Tech Corner

Sleep Apnea Monitoring (SAM)

NOTE: PLEASE NOTE THAT THE FOLLOWING INFORMATION IS A GENERAL DESCRIPTION OF THE FUNCTION. DETAILS AND PARTICULAR CASES ARE NOT DESCRIBED IN THE ARTICLE. FOR ADDITIONAL EXPLANATION PLEASE CONTACT YOUR SALES REPRESENTATIVE.

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MicroPort™ CRM

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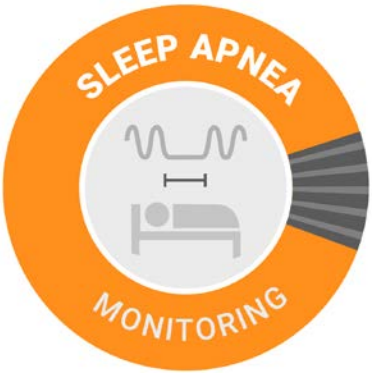
Sleep Apnea Monitoring* (SAM)

The Sleep Apnea Monitoring (SAM) function provides the physician with automatic screening of pacemaker patients for the risk of severe Sleep Apnea. SAM has been designed to detect, count and report abnormal breathing events during the night. These events are detected using the minute ventilation signal. This allows the calculation of respiratory disturbances over the last six months, representing sleep disordered breathing events at night.

The SAM (Sleep Apnea Monitoring) feature provides information on the number of abnormal breathing patterns in the minute ventilation signal at night, which could be used as an indicator of possible underlying breathing pathologies such as sleep apnea syndrome. Depending on the patient profile and/or other symptoms, the physician may discuss with the patient and may include a neurologist or a sleep specialist, as appropriate.



* *Not available for distribution or sale in the USA*

RELIABLE SCREENING FOR SEVERE SLEEP APNEA

Clinical need

Sleep Apnea is highly prevalent in pacemaker patients, often left undiagnosed[1] and untreated.

- The risk of HF is 58% higher in severe Sleep Apnea patients[2]
- The risk of AF is 4 times higher in Sleep Apnea patients[3]
- Sleep Apnea patients show resistance to pharmacological treatment [4,5]
- More recurrence of AF after AF ablation and cardioversion[6,7]

Designed solution

Correlated with the gold standard Apnea-Hypopnea Index[†], the 6-month trend data of SAM helps to monitor patients at risk.

Screening and monitoring patients with severe Sleep Apnea may lead to earlier and more optimal management of cardiovascular comorbidities[8], such as AF and HF.

AVAILABILITY

Sleep Apnea Monitoring is available in Microport single and dual-chamber pacemakers, from REPLY 200 and the next generations[‡]. Refer to the user's manual furnished with the device to check availability of the feature (www.microportmanuals.com).

SYNONYMS

SDB (Sleep Disordered Breathing) Monitoring.

INDICATION

Any patient may benefit from a screening of the Sleep Apnea.

There is no contraindication to this type of monitoring.

[†] *AHI, recorded using night polysomnography (= number of events / number of hours of sleep)*

[‡] *except OTO and CELEA pacemakers*

DESCRIPTION OF OPERATION

Minute Ventilation

The Minute Ventilation signal (MV) represents the expansion/contraction of the thorax in real time when the patient is breathing. It is derived from the periodic measurements of the transthoracic impedance.

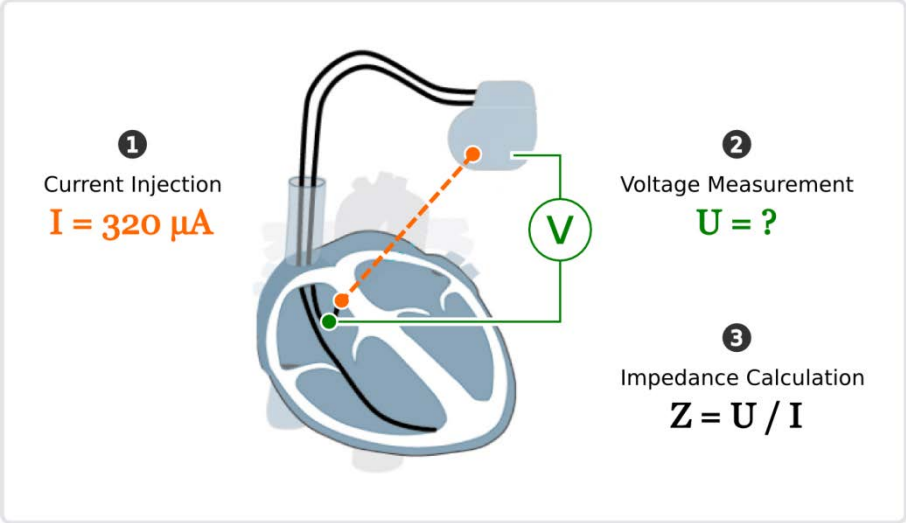
Dual-sensor rate responsive pacemakers are equipped with Minute Ventilation detection features for the purpose of rate response. The SAM function aims to use the MV signal in another way: the respiratory pattern analysis.

Transthoracic impedance measurement

The pacemaker determines MV by measuring transthoracic impedance. By emitting very low pulses of electrical current between the lead tip and the pacemaker, the device is able to measure the transthoracic impedance as it changes with inspiration and expiration.

Note: In SR devices, a bipolar lead is required to operate the MV sensor.

Variations in lung volume during breathing cause the impedance to change (for example due to the tissue dilatation, volume of air in the lungs, volume of blood in vessels, etc...), resulting in a change in the measured voltage. By using Ohm's Law, which states that the impedance (Z) is equal to the voltage (V) divided by the current (I) (Z = V/I), the device can determine the transthoracic impedance over time (dZ = dV/I). This measurement is performed every 125 ms.



Dual chamber pacemaker - Minute Ventilation. Current is injected into the system between the tip electrode and pacemaker. The voltage between the ring electrode and the pacemaker is measured, and the resultant impedance (Z) is calculated.

Calculation of transthoracic impedance: Z_{th} (Ohms)

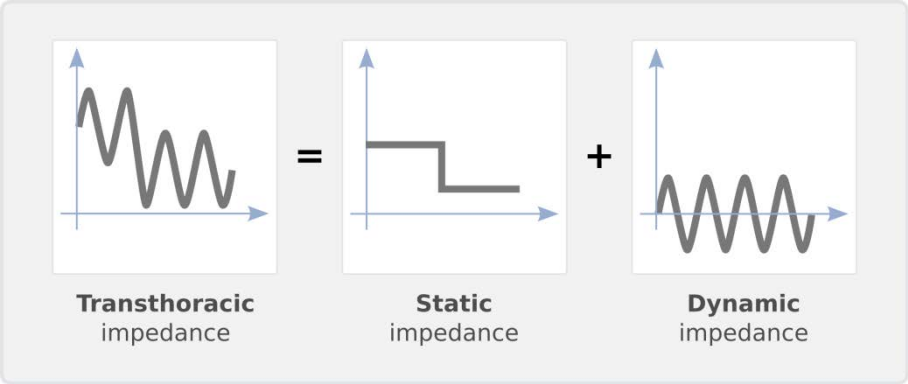
$$Z_{th}(\Omega) = \frac{dV\ (V)}{I\ (A)}$$

Patient position change management

A change of the patient's position results in a sudden change of the static impedance, moving from a fixed onset to another one.

The static impedance is related to fat, muscle and conjunctive tissue impedances, as well as the effects of lead position or long term evolution of body fluids. It will not be taken into account in the transthoracic impedance measurement. This temporary instability is removed via a high pass filter.

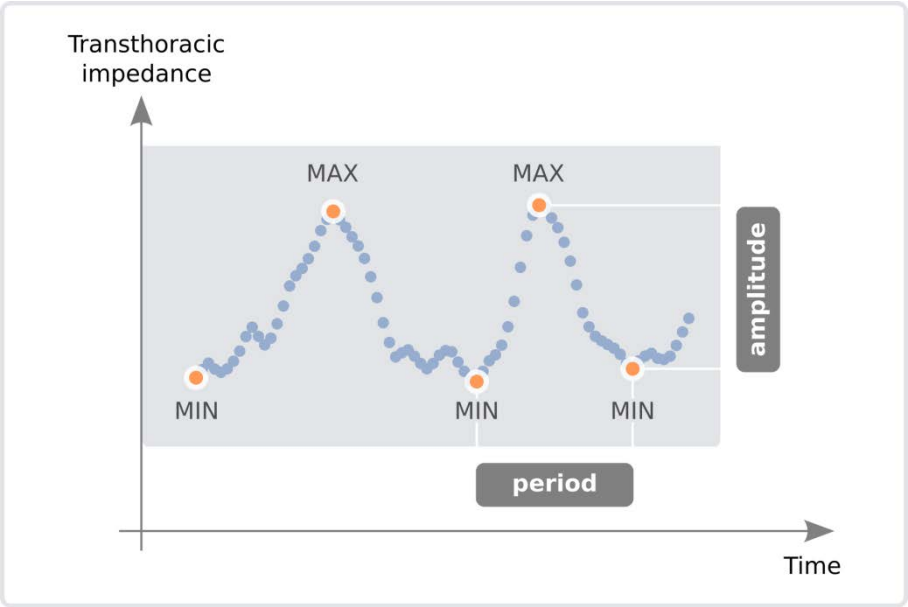
In the end, only the dynamic impedance is analyzed by the pacemaker and if the breathing cycle is marked "sudden change of static impedance", SAM invalidates the cycle.



Minute Ventilation Calculation

The pacemaker measures the Period and Amplitude of each breathing cycle, in order to calculate the Minute Ventilation (VE), which corresponds to the Amplitude (A) divided by the Period (P):

$$\text{Minute Ventilation (VE)} = \frac{\text{Amplitude } (\Omega)}{\text{Period (min)}}$$



Measure of MV in dynamic impedance: *For each cycle (inspiration-expiration), the sensor measures a MIN (+) and a MAX (+) value and determines an AMPLITUDE and a PERIOD.*

SAM algorithm

Abnormal breathing pattern identification

For the SAM application, transthoracic impedance signal is analyzed during the night to detect abnormal breathing patterns.

Abnormal breathing patterns are counted, and reported in the programmer screen.

At each identified breathing cycle, MV sensor provides SAM with:

- the period,
- the amplitude,
- a marker (characteristic of the reliability of this cycle).

Using these data, SAM performs the following operations:

1. Validation/exclusion of the cycle (according to the reliability marker and/or to previous cycles)
2. Check for ventilation pauses
3. Check for ventilation reductions
4. Confirmation of pause/ventilation reduction diagnostic (if any)
5. Update of the rolling variables (reference)

Each operation is detailed below:

1. Validation/exclusion of the cycle

The current cycle is excluded if:

- it reaches the timeout (period > 90 sec[§]). The cycle immediately following this time out cycle is also excluded,
- it is marked "sudden change of static impedance" (unstable signal). The cycle immediately following this sudden change of impedance cycle is also excluded,
- it presents a pronounced increase of period[**] compared to the previous cycle (except suspicion of apnea),
- it presents a pronounced increase of amplitude[††] compared to the mean amplitude of the 4 previous cycles (except exit of hypopnea),

When a pause or ventilation reduction is confirmed, the following cycle is excluded.

2. Check for ventilation pauses

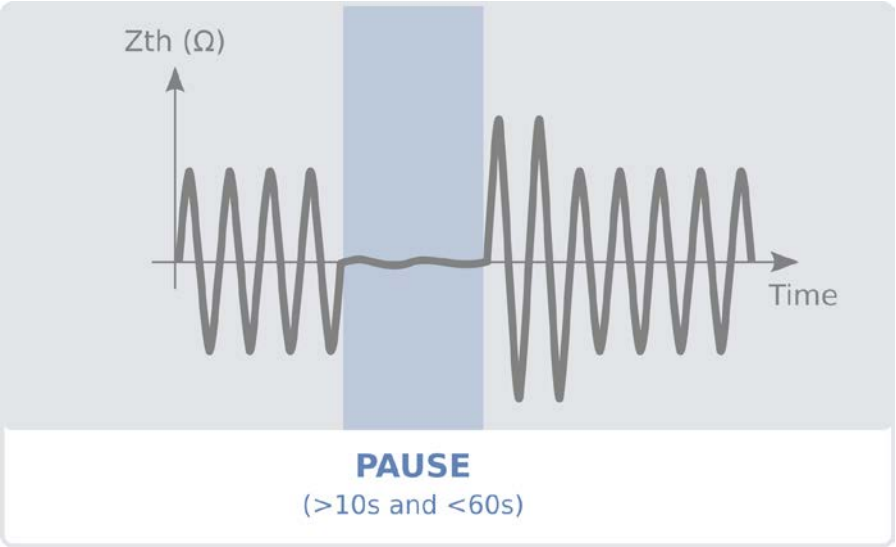
If the current cycle is not excluded, it is checked for pause as follows:

If the current cycle's period is greater than 10 seconds and shorter than 90 seconds[§], the current cycle represents the ventilation pause pattern.

[§] 60 sec in REPLY 200, KORA 100, KORA 250, ENO, TEO, and REPLY CRT-P pacemakers

[**] i.e. an increase of 4 seconds compared to the period of the previous cycle

[††] i.e. an increase of 4 times the average of the 4 previous amplitudes



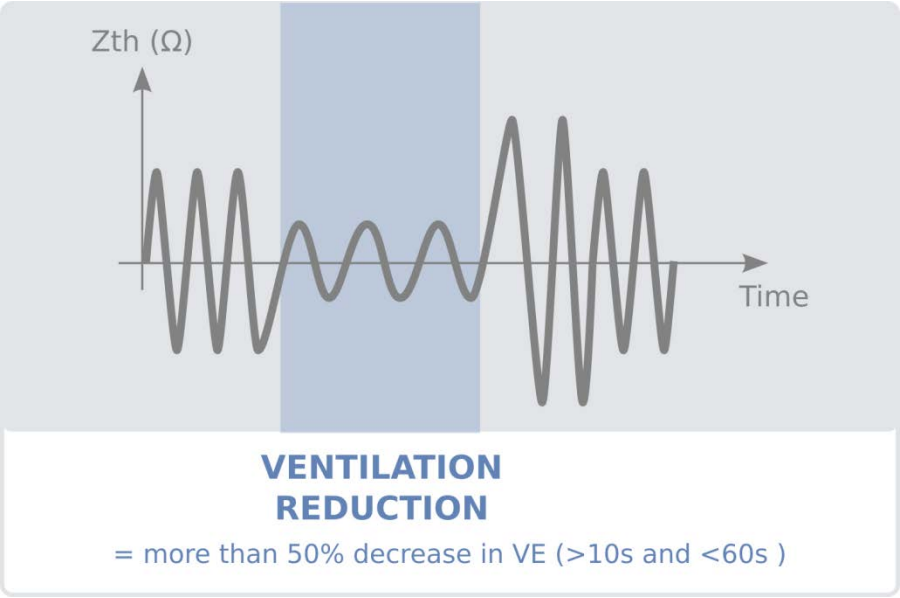
3. Check for ventilation reduction

If the current cycle is not excluded and does not present the pause pattern, it is checked for reduction as follows:

- If the VE value is lower than 50% of the mean 8 previous VE values, then the current cycle is suspected to be the beginning of a reduction and the mean 8 normal VE value is fixed as the VE reference. The exit of suspicion occurs when the VE value reaches the reference.
- If the cumulative time in suspected reduction is greater than 10 seconds and shorter than 90 seconds[**], the current cycles represents the ventilation reduction pattern[§§].

[**] 60 sec in REPLY 200, KORA 100, KORA 250, ENO, TEO, and REPLY CRT-P pacemakers

§§ As soon as a cycle is longer than 10 seconds, the reduction suspicion is cancelled and a pause suspicion starts.



4. Confirmation of ventilation pause/ventilation reduction diagnostic (if any)

Once a pause or reduction pattern is identified, the event is confirmed if less than 4 excluded cycles were identified in the 16 previous cycles preceding or during the suspicion.

If the event is confirmed, the corresponding counter (number of pauses or number of ventilation reductions) is increased.

5. Update of the rolling variable (reference)

If the cycle is not excluded and not suspected to be a pause nor a ventilation reduction:

- Update the last 8 VE values with the current VE value,
- Update the last 4 amplitudes with the current amplitude.

If the cycle is excluded, the above values are not updated.

Calculation of the RDI

At the end of the monitoring period, which is a 5-hour programmable period between 22:00 and 06:00 (by default 00:00-05:00), the total number of ventilation pauses and reductions is divided by 5 to obtain an occurrence of events per hour, called the Respiratory Disturbance Index (RDI).

$$\text{Respiratory Disturbance Index (RDI)} = \frac{\text{Number of ventilation pauses and reductions}}{\text{Number of hours of monitoring (5 hours)}}$$

Note: The SAM monitoring period should be adjusted based on the patient's sleep habits.

RDI Severity threshold: The DREAM study showed that patients with RDI > 20 are at risk of severe Sleep Apnea with 89% sensitivity and 85% specificity[9].

Validation of the night

If the transthoracic impedance signal is "disturbed" for the night, the RDI is not displayed: actually, a RDI calculated on a noisy signal (for example EMI) is not relevant, because it is based on pauses and ventilation reductions of "noise" instead of the breathing signal of the patient (this can occur when a patient is continuously moving when sleeping, or when a patient is active during the monitoring period).

The proportion of cycles marked with "sudden change of static impedance" (unstable signal) and cycles marked with "abnormal signal to noise ratio" (noisy signal) is calculated and used to determine whether or not to display the RDI of the night.

If more than 400 unstable cycles per hour or more than 400 noisy cycles per hour are detected, the night is considered as invalid.

PROGRAMMING

Programmable parameters

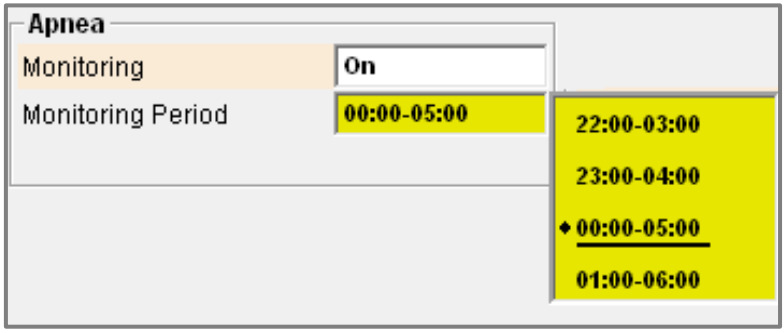
SAM Monitoring parameters are summarized in the table below:

Parameters	Values (bold: value by default
SAM Monitoring*	ON ; **OFF**
Monitoring Window	22:00-03:00 ; 23:00-04:00 ; **00:00-05:00** ; 01:00-06:00

**Automatic activation at first pacemaker interrogation after implantation*

Monitoring period

Respiratory cycles are analyzed to report abnormal breathing events during a 5-hour programmable period during the night. This fixed, adjustable time window at night can be programmed between 22:00 and 06:00 (by default 00:00-05:00) on the parameter screen.

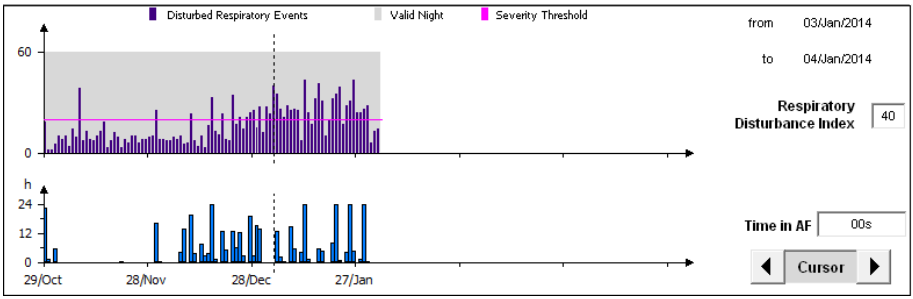


REPLY 200 parameter screen

AIDA Memories

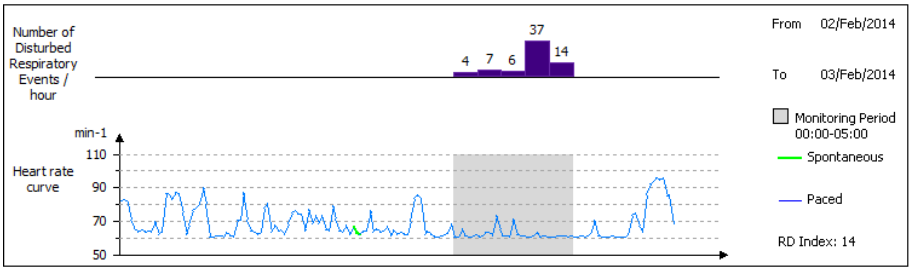
6 month data

A respiratory disturbance index (RDI) is calculated every night and reported since the last follow-up (up to the last 6 months). On the screen it is shown together with the time spent in AF (data per 24 hours).



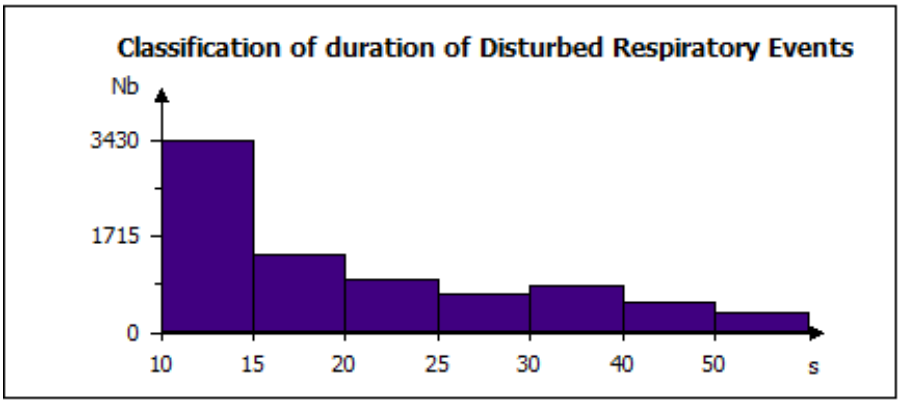
Last 24h night

The hourly number of RDI during the monitoring period is presented in parallel with the heart rate curve.



Histogram

Each column represents the number of events (since the last follow-up) for a given duration.



STUDIES AND RESULTS

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Refer to user's manual furnished with the device for complete instructions for use (www.microportmanuals.com).