Bittium

Respiro Analyst™

User Guide

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Published by

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Summary of Changes

Version	Date	Changes Between Releases	Status
3.0.0	2023.01.20	First release.	Approved
4.0.0	2023.04.11	Second release.	Approved
5.0.0	2023.08.08	Third release.	Approved

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1 INTRODUCTION

Bittium Respiro Analyst™ is a web application that enables sleep specialists to make polygraph analyses for Bittium Respiro™ recordings. Respiro Analyst provides accurate medical information on patients (polygraphy signals and preliminary analysis).

Respiro Analyst enables sleep specialists who are working in remote locations to analyze recordings made by the health centers and clinics. For the sleep specialist, the system provides a complete working environment for signal visualization and analysis. The sleep specialist can write a statement based on the analysis using integrated Statement Tool.

1.1 Intended purpose

Respiro Analyst is intended to be used as analysis software in overnight respiratory polygraphy, which is always carried out by a medical doctor's prescription. Use of this software for any other purpose is prohibited. Respiro Analyst is used typically in a hospital or a clinic. Software analyses patient's biosignals that have been recorded with Respiro™. Software does not actively monitor the patient's status or treat the patient and it cannot be used as a life-sustaining application. The annotated episodes should be considered as preliminary and should not be used as such as a basis for diagnosis. The user must be certain of the analyzed signals' purity and quality and he/she must ensure the correctness of the annotated episodes before making an analysis for a statement. Respiro Analyst is not designed to be used with children. The application is operated by sleep specialists and healthcare professionals (hospital).

1.1.1 Indications

Suspected sleep-related breathing disorder (obstructive sleep apnea, central sleep apnea, mixed sleep apnea, Cheyne-Stokes breathing).

1.1.2 Contraindications

- The product is not intended for pediatric patients. Age limit 18 years.
- Missing oximetry, airflow, or respiratory movement measurement.

1.1.3 User profile

The intended users of the application shall be medical professionals specialized in the field of sleep medicine. Training for the use of the application will be provided by the manufacturer at request. Special training is not a prerequisite for the use of the application.

1.1.4 Patient population

The product is not intended for pediatric patients. Age limit 18 years.

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1.2 Notes and warnings

- Bittium Respiro Analyst does not provide diagnoses.
- Bittium Respiro Analyst does not actively monitor the patient's status or treat the patient and it cannot be used as a life-sustaining application.
- Bittium Respiro Analyst is intended as a decision support system for trained medical professional, and it should not be used as the sole basis for making clinical decisions pertaining to patient diagnosis, care, or management. Any application of medical information from the program, other than the original design or intended use thereof, is not advised and is considered as the misuse of the software product.
- The numerical and graphical results and any interpretation given must be examined with respect to the overall clinical condition of the patient and the general recorded data quality.
- Consider the raw data.
- Indexes and scores provided by Bittium Respiro Analyst are not accurate before a trained person sets the start and stop times for sleep and all other relevant exclusion areas.
- Bittium Respiro Analyst does not perform pre-analysis for snoring nor ECG arrythmias. A trained professional must enter these annotations manually before their summary statistics are useful.
- All pre-annotations must be reviewed by a trained professional before using the summaries and indexes for decision support.

1.3 Clinical performance

Pre-analysis algorithms used in Respiro Analyst have been validated using two data sets, PhysioNet challenge 2018 (Table 1) and Bittium's proprietary dataset (Table 2), containing 175 recordings combined, annotated by certified sleep technologists or professionals specialized in sleep medicine.

- Datasets used for validating the performance:
    - Physionet challenge 2018 polysomnography dataset including 81 recordings with sufficient pressure airflow signal, manually scored by certified sleep technologists
        - Areas that patient is not asleep were not analyzed by algorithms
    - Bittium's proprietary respiratory polygraphy dataset including 94 recordings manually scored by sleep specialist as part of routine clinical care
        - Areas that were excluded by sleep specialist were not analyzed by algorithms
- Respiratory event algorithm
    - Respiratory event algorithm produces Hypopnea, Obstructive apnea, Central apnea and Mixed Apnea event annotations
    - Mean difference and standard deviation between the algorithm and the reference is
        - -0.15 ± 3.69 for Apnea-Hypopnea Index (AHI) in the Respiratory polygraphy dataset
        - 4.52 ± 4.25 for AHI in the Polysomnography dataset
        - -1.9 ± 3.18 for Central Apnea Index (CAI) in the Polysomnography dataset
        - 6.41 ± 5.61 for Obstructive Apnea Index (OAI) in the Polysomnography dataset

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- Oxygen desaturation event algorithm
  - Oxygen desaturation event algorithm produces Oxygen desaturation event annotations that have ≥3 % drop in oxygen saturation
  - Mean difference and standard deviation between the algorithm and the reference for Oxygen Desaturation Index (ODI3) is -0.14 ± 2.82 in the Respiratory polygraphy dataset

Table 1. Sensitivity, specificity, positive predictivity and negative predictivity of the detection of sleep apnea and different sleep apnea severity classes based on AHI in the PhysioNet Polysomnography dataset

Sleep apnea severity	Sensitivity	Specificity	Positive predictivity	Negative predictivity
normal (AHI < 5)	0.71	1.00	1.00	0.94
mild sleep apnea (5 <= AHI < 15)	0.50	0.91	0.71	0.81
moderate sleep apnea (15 <= AHI < 30)	0.78	0.73	0.71	0.80
severe sleep apnea (AHI >= 30)	1.00	0.91	0.46	1.00
sleep apnea (AHI >= 5)	1.00	0.71	0.94	1.00

Table 2. Sensitivity, specificity, positive predictivity and negative predictivity of the detection of sleep apnea and different sleep apnea severity classes based on AHI in the Bittium's proprietary Respiratory polygraphy dataset

Sleep apnea severity	Sensitivity	Specificity	Positive predictivity	Negative predictivity
normal (AHI < 5)	0.67	0.99	0.91	0.94
mild sleep apnea (5 <= AHI < 15)	0.84	0.89	0.79	0.92
moderate sleep apnea (15 <= AHI < 30)	0.80	0.91	0.77	0.93
severe sleep apnea (AHI >= 30)	0.91	0.96	0.87	0.97
sleep apnea (AHI >= 5)	0.99	0.67	0.94	0.91

1.4 Expected lifetime

Expected lifetime for Respiro Analyst is around [2] years when properly maintained. The expected lifetime for Respiro Analyst is subject to changes as per its schedule for major releases.

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1.5 System requirements

Recommended system requirements for using Respiro Analyst are:

- Intel(R) Core (TM) i5-8265U CPU @ 1.60GHz
- 8GB or more RAM
- Minimum recommended resolution: Full HD (1920 x 1080)
- Windows 10 operating system
- Mozilla Firefox, Google Chrome or Microsoft Edge browser
- Network: Min. reliable broadband connection

Note that Respiro Analyst is designed to work only with recordings made using Bittium Respiro.

Note that Respiro Analyst is available as a service (as a part of Bittium MedicalSuite™), no additional software needs to be installed on your computer. Please ask your service provider for correct URL where Respiro Analyst can be accessed.

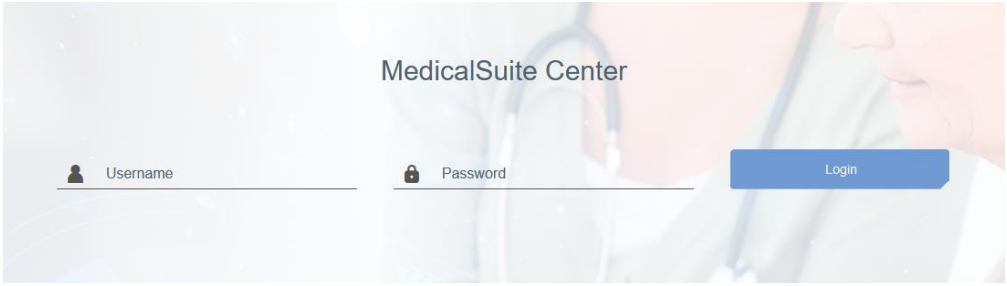
1.6 Cyber security

Install all security patches recommended by your OS vendor and update your browser regularly. Do not share accounts and keep your password safe. Do not use the computer used for clinical work for any other activities such as social media or playing games.

1.7 Signing in to Bittium Respiro Analyst

Before using Bittium Respiro Analyst you must log in to Bittium MedicalSuite Center using the credentials provided to you by your system administrator. For more information on Bittium MedicalSuite Center, see MedicalSuite HSAT Services Clinical Guide.

1. Log in to Bittium MedicalSuite Center.



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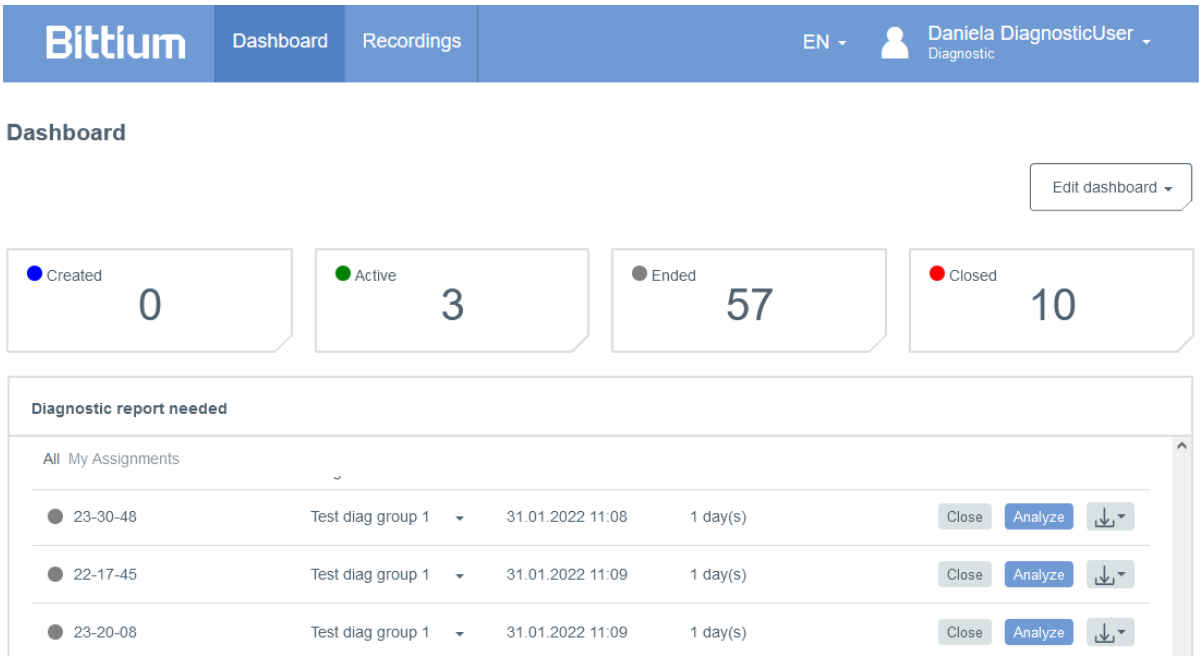
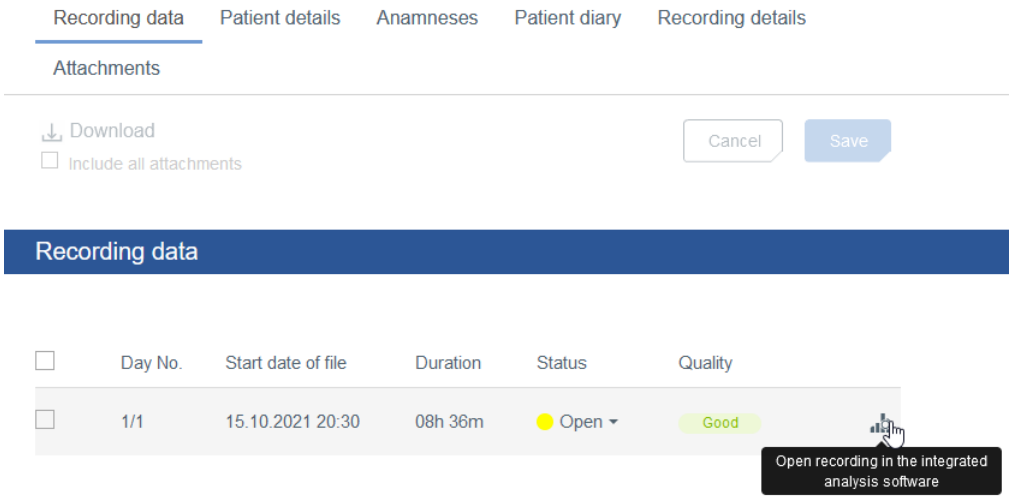
2. Click "Analyze" button in MedicalSuite Center Dashboard view to open the related recording in Respiro Analyst.



You can also open a recording in Respiro Analyst by selecting a recording in MedicalSuite Center Dashboard view and clicking the histogram icon on the Recording data tab as shown in the image below.



Note that the items appearing in MedicalSuite Center Dashboard view can be selected to be shown or hidden with the Edit dashboard function:

1. Click “Edit dashboard” button.
2. Hide unnecessary item(s) by clicking the item(s) on the drop-down list.
3. Change the order of the items by dragging and dropping them on the drop-down list.

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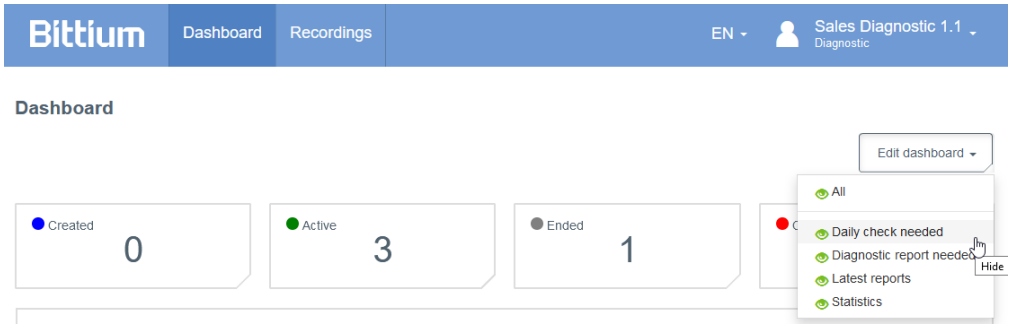

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2 BITTIUM RESPIRO ANALYST OVERVIEW

Bittium Respiro Analyst has three views under their own tabs that are Summary and statement view, Analysis view and the Report view.

2.1 Summary and statement

Summary and statement view provides an overview of the patient details, recording details and analysis results as well as a section for statement writing. This view allows a user to see the overall status of the patient and to write a statement. Analysis results are available when analyzing the recording and are updated automatically when event annotations are created or edited.

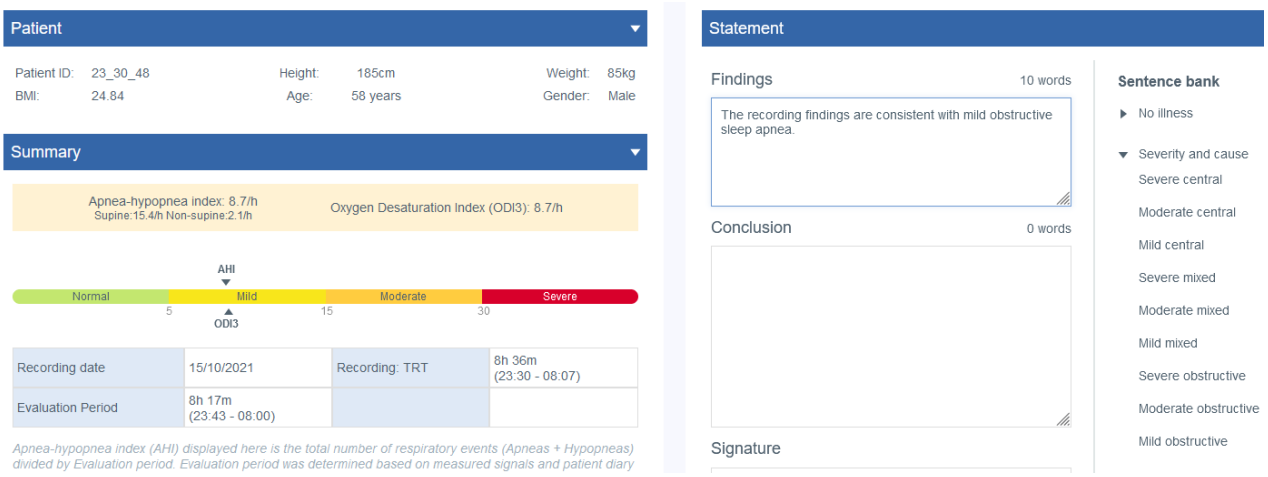

Figure 1 Respiro Analyst - Summary and statement view

Patient details

Patient details has been added beforehand in MedicalSuite Center and it contains basic patient information like:

- Patient ID
- Height
- Weight
- BMI (body mass index)
- Age
- Gender

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Summary

Summary contains the most important analysis results summarized:

Table 3 Summary

Item	Description
Recording date	Recording starting date.
Total recording time (TRT)	Entire elapsed recording time from start to end.
Evaluation period	Total recording time minus exclusion event annotations created by user due to e.g. artifacts in signals or the patient was awake.
Apnea-hypopnea index (AHI)	Total number of respiratory events (Apneas + Hypopneas) divided by Evaluation period. Note: AHI is a surrogate for Respiratory Event Index (REI).
Oxygen Desaturation Index (ODI3)	A total number of 3 % or higher desaturation events divided by Evaluation period.
Snoring	Percentage of snoring during the Evaluation period.

Analysis results

Analysis results are automatically calculated based on the event annotations in the Analysis view. Detailed analysis results are shown under the Summary section, providing details on the following areas:

- Respiratory events
- SpO_2
- Snoring
- Position
- Cardiac events and pulse

All analysis results are calculated from the Evaluation period, i.e. excluding the areas under exclusion event annotations.

Note that the analysis results related to snoring, cardiac events and Cheyne-Stokes breathing are available only if the related events are manually scored since there is no automatic pre-analysis for these events.

Analysis results are provided per each body position, i.e. calculating events occurred in the body position and - in case of indexes - divided by the time slept in the body position. Non-supine position includes left, right and prone body positions, while unknown position includes headstand and unknown body positions.

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Respiratory events

	Total	Supine	Non-supine				Upright	Unknown
			Total	Left	Right	Prone		
Apnea-hypopnea index (AHI)	8.7/h	15.4/h	2.1/h	4/h	1.4/h	0/h	0/h	0/h
Central apnea index (CAI)	0.6/h	1/h	0.2/h	0/h	0.3/h	0/h	0/h	0/h
Respiratory event (RE)	72	63	9	5	4	0	0	0
Obstructive apnea event	4	4	0	0	0	0	0	0
Central apnea event	5	4	1	0	1	0	0	0
Mixed apnea event	0	0	0	0	0	0	0	0
Hypopnea event	63	55	8	5	3	0	0	0
Cheyne-Stokes respiration (CS)	N/A							

Criteria used for hypopnea scoring: Oxygen desaturation ≥ 3 %

The airflow sensor used: Pressure Flow

SpO2

	Total	Supine	Non-supine	Upright	Unknown
Oxygen Desaturation Index ≥ 3% (ODI3)	8.7/h	15.1/h	2.4/h	0/h	0/h
Oxygen Desaturation Index ≥ 4% (ODI4)	1.7/h	2.7/h	0.7/h	0/h	0/h
Average SpO2	93%				
Minimum SpO2	89%				
SpO2 duration < 90%	0.1% (21s)				
SpO2 duration ≤ 88%	0% (0s)				

Snoring

	Total	Supine	Non-supine				Upright	Unknown
			Total	Left	Right	Prone		
Snoring	40%	81%	1%	0%	1%	0%	0%	0%

Position

Total	Supine	Non-supine				Upright	Unknown
		Total	Left	Right	Prone		
8h 17m	4h 6m	4h 11m	1h 14m	2h 56m	0s	0s	0s

Cardiac events and pulse

Average pulse	50bpm	Highest pulse	72bpm
Lowest pulse	42bpm	Asystoles	N/A
Atrial fibrillations	N/A	Bradycardias	N/A
Narrow complex tachycardias	N/A	Sinus tachycardias	N/A
Wide complex tachycardias	N/A	Other cardiac events	N/A

Figure 2 Summary view details

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Patient diary

Patient diary part includes information about the recorded night that has been added beforehand in MedicalSuite Center. The diary includes also events which are e.g. wake ups during a recording. A patient can mark events during a recording by pressing shortly the Respiro power button and a healthcare professional can specify details (e.g., going to bathroom) for the events marked by the patient as well as add new events after a recording in MedicalSuite Center.

Anamneses

Anamneses part includes detailed patient background information that has been added beforehand in MedicalSuite Center.

Recording details

Recording details part includes information about the organization that has made the recording and the used Respiro recording equipment.

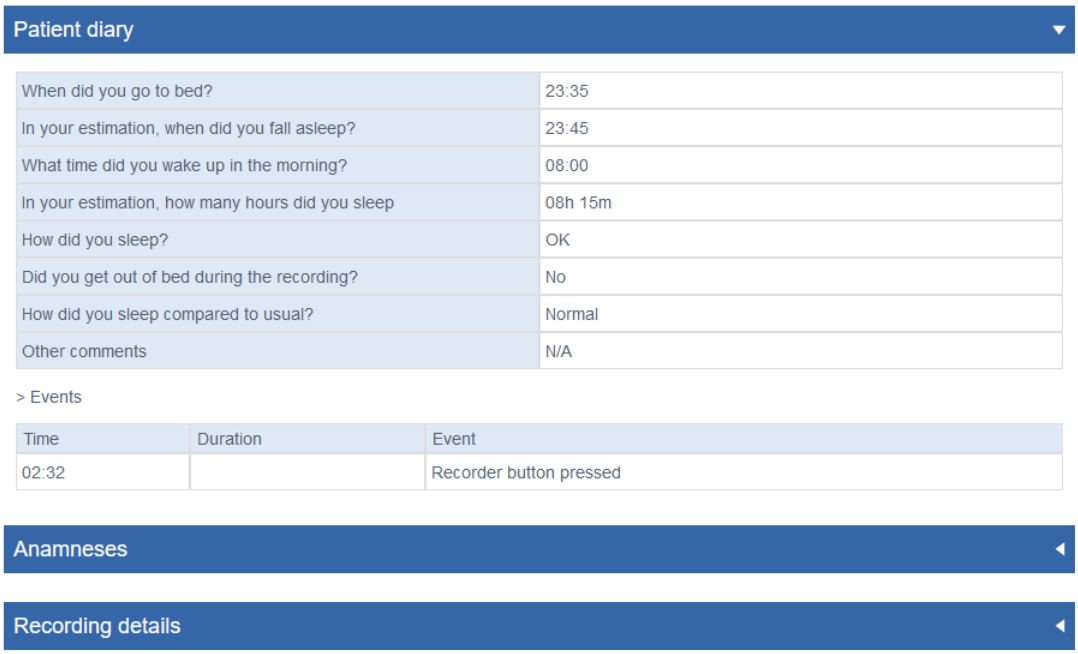

Figure 3 Patient diary, Anamneses and Recording details

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Statement

Statement tool contains text boxes for writing the findings and conclusion. The statement tool includes a sentence bank with predefined sentences which help in statement writing. The function is available when the recording's analysis summary is viewed. A statement can be signed by a sleep specialist.

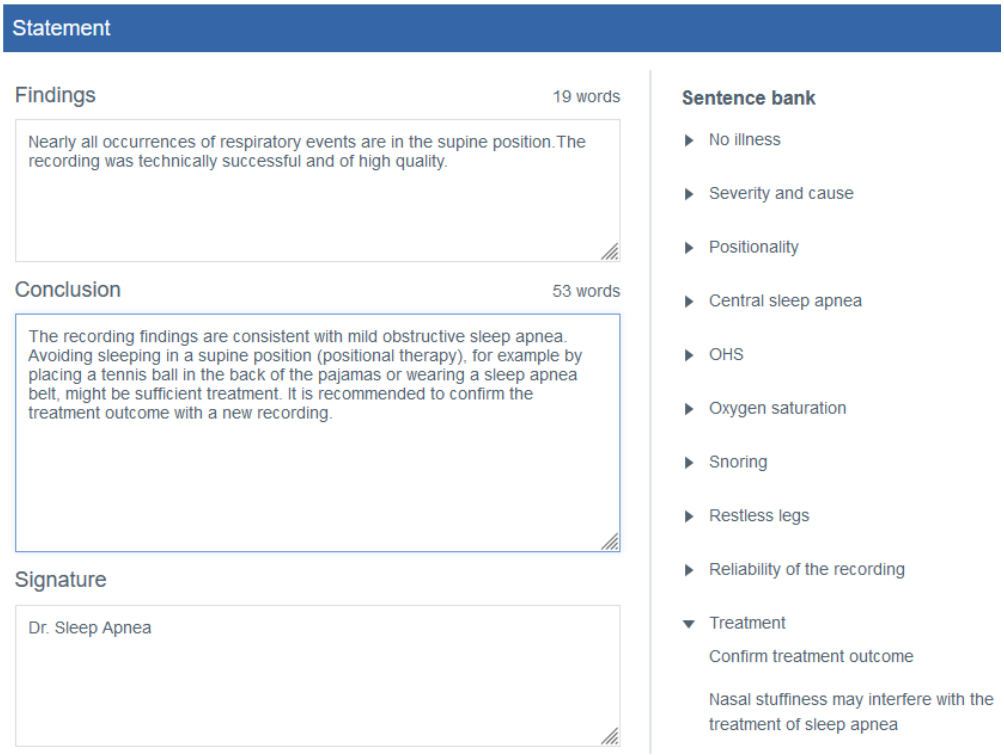

Figure 4 Statement section, part 1

Below the signature field there are selections that only affect what is shown in the statement report. For example, selected criteria for hypopnea scoring does not affect analysis or how analysis results are calculated but modifies the summary section of the statement so that Oxygen Desaturation Index ≥ 4% (ODI4) is used instead of ODI3 in the summary section. Similarly, the selection of used airflow sensor types does not affect analysis or how analysis results are calculated but the used airflow sensors are just mentioned in the statement report.

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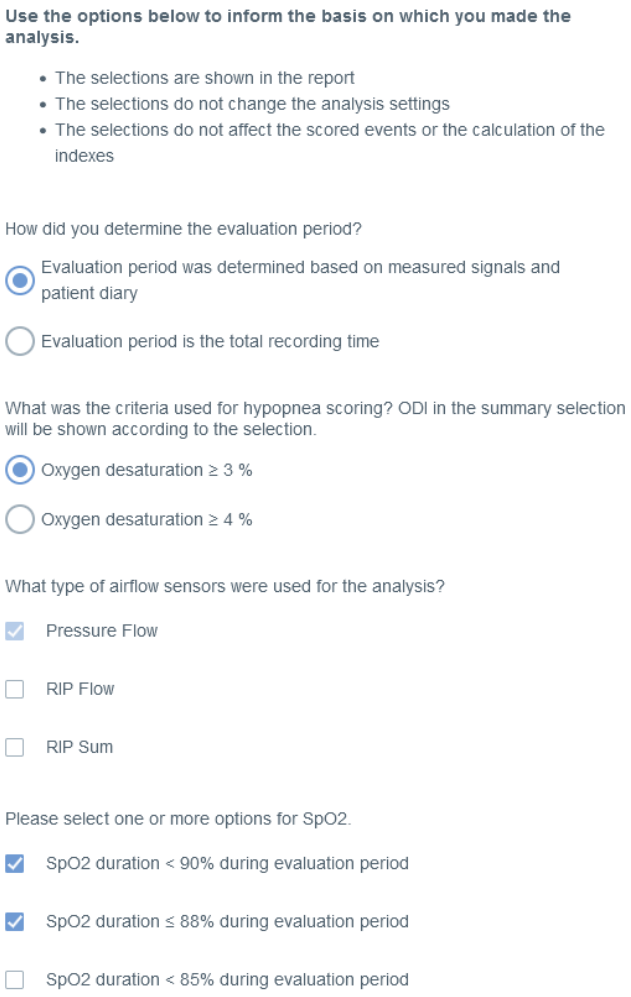

Figure 5 Statement section, part 2

2.2 Analysis

Analysis view shows the recording data in detail with inputs from different sensors and event annotations. Recording time scale can be adjusted between 5 seconds and 30 minutes or the entire recording can be viewed in one screen.

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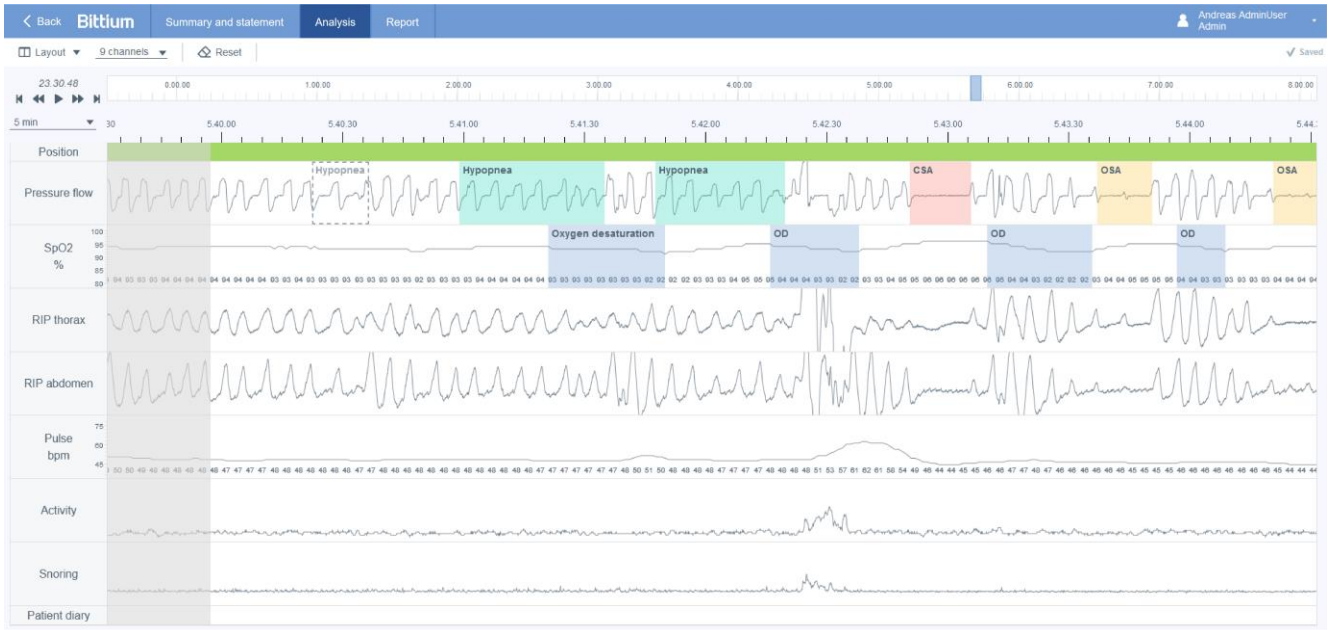

Figure 6 Respiro Analyst - Analysis view

Signals

All available signals are described in the table below. Note that available signals in a recording depends on the sensor configuration used in the recording.

Exact values for SpO_2 and pulse signals are displayed on the signal channel.

Table 4 Signal descriptions

Signal	Description
Position	Body positions are indicated with a color and an icon. Body positions: upright, supine, prone, left, right, headstand, and error.
Snoring	A snoring signal from a microphone displayed in logarithmic scale.
Pressure flow	A qualitative respiratory airflow derived from nasal cannula pressure signal using a square root transformation.
SpO_2	An oxygen saturation signal from a pulse oximeter.
RIP abdo-men	A respiratory effort signal from an abdominal RIP belt sensor.
RIP thorax	A respiratory effort signal from a thoracic RIP belt sensor.
Activity	A body activity signal derived from a three-dimensional accelerometer sensor.
Pulse	A pulse rate signal from a pulse oximeter.

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ECG	An electrocardiogram signal.
RIP sum	A sum of the RIP abdomen and thorax signals.
RIP flow	A qualitative respiratory airflow derived as time derivative of the RIP sum signal.
Patient diary	Estimated fall asleep and woke up times as well as other events from the patient diary.

Event annotations

Event annotations are notes which are based on the pre-analysis algorithms or entered by users such as sleep specialist and patient.

The pre-analysis algorithms can produce following event annotations:

- Artifact
- Central apnea
- Hypopnea
- Mixed apnea
- Obstructive apnea
- Oxygen desaturation

After the recording the data is automatically pre-analysed and event annotations are set. Most event annotations can be freely edited or removed and new ones can be added as required. See Event annotations section below for information on how to work with event annotations.

Annotations that the user can create are described in the table below:

Table 5 Annotations

Event annotation	Description	Related signals
Artifact	An artifact event marks disturbed signal area caused by e.g. sensor error, low quality signal or ECG lead off. Signal values under artifact annotations are not included in analysis results (e.g. minimum heart rate). Artifacts can be added by sleep specialist.	Snoring, Pressure Flow, SpO_2, RIP abdomen, RIP thorax, Activity, Pulse, ECG, RIP sum, RIP flow
Exclusion	Exclusion events define the parts of the recording that are not analyzed due to e.g. low quality signals or the patient was awake so that the Evaluation period is total recording time minus exclusion areas. Signal values under exclusion events are not included in analysis results (e.g. minimum heart rate).	Covers all signal channels
Central apnea	A central apnea event. Criteria for pre-analysis algorithm is a ≥90 % reduction in airflow lasting ≥10 seconds associated with	Pressure flow, RIP sum,

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	absent inspiratory effort throughout the entire period of absent airflow.	RIP flow
Cheyne-Stokes breathing	A Cheyne-Stokes breathing event.	Pressure flow, RIP sum, RIP flow
Hypopnea	A hypopnea event. Criteria for pre-analysis algorithm is a ≥30 % reduction in airflow lasting ≥10 seconds associated with a ≥3 % oxygen desaturation event.	Pressure flow, RIP sum, RIP flow
Mixed apnea	A mixed apnea event. Criteria for pre-analysis algorithm is a ≥90 % reduction in airflow lasting ≥10 seconds associated with absent inspiratory effort in the initial portion of the event, followed by resumption of inspiratory effort.	Pressure flow, RIP sum, RIP flow
Obstructive apnea	An obstructive apnea event. Criteria for pre-analysis algorithm is a ≥90 % reduction in airflow lasting ≥10 seconds associated with continued or increased inspiratory effort throughout the entire period of absent airflow.	Pressure flow, RIP sum, RIP flow
Oxygen desaturation	An Oxygen desaturation event. Criteria for pre-analysis algorithm is ≥3 % drop in oxygen saturation signal.	SpO_2
Snoring	A snoring event.	Snoring
Sinus tachycardia	A sinus tachycardia event.	ECG
Bradycardia	A bradycardia event.	ECG
Asystole	An asystole event.	ECG
Wide complex tachycardia	A wide complex tachycardia event.	ECG
Narrow complex tachycardia	A narrow complex tachycardia event.	ECG
Atrial fibrillation	An atrial fibrillation event.	ECG
Other cardiac event	Other cardiac event.	ECG
Unknown position	An ambiguous body position event marked by user. Analysis results are updated so that the created Unknown position event is considered.	Position

A special patient diary channel contains annotations that come from a diary that the patient has given. Annotations on the patient diary channel cannot be created or updated by the user. Table below lists the possible annotations visible in the channel.

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Table 6 Patient diary annotations

Diary annotation	Description
Recorder button pressed	Respiro button press marker
Fall asleep	Estimated fall asleep time
Woke up	Estimated woke up time
Drinking or eating	Patient indicates they are eating or drinking
Going to bathroom	Patient indicates they went to bathroom
Lying on bed	Patient indicates they are lying on the bed awake
Reading a book	Patient indicates they are reading a book
Other	Other type of event indication, which might have additional text included.

2.3 Report

Once the findings and the conclusion are entered in the statement section and the analysis is ready for a report, a draft version of the report can be generated by clicking the “Preview report” button. If everything is as it should in the report it can then be accepted by clicking the “Accept report” button on the top left-hand side of the view.

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Summary and statement | Analysis | Report

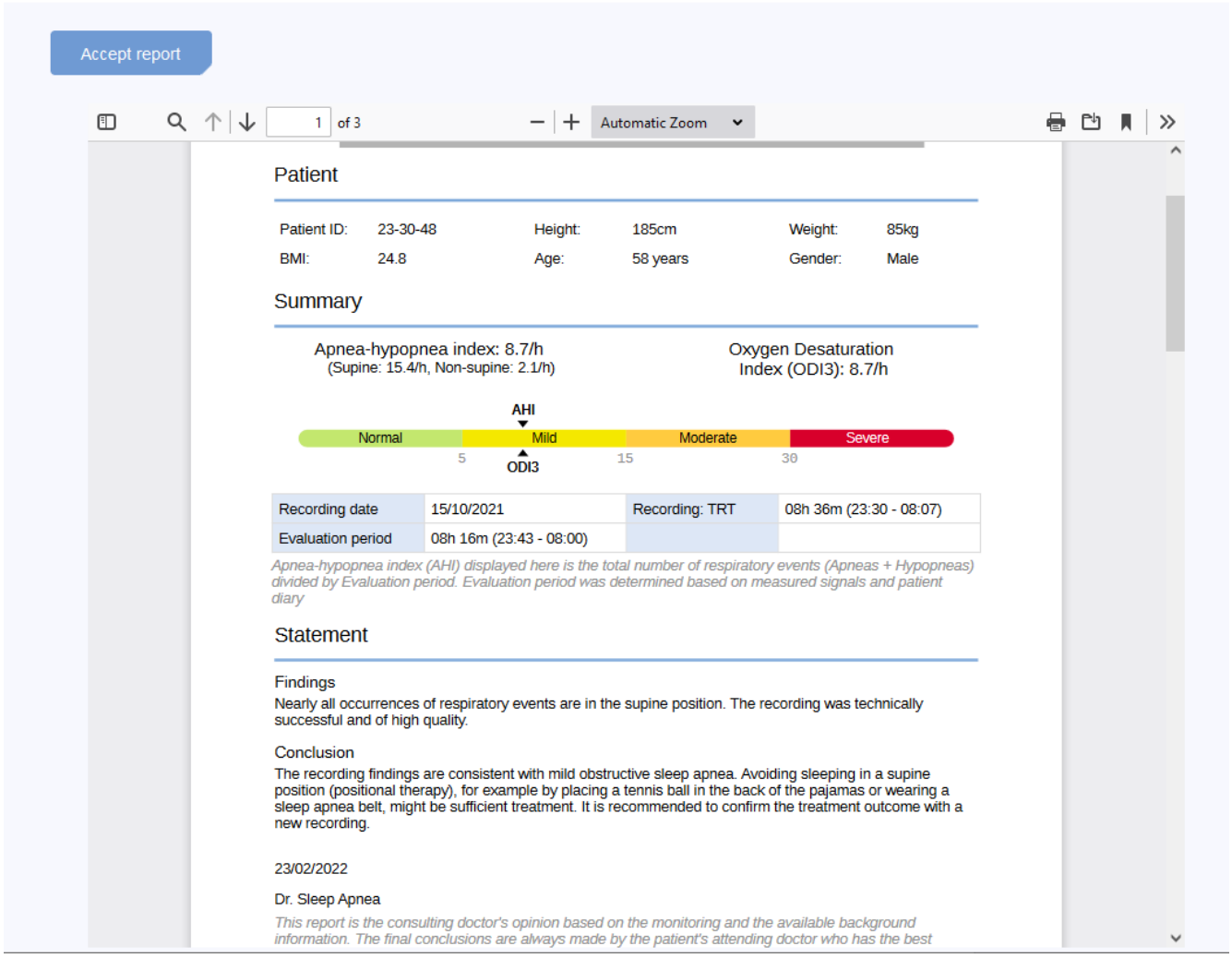

Figure 7 Draft report view

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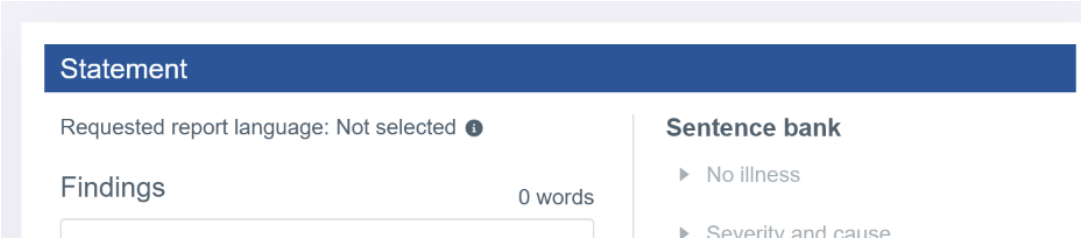
3 USING RESPIRO ANALYST

Bittium Respiro Analyst user interface is divided into three views under their own tabs that are Summary and statement view, Analysis view and the Report view.

All changes you make in Summary and statement view and Analysis view are saved immediately. Status of the saving is indicated in upper right corner. You can safely close browser window once indicator shows a check mark and reads "saved". You can resume work later from MedicalSuite Center. While the indicator displays "saving...", your changes might not have saved yet.

3.1 Selecting language

If report has been requested in a specific language, it is notified in the Statement section.



Preferred language for the Respiro Analyst can be selected from upper right section, next to user profile:

3.2 Scrolling

You can scroll the recording by using buttons or keyboard shortcuts described in the table below.

Table 7 Keyboard shortcuts

Button	Description	Keyboard shortcut
	A step backward	Left arrow key
	A step forward	Right arrow key
	To the beginning	
	To the end	

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3.3 Selecting time scale

The time scale shown above the signals can be adjusted to show the recording in increments between 5 seconds and 30 minutes or the entire recording can be displayed. The entire time of the recording can be seen at the very top of the Analysis view.

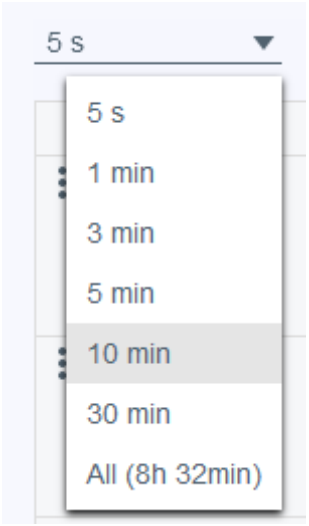

Figure 8 Selecting time scale

3.4 Scaling signal amplitude

When adjusting the signal automatically by clicking on the ~ symbol with two arrows, the minimum and maximum value of the current view is set as minimum and maximum value of the signal scale, with respect to certain minimum distance between the min and max values.

The signal amplitudes and scales can also be manually adjusted using the up and down arrows which appear when the mouse pointer is hovered above a signal row name. This way the signal will either flatten or show the changes in signal more clearly.

Figure 9 Automatic and manual scaling of a signal

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3.5 Changing the layout

3.5.1 Selecting visible channels

Visible signal channels can be selected from the list of available signal channels.

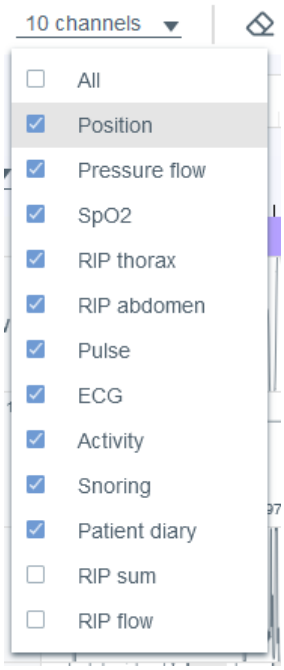

Figure 10 Visible channel selection

3.5.2 Changing the channel order

A channel row can be moved up or down by a drag and drop. Select the channel row you want to move and move the row while simultaneously holding the mouse button.

Figure 11 Changing the channel order

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3.5.3 Changing channel row height

Channel row height can be adjusted by hovering the mouse on the edge of the channel row until the mouse pointer changes to a symbol with two arrows pointing up and down.

Figure 12 Changing channel row height

3.5.4 Saving the layout

There are two layout options: Default and Your layout. After making layout changes, the current layout can be saved as Your layout by clicking Update your layout. Note that all changes done after Update your layout is selected discard the previously set layout changes.

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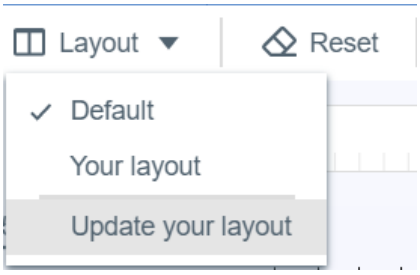

Figure 13 Layout options and saving the layout

Following items can be adjusted: order of channels, height of channels, which channels are visible and the selected time scale.

3.6 Event annotations

Event annotations are a central function in the Analysis view. Note that before manual scoring, the recording has been automatically pre-analyzed and event annotations have been set. These can be freely edited as required so for example, if an event has been pre-classified as a central apnea it can be changed to a mixed apnea or an obstructive apnea.

3.6.1 Accepting/ Removing event annotations

The unaccepted event annotations can be accepted by single-clicking the unaccepted event annotation. Note that pre-analysis produces also unaccepted event annotations as event proposals so that those can be easily accepted if necessary.

Event annotations can be removed by simply selecting the event annotation and then pressing “Delete” button from the keyboard or selecting “Remove” option from the list that opens. Note that after an event annotation has been removed it appears as an unaccepted event annotation. The unaccepted annotations have a grey dash line rectangle around them. The unaccepted event annotations are not counted for indexes or parameters in analysis results while all accepted event annotations are counted.

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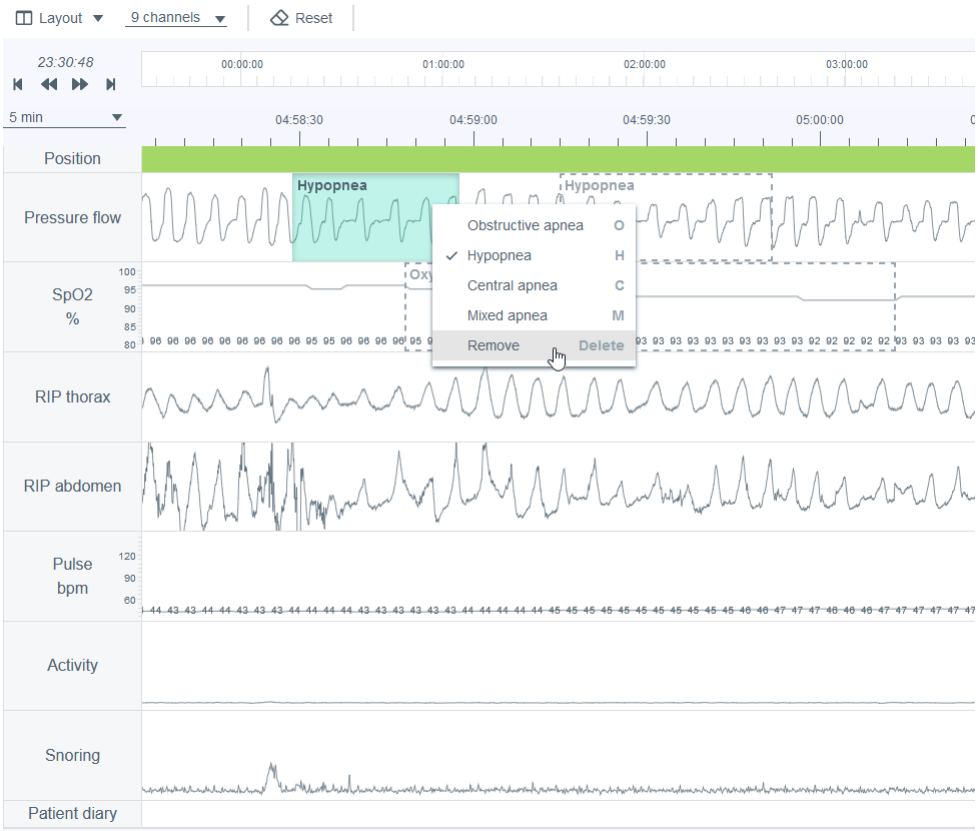

Figure 14 Removing an event annotation

3.6.2 Excluding part(s) of the recording from analysis

The part(s) of a recording can be excluded from analysis if there are for example artifacts or the patient was awake. The Evaluation period is defined based on exclusion event annotations so that the Evaluation period is the total recording time minus exclusion areas. You can exclude the part by painting the area and selecting exclude or you can paint the area and set start or end. The exclusion areas are disabled so that signal values under exclusion events are not included in analysis results (e.g. minimum heart rate). Additionally, event annotations fully under exclusion events are removed automatically. Optionally, it is also possible to select a reason (unknown, patient awake, sensor not attached, low quality) for an exclusion but the reason does not affect how the Evaluation period is calculated.

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Figure 15 Excluding a part of the recording – set time start

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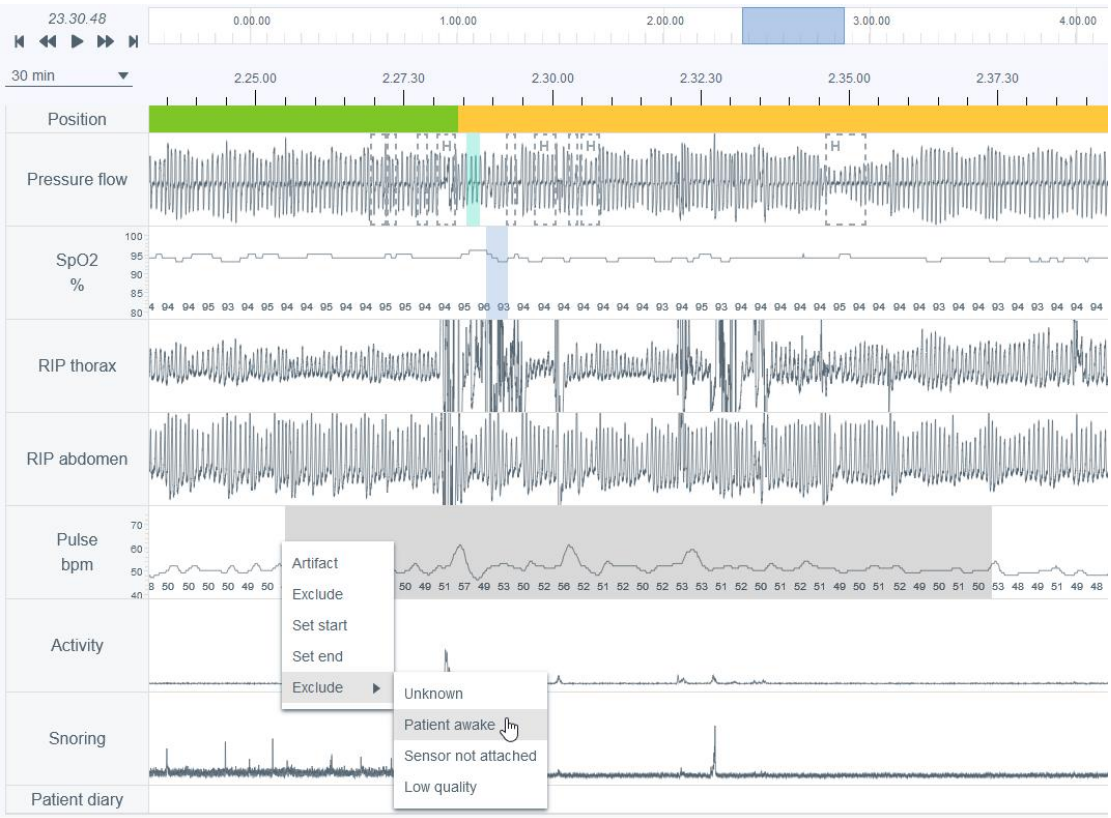

Figure 16 Excluding a part of the recording – selecting reason

3.6.3 Creating event annotations

Annotations can be easily created by selecting a part of any of the recorded signals (in the figure below a selection from Pressure flow) by clicking and holding the left or right mouse button and dragging the mouse pointer over the area to be annotated. After this is done a list of available options opens as shown in the figure below. User then selects the annotation class from the list or presses the related keyboard shortcut (shown also in the list). Note that the available options depend on the selected signal. Note also that annotations cannot be created totally inside the excluded signal periods.

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Figure 17 Creating event annotations

3.6.4 Editing event annotations

All event annotations, including automatically pre-analyzed event annotations, can be edited or removed by simply selecting the annotation and then selecting a suitable option from the list that opens or pressing the related keyboard shortcut (available shortcuts are shown also in the list that opens). In the example below a central apnea event annotation has been selected to be edited as an obstructive apnea.

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Figure 18 Changing annotation class

Annotation's duration can be changed by first hovering the mouse pointer over the annotation and then adjusting the annotation duration from the edges (start/end).

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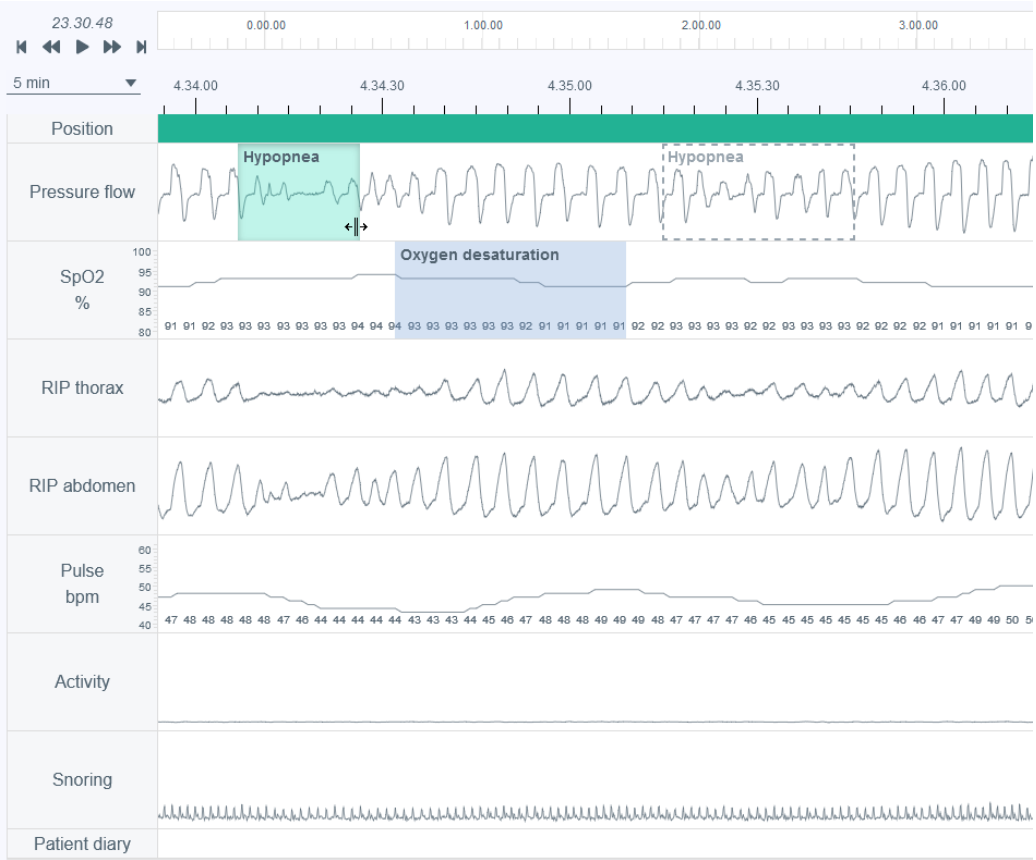

Figure 19 Changing annotation duration

3.6.5 Viewing event annotation details

Event annotation details can be viewed by placing a cursor over the event annotation. The information shown depends on the event type. Note that if a respiratory event is shorter than 10 seconds, the system will mention about it with a warning in the info box.

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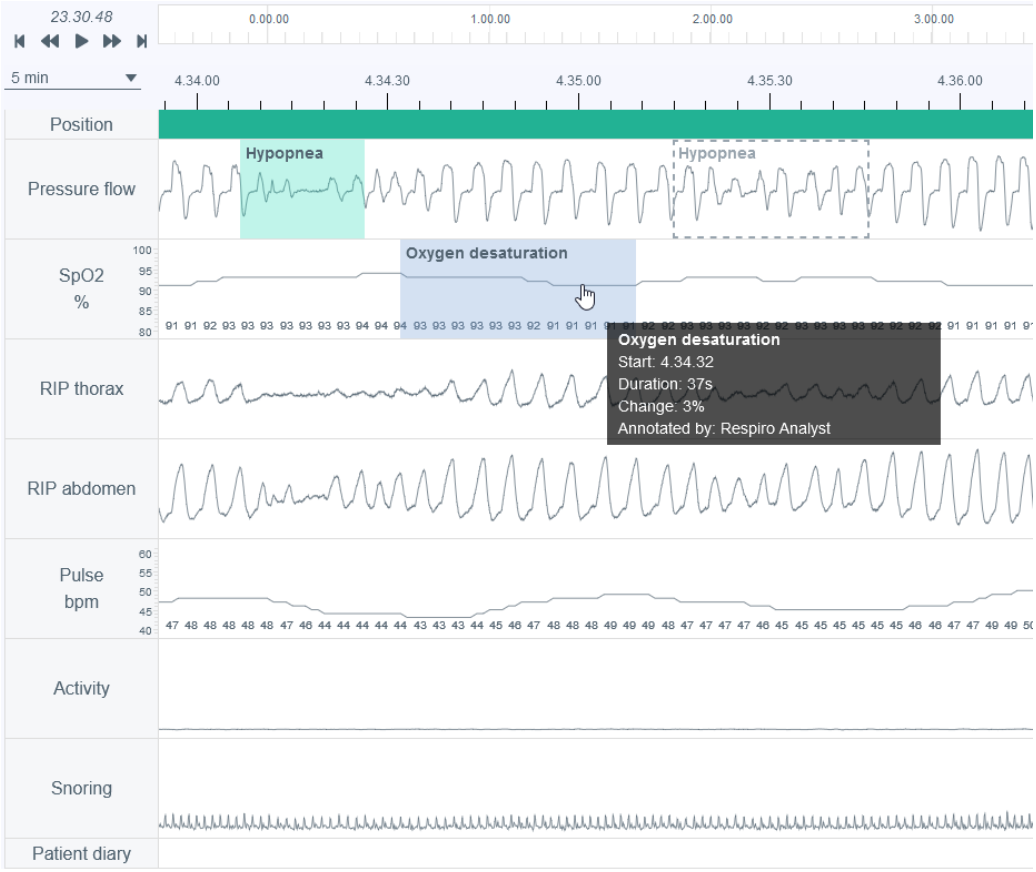

Figure 20 Viewing annotation details

3.6.6 Resetting event annotation changes

Event annotation changes can be reset using the “Reset” button on the top left-hand corner of the Analysis view. This resets all changes made by user(s) for the event annotations.

3.7 Statement writing

While writing the statement, a sleep specialist can examine the analysis results, anamneses and post-recording questionnaire information which can help to understand the overall status of the patient.

A statement can be saved so that a sleep specialist can continue and finish the work later or assign the recording to another user.

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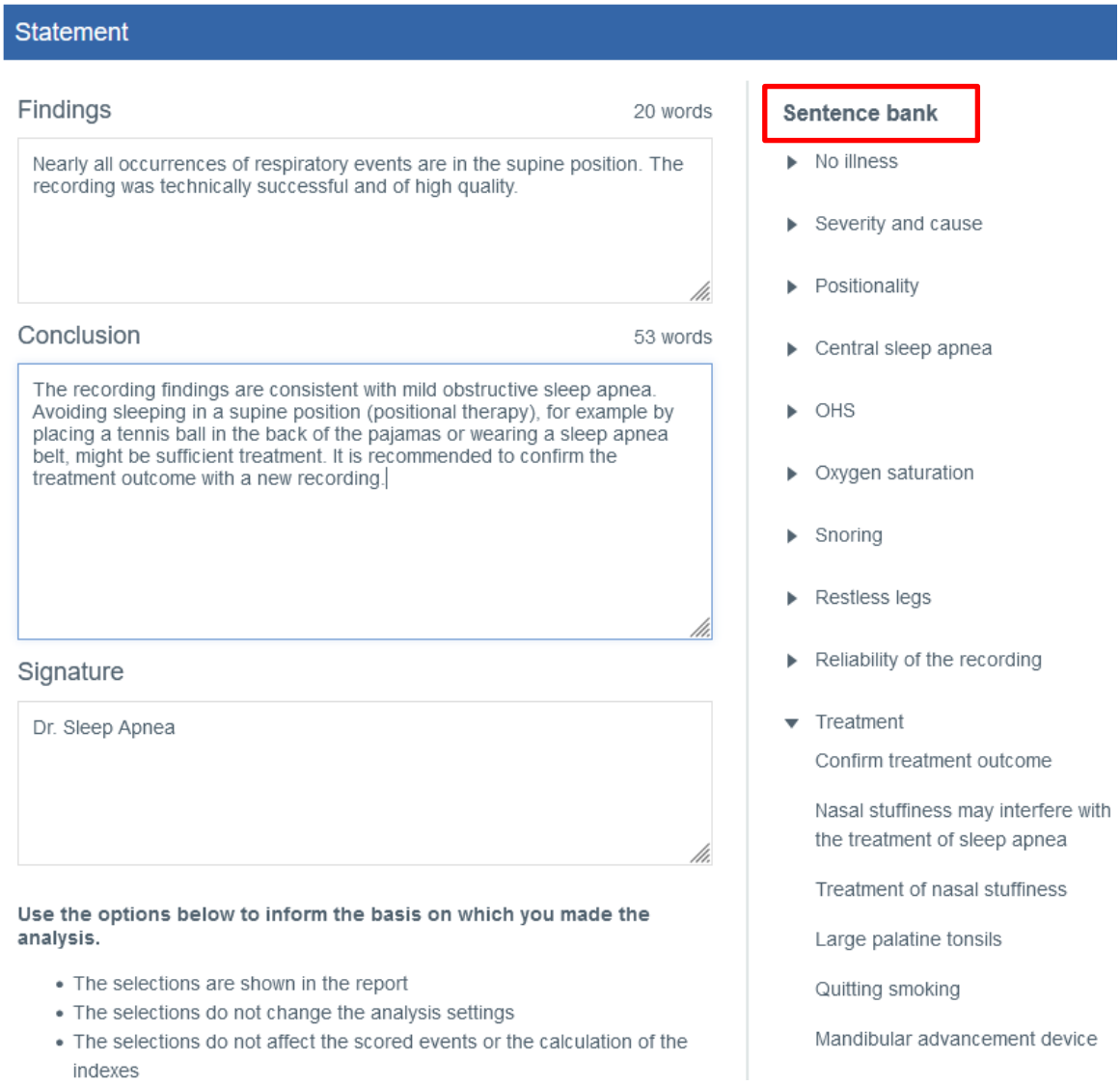

Figure 21 Statement section - Sentence bank

3.7.1 Using sentence bank

Statement tool includes a sentence bank that provides predefined sentences which speed up the statement writing for the findings and conclusions parts. The sentence bank is divided into different categories to make it easier to browse and organize them. The sentence bank is activated when a statement is edited. Sentences added from the sentence bank to findings and conclusion can be freely edited as required.

3.7.2 Signature

Signature should be added when the findings and conclusions are written and ready. Once a signature is given it is saved so it can be used again without a need to write a new one for every statement.

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3.7.3 Creating statement report document

After findings and conclusions are written and ready, a sleep specialist creates a statement report document that includes a written statement, analysis results, and information of the patient and recording. A preview of the report is available via clicking the “Preview report” button in the Statement section or clicking the Report tab. After review, a sleep specialist can accept the final report. Accepting the report will lead to the report being visible in MedicalSuite Center.

3.8 Troubleshooting

In case an error occurs in the Respiro Analyst due to e.g., lost network connection, a notification is prompted to check the network connection and reload the page. In this case follow the instructions and check carefully that changes you have made are saved.

If an unexpected error occurs in the internal calculations of the software, user is redirected to the MedicalSuite Center and the recording cannot be opened for analysis. In this case contact the manufacturer to report the error.

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4 PRODUCT SAFETY AND REGULATORY INFORMATION

4.1 Respiro Classification EU

MDR Classification: Class IIa medical device

4.2 EU Declaration of Conformity

Certificate of Conformity and Declaration of Conformity in accordance with the applicable directives and standards can be requested for Respiro Analyst from bbs@bittium.com.

4.3 Reporting of serious incidents

Any serious incident that has occurred in relation to the software must be reported to the manufacturer and the competent authority of the country in which the user and/or patient is established. Manufacturer contact information is provided at the end of this document.

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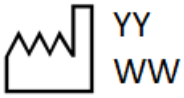
5 SYMBOLS AND LABELS

Symbol	Description
CE 0537	The device is CE-marked for the conformity to Council Regulation 2017/745 regarding medical devices.
	Consult instructions of use.
	Manufacturer.
	Date of manufacture.
MD	Medical device.
REF	Indicates the catalogue number so that the medical device can be identified.
	Warning statements describe conditions or actions that can result in personal injury or loss of life.

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