

RESMED

ApneaLink™

Your link to better sleep health



ApneaLink is a simple, cost-effective sleep-screening tool that objectively identifies patients at risk for obstructive sleep apnea (OSA).

Simplicity, cost-effectiveness and state-of-the-art technology combine in the ApneaLink, the ultimate choice for homecare providers, sleep labs and clinicians. The ApneaLink is one of the few true sleep-screening devices available for obstructive sleep apnea (OSA) patients, providing the link to an improved quality of life by cost-effectively testing chronic disease patients, intra-hospital pre-op surgical patients, occupational health patients and other high-risk patients.

The ApneaLink readily transitions patients from referring physicians to sleep centers.

ApneaLink is portable, battery-powered and user-friendly and will streamline any user's sleep-screening process. A versatile tool, ApneaLink can be used in the patient's home in remote locations (or any location where patients are sleeping).

Three easy steps can link you to more OSA patients and, most importantly, provide them a better quality of life:

- 1 Screening – ApneaLink
- 2 Diagnosis – Polysomnography
- 3 Treatment – ResMed PAP therapy

Why use ApneaLink?

Sleep-disordered breathing (SDB) is recognized as a serious health problem that impacts about 43 million US adults; however, more than 80% remain undiagnosed and untreated.¹ The ApneaLink connects clinicians to their patients by dramatically increasing the number of identified SDB patients through primary care and specialty referral sources, thereby routing more patients for diagnosis to a sleep center.

How does ApneaLink work?

The basic ApneaLink is a single-channel screening device that uses a simple nasal cannula to record patient breathing. It automatically analyzes and derives AHI, flow limitation and snoring and later automatically generates a simple, easy-to-interpret report with a color-keyed Risk Indicator for the clinician to review.

With oximetry, the ApneaLink records three channels of information: respiration, oximetry and pulse.



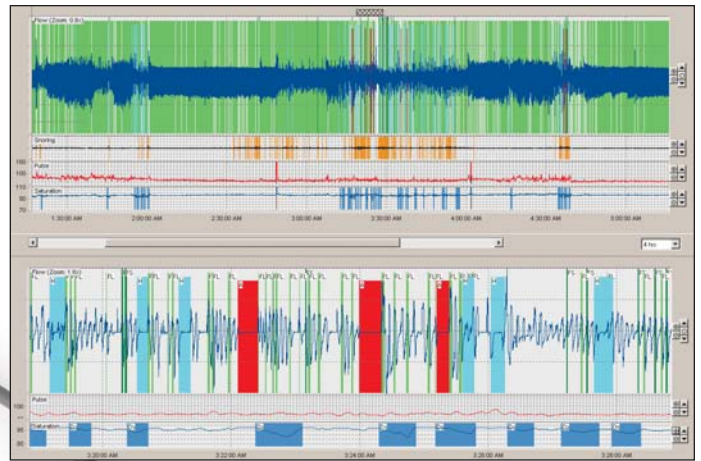
ApneaLink without oximetry

The basic ApneaLink is the perfect choice for those who need a cost-effective, accurate screening tool. Reliable and simple to use, the basic ApneaLink offers the following features and benefits:

- Add oximetry at any time, no software changes required—simply “plug & play”
- Automatically analyzes and derives AHI, AI and HI, flow limitation and snoring
- Uses one software set for both ApneaLinks (with and without oximetry)
- Auto-generates a simple, easy-to-interpret one-page report with a color-keyed Risk Indicator
- Can be used to identify intra-hospital preoperative patients at risk for SDB, thereby improving overall quality of care
- Enables referral sources to easily and objectively determine whether to refer a patient for further evaluation
- Cost-effectively screens chronic disease patients, drowsy drivers and other high-risk individuals
- Improves patient care by providing quicker access to the treatment care path
- Sensitivity 100%, specificity 87.5% at AHI of 10²

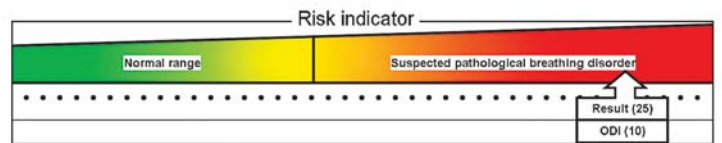
1 Young et al. State of the Art, *AJRCCM* 2002

2 Wang Y et al. *Pneumologie* 2003



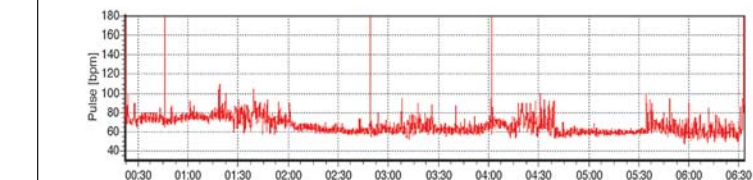
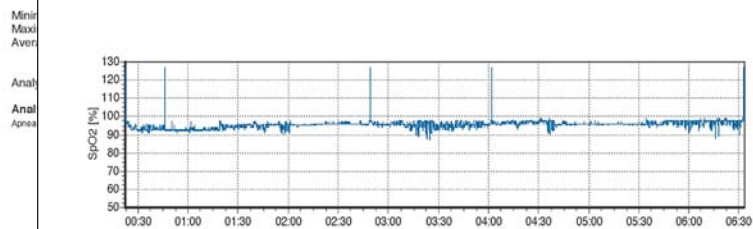
ApneaLink - Report of 07.03.2006 10:45

Treating physician		Referral to	
_____		_____	
Patient data			
First name:	With Oximetry	Patient ID:	1234
Name:	Severe Risk	DOB:	06.12.1944
Street:	_____	Height:	0 cm
Zip code, City:	_____	Weight:	0 kg
Phone:	_____	BMI:	0 kg/m ²
Recording		Evaluation	
Date:	12.12.2005	Start:	00:32
Start:	00:22	End:	06:33
End:	06:33	Duration:	5 h 58 min
Duration:	6 h 10 min		



Points evaluation from AHI + points evaluation from FLFS (see Clinical Manual for more details)

Analysis Indexes	Normal	Result	
AHI [*] :	20 < 5 / h	Average breaths per minute [bpm]:	13,02
RI [*] :	25 < 5	Breaths:	4671
Apnea index:	4 < 5 / h	Apneas:	23
Hypopnea index:	16 < 5 / h	Hypopneas:	97
% Flow lim. Br. without Sn (FL):	60 < Approx. 60	Flow lim. Br. without Sn (FL):	2800
% Flow lim. Br. with Sn (FS):	1 < Approx. 40	Flow lim. Br. with Sn (FS):	28
		Snoring events:	342
SpO₂ evaluation period: 6 h 0 min			
ODI Oxygen Desaturation Index [*] :	10 < 5 / h	No. of desaturations:	60
Average saturation:	95 94% - 98%	Saturation <= 90%:	1 min
Lowest saturation:	87 90% - 98%	Saturation <= 85%:	0 min
Baseline Saturation:	95 %	Saturation <= 80%:	0 min



Comments

ApneaLink with oximetry

ResMed's ApneaLink with oximetry is the premium choice in screening for OSA. In addition to the features and benefits of the basic ApneaLink device, the pulse oximeter provides two additional channels of information—pulse and pulse oximetry, all three channels in a simple "little blue box." A simple nasal cannula is used for sensing patient breathing. Oximetry and pulse are detected using a choice of either reusable or single-use patient sensors. The original ApneaLink software has been enhanced to show a two-page patient report with pulse and oximetry signals, detailed SpO₂ information and waveform data.

The ApneaLink with oximetry is perfect for those who want more information and are expanding their screening capabilities to other non-traditional patient areas, such as home oxygen patients.

TECHNICAL SPECIFICATIONS APNEALINK AND PULSE OXIMETER

Signal Recording

Breathing sounds
Respiratory flow
Blood oxygen saturation
Pulse
Battery voltage

Sampling Rates for the Channels

Respiratory flow/breathing sounds: 100 Hz
Saturation: 1 Hz
Pulse: 1 Hz
Battery: 1 Hz

Signal Processing

Signal recording: 20 Bit
Signal storage: 16 Bit

Internal Memory

Storage capacity: 15 MB
Recording period: 8 hours minimum

Power Supply to Recorder

2 NiMH rechargeable batteries: Mignon/AA/1.2V/
at least 2.1 Ah or
2 batteries: LR 6/Mignon/AA/1.5V/at least 2.1 Ah

Weight

Recorder (without rechargeable batteries or batteries):
Approximately 50 g (1.8 oz)
Pulse Oximeter: Approximately 30 g (1.1 oz)

Operating Conditions

Temperature: 20°C to 40°C (68°F to 104°F)
Humidity: 10% to 90% RH (non condensing)

Shipment/Storage Conditions*

Temperature: -20°C to +50°C (-4°F to +122°F)
Humidity: 10% to 90% RH

*Recorder without rechargeable batteries or batteries

Operating/Storage Air Pressure

800 hPa to 1060 hPa

Effective Range

Flow sensor: -10 hPa to +10 hPa
SpO₂: +/- 2 digits
Pulse: +/- 3 digits

Interfaces

Nasal pressure cannula: Luer connection
Pulse oximeter: 3-pin Binder plug
Computer: Fullspeed USB 1.1

Dimensions

Recorder (length x width x height): 125 x 60 x 30 mm
(4.9" x 2.4" x 1.2")
Pulse oximeter: (length x width x height): 53 x 20 x 15 mm
(2.1" x 0.8" x 0.6")

Electromagnetic Compatibility

Product complies with all applicable electromagnetic compatibility requirements (EMC) according to IEC60601-1-2, for residential, commercial and light industry environments. For further details, see "Guidance and Manufacturer's Declaration – Electromagnetic Emissions and Immunity" as follows.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions and Immunity

The ApneaLink is intended for use in the electromagnetic environment specified below. The customer or user of the ApneaLink should ensure that the system is used only in such an environment.

Emissions test	Compliance	Electromagnetic environment—guidance
RF emissions CISPR11	Group 1	The ApneaLink uses RF energy only for its internal function. Therefore, its RF emissions are very low and are unlikely to cause any interference in nearby electronic equipment
RF emissions CISPR11	Class B	The ApneaLink is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	—	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	—	

Medical Electrical Equipment needs special precautions with respect to EMC and needs to be installed and put into service according to EMC information provided in this document.

Warnings: The ApneaLink should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the ApneaLink should be observed to verify normal, operation in the configuration in which it will be used. The use of accessories other than those specified in this manual is not recommended. They may result in increased emissions or decreased immunity of the ApneaLink.

ORDERING INFORMATION & PRODUCT CODES

ApneaLink

US and Latin America	22302
Canada	22303

1 Apnealink device	1 Program CD
3 Nasal Cannulas	2 AA Batteries
1 Reusable Belt	1 Carrying Case
1 Quick Software Setup Guide	
1 USB download cable	

ApneaLink Oximetry Accessories Kit

US and Latin America	22304
Canada	22308

1 Nonin XPOD oximeter
1 Sensor clip
3 Disposable Sensors

Optional Accessories and Disposables (US, Latin America and Canada)

Nasal Cannulas (25/pk)	70388
Nasal/Oxygen Cannula (25/pk)	70319
Belt, reusable	629052
Belt, Single Use (24/pk)	70406
Sensor, Oximeter-Single Use	70412
Sensor, Oximeter (Flex Wrap)-Reusable	1431002
Tape, Sensor (for Flex Wrap Sensor), (25/pk)	70276
Sensor, Oximeter (Soft Sensor)-Reusable	70413

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