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# **COMPUMEDICS SLEEP MONITORING SYSTEM**

**510(k) Summary**

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## **General Information**

### ***Manufacturing Facility Address***

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Contact Names: David Burton, Managing Director  
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### ***Trade/Proprietary Name***

Compumedics Sleep Monitoring System:  
S-Series  
P-Series  
W-Series

### ***Common/Usual Name***

Sleep Assessment Device

### ***Reason for Premarket Notification***

The Compumedics Sleep Monitoring System is a new device.

### ***Device Classification***

Sleep Assessment Equipment has been assigned FDA product code 73MNR (Ventilative effort recorder breathing frequency monitor).

At least two devices have received clearance for commercial distribution as Class II medical devices via substantial equivalence (510(k)) determinations under this designation. Those devices are the Farrall Instruments, Incorporated Sleep Assessment Device (K792305, December 20, 1979 determination) and Somnitec Incorporated's Somnomic (K912817, July 26, 1991, determination).

Additionally, the Nicolet Expert Sleep/Wake System (K873535) and the SensorMedics Series 4000 Sleep System (K915856) have been cleared for commercial distribution through the determination of substantial equivalence under the 84GWQ product code (also under the Neurology panel designation).

In that all four of the above-named devices are sleep assessment equipment (like the subject Compumedics device), and all four of the above-named devices have been cleared for marketing through the substantial equivalence (510(k)) process, and as these latter two devices have been chosen as predicates for the subject device, we maintain that the Compumedics Sleep Monitoring System is similarly a Class II device, subject to market authorisation through the process of determination of substantial equivalence.

### ***Certification***

As the Compumedics Sleep Monitoring System is not claiming substantial equivalence to a Class III device, a certification statement is not required.

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### ***Predicate Devices***

Predicate devices claimed:

Nicolet Expert Sleep/Wake Analysis System  
SensorMedics Series 4000 System

The Compumedics Sleep Monitoring System is substantially equivalent to currently marketed SensorMedics Series 4000 and Nicolet Expert Sleep/Wake System. The Nicolet Expert Sleep/Wake System, manufactured by Nicolet Biomedical Instruments, Madison, Wisconsin 53711-0287, was subject of an approved 510(k) notification on October 26, 1987, (Ref. No. K873535). The SensorMedics Series 4000, manufactured by SensorMedics Corporation, Yorba Linda, California 92687, was subject of an approved 510(k) notification on October 26, 1992, (Ref. No. K915856).

### ***Technological Characteristics Compared to Predicates***

There are no substantial distinctions in technological characteristics among the predicate and subject devices.

### ***Performance Standards***

To date, no performance standards or special controls applicable to this type of device have been promulgated by the Agency.

### ***Intended Use***

The Compumedics Sleep Monitoring System is used as an aid in the diagnosis of sleep and respiratory related sleep disorders. The use of this sleep monitoring system is to be under the supervision of a physician, sleep technologist or clinician. The Compumedics Sleep Monitoring System is an information management tool to record, display, organize, summarize, redisplay (retrieve) and generate user-defined reports based on the subject's data received from monitoring devices typically used to evaluate sleep and sleep related respiratory disorders.

The users of the Compumedics Sleep Monitoring System are medical professionals who have received training in the areas of hospital procedures, physiological monitoring of human subjects, and sleep disorder investigation.



## Device Description

### Overview

Polysomnography involves recording of individual signals collected by various standard physiological monitoring and recording devices typically used for such studies. These include EEG, ECG, respiratory sensors, body position sensors, oximeters, etc. The Compumedics Sleep Monitoring System is a device which integrates the monitoring and recording function of these individual devices, and provides the means to gather all these signals simultaneously into a single "box" where these signals can be viewed, stored, and retrieved in formats selected by the clinician or sleep technologist.

### Polysomnography

Polysomnography (PSG) involves the continuous, overnight monitoring and recording of selected physiological variables to assist in evaluation of sleep and sleep related respiratory disorders. These variables may include neurological activity, heart rate, body movements, nasal and oral airflow, snoring noises, eye movements, and others. Electrical signals are sent from specialised sensors applied to various body parts (e.g. head, chest, face) to an integrated recording and/or displaying instrument called a polygraph.

There are three generic types of signals collected:

- a) *Bioelectrical Potentials*: These are signals produced by the body's own tissues, such as brain wave recordings [electroencephalogram (EEG)], eye movement recordings [electrooculogram (EOG)], muscle activity recordings [electromyogram (EMG)], and heart rate recordings [electrocardiogram (ECG)]. Bioelectrical potentials are recorded by placing sensors over the tissues generating these signals (e.g. on the scalp for EEG, chest for ECG, next to the eyes for EOG).
- b) *Non-electrical Physiologic Activity*: Non-electric physiological activity is translated into electrical signals by transducers. For example: a thermistor or thermocouple measures change in temperature to monitor nasal or oral airflow (cool upon inhalation, warm upon expiration); inductive respiratory bands measure chest/abdominal effort in response to movement; and position sensors monitor body position.
- c) *Other signals*: Other physiological activities translated into electrical signals by auxiliary devices. These may include devices such as oximetry to measure haemoglobin oxygen saturation (SaO<sub>2</sub>).

The patterns of these electrical signals are distinct in the different stages of sleep. At the onset of sleep, the brain's activity shifts into specific patterns. There are four stages of sleep: Stage 1 (light sleep), Stage 2, Stage 3/4 (slow wave), and REM (Rapid Eye Movement). Stages 1, 2, 3 and 4 are also collectively referred to as non-REM (NREM) sleep. Each stage is characterised by brain waves (EEG) of very specific frequencies and/or amplitudes. Stages of sleep may also be defined by certain types of eye movements (EOG) and muscle activities (EMG).

There is a regular progression of sleep stages for a normal sleep period. A sleep cycle is a period of REM sleep followed by NREM sleep. Typically, there are four to six sleep cycles per sleep period. Sleep disorders can cause disruptions in this normal pattern and their presence can be determined by monitoring changes in the sleep pattern. For example, when breathing through a blocked or partially blocked throat, the stress of this event may cause abrupt changes in brain activity, sometimes waking the person or moving them into a lighter stage of sleep. (e.g. Stage 1) prematurely. Often this results in a shorter total sleep time and reduced slow wave (Stage 3/4) and REM sleep. This sleep deprivation or fragmentation of normal sleep cycles may result in daytime sleepiness and poor daytime function.

Respiratory dysfunction occurring during sleep is referred to as sleep apnea and is a common condition contributing to sleep deprivation. When abnormal breathing episodes occur repetitively during a sleep period, a person is said to suffer from sleep apnea. An apnea episode or event occurs when the throat becomes totally blocked (obstructed) with complete or almost complete cessation of airflow lasting momentarily and is usually associated with oxygen desaturation or arousal. An hyponea occurs when



the throat is partially blocked, and when breathing continues but is diminished (about 70% reduction in airflow) and is also associated with oxygen desaturation or arousal. To resume breathing, hypopnea or apnea triggers increased inspiration efforts and within seconds, enough pressure builds up to open the obstructed throat, where a loud snort or gasp may result. Alternatively, snoring may result when throat tissues vibrate while breathing through a partially blocked throat.

One obvious consequence of sleep apnea is disturbance of one's sleep and possibly that of a bed partner, which may result in diminished activity or capacity during the day, and possibly embarrassment or marital discord. However, a more serious consequence of these breathing disorders is in causing repeated, episodic drops in the body's oxygen levels. It is hypothesised that this causes stress on the heart, contributes to high blood pressure and other heart ailments (heart attacks, angina, irregular heart rhythms) or possibly stroke.

PSG is used to monitor and record physiological signals during sleep to permit evaluation of sleep patterns and aid in the diagnosis of sleep disorders. Apneas and hypopneas that last longer than ten seconds are characterised by a drop in oxygen and a change in brain wave pattern. If the incidence of apnea and hypopneas during sleep is greater than an established baseline, a diagnosis of sleep apnea is determined. For accurate assessments of these respiratory "events", the following parameters are monitored:

- Brain activity (EEG) to determine the stage of sleep and arousals.
- Muscle activity (EMG) to determine the stage of sleep and arousals.
- Eye movements (EOG) to determine the stage of sleep and arousals.
- Thermistors or thermocouples monitor oral/nasal airflow.
- Sensors that measure thoracic and abdominal distension/movement with breathing monitor respiratory effort.
- Oximetry measures blood oxygen saturation levels (SaO<sub>2</sub>) by passing light through the finger capillaries and measuring absorption patterns.
- Body position is monitored (e.g. via position sensor and/or infrared video camera) to determine if supine, upright, or side position is common during an event.
- Heart rate (ECG) is monitored to evaluate stress related to breathing and arrhythmia detection.

Historically, this monitoring has been performed by individual devices dedicated to one, or a few, of these physiological parameters. Only in recent years have integrated sleep monitoring systems been designed and commercialised to collect all of this data simultaneously. The subject device is one such device.

Following the collection of sleep data by PSG monitoring, the first step in processing the study data involves segregating the physiological data obtained through PSG into specific time intervals, called "epochs". A typical epoch used is 20 or 30 seconds. (Epochs longer than 30 seconds could introduce a bias against short-lived sleep changes.) Once epochs are established, the clinician scores each epoch into standard sleep stages using the obtained physiological data. Scoring the data is based on established methodology (Rechtschaffen, A and Kales, A. A Manual of Standardised Terminology, Techniques and Scoring System for Sleep Stages of Human Subjects, United States National Institutes of Health publication No. 204, 1968). Using the scored epochs, the clinician next noted the times occurrence, the duration, and the relative distribution of the Rechtschaffen and Kales (R&K) sleep stages.

Manual segregation of data accumulated from many independent monitoring devices into epochs and sleep stage scoring can be a labour intensive, tedious, and time-consuming process. Electronic recording, storage, retrieval and display of the monitored physiological parameters by a single integrated device offers many advantages over manual processing and evaluation of chart recorded outputs. The subject Compumedics Sleep Monitoring System offers this automatic organisation of data, in addition to the fundamental monitoring and collection function.

The automated display of the polysomnographic information is neither unique nor novel, and merely represents the application of automated, computer-assisted display and graphing functions to the physiological data collected by physiological activity monitoring devices. This permits faster evaluation of the data by the clinician and facilitates diagnosis.



### **System Description**

The Compumedics Sleep Monitoring System consists of three sub-systems:

- S-Series
- P-Series
- W-Series

The S-Series is for monitoring multiple subjects simultaneously in the clinical setting. The P-Series allows for monitoring a single individual remotely, outside the clinical site (e.g. in their home). Both the S-Series and P-Series software modules operate using MS-DOS. The W-Series offers the user the capability to operate the Sleep Monitoring System in Windows (TM) instead of MS-DOS.

The Compumedics Sleep Monitoring System is comprised of hardware and software modules which allow for the collection and organisation of sleep study information. These modules have been expressly designed to be used in varying combinations to meet the wide range of needs of the sleep assessment device user. The minimum modules for the Compumedics Sleep Monitoring System consists of the following:

**S-Series:**

- (1 to 8) Patient Interface Box(es) - One for each patient
- (1 to 8) Preamplifier Module(s) - One for each patient
- (1) Workstation Module using MS-DOS Software

**P-Series:**

- (1) Patient Interface Box
- (1) Portable Main Unit
- (1) Memory Card

**W-Series:** Optional software for S-Series and P-Series to run Windows (TM)

The hardware and software modules are used in combinations to acquire, digitise, and record a variety of physiological signals during polysomnography (PSG) studies. Following the acquisition of the study data, the other hardware and software module combinations allow the sleep technician to review, process, generate reports, and archive all study information. The automated data processing functions the Compumedics Sleep Monitoring System can perform are:

- Sleep staging
- Respiratory scoring
- Detection of arousal events
- Detection of periodic leg movement (PLM) events

These sleep staging functions are based on standard Rechtschaffen and Kales (R&K) methodology (Rechtschaffen, A and Kales, A. A Manual of Standardised Terminology, Techniques and Scoring System for Sleep Stages of Human Subjects, United States National Institutes of Health publication No. 204, 1968).



### Compumedics Sleep Monitoring System Summary

Manufacturer Name Phone Number Model Names with Specific Model Numbers	Compumedics (613) 9419 5433 S-Series Sleep Monitoring System V7	Compumedics (613) 9419 5433 P-Series Sleep Monitoring System V2	Compumedics (613) 9419 5433 W-Series Sleep Monitoring System V2
<b>Comparison Categories</b>			
# Channels at (# per Patient)	48 @ 24 per 1	up to 36 per 1	up to 64 per 1
Records EEG, EOG and EMG	Y	Y	Y
Records ECG	Y	Y	Y
Records Intercostal EMG	Y	Y	Y
Records EMG from both Legs	Y	Y	Y
Records Air Flow	Y	Y	Y
Records Respiratory Effort	Y	Y	Y
Records Snoring Sounds	Y	Y	Y
Accepts Ext. Capnograph Signal	Y	Y	Y
Accepts Ext. pH Monitor Signal	Y	Y	Y
Accepts Ext. NPT Signals	Y	Y	Y
Oximeter (Built-In or External)	External	Built-in	External
Records Wrist Movement Rates	N/A	N/A	N/A
Records Body Sleeping Position	Y	Y	Y
Displays Raw Incoming Data	Y	Y	Y
Displays Raw Data for Interpretation	Y	Y	Y
A/D Vertical Resolution (in Bits)	8 or 12	8 or 12	8 or 12
Sampling Rate/Channel Samples/sec	Max 500 per channel	Max 250 per channel	Max 500 per channel
Storage Rate/Channel Samples/sec	Max 500 per channel	Max 250 per channel	Max 500 per channel
Storage Medium Archive Type	Magneto Optical/Zip	Magneto Optical/Zip	Magneto Optical/Zip
Storage Medium Capacity (Supplied)	1.7 Gb or greater	20 - 80 Mb	1.7 Gb or greater
Storage Required per 8 Hr Study	20 to 30 Mb	20 to 30 Mb	20 to 30 Mb
Montage Flexibility	Y	Y	Y
Sleep Stage Scoring	Y	Y	Y
Definable Sleep Event Criteria	Y	Y	Y
Adjustable Sleep Scoring Rules	Y	Y	Y
Apnea /-Hypopnea Scoring	Y	Y	Y
Definable Flow/Effort Criteria	Y	Y	Y
Adjustable Apnea/Hypopnea Rules	Y	Y	Y
Generates a Printed Report	Y	Y	Y
CPU Type and Clock Speed (Supplied)	Pentium 166 or greater	16 Bit /14 Mhz	Pentium 166 or greater
Resolution (Width x Height [Pixels])	1024 x 768 (MS-DOS)	1024 x 768 (MS-DOS)	1024 x 768 or greater
Type of Power Required	AC	Battery or AC	AC
Type of Low Level Amplifiers	Built-in or external	Built-in	Built-in or external
Ability to Do an In-Home Study	Y	Y	Y
Number of Units Sold	≈ 140 beds	≈ 120	≈ 10
Warranty on Parts and Labor	12 Months	12 Months	12 Months
Price for Data Recording Unit	* 44K AUS	* 18K7 AUS	* 44K AUS
Price for Data Analysis Workstation	* 18K7 AUS	* 18K7 AUS	* 18K7 AUS
1-Bed Data collection/Playback	* 60K AUS	* 39K4 AUS	* 60K AUS
2-Bed Data Collection/Playback	* 84K AUS	* 58K AUS	* 84K AUS
Date Information Approved	04/02/1997	04/02/1997	04/02/1997

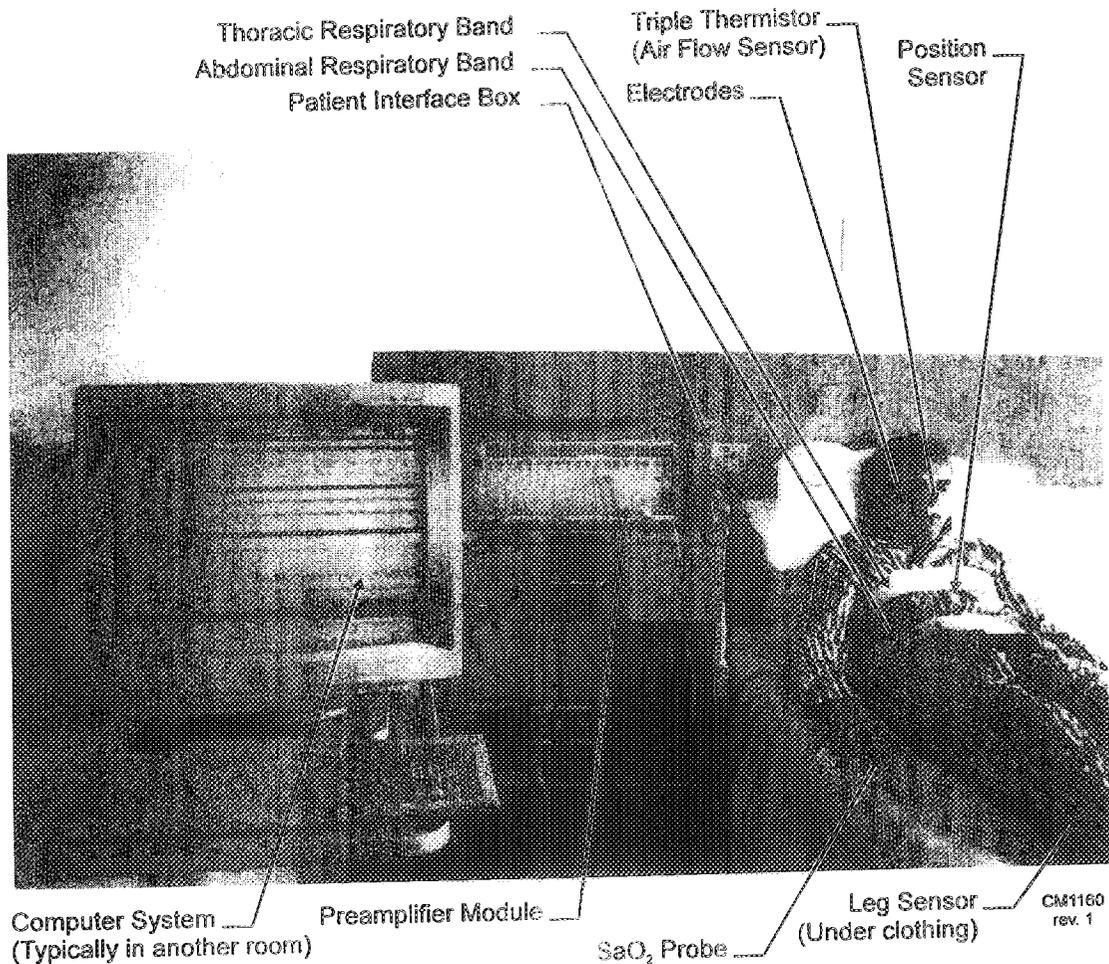
\* Prices may vary with specialised configurations



### S-Series Hardware Overview

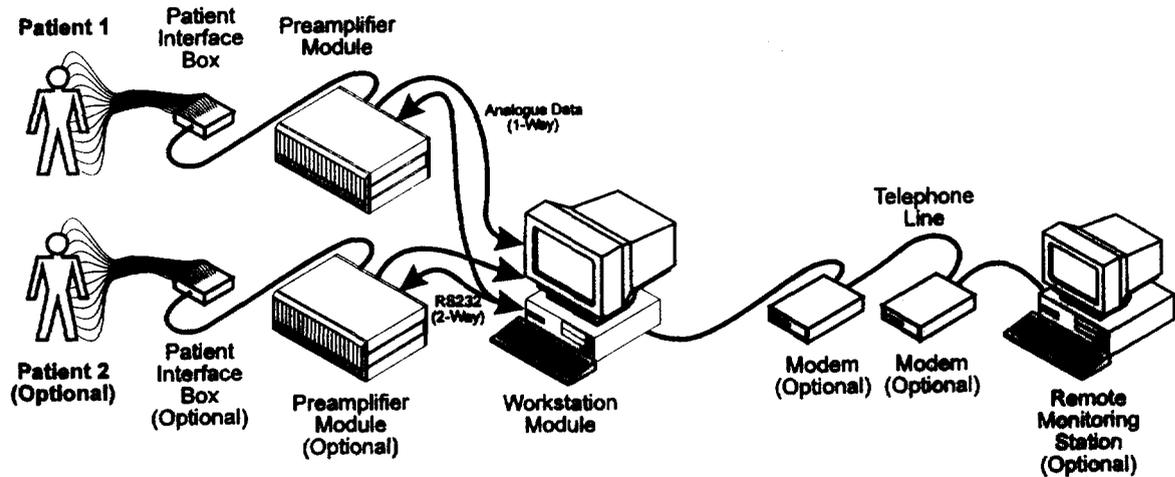
The diagrams of the S-Series depict typical configurations of the hardware modules. The photograph is a mock set-up of a sleep study demonstrating the use of the S-Series.

### S-Series Hardware Photograph





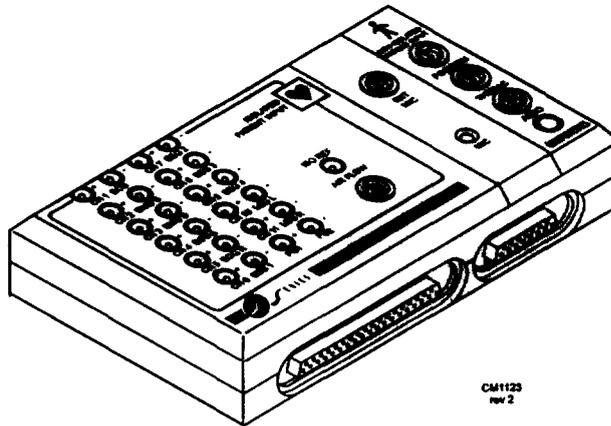
### S-Series System Diagram



### S-Series Patient Interface Box

The S-Series Patient Interface Box (PIB) is designed to fulfil the following functions:

- Electrode and sensor interface for the Compumedics Preamp Module Cards, as housed in the Compumedics Preamp Module.
- Remote electrode impedance measurement.



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rev 2

S-Series Patient Interface Box

The following input connectors are provided on the S-Series PIB

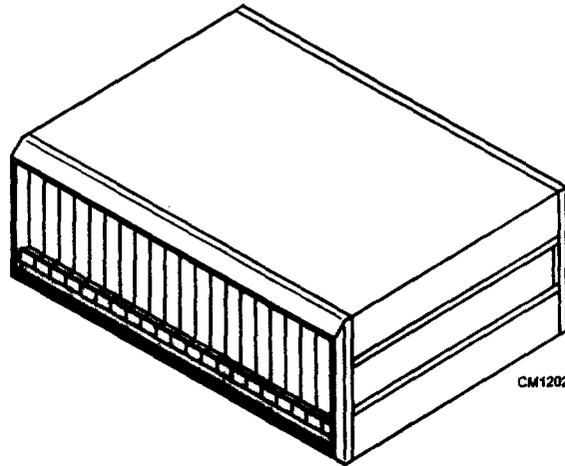
- Preamp channels 1 to 11. These are differential input channels allowing connection to the channels 1 to 11 of the Compumedics Preamp Module.
- Airflow Sensor
- Position Sensor
- Auxiliary input for Abdominal Respiratory Band (requires ACNONISO card in Preamp Module)
- Auxiliary input for Thoracic Respiratory Band (requires ACNONISO card in Preamp Module)
- Microphone. (The PIB also contains an internal microphone.)



### **S-Series Preamplifier Module**

The Preamplifier Module is a computerised system which performs all the conditioning of the signals from the patient for input to the Analogue to Digital (A/D) cards in the computer.

The Preamplifier Module is located next to the patient and is connected to the computer by cable installations.



**S-Series Preamplifier Module**

The complete range of Preamplifier Cards for each patient are housed in the Preamplifier Module. The Preamplifier Module has the provision for up to 20 input cards and one supervisory processor card. All Preamplifier Cards may be removed and replaced in the Preamplifier Module. The Preamplifier Cards are secured by two screws - one at the top and one at the bottom of the respective front panel.

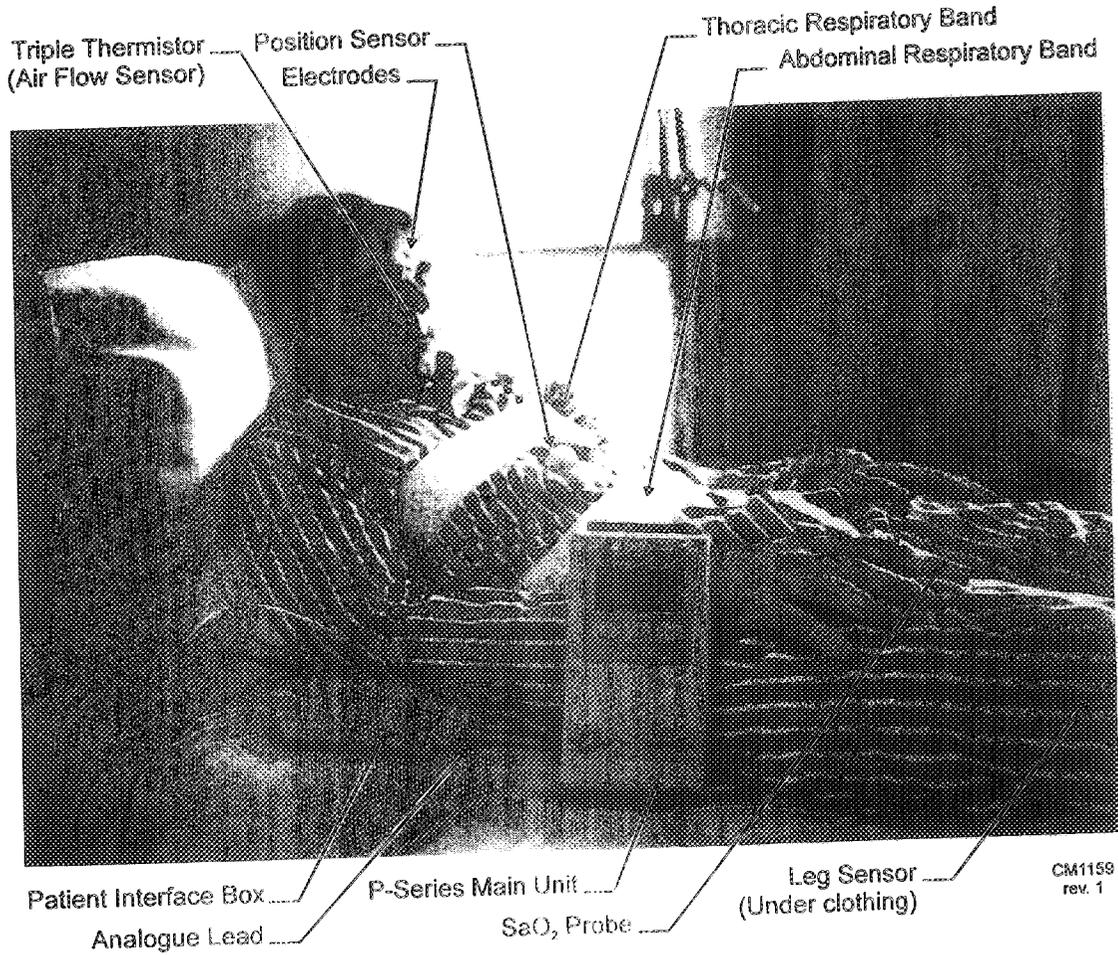
The Preamplifier Module and Preamplifier Cards have been designed to comply with the AS3200.1 medical standards.



### *P-Series Hardware Overview*

The diagrams of the P-Series depict typical configurations of the hardware modules. The photograph is a mock set-up of a sleep study demonstrating the use of the P-Series. The P-Series Main Unit and Patient Interface Box have been arranged in this fashion for the photograph only and would not be placed on the bed during the recording of an actual study.

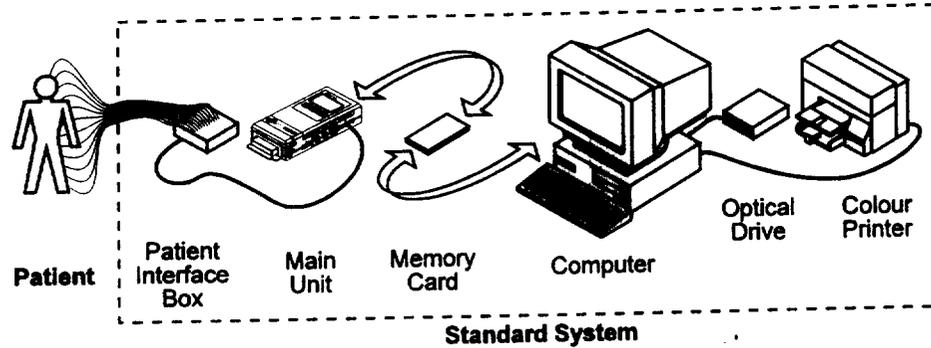
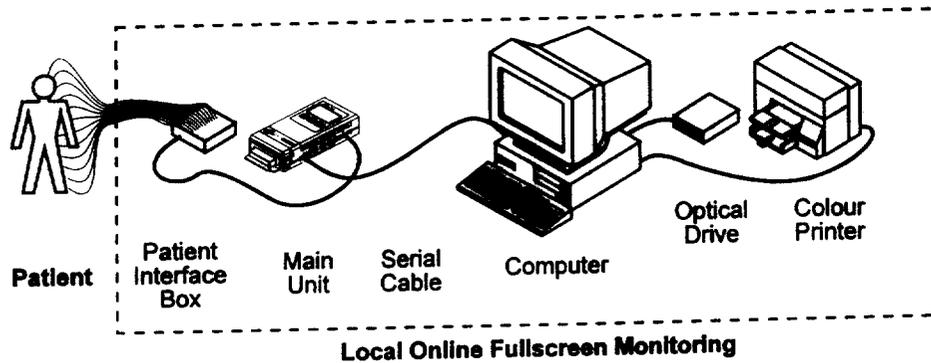
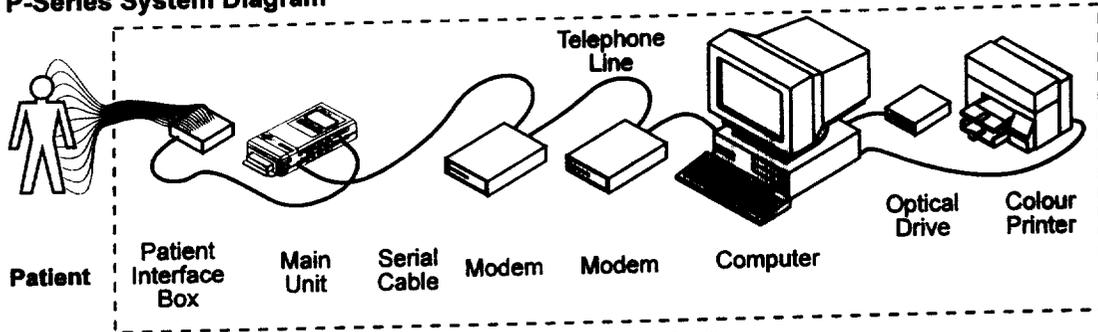
#### **P-Series Hardware Photograph**



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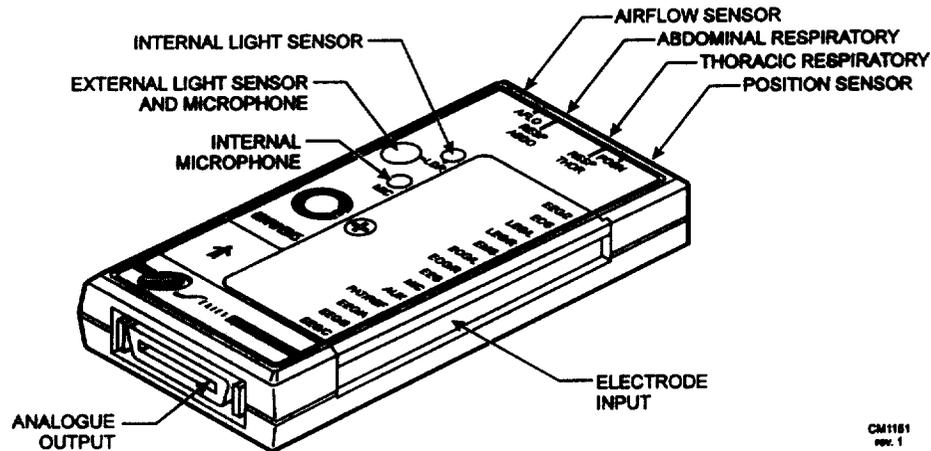
**P-Series System Diagram**





### P-Series Patient Interface Box

Electrodes attached to the patient are connected to the P-Series Patient Interface Box (PIB). The PIB amplifies the signals and then the amplified signals are passed to the Portable Main Unit using an analogue cable.



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page 1

P-Series Patient Interface Box

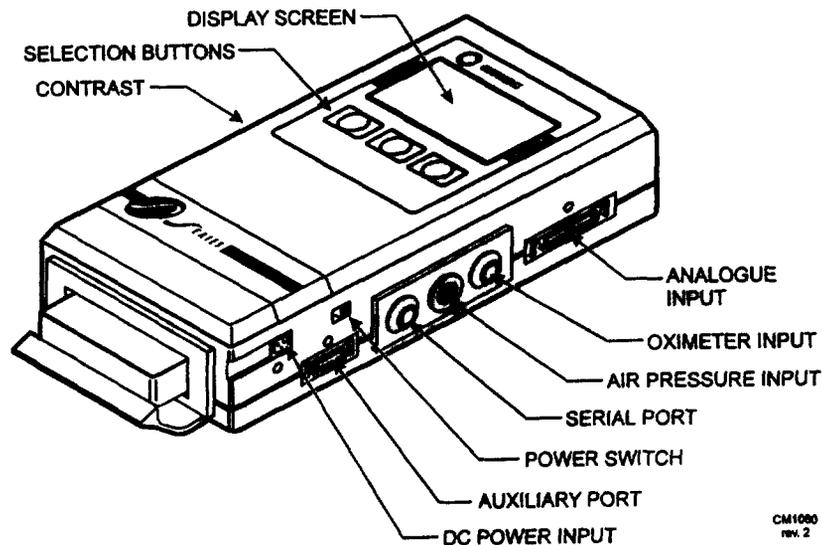
The following input connectors are provided on the P-Series PIB

- Airflow Sensor
- Abdominal Respiratory Band
- Thoracic Respiratory Band
- Position Sensor
- Brain activity (EEG and EEG/2)
- Heart activity (ECG)
- Leg movement sensor (LEG/L and LEG/R)
- Muscle activity (EMG)
- Eye movement (EOG/L and EOG/R)
- Microphone (MIC)
- Auxiliary input (AUX)
- Patient Reference (PAT/REF)
- EEG/A
- EEG/B
- EEG/C
- External LDR and Microphone
- Internal Microphone
- Internal Light Sensor



### P-Series Main Unit

The Main Unit is a key component of the Compumedics P-Series Sleep Monitoring System. It is used to digitise and record the patient's physiological signals onto a PCMCIA Memory Card.



P-Series Main Unit

### Electrodes and Sensors

Compumedics supplies a kit containing PSG monitoring electrodes and sensors. This kit contains 6 types of sensors and 2 types of electrodes.

The following electrodes and sensors are manufactured by Compumedics:

- Leg sensors
- Position sensors
- Triple thermistor (airflow sensor)
- Snap on electrode

The following electrodes and sensors are purchased from vendors:

- Inductive respiratory band
- Oral/nasal cannula sensor
- Oximeter probe
- Gold cup electrode



### ***Example of Use***

The Compumedics Sleep Monitoring System provides menus from which the sleep technician may select/assign criteria for automated collection and organisation of specific events, or for off-line data summarisation. Importantly, such decisions made by the sleep technician do not change the raw data recorded during PSG. The Compumedics Sleep Monitoring System will automatically score the PSG data according to either R&K default values or clinician-selected criteria, and hence, eliminates the need to manually score PSG data. Thus analysis can be performed by the clinician more efficiently and expeditiously.

As an example, processing the data for respiratory scoring involves marking the occurrences of respiratory events which are defined by various parameters. These parameters have set default values which must be accepted by the operator or can be defined by the operator for different patients or different study parameters. Periodic Leg Movement (PLM) events, Arousal events, and Sleep Staging can be scored in a similar manner based on defined parameters using either default settings or operator defined values.

Compumedics provides User Guides that contain examples of how to use the Compumedics Sleep Monitoring System for a sleep study.

### ***Functions Performed***

The Compumedics Sleep Monitoring System performs the following functions:

- Electronically records physiological parameters received by standard electrodes and sensors during a subject's sleep to allow for recall and off-line (retrospective) data analysis
- Permits on-line (real-time) display of data
- Allows operator to choose range for parameters for off-line (retrospective) data processing
- Automatically scores sleep stages, respiratory events, arousal events, and Periodic Leg Movement (PLM) events using either default values (based upon standard R&K scoring system) accepted, or those assigned by the sleep technician
- Generates and prints study graphics and reports

### ***Anatomical Sites***

The placement of the electrodes and sensors depends on the parameter being monitored for the sleep study. The following are some examples of placement of sleep study monitoring devices used by all three Systems.

#### **Position sensor**

- A transducer attached to the patient's clothing or skin over the sternum which indicates whether the subject is lying prone (front), supine (back), or on their right or left sides.

#### **Leg Sensor**

- When placed on a leg muscle (anterior tibialis), the sensor provides signal output proportional to leg muscle movement.

#### **Thermistor**

- Measures change in air temperature and is taped just beneath the subject's nose and just above the upper lip to monitor airflow through the oral and nasal cavities.

### ***Target Population***

The target population of all three systems are subjects undergoing evaluations sanctioned by sleep disorder centers where this technology has been used to record and evaluate sleep disorders since the 1950's.



## Summary of Technological Characteristics

The following comparison table outlines the similarities and difference between the Compumedics Sleep Monitoring System and the SensorMedics Series 4100 (Somnostar) and Series 4250 (Somnotrac) and the Nicolet Expert Sleep/Wake System.

### **Comparison of Compumedics S-Series Sleep Monitoring System, SensorMedics 4100 Series and Nicolet Expert Sleep/Wake Analysis System**

Features/Technical Information	Compumedics S-Series Sleep Monitoring System	SensorMedics 4100 Series (Somnostar)	Nicolet Expert Sleep/Wake Analysis System
Intended Use	Sleep Analysis	Same	Same
Number of Patients Can Monitor Simultaneously	1 per Preamp, 2 per Workstation Module and up to 8 per Full System	Same	Up to 4
Number of Hours of Monitoring	Limited by Storage	Same	Same
Data Inputs	From Existing ECG or Polygraphs	Same	Same
Number of Channels/Patient	20 Channels / Patient Digital Oversampling	16 channels	16 channels/patient
Automated Channel Calibration	Yes	Same	Semi-automated
General Software Capabilities	Operating, Analysis and Report Generation	Same	Same
Menu-Based Operations	Yes	Same	Same
Calibrate Input, User-Selectable Sampling Rates and Montage Library	Yes	Same	Same
Automated, Computer-Assisted or Manual Analysis Sleep Staging, Respiratory Scoring, PLMs Scoring, SaO <sub>2</sub> and Heart Rate, User-Defined Formats and Time Scales	Yes	Same	Same
Help-Menu with Glossary	Yes	Same	Same
Remote Telephonic Sleep Surveillance	Yes	Same	Same
Electrical Isolation Transformer	Yes	Same	Same
Capable of Setting Recording Parameters Remotely	Yes	Same	Same
Report Generation	Operator configurable	Same	Same
Power Utilisation	110/120VAC or 220/240VAC	117±10VAC, 220±20VAC	110 or 220 VAC +10%, 50 or 60 Hz
Computer Processor and Operating System	80486 or Pentium CPU	Same	68020 CPU
Monitor	Colour	Same	Same
Printer	Colour Inkjet	Same	Tektronix colour
Keyboard	Yes, and mouse	Same	Same
LAN and Modem Options	Yes	Same	Same



Features/Technical Information	Compumedics S-Series Sleep Monitoring System	SensorMedics 4100 Series (Somnostar)	Nicolet Expert Sleep/Wake Analysis System
Built-In Data Storage System	2.3 GB Magneto-Optical Drive	650 MB Optical Disk	(2) 3 1/2" Floppy Disks 80 MB Hard Disk
Preamplifiers	Yes	Same	Same

**Comparison of Compumedics P-Series Sleep Monitoring System and SensorMedics 4250 Series**

Features/Technical Information	Compumedics P-Series Sleep Monitoring System	SensorMedics 4250 Series (SomnoTrac)
Intended Use: Sleep Monitoring	Yes	Same
Number of Patients Can Monitor Simultaneously	1 per Unit	Same
Portable Design	Yes	Same
General Functionalities	Yes	Same
Data Collection	Yes	Same
Data Analysis	Optional	Same
Report Generation	Optional	Same
Capable of Data Transfer for Analysis and Report Generation	Yes	Same
Data Inputs	From Existing ECG or Polygraphs, 16 Biophysical Inputs, 24 or 36 Optional	Same
UltraShield Signal Conditioning	Yes	Same
Oximeter with Sat-Trac Signal Technology	Yes	Same
Data Analysis (Computer or Computer-Assisted).	Optional	Same
Comprehensive Report Generation	Optional	Same
Remote Telephonic Sleep Surveillance	Yes	Same
Remote Capability to Monitor Lead Quality	Yes	Same
Remote Capability to Monitor Recording Parameters	Yes	Same
Look Forward/Watch Back Display	Yes	Same



### ***Performance Testing***

The Compumedics Sleep Monitoring System and other sleep assessment devices are information managers which display and record data received from routinely-used monitoring devices used to evaluate sleep and sleep related respiratory disorders. They do not treat or provide therapeutic effect to the subject administer any energy to the subject, or perform diagnoses of a subject's disorder or condition, and hence, the devices pose no risk whatsoever to subjects.

In that the Compumedics Sleep Monitoring System and the predicate devices pose to measurable risk to the monitored subject, it is our position that the device characteristics delineated in the Substantial Equivalency Information Tables the functional, material, and related characteristics of the device and the currently marketed predicates are well and sufficient to permit a determination of comparative performance.

The Compumedics Sleep Monitoring System and the predicate devices currently marked in the US are all intended for use with polysomnography for recording of selected physiological parameters monitored for the evaluation of sleep disorders and sleep-related respiratory disorders.

The Compumedics Sleep Monitoring System is used as an aid in the diagnosis of sleep and respiratory related sleep disorders. The use of this sleep monitoring system is to be under supervision of a physician, sleep technologist or clinician. The Sleep Monitoring System is an information management tool so record, display, organise, summarise, redisplay (relative) and generate user-designed reports based on the subject's data received from monitoring devices typically used to evaluate sleep and sleep related respiratory disorders.

The Nicolet Expert Sleep/Wake Analysis System User Guide states this system "is intended for the acquisition, analysis, and reporting of electrophysiological signals. The system is specifically targeted for the automated analysis of polysomnographic recordings, that is, for the analysis of sleep and respiration."

The SensorMedics Series 4000 device offers "clinicians the flexibility of storing and analysing the sleep record in a variety of forms ... as data received from an Ampstar or other polygraph, it is digitally encoded on a laser-read optical disk ... a powerful report generator allows text, trends and graphic reports to be printed with laser printer quality. in user defined formats, or as an Epoch-By-Epoch disclosure." The indications for use of the SensorMedics Series 4000 device include monitoring and evaluation of respiratory disorders during sleep; effectiveness of CPAP treatment; obstructive, central and mixed sleep apnea; insomnia and narcolepsy evaluation; nocturnal myoclonus; and other disorders of sleep.

The comparison of the predicate devices' indications, albeit not identical word for word with the indication claim for the Compumedics Sleep Monitoring System, cover both facets of the Compumedics Sleep Monitoring System data acquisition, processing and archiving directly from electrophysiological recordings of patient activity and from other recording instruments. Therefore, they support the substantial equivalence of the indications statement for the subject device to those for the Nicolet and SensorMedics predicate devices.

### ***Physical Characteristics***

Referring to the comparison tables, the subject system has the same physical characteristics as the named predicate devices.

All three Systems monitor and process input from routinely-used monitoring devices for sleep and sleep related respiratory disorders. Signals from these monitoring devices pass through preamplifiers, which modify signal strength and filter back ground noise through analog digital (A/D) converters. Signals are processed and archived using a computer processor and operating system (detail provided in tables) and displayed on a colour monitor, or printed.



### ***Safety Characteristics***

The Compumedics Sleep Monitoring System and the other sleep assessment devices are information managers which display and record data received from routinely-used monitoring devices used to evaluate sleep and sleep related respiratory disorders. They do not treat or provide therapeutic effect to the subject, administer any energy to the subject, or perform diagnoses of a subject's disorder or condition, and hence, the devices pose no risk whatsoever to subjects. Further, the subject device conforms to IEC 601.1. and hence, poses no electrical safety risk.

### ***Design***

The Compumedics Sleep Monitoring System consists of a computerised system for collecting data directly from the patient or from independent, and commercially available, monitoring devices, such as the predicate Nicolet and SensorMedics devices, and for collating, processing and presenting reports of this data in a variety of user selected formats. The data sources can include bioelectric monitoring (e.g. EEG, ECG, EOG and EMG), physiological monitoring via transducers (e.g. thermistors, inductance respiratory bands) and other sources, such as pulse oximetry. As such, the subject device and predicate devices serve purely as an information gathering and management tool.

As with the predicate devices, the Compumedics Sleep Monitoring System consists of a monitoring and data processing unit which receives information from external monitoring sources. The Sleep Monitoring System also has available a portable system (P-Series) providing remote monitoring where the data can be output to the larger monitoring and processing unit. The SensorMedics 4000 Series also contains a portable system (4520 Series SomnoTrac) with the same function as the Compumedics P-Series.

Both the Compumedics Sleep Monitoring System and the SensorMedics 4000 System are capable of remote sleep surveillance via telephone, and all three systems are capable of remotely setting recording parameters. Each system operates from standard 110 or 240 VAC power, and contains a 16 bit or 32 bit computer processor and operating system, a colour monitor, a keyboard, a printer, and preamplifiers. All have substantial data storage capacity using a variety of storage techniques.

As with the predicate Nicolet and SensorMedics devices, the Compumedics Sleep Monitoring System is capable of accepting data from multiple subjects simultaneously and multiple data input channels. Automated channel calibration is provided. The number of monitoring achievable is limited by the memory and data storage capabilities of these device types.

The subject device and the predicate Nicolet and SensorMedics devices contain software which include or facilitate menu-based operations for selection of manual or computer-assisted analysis of data (including sleep staging, respiratory event scoring, PLM event scoring, SaO<sub>2</sub>, and heart rate), input calibration with user selected data sampling rates, a Help Menu with Glossary, and user defined report generation.

### ***Materials***

Materials comprising the Compumedics Sleep Monitoring System and the predicate SensorMedics and Nicolet devices are substantially equivalent. These devices consist of hard cases of metal and/or plastics, within which reside integrated circuitry, mechanical and electrical apparatus, and software.

### ***Power Source and Energy Delivered***

The subject device and the named predicate devices operate from standard 110 or 220 volt current and the portable system has the option of battery powered operation.

Neither the subject device, nor the predicate devices deliver any energy to the subject during operation.



***Are the Descriptive Characteristics Precise Enough to Ensure Equivalence?***

Comparing device characteristics delineated in the Substantial Equivalency Information Tables, the design, functional, material, and rated characteristics of the subject device and the currently marketed predicates are well identified, precise, and sufficient to permit a determination of substantial equivalence.

These and other sleep assessment devices are purely information managers which display and record data received from routinely used and commercially available polysomnography monitoring devices. They do not treat or provide therapeutic effect to the subject, administer any energy to the subject, or perform diagnoses of a subject's disorder or condition, and hence, the devices pose no risk whatsoever to the subjects.

In that the Compumedics Sleep Monitoring System and the predicate devices pose no measurable risk to the monitored subject, it is our position that the device characteristics identified in the Substantial Equivalency Information Tables permit sufficient characterisation and description of the significant functional and design aspects of the devices, and are adequate to permit a determination of substantial equivalence.



## Conclusions from Clinical Performance Data

### **Clinical test**

Clinical testing was performed using a side-by-side comparison of the Compumedics Sleep Monitoring System and the SensorMedics Series 4000 Sleep System (K915856).

Even though the R&K definitions of sleep stages has been standardised, there is still variability of sleep stage scoring. The article below describes the expected variability of scoring between two human scorers.

Several studies have also evaluated agreement in human vs. human scoring. Agreement between scorers ranged from 88% to 85% according to Gailard and Tissot (2) and Smith et. al. (3), on the basis of 60 second epochs. Recently Stantus et. al. (7) obtained an 82% reliability using 20-second epoch definition, and Ferri et. al. (14) found an agreement rate of 91.3% between two independent readers. Agreement in visual scoring of sleep stages among 10 laboratories in Japan (16) showed values ranging from 67.3% to 75.3% for two healthy subjects. Inter-reader agreement between different laboratories is broadly similar. Variations are based on different time bases and on the number of readers for the validation. The difference between readers has three major causes: 1) the scoring of slow-wave sleep, which illustrates the human subjectivity introduced into the rules applied to the threshold of  $75\mu\text{V}$  for delta wave recognition and in the detection of the percentage of delta waves in the epochs; 2) the scoring of stage 1 sleep, which is subject to great variation due to a lack of clearly characteristic features; and 3) application of "3-minute rules" in the standardized system (17).

Sleep Stage Scoring Using the Neural Network Model: Comparison Between Visual and Automatic Analysis in Normal Subjects and Patients.  
Sleep (1996) 19(1): 26-35

### **Results**

Sleep Staging of manually scored SensorMedics and Compumedics show similar appearance of traces. Distinguishable features appear in the same relative locations on the Compumedics Sleep Monitoring System when compared to the SensorMedics Sleep Monitoring System.

It has been noted that some of the traces output on the Compumedics Sleep Monitoring System have the reverse phase (i.e. opposite convention) than when compared to the SensorMedics Sleep Monitoring System. This difference in polarity does not influence the analysis performed by the Compumedics Sleep Monitoring System.

Concordance between manual and manual scoring, and manual and automatic scoring is within the range specified as being typical between two manual scorers within the article: "Sleep Stage Scoring Using the Neural Network Model: Comparison Between Visual and Automatic Analysis in Normal Subjects and Patients." Sleep (1996) 19(1): 26-35.

It has been shown that the Compumedics Sleep Monitoring System is substantially equivalent to the SensorMedics Sleep Monitoring System in the following areas:

- Compumedics Manual Analysis and SensorMedics Manual Analysis
- Compumedics Automatic Analysis and Compumedics Manual Analysis
- Comparison of random epochs of raw data for visualisation of signal quality
- Comparison of specific events (abnormal respiratory events, EEG arousal and different sleep stages)

This study shows that the Compumedics Sleep Monitoring System is substantially equivalent to the SensorMedics Sleep Monitoring System.



## Conclusion

As has been demonstrated by the descriptions and information contained within this document, the subject Compumedics Sleep Monitoring System is substantially equivalent to the predicate sleep assessment devices, the Nicolet Expert Sleep/Wake Analysis System and SensorMedics 4000 Series devices, currently marketed in the United States of America in terms of:

- Intended use and indications
- Method of use
- Effects
- Modes of operation
- Design
- Materials
- Technological characteristics
- Power source
- Safety