



ApneaGraph Spiro – AG200: Similarities & Differences.

From 2007 to 2013 / 2014 there has been an intensive international work on the diagnosis of Sleep Related Breathing Disorders (SRBD) and the Obstructive Sleep Apnea (OSA), resulting in the standardised recommendations from the American Academy of Sleep Medicine (AASM) 2014. This has several implications for the diagnostic tools used, and has led to an upgrade of the AG200.

The new unit is named ApneaGraph Spiro and has incorporated all the new AASM parameters. Awakenings due to increased breathing effort, Respiratory Effort Related Arousals (RERAs), are now included in the international OSA diagnosis: **OSA = AHI + RERA**. The RERAs constitute up to 50% of the OSA events, recommended diagnosed through Poes measurements, the new gold reference standard for respiratory effort. Total Sleep time (TST) demonstrating awake or asleep patients are reliably measured by actimetry. Thus, EEG is not needed.

The recommended parameters for obtaining the correct Internationally accepted diagnosis are: Airflow, Respiratory Effort (RE), Respiratory Arousals (RA), Total Sleep Time (TST), Oximetry, Pulse Recording and Body Position. The ApneaGraph Spiro (AGS) fulfils these criteria as the only device in the market.

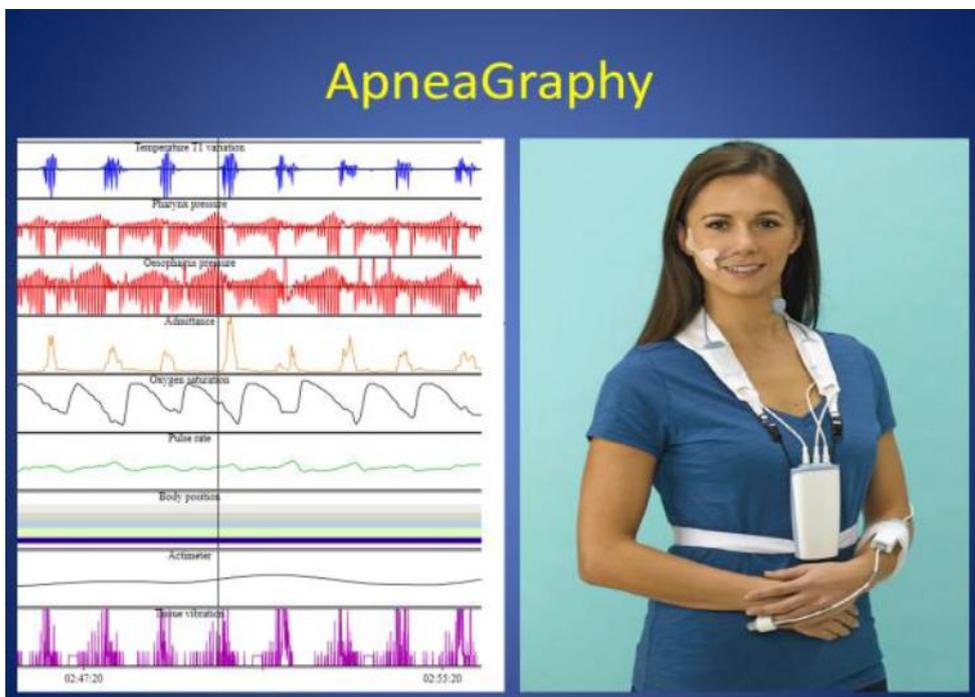
New meta-analyses report Continuous Positive Airway Procedure (CPAP) treatment compliance on 10 – 40%, and question the method as a gold standard. Additional treatment modalities as mandibular devices (MAD), surgery and positional trainers are requested. Some of these need additional information on the site of pharyngeal obstruction, for which Drug Induced Endoscopy (DISE) is frequently recommended. This despite of the far too short examination time as well as dubious and random methodology, hardly without conclusive positive outcome documentation. Unlike this, pharyngeal micro pressure-transducers, as incorporated in the new AGS, can objectively identify and document the site of narrowing, second by second, through the whole night.

The differences between recorded parameters of the AG200 and the AGS are listed in the table below.

AG 200	ApneaGraph Spiro
Breathing : Internal temperature sensors in the Pharynx. Respiratory Effort (RE) : Oesophageal Pressure. Pulse Rate (PR). Oxygen Saturation (SpO2).	Breathing : Internal temperature sensors in the Pharynx. Respiratory Effort (RE) : Oesophageal Pressure. Total Sleep Time (TST) : Actimetry. Respiratory Arousal (RA): Flow/Pressure Relation. Respiratory Effort Related Arousals (RERA) : Breathing Effort induced Arousals. Pulse Rate (PR). Oxygen Saturation (SpO2).

<p>Body Position: 2D Accelerometer (Supine, Prone, Left, Right).</p> <p>Snoring: Internal microphone in data logger.</p> <p>Site of Obstruction: Pharyngeal pressures.</p>	<p>Body Position: 3D Accelerometer (Supine, Prone, Left, Right, Upright).</p> <p>Snoring: Neck vibration & Airborne Sound in 4 frequency bands.</p> <p>Site of Obstruction: Pharyngeal pressures.</p>
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Some of the parameters and the equipment are shown below:



In addition to the new, innovative parameters, the design of the catheter has been improved. The diameter is now 1 mm diameter, it is soft and bendable, easy to introduce and without impact on the sleep quality. It is no longer vulnerable to bending and stretching. The entire catheter unit can be immersed in cleaning solution and several liquids may be used.

The sleep parameters required from polysomnography (PSG) in the diagnosis of SRBD / OSA are TST and RA. These can be reliably recorded and automatically interpreted by AGS respiratory parameters alone. Consequently, PSG with the cumbersome Electro-Encephalo-Graphy (EEG), is no longer needed.

RERAs are shown to have an effect like other OSA events and are found in up to 50% of the disease. They terminate with arousals, and can have high, low or multilevel pharyngeal localisation. The levels of RERA localisation are measured, second by second through the whole night, and summarised in the automatic analysis. As they are mostly found in sufferers with mild to moderate OSA having

predominantly upper pharyngeal narrowing, they are often subject to surgery, with satisfactory results.

Snoring is measured directly on the patient as vibrations of neck tissue (insensitive to background noise), as well as indirectly as airborne sound by a microphone. Different frequencies are recorded, but they are not calibrated against a decibel standard. When snoring occurs, different levels of pharyngeal narrowing can be demonstrated. Consequently, the level of snoring sound can be summarised for the whole night. This will have an impact on the choice of the choice of treatment - surgery or not.

Moreover, all the OSA events are characterised by the magnitude of Respiratory Effort through the whole night, expressed by the oesophageal pressure. This is considered the Gold Reference Standard for breathing effort, and an extremely important parameter when judging the degree of OSA. Used in evaluation of snorers, it can tell if the patient is a sufferer or not. A question that has been posed but not answered until now.

Although the AG200 has been used in ten thousands of patients, giving reliable diagnosis and important treatment advices, we must acknowledge the new information put forth and strive to fulfil the international diagnostic and treatment recommendations.

For this purpose, we have developed the **ApneaGraph Spiro**, a complete diagnostic tool for automated home recordings in diagnosing Obstructive Sleep Apnea and Sleep Related Breathing Disorders.