EZSCAN

User guide

Instruction for use

Version 2.42C

30 July 2013

To download the latest version of the software and the manual please go to
www.impeto-medical.com/distributor-resources

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Introduction

Use

EZSCAN is a chronoamperometric digital analyzer used for the **early detection of cardiometabolic risk**.

Principle

EZSCAN 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

EZSCAN is an electro-medical device that consists of:

- **A control panel and display**
- **A pair of foot electrodes**
- **A pair of hand electrodes**
- **A pair of head electrode***
- **A power cable**

EZSCAN is powered by Windows XP.

Installation

Carefully follow instructions in this 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.

* Optional

1. Unpacking

NOTE

Please make sure that the packaging has not altered during the transportation.

Contact the distributor if the transportation box has been damaged.

EZSCAN is shipped in a single transportation box with an Impeto Medical logo on the outside. Inside there are 3 smaller boxes:

1. A medium white box containing the reusable feet and hand electrodes,

2. A small white box containing the installation manual (and test certificates), the head electrodes cable†, the power cable and the electrodes locking support with assembly screws (2 + 1 spare screw).

3. A big white box containing the EZSCAN Master Unit, one bottle of ANIOS Surfa'Safe spray cleaner and the head gear electrodes‡.

WARNING

No modification of this equipment is allowed.

† Optional
‡ Optional

1.1. Unpack the master unit

1. Remove the cleaning spray and the head gear[§] from the big white box.

   Remove the Master Unit along with its 2 molded protection foams from the big white box.

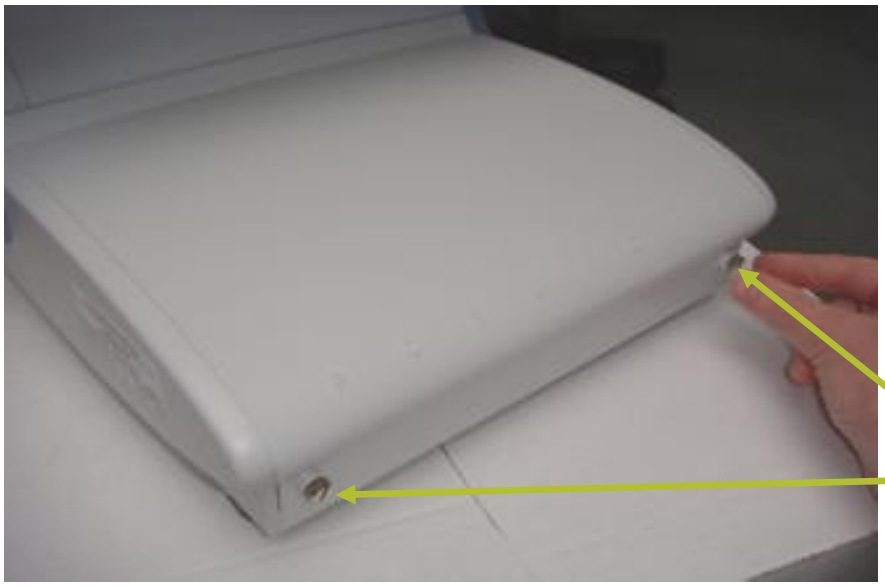
2. Put the Master Unit on one side to remove the first protection easily and safely the first protection foam.

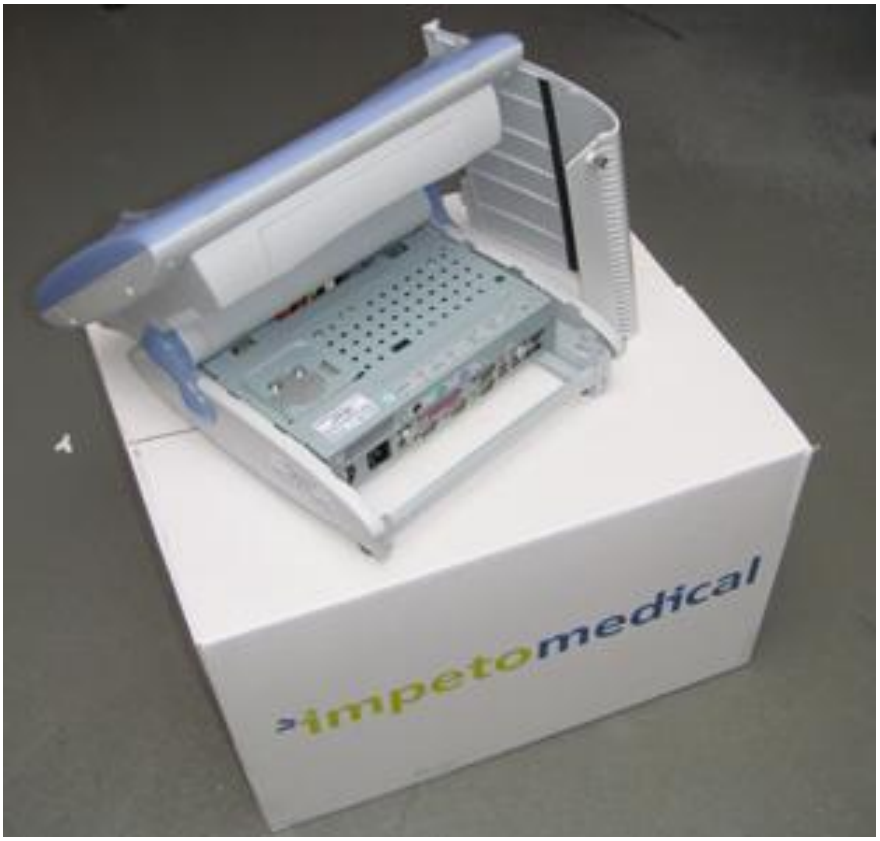
3. Put the Master Unit on its other side and remove the second protection foam, as well as the plastic bag.

[§] Optional

4 Keep the protection foams and plastic bag in the outer box, for future transportation needs.

5 Loosen the 2 retaining screws and remove the rear cover.


Retaining
screws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1.2. Unpack the electrodes

1 Remove the electrodes from the medium white box and separate them from their protective foams.

2 Remove the installation manual, the head electrodes cable**, the power cable and the electrode locking support from small box.

3 Remove all 3 cables and connectors from their plastic protection bags.

The hands electrodes are smaller than the feet electrodes.

** Optional


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2. Installation

1 Place the Master Unit on a desk or preferably a high table (h > 90 cm/3ft) with the screen facing the user.

NOTE

Please consult your distributor for the availability of an optional EZSCAN companion rolling stand which can also conveniently host a printer.

The electrodes must be placed on a plane surface to avoid all risks of falling.

Connecting the electrodes

2 Place the hands electrodes in front of the Master Unit, guide the cable under the metallic bar at the rear, and insert the MiniDin connector at the end of the Hands cable to the 'HANDS' connector (Green) at the back of the Master Unit :

3 Make sure to match the color of both socket and plug.

4 Push until a ‘click’ sound indicates the locking of the connector.

5 Double-check the locking by grabbing the cable itself gently backwards.

6 Place the Feet electrode on the floor in front of the Master Unit and connect its cable to the 'FEET' connector (Purple) at the back of the Master Unit, using the procedure above.

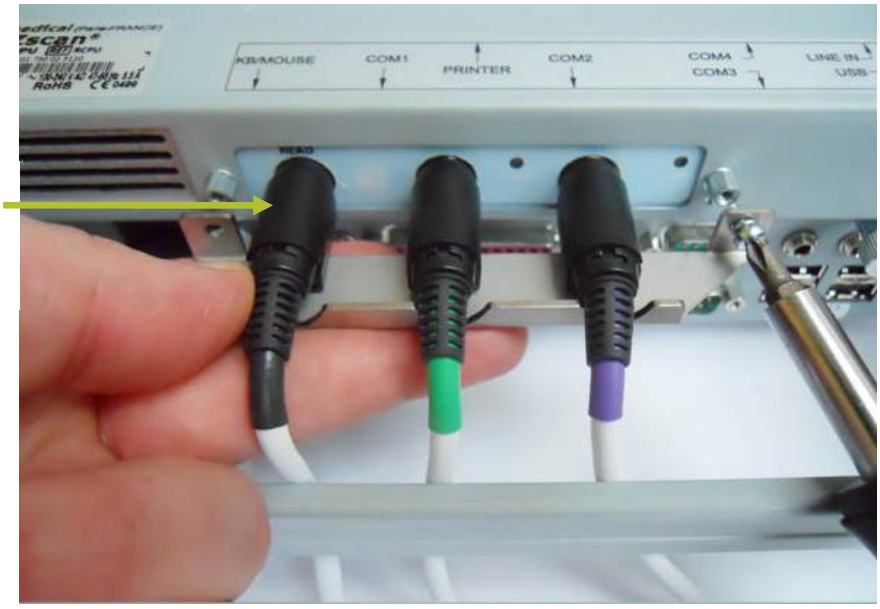
7 Connect as well the Head electrodes cable[††] to the 'HEAD' connector at the back of the Master Unit using the same procedure –if needed.

WARNING

Please cross check and verify that all electrode cables are connected to their respective receptacle (Head to HEAD, Hands to HANDS and Feet to FEET) and there is no inadvertent swapping. Make sure cable colors are matching socket colors.

8

Electrodes locking bracket



[††] Optional

Maintain the connectors in place by locking the bracket with 2 screws provided in the bracket plastic bag.

9

Power Cable

Insert the power cable into the PC standard 3-plug power socket (IEC-C14 inlet) at the back of the Master Unit.

10

Connect the power cable to the mains power socket on the wall. Double check the power socket can provide proper grounding.

NOTE

The supplied power cable is intended for EU countries.

For countries outside EU, please make sure using a national PC-type power cable with grounding connector. Make sure also correct grounding is provided at the wall socket.

WARNING

The electrical installation must comply with electrical standards of the country of use.

To avoid risk of electric shock, the equipment must only be connected to a mains supply with protective earth.

The wall socket must be easily accessible.

The device must not be used with the rear cover open.

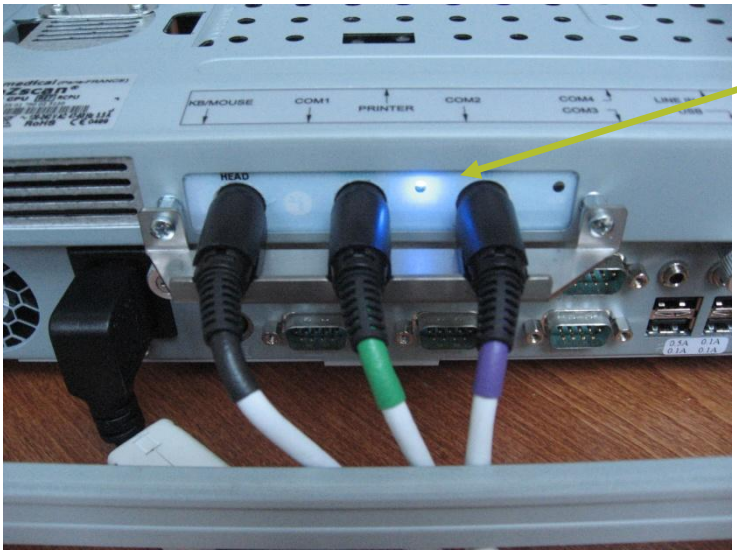
3. Quick test and configuration

3.1. Powering on EZSCAN

1 Open the door located below the screen at the front of the Master Unit.
Inside on the right there are 2 USB ports and 1 on/off button.

2 Press and release the on/off button to power up the Unit.
The Master Unit will run a self-check and then automatically display the EZSCAN home page.
Please, wait approximately 2 minutes for complete power on sequence.

3.2. Initial checking



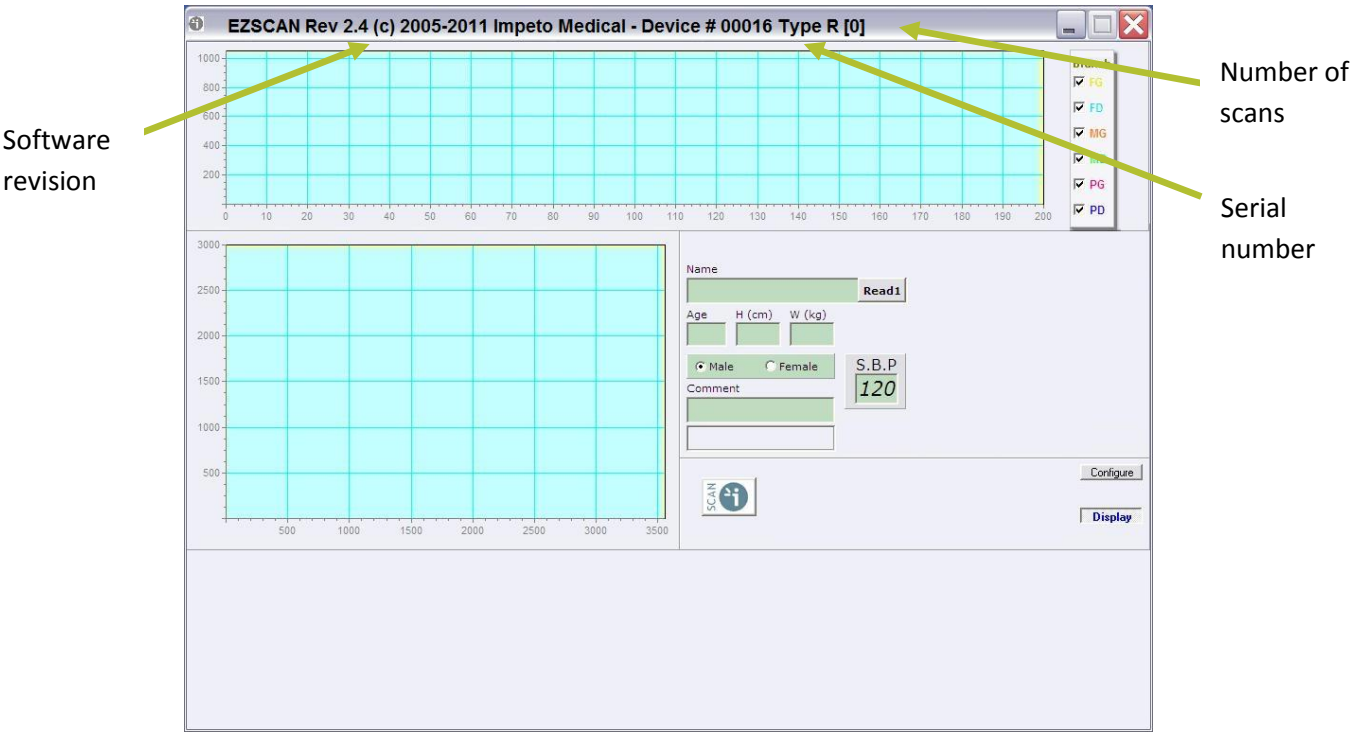
After initialization, the blue LED at the rear of the Master Unit should flash intermittently. The top row on the screen should display:

EZSCAN - rev. X.XXx ©2005-20XX Impeto Medical - device #YYYYY type Z [0]

Where:

- X.XXx indicates the software revision number,
- YYYYY indicates the serial number within the product model type Z.

The number in brackets indicates the number of scans.



IF: 1/ the blue LED is NOT ON

OR: 2/ the following message appear at the top of the screen:

“EZSCAN - rev. X.XXx ©2005-20XX Impeto Medical – not connected”,

Then, there is a problem with your EZSCAN Master Unit: please call Impeto Medical or your distributor for assistance.

Once this quick check procedure is successfully completed, replace the rear cover at the back of the Master Unit. Secure the cover in place using the 2 retaining screws.

WARNING

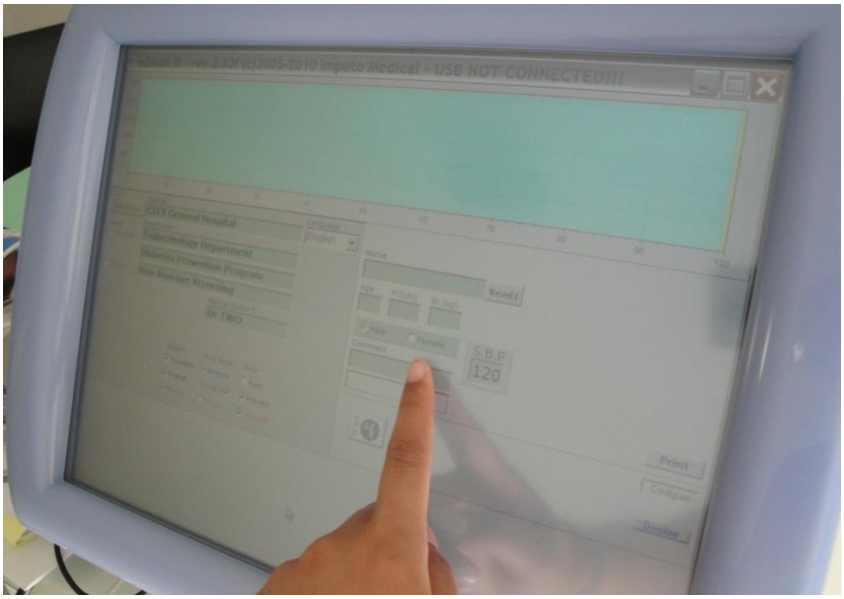
The patient must not touch the master unit.

REMOVING THE POWER CORD FROM MASTER UNIT OR FROM WALL SOCKET BEFORE COMPLETE UNIT SHUT OFF, MAY IRREMEDIABLY CORRUPT DATA ON THE UNIT'S HARD DISK.

3.3. Selection on the EZSCAN tactile screen

EZSCAN has a tactile screen. Simply touch the screen with your finger at the desired screen location to make a selection.

You can also use a mouse by plugging one into one of the USB port.



NOTE

Please refer to chapter 13.3 in case you feel the touch screen needs to be calibrated for better pointing accuracy.

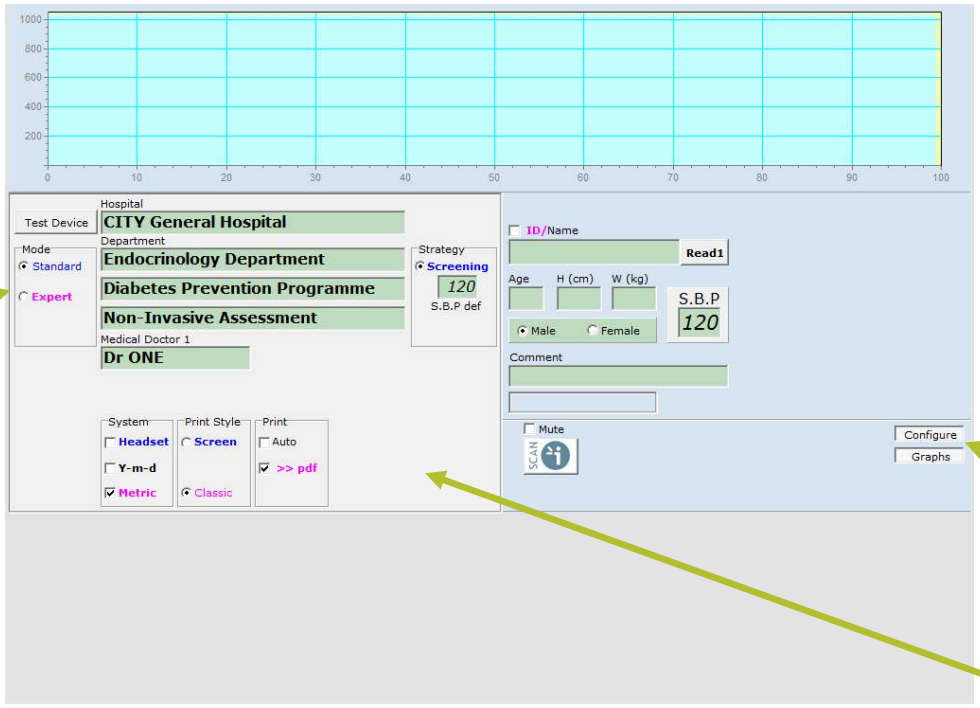
3.4. Mode selection

Two modes are available on EZSCAN:

The standard mode is the preferred mode to easily scan a new patient. It is a simple mode showing only the information needed to screen new patients.

The expert mode is the preferred mode to compare with scans previously done and select additional options.

Check the 'Mode' button according to your choice.



NOTE

Pressing the “Configure” button on the right will close/open the Configuration window.

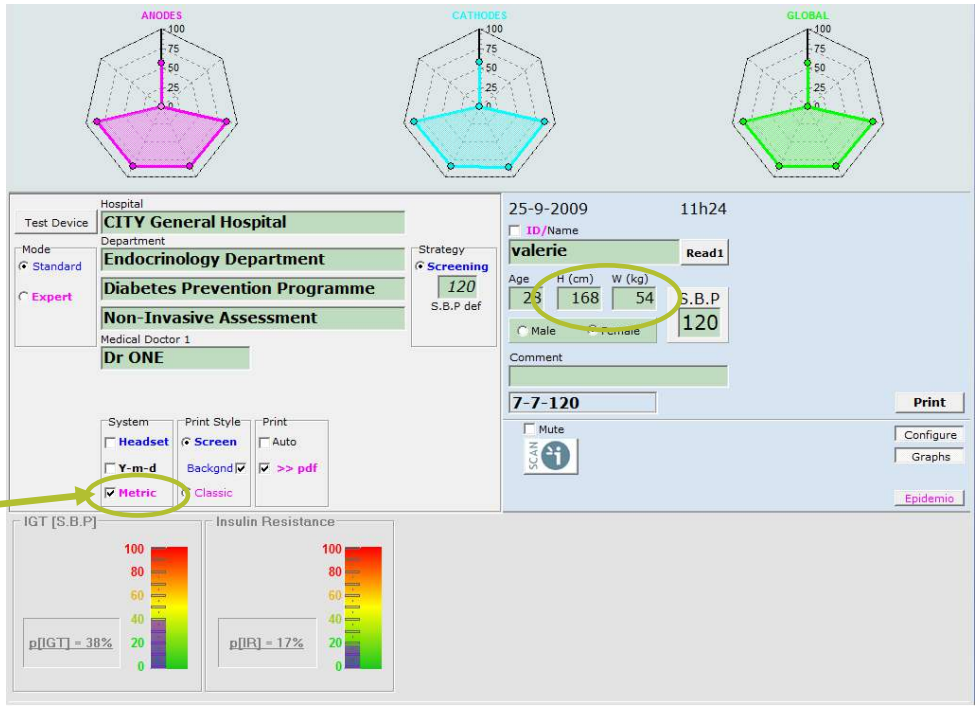
3.5. Metric selection

Two measurement systems are available for defining patients height and weight:

- Meter (cm) and Kilogram (kg),

OR

- Feet/inch (feet/in) and Pound (lb)



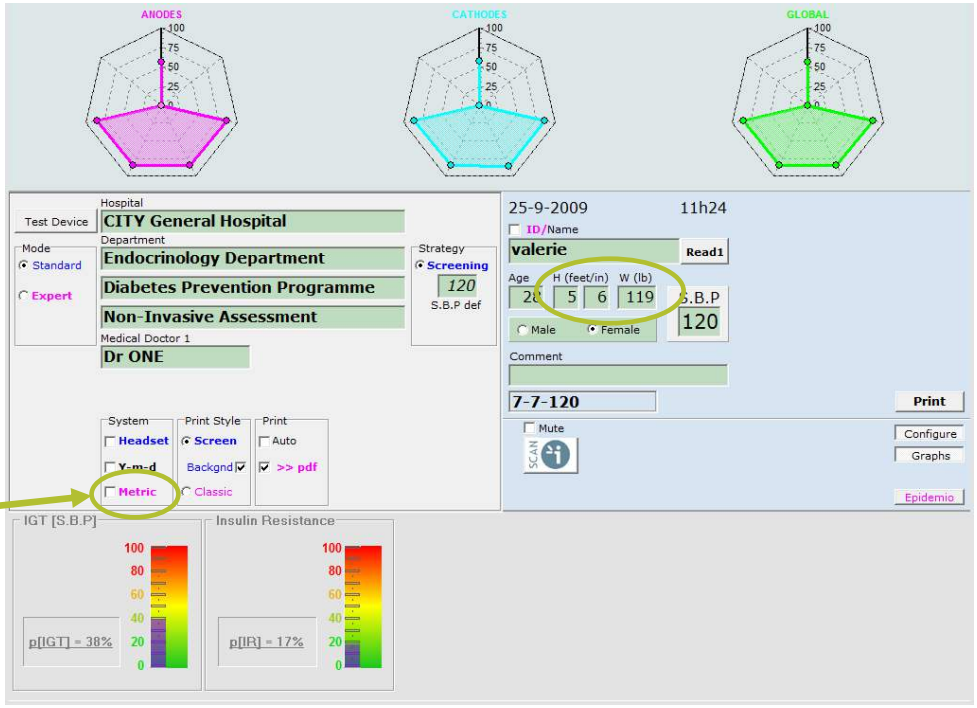
Metric checkbox

Check the Metric box if you wish to use cm and kg.

Uncheck the Metric box if you wish to use Feet and Pound.

The values will be instantly modified.

Metric checkbox



3.6. Date format selection

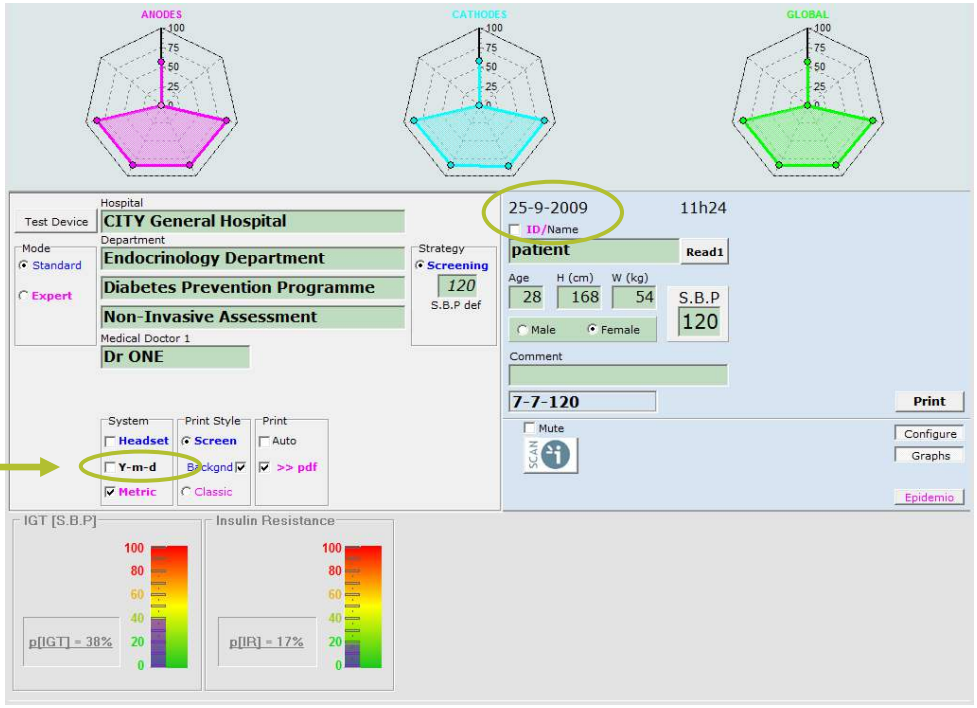
Two date formats are available:

- Day Month Year (D-m-Y)

OR

- Year Month Day (Y-m-d)

Date format checkbox

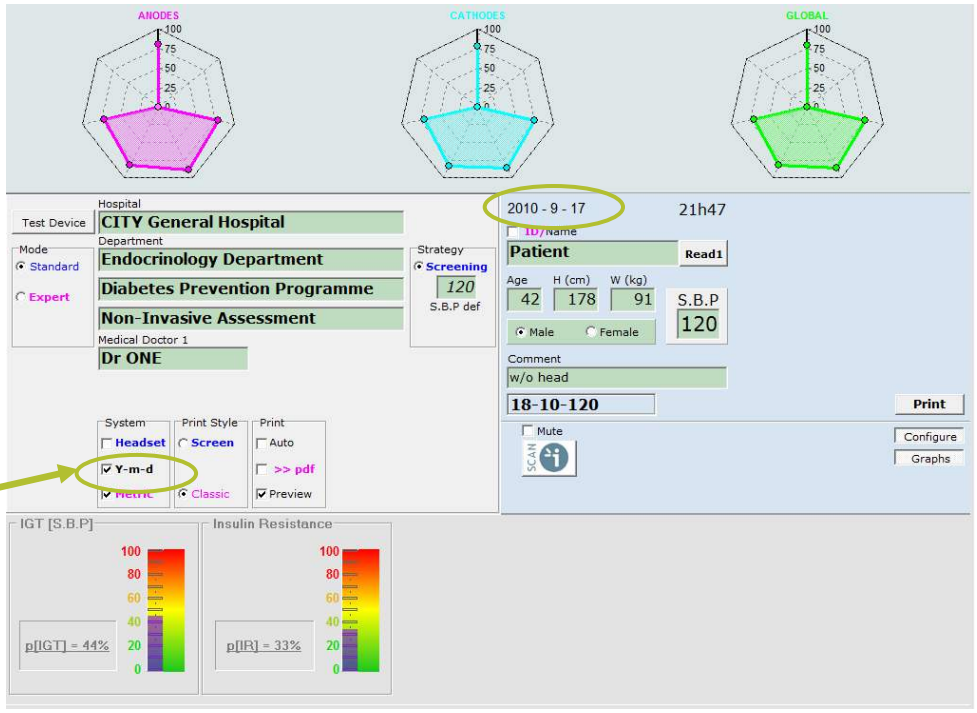


Check the date format checkbox if you wish to use Y-m-d format.

Uncheck the date format checkbox if you wish to use D-m-Y format.

This option will be taken into account for the next scan.

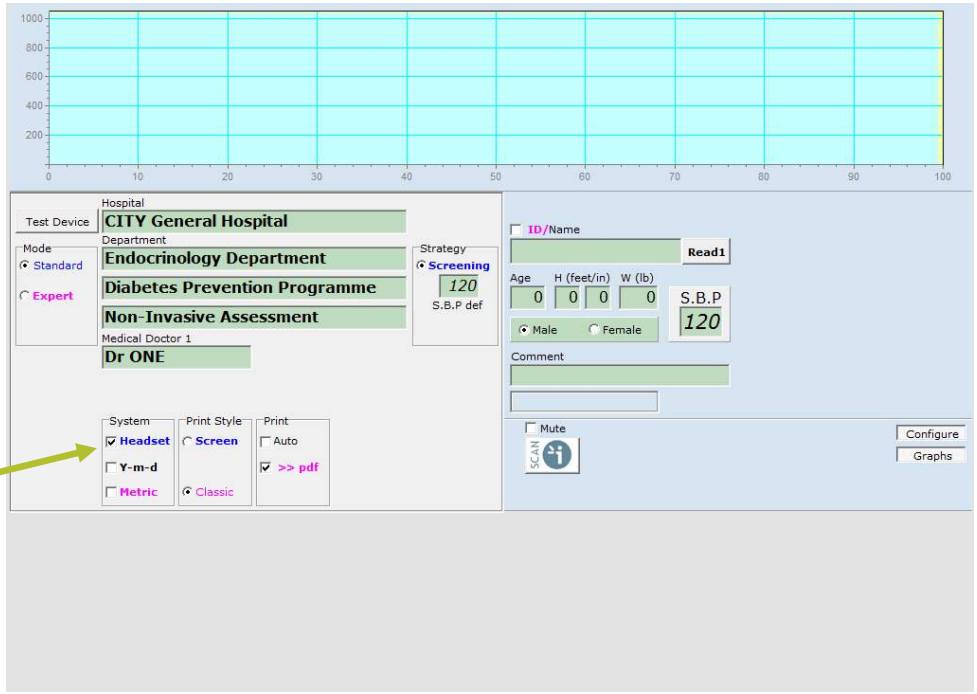
Date format checkbox



3.7. Headset selection

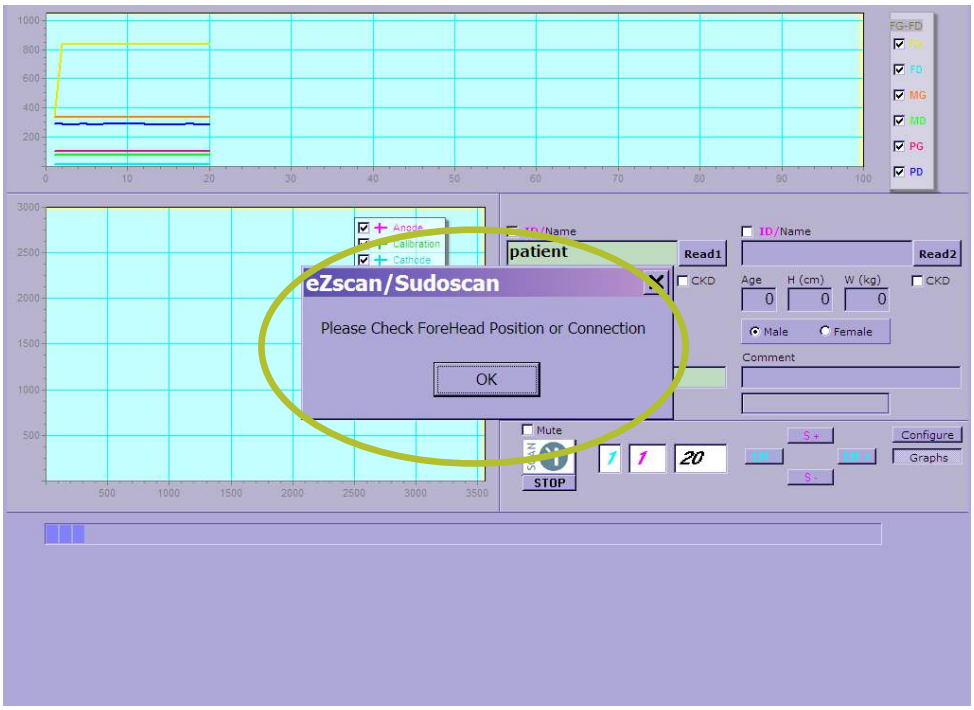
In order to increase the patient throughput on EZSCAN device, and the speed of screening large populations, it is possible to remove the Headset electrodes[‡‡], which will reduce drastically the patient installation time as well as the scanning time.

Uncheck the 'Headset' checkbox if you wish to use EZSCAN without the head electrodes[§§].



Headset checkbox

‡‡ Optional
§§ Optional



NOTE

If you checked the 'Headset' checkbox without plugging the headset electrodes an error message will appear during the calibration phase.

4. Standard Mode

The standard mode is used to easily scan a new patient.

4.1. Quick run

Before starting a scan, you will need to install the patient standing barefoot on the Feet electrodes and input a few patient details (name, age, height, weight, gender) using the touch screen display and the virtual keyboard appearing on the screen.

Inform the patient that this test is non-invasive and will take less than 3 minutes to perform.

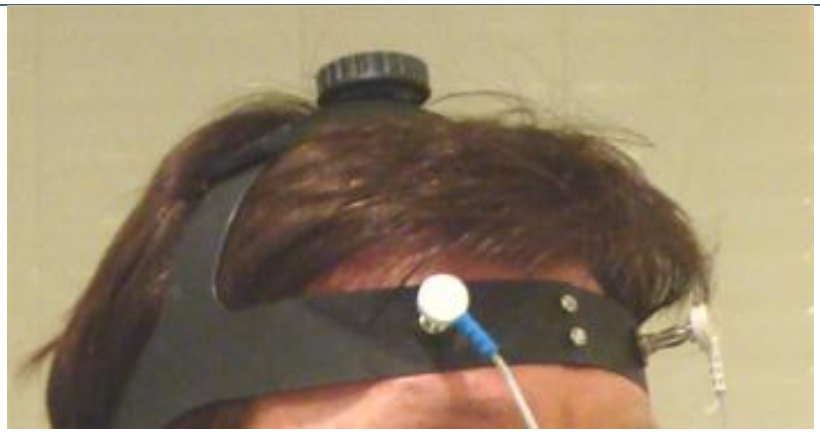
NOTE

For conventional data input, it is also possible to use any standard PC-type keyboard connected to one of the 6 USB connectors available on Master Unit's front or rear panels.

4.1.1. Patient set-up

1	Ask the patient to remove their shoes and socks.
2	Patient must stand with bare feet right in the middle of the Feet electrodes.
3	If needed, put in place the head gear*** with reusable electrodes and adjust its size to the patient head…
4	… and connect the blue side of the cable to the electrode placed to the right side of the patient's head and the white side on the left. *Make sure there is no hair between the skin and the electrodes.*

*** optional



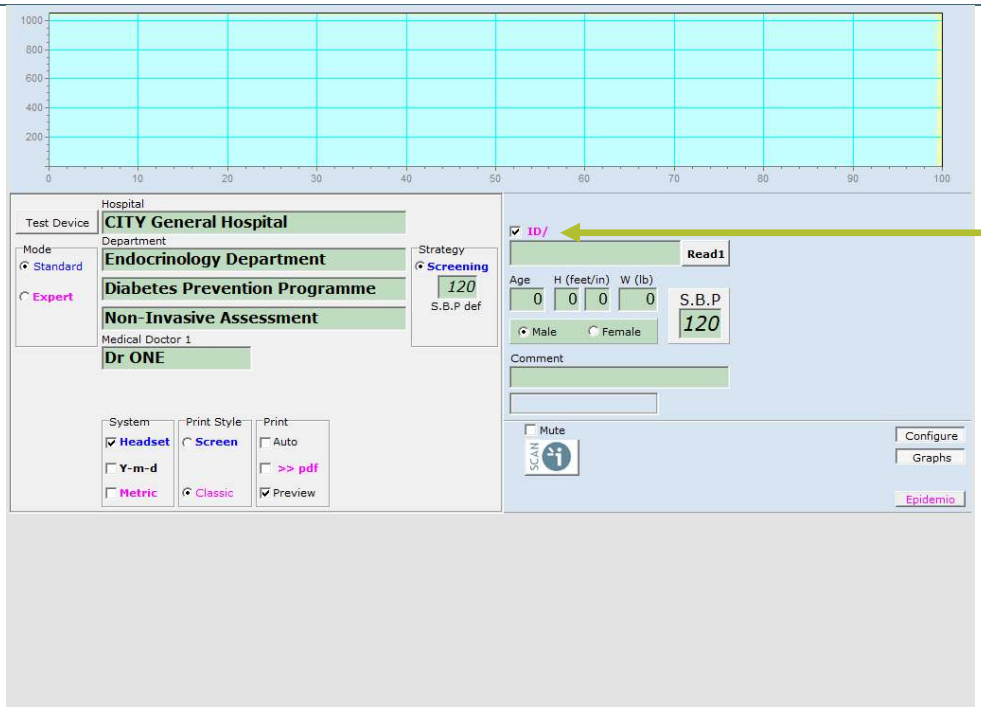
5

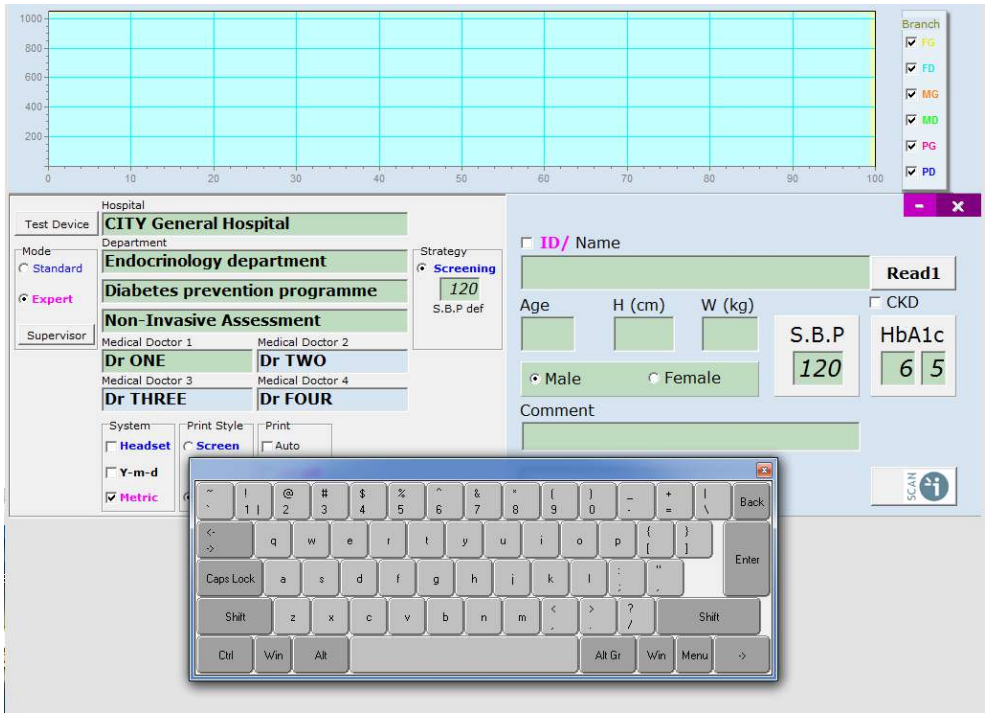
Double click on the Name green zone.
The patient data zone zooms to facilitate data entry.

Enter each data field by firmly double-clicking on the corresponding green zones, which will make the appropriate virtual keyboard appear.
The TAB key on the keyboard can also be used to jump from one field to the next.

- *NAME or Patient ID (IDENTITY CODE).* To automatically generate a unique ID, click on the ID check box.
- *AGE or Date of birth (see 5.3.2) (10 to 109 years)*
- *HEIGHT (100 to 249 cm)*
- *WEIGHT (10 to 199 kg) (see 3.5 for non-metric values)*
- *Select the appropriate GENDER*
- *Enter comments in the "comment" field if necessary.*

There is NO NEED to press the ENTER key after each field entry : just touch the screen on the NEXT desired field location.





NOTE

1) The Minimize button will zoom out the patient data window
2) The Shutdown button will zoom out the patient window and erase the data when double-click again on the Name green zone.

NOTE

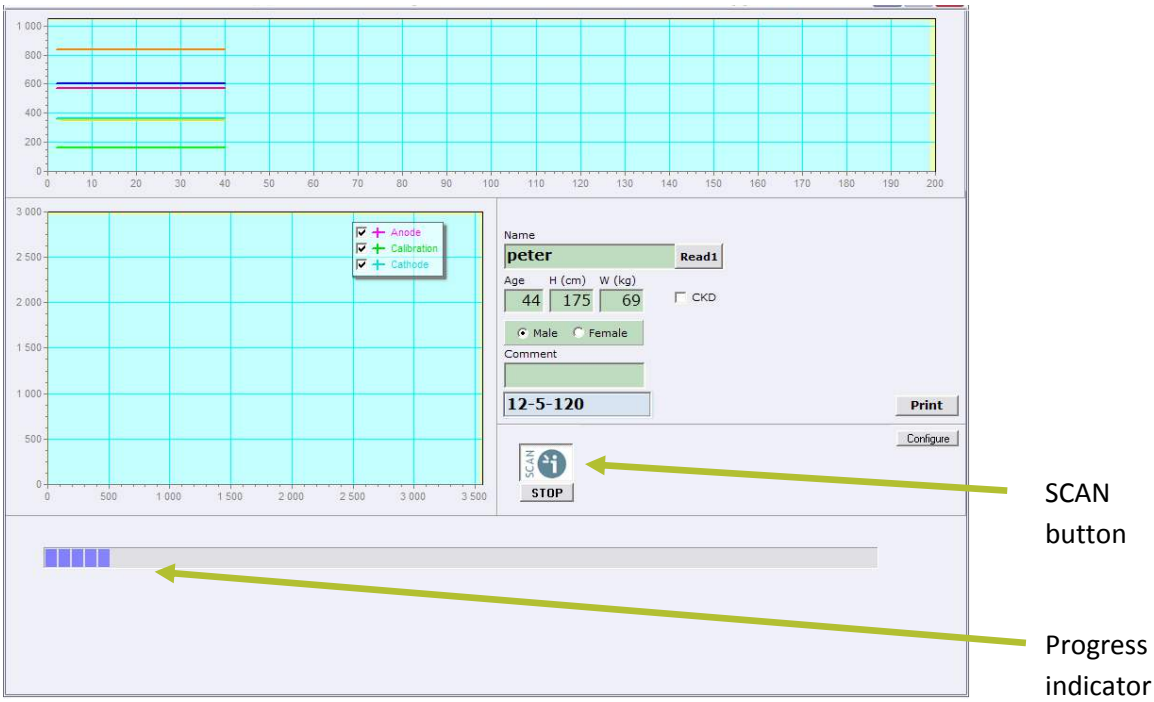
Double-check the data with your patient. Invalid (out of acceptable range) or missing data will be notified with a RED background and should prompt you to enter a new valid data.

6 Ask the patient to put his hands flat in the middle of the Hands electrodes.
Hands must be applied firmly with a constant pressure throughout all scan duration.

WARNING

The patient must not touch the master unit.

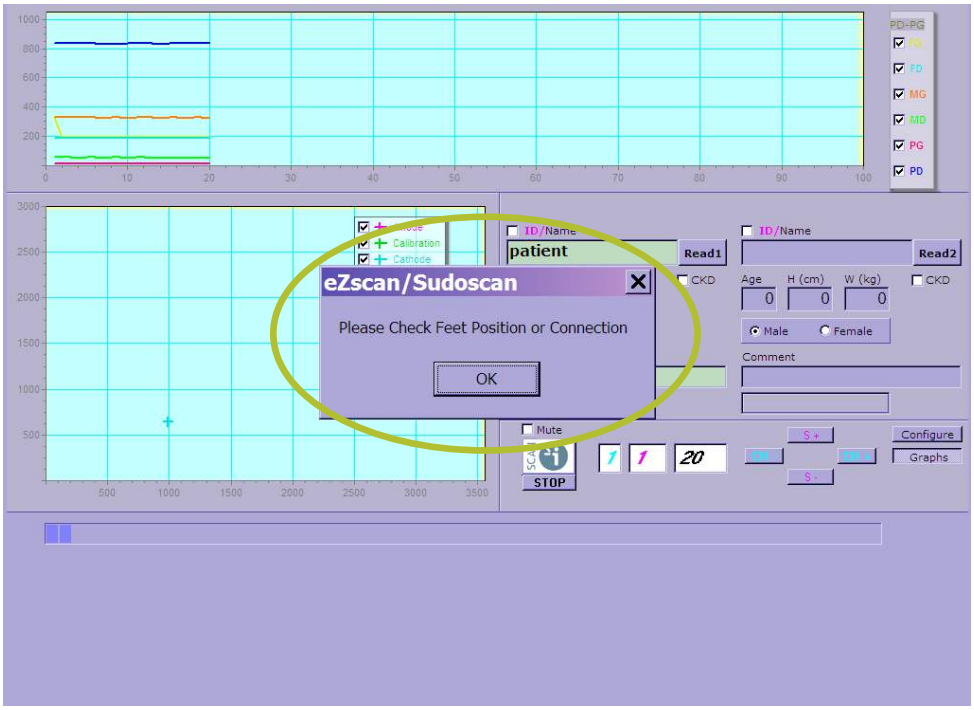
4.1.2. Start the measurement



Press the “SCAN” button to start the scanning procedure.

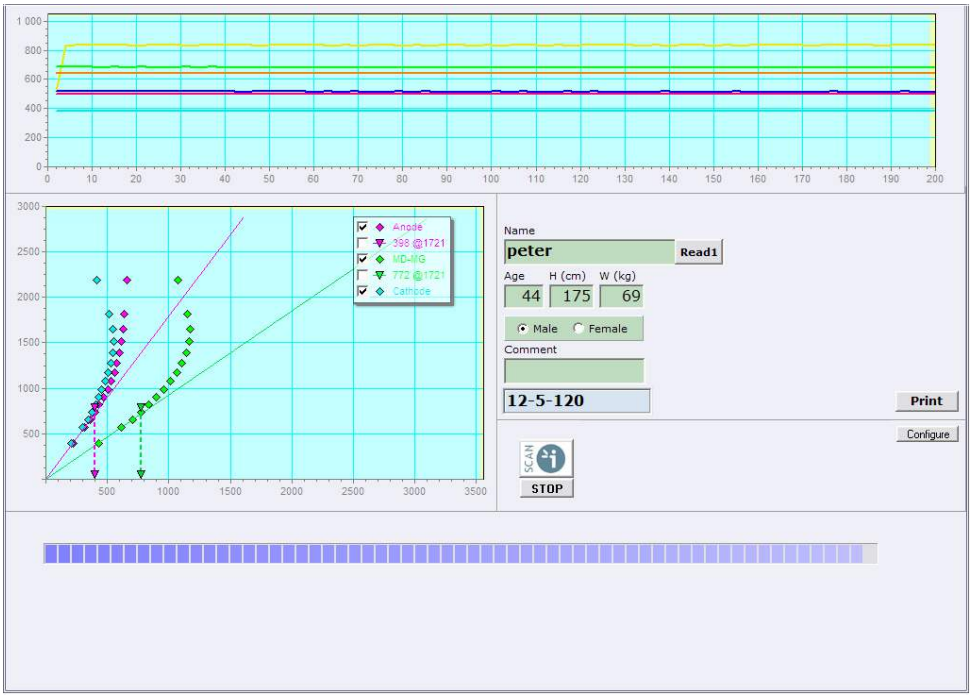
The test starts by a phase of automatic calibration.
During scanning, the patient is required not to move any parts of the hands or feet in contact with electrode surfaces.

The **patient should keep still** until the progress indicator shows the scan is completed.



NOTE

If any hand or foot contact is missing during the calibration, an error message will appear on the screen.



Scan progress can be monitored from the indicator at the bottom of the display.

Scan completion is confirmed by a double-bell sound.

4.1.3. Save patient data

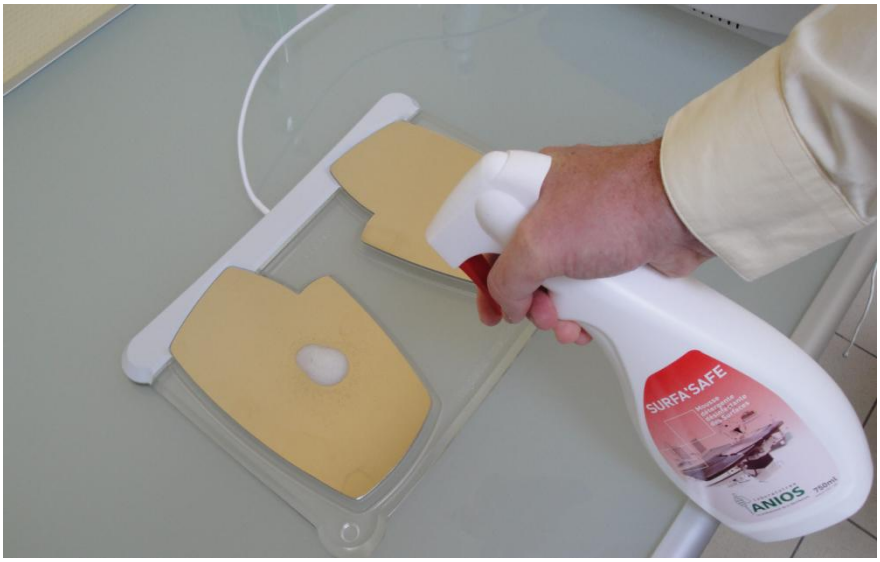
Upon completion of the scan, results are automatically displayed and all patients' data are automatically saved onto the Master Unit's hard disk.

4.2. Clean the electrodes

IMPORTANT

Immediately after each scan, it is important to clean all electrodes with the proper cleaning spray and soft tissues*.

It is not only necessary for health reasons, but it will also 'neutralize' the electrochemical reactions which have taken place on the electrodes during the scan, and stop the corrosion process which would otherwise quickly damage the electrodes surface.



1 Deposit only a small quantity of cleaning product on each electrode.

Avoid applying excessive cleaning liquid.

2 Wipe electrodes with a sheet of soft paper towel to until dry.

Use a new sheet for each electrode or as long as the surface of the electrodes are not completely dry.

HINT

Take advantage of the shiny mirror aspect of the electrodes to remove all traces from all areas!

***Impeto Medical recommends using Surfa'Safe from ANIOS Laboratories (France) or equivalent.**

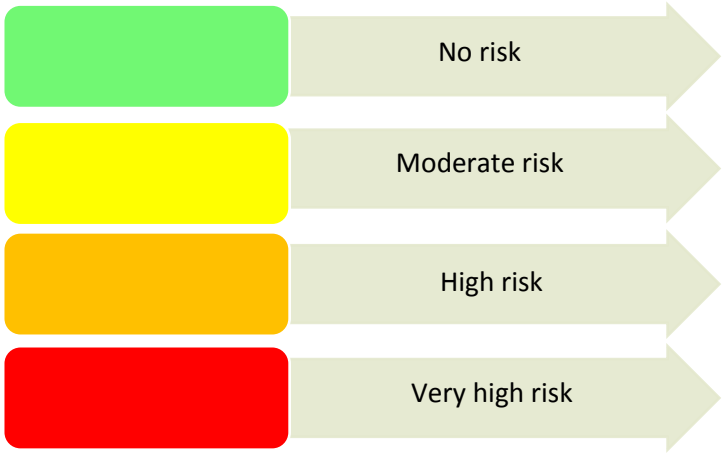
One 750ml bottle will allow cleaning all electrodes after each of 750 patients.

4.3. The results

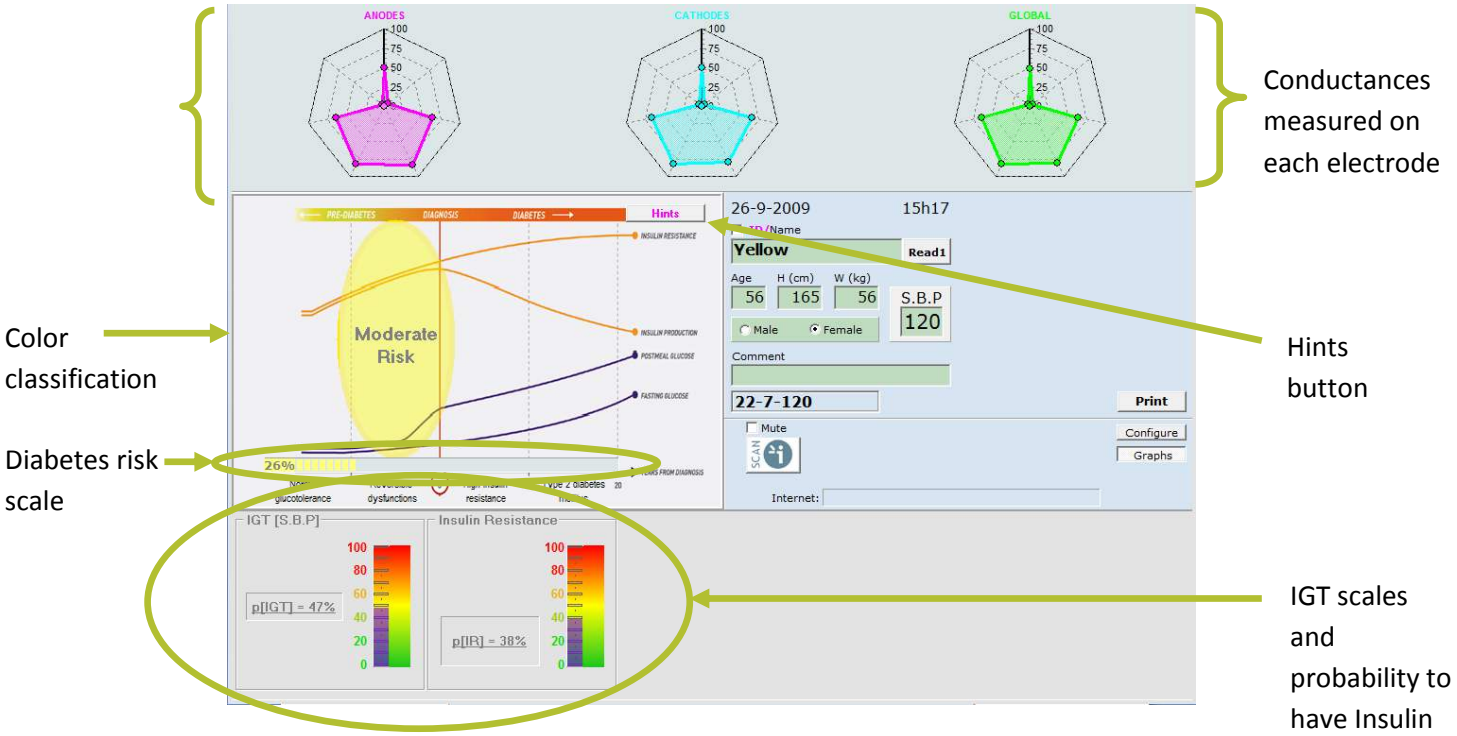
Results should be interpreted by a medical professional and take into account the patient's clinical history.

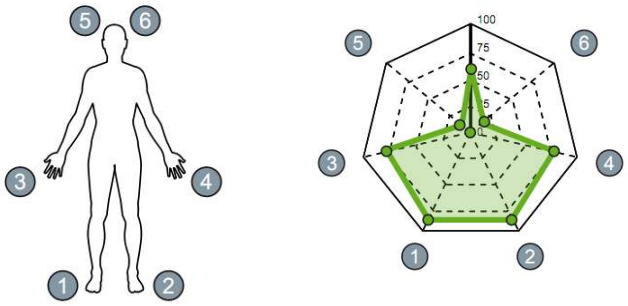
4.3.1. The screen results

Following a three minute data sampling period, EZSCAN allows simple reading of results with the colored-ellipse positions which indicate where the patient is on the diabetes historical curves'. Results are displayed according to diabetes risk with a color index.



Three radars on the top of the screen show the electro conductances measured on each electrode. A diabetes risk scale is displayed under the color classification.

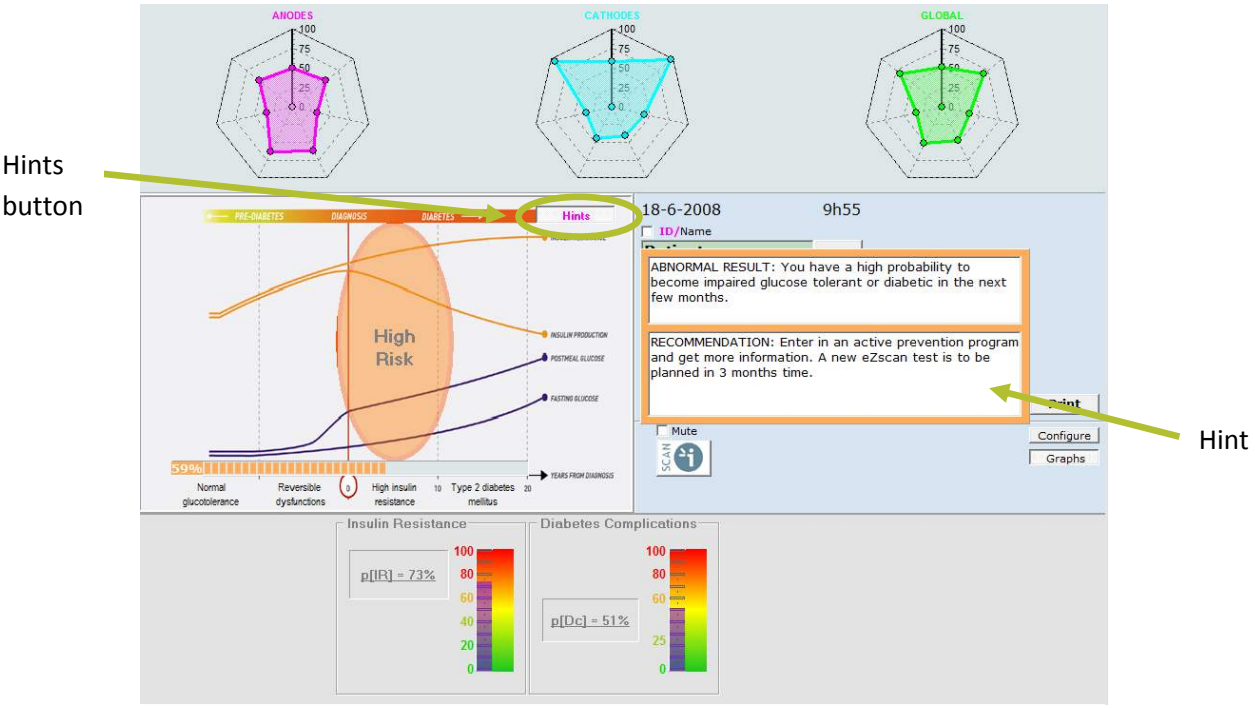




The superposition of the conductance graphs can be obtained by clicking on the Display button.

4.3.2. Quick hints

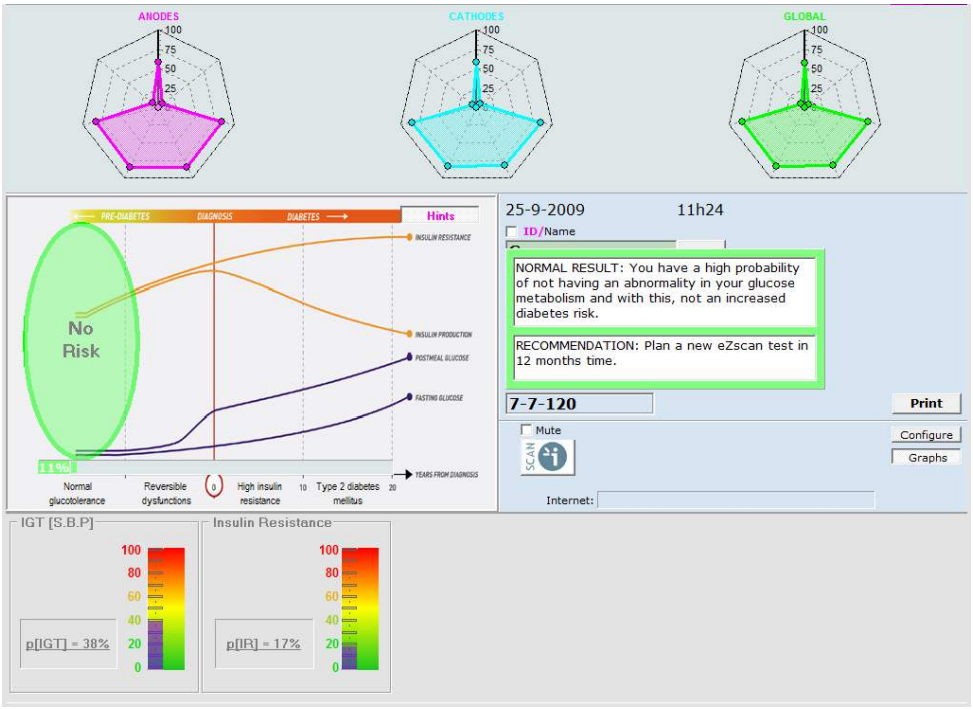
According to the subject color classification, some hints are given. That can help the doctor interpret the results.



Click on the Hints button to display the hints.

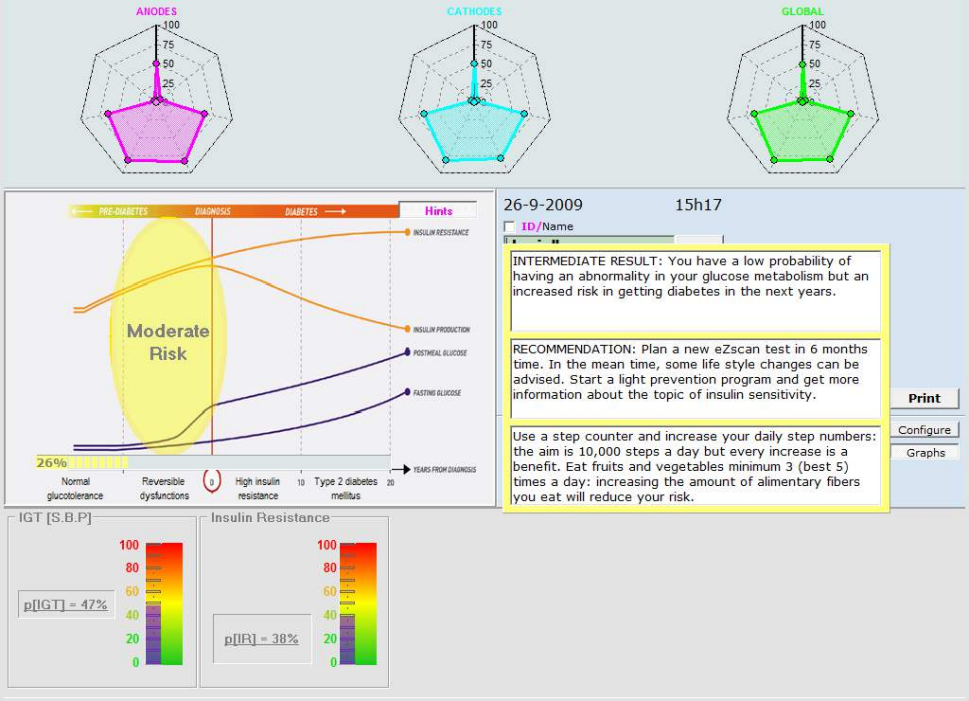
4.3.3. Hints and Quick interpretation of the results

4.3.3.1. Green patient



The green result corresponds to NGT (Normal Glucose Tolerance). The patient has a high probability of not having an abnormality in his glucose metabolism and with this, not an increased diabetes risk.

4.3.3.2. Yellow patient

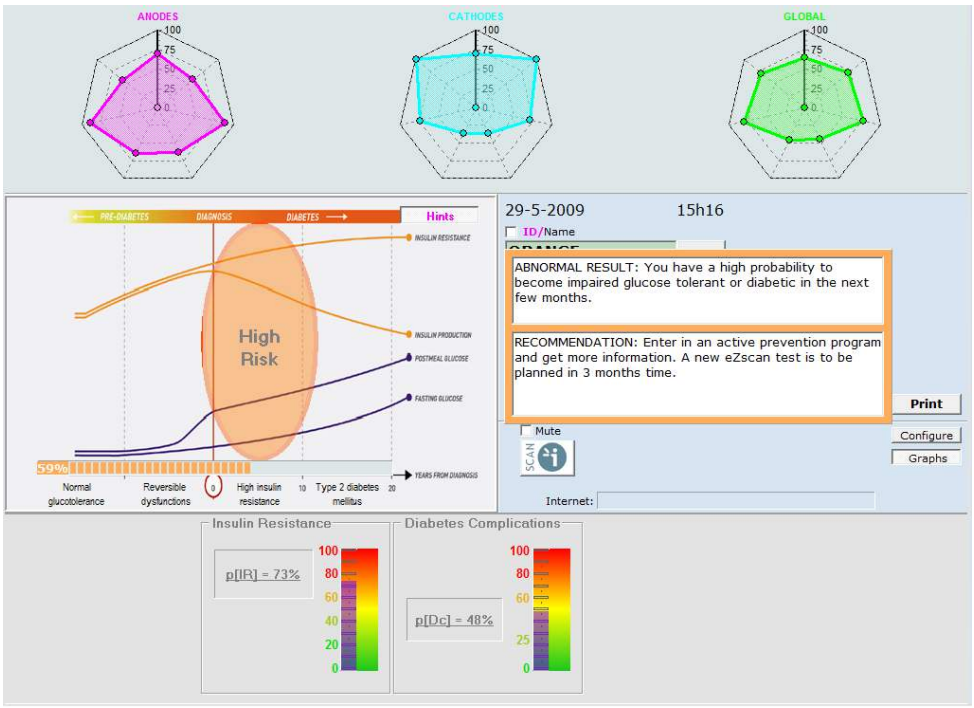


The process of nerve damage has already started but still unlikely to be detected by FPG (Fasting Plasma Glucose) Test. IGT can usually be found by an OGTT (Oral Glucose Tolerance Test)…which requires 2 blood sample tests separated by 2 hours!

The patient has a low probability of having an abnormality in his glucose metabolism but an increased risk in getting diabetes in the next years. At this stage, just paying more attention to nutrition habits and increasing exercise can reverse the disease process. Results can be seen after few weeks with a new EZSCAN test.

Regular tests are required to monitor patient's condition and prevent progression to T2DM (Type 2 Diabetes Mellitus).

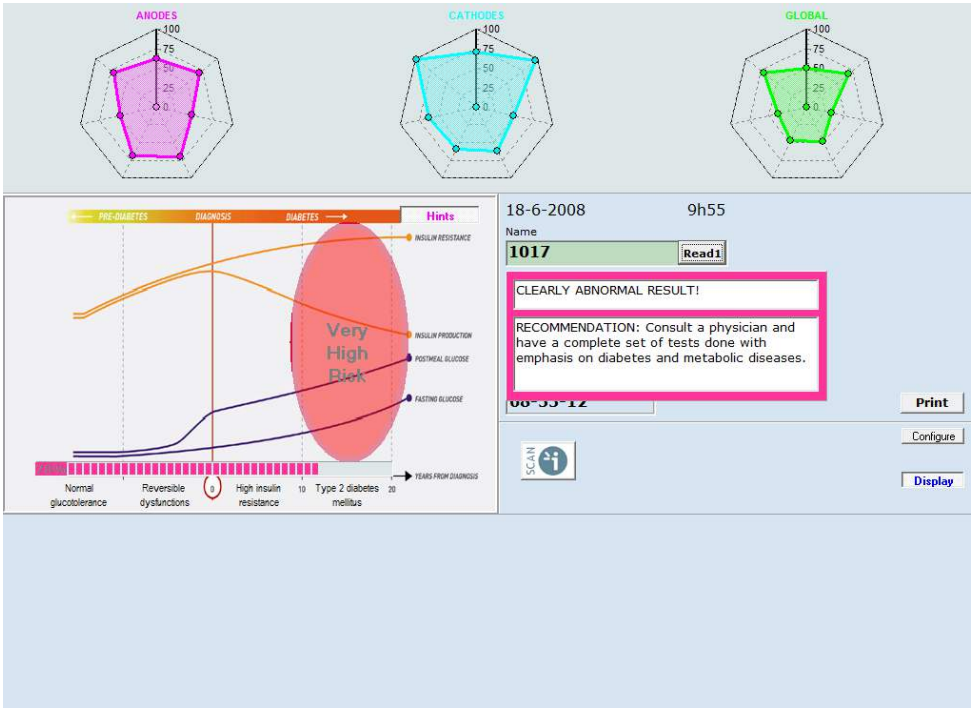
4.3.3.3. Orange patient



Metabolic disorders are present. The patient has a high probability to become impaired glucose tolerant or diabetic in the next few months.

Insulin resistance can lead to T2DM which is the beginning of measurable gap between insulin need and insulin production with small side effects. There are usually no physical symptoms perceived by patients until a few years later. Patient should be tested for metabolic status with blood pressure, OGTT, Cholesterol and triglyceride levels and will have to be checked every 3 months to follow up.

4.3.3.4. Red patient



The results are clearly abnormal! T2DM (Type 2 Diabetes Mellitus) seems already in place. Patient should be referred for OGTT and HbA1c. Severe complications become possible.
Regular EZSCAN tests may help in assessing emerging autonomous neuropathy (cf. Expert mode in 5.), which might be useful to prevent the patient developing complications like:

- Peripheral neuropathy with possible foot amputation,
- Cardiac neuropathy with increased risk of heart attack,
- Erectile dysfunction,
- Renal impairment,
- Retinopathy,
- Etc…

4.3.3.5. Clinical interpretation of the results

The EZSCAN results can be interpreted based on the results of several clinical trials conducted in Europe, India and China.

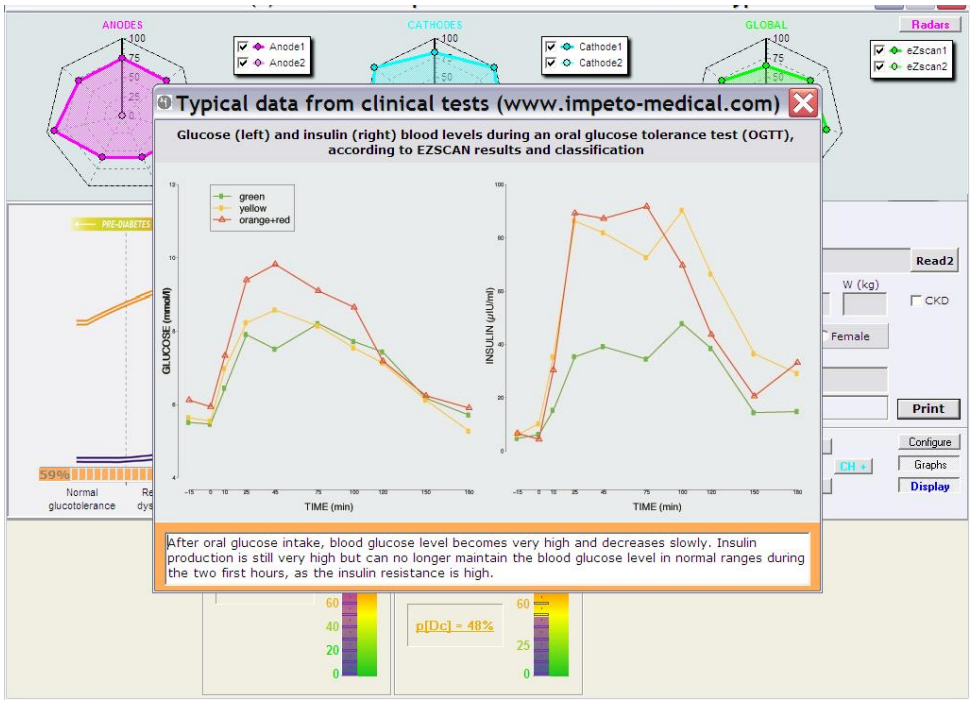
The aim of these clinical studies was to determine the ability of EZSCAN to detect abnormalities in carbohydrate metabolism as compared to a 2-hours OGTT (oral glucose tolerance test).

These studies showed a good correlation between the results of EZSCAN as compared to the OGTT, and that there is no bias on EZSCAN results due to ethnicities.

To know more about it, go to Appendix.

The results (Glucose and Insulin blood levels during an OGTT according to EZSCAN results and classification) can be displayed on screen for education and discussion purpose.

Double click on the background of the color graph (not on the colored bubble).



NOTE

The bottom part of this pop-up window is colored according to the ellipse and contains important useful explanations to understand the action of insulin and the relationship with the resulting blood sugar level.

5. Expert Mode

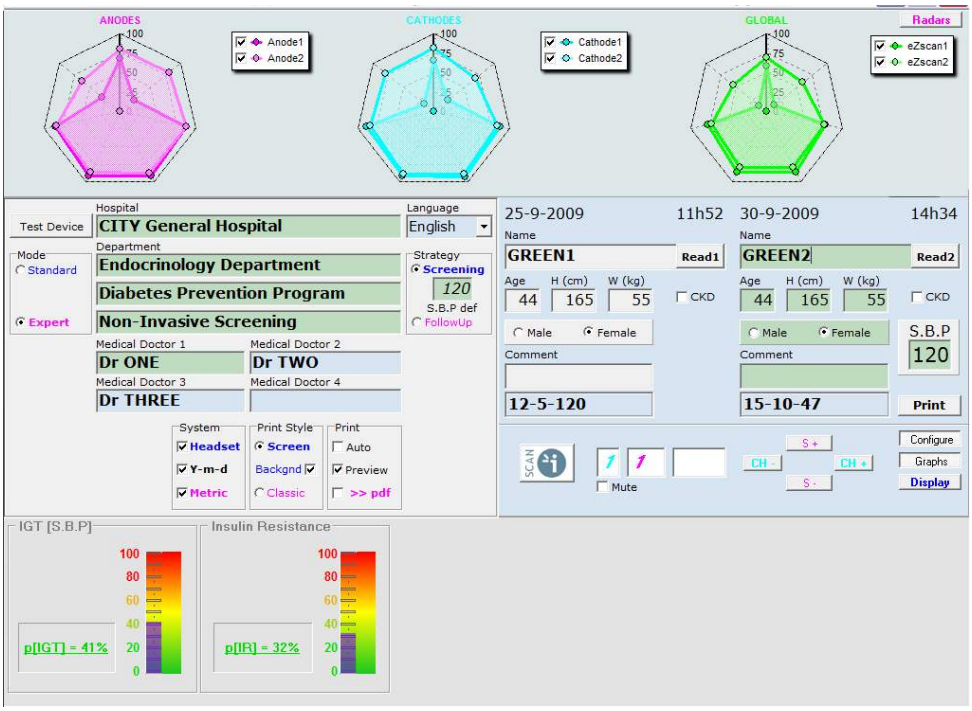
Proceed as described in chapter 4 to run a test.

The expert mode can be used in the context of a follow-up scan or to select more options.

Click on the ‘Expert’ checkbox.

5.1. Comparing two sets of results

In both strategies, it is possible to compare two results. This function can be useful during a follow up scan. It enables the doctor to assess patient progress.



1 Press the ‘READ 2’ button to open the current folder within the currently selected Medical Doctor.

To select another Medical Doctor (MD1, MD2, etc), click on the ‘Configure’ button and select the desired MD.

2 In the ‘Open File’ window, double-click on the selected patient’s name to retrieve his/her data.

NOTE

You can switch from patient 1 data to patient 2 data, by simply touching the corresponding name field and the results will be updated for each accordingly.

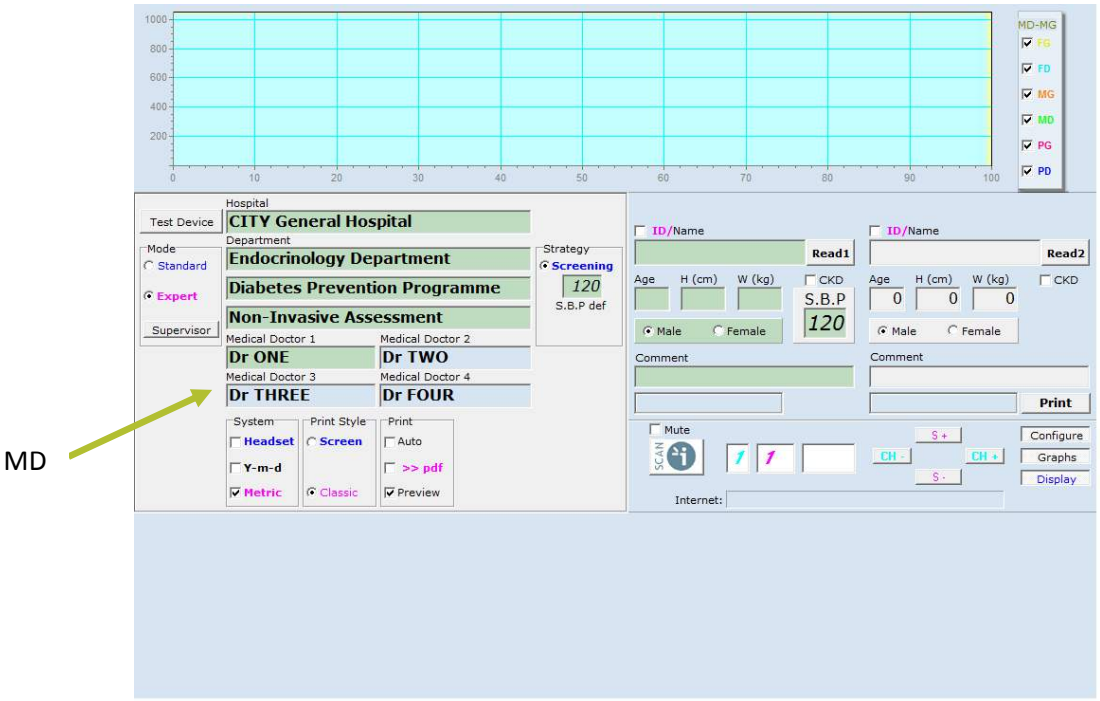
Go to section 7 for more instructions on retrieving patients' data.

The "PAT-2" panel is only used for purpose of reading and comparing two results. It is not possible to scan a new patient from the "PAT-2" panel.

5.2. Medical Doctor Selection

A Medical Doctor (MD) name can be defined and selected within 4 choices. Double-clicking on the desired Medical Doctor will bring the soft keyboard on the screen.

The doctor selected last remains selected until later changed (green background). Simply pointing at another doctor's name will select a specific folder for his own patients.



Click on the MD you wish. *The background of the selected MD becomes green.*

5.3. Supervisor Mode

The Supervisor mode is only accessible by your distributor.

The Supervisor mode allows to:

- Choose the language
- Choose the option of Date of Birth
- Modify the hints
- Set-up internet connection
- Set-up the report sending by email
- Set-up a server : copy data on a server, read patient data from a server
- Concatenate data
- Block the program minimization
- Exit or minimize the programme

Contact your distributor if you wish to have these options.

6. Print the results

The following instructions are available for both standard and expert mode.

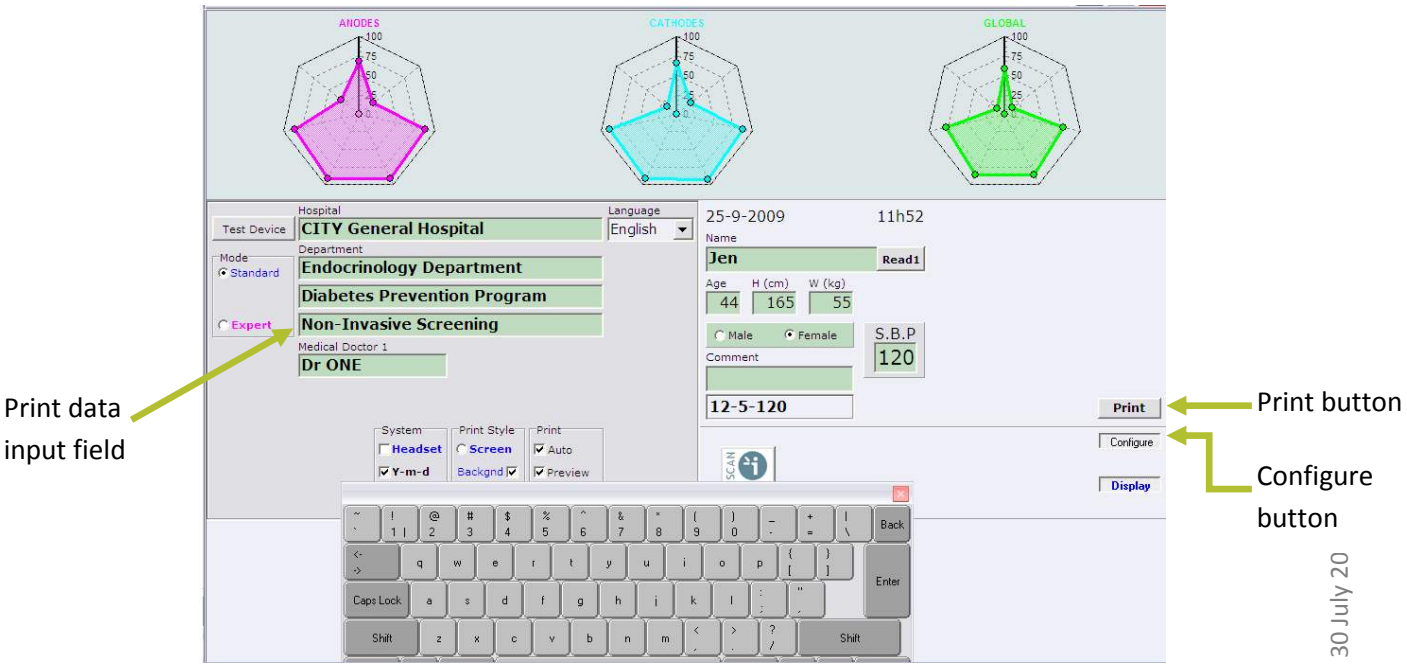
6.1. Configure the print report

1. Press the “Configure” button to open the Configuration window where the print report details can be specified.

2. Double-click on each field to prompt the alphanumerical keyboard to appear on screen.

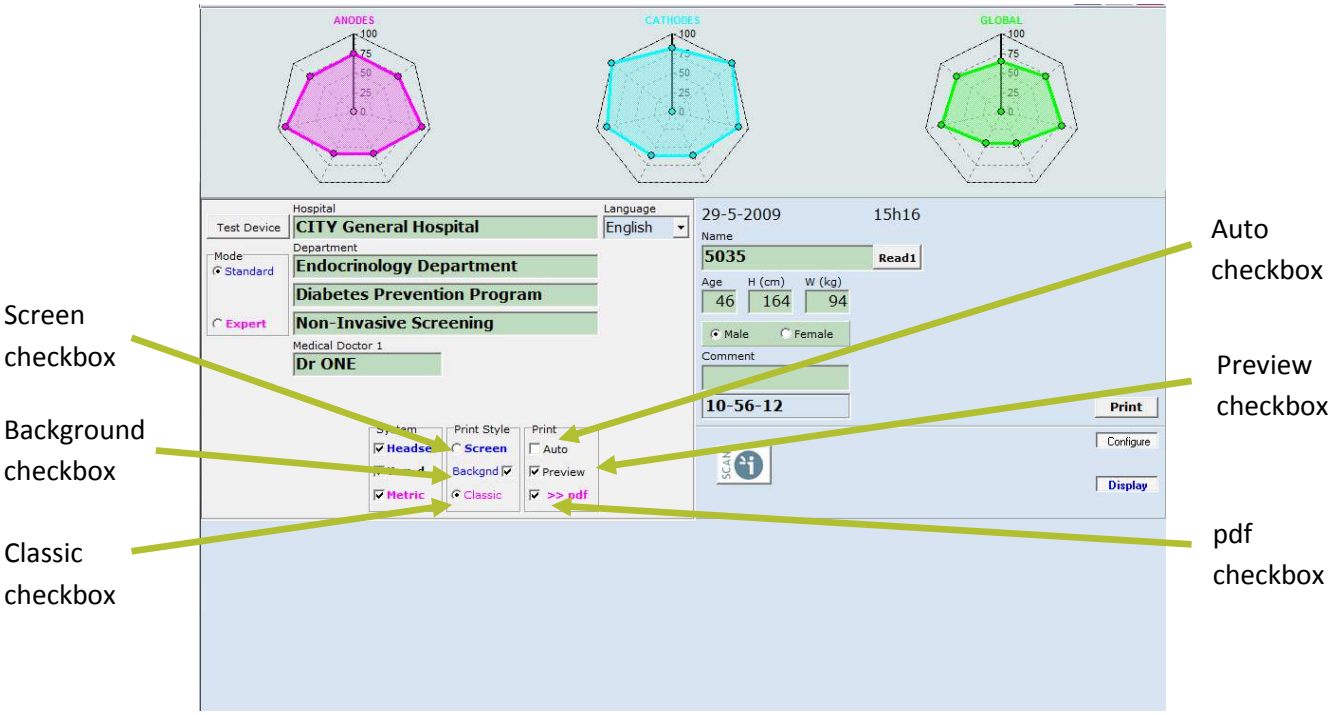
3. Enter the relevant information into the fields:

   NAME OF THE HOSPITAL
   NAME OF THE DEPARTMENT
   NAME OF THE DOCTOR



6.2. Configure the printer usage

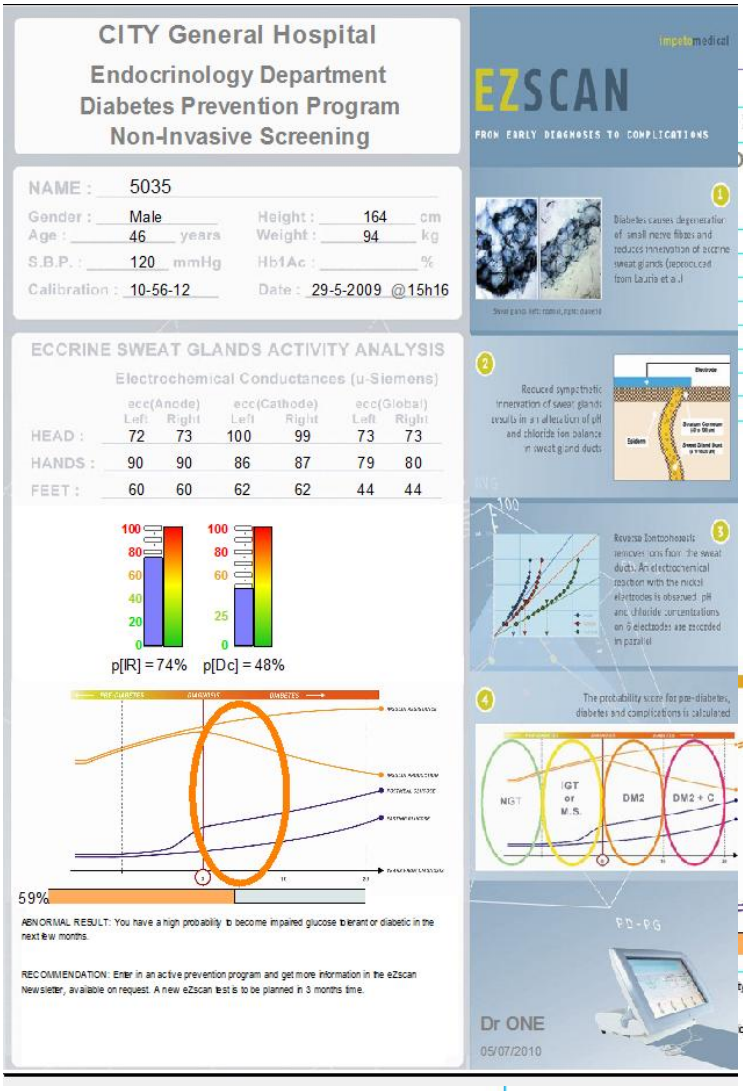
Two sets of printing parameters can be selected by the user.



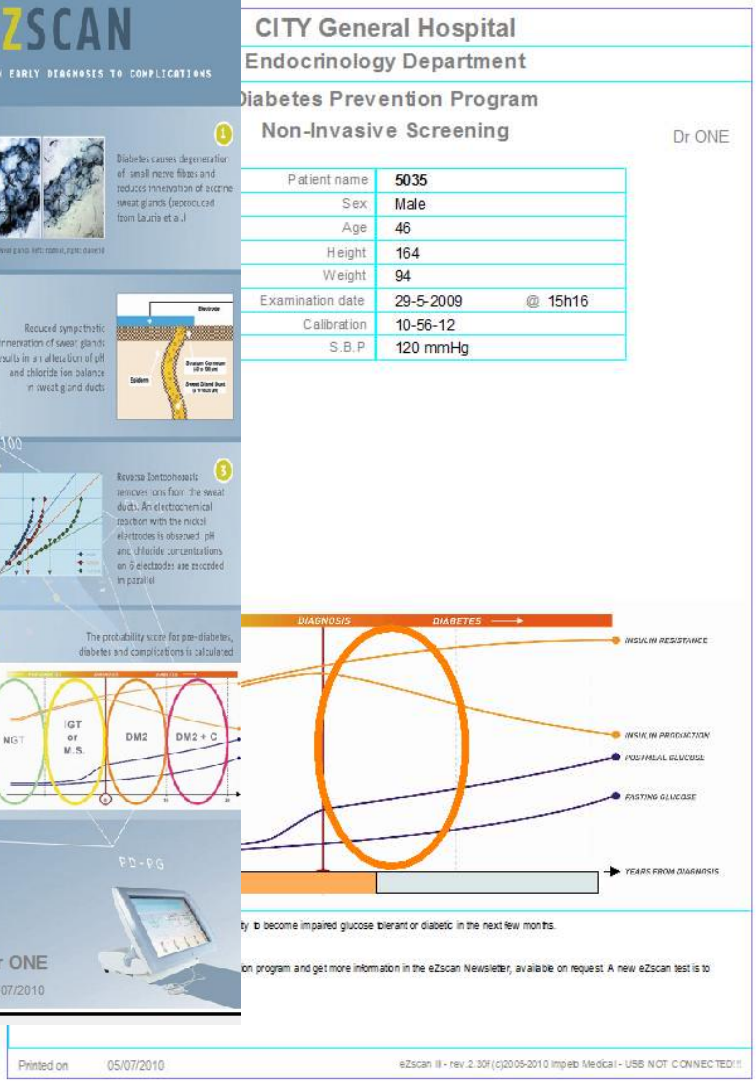
6.2.1. Print style

Two print styles are available.

1. Check the ‘Background’ checkbox if you want a background.
2. Choose the screen style you wish: ‘Screen’ or ‘Classic’ style.



'Screen' style



'Classic' style

NOTE

The 'Screen' style background is only available in English. Please contact your distributor to obtain the background in your language.

6.2.2. Print automatically

Check the ‘Auto’ button check-box for automatically printing a test report after the scan completion…

NOTE

Be sure of the printer installation and its configuration settings before selecting the “Auto” mode.

OR Uncheck the ‘Auto’ button check-box for selectively manually printing a report only upon pressing the ‘PRINT’ button.

6.2.3. Preview and Print

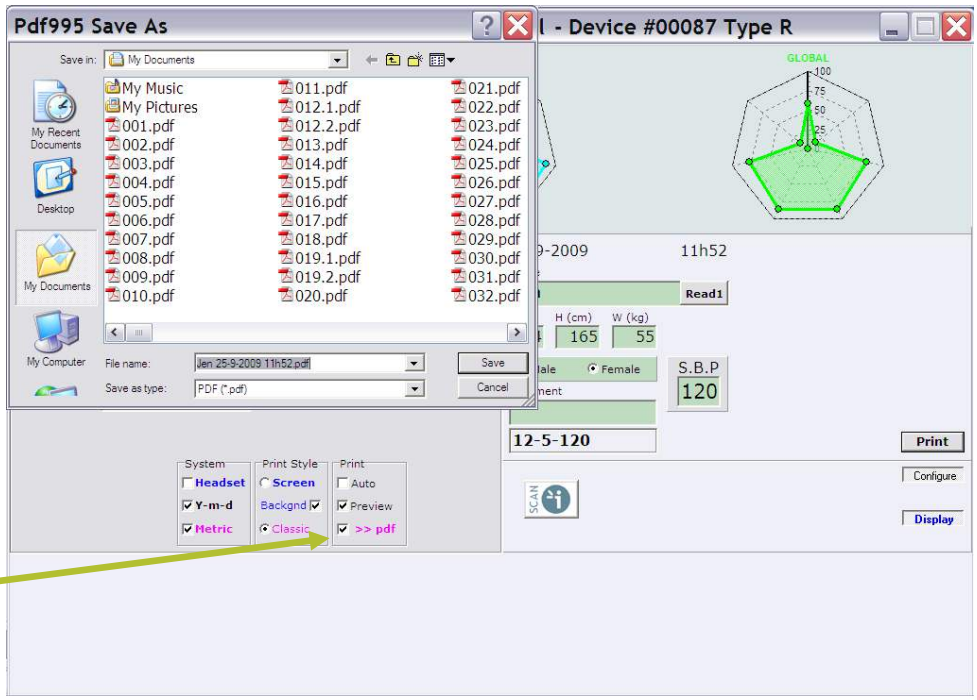
If you prefer to preview the report on screen before deciding to print it:

1. Check the ‘Preview’ option check-box. *A full page Print Preview with options including print*
2. Click on the Print button.
3. Click on  .

6.2.4. PDF report

1. Check the ‘pdf’ option check-box.
2. Click on the Print button.
3. By default, the file name is automatically filled with “Name of the patient Date Time” but you can modify it if you want.
4. Save the pdf.

pdf
checkbox



Press the “Configure” button again to close the Configuration window.

NOTE

In this version, the Save pdf window does not minimize when the user tries to go back to the program.

7. Retrieve previous patient data

The following instructions are available for both standard and expert mode.

All patients' data are automatically saved into specific folder on the Master Unit's hard disk. Data are arranged by Medical Doctor (MD1, MD2, etc.), date and time when the scan was done from the most recent to the most ancient.

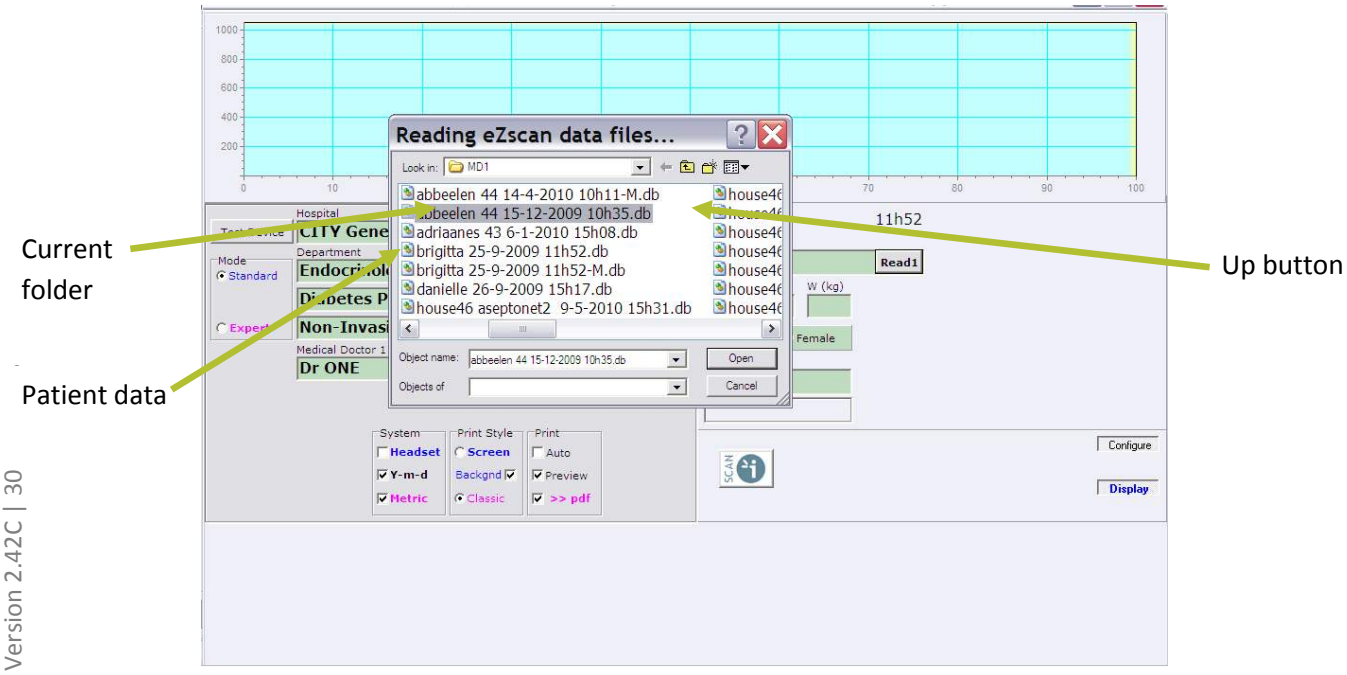
Three methods are available to look for a patient's scan result:

Method 1

1. Double-clicking on the 'Name' field to erase the previous patient's name *(the 'Name' field will become empty).*

2. Press the 'READ 1' button: the whole content of the selected Medical Doctor folder will automatically be displayed in the new window *(all the patients previously scanned).*

3. Double-Click on the patient's name you want to retrieve the data.



Method 2

1. Double-clicking on the 'Name' field to erase the previous patient's name *(the 'Name' field will become empty).*

2. Enter the patient's name you are looking for in the 'Name' field *(double check the spelling)*, then press the 'READ 1' button.

   Only this patient's previous scan results will be displayed in the new window.

Method 3

1. Double-clicking on the 'Name' field to erase the previous patient's name (the 'Name' field will become empty)

2. Enter the patient's first letter(s) name you are looking for in the 'Name' field (double check the spelling), then press the 'READ 1' button.

   All the patients whose names have the same beginning letters will be displayed.

Examples:

Enter 'M' in the 'Name' field and press the 'READ 1' button.

The new window will display all the patients whose names begin with an M.

NOTE

The 'Name' field is NOT case sensitive, and can contain digits (such as Patient ID/IDENTITY CODE).

Since the 'Name' field can contain a maximum of 30 characters, it is advisable to use the 'Comment' field to enter additional patient information such as ID code, etc…

8. Share patient's data

8.1. Transfer data to a USB key

Thanks to this function, the data can be transferred from one EZSCAN to another.

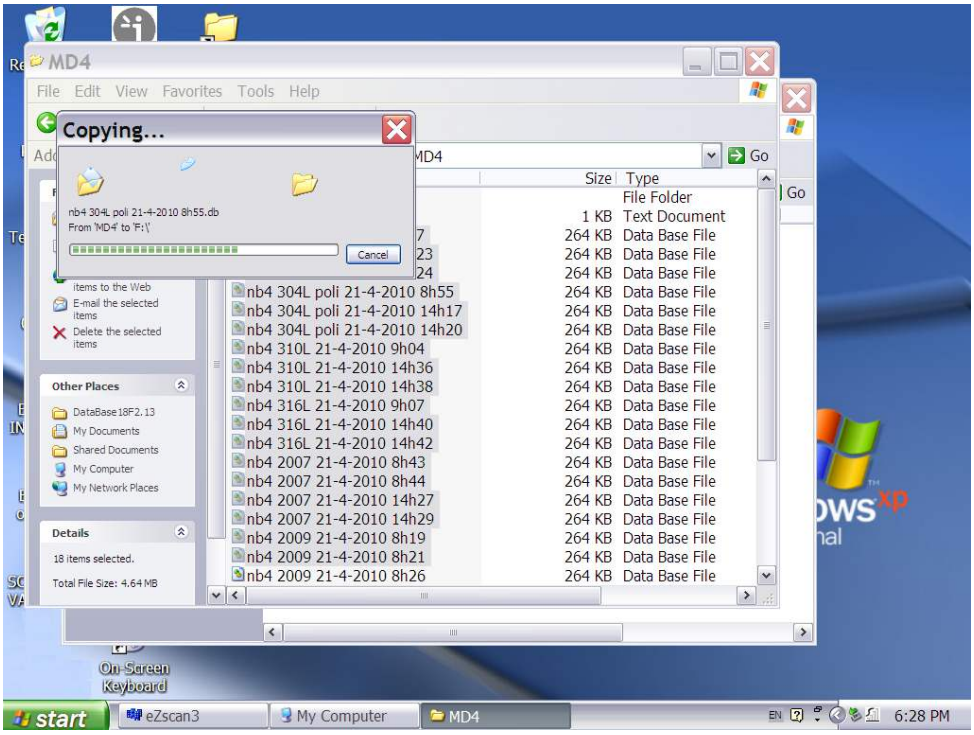
All patients' data are saved into a specific database folder on the Master Unit's hard disk, which can be found on C:\Program Files\IMPETO\.

To copy the entire data base:

1	DOUBLE-CHECK ON THE TARGET PC THAT IT IS FREE OF VIRUS.
2	Go to C:\Program Files\IMPETO\
3	Copy the 'DataBase18F2.13' entire folder to the external USB flash disk.

To copy one or more data:

1	DOUBLE-CHECK ON THE TARGET PC THAT IT IS FREE OF VIRUS.
2	Go to C:\Program Files\IMPETO\
3	Click on ‘DataBase18F2.13’
4	Click on MD1, MD2…according to where the data is stored.
5	Copy the Data to the external USB flash disk.



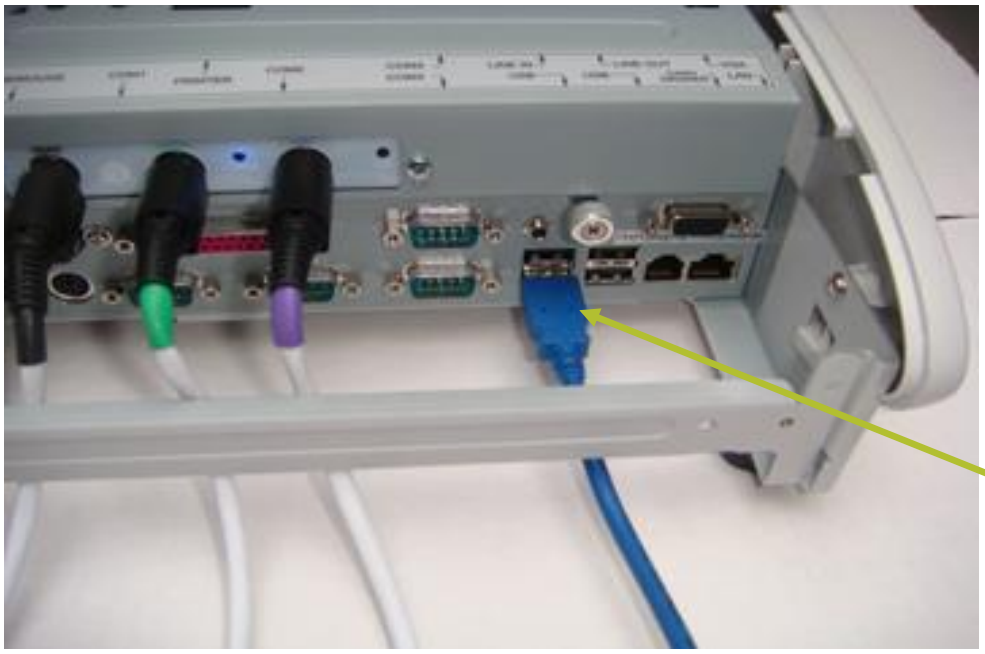
8.2. Access data through office local network

< Requires the installation of EZSCAN software on the remote computer >

>>> Check with your distributor.

9. Install a USB printer

1	DOUBLE-CHECKING ON ANOTHER PC THAT THE USB PRINTER IS FREE OF VIRUS.
2	Insert a USB key or a USB-compatible CD-ROM reader with the appropriate printer drivers for Windows XP or Windows 7.
3	Follow the standard Windows procedure to install the new printer drivers and configure the printer default options.



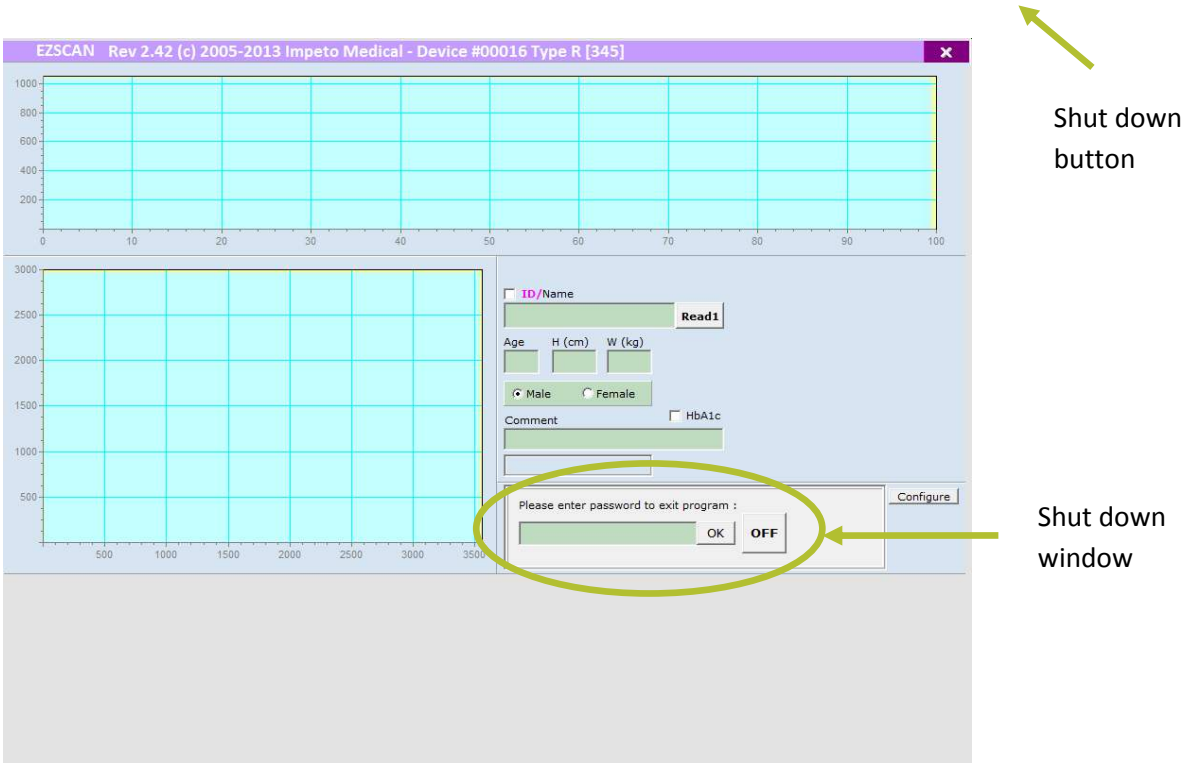
4 Connect the USB printer to one of the 2 USB ports available at the bottom part of the Master Unit's rear panel.

10. Switch off EZSCAN

1. Click on the Shut down button.

   A shut down window appears.

2. Click on OFF.



NOTE

Clicking only on the front button will no longer cause the device to hibernate. Proceed as previous to fully reset the operation.

WARNING

REMOVING THE POWER CORD FROM MASTER UNIT OR FROM WALL SOCKET BEFORE COMPLETE UNIT SHUT OFF, MAY IRREMEDIABLY CORRUPT DATA ON THE UNIT'S HARD DISK.

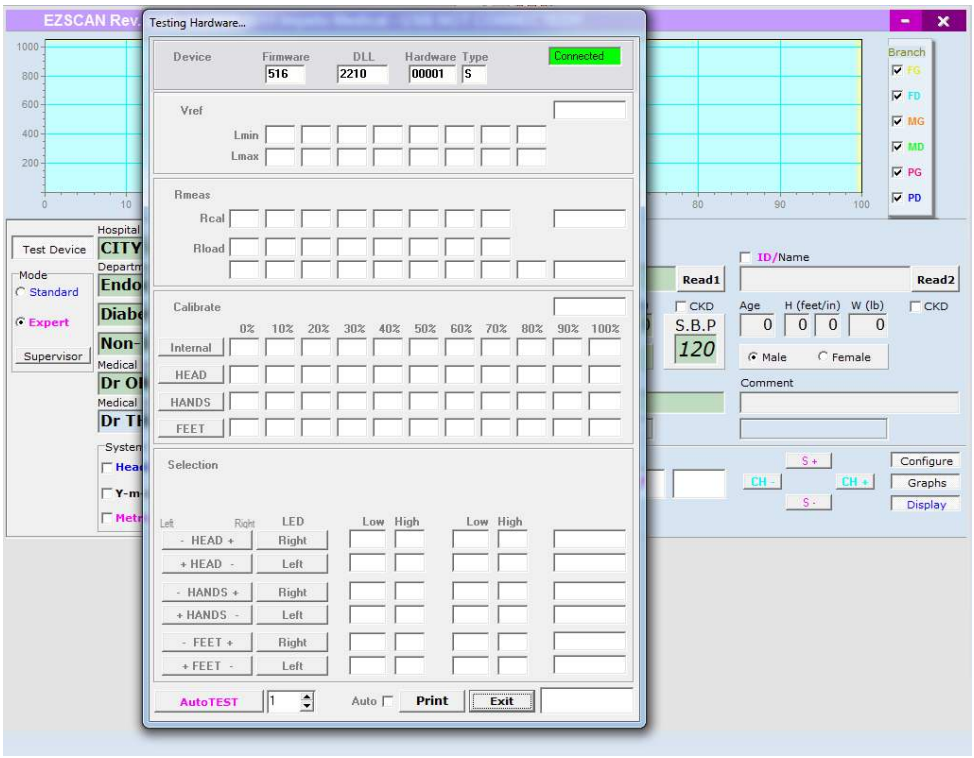
11. Disconnect the electrodes

1	Unscrew the electrodes locking support.
2	Grab the larger part of each connector and slide it softly backwards.

12. Troubleshooting

12.1. Check the cable connections

1. Press the “Configure’ button at the right side of the screen.
2. Press the “Test device” button (need to point to this) at the left side of the new window.



The lower part of this test panel will enable you to check the correct connection of the electrodes:

Pressing either –HANDS+ or +HANDS- buttons, should illuminate both sides of the hands electrodes.

Pressing the “Left” button close to the +HANDS- button should illuminate the left hand electrode only.

Pressing the “Right” button close to the –HANDS+ button should illuminate the right hand electrode only.

Pressing either –FEET+ or +FEET- buttons, should illuminate both sides of the feet electrodes.

Pressing the “Right” button close to the –FEET+ button should illuminate the right foot electrode only.

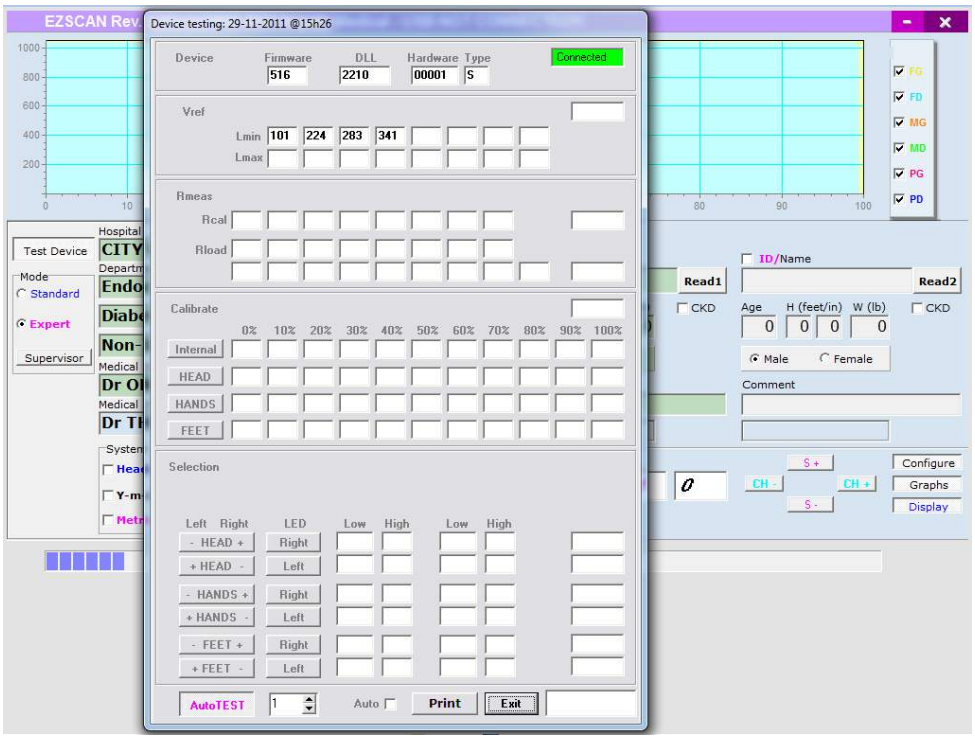
Pressing the “Left” button close to the +FEET- button should illuminate the left foot electrode only.

NOTE

The current aux electrode has no LED attached but should not need to be tested if the hands and feet electrodes are correctly connected to the Master Unit.

Failure to illuminate the correct electrode(s) should prompt you to double-check the physical cable connections and possibly swap the wrong cables before calling for assistance.

12.2. Test the EZSCAN hardware



1. Press the ‘Auto Test’ button to initiate the same complete Test and Calibration program which has been launched before leaving the factory; its print report (PDF format) is sitting on the desktop screen.

2. Press the “Exit” button, then the “Configure” button in order to get back to the EZSCAN home page.

NOTE

This test must be launched with NO PATIENT installed on electrodes.

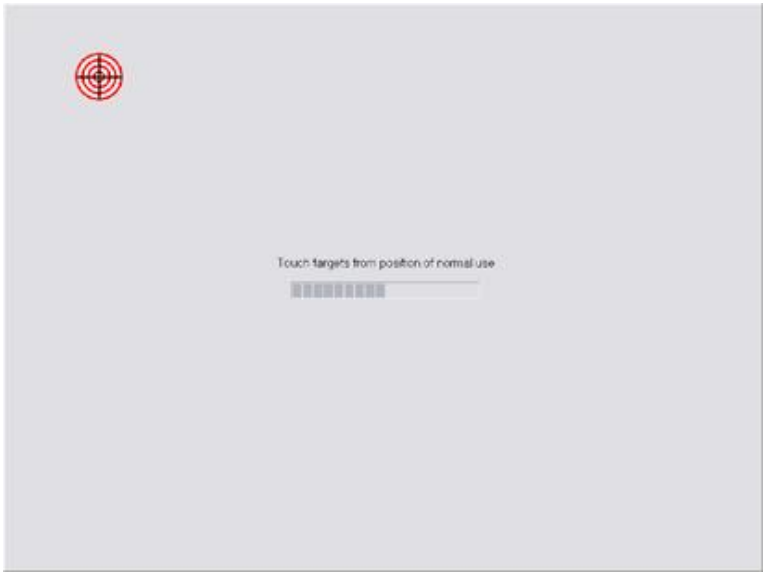
12.3. Calibrate the touch screen

In case the pointing capability on the touch screen does not appear accurate enough, follow the following procedure to calibrate or 'fine-tune' the EZSCAN touch screen operation:

1 Click on the ‘ELO Touch’ icon on the left to launch the ‘Touch Utility’ program.

2 Click on the ‘Align’ icon to launch a simple 3-step procedure.

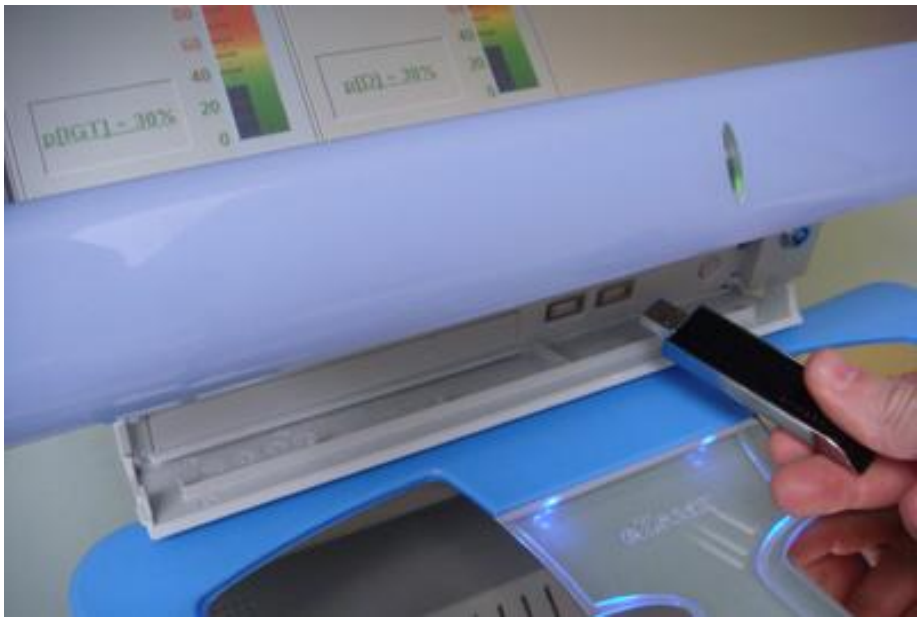
3 When requested, press with your finger on the 3 targets presented sequentially.



4 Press ‘Confirm’ box.

13. Upgrade EZSCAN firmware

Impeto Medical will regularly provide software upgrades to ensure continuous enhancement of EZSCAN products. Check with your distributor or on www.impeto-medical.com website for their availability on a regular basis.



1. Save the upgrader on a USB Flash Disk. Double check before on another PC that the flash disk is free of virus.

2. Insert the USB Flash Disk into one of the 2 USB ports available on the front panel below the screen.

3. Click on the self-extractible software upgrade file for automatic upgrading.
   The EZSCAN software will launch automatically.
   The upgrade process keeps in memory the language.

14. Precaution of use and technical specifications

Principle of EZSCAN

Low voltage is applied to electrodes in contact with the hands and feet, areas with the highest sweat gland density. The voltage extracts ions (Cl-, H+) which reach the electrodes, passing solely via the sweat gland ducts.
At low voltage, the stratum corneum acts as a capacitor and only the sweat ducts allow the transmission of ions from the skin. This ensures that the measurements taken correspond solely to the sweat gland function.

There is an observable electrochemical reaction between 1) the Cl- ions and the anode, and 2) the H+ ions and the cathode.

The device records electrochemical conductances related to the pH and concentration of the chloride ions supplied from the sweat glands and detected by the electrodes (on the hands and feet).

The EZSCAN system is composed of a EZSCAN electronic device integrated into a touch-screen Windows XP-based Industrial-grade PC computer and connected to 6 electrodes placed on the feet, the hands and head[†††], as well as EZSCAN acquisition control software also responsible for archiving the measurements taken on all patients.

General operation of EZSCAN

The patient positions his bare feet on the feet electrodes, applies the palms of his hands to the hands electrodes, and the operator can affix forehead electrodes[‡‡‡] to the head.

After entering the information specific to the patient (name, age, gender, height, weight), the operator will ask the software to activate the electronic circuitry of the Chronoamperometry device, which will apply DC reference voltages successively to electrode couples and will measure the evolution in time of the electrical current passing through the electrodes.

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

The number of measurements made by means of the EZSCAN device, as well as the number of the recorded patients is only limited by the capacity of the integrated hard disk.

[†††] optional
[‡‡‡] optional

At the end of the measurements cycle, which lasts approximately 2 minutes, the expert can visualize a synthesis of the reprocessed data of the patient and with the possibility of printing a sheet of results to include in the file of the patient.
No control is accessible to the patient and the use of the EZSCAN system is strictly reserved to physicians in the framework of a professional use in medical clinic or during visits in hospital.

Precautions of use and maintenance

Transport

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

If it is necessary to pack, to transport or deliver EZSCAN 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 electrode cables in the locations especially designed for them in the protection foams, not to damage them or weaken them.

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

Recycling

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

Protection against the very wet environments

It is advised not to use EZSCAN in a very wet environment.

EZSCAN 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 portable telephones or wireless fixed telephones can cause disturbances of the signal.

Electromagnetic compatibility

The use of portable and mobile RF communication devices (for example: cellular telephones) can influence the analysis carried out during the recording, as the recorded signals can be disturbed by electromagnetic interferences.

The device should not be used in the presence of ionizing radiations (x-rays, gamma rays …) because those could erase the internal storage.
For the tables concerning the electromagnetic emissions and the immunity of the recorder, see the appendices of this handbook.

Maintenance of the device and electrodes

No particular maintenance is necessary.

The external case and the cables of the electrodes can be cleaned using a slightly wet tissue or soaked with soapy water. Do NOT use any detergent product, nor alcohol or acetone.

To avoid corrosion like ensuring the best conditions of hygiene, the feet and hands electrodes must be cleaned immediately after each patient with an anti-bacterial and fungicidal solution.

Warranty

EZSCAN has one full year warranty period (12 months from the date of installation, parts and labor). After the warranty period has expired, customers can subscribe a service contract for the maintenance of their equipment.

Feet and hands electrodes, as well as their associated cables will have their wear and tear and hence are not covered by the warranty. Take care to maintain them in good condition of aspect and operation to prolong their lifespan to the maximum, then to order the replacement parts at Impeto Medical or its authorized distributors.

We do not guarantee the damages caused to the device in case of accidental power cuts.

WARNING

Only authorized persons by Impeto Medical can intervene 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 EZSCAN was opened and repaired by any unauthorized person. Warranty will hold well only against manufacturing defects and certainly not for any mechanical damage due to mishandlings. 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 EZSCAN and on the case

The following pictograms are affixed on EZSCAN:

Indicates that the parts applied of the device are of type BF (IEC 60601-1).

Date of manufacture (yyyy-mm)

I

Class of electric protection.

CE 120

EZSCAN 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 2002/95/EC)

<u>The following pictograms are affixed on the case:</u>

Handle with care

Fragile

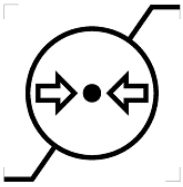
Keep dry

Keep stand

Recyclable

Shows the temperature limit between which the medical device can be exposed safely

Indicates the range of moisture in which the medical device can be exposed safely



Indicates the range of atmospheric pressure in which the medical device can be exposed safely

Use of the electrodes

The data relating to the use of the electrodes are provided as an indication.

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

It is also advisable to check if the electrode cable connectors are well inserted in the corresponding sockets at the rear of the EZSCAN Master Unit.

Clean the skin of the patient to establish a good electrode/skin contact.

WARNING

Use only the original electrodes provided by Impeto Medical.

Impeto Medical cannot guarantee the results of measurements carried out with electrodes coming from other manufacturers, even if they have a similar appearance!

When it is not used, the EZSCAN system can be stored without being necessary to disconnect the electrode cables.

WARNING

The maximum weight accepted by the electrodes is 200kg.

Forehead electrodes installation[§§§]

Put in place the head gear with the reusable electrodes and adjust its size to the patient head. The blue side of the cable will be connected to the electrode placed on the right side of the patient's head the white side on the left.

Positioning on the electrodes plates

The patient must position the sole of his bare feet in the center of the feet electrodes and his hands well flat in the center of the hands electrodes, hands must be applied firmly. Except in the event of characterized overweight, the patient will be preferably standing upright on the plate of the feet electrodes.

Interrupting or stopping the recording

The recorder will stop automatically at the end of the measurements cycle, after approximately 2 minutes.

To stop the recorder BEFORE the end of the measurements cycle, simply click on the same button which is now labeled "STOP" during the cycle of measurement.

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 between 18 and 35 degrees Celsius,
- Patient not having carried out an intense effort during 2 hours preceding the examination (except in the event of effort test),
- Cardiac holter measurements going on can be altered during the 2 minutes time scan.

[§§§] optional

Contra-indications

The repeated use of EZSCAN does not create any side effect, but no specific tests have been carried out to date under the following particular conditions, so it is advised not to proceed to measurements on the following patients:

- People with any open or bleeding wound at any electrode contact surface location,
- People with any type of implantable device except implantable cardiac pacemakers and implantable cardioverter defibrillators[****],
- People with missing leg(s) or hand(s),
- Pregnant Women or women who are uncertain about a possible pregnancy
- Subjects under the age of 21.

Calibration

EZSCAN performs automatically a self-calibration procedure at the beginning of each test. So it assures that each electrode got enough contacts to proceed for the measurements. Therefore, there is no need to calibrate the device before operation. However, it is possible to double-check the correct operation of the elements of the whole system by carrying out, in case of doubt or at least once in a year a calibration procedure using the "Calibration Test Box" accessory available from Impeto Medical.

If the calibration is interrupted the operator is informed by a ring bell and an error message.

Accessories and disposable parts

The following elements are available for EZSCAN:

Code	Description
eZMU	EZSCAN Master Unit
APH2	Hands plate with two electrodes and its connecting cable
APF2	Feet plate with two electrodes and its connecting cable
HDGR	Head gear with two electrodes[††††]
SCC2	Head electrodes cable with 2 clips[‡‡‡‡]
UMeZ	Installation manual
ASAFE	Bottle of ANIOS Surfa'Safe spray cleaner
ELOCK	Electrode locking support
RCPU	Rack Central Processor Unit

[****] Laboratory tests under the standard *ANSI/AAMI PC69:2007 : Active implantable medical devices— Electromagnetic compatibility— EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators* have demonstrated that EZSCAN measurements have no influence on the functioning of implantable cardiac pacemakers and implantable cardioverter defibrillators.

[††††] optional

[‡‡‡‡] optional

Technical specifications

• Description

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

EZSCAN is a class IIa medical device (according to the EEC directive 93/42) and a class II medical device (according to Health Canada).

EZSCAN complies with IEC 60601-1 Edition 3 (Medical Electrical Equipment, Part 1: General requirements for safety).
To ensure compliance with the Release 2 use an isolation transformer in accordance with IEC 60601-1.

• Characteristics of acquisition

Storage support:	160 Gb or 320 Gb Hard disk
Mode:	No compression
Frequency of acquisition:	100 Hz
Resolution:	1 nanoSiemens
Display units:	microSiemens
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 220V AC at 60 Hz 1,5A 220-240V AC at 50 Hz 1,5A
Class of electric protection:	I

• Sealing

Index of protection:	
Master Unit	IP20
Electrodes	IP41

• Mechanical characteristics

Master Unit alone	9,5 kg
Master Unit dimensions	38 x 38 x 33 cm
Weight of the Master Unit + electrodes:	13 kg
Weight of the transportation box:	17,5 kg

Dimensions of the shipping box: 55 x 48 x 51 cm

•Climatic conditions of use of the apparatus and electrodes

	Temperature	Moisture (without condensation)	Pressure
Operation	18° to 35°C (65° to 95°F)	20% to 80%	600 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		
EZSCAN is intended for use in the electromagnetic environment specified below. The customer or the user of EZSCAN should assure that it is used in such an electromagnetic environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	EZSCAN uses RF energy only for its internal function. 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	EZSCAN 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			
EZSCAN is intended for use in the electromagnetic environment specified below. The customer or the user of the EZSCAN should assure 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 % *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 EZSCAN requires continued operation during power mains interruptions, it is recommended that the EZSCAN 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 EZSCAN is intended for use in the electromagnetic environment specified below. The customer or the user of the EZSCAN should assure that it is used in such an electromagnetic environment.			
Immunity test	**Immunity test**	**Immunity test**	**Immunity test**
			Portable and mobile RF communications equipment should be used no closer to any part of the EZSCAN, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V rms 3 V/m	**Recommended separation distance** $d = 1.17 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz		$d = 1.17 \sqrt{P}$ 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 EZSCAN is used exceeds the applicable RF compliance level above, the EZSCAN should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the EZSCAN.

(2) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [*V*1] V/m.

WARNING

Utilize only a certified USB 2.0 high speed shielded printer cable, maximum length 120cm (3.9 ft).

The use of accessories, transducers and cables other than those specified, except for those delivered with the apparatus can have consequences such as increase of emissions or reduction of immunity of the apparatus.

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 EZSCAN			
EZSCAN is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the EZSCAN can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the EZSCAN 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.			

Certificate / Certificat FR12/01325

The management system of / Le système de management de

IMPETO MEDICAL

17 rue Campagne Première,
75014 PARIS, France

has been assessed and certified as meeting the requirements of
a été audité et certifié selon les exigences de

ISO 13485:2003
EN ISO 13485:2012

For the following activities / Pour les activités suivantes

The scope of registration appears on page 2 of this certificate.
Le domaine de certification apparait en page 2 de ce certificat.

This certificate is valid from 18 December 2012 until 17 December 2015
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 17 December 2015
Issue 3. Certified since 20 July 2012

Le certificat est valable du 18 décembre 2012 au 17 décembre 2015
et reste valide jusqu'à décision satisfaisante à l'issue des audits de suivi.
L'audit de renouvellement doit avoir lieu avant 17 décembre 2015
Version 3. Certifié depuis 20 juillet 2012

Authorised by/Autorisé par

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Issue / Version 3

Detailed scope/Domaine d'activité détaillé

Design, development, manufacture and servicing of non-invasive chrono-amperometric analyzers medical devices for the screening and the follow-up of diabete and cardiometabolic complications.

Conception, développement, fabrication et SAV de dispositifs médicaux non-invasifs chrono-ampérométriques d'analyse pour le dépistage et le suivi des complications du diabète et des maladies cardio-métaboliques.

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Appendix

EZSCAN, A NEW NON-INVASIVE TECHNOLOGY, HAS THE SAME SENSITIVITY TO DETECT ABNORMALITIES IN INSULIN RESISTANCE SUBJECTS AS THE 45MN OGTT GLUCOSE VALUES

PRESENTED AT EASD 2009

A. Ramachandran[1], A. Moses[2], C. Snehalatha[1], J. Deslypere[3]
[1]India Diabetes Foundation, Chennai, India, [2]Moses Diabetes Centre, Chennai, India, [3]SGS, Singapore, Singapore

AIMS

The EZSCAN is a new patented technology which uses low level DC voltage inducing reverse iontophoresis, together with chronoamperometry to evaluate the functions of tissues in specific locations of the body. The whole test takes only 3 minutes, does not require patient preparation and does not cause inconveniences for the subjects. The aim was to determine the ability of EZSCAN to detect abnormalities in carbohydrate metabolism as compared to a 45 minutes OGTT.

METHODS

A cross-sectional study was done in Chennai, India [1] in subjects who were not known to have any abnormalities in carbohydrate metabolism. Moreover all subjects underwent an OGTT 8 months before the study, showing a normal glucose tolerance status. A frequent sampling OGTT with measurements of glucose and insulin levels at 10 time points was done. Testing with the EZSCAN, a new non-invasive device to test carbohydrate metabolism [2-4], was also performed. A reading of < 40% was considered normal on the EZSCAN Insulin Resistance scale. Subjects were divided in three groups: normal (green color reading onthe EZSCAN; value < 40%) and abnormal (yellow color reading: value between 40% and 65% and orange/red color reading: value > 65%). The criterion of Abdul-Ghani et al. [5] was used for the cut-off values of the 45 min OGTT (8.6mmol/l).

RESULTS

A total of 30 subjects were assessed with the following demographics:

- Age: 41 ± 11 years
- BMI: 28 ± 6 $kg \cdot m^{-2}$
- M/F ratio: 1
- OGTT $_{45mins}$ (mmol/l): 8.66 ± 2.35
- OGTT $_{2hours}$ (mmol/l): 7.21 ± 2.21

Of the 11 subjects who were found to have abnormal $OGTT_{45mins}$ results (Fig.1A), 4 had IGT and 2 had DM. Five of these 6 cases tested positive with the EZSCAN (83% sensitivity), while 1 case (23 yrs old Type I DM) was not detected. There was a good correlation between the results of the EZSCAN as compared to the $OGTT_{45mins}$ (r=0.55, p=0.002).

Graphical plots of the time profile of glucose (Fig.1B) and insulin (Fig.1C) levels show that the EZSCAN measurements (green=normal EZSCAN reading and yellow, orange/red=abnormal EZSCAN reading) correlate better with the presence of insulin resistance rather than with insulin deficiency.

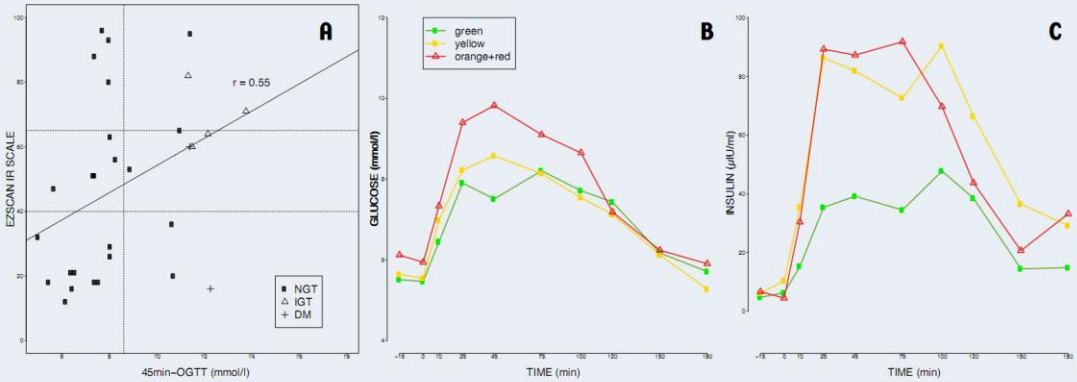

Fig.1 : Mean values of Glucose and Insulin concentrations over time as function of EZSCAN classification

CONCLUSION

The EZSCAN is a promising new tool able to detect the presence of early carbohydrate metabolism dysfunctions in insulin resistant subjects. Compared to tests currently done in daily practice, the EZSCAN is fast and noninvasive and it can be done at any moment of the day without fasting need.

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