Dear Valued Customer,

We hope the enclosed product meets your expectations. This document will help you to become familiar with the TM-FLOW SYSTEM.

WHAT IS TM-FLOW?

TM-FLOW INTENDED USE AND INDICATIONS FOR USE

TM-Flow is a medical Device Data System to be used 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 these devices, and then displays the data on 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 test results (autonomic and vascular assessment). This device provides values. It is the physician's responsibility to make proper judgments based on these numbers.
The TM-Flow's software data is stored 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 INTENDED 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 INTENDED USE

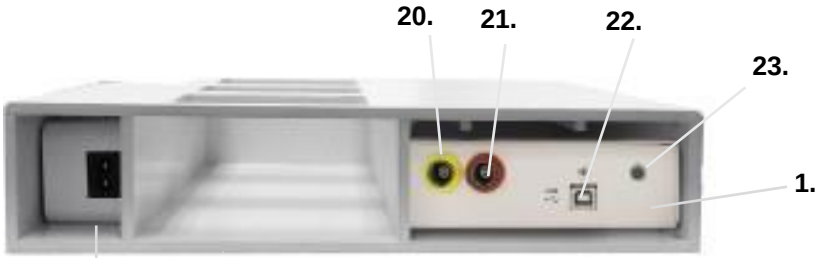
The SweatC device is a medical device used for the measurement of galvanic skin response related to the function of the sweat glands, providing values after each test.

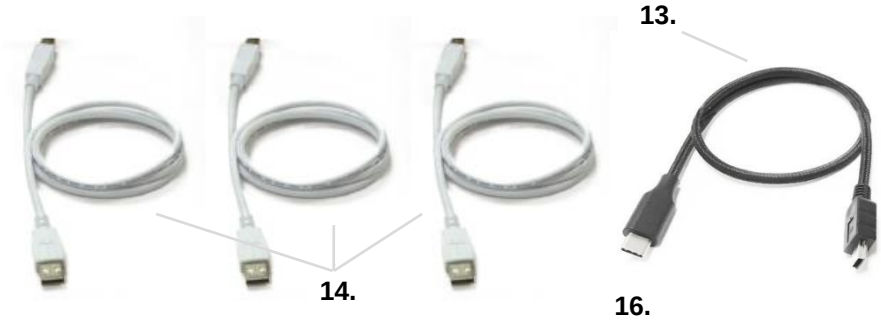
LD-OXI INTENDED USE

The LD-Oxi (oximeter) displays the photoplethysmography. It is used to assess vascular function and Heart Rate Variability (HRV), while at rest and during the Ewing tests.

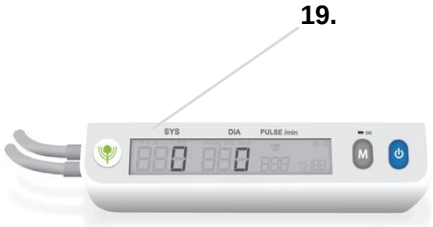
DISCLAIMER: *The devices provide values. It is the physician responsibility to make proper judgment. based on these numbers. All results should be considered within the clinical context of the patient's case. history, symptoms, known diagnosis from other diagnostics studies. current medications, treatment plan and therapies. The interpretation of the results is the responsibility of the medical doctor.*

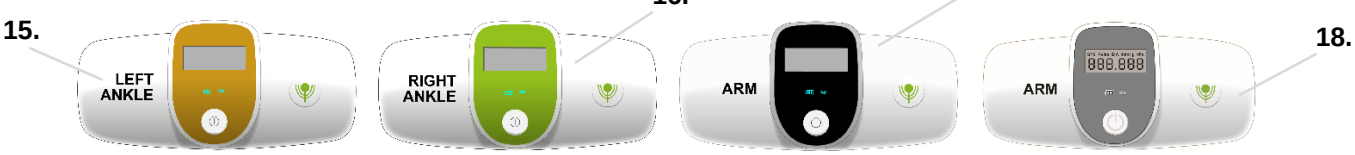
PACKAGE CONTENTS



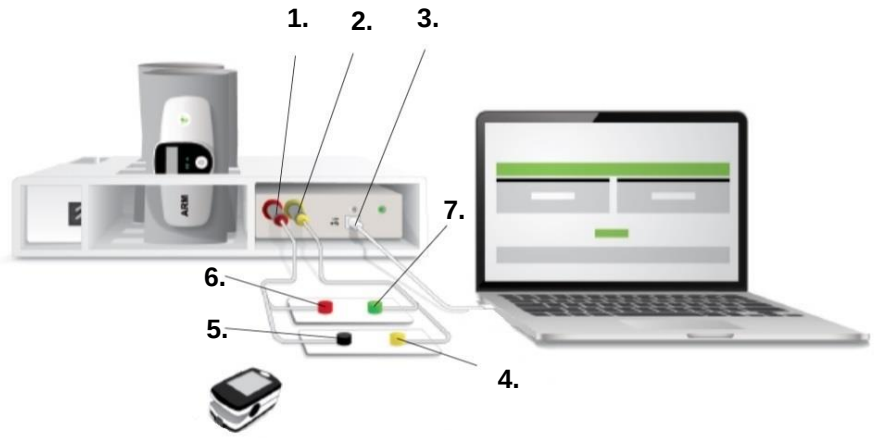


1. SweatC hardware.
2. USB Cable (SweatC)
3. Yellow foot electrode cable.
4. Red foot electrode cable.
5. Disposable electrodes.
6. Manometer.
7. Output manometer (mouthpiece).
8. USB charger power supply.
9. USB charger cord plug.
10. Bluetooth or USB Oximeter (LD-OXI).
11. Oximeter USB connection.
12. Oximeter USB charger.
13. Large Arm Cuff USB charging cable.
14. TBL-ABI USB charging cable.
15. TBL-ABI - Left Ankle.
16. TBL-ABI - Right Ankle.
17. TBL-ABI - Left Arm Cuff.
18. TBL-ABI – Right Arm Cuff
19. TBL-ABI - Large Arm Cuff.
20. Yellow SweatC connector.
21. Red SweatC connector.
22. SweatC USB connector.
23. On/Off light.



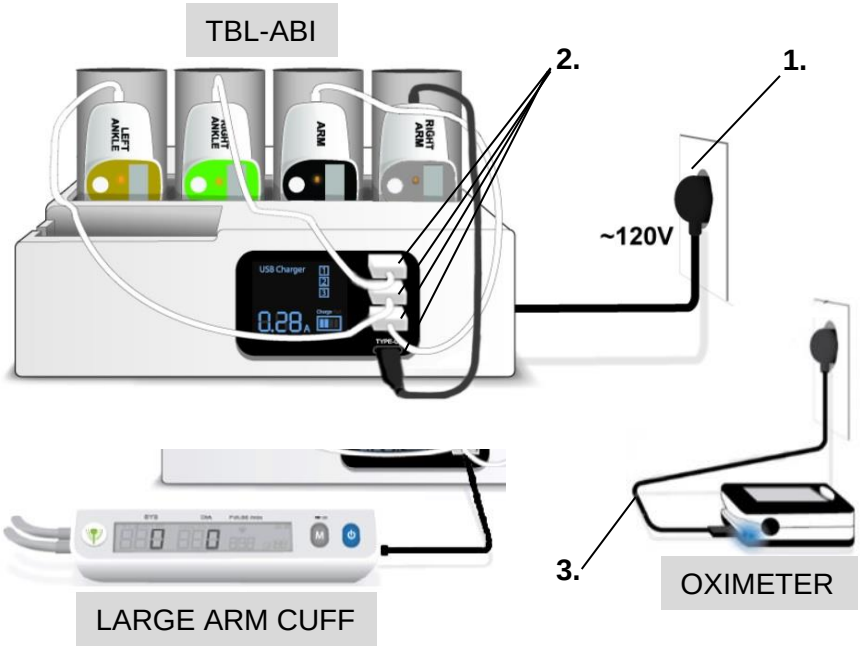


HARDWARE INSTALLATION & CONNECTION



1. Connect the red cable to the red SweatC connector.
2. Connect the yellow cable to the yellow SweatC connector.
3. Connect one end of the USB cable to the SweatC and the other end to the PC or USB HUB port.
4. Connect the yellow snap to the right foot electrode.
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 THE WIRELESS DEVICES



1. Plug the power cord to the USB charger supply port and the other end to the outlet (120V).
2. Connect each TBL-ABI USB charging cable to the USB charger ports.
3. Connect the Oximeter USB charger supply to the outlet (120V).

PROGRAM INSTALLATION

SYSTEM WITH COMPUTER
The software is already **pre-installed**.
Simply start the computer and then click on the TM-FLOW icon on your desktop. You will need to register to activate the measurements.

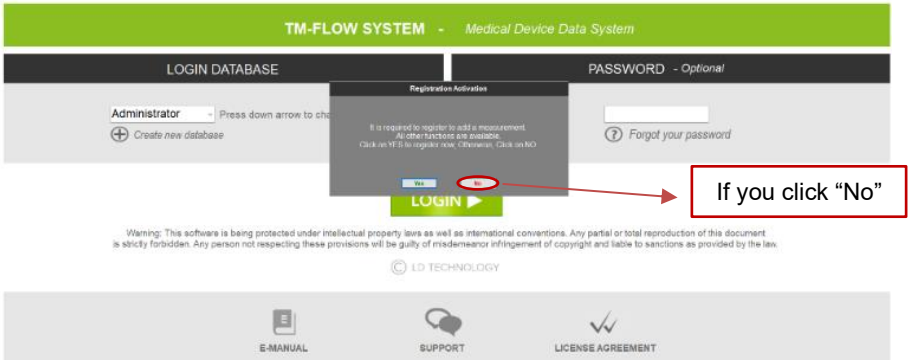
SYSTEM ONLY
If you use your own computer or a distributor's computer, please **call** or **email our technical support team if you did not** receive the link to install the software.
You will need to assign the Bluetooth device and register to activate your software.
If you need assistance, please call our technical support team:
Phone: **+1 (305) 379 - 9900**
Email: **contact@ldteck.com** or **lucia.ldteck@gmail.com**

PC REQUIREMENTS

Operating System	Windows 10
Laptop or desktop	IEC950 y/o UL1950.Brands: HP or Microsoft Surface PRO
Processor	Intel processor i5 or higher
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 or higher
Off-the-shelf software	ADOBE Reader Any Antivirus except McAfee
Connections	USB port and Bluetooth at least version 4.0
Interfaces	Keyboard, mouse and printer

NOTE!
1. The WIFI should be OFF during the measurement and ON only when you need it.
2. Never activate the McAfee antivirus (not compatible with our drivers).
3. Never use Dell or Lenovo laptops (not compatible with our drivers)
4. The laptop battery should be always on High performance (don't use saving or balanced mode)

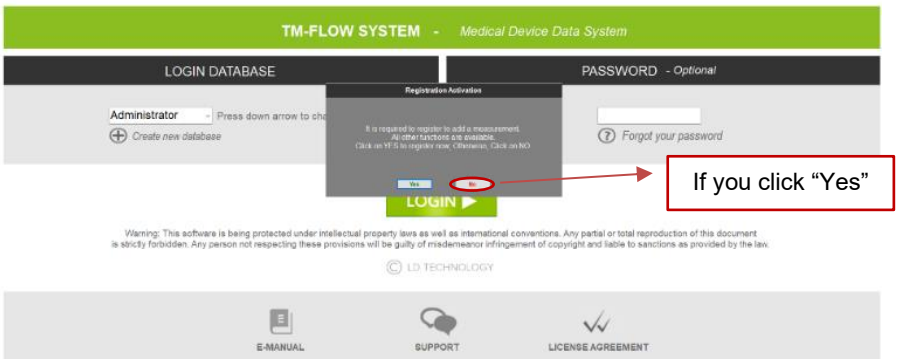
SOFTWARE REGISTRATION AND ACTIVATION



If you click "No"

If you click "No", you will have access to all features, but won't be able to perform a measurement.

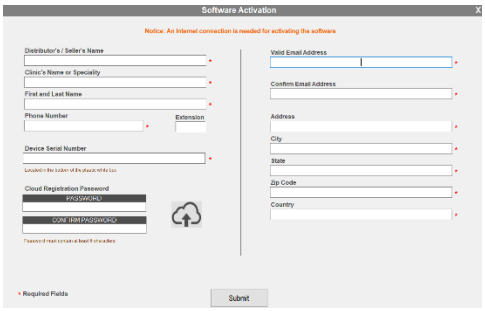
In order to have full access to perform measurements you will need to **register and activate the software**. By doing so, you will have full access to the Cloud as well.



If you click "Yes"

Click "Yes" and follow the procedures to have access to all features including performing measurements.

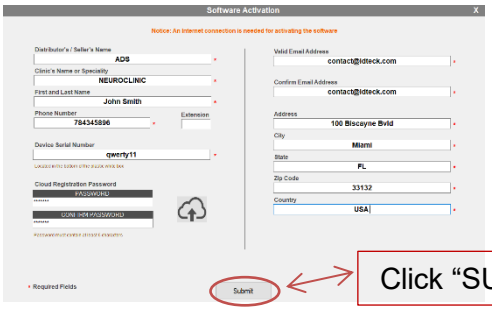
1.



STEP 1:

- Include the information required:
  - First and last name
  - Phone Number
  - Device Serial Number (you can find it under the white plastic box)
  - Valid Email Address and Cloud Registration Password
  - Address

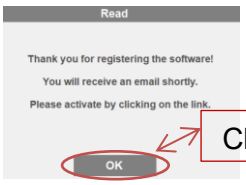
2.



Click "SUBMIT"

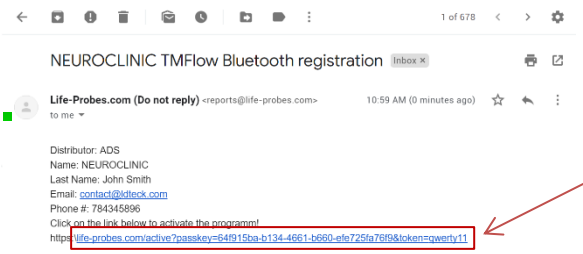
STEP 2:

- Once everything is correctly filled in, click on "SUBMIT". You will receive the message below. Click OK to receive the verification email.



Click "OK"

3.



STEP 3:

- Once everything is correctly filled in, click on "SUBMIT". You will receive the message below. Click OK to receive the verification email.

In addition, attached to this email you will receive the **Certificate Warranty**.

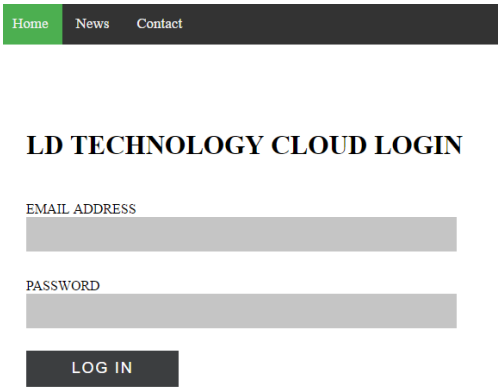
4.

STEP 4:

Access to the Cloud

- Go to the website www.ldteck.com
- Click on **Secure Cloud Access** (on the top right of the screen).

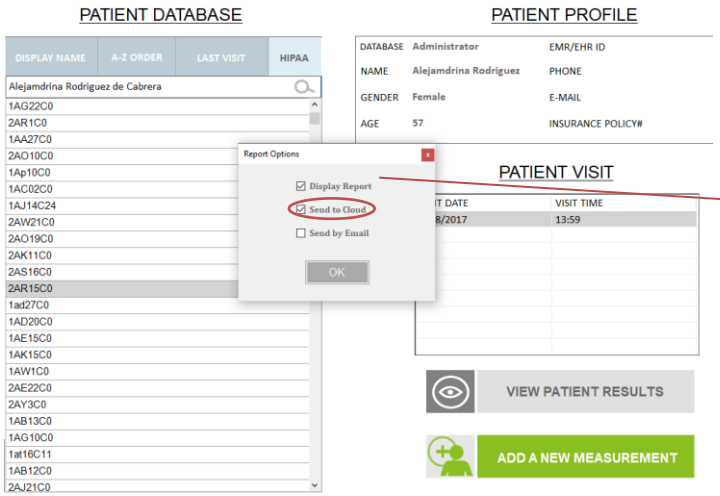
5.



STEP 5:

- Log in with the email address and password you used to register.

6.



STEP 6:

- You will have access to the patient database, profile, visit, etc.
- Click on **"Send to Cloud"** every time the "report options" message appears after you test a patient.

STEP 7:

- Click "View" to download the PDF report of the selected patient.

7.

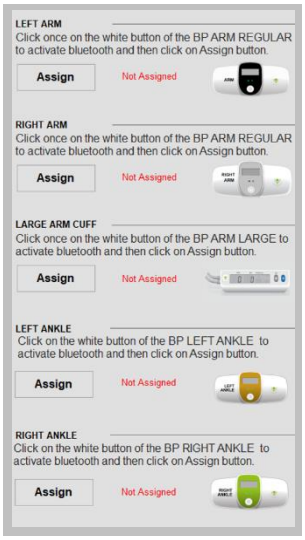
"Clicking on "remove", deletes the report from the Cloud".

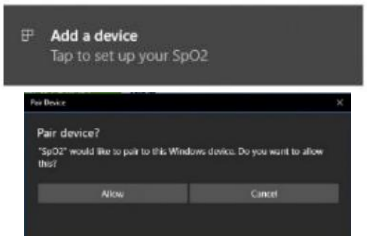
ASSIGNMENT OF TBL-ABI BLUETOOTH

Click on the «**Settings**» button to open the Setting options.

MAKE SURE **ONLY ONE** TBL-ABI IS TURNED ON.
ASSIGN ONE AT A TIME.

STEP 1



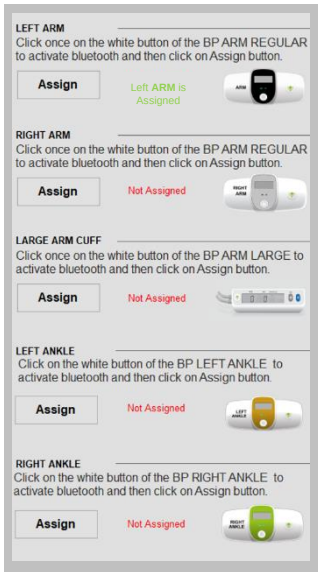


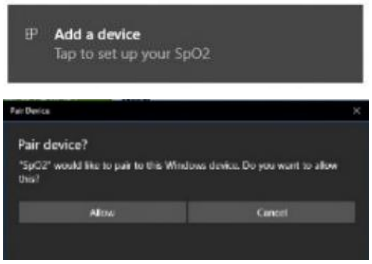
Click once on the white button of the black TBL-ABI. After, click on tab **“Assign”**.

Click on **“Add device”** and then select “allow” to pair.

The red displayed sentence **“ARM is Not Assigned”** will change to a green displayed sentence “**ARM is Assigned”**.

STEP 2



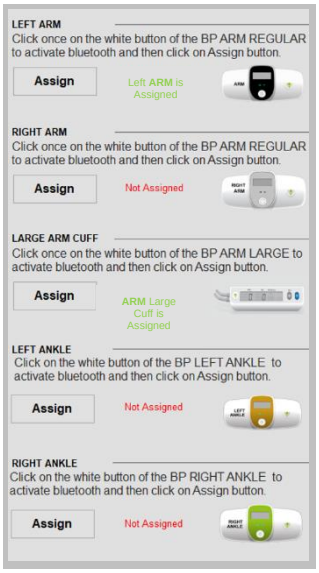


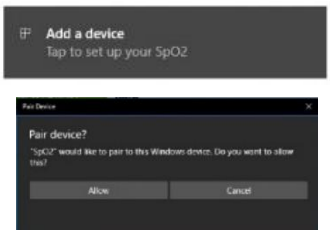
Click once on the blue button of the Large Cuff TBL-ABI. Next, click on tab **“Assign”** of the Bluetooth device.

Click on **“Add device”** and then select “allow” to pair.

The sentence displayed “ARM LARGE CUFF is Not Assigned” will change by a green sentence displayed “LARGE ARM CUFF is Assigned”.

STEP 3



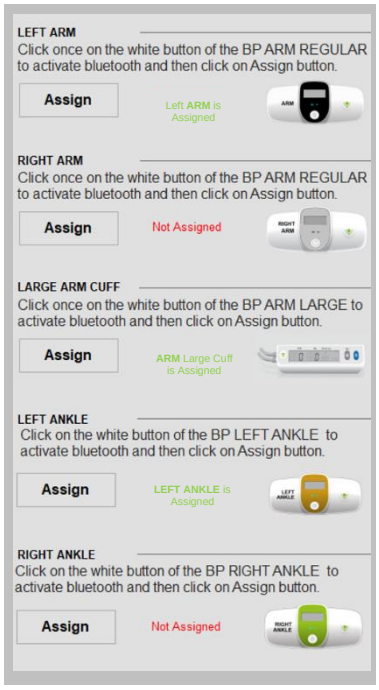


Click once on the white button of the gold TBL-ABI. After, click on tab **“Assign”** of the Bluetooth device.

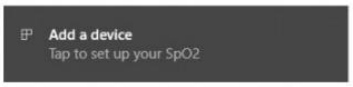
Click on **“Add device”** and then select “allow” to pair.

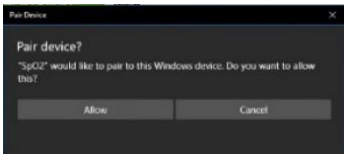
The red displayed sentence “**LEFT ANKLE is Not Assigned**” will change to a green displayed sentence “**LEFT ANKLE is Assigned**”.

STEP 4



Click one time on the white button of the green TBL-ABI. Next, click on tab **“Assign”** of the Bluetooth device.

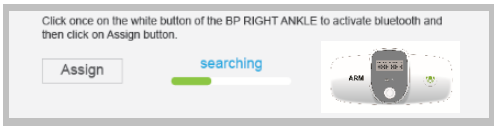




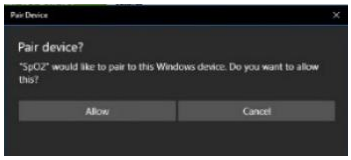
Click on **“Add device”** and then select “allow” to pair.

The red displayed sentence **“RIGHT ANKLE is Not Assigned**” will change to a green displayed sentence **“RIGHT ANKLE is Assigned”.**

STEP 5



Click one time on the white button of the grey TBL-ABI. Next, click on tab **“Assign”** of the Bluetooth device.



Click on **“Add device”** and then select “allow” to pair.

The red displayed sentence **“Right ARM is Not Assigned”** will change to a green displayed sentence “**Right ARM is Assigned”**.

STEP 6

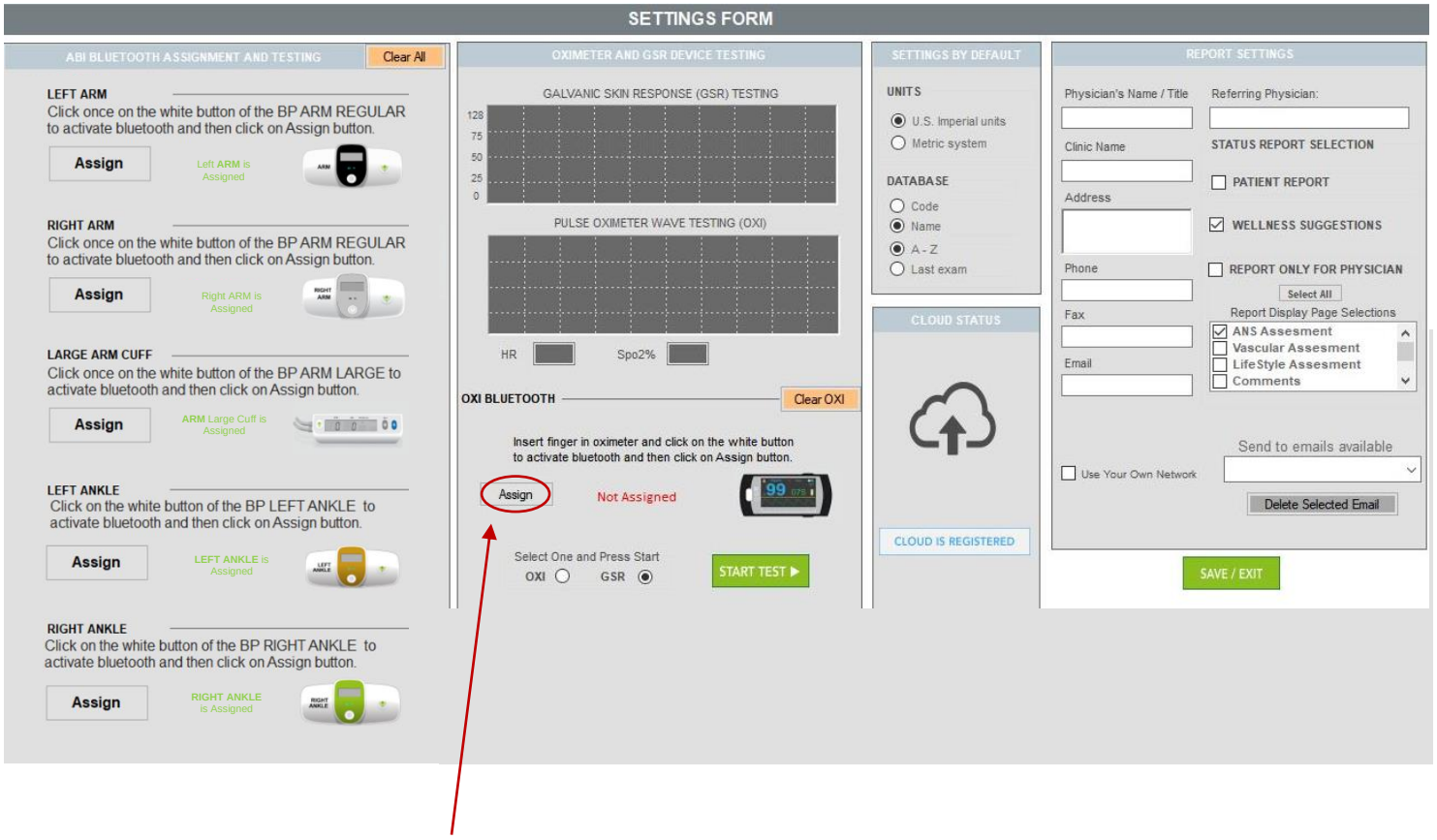
When all the devices have been assigned, click on the “**SAVE**” button.

<u>Now you are ready to use your TM-FLOW System.</u> For all measurement procedures, please refer to the **instructions for use** manual located in the software.

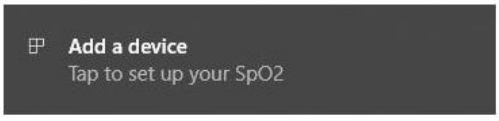
ASSIGNMENT OF OXIMETER

STEPS TO ACTIVATE:

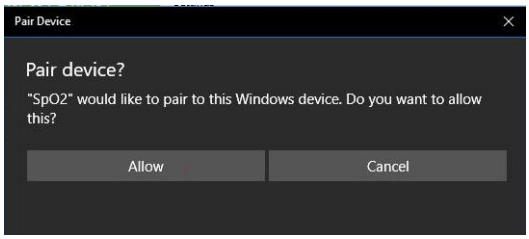
1. Go to the Settings Form.
2. Press the white button on the Oximeter to activate it.

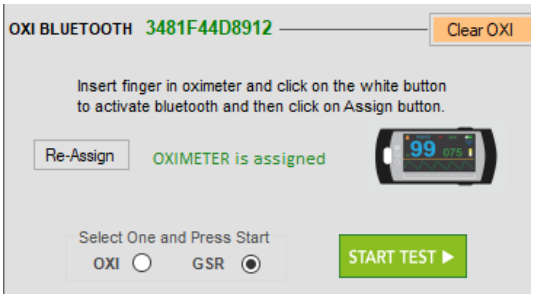


3. Click on the "**Assign"** button.
4. If you are adding a new device for the first time, then wait for the displayed message on the bottom right corner of the screen to appear and then **select add Bluetooth device**.



5. Click on "allow" to pair.
6. Once assigned, you should see the MAC address in green text next to the Clear OXI button.



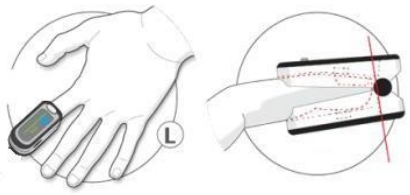


PLACEMENT OF OXIMETER

The oximeter should 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.



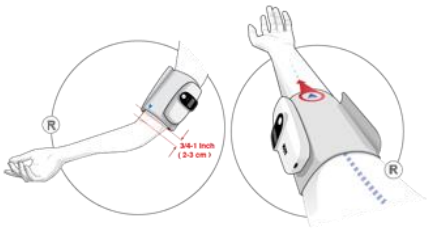
PLACEMENT OF CUFF

PREPARING THE CUFF

Applicable arm circumference:22cm – 32cm.

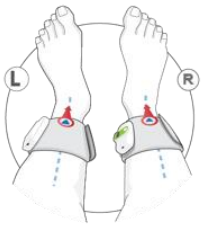
Set up the cuff as shown in the image.

ARM BLUETOOTH BLOOD PRESSURE



Place the cuffs on the left or right upper Arm (Box labelled “ARM”), 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.

LEFT AND RIGHT ANKLE BLUETOOTH BLOOD PRESSURE



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.

PLACEMENT OF SWEATC ELECTRODES

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

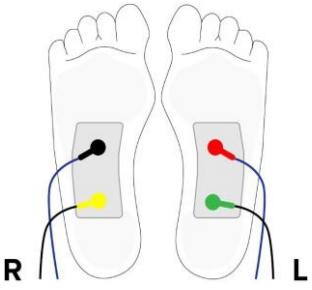
SweatC electrodes are single use.

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.



LIMIT SIZE OF THE CUFFS

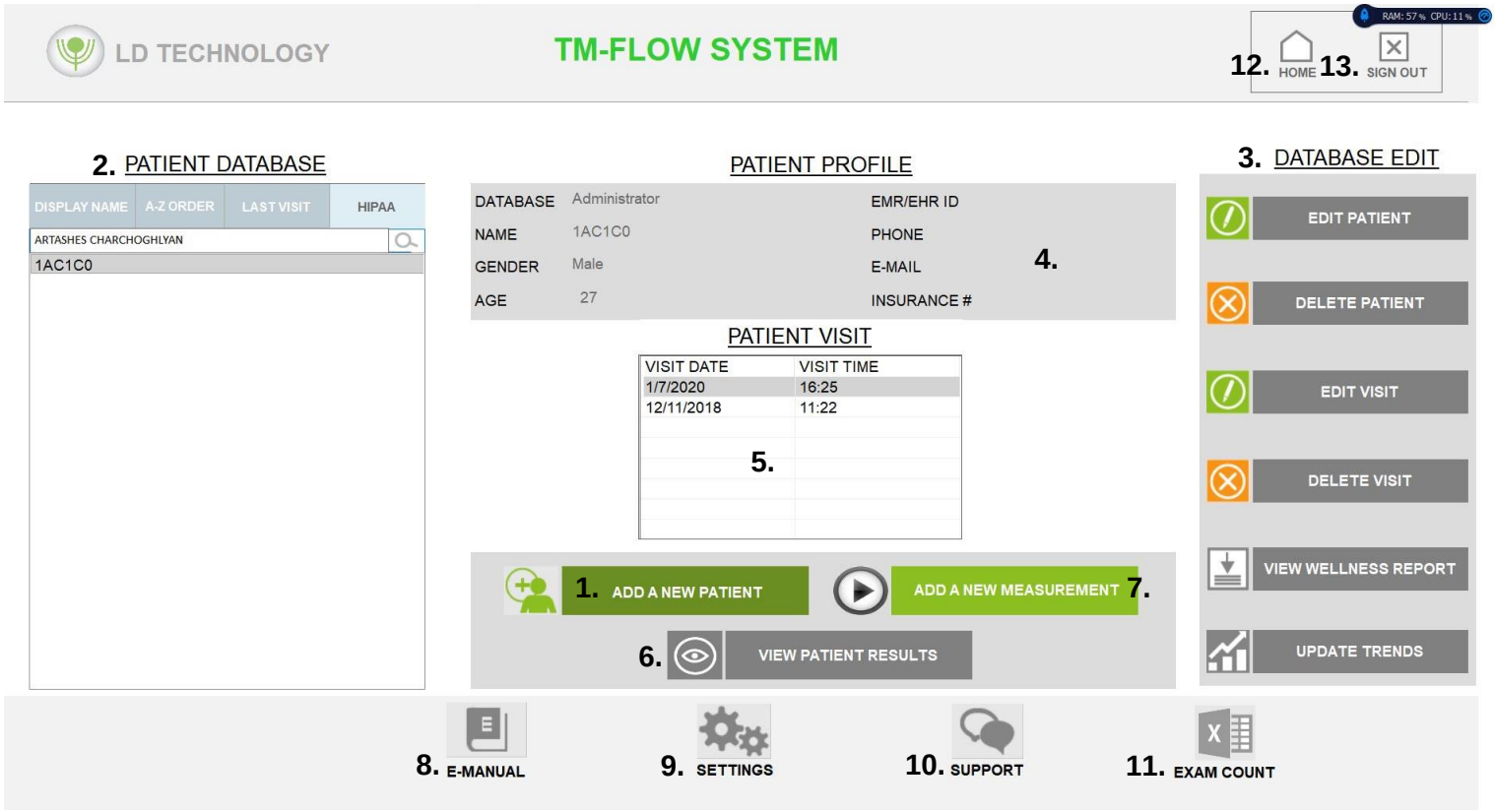
It is extremely important to use the correct size of the blood pressure cuff for the patient. Using an inappropriate cuff (the most common error in indirect BP measurement) can significantly distort BP readings.

TBL-ABI System uses cuffs from Adult cuffs from 10.5 inches to 13.6 inches.

Arm and ankle circumference measurement prior to BP measurement: measure around the middle of the upper part of the arm and ankles, at the midpoint (inches or centimeters).

If the circumference is greater than 13.5 inches, the patient cannot perform the exam.

SOFTWARE DASHBOARD



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 patient.
2. Patient database.
3. Database edit.
4. Patient profile.
5. Patient visit.
6. View results.
7. Start a new measurement.
8. E-manual.
9. Settings.
10. Support.
11. Exam count.
12. Sign out (closing the software).
13. Home (returning to the login page).