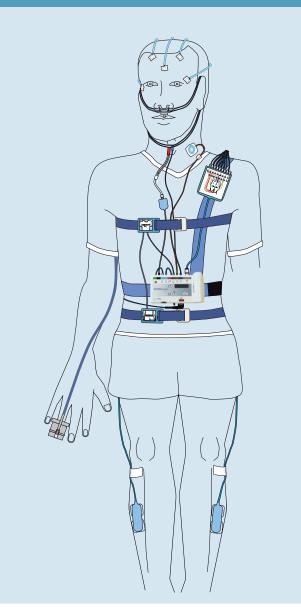


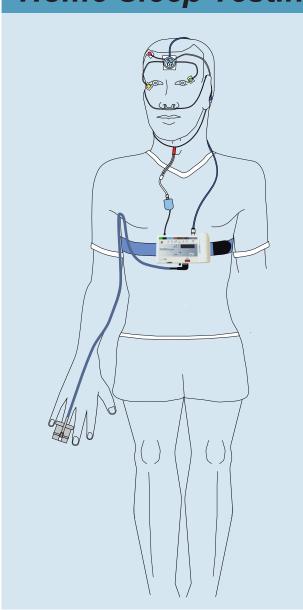
# **Same device - Multiple applications:**

# Full PSG



- Upgradeable up to 58 Channels
- Telemetry Data Transfer
- High Quality digital Video
- Pulse Transit Time
- Continuous Impedance Measurement

# Home Sleep Testing



- Upgradeable up to 34 Channels
- Durable active Sensors
- Simple Patient Application

- Data Transfer by CF card
- Customizable to any Sleep Testing Configuration
- Computer aided and Manual Scoring Modes
- Automatically generated graphic Report
- Delayed Start and multiple Recordings

FDA approved for adults only

# SOMNOscreen® plus - The only FDA cleared All-In-One Sleep Diagnostics System

## **Software Features**

Re-Analyzing: The data can be re-analyzed at any time.

Archiving: The data can be archived to CD, DVD or a network drive, i.e. NAS (RAID system).

**Report Generator:** Customizable reports and form letters.

Patient Data Management (optional): A powerful patient database for the efficient organization of all patient data.

- Permanent access to the complete numeric results list, sleep profiles and graphic results summary.
- Trend reports for comparing different tests done on the same patient. The data is stored in the database even after the case has been archived and deleted.
- Network-compatible patient data administration with a permanent patient list, search- and selection function

**Scheduler:** Calendar with scheduler function

Network link-up: GDT and HL7 Interface for link-up to surgery software or clinic system.

**Open Architecture:** All results and reports can be exported to MS Excel and SPSS. Raw data can be exported to EDF+ and ASCII format. EDF+ files can be imported into the software

### Data Transmission (optional)

- Built-in data transmitter in main unit (up to 65 ft)
  - Signal check at the patient's bedside
- Data transmission from a receiver to the PC through network
- External data transmitter (up to 33 ft) for data transmission of up to 32 systems parallel without interferences
- In any case: Backup of all measurement data on Compact Flash card, no loss of data

# **Configurations**

Signals and Sensors	Cardio- Resp	Home Sleep	PSG	EEG 32
Pulse Oxymeter (SpO <sub>2</sub> , PR, Pulse Waveform)	•	•	•	0
Marker Button				
Ambient Light				
Position				
Movement (Magnitude)				
Effort (Thorax)				
Effort (Abdomen)	0	0	0	0
2x RIP-Efforts	0	0		0
Pneumatic Efforts	0	0	0	0
Obstruction Level*	0	0		0
Flow (Thermistor)	0	0		0
Snore (Microphone)	0	0		0
PLM left	0	0		0
PLM right	0	0		0
PT / Leakage Flow (via ACT)	0	0	0	0
Motor Activity	0	0	0	0
Flow, CPAP/BiPAP Pressure, Snore (Pressure Sensor, Nasal Cannula)	•	•	•	0
10x EEG/EOG+2EMG+1ECG	0	0		0
25x EEG/EOG+6EMG+1ECG	0	0	0	
ECG	0	0		
EEG/EOG-Combi Electrode	0		0	0
Wireless Online Data Transfer	0	0	0	0
Signal-Check via Cable	0	0	0	0
Synchronized, Digital IR Video	0	0	0	0
Up to 16 ext. Channels via LAN	0	0	0	0
PSG Kit for EEG 32				0

optional

\* Patented, Patent Number US 11/364 174 US 2006/0217616 A1,7374542

## Video (optional)

- Infrared-Camera (resolution 640x480 px), optional with built-in data transmitter, interkom ready
- Infrared-HD Camera (resolution 2048x1536 px), optional with built-in data transmitter, interkom ready
- Infrared-Camera (resolution 768x576 px) with pan and zoom function, 18x optical zoom, can be operated by remote control by every network PC

# **Further Options**

- 3-channel ECG
- Pneumatic based effort sensors
- Sidestream capnography
- Wireless CPAP remote control
- Miniaturized Pneumotachograph for CPAP flow recordings or for calibrated volume and leakage determination

## FDA approved for adults only

This brochure is intended for the USA market only

# Medical Devices for Sleep Diagnostic SOMO Medicas of Sie

# SOMNOscreen® plus



- UP TO 58 CHANNELS
- AMBULATORY&STATIONARY
  - CONTINUOUS **DETERMINATION OF OBSTRUCTION LEVEL**
  - CONTINUOUS **IMPEDANCE RECORDING**
  - WIRELESS REAL-TIME **DATA TRANSFER**

From a screener to a full PSG System in the palm of your hand

**Upgradeable at any time!** 

- Fully portable Polysomnography System
- Wireless real-time data transmission of all signals to the PC
- Unlimited mobility for the patient and the sleep practitioner
- Wireless synchronization of digital IR-video and audio-recording

FDA approved for adults only







SOMNOmedics America Inc. · 815 Ponce de Leon Blvd, Suite P-209 · Coral Gables · FL 33134 toll free: 866 361 9937 · info@somnomedics-diagnostics.com · www.somnomedics-diagnostics.com











### FDA approved for adults only

# **SOMNOmedics**

SOMNOmedics strives to keep its technology compatible with the latest developments and the latest diagnostic clinical features. We, the SOMNOmedics team, take pride in our technology and have developed an innovative solution for Sleep Diagnostics and Therapy.

It will offer you, the practitioner as well as the patient, a flexible and reliable, easy to use system in the sleep laboratory, patient's home or anywhere else. SOMNOmedics offers the most advanced diagnostic system available

# SOMNOscreen® plus

the complete PSG system that allows you to perform all levels of sleep testing in any environment!



**Patient's Home** 



Medical Office / Sleep Lab

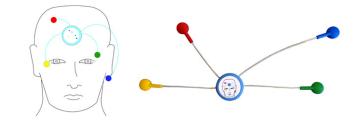


Hospital

**Mobility** - Sleep studies should be performed wherever it is most suitable for the sleep practitioner and the patient - in the patient's home, a medical office or in a hospital.

Miniaturization - SOMNOscreen® plus, currently the smallest full Polysomnography system available. Featuring up to 58-channels of polysomnoghraphic data, the palm sized unit can store the data on a Compact Flash Card and transmit it to a PC in real-time with the built-in transmitter.

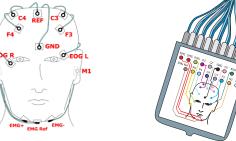
Versatility in application - Basic Respiratory Screening, CPAP/BiPAP/SV Titration, full PSG recording with or without video, 24-hour ambulatory EEG recording, stationary EEGmonitoring with video control or 24 hour ECG and Pulse Oximetry recording. The choice is yours.



#### Combi-Electrode

Our smallest head box for Home Sleep Test (Level 2) simplifies sleep quantification during ambulatory tests

FDA approved for adults only



PSG Headbox - complies with AASM criteria

## **Technical Features**

- Miniaturized, portable unit, worn by the patient
- Up to 58 channels 8 channels integrated in base unit
- Modular design upgradeable at any time
- Adjustable sampling rates up to 512/s (4096/s optional)
- · Continuous display and recording of electrode impedan-
- Display with control keys allows PC independent set-up
- · View and check signals on the display including system status and signal quality
- Li-lon battery for up to 33 hours of continuous recording and rechargeable without memory effect. The battery can be replaced quickly and easily
- Data is stored on industry standard High Speed Compact Flash Cards with up to 2 GB capacity or up to 100 hours of PSG recording time



Wireless real-time data transfer to the PC - The built-in data transmitter sends the recorded data to the PC via LANreceiver. All signals can be checked parallel at the patients' bedside on a tablet PC.

Wireless synchronisation of Video and Audio - Video and audio signals are recorded with the compact IR Camera and IR light source and can be transferred to the PC synchronously. A high compression level helps to limit the amount of data.

### Sensors

SOMNOmedics has designed and built a new generation of active sensors for the SOMNOscreen® plus. They provide excellent signal quality, are less susceptible to interference and reliable for extended periods.

All sensors are silicone embedded and have been proven to be comfortable to wear while remaining mechanically robust and consistent. Quick and easy cleaning allows the sensors to be prepared for the next patient.

Pediatric sensors are also available

#### Internal sensors

- Light Sensor: For determining the relevant measurement time (TIB)
- Movement: Detection of movement artefacts and for sleep/wake estimation (screening)
- Body Position: Detection of positions: left, right, supine, prone and upright



Pulse Oximeter: A high quality pulse oximeter for recording the SpO<sub>2</sub>, pulse rate and pulse waveform. The probe is a comfortable silicone-embedded finger probe

- Patient Marker: For the input of relevant time points which the patient may wish to document, for example taking medication, going to the toilet, etc.
- Internal Effort: Applicable either as a thoracic or abdo-

#### **External Sensors**



Miniaturized Headbox PSG: 10 referential inputs for EEG/EOG + REF,

2 referential inputs for EMG/EOG. 1 differential input for ECG

**Headbox EEG32:** For advanced

neurological diagnostics



Thermistor: Nasal/Oral Flow

Microphone: Snoring sound



**Pressure Sensor:** For measuring the CPAP pressure from a CPAP machine,

controlling CPAP during titration and

measuring flow using a nasal cannula



Effort Sensor: Thoracic and/or abdominal effort (Respiratory Inductive Plethysmography Belts or Strain Gauge Sensor)



EMG Sensors: Recording the leg EMG for periodic leg movement analysis



**EEG/EOG Combi Electrode:** 

2 EEG / 2 EOG for simplified ambulatory sleep scoring



**ECG Sensor:** Recording the ECG with an active three contact sensor for optimized signals

Auxiliary: Input of an external signal

# **Application**

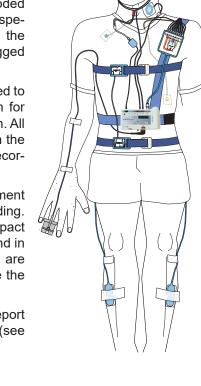
The SOMNOscreen® plus is positioned directly to either the abdomen or thorax.

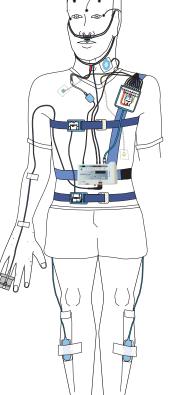
Sensor cables are color coded and the connectors are specially keyed, so that only the correct sensor can be plugged into the correct receptacle.

The unit can be programmed to automatically start and run for a pre-programmed duration. All Signals can be checked on the built-in display before recording starts!

Fast transfer of measurement data to the PC after recording. Simply insert the Compact Flash Card in the reader and in less than 20 seconds you are ready to open and analyze the

Complete analysis with a report printout within 2-3 minutes (see reports below).





# 8-34CHANNELSMODULARANDEXPANDABLE(PSG) 15 Headbox: 10 EEG/EOG referential + REF, 2 EMG referential, 1 ECG differential, GND, continuous impedance 11 External: 2x effort (RIP), snoring (microphone & nasal cannula), naso/oral flow (thermistor), motor activity, AUX, naso/oral flow (nasal cannula), PLM L, PLM R,

CPAP/BiPAP pressure

8 Internal: SpO<sub>2</sub>, pulse rate, pulse waveform, body position, movement, ambient light, marker button, effort

External Thermistor for naso/oral flow Abdominal effort

Activity sensor (3 axis) for actigraphy or PLM Active sensors for EMG/ECG Microphone for snore detection

Combi electrode for simplified sleep scoring EDA sensor (Electro Dermal Activity)

Pressure sensor (-36 to +36 cmH<sub>2</sub>O)

Naso/Oral Flow (cannula) Snore (cannula) **CPAP-Pressure** CPAP-Flow CPAP-Snore

### **DATA PROCESSING**

Sampling Rates adjustable from 4/s to 512/s (4096/s optional) Small file size through compressed data storage

Li Ion battery (rechargeable), up to 33 hours of ambulatory PSG and 61 hours of screening

#### SIZE AND WEIGHT 5.51" x 2.83" x 1.1", 9 oz (incl. battery)

SOFTWARE DOMINO

#### Efficient analysis and scoring software

INTERACTIVE KEYBOARD AND DISPLAY Signal check on display (blue backlit LCD display)

Programmable start and end times Menu controlled display

High-speed Compact Flash Card (up to 2 GB capacity)

Built-in data transmitter (up to 65 ft) with online signal check at the patients bedside via tablet PC

External data transmitter (up to 330 ft)

- Video Synchronized video HD resolution

  - Small file size thanks to high compression levels
  - · Fully synchronized with raw data and audio recording
  - Playback at different frame speeds (0.25 100 times)
- · Easy to edit, cut and archive.

## FDA approved for adults only

## **Analysis**

#### Analysis of all standard signals including:

- Apnea/Hypopnea calculation according to type and in correlation to Desaturations, Brady/Tachycardia and Micro Arousals
- Micro arousal detection according to the ASDA/AASM criteria
- Brady/Tachycardia and Arrhythmia analysis
- Calculation of the average frequency value (AFV)
- Alpha + Beta and Delta Frequency Bands from EEG Sleep Staging Analysis with Sleep Profile
- · Display of the Sleep Staging Reliability
- REM Detection and analysis of REM Density
- O<sub>2</sub> Desaturations Body position
- PTT Pulse Transit Time

PTT arousal analysis

- Snoring
- PLM detection

#### New information being developed, including: · Sleep fragmentation based on micro arousal and

- Flow Limitation Obstruction Level Analysis\* • HFV - Heart Rate Variability for various frequency
- FFT module for the sequential analysis of the raw
- Interater Variability Compare various analysts for quality checks



1 Index per hour (2) Time Line 3 Analysis channels

4 Raw data channels

6 Time base raw data (8) Events

#### **Different scoring modes:** for sleep staging for events

manual

5 Time base analysis

7 Sleep stages

(9) Events

edit by key

automatic

quick edit by mouse position

 edit by selection window semi-manual

repeat mode

Patented, Patent Number US 11/364 174 US 2006/0217616 A1,7374542