

Medical Devices for Sleep Diagnostics and Therapy

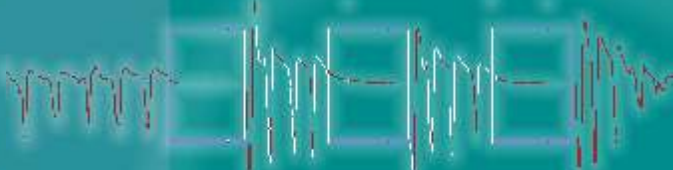
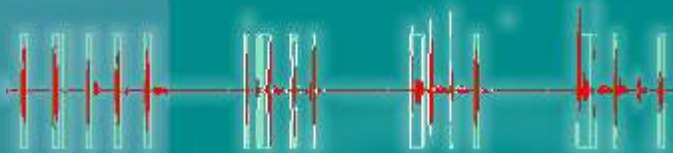
SOMNOmedics

SOMNOwatch™ plus

■ MINIMUM EFFORT

■ OPTIMUM DIAGNOSTICS

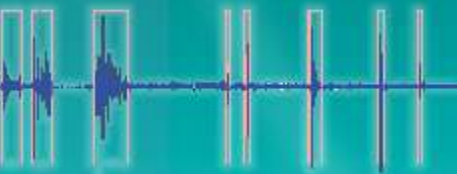
■ FLEXIBLE APPLICATION



**Respiration
(Flow and Snore)**



Tremor Analysis 3D



PLM-Recorder



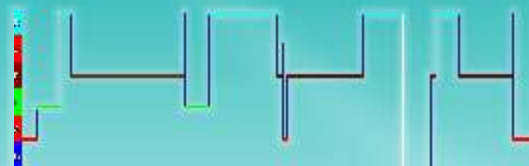
Actigraphy



**Sleep Profile
(Wake, REM, 1, 2, 3, 4)**



Long-term ECG Recording



Body Position

The All-rounder



SOMNOWatch™ plus

Ambulatory Multi-Channel Monitoring

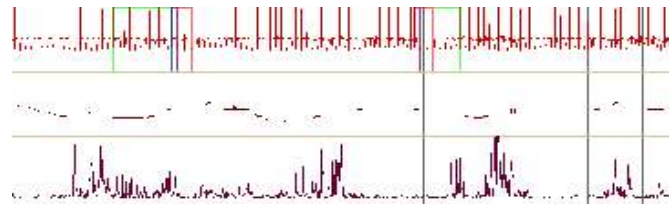
Miniaturised - Mobile - Flexible

The rapid progression in electronics has lead to a general miniaturisation in Mobile Medical Devices. The integration of multiple diagnostic functions into one single device allows for a flexible and cost effective system. **SOMNOWatch™ plus** is a powerful miniaturised multi channel recorder which includes the comfort and user friendliness of a watch.

As a multi-channel system, the **SOMNOWatch™ plus** can replace several common devices while providing excellent signal quality. **SOMNOWatch™ plus** can be used for **Actigraphy** in order to determine Circadian Rhythm, **PLM detection, Tremor Analysis, Single Channel ECG and EEG recording, Body Temperature, EDA, Respiratory Screening with Flow & Snoring, Body Position and Sleep/Wake Analysis.** The waterproof device is powered by a rechargeable Li-Ion battery and has an internal storage of 64 MB enabling long-term measurements of up to 45 days. Relevant points in time on the recording can easily be marked with the integrated Patient Marker.

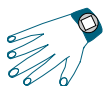
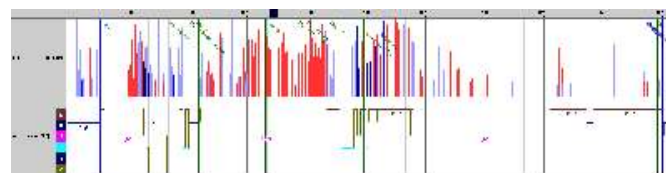


Exercise/Sport/Rehabilitation - To get important Motor Activity performance information during sport and exercise, the **SOMNOWatch™ plus** can be worn on the arm, leg, or body. Additionally, the **SOMNOWatch™ plus** can measure ECG. The software synchronizes Heart Rate with Motor Activity. The correlation of Motor Activity and Cardiovascular Stress is very important for optimising and monitoring exercise and rehabilitation progress. An internal buzzer can indicate low activity during the measurement.



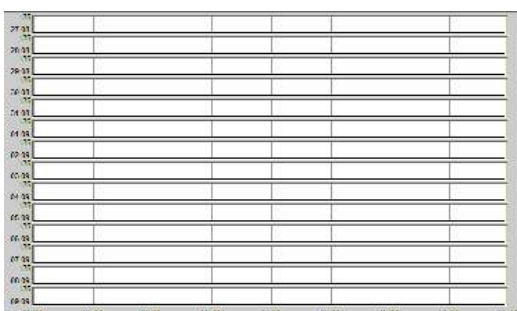
PLM and RLS Recorder

Applied to the ankle, **SOMNOWatch™ plus** can record Leg Movement continuously for up to 11 nights. It can differentiate between standing and lying using the integrated position sensor. With adjustable parameters, the software automatically recognises PLM movement patterns and evaluates the PLM index. By quantification of Motor Activity, RLS (Restless Legs) is rated. For an extended diagnosis, the EEG option can be added to provide EEG Derivation which can be used to provide the correlation of PLM's and Cortical Micro Arousals.



Actigraphy

Circadian Rhythm - SOMNOWatch™ plus is worn on the non-dominant arm for recording and objective recognition of the Sleep/Wake Rhythm. The activity is measured in epochs of 1 to 120 seconds and plotted as an Actigraphy Profile. The relevant measurement period (time in bed) is given using the integrated light sensor. As a result, disorders of the Circadian Rhythm e.g. for shift workers or pilots, can be documented. In Attention Deficit and Hyperactivity Disorder (ADHD), **SOMNOWatch™ plus** can be used to diagnose and monitor the therapy of hyperactive children. Certain periods can be assigned to specific events, such as School, School Breaks and leisure time.



Periodic Leg Movement (PLM)

	Sleep	REM	Non-REM	Wake	Total
Isolated-LMs (Index)	189 (45,0)	-	189 (45,0)	31 (544,5)	220 (51,7)
PLMs (Index)	235 (56,0)	-	235 (56,0)	22 (386,4)	257 (60,4)
Resp-LMs (Index)	14 (3,3)	-	14 (3,3)	1 (17,6)	15 (3,6)
Body Position -LMs (Index)	13 (3,1)	-	13 (3,1)	-	14 (3,3)
PLMs with Micro Arousal	58 (13,8)	-	58 (13,8)	3 (52,7)	61 (14,3)

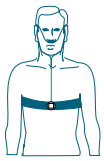
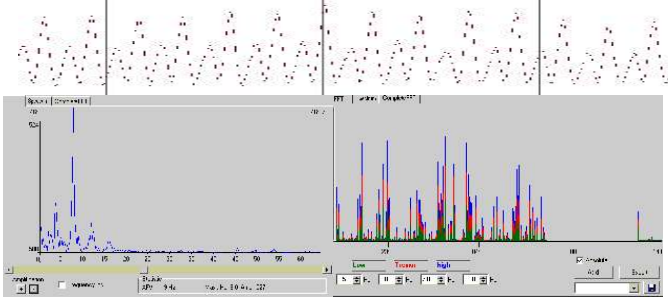
PLM Progression

Time	PLM
01:45 - 02:00	2 (8,32)
02:00 - 03:00	48 (48,00)
03:00 - 04:00	113 (113,00)
04:00 - 05:00	63 (63,00)
06:00 - 06:00	8 (8,00)
08:00 - 06:29	3 (6,02)



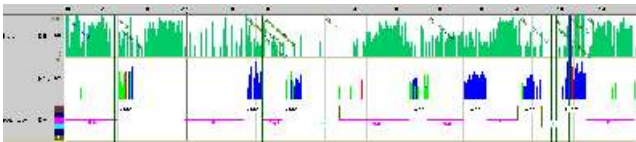
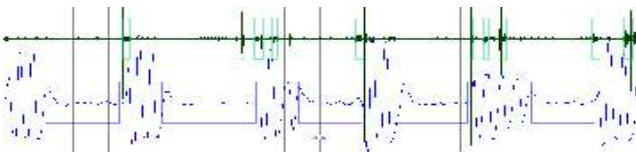
Movement Analyser

The high frequency acquisition of movement enables **SOMNOwatch™ plus** to make a very accurate frequency analysis using FFT. The recording of tremor intensity and tremor frequency can be achieved over a long period of time. This parameter can be used for the medical diagnosis and treatment of Parkinson's Disease.



Respiratory Screener

By using a combined sensor for Flow and Snore, the **SOMNOwatch™ plus** can be used as a Respiratory Screener. Worn on the thorax, it can record Body Position, Acceleration, Light, Flow, and Snoring. The correlation of Body Position, Apnoea/Hypopnoea and Snoring can easily be detected. In addition to the diagnosis of Sleep Apnoea, the **SOMNOwatch™ plus** can be used for recording patients connected to a CPAP machine.



Respiratory Analysis

Body Position	Prone	Supine	Left	Right	Upright
Sleep Time Fraction (%)	-	27,5	17,2	55,3	-
Total Events (Index)	-	171 (90,1)	7 (5,9)	13 (3,4)	-
Obstr. Apnoea (Index)	-	9 (4,7)	-	-	-
Central Apnoea (Index)	-	2 (1,1)	-	-	-
Mixed Apnoea (Index)	-	-	-	-	-
Hypopnoea (Index)	-	31 (16,3)	5 (4,2)	10 (2,6)	-
Flow Limitations (Index)	-	-	-	-	-

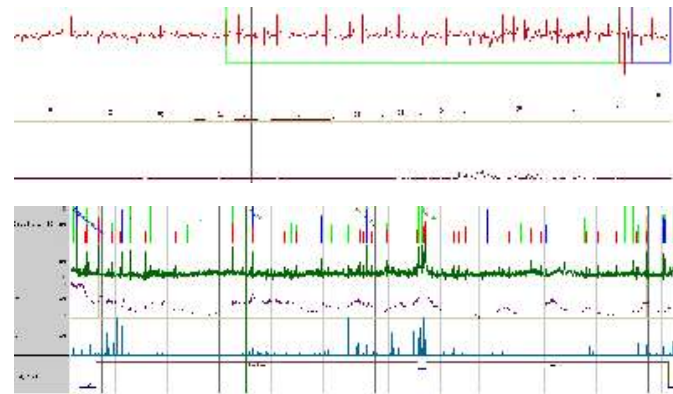
Snore

	All	Prone	Supine	Left	Right	Upright
Snore (Index)	2335 (338,3)	-	387 (276,0)	328 (276,5)	1620 (424,2)	-
Absolute Snore (min)	42,1	-	5,4	6,2	30,3	-
Snore Episodes (min)	164,8	-	16,1	26,6	122,2	-
Snore epis. (% Sleep Time)	38,8	-	-	-	-	-



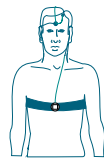
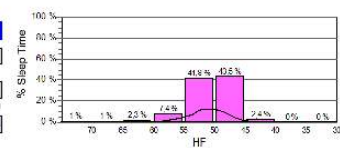
Long-term ECG

SOMNOwatch™ plus can store the raw data of a single channel ECG for up to 5 days. The correlation between Heart Rate, its Rhythm, Actigraphy and Body Position gives very interesting information for the diagnosis and rehabilitation of Cardiovascular diseases.



Heart rate

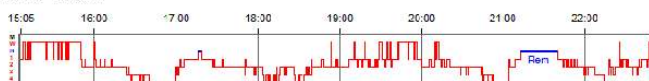
	Number (Index)	Time
Acc. (Index)	77 (10,0)	
Dec. (Index)	59 (7,6)	
Arrhythmia (Index)	230 (28,7)	
Maximum HF (bpm)	130	15:08:00
Minimum HF (bpm)	45	17:42:13
Average HF (bpm)	51	



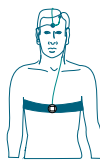
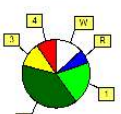
Sleep Recorder

In order to differentiate the sleep stages, the EEG option can be added to the Actigraphy of the **SOMNOwatch™ plus**. The additional data allows for the differentiation of not only the Sleep/Wake Profile but also Wake, REM, 1, 2, 3 and Stage 4.

Sleep Stages

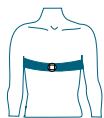
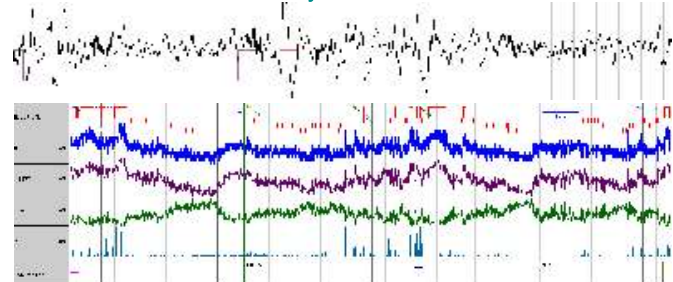


	06:44:36	Sleep Stage	Duration	(%) TIB	(%) Sleep
Total sleep time	06:44:36				
Sleep efficiency (%)	87,2				
Sustained sleep eff. (%)	87,2				
Sleep latency stage 1	-	Arbeitsfakt	-	-	-
Sleep latency stage 2	00:45:06	Movement	-	-	-
Rem latency	-	Wach	00:59:34	12,8	-
Total sleep period	06:56:30	REM	00:29:30	6,4	7,3
Sleep stage change (Index)	228 (29,5)	Stadium 1	01:37:06	20,9	24,0
Wake number	27 (4,0)	Stadium 2	03:00:30	38,9	44,6
		Stadium 3	00:52:00	11,2	12,9
		Stadium 4	00:45:30	9,8	11,2



Long-term EEG

With very little effort, the **SOMNOwatch™ plus** can record a single channel EEG for up to 5 days. The artefact identification is improved by the simultaneous measurement of Motor Activity. For an optimized analysis, the raw data is represented in the different EEG frequency bands. Spindles, K-complexes, and Micro Arousals are automatically scored.



Sleep Walking

SOMNOwatch™ plus is an excellent device for detecting this sleep disorder, as up to 45 days of Body Position, Light and Motor Activity can be recorded. The report discriminates between lying left, right, supine, prone, upright and walking.

Analysis

LED Status Indicator

Light Sensor

Patient Marker

External
Signal Input (AUX)
Interface/Charge



7 Channels

6 Internal (Body Position, 3 Activity Sensors (x,y,z - Axis), Ambient Light, Patient Marker)

1 External Signal Input (AUX) - upgradeable for up to 8 external channels

SENSORS FOR AUX

External Sensors	Pressure Sensor for Nasal (Oral) Flow + Snore
	Pressure Sensor for CPAP (0 to 15 cm H ₂ O)
	EEG Electrode
	ECG Electrode
	PLM Electrode (EMG/ACTI)
	Temperature Sensor
	EDA

Upgradeable for Resp. Analysis, Blood Pressure Recording, 6-channel EEG, Sleep Stage Recording, Long Term Temperature Measurement

DATA PROCESSING

12 Bit ADC

Adjustable Sampling Rates - 1/60s - 256/s

Adjustable Storage Rates - 1/60s - 256/s

Internal Data Storage 64 MB

Storage of raw or averaged data user selectable

POWERSUPPLY

Li-Ion Battery, 630 mAh (rechargeable)

SIZE & WEIGHT

45 mm diameter x 16 mm, 30 g (incl. Battery)

DEVICE FEATURES

Battery charging during data transfer through USB Port

Programmable Start- and End-times for up to 6 measurements

Device Status Indicator (transferring, recording, standby)

Patient Marker Button

Internal buzzer (programmable alarm sound)

Waterproof

SOFTWARE

Fast and accurate Analysis and Scoring Software for:

Respiratory Analysis, PLM-Detection, Sleep Staging, EDA, Tremor Analysis, EEG, Cardio Analysis, Actigraphy Analysis, Body Temperature

Editing of Events in the raw data

Automatic Artefact Detection

Automatic Report and Form Letters

Data Base (Option - compatible with SOMNOScreen™)

Raster View

Automatic Analysis of All Standard Signals

Actigraphy

Sleep/Wake Detection and Sleep Efficiency (time in bed)
Daily or weekly data display
REM/NREM Differentiation (ECG Option)
REM, 1, 2, 3 and Stage 4 Differentiation (EEG Option)

PLM

Automatic Identification of PLM & LM correlated to Body Position
PLM-Index Distribution
Quantification of the Motor Activity for RLS
Correlation of Cortical Micro Arousals (EEG Option)

Respiratory Screener

Apnoea/Hypopnoea Detection
Snore Detection
Body Position Correlation

EEG

1-Channel EEG, up to 5 days
FFT Module for sequential frequency analysis of the raw data
Spectral Analysis of Alpha, Beta, Delta and the Averaged Frequency Value (AVF)
Micro Arousal Analysis according to the ASDA-Criteria
Sleep Fragmentation
Artefact Detection

ECG

1-Channel ECG, up to 5 days
Recognition of Brady/Tachycardia and Arrhythmia
Heart Rate Variability (HRV)
Sympatho-Vagal Balance (SVB)

Temperature

Analysis of the Circadian Temperature Progression
Correlation to the Motor Activity

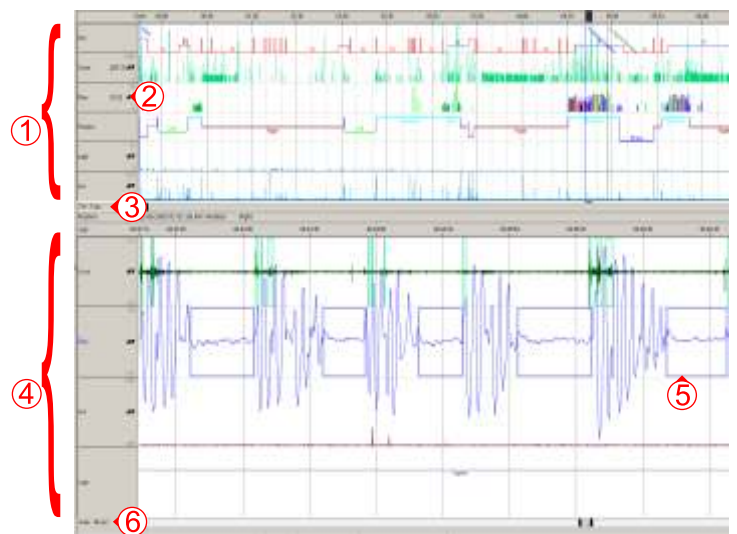
Tremor Analysis

Identification of Tremor Frequency & Tremor Intensity
Motion Efficiency

Actigraphy (Exercise, Sport, Rehabilitation)

Evaluation of Exercise Periods
Correlation of the Motor Activity and the Heart Frequency

Example of Respiratory Analysis



- | | |
|-----------------------------|------------------------|
| (1) Analysis Data | (2) Index per Hour |
| (3) Analysis Data Time-Base | (4) Raw Data |
| (5) Events | (6) Raw Data Time-Base |

- Fully automatic analysis with quick and easy manual editing
- All events colour coded and displayed in the raw data view
- External channel deselectable for higher recording capacity
- Measurements compressable for higher recording durations

Application/Configuration

Actigraphy Sleep/Wake	Actigraphy Training/Sport	PLM Recorder	Movement Analyser	Respiratory Screener	REM/NR Recorder	Long-term Body Position	Long-term ECG	Long-term EEG
Non-Dominant Arm	Arm - Leg Body	Leg	Arm - Leg	Thorax	Thorax	Thorax	Thorax	Thorax

Signals / Sensors	Application/Configuration								
	Actigraphy Sleep/Wake	Actigraphy Training/Sport	PLM Recorder	Movement Analyser	Respiratory Screener	REM/NR Recorder	Long-term Body Position	Long-term ECG	Long-term EEG
Internal	●*)	●	●	●	●	●	●	●	●
Movement	● ¹⁾	●	● ¹⁾	● ²⁾	● ¹⁾	● ¹⁾	● ¹⁾	● ¹⁾	—
Ambient Light	●	●	●	●	●	●	●	●	●
Patient Marker Button	●	●	●	●	●	●	●	●	●
External	○	○	○	○	○	—	○	—	—
Flow & Snore	○	○	○	○	—	●	○	●	—
ECG	○	○	○	○	—	●	○	●	—
EEG	○	○	○	○	—	—	○	—	●
CPAP	○	○	○	○	—	—	○	—	—
PLM - EMG or ACTI	○	○	○	○	—	—	○	—	—
Temperature	○	○	○	○	—	—	○	—	—
EDA	○	○	○	○	—	—	○	—	—

● Standard ○ Option ●*) Position ●¹⁾ Quantitative Recording ●²⁾ x, y, z - Axis



Data Transfer: USB with simultaneous battery charging

Intermittent Measuring: Programmable start and duration for up to 6 measurements

Patient Interface: LED Status Indicator

Programmable Alarm Sound

Data Synchronisation: Simultaneous use of two or more **SOMNOwatches™ plus** with synchronised analysis

Data Export: Raw Data (ASCII, RIFF, EDF), Results (Excel, Word, PDF, SPSS)

Report Generation: User friendly and flexible report and form letter generator

Patient Data Management (Option):

- Permanent access to the complete list of results, sleep profiles and graphical results
- Trend reports, integrated questionnaire
- The database is network compatible with a permanent patient list Search engine is provided to help locate the patient data

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