TM-FLOW SYSTEM

VASCULAR FUNCTION & AUTONOMIC NERVOUS SYSTEM ASSESSMENT
HARDWARE ELECTRONIC BOX REFERENCES:

- Electronic box: Ref. LD-Oxi
- Electronic box: Ref. SweatC
- Electronic box: Ref. TM-ABI

ACCESSORIES REFERENCES

- TM-ABI Reusable Blood pressure adult Cuff arm: RNC0001A-013BA
- TM-ABI Reusable Blood pressure adult Cuff left ankle: RNC0001A-013BLF
- TM-ABI Reusable Blood pressure adult Cuff right ankle: RNC0001A-013BRF
- TM-ABI Reusable Blood pressure Large cuffs sets: RNC0001A-013BXLS
- SweatC Disposable electrodes: Ref. PG 474W
- SweatC Reusable Cable yellow: Ref. PG395/15R2N
- SweatC Reusable Cable red: Ref. PG395/15R2N
- Manometer: MA40
- Outputs for manometer: OMA40
- TM-ABI USB Cable: Ref. USB-A
- 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.

Do not use in presence of Magnetic resonance

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: NOVEMBER, 5TH, 2016
• VERSION 3: JANUARY, 15TH, 2017
• VERSION 4: NOVEMBER, 1ST, 2017
• VERSION 5: JANUARY, 18TH, 2018
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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:

a) TM-ABI (Ankle brachial pressure Index measurement device).

b) SweatC (Galvanic Skin response)

c) LD-Oxy (Oximeter). When used in combination with TM-ABI and/or SweatC, and/or LD-Oxy 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 (sweat gland function, skin blood flow, Ewing tests and Ankle brachial Index). 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.

TM-ABI INTENTED USE

The TM-ABI is indicated for use on adult subjects at risk of having or developing peripheral arterial disease (PAD).

TM-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. TM-ABI can be used on patients with unilateral lower limb amputation. The TM-ABI System is intended to be used in spot checking patients. The TM-ABI provides information regarding patient risk. The physician has the responsibility of making proper judgments based on this information.

SWEATC INTENDED 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. It is the physician’s responsibility to make proper judgments based on these numbers. The device is indicated for use in the general adult population.

LD-OXI INTENTED USE

LD-Oxi oximeter displays the photoplethysmography. It used to determine vascular function and heart rate variability at rest and during the Ewing tests.
THE SWEATC DEVICE COMPRISES:
USB plug and play hardware device including interface box, 2 tactile disposable electrodes and cables.
The electrodes are placed on the skin directly on contact with the soles of the feet. The USB port is used for the protocol communication between hardware/software.

TM-ABI DEVICE COMPRISES
USB plug and play hardware including interface box, 3 blood pressure cuffs and valves.

LD-OXY COMPRISES
USB plug and play hardware including interface box and oximeter sensor.
The system is delivered with a set of adult ‘Standard’ or ‘Regular’ Cuffs – (Medium 27-24 cm) and arm large adult Cuff (35-44 cm)
Additional Adult thigh Cuff (45-52 cm) will be delivered upon request and quote.
How to connect the tube. Click into connection port.

To take off the tube, gently squeeze the metal tip and pull back and out of the connecting port.

**OXIMETER**

**LD-OXI**

Oximeter Probe and Cable

Oximeter USB connector cable.
Connect the oximeter probe cable to the usb connector cable.

**HARDWARE SOFTWARE CONNECTION**

**DRIVERS:**
The device is configured in the “plug and play” mode. Device driver installation is performed via setup.exe, however single driver installation can be performed by running dpinst.exe. Each time the device is connected to the laptop it will appear in the OS’s device manager under “Portable Devices.” When the device is disconnected, it will disappear from device manager.

**SETUP CONNECTION:**
- **PC connection**
- **TM-ABI connection**
- **LD-OXY connection**
- **SWEATC connection**

**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.

**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

The devices should not be used in association with or presence of defibrillators, cardiac pacemakers, patients connected to electronic life support devices, or any implanted electronic device.

SWEATC CONTRAINDICATIONS:

DON’T USE THE DEVICE IN THE FOLLOWING CONDITIONS:

- Placed on a floor made of carpeted material:
  Risk: 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%.
  Risk: 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).

- Presence of MRI or MR or CT SCAN.
  Risk: An Electromagnetic environment could short out the device. A message will appear and the measurement will stop (i.e. troubleshooting).

- 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.

TM-ABI CONTRAINDICATIONS

- Arterial catheter, AV stula, or pressure dressing.
- Venous pulsations may cause erroneous readings in blood pressure (e.g. tricuspid valve regurgitation).
- Bilateral mastectomy
**LD-OXI CONTRAINDICATIONS**

- When using the oximeter probe, use the finger of the arm not in use with the blood pressure cuff, arterial catheter, or 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.
- For elderly patients or subjects with a weak pulse due to shock, low ambient/body temperature, major bleeding, or use of a vascular contracting drug, the SpO2 waveform will be decreased or absent.
- Fingernail polish or false fingernails may cause inaccurate SpO2 readings.
- Venous pulsations may cause erroneous readings in blood pressure (e.g. tricuspid valve regurgitation).
- Be careful with low perfused patients. Using the blood pressure device may cause skin erosion and/or pressure necrosis.
- 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.

**WARNINGS**

- 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, TM-ABI and TM-Oxy 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, which could possibly result in injury or death. Inspect the patient cable. 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 anaesthetics. 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, and 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 such as:
• 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

• White-Coat Hypertension (anxiety)
• 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.
• Features: When the blood pressure reading is being taken, patient should be lying in a comfortable position.
• Considerations: Other factors include age, race, temperature, medication, emotional state, stress, exercise, smoking, and medical conditions such as diabetes, obesity, cardiovascular disease, irregular heartbeat, pregnancy and alcoholism. These factors need to be taken into account to determine an accurate measurement of blood pressure.
  - The accuracy of the blood pressure device should be verified, and we recommend that a calibration is performed annually.
  - The blood pressure device might not meet its performance specifications if stored or used outside of the temperature and humidity range.
  - Blood pressure measurements determined with this device are equivalent to those obtained by an intra-arterial blood pressure measurement device within the limits prescribed by the American National Standard for manual, electronic, or automated sphygmomanometers.
  - Cardiac arrhythmia may cause an irregular heartbeat, and may increase the measurement time.
  - If the patient is on a Heart-Lung machine, the measurement may not be possible.
  - Rapid pressure changes may not be possible to record.
  - Severe shock or hypothermia may give unreliable results since reduced blood flow to the peripheries will reduce pulsation of arteries.
LD Technology provides a CD or USB flash key with a setup program. When you open the CD or USB flash key you will have the following file:

Click on TM-Flow Setup and then follow the indications. The software and drivers will be automatically installed at the end of the process.

**FIRST TIME SOFTWARE ACTIVATION**
At the end of the setup window opens with the software code number. Click on in order to get your activation Pin code after registration.

**REGISTERING YOUR SOFTWARE**
Your computer must be connected to internet. The window open and you have to fill all the required information. The email and the password your created will allow you to receive the patient reports thought the secure cloud.

Click on and you will receive your Pin code activation in your email box. Enter the Pin code activation in the box

and then click on to access to your TM-FLOW software.
PRESENTATION OF THE SOFTWARE

SOFTWARE INTERFACE

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 agreement, consult the eManual, and contact the online technical support.

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**TM-FLOW SYSTEM**  -  Medical Device Data System

**LOGIN DATABASE**
- Administrator
- Create new database

**PASSWORD**  -  Optional
- Forgot your password

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Warning: This software is being protected under intellectual property laws as well as international conventions. Any partial or total reproduction of this document is strictly forbidden. Any person not respecting these provisions will be guilty of misdeemeanor infringement of copyright and liable to sanctions as provided by the law.
HOME SCREEN

THE TOOL PANEL

On the left side is the tool panel. The panel contains different tools available to the user on every screen. While on the home screen, the three tools you can access are:

**EMANUAL**: Click on this icon to open the TM-FLOW instruction for use.

**SUPPORT**: Provides access to online technical support during your TM-FLOW experience.

**LICENSE AGREEMENT BUTTON**: Click on the icon to view your current contract with LD Technology.

LOGIN TO DATABASE

The Database Login on the main panel of the home screen contains seven fields and buttons:

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

**+ CREATE NEW DATABASE BUTTON**: If you would like to create a new database, click on this button to enter a database name and optional password.

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

**PASSWORD**: Protect your database with a password.
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. IMPORT A PATIENT (FROM A FILE)
3. PATIENT DATABASE
4. DATABASE MANAGEMENT
5. PATIENT PROFILE
6. PATIENT MANAGEMENT
7. PATIENT VISIT
8. PATIENT VISIT MANAGEMENT
9. VIEW RESULTS
10. START A NEW MEASUREMENT
11. E-MANUAL
12. SETTINGS
13. SUPPORT
14. EXAM COUNT
15. SIGN OUT (CLOSING THE SOFTWARE)
16. 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 BUTTON :**
Log you out of the current database and returns you to the home screen.

**SIGN OUT BUTTON :**
Log you out to windows.

**SETTINGS :**
Clicking on this button will take you to the Settings Dashboard. Please see the Settings Dashboard instructions for further details.

**EXPORT DATA TO EXCEL :**
On the Settings Dashboard 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 panel contains all of your patients stored in the current database. Each selected patient’s information and associated visit(s) will appear on the right.

- Double clicking on the name of the patient will give you access to the test result of the patient. Also, click on View Result button does the same.
THE PATIENT MANAGEMENT PANEL

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 BUTTON:
The Delete Patient button will allow you to delete a patient from your database, and will bring up the following prompt:

![Patient Delete Message]

Are you sure you want to delete patient "A D"?

OK  Cancel

THE DATABASE MANAGEMENT PANEL

DISPLAY NAME BUTTON:
Displays the patient name.

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

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 BUTTON:
Clicking on the HIPAA button will encrypt your patient database list to comply with HIPAA regulations.
THE VISIT MANAGEMENT TOOLBOX

**VIEW PATIENT REPORT BUTTON:**
The view patient report will open the status report of the patient corresponding to the selected visit.

**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 physician notes form allows you to create notes for the current patient. The notes and optional uploaded signature will be reported in the patient report.

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**NOTE**

Clicking the «OK» button will save the notes.

Clicking the «Cancel» button will dispose of any note added.
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 fields on this form are mandatory, but may be helpful in patient record keeping.

By clicking on the «CONTINUE» button, 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**

**SETTIGNGS:**
Click on the Settings Button to open the Setting options.

---

**TESTING FOR DEVICE FUNCTIONALITY**

On the Settings Dashboard you can ensure the pulse oximeter, galvanic skin response device are functioning correctly.

To test the pulse oximeter, make sure the OXI checkbox is selected.

Press **START** to proceed. The pulse waveform should appear on your screen in the Pulse Oximeter Wave testing box.

To test the galvanic skin response device, make sure the GSR checkbox is selected.

Press **START** to proceed. The galvanic skin response data should appear on your screen in the GSR Testing box.
OXIMETER AND BLOOD PRESSURE DEVICE CALIBRATION

The performance should be checked each year by the distributors of the manufacturer. Simulators are required for oximeter calibration.

The calibration Services are included in the maintenance contract or invoiced if the product does not have an active and/or valid warranty or maintenance contract.

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<td>For access to calibration, please contact your local distributor.</td>
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CHANGING THE DEFAULT UNITS

On the Settings Dashboard you can change the default units used throughout the software interfaces between imperial and metric units by checking the corresponding box in the settings by default panel as follows:

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 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 encoding patient name. 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.
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, Address, phone number, Fax, and E-mail in the corresponding fields

- You can select the type of status reports you would like to print:
  - Patient report included the Wellness suggestions
  - Physician report
  - Trends

**Networks Options**

- Server or EMR Network

  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

  If you are not registered, select «Cloud is not activated». This window will open. Click on create an account and a secure server page will allow you to register in order to receive the report in your tablet, computer or smartphone.
CLEANING AND DISINFECTION METHODS

THE HARDWARE AND ACCESSORIES ARE NOT STERILE
Do not autoclave
Do not use ethylene oxide sterilization or immersing the devices and 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


The system includes a reusable oximeter probe and a blood pressure cuffs which contact intact skin of the patient’s left arm 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, Cables trunk of the cuff, 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

PRECAUTIONS

Be aware of Contraindications, Warnings, Cautions and Notes.

1. The device, cables and cuffs must be cleaned/disinfected and then air dried. The procedure must be performed before each patient.

2. 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).

3. The measurement is carried out with the patient in a lying or reclined position, the feet should be supported at the horizontal position.

4. The right index finger must be free of Fingernail polish or false fingernails.

5. Select the right size pressure cuff. The wrong size can cause erroneous readings. Use of a cuff that is too large, too small, or improperly wrapped will result in inaccurate readings. Each patient’s extremity should be properly measured to determine the most appropriate cuff size. See below.

6. 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.

7. Do not place the pressure cuff in the same arm if a catheter or intravenous infusion is in place.

8. Make sure that the air conductors are connected to the blood pressure cuffs, and that they are neither blocked nor tangled.

9. Ensure that the pressure cuffs are completely deflated.

10. 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.
   - Rest arm and feet on the exam table or reclined chair.
   - Patient is to remain still and not talk during the measurement.
OXIMETER PLACEMENT

1. The oximeter shall be placed on the right index finger.

2. 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.

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

CHOOSING THE RIGHT CUFF SIZES

It is extremely important to use the correct size of blood pressure cuff for the patient. Using an inappropriate cuff (which is the most common error in indirect BP measurement) can significantly distort BP readings. TM-ABI system is delivered with a Standard and Large adult cuffs. We can provide an Adult Thigh Cuff with additional cost.

Sizes of cuffs available, depending on the circumference of your arm:
Adult ‘Standard’ or ‘Regular’ Cuff-fits most average-sized people. Large Adult Cuff-fits most plus-sized people. Adult ‘Thigh’ Cuff-fits most supersized people or mid-sized people with heavy arms.

HOW TO CHOOSE THE RIGHT CUFF SIZE:

1. 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).

2. Use the conversion chart (inches to centimeters) of some of the most common arm/ankles circumferences.

3. The American Heart Association has developed general guidelines for cuff sizes. They are summarized in the following table.

<table>
<thead>
<tr>
<th>Cuff</th>
<th>Circumference range at Mitpoint (cm)</th>
<th>Circumference range at Mitpoint (inch)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult</td>
<td>27 - 34 cm</td>
<td>10.5 - 13.6 inch</td>
</tr>
<tr>
<td>Large Adult</td>
<td>35 - 44 cm</td>
<td>13.7 - 17.3 inch</td>
</tr>
<tr>
<td>Adult thigh Cuff</td>
<td>45 - 52 cm</td>
<td>17.4 - 20.4 inch</td>
</tr>
</tbody>
</table>

*These guidelines are from a study in the journal, Circulation (1993;88:2460-2467), by Dorothee Perlo, MD; Carlene Grim, MSN, SpDN; John Flack, MD; Edward D. Frohlich, MD; Martha Hill, PhD, RN; Mary McDonald, MSPH, RN; and Bruce Z. Morgenstern, MD, Writing Group. (This table is adapted from http://www.americanheart.org/presenter.jhtml?identifier=3000861.)
To perform Ankle Brachial Index measurement place the cuffs on the limbs like this:

1. Red cuff on an upper left or right arm.
2. Yellow cuff on left ankle.
3. Green cuff on right ankle.

Each cuff is also labeled: Arm, Left Ankle or Right Ankle.

Place the cuffs so that there is a finger’s width of room between the limb and the cuff.

The cuff on the upper arm must be placed so that the artery label (Artery) points towards the elbow. When placing the cuff observe the image on the left. The cuff tube should point towards the fingers.

The ankle cuffs must be placed so that the ankle label (Medial Ankle) points towards the inner side of the ankle. When placing the cuff, observe the image on the left.
**SWEATC ELECTRODES PLACEMENT**

**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.

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

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

**SweatC electrodes are single use.**

**ADDING A VISIT**

1. You can add a new visit by clicking on:

   ![CONTINUE button](continue-button-icon.png)

   The «Add a new measurement» tab will allow you to add a visit for the currently selected patient.

   *(If the patient is already registered in the database)*

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

The software will automatically convert between feet and inches to centimeters depending on which option is selected.

This error message will appear if no activity level has been 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** button, you will be taken to the «Patient Setup Steps» window. Please refer to the performing a measurement instructions for further details.

After you have added a visit (please reference adding a visit instructions for details), you can perform the patient measurement.
MEASUREMENT STEPS

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

PATIENT SETUP STEPS

- **ARM CUFF PLACEMENT**: The arm cuff can be placed on the right or left arm. The arm cuff should face down toward the wrist.
- **OXIMETER PLACEMENT**: Place the pulse oximeter on the index finger or the arm, not fitted with the blood pressure cuff.
- **ANKLE CUFF PLACEMENT**: The ankle cuffs should face up toward the knees.
- **DISPOSABLE PAD PLACEMENT**: Place the red strip electrode pad on the left foot. Place the black and yellow electrode pad on the right foot.

CHECKING DEVICES

Click **CONTINUE** when the button appears.

**CHECKING DEVICES**

- **Oximeter Test**: On
- **GSR Left Pad Test**: OK
- **GSR Right Pad Test**: OK
- **Blood Pressure**: OK

**Photoplethysmography and Heart Rate Detection**

- **Pulse Rate**: 79
- **O2%**: 95

**Click on continue when the button appears.**
During the checking, O2% 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 Right and left foot tests box should read **ON**

If the electrodes are not connected, the electrodes, the box will read **OFF**

If at the end of the calibration test, the Foot Test update box reads **OFF**, the following message will display:

- Please check the connections of all the cables on the feet disposable electrodes.

When the icon **START** appears, click on it to start the testing.

**TESTING AT REST RECORDING**

**THE MEASUREMENT WILL PROGRESS.**

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.
- In the section identified as BP Records, the pulse volume recording and change in the pressure 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**
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 manometer should be maintained at 40mm of mercury for 15 seconds.
   - After 15 seconds, 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 60 SECONDS
Instruct subject to inhale for 5 seconds and exhale for 5 seconds. Patient should breathe continuously and regularly.

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 right 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 « Cancel » 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.
MEASUREMENT ERROR MESSAGES

At any time during these recordings, several recording error messages can occur:

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. Please check the oximeter connections, and ensure that the patient has their index finger in the oximeter and no contraindications are present.

This message will appear if the oximeter is not correctly connected or if the patient does not have their index finger correctly inserted into the oximeter. Correcting the issue and clicking on OK will allow the measurement to progress.

This message will appear if the oximeter menu has been changed. Please refer page 10 of the present manual to correct the issue.

GENERAL TROUBLESHOOTING

SOLUTION:
- The SweatC is not connected to the USB port of the PC. Connect it.

- The SweatC Drivers are not installed. Go in Control Panel => Ports (COM &LP) and check if the drivers Master Media ESG USB device are installed. If no, you have to install the drivers.

- If the problem is not solved, unplug the USB cable of the SweatC box and plug again.
MESSAGE 2

SOLUTION:
- The USB cable is not connected from the USB box to the USB port of the PC. Connect it.
- The drivers of the TM-ABI device are not installed. Go in Control Panel=> Ports (COM &LP) and check if the drivers USB serial Port are installed. If no, you have to install the drivers.
- The TM-ABI is off or the battery power is too low. Click on the button ON of the device (the light should be green) or connect the AC/DC converter.

MESSAGE 3

SOLUTION:
- The Oximeter is not connected to the USB port of the PC. Connect it.
- The Oximeter Drivers are not installed. Go in Control Panel=> Ports (COM &LP) and Check if the drivers CP210x_VCP_Win_XP_S2K3 are installed. If no, you have to install the drivers.

MESSAGE 4

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

MESSAGE 5

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.
The results open automatically after the end of the exam.

**The results are displayed in 4 fixed windows:**
- Lifestyle window
- Homeostasis window
- Macrovascular window
- Autonomic Nervous system (ANS) window

**And 2 floating windows:**
- Markers overview
- Wellness program

**The fixed windows have 5 sections:**
- Scoring
- Markers
- Comments
- Graphs
- Modeling

Scoring and Modeling sections are the same in the 5 fixed windows.

**SCORING SYSTEM**

The TM-Flow calculated the Lifestyle, homeostasis, macrovascular 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.

Then, those scores are displayed in the scale (in %) from 0 to 25 with a color code corresponding to «Normal» (> 20), «Borderline» (<=20 and > 15) «Abnormal» (< 15 and > 10) and poor (<=10).

The cardiometabolic score is displayed in the 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 4 scores described above.
TRENDS

By clicking on «TRENDS» in the cardiometabolic score section, a window opens with trends of the cardiometabolic score.

By clicking on «TRENDS» in the bottom page, a window will open with the trends of the Lifestyle, homeostasis, macrovascular and Autonomic nervous system (ANS) scores.

MODELING

The modeling reflects the ANS balance at different organs.

Click on each organ in order to open a window with comment.

Each organ is displayed with a color code corresponding to «Normal», «Borderline» or «Abnormal».
Fixed windows:
By default, the *lifestyle markers* will be displayed in first.

**Body composition**

The body composition displayed the 3 compartments of the body:
- Fat Mass
- Dry lean mass
- Total body water

They are displayed in weight and percent of the total weight.

Each compartment is displayed with a color code corresponding to «Normal», «Borderline» or «Abnormal».

The sum in weight (Lbs) of the 3 compartments are equal to the Total Weight in Lbs.
By clicking on **homeostasis score**, the window with the markers, comments and graphs opens.

By clicking on **macrovascular score**, the window with the markers, comments and graphs opens.
By clicking on **ANS score** the window with the markers, comments and graphs opens.

Floating windows:
By clicking on “**Markers overview**” icon, the window with the main markers and trends opens.

By clicking on “**Wellness program**” icon, the pdf with lifestyle suggestions opens.
By clicking on the blue "i" icon, the pdf with meaning of the markers as well as the specificity and sensitivity of the markers 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.
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.

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

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

## ENVIRONMENTAL CONDITIONS
a) Temperature: -40°C ~ +60°C  
b) Relative humidity: 5% ~ 95%  
c) Atmospheric pressure: 500hPa ~ 1060hPa

## OPERATING ENVIRONMENT
a) Temperature: 10°C ~ 40°C  
b) Relative Humidity: 30% ~ 75%  
c) Atmospheric pressure: 700hPa ~ 1060hPa  
d) Operating altitude -500 ~ 4600 meter

### REUSABLE CABLE, OXIMETER PROBE, MANOMETER OUTPUT AND BP CUFFS

<table>
<thead>
<tr>
<th><strong>EC</strong></th>
<th><strong>ERP</strong></th>
<th><strong>SN</strong></th>
<th><strong>5V</strong></th>
</tr>
</thead>
</table>
| Manufacturer’s name and address | European authorized agent | Serial number of the device | Assigned Voltage: 5V D.C  
Maximal intensity: 500 mA |

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

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.

Non Sterile  
Latex Free  
Follow the instruction of disinfection
## 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: Maximum 1.28 V
- Intensity: Maximum 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: 44 cm²

### Cable
- Material and color code: 2 m 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.
<table>
<thead>
<tr>
<th>Information</th>
<th>Display mode</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimensions</td>
<td>Width: 25 cm, Height: 7.3 cm, Depth: 20 cm, Weight: 0.6 kg</td>
</tr>
</tbody>
</table>
| Display                           | 4.3’ color LCD screen with 16-bit color depth  
Resolution: 480 x 272 pixels and in the software installed in a computer |
| Power supply                      | Output: 5V DC/3.0A. Battery type: rechargeable lithium polymer Capacity: 2.300 mAh, Number of measurements per charge: 30 |
| Measurement Ranges                | Pressure: 0 to 299 mmHg Heart rate: 30 to 199 beats per min.                                  |
| Limit values of measurement errors| Pressure: 0 to 299 mmHg, Heart rate: 30 to 199 beats per min.                                  |
| Cu s inflation and deflation      | Pressure: 0 to 299 mmHg, Heart rate: 30 to 199 beats per min.                                  |
| Temperature and humidity range    | Pressure: 0 to 299 mmHg, Heart rate: 30 to 199 beats per min.                                  |

**NOTE** These specifications are subject to change without notice.
## LD-OXY HARDWARE

<table>
<thead>
<tr>
<th>Information</th>
<th>Display mode</th>
</tr>
</thead>
<tbody>
<tr>
<td>The pulse Oxygen Saturation (%SpO2)</td>
<td>2-digital OLED display.</td>
</tr>
<tr>
<td>Pulse Rate (bpm)</td>
<td>3-digital OLED display.</td>
</tr>
<tr>
<td>Pulse Intensity</td>
<td>Bar-graph OLED display.</td>
</tr>
</tbody>
</table>

### 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 value 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: 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 rechargeable lithium battery charges when connected to the USB port of the PC.
<table>
<thead>
<tr>
<th>Output of the Battery in charge</th>
</tr>
</thead>
<tbody>
<tr>
<td>Output current</td>
</tr>
<tr>
<td>Output power</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Oximeter light</th>
</tr>
</thead>
<tbody>
<tr>
<td>Red light</td>
</tr>
<tr>
<td>Infrared</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Dimensions and Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimensions</td>
</tr>
<tr>
<td>Weigh</td>
</tr>
</tbody>
</table>

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 TM-ABI uses a battery or an AC/DC converter as a Power Supply. 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 and the title bar displays the battery status indicator and the charging indicator.

The battery status indicator is displayed in the upper left corner 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).

The manufacturer does not guarantee reliable results or device safety if the device is used with accessories not shown in this document.

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

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
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 and brought into operation in accordance with EMC recommendations. System interference can be caused by close proximity of other equipment during radiofrequency communicator.

### GUIDANCE AND MANUFACTURER’S DECLARATION - ELECTROMAGNETIC EMISSION

<table>
<thead>
<tr>
<th>Emissions</th>
<th>Compliance</th>
<th>Electronic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions</td>
<td>GROUP 1</td>
<td>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.</td>
</tr>
<tr>
<td>CISPR11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RF emissions</td>
<td>Class A</td>
<td>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 supply network that supplies buildings used for domestic purposes.</td>
</tr>
<tr>
<td>CISPR11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Harmonics emissions IEC 61000-3-2</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations/ flicker emissions IEC 61000-3-2</td>
<td>PASS</td>
<td></td>
</tr>
</tbody>
</table>

### GUIDANCE AND MANUFACTURER’S DECLARATION - ELECTROMAGNETIC IMMUNITY

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 level</th>
<th>Compliance level</th>
<th>Electronic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD) IEC 61000-4-2</td>
<td>± 6 kV contact  ± 8 kV air</td>
<td>± 6 kV contact  ± 8 kV air</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%</td>
</tr>
<tr>
<td>Electrical fast transient/burst IEC 61000-4-4</td>
<td>± 2 kV for power supply lines ± 1 kV for signal lines</td>
<td>± 2 kV for power supply lines</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Surge IEC 61000-4-5</td>
<td>± 2 kV common mode ± 1 kV differential mode</td>
<td>± 2 kV common mode</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Immunity test</td>
<td>IEC 60601 level</td>
<td>Compliance level</td>
<td>Electronic environment - guidance</td>
</tr>
<tr>
<td>---------------------------------------------------</td>
<td>----------------</td>
<td>------------------</td>
<td>-----------------------------------</td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply input lines</td>
<td>&lt;5% UT (&gt;95% dip in UT) for 0.5 cycle</td>
<td>&lt;5% UT (&gt;95% dip in UT) for 0.5 cycle</td>
<td>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.</td>
</tr>
<tr>
<td>IEC 61000-4-11</td>
<td>40% UT (60% dip in UT) for 5 cycle</td>
<td>40% UT (60% dip in UT) for 5 cycle</td>
<td></td>
</tr>
<tr>
<td></td>
<td>70% UT (30% dip in UT) for 25 cycle</td>
<td>70% UT (30% dip in UT) for 25 cycle</td>
<td></td>
</tr>
<tr>
<td>&lt;5% UT (&gt;95% dip in UT) for 5 sec</td>
<td>&lt;5% UT (&gt;95% dip in UT) for 5 sec</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field</td>
<td>3 A/m</td>
<td>3 A/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC 61000-4-8</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiated RF</td>
<td>3 Vrms 80 MHz to 2500 MHz</td>
<td>3 Vrms 80 MHz to 2500 MHz</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the (equipment or system), including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td>
</tr>
<tr>
<td>IEC 61000-4-3</td>
<td></td>
<td></td>
<td>Recommended separation distance d=(3.5/V1)*P</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>d=(3.5/E1)*P 80 MHz to 800 MHz</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>d=(7/E1)*P 800 MHz to 2.5 GHz</td>
</tr>
<tr>
<td>Conducted RF</td>
<td>3 Vrms 150 kHz to 80 MHz</td>
<td>3 Vrms 150 kHz to 80 MHz</td>
<td>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from the fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.</td>
</tr>
<tr>
<td>IEC 61000-4-5</td>
<td></td>
<td></td>
<td>Interference may occur in the vicinity of equipment marked with the following symbol:</td>
</tr>
</tbody>
</table>

**NOTE 1** At 80 MHz and 800 MHz, the higher frequency range applies.

**NOTE 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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*a*Electromagnetic site surveys are recommended for specific locations. Determine that mobile or portable equipment is away from fixed RF transmitters and broadcast antennas. RF broadcast cannot be predicted accurately with accuracy to assess the electromagnetic environment due to strength in the location in which the equipment or system is used exceeds the applicable RF compliance levels. Additional measures such as reorienting, relocating the equipment or system may be necessary.

*b*Equipment may occur in the vicinity of equipment marked with the following symbol:
<table>
<thead>
<tr>
<th><strong>COMPUTER REQUIREMENTS</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Windows</strong></td>
</tr>
<tr>
<td><strong>Laptop or desktop</strong></td>
</tr>
<tr>
<td><strong>Processor</strong></td>
</tr>
<tr>
<td><strong>RAM</strong></td>
</tr>
<tr>
<td><strong>Hard disc</strong></td>
</tr>
<tr>
<td><strong>Graphics card</strong></td>
</tr>
<tr>
<td><strong>Screen Size</strong></td>
</tr>
<tr>
<td><strong>Screen Resolution</strong></td>
</tr>
<tr>
<td><strong>Off-the-Shelf software</strong></td>
</tr>
<tr>
<td><strong>Connections</strong></td>
</tr>
<tr>
<td><strong>Interfaces</strong></td>
</tr>
</tbody>
</table>
Clicking on the information icon opens a window with the website address: www.ldteck.com, where help and technical support service is available. 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, connect to www.ldteck.com

Then run the program LDQuick.exe and 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

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 use of a computer not in compliance with the standards IES or UL 950.

In case of customer refusal to purchase an extended warranty during the product lifecycle, each above item will be quoted and invoiced separately.
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.
FDA OWNER/OPERATOR NUMBER: 9097859
FDA ESTABLISHMENT REGISTRATION NUMBER: 3006146787
REF/ TM-FLOW SYSTEM 1900PX IFU VERSION 5 18/01/2018