LD TECHNOLOGY

TM-FLOW SYSTEM

VASCULAR FUNCTION & AUTONOMIC NERVOUS SYSTEM ASSESSMENT

SPECIFICATION DEVELOPER

LD TECHNOLOGY
100 N. BISCAYNE BLVD
MIAMI, FL, 33132 USA

ISO 13485-2016
Medical Device Data Systems (MDDS) Product Code: OUG

Prescription Use: Caution!
Federal law restricts this system to sale by or on the order of a physician.

PARTS LIST ASSOCIATED WITH TM-FLOW SYSTEM AND REFERENCES

HARDWARE ELECTRONIC BOX REFERENCES:

- Electronic box: Ref. LD-Oxi Bluetooth.
- Electronic box: Ref. SweatC.
- Electronic box: Ref. TBL-ABI / ARM REGULAR CUFF / RIGHT ARM CUFF/ ARM LARGE CUFF / LEFT ANKLE / RIGHT ANKLE.

ACCESSORIES REFERENCES:

- SweatC disposable electrodes: Ref. LD-SW.
- SweatC reusable cable yellow: Ref. LDT-19 Y.
- SweatC reusable cable red: Ref. LDT-19 R.
- Manometer: MA40.
- Outputs for manometer: OMA40.
- TBL-ABI USB cable for charging: Ref. USB-charge.
- SweatC USB cable: Ref. USB-B.
- TM-Flow software: Ref. SW TM-Flow.
- Instruction for use: Ref. IFU TM-Flow Software.
- Carrying case: Ref. Case 8045.

SYMBOLS IN THIS BOOK

CONTRAINDICATIONS: Cases in which the device should not be used.

WARNING: Something could hurt patient or operator.

FOLLOW THE INSTRUCTIONS FOR USE: Please read the operator's manual carefully before using device.

Safety Warning.

CAUTIONS: Reminds operator to pay attention to sources of error, which may cause patient injury, abnormal device function, system crashes, damaged equipment, etc...

NOTES: Important information such as suggestions, requirements and supplements.

VERSION DATE

VERSION 1: FEBRUARY, 4TH 2016.
VERSION 2: JANUARY, 15TH, 2017.
VERSION 3: JANUARY, 18TH, 2018.
VERSION 4: APRIL, 4TH, 2018.
VERSION 5: OCTOBER 25TH, 2019

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TYPE OF DEVICE

SOFTWARE CLASSIFICATION

Trade name: TM-FLOW System.
Regulation number: Medical Device Data. Systems (MDDS).
Product Code: OUG.
Classification: Class II.
Classification Panel: Cardiology/ Neurology Europe Class IIa.

GENERAL DESCRIPTION

TM-FLOW System comprises:

- 3 Bluetooth blood pressure devices with attached cuff.
- Galvanic skin response device.
- Bluetooth Oximeter.
- Sotfware installed on a computer.

DEVICES/HARDWARE CONNECTIONS

SweatC is a USB plug and play hardware including interface box.

TBL- ABI and LD - Oxi use Bluetooth communication protocol.

FEATURES OF THE TM-FLOW SYSTEM

- Measuring ankle brachial indices.
- Measuring the skin voltage during electrical stimulation.
- Mathematical and statistical analysis of the photoplethysmography.

INTENDED USE

TM-FLOW INTENDED USE AND INDICATIONS FOR USE

TM-Flow is a medical Device Data System for use with the following models having data management capabilities:

- TBL-ABI (ankle brachial pressure Index measurement device).
- SweatC (galvanic skin response).
- LD-Oxi (oximeter). When used in combination with TBL-ABI and/or SweatC and/or LD-Oxi devices, the TM-Flow software uploads the data of the devices, and then displays the data in a computer for enhanced data management.

The TM-Flow system is intended for use in clinical settings as an aid for health care professionals to review and evaluate the historical tests results (autonomic and vascular assessment). The device provides values. It is the physician responsibility to make proper judgments based on these numbers.
The TM-Flow software data is stored in the back up files located on the PC. The software is intended for use only with adult subjects.

*Prescription Use: Federal law restricts this device to sale by or on the order of a physician.

TBL-ABI INTENTED USE

The TBL-ABI is indicated for use on adult subjects at risk of having or developing peripheral arterial disease (PAD).
TBL-ABI is intended for the rapid measurement of ankle-brachial pressure index (ABPI), or ankle-brachial index (ABI), and pulse volume recording (PVR)/volume plethysmography in adults.

It is suitable for use in wound care assessment, for assessing symptomatic PAD and as a screening device for PAD.
It may also be used on patients with venous or arterial ulcers prior to the application of compression therapy.

SWEATC INTENTED USE

SweatC device is a medical device for the measurement of galvanic skin response related to the function of the sweat glands. The SweatC provides values.

LD-OXI INTENTED USE

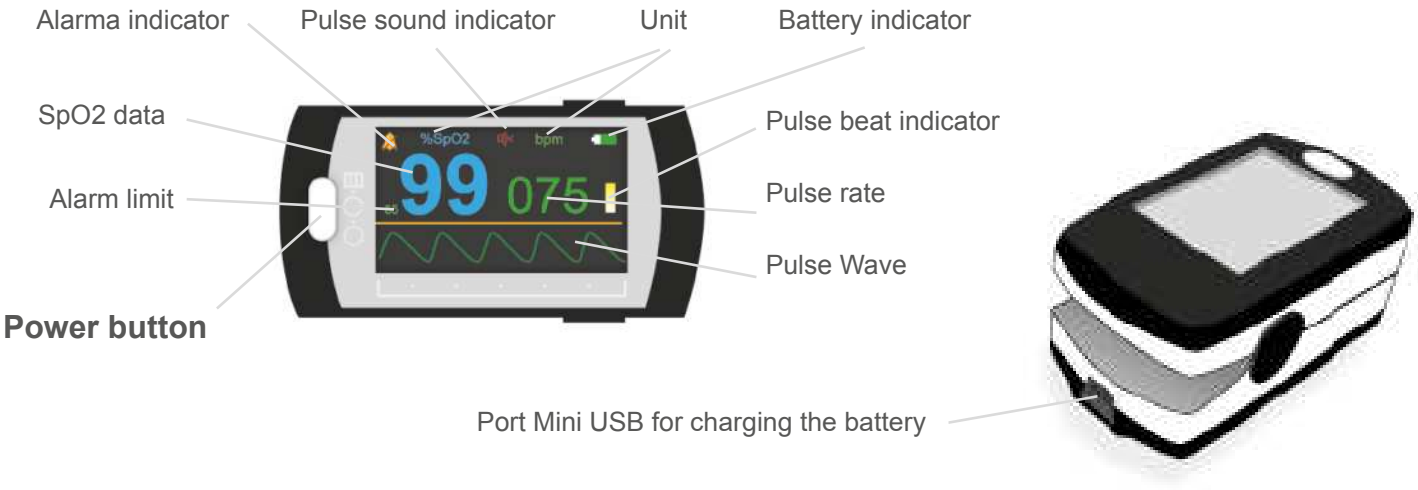
LD-Oxi (oximeter) displays the photoplethysmograph. It used to assess vascular function and heart rate variability at rest and during the Ewing tests.

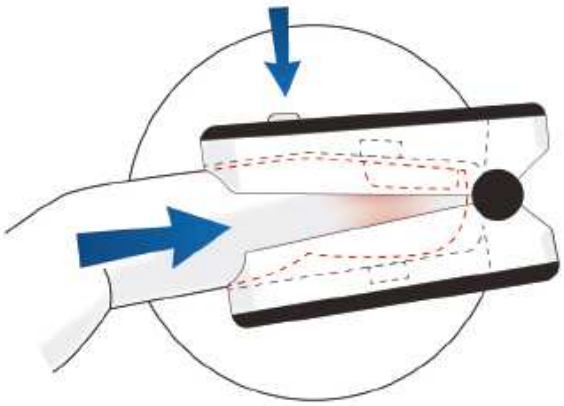
PACKAGE CONTENTS

1. SWEATC.
2. SWEATC USB CABLE.
3. YELLOW FOOT ELECTRODE CABLE.
4. RED FOOT ELECTRODE CABLE.
5. DISPOSABLE ELECTRODES.
6. MANOMETER.
7. OUTPUT MANOMETER.
8. CALIBRATION BOX.
9. USB CHARGER.
10. USB CHARGE CORD PLUG.
11. BLUETOOTH OXIMETER.
12. OXIMETER USB CHARGER CABLE.
13. TBL-ABI USB CHARGER CABLES.
14. LEFT ANKLE BP.
15. RIGHT ANKLE BP.
16. ARM BP .
17. RIGHT ARM CUFF .
18. LARGE ARM CUFF .

OXIMETER

OXIMETER SETTINGS





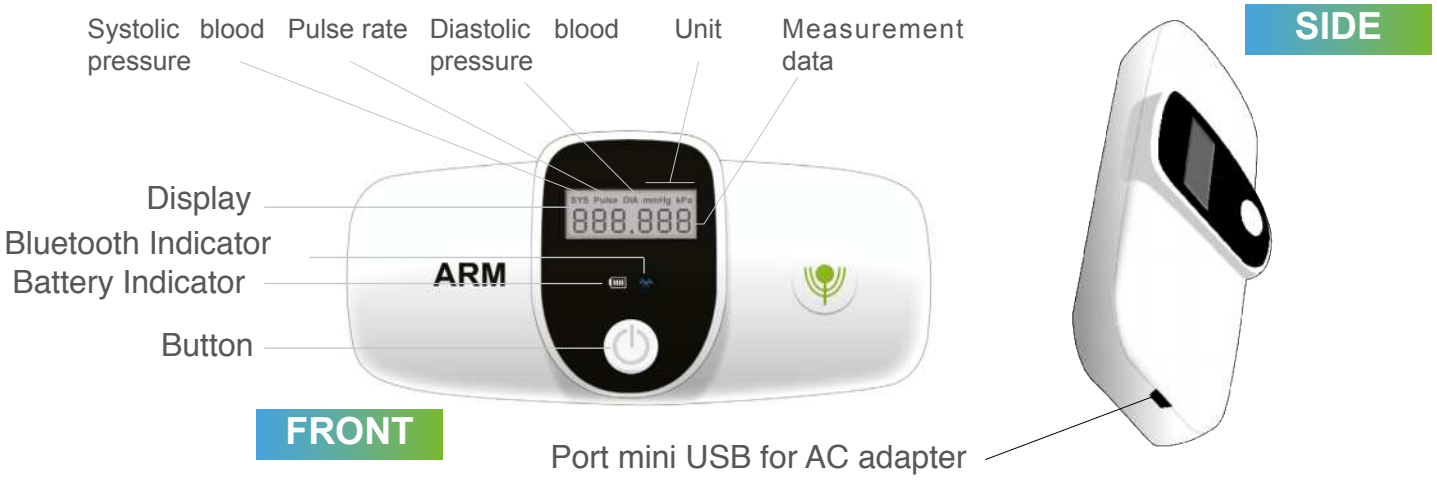
To start the oximeter, ***click*** on the white power button. If none finger is detected the oximeter will automatically shutdown in 5 seconds.

To keep the oximeter «ON» the index finger should be into the probe (the red light should be in contact with the nail).

The oximeter is setup to communicate with the software via Bluetooth communication.

BLOOD PRESSURE

BLUETOOTH BLOOD PRESSURE SETTINGS



Bluetooth indicator

- When the bluetooth icon flashes, it indicates that it is ready for connection.
- When the bluetooth icon light up, it indicates that the bluetooth is succesfully connected.

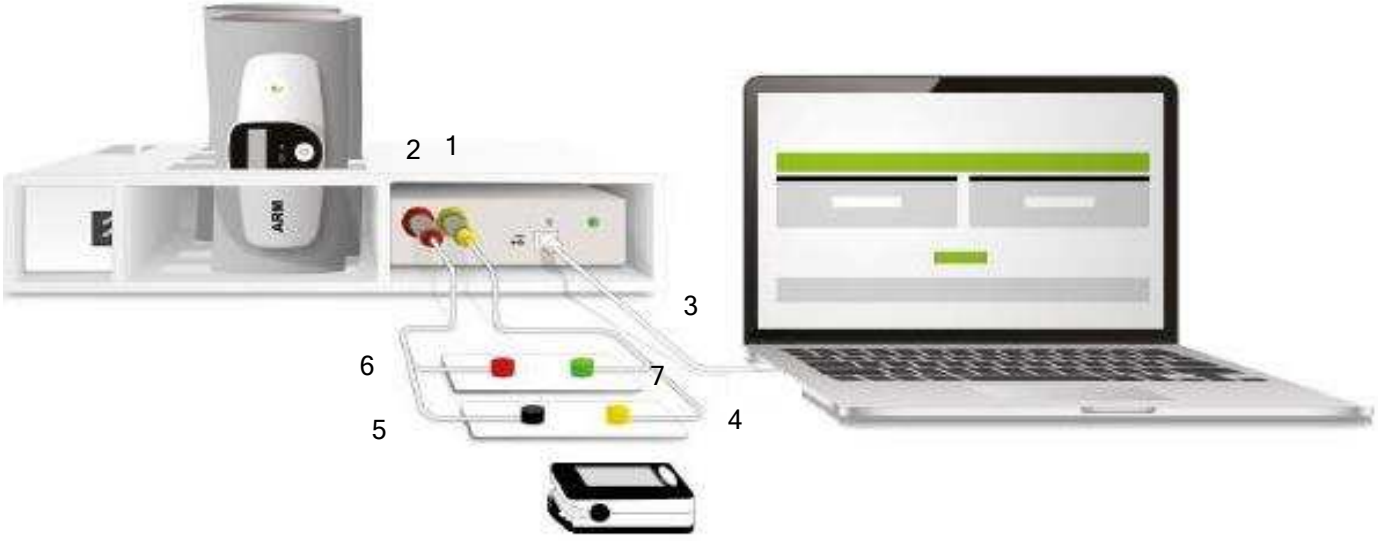
Battery indicator

- When the screen displays «***LOP***», it means the battery is not charged, Please charge it.

- When the «***-0-***» is flashing that means the battery is low.We recommend to charge the device before the measurement.

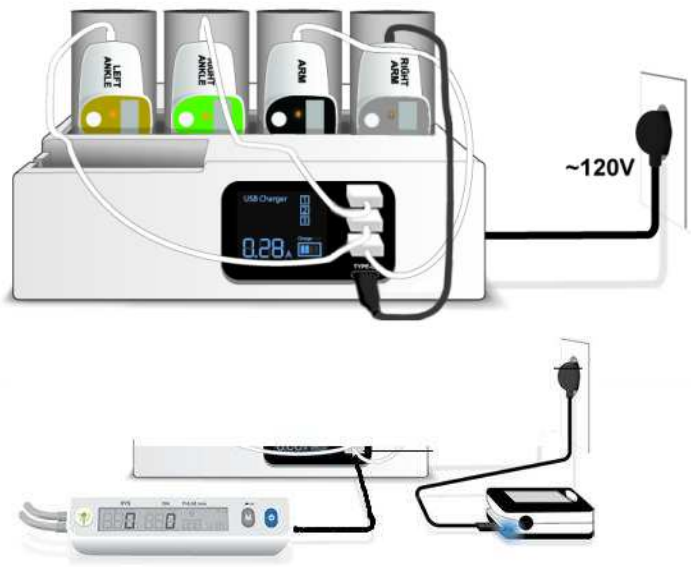
- During the charging process, the battery indicator is in orange. when the battery is fully charged, the battery indicator turns green.

TM-FLOW SETUP



1. Connect the yellow cable to the yellow SweatC port.
2. Connect the red cable to the red SweatC port.
3. Connect the USB SweatC cable to the PC USB port.
4. Connect the yellow snap to the right foot electrodes.
5. Connect the black snap to the right foot electrode.
6. Connect the red snap to the left foot electrode.
7. Connect the green snap to the left foot electrode.

CHARGING TBL-ABI AND OXIMETER



1. Plug the power cord from the USB charger to the outlet (120V).
2. Connect the white cable of each charger port of the black, gold and green blood pressure to the USB charger.
3. Connect the mini USB of the oximeter to the USB piece plug to the outlet (120V).
4. Connect the black cable of the charger port of the large cuff blood pressure to the USB charger.

When the Amps displays 0.00A, it means that the devices are fully charged and the USB charger stops to charge. therefore, there is no possibility of over charge.

UNDESIRABLE SIDE EFFECTS

When using the Sweat C, some patients may experience skin irritation or hypersensitivity due to the electrical stimulation of electrical conductive medium.

CONTRAINDICATIONS

GENERAL CONTRAINDICATIONS

- Patients undergoing external defibrillation.
- Patients connected to electronic life support devices, or any implanted electronic device such as Pacemaker or Insulin Pumps
- Bilateral mastectomy.

EMC - Do not use this device in the presence of:

- Magnetic resonance imaging (MR or MRI) equipment. MRI equipment may deliver induced current to the device.
- Strong electromagnetic sources, such as electro surgery equipment.
- Computed Tomography (CT) equipment.
- Floor made of carpeted material: a carpeted floor will increase the Electrostatic discharge and could cause the device to short out. A message will appear, and the measurement will stop (i.e. troubleshooting).
- Relative humidity < 30%: The low humidity will increase the Electrostatic discharge and could cause the device to short out. A message will appear, and the measurement will stop (i.e. troubleshooting).

Bluetooth interference - Do not use this device in the presence of:

- WIFI router at distance less than 10 feet and in the same room.
- Cellphones at distance less than 10 feet.
- Microwaves ovens, cables and connectors associated with satellite dishes, nearby power lines or power stations, cordless telephones , wireless speakers, some monitors and displays, cameras, baby monitors.

The distance between hardware and the computer must be less than 10 feet and in the same room

- Arterial catheters (access or therapy) on arm or leg or an arterio-venous (AV) fistula or shunt. The temporary interference of the blood flow could result in injury to the patient.
- Venous pulsations may cause erroneous reading in blood pressure (e.g. tricuspid valve regurgitation).
- Take caution with patients that have low perfusion. Using the blood pressure device may cause skin erosion and/or pressure necrosis.
- Dermatological lesions or calluses in contact with the electrodes , or excessive perspiration.
- Metal pins or prostheses on the level of the extremities or the joints.
- This device should not be used on pregnant women.
- An absence of one or more limbs.

DISCLAIMERS

The results of the exam must be considered with the clinical context of the patient's case history,symptoms,known diagnosis,current medications, treatment plan and therapies. Final interpretation of the exam is the sole responsibility of the practitioner.

Off label and investigational uses are related to the clinical studies (www.ldteck.com/studies) and comply with the 21 CFR 312.2 (b) (1).

WARNINGS

- Strengthen password protection is recommended when you set up your software.
- The oximeter probe shall not be placed on the finger of the arm with the blood pressure cuff.
- Don't use the blood pressure on the arm with arterial catheter, having an AV fistula or pressure dressing.
- Dyes introduced into the bloodstream, such as methylene blue, indocyanine green, indigo carmine, and fluorescein.
- Significant levels of dysfunctional hemoglobins, such as carboxyhemoglobin or methemoglobin, will affect the accuracy of the SpO2 measurement.
- Any condition that restricts blood flow, such as the use of a blood pressure cuff or extremes in systemic vascular resistance, may cause an inability to determine accurate pulse rate and SpO2 readings.
- Fingernail polish or false fingernails may cause inaccurate SpO2 readings.

Valsalva maneuver should not be performed on persons:

- Undergoing procedures with proliferative retinopathy.
- Systolic Blood pressure of 160mmHg or higher.
- Anyone who's had laser treatment for retinopathy within the past three months.

NOTE

- Galvanic skin response and habituation: There is a decrease of GSR amplitude observed after multiple electrical stimulations. It is not recommended to repeat the test before 20 minutes.
- The PC and/or other devices used and connected to the PC, should be in compliance with Standards IEC950 and/or UL1950. The labeling EC or UL in a computer will indicate the compliance to these standards. The use of a computer not in compliance with its standards could damage the hardware and provoke a breakdown.
- In case of a breakdown never open the hardware and/or try to repair it. LD TECHNOLOGY does not guarantee the safety and effectiveness of the device in the event of use with other accessories.
- The SweatC, TBL-ABI and Oximeter hardware are not sterile: Do not autoclave; do not use Ethylene Oxide sterilization or immersing the device and the accessories in liquid. The carrying case foam liner cannot be disinfected.

- Using a damaged patient cable may cause inaccurate readings. If the patient cable appears damaged, do not use it and contact the manufacturer.
- An incorrectly applied blood pressure cuff placement may give inaccurate readings.
- Do not use this device in the presence of flammable anesthetics. Spark hazards exist which may cause an explosion.
- Review the blood pressure cuff placement instructions below for proper application.
- The device cannot be stored in the carrying case. It should be stored in a clean, dry and disinfected area before use on any patient.
- Before shipping the hardware back to the manufacturer for repairs or calibration, the user must disconnect the cables and electrodes, disinfect the device and accessories prior to placing them in the return case.
- This device is intended for use by persons trained in professional health care. The operator must be thoroughly familiar with the information in this manual before using the device.
- If the systolic pressure is < 30 or > 255 mmHg or diastolic pressure < 15 or > 220 mmHg, the software will display an error message and will stop the measurement.
- Any blood pressure recording can be affected by the position of the subject, his or her physiologic condition and other factors.

Taking the blood pressure measurement:

- Less than 1 hour after meals.
- After exercise or sporting activity.
- After drinking alcohol or coffee.
- After bathing.
- Less than 1 hour after smoking.

Factors during Readings:

- Something as simple as moving the arm while blood pressure is being taken can affect the reading. If the sleeves of a shirt fit too tightly over the cuff or if the cuff size is wrong, the readings could be inaccurate.
- White-coat hypertension (anxiety).
- When the blood pressure reading is being taken, patient should be lying in a comfortable position.
- The accuracy of the blood pressure device should be verified and we recommend that a calibration is performed as per the manufacturer guidance.
- The blood pressure device might not meet its performance specifications if stored or used outside of the temperature and humidity range.
- Cardiac arrhythmia may cause an irregular heartbeat and may increase the blood pressure measurement time.
- If the patient is on a heart-lung machine, the blood pressure measurement may be inaccurate.
- Rapid pressure changes may inaccurate blood pressure readings.
- Severe shock or hypothermia may give unreliable blood pressure and oximeter results since reduced blood flow to the peripheries will reduce pulsation of arteries.

- Hazards arising from the Bluetooth connection which compromised device functionality have been minimized. Risk management was performed to meet ISO 14971:2012.
- Hazards arising from the Cybersecurity have been minimized. Risk management was performed to meet ISO 14971:2012.

INSTALLING THE SETUP PROGRAM

LD Technology sends a secure link (Setup) by email for installing the software.

Click on «***TM-FLOW Setup***» and then follow the indications. The software will be automatically installed and at the end of the process.

Click on the «***TM-FLOW***» icon on your desktop to open the software.

SOFTWARE ACTIVATION

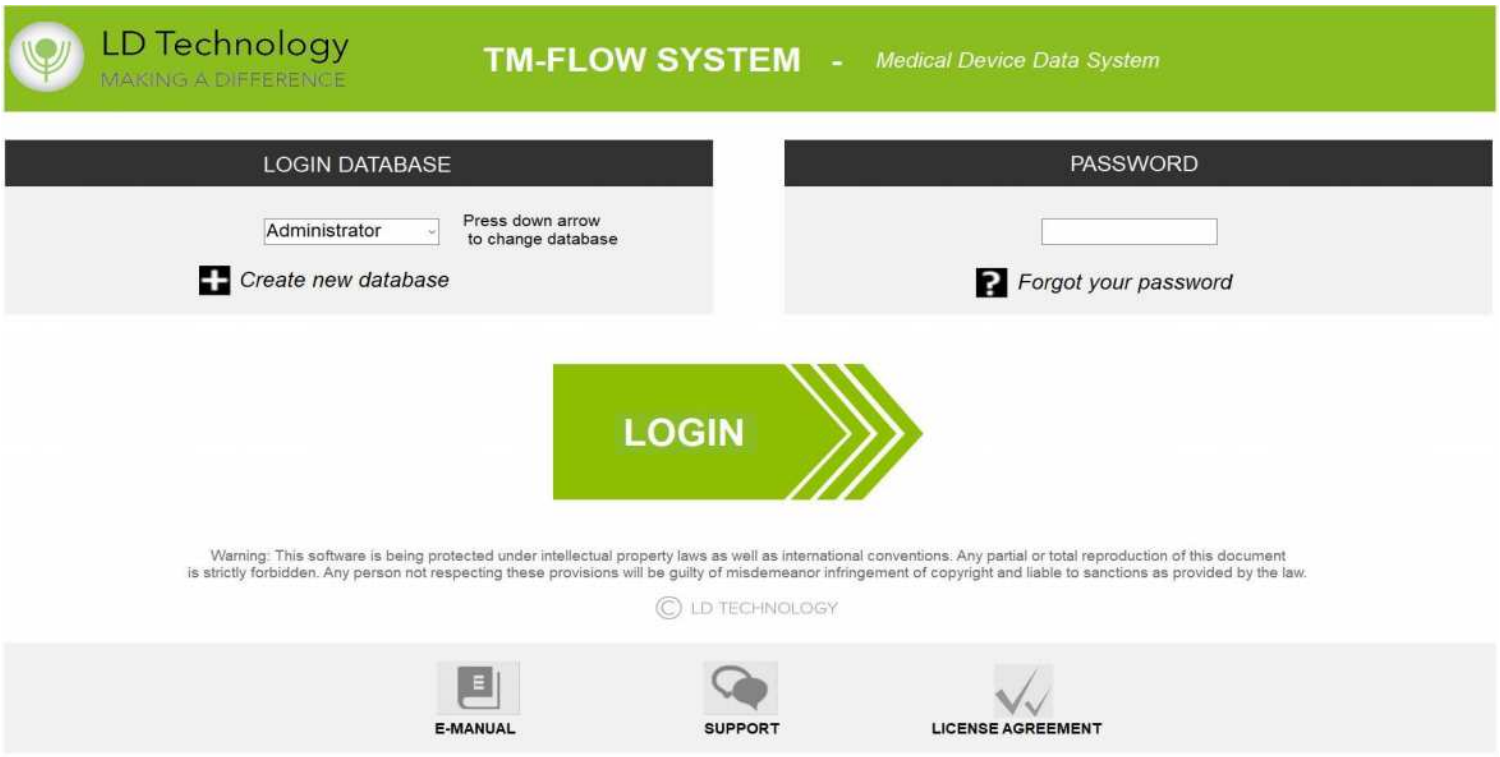
FIRST TIME SOFTWARE ACTIVATION

At the end of the setup window opens with the software code number.
Call the technical support +1 305 3799900
in order to get your activation Pin code .

PRESENTATION OF THE SOFTWARE

LOGIN PAGE

Starting and becoming familiarized with the TM-FLOW Software.
Click on the TM-Flow icon on your desktop to access the software. This will bring up the TM-FLOW home screen.
Here you can log into your patient database, create a new patient database, create a password, view your contract, view your license agrement, consult the E-Manual and contact the online technical support.



HOME SCREEN

The login page contains seven fields and buttons:

THE TOOL PANEL

The tool panel contains different tools available to the users. You can access to:

EMANUAL:
The eManual: opens the eManual in PDF format.

SUPPORT:
The Teamviewer quick support windows opens with ID and password.

LICENCE AGREEMENT:
The software licence agreement opens with the terms and conditions of the contract between the manufacturer and the users.

LOGIN TO DATABASE

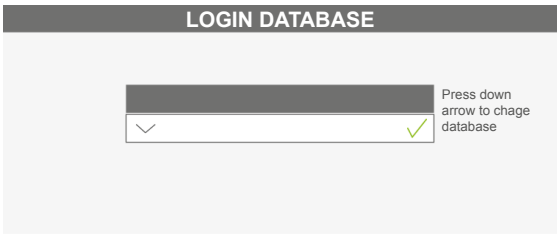
By default the Database Login name is Administrator.
The Database Login on the main panel of the home screen contains seven fields and buttons:

Forgot your password
Change your password

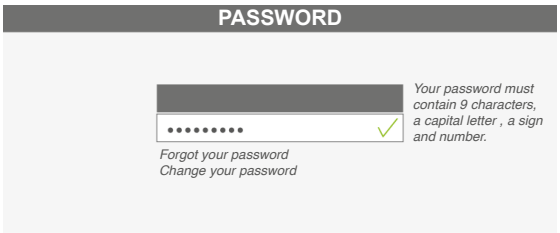
FORGOT YOUR PASSWORD BUTTON:
If you ever forget or change the password to one of your databases, this button will allow you to contact technical support.

+ Create new database

+ CREATE NEW DATABASE BUTTON:
If you would like to create a new database, clicking this button will prompt you to enter a database name.

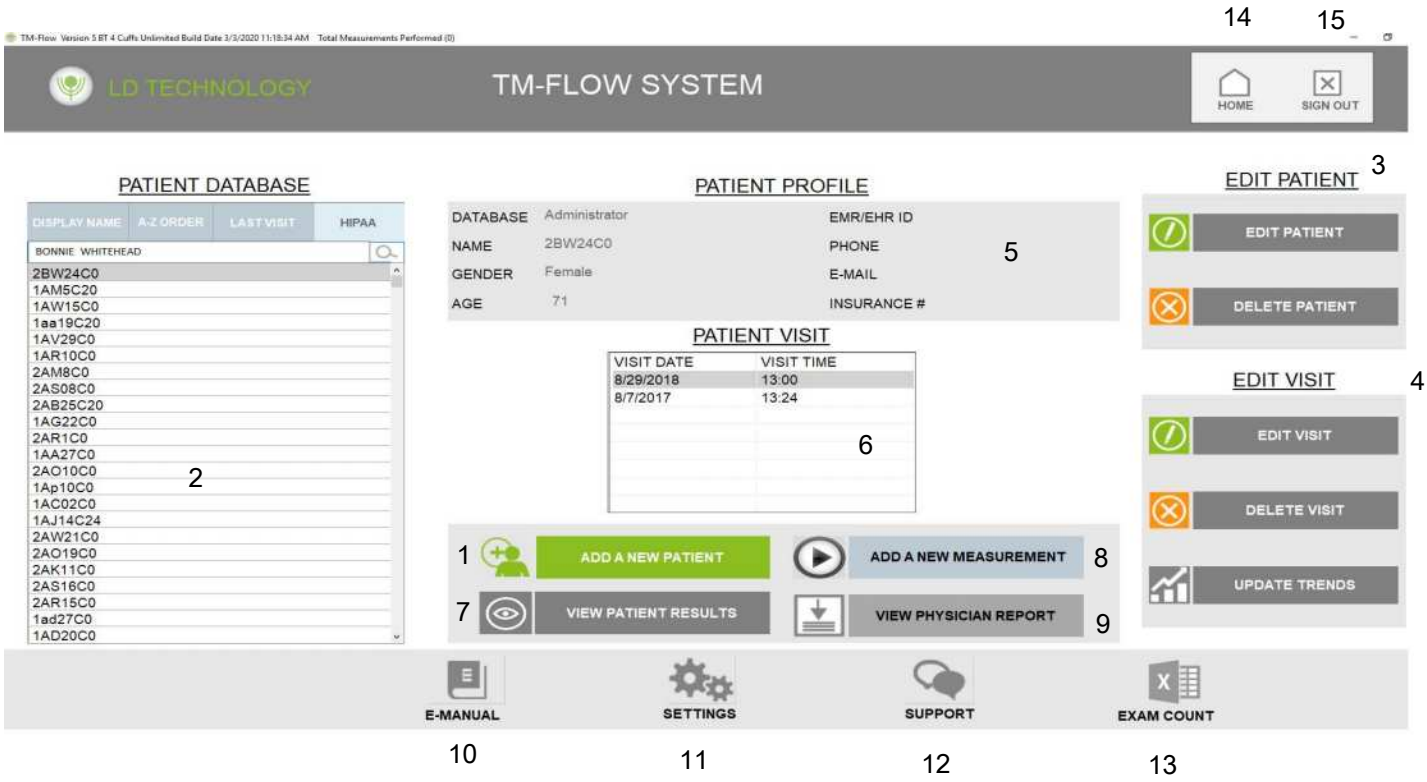


THE DATABASE LOGIN:
In the database field, select the patient database you would like to open from the dropdown box.



CREATE YOUR PASSWORD :
Your password must contain 9 characters, a capital letter, sign and number. Your password will be refused if it doesn't match to the requirements.
Pressing the button «***START***» will take you to the database dashboard screen.

DATABASE DASHBOARD



NOTE

Results and patient report buttons can be used only if a patient name and visit have been selected, otherwise the following error message will appear: "***Please select a patient and visit***".

1. Add a new patient.
2. Patient database.
3. Edit Patient.
4. Edit Visit.
5. Patient profile.
6. Patient visit.
7. View results.
8. Add a new measurement.
9. View Physician report
10. E-manual.
11. Settings
12. Support.
13. Exam count.
14. Sign out (closing the software).
15. Home (returning to the login page).

THE TOOL PANEL

The Tool Panel now has four new buttons in addition to the ones we previously introduced. These five buttons are as follows:

HOME

HOME BUTTON:
Log you out of the current database and returns you to the home screen.

SIGN OUT

SIGN OUT BUTTON:
Log you out to windows.

SETTINGS

SETTINGS:
Clicking on this button will take you to the settings dashboard.
Please see the settings section for further details.

EXAM COUNT

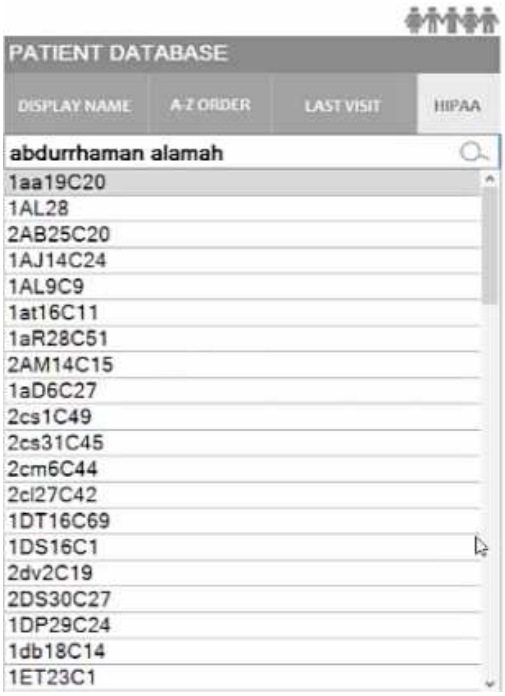
EXPORT DATA TO EXCEL:
You can export patient measurement information to Excel, which can be done by clicking on the measurements performed checkbox and pressing the button. All patient name and measurements date will be exported to Excel.

THE DATABASE PANEL

- The database dashboard is split into three separate panels: The database panel, the patient management panel, and the database management panel.

- Each panel contains buttons to easily organize your patient database, edit your patient database, add to your patient database, and select patient visits to view their visit records.

- The Database panel contains all of your patients stored in the current database. Each selected patient's visits will appear in in the visit box (on the right-hand side of the following image).



• Double clicking on a patient will open the currently selected visit test results. Please reference viewing patient results instructions for further details.

• Double clicking on a specific visit will open the visit test results.

THE DATABASE MANAGEMENT PANEL

DISPLAY NAME

DISPLAY NAME BUTTON:
Displays the patient name.

A-Z ORDER

A-Z ORDER BUTTON:
Clicking on the sort «***A-Z ORDER***» button will sort your patient database list in alphabetical order.

LAST VISIT

LAST VISIT BUTTON:
Clicking on the «***LAST VISIT***» button will sort your patient database by organizing the patients with the most recent visit at the top of the patient database list.

HIPAA

HIPAA BUTTON:
Clicking on the «***HIPAA***» button will encrypt your patient database list to comply with HIPAA regulations.

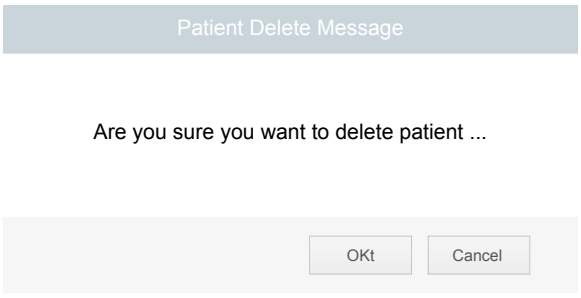
THE PATIENT MANAGEMENT PANEL


EDIT PATIENT

EDIT PATIENT BUTTON:
The «***EDIT PATIENT***» button will allow you to change general patient information. This will open the Patient Data form where you can input changes.


DELETE PATIENT

DELETE PATIENT BUTTON:
The «***DELETE PATIENT***» button will allow you to delete a patient from your database, and will bring up the following message. Click on «***OK***» to confirm.



THE VISIT MANAGEMENT TOOLBOX


PATIENT VIEW REPORT

VIEW PATIENT REPORT BUTTON:
The «***PATIENT VIEW REPORT***» button will open the status report of the patient corresponding to

EDIT VISIT BUTTON:
The «***EDIT VISIT***» button will edit the currently selected visit. Please refer to adding a visit instructions for further information on how the visit information should be entered.

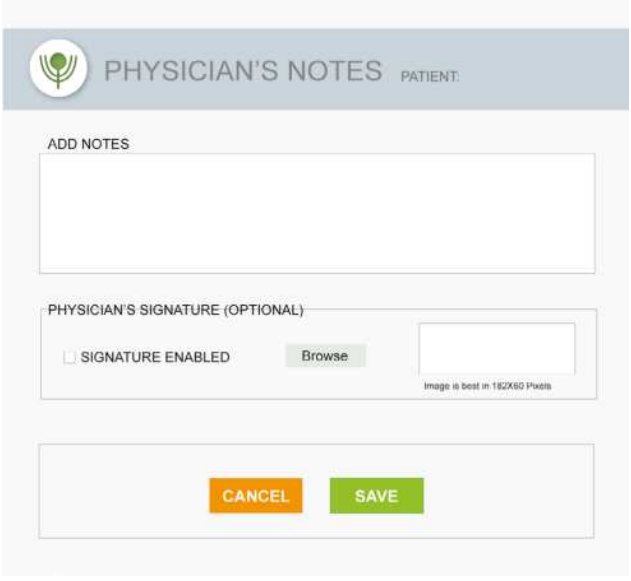
DELETE VISIT BUTTON:
The «***DELETE VISIT***» button will delete the currently selected patient visit. However, if only one patient visit exists, this button is inactive. You will have to click on «***DELETE PATIENT***» in order to clear the patient visit and re-enter patient information on the Patient Data form.

ADD PHYSICIAN NOTES BUTTON:
The «***ADD PHYSICIAN NOTES***» form allows you to create notes for the current patient. The notes and optional uploaded signature wil be reported in the patient report.

THE PATIENT MANAGEMENT TOOLBOX:

«***+ADD A NEW MEASUREMENT***» button will allow you to conduct a new measurement for the currently selected patient and bring you to the Visit form. Please refer to adding a visit instruction for further details.

«***VIEW RESULT***» button will allow you to view the test results for the currently selected patient visit. Please refer to viewing patient results instructions for further details.



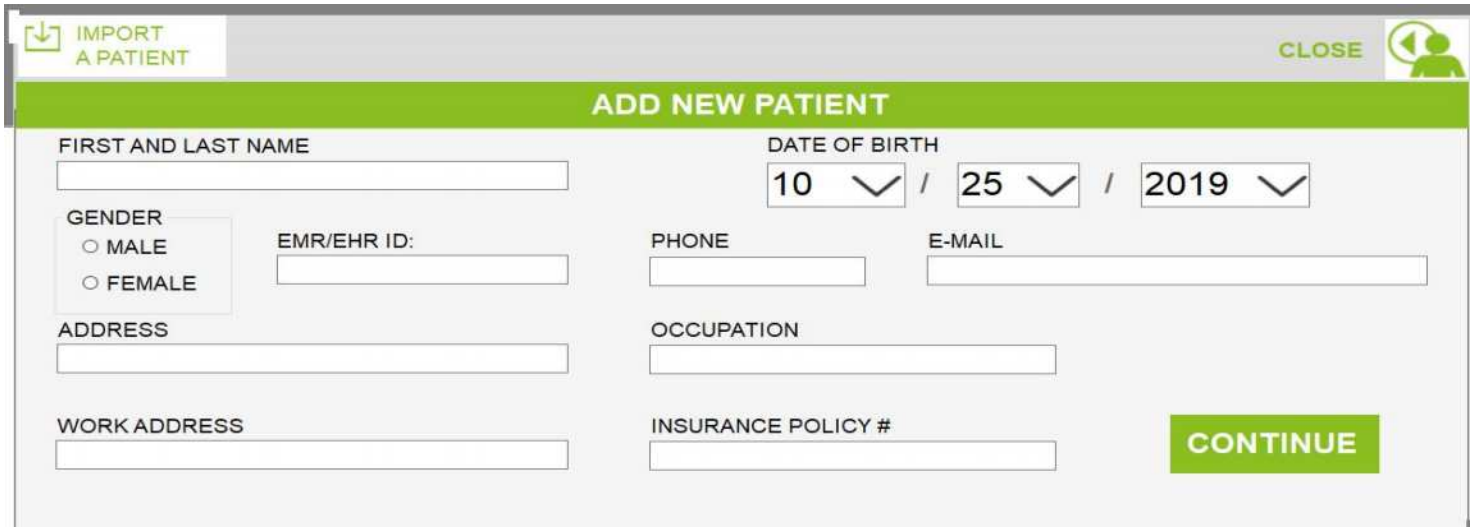
NOTE

The physician notes form allows you to create notes for the current patient clinical context along with practitioner notes, and allows you to upload additional laboratory tests for the currently selected visit.

Clicking the «***OK***» button will save the notes.

Clicking the «***CANCEL***» button will dispose of any note added.

PATIENT REGISTRATION

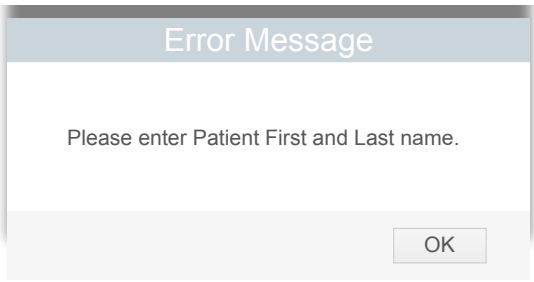


ADD A NEW PATIENT MENU:
To add a new patient to your database, complete the patient information. Once clicked on the save button, it will direct you to the visit form.

IMPORT A PATIENT BUTTON:
To add a new patient from another database, click on the icon, a window opens, select the patient name and then click on «***Ok***».

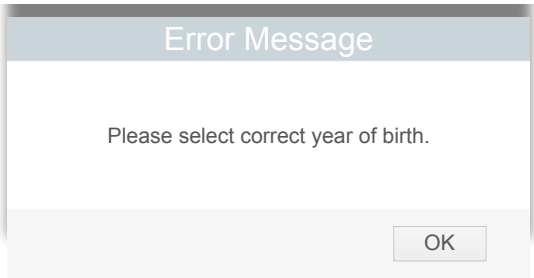
None of the other elds on this form are mandatory, but may be helpful in patient record keeping.

By clicking on the button «***CONTINUE***», you will be taken to the Visit form for further patient medical examination information. Please see adding a visit instructions for further details.

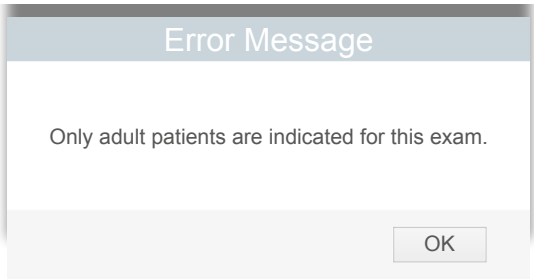


You will be prompted to enter the patient demographic information. If not entered, or entered incorrectly, you will receive the following error messages:

This error message will appear if you have not entered the first and last name of the patient OR if you have entered a first name, but not a last name or vice versa.



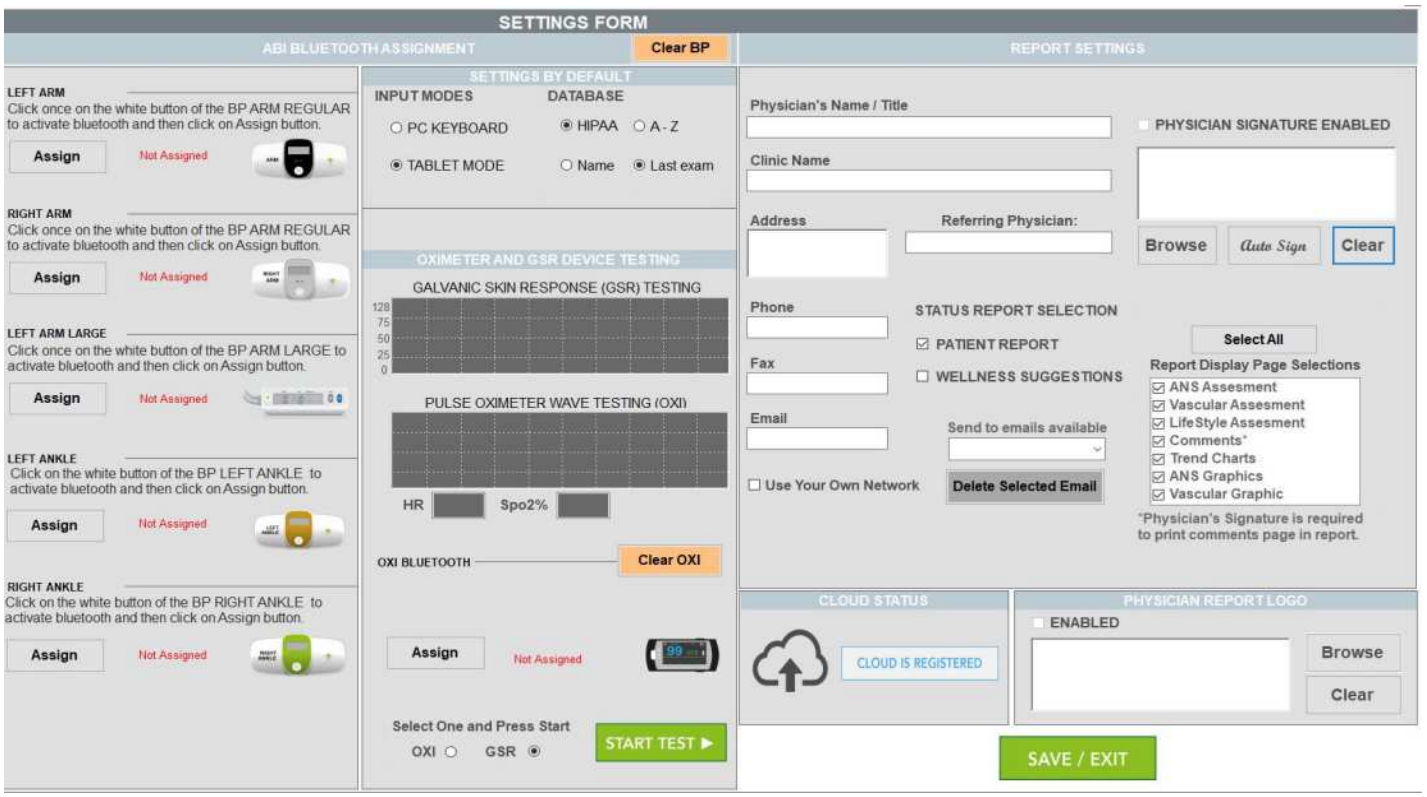
This error message will appear if the date of birth entered is not a possible date of birth (within the same year of current date).



This error message will appear if the age of the patient is not compatible with the indications of use.

SETTINGS

SETTINGS:
Click on the «***SETTINGS***» Button to open the Setting options.
It is possible to check the proper connection of the device.
In this window, click on different options to select your settings by default and customize your status report by clicking on «***STATUS REPORT***» management.



PAIRING, ASSIGNING AND TESTING OXIMETER

PAIRING : On the Settings Dashboard you have to pair and assign the oximeter. Insert your finger into the oximeter and click on the white button. Wait for the wave displays on the oximeter screen.
Then, click on "Assign". When the device is successfully assigned , a number appears on the top.

TESTING: To ensure the pulse oximeter device is functioning correctly.

To test the pulse oximeter, make sure the «***OXI***» check box is selected.

Press «***Start***» to proceed. The pulse waveform should appear on your screen in the pulse oximeter wave testing box.

TESTING SWEATC (GSR)

To test the galvanic skin response device, make sure the «GSR» check box is selected.

Press «***Start***» to proceed.The galvanic skin response data should appear on your screen in the GSR Testing box.

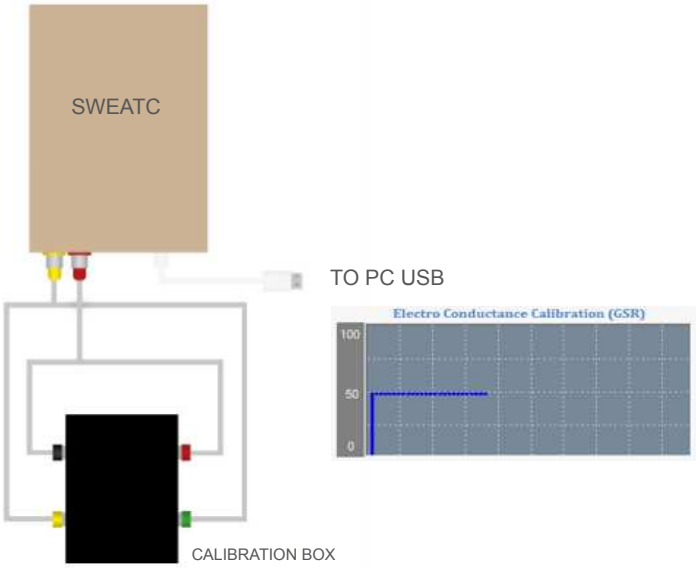
CALIBRATION

The SweatC hardware can be tested in office using a calibration box included in the package.

PROCEDURE OF SWEATC CALIBRATION:

Connect the red and green snaps on the left connectors of the calibration box and the black and yellow snaps on the right of the calibration box.**The measurement shall be 50** (Tolerance values +/- 2).

If either number is over or under, please contact technical support contact@ldteck.com.



OXIMETER AND TBL-ABI CALIBRATION

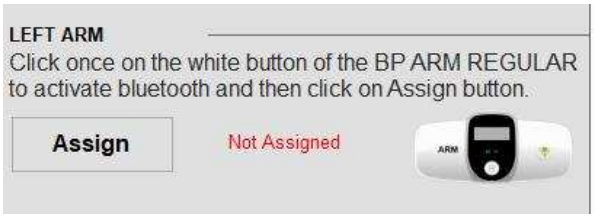
Oximeter and TBL-ABI blood pressure are warranty for 2-year calibration and must be returned to the manufacturer. If the user accepted the maintenance extend warranty (2 year payment of $800), the devices will be exchanged. Otherwise, the devices will be calibrated and returned to the user for $800.

TBL-ABI ASSINGING BLEUTOOTH

Click on the Settings Button to open the Setting options.

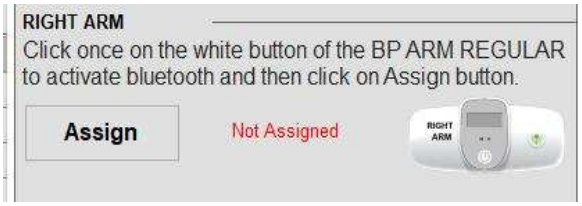
Make sure only one TBL-ABI turn on at the time.

STEP 1



- Click once on the white button of the black cover device and click on tab "***Assign***" of the Bluetooth #1
- The red sentence "**LEFT *ARM Not Assigned***" will change by a green sentence "**LEFT *ARM is Assigned "***

STEP 2



- Click once on the white button of the black cover device and click on tab "***Assign***" of the Bluetooth #1

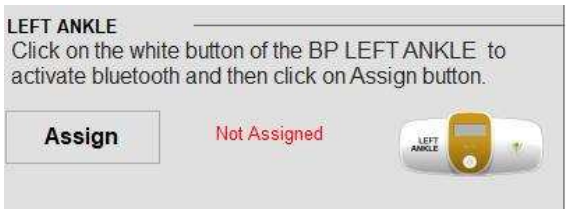
- The red sentence "**RIGHT*ARM Not Assigned***" will change by a green sentence " **RIGHT *ARM*** is ***Assigned*** ".

STEP 3

- Click once on the blue button of the Large cuff device and click on tab "***Assign***" of the Bluetooth #1L.

- The red sentence "***LARGE ARM CUFF Not Assigned***" will change by a green sentence "***LARGE ARM CUFF is Assigned***".

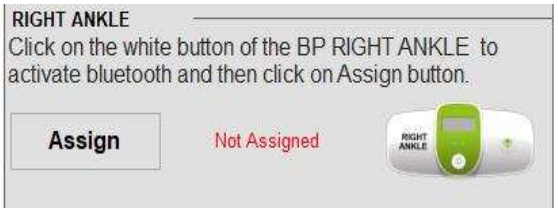
STEP 4



- Click once on the white button of the gold cover device ABI and click on tab "***Assign***" of the Bluetooth #2.

- The red sentence "***LEFT ANKLE Not Assigned***" will change by a green sentence "***LEFT ANKLE is Assigned***".

STEP 5



- Click one time on the white button of the green cover device and click on tab "***Assign***" of the Bluetooth #2.

- The red sentence "***RIGHT ANKLE Not Assigned***" will change by a green sentence "***RIGHT ANKLE is Assigned***"

5.When the 5 devices have been assigned, click on "***SAVE***" button.

6.Testing the correct assignment of all the cuffs: select the regular or large cuffs and follow the procedure..

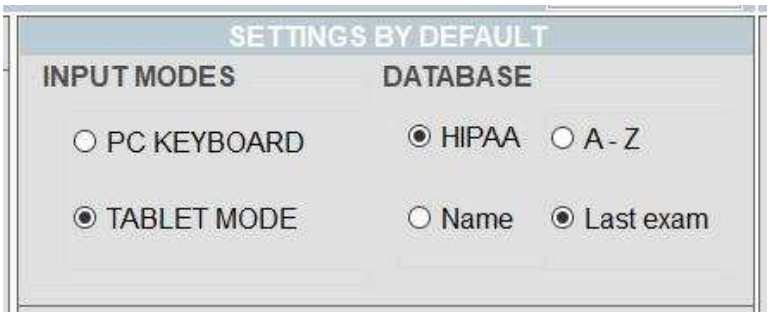
CHANGING THE DEFAULT UNITS

On the Settings Dashboard you can change the input modes and database management used throughout the software by checking the corresponding box in the settings by default panel as follows:

CHANGING THE DEFAULT DATABASE LIST ORGANIZATION.

You can change the default appearance of the patient database list by switching between code and name as seen in the following panel.

Choosing the code selection will ensure compliance with HIPAA regulations by encrypting patient data. Choosing the name selection will display the patient database items by first and last name.



Additionally, you can change the default organization of the patient database list by switching between the A-Z or Last exam selection in the following panel.

Choosing the A-Z selection will organize the patient database list in alphabetical order.

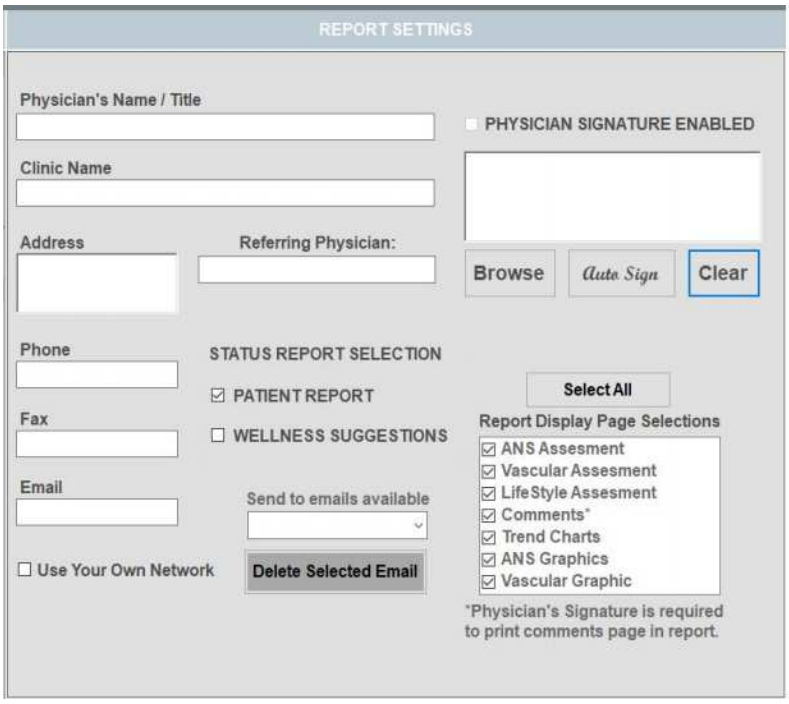
Choosing the Last exam selection will organize the patient database list by order of patients with the most recent examination dates.

CHANGING THE INPUT MODE

Just select PC Keyboard or Tablet mode.

CHANGING THE DEFAULT STATUS REPORT CONFIGURATION AND SETTINGS

On the Settings Dashboard, you can change the status report settings.



The Status Report Management form allows you to change the configuration of printed status reports.

- You can add the Physician's Name and Title, Referral, Personnel reviewed, Phone Number, Fax, Email, Name of Practice, Address and enable your signature and logo.

- Select your status report by default: Patient report, wellness suggestions or physician report. The physician report can be customized by selecting the pages you wish to print.

Networks Options

- Server or EMR Network.

NOTE

Select «***Use a Network***». Check the box and then click on «***Network Credentials***». This window will open. Fill the requested directory for your server or EMR and then click on «***Save***».

- Secure cloud access.

NOTE

If you are registered , your cloud is activated. Select "Send to the cloud" when you print the report. A secure server page located in the web site www.ldteck.com, will allow to you to access from a smart phone or computer to access to your patient reports.

THE HARDWARE AND ACCESSORIES ARE NOT STERILE
Do not autoclave.
Do not use Ethylene oxide sterilization or immersing the devices and/or the accessories in liquid.

INSTRUCTIONS TO CARRY OUT PREVENTIVE MAINTENANCE AND MAINTENANCE FREQUENCY

CLEANING / INFECTION CONTROL PROCEDURE.

The oximeter probe, cuffs, manometer outputs and cables should undergo cleaning and low-level disinfection prior to their first use and between each patient.

Unplug the USB port connection before cleaning or disinfecting.
The instructions for reprocessing the TM-Flow system reusable parts in contact with the intact skin of the patient:

- Oximeter probe
- Blood pressure cuffs.

Reprocessing has been validated according to the published method: Rutala, W.A., Weber D. J., & HICPAC. (2008). Guideline for Disinfection and Sterilization in Healthcare Facilities (2008). Atlanta, GA: Centers for Disease Control).

The system includes a reusable oximeter probe and blood pressure cuffs which contact intact skin of the patient's left arm and ankles and the right index finger, and per the Spaulding classification they are "noncritical items". Low-level disinfectants could be used for noncritical items. The low level disinfectants are listed in Environmental Protection Agency (EPA): http://www.epa.gov/.

We recommend after testing, the control of residues:

- Wipes with Ethyl or isopropyl alcohol (70-90%) for cleaning and disinfecting the reusable oximeters and cuff.

- Wipes with Ethyl or isopropyl alcohol (70-90%) could be used as well for the oximeter probes, blood pressure cuffs, electronic box, SweatC cables, computer, keyboard and mouse (surfaces environment).

The carrying case and the foam liner cannot be disinfected.

Do not use Sodium hypochlorite (5.25-6.15% household bleach diluted 1:500).

Do not use caustic or abrasive cleaning agents.

The carrying case cannot be used for storage of the device and accessories

The device and accessories should be stored in any clean area and need to be disinfected prior to being used on the patient.

TAKING A MEASUREMENT

ALL THE FOLLOWING STEPS SHOULD BE TAKEN.

PRECAUTIONS

BE AWARE OF CONTRAINDICATIONS, WARNINGS, CAUTIONS AND NOTES.

- The device, cables and cuffs must be cleaned/disinfected and then air dried. The procedure must be performed before each patient.
- The exam area should be comfortable and free of drafts and portable electric heaters. The ambient temperature should be between 70-73 degree F (21-23 degree C).
- The measurement is carried out with the patient in a lying or reclined position, the feet should be supported at the horizontal position.
- The right index finger must be free of fingernail polish or false fingernails.
- The arm cuff will be placed on the left arm and oximeter on the right index finger. Do not place the arm cuff on the same side extremity with the oximeter during measurement.
- Do not place the pressure cuff in the same arm if a catheter or intravenous infusion is in place.

To ensure a reliable reading follow these recommendations:

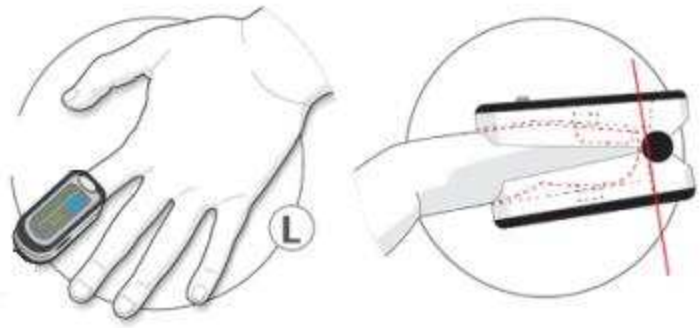
- Avoid eating, drinking alcohol, smoking, exercising, and bathing 1 hour prior to taking a measurement. Rest for at least 15 minutes prior to taking the measurement.
- Stress raises blood pressure. Avoid taking measurements during stressful times.
- Measurements should be taken in a quiet place.
- Remove tight-fitting clothing from the arm.
- Patient is to remain still and not talk during the measurement.

OXIMETER PLACEMENT

The oximeter shall be placed on the left index finger.

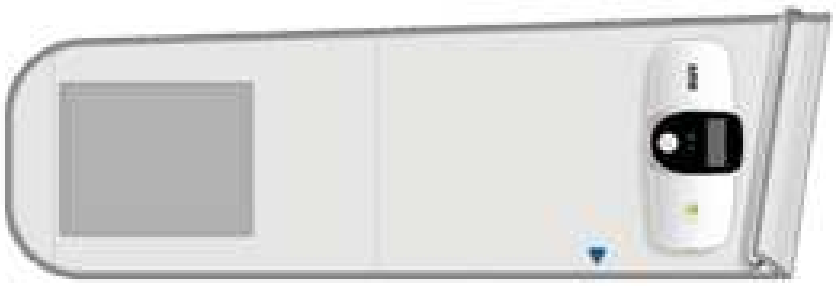
Do not allow the patient to shake their index finger, and ensure that patient is relaxed and in a stable state during the measurement process.

The data can be read directly from the screen on the measuring interface.



CUFF PLACEMENT

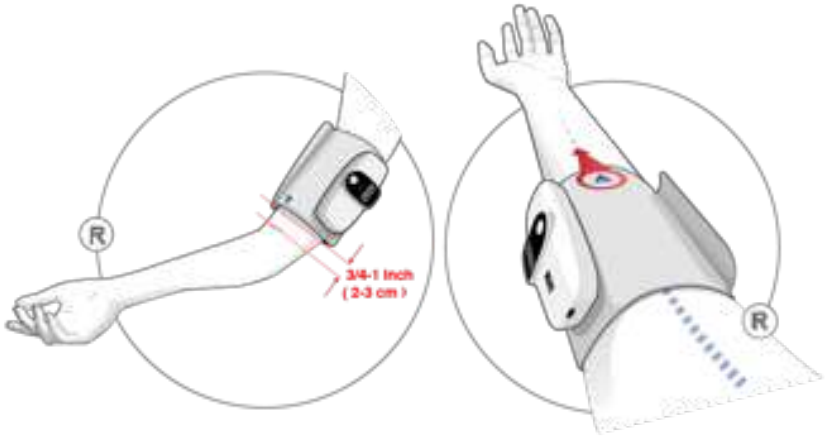
PREPARING OF THE CUFFS



Applicable arm circumference: 22cm-32cm.

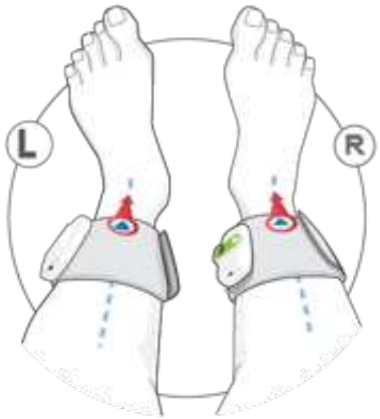
Setup the cuff as shown in the image.

ARM BLUETOOTH BLOOD PRESSURE



Place the cuffs on the left and right upper Arm (Box labelled “ARM” and "RIGHT ARM"),

LEFT AND RIGHT ANKLE BLUETOOTH BLOOD PRESSURE



The lower left Leg (box labelled “***LEFT ANKLE***”), and the lower right Leg (box labelled “***RIGHT ANKLE***”). Observe the following color markings: Black > left or right upper Arm, Yellow/Gold > lower left Leg, Green > lower right Leg. Place the cuffs so that there is a finger’s width of room between the limb and the cuff. The cuffs must be placed according to the artery label (Blue Arrow labelled “***DOWN***”). When placing the cuff observe the image below.

SWEATC ELECTRODES PLACEMENT

To fix the electrodes on the sole of the feet with the maximal contact with the skin:

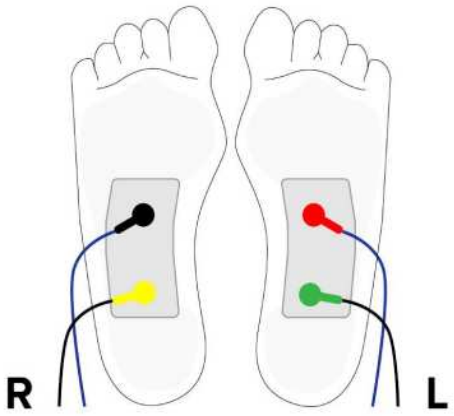
SweatC electrodes are single use.

The yellow cable connected to the left box output of the box will be connected as follow:

- Yellow snap on the right electrode.
- Green snap on the left electrode.

The red cable connected to the right output of the box will be connected as follow:

- Red snap on the left electrode.
- Black snap on the right electrode.



NOTE | Insert the cable snaps to electrode pads on a hard surface (i.e. table) prior to placing the pads onto the patient's skin.

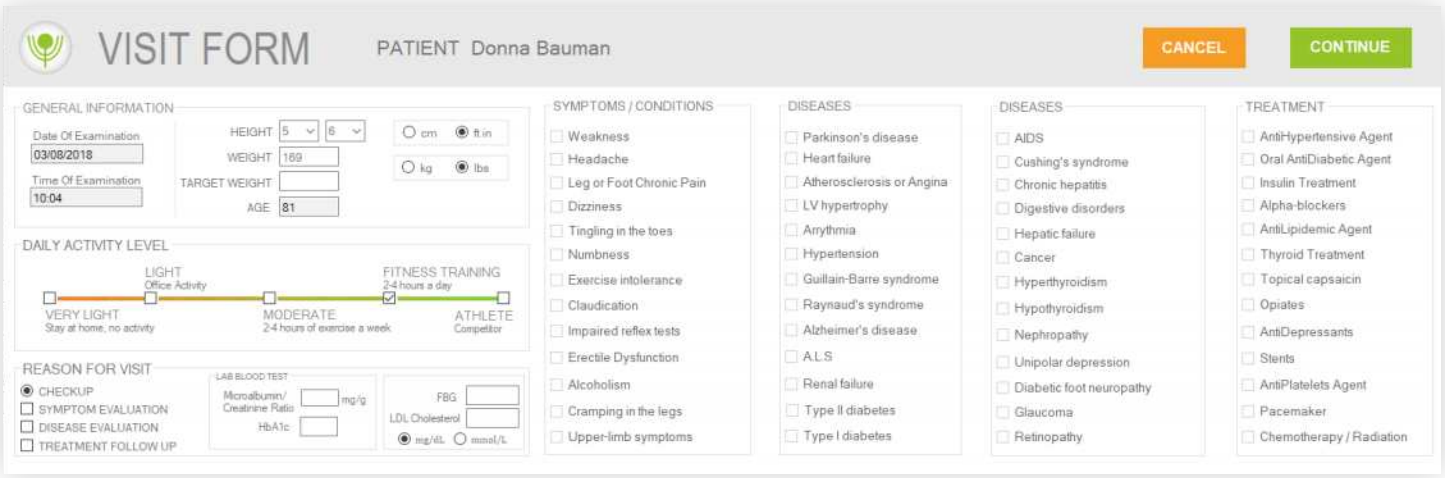
ADDING A VISIT

1. You can add a new visit by clicking on «***Continue***» (If the patent is already registered in the database).

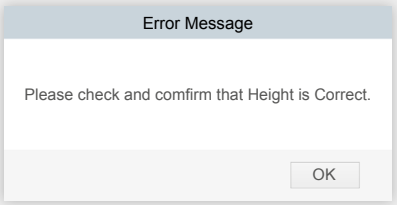
2. Once clicked, this tab will direct you to the Visit form.

The «***ADD A NEW MEASUREMENT***» tab will allow you to add a visit for the currently selected patient.

Be careful to check time and date of your Windows operating system.
The time and date of the visit will be automatically corresponding with your operating system.
Enter patient's weight (Kg or Pounds) and Height (Centimeter or Foot: choose in the window "***Setting***"). It is optional to complete the patient clinical context, and then click on «***OK***».



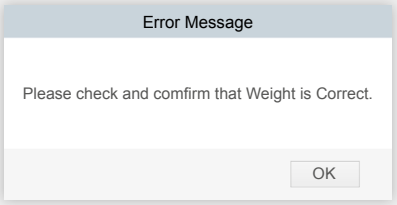
SEVERAL ERROR MESSAGES MAY APPEAR IF PATIENT INFORMATION IS ENTERED INCORRECTLY:



This error message will appear if the height is not entered correctly (both in Feet and in Inches, or only in Centimeters depending on which option has been selected).

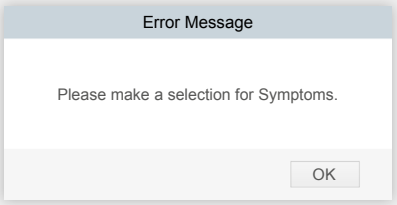
NOTE

The software will automatically convert between Feet and Inches to Centimeters depending on which option is selected.

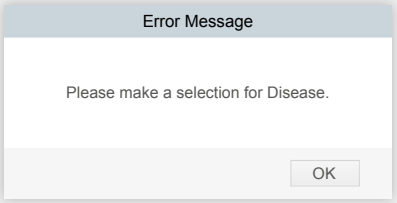


This error message will appear if no weight or an incorrect weight (<20Lbs ~ 9 Kg) has been entered.

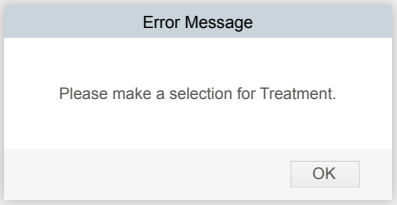
In order to select symptoms/conditions, diseases or treatments, the corresponding Reason for Visit checkboxes must be indicated.



This error message will appear if the symptom evaluation checkbox is selected, but no specific symptoms/conditions have been selected.



This error message will appear if the disease evaluation checkbox is selected, but no specific diseases have been selected.



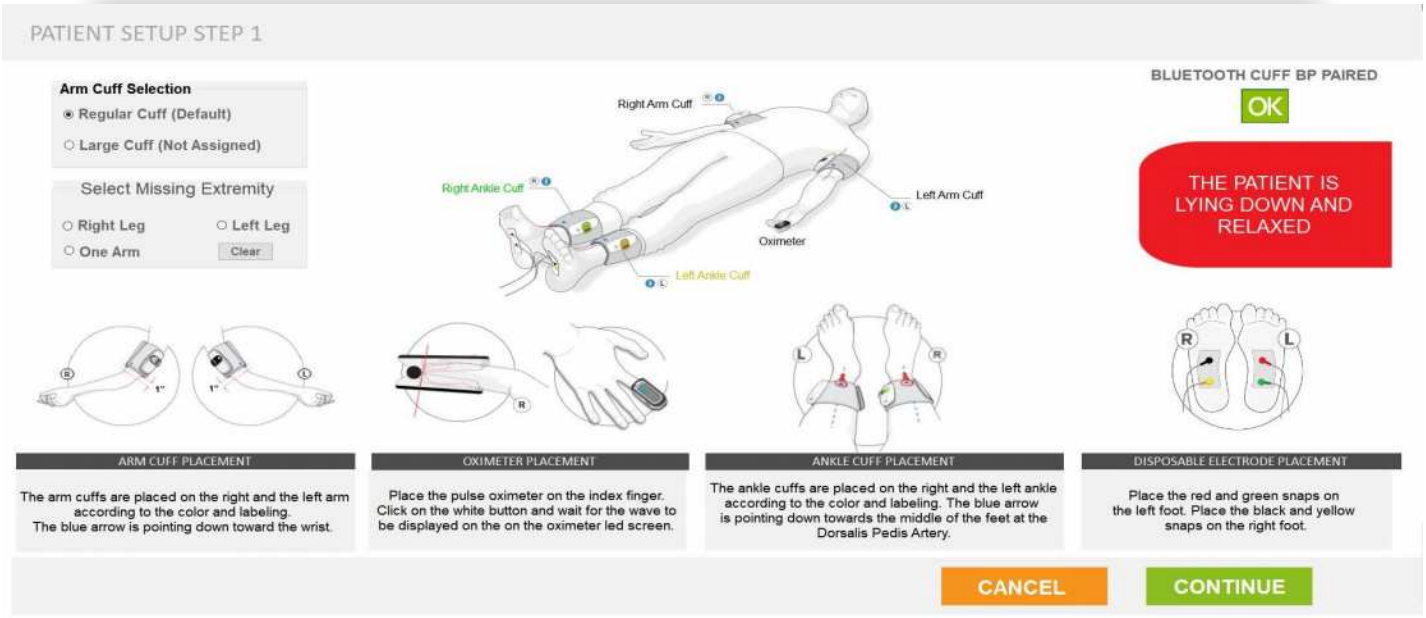
This error message will appear if the treatment follow up checkbox is selected, but no specific treatments have been selected.

By clicking on the «***Continue***» buton, you will be taken to the «***Patient Setup Steps***» window. Please refer to taking a measurment instructions for futher details.

START A MEASUREMENT

MEASUREMENT STEPS

THE FIRST SCREEN YOU WILL BE TAKEN TO IS THE PATIENT SETUP.



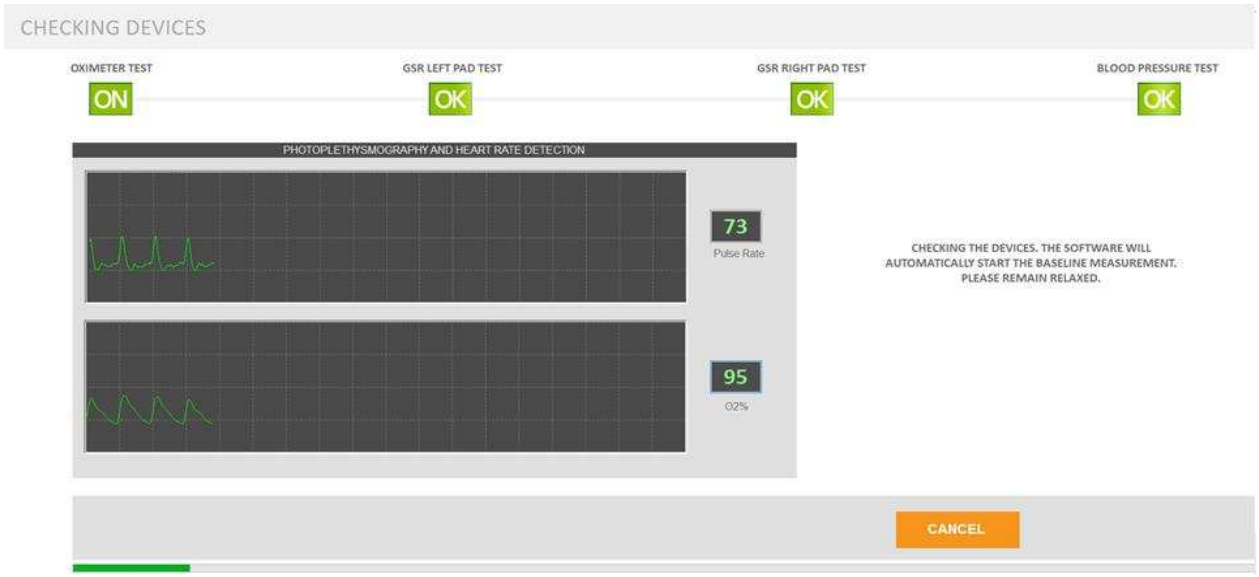
NOTE

Please select your right size cuff and / or there is a missing extremity for your patient before to click on «***CONTINUE***».

NOTE

Before to click on start, be sure that you click on the oximeter white button and check on the oximeter LED that the wave is display as well the SpO2 % and the Pulse rate.

CHECKING DEVICES



During the checking, SpO2% and pulse rate and photoplethysmography will display and update regularly and the progress bar will display how far along in the measurement you are.

The 4 tests box should read «***ON***».

If the electrodes are not connected or oximeter or blood pressure cuffs are not assigned , the corresponding boxes will read «***OFF***»

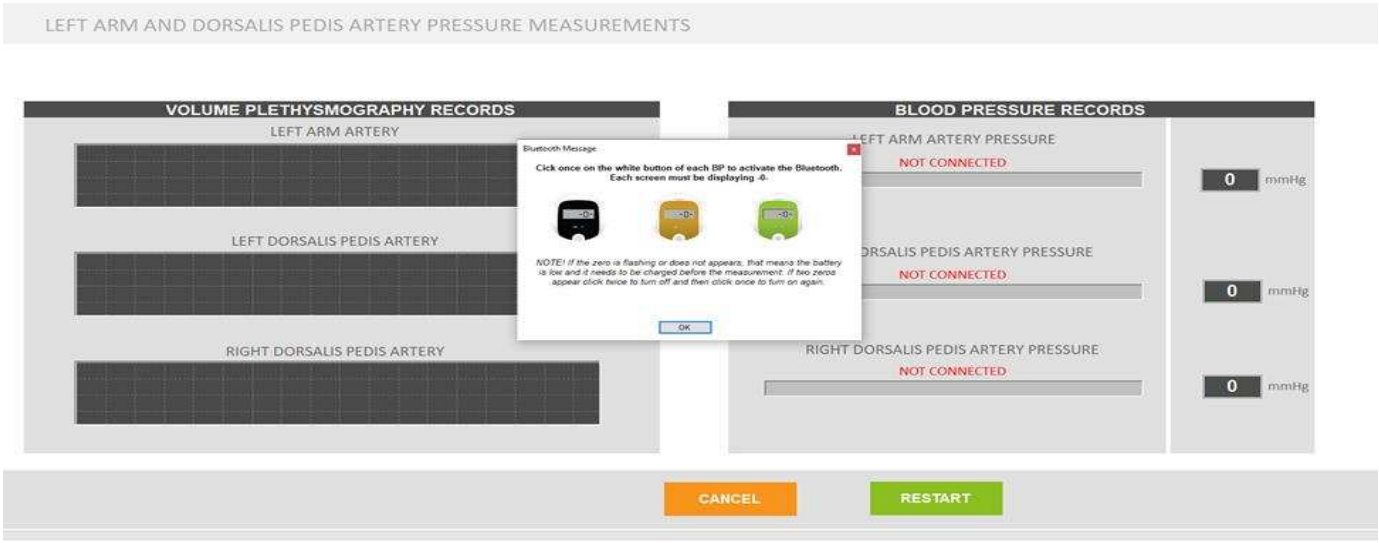
If all the boxes read "***ON***" , then the software will start autocratically the baseline measurement.

BASELINE MEASUREMENT: TESTING AT REST RECORDING

During the baseline recording,

- in the section PTG records, the digital arterial wave and heart rate detection first derivative will be displayed.
- In the section identified as GRS records, the voltage response at the right and left feet will be displayed.
- At any time during the baseline recording, you can click on «***CANCEL***» to be returned to the database patient page.
- Also, at any time during the baseline recording, you can restart by clicking on «***RESTART***».

ABI MEASUREMENT STEP 1: LEFT BRACHIAL AND DORSAL PEDIS ARTERIES



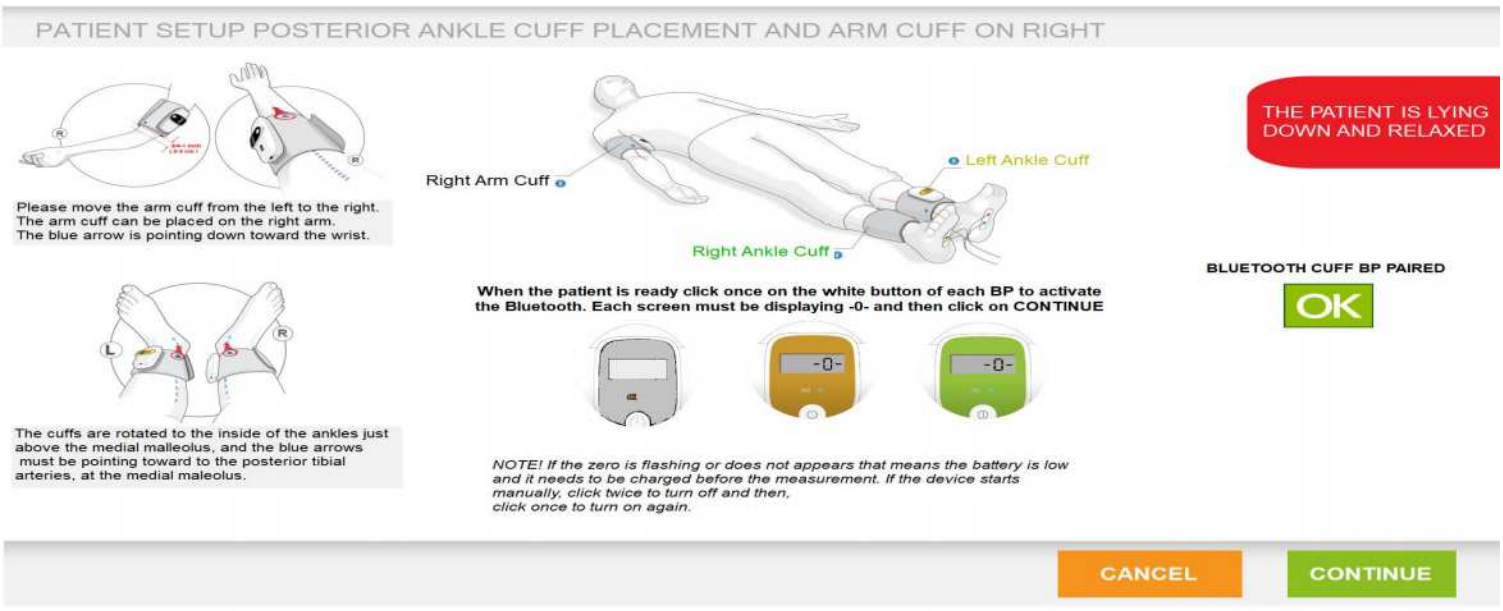
Click on the white button of each blood pressure device to activate the Bluetooth function , and then, click "***OK***"

If the patient is moving, you can restart the measurement by clicking on the tab «***RESTART***» Click again on each White button of the devices to activate the Bluetooth function and then, click on «***START***».

For any reason, you can cancel the measurement by clicking on the tab «***CANCEL***».

ABI MEASUREMENT STEP 2: RIGHT BRACHIAL AND POSTERIOR TIBIAL ARTERIES

Prepare the patient as shown on the image. The arm cuff is moving to the the right arm, the blue arrow toward the right brachial artery. The ankle cuffs must be rotated to the inside, the blue arrow toward the posterior tibial arteries, at the middle of the medial malleolus.



Click on each White button of the devices to activate the Bluetooth function.

Click on «***CONTINUE***» button to start the measurement.

CARDIAC AUTONOMIC REFLEX TESTS RECORDING

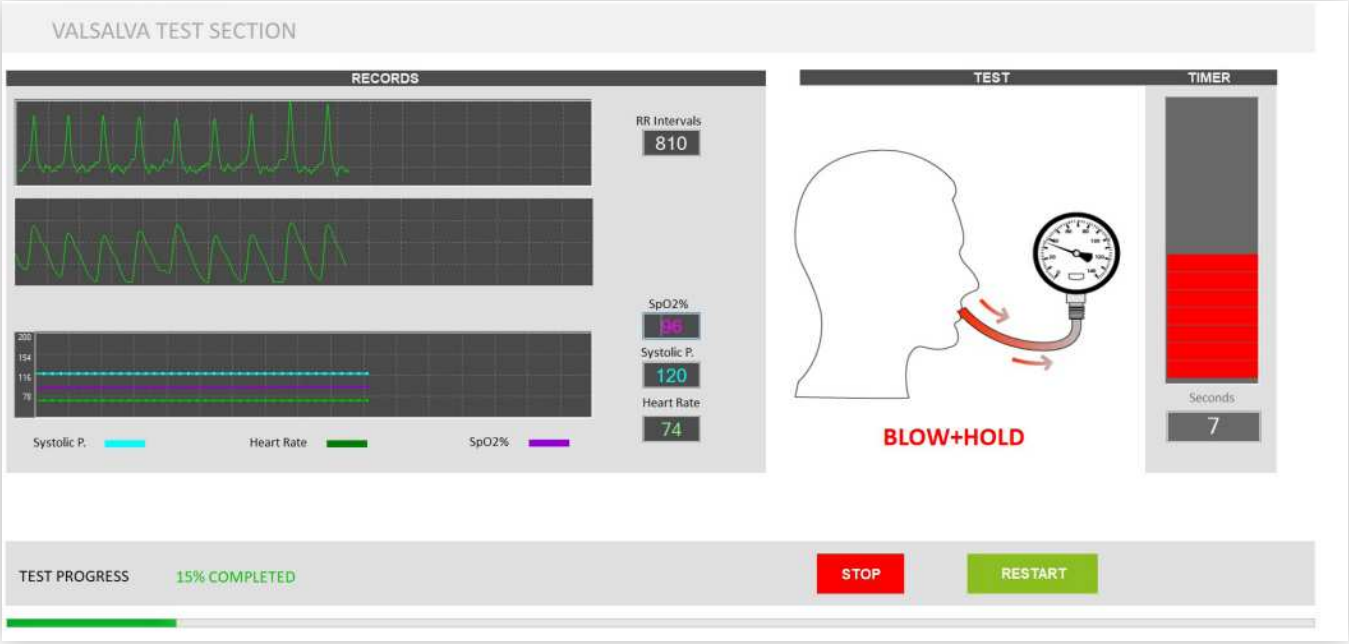
At the end of the first series of measurements, a window will open in order to perform the Valsalva test.

VALSALVA MANEUVER RECORDING

- Once the baseline measurement is complete, the test will progress to the Valsalva maneuver recording.
- Remove the electrode pads from the soles of the feet, and the pressure cuffs placed on the both ankles.
- At the start of the Valsalva maneuver recording, instructions will be shown on the screen to guide the patient and technician with vital information to properly complete the test.

VALSALVA MANEUVER

1. Connect the disposable output of the manometer as shows in the picture.
2. The technician has to instruct the patient to perform correctly the Valsalva maneuver.
3. - The patient has to blow into a manometer.
   - The mamometer should be maintained at 40mm of mercury for 15 secondes.
   - After 15 secondes, the patient will remove the manometer and relax
4. The technician should click on «***START***» when the patient is ready to begin the Valsalva maneuver.



- During the Valsalva maneuver recording, the Systolic pressure, heart rate, SpO2%, and digital arterial wave will be displayed.
- At any time during the Valsalva maneuver recording, you can click on «***STOP***» in order to skip the test and go directly to the deep breathing test.
- At any time during the Valsalva maneuver recording, you can restart the test by clicking on «***RESTART***».

DEEP BREATHING RECORDING

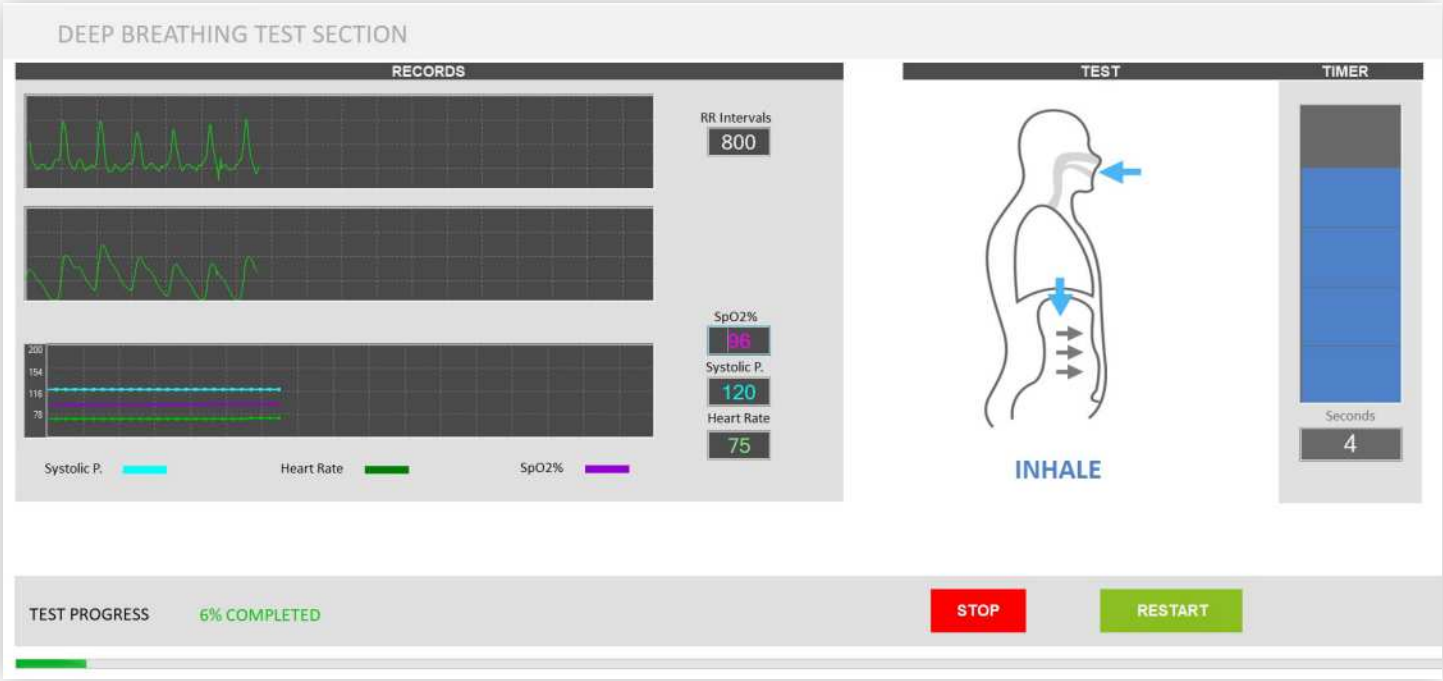
- Once the Valsalva recording is completed or skipped, the measurement will progress to the Deep breathing recording.
- At the start of the deep breathing recording, instructions will be shown on the screen to guide the patient and technician with vital information to properly complete the test.

DEEP BREATHING 30 SECONDS

Instruct subject to inhale for 5 seconds and exhale for 5 seconds. Patient should breathe continuously and regularly.

After the third expiration, click on «***START***».Care should be taken not to hyperventilate.

The technician should click on «***START***» when the patient is ready to begin the deep breathing exercises.



- During the deep breathing recording, the Systolic pressure, heart rate, SpO2%, and digital arterial wave will be displayed.

- At any time during the Deep Breathing recording, you can click on «***STOP***».The cardiac autonomic reflex test will be cancelled if you confirm the cancel message. The software will display the saved results.

Also, at any time during the deep breathing recording, you can restart by clicking on «***RESTART***».

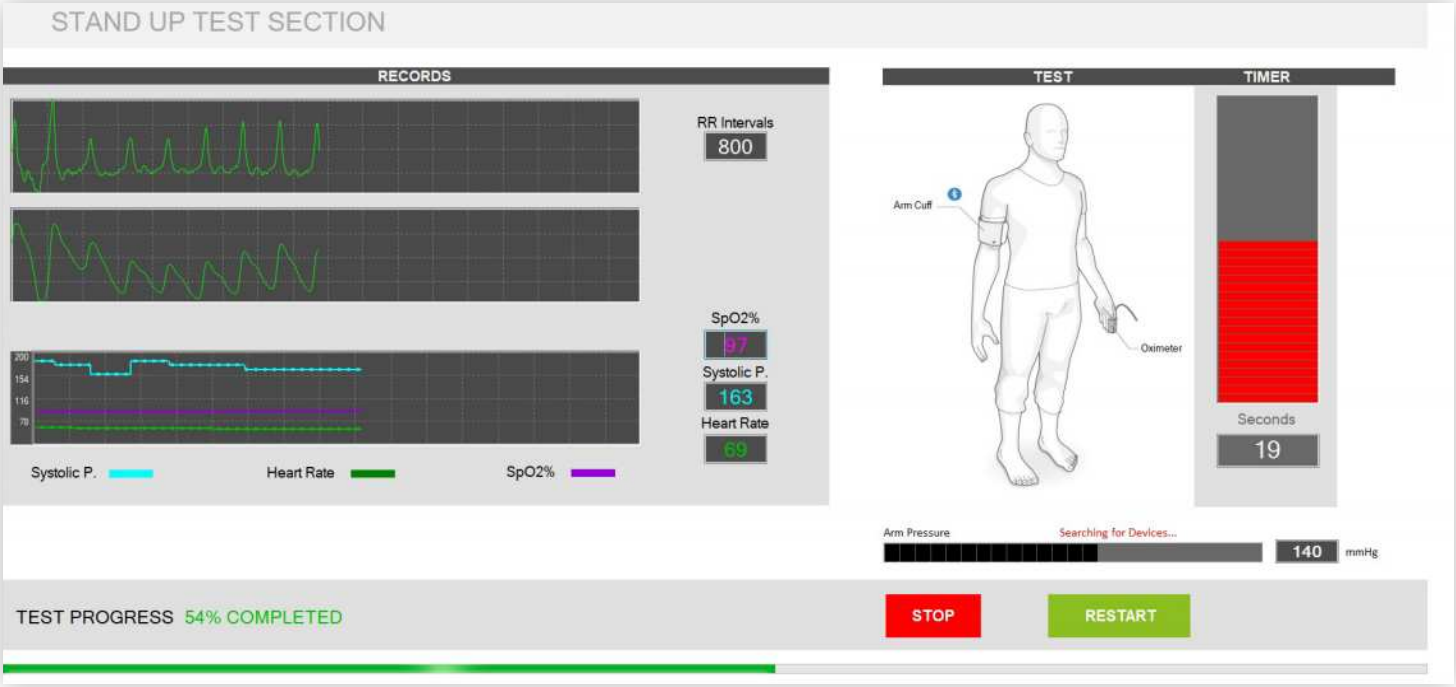
K30/15 (POSTURAL CHANGE OR STAND UP) RECORDING

Once the deep breathing recording is completed, the measurement will progress to the K30/15 recording.

- At the start of the K30/15 recording, instructions will be shown on the screen to guide the patient and technician with vital information to complete the test.

STAND UP
Be sure to keep your left index finger into the oximeter and then click on «***START***».

• The technician should click on «***START***» immediately after the patient progressively stands up (first sit and then stand up).



- During the Stand Up recording, the heart rate, SPO2% and digital arterial wave will be displayed.

- At any time during the standup recording, you can click on «***STOP***» to be returned to the saved results.

- Also, at any time during the K30/15 recording, you can restart by clicking on «***RESTART***».

At the end of this recording, the results data will be computed and displayed on the Patient Results. Please see viewing patient results instructions for further details.

TROUBLESHOOTING

GENERAL TROUBLESHOOTING

ERROR MESSAGES DURING THE MEASUREMENT:

Message 1

SOLUTION

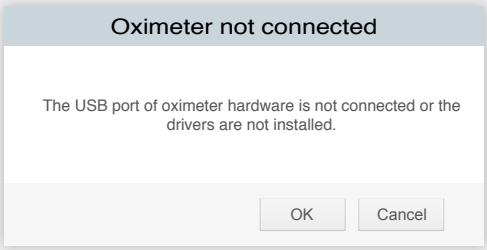
- The SweatC is not connected to the USB port of the PC. Connect it.
- The drivers of the SweatC are not installed. Call the Technical support.
- The one or two snap of the SweatC cables are not connected to the disposable electrodes.

Message 2

SOLUTION:

- The Bluetooth are not assigned, Return to «***SETTINGS***».
- The Bluetooth is not activated. Click on the White button of the blood pressure devices.
- Low Battery.

Message 3



SOLUTION:

This message will appear if the oximeter is not transmitting data correctly, if any oximeter contraindications are present, or if the patient has extremely low peripheral arterial blood levels.

- The Oximeter wireless is not connected. Connect the USB receptor and transmitter.
- The Oximeter Drivers are not installed. Call the technical support
- The oximeter is not «***ON***». Press on the White button.
- The oximeter menu has be changed. Please refer to «***Oximeter***» of the present manual to correct the issue.
- Low battery

Message 4

The feet electrodes are not connected.

SOLUTION:

- The cable(s) is not connected to the box.
- The disposable electrode is not in contact with the skin.

Message 5

Out of the range of performance.

SOLUTION:

- If the patient's weight or height is outside the range of possibilities, then the software will display an error message.
- If the patient's age is under 20 years old, the software will display an error message.

RESULTS

The results open automatically after the end of the exam.

The results are displayed in 3 fixed windows:

- Cardiometabolic risk window
- Macrovascular window
- Autonomic Nervous system (ANS) window

And 2 floating windows:

- Markers overview
- Wellness program

The fixed windows have 5 sections:

- Scoring
- Markers
- Charts and Comments
- Graphs
- Modeling

Scoring and Modeling sections are the same in the 3 fixed windows

By clicking on the box score, the sections Markers, charts, comments and graphs change according to the selection.

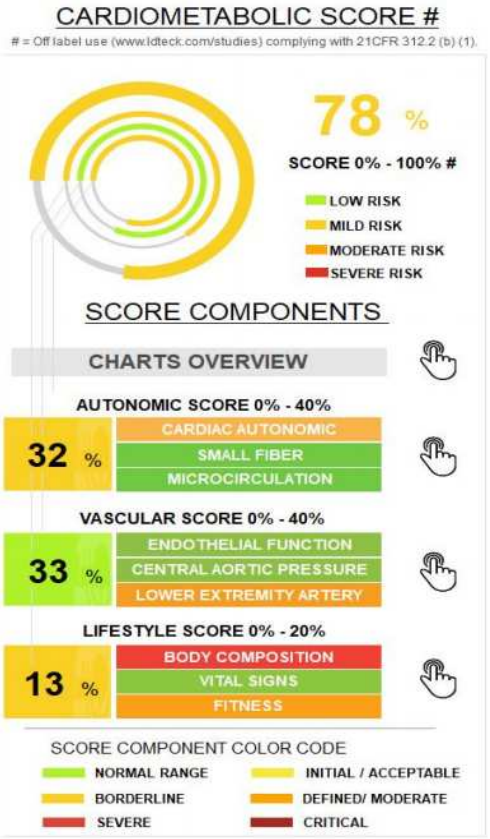
SCORING SYSTEM

The TM-Flow calculates the lifestyle, vascular and Autonomic nervous system (ANS) scores according to the value of the markers. For each marker the normal range is scored as 2, borderline at 1 and abnormal at 0. Each marker is displayed with a color code corresponding to «***NORMAL***» ,«***BORDERLINE***» or«***ABNORMAL***» according to the value of the ranges displayed between the color lines.
The autonomic and macrovascular scores are displayed in the scale (in %) from 0 to 40.

The lifestyle score is displayed in scale (in %) from 0 to 20

The total cardiometabolic score is displayed in scale (in %) from 0 to 100 . It is displayed with a color code corresponding to : « ***GOOD*** » , « ***ACCEPTABLE*** », «***BORDERLINE*** », «***POOR***» or «***VERY POOR***».

The cardiometabolic score is the sum of the 3 scores described above:

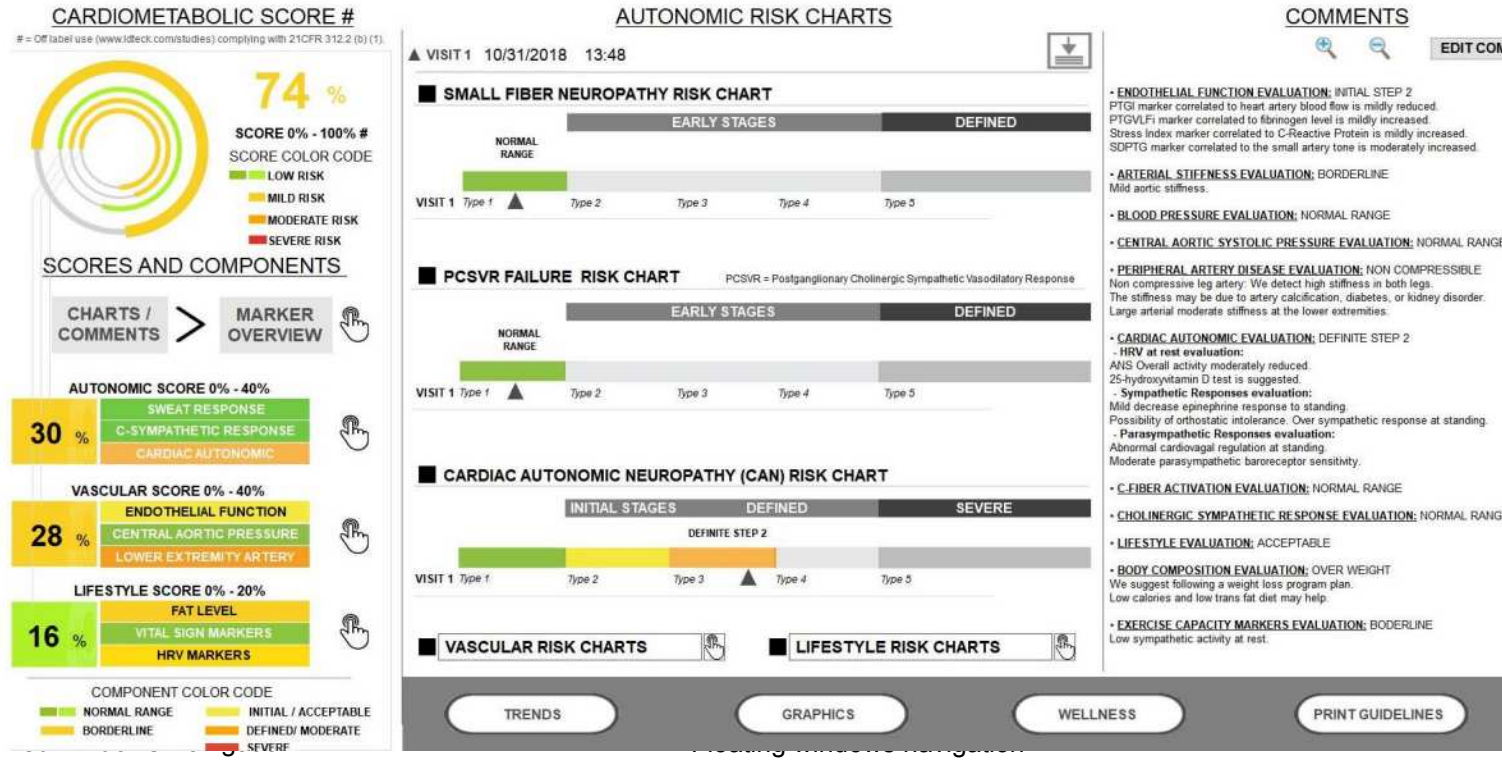


TRENDS

By clicking on «***TRENDS***»a window opens with trends of the scores.

NAVIGATION

FIXED WINDOWS: CARDIOVASCULAR SCORE/ CHARTS AND COMMENTS/ MARKERS OVERVIEW



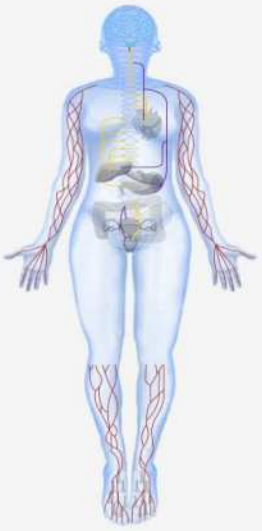
If one or several previous visits are available, select one visit, and then click on "Compare visit 2" to evaluate the marker evolution.

MARKER COMPARISON VISIT 1(ACTUAL VISIT) AND VISIT 2 (PREVIOUS VISIT)

MARKERS OVERVIEW

CURRENT VISIT 1 | COMPARE VISIT 2 | 7/10/2017 19:22

	VISIT 1	VISIT 2
LIFESTYLE		
FAT MASS *Age and Gender Dependent (%)*	42	42
HEART RATE *Age and Gender Dependent (bpm)*	95	81
BLOOD OXYGEN SATURATION *Spo2 >= 94 (%)*	97	96
SYMPATHETIC ACTIVITY *LF/HF <= 2*	0.48	1.54
EXERCISE RECOVERY *RMSSD Age Dependent (ms)*	42	26
ENDOTHELIAL FUNCTION		
INSULIN RESISTANCE *PTG TP <= 406 (ms2)*	355	486
INFLAMMATION *Stress Index < 180 (%)*	139	375
UPPER BLOOD FLOW *PTG Index >= 40 (Vs)*	34.5	48.0
COAGULATION *PTGVLF Index <= 32 (Vs / mS)*	20	22
VASCULAR TONE *SDPTG < 0.42 (ratio)*	0.23	0.13
SUDOMOTOR FUNCTION		
PCSVR *Left NO Peak >= 832 (mV)*	1280	1164
Right NO Peak >= 832 (mV)	1241	1113
SWEAT RESPONSE *Left Sweat Peak >= 832 < 1100 (mV)*	1280	1203
Right Sweat Peak >= 832 < 1100 (mV)	1280	1075



NORMAL ABNORMAL
ACCEPTABLE SEVERE
BORDERLINE

PCSVR =Post Ganglionic Cholinergic Sympathetic Vasodilatory Response

	VISIT 1	VISIT 2
CARDIAC AUTONOMIC FUNCTION		
EXERCISE TOLERANCE *SDANN Age dependent (ms)*	30	23
ANS OVERALL ACTIVITY AT REST *Total Power Age dependent (ms2)*	362	358
SYMPATHETIC REFLEX TESTS		
ADRENERGIC RESPONSE *DPRS < 10 and >-20 (mmHg)*	13	N/A
NORADRENERGIC RESPONSE *SPRS < 10 and >-20 (mmHg)*	7	N/A
PARASYMPATHETIC REFLEX TEST		
BARORECEPTOR RESPONSE *Valsalva Ratio >= 1.21*	1.39	1.73
VAGAL INNERVATION RESPONSE *E/I Ratio Age dependent*	1.10	1.16
CARDIAC FUNCTION RESPONSE *K3015 Ratio >= 1.04*	1.04	1.02
CENTRAL AORTIC PRESSURE		
Age/Gender dependent (mmHg)	102	85
LOWER EXTREMITY ARTERY		
LEFT ANKLE BRACHIAL INDEX *Left ABI >= 1.0 < 1.30 (ratio)*	1.18	1.21
RIGHT ANKLE BRACHIAL INDEX *Right ABI >= 1.0 < 1.30 (ratio)*	1.26	1.30
LEFT BLOOD FLOW *Amplitude >= 60 mV/min*	73	55
RIGHT BLOOD FLOW *Amplitude >= 60 mV/min*	81	82

CHARTS & COMMENTS

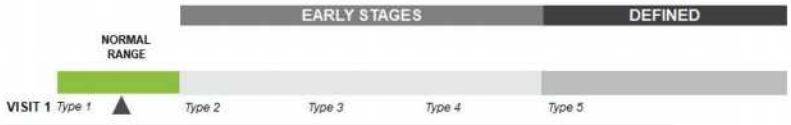
AUTONOMIC RISK CHARTS

▲ VISIT 1 10/3/2017 10:32 ◆ COMPARED VISIT 2 7/10/2017 19:22

SMALL FIBER NEUROPATHY RISK CHART

PCSVR FAILURE RISK CHART

PCSVR = Postganglionary Cholinergic Sympathetic Vasodilatory Response



CARDIAC AUTONOMIC NEUROPATHY (CAN) RISK CHART

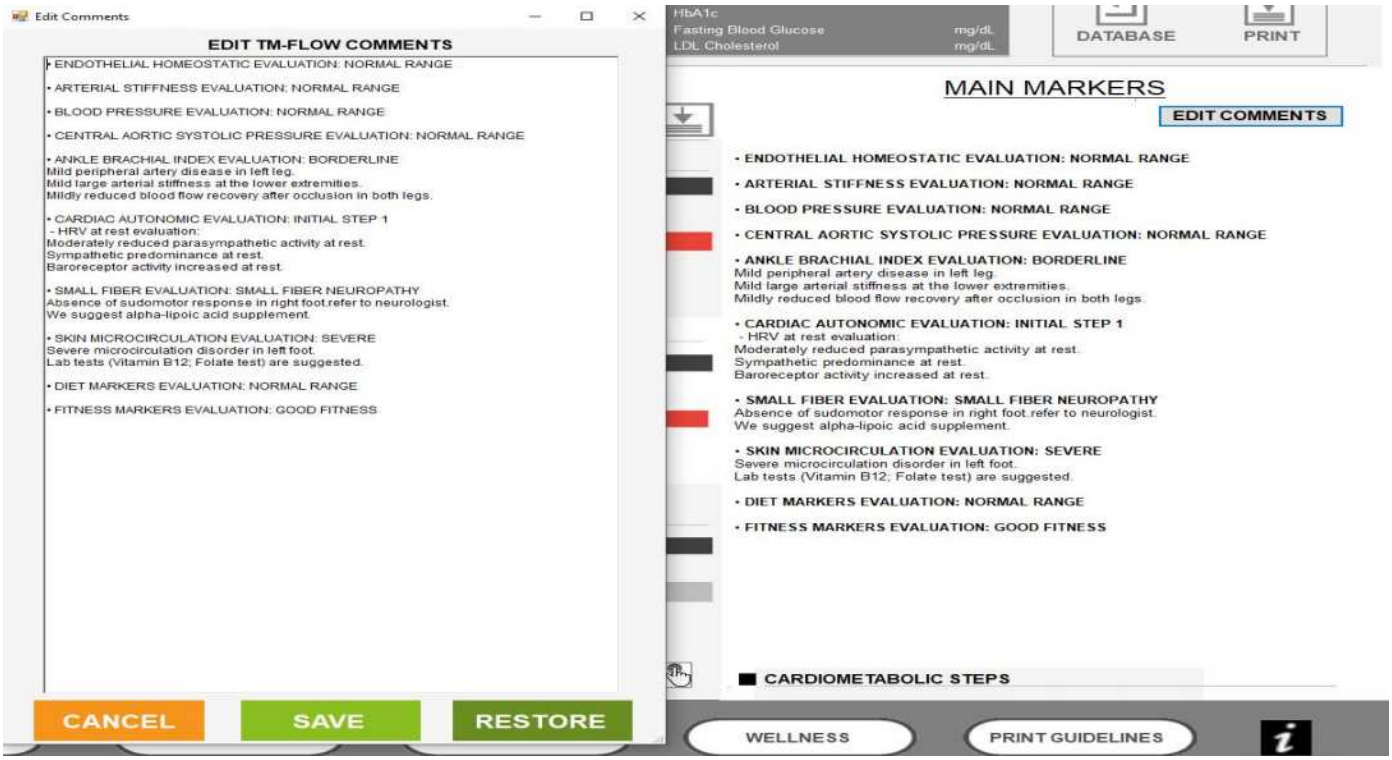
VASCULAR RISK CHARTS | LIFESTYLE RISK CHARTS

COMMENTS

EDIT COMMENTS

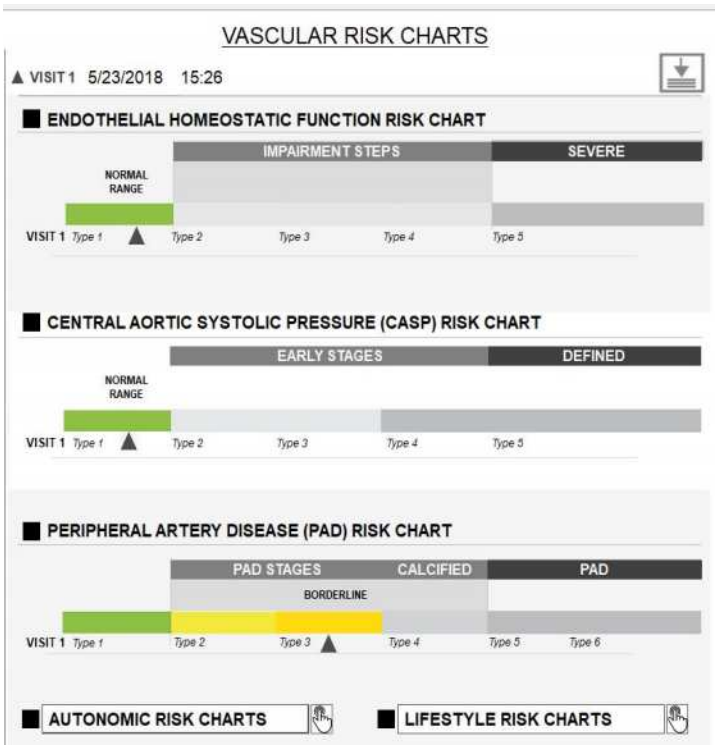
- **ENDOTHELIAL FUNCTION EVALUATION: ACCEPTABLE**
  PTGI marker corrrelated to heart artery blood flow is mildly reduced.
- **ARTERIAL STIFFNESS EVALUATION: NORMAL RANGE**
- **BLOOD PRESSURE EVALUATION: NORMAL RANGE**
- **CENTRAL AORTIC SYSTOLIC PRESSURE EVALUATION: NORMAL RANGE**
- **ANKLE BRACHIAL INDEX EVALUATION: NORMAL RANGE**
  Electrolytes lab test is suggested
- **CARDIAC AUTONOMIC EVALUATION: INITIAL STEP 1**
  - **HRV at rest evaluation:**
  Tachycardia at rest detected.
  ANS Overall activity severely reduced.
  25-hydroxyvitamin D test is suggested.
  Baroreceptor activity mildly decreased at rest.
  - **Sympathetic Responses evaluation:**
  Mild decrease epinephrine response to standing.
  - **Parasympathetic Responses evaluation:**
  Mild impairment in cardiovagal innervation response.
- **C-FIBER ACTIVATION EVALUATION: INFLAMMATION**
  Small fiber inflammation in both feet.
- **CHOLINERGIC SYMPATHETIC RESPONSE EVALUATION: NORMAL RANGE**
- **LIFESTYLE EVALUATION: BORDERLINE**
- **BODY COMPOSITION EVALUATION: OBESE TYPE 1**
  We suggest following a weight loss program plan.
  A Wellness Program with low calories may help.
- **EXERCISE CAPACITY MARKERS EVALUATION: FITNESS BODERLINE**
  Low sympathetic activity at rest.
  Tachycardia may affect the exercise capacity

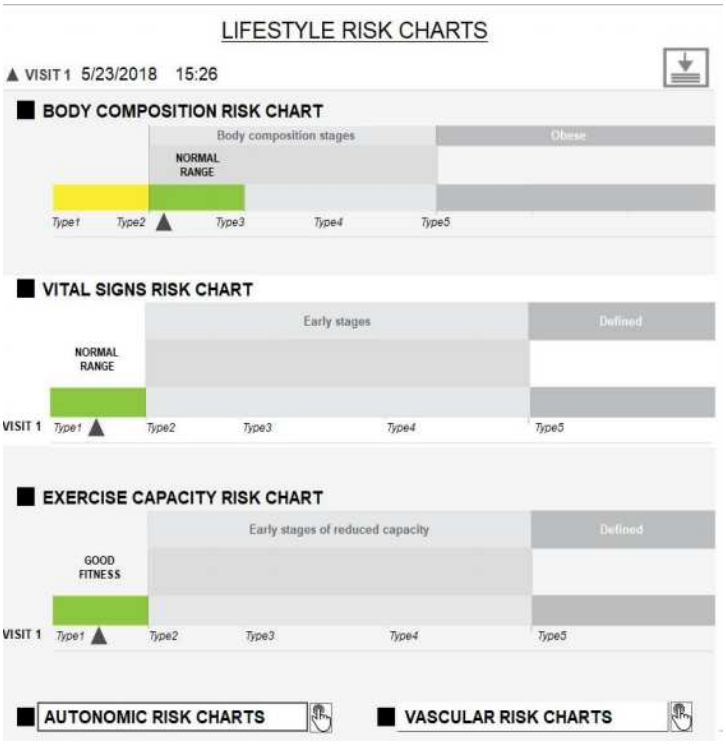
EDIT COMMENTS



Click on "***EDIT COMMENTS***" to add or change any comments and then, click on save , cancel or restore.

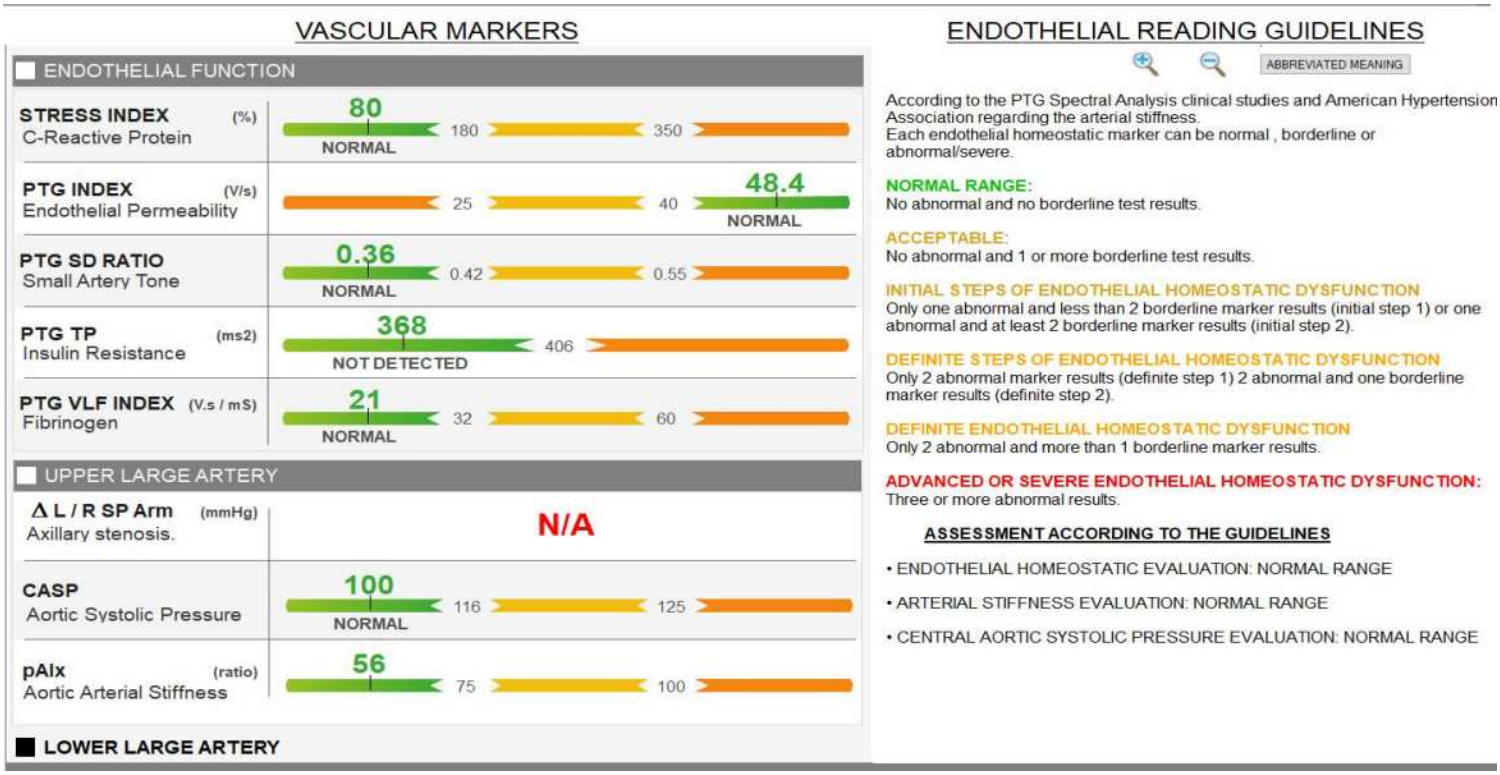
Click on " ***VASCULAR RISK CHARTS***" " or " **LIFESTYLE RISK CHARTS**" to open the corresponding charts



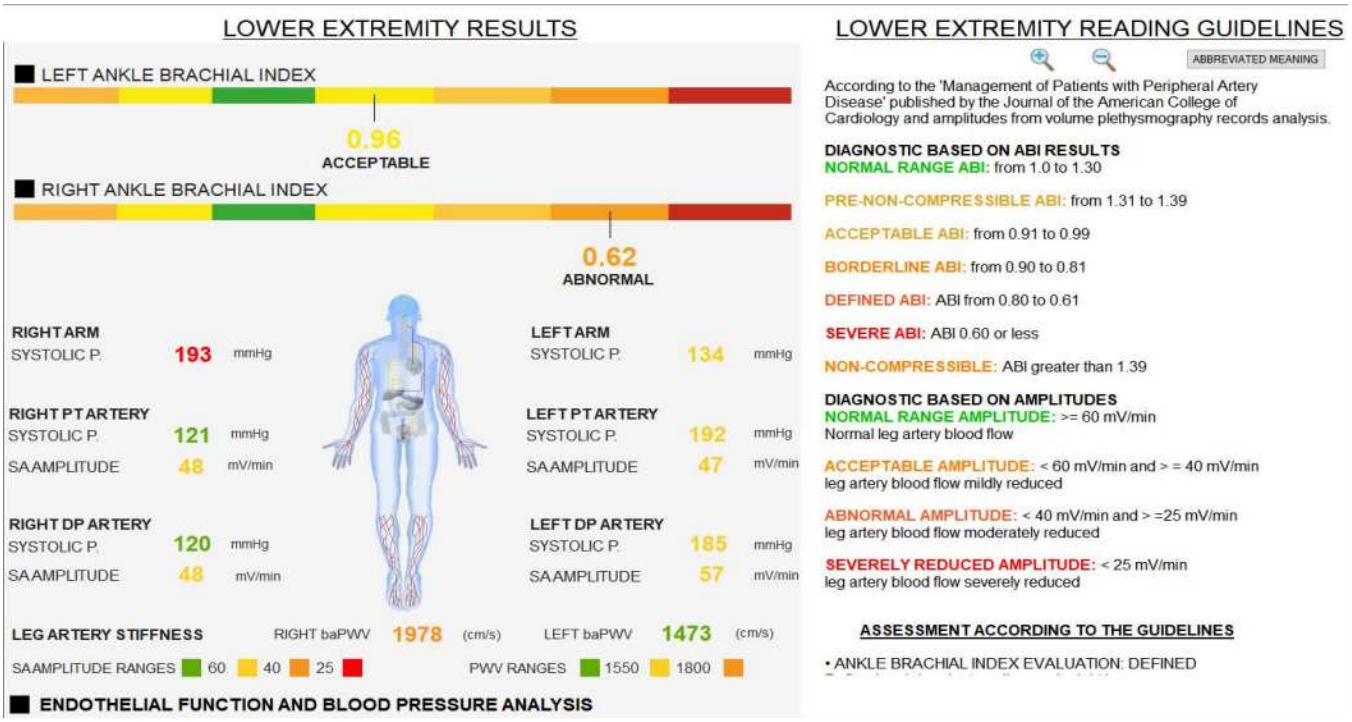


By clicking on «***LIFESTYLE SCORE***», the window with the markers, comments and guidelines.

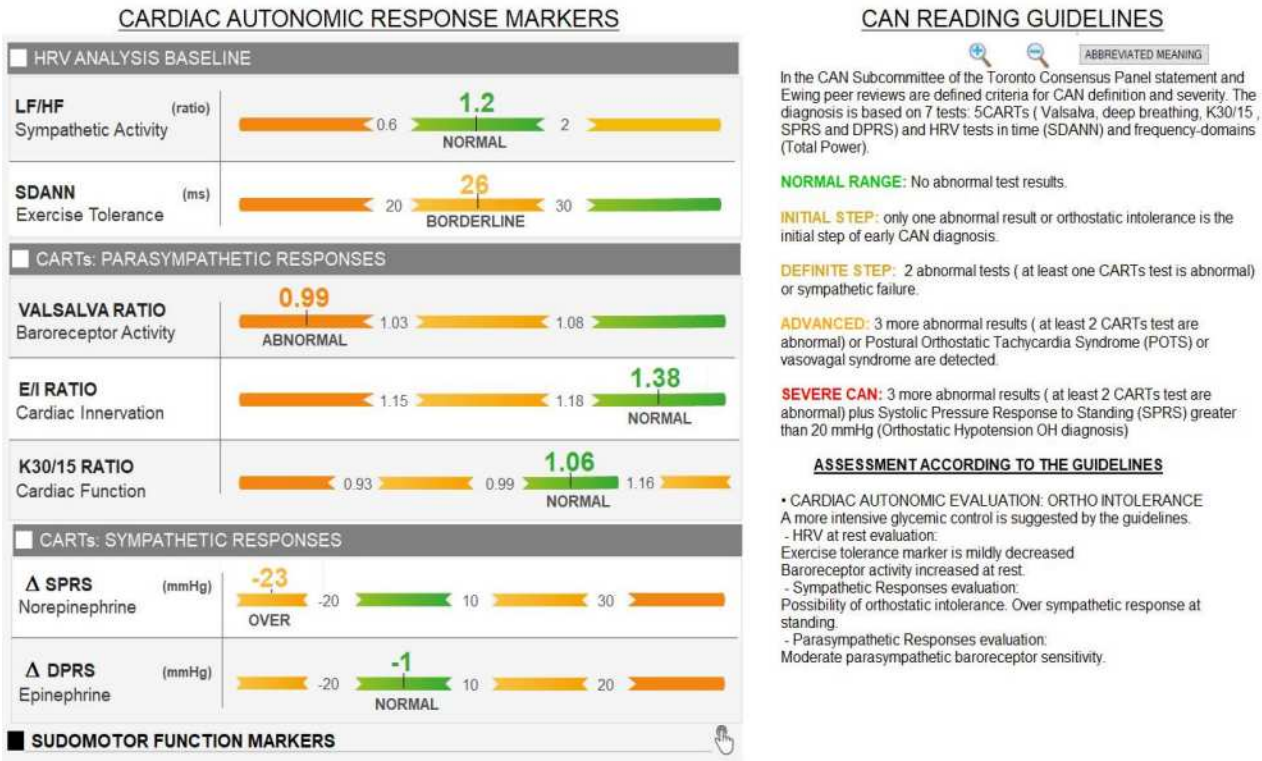
By clicking on «***VASCULAR SCORE***», the window with the markers, comments and charts opens.



Click on '***LOWER LARGE ARTERY***' to open the ankle brachial Indices values.

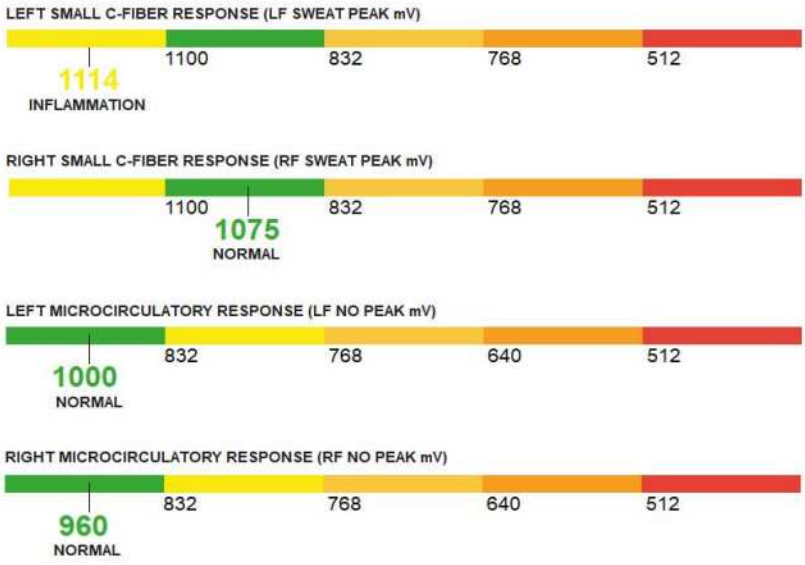


By clicking on «***ANS SCORE***» the window with the markers, comments and charts opens.



By clicking on « ***SUDOMOTOR FUNCTION MARKERS***» the window with the sudomotor test results opens.

SUDOMOTOR FUNCTION MARKER



SUDOMOTOR GUIDELINES

According to the SweatC clinical studies.
The sudomotor function is controlled by the cholinergic sympathetic system acting by the cholinergic autonomic nervous system fibers (C-Fibers).
The Quantitative Sudomotor Reflex Test uses a constant electrical stimulation of the C-Fibers. The C-Fibers activation induces first a microcirculation dilation (Peak NO for each foot) and then, a sweat response (Sweat Peak for each foot).

NORMAL RANGE
NO Peaks greater or equal to 832 mV and LF Sweat Peaks greater or equal to 832 and lower or equal to 1100 mV.

EARLY SIGN OF MICROCIRCULATORY DISORDER.
NO Peak lower than 832 mV and greater than 768 mV.

BORDERLINE MICROCIRCULATORY DISORDER.
NO Peak lower or equal to 768 mV and greater than 640 mV.

DEFINITE MICROCIRCULATORY DISORDER.
NO Peak lower or equal to 640 mV and greater than 512 mV.

SEVERE MICROCIRCULATORY DISORDER.
NO Peak lower or equal to 512 mV:

C-FIBER INFLAMMATION
Sweat Peak test result greater than 1100 mV

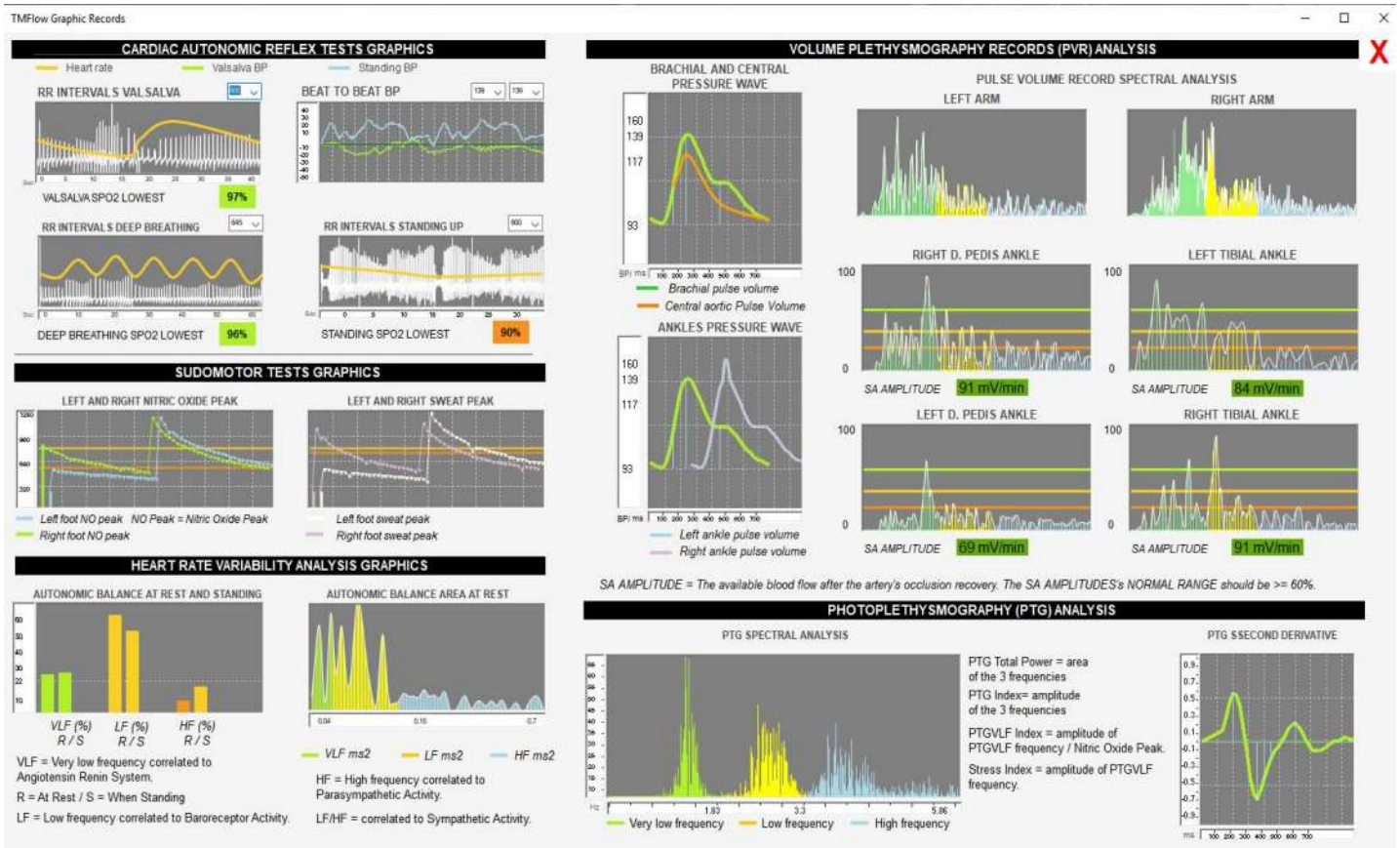
BORDERLINE REDUCED C-FIBER DENSITY
Sweat Peak test result lower than 832 mV and greater than 768 mV.

DEFINITE REDUCED C-FIBER DENSITY
Sweat Peak test result lower or equal to 768 mV and greater than 512 mV

SMALL FIBER NEUROPATHY
Sweat Peak test result lower or equal to 512 mV:

■ CARDIAC AUTONOMIC RESPONSE MARKERS

FLOATING WINDOW: By clicking on « ***GRAPHICS***» icon, the window with the the graphics opens



By clicking on «***WELLNESS PROGRAM***» icon, the pdf with lifestyle suggestions opens.

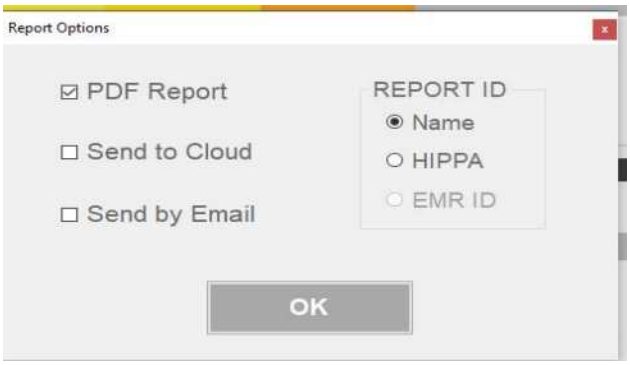
By clicking on «***GUIDELINES***» icon, the pdf with guidelines opens.

DATABASE BUTTON:
Return to Database Dashboard button is inactive while on the Database Dashboard but will return you to your Database Dashboard from any other screen.

STATUS REPORT

Click on the icon 

The displayed report is a PDF file that you can print for your patient. Select «***SEND TO THE CLOUD***» if you wish to receive the report to your secure cloud. Please, use your e-mail and the password you created for the registration of the software to access to the cloud.



Select " **SEND BY EMAI**L" if you wish to send the report to the patient, referral or EMR.

Select one of the report ID for save to the cloud or by email.

The status report interpretation is the responsibility of the practitioner and must be signed by the practitioner.

BACKUP

The Backup is named ***TM-FLOW_Admin*** in the ***C/Drive***, and the name of the patient is coded.
It is recommended to save the backup in flash key regularly.

BACK UP AND INSTALLATION ON A NEW LAPTOP:
Process to transfer your database:
Copy the backup ***TM-FLOW_Admin*** and paste in the ***C/Drive*** of the new laptop, and then select the database name.

CLOSING THE PROGRAM

By clicking on the icon 

, you are returned to Windows.

LABELLING

Non Sterile

Latex Free

Follow the instruction of disinfection

REUSABLE CABLE, OXIMETER PROBE, MANOMETER OUTPUT AND BP CUFFS

	Manufacturer ‘s name and address.
EC REP	European authorized agent.
SN	Serial number of the device.
	This symbol signifies double insulation (Class of insulation II).
	Type BF
5V ⎓	Assigned Voltage: 5V D.C Maximal intensity: 500 mA.
	Warning! Please follow the guidance and instructions of the manufacturer.
	No disposable product WEEE and 2002/95/ It-RoHS. Please contact Manufacturer to recycle your TM-Flow system. Do not discard.

Disposable foot electrodes are labelled with a lot number according to the year and week of manufacture.

In compliance with the European Directive on Waste Electrical and electronic Equipment (WEEE) 2002/96/EC.
Do not dispose of this product as unsorted municipal waste.

This device contains WEEE materials; Please contact your distributor regarding returning or recycling of the device. If you unsure how to reach your distributor, please call:
LD TECHNOLOGY (USA)
+ 1 305-379-9900.

YEAR OF MANUFACTURE

This year of manufacture is the four first numbers of the serial number or code bar stick on the bottom of the devices.

LIFE CYCLE OF THE SOFTWARE

LD-Oxy box, cables and cuffs have a normal lifecycle of three years.
SweatC and TBL-ABI boxes have a normal lifecycle of five years.

BIOCOMPATIBILITY

All accessories in contact with the skin are ISO 10993-1.

ENVIRONMENT CONDITIONS

- Temperature:-40ºC ~ +60ºC.
- Relative humidity: 5% ~ 95%.
- Atmospheric pressure: 500hPa ~ 1060hPa.

OPERATING ENVIRONMENT
Temperature: 10ºC ~ 40ºC.
Relative Humidity: 30% ~ 75%
Atmospheric pressure: 700hPa ~ 1060hPa.
Operating altitude -500 ~ 4600 meter.

SWEATC HARDWARE

General functions	
Measuring principle	Galvanic skin response.

Measuring mode and item	
Measuring sequence	Controlled by software icon «start».
Stopping the measurement	Controlled by software icon «cancel».
Measuring items	Voltage, Intensity and Conductance.

Measuring Range	
Voltage	Maximun 1.28 V..
Intensity	Maximun 200 mA..

Measuring Accuracy	
The max mean deviation	± 3%.

Power requirements	
Supply voltage	5V via USB port.

Disposable foot electrodes Ref. PG474W	
Material	Conductive cloth electrodes, Size: 44cm^2.

Cables	
Material amd color code	2m long armored insulated cable. Color-coded for ease of use. Red one on the left foot plate and Black one on the right foot plate.

Disposable foot electrodes are labelled with a lot number according to the year and week of manufacture.

NOTE | These specifications are subject to change without notice.

HARDWARE TECHNICAL SPECIFICATIONS

TBL-ABI HARDWARE

Measurement Range:	
Pressure:	0-270 (mmHg) (0-36[kPa).
Pulse Rate:	40/min-180/min.

Accuracy:	
Pressure:	±3mmHg (±0.4kPa).
Pulse Rate:	±5%

Operating environment:	
Temperature:	5°C- 40°C
Relative Humidity:	15 to 80%
Air Pressure:	80kPa - 106kPa

Storage and Transportation environment:	
Temperature:	-20°C - +55°C
Relative Humidity:	< = 93%
Air Pressure:	50kPa - 106kPa

Power Supply : DC 3.7v (Li batterie).

Unit Dimension (not including the cuff): 132mm(L) x 60mm(W) x 30mm(H).

Shock Protection: Internal power source; BF TYPE.

Unit Weight (including the cuff): Approximately 260g Applicable.

Arm Circumference: 10.5 inches (22cm) to 13.6 inches (32cm).

NOTE: These specifications are subject to change without notice.

Information	Display mode
The pulse Oxygen Saturation (%SpO2)	2-digital OLED display.
Pulse Rate (bpm)	3-digital OLED display.
Pulse Intensity	Bar-graph OLED display.
SpO2 Parameter Specification	
Measuring Range	0% ~ 100% (the resolution is 1%).
Accuracy	70% ~ 100% ± 2%, Below 70% unspecified.
Average value	Calculate the Average value of every 4 measured values. The deviation between average value and true valzue does not exceed 1%.
Pulse Parameter Specification	
Measuring range	30bpm ~ 250bpm, (the resolution is 1bpm).
Accuracy	± 2bpm during the pulse rate range of 30˜ 99bpm and 2% during pulse rate range of 100˜ 250bpm.
Average pulse rate	Moving calculation in the Average pulse rate every 4 Cardio- beat cycle. The deviation between average value and true value does not exceed 1%.
Safety Type	**BF Type**
Measuring mode	
Start and stop	Start: Controlled from the device. Stop: The device stops after 5 seconds by removing the finger. Measuring time: Controlled by the software. Real time recordings on the software.

Voltage 3.7 rechargable lithium battery charges when connected to the USB port of the PC.

Output of the Battery in charge	
Output current	350 mA.
Output power	1.25 W.

Oximeter light	
Red light	Wavelength is 660 nm, 6.65 mW.
Infrared	Wavelength is 880 nm, 6.75 mW.

Dimensions and Weight	
Dimensions	Length: 55 mm, Width: 32 mm, Height: 30 mm.
Weigh	Wavelength is 880 nm, 6.75 mm.

NOTE

These specifications are subject to change without notice.

ELECTRICAL SAFETY

The systems, which are connected to a computer, constitutes a programmable electro-medical system (PEMS). It is necessary for the computer to be placed away from the patient (i.e. EMC manufacturer guidance).

The PC, and other devices connected to the PC, should be in compliance with Standards IEC950 and/ or UL1950.
The EC or UL labeling on a computer will indicate compliance with these standards.
Risk: The use of a computer not in compliance with these standards could damage the hardware and provoke a system malfunction.

The TBL-ABI uses a battery. The battery has to be charged with an AC/DC Converter.
The battery begins to charge when the AC/DC power supply is connected, which is indicated by the battery status indicator. When the battery is charged, the charging process stops.
The battery status indicator is displayed in the right of the screen.

The required power is provided by a high-performance lithium polymer battery. The battery is not replaceable. The battery capacity is sufficient for approximately 30 measurements.

ACCESSORIES SAFETY:
Only the ACCESSORIES as specified by the manufacturer should be used to assure protection for the patient (i.e. System Components of the Instructions for Use).

In case of device malfunction, do not open the hardware and/or attempt to repair the

TM-FLOW SOFTWARE TECHNICAL SPECIFICATIONS:
- Hardware platform: Laptop or PC based workstation (Intel architecture).
- Operating system: Windows 7/8/10.
- Use of Off-the-Shelf software: Windows 7/8/10 and PDF.
- Language: C#.
- Microsoft Visual C# compiler requirements: 2 GB free space.
- Program size requirements 27Mb.

ELECTROMAGNETIC COMPATIBILITY

The equipment should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed carefully to verify normal operation.The equipment must be installed ans bought into operation in accordance with EMC recommandations. System interference can be caused by close proximity of other equipment during radiofrequency communicator.

GUIDANCE AND MANUFACTURER'S DECLARATION - ECLECTROMAGNECTIC EMISSION

The equipment or system is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment or system should assure that it is used in such environment.

Emissions	Compliance	Electronic environment - guidance
RF emissions - CISPR11	Group 1	The (equipment or system) uses RF energy only for its internal function. Therefore, its RF emissions are very low and are unlikely to cause any interference in nearby electronic equipment.
RF emissions - CISPR11	Class A	The (equipment or system) is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power suply network that supplies buldings used for domestic purposes.
Harmonics emissions - IEC 61000-3-2	Class A	
Voltage fluctuations / Flicker emissions - IEC 61000-3-2	PASS	

GUIDANCE AND MANUFACTURER'S DECLARATION - ECLECTROMAGNECTIC IMMUNITY

The equipment or system is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment or system should assure that it is used in such environment.

Immunity test	IEC 60601 Level	Compliance level	Electronic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2.	± 6 kV contact. ± 8 kV air.	Contacto ± 6 kV ± 8 kV air.	Floor should be wood, concrete or ceramic tile, if floors are covered with synthetic material, the relative humidity should ba at least 30%.
Electrical fast transient/burst IEC 61000-4-4.	± 2 kV for power supply lines. ± 1 kV for signal lines.	± 2 kV for power supply lines.	Mains power quality should be that of a typical commercial or hospital environment.
Surge 61000-4-5.	± 2 kV common mode. ±1 kV differential mode.	± 2 kV common mode.	Mains power quality should be that of a typical commercial or hospital environment.

Immunity test	IEC 60601 level	Compliance level	Electronic environment - guidance
Descensos de tensión, breves interrupciones y variaciones de tensión en las líneas de entrada de alimentación. IEC 61000-4-11	<5% UT (%% de inmersión en UT) durante 0,5 ciclos. 40% UT (60% de inmersión en UT) durante 5 ciclos. 70% UT (30 % de inmersión en UT) durante 25 ciclos. <5% UT (>95 % de inmersión en UT) abeto 5 seg	Descensos de tensión, breves interrupciones y variaciones de tensión en las líneas de entrada de alimentación. IEC 61000-4-11	Mains power quality should be that of a typical commercial or hospital environment. if the user of the (equipment or system) requires continued operation during power mains interruptions, it is recommended that the (equipment or system) be powered from an uninterruptible power supply or a battery.
Frecuencia de potencia (50-60 Hz) campo magnético, IEC 61000-4-8			Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital enviroenment.
RF radiada - IEC 61000-4-3	3 Vrms - 80 MHz a 2500 MHz	3 Vrms - 80 MHz a 2500 MHz	Portable and mobile RF communications equipenment should be used no closer to any part of the (equipenment or system), including cables, than the recommended separration distances calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance. d= (3.5/V1)√P d= (3,5/E1)√P - 80 MHz a 800 MHz d= (7/E1)√P - 800 MHz a 2,5 GHz Where P is the maximum output power rating of the transmitter in watts (w) according to the trasmitter manufacturer and d is the recommended separation distance in meters (m). Field strenghts from the fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. interference may occur in the vicinity of equipment maked with the following symbol: 
RF conducida - IEC 61000-4-5	3 Vrms - 150 KHz a 80 MHz	3 Vrms - 150 KHz a 80 MHz	

NOTE1: Al 80 MHz and 800 MHz, the highter frequency range applies.
NOTE 2: These guildelines may not apply in all situations Electromagnetic propagation is affected by absorption and reflection from structure, objects and people.

[a]Field strenghts 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 eletromagnetic environment due to strenght in the location in which the (equipment or system) is used exceeds the applicable RF compliance level above, the (equipment or system) should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the (equipment or system).

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

COMPUTER REQUIREMENTS

Windows	Windows 7/8/10
Laptop or desktop	IEC950 y/o UL1950
Processor	Intel
RAM	512 Mb or higher
Hard disc	10 Gb or higher
Graphics card	Minimun graphics memory 128 Kb
Screen Size	Any
Screen Resolution	1920 X 1020
Off-the-shelf software	Software for reading and writing PDF documents, Anti virus (optional but recommended if internet connection).
Connections	USB Port and Bluetooth at least 4.0
Interfaces	Keyboard, mouse, monitor, printer (required), CD or DVD-ROM (recommended).

SERVICE AFTER SALES

LD Technology support the full installation of the system online by providing the activation pin code and assigning the Bluetooth devices.

Technical support is open Monday to Friday from 9am to 5pm (EST).

All technical support activity requires that you have a working internet connection, and that you use **TeamViewer** technology for remote system access and/or online training. To access this service, click on the icon «***Setting***» on the software login page.
Send your ID to the technical support email. Do not close the window with your ID.

Important: Wait at your laptop until the technical support team contacts you on the screen. The system is fully guaranteed for one year. After sale support services are included with your purchase at no additional cost for the first year.

WARRANTY CONDITIONS

Your LD Technology Products (medical devices and/or accessories) are warranted to be free from defects in materials and workmanship appearing within one year from the date of installation.

The above warranties extend only to the original retail purchaser.

The original retail purchaser has the option to purchase each year and for 4 years an extend warranty for **$800/year**. The extend warranty will cover the hardware and accessories as well as the update of the software.

At our discretion, we will either repair or replace, free of charge, any LD Product covered by the above warranties.

Repair or replacement is our only responsibility, and your only remedy under the above warranties.

To obtain warranty service, please contact us for the address of the repair location, and for the return shipping and handling fee.

Keep your Proof of Purchase. In case of return of defective item, pack the product carefully to prevent damage in transit.

THE FOREGOING IS THE SOLE WARRANTY PROVIDED BY OUR COMPANY IN CONNECTION WITH THE PRODUCTS, AND OUR COMPANY HEREBY DISCLAIMS ANY OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. IMPLIED WARRANTIES AND OTHER TERMS THAT MAY BE IMPOSED BY LAW, IF ANY, ARE LIMITIED IN DURATION TO THE PERIOD OF THE ABOVE EXPRESS WARRANTY.
OUR COMPANY SHALL NOT BE LIABLE FOR LOSS OF USE OR ANY OTHER SPECIAL, INCIDENTAL, CONSEQUENTAIL OR INDIRECT COSTS, EXPENSES OR DAMAGES.

This warranty provides you with specific legal rights, and you may have other rights that vary by jurisdiction.
Because of special local requirements, some of the above limitations and exclusions may not apply to you.

THE GUARANTEE INCLUDES:

- Access to technical support online or by phone from 9am to 5pm from Monday to Friday, Eastern Time USA.
- Software updates for said year.
- Free training to be arranged between
-

CUSTOMER and approved distributors of the MANUFACTURER.

After the first year, a maintenance contract is offered by LD Technology or their distributors giving clients the opportunity to extend their warranty for one additional year.

The extended warranty is included during the lifecycle of each part of the system:
- Software updates
- Technical support

EXCLUSION OF WARRANTY:

- The warranty does not cover damages or malfunction that are not a result of defects in material and workmanship of the product, and damages or malfunction that result from modification, acident or abuse.

- The used computer is not in compliance with the standards UL 950.

CERTIFICATE OF GUARANTEE

LD TECHNOLOGY

MAKING A DIFFERENCE

TM-FLOW SYSTEM

CUSTOMER NAME:

CUSTOMER ADDRESS:

CUSTOMER EMAIL:

CUSTOMER PHONE:

SERIAL NUMBER:

DELIVERY DATE:

Please fill this form and send it to lucia.ldteck@gmail.com or contact.ldteck@gmail.com for warranty registration.

MANUFACTURER AND SPECIFICATION DEVELOPER

LD TECHNOLOGY
ISO 13485-2016

LD TECHNOLOGY

MAKING A DIFFERENCE

FDA Owner/Operator Number: 9097859

FDA Establishment Registration Number: 3006146787

REF: TM-FLOW System IFU October 25.2019 version 5

CE 2797

EC REP

Neomedica Iberia, SL C/ Estrella Polar, 14 Esc Iz 1°B, 28007 Madrid Spain