

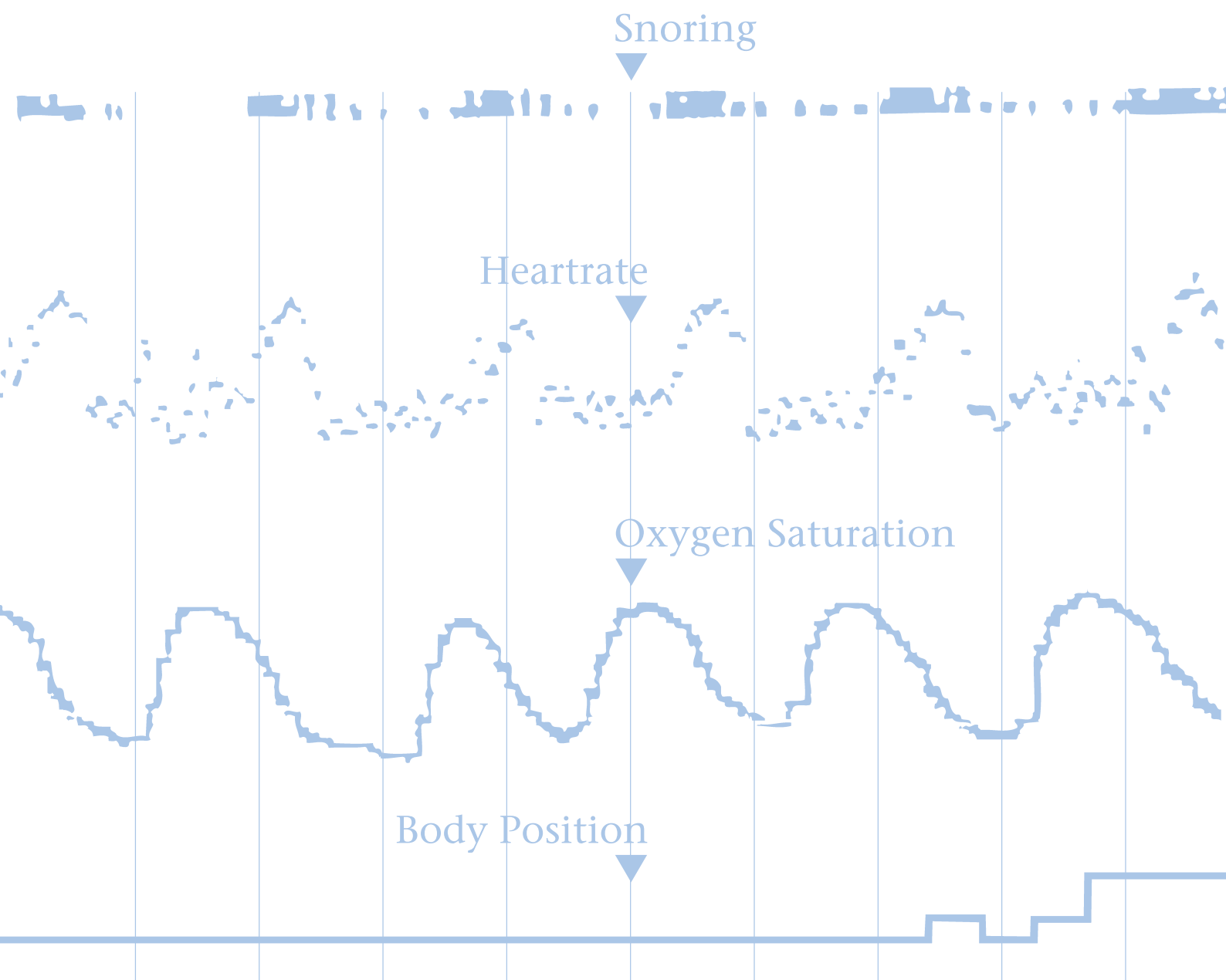
# Poly-MESAM®

The custom-configurable cardio-respiratory diagnosis system for in-patient and out-patient polygraphy

MAP

## Our Experience and Expertise – Your Advantage

The development of MESAM® II, our first, legendary sleep diagnosis system near the end of the 1980s, initiated a broad series of epidemiological research projects into sleep related breathing disorders (SRBD) around the globe. Based on the resulting experience and gained know-how MESAM® IV, the first four-channel diagnosis system was developed. Today, products of the MESAM® family are widely understood as synonym for and having pioneered the in-patient and out-patient sleep diagnosis. These products have been further developed to create the Poly-MESAM®, an individually configurable cardio-respiratory diagnosis system for in-patient and out-patient polygraphy.



# An Expression of our Joy in Innovation: The New User Software Poly-MESAM® for Windows®

With the introduction of the newly developed software, based on the proven algorithms of the MESAM® family of products, the Poly-MESAM® diagnosis system has achieved a new high. Some performance features of the new Poly-MESAM® for Windows® software are:

- Customisation of screen display , recording channels, event detection and report format to fit individual requirements and personal work style.
- Simultaneous entry of events during in-patient recording.
- Rapid edition and modification of events in Quick Mode.
- Integrated RLS / PLMS - analysis
- Export of analysis data in so-called "EDF" format (European Data Format) or via the Windows®-specific clipboard to be able to share information with your colleagues.
- Easy use of even seldom-accessed features by context-sensitive helpfunctions.
- Online dataveillance during recording with scroll fuction.
- ECG recording in online mode.
- Full compatibility to PneumoFlow®, the new MAP sensor which provides reliable information on respiratory events during diagnosis therapy.
- Simultaneous use of Poly-MESAM® for Windows® software and other standard software allow for efficient usage of your PC.
- Easy installation of Poly-MESAM® for Windows® software on your PC by simple menu guidance.
- No screen flickers and reduction of eyestrain while at work by a resolution of 640 x 480 up to 1024 x 768 pixels.
- The Poly-MESAM® for Windows® software is designed for the Windows® 95, 98 and NT operating systems which have become standard.

\* Poly-MESAM® is a registered trademark and product of MAP Medizin-Technologie GmbH.  
Poly-MESAM® is based on MESAM® II. Poly-MESAM® is commercially available since 1986.  
MESAM® II is considered a pioneer in the field of nighttime sleep diagnostics.

# An Ergonomic Workstation – an Essential Requirement for an Efficient and Time Saving Work Style

The Poly-MESAM® diagnosis system supports you through its clearly structured Poly-MESAM® for Windows® software, through its ergonomic design, its high standard of safety and rapid data analysis, in performing individual tasks.

## Installation

The menu-driven installation of the Poly-MESAM® for Windows software runs either automatically or by confirming the simple prompts on the screen. You can also custom-configure it to your own individual requirements.

The following languages are available: German, English, French, Spanish, Italian

## Training / Familiarisation with the software

Typical sample files with evaluations and clinical results along with the integrated context-sensitive help system make it easy to get used to working with and handling the diagnosis system. The following example files will be delivered:

- patient with obstructive sleep apnea
- patient, habitual snorer
- patient with PLMS (Periodic Limb Movement Syndrome)
- patient under nCPAP therapy control
- normal patient

## Using Poly-MESAM® for out-patient recordings

The Poly-MESAM® diagnosis system can be operated without a power supply in the mobile mode. Up to 8 channels can be recorded in this mode. The integrated 8 MB PCMCIA memory card allows you to record data for up to appr. 50 hours.

The data on the storage card can be read by any PC with a standard PCMCIA slot and is then immediately available for further evaluation. While the data is being recorded at night, signals

can still be checked without affecting the recording. This provides you with additional security during data acquisition.

## Recording of

- Heart rate (HR, recorded by 3 ECG electrodes) Standard
- Oxygen saturation (SpO<sub>2</sub>) Standard
- Body position (Pos) Standard
- Snoring sound (Micro) Optional
- Air flow (Flow) Optional
- Thoracic effort (Thor) Optional
- Abdominal effort (Abd) Optional

**additional:** external signal channel to monitor

- activity of the extremities (e.g. PLMS) Optional or
- airway pressure measurements Optional and
- continuous tracking of battery status of the recorder Standard

## Using Poly-MESAM® for in-patient recordings

When using the Poly-MESAM® for in-patient recordings, the ECG can be displayed additionally for the detection of heart rhythm irregularities. The bio-signals are displayed and stored continuously and directly on the connected PC.

Hereby, you are constantly and comprehensively informed about both the recording's and the patient's general status.

This mode also allows you to quickly mark events during a session or recording by using custom-configurable function keys.

## Additional recording of:

- ECG Standard



Typical screen during stationary use, 7-channel recording

## Displaying data on the screen

You may customise the signal display according to your requirements.

For example, colour as well as the arrangement and scaling of the channels can be individually configured. Manual processing of the analysis are highly facilitated by other aids such as numerical display of the signal values, displaying values in two windows (for example the complete night in one window and 30-second intervals in a second window). The recorded data becomes absolutely transparent.

## Data analysis

An 8-hours night is automatically analysed within approximately 10 seconds. This faster than ever before analysis represents an enormous savings of time for you. Along with detecting desaturations, variations in heart rate and snoring events, it also con-

tains a classification of respiratory events, limb movements, and a correct calculation of the indices. It is very easy to mark times to be excluded from calculation and analysis. The analysis is also supported by the option of scrolling through events, which makes editing faster and more efficient.

## Data report and printout

Reports can be individually configured. You may also print on any commercially available printer, even in color.

## Archiving data / network

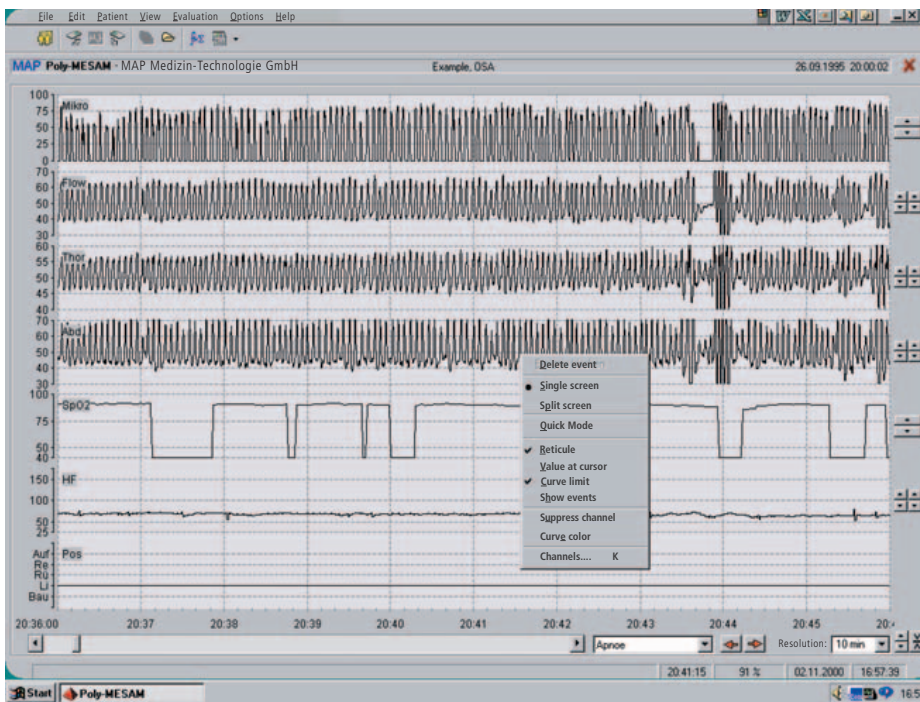
You can use any modern mass storage media for simple archiving and storage of data (ZIP, MOD, Jaz, SyJet, CD-R).

It has also become a standard feature to set up a central archive using the extensive network features.

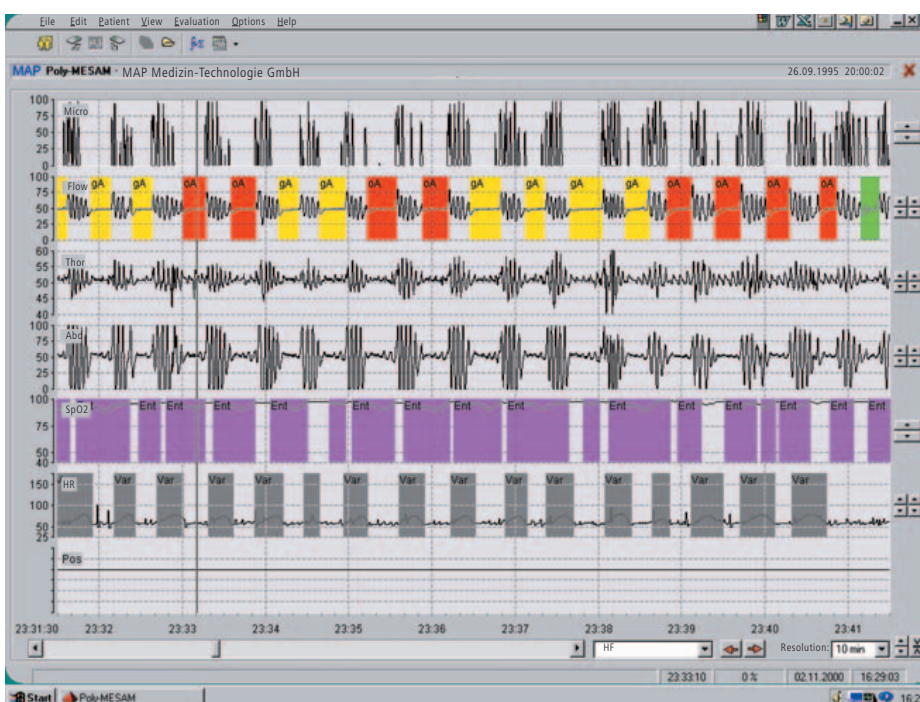
## Exporting data

Exporting data and recordings for subsequent statistical evaluation or for further correspondence with your colleagues is supported by the export feature and by saving data in the so-called EDF format (European Data Format).

Exporting data via the clipboard of the Windows operating system opens up additional possibilities for further processing.



Example for configuration possibilities of the screen



Typical screen after automatic analysis of a 7 channel study

# Wide Range of Sensors The Key for Successful Diagnosis

## Sensors and accessories

Your work with Poly-MESAM® will be supported by the available optimised sensors. In addition to the standard sensors we can offer specially configured sensors for pediatric use. Your Poly-MESAM® will support you in a wide range of applications.

## PneumoFlow® - The better, more comfortable measurement method

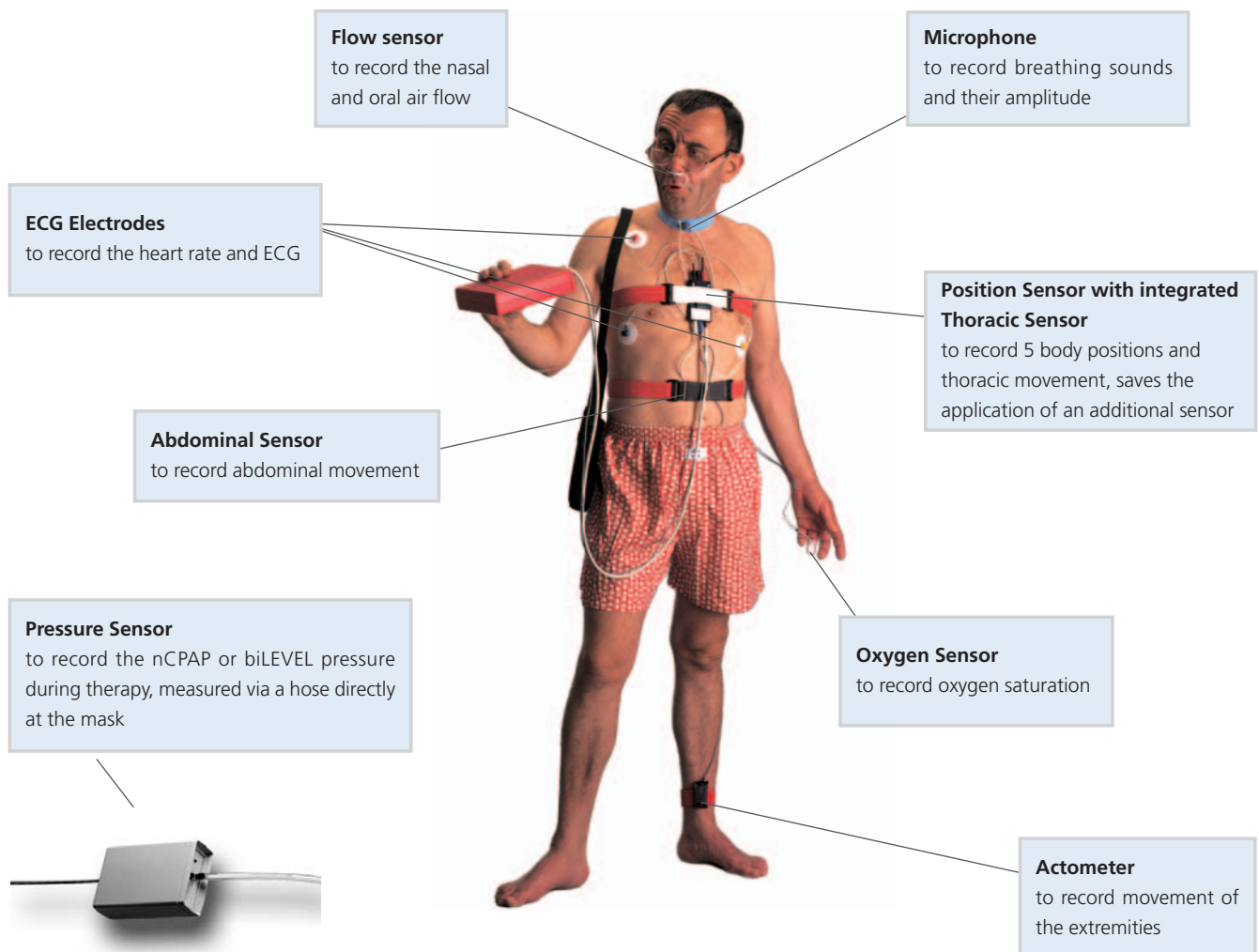
The new MAP PneumoFlow® provides you with reliable information on respiratory flow in the diagnosis of obstructive sleep apnea and in detecting flow limitations and upper airway resistance. Additionally, you may record snoring with PneumoFlow®, too.

For diagnosis, use standard, commercially available nasal cannulas when measuring flow and snoring signals. During the therapy night with a respiratory therapy device, the MAP measuring adapter PneumoControl provides precise results. PneumoFlow® gives you reliable raw data for your records, is easy to use and, importantly, is comfortable for your patients.

PneumoFlow® works according to the principle of pressure-difference measurement which is well known for its excellent signal quality. Studies prove, that the pressure-difference measurement offers a considerably higher sensitivity than the temperature difference measurement<sup>1</sup>.

PneumoFlow® is of course interoperable to a lot of common polysomnographic systems.

<sup>1</sup> Detection of Respiratory Events During NPSG: Nasal Cannula/Pressure Sensor Versus Thermistor; David M. Rapoport et al. ;Sleep 1997; 20(12): 1175-1184



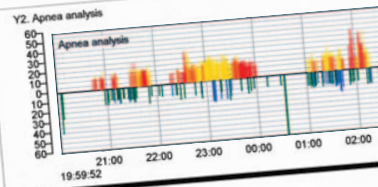
MAP Medizin-Technologie GmbH		Poly-MESAM for Windows 2.00	
Patient: Example OSA	Born: 4/10/1937	Physician: Dr. Somno	MAP
Recording: 26-09-95 20:00-07:01	Evaluator:	PID: 12345678	

1. Patient data		Physician : Dr. Somno
File name : Example-OSA	PID : 12345678	
Name : Example	Sex : M	
First Name : OSA	Height : 165	
Date of birth : 4/10/1937	Weight : 100	
Street : Oak Street	BMI : 36.73	
City : Munich	Diast. press. : 90	
Phone : 089-89518-6		

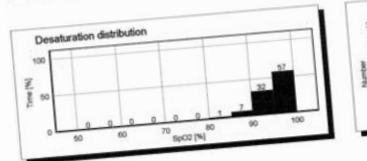
2. Recording	: 26-09-95 : 20:00:02 - 07:01:02	Duration: 11:01:00
Recording period	: 20:00:02 - 07:01:02	Duration: 10:34:27
Analysis period	:	Duration: 00:26:33
Excluded from analysis	: 00:18:30 (2.92 % of the evaluation period)	
SpO2-artefacts		

A. Indices	Phases / hour	Correlation with RDI
Parameter	54	-
RDI	42	78 %
Apnea index	12	22 %
Hypopnea index	52	64 %
Desaturation index	77	84 %
Heart rate variation index	4	0 %
Mobility index		

MAP Medizin-Technologie GmbH		MAP	
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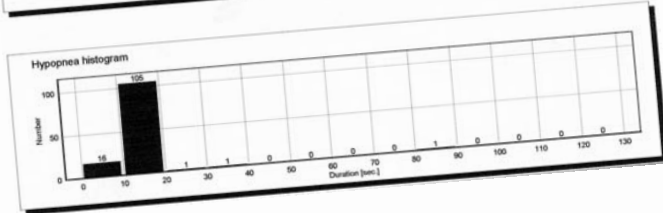
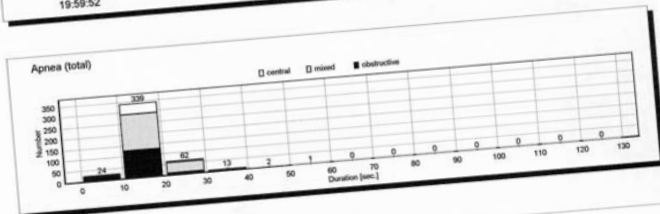
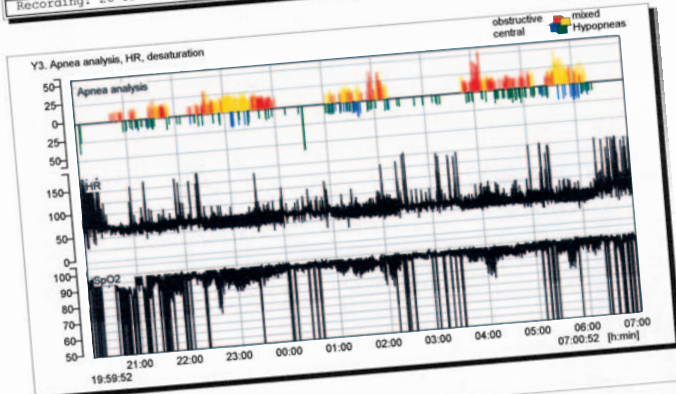


B. Apnea analysis results				
Class	all	10..20s	>20s	>40s
obstructive	168	148	20	2
mixed	221	168	53	1
central	52	47	5	0
total	441	363	78	3
Hypopneas	124	121	3	1

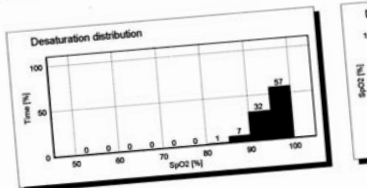
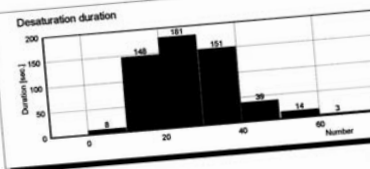


C. Desaturation analysis results	
Oxygen saturation	
Lowest minimum	
Mean minimum	
Mean saturation	
Mean basal saturation	
Maximum duration	
Mean duration	
Number of desaturations	
Desaturation index	

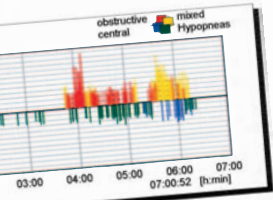
MAP Medizin-Technologie GmbH		Poly-MESAM for Windows 2.00	
Patient: Example OSA	Born: 4/10/1937	Physician: Dr. Somno	MAP
Recording: 26-09-95 20:00-07:01	Evaluator:	PID: 12345678	



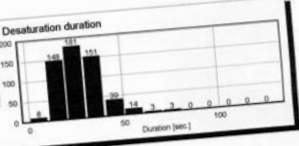
MAP Medizin-Technologie GmbH		MAP	
Patient: Example OSA	Born: 4/10/1937	Physician: Dr. Somno	MAP
Recording: 26-09-95 20:00-07:01	Evaluator:	PID: 12345678	



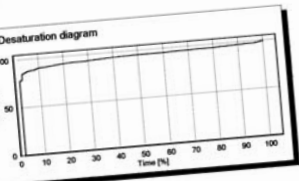
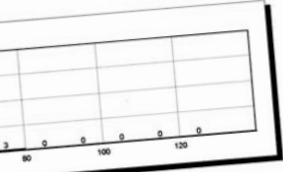
This patient shows deep desaturations during the night. A high index is reported by the patient. Obstructive sleep apnea as a indication



mean duration	max. duration	Index
16 s ± 7	54 s	16
19 s ± 5	46 s	21
16 s ± 3	23 s	5
17 s ± 6	54 s	42
14 s ± 7	86 s	12



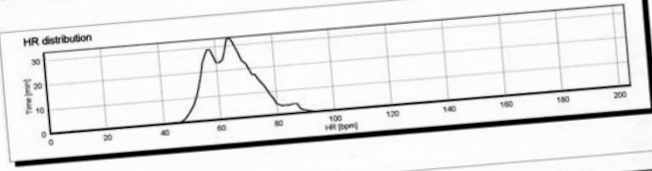
SpO2 <= 100 %	SpO2 <= 90%
71 %	71 %
90 % ± 3	87 % ± 0
95 % ± 2	87 % ± 0
96 % ± 3	88 % ± 0
76 s	76 s
27 s ± 15	30 s ± 0
547	220
52 / h	21 / h



Impact on vigilance during the night since years was for CPAP therapy is given.

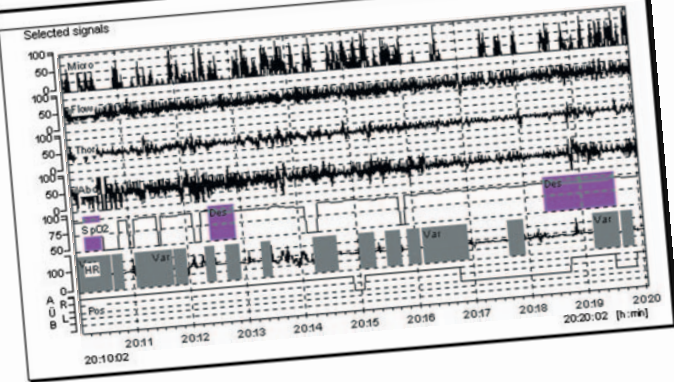
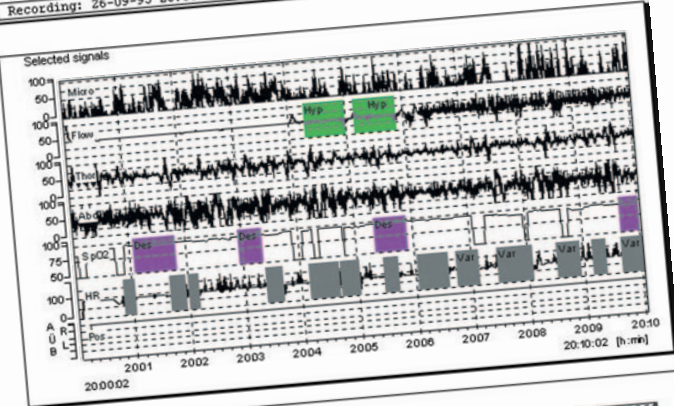
D. Body position sensor results, absolute and related to apneas

Body-position	Apneas Time	Mean duration		Apneas/ of Apneas	Position
		Number	Index		
Left	02:16:25	87	8	18 s ± 9	20 %
Right	01:56:35	122	12	16 s ± 5	28 %
Supine	03:10:35	221	21	17 s ± 5	50 %
Prone	00:05:56	4	0	22 s ± 7	1 %
Upright	03:31:29	7	1	12 s ± 1	2 %
All	10:34:27	441	42	17 s ± 6	100 %
Sum of all body position changes				= 45	
Mobility index (body position changes per hour)				= 4	



E. Snoring, heart rate

Snoring	Analysis duration		Heart rate
	Absolute	relative	
Snoring	00:55:29	9 %	66 bpm ± 5
Without snoring	00:35:53	6 %	67 bpm ± 7
With snoring	09:29:38	90 %	65 bpm ± 10
With loud snoring	10:34:27	100 %	65 bpm ± 10
Sum			
Mean heart rate increase with snoring/without snoring : 0,0 %			



# Poly-MESAM®

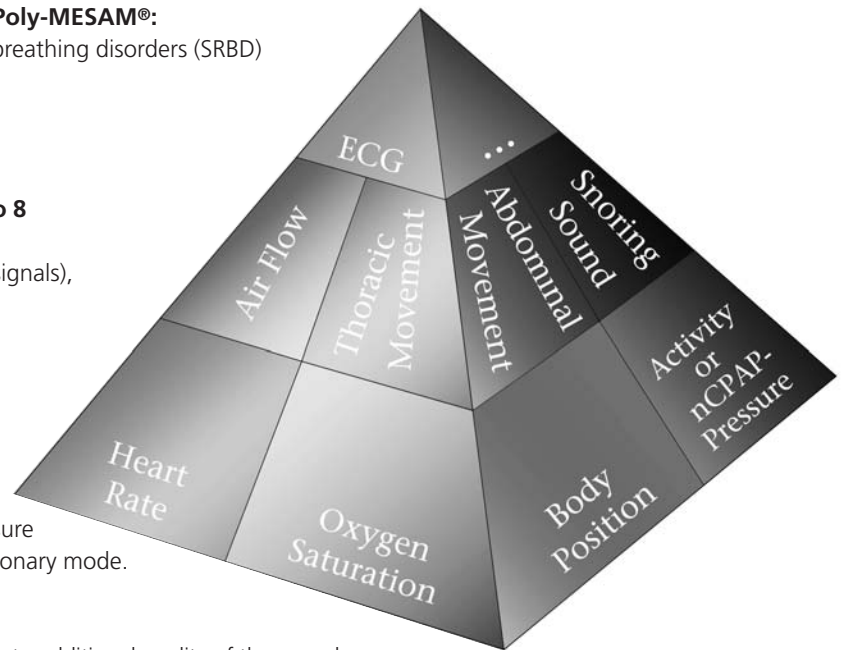
## Your Individually-Tailored Solution

### Examples for clinical assessments with the Poly-MESAM®:

- Early, out-patient diagnosis of sleep related breathing disorders (SRBD)
- nCPAP therapy control
- Recognition of nocturnal arrhythmias
- Diagnosis of LMS or PLMS

### The Poly-MESAM® is designed to record 4 to 8 channels simultaneously.

- Heart rate (HR, calculation based on 3 ECG signals),
- Oxygen saturation (SpO<sub>2</sub>),
- Body position (Body),
- Breathing sound (Micro),
- Air flow (Flow),
- Thoracic effort (Thor),
- Abdominal effort (Abd),
- External channel to monitor activities of extremities (e.g. PLMS) or nCPAP/biLEVEL pressure during therapy and recording of ECG in stationary mode.



The continuous tracking of the battery status leads to additional quality of the record.

## The Spectrum of Applications at a Glance

### ● Out-Patient Monitoring

Battery (rechargeable or single-use) or mains operation is possible. The device is designed for diagnosis and therapy control at the patient's home, at the private practice, and at the clinic.

### ● In-Patient Monitoring

In the stationary mode you can display all signals „online“. Additionally, the ECG will be displayed to enable the identification of arrhythmias. Automatically, all data is directly stored in the archive. The Poly-MESAM® will become an indispensable partner in your sleep lab, especially for your therapy controls.

### ● Acoustic Alarms

Two automatic acoustic alarms for oxygen desaturation and heart rate with individually programmable critical values are integrated in the stationary mode for the safe monitoring of risk patients.

### ● Stand Alone Pulse Oximeter

You may use the Poly-MESAM® as a stand alone pulse oximeter, as well as long-term recorder for oxygen saturation control.

### ● Extensive Sensor Assortment

An assortment of easily applicable and comfortable to wear sensors for single or multiple use allows universal usage, for e.g. pediatrics.

### ● Extended Analysis

The analysing software includes the detection of desaturations, heart rate variations, snoring events, PLM, and UAR as well as the classification of the different types of apnea. The parameters for the event detection may be chosen individually.

### ● Time Independent Programming

The Poly-MESAM® may be programmed in advance, hence ideal for weekend use and economical operation.

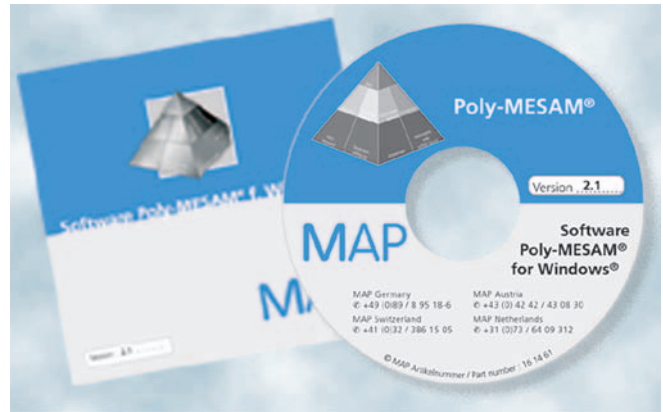
### ● Automatic analysis and calculation of

- Apneas (obstructive, central, mixed), Hypopneas
- SpO<sub>2</sub> desaturation
- Variations in heart rate
- LM and PLM
- Breathing sound
- Correlation analysis of different parameters
- Display of analysis as graphics and tables
- BMI calculation

# Poly-MESAM® Technical Specification




The Plus Package, your ready to use polygraphy solution



Poly-MESAM® Software

<b>Signal recording for:</b>	<ul style="list-style-type: none"> <li>• Heart rate</li> <li>• Oxygen saturation</li> <li>• Body position</li> <li>• ECG (in real-time mode)</li> <li>• Snoring sound</li> <li>• Air flow</li> <li>• Thoracic effort</li> <li>• Abdominal effort</li> <li>• External signal channel to monitor activity of the extremities (e.g. PLM) or airway pressure measurements</li> <li>• Battery</li> </ul>
<b>Sampling rates</b>	Up to 100 Hz, adjustable for each channel
<b>Analysis</b>	<ul style="list-style-type: none"> <li>• Apneas (obstructive, central, mixed), Hypopneas</li> <li>• SpO<sub>2</sub> desaturation</li> <li>• Variations in heart rate</li> <li>• LM, PLM</li> <li>• Breathing sound</li> <li>• AI, HI, RDI, BMI calculation</li> </ul>
<b>Archive</b>	Support of MOD's, ZIP drives, JAZ-, SyJet-drives and CD-R
<b>Network</b>	Support of Windows® networks
<b>Out-patient recording</b>	Recordings of up to 26-hour with 4 MB PCMCIA memory card and 8 channels
<b>In-patient recording</b>	Duration of recording and number of recordings is limited only by the mass storage media used; the average storage space required is about 20 MB per record or session (standard 8-hour night, 8 channels)

<b>Power supply for the Poly-MESAM® recorder</b>	<ul style="list-style-type: none"> <li>• 2 batteries 1.5 V, Typ LR14 or</li> <li>• 2 accumulators, 1.2 V, 2200 mAh</li> <li>• Alternatively power supply</li> </ul>
<b>Dimensions &amp; weight of the Poly-MESAM® recorder</b>	190 x 135 x 45 mm, appr. 530 g (without batteries)
<b>Software</b>	Poly-MESAM® for Windows®
<b>Hardware/minimum requirements for the PC</b>	<ul style="list-style-type: none"> <li>• 133 MHz Pentium</li> <li>• VGA graphics card</li> <li>• 64 MB RAM</li> <li>• 60 MB free storage space on hard drive</li> <li>• CD-ROM drive</li> <li>• Mouse</li> <li>• 1 free serial interface for connection to the Poly-MESAM® recorder</li> <li>• 1 free parallel interface for connection to an external PCMCIA drive or integrated PCMCIA drive</li> <li>• Any commercially available printer</li> <li>• Windows® operating system</li> </ul>
<b>Poly-MESAM® Plus Package</b>	<ul style="list-style-type: none"> <li>• pre-installed software Poly-MESAM® for Windows®</li> <li>• High-performance Laptop: <ul style="list-style-type: none"> <li>- Pentium III 500 MHz</li> <li>- 64 MB RAM</li> <li>- 6 GB hard drive</li> <li>- 3.5 inch disk drive</li> <li>- 640 MB CD-ROM drive</li> <li>- 12.1 inch color TFT LCD 800 x 600 Pixel</li> <li>- Equipped for audio</li> <li>- Integrated mouse</li> <li>- PCMCIA slot for 2 type II cards</li> <li>- Windows® 98 operating system</li> </ul> </li> </ul>

<b>Safety standards</b>	 CE mark according to EC Directive 93/42/EEC
<b>DIN EN 60601-1</b>	"General specification for the safety of medical electrical equipment."
<b>DIN EN 60601-1-2</b>	"Supplement: Electromagnetic compatibility, requirements and testing."

<b>Provided by</b>	
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