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1. Introduction

Intended Use

Somnolyzer 24x7 is a computer program (software) intended for use as an aid for the diagnosis of sleep and respiratory disorders.

Somnolyzer 24x7 is intended to be used for analysis (automatic scoring and manual re-scoring), display, redisplay (retrieve), summarize, reports generation and networking of data received from monitoring devices typically used to evaluate sleep and respiratory related sleep disorders.

The device is to be used under the supervision of a physician.

Caution! U.S. Federal law restricts this device to sale by, or on the order of, a licensed physician.

Somnolyzer 24x7

The Somnolyzer 24x7 system is a combination of hardware, software & network elements which when working in conjunction with appropriate human supervision, ensures that “raw” sleep recordings are analyzed and scored in the least possible time, with the maximum of accuracy and consistency.

The studies can be PSG or HST, and can be recorded with any of the following systems:

- Philips Respironics Sleepware 2.x
- Philips Respironics Sleepware G3
- Philips Respironics Stardust

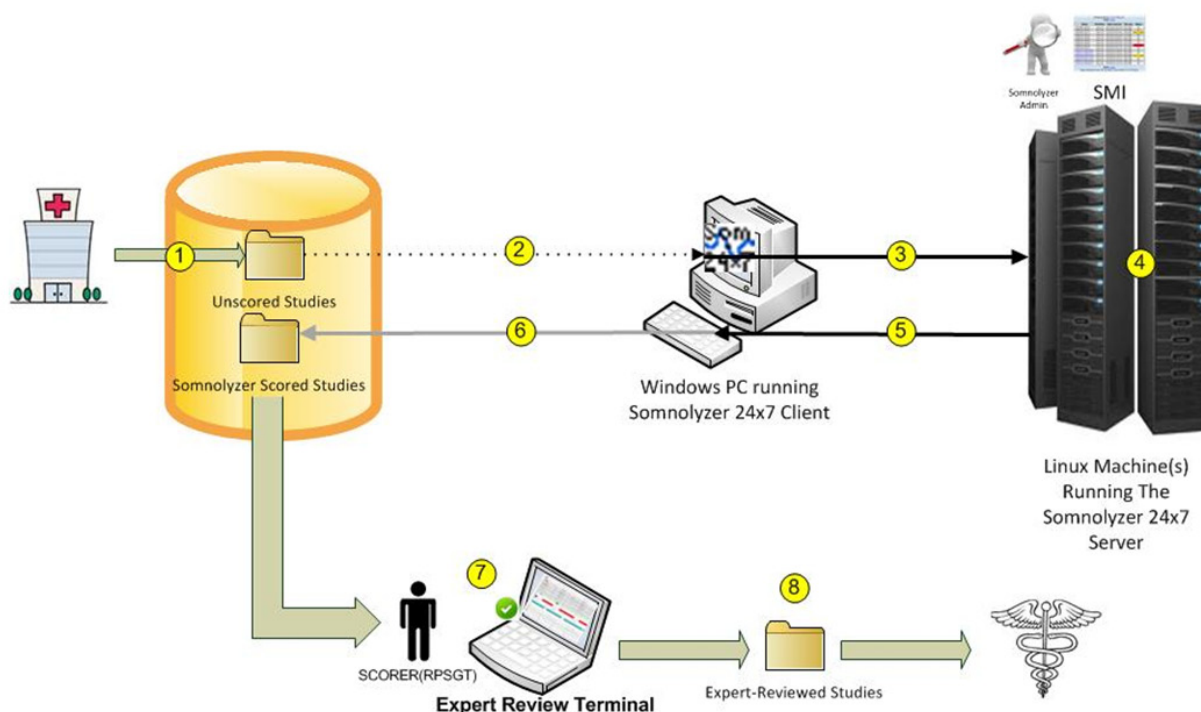


Figure 1: Typical Somnolyzer 24x7 workflow

The various steps in the workflow depicted in Figure 1: Typical Somnolyzer 24x7 workflow (denoted by encircled numbers) are described below:

1. Sleep recordings are transferred to a central data location in a folder (usually) named “Unscored Studies.” The organization of the incoming studies in terms of the folder structure of the Unscored folder is left to the user; e.g. it could be by date, by sending-lab etc.

2. The Somnolyzer Client (see chapter 2) is configured to monitor the Unscored Studies folder and once a valid study is fully transferred, it is marked in the Client interface as being ready for processing.
3. There are two options at this point:
 - a. The client automatically sends the studies to Somnolyzer, if pre-configured to do so.
 - b. The user sends each study manually to the Somnolyzer whenever desired.
4. The Somnolyzer processes each valid study sent to it according to the rules specified for the particular study. The Somnolyzer admin or the User can monitor the progress of each Study sent to the server using the Somnolyzer Web Interface called SMI.

Note: The scoring rules to be applied by the Somnolyzer for each study need to be specified before-hand. The pre-configuration of the applicable scoring rules per workflow is accomplished at the time of installation by Philips-Respironics personnel. Later on, if different rules need to be applied, or new workflows/rules need to be setup, the user needs to contact Philips Product support (somnolyzer.us@philips.com for North America, somnolyzer.int@philips.com for the Rest of the world).

5. The Somnolyzer Client detects that the results for a particular study are available. The results are then imported into the original study either:
 - a. Automatically – for Sleepware, Stardust & G3 based systems
 - b. Manually – for all other systems

After the import, whether manual or automatic, the scoring results show up in each interface the same way as they would if the scoring had been done by a Human Scorer.

There's also an additional file created by the Somnolyzer called the PFF file, one for each study. The PFF file is what makes Expert-Review possible (**Note:** In G3 based systems, the information contained in the PFF files is embedded into the interface along with the scoring results, so the additional PFF file is not created when using Sleepware G3).

6. The scored studies, along with the corresponding PFF files, are then moved by the Somnolyzer Client to a pre-designated folder typically named "Somnolyzer Scored Studies."
7. The Human Scorer then opens the study and also the PFF file (if a non-G3 system is used), and proceeds to execute the so called Expert-Review. The PFF file is opened with an EDF viewer known as Polyman. Usually the user also runs the non-Somnolyzer supported modules (ECG etc.) as provided by the recording system software.
8. After Expert-Review, the Scoring results are now valid and final, and a Sleep report can be created.

1.1 Overview

As seen above the different elements of the Somnolyzer 24x7 system that make the proper & efficient scoring of studies possible are:

The Somnolyzer Client: The main interface for the user to Somnolyzer. Main features:

- Runs on Windows
- Basic Framework to configure, manage and monitor the sending of studies to Somnolyzer & the receiving & proper import of the Somnolyzer results
- Support for different recording Systems, a single instance of the client can be used for handling multiple workflows for processing studies from different recording systems

Details: Chapter 2

The SMI: Web Interface to the Somnolyzer server. Main features:

- Ability to monitor the progress of each study sent to the Somnolyzer server by the Client

- Ability to view usage details including month-end reporting for accounting etc.
- Configuring of server side workflows(Admin only)

Details: Chapter 3

The Expert Review Procedure: The Somnolyzer results can sometimes be adversely influenced by (typically) bad data or recording procedures. The Expert-Review is a structured procedure designed to enable a fast over-read of the Somnolyzer results in order to ascertain quickly what parts of the study would need a closer inspection. This is accomplished by the above mentioned PFF file, which contained the so called Polysomnographic Trends(PFTs). A Somnolyzer-Trained Scorer has the ability to read and analyze the PFTs quickly and using this info can achieve a valid scoring in a small fraction of the time compared to a fully manual scoring procedure.

Details: Chapters 5 and 6

1.2 Definitions and Abbreviations

AASM	American Academy of Sleep Medicine
ECG	Electrocardiogram
EDF	European Data Format
EEG	Electroencephalography
EMG	Electromyography
EOG	Electrooculography
ER	Expert Review
HPF	High Pass Filter
HST	Home Sleep Testing
NREM	Non-REM
PFF	Polysomnographic Feature File
PFT	Polysomnographic Feature Trends
PSG	Polysomnography
RERA	Respiratory effort related arousal
REM	Rapid Eye Movement
R&K	Rechtschaffen and Kales
SEM	Slow Eye Movement
SMI	Somnolyzer Management Interface
SOREM	Sleep-onset REM

1.3 References

Conrad Iber, Ancoli-Israel Sonia, Andrew L. Chesson Jr, and Stuart F. Quan: **The AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology and Technical Specifications**. American Academy of Sleep Medicine, Westchester, IL, 2007.

Rechtschaffen A and Kales A: **A Manual of standardized terminology, techniques and scoring system for sleep stages of human subjects**. Public Health Service, U.S. Government Printing Office, 1968.

2. Somnolyzer Client

2.1 Introduction

This chapter is intended to provide an overview on the functionality and a basic understanding of the Somnolyzer Client software. The main role of the Somnolyzer Client is to enable users to send sleep recordings to Somnolyzer and convert the obtained results back into the native format.

2.2 Get started

2.2.1 Starting the Somnolyzer Client

To start the program double-click the desktop icon named “Somnolyzer Client.”

2.2.2 Closing the Somnolyzer Client

To exit the software choose menu “File” and “Exit.” All currently processing sleep recordings will be canceled.

2.3 Configuration of a Client workflow

A workflow defines how sleep recordings will be handled by the Somnolyzer Client.

To configure a workflow or to view an existing workflow, click “File” and “Configuration.”

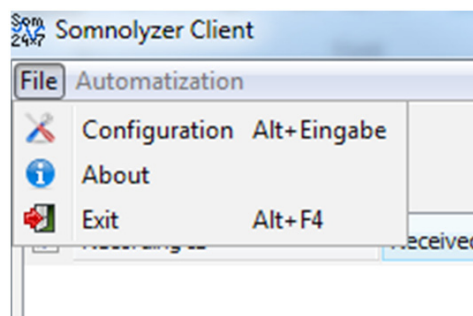


Figure 2: To open a workflow

A new window will open (Figure 3). To create a new workflow click “Create workflow.”

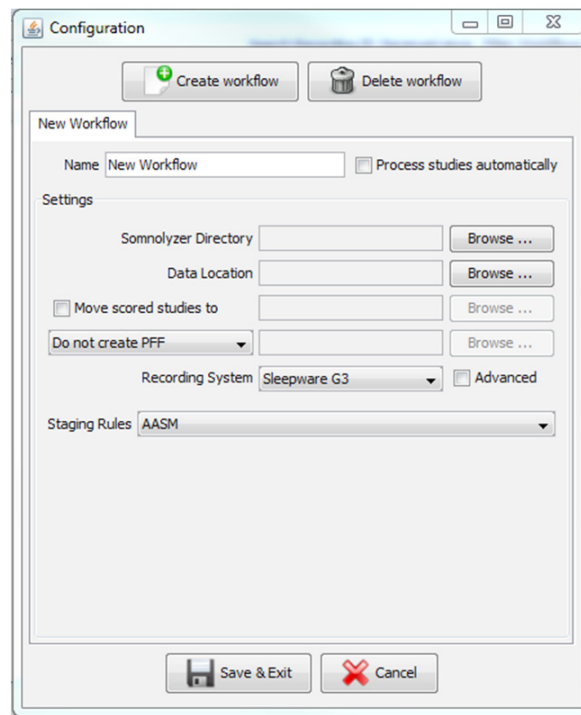


Figure 3: Configuration of a Client workflow

Name: Choose a unique name for the desired workflow. By default, the workflow is called “New Workflow.”

Process studies automatically: If the checkbox is marked, the Somnolyzer Client will pick up and process newly detected recordings in the data location automatically (send the recording to Somnolyzer for analysis and reimport the results). By default this check box is not selected and therefore detected recordings are only displayed in the main window. If desired, sending the recording to Somnolyzer must be manually triggered by clicking the “Send” button (Figure 10).

Somnolyzer Directory: This directory must point to the folder in the mapped drive from the Somnolyzer server (the details of how to connect to the mapped drive are provided by the Somnolyzer Install team) Click “Browse” to choose the correct Somnolyzer directory.

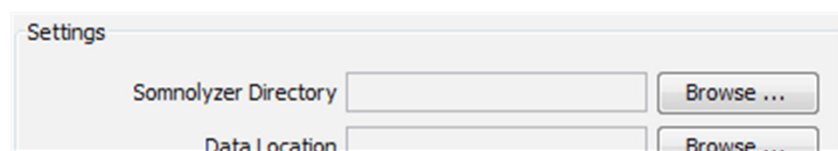


Figure 4: Somnolyzer Directory

Data Location: This directory is the location monitored by the Somnolyzer Client workflow. Every study the user wants to send to Somnolyzer has to be copied or moved to this directory in order to be analyzed. If a sleep recording is detected in this directory or in one of the subfolders, the Somnolyzer Client will display it in the main window (note: as mentioned before, if “Process studies automatically” option is checked, the recording will be automatically sent to Somnolyzer for processing). Click “Browse” to choose which directory the workflow should monitor.

Move scored studies to: If this check box isn’t selected the Somnolyzer Client will reimport the results after analysis into the “Data Location” defined above. By checking “move scored studies to” the user can choose the location where the processed sleep recording will be moved. Click “Browse” to choose a directory.

PFF: The PFF (Polysomnographic feature file, see 5.3) is a file delivered in addition to the results of Somnolyzer and is needed for Expert Review of all sleep recordings except Sleepware G3 recordings (see chapter 6). In a

Sleepware G3 workflow the PFF trends are directly imported into the recording, therefore it is recommended to choose the option “Do not create PFF.” If a recording system other than Sleepware G3 is selected it is recommended to select “Create PFF in study folder” or “Create PFF in location.” Depending on the choice, the PFF is created in the same directory as the processed sleep recording or in a separate location, respectively. Click “Browse” to choose the directory.

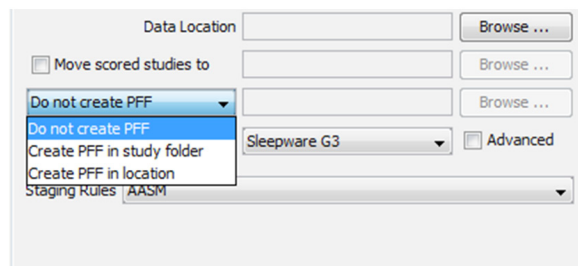


Figure 5: PFF options

Recording System: By choosing a recording system from the drop-down list, the Somnolyzer Client monitors the “Data Location” (see above) for sleep recordings of a specific recording system and will only process recordings of the this system.

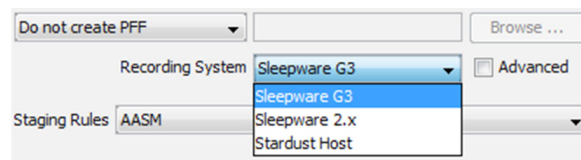


Figure 6: Recording systems

2.3.1 Sleepware G3

The Somnolyzer Client can process sleep recordings in Sleepware G3 format obtained from Alice 5, Alice 6, or Alice PDx devices. The staging rule must be set, by choosing between “AASM” and “RnK” from the drop down list. By selecting “Advanced,” the user can select additional settings for each recording system.

Advanced settings:

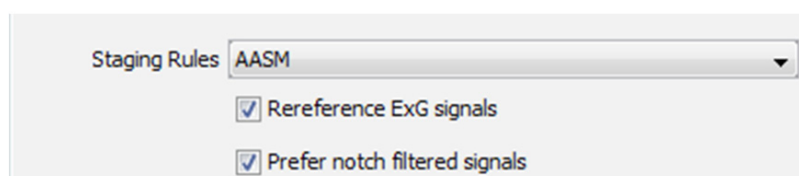


Figure 7: Advanced settings for the recording system G3

Rereference ExG signals: EOG/EEG data signals that are not referenced compatible to Somnolyzer are re-referenced if this configuration parameter is activated, and if technically possible (that means A1A2 or A2A1 channel has been recorded with the same sampling rate as the EEG/EOG channel that is to be re-referenced). Somnolyzer requires all EEG channels from one hemisphere to be referenced against a common reference on the opposite hemisphere. Both EOG channels are required to be referenced against a common reference (please refer to the AASM Manual 2007 (IV.1.B.1)).

Prefer notch filtered signals: If active, in case of ambiguous channels the notch filtered instead of unfiltered channels are exported.

2.3.2 Sleepware 2.x

The Somnolyzer Client can process sleep recordings in Sleepware 2.x format obtained from Alice 3, Alice 5, or Alice PDx devices.

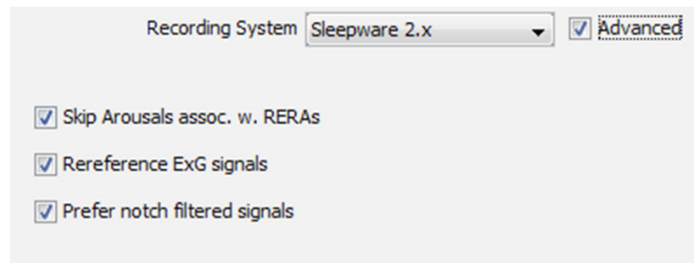
The screenshot shows a software interface for Sleepware 2.x. At the top, there is a dropdown menu labeled 'Recording System' with 'Sleepware 2.x' selected. To its right is a checkbox labeled 'Advanced' which is checked. Below these, there are three more checkboxes, all of which are checked: 'Skip Arousals assoc. w. RERAs', 'Rereference ExG signals', and 'Prefer notch filtered signals'.

Figure 8: Advanced settings for Sleepware 2.x

Advanced settings:

Skip Arousals assoc. w. RERAs: If active, the Somnolyzer Client removes spontaneous arousal events associated with RERAs in order to avoid them being counted twice in the Sleepware 2.x report module.

Rereference EXG signals: EOG/EEG data signals that are not referenced compatible to Somnolyzer are re-referenced if the this configuration parameter is activated, and if technically possible (that means A1A2 or A2A1 channel is present and recorded with the same sampling rate as the EEG/EOG channel that is to be re-referenced).

Prefer notch filtered signals: If active, in case of ambiguous channels the notch filtered instead of unfiltered channels are exported.

2.3.3 Stardust Host

The Somnolyzer Client can process Stardust sleep recordings in Stardust or Starmail (*.STARMAIL) format. Starmail files can be obtained by exporting the Stardust recording using the patient file utility in the Stardust Host software. The Light-off and Light-on time then has to be set manually, if desired. Otherwise Somnolyzer will analyze the entire sleep recording.

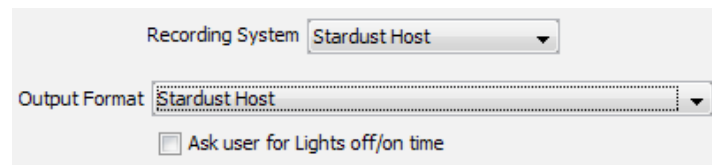
The screenshot shows a software interface for Stardust Host. At the top, there is a dropdown menu labeled 'Recording System' with 'Stardust Host' selected. Below this, there is another dropdown menu labeled 'Output Format' with 'Stardust Host' selected. At the bottom, there is a checkbox labeled 'Ask user for Lights off/on time' which is currently unchecked.

Figure 9: Settings for Stardust Host

Stardust recordings after the import of Somnolyzer results can be converted to the following formats: Stardust Host or Starmail.

2.4 User interface

2.4.1 Main window

The main Somnolyzer Client user interface consists of a menu bar, a tool bar, a study table, and a status bar.

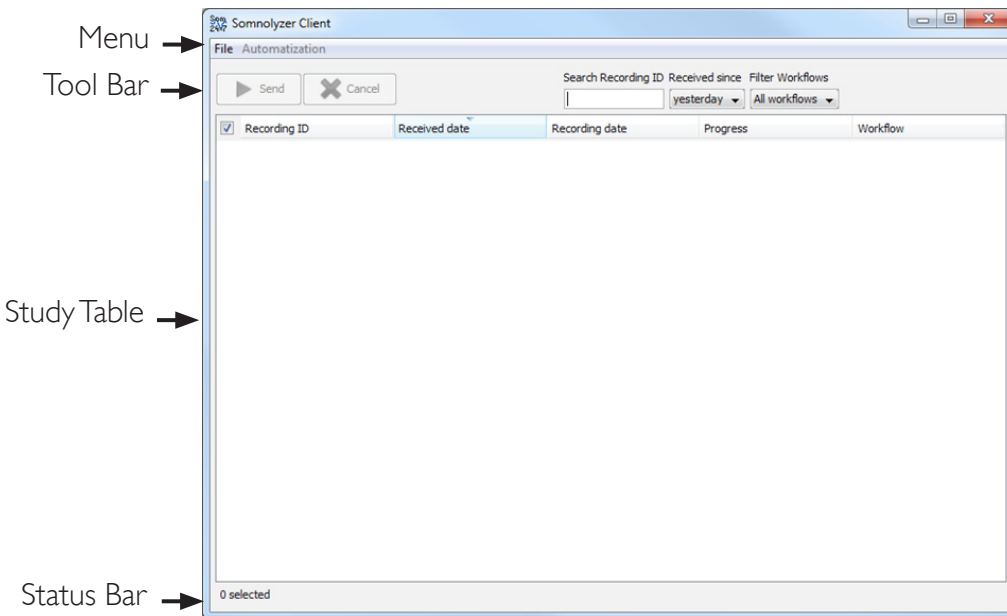


Figure 10: Main window

2.4.2 Menu

File>Configuration: to manage workflow(s) (see section 3.5).

File>About: The about dialog is displayed.

File>Exit: to exit the client. When the Client is closed the "data location" will not be monitored.

Automatization: The feature "Process studies automatically" (see section 2.3) can be switched on or off. For each workflow where this feature is enabled, a check mark is displayed next to the workflow name.

2.4.3 Tool bar

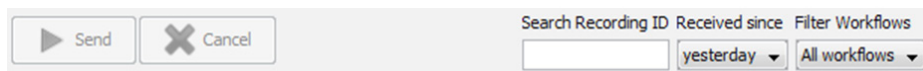


Figure 11: Tool bar

Send: Allows the user to send a sleep recording manually to Somnolyzer if the check box "Process studies automatically" is not selected. Whenever a sleep recording is detected in the "Data location," it will be listed in the study table. To send a particular sleep recording to Somnolyzer, the user has to select the check box next to the recording, and then click the "Send" button.

Cancel: After the processing of a sleep recording has been started (automatically or manually), the user has the option to cancel the process. The process will be displayed as in Figure 12. Any sleep recording can be resent by clicking on the "Send" button again.

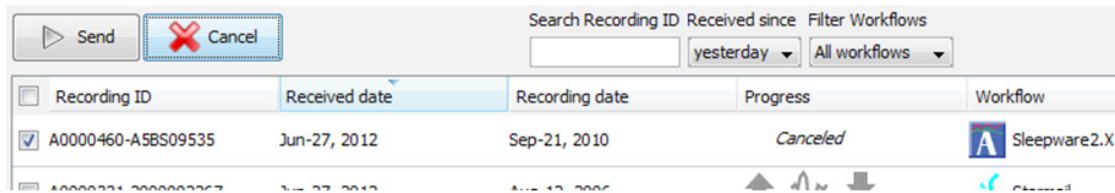


Figure 12:A canceled process

Search Recording ID: This text field allows searching for sleep recordings. Any match in the recording name (i.e. Recording ID) will be displayed. An empty search field will not affect the filter criteria.

Received since: This drop-down list allows the user to view sleep recordings over different periods. The detection date is the date, when the Somnolyzer Client detects a sleep recording in the monitored data location the first time. The user can choose between 2 days, 1 week, 1 month, or ever.

Filter Workflows: This drop-down list allows the user either to view sleep recordings from all workflows or to view only sleep recordings from a selected workflow.

2.4.4 Study table

In the study table, all sleep recordings are listed, which are located in the defined “Data locations” of all workflows and that meet the entered filter criteria (Workflow, Received since, and Search). The table consists of six columns: A check box per study, the recording-ID, received date, recording date, the progress status of Somnolyzer analysis and Workflow used for this study.

Check box: The user can either select all sleep recordings by clicking the check box in the table header or select them individually by clicking the check box next to the Recording ID. By selecting a sleep recording, the user can either start the process (click “Send” only if the “Process studies automatically” is not selected) or cancel it (by clicking the “Cancel” button).







Recording ID: The name of a detected sleep recording will be displayed in this column. Move the mouse over the table cell to display its location.

Received date: This date reflects the date, when the Somnolyzer Client detected the sleep recording in the “Data location.” Move the mouse over the table cell to display the full date and time.

Recording date: This timestamp reflects the day when the study was recorded. Move the mouse over the table cell to display the full date and time.

Progress: This column consists of three icons representing the three steps in the Somnolyzer process: Sending to the Somnolyzer server; the Somnolyzer analysis, and the receiving of the results. Every step can have different states:

Table 1: Different states of a sleep recording

 A0006436-2000003607	Jul-03, 2012	Feb-09, 2012		A sleep recording has been detected and is now being analyzed for validity
A0000458-A5BS09535	Jun-27, 2012	Sep-17, 2010		A valid sleep recording has been detected and is ready to be processed. This state only occurs when the “Process studies automatically” is not activated.
A0000458-A5BS09535	Jun-27, 2012	Sep-17, 2010		The sleep study is queued, and will be sent to Somnolyzer as soon as possible
A0000460-A5BS09535	Jun-27, 2012	Sep-21, 2010		The Somnolyzer Client is sending a sleep recording to the Somnolyzer Server
A0000459-A5BS09535	Jun-27, 2012	Sep-20, 2010		The Somnolyzer Server is analyzing the sleep recording

A0000331-2000002267	Jun-27, 2012	Aug-12, 2006		The sleep recording has been analyzed by Somnolyzer and the results are being reimported.
A0000126-SD0070	Jun-27, 2012	Jul-15, 2002		The sleep recording has been processed and is ready for Expert Review
A0000460-A5BS09535	Jun-27, 2012	Sep-21, 2010	<i>Canceled</i>	The process has been canceled by the user. The user can select the check box and resend the sleep recording

Additionally, a tool tip will be displayed when moving the cursor over the Progress symbols, which informs the user in which state the sleep recording currently is.

Workflow: In this column, users can easily see which Workflow has been applied for which sleep recording. An icon (Figure 12) indicates the corresponding recording system.

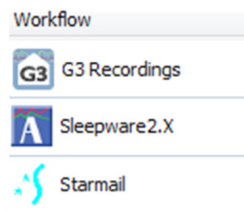


Figure 13: Recording systems

2.4.5 Status bar

The status bar informs the user which action is currently performed by the Somnolyzer Client.

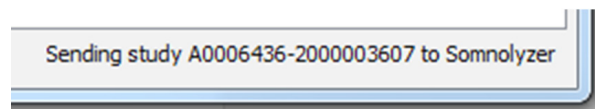


Figure 14: a status message

2.5 Processing sleep recordings

2.5.1 In automatic mode

If a workflow is configured in automatic mode (see section 2.3 “process studies automatically”), the Somnolyzer Client monitors the “Data location” for sleep recordings and as soon as a complete sleep recording is detected, the client will queue the sleep recording and send it to the Somnolyzer Server at the earliest opportunity. The status of the process can be monitored in the main windows.

2.5.2 In manual mode

If the check box “process studies automatically” is not selected, a detected sleep recording will be displayed in the main window, but not processed automatically until the user starts the process manually.

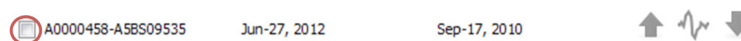


Figure 15: Selecting a sleep recording

To start to process, the user has to select the sleep recording by clicking the check box next to the Recording ID and click “Send.”

2.5.3 Re-sending a sleep recording

The user can re-send a sleep recording, if desired. In case a sleep recording is processed by the Somnolyzer; the user can cancel the process at any time by clicking on “Cancel” in the main window. The Somnolyzer Client will display the recording as follow:



Figure 16: the status of a canceled sleep recording

To re-send a sleep recording in order to be processed by the Somnolyzer again, the user has to select the sleep recording by clicking the check box next to the Recording ID and click “Send.” This will open a warning dialog. The user has the choice of sending all, none, or only unscored recordings to Somnolyzer, respectively.

2.6 Troubleshooting

Problem: The client doesn't show the sleep recording in the main window.

Answer: *Is the sleep recording in the “Data location” defined in the workflow?*

No: Copy the sleep recording in the folder.

Yes: *Has the correct sleep recording system been chosen?*

No: Change the recording system in the configuration window.

Yes: *Is the sleep recording complete?*

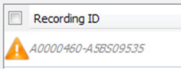
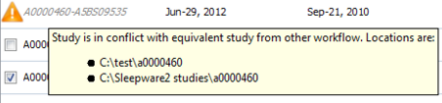


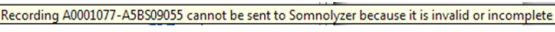
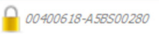

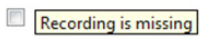


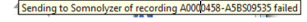
No: Make sure that the whole sleep recording has been copied.

Yes: Has the sleep recording already been processed more than 30 days ago and then moved away from the scored location?

Problem: The sleep recording can be seen in the main window, but is not sent to the Somnolyzer. Solutions are displayed in Table 2.

Table 2: Troubleshooting

Symbol	Meaning	Solution
	<p>The sleep recording is complete, but cannot be analyzed by Somnolyzer because some Channel labels are unknown</p>	<p>Open SMI (see 3.4.2) and add the label to the label list and send sleep recording again</p>
	<p>The sleep recording is complete, but cannot be analyzed by Somnolyzer</p>	<p>Check SMI (see 3.4.2) for the “insufficient Channels” Error</p> <p>or Call product support</p>

	 <p>Sleep recording will not be processed, because sleep recording exists already in another folder used by another workflow and pointing to the same Somnolyzer server workflow or scored location.</p>	<p>Remove all but one of the conflicting studies.</p>
<p>Alternatively</p>  <p>And</p> 	 <p>The sleep recording is invalid or incomplete, therefore the Somnolyzer Client continues to check it for completeness.</p>	<p>Check in recording system if sleep recording isn't corrupt or check in "data location" if the recording has been incompletely transferred for any reason.</p>
	<p>Sleep recording is locked, because it was opened in the recording system</p>	<p>Check if another user is editing the sleep recording and if not delete the *.lck file in the sleep recording folder.</p>
 	<p>The sleep recording has been deleted/moved away from the "Data location" or "scored location"</p>	<p>If it is intended to process this sleep recording again it has to be moved back to its location.</p>
  	<p>A sleep recording Mapped Somnolyzer Server drive not available.</p>	<p>Check if Somnolyzer Server is mapped</p>

3 Somnolyzer Management Interface

3.1 Introduction

The Somnolyzer Management Interface (SMI) is used to configure the Somnolyzer server workflows and monitor the progress of all studies sent to Somnolyzer by either Philips support or the user herself. Additionally, the user can look up the details of all previously processed studies including monthly reports for accounting purposes.

3.2 Access

The SMI can be accessed with any modern Web Browser using the servers IP address (or name if configured via DNS) under “http://<server-ip-address>/”.

3.2.1 Login

To login, the user needs to enter a username and password, and then click on the “Login” button. Those credentials are usually setup during the initial Somnolyzer setup but can be added or modified afterwards (see 3.5.2).

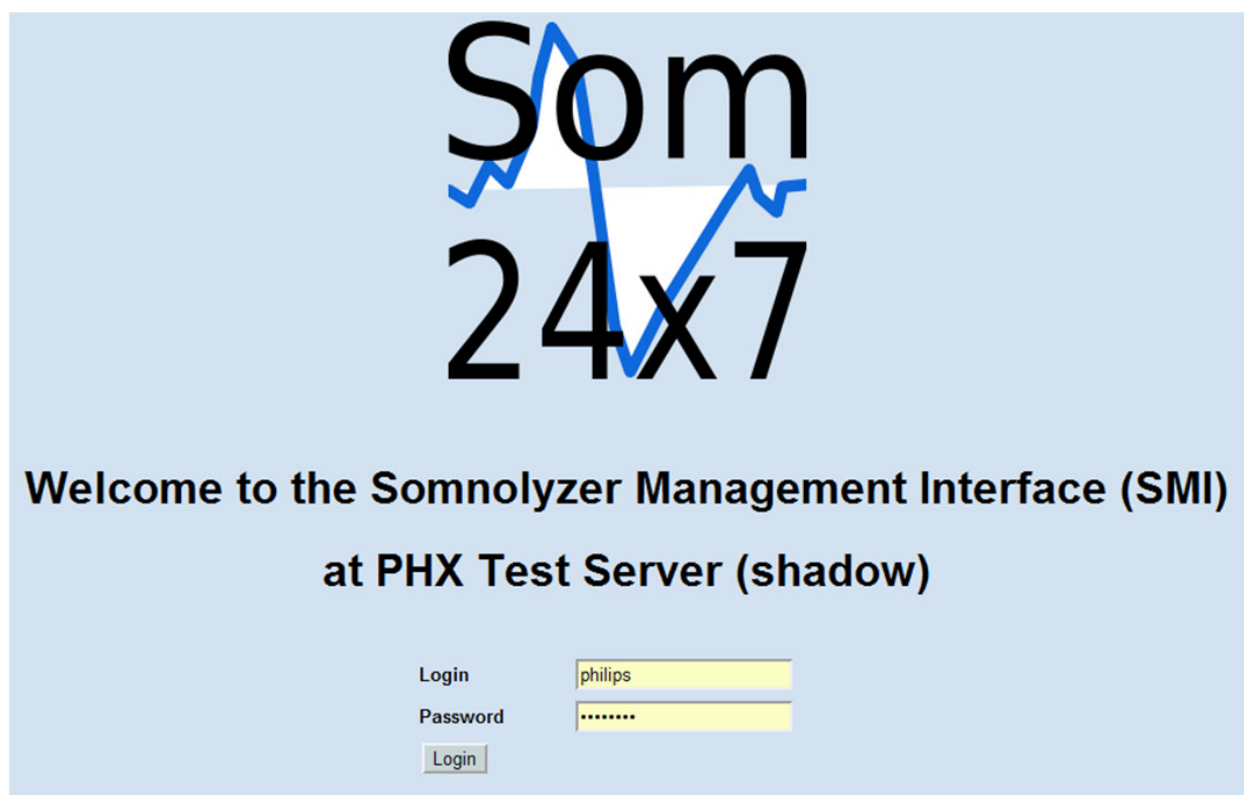


Figure 17: SMI login window

3.2.2 Logout

To prevent misuse, the user should logout if the SMI is no longer required, especially if that account has the Admin or Reviewer Role (see section 3.3 for details). To log out, the user needs to click on the “Logout” Button in the Navigation Panel of the SMI.

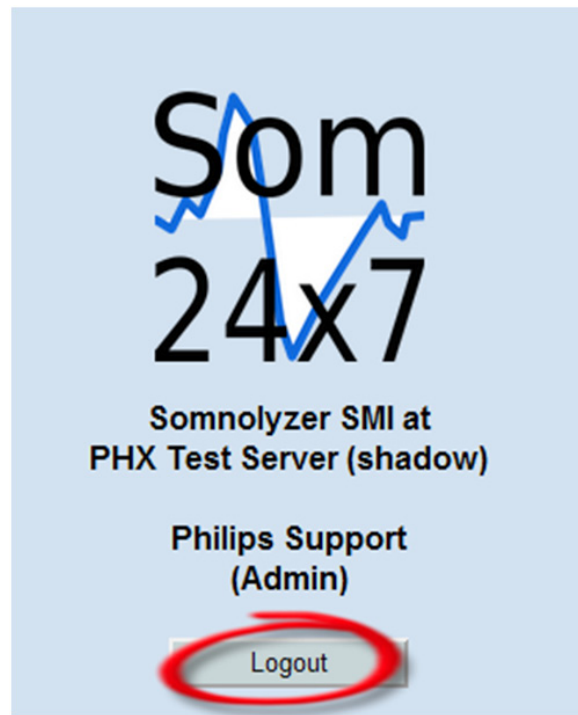


Figure 18: SMI logout button

3.3 Roles

The SMI supports three account roles with different privileges ("View only" lowest, "Admin" highest privileges).

3.3.1 View only

An account with the "View only" role assigned is able to view the Process Queue and the monthly overview in the Accounting menu.

3.3.2 Reviewer

An account with the "Reviewer" role assigned extends the "View only" role with the ability to handle the Labeling system and view the configured workflows and their assigned Somnolyzer configuration.

3.3.3 Admin

An account with the "Admin" role assigned has full privileges which extends the "Reviewer" role with the ability to configure Workflows and SMI Accounts.

3.4 Process Queue

The main window of the SMI is the Process Queue showing the details for each sleep recording that was processed on this Somnolyzer server. The Process Queue enables the direct search for sleep recordings with specific details and shows a list of sleep recordings with various filters applied. The list updates automatically every few seconds.

Filter Process Queue					
Study	Workflow	Date received yyyy-mm-dd	Status	Entries per Page	Refresh every x seconds

Figure 19: Process Queue Filters

3.4.1 Applying Filters

The filters can be used to either search for a specific sleep recording or just narrow down the list (for example, listing all sleep recordings from a specific month or all sleep recordings that produced an error). Some filters allow the search for a partial match.

Filter by Study Name

To look for sleep recordings with a specific name, enter the name in the Study text box, and click the “Filter” button.

Filter by Workflow Name

To look for sleep recordings processed using a specific workflow, enter the name of the workflow in the Workflow text box, and click the “Filter” button.

Filter by Date received

To look for sleep recordings processed on a specific day or in a specific month/year, enter the relevant date into the “Date received” text box, and click “Filter.” The date format used is “YYYY-MM-DD” (for example: 2012-03-16).

Filter Status

To look for sleep recordings in a particular state (Processing, Queued etc.), all the possible states are listed in the Status list box.

Entries per Page

The amount of entries displayed per page can be changed here.

Refresh every x seconds

By default, the Process Queue and any applied Filters will update every 30 seconds. The update interval can be changed here.

3.4.2 What Process Queue shows

The Process Queue shows the following details for each sleep recording:

Showing entries 201 to 220 from 344.

[First](#) [8](#) [9](#) [10](#) [11](#) [12](#) [13](#) [Last](#)

Study	Workflow	Date received	Status
A0000032-13516	aasm_4B	2012-10-11 15:30:02	OK
A0000030-13183	aasm_4B	2012-10-11 15:29:58	OK
A0000026-13520	aasm_4B	2012-10-11 15:29:54	OK
A0000015-13520	aasm_4B	2012-10-11 15:29:50	OK
A0000124-13516	aasm_4B	2012-10-11 15:29:42	OK
A0000051-13520	aasm_4B	2012-10-11 15:29:37	OK
A0000031-13516	aasm_4B	2012-10-11 15:29:33	OK
A0000026-13519	aasm_4B	2012-10-11 15:29:29	Check Labels
A0000024-13520	aasm_4B	2012-10-11 15:29:25	OK
A0000015-13183	aasm_4B	2012-10-11 15:29:21	OK
A0000053-13520	aasm_4B	2012-10-11 15:29:13	Error
A0000052-13520	aasm_4B	2012-10-11 15:29:09	OK
A0000041-13516	aasm_4B	2012-10-11 15:29:05	OK
A0000015-13519	aasm_4B	2012-10-11 15:29:02	Rejected
00000034-APDxX0038	aasm_4A	2012-10-11 15:28:55	OK
00040974-A5BS11186	aasm_4A	2012-10-11 15:28:37	OK
09000164-A5BS01817	aasm_4A	2012-10-11 15:28:00	OK
A0000213-2000000500	aasm_4A	2012-10-10 11:55:29	OK
A0000124-2000006370	aasm_4A	2012-10-10 11:49:48	OK
A0000113-2000000500	aasm_4A	2012-10-10 11:49:45	OK

[First](#) [8](#) [9](#) [10](#) [11](#) [12](#) [13](#) [Last](#)

Page refreshes every 30 seconds. (Last refresh 10:52:40 am)

Figure 20: Process Queue Example

Study name

The study name is a unique identifier for a sleep recording defined by the Somnolyzer Client. For example, a Sleepware study name would consist of the Acquisition number and the device ID. A study name colored in blue indicates a sleep recording that was processed more than once (regardless of the workflow used).

Study name tooltip

The tool tip of each study name shows the internally used filename. This filename includes information about the used workflow, the received date, and the lights out/on information, which is counted in epochs.

Workflow

Each sleep recording is processed using a specific workflow on the server. This is useful to keep track of sleep recordings from various locations or if sleep recordings need to be processed using different Somnolyzer configurations.

Date received

Indicates the date and time the sleep recording was sent to Somnolyzer for processing.

Status

The status of each sleep recording is available here. These are the following available states:

Queued

The sleep recording is picked up by Somnolyzer and waiting to be processed.

Check Labels

The sleep recording introduces unknown labels and is currently paused until those labels are assigned (see 3.6.2).

Rejected

The sleep recording does not have an Annotations channel and therefore cannot be processed. (**Note:** *This does not happen when sending sleep recordings using the Somnolyzer Client.*)



The progress of Somnolyzer analysis is shown as Percent.

Insufficient Channels

This error indicates that the sleep recording was processed using a strict Somnolyzer configuration and did not have all the required channels (for example, missing EMG channels necessary for staging).

Error

Somnolyzer could not successfully process this study for some reason.

OK Processing time: 00:15:35

Somnolyzer analysis is completed and the results are available for the Somnolyzer Client. The tool tip shows how long Somnolyzer needed to process the sleep recording.

3.5 Administration

3.5.1 Workflows

The list of available Somnolyzer configurations may vary/add up as individual Somnolyzer configurations are changed/installed over time.

Reviewer role

An account with the “Reviewer” role assigned can view all currently configured workflows and the assigned Somnolyzer configurations. Additionally, the descriptions for all available Somnolyzer configurations are viewable (Figure 21).

Available Workflows

Workflow Configuration		Workflow Configuration		Workflow Configuration	
aasm_4a	AASM 4A	aasm_4b	AASM 4B		

Available Somnolyzer Configurations

Configuration (Click for Details)		
AASM 4A	AASM 4B	AASM 4B Sensitive
RnK 4A	RnK 4B	RnK 4B Sensitive

Figure 21: Workflow view for Reviewer

Admin Role

An account with the “Admin” role assigned extends the privileges of the “Reviewer” role and adds the possibility to add or modify workflows. (**Note:** Deletion of workflows is not supported.)

To create a new workflow, enter the desired name, choose the Somnolyzer configuration that the workflow will be using, and click on “Add new Workflow.”

(**Note:** Only characters and numbers are allowed for the workflow name. Any special characters will be automatically removed upon creation of the workflow).

Create Workflow

Workflow Name	Configuration	
<input type="text" value="example"/>	<input type="text" value="AASM 4A"/>	<input type="button" value="Add new Workflow"/>

Figure 22: Workflow creation dialogue

To modify an existing workflow, select the desired Somnolyzer configuration from the Configuration list box to the right of the workflow-name.

Workflow	Configuration
aasm_4a	<input type="text" value="AASM 4A"/> <div> AASM 4A AASM 4B RnK 4A RnK 4B AASM 4B Sensitive RnK 4B Sensitive </div>

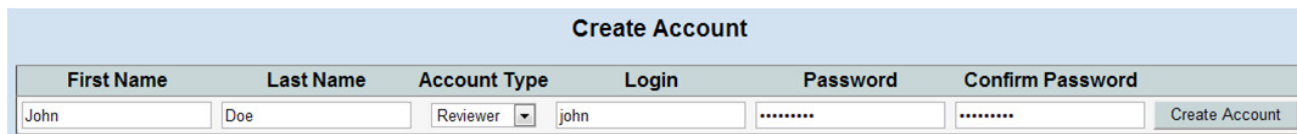
Figure 23: Reassign a different Somnolyzer Configuration

3.5.2 SMI Accounts

This menu is used to add or modify SMI access accounts.

To add a new account, enter the first and last name of the user, the desired Account Role, the username, and the password twice. Click “Create Account” to initiate the account creation.

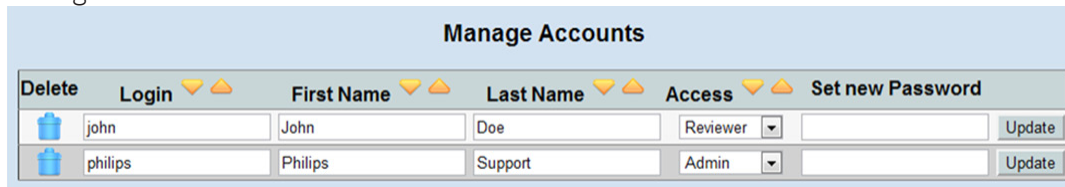
(**Note:** The password length must be between 8 and 20 characters and the password must consist of characters and numbers.)



The 'Create Account' dialog box contains a table with the following fields: First Name (John), Last Name (Doe), Account Type (Reviewer), Login (john), Password (masked with dots), and Confirm Password (masked with dots). A 'Create Account' button is located on the right side of the table.

Figure 24: SMI Account creation dialogue

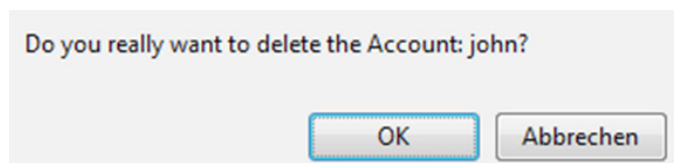
To modify an existing account change the values for that account and click on the corresponding “Update” button on the right side.



The 'Manage Accounts' table has columns: Delete, Login, First Name, Last Name, Access, and Set new Password. It lists two accounts: 'john' (Reviewer) and 'philips' (Admin). Each row has a blue trash icon in the 'Delete' column and an 'Update' button in the 'Set new Password' column.

Figure 25: Manage SMI accounts

To delete an existing account, click the corresponding blue Trash icon on the left side of that account and confirm the dialogue with “OK.”



The dialog box asks: 'Do you really want to delete the Account: john?'. It has two buttons: 'OK' and 'Abbrechen'.

Figure 26: Confirm SMI account deletion

3.6 Labeling

A very important part of the SMI is the Labeling system. To be able to correctly identify the specific channels in sleep recordings, Somnolyzer keeps a Database of assigned channel labels. The Database is a mapping of a channel label in use against a corresponding internal label (encapsulated within square brackets e.g. [EMYG] for Chin EMG) which the Somnolyzer can understand. In other words, if a certain channel label used is not already mapped to an Somnolyzer identifiable label, as far as the Somnolyzer is concerned, the channel does not exist. Thus the database of labels obviously needs to be very well maintained as Somnolyzer will not process sleep recordings with unknown channel labels in some cases, and in others the results might be suboptimal due to the possibility that some vital channels (for example “Chin EMG”) might not be identified(because of a missing mapping).

3.6.1 Somnolyzer Channels

[F3A2]	EEG F3 referenced to A2
[F4A1]	EEG F4 referenced to A1
[C3A2]	EEG C3 referenced to A2
[C4A1]	EEG C4 referenced to A1
[O1A2]	EEG O1 referenced to A2
[O2A1]	EEG O2 referenced to A1
[A1A2]	EEG A1 referenced to A2
[A2A1]	EEG A2 referenced to A1
[EOGL]	EOG 1 cm below the outer canthus of the left eye referenced to A2

[EOGR]	EOG 1 cm above the outer canthus of the right eye referenced to A2
[EMYG]	Chin EMG
[PLML]	Leg EMG left
[PLMR]	Leg EMG right
[AFLO]	Thermistor airflow signal
[PFLO]	Pressure transducer (Cannula) airflow signal
[CFLO]	CPAP mask airflow signal
[ABMV]	Abdominal effort signal
[CHMV]	Thoracic effort signal
[OSAT]	Blood oxygen saturation

3.6.2 Unknown Labels

Whenever Somnolyzer cannot identify all channels of a sleep recording the unknown labels will be listed in the “Unknown Labels” menu and the processing of that study will be “paused” until those labels are assigned.

(Note: Sleep recordings in the “paused” state for a week will be automatically considered erroneous.)

This list can be sorted by the following criteria:

- Alphabetically ascending
- Alphabetically descending
- Most recently added

To assign an unknown label, simply choose the appropriate Somnolyzer channel from the channel list next to the Label.

Labels that are not relevant for Somnolyzer need to be assigned as IGNO.

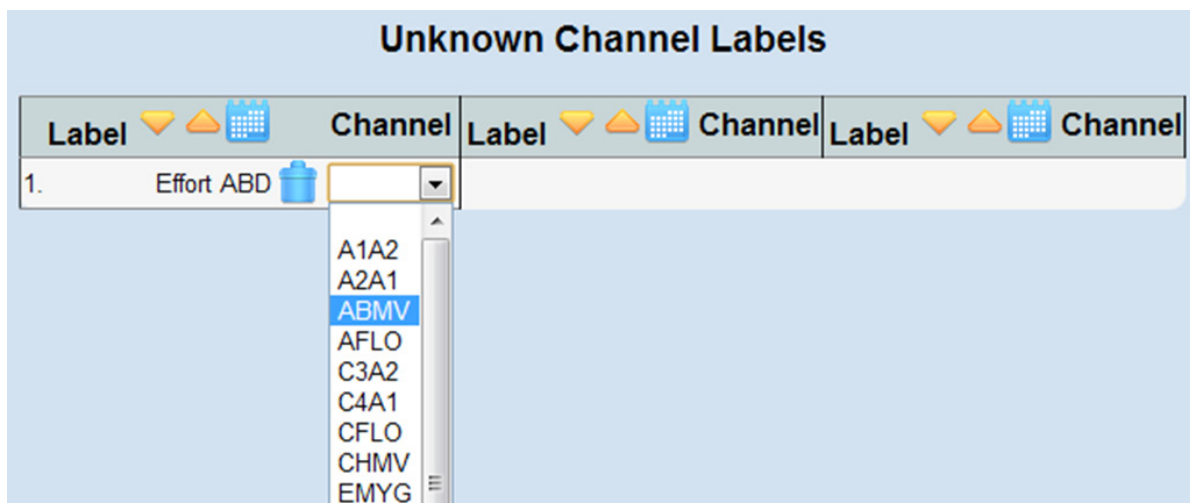


Figure 27: Assign unknown label

To delete an unknown label, simply click the blue trash icon next to the label and confirm with “OK.” *(Note: If the sleep recording including that label is currently paused the label will be added to the unknown labels again.)*

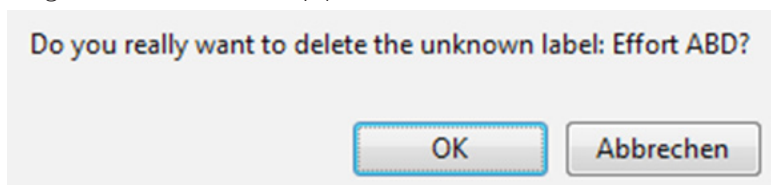


Figure 28: Confirm unknown label deletion

3.6.3 Known Labels

The list of all Somnolyzer known labels is available here.

This list can be sorted by the following criteria:

- Label name alphabetically ascending
- Label name alphabetically descending
- Channel name alphabetically ascending
- Channel name alphabetically descending
- Most recently modified

To re-assign a label, simply select a different channel name in the menu next to the current channel name.

Known Channel Labels					
Label		Channel		Label	
1. ECG	IGNO		2. ECG I	IGNO	
4. ECG I1HF	IGNO		5. EDF+ ANO	IGNO	
7. EEG C3-A2	C3A2		8. EEG C4-A1	C4A1	
10. EEG F4-A1	F4A1		11. EEG O1-A2	O1A2	
13. EEG T3-A1	IGNO		14. EEG T4-A2	IGNO	
16. Effort THO	CHMV		17. EMG Chin	EMYG	
19. EOG ROC-A2	EOGR		20. Flow Pressure	PFLO	
22. Flow Thermistor	AFLO		23. Leg 1	PLMR	
25. Snore	SNOR		26. SpO2	OSAT	

Figure 29: Re-assign channel label

To delete a label, simply click on the blue trash icon next to the label and confirm with “OK.”

Do you really want to delete the known label: ECG?

OK

Abbrechen

Figure 30: Confirm know label deletion

3.7 Accounting

The SMI keeps track of all sleep recordings for accounting. Reports of the amount of sleep recordings processed for each month of a year are available here.

2012					
Jan	Feb	Mar	Apr	May	Total 2012
13	52	88	142	219	514
View Details	View Details	View Details	View Details	View Details	View Details
Numbers by Workflow	Numbers by Workflow	Numbers by Workflow	Numbers by Workflow	Numbers by Workflow	Numbers by Workflow
CSV	CSV	CSV	CSV	CSV	CSV

Figure 31: Example of accounting overview

Accounting queries for a custom time period are available using the “Custom Period” button. Choose the start and end date using the calendar icon and click calculate.

Figure 32: Example of custom period

3.7.1 Calculation criteria

The numbers shown for each month/year are calculated using each of the following criteria:

- Sleep recording was processed without errors (Status “OK”)
- A sleep recording is only counted for the month where it was first processed without errors

3.7.2 View Details

Clicking “View Details” will show a list of all sleep recordings for that month/year matching the criteria in 3.7.1.

The details include:

- The unique ID of the sleep recording
- The workflow used to process the sleep recording
- The date the sleep recording arrived on the Somnolyzer server

A0000011-1202060060	test	2012-04-12 10:50:56
A0000013-2000000500	test	2012-04-12 10:51:00
A0000331-2000002260	test	2012-04-12 10:51:04

Figure 33: Example of monthly accounting details

3.7.3 Numbers by Workflow

Clicking “Numbers by Workflow” will show a list of all sleep recordings for that month/year by each available workflow and matching the criteria in 3.7.1.

Workflow	Amount
aasm4a	47
aasm4B	1

Figure 34: Example of monthly accounting details listed by each workflow

3.7.4 CSV Export of details

Clicking the green CSV icon will open the download dialogue to save the details listed under 3.7.2 as a .CSV file which can be then opened in any program that can import .CSV files (for example: MS Excel).

3.7.5 XML Export (Admin only)

When logged in with an account that has the “Admin” role, an additional icon is available. This functionality is currently not being used.

4. Somnolyzer Server Maintenance Console

4.1. Introduction

The Somnolyzer server console is used for basic administration (update network settings, update date and time settings) and to restart/shutdown the Somnolyzer server.

4.2. Access

The Somnolyzer server console can be accessed either directly on the server console or via network using SSH to the IP address of the server (Port 22).

4.3. Login

To login, the user needs to enter the username “admin” and a password, which was generated during the Somnolyzer installation.

4.4. Administrative options

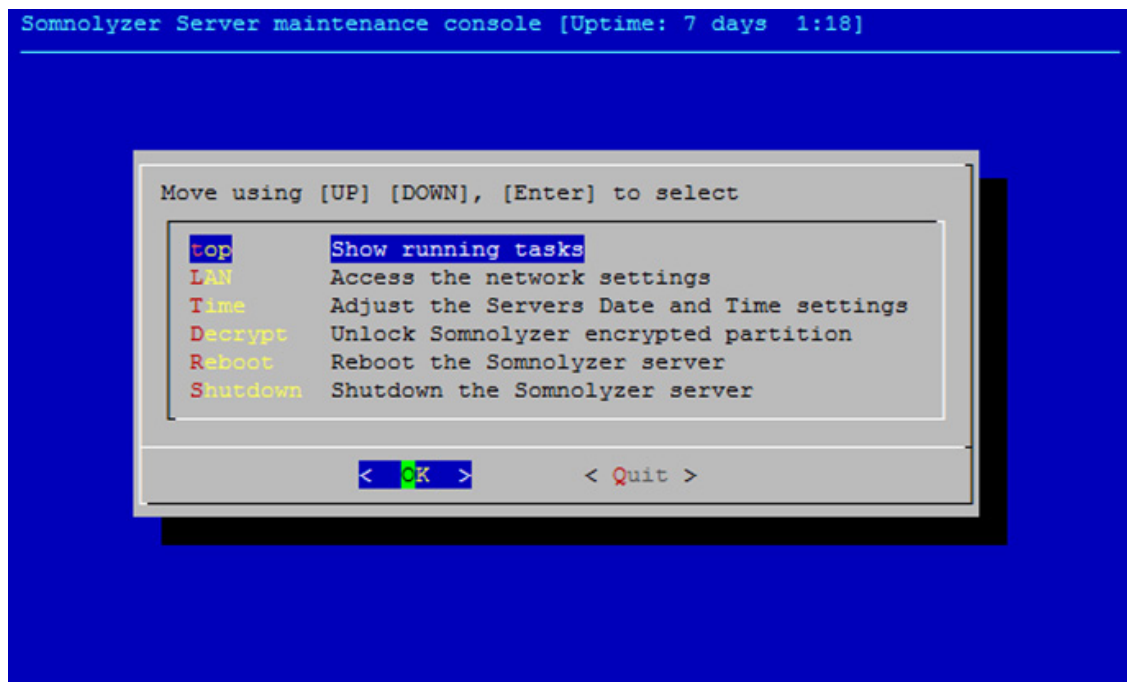


Figure 35: Administrative options

4.4.1. Top

Show running tasks on the Somnolyzer server using the Linux command “htop.” Exit this view using “q.”

4.4.2. LAN

Access the network settings menu of the OpenSuSe Linux tool YAST. Navigate the menu using the arrow and tab keys. (**Note:** Changing the network settings when connected via SSH might disrupt your current connection!)

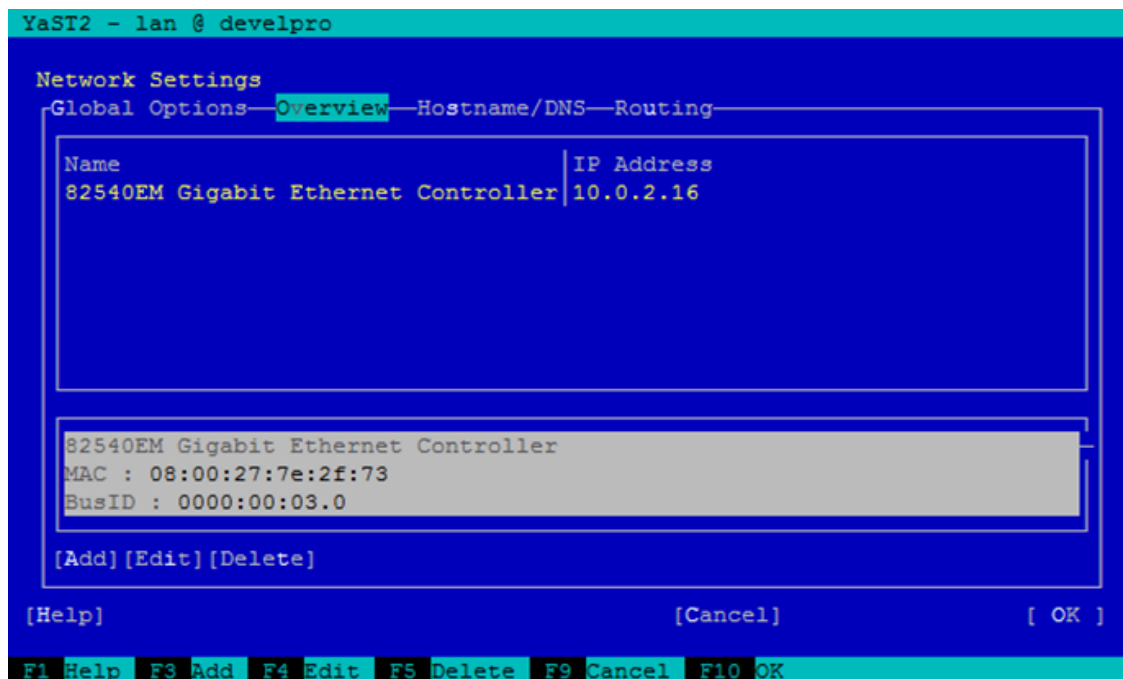


Figure 36: LAN network settings

4.4.3. Time

Access the Date and Time settings menu of the OpenSuSe Linux tool YAST. Navigate the menu using the arrow and tab keys.

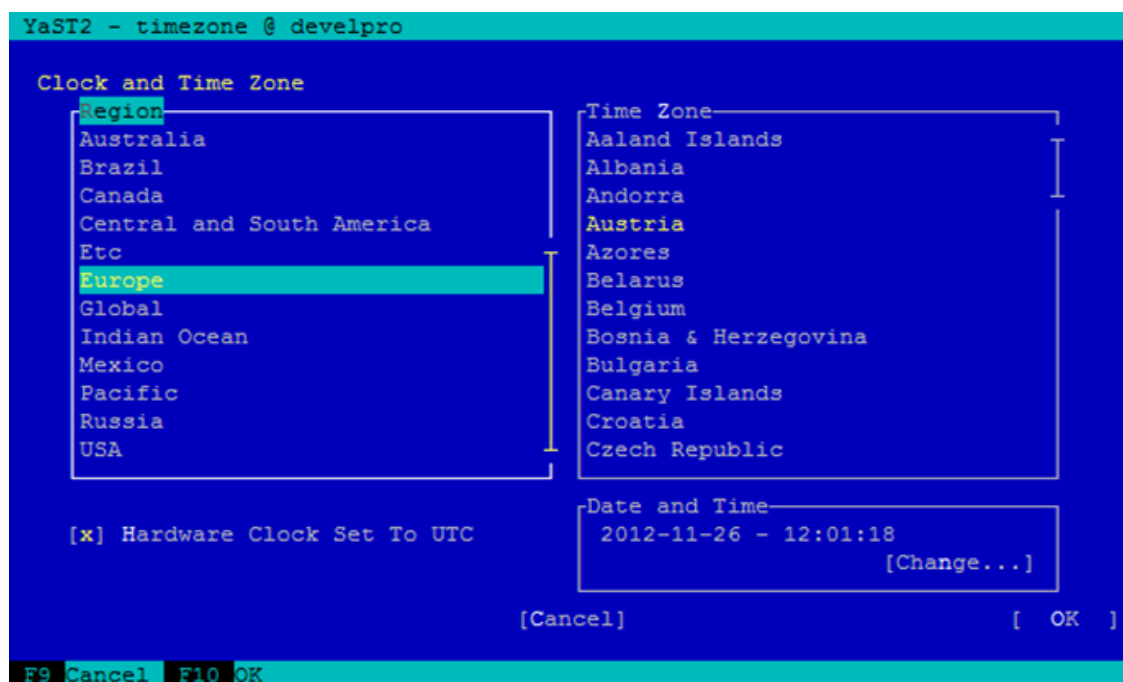


Figure 37: Date and Time settings

4.4.4. Decrypt (optional)

This option is only available on Somnolyzer servers using an encrypted Somnolyzer partition. Decryption is performed only by Philips Respironics authorized personnel.

4.4.5. Reboot

The Somnolyzer server will reboot exactly one minute after selecting “Yes.” (**Note:** Rebooting the server should not be done while Somnolyzer is still processing!)

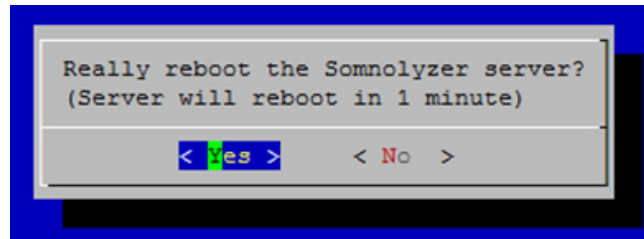


Figure 38: Reboot window

4.4.6. Shutdown

The Somnolyzer server will shut down exactly one minute after selecting “Yes.” (**Note:** Shutting down the server should not be done while Somnolyzer is still processing!)

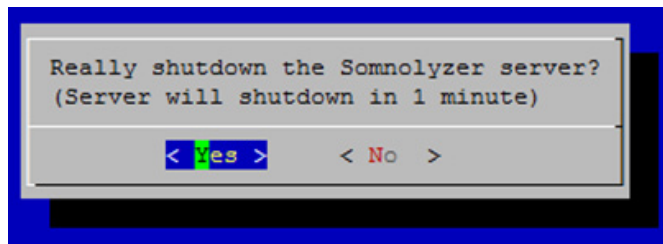


Figure 39: Shutdown window

5 Expert Review Guide (Sleepware G3 Version 3.3.1+)

5.1 Introduction

Somnolyzer 24x7 is a fully validated and reliable tool for computer-supported scoring of polysomnographic (PSG) sleep recordings. Given PSG signals of acceptable quality and fully compliant with the settings as required by the relevant scoring standard, sleep stages and events as derived automatically by Somnolyzer 24x7 are highly trustworthy, being indistinguishable in quality from any skilled visual scorer; and can in many cases be accepted with little manual intervention.

A visual expert review of scoring, performed by skilled scoring staff, is indispensable to ensure high-quality clinically valid results for any scoring procedure. This is not different for Somnolyzer 24x7. What is different, however, is the efficiency with which expert review for Somnolyzer 24x7 scorings can be performed, based on a structured and systematic procedure of several well-identified steps. The goal of expert review is twofold:

1. to ensure that the actual PSG measurement – the recorded signals – was done in a proper way and will not adversely influence any major clinical variable in the scoring report; and also to correct scoring decisions made by Somnolyzer 24x7 when poor recording quality does influence them.
2. to ensure that the computer-based procedure by Somnolyzer 24x7 has not misclassified a clinically important event.

While efforts to ensure point 1 above are minimized by ensuring high-quality and compliant data (thus turning Somnolyzer 24x7 also into a quality assurance tool for the PSG recording team), the steps needed to check point 2 are clearly identified, also typically requiring very little time and effort.

5.2 The Main Cornerstones of Efficient Expert Review

Efficient Expert Review (ER), focusing on the (usually rare) parts of a study that might need human oversight, can be performed by reviewing a scoring epoch by epoch (as is currently still required by AASM accreditation guidelines), or by an even more efficient procedure described below. The ER procedure is based on a specific set of graphical trends – collectively called the Polysomnographic Feature Trends (PFTs) – that the Somnolyzer 24x7 provides in addition to the actual scoring (see chapter 3 for a detailed description of the trends).

- For the *staging & arousal part*, the PFTs show a number of traces depicting the distribution of important sleep/wake related features as well as data quality information of EEG, EOG and chin EMG signals. This allows – based on a set of simple rules – the identification of major signal deficiencies and thus the identification of sections that require special attention during the ER.
- For the *respiratory & leg movement event part*, the PFTs show a number of traces depicting the distribution of the events as well as data quality information of respiratory and leg EMG signals. This allows – again based on a set of simple rules – the identification of major signal deficiencies and thus the identification of sections that require special attention during the ER.

This leads to an important observation one should keep in mind when using Somnolyzer 24x7:

Somnolyzer 24x7 allows a trained scorer to shift his focus from an epoch-by-epoch or event-by-event view to a global all-night overview. After some training, every skilled scorer will be able to use the compressed view, given by the PFTs, to finalize the scoring for a fully valid and highly reliable sleep report. Taking a look at single epochs or single events is only necessary in clearly identified areas, based on this global picture.

ER is performed in two major phases:

Phase 1: Staging & Arousals

Step 1: Confidence Check of the automated scoring

Step 2: Expert Review of scoring and raw data (semi-automated scoring)

Phase 2: Respiratory & Leg Movement Events

Step 1: Confidence Check of the automated scoring

Step 2: Expert Review of scoring and raw data (semi-automated scoring)

Step 1 of each phase is solely based on the interpretation of the PFTs, Step 2 also includes the review of the raw data.

5.3 The Polysomnographic Feature Trends (PFTs)

How to view the PFTs: Somnolyzer Workspaces in Sleepware G3

As discussed above the PFTs form the basis for the ER procedure. The PFTs are based on the main characteristic sleep/wake related features as well as information about signal quality, which are imported into the studies in G3 together with the results of Somnolyzer analysis.

There are four different Somnolyzer workspaces available in G3 which display the PFTs optimally for a most efficient expert review procedure:

Somnolyzer Staging Overview (for an example see Figure 40A)

Somnolyzer Staging Expert Review (for an example see Figure 63)

Somnolyzer Events Overview (for an example see Figure 40B)

Somnolyzer Events Expert Review (for an example see Figure 65)

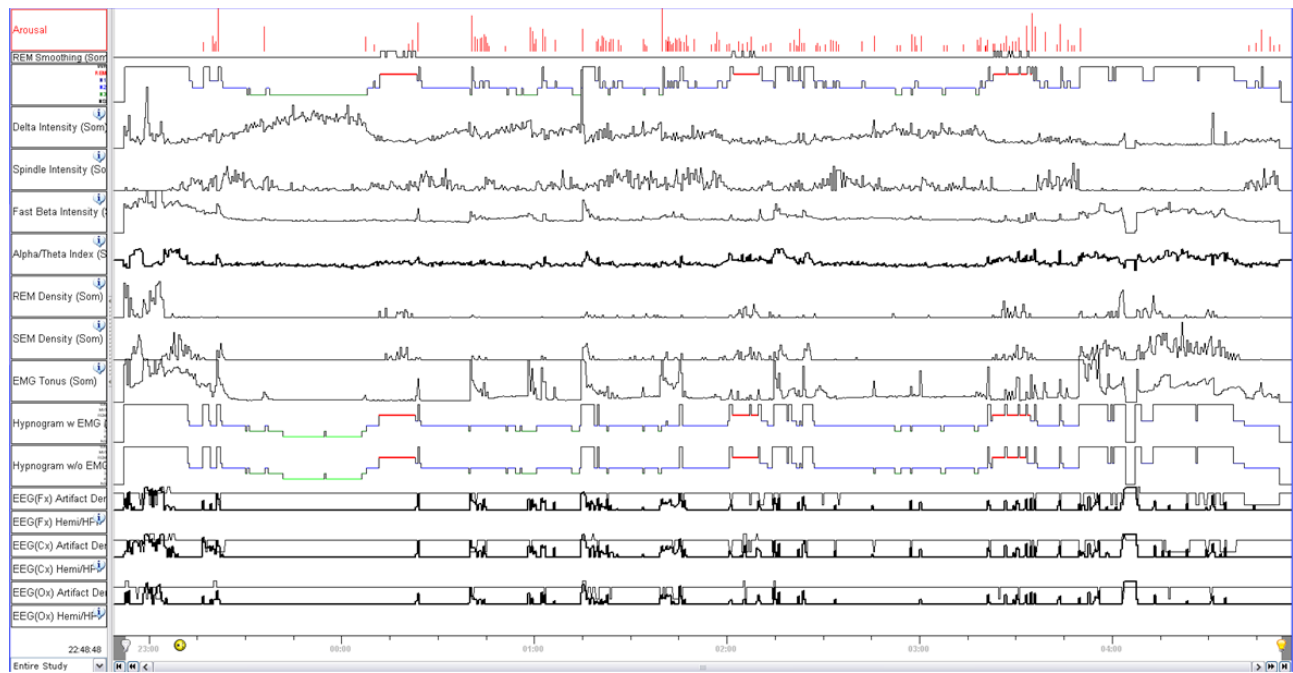
To apply a workspace, open the study, go to “Workspaces” > “Favorites” and select the Somnolyzer workspaces you want to apply (for further details see 5.7).

5.3.1 The Somnolyzer Overview Workspaces

(Somnolyzer Staging Overview and Somnolyzer Events Overview)

The Somnolyzer Staging Overview workspace displays all relevant trends in an all-night overview for staging & arousals and the Somnolyzer Events Overview displays all relevant trends for respiratory & leg movement events. Figure 40 shows an example of a diagnostic study, Figure 41 of a split-night study, and Figure 42 of a treatment study. The meaning of the different trends is described in the next two sections (5.3.2 and 5.3.3); their optimal usage for expert review is described in section 5.4.

A



B

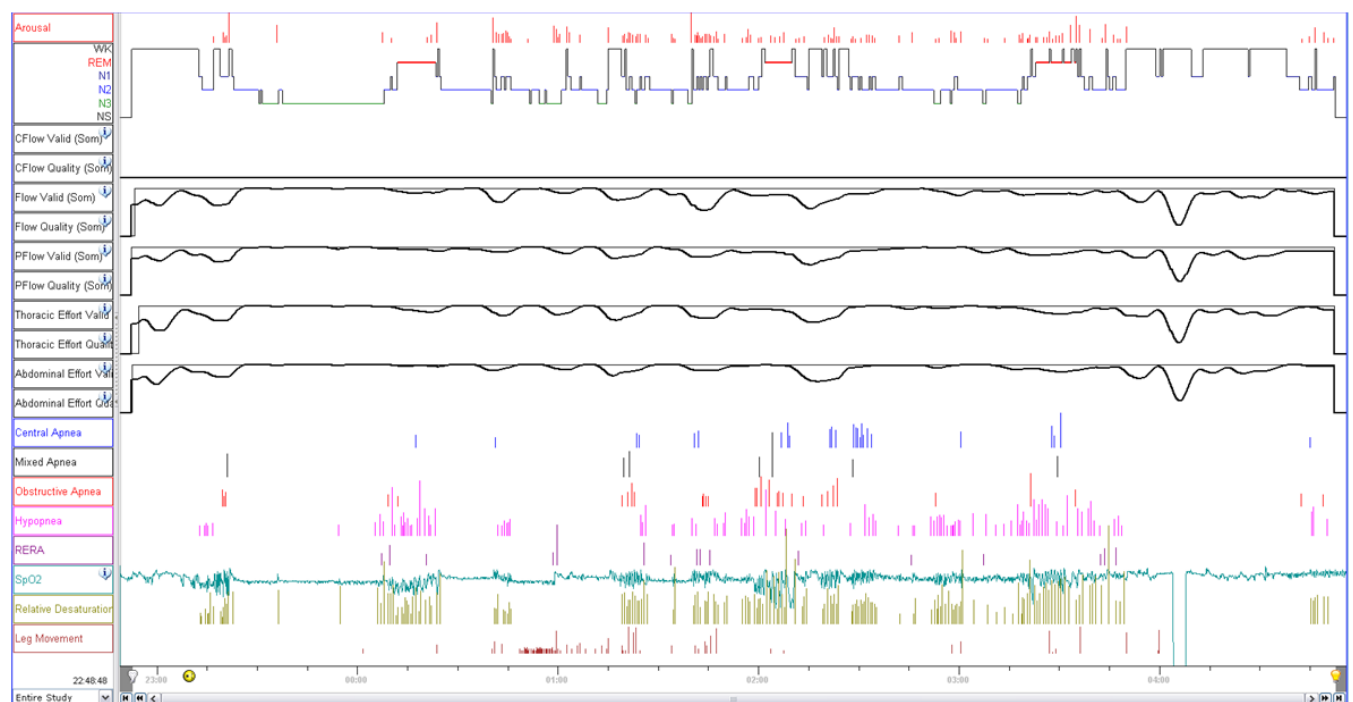
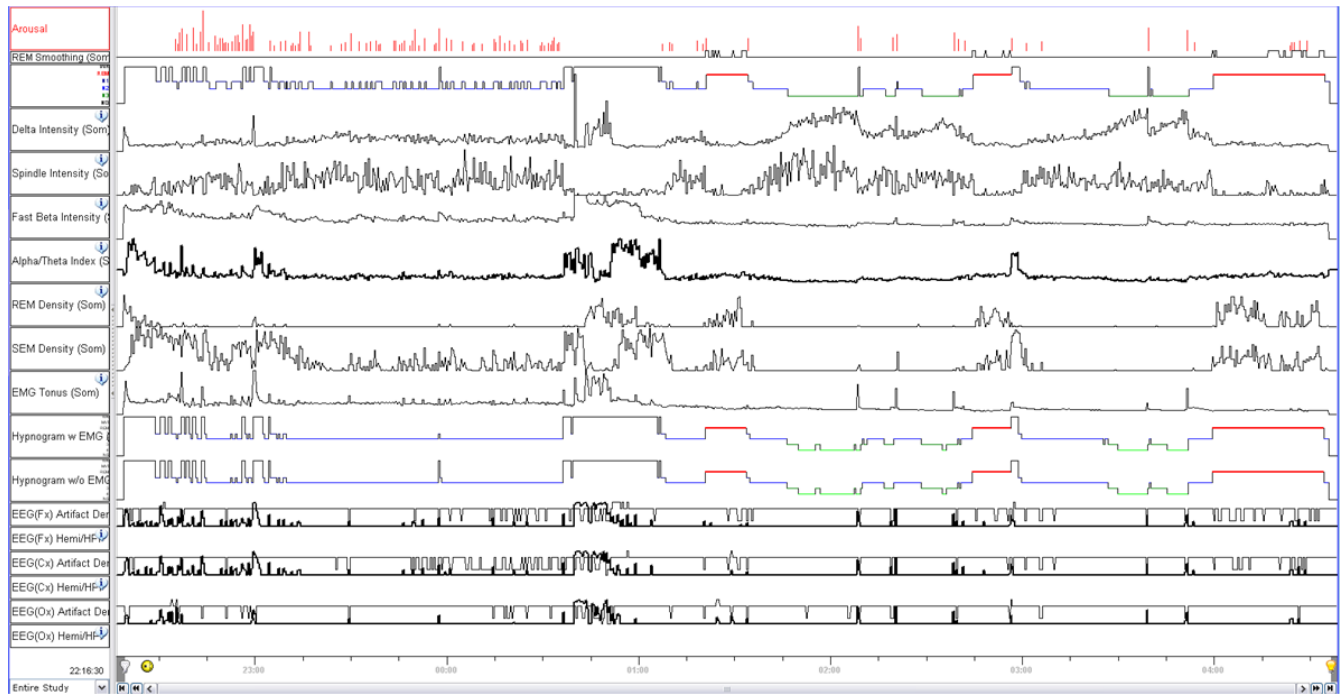


Figure 40: The Somnolyzer overview workspaces showing all PFTs for a diagnostic study. (A) Somnolyzer Staging Overview, (B) Somnolyzer Events Overview

A



B

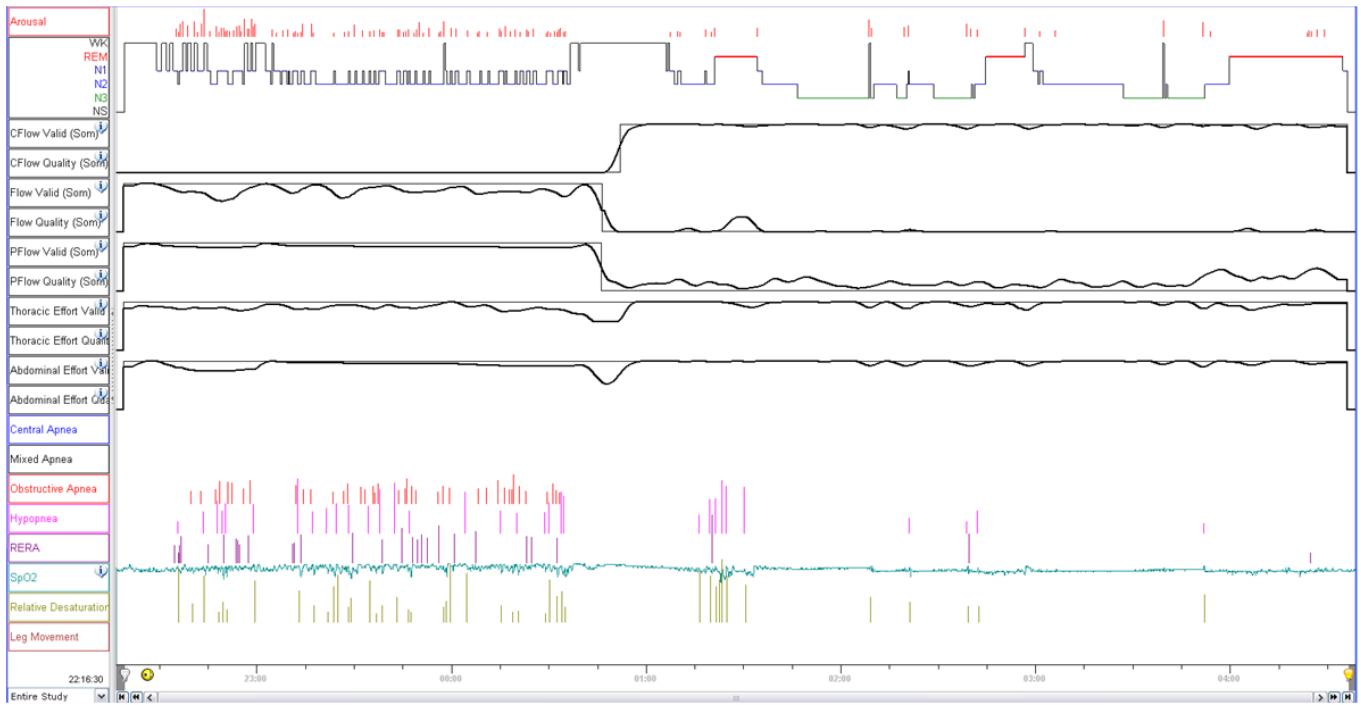
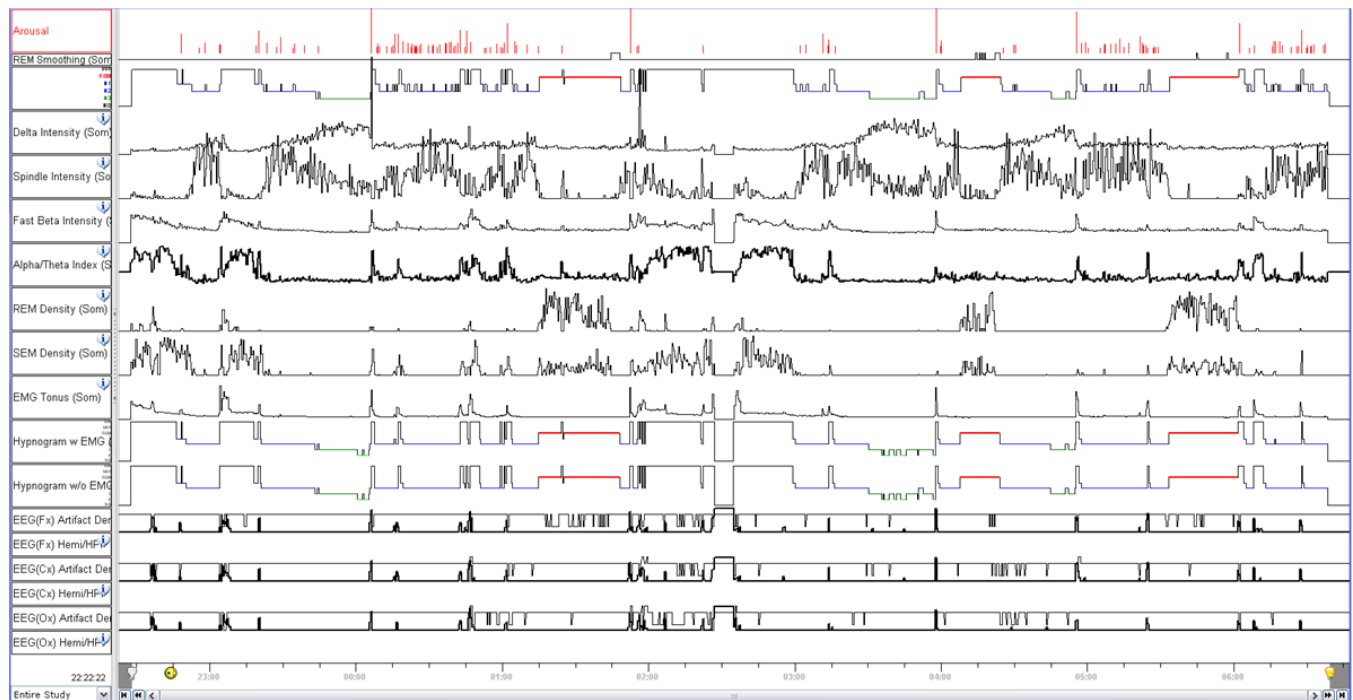


Figure 41: The Somnolyzer overview workspaces showing all PFTs for a split-night study. (A) Somnolyzer Staging Overview, (B) Somnolyzer Events Overview

A



B

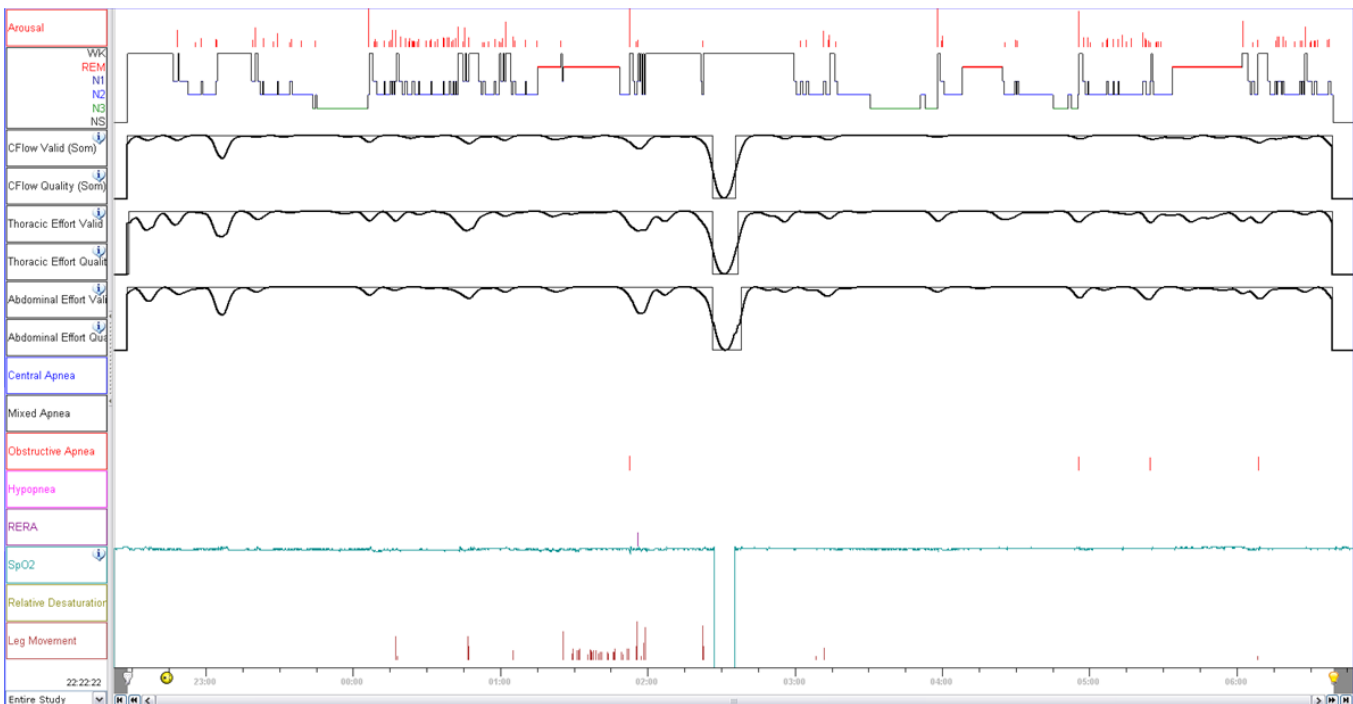


Figure 42: The Somnolyzer overview workspaces showing all PFTs for a treatment study. (A) Somnolyzer Staging Overview, (B) Somnolyzer Events Overview

5.3.2 The Workspace “Somnolyzer Staging Overview”

The workspace “Somnolyzer Staging Overview” includes all relevant trends for the ER of stages & arousals. The trends are Arousals, REM Smoothing, the Hypnogram, Delta Intensity, Spindle Intensity, Fast Beta Intensity, Alpha/Theta Index, REM Density, SEM Density, EMG Tonus, Hypnogram with EMG and without EMG as well as the Artifact Density including information concerning high pass filter and hemisphere switching. The meaning of the different trends is described below in detail.

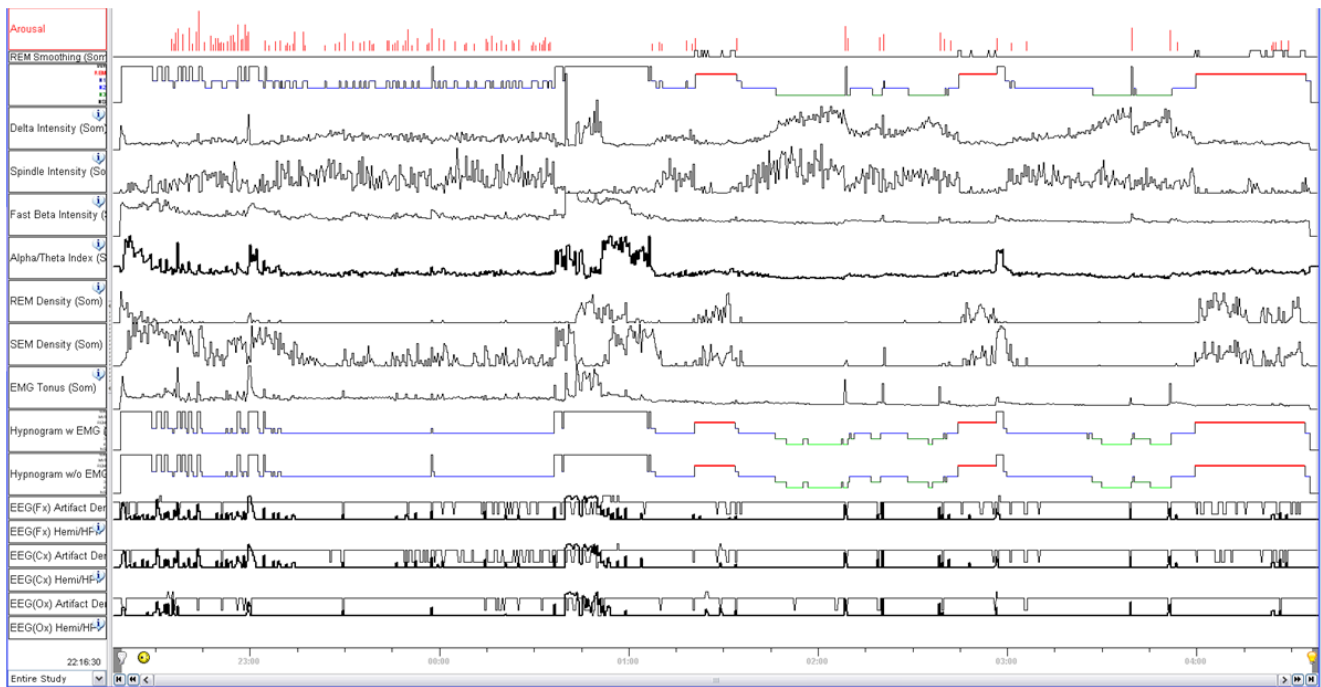


Figure 43: The workspace “Somnolyzer Staging Overview” used for expert review of stages & arousals

Description & Explanation of the Traces:

Arousal

The arousal trace indicates position and duration of arousals. The length of the blue lines indicates the duration of an arousal, scaled from 0 to 30 s. Note that the length of an arousal leading to an awakening is limited to 30 seconds.

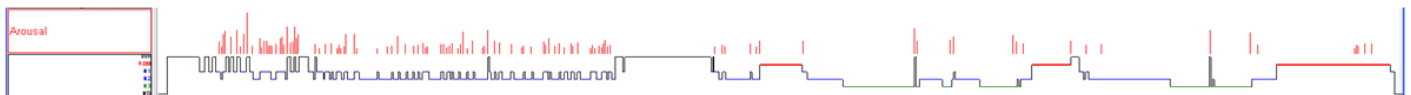


Figure 44: Arousal

REM Smoothing

This trace contains the following information:

- A deviation upwards indicates that Somnolyzer 24x7 has changed an epoch previously not assigned as R to stage R according to the rule for the transition between stage N2 and stage R (AASM Manual, 2007, IV.7.D) or according to the rule for the continuation of a period of stage R sleep (AASM Manual, 2007, IV.7.B).
- A deviation downwards indicates that Somnolyzer 24x7 has changed an epoch previously assigned as stage R to a NREM stage or wake, since the neighboring epochs do not support a REM phase (no such case occurs in the study shown in the figure below; for an example see end of the third REM).



Figure 45: Figure 6: REM Smoothing (Som)

Delta Intensity

This trace shows the intensity of delta waves. Note that, in addition to slow waves, all waves with frequencies between 0.5 Hz and 2 Hz are included in this trend independent of their amplitude. High delta activity speaks for stage N3, medium delta speaks for stage N2 (note the values in this trend for periods scored as N2 are not as high as those scored as N3) and very low delta speaks for stage R, stage N1 or stage W. Note the typical logarithmical increase of EEG delta activity in each NREM period in the second part of the night,

reflecting patient's increasing sleep depth. In contrast, sudden short increases – typically seen as spikes in stage W – are due to movement artifacts.

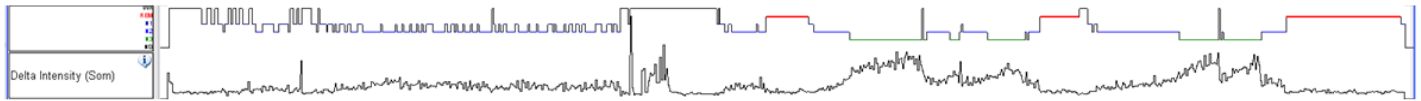


Figure 46: Delta Intensity (Som)

Spindle Intensity

This trace shows the intensity of probable sleep spindles. High values of spindle intensity speak for NREM sleep (especially N2), whereas very low values speak for R, W or N1. Note the increase in spindle intensity at the start of each NREM period. Usually the spindle intensity shows its maximum in N2 sleep with a decline towards slow wave sleep (see Figure 56 for a typical example).

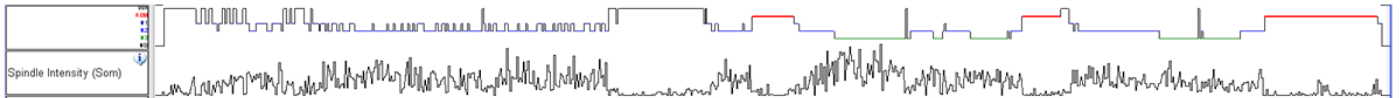


Figure 47: Spindle Intensity (Som)

Alpha/Theta Index

This trace shows the quotient of the activity in the alpha band to the activity in the theta band. High values speak for stage W, low values speak for sleep. Note, that during stage R the alpha/theta index might be higher compared to NREM, but is typically lower compared to W. Sudden increases in this index are indications for awakenings. If the alpha/theta index is elevated to a higher level without associated changes from NREM sleep to W or R these epochs have to be checked.

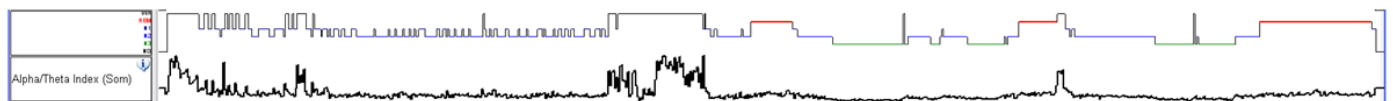


Figure 48: Alpha/Theta Index (Som)

Fast Beta Intensity

This trace shows the intensity of the activity in the fast-beta band. High values speak for muscle interference in the EEG channels and thus for stage W, low values speak for sleep. Note that awakenings are frequently accompanied by sudden increases (peaks) in the fast-beta intensity.

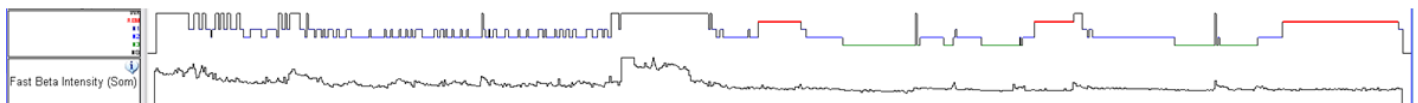


Figure 49: Fast Beta Intensity (Som)

REM Density

This trace shows the density of probable rapid eye movements. High REM density values speak for stage R or W. If there is either high or no REM density during the whole recording, EOG channels need to be checked.



Figure 50: REM Density (Som)

SEM Density

This trace shows the density of probable slow eye movements. High values speak for transitions between W and N1. SEMs may still be seen at the beginning of stage N2 periods. Typically SEMs are also present in stage

R, since rapid eye movements are usually superimposed on slow ones. If there is either high or no SEM density during the whole recording, EOG channels need to be checked.

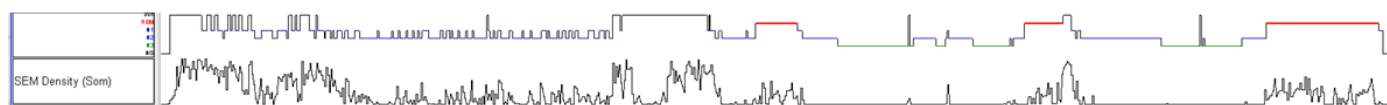


Figure 51: SEM Density (Som)

EMG Tonus

The trace shows the trimmed group mean of tonic chin EMG activity. High values speak for W and/or artifacts. Low values are usually seen during stage N2 and N3, with the lowest values in stage R. If EMG tone is very high or very low during the whole recording then the EMG signal needs to be checked.

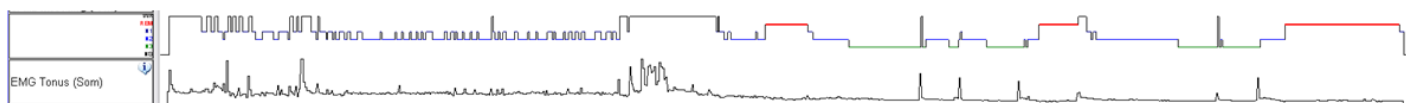


Figure 52: EMG Tonus (Som)

Interim Hypnograms

These traces show two interim Somnolyzer staging outputs. The hypnogram labeled “Hypnogram w EMG (Som)” is based on EOG, EEG and chin EMG channels. The hypnogram labeled “Hypnogram w/o EMG (Som)” uses EOG and EEG channels only and estimates muscle tonus from the high-frequency interference in the EOG and EEG signals. If the chin EMG signal is of good quality there should be no large differences between the two interim hypnograms.

Note that four additional rules are applied to determine the final hypnogram based on these interim results:

- Unscorable epochs that occur within a wake period are assigned as stage W (see Figure 40 and Figure 42 for examples).
- Epochs which contain more than 15 s of arousals are assigned as stage W (see the two short awakenings in the 2nd and 3rd NREM period in Figure 53).
- Stages assigned in the interim hypnogram as stage 4 (more than 50% of slow waves) are merged together with stages assigned as stage 3 into stage N3 (see the examples in the 2nd and 3rd NREM period in Figure 53).
- Stages assigned in the interim hypnogram as stage 1 or 2 are finally assigned as N1 or N2 in accordance with the rules defining start, continuation and end of a period of stage N2 sleep (AASM Manual, 2007, rule IV.5). In particular the rule defining the end of a period of stage N2 due to an arousal (AASM Manual, 2007, rule IV.5.C.1.b) may lead to changes from stage 2 to stage N1 (see the frequent shifts to N1 in the final hypnogram in the first part of the night in Figure 53).

If there are differences between the two interim hypnograms (e.g. one hypnogram shows a REM period and the other does not), then these epochs need to be checked. In this example there are only small deviations between the two hypnograms indicating good signal quality.



Figure 53: Interim Hypnograms: Hypnogram w EMG (Som) and Hypnogram w/o EMG (Som)

EEG Artifacts (Artifact Density and Hemi/HPF)

Detected artifacts are: missing data, high-amplitude artifacts, low-frequency artifacts (sweat, electrode and movement), high-frequency artifacts (muscle), and ocular artifacts. Separate traces show the artifact density per 30-s epoch with thick pen size for the frontal (EEG(Fx)), central (EEG(Cx)) and occipital (EEG(Ox)) channels. The traces are scaled between 0 s (i.e. no artifact) and 30 s (i.e. artifacts during the whole 30-s epoch).

Additional information is superimposed on the artifact density traces in thin pen size, scaled from -2 to +2:

- Hemi: A positive value (+1 or +2) indicates that the EEG channel from the default hemisphere is used. A negative value (-2 or -1) indicates a channel switch from the default to the alternative hemisphere for the respective EEG channel. Somnolyzer 24x7 switches from the EEG channel in the recommended default

hemisphere to the one in the alternative hemisphere, if the latter has fewer artifacts. As soon as the signal quality (fewer artifacts) is better in the default channel it is switched back. Note that the artifact density trace is based on the artifacts in the selected channel (i.e. the channel with better signal quality).

- HPF: A value of +1 or -1 indicates that no sweat artifacts have been detected and thus no additional high-pass filter (HPF) is used. A value of +2 or -2 indicates that sweat artifacts have been detected. To avoid misinterpretation of these low-frequency artifacts as slow-waves, Somnolyzer 24x7 minimizes the interference of this artifact by applying an additional high-pass filter in the respective EEG channel. As soon as no more sweat artifacts are detected, the additional high-pass filter is turned off.

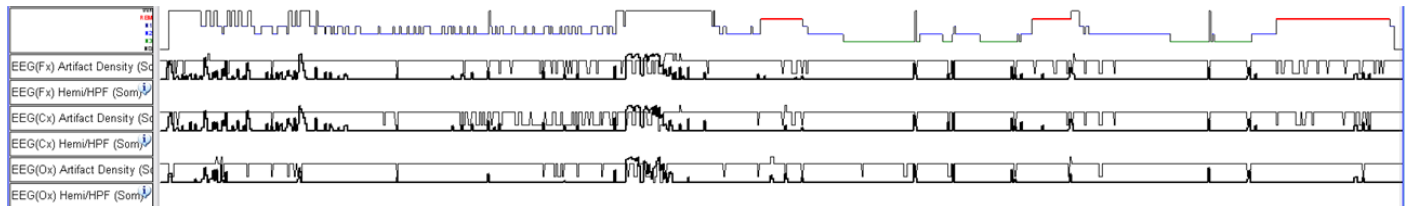


Figure 54:Artifact Density (Som) and Hemi/HPF (Som) for EEG(Fx), EEG(Cx) and EEG(Ox), respectively

5.3.3 The Workspace “Somnolyzer Events Overview”

The workspace “Somnolyzer Events Overview” includes all relevant trends for the expert review of respiratory and leg movement events. It displays Arousals, the Hypnogram, the Validity and Quality traces for the airflow from the therapy device (CFlow Valid and Quality), the airflow from the oronasal thermal sensor (Flow Valid and Quality), the airflow from the nasal air pressure transducer sensor (PFlow Valid and Quality), the respiratory effort from the chest/thorax sensor (Thoracic Effort Valid and Quality) and from the abdomen sensor (Abdominal Effort Valid and Quality) as well as Central Apnea, Mixed Apnea, Obstructive Apnea, Hypopnea and RERA events, then mean oxygen levels (SpO2) and Desaturation events (Relative Desaturation) as well as leg movement events (Leg Movement).

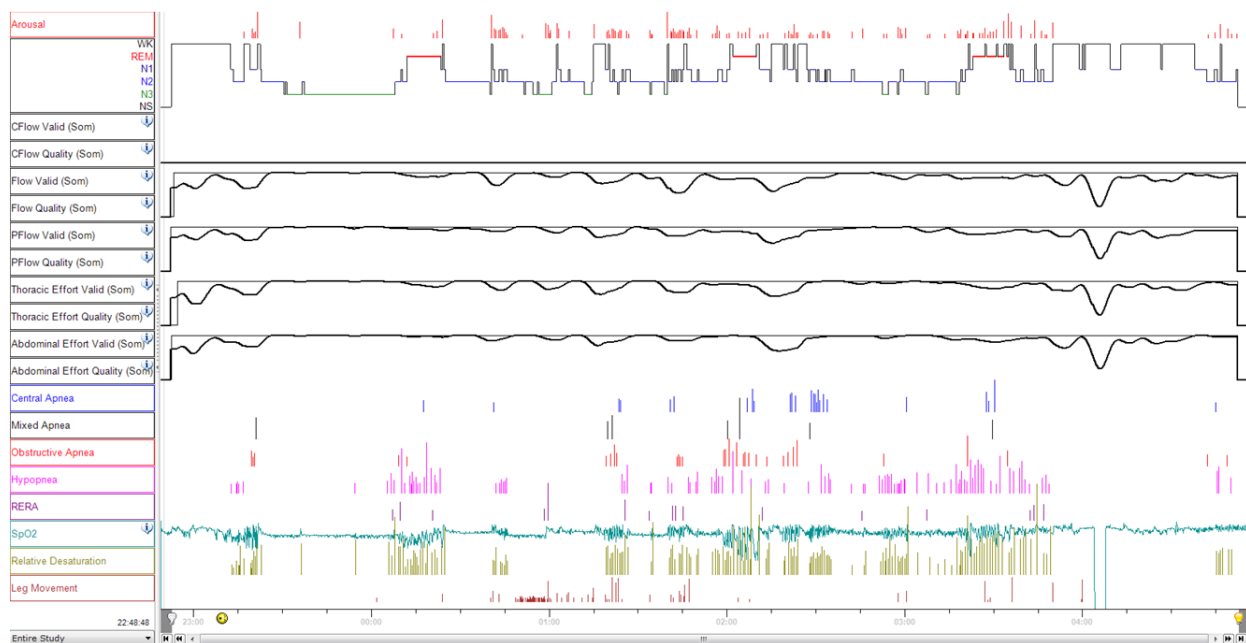


Figure 55:The workspace “Somnolyzer Events Overview” includes all relevant trends for the expert review of the respiratory and leg movement events

Description & Explanation of the Traces:

Apnea Events (Central, Mixed, Obstructive Apnea)

The apnea traces indicate position and duration of central, mixed and obstructive apneas by one line per event in blue (Central Apnea), green (Mixed Apnea) or red (Obstructive Apnea), respectively. The length of the line indicates the duration of the event scaled between 0 and 30 s.

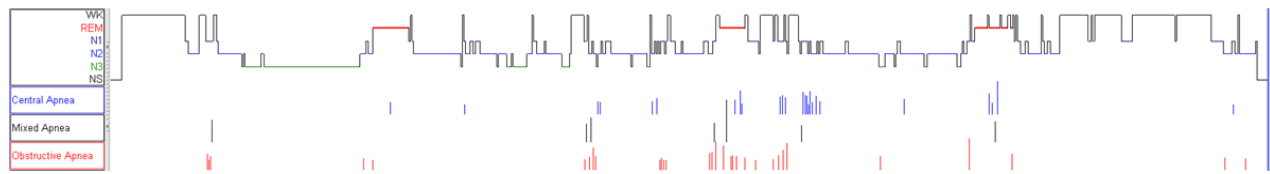


Figure 56: Central Apnea, Mixed Apnea, Obstructive Apnea

Hypopneas and RERAs

The hypopnea and the RERA traces indicate position and duration of hypopneas and RERAs by one line per event in pink (Hypopnea) or violet (RERA), respectively. The length of the line indicates the duration of the event scaled between 0 and 30 s.

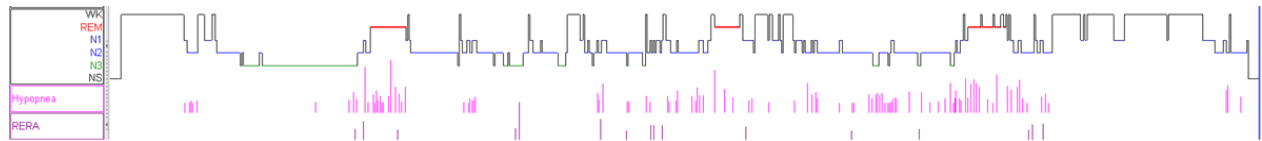


Figure 57: Hypopnea and RERA

Oxygen Saturation (Desaturations, Resp. Events, Mean Oxygen)

The desaturation trace (Relative Desaturation) indicates position and duration of desaturations by one line per event in green. The length of the line indicates the duration of the event scaled between 0 and 30 s.

The oxygen saturation trace (SpO2) displays the mean values per 30-s epoch, scaled between 80 and 100%.

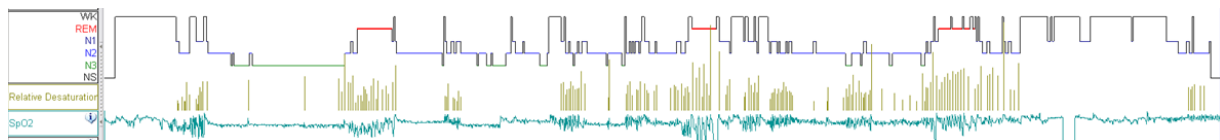


Figure 58: Relative Desaturation, SpO2

Quality of respiratory channels (Quality AFLO, PFLO, CFLO, CHMV, ABMV)

Validity and quality traces are displayed for the CPAP flow signal (CFlow), the oronasal thermal sensor signal (Flow), the nasal air pressure transducer signal (Pflow), the respiratory effort signal from the chest/thorax (Thoracic Effort) and the respiratory effort signal from the abdomen (Abdominal Effort). The information for each channel is twofold:

- The thick line displays an estimation of the signal quality of the respective sensor from 0% to 100%, with 100% indicating best signal quality.
- The value of 1 in the thin line indicates that the respective sensor was considered as valid and thus was used in the Somnolyzer analysis, a value of 0 indicates that the sensor was considered as invalid. Whenever a sensor was considered as invalid the alternative sensor (if valid) is used by Somnolyzer according to the notes of AASM Manual, 2007, rule VIII.1.

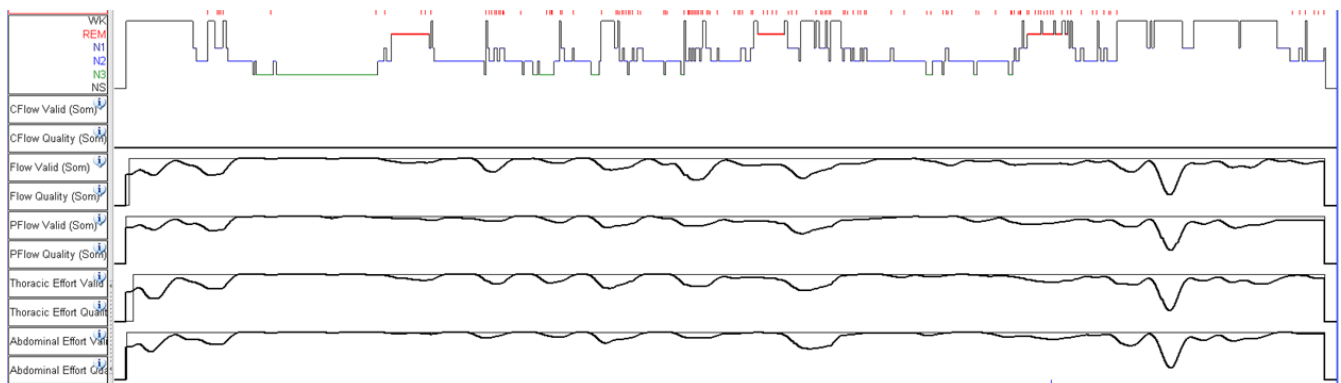


Figure 59: CFlow Valid (Som) and CFlow Quality (Som) (airflow from therapy device), Flow Valid (Som) and Flow Quality (Som) (ornasal thermal sensor), PFlow Valid (Som) and PFlow Quality (Som) (nasal air pressure transducer), Thoracic Effort Valid and Thoracic Effort Quality (chest/thoracic movement); Abdominal Effort Valid and Abdominal Effort Quality (abdominal movement)

Leg movements

The leg movement trace indicates position and duration of all leg movements by one line per event scaled from 0 to 10s.



Figure 60: Leg Movement

5.4 The Expert Review Procedure

The Expert Review (ER) is a structured step by step review procedure with the goal to ensure that the actual PSG measurement was done correctly and that Somnolyzer 24x7 has not misclassified any clinically relevant variable. By following the steps described below trained Expert Reviewers can shift their attention from single epochs to an all-night overview (staging) and from single events to the quality control of the recorded data (events). This results in valid (unbiased) and reliable (highly reproducible) results for both staging and events with minimal effort. ER is performed in two well defined phases which include 2 steps each:

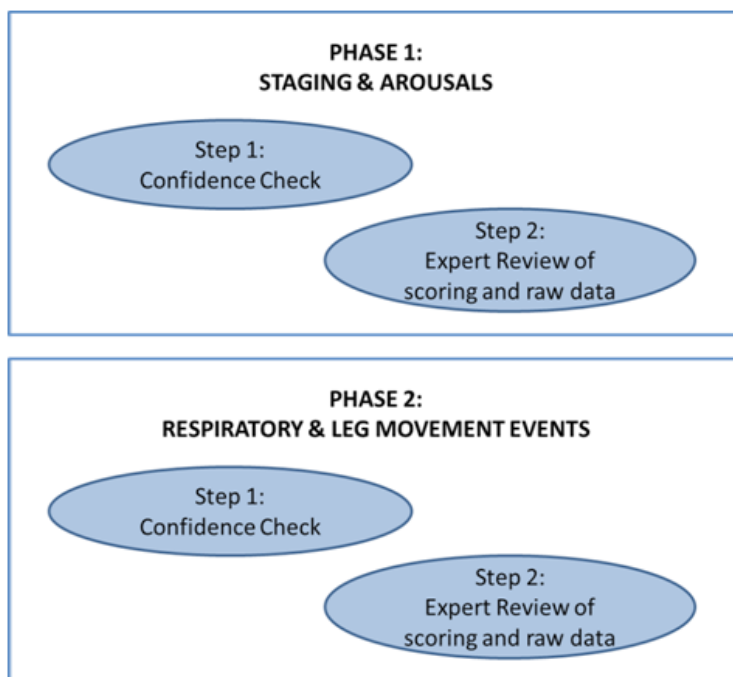


Figure 61: Overview of the Expert Review Procedure

5.4.1 Phase 1: Staging & Arousals

Step 1: Confidence Check

Step 1 is based on the overview display of the PFTs relevant for staging & arousals. This step focuses on identifying periods with poor signal quality, such as

- incorrectly referenced signals
- failing electrodes
- artifacts persistently distorting the signals
- extremely atypical patterns, far away from the norm.

The aim of Step 1 is the identification of sections that require either high or medium or only low levels of attention during Step 2 “**Expert Review of scoring and raw data.**” Note that the different attention levels will set the pace for scrolling through the raw data in Step 2.

In Table 3, the feature combination typically seen in the different sleep stages are summarized. Figure 62 gives a typical example highlighting one for each sleep stage.

Table 3: Manifestation of major sleep/wake related features in the different sleep stages

Stage	Spindles	Alpha/Theta	Delta	EMG	REM	SEM
W	-	+++	Spikes	+++	++(+)	+++
N1	-	(+)	-	+(+)	-	+++
N2	+++	-	+	+	-	(+)
N3	++	-	+++	-	-	-
R	-	+	-	-	+++	+++

'+', '++' and '+++' mark low, medium and large presence of the respective feature, '-' marks absence or very low presence. Thus, combinations of features are used to decide upon the validity of the respective stage decisions (on the level of prolonged phases, not single epochs).

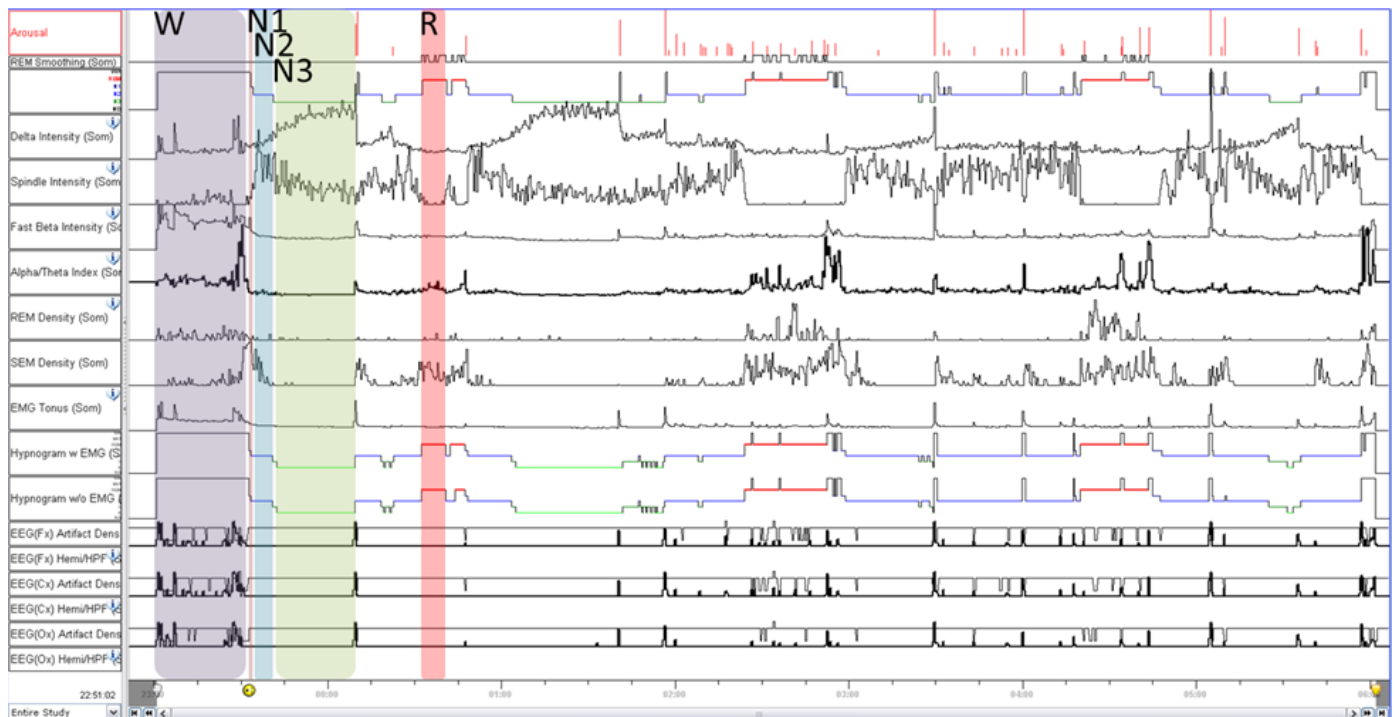


Figure 62 Typical feature combinations in the different sleep stages

Table 4 gives a step by step procedure for identifying the periods that require different levels of attention, in descending order of relevance. In Figure 62, the different levels of attention are highlighted for a typical study.

Table 4: Identification of the “level of attention” for scoring sleep stages

Level of Attention	Description	Example (Figures in Section 5.5)
High	Sleep onset	Figure 73 - Figure 83
	Start and end of the first REM period	Figure 73 - Figure 83
	Suspected first REM	Figure 74
	Sleep onset REM (as well as suspected sleep onset REM)	Figure 78, Figure 82
	Periods with different REM phases in the two interim hypnograms	Figure 79, Figure 80, Figure 83
	Periods with apparently inconsistent combination of features (for consistent feature combinations per sleep stage see Table 3)	Figure 79, Figure 81, Figure 83
Medium	Wake before sleep onset	Figure 73 - Figure 83
	REM periods with questionable NREM intrusions or adjacent periods of N1 Apparently missing REM periods with a feature combination that allows for REM	Figure 79, Figure 83
	Extended periods with frequent shifts between sleep and wake	Figure 79
	Extended periods with high artifacts densities	Figure 79
	Epochs marked as removed stage R in the REM Smoothing trace	Figure 79
Low	Periods with apparently consistent combination of features (see Table 3 for the typical feature combination per sleep stage)	Figure 73 - Figure 83

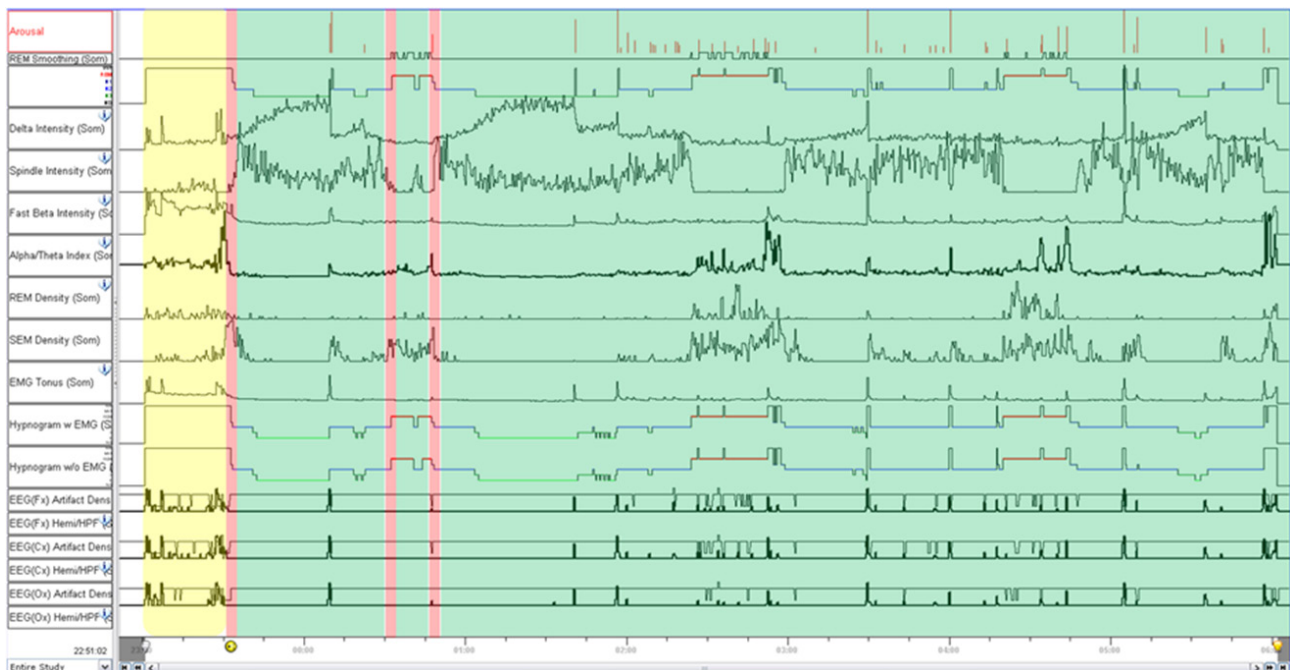


Figure 63: Different levels of attention for ER of staging and arousals. Sections that require high attention (i.e. slow scrolling in Step 2) are indicated in red, sections that require medium attention (i.e. medium scrolling in Step 2) are indicated in yellow, and sections that require low attention (i.e. fast scrolling in Step 2) are indicated.

Keeping this information in mind, the skilled Expert Reviewer will be able to adopt the scrolling speed during Step 2 to minimize the time necessary for ER on the one hand and to guarantee valid results for each individual study on the other hand.

A more detailed description and many more examples for Phase 1 “Staging & Arousals” - Step 1 “Confidence Check” are given in section 5.5 of this manual.

Step 2: Expert Review of scoring and raw data

Based on the segmentation of the study in sections that require different levels of attention, ER of staging and arousals can now be performed optimally using the Somnolyzer Staging Expert Review workspace, with the scrolling speed adapted to the different confidence levels (see tips and tricks in section 5.7 how to optimally use the Sleepware G3 viewer for Step 2).

The Somnolyzer Staging Expert Review workspace displays two panels: the upper panel contains the same trends as the Somnolyzer Staging Overview workspace and the bottom panel contains the raw data relevant for the expert review of staging & arousals.

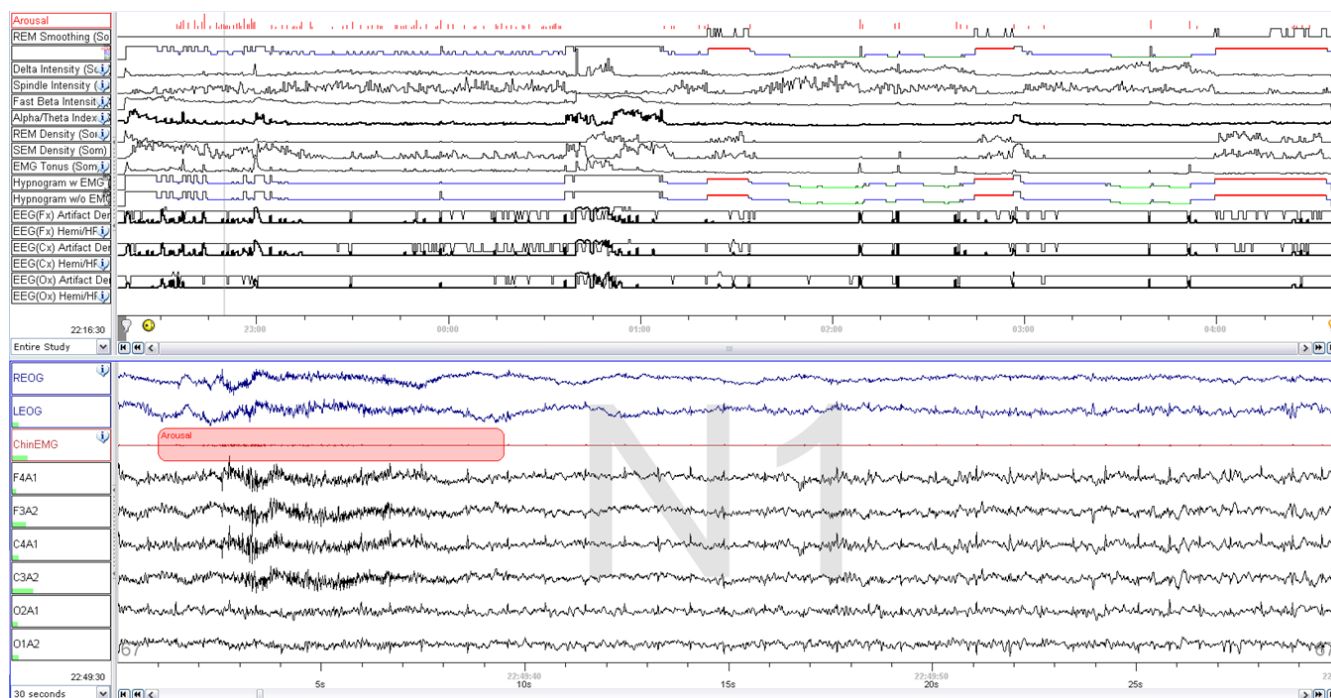


Figure 64: The workspace “Somnolyzer Staging Expert Review” shows raw data with marked arousals in the bottom panel and the PFTs in the upper panel

For sections that require **high level** of attention:

Review the scoring epoch-by-epoch (i.e. slow scrolling speed) and change incorrectly assigned sleep stages accordingly. Note that if an epoch is changed, it might be necessary to add or delete arousals in this epoch. Arousals might have to be added if an epoch is changed from W to sleep or from REM to NREM (since in NREM no concurrent increase in submental EMG is required). On the other hand, if an epoch is changed to REM all arousals not associated with an increase in EMG have to be deleted.

For sections that require **medium level** of attention:

Review the scoring with a faster scrolling speed and slow down to an epoch-by-epoch review if appropriate. As long as the stage in a given epoch is not changed and as long as the signal quality is reliable, there is no need for changing arousal scoring.

For sections that require **low level** of attention:

Review the scoring with fast scrolling speed and stop only if signals are not reliable or show anomalies. Typically neither staging nor arousals have to be changed in these sections.

In summary, it is recommended to review the whole study from lights-out to lights-on. While the majority of the study may be reviewed with fast scrolling speed, short yet significant portions of the study require epoch-by-epoch reviewing.

Note: The sensitivity of arousal scoring is configurable in Somnolyzer 24x7 and thus may be adapted to different interpretations. In case your interpretation varies systematically from the default Somnolyzer interpretation please contact Philips Respironics for a configuration request (North America: somnolyzer.us@philips.com; rest of the world: somnolyzer.int@philips.com).

5.4.2 Phase 2: Respiratory & Leg Movement Events

Step 1: Confidence Check

ER of respiratory and leg movement events is mainly focusing on signal quality control. If the signals are within a normal range and considered as valid by Somnolyzer, the scoring criteria are perfectly implemented. “Second-guessing” an event is only necessary when the signal quality is diminished or the signal shows major anomalies or is not considered as valid.

Step 1 is based on the overview display of the PFTs relevant for respiratory and leg movement events. This step focuses on identifying periods with poor signal quality, such as

- failing sensors
- artifacts persistently distorting the signals
- extremely atypical patterns, far away from the norm.

The aim of Step 1 is the identification of sections that require either high or medium or only low levels of attention during Step 2 “Expert Review of scoring and raw data.” Note that the different attention levels will set the pace for scrolling through the raw data in Step 2.

Table 5 gives a step by step procedure for identifying the periods that require different levels of attention, in descending order of relevance. In Figure 65, the different levels of attention are highlighted for a typical study.

Note that leg EMG signal quality has to be checked in studies with no detected leg movement events altogether or with perpetual leg movement events for long periods.

Table 5: Identification of the “level of attention” for scoring respiratory events

Level of Attention	Description
High	No valid respiratory and oxygen signals (not explained by unplugged sensors)
	No valid flow signals in sections with desaturations
	No valid effort signals in sections with detected apneas (Somnolyzer assigns all apneas as obstructive if no valid effort channel is available)
	Sections with desaturations, but without respiratory events
Medium	No valid signal in the recommended sensor
	Sections with respiratory events not leading to desaturations
	Valid flow signal but rather low signal quality
	Only one valid effort signal or only effort signals with rather low quality in sections with detected apneas
Low	Periods with apparently consistent associations between respiratory events and desaturation events
	Periods with no respiratory events and constantly high “mean oxygen saturation” values

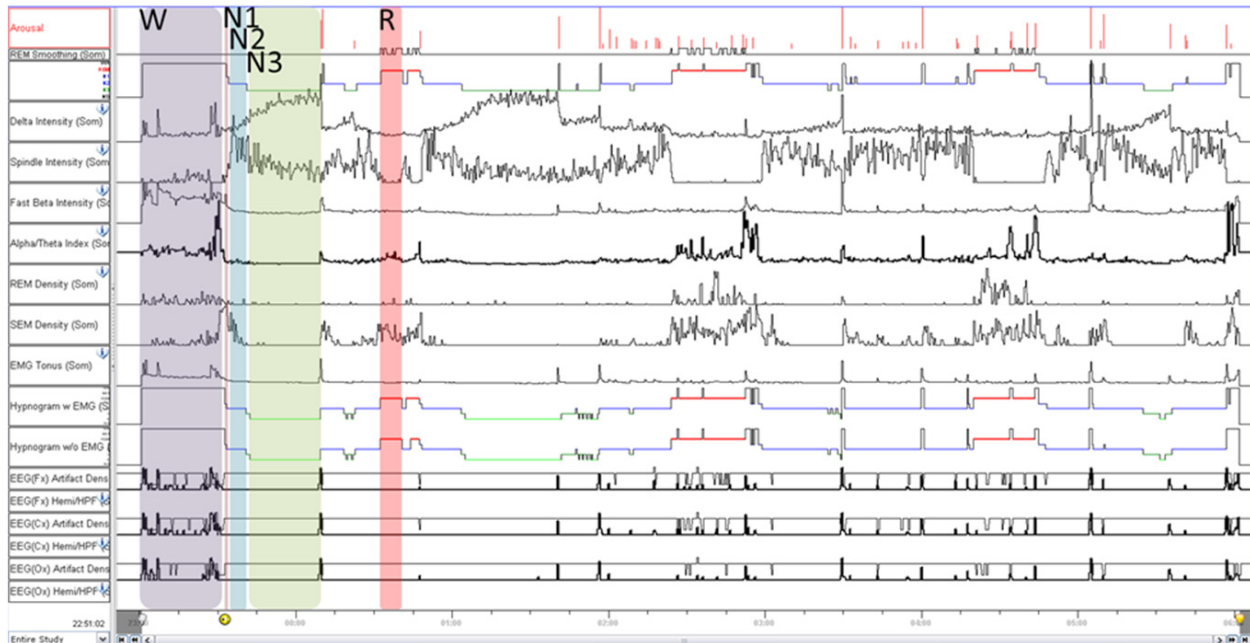


Figure 65: Different levels of attention for ER of respiratory events. Sections that require high attention (i.e. slow scrolling in Step 2) are indicated in red (in this example this concerns specifically the assignment of the central apneas), sections that require medium attention (i.e. medium scrolling in Step 2) are indicated in yellow (in this example due to reduced signal quality in both airflow channels), and sections that require low attention (i.e. fast scrolling in Step 2) are indicated in green.

Keeping this information in mind, the skilled Expert Reviewer will be able to adapt the scrolling speed during Step 2 to minimize the time necessary for ER on the one hand and to guarantee valid results for each individual study on the other hand.

A more detailed description and many more examples for Phase 2 “Respiratory & Leg Movement Events” - Step 1 “Confidence Check” are given in 4.6 of this manual.

Step 2: Expert Review of scoring and raw data

Based on the segmentation of the study in sections that require different levels of attention, ER of staging and arousals can now be performed optimally using the Somnolyzer Events Expert Review workspace, with the scrolling speed adapted to the different confidence levels (see tips and tricks in 5.7 how to optimally use the Sleepware G3 viewer for Step 2).

The Somnolyzer Events Expert Review workspace displays two panels: the upper panel contains the same trends as the Somnolyzer Events Overview workspace and the bottom panel contains the raw data relevant for the expert review of the respiratory events and the leg movements.

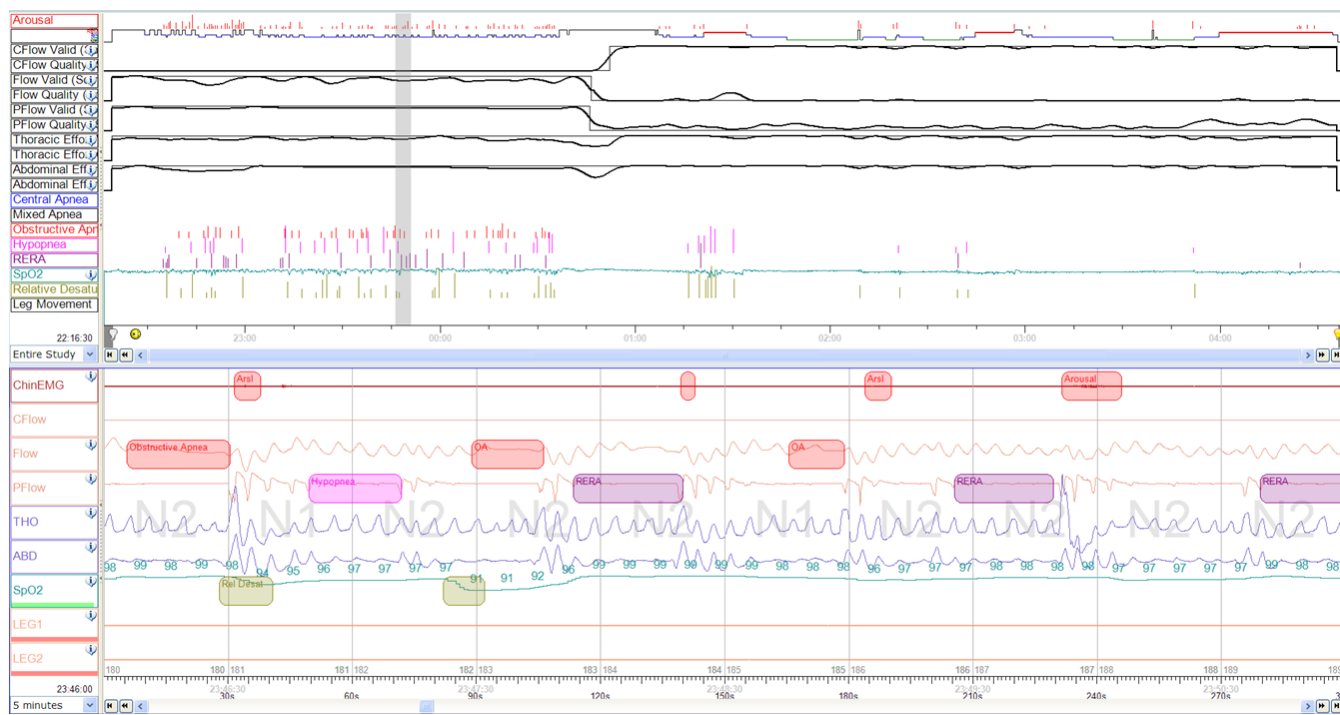


Figure 66:The workspace “Somnolyzer Events Expert Review” shows raw data with marked events in the bottom panel and the PFTs in the upper panel

For sections that require **high level** of attention:

Review the scoring in 5-min windows page-by-page (i.e. slow scrolling speed) and change incorrectly assigned events accordingly.

For sections that require **medium level** of attention:

Review the scoring in 5-min windows with a faster scrolling speed and slow down to a page-by-page review if appropriate.

For sections that require **low level** of attention:

Review the scoring in 5-min windows with fast scrolling speed and stop only if signals are not reliable or show anomalies. Typically no events have to be changed in these sections.

It is recommended in the AASM scoring manual to switch to an alternative respiratory channel when the signal from the recommended sensor is not reliable (see AASM Manual, 2007, rule VIII.1 including the notes). Thus, whenever a recommended sensor is considered as valid by Somnolyzer 24x7 (indicated in the PFTs) this sensor is used for event detection. If, however, the signal of a recommended sensor is considered as invalid and the signal of an alternative sensor is considered as valid, the alternative sensor is used for event detection. If no valid airflow sensor is available, Somnolyzer will not detect respiratory events for this period. If no valid respiratory effort channel is available, all apneas will be assigned as obstructive events.

To perform this step, the viewer software use for scoring should depict all relevant respiratory and EMG channels together with the respective events in 5-minute windows. This allows scrolling through the raw data and watching for signal anomalies in the respective channels (i.e. oronasal thermal sensor for apnea events, pressure transducer for hypopneas/RERAs, respiratory effort signals for apnea sub-classification, leg EMG for leg movements). As long as the signals are within normal ranges and free of major artifacts you can highly trust the marking of events. Thus, this step should normally be finished within a few minutes. Note that even if some signals are problematic, the events marked by Somnolyzer 24x7 are very likely the best possible guess.

In summary, it is recommended to review the whole study from lights-out to lights-on. While the majority of the study may be reviewed with fast scrolling speed, short yet possible significant portions of the study may require thorough reviewing.

Note: Somnolyzer 24x7 is configurable for different respiratory scoring rules. By default AASM Manual, 2007, rule VIII.4.A or B is applied for scoring hypopneas. Other scoring criteria are available on request. Concerning leg movements that occur concurrently with respiratory events, Somnolyzer 24x7 uses the recommended time window of 0.5 s (Note 1 in AASM Manual, 2007, rule VII.1). Other time windows are available on request. Please contact Philips Respironics for a configuration request (North America: somnolyzer.us@philips.com; rest of the world: somnolyzer.int@philips.com).

5.5 Description and Examples for Phase 1 “Staging & Arousals”

- Step 1 “Confidence Check”

As mentioned in section 5.4, Somnolyzer 24x7 can occasionally be misled by features that are not clearly expressed in the signals. The most critical sleep variables that can be arbitrarily influenced by even a slight misclassification are sleep latency and REM latency. Therefore the epoch-by-epoch review of sleep onset, first REM and discontinuities in REM phases are recommended - independent of plausibility and confidence level:

Sleep Onset – Inspect and verify the staging, epoch by epoch, around sleep onset, i.e. a few minutes before and after sleep onset as currently scored by Somnolyzer 24x7, while the period from lights-out until confirmed sleep onset may be reviewed at faster pace.

First REM – Inspect and verify the staging, epoch by epoch, of the first REM period scored by Somnolyzer 24x7, or (in case of an apparent REM latency larger than the first sleep cycle) the period where one would expect the first REM period to occur.

REM Discontinuity – Inspect and verify the staging, epoch by epoch, of longer stretches of NREM or wake intrusions in REM phases specifically if they are not clearly supported by the PFTs.

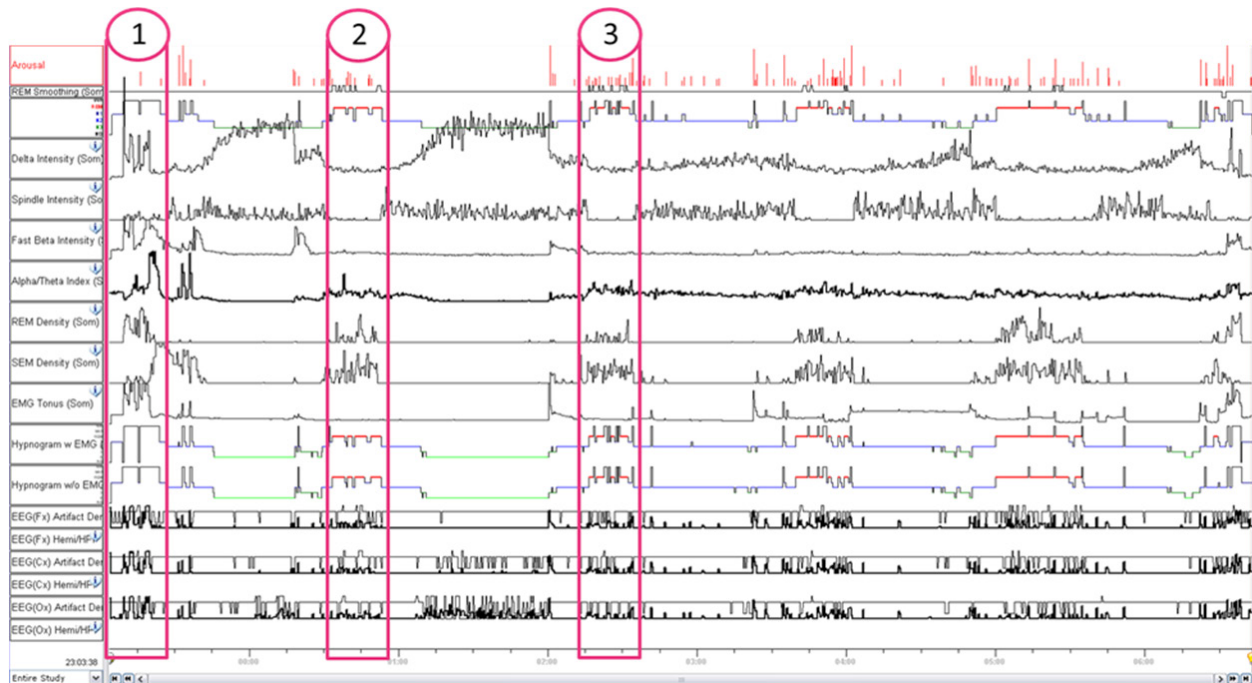


Figure 67: Three segments for which an epoch-by-epoch review is recommended: Sleep onset (1), first REM period (2), stretches of REM discontinuity (3)

Following the procedure recommended for step 2, it is not necessary to inspect other parts of the staging epoch-by-epoch. Doing so is left to the scorer's discretion. Remember, a high percentage (up to 25%) of any stage decision (be it from Somnolyzer 24x7 or any other skilled scorer) is likely to differ from a particular scorer's opinion while still being a fully valid decision. Changing such epochs will not change the clinical validity of the scoring, but instead is likely to increase their variability and thus decrease their reproducibility.

Validity of sleep/wake discrimination

- High values in the alpha/theta index trace and/or high SEM/REM density together with high EMG tone and absence of spindles speak for stage W. If W is scored in the absence of this feature combination, these epochs require increased attention (see examples in Figure 77 and Figure 78).
- Sleep onset always needs to be checked. Note that typically sleep onset occurs when no further spikes are seen in the delta intensity trace (i.e. no more movement artifacts), not yet clear spindle activity is seen in the spindle intensity trace, a decrease in fast beta activity is seen in the Fast Beta Intensity trace, there is a drop in the alpha/theta index as well as density REM and EMG tonus, while the SEM density has a local maximum.

Validity of REM/NREM discrimination

- Low EMG tone together with elevated REM (and SEM) density and low spindle and delta intensity speak for stage R. If R is scored in the absence of this feature combination, these epochs require increased attention.
- If a REM phase is apparently missing and the feature combination allows for REM, these epochs require increased attention (see Figure 75 and Figure 76).
- If there are differences in the REM phases between the two interim hypnograms (e.g. one hypnogram shows a REM period and the other does not), then these epochs need to be checked (see Figure 80 and Figure 81).
- If there is a long period of stage N1 this needs to be checked as to whether a REM period was missed, especially when the alpha/theta index is medium even if some SEM activity is present.
- The first REM period, or a suspected first REM period always need to be checked.
- Sleep onset REM, or a suspected sleep onset REM always need to be checked.
- Epochs marked by a blue line in the Smoothing REM trace need to be checked for a possibly missed REM period (see examples in Figure 79 and Figure 81).

Validity of Stage N2

- High spindle intensity, low alpha/theta index, no REMs, medium delta intensity speaks for N2. If N2 is scored in the absence of this feature combination, these epochs have to be checked (see Figure 81).

Validity of N3

- High delta intensity, low alpha/theta index, no REMs, medium spindle intensity and low EMG tone speak for N3. If N3 is scored in the absence of this feature combination, these epochs have to be checked.

A practical example

The first example demonstrates the results from Somnolyzer 24x7 staging, as one normally obtains if the PSG recording is compliant with all required standards and the signals are of sufficient quality without major artifacts or anomalies. This example is used to explain again all phases and steps of the expert review.

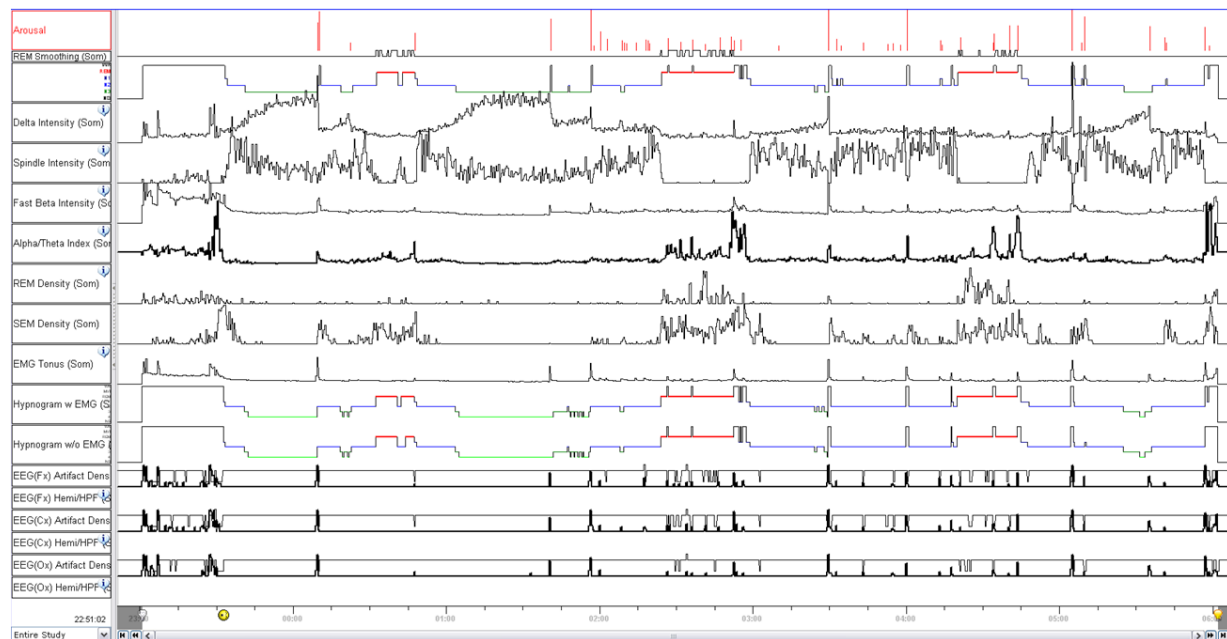


Figure 68: Polysomnographic Feature Trends (PFTs) for Staging & Arousals

The hypnogram looks reasonable and plausible.

Major sleep stages

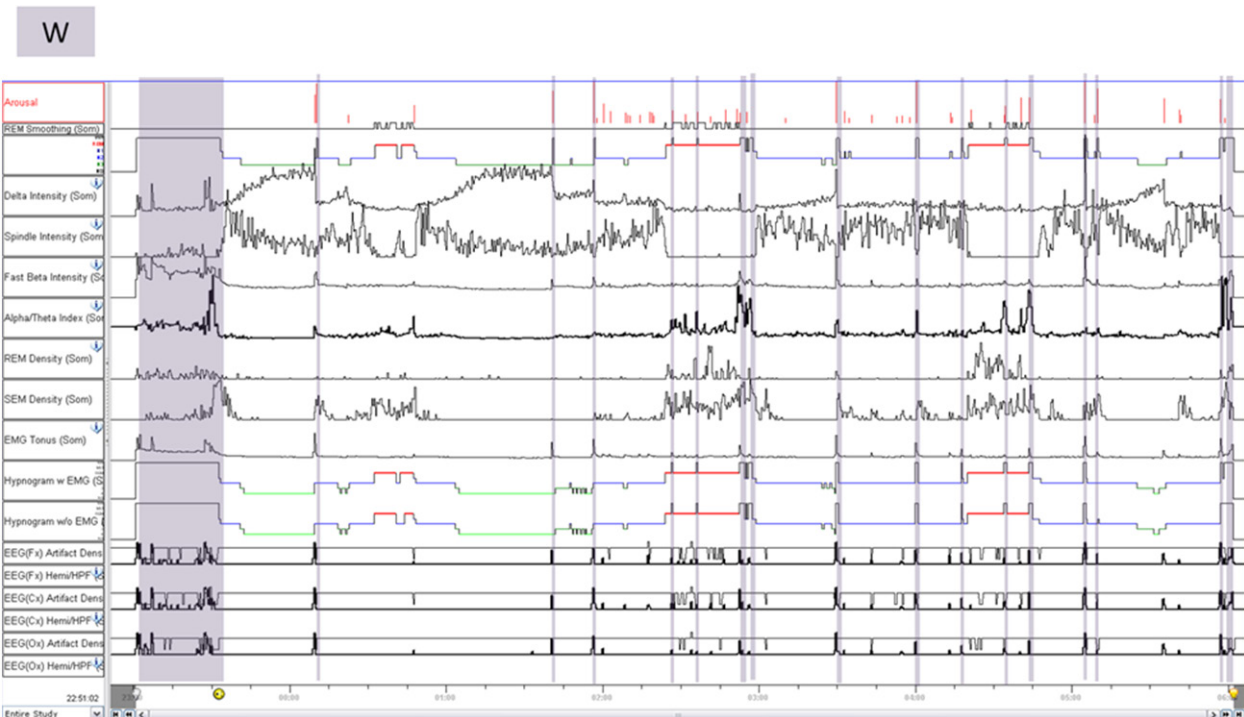


Figure 69: Polysomnographic Feature Trends (PFTs) for Staging & Arousals: Stage W

There is a major wake period between lights-out and sleep onset. This wake period is nicely supported by the traces of the PFTs:

- Both fast-beta intensity and alpha/theta index are elevated
- here is no delta intensity (with the exception of small peaks that result from signal artifacts common in wake) and no significant spindle intensity
- Some rapid and slow eye movements occur, with the latter increasing toward sleep onset
- The number of artifacts is relatively high, due to movements

The other (short) awakenings are all accompanied by peaks in alpha/theta index and/or fast-beta. Although the epoch-by-epoch check of sleep onset is highly recommended in any case, it is unlikely that any epoch needs to be changed, specifically since there is a concomitant sharp drop of the fast-beta intensity and the alpha/theta index associated with a sharp increase of slow eye movements and the end of rapid eye movements.

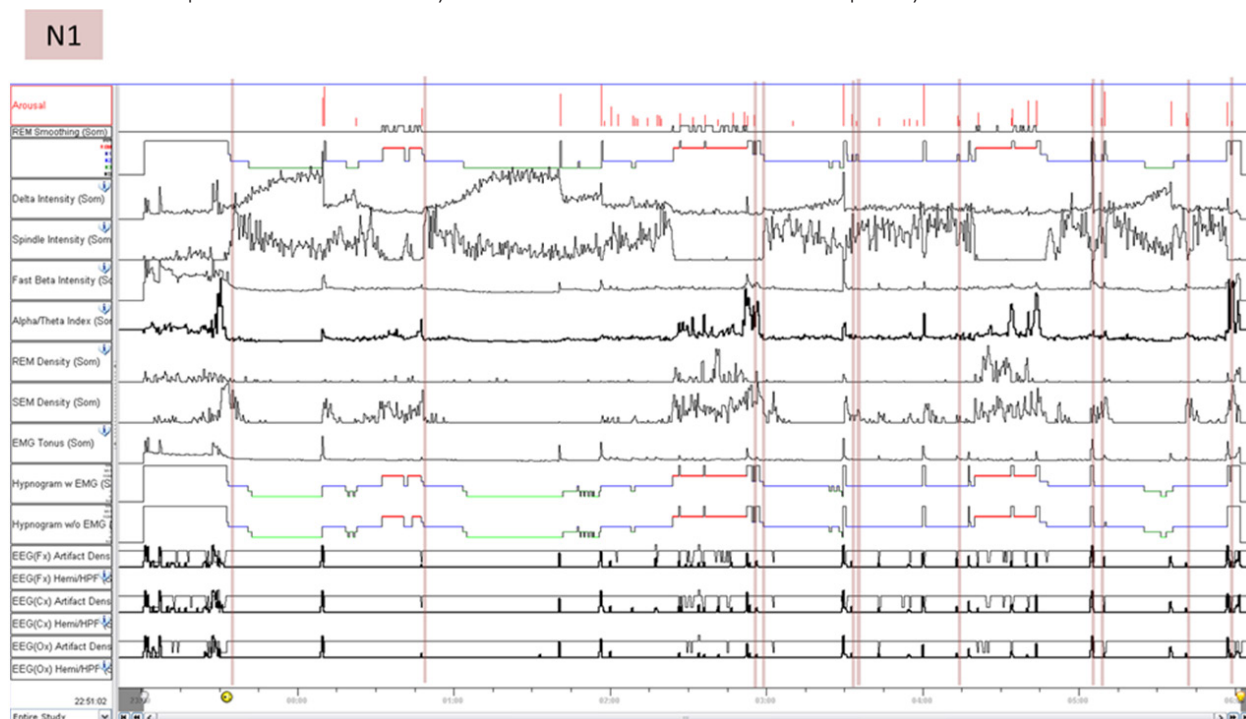


Figure 70: Polysomnographic Feature Trends (PFTs) for Staging & Arousals: Stage N1

The very short period of N1 following sleep onset is supported by

- A fast drop in both alpha/theta index and fast-beta intensity
- The termination of rapid eye movements
- No significant amount of delta and spindle intensity

There is no other major period of N1 that would need questioning in terms of whether a misclassification between N1 on the one hand and W or R at the other hand could alter the overall sleep architecture.

N2

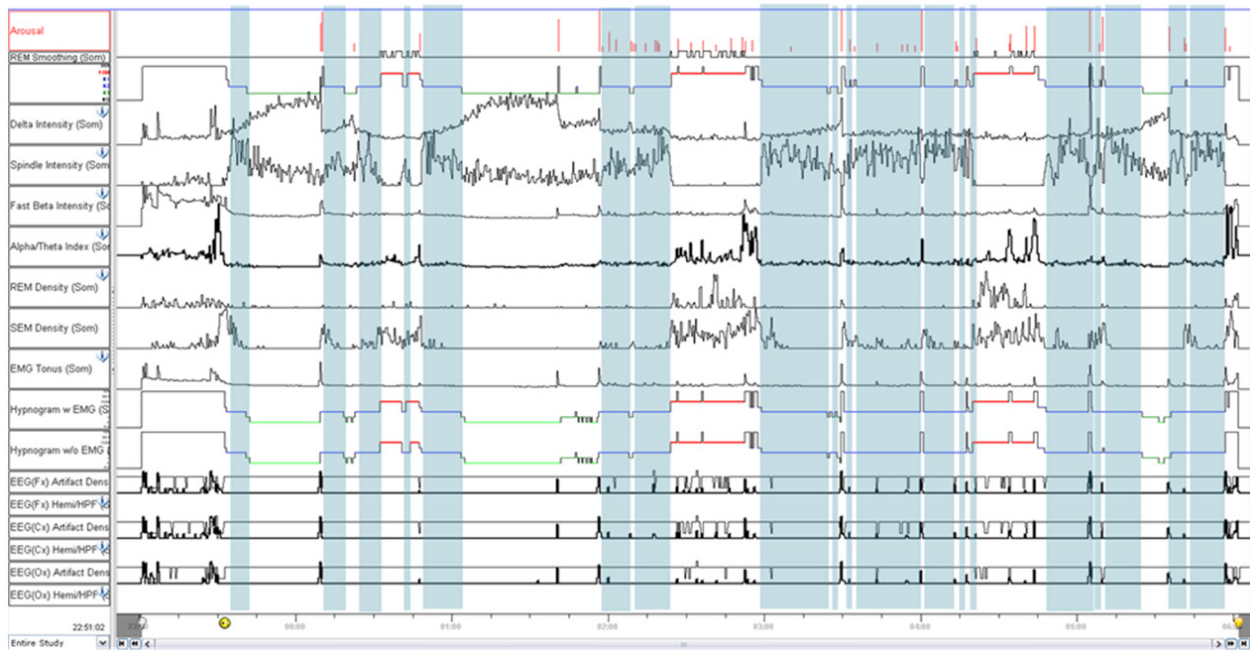


Figure 71: Polysomnographic Feature Trends (PFTs) for Staging & Arousals: Stage N2

The major periods of N2 sleep are all characterized by

- An elevated spindle intensity
- A rising or intermediate level of delta intensity (except when N3 is interspersed)
- Low values of alpha/theta index and fast-beta (except at short awakenings)
- The absence of rapid eye movements

N3

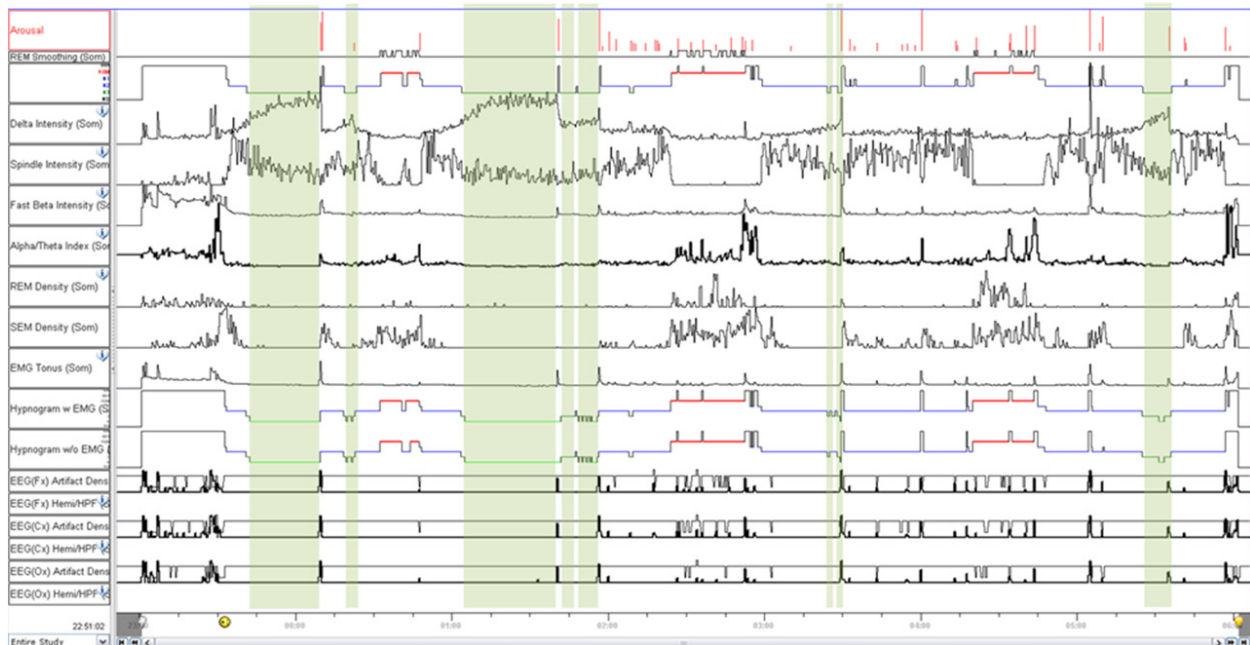


Figure 72: Polysomnographic Feature Trends (PFTs) for Staging & Arousals: Stage N3

Two major and one short period of N3 are nicely supported by

- Elevated levels of delta intensity
- Reduced levels of spindle intensity (as compared to N2). Note the concurrent increase of delta intensity and decrease of spindle intensity in all three N3 periods
- Very low levels of the alpha/theta index
- The absence of both rapid and slow eye movements

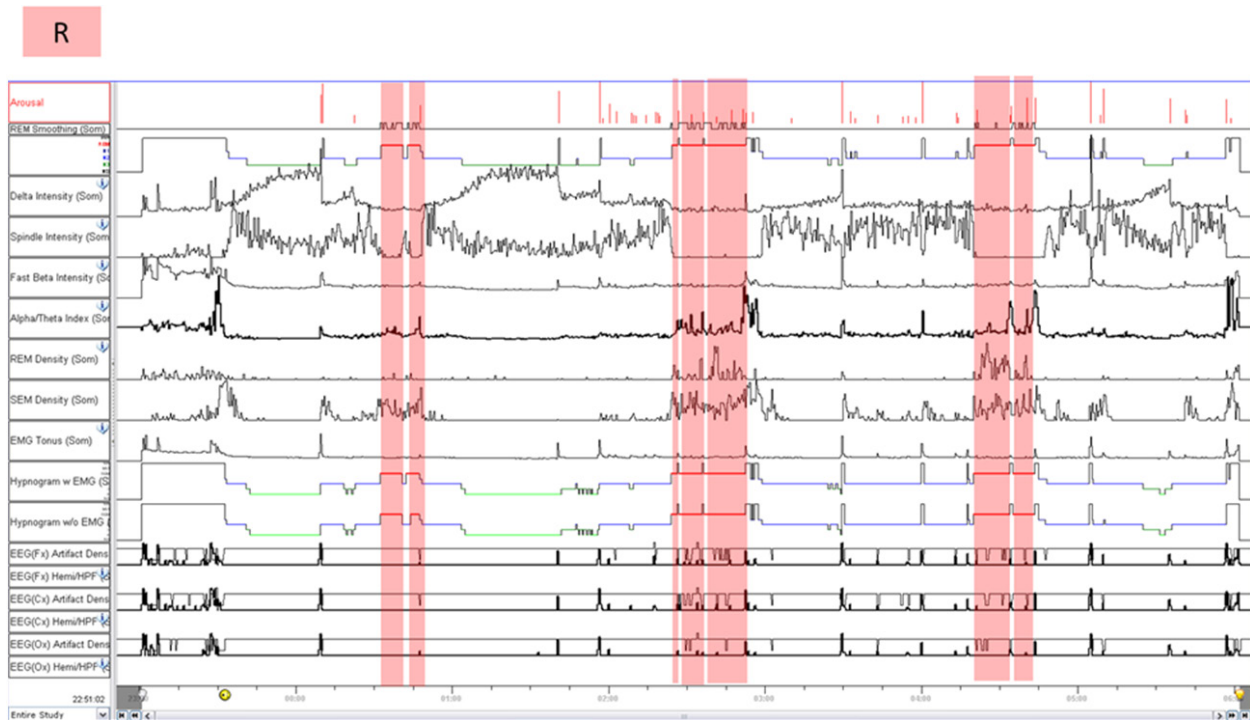


Figure 73: Polysomnographic Feature Trends (PFTs) for Staging & Arousal: Stage R

The three major periods of R are supported by

- Elevated levels of rapid and slow eye movements (note that only the first period of R seems to be an exception with respect to REMs, which is, however, a phenomenon frequently seen in the first period of R)
- Very low (to none) spindle intensity (with the exception of the N2 intrusion in the first R period)
- Elevated levels of alpha/theta index (which, however, is lower than during W)
- The absence of chin EMG activity (although the differences in EMG tone are not very pronounced here)

Furthermore, both interim hypnograms (with and without EMG) are perfectly consistent with each other. Thus, the REM-related features are unambiguously seen in EOG, EEG and chin EMG signals. Although checking the first R period epoch-by-epoch is highly recommended, it is unlikely that any epochs will need to be changed with respect to R.

There is no further anomaly or unusual event visible in the PFTs. Artifacts (with the exception of the first W period) are rare and at usual unavoidable levels. Only in few cases the alternative EEG channels has been used (negative values in the Hemi/HPF traces) and no major period with sweating that would have need the usage of the high pass filter occurred (values of +2 or -2 in the Hemi/HPF traces).

Validity of major sleep variables

Step 1 has identified few segments that warrant further high attention (i.e. epoch-by-epoch inspection). These segments correspond to sleep onset and the first R period:

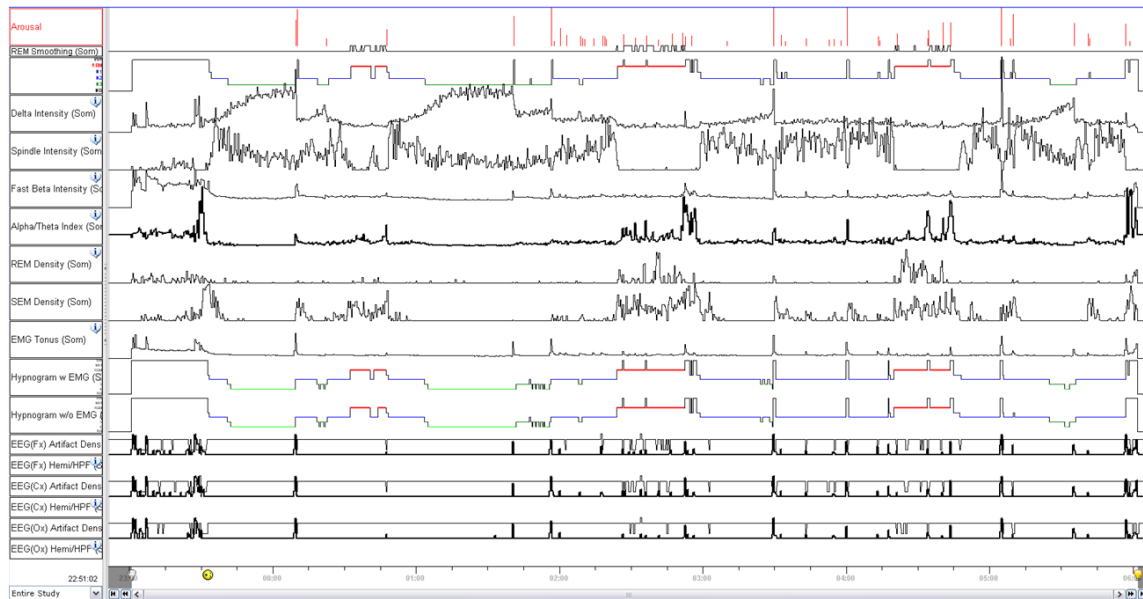


Figure 74: Polysomnographic Feature Trends (PFTs) for Staging & Arousal: Sleep onset & first REM period

A fairly quick walk-through with a slowdown at onset of N1 and R, respectively, will do.

The “REM Smoothing” trace indicates the application of R smoothing. All R periods, including their small interruptions, are supported by all other traces so well and no long REM smoothing period occurred. Thus further epoch-by-epoch review of the REM periods is not needed.

We conclude that ER of staging & arousals (step 2), following the procedure described in this manual, will not exceed 2-3 minutes in this case.

5.5.1 An Example of a First R Period Missed

In this example we note that the first period R occurs relatively late:

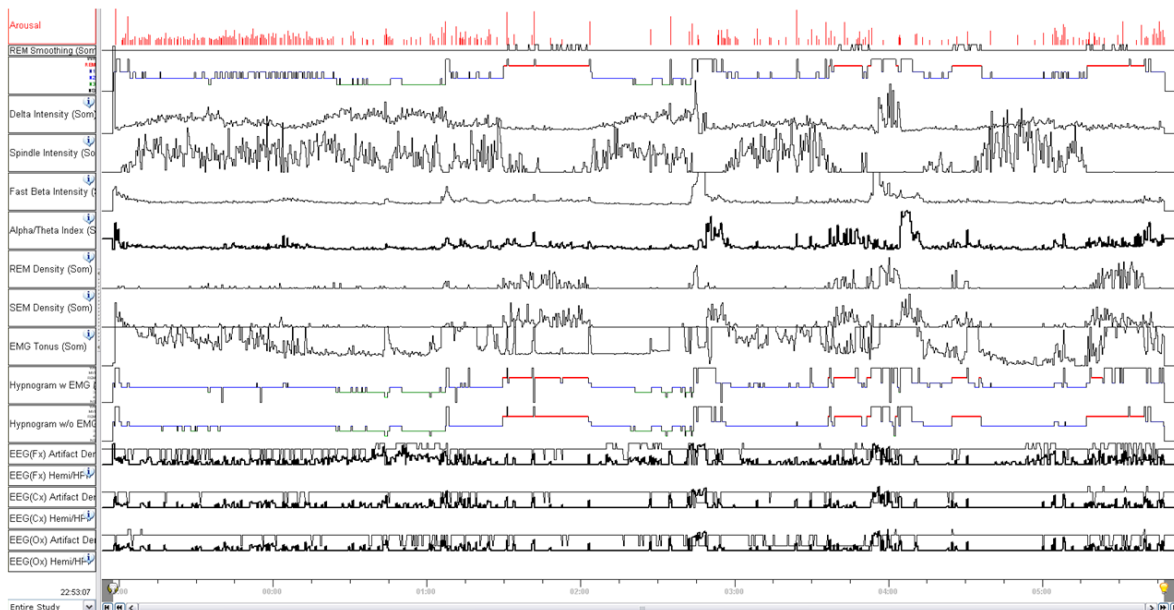


Figure 75: Polysomnographic Feature Trends (PFTs): First REM period?

“Checking the first R period” includes checking of whether it might have been missed due to too weak impressions of its major features.

R typically occurs only at periods where

- Spindle intensity and delta intensity are low
- Some eye movements occur (however, note that a single rapid eye movement might be sufficient to indicate R)
- Alpha/theta index is somewhat elevated, but typically lower than in W
- EMG tone is low

In this case, the only period that fulfills these criteria is the one marked below:

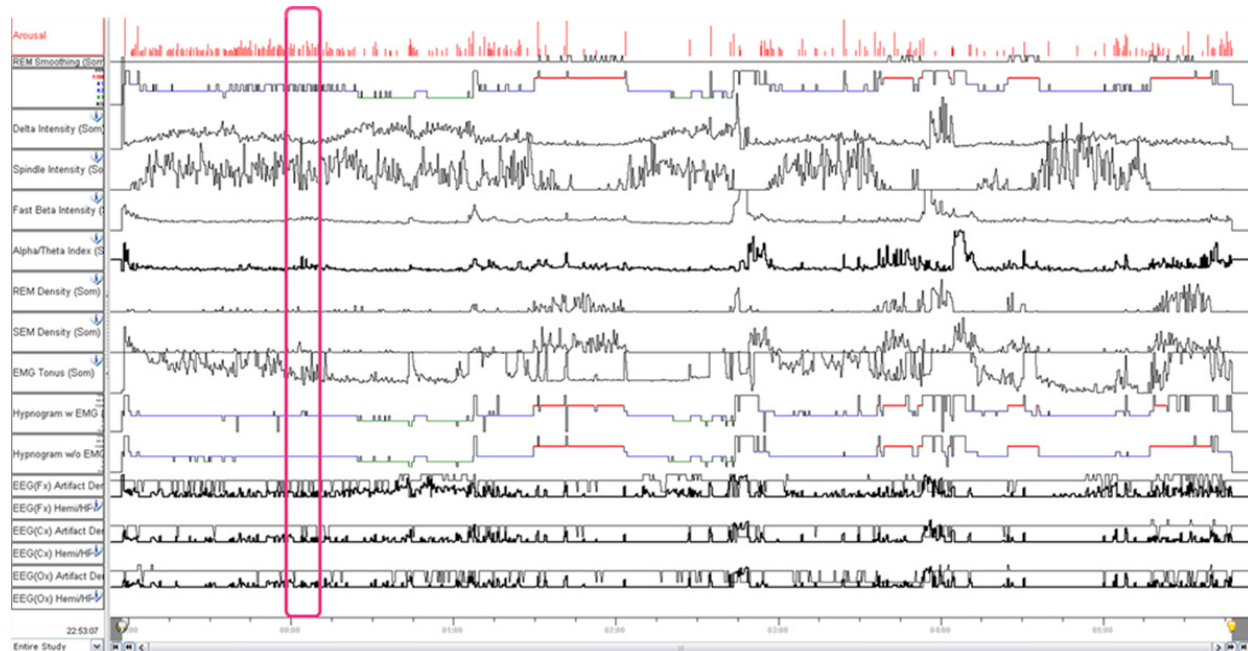


Figure 76 Polysomnographic Feature Trends (PFTs): First REM period

Note that, specifically in the first REM period, both spindles and K-complexes may be interspersed in stage R. The spindle and delta intensity traces, however, will usually show a minimum in such periods, as can be seen in the Figure above.

Epoch-by-epoch inspection of the marked period reveals that indeed it should be scored as R. Incidentally, the final R period would also warrant an epoch-by-epoch review given the inconsistency between the two interim hypnograms.

5.5.2 An Example of a Problematic Sleep Onset

The following PFTs reveal in Step 1 that staging around sleep onset (marked area) seems unusually fragmented.

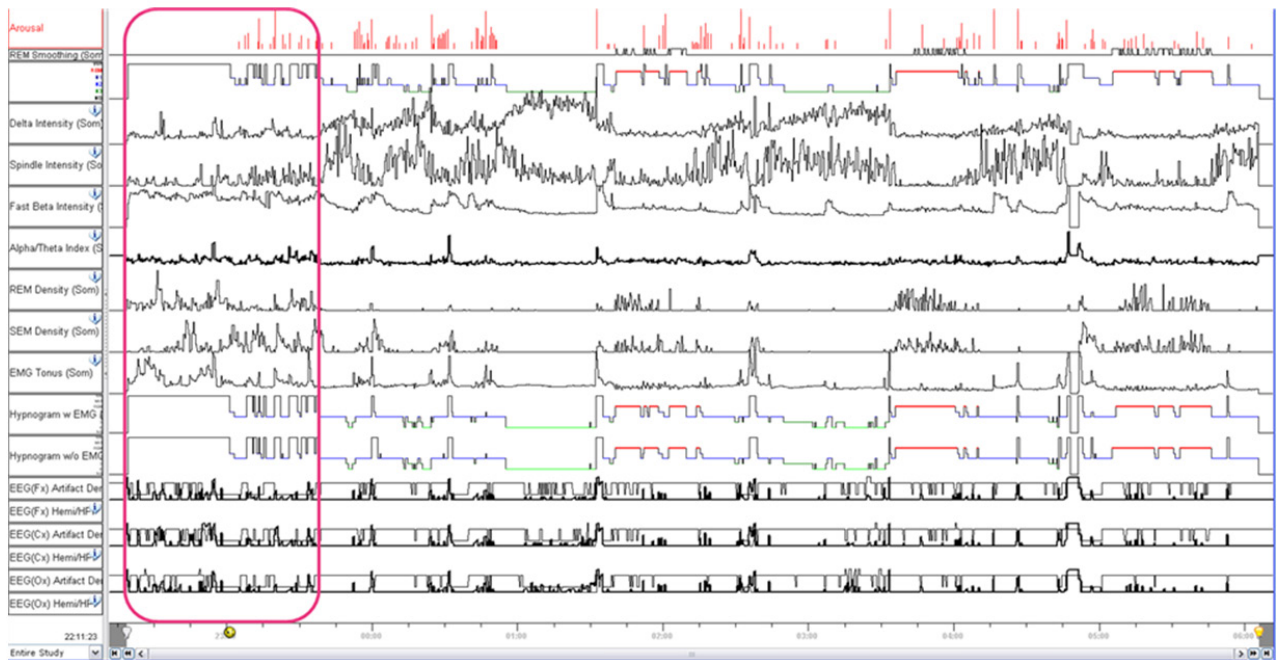


Figure 77: Polysomnographic Feature Trends (PFTs): Instable sleep onset

Step 1 confirms that while wakefulness during that period is supported by the PFTs, the many shifts between sleep and wake in the second part of the marked period do not seem to corroborate this. This underlines the importance of an epoch-by-epoch check of sleep onset, which in this case extends to the entire marked period.

5.5.3 An Example of Too Short Awakening Periods

The following PFTs reveal that the short awakenings in the marked areas could indeed be more pronounced, given the clear peaks in alpha/theta index.

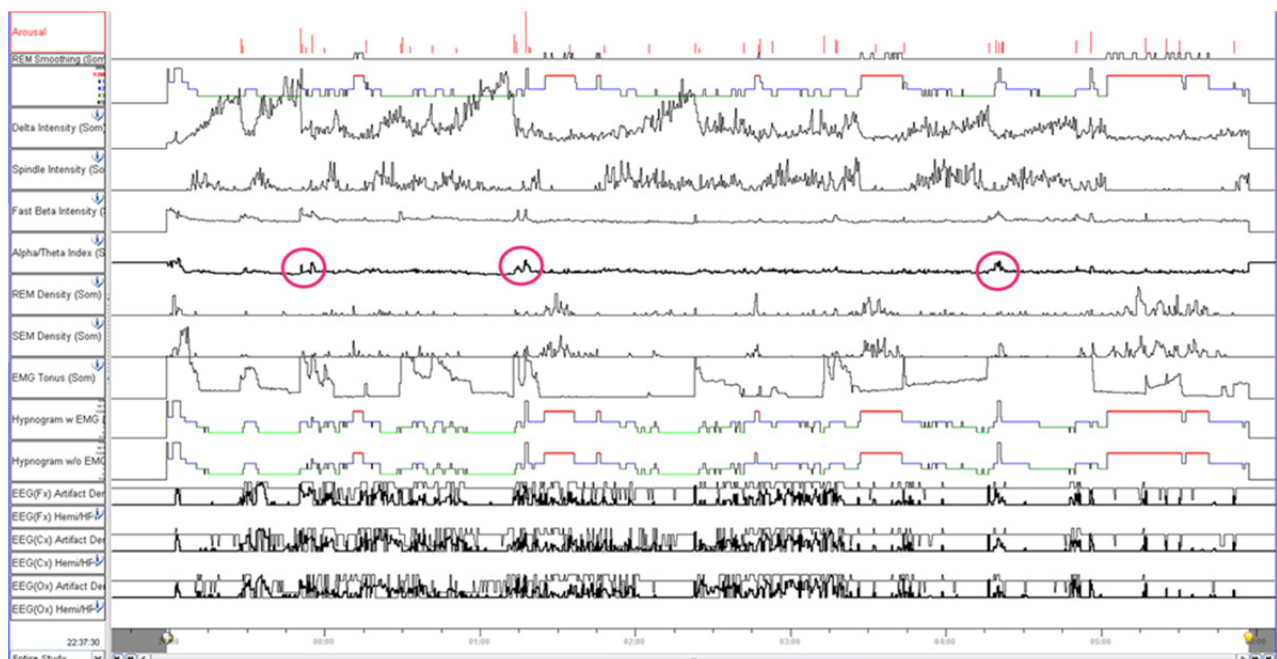


Figure 78 Polysomnographic Feature Trends (PFTs): Too short awakening periods?

5.5.4 An Example of Erroneous Sleep Onset REM

The following PFTs show a probable invalid sleep onset REM:

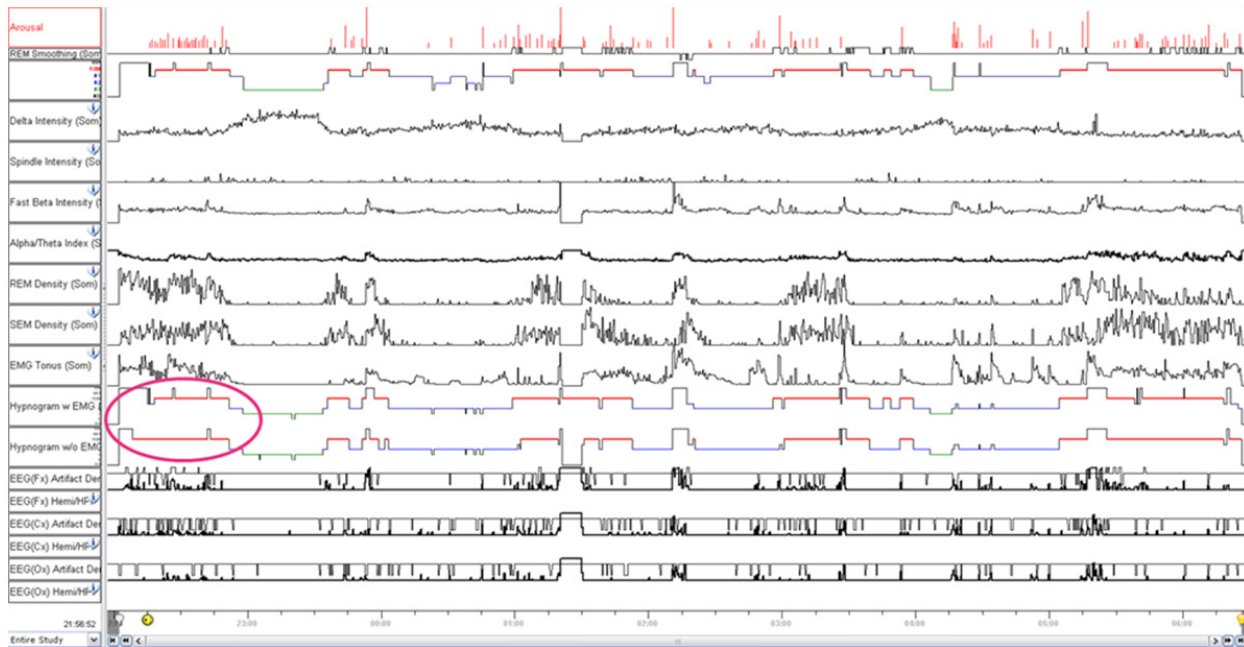


Figure 79: Polysomnographic Feature Trends (PFTs): Sleep-onset REM?

This should raise awareness during Step 1 in any case given the fact that Sleep-onset REM (SOREM) is rare, but a critical clinical warning sign. Here, we observe that the two interim hypnograms are inconsistent. Thus the entire marked period should be reviewed with high attention.

5.5.5 An Example for Problems Due to Artifacts

The following PFTs again show inconsistency between the hypnogram with and without EMG for some short periods. Additionally you can see a large number of artifacts. The Hemi/HPF traces further reveals a high number of switches and frequent applications of a high-pass filtering due to sweat artifacts, further underlining problems in the signal quality. Finally, sleep onset again is unusually fragmented.

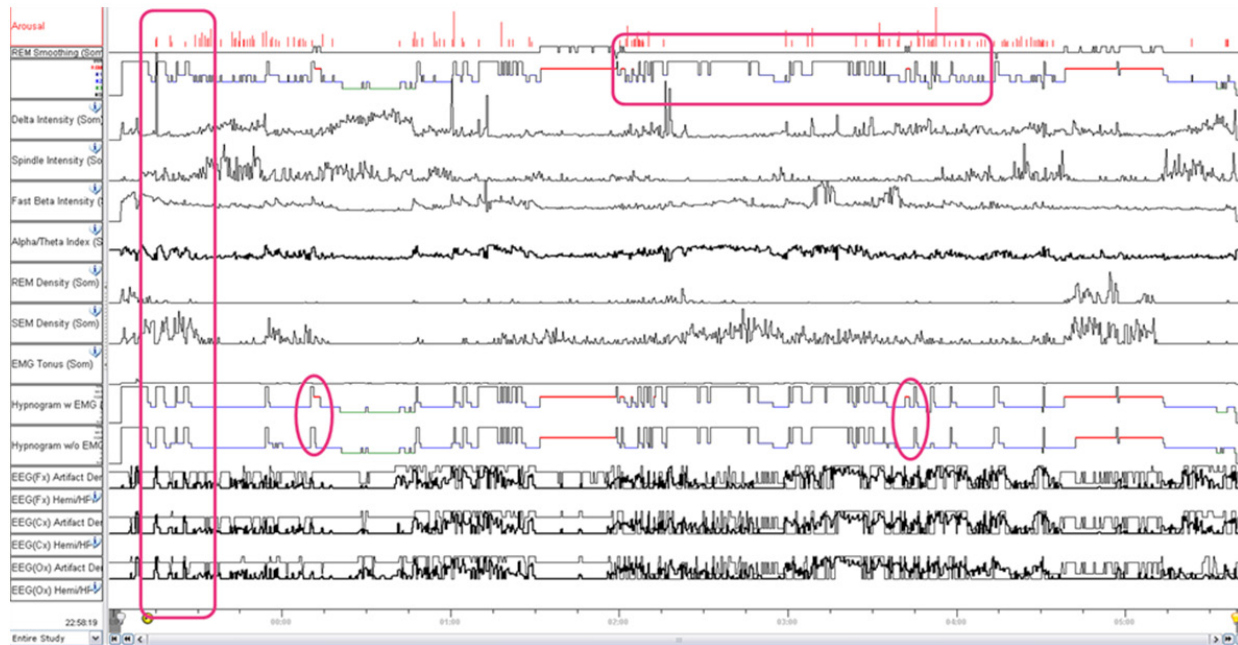


Figure 80: Polysomnographic Feature Trends (PFTs): Problems due to artifacts?

In this case, a fast epoch-by-epoch overview of the entire recording, with a slow-down at the marked areas, would be in place.

5.5.6 An Example of an Anomaly

The following PFTs reveal a rare (but occurring) anomaly: there is virtually no spindling intensity and only little delta intensity present:

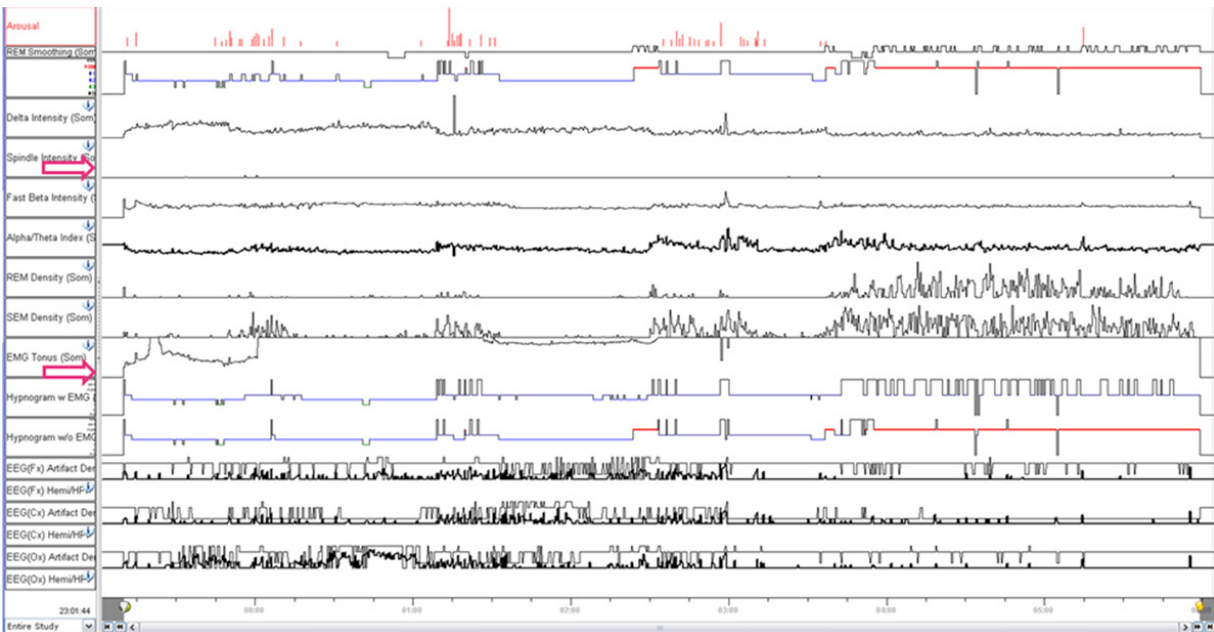


Figure 81: Polysomnographic Feature Trends (PFTs): Uncommon sleep characteristics

This can affect not only N2 scoring, but also the REM/NREM distinction, which is underlined by the inconsistency of the two interim hypnograms. This is another case where medium to higher attention is indicated for major parts of the recording. Note that the very long REM period at the end of the recording was correctly identified by Somnolyzer 24x7, even though the extremely high values of the chin EMG tone (above the displayed range) resulted in scoring of W/N1 in the hypnogram with EMG.

5.5.7 An Example of an Incorrect Montage

The following PFTs demand a high attention level for the entire recording: High alpha/theta index together with high REM density would speak for stage R or W (high REM density together with low muscle tone speaks for REM) but high or medium spindles and delta activity together with low muscle activity would speak for sleep stage N2 or N3.

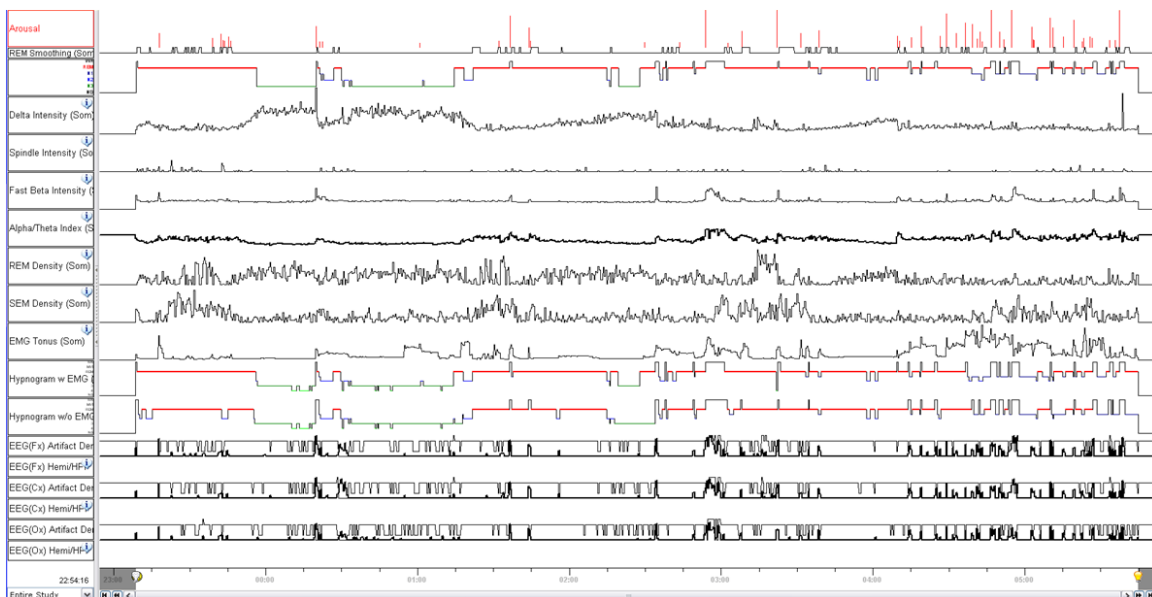


Figure 82: Polysomnographic Feature Trends (PFTs): Incorrect EOG montage

This is an example, where the PFTs points toward a general problem with the data. It turns out that the EOG channels were incorrectly referenced. After correction, the PFTs correspond to a near-perfect scoring:

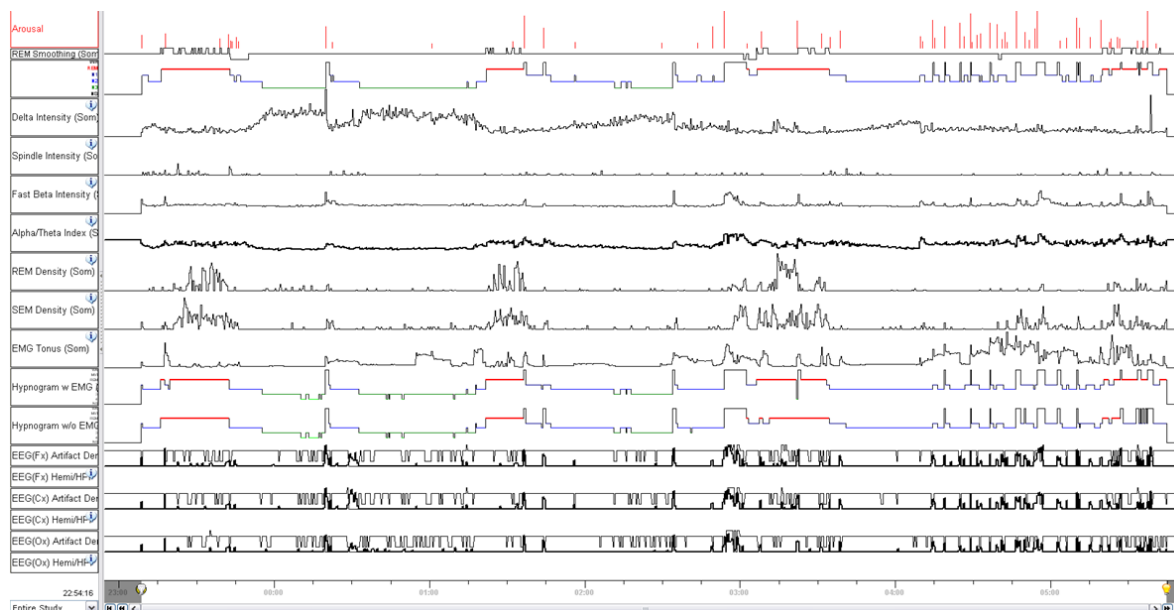


Figure 83: Polysomnographic Feature Trends (PFTs): Same example as Fig. 76 with corrected EOG montage

Note that the EEG based traces (delta intensity, spindle intensity, fast-beta intensity and the alpha/theta index) did not change while the EOG based traces (REM and SEM density) changed significantly, resulting in the correct staging after re-referencing of the EOG channels. The first REM period in this example in fact is a correctly assigned sleep-onset-REM.

5.5.8 Missing R Due to Elevated Fast-Beta

The following PFTs during Step1 raise suspicions about the inconsistent R periods.

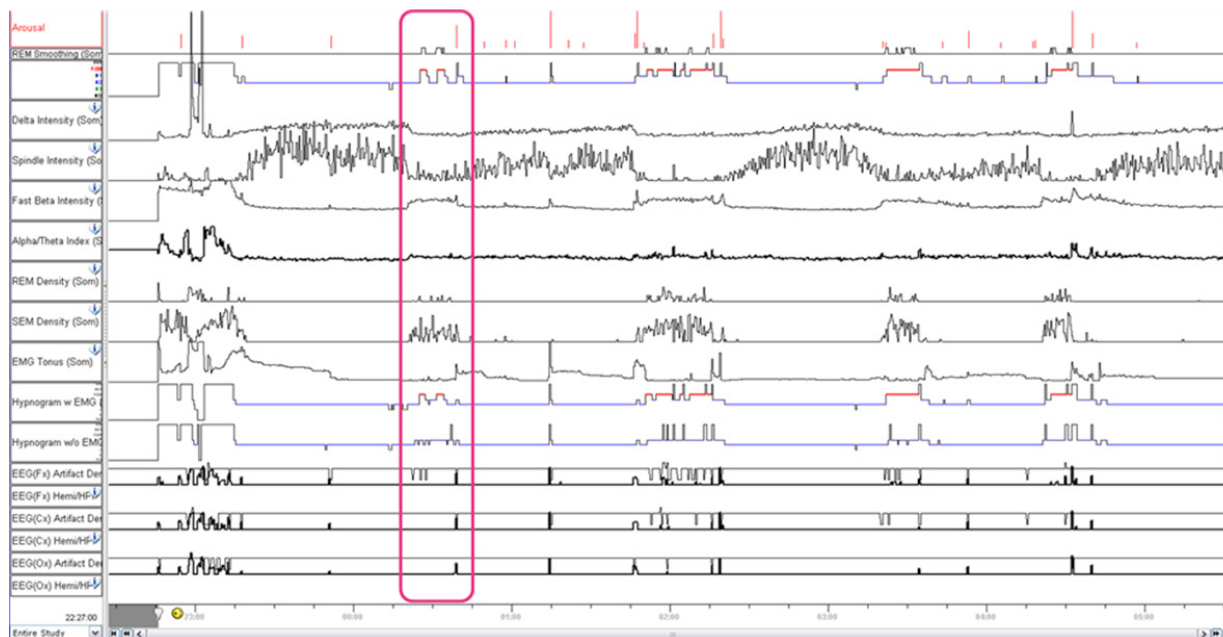


Figure 84: Polysomnographic Feature Trends (PFTs): Uncommon elevation of fast beta during stage R

In this case, however, no period prior to the first REM points toward any R staging that could have been missed. Instead, the traces spindle intensity, REM and SEM density and others suggest that in the marked area

stage R might start earlier and last longer than what is actually scored. This is covered by Phase 1 – Step 1 and a slowing down of scrolling speed is indicated for the marked area. Note the elevated fast-beta activity, which typically speaks for stage W as can be seen in the frequent awakenings prior to the first REM period.

5.6 Description and Examples for Phase 2 “Respiratory & Leg Movement Events” - Step 1 “Confidence Check”

Checking the PFTs for

- Quality and Validity of the respiratory signals– Inspect which channels have been used for the study and whether they have been considered as valid by Somnolyzer 24x7:
 - Airflow signals (Oronasal thermal sensor: Flow; nasal air pressure transducer: PFlow; flow from therapy device: CFlow): Sections not assigned as valid have to be inspected in step 2 “Expert Review of scoring and raw data” in 5 min-windows page by page.
 - Respiratory effort channels (Chest/thorax movements: Thoracic Effort; abdominal movements: Abdominal Effort): Sections not assigned as valid have to be reviewed in step 2 “Expert Review of scoring and raw data” in 5 min-windows if apneas occur concurrently to verify the sub-classification of the apnea events.
- Associations between respiratory events and desaturations – Desaturations which are not associated with a respiratory event as well as respiratory events not associated with desaturations may require careful visual inspection (except for RERAs of course).
- Plausibility of the event distribution – Look at the distribution of the events of the entire night and verify whether it appears plausible. Note any anomalies (such as large discrepancies between the first and second half of the night that are not explained by the night being a split-night or no leg movements at all which might indicate missing leg EMG data).

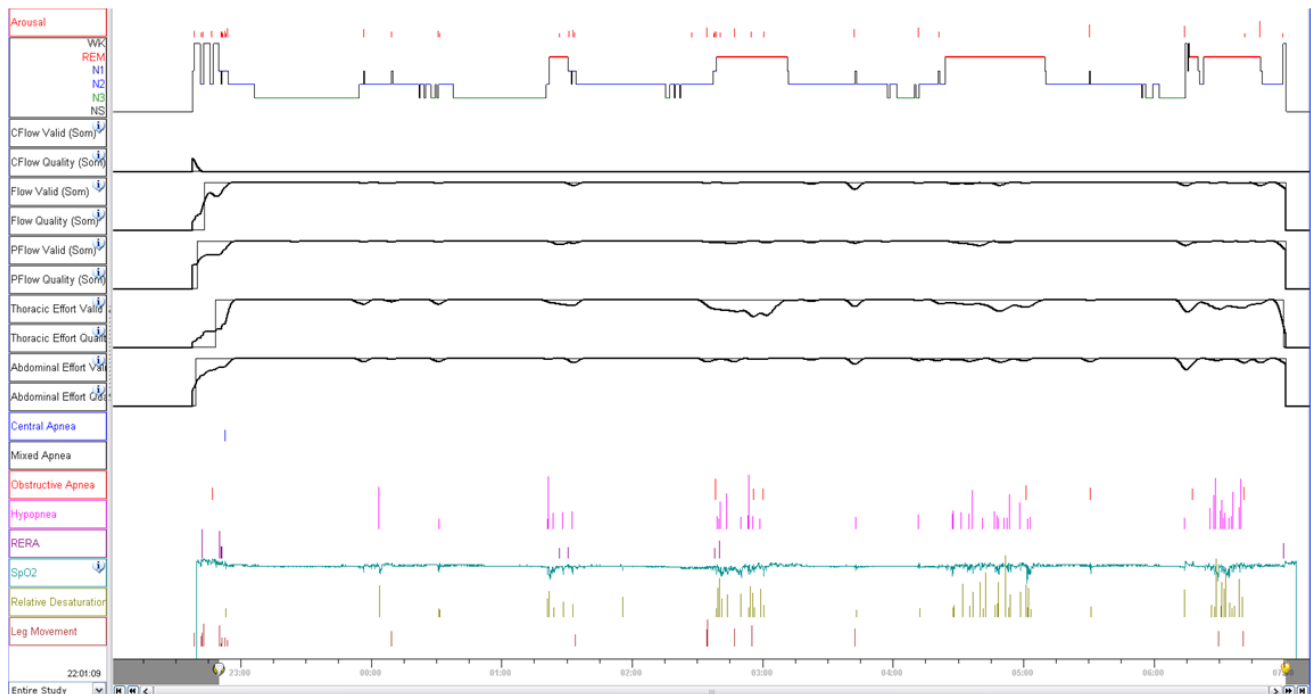


Figure 85: Example for diagnostic study. In this study both flow signals as well as both respiratory effort signals were considered as valid and therefore used for event detection throughout the whole night. No therapy device was used in this study. The obstructive and specifically the central apnea at sleep onset should be confirmed in Step 2. The distribution of all other events appears plausible.

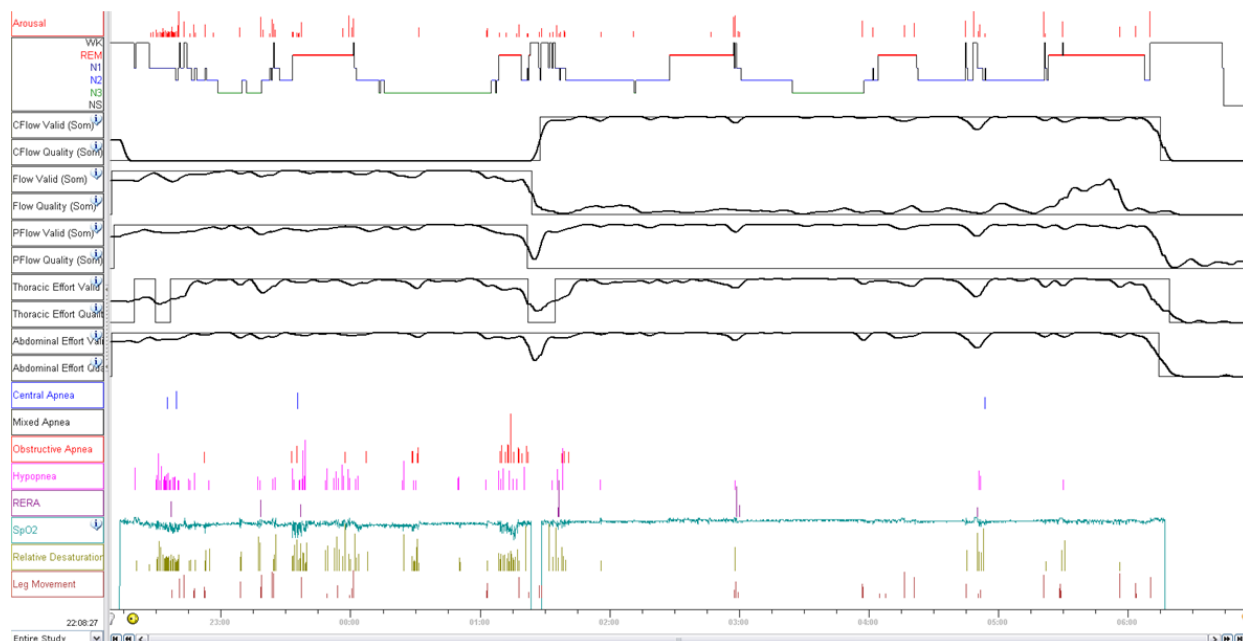


Figure 86: Example for a split-night study. In the first half of the night the flow from the oronasal thermal sensor (Flow) and the flow from the nasal pressure transducer (Pflow) are used for event detection. In the second half of the night the flow from the therapy device (CFlow) is the basis for the event detection. The effort belts are valid throughout the night, except for the time when the patient was unhooked. In addition, the thoracic effort was invalid during a short period in the beginning of the study. In the first part of the night apneas are detected from the Flow signal (for the periods marked as Flow Valid) and hypopneas and RERAs from the Pflow signal (for the periods marked as Pflow Valid), in the second part of the night all respiratory events are detected from the CFlow signal (marked as CFlow Valid).

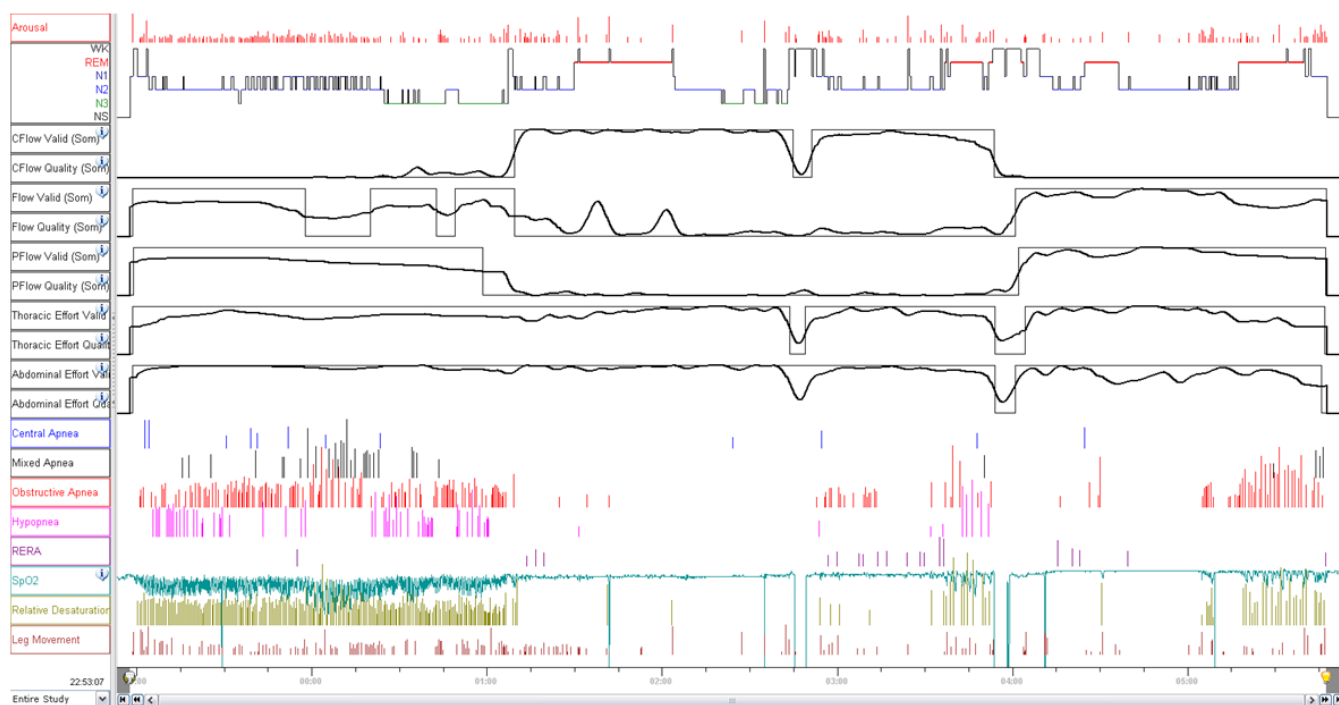


Figure 87: Example for a split-night study with only partial use of the therapy device. In the first part of the night the signals from the oronasal thermal sensor flow (Flow) and the nasal pressure transducer flow (Pflow) have been used. In the middle part the flow from therapy device (CFlow) is the basis for event detection. In the last part, the therapy device was turned off and the Flow and PFlow signals were used once again. See Figure 88 and Figure 89 for further inspection of the signal quality.

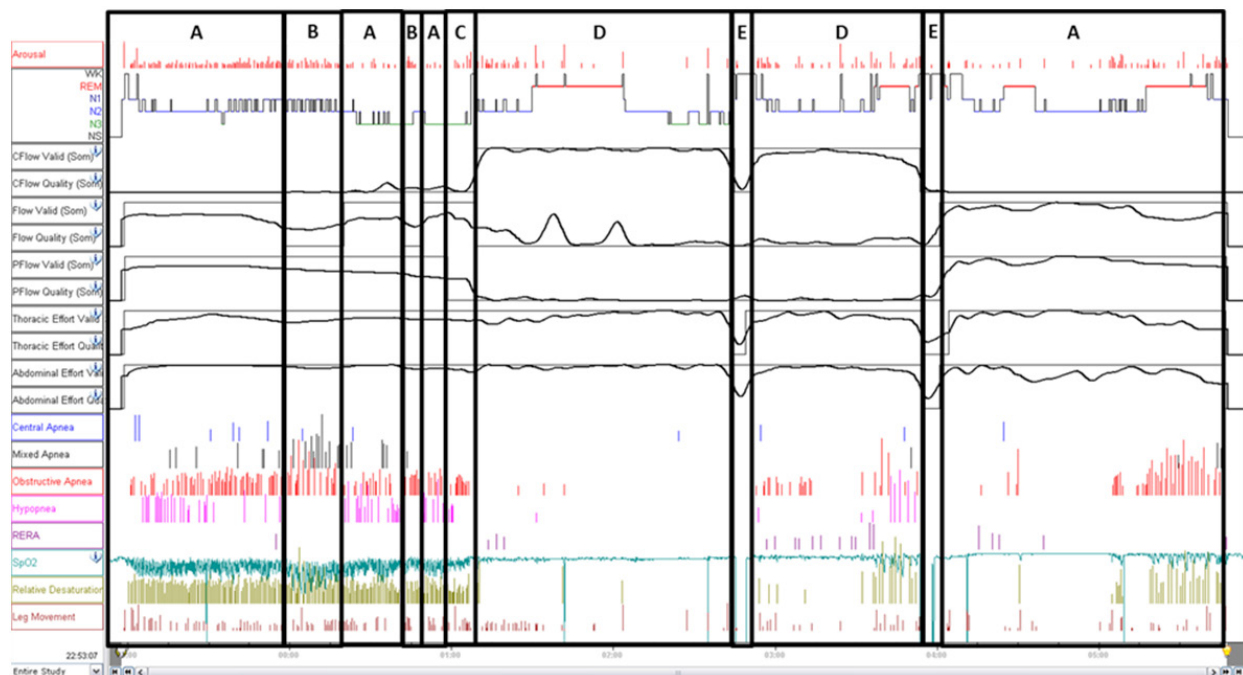


Figure 88: Same study as in Figure 86. In the periods marked as (A) apneas are detected from the Flow signal and hypopneas and RERAs from the PFlow signal since both signals are valid. In the periods marked as (B) all respiratory events are detected from PFlow since no CFlow is available and the Flow signal is considered as invalid. In the period marked as (C) all respiratory events are detected from the Flow signal since no CFlow is available and the PFlow is considered as invalid. In the periods marked as (D) all respiratory events are detected from the CFlow since the CFlow signal is considered as valid. And finally in the periods marked as (E) no valid airflow signal was available and thus no respiratory events are detected. Note that the patient was unhooked during both periods (E).

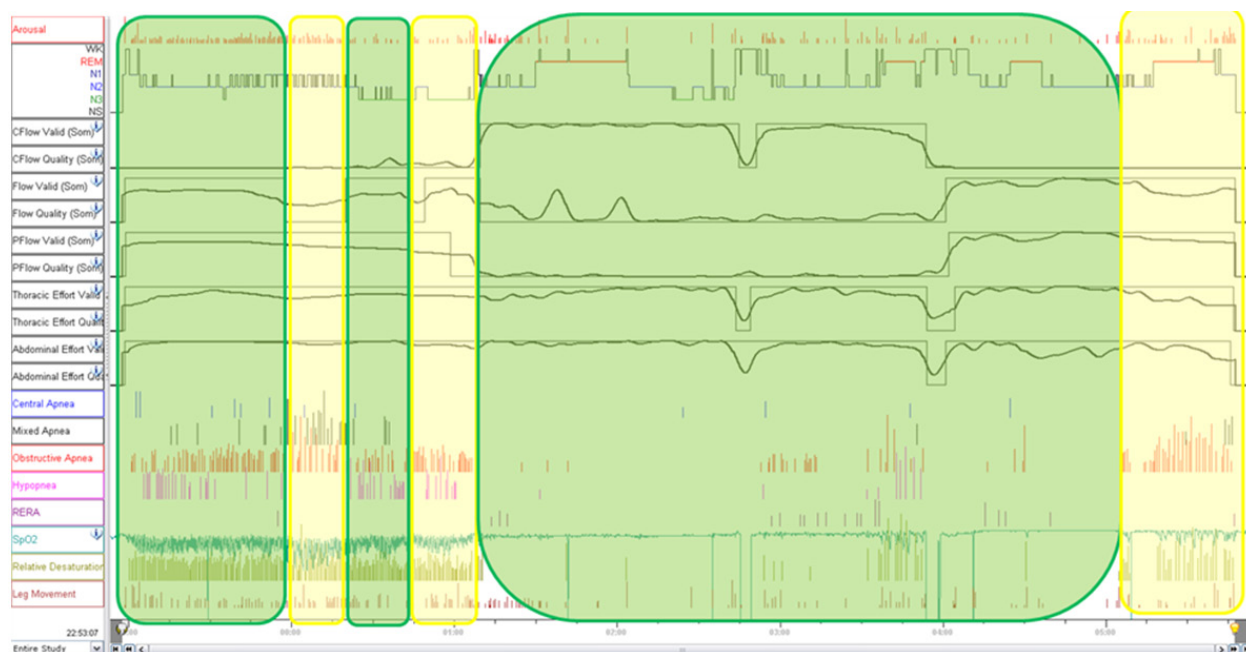


Figure 89: Same study as in Figure 84. Different levels of attention for ER of respiratory events. In this example there are no sections that require high attention (i.e. slow scrolling in Step 2), since during the periods without valid signals the patient is unhooked. Sections that require medium attention (i.e. medium scrolling in Step 2) are indicated in yellow (i.e. periods with rather low signal quality), and sections that require low attention (i.e. fast scrolling in Step 2) are indicated in green.

5.7 Tips and tricks for the most efficient expert review procedure using Sleepware G3 Version 3.3.1 or higher

5.7.1 Application and adaption of workspaces

To ensure an efficient performance of Expert Review, there are four different workspaces saved within G3 which are called: Somnolyzer Staging Overview, Somnolyzer Staging Expert Review, Somnolyzer Events Overview and Somnolyzer Events Expert Review. To apply these workspaces, open the study, go to “Workspaces”, “Favorites” and click on the respective workspace.



Figure 90: Application of a Somnolyzer Workspace

To automatically preload the Somnolyzer workspaces when an acquisition is opened go to “Workspaces,” “Organize Favorites,” click on the respective workspace, choose “Modify” and check “Preload when an acquisition is opened.”



Figure 91: Organize Workspace Favorites to preload Somnolyzer Workspaces when an acquisition is opened

5.7.2 General event display selection

By default, the Sleepware G3 viewer displays all possible events; many of them are not relevant for Expert Review of the Somnolyzer analysis. In Figure 92, all events relevant for ER of Somnolyzer results are enabled.

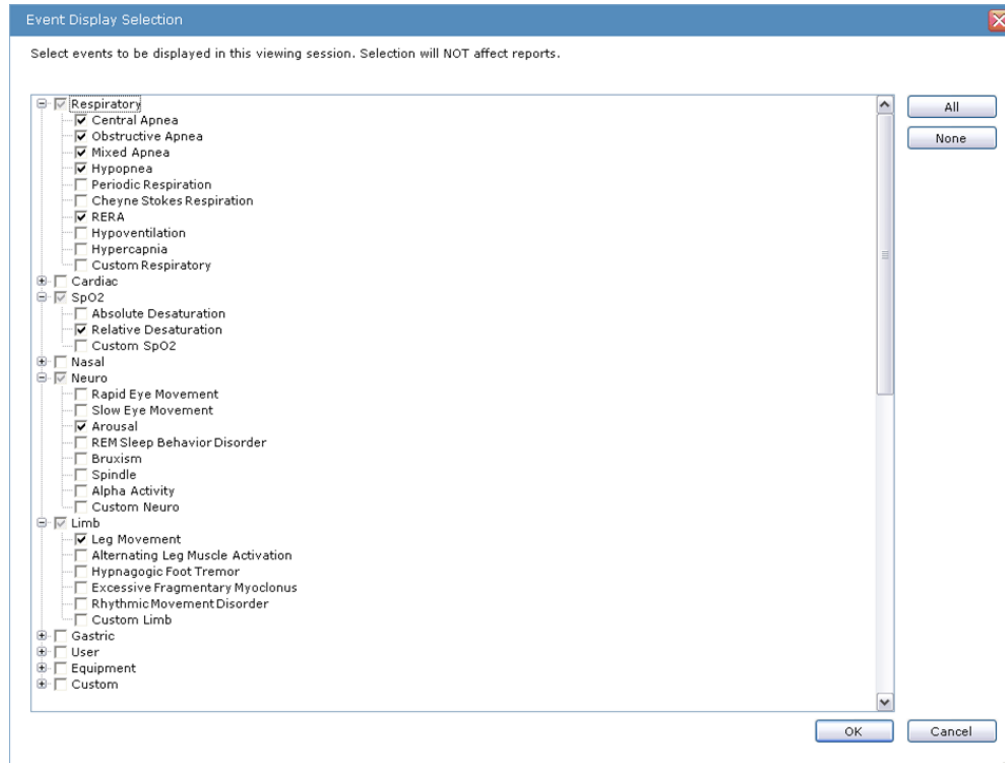


Figure 92: Event Display Selection displaying all events relevant for ER of Somnolyzer results

The most effective way to disable events which are not relevant for the ER of Somnolyzer results is shown in Figure 93. Go to “View”, “Event Display Selection” and disable “User” and “Neuro” and enable “Arousal” in the “Neuro” menu.

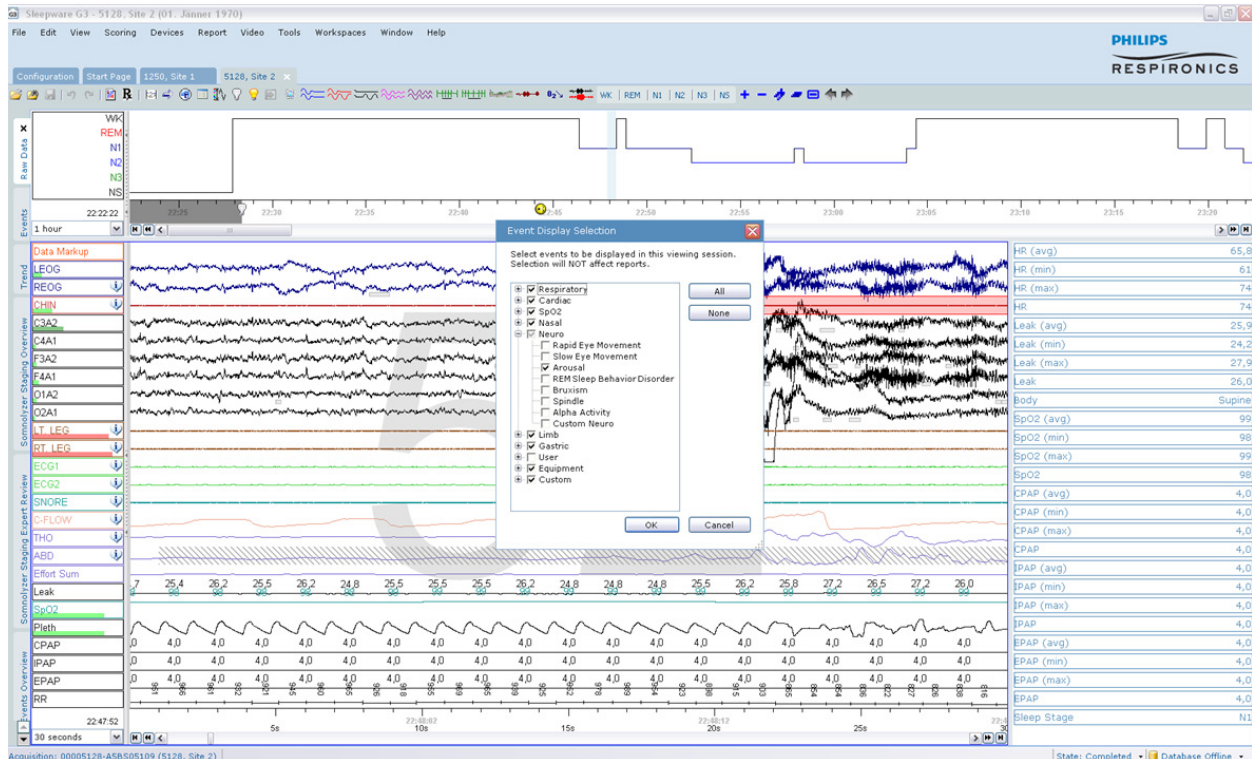


Figure 93: Optimize Event Display Selection settings for ER of Somnolyzer results

5.7.3 Scrolling speed for Step 2 “Expert Review of scoring and raw data”

As described in Step 2 of chapter 5 “The Expert Review Procedure” fast, medium or slow scrolling is recommended for different segments of a study, depending on the level of confidence. While slow and medium scrolling can be done as usual (by either pressing the Page Down button or move the mouse cursor on the scroll bar and make single left mouse button clicks), fast scrolling can be done most efficiently by moving the mouse cursor close to the right end of the scroll bar on bottom and by keeping the left mouse button pressed.

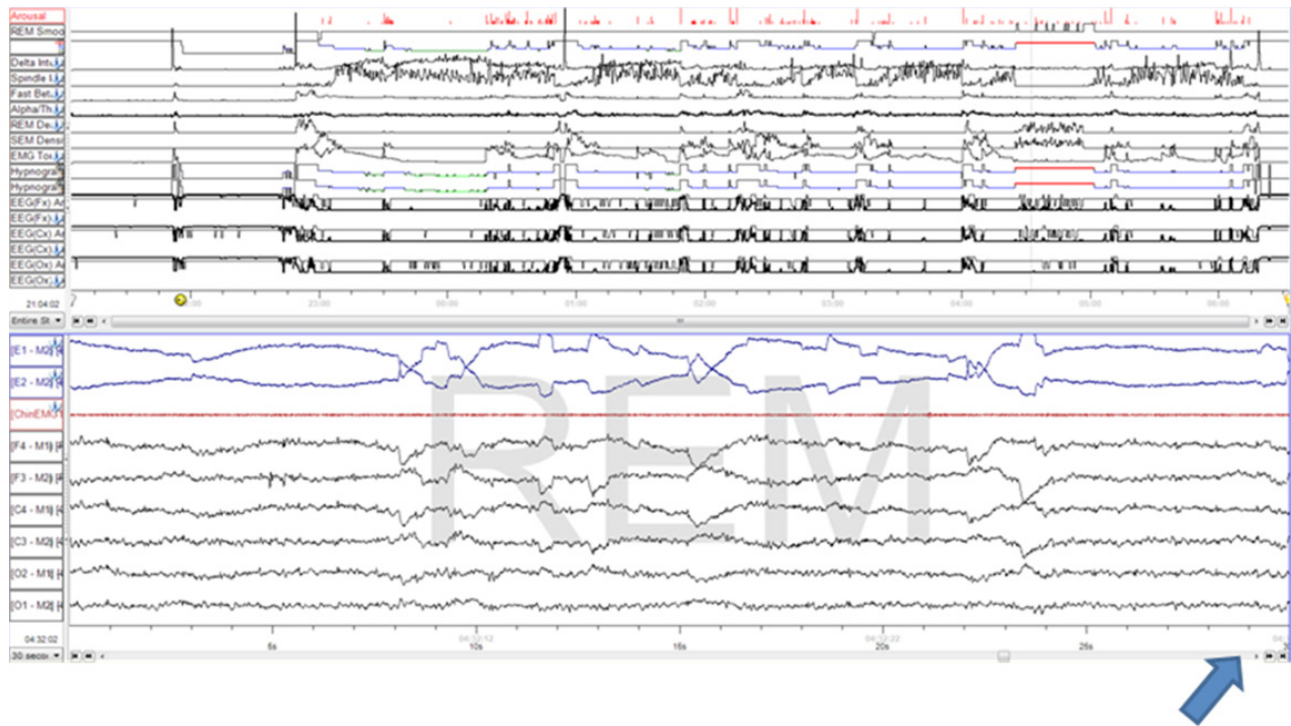


Figure 94: Recommended method for fast scrolling: Move the mouse cursor to the point indicated by the blue arrow and keep pressing the left mouse button

6 Expert Review Guide (Polyman Version 1.12.x)

6.1 Introduction

Somnolyzer 24x7 is a fully validated and reliable tool for computer-supported scoring of polysomnographic (PSG) sleep recordings. Given PSG signals of acceptable quality and fully compliant with the settings as required by the relevant scoring standard, sleep stages and events as derived automatically by Somnolyzer 24x7 are highly trustworthy, being indistinguishable in quality from any skilled visual scorer; and can in many cases be accepted with little manual intervention.

A visual expert review of scoring, performed by skilled scoring staff, is indispensable to ensure high-quality clinically valid results for any scoring procedure. This is not different for Somnolyzer 24x7. What is different, however, is the efficiency with which expert review for Somnolyzer 24x7 scorings can be performed, based on a structured and systematic procedure of several well-identified steps. The goal of expert review is twofold:

1. to ensure that the actual PSG measurement – the recorded signals – was done in a proper way and will not adversely influence any major clinical variable in the scoring report; and also to correct scoring decisions made by Somnolyzer 24x7 when poor recording quality does influence them.
2. to ensure that the computer-based procedure by Somnolyzer 24x7 has not misclassified a clinically important event.

While efforts to ensure point 1 above are minimized by ensuring high-quality and compliant data (thus turning Somnolyzer 24x7 also into a quality assurance tool for the PSG recording team), the steps needed to check point 2 are clearly identified, also typically requiring very little time and effort.

6.2 The Main Cornerstones of Efficient Expert Review

Efficient **Expert Review (ER)**, focusing on the (usually rare) parts of a study that might need human oversight, can be performed by reviewing a scoring epoch by epoch (as is currently still required by AASM accreditation guidelines), or by an even more efficient procedure described below. The ER procedure is based on a specific set of graphical trends – collectively called the **Polysomnographic Feature Trends (PFTs)** – that the Somnolyzer 24x7 provides in addition to the actual scoring (see chapter 3 for a detailed description of the trends)

- For the *staging & arousal part*, the PFTs show a number of traces depicting the distribution of important sleep/wake related features as well as data quality information of EEG, EOG and chin EMG signals. This allows – based on a set of simple rules – the identification of major signal deficiencies and thus the identification of sections that require special attention during the ER.
- For the *respiratory & leg movement event part*, the PFTs show a number of traces depicting the distribution of the events as well as data quality information of respiratory and leg EMG signals. This allows – again based on a set of simple rules – the identification of major signal deficiencies and thus the identification of sections that require special attention during the ER.

This leads to an important observation one should keep in mind when using Somnolyzer 24x7:

Somnolyzer 24x7 allows a trained scorer to shift his focus from an epoch-by-epoch or event-by-event view to a global all-night overview. After some training, every skilled scorer will be able to use the compressed view, given by the PFTs, to finalize the scoring for a fully valid and highly reliable sleep report. Taking a look at single epochs or single events is only necessary in clearly identified areas, based on this global picture

ER is performed in two major phases:

Phase 1: Staging & Arousals

Step 1: Confidence Check of the automated scoring

Step 2: Expert Review of scoring and raw data (semi-automated scoring)

Phase 2: Respiratory & Leg Movement Events

Step 1: Confidence Check of the automated scoring

Step 2: Expert Review of scoring and raw data (semi-automated scoring)

Step 1 of each phase is solely based on the interpretation of the PFTs, Step 2 also includes the review of the raw data.

6.3 The Polysomnographic Feature Trends (PFTs)

How to view the PFTs: Polyman and its associated templates

The PFTs which, as discussed above, form the basis for the ER procedure, are outputted by the Somnolyzer 24x7 in the form of the Polysomnographic Feature File (PFF). The PFF file in turn can be opened by an external (free) program called the. The PFF file is based on the main characteristic sleep/wake related features (PFTs) as well as information about signal quality, which are stored along with the hypnogram and the events in the EDF format (*.pff.edf).

Three different templates are available to display the PFTs optimized for the different phases of the expert review process by means of Polyman EDF-viewer. These templates are usually delivered together with the installation of the Somnolyzer Client or can be procured from Philips Respironics Support (North America: somnolyzer.us@philips.com; rest of the world: somnolyzer.int@philips.com).

To apply a template to a PFF file, open the PFF file within the Polyman Viewer and go to “File” – “Apply Template” – “Browse...”, choose the location where the templates have been stored before and select one of the three provided templates

01_overview.xml (for an example see Figure 95)

02_staging.xml (for an example see Figure 98)

03_events.xml (for an example see Figure 110)

6.3.1 The overview template (01_overview.xml)

The overview template displays all relevant trends in an all-night overview for both, the ER of staging & arousals and of respiratory & leg movement events. Figure 1 shows an example of a diagnostic study, Figure 96 of a split-night study and Figure 97 of a treatment study. While the other two templates show specifically the trends relevant for staging & arousals (02_staging.xml) or for respiratory & leg movement events (03_events.xml), the display based on the overview template (01_overview.xml) plots all available trends. Note, that obstructive, mixed and central apneas as well as hypopneas and RERAs are combined in one trace, respectively. The event types are distinguishable by their color (red: obstructive apnea, green: mixed apnea, blue: central apnea, pink: hypopnea, violet: RERA). By moving the cursor to an event, information about type and duration are shown in a tooltip. The meaning of the different trends is described in the next two sections (6.3.2 and 6.3.3), their optimal usage for expert review is described in section 6.4.

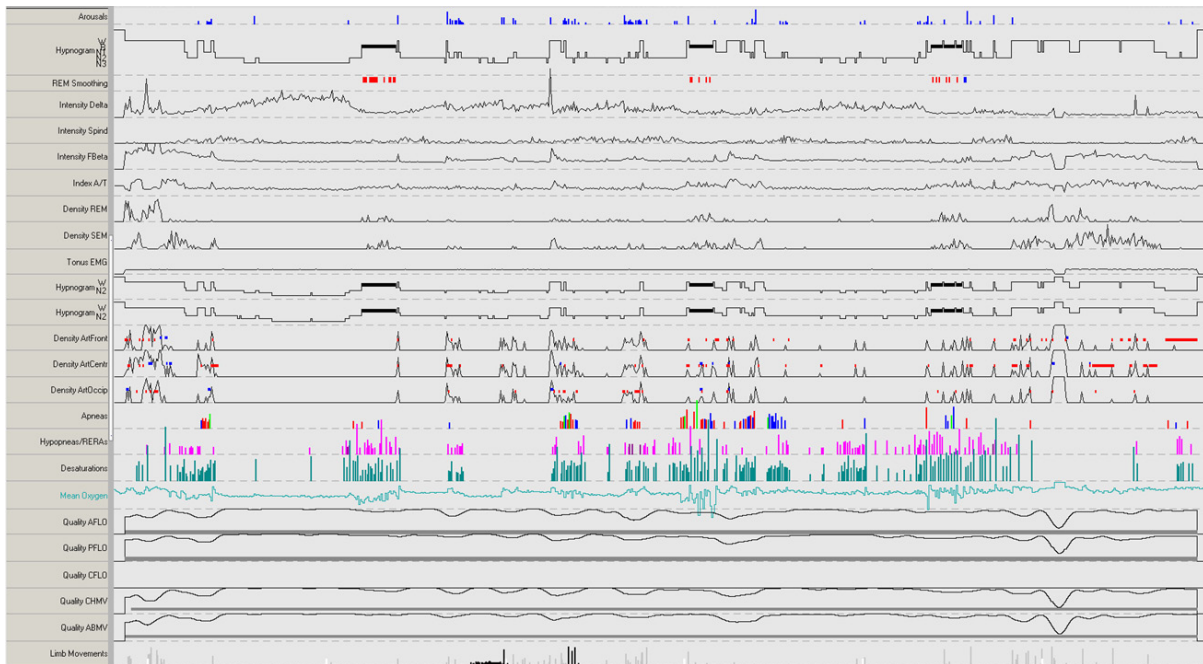


Figure 95:The overview template plot showing all PFTs for a diagnostic study

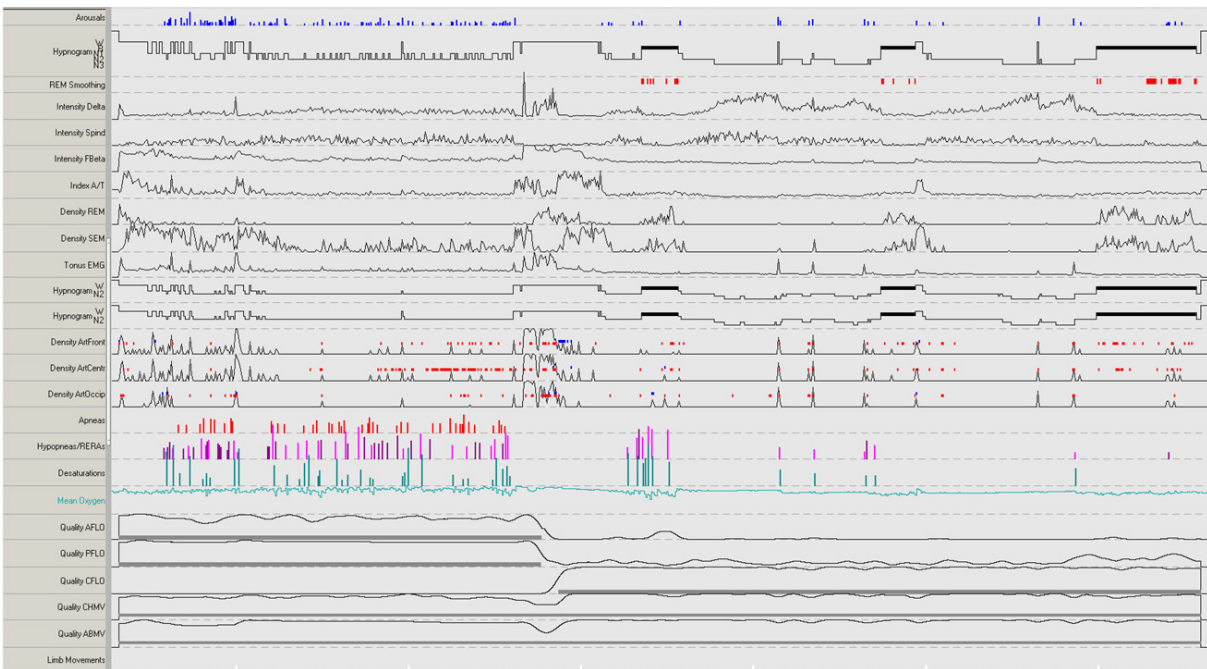


Figure 96:The overview template plot showing all PFTs for a split-night study

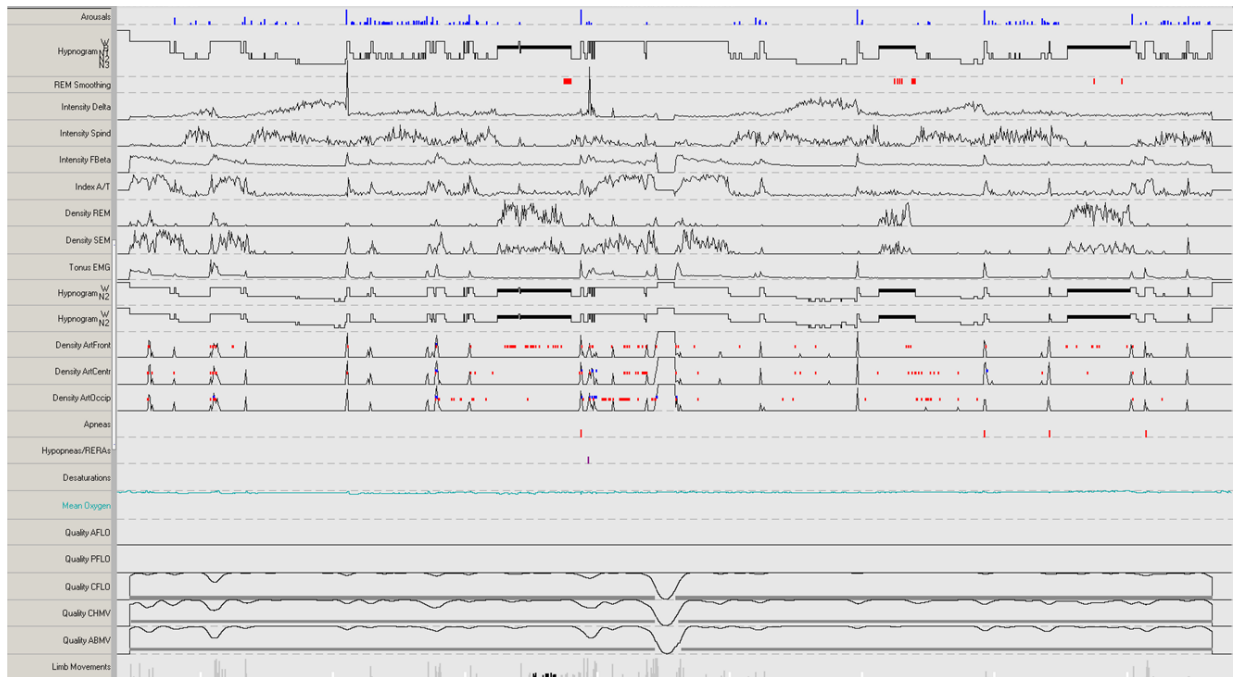


Figure 97: The overview template plot showing all PFTs for a treatment study

6.3.2 The staging template (02_staging.xml)

The staging template includes all relevant trends for the ER of stages & arousals. The trends are Arousal, the Hypnogram, REM Smoothing, Intensity Delta, Intensity Spindles, Intensity Fast Beta, Index Alpha/Theta, Density REM, Density SEM, Tonus EMG, Hypnogram with EMG and without EMG as well as the Density Artifacts including information concerning high pass filter and hemisphere switching. The meaning of the different trends is described below in detail.

Whenever a valid CFLO signal is present, a gray bar on top indicates periods where this signal has been used for event detection (see “Valid cflo” on top of Figure 93 for an example for a split-night study).

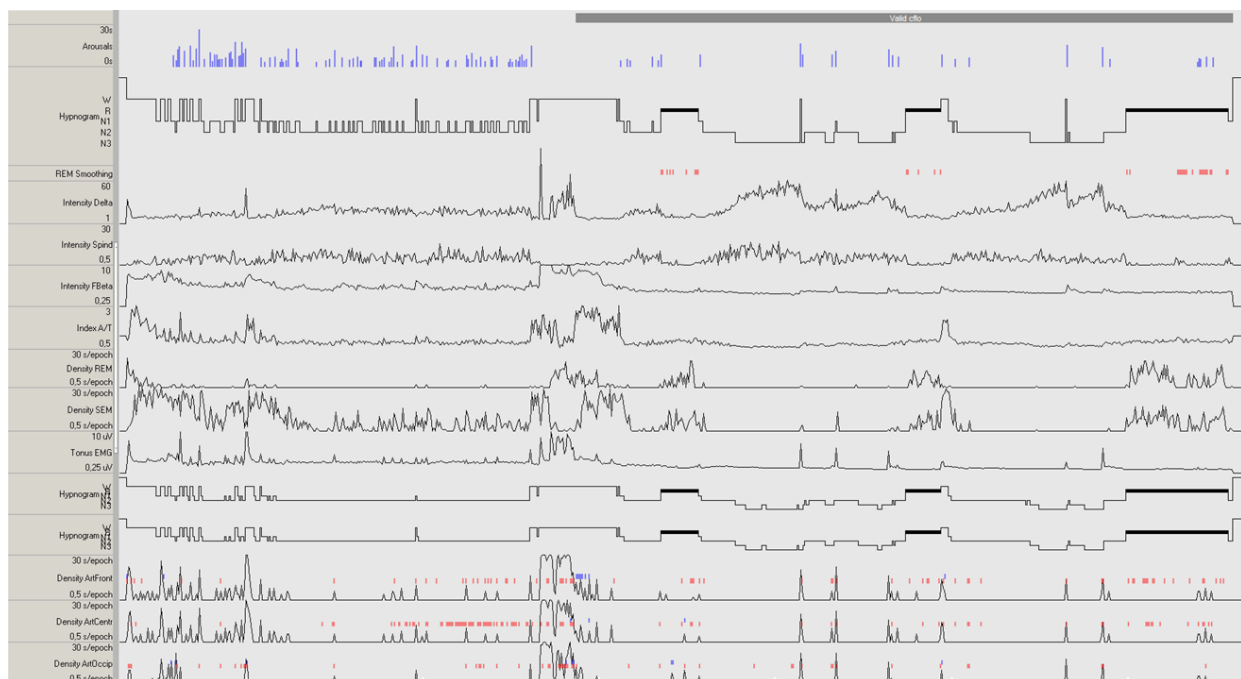


Figure 98: The staging template used for expert review of stages & arousals

Description and Explanation of the Traces:

Arousals

The arousal trace indicates position and duration of arousals. The length of the blue lines indicates the duration of an arousal, scaled from 0 to 30 s. Note that the length of an arousal leading to an awakening is limited to 30 seconds.

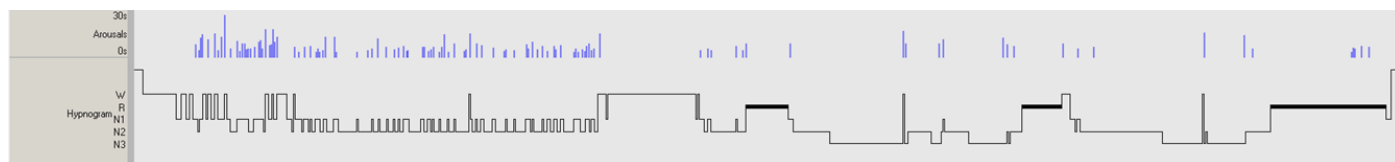


Figure 99: Arousals

REM Smoothing

This trace contains the following information:

- A red line indicates that Somnolyzer 24x7 has changed an epoch previously not assigned as R to stage R according to the rule for the transition between stage N2 and stage R (AASM Manual, 2007, IV.7.D) or according to the rule for the continuation of a period of stage R sleep (AASM Manual, 2007, IV.7.B).
- A blue line indicates that Somnolyzer 24x7 has changed an epoch previously assigned as stage R to a NREM stage or wake, since the neighboring epochs do not support a REM phase (no such case occurs in the study shown in the figure below; for an example see end of the third REM).

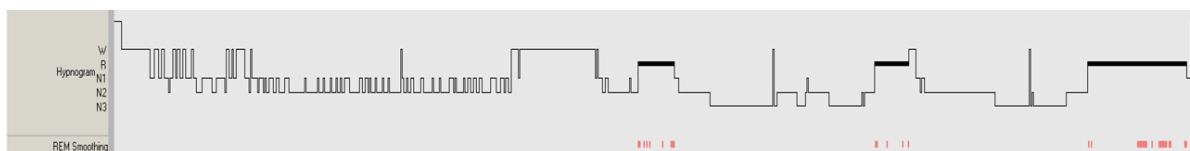


Figure 100: REM Smoothing

Intensity Delta

This trace shows the intensity of delta waves. Note that, in addition to slow waves, all waves with frequencies between 0.5 Hz and 2 Hz are included in this trend independent of their amplitude. High delta activity speaks for stage N3, medium delta speaks for stage N2 (note the values in this trend for periods scored as N2 are not as high as those scored as N3) and very low delta speaks for stage R, stage N1 or stage W. Note the typical logarithmical increase of EEG delta activity in each NREM period in the second part of the night, reflecting patient's increasing sleep depth. In contrast, sudden short increases – typically seen as spikes in stage W – are due to movement artifacts.

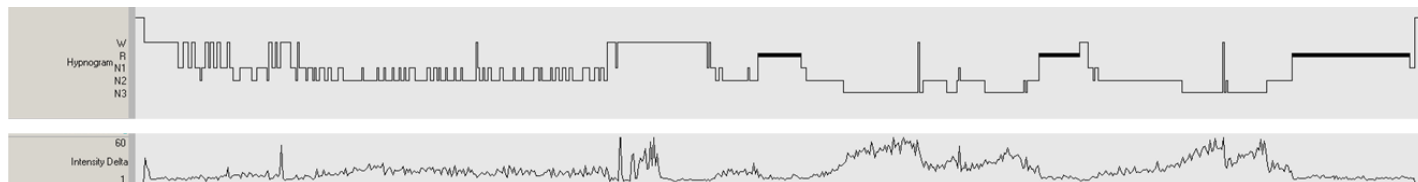


Figure 101: Intensity Delta

Intensity Spindle (Spind)

This trace shows the intensity of probable sleep spindles. High values of spindle intensity speak for NREM sleep (especially N2), whereas very low values speak for R, W or N1. Note the increase in spindle intensity at the start of each NREM period. Usually the spindle intensity shows its maximum in N2 sleep with a decline towards slow wave sleep (see Figure 116 for a typical example).

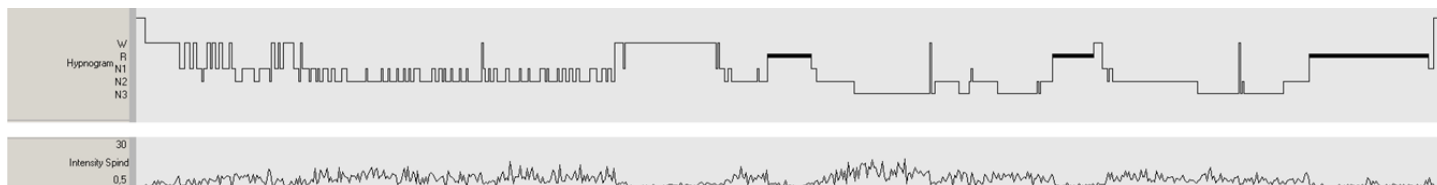


Figure 102: Intensity Spindle

Index Alpha/Theta (A/T)

This trace shows the quotient of the activity in the alpha band to the activity in the theta band. High values speak for stage W, low values speak for sleep. Note, that during stage R the alpha/theta index might be higher compared to NREM, but is typically lower compared to W. Sudden increases in this index are indications for awakenings. If the alpha/theta index is elevated to a higher level without associated changes from NREM sleep to W or R these epochs have to be checked.

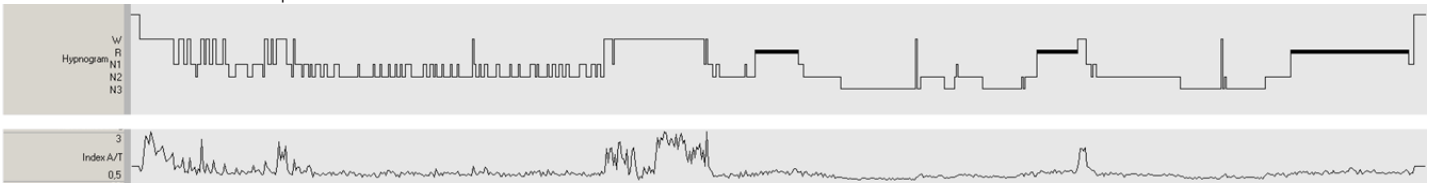


Figure 103: Index A/T

Intensity Fast-Beta (FBeta)

This trace shows the intensity of the activity in the fast-beta band. High values speak for muscle interference in the EEG channels and thus for stage W, low values speak for sleep. Note that awakenings are frequently accompanied by sudden increases (peaks) in the fast-beta intensity.

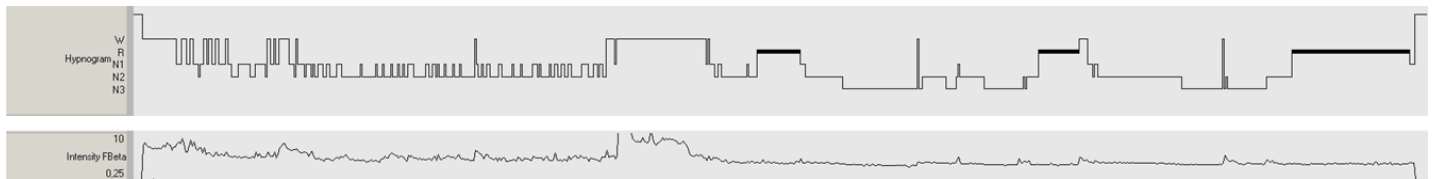


Figure 104: Intensity FBeta

Density REM

This trace shows the density of probable rapid eye movements. High REM density values speak for stage R or W. If there is either high or no REM density during the whole recording, EOG channels need to be checked.

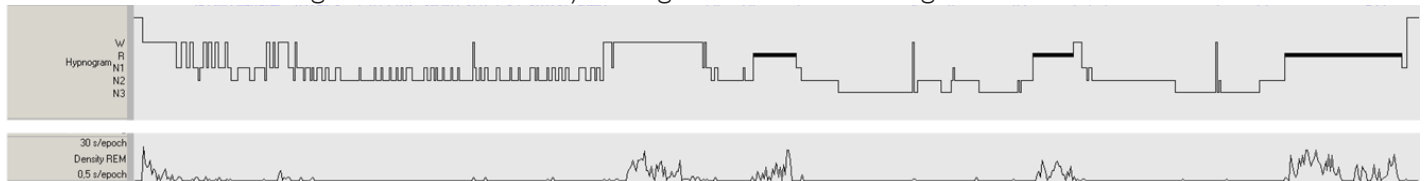


Figure 105: Density REM

Density SEM

This trace shows the density of probable slow eye movements. High values speak for transitions between W and N1. SEMs may still be seen at the beginning of stage N2 periods. Typically SEMs are also present in stage R, since rapid eye movements are usually superimposed on slow ones. If there is either high or no SEM density during the whole recording, EOG channels need to be checked.

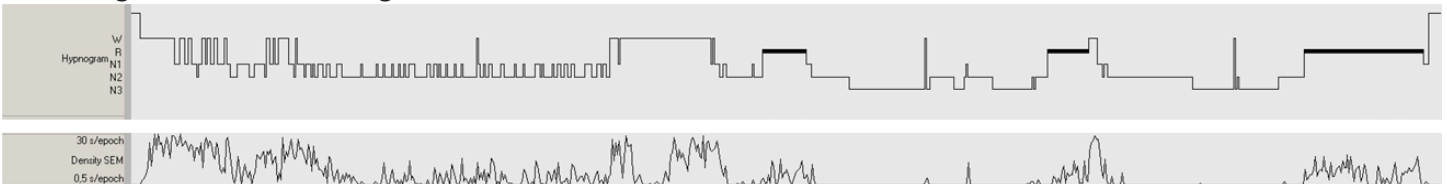


Figure 106: Density SEM

Tonus EMG

The trace shows the trimmed group mean of tonic chin EMG activity. High values speak for W and/or artifacts. Low values are usually seen during stage N2 and N3, with the lowest values in stage R. If EMG tone is very high or very low during the whole recording then the EMG signal needs to be checked.

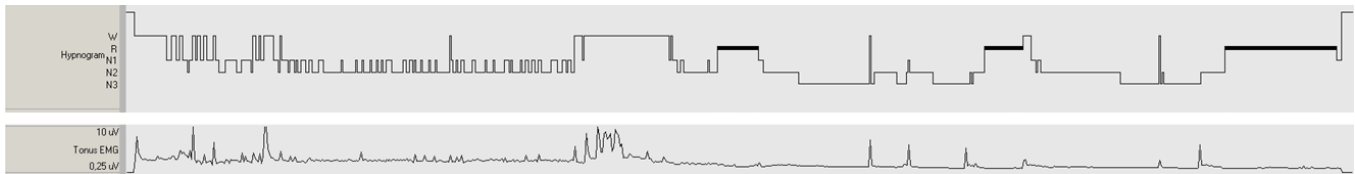


Figure 107: Tonus EMG

Interim Hypnograms

These traces show two interim Somnolyzer staging outputs. The hypnogram in the upper trace is based on EOG, EEG and chin EMG channels. The one in the lower trace uses EOG and EEG channels only and estimates muscle tonus from the high-frequency interference in the EOG and EEG signals. If the chin EMG signal is of good quality there should be no large differences between the two interim hypnograms.

Note that four additional rules are applied to determine the final hypnogram based on these interim results:

- Unscorable epochs that occur within a wake period are assigned as stage W (see Figure 95 and Figure 97 for examples).
- Epochs which contain more than 15 s of arousals are assigned as stage W (see the two short awakenings in the 2nd and 3rd NREM period in Figure 108).
- Stages assigned in the interim hypnogram as stage 4 (more than 50% of slow waves) are merged together with stages assigned as stage 3 into stage N3 (see the examples in the 2nd and 3rd NREM period in Figure 108).
- Stages assigned in the interim hypnogram as stage 1 or 2 are finally assigned as N1 or N2 in accordance with the rules defining start, continuation and end of a period of stage N2 sleep (AASM Manual, 2007, rule IV.5). In particular the rule defining the end of a period of stage N2 due to an arousal (AASM Manual, 2007, rule IV.5.C.1.b) may lead to changes from stage 2 to stage N1 (see the frequent shifts to N1 in the final hypnogram in the first part of the night in Figure 108).

If there are differences between the two interim hypnograms (e.g. one hypnogram shows a REM period and the other does not), then these epochs need to be checked. In this example there are only small deviations between the two hypnograms indicating good signal quality.

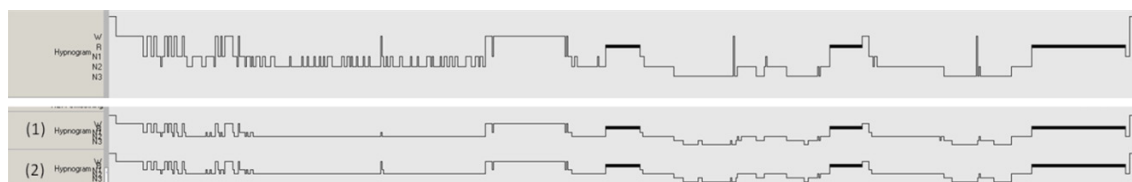


Figure 108: Interim Hypnograms: hypnogram with chin EMG (1) and hypnogram without chin EMG (2)

EEG Artifacts (Density ArtFront, ArtCentr, ArtOccip)

Detected artifacts are: missing data, high-amplitude artifacts, low-frequency artifacts (sweat, electrode and movement), high-frequency artifacts (muscle), and ocular artifacts. Separate traces show the artifact density per 30-s epoch for the frontal (Density ArtFront), central (Density ArtCentr) and occipital (Density ArtOccip) channels. The traces are scaled between 0 s (i.e. no artifact) and 30 s (i.e. artifacts during the whole 30-s epoch).

Additional information is superimposed on the artifact density traces:

- A red line indicates a channel switch from the default to the alternative hemisphere for the respective EEG channel. Somnolyzer 24x7 switches from the EEG channel in the recommended default hemisphere to the one in the alternative hemisphere, if the latter has fewer artifacts. As soon as the signal quality (fewer artifacts) is better in the default channel it is switched back. Note that the artifact density trace is based on the artifacts in the selected channel (i.e. the channel with better signal quality).

- A blue line indicates that sweat artifacts have been detected. To avoid misinterpretation of these low-frequency artifacts as slow-waves, Somnolyzer 24x7 minimizes the interference of this artifact by applying an additional high-pass filter in the respective EEG channel. As soon as no more sweat artifacts are detected, the additional high-pass filter is turned off.

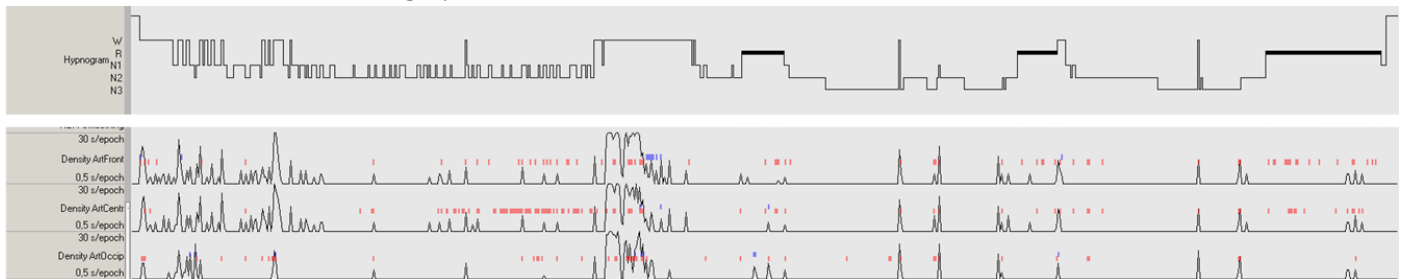


Figure 109: Density ArtFront, Density ArtCentr, Density ArtOccip

6.3.3 The event template (03_events.xlm)

The event template includes all relevant trends for the expert review of respiratory and leg movement events. It displays Arousals, the Hypnogram, Obstructive Apneas, Mixed Apneas and Central Apneas, Hypopneas and RERAs, Desaturations with violet dots below representing respiratory events, Mean Oxygen as well as the Quality traces for all the oronasal thermal sensor signal (Quality AFLO), the nasal air pressure transducer signal (Quality PFLO), the CPAP flow (Quality CFLO), the respiratory effort signal from the chest/thorax (Quality CHMV) and the respiratory effort signal from the abdomen (Quality ABMV) including the information on their validity as well as Limb Movements showing leg movements in grey and periodic leg movements in black.

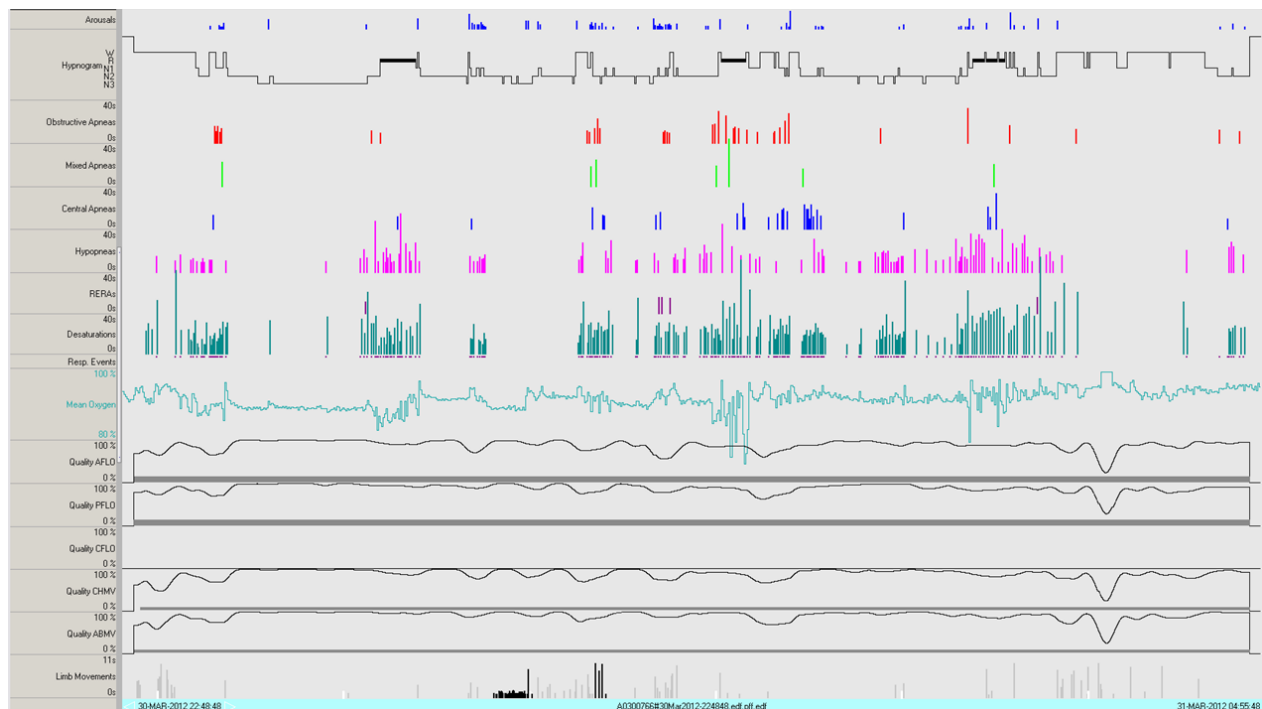


Figure 110: The event template includes all relevant trends for the expert review of the respiratory and leg movement events

Description and Explanation of the Traces:

Apnea Events (Obstructive, Mixed, Central Apneas)

The apnea traces indicate position and duration of obstructive, mixed and central apneas by one line per event in red (Obstructive Apnea), green (Mixed Apnea) or blue (Central Apnea), respectively (Figure 111). An example with obstructive, mixed and central apneas can be found in section 6.6 (Figure 141). The length of the line indicates the duration of the event scaled between 0 and 40 s.

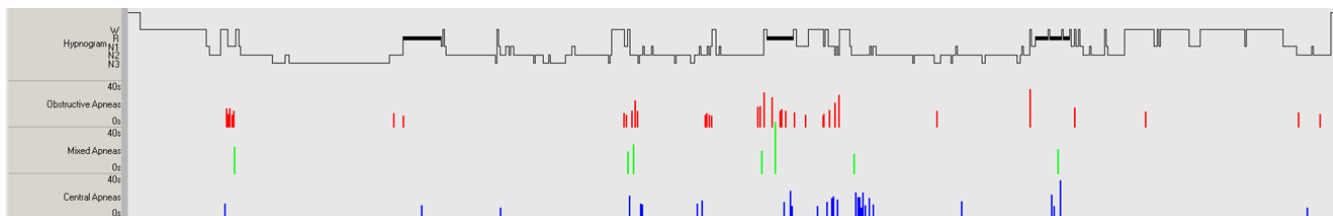


Figure 111: Obstructive Apneas, Mixed Apneas, Central Apneas

Hypopneas and RERAs

The hypopnea and the RERA traces indicate position and duration of hypopneas and RERAs by one line per event in pink (Hypopnea) or violet (RERA), respectively. The length of the line indicates the duration of the event scaled between 0 and 40 s.



Figure 112: Hypopneas and RERAs

Oxygen Saturation (Desaturations, Resp. Events, Mean Oxygen)

The desaturation trace (Desaturations) indicates position and duration of desaturations by one line per event in bluish-green. The length of the line indicates the duration of the event scaled between 0 and 40 s.

The respiratory events trace (Resp. Events) below the desaturation trace displays a violet dot for each respiratory event (apnea or hypopnea) to visualize associations between them. Unassociated events require more careful inspection.

The oxygen saturation trace (Mean Oxygen) displays the mean values per 30-s epoch, scaled between 80 and 100%.

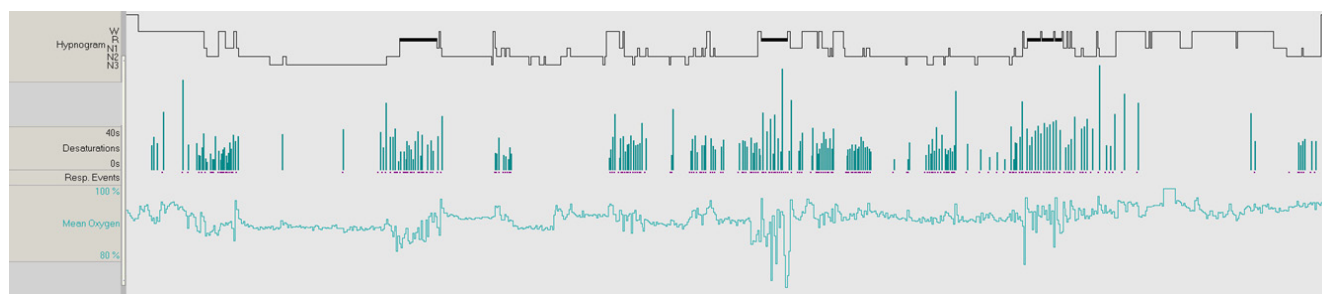


Figure 113: Desaturations, Resp. Events, Mean Oxygen

Quality of respiratory channels (Quality AFLO, PFLO, CFLO, CHMV, ABMV)

Quality traces are displayed for the oronasal thermal sensor signal (Quality AFLO), the nasal air pressure transducer signal (Quality PFLO), the CPAP flow signal (Quality CFLO), the respiratory effort signal from the chest/thorax (Quality CHMV) and the respiratory effort signal from the abdomen (Quality ABMV). The information for each channel is twofold:

- The thin line displays an estimation of the signal quality of the respective sensor from 0% to 100%, with 100% indicating best signal quality.
- The gray bar (at the bottom of the quality trace) indicates that the respective sensor was considered as valid and thus was used in the Somnolyzer analysis. Whenever a sensor was considered as invalid the alternative sensor (if valid) is used by Somnolyzer according to the notes of AASM Manual (2007) rule VIII.1.

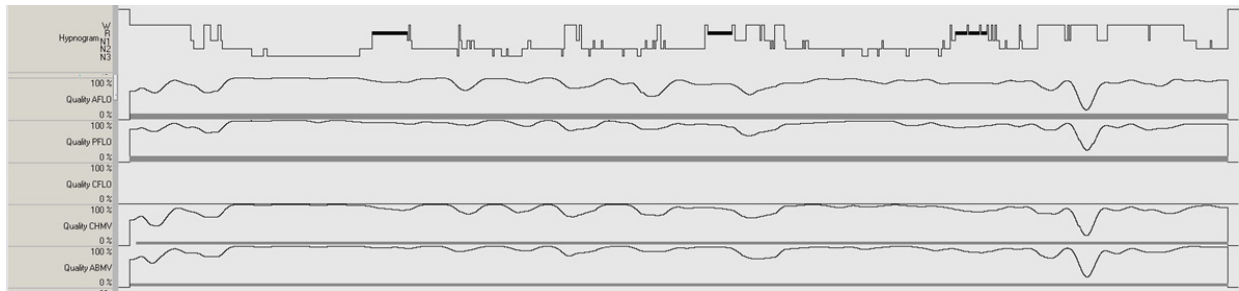


Figure 114: Quality AFLO (oronasal thermal sensor), Quality PFLO (nasal air pressure transducer), Quality CFLO (Flow therapy device), Quality CHMV (chest/thorax movement); Quality ABMV (abdominal movement)

Limb movements

The limb movement trace indicates position and duration of all leg movements by one line per event scaled from 0 to 11s. Leg movements that are part of PLM sequences are plotted in black, all other leg movements are plotted in gray.

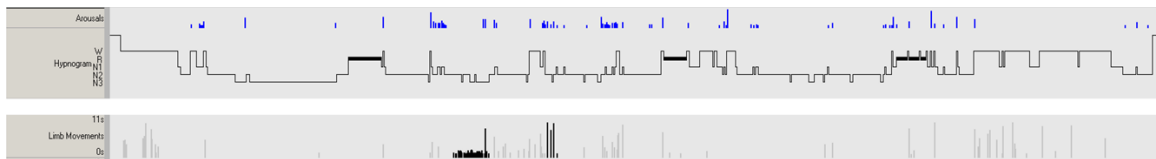


Figure 115: Limb Movements

6.4 The Expert Review Procedure

The Expert Review (ER) is a structured step by step review procedure with the goal to ensure that the actual PSG measurement was done correctly and that Somnolyzer 24x7 has not misclassified any clinically relevant variable. By following the steps described below trained Expert Reviewers can shift their attention from single epochs to an all-night overview (staging) and from single events to the quality control of the recorded data (events). This results in valid (unbiased) and reliable (highly reproducible) results for both staging and events with minimal effort. ER is performed in two well defined phases which include 2 steps each:

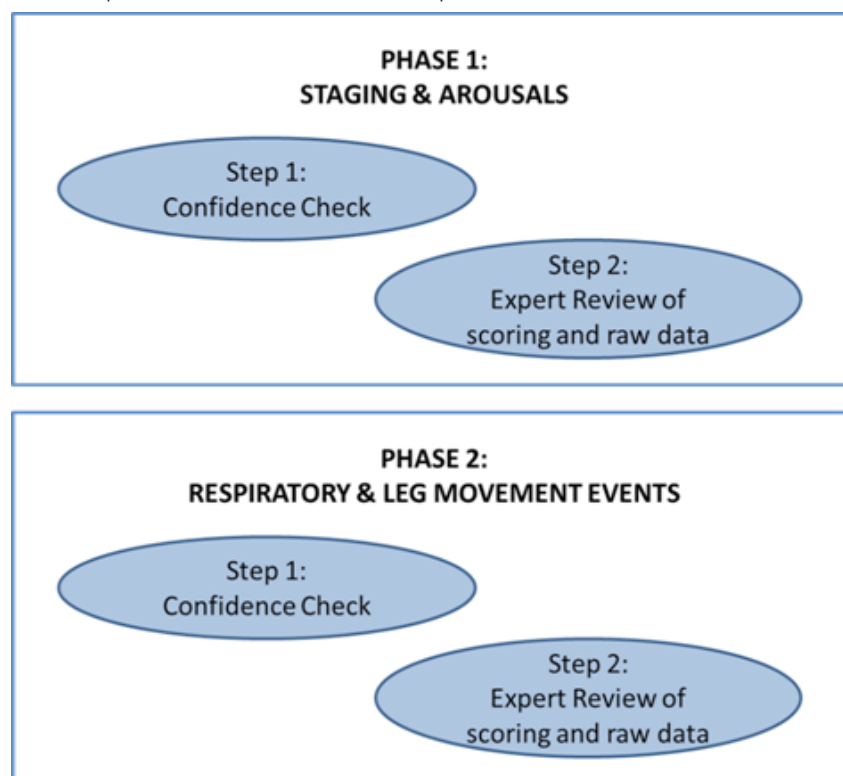


Figure 116: Overview of the Expert Review Procedure

6.4.1 Phase 1: Staging & Arousals

Step 1: Confidence Check

Step 1 is based on the overview display of the PFTs relevant for staging & arousals. This step focuses on identifying periods with poor signal quality, such as

- incorrectly referenced signals
- failing electrodes
- artifacts persistently distorting the signals
- extremely atypical patterns, far away from the norm.

The aim of Step 1 is the identification of sections that require either high or medium or only low levels of attention during Step 2 “**Expert Review of scoring and raw data.**” Note that the different attention levels will set the pace for scrolling through the raw data in Step 2.

In Table 6: Manifestation of major sleep/wake related features in the different sleep stages the feature combination typically seen in the different sleep stages are summarized. Figure 112 gives a typical example highlighting one for each sleep stage.

Table 6: Manifestation of major sleep/wake related features in the different sleep stages

Stage	Spindles	Alpha/Theta	Delta	EMG	REM	SEM
W	-	+++	Spikes	+++	++(+)	+++
N1	-	(+)	-	+(+)	-	+++
N2	+++	-	+	+	-	(+)
N3	++	-	+++	-	-	-
R	-	+	-	-	+++	+++

‘+’, ‘++’ and ‘+++’ mark low, medium and large presence of the respective feature, ‘-’ marks absence or very low presence. Thus, combinations of features are used to decide upon the validity of the respective stage decisions (on the level of prolonged phases, not single epochs).

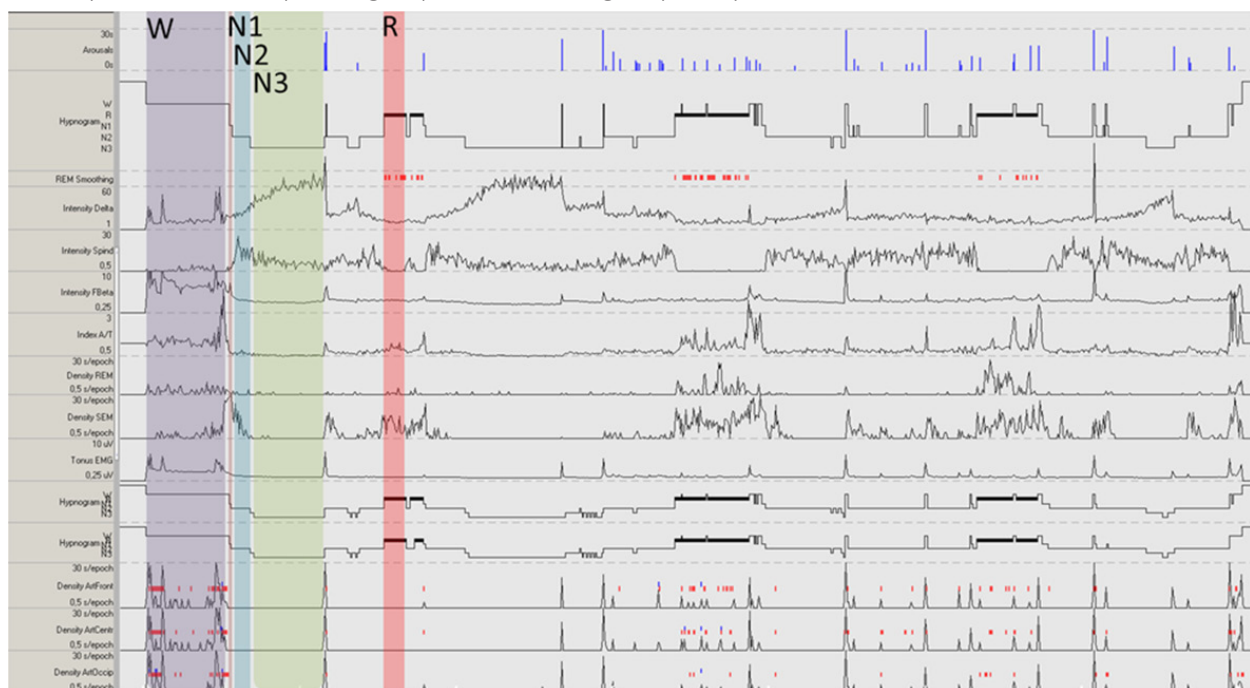


Figure 117: Typical feature combinations in the different sleep stages

Table 7 gives a step by step procedure for identifying the periods that require different levels of attention, in descending order of relevance. In Figure 118, the different levels of attention are highlighted for a typical study.

Table 7: Identification of the “level of attention” for scoring sleep stages

Level of Attention	Description	Example (Figures in Section 6.5)
High	Sleep onset	Figure 127 - Figure 137
	Start and end of the first REM period Suspected first REM Sleep onset REM (as well as suspected sleep onset REM)	Figure 127 - Figure 137 Figure 128 Figure 132, Figure 136
	Periods with different REM phases in the two interim hypnograms	Figure 133 Figure 134, Figure 137
	Periods with apparently inconsistent combination of features (for consistent feature combinations per sleep stage see Table 5)	Figure 131 Figure 135, Figure 137
Medium	Wake before sleep onset	Figure 127 - Figure 137
	REM periods with questionable NREM intrusions or adjacent periods of N1 Apparently missing REM periods with a feature combination that allows for REM	Figure 131 Figure 137
	Extended periods with frequent shifts between sleep and wake	Figure 133
	Extended periods with high artifacts densities	Figure 133
	Epochs marked as removed stage R in the REM Smoothing trace	Figure 134
Low	Periods with apparently consistent combination of features (see Table 3 for the typical feature combination per sleep stage)	Figure 127 - Figure 137



Figure 118: Different levels of attention for ER of staging and arousals. Sections that require high attention (i.e. slow scrolling in Step 2) are indicated in red, sections that require medium attention (i.e. medium scrolling in Step 2) are indicated in yellow, and sections that require low attention (i.e. fast scrolling in Step 2) are indicated in green.

Keeping this information in mind, the skilled Expert Reviewer will be able to adopt the scrolling speed during Step 2 to minimize the time necessary for ER on the one hand and to guarantee valid results for each individual study on the other hand.

A more detailed description and many more examples for Phase 1 “Staging & Arousals” - Step 1 “Confidence Check” are given in section 6.5 of this manual.

Step 2: Expert Review of scoring and raw data

Based on the segmentation of the study in sections that require different levels of attention, ER of staging and arousals can now be performed optimally, with the scrolling speed adapted to the different confidence levels.

For sections that require **high level** of attention:

Review the scoring epoch-by-epoch (i.e. slow scrolling speed) and change incorrectly assigned sleep stages accordingly. Note that if an epoch is changed, it might be necessary to add or delete arousals in this epoch. Arousals might have to be added if an epoch is changed from W to sleep or from REM to NREM (since in NREM no concurrent increase in submental EMG is required). On the other hand, if an epoch is changed to REM all arousals not associated with an increase in EMG have to be deleted.

For sections that require **medium level** of attention:

Review the scoring with a faster scrolling speed and slow down to an epoch-by-epoch review if appropriate. As long as the stage in a given epoch is not changed and as long as the signal quality is reliable, there is no need for changing arousal scoring.

For sections that require **low level** of attention:

Review the scoring with fast scrolling speed and stop only if signals are not reliable or show anomalies. Typically neither staging nor arousals have to be changed in these sections.

In summary, it is recommended to review the whole study from lights-out to lights-on. While the majority of the study may be reviewed with fast scrolling speed, short yet significant portions of the study require epoch-by-epoch reviewing.

Note: The sensitivity of arousal scoring is configurable in Somnolyzer 24x7 and thus may be adapted to different interpretations. In case your interpretation varies systematically from the default Somnolyzer interpretation please contact Philips Respironics for a configuration request (North America: somnolyzer.us@philips.com; rest of the world: somnolyzer.int@philips.com).

6.4.2 Phase 2: Respiratory & Leg Movement Events

Step 1: Confidence Check

ER of respiratory and leg movement events is mainly focusing on signal quality control. If the signals are within a normal range and considered as valid by Somnolyzer, the scoring criteria are perfectly implemented. “Second-guessing” an event is only necessary when the signal quality is diminished or the signal shows major anomalies or is not considered as valid.

Step 1 is based on the overview display of the PFTs relevant for respiratory and leg movement events. This step focuses on identifying periods with poor signal quality, such as

- failing sensors
- artifacts persistently distorting the signals
- extremely atypical patterns, far away from the norm.

The aim of Step 1 is the identification of sections that require either high or medium or only low levels of attention during Step 2 “Expert Review of scoring and raw data”. Note that the different attention levels will set the pace for scrolling through the raw data in Step 2.

Table 8 gives a step by step procedure for identifying the periods that require different levels of attention, in descending order of relevance. In Figure 119, the different levels of attention are highlighted for a typical study.

Note that leg EMG signal quality has to be checked in studies with no detected leg movement events altogether or with perpetual leg movement events for long periods.

Table 8: Identification of the “level of attention” for scoring respiratory events

Level of Attention	Description
High	No valid respiratory and oxygen signals (not explained by unplugged sensors)
	No valid flow signals in sections with desaturations
	No valid effort signals in sections with detected apneas (Somnolyzer assigns all apneas as obstructive if no valid effort channel is available)
	Sections with desaturations, but without respiratory events
Medium	No valid signal in the recommended sensor
	Sections with respiratory events not leading to desaturations
	Valid flow signal but rather low signal quality
	Only one valid effort signal or only effort signals with rather low quality in sections with detected apneas
Low	Periods with apparently consistent associations between respiratory events and desaturation events
	Periods with no respiratory events and constantly high “mean oxygen saturation” values

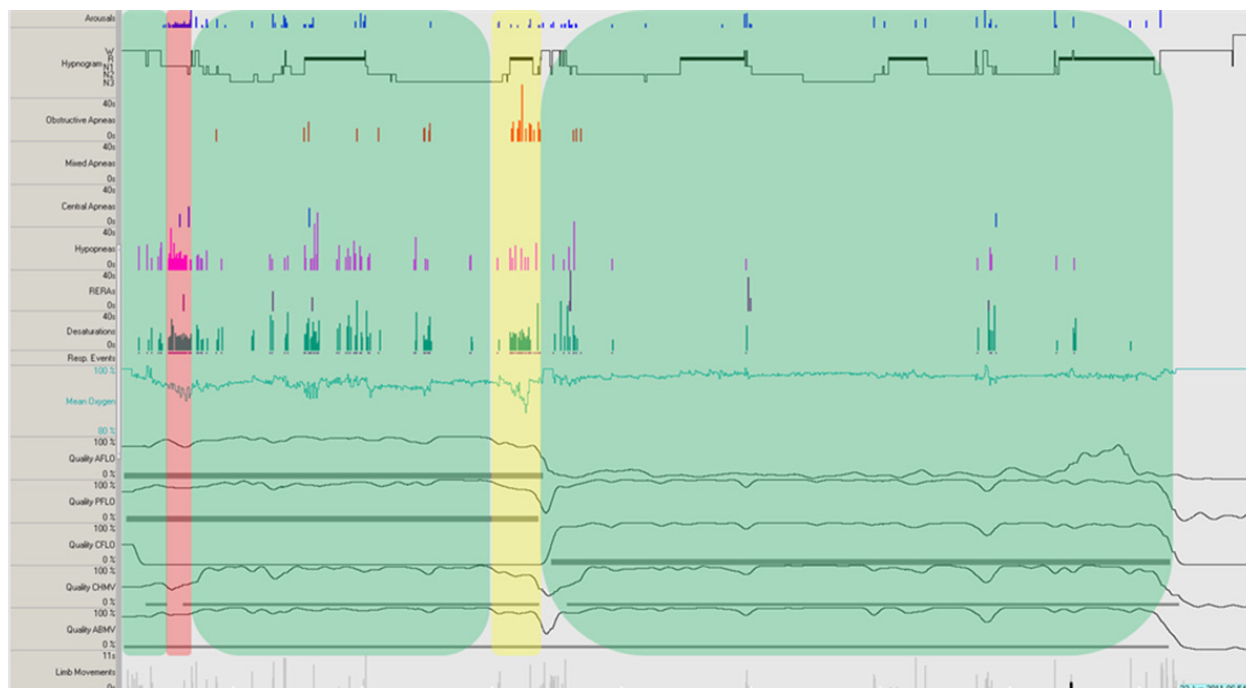


Figure 119: Different levels of attention for ER of respiratory events. Sections that require high attention (i.e. slow scrolling in Step 2) are indicated in red (in this example this concerns specifically the assignment of the central apneas), sections that require medium attention (i.e. medium scrolling in Step 2) are indicated in yellow (in this example due to reduced signal quality in both airflow channels), and sections that require low attention (i.e. fast scrolling in Step 2) are indicated in green.

Keeping this information in mind, the skilled Expert Reviewer will be able to adapt the scrolling speed during Step 2 to minimize the time necessary for ER on the one hand and to guarantee valid results for each individual study on the other hand.

A more detailed description and many more examples for Phase 2 “Respiratory & Leg Movement Events” - Step 1 “Confidence Check” are given in section 6 of this manual.

Step 2: Expert Review of scoring and raw data

Based on the segmentation of the study in sections that require different levels of attention, ER of staging and arousals can now be performed optimally, with the scrolling speed adapted to the different confidence levels.

For sections that require **high level** of attention:

Review the scoring in 5-min windows page-by-page (i.e. slow scrolling speed) and change incorrectly assigned events accordingly.

For sections that require **medium level** of attention:

Review the scoring in 5-min windows with a faster scrolling speed and slow down to a page-by-page review if appropriate.

For sections that require **low level** of attention:

Review the scoring in 5-min windows with fast scrolling speed and stop only if signals are not reliable or show anomalies. Typically no events have to be changed in these sections.

It is recommended in the AASM scoring manual to switch to an alternative respiratory channel when the signal from the recommended sensor is not reliable (see AASM Manual, 2007, rule VIII.1 including the notes). Thus, whenever a recommended sensor is considered as valid by Somnolyzer 24x7 (indicated in the PFTs) this sensor is used for event detection. If, however, the signal of a recommended sensor is considered as invalid and the signal of an alternative sensor is considered as valid, the alternative sensor is used for event detection. If no valid airflow sensor is available, Somnolyzer will not detect respiratory events for this period. If no valid respiratory effort channel is available, all apneas will be assigned as obstructive events.

To perform this step, the viewer software use for scoring should depict all relevant respiratory and EMG channels together with the respective events in 5-minute windows. This allows scrolling through the raw data and watching for signal anomalies in the respective channels (i.e. oronasal thermal sensor for apnea events, pressure transducer for hypopneas/RERAs, respiratory effort signals for apnea sub-classification, leg EMG for leg movements). As long as the signals are within normal ranges and free of major artifacts you can highly trust the marking of events. Thus, this step should normally be finished within a few minutes. Note that even if some signals are problematic, the events marked by Somnolyzer 24x7 are very likely the best possible guess.

In summary, it is recommended to review the whole study from lights-out to lights-on. While the majority of the study may be reviewed with fast scrolling speed, short yet possible significant portions of the study may require thorough reviewing.

Note: Somnolyzer 24x7 is configurable for different respiratory scoring rules. By default AASM Manual, 2007, rule VIII.4.A or B is applied for scoring hypopneas. Other scoring criteria are available on request. Concerning leg movements that occur concurrently with respiratory events, Somnolyzer 24x7 uses the recommended time window of 0.5 s (Note 1 in AASM Manual, 2007, rule VII.1). Other time windows are available on request. Please contact Philips Respironics for a configuration request (North America: somnolyzer.us@philips.com; rest of the world: somnolyzer.int@philips.com).

6.5 Description and Examples for Phase 1 “Staging & Arousals” - Step 1 “Confidence Check”

As mentioned in section 6.4, Somnolyzer 24x7 can occasionally be misled by features that are not clearly expressed in the signals. The most critical sleep variables that can be arbitrarily influenced by even a slight misclassification are sleep latency and REM latency. Therefore the epoch-by-epoch review of sleep onset, first REM and discontinuities in REM phases are recommended - independent of plausibility and confidence level:

Sleep Onset – Inspect and verify the staging, epoch by epoch, around sleep onset, i.e. a few minutes before and after sleep onset as currently scored by Somnolyzer 24x7, while the period from lights-out until confirmed sleep onset may be reviewed at faster pace.

First REM – Inspect and verify the staging, epoch by epoch, of the first REM period scored by Somnolyzer 24x7, or (in case of an apparent REM latency larger than the first sleep cycle) the period where one would expect the first REM period to occur.

REM Discontinuity – Inspect and verify the staging, epoch by epoch, of longer stretches of NREM or wake intrusions in REM phases specifically if they are not clearly supported by the PFTs.

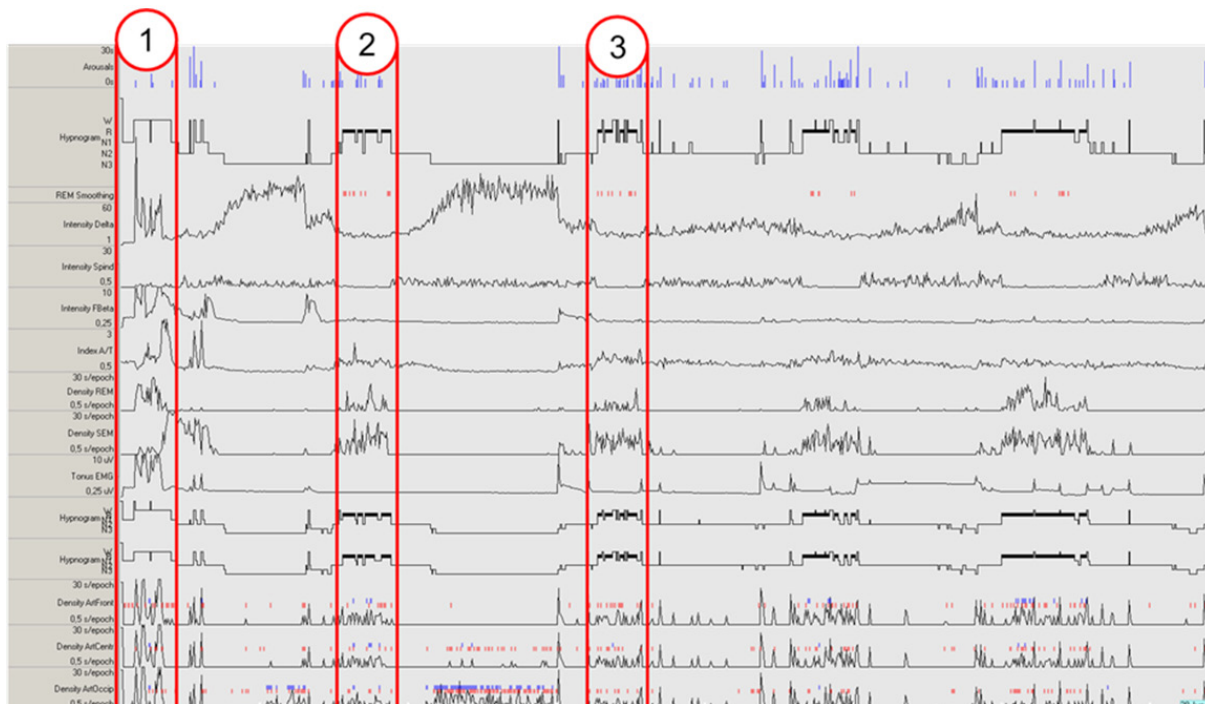


Figure 120: Three segments for which an epoch-by-epoch review is recommended: Sleep onset (1), first REM period (2), stretches of REM discontinuity (3)

Following the procedure recommended for step 2, it is not necessary to inspect other parts of the staging epoch-by-epoch. Doing so is left to the scorer's discretion. Remember, a high percentage (up to 25%) of any stage decision (be it from Somnolyzer 24x7 or any other skilled scorer) is likely to differ from a particular scorer's opinion while still being a fully valid decision. Changing such epochs will not change the clinical validity of the scoring, but instead is likely to increase their variability and thus decrease their reproducibility.

Validity of sleep/wake discrimination

- High values in the Index A/T trace and/or high SEM/REM density together with high EMG tone and absence of spindles speak for stage W. If W is scored in the absence of this feature combination, these epochs require increased attention (see examples in Figure 130 and Figure 131).
- Sleep onset always needs to be checked. Note that typically sleep onset occurs when no further spikes are seen in the delta intensity trace (i.e. no more movement artifacts), not yet clear spindle activity is seen in the spindle intensity trace, a decrease in fast beta activity is seen in the Intensity FBeta trace, there is a drop in the alpha/theta index as well as density REM and EMG tonus, while the SEM density has a local maximum.

Validity of REM/NREM discrimination

- Low EMG tone together with elevated REM (and SEM) density and low spindle and delta intensity speak for stage R. If R is scored in the absence of this feature combination, these epochs require increased attention.
- If a REM phase is apparently missing and the feature combination allows for REM, these epochs require increased attention (see Figure 128 and Figure 129).
- If there are differences in the REM phases between the two interim hypnograms (e.g. one hypnogram shows a REM period and the other does not), then these epochs need to be checked (see Figure 133 and Figure 134).
- If there is a long period of stage N1 this needs to be checked as to whether a REM period was missed, especially when the alpha/theta index is medium even if some SEM activity is present.
- The first REM period, or a suspected first REM period always need to be checked.
- Sleep onset REM, or a suspected sleep onset REM always need to be checked.
- Epochs marked by a blue line in the Smoothing REM trace need to be checked for a possibly missed REM period (see examples in Figure 132 and Figure 134).

Validity of Stage N2

- High spindle intensity, low alpha theta index, no REMs, medium delta intensity speaks for N2. If N2 is scored in the absence of this feature combination, these epochs have to be checked (see Figure 134: Polysomnographic Feature Trends (PFTs): Uncommon sleep characteristics.³⁴).

Validity of N3

- High delta intensity, low alpha theta index, no REMs, medium spindle intensity and low EMG tone speak for N3. If N3 is scored in the absence of this feature combination, these epochs have to be checked.

A practical example

The first example demonstrates the results from Somnolyzer 24x7 staging, as one normally obtains if the PSG recording is compliant with all required standards and the signals are of sufficient quality without major artifacts or anomalies. This example is used to explain again all phases and steps of the expert review.

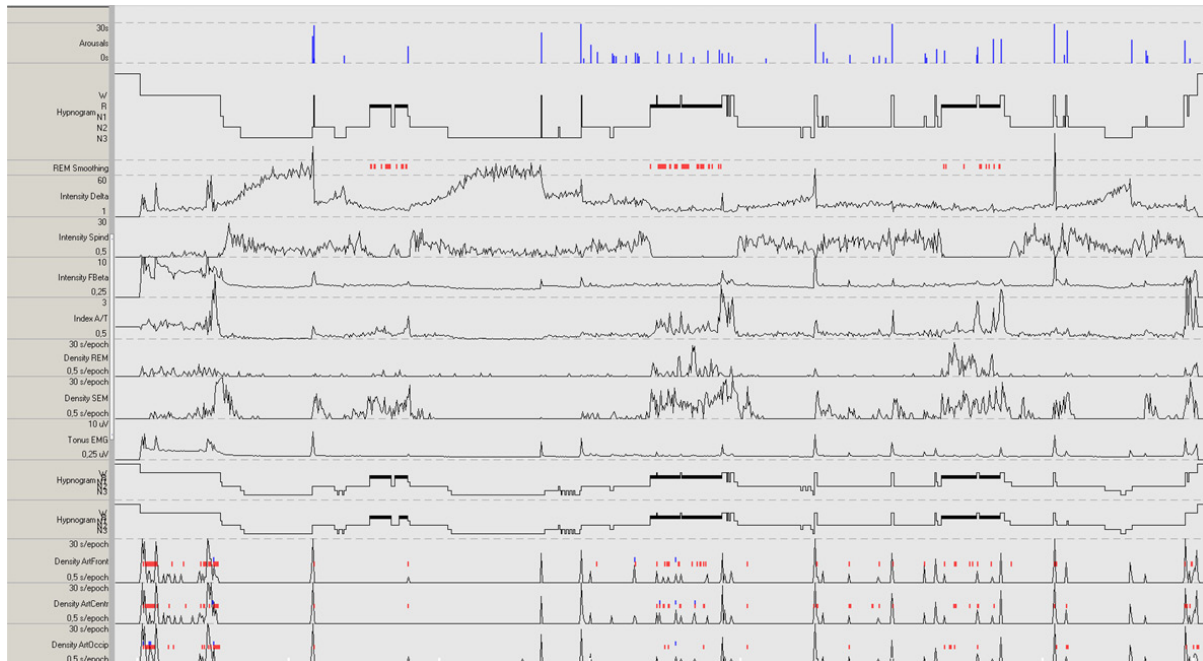


Figure 121: Polysomnographic Feature Trends (PFTs) for Staging & Arousals

The hypnogram looks reasonable and plausible.

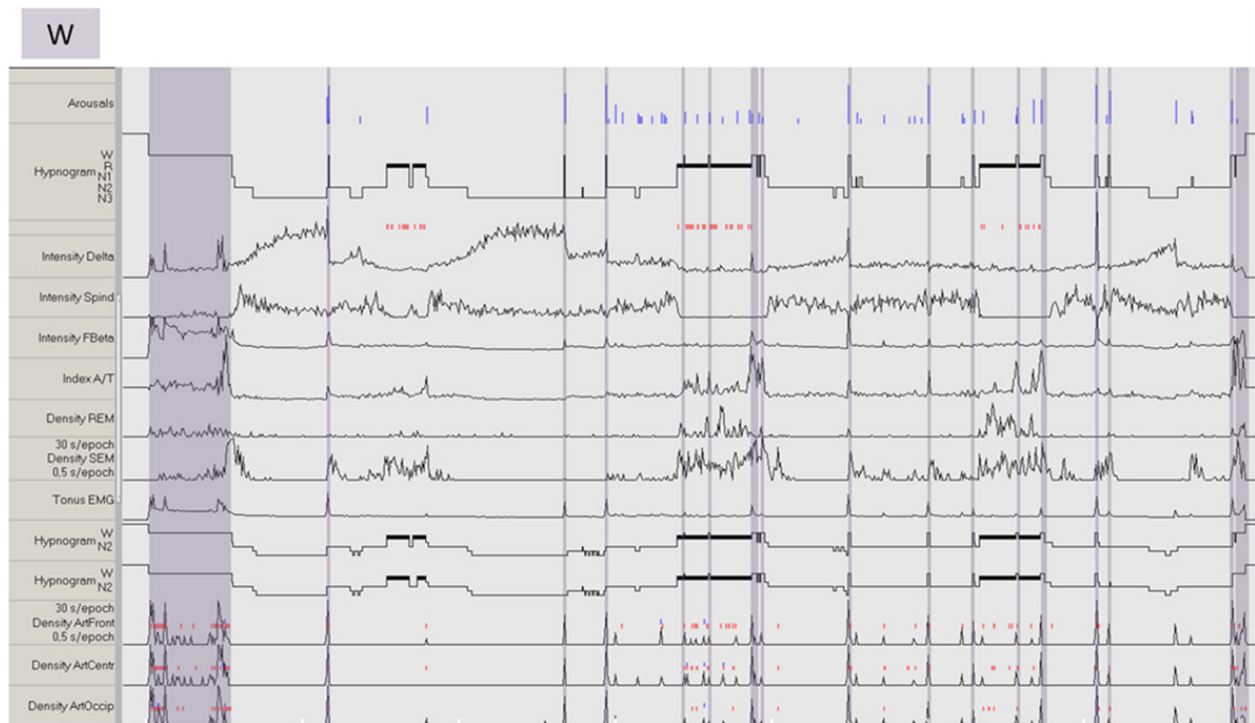


Figure 122: Polysomnographic Feature Trends (PFTs) for Staging & Arousals: Stage W

There is a major wake period between lights-out and sleep onset. This wake period is nicely supported by the traces of the PFTs:

- Both fast-beta intensity and alpha/theta index are elevated
- There is no delta intensity (with the exception of small peaks that result from signal artifacts common in wake) and no significant spindle intensity
- Some rapid and slow eye movements occur, with the latter increasing toward sleep onset
- The number of artifacts is relatively high, due to movements

The other (short) awakenings are all accompanied by peaks in alpha/theta index and/or fast-beta. Although the epoch-by-epoch check of sleep onset is highly recommended in any case, it is unlikely that any epoch needs to be changed, specifically since there is a concomitant sharp drop of the fast-beta intensity and the alpha/theta index associated with a sharp increase of slow eye movements and the end of rapid eye movements.

N1

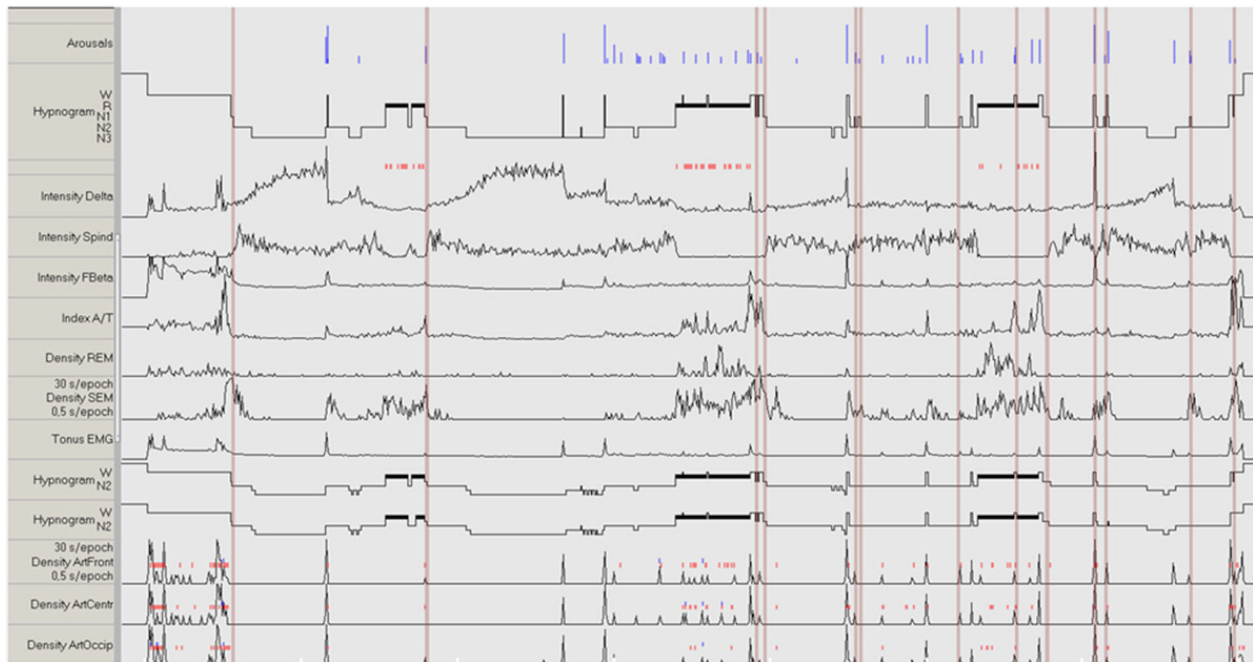


Figure 123: Polysomnographic Feature Trends (PFTs) for Staging & Arousal: Stage N1

The very short period of N1 following sleep onset is supported by

- A fast drop in both alpha/theta index and fast-beta intensity
- The termination of rapid eye movements
- No significant amount of delta and spindle intensity

There is no other major period of N1 that would need questioning in terms of whether a misclassification between N1 on the one hand and W or R at the other hand could alter the overall sleep architecture.

N2

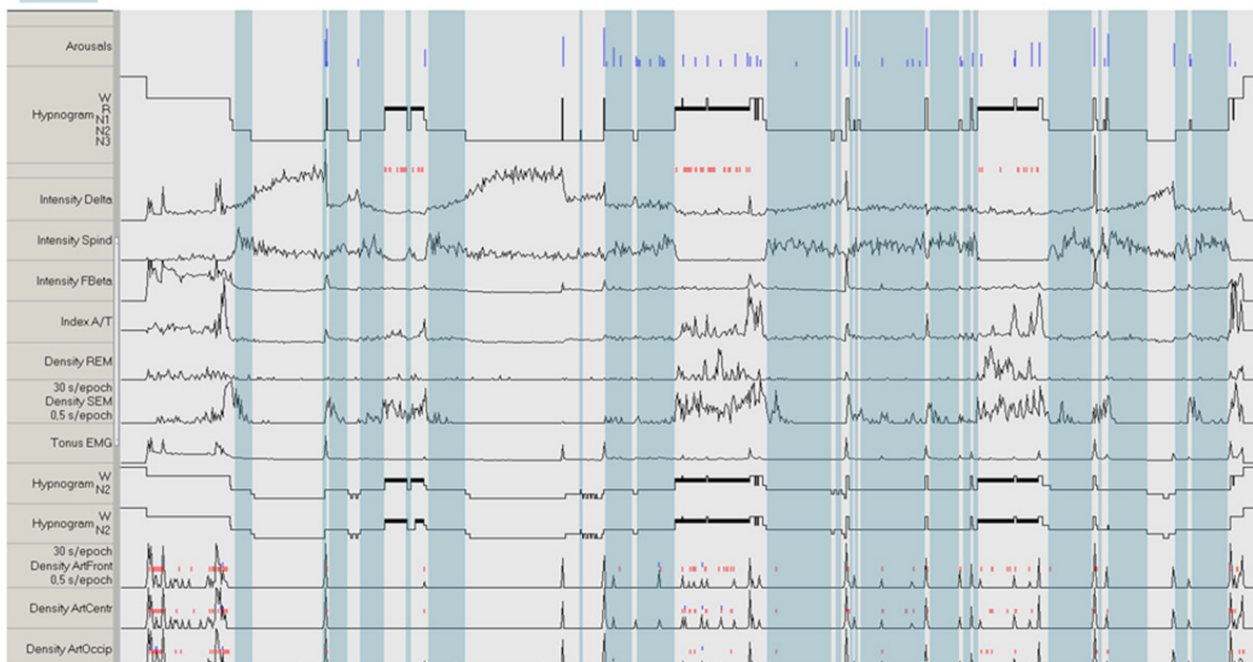


Figure 124: Polysomnographic Feature Trends (PFTs) for Staging & Arousal: Stage N2

The major periods of N2 sleep are all characterized by

- An elevated spindle intensity
- A rising or intermediate level of delta intensity (except when N3 is interspersed)
- Low values of alpha/theta index and fast-beta (except at short awakenings)
- The absence of rapid eye movements

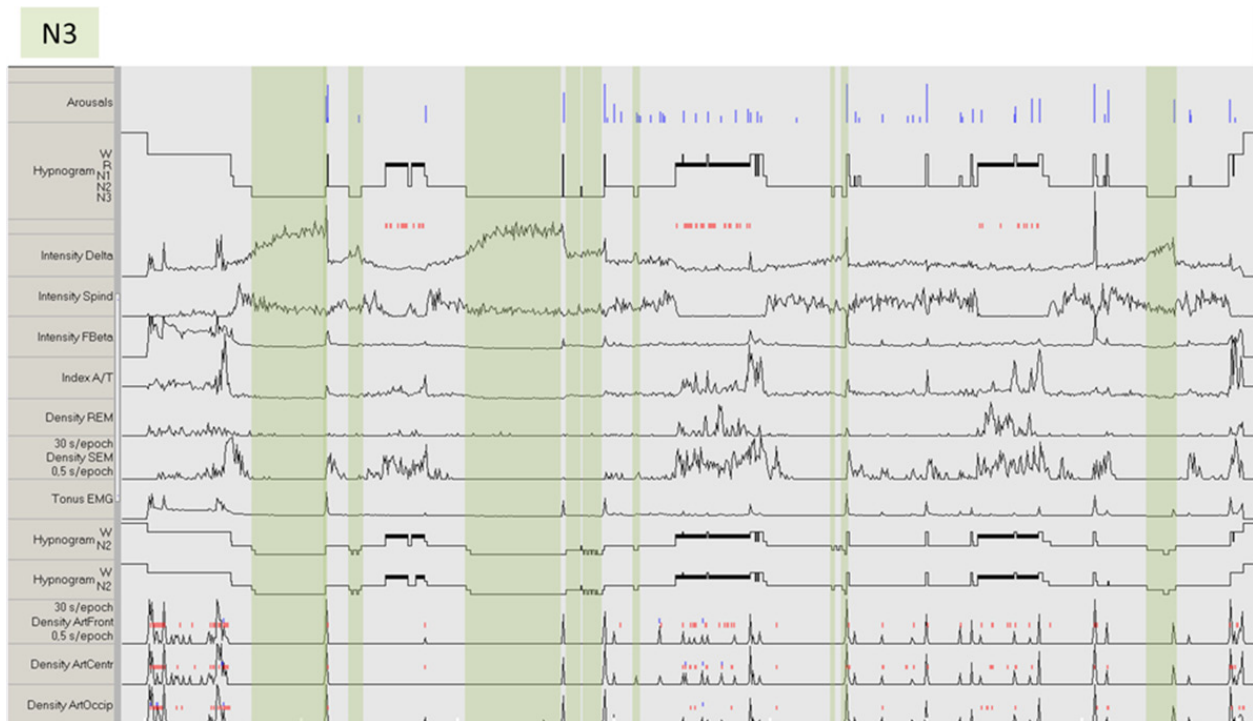


Figure 125: Polysomnographic Feature Trends (PFTs) for Staging & Arousals: Stage N3

Two major and one short period of N3 are nicely supported by

- Elevated levels of delta intensity
- Reduced levels of spindle intensity (as compared to N2). Note the concurrent increase of delta intensity and decrease of spindle intensity in all three N3 periods
- Very low levels of the alpha/theta index
- The absence of both rapid and slow eye movements

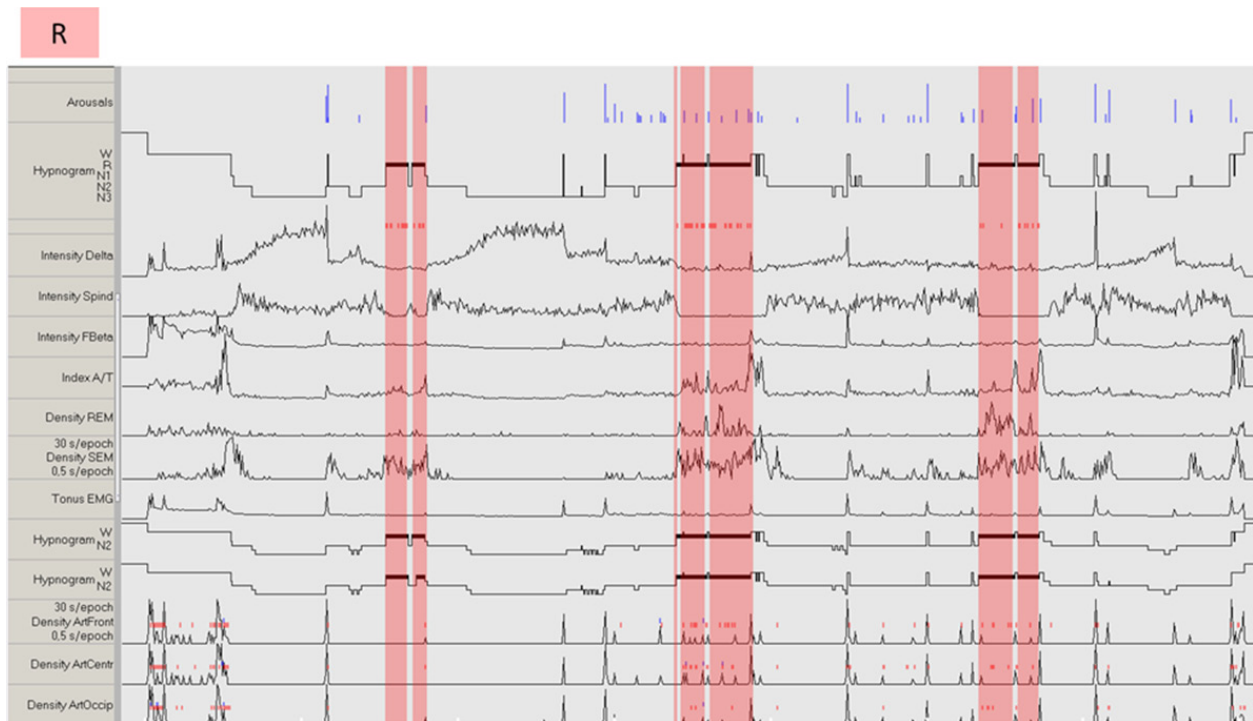


Figure 126: Polysomnographic Feature Trends (PFTs) for Staging & Arousals: Stage R

The three major periods of R are supported by

- Elevated levels of rapid and slow eye movements (note that only the first period of R seems to be an exception with respect to REMs, which is, however, a phenomenon frequently seen in the first period of R)
- Very low (to none) spindle intensity (with the exception of the N2 intrusion in the first R period)
- Elevated levels of alpha/theta index (which, however, is lower than during W)
- The absence of chin EMG activity (although the differences in EMG tone are not very pronounced here)

Furthermore, both interim hypnograms (with and without EMG) are perfectly consistent with each other. Thus, the REM-related features are unambiguously seen in EOG, EEG and chin EMG signals. Although checking the first R period epoch-by-epoch is highly recommended, it is unlikely that any epochs will need to be changed with respect to R.

There is no further anomaly or unusual event visible in the PFTs. Artifacts (with the exception of the first W period) are rare and at usual unavoidable levels. Only in few cases the alternative EEG channels has been used (red dots in the Density Art traces) and no major period with sweating that would have need the usage of the high pass filter occurred (blue dots in the Density Art traces).

Validity of major sleep variables

Step 1 has identified few segments that warrant further high attention (i.e. epoch-by-epoch inspection). These segments correspond to sleep onset and the first R period:

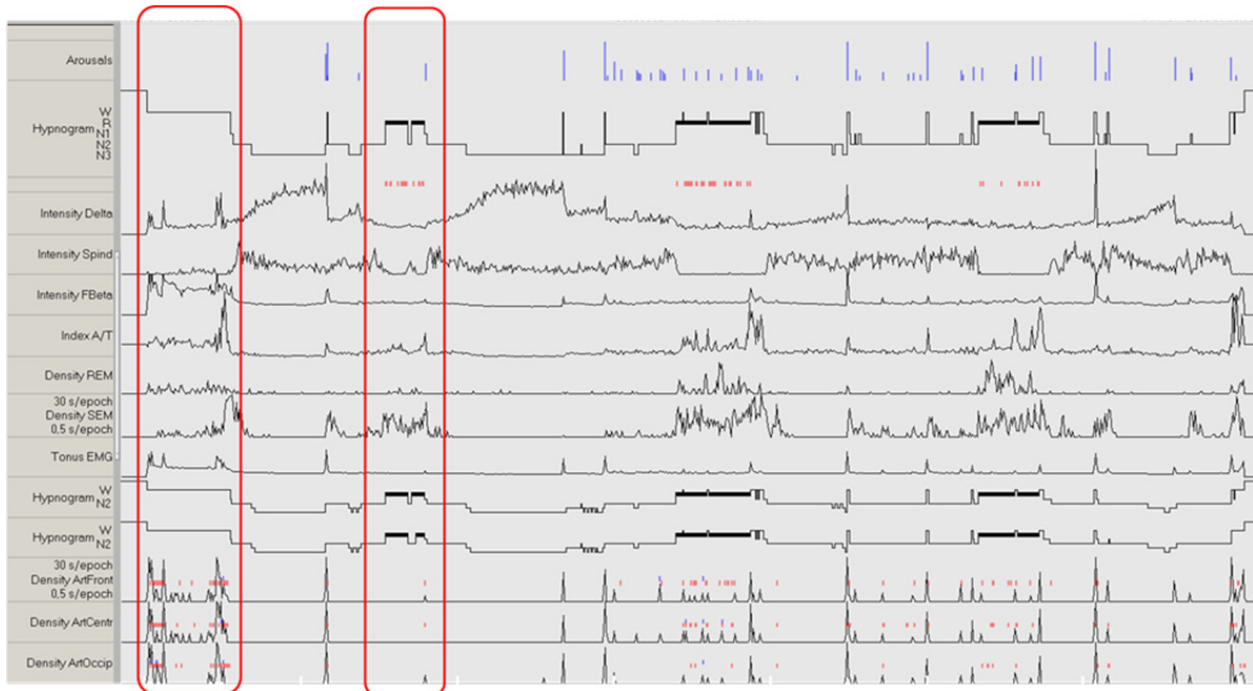


Figure 127: Polysomnographic Feature Trends (PFTs) for Staging & Arousals: Sleep onset & first REM period

A fairly quick walk-through with a slowdown at onset of N1 and R, respectively, will do.

The “Smoothing REM” trace indicates the application of R smoothing. All R periods, including their small interruptions, are supported by all other traces so well and no long REM smoothing period occurred. Thus further epoch-by-epoch review of the REM periods is not needed.

We conclude that ER of staging & arousals (step 2), following the procedure described in this manual, will not exceed 2-3 minutes in this case.

6.5.1 An Example of a First R Period Missed

In this example we note that the first period R occurs relatively late:

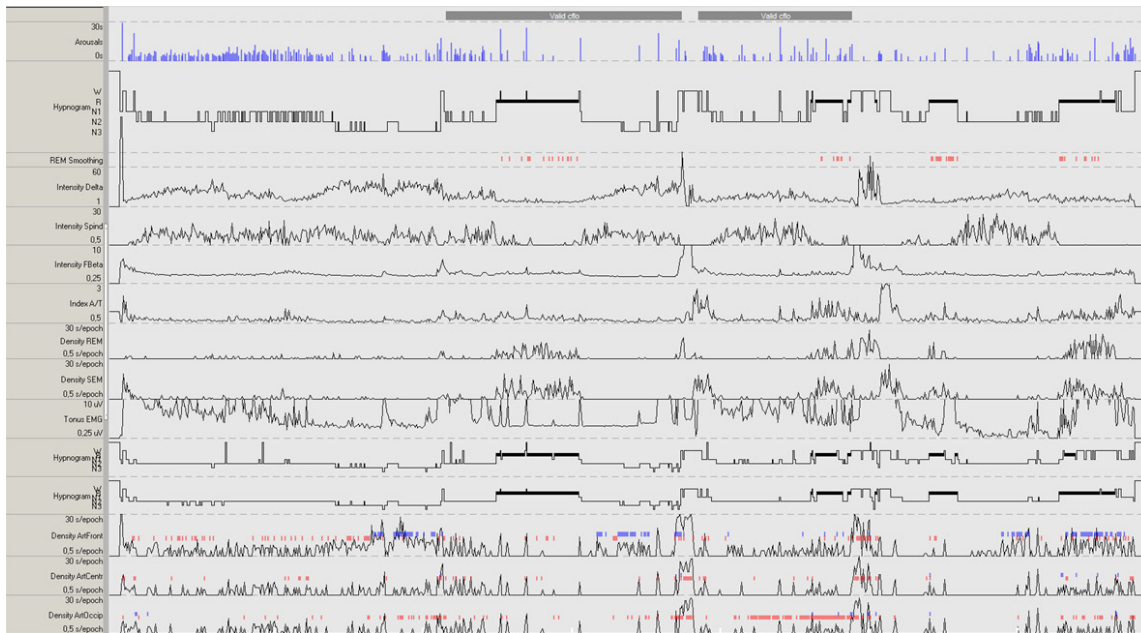


Figure 128: Polysomnographic Feature Trends (PFTs): First REM period?

“Checking the first R period” includes checking of whether it might have been missed due to too weak impressions of its major features.

R typically occurs only at periods where

- Spindle intensity and delta intensity are low
- Some eye movements occur (however, note that a single rapid eye movement might be sufficient to indicate R)
- Alpha/theta index is somewhat elevated, but typically lower than in W
- EMG tone is low

In this case, the only period that fulfills these criteria is the one marked below:

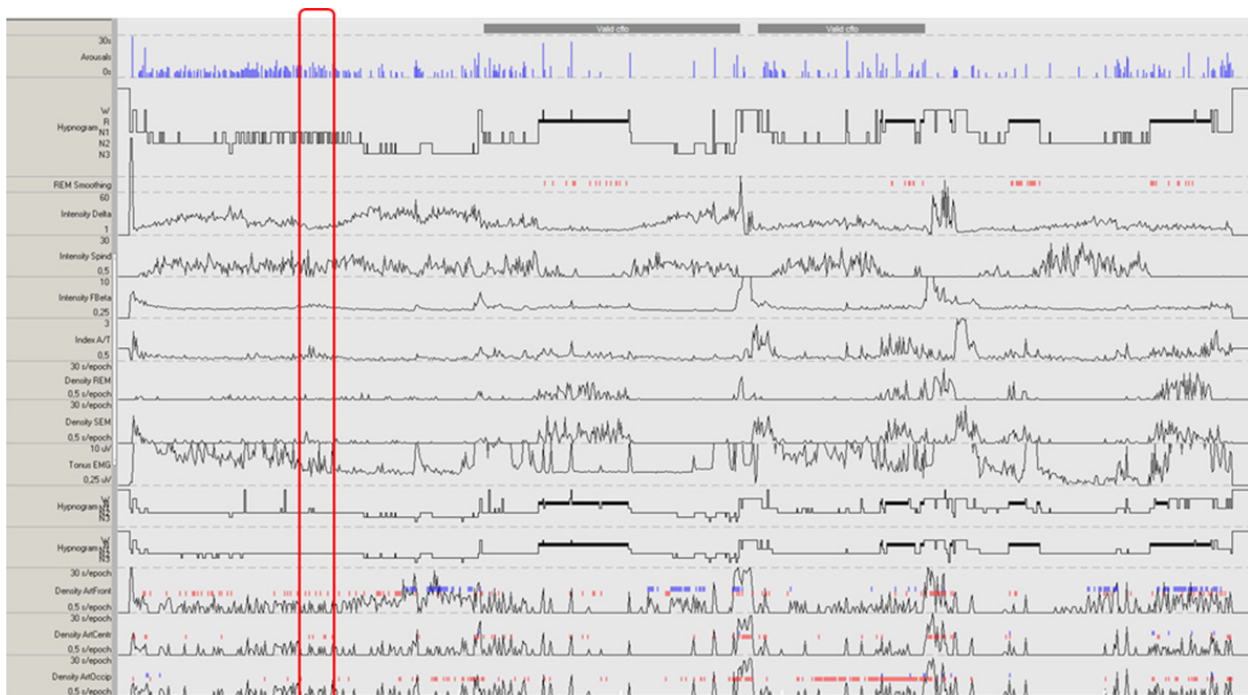


Figure 129: Polysomnographic Feature Trends (PFTs): First REM period

Note that, specifically in the first REM period, both spindles and K-complexes may be interspersed in stage R. The spindle and delta intensity traces, however, will usually show a minimum in such periods, as can be seen in the previous figure.

Epoch-by-epoch inspection of the marked period reveals that indeed it should be scored as R. Incidentally, the final R period would also warrant an epoch-by-epoch review given the inconsistency between the two interim hypnograms.

6.5.2 An Example of a Problematic Sleep Onset

The following PFTs reveal in Step 1 that staging around sleep onset (marked area) seems unusually fragmented.

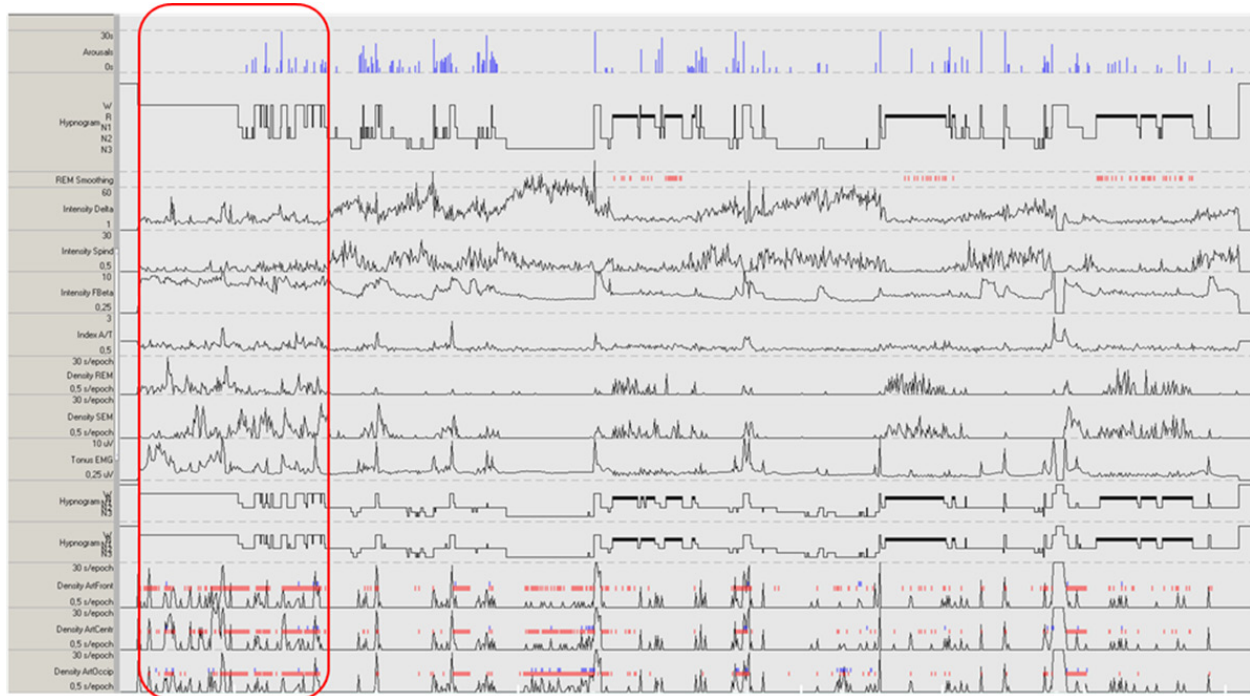


Figure 130: Polysomnographic Feature Trends (PFTs): Instable sleep onset

Step 1 confirms that while wakefulness during that period is supported by the PFTs, the many shifts between sleep and wake in the second part of the marked period do not seem to corroborate this. This underlines the importance of an epoch-by-epoch check of sleep onset, which in this case extends to the entire marked period.

6.5.3 An Example of Too Short Awakening Periods

The following PFTs reveal that the short awakenings in the marked areas could indeed be more pronounced, given the clear peaks in alpha/theta index.

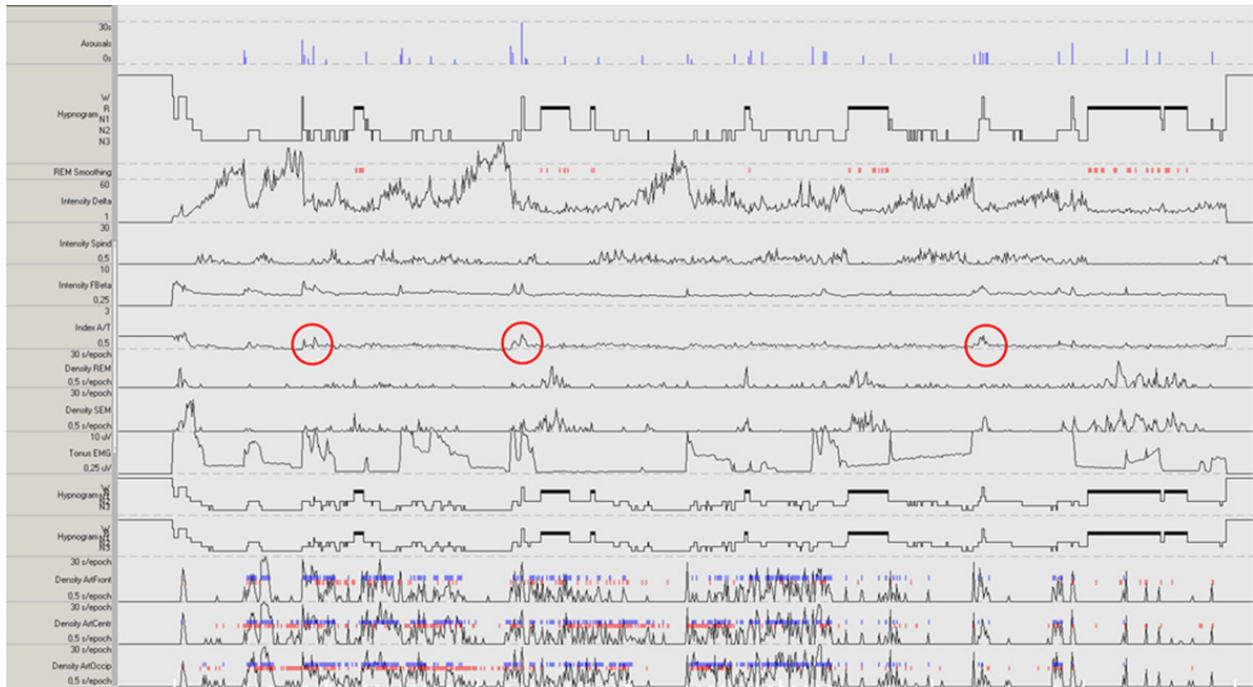


Figure 131: Polysomnographic Feature Trends (PFTs): Too short awakening periods?

Thus, in addition to sleep onset, these marked periods with elevated alpha/theta index should be subjected to an epoch-by-epoch review, as well.

6.5.4 An Example of Erroneous Sleep Onset REM

The following PFTs show a probable invalid sleep onset REM:

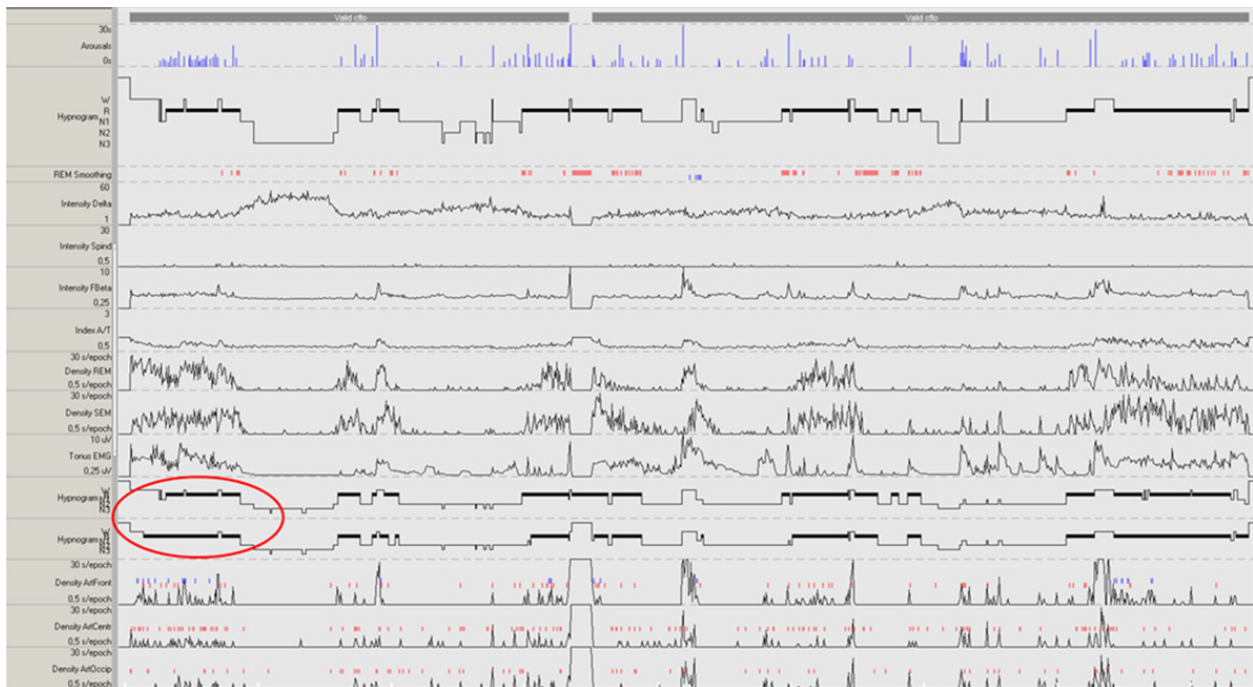


Figure 132: Polysomnographic Feature Trends (PFTs): Sleep-onset REM?

This should raise awareness during Step 1 in any case given the fact that Sleep-onset REM (SOREM) is rare, but a critical clinical warning sign. Here, we observe that the two interim hypnograms are inconsistent. Thus, the entire marked period should be reviewed with high attention.

6.5.5 An Example for Problems Due to Artifacts

The following PFTs again show inconsistency between the hypnogram with and without EMG for some short periods. Additionally you can see a large number of artifacts. The Density Artifact trace further reveals a high number of switches and frequent applications of a high-pass filtering due to sweat artifacts, further underlining problems in the signal quality. Finally, sleep onset again is unusually fragmented.

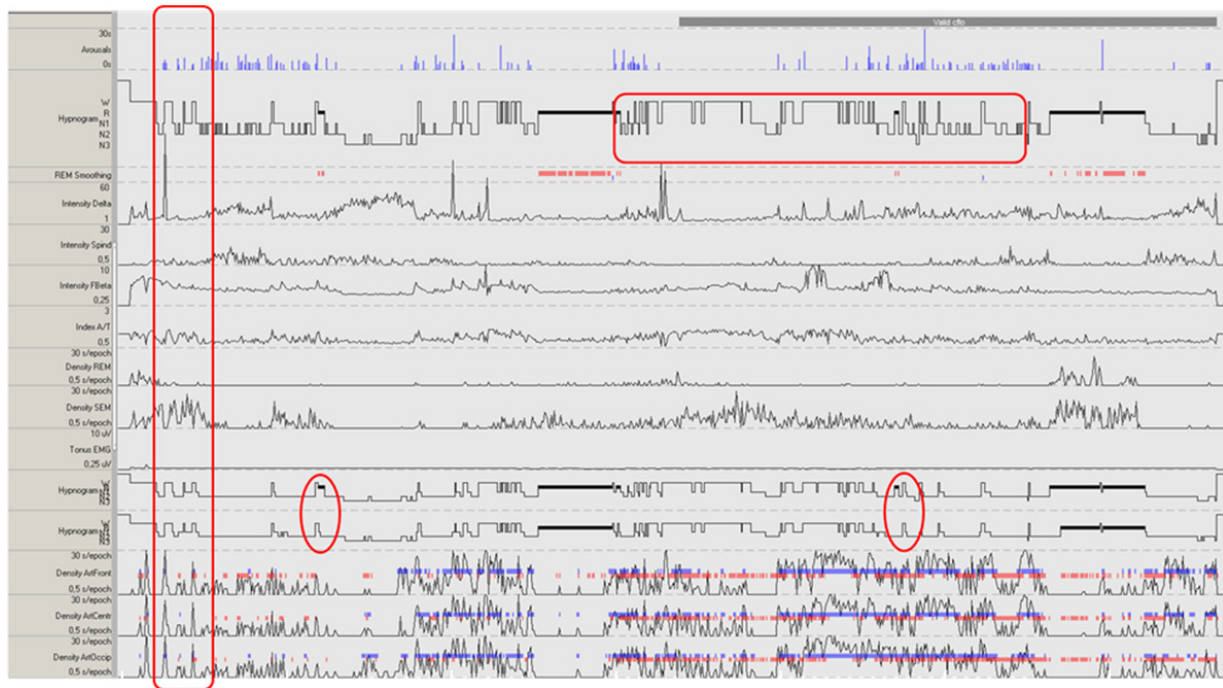


Figure 133: Polysomnographic Feature Trends (PFTs): Problems due to artifacts?

In this case, a fast epoch-by-epoch overview of the entire recording, with a slow-down at the marked areas, would be in place.

6.5.6 An Example of an Anomaly

The following PFTs reveal a rare (but occurring) anomaly: there is virtually no spindling intensity and only little delta intensity present:

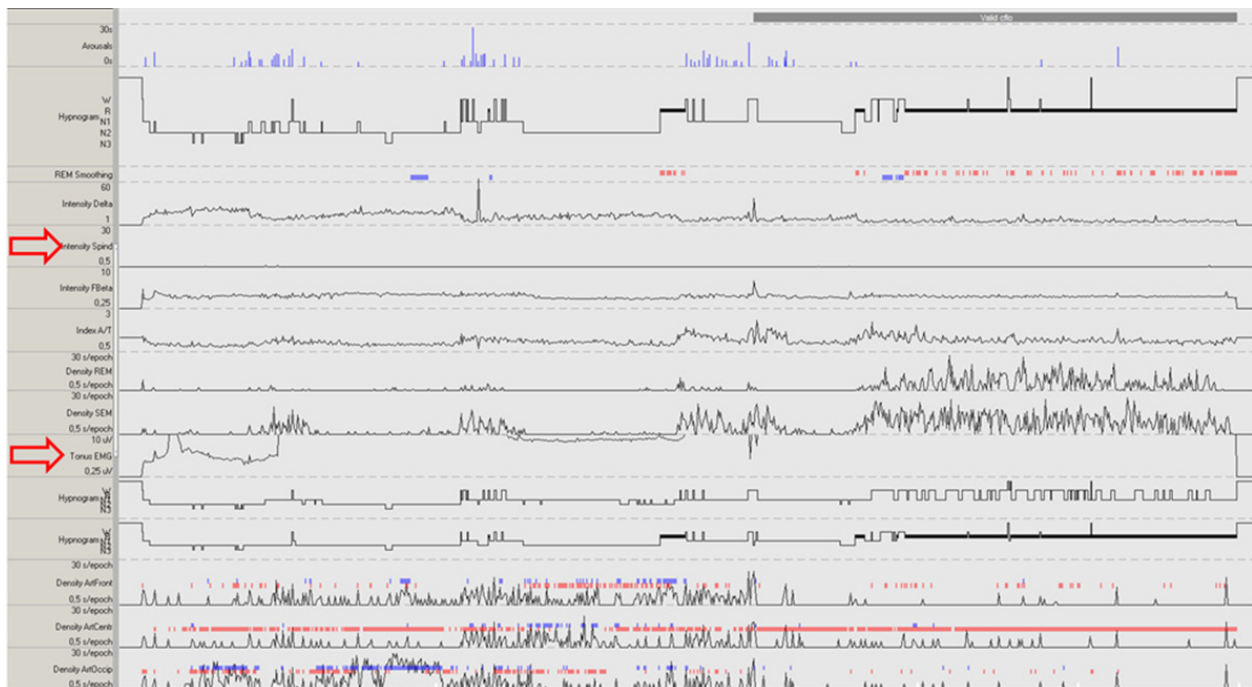


Figure 134: Polysomnographic Feature Trends (PFTs): Uncommon sleep characteristics

This can affect not only N2 scoring, but also the REM/NREM distinction, which is underlined by the inconsistency of the two interim hypnograms. This is another case where medium to higher attention is indicated for major parts of the recording. Note that the very long REM period at the end of the recording was correctly identified by Somnolyzer 24x7, even though the extremely high values of the chin EMG tone (above the displayed range) resulted in scoring of W/N1 in the hypnogram with EMG.

6.5.7 An Example of an Incorrect Montage

The following PFTs demand a high attention level for the entire recording: High alpha/theta index together with high REM density would speak for stage R or W (high REM density together with low muscle tone speaks for REM) but high or medium spindles and delta activity together with low muscle activity would speak for sleep stage N2 or N3.

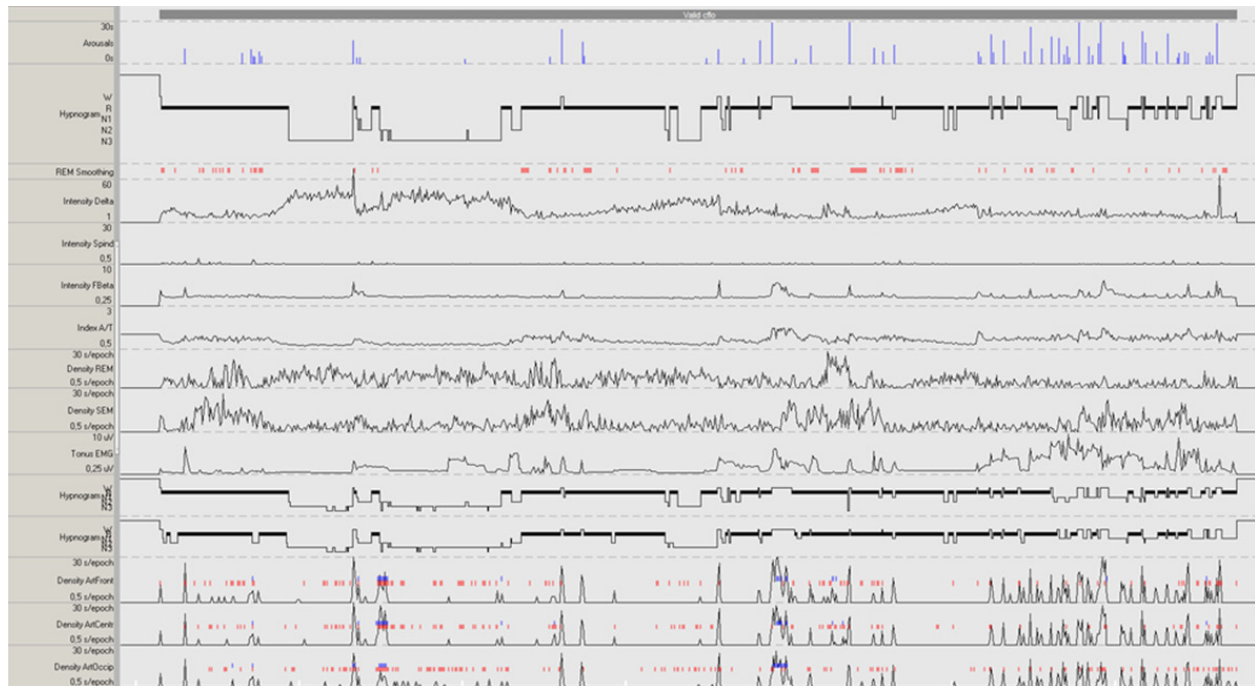


Figure 135: Polysomnographic Feature Trends (PFTs): Incorrect EOG montage

This is an example, where the PFTs points toward a general problem with the data. It turns out that the EOG channels were incorrectly referenced. After correction, the PFTs correspond to a near-perfect scoring:

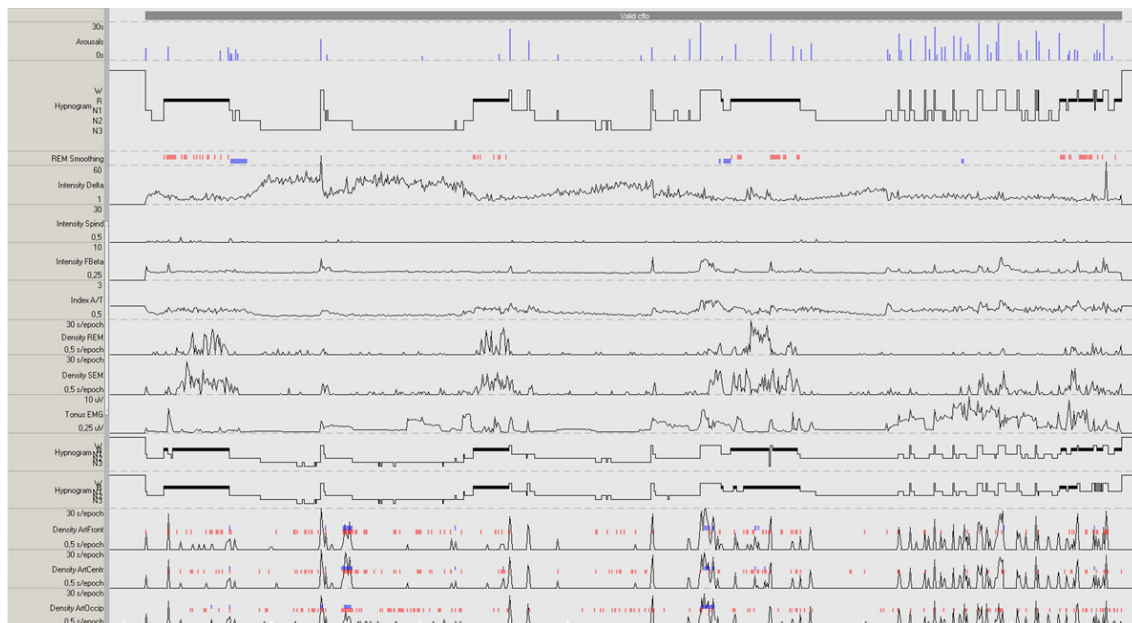


Figure 136: Polysomnographic Feature Trends (PFTs): Same example as Fig. 129 with corrected EOG montage

Note that the EEG based traces (delta intensity, spindle intensity, fast-beta intensity and the alpha/theta index) did not change while the EOG based traces (REM and SEM density) changed significantly, resulting in the correct staging after re-referencing of the EOG channels. The first REM period in this example in fact is a correctly assigned sleep-onset-REM.

6.5.8 Missing R Due to Elevated Fast-Beta

The following PFTs during Step1 raise suspicions about the inconsistent R periods.

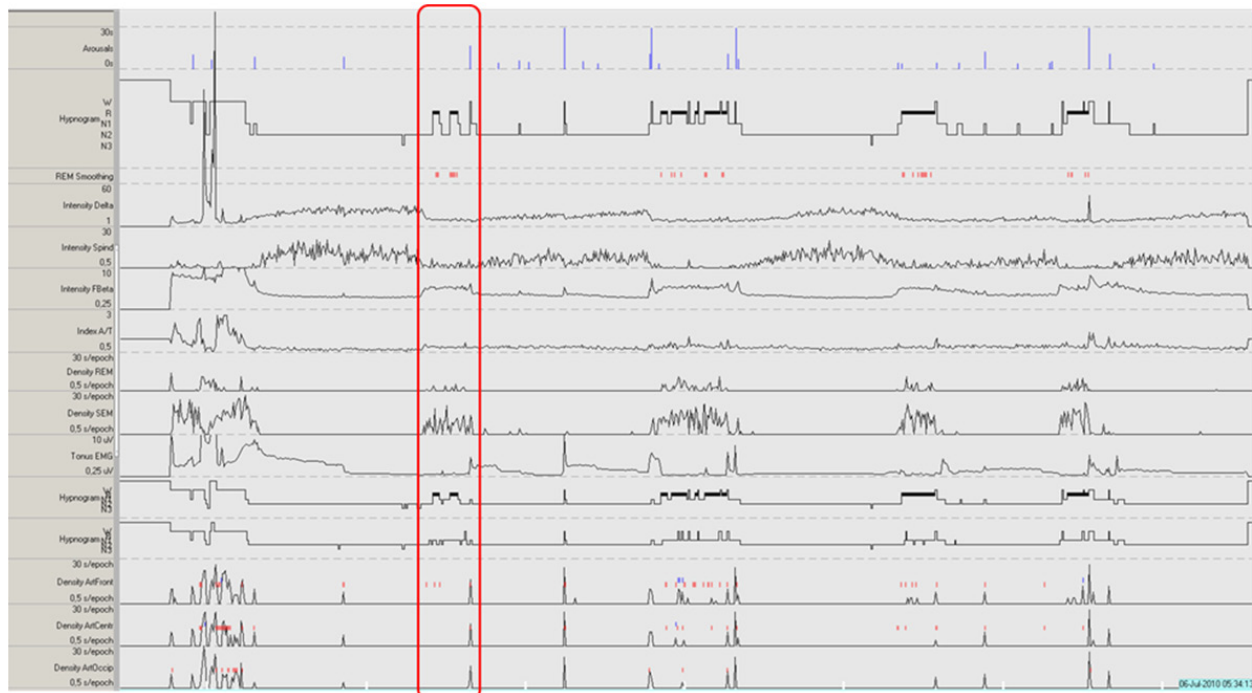


Figure 137: Polysomnographic Feature Trends (PFTs): Uncommon elevation of fast beta during stage R

In this case, however, no period prior to the first REM points toward any R staging that could have been missed. Instead, the traces spindle intensity, REM and SEM density and others suggest that in the marked area stage R might start earlier and last longer than what is actually scored. This is covered by Phase 1 –Step 1 and a slowing down of scrolling speed is indicated for the marked area. Note the elevated fast-beta activity, which typically speaks for stage W as can be seen in the frequent awakenings prior to the first REM period.

6.6 Description and Examples for Phase 2 “Respiratory & Leg Movement Events” - Step 1 “Confidence Check”

Checking the PFTs for

- **Quality and Validity of the respiratory signals**– Inspect which channels have been used for the study and whether they have been considered as valid by Somnolyzer 24x7:
 - Airflow signals (Oronasal thermal sensor: AFLO; nasal air pressure transducer: PFLO; flow from therapy device: CFLO): Sections not assigned as valid have to be inspected in step 2 “Expert Review of scoring and raw data” in 5 min-windows page by page.
 - Respiratory effort channels (Chest/thorax movements: CHMV; abdominal movements: ABMV): Sections not assigned as valid have to be reviewed in step 2 “Expert Review of scoring and raw data” in 5 min-windows if apneas occur concurrently to verify the sub-classification of the apnea events.
- **Associations between respiratory events and desaturations** – Desaturations which are not associated with a respiratory event as well as respiratory events not associated with desaturations may require careful visual inspection (except for RERAs of course).
- **Plausibility of the event distribution** – Look at the distribution of the events of the entire night and verify whether it appears plausible. Note any anomalies (such as large discrepancies between the first and second half of the night that are not explained by the night being a split-night or no leg movements at all which might indicate missing leg EMG data).

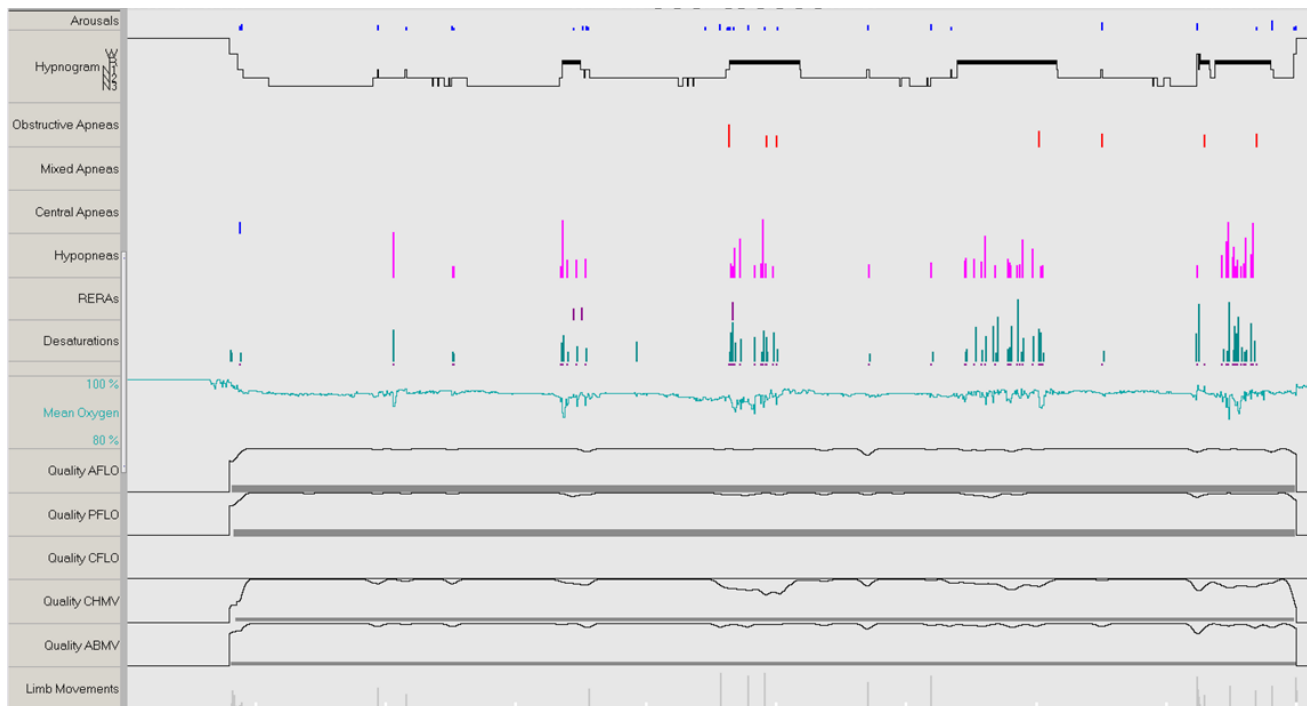


Figure 138: Figure B.1: Example for diagnostic study. In this study both flow signals as well as both respiratory effort signals were considered as valid and therefore used for event detection throughout the whole night. No therapy device was used in this study. The obstructive and specifically the central apnea at sleep onset should be confirmed in Step 2. The distribution of all other events appears plausible.

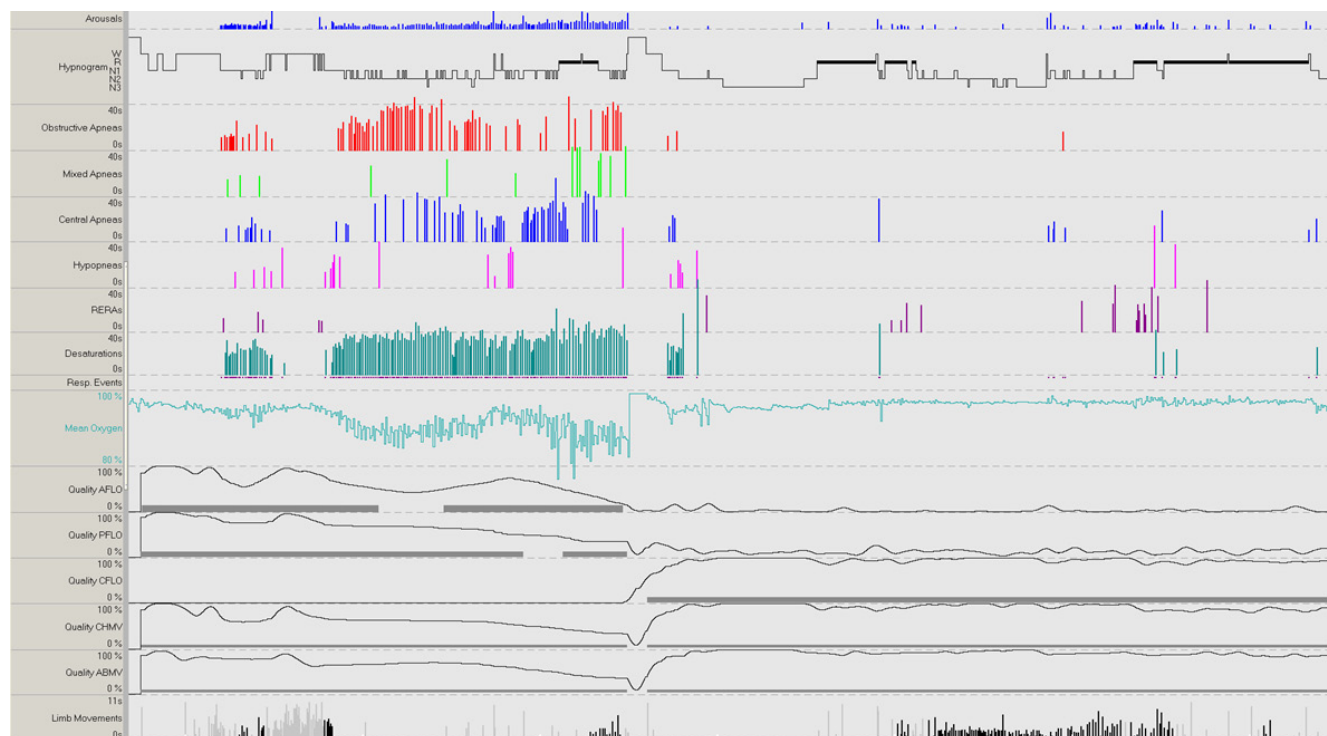


Figure 139: Example for a split-night study. In the first half of the night the AFLO (oronasal thermal sensor) and the PFLO (nasal pressure transducer) channels are used for event detection. In the second half of the night the CFLO (flow from therapy device) is the basis for the event detection. The effort belts are valid throughout the night, except for the time when the patient was unhooked. In the first part of the night apneas are detected from the AFLO signal (for the periods marked as valid AFLO) and hypopneas and RERAs from the PFLO signal (for the periods marked as valid PFLO), in the second part of the night all respiratory means are detected from the CFLO signal (marked as valid CFLO).

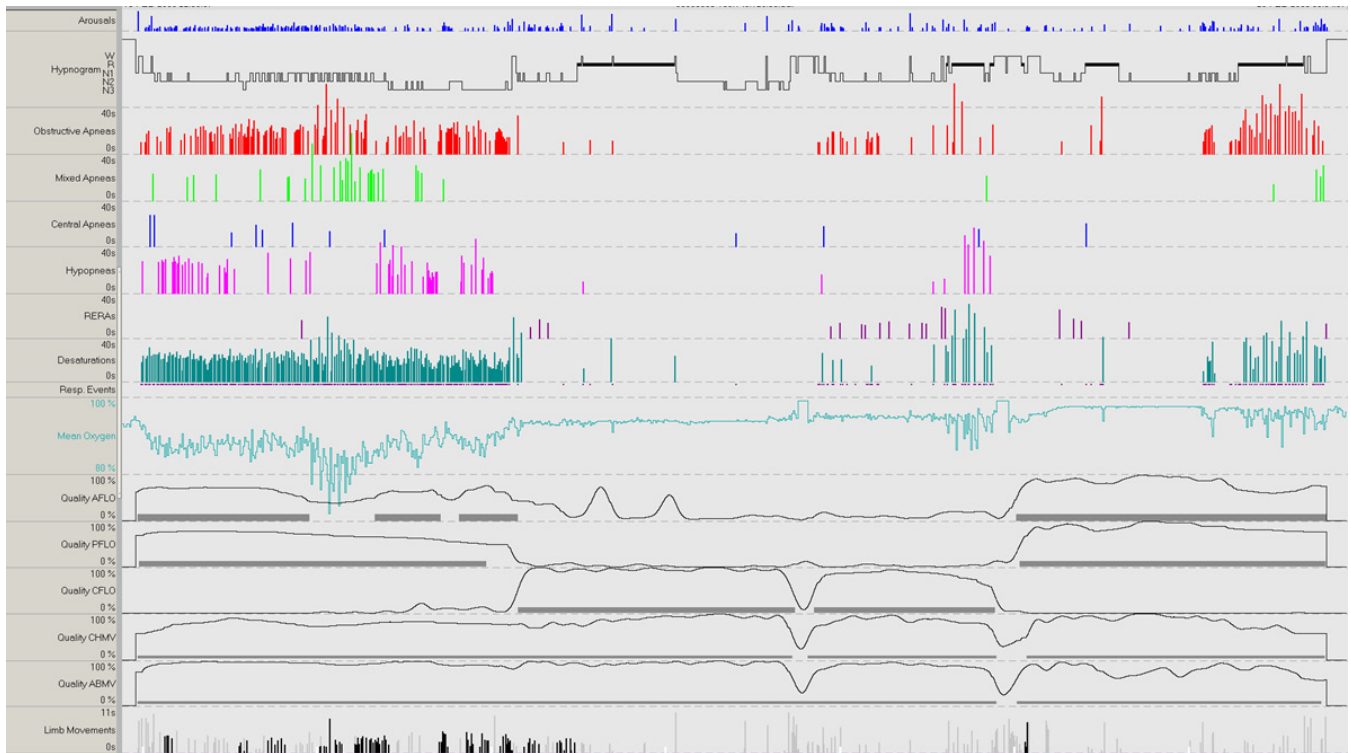


Figure 140: Example for a split-night study with only partial use of the therapy device. In the first part of the night the AFLO (oronasal thermal sensor) and the PFLO (nasal pressure transducer) signals have been used. In the middle part the CFLO (flow from therapy device) signal is the basis for the event detection. In the last part, the therapy device was turned off and the AFLO and PFLO signals were used once again. See Figure 141 and Figure 142 for further inspection of the signal quality.

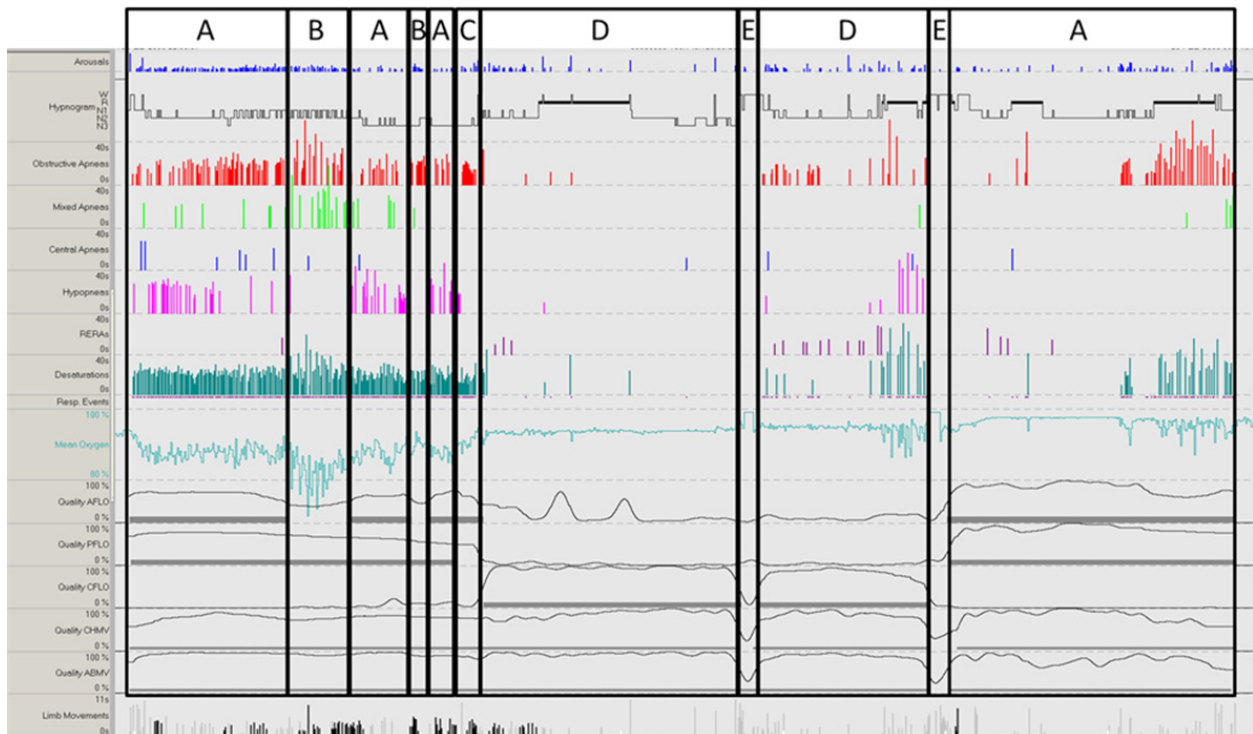


Figure 141: Same study as in Figure 135 In the periods marked as (A) apneas are detected from the AFLO signal and hypopneas and RERAs from the PFLO signal since both AFLO and PFLO are valid. In the periods marked as (B) all respiratory events are detected from PFLO since no CFLO is available and the AFLO is considered as invalid. In the period marked as (C) all respiratory events are detected from the AFLO since no CFLO is available and the PFLO is considered as invalid. In the periods marked as (D) all respiratory events are detected from the CFLO since the CFLO signal is considered as valid. And finally in the periods marked as (E) no valid airflow signal was available and thus no respiratory events are detected. Note that the patient was unhooked during both periods (E).

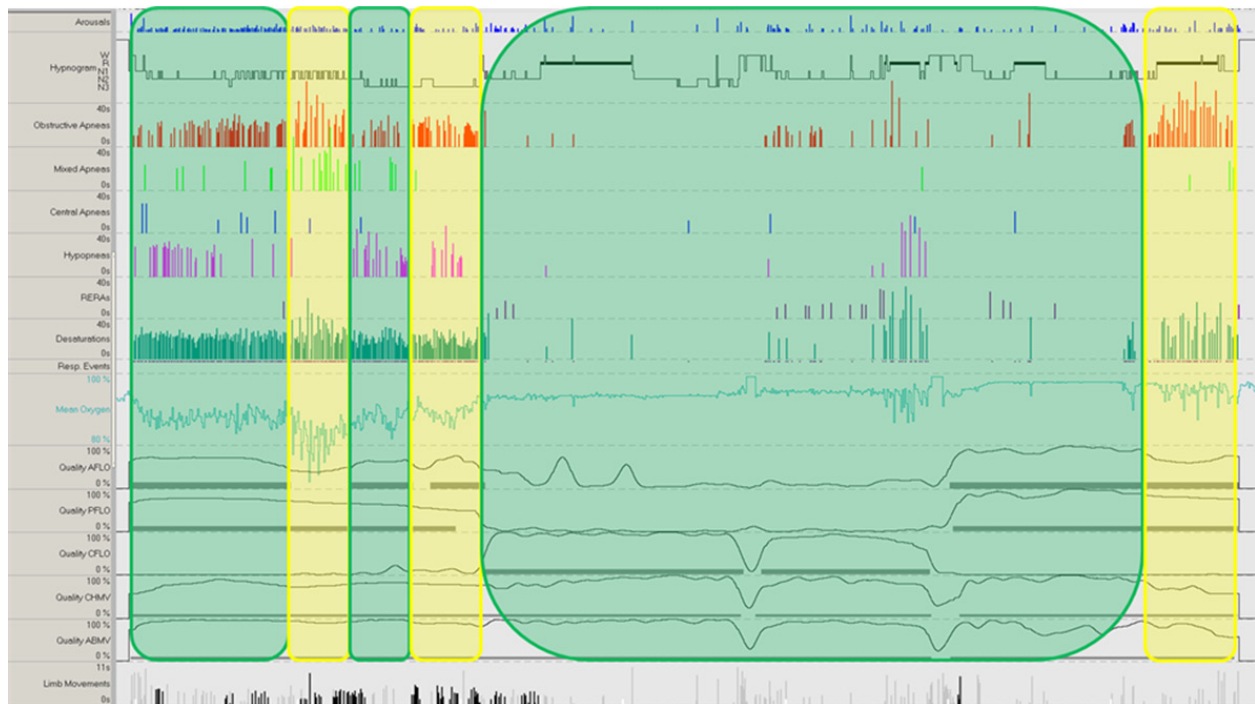
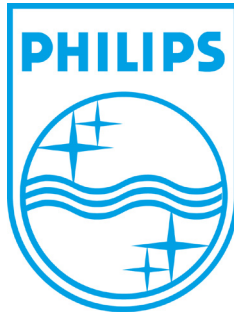


Figure 142: Figure B.5: Same study as in Figure 140 Different levels of attention for ER of respiratory events. In this example there are no sections that require high attention (i.e. slow scrolling in Step 2), since during the periods without valid signals the patient is unhooked. Sections that require medium attention (i.e. medium scrolling in Step 2) are indicated in yellow (i.e. periods with rather low signal quality), and sections that require low attention (i.e. fast scrolling in Step 2) are indicated in green.



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