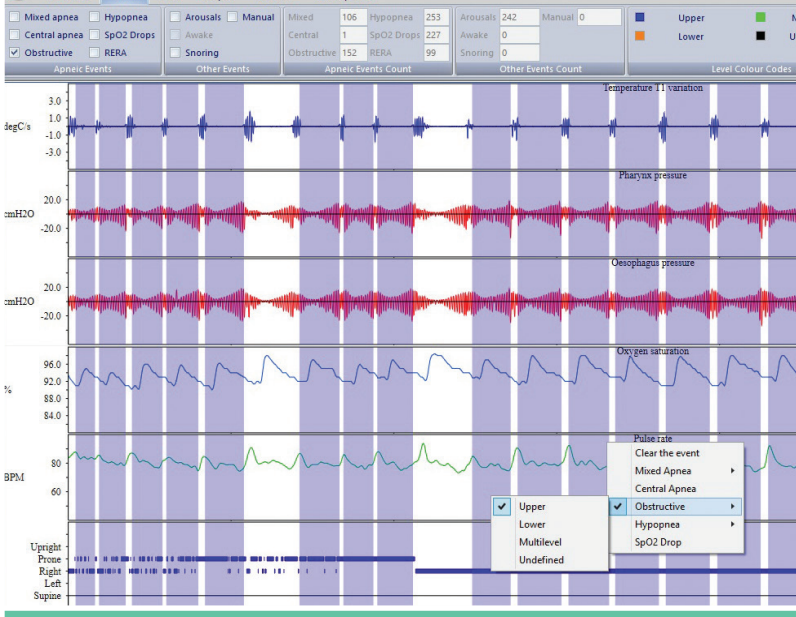


ApneaGraph® Spiro

Diagnose obstructive sleep apnea. Locate site of obstruction. Improve patient outcome.

- Ambulatory device for detection of Sleep Related Breathing Disorders (SRBD) and gold standard differentiation of Central – vs Obstructive Sleep Apnea (OSA)
- Diagnostic information on type, severity and location of OSA
- Guidance to optimum treatment e.g. surgery, mandibular advancement and CPAP
- **NEW:** Location of obstruction in snoring as well as OSA
- **NEW:** Improved snoring detection
- **NEW:** Actigraphy highlighting periods of patient activity (wake periods)
- **NEW:** Respiration frequency display over whole night recording
- **NEW:** Wireless communication for ease of set up and data review

Spiro Medical

ApneaGraph® Spiro. A focused diagnostic device for the assessment of sleep related breathing disorders (SRBD)

Why is ApneaGraph® Spiro different to other ambulatory polygraphic systems (Type II) on the market?

Current polygraphic systems were developed for the needs of the respiratory sleep medicine specialists, to establish the urgency of treatment, which in the respiratory medicine department is typically CPAP (Continuous Positive Airway Pressure) therapy.

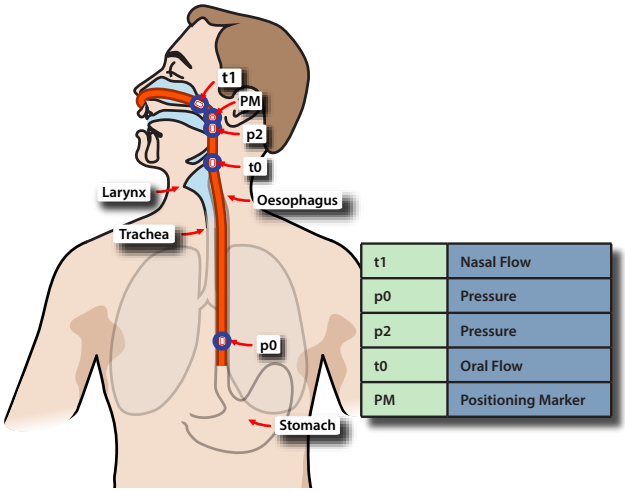
ApneaGraph® Spiro is an ambulatory polygraphic system developed for the more detailed diagnostic needs of innovative OSA treatment alternatives as well as established surgical OSA treatments.

The ApneaGraph® Spiro provides information on:

1. **Identification on site of obstruction in OSA and snoring**
2. **Differentiation of SRBD, Objective differentiation of Central vs Obstructive Respiratory Events**
3. **Severity of SRBD**
4. **Identification of respiratory arousals (RERA)**
5. **Obstructions limited to distinct sleep positions**

How does ApneaGraph® Spiro locate obstructions

The ApneaGraph® Spiro utilises two pressure transducers, one in the oesophagus and one just below the soft palate. By determining the relationship between the two pressure recordings, the ApneaGraph® Spiro identifies where the obstruction is most likely sited:



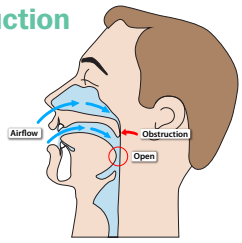
Identification of site of obstructions during sleep

Only with information about the site of obstruction during sleep, can the ENT Clinician decide on the best surgical intervention for the individual patient. The ApneaGraph® Spiro is the only system on the market offering this vital information.

Knowledge about the site of obstruction is also important for OSA treatment alternatives like airway stents or mandibular advancement devices.

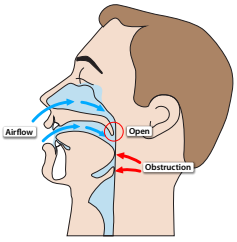
Upper pharyngeal obstruction

- Turbinates
- Septum
- Polyposis
- Soft palate
- Uvula



Lower pharyngeal obstruction

- Tonsil Hypertrophy
- Macroglossia
- Lingual Tonsils
- Epiglottis
- Narrow airways (Retrognathia, Micrognathia)
- Goiter



Differentiation of SRBD, objective differentiation of central vs obstructive respiratory events

ENT surgeons can only intervene successfully in patients with obstructive SRBDs. Surgery is not applicable, if the patient experiences predominately central SRBDs (reduction in or lack of Central Respiratory Drive).

Currently, a quantitative differentiation between central and obstructive SRBD can only be achieved by oesophageal pressure measurement of the ApneaGraph® Spiro.

Our newly implemented parameter Respiratory Effort Frequency (REF) is based on the oesophageal pressure recording. In addition to usual assessment of Normo-, Tachy- and Bradypnoe this algorithm increases the ability to differentiate easily between obstructive and central apneas and provides useful information in the assessment of Cheyne-Stoke Respiration (CSR).

Extent of SRBD

Surgical success is strongly linked to the severity of the SRBD. Patients with mild to moderate SRBD generally respond better to surgery than patients with more severe SRBD.

The ApneaGraph® Spiro aids the ENT clinician to identify the severity of the SRBD and therefore decide surgery is a suitable option for a patient.

Snoring

More and more patients desperately request help from snoring. The ApneaGraph® Spiro, by utilising the oesophageal pressure sensor quantifies respiratory effort and enables the clinician to identify snoring patients and their suitability for surgery or other treatment options.

The automated analysis enables the calculation of Respiratory Effort Related Arousals (RERA).

Snoring is now recorded with two different sensors, one contact microphone, and one airborne microphone, enabling more in-depth analyses. Snoring is meaningfully presented to allow an informed and effective discussion about suitable treatment options with the patient.

This capability of recording snoring is important to ENT Clinicians, but current polygraphic systems are unable to identify this patient group objectively.

Respiratory related arousals

Recent classification rules by the AASM have included Respiratory Effort Related Arousals (RERA) into OSA. RERA is a partial obstruction with increased respiratory effort that leads to an arousal which might contribute to daytime sleepiness and to co-morbitities of the patient.

AHI + RERA=OSA

The ApneaGraph® Spiro graphically shows RERA episodes on the display to improve clinical decision making.

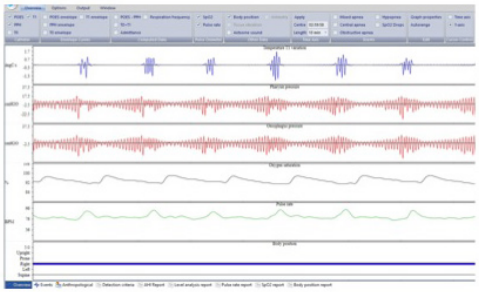
Raw data and the automatic analysis

Within seconds, the advisory automatic analysis provides the clinician with the data needed for an informed decision about the best possible surgical intervention, or alternative treatments tailored to the individual patient.

The automatic analysis results can be checked by scrolling through the raw data recordings in different time windows (between 8h and 30s). If required manual editing can be performed.

The report attractively presents the cardio-respiratory analysis to the doctor with meaningful numbers and visual depictions.

ApneaGraph® Spiro recording parameters



NEW: Modern Ribbon based layout, which allows customer friendly selection of display parameters or analysis reports.

The upper ribbons allow the clinician to choose display parameters, time frames, events highlights, cursor controls as well as additional derived displays to ease difficult analysis decisions.

The lower ribbon provides choice between display of parameters, patient data, detection criteria or analysis reports.

Display parameters:

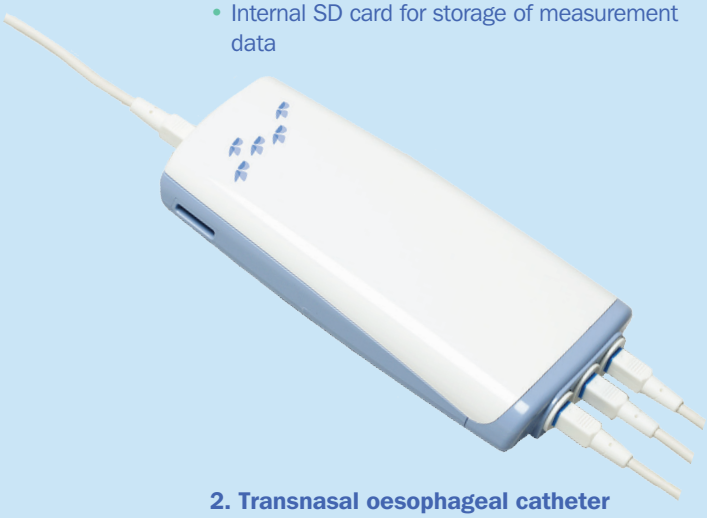
- **NEW:** 2 Respiratory Flow Recordings (nasal and oral)
- **NEW:** 2 Respiratory pressure recordings (pharyngeal and oesophageal pressure)
- **NEW:** Respiratory effort frequency
- **NEW:** Cumulative oral and nasal respiration
- **NEW:** Pressure difference display
- SpO2
- Pulse rate
- **NEW:** 2 Snoring recordings (one contact, one airborne microphone)
- Body position
- **NEW:** Actigraphy

What does the ApneaGraph® Spiro look like?

The ApneaGraph® Spiro typically consists of four components and performs time-controlled measurements of 10 recording parameters.

1. Torso unit:

- Time-controlled measurements of 8 cardio-respiratory parameters
- Accelerometer for body position
- Wireless Bluetooth for setup and remote patient monitoring
- Rechargeable battery
- Internal SD card for storage of measurement data



2. Transnasal oesophageal catheter

- Two pressure sensors (retropalatal and oesophageal)
- Two thermistors (nasal and oro-nasal)
- Two catheters with different recording modalities available:
  - Single use
  - Limited use (to 20 full nights). Multiple patients

3. Wrist unit

- Pulse Oxymeter
- Actigraphy

4. Neck unit

- Two microphones (one contact microphone, one airborne microphone)

If no catheter is being used for a patient an alternative recording mode is available

5. Wireless connectivity

- The new Apneagraph® Spiro has the facility for wireless communication and remote data review via android tablet and telephone.

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