Endo-PAT2000

User Manual

Itamar Medical REF OM1695012

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 ISO 13485:2003

See appendix B for contact information of the regulatory authorized representative

Record of Revisions

Revision: 14

Revision	Date	Description	Chapter	Pages
0	Jul 02	Preliminary	All	All
1	Oct 02	Base	All	All
2	May 03	Update	All	All
3	August 03	Update	All	All
4	September 03	Update	All	All
5	November 03	Update	All	All
6	May 04	Update following FDA clearance	All	All
7	December 04	Update	All	All
8	May 05	Update Appendix A	All	54
9	January 07	General update for new S/W version, arm supports and general overhaul of the manual	All	All
10	May, 07	General update for new S/W version, new USB to COM driver	All	All
11	June 08	Updating ISO logo, list of standards, Medes address. Adding of AI note.	All	i, 4, 5,74,77
12	Jan 09	Updating Itamar Medical address.	All	i, 64, 65, 73
13	July 09	General update for new S/W version (3.2.4). Correction in caution note regarding power supply. Corrections in installation of adaptor drivers. Updated patent information.	All	All
14	Jan 10	Probe expiration date	All	56

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1 General Information

This manual is part of the Endo-PAT2000 system.

1.1 Intended Purpose of the Endo-PAT2000

The Endo-PAT2000 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-PAT2000 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-PAT2000 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-PAT2000 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-PAT2000 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-PAT2000.
- 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-PAT2000 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-PAT2000 is classified as Class II medical device.

1.4 Manufacturers Notice

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

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1.5 Restrictions for Use

- Only qualified medical personnel may authorize the use of the Endo-PAT2000.
- 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)

- The Endo-PAT2000 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-PAT2000 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- general requirements for safety	IEC 60601-1
2.	Medical electrical equipment electromagnetic compatibility	IEC 60601-1-2
3.	Programmable electrical medical system Requirements for safety	IEC 60601-1-4
4.	Quality systems - Model for quality assurance in design, development, production, installation and servicing	ISO 9001:2008
5.	Quality systems medical devices	ISO 13485:2003
6.	Risk Analysis for Medical Device	ISO 14971
7.	Labeling Medical Devices	EN 980
8.	Medical Device Directive	MDD 93/42 EEC

		MDD 2007/47/EC
9.	Quality systems - Medical devices - System requirements for regulatory purposes (Health Canada)	CAN/CSA ISO 13485:1998
10.	CSA standard for safety	CSA 22.2 No. 601.1
11.	UL standard for safety	UL 60601-1
12.	Canadian Medical Devices Regulations	SOR/98-282

1.7 Conventions Used in this Manual

The following conventions are used throughout this manual:

Warnings

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

Cautions

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

Notes

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

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

Physicians, nurses, and medical technicians should read the Endo-PAT2000 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 EndoPAT-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.

	**WARNING** The Endo-PAT2000 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.

1. The Endo-PAT2000 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-PAT2000 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-PAT2000 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-PAT2000 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.
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.

	**WARNING** Probes manufactured before January 2007 contain 50 micrograms or less per gram of natural rubber latex water extractable protein which may cause allergic reactions. Do not use the latex probes on patients who have a known natural rubber protein allergy. Failure to heed this warning will compromise patient safety. The latex probes have a yellow membrane and come in boxes with labels notifying that they contain latex. The new, non-latex probes have green internal membranes.

2 System Overview

The Endo-PAT2000 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-PAT2000, 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-PAT2000 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-PAT2000 is supplied as a complete package comprising the following components:

- One Endo-PAT2000 device
- One Endo-PAT2000 software CD
- Three pneumo-electric tubing (2 tubes + 1 spare)
- Power adaptor
- Power cable
- Operation manual
- Set of 6 foam finger anchors

The supplied Endo-PAT2000 software package can be used with any IBM-compatible computer running English versions of Windows XP and Windows Vista. The automatic analysis module requires any type of internet browser or Excel 2000/2003.

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.

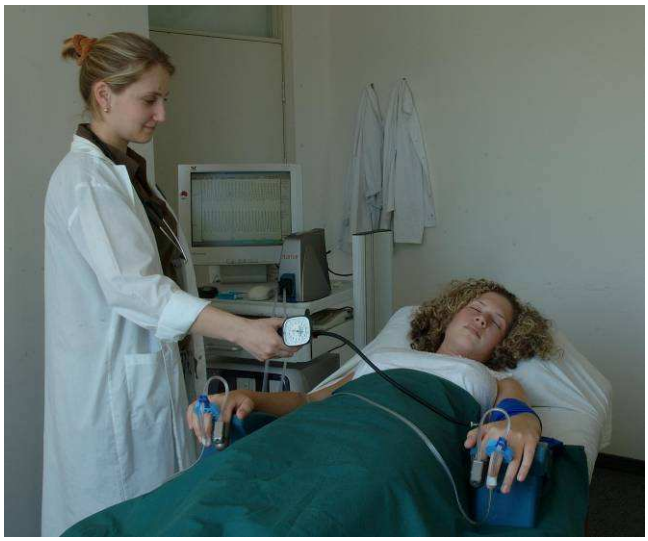


Figure 1 - Typical set-up

3.2 System description

The Endo-PAT2000 device top panel has:

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

Figure 2 - Endo-PAT2000

The front panel has two pneumatic input connectors for attaching the pneumo-electric tubing, connecting the PAT probes to the Endo-PAT2000 device.

The back panel has (Figure 2):

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

3.3 Connecting the Endo-PAT2000 to the Computer

NOTE

The Endo-PAT2000 system requires the use of a USB to Serial adapter. The Endo-PAT2000 can alternatively be connected to a serial (COM) port in the computer with a standard 9-pin RS232 cable.

1. Place the Endo-PAT2000 and computer 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-COM adapter to the communication port on the Endo-PAT2000, 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-PAT2000 and computer and tighten the connecting screws.
3. Connect both pneumo-electric tubing to the Endo-PAT2000 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-PAT2000 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

3.4 Endo-PAT2000 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-PAT2000 software.

	**NOTE** Uninstall previous Endo-PAT2000 software versions prior to installing a newer version. To uninstall the software please refer to section 3.6. Make sure to backup all your data prior to uninstalling any software.

2. Insert the Endo-PAT2000 software CD into the computer drive. The installation program will load automatically. Alternatively the user may select the 'setup.exe' command from the CD drive.
3. The Install Shield prepares the computer for installation. When prompted, click next to proceed with the installation (Figure 4).

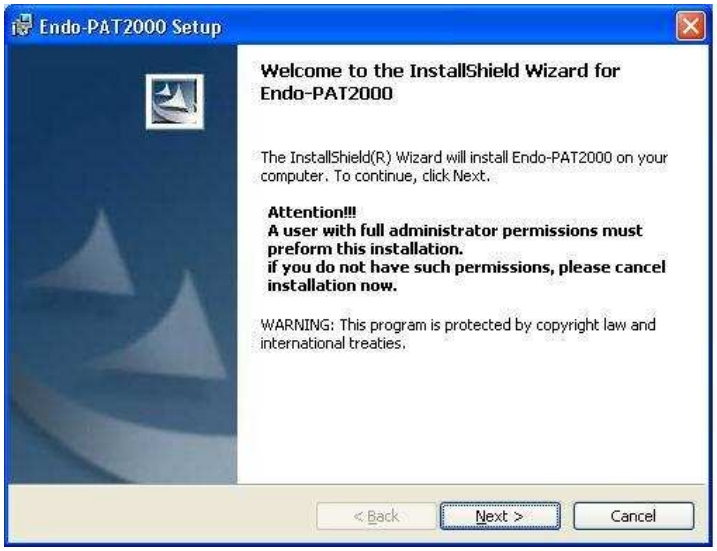


Figure 4 - Install shield wizard

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

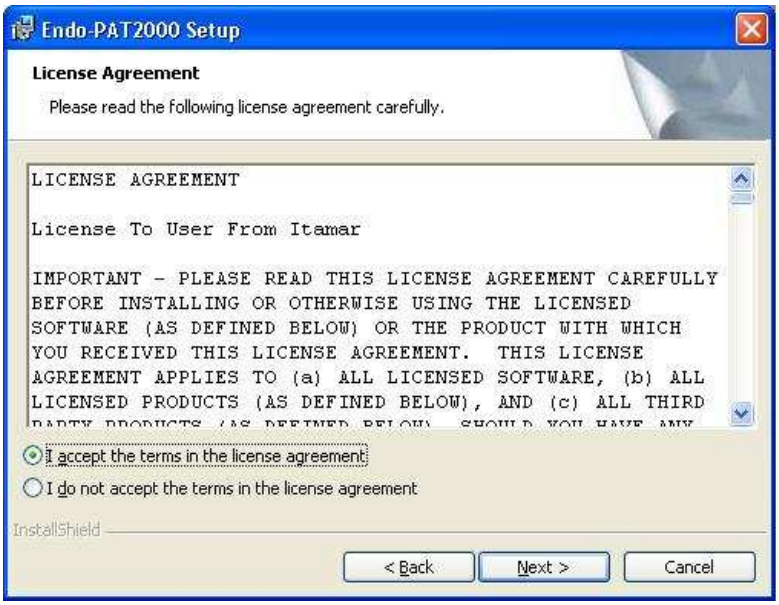


Figure 5 - License agreement

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).

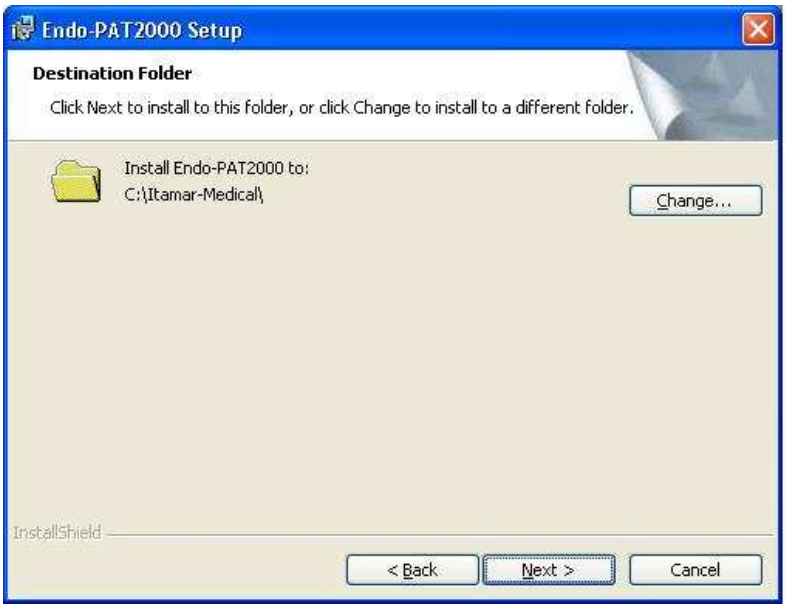


Figure 6 - Installation folder selection

	**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).

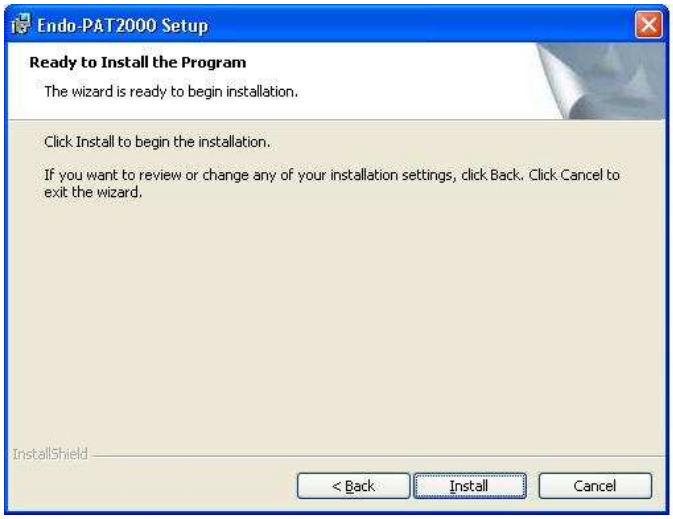


Figure 7 – Ready to install the program screen

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

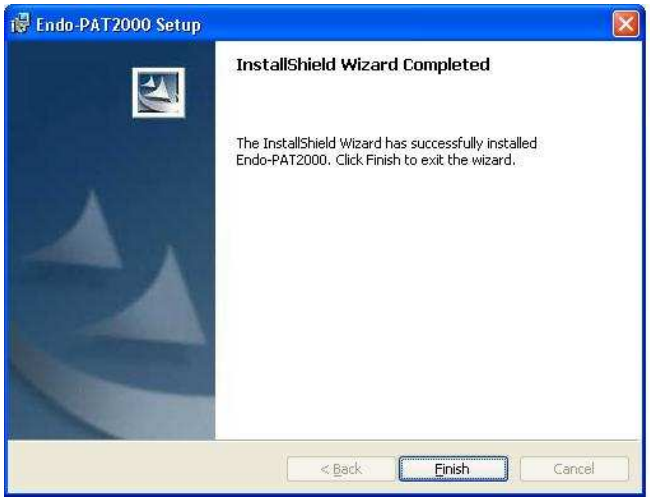


Figure 8 - Completion of installation

8. An icon will be added to the desktop.
9. If used, install the USB-to-COM driver as described in section 3.5.

3.5 Installing the RS-232 to USB adaptor

The RS-232 to USB adaptor connects the Endo-PAT2000 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 and for Windows Vista.

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, or to Appendix D for instructions on how to install the driver on Windows Vista Enterprise.

3.5.1 General instruction for installing the driver

1. The driver installation must be done before connecting the RS-232 to USB adaptor to the computer.
2. Insert the CD into the CD-ROM drive
3. Browse into the CD-ROM drive
   D:\Your_OS\SETUP
4. Execute the Driver's .exe file
5. Continue the installation process by clicking 'next' until installation ends
6. Connect the RS-232 to USB adapter to the computer.

Note

Restart your computer after installation of the Endo-PAT2000 software and the RS-232 to USB adaptor driver.

When the driver installation is completed, connect the USB adaptor to the computer and start the Endo-PAT2000 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 setting the configuration of the COM port.

3.6 Uninstalling Endo-PAT2000 Software

Enter the computer's Control Panel and select the Add/Remove programs option. Select the Endo-PAT2000 software and press "remove".

3.7 Shutting Down the System

1. Shut down the Endo-PAT2000 software program by selecting the Exit on the pull down File menu.
2. Switch OFF the Endo-PAT2000 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 9).

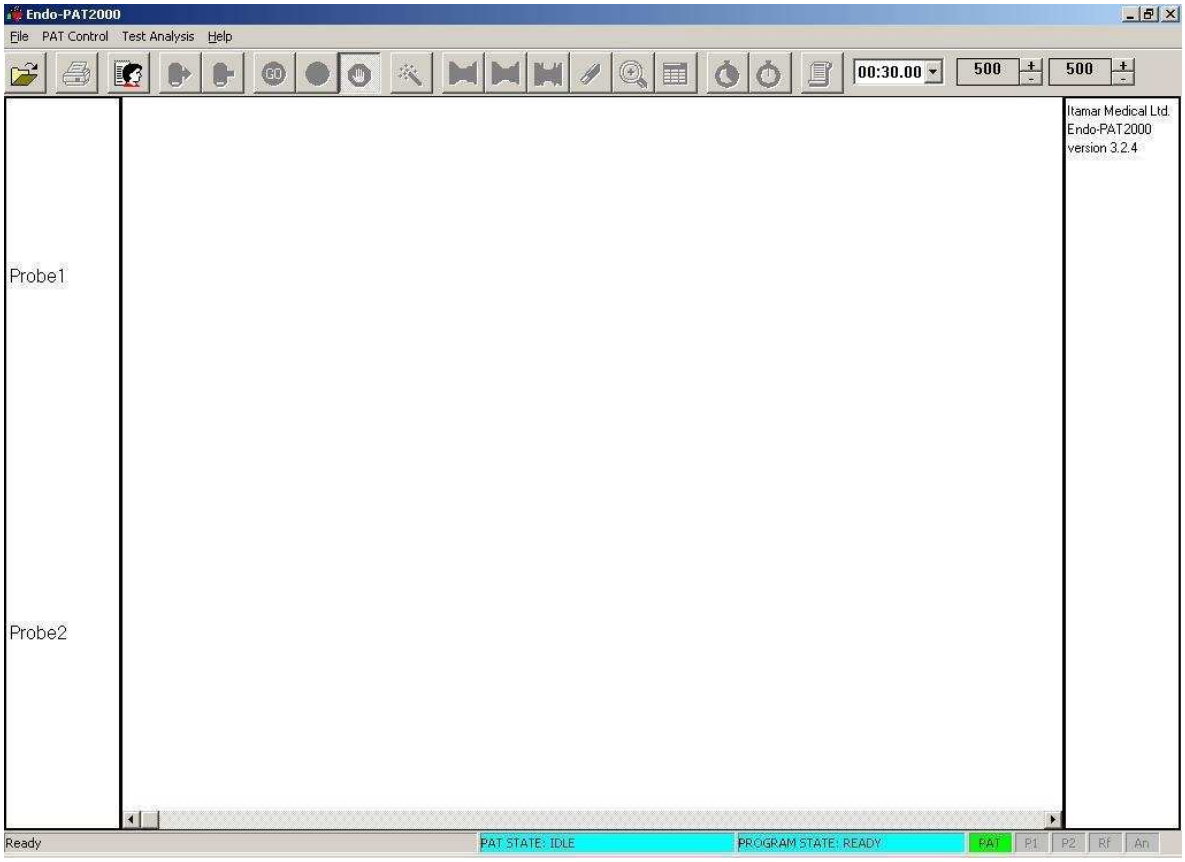


Figure 9 - Main screen

The Main Menu Screen is the gateway to the functions of the Endo-PAT2000 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 and Trend traces)
- PAT waveforms and Trend traces 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-PAT2000 software, a dialog box (Figure 10) will open. Click the OK button to enter the Setup menu. Complete the setup as described in section 4.4.

Figure 10 – Fill site name dialog box

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-PAT2000 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 Setup parameters
Test Analysis	Open Patient Information dialog box Automatic Analysis Select occlusion period Select Baseline Segment (in Research mode only) Select Test Segment (in Research mode only) Mark segment as artifact (in 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 Research mode only)
	Mark segment as T (in Research mode only)
	Mark segment as artifact (in 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 11 - 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 Set-up menu is used to configure the system. To ensure that the Endo-PAT2000 is ready for operation, the configuration of the signal channels and serial port is required.

To Configure the System:

1. Verify that the Endo-PAT2000 is properly connected to the PC and that it is switched on.
2. Click PAT Control, and then click Setup.

Figure 12 - The setup command

3. The following screen will appear:

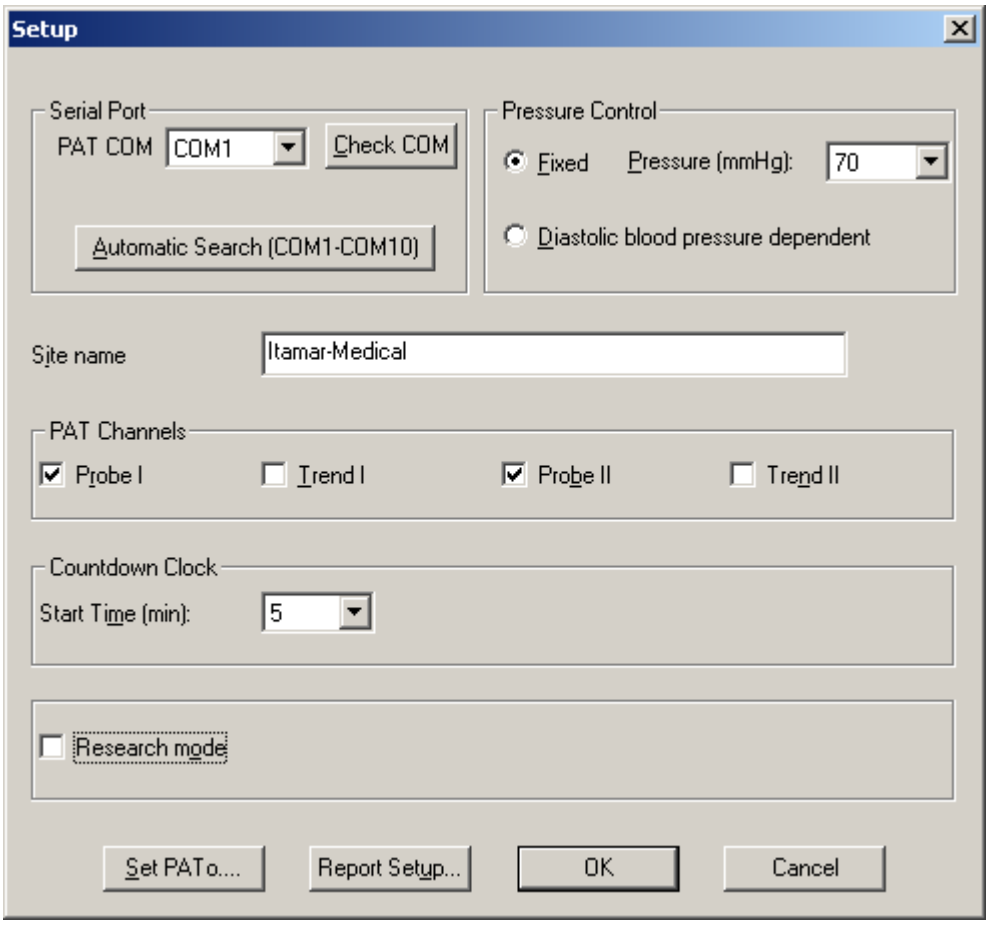


Figure 13 - The setup dialog box

4. Click “Automatic Search (COM1-COM10)” to allow the system to automatically identify the COM port to which the Endo-PAT2000 is connected.
5. If the automatic search fails, you can select or type the correct COM port for the Endo-PAT2000 manually in the relevant field. After selecting the desired COM port verify communication by clicking “Check COM”.
6. In the “PAT Channels” frame, select which channels should be displayed on screen. For normal operation both PAT channels should be selected.
7. 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.
8. To enable the Research mode, select the “Research mode” checkbox. The entire “Test analysis” menu is enabled.
9. To configure the report press the “Report Setup” button. This will open the “report appearance” dialog. 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. 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.

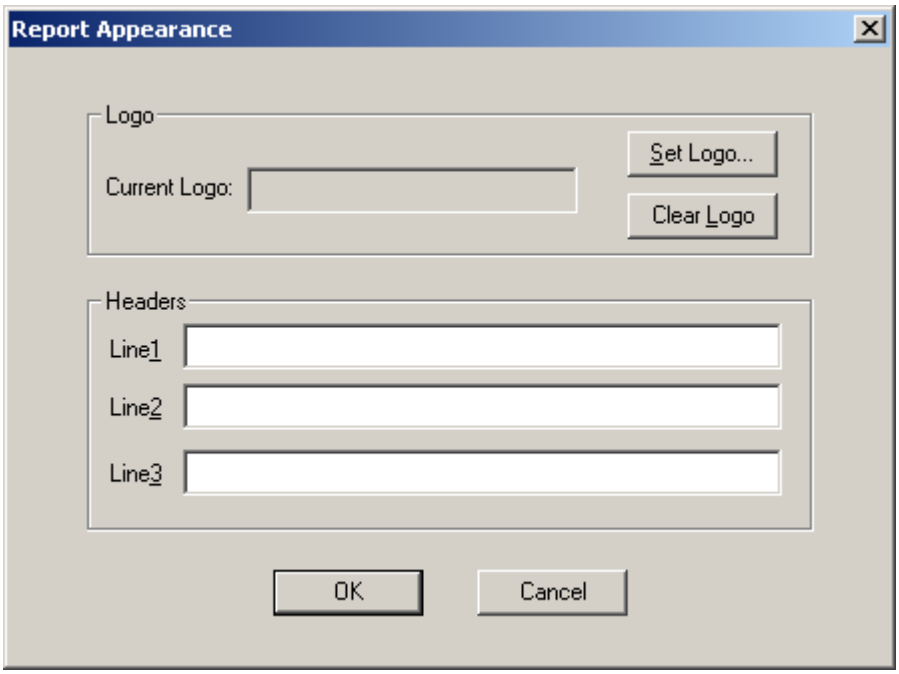


Figure 14 – Report Appearance dialog box

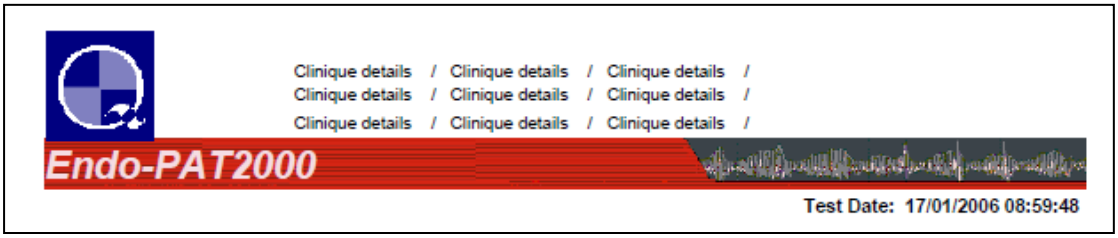


Figure 15 - The example for report header

10. The name of the operator performing the Endo-PAT2000 study can be saved with the study data. To create the master list from which the names are selected, click the "Set PATographer" to open the following dialog box:

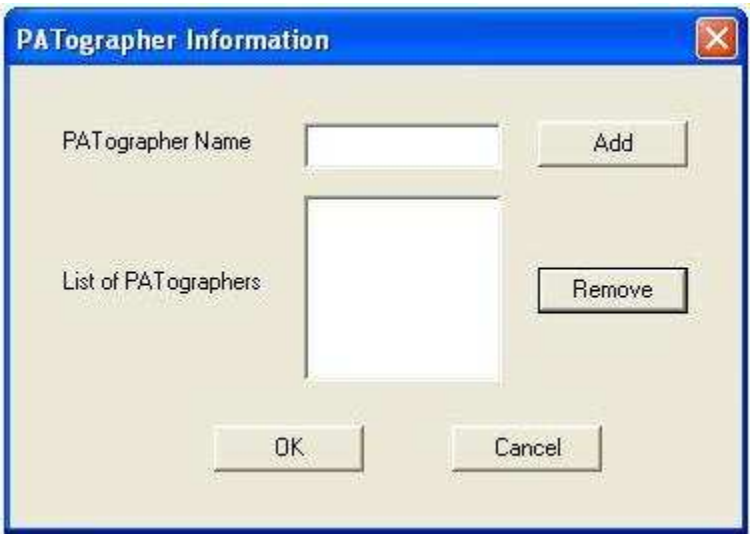


Figure 16 - The PATographer Information dialog box

11. Type the names of the PATographers in the top field and click "Add" after each one is entered. When 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".
12. 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.
13. 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.

14. 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, to select which signals are displayed. However, during a recording the COM field and the Pressure Control fields are disabled and cannot be modified.

4.4.1 Switching to the Research Mode

1. From the "PAT Control" menu, select the "Setup…" option.
   The Setup window is displayed.

2. In the Setup window, select the "Research mode" checkbox; then, click "OK"
   (Refer to Figure 13).

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-PAT2000 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

1. Switch on the computer, the Endo-PAT2000 device, and launch the Endo-PAT2000 software with the shortcut icon on the desktop. When the Endo-PAT2000 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 17). 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 17 - COM port search

5.2 Connecting the PAT Probe

Connect two new probes by inserting the connector tab into each probe slit (see Figure 18) and pressing the connector down onto the probe until the tab of the probe clicks into place (see Figure 19).

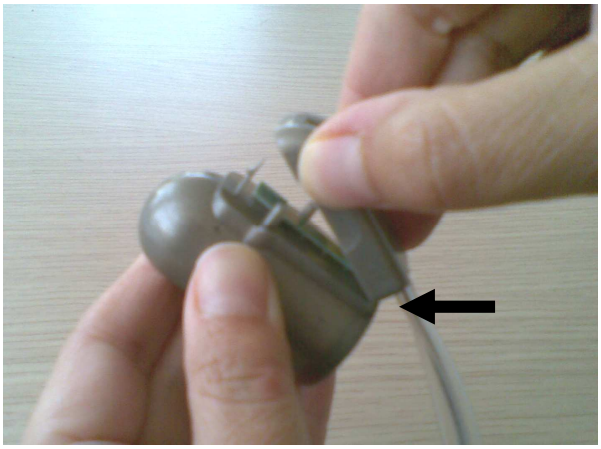


Figure 18 - Inserting into slit

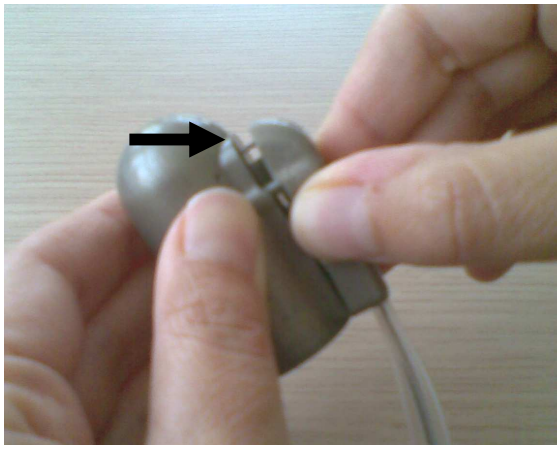


Figure 19 - Clicking in

To remove probes, press the tab (clip) marked by the arrow in Figure 20, and then lift the connector away from the probe (Figure 21). Used probes should be disposed of properly.

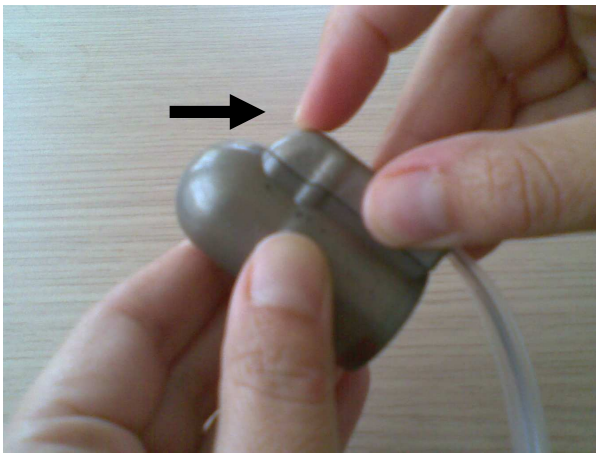


Figure 20 - Press to release

Figure 21 - 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 22)

2 All mandatory fields 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).

- Patient First and Last name - Enter the patient's complete name, initials or other identifier, or it can be left empty (optional field).
- 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 13).
- Systolic Blood Pressure – mandatory field.
- 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.

NOTE

Study data is saved in a data file that is automatically named with the **Patient ID** number. If the patient ID is for example 12345, then the file name will be 12345.s32.

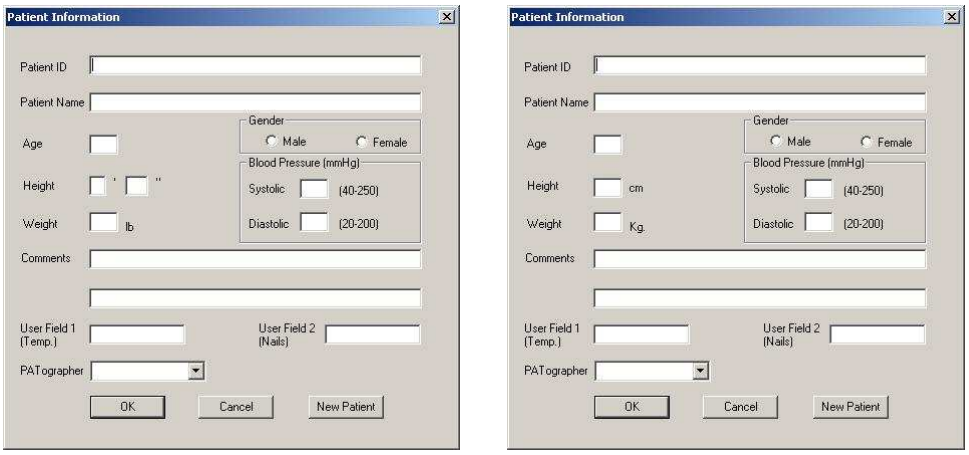


Figure 22 - Patient information dialog box (metric and US units)

After clicking OK the Patient Information dialog box will close.

NOTE

The computer's filing system will not allow the same Patient ID number for 2 different PAT studies. Designate new Patient ID's for the same patient by amending the original Patient ID number with sequential letters. For example—123456a, 123456b, etc.

When trying to use an existing ID number, the following message appears:

Figure 23 - File ID exists warning message

A different ID must be entered before you can proceed.

6 Conducting an Endo-PAT2000 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 12). 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 a 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 medication
- 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 deformations 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 & displaces the finger from the sensing region of the probe, resulting in a smaller PAT signal and inaccurate results. The index finger is the recommended finger for the study, however if this finger is too large to comfortably fit into

the probe or is otherwise unsuitable (see above), a different finger (except the thumb) may be used, as long as it is the same finger in both hands.

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

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

6.2.2 Initializing the PAT system

Activate the Endo-PAT2000 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 PAT study.

Ensure that the pneumo-electric tubings are properly connected to the Endo-PAT2000 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 24) will open.

Figure 24 - Used probes warning

	**WARNING** The probes are single use and disposable: they will not work properly, if they have already been used!

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 25-1). 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 25-2). 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 4.

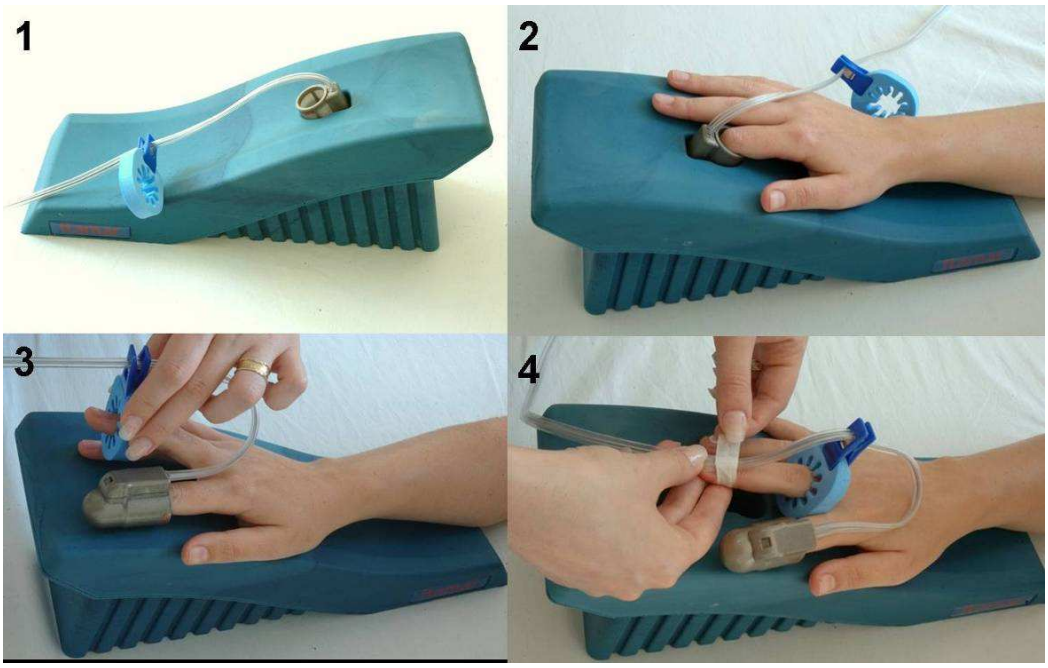


Figure 25 - Applying the PAT probes

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 25-3. Gently tape the tube to the tip of the anchor finger, over the finger-nail (Figure 25-4).

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 26.

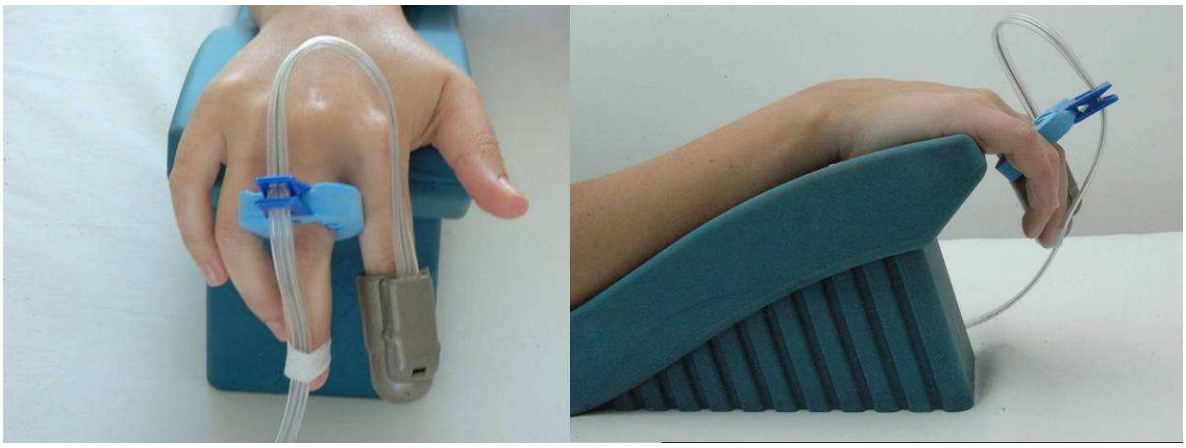


Figure 26 - Hands set-up

6.3 Performing the Study

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

6.3.1 Recording baseline

1. Click the Standby  icon, from the main screen. The system will display the signals from the two PAT channels, allowing the user to check the signals and adjust the signal gain/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 27) 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 Standby 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 Standby 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.

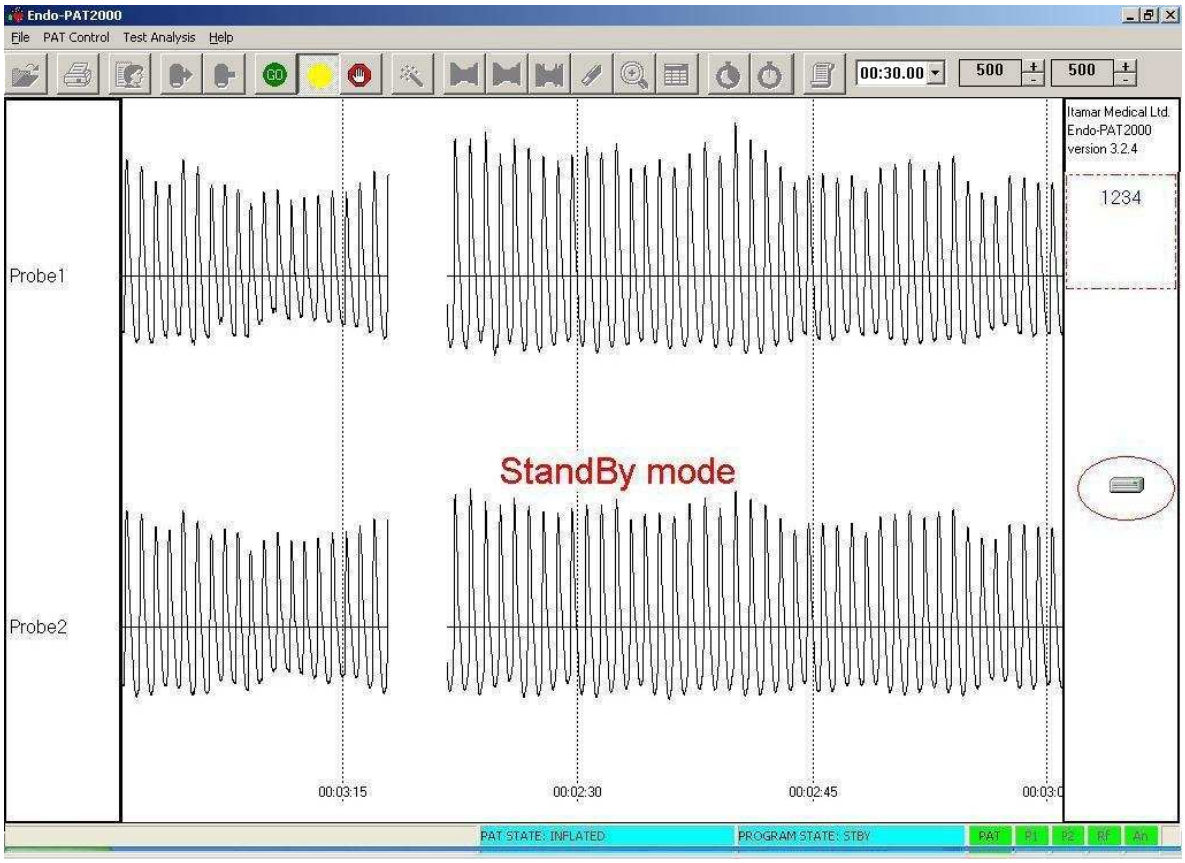


Figure 27 - StandBy mode

	**NOTE** While working in the StandBy mode, data is not recorded, and therefore it is impossible to review or save the study. The notification: "StandBy mode" (Figure 27) 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 28).

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

3. Initialize the stopwatch, by clicking the  icon.

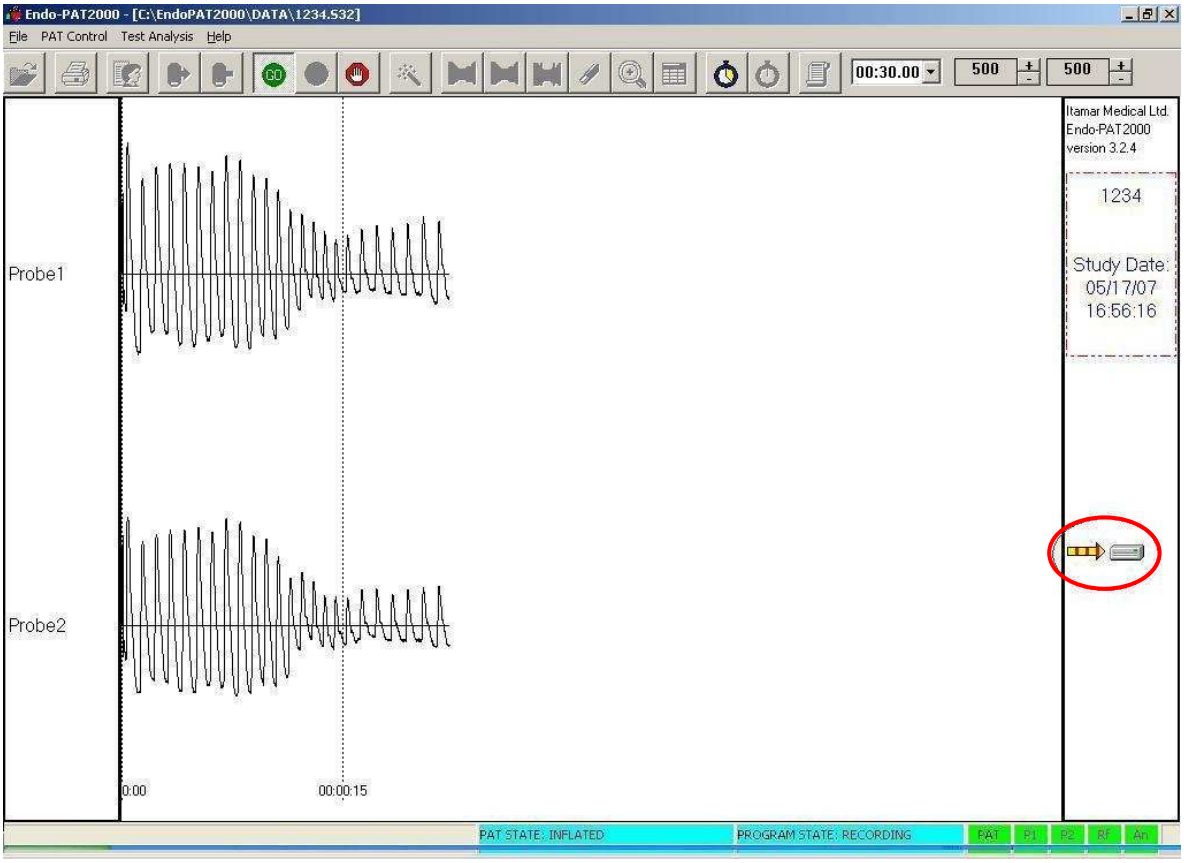


Figure 28 - Recording

	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 29).
6. Click the  icon to start the timer, when the cuff reaches the target occlusion pressure.

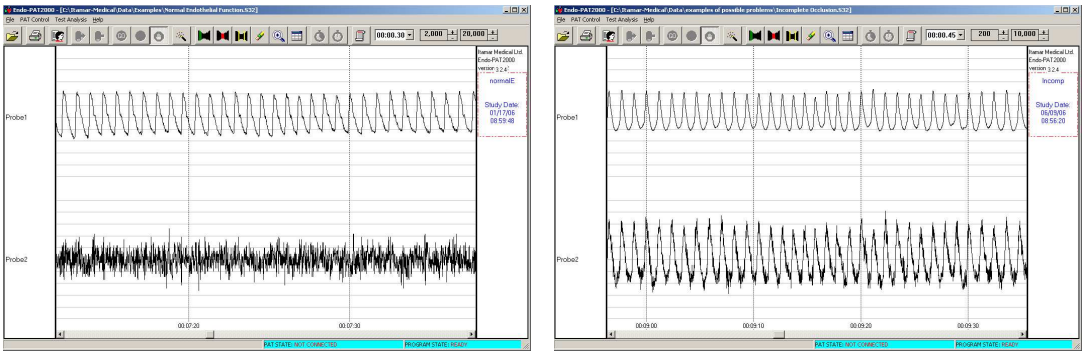
	**NOTE** Without marking the beginning of the occlusion by starting the timer, you will not have any means of knowing when the occlusion period began. Thus you will not know when to release the occlusion.

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

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 29 - Occlusion quality assessment

6.3.3 Post Occlusion period

1. 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**.

2. Stop the stopwatch, by clicking the  icon.

3. 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.

4. 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.

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 7.4.

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:

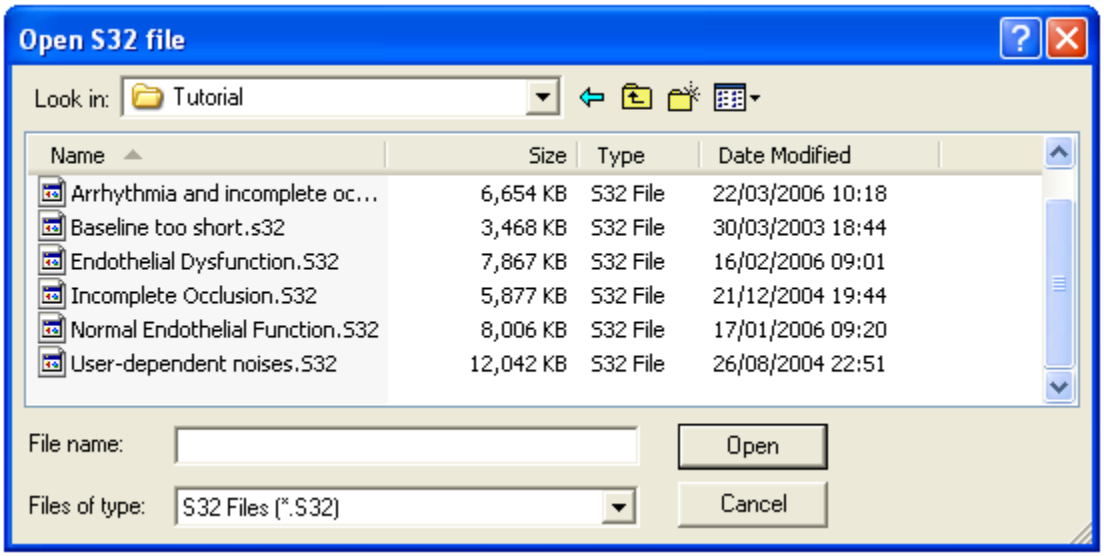


Figure 30 - Open file dialog box

Select the desired file from the list (note that the file name is the same ID number 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-PAT2000 main screen, the test result's value appears in the right column as shown in Figure 31.

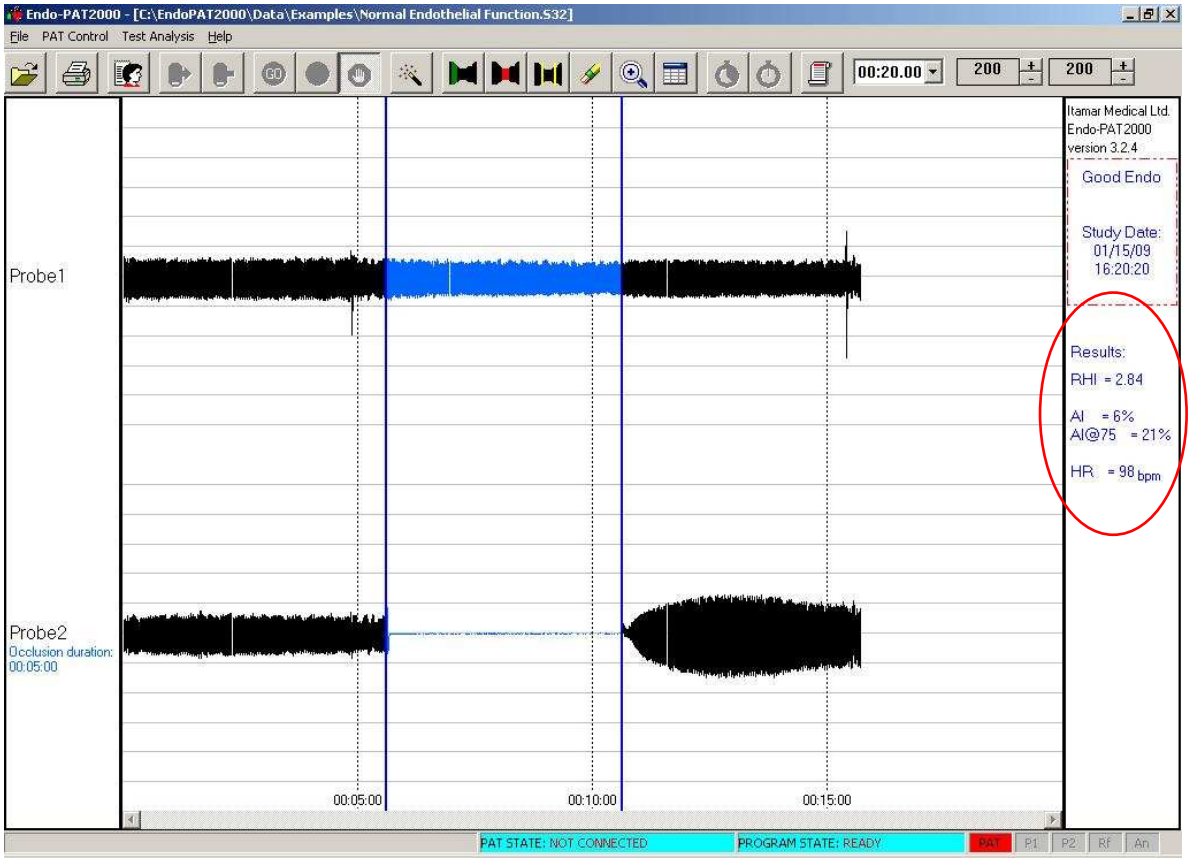


Figure 31 - Automatic analysis

NOTE

The AI (Augmentation Index) is calculated automatically from the PAT signal in non-US and in research versions only.

The automatic analysis identifies the occlusion, and marks it in blue. Proper identification of the occlusion area is critical for the automatic analysis to correctly select the regions used in its calculations. The user should verify that the marking of the occlusion area appears reasonable. If the automatically marked occlusion area appears wrong, it can be manually selected as described in section 7.2.1.

	**NOTE** After launching the Endo-PAT2000 software, you should wait 10 seconds before running the first test analysis. This is necessary to allow termination of background processes.

The Endo-PAT2000 study results (RHI & HR) are presented on the right side of the screen (Figure 31).

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.

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

To review the results of the study, click the  icon. 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 3 is a description of the information fields displayed in the table.

a	ID
b	FileName
c	RHI: Reactive Hyperemia Index (the test result)
d	BL HR:baseline heart-rate
e	AI:Augmentation Index
f	AI@75:Augmentation Index - normelized to HR 75bpm
g	AI_N pulses:number of pulses averaged to calculate the AI
h	AI_P1
i	AI_P2
j	Warnings/Errors
k-q	Patient info: Diastolic and Systolic Pressures, Gender, Age, Height, Weight, BMI
r	%ValidBL ROI:% valid PAT signals in the Baseline region of interest
s	%Valid Post Occ ROI:% valid signals in the post-occlusion region of interest
t-w	Occlusion info – begin, end, duration and automatic/manual border detection
x-z	Baseline duration, region of interest (ROI) duration, and total study duration
aa	MeanBL o - Mean PAT signal amplitude in the baseline region of interest value, for the occluded side (suffix “o”)
ab-ao	Post-occlusion signal to baseline signal ratios, at 14 consecutive 30 sec time segments, for the occluded side (suffix “o”)
ap	MeanBL c - Mean PAT signal amplitude in the baseline region of interest value, for the control side (suffix “c”)
aq-bd	Post-occlusion signal to baseline signal ratios, at 14 consecutive 30 sec time segments, for the control side (suffix “c”)
be	RecordingTime: Date and time of test recording
bf	AnalysisTime: Date and time of test analysis
bg	RecordingVersion: The software version used for the recording
bh	AnalysisVersion: The software version used for the analysis
bi-bj	Site name & PATographer identification
bk	Comment1
bl	Comment2
bm	UserField1
bn	UserField2
bo	FRHI

Table 3 - table information

(Note: fields *E* to *I* and *BO* will only appear in non-US and in research versions only)

NOTE

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

7.2.1 Manual Selection of 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 on the occluded PAT tracing so that the curser points at the beginning of the occlusion. Click and hold down the left mouse button and drag the mouse rightwards until the curser 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. From 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. Point the mouse at the beginning of the occlusion area. Right click on the mouse will open a popup menu (Figure 32). Select "Set Automatic 5 min Occlusion" from the popup menu. A five minutes segment starting at the curser 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. Point the mouse at the beginning of the occlusion. Right click to open a popup menu (Figure 32).

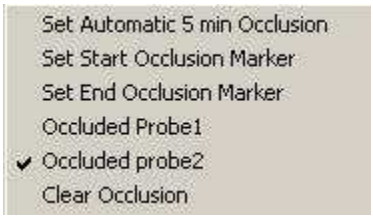


Figure 32 - Occlusion Popup Menu

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 32).

- 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 32).

7.3 Batch Analysis

The Endo-PAT2000 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 3) for all the analyzed files.

7.4 Manual Analysis (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 Research Mode. Refer to section 4.4.1.

7.4.1 Marking Segments and Artifacts

Tool bar icons provide quick and easy access to the tools used to mark segments and artifacts, 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 pointer at the beginning of an interval to be marked.

2. Drag the mouse 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.

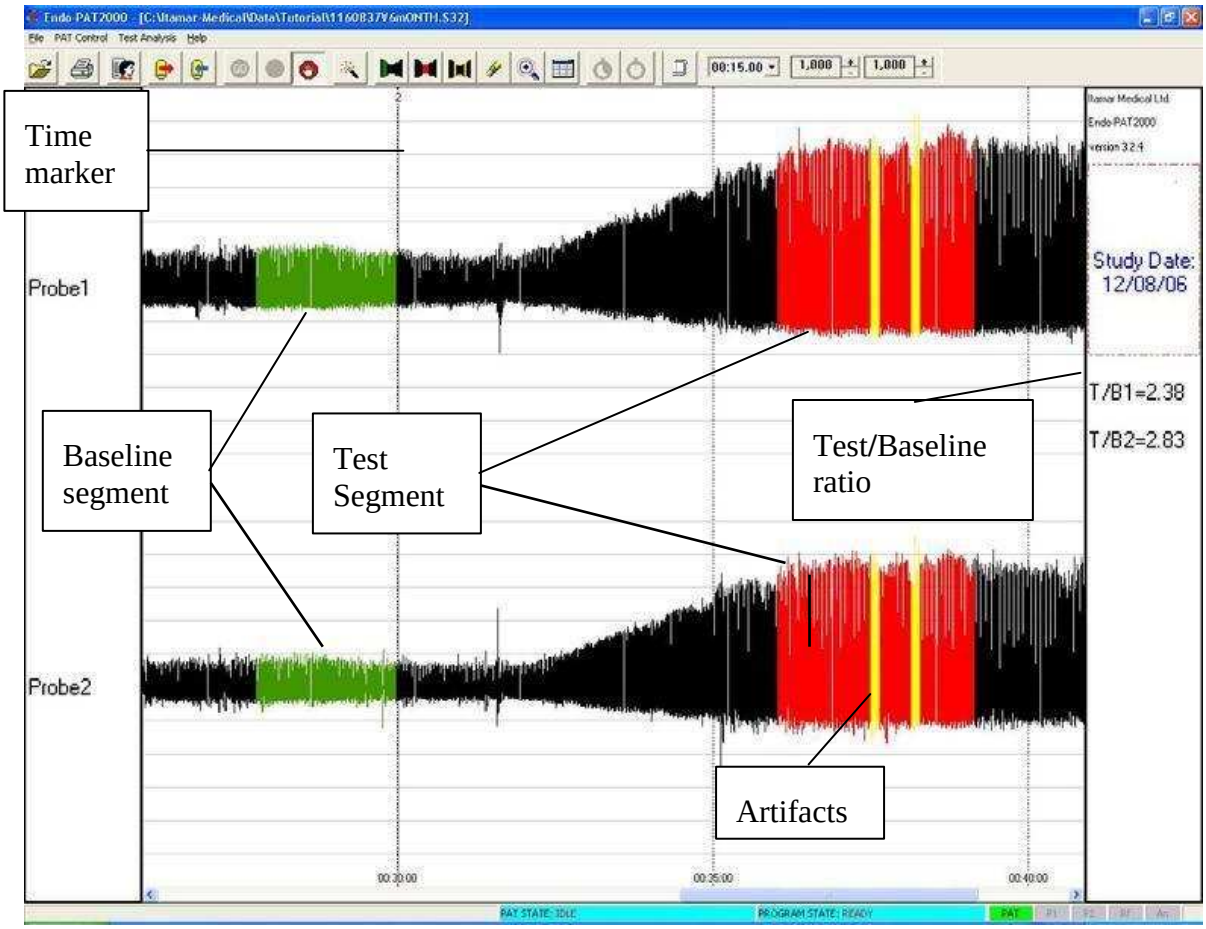


Figure 33 - Marking Segments and Artifacts

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 33).

	**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.

7.4.2 Analyzing PAT Ratios

After the B and T segments are marked, their PAT ratios are automatically calculated and the results displayed in the right side of the screen (Figure 33). 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 33) do not have any clinical implication. This feature is used only for research purposes and should not be regarded as device output concerning Endothelial Dysfunction.

7.5 Study report & 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.

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

7.6 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

This chapter describes preventative and regular maintenance for the Endo-PAT2000.

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.
2. The Endo-PAT2000 device should be free of dirt and debris. Using a soft, slightly damp cloth, gently wipe the exterior of the Endo-PAT2000 device, avoiding contact with open vents and plugs.
3. The probes should be discarded after each use and replaced with new ones.

9 Troubleshooting

	Description	**Possible Cause**	**Action**
1.	The Endo-PAT2000 does not switch on (the orange LED on the device is not on)	The Endo-PAT2000 power is switched off.	• Switch on the Endo-PAT2000 device.
		Power cable is not plugged to the power outlet.	• Switch off the Endo-PAT2000 device. • Plug the power cable to the power outlet. • Switch on the Endo-PAT2000 device.
		Power cable is not connected to the Endo-PAT2000 device.	• Switch off the Endo-PAT2000 device. • Plug the power cable to the Endo-PAT2000 device. • Switch on the Endo-PAT2000 device.
2.	No communication between PC station and Endo-PAT2000 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-PAT2000 power switch is off.	• Verify that the orange LED is on. • Switch on the Endo-PAT2000 device.
		Communication cable between PC station and Endo-PAT2000 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-PAT2000 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-PAT2000 device.	• Verify that the pneumatic probe cable is securely connected to the probe and to the Endo-PAT2000 device.
		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 StandBy mode); or there is a software-hardware communication error	• Deflate manually by pressing the deflate button on the Endo-PAT2000 device. • If you were in Standby 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 13

Table 4 - 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).
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).
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).

Table 5 - Error messages

10 Technical Information

10.1 System Requirements

- An IBM® or compatible PC Pentium/Celeron/AMD 1000 MHz CPU or higher
- Windows XP / Vista (32bit) operating system
- Any Internet browser or Excel 2000/2003
- 512 MB RAM for XP or 1GB for Vista
- 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)

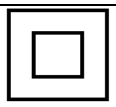
Optional Hardware

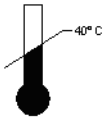
- Large removable media, such as CD-R or DVD-R for storage of study files
- Printer, higher resolution preferred. Color recommended

10.2 Operating System

English version Windows XP or Vista (32 bit).

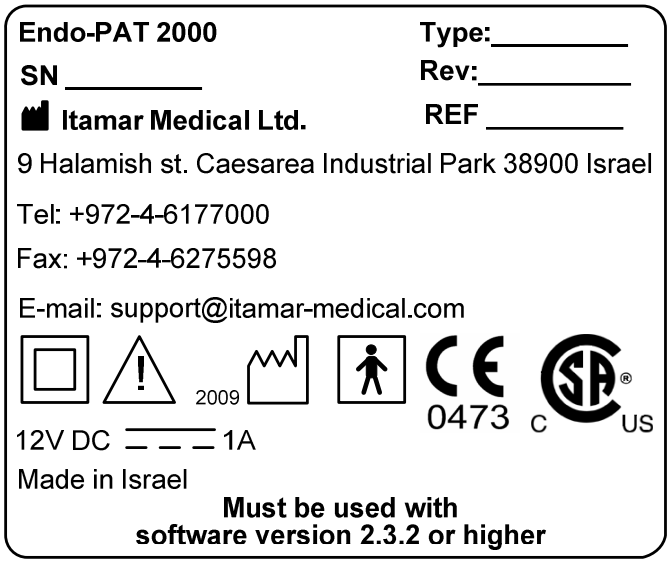
10.3 Technical information about labeling

	Double isolation of power supply
	Year of manufacture
	Pay attention, first read the user manual

	Type BF applied part
	The Endo-PAT2000 is certified by CSA
CE 0473	The Endo-PAT2000 complies with the CE EMC Directive and related standards. The unit is marked with the CE logo and a CE conformity card is included in every shipment.
	Use within 2.5 years from date of manufacture
	Single use only – do not sterilize
	Maximum allowed temperature
	Name and address of the manufacturer
REF	Catalogue Number
SN	Serial Number

10.4 Labeling

Label on the base of the Endo-PAT2000 main control unit:

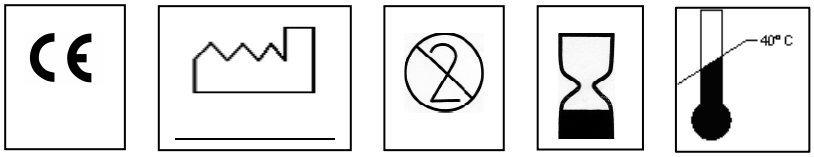


Packaging labels:

The following labels are attached to the package of the Endo-PAT2000 system:

Endo-PAT2000 Probe Package:

itamar **Probes for Endo-PAT**



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Caesarea Ind. Park, Israel

Tel: + 972 4 6177000

Fax: + 972 4 6275598

www.itamar-medical.com

10.5 Specifications for Endo-PAT2000

Properties		Description
PAT Probe		Itamar'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 hour per screen
	Bandwidth	30Hz
Power Supply	*Input*	100-240 VAC 50/60 Hz
	Output	12V DC, 3.3A
Operating Voltage		12 V
Temperature	*Operation*	Room temperature
	Storage	0 - 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 6 - Specifications

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Appendix B: Regulatory Authorized Representative

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England
Tel: +423-663-169205
Tel / Fax: +44 1923859810

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-PAT2000 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.

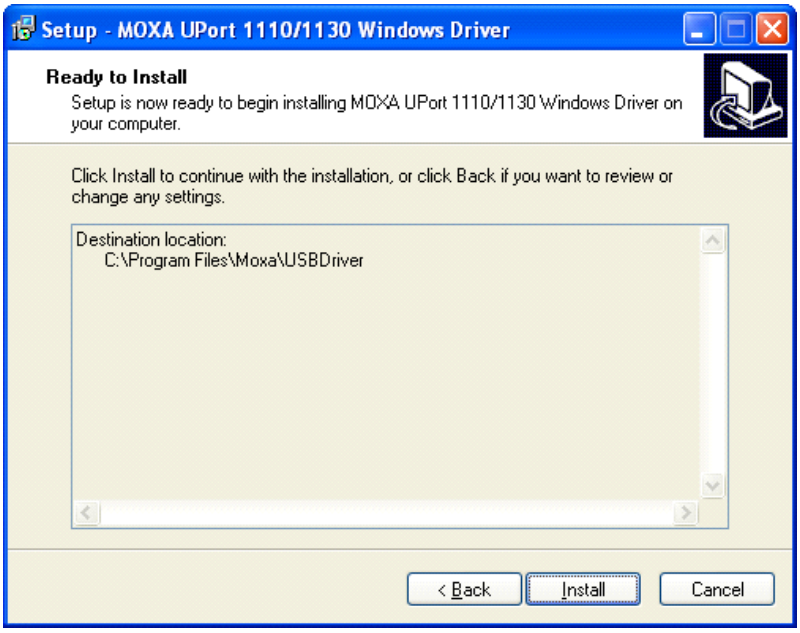

Figure 34: MOXA USB Installation – XP1

1.6 Click “Install”.

1.7 The following screen is displayed:

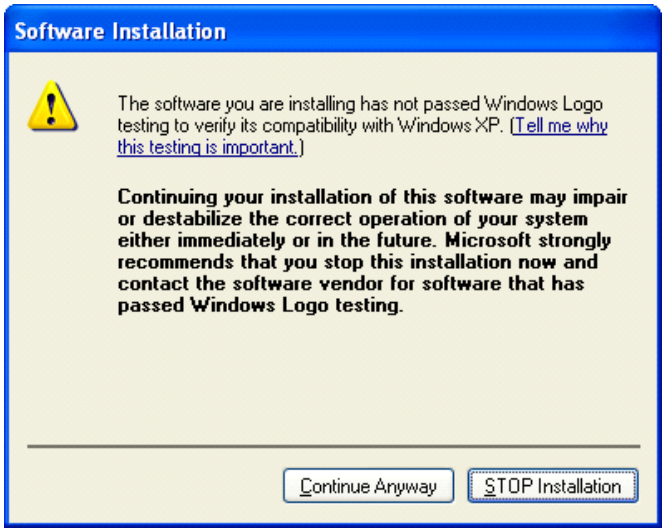

Figure 35: MOXA USB Installation – XP2

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

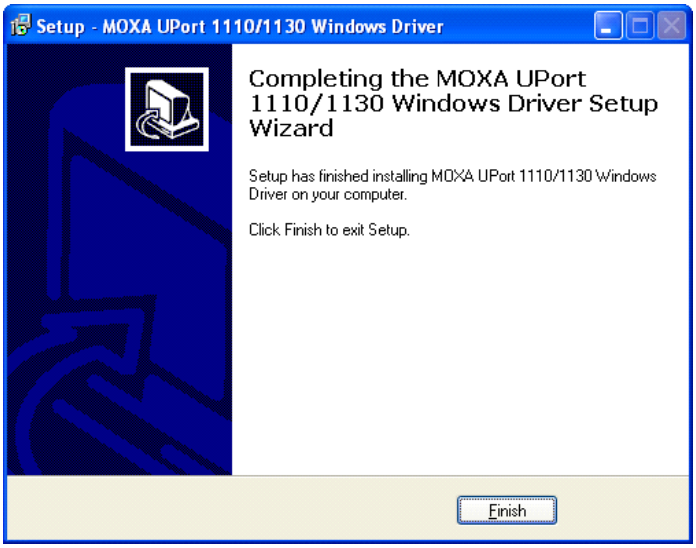

Figure 36: MOXA USB Installation – XP3

1.9 Click “Finish”.

2. Configuring the MOXA Adapter

2.1 Plug in the adapter to your USB port.

Figure 37: MOXA Adapter

2.2 Wait for the following windows to appear.

Figure 38: MOXA Adapter Configuration – XP2

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

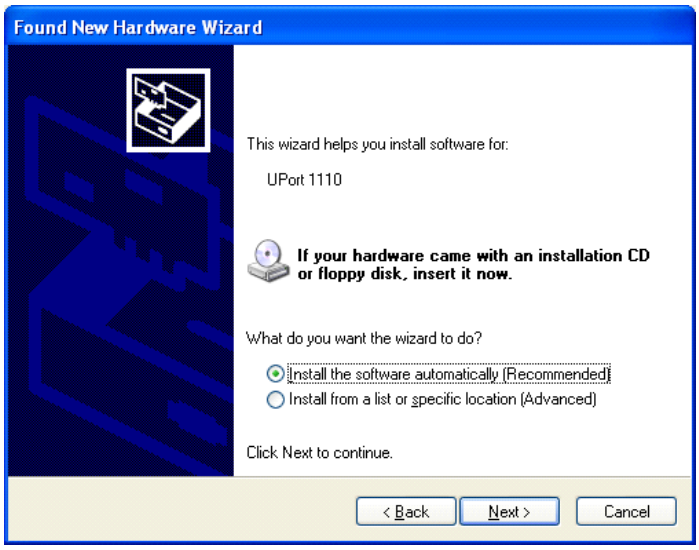

Figure 39: MOXA Adapter Configuration – XP3

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

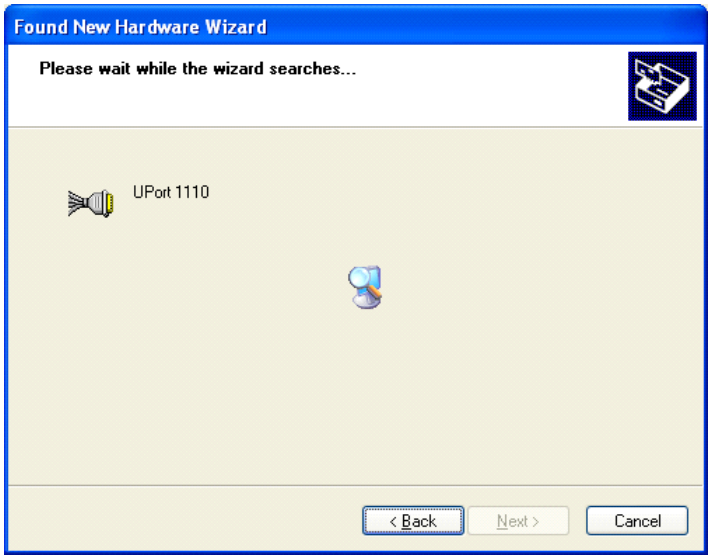

Figure 40: MOXA Adapter Configuration – XP4

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

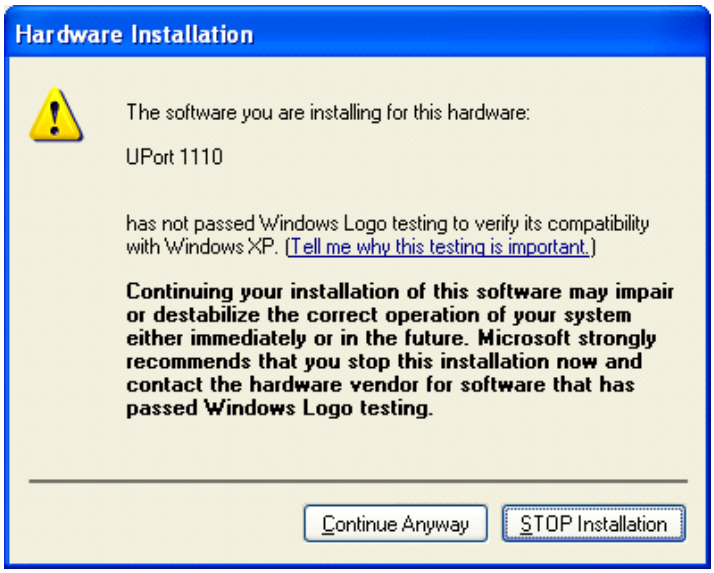

Figure 41: MOXA Adapter Configuration – XP5

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

Figure 42: 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-PAT2000

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

Figure 43- connect MOXA adaptor

3.2 Connect the COM TO COM cable to the ENDO device and tightly screw the bolts.

Figure 44 – connect COM TO COM

3.3 Open the Endo-PAT2000 software and verify that the “PAT” indicator on the bottom right is colored green.

Appendix D: installing the USB adapter for Windows Vista

This appendix describes how to install the MOXA adapter and driver for Windows Vista Enterprise edition

	**NOTE** The MOXA adapter must not be connected to the computer or to the Endo-PAT2000 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 \Vista\driv_win_uport1p_v1.4_build_07100420_whql file

	**NOTE** If the following window is opened, please press the **Allow** option.

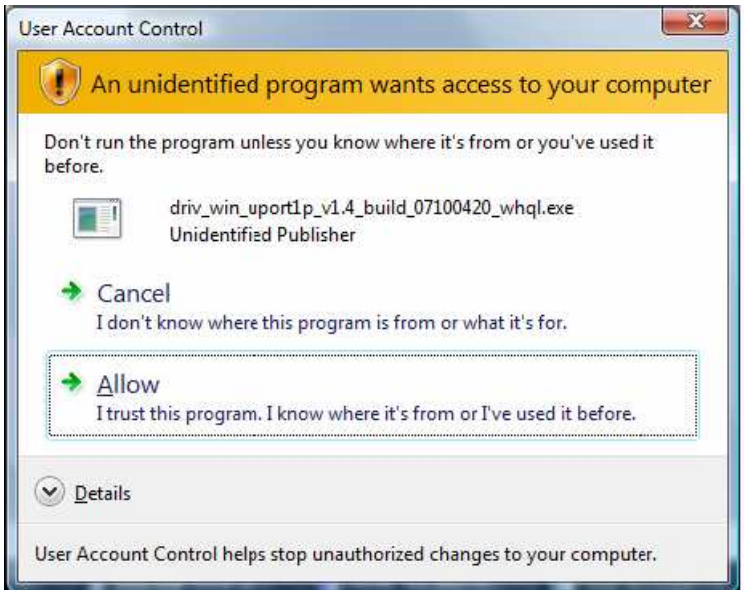

Figure 45: Windows Security Allowance

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

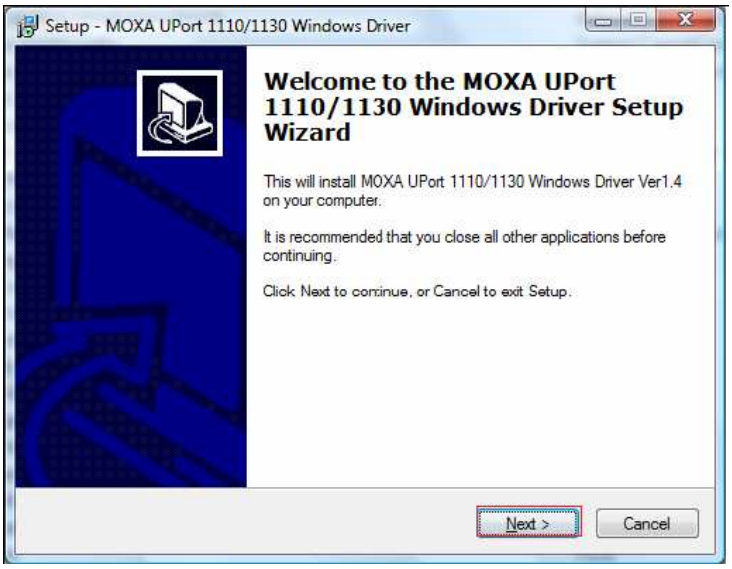

Figure 46: MOXA Uport driver installation

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

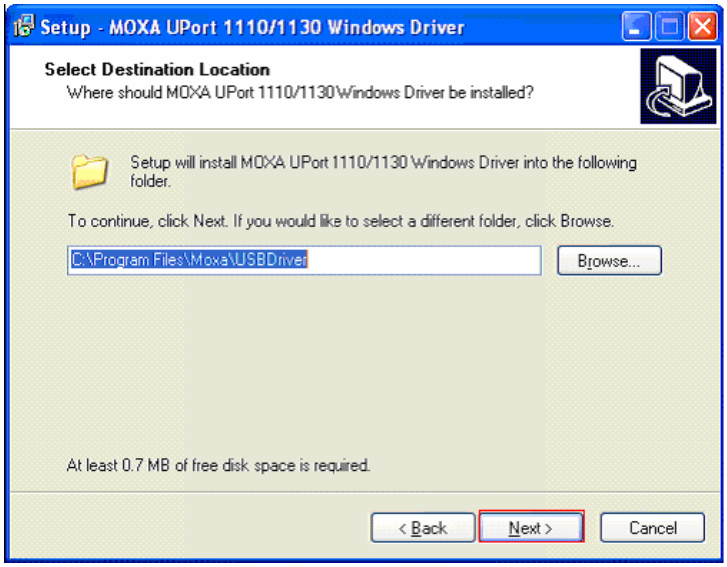

Figure 47: MOXA driver installation folder

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

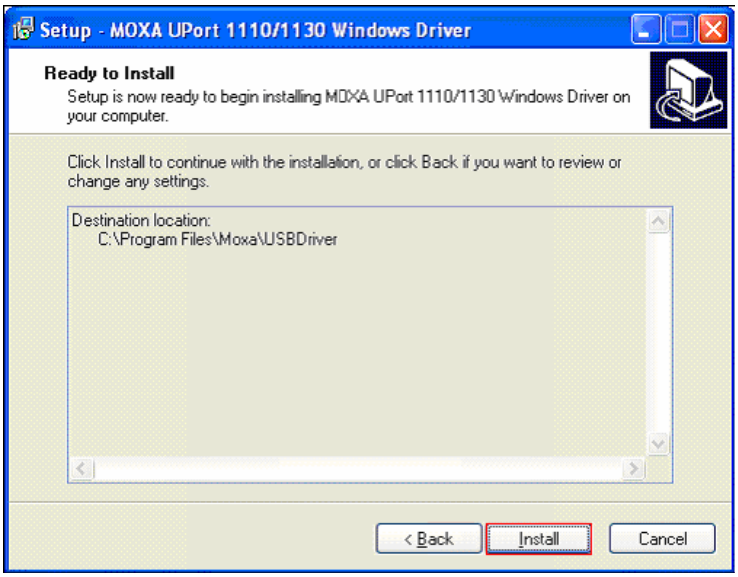

Figure 48: MOXA driver folder confirmation

1.6 Press the Finish button

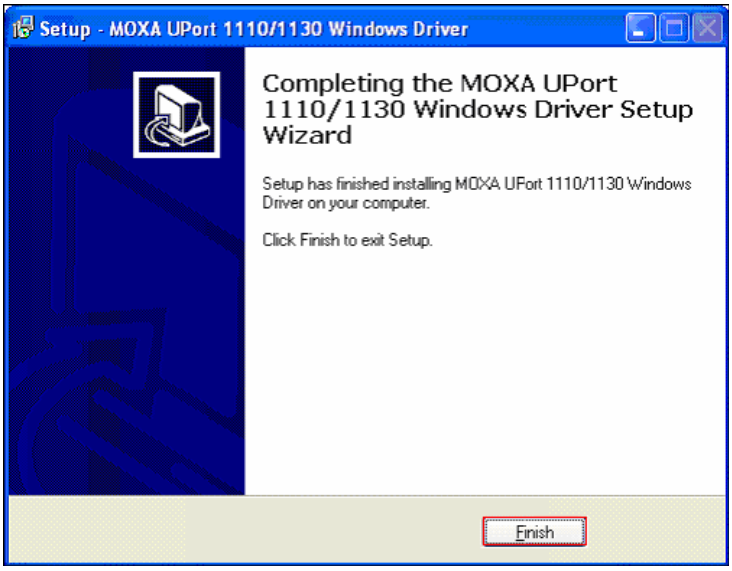

Figure 49: MOXA driver installation finish

2. Configuring the MOXA Adapter

2.1 Plug in the adapter to your USB port.

Figure 50: 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-PAT2000

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

Figure 51- connect MOXA adaptor

3.2 Connect the COM TO COM cable to the ENDO device and tightly screw the bolts.

Figure 52 – connect COM TO COM

3.3 Open the Endo-PAT2000 software and verify that the “PAT” indicator on the bottom right is colored green.