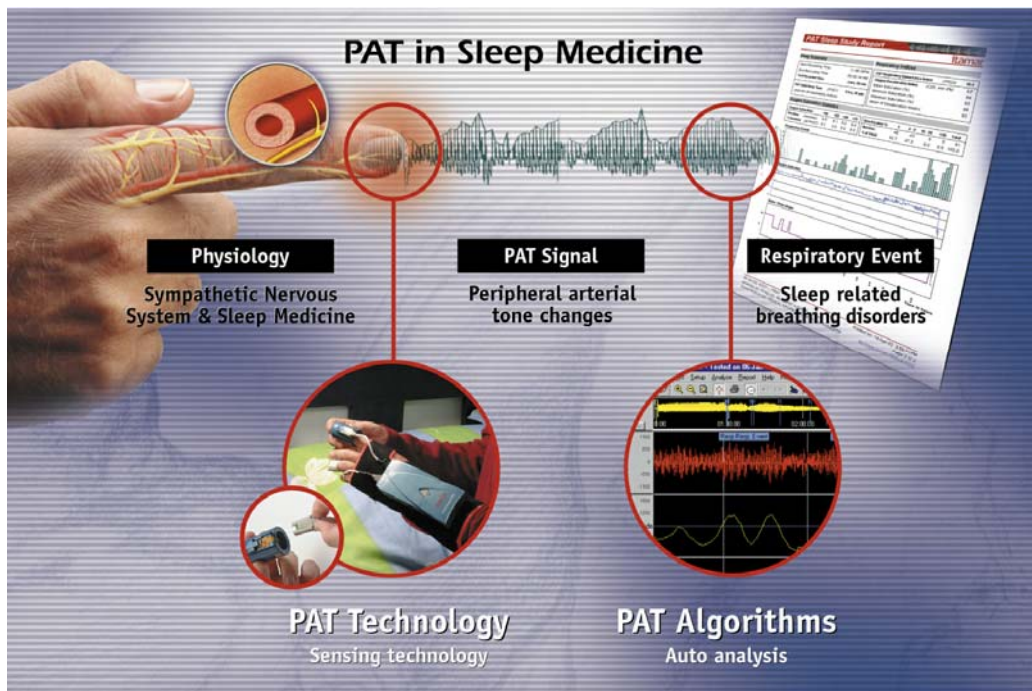


# itamar

## zzzPAT

### For Watch-PAT100 & Watch-PAT200

Software Operation Manual  
Itamar Medical Cat. No. OM2197432



**Caution:** Federal (U.S.) law restricts this device to sale by, or on the order of a physician.

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Software Version: 4.2.58

## Itamar Medical Ltd.

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Base- 5-0	November 2006	Version 4.0 <ul style="list-style-type: none"> <li>• Added support for Snoring and Body position sensor</li> <li>• Added 3rd optional page to Sleep report</li> <li>• New options at General Settings/Report Appearance for 1, 2 or 3 page report</li> <li>• Events report shows Resp.Events (RDI), Resp.Events (AHI) and</li> </ul>		All

		<p>desaturations only</p> <ul style="list-style-type: none"> <li>• File&gt;New Study Details: Removed all mandatory requirements except Patient ID</li> <li>• A backup of the database for every day of the week will be automatically performed behind the scenes</li> <li>• Automatic printout of labels (1 or 2 labels as configured) while the Compact Flash is initialized with patient data</li> <li>• “Follow up” report will show reviewed and reported studies</li> <li>• Patient's weight and height appear in Sleep report</li> <li>• Enable manual addition/deletion of Respiratory events</li> <li>• Export for Interpretation services option</li> <li>• The valid sleep time used for the calculation of the respiratory indices appears in the second page of the report</li> </ul>		
Base- 6-0	June 2008	<p>Version 4.2.56</p> <ul style="list-style-type: none"> <li>• Report changes</li> <li>• Support of MS-SQL server</li> <li>• New Study – new patient fields</li> <li>• Follow Up Report changes</li> <li>• Light/Deep Sleep stages</li> </ul>	All	All
Base- 7-0	August 2008	<p>Version 4.2.57 WP200 support</p>	All	All
Base- 8-0	August 2009	<p>Version 4.2.58 WP200 Patient Identification Bracelet support Multiple nights study</p>	All	All

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# 1 Introduction to the zzzPAT

## 1.1 Intended Use of the Watch-PAT100 & Watch-PAT200

The Watch-PAT100 ("WP100") and Watch-PAT200 ("WP200") are non-invasive home care devices for use with patients suspected to have sleep related breathing disorders. The WP100 and WP200 devices are used as a diagnostic aid for the detection of sleep-related breathing disorders and sleep staging (Rapid Eye Movement (REM) Sleep, Light Sleep and Deep Sleep). The devices generate a peripheral arterial tonometry ("PAT") Respiratory Disturbance Index ("PRDI"), Apnea-Hypopnea index ("PAHI") and PAT sleep staging identification ("PSTAGES"). The devices' "PSTAGES" provides supplemental information to its PRDI/PAHI. The devices' "PSTAGES" is not intended to be used as the sole or primary basis for diagnosing any sleep related breathing disorder, prescribing treatment, or determining whether additional diagnostic assessment is warranted.

The WP100 and WP200 are not indicated for children less than 17 years old.

## 1.2 The zzzPAT S/W – Definition

The zzzPAT is an analysis software package used with the WP100 or WP200 devices to aid in diagnosis of sleep related breathing disorders and detects REM, Light Sleep, Deep Sleep and Wake stages. The zzzPAT S/W displays the signals recorded by the WP100 or WP200 devices, automatically identifies breathing disordered events and REM, Light Sleep, Deep Sleep stages, and generates a comprehensive report for the physician.

## 1.3 Overview

Obstructive sleep apnea syndrome (OSAS) is considered a major public health problem. The prevalence of the syndrome is estimated at 2% to 5% in the adult population. It is characterized by recurrent events of complete or partial obstruction of the upper airways during sleep, often leading to hypoxemia, and/or arousals associated with sympathetic nervous system activation. The diagnosis and assessment of the sleep apnea patient is based on the Respiratory Disturbance Index (RDI), the number of Apneas, Hypopneas and Respiratory Effort Related Arousals (RERA) per hour of sleep and/or apnea-hypopnea index (AHI), along with sleep architecture. The common consequences of this sleep disruption are daytime sleepiness, poor daytime performance and increased vulnerability to accidents. Cardiovascular complications such as systemic/pulmonary hypertension, ischemic heart disease and arrhythmias are the major sequel of OSAS in the adult population.

The WP100 and WP200 are worn on the wrist and utilizes a plethysmographic based finger-mounted probe, to measure the PAT (Peripheral Arterial Tone) signal. The PAT

signal is a measurement of the pulsatile volume changes in the fingertip arteries which reflects the relative state of the arterial vasomotor activity, and thus indirectly the level of sympathetic activation. Peripheral arterial vasoconstriction, which mirrors sympathetic activation, is shown as attenuation in the PAT signal amplitude. The PAT signal is recorded continuously and stored on a removable flash disk along with pulse rate (derived from the PAT signal), data from a built in pulse-oximeter (the sensor is mounted on an adjacent finger) and an actigraph (embedded in the device). Following the sleep study, in an offline procedure, the recordings are automatically downloaded and analyzed using the proprietary zzzPAT software.

The zzzPAT algorithms use the four WP100 or WP200 channels (PAT, Pulse Rate, Oxygen saturation and actigraphy) for the detection of sleep related breathing disorders and sleep staging (Rapid Eye Movement (REM), Light Sleep, Deep Sleep and Wake). The software issues comprehensive reports of the study, with statistics and graphic presentation of the results. The whole night data can be viewed and the automatically detected events can be revised manually.

This manual provides the information necessary for routine use of the zzzPAT software.

### **Restrictions**

The tracings and calculations provided by the WP100 or WP200 systems are intended as an aid for Sleep Breathing Disorders diagnosis. They are explicitly not to be regarded as a sole incontrovertible basis for clinical diagnosis.

- The zzzPAT software should be used only on compatible computers that meet the requirements specified in this document.
- Running other programs, commercial or customized, simultaneously with the zzzPAT may interfere with its proper function.
- zzzPAT may not function properly under Windows XP when multiple sessions are running (i.e. when more than one user is logged on to the same PC simultaneously, and each user is running zzzPAT).
- zzzPAT is not supported on Windows XP in remote mode.

## 2 Installation

### 2.1 Overall Description of zzzPAT Software

zzzPAT is a proprietary PC software developed specifically for managing and analyzing data recorded by the WP100 and WP200 devices. The software displays and stores the recorded signals, and provides a set of analytical functions for interpretation purposes.


A Compact Flash reader (drive) is used to read the data recorded by the WP100 on a Compact Flash card. Please refer to Section 2.2 for required PC configuration.

A USB cable is used to read the data recorded by the WP200 on the internal SD card. The zzzPAT S/W automatically detects the data on the internal SD card once the WP200 is connected to the PC via the USB communication cable.

zzzPAT can operate in two modes:

**Standalone** - for use on a single PC with a local database.

**Shared Access** - for use in a networked environment where multiple zzzPAT stations access a single, shared database.

	<p style="text-align: center;"><b>Note</b></p> <p>It is strongly advised to coordinate the setting of <b>shared access</b> zzzPAT operation mode with an Itamar Medical representative. Extra training is crucial for proper operation.</p>
--	---

The zzzPAT mode of operation is determined during installation as further described in the Installation section of this operation manual.

A Compact Flash reader (drive) is used to read the data recorded by the WP100 on a Compact Flash card. Please refer to Section 2.2 for required PC configuration.

### 2.2 Hardware Requirements

#### 2.2.1 Hardware configuration

Computer Pentium 3 450MHz minimum / Pentium 4 1GHz or higher recommended

CD-ROM drive

1 available USB port / Additional serial port is recommended

XGA screen resolution (minimum 1024 x 768 pixels)


Colors set to 16 bits or higher

RAM 256MB minimum


Free disk space: 10GB minimum / 60GB recommended disk on database drive and at least 1.2GB on boot drive

### 2.2.2 Operating System

Windows XP with Service Pack 2 and above  
Windows Vista Home Premium  
Windows Vista Enterprise  
Windows Server 2003

	<p style="text-align: center;"><b>Note</b></p> <p>Software components needed for the proper installation of zzzPAT should be installed prior to zzzPAT installation (OS service packs or latest OS updates).</p>
---	--

### 2.3 Installation of the Compact Flash drive

	<p style="text-align: center;"><b>Note</b></p> <p>Refer to the installation instructions provided with the Compact Flash drive.</p>
--	---

- **WP100 device only:** The provided Compact Flash drive may require the installation of a driver depending on the Windows operating system version and the type of Compact Flash drive. Please refer to the instructions provided with the Compact Flash drive for installation instructions.

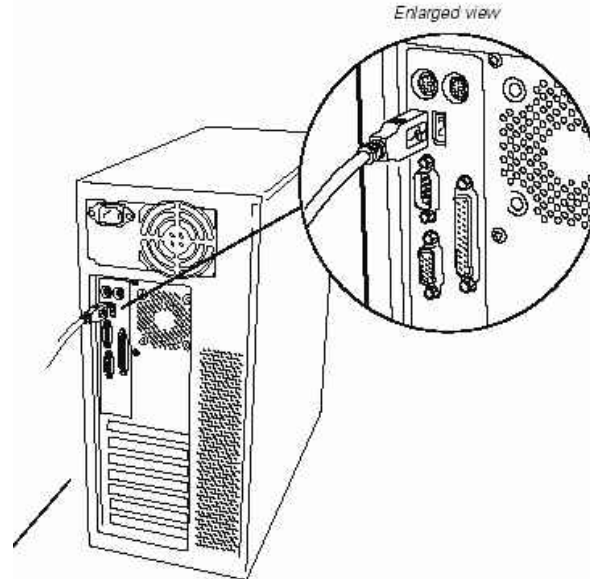


Figure 1 - USB attachment to the PC

## 2.4 Installing zzzPAT software

This process will install a single icon  on the desktop, which opens the zzzPAT analysis and reporting software. To open the New Study and Database Wizard applications, use the Start>Programs>zzzPAT command.

### Quick start instructions:

- **WP100 device only:** Verify that the Compact Flash drive is installed and plugged to the PC.
- Insert the zzzPAT CD into the computer's CD-ROM drive.
- If the CD-ROM drive is set to run automatically, the installation will begin automatically. If installation does not begin, refer to the section below.
- Follow the instructions on the screen.

### If the installation does not start automatically

- Double-click the My Computer icon on your desktop.
- Double-click the CD-ROM icon labeled zzzPAT.
- Double-click 'Setup.exe' .
- Follow the instructions on the screen.

You are now ready to run the zzzPAT software. See section 2.9 for instructions "Before using zzzPAT Software for the first time".

## 2.5 Step by step installation instructions

Prior to installation, verify that you are in full system administrator mode with full privileges.

1. Insert the zzzPAT installation CD into the CD drive. The installation program is activated, and the following dialog box appears. If the installation does not start automatically refer to section 2.4.

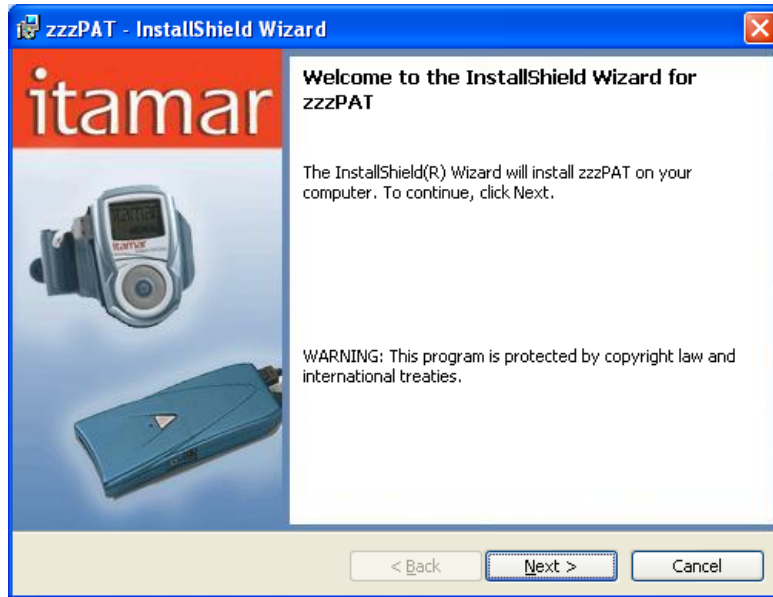


Figure 2 - zzzPAT installation dialog box

2. Click **Next**. The License Agreement appears.



Figure 3 - zzzPAT License Agreement



3. After reading the agreement, select **I accept the terms in the license agreement** and click **Next >** to continue.  
The 'Customer Information' dialog box appears.

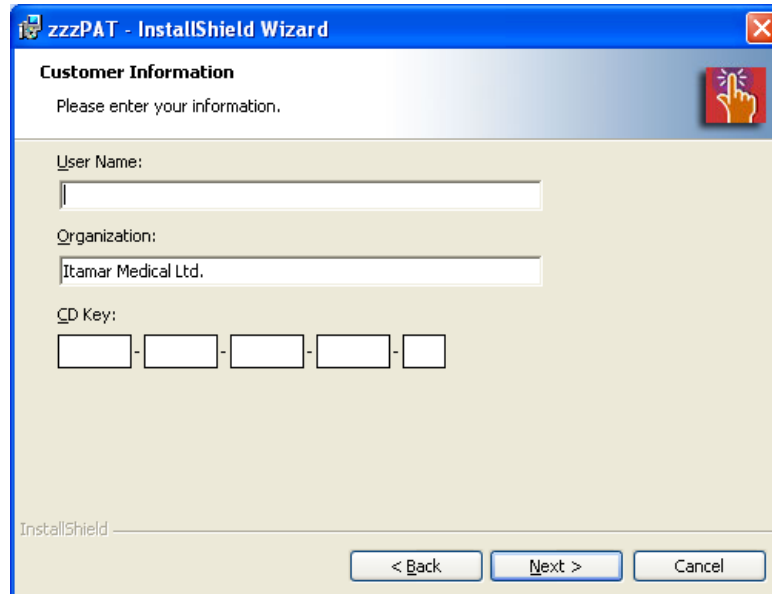


Figure 4 - Customer Information dialog box

4. Enter user name, company name and the serial number exactly as it appears on the cover of the zzzPAT installation disk.
5. Click **Next>** to continue.  
The 'Database Properties' dialog box appears.

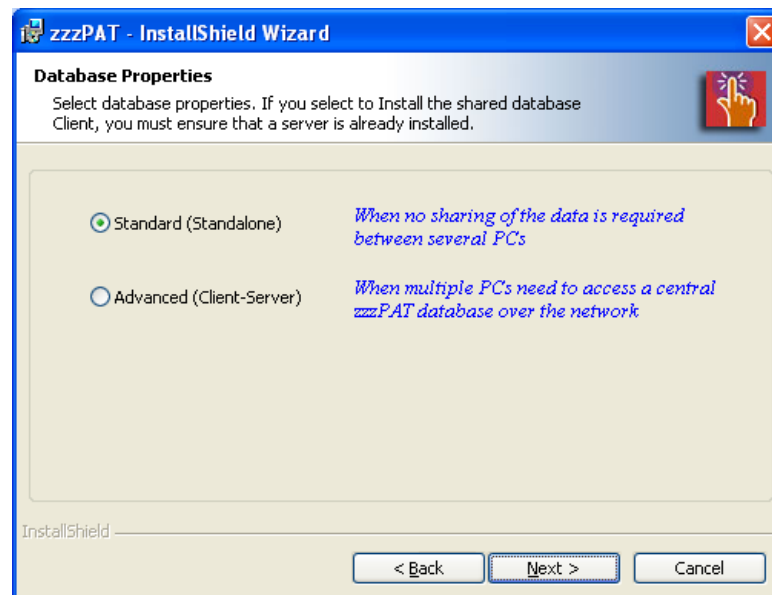


Figure 5 - Database Properties dialog box

### 2.5.1 Installations types

The zzzPAT software can be installed as a standalone or as a client/server configuration.

- "Standalone" - intended for users that do not require sharing that database with other zzzPAT stations.
- "Client/Server" intended for network installations with multiple zzzPAT stations accessing a central zzzPAT database over the network. If you wish to install this mode it is strongly advised to coordinate the installation with an Itamar Medical representative. Extra training is crucial for proper operation.
  - The "Server" mode is selected **only once prior** to installing the "Clients". This installation should be done on the dedicated computer which will serve as the server for the zzzPAT clients.
  - The "Client" mode is selected **only after** installing the "Server" and is **repeated for all clients**.

#### 2.5.1.1 Standard - Standalone installation only

The zzzPAT Installer will assist in selecting a destination location for the zzzPAT database. If the necessary folder does not exist, zzzPAT Installer will create the folder.

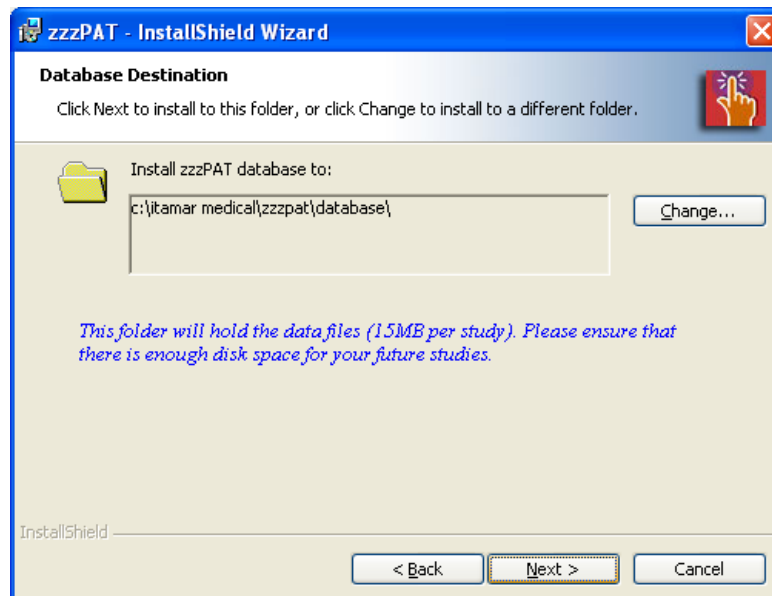


Figure 6 – Database Destination dialog box

If you wish to change the default folder, select the Change button. The 'Choose Folder' dialog appears.

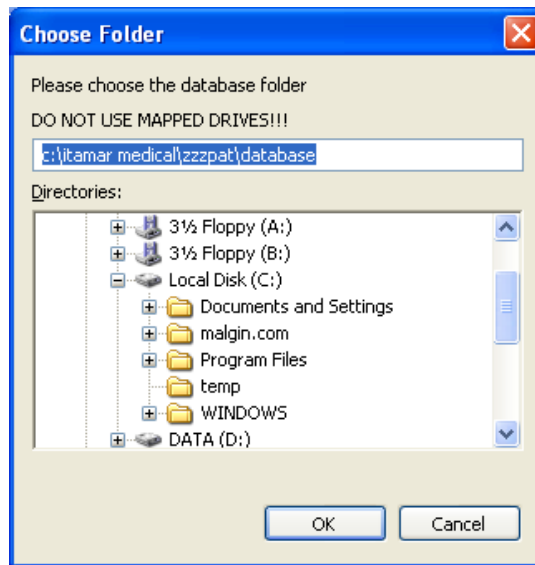


Figure 7 – Choose folder dialog box

Make sure you are not selecting a mapped drive. Select **OK** to Proceed.  
The zzzPAT Installer will assist in selecting a destination location for the zzzPAT application files. If you wish to change the default folder, select the Change button.

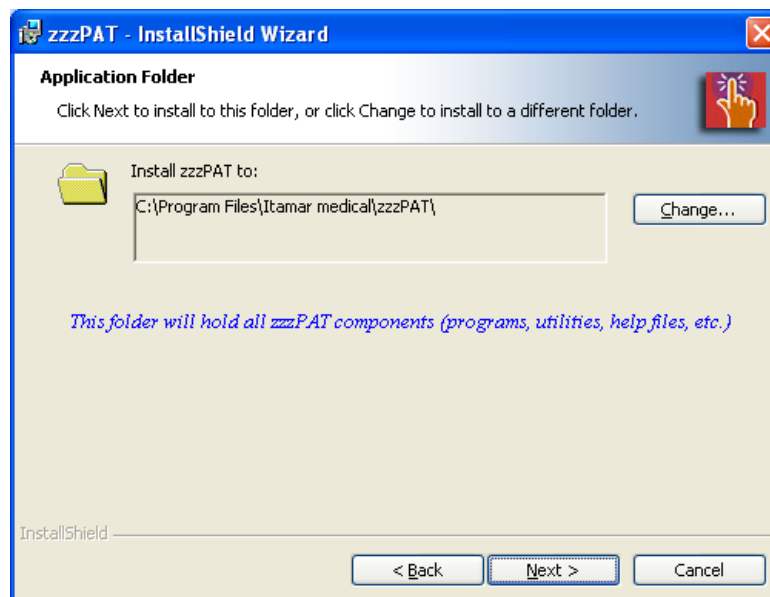


Figure 8 – Application folder dialog box

The last dialog before standalone installations summarizes your selections.  
After reading this summary, press **Install** to begin the installation.

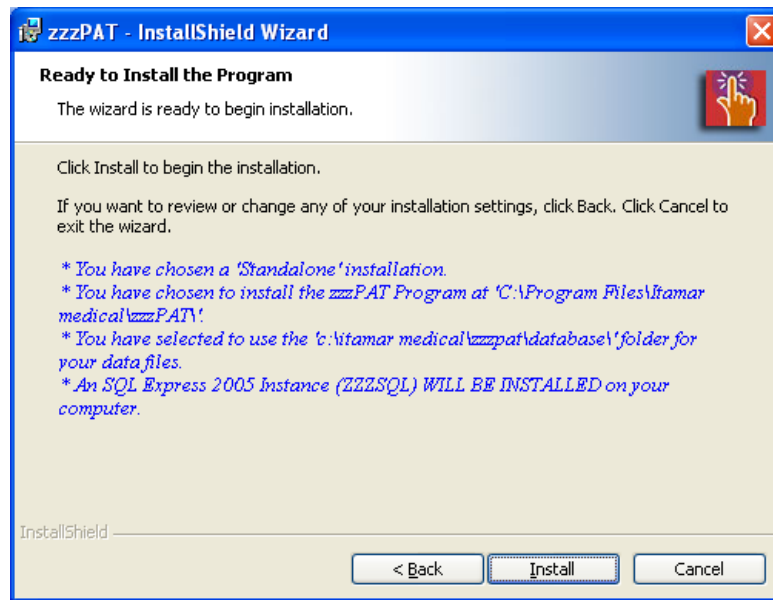


Figure 9 – Ready to Install dialog box

### 2.5.1.2 Advanced - Server installation only

The following selection will result in Server installation

The Server side installation creates a shared MS-SQL database that is used by multiple zzzPAT stations. Accordingly, the shared database needs to be created **only once per site installation**.

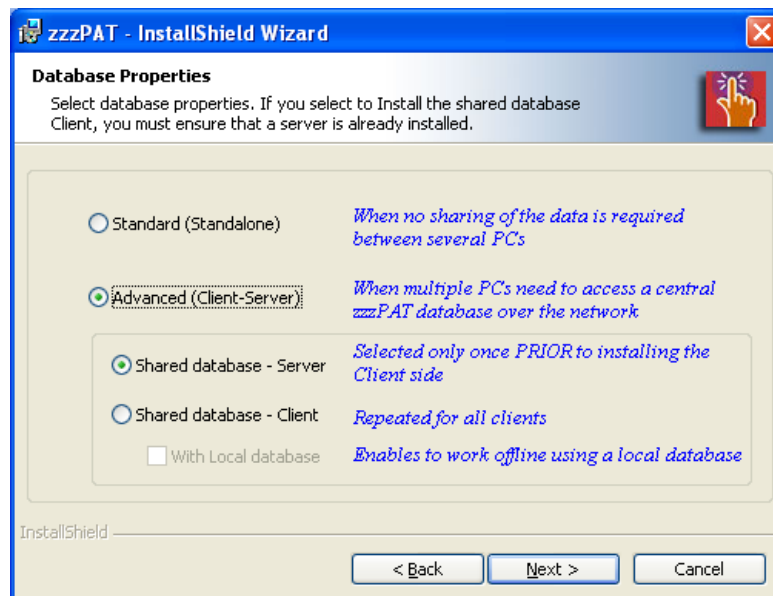


Figure 10 – Database Properties with Advanced options dialog box

The zzzPAT Installer will assist in selecting a destination location for the zzzPAT database.

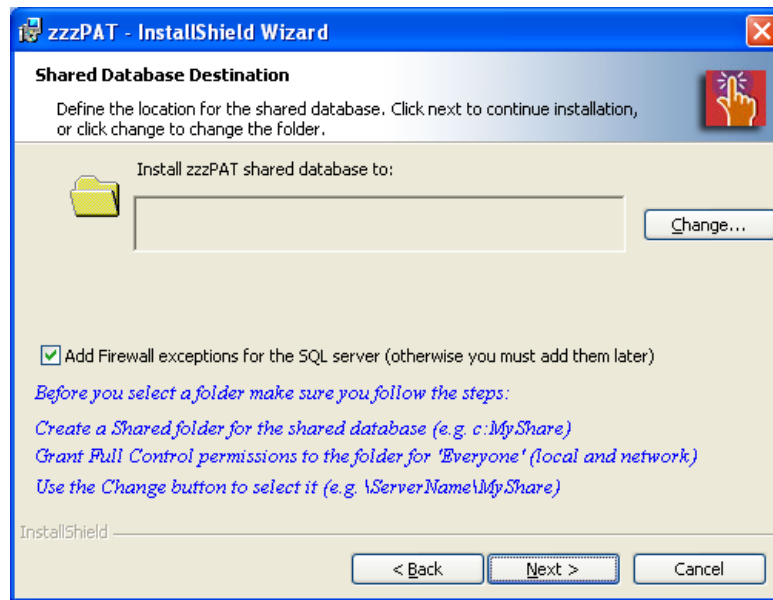



Figure 11 – Shared Database dialog box

Press the Change button to enter a UNC path for the database files folder. This folder will be accessed by all zzzPAT users so it needs to be shared in the network with full control permissions for the "Everyone" group.

	<p style="text-align: center;"><b>Note</b></p> <p><b>If you do not want to use the "Everyone" group</b>, please define a group of "zzzPAT" users and grant this group Full Access to this shared folder. In that case you will have to grant the <b>same permissions</b> to the following services:</p> <ul style="list-style-type: none"><li>SQL Server (ZZZSQL)</li><li>SQL Server VSS WRITER</li></ul>
---	---

The last dialog prior to beginning server installation summarizes your selections. After reading this summary, press **Install** to begin the installation.

### 2.5.1.3 Advanced - Client installation only

The following selection will result in Client installation

Prior to performing a Client side installation a Shared Database installation must be previously performed on a given PC.

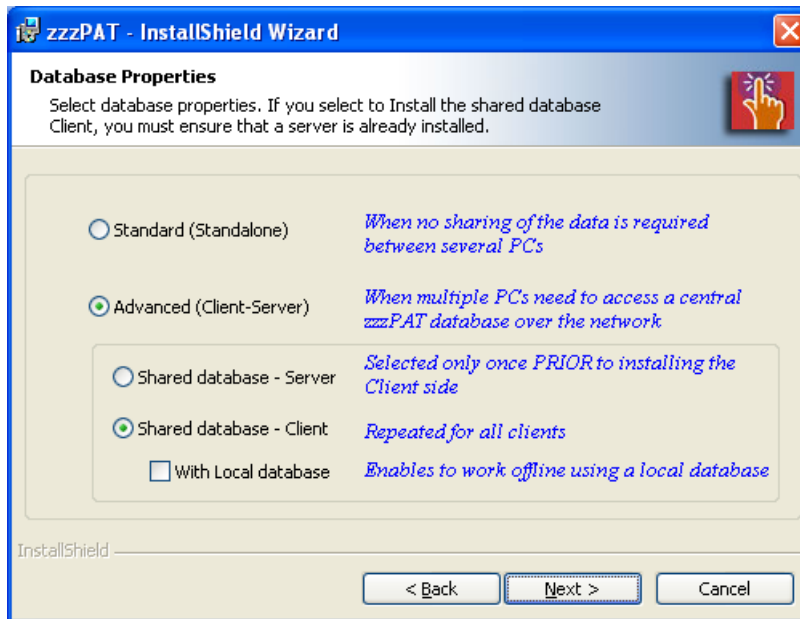


Figure 12 – Database Properties Advanced (Client) dialog box

The Client installation may also have a local database and during zzzPAT login the user can select to connect to the Shared or Local database. For this option you should check the “With Local database” check box.

It is not recommended to install the local database option unless offline work is anticipated with the particular computer.

Press **Next** to define the Shared Database.

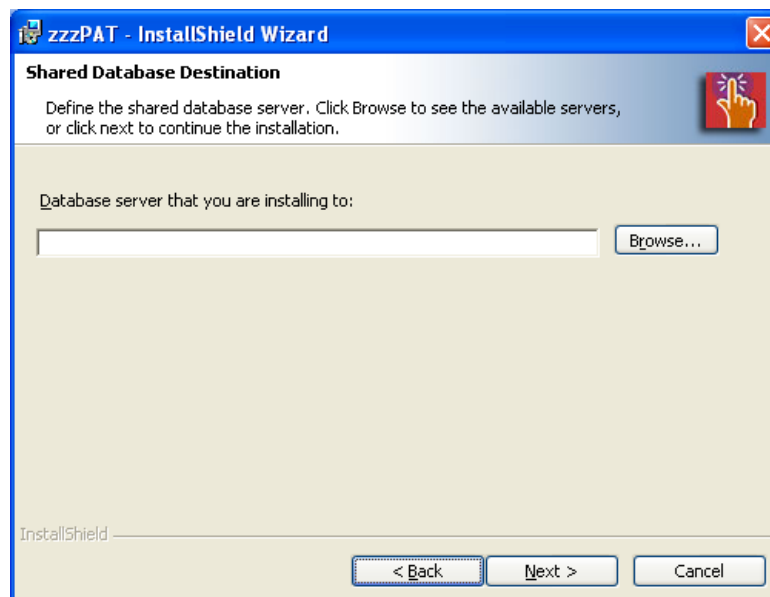


Figure 13 – Shared Database server dialog box

You can also enter the <name of the computer with the SQL server>\ZZZSQL , i.e. SQL\_PC\ZZZSQL

The zzzPAT installer will identify and display the currently defined database servers. Click Browse to see the ZZZSQL servers. The shared MS-SQL database can be selected from the list.

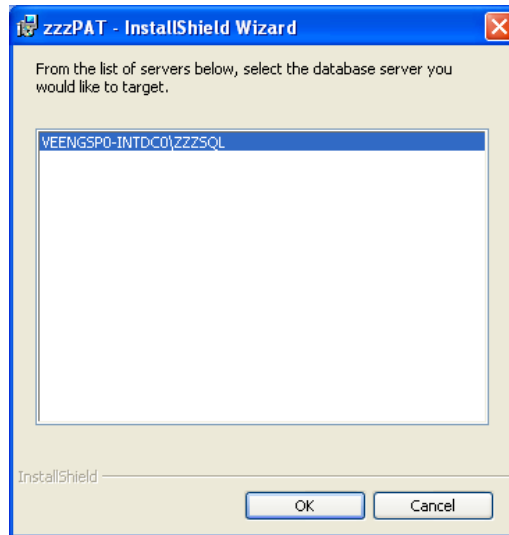


Figure 14 – Select Server dialog box

The zzzPAT Installer will assist in selecting a destination location for the zzzPAT application files. If you wish to change the default folder, select the Change button.

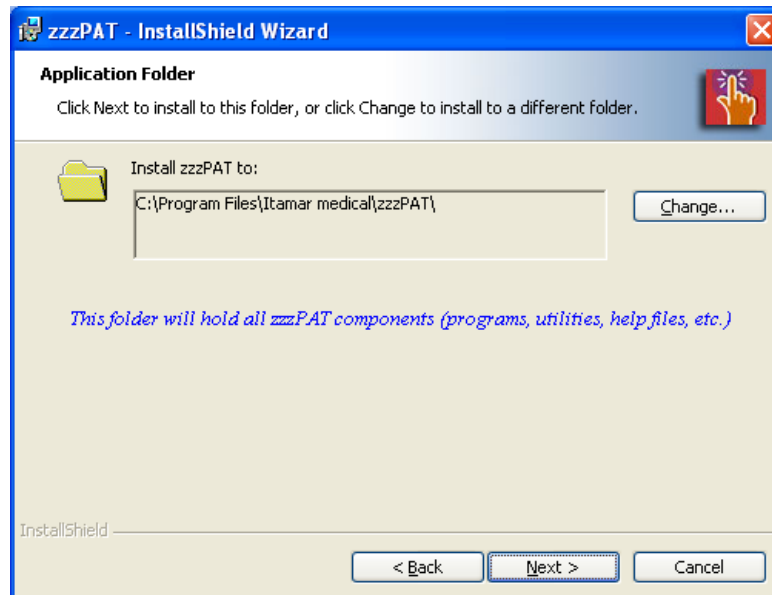


Figure 15 – Applications folder dialog box

Press **Next** to proceed.

The last dialog before client installation summarizes your selections. After reading this summary, press **Install** to begin the installation.

At the end of the installation the final dialog is displayed.

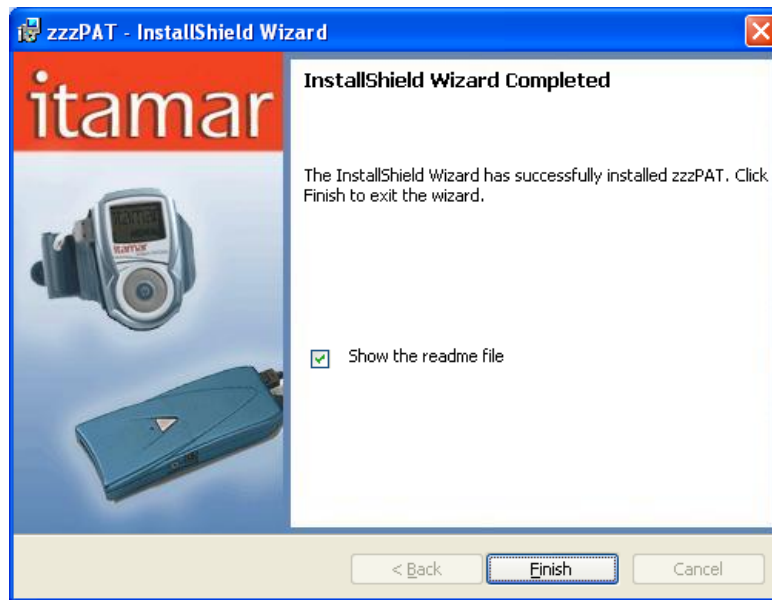




Figure 16 – Installation completed dialog box

At the end of the installation you should restart your computer

	<p style="text-align: center;"><b>Note</b></p> <p>A login name and password are needed to operate this software. The default administrator login information is: <b>Login name: 111</b> <b>Login password: 111</b> To modify the administrator login name and password, and to add/modify additional users, refer to section 2.9.</p>
---	---


	<p style="text-align: center;"><b>Warning</b></p> <ul style="list-style-type: none"><li>• Do not attempt to modify the zzzPAT software.</li><li>• It is recommended to close other programs when using zzzPAT to prevent possible conflicts.</li></ul>
---	--



## 2.6 Upgrading from previous versions

### 2.6.1 Upgrading a Standalone Installation


Before upgrading from a previous zzzPAT version, the older version must be uninstalled. The zzzPAT installer will identify if the older version has not been removed and will prompt you to uninstall it.

	<p style="text-align: center;"><b>Note</b></p> <p>Uninstalling zzzPAT does not remove the zzzPAT database, however, it is strongly recommended to backup the database before upgrading zzzPAT</p>
---	---


- Backup the entire database of the existing zzzPAT installation (see Database Wizard, Backup section 7.1.3).
- Uninstall the previous version using 'Add/Remove Programs' applet from the control panel.
- Select 'Setup.exe' from the zzzPAT installation CD-ROM to start the zzzPAT installation program.
- Follow stages 1-6 in section 2.5.

### 2.6.2 Upgrading a Shared Database Installation

Activating the Shared Database installation on an older version zzzPAT station will update the zzzPAT software only – the database will not be updated through the installer and will require a separate upgrade process described later in this section.

	<p style="text-align: center;"><b>Warning</b></p> <p>An upgraded zzzPAT will not always work with older versions of the database. Once an upgrade to a Shared Access installation zzzPAT station is made, both the local and shared access databases must be updated to the correct version before the zzzPAT can be put to use again.</p>
---	--

Before upgrading from a previous version of the zzzPAT, the older version must be uninstalled. The zzzPAT installer will identify if the older version has not been removed, and will prompt you to uninstall.

	<p style="text-align: center;"><b>Note</b></p> <p>Uninstalling zzzPAT does not remove the zzzPAT database, however, it is strongly recommended to backup the database before upgrading zzzPAT.</p>
---	--

- Backup the entire database of the existing zzzPAT installation (see Database Wizard, Backup section 7.1.3).
- Select 'Setup.exe' from the zzzPAT installation CD-ROM to start the zzzPAT installation program.
- Uninstall the previous zzzPAT version using 'Add/Remove Programs' applet from the control panel.
- Follow stages 1-5 in section 2.5.

### 2.6.2.1 Upgrading Databases

The upgrade will be performed automatically the first time zzzPAT is launched following an upgrade of zzzPAT, only if the database folder remained the same as the previous installation.

## 2.7 Defining the USB drive

To prepare a new study (**File>New Study Details** from zzzPAT), you must first define the USB drive.

**WP100 device only:** Place the Compact Flash card supplied with the WP100 in the USB drive that is connected to the PC with the zzzPAT software.

**WP200 device only:** Connect the device to the PC's USB drive using the supplied USB cable.

- Click **File>New Study Details** in zzzPAT. A dialog box will open (see Figure 38).
- Click **Select USB Drive** in the 'New Study' dialog box. The following window will appear:

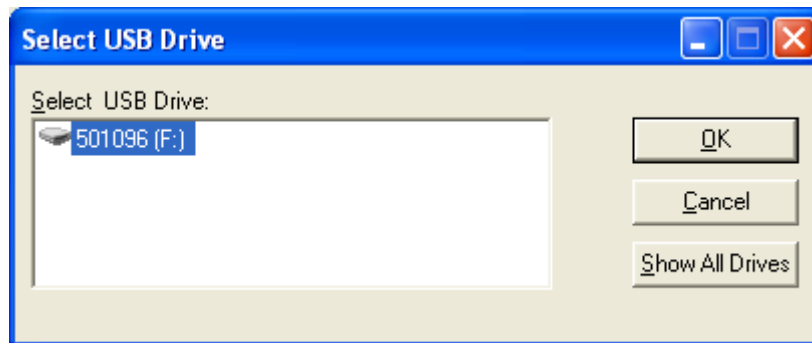


Figure 17 - Select USB Drive dialog box

- The USB drive with the Compact Flash card/WP200 device is identified by the zzzPAT, and is listed in this window. Click **OK** to confirm the drive selection.

## 2.8 Opening an ftp reception account with Itamar Support.

Opening an ftp signal reception account at Itamar Support after installing zzzPAT, will allow fast and efficient support if needed later. To do so:

- Open a sample study.
- Follow the steps in section 5.5.

## 2.9 Before using zzzPAT Software for the first time


In order to maintain the security of the information stored by the zzzPAT, it is recommended that you set new administration Login and Password, replacing the default setting.


### 2.9.1 Setting new login and Password for the zzzPAT Administrator

- Select **Tools>User Administration** from zzzPAT or navigate through: **Start>Programs>zzzPAT>Database Wizard** (see 2.6.2).
- Log in using the system default settings (in Shared Access mode this process needs to be repeated twice – once for the shared access database and once for the local database):
- Login: 111
- Password: 111
- A dialog box will open – Figure 18 for **Start>Programs>zzzPAT>Database Wizard** or Figure 19 for **Tools>User Administration**.




Figure 18 - zzzPAT database Wizard dialog box

- Click 'User Administration' icon . The 'User Administration' dialog box will open.
- Select 'Super User'.
- Click Edit User.
- Change the default Login from 111 to the new login.
- Change the default Password from 111 to a new password.
- Update the personal information.
- Click Save User.

	<p style="text-align: center;"><b>Note</b></p> <p>In Shared Access mode changing the administrator login for the shared access database needs to be performed only once. Changes to the local database administrator login needs to be changed in each of the zzzPAT stations.</p>
---	--

### 2.9.2 Setting a New user

Setting new user Login and Password and defining the permissions allowed for each user operating the zzzPAT.

- Launch the 'Database Wizard' and Click 'User Administration' icon  (see Section 2.9.1) or select **Tools>User Administration** from zzzPAT.
- The following dialog box will open:

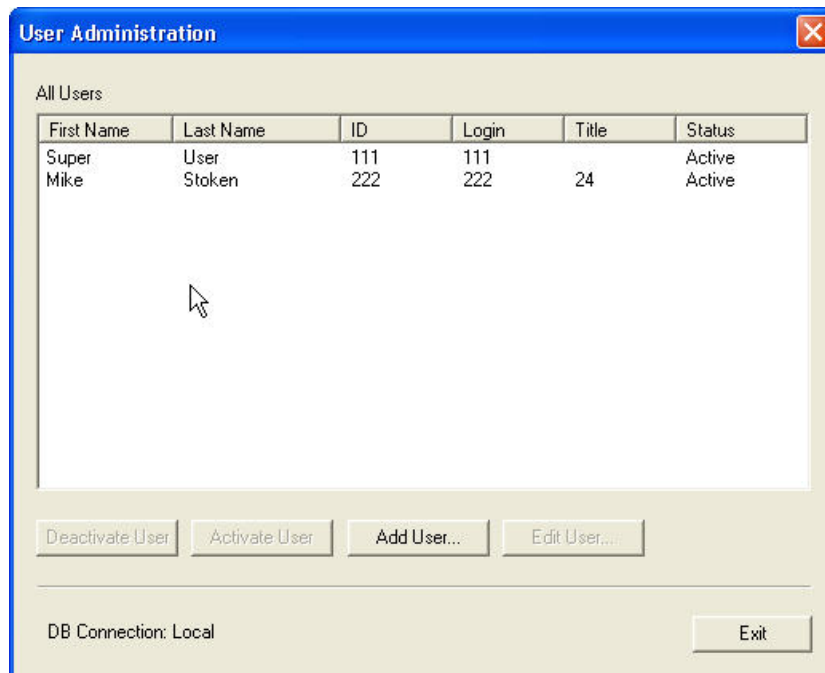


Figure 19 - User Administration dialog box

- Click **Add User**. The following dialog box will open:

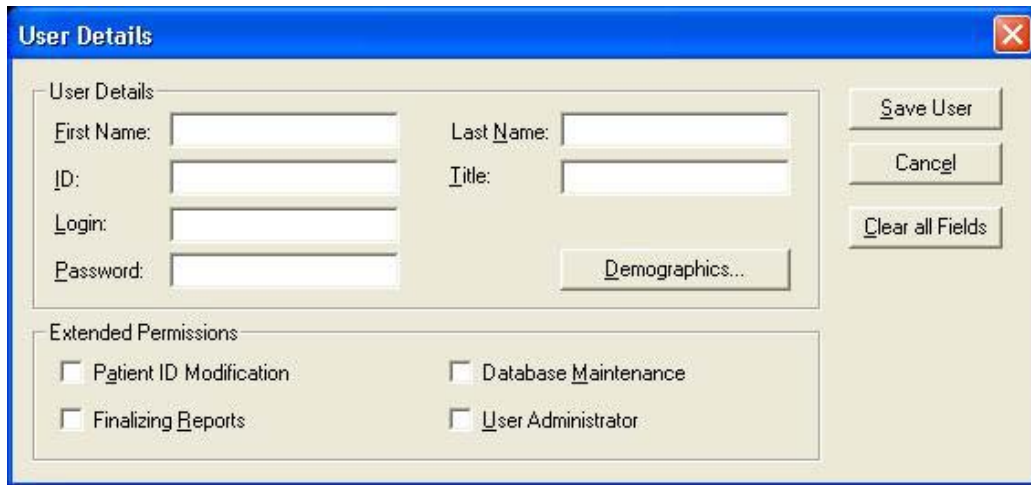


Figure 20 - User Details dialog box


- **User Details:** Fill all user details fields. **Demographics** information is optional.
- **Extended Permissions:** This section defines the functions each user is allowed to perform with the zzzPAT (see Table 1).


<b>Extended Permissions</b>	<b>Allowed activities</b>
No extended permissions selected	Basic User: <ul style="list-style-type: none"> <li>• Prepare a Compact Flash card for a new study</li> <li>• Load study into zzzPAT</li> <li>• Issue reports</li> </ul>
Patient ID Modification	Basic User plus: <ul style="list-style-type: none"> <li>• Modify a patient's ID</li> </ul>
Finalizing report	Basic User plus: <ul style="list-style-type: none"> <li>• Finalizing the report. This action locks the current analysis, so that no further changes can be made to the analysis and report.</li> </ul>
Database Maintenance	Basic User plus: <ul style="list-style-type: none"> <li>• Database export, import, delete, backup, restore and upgrade functions. (See section 5)</li> </ul>
System Administrator	Basic User plus: <ul style="list-style-type: none"> <li>• Adding users to zzzPAT and defining their permissions</li> <li>• Customizing capabilities for the General Settings</li> </ul>

Table 1 - User Permissions

To deactivate a user:

- Click on the User's name in the 'User Administration' dialog box.
- Click Deactivate User.

	<p style="text-align: center;"><b>Note</b></p> <p>Permanently removing a user from the system is not possible. User's information is part of the study records, and cannot be deleted.</p>
---	--

	<p style="text-align: center;"><b>Note</b></p> <p>The original user (originally named "Super User") cannot be deactivated. It can only be modified with a new name and password to ensure continued access with System Administrator's privileges.</p>
---	--

## 3 Setting Up zzzPAT Configuration

### 3.1 Setup>Set USB Drive

Sets the path to the Compact Flash drive (for WP100) or WP200 device.

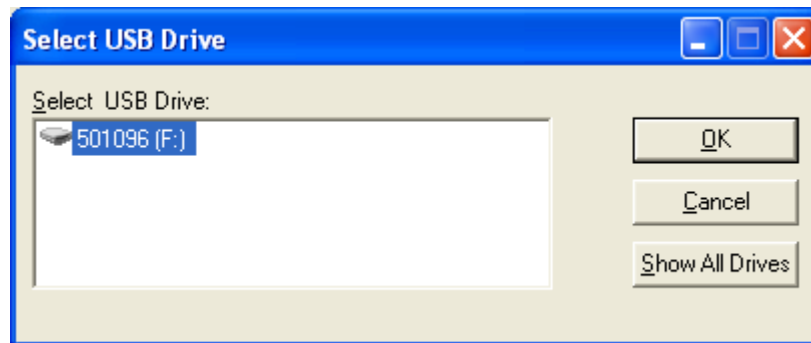


Figure 21 - Select USB Drive dialog box

### 3.2 Setup>Directories

Displays the zzzPAT working directory, the name of the currently connected database, the files directory (signal files data) and the USB drive.

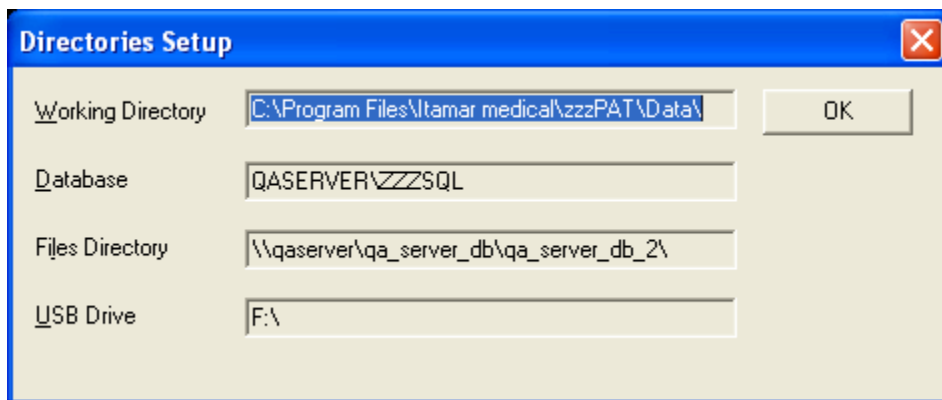



Figure 22 - Set Directories dialog box

### 3.3 Setup>User Settings

The user can change the following Setup parameters by opening the 'User Settings' dialog box from **Setup>User Settings**. 'User Settings' setup parameters are stored in the zzzPAT database for each user (either the local database in a standalone installation or the shared access database in a Shared Access installation).

	<p style="text-align: center;"><b>Note</b></p> <p>In a Shared Access mode, when a user logs in from several zzzPAT stations simultaneously, changes to some of the user configurable settings of zzzPAT may not be saved after the zzzPAT session ends</p>
---	--

When all settings changes are completed, click **OK** to close the Settings dialog box. The following dialog box will open:

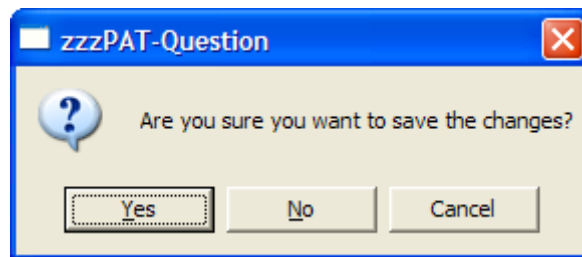


Figure 23 - Save settings for current user question

Clicking **Yes** will save the changes.

Clicking **No** will exit 'User Settings' Dialog Box.

Clicking **Cancel** will return the last displayed dialog box.

### 3.3.1 Setup>User Settings>Montage

Defines which channels will be presented on the zzzPAT screen, and in what order. This setting is saved in the 'User Profile' file.

The Montage page consists of a list of all signal channels available for viewing:

- PAT- PAT signal.
- Heart Rate - Derived from the PAT signal.
- PAT Amplitude - PAT signal envelope.
- SaO<sub>2</sub> - Arterial blood Oxygen saturation level.
- Actigraph - Actigraphy signal.
- WP100 or WP200 Stages – REM, Light Sleep, Deep Sleep and Wake stages.
- Body position
- Snore



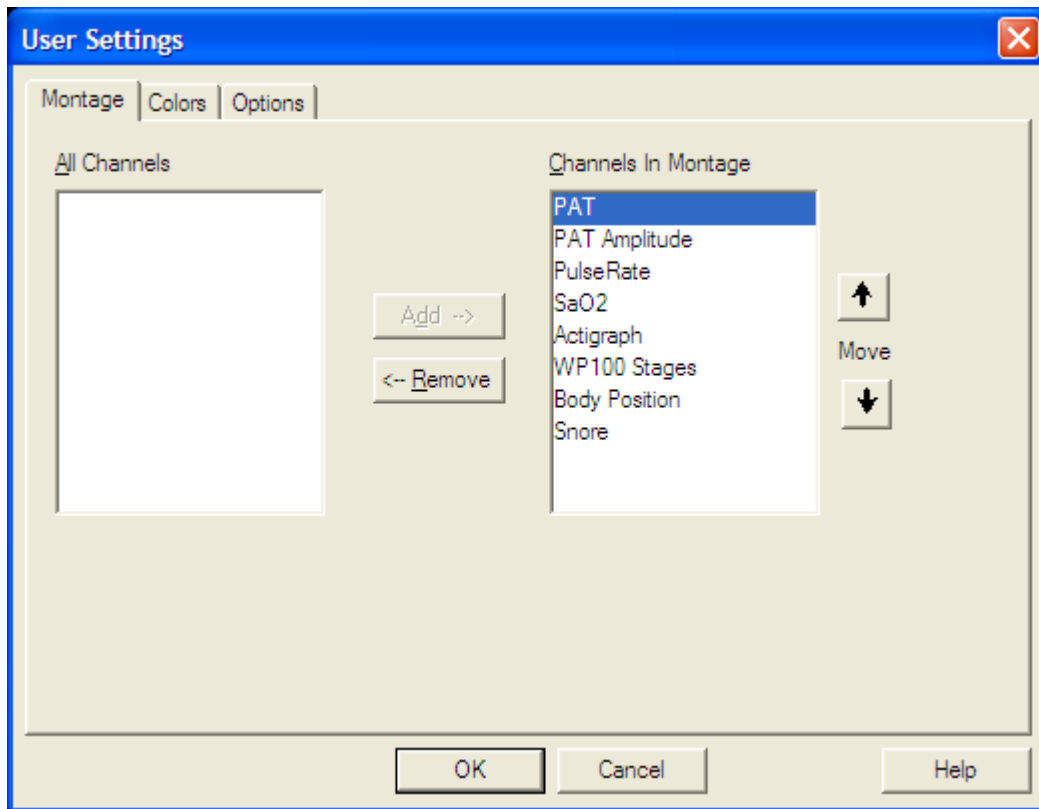


Figure 24 - Setting Montage of zzzPAT display

**To add a channel:**

- Select the channel in the 'All Channels' window and click **Add**.

**To remove a channel:**

- Select the channel in the 'Channels In Montage' window and click **Remove**.

**To change the order of appearance of the channels:**

- Select a channel and then click **↑** or **↓** until you reach the desired order.

### 3.3.2 Setup>User Settings>Colors

Colors Setup page (Figure 25) consists of a list of all the display elements that can be colored, allowing the user to personalize the screens. The example area provides a preview of the selected color scheme. This setting is saved in the 'User Profile' file.

**To change a color:**

- Select a display element from the list.
- Click the **Change Color** button to select a new color. The preview is displayed in the 'Example' area.

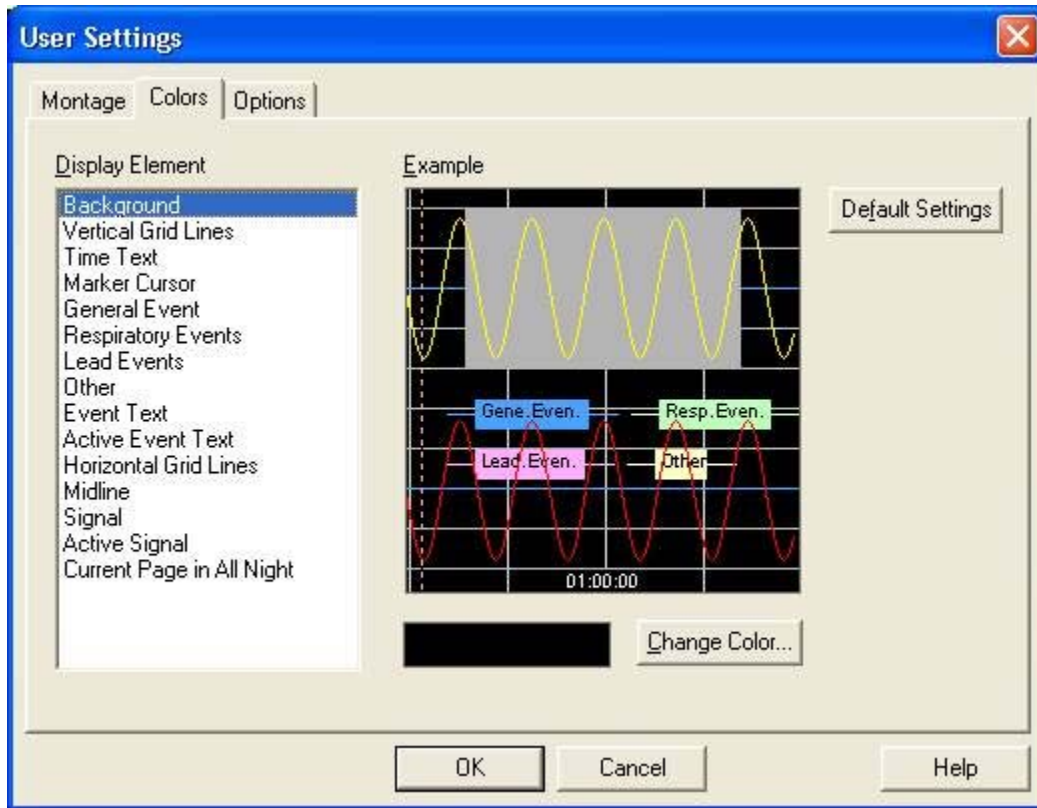



Figure 25 - Setting colors of zzzPAT display

	<p style="text-align: center;"><b>Note</b></p> <p>Be careful not to choose a color that blends into one of the background elements</p>
---	--

### 3.3.3 Setup>User Settings>Options

Defines if and when the 'Sleep Report' or 'Sleep Indices' report is displayed automatically.

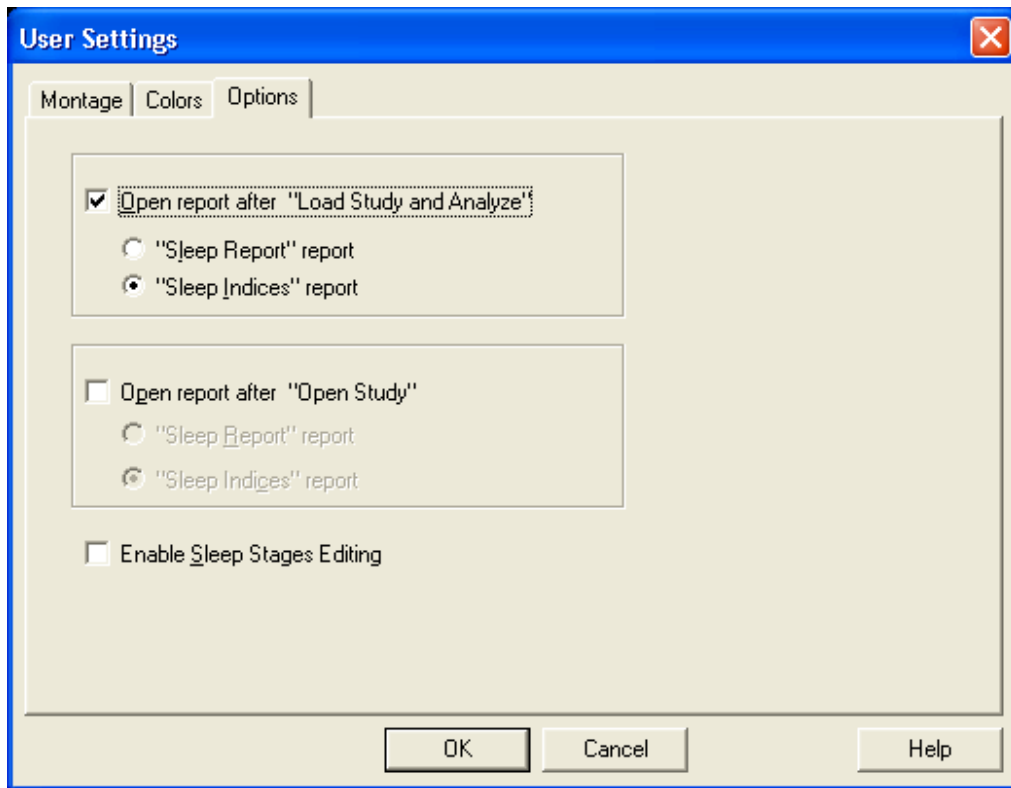


Figure 26 - Setting "Sleep Indices" report box

You can select to open a report either after "Load Study and Analyze" by selecting 'Open report after "Load Study and Analyze"' or/and for existing study by selecting 'Open report after "Open Study"'. Both options contain radio-buttons that enable you to select between Sleep Report and Sleep Indices report.

- When selecting "Sleep Report" report, the sleep report opens automatically.
- When selecting "Sleep Indices" report, the sleep indices report appears automatically on display, and the sleep report opens upon command.

You can select "Enable Sleep Stages Editing" if you want to be able to edit manually the Sleep stages (see Editing Sleep Stages).

### 3.4 Setup>General Settings

Only a user, with 'User Administration' permission, can change the following Setup parameters by opening the 'General Settings' dialog box from **Setup>General Settings**. 'General Settings' are stored in the zzzPAT database (either the local database in a standalone installation or the shared access database in a Shared Access installation).

These settings are global. Modified settings become available to all users.

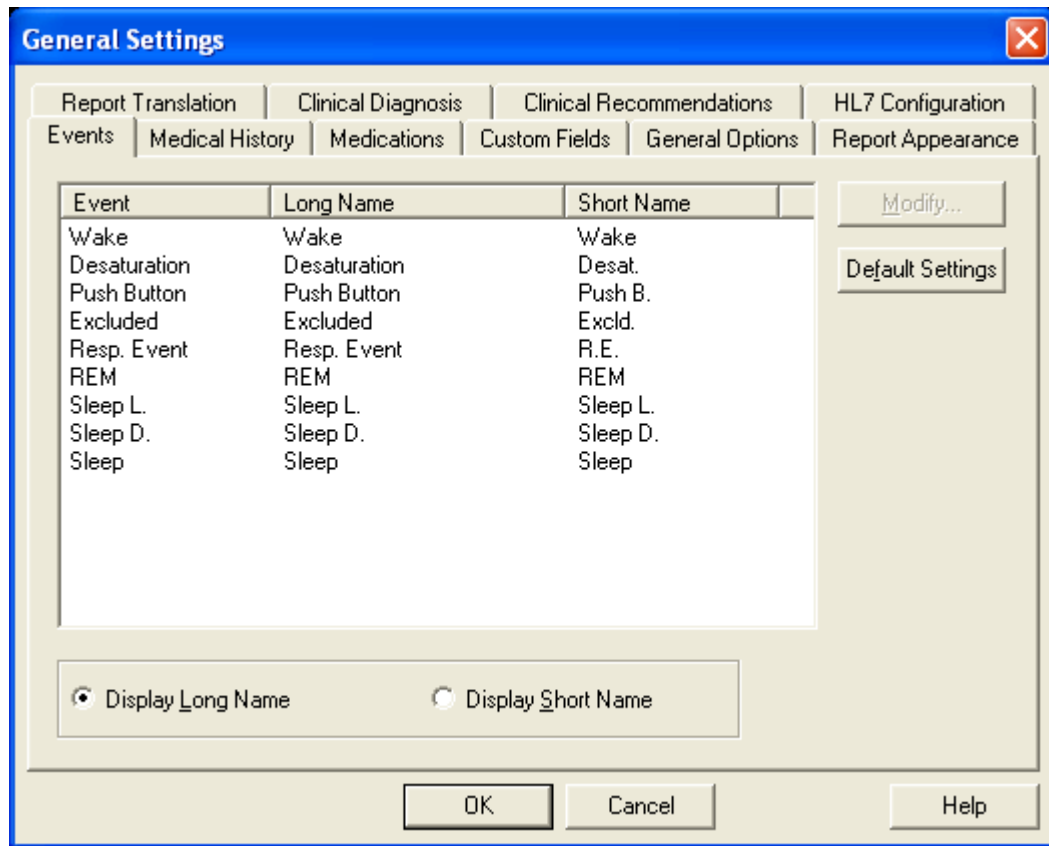


Figure 27 - General Settings Setting Dialog Box – Events Tab

When all settings changes are completed, click **OK** to close the General Settings dialog box. The following dialog box will open:

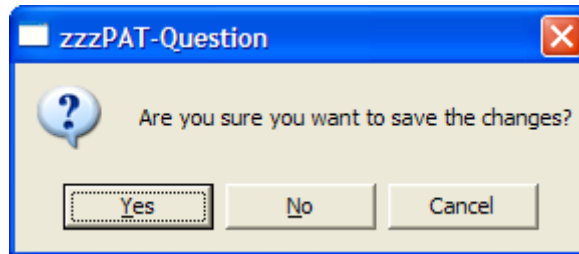


Figure 28 - Save settings question

- Clicking **Yes** will save the changes.
- Clicking **No** will exit 'General Settings' dialog box.
- Clicking **Cancel** will return the last displayed dialog box.


### 3.4.1 Setup>General Settings>Events

A list of Event types is listed in the events tab (Figure 27). The list includes event type, long name, short name and category for each event.

**To Modify an Event in the Settings list:**

- Click on the Event in the list box. The **Modify** and **Default Setting** buttons become enabled.
- Click the **Modify** button. 'Modify Event Definition' dialog opens.
- Enter the required names in the fields.
- Click 'OK' to confirm and exit.

**Default Settings** reverts to the default event list.

	<p style="text-align: center;"><b>Note</b></p> <p>Clicking the <b>Default Settings</b> will revert to default settings losing all user-defined settings.</p>
---	--

**3.4.2 Setup>General Settings>Medical History**

A preliminary list of medical condition descriptions is listed in the Medical History Tab (Figure 29).

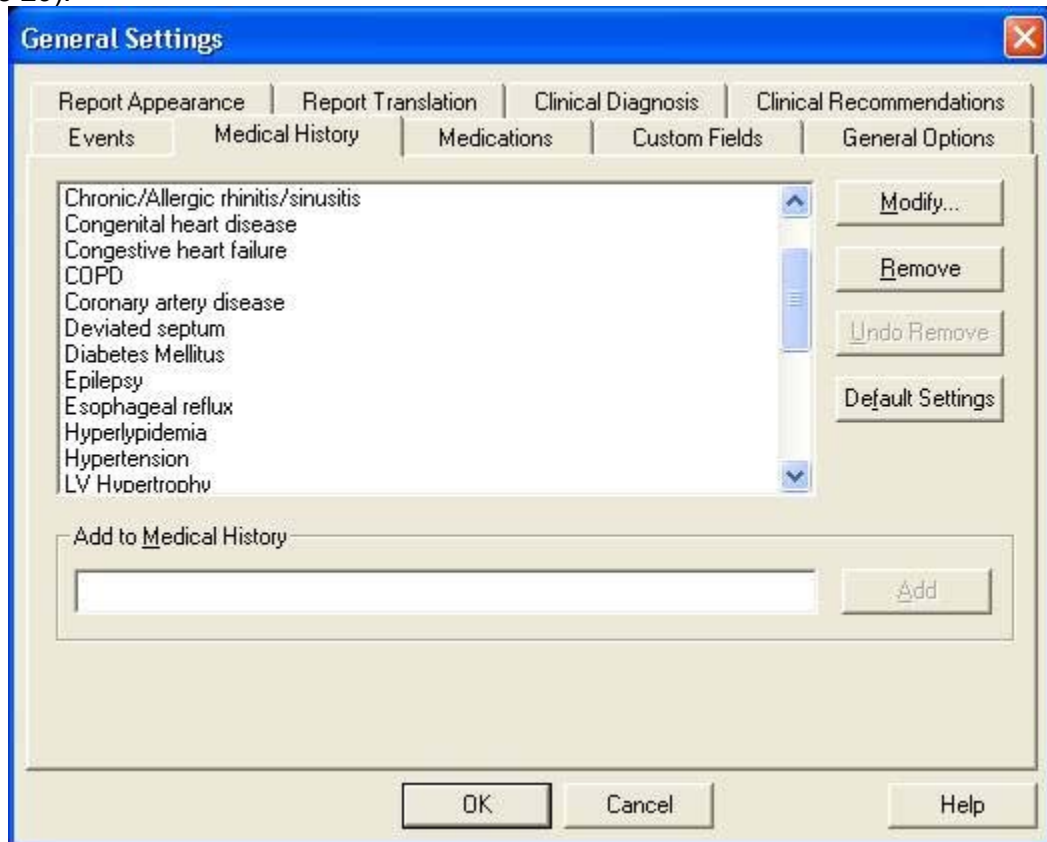


Figure 29 - General Settings Dialog Box – Medical History Tab

**To add a condition to the list:**

- Type the condition in the 'Add to Medical History' box. The **Add** button becomes enabled.
- Click **Add**.

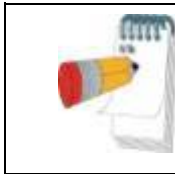
**To modify a condition:**

- Click on the condition.
- Click **Modify**. The 'Modify' dialog box opens with the selected condition name.
- Type in the desired changes.

**To remove a condition from the list:**

- Click on the condition.
- Click **Remove**.
- Click **OK** or **Apply**.

**Default Settings** reverts to the default list.



**Note**

Clicking the **Default Settings** will revert to default settings losing all user defined setting.

### 3.4.3 Setup>General Settings>Medications

A default list of Medications is listed in the medication tab.

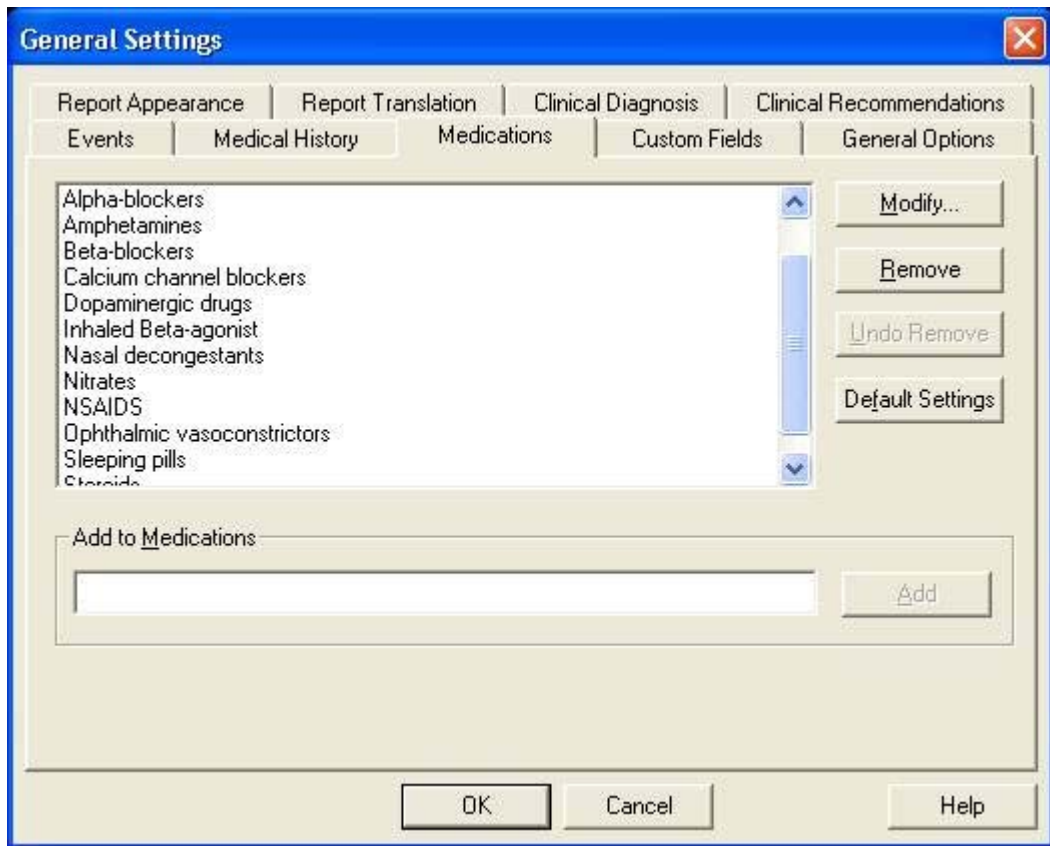


Figure 30 - General Settings Dialog Box – Medications Tab

**To add a Medication to the list:**

- Insert Medication name in the 'Add to Medication' text box. The **Add** button becomes enabled.
- Click **Add**.


**To modify a Medication:**

- Click on the listed Medication.
- Click **Modify**. The Modify dialog box opens with the selected Medication name.
- Type in the change requested.

**To remove a Medication from the list:**

- Click on the listed Medication.
- Click **Remove**.

**Default Settings** reverts to the default list.

	<p style="text-align: center;"><b>Note</b></p> <p>Clicking the <b>Default Settings</b> will revert to default settings losing all user defined setting.</p>
---	---

### 3.4.4 Setup>General Settings>Custom Fields

Up to three 'Custom Fields' can be defined and named by the user. These 'Custom Fields' can be used to organize your studies in the 'Select Patient Study' dialog box (Figure 46) and during the Export/Import process. These custom fields are available to all users.

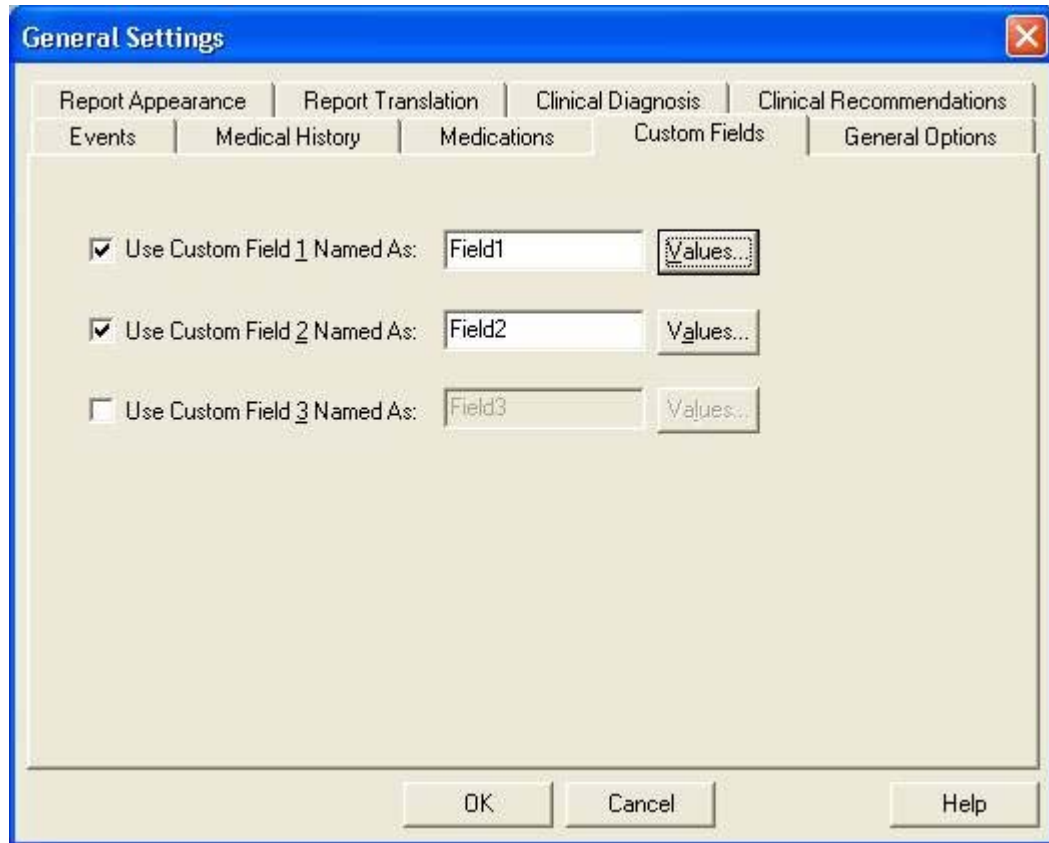


Figure 31 - General Settings Dialog Box – Custom Fields Tab

#### To enable a custom field:

- Check the box to the left of the custom field. The **Values** button becomes enabled.
- Write the title of your choice for this field in the text box (for example CHF).
- Click the **Values** button, the following dialog box will open:



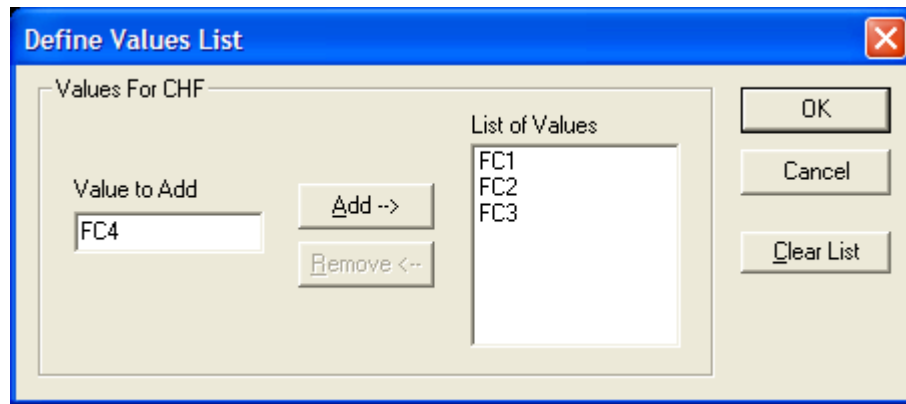



Figure 32 - Define Values List Dialog box

**To insert a value into the 'List of Values' field:**

- Write a value you wish to insert into the 'Value to add' text box, the **Add** and **Remove** buttons will become enabled.
- Click **Add**.

**To delete a value from the list of values you created:**

- Click on the value and click **Remove**.
- Click **OK** to save settings.

	<p style="text-align: center;"><b>Note</b></p> <p>Defining values can assist you when entering the information into these fields while preparing a 'New Study', but you can also type free text values into these fields.</p>
--	---

### 3.4.5 Setup>General Settings>General Options

Used to set up reminders to backup the database, alerts when available disk space is below 1GB and in order to enable features that not enabled by default (import packed studies, multi-night studies and tamper-proof testing).

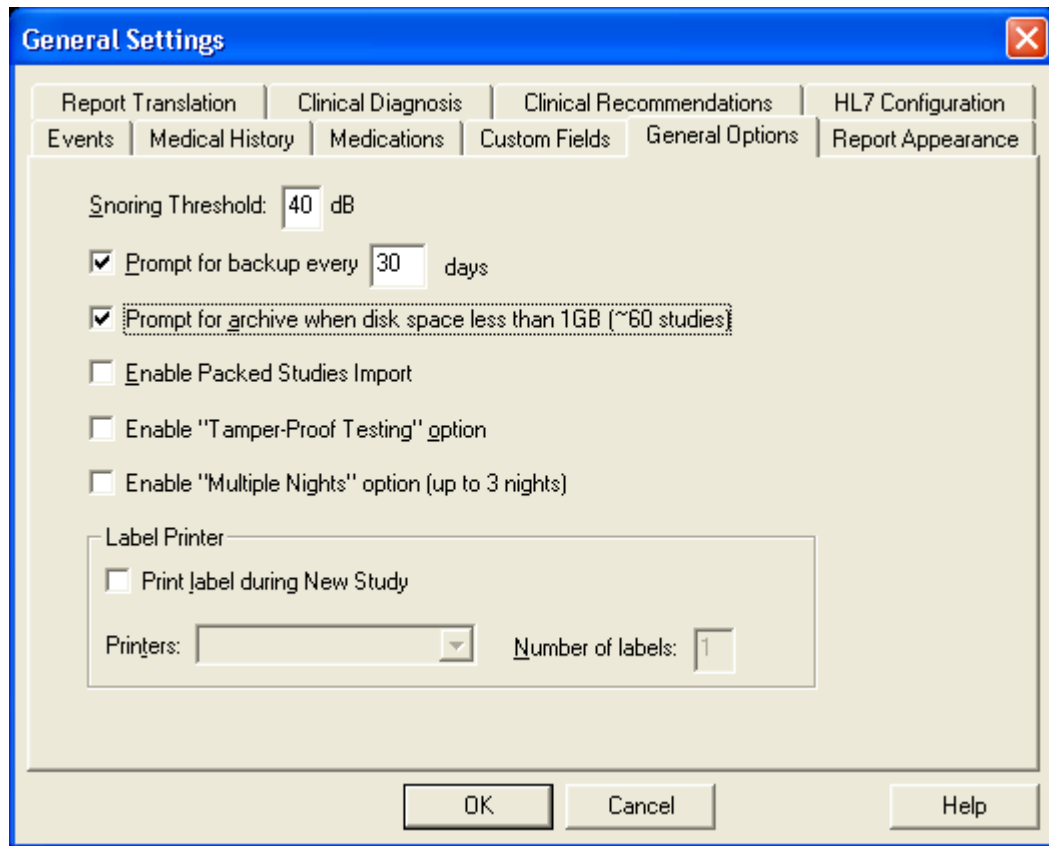



Figure 33 - General Settings Dialog Box – General Options Tab

- Select snoring threshold to be used in calculating snoring statistics (3<sup>rd</sup> page of report) – used only in non-USA version.
- Check “Prompt for backup every ...” and set the numbers of days to get a reminder message after the last backup of the database was performed.
- Check “Prompt for archive when disk space ...” to get an alert message when available disk space is lower than 1GB.
- Check “Enable Packed Studies Import” if you have access to packed studies from ftp uploads. By enabling this option you can import studies that were uploaded by ftp by selecting Tools>Import Packed studies option from the main menu.
- **For WP200 only:** Enable "Tamper-Proof Testing" if you want to use the Patient Identification Bracelet. By enabling this option you can select to use the bracelet while preparing a New study (see Preparing a New Study).
- **For WP200 only:** Check “Enable Multiple Nights" option if you want to enable the Watch-PAT200 recording up to 3 nights in a row while preparing a New study (see Preparing a New Study).

	<p style="text-align: center;"><b>Note</b></p> <p>The "Enable Tamper-Proof Testing" and "Enable Multiple Nights" options are available only when the WP200 internal S/W is version 2.2182 and higher.</p>
---	---

- Check "Print label during New Study" and set the label Printer and the number of labels if you wish to have labels automatically printed when you prepare "New Study Details". This feature will work only with pre-defined label printers. The printers must print at 3 secs/label at a minimum and must be defined by Itamar Medical. The information printed on the label (2x5 cm) will include the following fields: Patient ID, Patient First and Last name, Date of Compact Flash preparation and Coverage (field that may be used for additional data such as device #, etc.). The labels may be attached to WP100 or WP200 suitcases as to provide easy identification of the designated patient after the WP100 or WP200 devices have been initialized with the patient details.

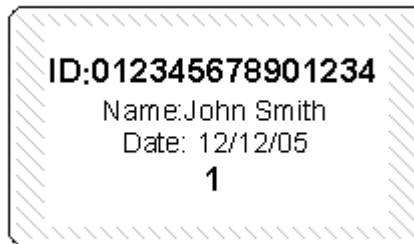



Figure 34 – Label example

	<p style="text-align: center;"><b>Note</b></p> <p>Contact Itamar Medical for a list of the supported label printers.</p>
---	--

### 3.4.6 Setup>General Settings>Report Appearance

Used to change the basic Report appearance, adding a logo, affiliation, header and footer.

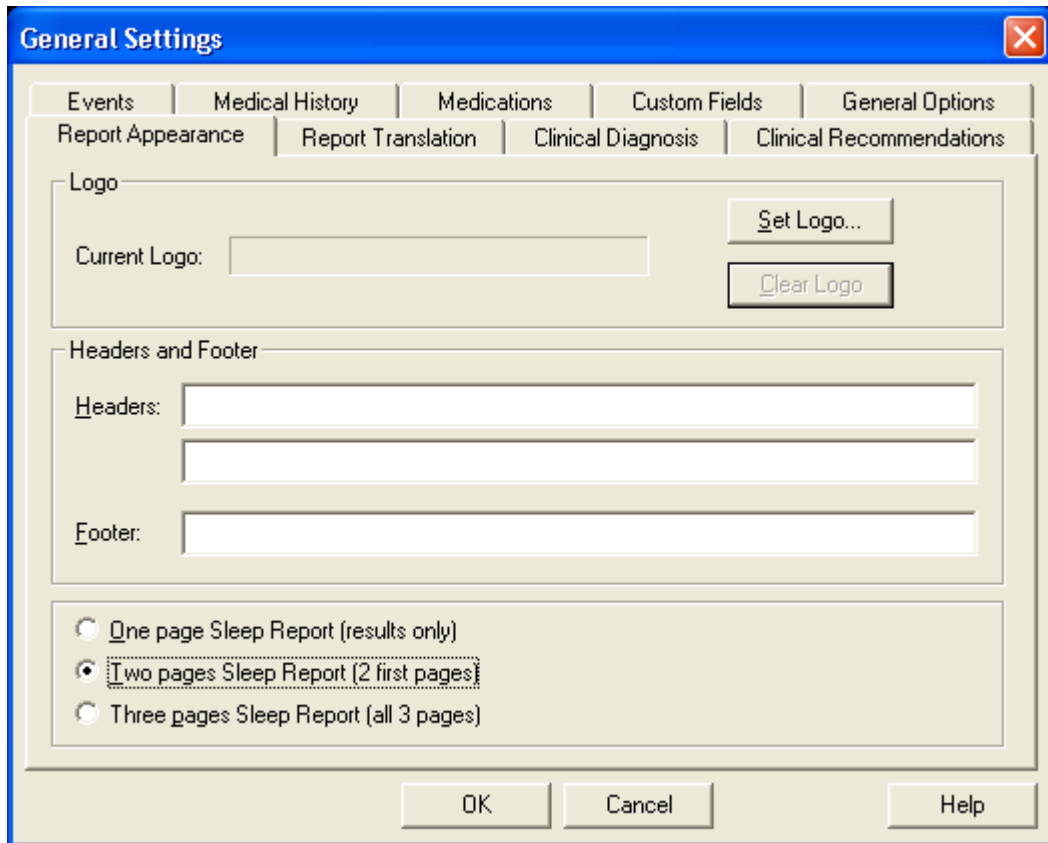


Figure 35 - General Settings Dialog Box – Report Appearance Tab

#### To add a logo to the sleep report:

- Click the **Set Logo...** to browse for the desired logo file. File may be in bitmap (BMP extension) or JPEG (JPG or JPEG extensions) formats. Highlight the logo file and click **Open** to add the icon. Note that actual icon size in the report does not exceed 140X100 pixels, therefore larger images will be resized for proper printing.
- To clear the selected logo click **Clear Logo**.

#### To add a header/footer to the sleep report:

- Type in the desired header text in the Headers field.
- Type in the desired footer text in the Footer Field.

#### To set the number of pages of the Sleep Report:

- Select "One page Sleep Report" to see the results (statistics and signals) page.

- Select "Two pages Sleep Report" (default) to see patient, physician and study information in addition to the "One page Sleep Report".
- Select "Three pages Sleep Report" to see sleep/wake states, sleep stages and respiratory indices charts in addition to "Two pages Sleep Report".

### 3.4.7 Setup>General Settings>Report Translation

Used to change the sleep report headings.

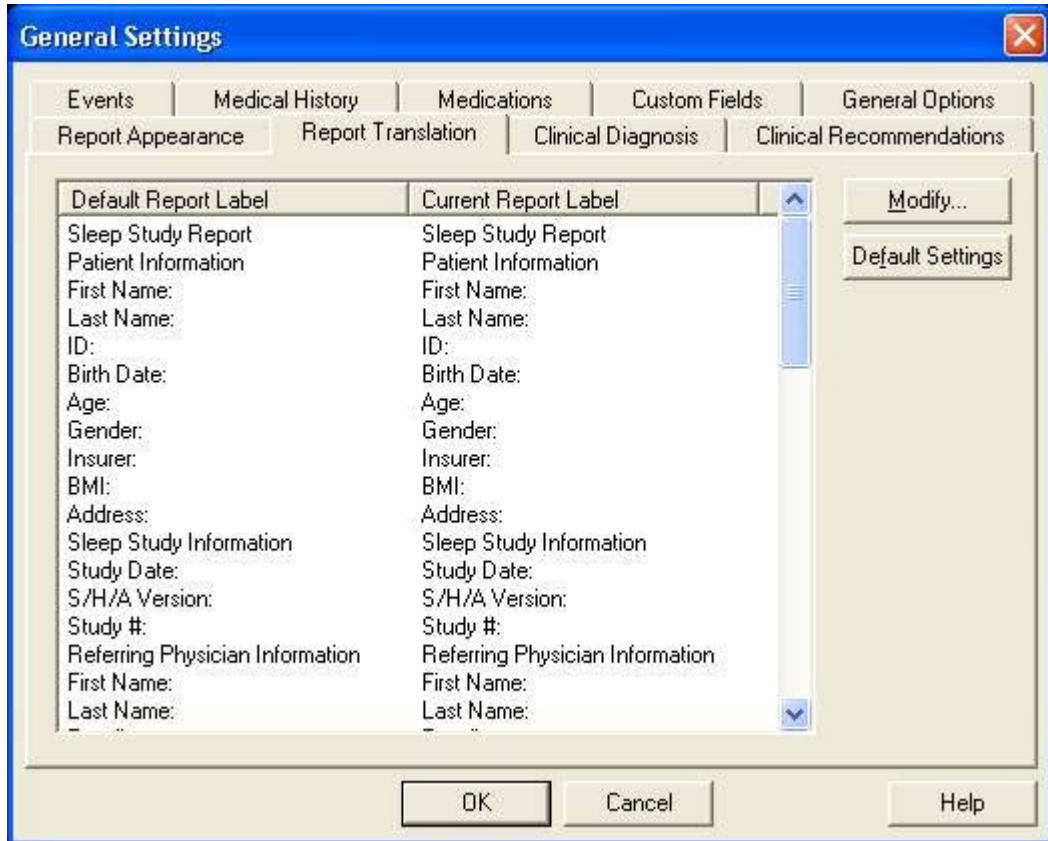



Figure 36 - General Settings Dialog Box – Report Translation Tab

#### To translate report headings to a different language:

- All report field labels may be changed by selecting the desired report field and clicking **Modify....** In the dialog box that opens you can type the new text to be used in the reports.
- Click **Default Settings** to revert to the default text for all report field labels.

	<p style="text-align: center;"><b>Note</b></p> <p>Clicking the <b>Default Settings</b> will revert to default settings losing all user defined report labels</p>
---	--

### 3.4.8 Setup>General Settings>Clinical Diagnosis

**To add a Clinical Diagnosis to the list:**

- Insert Clinical Diagnosis name in the 'Add to Clinical Diagnosis' text box. The **Add** button becomes enabled.
- Click **Add**.


**To modify a Clinical Diagnosis:**

- Click on the listed Clinical Diagnosis.
- Click **Modify**. The Modify dialog box opens with the selected Clinical Diagnosis name.
- Type in the change requested.

**To remove a Clinical Diagnosis from the list:**

- Click on the listed Clinical Diagnosis.
- Click **Remove**.

**Default Settings** reverts to the default empty list.

	<p style="text-align: center;"><b>Note</b></p> <p>Clicking the <b>Default Settings</b> will revert to empty settings losing all user defined setting</p>
--	--

### 3.4.9 Setup>General Settings>Clinical Recommendations

**To add a Clinical Recommendations to the list:**


- Insert Clinical Recommendations name in the 'Add to Clinical Recommendation' text box. The **Add** button becomes enabled.
- Click **Add**.

**To modify a Clinical Recommendation:**

- Click on the listed Clinical Recommendations.
- Click **Modify**. The Modify dialog box opens with the selected Clinical Recommendations name.
- Type in the change requested.

**To remove a Clinical Recommendation from the list:**


- Click on the listed Clinical Recommendations.
- Click **Remove**.

	<p style="text-align: center;"><b>Note</b></p> <p>Clicking the <b>Default Settings</b> will revert to empty settings losing all user defined setting.</p>
---	---



## 4 Using zzzPAT

### 4.1 Preparing a New Study

Preparing the Patient file is a mandatory stage in the preparation of the WP100 or WP200 devices for a sleep study. Before proceeding, make sure that the Compact Flash reader drive was defined as described in Section 2.7.

	<b>Warning</b>  <b>For WP100 only:</b> Use only Itamar provided Compact Flash cards. The Compact Flash cards used by the WP100 have a special format. Compact Flash Cards with regular format will not work and their use will result in a failed test! All references to “Compact Flash cards” in this user manual, refer to Itamar supplied Compact Flash Cards only.
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#### 4.1.1 Launching zzzPAT

- Launch ‘zzzPAT’ by clicking the zzzPAT icon  on your desktop or navigate through: **Start>Programs>zzzPAT>zzzPAT**.
- If the zzzPAT icon  is launched the following login dialog opens:

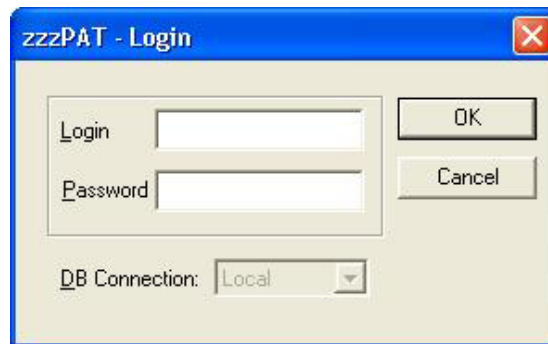




Figure 37 - Login Dialog Box

- Enter Login and Password. When a Shared Access mode is installed, the login screen allows the user to choose to which database the zzzPAT will connect.


	<p style="text-align: center;"><b>Note</b></p> <p>In Shared Access mode it is highly recommended to always connect to the Shared database - this will ensure all data is stored in one central location allowing future retrieval from all connected stations. Local database should be selected only if network access is not available, or for special purposes (training, travel etc...).</p>
---	--

	<p style="text-align: center;"><b>Note</b></p> <p>In Shared Access mode, if data was stored on the local database, it is recommended to export the data into the Shared Access database as soon as practical.</p>
---	---

- If applicable, select the desired database to connect to. Local database should be selected only if network access is not available, or for special purposes (training, travel etc...).
- Enter your login name and password and click **OK** to continue.

#### 4.1.2 Preparing a New Study

**For WP100 only:**

- Make sure a Compact Flash card is in the Compact Flash reader and connected to the PC with the zzzPAT software.
- Click **File>New Study Details** in zzzPAT, or click the 'New Study' icon  in the tool bar.
- The 'New Study' dialog box appears:



**New Study**

**Patient**

ID:  (Mandatory)

First Name:  Last Name:

Date of Birth:  /  /  Age:  Gender:  Male  Female

Height:  '  " Weight:  lb.

Neck Circ.:  " Epworth:

Demographics... Clinical Data...

**Physician**

License:

First Name:  Last Name:

Demographics...

**Study**

Coverage:  Payment Code:  More...

Time Zone: GMT+2:00

Save To USB  
Clear Page  
Read From USB  
Set USB Drive...  
Exit

USB Drive: F: Ready for prepare New Study.  
DB Connection: Shared

Figure 38 - New Study Dialog Box for WP100

**For WP200 only:**




- Make sure the device is connected to the PC with the zzzPAT software using the USB cable.
- Click **File>New Study Details** in zzzPAT, or click the 'New Study' icon  in the tool bar.
- The 'New Study' dialog box appears:


Figure 39 - New Study Dialog Box for WP200

- Fill the mandatory Patient ID in the **Patient** fields.
- Insert any additional information if needed, the rest of the fields are optional.
- Select "Study with Tamper-Proof Testing" if you want to use the Patient Identification Bracelet. By enabling this option you can use the bracelet in order to verify that the identified patient is indeed the one sleeping with the device (see Tamper-Proof testing in Watch-PAT200 Operation Manual). This option is shown only if the feature is enabled in Setup>General Settings>General Options.
- Select "Multiple Nights" option in order to run up to 3 nights with the same WP200 device (see Multi-night study in Watch-PAT200 Operation Manual). This option is shown only if the feature is enabled in Setup>General Settings>General Options.

- Click the **Save to USB** button.

	<p style="text-align: center;"><b>Note</b></p> <p>If the Patient ID field was left unfilled, a message will be displayed requesting the need to be filled. Fill in the missing information and press the <b>Save to USB</b> button again.</p>
---	---

	<p style="text-align: center;"><b>Note</b></p> <p>The units used for weight and height in the 'New Study' dialog box are defined by the regional settings of the PC.</p>
---	--

	<p style="text-align: center;"><b>Note</b></p> <p>The Epworth Score is used to determine the level of daytime sleepiness. An Epworth Sleepiness Scale Questionnaire can be found in the Misc folder under the zzzPAT Installation folder (the default is C:\Program Files\Itamar medical\zzzPAT\Misc).</p>
---	--

If the Compact Flash card/WP200 contains data (either a night study that has not been loaded to the zzzPAT Database or new patient data that has been prepared but not used in a study), the following dialog box opens:

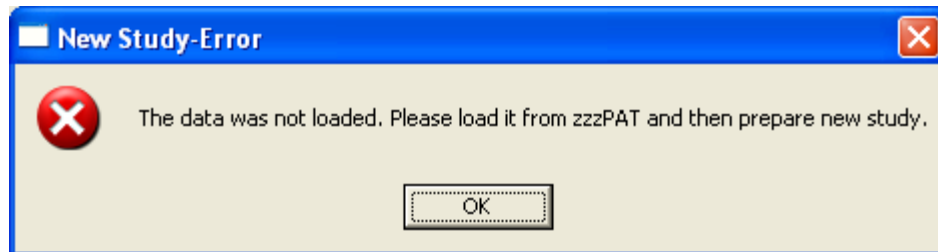


Figure 40 - Compact Flash Card/WP200 Not Loaded Dialog Box

- After saving the patient information to the Compact Flash card/WP200 the following message appears:

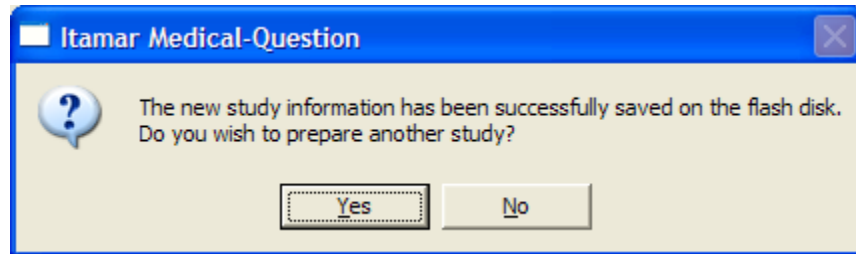


Figure 41 - New Study Termination Question

Click **Yes** - if you wish to prepare additional Compact Flash cards.  
Click **No** - if you wish to exit the 'New Study' dialog box.

- **For WP100 only:** Take the Compact Flash card from the Compact Flash reader and insert it into the appropriate compartment in the WP100. (Refer to the WP100 user manual).
- **For WP200 only:** Disconnect the USB cable from the WP200 device.

#### 4.1.3 New Study screen features

Besides the main screen fields required for preparing a new study, there are additional fields that allow thorough documentation of the patient's past and current medical condition. In addition, zzzPAT enables you to load patient details from previous studies. Other features in this screen enable organizing the studies into groups using categories of your choice.

##### 4.1.3.1 Synchronizing the WP100 device clock with the zzzPAT software

The internal clock of the WP100 device needs to be set correctly in order for the Study Date/Time to appear correctly after loading a study in zzzPAT.

Since zzzPAT version 3.0 all WP100 devices are delivered from Itamar Medical having the internal clock set to GMT (Greenwich Mean Time).


The "Time Zone" field in "New Study" screen contains the offset in hours that is added or subtracted to the Study Date/Time read from the WP100 device.


- If the WP100 device clock is set to GMT - this offset equals to the difference in hours between the computer's local time and GMT
- If the WP100 device clock is set to local time - this offset equals to zero (select GMT on the pull down menu)


To adjust for daylight savings or if you notice a discrepancy in hours between the actual Study Date/Time and the one obtained in zzzPAT, you can change the "Time Zone" field in "New Study" screen in order to compensate for the discrepancy:

- If zzzPAT date/time is later than the actual Study Date/Time - decrease the "Time Zone"

- If zzzPAT date/time is earlier than the actual Study Date/Time - increase the "Time Zone"

	<p style="text-align: center;"><b>Note</b></p> <p>You do not need to set the "Time Zone" field each time you prepare a New Study. The software "remembers" the last "Time Zone" used.</p>
---	---

	<p style="text-align: center;"><b>Note</b></p> <p>The local GMT offset can be found in <b>Start&gt;Settings&gt;Control Panel&gt;Date and Time&gt;Time Zone.</b></p>
---	---

	<p style="text-align: center;"><b>Note</b></p> <p>When you run Watch-PAT Monitor (version 2.1.45.1 and earlier) with WP100 devices whose clock is set to GMT the Date/Time test will fail. As long as the difference between the WP100 device clock and the computer clock is equal to the GMT offset, the device clock should be left unchanged.</p>
---	---

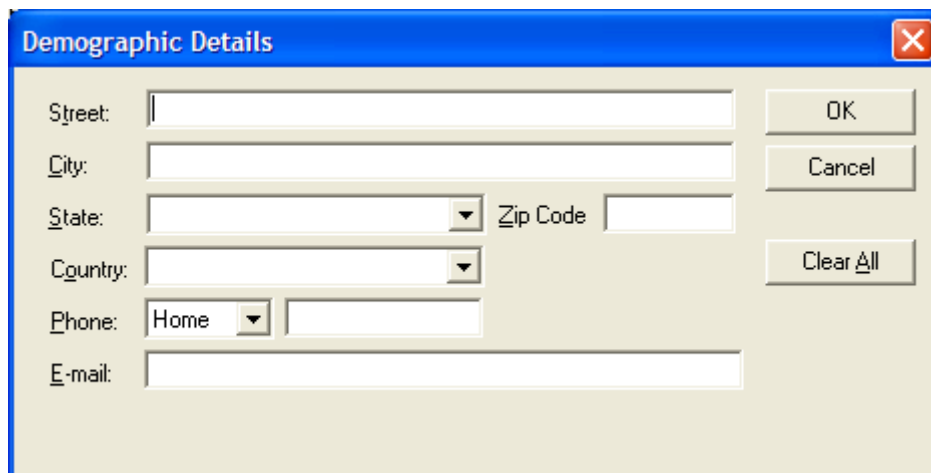
#### **4.1.3.2 Synchronizing the WP200 device clock with the zzzPAT software**

Select the "Synchronize WP200 clock with PC clock while 'Saving to USB'" option while preparing new study if the WP200 device clock needs too be set (see Figure 39).

#### **4.1.3.3 Documenting additional information**

**To add demographic information:**

- Click the **Demographics** button (see Figure 38). The following dialog box will open:



The image shows a dialog box titled "Demographic Details" with a blue header and a close button (X) in the top right corner. The dialog box contains several input fields and buttons. On the left side, there are labels for "Street:", "City:", "State:", "Country:", "Phone:", and "E-mail:". The "Street:" label is followed by a text input field. The "City:" label is followed by a text input field. The "State:" label is followed by a dropdown menu and a "Zip Code" label followed by a text input field. The "Country:" label is followed by a dropdown menu. The "Phone:" label is followed by a dropdown menu with "Home" selected and a text input field. The "E-mail:" label is followed by a text input field. On the right side of the dialog box, there are three buttons: "OK", "Cancel", and "Clear All".

Figure 42 - Demographic Details Dialog box

- Insert the information into the appropriate fields and click **OK** to save.

**To add optional clinical information:**

- Click the **Clinical Data** button. The following dialog box opens:

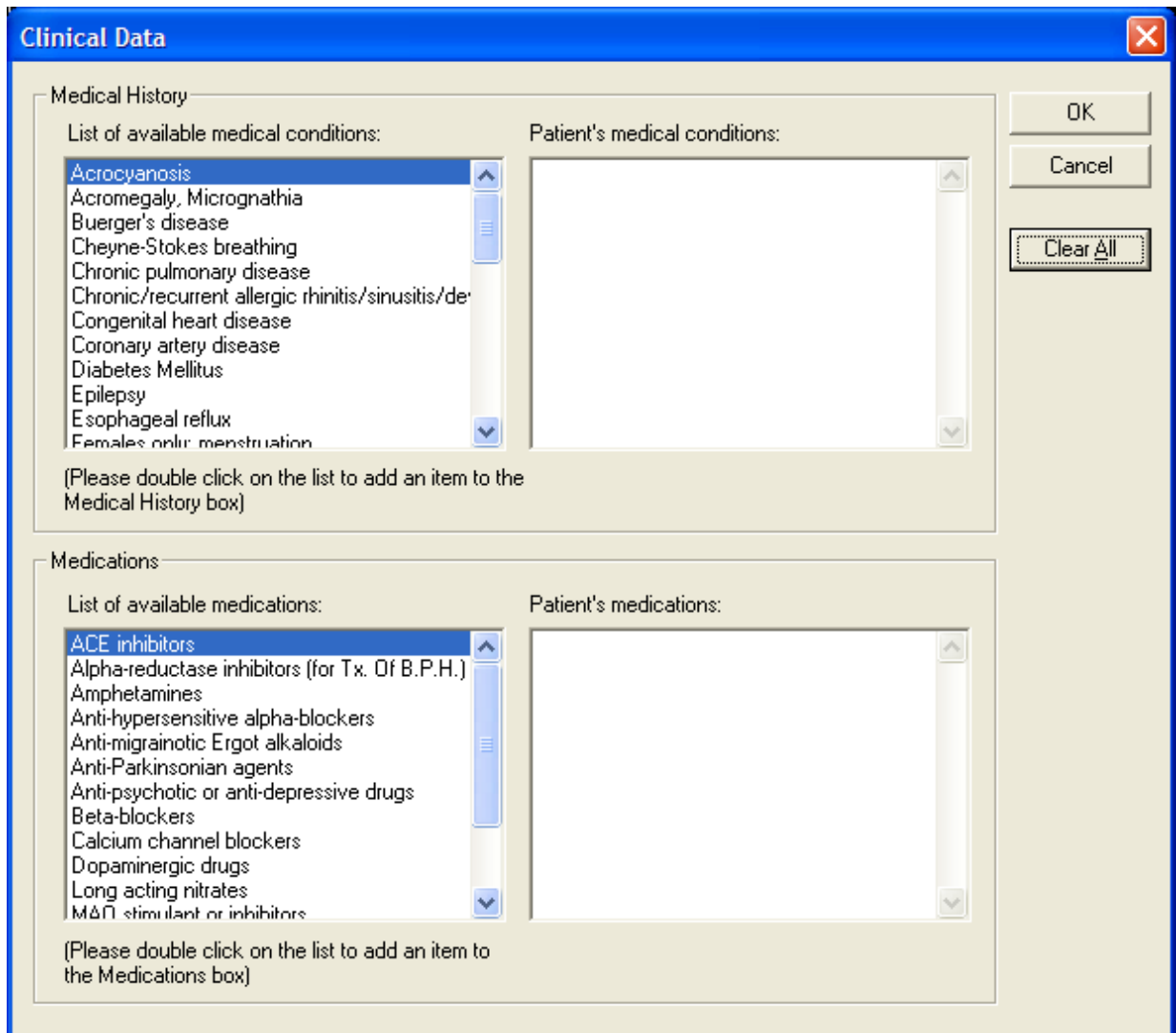


Figure 43 - Patient Clinical Data Dialog box


- Double click on the relevant items listed on the left, to add them to the Patient information or add information in free text.
- After adding the selected data click **OK** to save.

**To remove an item from your selection:**


- Highlight the item you want to delete.
- Hit delete key or right click and choose 'Delete' from the pop-up menu.
- Click **OK** to continue.

**4.1.3.4 Retrieving patient information from previous studies**


This feature allows retrieving patient information from previous studies into current 'New Study' dialog box. In addition it enables viewing the list of all patients in the zzzPAT database.

	<p style="text-align: center;"><b>Note</b></p> <p>If a patient has more than one study, only the latest patient details inserted will be displayed</p>
---	--

**To view a list of all the patients in the zzzPAT database:**

- In the 'New Study' dialog box (Figure 38), leave the fields: 'patient ID', 'first name' and 'last name' empty.
- Click , the 'Search Results' dialog box will open with a list of all the patients in the zzzPAT database.
- Select the study you need and click **OK**. The patient's information will be retrieved into the 'New Study' dialog box.

**To view patients by selected categories:**

- Enter patient ID, first or last name into the 'New Study' dialog box.
- Click , the 'Search Results' dialog box will open with a list of patients that will match the criteria inserted above.
- Select the patient you need and click **OK**. The patient's information will be retrieved into the 'New Study' dialog box.

**4.1.3.5 Classifying the patients by special categories or groups**

**To assign a study to a group or category:**

- Click the **More** button in the **Study (optional)** section of the 'New Study' dialog box. The following dialog box will open:

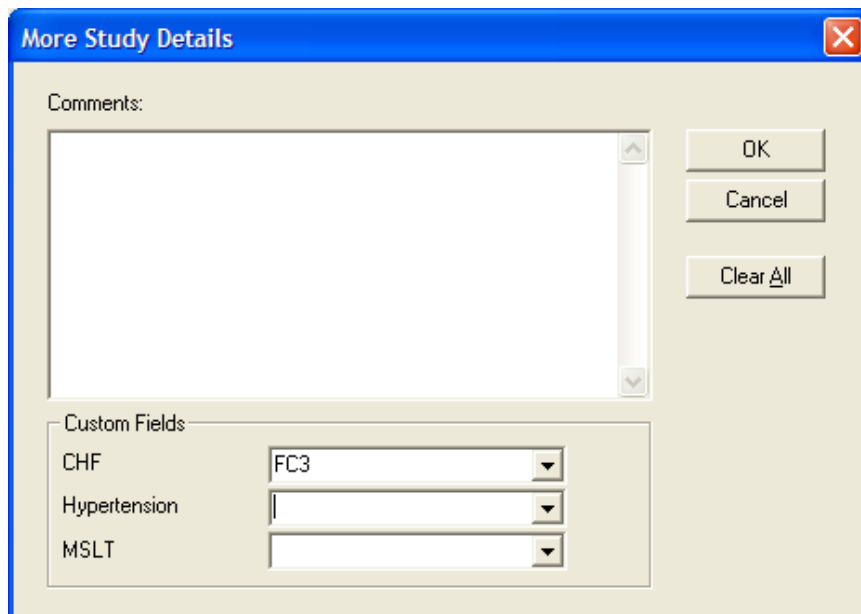




Figure 44 - More Study Details Dialog box




- You can enter free text in the 'Comments' field and select an existing study group from the list you previously prepared in the 'Study Custom Fields' or insert free text into the fields of the **Custom Fields** section.

	<p style="text-align: center;"><b>Note</b></p> <p>Up to three 'Custom Fields' can be defined and named by the user. If Study Custom Fields are not defined, they will appear in the 'More Study Details' Dialog box as read only (Figure 44). To define 'Custom Fields' see section 3.4.4.</p>
---	--

#### 4.1.3.6 Reviewing and editing information stored on a Compact Flash Card

	<p style="text-align: center;"><b>Warning</b></p> <p>It is possible to change information on a Compact Flash card only before the recording session. Changing information after a recording session will erase the recorded information on the Compact Flash card.</p>
---	--


- Insert the Compact Flash card into the Compact Flash reader.
- Open 'New Study' application. Click **Read From USB** button.
- If the information does not need to be edited, click **Exit**.
- Make any necessary changes and click **Save to Flash**.

	<p style="text-align: center;"><b>Note</b></p> <p>Study details, including patient information, can be viewed and modified after the study is loaded from the Compact Flash card to the zzzPAT database. See Section 4.2.7 for more details.</p>
---	--

## 4.2 Managing Patient Studies

After a WP100 sleep study, remove the Compact Flash card from the WP100 and insert it into the zzzPAT Compact Flash reader. The recorded digital data along with patient information are loaded into the zzzPAT database. The recorded data is automatically analyzed. The user can subsequently review, edit, add Diagnosis and Recommendations and produce a Sleep Report. Previously loaded studies can be opened and reviewed.

The remainder of this section assumes zzzPAT is running.

	<p style="text-align: center;"><b>Note</b></p> <p>When working in Shared Access mode it is important to login to the correct database in which the data needs to be stored. Typically that should be the Shared database, however if data was stored locally, local login may be required.</p>
---	--

#### 4.2.1 File>New Study Details

Prepares the Patient file on the WP100 Compact Flash card for a sleep study (Section 3).

#### 4.2.2 File>Load Study and Analyze

This command loads the sleep study data from the Compact Flash card and saves it into the zzzPAT database.

While loading the data the message 'Loading Study' (Figure 45) appears on the screen indicating that the data is being transferred from the Compact Flash card to the hard disk and the patient file is saved in the database.

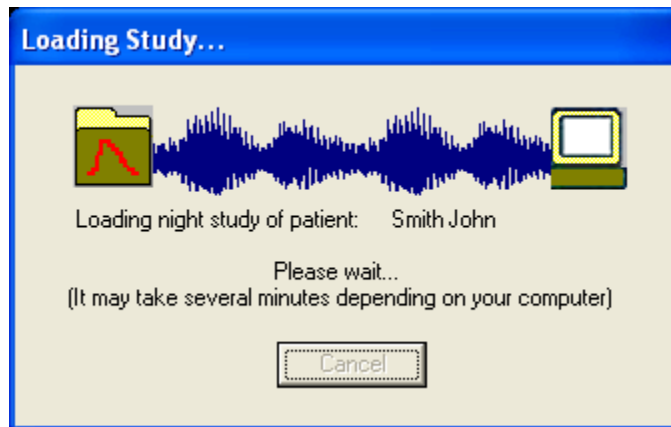



Figure 45 - Loading Study dialog box

At this stage Automatic Analysis is performed and the results are saved in the database. After the Automatic Analysis is completed the results are displayed on screen (see Figure 48). The user has the option to display the "Sleep report" or "Sleep Indices" report box automatically after loading a study (see 3.3.3).

When a multi-night study is loaded all the night studies are loaded automatically and the last loaded study will be displayed. Use the Open Study dialog to open and review all the night studies.

### 4.2.3 File>Open Study

Opens studies stored in the zzzPAT database from previously loaded studies (see Figure 46). Double click on a patient and the studies for that patient are listed with the date/time of each study. Double click the  study icon to load and display recorded information on the screen.

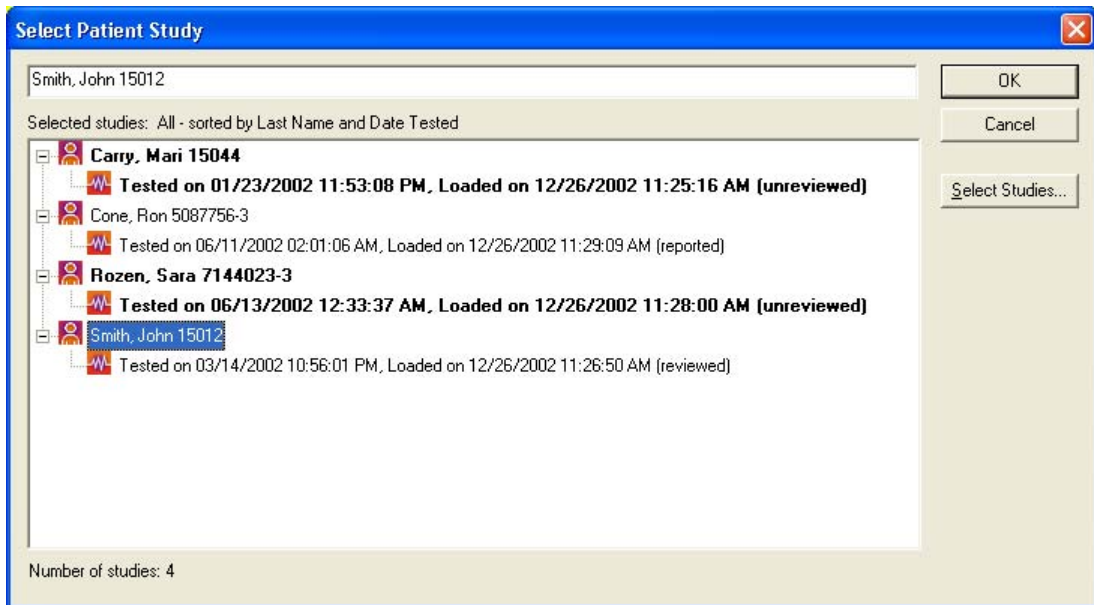


Figure 46 - Select Patient Study dialog box

#### Select Studies button

Enables the user to define, select and organize the displayed studies in the 'Select Patient Study' dialog box.

- Click **Select Studies**.  
The following Dialog box will open:

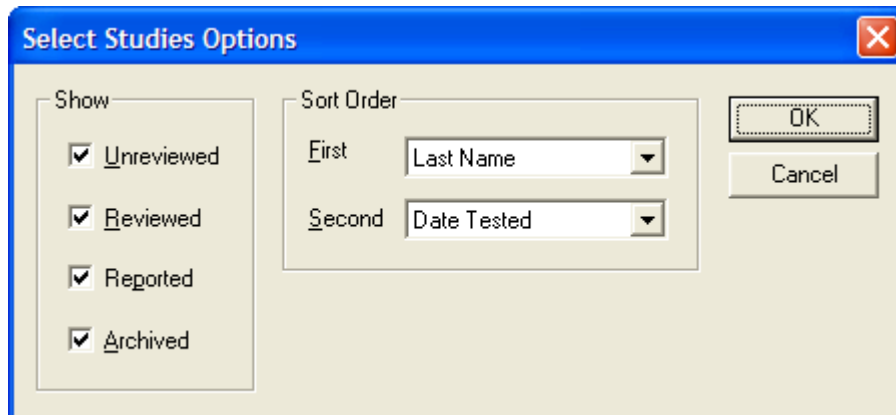



Figure 47 - Select studies option

**Show** section - Each study is associated to one of the following statuses (listed below). Checking the boxes to the left of these statuses enables the user to define, according to the following categories, which of the studies from the zzzPAT database will be displayed on the 'Select Patient Study' dialog box:

- |            |   |   |
|------------|---|---|
| Unreviewed | – | Study was loaded to zzzPAT and automatic analysis performed on it.  |
| Reviewed   | – | User modified events, entered Diagnosis or Recommendations, saved study results or produced a sleep report.   |
| Reported   | – | User selected the 'Set as Reported' option in the 'Clinical Diagnosis' dialog box. This study cannot be modified and no additional information can be inserted into the report. |
| Archived   | – | Study was extracted and removed from the database to an archive out-side the zzzPAT database. These studies cannot be reviewed unless retrieved back into the database first.   |

	<b>Note</b> The usual cycle of a study is: Unreviewed → Reviewed → Reported → Archived
---	--

**Sort Order** section - Enables the user to define the order by which the studies are displayed. It is possible to display the studies by ID, last name, date of study, date file loaded and additional user inserted criteria.

- |                      |   |   |
|----------------------|---|---|
| 'First' order field  | – | Contains system predefined criteria and user defined criteria inserted in 'Define Study custom Field' (see 4.1.3.5) |
| 'Second' order field | – | Contains only system predefined criteria.   |

#### **4.2.4 File>Save Study Results**

Saves the patient study results (events) currently being viewed without closing zzzPAT, and sets the study as reviewed. This feature is important when Respiratory events are edited (added or deleted) and the new events need to be saved for future zzzPAT sessions.

#### **4.2.5 File>Close Study**

Closes the patient study currently being viewed without closing zzzPAT.

#### **4.2.6 File>Exit**

Closes both the patient study being viewed and the zzzPAT.

### 4.2.7 Edit>Study Details

Opens the 'View Study Details' dialog box with current patient information. This information can be edited by clicking the **Edit** button. Authorization users can change the patient ID only once.

## 4.3 The Display Screen

The main screen displays the WP100 or WP200 recording waveforms with the events that were detected by the automatic analysis. The traces are displayed synchronized to a uniform time base.

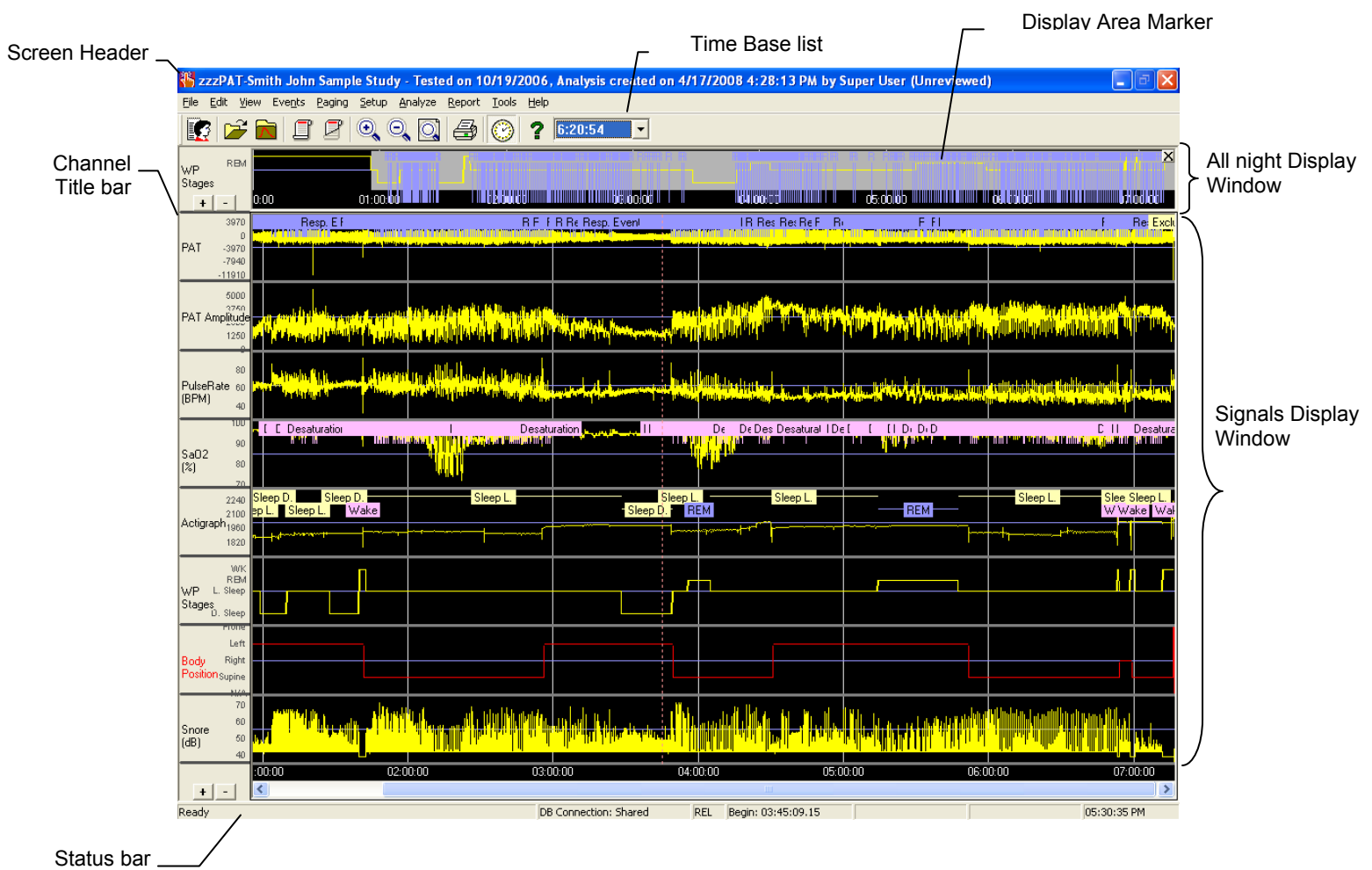


Figure 48 - zzzPAT display screen

The 'Screen Header' consists of 'zzzPAT', patient's name, ID number, Analysis status, date and time and the zzzPAT user's name. Events determined by the Automatic Analysis are displayed on the 'Signals Display Window'.

Placing the mouse cursor on an event pops up a tool-tip that contains:

- Event name
- Event source (Analysis or User)
- Start time
- Duration

#### 4.3.1 The All Night Window

It is possible to view any channel you select in an 'All Night Window' display even if you change the time base for viewing all the channels of the study.

- To display the All-Night window, navigate through **View>All Night Window**, check the 'All Night' option.  
Or **View>Channels**,  
The following dialog box will open:

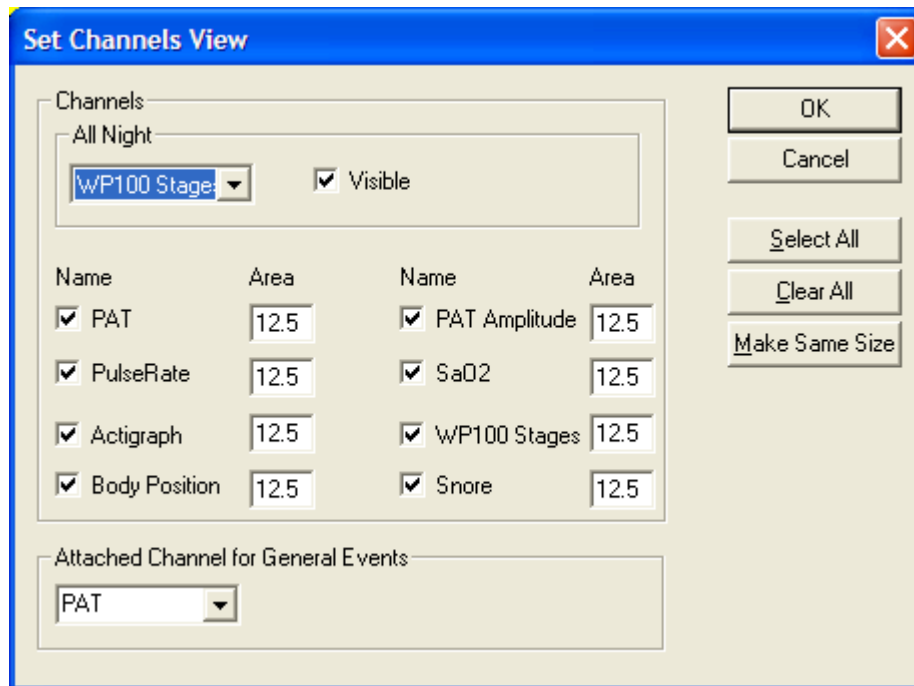


Figure 49 - Selecting the All night Window

- Check the box to the left of 'Visible' in the **All Night** section.
- Select the channel you wish to display in the 'All Night Window'.

#### To remove the 'All Night Window':

- Use the two options mentioned above or right click on the 'All Night Window' title window (left side of the screen), select 'Remove from View'.

#### 'All Night Window' features:

- The 'Display Area Marker' that appears as a highlighted rectangle in the 'All Night Window' (See Figure 48), is the section being viewed in the 'Signals Display Window'.

- It is possible to navigate through the recorded data through the 'All Night Window' by clicking on a spot on the 'All-Night' window, or by dragging the highlighted rectangle.
- When in the 'All Night Window' display, clicking the mouse right-button opens the following pop-up menu:



Figure 50 - All Night pop-up Menu

- Fit to Window – Auto fits the All Night window's signal so it is displayed in about 80% of the window's height.
- Invert Data – Inverts the y-Scale and signal of the All Night window.
- Show Channel Events – Displays channel events in the All Night window.
- Show Respiratory Events – Displays respiratory events in the All Night window.
- Grid On/Off – Toggles the grid in the All Night window.
- Properties – Opens up the 'Signal Properties - All Night' dialog box (see Figure 51).

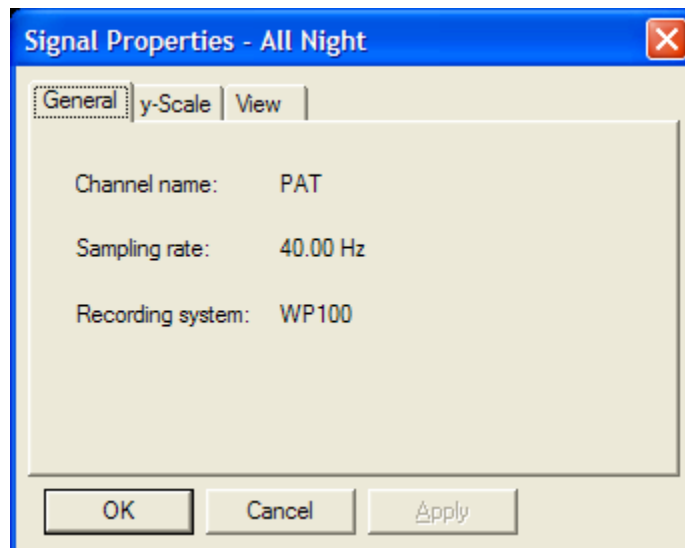


Figure 51 - Signal Properties – All Night window

Right clicking the mouse on the 'All Night' channel Title to the left of the All Night display opens a pop-up menu with the following options:

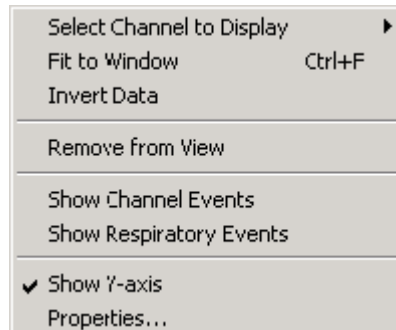


Figure 52 - All Night pop-up menu

- |                           |   |  |
|---------------------------|---|--|
| Select Channel to Display | – | Allows the user to choose which channel will be displayed in the 'All Night Display Window'. |
| Fit to window             | – | Auto fits the channel's signal so it occupies 80% of the window's height.                    |
| Invert Data               | – | Inverts the y-Scale and signal of the channel.   |
| Remove from View          | – | Removes the 'All Night Window' from the main screen.   |
| Show Channel Events       | – | Allows option of showing or not showing all the events on the All Night channel.             |
| Show Respiratory Events   | – | Allows option of showing or not showing only respiratory events on the All Night channel.    |
| Show Y-axis               | – | Shows the Y-axis for the selected channel.   |
| Properties                | – | Opens up a dialog box with the General, Y-Scale and View properties of the channel.          |

#### 4.3.2 Signals Display Window

The signals display window is located under the 'All Night' window. It displays the channels that are selected in the **View>Channels** menu.

#### 4.3.3 Channel Title Bar

'The Channel Title Bar' on the left of the screen shows the titles of the channels being displayed and the y-Scale of each channel.

#### 4.3.4 The Active Channel

Clicking on a channel or a channel title activates that channel (the color of the activated signal and titles will change).

A right-button click on a Channel title activates the channel and opens a pop-up menu with the following options:



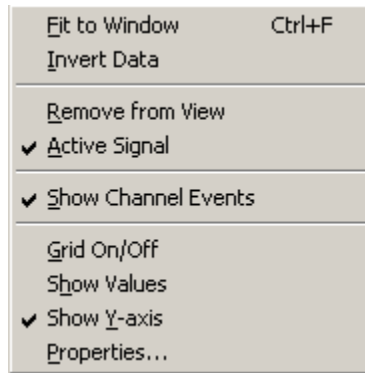


Figure 53 - Active channel pop-up menu

- |                     |   |
|---------------------|---|
| Fit to window       | – Auto fits the active channel’s signal so it occupies about 80% of the window’s height.          |
| Invert Data         | – Inverts the y-Scale and signal of the Active channel.   |
| Remove from View    | – Removes the currently active channel from the screen.   |
| Active Signal       | – Allows deactivating the signal.   |
| Show Channel Events | – Allows option of showing or not showing the events in the Active channel.                       |
| Grid On/Off         | – Toggles the grid in the Active channel.   |
| Show Values         | – Shows the values for each data point on the Active channel (effective only under maximum zoom). |
| Show Y-axis         | – Shows the Y-axis values for the Active channel.   |
| Properties          | – Opens up a dialog box with the General, y-Scale and View properties of the Active channel.      |

#### 4.3.5 Status Bar

The Status Bar at the bottom of the screen contains the following information:

- Database connection (Shared or Local)
- Real Time Clock
- Highlighted segment start time
- Highlighted segment end time
- Duration
- Time mode (REL/ABS)

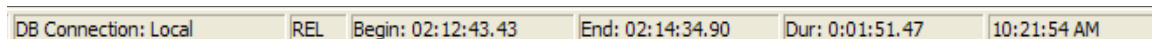


Figure 54 - zzzPAT screen Status Bar

## 4.4 Signal Display Options

### 4.4.1 View>Channels

Opens the following dialog box:

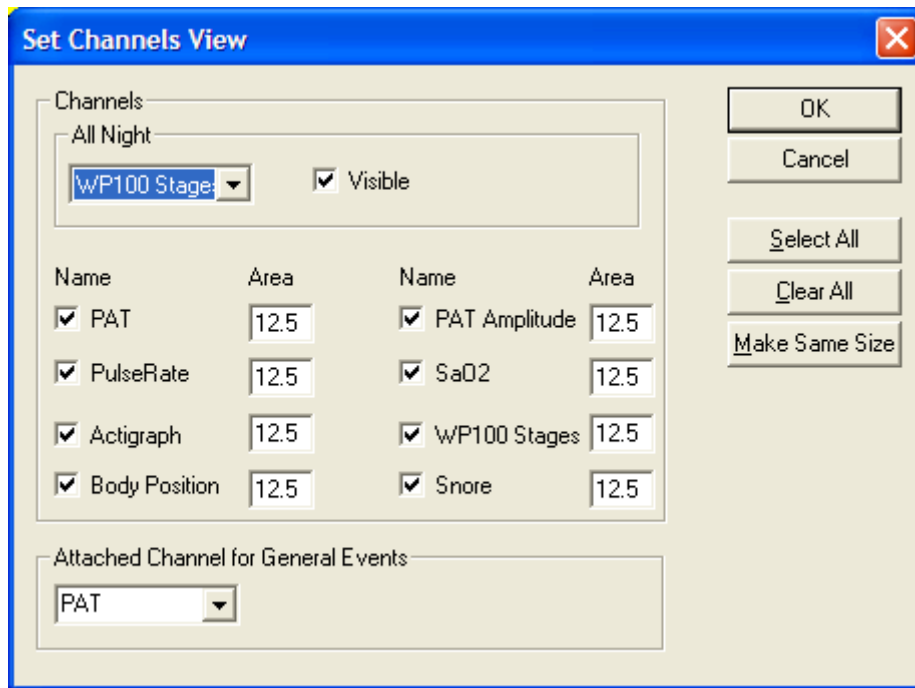


Figure 55 - Set Channels View Dialog Box

The **All Night** section is used to enable/disable the 'All Night display' and to select the channel for it.

Checking the boxes by the channel names defines the channels displayed on the zzzPAT screen.

The value entered into the 'Area' fields determines the channel's screen display relative size. The total sum of the values in the Area fields should be 100. Clicking the **Make Same Size** button rescales all channels to the same size.

The **Attached Channel for General Events** section is used to set the channel on which the general events are displayed. General events are events generated by the automatic analysis of the zzzPAT.

### 4.4.2 View>Set y-Scale

Opens the 'Set y-Scale' dialog box.

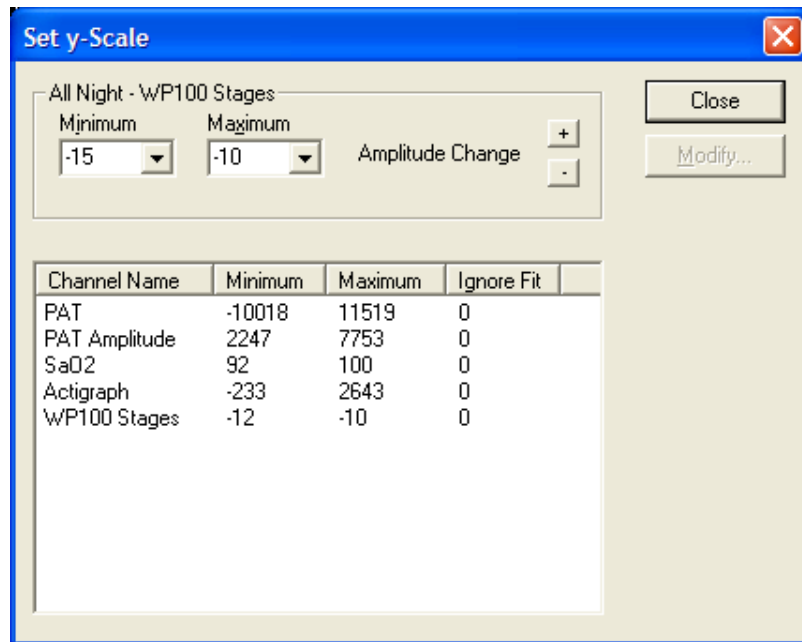


Figure 56 - Set y-Scale dialog box.

The **All Night** section allows editing the 'y-scale' for the 'All Night' channel.

**To edit the 'y-Scale' of all other channels:**

- Mark the channel on the 'Set y-Scale' dialog box.
- Click **Modify**. The following dialog box will open:

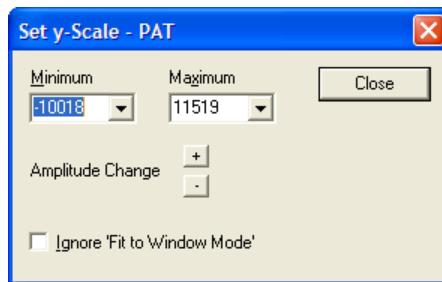




Figure 57 - Set y-Scale – per channel dialog box

- Select minimum/maximum ranges for the y-Scale or control the channel's gain with .
- Define whether to ignore 'Fit to Window Mode'. (See section 4.4.6).

**To edit the y-Scale using the zzzPAT screen:**

- Activate a channel by clicking anywhere on it.
- Click on the  buttons at the bottom of the channels Title Bar.

**To raise or lower the range scale of a channel:**

- Left click on the channel title bar and drag the scale range numbers.

**To zoom on a specific range of the channel:**

- Right click and drag to the desired range.

**4.4.3 View>Time Base**

Enables to select the time base by which the study is viewed on the zzzPAT screen. It is also possible to select the time base by using the 'Time Base Drop Down Menu' in the zzzPAT tool bar.

**4.4.4 View>Activate Channel Fit to Window**

Sets the signals display to automatically take 80% of the selected signal's window height. The size of the signal will automatically adjust to take no more than 80% of the vertical axis of its display.

Automatic 'Fit to Window' mode is applicable only for the section being viewed on the screen. It will be disabled when viewing the study by paging (using the Page Up and Page Down keys on the keyboard) or when scrolling (using the Right Arrow and Left Arrow keys on the keyboard).

**4.4.5 View >All Night Channel Fit to Window**

Activates the Fit to Window mode on the 'All Night Channel'.

**4.4.6 View>Fit To Window Mode**

This command activates a 'Fit To Window' mode on all the displayed channels. In this mode the size of the signal will automatically adjust to take no more than 80% of the vertical axis of its display.


All the channels will remain in 'Fit to Window' mode when viewing the study by paging (using the Page Up and Page Down keys on the keyboard) or when scrolling (using the Right Arrow and Left Arrow keys on the keyboard).

Note: It is recommended to disable the 'Fit to Window' Mode on the actigraphy channel. For instructions see section 4.4.2.

**4.4.7 View>Grid On/Off**

Displays the grid lines of the channel values. User may enable or disable the Grid On/Off feature for a specific channel by right clicking the mouse on the highlighted channel.


**4.4.8 View>Relative Time**

Choosing this option or clicking  on zzzPAT toolbar toggles the time mode of the study being viewed between Absolute Time mode and Relative Time mode.

In Relative Time mode the beginning of the study is always defined as 00:00:00 on the x-scale of the zzzPAT screen and the time is measured from the beginning of the study.

In Absolute Time mode the absolute time appears on the x-scale of the zzzPAT screen; i.e. the time registered by the WP100 or WP200 device.


#### **4.4.9 View>Zoom In**

To enable this option, highlight a section of the waveform by clicking and dragging the mouse. The option **View>Zoom In** and the corresponding toolbar button  become enabled.

Activating the 'Zoom In' option modifies the Time Base to fit the highlighted segment into the entire width of the Signals Display Window (Note that the Time Base window and the Status bar details are updated automatically).


When the time base is one second, the zoom in option is disabled.

#### **4.4.10 View>Zoom Out**

**View>Zoom Out** and corresponding toolbar button  are enabled when the current view is zoomed in.

Activating this option returns the view back to the previous zoom magnitude.

#### **4.4.11 View>Zoom Original**

**View>Zoom Original** and corresponding toolbar button  are enabled when current view is zoomed in. This option returns the view back to the original time scale.

#### **4.4.12 View>All Night Window**

Enable/disable the All Night Window (See section 4.3.1).

### **4.5 Review, Analysis and Report Study**

#### **4.5.1 Data Analysis**

The zzzPAT software performs an automated analysis of the WP100 or WP200 recorded signals, providing extensive information on the patient's sleep. The analysis provides an evaluation of respiratory events during sleep, oxygen saturation statistics and REM sleep statistics.

##### **4.5.1.1 Generating an Analysis**

Recorded study data is automatically analyzed after being loaded from the Compact Flash card. You can also execute automatic data analysis by clicking **Analyze>Reload study and analyze**.

This function reloads the saved study data and executes the automatic analysis. If the user changed the file (adding/deleting/modifying events), these changes will be erased and will not impact the analysis.

When used on a file that was previously analyzed and saved with an older version of zzzPAT, this function creates a new analysis using the current version of the zzzPAT software.

#### **4.5.1.2 REM Analysis**

REM analysis is part of the automatic analysis described above.

Under certain conditions, REM analysis is unable to conclusively determine REM periods from the recorded signals.

When this occurs, the display will include only sleep and wake stages, and in the report the REM statistics section shall be disabled stating "Inconclusive REM Detection".

#### **4.5.2 Event Management**

Events marked by automatic analysis are shown in color-shaded boxes. Placing the cursor on an event opens a tool-tip with the following information:

- Event name
- Event created by...(e.g. Automatic analysis or user)
- Start time
- Duration

#### **4.5.3 Edit>Copy**

When a signal section is highlighted, the Copy feature is enabled to allow user to copy the desired data either to the clipboard as an image or to files in binary format.

#### **4.5.4 Edit>Undo**

'Undo' is enabled only after changing events, enabling the user to undo the last operation.

#### **4.5.5 Edit>Redo**

'Redo' is enabled only after using the 'Undo' option, enabling the user to redo the last operation.

#### **4.5.6 Adding events**

Respiratory and user defined events can be added to the study by the user.

To add events:

- Mark the place you want to insert the event by clicking on the location with the mouse.
- Right click on the location and select the 'Add Event' command. Or by using the zzzPAT tool bar: **Events>Add Event**.  
The 'Add Events' Dialog box will open.

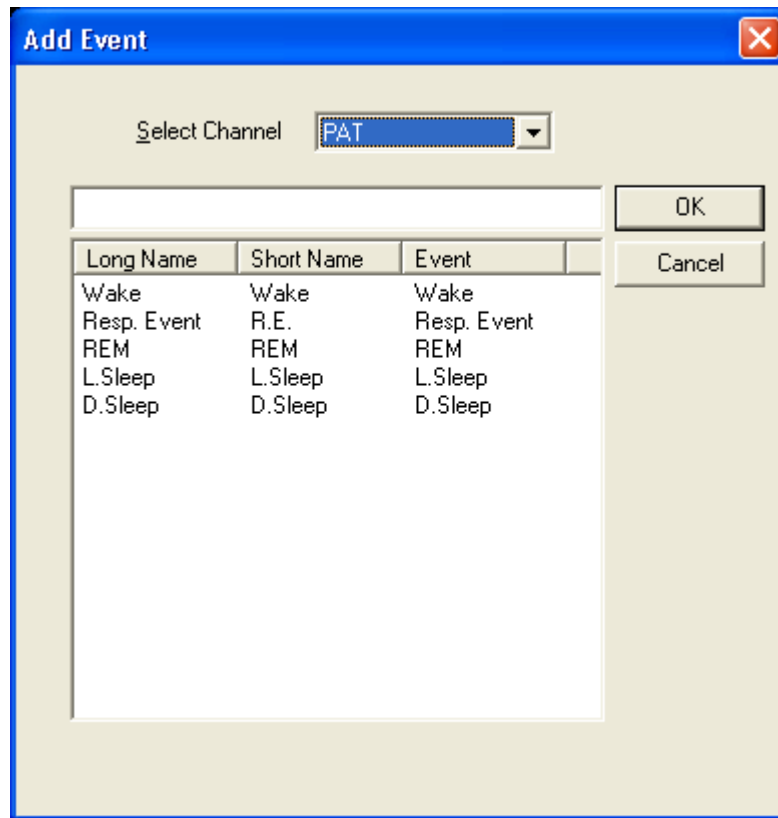


Figure 58: Add Event dialog box


- 'Select Channel' - Allows user to define the channel on which the added event will appear, by default the events will appear on the active channel unless a different channel is selected in the 'Select Channel' field.
- To add event - Double click on the event type in the list of events. Click **OK** to continue.
- It is also possible to add free text events into zzzPAT signal display using the Free Text editing box. This text will appear on the signal as an event but will not appear in the report

The changes in the database are saved by pressing the **Save study results** button.

#### 4.5.7 Deleting an Event

An event can be deleted by right mouse button click on the event and selecting 'Delete Event'.

Only Respiratory and user events can be deleted.

	<p><b>Note</b></p> <p>Adding or deleting a respiratory event affects the results in the report.</p>
---	---

#### 4.5.8 Events>GoTo Event

Allows the user to navigate through the study by certain event criteria. The following event type search options are available:

Previous Event	Ctrl+Left arrow
Next Event	Ctrl+Right arrow
Previous Same Type Event	Shift+Left arrow
Next Same Type Event	Shift+Right arrow
First Event for channel	Ctrl+Home
Last Event for channel	Ctrl+End

Figure 59 - Event Type Search options

#### 4.5.9 Events>Select Event

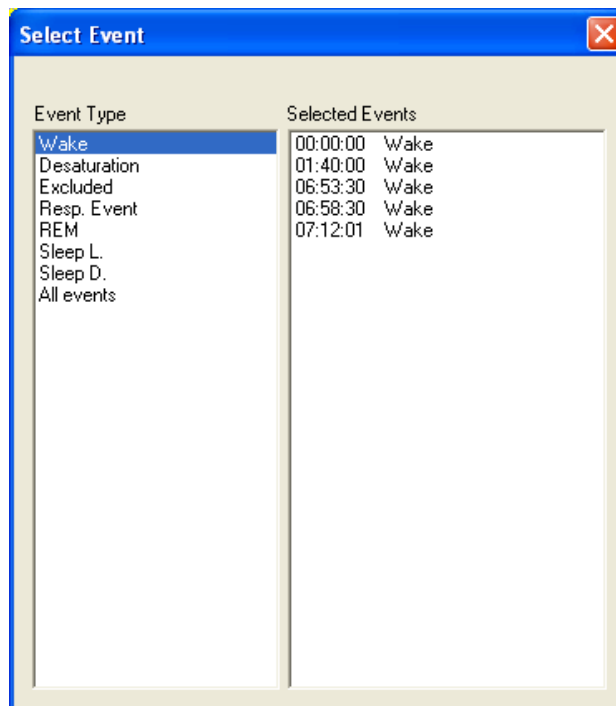


Figure 60 - Select Event dialog box

Enables the user to select a specific event for viewing. All existing events are listed by type and start time. User may select a specific event by clicking on it. The 'Selected



Events' field in the 'Select Event' window is updated to display the page with the specific event.

#### 4.5.10 Editing Sleep Stages

You are able to manually edit the Sleep stages if you already selected to enable this option (see Setup>General Settings>General Options). In order to edit the sleep stages right click the mouse while on top of the sleep stage and then select a new sleep stage from the "Replace with" menu (see Figure 61)





Figure 61 – Editing sleep stages

## 4.6 Reports

All reports can be reviewed on screen and printed.  
The toolbar in report view mode includes the following items:




Figure 62 - Report Toolbar

- To print a report, click on the printer icon.
- To export a report to a different format, such as pdf, rtf, html, etc., select the export icon .
- User can see how many pages there are in a report and choose which page to view by using the  icons.

#### 4.6.1 Report>Clinical Diagnosis

Allows adding a diagnosis and recommendations to the Sleep Report screen (see Figure 63). The information filled in this screen will appear on the first page of the Sleep Report.

- Sign the report by typing in your name or choosing it from the name menu bar.
- Check the 'Set as Reported' option to show that the current study analysis is final and that the Sleep Report is a final report for this analysis.

	<p style="text-align: center;"><b>Note</b></p> <p>Multiple analyses may be associated with a particular study. A new analysis will be created when selecting the 'Analyze&gt;Reload Study and Analyze' option on a study that had been previously 'Set as Reported'.</p>
---	--

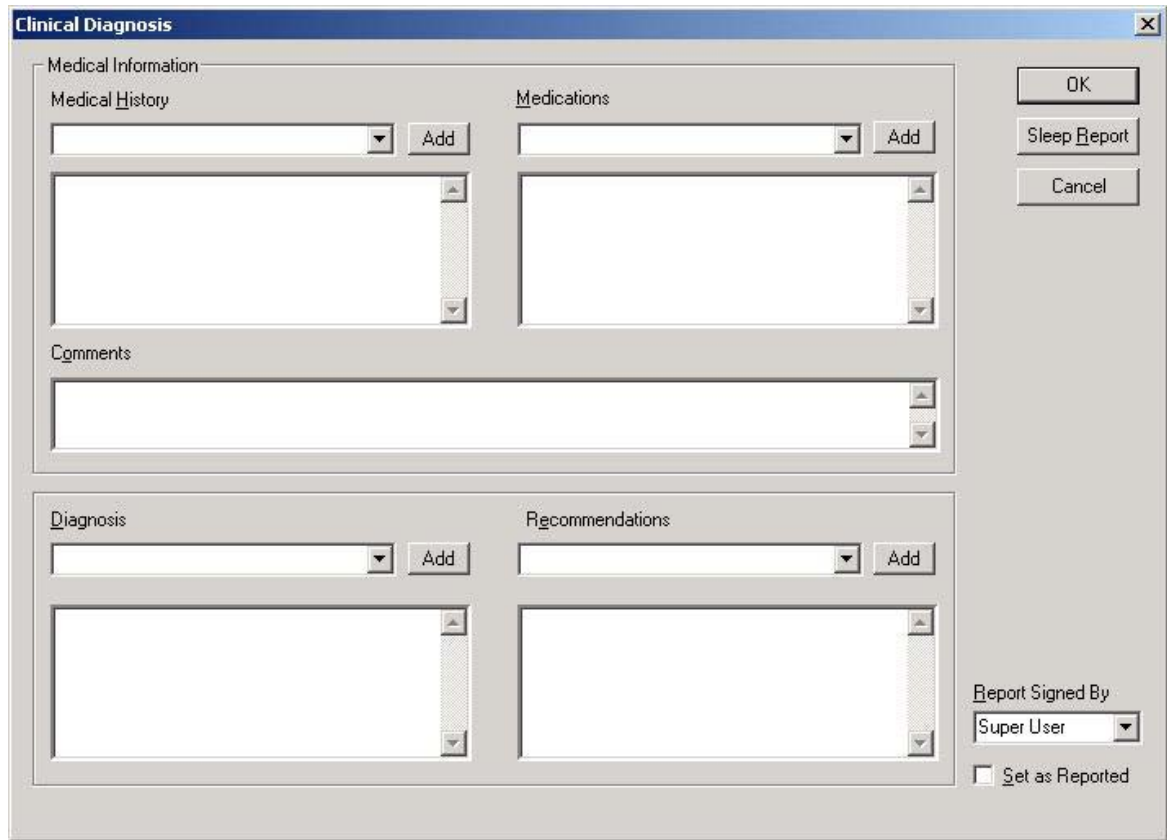

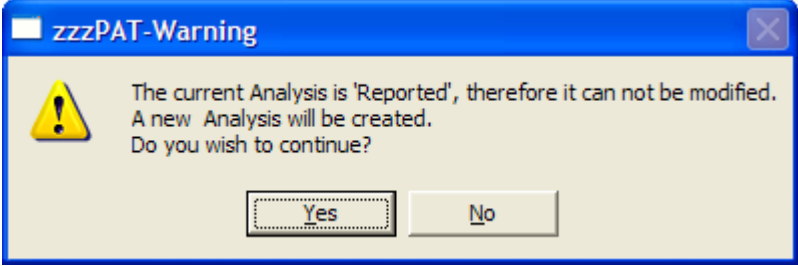


Figure 63 - Clinical Diagnosis dialog box

	<p style="text-align: center;"><b>Note</b></p> <p>Once a study is 'Set as Reported' any subsequent change to any of the 'Clinical Diagnosis' dialog fields (<b>Reports&gt;Clinical Diagnosis</b>) will trigger the following warning message:</p> 
	<p style="text-align: center;">Figure 64 - New Analysis Warning message</p> <p>Click <b>Yes</b> to save a new analysis without overwriting the existing analysis. Click <b>No</b> to cancel the new analysis request.</p>

#### 4.6.2 Report>Sleep Report

Generates a one, two or three page report that provides a summary of the subject's sleep study according to the settings in Setup>General Settings>Report Appearance section.

The first page of the report (Figure 66) includes Patient Information, the Sleep Study Information, Referring Physician, Medical history, Diagnosis and Recommendations.

The second page (Figure 67) presents the study results including Sleep Summary, PAT Respiratory Disturbance Index (pRDI), PAT Apnea Hypopnea Index (pAHI), Oxygen Saturation Statistics including the Oxygen Desaturation Index (ODI), mean, maximum and minimum oxygen saturation levels, Oxygen Saturation analysis, Pulse Rate statistics and REM Sleep analysis. It also includes graphical displays of Respiratory Events, Snore and Body Position chart (in case a Snore/Body Position sensor was used), Oxygen Saturation, Pulse Rate, Wake/Light Sleep/Deep Sleep and REM stages.

The third page (Figure 68) presents pie charts of sleep/wake states and sleep stages as well as a Respiratory indices chart.

Definitions:

**Sleep Time:** Total time in hours, during which the patient is asleep.

**PAT Respiratory Disturbance Index (pRDI):** the estimated number of respiratory events divided by the valid sleep time. Provided in Respiratory Events/Hour. The index is calculated during "All Night", REM and Non REM valid sleep time.

**PAT Apnea Hypopnea Index (pAHI):** the estimated number of Apneas and Hypopneas events divided by the valid sleep time. Provided in Apnea and Hypopnea events/Hour. The index is calculated during "All Night", REM and Non REM valid sleep time.

**Oxygen Desaturation Index (ODI):** the number of oxygen desaturation events (4% minimum desaturation) divided by the valid sleep time. Provided in Desaturation Events/Hour. The index is calculated during "All Night", REM and Non REM valid sleep time.

**REM % of Sleep Time:** REM sleep stages as percent of total sleep time.

**Snore level in dBs:** Because snoring can be a sign of sleep apnea, zzzPAT provides snore statistics. The threshold is determined according to DB. The amount of snoring is calculated as the percentage of sleep time over the specified DB threshold. The snoring volume level is graphically displayed (40 – 90 dB range).

**Body Position:** Five body position levels are graphically displayed (supine, right, left, prone and sit). Because the frequency of apneic events during sleep depends on patient position and sleep stage, zzzPAT provides information about the duration of sleep per each position – supine, prone, left, right, and sit. The corresponding percentage of time spent in each sleep position is displayed in a graph. Moreover, all recorded events such as respiratory disturbance index (RDI), apnea/hyperpnoea index (AHI), and desaturation index (ODI) are also provided in the report for each body position.

The Snore/Body Position data is displayed in a chart as shown here:

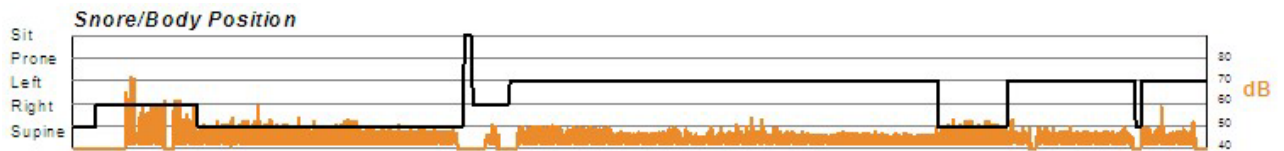



Figure 65 - Snoring and Body Position Statistics

	<p style="text-align: center;"><b>Note</b></p> <p>Several additional parameters such as Sleep Latency, REM Latency, Number of wakes and Sleep Efficiency are calculated but are only seen when using the "Export to csv" function (see Tools&gt;Export/Delete)</p>
---	--

THIS PLACE IS FOR THE PRACTICE LOGO

THIS LINE IS FOR ADDRESS AND AFFILIATION  
THIS LINE IS FOR ADDRESS AND AFFILIATION

## Sleep Study Report

### Patient Information

First Name:	<b>John</b>	Last Name:	<b>Doe</b>	ID:*	<b>000-00-0000</b>
Birth Date:	10/10/1953	Age:	52	Gender:	Male
Insurer:		BMI:			
Neck Circ.:		Epworth:			
Address:					

### Sleep Study Information

Study Date:	2/7/2005	S/H/A Version:	3.0.49.1 / 1.8 / 50
-------------	----------	----------------	---------------------

### Referring Physician Information

First Name:	John	Last Name:	Doe	E-mail:	
Work Phone:	415-482-9865	Mobile Phone:		Fax:	

### Medical Information

#### Medical History

Asthma  
Chronic/Allergic rhinitis/sinusitis

#### Medications

Inhaled Beta-agonist  
Nasal decongestants

### Summary & Diagnosis

Mild Sleep Apnea

Physician Name: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_

---

2/7/2005, SAMPLE STUDY1, SAMPLE\_STUDY1 Page 1 of 2 Printed on:6/17/2008

THIS LINE IS FOR ADDRESS AND AFFILIATION

Figure 66 - First page of Sleep Report

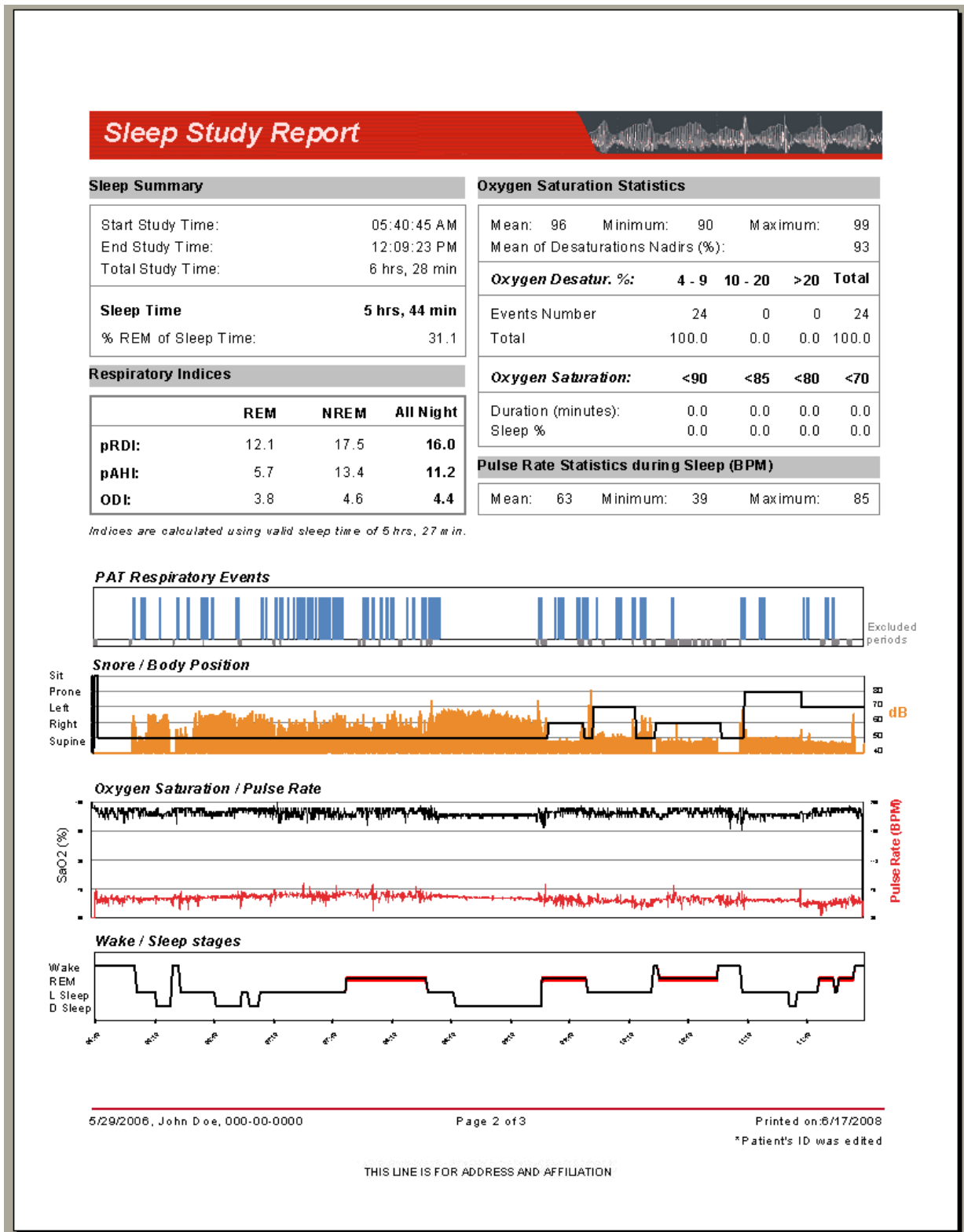


Figure 67 - Second page of Sleep Report

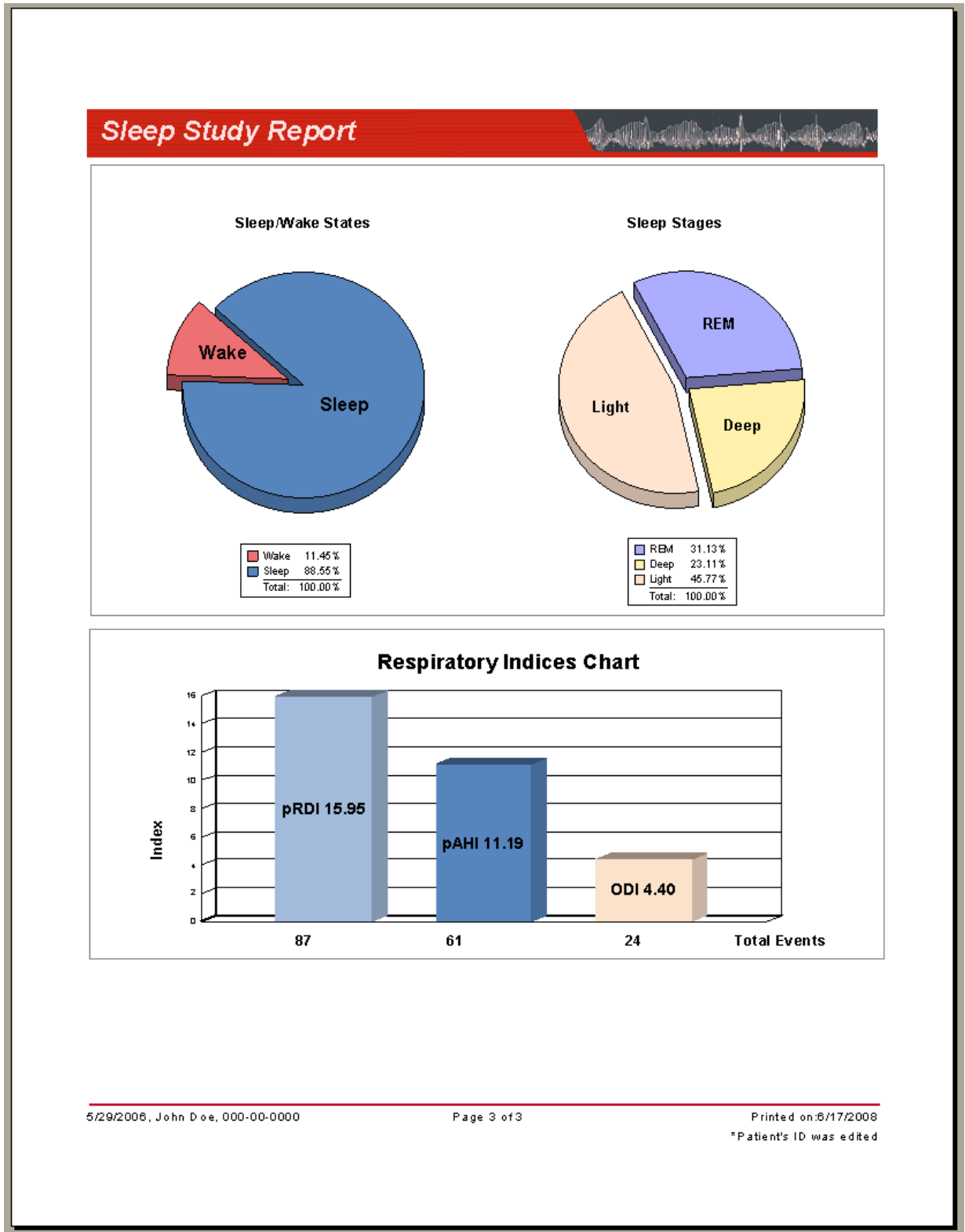


Figure 68 - Third page of Sleep Report (USA version)

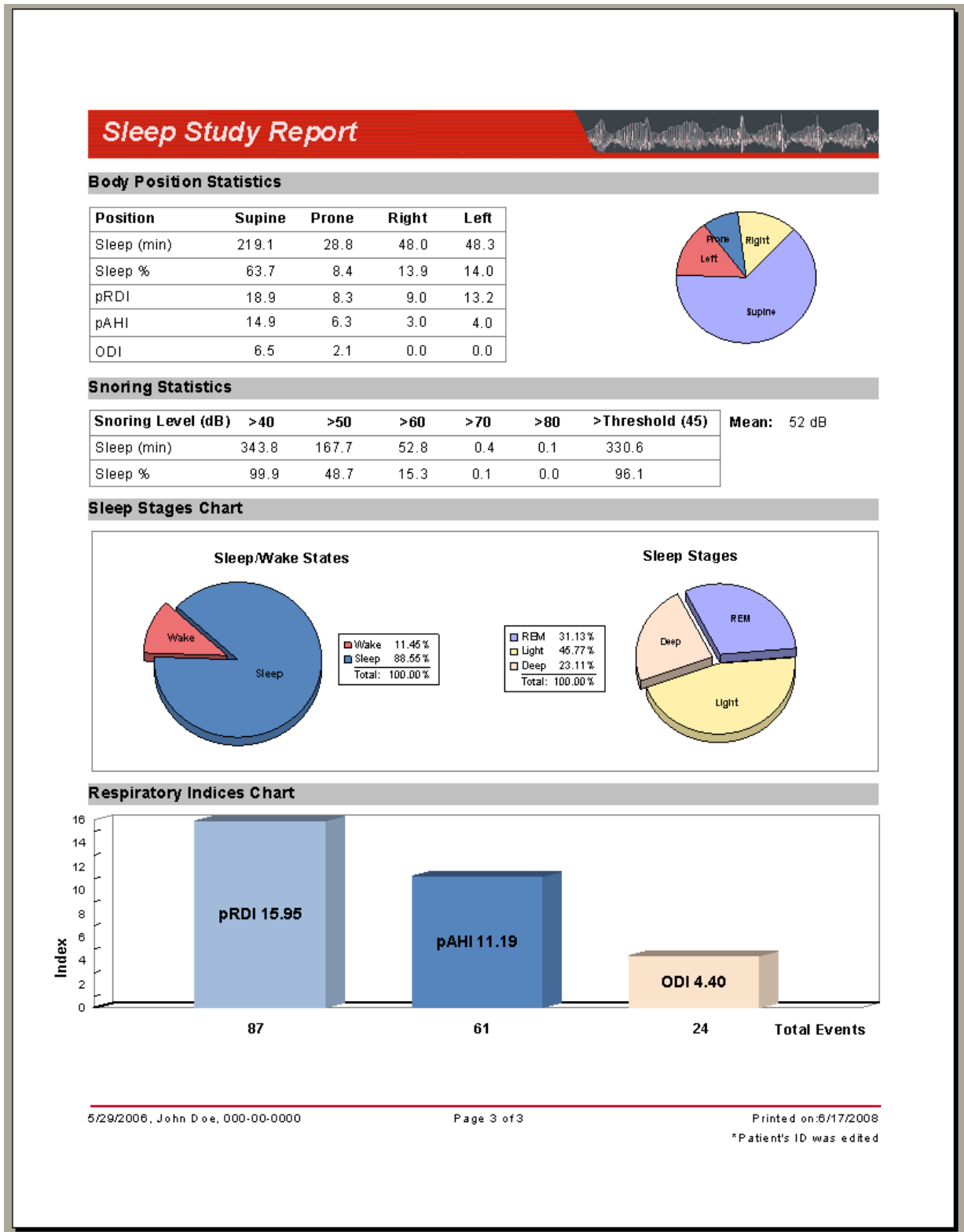


Figure 69 - Third page of Sleep Report (non-USA version)



#### 4.6.3 Report>Sleep Report for Selected Time Range

Generates a two-page report that provides a summary of the subject's sleep study in a **Selected Time Range** that is selected by the user.

The Selected Time Range report has the following title on the header of each page:



Figure 70 - Sleep Report for Selected Time Range Title


To generate a report for a selected time range:

- highlight the desired section of the waveform in the Signals Display Window, by clicking and dragging the mouse.
- click **Report>Sleep Report for Selected Time Range**.

The first page of the report includes Patient Information, the Sleep Study Information, Referring Physician, Medical history, Diagnosis and Recommendations.

The second page of the report presents the study results for the **Selected Time Range**, including Sleep Summary, PAT Respiratory Disturbance Index (pRDI), PAT Apnea Hypopnea Index (pAHI), Oxygen Saturation Statistics including the Oxygen Desaturation Index (ODI), mean, maximum and minimum oxygen saturation levels, Oxygen Saturation analysis, Pulse Rate statistics and REM Sleep analysis. It also includes graphical displays of Respiratory Events, Oxygen Saturation, Pulse Rate, Wake/Light Sleep/Deep Sleep and REM stages.

The third page of the report presents pie charts of sleep/wake states and sleep stages as well as a Respiratory indices chart.

	<p style="text-align: center;"><b>Note</b></p> <p>In the Selected Time Range report, the Start and End Study Times are the margins of the Selected Range.</p>
---	---

#### 4.6.4 Report>Event Report

This report provides statistics on different event types identified by the zzzPAT automatic analysis and by the User. A graphical representation provides a quick way of looking at the event distribution, and the summary section provides statistical information. When displayed on screen, the user can double-click on a particular event type (either on the chart or on the relevant row below the chart) to get a detailed list of all the events of this type (see Figure 71 - Event Report).

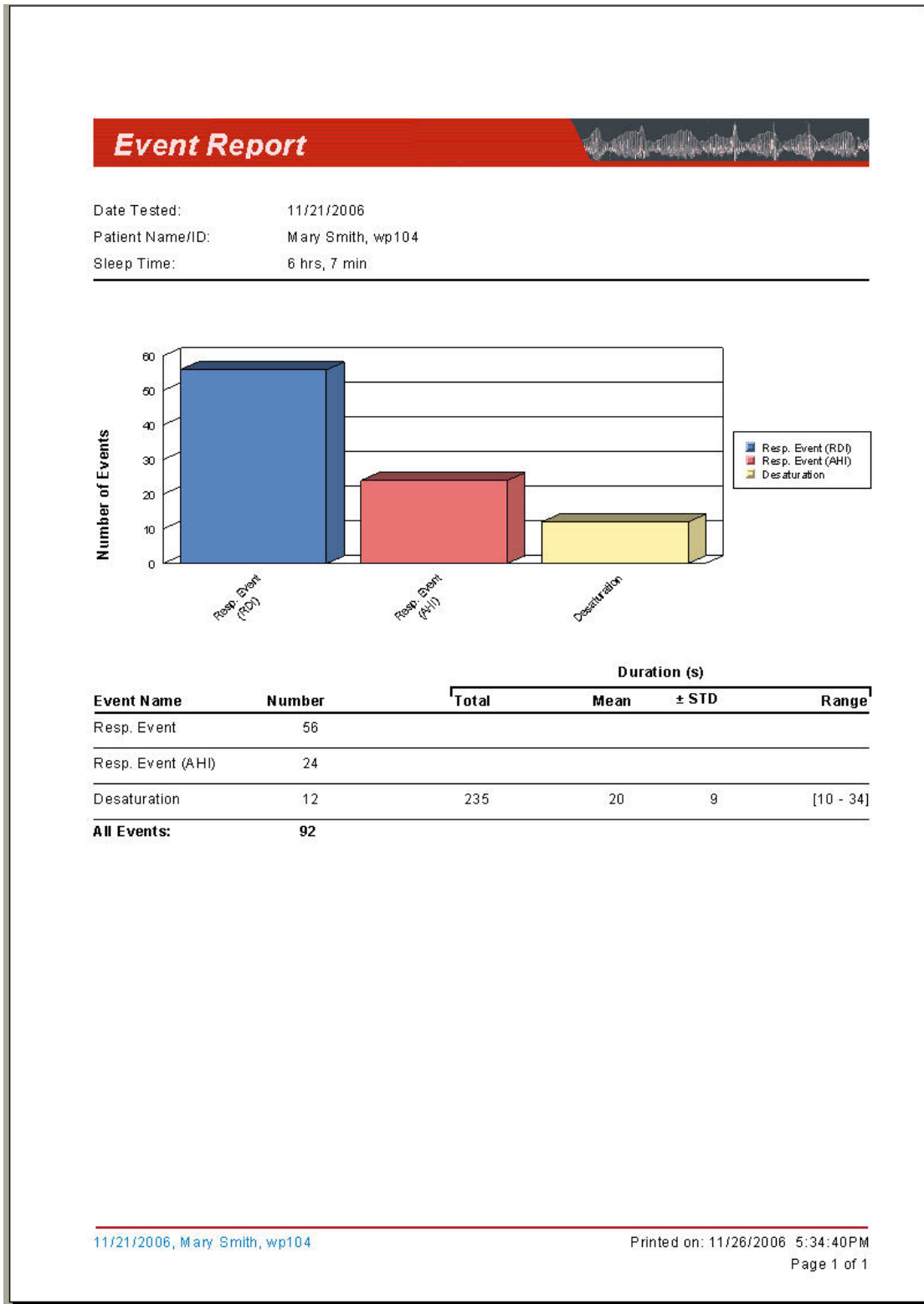




Figure 71 - Event Report

	<u>Time Start</u>	<u>Time End</u>	<u>Time Duration (s)</u>	<u>Percent</u>	
Desaturation	1:00:46	1:21:22	10	4	
Desaturation	1:59:40	2:20:34	28	4	
Desaturation	2:00:17	2:20:53	10	4	
Desaturation	2:02:01	2:22:56	29	6	
Desaturation	2:03:17	2:23:57	14	4	
Desaturation	2:05:17	2:26:03	20	4	
Desaturation	2:13:41	2:34:19	12	4	
Desaturation	2:17:05	2:37:46	15	4	
Desaturation	5:58:06	6:18:51	19	4	
Desaturation	5:59:27	6:20:24	31	5	
Desaturation	6:02:44	6:23:44	34	5	
Desaturation	6:04:38	6:25:17	13	5	
Desaturation	12	235	20	9	[10 - 34]

Figure 72 - Detailed Event Report



**Note**


Click on the upper right icon  to close the details screen and return to the main report.

#### 4.6.5 Report>Sleep Indices

This report provides a summary of study results, including pRDI, pAHI, ODI and Sleep Time.



Figure 73 - Sleep Indices report




**Note**

Generation of the “Sleep Report” will close the “Sleep Indices” report.

#### **4.6.6 Report>Patient Follow-up Report**

This report provides a way of comparing multiple studies for the same patient. A graphical representation of the pRDI, pAHI and ODI for the different studies provides a quick way of determining a trend through the studies.

In the European version of the report the Sleep % over 50 dB will be displayed as well.

	<p style="text-align: center;"><b>Note</b></p> <p>Unreviewed studies will not be presented in the Patient follow up report (see section 4.6.1).</p>
---	---

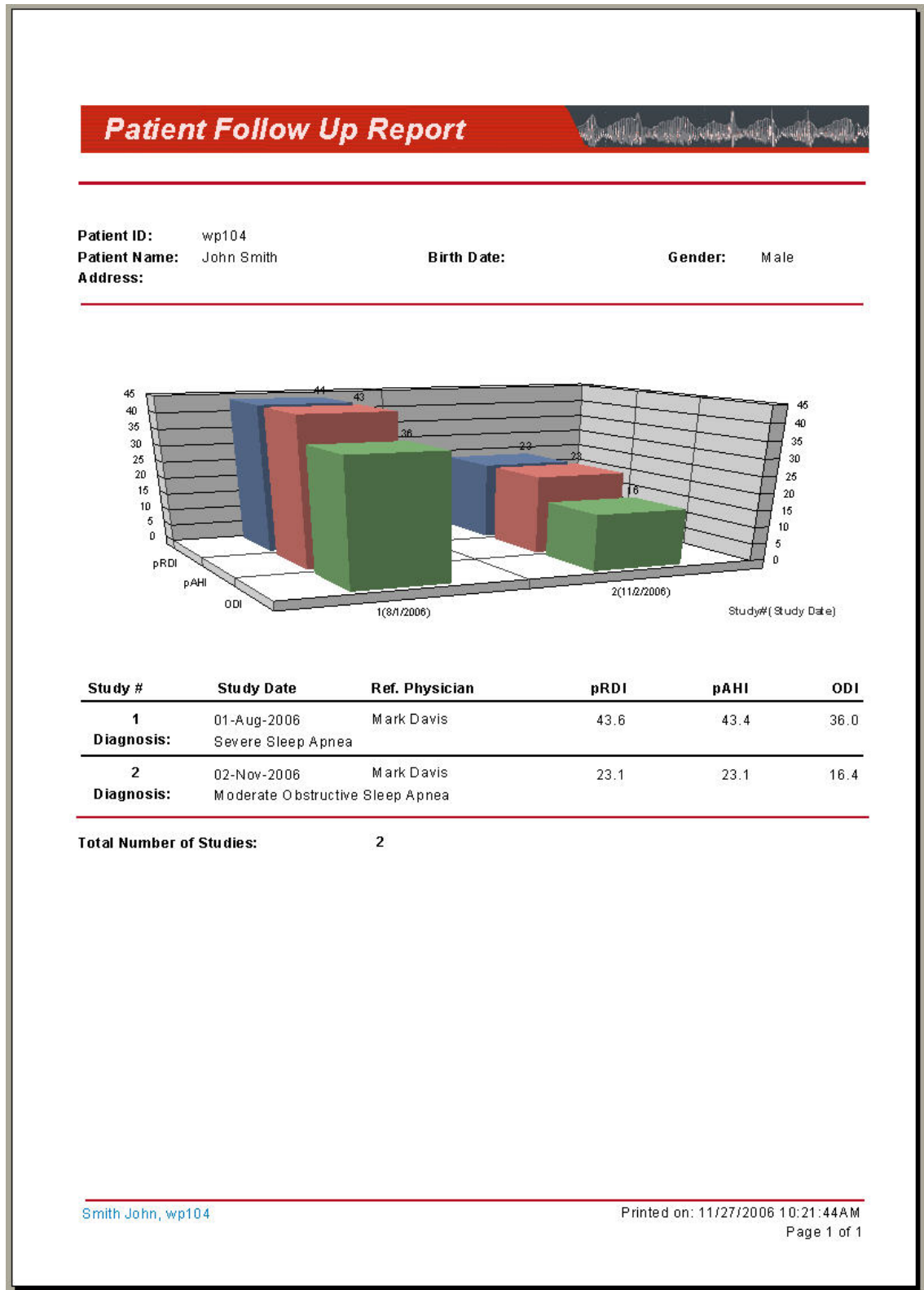


Figure 74 - Patient Follow Up Report (USA version)

#### **4.6.7 Report > Report for Patient**

This report is designed in the form of a letter addressed to the patient that informs the patient about the sleep test results. It provides the following patient details:

- Total sleep time
- Apnea/Hypopnoea index (AHI)
- Respiratory disturbance index (RDI)
- Desaturation index (ODI)
- Rapid eye movement (REM)

It also compares these to the normal average indices.

To produce the report for the patient:

1. In the **Report** menu, choose **Report for Patient**.
2. Print the report by clicking on the Printer icon




Figure 75 - Letter to the Patient

#### 4.6.8 Printing

zzzPAT offers the user several printing options. This section describes various options of printing the displayed signals. zzzPAT reports printing is described in Section 0.

##### 4.6.8.1 File>Print

The study signals recorded by the WP100 and the zzzPAT analysis can be printed by:

Either clicking on the print icon  on the toolbar or selecting **File>Print**.

User has a number of options for printing (Figure 76):

- Printing the entire study
- Printing the screen
- Printing specific sections defined by time range
- Printing specific channels

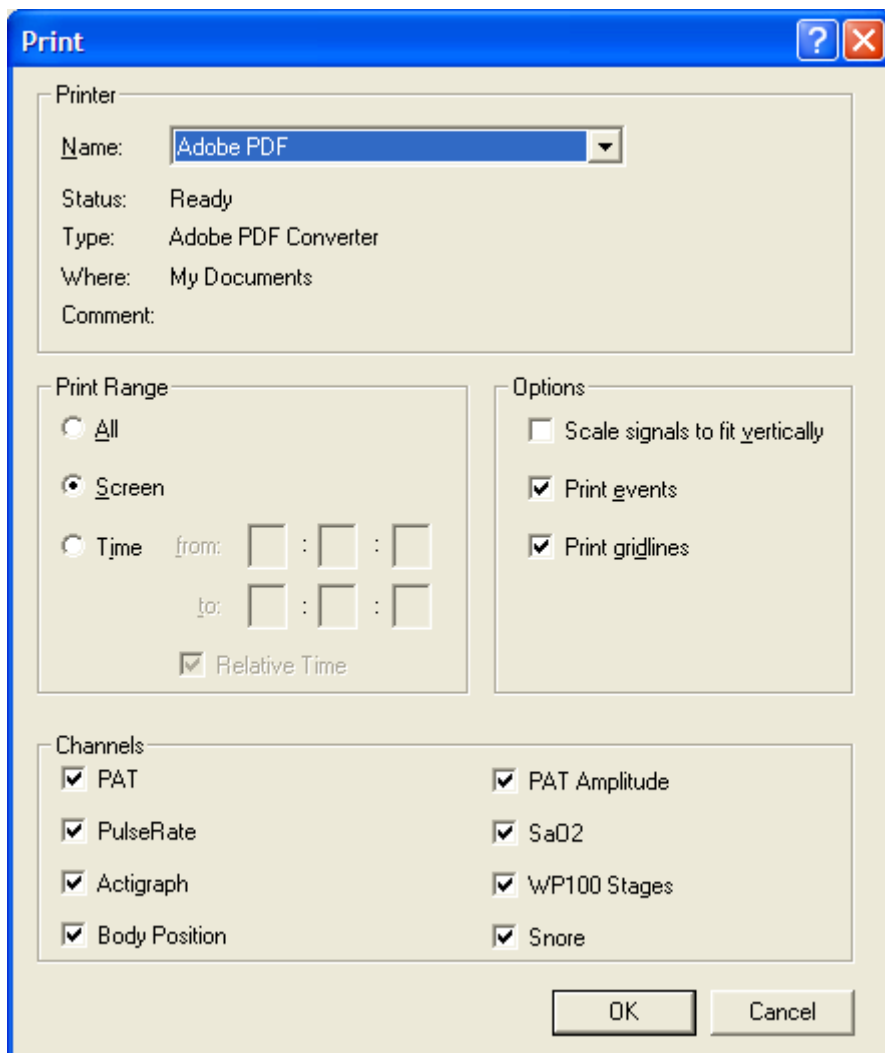


Figure 76 - Print dialog box



## 5 Exporting Data

### 5.1 File>Export Data

Enables the user to export and save recorded signals data either in binary or EDF format.

### 5.2 File>Export Events - Creating \*.txt File

Enables the user to export marked events into ACSII format. It creates an 'Event.txt' file that lists all events in a study by time of occurrence.

### 5.3 Tools>Export/Delete


See section 6.1.


### 5.4 Tools>Export General Settings

See section 6.5.

### 5.5 Transferring a Study to Itamar Medical

Used to save a study in a ZIP file, for transferring to Itamar Medical's support department. If zzzPAT has Internet access, this function allows the user to send the file directly, without saving first.

	<p style="text-align: center;"><b>Note</b></p> <p>The signals data that is transferred to Itamar does not include any patient information.</p>
---	--

	<p style="text-align: center;"><b>Note</b></p> <p>To use the zzzPAT ability to send files to Itamar, the zzzPAT station must have access to the Internet. If you not have access to internet use the alternative manual way to send signal data as describe in Appendix D: Manual Sleep data signal transfer.</p>
---	---

A study can be saved or transferred only if it is displayed in the 'Signals Display Window' or is stored in a Compact Flash card.

- Select a study:

## Itamar Medical Ltd.

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- by displaying it in the 'Signals Display Window'; or
- by inserting the Compact Flash card with the study into the Flash drive
- From zzzPAT click **Help>Prepare and Send Study to Itamar Medical...**

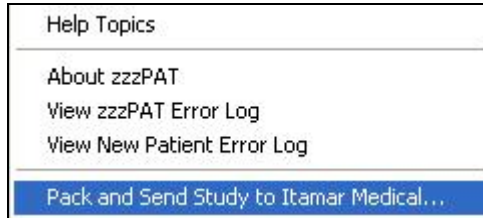


Figure 77 - Launching Transfer Files

The following Dialog Box appears:

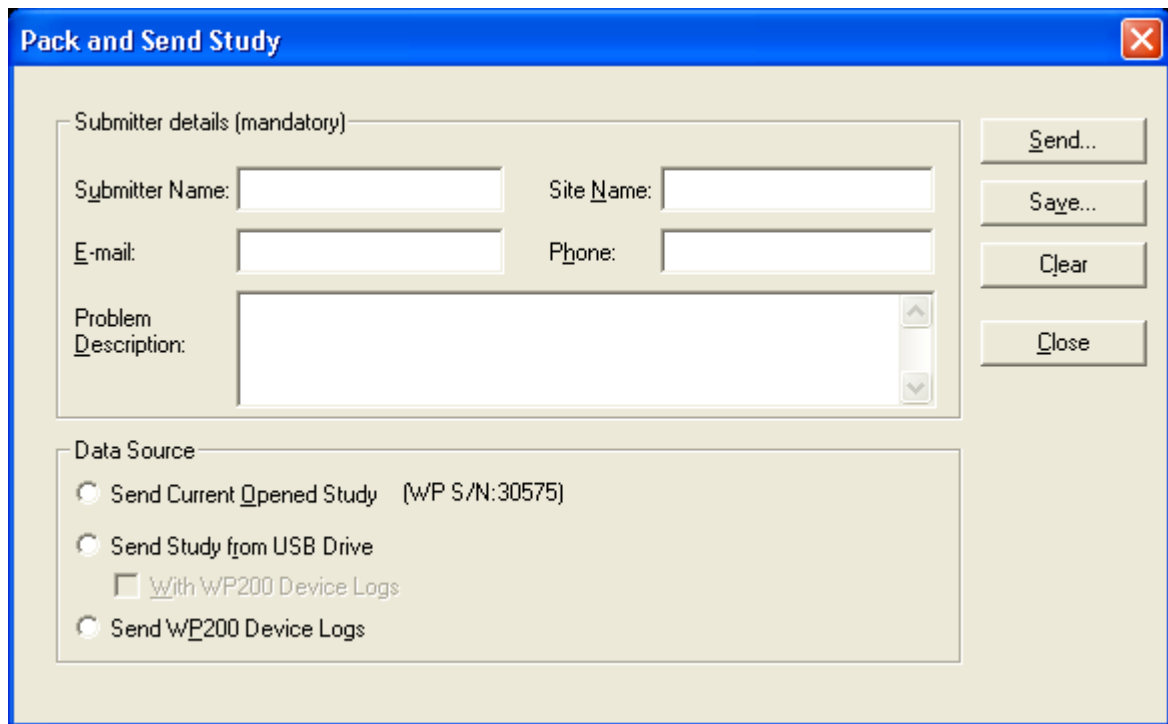


Figure 78 - Prepare and Send Study Dialog Box

- Select **Clear** to clear all fields. The last entered information is shown by default.
- Fill in the mandatory fields and check the radio button to indicate the desired option:
  - Check **Send Current Opened Study** if the case study is currently displayed on the Signal Window.
  - Check **Send Study From USB** if the case study is stored in the Compact Flash card (WP100) or in the WP200.
  - Check **Send WP200 Device Logs** in case the internal logs from the

WP200 device needs to be sent to Itamar for troubleshooting.

- To save the study click **Save....** The following dialog box appears:

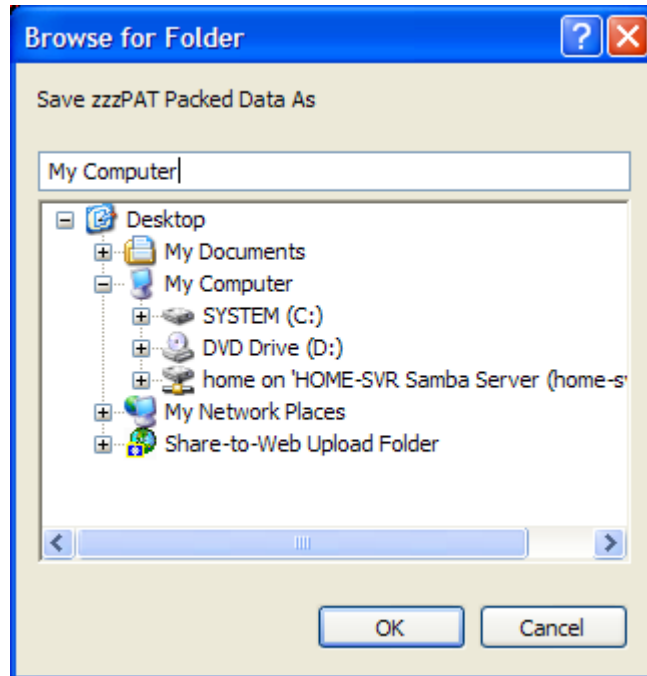


Figure 79 - Saving Case Study

- Select the destination for the saved file. The file will have the following name:
  - zzzPATPack\_DT.zzpWhere
  - D is the current date
  - T is the current time

### 5.5.1 Sending a file to Itamar automatically

To transfer the study to Itamar Medical's support department:

- From zzzPAT click **Help>Prepare and Send Study to Itamar Medical...**
- Fill in the mandatory fields and check the radio button to indicate the desired option:
  - Check **Send Current Opened Study** if the case study is currently displayed on the Signal Window.
  - Check **Send Study From USB** if the case study is stored in the Compact Flash card.
- Click **Send....** The following screen appears:

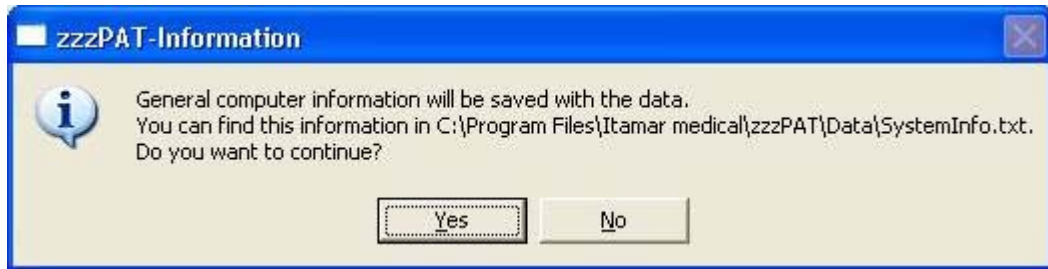



Figure 80 - Sending Study Confirmation

- Click **YES** to continue.

	<p style="text-align: center;"><b>Note</b></p> <p>General information about the computer configuration will be included in the transferred file. This information does not contain any patient information.</p>
---	---

The progress of the file transfer will be reported on the following screen:

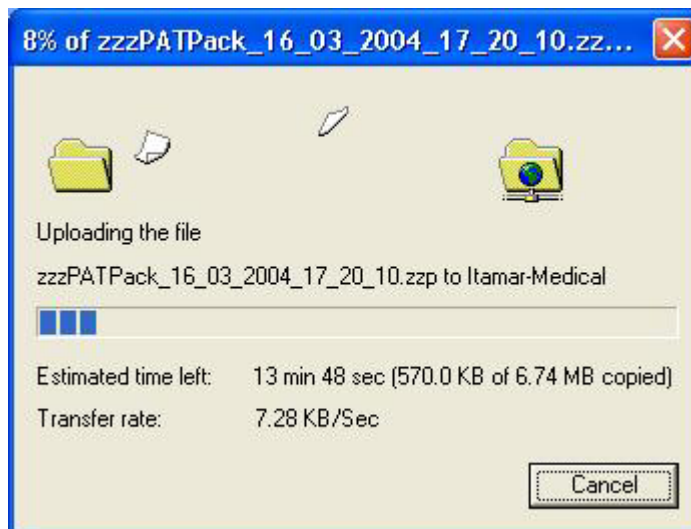


Figure 81 - Data Transfer Progress

Upon completion of the file transfer the following screen will appear:



Figure 82 - Data Transfer Successfully Completed

- Click **OK** to continue.

### 5.5.2 Sending a file to Itamar manually

If the zzzPAT station does not have Internet access, or the automatic send failed to complete, the file can be sent manually using the following procedure:

- Save the file as described in Section 5.5
- Copy the saved file to a PC that has Internet access
- Launch Internet Explorer (or a similar Internet browsing application)
- Upload the file using the Itamar ftp server, see Appendix D: Manual Sleep data signal transfer

## 6 Tools

### 6.1 Tools>Export/Delete

Allows the user to select the data of specific studies from the zzzPAT database and extract it to an archive database. This action enables freeing space on the PC hard disk, if needed, and archiving the data in other locations. Upon selection, the 'Export' dialog box will open:

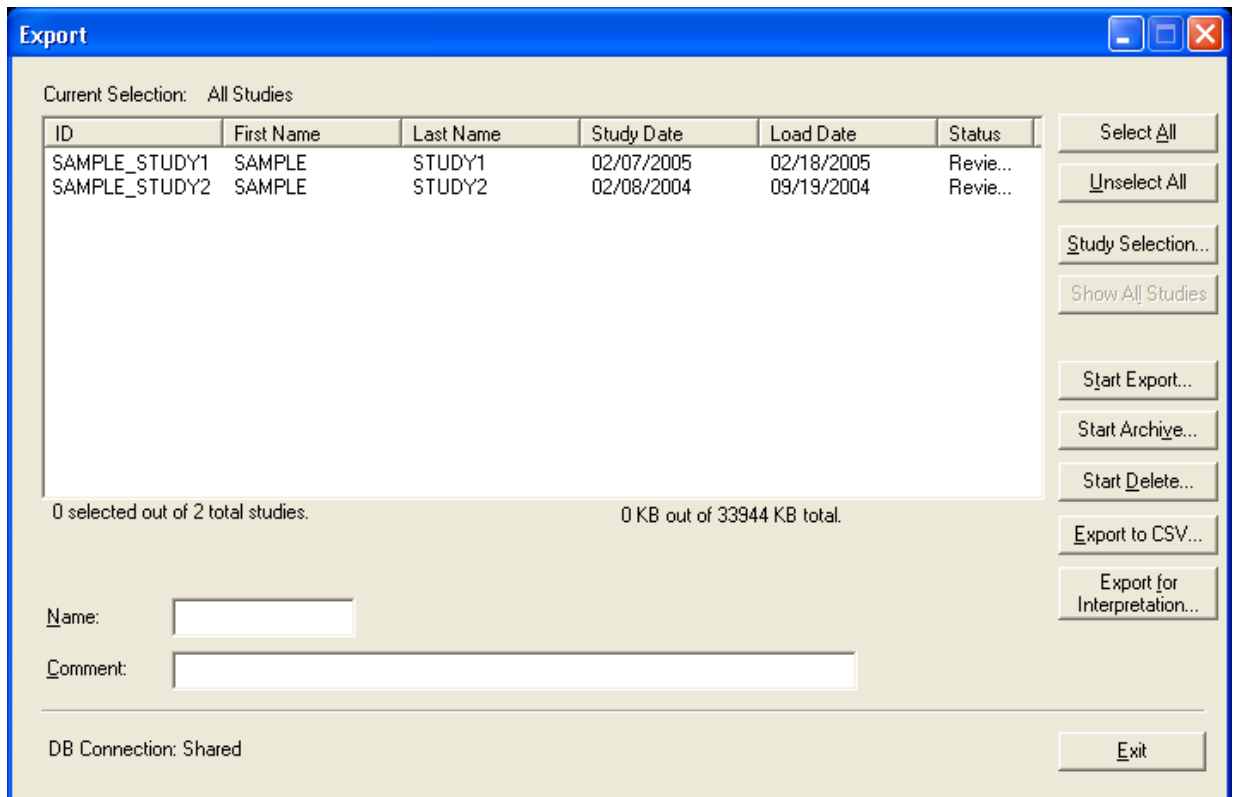



Figure 83 - Export Dialog box

This dialog box allows to export, archive or delete study data:

- **Export** function: Creates a file containing a copy of the selected study data as well as User's information for users associated with the exported files. Original files are not removed from the database.
- **Archive** function: Creates an archive file of the selected study data as well as User's information for users associated with the exported files, and removes the original data from the database.
- **Delete** function: Deletes the selected files from the database.

- **Export to CSV** function: Creates a file named zzzPAT.csv, which contains in one line all the Patient, Study, Physician, and Analysis fields information. In case that a study has two different analysis, the data will be exported in two lines; one line for each entry.

	<p><b>Note</b></p> <p>Sleep Statistics values will be empty in CSV export for studies that had not a report issued.</p>
---	---

- The **Delete** function has two options, as seen in Figure 84.
- Delete files and save a temporary copy. The deleted files are saved to a temporary folder, overwriting the previously saved files from the last time the function was used and the option to save a temporary copy was chosen (this function always uses the directory ...\\Itamar Medical\\zzzPAT\\Data\\zzDELETE to save the deleted files).
- Delete studies permanently. The deleted files are deleted permanently.

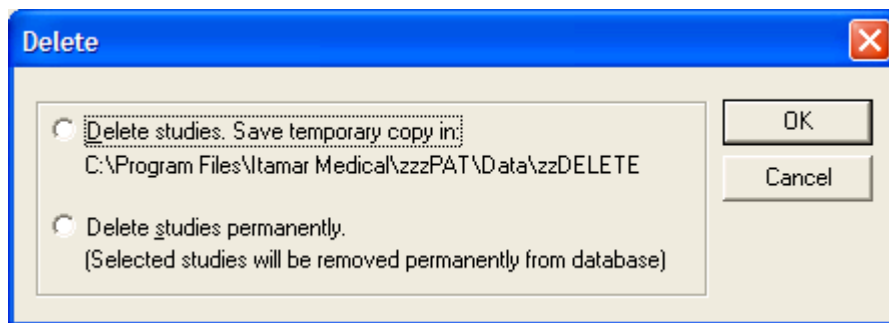


Figure 84 - Delete studies options Dialog box

- Temporarily saved deleted files can be restored by using the Import function of the Database Tools (see section 7.1.2).
- The temporarily saved file can be deleted from the hard disk (e.g. to free disk space) by following one of the below listed procedures:
- Delete one more study and select “Delete studies. Save temporary copy in:”. By doing so the previously saved deleted studies will be replaced by the single study deleted now, thus reducing the size of the saved files to one study only.
- Using Windows Explorer navigate to the folder that contains the saved deleted files (\\Program Files\\Itamar Medical\\zzzPAT\\Data\\zzDELETE) and delete its content in its entirety.

To commence Archive Export or Export to CSV operations proceed with the following:

- Name the archive (optional) in the ‘Name’ editing box (Name can consist of up to 8 characters).
- Add comments, if desired, in the ‘comments’ editing box.
- The exported/archived files will be saved in a folder named in accordance with the following convention:

- Exported files: 'zzExport\_name\_dd\_mm\_yy\_hh\_mm' with "name" being the optional data entered by the user
- Archived files: 'zzARCHIVE\_name\_dd\_mm\_yy\_hh\_mm' with "name" being the optional data entered by the user
- Export to CSV files: 'zzzCSVExport\_name\_dd\_mm\_yy\_hh\_mm' with "name" being the optional data entered by the user
- You can apply a filter to the files listed in the main field, by clicking **Study Selection....** The following dialog box will open:

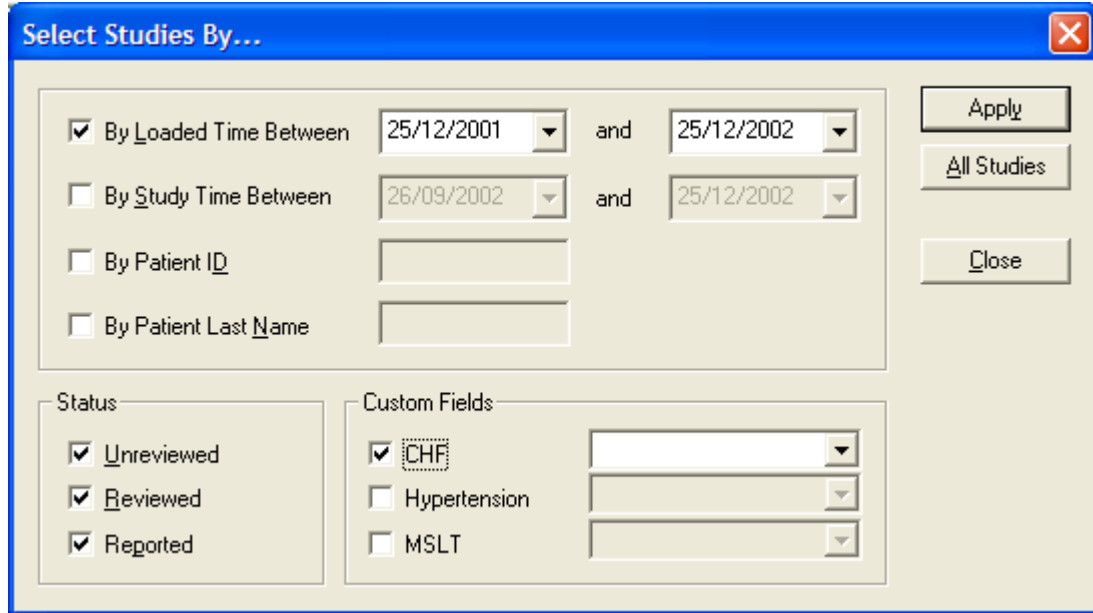



Figure 85 - Study Selection Dialog box

- To select studies by a specific criterion, check the box to the left of the desired criterion. In addition user can select whether to export studies by status: Unreviewed, Reviewed and Reported and by user predefined **Custom Fields** (see section 3.4.4). It is possible to select several criteria by which to export a single group of studies.

	<p style="text-align: center;"><b>Note</b></p> <p>The <b>Custom Fields</b> section will appear in the 'Select Studies By' dialog box, only if the user predefined these fields. See section 3.4.4 for details.</p>
---	--


- Select the studies you wish to export/archive/delete from the main field in the Export dialog box. You can click **Select All** to select all files, or you can select individual files by shift or control clicking on them.
- Once ready, click:
- **Start Export** to export the selected studies, or,
- **Start Archive** to archive the selected studies, or,



- **Start Delete...** to delete the selected studies, or,
- **Export to CSV** to export the selected studies to CSV format.
  
- Click **Exit** to close the Export dialog box.
- **Export for Interpretation** function: Prepares and copies the raw data files as one zipped file for later ftp upload to a secure server for interpretation services.

## 6.2 Tools>Import

Use to import previously archived studies that were removed from the zzzPAT database, back into the database. Upon selection the 'Import' dialog box will open.

	<b>Note</b>
	Together with the imported studies zzzPAT imports user information of users associated with the imported files if such users are not defined in zzzPAT. These users are imported with <b>Basic User Permissions</b> only (see Section 2.9.2).

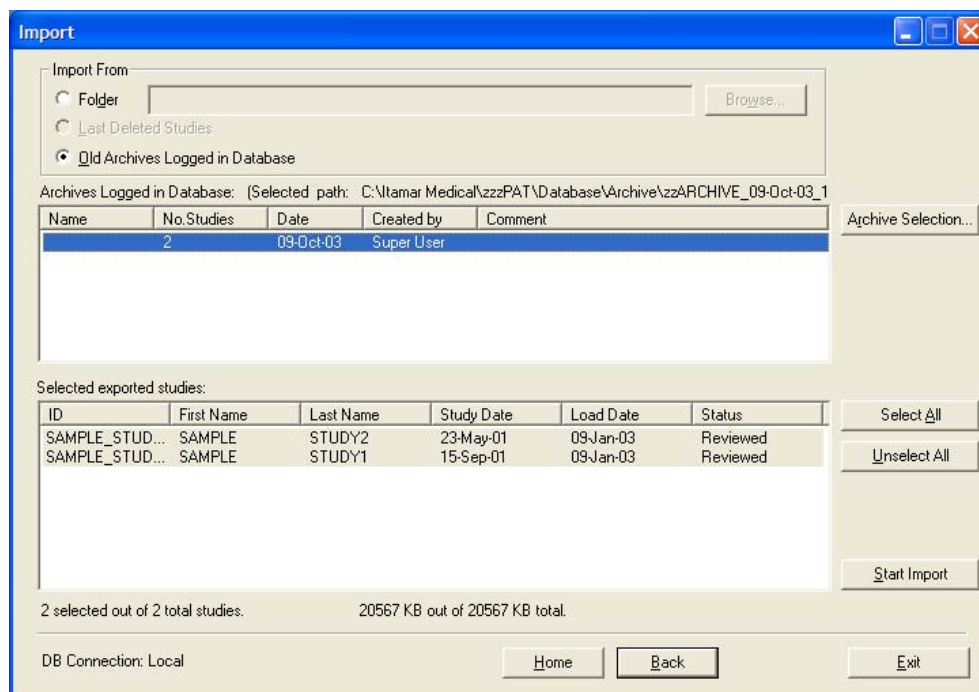


Figure 86 - Import Dialog Box


It is possible to locate the archived studies you wish to import by using the **Browse** option or by selecting them from a list of logged archives in the database. If previously deleted files were deleted using the "Save a temporary copy" option, selecting the Last Deleted Studies option will allow retrieval of these studies.

**Locating an Archive by browsing:**

- Select the 'Folder' radio button in the 'Import' dialog box. The **Browse** button will become enabled.
- Click on the **Browse** button and select the file you wish to import.

**Locating an Archive from a list of logged Archives in the database:**

By default all archives will be displayed in the 'Old Archives Logged in Database' list. The user can filter the archives displayed in this list by certain criteria.

	<p style="text-align: center;"><b>Note</b></p> <p>If the database was overwritten while upgrading zzzPAT or the database was erased due to restoring a back up database into it, no archives will displayed in the "Old Archives Logged in Database' Field.</p>
---	---

**To filter the archives that will be displayed in the 'Old Archives Logged in Database' field:**

- Select the "Old Archives Logged in Database' radio button.
- Click on the **Archive Selection** button. The following dialog box will open:

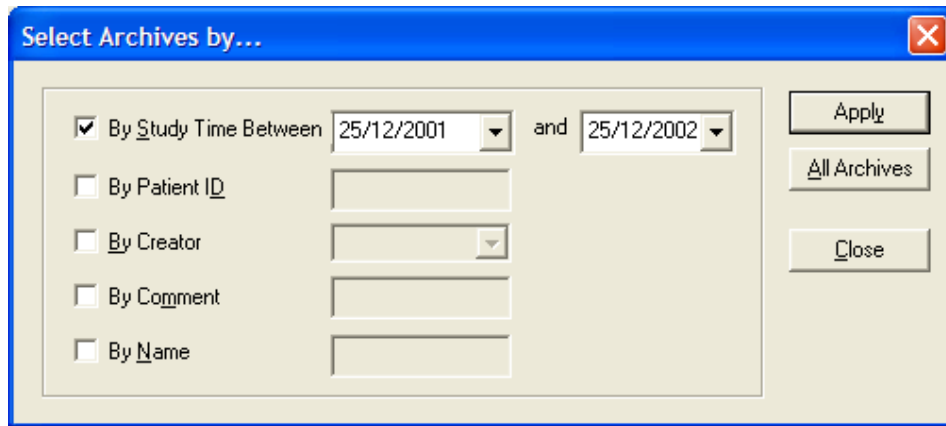



Figure 87 - Select Archive Dialog box

- Check the criteria by which you want to select the Archive.
- Insert the appropriate parameters for selection.
- Click **Apply**.
- Click **Close** to return to the 'Import' dialog box.
- You can restore the default display of all archives by clicking the **All Archives** button.
- Select the Archive you wish to import.

Once an Archive has been selected, all its studies will be displayed in the 'Selected exported studies' fields of the 'Import' dialog box.

- You can select individual studies you wish to retrieve by clicking on them with the mouse while holding down the **Ctrl** key on the keyboard, or you can import them all by clicking on the **Select All** button.
- Click **Start Import** to begin the process.

	<p style="text-align: center;"><b>Note</b></p> <p>You cannot import a study that is already available in the database</p>
---	---

### 6.3 Tools>Backup

Enables the user to copy the entire database to another location for back up. Upon selection the 'Backup' dialog box will open.

- Select the path for a backup directory by clicking on the **Browse** button, or by accepting the system default setting.
- Click **Start Backup** to begin the process.

#### **Automatic Backup**

A backup of the database for every day of the week will be automatically performed behind the scenes. Backing this way will minimize loss of data in case of database corruption. The backup of the database will be saved as zzPATday1.bak for Sunday, zzPATday2.bak for Monday, etc. The zzPATday1.bak will be overwritten next Sunday. The files will be saved under backup folder (C:\itamar medical\zzzpat\backup).

### 6.4 Tools>Restore

Use this application for restoring a backed-up database by overwriting the current database. Use this application to recover a database following a major database failure. Upon selection the 'Restore' dialog box will open.

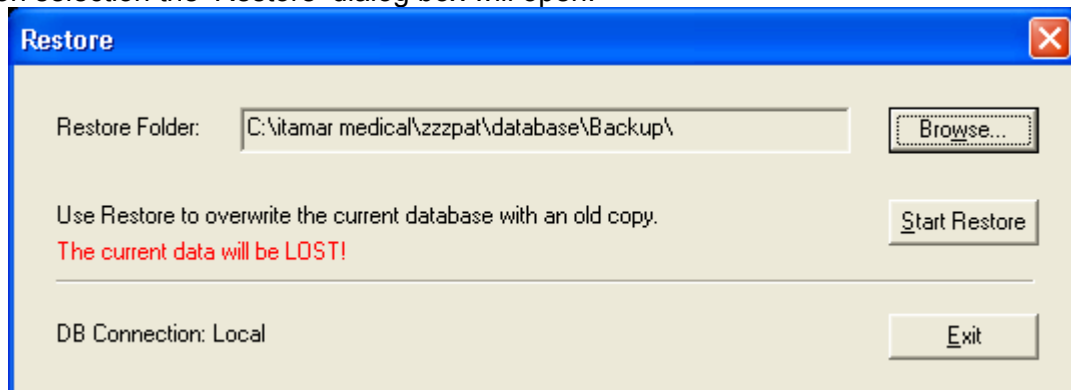



Figure 88 - Restore Dialog box

	<p><b>Warning</b></p> <p>Restoring a backed-up database overwrites the current database replacing all the data it contained!!!</p>
---	--

## 6.5 Tools>Export General Settings

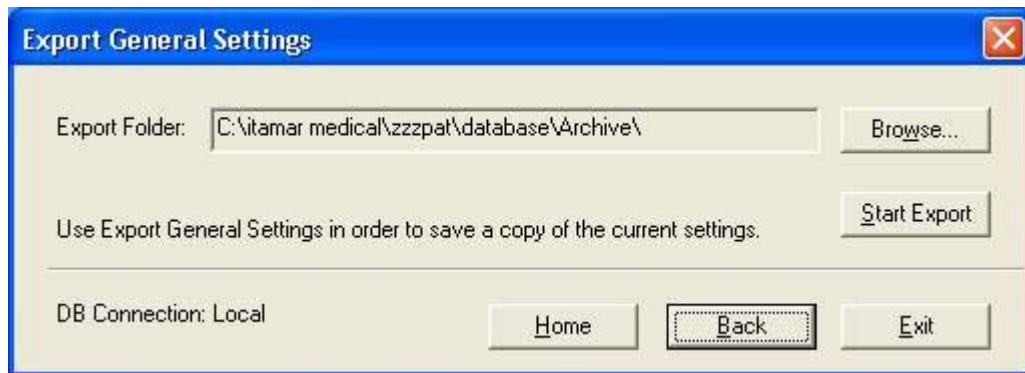


Figure 89 - Export General Settings Dialog Box

- Type the directory path or click '**Browse**' button to select the directory, where the General Setting configuration file will be saved.
- Click 'Start Export'.

## 6.6 Tools>Import General Settings

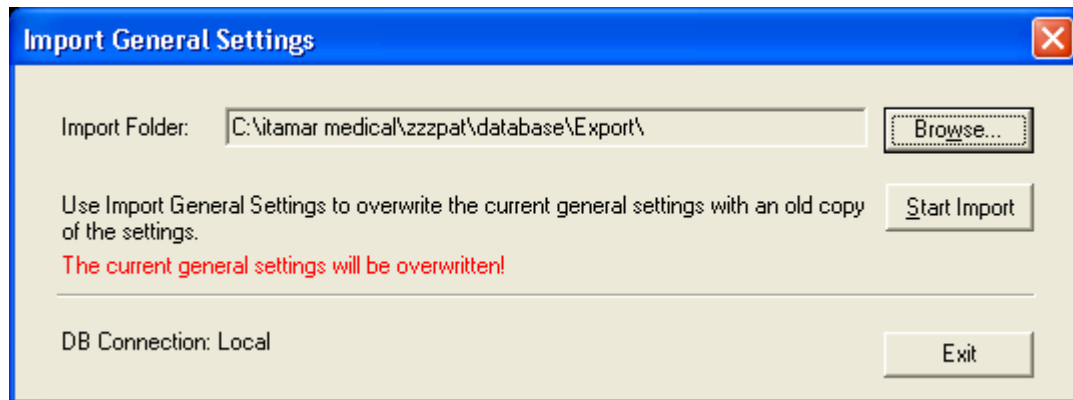


Figure 90 - Import General Settings Dialog Box

Click '**Browse**' to select the directory of the General Setting configuration file.

Click '**Start Import**' to continue.

## 6.7 Tools>User Administration

Please refer to Section 2.9.

## 7 Database Wizard

The zzzPAT Database Wizard contains three utilities:

**Database Tools** - Allows an authorized administrator to update and maintain the zzzPAT database.

**User Administration** - Allows an authorized administrator to add users to zzzPAT application and define the permissions attributed to them. (See chapter 2.9).

**Configuration Tools** - Allows an authorized administrator to Export and Import the General Settings.

- Select Start>Programs>zzzPAT>Database Wizard.

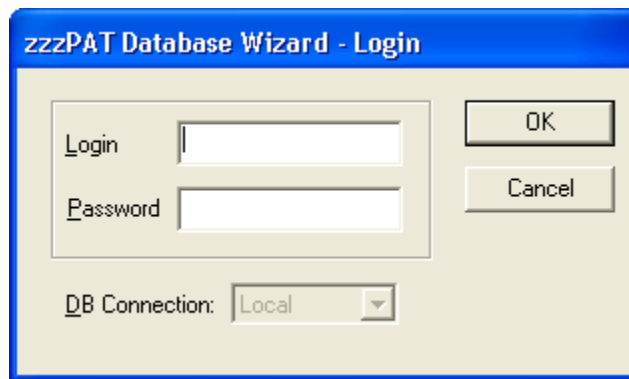


Figure 91 - Database Wizard Login

- Enter Login and Password, and select the desired database Connection.
- The Database Wizard will open:



Figure 92 - Database Wizard

## 7.1 Database Tools

Click on the 'Database Tools' icon . The following dialog box will appear:

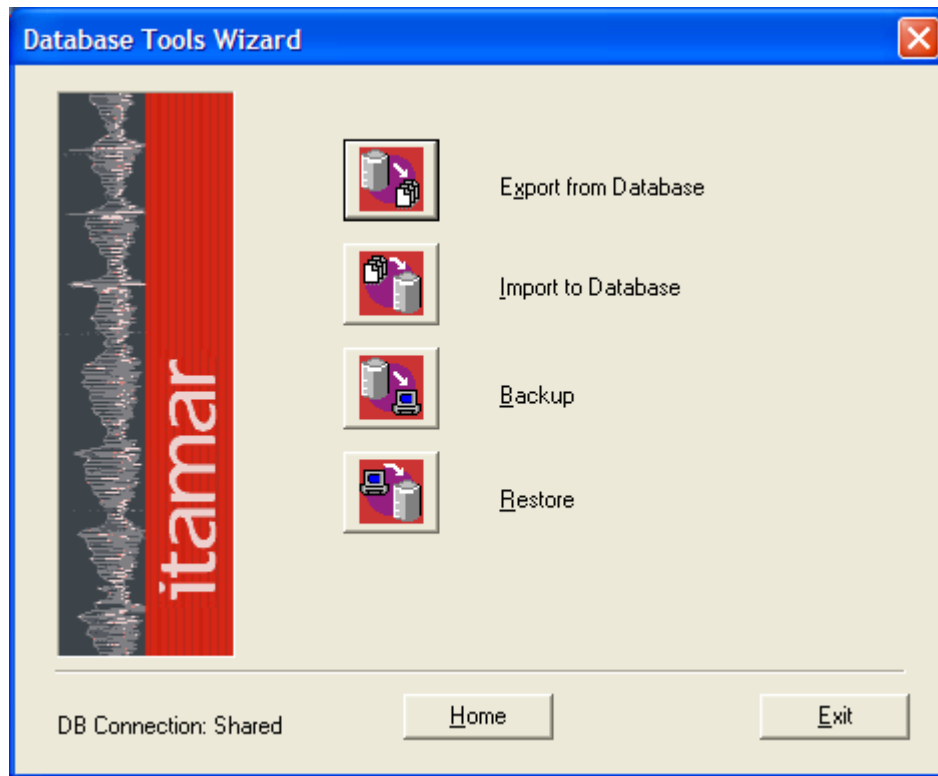




Figure 93 - Database Tools Wizard dialog box

### 7.1.1 Export From Database:

- Click the 'Export From Database' icon  in the 'Database Tool Wizard' window.
- Refer to Section 6.1 for a detailed explanation of the exporting procedure.

### 7.1.2 Import to Database

- Click on the 'Import to Database' icon  in the 'Database Tools Wizard' window.
- Refer to Section 6.2 for a detailed explanation of the importing procedure.

### 7.1.3 Backup

- Click on the 'Backup' icon  in the 'Database Wizard Tools' window.
- Refer to Section 6.3 for a detailed explanation of the backup procedure.



### 7.1.4 Restore

- Click on the 'Restore' icon  in the 'Database Wizard Tools' window.
- Refer to Section 6.4 for an explanation of the restoring procedure.

## 7.2 User Administration

Please refer to Section 2.9.

## 7.3 Configuration Tools

Used to copy General Settings from one zzzPAT station to another (see Figure 92).

Click the configuration tools icon . The following screen appears:

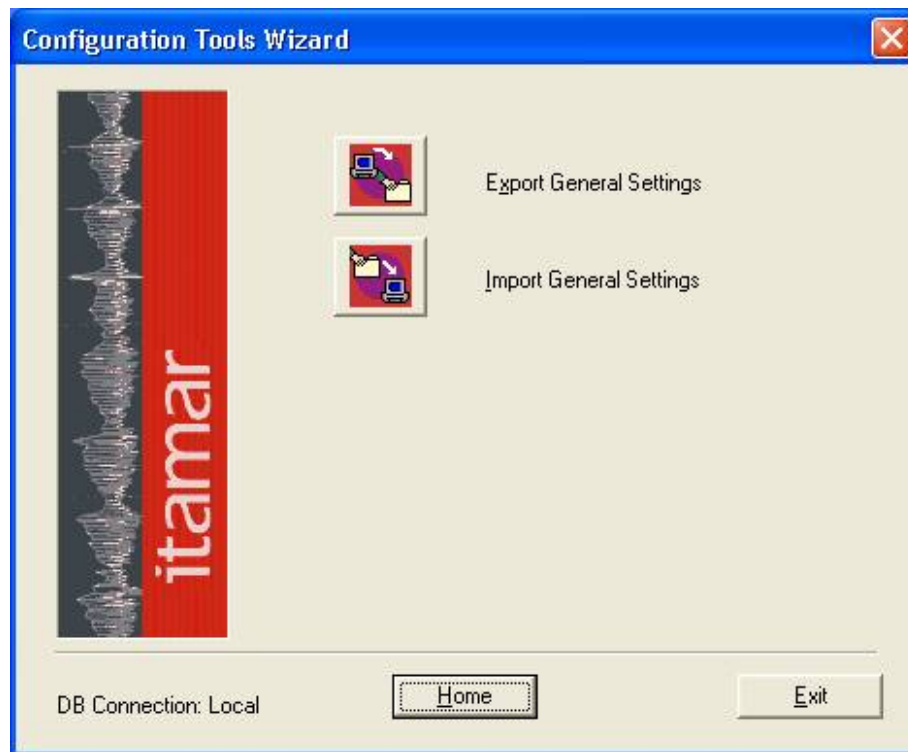



Figure 94 - Configuration Tool Wizard

- Click the 'Export General Settings' icon  to save the current General Settings configuration.

- Click the 'Import General Settings' icon  to apply a saved General Settings configuration.

### **7.3.1 Export General Settings**

- Click the 'Export General Settings' icon .
- Refer to Section 6.5 for a detailed explanation of the general settings exporting procedure.

### **7.3.2 Import General Settings**

- Click the 'Import General Settings' icon .
- Refer to Section 6.6 for a detailed explanation of the general settings importing procedure.

## 8 Troubleshooting

<b>Installation</b>		
<b>Trouble</b>	<b>Possible Cause</b>	<b>Solution</b>
zzzPAT installer fails to run.	Auto run function in Windows is not activated.	Open My Computer>zzzPAT CD and double click 'Setup.exe'.
	Windows version not compatible with zzzPAT.	Must have Windows 2000 or Windows XP for zzzPAT installer to run.
	Hardware configuration below minimum required.	Must have at least 128 MB RAM, and a Pentium processor for zzzPAT installer to run.
zzzPAT fails to recognize flash drive.	Compact Flash drive not installed	Install Compact Flash drive, when done, insert a CF card, run zzzPAT and select <b>Setup&gt;Set USB Drive</b> (see section Setup>Set USB Drive)
	Compact Flash drive needs to be re-defined.	Insert a CF card, run zzzPAT and select <b>Setup&gt;Set USB Drive</b> (see section Setup>Set USB Drive)
Under Windows XP, user cannot load study or operate 'Database Wizard' utilities, despite having proper zzzPAT user permissions.	User does not have writing permission to the drives these applications are located on.	Check user's writing permissions per section, and redefine as necessary.

Table 2 - Troubleshooting, Installation

<b>zzzPAT</b>		
<b>Trouble</b>	<b>Possible Cause</b>	<b>Solution</b>
<b>Analyze&gt;Reload Study and Analyze</b> option in the zzzPAT window is disabled	User does not have permission to operate this utility.	zzzPAT Administrator can modify user's Extended Permissions. (See section 2.9)
	Insufficient free space on hard disk	Free enough disk space to exceed the minimum requirement of 100MB and try again
Cannot <b>Load Study</b> (function is disabled)	There is less than 200MB of free hard disk space	Free enough disk space to exceed the minimum requirement of 200MB and try again
zzzPAT will not start, or behaves unpredictably	Some zzzPAT files may be damaged/overwritten	Uninstall and reinstall zzzPAT.

The open file does not show REM	File was saved with an older version of zzzPAT that did not have REM capabilities	Run the analysis by selecting <b>Analyze&gt;Reload Study and Analyze</b>
Events Report does not show defined header, footer and logo	The Report Appearance setting tab applies only to the Sleep Report	NA
Cannot generate Sleep Report - Sleep Report button is grayed out	Less than 100MB of free disk space	Free enough disk space to exceed the minimum requirement of 100MB and try again
	No study is loaded or study is non valid	Open the desired study. If the study is open, it may have invalid data and therefore is not usable
User cannot log on to zzzPAT	On Windows XP and Vista zzzPAT will not open if another session is open under a different user	Ensure no other user left an open zzzPAT session on the PC. If you cannot verify, restart PC
	User is not defined in zzzPAT	Define user by zzzPAT administrator
Send report by email fails	zzzPAT does not support Netscape as the email application	Define Microsoft Outlook (or Outlook Express) as the default mail client
Changes to Events Names do not show up on screen	Events names are saved with the saved analysis. Changes will become visible only after running analysis again	Run the analysis by selecting <b>Analyze&gt;Reload Study and Analyze</b>
Errors while printing	Non-compatible printer driver	A postscript printer driver provides the most reliable operation with the zzzPAT. Install a suitable postscript driver for the printer in use and try again
After clicking <b>New Study</b> in zzzPAT the dialog box disappears and zzzPAT is frozen	Inadvertent double clicking the <b>New Patient</b> button may cause the dialog box to be hidden in the background	Press <b>Alt-Tab</b> to bring the dialog box back to the front
"Enable multi-night option" does not show in New Study dialog	The WP200 has S/W version lower than 2.2182	Upgrade the WP200 S/W to the newest S/W (call Itamar Help Desk for the upgrade)
"Enable tamper-proof testing option" does not show in New Study dialog	The WP200 has S/W version lower than 2.2182	Upgrade the WP200 S/W to the newest S/W (call Itamar Help Desk for the upgrade)

Table 3 - Troubleshooting, zzzPAT

Shared Access Mode zzzPAT		
Trouble	Possible Cause	Solution
User cannot log on to zzzPAT	In Shared Access mode user may be defined in the shared database and not in the local one, or vice-versa	Define user in the second database, or, Exit zzzPAT and log on to the other zzzPAT database (either local or shared)
Cannot find saved file	File saved to the other database (either the local or shared database)	<ul style="list-style-type: none"> <li>• Verify to which database zzzPAT is connected (the database connection appears in the zzzPAT status bar)</li> <li>• Exit zzzPAT</li> <li>• Start zzzPAT and select the other database to connect to</li> <li>• Select <b>File&gt;Open</b> and search for the desired file</li> </ul>
Shared database is not available	Network is disconnected	<ul style="list-style-type: none"> <li>• Make sure the zzzPAT station is properly connected to the network, and that network services are available to it. Consult your system administrator if necessary</li> </ul>
Cannot open selected study	Study is in use by another zzzPAT user	<ul style="list-style-type: none"> <li>• Wait until the other user closes the study and try again</li> </ul>

Table 4 - Troubleshooting, Shared Access Mode zzzPAT

<b>Utilities</b>		
<b>Trouble</b>	<b>Possible Cause</b>	<b>Solution</b>
Preparing Compact Flash card for new study failed	Compact Flash card was removed from the Compact Flash reader before 'New Study' details were saved to it	Do not remove Compact Flash card from the Compact Flash reader before Figure 41 dialog box appears
<b>WP100 only:</b> New Study or zzzPAT do not recognize the Compact Flash card	Critical files were erased from the Compact Flash card	Using Windows Explorer, copy files patient.dat and sleep.dat from <b>Program Files\Itamar Medical\zzzPAT\Misc</b> to the Compact Flash card, and try again
	Compact Flash card was formatted to an unsupported format	Reformatted Compact Flash cards cannot be used with the Watch-PAT system and have to be replaced
<b>WP200 only:</b> New Study or zzzPAT do not recognize the WP200	Critical files were erased from the internal sd card or the volume name has been erased	Format drive with volume name "WP200" and then copy files patient.dat, sleep.dat and wp200-comm.dat from <b>Program Files\Itamar Medical\zzzPAT\Misc</b> to the WP200 drive
Database Tools button in the 'Database Wizard' window or Tools in zzzPAT is disabled	User does not have permission to operate this utility	zzzPAT Administrator can modify user's Extended Permissions (See section 2.9)
User Administration button in the 'Database Wizard' window or Tools>User Administration is disabled	User does not have permission to operate this utility	zzzPAT Administrator can modify user's Extended Permissions (See section 2.9)
Database Tools does not open	zzzPAT or New Study is running	Close zzzPAT or New Study and open Database tools
Super User forgot his password	-	Contact Itamar Medical Representative

Table 5 - Troubleshooting, Utilities

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## Appendix B: TECHNICAL SUPPLEMENT

The zzzPAT uses a set of algorithms and provides automatically the following indices and events:

- Sleep-wake events using the Automatic Sleep-Wake Algorithm (ASWA).
- Respiratory events index which includes Apnea Hypopnea and RERA: pRDI (PAT Respiratory Disorders Index).
- Apnea and Hypopnea Index: pAHI (PAT Apnea and Hypopnea Index).
- Oxygen Desaturation Index ODI.
- REM (REM) events using the Automatic REM Detection Algorithm (ARDA).
- Deep and Light Sleep (s1,s2 is light ) and s3-s4 is Deep sleep.

### Sleep-Wake

The sleep-wake output, obtained in 30 seconds epochs, is used by the other three algorithms to apply calculations in sleep sections only, while skipping over the wake sections.

### pRDI and pAHI

**pRDI** expresses the number of PAT respiratory events per hour of sleep, the index includes the following events: Apnea and Hypopnea and RERA (respiratory effort related arousal).

**pAHI** expresses the number of Apnea and Hypopnea per hour of sleep.

These events are derived from the following physiological parameters measured by the WP100:

- PAT signal amplitude - acquired by a pneumo-optical finger probe that measures the vasomotor changes of the arterial blood vessels in the finger. This reflects changes in sympathetic activity.
- Pulse rate - derived from the above PAT signal.
- Blood Oxygen saturation level - determined by an embedded pulse Oximeter.

**The first two parameters are associated with sympathetic activity related to respiratory episodes. The third parameter, oxygen saturation level decreases (desaturation) during a respiratory event. Actigraphy movement is often associated with respiratory episodes. These four physiological parameters are incorporated into two different decision- making processes that define, for each epoch identified as a sleep epoch and breathing disorders. These processes are described in the attached flow diagram.**

### ODI

This index expresses the number of Oxygen desaturation events during an hour of sleep. Desaturation event is determined when there is a reduction of 4% of the oxygen saturation baseline. The index includes the events that occurred during sleep time, and it does not includes events occurred during wake periods.

## **REM**

REM events are determined for sleep epochs only, based on information extracted from local windows applied to the amplitude and pulse-rate time-series of the PAT signal. For each epoch four parameters are extracted:

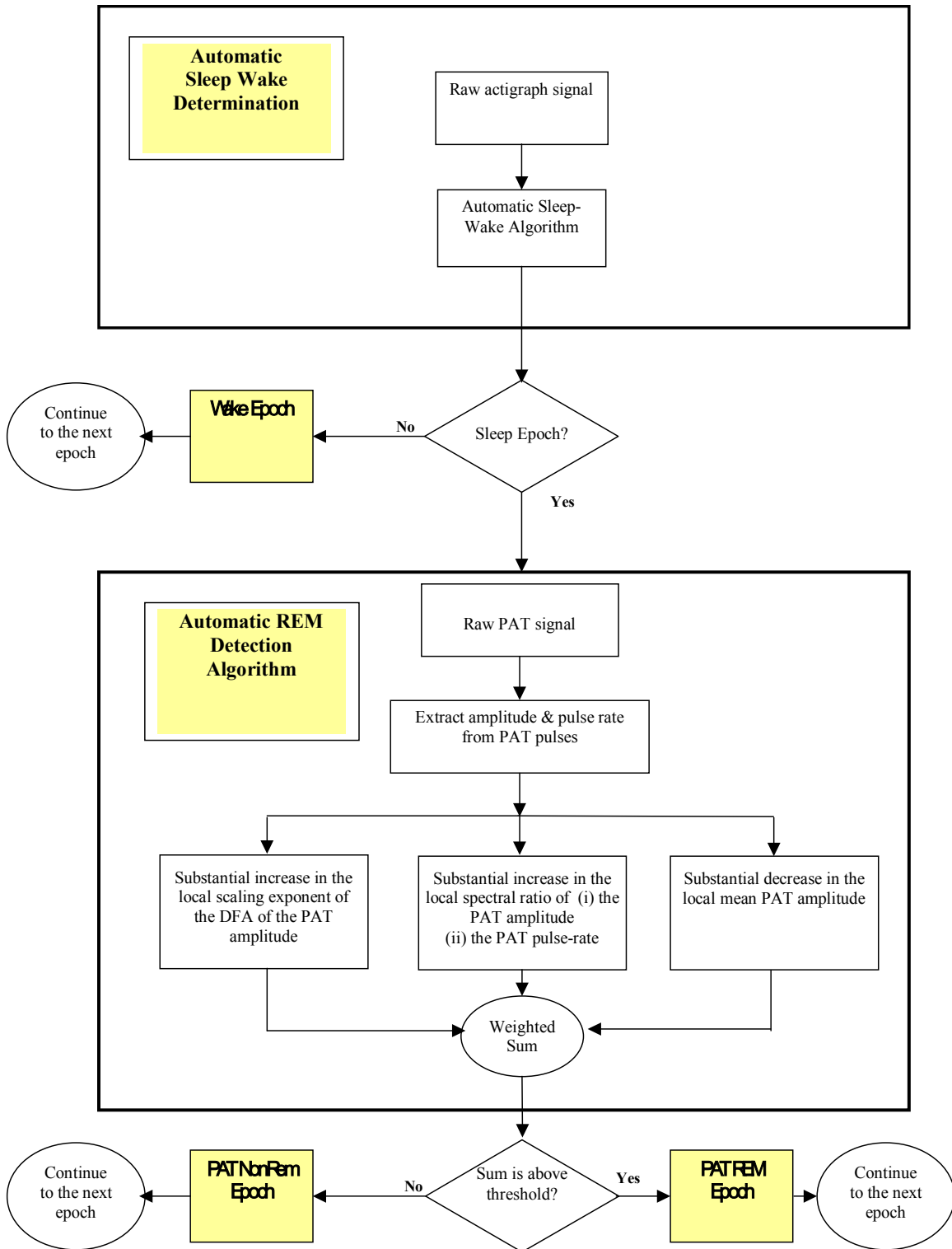
- Mean PAT amplitude time-series
- Scaling-exponent of the amplitude time-series using Detrended Fluctuation Analysis (DFA).
- Ratio of peak low-frequency-band to high-frequency-band in the PAT amplitude time-series spectrum.
- Ratio of peak low-frequency-band to high-frequency-band in the PAT pulse-rate time-series spectrum.

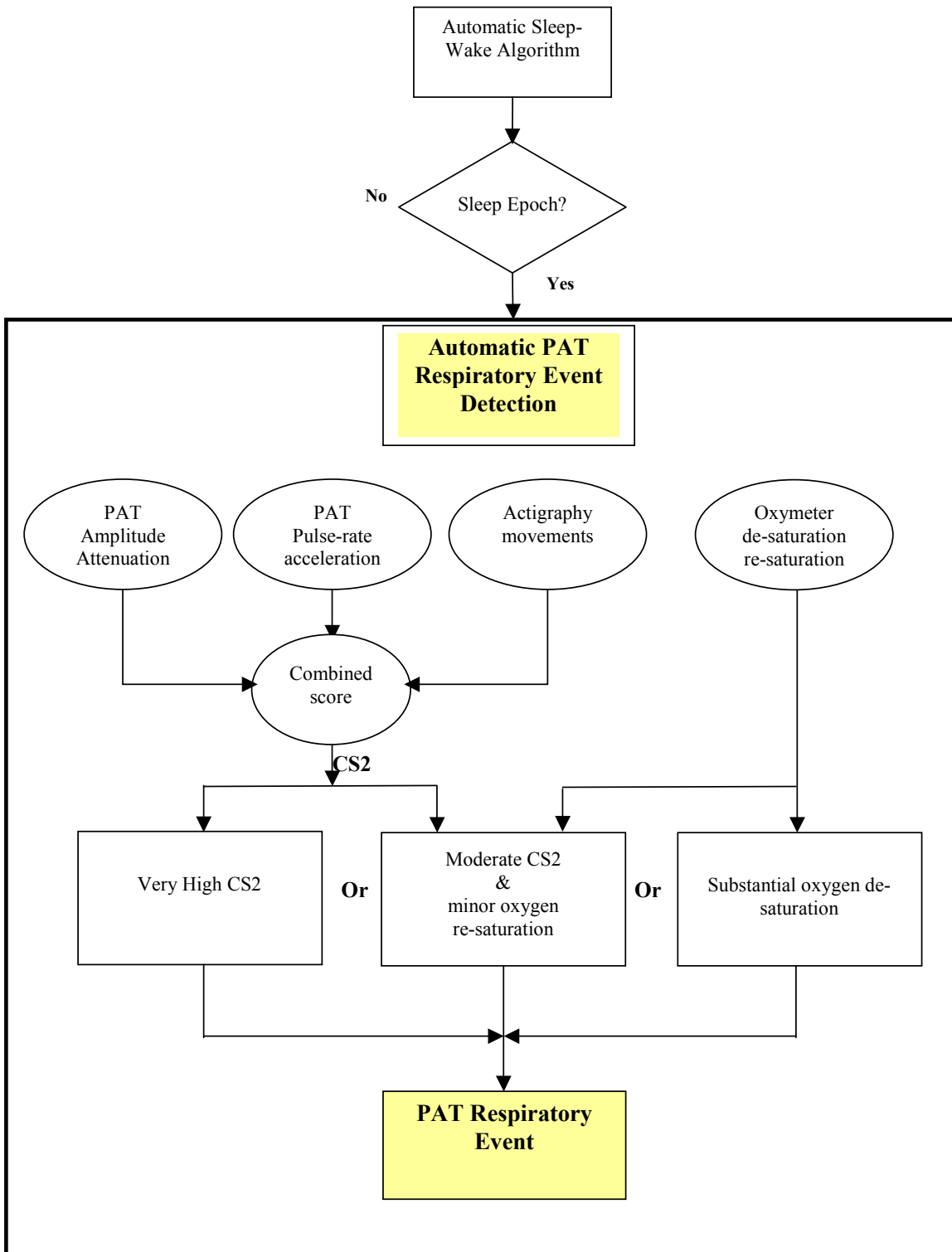
**These algorithms were optimized in clinical studies using simultaneous study of Watch-PAT with automated zzzPAT analysis, and in-lab standard polysomnography (PSG) recordings, which were scored manually according to the American Academy of Sleep Medicine (AASM) criteria. This set of sleep studies was defined, according to correct practice, as a training set. Once finalized, a separate set of studies was used to validate the algorithms.**

## **DEEP and Light sleep**

Epoch of Deep and light sleep are identified using the very same transformation of PAT amplitude and Pulse rate than for REM. This Provides the full PAT Hypnogram.

ZZZPAT analysis flow diagram







## Appendix C: Keyboard Shortcuts

### General:

In all dialogs or menus:

Press Alt +X (X is the character in the word that has underscore)

### Special Keys:

F1	– Help
Ctrl+N	– New study
Ctrl+O	– Open study
Ctrl+F4	– Close study
Ctrl+L	– Load from flash and analyze
Ctrl+P	– Print
Ctrl+C	– Copy
Ctrl+F	– Active channel fit to window
Shft+F	– Fit to window all signals
I	– Zoom in
O	– Zoom out
Ctrl+Left arrow	– Previous Event
Ctrl+Right arrow	– Next Event
Shift+Left arrow	– Previous Same Type Event
Shift+Right arrow	– Next Same Type Event
Ctrl+Home	– First Event for channel
Ctrl+End	– Last Event for channel
Ctrl+R	– Sleep Report
Ctrl+I	– Sleep Indices
Alt+Add	– Increment active signal amplitude
Alt+Minus	– Decrement active signal amplitude
Alt+ Right arrow	– Zoom In to next timebase
Alt+ Left arrow	– Zoom out to next timebase
Home	– Go to First Page
End	– Go to Last Page
Page Down	– Go to Next Page
Page Up	– Go to Previous Page
Left arrow	– Scroll left
Right arrow	– Scroll right

## Appendix D: Manual Sleep data signal transfer

<p><b>Sending data for evaluation to Itamar</b></p>	<ul style="list-style-type: none"> <li>• Open in zzzPAT the study you want to send</li> <li>• Select Help → Prepare And Send Study to Itamar Medical...</li> <li>• Fill in the required information and select “Send current open study”</li> <li>• Select “Save” and save the study in your local drive (Preferable into disk on key or other removable drive)</li> <li>• Browse into URL: <a href="http://support.itamar-medical.com/upload">http://support.itamar-medical.com/upload</a></li> <li>• Fill in the required information             <ul style="list-style-type: none"> <li>• PI / Physician Name</li> <li>• Submitter Name</li> <li>• Site Name</li> <li>• Site Type</li> <li>• Country</li> <li>• City</li> <li>• Phone Number</li> <li>• E-mail</li> </ul> </li> <li>• Enter study code: <i>call Itamar for code</i></li> <li>• Enter password: <i>call Itamar for password</i></li> <li>• Press Submit</li> <li>• Browse and enter the file you have saved</li> <li>• Enter description for file</li> <li>• Press Send</li> <li>• At the end of the upload process make sure to get a message: “List of successfully upload files” and the list of files you uploaded</li> </ul>	
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