Scoring Respiratory Events

The scorer will identify the following categories of discrete breathing events: obstructive apneas, central apneas and hypopneas.

Obstructive Apneas are identified when the amplitude (peak to trough) of the airflow (thermistry) signal decreases to a flat or almost flat signal (showing a 90% reduction of the amplitude of "baseline" breathing for 90% of the duration, this will be known as the 90% criteria) if this change lasts for ≥ duration of 10 seconds. It will be classified as an obstructive event unless it meets the criteria for a central apnea (absence of effort on both bands). *Baseline breathing* is defined as a period of regular breathing with stable oxygen levels. Without reliable airflow, the event will default to hypopnea. Identification of an apnea does not require a minimum desaturation criterion.

Hypopneas will be identified if ≥50% reduction of amplitude is visualized on either the nasal cannula or the respiratory SUM channel for a duration of at least 10 seconds and associated with >=3% desaturation. If the SUM and nasal cannula are not present, if a 50% reduction is seen on both belts (thoracic and abdominal), or 50% reduction on the airflow, and associated with >=3% desaturation, then a hypopnea may be scored. Discernable changes with desaturations that do not meet the rules of hypopnea are NOT scored as hypopneas. Identification of a hypopnea **does** require a minimum desaturation ≥3%.

A **Central Apnea** event is scored if NO displacement is noted on both chest and the abdominal inductance channels. Minimum duration of event is ≥10 seconds. Identification of an apnea does not require a minimum desaturation criterion. CA will be scored when all signals are "flat" unless signal deflection is due to cardiogenic artifact.

NOTE: CA is scored irregardless of desaturation

EXCLUDE: CA events that are post movement or post sigh (follows >= 150% of baseline effort) unless these are part of a series in which case scoring begins with the second event.

Hypopnea (H) must be associated with a 3% desaturation and characterized by either:

- 50% reduction in a Nasal cannula or the respiratory SUM channel + 3%
- 50% reduction in either belt + 3%
- Discernable reduction or switch to paradox in a "reliable" airflow signal or either effort channels + 3% desat
- When the airflow signal is unreliable ("choppy"), then obstructive events cannot be reliable scored. Then, they can be scored as hypopneas if they meet criteria.

Distinguishing Between Hypopneas and Apneas

This distinction only can be made for events in which airflow by thermistry is interpretable. (If airflow is uninterpretable, the event-based on inductance data is considered by default to be a hypopnea but must be associated with >=3% desat to be scored as a hypopnea.). Apneas are marked if >90% of the event shows absent or nearly absent airflow on the thermistor channel (and this reduction is 90% the amplitude of the surrounding breaths).

Distinguishing Between Central and Obstructive Events

Only events in which there is clear data from both the abdominal and chest signals can be distinguished as central or obstructive. (Events where one or both of these channels are missing or contain artifact are considered obstructive or hypopneic, but a hypopnea must be associated with ≥3% desaturation).

Often determining whether an event is central or obstructive is influenced by where the event is noted to begin and end. Sometimes small efforts are seen following a completely flat area, followed by a large ("breaking") breath. If a single non-artifactual deflection less than 25% of baseline breathing is seen at the beginning or the end of the period of flat signal, the event will be marked as central. (This recognizes that shortening the event slightly would make it a central event). However, if two or more consecutive small breaths less than 25% of baseline breathing (providing airflow is flat) are seen in the period in question, the event is marked as obstructive.

Determining whether an event is central or obstructive in areas of periodic breathing can be difficult because of uncertainties in deciding when to start and end such events. Often these areas contain breaths that gradually increase and decrease, sometimes decreasing to an imperceptible level. Marking longer events in these areas would result in identifying obstructive events; shorter events are more likely to appear central. When it is unclear as to when to start an event, look for evidence of paradoxical breathing. Change in phase angle between thoracic and abdomen is an indicator of upper airway obstruction (such events will be designated as obstructive). When still unclear, the event duration will be marked using the airflow channel. Identify the areas where airflow stops and starts, then assess whether the period is also associated with effort on either channel/band. Then the inductance channels will be visualized to decide whether during this period, any effort occurred. If any effort was visualized, the event will be considered "obstructive," otherwise, "central."

Duration criteria: The beginning of an Apnea/Hypopnea is marked at the end of the last "normal" breath; the end of the event is identified as the beginning of the first breath that exceeds the amplitude of the first reduced breath used to mark the beginning of the event. Duration is based on a "trough to trough" marking lasting at least 10 seconds.

Clarification of amplitude threshold relative to baseline: If one non-artifactual deflection is less than 25% of baseline breathing, then it is a central. If two deflections are less than 25% of baseline breathing providing airflow flat, then it is obstructive. Flat excludes cardiogenic oscillation. If airflow reliable and not flat or airflow unreliable, then default to hypopnea if the hypopnea is associated with ≥3% desaturation.

Contiguous respiratory events that have a single respiratory effort in the middle of two periods of absent efforts, each <6 seconds, <u>AND</u> that are associated with a 3% or greater desaturation should be combined into a single Hypopnea event.

Nasal Flow Limitation

Nasal flow limitation is derived from the nasal cannula signal. A normal flow signal will present as a regular sinus rhythm and curve. Flow limitation may occur with increase upper airway resistance, not sufficient enough to cause discrete apneas and hypopneas. A regular sinus curve will transform into a signal that resembles a lowercase 'H."

Desaturation (D) events

Isolated desaturation (non-artifact-related) that are unassociated with either apneas or hypopnea, but which have a clear beginning and end should be marked as **Desaturation** (**D**) events if they include a 3% or great decrement in pOx tracing from a stable baseline. Prolonged events (>= 30 seconds) without a clear beginning or end should be deleted.

Summary of Scoring Process

Each study will be manually scored in the two passes:

During the first pass:

- Review the channels and manually set time of "analysis start" and "analysis stop."
- The Respiratory signals from each study will be reviewed on a 2-5 minute basis (screen).
- The saturation channel will be edited for artifact and respiratory events will be marked manually according to the rules stated above using all signals.
- ECG is manually reviewed for any irregularities.

During second pass:

- Respiratory data (abdominal/chest/saturation) will be reviewed on 5 minute pages. The saturation channel will be edited for artifact and respiratory events will be marked manually according to the rules stated above using only Respiratory belts.
- Obstructive will be reclassified to either a Hypopnea or a Mixed Apnea (mixed apnea tag is chosen for report purposes only)
- "Mixed Apnea" is marked for any events that have a 50% reduction in either belt or sum with < 3% desaturation.

During 12 week treatment pass:

- Respiratory data (abdominal/chest/saturation) will be reviewed on 5 minute pages. The
 saturation channel will be edited for artifact and respiratory events will be marked manually
 according to the rules stated above using only Respiratory belts.
- Obstructive events will not be scored. Studies are collected without flow signals.
- Hypopnea, Central Apnea, and a "Mixed Apnea" will be scored using the same rules above.

Exclusion criteria during Embletta Screening

- 1) Severe OSA defined by
 - a) nocturnal oxygen saturation < 85% for > 10% of the record or
 - b) AHI <15 or >50
- 2) Central sleep apnea index > 5

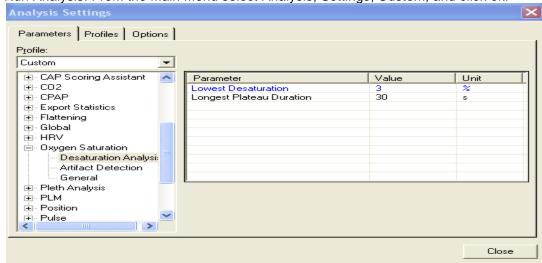
Those with markedly severe OSA (AHI >50; estimated prevalence 2-3%), will be excluded due to the severity of the physiological abnormality

Remlogic Software Analysis



- 2. Import recording: From the main menu, select File, import, Recording.
- 3. The Browse for folder dialog is displayed. Browse for recording that should be imported and select the file. Then click ok. *A progress bar is displayed while the recording is being copied in the Recording Manager.*
- 4. Open study and load scoring workspace.
- 5. Review signals, and set Analysis start (+) and Analysis stop (-).

6. Run Analysis: From the Main Menu select Analysis, Settings, Custom, and click ok.

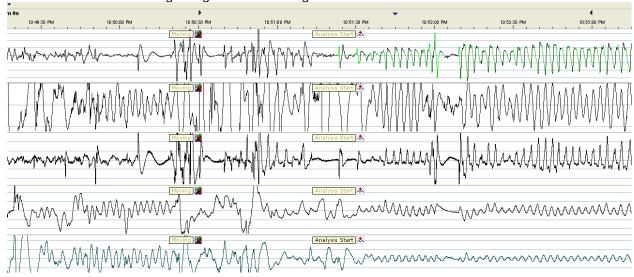


- * Under the custom setting verify the lowest Desaturation value to be 3
- 7. Run Analysis: From the Main Menu Select Respiratory Analysis. Select Thermistor for Apnea and select Sum for Hypopnea.
 - *If the thermistor is unreliable, click on skip analysis. If the SUM is unreliable, either default to Nasal flow or a working reliable belt.

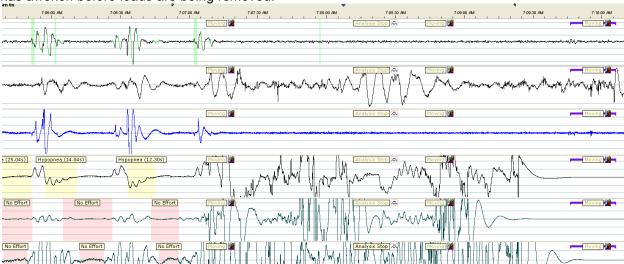
Analysis start and Analysis stop

The Analysis start and stop events determine what parts of the recording should be analyzed by the automatic analyzers. These events are marked in order to identify the analysis period.

 When reviewing signals for analysis start, look for an area where it appears the participant has settled down at the beginning of the recording.



 When reviewing signals for analysis stop, look for an area where it appears the participant has awoken before leads are being removed.



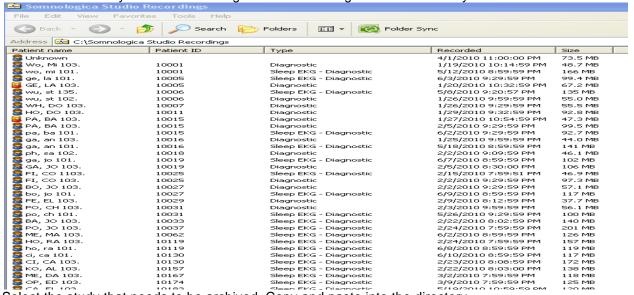
 Once you have marked Analysis start and Analysis stop your ready to begin the Respiratory Analysis portion.

Saving Scoring template, Generating Reports and Archiving

 Any recording that has been reviewed, analyzed, and scored should be saved as a workpad file- Save with the file name SCORED. To save the work pad Click on



- To generate a report from the Main Menu select Reports. HeartBeat Embletta sleep reports.*The report template used for the HeartBEAT study has been customized. If any issues arise with report generating contact EMBLA tech support.
- 3. Save the report with the study ID as a doc file and then resave as a txt file.
- 4. To archive the study locate the Remlogic studio recording folder located on your local drive.



5. Select the study that needs to be archived. Copy and paste into the directory.

6. The study once pasted into the directory will have a long string of letters and numbers.



Rename the file to reflect the study ID and the date the study was recorded and what stage in the scoring process.

10005_01202010s1 10005_01202010s2

10005_06032010s3 s1 first pass, s2 second pass, and s3 12week.

7. The folder should contain the following files.

 ■ 10027.docx
 145 KB
 Microsoft Office Wo...

 ■ 10027.txt
 3 KB
 Text Document

 → Flattening.ebm
 1,853 KB
 RemLogic Trace File

 ■ Recording.esrc
 9 KB
 ESRC File

 ➡ scored.ewp
 595 KB
 RemLogic Workpad ...

 ➡ Traces.edf
 51,228 KB
 EDF File