zzzPAT

For WatchPAT™

Software Operation Manual

Itamar Medical REF OM2197444

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

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Edition Table

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2	May 2020	Intended use WP1	1.3	
3	June 2021	Updated ODI calculated value and New Report Layout	4.6.1	
4	July 2021	NAF (Thermal Airflow sensor) Channel	App C	
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9	Jan 2024	Remove “Intended Use/ Indications for Use of the Watch-PAT200” Add arrhythmia detection Change the references to WP200(U) to WP200U	1. Throughout document	11 --
10	April 2025	Add Appendix B TECHNICAL SUPPLEMENT and change the “Regulatory representative” to Appendix D Add WP400	All	35

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1 Introduction to the zzzPAT

Note: Throughout this document, the term WatchPAT™ refers to all 4 devices—WP200U, WatchPAT™ 300, WatchPAT™ ONE, and WatchPAT™ 400 (only where commercially available)—unless specified otherwise.

The **Extended** and illustrated guidance can be found on Itamar-Medical WEB site (https://www.itamar-medical.com/support/downloads/)

1.1 Intended Use/ Indications for Use

The WatchPAT™ devices are non-invasive home care device for use with patients suspected to have sleep related breathing disorders. The WatchPAT™ devices 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 WP 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 WP 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 and an actigraph (embedded in the device). Snoring and Body Position signals are generated from the SBP/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 that are included with the SBP sensor. Following the sleep study, in an offline procedure, the recordings are automatically downloaded and analyzed using the proprietary zzzPAT software.

The zzzPAT algorithms use the four WP channels: PAT, Pulse Rate, actigraphy and Oxygen saturation for the detection of sleep related breathing disorders and sleep staging (Rapid Eye Movement (REM), Light Sleep, Deep Sleep and Wake). Using the RESBP's respiratory movement channel in addition to the other WP channels, allows further identification of central apnea.
The zzzPAT uses WP'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 device is 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: Throughout this document, the Snore and Body Position sensor is referring to both SBP sensor and RESBP sensor unless specified otherwise. In WP200U/ WatchPAT™ 300/ WatchPAT™ 400, the use of Snore and Body Position sensor is optional and according to physician preference. The use of RESBP sensor is subject to regulatory approval in the country.

Note: The arrhythmia feature is available only in approved territories.
This manual provides the information necessary for routine use of the zzzPAT software.

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

In WP200U/ WatchPAT™ 300 a USB cable is used in order to read the data recorded by the WP on the internal memory card. The zzzPAT S/W automatically detects the data on the internal memory card once the WP 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.
See Extended and illustrated guidance for detailed information.

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 WatchPAT200U 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 the Extended and illustrated guidance

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.

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.

See Extended and illustrated guidance for detailed description

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.

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

See Extended and illustrated guidance for detailed description

4 Using zzzPAT

4.1 Preparing a New Study

Preparing the Patient file is a mandatory stage in the preparation of the WP devices for a sleep study.

4.1.1 Launching zzzPAT

- Launch 'zzzPAT' by clicking the zzzPAT icon on your desktop.
- If the zzzPAT icon is launched the login dialog opens:
- 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
- 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 will be opened with fields according to default device type (WP200U/ WatchPAT™ 300/ WatchPAT™ ONE/ WatchPAT™ 400) according to the configuration.

4.1.2.1 Preparing a New Study (WP200U/ 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.
- 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 WP Operation Manual)..
- Select "Multiple Nights" option in order to run up to 3 nights with the same WP device
- 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 WP 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. 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 use the “Switch to WP-ONE/WatchPAT™ 400 Device” button
- Click the **Save to WatchPAT** button.

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

	**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.

If WP 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 Data Not Loaded dialog box opens

- After saving the patient information to the WP the successefully saved study message appears

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.
- Fill the mandatory fields: Patient ID, Patient Mobile Phone (WatchPAT™ ONE/ WatchPAT™ 400), 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)

- 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.
- Select "Multiple Nights" option in order to run up to 3 nights with the same WatchPAT™ ONE-M/ WatchPAT™ 400 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
- 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.

- To initiate study for WatchPAT™ 300 or WP200U Device use the “Switch to WP200/ WatchPAT™ 300 Device” button.

	**Note** 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.). o Make sure the patient is aware of this code. o 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.

	**Note** If same WatchPAT™ ONE/ WatchPAT™ 400 device SN is already registered, an error will appear to notify user to insert correct/other device SN. Fill in the correct information and press the **Register WatchPAT** button again.

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

- After registering the patient information to the Web Server the successefully saved study message appears:

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.

See Extended and illustrated guidance for detailed description

4.2 Managing Patient Studies

WP200U/ WatchPAT™ 300: After a WP 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 will be opened with all registered patients that the study was not yet retrieved from the web server. Select study to download and the recorded data will be loaded into the zzzPAT database for selected patient. The recorded data is automatically analyzed. Once a study is loaded the user can 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.

	Note

	To switch between WatchPAT™ ONE's/ WatchPAT™ 400's registered patients list to download study from WP200U/ WatchPAT™ 300 device select the "Switch to WP200/300 Device" button.

4.2.1 File>New Study Details

Prepares the Patient file on the WP 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' 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.
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. The user has the option to display the "Sleep report" or "Sleep Indices" report box automatically after loading a study

WP200U/WP300: 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.

	**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, improved firmware version available for device. It is strongly recommended to use the latest firmware version." Use 'Help'->'Visit our Web Page for Upgrading Watch-PAT Device' to download the upgrade software.

4.2.3 File>Open Study

Opens studies stored in the zzzPAT database from previously loaded studies. Double click on a patient and the studies for that patient are listed with the date/time of each study. Double click the  study icon to load and display recorded information on the screen.
If several Analysis exist for a study a dialog will appear prompting to select the Analysis to open.

Select Studies button
Enables the user to define, select and organize the displayed studies in the 'Select Patient Study' dialog box.
See Extended and illustrated guidance for detailed description

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 Analyisis with the current events and signals as a new Analysis. Allows to assign a name to the Analysis.
See Extended and illustrated guidance for detailed description

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:
See Extended and illustrated guidance for detailed description

4.2.10 Edit>Undo

Choosing “Undo” or clicking  on the zzzPAT toolbar enables the user to undo the last operation.

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 WP recording waveforms with the events that were detected by the automatic analysis. The traces are displayed synchronized to a uniform time base.

See Extended and illustrated guidance for detailed description

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**.
- 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’.

See Extended and illustrated guidance for detailed description

4.3.2 The Active Channel

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

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

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)

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)

See Extended and illustrated guidance for detailed description

4.5 Review, Analysis and Report Study

4.5.1 Data Analysis

The zzzPAT software performs an automated analysis of the WP recorded signals, The analysis provides an evaluation of respiratory events during sleep, oxygen saturation , pulse rate and sleep stages statistics. Also, it provides snoring and body position statistics when the SBP/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

See Extended and illustrated guidance for detailed description

4.6 Reports

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

- 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.

See Extended and illustrated guidance for detailed description

4.6.1 Report>Clinical Diagnosis

This option allows adding a diagnosis and recommendations to the Sleep Report screen. 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.
- 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 send to HL7.

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

The second page presents the study results including Sleep Summary, PAT Respiratory Disturbance Index (pRDI), PAT Apnea Hypopnea Index (pAHI), PAT Central Apnea Hypopnea Index (pAHIc)*, Number of events, Percentage of total sleep time with Cheyne-Stokes Respiration (%CSR)*, Oxygen Saturation Statistics including the Oxygen Desaturation Index (ODI), mean, maximum and minimum oxygen saturation levels, Oxygen Saturation analysis, Pulse Rate statistics, REM Sleep analysis, AHI Severity Graph, Cardiac Rhythm Analysis table and Hypoxic Burden.

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

The fourth page 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).

The 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. 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%.

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.

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

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.	

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.

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**.

See Extended and illustrated guidance for detailed description

4.6.4 Report>Event Report

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

4.6.5 Report>Sleep Indices

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

4.6.6 Report>Patient Follow-up Report

This report provides a way of comparing multiple studies for the same patient. A graphical representation of the pRDI, pAHI and ODI for the different studies provides a quick way of determining a trend through the studies.
The Sleep % over the defined Snoring threshold dB will be displayed as well.

4.6.7 Report > Report for Patient

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

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

It also compares these to the normal average indices.

	**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

4.6.8 Report > Detailed Report

This report's first page is the same as the first page of the sleep report 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**.

4.6.9 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. 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 is also included

4.6.10 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:

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

5 Exporting Data

See Extended and illustrated guidance for detailed description

6 Tools

See Extended and illustrated guidance for detailed description

7 Database Wizard

See Extended and illustrated guidance for detailed description

8 Troubleshooting

Installation		
Trouble	**Possible Cause**	**Solution**
zzzPAT installer fails to run.	Auto run function in Windows is not activated.	Open My Computer>zzzPAT CD and double click 'Setup.exe'.
	Windows version not compatible with zzzPAT.	Use PC with appropriate Operation System.
	Hardware configuration below minimum required.	Must have at least 128 MB RAM, and a Pentium processor for zzzPAT installer to run.
zzzPAT fails to recognize WatchPAT (WP200U only)	USB drive needs to be re-defined.	Select Setup->"Set WatchPAT Drive". Insert WatchPAT device to USB Drive. Click OK. "The system is searching for WatchPAT device" message should appear. At the end, a list containing the WP200U drive should be displayed. Select the WatchPAT drive.and click Ok.
Under Windows XP, user cannot load study or operate 'Database Wizard' utilities, despite having proper zzzPAT user permissions.	User does not have writing permission to the drives these applications are located on.	Check user's writing permissions per section, and redefine as necessary.

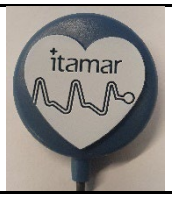
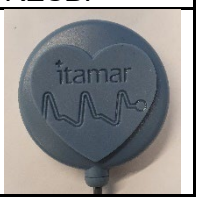
Table 1 - Troubleshooting, Installation

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.
	Insufficient free space on hard disk	Free enough disk space to exceed the minimum requirement of 100MB and try again
Cannot **Load Study** (function is disabled)	There is less than 200MB of free hard disk space	Free enough disk space to exceed the minimum requirement of 200MB and try again

zzzPAT will not start, or behaves unpredictably	Some zzzPAT files may be damaged/overwritten	Uninstall and reinstall zzzPAT.
The open file does not show REM	File was saved with an older version of zzzPAT that did not have REM capabilities or REM could not be calculated because of the algorithm restrictions.	Run the analysis by selecting **Analyze>Reload Study and Analyze**
Cannot generate Sleep Report - Sleep Report button is grayed out	Less than 100MB of free disk space	Free enough disk space to exceed the minimum requirement of 100MB and try again
	No study is loaded or study is invalid	Open the desired study. If the study is open, it may have invalid data and therefore is not usable
User cannot log on to zzzPAT	zzzPAT will not open if another session is open under a different user	Ensure no other user left an open zzzPAT session on the PC. If you cannot verify, restart PC
	User is not defined in zzzPAT	Define user by zzzPAT administrator
Send report by email fails	Microsoft Outlook was not defined as the default mail client.	Define Microsoft Outlook (or Outlook Express) as the default mail client
Changes to Events Names do not show up on screen	Events names are saved with the saved analysis. Changes will become visible only after running analysis again	Run the analysis by selecting **Analyze>Reload Study and Analyze**
Errors while printing	Non-compatible printer driver	A postscript printer driver provides the most reliable operation with the zzzPAT. Install a suitable postscript driver for the printer in use and try again

After clicking **New Study** in zzzPAT the dialog box disappears and zzzPAT is frozen	Inadvertent double clicking the **New Patient** button may cause the dialog box to be hidden in the background	Press **Alt-Tab** to bring the dialog box back to the front
"Enable multi-night option" does not show in New Study dialog	The WP has S/W version lower than 2.2182	Upgrade the WP S/W to the newest S/W (call Itamar Help Desk for the upgrade)
"Enable tamper-proof testing option" does not show in New Study dialog	The WP has S/W version lower than 2.2182	Upgrade the WP S/W to the newest S/W (call Itamar Help Desk for the upgrade)
No data of snoring and body position presented	SBP/RESBP sensor was not connected to WP	Make sure to connect SBP to WP. Make sure to connect RESBP to WP200U or WatchPAT™ 300 or WatchPAT™ 400 only
	RESBP sensor was connected to WP200 instead of WP200U/ WatchPAT™ 300/ WatchPAT™ 400	Make sure to connect RESBP to WP200U or WatchPAT™ 300 or WatchPAT™ 400 only
	Embedded SW not compatible	RESBP for WP200U: Make sure to use embedded SW 3.3228 and above
No data of Resp movement presented	RESBP sensor was not connected to WP200U or WatchPAT™ 300 or WatchPAT™ 400	Make sure to connect RESBP to WP200U or 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.

<table>
<tr>
<td>Warning Message:
Snore/Body Position data may not be properly presented in the study.
Please refer to operation manual for further information</td>
<td>Option 1:
If a digital RESBP is used with a device that is not supporting digital RESBP such as WatchPAT™ 200U, no valid signals will be recorded by the sensor and warning message will appear.

Option 2:
Momentary disconnections between the chest sensor and the WatchPAT™ device is identified during the study</td>
<td>Option 1:
Identifying digital vs analog RESBP sensor (Digital RESBP does not have white painting)
<table><tr><td>Analog RESBP</td><td>Digital RESBP</td></tr><tr><td>  </td><td>  </td></tr></table>Make sure that digital RESBP is only used with WatchPAT™ 300s or WatchPAT™ 400s.

Option 2:
Verify that the 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</td>
</tr>
<tr>
<td>Study Date is shown as 01/01/2000</td>
<td>New battery was not inserted before preparing new study</td>
<td>See section 4.2.9: Edit>Correct Study Date</td>
</tr>
<tr>
<td>SBP missing is shown in Device test from New Study window even though sensor is working properly</td>
<td>Old HW version</td>
<td>Reconnect the device and perform the device test again. or perform the device test from the device itself</td>
</tr>
</table>

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

Table 2 - 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 3 - 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 study successfully saved dialog box appears
WP200U only: New Study or zzzPAT do not recognize the WP200U	The volume name has been erased	Format drive with volume name "WP200"
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
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
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 4 - 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
https://www.itamar-medical.com/lmages/licensewp.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
Tel: 1 888 748 2627

Worldwide:
Itamar Medical Ltd.
9 Halamish Street, PO 3579
Caesarea 3088900, Israel
Tel: +972 4 617 7000

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.

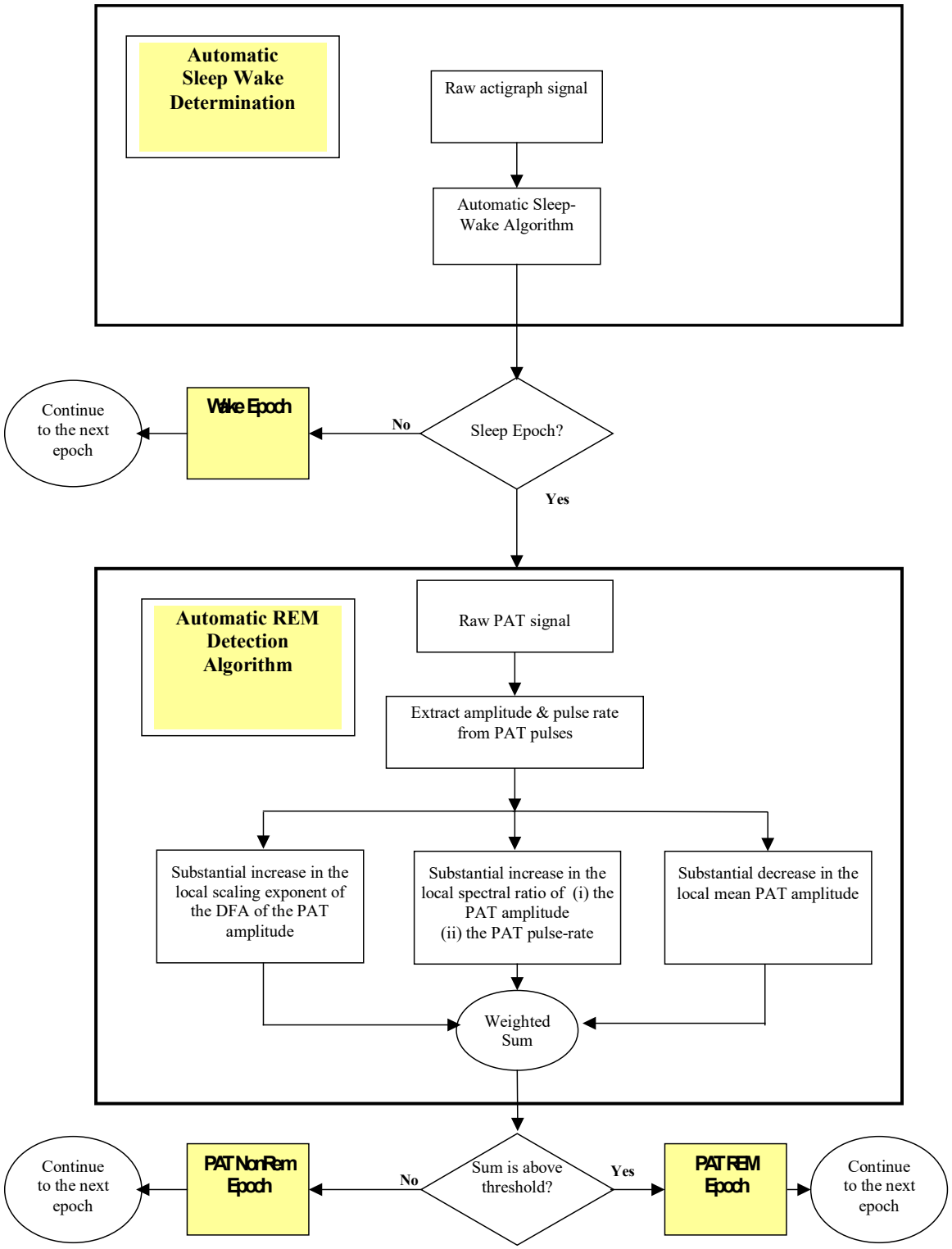
Cardiac Rhythm Analysis

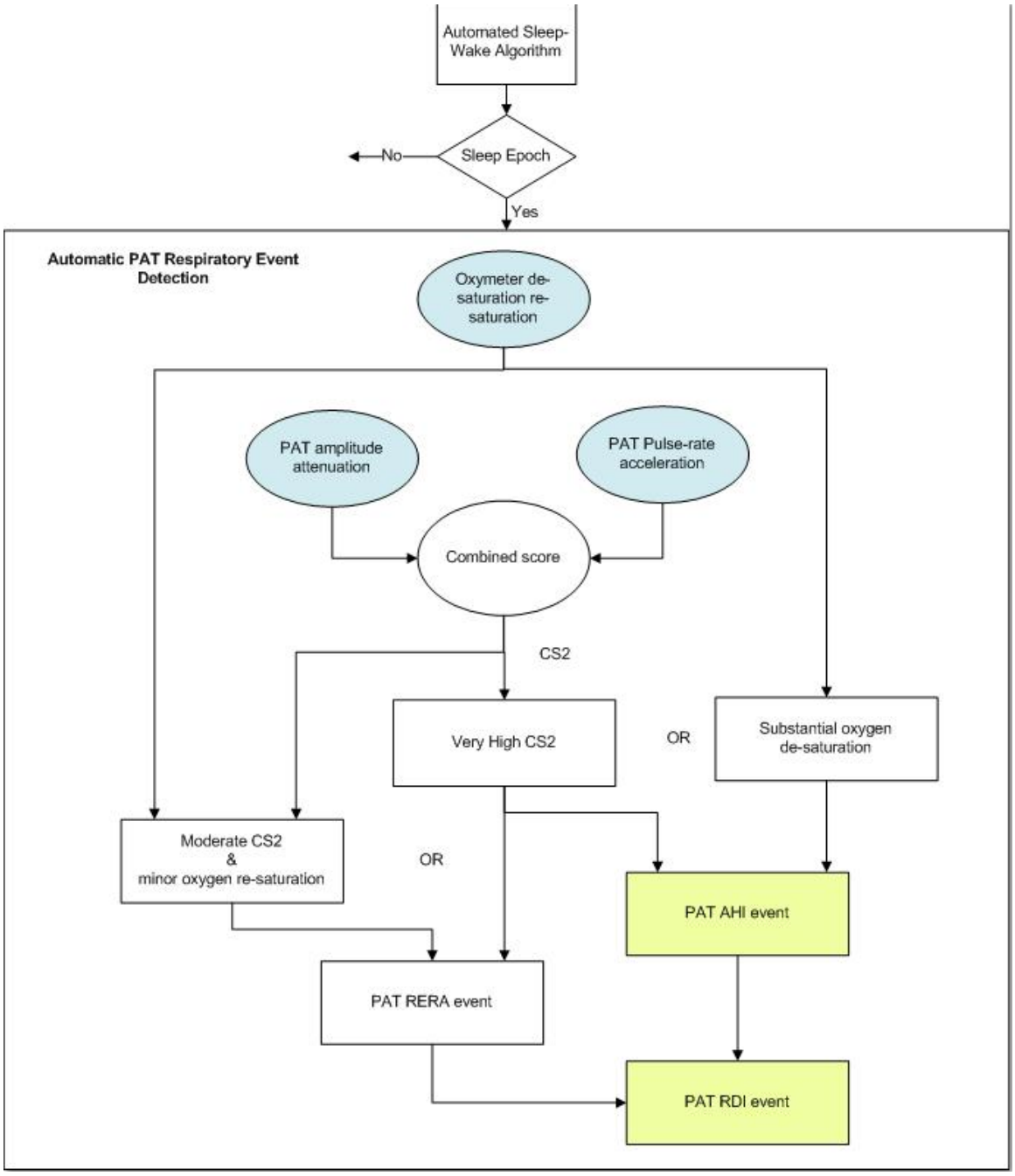
Suspected Atrial Fibrillation: time in AFib during sleep with pattern typical to atrial fibrillation (irregular-irregular heart rhythm), and the longest event duration (during sleep) with atrial fibrillation.
Note: The WP may not detect short AFib episodes (<60 seconds).

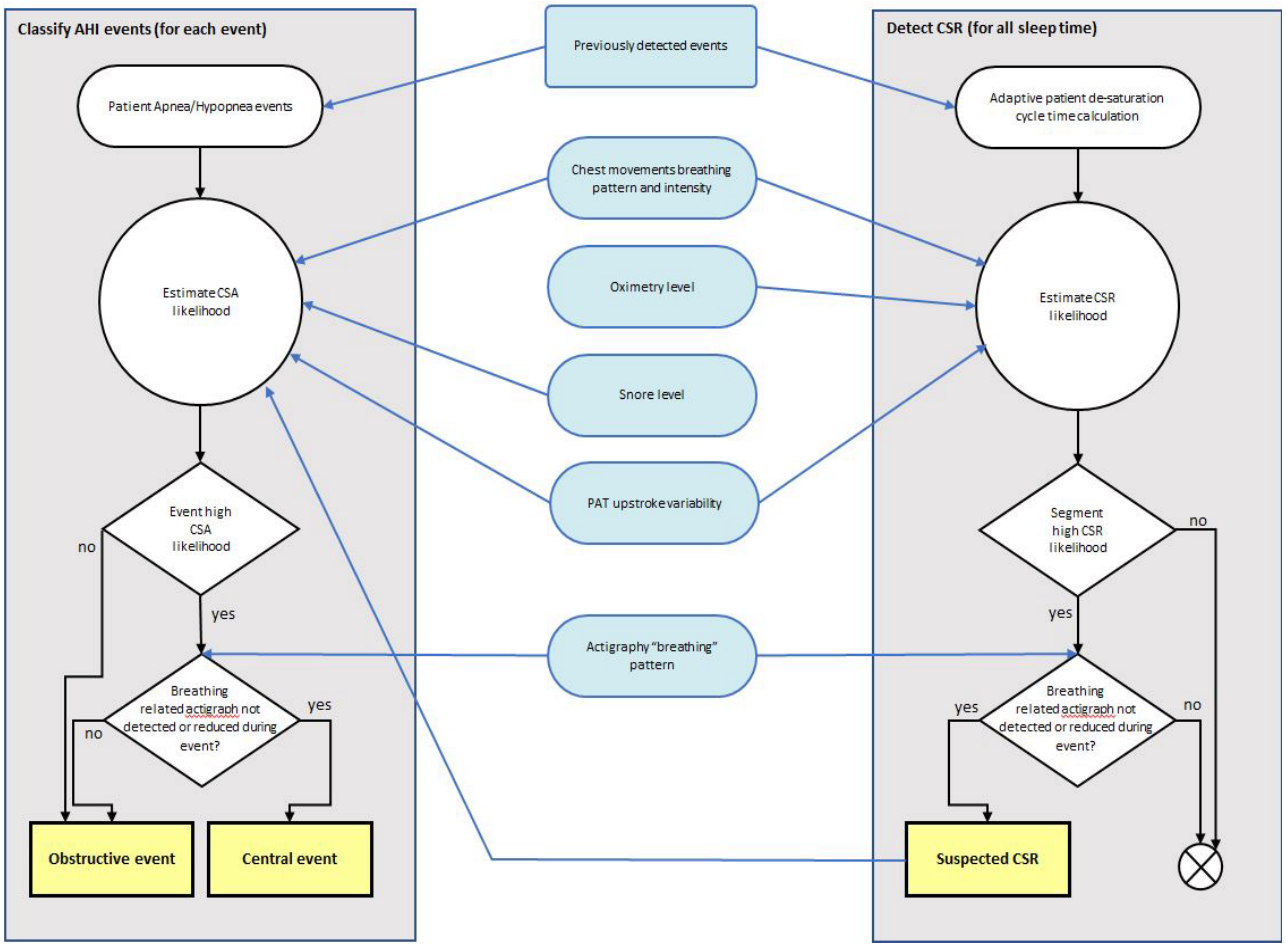
Premature Beats: number of events detected per minute of sleep.

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
Sleep Epoch
No
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

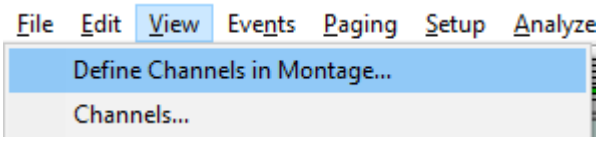

Classify AHI events (for each event)
Patient Apnea/Hypopnea events
Estimate CSA likelihood
Event high CSA likelihood
no
yes
Breathing related actigraph not detected or reduced during event?
no
yes
Obstructive event
Central event
Previously detected events
Chest movements breathing pattern and intensity
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: Enabling NAF (Thermal Airflow Sensor) Channel

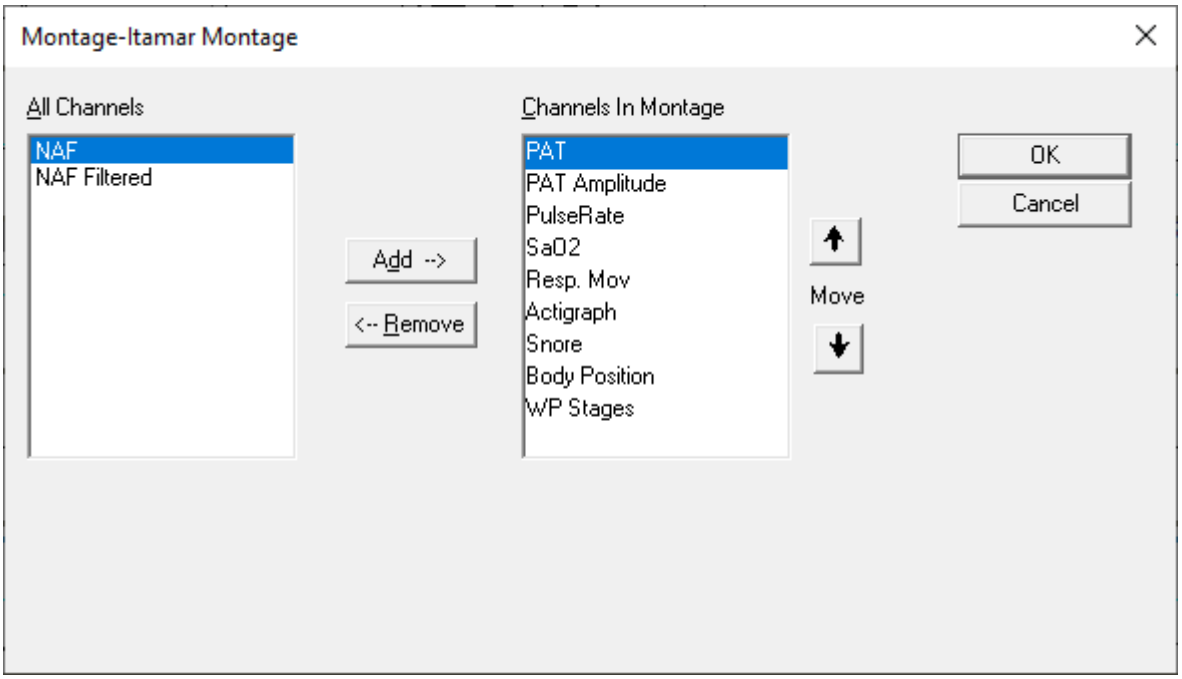
zzzPAT supports presenting NAF (Nasal Air Flow) signal within the channel view while NAF accessory is used during the study.

Enabling NAF Channel

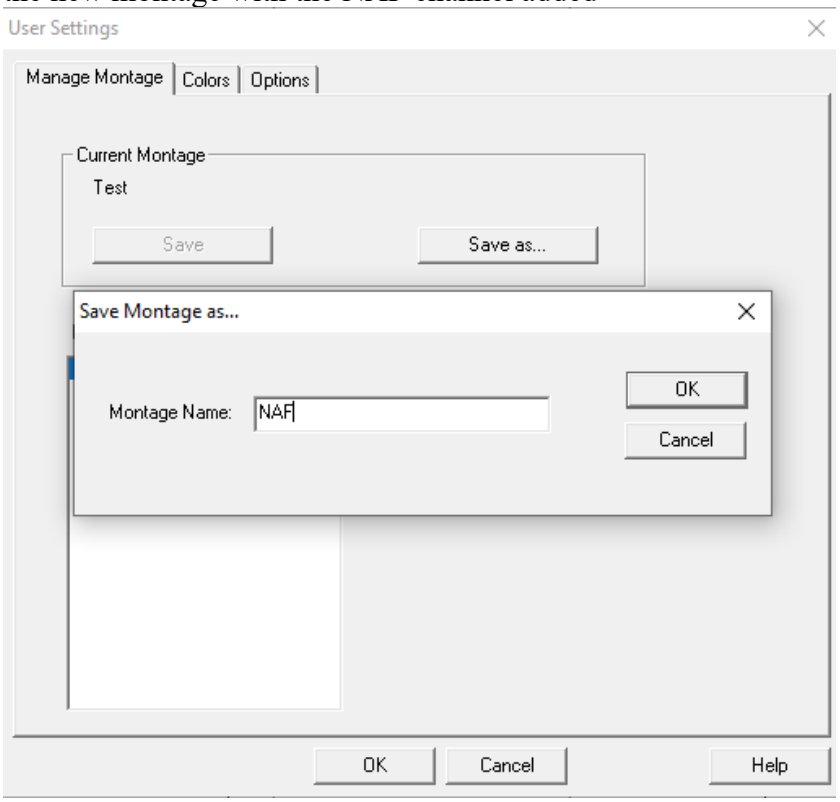
1. Open\Load a study that was recorded with NAF accessory connected
2. Under View, Define Channels in Montage



3. NAF and NAF Filtered (NAF channel with filter which reduces the noise on the signal) channels will appear on left list (All Channels)
   Mark the NAF Channel and click add and then click OK

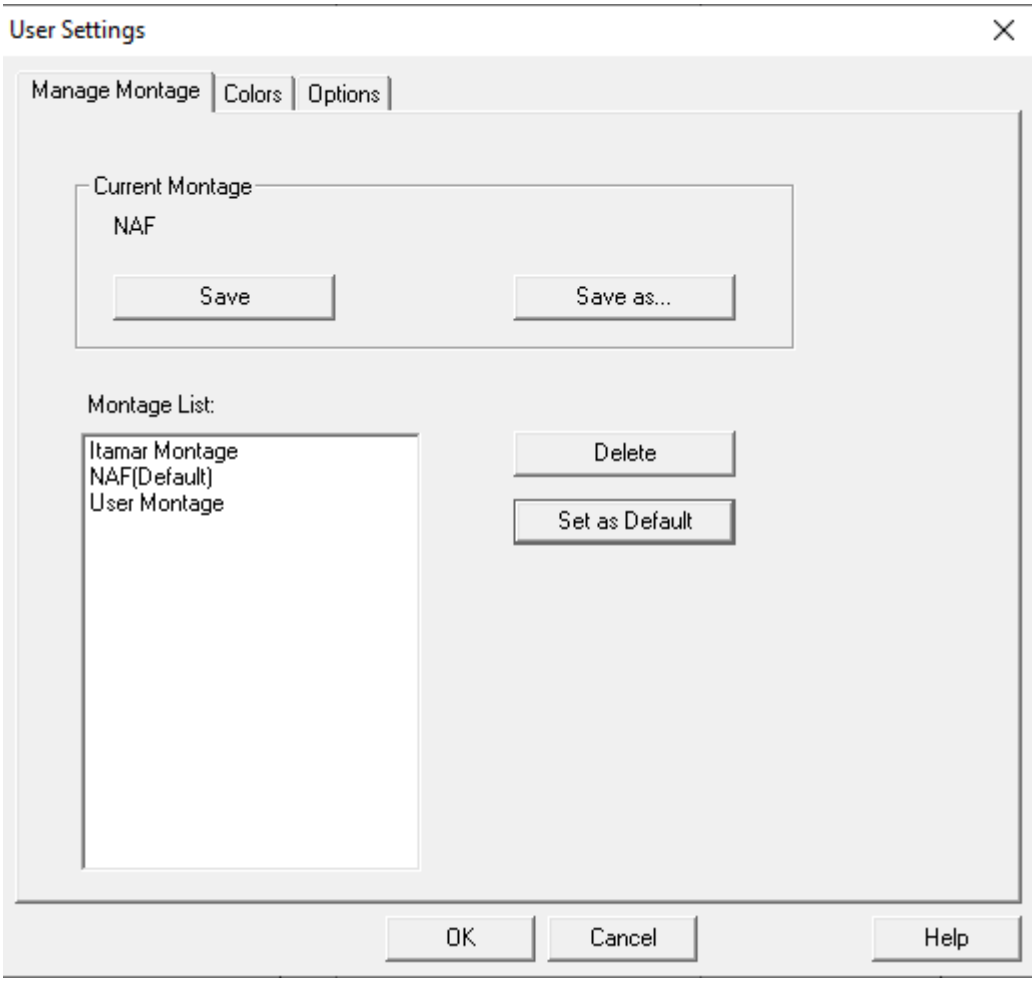


4. Go to Setup, User settings, Manage Montage tab. Click Save as and name the new montage with the NAF channel added



5. After Save the new Montage will be added to the Montage list.

6. Click Set as Default and click OK



Appendix D: Regulatory representative

Itamar Medical's authorized regulatory representative:

EC REP **Arazy Group GmbH**

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

Appendix E: Index