Endo PAT™2000 Device

User Manual

Itamar Medical REF OM1695214



This product and/or method of use, is covered by one or more of the following US patents: 6319205, 6322515, 6461305, 6488633, 6916289, 6939304, 7374540, as well as any pending US patent applications and corresponding patents and/or applications filed in other countries.

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ISO 9001:2008 and EN ISO 13485:2012

See appendix B for contact information of the regulatory authorized representative

Record of Editions

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2	May 03	Update	All	All
3	Aug 03	Update	All	All
4	Sept 03	Update	All	All
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		Updating Manufacturing Declarations	App.E	91-94
		Adding spare parts list	App.F	95
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		Updating misspelling	All	All
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Note: Latest version of the EndoPAT™ User Manual is available at:
http://www.itamar-medical.com/Support/Downloads.html

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1 General Information

This manual is part of the Endo PAT™2000 system.

1.1 Intended Use of the Endo PAT™2000 Device

The Endo PAT™2000 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 Endo PAT™2000 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 Endo PAT™2000 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

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 Endo PAT™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: π*(coronary artery diameter/2)^2*(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 (ΔCBF > 50% and ΔCAD > -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 Endo PAT™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: ΔCBF $\leq$ 50% OR ΔCAD $\leq$ -20%. Patients were then evaluated using the Endo PAT 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, 4.5-5.5 minutes of blood flow occlusion to one arm using an upper 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 Endo PAT™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 Endo PAT™2000 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

According to IEC 60601-1 / UL 60601-1 Endo PAT™2000 device is classified as Class IIa medical device.

1.4 Manufacturers Notice

The information in this document is subject to change without notice.

Itamar Medical Ltd. makes no warranty of any kind on this material, including but not limited to, the implied warranties of merchantability and fitness for a particular purpose. Itamar Medical Ltd. shall not be liable for errors contained herein or for incidental or consequential damages in connection with the furnishing, performance, or use of this material.

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1.5 Restrictions for Use

- Only qualified medical personnel may authorize the use of the Endo PAT™2000 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 Endo PAT™2000 system in whole, or in part, may not be modified in any way.

- The device is intended for diagnostic purposes only, and should not be used for monitoring.
- The device is not intended as a screening test in the general patient population.
- Itamar Medical Ltd. makes no representation whatsoever, that the act of reading this User Manual renders the reader qualified to operate, test or calibrate the system.
- The tracings and calculations provided by the Endo PAT™2000 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: ISO 9001 & ISO 13485

	STANDARD	#
1.	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	IEC 60601-1
2.	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	IEC 60601-1-2
3.	Medical electrical equipment - Part 1-4: General requirements for safety – Collateral Standard: Programmable electrical medical systems	IEC 60601-1-4
4.	Medical Device Software – Software Life Cycle Processes	IEC 62304
5.	Quality management systems - requirements	ISO 9001:2008
6.	Medical devices. Quality management systems. Requirements for regulatory purposes	EN ISO 13485:2012
7.	Medical devices - Quality management systems - Requirements for regulatory purposes (Health Canada)	CAN/CSA ISO 13485:2003
8.	Medical devices. Application of risk management to medical devices	ISO 14971

9.	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements	ISO 15223-1
10.	Graphical symbols for electrical equipment in medical practice	IEC TR 60878
11.	Graphical symbols -- Safety colours and safety signs -- Registered safety signs; refer to instruction manual/ booklet	ISO 7010-M002
12.	Information supplied by the manufacture with medical devices	EN 1041
13.	Medical Device Directive	MDD 93/42 EEC MDD 2007/47/EC
14.	FDA Quality Systems Regulation (QSR)	21 CFR part 820
15.	CSA standard for safety	CSA 22.2 No. 601.1
16.	UL standard for safety	UL 60601-1
17.	Canadian Medical Devices Regulations	SOR/98-282
18.	Medical devices - Application of usability engineering to medical devices	BS EN 62366

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.

Avertissements

Ils sont destinés à cerner les conditions ou les actions qui – au cas de non observation des instructions – risqueraient de mettre en péril la sécurité du patient ou affecter le bon fonctionnement du système et aboutir à une perte irréversible de données.



Cautions

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

Précautions

Elles sont destinées à cerner les conditions ou les actions qui risquent d'entraver l'acquisition de données et compromettre les résultats de l'examen.



Notes

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

Notes

Elles sont destinées à repérer une explication ou fournir une explication supplémentaire en vue de 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 Endo PAT™2000 device Operation Manual carefully, before operating the system.

All pictures are for illustrative purposes only.

1.8 Safety Precautions



WARNING

Only the power supply that is provided within the Endo PAT™2000 package will be used for the system.

Use of an inappropriate adapter may cause irreparable damage to the device and may compromise patient safety.

Avertissement

L'appareil sera alimenté uniquement à l'aide du boitier électrique inclus dans le kit Endo PAT™2000.

L'usage d'un adaptateur non approprié risque de provoquer des dégâts irréparables de l'appareil et de porter atteinte à la sécurité du patient.



WARNING

The Endo PAT™2000 device should only be installed with and connected to computer equipment that complies with EN60950 safety regulations.

Failure to heed these warnings may compromise patient safety.

Avertissement

L'appareil EndoPAT™2000 doit être installé et connecté uniquement à un ordinateur qui répond aux normes de sécurité EN60950.

La non observation de cet avertissement risque de porter atteinte à la sécurité de patient.

1. The Endo PAT™2000 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 Endo PAT™2000 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 Endo PAT™2000 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 Endo PAT™2000 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 Endo PAT™2000 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.

	**Caution** Federal law restricts this device to sale by or on the order of a physician. **Précaution** Selon la loi fédérale, la vente de cet appareil ne s'effectue que par ou sous ordre d'un médecin.

2 System Overview

The Endo PAT™2000 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 Endo PAT™2000 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 Endo PAT™2000 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 phases:

- 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 is automatically stored to the computer's hard disk and may subsequently be retrieved for off-line review and automatic analysis.

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 Endo PAT™2000 device is supplied as a complete package comprising the following components:

- One Endo PAT™2000 device
- One Endo PAT™2000 software CD
- Two pneumo-electric tubing
- Power adaptor
- Power cable
- Operation manual
- Set of 6 foam finger anchors
- USB adaptor

The supplied Endo PAT™2000 software package can be used with any Windows computer running English versions of Windows XP Windows 7 or Windows 8. The automatic analysis module requires any type of internet browser or Excel 2000 or newer.

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

Although individual system set-ups may vary, Figure 1 represents a typical setup of a study.



Figure 1 Typical set-up

3.2 System description

The Endo PAT™2000 device top panel has:

- Power LED indicator
- LED indicator for the device-computer communication status
- Probe's Deflate and Inflate buttons



Figure 2 - Endo PAT™2000 device

The front panel has two pneumatic input connectors for attaching the pneumo-electric tubing, connecting the PAT™ probes to the Endo PAT™2000 device.

The back panel has (Figure 2):

- Power supply DC connector
- Communication port
- ON/OFF switch

3.3 Connecting the Endo PAT™2000 device to the Computer

	**NOTE** The Endo PAT™2000 system requires the use of a serial (RS232) port in the computer with a standard 9-pin RS232 cable. The Endo PAT™2000 device can alternatively be connected through a USB to RS232 adapter (supplied with the system)

1. Place the Endo PAT™2000 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).
2. Connect the USB-to-RS232 adapter to the communication port on the Endo PAT™2000 device, and to one of the computer's USB ports. Hand-tighten the screws to secure the adaptor (see Figure 3). In case RS232 cable is used connect it to both Endo PAT™2000 device and computer and tighten the connecting screws.
3. Connect both pneumo-electric tubing to the Endo PAT™2000 device's front panel pneumo-electric connectors and secure by hand tightening the screws (see Figure 3).
4. Make sure the power switch is off. Connect the power supply first to the Endo PAT™2000 device and then to an electrical outlet. Turn the power switch on.
5. The power indicator light will glow orange, indicating that the power is turned on.



Figure 3 - Connection of pneumo-electric tubing and USB adaptor

	**NOTE** When using a USB to RS232 adaptor, connect the adaptor to the computer directly and not via USB hub.

3.4 Endo PAT™2000 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 Endo PAT™2000 software.

	**NOTE** Uninstall previous Endo PAT™2000 software versions prior to installing a newer version. To uninstall the software please refer to section 3.7. Make sure to backup all your data prior to uninstalling any software.

2. Insert the Endo PAT™2000 software CD into the CD drive. The installation program will load automatically. Alternatively you may execute the 'setup.exe' application from the installation CD.
3. The Installshield wizard prepares the computer for installation. When prompted, click next to proceed with the installation (Figure 4).

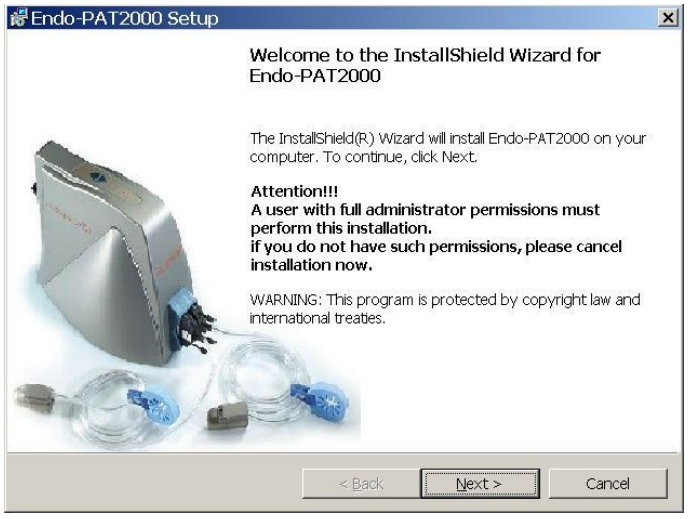


Figure 4 - Installshield wizard

4. Read the license agreement and select the "I accept" option to agree to license terms. Continue with the installation by pressing "next" (Figure 5). Click "I do not accept" if

you do not accept the license terms and wish to abort the installation.

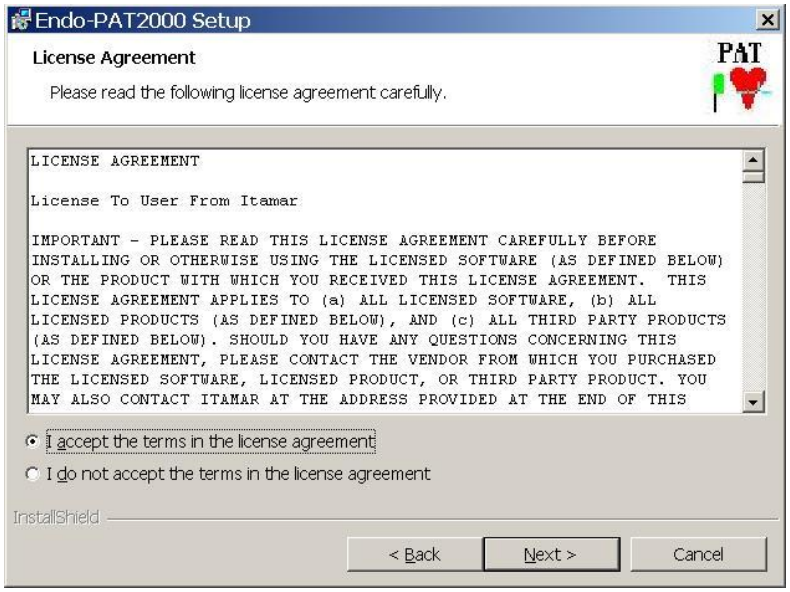


Figure 5 - License agreement

5. Click "Next" to set the default target folder for software installation, or click "Change" to select a different folder for the installation (Figure 6).

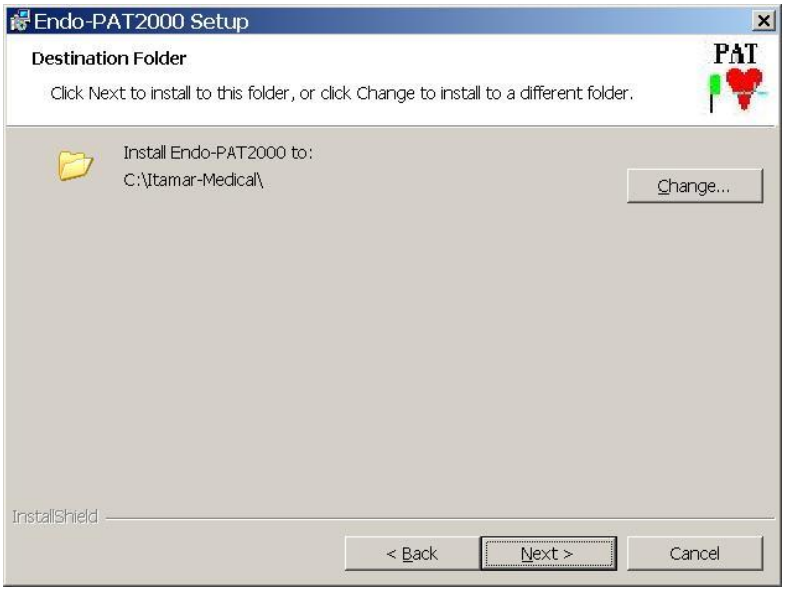


Figure 6 - Installation folder selection

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

6. Press "Install" to complete the installation process or "Back" to review or change any of your installation settings" (Figure 7).

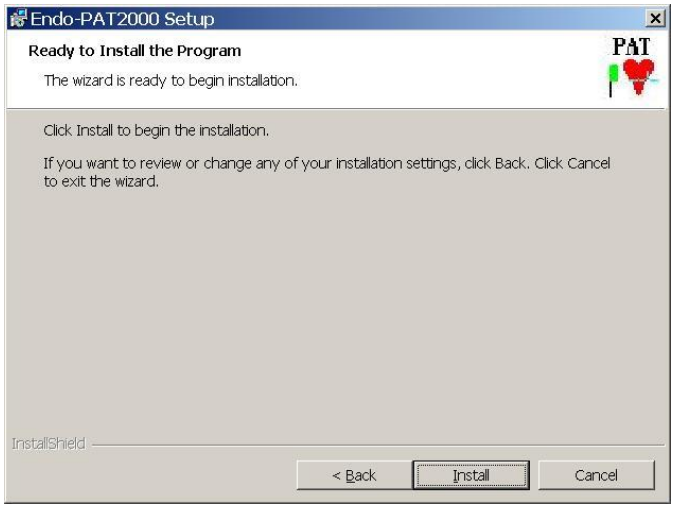


Figure 7 – Ready to install the program screen

7. Press "Finish" when the installation is completed (Figure 8).



Figure 8 - Completion of installation

8. Two icons will be added to the desktop after installation – link to the application and a link to the data folder (study files storage).
9. If used, install the USB-to-RS232 driver as described in section 3.5.



WARNING

The Endo PAT™2000 device is a PC operator device. Use antivirus software to protect your system and files.

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

Avertissement

L'appareil EndoPAT™2000 est utilisé avec un ordinateur. Il est recommandé d'utiliser un anti-virus afin de protéger votre ordinateur ainsi que vos fichiers.

Il est souhaitable d'effectuer régulièrement des sauvegardes des données.

3.5 Installing the RS-232 to USB adaptor

The RS-232 to USB adaptor connects the Endo PAT™2000 device to the computer's USB port. The adapter kit contains the adapter and a software installation CD with the appropriate drivers for Windows XP, Windows 7 or Windows 8 OS.

The installation process depends on your computer's operating system. Please refer to Appendix C for instructions on how to install the driver on Windows XP, or to Appendix D for instructions on how to install the driver on Windows 7 or Windows 8 OS.

3.5.1 General instruction for installing the driver

a. The driver installation must be done before connecting the RS-232 to USB adaptor to the computer.

b. Insert the CD into the CD-ROM drive

c. Browse into the CD-ROM drive
D:\Your_OS\SETUP

d. Execute the Driver's .exe file

e. Continue the installation process by clicking 'next' until installation ends



Note

Restart your computer after installation of the Endo PAT™2000 software and the RS-232 to USB adaptor driver.

After computer restart, connect the adaptor to computer's USB port and wait for new hardware recognition by the operating system.

When the adaptor installation is completed, start the Endo PAT™2000 software (refer to section 4). The software will search for the appropriate communication port to communicate with the connected RS-232 to USB adaptor as described in section 5.1.



Note

Refer to the configuration section (Section 4.4) for changing automatic COM port configuration.

3.6 Registration

Once the software and driver are installed the system is ready for use in its basic configuration.

Itamar Medical strongly recommends that you register your EndoPAT™ software installation. Registration enables you to benefit from our special offers when available, and to be able to activate some of our newer features. Registration enables Itamar Medical to notify you when new version of your product is available and helps Itamar Medical provide you with customer support.

To register the software installation you first need to create a registration request file. Use the following instructions to create registration file and register your installation:

3.6.1 Open the registration window: from the "PAT™ Control" menu select Registration…

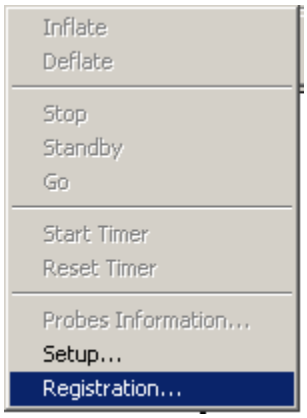


Figure 9 - Registration

3.6.2 The following dialog will be opened:

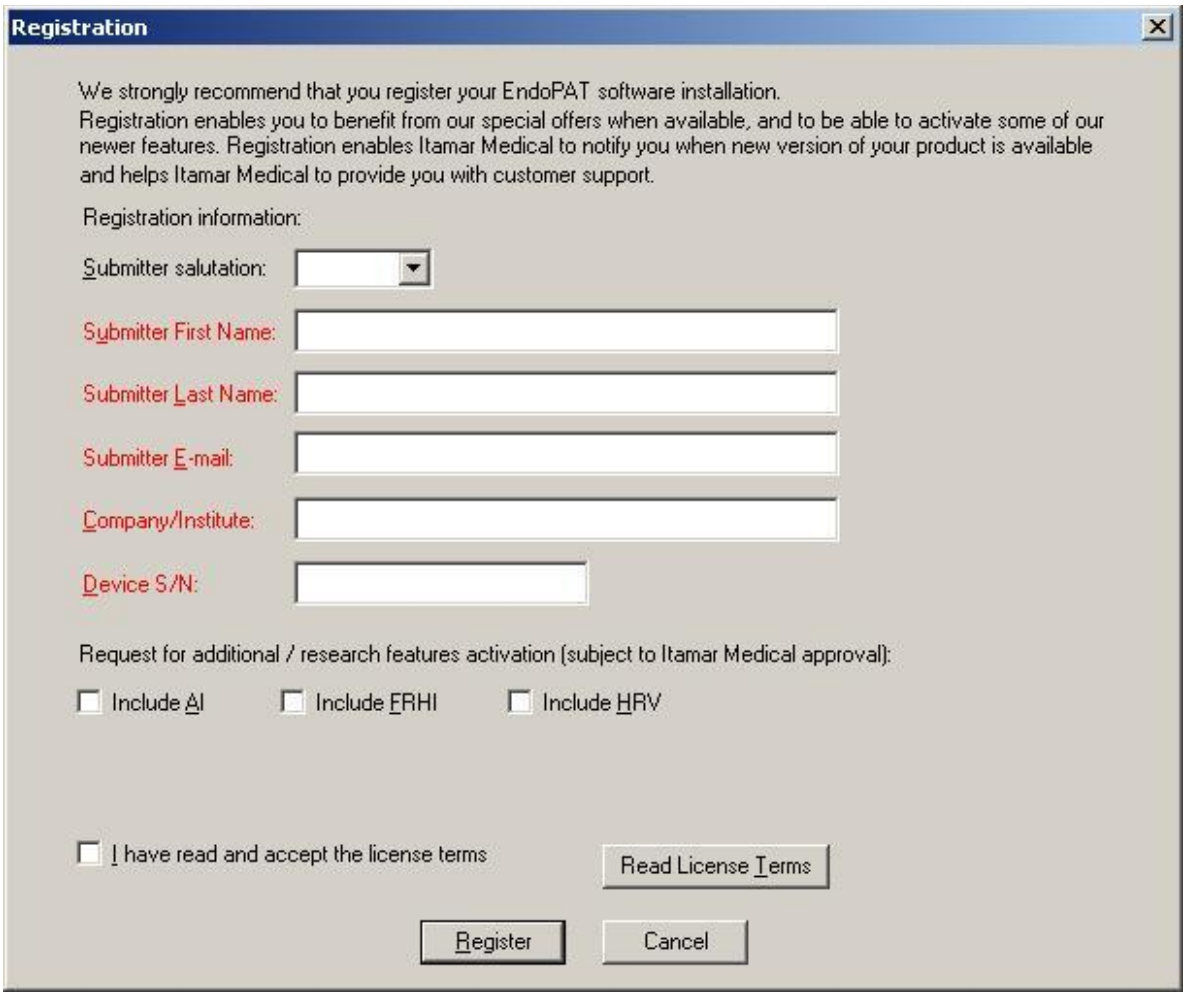


Figure 10 - Registration Dialog

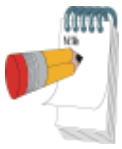
3.6.3 Enter the mandatory information: submitter name, e-mail, company or institute name and device SN. Device SN can be found at the bottom of the device.



NOTE

The E-mail entered in this dialog will be used for sending back the license file. Please make sure this is a correct e-mail address.

3.6.4 If you wish to enable any of the additional / research features, check the feature you want to activate. The use of these features is limited, and they will be opened subject to Itamar Medical's approval.

	**NOTE** AI, FRHI and HRV have not been submitted to the US Food and Drug Administration (FDA) for clearance and can therefore be used in the US solely for research purposes, and not for clinical use in a patient management setting.

3.6.5 Read and agree to the license terms.

3.6.6 Click register. You will receive a message (Figure 11) directing to the location of the registration request file (EndoRegistration.req).

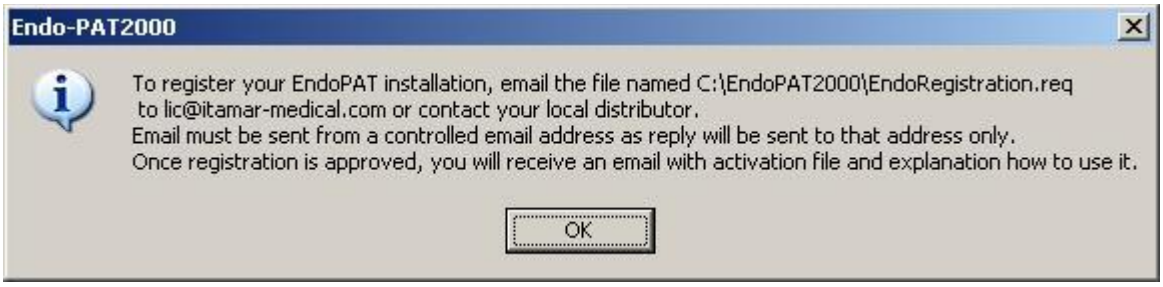
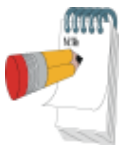
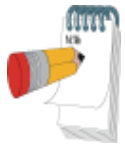


Figure 11 - Registration request file instructions

Once you obtain your EndoRegistration.req file, send it to lic@itamar-medical.com or contact your local distributor. Itamar Medical will receive your request, process it and you will receive the License.lic file by e-mail. Place the license file in your installation directory and restart the Endo PAT™ application.

	**NOTE** The License file is unique and will only enable your licensed features on the same computer generated the license request file.



NOTE

Registration may enable you to use different probe types. This will be done based on your agreement with Itamar Medical, and should not be requested separately. Contact Itamar Medical's representative or your local distributor for more information.

3.7 Uninstalling Endo PAT™2000 Software

Enter the computer's Control Panel and select the Add/Remove programs option. Select the Endo PAT™2000 software and press "Remove".

3.8 Shutting Down the System

a. Shut down the Endo PAT™2000 software program by selecting Exit in the pull down File menu.

b. Switch OFF the Endo PAT™2000 device using the on/off switch on the back panel.

4 Software Description

4.1 Main Screen

From the Windows™ desktop double click the 

icon. The following screen will appear (see Figure 12).

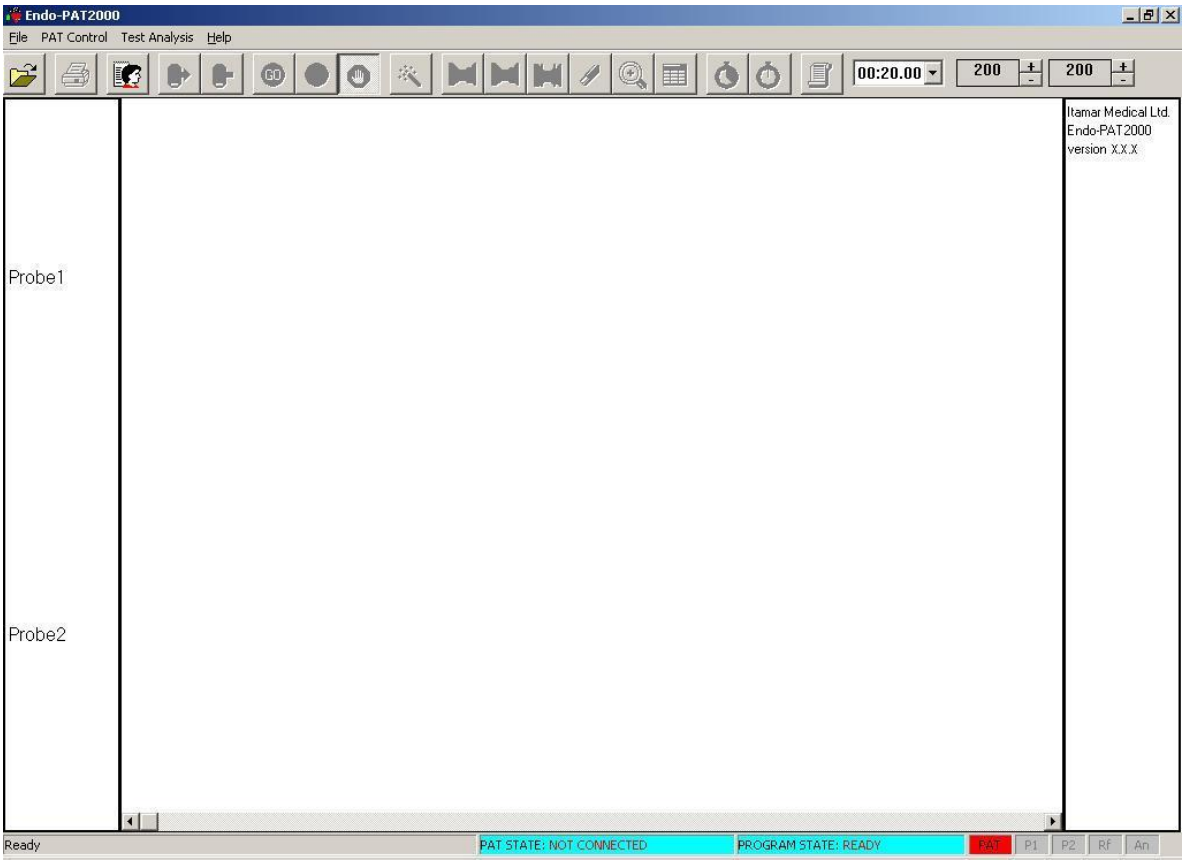


Figure 12 - Main screen

The Main Menu Screen is the gateway to the functions of the Endo PAT™2000 software. The three primary functions are: perform a study, review and analyze a study and system configuration.

The main screen includes:

1. Interfaces:

- Pull-down menu bar (section 4.2)
- Tool bar (section 4.3)
- Scroll bar (section 4.3.2)

2. Display windows:

- Channels identification column (for the PAT™ waveforms)
- PAT™ waveforms window
- Results/calculations column

3. Status bar:

- PAT™ state (communication status between PAT™ device and computer)
- Program status
- Probe status

When first launching the Endo PAT™2000 software, a dialog box (Figure 13) will open. Click the OK button and enter the Setup menu. Complete the setup as described in section 4.4.



Figure 13 – Fill site name dialog box

Upon first launching, the system will also display a Registration reminder message (Figure 14). This reminder will appear as long as there is no license file, and as long as this reminder was not turned off in setup screen. For more information about the need of license file see section 3.6). For more information about turning this reminder off – see section 4.4)



Figure 14 – Registration reminder

4.2 Main Screen Menu Commands

Table 1 describes the main screen pull-down menu commands:

Menu Item	Function
File	Open a previously-saved study Save study data Print screen Exit the Endo PAT™2000 Software
PAT™ Control	Inflate PAT™ probes Deflate PAT™ probes Stop a study Standby mode - view signals without recording GO - Start recording a study Start Timer Reset Timer Probes Information Setup parameters Registration
Test Analysis	Open Patient Information dialog box Automatic Analysis Select occlusion period Select Baseline Segment (in Manual Research mode only) Select Test Segment (in Manual Research mode only) Mark segment as artifact (in Manual Research mode only) Clear all marked segments Zoom In View report Open Batch Analysis dialog box
Help	Provides access to system information Link to Itamar Medical Uploading Service

Table 1 - Main screen pull down menu commands

4.3 Main Screen Tool Bar

The Main Screen tool bar buttons provide quick access to selected menu commands, opens result table, and to the Gain and Timing settings. Gain and Timing settings are used to adjust the Trace Window display.

Dimmed icons indicate that they are not active and cannot be used unless some actions are taken. For example the automatic analysis icon is not active unless there is a data file displayed and ready to be processed.

Table 2 lists each button and its function. "Mouse over" a button to trigger bubble help describing the button's function.

Button	Function
	Load file
	Print screen
	Open Patient Information Dialog Box
	Deflate PAT™ probes
	Inflate PAT™ probes
	Start study
	Standby
	Stop study
	Automatic Analysis
	Mark segment as B (in Manual Research mode only)
	Mark segment as T (in Manual Research mode only)
	Mark segment as artifact (in Manual Research mode only)
	Clear all segments
	Zoom In
	Open result of last calculation
	Start/Stop timer
	Reset timer to the value set in the Setup dialog box
	View Report
	Set time base and gains

Table 2 - Tool bar buttons and functions

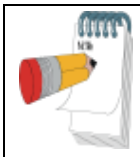
4.3.1 Gain and Time-base trace display Tools

Use the Gain command, to adjust the Trace Window display.



Figure 15 - Gain and time-base scroll boxes

The two gain tools adjust the traces' display of the PAT™ 1 and PAT™ 2 channels (The scroll boxes are in order from left to right: left is probe1 and right is probe2). Adjustments made to the PAT™ channel gain settings affect only the display of the corresponding trend channels.



NOTE

Adjusting gain or time-base settings affects only the display and not the recorded signal, even during the recording.

To adjust the Gain Setting, click the + or - sign next to the appropriate Gain Tool channel. The gain display setting is increased (+) or decreased (-) and the new setting takes effect accordingly.

To Adjust a Time Base Setting, click the Timing pull-down menu and select the desired time base setting. The time scale adjustment is automatic. When a file is open, an **All Study** option is available, allowing to automatically select the nearest time base interval that exhibits the entire study's data on screen.

4.3.2 Scroll Bar

Use the horizontal scroll bar and left and right scroll arrows at the bottom of the Trace Window to view the entire study. Scroll to the left to move backwards, and scroll to the right to move forward.

As trace data appears in the Display Window, the data is saved in the Patient Information file. The study can be analyzed and reviewed off-line in either relative or absolute time modes.

4.4 Configuring the System

The Setup menu is used to configure the system. To ensure that the Endo PAT™2000 system is ready for operation, the configuration of the signal channels and serial port is required.

To Configure the System:

1. Verify that the Endo PAT™2000 device is properly connected to the PC and that it is switched on.

2. Click PAT™ Control, and then select Setup.

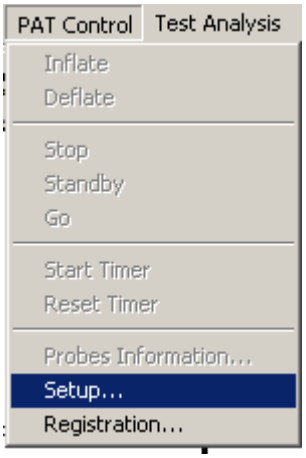


Figure 16 - The setup command

The following screen will appear:

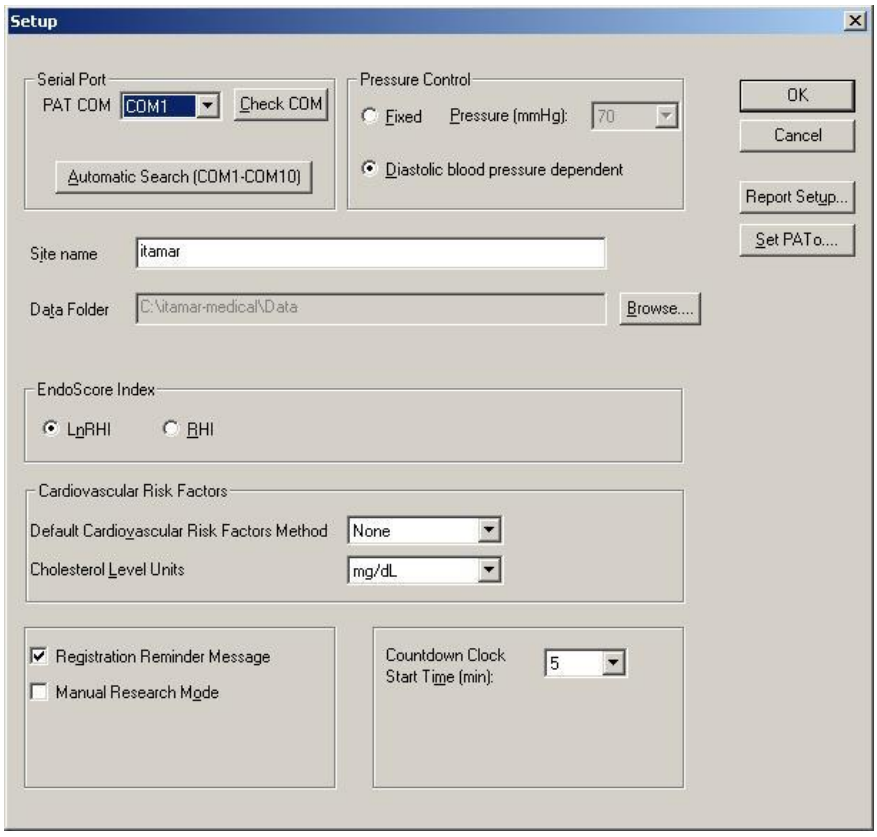


Figure 17 - The setup dialog box

3. Click "Automatic Search (COM1-COM10)" to allow the system to automatically identify the COM port to which the Endo PAT™2000 device is connected. If the

automatic search fails, you can select or type the correct COM port for the Endo PAT™2000 device manually in the relevant field. After selecting the desired COM port verify communication by clicking "Check COM".

4. Fill the "Site Name". This will turn off the dialog box asking to do it on system startup.
5. "Data Folder" is the folder where the studies are saved during test recording and by default is in subfolder "data" under the install folder chosen during installation. The Data Folder can be changed by browsing and selecting other folder.
6. Select the EndoScore™ index that will be used. The options are the LnRHI or the previous index- the RHI. See section 7.4 for more information about the 2 indices.
7. In the "Cardiovascular Risk Factors" frame enter the default method for calculating risk factor to be used in the system. This method will be used as the default option, but can be changed per patient. Go to section 7.5 to read more about the different Risk Factors methods.
8. In the same frame also set the units to be used for cholesterol measurement by your health system. The options are mg/dL or mmol/L. This will be used in the Cardiovascular Risk Factor calculation only.
9. Registration reminder message is presented as long as you didn't register the system and got a license file. As registering your system is optional, disabling this reminder is possible by turning this flag off. To read more about the registration process see section 3.6.
10. To enable the Manual Research mode, select the "Manual Research mode" checkbox. The entire "Test analysis" menu is enabled. See 7.5 below.
11. The Countdown Clock (timer) is set to "5" minutes by default. To change this value (1 through 15), select the appropriate value from the drop-down menu.
12. To configure the report press the "Report Setup" button. This will open the "Report Setup" dialog (see Figure 18). In this dialog the Clinique details (a logo and 3 text lines) can be updated. These details will be used as a header to all Endo PAT™ reports (see Figure 19).
    Notice that the logo size is limited: big images will be reduced to fit the page.
    Each of the 3 lines can contain up to 70 characters.
13. Select "Always Generate and Save Report.rtf File" to allow creation of rtf file that includes all the data in it. Uncheck it to disallow the creation of rtf file.
14. Select "Show Patient Historical EndoScore™ Results (by Patient ID – up to last 6 studies)" to include the current patient's previous EndoScore results in the follow-up section of the report.
    Select the additional criteria and deviation range from the current patient information, in order to choose the data accurately and identify the patient correctly, even if the patient information is not exactly the same (Age – with deviation range of years after compensating for elapsed time between tests, Height-with deviation

range of centimeters or inch, and Gender).
In case there are studies with same Patient ID that do not match the criteria ranges, a list of these studies will appear and the user will be able to select studies and add them to historical data.

15. The historical results shown are based on studies that were analyzed on the same computer. To import more EndoScore™ results from other directories select "Add Studies for Historical EndoScore™ Results".

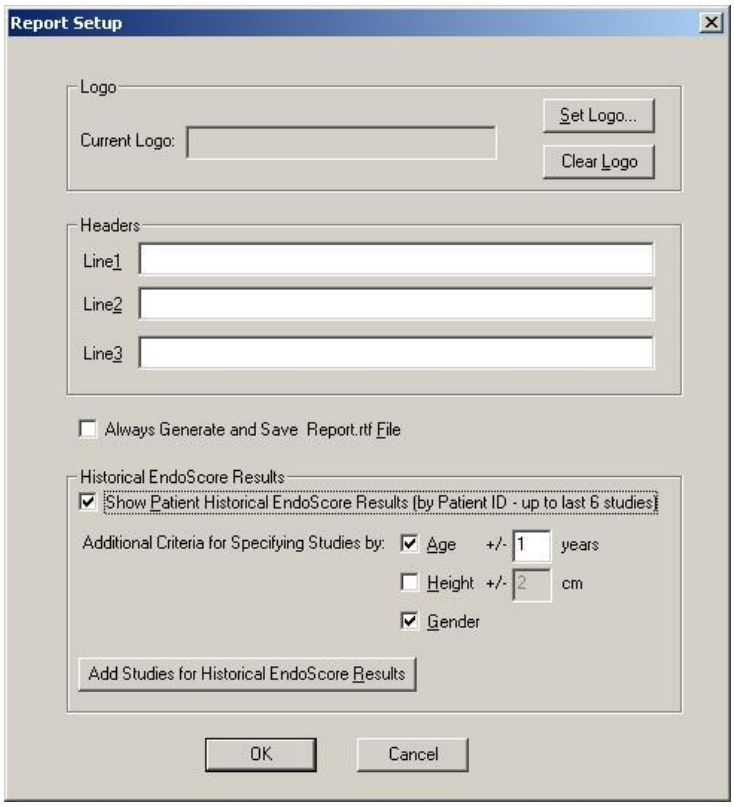


Figure 18 – Report Setup dialog box

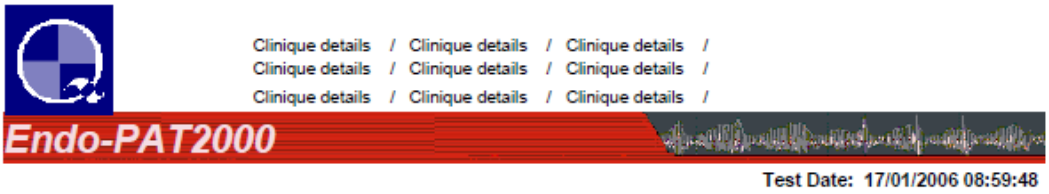


Figure 19 - The example for report header

16. The name of the operator performing the Endo PAT™2000 study can be saved with the study data. The system offers the user to choose from a predefined list, or enter names manually, if the manually entered name doesn't exist in the list it will be

automatically added to the list of offered names.
To create or change the master list from which the names are selected, click the "Set PATographer" to open the following dialog box:

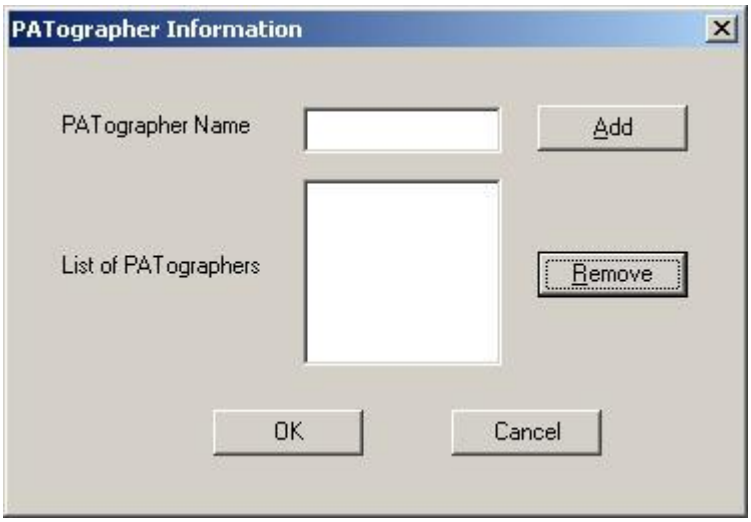


Figure 20 - The PATographer Information dialog box

Type the names of the PATographers in the top field and click "Add" after each one is entered. Once you finished entering all the names, click "OK" to save the information and exit. Click the "Cancel" button to exit without saving the changed information. You can remove unused names by selecting a name in the bottom field and clicking "Remove".

17. In the "Pressure control" frame select whether the probe inflation pressure is set to a pressure that is dependent on the patient's diastolic blood pressure (recommended mode) or to a fixed pressure.
    If a fixed pressure setting is selected, the inflation pressure can be changed from the default 50mmHg.



NOTE

If "Diastolic blood pressure dependent" is selected, the diastolic blood pressure of the patient must be entered prior to commencing the study. The study cannot start without this information.

18. When all the settings are correct, click OK.



NOTE

The default inflation pressure setting for the PAT™ Sensors is 50 mmHg in "fixed" mode. It is recommended that this is not exceeded, unless specified otherwise.



NOTE

Setup can be opened while recording a study, however, during a recording the COM field and the Pressure Control fields are disabled and cannot be modified.

4.5 Using the Timer (Countdown Clock)

Some phases in the study recording require strict timing. To operate the timer, refer to the following instructions:

- **To set the timer** (the number of complete minutes it will count), refer to the Setup menu (section 4.4)
- **To start the timer**, click the  icon. When the timer reaches "0", the timer indicator at the bottom right of the screen blinks red.
- **To stop the timer**, click the  icon again. The timer stops counting.
- **To restart the timer**, click the  icon. The timer resets and starts counting, according to the set-up in the setup screen.

4.6 Setting the Default Printer

Setting the default printer is performed in the normal manner by accessing the Printer Setup window from the Windows™ desktop.

5 Preparing for a Study

5.1 Preparing the System for a Study

Accessories that are required beside the Endo PAT™2000 system:

- A set of two PAT probes and anchors
- Blood pressure cuff (capable of sustaining high pressures for 5 minutes)
- Adhesive tape
- Pair of arm supports
- Timer/stopwatch (optional)

Switch on the computer, the Endo PAT™2000 device, and launch the Endo PAT™2000 software with the shortcut icon on the desktop. When the Endo PAT™2000 software is launched it performs an automatic COM port search and communication test with the device. If the software is unable to establish communication with the device, a COM-port search dialog box will open (Figure 21). While this dialog box is open the system continues trying to establish communication with the device, going through COM ports 1 to 10 in a cyclical manner. This continues until communication is established or "Work Disconnected" is selected.



Figure 21 - COM port search

5.2 Connecting the PAT™ Probe

Connect two new probes by inserting the connector tab into each probe slit (see Figure 22) and pressing the connector down onto the probe until the tab of the probe clicks into place (see Figure 23).



Figure 22 - Inserting into slit

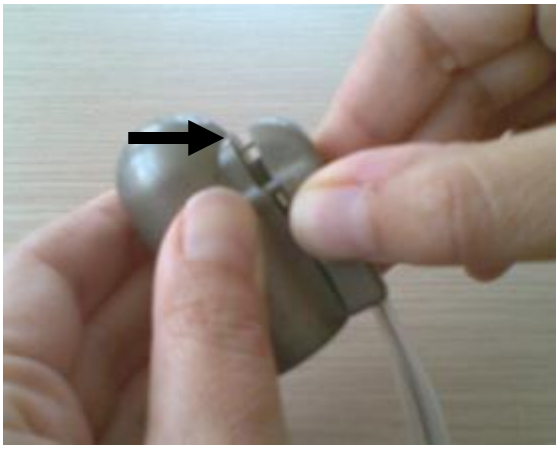


Figure 23 - Clicking in

To remove probes, press the tab (clip) marked by the arrow in Figure 24, and then lift the connector away from the probe (Figure 25). Used probes should be disposed of properly.



Figure 24 - Press to release



Figure 25 - Probe disconnected

5.3 Creating a Patient File

1 Click the  icon on the tool bar or activate from the Test Analysis menu the Patient Information dialog box. (see Figure 26)

2 All mandatory fields are highlighted in red and must be filled in order to proceed to the next step. The field description is as follows:

- Patient ID - Enter patient identification number (mandatory field).

- Visit – Enter visit number or code. Up to 9 characters. This field should be used to distinguish between several tests by the same patient (with the same ID). The patient ID and visit are used to generate the file name used by the system.
- Patient First and Last name - Enter the patient's complete name, initials or other identifier, or it can be left empty (optional field).

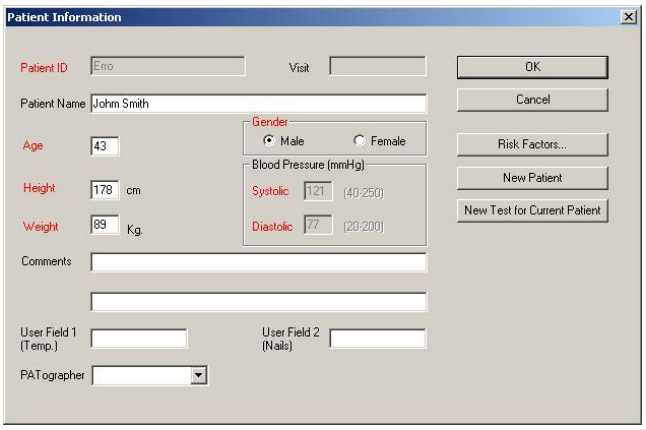
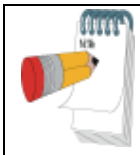
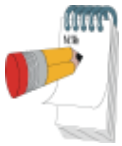


Figure 26 - Patient information dialog box (metric version)

- Age - Enter the patient's age. This can be done manually, or by pressing the arrow key until the correct age 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 (Figure 17).
- Systolic Blood Pressure – mandatory field, unless the "Fixed pressure" mode was selected in the set-up screen (Figure 17).
- Comments - optional field.
- User Field 1 (Temp.) - optional field. Up to 10 characters length of free text. Designed to enter the room temperature at the beginning of the test.
- User Field 2 (Nails) - optional field. Up to 10 characters length of free text. Designed to enter the patient's nail length – OK or over 5 mm/one fifth of an inch, beyond the tip of the finger tissue.
- PATographer - optional field - select from the pick list, or type directly into the field the name of the PATographer to be associated with the study.

- Risk Factors… - this will open a dialog box about additional inputs required to calculate Cardio-vascular Risk Factor. See paragraph 3 below.
- "New Patient" button will clear the dialog and allow filling the dialog in preparation for the next recording.
- "New Test for Current Patient" button will allow quick setup of a new test for the currently viewed patient. It will keep all fields in the dialog, except for Visit, Blood Pressure and PATographer.

	**NOTE** All text fields (ID, visit, patient name, comments, user fields and PATographer) should be entered using text letters and numbers.

	**NOTE** Study data is saved in a data file that is automatically named with the **Patient ID** and **Visit**. If the patient ID is for example 12345, and the visit is V1 then the file name will be 12345_V1.s32.

After clicking OK the Patient Information dialog box will be closed.

	**NOTE** The computer's file system will not allow the same Patient ID and Visit for 2 different PAT™ studies.

When attempting to use existing ID and Visit numbers, the following message appears:



Figure 27 – "File ID exists" warning message

A different ID or Visit must be entered before you can proceed.

3 Risk Factors: The Risk Factors dialog box enables entering additional data to be used in the calculation of Cardiovascular Risk. For more details about the different Risk

calculations see section 7.5.

- There are 3 possible methods for calculating the Cardiovascular Risk: Framingham Risk Score, SCORE Risk and Reynolds Risk Score.
- The default method is set in the setup (see 4.4), but it can be changed from patient to patient.
- A List of required parameters per calculation method can be found in Table 3. Mandatory fields are marked in red on the screen (per selected method).
- A warning will appear once patient information dialog is closed, if any of the mandatory fields is left blank. Calculated risk result in the report will not be available in such case.

Parameter	Required in			remark
	Framingham	SCORE	Reynolds	
Total cholesterol	✓	✓	✓	Either mg/dL or mmol/L
HDL cholesterol	✓		✓	
hsCRP			✓	High sensitivity CRP
Diabetic	✓(*)		✓(*)	Reynolds and Framingham doesn'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 3 – Risk Factors mandatory fields

Gray lines represent inputs that are used in the calculation of the Risk, but are part of the main Patient Information Dialog and not the Risk Factors Dialog.

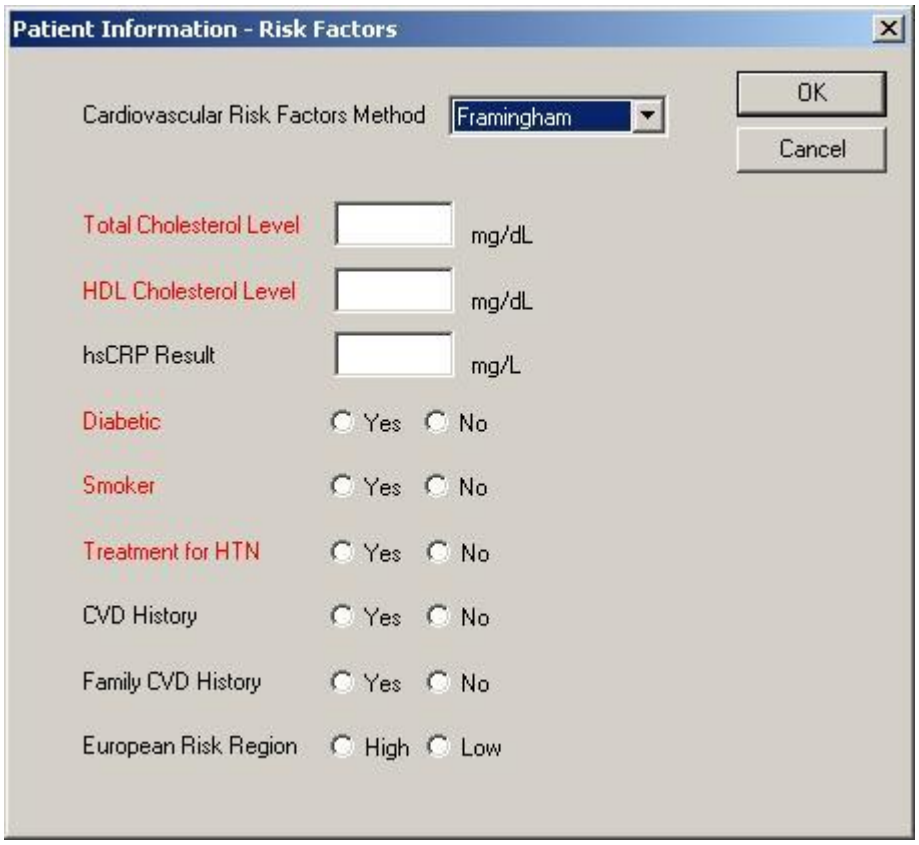


Figure 28 – Patient Information – Risk Factors

6 Conducting an Endo PAT™ 2000 Study

6.1 Pre-Study

6.1.1 General description

The Endo PAT™ 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 Endo PAT™ system. The system console has two separate external switches for inflating and deflating the probes. The probes can be inflated and deflated via the computer program as well.

The probes' pressure and the setting of displayed signals are configured through the setup function in the "PAT™ Control" pull down menu (see Figure 16). Signal gain and time base are set through icons appearing on the Tool Bar (see section 4.3.1).

If the probes' pressure mode was initially configured to a "fixed pressure", then the recommended pressure setting is 50mmHg.

The eligibility of a patient for an Endo PAT™ 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: 21ºC-24ºC (70ºF-75ºF).

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 upper arm blood pressure cuff should be applied snuggly, 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 Endo PAT™ 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 Endo PAT™ study).
- It is recommended to allow 5 minutes to pass between the time of the blood pressure measurement and the commencement of the Endo PAT™ baseline recording.

6.1.5 Positioning the patient

The patient should sit 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.

Avertissement

Les ongles trop longs risquent d'entraver les signaux ainsi que les résultats de l'examen.

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, all wireless communication in the computer is turned off and the device is connected directly to the computer.

6.2.2 Initializing the Endo PAT™ system

Activate the Endo PAT™2000 application. Enter patient details as required. Please note that the ID should be specifically assigned to the subject and is going to be allocated as the file name for the recorded Endo PAT™ study.

Ensure that the pneumo-electric tubings are properly connected to the Endo PAT™2000 device, and a new set of probes is installed and ready for use. If the probes are not new, when you try to inflate the probes a warning dialog-box (Figure 29) will open.



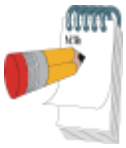
Figure 29 - Used probes warning

	**WARNING** The probes are single use and disposable: they will not work if they have already been used! **Avertissement** Les sondes sont destinées à un seul usage donc non réutilisables et sont jetables: elles ne fonctionneront pas si elles ont déjà été utilisées!

6.2.3 Patient preparation

First, ensure that a blood pressure cuff is placed on the upper arm of the designated test arm. Then, the PAT™ probes should be placed inside the appropriate sockets of the arm-supports (see Figure 30-1). Fully deflate the probes by clicking the  icon in the software 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 30-2). Inflate probes by pressing the Inflate button on the device or clicking the  icon.



NOTE

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

Place the blue foam anchor ring on the adjacent finger to the one with the probe on, as near as possible to the finger's root. 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 in section 9, Table 5.

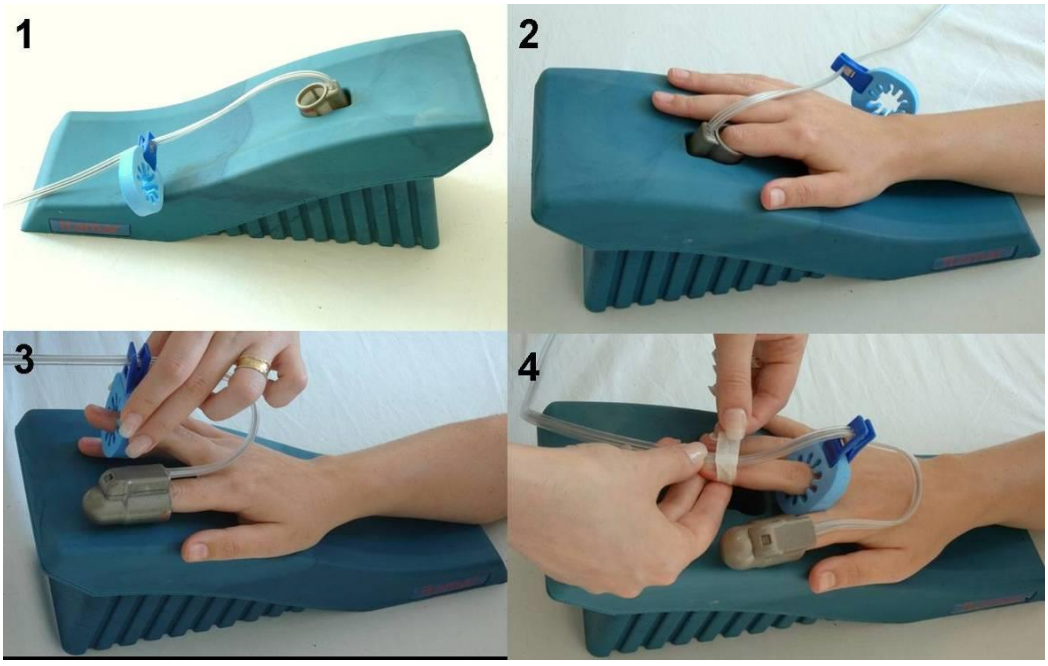


Figure 30 - Applying the PAT™ probes

Make sure the tubing forms a loop from the probe, reaching half of the palm and back to the anchor (and attached to the anchor with the integral clip) as shown in Figure 30-3. Gently tape the tube to the tip of the anchor finger, over the finger-nail (Figure 30-4).

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 (alternatively, rolled towels or bed-sheets can be used). Make sure that the probes are free and not in contact with any object (including the supporting surface), as shown in Figure 31.

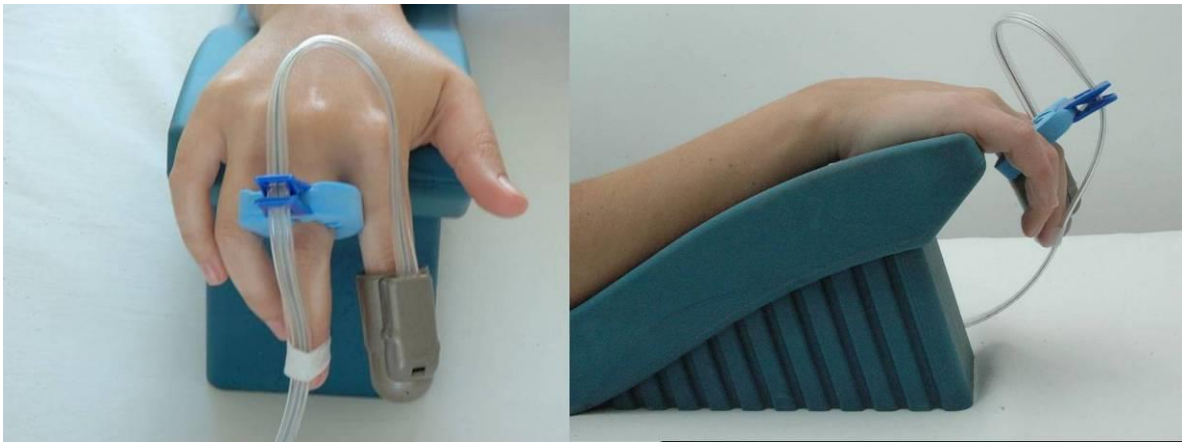


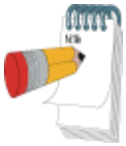
Figure 31 - Hands set-up

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 Stand By  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/scaling to properly visualize the PAT™ signals without saturating the screen. It is recommended to view the signal in a 1 minute screen (00:01:00). Signals from both PAT™ channels (Probe 1 and Probe 2) appear in the Trace Window (as well as the trend channels, if these are selected in the system setup). Visually inspect the PAT™ signal (see Figure 32) for at least 1 minute. If the signal seems noisy, make sure that the probes are not in touch with anything at all. 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, wait 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 (section 9).

	**NOTE** If you are in the Stand By mode, it is possible to stop the test, deflate & re-inflate the probes without losing the usability of the probes. Once  is pressed the probes cannot be reused after the  button is pressed.

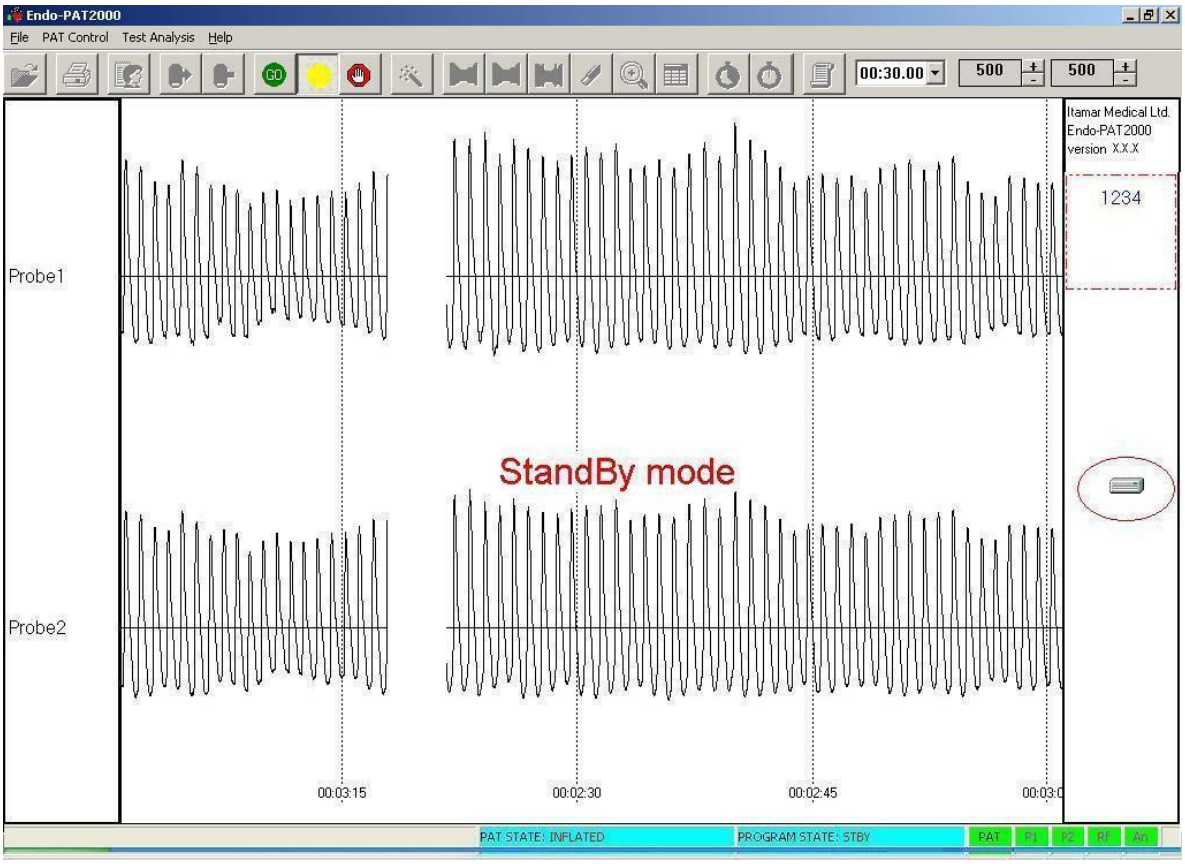
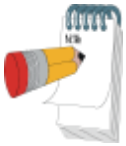
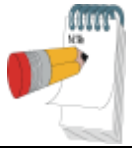


Figure 32 - StandBy mode

	**NOTE** While working in the Stand By mode, data is not recorded, and therefore it is impossible to review or save the study. The notification: "Stand By mode" (Figure 32) is displayed, and will disappear when the  button is clicked.

2. Click the  icon to begin study recording. Verify that the "recording" icon appears on the right hand side of the display (see the circled icon in Figure 33).

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

3. Initialize the stopwatch, by clicking the  icon.

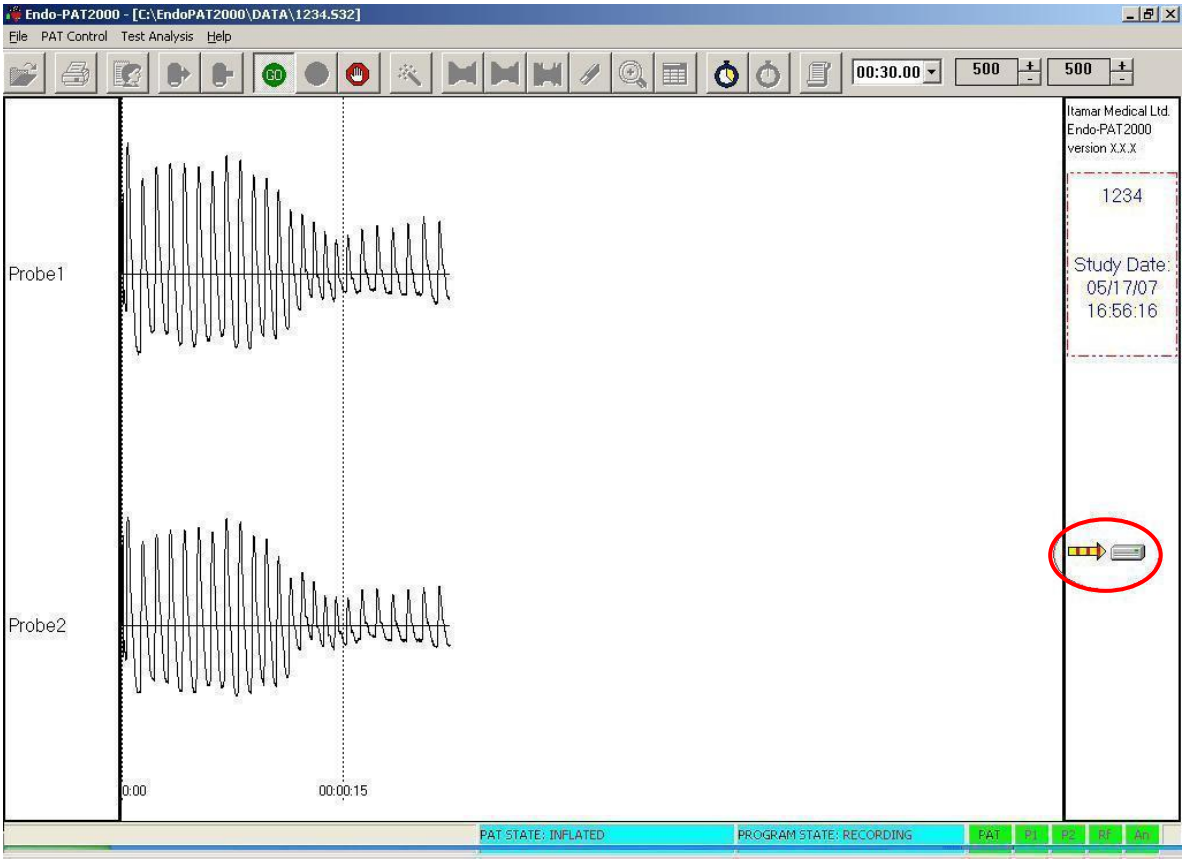


Figure 33 - Recording

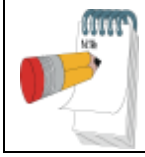
	**NOTE** After starting the recording the time scale will be set automatically so the full window will contain 1 minute. 15 seconds periods will be marked by dotted lines.

If the beginning of the recording is marked by patient motion artifacts or an unstable signal, consider troubleshooting procedures or extend the total period of baseline recording to give an overall period of at least 5 minutes of stable baseline data prior to the occlusion.

6.3.2 Performing arterial occlusion

After a stable period of baseline signal recording, prepare for the occlusion:

1. Change the time scale to 15 seconds (00:00:15).
2. Amplify the signal gain of the occluded arm (either probe 1 OR probe 2) to 20,000.
3. If a stop watch will be used during the occlusion – set it for down counting from 5 minutes.
4. Explain the procedure to the patient, stressing the importance of remaining still during the test, despite the transient, strange sensations (i.e. numbness) they might feel in their arm.
5. **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 (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 34).
6. Click the  icon to start the timer, when the cuff reaches the target occlusion pressure.

	**NOTE** Without marking the beginning of the occlusion by starting the timer, you will not have any means of knowing when the occlusion period began. Thus you will not know when to release the occlusion.

Warning

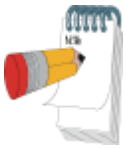
Inflating the BP cuff might cause some stress and discomfort to the patient. Pay attention to the patient's well-being.

Avertissement

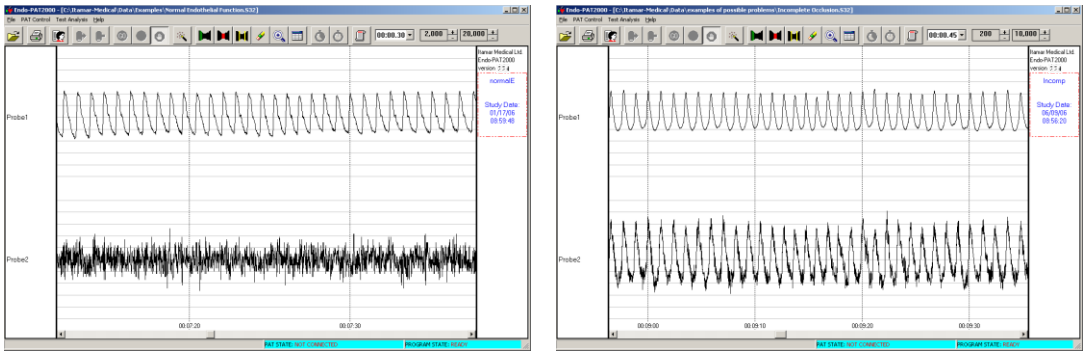
Le gonflement du brassard BP risque de mettre le patient dans un état de stress et de gêne. Soyez attentifs au confort du patient.

Maintain the arterial occlusion for exactly five minutes – periodically check the pressure in the occluding cuff to ensure proper inflation; increase pressure if required.

NOTE



Once the occlusion has been performed the test should not be re-started i.e. whatever problem occurs you should not stop the test and perform a new study on the same arm as vascular conditioning might have occurred. It is recommended to wait at least an hour prior to performing a new study and then to study the opposite arm.



Left – complete occlusion Right – incomplete occlusion

In both panels the bottom signal is the occluded arm.

Figure 34 - Occlusion quality assessment

6.3.3 Post Occlusion period

When exactly five minutes have passed, and the stopwatch indicator starts blinking red (the occlusion is complete), completely deflate the pressure cuff **as quickly as possible**.

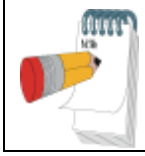
1. Stop the stopwatch, by clicking the  icon.
2. Click the  icon to start the timer. Continue to maintain the relaxed conditions throughout this period to ensure proper recording. The patient will experience strange

sensations after the cuff deflation & might feel an urge to move the test arm. This should be discouraged.

3. When the stopwatch indicator starts blinking red (the post occlusion is complete), stop the stopwatch, by clicking the  icon.

6.3.4 After the Study is Completed

Click the  icon to end the recording. This will also deflate automatically the probes, allowing their removal from the patient's fingers. Carefully remove the tape, PAT™ probes, anchors and the occluding upper arm 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 (the one taken off the adjacent finger) around each used probe prior to discarding the probes.

	**NOTE** If the probe doesn't deflate after ending the study with the  icon, manually deflate via the deflate button on the device.

Once you click the  icon to end the recording the patient file will be automatically saved to the hard disk, with the previously entered patient ID as the file name. By default, the data folder is located in the data folder, in the Itamar Medical folder in C drive.

It can also be accessed directly from the desktop by using the 

icon.

After finishing recording a study, open the recorded file for review (see next chapter).

6.3.5 Setting time markers

Time markers can be inserted manually into the data while recording. This is used only for manual data analysis, as described in section 7.9.

To insert a time marker press any of the 10 number keys on the keyboard. The time marker cannot be erased after it is set. However, it does not interfere with the data. You can set as many markers as you like.

7 Review and Analysis

During a PAT™ study, recorded signals are viewed in the display window and, 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

From the toolbar click the  icon or select Open File from the menu bar. The following dialog box appears:

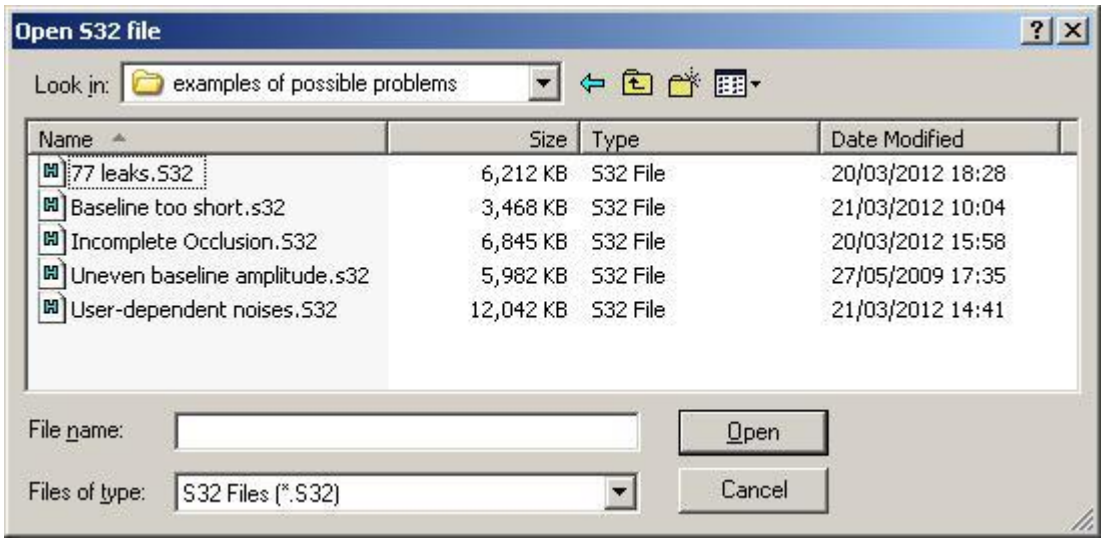


Figure 35 - Open file dialog box

Select the desired file from the list (note that the file name is the same patient and visit ID used when entering the patient's information) and click Open.

7.2 Automatic Analysis

Click the  Icon, or select Automatic Analysis from the Test Analysis menu.

In the Endo PAT™2000 main screen, the test result's value appears in the right column as shown in Figure 36.

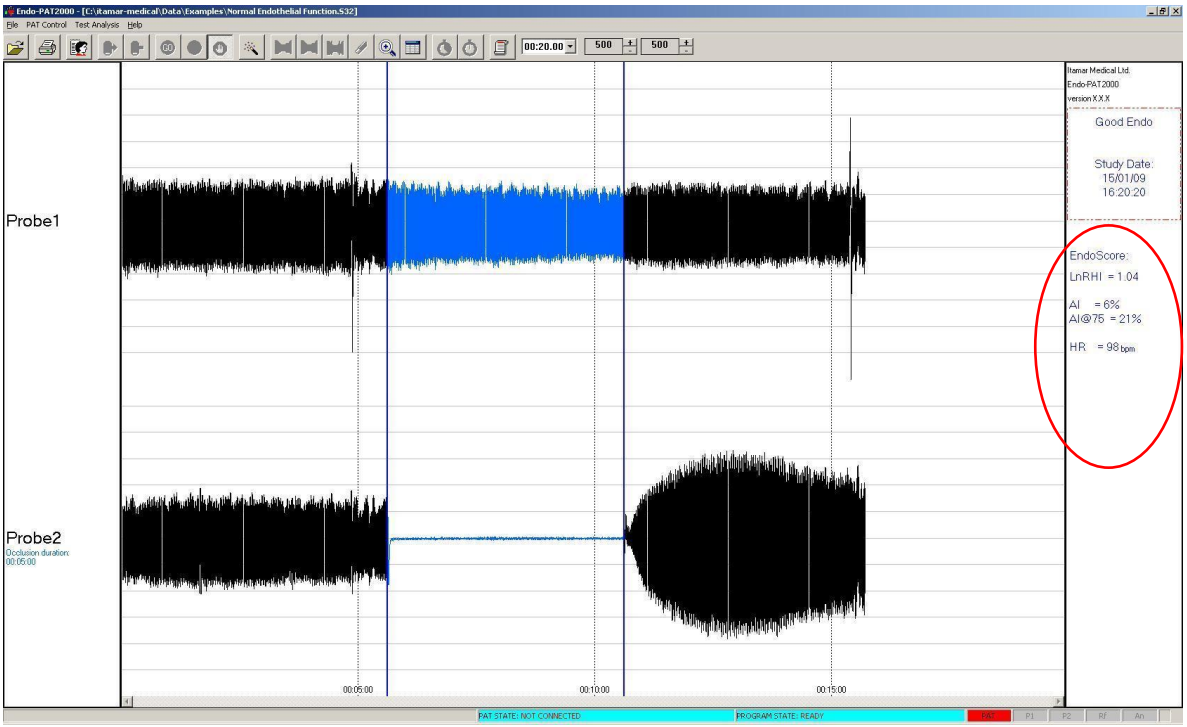
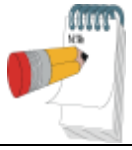
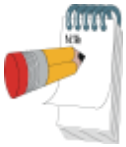


Figure 36 - Automatic analysis

	**NOTE** The AI (Augmentation Index) is one of the additional / Research parameters, and it is calculated and presented only if enabled as part of the license.

The automatic analysis identifies the occlusion borders and marks with two vertical blue lines its beginning and end, and also marks blue the whole signals area between these two lines. 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.

	**NOTE** After launching the Endo PAT™2000 software, you should wait 10 seconds before running the first test analysis. This is necessary to allow termination of background processes.

The Endo PAT™2000 study results (LnRHI or RHI and Heart Rate) are presented on the right side of the screen (Figure 36).

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 LnRHI > 0.51
Abnormal EndoScore™:	RHI ≤ 1.67 or LnRHI ≤ 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  icon to clear all markings from previous analyses. Select the occlusion borders using one of the following 3 alternative methods:

1. Position the mouse's cursor on the occluded PAT™ tracing so that it points at the beginning of the occlusion. Click and hold down the left mouse button and drag the cursor rightwards until it points at the end of the occlusion area. The selected area will have inverted colors and as you mark it, the length of the selected period will be marked just below Probe1 or Probe2 on the left hand side of the screen in blue. Release the mouse button. In the "Test Analysis" menu, select the "Select Occlusion Period" option to set the manually selected occlusion area. Occlusion markers (blue vertical lines) can be dragged to improve the fit of the occlusion area. Zoom-in to fine tune the location of the occlusion markers.

2. Position the mouse's cursor at the beginning of the occlusion area. Right click on the mouse will open a popup menu (Figure 37). Select "Set Automatic 5 min Occlusion" from the popup menu. A five minutes segment starting at the cursor position will be marked in blue. Occlusion markers (blue vertical lines) can be dragged to improve the fit of the occlusion area. Zoom-in to fine tune the location of the occlusion markers.

3. Position the mouse's cursor at the beginning of the occlusion. Right click to open a pop-up menu (Figure 37).

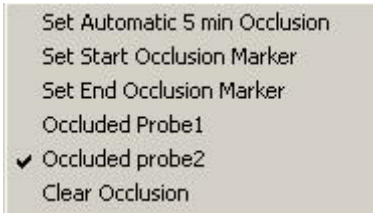
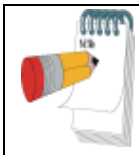


Figure 37 - Occlusion Popup Menu

Select "Set Start Occlusion Marker". Move to the location of the end of the occlusion period, right click, select "Set End Occlusion Marker". Occlusion markers (blue vertical lines) can be dragged to improve the fit of the occlusion area. Zoom-in to fine tune the location of the occlusion markers.

	**NOTE** It is recommended to change the time-base to a 1 minute screen (00:01:00) to make the identification of the occlusion borders easier. If the occlusion area extends beyond the edge of the window, the window will automatically scroll as you drag the mouse across its edge.

- The designated occluded probe is marked on screen by the blue text: "Occlusion duration:" under the Probe label, on the left side of the screen. The occluded probe is selected automatically by the software. It can be changed by right clicking on the mouse (anywhere in the signal window) and selecting the correct occluded probe (Figure 37).
- Once the manually selected occlusion is marked, click on the  icon to run the automatic analysis using the manually selected occlusion area.
- The manual changes of the occlusion borders can be saved by selecting the "Save" option from the "File" menu. These changes will be recorded into a file with an "M32" suffix, rather than the original raw data which will have the same file name, but an "S32" suffix (for example: johnSmith.S32 & johnSmith.M32). The M32 files are 1KB in size and only contain coordinates of the occlusion borders.

	**NOTE** Manual changes of the occlusion borders are automatically saved

- To remove the manually added occlusion markings, right click on the mouse and select "Clear Occlusion" (Figure 37).

7.3 Study Report

To review the study report select the "View report" option in the Test Analysis pull down menu or click the  icon. The report will be exported to a picture viewer (it will take a few seconds).

There are several pages in the Report. The first page contains data about the patient, the study, traces of the signals and the basic results (RHI/LnRHI and HR). The second page is Risk Factor page (when the risk score is calculated). It contains information about the selected Risk Factor method, the patient information used in the calculation, the Risk Factor result, and the expected change in Risk with age.

The 3rd and 4th pages contain data about the Augmentation Index and Hart Rate Variability (HRV) and will only be included in the report when these features are included in the license file and calculated.

This report can be printed or exported to other formats (i.e. PDF).

7.4 Endo PAT™2000 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 ≤ 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: LnRHI > 0.51
Abnormal: LnRHI ≤ 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 38 and Figure 39 respectively (blue represents the actual numbers and red represents the calculated equivalent normal distribution of the same mean and standard deviation).

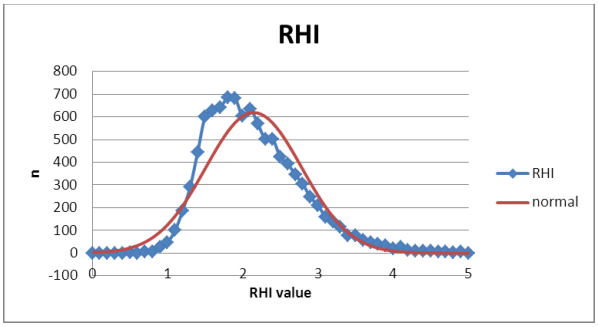


Figure 38 – non selective population histograms of RHI

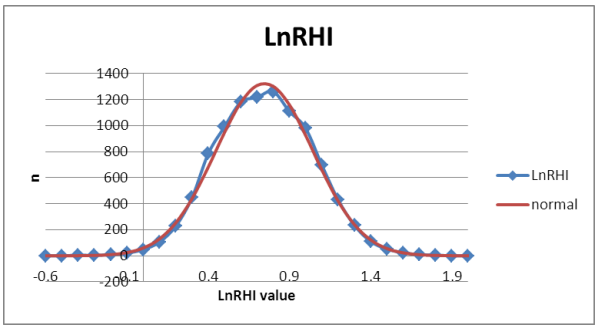


Figure 39 - non selective population histograms of LnRHI

The LnRHI distribution curve in a non-selected population is included in the report (Figure 40) and displays the LnRHI result in respect to non selected population.

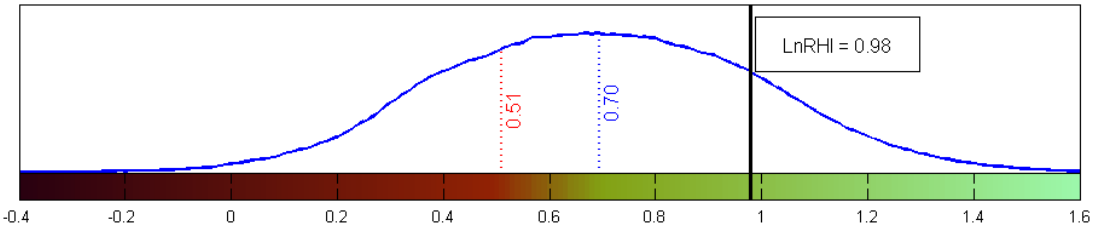


Figure 40 – LnRHI distribution in non-selective population

The graph presents the distribution function of the LnRHI in the nonselected 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 Patient Historical results

If the report setup allows for historical result to be presented, and there are previous EndoScore™ result for the current patient ID that meets the criteria and deviation range (as set in the report setup) the report will include a historical result section containing a table and a chart.

The table will include up to 6 EndoScore™ results with the matching date and time. The chart's bars will represented the EndoScore™ with the correct date order (see Figure 41).

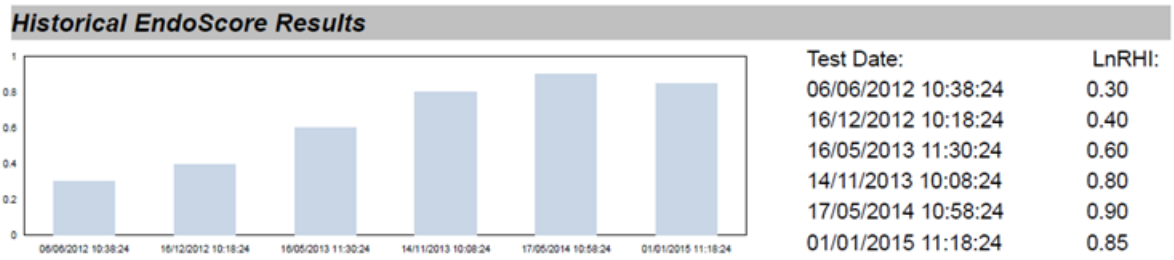


Figure 41– Historical EndoScore Results – table and chart

7.5 Cardiovascular Risk

EndoPAT™ software enables the calculation of 3 types of Cardiovascular Risk.

The software uses the information entered in the patient dialog box, and calculates the selected Risk. The result appears in the report, and in the tabular report.

7.5.1 Framingham Risk Score

Framingham Risk Score estimates the risk of developing hard CHD adverse events (myocardial infarction or coronary death) over a course of 10 years (Adults Treatment Panel III, JAMA 2001).

The risk is given in percentages.

The Framingham Risk Score applies only to people without known heart disease or diabetes.

For more information, visit
http://www.framinghamheartstudy.org/risk/hrdcoronary.html

7.5.2 SCORE

SCORE is the European risk prediction system providing a 10 year risk of fatal CVD. SCORE is representative of typical European populations, and the risk score system has been optimized for coronary prevention in European clinical practice.
Risk may be higher than indicated in:

- Sedentary or obese subjects, especially those with central obesity.

- Those with a strong family history of premature CVD
- The socially deprived
- Subject with diabetes – risk may be 5 fold higher in women with diabetes and 3 fold higher in men with diabetes compared to those without diabetes.
- Those with low HDL cholesterol or high triglycerides.
- Asymptomatic subject with evidence of preclinical arthrosclerosis, for example reduced ankle-brachial index.

The Endo PAT™ device is using the General version of the SCORE, using the low and high risk countries (and not national versions).
For this use:

European Low Risk:	Belgium, France, Greece, Italy, Luxembourg, Spain, Switzerland, and Portugal.
European High Risk	All other European Countries

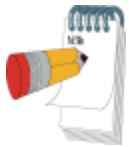
For more information, search SCORE in: www.escardio.org

7.5.3 Reynolds Risk Score

Reynolds Risk Score is designed to predict the risk of having a future heart attack, stroke, or other major heart disease in the next 10 years.
The Reynolds Risk Score is a newly developed score that includes information from the hsCRP blood test (a measure of inflammation) and whether or not either parents had a heart attack before age 60 (genetic predisposition) on top of the traditional risk factor analysis.
Reynolds Risk Score applies only to healthy population without diabetics above the age of 45. Female/Male with diabetics should not be evaluated using Reynolds Risk Score as they are already considered to be a high-risk group for both heart disease and stroke.

For more information visit: http://www.reynoldsriskscore.org/faq.aspx

7.6 Additional / Research Features



NOTE

Please note that the Endo PAT™ analysis of Augmentation Index (AI), Heart Rate Variability (HRV) and FRHI are not FDA cleared and can be applied for clinical use out of the US only.

	NOTE To activate any Additional / Research Feature, you should submit a request to Itamar Medical as part of the Registration process. See section 3.6 above.

7.6.1 Augmentation Index (AI)

Augmentation index is a measure of arterial stiffness, calculated based on pulse wave analysis of the signal measured by the Endo PAT™ device. Arterial stiffness is an independent risk factor for later CVD events, it reflects the structural nature and basal tonus of the vessel, and is not necessarily correlated to endothelial function.

AI in the Endo PAT™ is calculated from the PAT™ pulses at the base-line period of the occluded arm, by averaging multiple valid pulses and finding the systolic peak (P_1) and the backward reflected peak (P_2) and then using the formula: (P2-P1)/P1. See Figure 42.

As augmentation index is heart rate related, the result is then corrected to a standard of AI at heart rate of 75BPM ($AI_{@75}$).

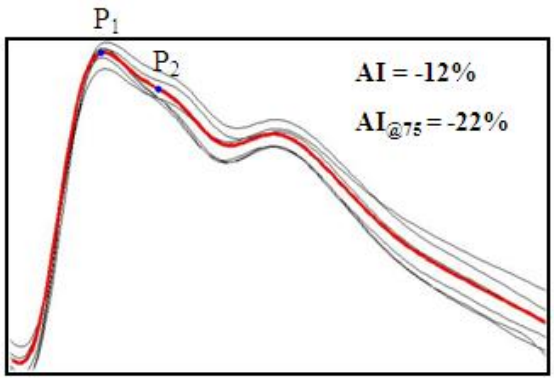


Figure 42 - AI calculation

Lower AI values (including negative results) reflect better arterial elasticity. AI is usually increasing with age, and is higher in female. The AI section in the report includes the AI result relative to large gender matched non-selective population.

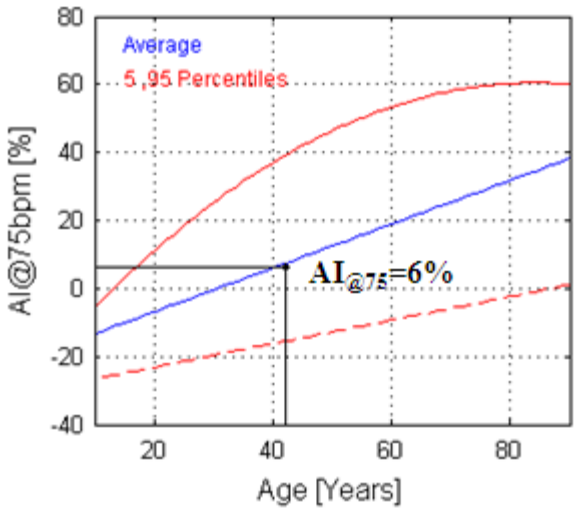


Figure 43 – AI result from the report (female example)

7.6.2 Heart rate variability (HRV)

Heart rate variability (HRV) is a measure of heart beat to beat variability in either time or frequency domain. HRV reflects the status of the autonomic nervous system (ANS) and particularly the balance between sympathetic and parasympathetic activities. Low HRV has been described as related to various pathological conditions.

The Endo PAT™ HRV is calculated from the baseline period, based on the European Society of Cardiology and the North American Society of Pacing Electrophysiology task force standard. It requires 5.5 complete minutes of base line, and includes all the time and frequency domain that can be calculated from this short (5minutes) time period. Results are available in the tabular report (Excel or HTML), and in the patient report as the last page which includes also some graphical results. See Figure 44and Figure 45 for the information presented in the report.

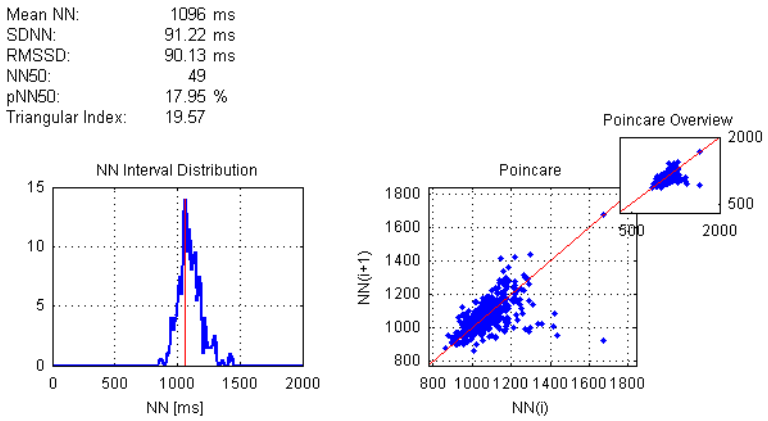


Figure 44- Time domain HRV in the report

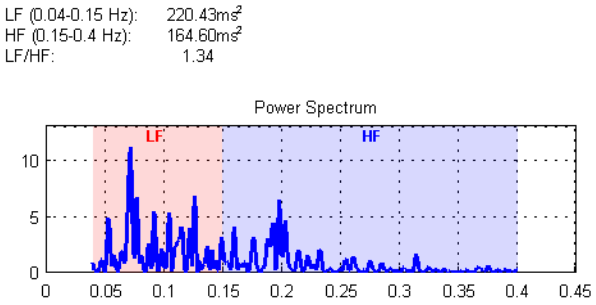


Figure 45- Frequency domain HRV in the report

7.6.3 FRHI

The Endo PAT™ device has been used in the Framingham Heart Studies for several years. 2008 Circulation paper by Hamburg et al (Cross-Sectional Relations of Digital Vascular Function to Cardiovascular Risk Factors in the Framingham Heart Study) presented an index to be used with the Endo PAT™ device, termed here as FRHI. Basically it is a natural log transform of the ratio between the post to pre occluded PAT™ amplitudes and the same ratio of the PAT™ amplitudes measured at the control arm. FRHI does not incorporate a correction to the baseline, and is using shorter post occlusion times (1.5-2minutes) than the RHI/LnRHI.

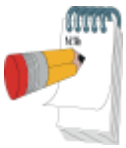
Researchers that want to use this index for research purposes can ask Itamar Medical to enable this index as part of the registration process. The FRHI will be added to the tabular report (see Table 4).

7.7 Tabular Report

Click the  icon to get tabular report.

The table lists relevant study parameters and results, for all analyses performed to date, with the last line in the table containing data from the most recent analysis performed.

Table 4 is a description of the information fields displayed in the table.



NOTE

Please note that the Endo PAT™ analysis of Augmentation Index (AI), Heart Rate Variability (HRV) and FRHI are not FDA cleared and can be applied for clinical use out of the US only.

A	ID
B	FileName
C	visit
D	RHI: Reactive Hyperemia Index (EndoScore™ result)
E	LnRHI: Natural Base log of Reactive Hyperemia Index (EndoScore™ result)
F	BL HR: baseline heart-rate
G	AI: Augmentation Index
H	AI@75: Augmentation Index - normalized to HR 75bpm
I	AI_N pulses: number of pulses averaged to calculate the AI
J	AI_P1
K	AI_P2
L	Warnings/Errors
M-AB	Patient info: Diastolic and Systolic Pressures, Gender, Age, Height, Weight, BMI,…
AC-AD	Risk method used and the calculated Risk
AE	%ValidBL ROI:% valid PAT™ signals in the Baseline region of interest
AF	%Valid Post Occ ROI:% valid signals in the post-occlusion region of interest
AG-AJ	Occlusion info – begin, end, duration and automatic/manual border detection
AK-AM	Baseline duration, region of interest (ROI) duration, and total study duration
AN	MeanBL o - Mean PAT™ signal amplitude in the baseline region of interest value, for the occluded side (suffix “o”)
AO-BB	Post-occlusion signal to baseline signal ratios, at 14 consecutive 30 sec time segments, for the occluded side (suffix “o”)
BC	MeanBL c - Mean PAT™ signal amplitude in the baseline region of interest value, for the control side (suffix “c”)
BD-BQ	Post-occlusion signal to baseline signal ratios, at 14 consecutive 30 sec time segments, for the control side (suffix “c”)
BR	RecordingTime: Date and time of test recording
BS	AnalysisTime: Date and time of test analysis
BT	RecordingVersion: The software version used for the recording
BU	AnalysisVersion: The software version used for the analysis
BV-BW	Site name & PATographer identification
BX	Comment1
BY	Comment2
BZ	UserField1
CA	UserField2
CB	FRHI
CC	HRV – error message
CD-CE	HRV – general information
CF-CK	HRV – time domain results
CL-CN	HRV – frequency domain results

Table 4 - Table information

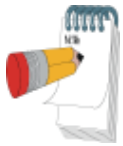
(Note: fields *G* to *K* and *CB-CN* contain additional / Research features restricted to non-US and in research versions only. They will be calculated based on the license file of the software)

7.8 Batch Analysis

The Endo PAT™2000 software allows the user to perform a batch automatic analysis on a group of studies as follows:

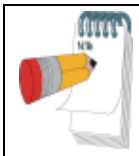
- The batch analysis command analyzes all the files located in a selected folder. If necessary, copy the files you wish to analyze to a new folder before proceeding.
- Select "Batch Analysis" From the Test Analysis menu.
- From the dialog box that opened, select the folder that contains the files you wish to analyze and click "OK".
- The automatic analysis will run on all the files in the selected folder. Once completed, a table will open automatically, containing all the analysis parameters (as described in Table 4) for all the analyzed files.

7.9 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

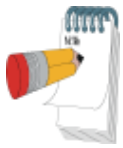
To enable the Manual Analysis functions, it is necessary to enable the Manual Research Mode. Refer to section 4.4.

7.9.1 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 two segment types (later to be used in calculations):

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



NOTE

While marking segments and artifacts, errors may be corrected by clicking the  icon ("Clear all segments"). This will also erase the occlusion border markings. This tool should be used only when using the manual options described in this chapter.

To Mark a Segment

1. In the Trace Window, position the mouse's cursor at the beginning of an interval to be marked.
2. Drag the cursor horizontally along the interval—the selected segment becomes highlighted.
3. Release the mouse button at the end of the desired interval—the selected segment remains highlighted.

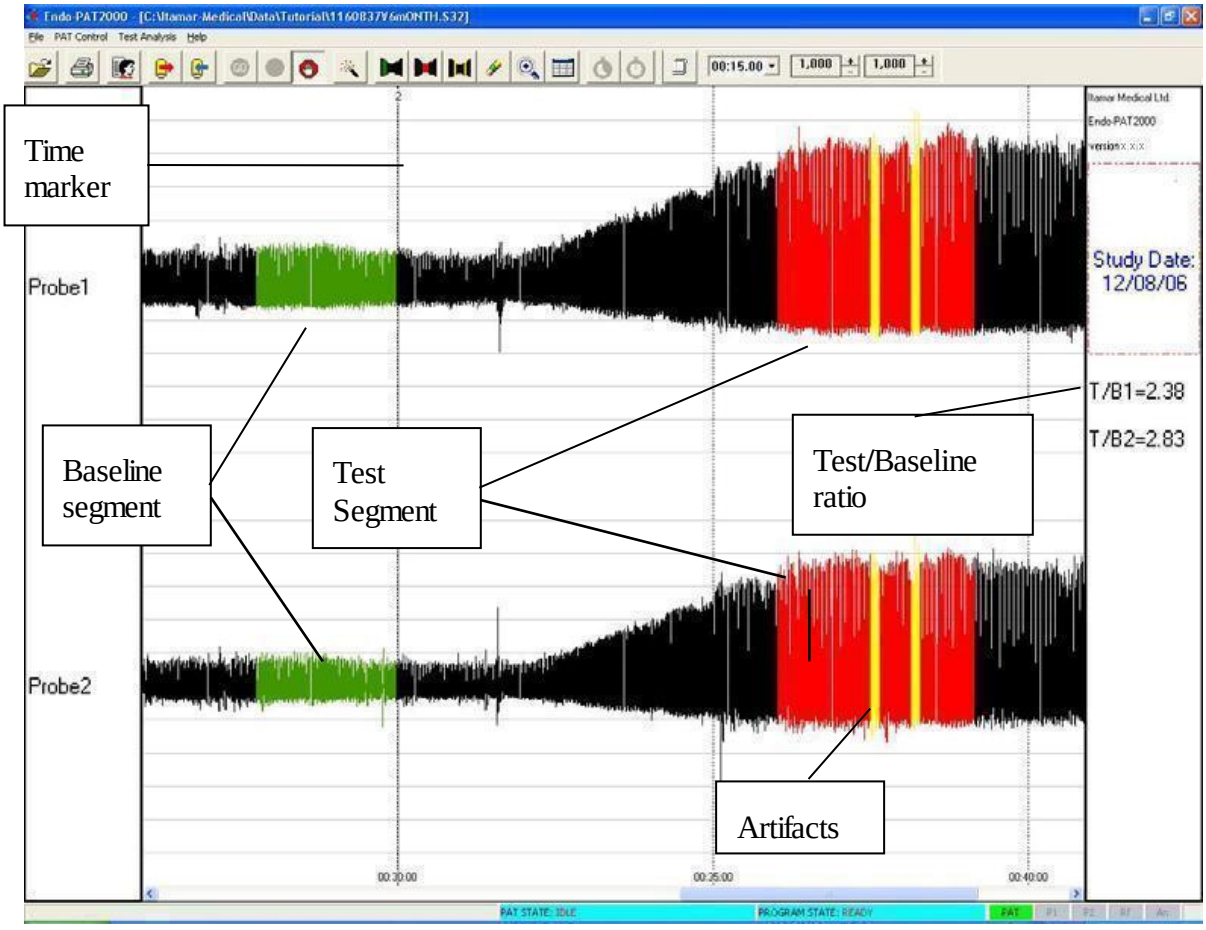
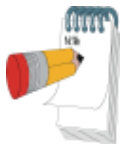


Figure 46 - Marking Segments and Artifacts

4. Set the highlighted segment to B, T or artifact, as appropriate:

- Select a segment and click  icon to mark it as the B segment - B segment traces are highlighted in green.
- Select a segment and click on the  icon to mark it as a T segment - T segment traces are highlighted in red.
- Select segments suspected as artifacts and click on the  icon to mark as an artifact segment - multiple segments can be selected - artifact segment traces are highlighted in yellow. These segments (marked in yellow) are not used in the calculation process.

Marked segments remain highlighted in the Trace Window (Figure 46).

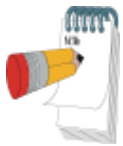


NOTE

If there are noise artifacts in the region of interest in the signal, you should first mark the artifacts as explained above. Then mark the B or T segment over the marked artifacts. If you do not mark the B or T segments over the artifact markings, the artifacts will not be edited out and will be calculated in the T/B analysis.

7.9.2 Analyzing PAT™ Ratios

After the B and T segments are marked, their PAT™ ratios are automatically calculated displayed in the right side of the screen (Figure 46). Note that these results might be slightly different from the automated analysis, as this tool doesn't include all the analysis logic.



NOTE

Automatically calculated segment ratios displayed in the right side of the screen (Figure 46) do not have clinical implication. This feature is used only for research purposes and should not be regarded as device output concerning Endothelial Dysfunction.

7.10 Study printing

You can print the displayed data at any time during off-line review and analysis. Clicking the  icon ("Print") will send the current screen to the default printer.

7.11 Uploading data to the server

The software offers a quick link to the Itamar Medical Uploading Service:
from the Help menu, click on "Link to Itamar Medical Uploading Service". Follow the instruction in the browser to upload files.

This function requires a connection to the internet. The software will open the default browser with the correct link.

8 Maintenance

8.1 Device maintenance

This chapter describes preventive and regular maintenance for the Endo PAT™2000 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 device.
2. The Endo PAT™2000 device should be free of dirt and debris. Using a soft, slightly damp cloth, gently wipe the exterior of the Endo PAT™2000 device, avoiding contact with open vents and plugs.
3. Used probes should be discarded after each use and replaced with new ones.
4. Refer to the Endo PAT™2000 Service Manual for additional information and spare parts list

8.2 Probe data

Probes' information - Serial Number, Production batch number and Status (used/ not used) can be received by selecting "Probes Information" option from the "PAT™ Control" menu when the device is connected and the probes are attached to tubes. The following screen will appear with the probes' information.

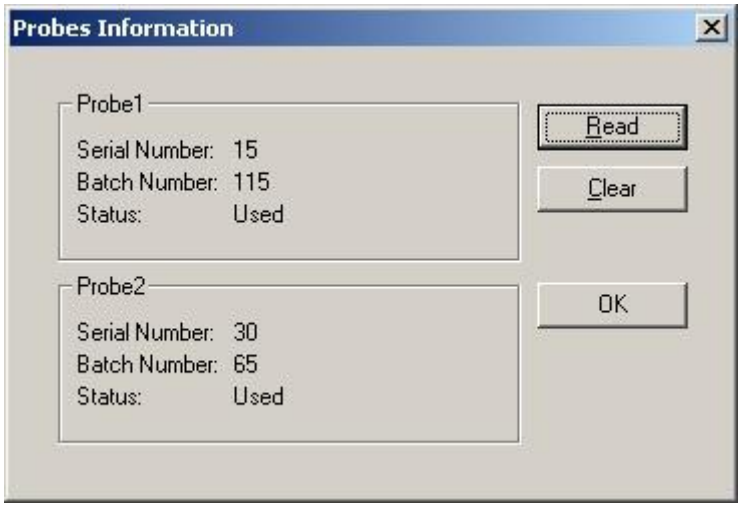


Figure 47 - Probes Information

If a probe is missing or cannot be read, NA will appear instead of probe's information.

9 Troubleshooting

	Description	Possible Cause	Action
1.	The Endo PAT™2000 device does not switch on (the orange LED on the device is not on)	The Endo PAT™2000 device power is switched off.	• Switch on the Endo PAT™2000 device.
		Power cable is not plugged to the power outlet.	• Switch off the Endo PAT™2000 device. • Plug the power cable to the power outlet. • Switch on the Endo PAT™2000 device.
		Power cable is not connected to the Endo PAT™2000 device.	• Switch off the Endo PAT™2000 device. • Plug the power cable to the Endo PAT™2000 device. • Switch on the Endo PAT™2000 device.
2.	No communication between PC station and Endo PAT™2000 device (the green LED on the device is not lit, the Study-icon in the main screen remains dimmed or the PAT button on the bottom right of the S/W screen is red instead of green)	Endo PAT™2000 power switch is off.	• Verify that the orange LED is on. • Switch on the Endo PAT™2000 device.
		Communication cable between PC station and Endo PAT™2000 device is not connected.	• Verify that the communication cable is connected properly.
		Another application (such as Palm Pilot Hot Sync) is assigned to the COM port.	• Close all background applications. • Verify that the COM port connected to the Endo PAT™2000 device is not in use by another application.
		The communication cable is connected to the wrong COM port.	• Plug communication cable into the other COM port. • Try setting another COM port in the application.
		USB to Serial adapter not installed, or installation did not complete properly.	• Follow instructions provided with the USB to Serial adapter to verify proper installation.
3.	Frequent pressure leaks during study	The pneumatic probe cable is not well connected to the probe or to the Endo PAT™2000 device.	• Verify that the pneumatic probe cable is securely connected to the probe and to the EndoPAT™2000 device and that the connections are free from lint or other residues.
		Faulty probe.	• Replace PAT™ probe.
		Faulty pneumatic cable.	• Replace pneumatic cable.

	Description	Possible Cause	Action
4.	Noisy signal	Something is in contact with the probes or the tubes	• 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 "Go" (and thus still in the Stand By mode); or there is a software-hardware communication error	• Deflate manually by pressing the deflate button on the Endo PAT™2000 device. • If you were in Stand By mode (= did not press "Go") you should retest the patient. It is recommended to wait for an hour and switch the test arm before retesting. • If you pressed "Go" make sure the study was recorded properly by opening it for analysis.
6.	The signal looks flat and does not react to gain amplification	The relevant PAT™ channel is not selected	• Refer to section 4.4 item 6 and Figure 17
7.	License doesn't fit the computer	The registration request was done on a different computer, or change of hard disk	• Redo the registration process and replace the license.lic file
8.	Software license expired	The license file has expired. All the capabilities enabled by the license will not work anymore	• Contact Itamar Medical customer support. • Redo the registration process and replace the license.lic file
9.	Very long inflate followed by Major Leak message	Multiple deflates before inflate	• 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 5 - Troubleshooting

The following table provides a list of system error messages that the user may encounter when attempting to run 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**
Unable to open file (-*n*)	The system cannot open the file. The code in parenthesis (*n*) provides additional information for technical support (call Itamar Medical customer support).
Signal Length Less Than Minimum Required	The recorded signal length is less than the minimum required to run an analysis (6 min).
Signal Length More Than Maximum Allowed	The recorded signal length is more than the maximum allowed to run an analysis (150 min).
Signal is too noisy	Noisy signal prevents proper operation of the analysis module.
Allocation Problem	Internal system failure (call Itamar Medical customer support).
Baseline duration is shorter than minimum required	Less than 2 min and 20 sec valid baseline signals.
Occlusion Time less than minimum required	Occlusion is 90 sec or less (might be rectified after manual occlusion marking).
Occlusion Time too long	More than 10 min occlusion (might be rectified after manual occlusion marking).
Post Occlusion duration is shorter than minimum required	Post occlusion less than 2 min and 30 sec. (Might be rectified after manual occlusion marking).
Undefined occlusion	The system cannot identify the occluded section of the study (might be rectified after manual occlusion marking).
Poor Occlusion Quality	Poor occlusion quality due to too many valid pulses identified during the occlusion.
Poor Signal Quality	Poor signal quality in the post occlusion period used by the analysis (1.5 - 2.5 min post occlusion).
Program Failure	Any other problem that prevents the program to complete the analysis (call Itamar Medical customer support).
Incomplete occlusion	There are measured pulses during the occlusion in the occluded hand. Occlusion quality is too low for a good hyperemic response.

Table 6 - Error messages

10 Technical Information

10.1 System Minimum Requirements

- An IBM® or compatible PC Pentium/Celeron/AMD 1000 MHz CPU or higher
- Any Internet browser or Excel 2000 and above
- 1 GB RAM for XP or 2 GB for Win7 / Win8
- 1 GB free hard disk space
- XGA display (1024 x 768 pixels) or better
- One available serial port, or one available USB port (with USB to Serial adapter installed)

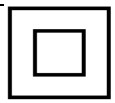
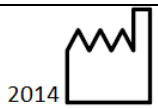
Optional Hardware

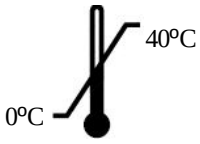
- Large removable media, such as CD-R or DVD-R for storage of study files
- Printer, higher resolution preferred. Color recommended

10.2 Operating System

Windows XP / Windows 7/ Windows 8 (x86/x64).

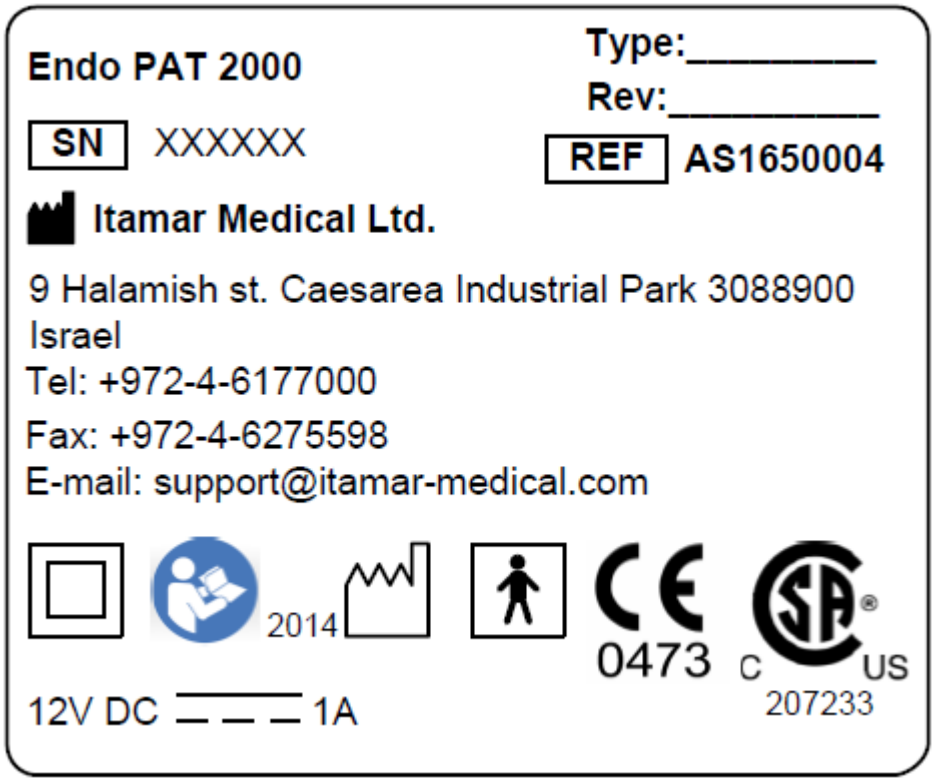
10.3 Technical information about labeling

	Double isolation
	Date of manufacture
	Follow instructions for use
	Type BF applied part
	The product is certified by CSA

CE	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
REF	Catalogue Number
SN	Serial Number

10.4 Labeling

Label on the base of the Endo PAT™2000 device (main control unit):



Packaging labels:

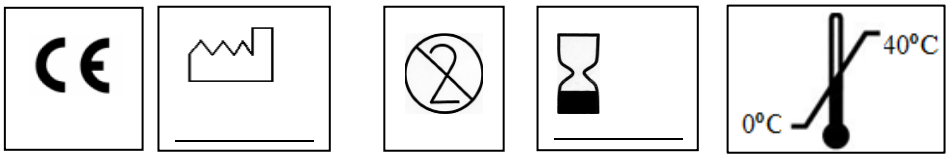
The following labels are attached to the master package of the Endo PAT™2000 system:



Endo PAT™2000 Probe Package:

itamar medical

Endo PAT™ Pneumatic PAT™ Probe



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

www.itamar-medical.com/images/licenseep.pdf

EC REP *Medes Ltd.*
5 Beaumont Gate, Shenley Hill,
Radlett, HertfordshireWD7 7AR.
England
Tel: +44 20 8123 8056
Tel / Fax: +44 1923859810

10.5 Specifications for Endo PAT™2000 system

Properties		Description
PAT™ Probe		Itamar Medical's proprietary probe only
Recording Time		Limited by hard disk space, ~8MB per study of 20 minutes
Sampling Resolution		12 bit
Indications		2 LED's - power supply and communication
PAT™ Channel	*Selective Gain*	1÷50,000
	Selectable Time Base	10 sec ÷ 2 hours per screen
	Bandwidth	30Hz
Power Supply	*Input*	100-240 VAC 50/60 Hz
	Output	12V DC, 2A
Operating Voltage		12 V
Temperature	*Operation*	Room temperature
	Storage	0 to 40 ^{0}C
	Transportation – Device	-20 to 60 ^{0}C
	Transportation – Probes	0 to 40 ^{0}C
Humidity	*Operating & Storage*	10% - 95% (non-condensing)
Dimensions	*L x W x H (max)*	240mm x 135 mm x 185 mm
	Weight	3.5 kg

Table 7 - Specifications

Appendix A: License Agreement and Limited Warranty

License to User from Itamar

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Appendix B: Regulatory Authorized Representative



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Tel: +44 20 8123 8056
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Appendix C: Installing the USB adaptor for Windows XP

This appendix describes how to install the MOXA adapter and driver for Windows XP Home and for Windows XP Pro editions

	**NOTE** The MOXA adapter must not be connected to the computer or to the Endo PAT™2000 device while the driver is installed.

1 Install the driver

1.1 Do not connect the USB adaptor to the computer yet.

1.2 Insert the "Moxa adapter drivers" CD into the CD-ROM drive.

1.3 Browse into CD-ROM-Drive :\XP

1.4 Double-click the **mxusb_setup_1.3.exe** file.

1.5 Complete the installation process by clicking 'next' on all screens, until the following screen is displayed.

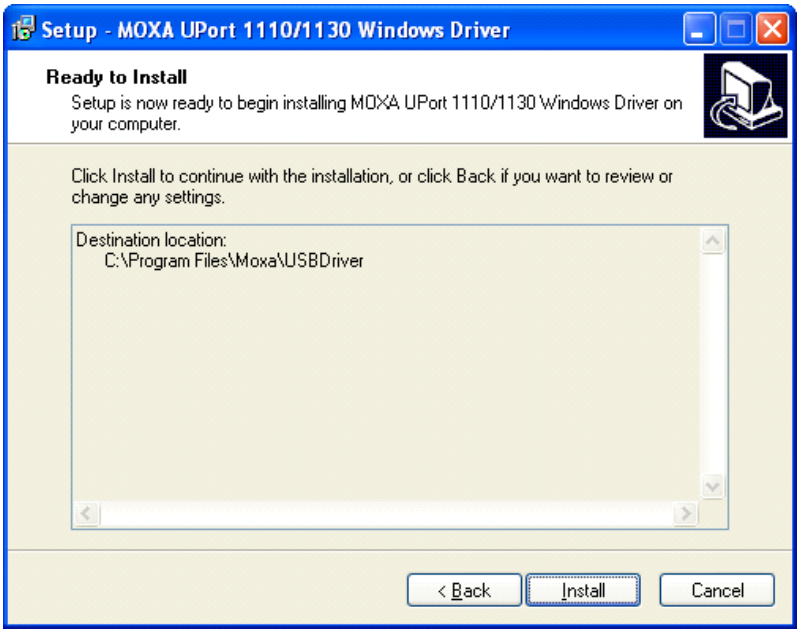


Figure 48 - MOXA USB Installation – XP1

1.6 Click "Install".

1.7 The following screen is displayed:

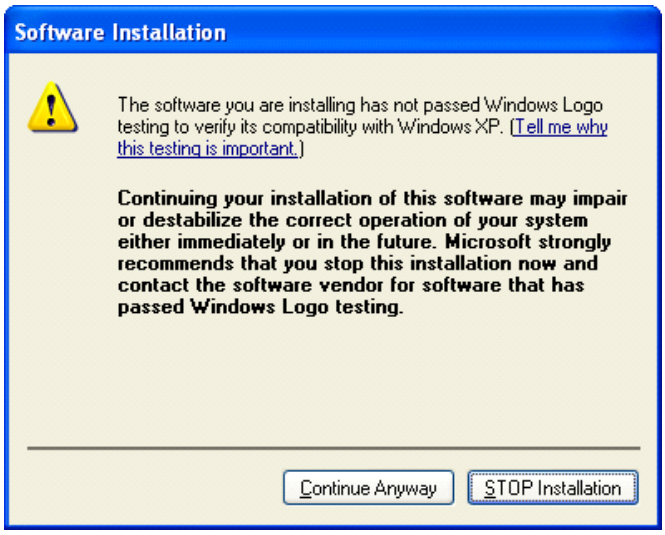


Figure 49 - MOXA USB Installation – XP2

1.8 Click "Continue Anyway" (you need to approve this warning twice). The following screen is displayed:

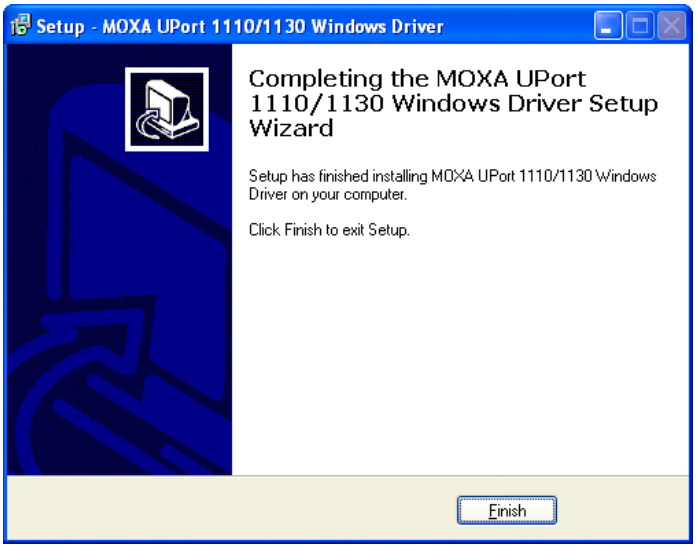


Figure 50 - MOXA USB Installation – XP3

1.9 Click "Finish".

2. Configuring the MOXA Adapter

2.1 Plug in the adapter to your USB port.



Figure 51 - MOXA Adapter

2.2 Wait for the following window to appear.



Figure 52 - MOXA Adapter Configuration – XP2

2.3 Select the "No, not this time" option, and click the "Next" button. The following window is displayed:

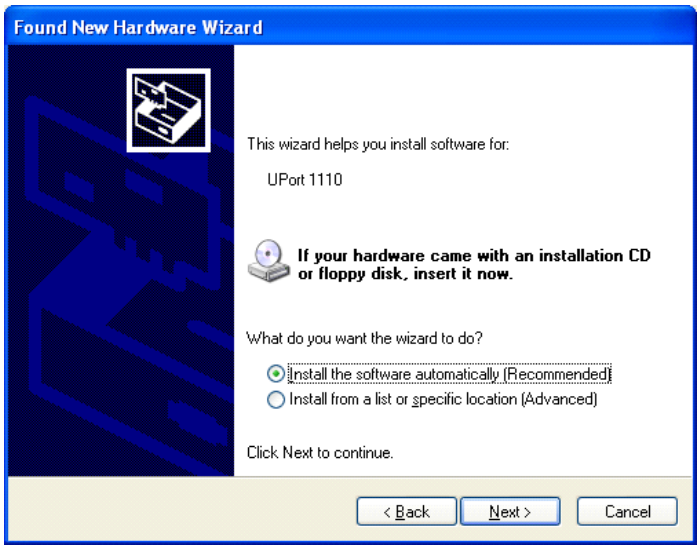


Figure 53 - MOXA Adapter Configuration – XP3

2.4 Select the "Install the software automatically (Recommended)" option, then click the "Next" button.
The following window appears:

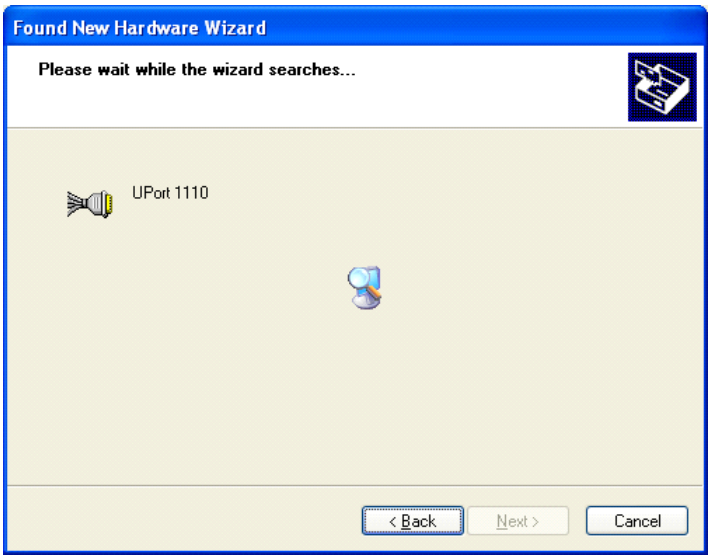


Figure 54 - MOXA Adapter Configuration – XP4

2.5 Wait for the installation wizard to find the **UPort 1110** driver; then, click the "Next" button.
The following window is displayed:

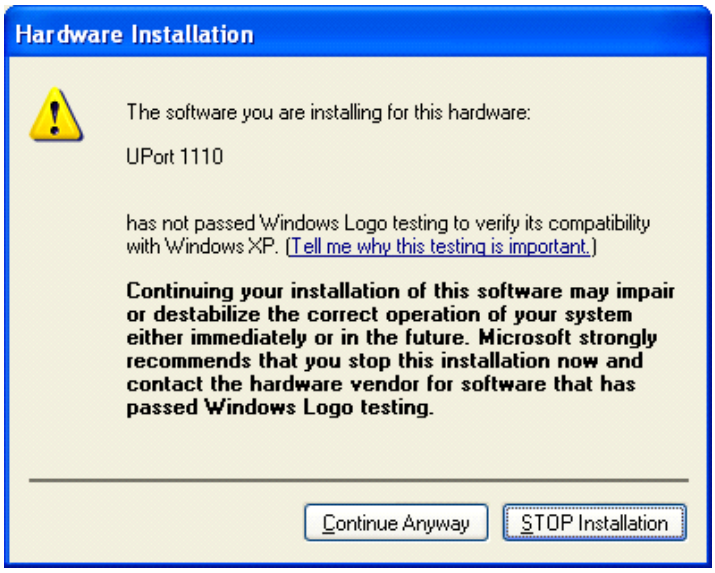


Figure 55 - MOXA Adapter Configuration – XP5

2.6 Click the "Continue Anyway" button.
The following window is displayed:



Figure 56 - MOXA Adapter Configuration – XP6

2.7 Click the "Finish" button.

2.8 Repeat steps 2-7 again when the "Welcome to the found new hardware wizard" window appears in order to install the second driver (required to complete the installation).

2.9 Move the adapter between all the USB sockets and let the system identify it.

3. Connecting the adapter to the Endo PAT™2000 device

3.1 Connect the MOXA Adapter to the COM TO COM cable and tightly screw the bolts.



Figure 57- connect MOXA adaptor

3.2 Connect the COM TO COM cable to the Endo PAT™2000 device and tightly screw the bolts.



Figure 58 – connect COM TO COM

3.3 Open the Endo PAT™2000 software and verify that the "PAT™" indicator on the bottom right is colored green.

Appendix D: Installing the USB adapter for Windows 7 or 8

This appendix describes how to install the MOXA adapter and driver for Win7 and Win8.

	**NOTE** The MOXA adapter must not be connected to the computer or to the Endo PAT™2000 device while the driver is installed.

1. Installing the MOXA driver

1.1 Insert the CDROM media into your CDROM drive.
1.2 Start the installation by double clicking on the \Win_7_8\driv_win_uport1p_v1.6_build_09062913_whql file

	**NOTE** If the following window (Figure 59 or Figure 60) is opened, please press Allow or Yes option.

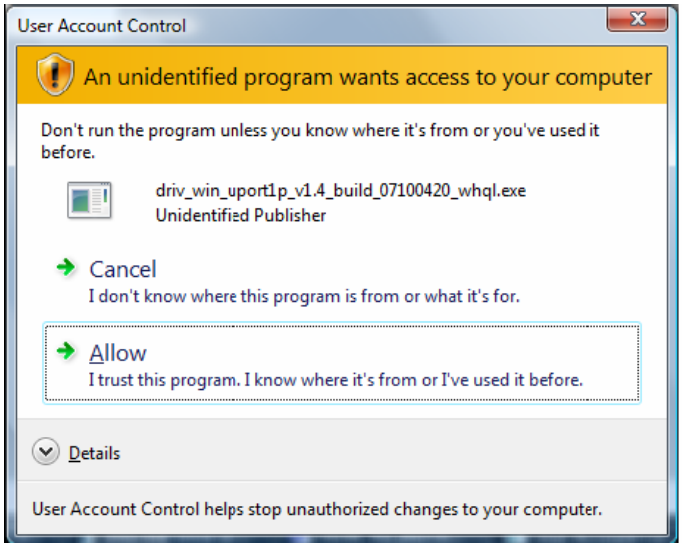


Figure 59 - Win Security

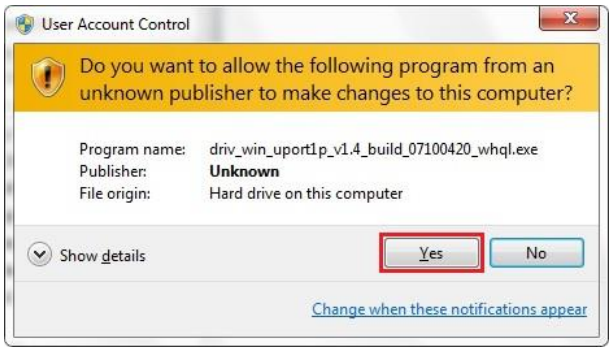


Figure 60 - Win7 Security

1.3 When the following window will open, press the Next Button.

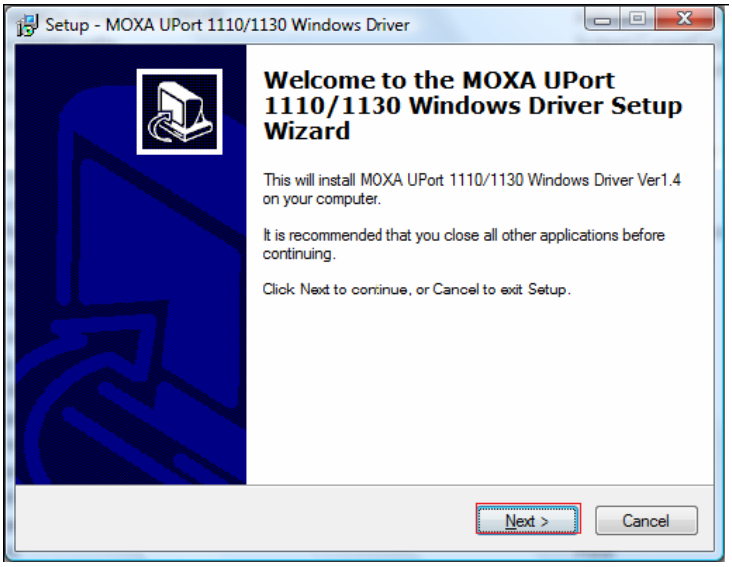


Figure 61 - MOXA Uport driver installation

1.4 The following window will open, press the Next button.

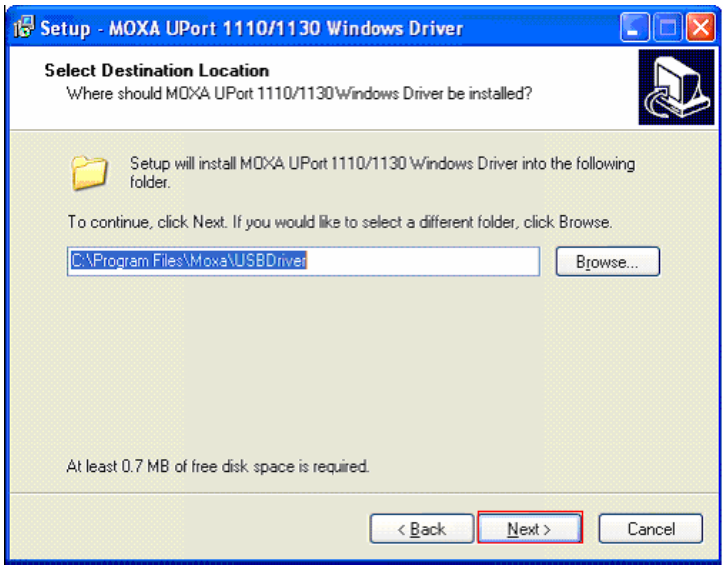


Figure 62 - MOXA driver installation folder

1.5 The following window will open, press the Install button.

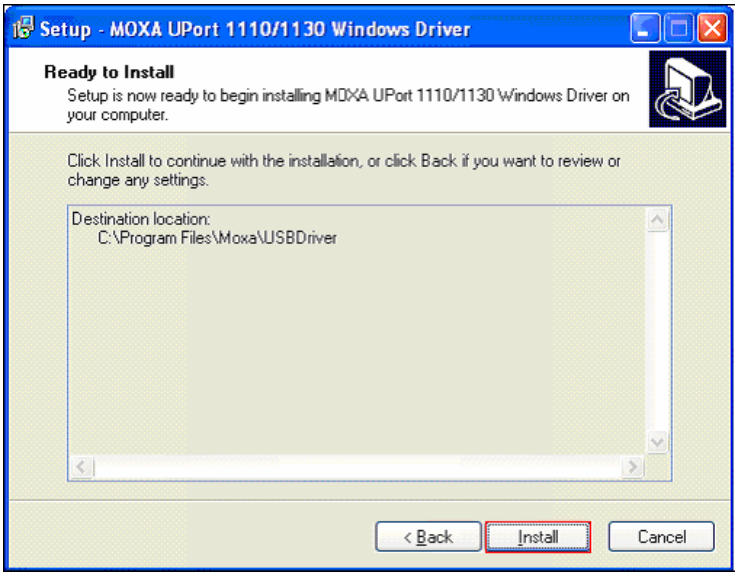


Figure 63 - MOXA driver folder confirmation

1.6 Press the Finish button

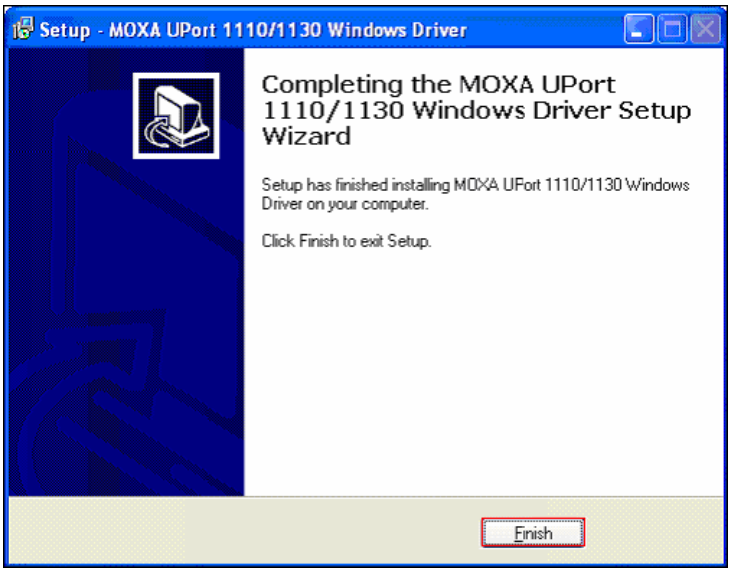


Figure 64 - MOXA driver installation finish

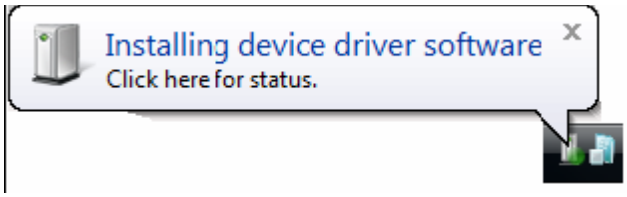
2. Configuring the MOXA Adapter

2.1 Plug in the adapter to your USB port.

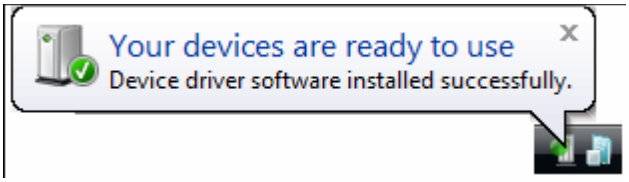


Figure 65 - The MOXA Adapter

2.2 The following icon should appear at the window notification area zone while windows installs the driver needed for the MOXA adapter (this is done automatically).



2.3 When the installation of the driver is done the following message should appear:



3. Connecting the adapter to the Endo PAT™2000 device

3.1 Connect the MOXA Adapter to the COM TO COM cable and tightly screw the bolts.



Figure 66- connect MOXA adaptor

3.2 Connect the COM TO COM cable to the Endo PAT™2000 device and tightly screw the bolts.



Figure 67 – connect COM TO COM

3.3 Open the Endo PAT™2000 software and verify that the "PAT™" indicator on the bottom right is colored green.

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

Electromagnetic Compatibility

Notes

- The Endo PAT™2000 (ED2000) 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 Endo PAT™2000.
- The recommended separation distances in this paragraph must therefore be complied with.
- The Endo PAT™2000 must not be used near or on top of another device. If this cannot be avoided, it is necessary near or on top of another device. If this cannot be avoided,lied with.to in o 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

- Endo PAT™2000 is intended for use in the electromagnetic environment specified in the following tables 1, 2, 4, 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 60601-1-2:2007

Guidance and manufacturer's declaration – electromagnetic emissions – Endo PAT™2000 (ED2000)

The **ED2000** is intended for use in the electromagnetic environment specified below ; The customer or the user of the **ED2000** should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The **ED2000** uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The **ED2000** is suitable for use in all establishments, including domestic establishments and those directly connected to the public low -voltage pow er supply netw ork that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class B	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 2 - from IEC 60601-1-2:2007

Guidance and manufacturer's declaration – electromagnetic immunity – Endo PAT™2000 (ED2000)

The **ED2000** is intended for use in the electromagnetic environment specified below; The customer or the user of the **ED2000** 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	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	
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 Not Applicable	Mains power quality should be that of a typical public low-voltage power supply network that supplies buildings used for domestic purposes, commercial or hospital, clinic environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical public low-voltage power supply network that supplies buildings used for domestic purposes, commercial or hospital, clinic environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 %UT (>95 %dip in UT) for 0,5 cycle 40 %UT (60 %dip in UT) for 5 cycles <5 %UT 70 %UT (30 %dip in UT) for 25 cycles <5 %UT <5 %UT (>95 %dip in UT) for 5 s	<5 %UT (>95 %dip in UT) for 0,5 cycle 40 %UT (60 %dip in UT) for 5 cycles <5 %UT 70 %UT (30 %dip in UT) for 25 cycles <5 %UT <5 %UT (>95 %dip in UT) for 5 s	Mains power quality should be that of a typical public low-voltage power supply network that supplies buildings used for domestic purposes, commercial or hospital, clinical environment. If the user of the **ED2000** requires continued operation during power mains interruptions; it is recommended that **ED2000** be powered from a separate power supply (UPS, etc.).
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical public low-voltage power supply network that supplies buildings used for domestic purposes, commercial or hospital, clinic environment.

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

Table 4 - from IEC 60601-1-2:2007

Guidance and manufacturer's declaration – electromagnetic immunity – Endo PAT™2000 (ED2000)

The **ED2000** is intended for use in the electromagnetic environment specified below; The customer or the user of the **ED2000** should assure that it is used in such an environment.

Immunity test	IEC 60601-1-2 Test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the **ED2000**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.17\sqrt{P}$
Radiated RF	3 V/m		$d = 1.17\sqrt{P}$ 80 MHz to 800 MHz
IEC 61000-4-3	80 MHz to 2,5 GHz	3 V/m	$d = 2.3\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W)according to the transmitter manufacturer and d is the recommended separation Distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ,[a] 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 **ED2000** is used exceeds the applicable RF compliance level above, the **ED2000** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **ED2000**.

b

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

Recommended Separation Distances

The Endo PAT™2000 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 Endo PAT™2000, according to the maximum output power of the equipment, as recommended in the table below.

Table 6 - from IEC 60601-1-2:2007

Recommended separation distances between portable and mobile RF communications equipment and the Endo PAT™2000 (ED2000)

Rated maximum output power of transmitter Watts [W]	Separation distance according to frequency of transmitter (in meters) Meters [m]		
	150kHz to 80MHz $d = 1.17\sqrt{P}$	80MHz to 800MHz $d = 1.17\sqrt{P}$	800MHz to 2.5GHz $d = 2.3\sqrt{P}$
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 Endo PAT™2000 (ED2000)

Rated maximum current (I) in a power bus or an appliance wire Amperes [A]	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 F: SPARE PARTS LIST

The following items can be ordered and purchased individually:

- Pneumatic PAT™ Probe (a box of 12 probes)
- Pneumo-electric tubing
- Power adaptor
- Power Cable
- USB adaptor
- RS 232 cable
- Set of 30 foam finger anchors
- Accessories Kit
- Endo PAT™2000 software CD
- Operation manual