zzzPAT
For WatchPAT™

Software Operation Manual

Itamar Medical REF OM2197434

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

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NOTE:

- Latest version of Software Operation Manual is available at:

https://www.itamar-medical.com/support/manuals

- A printed copy will be provided upon request, at no additional cost, within 7 calendar days.

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1 Introduction to the zzzPAT

Note: Throughout this document, the term WatchPAT™ refers to all 3 devices—WatchPAT™ 300, WatchPAT™ ONE, and WatchPAT™ 400 (only where commercially available)—unless specified otherwise.

1.1 Intended Use/Indications for Use of the WatchPAT™ 300, WatchPAT™ ONE, and WatchPAT™ 400

The WatchPAT™ 300, WatchPAT™ ONE, and WatchPAT™ 400 devices are non-invasive home care device for use with patients suspected to have sleep related breathing disorders. The WatchPAT™ 300 WatchPAT™ ONE, and WatchPAT™ 400 are 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 devices 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 device's PSTAGES and snoring level and body position provide supplemental information to its PRDI/PAHI/PAHIc. The device'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: The presentation of pAHIc is subject to regulatory approval in the country.

1.2 The zzzPAT S/W – Definition

The zzzPAT is an analysis software package used with the WatchPAT™ devices to aid in diagnosis of sleep related breathing disorders, detects REM, Light Sleep, Deep Sleep and Wake stages and measure snoring intensity and body position states. The zzzPAT S/W displays the signals recorded by the WatchPAT™ devices, automatically identifies breathing disordered events, sleep stages and snoring and body position data and generates a comprehensive report for the physician.

The analysis software also includes detection of cardiac arrhythmia as additional information to its sleep indices.

1.3 Overview

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

The WatchPAT™ 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 data from oximetry channels integrated into the uPAT probe (WatchPAT™ 300/WatchPAT™ ONE/WatchPAT™ 400)and an actigraph (embedded in the device). Snoring and Body Position signals are generated from the RESBP integrated sensor. 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. 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 WatchPAT™ channels: PAT, Pulse Rate, actigraphy and Oxygen saturation (recorded in WatchPAT™ 300/WatchPAT™ ONE/WatchPAT™ 400) for the detection of sleep related breathing disorders and sleep staging (Rapid Eye Movement (REM), Light Sleep, Deep Sleep and Wake). In WatchPAT™ 300, WatchPAT™ ONE, and WatchPAT™ 400 using the RESBP's respiratory movement channel in addition to the other WatchPAT™ channels, allows further identification of central apnea.

The zzzPAT uses WatchPAT™'s snoring and body position channels to generate snoring level and body position discrete states. 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.

The analysis software also includes detection of cardiac arrhythmia (i.e., Atrial Fibrillation, Premature Beats) as additional information to its sleep indices.

Note

The WatchPAT™ 300, WatchPAT™ ONE, and WatchPAT™ 400 are not intended to be used as a diagnostic device for any cardiac arrhythmia and are not intended to replace traditional methods of diagnosis of cardiac arrhythmia. The arrhythmia output flags patients suspected of having arrhythmias, thereby aiding the physician in deciding if further arrhythmia investigation is needed.

- A suspected arrhythmia flagging in the sleep report does not necessarily imply an arrhythmia condition is present but rather suggests that further investigation should be considered.
- The absence of arrhythmia flagging in the sleep report does not rule out any arrhythmia.
- In some patients, in particular those with a high density of premature beats or AFib, the device may under-detect arrhythmic events (both premature beats and AFib) and/or misclassify between premature beats and AFib.

Note: The arrhythmia feature is available only in territories approved for.

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

Restrictions

The tracings and calculations provided by the WatchPAT™ 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 WatchPAT™ device. The software displays and stores the recorded signals, and provides a set of analytical functions for interpretation purposes.

In WatchPAT™ 300 a USB cable is used in order to read the data recorded by the WatchPAT™ on the internal memory card. The zzzPAT S/W automatically detects the data on the internal memory card once the WatchPAT™ is connected to the PC via the USB communication cable.

In WatchPAT™ ONE and WatchPAT™ 400, an Internet connection is used in order to read the data recorded by the WatchPAT™ ONE/WatchPAT™ 400. The zzzPAT S/W automatically opens a list with all registered patients that the study was not yet retrieved from the web server.

Please refer to Section 2.3 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.

Warning

The WatchPAT™ device is a PC operated device. It is recommended to use antivirus software to protect your system and files and use adequate user access controls.

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

2.2 Network Communication and Interfaces

This section explains the network ports and interfaces the application uses to communicate and exchange data:

2.2.1 Health Level 7 (HL7) Interface

Functionality: Used for sending and receiving standardized healthcare data in HL7 format between the application and other healthcare systems.
Direction: Incoming and outgoing
Note: The HL7 interface ensures seamless integration with Electronic Health Records (EHR) and other clinical systems.

2.2.2 HTTPS Port 443

Functionality: Provides secure communication over the internet between the application and external systems or cloud services via HTTPS.
Direction: Outgoing
Note: Data exchanged over port 443 is encrypted to ensure data confidentiality and integrity.

2.2.3 SQL Database Ports (3306/1433)

Functionality: Port 3306 is used for MySQL database connections, and port 1433 is used for Microsoft SQL Server connections, enabling the application to retrieve and store data in external databases.
Direction: Incoming and outgoing
Note: These ports facilitate database queries and data exchange necessary for the operation and data management of the application.

2.2.4 USB Interface (for WP300 only)

Functionality: Allows the application to connect to external devices such as USB storage or medical peripherals for data transfer.
Direction: Incoming and outgoing
Note: USB ports may be used for transferring data to/from external devices or loading necessary configuration files. It is recommended to only connect trusted devices to maintain security.

2.2.5 General Internet Connectivity

Functionality: The application requires an active Internet connection for downloading updates, transmitting data via HTTPS, and communicating with remote servers.
Direction: Outgoing
Note: An Internet connection is necessary for secure data transmission and software updates. Ensure the clinic's firewall permits the required ports and protocols (e.g., HTTPS, SQL) for proper functionality.

	**Notes** All unused ports are disabled to prevent unauthorized access. It is important to secure the PC in compliance with the clinic's IT policies to ensure data privacy. Software Bill of Materials (SBOM) for zzzPAT is continuously maintained and reviewed by Itamar Medical. Latest version of the SBOM in a machine readable format is available upon request by contacting Itamar Support. Network and personal PC security are the clinic's responsibility.

2.3 Hardware Requirements

2.3.1 Hardware configuration

Intel Core i5 or above
1 available USB port (WatchPAT™ 300)
Minimum screen resolution: 1024 x 768 pixels
4GB RAM or higher (recommended 16GB)
Access to the local Network (WatchPAT™ ONE/WatchPAT™ 400)

2.3.2 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).

2.4 Software Requirements

2.4.1 Operating System supported

Windows 10
Windows 11

2.4.2 MS SQL Server supported

MS SQL Express 2022 (default)
MS SQL Server 2008 Standard/Enterprise (existing installation)
MS SQL Server 2012 Standard/Enterprise (existing installation)
MS SQL Server 2016 Standard/Enterprise (existing installation)

2.4.3 Microsoft .NET Framework required

Microsoft .NET Framework 2
Microsoft .NET Framework 4

2.4.4 Hotfixes required

Hotfix KB2999226 (Universal CRT) must be installed before the installation can be begin.

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

2.5 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.

2.5.1 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.

2.5.2 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 2.5.

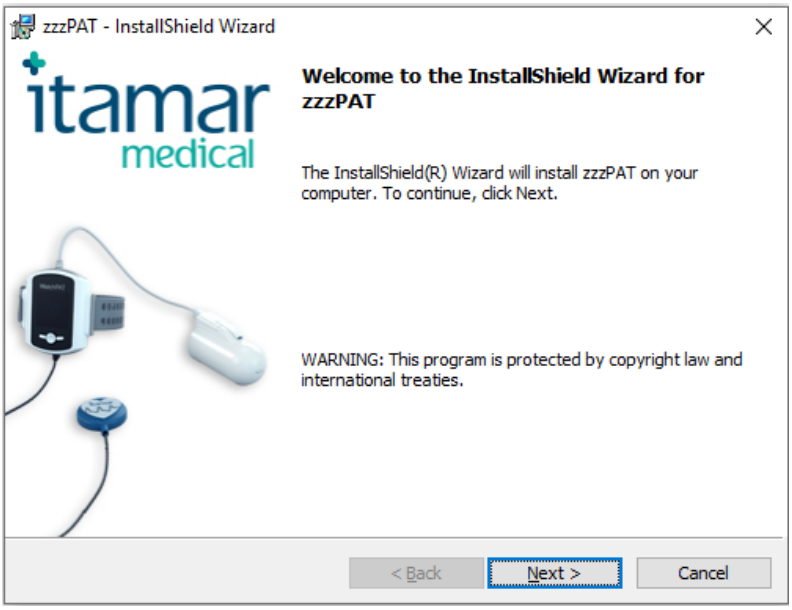


Figure 1 – zzzPAT installation dialog box

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.

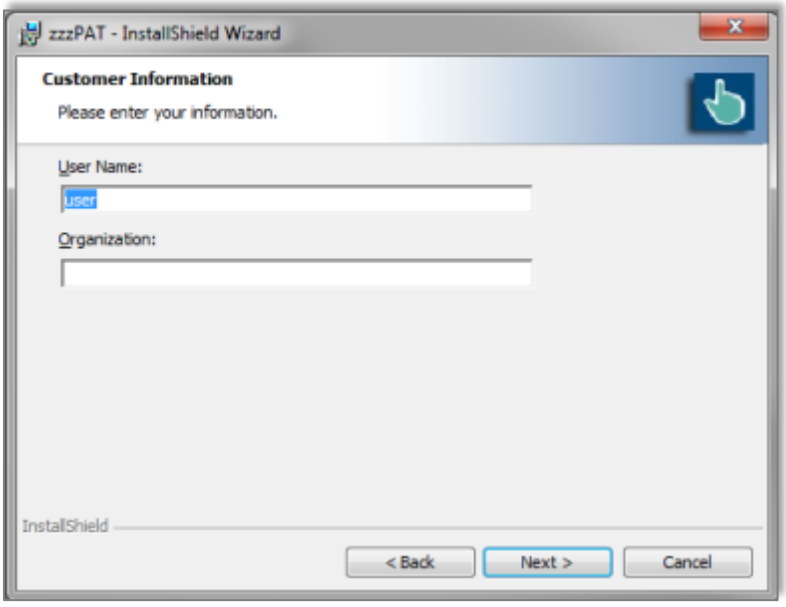


Figure 3 – Customer Information dialog box

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

Figure 4 – Database Properties dialog box

2.5.3 Installations types

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

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

2.5.3.1 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.

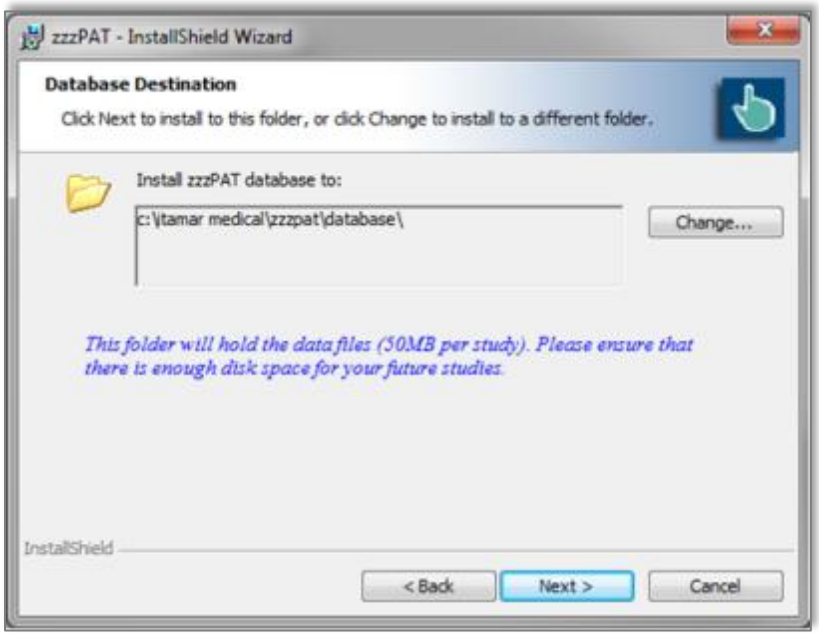


Figure 5 – Database Destination dialog box

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

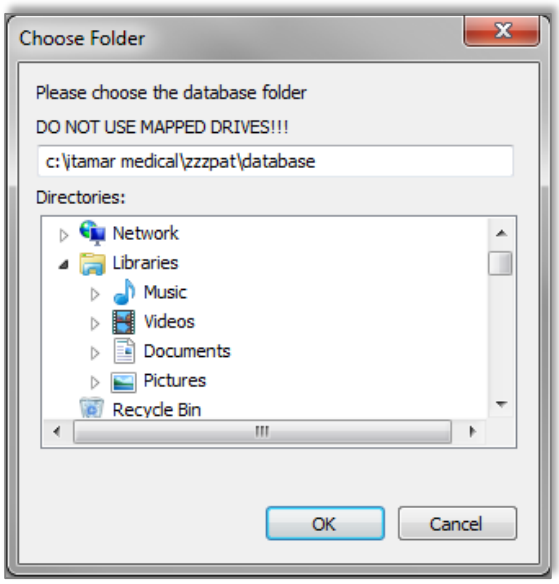


Figure 6 – Choose folder dialog box

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.

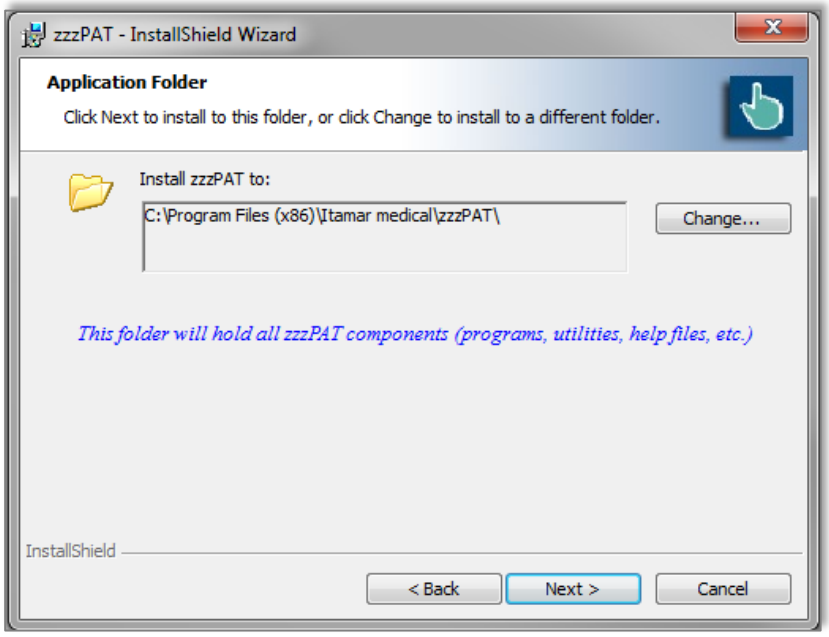


Figure 7 – Application folder dialog box

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

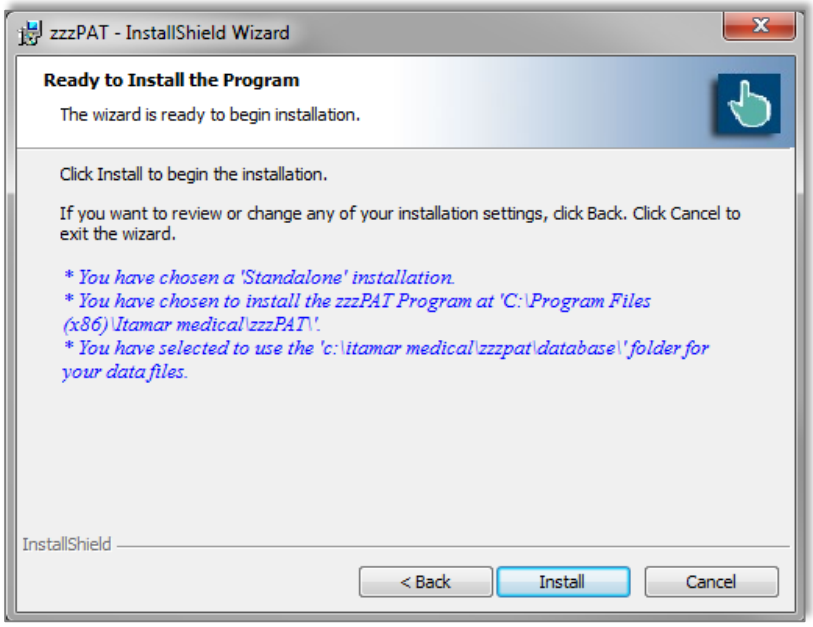


Figure 8 – Ready to Install dialog box

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 2.6.

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).

2.5.4 Upgrading from previous versions

2.5.4.1 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.

2.5.4.2 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 2.5.2.

2.5.4.3 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 2.5.2.

2.6 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.

	**Note** How to respond when detecting the cybersecurity risk: If an accident related to cybersecurity has occurred, contact Itamar Medical support and wait until administrator take steps.

2.6.1 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 opens – Figure 9 for **dbtools.exe** Figure 10 – User Administration dialog box or **Tools>User Administration**.

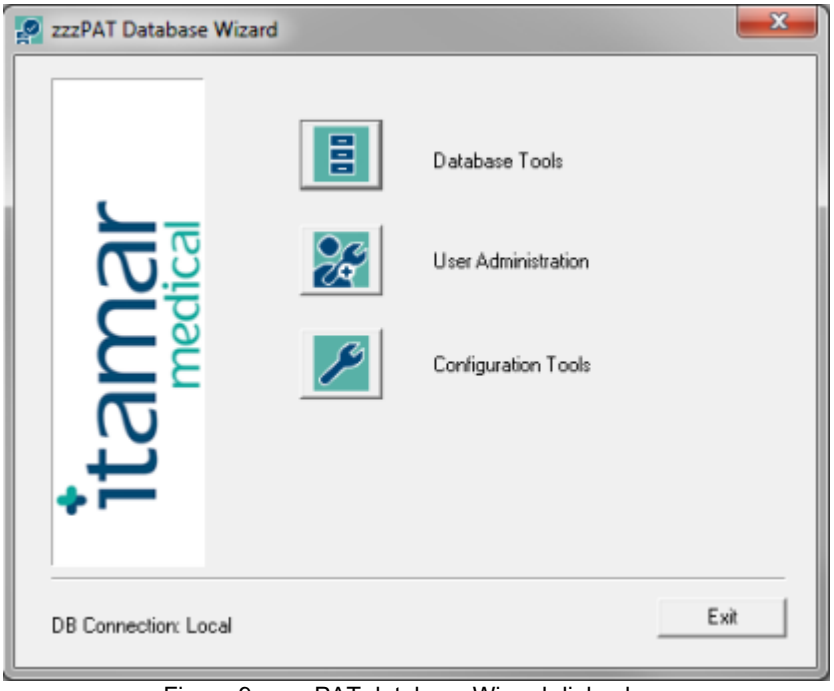


Figure 9 – zzzPAT database Wizard dialog box

- Click 'User Administration' icon  . The 'User Administration' dialog box opens.
- 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.

2.6.2 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 opens:

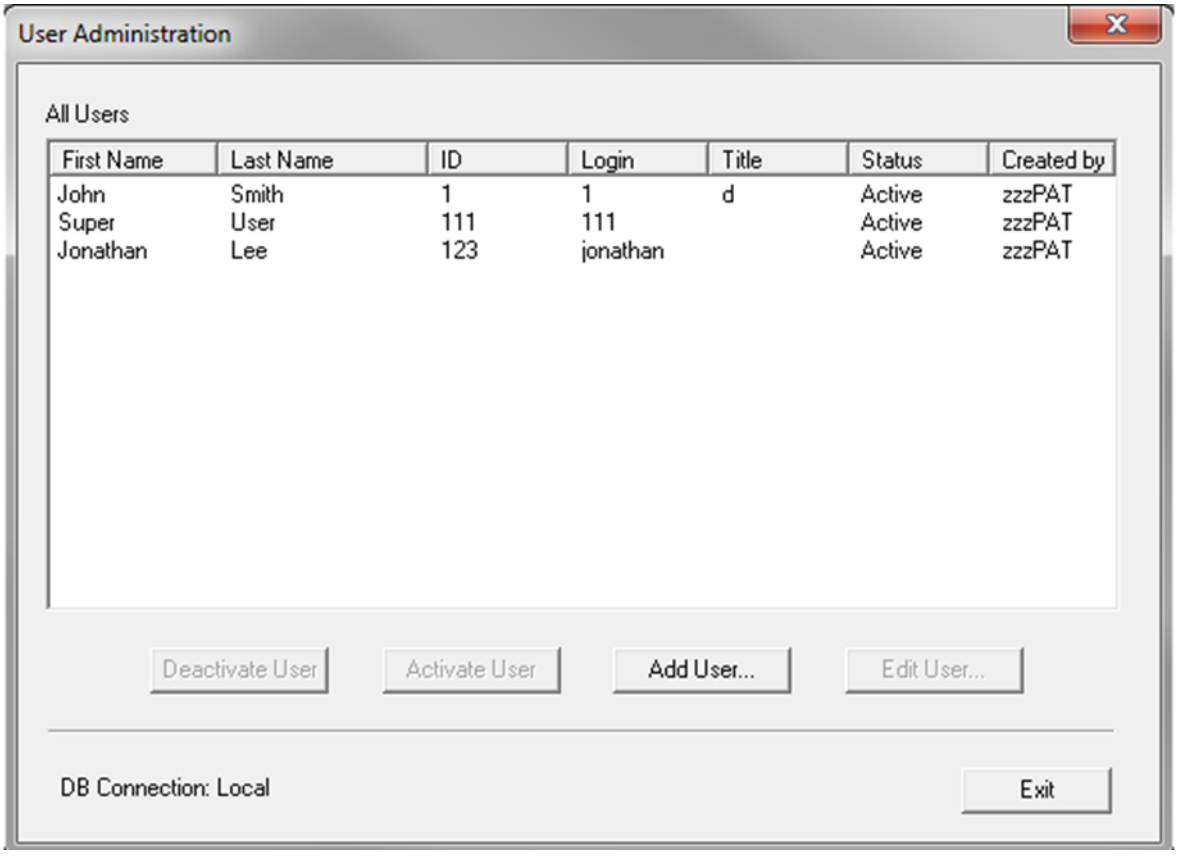


Figure 10 – User Administration dialog box

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 opens:

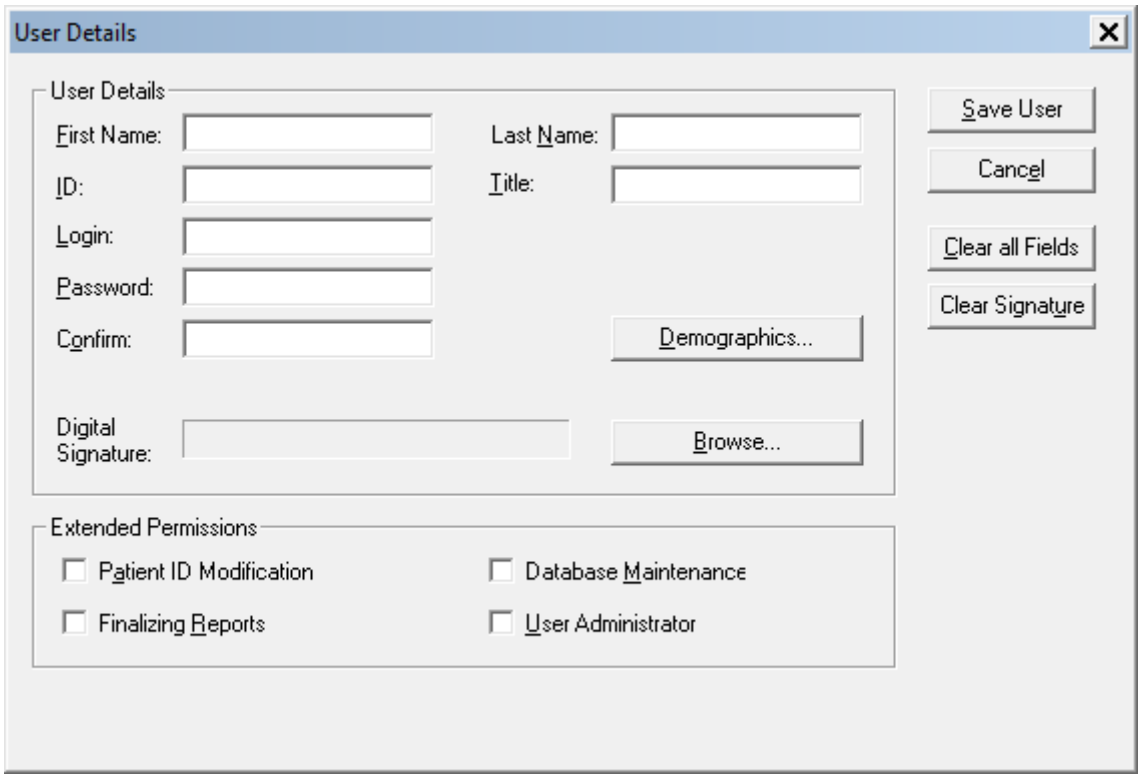


Figure 11 – User Details dialog box

- **User Details:** Fill all user details fields. **Demographics** information is optional.
- **Set Digital Signature** file to be saved in the report (when report is set as reported). Use the Browse button in order to select signature image file (jpg or png).
- **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) • Customizing capabilities for the General Settings
User Administrator	Basic User plus: • Adding users to zzzPAT and defining their permissions

Table 1 – User Permissions

2.6.3 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.

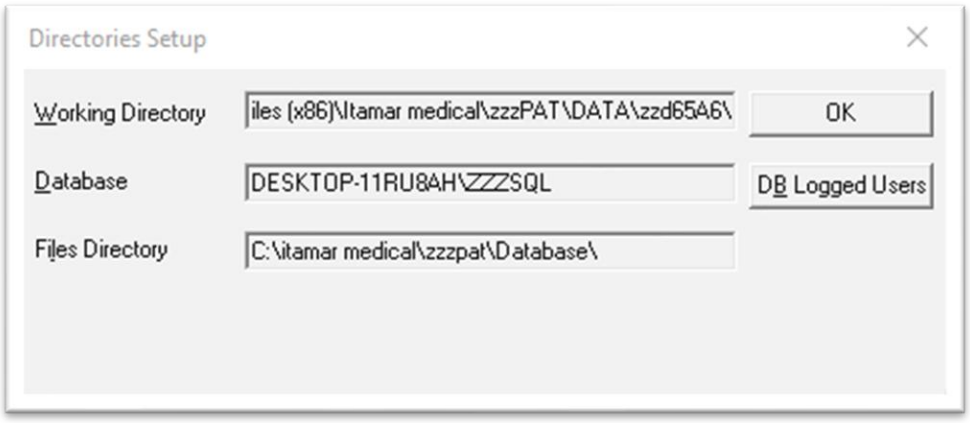


Figure 12 – Set Directories dialog box

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 opens**:**

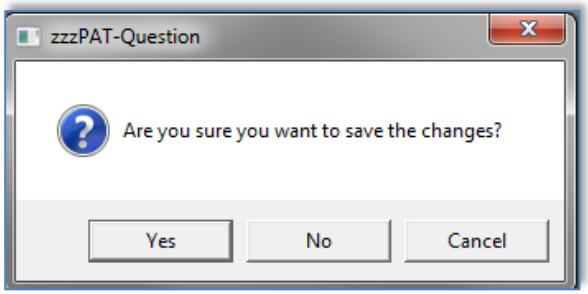


Figure 13 – Save settings for curent user question

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>Manage Montage

A montage defines which channels will be presented on the zzzPAT screen, in what order and size, which channel is displayed in "All Night" window and other parameters.
A number of montages may be defined and used according to the specific needs. The selection of the current montage can be easily done through the main screen's toolbar (see 4.3).

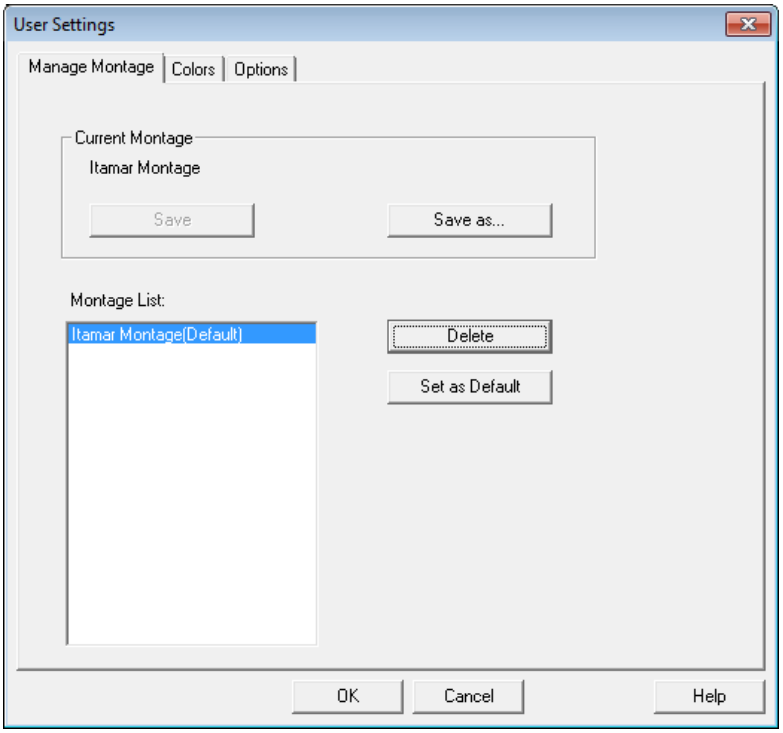


Figure 14 – Manage Montage of zzzPAT display

To Save the current montage:

- Click the “Save” option.

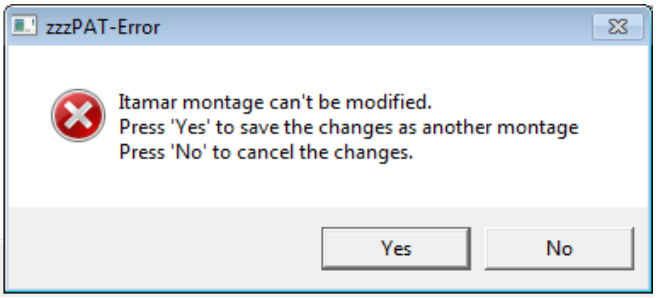
	**Note** If there were changes in the current montage and the user switches to a new montage the system will automatically ask the user if he wants to save the current montage

To create new montage:

- Click on “Save as…” to give a name to the new montage. The current montage will be saved to a new montage and can be edited (see 4.3.1 and 4.4).

To delete a montage:

- Select the montage and click on “Delete”.

	**Note** The Itamar montage cannot be modified or deleted. If you make a change and try to save it the following dialog opens:  If you press YES the montage will be saved as a new montage.

To set a montage as the default montage:

- Select the montage and click on “Set as Default”. This montage will be used from now on when zzzPAT is opened.

3.2.2 Setup>User Settings>Colors

Colors Setup page (Figure 15) 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.

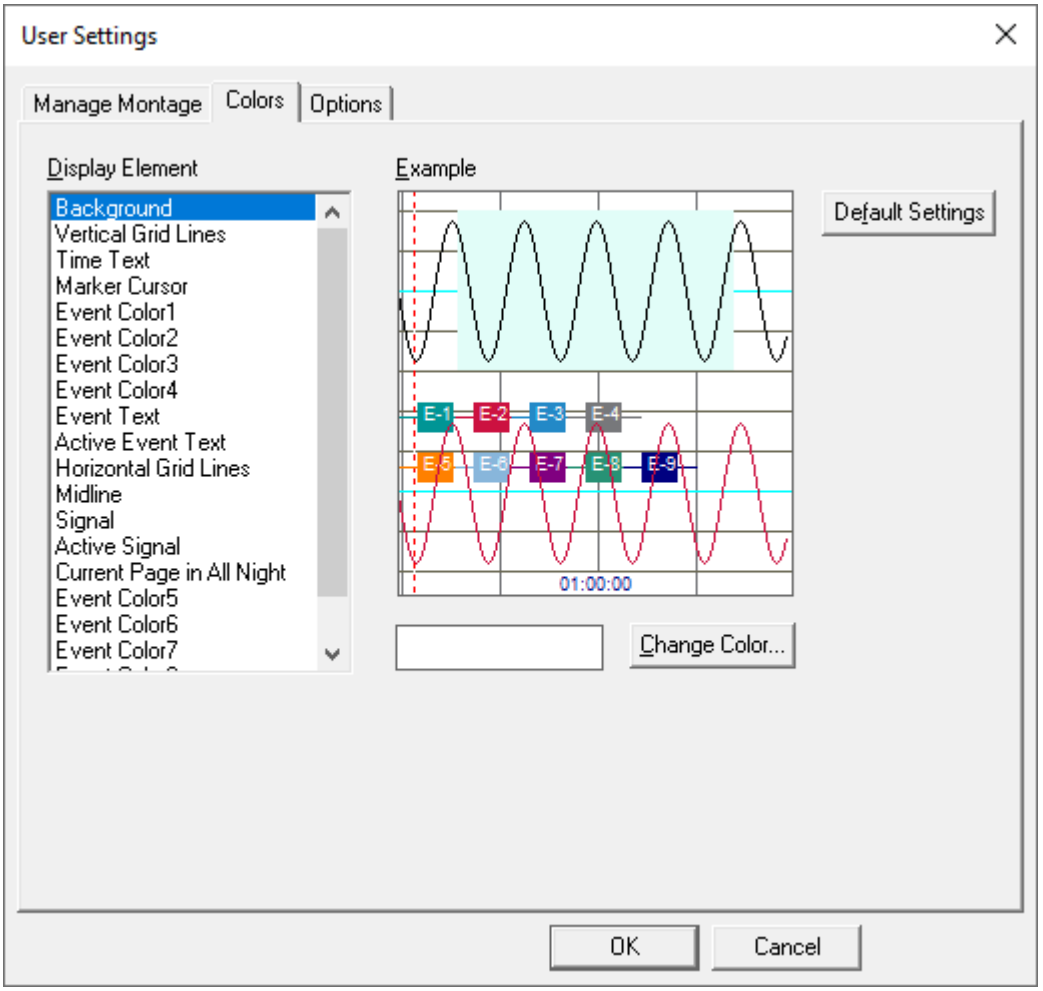


Figure 15 – Setting colors of zzzPAT display

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

3.2.3 Setup>User Settings>Options

Open report - defines if and when the 'Sleep Report' or 'Sleep Indices' report is displayed automatically.

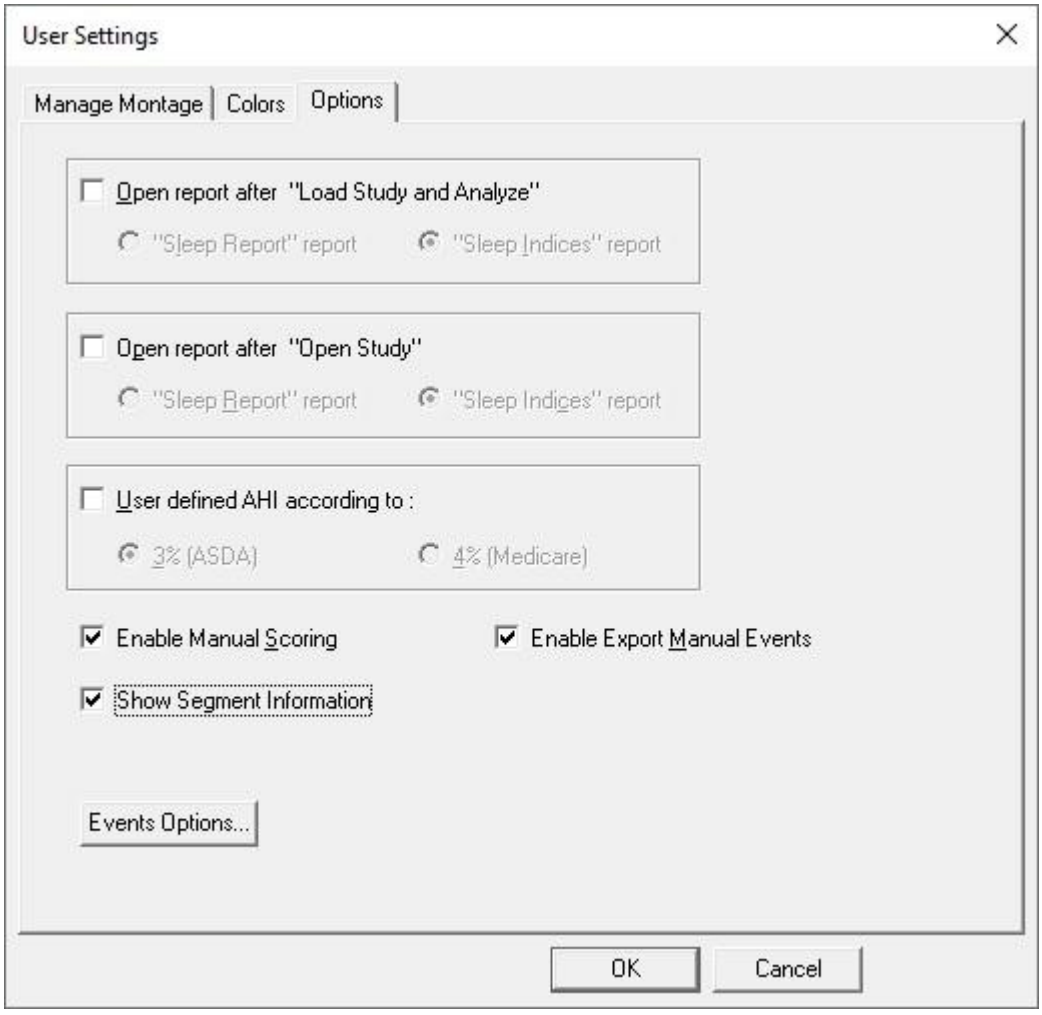


Figure 16 – Setting "Options"

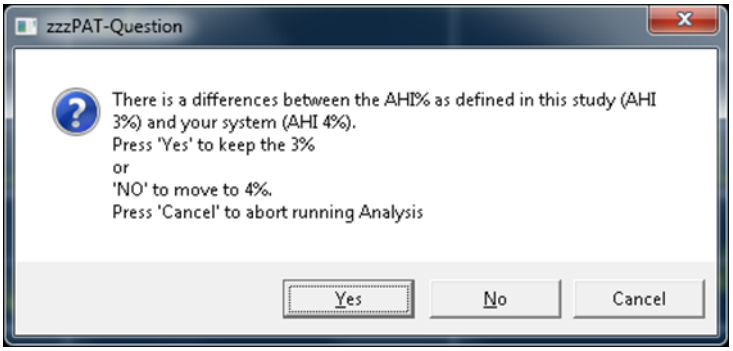
You can select to **open a report** either after "Load Study and Analyze" by selecting 'Open report after "Load Study and Analyze"' or/and for existing study by selecting 'Open report after "Open Study"'. Both options contain radio-buttons that enable you to select between Sleep Report and Sleep Indices 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 **AASM or Medicare** protocol for calculating pAHI and pRDI indices on a user level, see 3.3.6.

Note

If the study was saved with a different option that the currently used one (AASM or Medicare), you will get a message when re-analyzing the study.



You can then select to change the option by which the indices will be calculated.

You can select "**Enable Manual Scoring**" if you want to be able to edit manually the events and sleep stages (see 4.5.8).

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).

You can select "**Show Segment Information**" if you want to automatically see the information of the selected segment's active signal, i.e. begin, end and duration of segment as well as maximum and minimum values when relevant (see Figure 17 – Showing Segment Information).

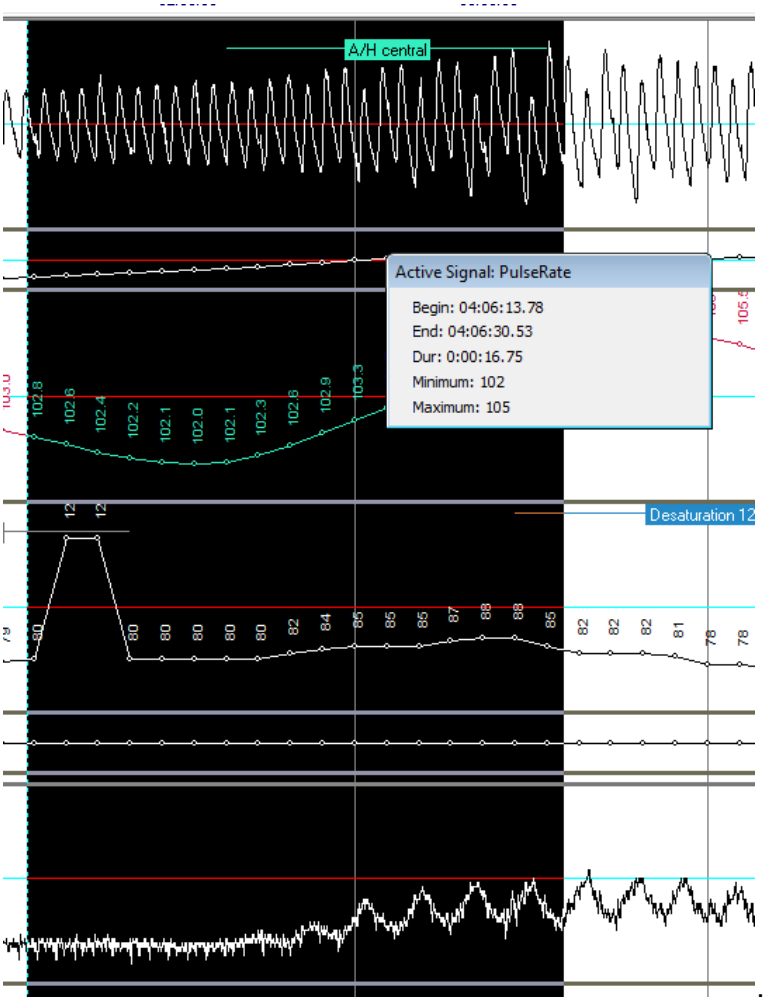


Figure 17 – Showing Segment Information

Clicking the "**Events Options**" button opens the “Events Options” window. In this window you can select which event types will cause the timeline to move to and highlight the next event of the same type which was deleted (see section 4.5.4: Deleting an Event or Changing its Type).

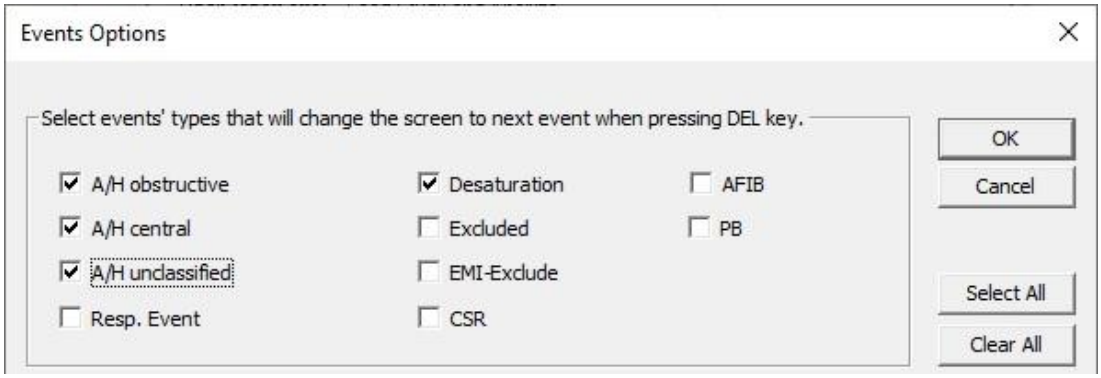


Figure 18 – Event Options Window

	**Note** Some of the event types in the Events Options window will already be checked by default.

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.

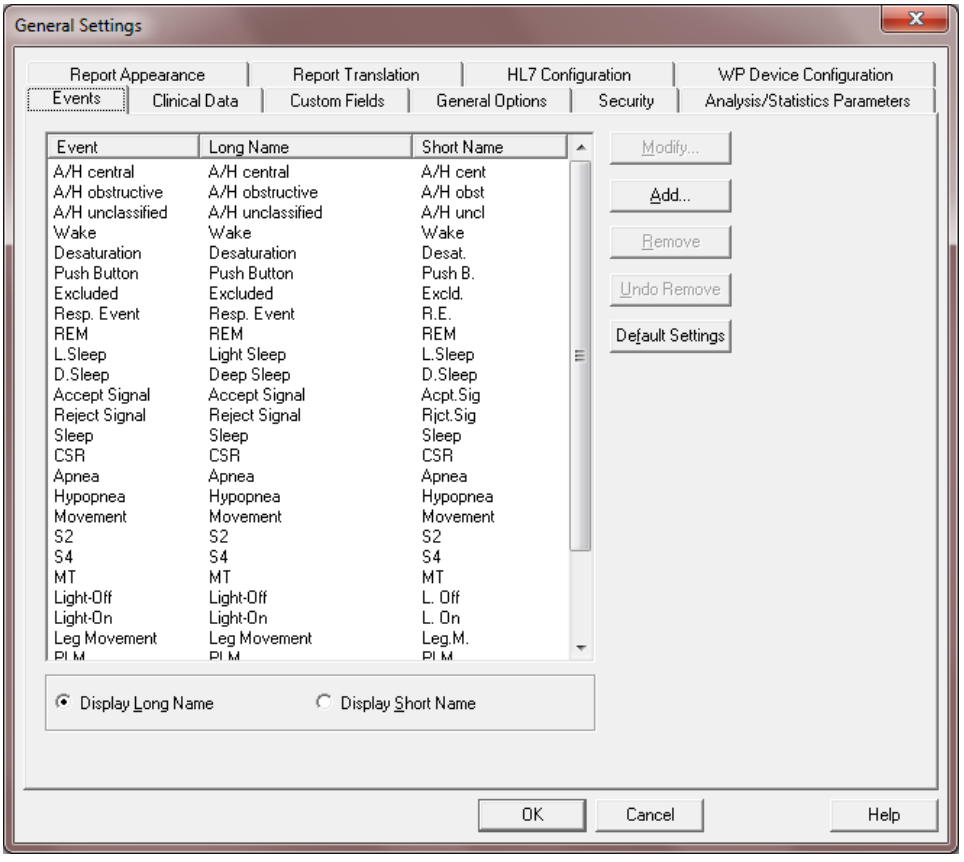


Figure 19 – General Settings Setting Dialog Box – Events Tab

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

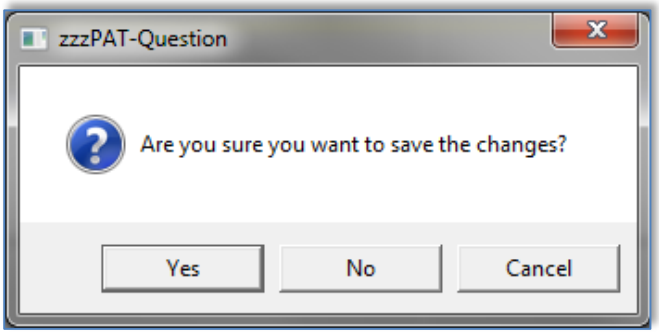


Figure 20 – Save Settings for curent user question

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 19). 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 21).

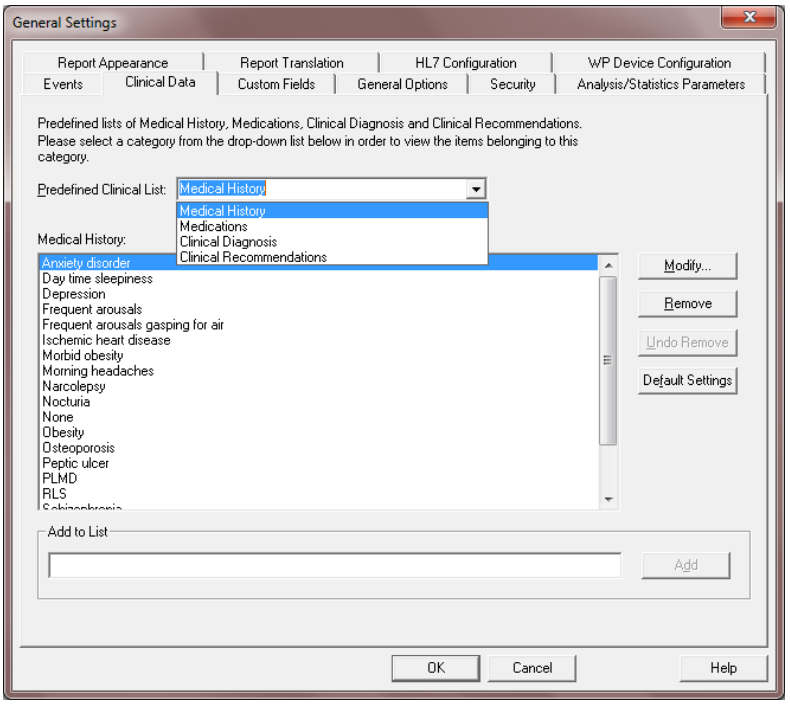


Figure 21 – General Settings Dialog Box – Clinical Data

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

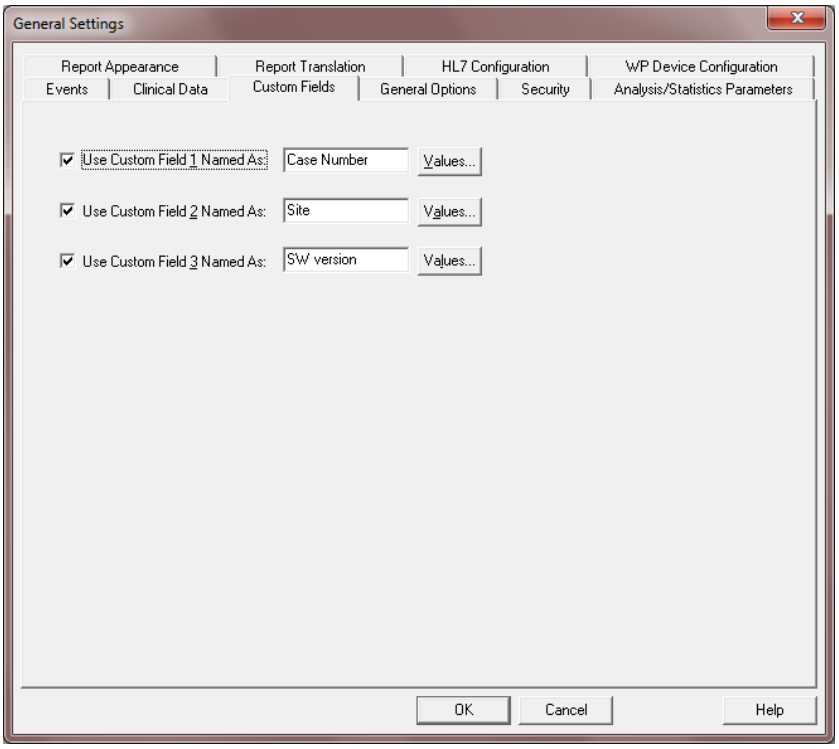


Figure 22 – General Settings Dialog Box – Custom Fields Tab

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 opens:

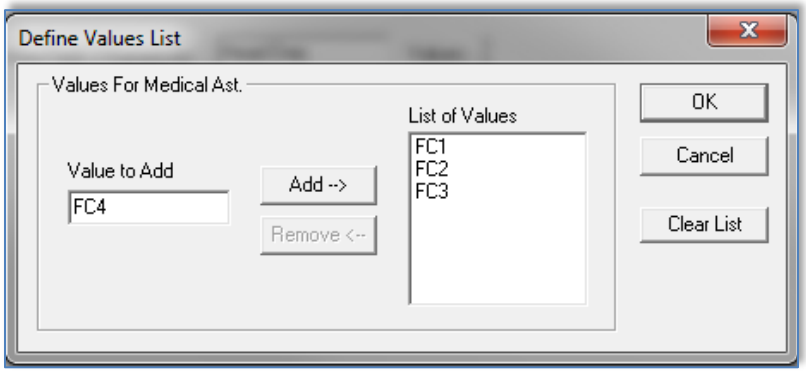


Figure 23 – Define Values List Dialog box

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 (WatchPAT™ 300), tamper-proof testing (WatchPAT™ 300) and login options).

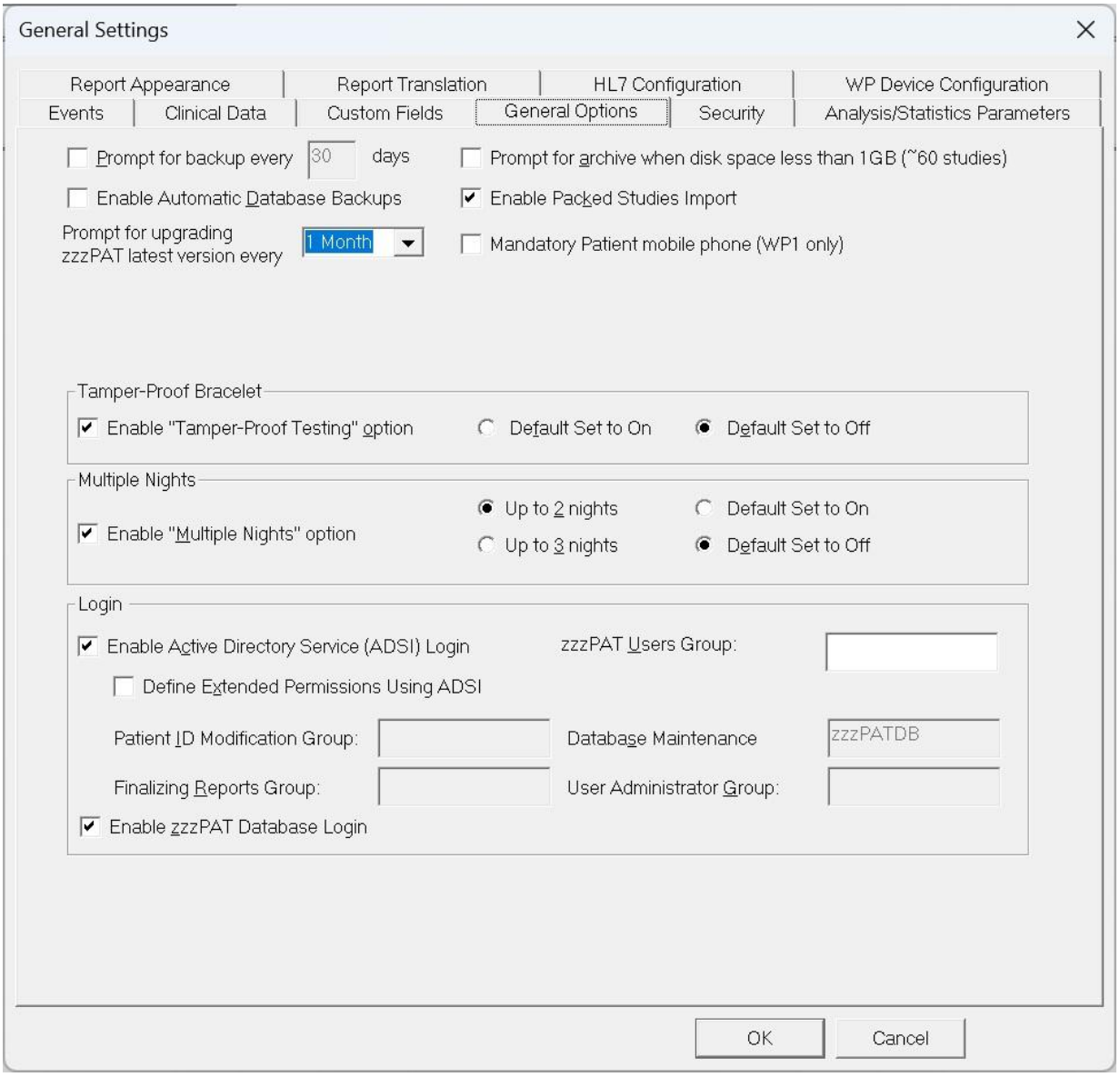


Figure 24 – General Settings Dialog Box – General Options Tab

- 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.
- In the “Prompt for upgrading zzzPAT latest version every …” select how often you would like to be prompted to upgrade the software. At the set time the following pop-up notification is displayed.

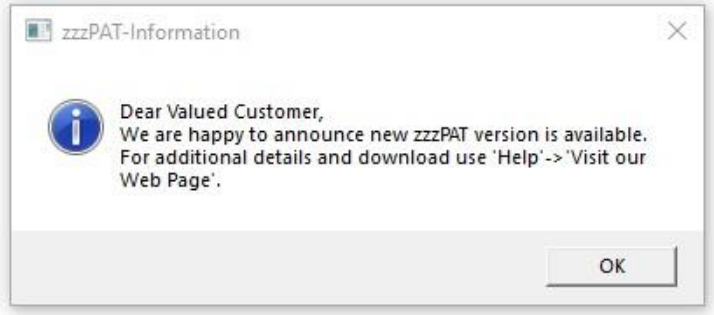


Figure 25 – Device Information Dialog Box

- WatchPAT™ ONE: Check “Mandatory Patient mobile phone” to make entering the patient’s phone number mandatory when preparing a new study (see Preparing a New Study).

	**Note** For WatchPAT™ 400, entering the patient’s mobile phone number is always mandatory.

- WatchPAT™ 300: 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.
- WatchPAT™ 300/WatchPAT™ ONE/WatchPAT™ 400: Check “Enable Multiple Nights" option if you want to enable the WatchPAT™ to record up to 2 or 3 nights in a row while preparing a new study (see Preparing a New Study). There are two options for Multi Nights study:

- Select “Up to 3 nights”: charging is necessary between the nights (maximum length of study is approximately 10 hours).
  - Extra batteries must be supplied in case of WatchPAT™ 300 and WatchPAT™ ONE.
- Select “Default Set to On” if you want to have the "Enable Multiple Nights" option and the chosen number of nights selected by default.
- Select “Default Set to Off” if you do not want to have the "Enable Multiple Nights" option and the chosen number of nights selected by default.

	**Note** The "Enable Tamper-Proof Testing" and "Enable Multiple Nights" options are available only when the WatchPAT™ 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 2.6.2).

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 **Verify user when pressing 'Set as Reported'** to require the user to enter their username and password when the 'Set as Reported' option is selected in the Clinical Diagnosis screen (see section 4.6.1).
- 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

It is recommended to keep the options below.
Strong password and password expiration option will not affect users logging using Active Directory Service (ADSI).
If password is expired, the access is disabled.
After XX time, the application locks.
Password should meet the defined regulation.
No trace of the personal data is left.

- 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.

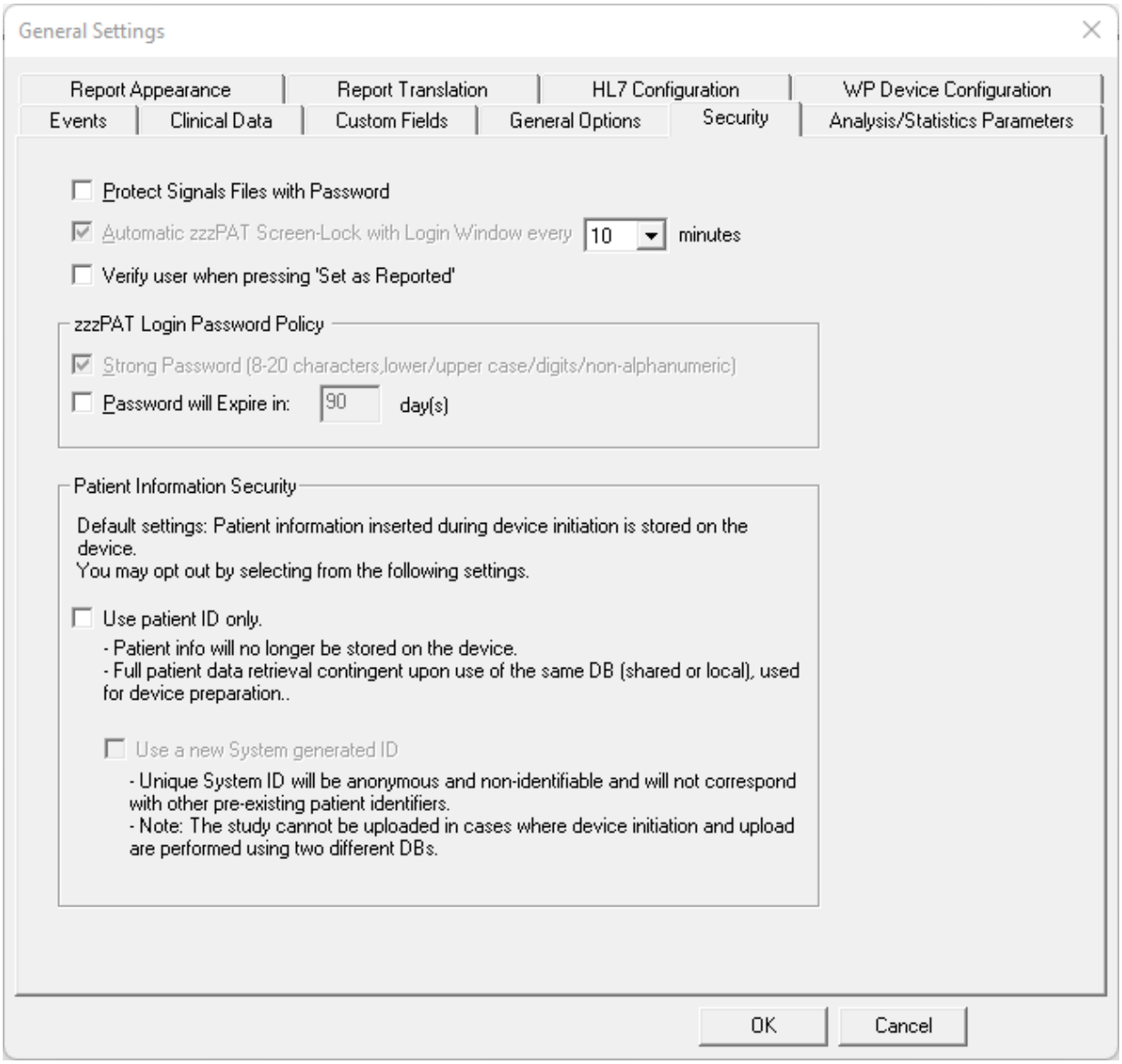


Figure 26 – General Settings Dialog Box – Security Tab

3.3.6 Setup>General Settings>Analysis/Statistics Parameters

Used to modify parameters that affect analysis or report.

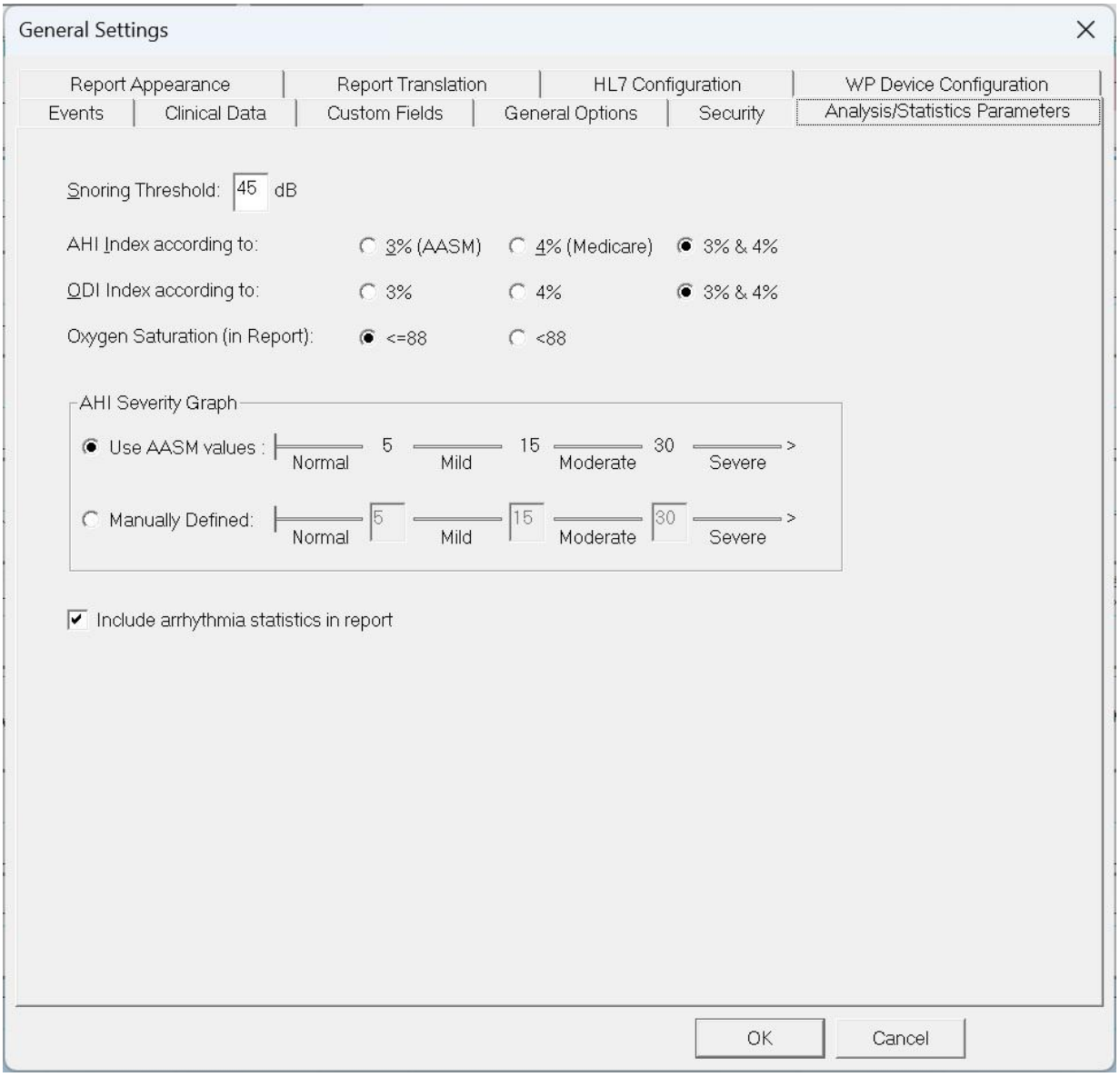


Figure 27 – General Settings Dialog Box – Analysis/Statistics Parameters Tab

- Select snoring threshold to be used in calculating snoring statistics (3rd page of report).

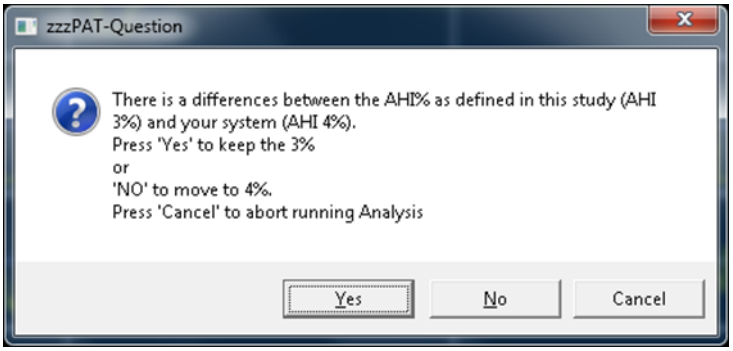
- Select the AASM or Medicare protocol for calculating pAHI and pRDI indices on a site level. The automatic analysis will calculate respiratory events for pAHI and pRDI indices using desaturations of 3% and above (AASM definition) or desaturations of 4% and above (Medicare definition) for all studies 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. Select “3% & 4%” to include both the 3% and 4% results in the report.

Note

The default settings to use AASM 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.

Note

If the study was saved with a different option that the currently used one (AASM or Medicare), you will get a message when re-analyzing the study.



You can then select to change the option by which the indices will be calculated.

- Select the ODI index value to calculate ODI indices on a site level. The automatic analysis will calculate events for ODI indices using desaturations of 3% and above or desaturations of 4% and above for all studies for this site. The Sleep report will show the calculated ODI indices with an indication of the value used for the calculation.

Note

- **If you select 3% for AHI Index:** the option to select 3%, 4%, or 3% & 4% for ODI Index is available.
- **If you select 4% for AHI Index:** the ODI Index of 4% is automatically selected.
- **If you select 3% & 4% for AHI Index:** the option to select 3%, 4%, or 3% & 4% for ODI Index is available.

- 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.

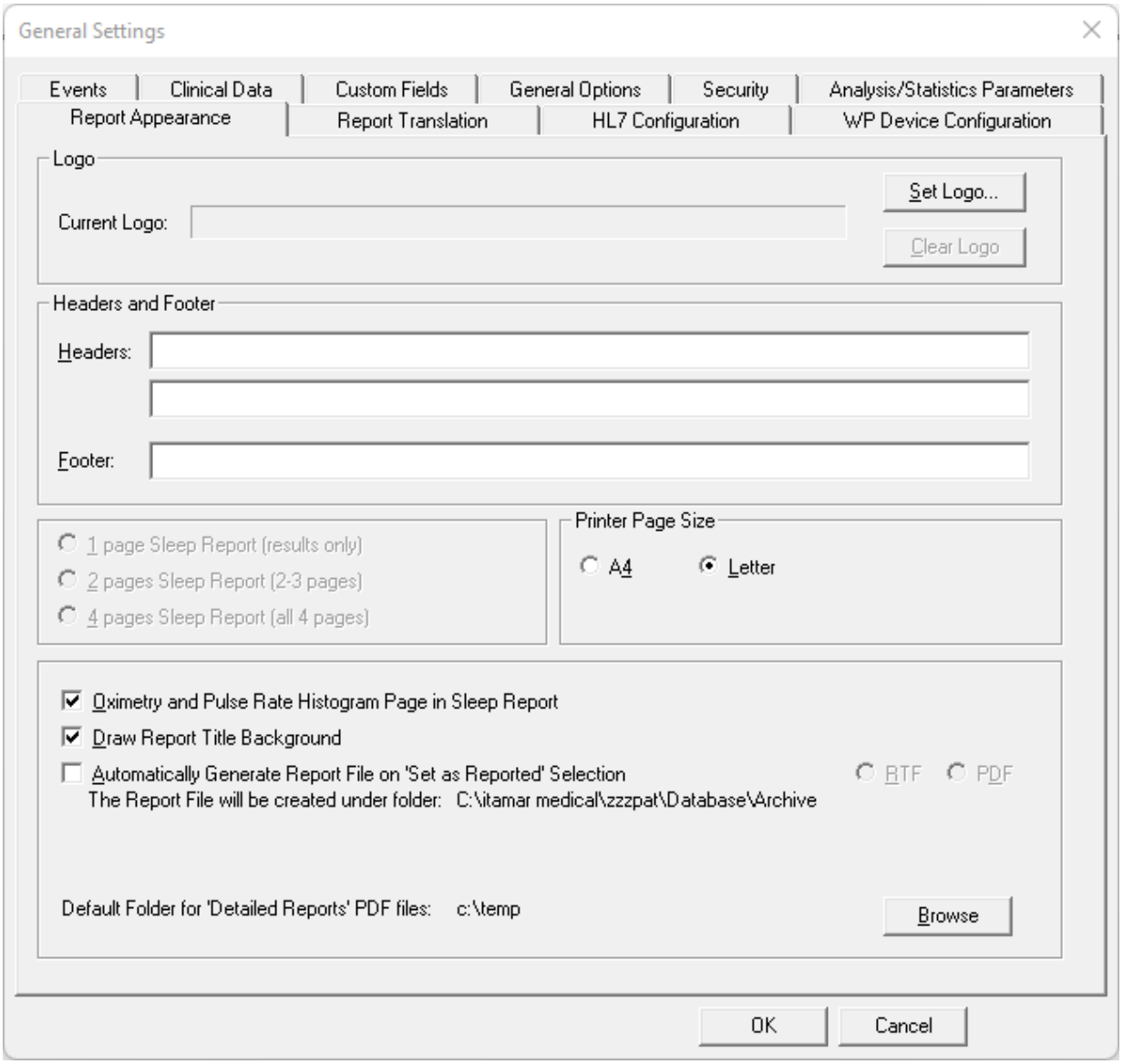


Figure 28 – General Settings Dialog Box – Report Appearance Tab

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 Printer page size of the Sleep Report:

- Select "A4" or “Letter” page size.

To add additional historgrams for pulse rate and oximetry:

- Select “Oximetry and Pulse Rate Histogram Page in Sleep Report”. The additional page will be added to the end of the sleep report (see section 4.6.2).

To show the bitmap on the top of Sleep report:

- Select “Draw Report Title Background”.

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.

To show your company’s customized Sleep Report (provided by Itamar according to your specifications):

- Select “Customized Report”. When checking this option the customized report will replace the default zzzPAT report.

To define where the detailed report is saved:

- Click “Browse” and select a folder. The detailed report will be saved as a PDF file in this folder.
- See section 4.6.6 for more information about the detailed report.

3.3.8 Setup>General Settings>Report Translation

Used to change the sleep report headings.

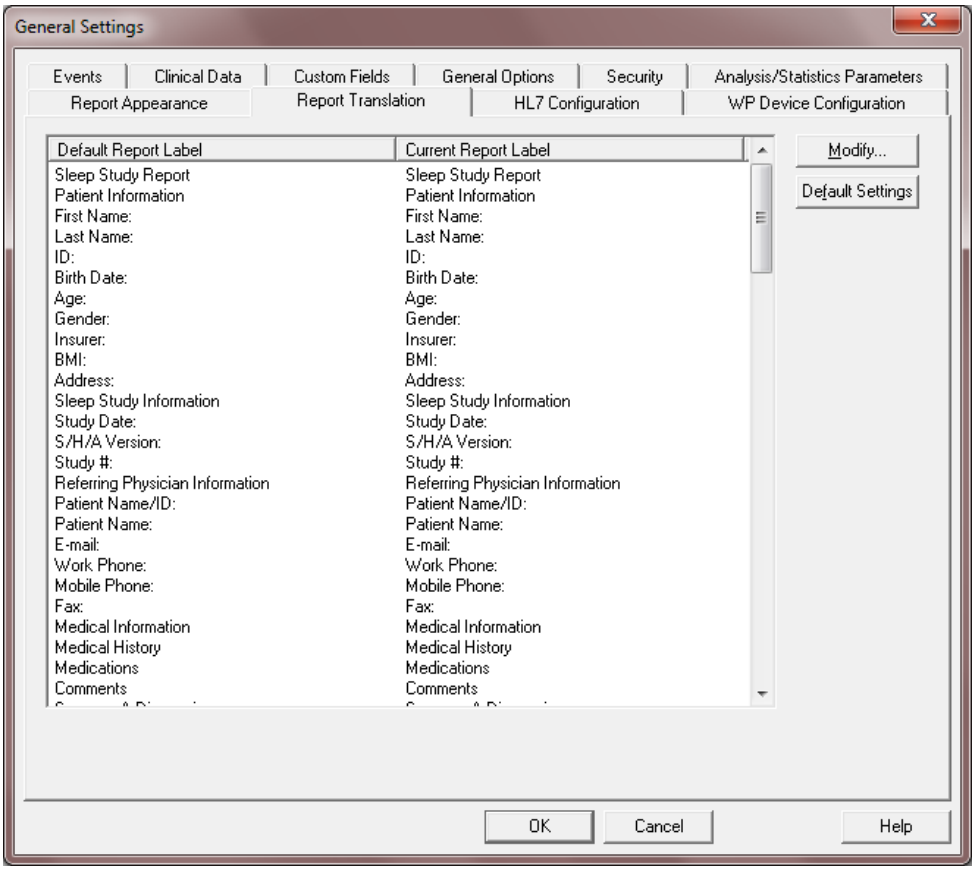


Figure 29 – General Settings Dialog Box – Report Translation Tab

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 support for HL7 configuration.
HL7 addon service can be un-installed or deactivated.

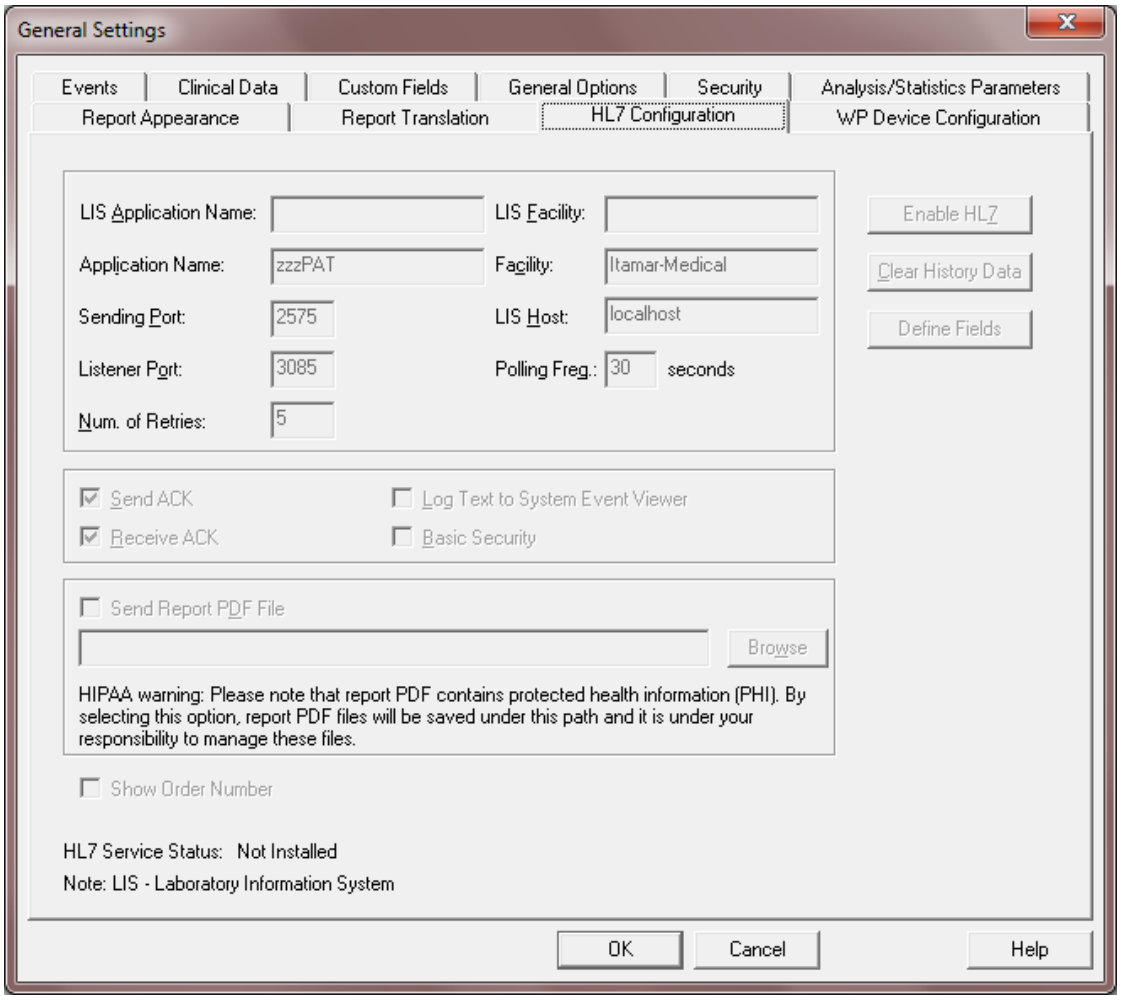


Figure 30 – General Settings Dialog Box – HL7 Configuration

- "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 support 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.
- "Define Fields" enables selecting which fields will be sent in result message and also changing the field names.

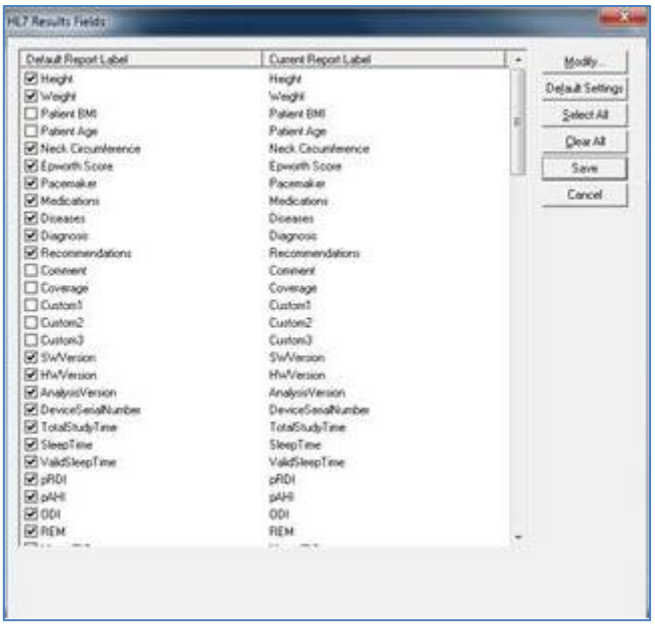


Figure 31 – General Settings Dialog Box – HL7 Configuration/Modify fields dialog

- "Modify" function can change the name of the field
- "Default Settings" will change names back to default
- "Select All" will select all fields to be sent in result message
- "Clear All" will clear all fields so none of the fields will be sent in result message (however, at least one field must be selected)
- "Save" will save all changes
- "Cancel" will cancel all changes

Note

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

3.3.10 Setup>General Settings>WP Device Configuration

Used to select which type of WatchPAT™ devices are to be used, and to set up WatchPAT™ ONE and WatchPAT™ 400 configuration settings.

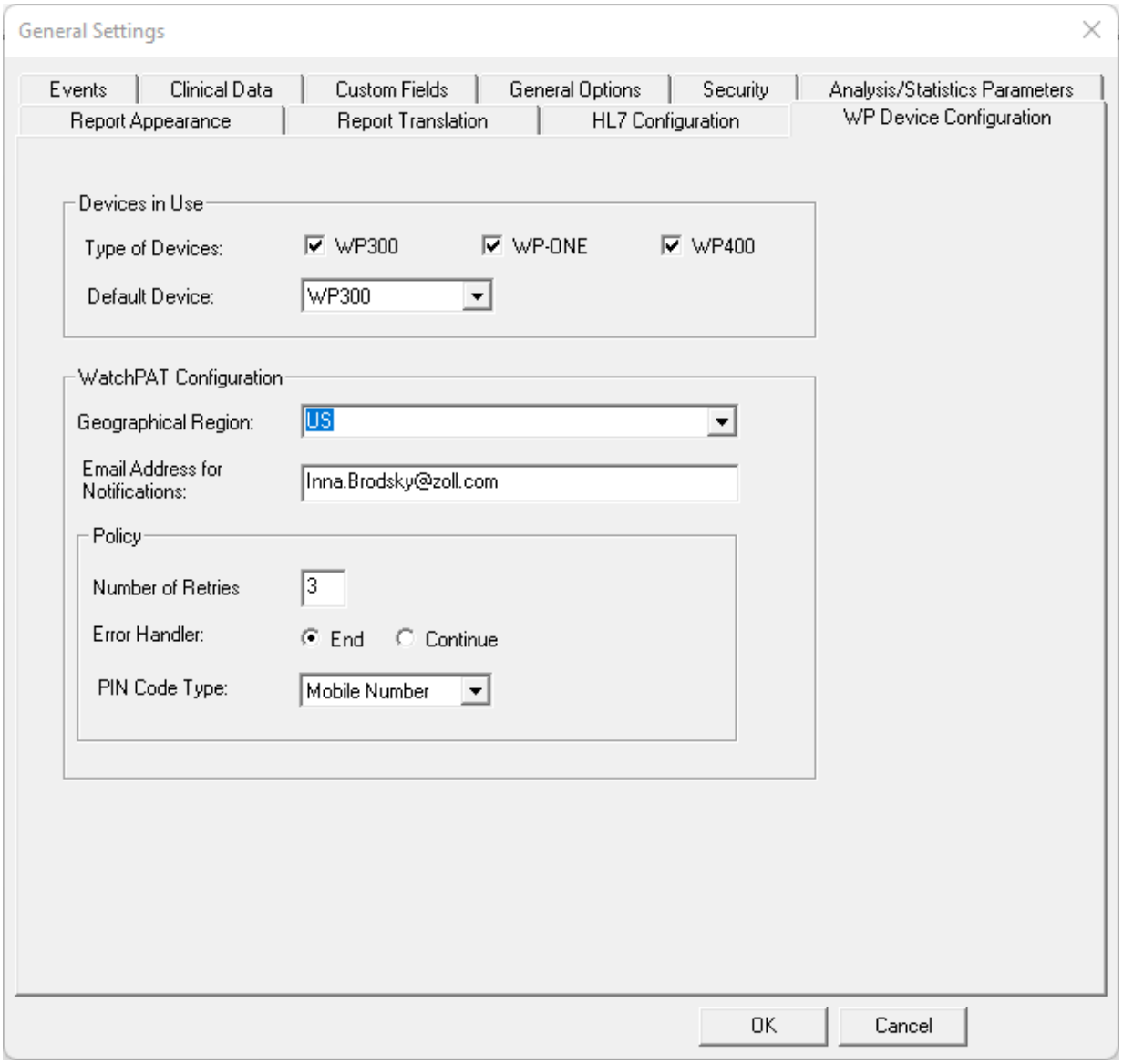


Figure 32 – General Settings Dialog Box – WP Device Configuration

- "Type of Devices" is used to define WatchPAT™ devices to be supported by zzzPAT
- "Default Device" is used to set the default device.

WatchPAT Configuration section (for WatchPAT™ ONE and WatchPAT™ 400):

- "Geographical Region" is used to select the geographical region of the study so the study files will saved in the corresponding FTPS server.
- "Email Address for Notifications" is used for setting an email address to which

notifications are sent when study is completed.

- “Number of Retries” is used to set the number of retries the patient has available when inserting the PIN code during setup.
- “Error Handler” is used to set the action in case number of retries is exceeded, End study or Continue.
- “PIN code type” is used to select the type of code to be used by the patient. This 4 digit code can be the last 4 digits of Social security, Credit Card, Mobile number, etc.

4 Using zzzPAT

4.1 Preparing a New Study

Preparing the Patient file is a mandatory stage in the preparation of the WatchPAT™ devices for a sleep study. Before proceeding, make sure that the WatchPAT™ drive was defined as described in Section **Error! Reference source not found.**.

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 33 – 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

The New study window opens with fields according to default device type (WatchPAT™ 300/WatchPAT™ ONE/WatchPAT™ 400) according to the configuration.

4.1.2.1 Preparing a New Study (WatchPAT™ 300)

	**Note** Prepare the device according to the steps that are described in the device’s operation manual.

- Make sure to insert a new battery before connecting the device to the PC.
- 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:

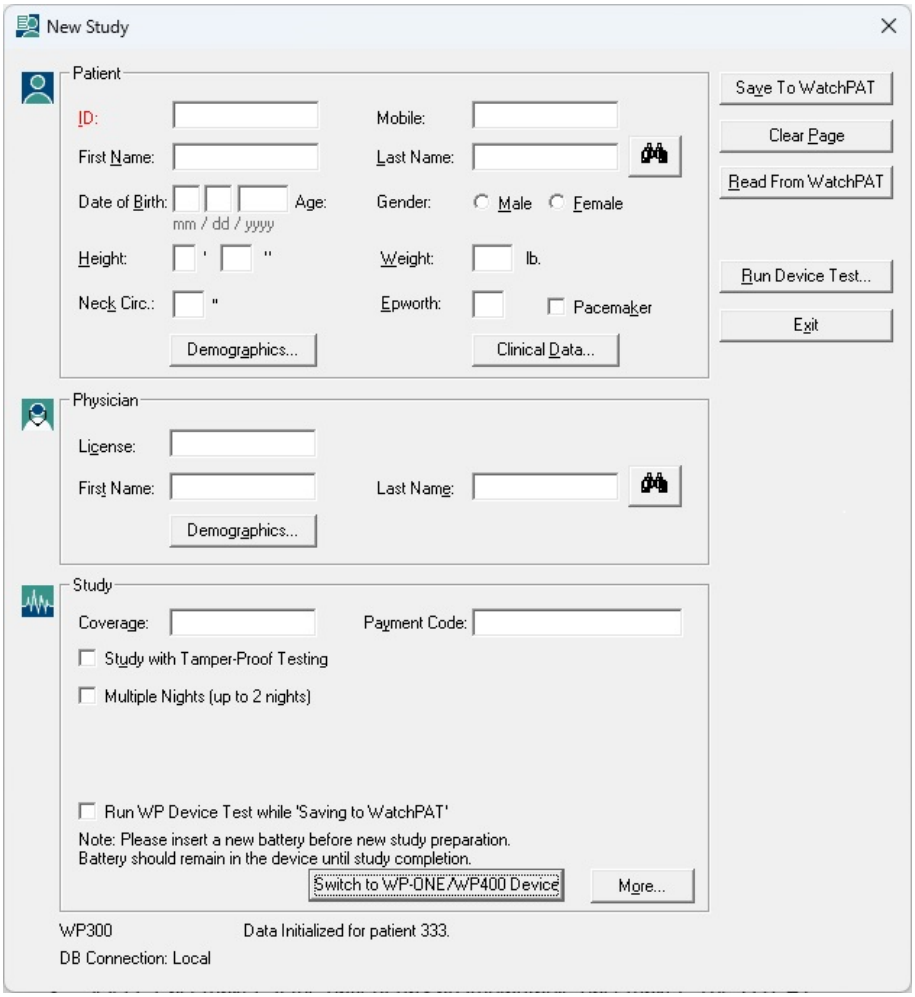


Figure 34 – New Study Dialog Box for WatchPAT™ 300

- 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 WatchPAT™ Operation Manual).
    - This option is shown only if the feature is enabled in Setup>User Settings>Options.
    - This option will be selected by default if “Default set to On” is selected in the “Tamper-Proof Bracket” section of the General Settings dialog box (see section 3.3.4: Setup>General Settings>General Options).
- Select "Multiple Nights" option in order to run up to 2 or 3 nights with the same WatchPAT™ device (see Multi-night study in WatchPAT™ Operation Manual).
    - This option is shown only if the feature is enabled in Setup>General Settings>General Options.
    - This option will be selected by default if “Default set to On” is selected in the “Multiple Nights” section of the General Settings dialog box (see section 3.3.4: Setup>General Settings>General Options).
- WatchPAT™ 300: The “Run Device Test” option appears only when a device is connected. By selecting this option, the connected device will be tested and the results will appear in a separate window. This test will perform the same “Test Device” operation run from a standalone device (see Operator Tests in WatchPAT™ Operation Manual).
- WatchPAT™ 300: The "Run device test while saving..” option appears only when a device is connected. By selecting this option, the connected device will be tested automatically when user selects the 'Save to WatchPAT' and the results will appear in separated window (see Figure 35). This test will perform the same “Test Device” operation run from a standalone device.
- To register a study for the WatchPAT™ ONE/WatchPAT™ 400 device, click the “Switch to WP-ONE/WP-400 Device” button.
- 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).

	Note WatchPAT™ 300: If the WatchPAT unit's battery is low, a pop-up message will appear after clicking the **Save to WatchPAT** button indicating that the battery needs to be replaced.

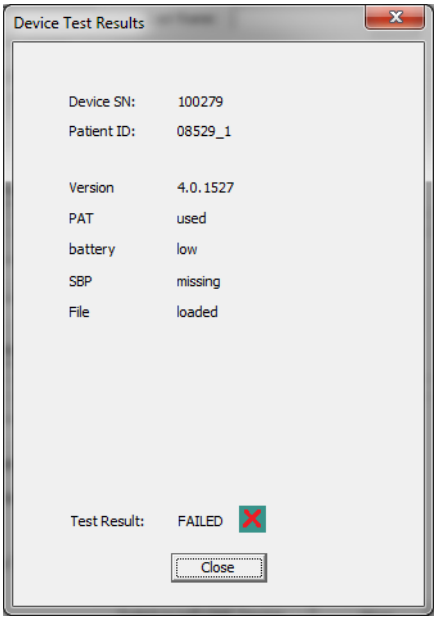


Figure 35 – WatchPAT™ 300 Device Test results Dialog Box

If WatchPAT™ 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:

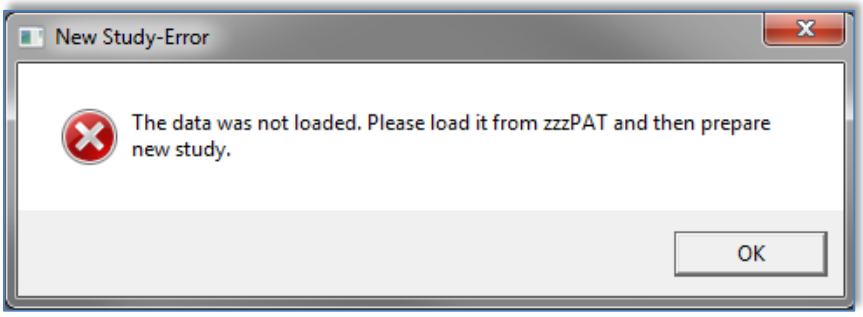


Figure 36 – WatchPAT™ Not Loaded Dialog Box

- After saving the patient information to the WatchPAT™ the following message appears:

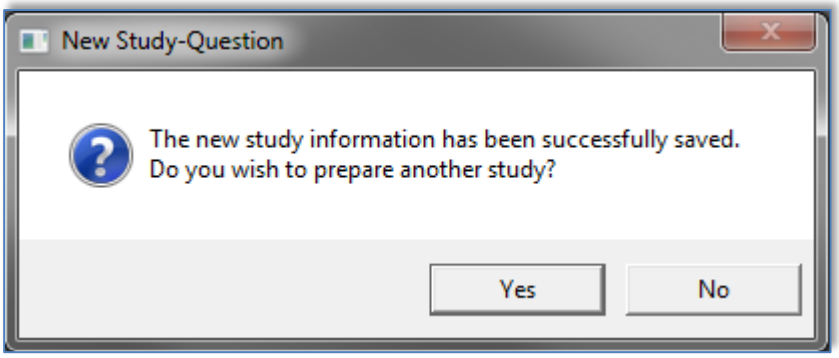


Figure 37 – New Study Termination Question

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.

4.1.2.2 Preparing a New Study (WatchPAT™ ONE /WatchPAT™ 400)

- Make sure that there is an active internet connection
- Click **File>New Study Details** in zzzPAT, or click the 'New Study' icon in the tool bar.

- The 'New Study' dialog box appears:

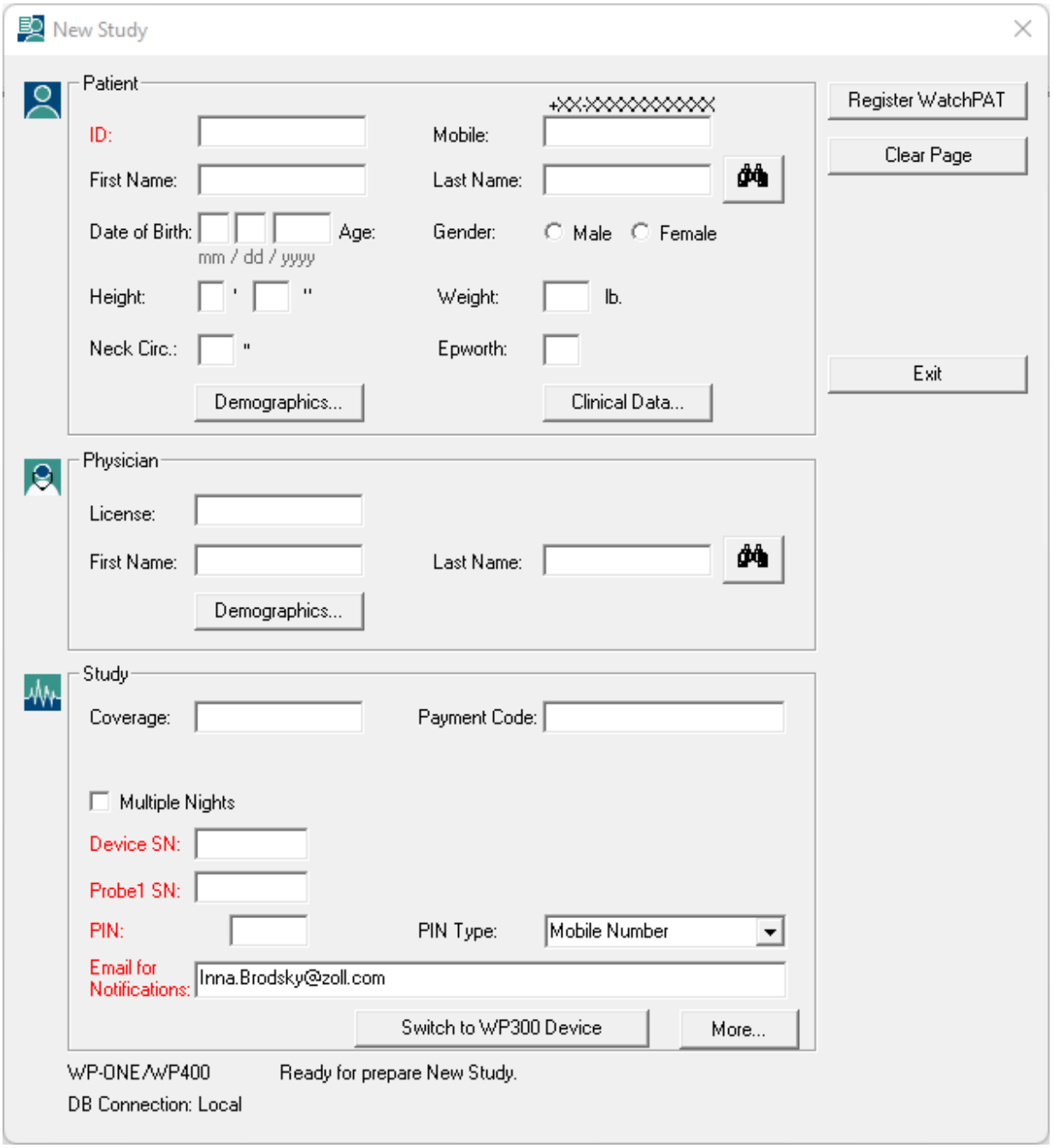


Figure 38 – New Study Dialog Box for WatchPAT™ ONE/WatchPAT™ ONE-M/WatchPAT™ 400

- Fill the mandatory fields: Patient ID, Device SN, and PIN.

	**Note** The “Mobile” field will be marked as mandatory if the “Mandatory Patient mobile phone” field was checked (see Setup>General Settings>General Options).

Note

The mobile phone number must be entered using the following format:
+[country code]-[area code or mobile prefix] [phone number]
(for example: +1-5544667889)

- Select "Multiple Nights" option in order to run up to 3 nights with the same WatchPAT™ ONE-M device by chaging the probe each night. This option is shown only if the feature is enabled in Setup>General Settings>General Options. When “Multiple Nights” is checked, the selection of “2 Nights” or “3 Nights” will appear and the default selected option will be according to what is defined in General Options. Additional mandatory text boxes will appear to define the additional probes’ SN numbers.
- When using the WatchPAT™ 400 device, it is mandatory to add Probe SN numbers. Either two or three probe numbers need to be added, depending on whether “2 Nights” or “3 Nights” was selected).

Note

In the “Select Study to Download” window (see

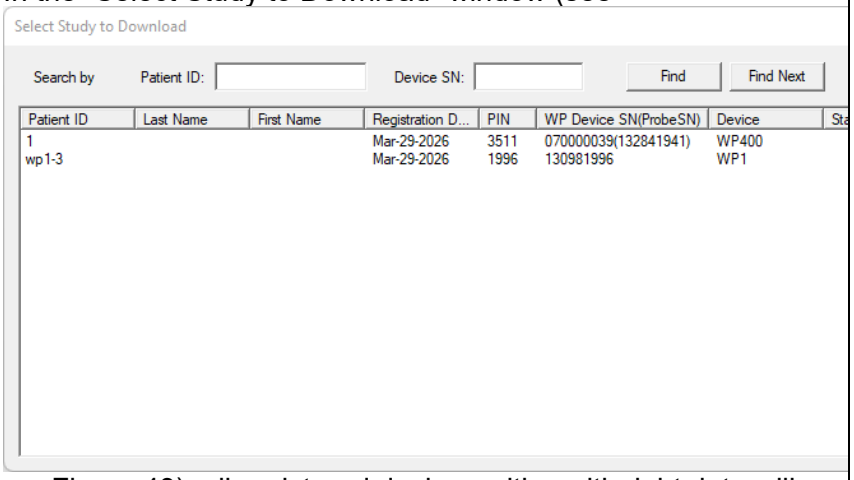


Figure 43), all registered devices with multi-night data will list the device SN number followed by the probe SN number(s) in parentheses.

- Make sure the Email address appears on screen is the correct address for receiving email notifications (Email address is defined during setup).
- Insert any additional information if needed, the rest of the fields are optional.

Notes

PIN number is 4-digit code used to identify the patient and therefore MUST be a number that correlates to the specific patient (4 last digits of Social Security, Phone number, Credit card, etc.).

- Make sure the patient is aware of this code.
- DO NOT use any default or similar number for different patients and do not write the code on the box

Example:
PIN:1111->NOT GOOD
PIN: Last 4 phone # digits (i.e 2983) -> GOOD

If mobile number input is mandatory, the 4 last digits of the mobile phone number will be used as a PIN code.

- Click the “Register WatchPAT” button to register the device and the probes. Registration will be unsuccessful in the following cases:
  - If one of the SN numbers is invalid or missing.
  - If one of the SN numbers is already registered.

Note

If the same WatchPAT™ ONE/WatchPAT™ 400 probe SN is already registered, an error will appear to notify user to insert the correct/other device SN.
Fill in the correct information and click the “Register 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).

Note

	To initiate study for WatchPAT™ 300 Device use the “Switch to WatchPAT™ 300 Device” button.

- After registering the patient information to the Web Server the following message appears:

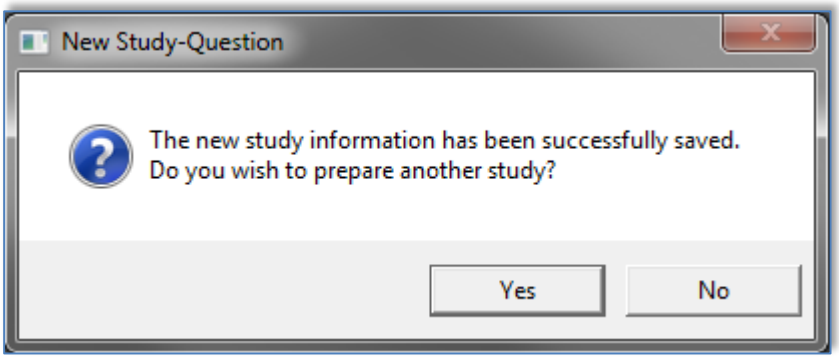


Figure 39 – New Study Termination Question

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

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 Documenting additional information

To add demographic information:

- Click the **Demographics** button (see Figure 34). The following dialog box opens:

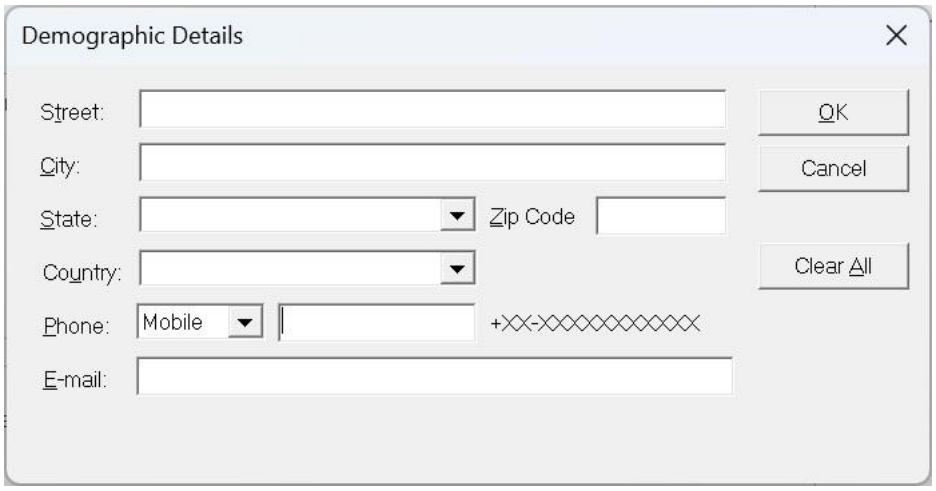


Figure 40 – Demographic Details Dialog Box

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

	**Note** The mobile phone number must be entered using the following format: +[country code]-[area code or mobile prefix] [phone number] (for example: +1-5544667889)

To add optional clinical information:

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

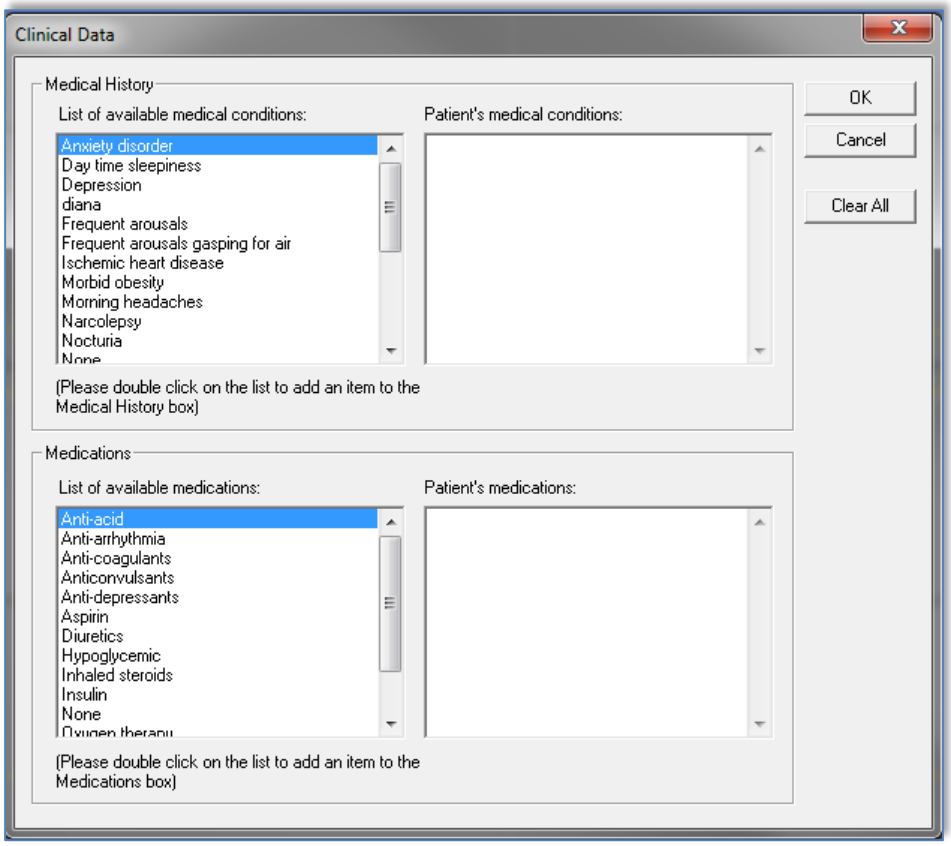


Figure 41 – Patient Clinical Data Dialog box

- 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.

4.1.3.2 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 34), leave the fields: 'patient ID', 'first name' and 'last name' empty.
- Click  , the 'Search Results' dialog box opens 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 opens 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.

4.1.3.3 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 opens:

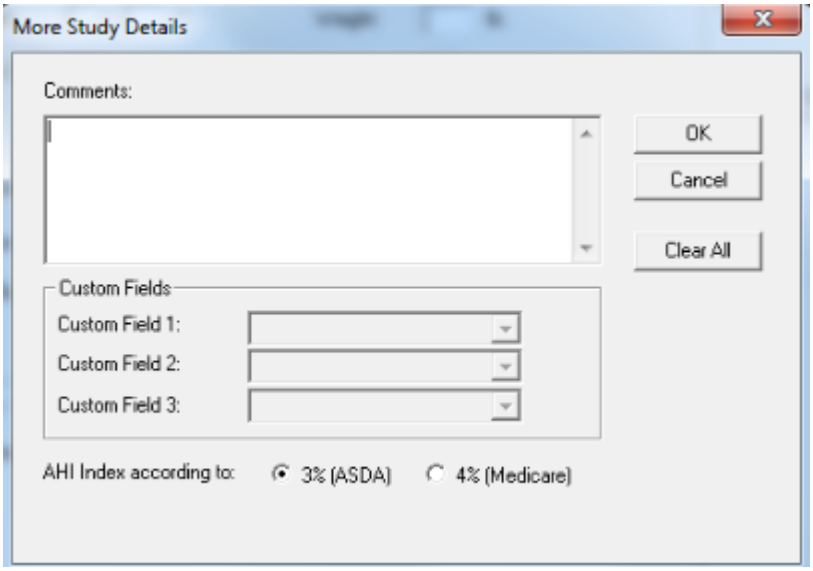


Figure 42 – More Study Details Dialog box

- 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 42). To define 'Custom Fields' see section 3.3.3.

- You can select AASM or Medicare protocol for calculating pAHI and pRDI indices on a study level, see 3.3.6.

4.1.3.4 Reviewing and editing information stored on a WatchPAT™ (WatchPAT™ 300)

	**Warning** It is possible to change information on a WatchPAT™ only before the recording session. Changing information after a recording session will erase the recorded information on the device (at that time the study is already loaded to zzzPAT).

- Insert the WatchPAT™ 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 WatchPAT™ to the zzzPAT database. See Section 4.2.8 for more details.

4.2 Managing Patient Studies

WatchPAT™ 300: After a WatchPAT™ 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.

WatchPAT™ ONE/WatchPAT™ 400: After a WatchPAT™ sleep study is done, open zzzPAT application and press **File>Load Study and Analyze** from the main menu. A window opens with all registered patients that the study was not yet retrieved from the web server (see

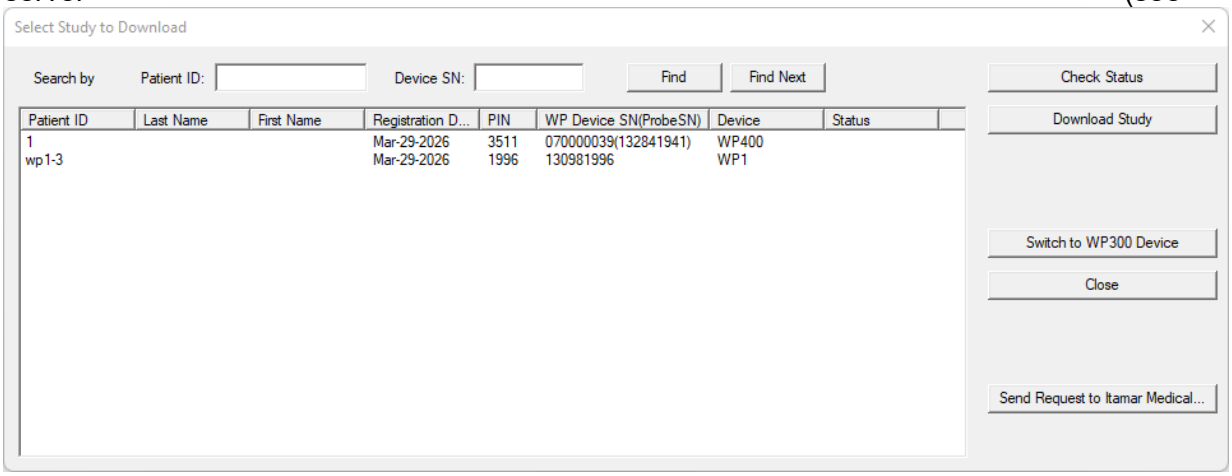


Figure 43). Select study to download and the recorded data will be loaded into the zzzPAT database for selected patient. The recorded data is automatically analyzed. The user can subsequently review, edit, add Diagnosis and Recommendations and produce a Sleep Report. Previously loaded studies can be opened and reviewed.

	**Note** The list of all registered WatchPAT™ ONE/WatchPAT™ 400 devices includes a “Status” column with the following options: “Ready”, “Not started” and “In process”. Press the “Check Status” button to update the status for all the registered devices.

	**Note** It is possible to search for patients using the Patient ID, and for devices using the Device SN.

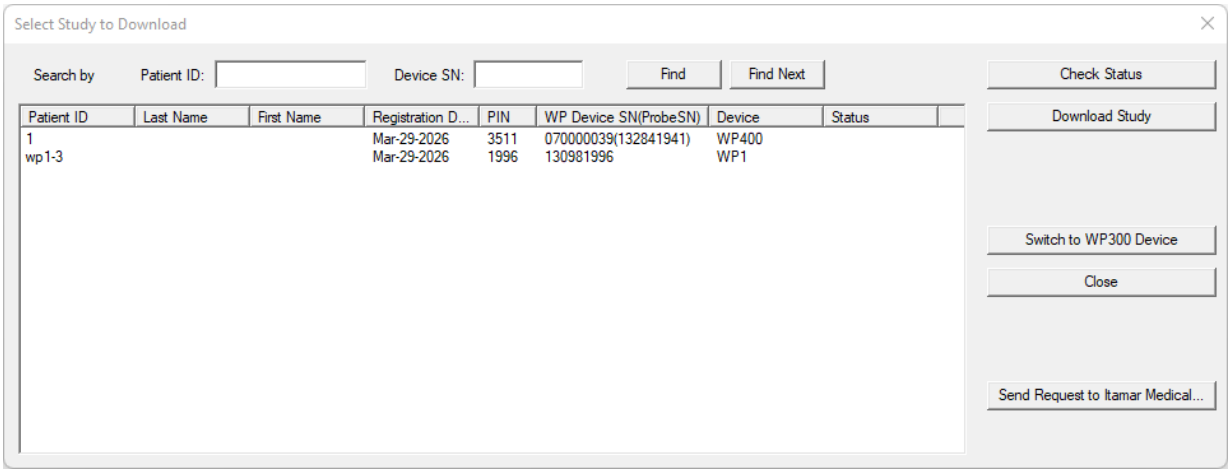


Figure 43 – List of WatchPAT™ ONE’s/WatchPAT™ 400’s registered patients

	**Note** To switch between WatchPAT™ ONE’s/WatchPAT™ 400’s registered patients list to download study from WatchPAT™ 300 device select the “Switch to 300 Device” button.

	**Note** If selected registered patient didn't yet sleep with the WatchPAT™ ONE/WatchPAT™ 400 device a proper message shall appear on screen.

	**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 WatchPAT™ 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 44) 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.

Note

When loading a study using the WatchPAT™ 300 device, the firmware version is checked. If the device doesn't have the latest firmware version installed, the following notification is displayed:
"There is a newer firmware version available for Device Number XXX. It is recommended to use the latest firmware version.
Use 'Help'->'Visit our Web Page for Upgrading Watch-PAT Device' to download the upgrade software."
See section 5.8: Upgrading WatchPAT™ Device firmware (WatchPAT™ 300) for more information about upgrading the firmware version.

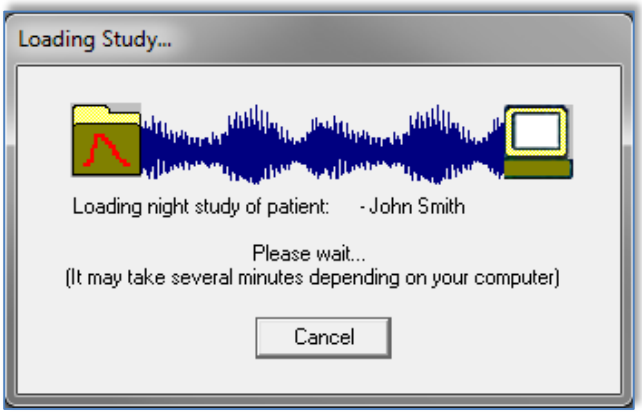


Figure 44 – Loading Study dialog box

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

WatchPAT™ 300: 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 45). 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 about the study on the screen.

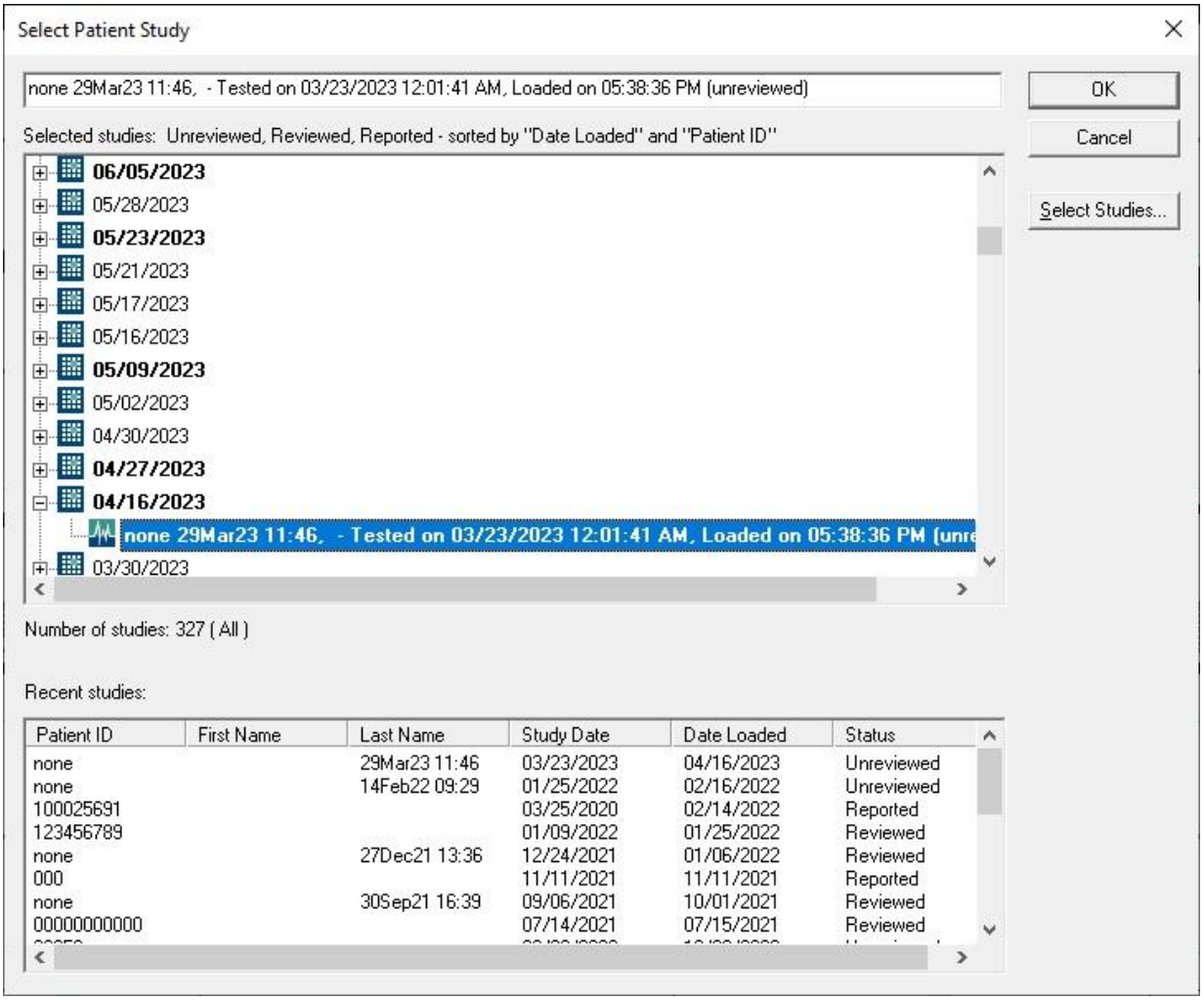


Figure 45 – Select Patient Study dialog box

If several analyses exist for a study a dialog will appear prompting to select the Analysis to open.

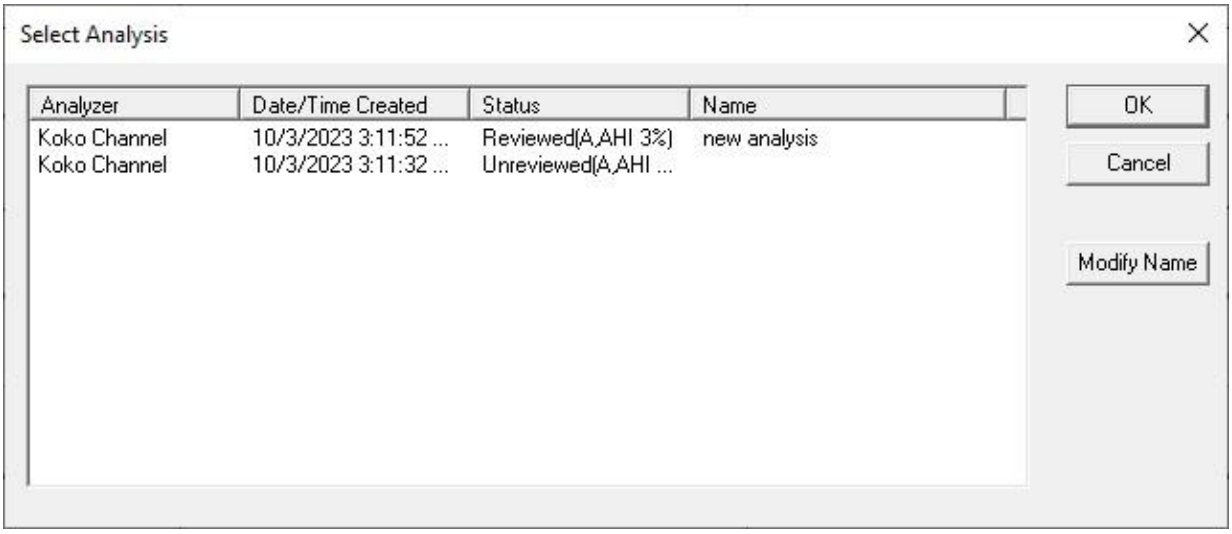


Figure 46 – Select Analysis dialog box

The list of analyses also includes a column with the names assigned to each Analysis.

Modify Name button
Enablles the user to edit an Analysis name, or to add a name to an Analysis that was not assigned one.

- Click **Modify Name** button in the 'Select Analysis' dialog box.

The "Save Analysis as" dialog box opens which allows you to add/edit the Analysis name (see section 4.2.5: File>Save as New Analysis).

Select Studies button
Enables the user to define, select and organize the displayed studies that are listed in the 'Select Patient Study' dialog box.

- Click **Select Studies** button in the 'Select Patient Study' dialog box.

The following dialog box opens:

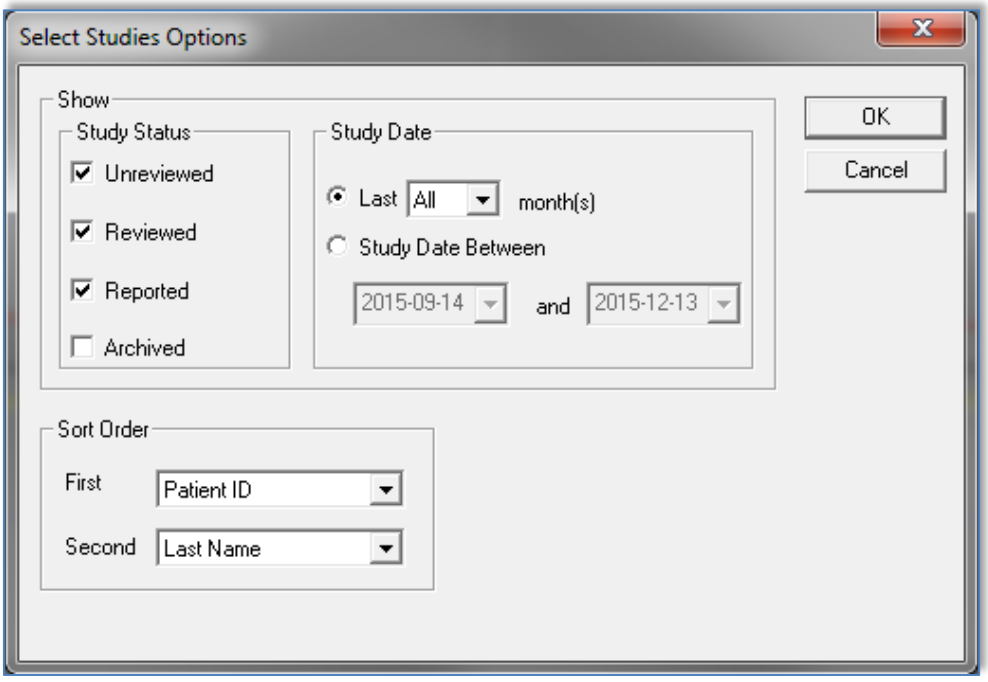


Figure 47 – Select studies options dialog box

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.
	–	

4.2.3.1 Recent Studies

The "Recent studies" section of the Select Patient Study window lists the 20 most recent studies which were opened. This list is sorted by the date the studies were opened, with the most recent study on top. Double click one of the rows to load and display recorded information about that study on the screen.

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>Save as New Analysis

Saves the current Analysis, with the current events and signals, as a new Analysis. The following dialog box opens which will allow you to assign a name to the Analysis:

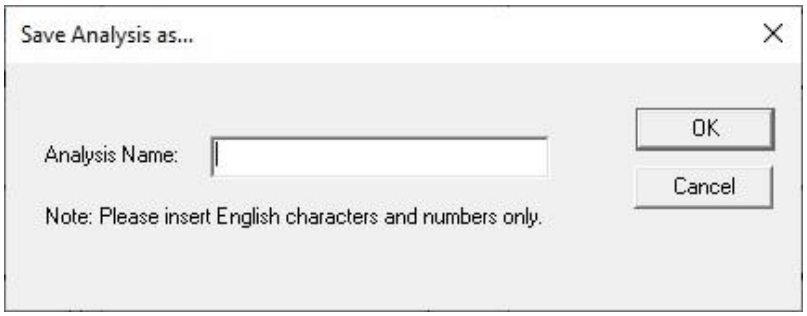


Figure 48 – Save Analysis as dialog box

This name will make it easier for you to identify the Analysis.

	**Note** Only English letters and numbers can be part of the name.

	**Note** If you choose not to assign a name to the analysis, leave the field blank and click **OK**.

To modify the Analysis name, click the **Modify Name** button in the Select Analysis dialog box (see Figure 46 – Select Analysis dialog box).

4.2.6 File>Close Study

Closes the patient study currently being viewed without closing zzzPAT.

4.2.7 File>Exit

Closes both the patient study being viewed and the zzzPAT.

4.2.8 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.

4.2.9 Edit>Correct Study Date

	**Note** The “Correct Study Date” option is enabled only for WatchPAT™ 300 and only if the date defaults to 1/1/2000.

WatchPAT™ 300: After initiating the device for a new study, if the device is left without a battery for a few hours or more, its internal clock is reset and the study date will default to 01/01/2000 and the time will default to 12 AM. The ‘Correct Study Date’ option opens the following dialog box, allowing the user to set the correct study date and time:

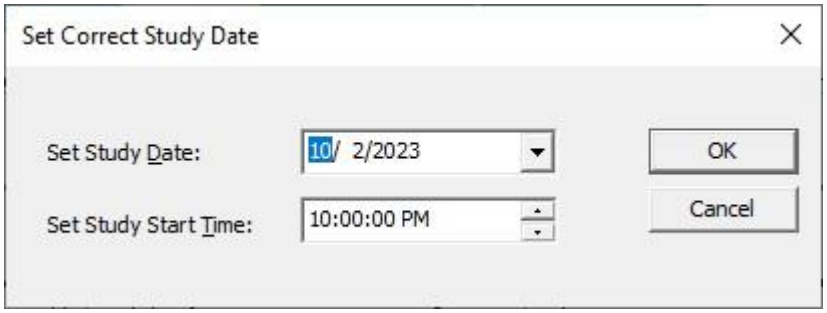


Figure 49 – Set Correct Study Date dialog box

	**Note** **IMPORANT:** The study date can only be changed once.

	**Note** The study date which first appears in the dialog box is one day before the date the study was loaded to the system.

	**Note** The raw data (sleep.dat) will not be changed when changing the study date.

4.2.10 Edit>Undo

Choosing “Undo” or clicking  on the zzzPAT toolbar enables the user to undo the last operation. 'Undo' is enabled only after changing events (manual editing).

4.2.11 Edit>Sleep Stages Editing Using Mouse

Choosing this option or clicking  on the zzzPAT toolbar toggles the option that allows to manually edit the sleep stages and CSR times with the mouse. If option is selected and mouse hovers over a sleep stage event (i.e. Light Sleep) the mouse arrow changes to a hand and the selected event may be dragged or resized accordingly.

4.2.12 Edit>Copy…

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

4.3 The Display Screen

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

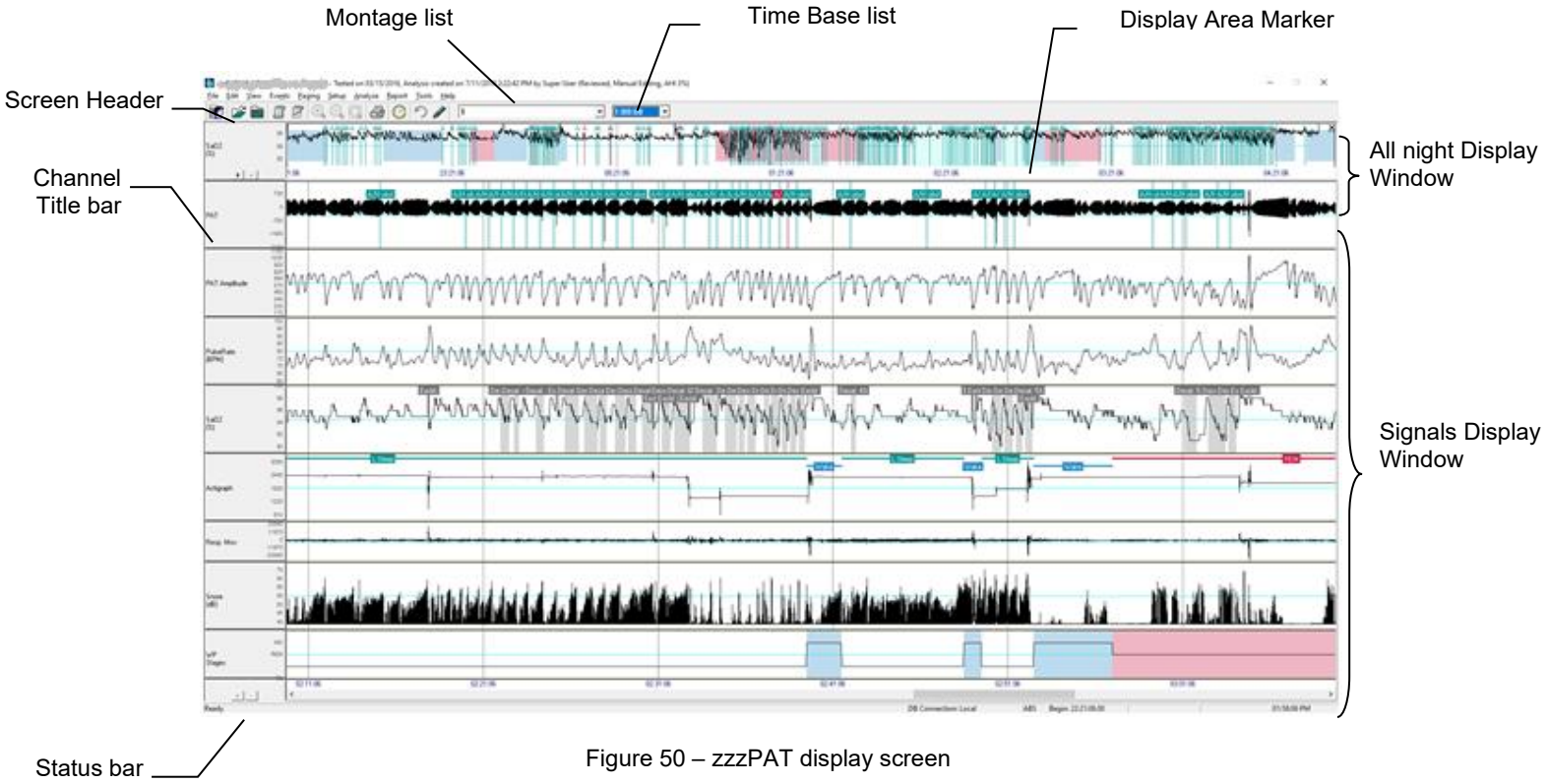


Figure 50 – zzzPAT display screen

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 opens:

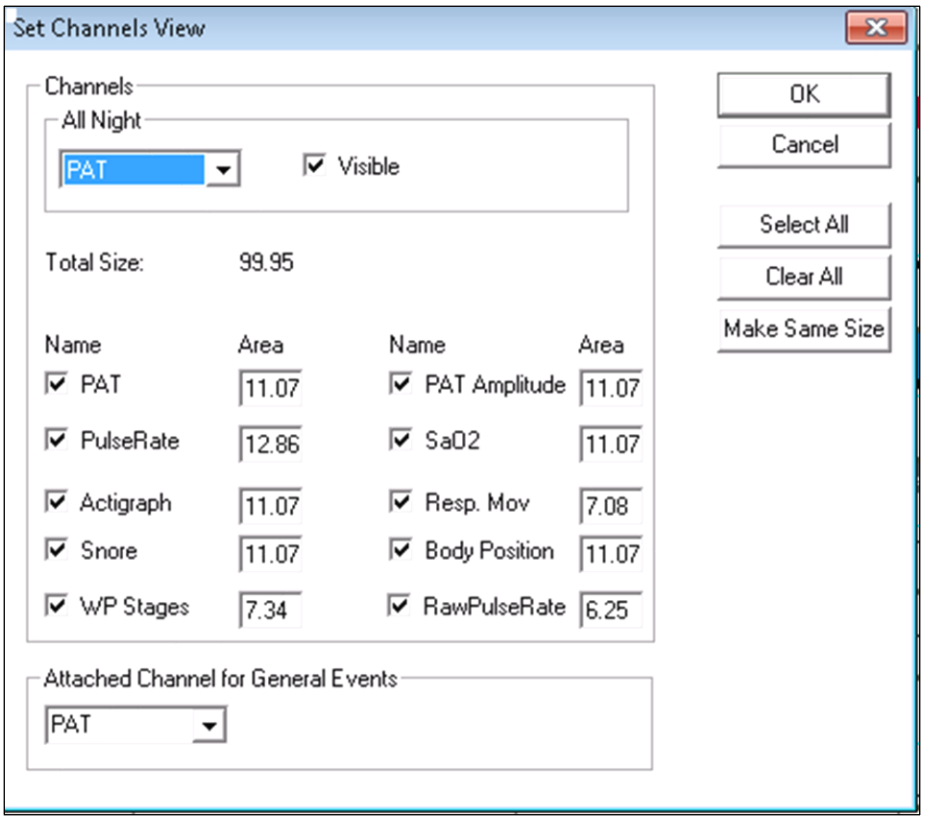


Figure 51 – Selecting the All night Window

- 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.

	Note

	User can change the active signal size also using the mouse from the main window.

	Note User can change the order of the signals in the view by dragging the active signal to the desired location from the main window.

	Note Channels' order and size are saved as part of the montage.

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 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 50), 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:

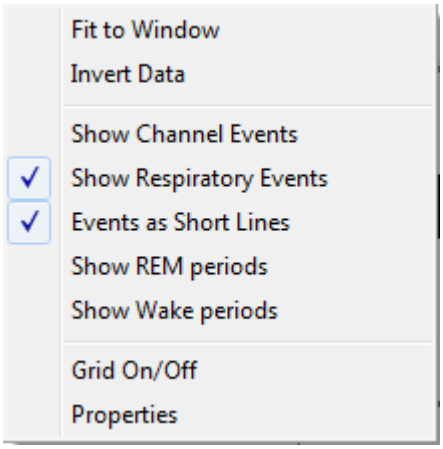


Figure 52 – All Night pop-up Menu

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.

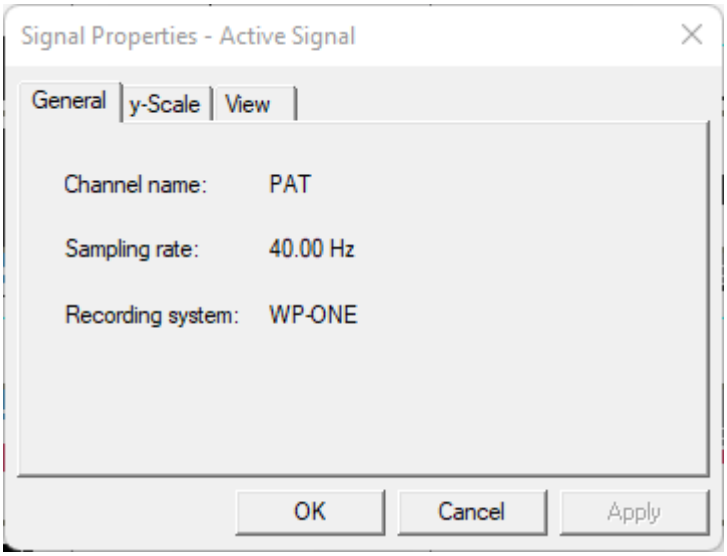
Events as Short Lines – Option to show full vertical line on the events in all-night window or just short lines so the channel data will be not covered by event lines.

Show REM periods – Mark REM periods on all night window with background regardless of the channel selected in all night screen

Show Wake periods – Mark Wake periods on all night window with background regardless of the channel selected in all night screen

Grid On/Off – Toggles the grid in the All Night window.

Properties – Opens up the 'Signal Properties - All Night' dialog box (see



–

– Figure 53).

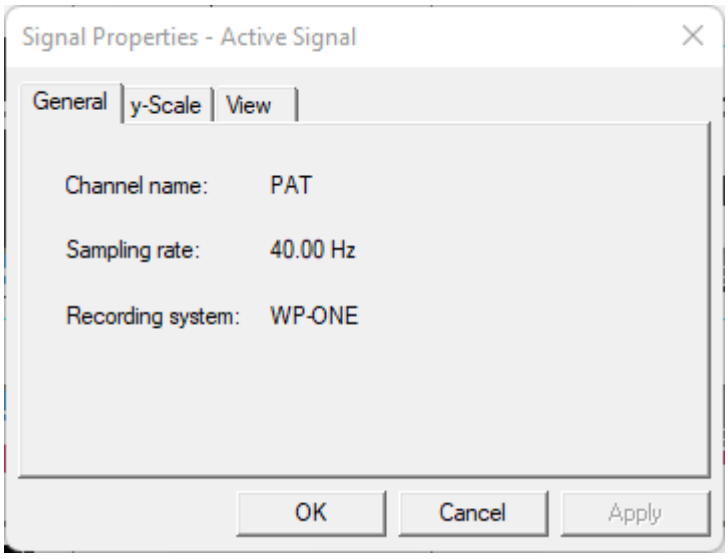


Figure 53 – Signal Properties – All Night window

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

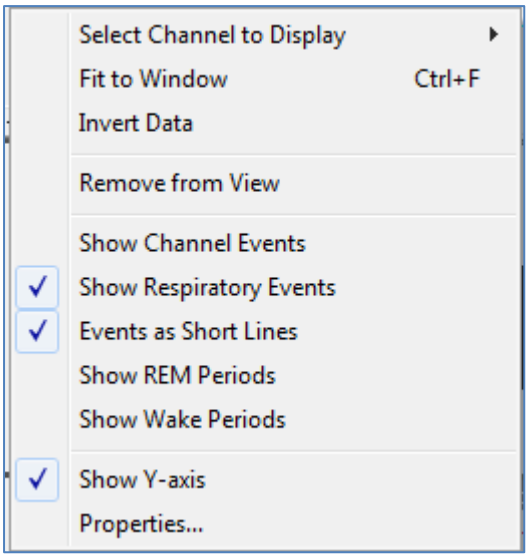


Figure 54 – All Night pop-up menu

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 52 explanations.

	**Note** The options "Show REM Periods" and "Show Wake Periods" are also available for the WP Stages signal (through the Properties menu).

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).

	**Note** User can change the active signal size and location also using the mouse. This information will be saved as part of the montage.

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

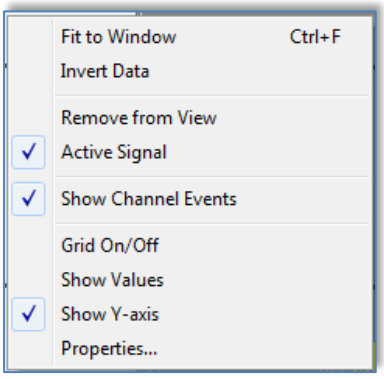


Figure 55 – Active channel pop-up menu

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.

Note

The channel's setting are saved as part of the montage

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)

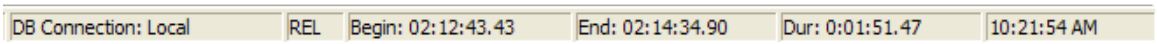


Figure 56 – zzzPAT Screen - Status Bar

4.4 Signal Display Options

4.4.1 View>Define Channels in Montage

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

- PAT- PAT signal.
- Pulse Rate - Derived from the PAT signal.
- PAT Amplitude - PAT signal envelope.
- SpO_2 - Arterial blood Oxygen saturation level.
- Actigraph - Actigraphy signal.
- WP Stages – REM, Light Sleep, Deep Sleep and Wake stages.
- Body Position (optional)
- Snore (optional)
- Resp.Mov (optional)
- RawPulseRate

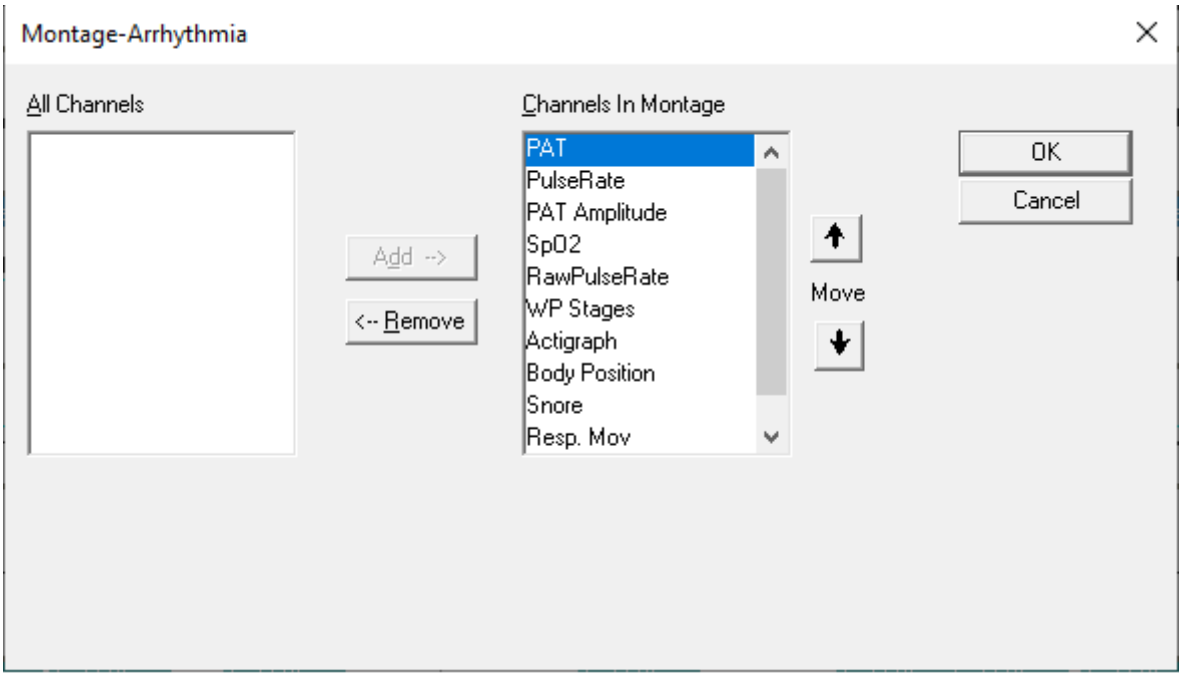


Figure 57 – Montage screen

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.

Note

User can change the order of the signals in the view by dragging the active signal to the desired location from the main window. However adding a channel to the montage is available only from this screen.

4.4.2 View>Channels

See The All Night Window and View Channels section.

4.4.3 View>Set y-Scale

Opens the 'Set y-Scale' dialog box.

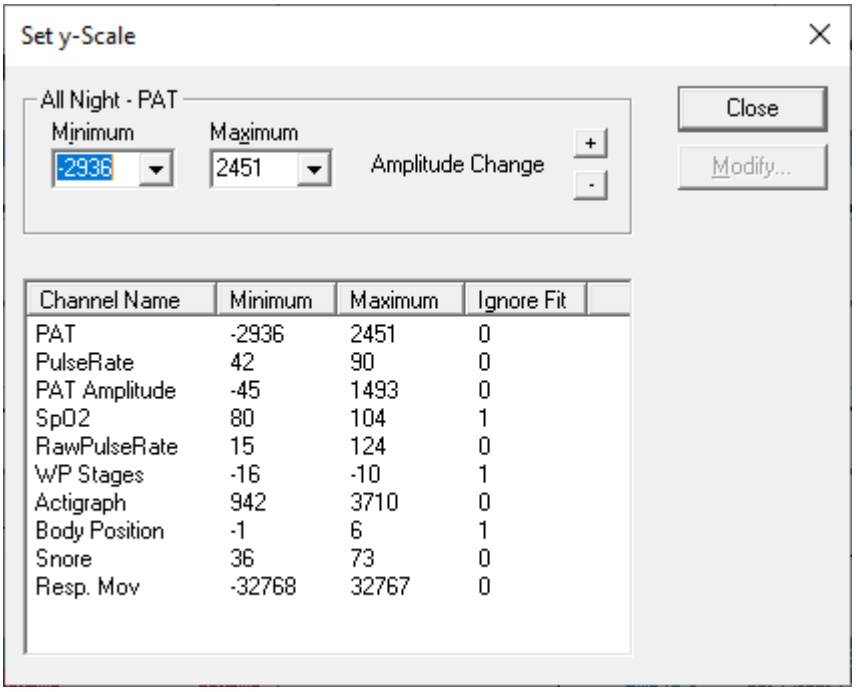


Figure 58 – Set y-Scale dialog box.

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 opens:

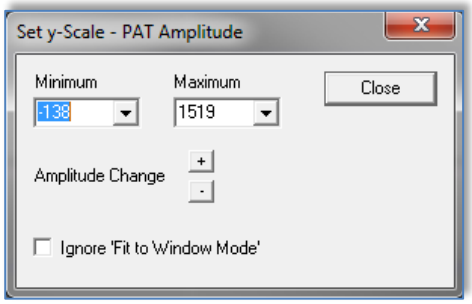


Figure 59 – Set y-Scale – per channel dialog box

- 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 4.4.7).

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.

4.4.4 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.

4.4.5 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, or moving the mouse scroll wheel up and down).

4.4.6 View >All Night Channel Fit to Window

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

4.4.7 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, or moving the mouse scroll wheen up and down).

Note: It is recommended to disable the 'Fit to Window' Mode on the actigraphy channel. For instructions see section 4.4.3.

4.4.8 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 highlighted channel.

4.4.9 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 WatchPAT™ device.

4.4.10 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.

4.4.11 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.

4.4.12 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.

4.4.13 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 WatchPAT™ 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 RESBP 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

Events are colored by type and have colored background by type. To change the color of a specific type, select an event from the type you want to change, right click it and choose Event Properties. Selecting a different color will change the color of all events of this type. See Figure 60. The current selected color is marked by 'V'.

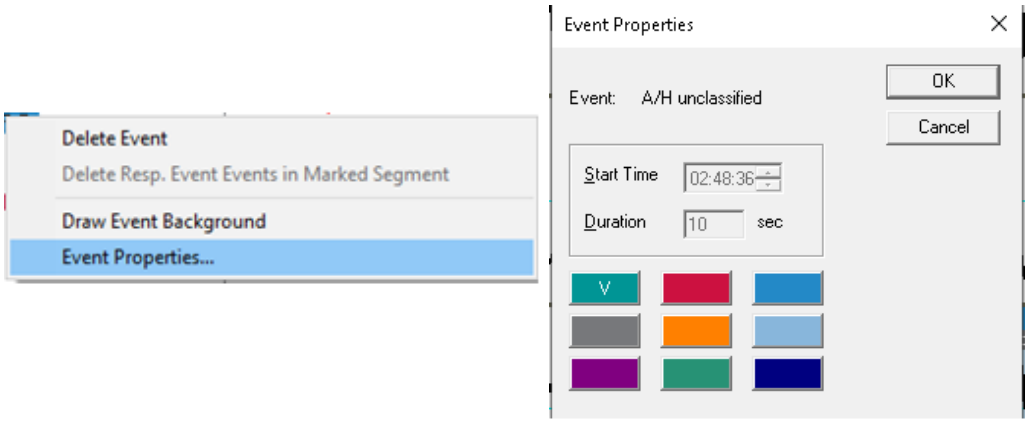


Figure 60 – Change event color

	**Note** Changing a respiratory event color will also change the color of the line related to the event in the “All Night” view. Changing the color of Wake and REM events will change the coloring of these events in the “All Night” view and in the WP Stages channel in case these options are selected.

To mark the background of a specific event type or remove an existing background, select an event of the type, right click and select Draw event background.

	**Note** Select Events>Remove Background from All Events to remove the background marking from all events in view.

4.5.3 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 the location and select the “Add Event”"command. Or by using the zzzPAT tool bar **Events>Add Event**
  The “Add Event” dialog box opens.

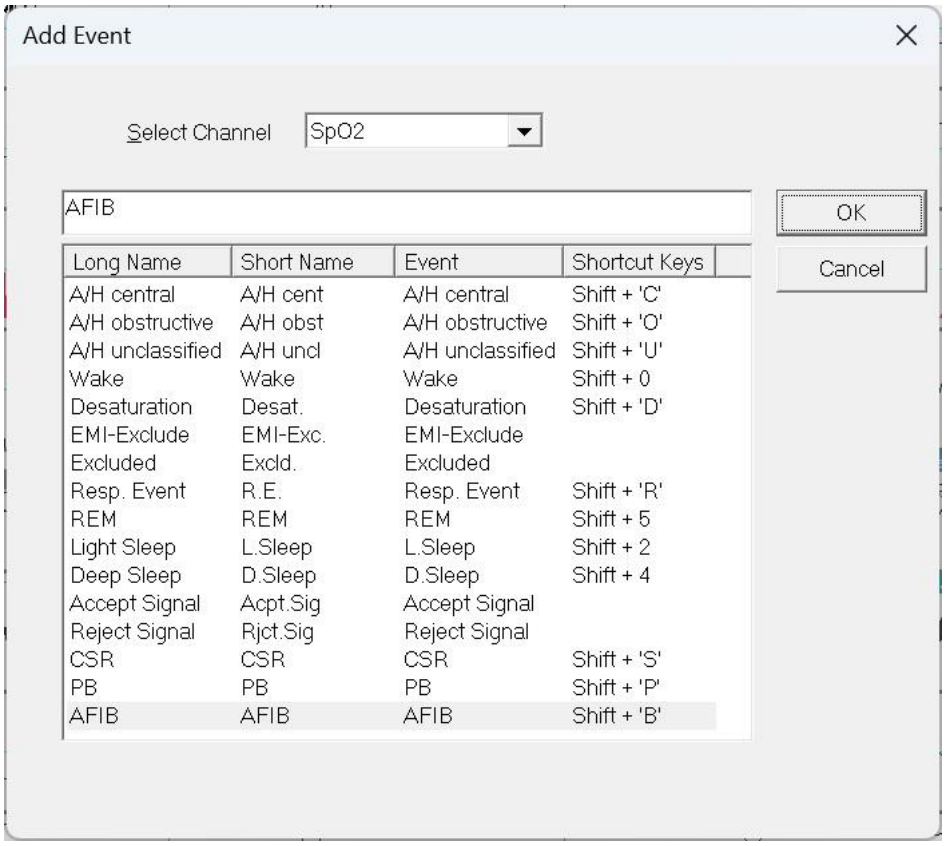


Figure 61 – Add Event dialog box

- '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).

4.5.4 Deleting an Event or Changing its Type

An event can be deleted by right clicking the event and selecting ‘Delete Event’. To delete an event and have the next event on the same channel highlighted, right click the event and select ‘Delete Event and Move to Next’. The timeline then moves so that the next event, now highlighted, is visible.

Note

Highlighting an event and pressing the ‘Delete’ key on the keyboard accomplishes the same action as right clicking the event and selecting ‘Delete Event and Move to Next’.

The ‘Delete Event and Move to Next’ option is not available for all events.

In Setup>User Settings>Options it is possible to define which event types will cause the timeline to move to and highlight the next event of the same type which was deleted.

If a segment is selected and the cursor is on a specific event, you may Delete all events of the same type in the segment. The Undo fuction may not be available after this operation (a message will indicate it before the operation starts).

An event can also be Replaced with another type of event by right clicking the event and select ‘Replace with’. If a segment is selected and the cursor is on a specific event, you may Replace all events of the same type in the segment with another type of event. The Undo fuction may not be available after this operation (a message will indicate it before the operation starts).

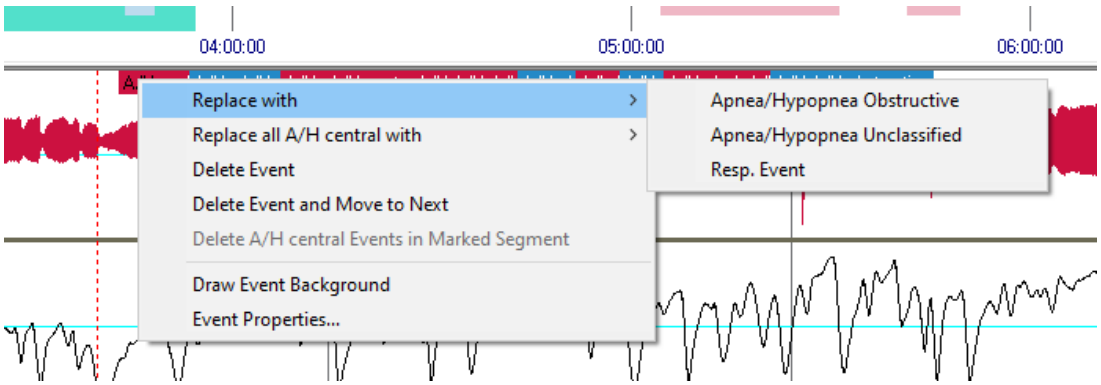


Figure 62 – Replace with option

If a segment is selected and the cursor is not on a specific event, you may Delete all events of the active signal in the segment.

	**Note** The “Replace with” operation is available for A/H and Resp. events on studies with RESBP sensor or for sleep stages.

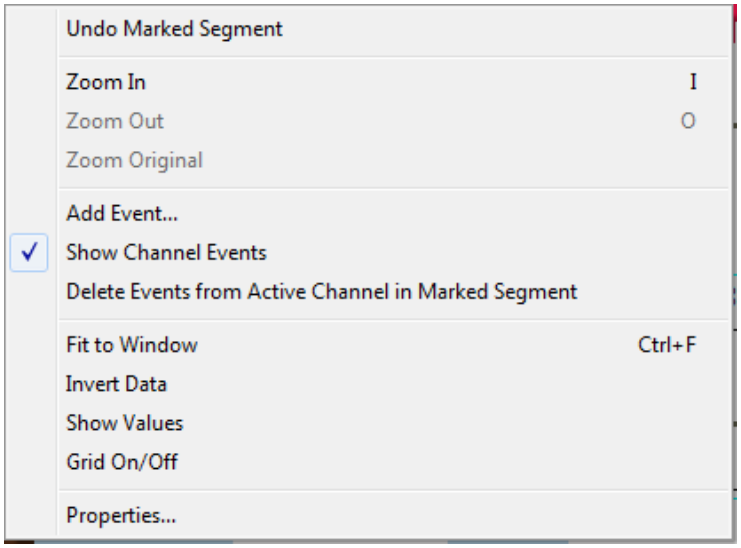


Figure 63 – Right Clicking Segment

	**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.

4.5.5 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:

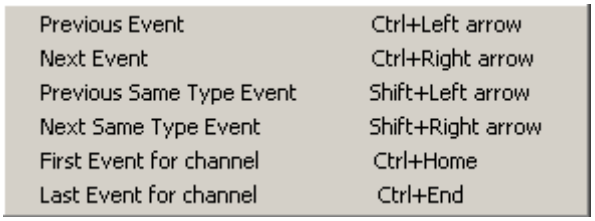


Figure 64 – Event Type Search options

4.5.6 Events>Select Event

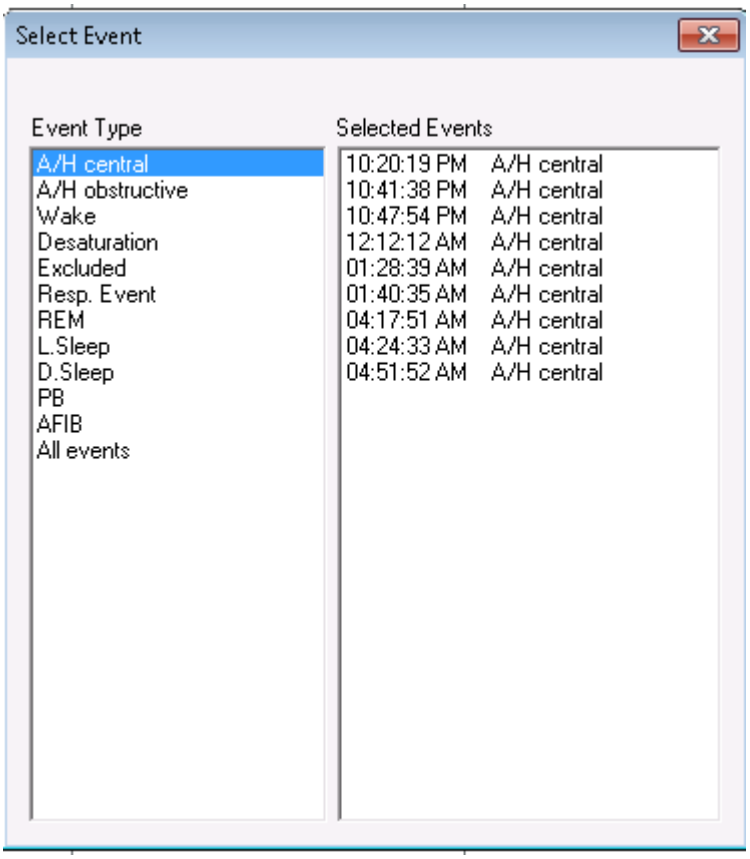


Figure 65 – Select Event dialog box

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.

4.5.7 Events>Remove Background from All Events

This option will remove the background from all events at once.

You may draw a background on any event type for easier viewing of event boundaries. In order to select this option you have to right click the event and select "Draw event Background" option. You may also remove the background from an event type by de-selecting the option.

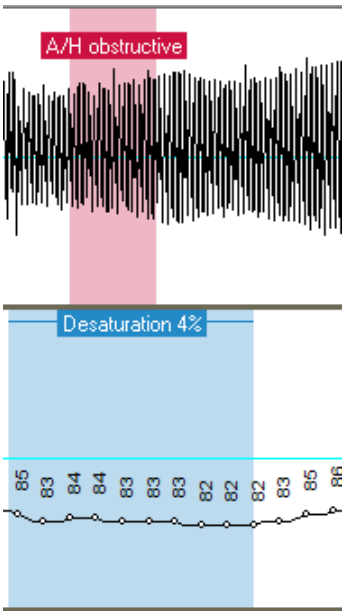


Figure 66 – Draw Background of Events

4.5.8 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 while on top of the sleep stage and then select a new sleep stage from the "Replace with" menu (see Figure 67)

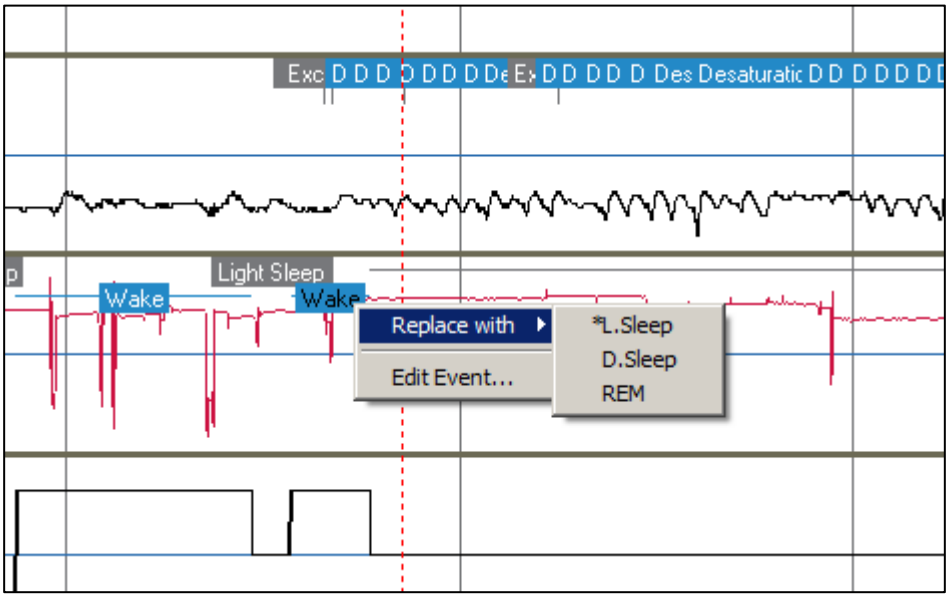


Figure 67 – Editing sleep stages

	**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:

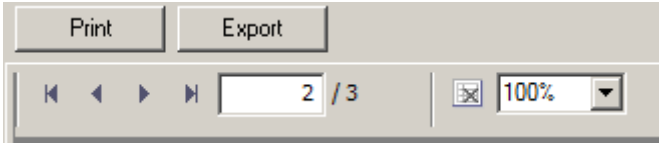


Figure 68 – Report Toolbar

- 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 69). 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 **'No AHI Central Statistics'** option to omit central apnea statistics in report.
- 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. If in General Settings the 'Verify user when pressing 'Set as Reported'' option is checked (see section 3.3.5), a pop-up window opens requiring the user to enter their user name and password before proceeding with adding the clinical diagnosis.
- Check **'Send to LIS'** 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 sent 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'.

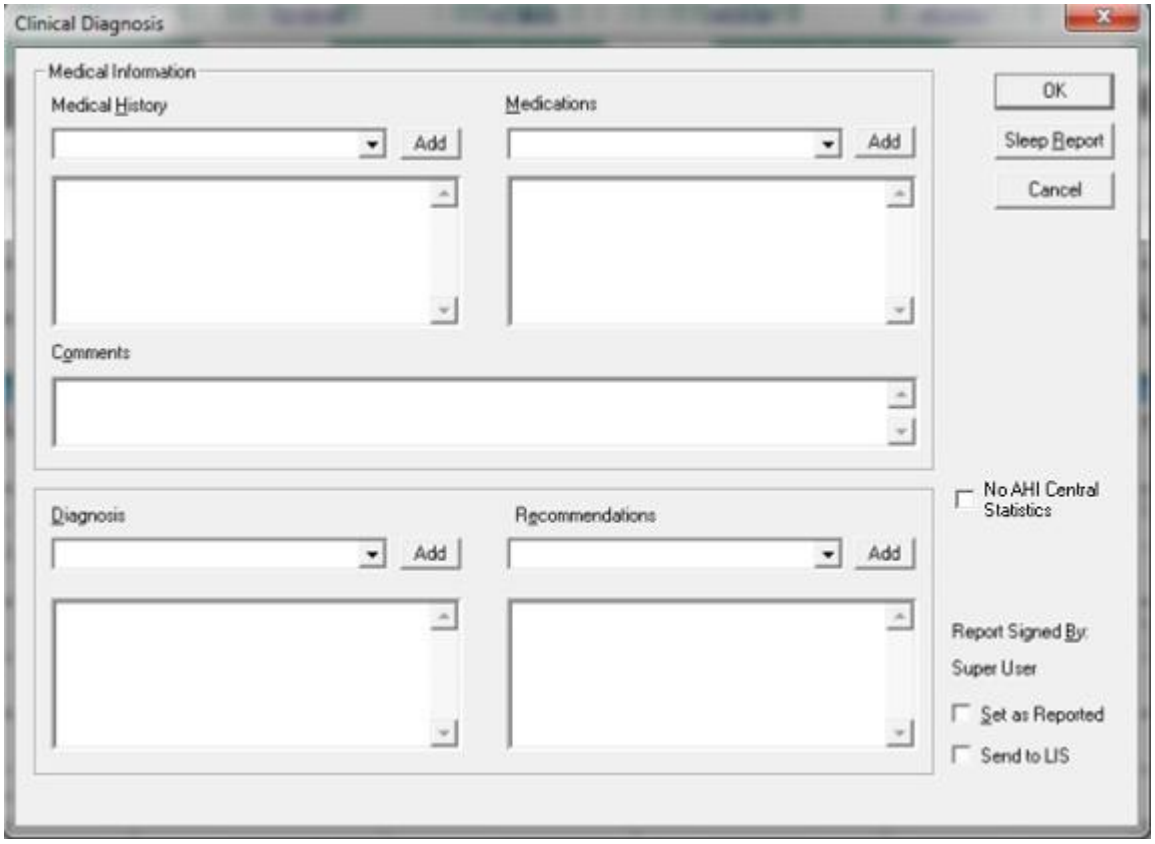


Figure 69 – Clinical Diagnosis dialog box

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:

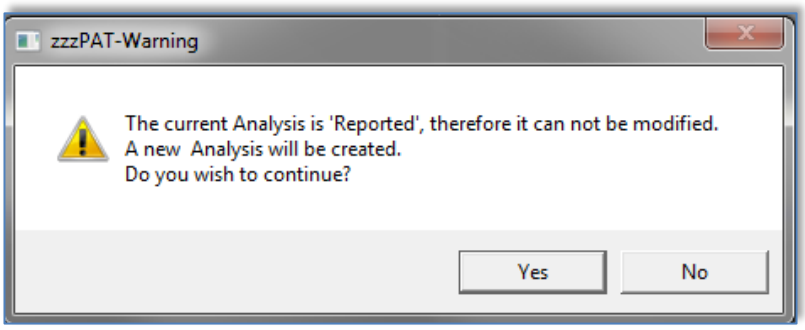


Figure 70 – New Analysis Warning message

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, four, or five-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 73 – First page of Sleep Report) includes Patient Information, the Sleep Study Information, Referring Physician, Medical history, Diagnosis and Recommendations.

The second page (Figure 74 – 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, Hypoxic Burden, Pulse Rate statistics, REM Sleep analysis, AHI Severity Graph, and Cardiac Rhythm Analysis table.

The third page (Figure 75 – Third page of Sleep Report) presents graphical displays of Respiratory Events, Snore and Body Position chart (in case a Snore/Body Position sensor was used), Oxygen Saturation, Pulse Rate (including distribution of the Pulse Rate and Raw Pulse Rate), PAT amplitude**,** Wake/Light Sleep/Deep Sleep and REM stages.

The fourth page (Figure 76 – Fourth page of Sleep Report) 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).

The fifth page (Figure 77 – Fifth Page of Sleep Report (Optional)) is an optional page which is not printed by default. To have this page printed, you must first select the option “Oximetry and Pulse Rate Histogram Page in Sleep Report” in General Settings (see section 3.3.7). The following oximetry and pulse rate histograms will be displayed on this page:

- Oxygen saturation distribution: Number of seconds for each oxygen saturation value
- Number of desaturation events for each oxygen saturation resaturation peak point
- Number of desaturation events for each desaturation depth
- Number of desaturation events for each minimum point at desaturation event (nadir)
- Pulse rate distribution: Number of seconds for each pulse rate value

If there is no valid sleep time, the histograms will be empty.

**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 (set value of 3% or 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.

Note

In the **Oxygen Saturation Statistics** section, the first column of the **Oxygen Destur. %** area will be titled “3-9” or “4-9”, depending on whether the ODI Index was set according to 3% or 4% (see section 3.3.6: Setup>General Settings>Analysis/Statistics Parameters).

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

Hypoxic Burden: The term hypoxic burden refers to a measure that quantifies the total impact of oxygen deprivation during sleep. This calculation takes into account both the frequency and severity of oxygen desaturation events, representing the accumulated deprivation of oxygen during sleep. The hypoxic burden is calculated based on two methods: (1) throughout sleep using a 90% oxygen saturation threshold , (2) based on desaturation events, referencing the pre-event oxygen saturation level.

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:

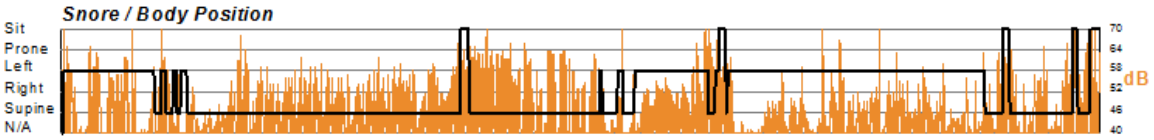


Figure 71 – Snoring and Body Position Statistics

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 section 3.3.5.

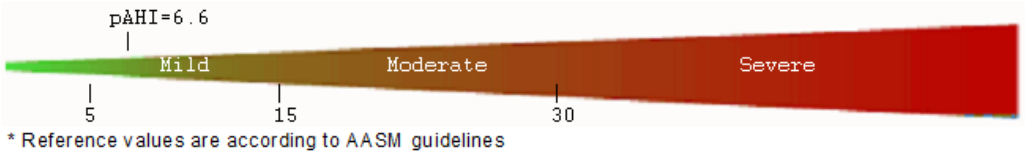
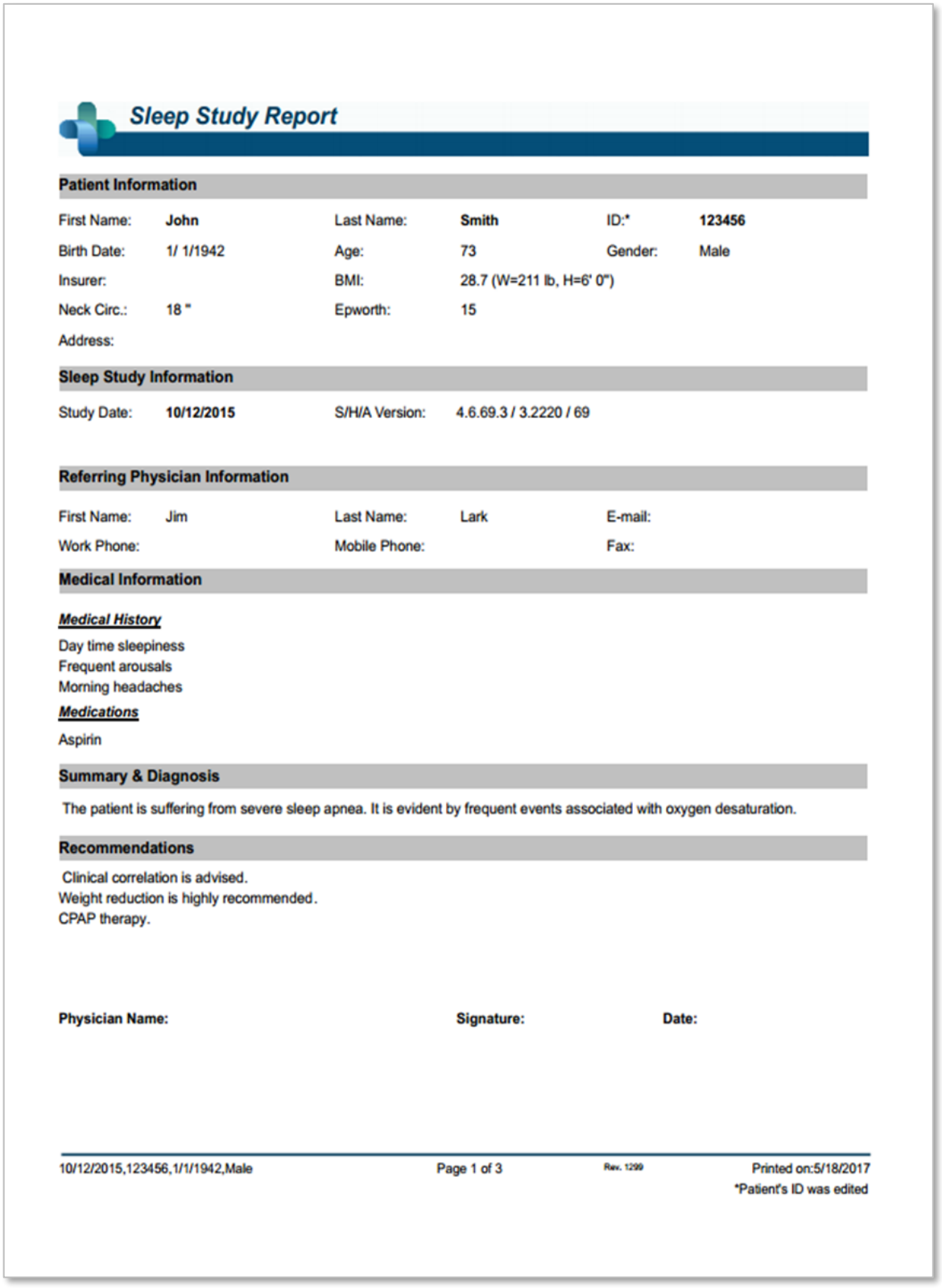


Figure 72 – AHI Severity Graph

Cardiac Rhythm Analysis: displays Premature Beats as Events per minute, and Suspected Atrial Fibrillation as Total Duration in Sleep and Longest Event Duration.

	**Note** In cases where the longest episode detected is shorter than 60 seconds, review of the PAT signal for irregularly irregular rhythm in the location of the episode is recommended.



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 73 – First page of Sleep Report

Sleep Study Report

Sleep Summary

Start Study Time:	10:17:05 PM
End Study Time:	7:11:47 AM
Total Recording Time:	8 hrs, 54 min
Total Sleep Time	**8 hrs, 14 min**
Indices are calculated using technically valid sleep time of	8 hrs, 7 min
% REM of Sleep Time:	22.4

Respiratory Indices

	Total Events	REM	NREM	All Night
pAHI 3%:	555	62.6	70.0	**68.4**
ODI 3%:	539	61.5	67.8	**66.4**
pAHI 4%:	495	59.9	61.3	**61.0**
ODI 4%:	472	58.7	58.0	**58.1**
pRDI:	559	63.7	70.3	**68.8**
pAHIc 3%:	73	5.5	10.2	**9.1**
pAHIc 4%:	71	5.0	10.0	**8.9**
% CSR:	0.0			

pRDI is calculated using oxi desaturation ≥ 3%

Indices are calculated using technically valid sleep time of 8 hrs, 7 min. Central-Indices are calculated using technically valid sleep time of 7 hrs, 58 min.

Oxygen Saturation Statistics

Mean:	91	Minimum:	60	Maximum:	99
Mean of Desaturations Nadirs (%):					86

Oxygen Desatur. %:	**3-9**	**10-20**	**>20**	**Total**
Events Number	282	218	39	539
Total	52.3	40.4	7.2	100.0

Oxygen Saturation	**<90**	**<=88**	**<85**	**<80**	**<70**
Duration (minutes):	127.7	110.5	62.3	28.2	2.7
Sleep %	25.8	22.3	12.6	5.7	0.5

Hypoxic Burden (% x min)	**TST**	**Per hour**
Desaturation area under SpO2 baseline	1909	235
Area under 90% SpO2	870	107

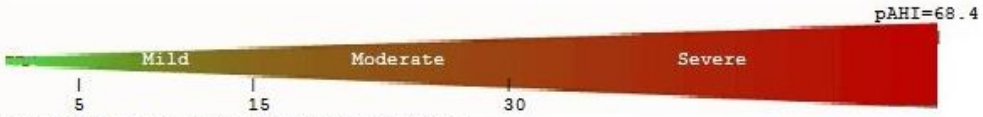
Pulse Rate Statistics during Sleep (BPM)

Mean:	86	Minimum:	67	Maximum:	114

Cardiac Rhythm Analysis In Sleep

Suspected Atrial Fibrillation (h:mm:ss)	
Total duration	Not detected
Longest event duration	Not detected
Premature beats	
Events per min	<0.1

Events are calculated using technically valid sleep time of 8 hrs, 13 min.



* Reference values are according to AASM guidelines

Figure 74 – Second page of Sleep Report

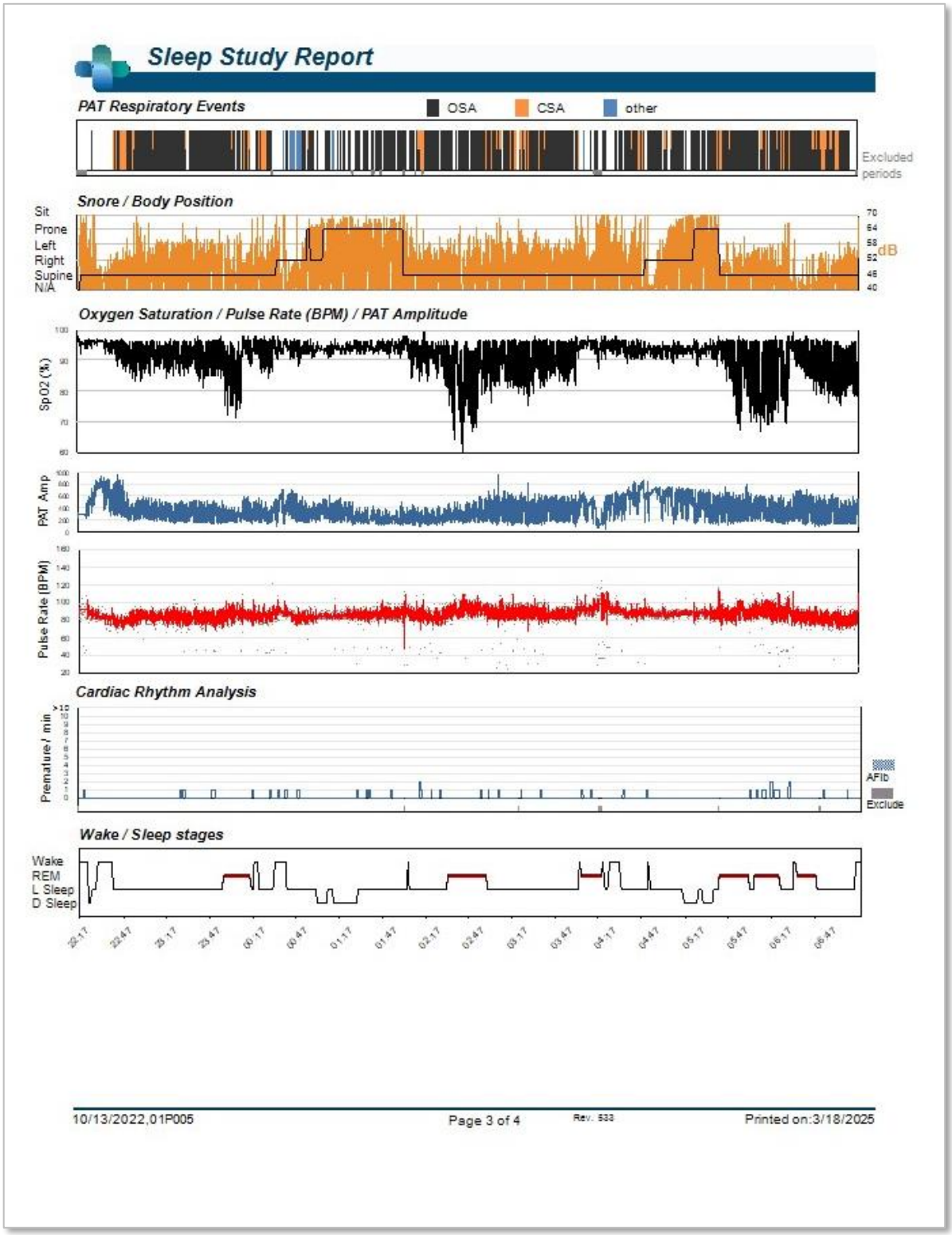
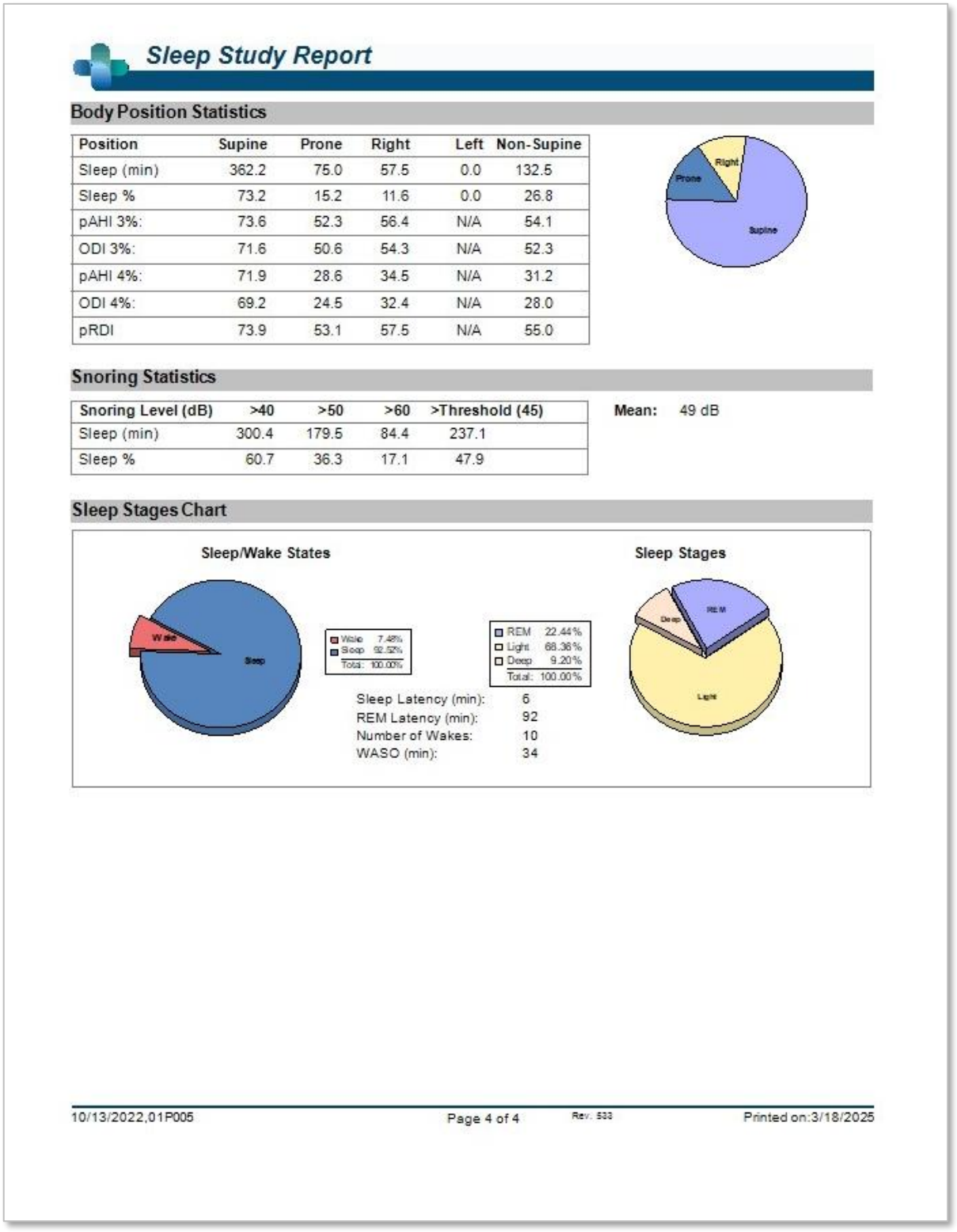


Figure 75 – Third page of Sleep Report



Sleep Study Report

Body Position Statistics

Position	Supine	Prone	Right	Left	Non-Supine
Sleep (min)	362.2	75.0	57.5	0.0	132.5
Sleep %	73.2	15.2	11.6	0.0	26.8
pAHI 3%:	73.6	52.3	56.4	N/A	54.1
ODI 3%:	71.6	50.6	54.3	N/A	52.3
pAHI 4%:	71.9	28.6	34.5	N/A	31.2
ODI 4%:	69.2	24.5	32.4	N/A	28.0
pRDI	73.9	53.1	57.5	N/A	55.0

Snoring Statistics

Snoring Level (dB)	>40	>50	>60	>Threshold (45)
Sleep (min)	300.4	179.5	84.4	237.1
Sleep %	60.7	36.3	17.1	47.9

Mean: 49 dB

Sleep Stages Chart

Sleep Latency (min): 6
REM Latency (min): 92
Number of Wakes: 10
WASO (min): 34

Figure 76 – Fourth page of Sleep Report

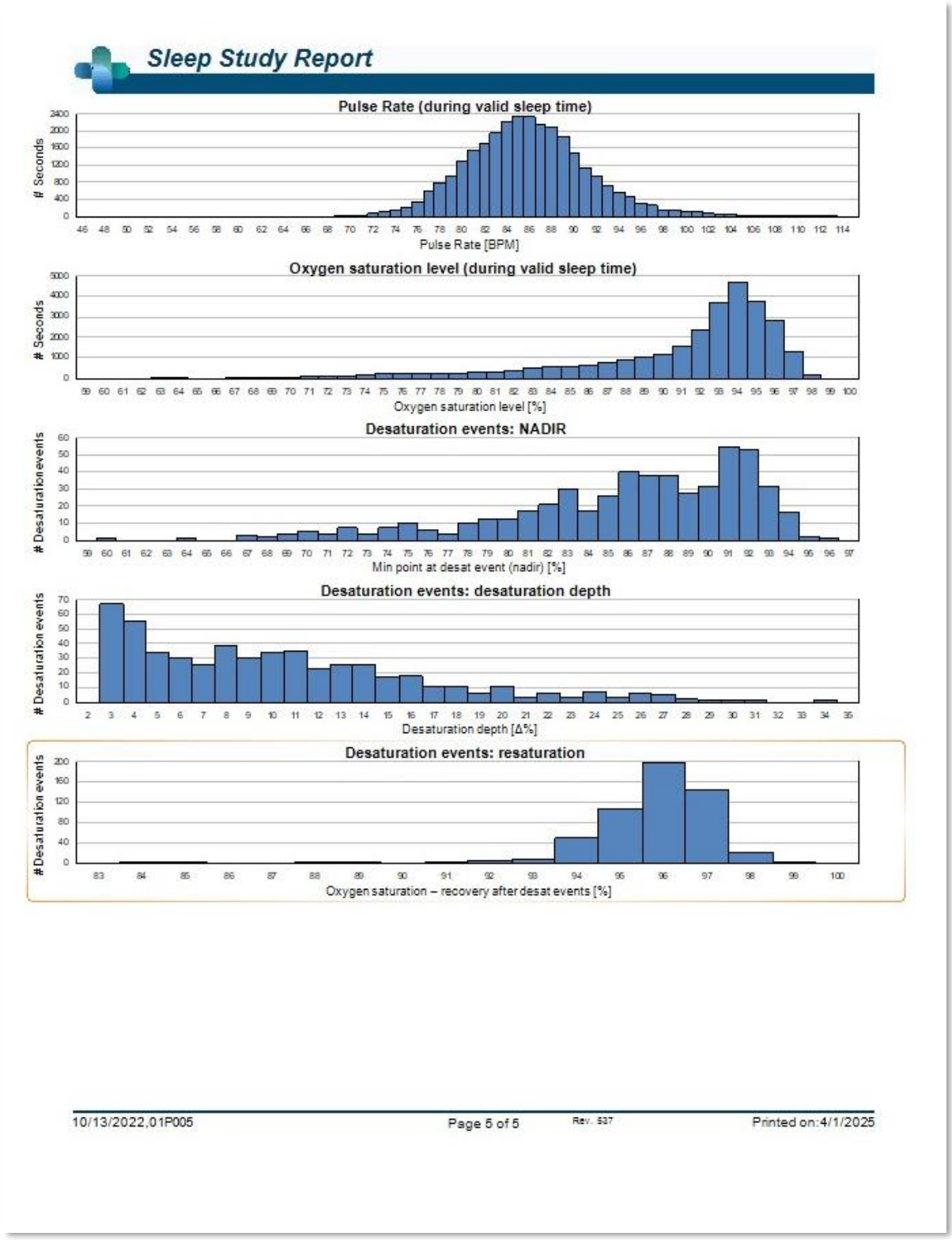


Figure 77 – Fifth Page of Sleep Report (Optional)

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 78 – 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, REM Sleep analysis and AHI Severity Graph.
The third page presents graphical displays of Respiratory Events, Oxygen Saturation, Pulse Rate, PAT amplitude**,** Wake/Light Sleep/Deep Sleep and REM stages, Snore and Body Position chart (in case a Snore/Body Position sensor was used).
The fourthpage presents 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.

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

4.6.4 Report>Sleep Indices

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

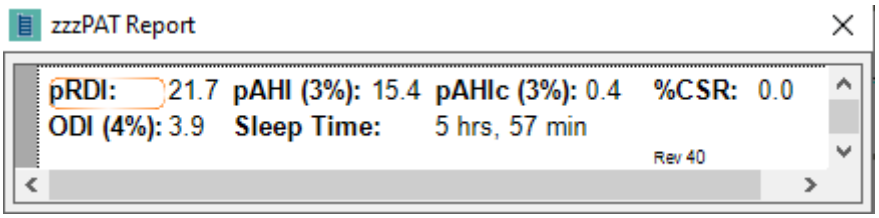


Figure 79 – Sleep Indices report

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

4.6.5 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.

Note

The zzzPAT installation will install 3 patientletter.ini files: one for male, one for female, and the default currently used. If the patient's gender is defined, then the relevant template will be displayed when producing the patient report in a language which has gramatical gender; however, if the patient's gender is not defined then the "male" template will be displayed.

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 80 – Report for Patient

4.6.6 Report > Detailed Report

This report's first page is the same as the first page of the sleep report (see Figure 73). The rest of the report's pages present graphical displays of Respiratory Events, Snore and Body Position chart (in case a Snore/Body Position sensor was used), Oxygen Saturation, Pulse Rate, PAT amplitude, Wake/Light Sleep/Deep Sleep and REM stages. Each page represents one hour of sleep time.

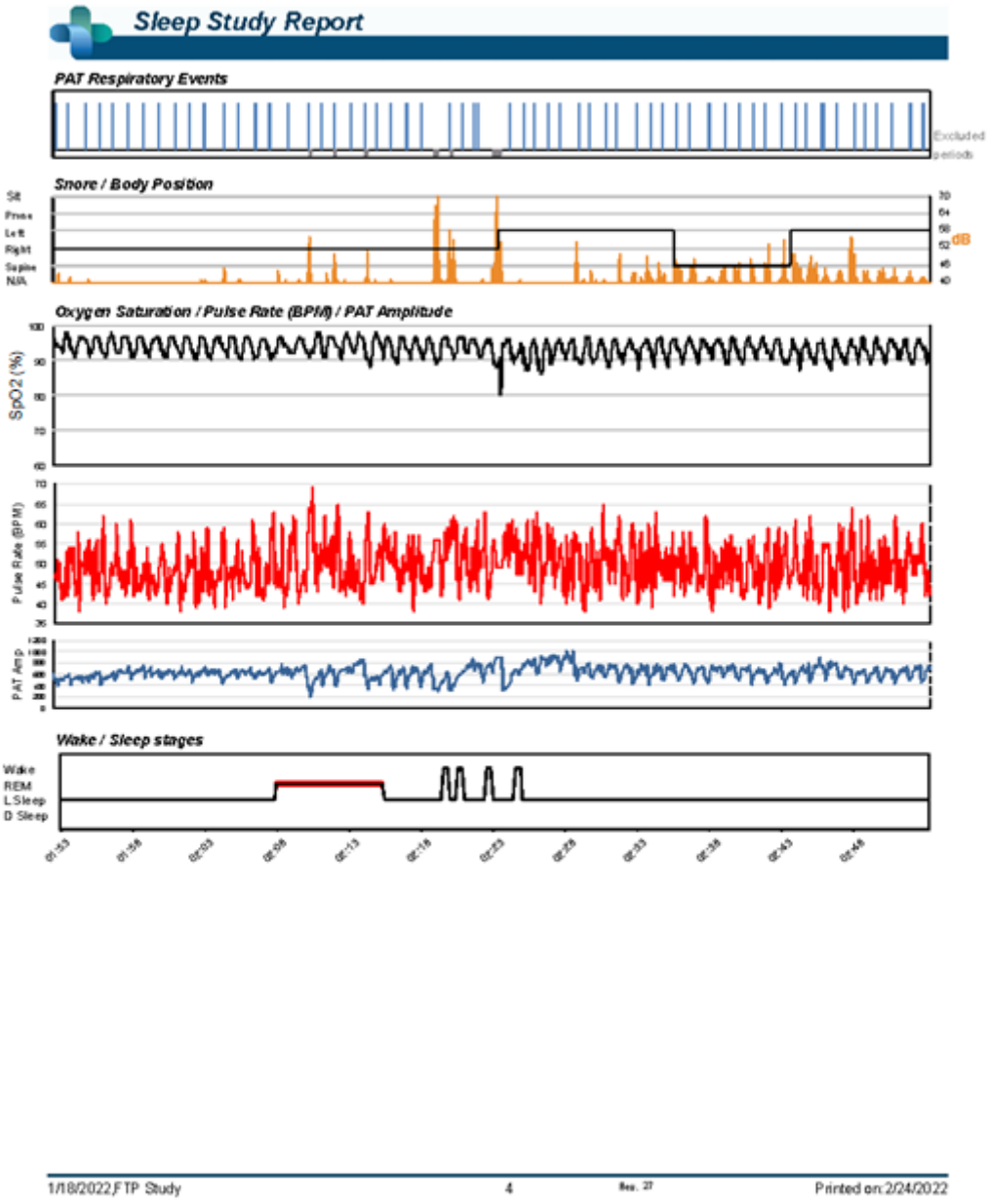


Figure 81 – Sample Page from Detailed Report

4.6.7 Report > Multi-night Summary Report

This summary report presents multi-night sleep statistics. It is enabled only if the currently opened study contains WatchPAT™ ONE multi-night data (see section 4.1.2.2 regarding preparing a new WatchPAT™ ONE study with multi-nights option selected). The report includes up to 3 studies (one study per column), each with the same WatchPAT™ ONE device information and patient statistics information. A column with averages of the studies' values (see below) is also included.

Note

If there are less than three nights in the study set, the remaining night's columns will be empty.

AHI/ODI is displayed as either 3% or 4%.

In the Average column, AHI/ODI values will consist of the average of just the nights with the same AHI/ODI configuration. For example, given a three-night study with the following AHI/ODI values: Study1 - AHI3%/ODI3%; Study2 - AHI3%/ODI3%; Study3 - AHI3%/ODI4%. The average column will be of Study1 and Study2 only, and the Average heading will indicate "AHI3%/ODI3%". In the rest of the Average column, average values will be computed from available nightly values, and N/A values will be ignored. If all nightly values are N/A, the average will be empty.

Note

Usually the AHI/ODI percent configuration is defined once per site and would thus be the same for all the studies.

Sleep Summary

Night #	1	2	3	Average
Study Date	11/03/2014	12/03/2014	13/03/2014	
Oxygen Desatur. %	AHI 3%, ODI 3%	AHI 3%, ODI 3%	AHI 3%, ODI 3%	AHI 3%, ODI 3%
Start Study Time	23:34:56	23:23:19	23:31:13	
End Study Time	9:20:08	9:08:31	8:11:02	
Total Recording Time	9 hrs, 45 min	9 hrs, 45 min	8 hrs, 39 min	9 hrs, 23 min
Total Sleep Time	8 hrs, 26 min	7 hrs, 46 min	7 hrs, 34 min	7 hrs, 55 min
Sleep Latency (min)	6	5	20	10
REM Latency (min)	226	261	53	180
pRDI	9.3	9.8	12.8	10.6
pAHI	0.7	1.3	0.7	0.9
ODI	0.7	1.3	0.7	0.9
REM/NREM pRDI	19.2 / 6.5	20.6 / 6.7	24.3 / 9.0	21.4 / 7.4
REM/NREM pAHI	2.2 / 0.3	3.9 / 0.6	1.1 / 0.5	2.4 / 0.5
REM/NREM ODI	2.2 / 0.3	3.9 / 0.6	1.1 / 0.5	2.4 / 0.5
pAHIc				
REM/NREM pAHIc				
% CSR				
Oxygen Saturation Statistics (%)				
Mean	97	97	97	97
Minimum /Maximum	95 / 100	93 / 99	95 / 100	94 / 99
Mean of Desaturations Nadirs	96	96	96	96
Oxygen Saturation Duration (minutes) / Sleep %				
<90	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0
<=88	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0
<85	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0
<80	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0
<70	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0
Oxygen Desatur. Events Number / Sleep %				
3|4 - 9	0 / 0.0	0 / 0.0	0 / 0.0	0 / 0.0
10 - 20	0 / 0.0	0 / 0.0	0 / 0.0	0 / 0.0
> 20	0 / 0.0	0 / 0.0	0 / 0.0	0 / 0.0
Pulse Rate (BPM)				
Mean	61	61	61	61
Minimum /Maximum	43 / 107	41 / 105	39 / 99	41 / 103
Sleep Stages (%)				
REM	21.6	20.1	25.0	22.2
Light	56.8	55.3	53.7	55.3
Deep	21.6	24.7	21.3	22.5
Sleep %	86.5	79.7	87.4	84.5
SnoringDuration (minutes) / Sleep %				
> Threshold (0)				
Mean (dB)				
Body Position Statistics				
Supine Duration (minutes) / %				
Non-Supine Duration (minutes) / %				
Prone Duration (minutes) / %				
Right Duration (minutes) / %				
Left Duration (minutes) / %				
Supine pAHI / pRDI / ODI				
Non-Supine pAHI / pRDI / ODI				
Prone pAHI / pRDI / ODI				
Right pAHI / pRDI / ODI				
Left pAHI / pRDI / ODI				

Figure 82 – Multi-night Summary Report

4.6.8 Printing

The study signals recorded by the WatchPAT™ 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

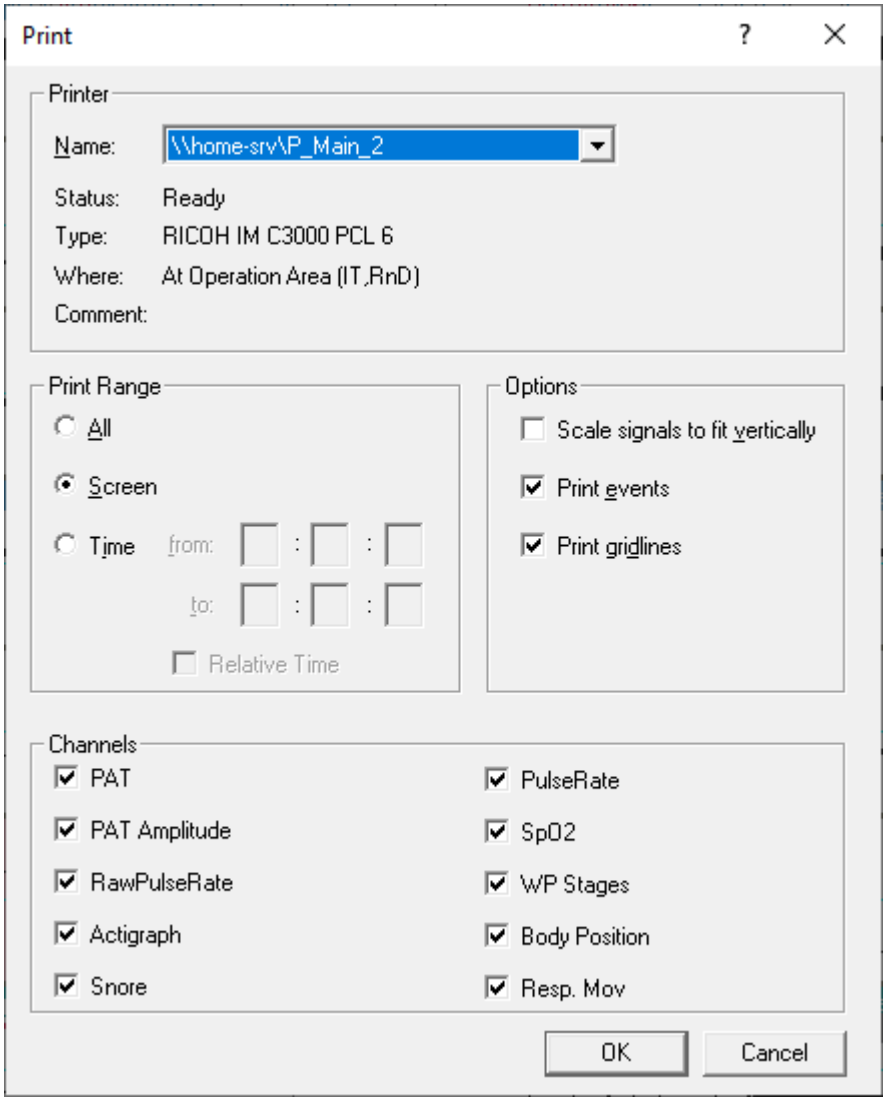


Figure 83 – Print dialog box

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.
The export data as “second by second CSV” creates a comma separated file with one line per each second of the study. The file contains information about the sleep stages, SpO2, pulse rate, snore level, body possition, PAT amplitude, different events type and the analysis excluded times in each second.

Note

The pulse rate in this format is multiplied by 100, so 6000 stands for 60 pulse per minutes.

SpO_2 level of 127 indicates a non read at that second.

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 Tools>Export General Settings.

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..

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...**

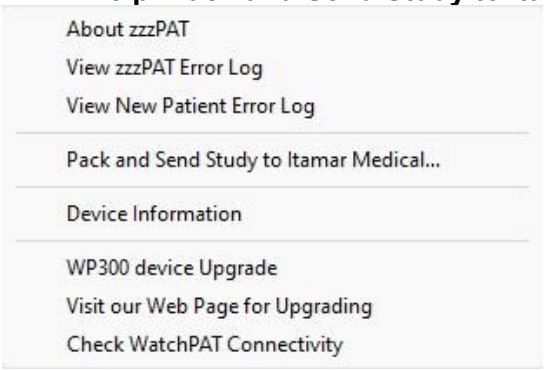


Figure 84 – Launching Transfer Files

The following dialog box appears:

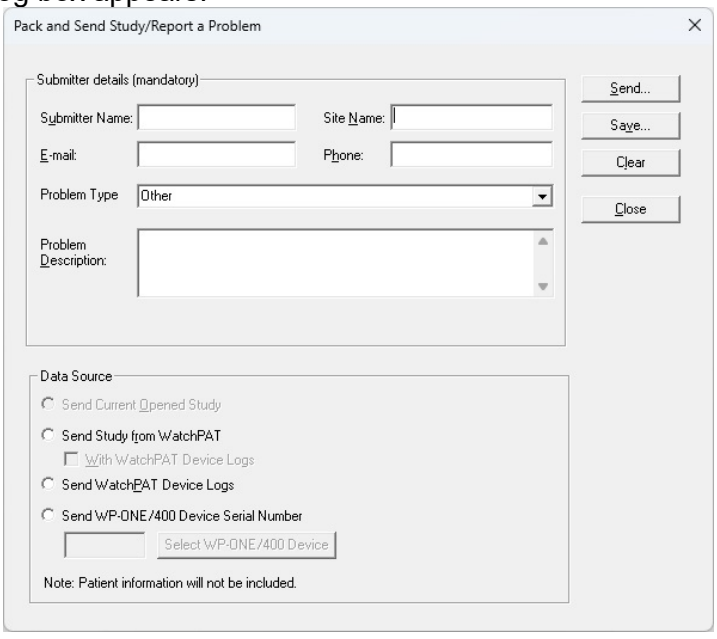


Figure 85 – Prepare and Send Study Dialog Box

- The last entered information is shown by default. Select **Clear** to clear all fields
- Fill in the mandatory fields
- Select the relevant problem type from the dropdown list:

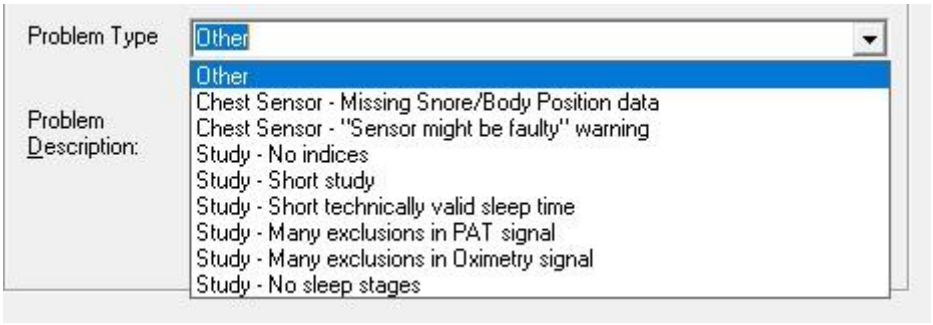


Figure 86 – List of Problem Types

- 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.
  - WatchPAT™ 300: Check **Send Study From WatchPAT** if the case study is stored in the WatchPAT™.
  - WatchPAT™ 300: Check **Send WatchPAT Device Logs** in case the internal logs from the WatchPAT™ device needs to be sent to Itamar for troubleshooting.
  - WatchPAT™ ONE/WatchPAT™ 400: Check **Send WP-ONE/400 Device Serial Number** for any inquiry.

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

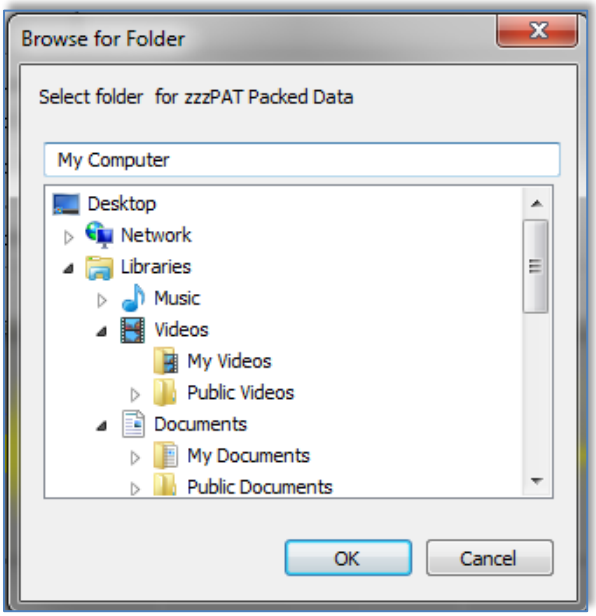


Figure 87 – Saving Case Study

- 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:

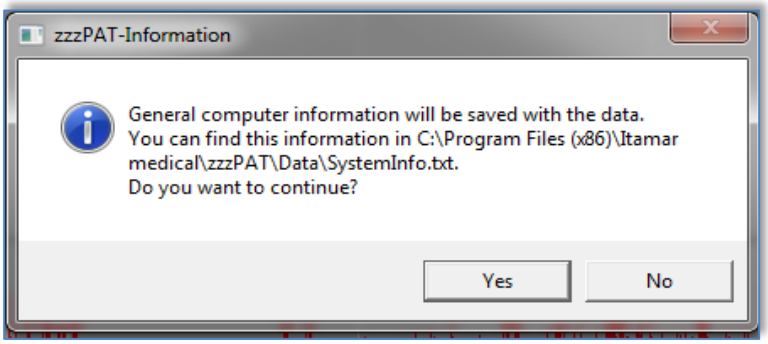


Figure 88 – Sending Study confirmation

  - 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:

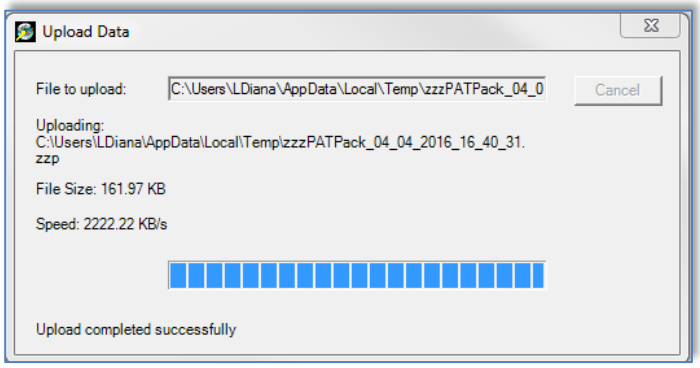


Figure 89 – Data Transfer Progress

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

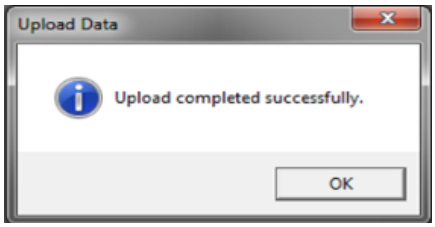


Figure 90 – Data Transfer Successfully Completed

- 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 file and transfer it manually by your preferred method.

5.7 Displaying WatchPAT™ Device Information (WatchPAT™ 300)

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 from device firmware version >2.2191 or above)
- Probe S/N (supported from device firmware version >2.2191 or above)
- Device S/N

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

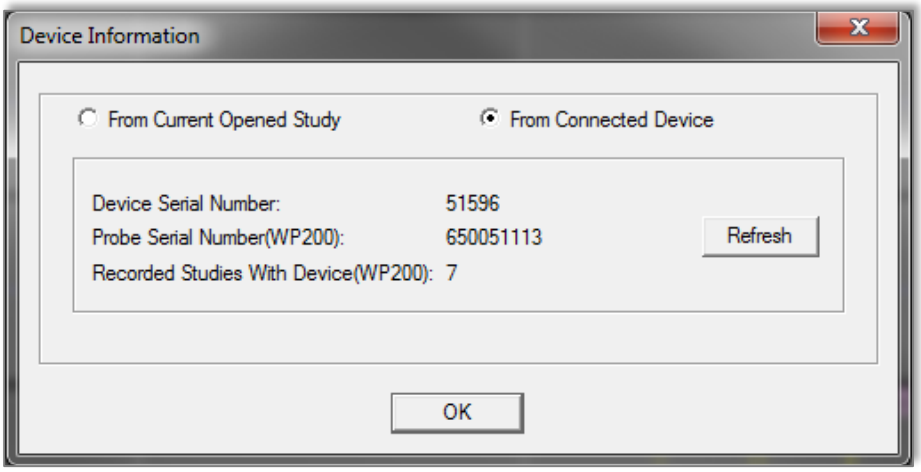


Figure 91 – Device Information Dialog Box

5.8 Upgrading WatchPAT™ Device firmware (WatchPAT™ 300)

Every time a study is loaded into zzzPAT, the software compares the current firmware version number on the device with the latest firmware version number which appears online. If they are not the same (i.e., the firmware on the device is outdated), the following pop-up message appears:

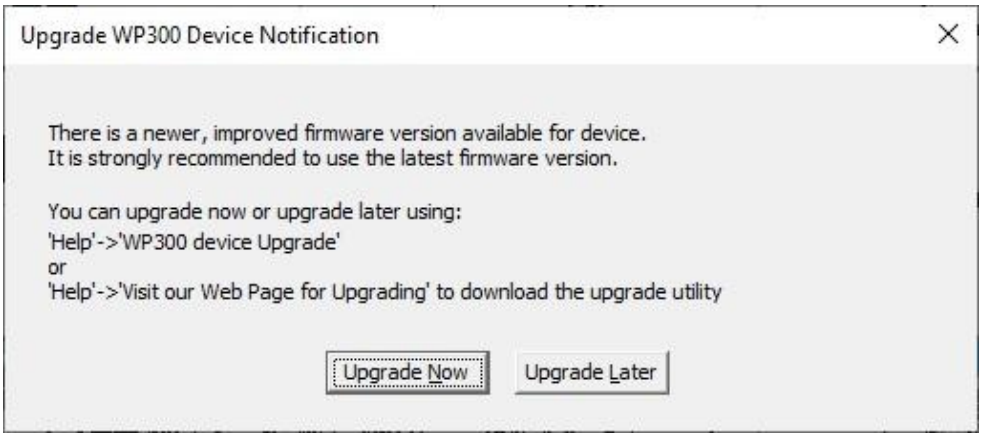


Figure 92 – Device Information Dialog Box

You can either click the **Upgrade Now** button to upgrade the firmware at that moment, or the **Upgrade Later** button to upgrade the firmware at a later time.

Another option for upgrading WatchPAT™ 300 firmware is to click **Help>Wp300 device upgrade**.

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 opens:

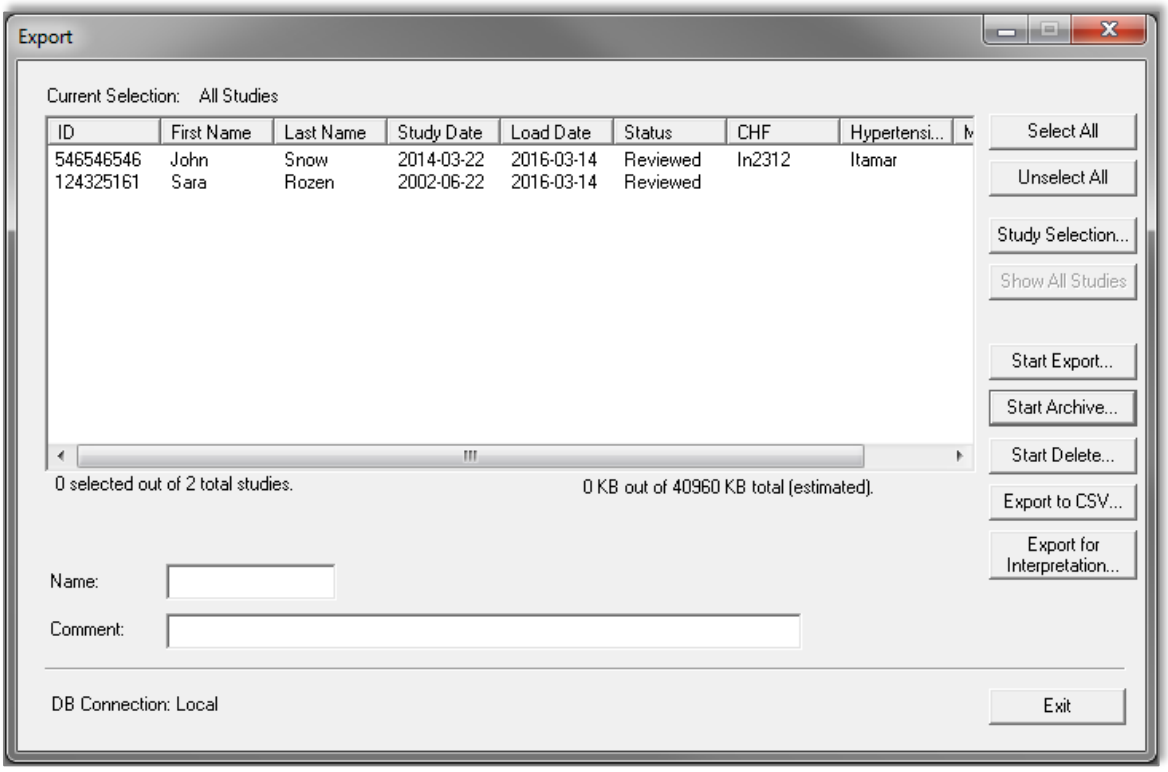


Figure 93 – Export Dialog box

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 94 .
- 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.

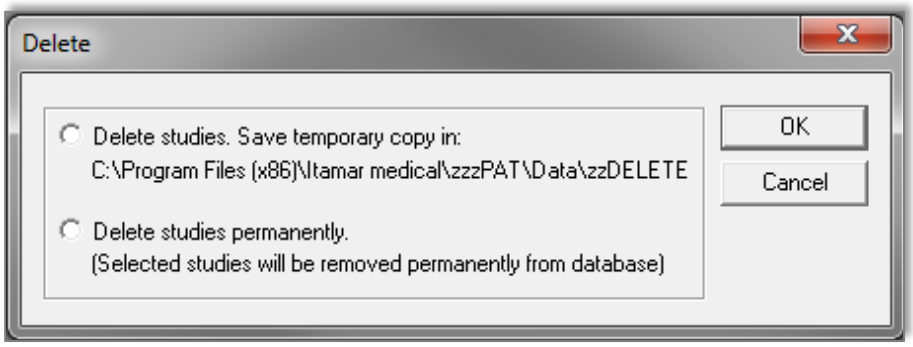


Figure 94 – Delete studies options Dialog box

- 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 opens:

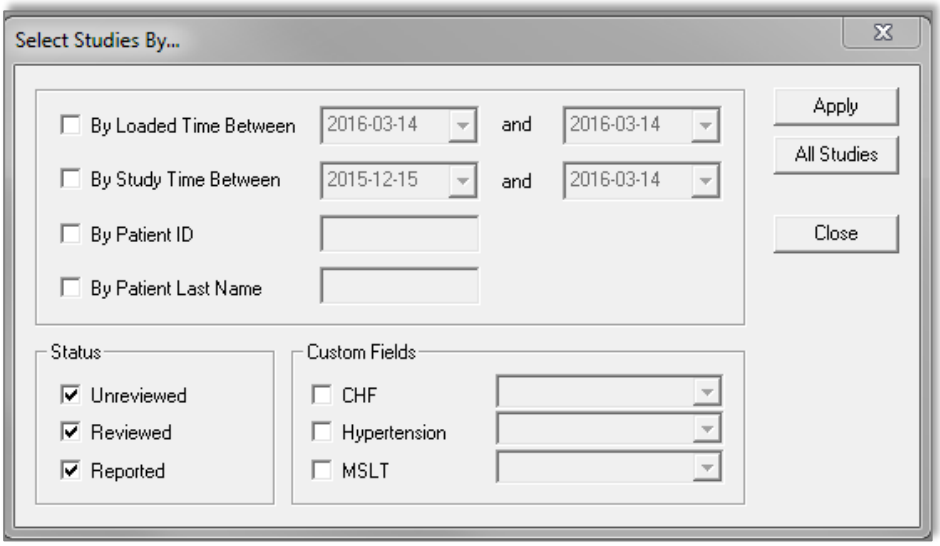


Figure 95 – Study Selection Dialog box

- 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 opens.

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 2.6.2).

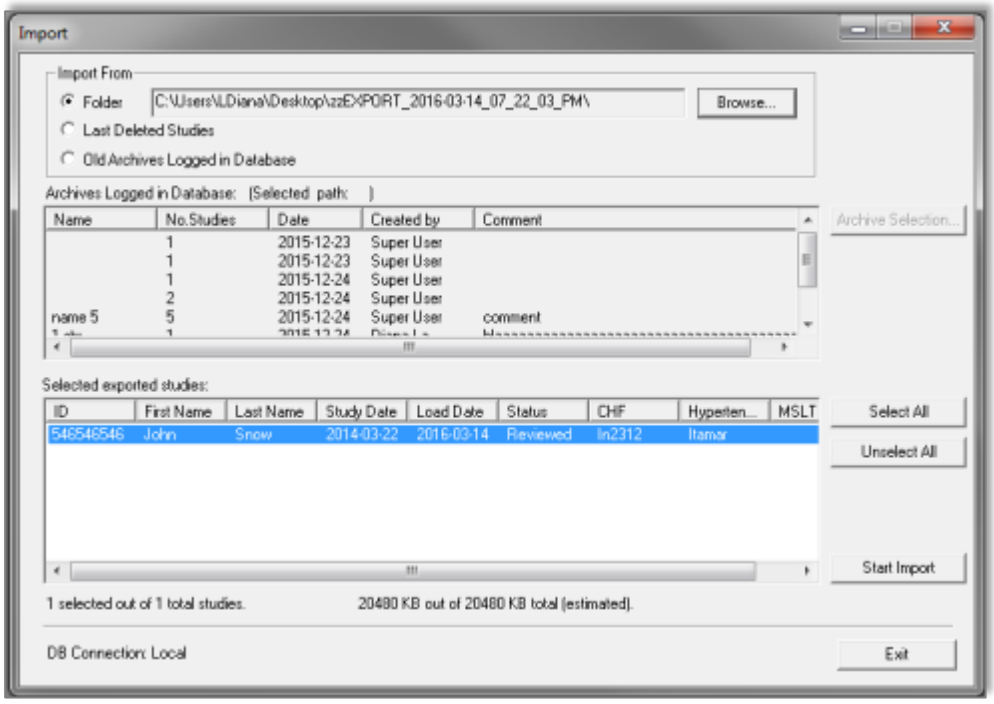


Figure 96 – Import Dialog Box

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 opens:

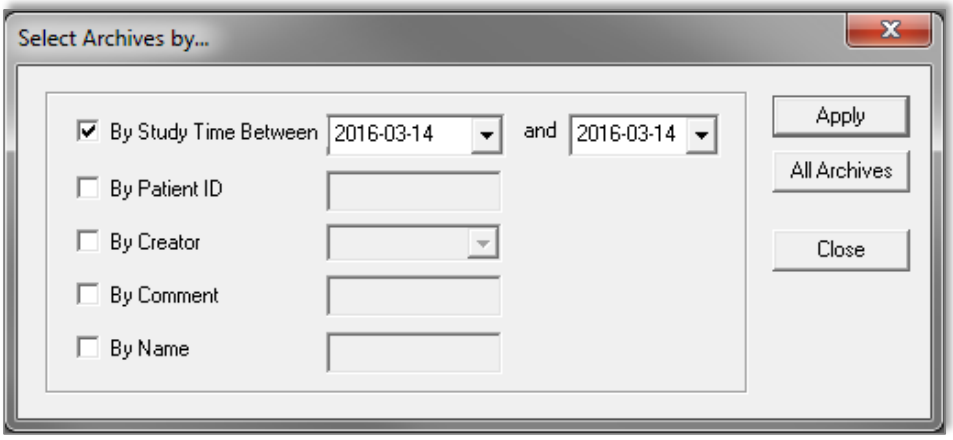


Figure 97 – Select Archive Dialog box

- 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 opens.

- 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 up 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 opens.

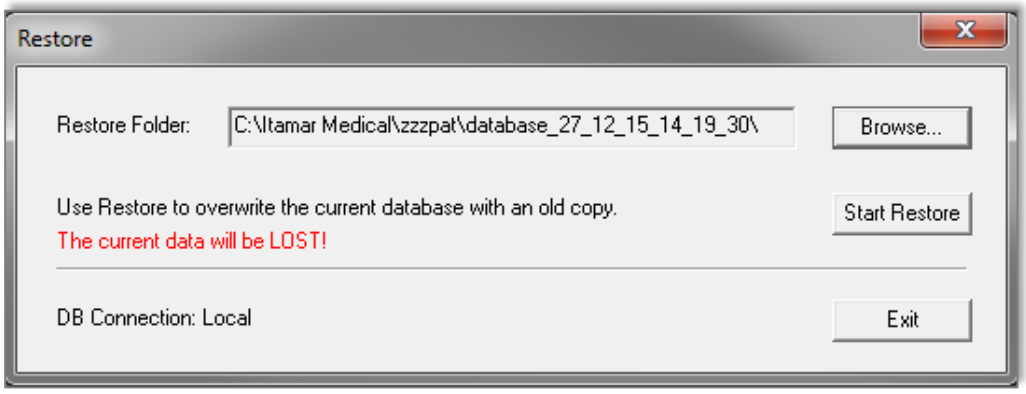


Figure 98 – Restore Dialog box

	**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.

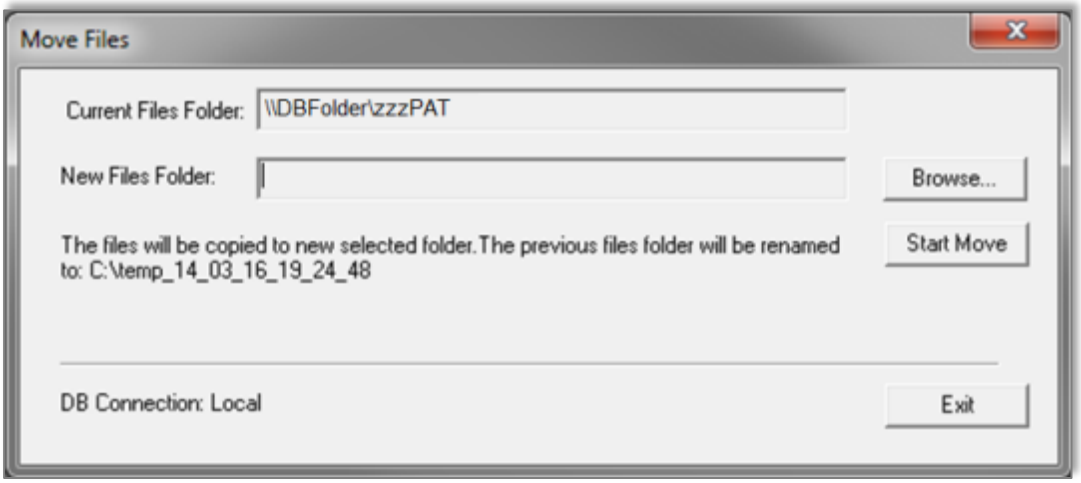


Figure 99 – Move Files dialog box

"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

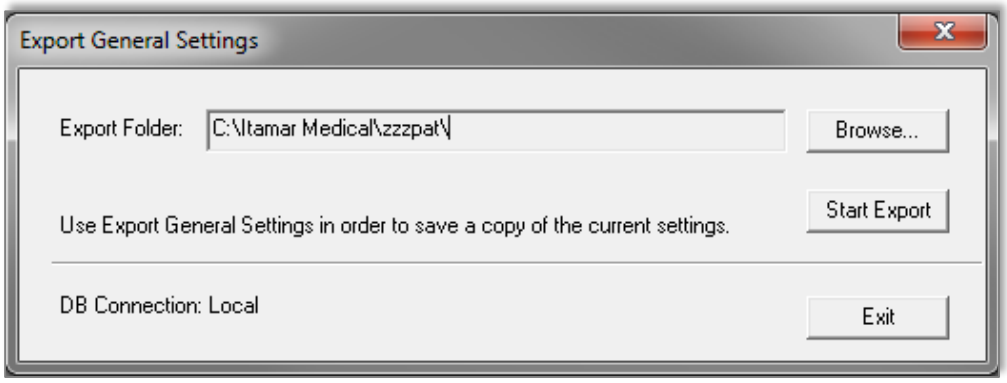


Figure 100 – Export General Settings Dialog Box

- 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

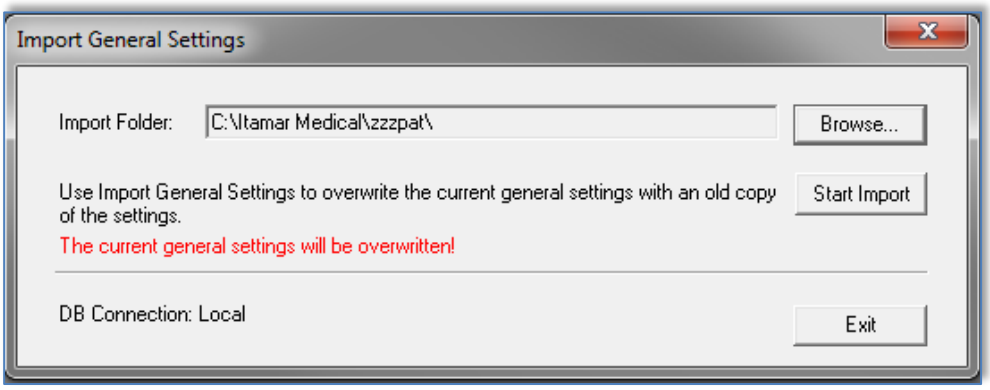


Figure 101 – Import General Settings Dialog Box

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 2.6.2

6.9 Tools>Export Activity log

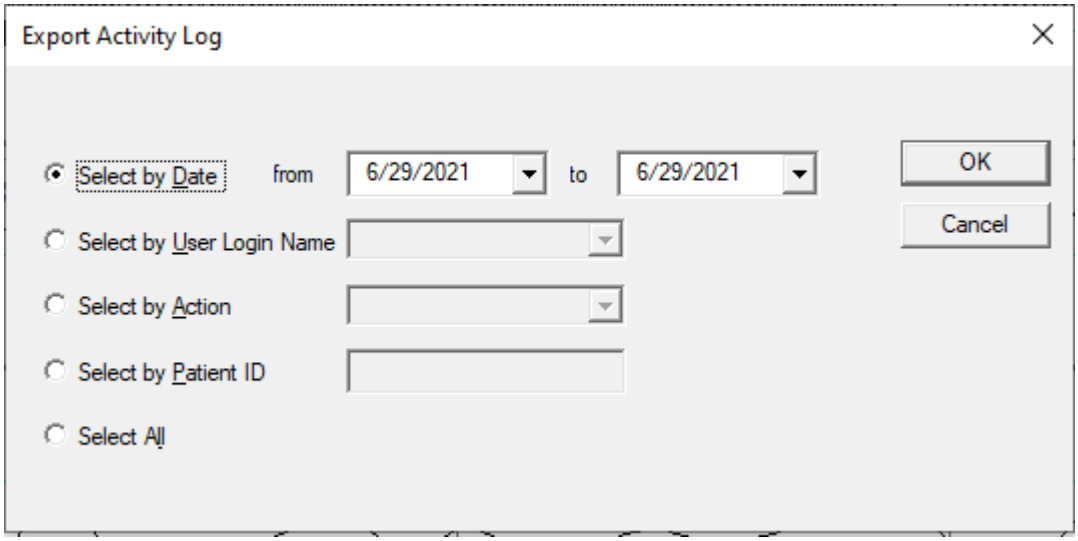


Figure 102 – Export Activity log window

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.

6.10 For WatchPAT™ ONE/WatchPAT™ 400: Tools>Manage WatchPAT One Registered Devices…

On selecting this option, a dialog will display all registered devices that were not yet uploaded to zzzPAT.

- The dialog will present a list of registered devices with Patient ID, First and Last names, Registration date, Pin number and device Serial number information (see Figure 103)
- "Reset Retries Counter" - resets retries counter for any device in the list
- "Hide Registered Device" – hides selected device in the registered devices list
- "Show Hidden Registered Devices" - displays a list of all hidden devices from the list in order to select the one device to bring it back to the list (see Figure 104)

- "Unhide Registered Device" – makes selected device visible in the registered devices list
- "Show Registered Devices" - displays a list of all visible devices in the registered devices list
- "Unregister device" – unregisters a WatchPAT™ ONE/WatchPAT™ 400 device that was registered but was not used for recording. An unregistered device can be registered again.
- "Send Request to Itamar Medical…" – sends an information request to itamar Medical support for this WatchPAT™ ONE/WatchPAT™ 400 device. Selecting this option opens the "Pack and Send Study" dialog where the problem can be described before the inquiry is sent, see 5.6.

Note

It is possible to search for patients using the Patient ID, and for devices using the Device SN.

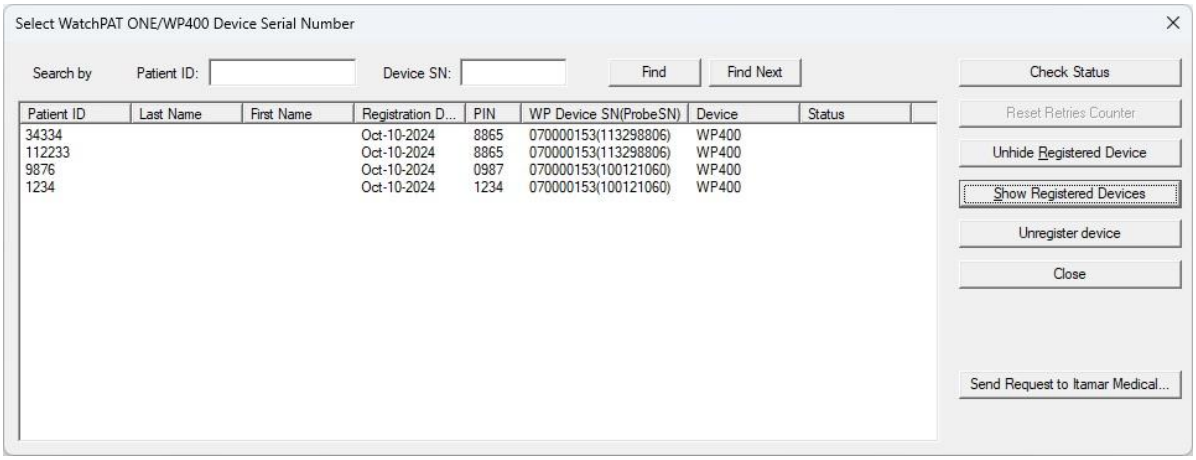


Figure 103 – Manage WatchPAT™ ONE/WatchPAT™ 400 registered devices window – visible in the list

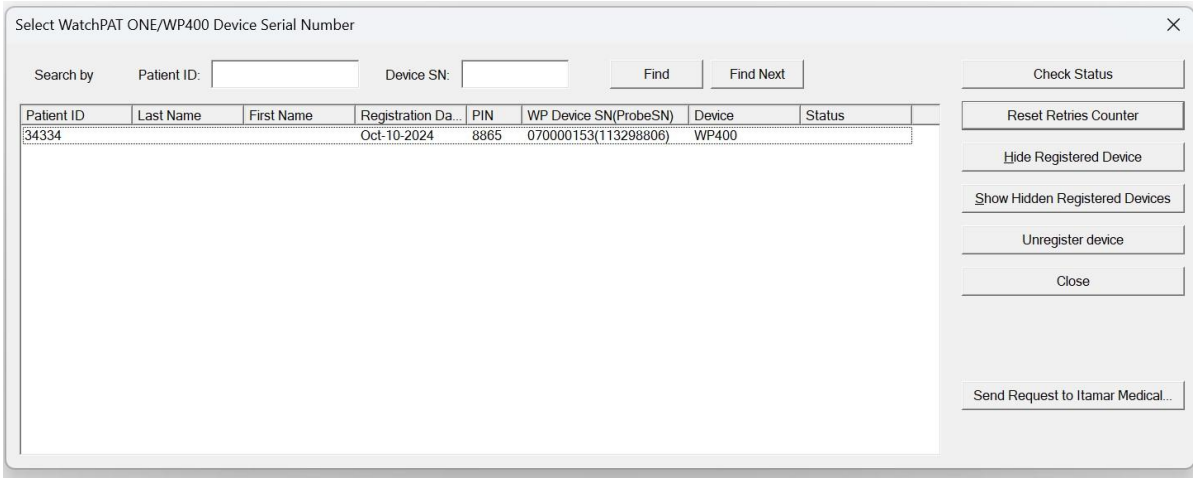


Figure 104 – Manage WatchPAT™ ONE/WatchPAT™ 400 registered devices window – hidden from the list

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 105 – Database Wizard Login

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

7.1 Database Tools

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

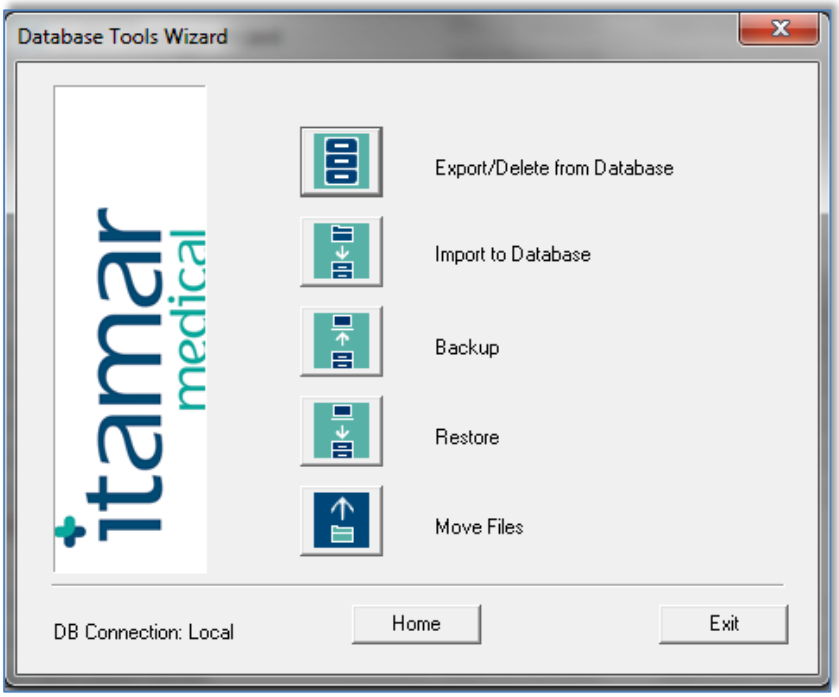


Figure 106 – Database Tools Wizard dialog box

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 2.6

7.3 Configuration Tools

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

Click the configuration tools Icon  . The following screen appears:

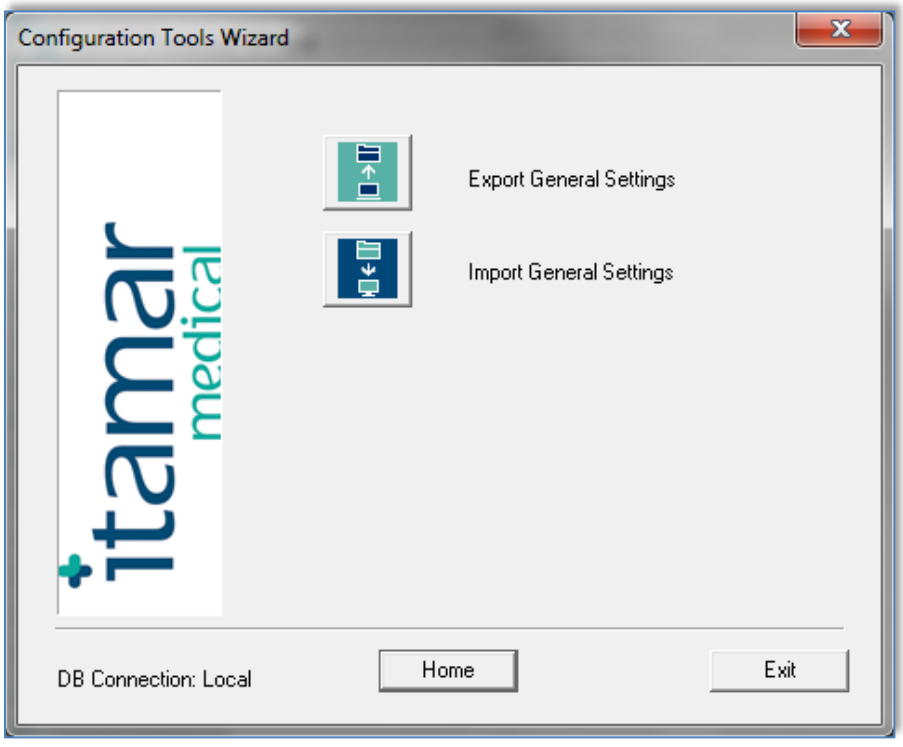


Figure 107 – Configuration Tool Wizard

- 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 0 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.

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 2.6.2)
	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 or export the report as PDF file and use your default mail to send it.
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 WatchPAT™ has S/W version lower than 2.2182	Upgrade the WatchPAT™ S/W to the newest S/W (call Itamar Help Desk for the upgrade)
No data of snoring and body position presented	RESBP sensor was not connected to WatchPAT™	Make sure to connect RESBP to WatchPAT™ 300 or WatchPAT™ 400 only
No data of Resp movement presented	RESBP sensor was not connected to WatchPAT™ 300 or WatchPAT™ 400	Make sure to connect RESBP to WatchPAT™ 300 or WatchPAT™ 400 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 support.
Warning Message: Snore/Body Position data may not be properly presented in the study. Please refer to operation manual for further information	Momentary disconnections between the chest sensor and the WatchPAT™ device are identified during the study	• Verify that the RESBP (chest sensor) is properly connected to the WatchPAT™ device. • Verify that the chest sensor cable or connector does not have any physical damage. • Verify that Snore/Body Position chart contains data. • Verify Body Position does not contain various NA values after first 10 minutes. • Verify Snore values are not high most of the study. If required contact Itamar Medical support
Study Date is shown as 01/01/2000	New battery was not inserted before preparing new study	See section 4.2.9: Edit>Correct Study Date

SBP missing is shown in Device test from New Study window even though sensor is working properly	Old HW version	Reconnect the device and perform the device test again. or perform the device test from the device itself
Error message when trying to prepare a new study: The Data was not loaded, please load from zzzPAT and then prepare new study	Either the study was not loaded or device need to be unlocked	Make sure study was indeed loaded. Run the **UnlockWP300.exe** file under C:\Program Files (x86)\Itamar medical\zzzPAT\BIN
Data breach affecting health and safety	S/W device appears to have been impacted by a cyber security issue	Immediately report to ZOLL Itamar 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	The device was disconnected from the USB too soon.	Do not remove the device before Figure 37 dialog box appears
WatchPAT™ 300 **only**: New Study or zzzPAT do not recognize the WatchPAT™ 300	The FTDI drivers were not properly installed	Make sure the FT4222H Interfaces A, B, C, D appear on the “Universal Serial Bus controllers” section of Device Manager when a WatchPAT™ 300 is connected to USB. In case these interfaces do not appear please try to install the FTDI drivers (CDM212362_Setup.exe) located in folder C:\Program Files (x86)\Itamar medical\zzzPAT\Misc.
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 2.6.2)
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 2.6.2)
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

Appendix A: LICENSE AGREEMENT

This License Agreement represents the complete and exclusive understanding between you and Itamar Medical. The document can be viewed at www.itamar-medical.com/wp-content/uploads/2025/02/License-Agreement-February-2025.pdf

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

USA:
Itamar Medical Inc.
3290 Cumberland Club Drive, Suite 100
Atlanta, Georgia 30339, USA
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Caesarea 3088900, Israel
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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.
- 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% or 3% (based on user configuration) 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

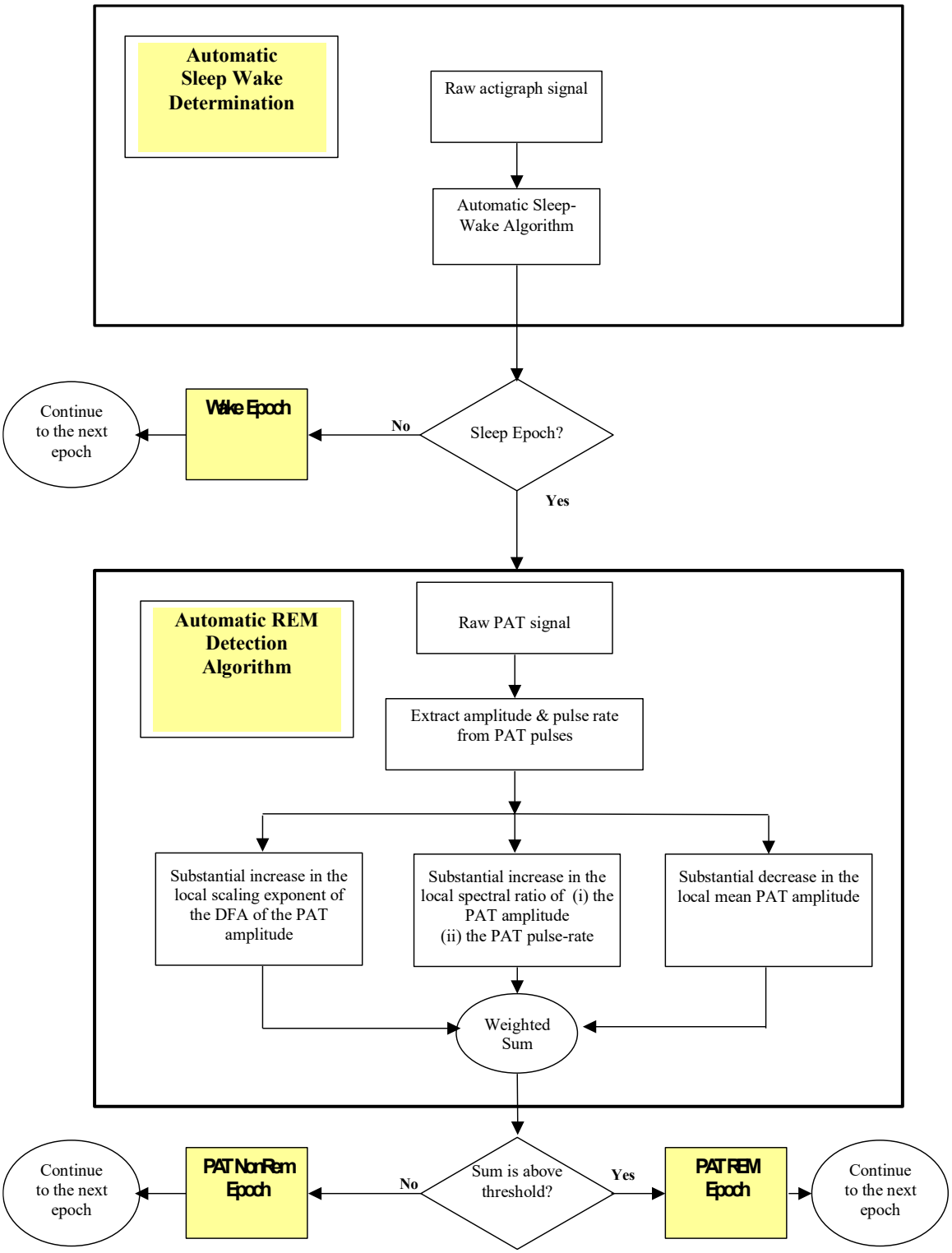
Epoch of Deep and light sleep are identified using the very same transformation of PAT amplitude and pulse rate than for REM. This Provides the full PAT Hypnogram.

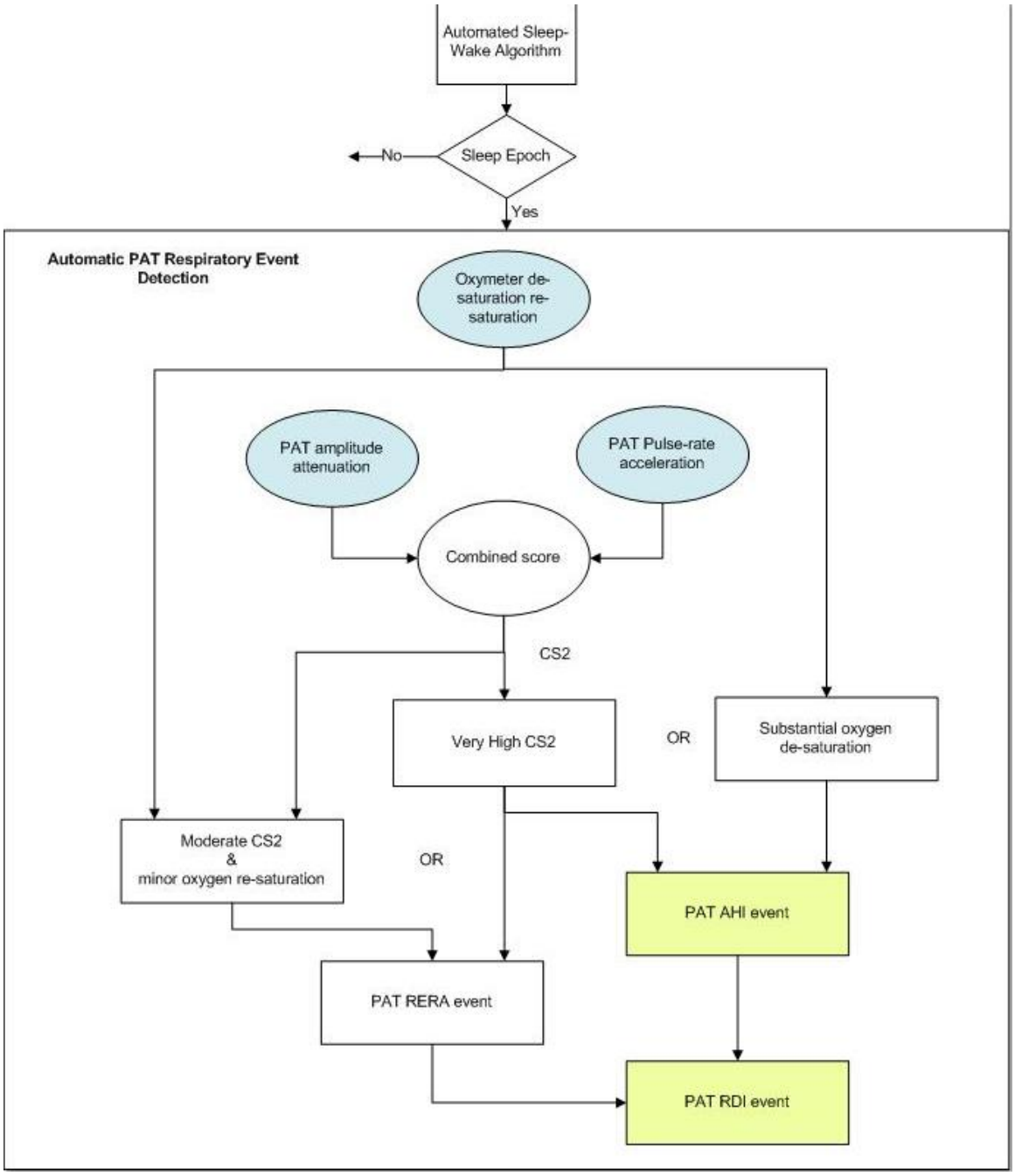
Cardiac Rhythm Analysis

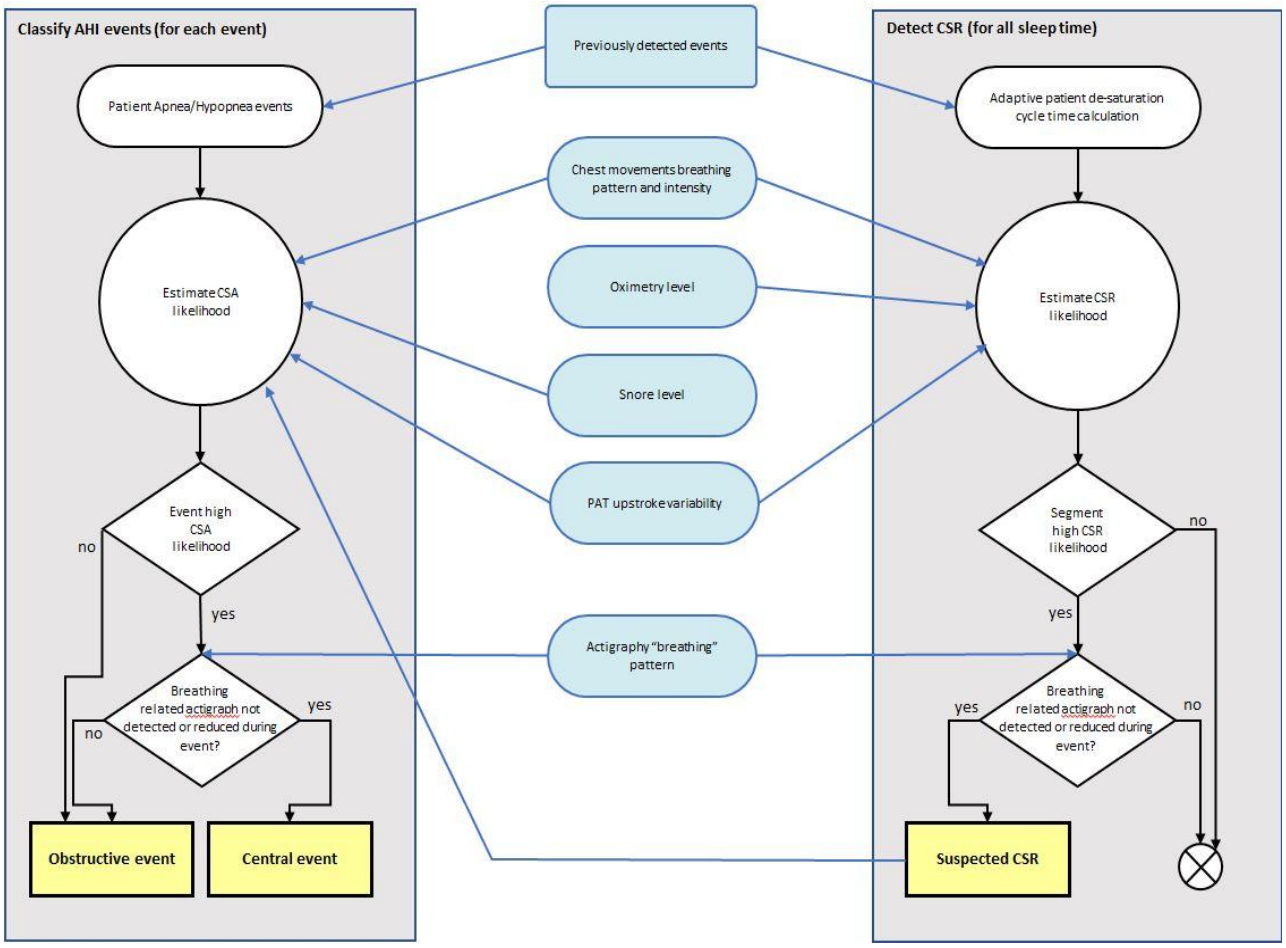
Suspected Atrial Fibrillation: time in AFib during sleep with pattern typical to atrial fibrillation (irregular-irregular heart rhythm), and the longest event duration (during sleep) with atrial fibrillation.
Note: The WP may not detect short AFib episodes (<60 seconds).

Premature Beats: number of events detected per minute of sleep.
Note: In some patients, in particular those with a high density of premature beats or AFib, the device may under-detect arrhythmic events (both premature beats and AFib) and/or misclassify between premature beats and AFib.

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


Classify AHI events (for each event)
Patient Apnea/Hypopnea events
Estimate CSA likelihood
Event high CSA likelihood
no
yes
Breathing related actigraph not detected or reduced during event?
no
yes
Obstructive event
Central event
Previously detected events
Chest movements breathing pattern and intensity
Oximetry level
Snore level
PAT upstroke variability
Actigraphy "breathing" pattern
Detect CSR (for all sleep time)
Adaptive patient de-saturation cycle time calculation
Estimate CSR likelihood
Segment high CSR likelihood
no
yes
Breathing related actigraph not detected or reduced during event?
yes
no
Suspected CSR

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
Shift+O	– Insert an A/H obstructive event on the highlighted section of a signal
Shift+C	– Insert an A/H central event on the highlighted section of a signal
Shift+U	– Insert an A/H unclassified event tag on the highlighted section of a signal
Shift D	– For Desat
Shift S	– For CSR
Shift B -	– For Afib
Shift P	– For PB
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

Note: Can also move the mouse scroll wheel up to scroll left.

Right arrow	– Scroll right

Note: Can also move the mouse scroll wheel down to scroll right.

Delete	– Delete selected event

Appendix D: Regulatory representative

Itamar Medical's EU authorized regulatory representative:

EC REP **Arazy Group GmbH**

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

Itamar Medical's UK authorized regulatory representative is:

UK Responsible Person: MEDES LIMITED
5 Beaumont Gate, Shenley Hill, Radlett,
Hertfordshire WD7 7AR, England, UK
MEDES@arazygroup.com

Appendix E: Index