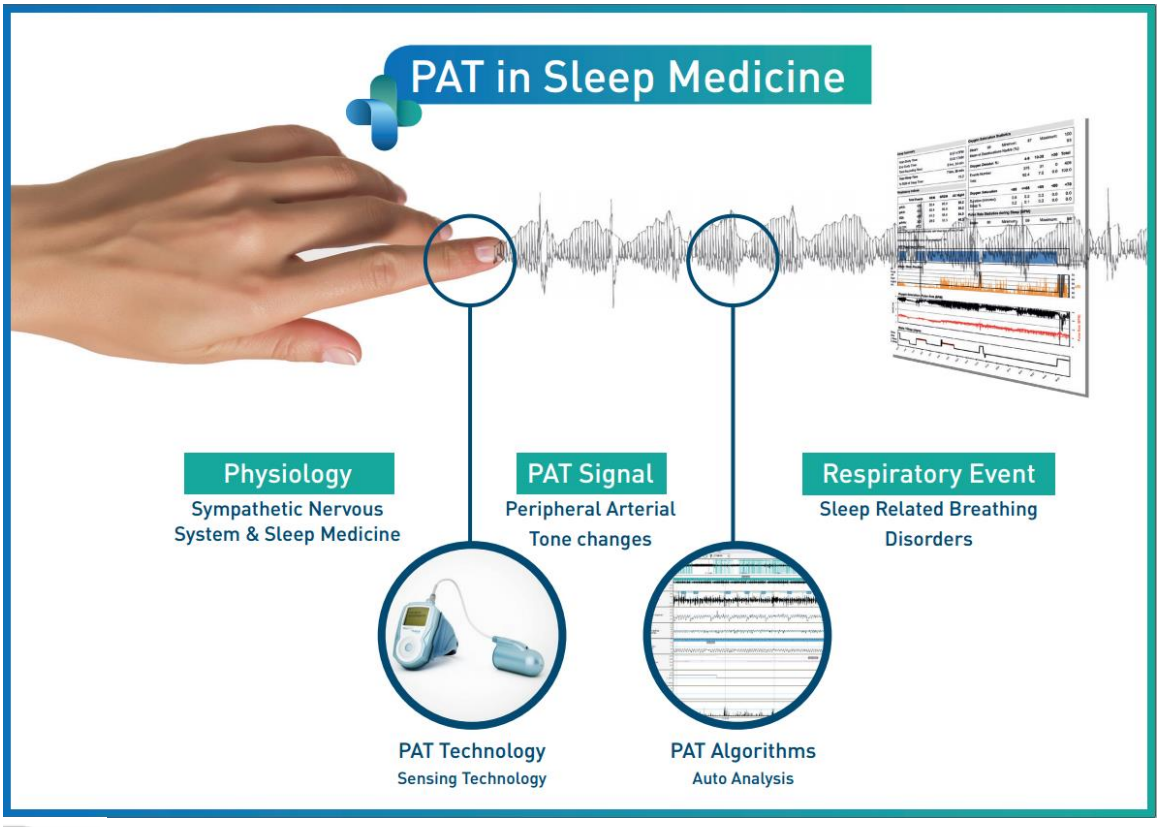
zzzPAT

For Watch-PAT™200 & 200U

Software Operation Manual

Itamar Medical REF OM2197434



℞only **Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner**

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Software Version: 4.6.69.x

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See appendix D for contact information of the regulatory authorized representative

Edition Table

Edition	Date	Description	Chapter	Pages
Base- 0-0	December 2000	Preliminary	All	All
Base–1-0	May 2001	1	All	All
1-2	October 2001	Build 032	All	All
1-3	December 2001	Update	4,App. A, B	15, 64
1-4	April 2002	Build 035	All	All
1-5	January 2003	Rev. 2.0	All	All
Base–2-0	November 2003	Addition of workgroup functionality Revised chapter order Added Index Combined to cover both versions 1.5 and 2.4	All	All
Base- 3-0	March 2004	Addition of AHI Single Icon application Addition of file transferring option Time Range and Sleep Indices report User and General Settings Export to CSV	All	All
Base- 4-0	February 2005	Version 3.0 • Improved REM Analysis • Database Wizard functions are integrated within zzzPAT (under "Tools" menu) • Direct Export of Studies to CD-Writer (Win XP only) • Patient ID can be edited • Option to open Sleep report automatically after "Load from Flash" or "Open Study" • Toolbar improvement • Removed need for WP100 Device clock setting • Removed Win 98 support		All
Base- 5-0	November 2006	Version 4.0 • Added support for Snoring and Body position sensor • Added 3rd optional page to Sleep report • New options at General Settings/Report Appearance for 1, 2 or 3 page report • Events report shows Resp.Events (RDI), Resp.Events (AHI) and		All

		desaturations only • File>New Study Details: Removed all mandatory requirements except Patient ID • A backup of the database for every day of the week will be automatically performed behind the scenes • Automatic printout of labels (1 or 2 labels as configured) while the Compact Flash is initialized with patient data • "Follow up" report will show reviewed and reported studies • Patient's weight and height appear in Sleep report • Enable manual addition/deletion of Respiratory events • Export for Interpretation services option • The valid sleep time used for the calculation of the respiratory indices appears in the second page of the report		
Base- 6-0	June 2008	Version 4.2.56 • Report changes • Support of MS-SQL server • New Study – new patient fields • Follow Up Report changes • Light/Deep Sleep stages	All	All
Base- 7-0	August 2008	Version 4.2.57 WP200 support	All	All
Base- 8-0	August 2009	Version 4.2.58 WP200 Patient Identification Bracelet support Multiple nights study	All	All
Base- 9-0	July 2010	Version 4.3.60 Windows 7 support Login – Active directory Multiple nights study without charging	All	All
Base-10	June 2011	Version 4.3.61 New report options New filters for "Open Study" Add 88% in Oxygen Saturation AHI index according to 3% or 4% desaturations		
11	July 2014	Adding note - manual editing for pacemaker	4.5.6 -	65 I

		Trademark note		
12	August 2014	Version 4.4.64 Trademarks Update Itamar medical address Intended use WP200U updates	1, 2.1, 2.2, 2.6, 2.7, 2.9, 3, 4, 8, App.B, App. F	Cover 11-13, 24-26, 31-46, 47-90, 110-112, 120-123
13	October 2015	Intended use clarification Operating System HL7 Settings AHI Severity graph Changed warning symbol	1.1 2.2.2 3.4.8 3.4.5, 4.6.2 2.5,2.6. 3.4.9, 4.1, 4.1.3.6, 6.4	11 13 46,47 43,79, 82,83 Cover, 24, 25, 47, 49, 58, 104
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15	February 2017	Changed General Settings>Statistics tab	3.3.5	38
16	May 2017	Update Rx caution Updated intended use to include AHIc for WP200U Update overview Update user settings Update general settings analysis params Update general settings HL7 config Update new study screen (more) Update sleep report with AHIc and %CSR Update Sleep Report for Selected Time Range with AHIc and %CSR Update technical supplement to include AHIc and %CSR and new charts	- 1.1 1.2 1.4 3.2.3 3.3.6 3.3.9 4.1.3 4.6.2 4.6.3 App B	- 11 12 31 41 47 56 76 82 119-124
17	June 2017	Update Company Standards Updated Troubleshooting for invalid oximetry values Added notes regarding the use of RESBP, pAHIc and %CSR	- 8 1.2,1.4,4.6.2, 4.6.3,App B	i 113 11,12,78, 84,123
18	Jan 2018	Adding CE marking with the accompanying BSI notified body number 0086 Updating Intertek certification marks	-	i

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1 Introduction to the zzzPAT

1.1 Intended Use/ Indications for Use of the Watch-PAT200

The Watch-PAT200 (“WP200”) is non-invasive home care device for use with patients suspected to have sleep related breathing disorders. The WP200 device is 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 device generate a peripheral arterial tonometry ("PAT") Respiratory Disturbance Index ("PRDI"), Apnea-Hypopnea index ("PAHI") and PAT sleep staging identification ("PSTAGES") and optional snoring level and body position discrete states from an external integrated snoring and body position (SBP) sensor. The device’s "PSTAGES" and SBP provide supplemental information to its PRDI/PAHI. The device’s "PSTAGES" and SBP are 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.

1.2 Intended Use/ Indications for Use of the Watch-PAT200U

The Watch-PAT200U (WP200U) device is a non-invasive home care device for use with patients suspected to have sleep related breathing disorders. The WP200U is a diagnostic aid for the detection of sleep related breathing disorders, sleep staging (Rapid Eye Movement (REM) Sleep, Light Sleep, Deep Sleep and Wake), snoring level and body position. The WP200U generates a peripheral arterial tonometry ("PAT") Respiratory Disturbance Index ("PRDI"), Apnea-Hypopnea index ("PAHI"), Central Apnea-Hypopnea index ("PAHIc"), PAT sleep staging identification (PSTAGES) and optional snoring level and body position discrete states from an external integrated snoring and body position sensor. The WP200U's PSTAGES and snoring level and body position provide supplemental information to its PRDI/PAHI/PAHIc. The WP200U's PSTAGES and snoring level and body position are 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.

PAHIc is indicated for use in patients 17 years and older. All other parameters are indicated for 12 years and older.

Note: pAHIc is currently available only in the US

1.3 The zzzPAT S/W – Definition

The zzzPAT is an analysis software package used with the WP200(U) 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 WP200(U) devices, automatically identifies breathing disordered events and REM, Light Sleep, Deep Sleep stages, and generates a comprehensive report for the physician.

1.4 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 WP200(U) device is 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 in the device along with pulse rate (derived from the PAT signal), together with either data from oximetry channels integrated into the uPAT probe (WP200U), or from a built-in pulse-oximetry sensor (WP200) and an actigraph (embedded in the device). Snoring and Body Position signals are generated from the SBP/RESBP integrated sensor (optional). The RESBP (Respiratory Effort Snoring and Body Position) sensor records the subject's chest movement signal in addition to the snoring and body position signals that are included with the SBP sensor. 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 WP200(U) channels: PAT, Pulse Rate, actigraphy and Oxygen saturation (either recorded in WP200 or derived in W200U) for the detection of sleep related breathing disorders and sleep staging (Rapid Eye Movement (REM), Light Sleep, Deep Sleep and Wake). In WP200U only, using the RESBP's respiratory movement channel in addition to the other WP channels, allows further identification of central apnea.
The zzzPAT uses WP200(U)'s snoring and body position channels to generate snoring level and body position discrete states. The use of SBP/RESBP sensor is optional and according to physician preference. 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.

Note: Throughout this document, the Snore and Body Position sensor is referring to both SBP sensor and RESBP sensor unless specified otherwise. The use of RESBP sensor is subject to regulatory approval in the country.

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

Restrictions

The tracings and calculations provided by the WP200(U) 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.
- Sleep/Hibernate features should be disabled in case of shared database configuration.
-

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 WP200(U) device. The software displays and stores the recorded signals, and provides a set of analytical functions for interpretation purposes.

A USB cable is used to in order to read the data recorded by the WP200(U) on the internal SD card. The zzzPAT S/W automatically detects the data on the internal SD card once the WP200(U) is connected to the PC via the USB communication cable. Please refer to Section 2.2 for required PC configuration.

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.

	Note It is strongly advised to coordinate the setting of **shared access** zzzPAT operation mode with an Itamar Medical representative. Extra training is crucial for proper operation.

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

2.2 Hardware Requirements

Hardware configuration:

Computer Pentium 4 3GHz or higher
CD-ROM drive (optional)
1 available USB port
XGA screen resolution (minimum 1024 x 768 pixels)
Colors set to 16 bits or higher
RAM 1GB or higher

Disk space requirements:

- **Standalone installation**
  - 10GB minimum / 60GB recommended disk space on Files folder and at least 1.2GB on boot drive
- **Shared installation**
  - SQL DB drive – 1.2GB if using our default MS SQL Express installation and enough for 1 year worth of studies (500 KB / study).

- Shared Files folder for raw data signal files - enough for 1 year worth of studies (30 MB / study).

Operating System:

Windows Server 2008 Service Pack 1 and above
Windows 7 with Service Pack 1
Windows 8
Windows 10

	Note Software components needed for the proper installation of zzzPAT should be installed prior to zzzPAT installation (OS service packs or latest OS updates).

2.3 Installing zzzPAT software

zzzPAT can be installed either by CD or by downloading from Itamar website (itamar-medical.com).

This process will install a single Icon on the desktop, which opens the zzzPAT analysis and reporting software.

Quick start instructions:
CD installation:

- 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.

Web Download:

- Go to Itamar website (itamar-medical.com) and download the zzzPAT software. In case of any issues with the download or installation process, please refer to the Clinical Account Specialist representative in your area.

You are now ready to run the zzzPAT software. See section Using zzzPAT Software in a secure way.

2.3.1 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 disk 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 2.3.

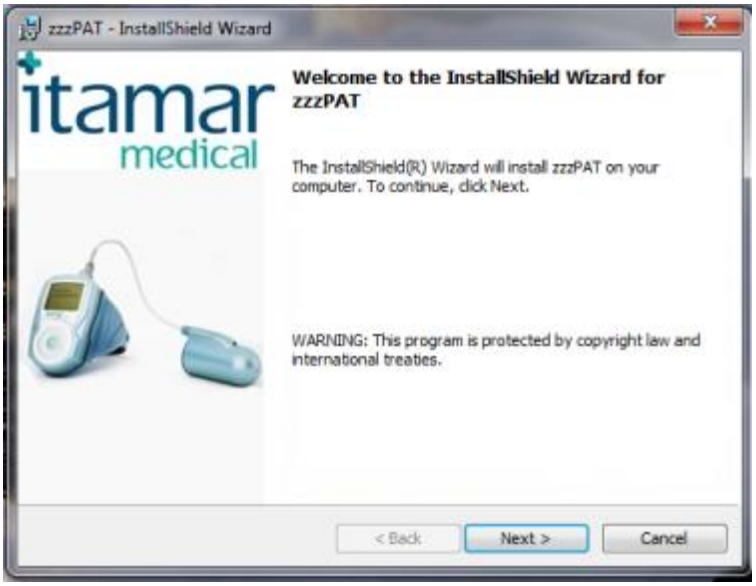


Figure 1 - zzzPAT installation dialog box

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

Figure 2 - zzzPAT License Agreement

3. After reading the agreement, select **I accept the terms in the license agreement** and click **Next** to continue.

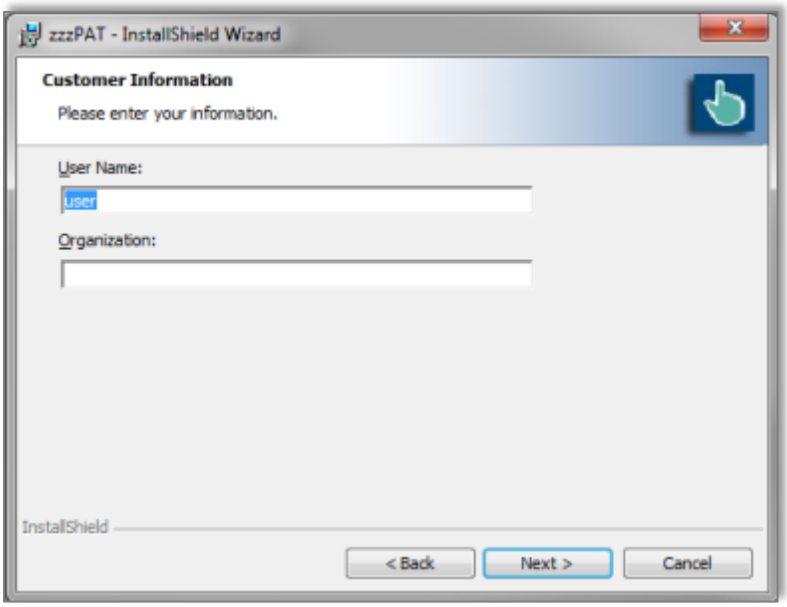


Figure 3 - Customer Information dialog box

4. Enter user name, company name and Click **Next** to continue. The 'Database Properties" dialog box appears.

Figure 4 - Database Properties dialog box

2.3.2 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**.

2.3.2.1 Standard - Standalone installation only

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

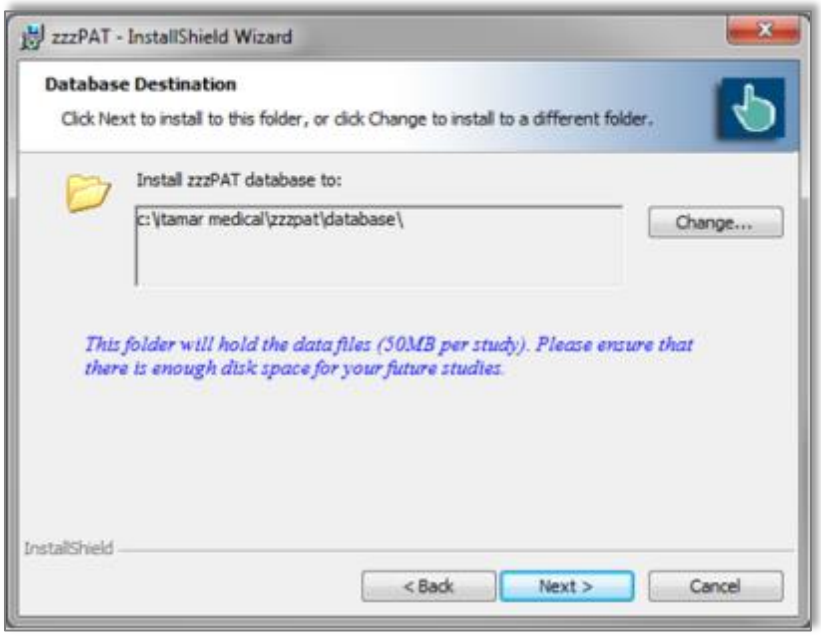


Figure 5 – Database Destination dialog box

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

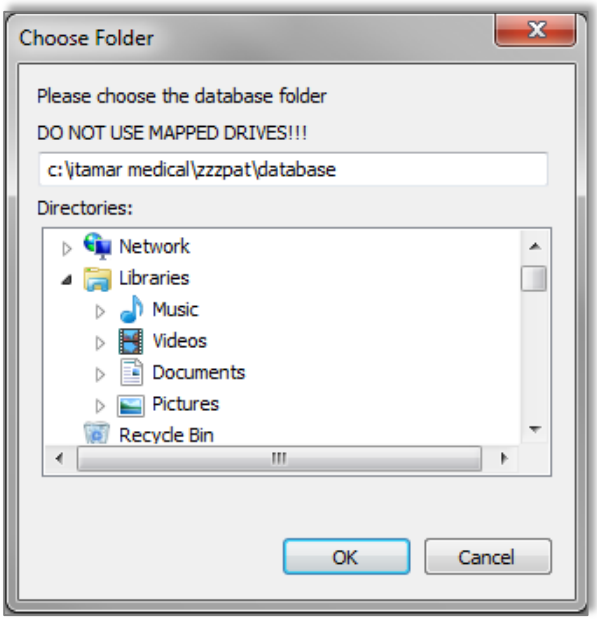


Figure 6 – Choose folder dialog box

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.

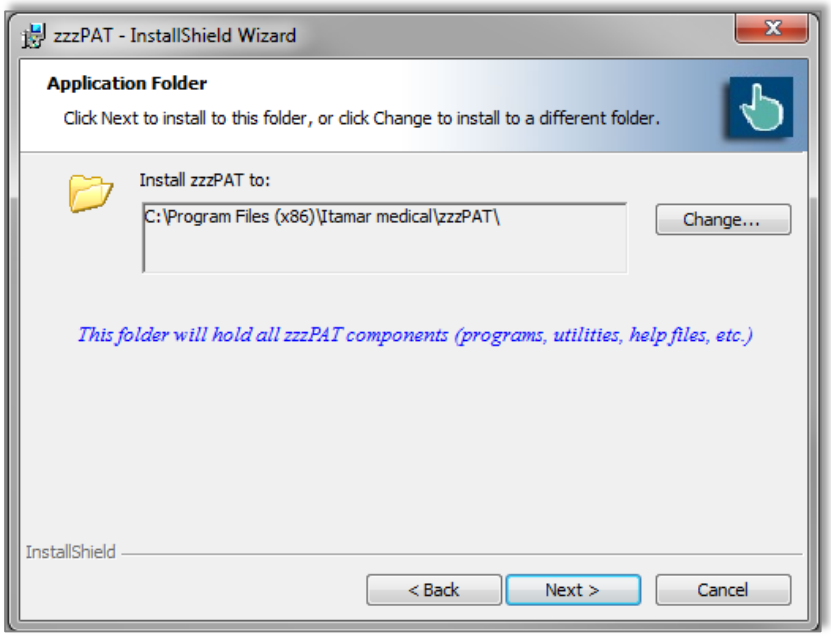


Figure 7 – Application folder dialog box

The last dialog before standalone installations summarizes your selections.

After reading this summary, press **Install** to begin the installation.

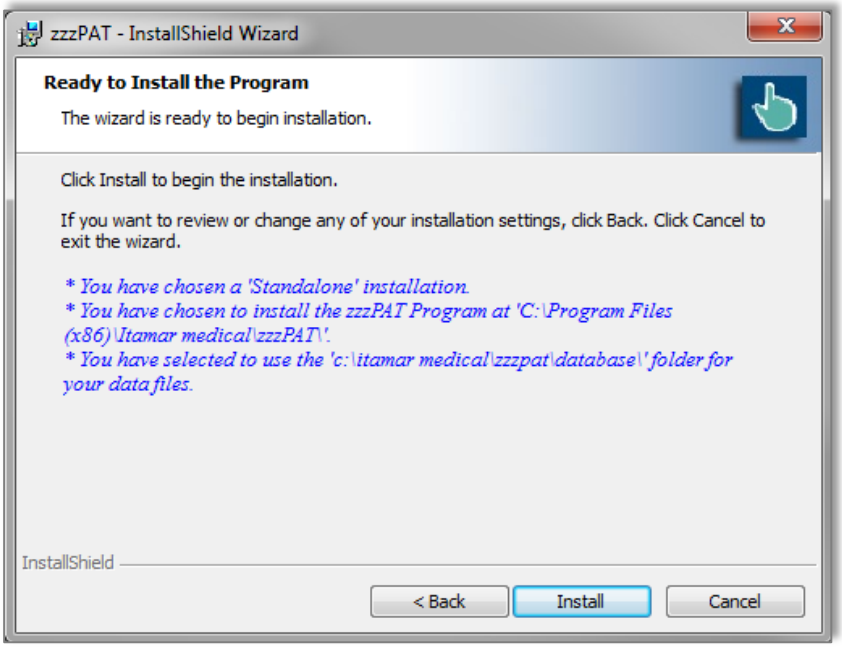


Figure 8 – Ready to Install dialog box

At the end of the installation you should restart your computer.

Note

A login name and password are needed to operate this software.
The default administrator login information is:
Login name: 111
Login password: 111
To modify the administrator login name and password, and to add/modify additional users, refer to section 2.5.

Warning

- Do not attempt to modify the zzzPAT software.
- It is recommended to close other programs when using zzzPAT to prevent possible conflicts.

For any other installation except the Standalone please refer to the **Installation guide.pdf** (can be found in the installation CD).

2.3.3 Upgrading from previous versions

2.3.3.1 Upgrading using the Patch program

You can find the Patch program inside the installation CD or in http://www.itamar-medical.com web site under the Support>Downloads section.
The Patch program will update your software to the latest version.

2.3.3.2 Upgrading a Standalone Installation

	Note Uninstalling zzzPAT does not remove the zzzPAT database, however, it is strongly recommended to backup the database before upgrading zzzPAT.

- 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 in section 2.3.1.

2.3.3.3 Upgrading a Shared Database Installation

Use the Patch program to upgrade the clients unless you need to uninstall and re-install from the beginning.
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 that is done automatocally during the first time zzzPAT is launched after the upgrade.

	Note Uninstalling zzzPAT does not remove the zzzPAT database, however, it is strongly recommended to backup the database before upgrading zzzPAT.

- Backup the entire database of the existing zzzPAT installation (see Database Wizard, Backup section 7.1.3).
- Uninstall the previous zzzPAT 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 in section 2.3.1.

.

2.4 Defining the WatchPAT drive

To prepare a new study (**File>New Study Details** from zzzPAT), you must first define the WatchPAT drive.
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 31).
- Click **Set WatchPAT Drive** in the 'New Study' dialog box. The following window will appear:

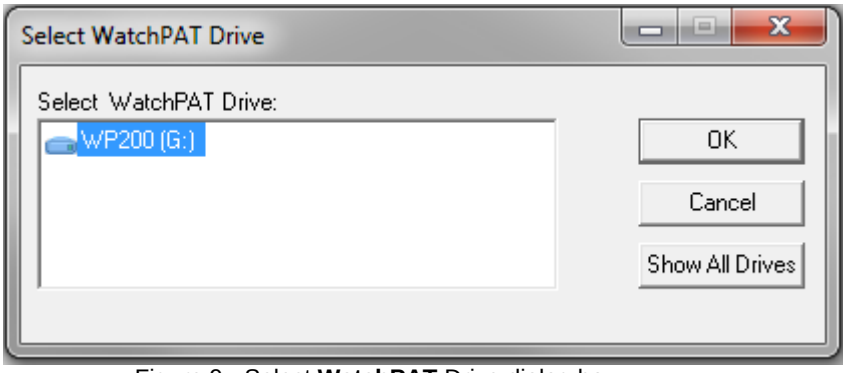


Figure 9 - Select **WatchPAT** Drive dialog box

- The WP200(U) device is identified by the zzzPAT, and is listed in this window. Click **OK** to confirm the drive selection.

2.5 Using zzzPAT Software in a secure way

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.

2.5.1 Setting new login and Password for the zzzPAT Administrator

You can either use the Active Directory Service option to define the users or you can use the User Administration functionality as described below:

- Select **Tools>User Administration** from zzzPAT or navigate through the installation folder of zzzPAT to the dltools.exe from the BIN folder.
- 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 10 for **dbtools.exe** Figure 11 - User Administration dialog box or **Tools>User Administration**.

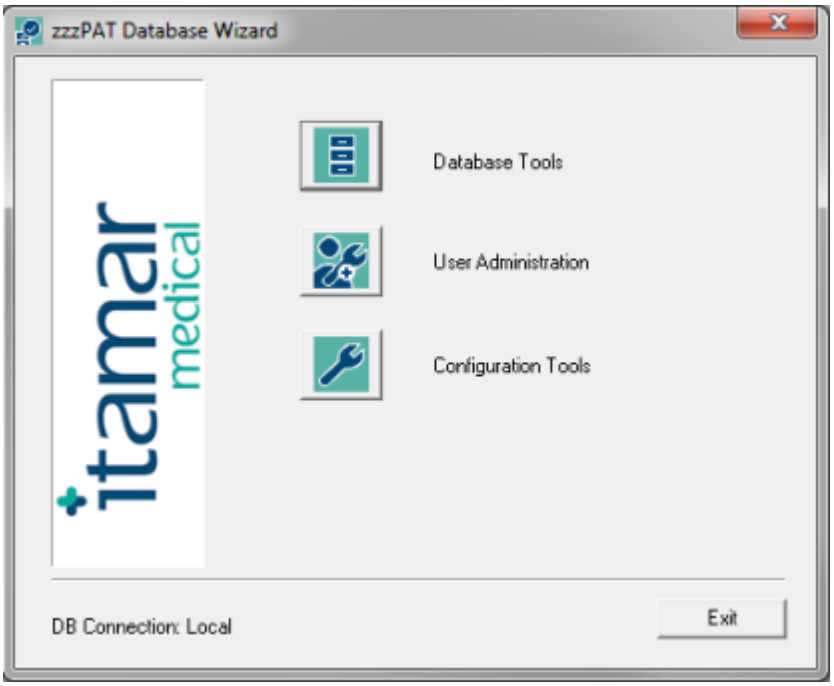


Figure 10- zzzPAT database Wizard dialog box

- 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.

Note

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.

2.5.2 Setting a New user

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

If the users are defined by ADSI see 3.3.4 for instructions on how to set new users and define permissions**.**

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

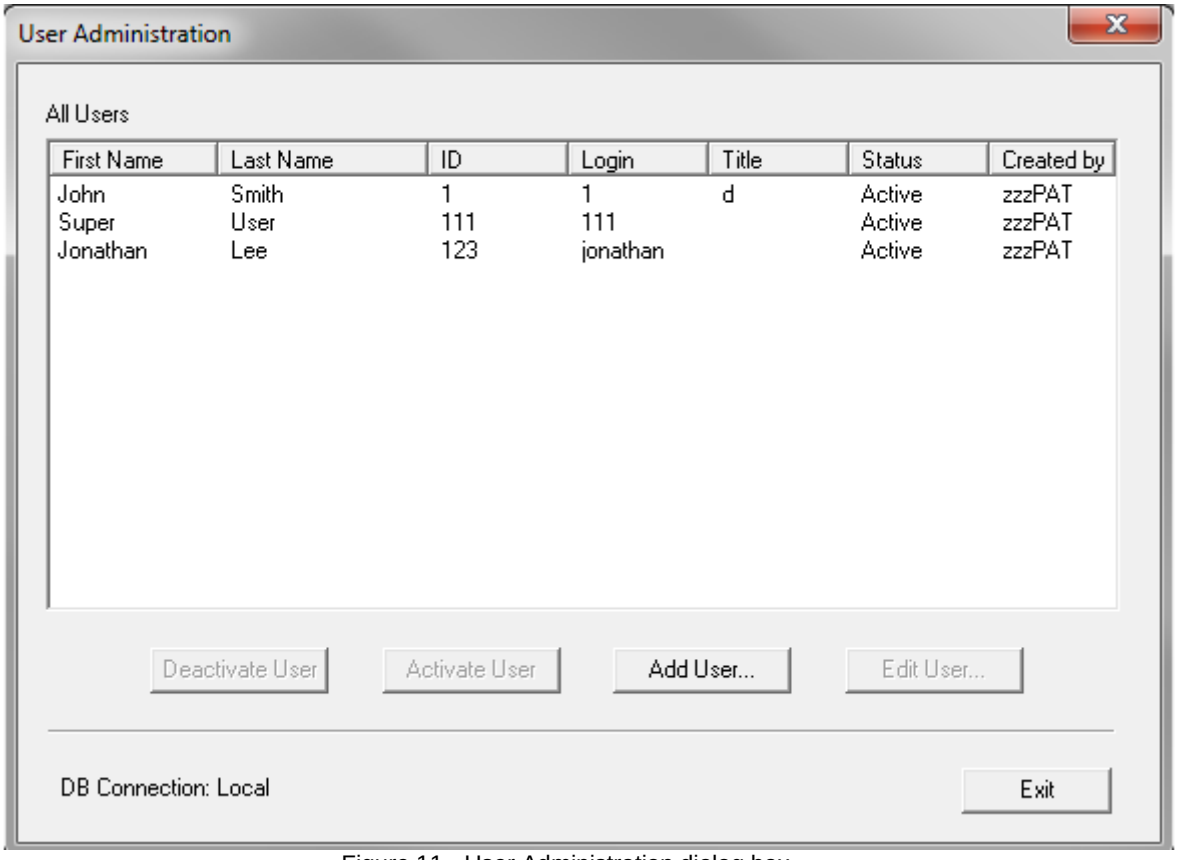


Figure 11 - User Administration dialog box

Note

The column "Created by" denotes if the user was defined by zzzPAT or was defined by Active Directory service (in this case "Created by" is ADSI).
"Activate User" / "Deactivate User" will not be functional for user that was defined by Active Directory service.

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

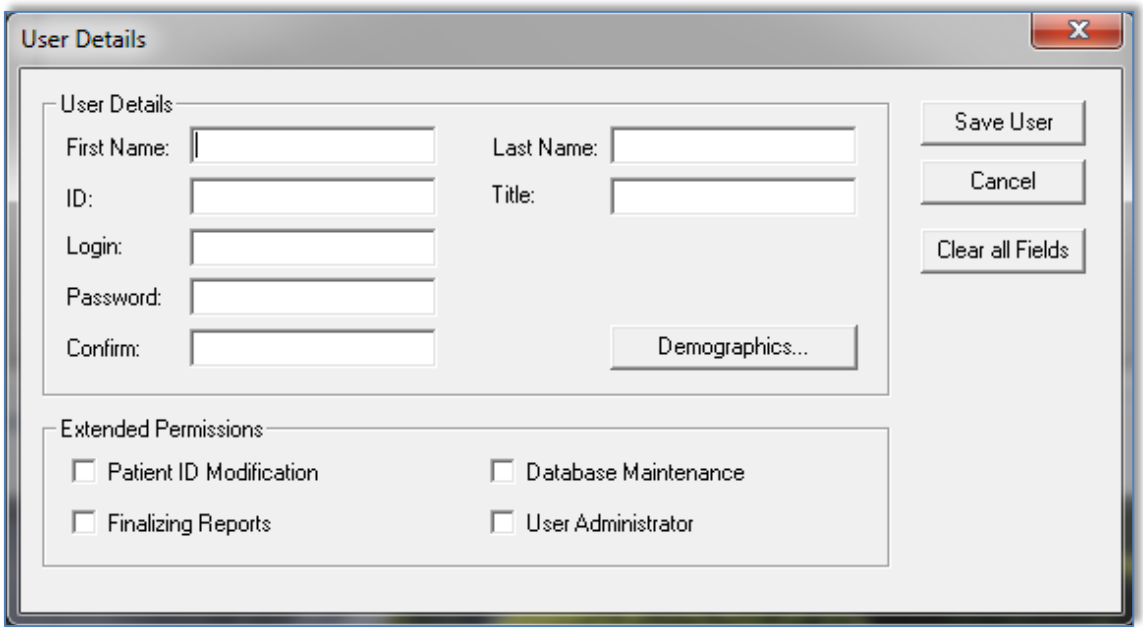


Figure 12 - User Details dialog box

- **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).
- **Extended Permissions for users defined by Active Directory service and set to be defined by ADSI cannot be set in zzzPAT (**see 3.3.4**).**

Extended Permissions	Allowed activities
No extended permissions selected	Basic User: • Prepare a new study • Load study into zzzPAT • Issue reports
Patient ID Modification	Basic User plus: • Modify a patient's ID
Finalizing report	Basic User plus: • Finalizing the report. This action locks the current analysis, so that no further changes can be made to the analysis and report.
Database Maintenance	Basic User plus: • Database export, import, delete, backup, restore and upgrade functions. (See section 5)
System Administrator	Basic User plus: • Adding users to zzzPAT and defining their permissions • Customizing capabilities for the General Settings

Table 1 - User Permissions

2.5.3 Deactivating a user:

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

	Note Permanently removing a user from the system is not possible. User's information is part of the study records, and cannot be deleted.

	Note 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. The change of the password of Super user should be handled with care.

3 Setting Up zzzPAT Configuration

3.1 Setup>Directories

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

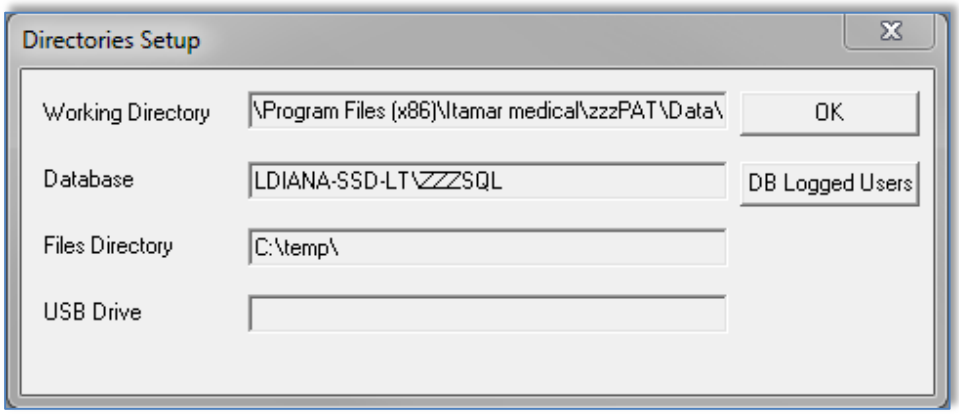


Figure 13- Set Directories dialog box

Select “DB Logged Users” in order to see who is connected to the shared database.
The list will contain all computers’ names that use the same shared database and have the zzzPAT application up and running.

3.2 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).

	Note 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

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

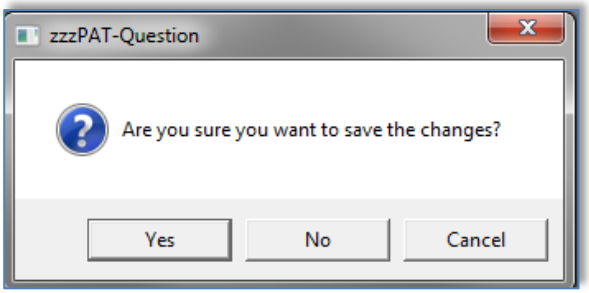


Figure 14 - Save settings for curent user question

Clicking **Yes** will save the changes.
Clicking **No** will exit 'User Settings' Dialog Box.
Clicking **Cancel** will return the last displayed dialog box.

3.2.1 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 enveloppe.
- SaO_2 - Arterial blood Oxygen saturation level.
- Actigraph - Actigraphy signal.
- Stages – REM, Light Sleep, Deep Sleep and Wake stages.
- Body position
- Snore
- Resp.Mov

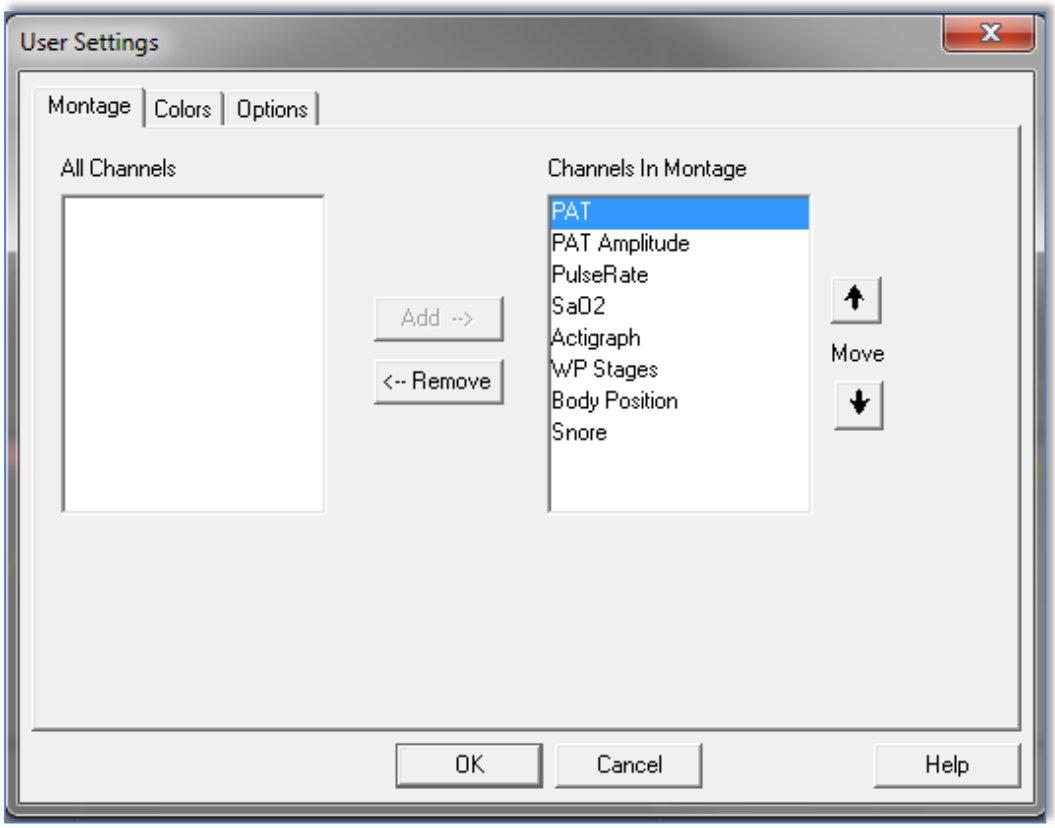


Figure 15- Setting Montage of zzzPAT display

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.

3.2.2 Setup>User Settings>Colors

Colors Setup page (Figure 16) 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.

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.

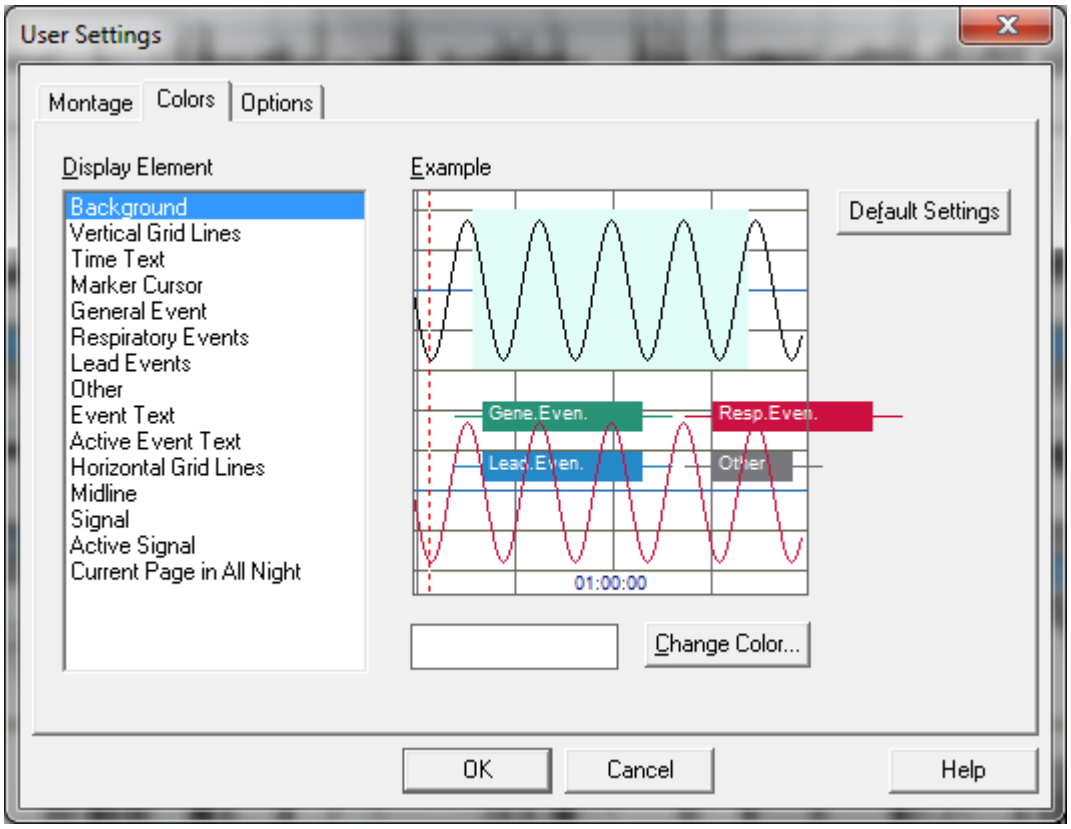


Figure 16 - Setting colors of zzzPAT display

	Note Be careful not to choose a color that blends into one of the background elements

3.2.3 Setup>User Settings>Options

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

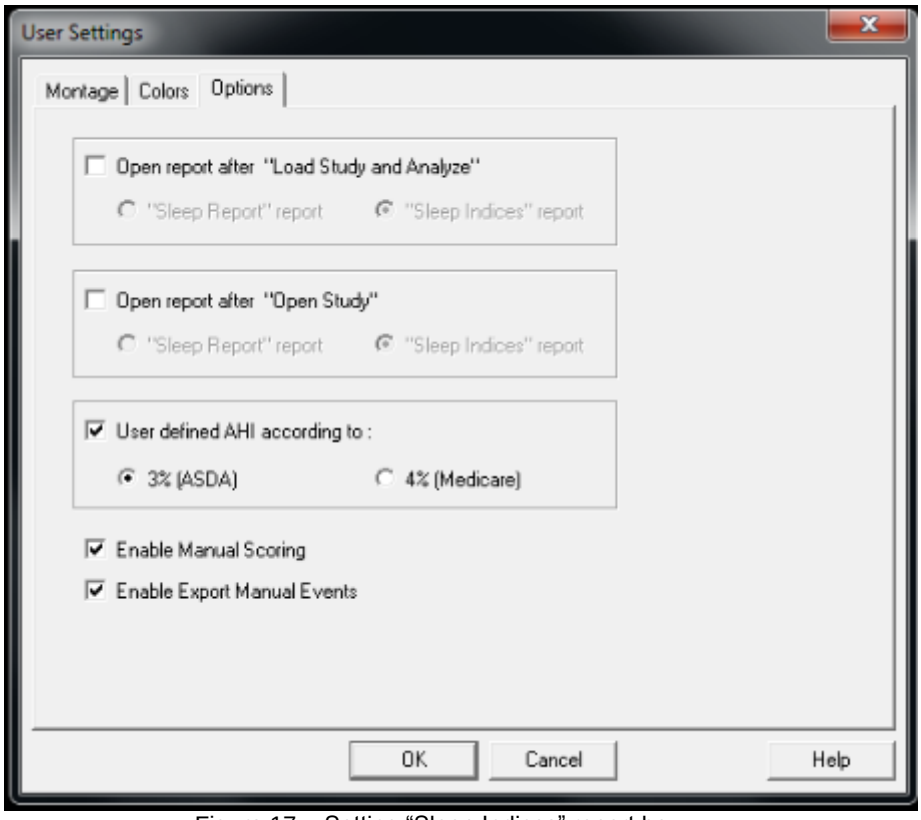


Figure 17 - Setting “Sleep Indices” report box

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 ASDA or Medicare protocol for calculating pAHI and pRDI indices on a user level. If you choose to enable this parameter, the automatic analysis will calculate respiratory events for pAHI and pRDI indices using desaturations of 3% and above (ASDA definition) or desaturations of 4% and above (Medicare definition) for all studies for this user. The Sleep report will show the calculated pAHI and pRDI indices with a note to indicate the protocol used for the calculation.

Note

The default settings to use ASDA or Medicare protocol for pAHI/pRDI calculation is according to site level and is defined in General Setting (Analysis/Statistics Parameters). A user may change this protocol (for his use only) by selecting one of the protocols under ‘User defined AHI according to’ checkbox in User settings. A user may change this protocol for specific study during new study preparation by selecting one of the protocols under ‘AHI index according to’ in Study details screen. In order to apply this change on existing studies in the database, you need to rerun the analysis.

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

You can select "Enable Export Manual Events" if you want to be able to export manual event changes (used by sleep specialists working with CloudPAT web service).

3.3 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.

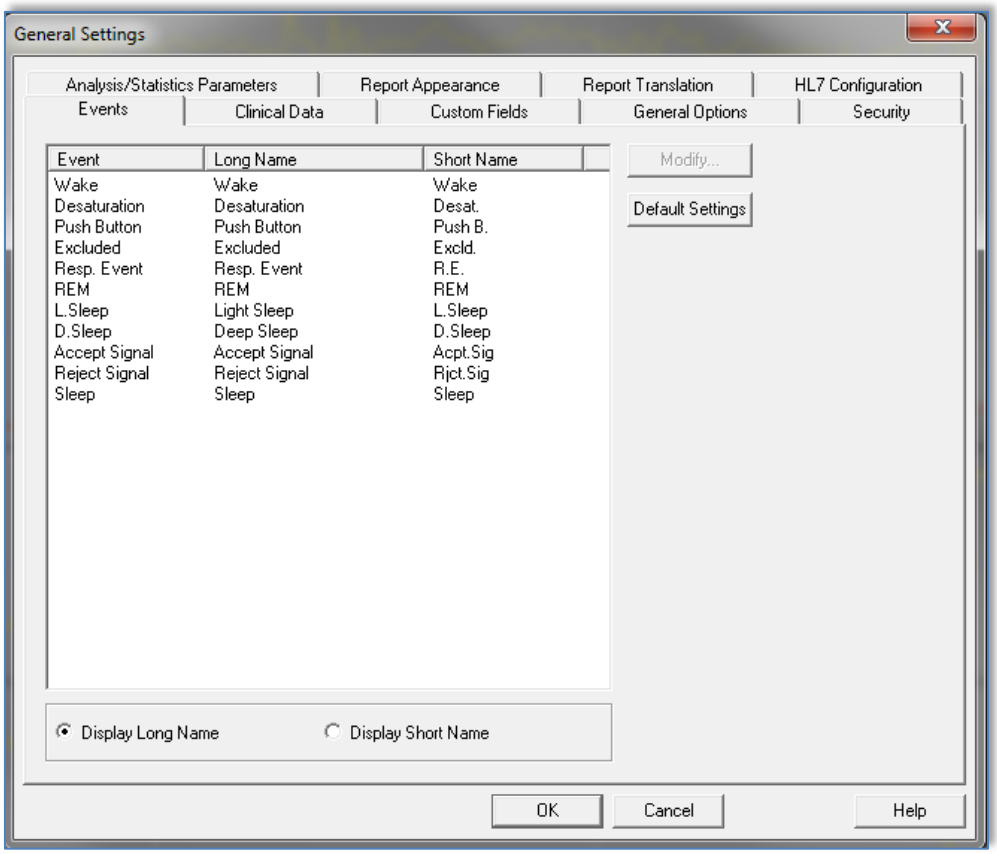


Figure 18 - General Settings Setting Dialog Box – Events Tab

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

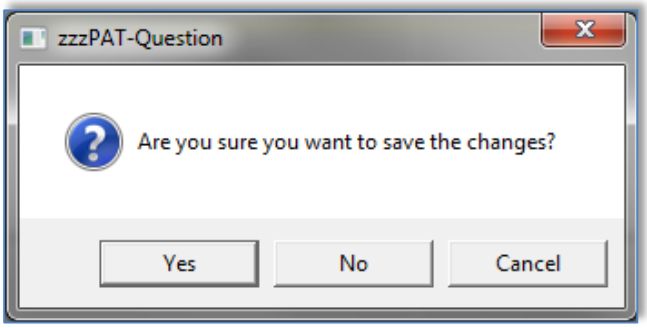


Figure 19 - Save Settings for curent user question

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

3.3.1 Setup>General Settings>Events

A list of Event types is listed in the events tab (Figure 18). 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.

Note

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

3.3.2 Setup>General Settings>Clinical Data Medical History

A preliminary list of medical conditions, medications, clinical diagnoses and clinical recommendations are listed in the Clinical Data tab while the selected type is selected in the "Predefined Clinical List" pull down menu (Figure 20).

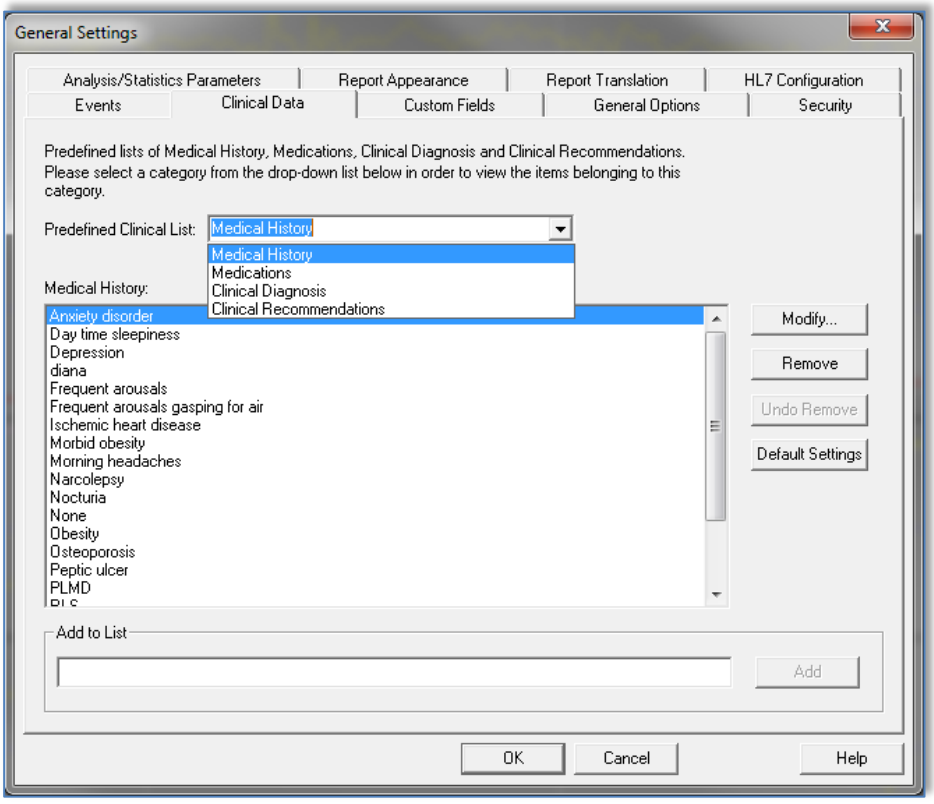


Figure 20 - General Settings Dialog Box – Clinical Data

To add a description to the list:

- Type the description in the 'Add to List' box. The **Add** button becomes enabled.
- Click **Add**.

To modify a description:

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

To remove a description from the list:

- Click on the description.
- 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.

3.3.3 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 38) and during the Export/Import process. These custom fields are available to all users.

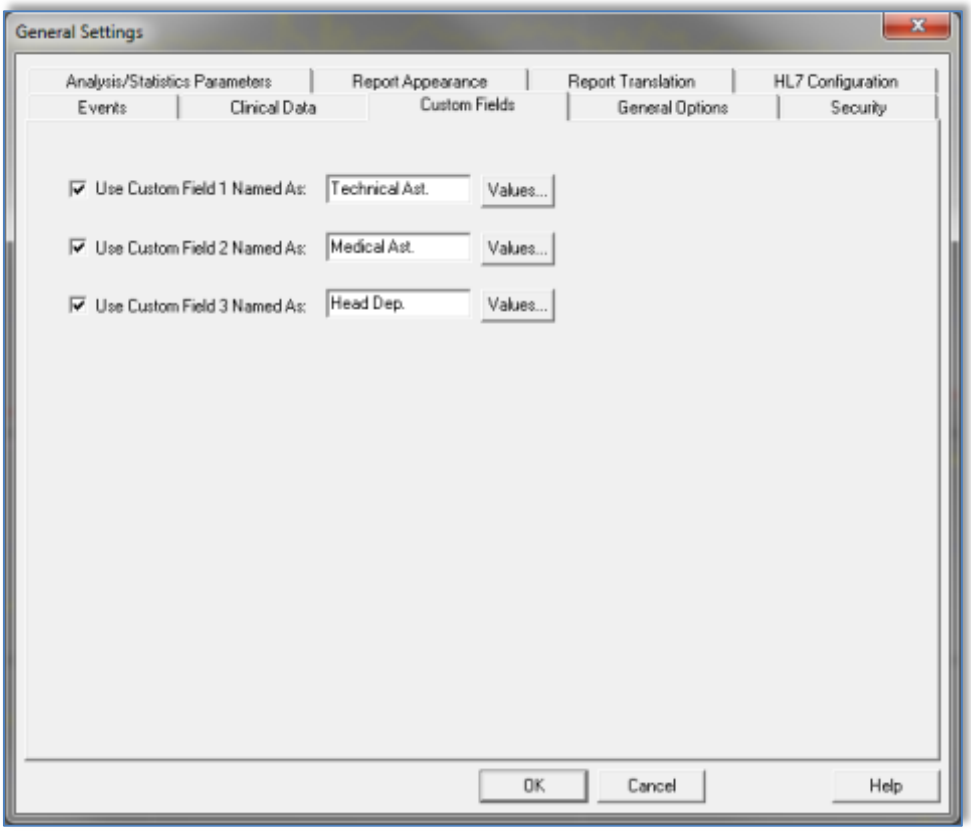


Figure 21 - General Settings Dialog Box – Custom Fields Tab

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:

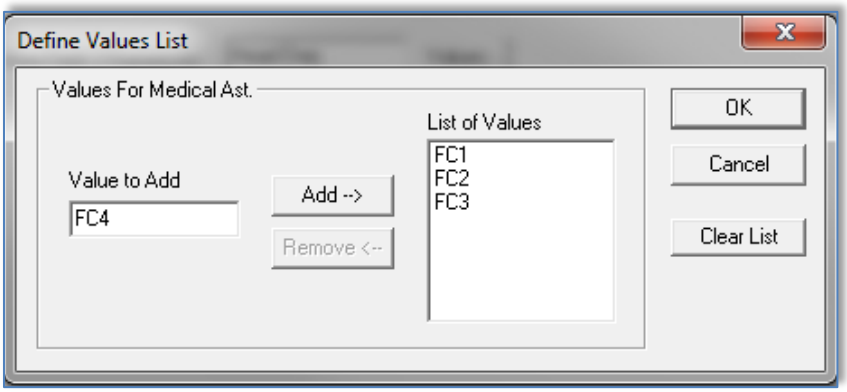


Figure 22 - Define Values List Dialog box

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.

Note

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.

3.3.4 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, tamper-proof testing and login options).

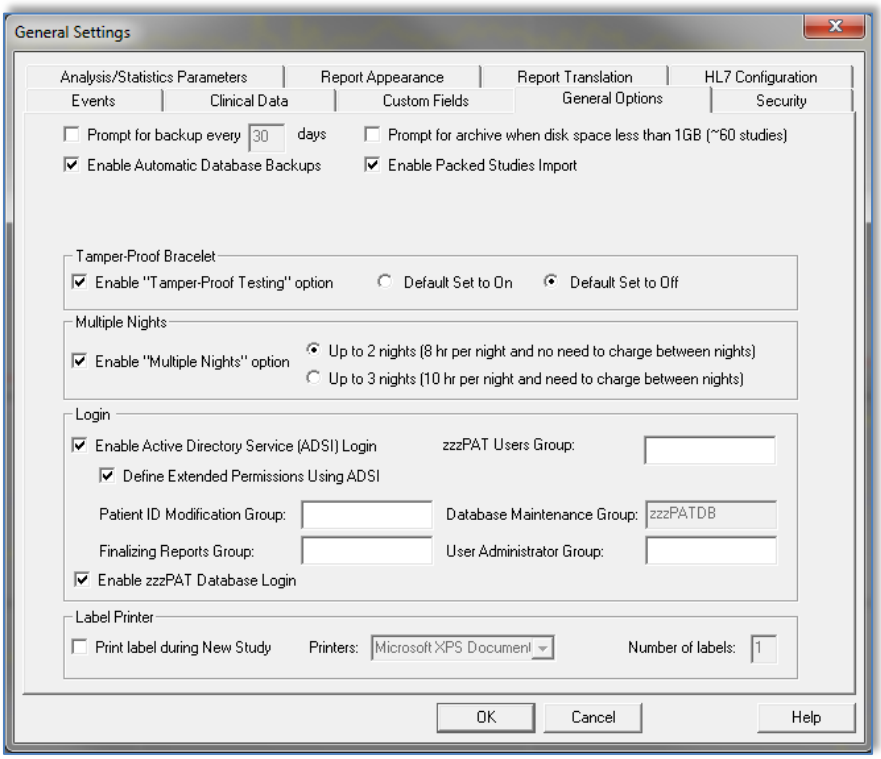


Figure 23 - General Settings Dialog Box – General Options Tab

- 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 “Enable Automatic Database Backups” in order to automatically make a backup of the database files when exiting zzzPAT (see Tools>Backup). The process of backing is very quick (no raw data files are backed up) and it is recommended to leave the option checked.
- 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.
- 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).
    - Select “Default Set to On” if you want to have the "Tamper-Proof Testing" option selected by default.
    - Select “Default Set to Off” if you do not want to have the "Tamper-Proof Testing" option selected by default.
- 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). There are two options for Multi Nights study:

- Up to two nights with no charging needed between the nights (maximum length of study is approximately 8 hours)
- Up to three nights when charging is necessary between the nights (maximum length of study is approximately 10 hours). The WP200(U)'s power supply must be supplied to the patient.

	Note 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.

- Select "Enable Active Directory Service (ADSI) Login" if you wish to use the Active Directory Service for login to zzzPAT (using your domain name and password). The zzzPAT users group name must be defined if this option is selected
- Select "Define Extended permissions Using ADSI" check box if you wish to control user's extended permissions by ADSI and not zzzPAT database. zzzPAT has 4 internal groups for permissions (see 2.5.2).
- 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 the WP200(U) suitcases as to provide easy identification of the designated patient after the WP200(U) device have been initialized with the patient details.

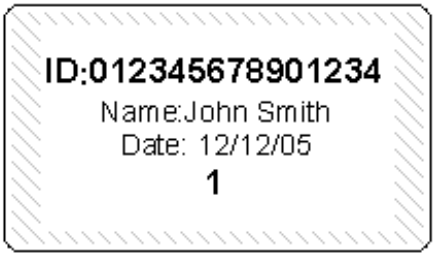


Figure 24 – Label example

	Note Contact Itamar Medical for a list of the supported label printers.

3.3.5 Setup>General Settings>Security

Used to enforce the Security of the application by allowing the user to define one or more of the following:

- Check **Protect Data with Password** option in order to ensure that all the studies are protected by encryption. This means that only authorized personnel can have access to the study and all export of information must be done through the zzzPAT application.
- Check **Automatic zzzPAT Screen-Lock with Login window every 10/20/30/40/50/60 minutes** option in order to lock the users screen after the defined amount of time. The user will be able to re-login to the application by inserting the password.
- Check **Strong password (8-20) characters, lower/upper case/digits/non-alphanumeric** option in order to force the use of stronger and more secure passwords by the users of the application. When this option is checked, every new user in the system will be asked to create a strong password, i.e:
  - at least 8 characters long
  - containing at least one character from 3 out of the following 4 groups:
    - Lowercase letters
    - Upper case letters
    - digits (0-9)
    - non-alphanumeric symbols (` ~ ! @ # $ % ^ &, etc.)
- Check **Password will expire in X days** (X between 1 to 365) option in order to define the time after which the user will be prompted to replace the password. The new password must be different than the last 3 passwords.

	Note Strong password and password expiration option will not affect users logging using Active Directory Service (ADSI).

- Check **Use Patient ID only** option in order to omit the patient information other that the ID to be stored on the device upon device initialization. If this option is checked you must use the same database for uploading the study in order to retrieve patient information (other that the ID) entered upon device initialization.

- Check **Use a new System generated ID only** option in order to have completely anonymous data stored on the device upon device initialization. The system will generate a unique number that will be used instead of the entered patient ID. If this option is checked you must use the same database for uploading the study, otherwise the upload will fail.

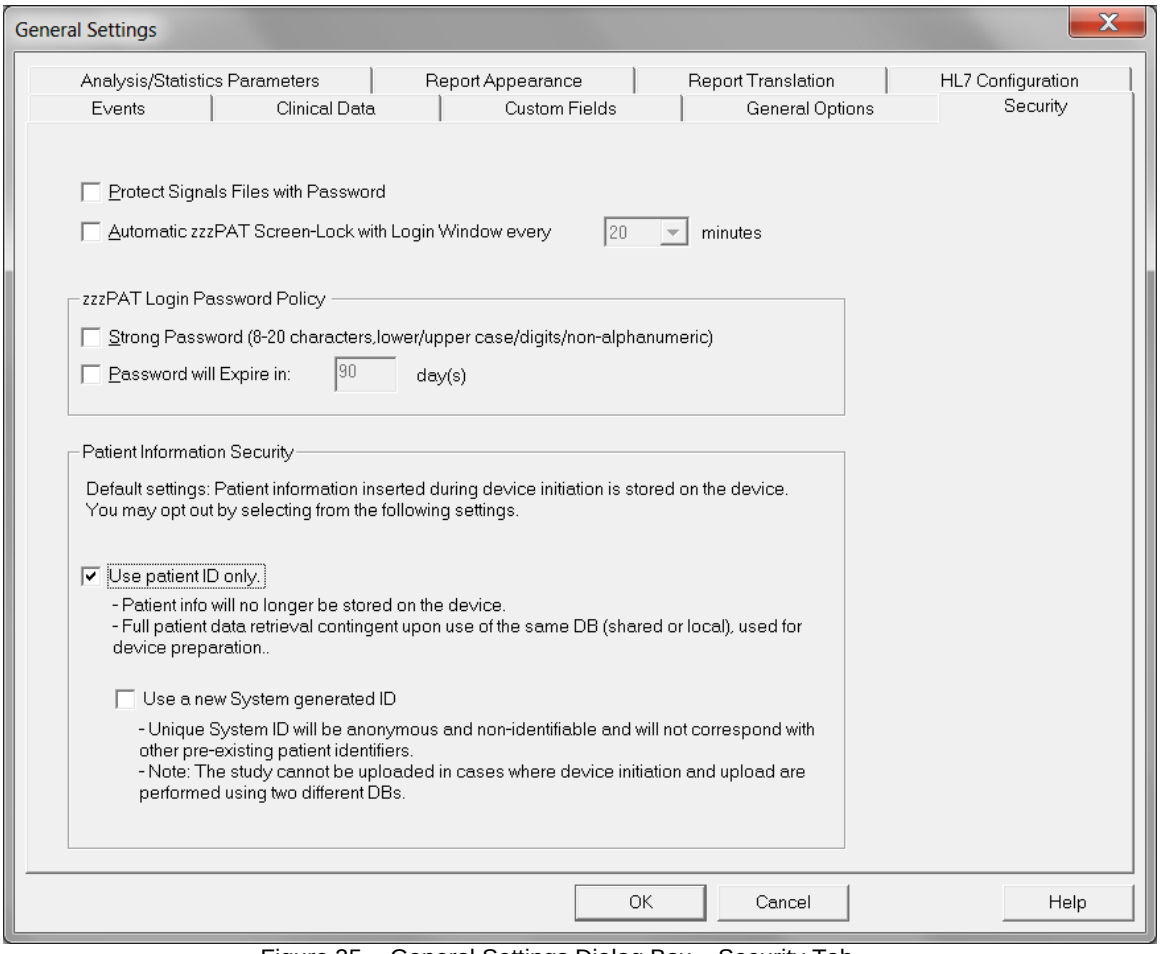


Figure 25 - General Settings Dialog Box – Security Tab

3.3.6 Setup>General Settings>Analysis/Statistics Parameters

Used to modify parameters that affect analysis or report.

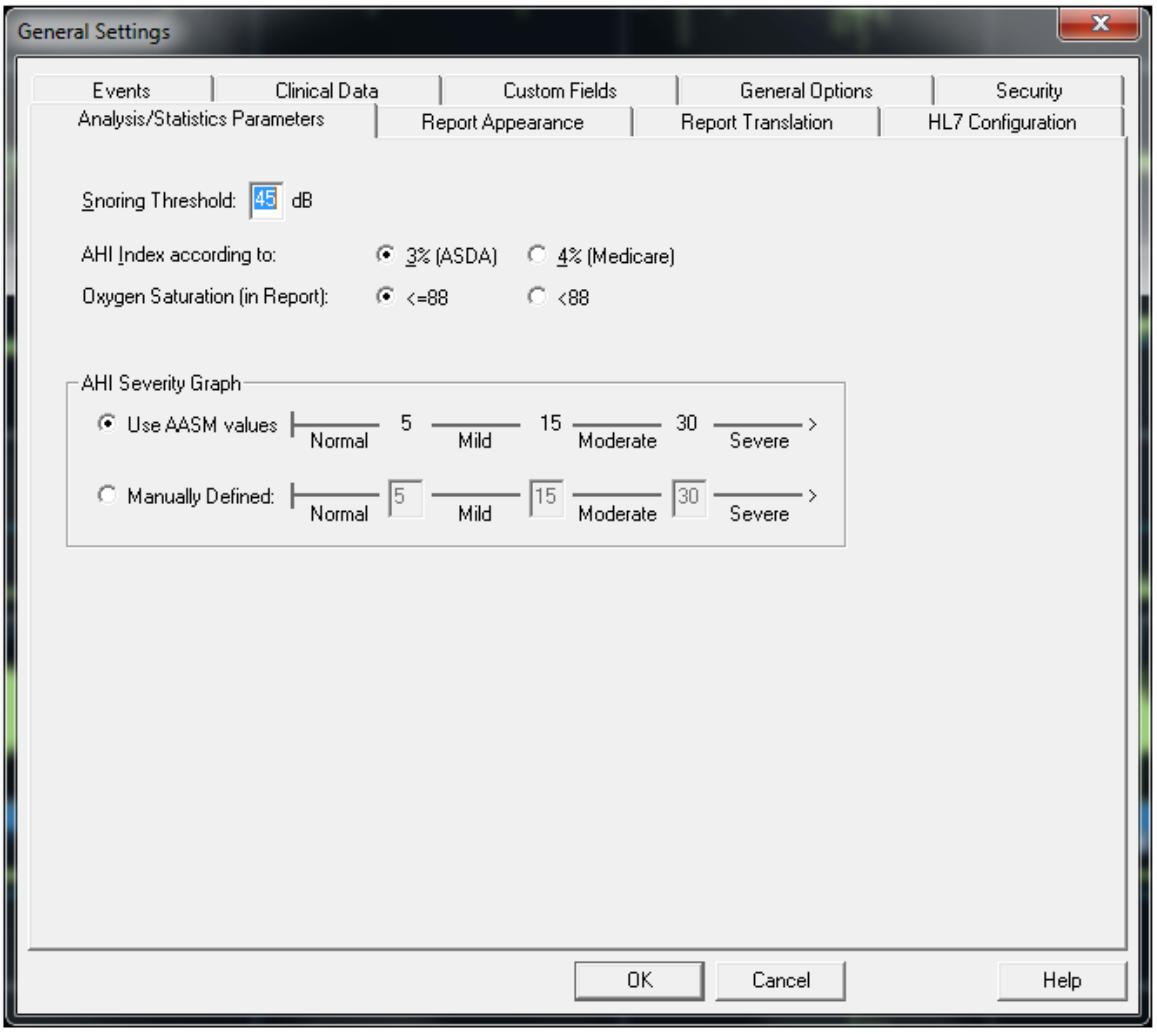


Figure 26 - General Settings Dialog Box – Analysis/Statistics Parameters Tab

- Select snoring threshold to be used in calculating snoring statistics (3rd page of report).
- Select the ASDA or Medicare protocol for calculating pAHI and pRDI indices on a site level. The automatic analysis will calculate respiratory events for pAHI and pRDI indices using desaturations of 3% and above (ASDA definition) or desaturations of 4% and above (Medicare definition) for all studies for this site. The Sleep report will show the calculated pAHI and pRDI indices with a note to indicate the protocol used for the calculation.

Note

The default settings to use ASDA or Medicare protocol for pAHI/pRDI calculation is according to site level and is defined in General Setting (Analysis/Statistics Parameters). A user may change this protocol (for his use only) by selecting one of the protocols under 'User defined AHI according to' checkbox in User settings. A user may change this protocol for specific study during new study preparation by selecting one of the protocols under 'AHI index according to' in Study details screen. In order to apply this change on existing studies in the database, you need to rerun the analysis.

- Select the comparison operator for oxygen saturation level value of 88 (<88 or <=88).
- Select the AASM values or manually define the ranges to be used in calculating the AHI Severity graph (3rd page of report). See section Report>Sleep Report for more details.

3.3.7 Setup>General Settings>Report Appearance

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

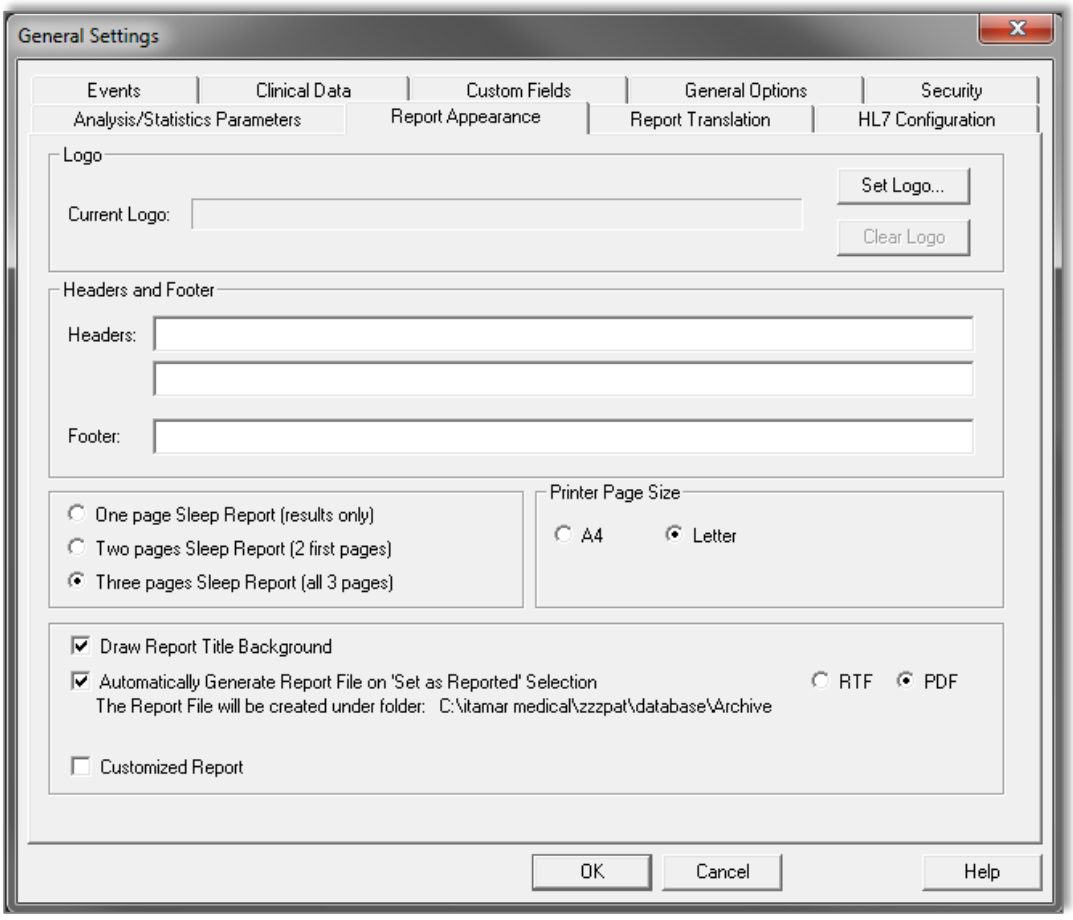


Figure 27 - General Settings Dialog Box – Report Appearance Tab

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".

To set the Printer page size of the Sleep Report:

- Select "A4" or “Letter” page size.

Select “Draw Report Title Background” in order to show the bitmap on the top of Sleep report.
Select “Customized Report” in order to show your company’s customized Sleep Report (provided by Itamar according to your specifications). When checking this option the customized report will replace the default report of zzzPAT.

To generate the Report File on ‘Set as Reported’ Selection:

- Check the option of “Automatically generate report file on ‘Set as Reported’ selection”.

Checking it enables one of the 2 options of saving the study: as RTF or PDF (the default option). This implies that every time a study is ‘Set as reported’ automatically a copy of the reported study is saved in the Archive folder (found under the database folder, the default being C:\Itamar Medical\zzzpat\database\Archive) in the chosen format.

3.3.8 Setup>General Settings>Report Translation

Used to change the sleep report headings.

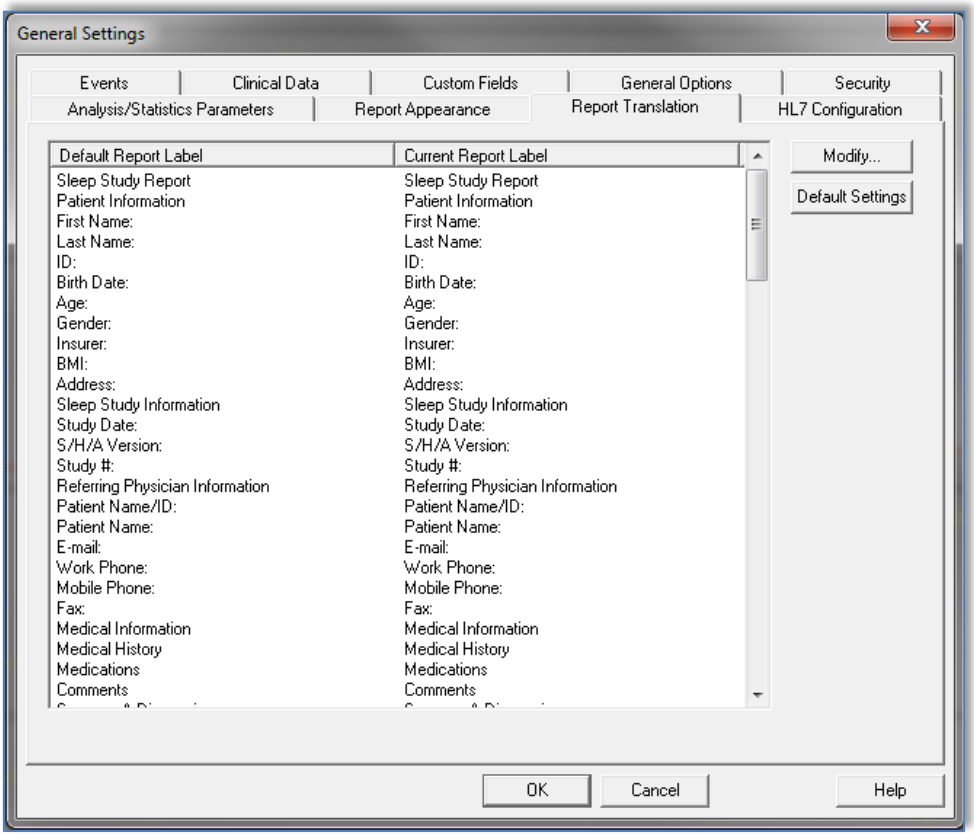


Figure 28 - General Settings Dialog Box – Report Translation Tab

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.

Note

Clicking the **Default Settings** will revert to default settings losing all user defined report labels

3.3.9 Setup>General Settings>HL7 Configuration

Used to enable and configure communication with the LIS (Laboratory Information System).
If the LIS option is enabled, results and report PDF files can be exported to LIS through the Export dialog, see “Tools>Export/Delete”.

	Note In order to enable this dialog the HL7 Service must be already installed on the PC where zzzPAT DB is installed.

	Note Contact Itamar Medical in order to receive support for HL7 configuration.

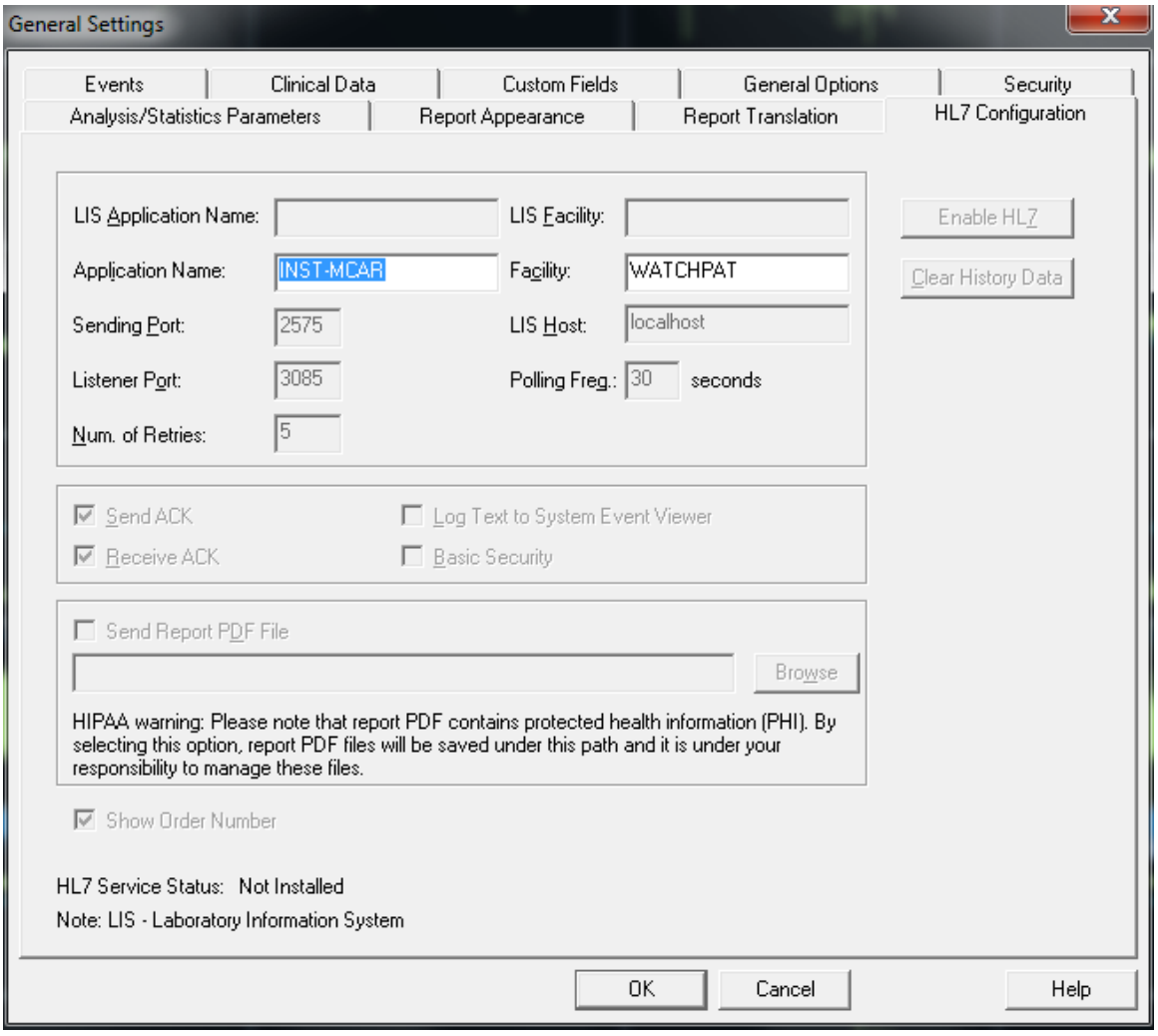


Figure 29 - General Settings Dialog Box – HL7 Configuration

- "LIS Application Name" is the identifier of the LIS used for HL7 messages. If "Basic Security" option is selected, this field is mandatory and only inbound messages with this identifier are intercepted by the zzzPAT application.
- "LIS Facility" is the identifier of the LIS facility used for HL7 messages. If "Basic Security" option is selected, this field is mandatory and only inbound messages with this identifier are intercepted by the zzzPAT application.
- "Sending Port" is the network port that the LIS listens on.
- "Listener Port" is the network port that the zzzPAT application listens on.
- "Num. of Retries" defines the number of retries when sending messages.
- "Polling Freq." defines how long to wait before retrying.
- "Send ACK" option defines whether or not to send an ACK.
- "Receive ACK" option defines whether or not to receive ACK on outgoing messages.
- "Send Report PDF File" option defines whether or not to send the zzzPAT sleep report as a pdf file along with the test results.
  If option is selected, a path must be entered through the "Browse" function, to be used as a depository for the pdf files.
  It's recommended to use a network path. Make sure appropriate users have write permissions to this path.
- "Show Order number" option enables to search in "New study" dialog the patient by its order number.

Warning

HIPPA Warning: The report PDF contains protected health information (PHI). By selecting this option, report PDF files will be saved under the selected path and it is under your responsibility to manage and protect these files.

Note

The study report must be viewed in order for the pdf file to be created. It is recommended to use option 'Open report after "Load Study and Analyze" in order to automatically open the report, see Setup>User Settings>Options. If study is re-analyzed, manually edited or analysis parameters are changed, the report should be viewed after the changes so the pdf can be recreated.

- "Log Text to System Event Viewer" option defines whether or not to log the full message text.
- "Basic Security" option defines whether or not to handle security. If this option is selected then only messages coming from the "LIS Application Name" and "LIS Facility" are intercepted by the zzzPAT application.

- "Disable HL7" function stops the HL7 service. The function is supported only for stand-alone zzzPAT and only if user has admin permissions on running PC and zzzPAT has been started with the "Run As Administrator" option. For Shared database cases, have your IT person contact Itamar Medical for instructions.
- "Clear History Data" function cleans up all messages in queue and should be used in case of a malfunction in order reset the HL7 service.

Note

For outbound messages (studies results) the LIS application name is "zzzPAT" and Facility is "Itamar-Medical".

4 Using zzzPAT

4.1 Preparing a New Study

Preparing the Patient file is a mandatory stage in the preparation of the WP200(U) devices for a sleep study. Before proceeding, make sure that the WatchPAT drive was defined as described in Section 2.4.

4.1.1 Launching zzzPAT

- Launch 'zzzPAT' by clicking the zzzPAT icon on your desktop.
- If the zzzPAT icon is launched the following login dialog opens:

Figure 30 - 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.
- The login dialog has two options for Login type:
  - Active Directory (current domain server).
  - Users from zzzPAT database

When Active Directory option is used, the application will check if group "zzzPAT" exists in current domain and the user name is a member of the group. If so, it will authenticate the password. If user is new to zzzPAT then the user will be defined in zzzPAT database with normal permissions. Administration zzzPAT permissions can be set only via zzzPAT's User Administration function.

	Note The ‘’zzzPAT” group name can be modified through the Setup>General Settings>General Options tab

	Note 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…).

	Note 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.

- If applicable, select the desired database to connect to.
- Enter your login name and password and click **OK** to continue.

4.1.2 Preparing a New Study

- 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:

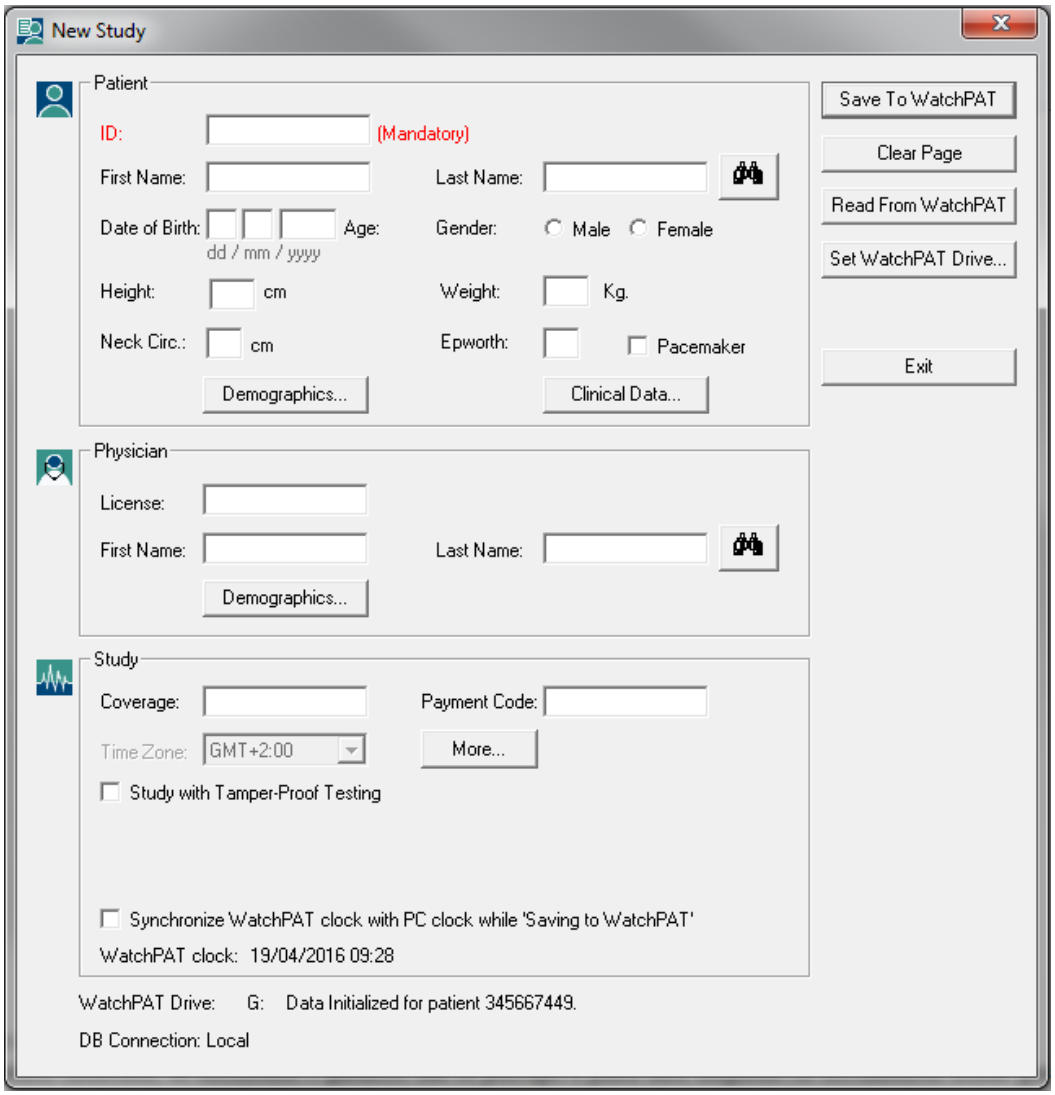


Figure 31 - New Study Dialog Box for WP200(U)

- Fill the mandatory Patient ID in the **Patient** fields.
- Insert any additional information if needed, the rest of the fields are optional.
- Select “Pacemaker” if the patient has an implantable pacemaker. The zzzPAT will automatically detect segments where the PAT pulses seem to be paced, i.e. very low pulse rate variations (near to stable) and exclude these segments from the analysis.

	Note Some types of pacemakers are excluding the use of the WatchPAT device. See the **exclusion criteria** section of the device operating manual for more details.

- 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>User Settings>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 WatchPAT** button.

	Note 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 **Save To WatchPAT** button again.

	Note The units used for weight and height in the 'New Study' dialog box are defined by the regional settings of the PC.

	Note 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).

If WP200(U) 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:

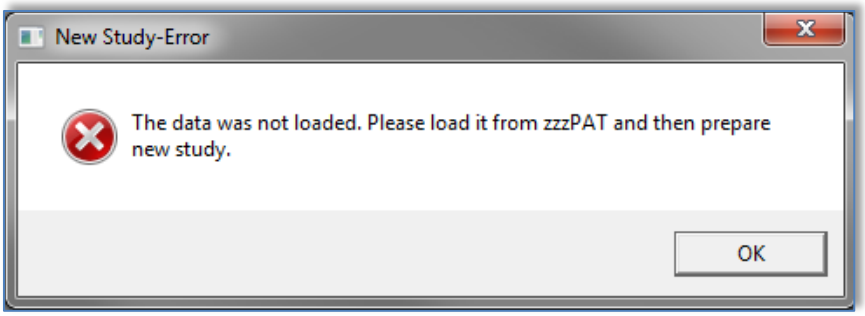


Figure 32 - WP200 Not Loaded Dialog Box

- After saving the patient information to the WP200(U) the following message appears:

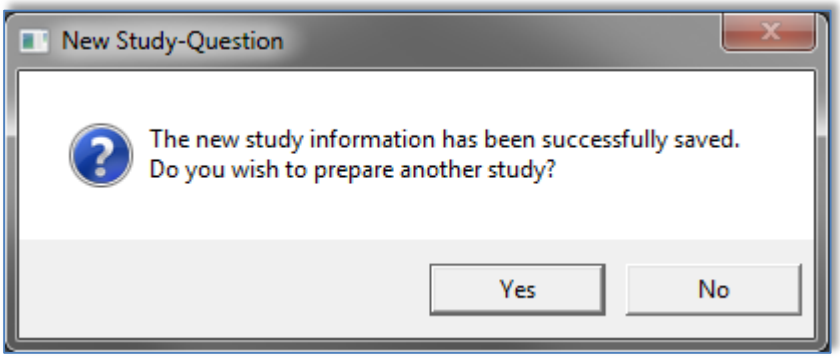


Figure 33 - New Study Termination Question

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

- Disconnect the USB cable from the 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 WP200(U) device clock with the zzzPAT software

Select the "Synchronize WatchPAT clock with PC clock while Saving to WatchPAT" while preparing a new study if the WP200(U) device clock needs to be set (see Figure 31).

4.1.3.2 Documenting additional information

To add demographic information:

- Click the **Demographics** button (see Figure 31). The following dialog box will open:

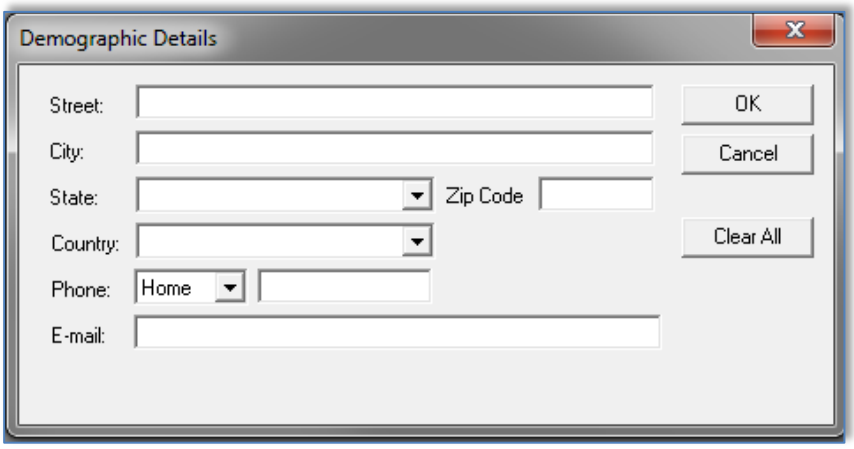


Figure 34 - Demographic Details Dialog box

- 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:

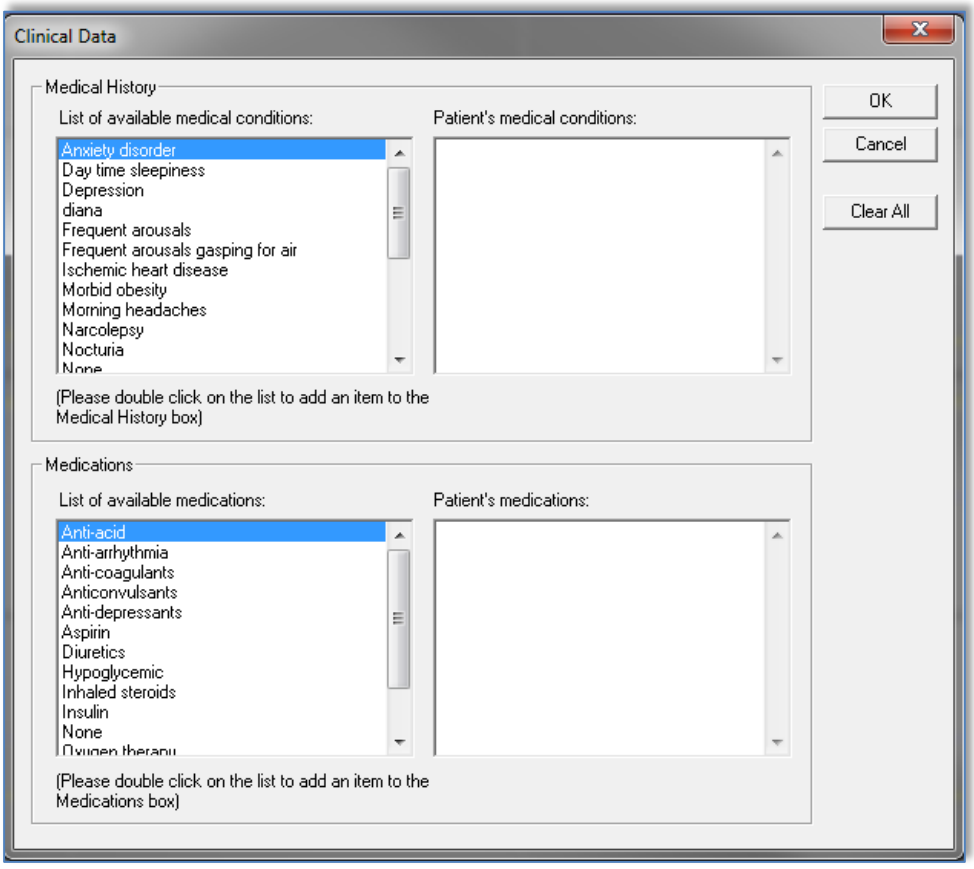


Figure 35 - Patient Clinical Data Dialog box

- 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.

4.1.3.3 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.

	Note If a patient has more than one study, only the latest patient details inserted will be displayed.

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

- In the 'New Study' dialog box (see Figure 31), 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.

4.1.3.4 Study details

To assign a study to a group or category for classifying patients by special group/category:

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

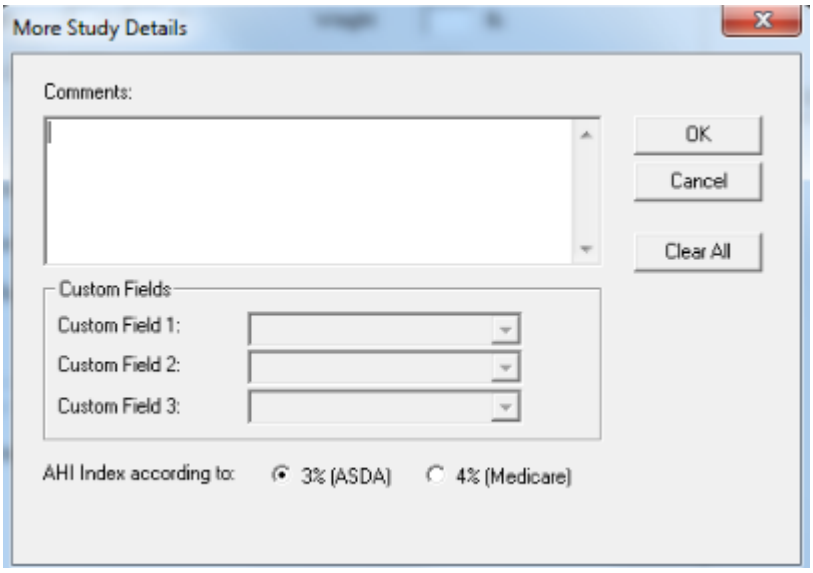


Figure 36 - More Study Details Dialog box

- 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.

	Note 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 36). To define 'Custom Fields' see section 3.3.3.

- You can select ASDA or Medicare protocol for calculating pAHI and pRDI indices on a study level. The automatic analysis will calculate respiratory events for pAHI and pRDI indices using desaturations of 3% and above (ASDA definition) or desaturations of 4% and above (Medicare definition) for this study only. The Sleep report will show the calculated pAHI and pRDI indices with a note to indicate the protocol used for the calculation.

	Note The default settings to use ASDA or Medicare protocol for pAHI/pRDI calculation is according to site level and is defined in General Setting (Analysis/Statistics Parameters). A user may change this protocol (for his use only) by selecting one of the protocols under 'User defined AHI according to' checkbox in User settings. A user may change this protocol for specific study during new study preparation by selecting one of the protocols under 'AHI index according to' in Study details screen. In order to apply this change on existing studies in the database, you need to rerun the analysis.

4.1.3.5 Reviewing and editing information stored on a WP200 drive

	Warning It is possible to change information on a WP200 drive only before the recording session. Changing information after a recording session will erase the recorded information on the drive.

- Insert the WP200 into the USB drive.
- Open 'New Study' application. Click **Read From WatchPAT** button.
- If the information does not need to be edited, click **Exit**.
- Make any necessary changes and click **Save to WatchPAT**.

	Note Study details, including patient information, can be viewed and modified after the study is loaded from the WP200 drive to the zzzPAT database. See Section 4.2.7 for more details.

4.2 Managing Patient Studies

After a WP200 sleep study is done, connect the WatchPAT into the USB, open zzzPAT application and press File>Load Study and Analyze from the main menu. 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.

	Note

	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.

4.2.1 File>New Study Details

Prepares the Patient file on the WP200(U) for a sleep study (Section 4.1).

4.2.2 File>Load Study and Analyze

This command loads the sleep study data from the device and saves it into the zzzPAT database.
While loading the data the message 'Loading Study' (Figure 37) appears on the screen indicating that the data is being transferred from the WatchPAT to the hard disk and the patient file is saved in the database.

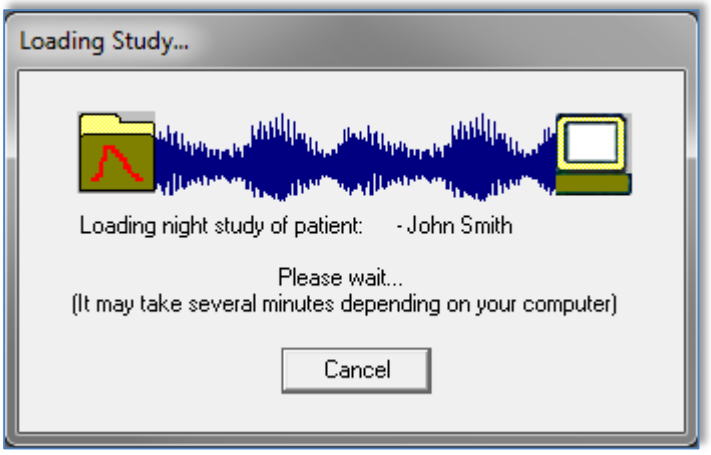


Figure 37 - Loading Study dialog box

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 40). The user has the option to display the "Sleep report" or "Sleep Indices" report box automatically after loading a study (see 3.2.3).

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 38). 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.

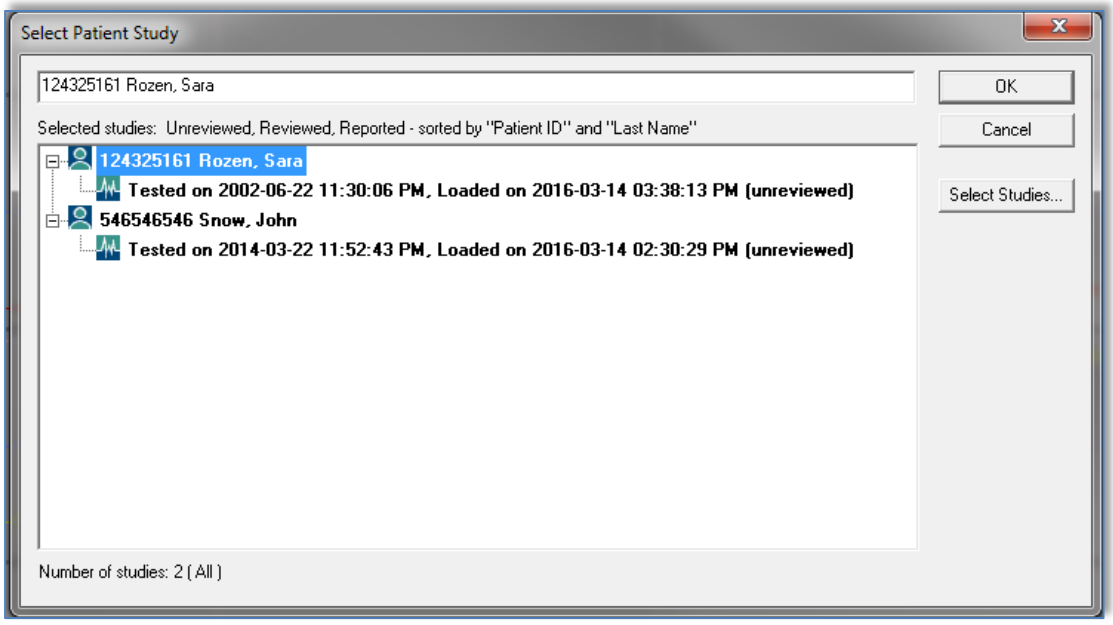


Figure 38 - Select Patient Study dialog box

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:

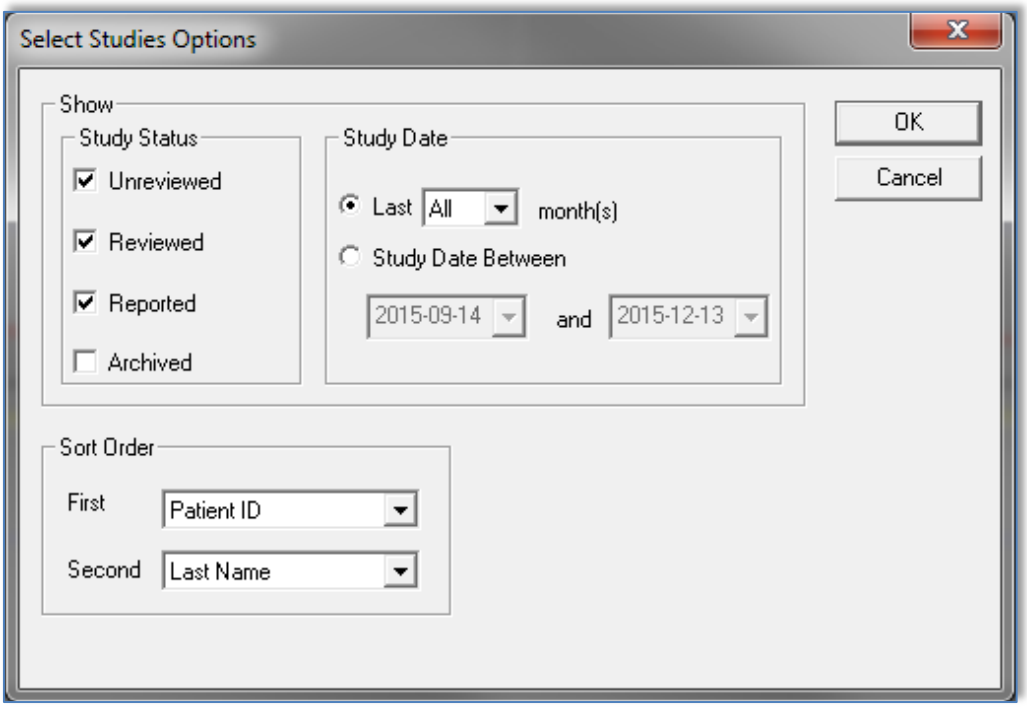


Figure 39 - Select studies options dialog box

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.

Note

The Archived option is unchecked automatically every time the "Select Patient Study" dialog box is opened.
In order to view archived studies the "Archived" option must be selected each time in the "Select studies options" dialog box.

Note

The typical 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 3.3.3).

'Second' order field – Contains only system predefined criteria.

Study Date section - enables the user to filter which studies are displayed.

'Last xx months' – Shows studies recorded during the last xx months (xx=1, 3, 6,12,18 or All months)

'Study Date Between" – Show studies recorded between selected ranges.

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. Authorized users can change the patient ID only once.

4.3 The Display Screen

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

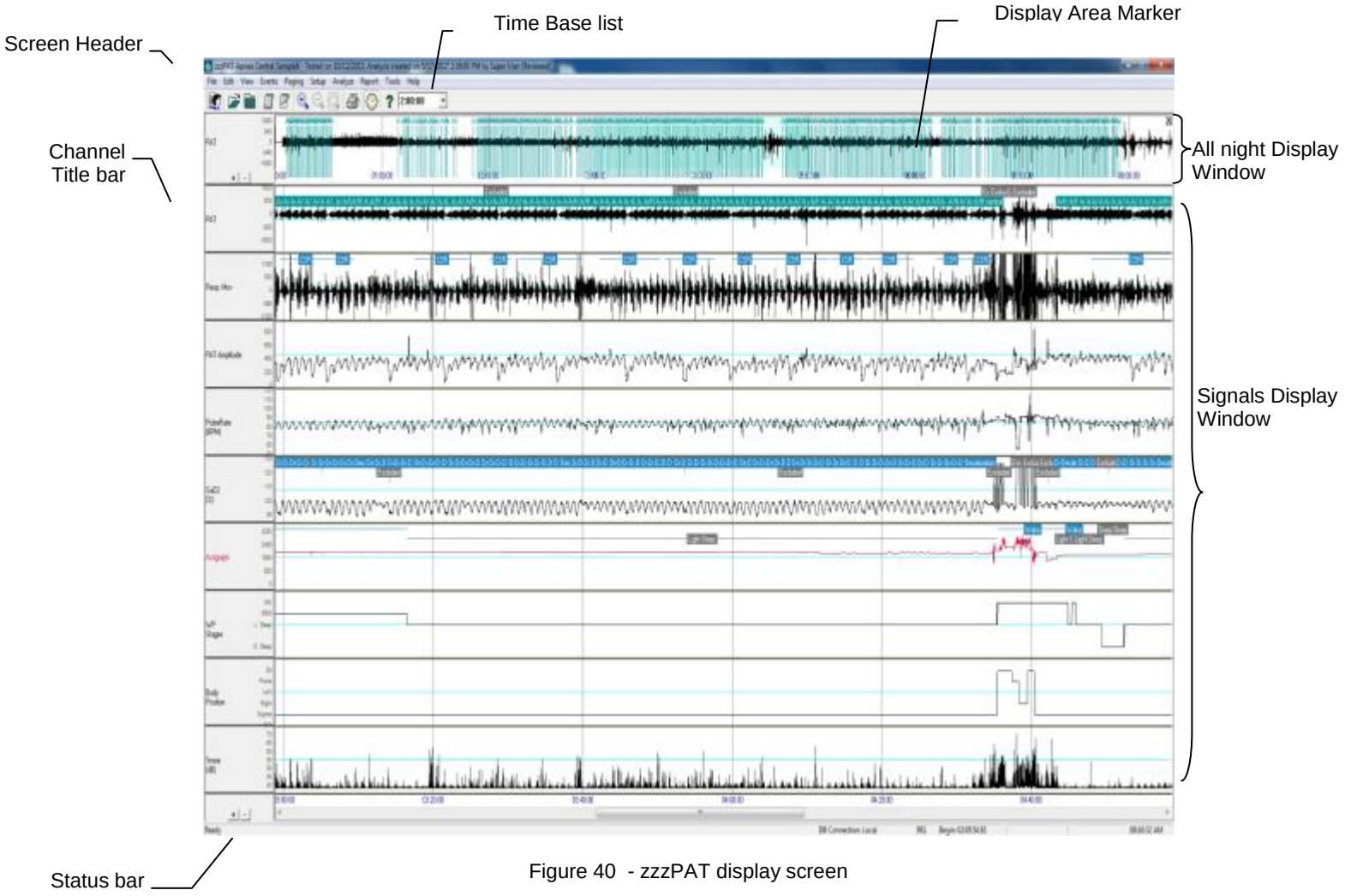


Figure 40 - zzzPAT display screen

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 and View Channels

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:

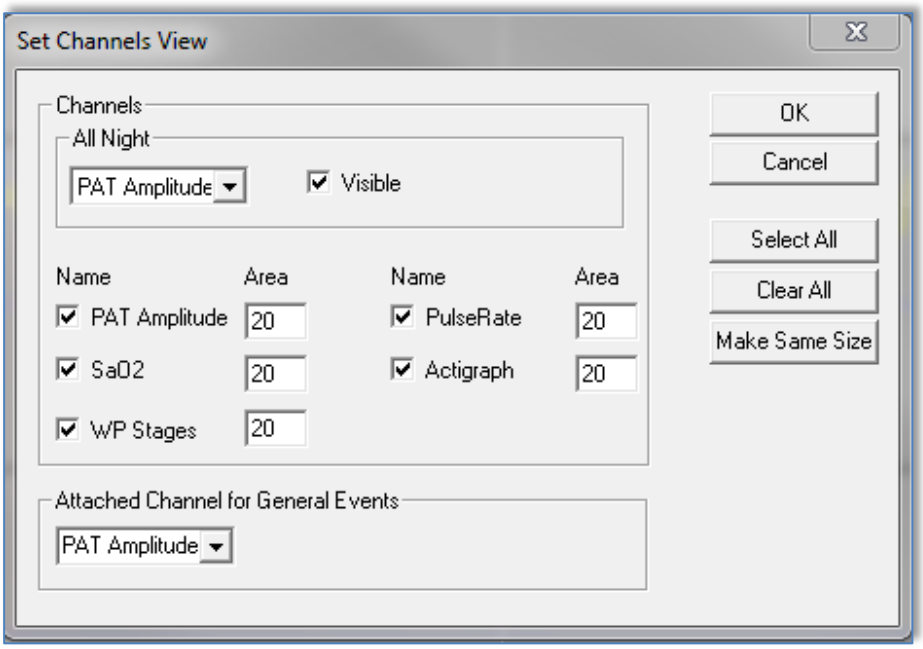


Figure 41 - Selecting the All night Window

- 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'.

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.

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 40), 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:

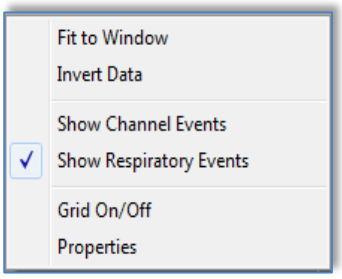


Figure 42 - All Night pop-up Menu

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 43).

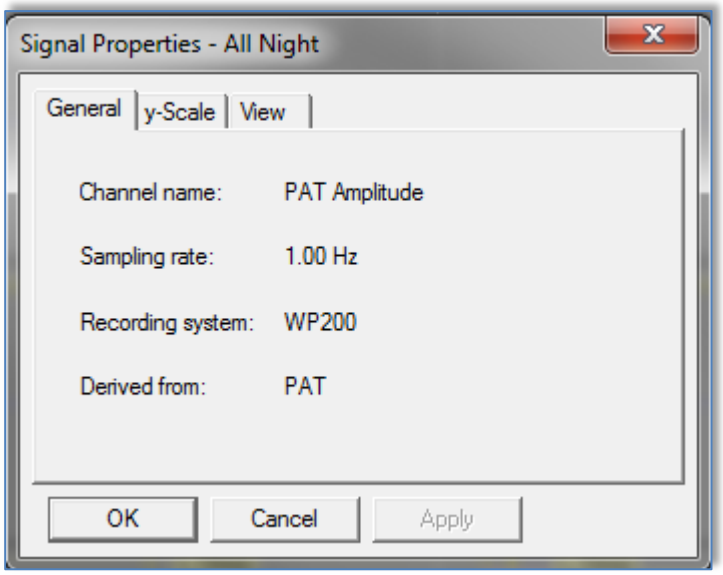


Figure 43 - Signal Properties – All Night window

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

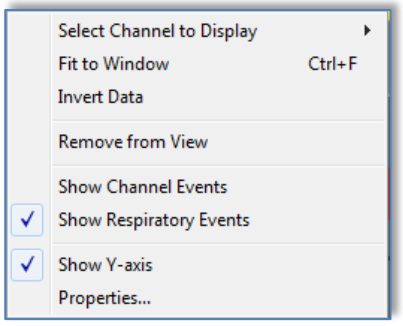


Figure 44 - All Night pop-up menu

Select Channel to Display – Allows the user to choose which channel will be displayed in the 'All Night Display Window'.

The rest of the options are the same as in Figure 42 explanations.

4.3.2 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:

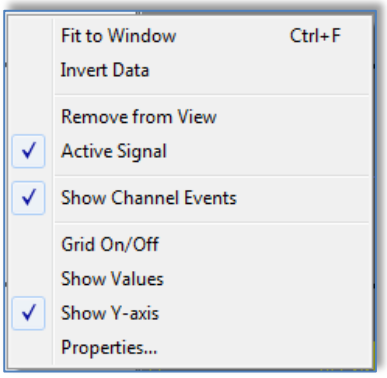


Figure 45 - Active channel pop-up menu

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.

4.3.3 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)

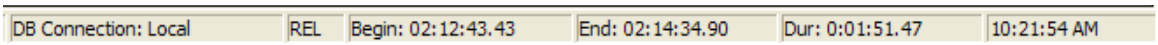


Figure 46 - zzzPAT Screen - Status Bar

4.4 Signal Display Options

4.4.1 View>Channels

See The All Night Window and View Channels section.

4.4.2 View>Set y-Scale

Opens the 'Set y-Scale' dialog box.

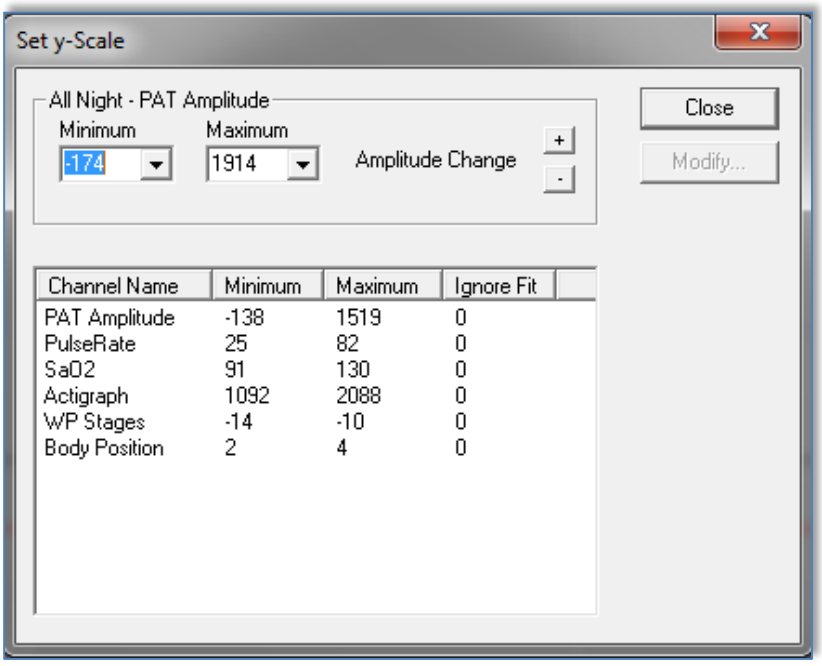


Figure 47 - Set y-Scale dialog box.

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:

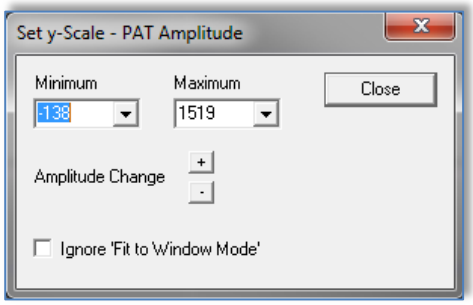


Figure 48 - Set y-Scale – per channel dialog box

- 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 WP200(U) 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 WP200(U) recorded signals, providing extensive information on the patient's sleep. The analysis provides an evaluation of respiratory events during sleep, oxygen saturation , pulse rate and sleep stages statistics. Also, it provides snoring and body position statistics when the SBP sensor is used.

4.5.1.1 Generating an Analysis

Recorded study data is automatically analyzed after being loaded from the device. 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.

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 and sleep stages 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, desaturation 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 Event' Dialog box will open.

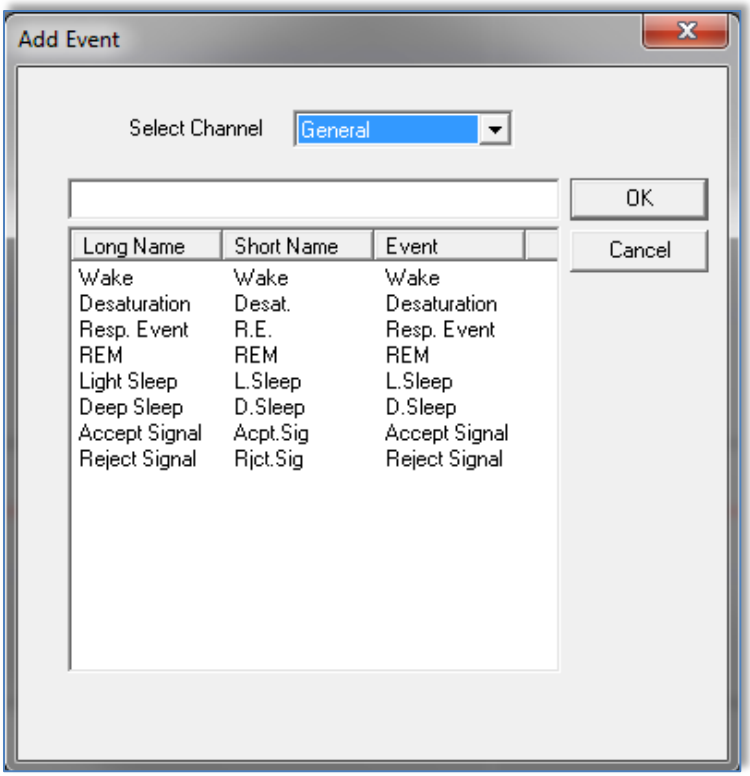


Figure 49 - Add Event dialog box

- '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.

	Note In case of patient with pacemaker the physician should manually edit to 'reject' event segments where the PAT pulses seem to be paced i.e. very low pulse rate variations (near to stable).

4.5.7 Deleting an Event

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

	Note Adding or deleting a respiratory or desaturation event affects the results in the report**.** A note will appear in the footer of the Sleep Report indicating that the Automatic Analysis was manually changed by the user.

4.5.8 Events>GoTo Event

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

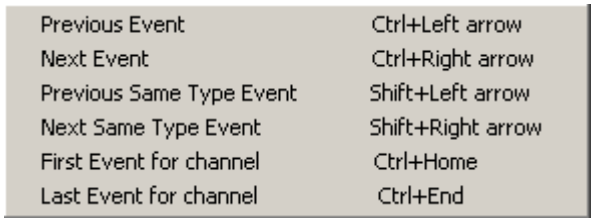


Figure 50 - Event Type Search options

4.5.9 Events>Select Event

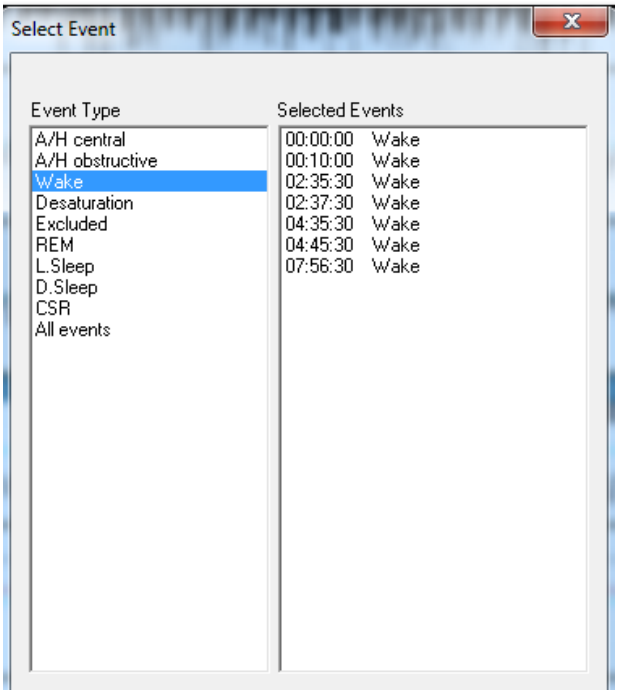


Figure 51 - Select Event dialog box

This option 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 52)

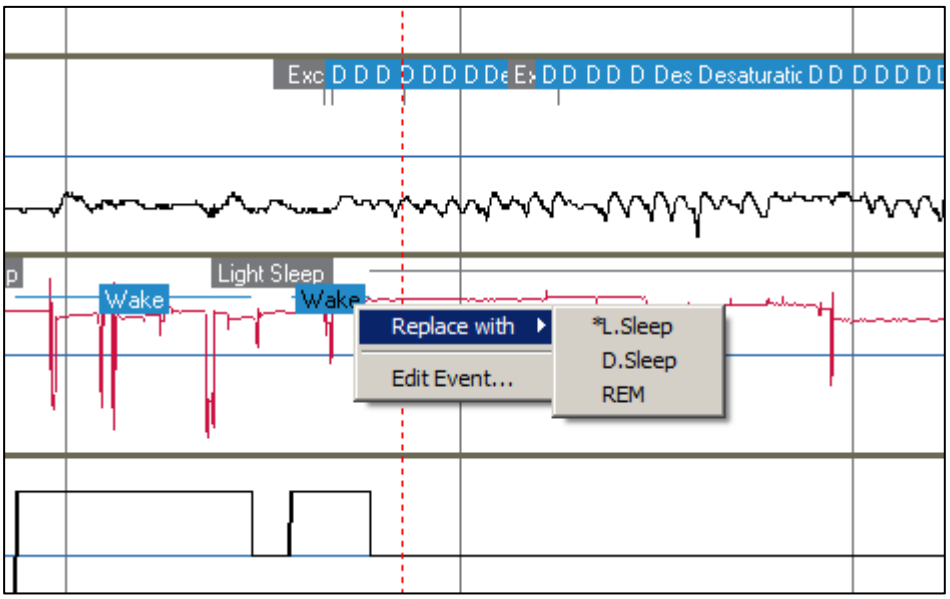


Figure 52 – Editing sleep stages

Note

Editing the sleep stages affects the results in the report. The * in front of the alternative event name denotes the last event preceding the current event.
A note will appear in the footer of the Sleep Report indicating that the Automatic Analysis was manually changed by the user.

4.6 Reports

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

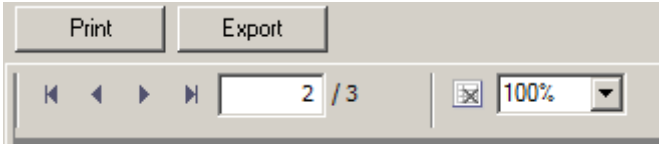


Figure 53 - Report Toolbar

- To print a report, click on the Print button.
- To export a report to a different format, such as pdf, rtf, html, etc., click on the Export button .
- 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

This option allows adding a diagnosis and recommendations to the Sleep Report screen (see Figure 54). 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.
- Check **'Send to HL7'** option in case the HL7 service is installed and enabled in order to send the specific study to HL7. Notice that the checkbox needs to be marked for each study that needs to be send to HL7.

Note

Multiple analyses may be associated with a particular study. A new analysis will be created when selecting the 'Analyze>Reload Study and Analyze' option on a study that had been previously 'Set as Reported'.

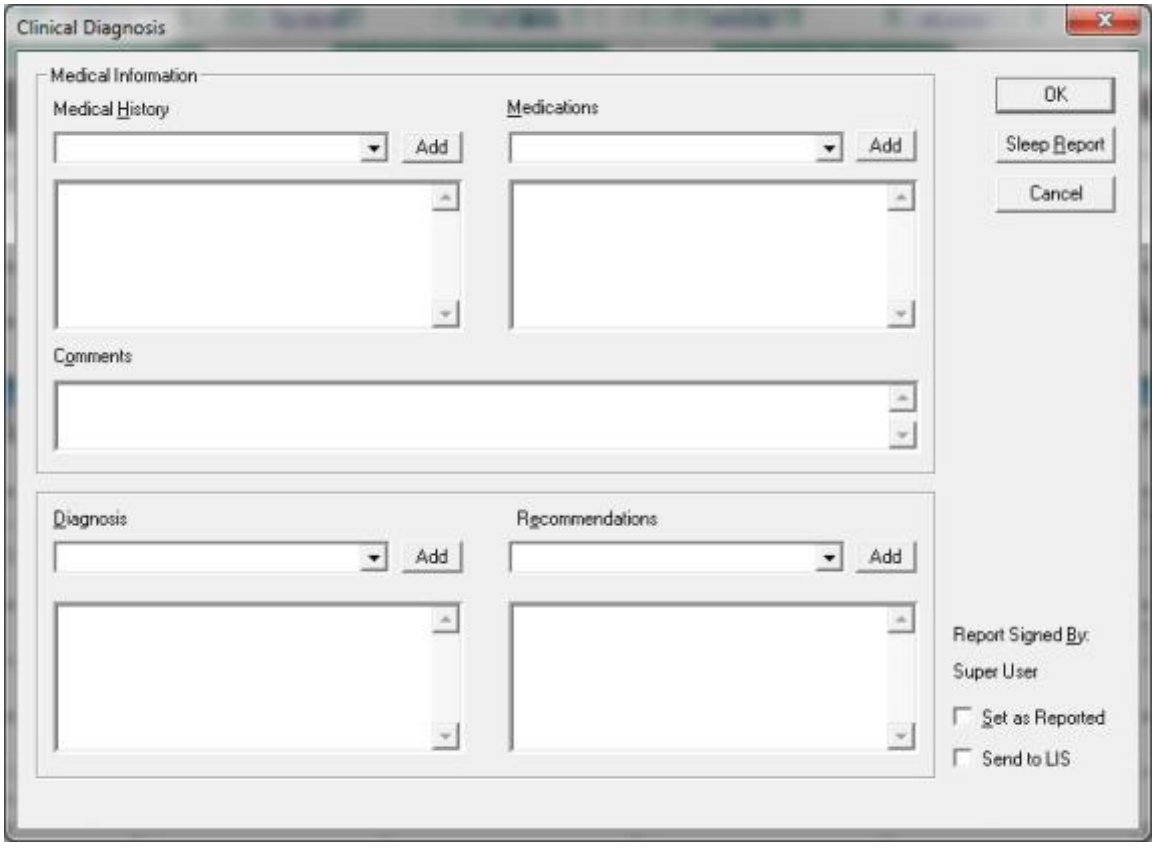


Figure 54 - Clinical Diagnosis dialog box

Note

Once a study is 'Set as Reported' any subsequent change to any of the 'Clinical Diagnosis' dialog fields (**Reports>Clinical Diagnosis**) will trigger the following warning message:

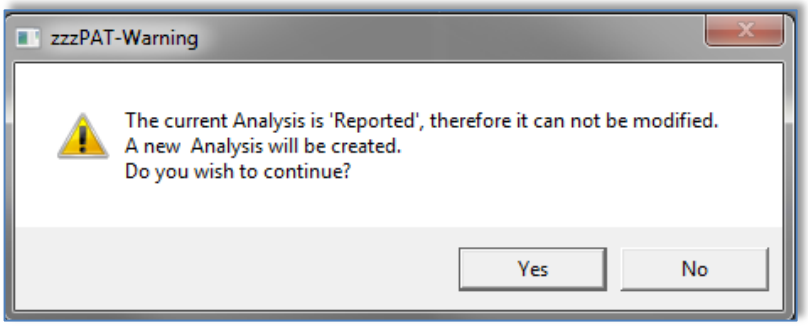


Figure 55 - New Analysis Warning message

Click **Yes** to save a new analysis without overwriting the existing analysis.
Click **No** to cancel the new analysis request.

4.6.2 Report>Sleep Report

The 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 58 - First page of Sleep Report) includes Patient Information, the Sleep Study Information, Referring Physician, Medical history, Diagnosis and Recommendations.

The second page (Figure 59 - Second page of Sleep Report) presents the study results including Sleep Summary, PAT Respiratory Disturbance Index (pRDI), PAT Apnea Hypopnea Index (pAHI), PAT Central Apnea Hypopnea Index (pAHIc)*, Number of events, Percentage of total sleep time with Cheyne-Stokes Respiration (%CSR)*, 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 presents AHI Severity Graph, pie charts of sleep/wake states and sleep stages, Sleep Latency, REM Latency, Number of wakes and Sleep Efficiency and Snore and Body Position statistics (in case a Snore/Body Position sensor was used).

**pAHIc and %CSR data are supplied in case RESBP sensor was used. The presentation of pAHIc and %CSR is subject to regulatory approval in the country.*

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.

PAT Central Apnea Hypopnea Index (pAHIc): the estimated number of Central Apneas and Hypopneas events divided by the valid sleep time*. Provided in Central Apnea and Hypopnea events/Hour.

Percentage of total sleep time with Cheyne-Stokes Respiration (%CSR): the estimated percentage of CSR pattern from the valid sleep time*.

**valid sleep time in pAHIc and %CSR might be different from the valid sleep time used in the calculation of other indices, as the RESBP sensor needs to be valid for this calculation as well.*

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 – 70 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 (pRDI), apnea/hyperpnoea index (pAHI), and desaturation index (ODI) are also provided in the report for each body position as well as non-supine position.

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

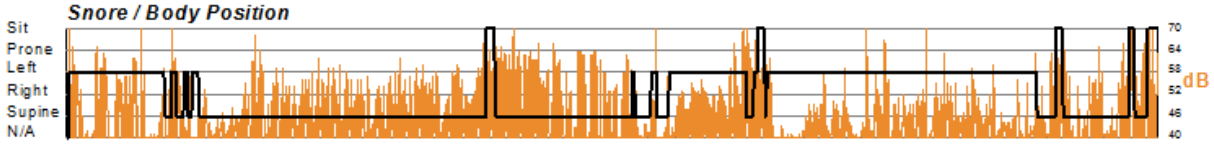


Figure 56 - Snoring and Body Position Statistics

AHI Severity Graph: Indicates the severity of obstructive sleep apnea (OSA). According to the American Academy of Sleep Medicine (AASM) it is categorized into mild (5-15 events/hour), moderate (15-30 events/hr), and severe (>30 events/hr). The severity categorization limits can be modified, see Setup>General Settings>Analysis/Statistics Parameters.

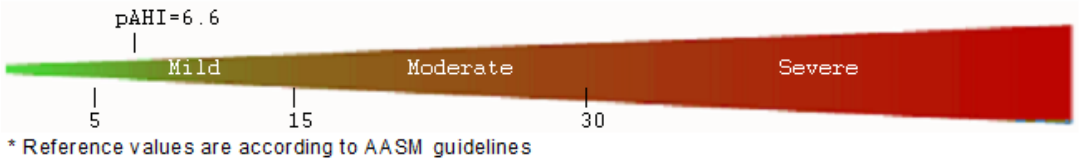
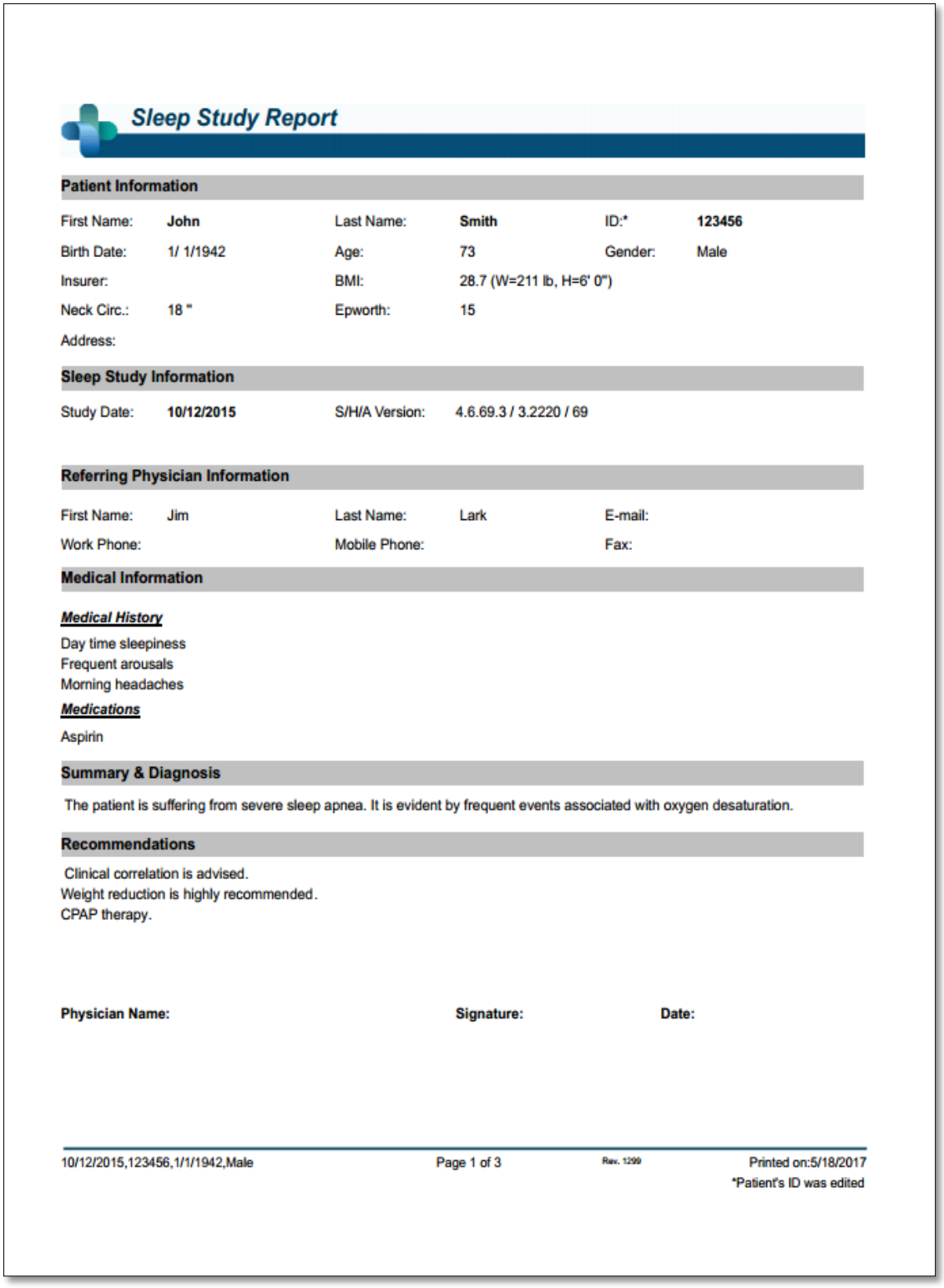


Figure 57 - AHI Severity graph



Sleep Study Report

Patient Information

First Name:	**John**	Last Name:	**Smith**	ID:*	**123456**
Birth Date:	1/ 1/1942	Age:	73	Gender:	Male
Insurer:		BMI:	28.7 (W=211 lb, H=6' 0")		
Neck Circ.:	18 "	Epworth:	15		
Address:					

Sleep Study Information

Study Date:	**10/12/2015**	S/H/A Version:	4.6.69.3 / 3.2220 / 69

Referring Physician Information

First Name:	Jim	Last Name:	Lark	E-mail:	
Work Phone:		Mobile Phone:		Fax:	

Medical Information

Medical History

Day time sleepiness
Frequent arousals
Morning headaches

Medications

Aspirin

Summary & Diagnosis

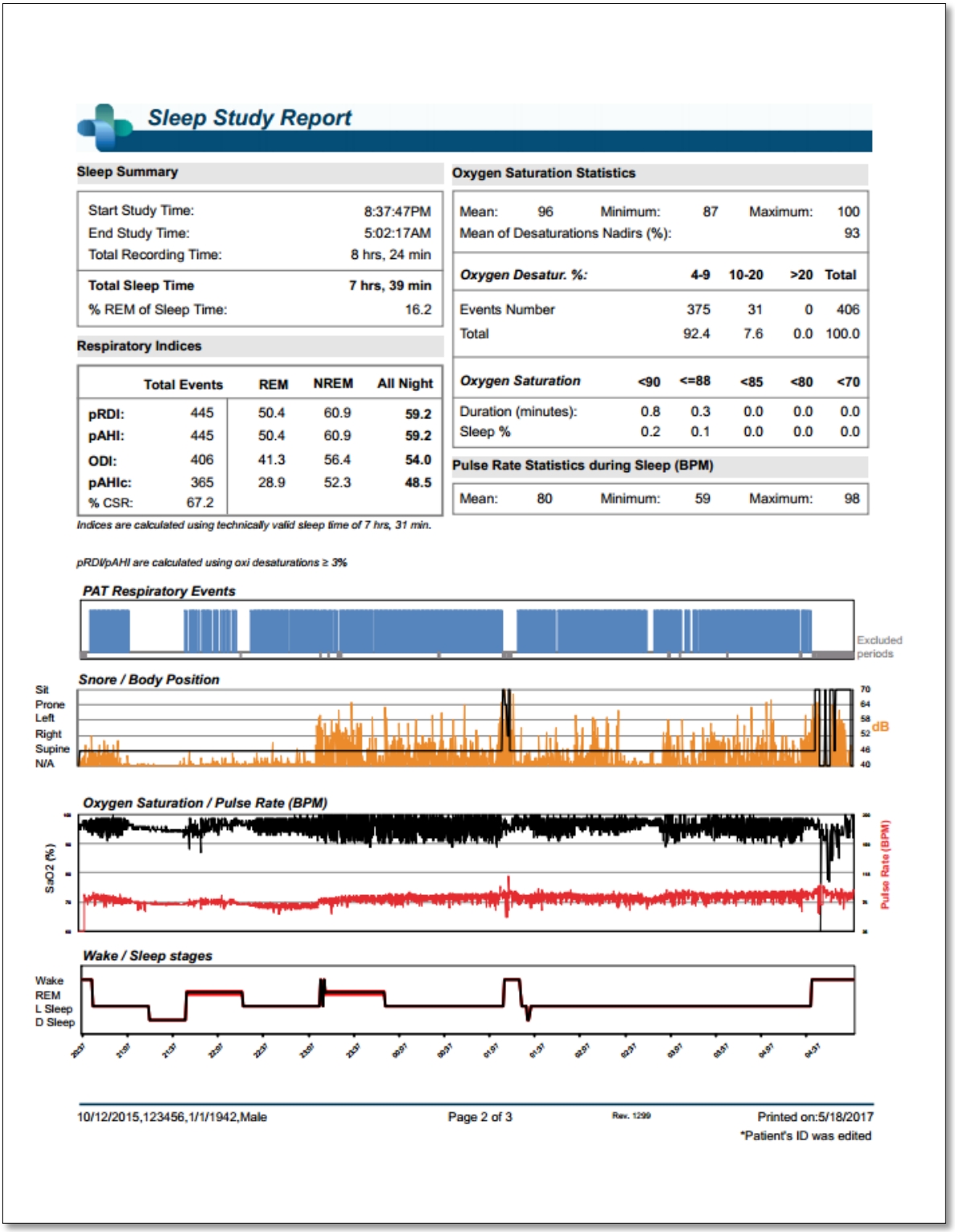
The patient is suffering from severe sleep apnea. It is evident by frequent events associated with oxygen desaturation.

Recommendations

Clinical correlation is advised.
Weight reduction is highly recommended.
CPAP therapy.

Physician Name: **Signature:** **Date:**

Figure 58 - First page of Sleep Report



Sleep Study Report

Sleep Summary

Start Study Time:	8:37:47PM
End Study Time:	5:02:17AM
Total Recording Time:	8 hrs, 24 min
Total Sleep Time	**7 hrs, 39 min**
% REM of Sleep Time:	16.2

Respiratory Indices

	Total Events	REM	NREM	All Night
pRDI:	445	50.4	60.9	**59.2**
pAHI:	445	50.4	60.9	**59.2**
ODI:	406	41.3	56.4	**54.0**
pAHIc:	365	28.9	52.3	**48.5**
% CSR:	67.2			

Indices are calculated using technically valid sleep time of 7 hrs, 31 min.

pRDI/pAHI are calculated using oxi desaturations ≥ 3%

Oxygen Saturation Statistics

Mean: 96 Minimum: 87 Maximum: 100
Mean of Desaturations Nadirs (%): 93

Oxygen Desatur. %:	4-9	10-20	>20	Total
Events Number	375	31	0	406
Total	92.4	7.6	0.0	100.0

Oxygen Saturation	<90	<=88	<85	<80	<70
Duration (minutes):	0.8	0.3	0.0	0.0	0.0
Sleep %	0.2	0.1	0.0	0.0	0.0

Pulse Rate Statistics during Sleep (BPM)

Mean: 80 Minimum: 59 Maximum: 98

PAT Respiratory Events

Excluded periods

Snore / Body Position

Sit
Prone
Left
Right
Supine
N/A

70 64 58 52 46 40 dB

Oxygen Saturation / Pulse Rate (BPM)

SaO2 (%)

Pulse Rate (BPM)

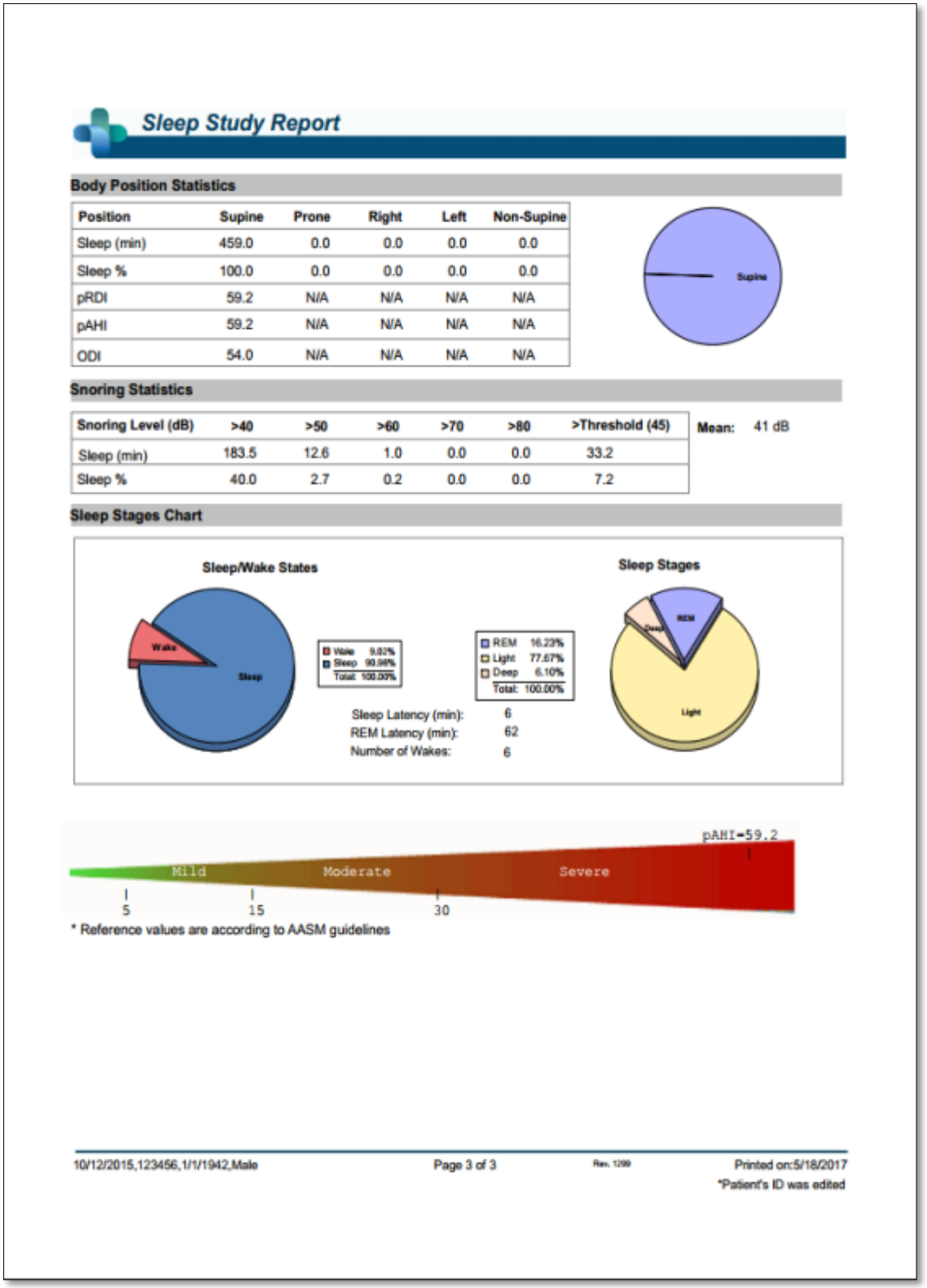
Wake / Sleep stages

Wake
REM
L Sleep
D Sleep

10/12/2015,123456,1/1/1942,Male Page 2 of 3 Rev. 1299 Printed on:5/18/2017

*Patient's ID was edited

Figure 59 - Second page of Sleep Report



Sleep Study Report

Body Position Statistics

Position	Supine	Prone	Right	Left	Non-Supine
Sleep (min)	459.0	0.0	0.0	0.0	0.0
Sleep %	100.0	0.0	0.0	0.0	0.0
pRDI	59.2	N/A	N/A	N/A	N/A
pAHI	59.2	N/A	N/A	N/A	N/A
ODI	54.0	N/A	N/A	N/A	N/A

Snoring Statistics

Snoring Level (dB)	>40	>50	>60	>70	>80	>Threshold (45)
Sleep (min)	183.5	12.6	1.0	0.0	0.0	33.2
Sleep %	40.0	2.7	0.2	0.0	0.0	7.2

Mean: 41 dB

Sleep Stages Chart

Sleep Latency (min): 6
REM Latency (min): 62
Number of Wakes: 6

* Reference values are according to AASM guidelines

Figure 60 - Third page of Sleep Report

4.6.3 Report>Sleep Report for Selected Time Range

This option 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 61 - 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.

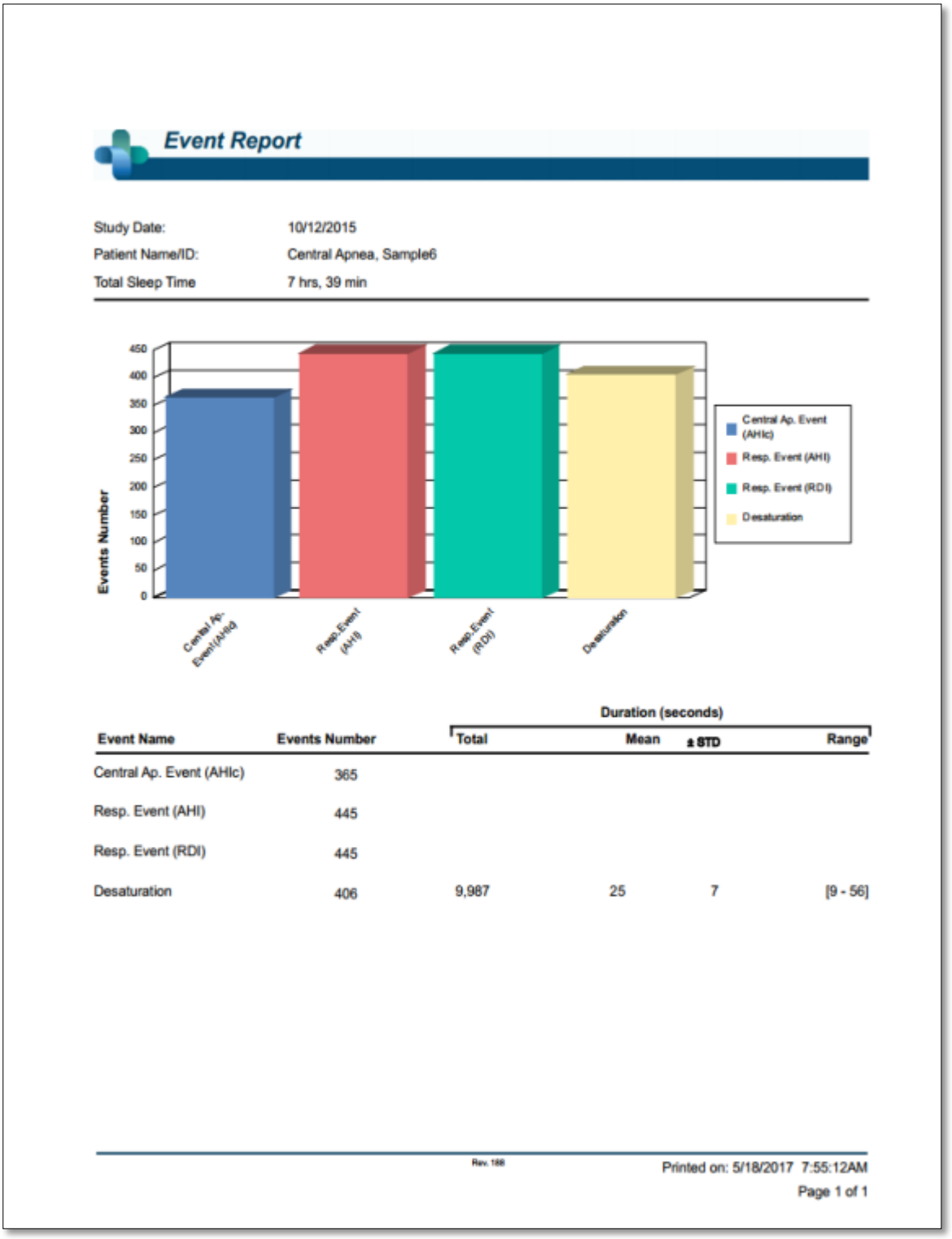
The second page of the report presents the study results for the **Selected Time Range,** including Sleep Summary, PAT Respiratory Disturbance Index (pRDI), PAT Apnea Hypopnea Index (pAHI), PAT Central Apnea Hypopnea Index (pAHIc)*, Number of events, Percentage of total sleep time with Cheyne-Stokes Respiration (%CSR)*, 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, Snore and Body Position chart (in case a Snore/Body Position sensor was used).
The third page presents AHI Severity Graph, pie charts of sleep/wake states and sleep stages, Sleep Latency, REM Latency, Number of wakes and Sleep Efficiency and, Snore and Body Position statistics (in case a Snore/Body Position sensor was used).
**pAHIc and %CSR data are supplied in case RESBP sensor was used. The presentation of pAHIc and %CSR is subject to regulatory approval in the country.*

	Note In the Selected Time Range report, the Start and End Study Times are the margins of the Selected Range.

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 name (on the relevant

row below the chart) to get a detailed list of all the events of this type (see Figure 62 - Event Report).



Event Report

Study Date: 10/12/2015
Patient Name/ID: Central Apnea, Sample6
Total Sleep Time 7 hrs, 39 min

Event Name	Events Number	Duration (seconds) Total	Mean	± STD	Range
Central Ap. Event (AHIc)	365				
Resp. Event (AHI)	445				
Resp. Event (RDI)	445				
Desaturation	406	9,987	25	7	[9 - 56]

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Page 1 of 1

Figure 62 - Event Report

	Time Start	Time End	Time Duration (s)	Percent	
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 63 - 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 64 - Sleep Indices report

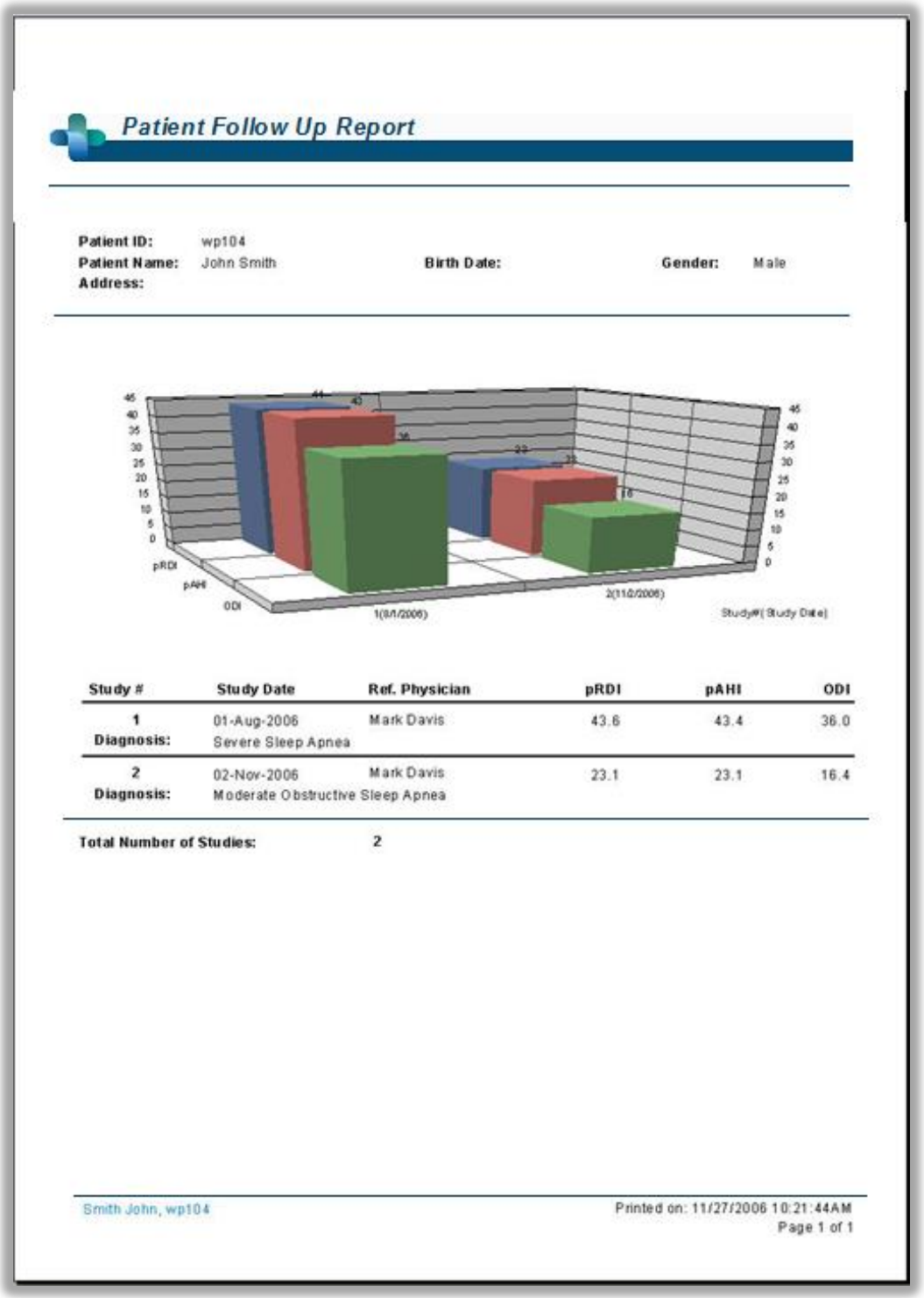
Note

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.
The Sleep % over the defined Snoring threshold dB will be displayed as well.

	Note Unreviewed studies will not be presented in the Patient follow up report (see section 4.2.3).



Patient Follow Up Report

Patient ID: wp104
Patient Name: John Smith **Birth Date:** **Gender:** Male
Address:

Study #	Study Date	Ref. Physician	pRDI	pAHI	ODI
1	01-Aug-2006	Mark Davis	43.6	43.4	36.0
Diagnosis:	Severe Sleep Apnea				
2	02-Nov-2006	Mark Davis	23.1	23.1	16.4
Diagnosis:	Moderate Obstructive Sleep Apnea				

Total Number of Studies: 2

Smith John, wp104
Printed on: 11/27/2006 10:21:44AM
Page 1 of 1

Figure 65 - Patient Follow-up Report

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/Hypopnea 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

Sleep Study Report

Name of Patient: John Snow
Name of Referring Doctor: John Smith
Date of Study: 2002-01-10

Dear John Snow,

I would like to thank you for undertaking the Watch-PAT ambulatory sleep study. I would now like to review with you the results that you received.

Your total study time (which is calculated from the time you turned the device on until you pulled it off) was 10 hrs, 16 min. But as we are testing for obstructive sleep apnea and are interested in the time that you were asleep, your total sleep time was 6 hrs, 21 min. On average, a person with normal sleep habits sleeps between 6 - 8 hours a night.

Looking at your sleep statistics we can learn some vital information:

Your apnea/hypopnea index (abbreviated as AHI) was found to be 51.5. This score is the average numbe of apnea and hypopnea events per hour of sleep during the night. Apnea event is an episode of fully occluded breathing of more than 10 seconds, and an hypopnea event is an episode of partial occlusion. The normal range of the AHI score is 5 or lower.

Your respiratory disturbance index (RDI) was found to be 52.5. This score is calculated in a very similar way as the AHI but an additional type of respiratory events named RERA are also counted. RERA is the abbreviation for Respiratory Effort Related Arousal and is essentially a very short arousal of a few seconds that follows partial occlusion of the airways. The normal range of the RDI score is also 5 or lower.

Your oxygen desaturation index (ODI) was found to be 33.7. This score is the average number of times the oxygen in your blood dropped by 4% or more during an hour of sleep. As you can imagine, the more your oxygen drops the harder the heart must work. The normal range of the ODI is 5 or lower.

Looking at your REM sleep stage (Rapid Eye Movement) we find that you were in this stage 0.0% of your sleep time. REM sleep is very important as during this stage your body is being replenished and nurtured. The normal range of the REM score is between 15 to 30% pending some other conditions. REM stage is also believed to be the time during which we dream.

If I can be of any further assistance, please contact my front desk to make an appointment.

Regards,

Printed on: 2016-03-14

Figure 66 - Report for Patient

4.6.8 Printing

The study signals recorded by the WP200(U) 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 (see Figure below):

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

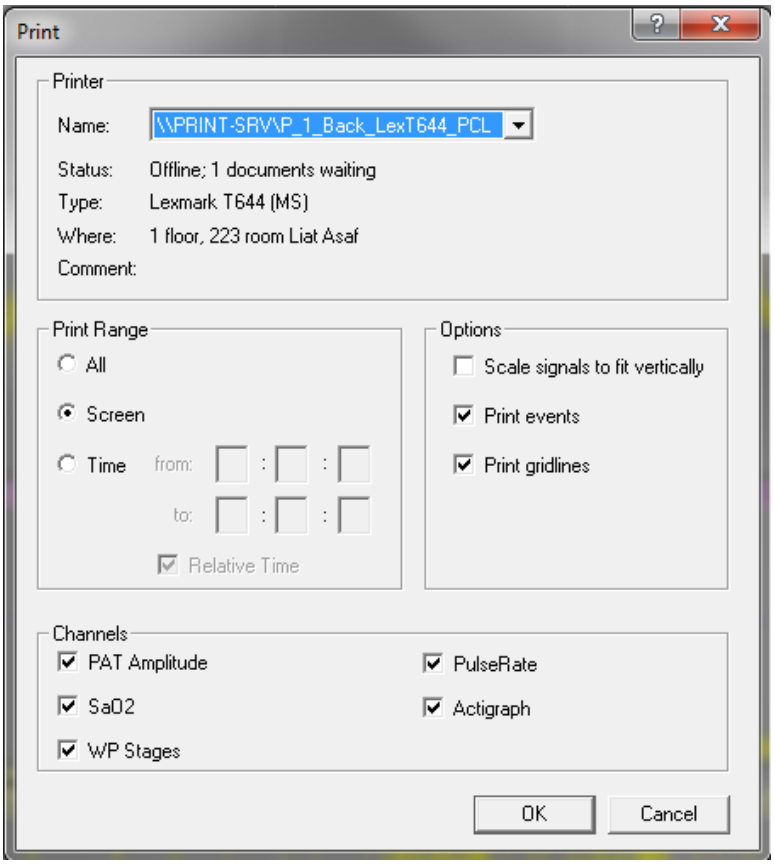


Figure 67 - Print dialog box

5 Exporting Data

5.1 File>Export Data

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

5.2 File>Export Events - Creating *.txt File

This option 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 File>Export Manual Events

This function is used by sleep specialists working with CloudPAT web service. It enables the user to export manually modified events.

5.4 Tools>Export/Delete

See section 6.1.

5.5 Tools>Export General Settings

See section 6.5.

5.6 Transferring a Study to Itamar Medical

This option is 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.

	Note The signals data that is transferred to Itamar does not include any patient information.

	Note 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 E: Manual Sleep data signal transfer**.

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

- Select a study:
  - by displaying it in the 'Signals Display Window'; or
  - by connecting the device

- From zzzPAT click **Help>Pack and Send Study to Itamar Medical...**

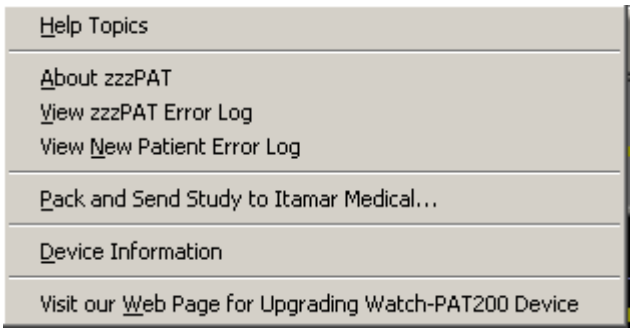


Figure 68 - Launching Transfer Files

The following Dialog Box appears:

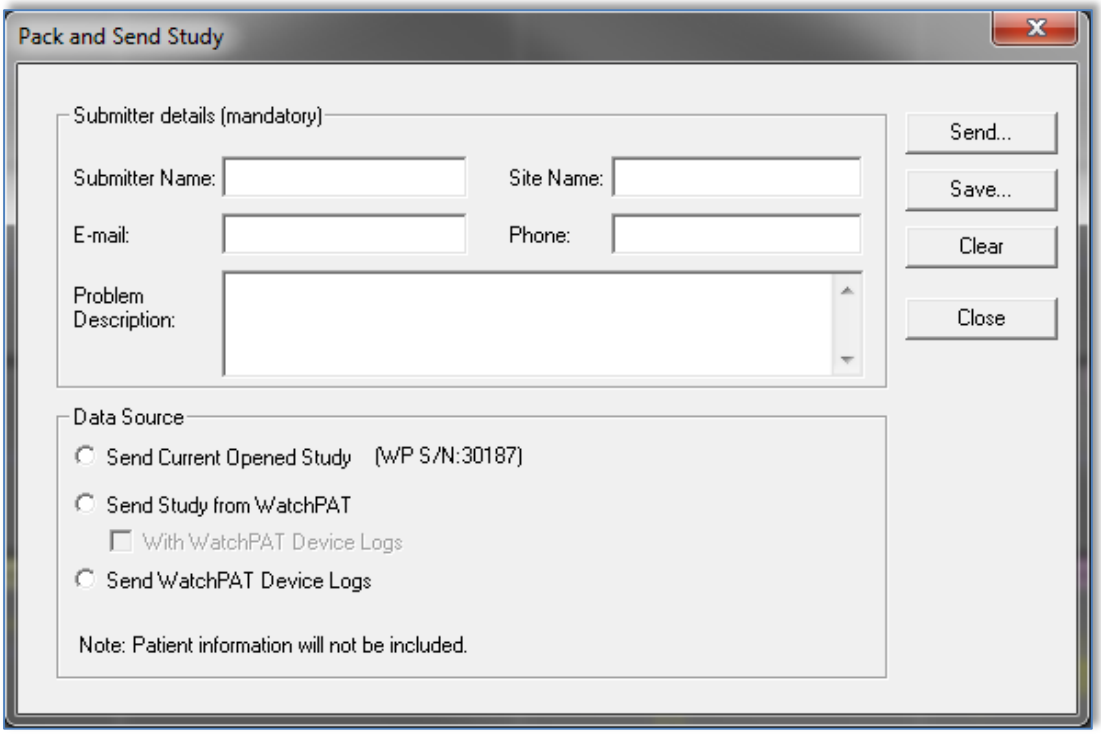


Figure 69 - Prepare and Send Study Dialog Box

- The last entered information is shown by default. Select **Clear** to clear all fields
- 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 WatchPAT** if the case study is stored in the WP200(U).
- Check **Send WatchPAT Device Logs** in case the internal logs from the WP200(U) device needs to be sent to Itamar for troubleshooting.

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

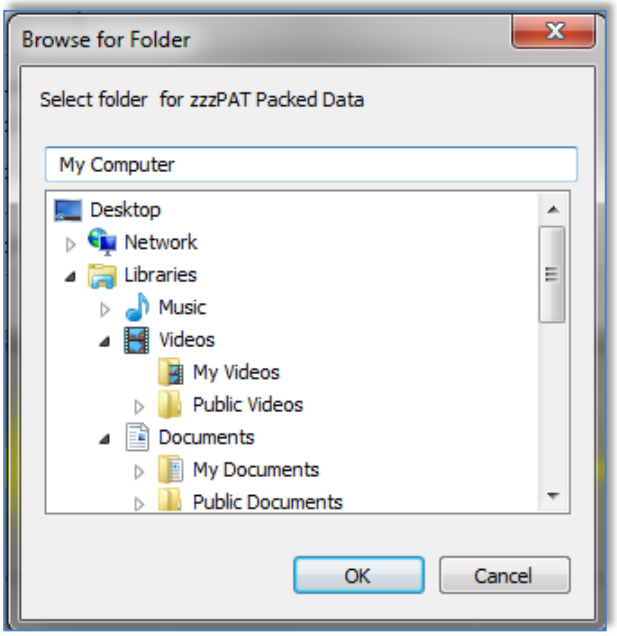


Figure 70 - Saving Case Study

- Select the destination for the saved file. The file will have the following name:
  - zzzPATPack_DT.zzp

  Where
  - D is the current date
  - T is the current time

- **To Send** a study to Itamar automatically
  - Click **Send…**. The following screen appears:

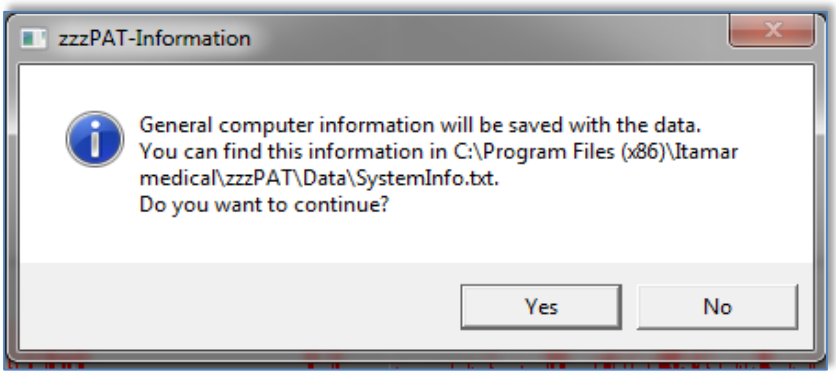


Figure 71 - Sending Study confirmation

- Click YES to continue.

Note

General information about the computer configuration will be included in the transferred file. This information does not contain any patient information.

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

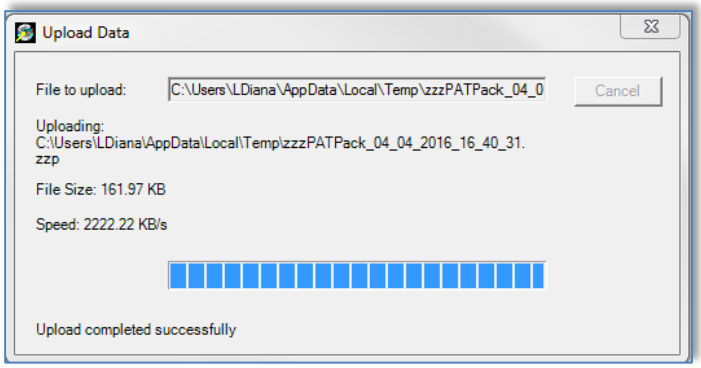


Figure 72 - Data Transfer Progress

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

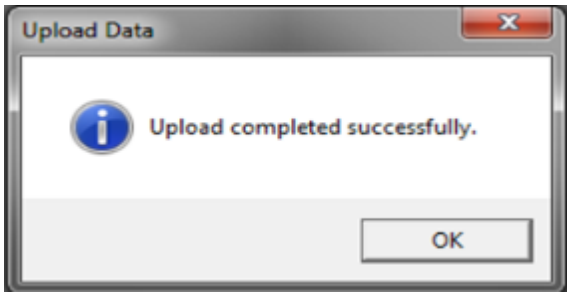


Figure 73 - Data Transfer Successfully Completed

- Click **OK** to continue.

- **To Send** a study 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 5.6
- Copy the saved file to a PC that has Internet access
- Launch your Internet browser
- Upload the file using the Itamar ftp server, see Appendix E: Manual Sleep data signal transfer

5.7 Displaying Watch-PAT200 Device Information

From zzzPAT click **Help>Device Information** in order to display device information.
A dialog box appears with the following information:

- Number of studies made with the connected device (supported for device firmware version >2.2191 or above)
- Probe S/N (supported for device firmware version >2.2191 or above, when using supporting version of PAT probes, having serial number embedded)
- Device S/N

The information can be taken either from the opened study or from the connected WP200 device. The information will be “N/A” in case of not supported firmware versions.

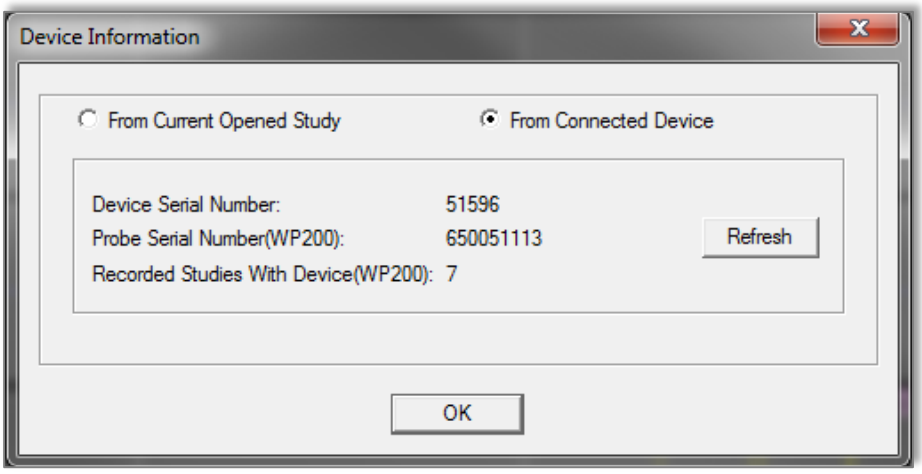


Figure 74 – Device Information Dialog Box

5.8 Upgrading Watch-PAT200 Device firmware

From zzzPAT click **Help>Visit our Web Page for Upgrading Watch-PAT200 Device** in order to open a link to Itamar's web page and download the latest firmware version.

6 Tools

6.1 Tools>Export/Delete

This dialog 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:

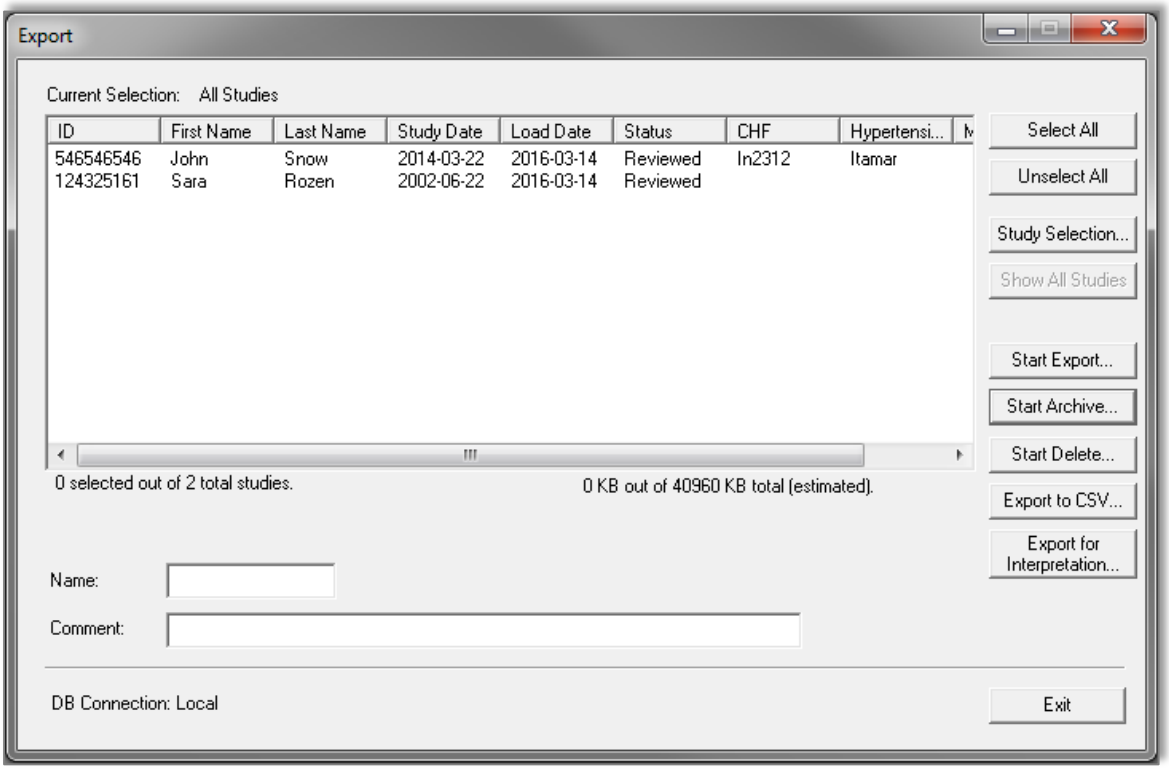


Figure 75 - Export Dialog box

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.

	Note Sleep Statistics values will be empty in CSV export for studies that had not a report issued.

- The **Delete** function has two options, as seen in Figure 76 .
- 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.

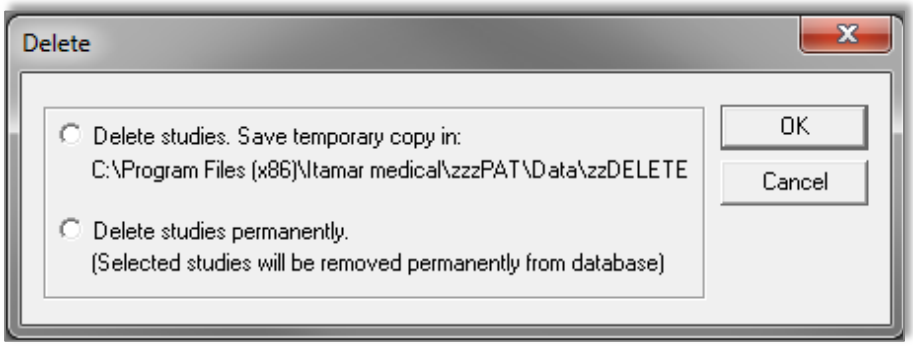


Figure 76 - Delete studies options Dialog box

- 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:

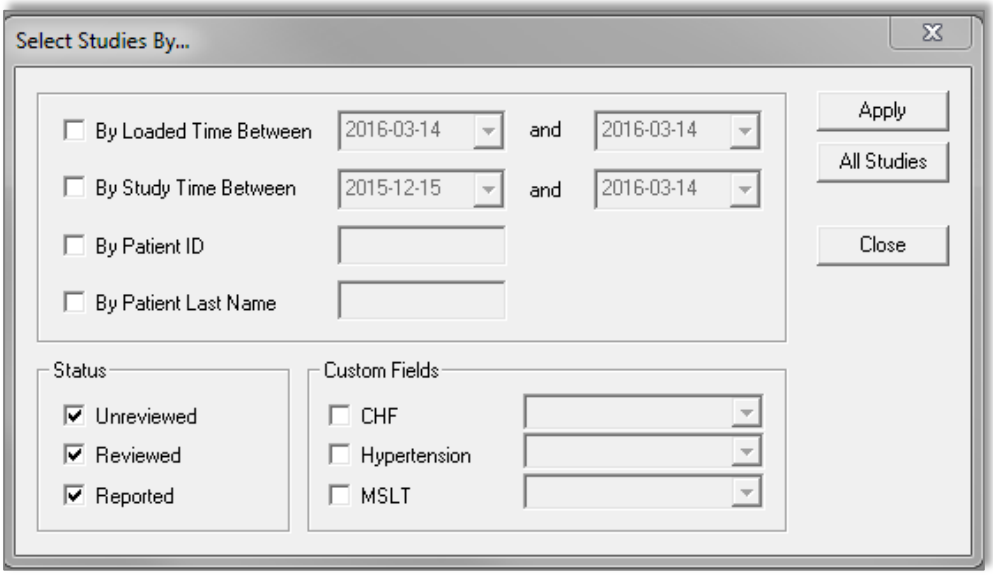


Figure 77 - Study Selection Dialog box

- 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: Un-reviewed, Reviewed and Reported and by user predefined **Custom Fields** (see section 3.3.3). It is possible to select several criteria by which to export a single group of studies.

Note

The **Custom Fields** section will appear in the ‘Select Studies By’ dialog box, only if the user predefined these fields. See section 3.3.3 for details.

- 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.

Note

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 **Basic User Permissions** only (see Section 2.5.2).

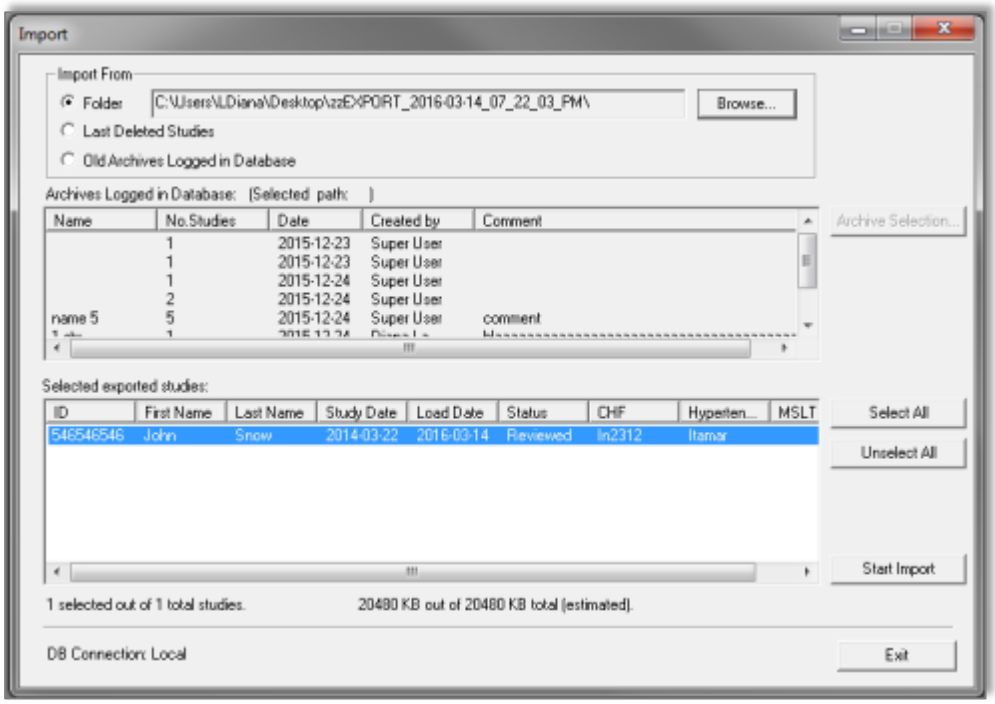


Figure 78 - Import Dialog Box

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.

	Note 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.

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:

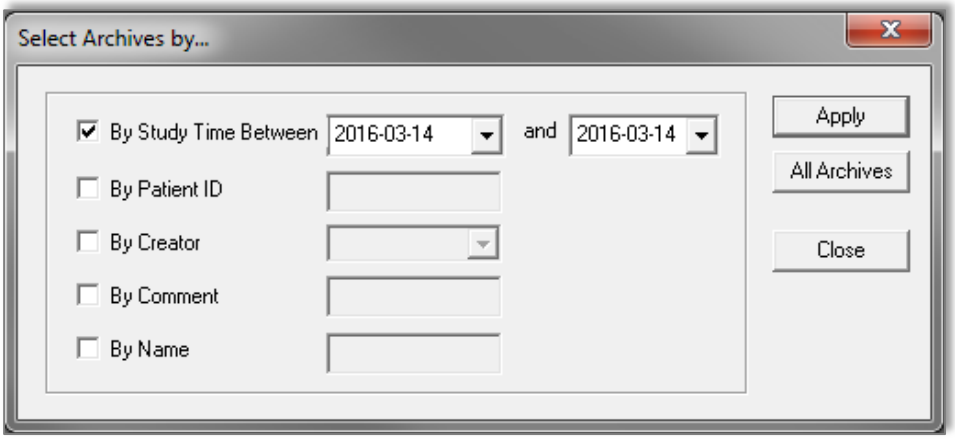


Figure 79 - Select Archive Dialog box

- 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.

	Note You cannot import a study that is already available in the database

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, parallel to the Files folder (default 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.

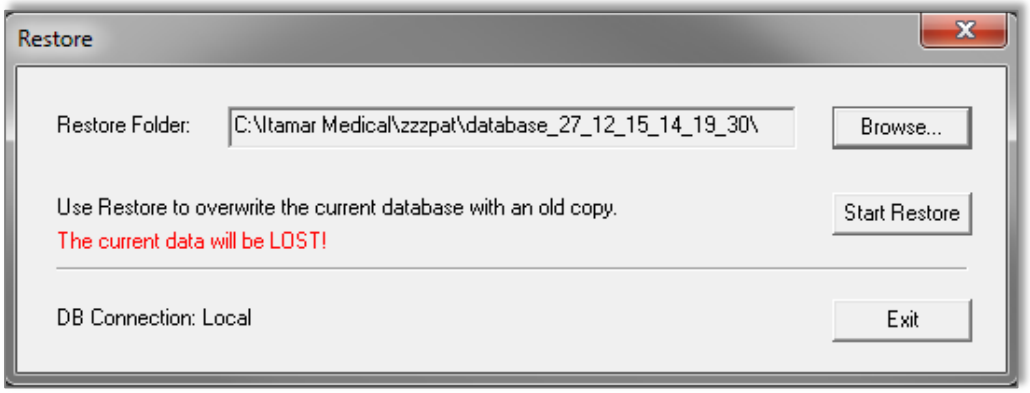


Figure 80 - Restore Dialog box

	Warning Restoring a backed-up database overwrites the current database replacing all the data it contained!!!

6.5 Tools>Move Files to New Location…

Allows user (Administrator) to move all the data files to a new folder and work from now on with the new files folder.

	Note The zzzPAT software uses a Files folder where all raw data and signal data files are kept. Each study needs around 50 MB disk space. The Files folder path used is kept inside the SQL Server database that holds all patient, study and analysis information and can only be modified using this function.

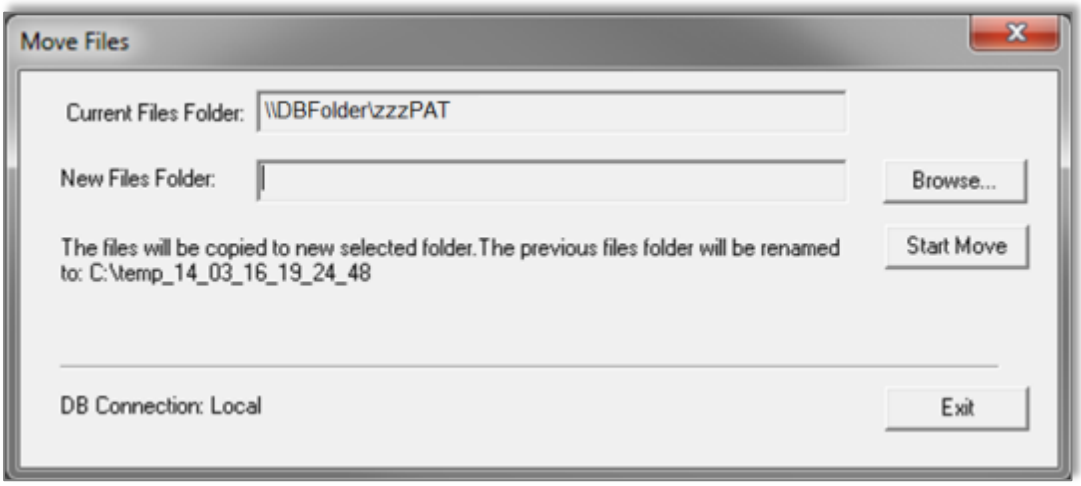


Figure 81 – Move Files dialog box

"Current Files Folder" – Displays the current Files Folder.
"New Files Folder" – Use the Browse button in order to select a new Files folder
"Start Move" – Implements the move (relocating) of all data files to the new Files folder. The previous files folder name is changed to Files_Date_Time (Date-dd_mm_yy Time-hh_mm_ss)

6.6 Tools>Export General Settings

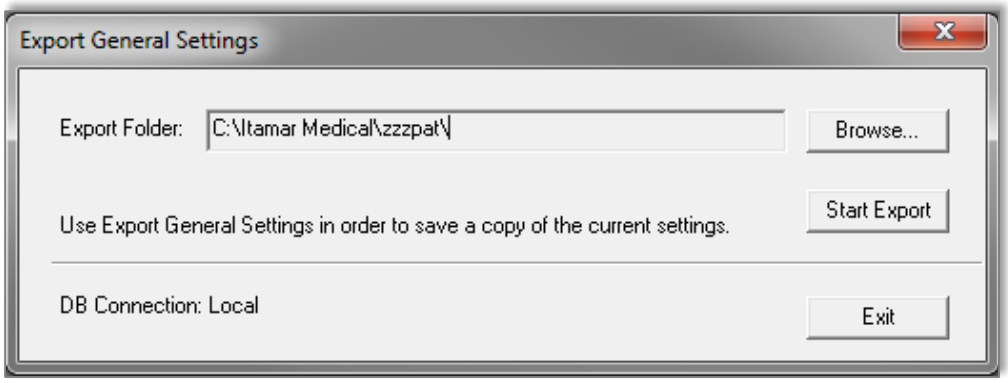


Figure 82 - Export General Settings Dialog Box

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

6.7 Tools>Import General Settings

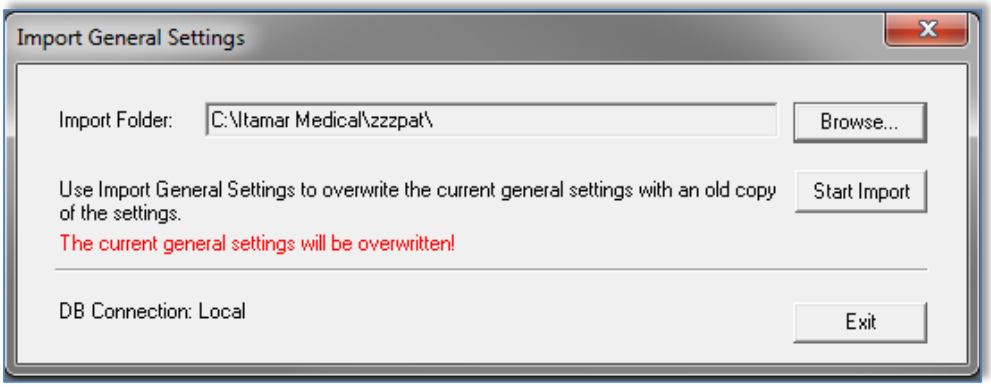


Figure 83 - Import General Settings Dialog Box

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

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

6.8 Tools>User Administration

Please refer to Section 2.5.2

6.9 Tools>Export Activity log

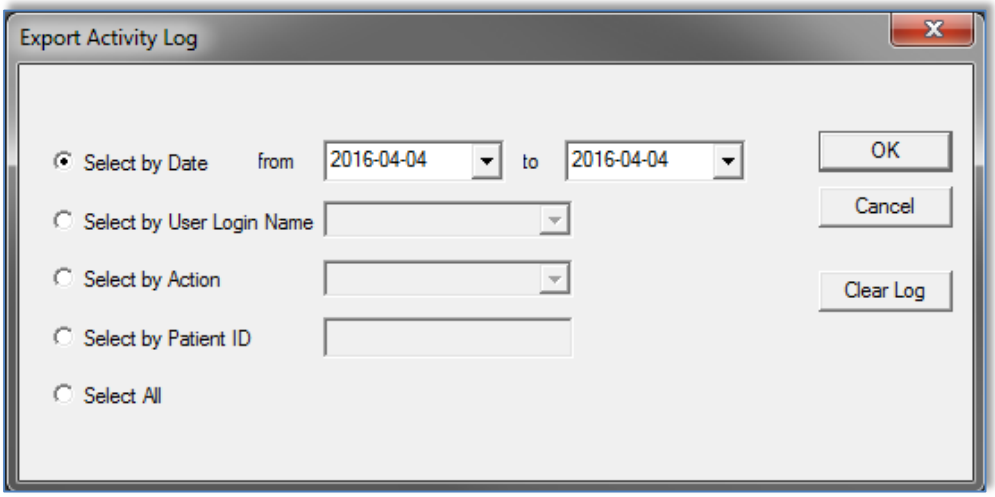


Figure 84 – Export Activity log window

Export Activity log option monitors actions performed by users and that can be exported in csv format based on filters such as: Date, User login Name , Action, Patient ID or All.

Note that only one of such filters can be chosen at a time.
Example: A user with proper permissions can export all the studies that were 'Set as Reported' or he can export all the audit data regarding a specific Patient ID.

	Note In cases when the action is performed on a set of studies (i.e. Export studies) the log keeps general information about actions performed but no information about specific studies. The **Export Activity log** option is available in Administrator mode only.

7 Database Wizard

The zzzPAT Database Wizard application can be opened by double clicking on Dbtool.exe in the BIN folder (under the Installation folder) and it 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 6.8).

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

Figure 85 - Database Wizard Login

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

7.1 Database Tools

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

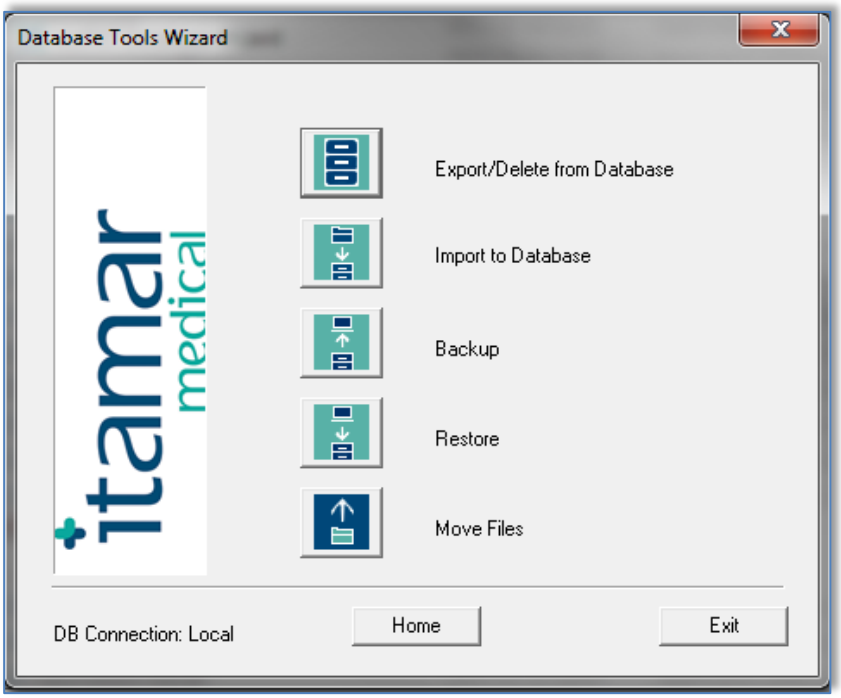


Figure 86 - Database Tools Wizard dialog box

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.

7.1.5 Move Files

- Click on the 'Move Files' icon in the 'Database Wizard Tools' window.
- Refer to Section 6.5 for a detailed explanation of the Move Files procedure.

7.2 User Administration

Please refer to Section **Error! Reference source not found.**.

7.3 Configuration Tools

Used to copy General Settings from one zzzPAT station to another.

Click the configuration tools Icon . The following screen appears:

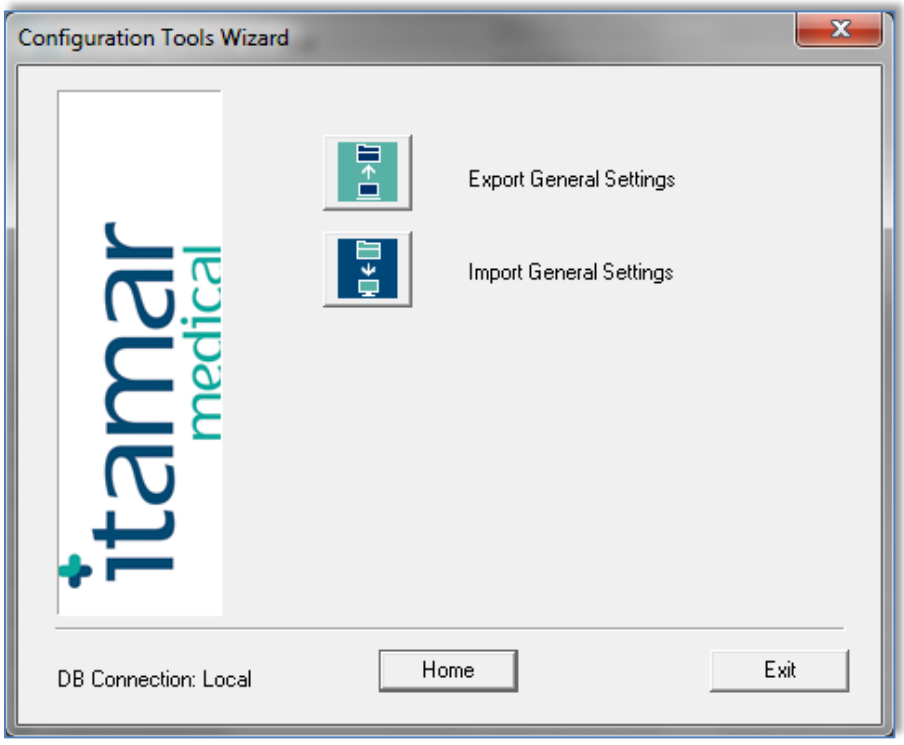


Figure 87 - Configuration Tool Wizard

- 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 6.7 for a detailed explanation of the general settings importing procedure.

8 Troubleshooting

Installation		
Trouble	**Possible Cause**	**Solution**
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.	Use PC with appropriate Operation System.
	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 WatchPAT	USB drive needs to be re-defined.	Select Setup->"Set WatchPAT Drive". Insert WatchPAT device to USB Drive. Click OK. "The system is searching for WatchPAT device" message should appear. At the end, a list containing the WP200 drive should be displayed. Select the WatchPAT drive.and click Ok.
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

zzzPAT		
Trouble	**Possible Cause**	**Solution**
Analyze>Reload Study and Analyze 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 2.5.2)
	Insufficient free space on hard disk	Free enough disk space to exceed the minimum requirement of 100MB and try again
Cannot **Load Study** (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 or REM could not be calculated because of the algorithm restrictions.	Run the analysis by selecting **Analyze>Reload Study and Analyze**
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 invalid	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	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	Microsoft Outlook was not defined as the default mail client.	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 **Analyze>Reload Study and Analyze**
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 **New Study** in zzzPAT the dialog box disappears and zzzPAT is frozen	Inadvertent double clicking the **New Patient** button may cause the dialog box to be hidden in the background	Press **Alt-Tab** 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)
No data of snoring and body position presented	SBP/RESBP sensor was not connected to WP200/U	Make sure to connect SBP to WP200/U. Make sure to connect RESBP to WP200U only
	RESBP sensor was connected to WP200 instead of WP200U	Make sure to connect RESBP to WP200U only
	Embedded SW not compatible	RESBP: Make sure to use embedded SW 3.3228 and above
No data of Resp movement presented	RESBP sensor was not connected to WP200U	Make sure to connect RESBP to WP200U only
Invalid Oximetry reading (oximeter values of 127%)	Signal inadequacy due to Sensor fault / reading during motion / poor pulsatile signal strength	If the invalid oximetry reading is repeated even at rest conditions then change uPAT probe. If still invalid change uPAT cable or contact Itamar Medical customer support.

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)	• Verify to which database zzzPAT is connected (the database connection appears in the zzzPAT status bar) • Exit zzzPAT • Start zzzPAT and select the other database to connect to • Select **File>Open** and search for the desired file
Shared database is not available	Network is disconnected	• 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
Cannot open selected study	Study is in use by another zzzPAT user	• Wait until the other user closes the study and try again

Table 4 - Troubleshooting, Shared Access Mode zzzPAT

Utilities		
Trouble	**Possible Cause**	**Solution**
Preparing for new study failed	WP200(U): The device was disconnected from the USB too soon.	Do not remove the device before Figure 33 dialog box appears
WP200(U) only: New Study or zzzPAT do not recognize the WP200(U)	The volume name has been erased	Format drive with volume name "WP200"
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 2.5.2)
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 2.5.2)
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)
- Oximetry algorithms to calculate saturation level (WP200U only).
- Respiratory events index which includes Apnea Hypopnea and RERA: pRDI (PAT Respiratory Disorders Index).
- Apnea and Hypopnea Index: pAHI (PAT Apnea and Hypopnea Index).
- Central Apnea and Hypopnea Index: pAHIc (PAT Central Apnea and Hypopnea Index).
- Cheyne-Stokes Respiration detection algorithm to calculate %CSR during sleep
- 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 WatchPAT

- 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.

pAHIc and CSR%

pAHIc expresses the number of Central Apnea and Hypopnea events per hour of sleep. These events are classified as central out of all apnea/hypopnea events.

- These events are identified based on the RESBP sensor, snoring, oximetry, PAT waveform and using actigraphy analysis.

%CSR expresses the relative time in which periodic breathing was detected based on RESBP sensor, oximetry, PAT waveform and using actigraphy analysis.

Note: The calculation of pAHIc and %CSR is subject to regulatory approval in the country

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:

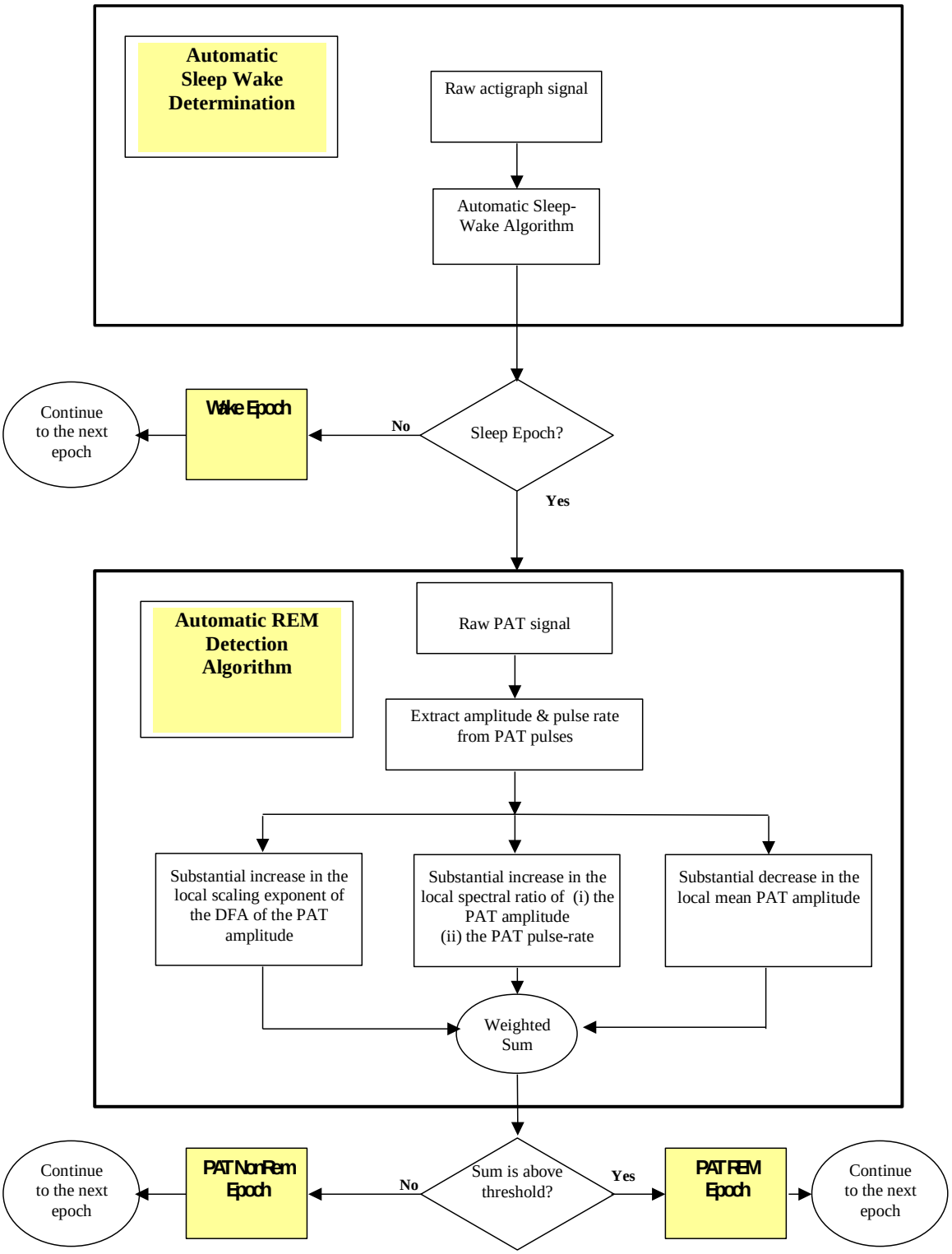
- Mean PAT amplitude time-series
- Scaling-exponent of the amplitude time-series using Detrended Fluctuation Analysis (DFA).
- Ratio of peak low-frequency-band to high-frequency-band in the PAT amplitude time-series spectrum.
- Ratio of peak low-frequency-band to high-frequency-band in the PAT pulse-rate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

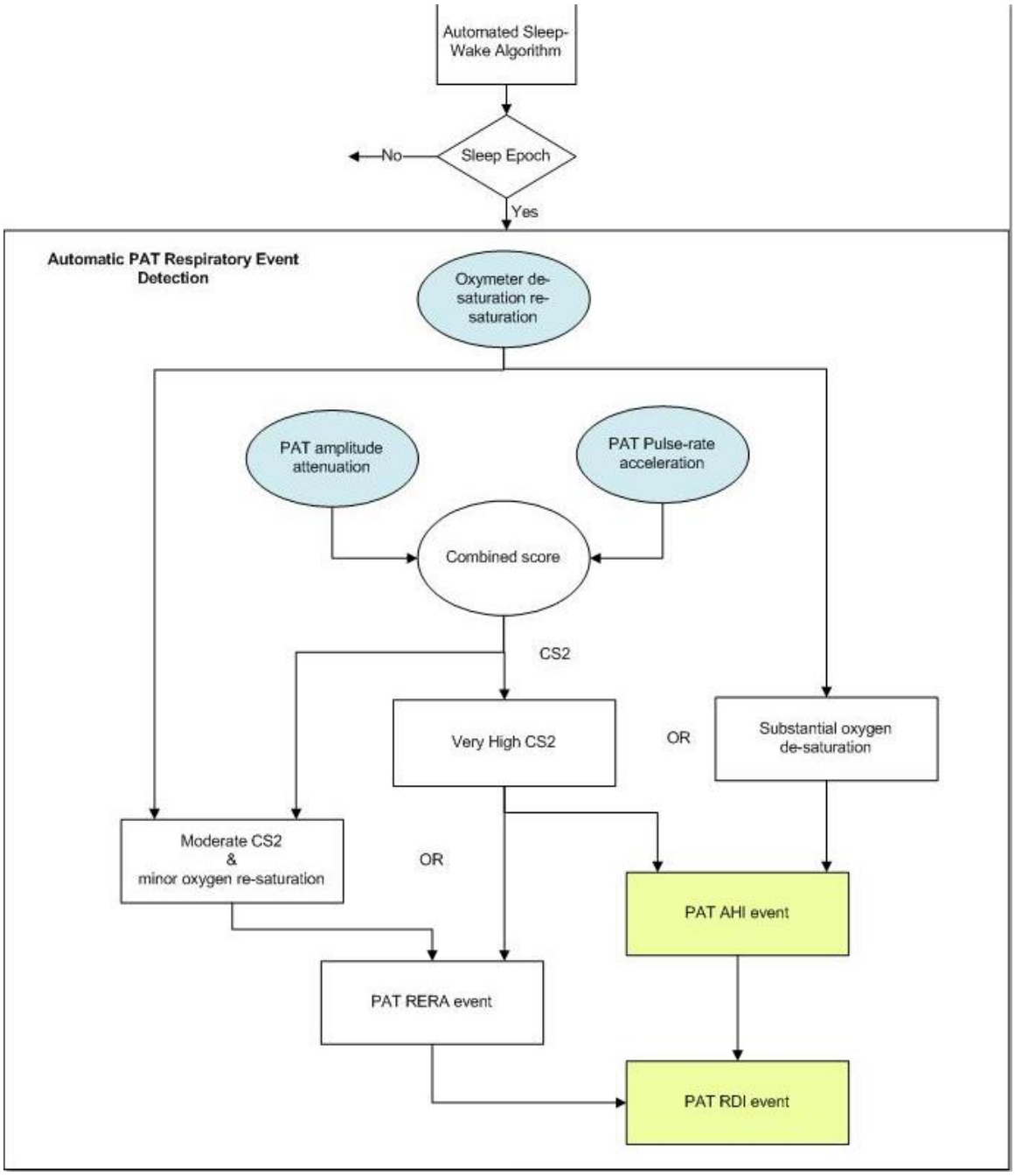
These algorithms were optimized in clinical studies using simultaneous study of Watch-PAT with automated zzzPAT analysis, and in-lab standard polysomnography (PSG) recordings, which were scored manually according to the American Academy of Sleep Medicine (AASM) criteria. This set of sleep studies was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

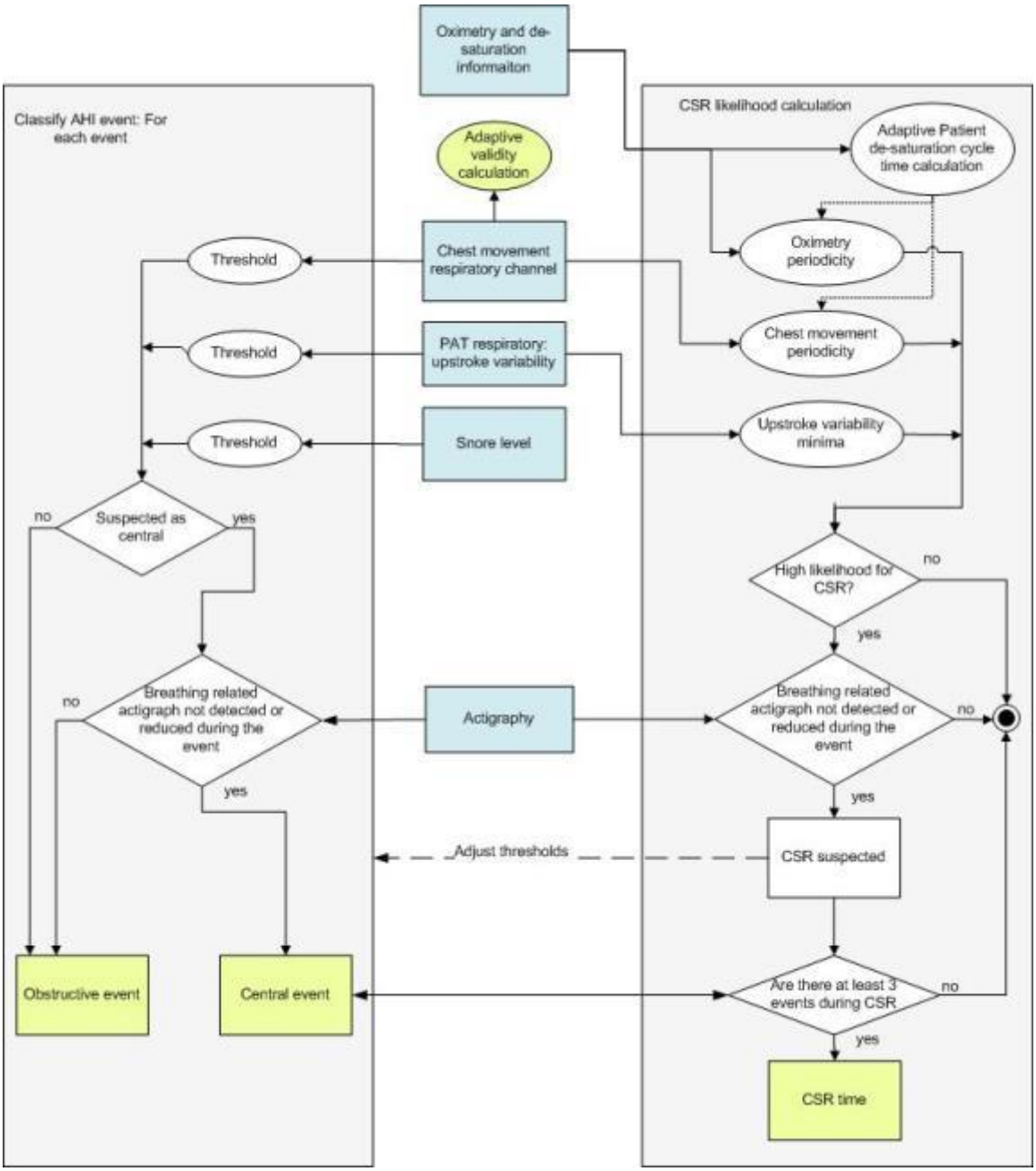
DEEP and Light sleep

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




Automated Sleep-Wake Algorithm
No
Sleep Epoch
Yes
Automatic PAT Respiratory Event Detection
Oxymeter de-saturation re-saturation
PAT amplitude attenuation
PAT Pulse-rate acceleration
Combined score
CS2
Very High CS2
OR
Substantial oxygen de-saturation
Moderate CS2 & minor oxygen re-saturation
OR
PAT AHI event
PAT RERA event
PAT RDI event


Oximetry and de-saturation informaiton
Classify AHI event: For each event
CSR likelihood calculation
Adaptive validity calculation
Adaptive Patient de-saturation cycle time calculation
Chest movement respiratory channel
Oximetry periodicity
Threshold
PAT respiratory: upstroke variability
Chest movement periodicity
Threshold
Snore level
Upstroke variability minima
Threshold
no
Suspected as central
yes
High likelihood for CSR?
no
yes
no
Breathing related actigraph not detected or reduced during the event
Actigraphy
Breathing related actigraph not detected or reduced during the event
no
yes
yes
Adjust thresholds
CSR suspected
Obstructive event
Central event
Are there at least 3 events during CSR
no
yes
CSR time

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
Ctrl+Home – First Event for channel
Ctrl+End – Last Event for channel
Ctrl+R – Sleep Report
Ctrl+I – Sleep Indices

Alt+Plus – 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

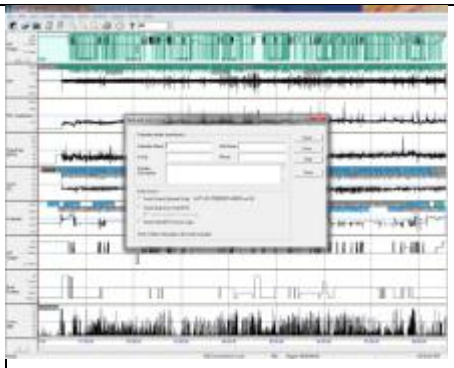
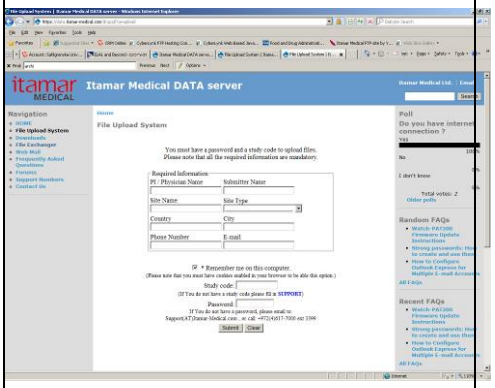
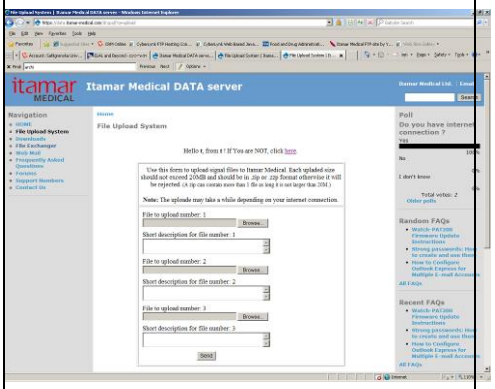
Appendix D: Regulatory representative

Itamar Medical's authorized regulatory representative is:

EC REP	MEDES Ltd.

5 Beaumont Gate, Shenley Hill,
Radlett, Hertfordshire WD7 7AR.
England
Tel: +44 208123 8056
Tel / Fax: +44 1923859810

Appendix E: Manual Sleep data signal transfer

Sending data for evaluation to Itamar	• Open in zzzPAT the study you want to send
	• Select Help → Prepare And Send Study to Itamar Medical…
	• Fill in the required information and select "Send current open study"
	• Select "Save" and save the study in your local drive (Preferable into disk on key or other removable drive)
	• Browse into URL: http://support.itamar-medical.com/upload
	• Fill in the required information
	  ◦ PI / Physician Name
	  ◦ Submitter Name
	  ◦ Site Name
	  ◦ Site Type
	  ◦ Country
	  ◦ City
	  ◦ Phone Number
	  ◦ E-mail
	• Enter study code: *call Itamar for code*
	• Enter password: *call Itamar for password*
	• Press Submit
	• Browse and enter the file you have saved
	• Enter description for file
	• Press Send
	• 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
		
		 
		 

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