




Endo PAT™x System Operation Manual for US

Itamar Medical **REF** OM1695240



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ITAMAR MEDICAL LTD.
9 Halamish St., P.O.Box 3579
Caesarea Ind. Park, 3088900, Israel
Tel + 972 4 6177000
Fax + 972 4 6275598
www.itamar-medical.com



EN ISO 13485:2016

See appendix B for contact information of the regulatory authorized representative

Record of Editions

Revision	Date	Description	Chapter	Pages
1	03 Jan 2022	Initial release similar to OM1695230 Ed.4 EndoPATx Operation manual draft that has been part of the EndoPATx K211557 FDA Clearance at 29-Dec-2022 (new part number to differentiate from the CE cleared OM1695230 Ed.3)	All	All

Note: Latest version of the EndoPAT™x Operation Manual is available at:



<http://www.itamar-medical.com/Support/Downloads.html>

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1 General Information

This operation manual is part of the EndoPAT™x system.

1.1 Intended Use of the EndoPAT™x Device

The EndoPAT™x device is a non-invasive device, intended for use as a diagnostic aid in the detection of coronary artery Endothelial Dysfunction (positive or negative) using a reactive hyperemia procedure.

The EndoPAT™x Device has been shown to be predictive of coronary artery Endothelial Dysfunction in the following patient population: patients with signs or symptoms of ischemic heart disease, who are indicated for coronary artery angiography, but who lack angiographic evidence of obstructive coronary artery disease. The device is intended to be used in a hospital or clinic environment by competent health professionals

The EndoPAT™x device is not intended for use as a screening test in the general patient population. It is intended to supplement, not substitute, the physician's decision-making process. It should be used in conjunction with knowledge of the patient's history and other clinical findings.

1.2 Performance and clinical study information



NOTE EndoPAT™x is the successor of EndoPAT™2000, the currently available device, with the same intended use, same functionality, and equivalent performance. The information below is based on EndoPAT™2000 results.

The following sensitivity and specificity data were revealed from a clinical study that was performed at the Mayo Clinic Rochester, MN and that had been designed to evaluate the safety and effectiveness of the EndoPAT™2000 device as an aiding tool in the diagnosis of coronary artery Endothelial Dysfunction versus a Gold Standard for coronary Endothelial Dysfunction evaluation, the Intra-coronary Acetylcholine (Ach) Challenge method:

All subjects: Sensitivity = 82% (45/55), 95% lower confidence bound = 71%
 Specificity = 77% (30/39), 95% lower confidence bound = 63%

Females: Sensitivity = 91% (30/33), 95% lower confidence bound = 78%
 Specificity = 74% (17/23), 95% lower confidence bound = 55%

Males: Sensitivity = 68% (15/22), 95% lower confidence bound = 48%
 Specificity = 81% (13/16), 95% lower confidence bound = 58%

The Gold Standard for Endothelial Dysfunction evaluation, the Intra-coronary Acetylcholine (Ach) Challenge method, is routinely performed at the Mayo Clinic.

According to the Intra-coronary Acetylcholine (Ach) Challenge method, a catheter is positioned in the origin of the left main coronary artery and Ach is infused with incremental concentration followed by coronary angiogram. The coronary artery diameter is measured in the segment 5mm distal to the tip of a Doppler wire using a computer-based image analysis system. Average peak velocity (APV) is derived from the Doppler flow velocity spectra and coronary blood flow (CBF) is determined as: $\pi^*(\text{coronary artery diameter}/2)^2*(\text{APV}/2)$. Endothelium-dependent coronary flow reserve is calculated as percent change in CBF in response to the Ach challenge.

Normal coronary endothelial function is defined as an increase in CBF of >50% and an increase or less than 20% decrease in the coronary artery diameter in response to the maximum dose of intra-coronary Ach ($\Delta\text{CBF} > 50\%$ and $\Delta\text{CAD} > -20\%$)

[Al Suwaidi J, Hamasaki S, Higano ST, Nishimura RA, Holmes DR Jr, Lerman A. **Long-term follow-up of patients with mild coronary artery disease and endothelial dysfunction.** *Circulation* 101:948-954, 2000]

Synopsis of Clinical Study Protocol:

Objectives:

To evaluate the EndoPAT™2000 device relative to a gold standard procedure as a diagnostic aid for detecting coronary endothelial dysfunction.

Methodology:

Patients, who had been referred to diagnostic angiography cardiac catheterization laboratory for diagnostic angiography secondary to signs or symptoms of ischemic heart disease and suspected coronary endothelial dysfunction and were found to have normal or near to normal angiogram, underwent Intra-coronary Acetylcholine (Ach) challenge test to assess attenuation in required increases to coronary blood flow (CBF) and coronary artery diameter (CAD), where each of these parameters served as an indicator for coronary endothelial dysfunction. Coronary endothelial dysfunction is diagnosed if one of the following changes is observed in response to the Ach challenge test: $\Delta\text{CBF} \leq 50\%$ OR $\Delta\text{CAD} \leq -20\%$. Patients were then evaluated using the EndoPAT™ 2000, which measures Peripheral Arterial Tone (PAT™) signal changes at the fingertip, to a reactive hyperemia challenge. The PAT™ signal is a measure of the digital pulsatile volume changes and is measured with a non-invasive disposable PAT™ probe. The reactive hyperemia procedure consists of a 3-10 minute baseline recording, 3-5 minutes of blood flow occlusion to one arm using an lower arm blood pressure cuff, and 3-5 minutes of recording after cuff release. The expected response is of a post occlusion increase of the PAT™ signal amplitude and the PAT™ score is provided automatically by the system's software and is basically the ratio between the post- to pre- occlusion average signal size, corrected for systemic changes and baseline level.

Planned Enrollment: 100 patients

Actual Enrollment: 111

Safety Analysis Cohort: 110 (One patient withdrew consent)

Efficacy Analysis Cohort: 94

Criteria for inclusion:

- Patient Age > 17
- Patient referred to diagnostic angiography
- Normal or near normal angiogram (< 30% stenosis)
- Evaluation in catheterization laboratory
- Signed informed consent

Criteria for exclusion:

- Deformities of fingers that preclude adequate signal acquisition with the EndoPAT™2000 device.
- Short acting NTG less than 6 hours prior to study and calcium channel blockers or alpha-blockers less than 24 hours prior to study.

1.3 **Equipment Classification**

The EndoPAT™x device is classified as a Class IIa medical device in accordance with Rule 10 of Annex IX of the Medical Device Directive 93/42 EEC, 2007/47/EC

1.4 **Manufacturers Notice**

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1.5 **Restrictions for Use**

- Only qualified medical personnel may authorize the use of the EndoPAT™x device.
- In the event of equipment malfunction all repairs should be executed by authorized Itamar Medical Ltd. personnel or licensed service agents.
- The eligibility of a patient for a PAT™ study is generally based upon the patient's medical status. The following should not be considered for the PAT™ study:
 - Deformities of the digits of the upper extremities, which preclude adequate signal acquisition
 - Patients under the effect of short-acting NTG (3 hours washout period)
 - Patient suffering from a medical condition prohibiting blood flow occlusion in both arms. If occlusion is prohibited in only one arm then the reactive hyperemia procedure that includes the inflation of a blood pressure cuff to a supra-systolic pressure should be performed on the other arm.
- The EndoPAT™x system in whole, or in part, may not be modified in any way.

- The device is intended for diagnostic aid purposes only, and should not be used for monitoring.
- The device is not intended as a screening test in the general patient population.
- The device is not defibrillation proof.
- Itamar Medical Ltd. makes no representation whatsoever, that the act of reading this Operation Manual renders the reader qualified to operate, test or calibrate the system.
- The tracings and calculations provided by the EndoPAT™x system are intended as tools for the competent diagnostician. They are explicitly not to be regarded as a sole incontrovertible basis for clinical diagnosis.
- In the event that the system does not operate properly, or if it fails to respond to the controls in the manner described in this manual, the operator should refer to the **Troubleshooting** section. If necessary, contact our service office to report the incident and to receive further instructions (customer support can be reached at +972-4-617 7000 ext. 399, or from the US: (800) 206 6952 ext. 399).

1.6 Quality Assurance System: EN ISO 13485

	STANDARD	#
1.	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	EN 60601-1:2006 EN 60601-1:2006/AC:2010 EN 60601-1:2006/A1:2013 IEC 60601-1:2005/A1:2012 [the product was developed according to IEC 60601-1:2005 + CORR.1:2006 + CORR.2:2007 + AM1:2012 (3 rd ed+AM1) ANSI/AAMI ES60601-1:2005/(R) 2012 and A1:2012, C1:2009/(R) 2012 and A2:2010/(R) 2012 CAN/CSA -C22.2 No.60601-1 :08]

	STANDARD	#
2.	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2:2015 [the product was developed according to: IEC 60601-1-2: 2014 (Ed.4)]
3.	Medical Device Software – Software Life Cycle Processes	EN 62304:2006 [the product was developed according to: IEC 62304: 2006 + AMD1:2015]
4.	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process	EN ISO 10993-1: 2009
5.	Medical devices. Quality management systems. Requirements for regulatory purposes	EN ISO 13485:2016
6.	Medical devices. Application of risk management to medical devices	EN ISO 14971: 2012
7.	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements	EN ISO 15223-1:2016 [the product was developed according to: ISO 15223-1: 2016]
8.	Graphical symbols for electrical equipment in medical practice	IEC/TR 60878: 2015
9.	Graphical symbols -- Safety colours and safety signs -- Registered safety signs; refer to instruction manual/ booklet	ISO 7010:2019 -M002
10.	Information supplied by the manufacture with medical devices	EN 1041: 2008 + A1:2013
11.	Medical Device Directive	MDD 93/42 EEC:1993 MDD 2007/47/EC:2007
12.	FDA Quality Systems Regulation (QSR)	21 CFR part 820

	STANDARD	#
13.	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	EN 60601-1-6:2010 [the product was developed according to: IEC 60601-1-6:2010 + AMD1:2013]
14.	Medical devices - Application of usability engineering to medical devices	EN 62366:2008 [the product was developed according to: IEC 62366 : 2007 + AMD1:2014 and IEC 62366-1 : 2015]
15.	Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment	RoHS - Directive 2011/65/EU (RoHS 2)

1.7 Conventions Used in this Manual

The following conventions are used throughout this manual:



WARNINGS Are used to identify conditions or actions, which - if the instructions are ignored - may violate patient safety, or could cause damage/malfunction of the system, resulting in the irretrievable loss of data.



CAUTIONS Are used to identify conditions or actions that could cause interference with data acquisition and/or impair study results.



NOTES Are used to identify an explanation, or to provide additional information for purposes of clarification.

There are no additional warnings and cautions, other than those provided in the appropriate sections of this manual.

Physicians, nurses, and medical technicians should read the EndoPAT™x device Operation Manual carefully, before operating the system.



NOTE All pictures, images and screenshots in this operation manual are for illustrative purposes only and may vary in the actual system.

1.8 Safety Precautions



WARNING To avoid the risk of electric shock, this equipment must only be connected to a separate supply main with protective earth. Only the power cable that is provided within the EndoPAT™x package will be used for the system. Use of an inappropriate cable may cause irreparable damage to the device and may compromise patient safety or electro-magnetic compliance.



WARNING The EndoPAT™x device should only be installed with and connected to computer equipment that complies with IEC 60950-1 or IEC 62368-1.
Failure to heed these warnings may compromise patient safety.



WARNING Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.



WARNING Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.



WARNING Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the EndoPAT™x device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.



WARNING The device is not intended to be used within the Magnetic Resonance (MR) environment.

1. The EndoPAT™x device has been designed and manufactured to meet all safety requirements applicable to medical equipment. To ensure maximum operation safety the system should be used and maintained in strict compliance with the safety precautions, warnings and operating instructions provided in this manual.
2. The system contains no user-serviceable parts. It should be maintained and serviced only by qualified service personnel, authorized by Itamar Medical Ltd.
3. Purchasers of the EndoPAT™x device should ensure that only suitably trained, qualified personnel are authorized to operate the equipment. Unauthorized personnel should not be allowed access to the system. It is recommended that a list of authorized operators be maintained.
4. The EndoPAT™x device Operation Manual should be carefully studied by the authorized operators and stored where it is easily accessible. Periodic review of the manual is recommended.
5. The EndoPAT™x system is a whole system. To eliminate risk of electrical shock, do not attempt to open or remove system covers or plugs.
6. Do not operate or activate mobile phones, or other devices capable of causing electro-magnetic interference, nearby the system. Turn off wireless communication in the computer running the EndoPAT™x application.
7. Avoid placing liquids or food on any part of the system. Do not allow conductive fluids to leak into the active circuit components of the system as this may cause a short circuit, which could result in an electrical fire. In this event, only fire extinguishers approved for use on electrical fires should be used.
8. Do not allow fluids to come in contact with the pneumatic connection in the device.
9. Do not operate the equipment in the presence of explosive liquids, vapors, or gases.
10. In the event that the system does not operate properly, or if it fails to respond to the controls in the manner described in this manual, the operator should contact customer support.
11. Do not apply the probe to an infected finger or wounded skin.
12. Do not place any objects or equipment, including laptop computers, on top of the EndoPAT™x device.

2 System Overview

The EndoPAT™x device is a computer-based system for non-invasively assessing vascular endothelial dysfunction. It is based on the use of Peripheral Arterial Tone (PAT™) signal technology, during a clinically established procedure, which measures post-ischemic vascular responsiveness following upper arm blood flow occlusion.

PAT™ signal technology is a newly developed proprietary technology for measuring the magnitude and dynamics of arterial tone changes in peripheral arterial beds. PAT™ technology measures peripheral arterial tone, by recording digital pulsatile volume changes without involving painful and risky invasive procedures.

The non-invasive PAT™ probe, used with the EndoPAT™x device, is a new type of finger plethysmograph that imparts a uniform pressure field to the distal two thirds of the finger including its tip. It was designed to avoid many of the existing problems associated with conventional plethysmographic devices such as distal venous distention and the resulting induction of reflex veno-arteriolar constriction, and it has a higher dynamic range of changes and better clamping to the finger. Its extended pressure field also excludes spurious venous signals while continuously recording the digital arterial pulse wave.

Studies using the EndoPAT™x device are easily performed in any clinical setting, with a minimal period of training required. The system is fully computerized, and the recorded signals are simultaneously displayed on a PC or laptop screen. Recorded data is automatically saved, facilitating subsequent review and computerized automatic analysis. Due to the fact that analysis is performed automatically, there is no question of inter or intra operator interpretation variability.

The PAT™ software program is easy to use and has two main operating modes:

- Real time recording and display
- Off-line display and analysis

Since the system records data in real time, it is possible to follow events as they occur.

Data acquired during a study can be downloaded to the computer's hard disk and may subsequently be retrieved for off-line review and automatic analysis.

EndoPAT™x is the successor of EndoPAT™2000, the currently available device, with the same intended use, same functionality, and equivalent performance.

2.1 How to Use this Manual

This Operation Manual is designed as a general guide to help the user in operating the system. The user will find step-by-step instructions for performing a PAT™ study, and instructions for maintenance of the system.

3 Installing the System

3.1 Basic System Configuration

The EndoPAT™x device is supplied as a complete package comprising the following components:

- One EndoPAT™x device
- One EndoPAT™x software CD
- Two pneumo-electric tubing
- Power cable
- Operation manual
- Set of 6 foam finger anchors
- USB cable



Figure 1 – Typical Setup of EndoPAT™x Study

The supplied EndoPAT™x software package can be used with any Windows™ computer running Windows 10.

For details regarding hardware and software requirements, refer to System Requirements in Section 10.1.

Although individual system set-ups may vary, Figure 1 – Typical Setup of EndoPAT™x Study represents a typical setup of a study.



CAUTION The EndoPAT™x device shall be installed on a flat surface with 30cm distance from heat-generating equipment. Do not place anything on the EndoPAT™x device.

3.2 System description

The EndoPAT™x device front panel has the following indicators (see Figure 2 – EndoPAT™x System):

- POWER LED indicator
- COMM LED indicator for the device-computer communication status
- ERROR LED indicator for error status
- Probes' Deflate and Inflate buttons

The following connectors are located on the rear panel (see Figure 2 – EndoPAT™x System):

- Two pneumatic input connectors for attaching the pneumo-electric tubing, connecting the PAT™ probes to the EndoPAT™x device
- Power supply AC Inlet connector with ON/OFF switch and fuse drawer
- USB Communication port

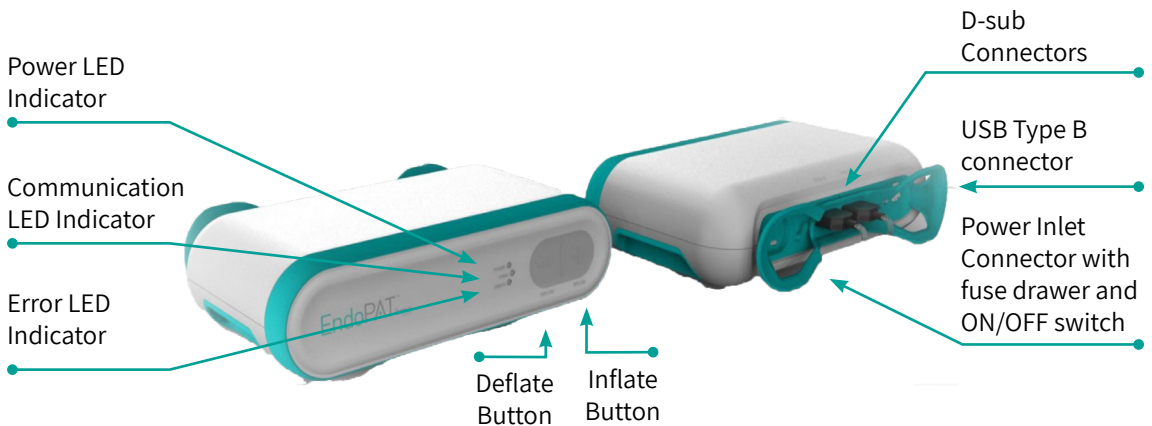


Figure 2 – EndoPAT™x System



NOTE The third conductor in the power supply cord functions only as earthing.

3.3 Connecting the EndoPAT™x device to the computer



NOTE The EndoPAT™x system requires the use of a USB cable (supplied with the system) for connecting to the computer.

1. Place the EndoPAT™x device and computer on a stable platform in close proximity to the examination bed or chair. The device should be placed at a distance from the bed or chair that is shorter than the pneumo-electric tubing (less than 1.8 meters/ 6 feet).



NOTE Refer to APPENDIX C: MANUFACTURING DECLARATIONS ACCORDING TO IEC 60601-1-2 for specific installation instructions for avoiding electro-magnetic interference between the EndoPAT™x and other electrical equipment.

2. Connect the USB cable to the communication port on the EndoPAT™x device, and to one of the computer's USB ports. Use the strain relief knob on the EndoPAT™x rear panel for ensuring that the USB cable is not unintentionally detached from the device (Figure 3).
3. Connect both pneumo-electric tubing to the EndoPAT™x device's back panel pneumo-electric connectors and secure by hand tightening the screws.
4. Make sure the power switch is off. Connect the power supply first to the EndoPAT™x device and then to an electrical outlet. Turn the power switch on.
5. The power indicator light will glow, indicating that the power is turned on.

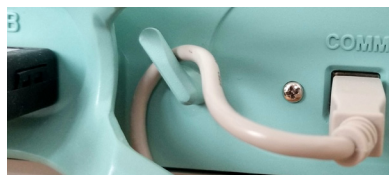


Figure 3 - Knob for USB Cable

3.4 EndoPAT™x Software Installation



NOTE Prior to software installation, verify that you are in full system administrator mode with full privileges. Otherwise, the installation might not succeed and could cause operational problems.

1. Close all open applications operating on the computer, including background applications, before installing the EndoPAT™x software.



NOTE Uninstall previous EndoPAT™x software versions prior to installing a newer version. To uninstall the software please refer to section 3.5.

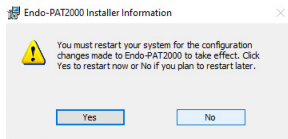
Make sure to backup all your patient data and system configuration prior to uninstalling any software.

2. Insert the EndoPAT™x software CD into the CD drive. The installation program will load automatically. Alternatively, you may execute the Itamar-Installer application from the installation CD.
3. The install wizard prepares the computer for installation. When prompted, click next to proceed with the installation.
4. Click “Next” to set the default target folder for software installation or click “Change” to select a different folder for the installation.



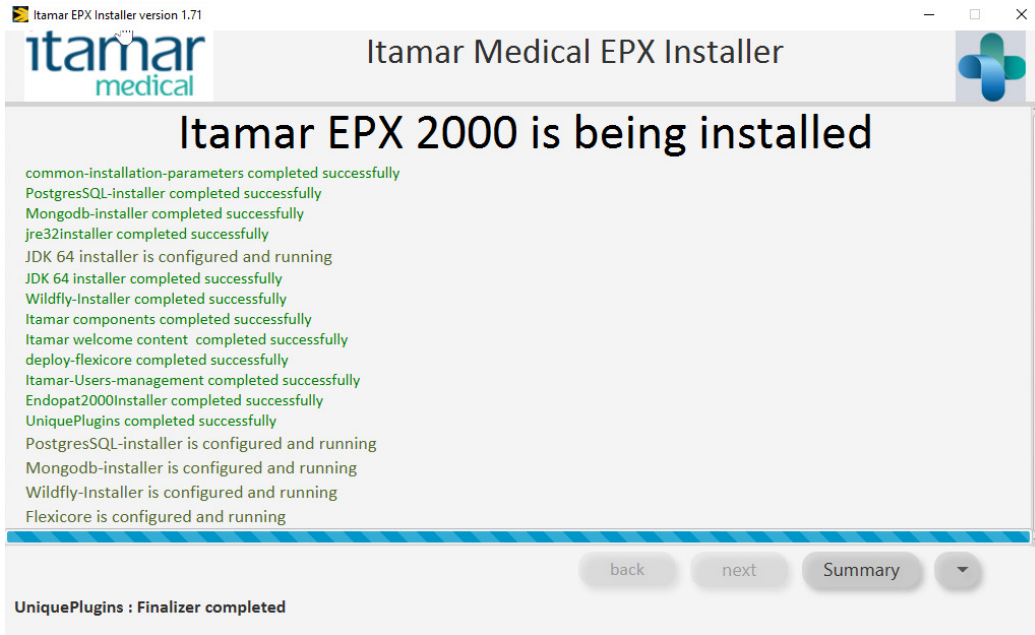
NOTE It is not recommended to install the program in the “My Documents” or “Desktop” folders.

5. Press “Install Now” to complete the installation process or “Back” to review or change any of your installation settings.
6. Press “continue” when installation permission is requested.
7. Press “Next” when the EndoPAT™2000 installation wizard is opened
8. Sign “Accept” and “Next” on License Agreement then “Next” and “Install”



9. When screen appears press “No” (don’t confirm restart!)

10. When the below screen appears click on “Summary”



- 11. Then you should see “Itamar EPx was successfully installed”
- 12. Click on the small arrow on the right corner and choose “Quit”
- 13. Confirm to stop the installation and exit the installer on the popup window by clicking “OK”
- 14. An icon will be added to the desktop after installation – link to the EndoPAT™x application.



WARNING The EndoPAT™x device is a PC operator device. Use antivirus software and password protected screen saver to protect your system and files.

You should also consider routine backups to ensure your ability for data recovery if needed.

3.5 **Uninstalling EndoPAT™x Software**

Use the EndoPAT™x install wizard to uninstall the application from your PC.

3.6 **Shutting Down the System**

- a. Shut down the EndoPAT™x software program by clicking on the “X” on the upper right corner.
- b. Switch OFF the EndoPAT™x device using the on/off switch on the back panel.

4 EndoPAT™x Application Description

The following screens describe the full application. Viewer mode has the relevant subset of the controls (the title of the screen might be different).

4.1 EndoPAT™x User Roles

There are three user roles for the EndoPAT™x:

- 1) EndoPAT™x Operator: assigned with privileges for conducting EndoPAT™x studies, managing patients and data, exporting/importing, and generating printing automatic reports.
- 2) EndoPAT™x Doctor (Reviewer): review and edit EndoPAT™x study signals, access to a comparison view of all test results of single patient, generate the report for patient view.
- 3) Local Administrator is assigned with privileges to set username, role and password as well as import export studies and generate system logs.

Roles are assigned separately to individual EndoPAT™x user.

4.2 Creating User Roles

Login Screen

From the Windows™ desktop double click the EndoPAT™x Application icon to open the EndoPAT™x Login screen.

By default, the basic users exist. To create specific users the designated Local Admin should log in.

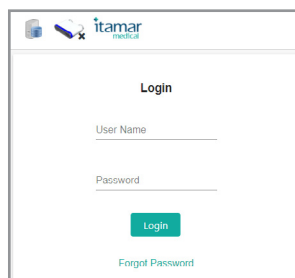


Figure 4 - Login Screen

Once logged in as Local Admin press on the arrow on upper right side of the screen. A pull-down menu will open with optional tasks (Figure 5 - Local admin pull down menu).

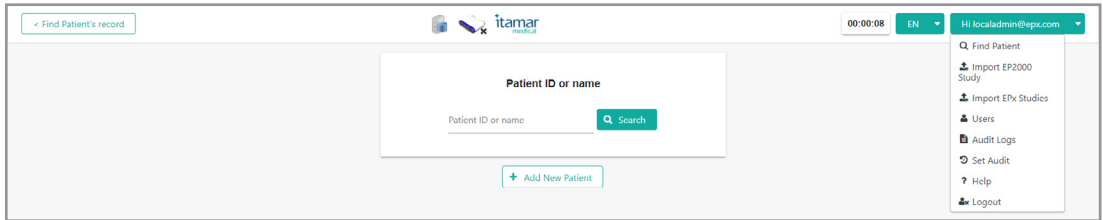


Figure 5 - Local admin pull down menu

Select Users, a list of existing users will appear and an option to Create Users.

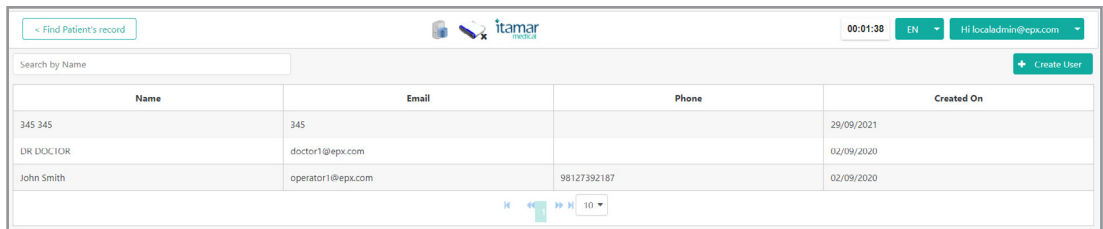


Figure 6 - List of Users

Select Create User, the following screen will appear

The screenshot shows the 'Add User' modal form. It contains the following fields and options:

- Input fields for First Name, Last Name, Email, Password, and Phone Number.
- A section titled 'Roles' with three checkboxes: Doctor, Operator, and Local Administrator.
- Buttons for 'Save' (with a checkmark icon) and 'Cancel' (with an 'X' icon) at the bottom.

Figure 7- Create User

Insert user's information and provide him with a single role (single role per username). Select Save. Provide the user with their username and password.



NOTE The system does not send an automatic email to the user, the Local Admin should provide the name and password to each user created.

4.3 Operator – Patient Management Screens

4.3.1 Search for an existing patient

The screenshot shows a web interface for patient management. At the top, there is a label 'Patient ID or name'. Below this is a text input field with the placeholder text 'Patient ID or name'. To the right of the input field is a green button with a magnifying glass icon and the text 'Search'. Below the input field and search button is a light blue button with a plus sign icon and the text '+ Add New Patient'.

Figure 8 - Search/Create Patient

Enter the patient’s name or identifier (ID). The system automatically displays the drop-down list of patients that match the entered name / ID after entering at least 1 character. You may select the patient from the drop-down list or click on Search button to open a search window, listing the patients that match the entered details.

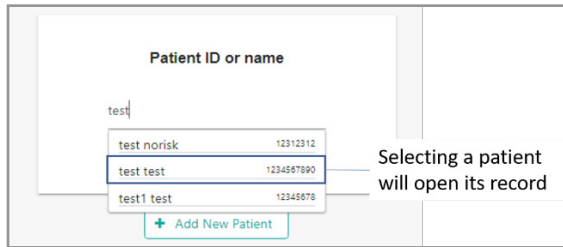


Figure 9 - Selecting Name/ID From List

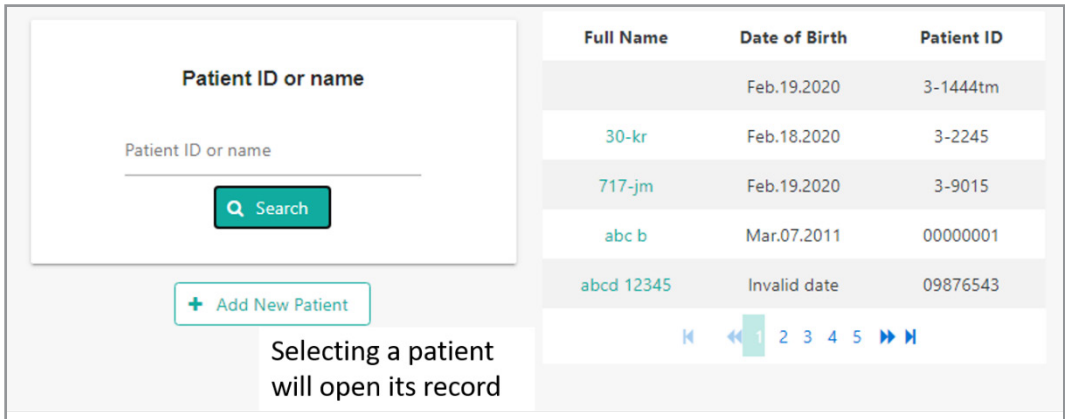


Figure 10 - Search Button List

Selecting a patient either from the drop-down list or Search results opens the Patient Record.

4.3.2 Add New Patient

To add a new Patient, click on the “+ Add new patient” button.

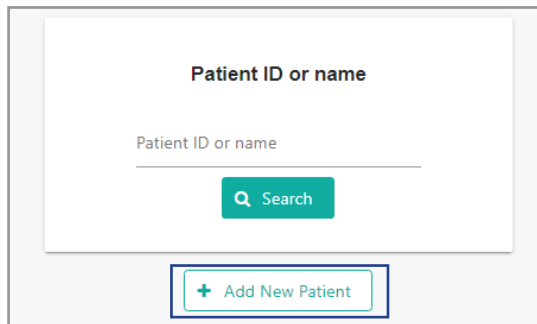


Figure 11- Add New Patient

Add New Patient window is opened for inserting the new patient’s details and risk factors (optional).

Figure 12 - New Patient

When form is filled, click “Save and Continue” button to open Patient Record screen.

4.3.3 Patient Record Screen - Operator

The Patient Record Screen displays the personal details and risk factors (optional). In addition, Previous Test Records can be accessed through this link. Use this screen to initiate an EndoPAT™x Test on a new or an existing patient through the TEST Section of this window. Patient information and risk factor parameters can be updated/edited.

Figure 13 – Patient Record and New Study

4.3.3.1 Update/Edit Patient details.

Clicking on UPDATE on the personal details sections opens the following pop-up window. Click Apply to update the details and return to the Patient Records screen.

Personal Details

First Name *
D
Max 15 characters 1/15

Last Name *
S
Max 15 characters 1/15

Male

12/02/1999

Height (cm) *
156

Weight (kg) *
67

Patient ID *
E2345456

Cancel Apply

Figure 14 - Edit/Update Patient Info



NOTE Patient ID cannot be modified and updated.

4.3.3.2 Update/Edit patient Risk Factors

To review and update the risk factors click on the Risk Factors link through Patient Information and New Study window (Figure 13).

Select Method: Reynolds, Framingham, European

The screenshot shows a dialog box titled "Risk Factors" with a close button (X) in the top right corner. Below the title bar, there is a section "Risk Factors" with a horizontal line. Underneath, the text "Select method:" is followed by a dropdown menu showing "Framingham". Below this, there are two input fields: "Total Cholesterol (mmol/L)" with a value of "0" and "Hdl Cholesterol" with a value of "0". To the right of these fields are four toggle switches: "Diabetic", "Smoker", "htn", and "CVD History", all of which are currently turned off. At the bottom of the dialog box are two buttons: "Cancel" and "Apply".

Figure 15 – Insert Risk Factors-Framingham

The screenshot shows a dialog box titled "Risk Factors" with a close button (X) in the top right corner. Below the title bar, there is a section "Risk Factors" with a horizontal line. Underneath, the text "Select method:" is followed by a dropdown menu showing "Reynolds". Below this, there are three input fields: "HDL Cholesterol" with a value of "0", "HSCRP" with a value of "0", and "Total Cholesterol (mg/dL)" with a value of "0". To the right of these fields are four toggle switches: "Diabetic", "Smoker", "Family CVD History", and "CVD History", all of which are currently turned off. At the bottom of the dialog box are two buttons: "Cancel" and "Apply".

Figure 16 - Insert Risk Factor - Reynolds

The screenshot shows a dialog box titled "Risk Factors" with a close button (X) in the top right corner. Below the title bar, there is a section "Risk Factors" with a horizontal line. Underneath, the text "Select method:" is followed by a dropdown menu showing "European". Below this, there is one input field: "Total Cholesterol (mg/dL)" with a value of "0". To the right of this field are three toggle switches: "Smoker", "CVD History", and "European Risk Region", all of which are currently turned off. At the bottom of the dialog box are two buttons: "Cancel" and "Apply".

Figure 17 – Insert Risk Factor - European

4.3.3.3 Access previous patient EndoPAT™x test records.

To access previous Patient EndoPAT™x test records, click on Previous Test Records in Patient information and new Study window (Figure 13).

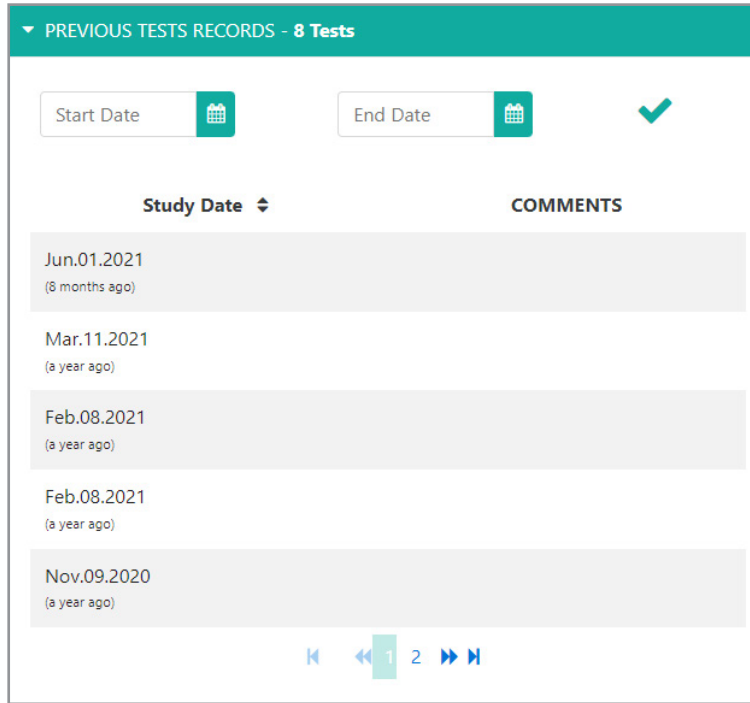


Figure 18 - List of Previous Studies

Selecting a study from this list opens a pop-up screen that allows the review of the study signal, export the signal, view, and issue an automated report and export to CSV format. In addition, it allows to update the Risk factors for the specific study and shows the risk factor data of the patient during the study.

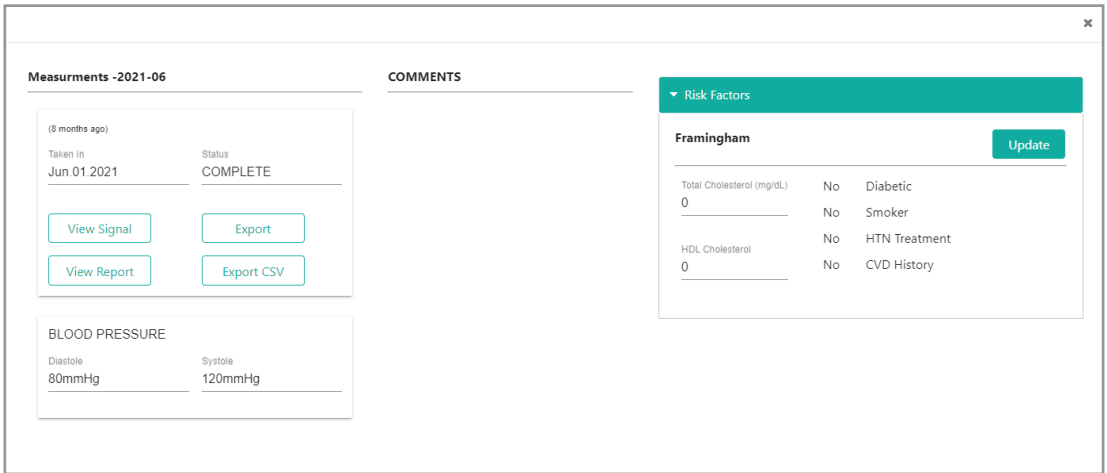


Figure 19 - Previous Study Options

4.3.3.4 View Signal

Selecting View Signal will open the previous study and enable the auto analysis of the data.

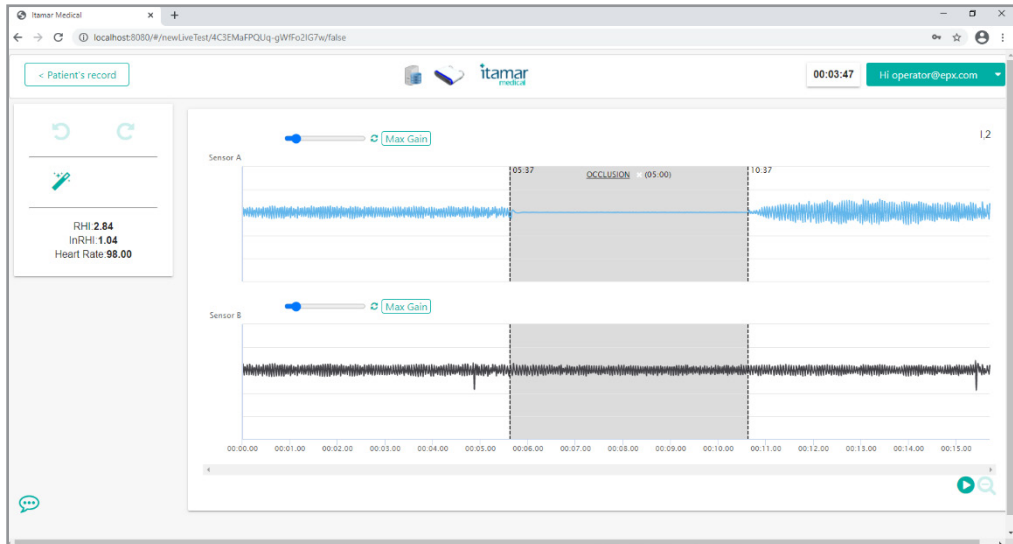



Figure 20 - View Signal Screen

Pressing the Magic Wand Icon  will generate the RHI, LnRHI and HR.

Click Patient Record  button to return to the Patient Records screen.

4.3.3.5 Export

Selecting the Export option from the Previous Study option (Figure 19) will create a file that can be imported to another EndoPAT™x system (Figure 21 below)

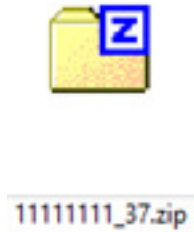


Figure 21 - Exported EndoPAT™x File

4.3.3.6 View Report

Selecting View Report will create an automated report in HTML format. See below (Figure 22)

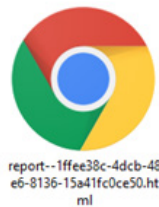


Figure 22 - Report File

Once the report is opened it can be saved as pdf or sent to print.

4.3.3.7 Export to CSV



Figure 23 - CSV File

Exporting the study to CSV will create a CSV file with all test data.

4.4 Conducting EndoPAT™x Study – Operator

The **Test** section of the screen (Figure 13) is used to finalize new study information and initiate an EndoPAT™x Study. Please note that to initiate a new test, the EndoPAT™x device must be turned on and connected.

Patient setup and test environment are important for study success, review Preparing for a Study, section 5, before commencing a new test. Review section 6 Conducting an EndoPAT™x Study, for additional important details.

This section will describe the screens as seen by the operator when performing an EndoPAT™x test.

4.4.1 Initiating a new EndoPAT™x study

In the TEST section of patient information screen, insert patient’s blood pressure information and visit number.

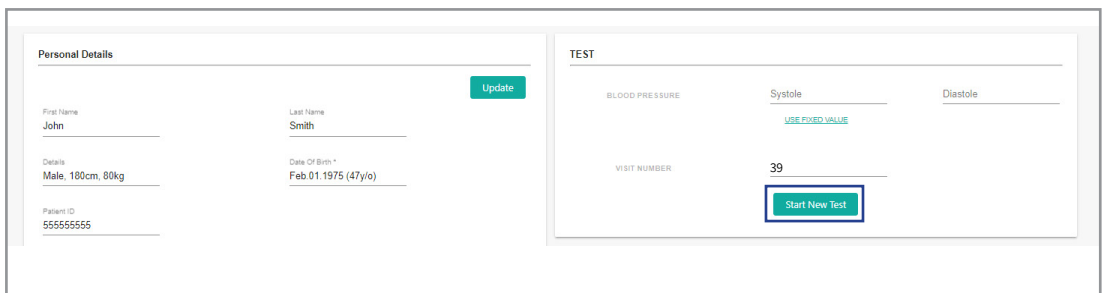


Figure 24 - Initiating New Test

When data insertion is completed, click Start New Test button to start the EndoPAT™ study. The following window will open.

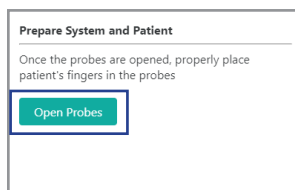


Figure 25 - Open Probs

Follow the instructions in section 5 Preparing for a Study and section 6 Conducting an EndoPAT™x Study for detailed patient hookups.

Selecting Open Probes will open the main study screen (Figure 26)

4.4.2 EndoPAT™x Study - Main Screen

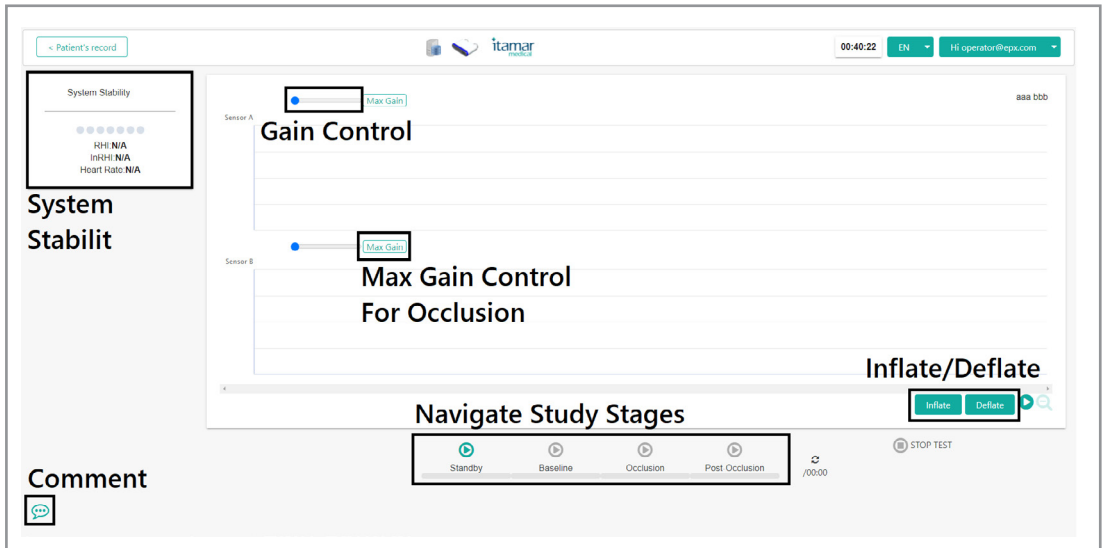


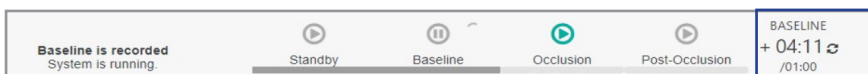
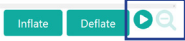


Figure 26 - New Study Screen

The main screen of EndoPAT™x study includes the following main sections:


- System stability
 - Indication of leakage detection
- PAT™ Signal Waveform Viewer
 - Display the acquired PAT™ signals from Probe A and B
 - Separate gain for each signal . Max Gain button enables optimal view of occlusion quality in the occluded signal. It should be selected on the designated occluded hand just before occlusion.
 - Study stage bookmarks and Study Control buttons enable navigation between the study stages.  Selecting the enabled (green) stage icon will display the signals of that stage on the screen and enable navigation between the various stages.
 - Once Baseline, Occlusion or Post Occlusion are selected, a timer will display the recorded section duration, the next stage will be enabled (green) following defined recording time of present stage.






- Zoom out buttons 
- Study Control

- Stop the study in middle of test if needed. 
- Navigation between study stages
- Inflate and Deflate buttons  for patient setup

4.4.3 Standby Stage

Once probes are properly connected (see section Preparation of fingers and hands before a study), and the system completes its internal tests, the Standby button turns enabled ()




When Standby button is clicked, the system inflates the probes to pre-configured pressure, starts the PAT™ signal display and Standby button changes to (). In Standby mode the system displays the signals. The operator can adjust gain for optimal view. The signal is not being recorded in Standby mode once the system is stable and signal quality is acceptable start the recording by pressing the Baseline button  .




NOTE Standby mode is for assessing signal quality and assuring system stability before recording.


Signals are not being recorded during Standby!

4.4.4 Baseline

Click on the Baseline button () to enter the Baseline Stage. The icon is changed () to reflect that the stage is active. Standby Stage bookmark and Standby  Button will be displayed greyed-out on the Study progression timeline.

Baseline Stage timer () is displayed, indicating the time elapsed since stage initiation and the recommended time for this stage. If stage elapsed time exceeds the recommended time, a “+” sign is displayed before the timer.

A Stage Reset button is displayed next to the time to allow restarting the stage.

When Baseline Stage timer reaches the recommended time, the Occlusion Stage icon becomes enabled () allowing the transition to Occlusion Stage.

Baseline recommended time is 6 minutes.

Just before end of Baseline stage and before inflation of the blood pressure cuff, press the Max Gain Max Gain button on the designated occluded signal.

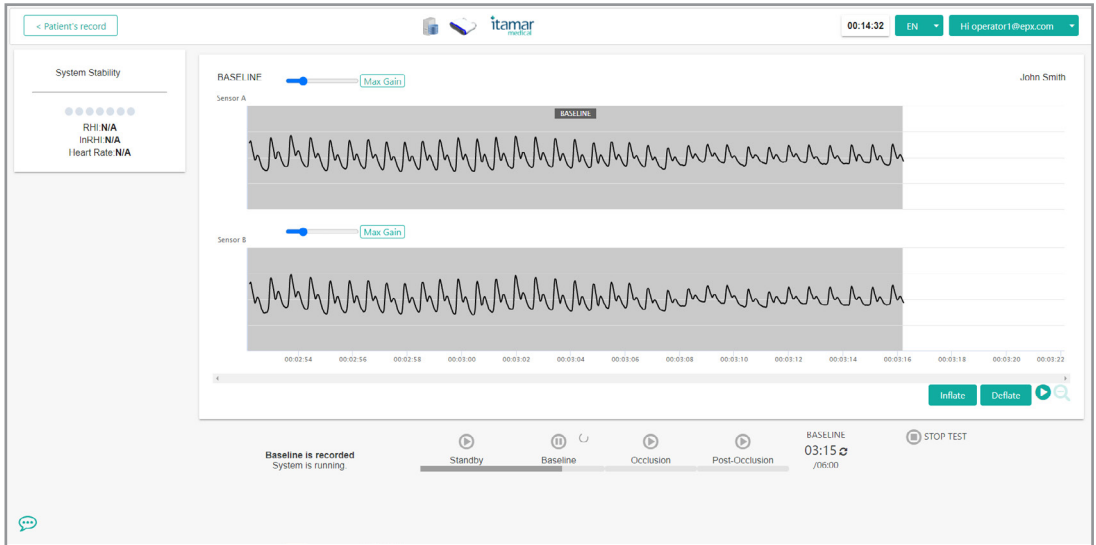


Figure 27 - Baseline

4.4.5 Occlusion Stage



Follow instruction in 6.3.2 for performing a correct occlusion. Once the blood pressure cuff is inflated click on the Occlusion Stage icon (Occlusion) to start the Occlusion Time

count. The Occlusion icon is changed (Occlusion) to reflect that the stage is active. The Baseline Stage icon is greyed out Baseline . Baseline Stage bookmark will be displayed grayed out on the study timeline. A new Occlusion bookmark will be displayed, progressing on the timeline as new signals are acquired.

Review the quality of occlusion by inspecting the occluded signal at MAX Gain. If needed, increase pressure in the blood pressure cuff to improve occlusion quality.


Occlusion Stage timer (OCCLUSION
+ 05:39 ⚙
/05:00) is displayed, displaying time elapsed since the stage started and the recommended time for this stage. If stage elapsed time exceeds the recommended time, a “+” sign is displayed before the timer.


When Occlusion Stage timer reaches the recommended time, the Post-Occlusion Stage


icon becomes enabled () allowing the transition to Post-Occlusion Stage. Occlusion time is 5 minutes and should not be extended even if additional pressure is required to improve occlusion quality following review of occlusion quality. When the timer displays exactly 5 min, quickly release the air from the blood pressure cuff on the occluded arm and click on Post Occlusion icon ().

4.4.6 Post occlusion Stage


Click on the Post-Occlusion Stage icon () to start the Post-Occlusion Stage timer and timeline. The icon is changed () to reflect that the stage is active.

Baseline and Occlusion () Stage bookmarks will be displayed greyed out on the study progression viewer and a new Post Occlusion bookmark will be displayed, progressing on the timeline as new signals are acquired.

Click on Max Gain () button to return to original signal Gain setting.

Post-Occlusion Stage timer () is displayed, indicating the time elapsed since stage started and the recommended time for this stage. If stage elapsed time exceeds the recommended time, a “+” sign is displayed before the timer.

A Stage Reset button is displayed next to the time to allow restarting the stage.

When stage time reaches the recommended time, the Finish Test button () is enabled. Click on the Finish Test button to conclude the test. Probes will deflate automatically, and the following message will appear.

Post occlusion time is 5 minutes.

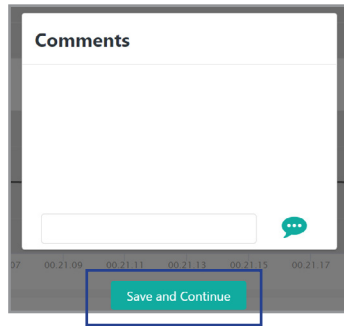


Figure 28 - End of Study Comment

4.4.7 Post-test study screen and automated analysis.

Insert comments if needed and Press Save and Continue. The Patient file will be displayed on the screen.

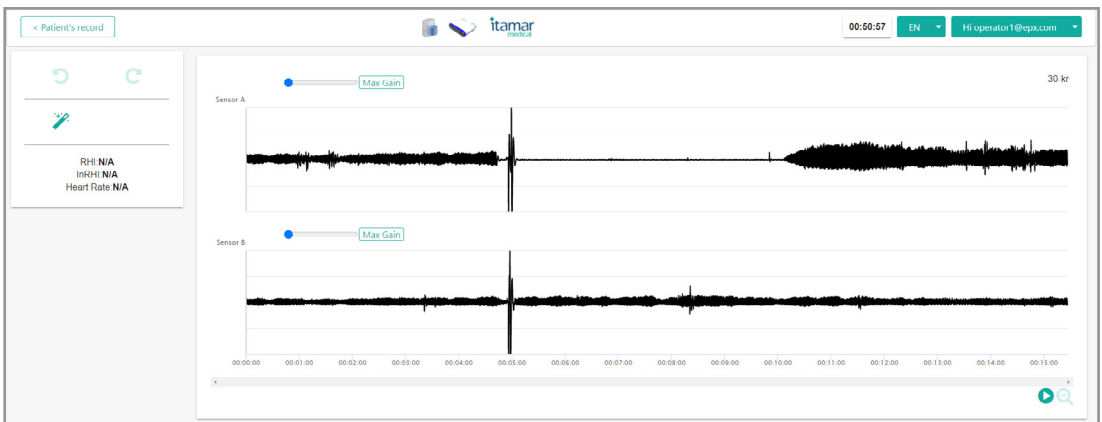





Figure 29 - Study Screen

Press the Magic Wand Icon , the study will be analyzed, and results will appear on the screen along with occlusion borders.

4.4.8 **Stopping the Study**

At any point during the study, you may click on the Stop Test button ( STOP TEST). This will automatically release the air pressure and deflate the probes. Stopping a test at any point after “Standby” will stamp the probes as “used” and new probes should be attached if restarting the study. In addition, visit number will need to be adjusted in the repeat study.

4.4.9 **Study Comments**

At any point during the study, you may click on the Comments button () to insert relevant comments about the current study.

4.4.10 Operational Warning and Error Indications

When an unwanted system condition is detected when running the study, the user is provided with error / warning indication at the bottom of the screen.



Figure 30 - Error Indicator

Clicking on either error tooltip or error indication open the following error report:

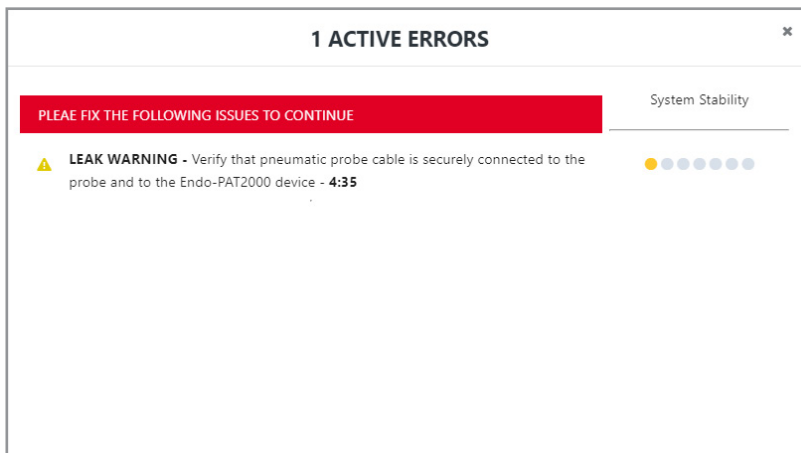




Figure 31 - Detail of Error

Symbol	Severity
	Sever error condition that impacts study execution
	Minor/moderate error condition that might impact study execution if not handled in timely manner

The time in which the error condition was detected is indicated.

4.5 Reviewing the EndoPAT™x Study – Doctor (Reviewer)

This section is applicable only to a user with the Doctor role.

4.5.1 Locating EndoPAT™x Study for review

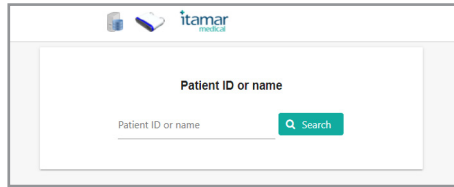


Figure 32 - Search Patient

Enter the patient’s name or identifier (ID). The system automatically displays the drop-down list of patients that match the entered name / ID. You may select the patient from the drop-down list or click on Search button to open a search window, listing the patients that match the entered details.

Full Name	Date of Birth ↕	Patient ID ↕
asra sdfaf	Dec.09.2020	23412234234
cc	Sep.02.2020	3-0428
D S	Dec.02.1999	E2345456
DSAC ASD	Aug.03.2021	1234567891
E AA	Nov.14.2001	e303030300

Figure 33 - Search Button List of Patients

Selecting a Patient from the list will open the patient record view Figure 34

4.5.2 EndoPAT™x Patient Record Views

4.5.2.1 Patient Record has two offline views for data display to the physician after the study has been completed: Doctor View and Patient View. Patient Record – Doctor View

The Patient Record, Doctor View displays patient’s details and allows their update (Figure 34, top panel).

Below patient details, the results of the patient’s EndoPAT™x studies are displayed in a graphic comparative format listed by study date and time (Figure 34, lower panel).

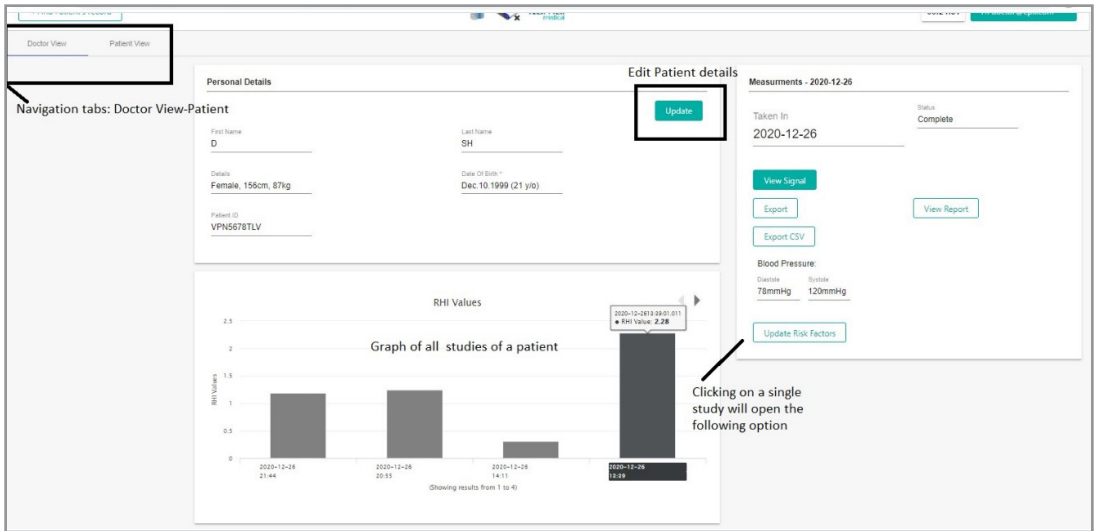


Figure 34 - Patient Record – Doctor View

Clicking on a specific study will open the following pop-up screen

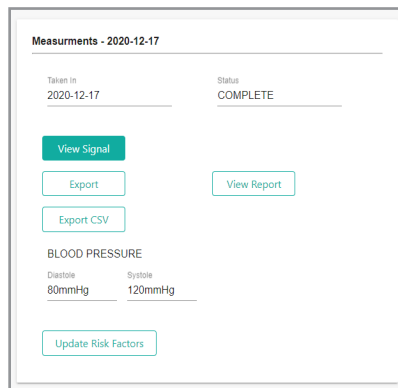


Figure 35 – Patient Record – Doctor View: Single Study Review Options

Single study review includes the following options:

- View Signal: Review signal and edit occlusion borders (if needed).
- Export: view section 4.3.3.5
- Export CSV: view section 4.3.3.7
- View Report: view section 4.3.3.6

4.5.2.2 Patient Record – Patient View

The Patient Record, Patient View (Figure 36) displays the graphs of results and medical indices of a single patient. For discussion on the RHI (Reactive Hyperemia Index) score, please refer to section 7.2. Note that the Other Medical Indices do not affect the RHI score calculation and are entered manually by the operator.



Figure 36 - Patient Record – Patient View

4.5.3 Study PAT™ Signal Review Screen

The main screen of EndoPAT™x study review includes the following main sections:

- PAT™ Signal Waveform Viewer
 - Display the acquired PAT™ signals from Probe A and B
 - Separate gain control for each signal
 - Study stage bookmarks
 - Time scale zoom
 - Timeline marker
- Editing Toolbar
 - Undo and Redo last change
 - Wand tool to automatically define study stages
 - Eraser to exclude selected section of PAT™ signal

- Study Results
 - Calculated scores and parameters

Figure 37 below describes the main screen of EndoPAT™x study.

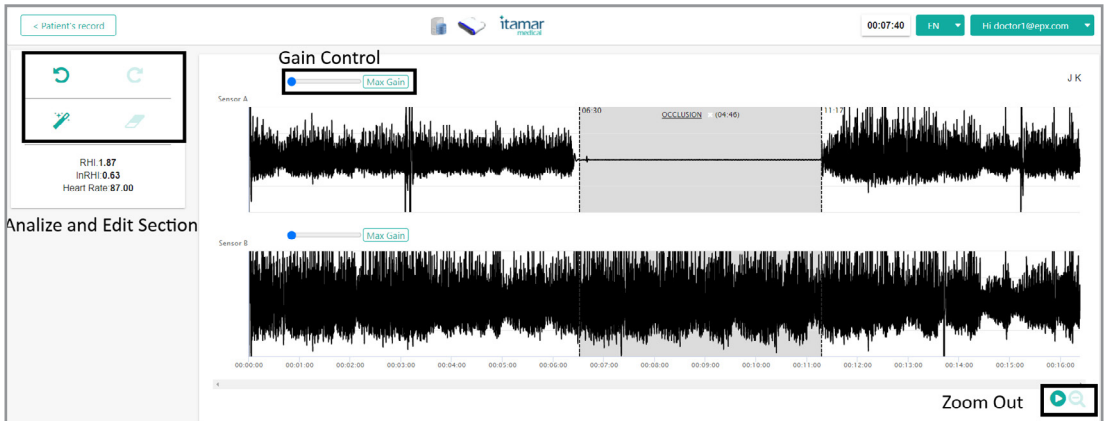


Figure 37 - EndoPAT™x Study Review Main Screen


4.5.4 EndoPAT™x Study Editing

4.5.4.1 Automatic Analysis

Automatic analysis is performed by clicking on the Wand button in the Editing Toolbar. Stage bookmarks are placed and signals that do not pass qualification criteria are excluded.

4.5.4.2 Adjusting stage bookmarks

Once automatic analysis is performed (see 4.5.4.1), Occlusion bookmarks are displayed on the PAT™ Waveform Viewer. You can adjust the stage timing by dragging the bookmark.

Hover the mouse over the bookmark until the mouse icon is changed to . Select using the left button and drag to desired time. During the dragging, the study time of the marker is indicated next to the occlusion headline

OCCLUSION x (05:56)

4.5.5 Manual Analysis (Manual Research Mode only)



NOTE Since the manual analysis (T/B) does not incorporate certain mandatory features of the automatic analysis (e.g., contra-lateral arm correction and base line correction), it can serve for research purposes only (not necessarily endothelial dysfunction applications).



NOTE To enable the Manual Analysis functions, it is necessary to enable the Manual Research Mode by Itamar Medical technician

4.5.5.1 Marking Segments and Artifacts

Tool bar icons provide quick and easy access to the tools used to mark segments and artifacts in research studies, as well as to facilitate automatic ratio calculations between PAT™ traces recorded at different time segments. This feature can define any number of time intervals as artifacts, and thereby exclude them from the ratio calculations.

You can mark segments in the Trace Window, identifying three segment types (later to be used in calculations):

- B (Baseline) segment
- T (Test) segment
- A (Artifact) segment

To Mark a Segment

1. Set Baseline, Test or Artifact on the segment selection area.
2. In the Trace Window, position the mouse's cursor at the beginning of an interval to be marked.
3. Drag the cursor horizontally along the interval—the selected segment becomes highlighted.
4. Release the mouse button at the end of the desired interval—the selected segment remains highlighted, and headline indicates its type.

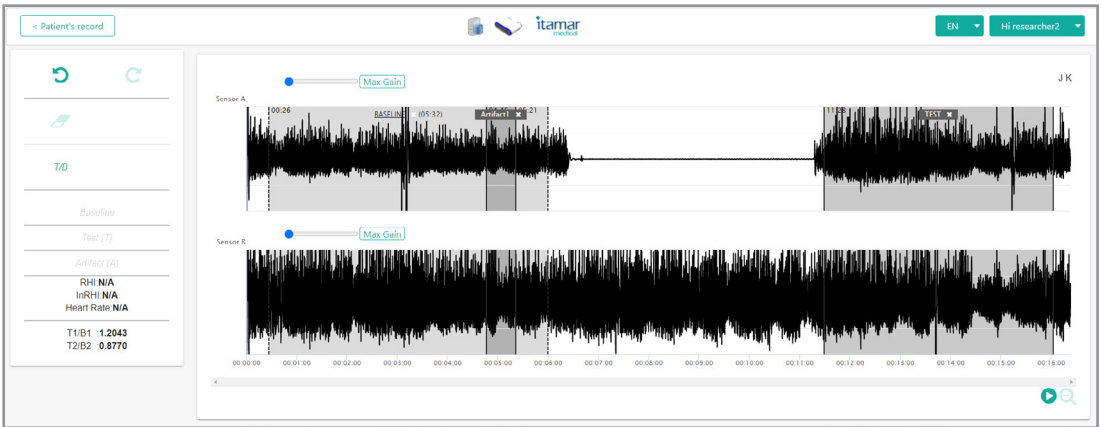


Figure 38 – Manual Research Mode Analysis and Signal View Screen

4.5.5.2 Analysing PAT™ Ratios

After the B and T segments are marked, their PAT™ ratios can be calculated by clicking T/B icon and then displayed in the left side of the screen. Note that these results might be slightly different from the automated analysis, as this tool doesn't include all the analysis logic.



NOTE Calculated segment ratios displayed in the left side of the screen do not have clinical implication. This feature is used only for research purposes and should not be regarded as device output concerning Endothelial Dysfunction.

4.5.6 Printing EndoPAT™x Study Report

Select the Print option on the browser to print the study report.

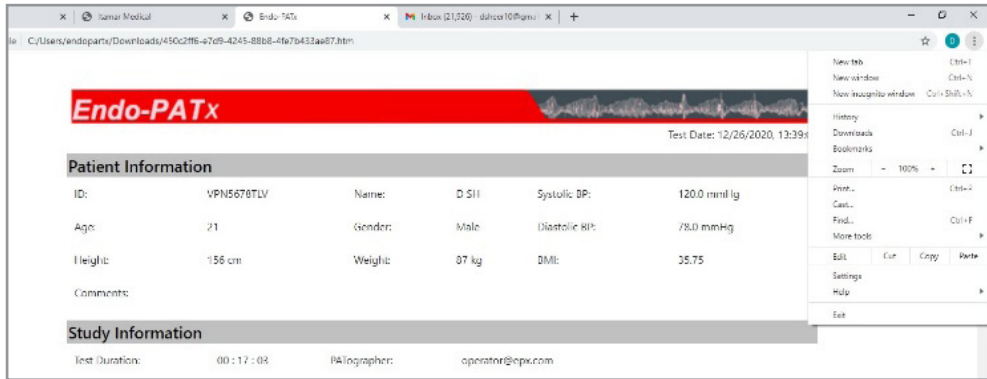


Figure 39 - Print Report Through Browser Menu

5 Preparing for a Study

5.1 Preparing the System for a Study

Accessories that are required beside the EndoPAT™x system:

- A set of two single-use PAT™ probes and anchors
- Blood pressure cuff (capable of sustaining high pressures for 5 minutes)
- Adhesive tape
- Pair of arm supports



WARNING Inspect the system, cables, and accessories for mechanical damage.

The use of damaged equipment may impact patient and operator safety and system performance.

Switch on the computer and the EndoPAT™x device. Launch the EndoPAT™x software and login to the system.

5.2 Connecting the PAT™ Probe

Connect two new probes by inserting the connector tab into each probe slit (see Figure 40) and pressing the connector down onto the probe until the tab of the probe clicks into place (see Figure 41).



Figure 40 - Inserting into slit

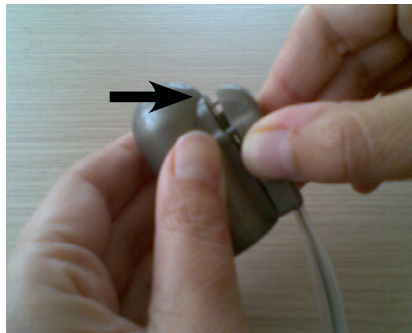


Figure 41 - Clicking in

To remove probes, press the tab (clip) marked by the arrow in Figure 42, and pull the connector away from the probe (Figure 43). Used probes should be disposed properly.

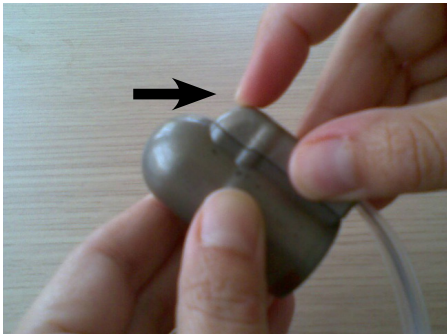


Figure 42 - Press to release



Figure 43 - Probe disconnected

5.3 Creating/Updating Patient's Record

- 1 Search for existing Patient (4.3.1) or create a new patient record (4.3.2).
- 2 Update or enter manually current patient details as follows:

All mandatory fields are marked with asterisk and must be filled to proceed to the next step. The field description is as follows:

- Patient ID - Enter patient identification number or identifier (mandatory field). This identifier must be unique within the clinic.



NOTE The system will not allow creation of Patient ID that is already in the system.

- Patient First and Last name - Enter the patient's complete name, initials, or another identifier.
- Date of Birth - Enter the patient's month, day, and year of birth. This can be done manually, or by pressing the arrow key until the correct value appears in the window (mandatory field).
- Gender - select either male or female (mandatory field).
- Patient Height and Weight - mandatory fields. Units are set according to the computer defaults – either centimeters and Kg or feet-inch and lbs.
- Diastolic Blood Pressure – mandatory field, unless the “Fixed pressure” mode was selected in the set-up screen.
- Systolic Blood Pressure – mandatory field, unless the “Fixed pressure” mode was selected in the set-up screen.



NOTE All text fields should be entered using text letters and numbers.

- 3 Enter/update Patient’s Risk Factors - Select the risk factor method (Framingham Risk Score, European Risk Score or Reynolds Risk Score) and fill in the additional inputs required to calculate Cardio-vascular Risk Factor. See Table 1 – Risk Factors mandatory fields below.

Parameter	Required in			Remark
	Framingham	European	Reynolds	
Total cholesterol	✓	✓	✓	Either mg/dL or mmol/L
HDL cholesterol	✓		✓	
hsCRP			✓	High sensitivity CRP
Diabetic	✓(*)		✓(*)	Reynolds and Framingham don’t support diabetic patients. the risk will be calculated only if positively indicating the patient is not diabetic.
Smoker	✓	✓	✓	
CVD history	✓	✓	✓	All methods fit primary prevention. Risk will not be calculated for patients with CVD
Family CVD history			✓	Either of the patient’s parent had a heart attack before they reached the age of 60.
European risk region		✓		Low risk countries include: Belgium, France, Greece, Italy, Luxemburg, Spain, Switzerland and Portugal. Use high-risk option to other countries in Europe
Treatment for hyper tension (HTN)	✓			
Age*	✓	✓	✓	Taken from the patient information main dialog box
Gender*	✓	✓	✓	
Systolic blood pressure*	✓	✓	✓	

Table 1 – Risk Factors mandatory fields

* Parameters that are used in the calculation of the Risk but are part of the main Patient Information Dialog and not the Risk Factors Dialog.

4 Enter Test parameters

Enter the patient's blood pressure (or select "Use Fixed Values").

Enter Visit number (Mandatory)

5 Click "Start New Test" to start the EndoPAT™x study flow. Follow the instructions detailed in 6 Conducting an EndoPAT™x Study.

6 Conducting an EndoPAT™x Study

6.1 Pre-Study



WARNING Use the blood pressure cuff-set provided by Itamar Medical for arm occlusion.

Usage of non-certified cuff- might compromise the results.

6.1.1 General description

The EndoPAT™ system is comprised of a system console and two independent sensing probes coupled to connecting pneumo-electric tubing and foam finger mounting rings. The system console is connected to a computer loaded with a specific program for controlling the EndoPAT™ system. The system console has two separate external buttons for inflating and deflating the probes. The probes can be inflated and deflated via the computer program as well.

The eligibility of a patient for an EndoPAT™ study is entirely at the discretion of the patient's physician, and is generally based upon the following criteria:

- Symptoms and complaints
- Medical history
- Risk factors
- Current medications
- Restrictions on use (Section 1.5)

6.1.2 System warm up

The system should be turned on and allowed to warm up for at least 20 minutes before commencing patients' studies. It is recommended that the system would not be turned off until the last study for the day has been completed.

6.1.3 Pre-study adaptation period

Thermoneutral room temperature must be maintained at all times: 22°C-24°C (70°F-75°F).

Any restrictive clothing that could interfere with blood flow to the arms should be removed. Heavy coats or clothes with thick sleeves should not be worn. Watches or rings or other jewelry on the hands and fingers should be removed.

The blood pressure cuff should be applied snugly, but without excess pressure,

which might hamper venous blood return, causing venous pooling in the arm (which is deleterious to the test performed).

The patient should then be comfortably seated or allowed to lie down in the study room and relax for at least 15 minutes or a sufficient period to reach a relaxed cardiovascular steady-state and to adjust to the room temperature.

6.1.4 Patient blood pressure measurement

The blood pressure measurement procedure may affect the vascular conditions of the patient. Therefore, if blood pressure measurement needs to be taken prior to the EndoPAT™ study, the following should be considered:

- The blood pressure should be measured from the patient's control arm (the arm that is not occluded during the EndoPAT™ study).
- It is recommended to allow 30 minutes between the time of the blood pressure measurement and commencement of the EndoPAT™ test.

6.1.5 Positioning the patient

The patient should sit in a reclining chair or lie down comfortably. In either case the patients' hands must be supported at approximately heart level.

6.1.6 Preparation of fingers and hands before a study

The finger should be inspected for any deformities or injuries that could affect the study. The probe should not be used on a finger that is cut, injured or unusually sensitive. Fingernails should be trimmed and filed if necessary to avoid damaging the internal membranes of the PAT™ probes & displacing the finger from the sensing region of the probe, resulting in a smaller PAT™ signal and inaccurate results. The index finger is the recommended finger for the study, however if this finger is too large to comfortably fit into the probe or is otherwise unsuitable (see above), a different finger (except the thumb) may be used, as long as it is the same finger in both hands.



WARNING Long nails may cause distorted PAT™ signals and may cause the study to fail.

Before inserting the fingers into the probes, ensure all heavy clothes, tight fitting sleeves, rings, watches, and jewelry were removed from patient's hands and arms.

6.2 Patient and System Setup

6.2.1 Study conditions

The study should be conducted in a quiet and relaxed atmosphere. Phones, beepers, and other devices which can cause startling noises should be turned off; otherwise, the startle effect on the patient might affect the test result. The patient should be kept comfortable and fully relaxed and asked to refrain from talking. Staff should avoid talking to the patient and between themselves as much as possible. These conditions should be kept throughout the entire study.

To avoid communication problem, make sure there are no other applications running on the system's computer, and the device is connected to the computer and to the electricity.

6.2.2 Initializing the EndoPAT™x system

Activate the EndoPAT™x application. Enter patient details and study parameter as required.

Ensure that the pneumo-electric tubes are properly connected to the EndoPAT™x device, and a new set of probes is connected. If the probes have been used, a warning message will be displayed when you try to inflate the probes.

6.2.3 Patient preparation

First, ensure that a blood pressure cuff is placed on the designated test arm. Then, the PAT™ probes should be placed inside the appropriate sockets of the arm-supports (see Figure 44 Figure 45-1). Fully deflate the probes by clicking the Defalte button in the application or by pressing the “Deflate” button on the device.

Place the study fingers into the probes, making sure the fingers are inserted all the way to the end of the probe (see Figure 44 - Applying the PAT™ probes). Inflate probes by pressing the Inflate button on the device or clicking the “Inflate probe” button in the application.



NOTE The index fingers are preferred; however, any finger (other than the thumb) may be used, provided that the same finger is used on both hands.

Place the blue foam anchor ring on the adjacent finger to the one with the probe on. The anchors should be placed as far back as possible on the finger so that they do not come in contact with the PAT™ probe (such contact may result in mechanical artifacts during recording) – see troubleshooting guide (Appendix C).



Figure 44 - Applying the PAT™ probes

Make sure the tubing forms a loop from the probe, back to the anchor as shown in Figure 44.

The patient should be instructed to refrain from moving the fingers to the extent possible.

Both patients' forearms should be supported on the arm supports . Make sure that the probes are free from contact with any object (including the supporting surface), as shown in Figure 45.

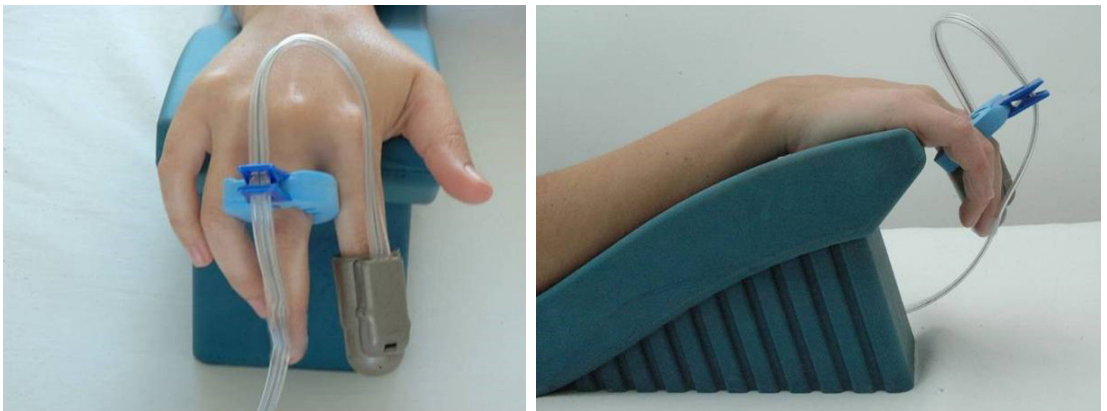


Figure 45 - Hands set-up

6.3 Performing the Study



NOTE Do not change the time or date of the computer during the study. Changing the windows time while recording might result in corrupted study.

6.3.1 Recording baseline

1. Click the **STANDBY** icon, from the main screen. The system will display the signals from the two PAT™ channels, allowing the user to check the signals and adjust the signal gain to properly visualize the PAT™ signals. Signals from both PAT™ channels (Probe A and Probe B) appear in the Trace Window. Visually inspect the PAT™ signal for at least 1 minute. If the signal seems noisy, make sure that the probes are not in touch with anything. As the system equilibrates, having a few leaks in the first few minutes is normal. If you encounter more than 2-3 leaks per minute, continue in Stand By mode for a few more minutes, until at least a minute passed since the last leak, or refer to the troubleshooting section (Appendix C).



NOTE Cold fingers will have small PAT™ signals, with higher noise levels.



NOTE While in the **Standby** stage, it is possible to stop the test, deflate & re-inflate the probes without losing the usability of the probes. Once **Baseline** is pressed the probes cannot be reused after the **Stop Test** button is pressed.



NOTE While in the Standby mode, data is not recorded.

2. Click the **BASELINE** icon to begin study recording.

6.3.2 Performing arterial occlusion

After a stable period of the required baseline signal recording (5-6min.), prepare for the occlusion:

1. Select Max Gain button Max Gain of the occluded arm (either probe A or probe B).
2. Inform the patient you are about to inflate the blood pressure cuff, stressing the importance of remaining still during the test.
3. **Rapidly** inflate the blood pressure cuff to a supra-systolic level (the recommended pressure is at least 60mmHg above systolic blood pressure and no less than 200mmHg). Verify total cessation of blood flow to the hand (as reflected by a total absence of PAT™ signal from the occluded hand). If the appearance of any PAT™ signal is noted, increase cuff pressure by an additional 50 mmHg and up to 300mmHg (See Figure 46).



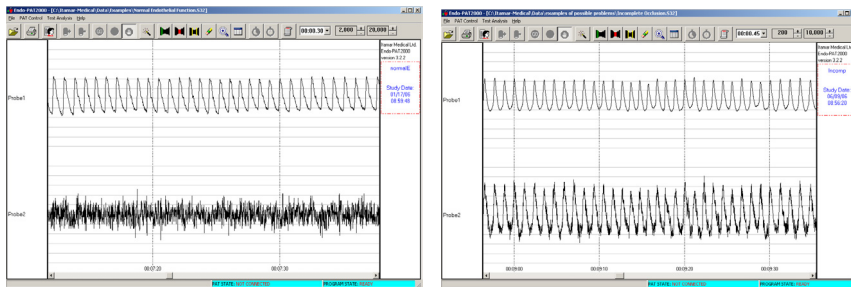
WARNING Inflating the BP cuff might cause some stress and discomfort to the patient. Pay attention to the patient's well-being.

4. Maintain the arterial occlusion for exactly five minutes – periodically check the pressure in the occluding cuff is maintained; increase pressure if required.



NOTE Once the occlusion has been performed the test should not be re-started.

It is recommended to wait at least 2 hours prior to performing a new study.



Left – complete occlusion

Right – incomplete occlusion

In both panels the bottom signal is the occluded arm.

Figure 46 - Occlusion quality assessment


6.3.3 Post Occlusion period

When exactly five minutes have passed, deflate the pressure cuff **as quickly as possible**.

1. Continue to maintain the relaxed conditions throughout this period. The patient might experience discomfort after the cuff deflation & might feel an urge to move the test arm. This should be discouraged.
2. When post occlusion is complete (5 minutes), stop the study by clicking the **Finish Test** button.

6.3.4 After the Study is Completed

Clicking the **Finish Test** button ends the recording. This will also deflate the probes automatically, allowing their removal from the patient’s fingers. Carefully remove the PAT™ probes, anchors, and the blood pressure cuff from the patient. Disconnect the PAT™ probes and discard them. As it is impossible to visually differentiate used from unused probes, we recommend placing a piece of tape around each used probe prior to discarding the probes.

	<p>NOTE If the probe doesn’t deflate after ending the study with the Finish Test button, manually deflate via the deflate button on the device. This button can also be used in case of emergency for deflating the probe during test.</p>
---	--

After completion of a study the study signal will be automatically opened on the screen.


7 Review and Analysis


During a PAT™ study, recorded signals are viewed in the display window, based on the appearance of the traces, a qualitative evaluation can be performed. However, subsequent review of the study using the special features described in this chapter facilitates a quantitative analysis of the acquired data. It is recommended to review each study upon completion of its recording.

7.1 Study Data Retrieval

Locate the desired study by searching for the patient record and selecting the EndoPAT™x study or from the list of recent EndoPAT™x studies (4.5.2). Selecting the desired study opens the Study PAT™ Signal Review Screen (4.5.3)

7.2 Automatic Analysis

Click the Wand  Icon in the editing toolbar to perform the automatic analysis. The automatic analysis identifies the occlusion borders and marks with two vertical lines its beginning and end, and marks the whole signals area between these two lines in grey. Proper identification of the occlusion area is critical for the automatic analysis to correctly select the regions and time references used in its calculations. The user should verify that the marking of the occlusion area appears properly. If the automatically marked occlusion area appears wrong, it can be manually corrected as described in section 7.2.1.

If manual corrections are performed, click the Wand  Icon to perform the analysis based on edits performed.

Study results will appear in the Study Results section (4.5.3).

The RHI (Reactive Hyperemia Index) or LnRHI (natural log of RHI) is the post-to-pre occlusion PAT™ signal ratio in the occluded arm, relative to the same ratio in the control arm, corrected for baseline vascular tone of the occluded arm where:

Normal EndoScore™:	$RHI > 1.67$ or $\text{LnRHI} > 0.51$
Abnormal EndoScore™:	$RHI \leq 1.67$ or $\text{LnRHI} \leq 0.51$


The HR (Heart Rate) is calculated from the PAT™ signals in the baseline region of interest.

7.2.1 Manual Correction of the Occlusion Borders

Click the magic wand to create the automatic analysis borders.

Select the occlusion borders as follow:

Once automatic analysis is performed (see 4.5.4.1), Occlusion bookmarks are displayed on the PAT Waveform Viewer. You can adjust the stage timing by dragging the bookmark. Hover the mouse over the bookmark until the mouse icon is changed

to . Select using the left button and drag to desired time. During the dragging, the study time of the marker is indicated next to the headline **OCCLUSION** × (04:54). Once the manually selected occlusion is marked, click on the magic wand icon to run the automatic analysis using the manually selected occlusion area.



NOTE Manual changes of the occlusion borders are automatically saved.

7.3 Study Report

To review the study report, select the “View report” option.

The Report contains data about the patient, the study, traces of the signals and the basic results (RHI/LnRHI and HR).

7.4 EndoPAT™x study results

7.4.1 EndoScore™ result: RHI and LnRHI

The RHI (Reactive Hyperemia Index) is the post-to-pre occlusion PAT™ signal ratio in the occluded arm, relative to the same ratio in the control arm, corrected for baseline vascular tone of the occluded arm where:

Normal: $RHI > 1.67$

Abnormal: $RHI \leq 1.67$

This index and threshold were used in the validation study presented at section 1.2 of this manual and they reflect endothelial function.

The LnRHI is a natural log transformation of the same index, where:

Normal: $\text{LnRHI} > 0.51$

Abnormal: $\text{LnRHI} \leq 0.51$

This transformation is a monotonic transformation; therefore, it does not change the dichotomous diagnosis (normal/abnormal) for any individual test.

LnRHI provides a better double-sided distribution that is very close to normal distribution (Gaussian) in its nature. The histograms of RHI and LnRHI (based on the analysis of large dataset of nonselective populations) are shown in Figure 47 and Figure 48 respectively (blue represents the actual numbers and red represents the calculated equivalent normal distribution of the same mean and standard deviation).

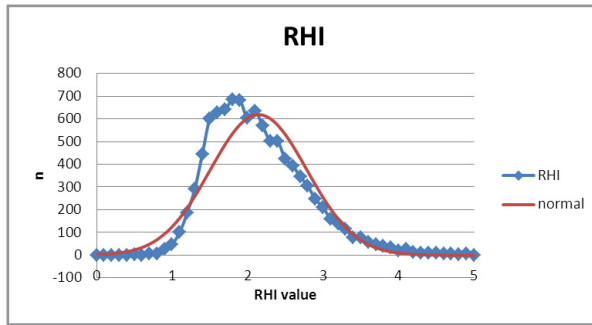


Figure 47 – non selective population histograms of RHI

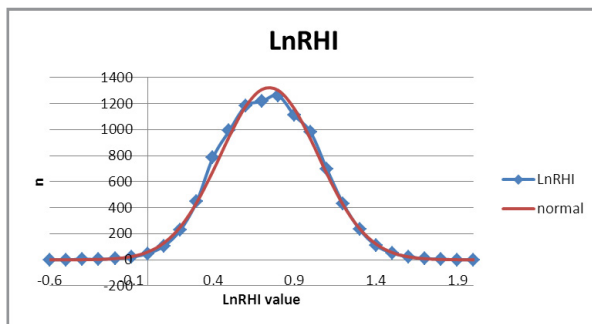


Figure 48 - non selective population histograms of LnRHI

The LnRHI distribution curve in a non-selected population is included in the report (Figure 49) and displays the LnRHI result in respect to non-selected population.

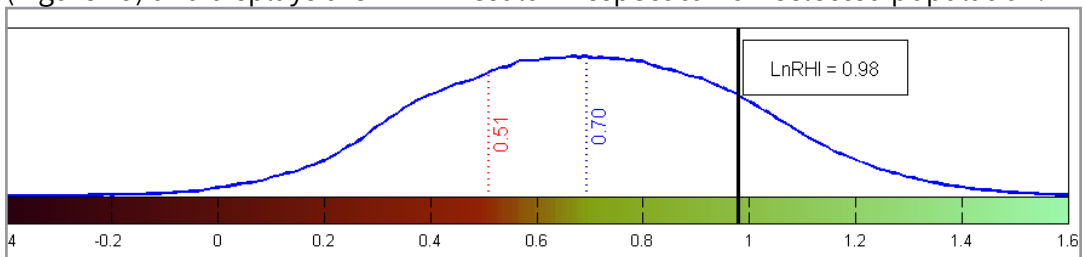


Figure 49 – LnRHI distribution in non-selected population

The graph presents the distribution function of the LnRHI in the non-selected population. The data used is composed of nearly 10,000 data points collected from different study cohorts worldwide.

The mean / median LnRHI in the population (0.7, marked in blue) and the dichotomy threshold for normal endothelial function (0.51, marked in red) are presented as vertical lines on the graph.

The individual EndoScore™ result of the patient is presented on this graph (bold black line and a result frame) to aid assess the patient condition in respect to the dichotomous threshold and the general population.

In case that Endothelial Function Index in the software is set to RHI and not to LnRHI, the same LnRHI graph will appear and the RHI values (threshold, population median/ mean, and study results) will appear in brackets next to the LnRHI values in the graph.

7.4.2 Heart Rate

The HR (Heart Rate) is calculated from the PAT™ signals in the baseline region of interest.

7.4.3 Analysis Errors

The user may encounter a system error message when running the automatic analysis. Such an error would disqualify the results of the analysis. Some of the errors may be corrected after proper re-marking of the manual occlusion (if the errors are caused by a wrong automatic detection of the occlusion borders). However, some errors have no user corrective actions that can remedy these situations. All error messages indicate that the system could not complete the analysis of the study. Consequently, RHI result is not provided and “N/A” or “0” is presented instead of the calculated value. *(please note: in a normal adequate operation of the system the algorithms that calculates RHI is never supposed to provide a “0” result).*

Table 3 in section 9.3, provides a list of system error messages.

7.5 Study printing

You can print the displayed data at any time during off-line review and analysis by selecting the Print option through Windows pull down menu.

8 Maintenance

8.1 Device maintenance

This chapter describes preventive and regular maintenance for the EndoPAT™x system.

Only qualified medical personnel should use this equipment. In the event of equipment malfunction all repairs should be executed by qualified Itamar Medical personnel or authorized service agents.

Maintenance instructions should be followed closely to avoid unnecessary equipment failure or potential health hazards to the user or patient.

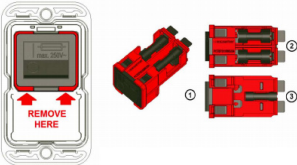
1. Inspect all cords and ensure they are not frayed or damaged. Verify that all plugs, connectors, and cables are securely connected. Gently wrap tubes around the rear panel of the device.
2. The EndoPAT™x device should be free of dirt and debris. Using a soft, slightly damp cloth, gently wipe the exterior of the EndoPAT™x device, avoiding contact with open vents and plugs.
3. Used probes should be discarded after each use and replaced with new ones.



NOTE When the device is stored or not used for long durations, it is recommended to keep the probes connected to their connector. This would prevent dust and humidity from entering the device's pneumatic system.

9 Troubleshooting and System Error Messages

9.1 Troubleshooting

	Description	Possible Cause	Action
1	The EndoPAT™x device does not switch on (the POWER LED on the device is not on)	The EndoPAT™x device power is switched off.	<ul style="list-style-type: none"> Switch on the EndoPAT™x device.
		Power cable is not plugged to the power outlet.	<ul style="list-style-type: none"> Switch off the EndoPAT™x device. Plug the power cable to the power outlet. Switch on the EndoPAT™x device.
		Power cable is not connected to the EndoPAT™x device.	<ul style="list-style-type: none"> Switch off the EndoPAT™x device. Plug the power cable to the EndoPAT™x device. Switch on the EndoPAT™x device.
		Fuse is burnt	<ul style="list-style-type: none"> Switch off the EndoPAT™x device. Unplug the power cable to the EndoPAT™x device. <p>Removal of the combined switch / fuse holder unit</p>  <ul style="list-style-type: none"> With a screwdriver No 1 or smaller remove the unit (1) from the filter. Replace the burnt fuse located on the topside (2) behind the switch. Note: On the bottom side (3) is a spare fuse. Return the fuse holder to the switch, plug in the power cable and turn on the EndoPAT™x device.
2	No communication between PC station and EndoPAT™x device (the COMM LED on the device is not lit)	EndoPAT™x power switch is off.	<ul style="list-style-type: none"> Verify that the orange LED is on. Switch on the EndoPAT™x device.
		Communication cable between PC station and EndoPAT™x device is not connected.	<ul style="list-style-type: none"> Verify that the communication cable is connected properly.
		Another application is assigned to the COM port.	<ul style="list-style-type: none"> Close all background applications. Verify that the COM port connected to the EndoPAT™x device is not in use by another application.
		The communication cable is connected to the wrong COM port.	<ul style="list-style-type: none"> Plug communication cable into the other COM port. Try setting another COM port in the application.

	Description	Possible Cause	Action
3	Frequent pressure leaks during study	The pneumatic probe cable is not well connected to the probe or to the EndoPAT™x device.	<ul style="list-style-type: none"> Verify that the pneumatic probe cable is securely connected to the probe and to the EndoPAT™x device and that the connections are free from lint or other residues.
		Faulty probe.	<ul style="list-style-type: none"> Replace PAT™ probe.
		Faulty pneumatic cable.	<ul style="list-style-type: none"> Replace pneumatic cable.
4	Noisy signal	Something is in contact with the probes or the tubes	<ul style="list-style-type: none"> Make sure the probes are not touched by other fingers, that they are not rested on any surface and that the tube between the probe and foam anchor is not rested on the back of the hand. If the probe is in touch with the foam anchor on the adjacent finger you should either remove the foam anchor and trim its side on the diagonal, so it will not touch the probe or alternatively, place the foam anchor on the little finger and place a thin piece of rolled gauze as a separator between the test finger and the adjacent finger, securing it in place with some medical tape.
5	The probes do not deflate automatically after pressing stop	Either you neglected to press “Baseline” (and thus still in the Standby mode); or there is a software-hardware communication error	<ul style="list-style-type: none"> Deflate manually by pressing the deflate button on the EndoPAT™x device. If probes still don't deflate by pressing the deflate button on the EndoPAT™x device and you were not at Stand By mode, you can deflate the probes by removing and pulling the connector away from the probe. If you were in Stand By mode (= did not press “Baseline”) you should retest the patient. It is recommended to wait for an hour and switch the test arm before retesting. If you pressed “Baseline” make sure the study was recorded properly by opening it for analysis.
6	Very long inflate of the probe followed by Major Leak message	Multiple deflates of the probe before probe's inflate	<ul style="list-style-type: none"> Verify proper connection of both tubes and probes. Deflate once from the software interface or using the button on top of the device then inflate

Table 2 - Troubleshooting

9.2 System Error Messages

The following table provides a list of system error messages that the user may encounter when running the analysis. Some of the errors may be corrected after proper manual occlusion marking (if the errors are caused by a wrong automatic detection of the occlusion borders). However, some errors have no user corrective actions that can remedy these situations. All error messages indicate that the system could not complete the analysis of the study.

Message	Explanation
ShortSignal	Short Signal i.e. the recorded signal length is less than the minimum required to run an analysis (6 min).
LongSignal	Long Signal i.e. the recorded signal length is more than the maximum allowed to run an analysis (150 min).
SignalNoisy	Signal Noisy i.e. noisy signal prevents proper operation of the analysis module.
ShortBaseLine	Short Baseline i.e. baseline duration is shorter than minimum required less than 2 min and 20 sec valid baseline signals.
ShortOccLength	Short Occlusion i.e. Occlusion Time less than minimum required. Occlusion is 90 sec or less (might be rectified after manual occlusion marking).
LongOccLength	Long Occlusion i.e. Occlusion Time more than maximum allowed. More than 10 min occlusion (might be rectified after manual occlusion marking).
ShortPostOcc	Post Occlusion duration is shorter than minimum required i.e. less than 2 min and 30 sec. (Might be rectified after manual occlusion marking).
UndefinOcc	Undefined occlusion i.e. the system cannot identify the occluded section of the study (might be rectified after manual occlusion marking).
PoorSigQuality	Poor signal quality in the post occlusion period used by the analysis (1.5 - 2.5 min post occlusion).
AllocationMemory or NoCorrPulse	Program Failure i.e. System software problems that prevents the program to complete the analysis (call Itamar Medical customer support).
BT_MajorBreakThrough	Meaning incomplete occlusion. The amount of blood flow detected during the occlusion period is too high, i.e. there are measured pulses during the occlusion in the occluded hand. Occlusion quality is too low for a good hyperemic response.
OpenFile	Error Reading File i.e. the system was not able to read the file provided

Table 3 - Error messages

10 Technical Information

10.1 System Minimum Requirements

- An IBM® or compatible PC with dual core processor 1.4 GHZ CPU or higher
- Internet browsers Chrome version 70, Edge version 44, Firefox version 63 or above versions
- 8.00 GB RAM, Windows 10 64 bits
- 20 GB free hard disk space
- 1080p display or better
- One available USB 2.0 port (for connecting the DAS)
- Optional 2nd USB port for local printer


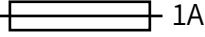


Optional Hardware










- Printer, Color recommended

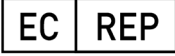




10.2 Operating System

Windows 10 64bit.

10.3 Technical information about labeling

SYMBOL	EXPLANATION
	Protective Earth
	Fuse (1 Amper)
	Date of manufacture
	Follow instructions for use

SYMBOL	EXPLANATION
	Type BF applied part
	The product complies with the CE mark according to MDD (Medical Device Directive) and related standards. The product is marked with the CE logo.
	Use-by date
	Single use, do not re-use
	Temperature limit
	Medical device Manufacturer
	Catalogue Number
	Serial Number
	According to the WEEE Directive 2012/19/EU, all waste electrical and electronic equipment (EEE) should be collected separately and not disposed of with regular household waste. Please dispose this product and all of its parts in a responsible and environmentally friendly way.

SYMBOL	EXPLANATION
	<p>Authorized representative in the European Community</p>
	<p>Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner</p>
	<p>Medical Device</p>
	<p>The product is certified by TUV Rheinland</p>
<p>UDI code:  (01)07290109225425(11)YYMMDD(21)XXXXXXXX</p>	<p>The Unique Device Identification System is intended to assign a unique identifier to medical devices</p>

10.4 Labeling

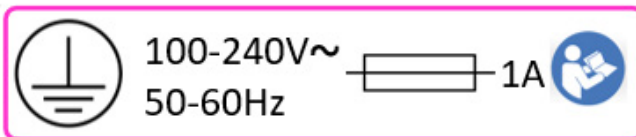
10.4.1 System Label

The System Label is located at the bottom of the EndoPAT™x device:



10.4.2 Power Rating Label

The Power Rating Label is located near the power inlet connector of the EndoPAT™x device:



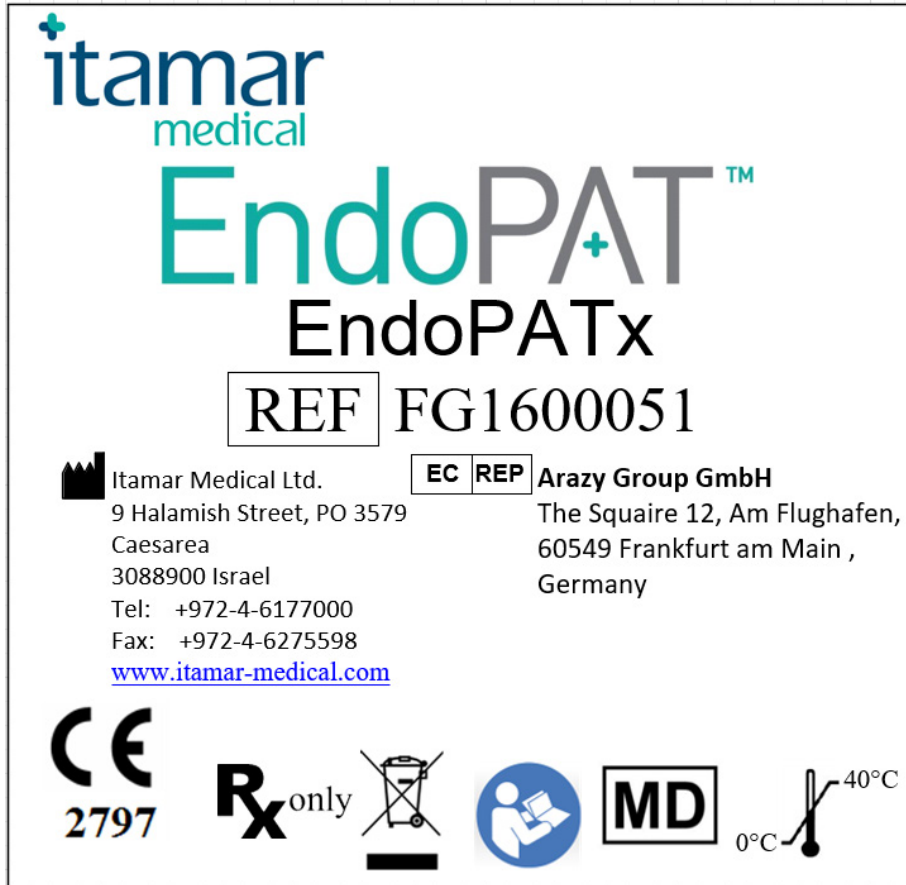
10.4.3 Applied Part Label

The Applied Part Label is located near the Pneumatic Cable Connectors of the EndoPAT™x device:



10.4.4 Packaging labels

The following labels are attached to the master package of the EndoPAT™x system:



10.5 Specifications of EndoPAT™x system

Properties		Description
PAT™ Probe		Itamar Medical's proprietary probe only
Recording Time		Limited by hard disk space, ~35MB per study of 20 minutes
Indications		3 LED's - power, communication, error
PAT™ Channel	<i>Selective Gain</i>	1 ÷ 50,000
	<i>Selectable Time Base</i>	10 sec ÷ 2 hours per screen
Power Supply	<i>Input</i>	100-240 VAC 50/60 Hz
	<i>Isolation</i>	Double Patient Isolation (4kVAC)
	<i>Fuse</i>	1A (x2)
Temperature	<i>Operation</i>	Room temperature (Clinical setting recommendations: 22°C-24°C)
	<i>Storage</i>	0 to 40 °C
	<i>Transportation</i>	-20 to 60 °C
Humidity	<i>Operating & Storage</i>	10% - 95% (non-condensing)
Atmospheric Pressure:	<i>Operating</i>	70-106 [kPa]
	<i>Storage & Transportation</i>	57.2-106 [kPa]
Dimensions	<i>L x W x H (max)</i>	430mm x 350mm x 115mm
	<i>Weight</i>	5.0 kg

Table 4 - Specifications

Appendix A: License Agreement and Limited Warranty

This License Agreement represents the complete and exclusive understanding between you and Itamar Medical.

The document can be viewed at

<https://www.itamar-medical.com/wp-content/uploads/2020/09/License-Agreement-09.2020.pdf>

Should you have any questions concerning this License Agreement, or if you desire to contact Itamar Medical for any reason, please write to:

USA:

Itamar Medical Inc.
3290 Cumberland Club Drive, Suite 100
Atlanta, Georgia 30339, USA
Tel: 1 888 748 2627

Worldwide:

Itamar Medical Ltd.
9 Halamish St., P.O.Box 3579
Caesarea Ind. Park, 3088900, Israel
Tel: +972 4 617 7000

Appendix B: Regulatory Authorized Representative



Arazy Group GmbH

The Squire 12, Am Flughafen,
60549 Frankfurt am Main, Germany

APPENDIX C: MANUFACTURING DECLARATIONS ACCORDING TO IEC 60601-1-2

Electromagnetic Compatibility

Notes

- The EndoPAT™x requires special precautions with regard to electromagnetic compatibility.
- It must be installed and prepared for use as described in section 3 - Installing the System.
- Certain types of mobile telecommunication devices such as mobile telephones are likely to interfere with the EndoPAT™x.
- The recommended separation distances in this paragraph must therefore be complied with.
- The EndoPAT™x must not be used near or on top of another device. If this cannot be avoided, it is necessary - before clinical use - to check the equipment for correct operation under the conditions of use.
- The use of accessories other than those specified or sold by Itamar Medical as replacement parts may have the consequence of increasing the emissions or decreasing the immunity of the unit.

Electromagnetic Emissions

- EndoPAT™x is intended for use in the electromagnetic environment specified in the following tables 1, 2, 3, 4, 5, 6 and 6a below.
- The user and/or installer of the unit must ensure that it is used in such an environment.

Table 1 – from IEC 60601-1-2:2014		
Guidance and manufacturer’s declaration – electromagnetic emissions – EndoPAT™x (EPX)		
The EDx is intended for use in the electromagnetic environment specified below; The customer or the user of the EPX should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1 Class B	The EPX uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonic emissions IEC 61000-3-2	Class B	The EPX is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 2 - from IEC 60601-1-2:2014**Guidance and manufacturer's declaration – electromagnetic immunity – EndoPAT™x (EPX)**

The **EDx** is intended for use in the electromagnetic environment specified below; The customer or the user of the **EPX** should assure that it is used in such an environment.


Immunity test	IEC 60601-1-2 Test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	8 kV contact 2, 4, 8, 15kV air	8 kV contact 2, 4, 8, 15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/ burst IEC 61000-4-4	2 kV for power supply lines 1 kV for input/output lines	2 kV for power supply lines 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	1 kV line(s) to line(s) 2 kV line(s) to earth 2 kV Signal input/output) to earth	1 kV line(s) to line(s) N/A N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT; 0.5cycle at 0°, 45°, 90°, 135°,180°, 225°, 270° and 315° 0% UT; 1cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycle	0% UT; 0.5cycle at 0°, 45°, 90°, 135°,180°, 225°, 270° and 315° 0% UT; 1cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the EndoPAT™x requires continued operation during power mains interruptions, it is recommended that the EndoPAT™x be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 (A/m)	30 (A/m)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: UT is the a.c. mains voltage prior to application of the test level.

Table 3 - from IEC 60601-1-2:2014

Guidance and manufacturer’s declaration – electromagnetic immunity – EndoPAT™x (EPX)

The **EPX** is intended for use in the electromagnetic environment specified below; The customer or the user of the **EPX** should assure that it is used in such an environment.

Immunity test	IEC 60601-1-2 Test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3V, 6V 10V/m 10V/m from 0.15 to 80MHz; 10V/m from 0.15 to 80MHz and 80% AM at 1kHz 10V/m from 80MHz to 2.7GHz	3V, 6V 10V/m 10V/m from 0.15 to 80MHz; 10V/m from 0.15 to 80MHz and 80% AM at 1kHz 10V/m from 80MHz to 2.7GHz	Portable and mobile RF communications equipment should be used no closer to any part of the EndoPAT™x, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{12}{V_2} \right] \sqrt{P}$ $d = \left[\frac{12}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{23}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. D Interference may occur in the vicinity of equipment marked with the following symbol: 

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

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

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

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 4 - from IEC 60601-1-2:2014

Recommended separation distances between portable and mobile RF communications equipment and the EndoPAT™X

The **EPX** is intended for use in the electromagnetic environment specified below; The customer or the user of the **EPX** should assure that it is used in such an environment.

Rated maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m]			
	150 kHz to 80 MHz outside ISM bands	150 kHz to 80 MHz in ISM bands	80 MHz to 800 MHz	800 MHz to 2,5 GHz
	$d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$	$d = \left[\frac{12}{V_2} \right] \sqrt{P}$	$d = \left[\frac{12}{E_1} \right] \sqrt{P}$	$d = \left[\frac{23}{E_1} \right] \sqrt{P}$
0.01	0.12	0.2	0.4	1
0.1	0.37	0.64	1.3	2.6
1	1.17	2	4	8
10	3.7	6.4	13	26
100	11.7	20	40	80

Table 5 - from IEC 60601-1-2:2014

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

The **EPX** is intended for use in the electromagnetic environment specified below; The customer or the user of the **EPX** should assure that it is used in such an environment.

Test frequency (MHz)	Band a) (MHz)	Service a)	Modulation b)	Maximum power (W)	Distance (m)	Immunity Test level (V/m)	Compliance level (V/m)
385	380 – 390	TETRA 400	Pulse modulation b) 18 Hz	1.8	0.3	27	27
450	430 – 470	GMRS 460, FRS 460	FM c) ± 5 kHz deviation 1 kHz sine	2	0.3	28	28
710	704 – 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0.2	0.3	9	9
745							
780							
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0.3	28	28
870							
930							

Test frequency (MHz)	Band a) (MHz)	Service a)	Modulation b)	Maximum power (W)	Distance (m)	Immunity Test level (V/m)	Compliance level (V/m)
1720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulationb) 217 Hz	2	0.3	28	28
1845							
1970							
2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulationb) 217 Hz	2	0.3	28	28
5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulationb) 217 Hz	0.2	0.3	9	9
5500							
5785							
<p>NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.</p> <p>a) For some services, only the uplink frequencies are included. b) The carrier shall be modulated using a 50 % duty cycle square wave signal. c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.</p>							

Table 5 - Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment							
Test frequency (MHz)	Band ^{a)} (MHz)	Service ^{a)}	Modulation^{b)}	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)	Compliance level (V/m)
385	380 – 390	TETRA 400	Pulse modulation ^{b)} 18 Hz	1.8	0.3	27	27
450	430 – 470	GMRS 460, FRS 460	FM ^{c)} ± 5 kHz deviation 1 kHz sine	2	0.3	28	28
710	704 – 787	LTE Band 13, 17	Pulse modulation ^{b)} 217 Hz	0.2	0.3	9	9
745							
780							
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation ^{b)} 18 Hz	2	0.3	28	28
870							
930							
1720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation ^{b)} 217 Hz	2	0.3	28	28
1845							
1970							
2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ^{b)} 217 Hz	2	0.3	28	28
5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation ^{b)} 217 Hz	0.2	0.3	9	9
5500							
5785							
<p>NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.</p>							
<p>^{a)} For some services, only the uplink frequencies are included. ^{b)} The carrier shall be modulated using a 50 % duty cycle square wave signal. ^{c)} As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.</p>							

Recommended Separation Distances

The EndoPAT™x is intended for use in an electromagnetic environment in which radiated radiofrequency disturbances are controlled.

The user and/or installer of the unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile radiofrequency communications equipment (emitters) and the EndoPAT™x, according to the maximum output power of the equipment, as recommended in the table below.

Table 6 - from IEC 60601-1-2:2014			
Recommended separation distances between portable and mobile RF communications equipment and the EndoPAT™x (EPX)			
Rated maximum output power of transmitter	Separation distance according to frequency of transmitter (in meters)		
	Watts [W]	150kHz to 80MHz $d = 1.17\sqrt{P}$	80MHz to 800MHz $d = 1.17\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.73
1	1.17	1.17	2.3
10	3.7	3.7	7.3
100	11.7	11.7	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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

Table 6a	
Recommended separation distances between Power bus or an appliance wire and the EndoPAT™x (EPX)	
Rated maximum current (I) in a power bus or an appliance wire	Separation distance (in meters)
	Meters [m]
	$R = I/2\pi H = I/18.8$
0.1	0.005
1	0.05
10	0.53
100	5.3
1000	53.2

NOTE 1 The power frequency magnetic field immunity of $H=3$ A/m is met.

APPENDIX D: SPARE PARTS LIST

The following items can be ordered and purchased individually:

Pneumatic PAT™ Probe (a box of 12 probes)

Pneumo-electric tubing

Set of 30 foam finger anchors

Accessories Kit

Power Cable

USB cable

EndoPAT™x software CD

Operation manual