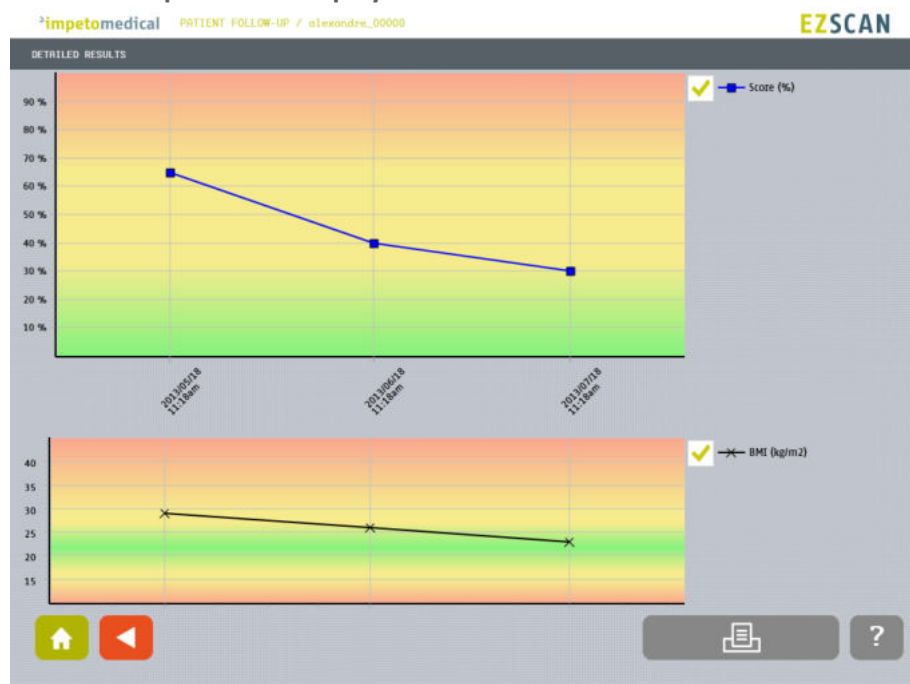


The follow-up of a patient is displayed when at least 2 exams are selected for the same patient and it is possible to display up to 15 exams.

Click on the follow-up button.



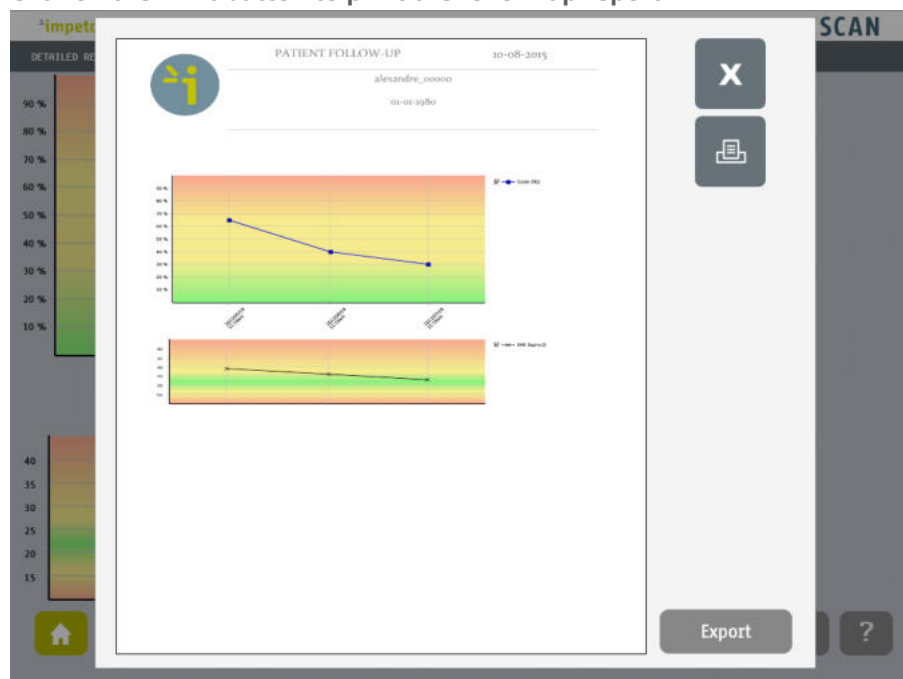
The follow-up screen is displayed.



The top graph describes the eZscan score evolution. It is possible to display the score values by clicking on the curve.

The bottom graph describes the evolution of the Body Mass Index (BMI).

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

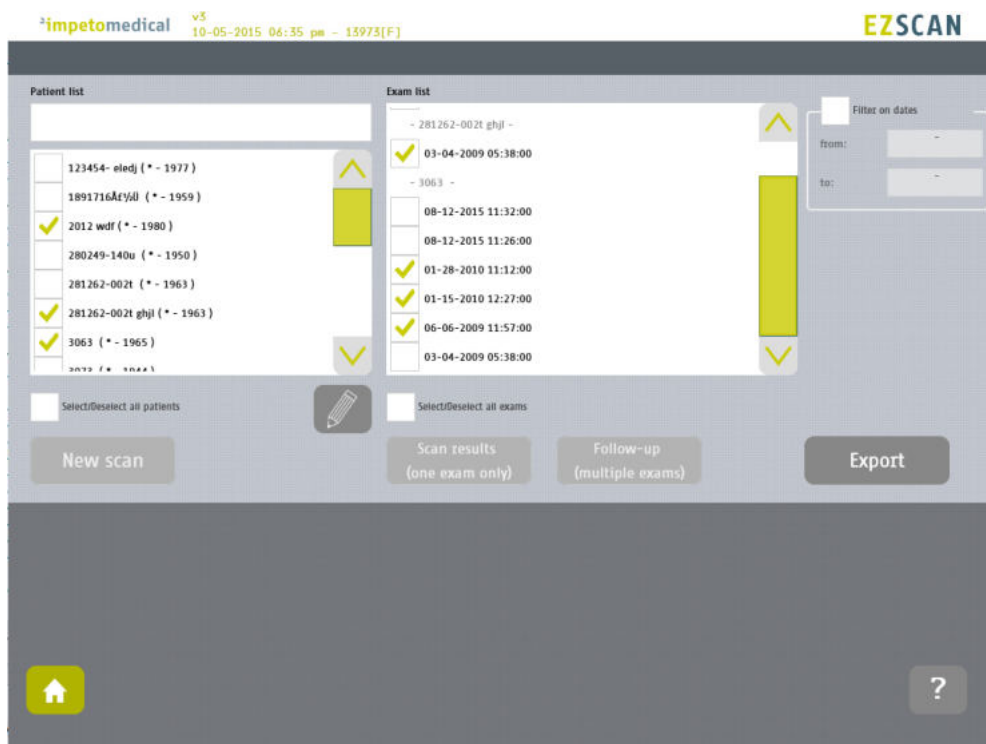


The PDF report is generated and stored within the system. To print the report physically, ensure that a printer has been selected and click on the print button.

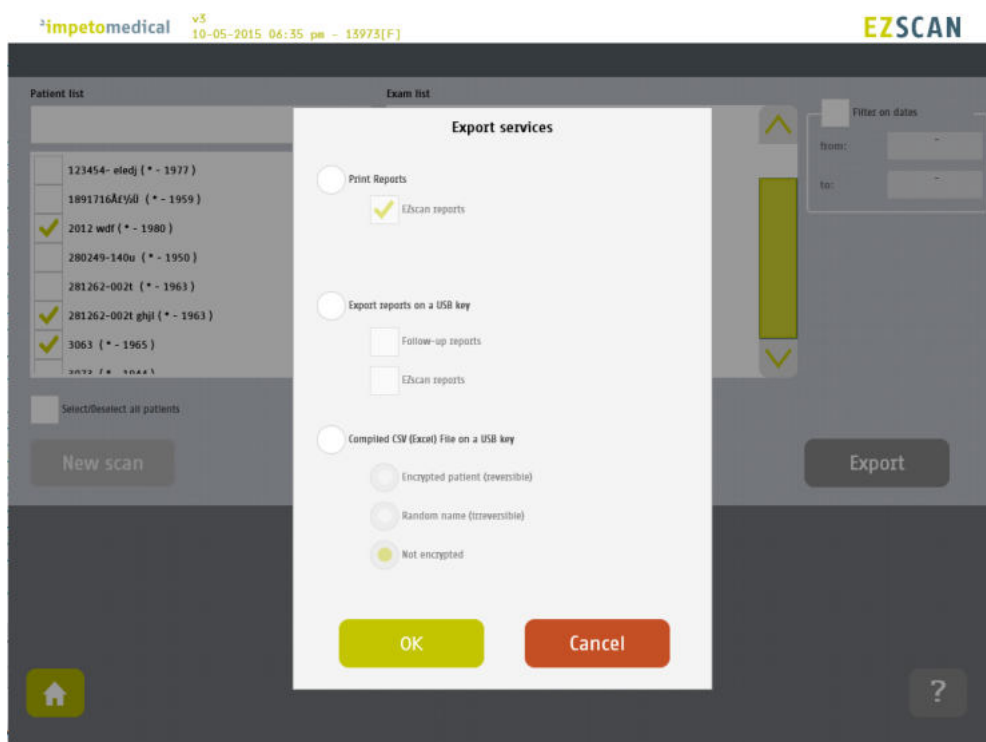
To export the report on a USB key, click on the Export button and follow the instructions on the screen.

8.6 How to export data

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



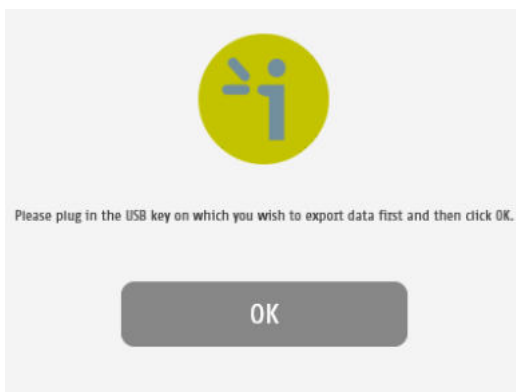
Select an option:



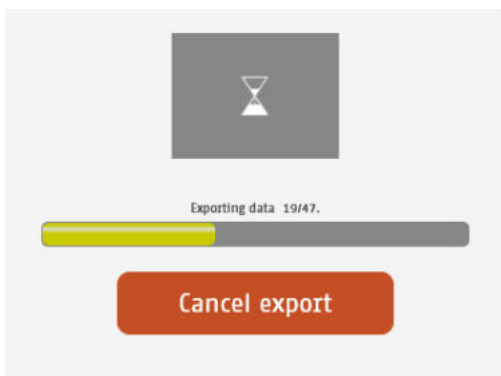
The different options are:

- Print the reports: If a printer is selected, the reports for the selected exams will be physically printed.
- Export the reports: You can export the different reports (eZscan and/or follow-up) for the selected exams on a USB key.
Stored within /ExportReports/ directory.
- Compile and export a CSV file: including relevant data for the selected exams.
Exported data are detailed within annexes (ref. p). The encryption of patients' names and first names is optional (reversible, irreversible or none).
Stored within /CompiledCSV/ directory.

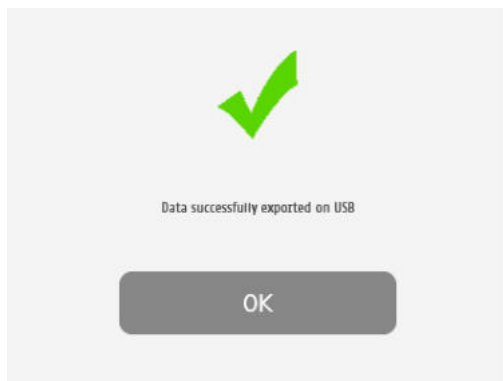
Validate and in case of export, verify that the USB key is free of viruses and correctly plugged into the system:



Validate and the files are exported:



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

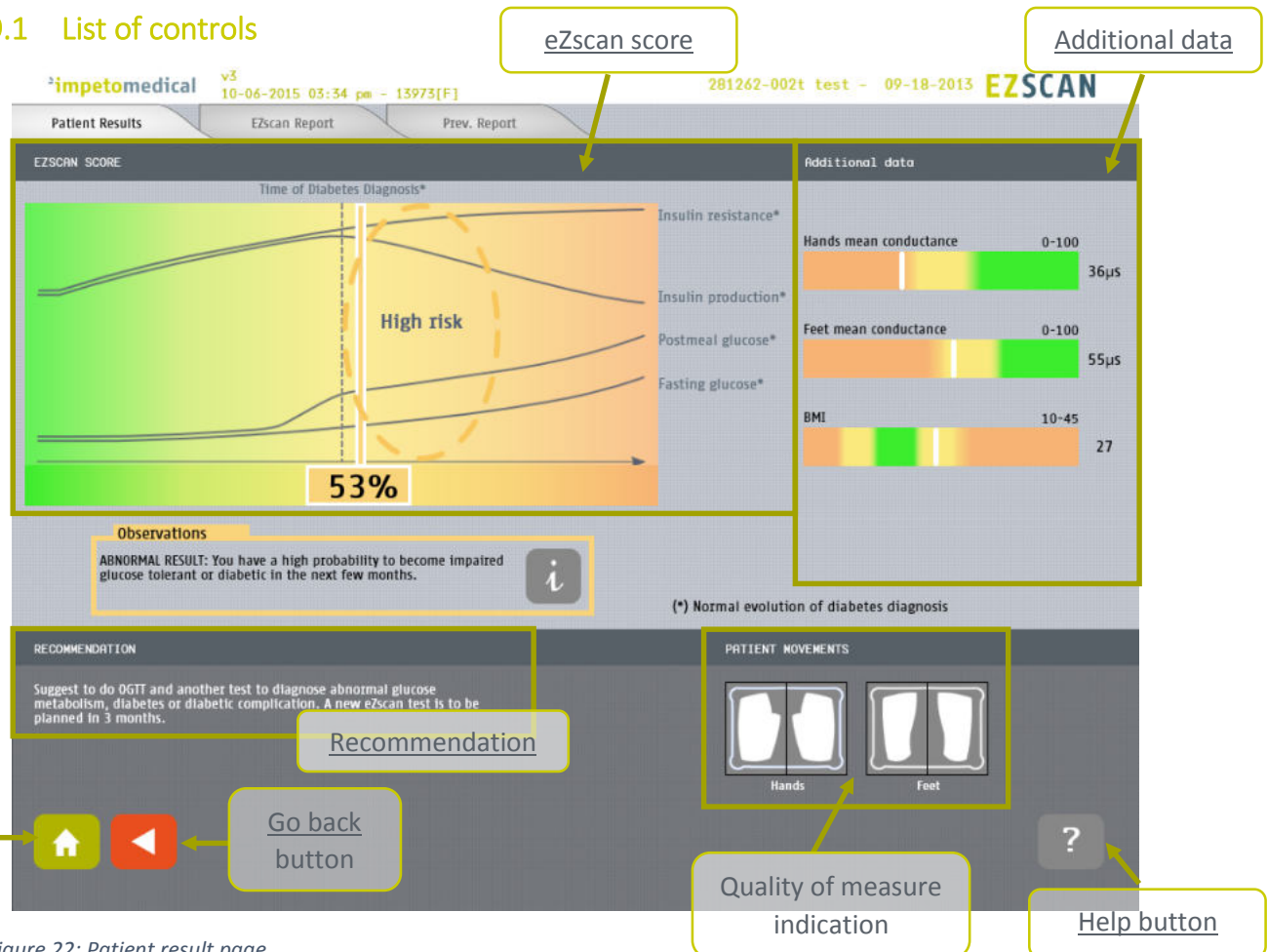



Figure 22: Patient result page

- 1 Click on the Patient Results tab to view the on-screen results.
- 2 Click on the eZscan Report tab to access the Report page (ref. p56). For more information on the results interpretation, go to p51.
- 3 When available, click on Previous Report tab to visualize the last generated report for the selected patient. This option can be enabled in Tools and Settings (ref. p19).
- 4 Click of the  button to display some explanations about the normal evolution of diabetes. For more information about these explanations, go to p51.

9.1.1 Other controls

Click on the Home button () to access the home page (ref. p8).

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

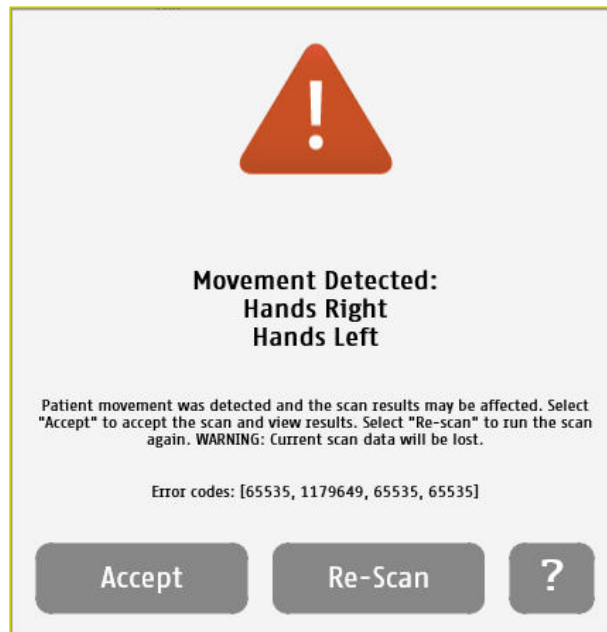
Click on the Go back () button to go back in the application.

9.2 Results

The eZscan device immediately populates results after a scan. The score is computed using demographic data and measured Galvanic Skin Response for each extremity. The results are expressed as a score (from 0 to 100), the BMI value in kg/m², and when activated (ref. p21 for supervisor settings) skin mean 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 Quality of Measure

If the patient moves during the scan, the following message appears on the screen:



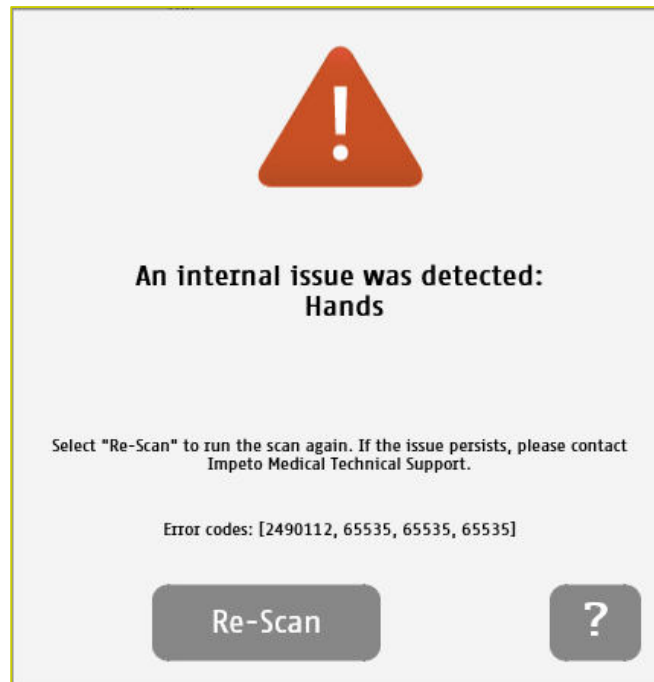
The user is given the opportunity to accept the results or re-scan the patient. Selecting **Accept** will include the current results in the patient's follow-up. The reports will be generated with a mention that the patient moved during scan and that results may be affected.

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. p80*).

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 Low risk of diabetes

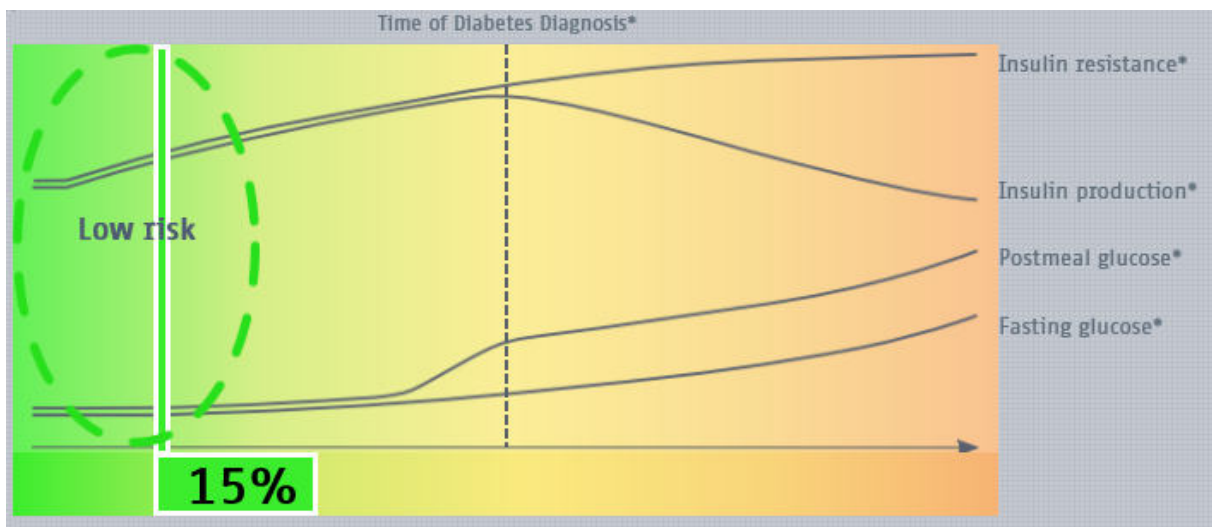


Figure 23: eZscan score with a low risk of diabetes

The results of the scan show a low risk of diabetes. The recommendations are to plan a new eZscan test in 12 months.

The observations are indicated as follows:

Observations

NORMAL RESULT: You have a high probability of not having an abnormality in your glucose metabolism and with this, not an increased diabetes risk.

By clicking of the button, additional explanations regarding the potential risk of diabetes are displayed:



Figure 24: Explanations for a low eZscan score

9.3.3 Moderate risk of diabetes

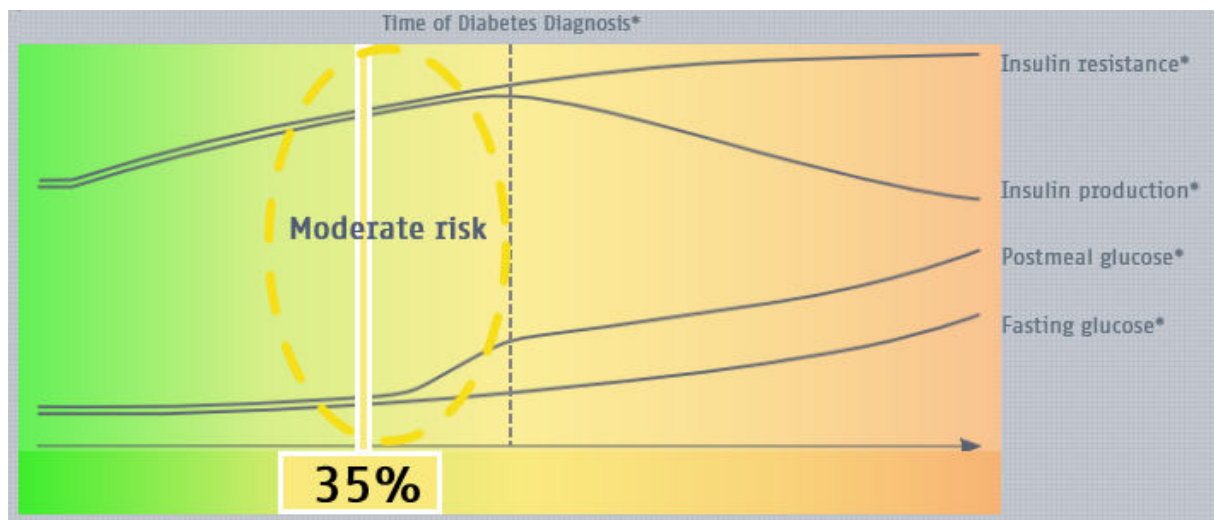


Figure 25: eZscan score with a moderate risk of diabetes

The results of the scan show a moderate risk of diabetes. The recommendations are to do OGTT to confirm if there is abnormal glucose metabolism. Plan a new eZscan test in 6 months and some life style changes can be advised by the physician.

The observations are indicated as follows:

Observations

INTERMEDIATE RESULT: You have a low probability of having an abnormality in your glucose metabolism but an increased risk in getting diabetes in the following years.

i


By clicking of the  button, additional explanations regarding the potential risk of diabetes are displayed:



Figure 26: Explanations for a moderate eZscan score

9.3.4 High risk of diabetes

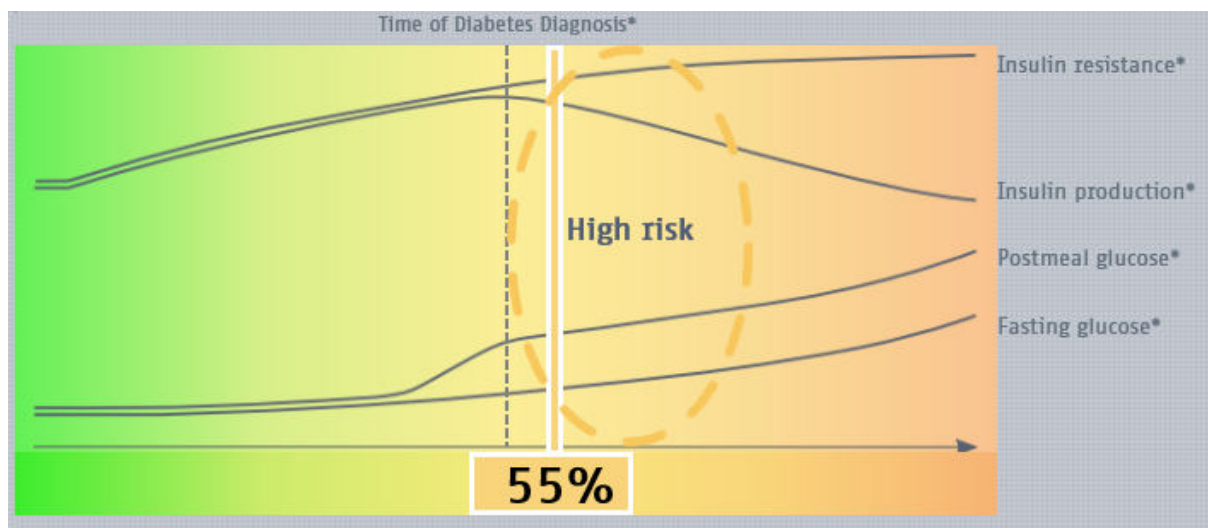


Figure 27: eZscan score with a high risk of diabetes

The results of the scan show a high risk of diabetes. The recommendations are to do OGTT and another test to diagnosis abnormal glucose metabolism, diabetes or diabetic complication. A new eZscan test is to be planned in 3 months.

The observations are indicated as follows:

Observations

ABNORMAL RESULT: You have a high probability to become impaired glucose tolerant or diabetic in the next few months.

The additional explanations are the same as the moderate risk.

9.3.5 Very high risk of diabetes

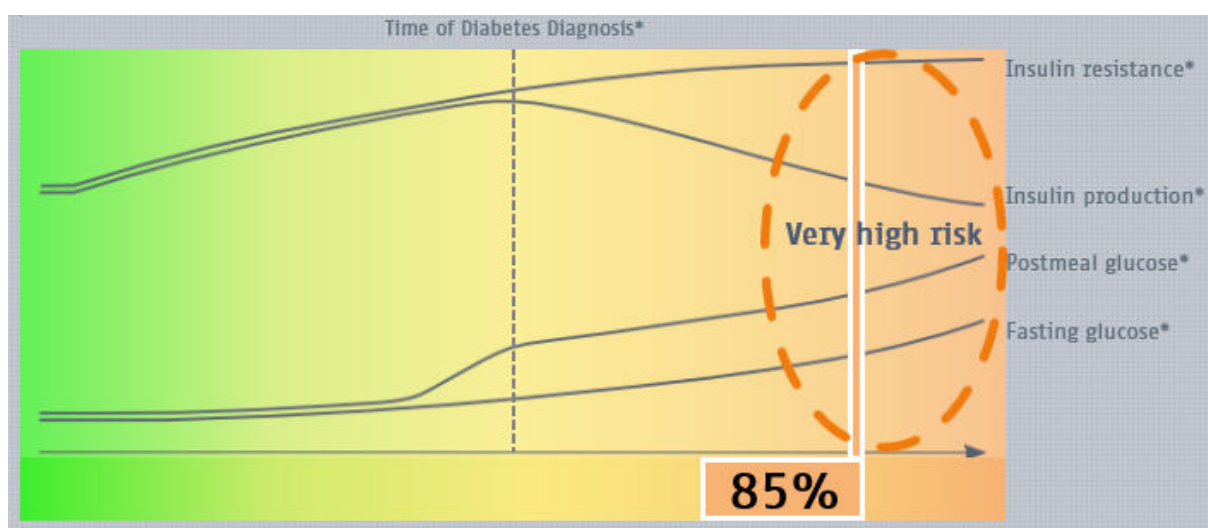



Figure 28: eZscan score with a very high risk of diabetes

The results of the scan show a very high risk of diabetes. The recommendations are to consult a physician and have a complete set of tests done with emphasis on diabetes and complication. A new eZscan test is to be planned in 1 months.

The observations are indicated as follows:



By clicking of the  button, additional explanations regarding the potential risk of diabetes are displayed:



10 Report page

10.1 EZscan report

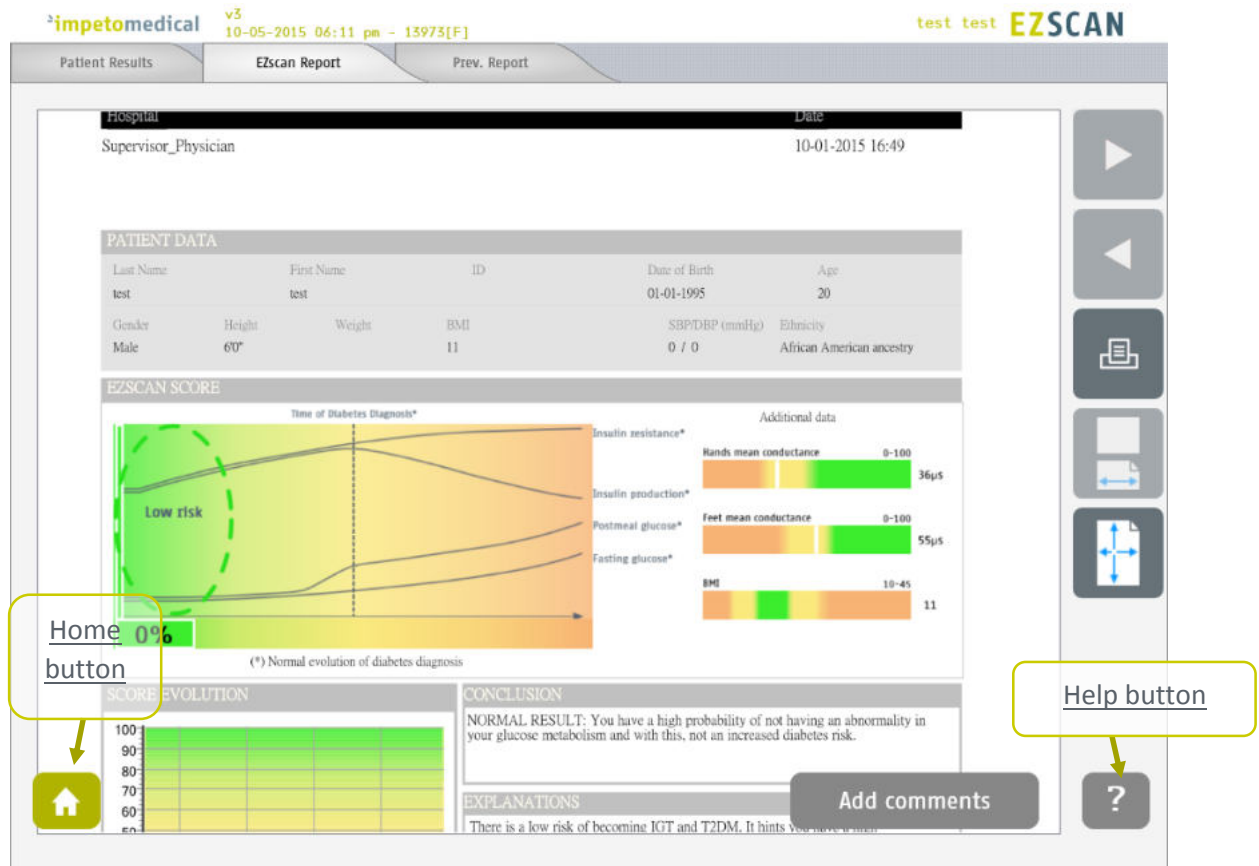


Figure 29: EZscan report page

- 1 Click on the Patient Results tab to view the results (*ref. p48*).
- 2 Navigate in the report (▶ and ◀ buttons)
- 3 Click on the Print button to physically print the report.
- 4 Click on the zoom buttons to display a full page view or page-width view
- 5 Click on Add comments button to enter new comments on the eZscan report.

10.1.1 Other controls

Click on the Home button (🏠) to access the home page (*ref. p8*).

Click on the Help button (❓) button to access the contextual help.

NOTE

When the option is enabled from additional supervisor settings (*ref. p21*), the report for the previous exam is displayed next to the new one.

10.2 Add comments on reports

While the user is visualizing the report, it is possible to add comments and select medication from a list.

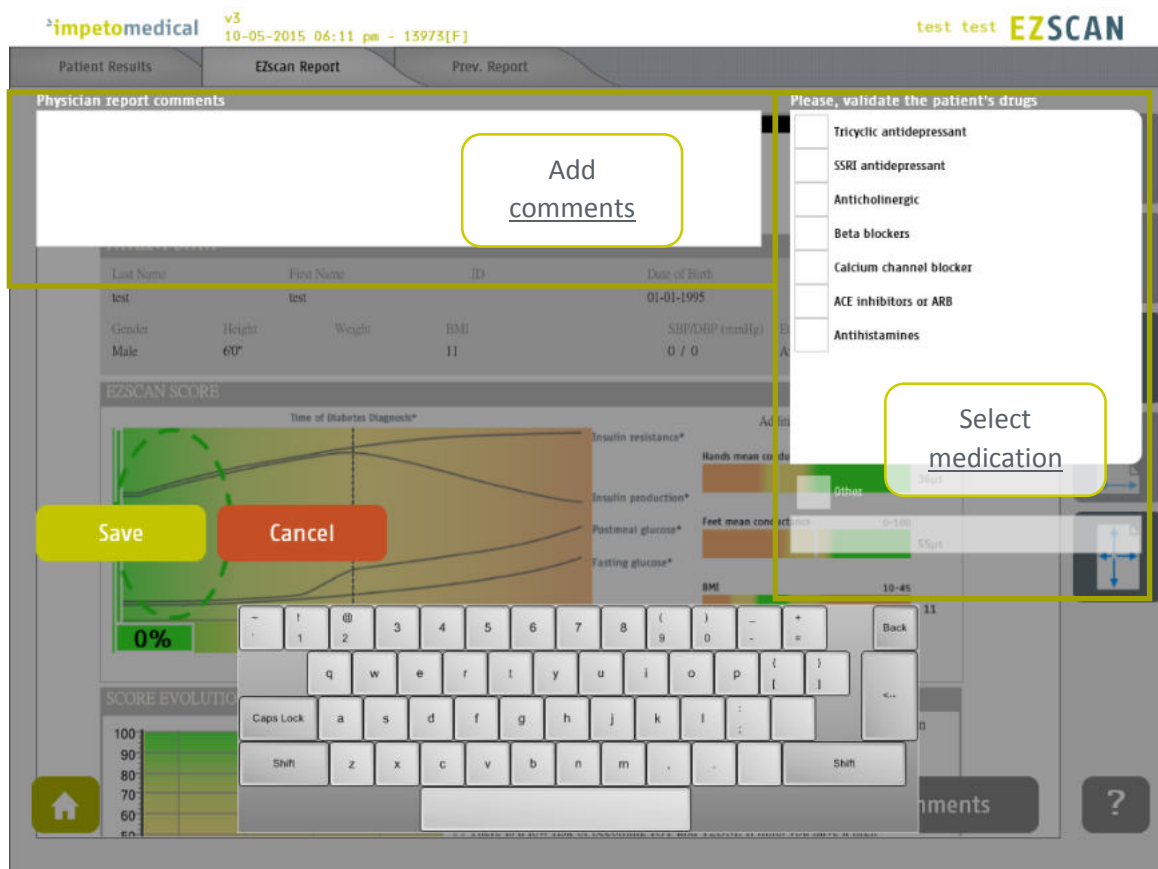


Figure 30: Add comments on reports

- 1 Add comments on the eZscan report.
- 2 Select a medication amongst the ones available in the list or add medication using the Other field.
- 3 Save the comments and generate the report(s) again or cancel the changes and go back to the report.

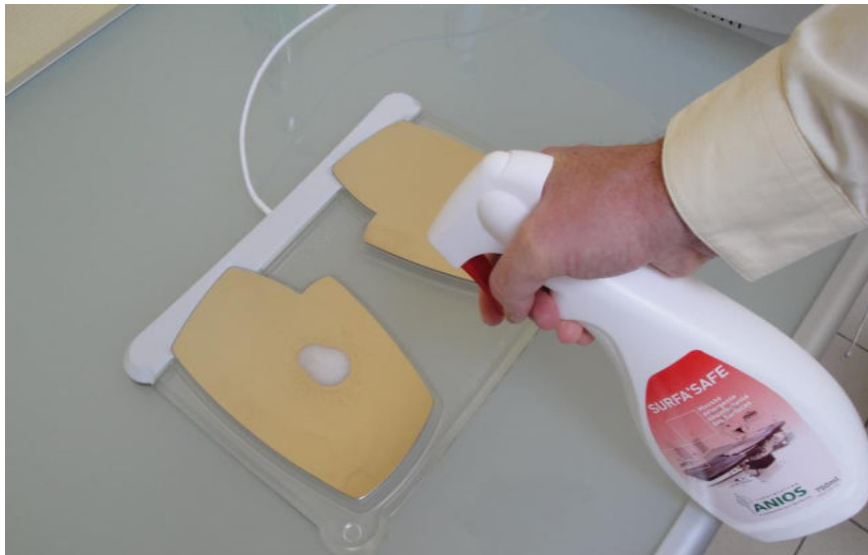
11 Cleaning the sensor plates



IMPORTANT

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

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 sensor plates until dry.**
-

Use a new sheet for each sensor plate.



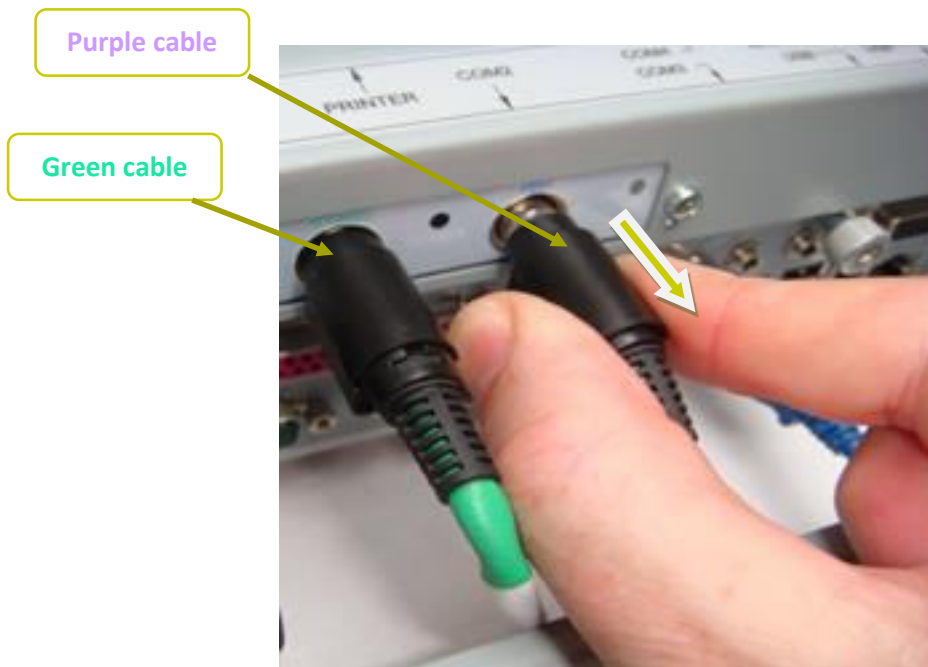
IMPORTANT

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



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. p20*).

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



IMPORTANT

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 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 Impeto Scan Devices 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 along 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. p80*).**
-

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. p80*).

16 Annexes

16.1 Data export within CSV files (Excel compatible)

16.1.1 Data in compiled CSV from a standard user account

- 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 for a normal scan)
- QoM_Accepted: When QoM is 0, QoM_Accepted is 0 if the exam was discarded, 1 for a normal scan
- Medication
- Medication_Other: Added medication
- ReportEzscanComment: Comments on eZscan reports
- Height
- Weight
- SBP: Systolic Blood Pressure
- DBP: Diastolic Blood Pressure
- HB1AC: Glycated hemoglobin
- Waist
- Nephro sc.: Nephropathy score
- eZscan sc.: eZscan score
- Hands_Asym: Hands asymmetry
- Feet_Asym: Feet asymmetry
- CAN Sc.: Cardiac Autonomic Neuropathy score

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 for a normal scan)
- 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 for a normal scan		
•	Medication	•	PGA_CBN
•	Medication_Other	•	PGA_Threshold
•	Hands_Esc_Goal	•	PGA_Coeff
•	Feet_Esc_Goal	•	PGA_CH
•	RawFile	•	PGA_CHN
•	RawFile_SHA256	•	MDC_Offset
•	CalibRawFile	•	MDC_CB
•	CalibRawFile_SHA256	•	MDC_CBN
•	ReportDoctorComment: Comments on doctor reports	•	MDC_Threshold
•	ReportPatientComment: Comments on patient reports	•	MDC_Coeff
•	ReportEzscanComment: Comments on eZscan reports	•	MDC_CH
•	Height	•	MDC_CHN
•	Weight	•	MGC_Offset
•	SBP: Systolic Blood Pressure	•	MGC_CB
•	DBP: Diastolic Blood Pressure	•	MGC_CBN
•	HB1AC: Glycated hemoglobin	•	MGC_Threshold
•	Waist	•	MGC_Coeff
•	Keywords	•	MGC_CH
•	MDA_Offset	•	MGC_CHN
•	MDA_CB	•	PDC_Offset
•	MDA_CBN	•	PDC_CB
•	MDA_Threshold	•	PDC_CBN
•	MDA_Coeff	•	PDC_Threshold
•	MDA_CH	•	PDC_Coeff
•	MDA_CHN	•	PDC_CH
•	MGA_Offset	•	PDC_CHN
•	MGA_CB	•	PGC_Offset
•	MGA_CBN	•	PGC_CB
•	MGA_Threshold	•	PGC_CBN
•	MGA_Coeff	•	PGC_Threshold
•	MGA_CH	•	PGC_Coeff
•	MGA_CHN	•	PGC_CH
•	PDA_Offset	•	PGC_CHN
•	PDA_CB	•	PGZ: Right hand conductance
•	PDA_CBN	•	MGZ: Left hand conductance
•	PDA_Threshold	•	PDZ: Right feet conductance
•	PDA_Coeff	•	PGZ: Left feet conductance
•	PDA_CH	•	pIGT: Probability of Impaired Glucose Intolerance
•	PDA_CHN	•	pIR: Probability of Insulin Resistance
•	PGA_Offset	•	pDC: Probability of Diabetes Complication
•	PGA_CB	•	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 a 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
p61	Troubleshoot the system
	User Log in / Log off
p7	Home page
p9	Log in page
	Test the system hardware (via Quality Check):
p8	Home page
p13	Quality check page
	Quick start a scan by entering demographical patient data:
p8	Home page
p34	Scan pages
p35	Patient setup & start a scan
p58	Clean the sensor plates
	Export reports to USB key:
p8	Home page
p39	Patient History page
p45	How to export data
p59	Replace the sensor plates
	Configure the hospital information:
p8	Home page
p18	Standard user – List of controls
	Select the printer driver:
p8	Home page
p18	Standard user – List of controls
	Retrieve previous patient data:
p8	Home page
p39	Patient History page
	Change password:
p8	Home page
p9	Log in page
p11	Password modification

17.2 For a supervisor user only

Access to the desktop:	
p8	Home page
p20	Standard user – List of controls
Install an USB printer:	
p8	Home page
p20	Supervisor users – Additional list of controls
p60	USB printer drivers installation
Upgrade the application software	
p8	Home page
p20	Supervisor users – Additional list of controls
p61	Install software updates
Select the user for configuration purposes	
p8	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
Select the language for display:	
p8	Home page
p20	Supervisor users – Additional list of controls
Metric selection	
p8	Home page
p21	Supervisor users – Configuration (2) tab
Date format selection	
p8	Home page
p21	Supervisor users – Configuration (2) tab
Printing configuration	
p8	Home page
p21	Supervisor users – Configuration (2) tab
Access to import/export services	
p8	Home page
p26	Import data for a selected physician
p29	Export data on a USB key for a selected physician
Set/reset the password of any user	
p8	Home page
p20	Supervisor users – Additional list of controls
p21	Supervisor users – Configuration (2) tab

18 Precaution of use and technical specifications

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

Precautions of use and maintenance

Transport

The system SUDOSCAN is delivered under the conditions of packing described previously.

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



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:



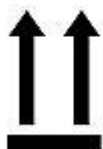
Handle with care



Fragile



Keep dry



Keep upright



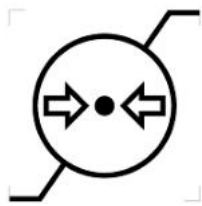
Recyclable



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 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 or implantable cardioverter defibrillator.

• 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

- **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. 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.
RF emissions CISPR 11	Class B	
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 transient/burst fast IEC 61000-4-4	±12 kV for power supply lines ±11 kV for input/output lines	±12 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) ±12 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 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) 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 UT 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	3 Vrms 150 kHz to 80 MHz	3 V rms	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 $d = 1.17 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1.17 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.33 \sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (1) should be less than the compliance level in each frequency range. (2) Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

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

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

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

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

Contacts



Impeto Medical

17, rue Campagne Première
75014 PARIS – FRANCE

Tel: +33 (0)1 4320 1640

Fax: +33 (0)1 4335 1833

Mail: info@impeto-medical.com

<http://www.impeto-medical.com/fr/>

Impeto Medical, Inc.

8910 University Center Lane, Suite 615
SAN DIEGO, CA 92122 - USA

Tel: (858) 450.2800

Fax: (858) 450.2804

<http://www.sudoscan.com/>



Cleared in 2006



Cleared in 2010