U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(cwf)
FOLDER:	K061996 - 739 pages
COMPANY:	EB NEURO, S.P.A. (EBNEURSP)
PRODUCT:	VENTILATORY EFFORT RECORDER (MNR)
SUMMARY:	Product: SANDMAN POCKET
DATE REQUESTED:	Aug 3, 2016
DATE PRINTED:	Aug 3, 2016
Note:	Printed

K061996

OCT - 3 2006

510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR¶807.92(a).

807.92(a)(1)

Submitter Information

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The Anson Group
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Facsimile: (317) 569-9520

Contact Person: Carri Graham

Date: June 12, 2006

807.92(a)(2)

Trade Name: Sandman Pocket

Common Name: Ventilatory Effort Recorder

Classification Name(s): Ventilatory Effort Recorder

Classification Number: MNR

807.92(a)(3)

Predicate Device(s)

Nellcor Puritan Bennett Inc. Respironics, IN	SUZANNE Alice 5	K990565 K040595

Additional Substantial Equivalence Information is provided in the following Substantial Equivalence Comparison Table.

807.92 (a)(4)

Device Description

The *Sandman Pocket* is a physiological data recorder that is part of a polysomnography system. It consists of two units: the **Recorder Unit**, which stores the data and sends it to a USB port, and **Headbox Unit**, which is the connection point for all patient sensors with the exception of the Nellcor Puritan Bennett oximetry probe.

The role of the *Sandman Pocket* is only to capture the data and pass it to the host with the necessary accuracy and reliability according to the product and communication control specifications.

A fundamental characteristic of the *Sandman Pocket* is the ability to be an ambulatory/portable physiological data recorder. Because of its small size and light weight (about 210 grams including the battery), the system is compact and durable.

The **Headbox Unit** is used for connecting patient electrodes and sensors. It includes Bipolar channels, pressure sensors, power supply for a dedicated body position sensor, an abdomen sensor, a chest sensor, a snore sensor and a thermistor. The patient inputs are isolated with a CF type isolation level. The Sandman Pocket device is provided without standard sensors. The system builder should integrate the device with FDA cleared Nellcor Puritan Bennett sensors only and specified for the usage with NELL-1 module.

The **Headbox Unit** captures the biological signals from the human body surface through specialized sensors and electrodes, while the **Recorder Unit** amplifies the very low electrical signal and filters the signals to make an optimal ANALOG to DIGITAL conversion. The data, once converted in numerical form, are sent to a host computer for review and analysis. The host can "program" the amplifier behavior by setting the sampling frequency and the dynamic range allowed and so on.

The host computer reads the acquired data through a dedicated interchange protocol, and allows a clinician to analyze the data using sleep review analysis software, provided by the end user or system builder. The clinician must use an electrically isolated computer (with a medical grade isolation transformer or medical grade power supply) or battery-supplied laptop when the Sandman Pocket device is connected to the host PC and the patient is connected to the Sandman Pocket Headbox.

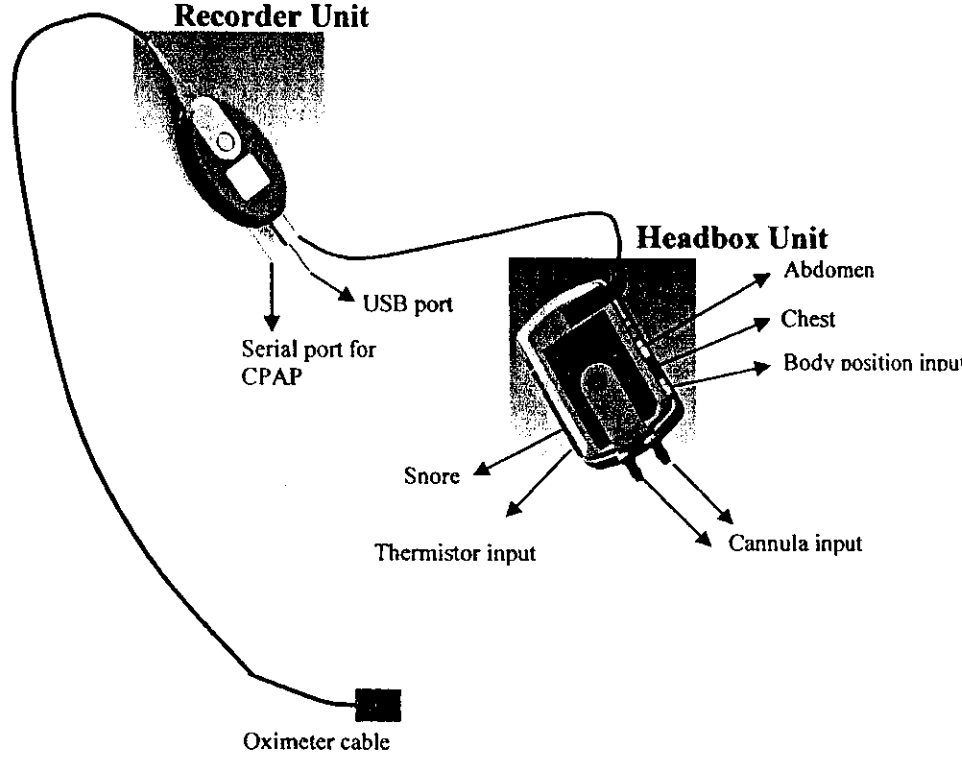
The *Sandman Pocket* system is not in any way involved in the data management performed by the host.
The host computer must operate using one of the following Operating System:
Microsoft Windows 98 / ME / NT / 2K / XP.

The device has a built-in impedance meter. This function allows the clinician to check the electrode contact impedance and display the results of the check on the display. The

display is located in the Recorder Unit, while the circuitry controlling the impedance meter is located in the Headbox Unit.

The *Sandman Pocket* can be powered through 3 Alkaline 1.5V standard non rechargeable batteries or via the USB cable. The user is recommended to use a medical grade type PC.

The *Sandman Pocket* system consists of two interconnected units: the Headbox Unit and the Recorder Unit.



SANDMAN POCKET System Connection Diagram

The **Headbox Unit** has the following functions:

- Physically connects the source of signals (the patient) to the amplifier.
- Provide impedance testing capabilities
- Provide Analog to Digital (A/D) conversion

The **Recorder Unit** has the following functions:

- Amplify and isolate signals coming from the electrodes
- Reference input channels
- Generate calibration pulse
- Provide dynamic range (gain), sampling rate and active channels selection
- Performs antialiasing filtering for optimal Analog to Digital conversion
- Provide, when requested, the Pulse Transition Time (PTT) calculation.
- Send the digital data through the USB interface to the host
- Provide the Oximeter option
- Manage the display
- Manage the Time
- Manage the batteries power supply

807.92(a)(5)

Intended Use(s)

The *Sandman Pocket* is intended for use in collecting and recording physiological data to be used in polysomnography and sleep disorder studies. The Sandman Pocket is intended for pediatric through adult patient populations, and can be used in either home or hospital environments.

The Sandman Pocket is not intended for use as life supporting equipment such, as a vital sign monitoring in an intensive care unit. The device does not produce alarms and is not intended as an automated apnea monitor.
The Sandman Pocket is only to be used under the direction or supervision of a physician, technologist or clinician.

807.92(a)(6)

Technological Characteristics
Substantial Equivalence Comparison Table

Product Characteristic	***Suzanne*** **(Predicate Device)** **Nellcor Puritan Bennet** **K990565**	***Alice 5*** **(Predicate Device)** **Respironics** **K040595**	***Sandman Pocket*** **(submission device)** **EB Neuro** **Via this Submission**
Regulatory			
Device class	Class II	Class II	Class II
Product code	MNR	GWQ	MNR
Device type	Ventilator Effort Recorder	Electroencephalograph	Ventilator Effort Recorder
Regulation Number	868.2375	882.1400	868.2375

Product Characteristic	***Suzanne*** **(Predicate Device)** **Nellcor Puritan Bennet** **K990565**	***Alice 5*** **(Predicate Device)** **Respironics** **K040595**	***Sandman Pocket*** **(submission device)** **EB Neuro** **Via this Submission**
Labelling			
Intended use	Intended for use in collecting and recording physiological data to be used in diagnosing sleep disorders	Intended to record, display and print physiological information to clinicians/physicians. These parameters are presented graphically on a computer screen for diagnostic review, similar in application to the use of a traditional paper based polygraph recorder. The device will be used in hospitals, institutions, sleep centers or clinics, or other test environments where adult or infant patients require the documentation of various sleep or other physiological disorders. This device does not provide alarms and is not intended for use as an automated apnea monitor.	Intended for use in collecting and recording physiological data to be used in polysomnography and sleep disorder studies. For use in either home or hospital environments with a pediatric through adult patient population. This device does not provide alarms and is not intended for use as an automated apnea monitor
Target population	Pediatric through adult (excluding neonates and infants)	Pediatric through adult (including all pediatric subpopulations)	Pediatric through adult (including all pediatric subpopulations)
Environment of use	Hospital and home	Hospitals, institutions, sleep centers, or other test environments.	Hospital and home

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Warnings	Items related to sensor irritation, strangulation avoidance and off-label use.	Items related to sensor irritation, strangulation avoidance, and off-label use.	Items related to sensor irritation, strangulation avoidance and off-label use.
Contraindications	Items related to design and indicated use limitations, such as not for use in the presence of flammable anesthetics or in conjunction with defibrillation equipment.	Items related to design and indicated use limitations, such as not for use in the presences of flammable substances or anesthetic mixtures with air oxygen or nitrous oxide, defibrillation, and MRI equipment, and not for use as automated apnea monitor or a continuous monitor.	Items related to design and indicated use limitations, such as not for use in the presence of flammable anesthetics or in conjunction with defibrillation equipment. The Sandman Pocket is not intended for use as life support equipment such as a vital sign monitoring in intensive care unit. The device does not produce alarms and is not intended as an automated apnea monitor. The Sandman Pocket is only to be used under the direction or supervision of a physician, technologist or clinician. It will not prevent or restore the interruption or loss of any physiological system.
Prescription status	Available only on the order of a physician.	Available only on the order of a physician.	Available only on the order of a physician.

Product Characteristic	***Suzanne*** **(Predicate Device)** **Nellcor Puritan Bennet** **K990565**	***Alice 5*** **(Predicate Device)** **Respironics** **K040595**	***Sandman Pocket*** **(submission device)** **EB Neuro** **Via this Submission**
Service instructions	No field service allowed.	No field service allowed.	No field service allowed.
Design			
Communication Interfaces	Physiological signals are sent to the Slow Wave and Fast Wave headbox through the sensor cables. The Slow Wave and Fast Wave headboxes sends the data to the Recorder Plus module where the data is stored either to a flash memory card or to a PC via a fiber optic interface.	Physiological signals are sent from the patient sensors to the headbox through the sensor cables. The data is sampled and sent to the base station where it is stored on a disk until it is sent through an Ethernet connection to a Host PC.	Physiological signals are sent from the patient sensors to the amplifier box through the sensor cables. The amplifier box sends the data to the recorder where the data is stored in flash memory in both attended and unattended studies. During attended studies, the data is also transmitted to a computer in real-time via a USB cable. After unattended studies, data can be downloaded from the recorder using a USB cable.
Microprocessor	Siemens 80C537 12 MHz	Unknown	Texas Instruments TMS320UC5402 on recorder Texas Instruments MSP430F169 on headbox
A/D Resolution	12 bit	16 bit	16 bit

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Data recording	On PCMCIA card, magnetic disk or optical disk (via a personal computer).	Computer hard drive, compact disc, or transferred via Ethernet connection to a Host PC.	On internal NAND flash chip
Configuration	Desktop and wearable	Desktop only	Wearable
Amount of memory required for a typical 8 hour study.	20 MB	600 MB without audio/ video 6 GB with audio/video NOTE: Alice 5 can collect up to 21 neurological channels. These channels are recorded at very high sampling rates. In addition, Alice 5 records video at very high frame rates with no compression. These two factors contribute to the large study size. All data are stored to computer hard disk.	28 MB

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Sampling rate	Slow waves : 12 samples/s Fast waves : 120 samples/s	Neurological channels 2000 samples/s	Fast waves: For example, ECG programmable up to 2048 sample/s Medium waves: For example, EMG, EOG, Snore programmable up to 1024 sample/s Slow waves: For example, airflow, respiratory effort, body position programmable up to 256 sample/s
Power	Battery powered (internal) or Medical Grade AC-DC Power Supply	Medical grade AC Power Supply	Battery powered or USB powered
Sensors	Commercially available sensors only	Commercially available sensors only	FDA Cleared sensors only

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Performances			
Maximum number of channels	35	55	22
Recording channels			
EEG	Yes	Yes	Yes
EOG	Yes	Yes	Yes
EMG	Yes	Yes	Yes
ECG	Yes	Yes	Yes
Respiratory efforts	Yes	Yes	Yes
Airflow	Yes	Yes	Yes
Ambient sounds	Yes	Yes	No
Body position	Yes - internal	Yes - external	Yes - external
Ambient light	Yes - internal	No	No
SpO_2	Yes - internal	Yes - internal	Yes - internal
Pulse rate	Yes - internal	Yes - internal	Yes - internal
Plethysmograph	No	Yes	Yes
Differential pressure	Yes - internal	Yes - external	Yes - internal
Actimeter	No	Yes	No
Derived channel	N/A	Pulse Transit Time (PTT) – A calculation of the time between the occurrence of the R wave on the EKG and the peak flow on the plethysmogram. RR Interval – Measurement of the period of time between two consecutive R waves on the EKG. Displays as a real-time beat-to-beat heart rate calculation.	Pulse Transit Time (PTT) – A calculation of the time between the occurrence of the R-wave on the EKG and 50% ascending slope on the plethysmogram. Heart rate – Derived from the ECG channel

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Passbands			
EEG	0.625 to 18 Hz	Neurological Channels	0.1 to 135 Hz
EOG	0.625 to 18 Hz	0.32 to 106 Hz	0.1 to 135 Hz
EMG	0.625 to 18 Hz		0.1 to 135 Hz
ECG	0.625 to 18 Hz		0.1 to 135 Hz
Respiratory efforts	0.055 to 1.25 Hz		0.1 to 45 Hz
Airflow	0.1 to 1.3 Hz		0.015 to 10 Hz
Ambient sounds	None		None
Pressure sensor	0 to 175 Hz		DC to 15 Hz
SpO_2	NPB proprietary		NPB proprietary
Pulse rate	NPB proprietary		NPB proprietary

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CPAP (Continuous Positive Airway Pressure)	*Suzanne* supports all models of CPAP devices because the CPAP device connections were air-based rather than electrically based. Using a pneumotachograph kit, users could connect hoses and adapters to the CPAP device and the flow and pressure nipples on the *Suzanne* slow wave headbox to measure CPAP airflow and/or air pressure at the mask out-take during nasal CPAP/Bi-level titration.	*Alice 5* supports the use of all Respironics lab therapy devices: Aria LX BiPAP Pro Duet LX Harmony HeartPAP REMStar Auto REMStar Pro REMStar Pro with C-Flex Synchrony Virtuoso LX	*Sandman Pocket* stores data from Nellcor Puritan Bennett GK420E, GK425, and GK425ST CPAP devices. When the recorder is also connected to the host computer, the *Sandman Pocket* not only stores data in the on-board memory, but also acts as a passive bridge between the aforementioned GK CPAP and the host computer by receiving data streams from the CPAP and transmitting the data streams to the host computer and vice versa. When the *Sandman Pocket* is connected to a third party CPAP device and a host computer, *Sandman Pocket* acts as a passive bridge between the third party CPAP device and the computer by receiving data streams from the CPAP and transmitting the data streams to the host computer and vice versa. Alternatively, *Sandman Pocket* may also handle CPAP device connections in the same manner as Suzanne.

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Mechanical safety	Device complies with the requirements of Nov' 93 Draft Reviewer's Guidance	Device complies with the International Standard IEC 60601-1 CSA C22.2 No. 601.1 EN 60601-1 UL 60601-1 AS 3200.1.0* *Australian Deviation to IEC 60601-1	Device complies with the International Standard IEC 60601-1 CSA C22.2 No 601-1-M90 UL 2601
Electrical safety	Device complies with the International Standard CSA C22.2 No. 601-1-M90 UL 2601 Device complies with the requirements of Nov' 93 Draft Reviewer's Guidance	Device complies with the International Standard IEC 60601-1 Guidance, when applicable, has been adopted from the following standards: IEC 60601-2-25 IEC 60601-1-26 IEC 60601-2-40 IEC 60601-2-49	Device complies with the International Standard IEC 60601-1 IEC 60601-1-4 IEC 60601-1-26 CSA C22.2 No 601-1-M90 UL 2601

Product Characteristic	***Suzanne*** **(Predicate Device)** **Nellcor Puritan Bennet** **K990565**	***Alice 5*** **(Predicate Device)** **Respironics** **K040595**	***Sandman Pocket*** **(submission device)** **EB Neuro** **Via this Submission**
Electromagnetic Compatibility (EMC)	Device complies with the following EMC standards IEC 60601-1 IEC 61000-4-2 IEC 61000-4-3 IEC 61000-4-6 Mil Std 462D IEC 61000-4-4 IEC 61000-4-5 EN55011 Class B Device complies with the requirements of Nov' 93 Draft Reviewer's Guidance	Device complies with the International Standard IEC 60601-1-2, including the following standards: CISPR 11 IEC 61000-3-2 IEC 61000-3-3 IEC 61000-4-2, IEC 61000-4-3 IEC 61000-4-4, IEC 61000-4-5, IEC 61000-4-6, IEC 61000-4-8 IEC 61000-4-11	Device complies with the International Standard IEC 60601-1- 2, including the following standards: IEC 61000-3-2 IEC 61000-3-3 IEC 61000-4-2 IEC 61000-4-3, IEC 61000-4-4, IEC 61000-4-5, IEC 61000-4-6, IEC 61000-4-8 IEC 61000-4-11 EN55011 class B EN55014-1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 3 2006

Regulatory Technology Services LLC
C/O Mr. Mark Job
Responsible Third Party Official
EB NEURO, S.P.A.
1394 25th Street NW
Buffalo, Minnesota 55313

Re: K061996
Trade/Device Name: Sandman Pocket
Regulation Number: 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: September 22, 2006
Received: September 25, 2006

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

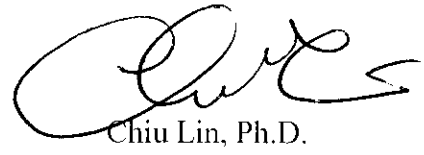
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Sandman Pocket

Indications For Use:

Intended for use in collecting and recording physiological data to be used in polysomnography and sleep disorder studies. The Sandman Pocket is indended for pediatric through adult patient populations, and can be used in either home or hospital environments.

The Sandman Pocket is not intended for use as life supporting equipment, such as a vital sign monitoring in on intensive care unit. The device does not produce alarms and is not intended as an automated apnea monitor.
The Sandman Pocket is only to be used under the direction or supervision of a physician, technologist or clinician.

Prescription Use ____X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Sign-Off)
...n of Anesthesiology, General Hospital,
...ion Control, Dental Devices
...Number: K061996

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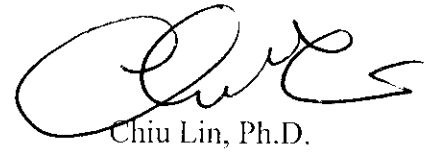

Chiu Lin, Ph.D.
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Prescription Use ____X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K061996

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

August 11, 2006

EB NEURO, S.P.A.
c/o REGULATORY TECHNOLOGY SERVICES,
1394 25TH STREET, NW
BUFFALO, MN 55313
ATTN: MARK JOB

510(k) Number: K061996
Device: SANDMAN POCKET

Extended Until: 17-OCT-2006

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information is not received by the "Extended Until" date shown above your premarket notification will be considered withdrawn.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

Correspondence

Date: August 8, 2006

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

RE: Premarket Notification K061996 EB Neuro S.P.A. Sandman Pocket

To Whom It May Concern:

This letter is a request for a 60 day extension in order to complete the preparation of the response to the letter requesting additional information dated July 20, 2006.

If you should have any questions regarding this submission please contact me at 763 682 4139 or fax 763 682 4420. Please fax any correspondence regarding this submission to Regulatory Technology Services LLC.

Sincerely,

Mark Job
Responsible Third Party Official

Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

AN

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

July 20, 2006

EB NEURO, S.P.A.
c/o REGULATORY TECHNOLOGY SERVICES,
1394 25TH STREET, NW
BUFFALO, MN 55313
ATTN: MARK JOB

510(k) Number: K061996
Product: SANDMAN POCKET

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html.

If after 30 days the requested information, or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system. Please note our guidance document entitled, "Guidance for Industry and FDA Staff FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html . Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission. Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisor Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

July 14, 2006

EB NEURO, S.P.A.
c/o REGULATORY TECHNOLOGY SERVICES,
1394 25TH STREET, NW
BUFFALO, MN 55313
ATTN: MARK JOB

510(k) Number: K061996
Received: 14-JUL-2006
Product: SANDMAN POCKET

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

Please note the following documents as they relate to 510(k) review: 1)Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k))Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act (MDUFMA). Please review this document at www.fda.gov/cdrh/mdufma/guidance/1219.html. 2)Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k). 3)Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRHs eCopy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsub.html.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/". If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsma/dsmastaf.html. If you have policy or procedural questions, please contact anyone on the 510(k) Staff at (301)594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

K061996

FDA Cover Letter

Regulatory Technology Services LLC

Date: July 12, 2006

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

RE: Premarket Notification

To Whom It May Concern:

Enclosed in duplicate is the following information:

A. Purpose of Submission: New Device

B. Name and Address of the Third Party:

Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

C. Name and Address of the Manufacturer:

EB Neuro

v. Fanfani, 111/a

Florence Italy 50127

K06
AN
II

D. Device Name

Trade or Proprietary Name: Sandman Pocket

Classification Name: Ventilator Effort Recorder

Regulation Number: 21 CFR 868.2375

Recommendation: Substantially Equivalent

Date Submission was received by
Regulatory Technology Services LLC: June 14, 2006

We have enclosed the following materials:

E. Authorization Letter from the applicant (MAL-F-0006).
F. Complete 510(k) application submitted by the applicant.
G. Documented review of the 510(k) application (RPP-F-0012, RPP-F-14 and all correspondence and documents related to the review).
H. Conflict of Interest Certification (COI-F-0018)
I. Certification (RPP-F-0020)

If you should have any questions regarding this submission please contact me at 763 682 4139 or fax 763 682 4420 or email at mark@markjob.com. Please fax any correspondence regarding this submission to Regulatory Technology Services LLC.

Sincerely,

Mark Job
Responsible Third Party Official

Submission Certification

1. I certify that Regulatory Technology Services LLC continues to meet the personnel qualifications and prevention of conflict of interest criteria reviewed by the FDA;

2. In addition, I state that Regulatory Technology Services LLC believes that statements made in the review are true and accurate to the best knowledge of Regulatory Technology Services LLC;

3. Regulatory Technology Services LLC's review is based on the 510(k) that is attached with the review; and

4. Regulatory Technology Services LLC understands that the submission of false information to the government is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 33(q).

MARK JOB

Print Name of Accredited Person Responsible Official

Signature

Date: 12 July 2006

Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Indications for Use

510(k) Number (if known):

Device Name: Sandman Pocket

Indications For Use:

Intended for use in collecting and recording physiological data to be used in polysomnography and sleep disorder studies. The Sandman Pocket is indended for pediatric through adult patient populations, and can be used in either home or hospital environments.

The Sandman Pocket is not intended for use as life supporting equipment, such as a vital sign monitoring in on intensive care unit. The device does not produce alarms and is not intended as an automated apnea monitor.
The Sandman Pocket is only to be used under the direction or supervision of a physician, technologist or clinician.

Prescription Use ____X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR¶807.92(a).

807.92(a)(1)

Submitter Information

Carri Graham
Official Correspondent
The Anson Group
11460 N. Meridian St.
Suite 150
Carmel, IN 46032

Phone: (317) 569-9500 x 103
Facsimile: (317) 569-9520

Contact Person: Carri Graham

Date: June 12, 2006

807.92(a)(2)

Trade Name: Sandman Pocket

Common Name: Ventilatory Effort Recorder

Classification Name(s): Ventilatory Effort Recorder

Classification Number: MNR

807.92(a)(3)

Predicate Device(s)

Nellcor Puritan Bennett Inc. Respironics, IN	SUZANNE Alice 5	K990565 K040595

Additional Substantial Equivalence Information is provided in the following Substantial Equivalence Comparison Table.

807.92 (a)(4)

Device Description

The *Sandman Pocket* is a physiological data recorder that is part of a polysomnography system. It consists of two units: the **Recorder Unit**, which stores the data and sends it to a USB port, and **Headbox Unit,** which is the connection point for all patient sensors with the exception of the Nellcor Puritan Bennett oximetry probe.

The role of the *Sandman Pocket* is only to capture the data and pass it to the host with the necessary accuracy and reliability according to the product and communication control specifications.

A fundamental characteristic of the *Sandman Pocket* is the ability to be an ambulatory/portable physiological data recorder. Because of its small size and light weight (about 210 grams including the battery), the system is compact and durable.

The **Headbox Unit** is used for connecting patient electrodes and sensors. It includes Bipolar channels, pressure sensors, power supply for a dedicated body position sensor, an abdomen sensor, a chest sensor, a snore sensor and a thermistor. The patient inputs are isolated with a CF type isolation level. The Sandman Pocket device is provided without standard sensors. The system builder should integrate the device with FDA cleared Nellcor Puritan Bennett sensors only and specified for the usage with NELL-1 module.

The **Headbox Unit** captures the biological signals from the human body surface through specialized sensors and electrodes, while the **Recorder Unit** amplifies the very low electrical signal and filters the signals to make an optimal ANALOG to DIGITAL conversion. The data, once converted in numerical form, are sent to a host computer for review and analysis. The host can "program" the amplifier behavior by setting the sampling frequency and the dynamic range allowed and so on.

The host computer reads the acquired data through a dedicated interchange protocol, and allows a clinician to analyze the data using sleep review analysis software, provided by the end user or system builder. The clinician must use an electrically isolated computer (with a medical grade isolation transformer or medical grade power supply) or battery-supplied laptop when the Sandman Pocket device is connected to the host PC and the patient is connected to the Sandman Pocket Headbox.

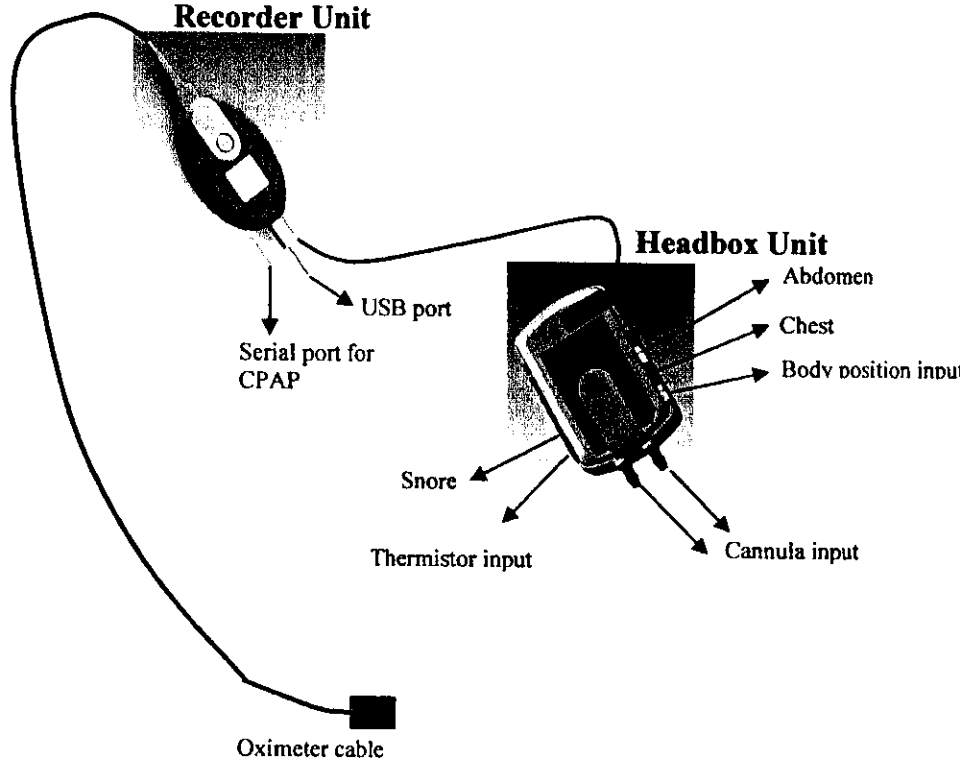
The *Sandman Pocket* system is not in any way involved in the data management performed by the host.
The host computer must operate using one of the following Operating System:
Microsoft Windows 98 / ME / NT / 2K / XP.

The device has a built-in impedance meter. This function allows the clinician to check the electrode contact impedance and display the results of the check on the display. The

display is located in the Recorder Unit, while the circuitry controlling the impedance meter is located in the Headbox Unit.

The *Sandman Pocket* can be powered through 3 Alkaline 1.5V standard non rechargeable batteries or via the USB cable. The user is recommended to use a medical grade type PC.

The *Sandman Pocket* system consists of two interconnected units: the Headbox Unit and the Recorder Unit.



SANDMAN POCKET System Connection Diagram

The **Headbox Unit** has the following functions:

- Physically connects the source of signals (the patient) to the amplifier.
- Provide impedance testing capabilities
- Provide Analog to Digital (A/D) conversion

The **Recorder Unit** has the following functions:

- Amplify and isolate signals coming from the electrodes
- Reference input channels
- Generate calibration pulse
- Provide dynamic range (gain), sampling rate and active channels selection
- Performs antialiasing filtering for optimal Analog to Digital conversion
- Provide, when requested, the Pulse Transition Time (PTT) calculation.
- Send the digital data through the USB interface to the host
- Provide the Oximeter option
- Manage the display
- Manage the Time
- Manage the batteries power supply

807.92(a)(5)

Intended Use(s)

The *Sandman Pocket* is intended for use in collecting and recording physiological data to be used in polysomnography and sleep disorder studies. The Sandman Pocket is intended for pediatric through adult patient populations, and can be used in either home or hospital environments.

The Sandman Pocket is not intended for use as life supporting equipment such, as a vital sign monitoring in an intensive care unit. The device does not produce alarms and is not intended as an automated apnea monitor.
The Sandman Pocket is only to be used under the direction or supervision of a physician, technologist or clinician.

Technological Characteristics
Substantial Equivalence Comparison Table

Product Characteristic	***Suzanne*** **(Predicate Device)** **Nellcor Puritan Bennet** **K990565**	***Alice 5*** **(Predicate Device)** **Respironics** **K040595**	***Sandman Pocket*** **(submission device)** **EB Neuro** **Via this Submission**
Regulatory			
Device class	Class II	Class II	Class II
Product code	MNR	GWQ	MNR
Device type	Ventilator Effort Recorder	Electroencephalograph	Ventilator Effort Recorder
Regulation Number	868.2375	882.1400	868.2375

Product Characteristic	***Suzanne*** **(Predicate Device)** **Nellcor Puritan Bennet** **K990565**	***Alice 5*** **(Predicate Device)** **Respironics** **K040595**	***Sandman Pocket*** **(submission device)** **EB Neuro** **Via this Submission**
Labelling			
Intended use	Intended for use in collecting and recording physiological data to be used in diagnosing sleep disorders	Intended to record, display and print physiological information to clinicians/physicians. These parameters are presented graphically on a computer screen for diagnostic review, similar in application to the use of a traditional paper based polygraph recorder. The device will be used in hospitals, institutions, sleep centers or clinics, or other test environments where adult or infant patients require the documentation of various sleep or other physiological disorders. This device does not provide alarms and is not intended for use as an automated apnea monitor.	Intended for use in collecting and recording physiological data to be used in polysomnography and sleep disorder studies. For use in either home or hospital environments with a pediatric through adult patient population. This device does not provide alarms and is not intended for use as an automated apnea monitor
Target population	Pediatric through adult (excluding neonates and infants)	Pediatric through adult (including all pediatric subpopulations)	Pediatric through adult (including all pediatric subpopulations)
Environment of use	Hospital and home	Hospitals, institutions, sleep centers, or other test environments.	Hospital and home

Product Characteristic	***Suzanne*** **(Predicate Device)** **Nellcor Puritan Bennet** **K990565**	***Alice 5*** **(Predicate Device)** **Respironics** **K040595**	***Sandman Pocket*** **(submission device)** **EB Neuro** **Via this Submission**
Warnings	Items related to sensor irritation, strangulation avoidance and off-label use.	Items related to sensor irritation, strangulation avoidance, and off-label use.	Items related to sensor irritation, strangulation avoidance and off-label use.
Contraindications	Items related to design and indicated use limitations, such as not for use in the presence of flammable anesthetics or in conjunction with defibrillation equipment.	Items related to design and indicated use limitations, such as not for use in the presences of flammable substances or anesthetic mixtures with air oxygen or nitrous oxide, defibrillation, and MRI equipment, and not for use as automated apnea monitor or a continuous monitor.	Items related to design and indicated use limitations, such as not for use in the presence of flammable anesthetics or in conjunction with defibrillation equipment. The Sandman Pocket is not intended for use as life support equipment such as a vital sign monitoring in intensive care unit. The device does not produce alarms and is not intended as an automated apnea monitor. The Sandman Pocket is only to be used under the direction or supervision of a physician, technologist or clinician. It will not prevent or restore the interruption or loss of any physiological system.
Prescription status	Available only on the order of a physician.	Available only on the order of a physician.	Available only on the order of a physician.

Product Characteristic	***Suzanne*** **(Predicate Device)** **Nellcor Puritan Bennet** **K990565**	***Alice 5*** **(Predicate Device)** **Respironics** **K040595**	***Sandman Pocket*** **(submission device)** **EB Neuro** **Via this Submission**
Service instructions	No field service allowed.	No field service allowed.	No field service allowed.
Design			
Communication Interfaces	Physiological signals are sent to the Slow Wave and Fast Wave headbox through the sensor cables. The Slow Wave and Fast Wave headboxes sends the data to the Recorder Plus module where the data is stored either to a flash memory card or to a PC via a fiber optic interface.	Physiological signals are sent from the patient sensors to the headbox through the sensor cables. The data is sampled and sent to the base station where it is stored on a disk until it is sent through an Ethernet connection to a Host PC.	Physiological signals are sent from the patient sensors to the amplifier box through the sensor cables. The amplifier box sends the data to the recorder where the data is stored in flash memory in both attended and unattended studies. During attended studies, the data is also transmitted to a computer in real-time via a USB cable. After unattended studies, data can be downloaded from the recorder using a USB cable.
Microprocessor	Siemens 80C537 12 MHz	Unknown	Texas Instruments TMS320UC5402 on recorder Texas Instruments MSP430F169 on headbox
A/D Resolution	12 bit	16 bit	16 bit

Product Characteristic	***Suzanne*** **(Predicate Device)** **Nellcor Puritan Bennet** **K990565**	***Alice 5*** **(Predicate Device)** **Respironics** **K040595**	***Sandman Pocket*** **(submission device)** **EB Neuro** **Via this Submission**
Data recording	On PCMCIA card, magnetic disk or optical disk (via a personal computer).	Computer hard drive, compact disc, or transferred via Ethernet connection to a Host PC.	On internal NAND flash chip
Configuration	Desktop and wearable	Desktop only	Wearable
Amount of memory required for a typical 8 hour study.	20 MB	600 MB without audio/ video 6 GB with audio/video NOTE: Alice 5 can collect up to 21 neurological channels. These channels are recorded at very high sampling rates. In addition, Alice 5 records video at very high frame rates with no compression. These two factors contribute to the large study size. All data are stored to computer hard disk.	28 MB

Product Characteristic	***Suzanne*** **(Predicate Device)** **Nellcor Puritan Bennet** **K990565**	***Alice 5*** **(Predicate Device)** **Respironics** **K040595**	***Sandman Pocket*** **(submission device)** **EB Neuro** **Via this Submission**
Sampling rate	Slow waves : 12 samples/s Fast waves : 120 samples/s	Neurological channels 2000 samples/s	Fast waves: For example, ECG programmable up to 2048 sample/s Medium waves: For example, EMG, EOG, Snore programmable up to 1024 sample/s Slow waves: For example, airflow, respiratory effort, body position programmable up to 256 sample/s
Power	Battery powered (internal) or Medical Grade AC-DC Power Supply	Medical grade AC Power Supply	Battery powered or USB powered
Sensors	Commercially available sensors only	Commercially available sensors only	FDA Cleared sensors only

Product Characteristic	***Suzanne*** **(Predicate Device)** **Nellcor Puritan Bennet** **K990565**	***Alice 5*** **(Predicate Device)** **Respironics** **K040595**	***Sandman Pocket*** **(submission device)** **EB Neuro** **Via this Submission**
Performances			
Maximum number of channels	35	55	22
Recording channels			
EEG	Yes	Yes	Yes
EOG	Yes	Yes	Yes
EMG	Yes	Yes	Yes
ECG	Yes	Yes	Yes
Respiratory efforts	Yes	Yes	Yes
Airflow	Yes	Yes	Yes
Ambient sounds	Yes	Yes	No
Body position	Yes - internal	Yes - external	Yes - external
Ambient light	Yes - internal	No	No
SpO_2	Yes - internal	Yes - internal	Yes - internal
Pulse rate	Yes - internal	Yes - internal	Yes - internal
Plethysmograph	No	Yes	Yes
Differential pressure	Yes - internal	Yes - external	Yes - internal
Actimeter	No	Yes	No
Derived channel	N/A	Pulse Transit Time (PTT) – A calculation of the time between the occurrence of the R wave on the EKG and the peak flow on the plethysmogram. RR Interval – Measurement of the period of time between two consecutive R waves on the EKG. Displays as a real-time beat-to-beat heart rate calculation.	Pulse Transit Time (PTT) – A calculation of the time between the occurrence of the R-wave on the EKG and 50% ascending slope on the plethysmogram. Heart rate – Derived from the ECG channel

Product Characteristic	***Suzanne*** **(Predicate Device)** **Nellcor Puritan Bennet** **K990565**	***Alice 5*** **(Predicate Device)** **Respironics** **K040595**	***Sandman Pocket*** **(submission device)** **EB Neuro** **Via this Submission**
Passbands			
EEG	0.625 to 18 Hz	Neurological Channels 0.32 to 106 Hz	0.1 to 135 Hz
EOG	0.625 to 18 Hz		0.1 to 135 Hz
EMG	0.625 to 18 Hz		0.1 to 135 Hz
ECG	0.625 to 18 Hz		0.1 to 135 Hz
Respiratory efforts	0.055 to 1.25 Hz		0.1 to 45 Hz
Airflow	0.1 to 1.3 Hz		0.015 to 10 Hz
Ambient sounds	None		None
Pressure sensor	0 to 175 Hz		DC to 15 Hz
SpO_2	NPB proprietary		NPB proprietary
Pulse rate	NPB proprietary		NPB proprietary

Product Characteristic	***Suzanne*** **(Predicate Device)** **Nellcor Puritan Bennet** **K990565**	***Alice 5*** **(Predicate Device)** **Respironics** **K040595**	***Sandman Pocket*** **(submission device)** **EB Neuro** **Via this Submission**
CPAP (Continuous Positive Airway Pressure)	*Suzanne* supports all models of CPAP devices because the CPAP device connections were air-based rather than electrically based. Using a pneumotachograph kit, users could connect hoses and adapters to the CPAP device and the flow and pressure nipples on the *Suzanne* slow wave headbox to measure CPAP airflow and/or air pressure at the mask out-take during nasal CPAP/Bi-level titration.	*Alice 5* supports the use of all Respironics lab therapy devices: Aria LX BiPAP Pro Duet LX Harmony HeartPAP REMStar Auto REMStar Pro REMStar Pro with C-Flex Synchrony Virtuoso LX	*Sandman Pocket* stores data from Nellcor Puritan Bennett GK420E, GK425, and GK425ST CPAP devices. When the recorder is also connected to the host computer, the *Sandman Pocket* not only stores data in the on-board memory, but also acts as a passive bridge between the aforementioned GK CPAP and the host computer by receiving data streams from the CPAP and transmitting the data streams to the host computer and vice versa. When the *Sandman Pocket* is connected to a third party CPAP device and a host computer, *Sandman Pocket* acts as a passive bridge between the third party CPAP device and the computer by receiving data streams from the CPAP and transmitting the data streams to the host computer and vice versa. Alternatively, *Sandman Pocket* may also handle CPAP device connections in the same manner as Suzanne.

Product Characteristic	***Suzanne*** **(Predicate Device)** **Nellcor Puritan Bennet** **K990565**	***Alice 5*** **(Predicate Device)** **Respironics** **K040595**	***Sandman Pocket*** **(submission device)** **EB Neuro** **Via this Submission**
Mechanical safety	Device complies with the requirements of Nov' 93 Draft Reviewer's Guidance	Device complies with the International Standard IEC 60601-1 CSA C22.2 No. 601.1 EN 60601-1 UL 60601-1 AS 3200.1.0* *Australian Deviation to IEC 60601-1	Device complies with the International Standard IEC 60601-1 CSA C22.2 No 601-1-M90 UL 2601
Electrical safety	Device complies with the International Standard CSA C22.2 No. 601-1-M90 UL 2601 Device complies with the requirements of Nov' 93 Draft Reviewer's Guidance	Device complies with the International Standard IEC 60601-1 Guidance, when applicable, has been adopted from the following standards: IEC 60601-2-25 IEC 60601-1-26 IEC 60601-2-40 IEC 60601-2-49	Device complies with the International Standard IEC 60601-1 IEC 60601-1-4 IEC 60601-1-26 CSA C22.2 No 601-1-M90 UL 2601

Product Characteristic	***Suzanne*** **(Predicate Device)** **Nellcor Puritan Bennet** **K990565**	***Alice 5*** **(Predicate Device)** **Respironics** **K040595**	***Sandman Pocket*** **(submission device)** **EB Neuro** **Via this Submission**
Electromagnetic Compatibility (EMC)	Device complies with the following EMC standards IEC 60601-1 IEC 61000-4-2 IEC 61000-4-3 IEC 61000-4-6 Mil Std 462D IEC 61000-4-4 IEC 61000-4-5 EN55011 Class B Device complies with the requirements of Nov' 93 Draft Reviewer's Guidance	Device complies with the International Standard IEC 60601-1-2, including the following standards: CISPR 11 IEC 61000-3-2 IEC 61000-3-3 IEC 61000-4-2, IEC 61000-4-3 IEC 61000-4-4, IEC 61000-4-5, IEC 61000-4-6, IEC 61000-4-8 IEC 61000-4-11	Device complies with the International Standard IEC 60601-1- 2, including the following standards: IEC 61000-3-2 IEC 61000-3-3 IEC 61000-4-2 IEC 61000-4-3, IEC 61000-4-4, IEC 61000-4-5, IEC 61000-4-6, IEC 61000-4-8 IEC 61000-4-11 EN55011 class B EN55014-1

Conflict of Interest
Declaration and Certification
For the review of the 510(k) submission from

Applicant: EB Neuro

Device Name or Model Name: Sandman Pocket

Initials

I have read and understand Regulatory Technology Services LLC's Conflict of interest and Confidentiality Procedure (COI-S-0023), regarding conflict of interests and the attachments accompanying the procedure and am aware of my responsibilities under them.

I have not been employed within the last two years by the firm who submitted the 510(k) for evaluation.

I did not charge fees contingent or based upon the recommendation for initial classification (SE decision).

I have not performed testing in connection with this specific device 510(k).

I understand that the Accredited Persons (AP) Program requires that the Accredited Person or any of its personnel involved in 510(k) reviews, which includes those who have authority over the review process, have no ownership or other financial interest in a device manufacturer or distributor that presents the appearance of a conflict of interest.

I do not participate in the design, manufacture or distribution of any medical device.

I do not provide consultative services to any device manufacturer or distributor regarding specific devices.

Signed: _____

Printed Name: Mark Job

Date: June 14, 2006

510(k) Applicant's Name: EB Neuro

Primary Reviewer: Mark Job

Signature: [signature] Date: July 12, 2006

Print Name: Mark Job Title: Reviewer

Responsible Third Party Official

Signature: [signature] Date: July 13, 2006

Print Name: Pedro E. Gonzalez Title: Supervisor

Regulatory Technology Services LLC

	Yes*	No*	
1. Is product a device?	X		If NO= Stop
2. Is device subject to 510(k)?	X		If NO= Stop
3. Same indication statement?	X		If YES=Go to 5
4. Do differences alter the effect or raise new issues of safety or effectiveness?			If YES=Stop NE
5. Same technological characteristics?	X		If YES=Go to 7
6. Could the new characteristics affect safety or effectiveness?			If YES=Go to 8
7. Descriptive characteristics precise enough?	X		If NO=Go to 10 If YES=Stop **SE**
8. New types of safety or effectiveness questions?			If YES=Stop NE
9. Accepted scientific methods exist?			If NO=Stop NE
10. Performance data available?			If NO=Request Data
11. Data demonstrate equivalence?			Final Decision:

*Note: In Addition to completing page 2, "yes" responses to questions 4,6,8, and 11, and every "no" response requires an explanation on page 3. Document the decision path by marking the arrows followed on the FDA flowchart.

1. Intended Use: The EB Neuro Sandman Pocket is indicated for use in collecting and recording physiological data to be use in polysomnography and sleep disorder studies. The device is intended to be used for pediatric through adult patient populations and at home or in a hospital environment. The device is not intended to be used for use a life support monitor or vital signs monitor in an intensive care unit. The device does not include alarms and is not intended to be used as an automatic apnea alarm monitor. The device is intended to be use under the order of a physician or under the supervision of a physician, technician or clinician. The indications for use form provided by the manufacturer is included on page 4 of the submission.

2. *Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. The following should be considered when preparing the summary of the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain a drug or a biological product as a component? Is this device a kit? Provide a summary about the device's design, materials, physical properties, and toxicology profile if important.*

Summary:

Submission Information

This submission has been submitted by EB Neuro as a new device. The model name of the device is EB Neuro Sandman Pocket.

Administrative Information

A Truthful and Accuracy Statement is included on page 6 located in the Tab by the same name. A 510(k) Summary is included on pages 7 and 21 of the submission.

Reason for the Submission

This is a new device.

Device Classification

This device is classified under 21CFR868.2375 under product code MNR.

Intended Use

The Sandman Pocket is indicated for use in collecting and recording physiological data to be use in polysomnography and sleep disorder studies. The device is intended to be used for pediatric through adult patient populations and at home or in a hospital environment. The device is not intended to be used for use a life support monitor or vital sing monitor in an intensive care unit. The device does not include alarms and is not intended to be used as an automatic apnea alarm monitor. The device is intended to be use under the order of a physician or under the supervision of a physician, technician or clinician. This statement included in the 510(k) summary is also in line with the user manual and the indications for use form. This statement is comparable to the predicate device intended use statements.

Device Description

The *Sandman Pocket* is a physiological data recorder that is part of a polysomnography system. It consists of two units: the ***Recorder Unit,*** which stores the data and sends it to a USB port, and ***Headbox Unit***, which is the connection point for all patient sensors with the exception of the Nellcor Puritan Bennett oximetry probe.

The role of the *Sandman Pocket* is only to capture the data and pass it to the host with the necessary accuracy and reliability according to the product and communication control specifications.

A fundamental characteristic of the *Sandman Pocket* is the ability to be an ambulatory/portable physiological data recorder. Because of its small size and light weight (about 210 grams including the battery), the system is compact and durable.

The ***Headbox Unit*** is used for connecting patient electrodes and sensors. It includes Bipolar channels, pressure sensors, power supply for a dedicated body position sensor, an abdomen sensor, a chest sensor, a snore sensor and a thermistor. The patient inputs are isolated with a CF type isolation level. The Sandman Pocket device is provided without standard sensors. The system builder should integrate the device with FDA cleared Nellcor Puritan Bennett sensors only and specified for the usage with NELL-1 module.

The ***Headbox Unit*** captures the biological signals from the human body surface through specialized sensors and electrodes, while the ***Recorder Unit*** amplifies the very low electrical signal and filters the signals to

make an optimal ANALOG to DIGITAL conversion. The data, once converted in numerical form, are sent to a host computer for review and analysis. The host can "program" the amplifier behavior by setting the sampling frequency and the dynamic range allowed and so on.

The host computer reads the acquired data through a dedicated interchange protocol, and allows a clinician to analyze the data using sleep review analysis software, provided by the end user or system builder. The clinician must use an electrically isolated computer (with a medical grade isolation transformer or medical grade power supply) or battery-supplied laptop when the Sandman Pocket device is connected to the host PC and the patient is connected to the Sandman Pocket Headbox.

The *Sandman Pocket* system is not in any way involved in the data management performed by the host. The host computer must operate using one of the following Operating System: Microsoft Windows 98 / ME / NT / 2K / XP.

The device has a built-in impedance meter. This function allows the clinician to check the electrode contact impedance and display the results of the check on the display. The display is located in the Recorder Unit, while the circuitry controlling the impedance meter is located in the Headbox Unit.

The *Sandman Pocket* can be powered through 3 Alkaline 1.5V standard non rechargeable batteries or via the USB cable. The user is recommended to use a medical grade type PC.

The *Sandman Pocket* system consists of two interconnected units: the Headbox Unit and the Recorder Unit.

The **Headbox Unit** has the following functions:

- Physically connects the source of signals (the patient) to the amplifier.
- Provide impedance testing capabilities
- Provide Analog to Digital (A/D) conversion

The **Recorder Unit** has the following functions:

- Amplify and isolate signals coming from the electrodes
- Reference input channels
- Generate calibration pulse

- Provide dynamic range (gain), sampling rate and active channels selection
- Performs anti-aliasing filtering for optimal Analog to Digital conversion
- Provide, when requested, the Pulse Transition Time (PIT) calculation.
- Send the digital data through the USB interface to the host
- Provide the Oximeter option
- Manage the display
- Manage the Time
- Manage the battery power supply

Safety Features: The *SANDMAN POCKET* is battery powered and has been designed to comply with national and international standard. A declaration of conformance is included in the addition all information dated July 12, 2006. The device is intended to collect data which is passed on to be review and used for a diagnosis which not part of this device. The device does not incorporate any type of alarm or indicator to alert the user.

Software: The device includes software for control of certain functions. The device software does not include algorithms which analyze the data collected. The software is employed to manage the data acquisition and the communication with the computer and peripheral devices. The software also provides a graphical display and interface pad for the user convenience. The display provides status of the device for example the battery level, available memory, time and data display.

Accessory connected devices: The additional information dated July 12, 2006 includes a list of devices which have been previously cleared. These devices are connected to the device to facilitate the connection of the data used for the study.

Software

The software used for the *SANDMAN POCKET* is considered to be of minor level of concern as determined by the decision matrix provided in the FDA Guidance Titled: *"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"* dated: May 11, 2005. The additional information dated July 12, 2006 provides the rational for the determination. The submission includes all information required by the guidance document. The software description is included in the additional information dated July 12, 2006. The revised software description is included in the additional information dated July 12, 2006. The description describes how the software is used control the data acquisition from the devices connected to the device. The software also describes the interface with device and PC host computer to allow the clinician or physician to download the data collect. The device hazard analysis is included in a separate TAB in the original submission. The

functional test plan and the results are included in additional information dated July 12, 2006. The test plan presented verifies all system functions. The submission includes and meets all requirements of the software guidance documents for the software used with the system. No new concerns or questions related to safety and effectiveness have been raised as result of the use of the software employed.

Comparison to Legally Marketed Devices

The predicate devices identified in the Comparison Information TAB. The predicate devices are the SUZANNE (Nellcor Puritan Bennet cleared under K990565) and the ALICE 5 (Respironics cleared under K040595). The comparison table included in the submission demonstrates the two predicate devices have comparable intended use as the new device (SANDMAN POCKET). All of the devices (new and predicate) are intended to be used with the same patient population. The devices are intended to collect the same physiological data from the patient. All devices have the ability to collect data from a CPAP device which can be used during the study. The electrical, mechanical and EMC characteristics are comparable.

Similarities: Both *Suzanne* and *Sandman Pocket* are portable recording devices intended to record polygraphy / polysomnograph data (multifunctional ambulatory recorders) in clinical and home environments. When used in a home setting, the patient goes to the physician's office to get hooked up to the system, goes home and sleeps in his/her own bed, and then returns the next day with the recording system and its stored data.

Suzanne, Alice 5, and *Sandman Pocket* use one common electrode reference to establish a patient ground (not earth ground) against which all other electrical inputs are referenced. Each device's measurement values and waveforms contain many of the same channels of information.

All devices detect electrical signals or other signals (impedance change, pressure) which are then converted to digital data. None of the systems actually deliver energy to the patient – they receive signals from the patient, amplify and filter these signals, and record the digital data derived from the signals.

None of the hardware devices perform data analysis. The waveforms are stored in the on-board memory *(Suzanne* and *Sandman Pocket)* or to the base station *(Alice 5)* and then the data is transferred to a host system, which runs sleep review and analysis software used by a trained clinician to analyze the data either by manually scoring or auto-scoring the recorded data. The software on the host system and its behavior is outside of the scope of all the referenced devices.

Both *Suzanne* and *Sandman Pocket can* be powered using batteries. The *Suzanne* operates using built-in NiMH rechargeable batteries. *Suzanne* could also operate

using a medical grade AC to DC power supply. This power supply also recharges the NiMH batteries. The *Sandman Pocket* operates with 3 AA size 1.5 V dry cell batteries. The Sandman Pocket can also be powered via a standard USB cable; in this case, the PC can be a battery powered laptop or a desktop computer equipped with a medical grade isolation transformer.

All devices amplify, filter and digitally convert data. *Suzanne* and *Sandman Pocket* perform this amplification, filtration, and digital conversion in the headbox, while *Alice 5* amplifies and filters the signal in the headbox and digitizes the signals in the base station. Communication between the headbox and the recorder *(Suzanne* and *Sandman Pocket)* is digital to achieve a highly reliable data transfer with low EMI susceptibility.

Both *Suzanne* and *Sandman Pocket* incorporate the preamp of each channel in the headbox, this could be considered to increase the comfort of the patient

Like Suzanne, *Sandman Pocket can* handle CPAP device connection by connecting a pneumotachograph kit to the CPAP device and the FDA cleared pressure transducer on the *Sandman Pocket.*

Like *Alice5, Sandman Pocket may* be connected to a digital CPAP device in order to acquire data and store the data together with the other input signals.

In any configuration, the *Sandman Pocket* is not capable of setting or modifying the CPAP parameters. Changing the CPAP device settings may only be done by the user with either a CPAP remote control connected directly to the CPAP device or from the host computer using sleep review and analysis software capable of changing the CPAP parameters.

Differences: *Sandman Pocket* calculates PTT as the time between the R-wave (the highest point of the ECG signal) and the 50% ascending slope of the plethysmogram waveform. *Alice 5,* on the other hand, calculates PIT as the time between the R-wave of the ECG signal and the peak flow of the plethysmogram waveform. *Suzanne* does not calculate PTT.

Both *Sandman Pocket* and *Alice 5* use the peak of the R-wave, but *Sandman Pocket* and *Alice 5* use different points to denote the end of the calculated time of PTT. However, there is no clinical difference between these methods because the value used to end the calculated time of the PTT is a convention that varies from researcher to researcher. A survey of the literature shows that there are published papers that use 25%, 50% and 100% of the Pleth waveform as the end of the calculated time of PTT.

Conclusion: The *SANDMAN POCKET* is similar to the predicate devices with regards to intended use, performance parameters, features and materials. The *SANDMAN POCKET* is substantially equivalent to the predicate devices. The comparison does not raise any new concerns or questions related to the safety and effectiveness.

Proposed Device Labeling

The submission includes labeling which includes labels on the device, a technical manual, and a user manual. The labels on the device include warnings and indication which allow an intuitive user to understand the operation of the device. The labeling includes the intended use, the prescription statement, warnings, cautions, precautions, contraindications, directions for use, maintenance, and cleaning instructions. The labeling meets the requirements of the bluebook memo.

Reviewer's Analysis

As the reviewer of this submission I have reviewed the instructions for use, the submitter's description of the device and compared this information against the information concerning the predicate devices provided by the submitter. The specifications, features, intended use, safety features, etc. for the predicate device and the new device have been compared. The differences are considered to be minimal in relationship to the previously cleared devices. Compliance to the IEC 60601-1 electrical safety standard provides confidence that this device is safe electrically. The labeling included in the submission was reviewed. There are no new questions of safety and effectiveness raised during this review.

Reviewer's Recommendation

Based upon the above summary, a substantially equivalent decision is recommended.

Classification Name: Ventilator Event Recorder
Regulatory Class: II
Product Code: MNR
Classification Number: 21 CFR 868.2375

Explanations To "Yes" and "No" Answers to Questions On Page 1 As Needed.

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

6: Explain how new characteristics could or could not affect safety or effectiveness:

7: Explain how descriptive characteristics are not precise enough:

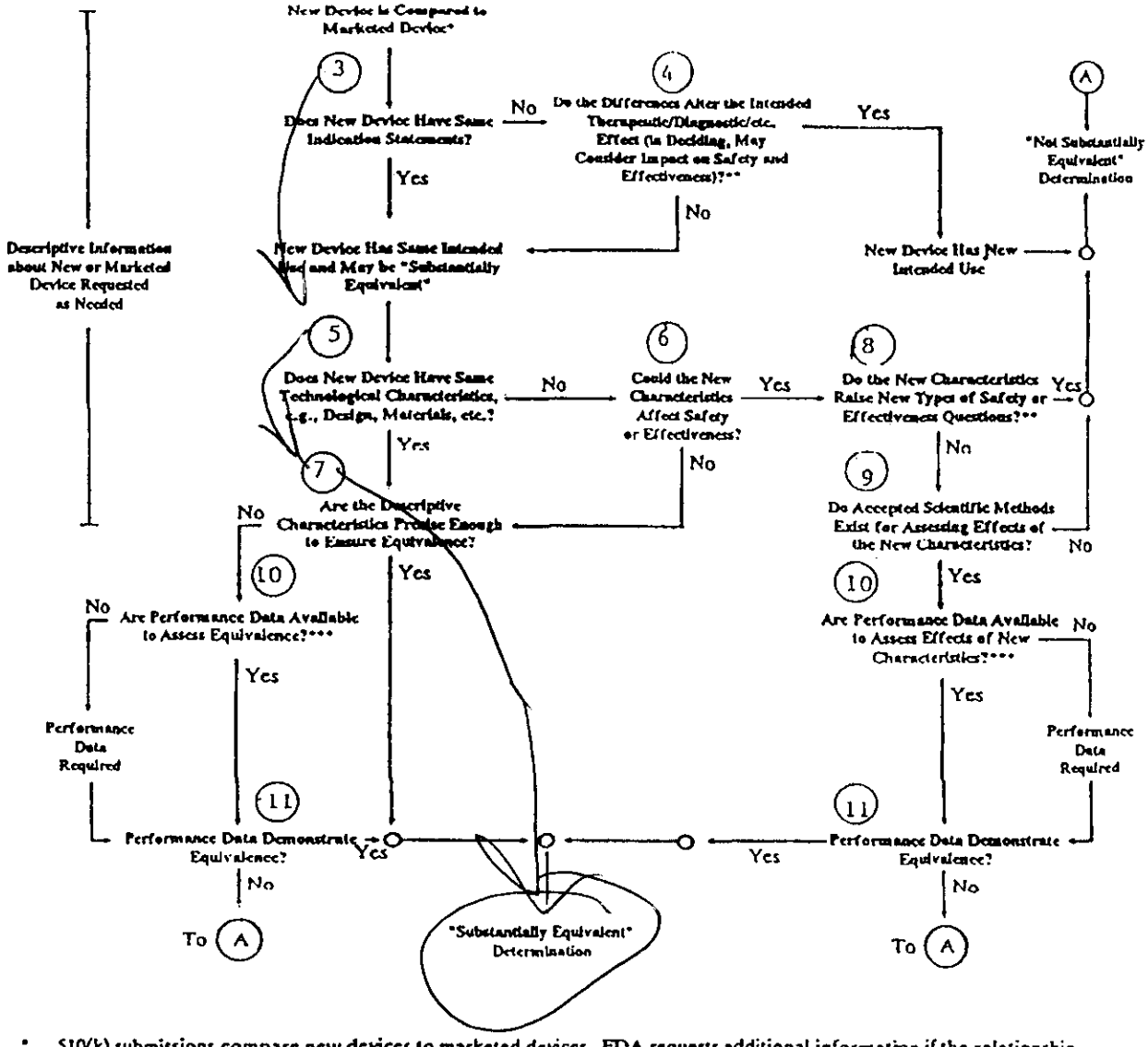
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



* 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

MARK JOB

From: Allison Scott [AScott@AnsonGroup.com]
Sent: Wednesday, July 12, 2006 7:57 AM
To: MARK JOB
Subject: Deficiencies - Docs for point 2 and 3

Mark-
Please find attached the Verification/Validation and Traceability Analysis documents to answer Deficiencies 2 and 3. These documents were originally written in Italian and have been translated into English for this submission, so the language may be rough.

Also the client made some changes to the user manual including adding in chapter 1 (par. 1.1.3) that the device is in accordance with IMQ-CSA observation regarding compliance to ISO 9919 (pulse oximetry), as well as adding parag. 1.1.3.1 and 1.3.1.2 regarding responsibility of system builder for the compliance to ISO9919 of the complete final system.

Please let me know if you have further questions. Also, could you notify me when the submission goes to FDA?
Thank you.

Allison Driskell Scott
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NOTE:
THE OTHER POINTS
WERE COVERED IN A
SERIES OF EMAILS
WHICH INCLUDED ONLY
THE ATTACHMENTS

MARK JOB
REVIEWER
12 July 2006

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data .
vs.rif. .
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DECLARATION OF CONFORMITY

I certify that, in my capacity as Managing Director of EB Neuro, S.p.A., the Sandman Pocket has been tested and complies with the following recognized standards:

CSA Standards:	
CAN/CSA-C22.2 No. 0-M91	General Requirements – Canadian Electrical Code, Part II.
CAN/CSA-C22.2 No. 601.1-M90	Medical Electrical Equipment Part 1: General Requirements for Safety.
CAN/CSA-CC22.2 No. 601.1S1-94	Supplement No. 1-94 to CAN/CSA-C22.2 No. 601.1-M90 - Medical Electrical Equipment Part 1: General Requirements for Safety.
CAN/CSA-C22.2 No. 601.1-B98 Am.2	Amendment 2:1998 to CAN/CSA-C22.2 No. 601.1-M90 - Medical Electrical Equipment Part 1: General Requirements for Safety.
CAN/CSA-C22.2 No. 601-2-26-98	Medical Electrical Equipment Part 2: Particular requirements for the safety of Electroencephalographs.
IEC Standards:	
IEC 601-1:1988	Medical Electrical Equipment - Part 1: General Requirements for Safety.
IEC 60601-1 Amendment No. 1:1991	Amendment 1 to 60601-1:1988.
IEC 60601-1 Amendment No. 2:1995	Amendment 2 to 60601-1:1988.
IEC 60601-1-1:2000	Medical Electrical Equipment – Part 1-1: General Requirements for Safety. Collateral standard: Safety Requirements for Medical Electrical Systems.
IEC 60601-2-26:2002 (2nd Edition)	Medical Electrical Equipment Part 2: Particular requirements for the safety of Electroencephalographs.
IEC 60601-1-2:2001 (2nd Edition)	Requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests
IEC 60601-1-4:1999+A1:2001	Medical Electrical Equipment – Part 1-4: General Requirements for Safety. Collateral standard: Programmable electrical medical systems
UL Standards:	
UL Std No. 60601-1 (1st Edition)	Safety of Medical Electrical Equipment, Part 1: General Requirements for Safety.
ISO Standards:	
ISO 9915:2005 (2nd Edition)	Medical Electrical Equipment: Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.

EN Standards:

EN 55011:1998 Class B	Industrial, scientific and medical (ISM) radio-frequency equipment. Radio distrurbance characteristics. Limits and methids of measurement.
EN 55011 Amendment No. 1:1999	Amendment 1 to EN550011:1998
EN 55011 Amendment No. 2:2002	Amendment 2 to EN550011:1998
EN 55014-1:2000	Electromagnetic Compatibility. Part 1 : Emission – Production family standard.
EN 55014-1 Amendment No. 1:2001	Amendment 1 to EN 55014-1:2000
EN 55014-1 Amendment No. 2:2002	Amendment 2 to EN 55014-1:2000
EN 61000-3-2:2000	Electromagnetic Compatibility (EMC) Part 3 – Section 2 - Limits for Harmonic Current Emissions.
EN 61000-3-3:1995	Electromagnetic Compatibility (EMC) – Part 3 – Section 3 - Limitation of Voltage Fluctuactions and Flicker.
EN 61000-3-3 Amendment No. 1:2001	Amendment 1 to EN 61000-3-3:1995
EN 61000-4-2:1995	Electromagnetic Compatibility (EMC) Part 4 – Section 2 - Electrostatic Discharge Immunity.
EN 61000-4-2 Amendment No 1:1998	Amendment 1 to EN 61000-4-2:1995
EN 61000-4-2 Amendment No 2:2001	Amendment 1 to EN 61000-4-2:1995
EN 61000-4-3:1996	Electromagnetic Compatibility (EMC) Part 4 – Section 3 - Radiated, Radiofrequency Electromagnetic Field Immunity.
EN 61000-4-3 Amendment No. 1:1998	Amendment 1 to EN 61000-4-3:1996
EN 61000-4-3 Amendment No. 2:2001	Amendment 2 to EN 61000-4-3:1996
EN 61000-4-4:1995	Electromagnetic Compatibility (EMC) Part 4 – Section 4 - Electrical Fast Transient/Burst Immunity.
EN 61000-4-4 Amendment No. 1:2001	Amendment 1 to EN 61000-4-4:1995
EN 61000-4-4 Amendment No. 2:2001	Amendment 2 to EN 61000-4-4:1995
EN 61000-4-5:1995	Electromagnetic Compatibility (EMC) Part 4 – Section 5 - Surge Immunity..
EN 61000-4-5 Amendment No. 1:2001	Amendment 1 to EN 61000-4-5:1995
EN 61000-4-6:1996	Electromagnetic Compatibility (EMC) Part 4 – Section 6 - Immunity to Conducted Disturbances introduces by Radio-frequency fields.
EN 61000-4-6 Amendment No. 1:2001	Amendment 1 to EN 61000-4-6:1996
EN 61000-4-8:1993	Electromagnetic Compatibility (EMC) Part 4 – Section 8 - Power Frequency Magnetic Field Immunity.
EN 61000-4-8 Amendment No. 1:2001	Amendment 1 to EN 61000-4-8:1993
EN 61000-4-11:1994	Electromagnetic Compatibility (EMC) Part 4 – Section 11 - Voltage Dips, Short Interruptions and Voltage Variation Immunity.
EN 61000-4-11 Amendment No. 1:2001	Amendment 1 to EN 61000-4-11:1994

Signature

Ing. A. Torsoli - Managing Director
EB Neuro S.p.A.

July 03, 2006
Date

LIST OF SPECIFIED MODEL OF SENSORS AND PERIPHERAL DEVICES FOR SANDMAN POCKET POLYSOMNOGRAPH RECORDER

Device / Sensor type	Sandman Pocket input	Trademark	Model	510(k)	Note
CPAP device	CPAP connector	TYCO Healthcare Nancy	Puritan Bennet -GoodKnight 420E	K031470	(Note 1)
CPAP device	CPAP connector	Mallinckrodt Development France	GoodKnight 425	K041819	(Note 1)
CPAP device	CPAP connector	Nellcor Puritan Bennet	GoodKnight 425ST	K050072	(Note 1)
Oximeter sensor	Oximeter connector	Nellcor Puritan Bennet	DS-100A	K913749	(Note 2)
Oximeter sensor	Oximeter connector	Nellcor Puritan Bennet	MAX-A	K052186	(Note 2)
Pressure sensor	Cannula input	Not specified	Not specified	---	Generic external cannula FDA cleared (CE marked)
Body Position	Body Position input	PRO-TECH Service	SPI	K940013	(Note 3)
Breath sensor	Thermistor input	EDENTEC	971	K913749	(Note 3)
Piezo Snore sensor	Snore input	PRO-TECH	1696	K940015	(Note 3)
Piezo Effort sensor	Chest input	PRO-TECH	1460	K923402	(Note 3)
Piezo Effort sensor	Abdomen input	PRO-TECH	1460	K923402	(Note 3)
ECG electrodes	ECG input	Not specified	Not specified	---	Generic ECG/EEG safety plug electrodes FDA cleared (CE marked)
EXG electrodes	EXG 1 / EXG 2 inputs	Not specified	Not specified	---	Generic ECG/EEG safety plug electrodes FDA cleared (CE marked)
GND reference electrode	ISO GND input	Not specified	Not specified	---	Generic ECG/EEG safety plug electrodes FDA cleared (CE marked)

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(Note 1)
The CPAP models indicated are those models (as detailed in the User Manual) for which the Sandman Pocket is capable to "interpret" the communication protocol and insert the data becoming from the CPA in the data packet stored on the on board memory and/or sent to the host computer.
As specified in the User manual also a "generic" digital controlled CPAP can be used by the System Builder, but in this case the above performance is lost and the Sandman pocket simply acts as a bidirectional bridge between the CPAP device and the host computer not interpreting or using in any way the data becoming from the CPAP.

(Note 2)
These model/type of Oximetry sensors are those on which design, verification and validation have been conducted. These are the recommended models, however Sandman Pocket User manual allow the System Builder to provide other under its responsibility with the condition that the alternative are a model/type approved by Nellcor Puritan Bennet for it NELL-1 oximetry module (the one installed inside the Sandman Pocket)

(Note 3)
This model/type of sensors are those on which design, verification and validation have been conducted. These are the recommended models, however Sandman Pocket User manual allow the System Builder to provide other under its responsibility with the condition that the alternative sensor is electrically and mechanically equivalent to the specified mode/types, and that the alternate model is in conformity with FDA clearance requirements for US market (and 93/42/CEE Directive for EU market).

Software Information

1 Introduction

The information in this section is given in accordance with the "***Guidance for the Content of Premarket Submissions for Software contained in Medical Devices***". issued by FDA on May 11, 2005. In the rest of this section this guidance will be referred to as "Software Guidance"

1.1 Terminology

DAM – Digital Acquisition Module (also called the Recorder Unit)
ARM – Analog Reconfigurable Module (also called the Yoke, Amplifier, or Headbox)

1.2 Software Version

The software contained in the Sandman Pocket is version number 1.00. There have been no previous versions of this software. The software code is: B8630103100. The software release date is: May 2, 2006.

2 Level of Concern

The Sandman Pocket amplifier has been assessed to carry a **Minor Level of Concern**. This decision has been made using the tables available in the Software Guidance.
The term "Software Device" refers to the embedded Sandman Pocket firmware.

Table 1 Major Level of Concern - If the answer to any one question below is Yes, the Level of Concern for the Software Device is likely to be Major.

1_1. Does the Software Device qualify as Blood Establishment Computer Software?
NO – The Sandman Pocket is not a Blood Establishment Computer Software.

1_2. Is the Software Device intended to be used in combination with a drug or biologic?
NO - The Sandman Pocket is not intended to be used in combination with drugs or biologics.

1_3. Is the Software Device an accessory to a medical device that has a Major Level of Concern?
NO - The Sandman Pocket is not intended to be used as an accessory of a Medical Device carrying a Major Level of Concern

1_4. Prior to mitigation of hazards, could a failure of the Software Device result in death or serious injury, either to a patient or to a user of the device?
NO, in the event of a software failure, the acquisition may be abnormally interrupted or the data recorded and/or transferred to the host computer may be corrupted and consequently not usable. In the event of corrupted data, the host computer software and clinical judgment would be exercised to override the information provided by the amplifier.
The monitored data is not intended to alarm or trigger alarm for any conditions.

Examples of this include the following:

a. Does the Software Device control a life supporting or life sustaining function?
NO, the software embedded on the SANDMAN POCKET system is only used to collect physiological data, record them on an on-board memory, and to transfer the recorded data to a host computer through a standard USB interface.

b. Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators?

NO, the software controls no delivery of energy at all.

c. Does the Software Device control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury?

NO, the software embedded on the SANDMAN POCKET system is only used to collect physiological data, store them on an on-board memory, and to transfer the acquired data to a host computer, in real time, during the acquisition or in a successive time, reading back the on-board memory. The software does not interpret the acquired data in any way, nor does the software assign any "*diagnostic meaning*" to particular signals.

d. Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death?

NO, the software embedded on the SANDMAN POCKET system is only used to collect physiological data, store them on an on-board memory, and to transfer the acquired data to a host computer, in real time, during the acquisition or in a successive time, reading back the on-board memory. The software does not interpret the acquired data in any way, nor does the software assign any "*diagnostic meaning*" to particular signals.

e. Does the Software Device provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary?

NO, the SANDMAN POCKET is simply a "recording device", the embedded software is only used to collect physiological data, store them on an on-board memory, and to transfer the acquired data to a host computer, in real time, during the acquisition or, more typically, in a successive time, reading back the on-board memory. The software does not provide any alarm mechanism based on the acquired data, nor does it "control" in any way vital parameters. Any eventual real time elaboration performed on the acquired signals by the host computer is outside the scope of the recorder and is the responsibility of the "medical system" of which the SANDMAN POCKET is only one part.

Table 2 Moderate Level of Concern - If the Software Device is not Major Level of Concern and the answer to any one question below is Yes, the Level of Concern is likely to be Moderate.

2_1. Is the Software Device an accessory to a medical device that has a Moderate Level of Concern?

NO - The Sandman Pocket is not intended to be used as an accessory of a Medical Device carrying a Moderate Level of Concern.

2_2. Prior to mitigation of hazards, could a failure of the Software Device result in Minor Injury, either to a patient or to a user of the device?

NO, in the event of a software failure, the acquisition may be abnormally interrupted or the data recorded and transferred to the host computer may be corrupted and consequently unusable. In the event of corrupted data, the host computer software and clinical judgment would be exercised to override the information provided by the recorder.

The monitored data is not intended to alarm or trigger alarm for any conditions.

2_3. Could a malfunction of, or a latent design flaw in, the Software Device lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury?

NO, for the same reason as stated in the question above.

If the answers to all of the questions in Tables 1 and 2 above are No, the Level of Concern is Minor.

CONCLUSION

The Sandman Pocket software carries a **Minor Level of Concern**.

3 Software Description / Requirement

The functional software embedded in the acquisition system (later on referred to as "firmware") is distributed on each of the two functional modules constituting the system:

1) Digital Acquisition Unit (DAM)
2) Amplifier box (Yoke/ARM)

Digital Acquisition Module
This is the main module of the device. It communicates with the amplifier unit via an asynchronous serial link and with the host PC via a USB connection. It can acquire data under the direct contol of the host PC (attended mode) or store them in the internal memory at the preprogrammed time.

Amplifier box (Yoke/ARM)
This module hosts the amplifier chains and the Analog to Digital converters, and communicates with the digital module via a RS485 serial link.

DAM hosts a programmable DSP, and Yoke hosts a programmable microcontroller. Both modules run a firmware stored in the on-board Flash EEPROM. Once programmed in the factory, the firmware can be upgraded in both modules via the USB link. Details of the communication protocol between DAM and host PC can be found in the document B86100103100_W1.

3.1.1 Device Features Controlled by Software.

3.1.1.1 Acquisition System Recognition.

DAM is connected via a standard USB link to the host PC, and performs device identification and enumeration according to the specifications of USB_2.0 (or USB_1.1, if the host PC supports only this standard).

3.1.1.2 Host PC – DAM communication interface

DAM is a slave of the host PC: commands are actually issued only from the host PC to DAM. The communication protocols require 4 USB pipes:

- A bulk OUT pipe to send command from PC to DAM
- A bulk IN pipe to transport back parameters from DMM to PC
- A Bulk IN pipe to transport acquired data from DAM to the PC.
- An interrupt pipe to notify the presence of acquired data to host PC.

Low level data transport, including packet handshaking and data integrity is performed by the USB interface.
The use of different pipes for data transefer and command handshaking make it possible to issue commands and acquire status information without stopping the data flow.

3.1.1.3 Sampled Data Collection.

Sampled data returned from the Yoke are downsampled to the rate required by the host PC, stored internally in a large buffer and sent to the host PC via the appropriate IN pipe. If selected, data can be stored also in the internal Mass storage memory and downloaded at the end of the recording.

No data compression is performed on such data samples: they are 2's complement 16 bit data.

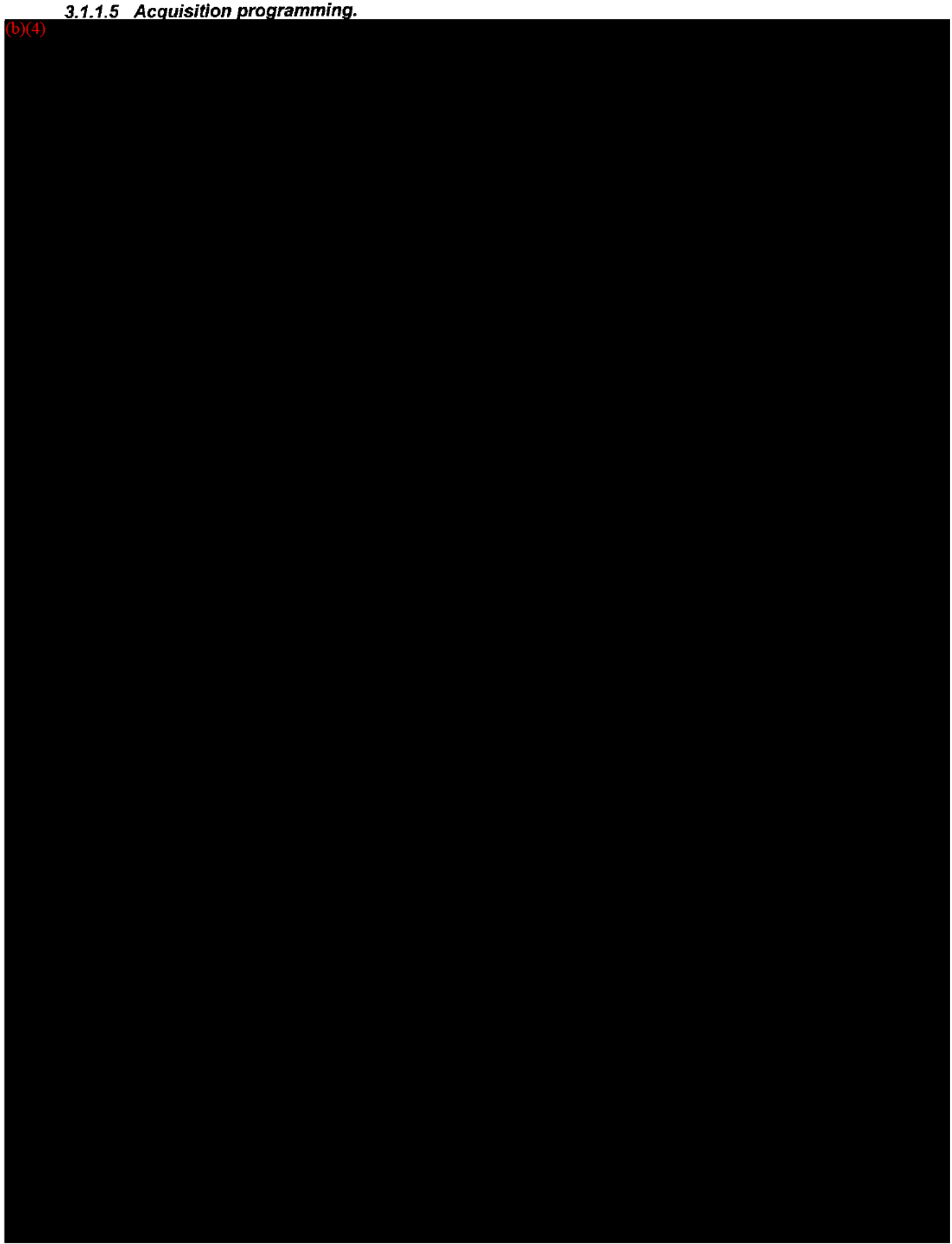
3.1.1.4 DAM unit - Amplifiers box interfacing.

The communication interface between the two units is a bidirectional, RS-485 asynchronous serial link. The forward direction (from DAM to Amplifier box) is used to issue simple commands and to ask for device information and status parameters; the reverse direction (from Amplifier box to

DAM) is used to transfer the data acquired by the sampling logic and to return the parameters requested by DAM.

3.1.1.5 Acquisition programming.

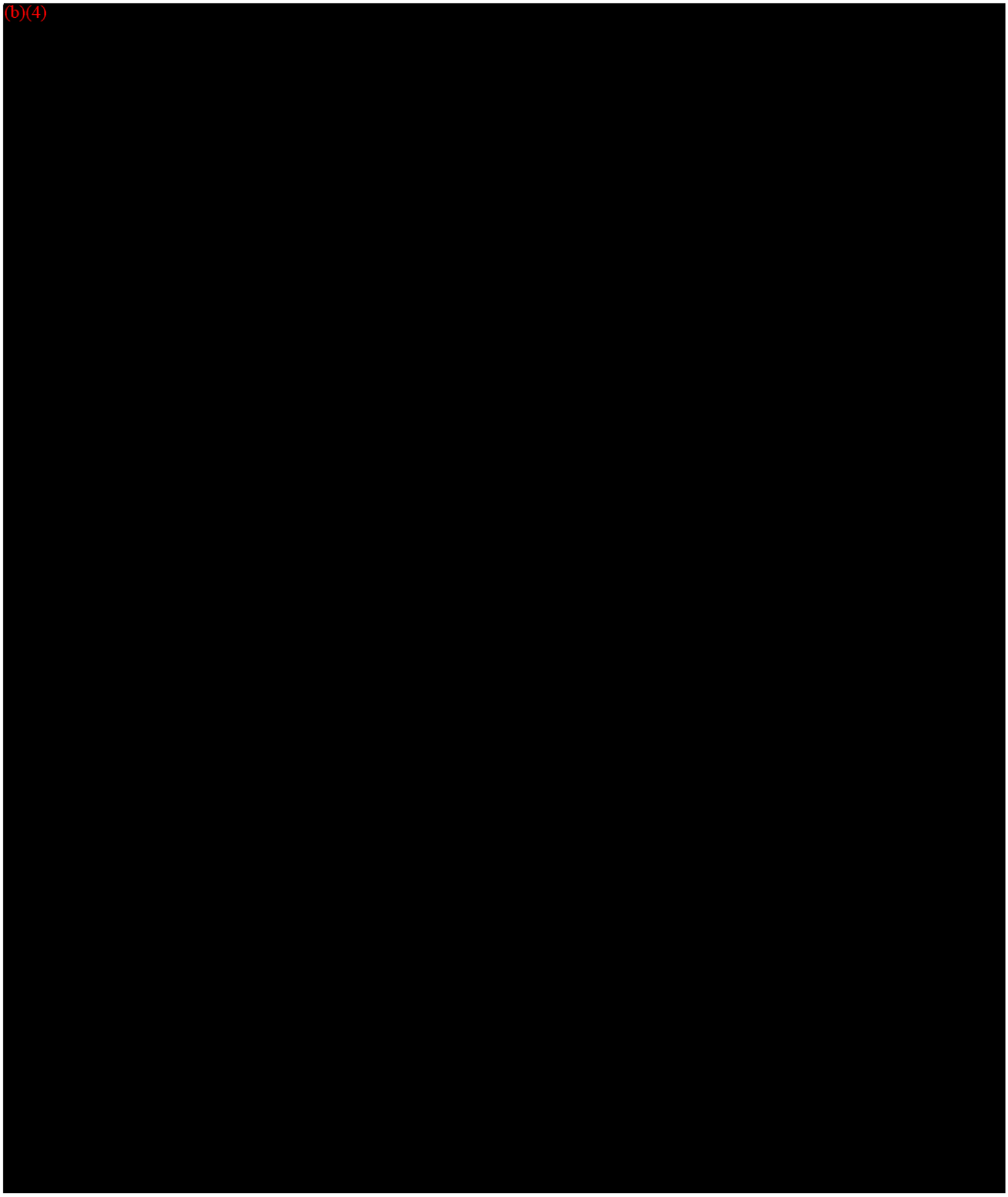
(b)(4)



4 Software Architecture.

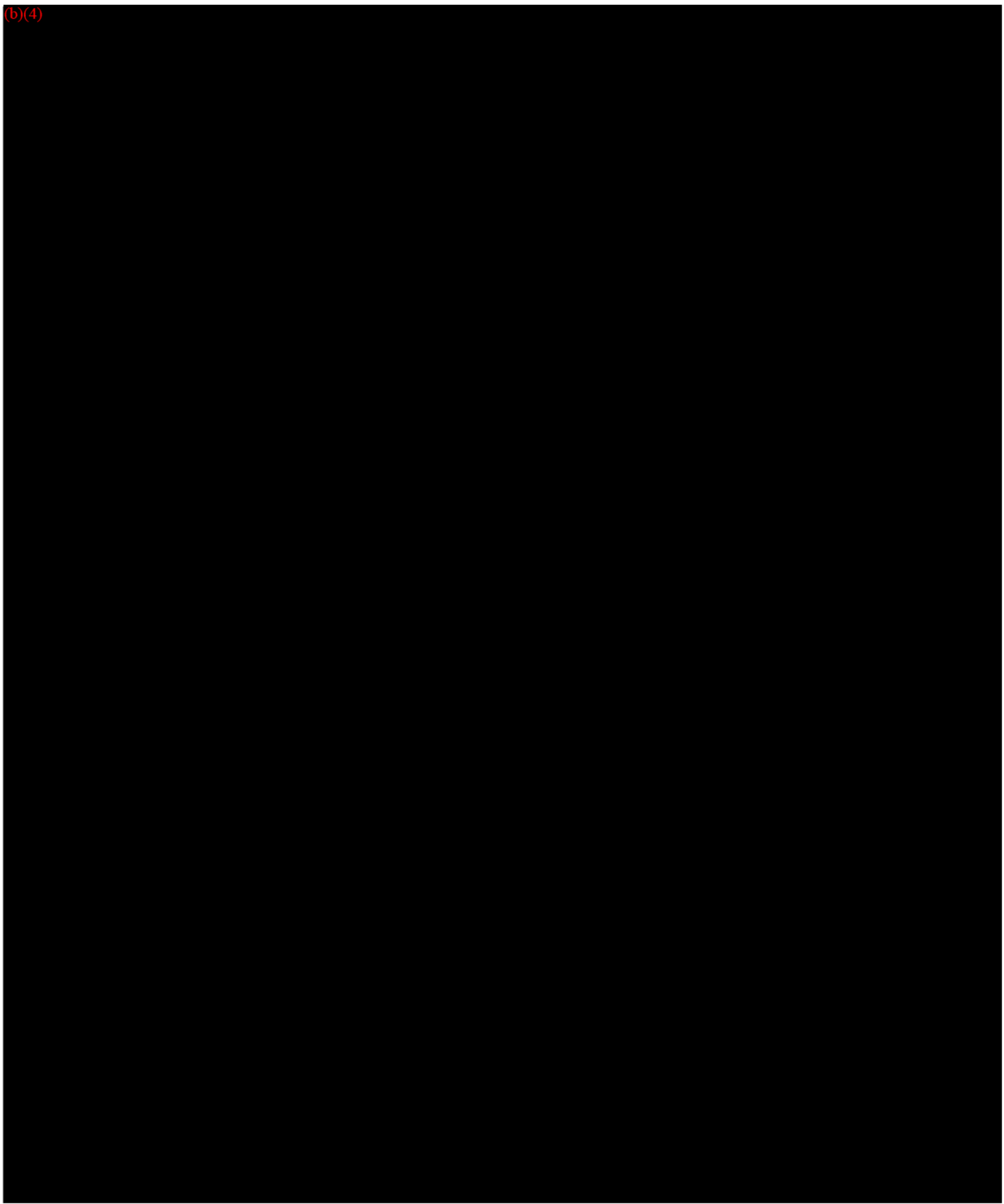
4.1.1 Introduction.

(b)(4)



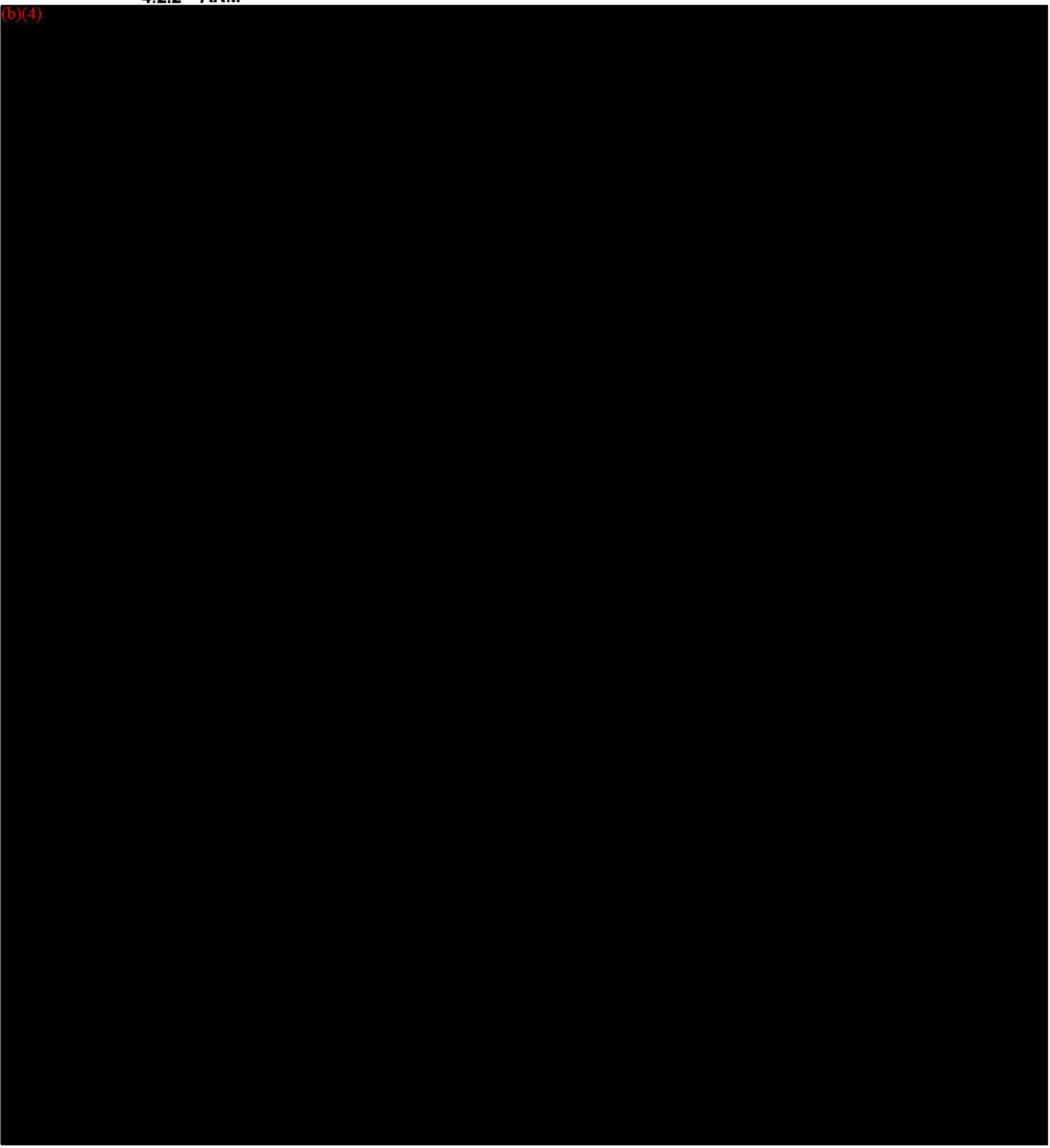
4.2 Software Flowchart.

(b)(4)



4.2.2 ARM

(b)(4)



5 Software Hazard Analysis

(b)(4)

(b)(4) Software Verification

(b)(4) Software Verification

(b)(4) Software Verification

(b)(4) Software Verification

(b)(4) Software Verification

(b)(4) Software Verification

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(b)(4) Software Verification

(b)(4) Software Verification

(b)(4) Traceability Analysis

[redacted]

(b)(4) Traceability Analysis

(b)(4) Traceability Analysis

Sandman Pocket

Polysomnograph Recorder

CE 0051 C SP US

Operator manual
(for OEM System Builder)

B830 0065 411

Rev. A

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EBNeuro
- FLORENCE -

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CHAPTER 1
INFORMATION ABOUT SAFETY

1.1 INFORMATION ABOUT THE MANUAL

Information in this document is subject to change and revision without notice.

Issues:

First edition: **B830 0065 411 - Rev. A - May 2006**

This manual is to be considered as an important component of the equipment. When installing the system for the first time, the user should accurately check the content of the Manual in order to verify its integrity and completeness.

In the event the Operator Manual should be ruined, incomplete or inadequate, please contact EBNeuro in order to immediately restore or replace the uncompliant Manual.

The official versions of the Operator Manual, of which EBNeuro is directly responsible, are the Italian and the English versions. For countries in which languages other than Italian or English are spoken, the official Manual is the version in English. EBNeuro does not undertake any responsibility for any translations in other languages made by distributors or users or third parties.

Observance of the operating procedures and the warnings described in this Manual is a basic requirement for the correct working of the equipment and to guarantee the patient's and the user's safety.

The Manual must be read in full in front of the equipment prior to use, in order to become familiar with the operating procedures, the commands, the connections to the peripheral instruments, and the precautions for a correct and safe usage.

The Operator Manual should be kept, complete and readable in every part, in a safe place. It should be easily accessible to the user when using the equipment.

The equipment Service Manual is available on request. This Manual contains all information directed to the qualified staff in charge for servicing.

1.1.1 CONVENTIONS

In this Operator Manual the following conventions are used:

NOTE

NOTE messages contain important information to be underlined with respect to the rest of the text. They generally contain information useful to the user to correctly perform and use the operating procedures of the equipment.

WARNING

WARNING messages appear in the Manual prior to procedures or operations that should be observed in order to avoid any data losses or damages to the equipment.

ATTENTION

ATTENTION messages appear in the Manual with reference to the description of procedures and operations that, if not performed correctly, could cause damages to the user or the patient.

1.2 DECLARATION OF RESPONSIBILITY BY THE MANUFACTURER

MANUFACTURER: **EBNeuro S.p.A.**
Operatine office:
FIRENZE
Via Pietro Fanfani, 111/A
50127 - Firenze
Phone +39 055 4565111
Fax +39 055 4565123

EBNeuro is responsible for safety, reliability and performances of the equipment only when the equipment is used in compliance with the following conditions:

- Calibrations, modifications or servicing must be performed by qualified staff expressly authorized by EBNeuro.
- The equipment must only be opened and its internal parts must be accessed to by maintenance qualified staff expressly authorized by EBNeuro.
- The environment where the equipment is used must be in compliance with the safety directions.
- The electric wiring of the building must be designed according to local standards and perfectly working.
- Parts of the equipment that can be replaced by the user and accessories, must be replaced with items of the same kind and with the same characteristics.
- The connection of the equipment with peripherals or other instruments supplied by the mains electricity must be performed according to the EN 60601-1-1 standards (standards for Electro-medical systems) and to the EN 60601-1-2 standards (standards for electromagnetic compatibility).
- Usage and maintenance of the equipment and of its accessories must be performed in compliance with the instructions described in this Manual.
- All parts of this Manual must be maintained as a complete and readable document.
- The equipment is used and serviced until its "End of Life".

1.3 USAGE RESTRICTIONS AND SAFETY PRECAUTIONS

In order for the system to be operated in a safe manner and to ensure the safety of both the patient and the user it is important that all precautions listed below are followed:

ATTENTION

Prior to usage, verify that all the safety requirements are satisfied.
The equipment must not be supplied by or connected to other instruments until such safety conditions are restored.

ATTENTION

The EBNeuro Sandman Pocket Recorder is not intended for the "end user", rather it is intended as an OEM product to be used by a "System Builder" as a piece of its own medical systems.
It is responsibility of the System Builder to use the EBNeuro Sandman Pocket Recorder strictly following any technical specification and precaution of use described in this manual.
EBNeuro is not providing nor any sensor, lead or cable, nor any wearing system to the System Builder, nor EBNeuro is providing any "system software" suitable for a complete polysomnographic or sleep study system.
It is completely under the responsibility of the System Builder to provide all the accessories and any eventual wearing system. System Builder should address any safety and effectiveness consideration related to the whole medical system he is "manufacturing" and should provide any instructions and warnings against the correct connection and units/cable placing of any system's part (as an example to avoid any possible strangulation risk). This applies in particular to the use of EBNeuro Sandman Pocket Recorder in pediatric studies.

ATTENTION

The EBNeuro Sandman Pocket Recorder is only to be used under the direction and supervision of a physician, technologist or clinician. It will not prevent or restore the interruption or loss of any physiological system.

ATTENTION

The Sandman Pocket modules (recorder unit and headbox unit) require to be placed on patient body by using a proper wearing system.
The wearing system allows both to properly and easily place the device on patient body and to avoid that Sandman Pocket modules get in direct contact with patient's skin. It is very recommended to avoid contact between Sandman Pocket modules and patient skin in order to prevent both any possible irritation or biocompatibility problem to the patient and any possible damage to the device due to hurts or patient's perspiration. Wearing system is under responsibility of System Buider.

1.3.1 ELECTRIC SAFETY

Leakage current
The maximum patient leakage current from the equipment, measured according to the IEC 601-1 standard (for Class I Type CF) is less than 10 μA.

Patient Connection
All patient connections to the *Sandman Pocket* amplifier are through the *Sandman Pocket* headbox using the input sockets provided, or through the dedicated connectors for pressure, body position, oximeter sensors. Any patient electrodes or sensors connected to the device by any other means constitutes an unsafe condition that could result in injury or death to the patient.

ATTENTION

All connections on the headbox are isolated from AC power ground.
Do NOT join these connections to earth ground or AC power ground since such an action constitute an unsafe condition that could result in serious injury or accidental death to the patient.

ATTENTION

The electrode and sensor through which the signal is captured from the body of the patient are not part of the Sandman Pocklet recorder system, in any case it is MANDATORY to use only electrode or sensor approved for commercial use by FDA (USA) or CE marked (93/42EEC European directive) depending on the country the system is used.

ATTENTION

It is strongly recommended to check the overall functionality of the system before starting any recording.
In case any anomalies or malfunctioning should be noticed, immediately disconnect the patient from the system (if a patient is already connected), switch off the system and ask for service to qualified personnel.
In particular (for example) if, with a patient connected to the system, some "flat" tracing should be noticed on the monitor during recording: in this case if the problem should not be easily solved (poor electrode connection, broken lead etc) immediately acts as above, disconnect the patient, do not use the system and ask for servicing.

ATTENTION

During "long term recording" it is strongly recommended to periodically check that all the system works regularly without any sign of malfunctioning. If any anomalies or flat traces should be noted act as in the previous warning.

ATTENTION

If skin irritation occurs, discontinue recording and disconnect the patient.
Refers to user instruction of sensors, electrodes and paste for further information.
Use only electrodes, sensors and paste according to the requirements of FDA (USA) or 93/42/EEC Medical Devices Directive (CE mark for European Community).

ATTENTION

The operator is responsible for checking the compatibility of the pulse oximeter module, sensor and patient cable prior to use. Incompatible components can result in degraded performances and/or device malfunction with potentially injury and hazard to the patient.
Use only sensors and patient cables specified by the manufacturer of oximetry device and provided by System Builder with the polysomnographic recorder system.

To ensure the safety of the patient and the operator, please follow all the warnings and caution listed in this manual.

- **Take care when using the equipment at the same time as other instruments.** In the event the patient is connected to several instruments at the same time, it is important to remember that the sum of the leakage currents produced by each instrument may endanger the patient.

- **Take care when using the equipment at the same time as other instruments that emit radio frequency**. In the event the equipment is used in an operating room at the same time as a radio knife (Radio-Frequency instrument = RF), it is necessary to hold the radio knife point as far as possible from the electrodes, in order to reduce the risk of RF currents flowing through the electrodes may result in burns. This may be reduced by using electrodes with a larger surface area, in order to limit the RF current density to acceptable values. If it is not possible to use the proper electrodes, it is recommended to disconnect the patient from the equipment before using radio-frequency instruments.

- **The equipment is not protected against the defibrillator discharges**. Please remember that the equipment is not protected against the defibrillator discharges; for this reason, if it is necessary to use a defibrillator, it is necessary to disconnect the patient from the equipment in order to avoid the possibility of patient being burns in the electrode contact areas and the equipment experiencing irreversible damages.

- **Avoid contact of patient and electrodes with other conductive metal items**. When the equipment is connected to other instruments supplied by the mains supply, the whole input circuit to which the patient is connected is electrically isolated (*floating* isolation). It is necessary to avoid the patient and any conductive part of the system connected to the patient (electrodes, connectors, and transducers) coming into contact with conductive parts (ground included) of other devices. Please observe this precaution to avoid compromising the equipment isolation level. This precaution must be observed in order to avoid that accessible metal parts of the device get in touch with external conductive parts thus damaging the isolation level of the equipment.

- **Do not connect additional Multiple Portable Socket-Outlet or extension cord.** Multiple Portable Socket-Outlet or extension cord shall not be connected to the system.

- **Observe the EN 60601-1-1 and the EN 60601-1-2 standards when connecting the system to other instruments**. The connection of the equipment with other devices is allowed only when the safety requirements for the patient, the user and the environment are not compromised. If the Manual does not contain enough information about the possibility of interconnection with other devices, the user should contact the manufacturer or the nearest authorized servicing center to have information about the effects that coupling devices may have on the patient, the user and the environment.

- **Replace damaged parts immediately**. Cables, connectors, accessories, or other parts of the equipment must be replaced immediately when damaged or if they are not working correctly. Please contact the nearest authorized service center immediately for replacement parts.

- **Use only accessories and peripherals of type specified by EBNeuro**. In order to guarantee all the safety requirements, it is necessary to use only the accessories and peripherals specified in this Manual as part of the system, which have been tested with the equipment. The usage of accessories and consumer goods supplied by other manufacturers or not specifically indicated by EBNeuro may not guarantee the safety and the correct working of the equipment. Use only peripherals in compliance with the standards of the class they belong to.

- **Check the functionality of the system before starting any recording.** It is strongly recommended to check the overall functionality of the system before starting any recording. In case any anomalies or malfunctioning should be noticed, immediately disconnect the patient from the system (if a patient is already connected), switch off the system and ask for service to qualified personnel. In particular (for example) if, with a patient connected to the system, some anomalous tracing, like isoelectric or greatly artefacted signal, should be noticed on the monitor during recording: in this case if the problem should not be solved with the assembly standard technique (poor electrode connection, broken lead etc) immediately acts as above, disconnect the patient, do not use the system and ask for servicing.

- **Periodically check that all the system works regularly during "long term recording".** During "long term recording" (more than one hour) it is strongly recommended to periodically check that all the system works regularly without any sign of malfunctioning. If any anomalies or flat traces should be noted act as in the previous warning. In particular any electrode site used for long term must be checked for irritation and redness. Check each electrode periodically to evaluate the skin condition under the electrode. Redness, blistering and permanent skin scarring can occur if electrodes are not regularly monitored.

- **Take care when using the equipment on patients with a heart pace-maker**. It is necessary to be careful when using the equipment in the case of patients with implanted electric devices, especially heart pace-makers, because the equipment may cause the cardiac stimulator malfunctions. Patients with cardiac pacemakers should not undergo any examination with this equipment without authorization and under the severe control of a specialized physician.

- **The equipment works with non rechargeable AA Alkaline batteries.** Batteries must be replaced at the beginning of each recording. Batteries are not supplied by EBNeuro and are not part of the amplifier. Take care to connect each battery with the right polarity (see section 4.2).

1.3.2 SAFETY OF THE OPERATING ENVIRONMENT

- **The equipment is not designed to be used in locations with inflammable vapors or gases that may cause explosions**. The equipment must not be used in atmospheres with a high concentration of oxygen or in buildings where inflammable substances or anesthetic agents are present. The atmosphere is considered as oxygen-saturated when the oxygen or nitrous oxide (NO_2) concentration contained in the environment is over 24%.

- **The equipment and its internal parts are not protected against the inflow of liquids.** Avoid operating the equipment in a environment where there is a risk of water dripping, sprinkling or immersion. Do not use the system in a environment where liquid inflow is likely. Instruments that have been subject to liquid penetration must be immediately cleaned and checked by authorized qualified staff.

- **Use the equipment within the environmental limits of temperature, humidity and pressure specified**. The equipment is designed to work in environmental conditions that, in compliance with the IEC 601-1 directions, are defined as standard:

- temperature	+5°C / +40°C
- relative humidity	30% / 75% RH
- atmospheric pressure	700 / 1060 hPa

  It is important to remember that since the equipment is portable it can be used outside hospital. It is important not to use it when the above mentioned environmental conditions are not satisfied. In particular care in protecting the equipment from humidity when moving it from one place to another.

- **Be careful using the equipment when it is moved between locations with different temperatures to avoid any possible internal condensation**. If the equipment is stored or kept in a cold place and is rapidly moved to be used in a warmer building, condensation may occur (humidity or misting over the internal or external surface of the equipment). In this case it is necessary to wait for the condensation to be completely evaporated before powering up and using the equipment.

- **Make sure the electric wiring of the building is safe when connecting to other mains powered devices**. When the equipment is connected to peripherals or other mains powered devices, make sure that the latter are connected only to mains outlets with protective grounding. This protection is fundamental for the patient's and the user's safety: therefore, it is necessary that the electric wiring of the building guarantees efficient protective grounding.

- **Be careful using the equipment in locations disturbed by strong magnetic fields**. The equipment is compliant with the EMC requirements (ElectroMagnetic Compatibility) according to that specified by the 89/336/EEC European Directive. In every case it is recommended to keep the equipment away from significance sources and induced electromagnetic fields that surpass

the values prescribed by the standard in order to avoid any possible instabilities and malfunctioning of the equipment

- **Be careful when using the equipment near short-wave or micro-wave devices**. If the equipment is used in an area where there are also therapeutic short-wave or micro-wave devices, it is necessary to remember that these may cause instability and interfere with the correct performance of the equipment. Do not place the equipment near X-ray or diathermy devices.

1.3.3 PULSE-OXIMETER WARNING NOTES

A Pulse-Oximeter module is installed inside the *Sandman Pocket* recorder. This device is the NELL-1 pulse-oximetry module board manufactured by Nellcor Puritan Bennett (USA).

When utilizing the pulse oximeter module who is integrating the *Sandman Pocket* device in its own system (**System Builder**) must take carefully in count the following safety precautions and usage restriction notes:

- **Intended use of the option.** The *Sandman Pocket* device constitutes "simply" the acquiring front end of SpO_2 and pulse rate data. In particular notice that:
  - The *Sandman Pocket* device limits its role to allow the host system to control of the NELL-1 module and to read the calculated data values. And store this data on the recorder memory and/or pass it to the host computer.
  - The *Sandman Pocket* device does not rely in any way with the processing of the SpO_2 and pulse rate data. These eventual process are under the complete control and responsibility of the host system software.
  - The *Sandman Pocket* doesn't interpreter or evaluate data retrieved from NELL-1 oximeter. PTT is simply calculated as a "time interval" between two fiducial points.
  - The *Sandman Pocket* supports the NPB (Tyco) GK420E, GK425ST and GK425 CPAP models.
  - **The SANDMAN POCKET device is NOT involved in any alarm managing. The SANDMAN POCKET device is NOT provided with an SpO_2 alarm.**
  - **Pulse-Oximetry module of SANDMAN POCKET device is intended NOT for continuous monitoring.**
  - The System Builder is responsible of the use of the oximetry data. In particular the System builder may assure that this use will meet the requirements of the EN 865 and ISO 9919 standards (if applicable).
  - The System Builder application software is responsible of the use and display of the oximetry data. In particular the System builder may assure that this use will meet the requirements of the ISO 9919 standards (for applicable clauses).
- **Allowable sensors.** The *Sandman Pocket* device is provide without standard sensors. System Builder should integrate the device with Nellcor Puritan Bennett approved sensors only and specified for the usage with NELL-1 module.

Information regarding this point can be obtained directly by Nellcor Puritan Bennett or EBNeuro S.p.A. (reference to NELL-! Engineering Product Specification document).

In any case it is mandatory to use only sensors approved for commercial use by FDA (USA) and/or CE marked according to 93/42/EEC directive.

The System Builder is responsible for checking the compatibility of the pulse oximetry module, sensors and patient cable provided to the user when the final complete system is defined. Incompatible components can result in degraded performance and/or device malfunction with potentially injuries to tha patient.

The System Builder is responsible to provide tothe user information regarding allowable probes and cables to be used with NELL-1 oximeter module.

- **Accuracy of acquired data.** The accuracy of oximetry data depends on the sensor used with the device. System Builder should determine the accuracy according to the technical characteristics of the chosen sensor(s). Please make reference to the manufacturer's documentation of sensor.

  In operation, the accuracy of the oximetry data can be affected in general by the following external conditions:

  - High-frequency electrical noise, including electrosurgical equipments and defibrillators;
  - Possible interference with magnetic resonance imaging (MRI) procedures;
  - Excessive patient movement or ipose motion;
  - Intravascular dye injections;
  - Significant concentrations of dysfunctional hemoglobin, such as carboxyhemoglobin and methemoglobin;
  - Sensor temperature (maintain between 28°C and 42°C for best operation);
  - External illumination more than 5000 lumens/square meter (typical office lighting);
  - Improper sensor application;
  - Venous pulsation;
  - Placement of the sensor on an extremity that has a blood pressure cuff, arterial catheter or intravascular line;
  - Ambient light and photodynamic therapy;
  - Diagnostic testing;
  - Low perfusion;
  - Electromagnetic interferences,
  - Disfunctional heamoglobin
  - Presence of certain dyes
  - Inappropriate positioning of pulse oximeter probe

1.3.3.1 ISO 9919 compliance for NELL-1 pulse oximetry module

For information regarding the ISO 9919 compliance for NELL-1 pulse oximetry integrated module (Nellcor Puritan Bennet) refer to NELL-1 Engineering Product Specification document.
With reference to the ISO 9919 requirements, this document proprietary of Nellcor provides supplemental information regarding the following topics:

- Applicability
- Safety
- Range of Peack Wavelengths and Maximun Output Power (plethysmographic waveform output, fast response mode).
- Data Update Period, Effect of Data Averaging and other Signal Processing
- Test Consideration and Oximetry Accuracy (functional testers and patient simulators, accuracy and motion tollerance, accuracy with low perfusion, accuracy of SpO_2)
- Compliance

Please contact Nellcor Puritan Bennet directly for infomation regarding NELL-1 Technical characteristics and compliance.

1.3.3.2 System Builder responsibility and ISO 9919

The information included in this manual is supplied to assist System Builder in succesfully integration of EBNeuro Sandman Pocket Polysomnograph Recorder base system in a complete final system in accordance with ISO 9919 standard.

It is recommended that System Builders inplementing Sandman Pocket recorder (provided with integrated NELL-1 pulse oximetry module inside) in their final complete system obtain a copy of ISO 9919 standard and carefully review this standard for applicability to their intended final device/system.
Because many clauses of ISO 9919 are system-related, these will have to be addressed at final system level (acquisition/recording equipment, oximetry module, sensors, patient cable, clinical software application and other peripherals), and cannot be addressed solely by the NELL-11 oximetry module manufacturer or solely by the Sandman Pocket Polsomnograph Recorder base system.

It is the responsibility of the System Buider to test the final complete system (acquisition/recording equipment, oximetry module, sensors, patient cable, clinical software application and other peripherals) in accordance with the following clauses, and other system-related clauses which may apply to the finish complete system.
These clauses include, but are not limited to:
Clauses: 6.1, 6.1, 6.8.1, 6.8.2, 21.5, 21.101, 21.102, 36, 44.6, 49.101, 49.102, 50.101, 50.102, 50.103, 50.104, 51.102, 54, 101, 102.1, 102.2, 103 and 201.1.2

1.4 GRAPHIC SYMBOLS IN COMPLIANCE WITH THE IEC 60601-1 STANDARDS

The following table shows description and localization of all graphic symbols in compliance with the IEC 60601-1 safety standards present on the equipment panels and on any other instruments or external devices to which the equipment may be connected.

IEC 601-1 SYMBOL	DESCRIPTION	POSITION
	**Alternating current**	Symbol placed on the connection points between the equipment and the mains (alternating current source).
	**Direct current**	Symbol placed on the connection points to direct current source.
	**Equipotential terminal**	Symbol placed on the outlet connecting the equipment to the equipotential node of the building, if any.
	**Protective earth (ground)**	Symbol placed on the connection points between the equipment and the protective grounding.
	**High voltage**	Symbol placed on circuits or equipment parts with high voltage.
	**Attention! Refer to the attached instructions.**	Symbol placed on items for which it is important to read the Operator Manual for relevant information (see ATTENTION paragraph).
	**Device with CF-type applied parts**	Symbol placed on applied parts to the patient with a CF-protection level.
	**Device with BF-type applied parts**	Symbol placed on applied parts to the patient with a BF-protection level.
	**Device with B-type applied parts**	Symbol placed on applied parts to the patient with a B-protection level.

IEC 601-1 SYMBOL	DESCRIPTION	POSITION
	**Off (disconnected from the mains)**	Symbol placed on the off/on positions of the whole equipment general power switch.
	On (connected to the mains)	Symbol placed on the off/on positions of the whole equipment general power switch.
	**Off (for a single part of equipment)**	Symbol placed on the off/on switch of a single part of the equipment.
	**On (for a single part of the equipment)**	Symbol placed on the off/on switch of a single part of the equipment.

1.5 OTHER GRAPHIC SYMBOLS

The following table shows description and localization of all symbols placed on the equipment panels and on any other instruments or external devices to which the equipment may be connected.

SYMBOL	DESCRIPTION	POSITION
	**Input**	Symbol placed on the signal input or mains voltage input connectors of the equipment.
	**Output**	Symbol placed on the signal output or the mains voltage output connectors of the equipment.
+	**Positive**	Symbol placed on the battery insertion points. The symbol indicates the position of the battery positive pole.
—	**Negative**	Symbol placed on the battery insertion point. The symbol indicates the position of the battery negative pole.
LOT	**Lot number**	Symbol placed on the identification label of the medical device together with the device lot number.
REF	**Reference number**	Symbol placed on the identification label of the medical device together with the device reference number.
	Serial number	Symbol placed on the identification label of the medical device together with the device serial number.
	**Date of manufacture**	Symbol placed on the identification label of the medical device together with the device manufacture date.
	**Crossed-out wheeled bin**	Symbol placed on the identification label of the medical device. This symbol indicates the prohibition of throw the medical device in the household wheeled bin device when at its "end of life".
	**Use by**	Symbol placed on the identification label of the medical device together with the device expiration date.
	**Do not reuse**	Symbol placed on the identification label of the medical device. This symbol indicates that the device is a disposable one and cannot be used more than once.
	**Alarm Inhibit "No SpO_2 Alarm"**	Symbol placed on the Oximeter imput connector of the device. This symbol indicates that this device is not provided with an SpO_2 alarm.

SYMBOL	DESCRIPTION	POSITION
STERILE	**Sterile**	Symbol placed on the identification label of the medical device indicating a sterile device.
STERILE	**Sterilization with steam or dry heat**	Symbol placed on the identification label of the medical device indicating a sterile device and the sterilization method used (steam or dry heat).
STERILE EO	**Sterilization with ethylene oxide**	Symbol placed on the identification label of the medical device indicating a sterile device and the sterilization method used (ethylene oxide).
STERILE R	**Sterilization by irradiation**	Symbol placed on the identification label of the medical device indicating a sterile device and the sterilization method used (irradiation).

1.6 ATTENTION SYMBOL

The **ATTENTION** symbol shown below, placed on the equipment casing, refers the user to the Operator Manual for information, warnings and suggestions which are particularly important for a correct and safe use of the equipment.

In particular, when it is placed on points connecting cables to peripherals, this symbol refers the user to carefully read the Operator Manual for instructions concerning the nature of such cables and peripherals and the modalities for a correct and safe connection.

For location of the ATTENTION symbols placed on the equipment, please refer to chapter "*Installation and connections*" of this Operator Manual. That chapter shows the pictures of the equipment panels with the corresponding commands, connections, symbols, and labels. Each attention symbol comes with a detailed explanation of its meaning.

1.7 CROSSED-OUT WHEELED BIN

The symbol shown below placed on the product or on its packaging indicates that this product must not be disposed of with your other household waste at its "End of Life". Instead, it is your responsibility to dispose of your waste equipment by handing it over to a designated collection point for the recycling of waste electrical and electronic equipment.

The separate collection and recycling of your waste equipment at the time of disposal will help to conserve natural resources and ensure that it is recycled in a manner that protects human health and the environment.
For more information about where you can drop off at its "End of Life" your waste equipment for recycling, please contact your local city office, your household waste disposal service or the shop where you purchased the product or contact the manufacturer of device at www.ebneuro.com or at support@ebneuro.com or contact the EBNeuro main office (par 11.2 of the manual).

Safety, performances and effectiveness of device and availability of its spare parts are guaranteed by the manufacturer until device "End of Life".
EBNeuro, as manufacturer, define the "*End of Life*" time for *Sandman Pocket* modules in 7 (seven) years starting from the production date (see identification label).

1.8 PRODUCT TRACEABILITY

In order to guarantee the traceability of the product, according to what stated in the ISO 13485 quality standards and the 93/42/EEC European Directive on Medical Devices, EBNeuro kindly requests the original owner of the equipment provides information regarding the transfer of the system to a third party, by sending a photocopy of the completely filled-in Product traceability form (see enclosure 1.7), or by communicating in writing the data indicated in the form.
The data concerning the device can be found on its identification label.

The form can be sent either directly or through any subsidiary or the nearest authorized distributor to the Quality Assurance Department of any EBNeuro operating office. The list of the main EBNeuro head and branch offices in Italy and overseas is contained in chapter "*Request for assistance*" of this manual.

1.9 VIGILANCE SYSTEM

The device is subject to a vigilance system (post-marketing vigilance) that EBNeuro and its distributors and retailers apply to the products that are put on the market to safeguard the patient and the physician from serious or potentially serious hazards during the normal use of the equipment, in order to be able to remove the source of such hazards with the best efficiency and timing.

To the purpose of helping EBNeuro take any timely and effective corrective measure, it is extremely important that the user performs a careful inspection of the equipment performance in order to identify or foresee any dangerous situation for the patient's and the user's health.

For this reason, the user shall give immediate communication of any malfunction or deterioration of the characteristics or the performances of the equipment or any mistake found in these instructions that caused or could cause serious damages to the patient's and the user's health.
In this case, the user may send a photocopy of the proper duly filled-in *Post-Marketing Vigilance Form* (see enclosure 1.8), or communicate in writing the data indicated in the form.

The instrument's data can be collected from it's identification label.

The form shall be sent either directly or through any subsidiary or the nearest authorized distributor to the Quality Assurance Department of any EBNeuro operating office. The list of the main EBNeuro head and branch offices in Italy and abroad is contained in chapter "*Request for assistance*" of this manual.

Enclosure 1-7

PRODUCT TRACEABILITY FORM

To: EBNeuro S.p.A.
Quality Assurance Department
Via Pietro Fanfani, 111/A
50127 Florence

System/device name.....

Device code / reference number (REF) .....

Device serial (SN) / lot number (LOT) .....

Name and address of the former owner .....
.....
.....
.....

Name and address of the present owner .....
.....
.....
.....

Date:.....

Signature

.....

(please name in full)

(ref. Operator Manual code B830 0065 411 Rev. A)

enclosure 1-8

POST-MARKETING VIGILANCE FORM

To: EBNeuro S.p.A.
Quality Assurance Department
Via Pietro Fanfani, 111/A
50127 Florence

System/device name.....

Device code/reference number (REF) .....

Device serial (SN)/lot number(LOT) .....

Description of the real or potential hazard.....
.....
.....
.....
.....

User's comments/suggestions .....
.....
.....
.....
.....

User's address.....
Phone..... Fax .....

Department where the device is installed.....
Person in charge of the department.....

Data:.....

Signature

.....

(please name in full)

(ref. Operator Manual code B830 0065 411 Rev. A)

1.10 INFORMATION ABOUT RECYCLING OF MATERIALS

In accordance with the specific European directives, EBNeuro aims to continuously improve the design and the manufacture of electromedical devices in order to reduce as much as possible any negative impact on the environment caused by the management of component parts, consumer materials, packaging and the disposal of devices when at their "end of life".

Packaging materials were designed and produced so as to allow the easy reuse and the salvage, including recycling, of most parts of the material and to reduce the quantity of garbage or residual products for discharge as much as possible. In particular, packaging materials have been produced so as to limit the presence of harmful metals and of other dangerous substances to minimum quantities in emissions, ashes or lixiviation residual products. The total concentration levels of heavy metals such as Lead, Cadmium, Mercury and hexavalent Chrome contained in the packaging materials are in accordance with the limits established by the directives in force related to this subject.

In order to cause minimum consequences to the environment, the design of the device includes the highest possible miniaturization of the circuits, with the least possible differentiation of materials and components, with a selection of substances that guarantee the highest possibility to recycle and re-use the components and to dispose of them without risks for the environment.

The device is designed to guarantee the easy separation or disassembling of the materials containing polluting substances from the others, in particular during the operations of servicing and replacing parts. In particular, the largest plastic components are marked according to their plastic contents in order to make it easier to recycle the product.

ATTENTION

Please refer to local codes and laws for proper disposal/recycle requirements of packaging and consumer materials and of the device when at its "end of life".

1.11 ELECTROMAGNETIC COMPATIBILITY

The device is designed for use in the electromagnetic environments declared in the tables below, in compliance with the IEC 60601-1-2:2001 (second edition) standard. The operator must assure that the device is used in an environment compliant to this standard.

Table 1 - Electromagnetic Emissions

Emission Test	Compliance	Electromagnetic Environment
Radiated and conducted RF emission CISPR 11	Class B	The device is suitable for use in domestic establishment and in all establishments directly connected to the low voltage power supply network (electrical mains) which supplies buildings used for domestic purpose.
	Group 1	The device use RF energy only for its internal function and to operate. Therefore, the RF emission is very low and not likely to cause any interference in nereby electronic equipment.
Harmonic emission IEC 61000-3-2	Complies	The device is suitable for use in establishments directly connected to a public low voltage power supply network (electrical mains)
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	The device is suitable for use in establishments directly connected to a public low voltage power supply network (electrical mains)

Table 2 - Electromagnetic Immunity

Immunity Test	IEC 60601-1-2 Test Level	Compliance	Electromagnetic environment
Electrostatic Discharge (ESD) IEC 61000-4-2	6 kV in contact 8 kV on air	IEC 60601-1-2 Test Levels	Residential **(Note 1)**
Electrical fast transient/burst IEC 61000-4-4	2 kV for power supply line 1 kV for input/output lines >3m	IEC 60601-1-2 Test Levels	Residential **(Note 2)** **(Note 3)**
Surge IEC 61000-4-5	1 kv differential mode 2 kV common mode	IEC 60601-1-2 Test Levels	Residential **(Note 2)** **(Note 3)**

Voltage dips, short interruptions and voltage variation on power supply input lines IEC 61000-4-11	0 % of rated voltage (voltage dip 100 %) for 0.5 cycles 40 % of rated voltage (voltage dip 60 %) for 5 cycles 70 % of rated voltage (voltage dip 30 %) for 25 cycles 0 % of rated voltage (voltage dip 100 %) for 5 cycles		
Magnetic fields at mains frequency (50/60 Hz) IEC 61000-4-8	3 A/m		
Radiated RF fields IEC 61000-4-3	Non-life-supporting equipment 3 V/m form 80 MHz to 2.5 GHz	IEC 60601-1-2 Test Levels	Residential **(Note 4)**
Radiated RF fields IEC 61000-4-6	Non-life-supporting equipment 3 V form 150 kHz to 80 MHz		

Measures to be taken

Note 1: The foor should be in antistatic material (wood, ceramic, ect.). If covered by syntetic material, relative humidity should be maintained at least at 30%

Note 2: The qualily of the electrical power supply and the mains frequency magnetic fields should be typical of domestic, commercial and hospital environments.

Note 3: If the operator has to work without a break while power supply is interrupted, it is necessary to have power supplied through a UPS (Uninterruptible Power Supply) unit.

Note 4: Mobile or portable radio frequency (RF) communication appliance should be used at longer distances than those indicated on the following Table 3.
Electromagnetic transient can happens near appliances bearing the symbol shown below

1.11.1 Recommended distances from Radiofrequency (RF) communication systems

As stated in this chapter 1 "Information about safety" of this operator manual, it is recommended to not use Radiofrequency (RF) transmission system near the *Sandman Pocket* amplifier system. RF systems can cause interference which may cause instability and interfere with the correct working of the equipment and it may alters the EEG signal acquired tracings.

The operator can prevent interference caused by electromagnetic field by maintaining a minimum distance between thye *Sandman Pocket* amplifier system and the RF communication system being used (cell phones, mobile phones, etc,). The following table shows the minimum distances in meters, according to the maximum power at RF system output.

Table 3 – Recommended separation distances from RF sources

RF Source	Typical Rated Power (W)	Distance (m)
Microcellular phone CT1, CT2, CT3	0.01	0.3
DECT cellular phone, Wireless Information Technology equipments (modems, LANs)	0.25	2
Cellulat phone, hand-held (USA)	0.6	2
Cellulat phone, hand-held (e.g. GSM and NMT, Europe DECS 1800)	2 8	4 7
Walkie-talkie (rescue, police, fire, maintenance)	5	3
Cellular phone, bag	16	10
Mobile radio (rescue, police, fire)	100	30

For transmitters the maximum output power of which is not within the values range in the table, the recommended minimum distance can be estimated by analyzing the equation in the table applicable to the transmitter frequency:

For transmitters using frequencies range from **150 kHz to 80 MHz** and from **80 MHz to 800 MHz**, the distance can be estimated using the equation:

$$d = 1.2\sqrt{P}$$

For transmitters using frequencies range from **800 MHz to 2.5 GHz**, the distance can be estimated using the equation:

$$d = 2.3\sqrt{P}$$

where P is the rated power of the transmitter in Watt (W) according to the transmitter manufacturer specifications.

Note: As a precaution, always apply the greater distance supplied by the table.

Note: Electromagnetic fields are subjected to absorption and reflection in the presence of structures, objects and people. The values in the table are general guidelines.

The operator must remember that the intensity of the electromagnetic fields generated by fixed transmitters (radio-base stations for cellular or cordless phone, TV and radio transmissions, amateur radio transmission, etc.) cannot be predicated on theoretical basis.
Consequently, a direct measure may be necessary in the used environment of *Sandman Pocket* system.

If the intensity of the electromagnetic fields exceeds that specified in the immunity levels shown in the previous tables, and the bioelectric signal Amplifier system behaves incorrectly working, additional measures may be necessary. I.e. orienting or locating the *Sandman Pocket* system in a different way.

1.12 BIOCOMPATIBILITY AND INFECTIONS CONTROL

No system components is intended to be in contact with the patient.
Electrodes and sensors are not intended to be parts of the "*Sandman Pocket*" system.
All the body contacting material are no part of the system, in any case remember that electrodes and sensors MUST meet the requirements of FDA (USA) or 93/42/EEC Medical Devices Directive (CE marked).

ATTENTION

The residual products of every exam (disposable electrodes, gel or paste residues, etc.) must be considered as potentially infected and therefore treated as special waste. Please refer to local codes fro proper disposal of such materials.

1.13 DECLARATION OF CONFORMITY

CE 0051

The equipment has been manufactured by applying the quality guarantee system approved for design, manufacturing and final check of the product and meets the requirements of **Annex II** of the **93/42/EEC** Directive on Medical Devices (**MDD**). For these reasons the equipment is marked with the **CE** mark.
The approval is issued by IMQ S.p.A. (Milan – Italy) as Notified Body notified by European Commission. IMQ Notified Body identifier number is **0051**.

C SP US

The equipment is marked with the **cCSAus** quality mark. This safety mark is valid both Canadian and U.S. market.

1.14 CAUTION FOR THE U.S. MARKET

Federal law restricts this device to sale by or on the order of a physician.

For your notes:

CHAPTER 2
DESCRIPTION OF THE DEVICE

2.1 DESCRIPTION OF THE SYSTEM

The *Sandman Pocket* is part of a Polysomnography system. It consists of two unit: the **Recorder Unit**, which store the data and sent to an USB port, and **Headbox Unit**, connection point for all patient sensors with the exception of the oximetry probe.

Intended use:

The Sandman Pocket is to be used for collecting and recording physiological data to be used in polisomnography and sleep disorder studies. A pediatric through adult patient population is intended for the Sandman Pocket, which can be used in either home or hospital environments.

The *Sandman Pocket* role is only that to capture the data and to pass them to the host with the necessary accuracy and reliability following the specification of the product and those of the communication control.

A *Sandman Pocket* fundamental characteristic is the to be an ambulatory/portable equipment: small size and light weight (about 210 gr included battery), compact and solid.

The **Headbox Unit** is used for insertion of patient electrodes and sensors and it include Bipolar channels, pressure sensors, and supply power for a dedicated body position sensor, an abdomen sensor, an chest sensor, an snore sensor and a thermistor.

The patient inputs are isolated with a CF type isolation level.

The **Headbox Unit** capture the biological signals from the human body surface through specialized sensors and electrodes, while the **Recorder Unit** amplify the very low electrical signal, filter it to accomplishes an antialiasing in order to make an optimal ANALOG to DIGITAL conversion. The data, once converted in numerical form, are "passed" to an host computer that at this point is free to elaborate the data following the logic of the application software running on the host. Of course the host can "program" the amplifier behavior setting the sampling frequency, the dynamic range allowed and so on.

The host computer read the acquired data through a dedicated interchange protocol, and then elaborate the data with its own internal logic. The requirement posed by the *Sandman Pocket* device to the host PC when the recorder is connected to PC and, at the same time the patient too is connected the the Sandman Pocket Headbox, is to be:

- a computer compliant to IEC 60601-1 medical safety standards directly powered by the mains.
- a computer conforming to IEC 60950 standard powered through an Isolation Transformer module IEC 60601-1 medical standard compliant.
- a batteries powered laptop conforming to IEC 60950 standard

The *Sandman Pocket* system will not be in any way involved in the data management performed by the host.
The host computer must operate under one of the following Operating System: Microsoft Windows 98 / ME / NT / 2K / XP.

The device have a built-in impedance meter. This function allows to check the electrode contact impedance and display the result of the check on the display. The display is located in the Recorder Unit while the circuitry controlling the impedance meter is located in the Headbox Unit.

The *Sandman Pocket* can be powered through 3 Alkaline 1.5V standard non rechargeable batteries or via the USB cable. In this case take care to use a PC powered through a IEC 60601-1 isolation transformer or a battery powered PC.

The *Sandman Pocket* "system" consists of 2 interconnected units: the Headbox Unit and the Recorder Unit.

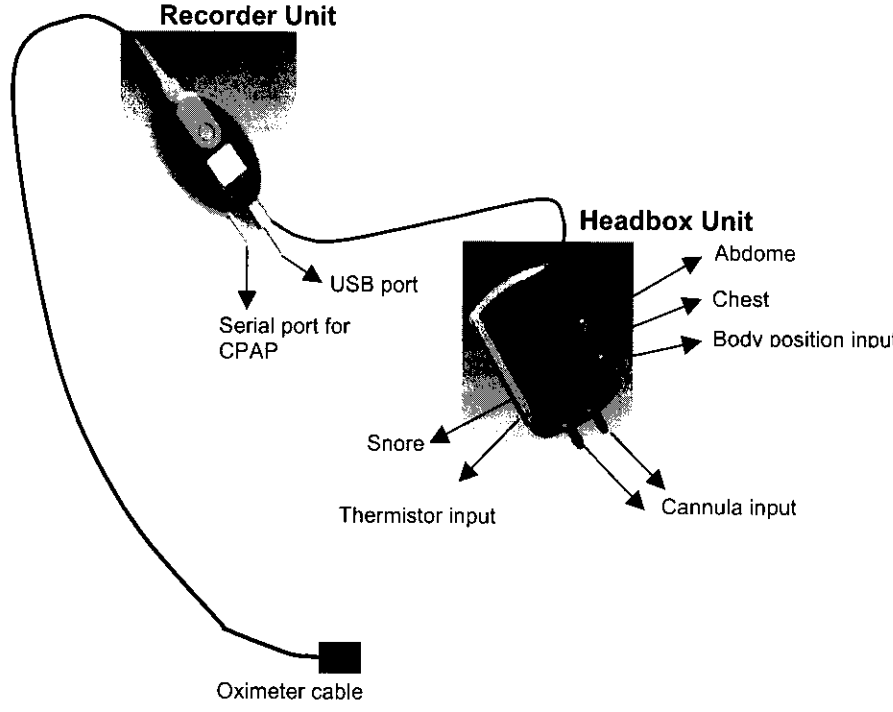


Figure 2-1 SANDMAN POCKET system connection diagram

The **Headbox Unit** has the following functions:

- Physically connects the source of signals (the patient) to the amplifier.
- Provide impedance testing capabilities
- Provide Analog to Digital (A/D) conversion

The **Recorder Unit** has the following functions:

- Amplify and isolate signals coming from the electrodes
- Reference input channels
- Generate calibration pulse
- Provide dynamic range (gain), sampling rate and active channels selection
- Provide the opportune antialiasing filtering to perform optimal Analog to Digital conversion
- Send the digital data trough the USB interface
- Provide the Oximeter option
- Provide to the display management
- Manage the Time
- Manage the batteries power supply

:

2.2 SANDMAN POCKET HEADBOX DESCRIPTION

The following figures show the SANDMAN POCKET **Headbox Unit** in which the main parts are indicated:

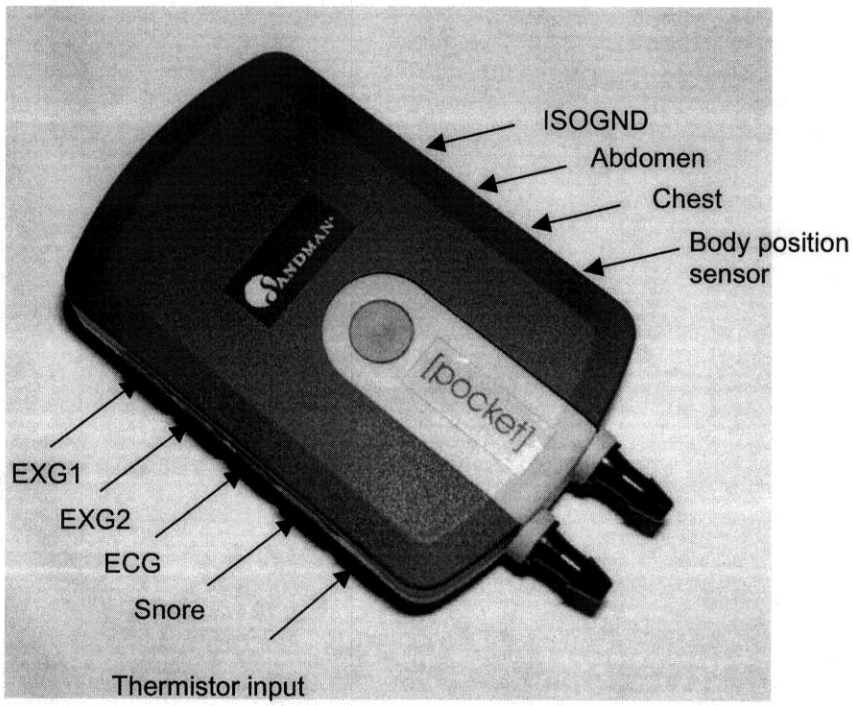


Figure 2-3 SANDMAN POCKET Headbox Unit

2.2.1 PATIENT INPUT SOCKETS DESCRIPTION

The following figure shows the 9 patient input sockets configuration in which the different type of input are indicated:

N° 1 EKG bipolar inputs with AC coupling

N° 5 dedicated bipolar input for Snore, Chest, Abdomen, Thermistor, Body Position

N° 2 EXG bipolar inputs (AC or DC coupling, settable via software).

N° 1 sockets for isolated patient ground

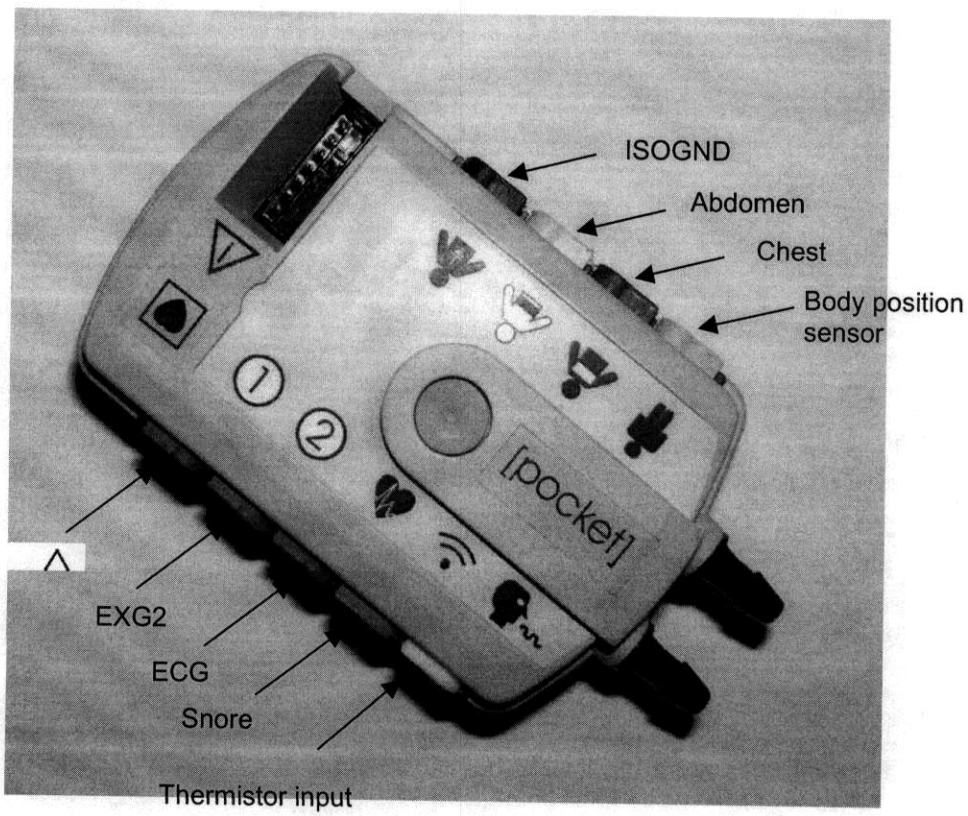


Figure 2-4 SANDMAN POCKET patient input sockets.

In details:

Bipolar Inputs.

① **EXG1** **1 connector (blu).** This connector is used to connect **EEG, EKG** electrodes.

② **EXG2** **1 connector (blu).** This connector is used to connect **EEG, EKG** electrodes.

♥ **EKG** **1 connector (red).** This connector is used to connect a dedicated **EKG** electrode.

ATTENTION

All the patient applied parts and corresponding input sockets of SANDMAN POCKET acquisition module (patient inputs) are electrically isolated from the mains according to IEC 60601-1 standard requirements for Type CF equipments. This characteristic is indicated to the operator with the proper symbol placed on the external cover of the device in correspondence of the input sockets (see description of par. 1.4 of the manual).

ATTENTION

All the n° 9 input sockets of SANDMAN POCKET acquisition module accept Female 2 pole 1mm standard touchproof safety connectors.

ATTENTION

The SANDMAN POCKET amplifier system is provided without accessories, electrodes and sensor probes for signals acquisition from patient body. Sensors, electrodes and external peripheral are not part of the Sandman Pocket system.
It is necessary integrate the device with sensors and electrodes CE marked according to 93/42/EEC European directive (MDD) on Medical Devices. For the usage on US market it is mandatory to use only sensor approved for commercial use by FDA (USA). All the sensors and other external peripheral device used with Sandman Pocket device must be preventively validated and specified under the responsibility of the System Builder.

Dedicated Bipolar Inputs.

BODY POSITION connector (light gray). This connector is used to connect a dedicated body position sensor.

ATTENTION

This channel has been designed to work with the PRO-TECH body position sensor model SPI or electrically/functionally equivalent.
The SANDMAN POCKET guarantees only the respect of the technical specification regarding this input (range, conversion factor), regulatory aspects of the physical transducer (for example FDA clearance, CE marking) falls under the responsibility of the system builder's who utilizes the SANDMAN POCKET Amplifier to build a complete system.

THERMISTOR connector (orange). This connector is used to connect a dedicated airflow thermistor sensor.

ATTENTION

This channel has been designed to work with an Edentec Breathsensor model 971 or electrically/functionally equivalent.
The SANDMAN POCKET guarantees only the respect of the technical specification regarding this input (range, conversion factor), regulatory aspects of the physical transducer (for example FDA clearance, CE marking) falls under the system integrator who utilizes the SANDMAN POCKET Amplifier to build a complete system.
The headbox contains the necessary circuitry to feed the thermistor so no additional components are required to use the sensor. Typical output of the thermocouple is 400 uVp-p. The maximum output of the thermistor is 1mVp-p with a temperature excursion of 20 °C. The NPB Breath sensor is connect via a standard connect. The inputs must be AC-coupled, self-referenced, differential amplifiers.

ATTENTION

The Thermistor must be a disposable component.

SNORE connector (white). This connector is used to connect a dedicated Snore sensor.

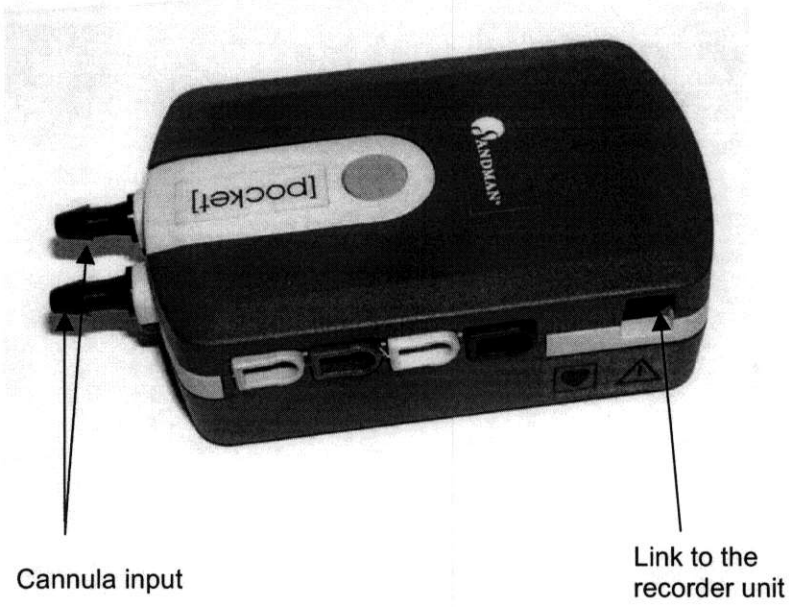
CHEST connector (dark gray). This connector is used to connect a dedicated Chest sensor.

ABDOMEN connector (light gray). This connector is used to connect a dedicated Abdomen sensor.

ISOGND connector (back). This connector is used to connect a dedicated isolated patient ground electrode.

2.2.2 CONNECTORS DESCRIPTION

The following figures show in details the connectors of SANDMAN POCKET acquisition module:



Figures 2-4 and 2-5 – Acquisition module connectors

- **CANNULA INPUT** This input is used to connect a pressure sensor capable of measuring Nasal Cannula pressure.

ATTENTION

The SANDMAN POCKET has incorporated a pressure transducer HONEYWELL mod 26PC01SMT.
Scope of this input is to be connected to an external device (like for example a Nasal Cannula) which provides a "pressure" to the SANDMAN POCKET; by means of the transducer the SANDMAN POCKET amplifier "converts" the pressure value in a voltage and pass this information to the host computer.
This information is intended to be used as reference only (for example to allow the host computer to create a trends of the pressure value), it is intended not useful to "control" any external device whose behavior should be critical for the patient.

ATTENTION

The Cannula must be a disposable component.

- **SANDMAN HEADBOX CABLE** connector. This connector is used to connect the Headbox Unit with the Recorder Unit.

2.2.3 EVENT MARKER BUTTON

The following figure shows the event marker button placed on the front cover of the SANDMAN POCKET acquisition module.

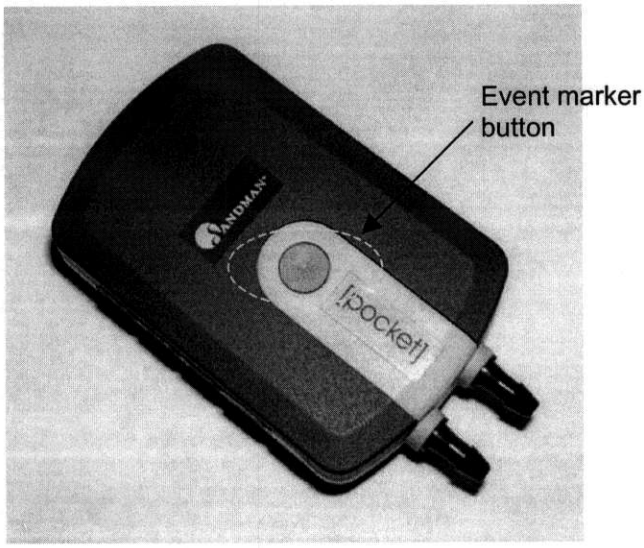


Figure 2-7 – Event marker button

The event marker button allows the user to register on the device the time of an particular event occurred.

2.3 SANDMAN POCKET RECORDER UNIT DESCRIPTION

The following figure shows the SANDMAN POCKET amplifier box in which the main parts are indicated:

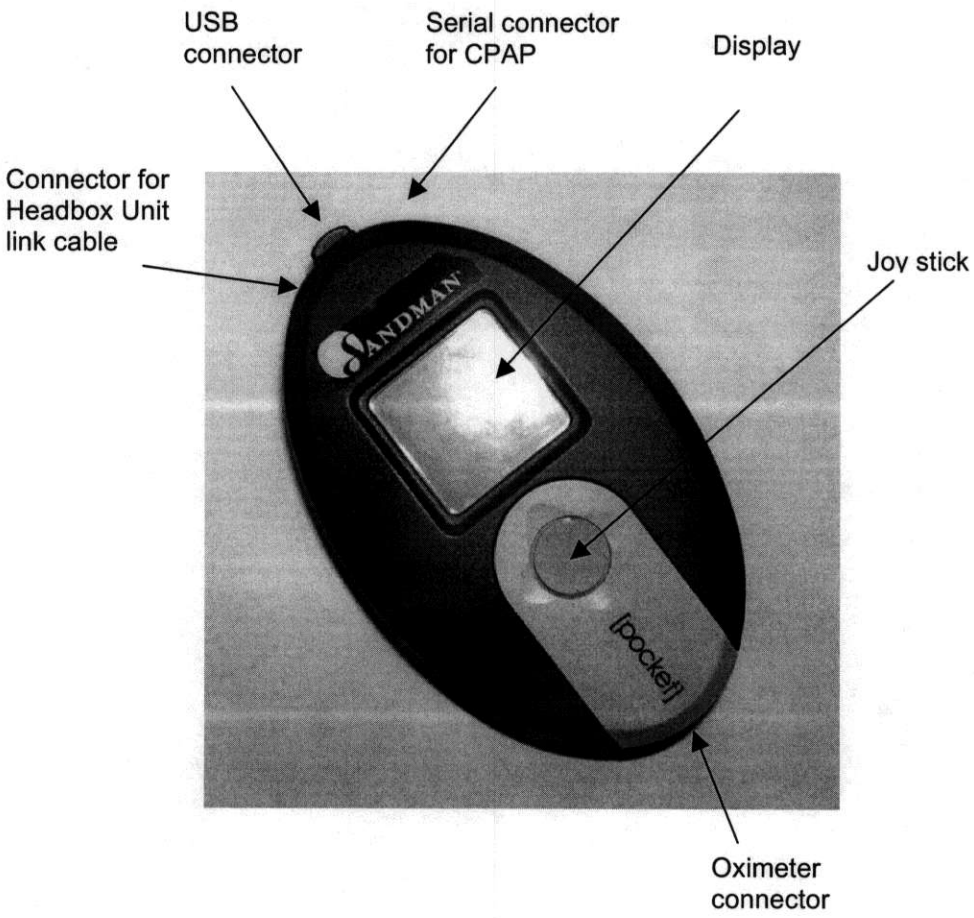
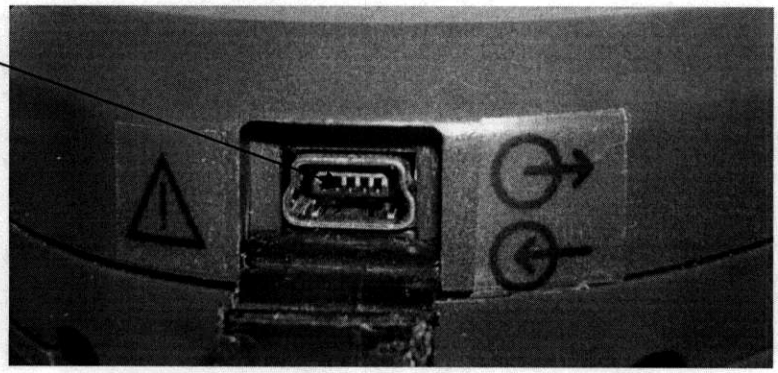


Figure 2-8 – SANDMAN POCKET amplifier box

2.3.1 CONNECTORS DESCRIPTION

The following figures show in details the connectors of SANDMAN POCKET amplifier module:



Figures 2-9, 2-10 and 2-11 – Amplifier module connectors

Where:

1. **SERIAL CONNECTOR** (RS232 connector). This connector is used to connect the SANDMAN POCKET to the CPAP.

2. **USB** connector (USB 2.0 miniB). This connector is used to connect the SANDMAN POCKET to PC.

3. **SANDMAN HEADBOX CABLE** connector. This connector is used to connect the Recorder Unit with the Headbox Unit.

4. **OXIMETER LINK** connector (shroud). This connector is used to connect axclusively an oxymetry sensor (Nellcor Puritan Bennett model DS-100 A).

ATTENTION

The amplifier uses a Nellcor Puritan Bennet (NPB) NELL-1 Pulse Oximetry module inside. Use only with Nellcor Puritan Bennet (NPB) DS-100 A or MAX-A sensors or equivalent, which are validated for use with NELL-1 module.

ATTENTION

Use serial connector to connect Sandman Pocket Recorder to NPB (Tyco) model GoodKnight 420/425 series CPAP device only or equivalent. In particular Sandman Pocket supports the NPB (Tyco) GK420E, GK425 and GK 425ST CPAP models.

ATTENTION

Use USB connector to connect sandman Pocket Recorder to a USB port of a host only.
Host PC must to comply to IEC 60950 safety standard and it must be powered through an IEC 60601-1 safety standard compliant isolation transformer module.

ATTENTION

The OXIMETER LINK connector is protected from a proper protection plug. Remove this plug in the case of connection with oximetry sensor (NPB DS-100 A). When is remove the sensor connection the connector must be protected with the proper plug.

ATTENTION

The USB connector is protected from a proper protection plug. Remove this plug in the case of connection with the Host PC. When is remove the Host PC connection the connector must be protected with the proper plug.

2.4 PULSE OXIMETRY MODULE

The SANDMAN POCKET recorder unit contains the Nellcor pulse oximetry module, model NELL-1. The NELL-1's major features are to interface with sensors and provide to an Host system patient data as

- Oxygen saturation (SpO2)
- Pulse rate
- Pulse waveform and pulse amplitude modulation (Blip)
- Motion indicator
- Sensor disconnect indicator
- Sensor off patient indicator

The NELL-1 is capable of communicating with the Host via a serial communication link.

2.4.1 INTENDED USE OF THE PULSE OXIMETRY MODULE.

The SANDMAN POCKET device constitutes "simply" the acquiring front end of SpO_2 and pulse rate data. In particular notice that:

- The SANDMAN POCKET device limits its role to allow the host system to control of the NELL-1 module and to read the calculated data values.

- The SANDMAN POCKET device does not rely in any way with the processing of the SpO_2 and pulse rate data. These process are under the complete control and responsibility of the host system software.

- **The SANDMAN POCKET device is NOT involved in any alarm managing. The SANDMAN POCKET device is NOT provided with an SpO_2 alarm.**

- **Pulse-Oximetry module of SANDMAN POCKET device is intended NOT for continuous monitoring.**

- The System Builder is responsible of the use of the oximetry data. In particular the System builder may assure that this use will meet the requirements of the EN 865 and ISO 9919 standards (if applicable).

ATTENTION

Refer to section 1.3 of this manual for further warning notes on the Pulse Oximetry Module usage

For your notes:

CHAPTER 3
CALIBRATION

This chapter describes the calibration procedures for the system amplifier chains only.

SANDMAN POCKET amplifier system provides two different kinds of "calibration".

3.1 "PHYSICAL" SYSTEM CALIBRATION

This is the "real" standard calibration procedure. A physical signal (its amplitude and frequency are known) is injected into the input of each channel. The results of the entire processing (analog and digital) are measured and evaluated in order to verify that the signal processing chain is correctly working.
This kind of calibration allows to "adjust" the possible small gain values differences among the channels.
Physical calibration is a task under the control of authorizated people (service people).

From this acquired data the corrective factors (calibration constants) are calculated in order to uniform the gain of each channel.
The calibration constants are stored in a flash memory on the POCKET amplifier box and then transmitted to the PC. The calibration constants are applied during each acquisition and they will be valid until the next physical calibration is made.

3.2 "RECORDING" SYSTEM CALIBRATION

This kind of calibration is normally performed at the beginning and/or at the end of each recording.
The calibration activation is under the operator's management and responsibility.
Under the HOST PC control, the amplifier system generates the calibration signal (square wave 1Hz frequency – 50μV amplitude).
This signal is sent to the PC and it allows to check the signal transferring chain, the communication protocol with HOST PC and digital processing chain (digital filters, digital gain, etc.).

For your notes:

CHAPTER 4
HOST COMPUTER - BATTERY

4.1 REQUIREMENTS FOR HOST COMPUTER

Application software on the host computer is under the responsibility of the "System Builder" so it has the responsibility to evaluate and validate the specific host, its Operative System, its minimum hardware/software and its safety requirements relating to the intended use / technical specification of the whole system.

When used to download the recorded data, the host computer must only provide a standard USB 2.0 compliant interface to be connected to the Sandman Pocket Recorder.

When the host computer is connected to the Sandman Pocket recorder during set up or data acquisition monitoring (so with that patient attached to the headbox unit of the recorder) the computer should be :

- a computer fully compliant to IEC 60601-1 medical safety standards directly powered by the mains.
- a computer conforming to IEC 60950 standard powered through an Isolation Transformer module IEC 60601-1 medical standard compliant.
- a batteries powered laptop conforming to IEC 60950 standard

4.2 GENERAL PRECAUTIONS USING BATTERY

When Sandman Pocket recorder is working in "Holter" modality the only power source are the internal batteries. The batteries are housed in the specific space provided in the bottom part of the recorder unit of the Sandman Pocket. The batteries must always present in the instrument during usage.

During the installation procedure of the batteries, it is best you observe the following warnings:

- Before replacing the batteries make sure the device is not connected to the host PC.
- Remove the batteries when the recording has ended or when the device is not in use.
- Use completely full-charged batteries for each new recording.
- The use of batteries, which do not comply with the given ratings, will not guarantee a correct functioning and especially the recording endurance characteristics of the instrument.
- The alkaline batteries are not rechargeable and they must be disposed of by following the regulations of the specific Country.

ATTENTION

The Holter modality require the internal battery kit. Use new batteries at each new recording session.

ATTENTION

The Sandman Pocket Recorder must be equipped with the following battery cells: n°3 alkaline dry cell AA Size - V =1.5 Vn.

4.3 BATTERY REPLACEMENT

The condition of low charge batteries is shown on the display of the device by a dedicated message. With reference to the following figure, replace the internal main batteries by following the suggested procedure.

The batteries must necessarily be substituted with batteries having the same characteristics. The use of batteries that differ from those specified does not guarantee a correct functioning of the instrument with special regards to the recording range of the instrument.

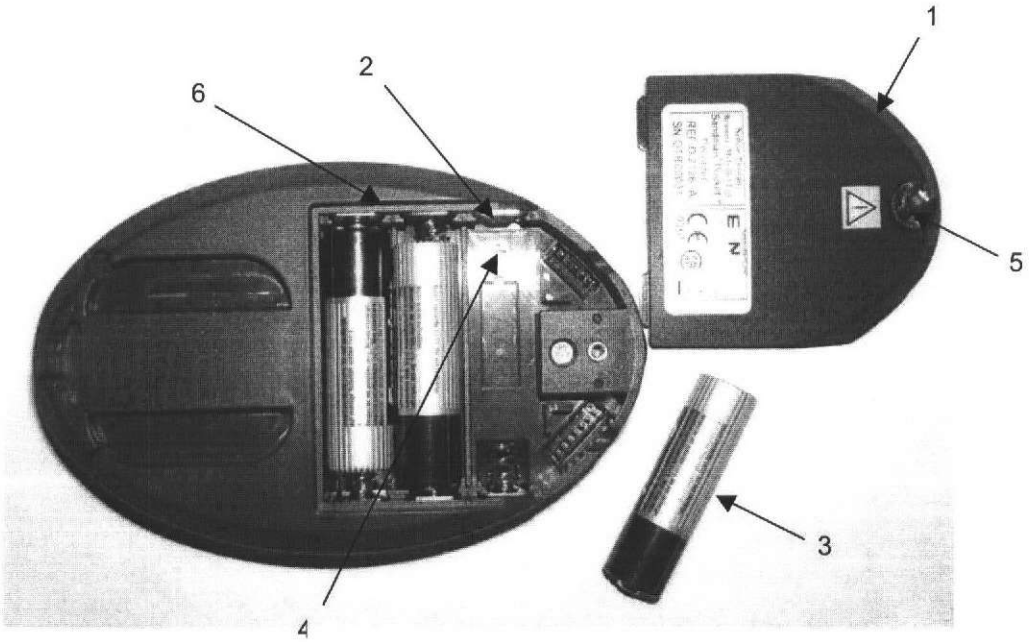


Fig. 4.2.1 – Replacement of the batteries

To replace the batteries :

- Disconnect the device from any other system or auxiliary unit.
- Remove the cover (ref. **1**) of the battery housing placed on the device's lower panel. Remove the proper cover blocking screw (ref. **5**) by using a suitable tool (flat tip screwdriver or a coin) and then push it towards.
- Remove the 3 battery cells from the housing one at a time avoiding to damage the electric contacts (ref. **2**) placed on the internal side of the housing.
- Keep the discharged batteries separate from the new ones. The just removed batteries cannot be used again and they must be disposed of.
- Wait at least 30 seconds and then insert the 3 new battery cells (ref. **3**) paying attention to the polarity as shown on the bottom of the housing (ref. **4**). The newly inserted batteries must absolutely correspond to the type indicated by EBNeuro and must also have the same characteristics.
- Place again the cover of the battery housing on device by inserting it in the proper runners (ref. **6**) and push it until it is completely closed. Then fix the cover with the proper screw by using a suitable toos (flat tip screwdriver or a coin).

Before using the instrument make sure the batteries have been correctly inserted in their housing by checking also their polarity orientation. Remove batteries from the instrument each time the recording has ended and when the instrument is not in use.

The replaced batteries cannot be used again in any way. The discharged batteries must be disposed of in accordance with the waste regulations of the country in which the instrument is in use.

CHAPTER 5
CONNECTIONS

5.1 CONNECTING THE SYSTEM

With reference to the description of the device (chapter 2 of this manual) please install the SANDMAN POCKET amplifier system by performing the connections described in the following steps and images.

5.1.1 HOLTER MODALITY

In this modality the SANDMAN POCKET work stand alone. The Recorder Unit pose all not utilized peripherals in Low Power Mode (LPM). The SANDMAN POCKET executes the data acquisition, the A/D conversion and the storage in the internal memory. In Holter modality the only power sources are the batteries.

ATTENTION

The EBNeuro Sandman Pocket Recorder is not intended for the "end user", rather it is intended as an OEM product to be used by a "System Builder" as a piece of its own medical systems.
It is responsibility of the System Builder to use the EBNeuro Sandman Pocket Polysomnograph Recorder strictly following any technical specification and precaution of use described in this manual.
EBNeuro is not providing nor any sensor, electrodes, accessories, lead or cable, nor any wearing system to the System Builder.
It is completely under the responsibility of the System Builder to provide all the accessories, any wearing system and any related instruction in its system labeling and any necessary warnings against the correct connection and units/cable placing to avoid any possible strangulation risk. This applies in particular to the use of EBNeuro Sandman Pocket Polysomnograph Recorder in pediatric studies.

ATTENTION

The Sandman Pocket modules (recorder unit and headbox unit) require to be placed on patient body by using a proper wearing system.
The wearing system allows both to properly and easily place the device on patient body and to avoid that Sandman Pocket modules get in direct contact with patient's skin.
It is very recommended to avoid contact between Sandman Pocket modules and patient skin in order to prevent both any possible irritation or biocompatibility problem to the patient and any possible damage to the device due to hurts or patient's perspiration. Wearing system is under responsibility of System Buider.

ATTENTION

The following figures are provided for reference only to show the interconnection of the parts of the system.

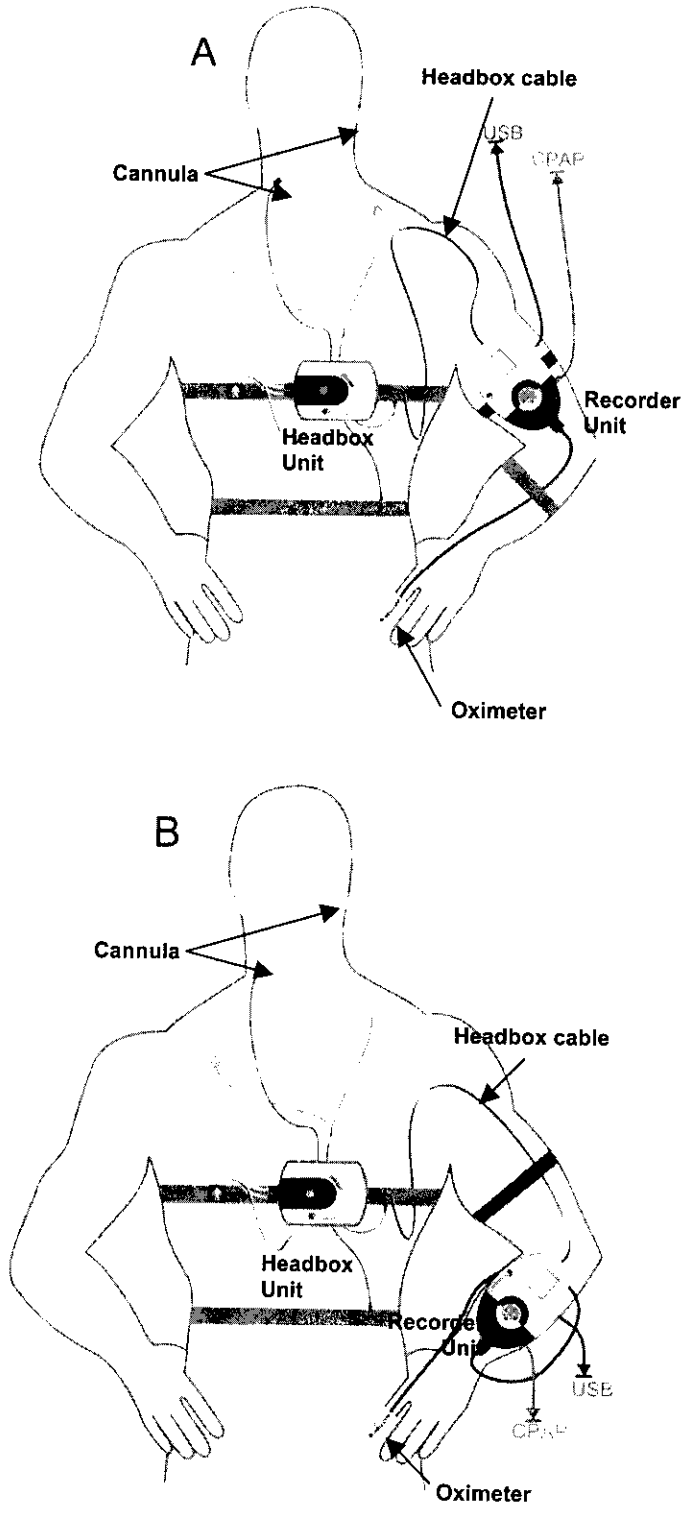


Figure 5.1.1 – SANDMAN POCKET amplifier system installation (reference examples only)

5.1.2 MONITORING MODALITY

In this modality SANDMAN POCKET is connected to PC and executes the data transfer to PC. The USB channel is active; the power supply can be draw from PC (500mA to 5V).

- Connect the Headbox Unit to the Recorder Unit with the apposite **Headbox cable cod. B9730701001**.
- Connect trough the USB port to the USB port of HOST PC.

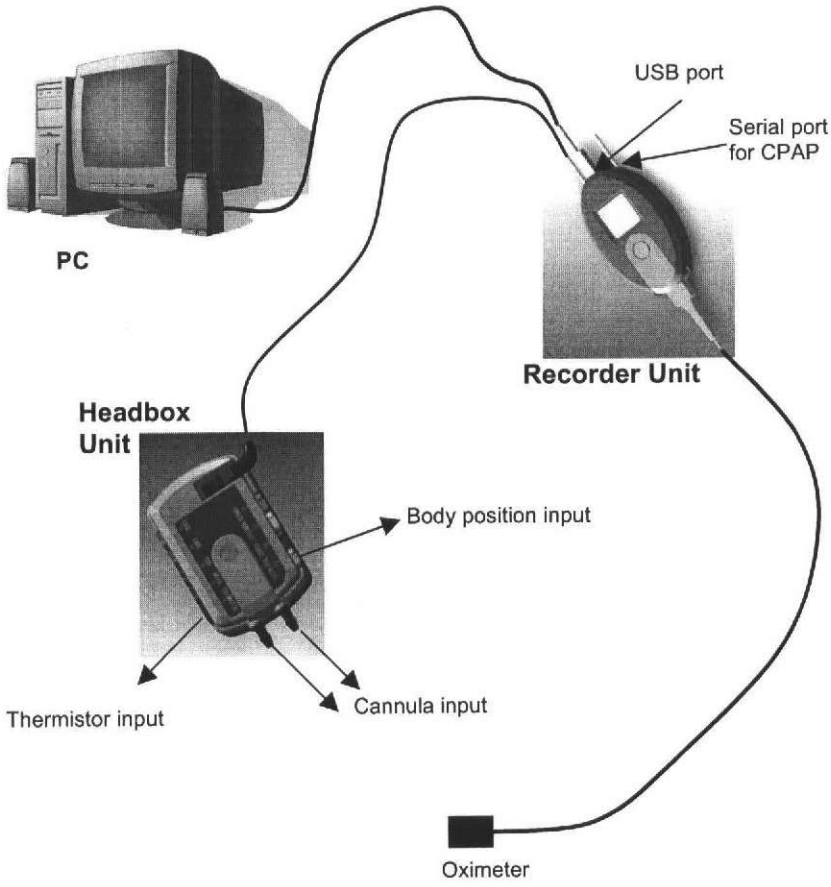


Figure 5.1.2 – SANDMAN POCKET host computer connection

5.2 FINAL WARNINGS FOR THE PATIENT

Before leaving the laboratory, warn the patient that the electrodes must not be touched or moistened and that the lead wires must not be pulled in any way.

The unit has a event recorder button. Patient can stake the key to highlight an event. Physician must inform the patient about the correct use of these features.

ATTENTION

The patient should be informed on the correct use of the recorder's functional key.

ATTENTION

The patient must not remove the batteries cover.

ATTENTION

The patient must not connect any device to the USB connector and must not open the USB plug.

ATTENTION

The patient must not remove electrodes.

Physician must inform the patient about the correct use of the unit .

CHAPTER 6
POWERING THE DEVICE

The SANDMAN POCKET amplifier module is powered through 3 alkaline batteries which provide each 1.5 VDC in Holter Mode. When working in Monitoring Mode the Sandman Pocket is powered through USB.

6.1 SWITCHING ON/OFF THE DEVICE

The system can be switched on in two different ways:

- through a long pressure on the joystick button
- programming the switch on by PC.

When the display light, the system is power on. Pocket performs a Power On Self Test (POST) each time it is turned on. During POST Sandman Pocket detects any major problems that prevents its normal operation. When Sandman Pocket fails the POST it not enter Normal operating mode and the LCD displays an error code/message stating the cause of the error. Successful completion of POST permit Sandman Pocket to proceed to its Normal operating mode.

At the same way, the system can be switched off:

- through a long pressure on the joy stick button
- programming the switch off by PC

The host PC has the complete control on the ON/OFF state of amplifier system by the described procedure. Please note that "OFF" state means "STAND-BY" state.

"STAND-BY" state: Sandman Pocket Recording unit is programmed by the PC and the unit is turned OFF. As soon the programmed DATE/TIME is reached the unit automatically switch ON and starts to record signals.

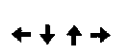
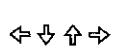
When operating on battery power alone; if Pocket detects low battery it has at least 20 minutes of battery power left it automatically cease collection and complete the process of saving the current sleep study file to its internal memory. At this time the backlight of the LCD turn on and displays a message informing the user that the battery power is severely low and Pocket is terminating the sleep study file so it is properly saved to its internal memory.

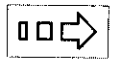
For your notes:

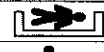
CHAPTER 7
STATUS MESSAGES

7.1 LIST OF THE STATUS MESSAGES

Following is a complete list of the messages shown on the instrument's display, with a brief explanation of their meaning and, eventually, a suggestion to resolve the problem in case of an error message.

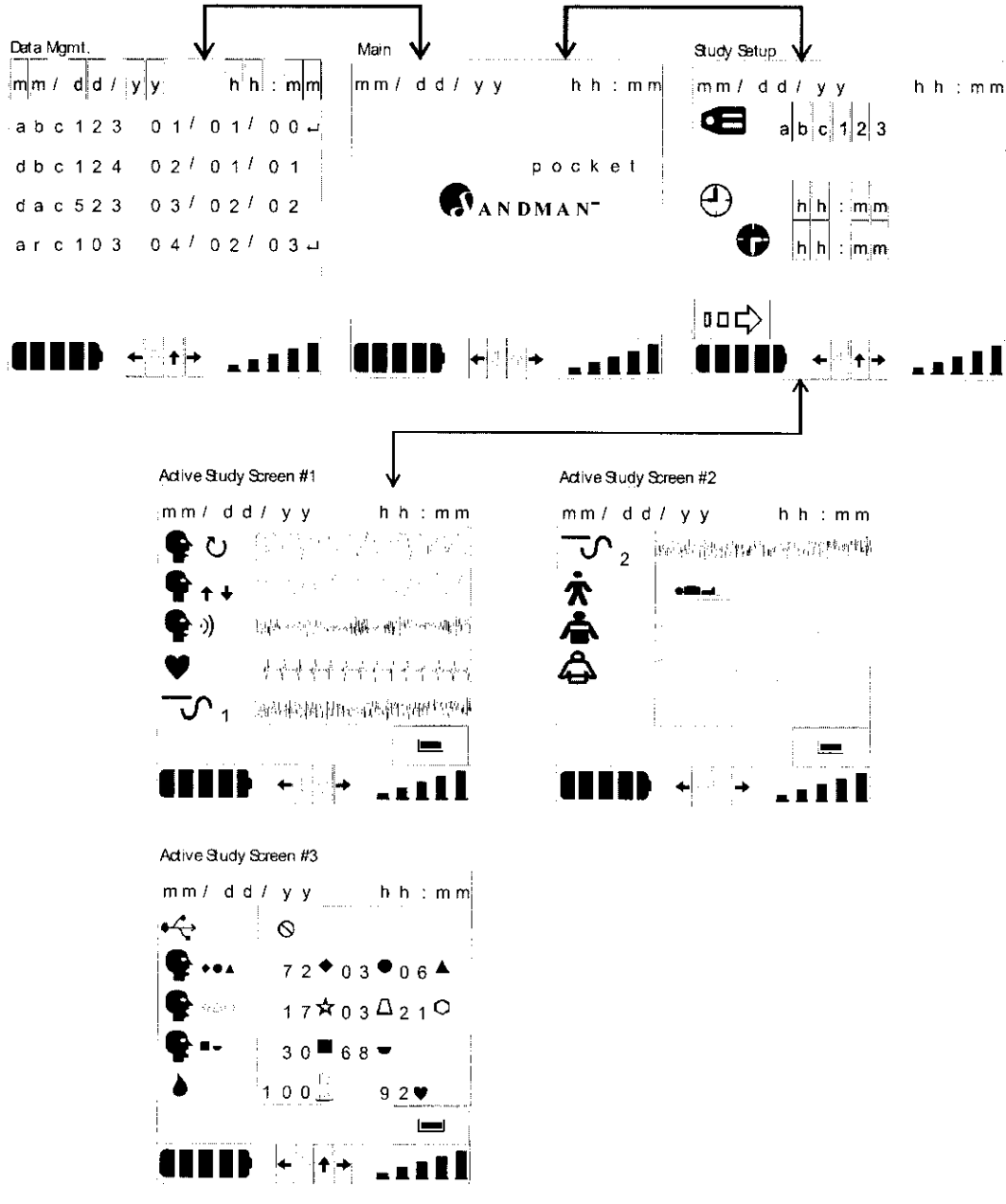
Symbol	Description	Detail
	"Battery Guage"	The Battery Guage will be used to indicate the status of Pocket's batteries.
	Battery level is good	Indicates that Pocket will be capable of recording a full night's study.
	Battery level is fair	Indicates there is a "fair" chance that Pocket will be capable of recording a full night's study, but, the user should change all of the batteries in order to be sure.
	Battery level is poor	Indicates there is a "poor" chance that Pocket will be capable of recording a full night's study and the user should immediately change all of the batteries.
	"Memory Guage"	The Memory Guage will be used to indicate the amount of Pocket's internal memory that is available to store sleep study data.
	100% Memory available	Each segment represents 20% of the internal memory.
	80% Memory available	
	60% Memory available	
	Selectable field	Using the Joypad control the user can position a "cursor" in fields with this colour background. When the "cursor" is in one of these fields the background colour will turn black and the foreground image or text will turn white. This field can be used for "softkeys" or for text that can be edited.
	Currently valid Joypad control directions	Pressing the Joypad control in these directions causes the cursor to navigate to the next available field.
	Currently invalid Joypad control directions	Pressing the Joypad control in these directions does nothing.

Symbol	Description	Detail
	Downloaded File	Appears beside sleep study files that have been previously downloaded off of Pocket's Recorder (files without this icon have never been downloaded).
	File name or "tag"	Indicates the filename field
	Start Time	User programmable time at which Pocket will begin recording sleep study data.
	End Time	User programmable time at which Pocket will stop recording sleep study data.
	"Start Now" softkey	The "Start Now" softkey will do nothing if the user has not entered a filename. When the "cursor" is in this field and the user presses down on the center part of the Joypad control Pocket will begin to record data until the user presses the "Stop Now" softkey.
		The "Start Now" softkey will look like this when the "cursor" is in this field.
	"Stop Now" softkey	When the "cursor" is in this field and the user presses down on the center part of the Joypad control Pocket will immediately stop recording data and finalize the current sleep study (this softkey will override any programmed Stop Time).
		The "Stop Now" softkey will look like this when the "cursor" is in this field.
	Oral/Nasal Cannula	Appears beside the trace that illustrates data captured at the Headbox's Cannula input.
	Thermistor	Appears beside the trace that illustrates data captured at the Headbox's Thermistor input.
	Snore Sensor	Appears beside the trace that illustrates data captured at the Headbox's Snore input.
	EKG	Appears beside the trace that illustrates data captured at the Headbox's EKG input.
	E-x-G1	Appears beside the trace that illustrates data captured at the Headbox's E-x-G1 input.
	E-x-G2	Appears beside the trace that illustrates data captured at the Headbox's E-x-G2 input.

Symbol	Description	Detail
	Body Position Sensor	Appears beside the image that illustrates data captured at the Headbox's Body Position input.
		Prone body position
		Supine body position
		Left side body position
		Right side body position
		Upright body position
	Chest Effort Belt	Appears beside the trace that illustrates data captured at the Headbox's Chest Effort Belt input.
	Abdominal Effort Belt	Appears beside the trace that illustrates data captured at the Headbox's Abdominal Effort Belt input.
	USB Connection Status	
	⊘	There is no valid USB connection present
	√	USB power is present, but, communication is not available. May indicate that Sandman Pocket is being powered by its "Line Power Module" or the USB port is experiencing communication problems.
	√√	Both USB power and communication are present and functioning.
	CPAP data; channels 1 through 3	
	◆	Appears to the right of CPAP channel 1's data.
	●	Appears to the right of CPAP channel 2's data.
	▲	Appears to the right of CPAP channel 3's data.
	CPAP data; channels 4 through 6	
	☆	Appears to the right of CPAP channel 4's data.
	△	Appears to the right of CPAP channel 5's data.
	⬡	Appears to the right of CPAP channel 6's data.
	CPAP data; channels 7 & 8	
	■	Appears to the right of CPAP channel 7's data.
	▬	Appears to the right of CPAP channel 8's data.
	NELL-1 Blood Oximetry Data	

Symbol	Description	Detail
	NELL-1 Blood Oximetry Data	
		Appears to the right of SpO_2 data received from the NELL-1. This data is shown in percent saturation (%).
		Appears to the right of Pulse data received from the NELL-1. This data is shown in bets per minute (bpm).

7.2 MENU



For your notes:

CHAPTER 8
MAINTENANCE

8.1 GENERAL INFORMATION ABOUT MAINTENANCE

In order to keep the device working for a long time and to ensure the patient's and the operator's safety, it is necessary that the general checks indicated below are periodically performed by medical or paramedical qualified staff or by technical staff authorized by EBNeuro.

- Perform a sight inspection of all the components, the accessories, and the connections of the device to the peripherals in order to identify any traces of failure, damage, or disconnection.
- Verify that all labels and any warning or instructions printed on the device are readable.
- Check that the performances and the working of the device are correct.
- Clean the external surface of the device carefully with the recommended products only.
- Replace parts or accessories only with other having the same characteristics or expressly indicated by EBNeuro.
- Discard replaced parts, accessories, and the device at its "end of life" according to the local standards and directives currently in force.

For all ordinary maintenance operations pertaining the devices of the SANDMAN POCKET system (electromedical system to which the SANDMAN POCKET device is connected or auxiliary components not produced by EBNeuro such as personal computers, monitors, printers, consumers accessories and so on), please refer to the corresponding user's manual provided with them.

For detailed information on battery installation and substitution operation of the SANDMAN POCKET system, refer to the appropriate paragraphs of Chapter 4.

8.2 SAFETY CHECKS

It is essential to periodically check the equipment and the devices or systems it is connected to and all the interconnection cables in order to ensure that the equipment continues working efficiently and safely. It is also necessary to check the equipment to remove any dust deposits. Preventive or corrective maintenance operations must be performed by qualified technical staff expressly authorized by EBNeuro.

A sight inspection of the interconnection cables, with particular care for Headbox cable between Sandman Pocket Recorder and Headbox) and CPAP cables (between Sandman Pocket and CPAP device) and for all the other cables (oximentry cable and sensors), can be performed also by medical or paramedical staff in order to remark any breaking or disconnection. In case of need, immediately contact a qualified technician to solve the problem detected before continuing to use the equipment or connecting it to other devices. For the technical assistance request procedures, please refer to chapter "Request for assistance" of the manual.

ATTENTION

Safety checks must be accurately performed periodically and at least twice a year.

8.2.1 ENVIRONMENT ELECTRICAL EQUIPMENT

A danger for the patient's health is determined, first of all, by the efficiency of the electrical equipment of the building where the equipment is used. The isolation safety guaranteed by Class I to which the device belongs is useless, in the event the device is powered by the specified external AD/DC adapter or it is connected to a device or a system supplied by the mains, if the wiring is not provided with a good earth plate, accessible though the mains outlet.

It is fundamental that qualified technicians check the electric wiring periodically with particular care for efficiency of the main outlets.

ATTENTION

If the integrity of the environment's electrical equipment, and in particular the protective earth, is not reliable for safety, do not power or use the equipment until the safety conditions are restored.

8.2.2 INTERCONNECTION CABLES AND CONNECTORS

It is necessary to check periodically the integrity of the interconnection cables between the instrument and the other devices that compose the system.

Elementary precautions may prevent prematurely breaking or deteriorating of the cables. Be careful when removing the cables from the corresponding connectors on the equipment panel; take the cable terminal connector resolutely, though with delicacy, out of the connector. Avoid twisting or tearing cables, which may cause breaks and interruptions to the conductors.

Monthly check cables for abrasion and wear. Replace any cable with exposed wire or shield.

Check the connectors on the ends of cable for bent or broken pins. Replace the cable with damaged connector.

WARNING

Sandman Pocket cables ("headbox link cable" and "CPAP link cable") are condidered by the manufacturer as "long term reusable cables". This means that the cable have a expected life time of one year.
The cables are continuously stressed by mechanical events and chemical agents (patient's perspiration) so EBN suggests replacing the cable after 1 year. Of course the user can use the cables also after the expiration date, also because the reliability of the cables depends on how often the cable is really used, but anyway after 1 year manufactuer warranty expires.

Please refer to chapter 10 "Component and accessories" for part number references of these cableas in order to replace them.

8.3 CLEANING THE DEVICE

It is necessary to keep the equipment clean in order to avoid dust deposits, which could interfere with the efficiency of all the system components.

WARNING

Do not immerse the equipment nor its parts in liquids, do not oil any part of it and avoid cleaning the external surface with alcoholic disinfectants that could cause damages and decolorization of the printed surfaces

ATTENTION

Before cleaning any part of the equipment turn off (O) the equipment power switch and disconnect the equipment from any other equipment or external devices and remove the internal batteries.

ATTENTION

The equipment external surface must be cleaned with a cloth lightly moistened with warm water and soap. Wipe the washed parts with a dry cloth.

ATTENTION

Make sure no liquid seeps into the instrument and check it's complete dryness before inserting the batteries or before connecting it with other devices, thus switching it on.

ATTENTION

To avoid the contact of the device with the skin, if not possible used a biocompatible bag.

8.4 PARTICULAR WARNINGS FOR CRITICAL COMPONENTS

The instrument is provided with a LCD (Liquid Crystal Display), and it uses alkaline battery cells, which contain small quantities of toxic materials.

In order to avoid personal injuries and to reduce the negative impact on the environment, make sure you carefully follow these instructions:

LDC Display:

- The LCD is fragile (glass) and must be treated with much care: for this reason we recommend to protect the device with the proper carrying bag during transportation or when it is not used.
- In the event the LCD glass should break and liquid spill out of it, make sure you do not touch it. Wash with water for at least 15 minutes any body part that may have been in contact with it carefully. Should you experience any symptom after this period, ask for immediate medical help.

Batteries:

- Avoid terminal parts of the battery pack coming in contact with metal objects.
- Keep the battery pack away from heat sources or flames.
- Do not immerse the battery pack and avoid exposing it to rain or humidity.
- Avoid to directly hitting the battery pack.
- Do not attempt to disassemble, burn or cause short-circuits to the battery. Such operations may cause a fire or emission of toxic chemical substances.
- Remove the battery at the end of the recording.

For your notes:

CHAPTER 9
TECHNICAL CHARACTERISTICS

9.1 SANDMAN POCKET POLYSOMNOGRAPH RECORDER SYSTEM

Product name	**Sandman Pocket**
Description	Active, non-invasive medical device
Intended use	Intended for use in collecting and recording physiological data to be used in polisomnography and sleep disorder studies. A pediatric through adult patient population is intended for the Sandman Pocket, which can be used in either home or hospital environments.
Classification according MDD 93/42/EEC	Class II b

Standards applied

93/42/EEC	Medical Device European Directive(MDD)
EN 60601-1-1	Collateral safety standard for electromedical systems;
EN 60601-1-2	Collateral safety standard for devices EMC test;
EN 60601-1-4	Safety standard for devices containing Programmable systems;
EN 60601-2-26	Standard on particular safety requirements for electroencephalographs

Type of protection against electric shocks

Internally powered equipment

Protection level against electrical direct and indirect contacts

CF type	(ECG, EXG1, EXG2, Thermistor, Body Position, Snore, Chest, Cannula, Abdomen inputs and ISOGND)
B type	(Oximeter, CPAP)

Protection level against inflow of solids and liquids	Common (IP20)	
Operational mode	Continuous, within the specified limits	
Environmental conditions for usage	Temperature	from +5°C to +40°C
	Relative humidity	from 30% to 75% RH
	Atmospheric pressure	from 700hPA to 1060hPA
Environmental conditions for storage (max. 15 weeks)	Temperature:	from -30°C to +60°C
	Relative humidity	from 5% to 95% RH (excluding condensation)
	Atmospheric pressure	from 500hPA to 1060hPA

9.2 RECORDER UNIT

Device rated values	Manufacturer:	EBNeuro S.p.A.
	Trademark:	Nellcor Puritan Bennett (Melville)
	Model:	POCKET Recorder
	EBNeuro code:	B9700650000
	NBM code (REF)	D.2126
	Year of manufacture	
	Serial Number (SN)	
	CE0051 mark (93/42/EEC)	
	cCSAus mark	

DC/AC coupling EXG bipolar channel	2
AC coupling ECG bipolar channels	1
AC coupling dedicated bipolar channels	5 (Thermistor; Snore; Chest; Abdomen; Cannula)
DC coupling dedicated bipolar channels	1 (Body Position)
Impedance measurement	By means of injected current (16 Hz - 0.01 µA/electrode)
A/D conversion	16 bits SAR A/D

Resolution, Dynamic and Noise

Bipolar channels

Coupling	Gain Setting+Resolution	Full Scale Range	Noise(0.1Hz-70Hz)
AC	1/8 µV/bit	8000µVp-p	0.5 µVrms max
DC	30 µV/bit	±1Vpp	

Frequency Response Raw Data

High-Pass filters	monopolar channels: DC or 0.099Hz 1st order filter (selected by a software controlled switch) bipolar channels: 0.099 1st order filter
Anti-aliasing Low-Pass filters (3 th order filter)	Frequency cut 135 Hz for ECG, EXG1, EXG2, Snore 45 Hz for Abdomen and Chest Attenuation 24dB/octave

Selectable Sampling Rate

Channel	Storage rates [sample/second]
Thermistor	128, 64, 32,16, 8
Chest	16, 8, 4
Abdomen	16, 8, 4
Snore	128, 64
Body Pos	4, 2, 1
Cannula	128, 64, 32, 16, 8
EXG1	128,64
EXG2	128, 64
EKG	128, 64

Sampling Skew	90 µs max
CMMR	>100 dB
IMRR	>120 dB
Max DC Offset (AC mode)	± 300 mV
Amplifier box – PC interface	USB 2.0 miniB (12Mbit/s)
Human interface	n° 1 display n° 1 joy-stik

Power supply

- Internal batteries (4.5V DC)
- USB connection (Host PC) 5V DC – 270mV

Internal batteries

- Number and type: 3 alkaline cells AA size
- Nominal voltage: 1.5 Vn

Consumption 270 mW Recorder and Headbox

Case

Material: ABS
Dimensions: 127 x 80 x 30 mm
Weight: - about 102 g (without batteries)
- about 173 g (with batteries)

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9.3 HEADBOX

Device rated values	Manufacturer:	EBNeuro S.p.A.
	Trademark:	Nellcor Puritan Bennett (Melville)
	Model:	POCKET Headbox
	EBNeuro code:	B9630650000
	NPB code (REF)	D.2127
	Year of manufacture	
	Serial Number (SN)	
	CE0051 mark (93/42/EEC)	
	cCSAus mark	
Case	Material:	ABS
	Dimensions:	70 x 45 x 22 mm
	Weight:	40 g
Electrode connectors	3 active – two active connection to each input (bipolar)	
	5 dedicated – two connection to each input (bipolar)	
	1 for isolated patient ground	
Cable for connection to the recorder unit	Headbox Cable	
Cable for connection to the CPAP		
Interfaces	Body position connector	
	Thermistor connector	
	Sore connector	
	Abdomen connector	
	Chest connector	
	Oximeter connector	
	Pressure sensor (Honeywell 26PC01SMT)	
Human interface	n° 1 event marker button	

9.4 PULSE OXIMETRY PRINTED CIRCUIT BOARD

Nellcor Puritan Bennet NELL-1 Pulse Oximetry Module
(Refer to NPB documentation for specifications and accessories)

CHAPTER 10
COMPONENTS AND ACCESSORIES

10.1 SANDMAN POCKET - AMPLIFIER SYSTEM – cod B9800065400

CODE	DESCRIPTION	QUANTITY
STANDARD COMPONENTS		
B9700065400	Recorder module	1
B9630065400	Headbox module	1
B9730701001	Headbox cable	1
B9730701002	CPAP cable	1
B8300065411	Operator Manual - English	1
B9400065400	complete package	1
OPTIONAL COMPONENTS		
Service Manual:		
B8310065400	Service Manual - English	

10.2 SANDMAN POCKET CODES COMPARISON TABLE

In the following table are listed the main components of SD20 system. For the components, are indicated the equivalent Nellcor Puritan Bennett codes which are written on the identification labels of devices.

DESCRIPTION	SANDMAN DIGITAL EBNeuro code	SANDMAN DIGITAL Nellcor P. B. code
Recorder module	B970 0065 400	D.2126
Headbox module	B963 0065 400	D.2127
Headbox cable POCKET	B973 0701 001	D.7214
CPAP cable POCKET	B973 0701 002	D.7215

CHAPTER 11
REQUEST FOR ASSISTANCE

11.1 OBTAINING SERVICE

In case of problems such as failure of the device or anyway in case of partial or incorrect working that cannot be solved through usual maintenance operations, please contact one of the main offices or branches of EBNeuro or the nearest retailer or authorized servicing center.

ATTENTION

In case of failure of the device or if it starts working in a way not complying with what is written in the manual, especially as far as safety is concerned, STOP USING IT IMMEDIATELY and contact the technical service. Do not use the device until the safety conditions have been checked and restored.

NOTE

In order to speed up the procedures to start the intervention of the technical service and to make it easier for the specialized technical staff to identify the problem on the first phone call by the customer, please fill in the form below in this page.
The equipment data may be found on the equipment identification label.

REQUEST FOR ASSISTANCE

EBNeuro Device/system name.....

EBNeuro Device code/reference number (REF) .....

Serial number (SN) or lot number (LOT) .....

Current software version (Rel) .....

11.2 EBNEURO MAIN OFFICES

Please find below the addresses of the EBNeuro main offices.

OPERATING OFFICES

EBNeuro S.p.A.
Operatine office:
FIRENZE
Via Pietro Fanfani, 111/A
50127 - Firenze
Phone 055-4565111
Fax 055-4565123

EBNeuro S.p.A.
Operatine office:
VERONA
Via Bologna, 1
37020 - Arbizzano di Valpolicella (VR)
Phone 045-6028111
Fax 045-6028100

Date: June 30, 2006

Allison Scott
The Anson Group
c/o EB Neuro
11460 N. Meridian Street, Suite 150
Carmel, IN 46032

Re: Sandman Pocket

Dear Ms. Scott,

We have completed the substantive review according to the 510(k) checklist, the FDA guidance documents titled ***"Format for Traditional and Abbreviated 510(k)s"*** **Dated: August 12, 2005** for preparing a 510(k) **and contact with the Anesthesiology Branch Chief** for device under third party review. We have found items that are missing or require clarification. These deficiencies are described in the attached Record of Deficiencies from the Substantive Review. Please respond to each of these items in writing. Submitting a revised submission is not required only a response with the new or revised documents is necessary. Your submission is on hold until we receive the additional information.

If you have any questions, please do not hesitate to contact me. You may reach me at 763 682 4139.

Sincerely,

Mark Job
Reviewer

SIV

Record of Deficiencies From Substantive Review

Device Name or Model Name: Sandman Pocket

Date: June 30, 2006

Please provide the following items as required according to 510(k) checklist, a FDA general guidance document for preparing a 510(k) and a discussion with the FDA (Anesthesiology Devices branch) concerning the review of a device included in the expansion pilot.

1. The submission does not include a declaration of conformance for the recognized consensus standards (i.e. IEC 60601-1, UL 60601-1, IEC 60601-1-2, etc).

2. The submission states the device is intended to be used with specific models of sensors and peripheral devices, please include the manufacturer, model number and 510(k) clearance number for each of these devices.

The following deficiencies are related to the FDA guidance document titled: "**Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" Dated: May 11, 2005**

3. The submission does not include a Traceability Analysis which links together the product design requirements, design specifications, and testing requirements. Traceability Analysis provides a means of tying together identified hazards with the implementation and testing of the mitigations. The software guidance recommends your submission include explicit traceability among these activities and associated documentation because they are essential to effective product development and to our understanding of product design, development and testing, and hazard mitigations. The Traceability Analysis commonly consists of a matrix with line items for requirements, specifications and tests, and pointers to hazard mitigations. The Traceability Analysis could document traceability simply through a shared organizational structure with a common numbering scheme; however, we recommend the submission include some mechanism, such as a matrix for guiding the reviewer through the information you submit.

4. The submission does not include the results of the verification and validation of the whole system. The information which is included in the submission does not demonstrate all software and hardware specification have been validated.

5. The submission does not include the revision log including the release version and date.

6.

Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Summary of Discussion with Branch Chief

Regulatory Technology Services LLC

Date:	June 23, 2006	FDA Branch:	Anesthesiology
Reviewer:	Mark Job	Branch Chief:	Ann Graham
Review	Sandman Pocket		

The following is a record of the discussion between the reviewer and the branch chief.

The following email from Ann Graham includes the necessary requirements for completing a review of a device included in the list of expansion devices which do not have a guidance document available. This email exchange includes all of the necessary elements to summarize the requirements for Regulatory Technology Services LLC to complete the review of this submission.

MARK JOB

From: Graham, Ann A. [ann.graham@fda.hhs.gov]
Sent: Friday, June 23, 2006 10:05 AM
To: 'MARK JOB'
Subject: RE: THIRD PARTY REVIEW INQUIRY - Pilot Device

Mark,

Looks good to me. Clinicals not required if all is as you state. Looks like you are ready to submit, once your review is finished. Ann

---

From: MARK JOB [mailto:markjob@bwig.net]
Sent: Friday, June 23, 2006 10:33 AM
To: Graham, Ann A.
Subject: RE: THIRD PARTY REVIEW INQUIRY - Pilot Device
Importance: High

Hello Ann,

Thank you for your quick response.

The following are the answers to your questions.

1. Will the device store the data it collects?

This device has the ability to store data. The data would be down loaded to a PC for review.

2. Will the data undergo any transformation or is the new device a pass-through to another device?

The device will not perform clinical analysis or computation of vital physiological parameter. The only computed parameter is described as a Pulse Transit Time (PTT) signal. The PTT is defined as the algorithm used to calculate the time difference between the R-wave in the ECG signal and 50% of the ascending edge of the pressure wave when measured by a pulse oximeter.

3. Will the mfr make any claims about apnea, hypopnea or snoring?

No, the device description states this device is intended to be part a full sleep disorder collection, analysis, and therapy system.

4. Is your software making any calculations or is it simply logging in data?

Described as only logging data for download later.

5. Does the device manipulate the data - does it create an apnea/hypopnea index, for example?????

Does not manipulate the data.

6. Will it be used to detect snoring?

Does not claim to detect snoring.

Please let me know if you need anything further.

Best regards,

Mark Job
Phone: 763 682 4139
FAX: 763 682 4420
Email: mark@markjob.com

-----Original Message-----
From: Graham, Ann A. [mailto:ann.graham@fda.hhs.gov]
Sent: Friday, June 23, 2006 8:59 AM
To: 'MARK JOB'
Subject: RE: THIRD PARTY REVIEW INQUIRY - Pilot Device

Mark,

Does the device manipulate the data - does it create an apnea/hypopnea index, for example????? Will it be used to detect snoring?

I am trying to determine whether clinical data will be necessary as part of this 510(k). If you cannot answer these questions, please contact the device manufacturer and ask him. Please consider answering my earlier questions also.

Ann

From: MARK JOB [mailto:markjob@bwig.net]
Sent: Monday, June 19, 2006 1:11 PM
To: Graham, Ann A.
Subject: RE: THIRD PARTY REVIEW INQUIRY - Pilot Device

Hello Ann,

I am just checking in to see if you have any further insight.

Thanks for your time.

Please let me know.

Best regards,

(b)(4) [redacted]

Phone: 763 682 4139
FAX: 763 682 4420
Email: mark@markjob.com

-----Original Message-----
From: MARK JOB [mailto:markjob@bwig.net]
Sent: Wednesday, June 14, 2006 6:13 PM
To: 'Graham, Ann A.'
Subject: RE: THIRD PARTY REVIEW INQUIRY - Pilot Device

Hello Ann,

The intended use of the device will be for collecting and recording physiological data used in the polysomnography and sleep order studies. The device is intended to be used for pediatric to adult patient population at home or in a hospital environment.

The submission on the surface does not appear to include alarms or specifically intended to function as an apnea monitor. This device appears to be only a data collection system.

Please let me know your thoughts.

Thanks for your time.

Best regards,

Mark Job
Phone: 763 682 4139
FAX: 763 682 4420
Email: mark@markjob.com

-----Original Message-----
From: Graham, Ann A. [mailto:ann.graham@fda.hhs.gov]
Sent: Monday, June 12, 2006 9:33 AM
To: 'MARK JOB'
Cc: Rechen, Eric J.
Subject: RE: THIRD PARTY REVIEW INQUIRY - Pilot Device

Dear Mark,

I need a little more information before I respond to your email below. Will the device store the data it collects? Will the data undergo any transformation or is the new device a pass-through to another device? Will the mfr make any claims about apnea, hypopnea or snoring? Is your software making any calculations or is it simply logging in data?

Thanks for your email and hope to hear from you soon.

Ann

From: MARK JOB [mailto:markjob@bwig.net]
Sent: Friday, June 09, 2006 9:31 AM
To: Graham, Ann A.
Cc: Rechen, Eric J.
Subject: THIRD PARTY REVIEW INQUIRY - Pilot Device

Hello Ann,

I have recently entered into a contract to review a submission which is listed as a pilot device.

The consultant preparing the submission has classified the device under product code MNR - 21CFR 868.2375.

The indications for use of one predicate states device is intended for collecting and recording physiological dated to be used for diagnosis of sleep disorders. I presume the new device will be very similar if not exact.

I plan to use the general guidance for formatting traditional and abbreviated 510(k)'s. I also would expect the device to comply with the IEC 60601-1 safety standard. I also would expect the submission to include performance testing to demonstrate substantial equivalence. I would not expect any parts of the system to be sterile but I would expect any parts contacting the patient to meet the requirements of ISO 10993 at least for intact skin contact.

Please let me know if there are any other issues I should consider when I perform this review.

Thank you for your time.

Best regards,

Mark Job
Phone: 763 682 4139
FAX: 763 682 4420
Email: mark@markjob.com

Date: June 15, 2006

Allison Scott
The Anson Group
c/o EB Neuro
11460 N. Meridian Street, Suite 150
Carmel, IN 46032

Re: Sandman Pocket

Dear Ms. Scott,

This letter is to acknowledge on June 13, 2006, Regulatory Technology Services LLC received the 510(k) dated June 12, 2006 for the EB Neuro Sandman Pocket.

We have completed the administrative review according to the 510(k) checklist, the FDA guidance documents titled ***"Format for Traditional and Abbreviated 510(k)s"*** **Dated: August 12, 2005** for preparing a 510(k) **and contact with the Anesthesiology Branch Chief** for device under third party review. We have found all required items present and have begun the substantive review. We will keep you informed as the review continues.

If you have any questions, please do not hesitate to contact me. You may reach me at 763 682 4139.

Sincerely,

Mark Job
Reviewer

Part Acceptance / Non-acceptance

1. Accredited Person:

Name: Regulatory Technology Services LLC

Address 1394 25th Street NW

Buffalo, MN 55313

Contact: Mark Job

Telephone: 763 682 4139 Fax: 763 682 4420

2. Foreign Accredited Person, Specify a Domestic Correspondent:

Name: N/A

Address

Contact:

Telephone: Fax:

3. 510(k) Owner (Applicant, Manufacturer, other persons preparing 510(k))

Name: EB Neuro

Address v. Pietro DanFani II/A

Florence, Italy 50127

Contact: Andrea Checchi

Telephone: 390554565131 Fax: 390554565123

STOP!

Before completing items 4 to 9 below, complete pages 3 – 6 of this document.

4. Device Name:

Trade or Proprietary Name: Sandman Pocket

Classification Name: Ventilator Effort Recorder

5. CFR Classification Citation: 21 CFR 868.2375 (see 21 CFR 862 through 892)

6. Classification Panel: Anesthesiology

7. Based on my completion of this document, I recommend that this 510(k):

☒ Be accepted for substantive review and I have notified the 510(k) owner using RPP-F-0016.

☐ Not be accepted for substantive review and I have listed the deficiencies on RPP-F-0016.

8. Primary Reviewer

Signature June 14, 2006 Date

Mark Job

Print Name

9. Supervisor

Signature July 13, 2006 Date

Pedro E. Gonzalez

Print Name

Checklist Questions:	YES	NO	Instructions
1. a). Is the device one that FDA has determined as being acceptable for third party review?	☒	☐	If NO, telephone DSMA for instructions. --STOP REVIEW--
1 b). Have you confirmed that the manufacturer has not engaged in forum shopping?	☒	☐	If NO, telephone DSMA for instructions. --STOP REVIEW--
2. Is the device trade or proprietary name included?	☒	☐	If NO, note deficiency on RPP-F-0013.
3. Is the device common or usual name included?	☒	☐	If NO, note deficiency on RPP-F-0013.
4. Is the device classification name, class of the device, and regulation number (21 CFR 868.2375) included?	☒	☐	If NO, note deficiency on RPP-F-0013.
5. Is the classification panel included?	☒	☐	If NO, note deficiency on RPP-F-0013.
6. Has the applicant complied with Section 514 of the Act? (Section 514 relates to performance standards for class II devices. At this time, there are no 514 standards. Therefore, your answer should be yes.)	☒	☐	If NO, note deficiency on RPP-F-0013.
7. Does the submission include proposed labels, labeling, and advertisements (if available) that describe the device, its intended use, and directions for use (ODE Guidance Memorandum #G91-1)?	☒	☐	If NO, note deficiency on RPP-F-0013.
8. Does the submission contain the "Indications for Use" form?	☒	☐	If YES, indicate page number 4. If NO, note deficiency on RPP-F-0013.

Checklist Questions:	YES	NO	Instructions
9. Does the submission contain an acceptable 510(k) Summary of Safety and Effectiveness (per 21 CFR 807.92) OR an acceptable 510(k) Statement (per 21 CFR 807.93) that safety and effectiveness information will be made available to any person upon request?	☒	☐	If YES, indicate page number 7-21 If NO, note deficiency on RPP-F-0013.
10. Does the submission contain photographs of the device if applicable?	☒	☐	If NO, note deficiency on RPP-F-0013.
11. Does the submission contain drawings for the device with dimensions and tolerances if applicable?	☐ N/A	☐	If NO, note deficiency on RPP-F-0013.
12. Does the submission identify the device to which equivalence is claimed?	☒	☐	
13. If the answer to question 12 is YES, did the applicant identify:			
a. Predicate device (referred to as marketed device)?	☐	☒	
b. Legally marketed device (referred to as marketed device)?	☒	☐	Note deficiency on RPP-F-0013.
Note: A predicate device is a device that was legally in commercial distribution in the U.S. on or before May 28, 1976 (referred to as a pre-amendments device) or a device that was marketed after May 28, 1976 (referred to as a post amendments device) that was reclassified from class III to class I or II. A marketed device can be a predicate device but is most often a device that FDA has determined is SE to another marketed device (21 CFR 807.92(a)3). IT IS YOUR RESPONSIBILITY TO MAKE SURE THAT THE PREDICATE DEVICE OR LEGALLY MARKETED DEVICE IDENTIFIED IS LEGITIMATE. If it is not, the review must STOP. Telephone DSMA for assistance.			List all 510(k) control numbers: K040595 K990565

Checklist Questions:	YES	NO	Instructions
14. Does the submission contain information about the marketed device(s) identified in questions 12 and 13 above to which equivalence is claimed, including labeling and a description of the device?	☒	☐	If NO, note deficiency on RPP-F-0013.
15. Does the submission contain a statement/comparison of similarities and/or differences between the new device and the marketed device? (The new device that is the subject of this 510(k) can be either a new device or a modification to the existing device.)	☒	☐	If NO, note deficiency on RPP-F-0013.
16. Does the submission contain the Truthful and Accurate Statement (per 21 CFR 807.87(j))?	☒	☐	If YES, indicate page number 6. If NO, note deficiency on RPP-F-0013.
17. Does the submission contain the submitter's name, address, contact person, telephone number, and fax number?	☒	☐	If NO, note deficiency on RPP-F-0013.
18. If there is a representative or consultant, does the submission contain their name, address, contact person, telephone number, and fax number?	☒	☐	If NO, note deficiency on RPP-F-0013.
19. Does the submission contain a table of contents with pagination?	☒	☐	If NO, note deficiency on RPP-F-0013.
20. If the submitter has a manufacturing facility (contract or owned), and/or a sterilization facility (contract or owned), is the address(es) contained in the submission?	☒	☐	If NO, note deficiency on RPP-F-0013.
21. Does the submission contain a comparison table of the new device to the marketed device?	☒	☐	If NO, note deficiency on RPP-F-0013.
22. Does the submission contain information about the action taken to comply with voluntary standards?	☒	☐	If NO, note deficiency on RPP-F-0013.

Checklist Questions:	YES	NO	Instructions
23. Does the submission contain performance data (can be bench or animal but not clinical), i.e.: Is there performance data for the marketed device? a. Bench testing? b. Animal testing? Is there performance data for the new device? a. Bench testing? b. Animal testing?	☒ ☐ N/A ☒ ☐ N/A	☐ ☐ ☐ ☐	If NO, note deficiency on RPP-F-0013. If NO, note deficiency on RPP-F-0013.
24. If the device is labeled as sterile, does the submission contain sterilization data?	☐ N/A	☐	If NO, note deficiency on RPP-F-0013.
25. Does the device incorporate a computer or computer software? a. If YES, is there information about the hardware? b. If YES, is there information about the software?	☒ ☒ ☒	☐ ☐ ☐	If NO, note deficiency on RPP-F-0013.
26. a) Is there a specific guidance document for this type of device? Title: _____	☐	☒	If YES, continue review with checklist from the specific guidance document and return to question 27. If NO, proceed to question 26 b).
26 b) Contact the appropriate ODE Branch Chief to obtain information for reviewing this type of device. Has a summary of this discussion been documented?	☒	☐	If YES, answer question 27. If NO, do not proceed to question 27; stop review until summary completed.
27 Is this 510(k) sufficiently complete to allow substantive review?	☒	☐	If YES, continue review using specific guidance document or if no specific guidance document, continue the review using documentation forms. If NO, note deficiency on RPP-F-0013.

Authorization Form

Regulatory Technology Services LLC

Date:

Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: Authorization for Accredited Person Review of 510(k)

To Whom It May Concern:

Enclosed is the Premarket Notification 510(k) for the following product Sandman Pocket manufactured by EB Neuro S.p.A.

We at EB Neuro S.p.A. (*name of manufacturer*) hereby authorize Regulatory Technology Services LLC to submit the enclosed 510(k) to the Food and Drug Administration (FDA) on our behalf, discuss its contents with the FDA, and function as the Accredited Person to perform the third party review.

We certify that we have not contacted another Accredited Person to perform the review of this 510(k) submission.

We accept the quote for 510(k) review services including the Regulatory Technology Services LLC Terms and Conditions.

Sincerely,

Signature and
Name of Manufacturer Representative ANDREA CHECCHI

EB Neuro S.p.A.
Resp. Assicurazione Qualità
Andrea Checchi

360

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: September 30, 2004.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)
5/12/2006	Third Party Reviewed - No User Fee Required	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (120 day)	☐ Original PDP	☐ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☒ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA &HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other
☐ Supplement	☐ Supplement			*(describe submission):*
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
EB Neuro, S.p.A.	9617286		
Division Name *(if applicable)*	Phone Number *(including area code)*		
	(011) 390554565111		
ɜet Address	FAX Number *(including area code)*		
▾ıa Fanfani, 111/a	(011) 390554565123		
City	State / Province	ZIP/Postal Code	Country
Florence		50127	Italy
Contact Name			
Antonio Torsoli			
Contact Title	Contact E-mail Address		
Managing Director	torsoli@ebneuro.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
The Anson Group, LLC			
Division Name *(if applicable)*	Phone Number *(including area code)*		
	(317) 569-9500		
Street Address	FAX Number *(including area code)*		
11460 N. Meridian St., Suite 150	(317) 569-9520		
City	State / Province	ZIP/Postal Code	Country
Carmel	IN	46032	U.S.A.
Contact Name			
Carri Graham			
ntact Title	Contact E-mail Address		
nsultant	cgraham@ansongroup.com		

3 of 6

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Repose to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify)*:

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	MNR	2	GWQ	3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached
☐ 510 (k) statement

rmation on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K990565	1	SUZANNE	1	Nellcor Puritan Bennett, Inc.
2	K040595	2	ALICE 5	2	Respironics, Inc.
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Ventilator Effort Recorder

	Trade or Proprietary or Model Name for This Device		Model Number
	Sandman Pocket	1	
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 XXXXXX	2 XXXXXX	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
MNR	868.2375	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel

Anesthesiology

Indications *(from labeling)*

Intended for use in collecting and recording physiological data to be used in polysomnography and sleep disorder studies. The Sandman Pocket is intended for pediatric through adult patient populations, and can be used in either home or hospital environments.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.

FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☑ Original ☐ Add ☐ Delete	FDA Establishment Registration Number: 9617286	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name: EB Neuro, S.p.A.		Establishment Registration Number: 9617286	
Division Name *(if applicable)*		Phone Number *(including area code)*: (011) 390554565111	
Street Address: Via Fanfani, 111/a		FAX Number *(including area code)*: (011) 390554565123	
City: Florence	State / Province	ZIP Code: 50127	Country: Italy
Contact Name: Antonio Torsoli	Contact Title: Managing Director	Contact E-mail Address: torsoli@ebneuro.com	

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*: ( )	
et Address		FAX Number *(including area code)*: ( )	
City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*: ( )	
Street Address		FAX Number *(including area code)*: ( )	
City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
	Standards No. 60601-1 1995	Standards Organization IEC	Standards Title Medical Electrical Equipment - General Requirement for Safety	Version	Date
2	Standards No. 60601-1-2 2001	Standards Organization IEC	Standards Title Medical Electrical Equipment - Electromagnetic Compatibility	Version	Date
3	Standards No. 60601-1-26 1994	Standards Organization IEC	Standards Title Medical Electrical Equipment - Particular Requirements for the Programmable Electrical Medical Systems	Version	Date
4	Standards No. 60601-1-4 2000	Standards Organization IEC	Standards Title Medical Electrical Equipment - General Requirement for the Safety of Electroencephalographs	Version	Date
	Standards No. UL 60601-1	Standards Organization UL	Standards Title Medical Electrical Equipment - General Requirement for Safety	Version	Date
6	Standards No. CAN/CSA-C22.2 601.1-M90	Standards Organization CSA	Standards Title Medical Electrical Equipment - General Requirement for Safety	Version	Date
7	Standards No. UL 2601	Standards Organization UL	Standards Title	Version	Date

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

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ANSON GROUP

VIA Federal Express

June 12, 2006

Regulatory Technology Services
Mark Job
1394 25th Street NW
Buffalo, MN 55313

Subect: Sandman Pocket 510(k)

Dear Mr. Job:

Pursuant to the requirements of Section 510(k) of the Federal Food, Drug and Cosmetic Act, EB Neuro hereby notifies FDA of its intention to market the above referenced device.

We believe the information contained herein is sufficient for the FDA to reach a decision regarding this submission. Should additional information be required, please contact Carri Graham at cgraham@ansongroup.com or 317.569.9500 x103.

We appreciate the administrative and scientific considerations relevant to this submission and hope the FDA will reach its decision as expeditiously as possible.

Sincerely,

for CAGraham

Carri Graham
The Anson Group
11460 N Meridian St., Ste. 150
Carmel, Indiana 46032

Telephone: (317) 569-9500
Fax: (317) 569-9520

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Foreword

Much of the information contained within this submission has been provided as received from the manufacturer, EB Neuro located in Florence, Italy. In some areas the English may appear to be a bit broken due to the differences between the Italian and English languages. We believe, however, that in all cases the text is understandable.

The purpose of this 510(k) submission is to obtain marketing clearance for the Sandman Pocket Polysomnograph Recorder. The legally marketed predicate devices are Nellcor's Suzanne cleared via K990565 and Respironics' Alice 5 cleared via K040595.

The *SANDMAN POCKET Amplifier* is not intended for direct use by a clinician but rather by a manufacturing company, which wants to build a full sleep disorder collection, analysis and therapy system.

To clarify some of the terminology used throughout the submission:
DAM – is the Digital Acquisition Module (also called the Recorder Unit)
ARM – is the Analog Reconfigurable Module (also called the Yoke, Amplifier or Headbox)

The NELL1 pulse oximeter is to be used with the Sandman Pocket and has previously been used with the EB Neuro SD20, cleared via K040113.

Administrative Information

Pursuant to Section 510(k) of the Food, Drug and Cosmetic Act, and Part 807, Title 21 of the Code of Federal Regulations, EB Neuro, S.p.A. submits the following information as premarket notification:

Type of Submission: Traditional 510(k)

Proprietary Name:	Sandman Pocket
Classification Name:	Ventilatory Effort Recorder
Classification:	Class II
Performance Standard:	None established under section 514
Intended Use:	The Sandman Pocket is intended for use in collecting and recording physiological data to be used in polysomnography and sleep disorder studies. The Sandman Pocket is intended for pediatric through adult patient populations, and can be used in either home or hospital environments.
Registration:	The device will be manufactured by: EB Neuro, S.p.A. Via P. Fanfani, 111/a Florence 50127 Italy Registration Number: 9617286
Safety and Effectiveness:	A summary of Safety and Effectiveness is included in this submission.

Indications for Use

510(k) Number (if known):

Device Name: Sandman Pocket

Indications For Use:

Intended for use in collecting and recording physiological data to be used in polysomnography and sleep disorder studies. The Sandman Pocket is indended for pediatric through adult patient populations, and can be used in either home or hospital environments.

The Sandman Pocket is not intended for use as life supporting equipment, such as a vital sign monitoring in on intensive care unit. The device does not produce alarms and is not intended as an automated apnea monitor.
The Sandman Pocket is only to be used under the direction or supervision of a physician, technologist or clinician.

Prescription Use ____X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

The following section is page numbered independently from the remainder of the submission.

1 Introduction

1.1 Purpose

This document identifies the hazards related to the use of the SANDMAN POCKET system and demonstrates the means used to control those hazards.
The document summarizes the content of the original EBNeuro documents "Risk Analysis" developed following the EBNeuro Quality Procedures and originally written in Italian.

1.2 Risk Analysis Method

The hazards are identified within different groups (electrical hazards, software depending hazards,...). For each hazard, the risk is assessed by using the method described hereafter, following the method suggested by ISO 14971.

Severity

This quantifies the consequence that could result from the occurrence of the hazard

1 – Negligible : hazard has small or no potential to cause an injury.
2 – Marginal : hazard has potential to cause an injury.
3 – Critic : hazard has potential to cause a death or a serious injury.
4 – Catastrophic : hazard has potential to cause multiple deaths or serious injuries

Occurrence

This quantifies the probability for such a hazard to occur. It is estimated considering the intended use of the devices

1 – Incredible
2 – Unlikely
3 – Rare
4 – Occasional
5 – Likely
6 – Frequent

Level of Risk

(b)(4)

- **Intolerable (I) :** The risk is intolerable. Methods must be adopted to reduce the severity of the risk and/or its frequency of occurrence.
- **ALARP (L) :** As Low As Reasonably Possible region. Risk is tolerable only if the risk management cost (to further reduce the risk) is too high in comparison to the benefits.
- **Widely accepted (A) :** the risk is acceptable.

1.3 Risk Management

A mitigation method is to be given to each hazard according to its level of risk. The solution can be a design improvement, a modification of the labeling, a test or any other means.
It is important to be sure that the solution does not create a new hazard; otherwise, this new hazard must be assessed.

1.4 Groups of Analyze

The hazards are numbered with a letter followed by a number.
The letter represents the hazard group as specified below :

A. Chemical and biological related hazard
B. Electrical related hazard
C. Mechanical and Thermal related hazard
D. Environmental related hazard
E. Device performance (Software) related hazard
F. Inappropriate accessories related hazard
G. Labeling related hazard

2 Intended Use

The Sandman Pocket is intended for use in collecting and recording physiological data to be used in polysomnography and sleep disorder studies. This device may be used in the home or hospital setting. The Sandman Pocket is not intended for use as a life supporting equipment, such as a vital sign monitor in an intensive care unit. The device does not produce alarms and is not intended as an automated opera monitor.

The SANDMAN POCKET is an amplifier system that amplifies bioelectric signal captured through appropriate sensors attached to the surface of the human body, converts those signal in digital form and stores them on an on board memory. No compression mechanism is used. The recorded data can be passed to a host system through an USB standard connection. The device does not modify the signal with the obvious exception of its "analog" conditioning and the conversion in numeric form.

Target Population: The EBNeuro Sandman Pocket Amplifier is intended to be used on both the adult and pediatric populations, without exclusion of any pediatric subgroups (Neonatal, Infant, Child, Adolescent; ref. to *FDA Guidance for Industry and FDA Staff – Premarket Assessment of Pediatric Medical Devices*). EBNeuro design and technical specifications (input signal characteristics, sampling rates, etc) of the device have been developed in accordance to this assertion.

The Sandman Pocket is only for use under the direction or supervision of a physician, technologist or clinician.

3 General Hazard Analysis

The device carries a Minor Level of Concern: this assumption is based on the following factors:

- The possible risk or danger to the patient or user from use of the device.

  There is no risk of injury to the patient or operator due to the use of this device. It is powered by 3 internal 1,5 Volts, AA size dry cell batteries. The device is fully compliant with the requirements of the normative IEC 601-1 / IEC 601-1-1 (medical devices safety) and IEC 601-1-2:2003 (Edit. 2) (EMC)

- The degree to which the device can influence therapy or patient diagnosis.

  The device does not control, either directly or indirectly, any therapy administration. It does not monitor the status of critical physiologic parameters and has no alarming mechanism for this purpose. The device does not provide any patient diagnosis.

  The EBNeuro Sandman Pocket is only to be used under the direction and/or supervision of a physician, technologist or clinician. It does not perform any life supporting or life sustaining fuction.

  The device does not produce alarms and is not intended as an automated apnea monitor.

In conclusion, the SANDMAN POCKET system is a non invasive data-collecting device that poses no risk to the patient or to the operator.
The device is intended to collect and record on internal memory patient data collected using surface electrodes. The collected data can be later passed to a host system for its own purposes. The analysis performed by a clinician using the review and analysis software on the host system is outside of the scope of the SANDMAN POCKET system, whose role is to accurately and reliably acquire and store the mentioned data.

NOTE 1

The risk analysis has been conducted taking into account the devices intended use and in particular the following points:

a) The EBNeuro Sandman Pocket is not intended for the "end user", rather it is intended as an OEM product to be used by a "System Builder" as a piece of its own Medical Systems. It is the responsibility of the System Builder to use the EBNeuro Sandman Pocket Recorder strictly following any technical specification and precaution of use described in the Sandman Pocket OEM User Manual provided by EBNeuro.
b) EBNeuro is not providing any sensor, lead, cable, or any wearing system to the System Builder.
c) The Sandman Pocket, as manufactured by EBNeuro, is intended to be used both in adult and pediatric populations without exclusion of any pediatric subgroups (ie Neonatal, Infant, Child, Adolescent; ref. to *FDA Guidance for Industry and FDA Staff – Premarket Assessment of Pediatric Medical Devices*). EBNeuro design and technical specifications (input signal characteristics, sampling rates etc) of the device have been developed in

accordance with this assertion.
Due to the fact that EBNeuro is not providing any sensor, lead, cable, or any wearing system, it is completely under the responsibility of the System Builder to address any safety and effectiveness questions linked to the entire medical system he is "manufacturing"; in other words, the System Builder should conduct any risk management activities linked to the overall intended use and target population of its own medical system (for example, the risk linked to the accessories, any eventual wearing system and any related instruction and warnings against the correct connections and units/cable placement to avoid any possible strangulation risk). This applies in particular to the use of Sandman Pocked based system in pediatric studies.

The situation described in the above points is clearly stated in the Sandman Pocket labeling (EBNeuro Sandman Pocket OEM User Manual).

NOTE 2

The following risks have been evaluated and have been established as "not applicable" to the Sandman Pocket:

- Substances delivered/extracted from the patient.
- Biological material processed.
- Sterility (no applied part provided with Sandman Pocket).
- Modify the patient environment.
- Mechanical forces.

4 Electrical, Mechanical, Thermal and Environmental Hazard Analysis

The device fully conforms to the requirements of the IEC 601-1, IEC 601-1-1 and IEC 601-1-2:2003, so the hazard related to electrical safety aspect and environmental aspect (EMC) are briefly treated in this document due to the fact that the risk management is covered by the requirements of the mentioned normative. However, electrical safety risks will be listed in the summary table in the last section of this document (see section 5).
Only some hazards of these categories are briefly discussed below, for the others hazards (whose management is "covered" by the IEC 60601-1 or IEC 60601-1-2 conformance) refer directly to the summary table.

Hazard (B1- B2)

Electrical shock when using the device

Management

Device fully complies with IEC 60601-1- standards. (class II - BF type)

Hazard (B3)

Electrical shock when powering the unit through the host computer USB port

Management

Labeling clearly warns about this situation by imposing the use of an isolation transformer to feed the host computer.
However, if this precaution should be missed and the host computer meets EN 60950 Information Technology standards, the power feeding the Sandman Pocket is considered a "safe low voltage" so the probability to cause injuries may be considered at the limit of the "incredible" threshold.

Hazard (B4)

Battery inserted in the wrong way

Management

Power circuit designed in a way to be protected from the battery inversion. The device in this condition simply does not work. Any damage to the battery or to the device is avoided.

Hazard (D3)

Susceptibility in operating, transport or storage environment to temperature and humidity

Management

Device complies with IEC 60601-1 recommended temperature and humidity range both operating and storage (non-operating).

Labeling clearly indicates such limits.

Hazard (D4)

Use in presence of flammable anesthetic or oxygen enhanced environment.

Management

User Manual clearly warns about these situations and states not to use the unit in such environments.
If this restriction is not observed, the risk of fire is improbable because of the technology used in the Pocket. For examle, the Pocket is battery powered, very low power supply, and circuit or assembly that may cause ignition.

Hazard (A1 – A2)

Biocompatibility.

Management

No part of the Sandman Pocket is specified to be in direct and continuous contact with the patient body. However, the Sandman Pocket enclosure is made of non-toxic material (Polycarbonate). The Sandman Pocket recorder is provided without any applied parts (electrodes, sensors etc). EBNeuro only specifies that any accessory of the device should conform to FDA requirements for North America and European Directive 93/42/EEC for Europe. It is the responsibility of the system builder to conform to these requirements. Labeling (chapter 8) gives instructions and warnings related to the use of batteries (new or discharged) and the use of the Pocket in the event of a broken LCD display, which contains material that may irritate in the skin.

5 Manufacturing process related Hazard (D5)

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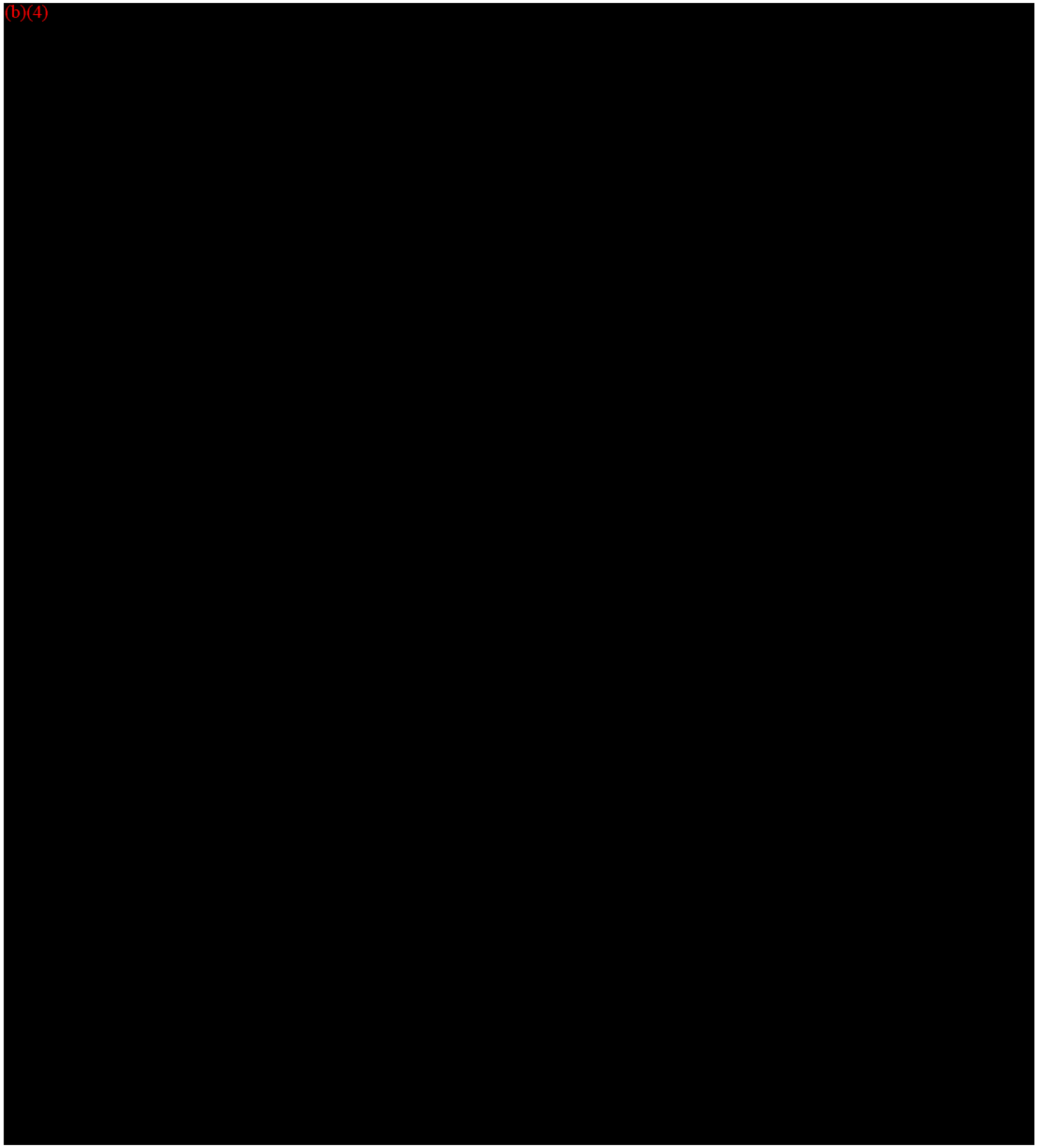

8 Software Hazard Analysis

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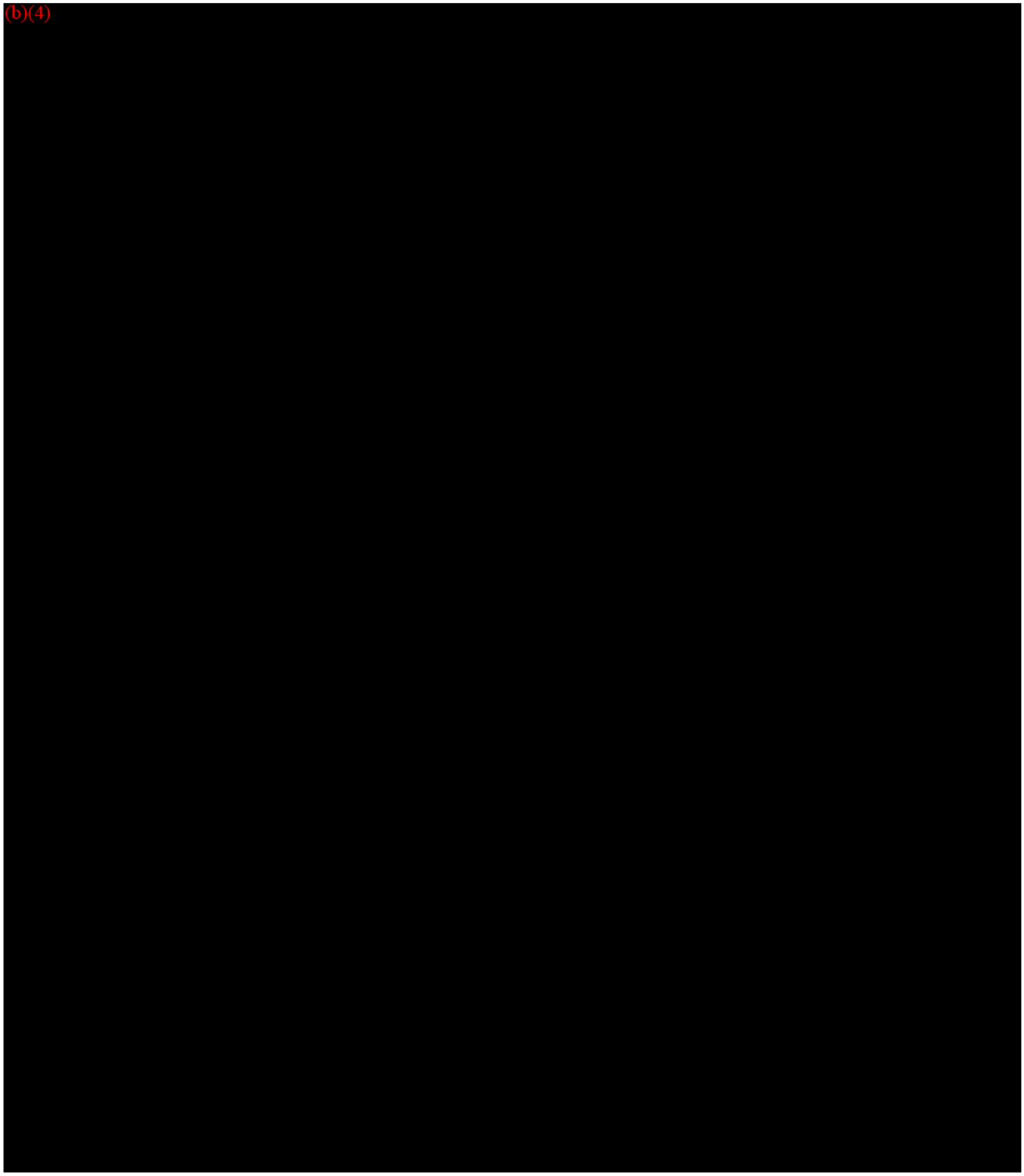

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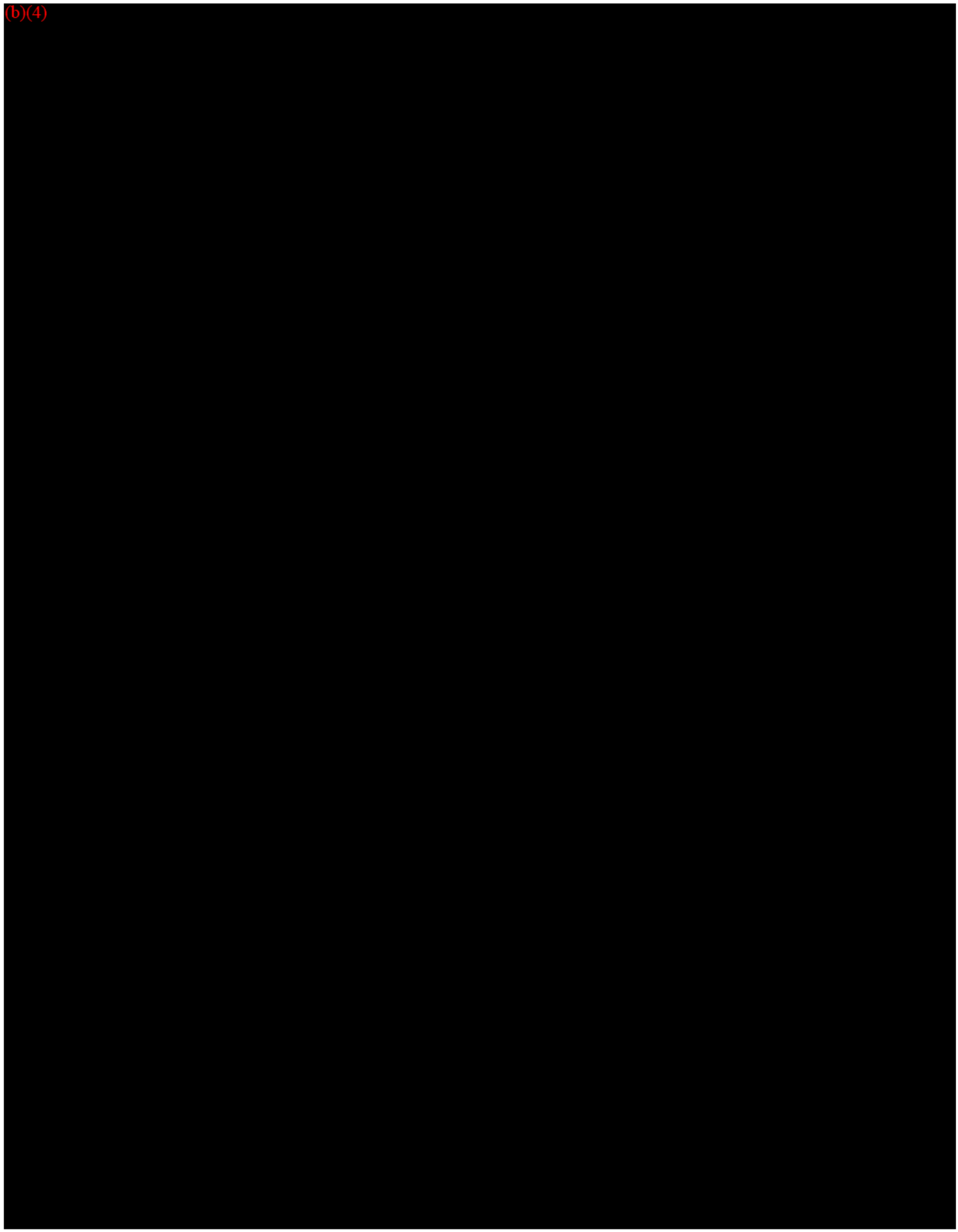

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CONCLUSION

The Sandman Pocket carries a **Minor Level of Concern.**

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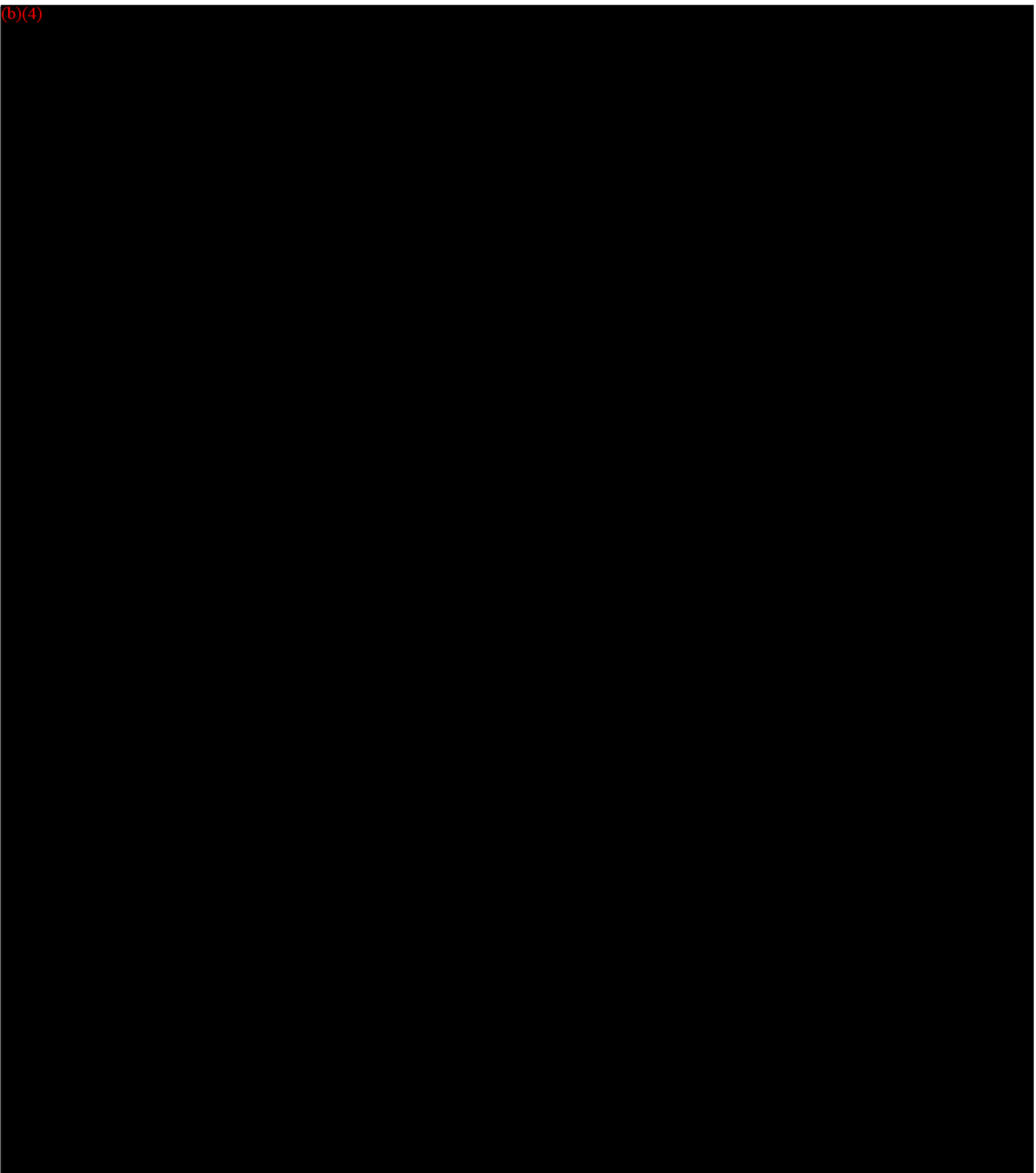

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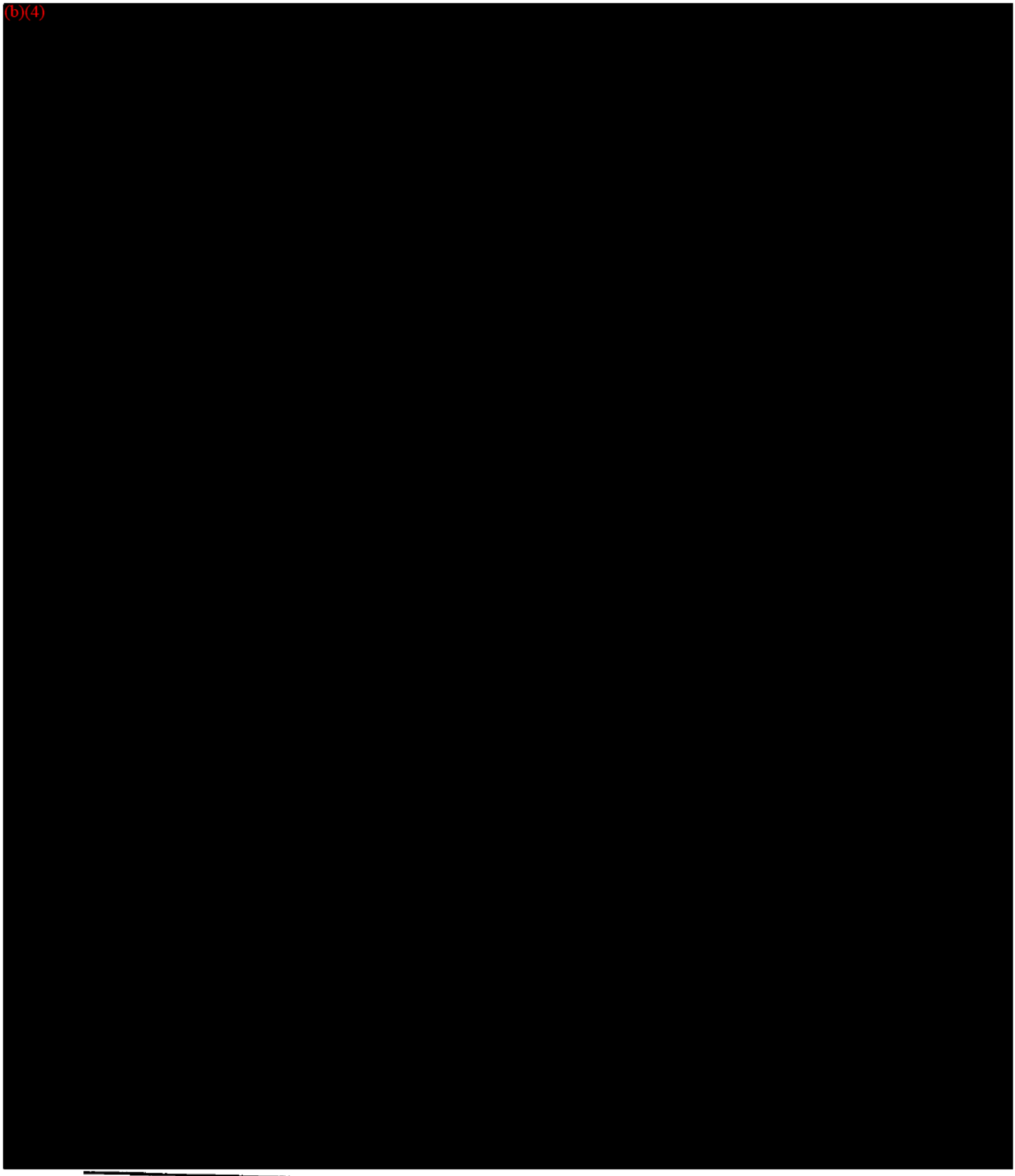

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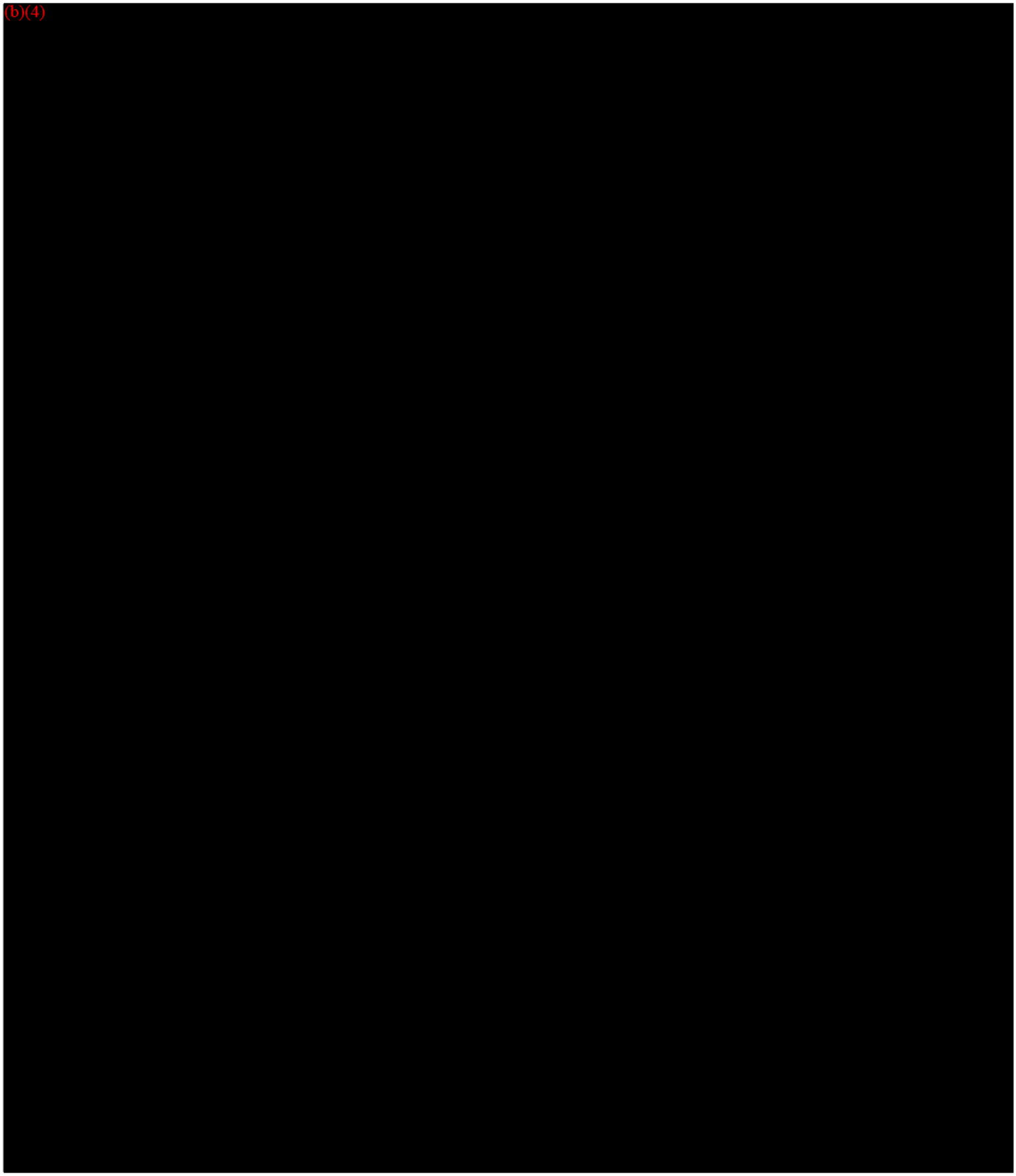

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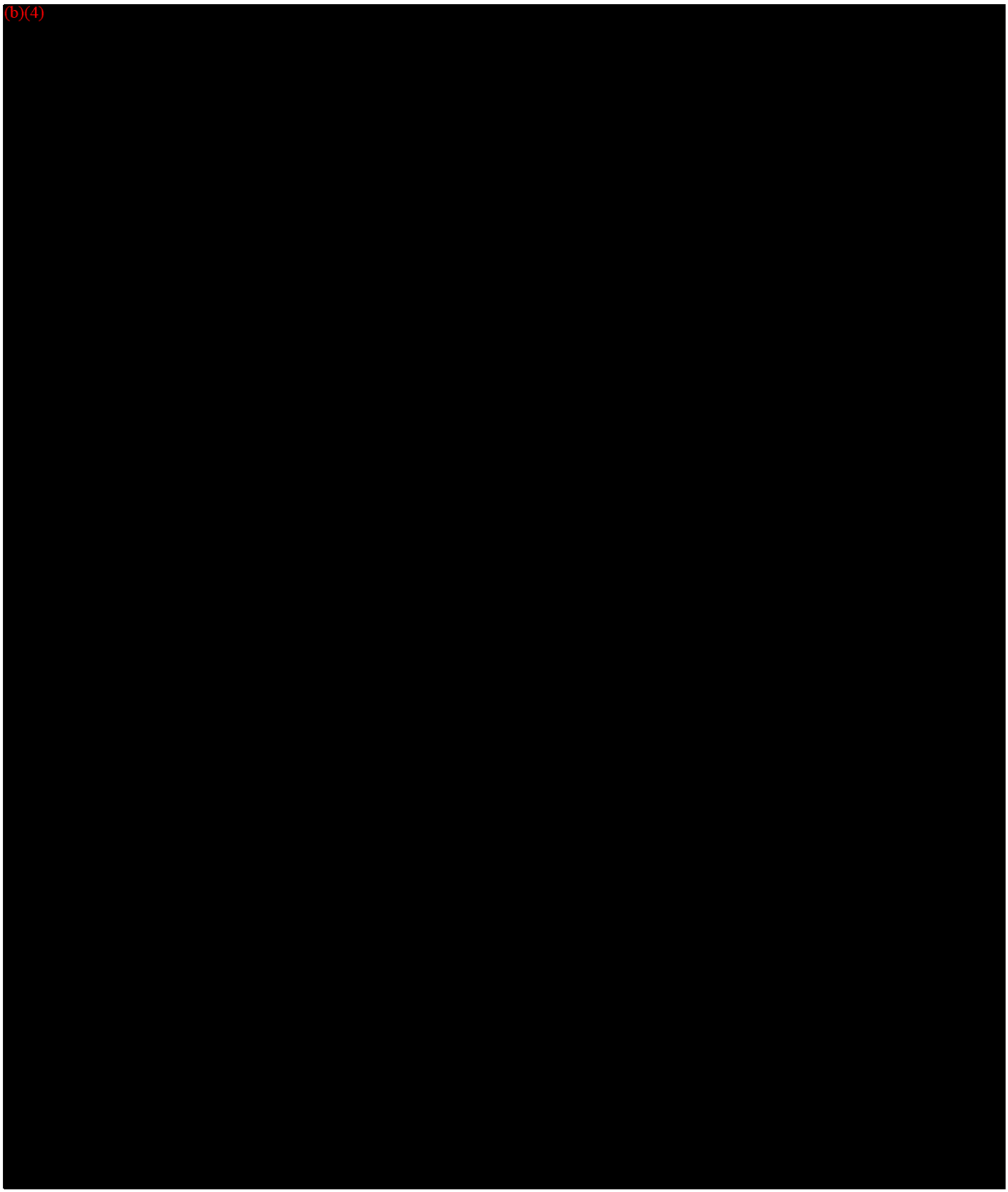

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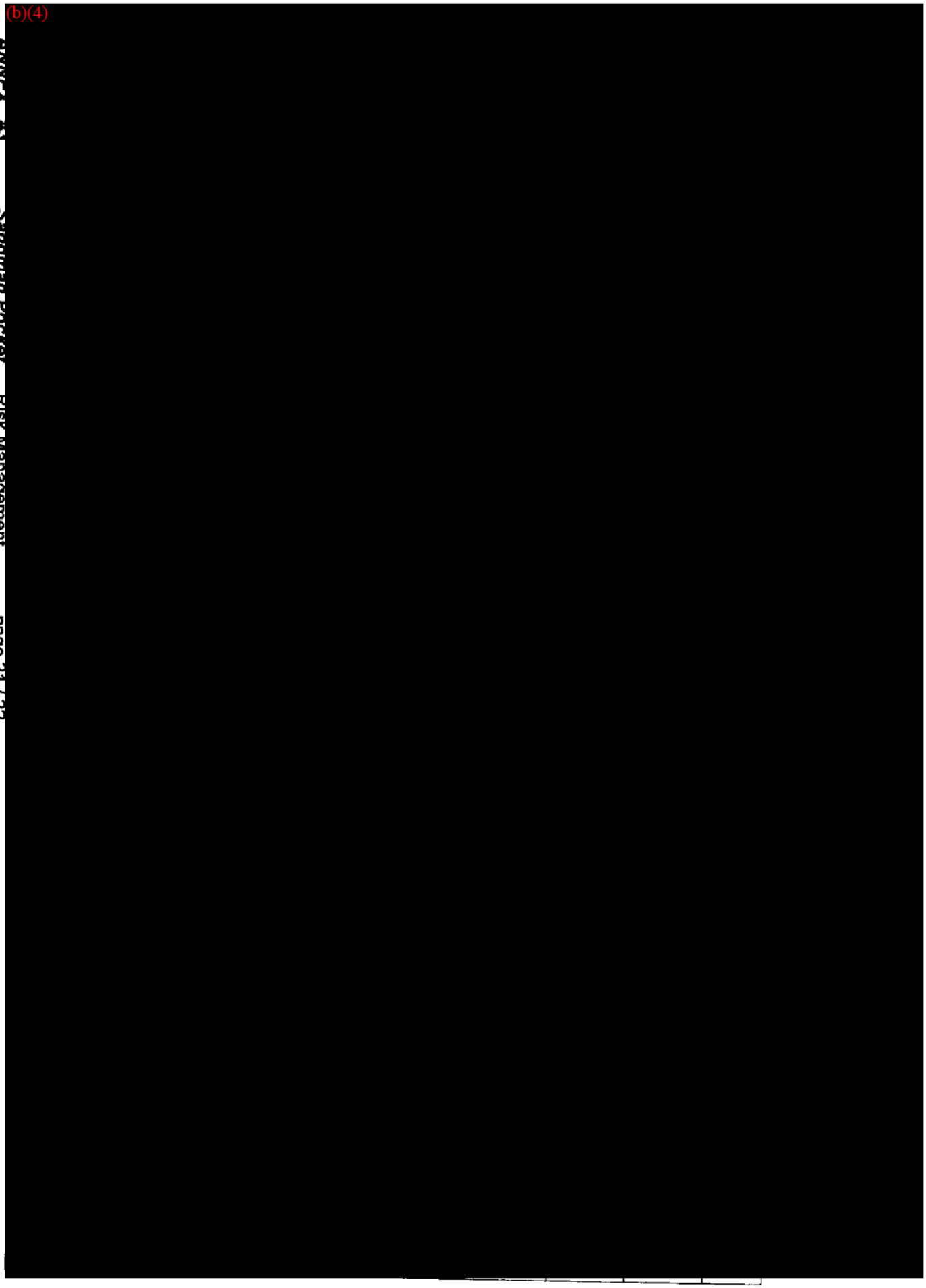

ANNEX #3 Sandman Pocket Risk Management page 21 / 22

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Direzione
Via Pietro Fanfani, III/A
50127 Firenze

Sede Legale:
Via Pietro Fanfani, III/A
50127 Firenze
Capitale Sociale Euro 765.000 int.vers.
CCIAA di Firenze R.E.A.493655
N.iscriz.Registro delle Imprese e
Codice Fiscale 01772220065
Partita IVA 04888840487

Sede Operativa:
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Sede Operativa:
Verona
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37020 Arbizzano di Valpolicella
Telefono:045/6028111
Telefax :045/6028100
produzione@ebneuro.com

Premarket Notification
Truthful and Accurate Statement

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Managing Director of EBNeuro SpA, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Signature

Ing. A. Torsoli – Managing Director
Name/Title

JUNE 08, 2005
Date

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510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR¶807.92(a).

807.92(a)(1)

Submitter Information

Carri Graham
Official Correspondent
The Anson Group
11460 N. Meridian St.
Suite 150
Carmel, IN 46032

Phone: (317) 569-9500 x 103
Facsimile: (317) 569-9520

Contact Person: Carri Graham

Date: June 12, 2006

807.92(a)(2)

Trade Name: Sandman Pocket

Common Name: Ventilatory Effort Recorder

Classification Name(s): Ventilatory Effort Recorder

Classification Number: MNR

807.92(a)(3)

Predicate Device(s)

Nellcor Puritan Bennett Inc. Respironics, IN	SUZANNE Alice 5	K990565 K040595

Additional Substantial Equivalence Information is provided in the following Substantial Equivalence Comparison Table.

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807.92 (a)(4)

Device Description

The *Sandman Pocket* is a physiological data recorder that is part of a polysomnography system. It consists of two units: the **Recorder Unit**, which stores the data and sends it to a USB port, and **Headbox Unit**, which is the connection point for all patient sensors with the exception of the Nellcor Puritan Bennett oximetry probe.

The role of the *Sandman Pocket* is only to capture the data and pass it to the host with the necessary accuracy and reliability according to the product and communication control specifications.

A fundamental characteristic of the *Sandman Pocket* is the ability to be an ambulatory/portable physiological data recorder. Because of its small size and light weight (about 210 grams including the battery), the system is compact and durable.

The **Headbox Unit** is used for connecting patient electrodes and sensors. It includes Bipolar channels, pressure sensors, power supply for a dedicated body position sensor, an abdomen sensor, a chest sensor, a snore sensor and a thermistor. The patient inputs are isolated with a CF type isolation level. The Sandman Pocket device is provided without standard sensors. The system builder should integrate the device with FDA cleared Nellcor Puritan Bennett sensors only and specified for the usage with NELL-1 module.

The **Headbox Unit** captures the biological signals from the human body surface through specialized sensors and electrodes, while the **Recorder Unit** amplifies the very low electrical signal and filters the signals to make an optimal ANALOG to DIGITAL conversion. The data, once converted in numerical form, are sent to a host computer for review and analysis. The host can "program" the amplifier behavior by setting the sampling frequency and the dynamic range allowed and so on.

The host computer reads the acquired data through a dedicated interchange protocol, and allows a clinician to analyze the data using sleep review analysis software, provided by the end user or system builder. The clinician must use an electrically isolated computer (with a medical grade isolation transformer or medical grade power supply) or battery-supplied laptop when the Sandman Pocket device is connected to the host PC and the patient is connected to the Sandman Pocket Headbox.

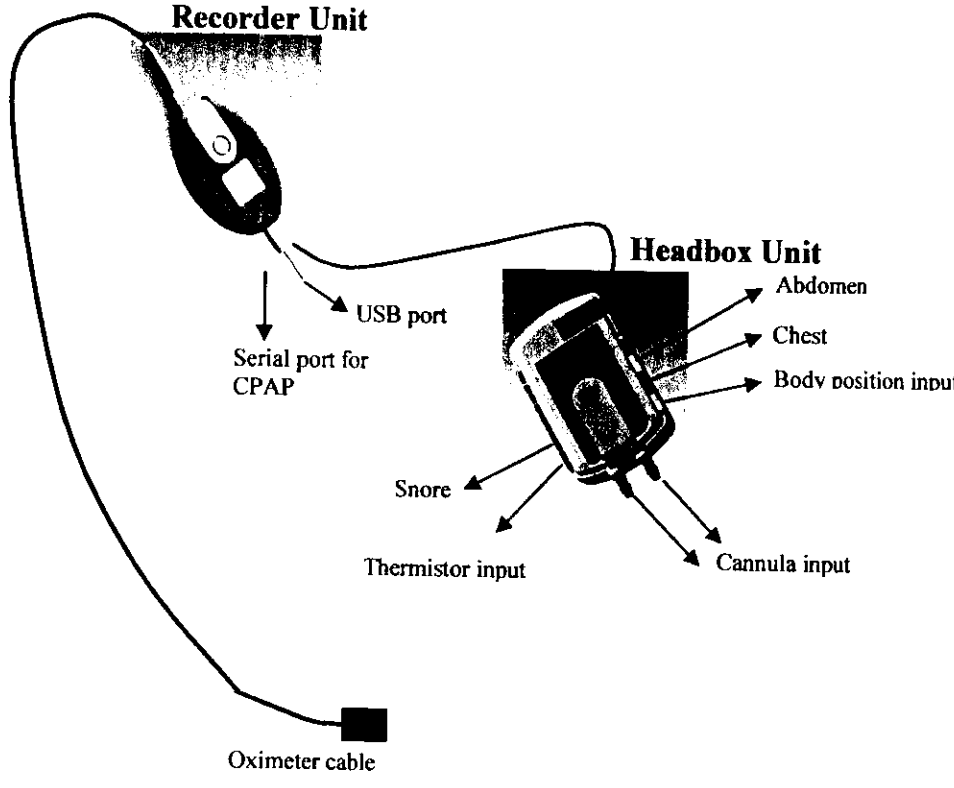
The *Sandman Pocket* system is not in any way involved in the data management performed by the host.
The host computer must operate using one of the following Operating System:
Microsoft Windows 98 / ME / NT / 2K / XP.

The device has a built-in impedance meter. This function allows the clinician to check the electrode contact impedance and display the results of the check on the display. The

display is located in the Recorder Unit, while the circuitry controlling the impedance meter is located in the Headbox Unit.

The *Sandman Pocket* can be powered through 3 Alkaline 1.5V standard non rechargeable batteries or via the USB cable. The user is recommended to use a medical grade type PC.

The *Sandman Pocket* system consists of two interconnected units: the Headbox Unit and the Recorder Unit.



SANDMAN POCKET System Connection Diagram

The **Headbox Unit** has the following functions:

- Physically connects the source of signals (the patient) to the amplifier.
- Provide impedance testing capabilities
- Provide Analog to Digital (A/D) conversion

The **Recorder Unit** has the following functions:

- Amplify and isolate signals coming from the electrodes
- Reference input channels
- Generate calibration pulse
- Provide dynamic range (gain), sampling rate and active channels selection
- Performs antialiasing filtering for optimal Analog to Digital conversion
- Provide, when requested, the Pulse Transition Time (PTT) calculation.
- Send the digital data through the USB interface to the host
- Provide the Oximeter option
- Manage the display
- Manage the Time
- Manage the batteries power supply

807.92(a)(5)

Intended Use(s)

The *Sandman Pocket* is intended for use in collecting and recording physiological data to be used in polysomnography and sleep disorder studies. The Sandman Pocket is intended for pediatric through adult patient populations, and can be used in either home or hospital environments.

The Sandman Pocket is not intended for use as life supporting equipment such, as a vital sign monitoring in an intensive care unit. The device does not produce alarms and is not intended as an automated apnea monitor.
The Sandman Pocket is only to be used under the direction or supervision of a physician, technologist or clinician.

807.92(a)(6)

Technological Characteristics
Substantial Equivalence Comparison Table

Product Characteristic	***Suzanne*** **(Predicate Device)** **Nellcor Puritan Bennet** **K990565**	***Alice 5*** **(Predicate Device)** **Respironics** **K040595**	***Sandman Pocket*** **(submission device)** **EB Neuro** **Via this Submission**
Regulatory			
Device class	Class II	Class II	Class II
Product code	MNR	GWQ	MNR
Device type	Ventilator Effort Recorder	Electroencephalograph	Ventilator Effort Recorder
Regulation Number	868.2375	882.1400	868.2375

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Product Characteristic	***Suzanne*** **(Predicate Device)** **Nellcor Puritan Bennet** **K990565**	***Alice 5*** **(Predicate Device)** **Respironics** **K040595**	***Sandman Pocket*** **(submission device)** **EB Neuro** **Via this Submission**
Labelling			
Intended use	Intended for use in collecting and recording physiological data to be used in diagnosing sleep disorders	Intended to record, display and print physiological information to clinicians/physicians. These parameters are presented graphically on a computer screen for diagnostic review, similar in application to the use of a traditional paper based polygraph recorder. The device will be used in hospitals, institutions, sleep centers or clinics, or other test environments where adult or infant patients require the documentation of various sleep or other physiological disorders. This device does not provide alarms and is not intended for use as an automated apnea monitor.	Intended for use in collecting and recording physiological data to be used in polysomnography and sleep disorder studies. For use in either home or hospital environments with a pediatric through adult patient population. This device does not provide alarms and is not intended for use as an automated apnea monitor
Target population	Pediatric through adult (excluding neonates and infants)	Pediatric through adult (including all pediatric subpopulations)	Pediatric through adult (including all pediatric subpopulations)
Environment of use	Hospital and home	Hospitals, institutions, sleep centers, or other test environments.	Hospital and home

Product Characteristic	***Suzanne*** **(Predicate Device)** **Nellcor Puritan Bennet** **K990565**	***Alice 5*** **(Predicate Device)** **Respironics** **K040595**	***Sandman Pocket*** **(submission device)** **EB Neuro** **Via this Submission**
Warnings	Items related to sensor irritation, strangulation avoidance and off-label use.	Items related to sensor irritation, strangulation avoidance, and off-label use.	Items related to sensor irritation, strangulation avoidance and off-label use.
Contraindications	Items related to design and indicated use limitations, such as not for use in the presence of flammable anesthetics or in conjunction with defibrillation equipment.	Items related to design and indicated use limitations, such as not for use in the presences of flammable substances or anesthetic mixtures with air oxygen or nitrous oxide, defibrillation, and MRI equipment, and not for use as automated apnea monitor or a continuous monitor.	Items related to design and indicated use limitations, such as not for use in the presence of flammable anesthetics or in conjunction with defibrillation equipment. The Sandman Pocket is not intended for use as life support equipment such as a vital sign monitoring in intensive care unit. The device does not produce alarms and is not intended as an automated apnea monitor. The Sandman Pocket is only to be used under the direction or supervision of a physician, technologist or clinician. It will not prevent or restore the interruption or loss of any physiological system.
Prescription status	Available only on the order of a physician.	Available only on the order of a physician.	Available only on the order of a physician.

Product Characteristic	***Suzanne*** **(Predicate Device)** **Nellcor Puritan Bennet** **K990565**	***Alice 5*** **(Predicate Device)** **Respironics** **K040595**	***Sandman Pocket*** **(submission device)** **EB Neuro** **Via this Submission**
Service instructions	No field service allowed.	No field service allowed.	No field service allowed.
Design			
Communication Interfaces	Physiological signals are sent to the Slow Wave and Fast Wave headbox through the sensor cables. The Slow Wave and Fast Wave headboxes sends the data to the Recorder Plus module where the data is stored either to a flash memory card or to a PC via a fiber optic interface.	Physiological signals are sent from the patient sensors to the headbox through the sensor cables. The data is sampled and sent to the base station where it is stored on a disk until it is sent through an Ethernet connection to a Host PC.	Physiological signals are sent from the patient sensors to the amplifier box through the sensor cables. The amplifier box sends the data to the recorder where the data is stored in flash memory in both attended and unattended studies. During attended studies, the data is also transmitted to a computer in real-time via a USB cable. After unattended studies, data can be downloaded from the recorder using a USB cable.
Microprocessor	Siemens 80C537 12 MHz	Unknown	Texas Instruments TMS320UC5402 on recorder Texas Instruments MSP430F169 on headbox
A/D Resolution	12 bit	16 bit	16 bit

Product Characteristic	***Suzanne*** **(Predicate Device)** **Nellcor Puritan Bennet** **K990565**	***Alice 5*** **(Predicate Device)** **Respironics** **K040595**	***Sandman Pocket*** **(submission device)** **EB Neuro** **Via this Submission**
Data recording	On PCMCIA card, magnetic disk or optical disk (via a personal computer).	Computer hard drive, compact disc, or transferred via Ethernet connection to a Host PC.	On internal NAND flash chip
Configuration	Desktop and wearable	Desktop only	Wearable
Amount of memory required for a typical 8 hour study.	20 MB	600 MB without audio/ video 6 GB with audio/video NOTE: Alice 5 can collect up to 21 neurological channels. These channels are recorded at very high sampling rates. In addition, Alice 5 records video at very high frame rates with no compression. These two factors contribute to the large study size. All data are stored to computer hard disk.	28 MB

Product Characteristic	***Suzanne*** **(Predicate Device)** **Nellcor Puritan Bennet** **K990565**	***Alice 5*** **(Predicate Device)** **Respironics** **K040595**	***Sandman Pocket*** **(submission device)** **EB Neuro** **Via this Submission**
Sampling rate	Slow waves : 12 samples/s Fast waves : 120 samples/s	Neurological channels 2000 samples/s	Fast waves: For example, ECG programmable up to 2048 sample/s Medium waves: For example, EMG, EOG, Snore programmable up to 1024 sample/s Slow waves: For example, airflow, respiratory effort, body position programmable up to 256 sample/s
Power	Battery powered (internal) or Medical Grade AC-DC Power Supply	Medical grade AC Power Supply	Battery powered or USB powered
Sensors	Commercially available sensors only	Commercially available sensors only	FDA Cleared sensors only

Product Characteristic	***Suzanne*** **(Predicate Device)** **Nellcor Puritan Bennet** **K990565**	***Alice 5*** **(Predicate Device)** **Respironics** **K040595**	***Sandman Pocket*** **(submission device)** **EB Neuro** **Via this Submission**
Performances			
Maximum number of channels	35	55	22
Recording channels			
EEG	Yes	Yes	Yes
EOG	Yes	Yes	Yes
EMG	Yes	Yes	Yes
ECG	Yes	Yes	Yes
Respiratory efforts	Yes	Yes	Yes
Airflow	Yes	Yes	Yes
Ambient sounds	Yes	Yes	No
Body position	Yes - internal	Yes - external	Yes - external
Ambient light	Yes - internal	No	No
SpO_2	Yes - internal	Yes - internal	Yes - internal
Pulse rate	Yes - internal	Yes - internal	Yes - internal
Plethysmograph	No	Yes	Yes
Differential pressure	Yes - internal	Yes - external	Yes - internal
Actimeter	No	Yes	No
Derived channel	N/A	Pulse Transit Time (PTT) – A calculation of the time between the occurrence of the R wave on the EKG and the peak flow on the plethysmogram. RR Interval – Measurement of the period of time between two consecutive R waves on the EKG. Displays as a real-time beat-to-beat heart rate calculation.	Pulse Transit Time (PTT) – A calculation of the time between the occurrence of the R-wave on the EKG and 50% ascending slope on the plethysmogram. Heart rate – Derived from the ECG channel

Product Characteristic	***Suzanne*** **(Predicate Device)** **Nellcor Puritan Bennet** **K990565**	***Alice 5*** **(Predicate Device)** **Respironics** **K040595**	***Sandman Pocket*** **(submission device)** **EB Neuro** **Via this Submission**
Passbands			
EEG	0.625 to 18 Hz	Neurological Channels 0.32 to 106 Hz	0.1 to 135 Hz
EOG	0.625 to 18 Hz		0.1 to 135 Hz
EMG	0.625 to 18 Hz		0.1 to 135 Hz
ECG	0.625 to 18 Hz		0.1 to 135 Hz
Respiratory efforts	0.055 to 1.25 Hz		0.1 to 45 Hz
Airflow	0.1 to 1.3 Hz		0.015 to 10 Hz
Ambient sounds	None		None
Pressure sensor	0 to 175 Hz		DC to 15 Hz
SpO_2	NPB proprietary		NPB proprietary
Pulse rate	NPB proprietary		NPB proprietary

Product Characteristic	***Suzanne*** **(Predicate Device)** **Nellcor Puritan Bennet** **K990565**	***Alice 5*** **(Predicate Device)** **Respironics** **K040595**	***Sandman Pocket*** **(submission device)** **EB Neuro** **Via this Submission**
CPAP (Continuous Positive Airway Pressure)	*Suzanne* supports all models of CPAP devices because the CPAP device connections were air-based rather than electrically based. Using a pneumotachograph kit, users could connect hoses and adapters to the CPAP device and the flow and pressure nipples on the *Suzanne* slow wave headbox to measure CPAP airflow and/or air pressure at the mask out-take during nasal CPAP/Bi-level titration.	*Alice 5* supports the use of all Respironics lab therapy devices: Aria LX BiPAP Pro Duet LX Harmony HeartPAP REMStar Auto REMStar Pro REMStar Pro with C-Flex Synchrony Virtuoso LX	*Sandman Pocket* stores data from Nellcor Puritan Bennett GK420E, GK425, and GK425ST CPAP devices. When the recorder is also connected to the host computer, the *Sandman Pocket* not only stores data in the on-board memory, but also acts as a passive bridge between the aforementioned GK CPAP and the host computer by receiving data streams from the CPAP and transmitting the data streams to the host computer and vice versa. When the *Sandman Pocket* is connected to a third party CPAP device and a host computer, *Sandman Pocket* acts as a passive bridge between the third party CPAP device and the computer by receiving data streams from the CPAP and transmitting the data streams to the host computer and vice versa. Alternatively, *Sandman Pocket* may also handle CPAP device connections in the same manner as Suzanne.

Product Characteristic	***Suzanne*** **(Predicate Device)** **Nellcor Puritan Bennet** **K990565**	***Alice 5*** **(Predicate Device)** **Respironics** **K040595**	***Sandman Pocket*** **(submission device)** **EB Neuro** **Via this Submission**
Mechanical safety	Device complies with the requirements of Nov' 93 Draft Reviewer's Guidance	Device complies with the International Standard IEC 60601-1 CSA C22.2 No. 601.1 EN 60601-1 UL 60601-1 AS 3200.1.0* *Australian Deviation to IEC 60601-1	Device complies with the International Standard IEC 60601-1 CSA C22.2 No 601-1-M90 UL 2601
Electrical safety	Device complies with the International Standard CSA C22.2 No. 601-1-M90 UL 2601 Device complies with the requirements of Nov' 93 Draft Reviewer's Guidance	Device complies with the International Standard IEC 60601-1 Guidance, when applicable, has been adopted from the following standards: IEC 60601-2-25 IEC 60601-1-26 IEC 60601-2-40 IEC 60601-2-49	Device complies with the International Standard IEC 60601-1 IEC 60601-1-4 IEC 60601-1-26 CSA C22.2 No 601-1-M90 UL 2601

Product Characteristic	***Suzanne*** **(Predicate Device)** **Nellcor Puritan Bennet** **K990565**	***Alice 5*** **(Predicate Device)** **Respironics** **K040595**	***Sandman Pocket*** **(submission device)** **EB Neuro** **Via this Submission**
Electromagnetic Compatibility (EMC)	Device complies with the following EMC standards IEC 60601-1 IEC 61000-4-2 IEC 61000-4-3 IEC 61000-4-6 Mil Std 462D IEC 61000-4-4 IEC 61000-4-5 EN55011 Class B Device complies with the requirements of Nov' 93 Draft Reviewer's Guidance	Device complies with the International Standard IEC 60601-1-2, including the following standards: CISPR 11 IEC 61000-3-2 IEC 61000-3-3 IEC 61000-4-2, IEC 61000-4-3 IEC 61000-4-4, IEC 61000-4-5, IEC 61000-4-6, IEC 61000-4-8 IEC 61000-4-11	Device complies with the International Standard IEC 60601-1- 2, including the following standards: IEC 61000-3-2 IEC 61000-3-3 IEC 61000-4-2 IEC 61000-4-3, IEC 61000-4-4, IEC 61000-4-5, IEC 61000-4-6, IEC 61000-4-8 IEC 61000-4-11 EN55011 class B EN55014-1

The following section is page numbered independently from the remainder of the submission.

1 System description

1.1 Background

The *SANDMAN POCKET Amplifier* is a portable multi-channel polysomnograph recording device that digitally amplifies physiological activity and records data onto an internal *NAND flash memory* chip or sends it directly to a PC via the *USB* port. The *SANDMAN POCKET* system is modular in design. It consists of a *Recorder* and, a data acquisition module called the "*Headbox*". This small, lightweight recording system is comfortable for the patient and simple for the clinician to set up.
The patient can sleep and move freely while recordings are being made, allowing the exams to be done in the patient's home. The acquired data can then be used as an aid in the diagnosis of sleep related disorders by a qualified physician.

The data are acquired by a combination of FDA cleared electrodes, sensors and transducers.
Signal types can include electrocardiogram, pressure, airflow, snore, respiratory effort, body position, oxygen saturation pulse rate and pulse waveform.

The *SANDMAN POCKET Amplifier* is manufactured by EBNeuro and intended for use in collecting and recording physiological data to be used in polysomnography and sleep disorder studies. The Sandman Pocket is intended for pediatric through adult patient populations and can be used in either home or hospital environments.

The *SANDMAN POCKET Amplifier* is not intended for direct use by a clinician but rather by a manufacturing company, which want to build a full sleep disorder collection, analysis and therapy system.

1.2 Device Evolution

The *SANDMAN POCKET Amplifier* is the result of the EBNeuro advanced design in this field. The *SANDMAN POCKET Amplifier* project was managed on the experience made by EBNeuro R&D staff in similar projects developed in the past.
Personnel involved in the design participated in the development of many other bioelectric amplifiers that are FDA and CSA cleared.

1.3 The SANDMAN POCKET Amplifier

The *SANDMAN POCKET Amplifier* is comprised of two main modules and can be used either in attended or unattended mode. A typical attended study configuration may include some or all of the following components:

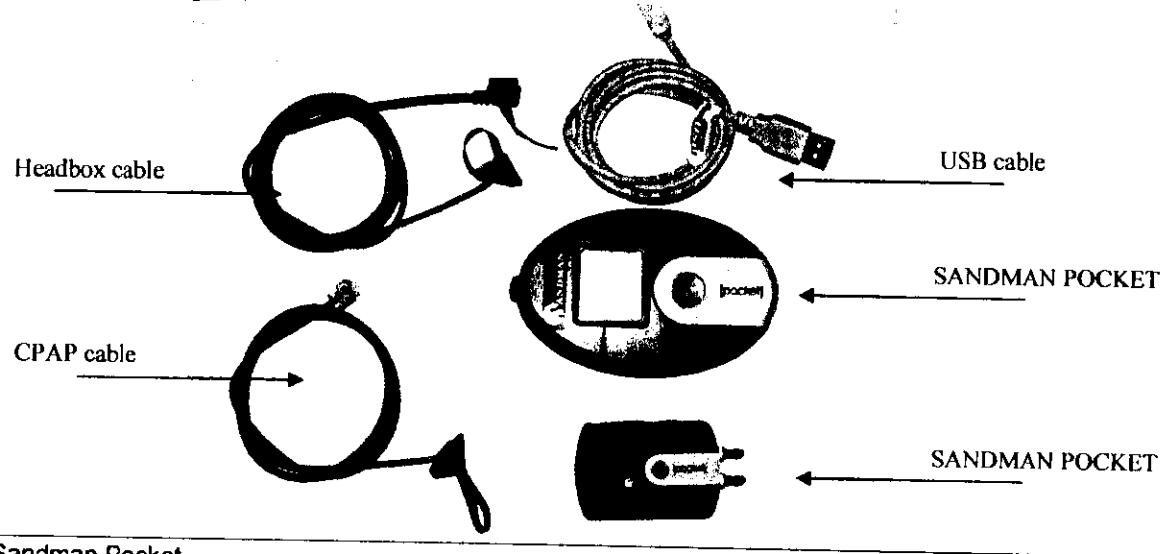
- SANDMAN POCKET Recorder
- SANDMAN POCKET Headbox
- Link cable Recorder – Headbox
- Link cable Recorder CPAP
- USB 2.0 High speed cable

All FDA cleared sensors with cables (effort belts, airflow sensor (thermistor), BreathSensor™ and BreathSensor™ Airflow Cable, microphone, Pneumotachograph kit, Nellcor®OxiMax™ oximeter extension cable and MAX-A OxiMax Sensor, and electrodes with jumper cables), wearing system (Recorder - Headbox pouch) are the responsibility of the System builder.

As specified above, the *SANDMAN POCKET Amplifier* can be used in Attended Mode - *Monitoring* or Unattended Mode – *Holter*.
During *Monitoring* mode, the amplifier is able to transfer data to the PC via the USB channel; polysomnograph signals are digitalized and simultaneously stored in the internal recorder memory while they are sent to the host computer.
Through the System builder display/analysis software tools, clinicians are able to monitor the polysomnograph signals from the SANDMAN POCKET, check the impedance of the electrodes, set up the patient preset, verify the amount of memory used, and download existing studies data.

During *Holter* mode, the *SANDMAN POCKET Amplifier* stores the digitalized polysomnograph signals in the internal memory according to the Patient preset configured by clinicians prior to sending the patient home with the Sandman Pocket Amplifier.

The *SANDMAN POCKET Amplifier* does not perform clinical analysis, nor does the SANDMAN POCKET Amplifier compute vital physiological parameters. The only computed parameter is the Pulse Transit Time (PTT) signal, which is derived using proven, widely recognized algorithms that calculate the time difference between R-wave of the QRS complex in ECG signal (the most prominent part of the ECG signal) and 50% of the ascending edge of the Pressure wave, as measuted by a pulse oximeter.



The Sandman Pocket

Figure 1: SANDMAN POCKET Amplifier

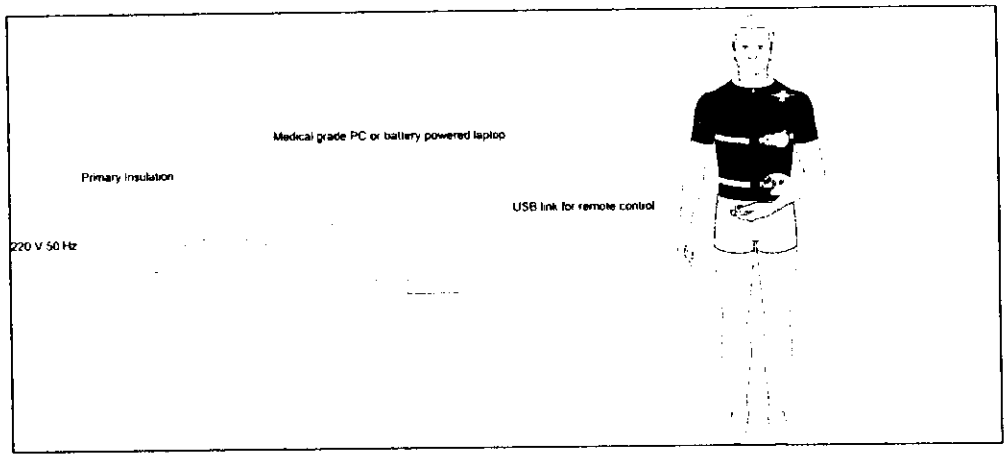


Figure 2: System setup

1.3.1 SANDMAN POCKET – Recorder

1.3.1.1 Interface

The SANDMAN POCKET Recorder is the central module of the SANDMAN POCKET Amplifier. It records data from the connected Headbox, the integrated FDA cleared Nell1 oximeter and the external optional CPAP module, to the internal NAND memory chip or to the PC via a USB 2.0 interface.

The SANDMAN POCKET Recorder operates with a safe USB power supply (battery powered laptop or desktop with medical grade insolation transformer) or with 3 dry cell AA batteries. The cable and batteries are adequately protected. The connectors on the USB cable are over-molded and with a unique number of pins, so the user cannot plug the cable into the wrong input. In addition, the USB connector has a plastic piece allowing easy insertion and prevention of the USB being inserted incorrectly- see Figure 3. The USB input is also protected with a rubber cup to limit dust and liquid ingress. The batteries are adequately protected by a removable battery cover, which is held firmly in place by a thumb-screw. The batteries' polarity is clearly marked and the hardware is protected against inversion. The FDA cleared Oximax sensor receptacle is polarized and can be protected with a rubber cap when not in use. A joystick allows the user to easily navigate the recorder sub-menus. Information is displayed on the graphical liquid crystal display (LCD), which is equipped with a backlight, to allow the users to view information on the display in poorly lit rooms.

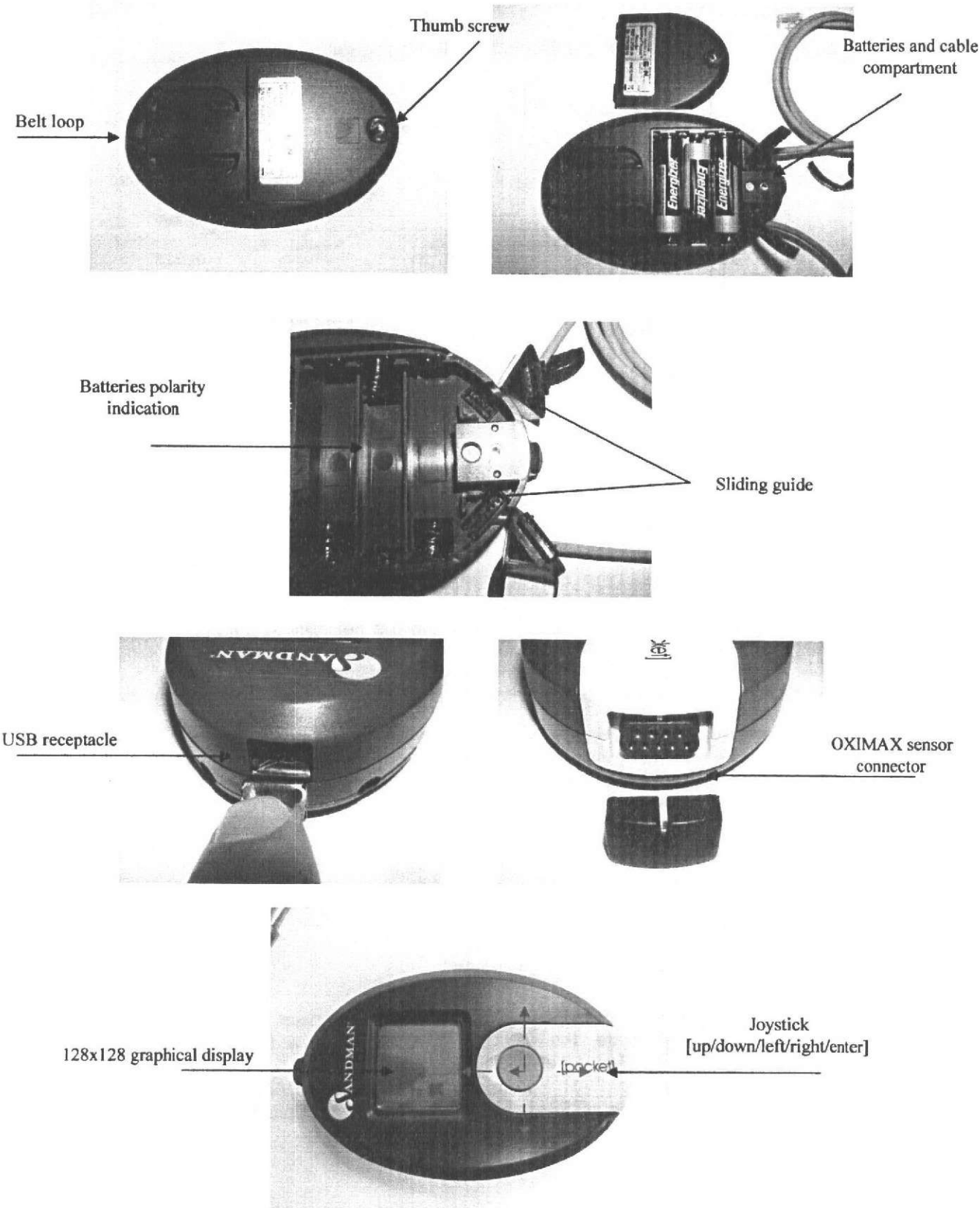


Figure 3: SANDMAN POCKET - Recorder interface

1.3.1.2 Subsystem

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1.3.1.2.1 DSP and Memory

(b)(4)

(b)(4)

[redacted]

1.3.1.3 USB Transceiver

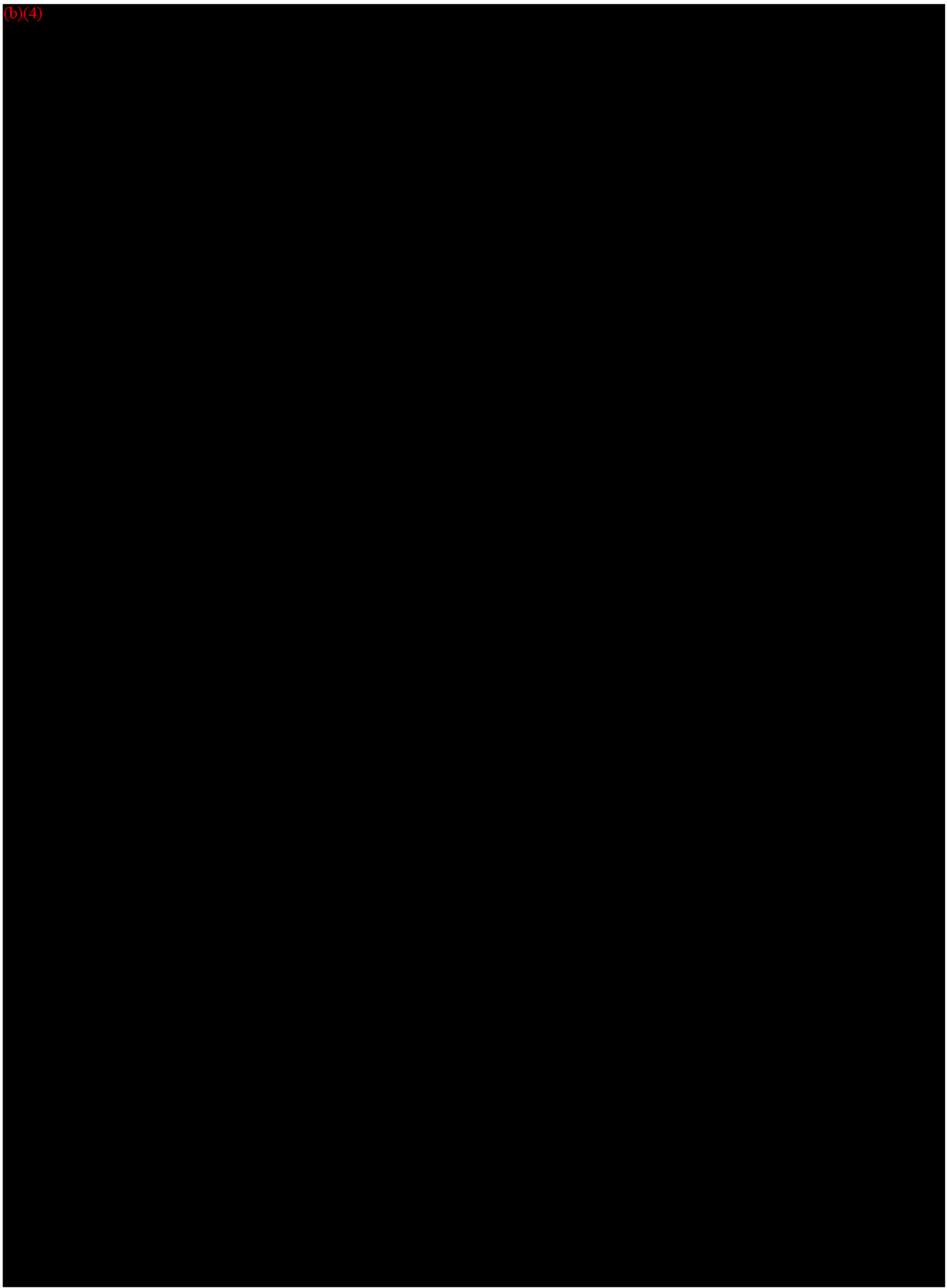
(b)(4)

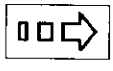
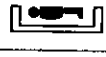
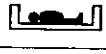
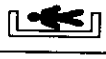
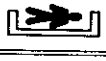
[redacted]

1.3.1.4 PLD

(b)(4)

[redacted]



Symbol	Description	Detail	Screen
	Selectable field	Using the Joypad control, the user can position a cursor in fields with this color background. When the cursor is in one of these fields the background color will turn black and the foreground image or text will turn white. This field can be used for softkeys or for text that can be edited.	All screens
	Currently valid Joypad control directions	Pressing the Joypad control in these directions causes the cursor to navigate to the next available field.	All screens
	Currently invalid Joypad control directions	Pressing the Joypad control in these directions does nothing.	All screens
	Downloaded File	Appears beside sleep study files that have been previously downloaded off of the Pocket Recorder (files without this icon have never been downloaded).	Data Management Screen
	File name or "tag"	Indicates the filename field	Study Setup Screen
	Start Time	User programmable time at which Pocket will begin recording sleep study data.	Study Setup Screen
	End Time	User programmable time at which Pocket will stop recording sleep study data.	Study Setup Screen
	"Start Now" softkey	The "Start Now" softkey will do nothing if the user has not entered a filename. When the cursor is in this field and the user presses down on the center part of the Joypad control, Pocket will begin to record data until the user presses the "Stop Now" softkey.	Study Setup Screen
		The "Start Now" softkey will look like this when the cursor is in this field.	Study Setup Screen
	"Stop Now" softkey	When the cursor is in this field and the user presses down on the center part of the Joypad control, Pocket will immediately stop recording data and finalize the current sleep study (this softkey will override any programmed Stop Time).	ALL Active Study Screens
		The "Stop Now" softkey will look like this when the cursor is in this field.	ALL Active Study Screens
	Oral/Nasal Cannula	Appears beside the trace that illustrates data captured at the Yoke's Cannula input.	Active Study Screen #1
	Thermistor	Appears beside the trace that illustrates data captured at the Yoke's Thermistor input.	Active Study Screen #1
	Snore Sensor	Appears beside the trace that illustrates data captured at the Yoke's Snore input.	Active Study Screen #1
	EKG	Appears beside the trace that illustrates data captured at the Yoke's EKG input.	Active Study Screen #1
	E-x-G1	Appears beside the trace that illustrates data captured at the Yoke's E-x-G1 input.	Active Study Screen #1
	E-x-G2	Appears beside the trace that illustrates data captured at the Yoke's E-x-G2 input.	Active Study Screen #2
	Body Position Sensor	Appears beside the image that illustrates data captured at the Yoke's Body Position input.	Active Study Screen #2
		Prone body position	Active Study Screen #2
		Supine body position	Active Study Screen #2
		Left side body position	Active Study Screen #2
		Right side body position	Active Study Screen #2

Symbol	Description	Detail	Screen
		Upright body position	Active Study Screen #2
	Chest Effort Belt	Appears beside the trace that illustrates data captured at the Yoke's Chest Effort Belt input.	Active Study Screen #2
	Abdominal Effort Belt	Appears beside the trace that illustrates data captured at the Yoke's Abdominal Effort Belt input.	Active Study Screen #2
	USB Connection Status		Active Study Screen #3
	⊘	There is no valid USB connection present	Active Study Screen #3
	♩	USB power is present, but, communication is not available. May indicate that Pocket is being correctly powered but the USB port is experiencing communication problems.	Active Study Screen #3
	♩♩	Both USB power and communication are present and functioning.	Active Study Screen #3
	CPAP data; channels 1 through 3		Active Study Screen #3
	◆	Appears to the right of CPAP channel 1's data.	Active Study Screen #3
	●	Appears to the right of CPAP channel 2's data.	Active Study Screen #3
	▲	Appears to the right of CPAP channel 3's data.	Active Study Screen #3
	CPAP data; channels 4 through 6		Active Study Screen #3
	☆	Appears to the right of CPAP channel 4's data.	Active Study Screen #3
	△	Appears to the right of CPAP channel 5's data.	Active Study Screen #3
	⬡	Appears to the right of CPAP channel 6's data.	Active Study Screen #3
	CPAP data; channels 7 & 8		Active Study Screen #3
	■	Appears to the right of CPAP channel 7's data.	Active Study Screen #3
	▬	Appears to the right of CPAP channel 8's data.	Active Study Screen #3
	MP100 Blood Oximetry Data		Active Study Screen #3
		Appears to the right of SpO_2 data received from the MP100. This data is shown in percent saturation (%).	Active Study Screen #3
	♥	Appears to the right of Pulse data received from the Oximax Sensor linked to the NELL-1 internal oximeter module. This data is shown in beats per minute (bpm).	Active Study Screen #3

Table 2: SANDMAN POCKET Symbols

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1.3.1.6 Switching ON or OFF

The SANDMAN POCKET recorder can operate from 3 dry cell AA batteries or from the safe +5V USB power supply.
If the unit operates from batteries, the power on/off is controlled by the internal programmable self-powered RTC (coin battery) through the enter joystick function. Holding the enter button for more than 2 seconds turns the unit on/off.
If the unit is connected to the PC via the USB cable, the connection is automatically recognized and unit starts up.
The last power up function is the programmable sleep function. Clinicians can program a delayed start up, within 12 hours from the patient setup. In this case, the unit enters sleep mode and automatically "wakes up" when the internal RTC time matches the programmed start time.

1.3.1.7 Nell 1 Oximeter

The SANDMAN POCKET recorder is equipped with the Nell 1 oximeter board, based on Nellcor OxiMax technology, which is featured in the Nellcor Puritan Bennett line of the FDA cleared OxiMax devices (K012891).
In the past, the pulse oximeter, monitor housed the sensor calibration information, and sensor designs had to conform to the preprogrammed data in order to calculate function oxygen saturation

in arterial hemoglobin (SpO2). With the OxiMax technology, Nellcor Puritan Bennett has moved the calibration and operating characteristics for its particular design.

With the OxiMax is a system in the NELL-1 pulse oximeter board which uses the calibration data contained in Nellcor brand OxiMax sensors when calculating the patient's SpO2. Using the calibration data from the individual sensor rather than the pulse oximeter board significantly improves the accuracy of the information and the number of sensors that may be used with the pulse oximeter board, because the calibration coefficients used in the calculations are tailored to the specific sensor.

The NELL-1 is designed to enable the finished Host system to meet or exceed EMC and safety standards for medical devices and is designed to meet the following standards:

- Magnetic Field Emissions per RE101, MIL-STD-461
- Radiated Emissions [CISPR 11, Class B, Group 1] per IEC 60601-1-2:2001 section 36.201.1
- Conducted Emissions [CISPR 11, Class B, Group 1] per IEC 60601-1-2:2001 section 36.201.1
- ESD per IEC61000-4-2 level 3 table top equipment, with the modifications listed in
- IEC 60601-1-2:2001 section 36.202.2b
- Radiated RF Immunity per IEC 61000-4-3 level 3, with the modifications listed in
- IEC 60601-1-2:2001 section 36.202.3b
- Conducted EM Immunity per IEC 61000-4-6 level 2, with the modifications listed in IEC 60601-1-2:2001 section 36.202.6b
- Magnetic Field Immunity per MIL-STD-461, RS101
- Quasi Static Electric Fields per FDA Reviewers Guidance for Premarket notification Submission, November 1993 (h)(7)(ii)(f), (m)(7)(ii)(f)
- Component and Material Flammability per UL544 to achieve 94V-2
- Pulse Oximetry per EN 865:1997, ASTM 1415:1992 and ISO 9919:92

The SANDMAN POCKET Recorder collects the data coming from the NELL 1 UART channel and stores the data in the internal memory.

1.3.1.8 CPAP option

The SANDMAN POCKET recorder is able to collect data from the Nellcor Goodknight CPAP 42x series.

1.3.1.9 PTT calculation

(b)(4)

[redacted]

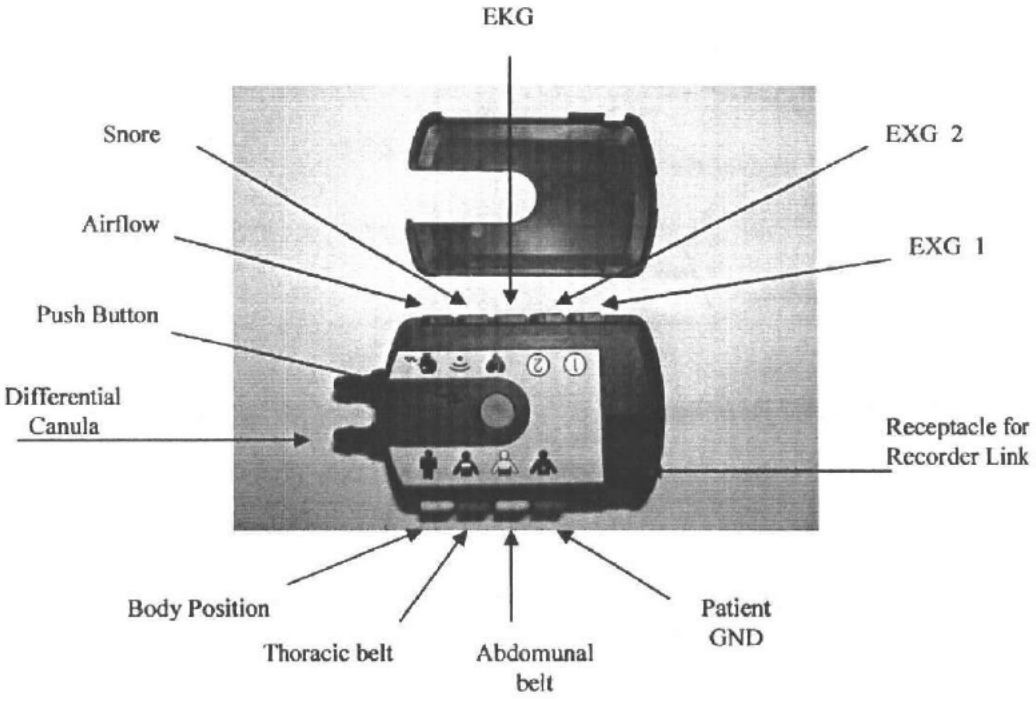
(b)(4)

1.3.2 SANDMAN POCKET Headbox

The SANDMAN POCKET headbox is used to acquire various physiological signals from the patient.
Supported connections are:

- Airflow (nasal and oral using a reusable thermistor or disposable BreathSensor™),
- Respiratory effort belts (thorax and abdominal)
- Ambient noise/snoring
- Body position
- EEG
- 2x EXG
- Snore
- Pressure (Canula)

All the bioelectric channels are bipolar with each lead referenced to the other. Connectors are 1.5 mm touch proof connectors from Plastics One.
As previously stated all sensors with cables (effort belts, airflow sensor (thermistor), BreathSensor™ and BreathSensor™ Airflow Cable, microphone, Pneumotachograph kit, Nellcor®OxiMax™ oximeter extension cable and MAX-A OxiMax Sensor, and electrodes with jumper cables), wearing system (Recorder - Headbox pouch) are responsibilities of the System builder.



1.3.2.1 SANDMAN POCKET Headbox internal architecture

(b)(4)

[redacted]

Figure 6: SANDMAN POCKET Headbox subsystem

(b)(4)

Figure 7: ADG 627 internal schematics

(b)(4)

2 System Performance

2.1 Recorder and Headbox

Product name **SANDMAN POCKET**

Configurations The acquisition system comprises two units:

- **B 970 0065 400: SANDMAN POCKET recorder**
- **B 963 0065 400: SANDMAN POCKET headbox**

Description Active, non-invasive medical device

Intended use Intended for use in collecting and recording physiological data to be used in polysomnography and sleep disorder studies. The Sandman Pocket is intended for pediatric through adult patient populations and can be used in either home or hospital environments.

Classification according to MDD 93/42/EEC
Class II b

Standards applied

93/42/EEC	Medical Device European Directive (MDD);
EN 60601-1	General safety standard for electromedical equipments;
EN 60601-1-2	Collateral safety standard for devices EMC test;
EN 60601-1-4	Safety standard for devices containing Programmable systems;
EN 60601-2-26	Standard on particular safety requirements for electroencephalographs

Type of protection against electric shocks
Class III equipment when internally powered with battery.

(Class I when powered by +5V retrieved from the USB port of a Class I Medical grade PC).

Protection level against electrical direct and indirect contacts

CF type (patient inputs)
B type (auxiliary communication channel)

Protection level against inflow of solids and liquids

Common (IP22)

Operational mode: Continuous, within the specified limits

Power on mode:
- Through enter key (hold more than 2 seconds).
- Programmable within 12 hours.

Power off mode:
- Through enter key (hold more than 2 seconds). Unavailable during the recording session.
- Automatic at the end of the recording

Environmental conditions for usage

- Temperature:
- Relative humidity:
- Atmospheric pressure:

(b)(4) [redacted]

Environmental conditions for storage (max. 15 weeks)

- Temperature:
- Relative humidity:
- Atmospheric pressure:

(b)(4) [redacted]

External dimensions and weight

Recorder:

Height:
Width:
Depth:
Weight:

Headbox:

Height:
Width:
Depth:
Weight:

(b)(4) [redacted]

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Device rated values

Manufacturer:	EBNeuro S.p.A.
Model:	SANDMAN POCKET
Code (REF):	B9700065400
Year of manufacture	
Serial Number (SN)	
CE0051 mark (93/42/EEC)	
cCSAus mark	

SANDMAN POCKET channels:
Total n° of channels: 22

Analog Channels: 9

Thermistor:	dedicated transducer channel
Chest:	dedicated transducer channel
Abdomen:	dedicated transducer channel
Snore:	dedicated transducer channel
Body Position:	dedicated transducer channel
Canula:	dedicated air flow channel
EXG1:	Bio-Electric AC/DC channel
EXG1:	Bio-Electric AC/DC channel
EKG:	Bio-Electric AC channel

Digital Channels: 13

PTT:	computed channel from EKG and P_WAVE
SPO2:	from Nell 1 oximeter
Rate	from Nell 1 oximeter
Pleth:	from Nell 1 oximeter
Pressure/2:	from CPAP
BPM:	from CPAP
IER:	from CPAP
TEMP:	from CPAP
Rough Flow:	from CPAP
Flow:	from CPAP
Filtered Flow:	from CPAP
Pressure Slope:	from CPAP

Impedance measurement	By means of injected current (16 Hz - 0.01 μA/electrode) results displayed in the LCD
A/D conversion	16 bits SAR A/D

Resolution, Dynamic and Noise

(b)(4)

[redacted]

High-Pass filters (1st order filter)

EKG, SNORE, CHEST selectable 0.099 Hz or 0.99 Hz

EXGx channels: selectable DC or 0.099 Hz or 0.99 Hz.

Anti-aliasing Low-Pass filters (3th order filter)

Frequency cut (b)(4) [redacted]

Low-Pass filters (A/D converter output)

Frequency cut (b)(4) [redacted]

Selectable Sampling Rate

[Hz]	128	64	32	16	8	4	2	1
Thermistor	(b)(4) [redacted]							
Chest								
Abdomen								
Snore								
Body Position								
Canula								
EXG1								
EXG1								
EKG								

(b)(4)

Sampling Skew

(b)(4)

IMRR (b)(4)

Amplifier box – PC interface (b)(4)

compliant

I/O connections

Headbox: (b)(4)

Recorder: (b)(4)

Other interface:

Headbox:

Recorder:

(b)(4)

Power supply:

Consumption

Case

2.2 Calibration

The system provides two types of calibration

2.3 Physical system calibration

(b)(4)

[redacted]

2.4 System Record Calibration

(b)(4)

[redacted]

Software Description

The information in this section is given in accordance with the "Guidance for the Content of Premarket Submission for Software Contained in Medical Device" issued by FDA on May 11, 2005. See "Software Information" document.

3 Device Hazard Analysis

A Hazard Analysis has been performed. See "Risk Analysis" document.

Actions related to design, labeling and testing were implemented in each case to control the probability and impact of the identified hazards. As a result, all risks are controlled at an acceptable level.

EBNeuro asserted that the device carries a Minor Level of Concern based on the following factors:

- (b)(4)
- [redacted]

In conclusion, the *SANDMAN POCKET Amplifier* is a non invasive data-collecting device that poses no risk to the patient or to the operator.

4 Design Specification

Hardware design specifications are included in the document MCRD A00 from Nellcor Puritan Bennet company, which is included in this submission.
The software carries a minor level of concern.

5 Traceability Analysis

Traceability of the product will be carried following the EBNeuro Quality Procedure PQ-07-05-03.
The software carries a minor level of concern.

6 Development

Development has been carried following the EBNeuro Quality Procedures PQ-07-01-01, PQ-07-03-01, PQ-07-03-03, PQ-07-03-03, PQ-07-03-04 and PQ-07-03-05 and related Internal Technical Standards.
The software carries a minor level of concern.

7 Validation, Verification and Testing

The firmware has been tested in accordance to the Project Test Plan as required by EBNeuro internal Quality Procedure PQ-07-03-01 and PQ-07-03-02 and related Internal Technical Standard (B8390031000 NT).
The result of testing is asserted in the related RS test reports.

8 Revision Level History

Revision History will be carried following the EBNeuro Quality Procedures PQ-07-01-01, PQ-07-03-01, PQ-07-03-03, PQ-07-03-03, PQ-07-03-04 and PQ-07-03-05 and related Internal Technical Standards.
The software carries a minor level of concern.

9 Unresolved Anomalies

The software carries a minor level of concern.

10 Release Version Number

The software was released with the version number 01.00

REVISIONS			
SYM	DESCRIPTION	DATE	APPROVAL
C	RELEASE/CHANGE PER ECO-R154335	10/27/05	CMW/CXH

NELL-1
HOST INTERFACE SPECIFICATION

		PROPRIETARY & CONFIDENTIAL	THIS DOCUMENT MAY NOT BE COPIED, DISCLOSED, OR USED IN WHOLE OR IN PART WITHOUT THE CONSENT OF NELLCOR PURITAN BENNETT INCORPORATED.		
NO. REQ'D.	NEXT ASSEMBLY	TITLE: SPECIFICATION, HOST INTERFACE, NELL-1		NELLCOR PURITAN BENNETT 4280 Hacienda Drive Pleasanton, California 94588	
DIMENSIONAL TOLERANCES UNLESS OTHERWISE NOTED					
DEC.	FRAC. ANG.	DRAFTER K. Sawatari DATE 05/10/04		FILENAME: 068681C00.DOC	
.XX ±	± ±	ENGINEER K. Sawatari DATE 05/10/04	A	DRAWING NUMBER	REV.
		CHECKED K. Sawatari DATE 05/10/04		068681	C
.XXX ±	SCALE	APPROVED D. Bordon DATE 05/25/04		SHEET 1 OF 56	

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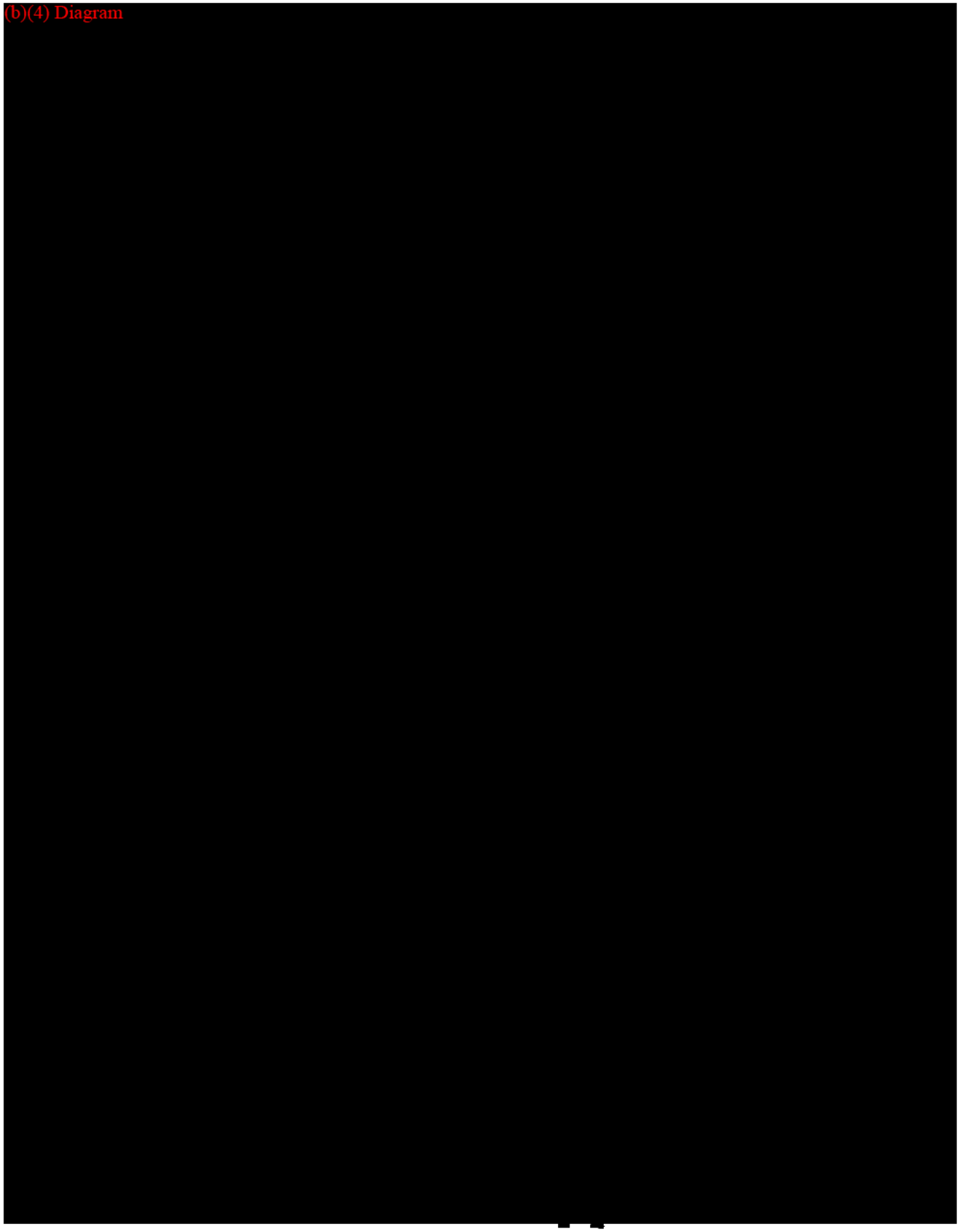
(b)(4) Diagram

(b)(4) Diagram

(b)(4) Diagram



(b)(4) Diagram

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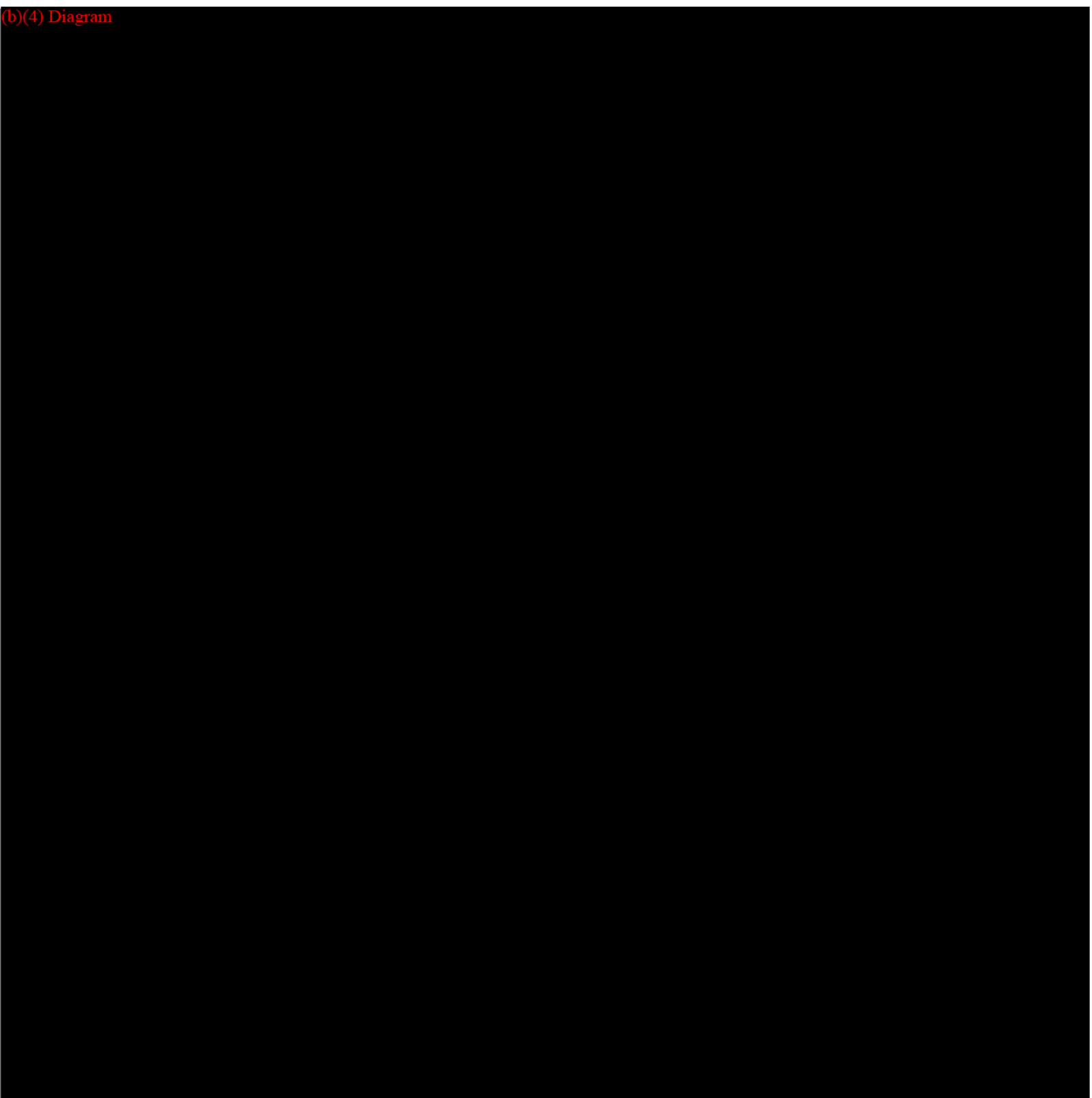

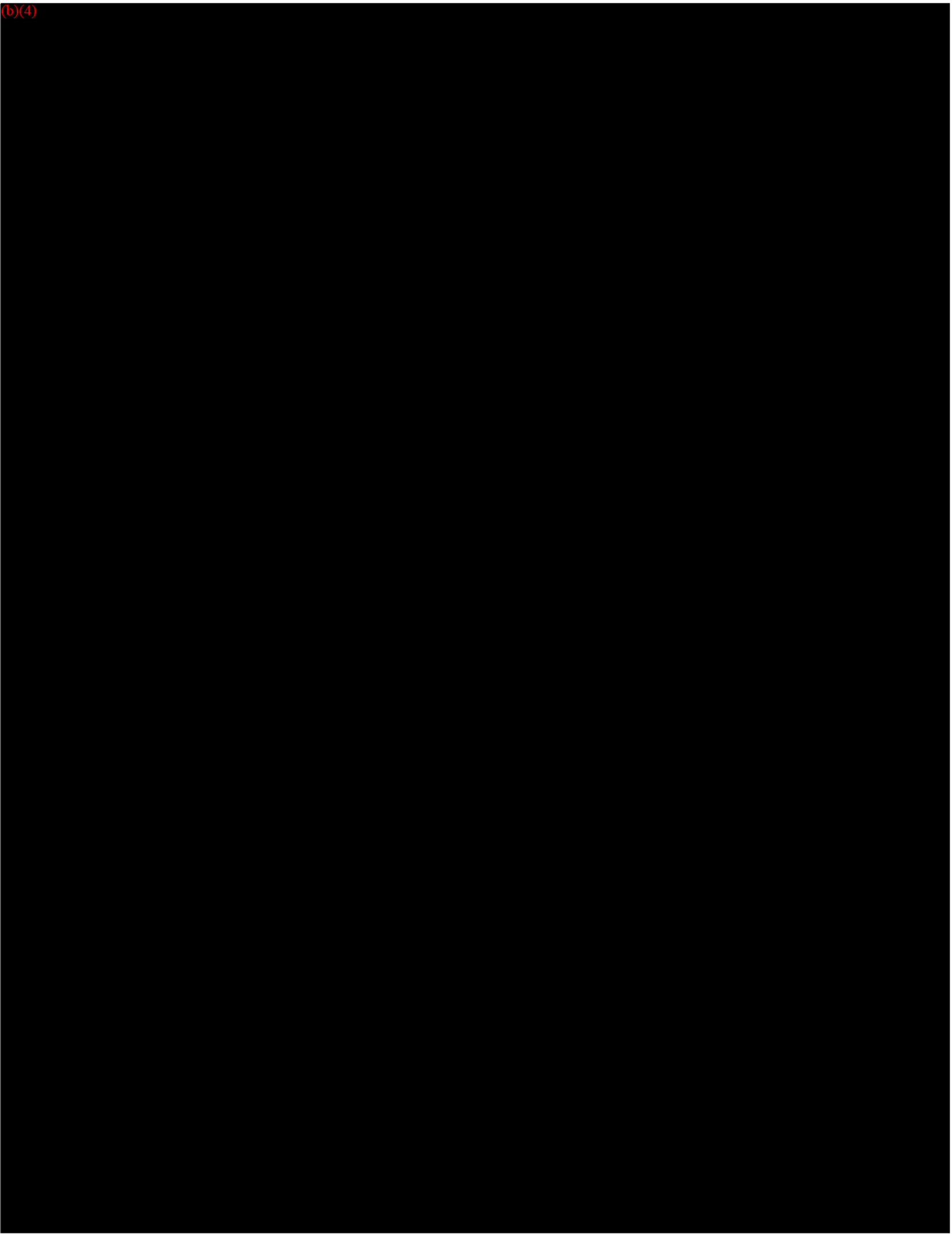
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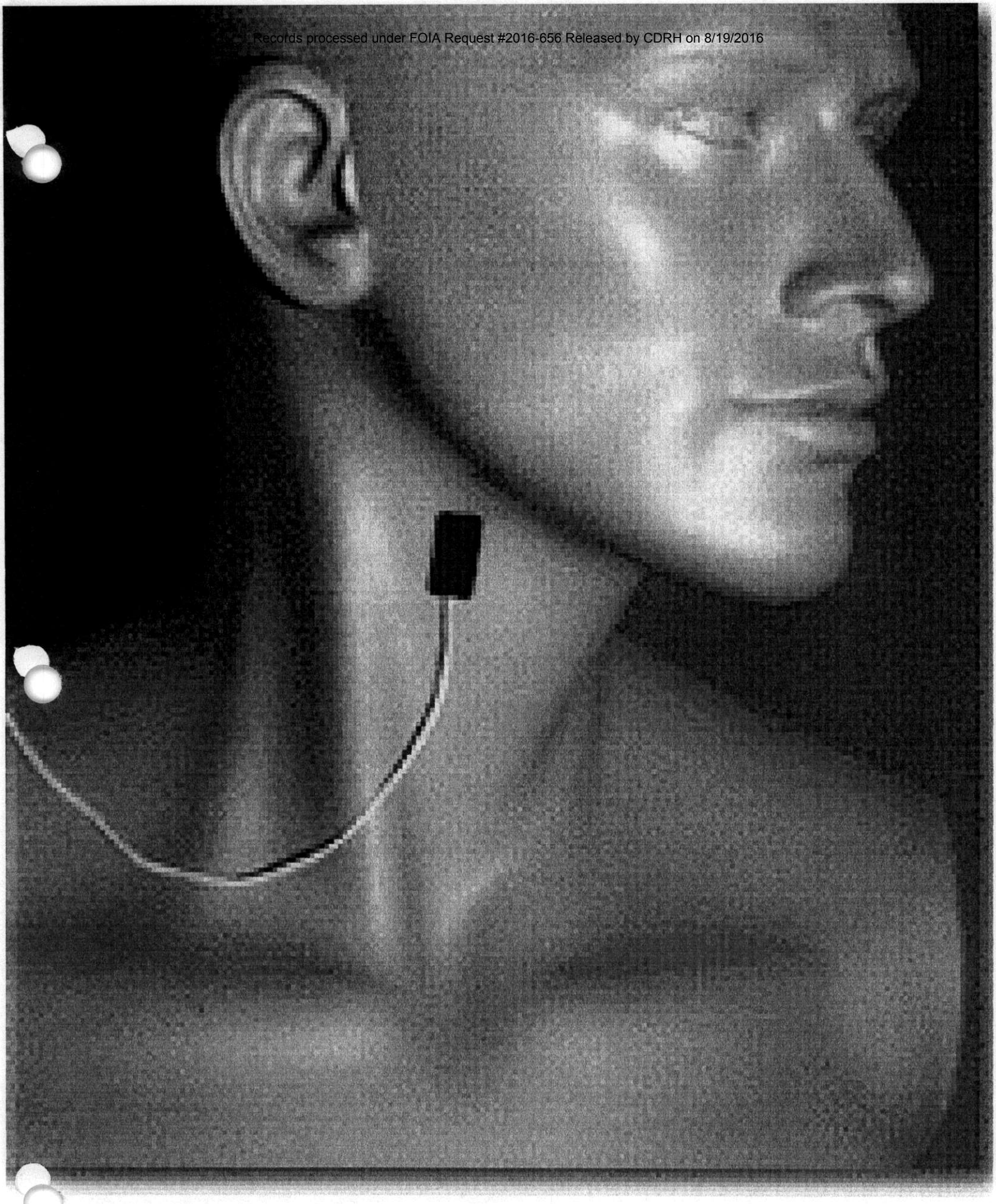
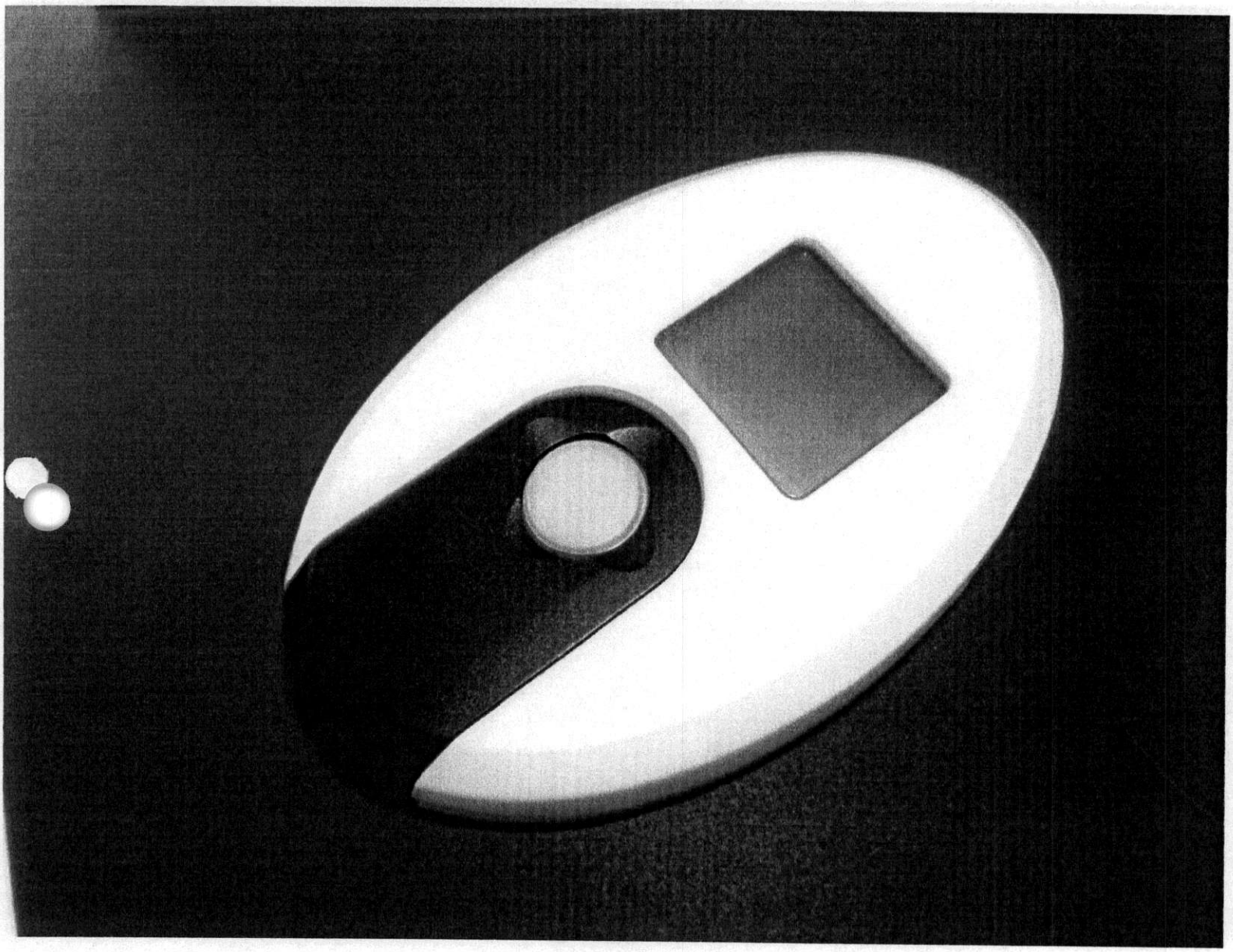
(b)(4) Schematic drawing

(b)(4) Schematic drawing





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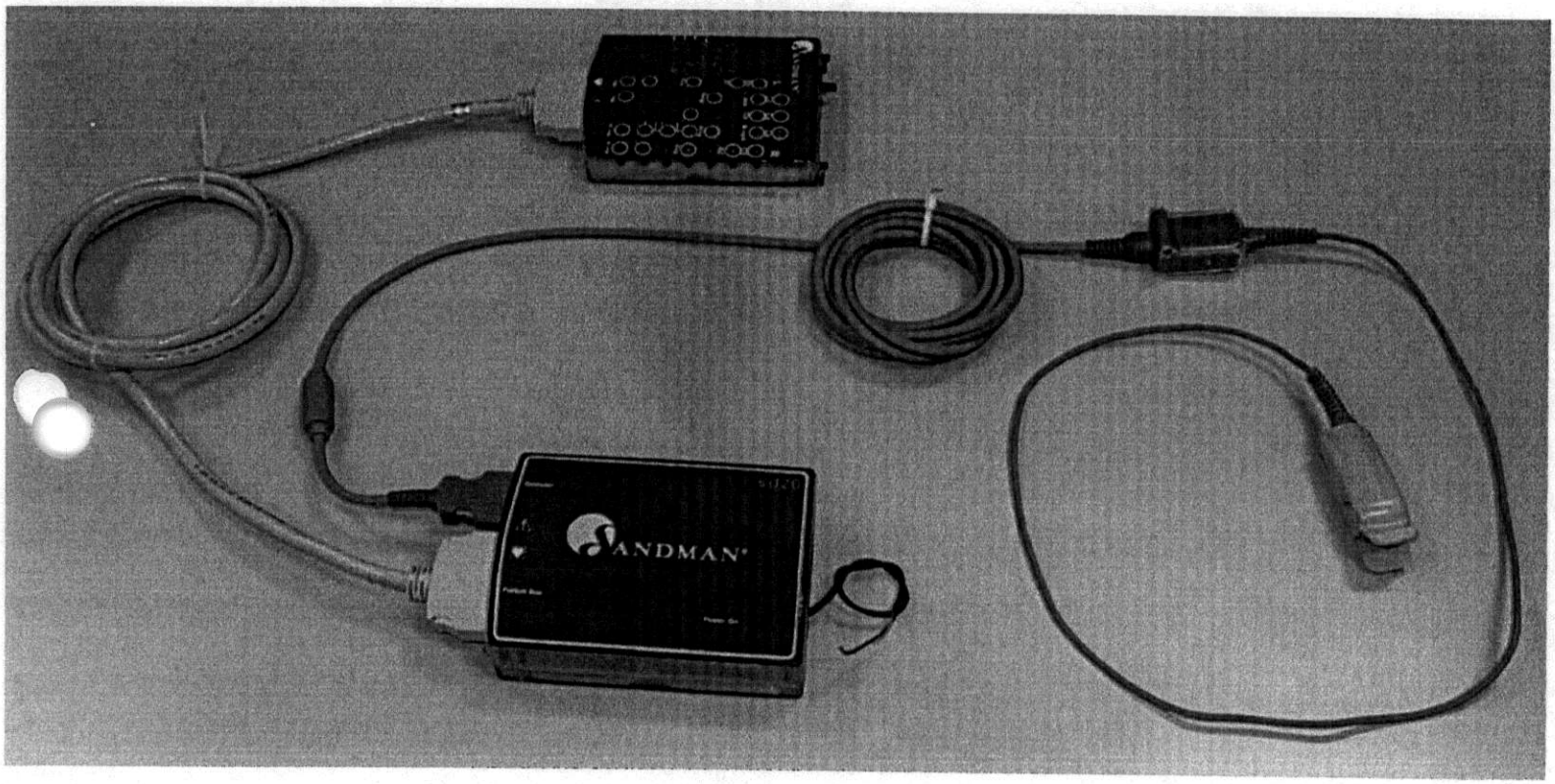

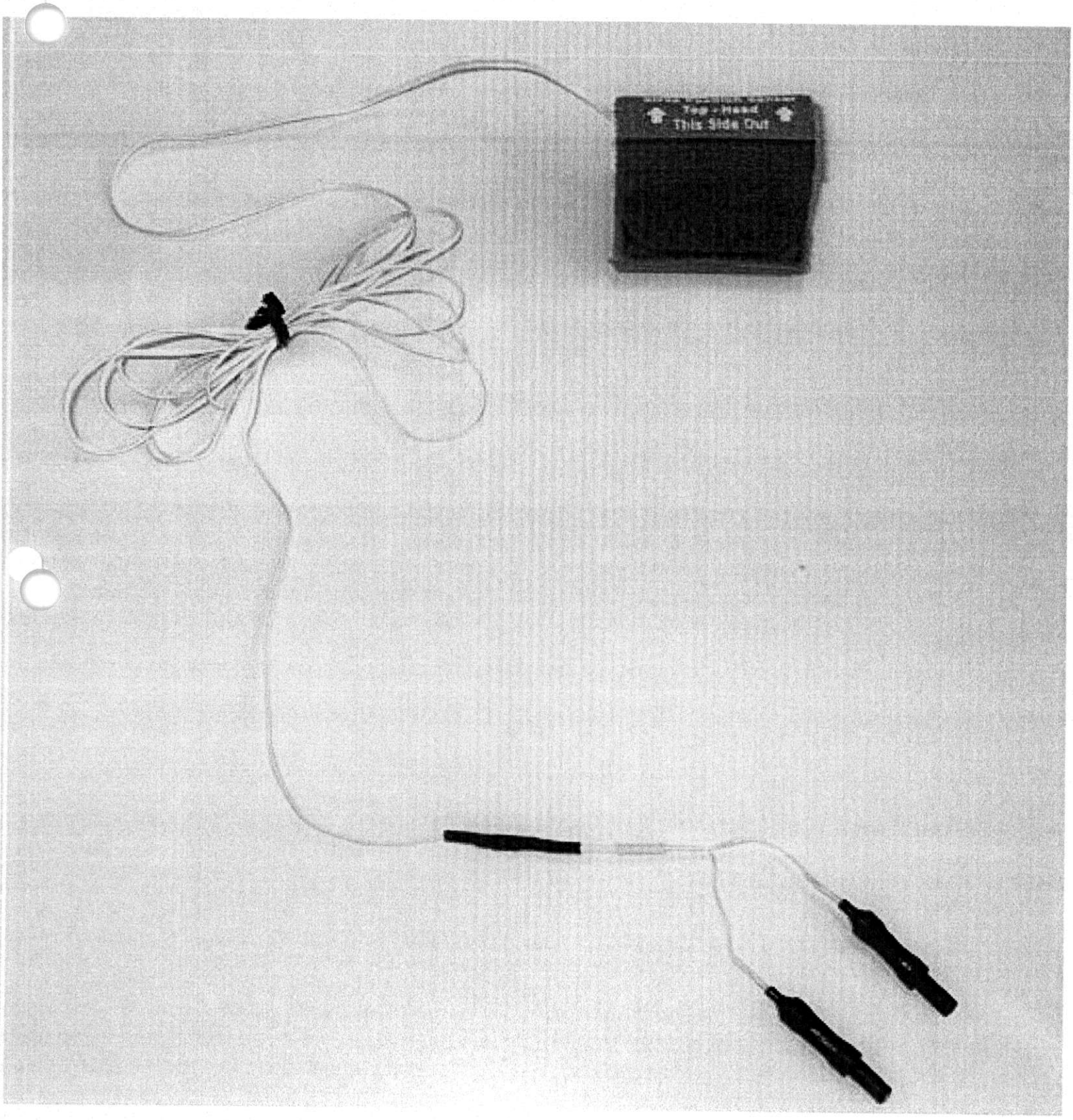

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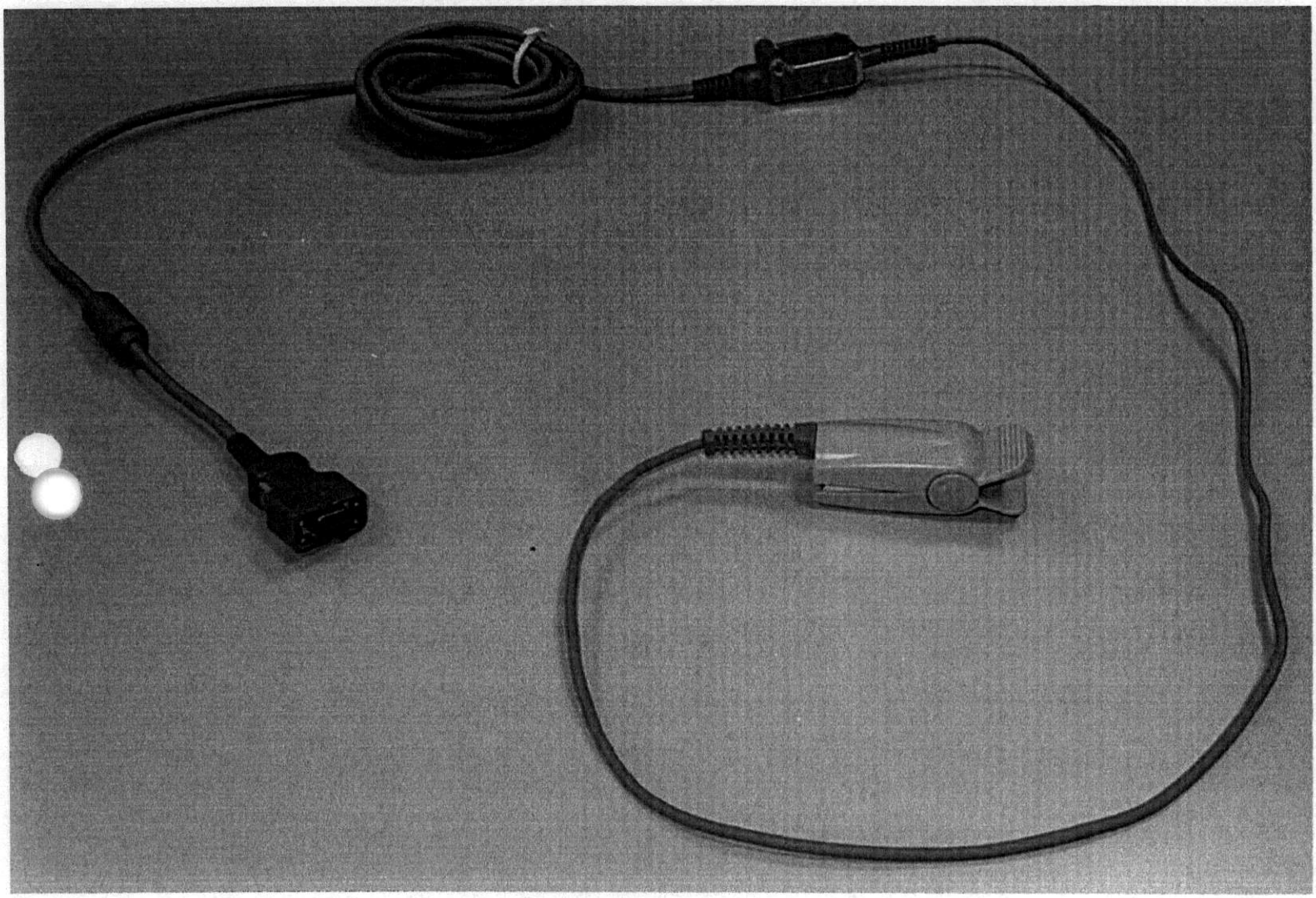

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The following section is page numbered independently from the remainder of the submission.

Sandman Pocket

Polysomnograph Recorder

CE 0051 c SP us

Operator manual
(for OEM System Builder)

B830 0065 411

Rev. A

Sandman Pocket

Polysomnograph Recorder

Operator manual
(for OEM System Builder)

B830 0065 411
Rev. A

CE 0051 C SA US

EDITION:

May 2006

EBNeuro
- FLORENCE -

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CHAPTER 1
INFORMATION ABOUT SAFETY

1.1 INFORMATION ABOUT THE MANUAL

This document contains proprietary information. No part of this publication may be photocopied or reproduced without the prior written permission of EBNeuro.

Information in this document is subject to change and revision without notice.

Issues:

First edition: **B830 0065 411 - Rev. A - May 2006**

This manual is to be considered as an important component of the equipment. When installing the system for the first time, the user should accurately check the content of the Manual in order to verify its integrity and completeness.

In the event that the Operator Manual should be ruined, incomplete or inadequate, please contact EBNeuro in order to immediately restore or replace the uncompliant Manual.

The official versions of the Operator Manual, of which EBNeuro is directly responsible, are the Italian and the English versions. For countries in which languages other than Italian or English are spoken, the official Manual is the version in English. EBNeuro does not undertake any responsibility for any translations in other languages made by distributors or users or third parties.

Observance of the operating procedures and the warnings described in this Manual is a basic requirement for the correct working of the equipment and to guarantee the patient's and user's safety.

The Manual must be read in full in front of the equipment prior to use, in order to become familiar with the operating procedures, the commands, the connections to the peripheral instruments, and the precautions for a correct and safe usage.

The Operator Manual should be kept, complete and readable in every part, in a safe place. It should be easily accessible to the user when using the equipment.

The equipment Service Manual is available upon request. This Manual contains all information directed to the qualified staff in charge for servicing.

1.1.1 CONVENTIONS

In this Operator Manual, the following conventions are used:

NOTE

NOTE messages contain important information to be underlined with respect to the rest of the text. They generally contain information useful to the user to correctly *perform and use the operating procedures of the equipment.*

WARNING

WARNING messages appear in the Manual prior to procedures or operations that should be observed in order to avoid any data losses or damages to the equipment.

ATTENTION

ATTENTION messages appear in the Manual with reference to the description of procedures and operations that, if not performed correctly, could cause harm to the user or the patient.

1.2 DECLARATION OF RESPONSIBILITY BY THE MANUFACTURER

MANUFACTURER: **EBNeuro S.p.A.**
Operating office:
FIRENZE
Via Pietro Fanfani, 111/A
50127 - Firenze
Phone +39 055 4565111
Fax +39 055 4565123

EBNeuro is responsible for safety, reliability and performances of the equipment only when the equipment is used in compliance with the following conditions:

- Calibrations, modifications or servicing must be performed by qualified staff expressly authorized by EBNeuro.
- The equipment must only be opened and its internal parts must be accessed to by maintenance qualified staff expressly authorized by EBNeuro.
- The environment where the equipment is used must be in compliance with the safety directions.
- The electric wiring of the building must be designed according to local standards and perfectly working.
- Parts and accessories of the equipment that can be replaced by the user, must be replaced with items of the same kind and with the same characteristics.
- The connection of the equipment with peripherals or other instruments supplied by the mains electricity must be performed according to the EN 60601-1-1 standards (standards for Electro-medical systems) and to the EN 60601-1-2 standards (standards for electromagnetic compatibility).
- Usage and maintenance of the equipment and its accessories must be performed in compliance with the instructions described in this Manual.
- All parts of this Manual must be maintained as a complete and readable document.
- The equipment is used and serviced until its "End of Life".

1.3 USAGE RESTRICTIONS AND SAFETY PRECAUTIONS

In order for the system to be operated in a safe manner, and to ensure the safety of both the patient and the user, it is important that all precautions listed below are followed:

ATTENTION

Prior to usage, verify that all the safety requirements are satisfied.
The equipment must not be supplied by or connected to other instruments until such safety conditions are restored.

ATTENTION

The EBNeuro Sandman Pocket Recorder is not intended for the "end user", rather it is intended as an OEM product to be used by a "System Builder" as a piece of its own medical systems.

It is the responsibility of the System Builder to use the EBNeuro Sandman Pocket Recorder strictly following any technical specification and precaution of use described in this manual.

EBNeuro is not providing any sensor, lead or cable, nor any wearing system to the System Builder, nor is EBNeuro providing any "system software" suitable for a complete polysomnographic or sleep study system.

It is completely under the responsibility of the System Builder to provide all the accessories and any eventual wearing system. System Builder should address any safety and effectiveness consideration related to the whole medical system he is "manufacturing" and should provide any instructions and warnings against the correct connection and units/cable placing of any system's part (as an example to *avoid any possible strangulation risk). This applies in particular to the use of* EBNeuro Sandman Pocket Recorder in pediatric studies.

ATTENTION

The EBNeuro Sandman Pocket Recorder is only to be used under the direction and *supervision of a physician, technologist or clinician. It will not prevent or restore* the interruption or loss of any physiological system.

1.3.1 ELECTRIC SAFETY

Leakage current
The maximum patient leakage current from the equipment, measured according to the IEC 601-1 standard (for Class I Type CF) is less than 10 μA.

Patient Connection
All patient connections to the *Sandman Pocket* amplifier are through the *Sandman Pocket* headbox using the input sockets provided, or through the dedicated connectors for pressure, body position, oximeter sensors. Any patient electrodes or sensors connected to the device by any other means constitutes an unsafe condition that could result in injury or death to the patient.

ATTENTION

All connections on the headbox are isolated from AC power ground.
Do NOT join these connections to earth ground or AC power ground since such an *action constitutes an unsafe condition that could result in serious injury or* accidental death to the patient.

ATTENTION

The electrode and sensor through which the signal is captured from the body of the patient are not part of the amplifier system. In any case, it is MANDATORY to use only electrodes or sensors approved for commercial use by FDA (USA) or CE marked (93/42EEC European directive), depending on the country the system is used.

ATTENTION

It is strongly recommended to check the overall functionality of the system before starting any recording.
In case any anomalies or malfunctioning should be noticed, immediately disconnect the patient from the system (if a patient is already connected), switch off the system and ask for service from qualified personnel.
In particular (for example) if, with a patient connected to the system, some "flat" tracing should be noticed on the monitor during recording In this case, if the problem should not be easily solved (poor electrode connection, broken lead etc) immediately disconnect the patient, do not use the system and ask for servicing.

ATTENTION

During "long term recording" it is strongly recommended to periodically check that the system works regularly without any sign of malfunctioning. If any anomalies or flat traces should be noted, disconnect the patient, do not use the system and ask for servicing.

ATTENTION

If skin irritation occurs, discontinue recording and disconnect the patient. Refer to the user instructions of the sensors, electrodes and paste for further information. Use only electrodes, sensors and paste according to the requirements of FDA (USA) or 93/42/EEC Medical Devices Directive (CE mark for European Community).

To ensure the safety of the patient and the operator, please follow all the warnings and cautions listed in this manual.

- **Take care when using the equipment at the same time as other instruments**. In the event that the patient is connected to several instruments at the same time, it is important to remember that the sum of the leakage currents produced by each instrument may endanger the patient.

- **Take care when using the equipment at the same time as other instruments that emit radio frequency**. In the event that the equipment is used in an operating room at the same time as a radio knife (Radio-Frequency instrument = RF), it is necessary to hold the radio knife point as far as possible from the electrodes, in order to reduce the risk of RF currents flowing through the electrodes which may result in burns to the patient. This may be reduced by using electrodes with a larger surface area, in order to limit the RF current density to acceptable values. If it is not possible to use the proper electrodes, it is recommended to disconnect the patient from the equipment before using radio-frequency instruments.

- **The equipment is not protected against the defibrillator discharges**. Please remember that the equipment is not protected against the defibrillator discharges. If it is necessary to use a defibrillator, it is necessary to disconnect the patient from the equipment in order to avoid the possibility of patient being burned in the electrode contact areas and the equipment experiencing irreversible damages.

- **Prevent contact of patient and electrodes with other conductive metal items**. When the equipment is connected to other instruments supplied by the mains supply, the whole input circuit to which the patient is connected is electrically isolated (*floating* isolation). It is necessary to prevent the patient, and any conductive part of the system connected to the patient (electrodes, connectors, and transducers), from coming into contact with conductive parts (ground included) of other devices. Please observe this precaution to avoid compromising the equipment isolation level. This precaution must be observed in order to avoid that accessible metal parts of the device touching external conductive parts, thus damaging the isolation level of the equipment.

- **Do not connect additional Multiple Portable Socket-Outlet or extension cords.** Multiple Portable Socket-Outlet or extension cords shall not be connected to the system.

- **Observe the EN 60601-1-1 and the EN 60601-1-2 standards when connecting the system to other instruments**. The connection of the equipment with other devices is allowed only when the safety requirements for the patient, the user and the environment are not compromised. If the Manual does not contain enough information about the possibility of interconnection with other devices, the user should contact the manufacturer or the nearest authorized servicing center to have information about the effects that coupling devices may have on the patient, the user and the environment.

- **Replace damaged parts immediately**. Cables, connectors, accessories, or other parts of the equipment must be replaced immediately when damaged or if they are not working correctly. Please contact the nearest authorized service center immediately for replacement parts.

- **Use only accessories and peripherals of type specified by EBNeuro**. In order to guarantee all the safety requirements, it is necessary to use only the accessories and peripherals specified in this Manual as part of the system, which have been tested with the equipment. The usage of accessories and consumer goods supplied by other manufacturers or not specifically indicated by EBNeuro do not guarantee the safety and the correct working of the equipment. Use only peripherals in compliance with the standards of the class they belong to.

- **Check the functionality of the system before starting any recording.** It is strongly recommended to check the overall functionality of the system before starting any recording. In case any anomalies or malfunctioning should be noticed, immediately disconnect the patient from the system (if a patient is already connected), switch off the system and ask for service from a qualified personnel. In particular (for example) if, with a patient connected to the system, some anomalous tracing, like isoelectric or greatly artefacted signal, should be noticed on the monitor during recording. If the problem can not be solved with the assembly standard technique (poor electrode connection, broken lead, etc), immediately disconnect the patient, do not use the system and ask for servicing.

- **Periodically check that the system works regularly during "long term recording".** During "long term recording" (more than one hour), it is strongly recommended to periodically check that the system works regularly without any sign of malfunctioning. If any anomalies or flat traces should be noted, immediately disconnect the patient, do not use the system and ask for servicing. In particular, any electrode site used for long term must be checked for irritation and redness. Check each electrode periodically to evaluate the skin condition under the electrode. Redness, blistering and permanent skin scarring can occur if electrodes are not regularly monitored.

- **Take care when using the equipment on patients with a heart pace-maker**. It is necessary to use caution when using the equipment in patients with implanted electric devices, especially heart pace-makers, because the equipment may cause the cardiac stimulator to malfunction. Patients with cardiac pacemakers should not undergo any examination with this equipment without authorization and close supervision of a specialized physician.

- **The equipment works with non rechargeable AA Alkaline batteries.** Batteries must be replaced at the beginning of each recording. Batteries are not supplied by EBNeuro and are not part of the amplifier. Take care to connect each battery with the correct polarity (see section 4.2).

1.3.2 SAFETY OF THE OPERATING ENVIRONMENT

- **The equipment is not designed to be used in locations with flammable vapors or gases that may cause explosions**. The equipment must not be used in atmospheres with a high concentration of oxygen or in buildings where flammable substances or anesthetic agents are present. The atmosphere is considered as oxygen-saturated when the oxygen or nitrous oxide (NO_2) concentration contained in the environment is over 24%.

- **The equipment and its internal parts are not protected against the inflow of liquids.** Avoid operating the equipment in an environment where there is a risk of water dripping, sprinkling or immersion. Do not use the system in an environment where liquid inflow is likely. Instruments that have been subject to liquid penetration must be immediately cleaned and checked by authorized qualified staff.

- **Use the equipment within the environmental limits of temperature, humidity and pressure specified**. The equipment is designed to work in environmental conditions that, in compliance with the IEC 601-1 directions, are defined as standard:

- temperature	+5°C / +40°C
- relative humidity	30% / 75% RH
- atmospheric pressure	700 / 1060 hPa

  It is important to remember that since the equipment is portable it can be used outside hospital. It is important not to use it when the above mentioned environmental conditions are not satisfied. In particular, take care in protecting the equipment from humidity when moving it from one place to another.

- **Be careful using the equipment when it is moved between locations with different temperatures to avoid any possible internal condensation**. If the equipment is stored or kept in a cold place and is rapidly moved to a warmer building, condensation may occur (humidity or misting over the internal or external surface of the equipment). In this case, it is necessary to wait for the condensation to be completely evaporated before powering up and using the equipment.

- **Make sure the electric wiring of the building is safe when connecting to other mains powered devices**. When the equipment is connected to peripherals or other mains powered devices, make sure that the latter are connected only to mains outlets with protective grounding. This protection is fundamental for the patient's and the user's safety: therefore, it is necessary that the electric wiring of the building guarantees efficient protective grounding.

- **Be careful using the equipment in locations disturbed by strong magnetic fields**. The equipment is compliant with the EMC requirements (ElectroMagnetic Compatibility) according to that specified by the 89/336/EEC European Directive. In every case it is recommended to keep the equipment

away from significance sources and induced electromagnetic fields that surpass the values prescribed by the standard in order to avoid any possible instabilities and malfunctioning of the equipment

- **Be careful when using the equipment near short-wave or micro-wave devices**. If the equipment is used in an area where there are also therapeutic short-wave or micro-wave devices, it is necessary to remember that these may cause instability and interfere with the correct performance of the equipment. Do not place the equipment near X-ray or diathermy devices.

1.3.3 PULSE-OXIMETER WARNING NOTES

A Pulse-Oximeter module is installed inside the *Sandman Pocket* recorder. This device is the NELL-1 pulse-oximetry module board manufactured by Nellcor Puritan Bennett (USA).

When utilizing the pulse oximeter module integrated in the *Sandman Pocket* device in its own system, System Builder must observe the following safety precautions and usage restriction notes:

- **Intended use of the option.** The *Sandman Pocket* device constitutes "simply" the acquiring front end of SpO_2 and pulse rate data. In particular notice that:
  - The *Sandman Pocket* device limits its role to allow the host system to control the NELL-1 module and to read the calculated data values and store this data on the recorder memory and/or pass it to the host computer.
  - The *Sandman Pocket* device does not rely in any way with the processing of the SpO_2 and pulse rate data. These eventual process are under the complete control and responsibility of the host system software.
  - The *Sandman Pocket* does not interpret or evaluate data retrieved from NELL-1 oximeter. PTT is simply calculated as a "time interval" between two fiducial points.
  - The *Sandman Pocket* supports the NPB (Tyco) GK420E, GK425ST and GK425 CPAP models.
  - **The *Sandman Pocket* device is NOT involved in any alarm managing. The Pulse-Oximetry module of *Sandman Pocket* device is NOT intended FOR CONTINUOUS MONITORING.**
  - The System Builder application software is responsible for the use and display of the oximetry data. In particular, the System builder may assure that this use will meet the requirements of the EN 865 and ISO 9919 standards (if applicable).

- **Allowable sensors.** The *Sandman Pocket* device is provide without standard sensors. System Builder should integrate the device with Nellcor Puritan Bennett approved sensors only and specified for the usage with NELL-1 module.
  Information regarding this point can be obtained directly by Nellcor Puritan Bennett or EBNeuro S.p.A.
  In any case it is mandatory to use only sensors approved for commercial use by FDA (USA) and/or CE marked according to 93/42/EEC directive.

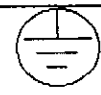
- **Accuracy of acquired data.** The accuracy of oximetry data depends on the sensor used with the device. System Builder should determine the accuracy according to the technical characteristics of the chosen sensor(s). Please reference the manufacturer's documentation for the sensors.

  In operation, the accuracy of the oximetry data can be affected by the following external conditions:

  - High-frequency electrical noise, including electrosurgical equipment and defibrillators;
  - Possible interference with magnetic resonance imaging (MRI) procedures;
  - Excessive patient movement;
  - Intravascular dye injections;
  - Significant concentrations of dysfunctional hemoglobin, such as carboxyhemoglobin and methemoglobin;
  - Sensor temperature (maintain between 28°C and 42°C for best operation);
  - External illumination more than 5000 lumens/square meter (typical office lighting);
  - Improper sensor application;
  - Venous pulsation;
  - Placement of the sensor on an extremity that has a blood pressure cuff, arterial catheter or intravascular line;

1.4 GRAPHIC SYMBOLS IN COMPLIANCE WITH THE IEC 60601-1 STANDARDS

The following table shows description and localization of all graphic symbols in compliance with the IEC 60601-1 safety standards present on the equipment panels and on any other instruments or external devices to which the equipment may be connected.

IEC 601-1 SYMBOL	DESCRIPTION	POSITION
	**Alternating current**	Symbol placed on the connection points between the equipment and the mains (alternating current source).
	**Direct current**	Symbol placed on the connection points to direct current source.
	**Equipotential terminal**	Symbol placed on the outlet connecting the equipment to the equipotential node of the building, if any.
	**Protective earth (ground)**	Symbol placed on the connection points between the equipment and the protective grounding.
	**High voltage**	Symbol placed on circuits or equipment parts with high voltage.
	**Attention! Refer to the attached instructions.**	Symbol placed on items for which it is important to read the Operator Manual for relevant information (see ATTENTION paragraph).
	**Device with CF-type applied parts**	Symbol placed on applied parts to the patient with a CF-protection level.
	**Device with BF-type applied parts**	Symbol placed on applied parts to the patient with a BF-protection level.
	**Device with B-type applied parts**	Symbol placed on applied parts to the patient with a B-protection level.

IEC 601-1 SYMBOL	DESCRIPTION	POSITION
	**Off (disconnected from the mains)**	Symbol placed on the off/on positions of the whole equipment general power switch.
	On (connected to the mains)	Symbol placed on the off/on positions of the whole equipment general power switch.
	**Off (for a single part of equipment)**	Symbol placed on the off/on switch of a single part of the equipment.
	**On (for a single part of the equipment)**	Symbol placed on the off/on switch of a single part of the equipment.

1.5 OTHER GRAPHIC SYMBOLS

The following table shows description and localization of all symbols placed on the equipment panels and on any other instruments or external devices to which the equipment may be connected.

SYMBOL	DESCRIPTION	POSITION
	**Input**	Symbol placed on the signal input or mains voltage input connectors of the equipment.
	**Output**	Symbol placed on the signal output or the mains voltage output connectors of the equipment.
+	**Positive**	Symbol placed on the battery insertion points. The symbol indicates the position of the battery positive pole.
—	**Negative**	Symbol placed on the battery insertion point. The symbol indicates the position of the battery negative pole.
LOT	**Lot number**	Symbol placed on the identification label of the medical device together with the device lot number.
REF	**Reference number**	Symbol placed on the identification label of the medical device together with the device reference number.
SN	**Serial number**	Symbol placed on the identification label of the medical device together with the device serial number.
	**Date of manufacture**	Symbol placed on the identification label of the medical device together with the device manufacture date.
	**Crossed-out wheeled bin**	Symbol placed on the identification label of the medical device. This symbol indicates the prohibition of throw the medical device in the household wheeled bin device when at its "end of life".
	**Use by**	Symbol placed on the identification label of the medical device together with the device expiration date.
	**Do not reuse**	Symbol placed on the identification label of the medical device. This symbol indicates that the device is a disposable one and cannot be used more than once.

SYMBOL	DESCRIPTION	POSITION
STERILE	**Sterile**	Symbol placed on the identification label of the medical device indicating a sterile device.
STERILE	**Sterilization with steam or dry heat**	Symbol placed on the identification label of the medical device indicating a sterile device and the sterilization method used (steam or dry heat).
STERILE EO	**Sterilization with ethylene oxide**	Symbol placed on the identification label of the medical device indicating a sterile device and the sterilization method used (ethylene oxide).
STERILE R	**Sterilization by irradiation**	Symbol placed on the identification label of the medical device indicating a sterile device and the sterilization method used (irradiation).

1.6 ATTENTION SYMBOL

The **ATTENTION** symbol shown below, placed on the equipment casing, refers the user to the Operator Manual for information, warnings and suggestions which are particularly important for a correct and safe use of the equipment.

In particular, when it is placed on points connecting cables to peripherals, this symbol refers the user to carefully read the Operator Manual for instructions concerning the nature of such cables and peripherals and the modalities for a correct and safe connection.

For location of the ATTENTION symbols placed on the equipment, please refer to chapter "*Installation and connections*" of this Operator Manual. That chapter shows the pictures of the equipment panels with the corresponding commands, connections, symbols, and labels. Each attention symbol comes with a detailed explanation of its meaning.

1.7 CROSSED-OUT WHEELED BIN

The symbol shown below placed on the product or on its packaging indicates that this product must not be disposed of with your other household waste at its "End of Life". Instead, it is your responsibility to dispose of your waste equipment by handing it over to a designated collection point for the recycling of waste electrical and electronic equipment.

The separate collection and recycling of your waste equipment at the time of disposal will help to conserve natural resources and ensure that it is recycled in a manner that protects human health and the environment.
For more information about where you can drop off at its "End of Life" your waste equipment for recycling, please contact your local city office, your household waste disposal service or the shop where you purchased the product or contact the manufacturer of device at www.ebneuro.com or at support@ebneuro.com or contact the EBNeuro main office (par 11.2 of the manual).

Safety, performances and effectiveness of device and availability of its spare parts are guaranteed by the manufacturer until device "End of Life".
EBNeuro, as manufacturer, define the "*End of Life*" time for *Sandman Pocket* modules in 7 (seven) years starting from the production date (see identification label).

1.8 PRODUCT TRACEABILITY

In order to guarantee the traceability of the product, according to ISO 13485 quality standards and the 93/42/EEC European Directive on Medical Devices, EBNeuro kindly requests the original owner of the equipment provides information regarding the transfer of the system to a third party, by sending a photocopy of the completely filled-in Product traceability form (see enclosure 1.7), or by communicating in writing the data indicated in the form.
The data concerning the device can be found on its identification label.

The form can be sent either directly or through any subsidiary or the nearest authorized distributor to the Quality Assurance Department of any EBNeuro operating office. The list of the main EBNeuro head and branch offices in Italy and overseas is contained in chapter "*Request for assistance*" of this manual.

1.9 VIGILANCE SYSTEM

The device is subject to a vigilance system (post-marketing vigilance) that EBNeuro and its distributors and retailers apply to the products that are put on the market to safeguard the patient and the physician from serious or potentially serious hazards during the normal use of the equipment, in order to be able to remove the source of such hazards with the best efficiency and timing.

To the purpose of helping EBNeuro take any timely and effective corrective measure, it is extremely important that the user performs a careful inspection of the equipment performance in order to identify or foresee any dangerous situation for the patient's and the user's health.

For this reason, the user shall give immediate communication of any malfunction or deterioration of the characteristics or the performances of the equipment or any mistake found in these instructions that caused or could cause serious damages to the patient's and the user's health.
In this case, the user may send a photocopy of the proper duly filled-in *Post-Marketing Vigilance Form* (see enclosure 1.8), or communicate in writing the data indicated in the form.

The instrument's data can be collected from it's identification label.

The form shall be sent either directly or through any subsidiary or the nearest authorized distributor to the Quality Assurance Department of any EBNeuro operating office. The list of the main EBNeuro head and branch offices in Italy and abroad is contained in chapter "*Request for assistance*" of this manual.

Enclosure 1-7

PRODUCT TRACEABILITY FORM

To: EBNeuro S.p.A.
Quality Assurance Department
Via Pietro Fanfani, 111/A
50127 Florence

System/device name.....

Device code / reference number (REF) .....

Device serial (SN) / lot number (LOT) .....

Name and address of the former owner .....
.....
.....
.....

Name and address of the present owner .....
.....
.....
.....

Date:.....

Signature

.....

(please name in full)

(ref. Operator Manual code B830 0065 411 Rev. A)

enclosure 1-8

POST-MARKETING VIGILANCE FORM

To: EBNeuro S.p.A.
Quality Assurance Department
Via Pietro Fanfani, 111/A
50127 Florence

System/device name.....

Device code/reference number (REF) .....

Device serial (SN)/lot number(LOT) .....

Description of the real or potential hazard.....
.....
.....
.....
.....

User's comments/suggestions .....
.....
.....
.....
.....

User's address.....
Phone..... Fax .....

Department where the device is installed.....
Person in charge of the department.....

Data:.....

Signature

.....

(please name in full)

(ref. Operator Manual code B830 0065 411 Rev. A)

1.10 INFORMATION ABOUT RECYCLING OF MATERIALS

In accordance with the specific European directives, EBNeuro aims to continuously improve the design and the manufacture of electromedical devices in order to reduce as much as possible any negative impact on the environment caused by the management of component parts, consumer materials, packaging and the disposal of devices when at their "end of life".

Packaging materials were designed and produced so as to allow the easy reuse and the salvage, including recycling, of most parts of the material and to reduce the quantity of garbage or residual products for discharge as much as possible. In particular, packaging materials have been produced so as to limit the presence of harmful metals and of other dangerous substances to minimum quantities in emissions, ashes or lixiviation residual products. The total concentration levels of heavy metals such as Lead, Cadmium, Mercury and hexavalent Chrome contained in the packaging materials are in accordance with the limits established by the directives in force related to this subject.

In order to minimize the consequences to the environment, the design of the device includes the highest possible miniaturization of the circuits, with the least possible differentiation of materials and components, with a selection of substances that guarantee the highest possibility to recycle and re-use the components and to dispose of them without risks to the environment.

The device is designed to guarantee the easy separation or disassembling of the materials containing polluting substances from the others, in particular during the operations of servicing and replacing parts. In particular, the largest plastic components are marked according to their plastic contents in order to make it easier to recycle the product.

ATTENTION

Please refer to local codes and laws for proper disposal/recycle requirements of packaging and consumer materials and of the device when at its "end of life".

1.11 ELECTROMAGNETIC COMPATIBILITY

The device is designed for use in the electromagnetic environments declared in the tables below, in compliance with the IEC 60601-1-2:2001 (second edition) standard. The operator must assure that the device is used in an environment compliant to this standard.

Table 1 - Electromagnetic Emissions

Emission Test	Compliance	Electromagnetic Environment
Radiated and conducted RF emission CISPR 11	Class B	The device is suitable for use in domestic establishment and in all establishments directly connected to the low voltage power supply network (electrical mains) which supplies buildings used for domestic purpose.
	Group 1	The device use RF energy only for its internal function and to operate. Therefore, the RF emission is very low and not likely to cause any interference in nereby electronic equipment.
Harmonic emission IEC 61000-3-2	Complies	The device is suitable for use in establishments directly connected to a public low voltage power supply network (electrical mains)
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	The device is suitable for use in establishments directly connected to a public low voltage power supply network (electrical mains)

Table 2 - Electromagnetic Immunity

Immunity Test	IEC 60601-1-2 Test Level	Compliance	Electromagnetic environment
Electrostatic Discharge (ESD) IEC 61000-4-2	6 kV in contact 8 kV on air	IEC 60601-1-2 Test Levels	Residential **(Note 1)**
Electrical fast transient/burst IEC 61000-4-4	2 kV for power supply line 1 kV for input/output lines >3m	IEC 60601-1-2 Test Levels	Residential **(Note 2)** **(Note 3)**
Surge IEC 61000-4-5	1 kv differential mode 2 kV common mode	IEC 60601-1-2 Test Levels	Residential **(Note 2)** **(Note 3)**

Voltage dips, short interruptions and voltage variation on power supply input lines IEC 61000-4-11	0 % of rated voltage (voltage dip 100 %) for 0.5 cycles 40 % of rated voltage (voltage dip 60 %) for 5 cycles 70 % of rated voltage (voltage dip 30 %) for 25 cycles 0 % of rated voltage (voltage dip 100 %) for 5 cycles		
Magnetic fields at mains frequency (50/60 Hz) IEC 61000-4-8	3 A/m		
Radiated RF fields IEC 61000-4-3	Non-life-supporting equipment 3 V/m form 80 MHz to 2.5 GHz	IEC 60601-1-2 Test Levels	Residential **(Note 4)**
Radiated RF fields IEC 61000-4-6	Non-life-supporting equipment 3 V form 150 kHz to 80 MHz		

Measures to be taken

Note 1: The foor should be in antistatic material (wood, ceramic, ect.). If covered by synthetic material, relative humidity should be maintained at least at 30%

Note 2: The qualily of the electrical power supply and the mains frequency magnetic fields should be typical of domestic, commercial and hospital environments.

Note 3: If the operator must work without a break while power supply is interrupted, it is necessary to have power supplied through a UPS (Uninterruptible Power Supply) unit.

Note 4: Mobile or portable radio frequency (RF) communication appliances should be used at longer distances than those indicated on the following Table 3.
Electromagnetic transient can happen near appliances bearing the symbol shown below

1.11.1 Recommended distances from Radiofrequency (RF) communication systems

As stated in this chapter 1 "Information about safety" of this operator manual, it is recommended to not use Radiofrequency (RF) transmission system near the *Sandman Pocket* amplifier system. RF systems can cause interference which may cause instability and interfere with the correct working of the equipment and it may alters the EEG signal acquired tracings.

The operator can prevent interference caused by electromagnetic field by maintaining a minimum distance between the *Sandman Pocket* amplifier system and the RF communication system being used (cell phones, mobile phones, etc,). The following table shows the minimum distances in meters, according to the maximum power at RF system output.

Table 3 – Recommended separation distances from RF sources

RF Source	Typical Rated Power (W)	Distance (m)
Microcellular phone CT1, CT2, CT3	0.01	0.3
DECT cellular phone, Wireless Information Technology equipments (modems, LANs)	0.25	2
Cellular phone, hand-held (USA)	0.6	2
Cellular phone, hand-held (e.g. GSM and NMT, Europe DECS 1800)	2 8	4 7
Walkie-talkie (rescue, police, fire, maintenance)	5	3
Cellular phone, bag	16	10
Mobile radio (rescue, police, fire)	100	30
For transmitters that have a maximum output power of which is not within the value ranges in the table, the recommended minimum distance can be estimated by analyzing the equation in the table applicable to the transmitter frequency: For transmitters using frequencies ranging from **150 kHz to 80 MHz** and from **80 MHz to 800 MHz**, the distance can be estimated using the equation: $d = 1.2\sqrt{P}$ For transmitters using frequencies ranging from **800 MHz to 2.5 GHz**, the distance can be estimated using the equation: $d = 2.3\sqrt{P}$ P is the rated power of the transmitter in Watt (W) according to the transmitter manufacturer specifications.		
Note: As a precaution, always apply the greater distance supplied by the table. **Note:** Electromagnetic fields are subjected to absorption and reflection in the presence of structures, objects and people. The values in the table are general guidelines.		

The operator must remember that the intensity of the electromagnetic fields generated by fixed transmitters (radio-base stations for cellular or cordless phone, TV and radio transmissions, amateur radio transmission, etc.) cannot be predicted on theoretical basis.
Consequently, a direct measure may be necessary in the used environment of *Sandman Pocket* system.

If the intensity of the electromagnetic fields exceeds that specified in the immunity levels shown in the previous tables, and the bioelectric signal Amplifier system behaves incorrectly, additional measures may be necessary. I.e. orienting or locating the *Sandman Pocket* system in a different way.

1.12 BIOCOMPATIBILITY AND INFECTIONS CONTROL

No system components are intended to be in contact with the patient.
Electrodes and sensors are not intended to be parts of the "*Sandman Pocket*" system.
The body contacting material are no part of the system. In any case, electrodes and sensors MUST meet the requirements of FDA (USA) or 93/42/EEC Medical Devices Directive (CE marked).

ATTENTION

The residual products of every exam (disposable electrodes, gel or paste residues, etc.) must be considered as potentially infected and therefore treated as special waste. Please refer to local codes for proper disposal of such materials.

1.13 DECLARATION OF CONFORMITY

CE 0051

The equipment has been manufactured by applying the quality guarantee system approved for design, manufacturing and final check of the product and meets the requirements of **Annex II** of the **93/42/EEC** Directive on Medical Devices **(MDD)**. For these reasons the equipment is marked with the **CE** mark.
The approval is issued by IMQ S.p.A. (Milan – Italy) as Notified Body notified by European Commission. IMQ Notified Body identifier number is **0051**.

C SA US

The equipment is marked with the **cCSAus** quality mark. This safety mark is valid in both Canadian and U.S. markets.

1.14 CAUTION FOR THE U.S. MARKET

Federal law restricts this device to sale by or on the order of a physician.

CHAPTER 2
DESCRIPTION OF THE DEVICE

2.1 DESCRIPTION OF THE SYSTEM

The *Sandman Pocket* is part of a Polysomnography system. It consists of two units: the **Recorder Unit**, which stores the data and sends it to a USB port; and the **Headbox Unit**, which is the connection point for all patient sensors, with the exception of the oximetry probe.

Intended use:

The Sandman Pocket is to be used for collecting and recording physiological data to be used in polisomnography and sleep disorder studies. The Sandman Pocket is intended for pediatric through adult patient populations can be used in either home or hospital environments.

The *Sandman Pocket* role is only to capture the data and pass them to the host with the necessary accuracy and reliability following the specification of the product and those of the communication control.

A fundamental characteristic of the *Sandman Pocket* is to be an ambulatory/portable equipment: small size and light weight (about 210 gr included battery), compact and solid.

The **Headbox Unit** is used for insertion of patient electrodes and sensors. It includes Bipolar channels, pressure sensors, and supply power for a dedicated body position sensor, a abdomen sensor, a chest sensor, an snore sensor and a thermistor.

The patient inputs are isolated with a CF type isolation level.

The **Headbox Unit** captures the biological signals from the human body surface through specialized sensors and electrodes, while the **Recorder Unit** amplifies the very low electrical signal, filters it to accomplishe an antialiasing, in order to make an optimal ANALOG to DIGITAL conversion. The data, once converted in numerical form, are "passed" to a host computer that, at this point, is free to elaborate the data following the logic of the application software running on the host. The host can "program" the amplifier behavior setting, sampling frequency, dynamic range allowed, and so on.

The host computer reads the acquired data through a dedicated interchange protocol, and then elaborates the data with its own internal logic. The requirement

posed by the *Sandman Pocket* device to the host PC when the recorder is connected to PC and, at the same time the patient too is connected the the Sandman Pocket Headbox, is to be a "Medical Grade PC" (with isolation transformer or medical power supply) or a battery supplied laptop.
The *Sandman Pocket* system will not be in any way involved in the data management performed by the host.
The host computer must operate under one of the following Operating System: Microsoft Windows 98 / ME / NT / 2K / XP.

The device has a built-in impedance meter. This function allows to check the electrode contact impedance and display the result of the check on the display. The display is located in the Recorder Unit while the circuitry controlling the impedance meter is located in the Headbox Unit.

The *Sandman Pocket* can be powered through 3 Alkaline 1.5V standard non rechargeable batteries or via the USB cable. Be sure to use a medical grade type PC.

The *Sandman Pocket* "system" consists of 2 interconnected units: the Headbox Unit and the Recorder Unit.

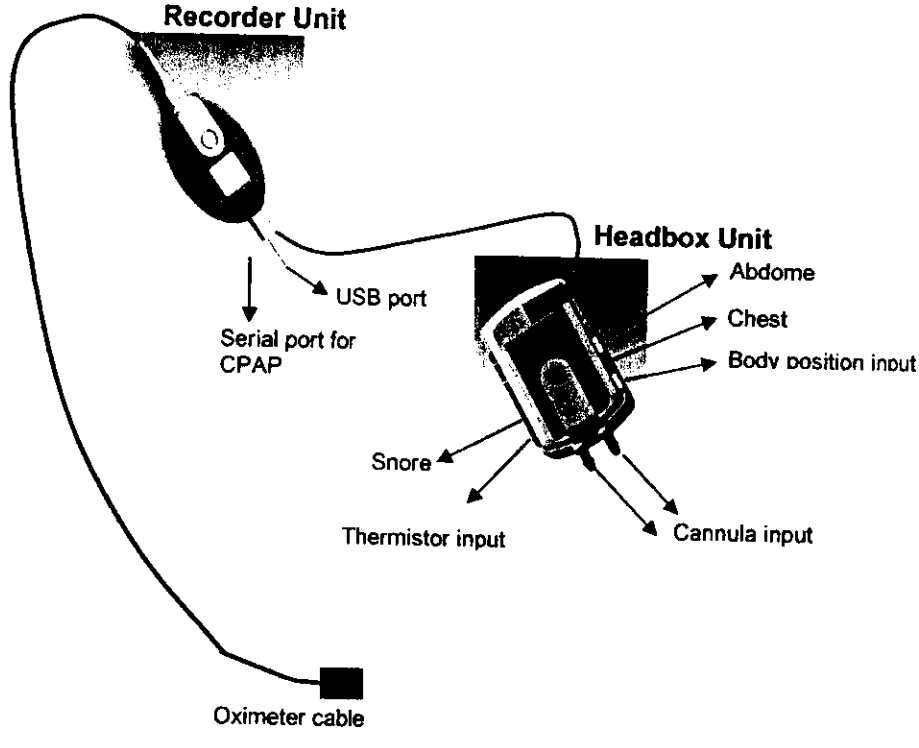


Figure 2-1 SANDMAN POCKET system connection diagram

The **Headbox Unit** has the following functions:

- Physically connects the source of signals (the patient) to the amplifier.
- Provide impedance testing capabilities
- Provide Analog to Digital (A/D) conversion

The **Recorder Unit** has the following functions:

- Amplify and isolate signals coming from the electrodes
- Reference input channels
- Generate calibration pulse
- Provide dynamic range (gain), sampling rate and active channels selection
- Provide the opportune antialiasing filtering to perform optimal Analog to Digital conversion
- Send the digital data trough the USB interface
- Provide the Oximeter option
- Provide to the display management
- Manage the Time
- Manage the batteries power supply

:

2.2 SANDMAN POCKET HEADBOX DESCRIPTION

The following figures show the SANDMAN POCKET **Headbox Unit** in which the main parts are indicated:

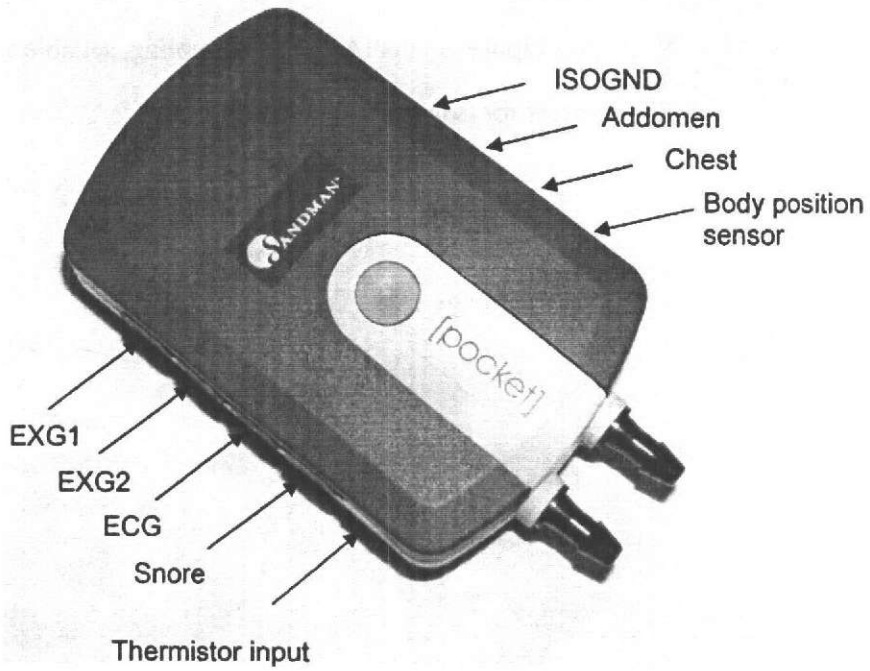


Figure 2-3 SANDMAN POCKET Headbox Unit

2.2.1 PATIENT INPUT SOCKETS DESCRIPTION

The following figure shows the 9 patient input sockets configuration in which the different types of input are indicated:

N° 1 EKG bipolar inputs with AC coupling

N° 5 dedicated bipolar input for Snore, Chest, Abdomen, Thermistor, Body Position

N° 2 EXG bipolar inputs (AC or DC coupling, settable via software).

N° 1 sockets for isolated patient ground

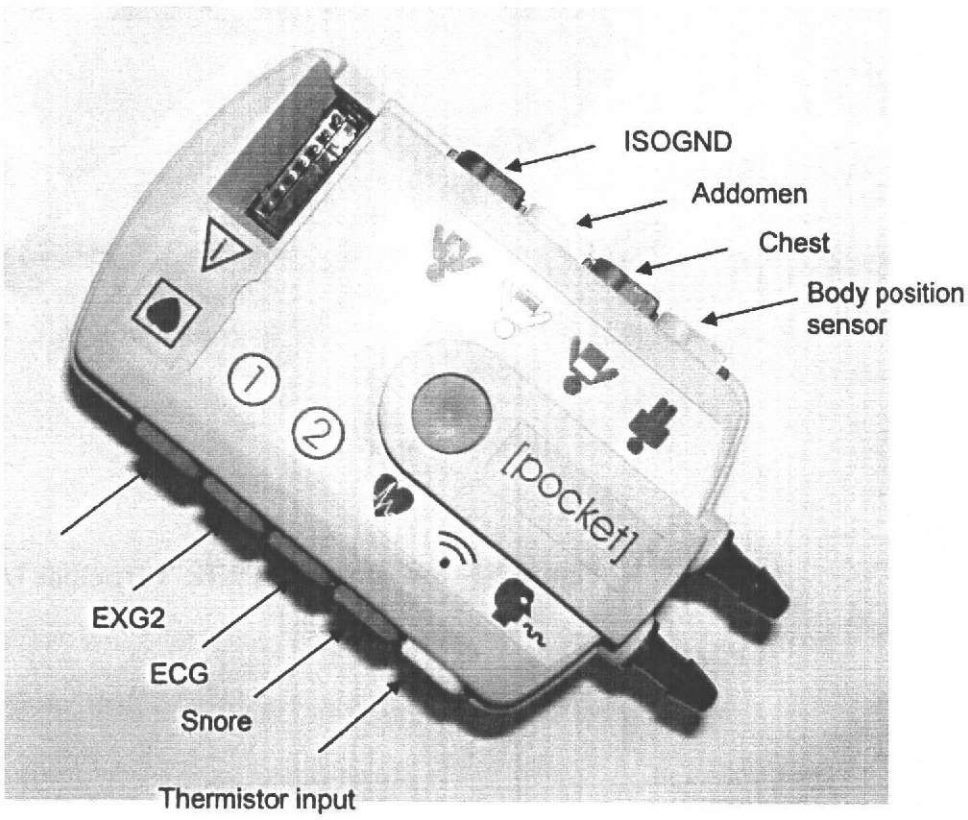


Figure 2-4 SANDMAN POCKET patient input sockets.

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In details:

Bipolar Inputs.

① **EXG1** **1 connector (blu).** This connector is used to connect **EEG, EKG** electrodes.

② **EXG2** **1 connector (blu).** This connector is used to connect **EEG, EKG** electrodes.

♥ **EKG** **1 connector (red).** This connector is used to connect a dedicated **EKG** electrode.

ATTENTION

All the patient applied parts and corresponding input sockets of SANDMAN POCKET acquisition module (patient inputs) are electrically isolated from the mains according to IEC 60601-1 standard requirements for Class I, Type CF equipments. This characteristic is indicated to the operator with the proper symbol placed on the external cover of the device in correspondence of the input sockets (see description of par. 1.4 of the manual).

ATTENTION

All the n° 9 input sockets of SANDMAN POCKET acquisition module accept Female 2 pole 1mm standard touchproof safety connectors.

ATTENTION

The SANDMAN POCKET amplifier system is provided without accessories, electrodes and sensor probes for signals acquisition from patient body. It is necessary to integrate the device with sensors and electrodes CE marked according to 93/42/EEC European directive (MDD) on Medical Devices. For usage in the US market, it is mandatory to use only sensors approved for commercial use by FDA (USA.)

Dedicated Bipolar Inputs.

BODY POSITION connector (light gray). This connector is used to connect a dedicated body position sensor.

ATTENTION

This channel has been designed to work with the PRO-TECH body position sensor model SPI or electrically/functionally equivalent.
The SANDMAN POCKET guarantees only the respect of the technical specification regarding this input (range, conversion factor), regulatory aspects of the physical transducer (for example FDA clearance, CE marking) falls under the responsibility of the system builder's who utilize the SANDMAN POCKET Amplifier to build a complete system.

THERMISTOR connector (orange). This connector is used to connect a dedicated airflow thermistor sensor.

ATTENTION

This channel has been designed to work with an Edentec Breathsensor model 971 or electrically/functionally equivalent.
The SANDMAN POCKET guarantees only the respect of the technical specification regarding this input (range, conversion factor), regulatory aspects of the physical transducer (for example FDA clearance, CE marking) falls under the responsibility of the system builders who utilize the SANDMAN POCKET Amplifier to build a complete system.
The headbox contains the necessary circuitry to feed the thermistor, so no additional components are required to use the sensor. Typical output of the thermocouple is 400 uVp-p. The maximum output of the thermistor is 1mVp-p, with a temperature excursion of 20 °C. The Nellcor Breathsensor is connect via a standard connections. The inputs must be AC-coupled, self-referenced, differential amplifiers.

ATTENTION

The Thermistor must be a disposable component.

SNORE connector (white). This connector is used to connect a dedicated Snore sensor.

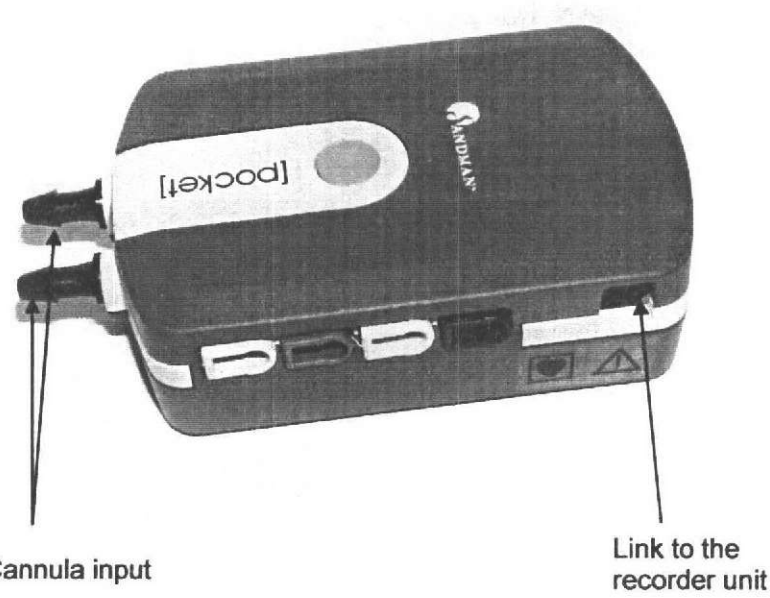
CHEST connector (dark gray). This connector is used to connect a dedicated Chest sensor.

ABDOMEN connector (light gray). This connector is used to connect a dedicated Abdomen sensor.

ISOGND connector (back). This connector is used to connect a dedicated isolated patient ground electrode.

2.2.2 CONNECTORS DESCRIPTION

The following figures show in detail the connectors of SANDMAN POCKET acquisition module:



Figures 2-4 and 2-5 – Acquisition module connectors

- **CANNULA INPUT** This input is used to connect a pressure sensor capable of measuring Nasal Cannula pressure.

ATTENTION

The SANDMAN POCKET has incorporated a pressure transducer HONEYWELL mod 26PC01SMT.
Scope of this input is to be connected to an external device (for example, a Nasal Cannula) which provides a "pressure" to the SANDMAN POCKET. By means of the transducer the SANDMAN POCKET amplifier "converts" the pressure value in a voltage and passes this information to the host computer.
This information is intended to be used as reference only (for example, to allow the host computer to create a trends of the pressure value), it is intended not useful to "control" any external device whose behavior should be critical for the patient.

ATTENTION

The Cannula must be a disposable component.

- **SANDMAN HEADBOX CABLE** connector. This connector is used to connect the Headbox Unit with the Recorder Unit.

2.2.3 EVENT MARKER BUTTON

The following figure shows the event marker button placed on the front cover of the SANDMAN POCKET acquisition module.

Figure 2-7 – Event marker button

The event marker button allows the user to register the timeat which a particular event occurred.

2.3 SANDMAN POCKET RECORDER UNIT DESCRIPTION

The following figure shows the SANDMAN POCKET amplifier box in which the main parts are indicated:

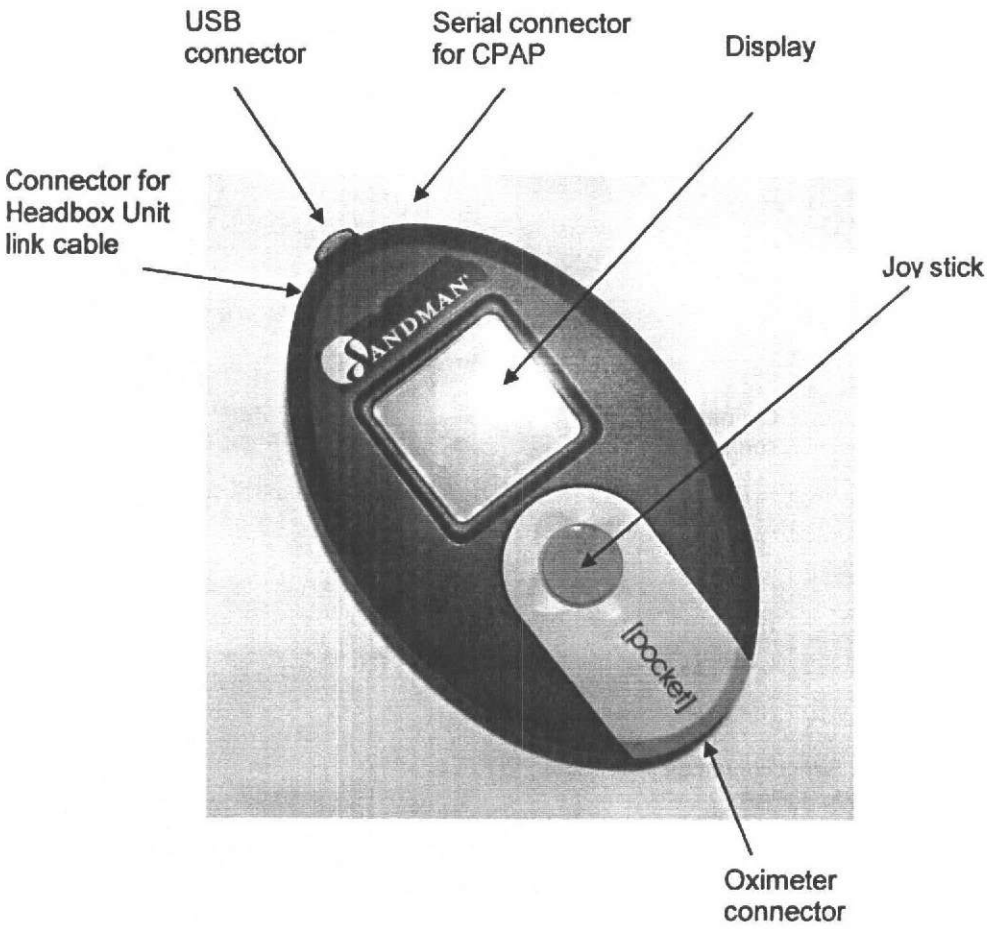
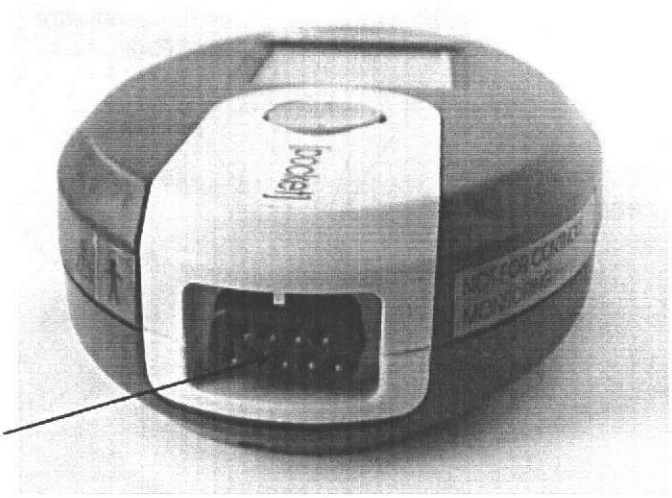
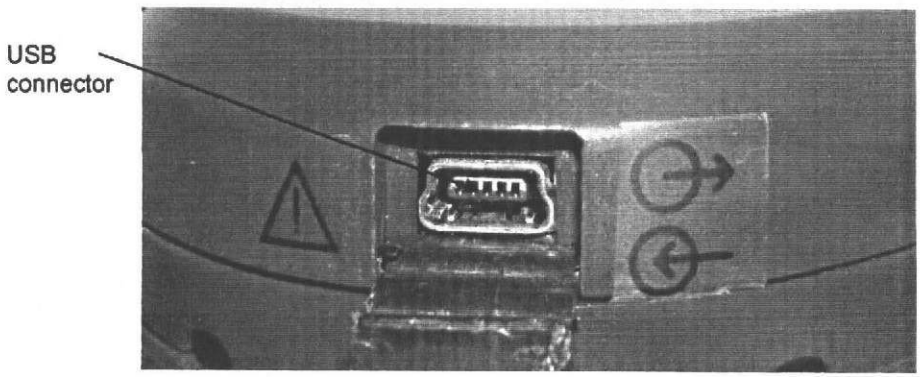


Figure 2-8 – SANDMAN POCKET amplifier box

2.3.1 CONNECTORS DESCRIPTION

The following figures show in details the connectors of SANDMAN POCKET amplifier module:





Figures 2-9, 2-10 and 2-11 – Amplifier module connectors

Where:

1. **SERIAL CONNECTOR** (RS232 connector). This connector is used to connect the SANDMAN POCKET to the CPAP.

2. **USB** connector (USB 2.0 miniB). This connector is used to connect the SANDMAN POCKET to PC.

3. **SANDMAN HEADBOX CABLE** connector. This connector is used to connect the Recorder Unit with the Headbox Unit.

4. **OXIMETER LINK** connector (shroud). This connector is used to connect axclusively an oxymetry sensor (Nellcor Puritan Bennett model DS-100 A).

ATTENTION

The amplifier uses a Nellcor Puritan Bennet (NPB) NELL-1 Pulse Oximetry module inside.
Use only with DS-100 A sensors or equivalent.

ATTENTION

Use a serial connector to connect Sandman Pocket Recorder to NPB (Tyco) model GoodKnight 420/425 series CPAP device only or equivalent.

ATTENTION

Use USB connector to connect sandman Pocket Recorder to a USB port of a host PC only.
Host PC must comply to IEC 60950 safety standard and powered through an IEC 60601-1 safety standard compliant.

ATTENTION

The OXIMETER LINK connector is protected from dust and dirt by a plug. Remove this plug in when connecting the oximetry sensor (NPB DS-100 A). When is the sensor removed, replace the protection plug.

ATTENTION

The USB connector is protected from dut and dirt by a plug. Remove this plug when connecting to the Host PC. When the Host PC connection is removed, replace the protection.

2.4 PULSE OXIMETRY MODULE

The SANDMAN POCKET recorder unit contains the Nellcor pulse oximetry module, model NELL-1. The NELL-1's major features are to interface with sensors and provide a Host system with patient data such as:

- Oxygen saturation (SpO2)
- Pulse rate
- Pulse waveform and pulse amplitude modulation (Blip)
- Motion indicator
- Sensor disconnect indicator
- Sensor off patient indicator

The NELL-1 is capable of communicating with the Host via a serial communication link.

2.4.1 INTENDED USE OF THE PULSE OXIMETRY MODULE.

The SANDMAN POCKET device constitutes "simply" the acquiring front end of SpO_2 and pulse rate data. In particular, notice that:

- The SANDMAN POCKET device limits its role to allow the host system to control of the NELL-1 module and to read the calculated data values.
- The SANDMAN POCKET device does not rely in any way with the processing of the SpO_2 and pulse rate data. These process are under the complete control and responsibility of the host system software.
- **The SANDMAN POCKET device is NOT involved in any alarm managing. The Pulse-Oximetry module of SANDMAN POCKET device is NOT intended for continuous monitoring.**
- The System Builder is responsible of the use of the oximetry data. In particular, the System Builder may assure that this use will meet the requirements of the EN 865 and ISO 9919 standards (if applicable).

ATTENTION

Refer to section 1.3 of this manual for further warning notes on the Pulse Oximetry Module usage

For your notes:

CHAPTER 3
CALIBRATION

This chapter describes the calibration procedures for the system amplifier chains only.

The SANDMAN POCKET amplifier system provides two different kinds of "calibration".

3.1 "PHYSICAL" SYSTEM CALIBRATION

This is the "real" standard calibration procedure. A physical signal (its amplitude and frequency are known) is injected into the input of each channel. The results of the entire processing (analog and digital) are measured and evaluated in order to verify that the signal processing chain is correctly working.
This kind of calibration allows to "adjust" the possible small gain values differences among the channels.
Physical calibration is a task under the control of authorizated people (service people).

From this acquired data, the corrective factors (calibration constants) are calculated in order to uniform the gain of each channel.
The calibration constants are stored in a flash memory on the SANDMAN POCKET amplifier box and then transmitted to the PC. The calibration constants are applied during each acquisition and they will be valid until the next physical calibration is made.

3.2 "RECORDING" SYSTEM CALIBRATION

This kind of calibration is normally performed at the beginning and/or end of each recording.
The calibration activation is under the operator's management and responsibility.
Under the HOST PC control, the amplifier system generates the calibration signal (square wave 1Hz frequency – 50μV amplitude).
This signal is sent to the PC and it allows to check the signal transferring chain, the communication protocol with HOST PC and digital processing chain (digital filters, digital gain, etc.).

For your notes:

CHAPTER 4
HOST COMPUTER - BATTERY

4.1 REQUIREMENTS FOR HOST COMPUTER

Application software on the host computer is under the responsibility of the System Builder. The System Builder must evaluate and validate the specific host, its Operative System, its minimum hardware/software and its safety requirements relating to the intended use / technical specification of the entire system.

When used to download the recorded data, the host computer must only provide a standard USB 2.0 compliant interface to be connected to the Sandman Pocket Recorder.

When the host computer is connected to the Sandman Pocket recorder during set-up or data acquisition monitoring (with the patient attached to the headbox unit of the recorder), the computer should be :

- a computer fully conforming to IEC 60601-1 standards (Medical grade computer)
- a computer conforming to IEC 60950 standard provided with an Isolation power transformer (IEC 60601-1 compliant).
- a battery powered laptop conforming to IEC 60950 standard

4.2 GENERAL PRECAUTIONS USING BATTERY

When the Sandman Pocket recorder is working in "Holter" modality, the only power source are the internal batteries. The batteries are housed in the specific space provided in the bottom part of the recorder unit of the Sandman Pocket. The batteries must always be present in the instrument during usage.

During the installation procedure of the batteries, observe the following warnings:

- Before replacing the batteries, make sure the device is not connected to the host PC.
- Remove the batteries when the recording has ended or when the device is not in use.
- Use completely full-charged batteries for each new recording.
- The use of batteries, which do not comply with the given ratings, will not guarantee a correct functioning and especially the recording endurance characteristics of the instrument.
- Alkaline batteries are not rechargeable and must be disposed of by following the regulations of the specific Country.

ATTENTION

The Holter modality requires the internal battery kit. Use new batteries at each new recording session.

ATTENTION

The Sandman Pocket Recorder must be equipped with the following battery cells: n°3 alkaline dry cell AA Size - V =1.5 Vn.

4.3 BATTERY REPLACEMENT

The condition of low charge batteries is shown on the display of the device by a dedicated message. With reference to the following figure, replace the internal main batteries by following the suggested procedure.

The batteries must necessarily be substituted with batteries having the same characteristics. The use of batteries that differ from those specified does not guarantee a correct functioning of the instrument with special regards to the recording range of the instrument.

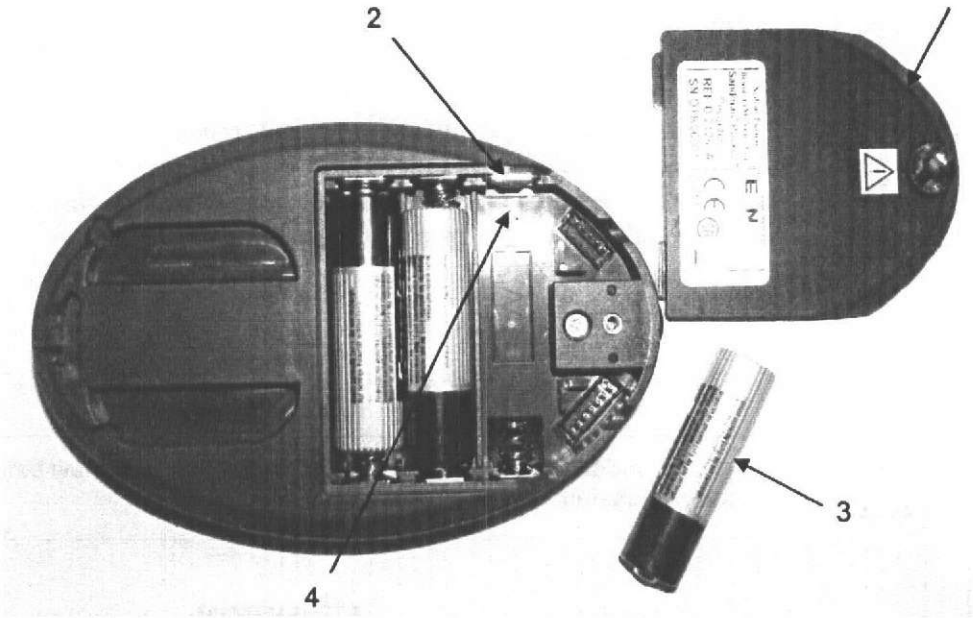


Fig. 4.2.1 – Replacement of the batteries

To replace the batteries :

- Disconnect the device from any other system or auxiliary unit.
- Remove the cover (ref. **1**) of the battery housing placed on the instrument's lower panel by pressing with a finger towards the direction shown on the cover itself.
- Remove the 3 battery cells from the housing one at a time, avoiding damage to the electric contacts (ref. **2**) placed on the internal side of the housing.
- Keep the discharged batteries separate from the new ones. The discharged batteries cannot be used again and they must be disposed of.
- Wait at least 30 seconds and then insert the 3 new battery cells (ref. **3**) paying attention to the polarity as shown on the bottom of the housing (ref. **4**). The newly inserted batteries must absolutely correspond to the type indicated by EBNeuro and must also have the same characteristics.
- Replace the cover of the battery housing by inserting it in the proper runners and push it until it is completely closed. The correct positioning is signaled by a "click".

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Before using the instrument, ensure that the batteries have been correctly inserted in their housing by checking also their polarity orientation. Remove batteries from the instrument each time the recording has ended and when the instrument is not in use.

The replaced batteries cannot be used again in any way. The discharged batteries must be disposed of in accordance with the waste regulations of the country in which the instrument is in use.

CHAPTER 5
CONNECTIONS

5.1 CONNECTING THE SYSTEM

With reference to the description of the device (chapter 2 of this manual) please install the SANDMAN POCKET amplifier system by performing the connections described in the following steps and images.

5.1.1 HOLTER MODALITY

In this modality, the SANDMAN POCKET works stand-alone. The Recorder Unit does not utilize all peripherals in Low Power Mode (LPM). The SANDMAN POCKET executes the data acquisition, the A/D conversion and the storage in the internal memory.
In Holter modality the only power sources are the batteries.

ATTENTION

The EBNeuro Sandman Pocket Recorder is not intended for the "end user", rather it is intended as an OEM product to be used by a "System Builder" as a piece of its own medical systems.

It is the responsibility of the System Builder to use the EBNeuro Sandman Pocket Recorder strictly following any technical specification and precaution of use *described in this manual*.

EBNeuro is not providing any sensor, lead or cable, nor any wearing system to the System Builder.

It is completely under the responsibility of the System Builder to provide all the accessories, any eventual wearing system and any related instruction in its system labeling and any necessary warnings against the correct connection and units/cable placing to avoid any possible strangulation risk. This applies in particular to the use of EBNeuro Sandman Pocket Recorder in pediatric studies.

ATTENTION

The following figures are provided for reference only to show the interconnection of the parts of the system.

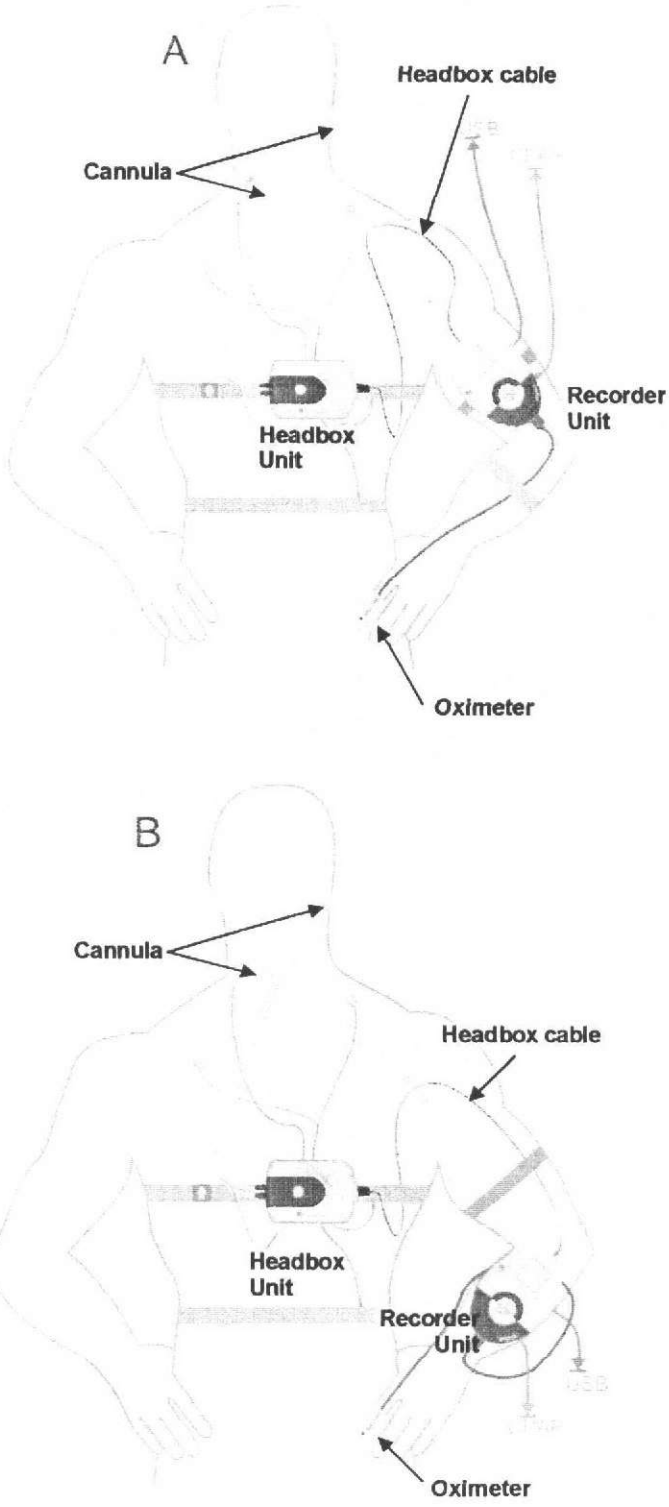

Figure 5.1.1 – SANDMAN POCKET amplifier system installation (reference examples only)

5.1.2 MONITORING MODALITY

In this modality, the SANDMAN POCKET is connected to a PC and executes the data transfer to the PC. The USB channel is active; the power supply can be draw from PC (500mA to 5V).

- Connect the Headbox Unit to the Recorder Unit with the **Headbox cable cod. B9730701001**.
- Connect through the USB port on the SANDMAN POCKET to the USB port of the HOST PC.

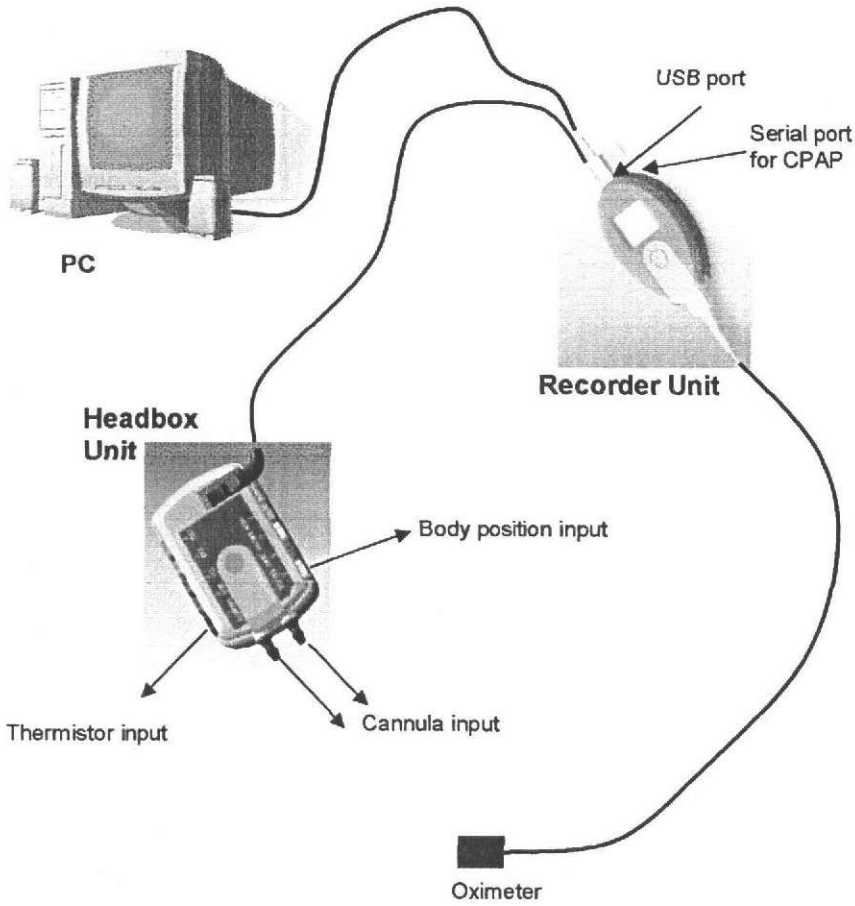

Figure 5.1.2 – SANDMAN POCKET Host Computer Connection

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5.2 FINAL WARNINGS FOR THE PATIENT

Before leaving the laboratory, warn the patient that the electrodes must not be touched or moistened and that the lead wires must not be pulled in any way.

The unit has an event recorder button. Patient can press the key to highlight an event. Physician must inform the patient about the correct use of these features.

ATTENTION

The patient should be informed on the correct use of the recorder's functional keys.

ATTENTION

The patient must not remove the batteries cover.

ATTENTION

The patient must not connect any device to the USB connector and must not open the USB plug.

ATTENTION

The patient must not remove electrodes.

Physician must inform the patient about the correct use of the unit .

CHAPTER 6
POWERING THE DEVICE

The SANDMAN POCKET amplifier module is powered through 3 alkaline batteries which provide 1.5 VDC each in Holter Mode. When working in Monitoring Mode, the Sandman Pocket is powered through USB.

6.1 SWITCHING ON/OFF THE DEVICE

The system can be switched ON in two different ways:

- through a long pressure on the joystick button
- programming the switch on by PC.

When the display light is lit, the system is powered ON. Sandman Pocket performs a Power On Self Test (POST) each time it is turned on. During POST, Sandman Pocket detects any major problems that prevents its normal operation. When Sandman Pocket fails the POST, it does not enter Normal operating mode and the LCD displays an error code/message stating the cause of the error. Successful completion of POST permits Sandman Pocket to proceed to its Normal operating mode.

At the same way, the system can be switched OFF:

- through a long pressure on the joy stick button
- programming the switch off by PC

The host PC has the complete control on the ON/OFF state of amplifier system by the described procedure. Please note that "OFF" state means "STAND-BY" state.

"STAND-BY" state: Sandman Pocket Recording unit is programmed by the PC and the unit is turned OFF. As soon the programmed DATE/TIME is reached the unit automatically switch ON and starts to record signals.

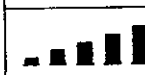
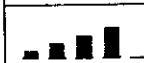
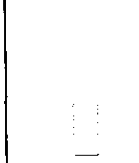
When operating on battery power alone; if Pocket detects low battery, it has at least 20 minutes of battery power left until it automatically ceases collection and completes the process of saving the current sleep study file to its internal memory. At this time, the backlight of the LCD turns on and displays a message informing the user that the battery power is severely low and Pocket is terminating the sleep study file so it is properly saved to its internal memory.

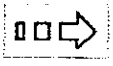
For your notes:

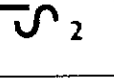
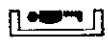
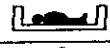
CHAPTER 7
STATUS MESSAGES

7.1 LIST OF THE STATUS MESSAGES

Following is a complete list of the messages shown on the instrument's display, with a brief explanation of their meaning and, eventually, a suggestion to resolve the problem in case of an error message.

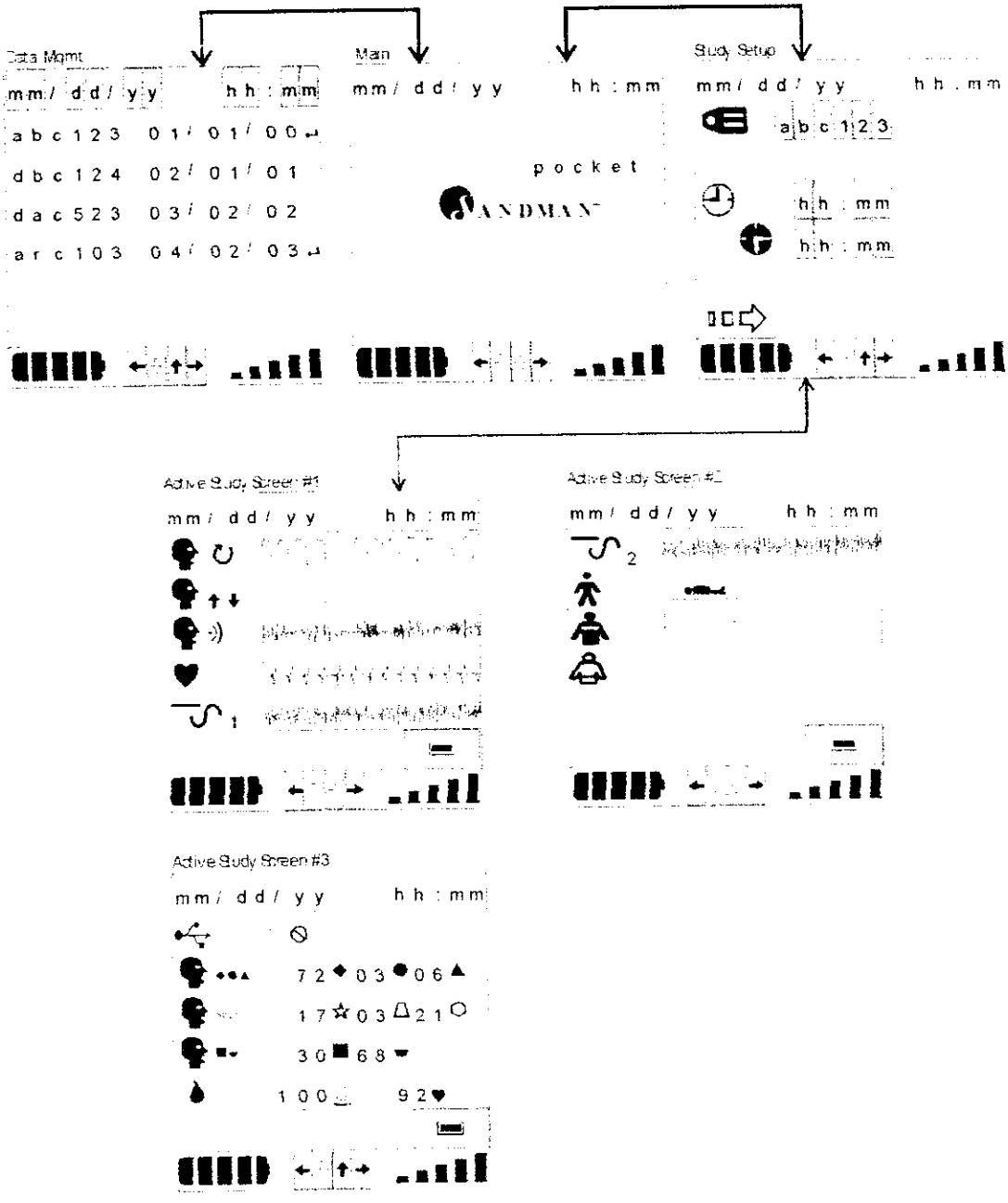
Symbol	Description	Detail
	"Battery Guage"	The Battery Guage will be used to indicate the status of Pocket's batteries.
	Battery level is good	Indicates that Pocket will be capable of recording a full night's study.
	Battery level is *fair*	Indicates there is a "fair" chance that Pocket will be capable of recording a full night's study, but, the user should change all of the batteries in order to be sure.
	Battery level is poor	Indicates there is a "poor" chance that Pocket will be capable of recording a full night's study and the user should immediately change all of the batteries.
	"Memory Guage"	The Memory Guage will be used to indicate the amount of Pocket's internal memory that is available to store sleep study data.
	100% Memory available	Each segment represents 20% of the internal memory.
	80% Memory available	
	60% Memory available	
	Selectable field	Using the Joypad controls the user can position a "cursor" in fields with this color background. When the "cursor" is in one of these fields, the background color will turn black and the foreground image or text will turn white. This field can be used for "softkeys" or for text that can be edited.
← ↓ ↑ →	Currently valid Joypad control directions	Pressing the Joypad control in these directions causes the cursor to navigate to the next available field.

Symbol	Description	Detail
	Currently invalid Joypad control directions	Pressing the Joypad control in these directions does nothing.
	Downloaded File	Appears beside sleep study files that have been previously downloaded off of Pocket's Recorder (files without this icon have never been downloaded).
	File name or "tag"	Indicates the filename field
	Start Time	User programmable time at which Pocket will begin recording sleep study data.
	End Time	User programmable time at which Pocket will stop recording sleep study data.
	"Start Now" softkey	The "Start Now" softkey will do nothing if the user has not entered a filename. When the "cursor" is in this field and the user presses down on the center part of the Joypad control, Pocket will begin to record data until the user presses the "Stop Now" softkey.
		The "Start Now" softkey will look like this when the "cursor" is in this field.
	"Stop Now" softkey	When the "cursor" is in this field and the user presses down on the center part of the Joypad control, Pocket will immediately stop recording data and finalize the current sleep study (this softkey will override any programmed Stop Time).
		The "Stop Now" softkey will look like this when the "cursor" is in this field.
	Oral/Nasal Cannula	Appears beside the trace that illustrates data captured at the Headbox's Cannula input.
	Thermistor	Appears beside the trace that illustrates data captured at the Headbox's Thermistor input.
	Snore Sensor	Appears beside the trace that illustrates data captured at the Headbox's Snore input.
	EKG	Appears beside the trace that illustrates data captured at the Headbox's EKG input.
	E-x-G1	Appears beside the trace that illustrates data captured at the Headbox's E-x-G1 input.

Symbol	Description	Detail
	E-x-G2	Appears beside the trace that illustrates data captured at the Headbox's E-x-G2 input.
	Body Position Sensor	Appears beside the image that illustrates *data captured at the Headbox's Body* Position input.
		Prone body position
		*Supine body position*
		Left side body position
		Right side body position
		*Upright body position*
	Chest Effort Belt	Appears beside the trace that illustrates data captured at the Headbox's Chest Effort Belt input.
	Abdominal Effort Belt	Appears beside the trace that illustrates data captured at the Headbox's Abdominal Effort Belt input.
	*USB Connection Status*	
	⊘	There is no valid USB connection present
	♩	USB power is present, but, communication is not available. May indicate that Sandman Pocket is being powered by its "Line Power Module" or the USB port is experiencing communication problems.
	♩♩	Both USB power and communication are present and functioning.
	CPAP data; channels 1 through 3	
	◆	*Appears to the right of CPAP channel 1's* data.
	●	Appears to the right of CPAP channel 2's data.
	▲	Appears to the right of CPAP channel 3's data.
	CPAP data; channels 4 through 6	
	☆	*Appears to the right of CPAP channel 4's* data.
	△	Appears to the right of CPAP channel 5's data.
	○	Appears to the right of CPAP channel 6's data.
	CPAP data; channels 7 & 8	
	■	*Appears to the right of CPAP channel 7's* data.

Symbol	Description	Detail
		Appears to the right of CPAP channel 8's data.
	NELL-1 Blood Oximetry Data	
		Appears to the right of SpO_2 data received from the NELL-1. This data is shown in percent saturation (%).
		Appears to the right of Pulse data received from the NELL-1. This data is shown in bets per minute (bpm).

7.2 MENU



For your notes:

CHAPTER 8
MAINTENANCE

8.1 GENERAL INFORMATION ABOUT MAINTENANCE

In order to keep the device working for a long time and to ensure the patient's and the operator's safety, it is necessary that the general checks indicated below are periodically performed by medical or paramedical qualified staff or by technical staff authorized by EBNeuro.

- Perform a sight inspection of all the components, the accessories, and the connections of the device to the peripherals in order to identify any traces of failure, damage, or disconnection.
- Verify that all labels and any warning or instructions printed on the device are readable.
- Check that the performances and the workings of the device are correct.
- Clean the external surface of the device carefully with the recommended products only.
- Replace parts or accessories only with others having the same characteristics or those expressly indicated by EBNeuro.
- Discard replaced parts, accessories, and the device at its "end of life" according to the local standards and directives currently in force.

For all ordinary maintenance operations pertaining to the devices of the SANDMAN POCKET system (electromedical system to which the SANDMAN POCKET device is connected or auxiliary components not produced by EBNeuro such as personal computers, monitors, printers, consumers accessories and so on), please refer to the corresponding user's manual provided with them.

For detailed information on battery installation, substitution and recharge operation of the auxiliary batteries of the SANDMAN POCKET system, refer to the appropriate paragraphs of Chapter 4.

8.2 SAFETY CHECKS

It is essential to periodically check the equipment and the devices or systems it is connected to and all the interconnection cables in order to ensure that the equipment continues working efficiently and safely. It is also necessary to check the equipment to remove any dust deposits. Preventive or corrective maintenance operations must be performed by qualified technical staff expressly authorized by EBNeuro.

A sight inspection of the interconnection cables, with particular care for the cable between equipment and the AC/DC adapter and for all the power cords (mains cable), can be performed also by medical or paramedical staff in order to remark any breaking or disconnection. In case of need, immediately contact a qualified technician to solve the problem detected before continuing to use the equipment or connecting it to other devices. For the technical assistance request procedures, please refer to chapter "Request for assistance" of the manual.

ATTENTION

Safety checks must be accurately performed periodically and at least twice a year.

8.2.1 ENVIRONMENT ELECTRICAL EQUIPMENT

A danger for the patient's health is determined, first of all, by the efficiency of the electrical equipment of the building where the equipment is used. The isolation safety guaranteed by Class I to which the device belongs is useless, in the event the device is powered by the specified external AD/DC adapter or it is connected to a device or a system supplied by the mains, if the wiring is not provided with a good earth plate, accessible though the mains outlet.

It is fundamental that qualified technicians check the electric wiring periodically with particular care for efficiency of the main outlets.

ATTENTION

If the integrity of the environment's electrical equipment, and in particular the protective earth, is not reliable for safety, do not power or use the equipment until *the safety conditions are restored.*

8.2.2 INTERCONNECTION CABLES AND CONNECTORS

It is necessary to check periodically the integrity of the interconnection cables between the instrument and the other devices that compose the system.

Elementary precautions may prevent prematurely breaking or deteriorating of the cables. Be careful when removing the cables from the corresponding connectors on the equipment panel; take the cable terminal connector resolutely, though with delicacy, out of the connector. Avoid twisting or tearing cables, which may cause breaks and interruptions to the conductors.

Monthly check cables for abrasion and wear. Replace any cable with exposed wire or shield. Check the connectors on the ends of cable for bent or broken pins. Replace the cable with damaged connector.

8.3 CLEANING THE DEVICE

It is necessary to keep the equipment clean in order to avoid dust deposits, which could interfere with the efficiency of all the system components.

WARNING

Do not immerse the equipment nor its parts in liquids, do not oil any part of it and avoid cleaning the external surface with alcoholic disinfectants that could cause *damages and decolorization of the printed surfaces*

ATTENTION

***Before cleaning any part of the equipment turn off (O) the equipment power switch* and disconnect the equipment from any other equipment or external devices and remove the internal batteries.**

ATTENTION

The external surface of the equipment must be cleaned with a cloth lightly moistened with warm water and soap. Wipe the washed parts with a dry cloth.

ATTENTION

Make sure no liquid seeps into the instrument and check it's complete dryness before inserting the batteries or before connecting it with other devices, thus *switching it on.*

ATTENTION

Avoid contact of the device with the patient's skin. If necessary, use a biocompatible bag.

8.4 PARTICULAR WARNINGS FOR CRITICAL COMPONENTS

The instrument is provided with a LCD (Liquid Crystal Display), and it uses alkaline battery cells, which contain small quantities of toxic materials.

In order to avoid personal injuries and to reduce the negative impact on the environment, make sure you carefully follow these instructions:

LDC Display:

- The LCD is fragile (glass) and must be treated with much care: for this reason we recommend protecting the device with the proper carrying bag during transportation or when it is not used.
- In the event that the LCD glass should break and liquid spill out of it, make sure you do not touch it. Wash with water for at least 15 minutes any body part that may have been in contact with it carefully. Should you experience any symptom after this period, ask for immediate medical help.

Batteries:

- Avoid terminal parts of the battery pack coming in contact with metal objects.
- Keep the battery pack away from heat sources or flames.
- Do not immerse the battery pack and avoid exposing it to rain or humidity.
- Avoid directly hitting the battery pack.
- Do not attempt to disassemble, burn or cause short-circuits to the battery. Such operations may cause a fire or emission of toxic chemical substances.
- Remove the battery at the end of the recording.

CHAPTER 9
TECHNICAL CHARACTERISTICS

9.1 SANDMAN POCKET POLYSOMNOGRAPH RECORDER SYSTEM

Product name	**Sandman Pocket**
Description	Active, non-invasive medical device
Intended use	Intended for use in collecting and recording physiological data to be used in polisomnography and sleep disorder studies. The Sandman Pocket is intended for pediatric through adult patient populations and can be used in either home or hospital environments.
Classification according MDD 93/42/EEC	Class IIb

Standards applied

93/42/EEC	Medical Device European Directive(MDD)
EN 60601-1-1	Collateral safety standard for electromedical systems;
EN 60601-1-2	Collateral safety standard for devices EMC test;
EN 60601-1-4	Safety standard for devices containing Programmable systems;
EN 60601-2-26	Standard on particular safety requirements for electroencephalographs

Type of protection against electric shocks

Class I equipment (when powered trough USB port of the host computer).

Internal powered equipment

Protection level against electrical direct and indirect contacts

CF type (ECG, EXG1, EXG2, Thermistor, Body Position, Snore, Chest, Cannula, Abdomen inputs and ISOGND)
B type (Oximeter, CPAP)

Protection level against inflow of solids and liquids	Common (IP20)	
Operational mode	Continuous, within the specified limits	
Environmental conditions for usage	Temperature	from +5°C to +40°C
	Relative humidity	from 30% to 75% RH
	Atmospheric pressure	from 700hPA to 1060hPA
Environmental conditions for storage (max. 15 weeks)	Temperature:	from -30°C to +60°C
	Relative humidity	from 5% to 95% RH (excluding condensation)
	Atmospheric pressure	from 500hPA to 1060hPA

9.2 RECORDER UNIT

Device rated values	Manufacturer:	EBNeuro S.p.A.
	Trademark:	Nellcor Puritan Bennett (Melville)
	Model:	POCKET Recorder
	EBNeuro code:	B9700650000
	NBM code (REF)	D.2126
	Year of manufacture	
	Serial Number (SN)	
	CE0051 mark (93/42/EEC)	
	cCSAus mark	

DC/AC coupling EXG bipolar channel	2
AC coupling ECG bipolar channels	1
AC coupling dedicated bipolar channels	5 (Thermistor; Snore; Chest; Abdomen; Cannula)
DC coupling dedicated bipolar channels	1 (Body Position)
Impedance measurement	By means of injected current (16 Hz - 0.01 µA/electrode)
A/D conversion	16 bits SAR A/D

Resolution, Dynamic and Noise

Bipolar channels

Coupling	Gain Setting+Resolution	Full Scale Range	Noise(0.1Hz-70Hz)
AC	1/8 µV/bit	8000µVp-p	0.5 µVrms max
DC	30 µV/bit	±1Vpp	

Frequency Response Raw Data

High-Pass filters	monopolar channels DC or 0.099Hz 1st order filter (selected by a software controlled switch) bipolar channels 0.099 1st order filter
Anti-aliasing Low-Pass filters (3 th order filter)	Frequency cut 135 Hz for ECG, EXG1, EXG2, Snore 45 Hz for Abdomen and Chest Attenuation 24dB/octave

Selectable Sampling Rate

Channel	Storage rates [sample/second]
Thermistor	128, 64, 32,16, 8
Chest	16, 8, 4
Abdomen	16, 8, 4
Snore	128, 64
Body Pos	4, 2, 1
Cannula	128, 64, 32, 16, 8
EXG1	128,64
EXG2	128, 64
EKG	128, 64

Sampling Skew	90 µs max
CMMR	>100 dB
IMRR	>120 dB
Max DC Offset (AC mode)	± 300 mV
Amplifier box – PC interface	USB 2.0 miniB (12Mbit/s)
Human interface	n° 1 display n° 1 joy-stik

Power supply

- Internal batteries (4.5V DC)
- USB connection (Host PC) 5VDC – 270mV

Internal batteries

- Number and type: 3 alkaline cells AA size
- Nominal voltage: 1.5 Vn

Consumption 270 mW Recorder and Headbox

Case

Material:	ABS
Dimensions:	127 x 80 x 30 mm
Weight:	- about 102 g (without batteries) - about 173 g (with batteries)

9.3 HEADBOX

Device rated values	Manufacturer:	EBNeuro S.p.A.
	Trademark:	Nellcor Puritan Bennett (Melville)
	Model:	POCKET Headbox
	EBNeuro code:	B9630650000
	NPB code (REF)	D.2127
	Year of manufacture	
	Serial Number (SN)	
	CE0051 mark (93/42/EEC)	
	cCSAus mark	

Case	Material:	ABS
	Dimensions:	70 x 45 x 22 mm
	Weight:	40 g

Electrode connectors 3 active – two active connection to each input (bipolar)
5 dedicated – two connection to each input (bipolar)
1 for isolated patient ground

Cable for connection to the recorder unit Headbox Cable

Cable for connection to the CPAP

Interfaces
Body position connector
Thermistor connector
Sore connector
Abdomen connector
Chest connector
Oximeter connector
Pressure sensor (Honeywell XPL04DTC)

Human interface n° 1 event marker button

9.4 PULSE OXIMETRY PRINTED CIRCUIT BOARD

Nellcor Puritan Bennet NELL-1 Pulse Oximetry Module
(Refer to NPB documentation for specifications and accessories)

CHAPTER 10
COMPONENTS AND ACCESSORIES

10.1 SANDMAN POCKET - AMPLIFIER SYSTEM – cod B9800065400

CODE	DESCRIPTION	QUANTITY
STANDARD COMPONENTS		
B9700065400	Recorder module	1
B9630065400	Headbox module	1
B9730701001	Headbox cable	1
B9730701002	CPAP cable	1
B8300065411	Operator Manual - English	1
B9400065400	complete package	1
OPTIONAL COMPONENTS		
Service Manual:		
B8310065400	Service Manual - English	

10.2 SANDMAN POCKET CODES COMPARISON TABLE

In the following table are listed the main components of Sandman Pocket system. For the components, are indicated the equivalent Nellcor Puritan Bennett codes which are written on the identification labels of devices.

DESCRIPTION	SANDMAN DIGITAL EBNeuro code	SANDMAN DIGITAL Nellcor P. B. code
Recorder module	B970 0065 400	D.2126
Headbox module	B963 0065 400	D.2127
Headbox cable POCKET	B973 0701 001	D.7214
CPAP cable POCKET	B973 0701 002	D.7215

CHAPTER 11
REQUEST FOR ASSISTANCE

11.1 OBTAINING SERVICE

In case of problems, such as failure of the device, or in case of partial or incorrect working that cannot be solved through usual maintenance operations, please contact one of the main offices or branches of EBNeuro or the nearest retailer or authorized servicing center.

ATTENTION

In case of failure of the device or if it starts working in a way not complying with what is written in the manual, especially as far as safety is concerned, STOP USING IT IMMEDIATELY and contact the technical service. Do not use the device until the *safety conditions have been checked and restored.*

NOTE

In order to speed up the procedures to start the intervention of the technical service and to make it easier for the specialized technical staff to identify the problem on the first phone call by the customer, please fill in the form below in this page.
The equipment data may be found on the equipment identification label.

REQUEST FOR ASSISTANCE

EBNeuro Device/system name.....

EBNeuro Device code/reference number (REF) .....

Serial number (SN) or lot number (LOT) .....

Current software version (Rel) .....

11.2 EBNEURO MAIN OFFICES

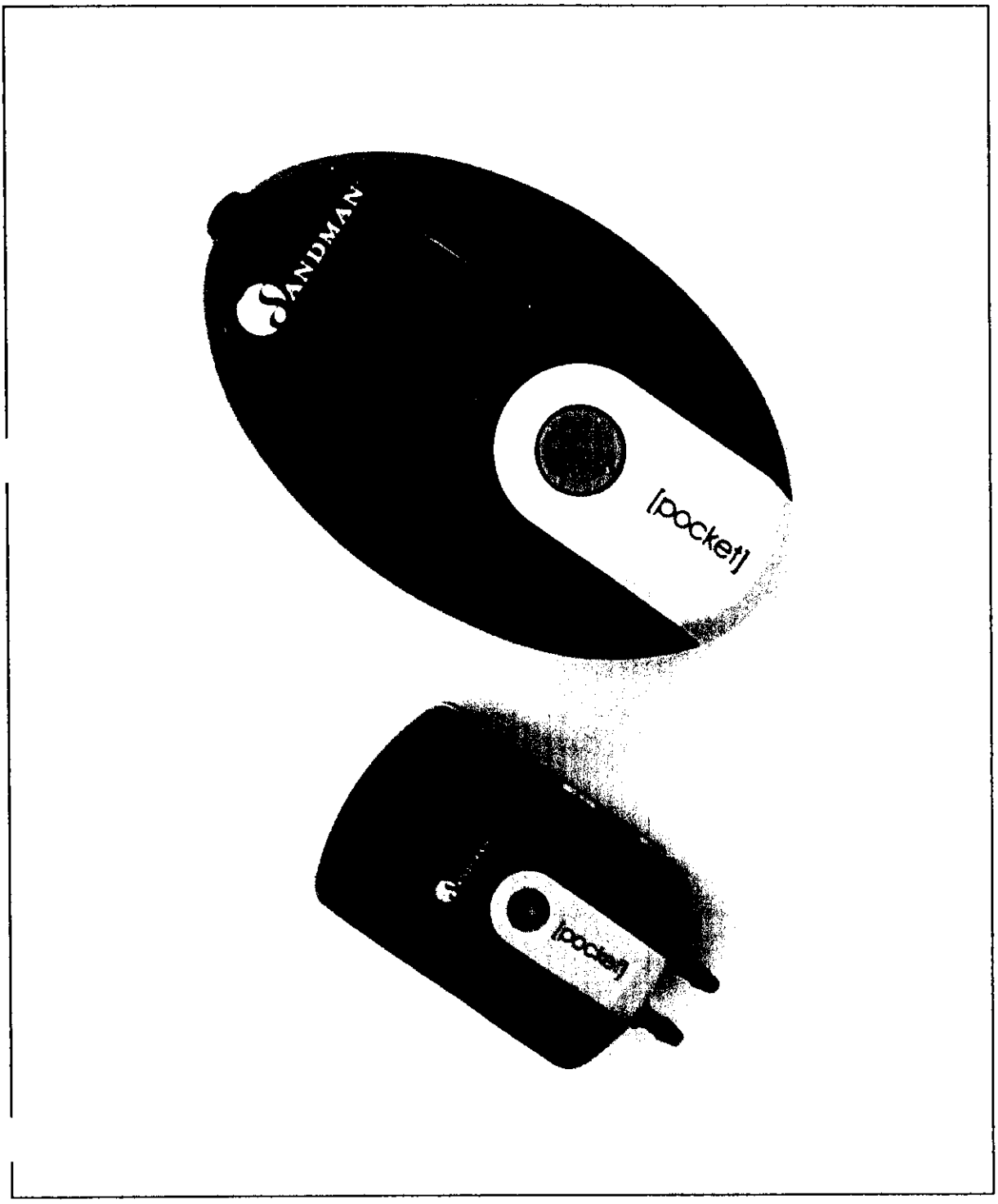
Please find below the addresses of the EBNeuro main offices.

OPERATING OFFICES

EBNeuro S.p.A.
Operatine office:
FIRENZE
Via Pietro Fanfani, 111/A
50127 - Firenze
Phone 055-4565111
Fax 055-4565123

EBNeuro S.p.A.
Operatine office:
VERONA
Via Bologna, 1
37020 - Arbizzano di Valpolicella (VR)
Phone 045-6028111
Fax 045-6028100

SANDMAN POCKET
Polysomnograph Recorder System



ESCRIPTION

The ***Sandman Pocket*** *Amplifier* is a portable multi-channel polysomnograph recording device that digitally amplifies physiological activity and records data onto an internal *NAND flash memory* chip or sends it directly to a PC via the *USB* port. The ***Sandman Pocket*** system is modular in design. It consists of a *Recorder* and, a data acquisition module called "*Headbox*". This small, lightweight recording system is comfortable for the patient and simple for the clinician to set up.
The patient can sleep and move freely while recordings are being made, allowing the exams to be done in the patient's home. The acquired data can then be used as an aid in the diagnosis of cardiac and/or respiratory related sleep disorder by qualified physician.

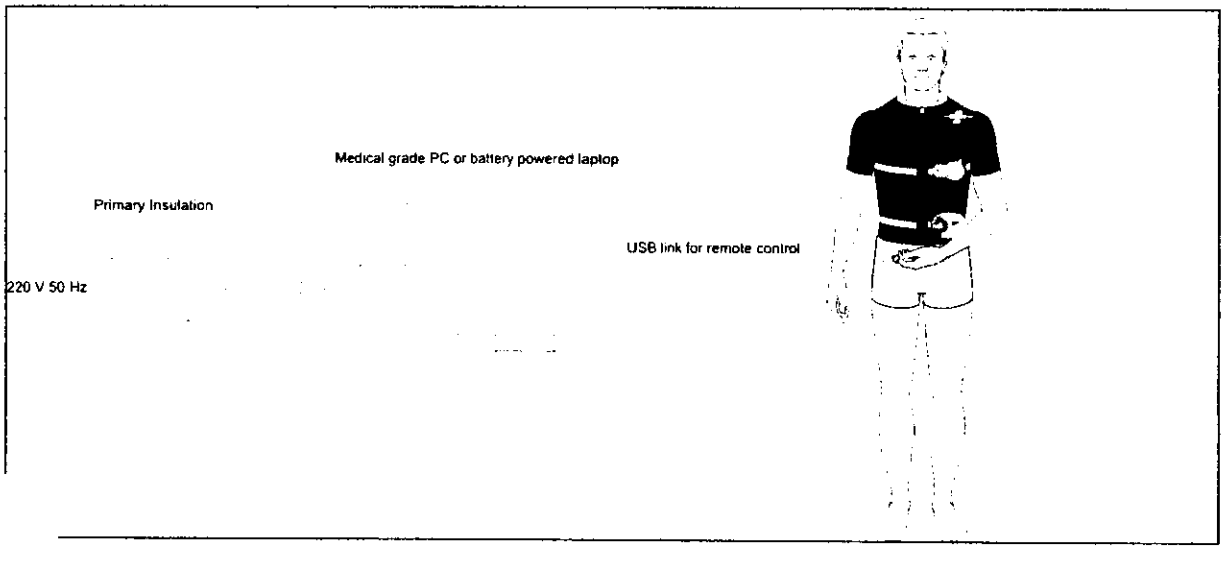
The data are acquired by a combination of electrodes, sensors and transducers.
Signal types can include electrocardiogram, pressure, airflow, snore, respiratory effort, body position, oxygen saturation pulse rate and pulse waveform.

The ***Sandman Pocket*** *Amplifier* is manufactured by EBNeuro and intended for use in collecting and recording physiological data to be used in polisomnography and sleep disorder studies. The Sandman Pocket pediatric through adult patient populations and can be used in either home or hospital environments.

The ***Sandman Pocket*** *Amplifier* is not intended for a direct use by clinician but rather by a anufacturer company that wants to build a full sleep disorder analysis system.

Sandman Pocket *Amplifier* is the result of the EBNeuro advanced design in this field.

The ***Sandman Pocket*** *Amplifier* project was managed on the experience made by EBNeuro R&D staff in similar projects developed in the past.
Personnel involved in the design participated in the development of many other bioelectric amplifiers, FDA and CSA cleared.



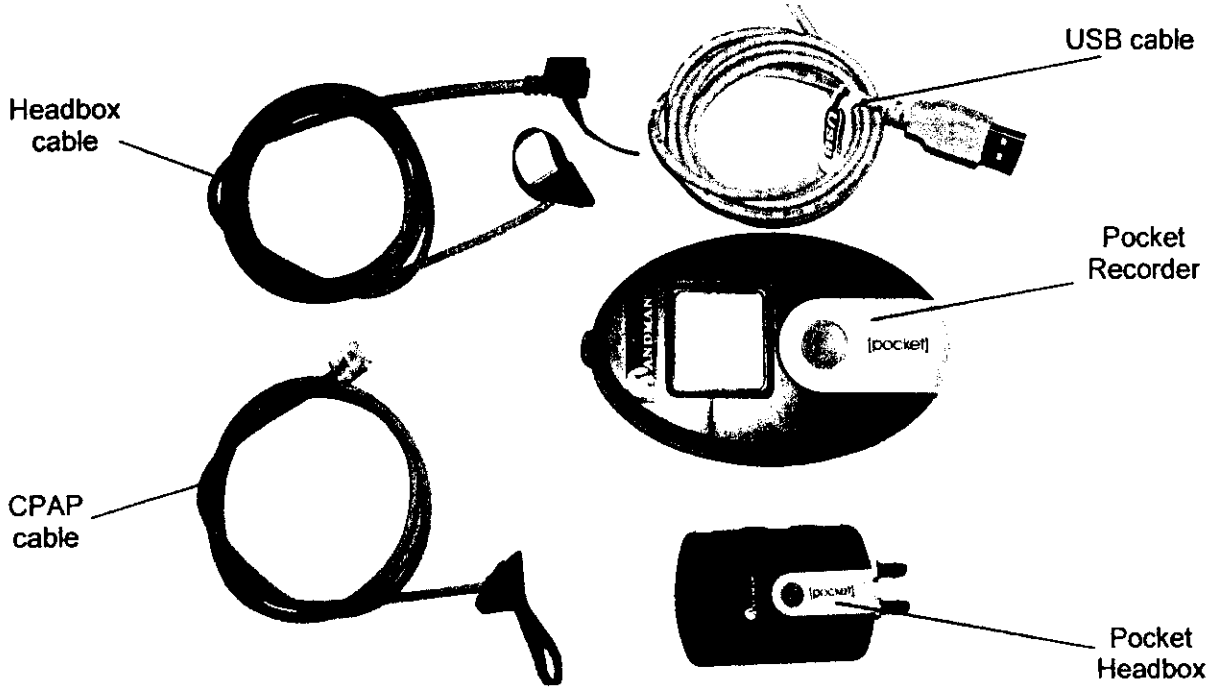
e ***Sandman Pocket*** *Amplifier* is comprised of two main modules and can be used either in attended or unattended mode. A typical attended study configuration may include some or all of the following components:

- SANDMAN POCKET Recorder
- SANDMAN POCKET Headbox
- Link cable Recorder – Headbox
- Link cable Recorder CPAP
- USB 2.0 High speed cable

All sensors with cables (effort belts, airflow sensor (thermistor), BreathSensor™ and BreathSensor™ Airflow Cable, microphone, Pneumotachograph kit, Nellcor®OxiMax™ oximeter extension cable and MAX-A OxiMax Sensor, and electrodes with jumper cables), wearing system (Recorder - Headbox pouch) are responsibilities of the System builder.

As specified above, the ***Sandman Pocket*** *Amplifier* can be used in Attended Mode - *Monitoring* or Unattended Mode – *Holter.*
During *Monitoring* operations, the amplifier is able to transfer data to the PC via the USB channel; polysomnograph signals are digitalized and simultaneously stored in the internal recorder memory while they are sent.
Clinicians are able to monitor the polysomnograph signals (through the System builder display/analysis SW tools), issue the Ohmmeter command (for impedance check), set up the patient preset, verify the usage memory, download existing studies and fully control the ***Sandman Pocket*** *Amplifier* configured as *Slave Device.*

During *Holter* operations, the ***Sandman Pocket*** *Amplifier* stores the digitalized polysomnograph signals in the internal memory according to the Patient preset configured by clinicians in the previous stage.



TECHNICAL CHARACTERISTICS

Sandman Pocket complete system

Product name **Sandman Pocket**

Description Active, non-invasive medical device

Intended use Intended for use in collecting and recording physiological data to be used in polisomnography and sleep disorder studies. The Sandman Pocket is intended for pediatric through adult patient population, and can be used in either home or hospital environments.

The Sandman Pocket is not intended for use as life support equipment such as a vital sign monitoring in intensive care unit. The device does not produce alarms and is not intended as an automated apnea monitor.
The Sandman Pocket is only to be used under the direction or supervision of a physician, technologist or clinician. It will not prevent or restore the interruption or loss of any physiological system.

Classification according MDD 93/42/EEC

Class II b

Standards applied

93/42/EEC	Medical Device European Directive(MDD)
EN 60601-1-1	Collateral safety standard for electromedical systems;
EN 60601-1-2	Collateral safety standard for devices EMC test;
EN 60601-1-4	Safety standard for devices containing Programmable systems;
EN 60601-2-26	Standard on particular safety requirements for electroencephalographs

Type of protection against electric shocks

Class I equipment when powered by specified supply chain: +5V USB retrieved from a Class I Medical grade PC.

Class III equipment when internnally powerded with battery.

Protection level against electrical direct and indirect contacts	CF type	(ECG, EXG, Thermistor, Body Position, Snore,Chest, Cannula Abdomen inputs)
	B type	(Oximeter)
Protection level against inflow of solids and liquids		Common (IP20)
Operational mode		Continuous, within the specified limits
Environmental conditions for usage	Temperature	from +5°C to +40°C
	Relative humidity	from 30% to 75% RH
	Atmospheric pressure	from 700hPA to 1060hPA
Environmental conditions for storage (max. 15 weeks)	Temperature:	from -30°C to +60°C
	Relative humidity	from 5% to 95% RH (excluding condensation)
	Atmospheric pressure	from 500hPA to 1060hPA

Recorder Unit

DC/AC coupling EXG bipolar channel	2
AC coupling ECG bipolar channels	1
AC coupling dedicated bipolar channels	5 (Thermistor; Snore; Chest; Abdomen; Cannula)
DC coupling dedicated bipolar channels	1 (Body Position)
Impedance measurement	By means of injected current (16 Hz - 0.01 μA/electrode)
A/D conversion	16 bits SAR A/D

Resolution, Dynamic and Noise

Bipolar channels

Coupling	Gain Setting+Resolution	Full Scale Range	Noise(0.1Hz-70Hz)
(b)(4)			

Frequency Response Raw Data

High-Pass filters

Anti-aliasing Low-Pass filters (3 th order filter)

(b)(4)

Selectable Sampling Rate

Channel	Storage rates [sample/second]
Thermistor	(b)(4)
Chest	
Abdomen	
Snore	
Body Pos	
Cannula	
EXG1	
EXG2	
EKG	

Sampling Skew

CMMR

IMRR

Max DC Offset (AC mode)

Amplifier box – PC interface

Human interface

(b)(4)

Power supply	Internal batteries (4.5V DC)
Internal batteries	(b)(4)
Consumption	
Case	

eadbox Unit

Electrode connectors 3 active – two active connection to each input (bipolar)
5 dedicated – two connection to each input (bipolar)
1 for isolated patient ground

Cable for connection to the recorder unit POCKET Link Cable

Cable for connection to the CPAP

Interfaces
Body position connector
Thermistor connector
Sore connector
Abdomen connector
Chest connector
Oximeter connector
Pressure sensor (Honeywell XPL04DTC)

Human interface n° 1 event marker button

Case

Material:	ABS
Dimensions:	70 x 45 x 22 mm
Weight:	40 g

EB Neuro S.p.A

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The following section is page numbered independently from the remainder of the submission.

OxiMax®
NELL-1

Pulse Oximetry System Guide

Cet appareil ISM est conforme à la norme NMB-001 Canada.

Nellcor Puritan Bennett Inc. is an affiliate of Tyco Healthcare.

To obtain information about a warranty, if any, contact Nellcor's Technical Services Department, or your local representative.

Purchase of this instrument confers no express or implied license under any Nellcor Puritan Bennett patent to use the instrument with any sensor that is not manufactured or licensed by Nellcor Puritan Bennett.

Table of Contents

Preface

1 – Introduction

2 – Host Interface

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Preface

This manual provides detailed information about the *Nellcor* NELL-1 pulse oximetry module, and how to use it as the core component of a pulse oximetry instrument. The manual describes key features and how to use them, and provides *OxiMax*® performance and functionality available with the NELL-1, as well as detailed information on how to use the Standard Host Interface Protocol (SHIP).

Nellcor OxiMax technology is a system in the NELL-1 pulse oximeter board that uses calibration data contained in *Nellcor* brand *OxiMax* sensors when calculating the patient's SpO_2. Using calibration data from the individual sensor rather than the pulse oximeter board significantly improves the accuracy of the information, because the calibration coefficients used in the calculations are tailored to the information detected in the sensor.

Although this manual does include a brief introduction to pulse oximetry, it is not intended to teach the subject in detail, and does not contain tutorial information. Users are expected to be experienced in working with pulse oximetry equipment and should be familiar with the requirements and regulations governing the use of such equipment.

Overview

This section of the manual contains the following topics:

- Manual Organization
- Getting Help
- Related Documents
- Manual Conventions

Manual Organization

This manual is organized into four chapters, as follows:

Chapter 1: Introduction

This chapter briefly describes the features of the NELL-1.

Chapter 2: Additional Information

This chapter describes the NELL-1 features in more detail, as well as potential issues for host implementation.

Chapter 3: Operator's Manual Recommendations

This chapter lists recommendations related to pulse oximetry that need to be considered for the operators manual.

Chapter 4: Specifications

This chapter lists the specifications for the NELL-1.

Getting Help

Nellcor is a strong believer in customer satisfaction. Our products are designed to provide you with the best performance for your money and we want to make sure you are completely satisfied with our products. One way of doing this is to provide you with the best support. Nellcor provides two types of support, described on the next page. Before you call for help, however, please read the next section.

Before Calling Support

Many problems can be quickly solved with the information in this manual or in the manuals listed under on the next page.

If you are unable to solve a problem using these manuals and need help from Nellcor Technical Support, please do the following before you call:

- Write down the exact problem and any details which may help us solve the problem. If you can consistently reproduce the problem, please list the steps to reproduce it.
- Have the following information available when you call:
  - Product name and version number.
  - The wording of any error messages from the product.
  - If the problem is new and has not occurred previously, list any recent changes you may have made to the Host System.

Engineering Integration Support

NELL-1 Host System developers should contact Engineering Integration Support when they need help integrating the NELL-1 into their Host system. Developers should contact their Nellcor account manager for a referral to the appropriate Engineer for help.

Technical Support

If the NELL-1 module appears defective, contact Nellcor Technical Support at 1-800-635-5267 (1-800-NELLCOR). In addition, refer to the **Service and Support** page on the Nellcor web site at **www.nellcor.com.**

Related Documents

For further information about the NELL-1 and related Nellcor products, see the following Nellcor documents:

- *NELL-1 Host Interface Specification*
- *NELL-1 Engineering Product Specification*
- *OxiMax N-600 Operator's Manual*

Manual Conventions

Table 1 shows the text formatting conventions that are used in this document.

Table 1. Text Formatting Conventions

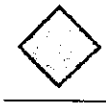
Convention	How Used
bold	Bold text in a sentence indicates selectable commands or menu choices, or text or commands that are to be entered. It is also used to highlight the first use of a new term. This term may be defined in a Glossary or described in the text.
italics	Text in italics is used to call attention to important information and is used for document titles. In addition, italics distinguishes various software elements, such as function terms and commands, file names, and directory path names.

Chapter 1
Introduction

Overview

This chapter briefly describes the NELL-1 pulse oximeter module and its features. The following major topics are included:

- Module Description
- Default Reset Values
- *OxiMax* Technology
  - Low Power
  - Selecting NELL-1 Features
  - *OxiMax* Sensors
  - Signal Processing
  - Alarms
  - Patient's Pleth Waveform
  - Variable Pitch Pulse Tone
  - BLIP Bar
  - Analog Out
  - *SatSeconds*™ Alarm Management Technology
  - Response Mode
  - Sensor Adjust (OxiMax Sensor Messages)
  - *C-Lock*™ ECG Synchronization
  - Sleep Mode
  - Pulse Strength Reporting (% Modulation)
  - Sensor Event Recording



Note: This document provides an explanation of all NELL-1 features; if additional information is required, contact Nellcor OEM Product Engineering Support.

Module Description

The *Nellcor* NELL-1 pulse oximetry module is a small printed circuit board assembly that provides the core components of a low power pulse oximeter system with *OxiMax* performance. It is designed for OEM use and supports the full line of *Nellcor OxiMax* Sensors, including the new MaxFast™ Adhesive Forehead Sensor.

The following features are included in the NELL-1 and are available via the Standard Host Interface Protocol (SHIP).

- ***OxiMax* Technology** - measures and reports SpO_2 and Pulse Rate with identified pulse at least once per second. *OxiMax* Technology incorporates the N-600 algorithm that improves the accuracy of the patient's SpO_2 and pulse rate measurements.
- **Sensor Connection Status** - reports whether the sensor is connected to the monitor or not.
- **Sensor Attached to the Patient** - reports when the sensor is no longer attached to the patient.
- **Pulse Timeout** - reports when the NELL-1 detects the loss of the patient's physiologic signal.
- **Pulse Search** - reports that the NELL-1 is searching for a pulse prior to reporting the first SpO_2 and pulse rate.
- **Waveform and Blip** - reports plethysmograph waveform and pulse amplitude.
- **Interference** - reports when waveform interference is detected.
- **Sensor Event** - records patient event information to the sensor.
- **Sensor Adjust** - reports sensor adjustment information to assist with optimal sensor placement on the patient.
- **ECG Synchronization (*C-Lock*)** - improves the ability to monitor difficult-to-monitor patients by providing the pulse detect algorithm with a signal synchronized with the ECG R-wave.
- **Sleep Mode** - a non-operational mode that provides for additional power savings.

Low Power

With the NELL-1, the OEM has the latest in pulse oximetry technology from Nellcor that supports the full *OxiMax* feature set. At the same time, the NELL-1 requires a maximum power of only 100 milliwatts for even the most difficult patients. For typical patients, the NELL-1 uses as little as 65 milliwatts.

Default Reset Values

All reset values are equivalent to power-up values, and all power-up default values are restored. [illegible] lists the default reset values.

Table 2. Default Reset Values

Setting	Value
Alarm Limit Settings High Sat Low Sat High Rate Low Rate	Adult 100 85 170 40
Sensor Event SpO_2 Limit Settings High Sat Low Sat	 100 85
Saturation Response Mode	Normal
Percent Modulation Message	Disabled
SatSeconds Alarm Management	Disabled
Sensor Adjust	Disabled
Sleep Mode	Disabled
Wave Blip Report	Sent on every sample message
C-Lock	Enabled
Sensor Event Recording	Disabled
Sensor Event Type	SpO_2-Only
Sensor Event Read Message	Closed

Selecting NELL-1 Features

The defaults for the NELL-1 are the minimum settings for features required to perform the primary function of reporting SpO_2 and pulse rate measurements to the Host system. In addition, the NELL-1 default limit values are the same as those used in *Nellcor* brand oximeters. The Host System designer must determine which of the NELL-1 features will be implemented in the final product.

Note: Nellcor recommends that at startup, the Host System notify the NELL-1 of changes to the default values ([illegible]) immediately after receiving the Version Message.

OxiMax Technology

OxiMax Sensors

OxiMax-compatible sensors, which can be identified by the deep lavender/blue (or white) color of their plug, are the *only* sensors that can be used with the NELL-1. Each sensor contains the following information:

- Model type
- Calibration data
- Error detection data
- Troubleshooting codes

When an *OxiMax*-compatible sensor is connected to a pulse oximeter that uses *OxiMax* technology, the pulse oximeter first reads the information in the *OxiMax* sensor memory chip and checks for errors before monitoring begins.

Signal Processing

The *OxiMax* NELL-1 uses Cardiac Gated Averaging (CGA) to process the red and IR waveforms. CGA processing attenuates signals that do not occur synchronously with the average rhythm of the heartbeat. The result is accurate and reliable SpO_2 and pulse rate values.

Alarms

OxiMax Technology, featured in the NELL-1, provides a richer set of alarm notification and display requirement information for use in developing a host's user interface consistent with the behavior of Nellcor's stand-alone monitors, such as the N-600. This helps take the guess work out of alarm management.

Alarm management is vital in the following circumstances:

- SpO_2 high or low limit has been reached.
- Pulse rate high or low limit has been reached.
- The sensor is removed from (or has fallen off of) a patient.
- The sensor is disconnected from the instrument.
- The sensor is no longer able to provide pulse oximetry measurements and notifies the Host of a pulse timeout alarm.

Patient's Pleth Waveform

Many pulse oximeters feature a visual display that shows the patient's waveform, which represents the input data from the attached sensor. This display, in turn, provides the clinician with an indication of the strength and quality of the input data.

The NELL-1 provides the Host with an 8-bit waveform report that is scaled from the 20-bit sensor IR optical input signal. This 8-bit output is called the patient's plethysmographic waveform, and is reported as an integer number in the range of 0 to 255.

Any time that a sensor is disconnected or the LED signals are being adjusted, the reported value is 127.

Two key issues exist in regard to the patient's waveform:

- The need to re-scale values to fit into the available display area.
- The need to consider how signal timing relates to the hardware timing requirements of the display, given that the waveform and BLIP values are sent out every 13.2 milliseconds.

In the same SHIP message, the Host is notified when a pulse is identified; at this time, an audible tone is typically sounded. Nellcor monitors use the variable-pitch pulse tone described below.

Variable Pitch Pulse Tone

A common feature of oximeters based on Nellcor technology is Nellcor's variable-pitch pulse tone that sounds each time the NELL-1 identifies a single patient's pulse. The pitch (frequency) of the pulse tone varies with saturation. Using this feature, caregivers can be in the vicinity of the patient and—by sound only—determine if the pulse rate and SpO_2 measurements are changing without having to take the time to monitor the front panel of the oximeter.

The relationship between pulse tone and saturation is:

pulse tone (Hz) = (5 x Sat%Value) + 162

where *Sat%Value* is the saturation value reported by the NELL-1. The duration of the pulse tone should be 50 ms. Nellcor recommends that a speaker drive waveform that is rich in harmonics be used, such as a square wave. Avoid using a single frequency sine waveform.

BLIP Bar

Another visual indicator that many pulse oximeters provide is a BLIP bar meter. The NELL-1 reports BLIP as a four-bit integer number in the range of zero to 15. This data is derived from the input IR signal and indicates the relative size (amplitude) of the pulse. The reported BLIP value is updated at the same rate as the 8-bit waveform, and the BLIP meter varies (up and down) at the rate of the reported pulse. The BLIP meter is a graphical bar display where, as the detected pulse becomes stronger, more bars light at the peak of each pulse.

Analog Out

Another NELL-1 output that is related to the patient's waveform is called Analog Out. Some OEMs prefer to use the analog output as the patient's waveform display. The Host does not receive this as a serial communication message like the pleth waveform described above. Instead, a pin on the NELL-1 printed circuit board outputs an analog signal that has an average voltage equivalent to the reported pleth waveform. The host is expected to provide additional buffering, if needed.

SatSeconds Alarm Management Technology

SatSeconds is a proprietary Nellcor alarm management technique that helps reduce false and nuisance alarms when using *Nellcor* pulse oximetry.

Nuisance Alarms

False or nuisance alarms are a common concern with pulse oximetry monitoring. They are often triggered by minor brief desaturation events that are clinically insignificant. When sounding repeatedly, alarms are easily ignored—as if they were background noise—or are sometimes silenced because they are too annoying. Nellcor's *SatSeconds* Alarm Management feature offers a better way to manage nuisance alarms without the risk of sacrificing patient safety.

Conventional Alarm Example

In this example, the clinician sets an upper SpO_2 limit of 98% and a lower SpO_2 limit of 85%. As long as the patient's SpO_2 remains within those limits, no alarm will sound. However, if the patient's SpO_2 falls as little as one percentage point below the lower limit (84%), the alarm will sound immediately, even if the patient's SpO_2 stays below the limit for only a second. The same is true if the patient's SpO_2 rises only one percent above the upper limit (99%) for only a second.

SatSeconds Operation

SatSeconds is the product of the time and magnitude that a patient exceeds SpO_2 alarm limits. For example, three points below the alarm limit for 10 seconds equals 30 *SatSeconds*. An alarm is triggered only when a desaturation event reaches the *SatSeconds* limit. *SatSeconds* has a built-in safety feature that sounds an alarm whenever three SpO_2 violations of any amount or duration occur within a 60-second period.

Alarm Example Using *SatSeconds*

Continuing with the example above: if *SatSeconds* were set to 25 and the patient's SpO_2 measurement drops to 84%, the alarm would not sound. Instead, the *SatSeconds* alarm processing begins. For an alarm to sound, the SpO_2 measurement would have to stay at 84% for 25 seconds. If the SpO_2 measurement drops to 80%, an alarm would occur within five seconds.

Using *SatSeconds*

When including *SatSeconds* in a pulse oximeter system, ensure that the user interface includes the five *SatSeconds* settings (*Off*, *10*, *25*, *50* and *100*).

To activate the *SatSeconds* function in the NELL-1, a clinician simply sets a *SatSeconds* limit (*10*, *25*, *50* or *100*) that is suited to his or her clinical environment and patient conditions.

Note: When *SatSeconds* is activated, the Host's user interface may display the current *SatSeconds* value. For example, the *Nellcor OxiMax N-600* pulse oximeter provides a *SatSeconds* display in the form of a clock.

Response Mode

Response mode selection affects the module's averaging time (speed of response) to changes in SpO_2 values. Two response modes, *Normal* and *Fast,* are available ( ).

Table 3. Response Modes

Response Mode	Description
Normal	The Normal response mode reports changes to a patient's SpO_2 measurement within four to six seconds under interference-free conditions. This is the default response mode for the NELL-1.
Fast	The Fast response mode reports changes to a patient's SpO_2 in less than four seconds under interference-free conditions. It is used when better fidelity is needed in seeing how deep a transient desaturation event goes. It can be used to track short-lived desaturation events. Nellcor has found that during sleep-lab studies or monitoring neonates, clinicians many times prefer the "Fast" response mode option. The disadvantage of the "Fast" response mode is that unless clinicians are used to monitoring frequent desaturation events, they may be uncomfortable with watching the SpO_2 values vary as much as they may in this mode.

Note: The default response mode for the NELL-1 is Normal. However, if you plan on making Fast mode available, you may want to consider implementing a response mode indicator on the display.

Sensor Adjust (*OxiMax* Sensor Messages)

The Sensor Adjust feature on the NELL-1 is active when SpO_2 cannot be measured. When the NELL-1 provides the Host with an *OxiMax* Sensor Message, this indicates that, although the *OxiMax* sensor is functioning correctly, the site to which the *OxiMax* sensor applies, or the application method, is not optimal for calculating SpO_2.

The Sensor Adjust message contains up to three potential causes of its inability to measure SpO_2, and up to five recommended actions for correcting the problem. If the display capability of the Host monitor is not sufficient to handle such a large list, it is recommended that the number of displayed causes and recommendations be scaled back.

The potential causes and recommendations are listed in order of priority; the first potential cause reported has the highest probability of being the root cause, and the first recommendation has the highest probability of correcting the problem.

Potential Causes

The following is a list of the potential causes that are reported:

- NELL-1 detects that the sensor is not attached to the patient
- Weak pulse from the patient is causing the NELL-1 not to acquire

- Excessive Infrared light is causing the NELL-1 not to acquire.
- Excessive Electrical or optical interference is causing the NELL-1 not to acquire.
- High pulse amplitude is causing the NELL-1 not to acquire.

Recommendations

The following is a list of recommendations that are reported:

- Recommend repositioning sensor
- Recommend checking if the sensor is on too tight
- Recommend trying an alternate site for the sensor placement
- Recommend optically covering the sensor site
- Recommend using an *OxiMax* adhesive sensor
- Recommend using an ear, nasal, or forehead sensor
- Recommend using a headband with the forehead sensor
- Recommend checking the bandage assembly.
- Recommend checking if patient has nail polish and potentially remove the polish
- Recommend checking for and eliminating external interference
- Recommend cleaning sensor site
- Recommend securing the sensor cable

C-Lock ECG Synchronization

The NELL-1 *OxiMax* Technology supports the Cardiac-Gated averaging (*C-Lock*) feature. This feature enhances the reporting of SpO_2 and pulse rate by improving the signal-to-noise ratio by averaging away cardiac-asynchronous noise, while constructively adding the cardiac-synchronous signal.

C-Lock is intended to improve the ability to measure SpO_2 with difficult-to-monitor patients by providing the pulse detect algorithm with a signal synchronized with the ECG R-wave. There are instances where the *C-Lock* feature enables the saturation algorithm to better tolerate the typical artifact. The ensemble averaging can be triggered from the optical signal; but, in some conditions, it will perform better if it is triggered from a reliable ECG source.

The Host can provide the NELL-1 with ECG synchronization in two ways: either via a direct hardware *C-Lock* signal, or via a SHIP message where the Host detects the ECG trigger and in turn notifies the NELL-1 via software.

Sleep Mode

If incorporated into a battery-powered design, the NELL-1 provides two ways for extending the time of operation before changing or recharging the battery. First, the NELL-1 automatically enters a lower power mode during optimal monitoring conditions. Second, it features a Sleep Mode.

The Host software handles control of Sleep Mode and can command the NELL-1 to "sleep;" that is, to stop monitoring the patient. When patient monitoring is required again, the Host software commands the NELL-1 to "wake-up."

For example, if the NELL-1 is incorporated in a pulse oximeter that is used primarily for spot-checking of patients, Sleep Mode can be turned on *between* patients to conserve power. The advantage of using Sleep Mode is that patient monitoring can resume faster than if the NELL-1 is simply powered off.

Pulse Strength Reporting (% Modulation)

Another report that some clinicians find helpful is a measurement of the patient's signal strength. The NELL-1 reports pulse strength, which is a measurement of percent modulation (% Mod) of the input IR signal. The % Mod is the maximum measured modulation (reported in increments of a tenth of percent) over a one-second interval. Percent modulation is a more accurate measurement of signal strength than the relative measurement available with the BLIP bars.

Sensor Event Recording

The *OxiMax*'s adhesive sensors are capable of storing patient event data. A sensor event record on the sensor's memory chip allows alarm event history to travel with the patient for quick assessment at every point of care where *OxiMax* monitors are used.

Two different types of Sensor Event data can be written to a sensor: SpO_2-only or SpO_2 and pulse rate event data. A single *OxiMax* sensor will never contain more than one type of Sensor Event data.

Patient event data is stored on the memory chip of adhesive *OxiMax* sensors (single-patient-use *OxiMax* sensors only). The event data is stored (recorded) with the limit/threshold settings that were active at the time of the event on the recording monitor. These events can be viewed on any *OxiMax* monitor that supports Sensor Event Recording.

An event occurs when the SpO_2 value exceeds either the upper or the lower event limits for at least 15 seconds. While the SpO_2 remains in violation, the SpO_2 value is saved by the NELL-1 every 30 seconds.

- If the sensor event SpO_2 *high* limit triggered the event, the saved SpO_2 is the *maximum* SpO_2 value for the 30-second period.
- If the sensor event SpO_2 *low* limit triggered the event, the saved SpO_2 is the *minimum* SpO_2 value for the 30-second period.

The first sensor event record will be stored in the *OxiMax* sensor after the limit has been exceeded for 30 seconds. Thereafter, sensor events are written to the *OxiMax* sensor every five minutes.

Chapter 2
Additional Information

Overview

This section provides additional information on how the NELL-1 supports the design needs of a pulse oximeter patient monitor. This section does not completely cover all design aspects; it is intended to supplement the information covered earlier in this document.

This chapter contains additional information about the following major topics:

- Host Communications
- Startup and Reset Operation
- Sensor Event Recording
- Error Handling and Recovery

Host Communications

The NELL-1 uses the Standard Host Interface Protocol (SHIP), which is a serial protocol communicating at 19200 baud with the OEM's host processor.

SHIP messages are encapsulated in a packet that consists of six fields, as shown below.

Packet:

[0x55]	[STX]	[SIZE]	[Message1].....[MessageN]	[validity check]	[ETX]

STX = 0x02 and ETX = 0x03.

The validity check field is an 8-bit (1 byte) CRC for data transmission/receipt validation.

Each packet can contain one or more messages.

SHIP Message:

[KEY]	[SIZE]	[Value1].....[ValueN]

Each message is assigned a unique KEY value; the size of each message varies.

Startup and Reset Operation

On startup or reset, the Host must supply the NELL-1 module with the following information:

- To support Sensor Trend Event recording, the Host System must supply the NELL-1 with the date and time as part of the startup process.
- The Host System must supply its default setup values if they differ from the default setup values of the NELL-1.

Note: The NELL-1 does not save the host's setup changes. On startup and reset, the NELL-1 defaults to its default startup values.

Note: Host systems should use the Hardware Reset whenever a serious error condition exists, because the NELL-1 may not be able to receive, parse and execute the software reset command. The System Reset Command is useful for testing or performing a "warm start" to a known state.

Note: All resets are equivalent to power up, and all power-up default values are restored.

Saturation / Pulse Rate / Status Reporting

A key function of a pulse oximeter is to display the current measured values for saturation and pulse rate. Additionally, display indicators provide status information and alarm notification.

The saturation measurement, pulse rate measurement, status information, and alarm notification are all contained in a single message: the [j] Oxismart message.[1] The NELL-1 sends this message whenever there is a new measurement of SpO_2 and pulse rate, there is a change in status, or every two seconds (minimum). For more information, refer to the *NELL-1 Host Interface Specification.*

lists the status information provided by the NELL-1. The Host should not take any of these status messages, by themselves, as an alarm. If an alarm condition *does* exist, the NELL-1 provides an alarm notification in addition to the status message(s).

Table 4. Status Information

Status Message	Meaning
Sensor is connected or not	Consider providing an indicator so the user knows when a valid sensor is connected.
Interference is occurring; typically, an indicator is provided to the user.	Pulse Search is occurring; typically, an indicator is provided to the user.

1. The NELL-1 supports the optional [!] SatRateStatus message, which has backward capability with earlier OEM modules.

Table 4. Status Information (Continued)

Status Message	Meaning
Sensor is not attached to the patient.	Typically, the user is notified when the sensor is no longer attached to the patient.
Signal synched with ECG	If an ECG input is used to improve measurement, this status notifies the Host that the *C-Lock* signal is being synched with the ECG. User notification is optional.
Reset occurred	This status is used to inform the Host that the NELL-1 has reset.
New measurement	The message contains a new SpO_2 and pulse rate measurement.

Saturation values can range from 1% to 100% and pulse rate values can range from 20 bpm to 300 bpm.

The NELL-1 also provides status and display attributes for both the SpO_2 and pulse rate measurements that are used on Nellcor monitors. Display attributes are:

- Display blank for value
- Display solid value
- Flash the value on the display
- Display dashes for value

Alarms

Alarms are typically visual and/or audible indications to the user that some action should be taken to correct a potentially unsafe condition. For pulse oximeters, such unsafe conditions can include:

- Saturation and/or pulse rate values exceed preset thresholds
- The inability to determine the saturation and pulse rate
- The sensor becomes disconnected from the monitoring device
- The sensor falls off the patient or shifts to a position that results in an inadequate signal for determining saturation

This section describes the NELL-1's alarm management system, along with issues the Host designer should consider when presenting alarm information to the user.

Alarm Conditions

The NELL-1 presents alarm conditions as one of three mutually exclusive priority levels: low, medium, and high. Higher priority alarms always supersede lower priority alarms. The Host must monitor the alarm status reported by the NELL-1 and translate it into the appropriate visual and audible notifications, as shown in .

Table 5. Alarm Conditions

Alarm Priority	Conditions
Low	A sensor was connected and becomes disconnected *or* A sensor was attached to the patient and becomes unattached.
Medium	Saturation is below or equal to the Low Saturation Alarm Limit, above or equal to the High Saturation Alarm Limit, or *SatSeconds* > *SatSeconds* Limit if *SatSeconds* is enabled. *and/or:* Pulse Rate is below or equal to the Low Pulse Rate Alarm Limit or above or equal to the High Pulse Rate Alarm Limit.
High	A Pulse Timeout occurs that is *not* due to a sensor becoming disconnected or becoming unattached to the patient.

Note: If *SatSeconds* is enabled, a Saturation Limit alarm will not occur immediately. The Medium Priority alarm will occur once the *SatSeconds* threshold has been reached or the *SatSeconds* feature is disabled and the Saturation Limit violation is still present.

If *SatSeconds* is used, it might be desirable to provide a visual indicator to the user of the current *SatSeconds* operation or value. On the *OxiMax* N-600, this is done using a clock that provides a relative measurement of the *SatSeconds* value.

In addition to alarm priority, the NELL-1 communicates the following status:

- Saturation within or outside the saturation limits
- Pulse Rate within or outside the pulse rate limits

Alarm Limits

The NELL-1 allows the Host to set the high and low limits for the Saturation and Pulse Rate alarms. These values can be changed at any time–including when an alarm is occurring. The defaults and valid ranges are shown in .

Table 6. Alarm Limits

Parameter	Default	Lower Limit	Upper Limit
Saturation Alarm Limits Low High	 85 100	 20 SpO_2 Low + 1	 SpO_2 High -1 100
Pulse Rate Alarm Limits Low High	 40 170	 20 Rate Low + 1	 Rate High - 1 250

It is the Host's responsibility to design a mechanism that allows the user to view and adjust the limits if this capability is desired. While the NELL-1 does range check the values before accepting them, it is Nellcor's recommendation that the Host perform its own range checking before transmitting the settings to the NELL-1.

Alarm Notification

Table 7 shows how the *OxiMax* N-600 notifies the user via visual and audible indications when an alarm occurs. These are suggestions only; it is the Host designer's responsibility to ensure that the notification mechanism meets the regulatory requirements for the market in which the device is used.

Table 7. Alarm Indications

Alarm Priority	Visual Indication[1]	Audible Indication
Low	Saturation and Pulse Rate displays continually on.	A series of repeating tones, each at 500 Hz, on for 400 ms and off for 3200 ms.
Medium	Saturation display alternates between values and blanks at a rate of 0.7 Hz – 0.8 Hz with a 50% – 60% ON duty cycle if the NELL-1 indicates a Saturation alarm is present. Pulse Rate display alternates between values and blanks at a rate of 0.7 – 0.8 Hz with a 50% – 60% on duty cycle if the NELL-1 indicates a Pulse Rate alarm is present.	A series of repeating tones, each at 752 Hz, on for 400 ms and off for 3200 ms.
High	Saturation and Pulse Rate displays alternate between values and blanks at a rate of 1.6 Hz to 1.76 Hz with a 50% to 60% on duty cycle.	A series of repeating tones, each at 932 Hz, on for 255 ms and off for 75 ms.

1. The NELL-1 provides the visual attribute to apply to the saturation and pulse rate displays via status information listed above. Therefore, the Host does not have to use the Alarm Priority to determine how to control the display.

For all audible alarms, the alarm volume must be set per regulatory requirements.

The NELL-1 does not implement a mechanism to suppress alarms. Since the visual and audible alarm indications are the Host's responsibility, so too is suppression of alarms.

Sensor Event Recording

Note: When recording sensor event records to the sensor, the sensor extrapolates from the date and time provided by the Host. The accuracy of the date/time is the responsibility of the Host. It is recommended that the Host user set the date/time to the correct value *before* a sensor event record-enabled sensor is connected, and that this date/time not be changed while the sensor remains connected. Since a sensor with sensor event record data can be transported from one monitor to another, having discrepancies in the date/time between monitors and the sensor event record data will affect the order the sensor event record data appears. To prevent this, all monitors within an institution should be set to the same date and time.

Note: To support Sensor Event Recording, the Host System must provide the following voltages to the NELL-1: +3 volts, +5 volts, and +12 volts.

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Additional information on Sensor Event Recording:

- The Host must set the date and time on the NELL-1 *before* Sensor Event Recording can be started.
- The NELL-1 reads in the Sensor Event data currently stored in the DigiCAL when the sensor is first connected.
- Sensor Event data can be appended to data currently stored on the DigiCAL.
- The Host can read the Sensor Event data from the NELL-1 during the time the current sensor is connected.
- The Host reads Sensor Event data *one* record at a time. Each record contains data for only *one* event, as described earlier.
- The NELL-1 sends a Sensor Event record *only* when requested by the Host, which differs from other communications between the Host and the NELL-1.
- Each Sensor Event record contains the following:
  - Year / Month / Day Hour / Minute / Second the data was recorded
  - SpO_2 and pulse rate value recorded
  - The reason it occurred (if this is the last Sensor Event record)

An example of a reason that a sensor event terminates a sequence of records would be *sensor off.*

Error Handling and Recovery

The NELL-1 reports errors whenever they occur. The error message contains both a unique error and a unique recovery number. Nellcor recommends that the Host log *all* error messages reported by the NELL-1.

The Host is not required to concern itself with the specific error numbers. The NELL-1 maps all errors to a specific recovery code. The Host must implement controls to manage these recoveries.

For additional information, refer to the *NELL-1 Host Interface Specifications.*

Chapter 3

Operator's Manual Recommendations

Overview

Following is a list of recommended mitigations to hazards that the Host developer should add to the operator's manual or the monitor's operating instructions if the monitor uses a NELL-1 oximetry module.

Note: This section is not intended to represent the complete set of operating instructions.

Recommendations

Note: The NELL-1 pulse oximetry module has not been tested in the presence of flammable anesthetics or gases.

- For systems powered from AC: use hospital grade line cords.
- Consult the sensor DFU for proper sensor application.
- Periodically inspect extension cables and sensors for damage. Do not use damaged cables or sensors.
- Although Nellcor Oximetry recommends that host system design comply with EMC standards, warn the caregiver of the effects of electromagnetic interference (EMI). This includes devices such as defibrillators, MRIs, or electro-surgical units.
- Use only *Nellcor OxiMax* SpO_2 sensors and accessories.
- Inform the caregiver: do *not* immerse sensors.
- Inform host operator: review safety labeling based on the intended use of the equipment.
- Inform the caregiver about the operating temperature range of the host system.
- Inform the caregiver: do not use NIBP or constricting instruments on the same appendage as the sensor.
- Warn the caregiver that intravascular dyes (such as indocyanine green, methylene blue, etc.) and darkly pigmented skin can adversely affect SpO_2 readings.
- Warn the caregiver that significant amounts of dysfunctional hemoglobins (such as carboxyhemoglobin, methemoglobin, etc.) may adversely effect oximetry performance.
- Warn the caregiver that oximetry performance may be impaired when patient perfusion is low or signal attenuation is high.
- Warn the caregiver that long cables (such as the sensor or extension cable) may cause patient strangulation if routed incorrectly.
- Inform the caregiver when the pulse is lost.

- Inform the caregiver about the effects of motion on pulse oximetry.
- Inform the caregiver when the sensor is off or disconnected.
- The Host should notify the caregiver if an *unrecognized* sensor is connected to the NELL-1.
- The user should implement a periodic testing strategy. Handheld, battery-operated Pulse Simulation testers (SRC-MAX) are available from Nellcor. Contact Nellcor's Technical Services Department at 1.800.635.5267, or your local Nellcor representative.

Chapter 4
Specifications

Overview

This chapter lists the operational, environmental, and regulatory specifications for the NELL-1 Pulse Oximeter board. The following major topics are included:

- Measurement Range/Accuracy
- Physical Dimensions
- Environmental Operating Conditions
- Environmental Shipping and Storage Conditions
- Regulatory Compliance
- Trademarks and Patents

Measurement Range/Accuracy

lists the NELL-1's measurement range and accuracy parameter values.

Table 8. NELL-1 Measurement Range and Accuracy

Parameter		Specification
Range	Pulse Rate	20 bpm to 300 bpm (beats per minute)
	Saturation	1% to 100% SpO_2
Accuracy[1]	Pulse Rate	20 bpm to 250 bpm ± 3 bpm
	Saturation	Nellcor publishes an *Oxygen Saturation Accuracy Specification Grid* that contains accuracy specifications for a *Nellcor Oximetry N-600* pulse oximeter when used with various *Nellcor* oximetry sensors. It is the responsibility of the designer of the host system to determine which *Nellcor* oximetry sensors the designer will recommend for use with its host system and, as a part of that determination, to state oxygen saturation accuracy of the host system when used with each of the recommended sensors.

1. Parameters stable during measurement.

The accuracy specifications in the *Oxygen Saturation Accuracy Specification Grid*, mentioned in and available at , were derived from monitor and sensor tests performed on healthy adult volunteers in induced hypoxia studies. The accuracy of oximetry readings can be affected by the following factors:

- High-frequency electrical noise, including electro-surgical apparatus and defibrillators
- Excessive patient movement

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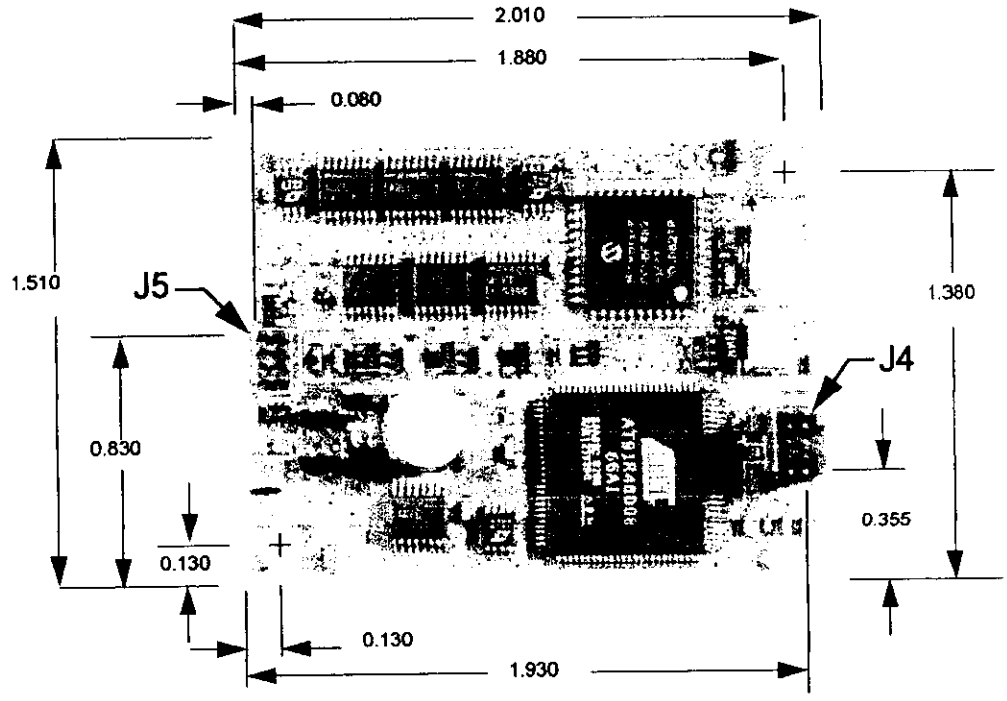
- Intravascular dye injections
- Significant concentrations of dysfunctional hemoglobin, such as carboxyhemoglobin and methemoglobin
- Sensor temperature (maintain between 28 °C and 41 °C for best operation)
- External illumination of more than 5,000 lumens/square meter (such as office lighting)
- Improper sensor application
- Low patient perfusion or high signal attenuation
- Venous pulsations
- Placement of the sensor on an extremity that has a blood pressure cuff, arterial catheter, or intravascular line

Note: Neonatal accuracy differs from adult accuracy on some *Nellcor* oximetry sensors. Refer to notes on the *Nellcor OxiMax N-600 Oxygen Saturation Accuracy Specification Grid*, available at .

Physical Dimensions

Figure 1. NELL-1 Physical Dimensions



Nellcor recommends that an OEM Customer obtain an actual NELL-1 module for mechanical design purposes.

Environmental Operating Conditions

The NELL-1 operates within specifications at enclosure temperatures from 0 °C to +60 °C. Environmental operating conditions are listed in [redacted]. Note that the sensor temperature range for specified SpO_2 measurement accuracy is more limited. *See the OxiMax N-600 Oxygen Saturation Accuracy Specification Grid.*

Table 9. NELL-1 Environmental Operating Conditions

Parameter	Specification
Operating Temperature	0 °C to 60 °C
Relative Humidity	15% to 95% non-condensing
Altitude	1,000 feet below sea level to 10,000 feet above sea level
Mechanical Shock	Per IEC 600068-2-27, 100G, 6 ms half sine.
Sinusoidal Vibration	Per IEC 600068-2-6, 10 Hz to 500 Hz, 1 G peak, 10 sweeps/axis
Random Vibration	Per IEC 600068-2-34, 20 Hz to 500 Hz, 0.02 g2/Hz

Environmental Shipping and Storage Conditions

The NELL-1 may be stored or shipped under the following environmental conditions:

Table 10. NELL-1 Environmental Shipping and Storage Conditions

Parameter	Specification
Storage Temperature	-40 °C to +70 °C
Relative Humidity	15% to 95% non-condensing
Storage Altitude	1,000 feet below sea level to 20,000 feet above sea level
Vibration	Per NSTA Project 1A
Drop	Per NSTA Project 1A

Regulatory Compliance

The NELL-1 is designed to enable the finished Host system to meet or exceed EMC and safety standards for medical devices and is designed to meet the following standards:

- Magnetic Field Emissions per RE101, MIL-STD-461
- Radiated Emissions [CISPR 11, Class B, Group 1] per IEC 60601-1-2:2001 section 36.201.1
- Conducted Emissions [CISPR 11, Class B, Group 1] per IEC 60601-1-2:2001 section 36.201.1
- ESD per IEC61000-4-2 level 3 table top equipment, with the modifications listed in IEC 60601-1-2:2001 section 36.202.2b
- Radiated RF Immunity per IEC 61000-4-3 level 3, with the modifications listed in IEC 60601-1-2:2001 section 36.202.3b

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- Conducted EM Immunity per IEC 61000-4-6 level 2, with the modifications listed in IEC 60601-1-2:2001 section 36.202.6b
- Magnetic Field Immunity per MIL-STD-461, RS101
- Quasi Static Electric Fields per FDA Reviewers Guidance for Premarket Notification Submission, November 1993 (h)(7)(ii)(f), (m)(7)(ii)(f)
- Component and Material Flammability per UL544 to achieve 94V-2
- Pulse Oximetry per EN 865:1997, ASTM 1415:1992 and ISO 9919:92

Trademarks and Patents

The following are registered trademarks of Nellcor Puritan Bennett: *Nellcor, C-Lock, Durasensor, Dura-Y, Oxicliq, OxiMax, PediCheck, VetSat, Max-Fast, Oxiband, SatSeconds, SoftCare,* and *Nellcor OxiMax Works Here* logo. The NELL-1 OEM oximetry module is covered by one or more of the following U.S. patents and foreign equivalents: 4,802,486; 4,869,254; 4,928,692; 4,934,372; 4,960,126; 5,078,136; 5,485,847; 5,743,263; 5,865,736; 6,035,223; 6,298,252; 6,463,310; 6,591,123; 6,675,031; 6,708,049; 6,801,797; Re. 35,122. Patent and trademark notices on the Host system's product labeling, literature, and packaging may be required as a result of these patents and trademarks, or in accordance with the OEM agreement between Nellcor and the host system designer/manufacturer.

Representations About Nellcor Products and Technology

The manufacturer, designer, and/or seller of the host system are not authorized—and must not make any statements, claims, or representations about—the Nellcor NELL-1 pulse oximeter module, the technology contained in the module, the Nellcor sensors or accessories to be used with such a module, or the performance of any such products or technology that are not contained within this document or other relevant, official documentation published by Nellcor for its products. However, this does not preclude the designer of the host system from determining oximetry accuracy specifications for its products, as indicated elsewhere in this document.

NELLCOR

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Manufactured in the U.S.A.

tyco Healthcare

P/N 10005607A-1005

The following section is page numbered independently from the remainder of the submission.

Substantial Equivalence Comparision Table

Product Characteristic	*Suzanne* (Predicate Device) Nellcor Puritan Bennet K990565	*Alice 5* (Predicate Device) Respironics K040595	*Sandman Pocket* (submission device) EB Neuro Via this Submission
Regulatory			
Device class	Class II	Class II	Class II
Product code	MNR	GWQ	MNR
Device type	Ventilator Effort Recorder	Electroencephalograph	Ventilator Effort Recorder
Regulation Number	868.2375	882.1400	868.2375
Labelling			
Intended use	Intended for use in collecting and recording physiological data to be used in diagnosing sleep disorders	Intended to record, display and print physiological information to clinicians/physicians. These parameters are presented graphically on a computer screen for diagnostic review, similar in application to the use of a traditional paper based polygraph recorder. The device will be used in hospitals, institutions, sleep centers or clinics, or other test environments where adult or infant patients require the documentation of various sleep or other physiological disorders. This device does not provide alarms and is not intended for use as an automated apnea monitor.	Intended for use in collecting and recording physiological data to be used in polysomnography and sleep disorder studies. For use in either home or hospital environments with a pediatric through adult patient population. This device does not provide alarms and is not intended for use as an automated apnea monitor
Target population	Pediatric through adult (excluding neonates and infants)	Pediatric through adult (including all pediatric subpopulations)	Pediatric through adult (including all pediatric subpopulations)

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Product Characteristic	***Suzanne*** **(Predicate Device)** **Nellcor Puritan Bennet** **K990565**	***Alice 5*** **(Predicate Device)** **Respironics** **K040595**	***Sandman Pocket*** **(submission device)** **EB Neuro** **Via this Submission**
Environment of use	Hospital and home	Hospitals, institutions, sleep centers, or other test environments.	Hospital and home
Warnings	Items related to sensor irritation, strangulation avoidance and off-label use.	Items related to sensor irritation, strangulation avoidance, and off-label use.	Items related to sensor irritation, strangulation avoidance and off-label use.
Contraindications	Items related to design and indicated use limitations, such as not for use in the presence of flammable anesthetics or in conjunction with defibrillation equipment.	Items related to design and indicated use limitations, such as not for use in the presences of flammable substances or anesthetic mixtures with air oxygen or nitrous oxide, defibrillation, and MRI equipment, and not for use as automated apnea monitor or a continuous monitor.	Items related to design and indicated use limitations, such as not for use in the presence of flammable anesthetics or in conjunction with defibrillation equipment. The Sandman Pocket is not intended for use as life support equipment such as a vital sign monitoring in intensive care unit. The device does not produce alarms and is not intended as an automated apnea monitor. The Sandman Pocket is only to be used under the direction or supervision of a physician, technologist or clinician. It will not prevent or restore the interruption or loss of any physiological system.
Prescription status	Available only on the order of a physician.	Available only on the order of a physician.	Available only on the order of a physician.
Service instructions	No field service allowed.	No field service allowed.	No field service allowed.

Product Characteristic	***Suzanne*** **(Predicate Device)** **Nellcor Puritan Bennet** **K990565**	***Alice 5*** **(Predicate Device)** **Respironics** **K040595**	***Sandman Pocket*** **(submission device)** **EB Neuro** **Via this Submission**
Design			
Communication Interfaces	Physiological signals are sent to the Slow Wave and Fast Wave headbox through the sensor cables. The Slow Wave and Fast Wave headboxes sends the data to the Recorder Plus module where the data is stored either to a flash memory card or to a PC via a fiber optic interface.	Physiological signals are sent from the patient sensors to the headbox through the sensor cables. The data is sampled and sent to the base station where it is stored on a disk until it is sent through an Ethernet connection to a Host PC.	Physiological signals are sent from the patient sensors to the amplifier box through the sensor cables. The amplifier box sends the data to the recorder where the data is stored in flash memory in both attended and unattended studies. During attended studies, the data is also transmitted to a computer in real-time via a USB cable. After unattended studies, data can be downloaded from the recorder using a USB cable.
Microprocessor	Siemens 80C537 12 MHz	Unknown	Texas Instruments TMS320UC5402 on recorder Texas Instruments MSP430F169 on headbox
A/D Resolution	12 bit	16 bit	16 bit
Data recording	On PCMCIA card, magnetic disk or optical disk (via a personal computer).	Computer hard drive, compact disc, or transferred via Ethernet connection to a Host PC.	On internal NAND flash chip
Configuration	Desktop and wearable	Desktop only	Wearable

Product Characteristic	***Suzanne*** **(Predicate Device)** **Nellcor Puritan Bennet** **K990565**	***Alice 5*** **(Predicate Device)** **Respironics** **K040595**	***Sandman Pocket*** **(submission device)** **EB Neuro** **Via this Submission**
Amount of memory required for a typical 8 hour study.	20 MB	600 MB without audio/ video 6 GB with audio/video NOTE: Alice 5 can collect up to 21 neurological channels. These channels are recorded at very high sampling rates. In addition, Alice 5 records video at very high frame rates with no compression. These two factors contribute to the large study size. All data are stored to computer hard disk.	28 MB
Sampling rate	Slow waves : 12 samples/s Fast waves : 120 samples/s	Neurological channels 2000 samples/s	Fast waves: For example, ECG programmable up to 2048 sample/s Medium waves: For example, EMG, EOG, Snore programmable up to 1024 sample/s Slow waves: For example, airflow, respiratory effort, body position programmable up to 256 sample/s
Power	Battery powered (internal) or Medical Grade AC-DC Power Supply	Medical grade AC Power Supply	Battery powered or USB powered
Sensors	Commercially available sensors only	Commercially available sensors only	FDA Cleared sensors only
Performances			
Maximum number of channels	35	55	22

Product Characteristic	***Suzanne*** **(Predicate Device)** **Nellcor Puritan Bennet** **K990565**	***Alice 5*** **(Predicate Device)** **Respironics** **K040595**	***Sandman Pocket*** **(submission device)** **EB Neuro** **Via this Submission**
Recording channels			
EEG	Yes	Yes	Yes
EOG	Yes	Yes	Yes
EMG	Yes	Yes	Yes
ECG	Yes	Yes	Yes
Respiratory efforts	Yes	Yes	Yes
Airflow	Yes	Yes	Yes
Ambient sounds	Yes	Yes	No
Body position	Yes - internal	Yes - external	Yes - external
Ambient light	Yes - internal	No	No
SpO_2	Yes - internal	Yes - internal	Yes - internal
Pulse rate	Yes - internal	Yes - internal	Yes - internal
Plethysmograph	No	Yes	Yes
Differential pressure	Yes - internal	Yes - external	Yes - internal
Actimeter	No	Yes	No
Derived channel	N/A	Pulse Transit Time (PTT) – A calculation of the time between the occurrence of the R wave on the EKG and the peak flow on the plethysmogram. RR Interval – Measurement of the period of time between two consecutive R waves on the EKG. Displays as a real-time beat-to-beat heart rate calculation.	Pulse Transit Time (PTT) – A calculation of the time between the occurrence of the R-wave on the EKG and 50% ascending slope on the plethysmogram. Heart rate – Derived from the ECG channel
Passbands			
EEG	0.625 to 18 Hz	Neurological Channels 0.32 to 106 Hz	0.1 to 135 Hz
EOG	0.625 to 18 Hz		0.1 to 135 Hz
EMG	0.625 to 18 Hz		0.1 to 135 Hz
ECG	0.625 to 18 Hz		0.1 to 135 Hz
Respiratory efforts	0.055 to 1.25 Hz		0.1 to 45 Hz
Airflow	0.1 to 1.3 Hz		0.015 to 10 Hz
Ambient sounds	None		None
Pressure sensor	0 to 175 Hz		DC to 15 Hz
SpO_2	NPB proprietary		NPB proprietary
Pulse rate	NPB proprietary		NPB proprietary

Product Characteristic	***Suzanne*** **(Predicate Device)** **Nellcor Puritan Bennet** **K990565**	***Alice 5*** **(Predicate Device)** **Respironics** **K040595**	***Sandman Pocket*** **(submission device)** **EB Neuro** **Via this Submission**
CPAP (Continuous Positive Airway Pressure)	*Suzanne* supports all models of CPAP devices because the CPAP device connections were air-based rather than electrically based. Using a pneumotachograph kit, users could connect hoses and adapters to the CPAP device and the flow and pressure nipples on the *Suzanne* slow wave headbox to measure CPAP airflow and/or air pressure at the mask out-take during nasal CPAP/Bi-level titration.	*Alice 5* supports the use of all Respironics lab therapy devices: Aria LX BiPAP Pro Duet LX Harmony HeartPAP REMStar Auto REMStar Pro REMStar Pro with C-Flex Synchrony Virtuoso LX	*Sandman Pocket* stores data from Nellcor Puritan Bennett GK420E, GK425, and GK425ST CPAP devices. When the recorder is also connected to the host computer, the *Sandman Pocket* not only stores data in the on-board memory, but also acts as a passive bridge between the aforementioned GK CPAP and the host computer by receiving data streams from the CPAP and transmitting the data streams to the host computer and vice versa. When the *Sandman Pocket* is connected to a third party CPAP device and a host computer, *Sandman Pocket* acts as a passive bridge between the third party CPAP device and the computer by receiving data streams from the CPAP and transmitting the data streams to the host computer and vice versa. Alternatively, *Sandman Pocket* may also handle CPAP device connections in the same manner as Suzanne.

Product Characteristic	***Suzanne*** **(Predicate Device)** **Nellcor Puritan Bennet** **K990565**	***Alice 5*** **(Predicate Device)** **Respironics** **K040595**	***Sandman Pocket*** **(submission device)** **EB Neuro** **Via this Submission**
Mechanical safety	Device complies with the requirements of Nov' 93 Draft Reviewer's Guidance	Device complies with the International Standard IEC 60601-1 CSA C22.2 No. 601.1 EN 60601-1 UL 60601-1 AS 3200.1.0* *Australian Deviation to IEC 60601-1	Device complies with the International Standard IEC 60601-1 CSA C22.2 No 601-1-M90 UL 2601
Electrical safety	Device complies with the International Standard CSA C22.2 No. 601-1-M90 UL 2601 Device complies with the requirements of Nov' 93 Draft Reviewer's Guidance	Device complies with the International Standard IEC 60601-1 Guidance, when applicable, has been adopted from the following standards: IEC 60601-2-25 IEC 60601-1-26 IEC 60601-2-40 IEC 60601-2-49	Device complies with the International Standard IEC 60601-1 IEC 60601-1-4 IEC 60601-1-26 CSA C22.2 No 601-1-M90 UL 2601
Electromagnetic Compatibility (EMC)	Device complies with the following EMC standards IEC 60601-1 IEC 61000-4-2 IEC 61000-4-3 IEC 61000-4-6 Mil Std 462D IEC 61000-4-4 IEC 61000-4-5 EN55011 Class B Device complies with the requirements of Nov' 93 Draft Reviewer's Guidance	Device complies with the International Standard IEC 60601-1-2, including the following standards: CISPR 11 IEC 61000-3-2 IEC 61000-3-3 IEC 61000-4-2, IEC 61000-4-3 IEC 61000-4-4, IEC 61000-4-5, IEC 61000-4-6, IEC 61000-4-8 IEC 61000-4-11	Device complies with the International Standard IEC 60601-1- 2, including the following standards: IEC 61000-3-2 IEC 61000-3-3 IEC 61000-4-2 IEC 61000-4-3, IEC 61000-4-4, IEC 61000-4-5, IEC 61000-4-6, IEC 61000-4-8 IEC 61000-4-11 EN55011 class B EN55014-1

Discussion of Similarities and Differences

Similarities:

- Both *Suzanne* and *Sandman Pocket* are portable recording devices intended to record polygraphy/polysomnograph data (multifunctional ambulatory recorders) in clinical and home environments. When used in a home setting, the patient goes to the physician's office to get hooked up to the system, goes home and sleeps in his/her own bed, and then returns the next day with the recording system and its stored data.
- *Suzanne*, *Alice 5*, and *Sandman Pocket* use one common electrode reference to establish a patient ground (not earth ground) against which all other electrical inputs are referenced. Each device's measurement values and waveforms contain many of the same channels of infomation.
- All devices detect electrical signals or other signals (impedence change, pressure) which are then converted to digital data. None of the systems actually deliver energy to the patient – they receive signals from the patient , amplify and filter these signals, and record the digital data derived from the signals.
- None of the hardware devices perform data analysis. The waveforms are stored in the on-board memory (*Suzanne* and *Sandman Pocket*) or to the base station (*Alice 5*) and then the data is transferred to a host system, which runs sleep review and analysis software used by a trained clinician to analyze the data either by manually scoring or auto-scoring the recorded data. The software on the host system and its behaviour is outside of the scope of all the referenced devices.
- Both *Suzanne* and *Sandman Pocket* can be powered using batteries. The *Suzanne* operates using built-in NiMH rechargeable batteries. *Suzanne* could also operate using a medical grade AC to DC power supply. This power supply also recharges the NiMH batteries. The *Sandman Pocket* operates with 3 AA size 1.5 V dry cell batteries. The Sandman Pocket can also be powered via a standard USB cable; in this case, the PC can be a battery powered laptop or a desktop computer equipped with a medical grade isolation transformer.
- All devices amplify, filter and digitally convert data. *Suzanne* and *Sandman Pocket* perform this amplification, filtration, and digital conversion in the headbox, while *Alice 5* amplifes and filters the signal in the headbox and digitizes the signals in the base station. Communication between the headbox and the recorder (*Suzanne* and *Sandman Pocket*) is digital to achieve a highly reliable data transfer with low EMI susceptibility.
- Both *Suzanne* and *Sandman Pocket* incorporate the preamp of each channel in the headbox, so the system is more comfortable to wear because less modules are attached to the patient.
- Like Suzanne, *Sandman Pocket* can handle CPAP device connection by connecting a pneumotachograph kit to the CPAP device and the FDA cleared pressure transducer on the *Sandman Pocket*.

  Like *Alice5, Sandman Pocket* may be connected to a digital CPAP device in order to acquire data and store the data together with the other input signals.

  When *Sandman Pocket* is connected to a Nellcor Puritan Bennett GK420E, GK425, or GK425ST CPAP device in unattended mode (*Sandman Pocket* is not connected to a host computer), the *Sandman Pocket* stores the data in the onboard memory. It is the responsibility of the system builder to create review and analysis software that can download data from the *Sandman Pocket* and display the CPAP data.

  When *Sandman Pocket* is connected to a Nellcor Puritan Bennett GK420E, GK425, or GK425ST CPAP device and a host computer, the *Sandman Pocket* stores data in the onboard memory, and also acts as a passive bridge between the CPAP device and the computer by receiving data streams from the CPAP device and transmitting the data streams to a host computer and vice versa. It is the responsibility of the system builder to create review and analysis software that can communicate with the series of CPAP devices and display the CPAP data.

When the *Sandman Pocket* is connected to a third party CPAP device and a host computer, *Sandman Pocket* acts as a passive bridge between the third party CPAP device and the computer by receiving data streams from the CPAP device and transmitting the data streams to a host computer and vice versa. In this mode, any CPAP device with a known RS232 serial protocol may be used. It is the responsibility of the system builder to create review and analysis software that can communicate with the third party CPAP device and display the CPAP data.

In any configuration, the *Sandman Pocket* is not capable of setting or modifying the CPAP parameters. Changing the CPAP device settings may only be done by the user with either a CPAP remote control connected directly to the CPAP device or from the host computer using sleep review and analysis software capable of changing the CPAP parameters.

Differences:

- *Sandman Pocket* (b)(4) [redacted]

Both *Sandman Pocket* and *Alice 5* use the peak of the R-wave, but *Sandman Pocket* and *Alice 5* [redacted] (b)(4) [redacted]

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[1] Jérôme Argod, Jean-Louis Pépin, and Patrick Levy in their study "Differentiating Obstructive and Central Sleep Respiratory Events through Pulse Transit Time" calculated PTT as "the interval between the ECG R-wave and the point on the pulse waveform that is 50% the height of the maximum value (as detected with photoplethysmography)" (1779).

Argod, Jérôme, Jean-Louis Pépin, and Patrick Levy. "Differentiating Obstructive and Central Sleep Respiratory Events through Pulse Transit Time." American Journal of Respiratory Critical Care Medicine 158 (1998): 1778–1783.

[2] D.J. Pitson and J.R. Stradling in their article "Value of beat-to-beat blood pressure changes, detected by pulse transit time, in the management of the obstructive sleep apnoea/hypopnoea syndrome" state that they measured PTT "in real time as the interval from the QRS complex to a threshold on the rising edge of the finger pulse. The threshold is calculated as 25% of the height of the pulse during a time window of 280 ms after the QRS" (686).

Pitson, D.J., and J.R. Stradling. "Value of beat-to-beat blood pressure changes, detected by pulse transit time, in the management of the obstructive sleep apnoea/hypopnoea syndrome." European Respiratory Journal 12 (1998): 685–692.

[3] In their article "Impaired response to HAART in HIV-infected individuals with high autonomic nervous system activity", Steve W. Cole et al. describe pulse transit time as the "duration from EKG R spike to subsequent finger photoplethysmograph peak" (12695).

Steve W. Cole, Bruce D. Naliboff, Margaret E. Kemeny, Marshall P. Griswold, John L. Fahey, and Jerome A. Zack. "Impaired response to HAART in HIV-infected individuals with high autonomic nervous system activity." PNAS 98.22 (2001): 12695–12700.

For *Sandman Pocket*, we chose 50% of the ascending slope of the plethysmogram waveform because it is more widely used. No one method is "right" or "wrong", so there is no clinical difference between the methods.

- *Unlike Alice 5*, the *Sandman Pocket and Suzanne* may be used in both lab and home evironments. *Alice 5* is only for use in clinical evironments.
- *Alice 5* requires more data storage space because the study file sizes are larger. Unlike *Sandman Pocket* and *Suzanne*, which are screening devices, *Alice 5* is a full polysomnographic (PSG) system that can collect up 55 channels, 21 of which are neurological channels that are recorded at very high sampling rates. Alice 5 also records video at very high frame rates with no compression. The number of neurological channels recorder, the high sampling rate for neurological channels, and the high frame rates for recorder video contribute to the large study size. Unlike *Sandman Pocket* and *Suzanne*, which store data to flash memory, *Alice 5* stores data to a computer hard disk.
- In *Suzanne*, the sampling rate and bandpass filters are hardware fixed parameters. The user cannot change the sampling rate or bandpass filters.

  Alice 5 uses a 2000 Hz sampling rate on neurological channels. The sampling rates of Alice 5 and Sandman Pocket are comparable and more than sufficient to accurately reproduce the signal.

(b)(4) [redacted]

- (b)(4) [redacted]
- [redacted]

The limitations of the Suzanne bandpass filter and the suitability of the Sandman Pocket bandpass filter is best understood by discussing the average, upper and lower breaths per minute and frequencies ranges associated with adult, infant and neonatal populations. Neonates and infants breathe faster than adolescents and adults. See Table 1 for normal breathing rates according to patient population:

Table 1 Normal Breathing Rates by Patient Population[4]

Patient Population	Rate in breaths per minute	Frequency Range in Hz
Neonates	(b)(4)	
Infants		
Preschoolers		
Adolescents		
Adults		

(b)(4)

[redacted]

[4] Data from Family practice notebook.com. Online accessed 18 May 2006, URL http://www.fpnotebook.com/LUN55.htm
[5] Gagliardi, Luigi, Franca Rusconi and the working party on respiratory rate. "Respiratory rate and body mass in the first three years of life." Archives of Disease in Childhood 76 (1997): 151 – 154.
Also available for download at http://adc.bmjjournals.com/cgi/content/full/76/2/151

Hardware Functional Testing:

This testing verified the electrical function of and supply to the headboxes and recorder, the digital characterization of the data recorder, the communication between modules and system components, the frequency response, the filtering, and the battery function. The test reports that demonstrate the compliance of *Sandman Pocket* to the design specifications are part of the Design History File maintained by EBNeuro.

Hardware Safety and Environmental Testing:

The *Sandman Pocket* complies with the following standards: IEC 60601-1 (CSA C22.2 No 601-1-M90 / UL 2601) for electrical and mechanical safety and IEC 60601-1-2 for electromagnetic compatibility.

The primary test report demonstrating the compliance of *Sandman Pocket* to the above standards was performed by an external accredited CB organization, and these test reports are part of the Design History File maintained by EBNeuro.

[suzanneportablerecordingsystem]

- Compact, lightweight, fully portable sleep recorder.
- Reliable and easy to use, designed for convenient attended or unattended studies.
- Modular concept for plug and play custom configurations (10-35 channel montage options).
- Setup module for quick and easy signal preview prior to start-up (no computer required).
- State-of-the-art fiber optic link for computer interface for attended studies (optional).
- Battery powered for up to 20 hours of recording, quick recharge during normal use. DC line power also available.
- Score studies using Sandman® analysis software for Suzanne™.
- 24-hour telephone technical support.

SANDMAN®

SANDMAN®

[suzanneportablerecordingsystem]

Power Features

- Modular configuration allows for recordings of 10, 18, 26, 35 channels
- Two Available Recording Modes: Flash card with recorder for unattended studies, Real time with computer via 100' fiber optic cable for attended studies
- Flash Card: SanDisk available in 32, 64, 128 Megabytes
- Featuring built-in NPB MP506 oximetry; reads through motion
- Large signal review screen on the setup module for viewing signal integrity (adjustable)
- Snore microphone for best sound representation available
- High quality, sturdy, reliable, medical grade Lemo connectors (same model selected by NASA for new space station)
- Battery: Superior NiMh technology, has no memory effect for longer battery life
- DC Line power option for convenient interface with AC power outlets
- Carry Case: 20 lbs including all parts and accessories, constructed from rugged and lightweight material
- Uses standard 1.5 mm electrode pin connectors
- Exceptional 60 Hz noise rejection
- Outstanding noise immunity for all signals with 50 Hz noise rejection

Recorded Parameters

Fast Wave Headbox (8 channels)

- 8 bipolar electrode inputs (16 differential electrode connections) suitable for EEG, EOG, EMG (chin and leg), EKG

Slow Wave Headbox (8 channels)

- Oral/nasal airflow thermistor
- Effort belts (2)
- Snore sound microphone
- CPAP/bi-level/mask flow/flow limitation with pneumotachograph
- CPAP/bi-level/esophogeal pressure
- Light sensor
- Body position

DC Isolation Box (optional)

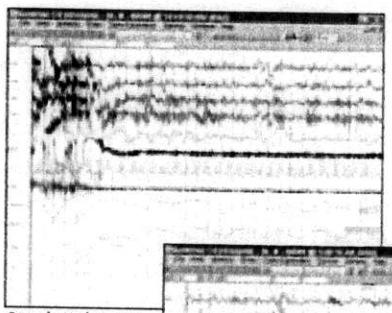
- DC expansion – for 1 additional DC input 1/8" phono plug

Recorder

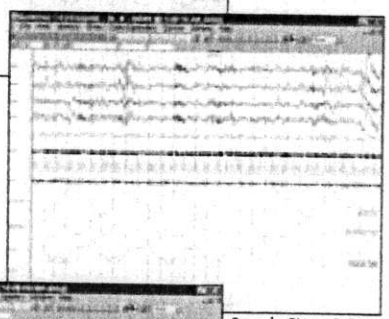
- SpO_2
- Pulse Rate
- Sandman Disposable Breath sensor (optional)

Plug and Play Module (options)

Flash Card	Real Time (with computer)
1 Fast wave	1 Fast wave
1 Slow wave	1 Slow wave
1 Fast wave & 1 Slow wave	1 Fast wave & 1 Slow wave
2 Fast wave & 1 Slow wave	2 Fast wave & 1 Slow wave
	3 Fast wave & 1 Slow wave
	4 Fast wave



Sample Wake Data



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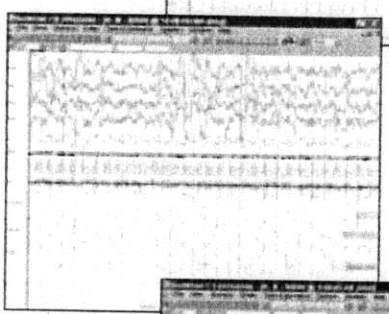

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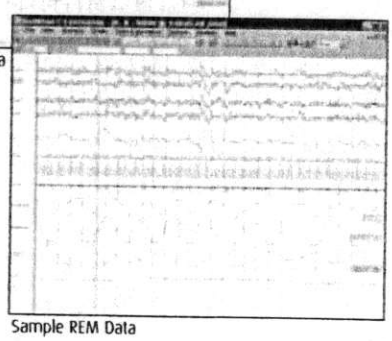

Sample REM Data

Specifications subject to change without notice.
Doc No. D.MK000002.00 REV A04

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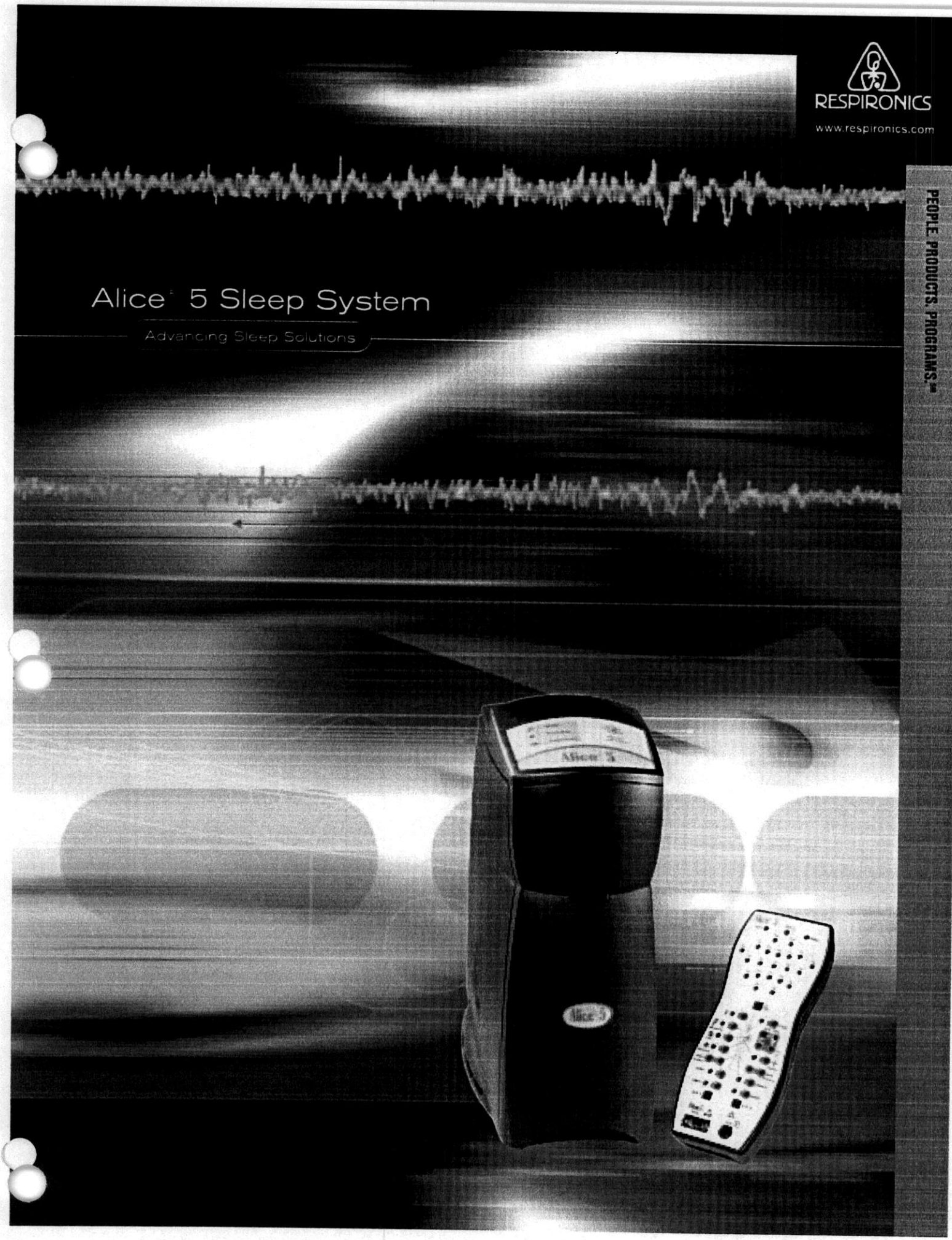

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Alice 5 Sleep System Advances through Simplification

The Alice 5 Sleep System is a polysomnography system that records, displays and prints physiological information for clinicians or physicians. The system helps to simplify the integration of lab devices through a high-tech consolidation that requires a maximum of two cables. While less cumbersome, the system's simple integration does not sacrifice output, resulting in usable data for patient analysis. These parameters are presented graphically on a computer screen for diagnostic review, similar in application to the use of a traditional paper-based polygraph recorder. The system is appropriate for adult and infant patients.

Alice 5 collects data from sensors placed on a patient and delivers the information to a computer running the Alice Sleepware application. Alice® Sleepware™ is a Window's®-based software program designed to monitor, display, process and download polysomnographic data.

Full Integration Over a Network Cable or Wireless

Current sleep lab scenarios require four or more cables that run from the bedroom where the patient lies to the tech room. With Alice 5, a maximum of only two cables or a wireless connection are needed. The limited cabling used with the Alice 5 provides polysmonography data, complete titration information, and control of Respironics lab therapy devices with intercom and video over the network. The Alice 5 supports the use of all Respironics lab therapy devices.

In addition, video and audio recording and intercom options are available for equipped labs.

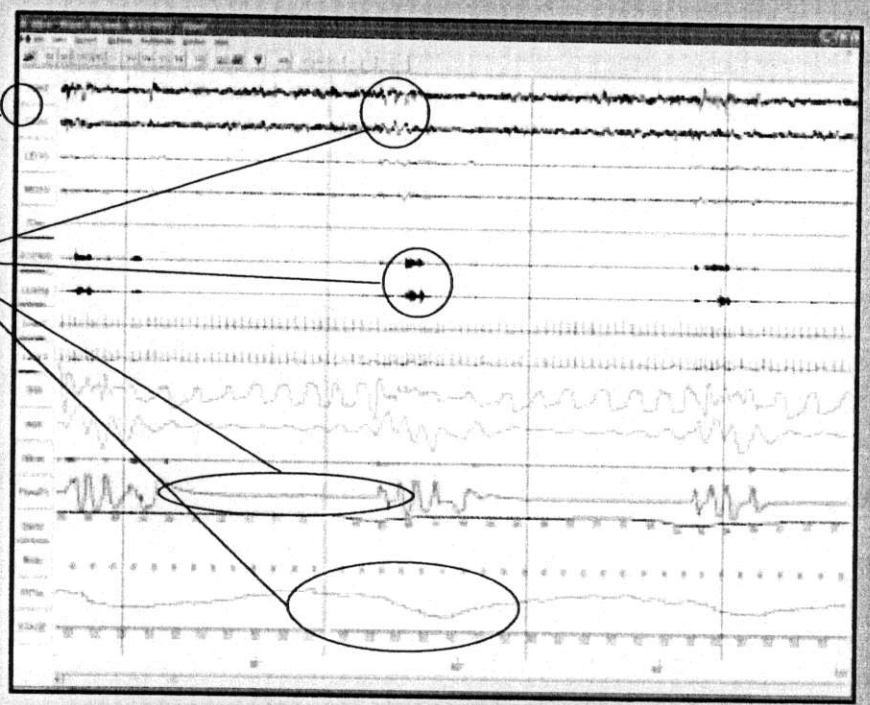
The Alice 5 system records, displays and prints physiological data.

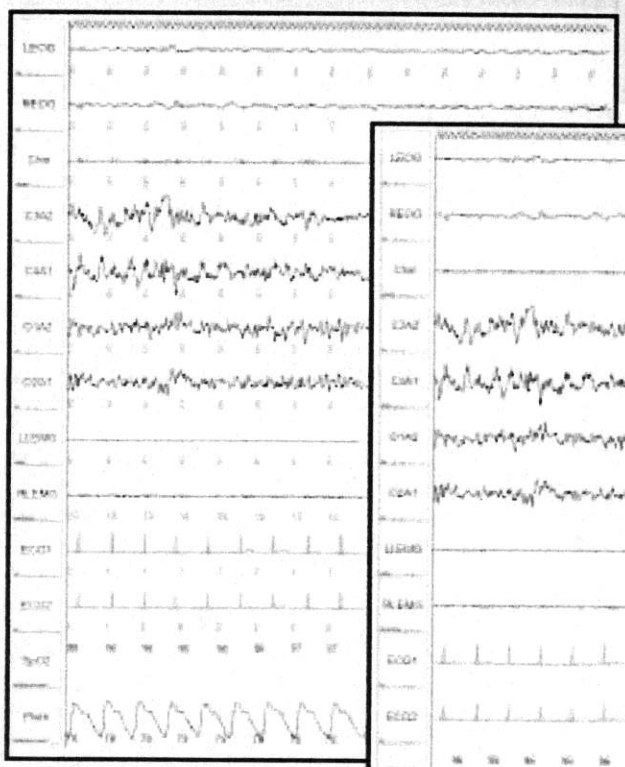
Capability to 55 Total Channels

The Alice 5 headbox offers expanded Neuro and PSG inputs and the system in total can record up to 55 channels. The headbox incorporates an initiative 10-20 Neuro input layout for times where additional Neuro inputs are required to evaluate your patient properly. In addition to having discrete left/right Leg EMG, there are also two additional differential EMG channels that may be used for other channels such as Intercostal or Arm EMG. Recognizing emerging standards as well as lab diversity, Respironics now offers both pressure-based flow and thermistry in the headbox design. Masimo Oximetry—which facilitates high-quality signals for patients of all ages—is integrated into the Alice 5 design.

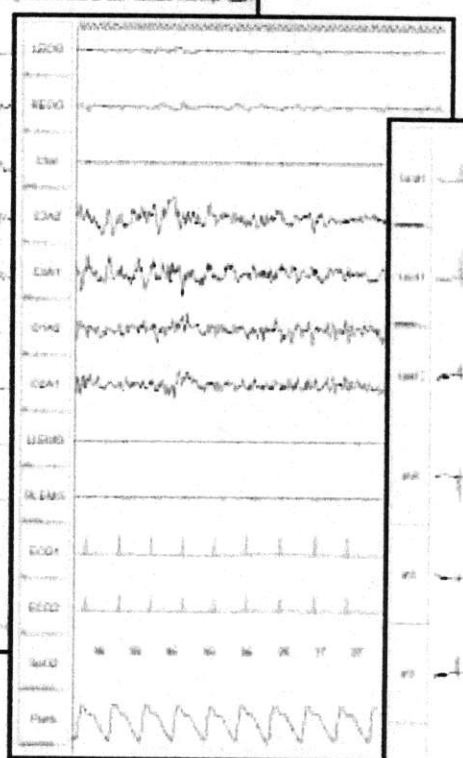
The colored bars indicate real-time signal impedance (EEG/EOG/EMG) or signal quality (ECG/Oximetry).

The red flow channel below shows apneas (no flow). At the end of each apnea, there is an arousal (EEG) and leg movement (both R LEMG & L LEMG channels). The PTTm trace shows a PTT change in response to the arousal.

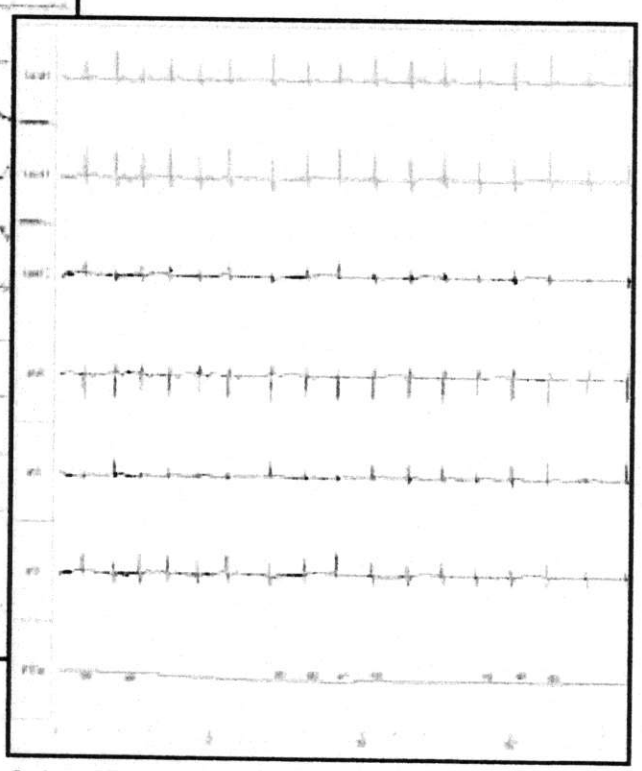




Numeric Value Impedance View.



Real-time/Post Acquisition Impedance View

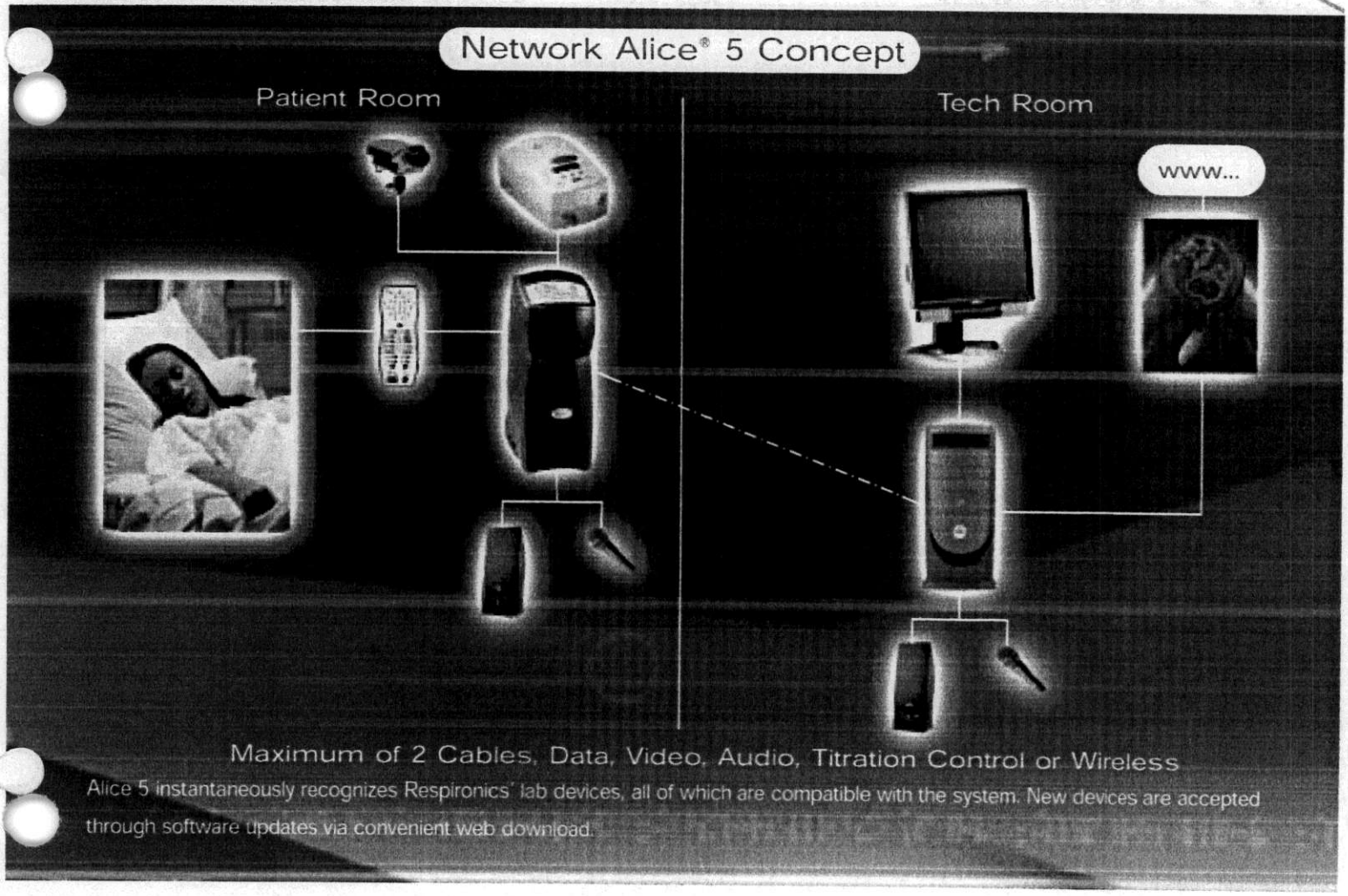


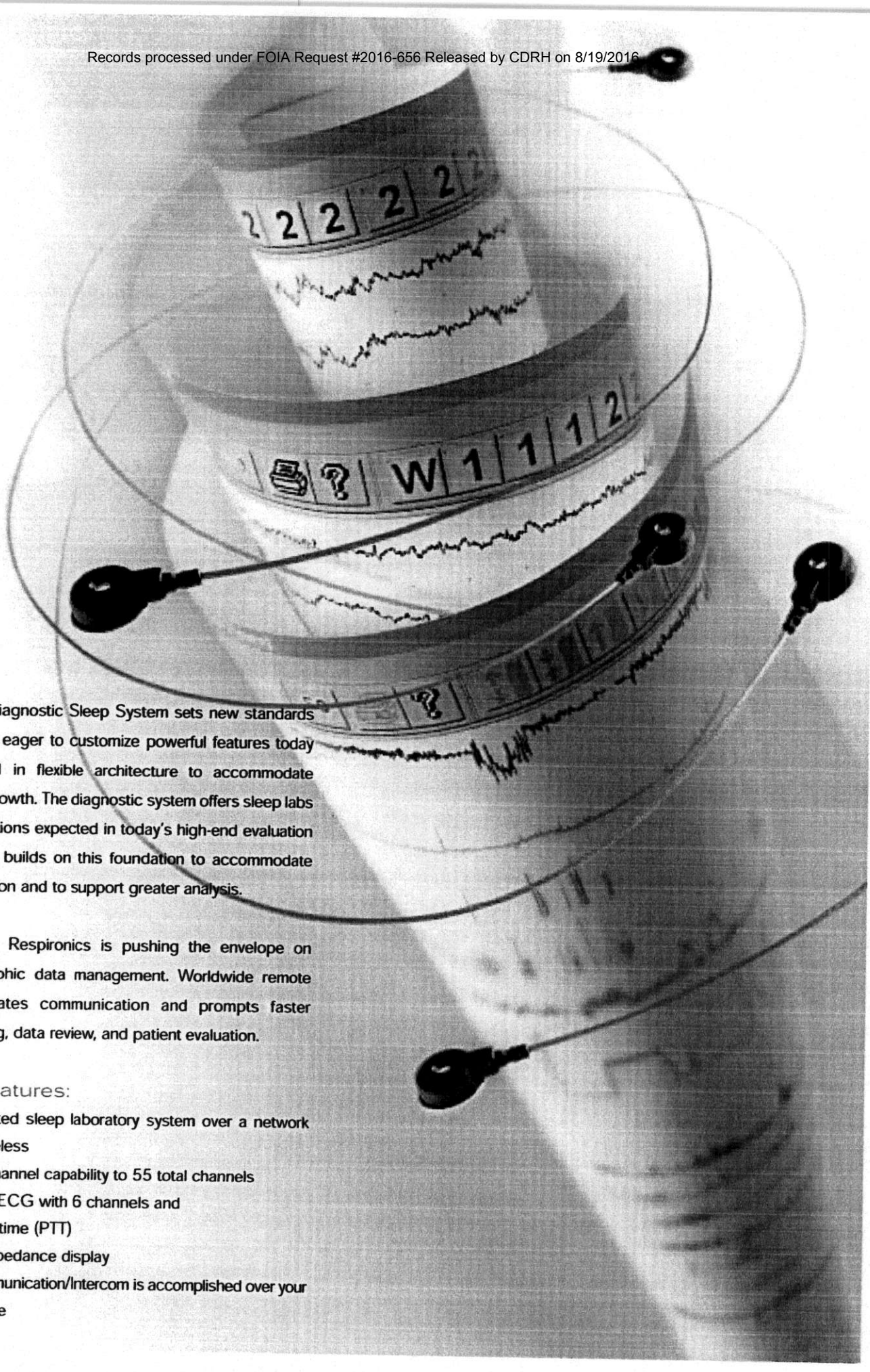
Six-Lead ECG with PTT.

High-Quality ECG with 6 Channels and Pulse Transit Time (PTT)

Respironics recognizes the relationship between sleep and cardiology, and has designed the Alice 5 to record 3 ECG leads +ground. This yields recordings of lead I and lead II and computed channels including leads III aVL, aVR and aVF. With the high quality ECG (up to 500 Hz data storage) and Masimo Oximetry, Alice 5 provides a high quality Pulse Transit Time (PTT). Arousals trigger sub-cortical autonomic arousals. One result is an increase in blood pressure that is reflected as a reduction in the PTT.

Checking impedance of your electrodes usually means leaving your patient's raw data to perform this function. The Alice 5 has been designed with an innovation of providing Real-Time Impedance. Sleep labs gain Real-Time insight into the quality of patient data through a continuous display on each EXG channel and oximetry of impedance/signal quality. Continuous display of actual numeric impedance value is available. All of this information is also available during post acquisition review of the data.





The Alice 5 Diagnostic Sleep System sets new standards for sleep labs eager to customize powerful features today but interested in flexible architecture to accommodate tomorrow's growth. The diagnostic system offers sleep labs standard functions expected in today's high-end evaluation platforms, but builds on this foundation to accommodate facility expansion and to support greater analysis.

With Alice 5, Respironics is pushing the envelope on polysomnographic data management. Worldwide remote access facilitates communication and prompts faster troubleshooting, data review, and patient evaluation.

Alice 5 Features:

- Fully integrated sleep laboratory system over a network cable or wireless
- Expanded channel capability to 55 total channels
- High quality ECG with 6 channels and pulse transit time (PTT)
- Real time impedance display
- Patient Communication/Intercom is accomplished over your network cable

Ordering Information

1011225 [illegible]	Base Station [illegible] Power Supply [illegible] Headbox AC Power Cord Speakers Headbox Wall Mounting Kit Patient Cable Headbox Carrying Pouch Microphone Kit Headbox Shoulder Strap Mouse Pad Alice 5 Setup & User's Guide
101122[illegible]	Base Station AC Power Cord Headbox Headbox Wall Mounting Kit Patient Cable Headbox Carrying Pouch Microphone Kit Headbox Shoulder Strap Mouse Pad Alice 5 Setup & User's Guide Power Supply

Specifications

Total Channels	55
Analog Inputs	12 total, 10 in the Base Station, 2 in the Headbox
Neurological Channels	
Specifications	
Number of Channels	21 (10 left, 9 right, 2 reference), 2 EOG
Input Impedance	1.66 Mohm per Electrode 3.33 differential
Bandwidth	0.32 Hz to 106 Hz
Input Signal Range	± 3.3 mV
Digital Resolution	16 bits
Sample Rate	2000 Hz
Max Storage Rate	200 Hz
Electrode Impedance Testing	100 Hz square wave between patient electrodes
Calibration Signal	Signal injection: 1 Hz, 98 mVpp Square wave to amplifier inputs
Communication Interfaces	Signals sent from Patient Interface to Headbox through sensor cables.
	Data is sampled and sent to the Base Station where it is stored on a disk or sent through an ethernet connection to a Host PC
Digital Filters available during analysis	
	0.5 to 100 Hz high pass filter
	0.5 to 100 Hz low pass filter
	50 or 60 Hz Notch filter
	Antialiasing filter
System Physical Characteristics	
BaseStation:	
Size	14 L x 5 W x 12.5 H (in)
Weight	7.8 lb
Headbox:	
Size	10 L x 4 W x 2 H (in)
Weight	1.6 lb

RESPIRONICS

www.respironics.com

Customer Service: 1-800-345-6443 or 724-387-4000
Respironics Europe: +33-1-55-60-19-80
Respironics Asia Pacific: +61-3-5280-9611

1024199 KB 10/28/04 [illegible]

SLEEP MANAGEMENT

CHRONIC RESPIRATORY MANAGEMENT

TOTAL VENTILATION SOLUTIONS

RESPIRATORY DRUG DELIVERY

NEONATAL & INFANT CARE

617

EB Neuro S.p.A.
Direzione
Via Pietro Fanfani, III/A
50127 Firenze

Sede Legale:
Via Pietro Fanfani, III/A
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Capitale Sociale Euro 765.000 int.vers.
CCIAA di Firenze R.E.A.493655
N. iscriz. Registro delle Imprese e
Codice Fiscale 01772220065
Partita IVA 04888840487

Sede Operativa:
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ebn@ebneuro.com

Sede Operativa:
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Telefono:045/6028111
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produzione@ebneuro.com

Biocompatibility Certification

EB Neuro certifies that the SANDMAN POCKET Amplifier materials coming in direct contact with the patient or user and referenced on the following page, are identical to those of the predicate devices (Nellcor's Suzanne cleared via K990565 and Respironics' Alice 5 cleared via K040595) and in compliance with ISO 10993.

Signature

Date: June 08, 2005

Ing A. Torsoli – Managing Director
Name/Title

The only materials coming into direct patient contact are those which compose the electrodes and leads. The electrodes and leads are not provided by EB Neuro and are to be purchased separately by the user. The SANDMAN POCKET Amplifier User Manual states that the user should use only FDA approved electrodes and leads.

Software Information

1 Introduction

The information in this section is given in accordance with the "***Guidance for the Content of Premarket Submissions for Software contained in Medical Devices***". issued by FDA on May 11, 2005. In the rest of this section this guidance will be referred to as "Software Guidance"

1.1 Terminology

DAM – Digital Acquisition Module (also called the Recorder Unit)
ARM – Analog Reconfigurable Module (also called the Yoke, Amplifier, or Headbox)

2 Level of Concern

The Sandman Pocket amplifier has been assessed to carry a **Minor Level of Concern**. This decision has been made using the tables available in the Software Guidance.
The term "Software Device" refers to the embedded Sandman Pocket firmware.

Table 1 Major Level of Concern - If the answer to any one question below is Yes, the Level of Concern for the Software Device is likely to be Major.

1_1. Does the Software Device qualify as Blood Establishment Computer Software?
NO – The Sandman Pocket is not a Blood Establishment Computer Software.

1_2. Is the Software Device intended to be used in combination with a drug or biologic?
NO - The Sandman Pocket is not intended to be used in combination with drugs or biologics.

1_3. Is the Software Device an accessory to a medical device that has a Major Level of Concern?
NO - The Sandman Pocket is not intended to be used as an accessory of a Medical Device carrying a Major Level of Concern

1_4. Prior to mitigation of hazards, could a failure of the Software Device result in death or serious injury, either to a patient or to a user of the device?
NO, in the event of a software failure, the acquisition may be abnormally interrupted or the data recorded and/or transferred to the host computer may be corrupted and consequently not usable. In the event of corrupted data, the host computer software and clinical judgment would be exercised to override the information provided by the amplifier.
The monitored data is not intended to alarm or trigger alarm for any conditions.

Examples of this include the following:

a. Does the Software Device control a life supporting or life sustaining function?
NO, the software embedded on the SANDMAN POCKET system is only used to collect physiological data, record them on an on-board memory, and to transfer the recorded data to a host computer through a standard USB interface.

b. Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators?
NO, the software controls no delivery of energy at all.

c. Does the Software Device control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury?

NO, the software embedded on the SANDMAN POCKET system is only used to collect physiological data, store them on an on-board memory, and to transfer the acquired data to a host computer, in real time, during the acquisition or in a successive time, reading back the on-board memory. The software does not interpret the acquired data in any way, nor does the software assign any "*diagnostic meaning*" to particular signals.

d. Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death?

NO, the software embedded on the SANDMAN POCKET system is only used to collect physiological data, store them on an on-board memory, and to transfer the acquired data to a host computer, in real time, during the acquisition or in a successive time, reading back the on-board memory. The software does not interpret the acquired data in any way, nor does the software assign any "*diagnostic meaning*" to particular signals.

e. Does the Software Device provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary?

NO, the SANDMAN POCKET is simply a "recording device", the embedded software is only used to collect physiological data, store them on an on-board memory, and to transfer the acquired data to a host computer, in real time, during the acquisition or, more typically, in a successive time, reading back the on-board memory. The software does not provide any alarm mechanism based on the acquired data, nor does it "control" in any way vital parameters. Any eventual real time elaboration performed on the acquired signals by the host computer is outside the scope of the recorder and is the responsibility of the "medical system" of which the SANDMAN POCKET is only one part.

Table 2 Moderate Level of Concern - If the Software Device is not Major Level of Concern and the answer to any one question below is Yes, the Level of Concern is likely to be Moderate.

2_1. Is the Software Device an accessory to a medical device that has a Moderate Level of Concern?

NO - The Sandman Pocket is not intended to be used as an accessory of a Medical Device carrying a Moderate Level of Concern.

2_2. Prior to mitigation of hazards, could a failure of the Software Device result in Minor Injury, either to a patient or to a user of the device?

NO, in the event of a software failure, the acquisition may be abnormally interrupted or the data recorded and transferred to the host computer may be corrupted and consequently unusable. In the event of corrupted data, the host computer software and clinical judgment would be exercised to override the information provided by the recorder.
The monitored data is not intended to alarm or trigger alarm for any conditions.

2_3. Could a malfunction of, or a latent design flaw in, the Software Device lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury?

NO, for the same reason as stated in the question above.

If the answers to all of the questions in Tables 1 and 2 above are No, the Level of Concern is Minor.

CONCLUSION
The Sandman Pocket software carries a **Minor Level of Concern.**

3 Software Description / Requirement

The functional software embedded in the acquisition system (later on referred to as "firmware") is distributed on each of the two functional modules constituting the system:

1) Digital Acquisition Unit (DAM)
2) Amplifier box (Yoke/ARM)

Digital Acquisition Module
This is the main module of the device. It communicates with the amplifier unit via an asynchronous serial link and with the host PC via a USB connection. It can acquire data under the direct contol of the host PC (attended mode) or store them in the internal memory at the preprogrammed time.

Amplifier box (Yoke/ARM)
This module hosts the amplifier chains and the Analog to Digital converters, and communicates with the digital module via a RS485 serial link.

DAM hosts a programmable DSP, and Yoke hosts a programmable microcontroller. Both modules run a firmware stored in the on-board Flash EEPROM. Once programmed in the factory, the firmware can be upgraded in both modules via the USB link. Details of the communication protocol between DAM and host PC can be found in the document B86100103100_W1.

3.1.1 Device Features Controlled by Software.

3.1.1.1 Acquisition System Recognition.

DAM is connected via a standard USB link to the host PC, and performs device identification and enumeration according to the specifications of USB_2.0 (or USB_1.1, if the host PC supports only this standard).

3.1.1.2 Host PC – DAM communication interface

DAM is a slave of the host PC: commands are actually issued only from the host PC to DAM. The communication protocols require 4 USB pipes:

- A bulk OUT pipe to send command from PC to DAM
- A bulk IN pipe to transport back parameters from DMM to PC
- A Bulk IN pipe to transport acquired data from DAM to the PC.
- An interrupt pipe to notify the presence of acquired data to host PC.

Low level data transport, including packet handshaking and data integrity is performed by the USB interface.
The use of different pipes for data transefer and command handshaking make it possible to issue commands and acquire status information without stopping the data flow.

3.1.1.3 Sampled Data Collection.

Sampled data returned from the Yoke are downsampled to the rate required by the host PC, stored internally in a large buffer and sent to the host PC via the appropriate IN pipe. If selected, data can be stored also in the internal Mass storage memory and downloaded at the end of the recording.

No data compression is performed on such data samples: they are 2's complement 16 bit data.

3.1.1.4 DAM unit - Amplifiers box interfacing.

The communication interface between the two units is a bidirectional, RS-485 asynchronous serial link. The forward direction (from DAM to Amplifier box) is used to issue simple commands and to ask for device information and status parameters; the reverse direction (from Amplifier box to

DAM) is used to transfer the data acquired by the sampling logic and to return the parameters requested by DAM.

3.1.1.5 Acquisition programming.

Data acquisition can be programmed by the host PC: enabled channels, sampling rates, coupling and other parameters can be modified according by the user. The device can store up to seven different presets at the same time in the internal memory.
Multirate sampling (different sampling rates for different channels) is supported. Data are transferred on a "per packet " basis: data are transferred at the minimum samplig rate and each packet contains all (and only) the data sampled during that timeslice. The unit performs a digital downsampling to assure the appropriate bandwidth for each channel.

3.1.2 Other Features Controlled by Software.

3.1.2.1 Acquisition control.

The system acquires signals whose analysis is performed by an application running on the host PC: the unit's firmware is not capable of interpreting or classifying the acquired data. It only calculates the Pulse Transit Time (PTT) measurement as the time elapsed between two specific events in the EKG and oxymetry signals. Specifically, the PTT calculation is derived using proven, widely recognized algorithms that calculate the time difference between R-wave of the QRS complex of the ECG signal (the most prominent part of the ECG waveform) and 50% of the ascending edge of the Pressure wave, as measured by a pulse oximeter. If required, the unit is also capable of measuring the impedance of the electrodes and leads used for data acquisition. Impedance values are either stored in the internal memory (unattended recording) or sent to the host PC if requested by a specific command.

3.1.2.2 LCD user interface.

On DAM module, there is a graphical LCD display of 128x128 pixels, together with a 5 positions control pad. The graphic interface is capable to display status informations and to select a simple subset of features:

- System selftest
- Acquisition mode and status information (available memory, battery status, time and data display.
- Impedance evaluation
- Alerts
- Generic text and graphic printout under the control of the host pc.

3.1.3 External device interfacing.

DAM is equipped with two standard RS-232 channels: one is used to communicate via the embedded oximeter board (Nellcor Puritan Bennet Nell-1 oximeter); the other is available for communication with any external serial devices. The communication with this device is under the control of the host PC. The unit is, however, capable to communicating with a GK425 device to retrieve the status parameters.

3.1.4 Software Limitations, Customization and Update.

This acquisition system is not intended to perform vital signs monitoring: therefore its firmware performs NO analysis of the signals and provides NO alarms of clinical relevance.
The resident firmware code, allocated into a Flash EEPROM, can be updated via the control software without opening the device's case.
Serial number, device identification data, and samples adjusting factors are stored in a dedicated Flas EEPROM section and are not erased by the firmware upgrade

4 Software Architecture.

4.1.1 Introduction.

The embedded software (firmware) for DAM module is distributed in two independent modules, one that contains the code and one that contains the bitmaps and the fonts for the graphic user interface. The firmware images are stored in the EEPROM embedded in the device and can be upgrade independently.
The program implements a real-time system driven by interrupt triggered events. Interrupt service routines are prioritized to guarantee the execution of time critical tasks, and they can dispatch services to be executed in the background via a round-robin task queue.
For the Yoke module, the firmware is generated in a single image and stored in the EEPROM available inside the MCU. Again, the firmware is a real-time system based on prioritized interrupts and on a round-robin task queue for the execution of low priority tasks.

4.1.2 DAM module.

High priority tasks performed by interrupt service routines:
- Data downsampling
- low level UART management
- low level USB management

Low priority tasks performed in background:
- data transmission
- data storage
- LCD management
- UART communication
- USB protocol handling
- handling of control protocol on the USB link
- handling of the communication protocol with ARM
- PTT computation

4.1.3 ARM module

High priority tasks performed by interrupt service routines:
- data sampling and transmission, precisely timed by internal clock divisor;
- low level command receiving.

Low priority tasks performed in background:
- command parsing and processing;
- setup of channel properties.

4.2 Software Flowchart.

4.2.1 DAM

(b)(4)

4.2.2 ARM

(b)(4)

5 Software Hazard Analysis

Hazard analysis related to the software is included in the Risk Analysis section of this submission.

6 Software Development Environment.

The firmware for DAM unit was developed in a mixture of "C" and assembly language for the Texas Instruments TI TMS320C54X DSP family, using the standard TI compiler and assembler for that family.
The development was achieved by the JTAG based TI Code Composer Studio IDE, which in a transparent manner provides a real-time emulation for the acquisition system. Once compiled, the same JTAG emulator has been employed for the ICE first time programming of the Flash EPROMS resident firmware.
No real time operating system RTOS or off-the-shelf components were used and/or included in the final embedded code.
The firmware of the Yoke unit was developed in "C" and assembly language for the Texas Instruments MSP43x Family using the standard TI compiler and assembler for that family. The development was achieved by the Jtag based Code Studio IDE, the first time programming is accomplished by the device bootloader and a dedicated serial adapter.

The following section is page numbered independently from the remainder of the submission.

Report Interno

Titolo : Sandman Pocket Pulse Transit Time Measurement algorithm validation		Cod : **0065RPT_20** Rev: **A** pag **1 / 17**
Compilato: M. Venturi	Approvato: V. Roma	Data 25-05-06

(b)(4)

[redacted]

(b)(4) Software Validation

(b)(4) Software Validation

(b)(4) Software Validation

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(b)(4) Software Validation

Open Source ECG Analysis Software Documentation

Patrick S. Hamilton
E.P. Limited

For information on obtaining the most recent version E.P. Limited's Open Source ECG Analysis Software, visit or web site (http://www.eplimited.com/).

References

[1] Moody, G.B., Mark, R.G., "Development and evaluation of a 2-lead ECG analysis program," Computers in Cardiology. 1982; 39-44.

[2] Forbes, A.D., Helfenbein, E.D., Heumann, J.M., Jimison, H.B., Lindauer, J.M., Platt, J.S., "Ambulatory arrhythmia analysis: a dual-channel, Baysian approach," Computers in Cardiology. 1985; 373-375.

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[8] Tompkins WJ (ed.). *Biomedical Digital Signal Processing: C-Language Examples and Laboratory Experiments for the IBM PC*. 1993. Englewood Cliffs, NJ: PTR Prentice Hall.

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102

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Michael Husband

Subject: 510(k) Number K061996/S1

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☒ Requires additional information (other than refuse to accept).
- ☒ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?	☐ YES	☒ NO
Is this device subject to the Tracking Regulation?	☒ YES	☐ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☒ NO
Is this a prescription device?	☒ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☒ YES	☐ NO
Special 510(k)?	☐ YES	☒ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☒ NO

Truthful and Accurate Statement ☐ Requested ☒ Enclosed

☒ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices

☒ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source ☐ YES ☐ NO Material of Biological Origin ☐ YES ☐ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: MNR 868.2375 class II

Additional Product Code(s) with panel (optional):

Review: _____ 10/2/06
(Branch Chief) (Branch Code) (Date)

Final Review: _____ 10/2/06
(Division Director) (Date)

Revised:4/2/03

REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K 061996/S1

Reviewer: Michael Husband

Division/Branch: DAGID/ARDB

Device Name: Sandman Rocket

Product To Which Compared (510(K) Number If Known): K040595

		YES	NO	
1.	Is Product A Device	✓		If NO = Stop
2.	Is Device Subject To 510(k)?	✓		If NO = Stop
3.	Same Indication Statement?	✓		If YES = Go To 5
4.	Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5.	Same Technological Characteristics?	✓		If YES = Go To 7
6.	Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7.	Descriptive Characteristics Precise Enough?		✓	If NO = Go To 10 If YES = Stop SE
8.	New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9.	Accepted Scientific Methods Exist?			If NO = Stop NE
10.	Performance Data Available?	✓		If NO = Request Data
11.	Data Demonstrate Equivalence?	✓		Final Decision: SE

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use: See 3P memo

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

See 3P memo.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics are not precise enough:
See 3P memo

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent.:
See memo

ATTACH ADDITIONAL SUPPORTING INFORMATION

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		
2. Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP purposes?		
4. If, not, has POS been notified?		
5. Is the product a device?		
6. Is the device exempt from 510(k) by regulation or policy?		
7. Is the device subject to review by CDRH?		
8. Are you aware that this device has been the subject of a previous NSE decision?		
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Third Party Review Memo
K061996

Date: September 26, 2006
To: The Record
From: Michael Husband
Company Name: EB Neuro S.P.A.
Device Name: Sandman Pocket
Contact: (b)(4)
Phone: (b)(4) Third party

Office: HFZ-480
Division: DAGID/ARDB

(b)(4)

The third party reviewer has stated that the sponsor has addressed all of the issues raised by Ann Graham on July 19, 2006. A brief review of the additional information shows that the issues raised have been addressed.

Recommendation:

I concur with the third party reviewer and recommend the device be found substantially equivalent to the predicate. This device should be classified as follows:

- Class II (two)
- 73 MNR
- 21 CFR 868.2375 Ventilatory Effort Recorder

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) Anne Dykstra

Subject: 510(k) Number K061996

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☒ Requires additional information (other than refuse to accept). AI
- ☐ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?	☐ YES	☐ NO
Is this device subject to the Tracking Regulation?	☐ YES	☐ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☐ NO
Is this a prescription device?	☐ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☐ NO
Special 510(k)?	☐ YES	☐ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☐ NO

Truthful and Accurate Statement ☐ Requested ☐ Enclosed

☐ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices

☐ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) _____

Animal Tissue Source ☐ YES ☐ NO Material of Biological Origin ☐ YES ☐ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 day

Predicate Product Code with class: MNR (Class II (2))

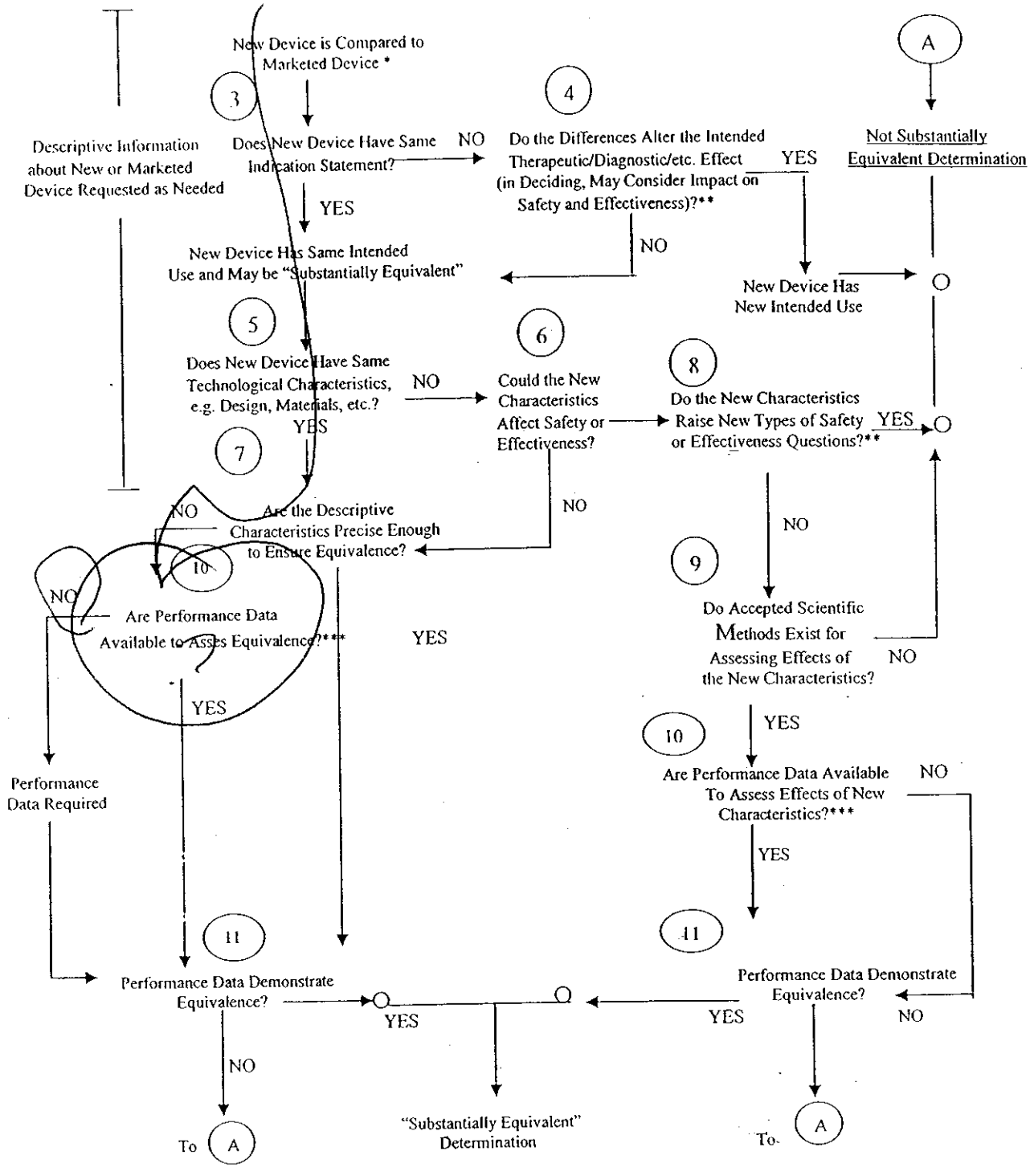
Additional Product Code(s) with panel (optional): _____

Review: Anne Dykstra (Branch Chief) HFZ. 480 (Branch Code) 1/19/06 (Date)

Final Review: _____ (Division Director) (Date)

Revised:4/2/03

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



- ✣ 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- ✣✣ This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- ✣✣✣ Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

THIRD PARTY REVIEW CHECKLIST

1. Is this 510(k) eligible for third party review, i.e.:		
a. Is the device on the list of eligible devices?*	Yes	No
b. Can a determination of substantial equivalence be made without clinical data?	Yes	No
c. Are you aware of the 510(k) holder being the subject of an Integrity Investigation?	Yes	No

IF THE ANSWER IS "NO" TO A or B above, or "YES" to C above, PLEASE BRING THE SUBMISSION TO POS IMMEDIATELY.

Are the following elements included in the submission:

2. A cover letter signed by the third party's official correspondent clearly identifying:		
a. The purpose of the submission	Yes	No
b. The name and address of the third party	Yes	No
c. The name and address of the 510(k) holder	Yes	No
d. The name of the device (trade name, common or usual name, and FDA classification name)	Yes	No
e. The third party's recommendation with respect to the substantial equivalence of the device	Yes	No
f. The date the third party first received the 510(k) from the 510(k) holder	Yes	No

3. A letter signed by the 510(k) holder authorizing the third party to submit the 510(k) on its behalf and to discuss its contents with FDA.	Yes	No

4. The complete 510(k) conforming to FDA's established requirements relating to content and form of such submissions.	Yes	No

5. A complete review of the 510(k), signed by all personnel who conducted the third party review and by an individual within the third party responsible for supervising third party reviews, with a recommendation concerning the substantial equivalence of the device.	Yes	No

6. A certification that:		
a. The third party continues to meet the personnel qualifications and prevention of conflict of interest criteria reviewed by FDA	Yes	No
b. Statements made in the third party's review are true and accurate to the best knowledge of the third party	Yes	No
c. The third party's review is based on the 510(k) that it is submitting with the review	Yes	No
d. The third party understands that the submission to the government of false information is prohibited	Yes	No

7. Are the following forms included in the submission as discussed in the Center's guidance document entitled Third Party Review-An Instruction Manual for Conducting Reviews of Premarket Notifications:		
a. Third Party Premarket Notification (510(k)) Checklist for Acceptance Decision (Parts I and II)	Yes	No
b. Record of Deficiencies, if applicable (attachment 1a)	Yes	No
c. Indications for Use Form	Yes	No
d. 510(k) Summary or Statement (attachment 1c)	Yes	No
e. 510(k) Truthful and Accurate Statement (attachment 1d)	Yes	No
f. Third Party "Substantial Equivalence" (SE) Decision Making Documentation (attachment 2)	Yes	No

IF ANY OF THE ABOVE INFORMATION IS NOT INCLUDED WITH THE THIRD PARTY'S SUBMISSION OR IS NOT ADEQUATE, CONTACT THE THIRD PARTY AND ATTEMPT TO RESOLVE THE DEFICIENCY. PLEASE INCLUDE A MEMORANDUM TO THE RECORD OF THE TELEPHONE CALL. WHEN THE INFORMATION IS RECEIVED PLEASE REVISE THIS CHECKLIST OR COMPLETE A NEW ONE.

COMMENTS: _____

_____

_____

*If the third party incorrectly classified the device and it is not a device type eligible for third party review please bring to POS.

To: K061996

From: Chief, ARDB

Subject: Additional information

Upon review of this third-party file, ARDB identified the following deficiencies and has asked Regulatory Technology Services, Mark Job, principle reviewer, to provide the additional information. We cannot concur with the SE recommendation until we review the requested data.

Ann Graham

Graham, Ann A.

From: Graham, Ann A.
Sent: Wednesday, July 19, 2006 1:55 PM
To: 'mark@markjob.com'
Subject: PSG

Mark,

A few issues about this file need to be clarified before I can concur with your SE recommendation:

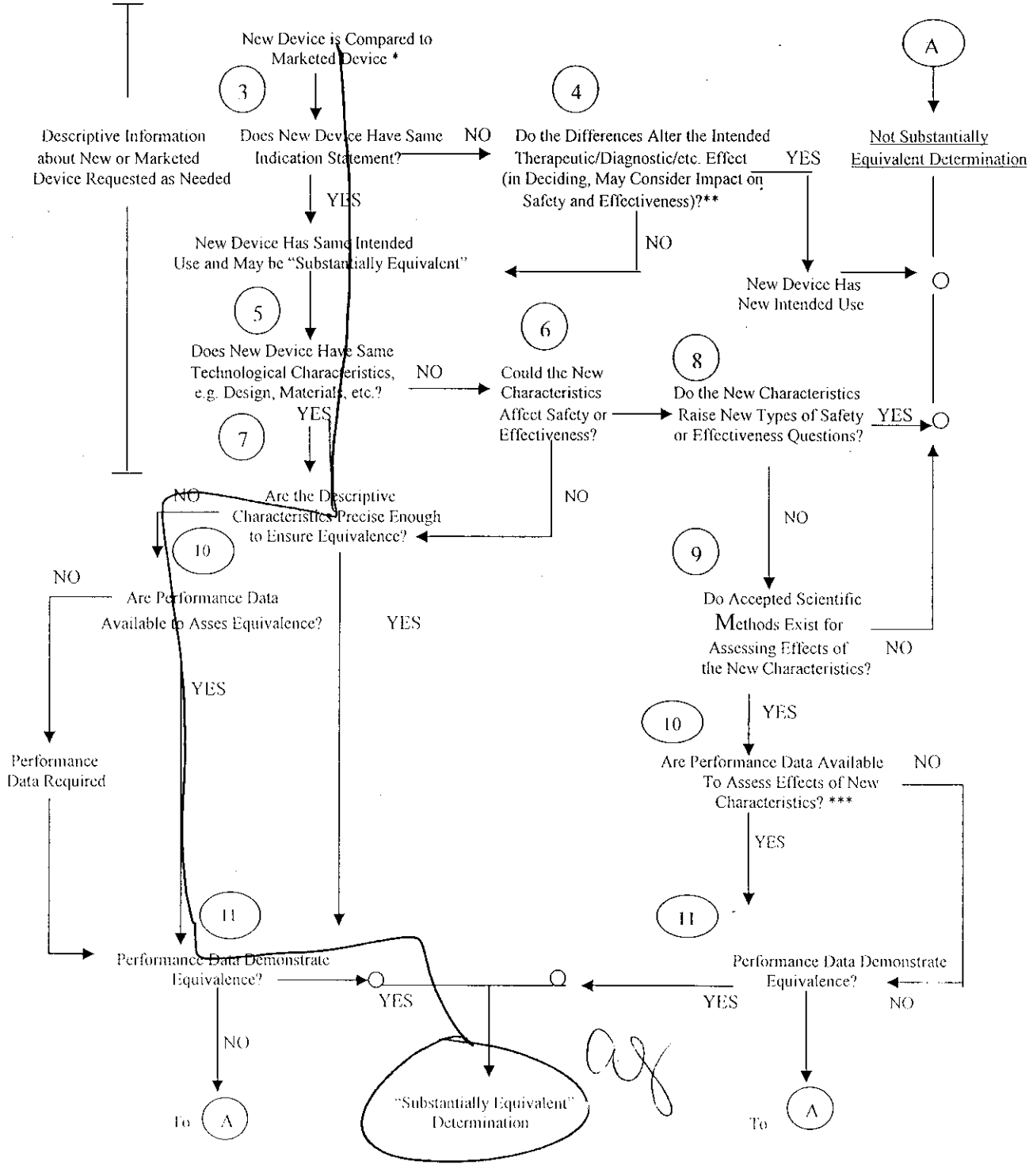
(b)(4) Third party Review

[redacted]

I'm placing the file on hold and you will have 30 days to respond.

Ann Graham

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

September 25, 2006

EB NEURO, S.P.A.
c/o REGULATORY TECHNOLOGY SERVICES,
1394 25TH STREET, NW
BUFFALO, MN 55313
ATTN: MARK JOB

510(k) Number: K061996
Product: SANDMAN POCKET

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

K061996/S1

Date: September 22, 2006

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

RE: Premarket Notification K061996
EB NEURO S.P.A. Sandman Pocket

To Whom It May Concern:

Enclosed in duplicate is the additional information received from EB NEURO S.P.A. regarding K061996. This information has been reviewed in detail (see attached) and was found to answer the questions raised from an email dated July 19, 2006 from Ann Graham.

Recommendation: Substantial Equivalence

If you should have any questions regarding this submission please contact me at 763 682 4139 or fax 763 682 4420 or email at mark@markjob.com. Please fax any correspondence regarding this submission to Regulatory Technology Services LLC.

Sincerely,

Mark Job
Responsible Third Party Official

K50

Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Attachment 1

The EB NEURO S.P.A. consultant (Anson Group – Allison Scott) has provided a detail letter outlining the question and the resolution. This letter is included in this supplement.

Item 1:

The revised substantial equivalence table includes a comparison of the signal analysis operating characteristics and indications for use. The software verification and validation indicates the performance (similar to the predicate device) has been performed. This is acceptable response to the questions raised by FDA.

Item 2:

The supplement information includes information from the original submission demonstrating the all product performance tested. This is an acceptable response to the questions raised by FDA.

Item 3:

The list of standards provided in the supplement demonstrates compliance to all appropriate standards. The list is over stated and could simply be demonstrated by stating compliance to UL 60601-1 which is the top level standard which requires compliance to all of the lower standards which are also included in the list. The response is acceptable to the question raised by FDA.

Item 4:

The supplemental information includes all of the information to support the software guidance for a moderate level of concern. This response is acceptable to the questions raised by FDA.

Item 5:

As requested, the labeling has been revised to include appropriate caution statement for prescription devices. An acceptable response to the questions raised by FDA.

Item 6:

As requested, the labeling has been revised to include appropriate to revise the use of caution and warnings to be in line with the predicate labeling. An acceptable response to the questions raised by FDA.

The additional information supplied by the manufacturer in response to the questions raised by the FDA have been reviewed by this third party reviewer and found to answer those questions. Therefore a substantially equivalent decision is recommended.

ANSON GROUP

September 19, 2006

Ann Graham
FDA/CDRH- HFZ-480
9200 Corporate Drive, Room 240C
Rockville, MD 20850

RE: Response to Reviewer Deficiencies of July 11, 2006

Ms Graham-
In response to your noted deficiencies of July 11, 2006 for the EBNeuro Sandman Pocket 510(k), please find our responses in bold within this letter.

1) There was no comparison performance data between the subject device (Sandman) and the predicate device NPB Suzanne, and Alice 5. A complete comparison for signal analysis, operating characteristics and indications for use must be included in the 510(k).

(b)(4) [redacted]

2) All the product characteristics in the comparison information section should be validated with a rationale or performance data. For example, when the Sandman is connected to a third party pass CPAP device and a computer, the device acts as a passive bridge. Verification of the passive activity needs to be submitted in the 510(k).

(b)(4) [redacted]

3) You listed several standards but did not give any details to which part of the standard the sponsor is claiming conformance.

(b)(4) [redacted]

11460 N. Meridian Street, Suite 150 Carmel, IN 46032 **Ph.** (317) 569-9500 **Fax** (317) 569-9520 **TF** (866) 521-9500
www.ansongroup.com

ANSON GROUP

(b)(4)

[redacted]

4) If the software in the Sandman contains a QRS recognition algorithm, then the software is a moderate level of concern.

(b)(4)

[redacted]

5) The labeling needs the exact prescription legend "Caution: Federal law restricts this device to sale by or on the order of a physician."

The labeling has been changed. Please see the revised user manual in Appendix E. Only chapters that are affected by this change are being submitted in Appendix E.

6) All of the statements in the labeling beginning with Attention need to be changed to cautions or warning statements consistent with predicate labeling.

The labeling has been changed. Please see the revised user manual in Appendix E. Only chapters that are affected by this change are being submitted in Appendix E.

Should you have further questions, please feel free to contact me at ascott@ansongroup.com or 317-569-9500 x106. Thank you for your time in reviewing this submission.

Sincerely,

Allison Scott

Allison Scott

CC: Mark Job

Substantial Equivalence Comparision Table

Product Characteristic	*Suzanne* (Predicate Device) Nellcor Puritan Bennet K990565	*Alice 5* (Predicate Device) Respironics K040595	*Sandman Pocket* (submission device) EB Neuro Via this Submission
Regulatory			
Device class	Class II	Class II	Class II
Product code	MNR	GWQ	MNR
Device type	Ventilator Effort Recorder	Electroencephalograph	Ventilator Effort Recorder
Regulation Number	868.2375	882.1400	868.2375
Labelling			
Intended use	Intended for use in collecting and recording physiological data to be used in diagnosing sleep disorders	Intended to record, display and print physiological information to clinicians/physicians. These parameters are presented graphically on a computer screen for diagnostic review, similar in application to the use of a traditional paper based polygraph recorder. The device will be used in hospitals, institutions, sleep centers or clinics, or other test environments where adult or infant patients require the documentation of various sleep or other physiological disorders. This device does not provide alarms and is not intended for use as an automated apnea monitor.	Intended for use in collecting and recording physiological data to be used in polysomnography and sleep disorder studies. For use in either home or hospital environments with a pediatric through adult patient population. This device does not provide alarms and is not intended for use as an automated apnea monitor
Target population	Pediatric through adult (excluding neonates and infants)	Pediatric through adult (including all pediatric subpopulations)	Pediatric through adult (including all pediatric subpopulations)

Product Characteristic	***Suzanne*** **(Predicate Device)** **Nellcor Puritan Bennet** **K990565**	***Alice 5*** **(Predicate Device)** **Respironics** **K040595**	***Sandman Pocket*** **(submission device)** **EB Neuro** **Via this Submission**
Environment of use	Hospital and home	Hospitals, institutions, sleep centers, or other test environments.	Hospital and home
Warnings	Items related to sensor irritation, strangulation avoidance and off-label use.	Items related to sensor irritation, strangulation avoidance, and off-label use.	Items related to sensor irritation, strangulation avoidance and off-label use.
Contraindications	Items related to design and indicated use limitations, such as not for use in the presence of flammable anesthetics or in conjunction with defibrillation equipment.	Items related to design and indicated use limitations, such as not for use in the presences of flammable substances or anesthetic mixtures with air oxygen or nitrous oxide, defibrillation, and MRI equipment, and not for use as automated apnea monitor or a continuous monitor.	Items related to design and indicated use limitations, such as not for use in the presence of flammable anesthetics or in conjunction with defibrillation equipment. The Sandman Pocket is not intended for use as life support equipment such as a vital sign monitoring in intensive care unit. The device does not produce alarms and is not intended as an automated apnea monitor. The Sandman Pocket is only to be used under the direction or supervision of a physician, technologist or clinician. It will not prevent or restore the interruption or loss of any physiological system.
Prescription status	Available only on the order of a physician.	Available only on the order of a physician.	Available only on the order of a physician.
Service instructions	No field service allowed.	No field service allowed.	No field service allowed.

Product Characteristic	***Suzanne*** **(Predicate Device)** **Nellcor Puritan Bennet** **K990565**	***Alice 5*** **(Predicate Device)** **Respironics** **K040595**	***Sandman Pocket*** **(submission device)** **EB Neuro** **Via this Submission**
Design			
Communication Interfaces	Physiological signals are sent to the Slow Wave and Fast Wave headbox through the sensor cables. The Slow Wave and Fast Wave headboxes sends the data to the Recorder Plus module where the data is stored either to a flash memory card or to a PC via a fiber optic interface.	Physiological signals are sent from the patient sensors to the headbox through the sensor cables. The data is sampled and sent to the base station where it is stored on a disk until it is sent through an Ethernet connection to a Host PC.	Physiological signals are sent from the patient sensors to the amplifier box through the sensor cables. The amplifier box sends the data to the recorder where the data is stored in flash memory in both attended and unattended studies. During attended studies, the data is also transmitted to a computer in real-time via a USB cable. After unattended studies, data can be downloaded from the recorder using a USB cable.
Microprocessor	Siemens 80C537 12 MHz	Unknown	Texas Instruments TMS320UC5402 on recorder Texas Instruments MSP430F169 on headbox
A/D Resolution	12 bit	16 bit	16 bit
Data recording	On PCMCIA card, magnetic disk or optical disk (via a personal computer).	Computer hard drive, compact disc, or transferred via Ethernet connection to a Host PC.	On internal NAND flash chip
Configuration	Desktop and wearable	Desktop only	Wearable

Product Characteristic	***Suzanne*** **(Predicate Device)** **Nellcor Puritan Bennet** **K990565**	***Alice 5*** **(Predicate Device)** **Respironics** **K040595**	***Sandman Pocket*** **(submission device)** **EB Neuro** **Via this Submission**
Amount of memory required for a typical 8 hour study.	20 MB	600 MB without audio/ video 6 GB with audio/video NOTE: Alice 5 can collect up to 21 neurological channels. These channels are recorded at very high sampling rates. In addition, Alice 5 records video at very high frame rates with no compression. These two factors contribute to the large study size. All data are stored to computer hard disk.	28 MB
Sampling rate	Slow waves : 12 samples/s Fast waves : 120 samples/s	Neurological channels 2000 samples/s	Fast waves: For example, ECG programmable up to 2048 sample/s Medium waves: For example, EMG, EOG, Snore programmable up to 1024 sample/s Slow waves: For example, airflow, respiratory effort, body position programmable up to 256 sample/s
Power	Battery powered (internal) or Medical Grade AC-DC Power Supply	Medical grade AC Power Supply	Battery powered or USB powered
Sensors	Commercially available sensors only	Commercially available sensors only	FDA Cleared sensors only
Performances			
Maximum number of channels	35	55	22

Product Characteristic	***Suzanne*** **(Predicate Device)** **Nellcor Puritan Bennet** **K990565**	***Alice 5*** **(Predicate Device)** **Respironics** **K040595**	***Sandman Pocket*** **(submission device)** **EB Neuro** **Via this Submission**
Recording channels			
EEG	Yes	Yes	Yes
EOG	Yes	Yes	Yes
EMG	Yes	Yes	Yes
ECG	Yes	Yes	Yes
Respiratory efforts	Yes	Yes	Yes
Airflow	Yes	Yes	Yes
Ambient sounds	Yes	Yes	No
Body position	Yes - internal	Yes - external	Yes - external
Ambient light	Yes - internal	No	No
SpO_2	Yes - internal	Yes - internal	Yes - internal
Pulse rate	Yes - internal	Yes - internal	Yes - internal
Plethysmograph	No	Yes	Yes
Differential pressure	Yes - internal	Yes - external	Yes - internal
Actimeter	No	Yes	No
Derived channel	N/A	Pulse Transit Time (PTT) – A calculation of the time between the occurrence of the R wave on the EKG and the peak flow on the plethysmogram. RR Interval – Measurement of the period of time between two consecutive R waves on the EKG. Displays as a real-time beat-to-beat heart rate calculation.	Pulse Transit Time (PTT) – A calculation of the time between the occurrence of the R-wave on the EKG and 50% ascending slope on the plethysmogram. Heart rate – Derived from the ECG channel
Passbands			
EEG	0.625 to 18 Hz	Neurological Channels 0.32 to 106 Hz	0.1 to 135 Hz
EOG	0.625 to 18 Hz		0.1 to 135 Hz
EMG	0.625 to 18 Hz		0.1 to 135 Hz
ECG	0.625 to 18 Hz		0.1 to 135 Hz
Respiratory efforts	0.055 to 1.25 Hz		0.1 to 45 Hz
Airflow	0.1 to 1.3 Hz		0.015 to 10 Hz
Ambient sounds	None		None
Pressure sensor	0 to 175 Hz		DC to 15 Hz
SpO_2	NPB proprietary		NPB proprietary
Pulse rate	NPB proprietary		NPB proprietary

20

Product Characteristic	***Suzanne*** **(Predicate Device)** **Nellcor Puritan Bennet** **K990565**	***Alice 5*** **(Predicate Device)** **Respironics** **K040595**	***Sandman Pocket*** **(submission device)** **EB Neuro** **Via this Submission**
CPAP (Continuous Positive Airway Pressure)	*Suzanne* supports all models of CPAP devices because the CPAP device connections were air-based rather than electrically based. Using a pneumotachograph kit, users could connect hoses and adapters to the CPAP device and the flow and pressure nipples on the *Suzanne* slow wave headbox to measure CPAP airflow and/or air pressure at the mask out-take during nasal CPAP/Bi-level titration.	*Alice 5* supports the use of all Respironics lab therapy devices: Aria LX BiPAP Pro Duet LX Harmony HeartPAP REMStar Auto REMStar Pro REMStar Pro with C-Flex Synchrony Virtuoso LX	*Sandman Pocket* stores data from Nellcor Puritan Bennett GK420E, GK425, and GK425ST CPAP devices. When the recorder is also connected to the host computer, the *Sandman Pocket* not only stores data in the on-board memory, but also acts as a passive bridge between the aforementioned GK CPAP and the host computer by receiving data streams from the CPAP and transmitting the data streams to the host computer and vice versa. When the *Sandman Pocket* is connected to a third party CPAP device and a host computer, *Sandman Pocket* acts as a passive bridge between the third party CPAP device and the computer by receiving data streams from the CPAP and transmitting the data streams to the host computer and vice versa. Alternatively, *Sandman Pocket* may also handle CPAP device connections in the same manner as Suzanne.

Product Characteristic	***Suzanne*** **(Predicate Device)** **Nellcor Puritan Bennet** **K990565**	***Alice 5*** **(Predicate Device)** **Respironics** **K040595**	***Sandman Pocket*** **(submission device)** **EB Neuro** **Via this Submission**
Mechanical safety	Device complies with the requirements of Nov' 93 Draft Reviewer's Guidance	Device complies with the International Standard IEC 60601-1 CSA C22.2 No. 601.1 EN 60601-1 UL 60601-1 AS 3200.1.0* *Australian Deviation to IEC 60601-1	Device complies with the International Standard IEC 60601-1 CSA C22.2 No 601-1-M90 UL 2601
Electrical safety	Device complies with the International Standard CSA C22.2 No. 601-1-M90 UL 2601 Device complies with the requirements of Nov' 93 Draft Reviewer's Guidance	Device complies with the International Standard IEC 60601-1 Guidance, when applicable, has been adopted from the following standards: IEC 60601-2-25 IEC 60601-1-26 IEC 60601-2-40 IEC 60601-2-49	Device complies with the International Standard IEC 60601-1 IEC 60601-1-4 IEC 60601-1-26 CSA C22.2 No 601-1-M90 UL 2601
Electromagnetic Compatibility (EMC)	Device complies with the following EMC standards IEC 60601-1 IEC 61000-4-2 IEC 61000-4-3 IEC 61000-4-6 Mil Std 462D IEC 61000-4-4 IEC 61000-4-5 EN55011 Class B Device complies with the requirements of Nov' 93 Draft Reviewer's Guidance	Device complies with the International Standard IEC 60601-1-2, including the following standards: CISPR 11 IEC 61000-3-2 IEC 61000-3-3 IEC 61000-4-2, IEC 61000-4-3 IEC 61000-4-4, IEC 61000-4-5, IEC 61000-4-6, IEC 61000-4-8 IEC 61000-4-11	Device complies with the International Standard IEC 60601-1- 2, including the following standards: IEC 61000-3-2 IEC 61000-3-3 IEC 61000-4-2 IEC 61000-4-3, IEC 61000-4-4, IEC 61000-4-5, IEC 61000-4-6, IEC 61000-4-8 IEC 61000-4-11 EN55011 class B EN55014-1

Discussion of Similarities and Differences

Similarities:

- Both *Suzanne* and *Sandman Pocket* are portable recording devices intended to record polygraphy/polysomnograph data (multifunctional ambulatory recorders) in clinical and home environments. When used in a home setting, the patient goes to the physician's office to get hooked up to the system, goes home and sleeps in his/her own bed, and then returns the next day with the recording system and its stored data.
- *Suzanne*, *Alice 5*, and *Sandman Pocket* use one common electrode reference to establish a patient ground (not earth ground) against which all other electrical inputs are referenced. Each device's measurement values and waveforms contain many of the same channels of infomation.
- All devices detect electrical signals or other signals (impedence change, pressure) which are then converted to digital data. None of the systems actually deliver energy to the patient – they receive signals from the patient , amplify and filter these signals, and record the digital data derived from the signals.
- None of the hardware devices perform data analysis. The waveforms are stored in the on-board memory (*Suzanne* and *Sandman Pocket*) or to the base station (*Alice 5*) and then the data is transferred to a host system, which runs sleep review and analysis software used by a trained clinician to analyze the data either by manually scoring or auto-scoring the recorded data. The software on the host system and its behaviour is outside of the scope of all the referenced devices.
- Both *Suzanne* and *Sandman Pocket* can be powered using batteries. The *Suzanne* operates using built-in

(b)(4)

When the *Sandman Pocket* is connected to a third party (b)(4)

In any configuration, the *Sandman Pocket* is not capable of setting or modifying the CPAP parameters. Changing the CPAP device settings may only be done by the user with either a CPAP remote control connected directly to the CPAP device or from the host computer using sleep review and analysis software capable of changing the CPAP parameters.

Differences:

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[1] Jérôme Argod, Jean-Louis Pépin, and Patrick Levy in their study "Differentiating Obstructive and Central Sleep Respiratory Events through Pulse Transit Time" calculated PTT as "the interval between the ECG R-wave and the point on the pulse waveform that is 50% the height of the maximum value (as detected with photoplethysmography)" (1779).

Argod, Jérôme, Jean-Louis Pépin, and Patrick Levy. "Differentiating Obstructive and Central Sleep Respiratory Events through Pulse Transit Time." American Journal of Respiratory Critical Care Medicine 158 (1998): 1778–1783.

[2] D.J. Pitson and J.R. Stradling in their article "Value of beat-to-beat blood pressure changes, detected by pulse transit time, in the management of the obstructive sleep apnoea/hypopnoea syndrome" state that they measured PTT "in real time as the interval from the QRS complex to a threshold on the rising edge of the finger pulse. The threshold is calculated as 25% of the height of the pulse during a time window of 280 ms after the QRS" (686).

Pitson, D.J., and J.R. Stradling. "Value of beat-to-beat blood pressure changes, detected by pulse transit time, in the management of the obstructive sleep apnoea/hypopnoea syndrome." European Respiratory Journal 12 (1998): 685–692.

[3] In their article "Impaired response to HAART in HIV-infected individuals with high autonomic nervous system activity", Steve W. Cole et al. describe pulse transit time as the "duration from EKG R spike to subsequent finger photoplethysmograph peak" (12695).

Steve W. Cole, Bruce D. Naliboff, Margaret E. Kemeny, Marshall P. Griswold, John L. Fahey, and Jerome A. Zack. "Impaired response to HAART in HIV-infected individuals with high autonomic nervous system activity." PNAS 98.22 (2001): 12695–12700.

For *Sandman Pocket*, we chose 50% of the ascending slope of the plethysmogram waveform because it is more widely used. No one method is "right" or "wrong", so there is no clinical difference between the methods.

- *Unlike Alice 5*, the *Sandman Pocket and Suzanne* may be used in both lab and home evironments. *Alice 5* is only for use in clinical evironments.
- *Alice 5* requires more data storage space because the study file sizes are larger. Unlike *Sandman Pocket* and *Suzanne*, which are screening devices, *Alice 5* is a full polysomnographic (PSG) system that can collect up 55 channels, 21 of which are neurological channels that are recorded at very high sampling rates. Alice 5 also records video at very high frame rates with no compression. The number of neurological channels recorder, the high sampling rate for neurological channels, and the high frame rates for recorder video contribute to the large study size. Unlike *Sandman Pocket* and *Suzanne*, which store data to flash memory, *Alice 5* stores data to a computer hard disk.
- In *Suzanne*, the sampling rate and bandpass filters are hardware fixed parameters. The user cannot change the sampling rate or bandpass filters.

  Alice 5 uses a 2000 Hz sampling rate on neurological channels. The sampling rates of Alice 5 and Sandman Pocket are comparable and more than sufficient to accurately reproduce the signal.

  In the *Sandman Pocket*, (b)(4) [redacted]

  The *Sandman Pocket* also uses a (b)(4) [redacted]

  Alice 5 also uses a wide hardware bandpass filter of 0.32 to 106 Hz on neurological channels. As with *Sandman Pocket*, users can apply additional high and low frequency filters from the Alice software while reviewing data. Again, these additional software filters do not change the actual data collected, but rather these filters change only how the clinician views the data.
- *Suzanne* converts data to 12 bit resolution, whereas the *Sandman Pocket* and *Alice 5* have 16 bit resolution. This increased resolution improves the digital representation of the analog signal.
- Unlike Suzanne, the Sandman Pocket is indicated for use with an adult through pediatric patient population, including neonates and infants. Suzanne was deemed unsuitable for infant studies because the bandpass filter of 0.1 to 1.3 Hz excluded frequencies above 1.3 Hz, which are associated with high breathing rates in infants above 78 breaths per minute. As such the patient population was limited to an Adult through Pediatric population, excluding neonates and infants. Unlike Suzanne, Sandman Pocket has a wider airflow bandpass filter of 0.015 to 10 Hz to accommodate the wide breathing rate range of 6 to 90 breaths per minute, which is sufficient for both high and low breathing rates in sleep studies across the entire adult and pediatric patient population, including the neonate and infant subpopulation.

The limitations of the Suzanne bandpass filter and the suitability of the Sandman Pocket bandpass filter is best understood by discussing the average, upper and lower breaths per minute and frequencies ranges associated with adult, infant and neonatal populations. Neonates and infants breathe faster than adolescents and adults. See Table 1 for normal breathing rates according to patient population:

Table 1 Normal Breathing Rates by Patient Population[4]

Patient Population	Rate in breaths per minute	Frequency Range in Hz
Neonates	(b)(4)	
Infants		
Preschoolers		
Adolescents		
Adults		

(b)(4)

-

[4] Data from Family practice notebook.com. Online accessed 18 May 2006, URL http://www.fpnotebook.com/LUN55.htm
[5] Gagliardi, Luigi, Franca Rusconi and the working party on respiratory rate. "Respiratory rate and body mass in the first three years of life." Archives of Disease in Childhood 76 (1997): 151 – 154.
Also available for download at http://adc.bmjjournals.com/cgi/content/full/76/2/151

Hardware Functional Testing:

This testing verified the electrical function of and supply to the headboxes and recorder, the digital characterization of the data recorder, the communication between modules and system components, the frequency response, the filtering, and the battery function. The test reports that demonstrate the compliance of *Sandman Pocket* to the design specifications are part of the Design History File maintained by EBNeuro.

Hardware Safety and Environmental Testing:

The *Sandman Pocket* complies with the following standards: IEC 60601-1 (CSA C22.2 No 601-1-M90 / UL 2601) for electrical and mechanical safety and IEC 60601-1-2 for electromagnetic compatibility.

The primary test report demonstrating the compliance of *Sandman Pocket* to the above standards was performed by an external accredited CB organization, and these test reports are part of the Design History File maintained by EBNeuro.

BN Euro

Report Interno

Titolo : **SW Traceability Analisys**			Cod : **0065_TA** Rev: **A** pag **1 / 3**
Compilato:E. Carnati	Controllato:P. Giovagnola	Approvato:V. Roma	Data: 02-05-06

(b)(4)

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(b)(4) Traceability Analysis

(b)(4) Traceability Analysis

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DECLARATION OF CONFORMITY

I certify that, in my capacity as Managing Director of EB Neuro, S.p.A., the Sandman Pocket has been tested and complies with the following recognized standards:

CSA Standards:	
CAN/CSA-C22.2 No. 0-M91	General Requirements Canadian Electrical Code, Part II.
CAN/CSA-C22.2 No. 601.1-M90	Medical Electrical Equipment Part 1: General Requirements for Safety.
CAN/CSA-C22.2 No. 601.1S1-94	Supplement No. 1-94 to CAN/CSA-C22.2 No. 601.1-M90 - Medical Electrical Equipment Part 1: General Requirements for Safety.
CAN/CSA-C22.2 No. 601.1-B98 Am.2	Amendment 2:1998 to CAN/CSA-C22.2 No. 601.1-M90 - Medical Electrical Equipment Part 1: General Requirements for Safety.
CAN/CSA-C22.2 No. 601-2-26-98	Medical Electrical Equipment Part 2: Particular requirements for the safety of Electroencephalographs.
IEC Standards:	
IEC 601-1:1988 IEC 60601-1 Amendment No. 1:1991 IEC 60601-1 Amendment No. 2:1995	Medical Electrical Equipment - Part 1: General Requirements for Safety. Amendment 1 to 60601-1:1988. Amendment 2 to 60601-1:1988.
IEC 60601-1-1:2000	Medical Electrical Equipment Part 1-1: General Requirements for Safety. Collateral standard: Safety Requirements for Medical Electrical Systems.
IEC 60601-2-26:2002 (2nd Edition)	Medical Electrical Equipment Part 2: Particular requirements for the safety of Electroencephalographs.
IEC 60601-1-2:2001 (2nd Edition)	Requirements for safety Collateral standard: Electromagnetic compatibility Requirements and tests
IEC 60601-1-4:1999+A1:2001	Medical Electrical Equipment Part 1-4: General Requirements for Safety. Collateral standard: Programmable electrical medical systems
UL Standards:	
UL Std No. 60601-1 (1st Edition)	Safety of Medical Electrical Equipment, Part 1: General Requirements for Safety.
ISO Standards:	
ISO 9915:2005 (2nd Edition)	Medical Electrical Equipment: Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.

EN Standards:

EN 55011:1998 Class B	Industrial, scientific and medical (ISM) radio-frequency equipment. Radio disturbance characteristics. Limits and methids of measurement.
EN 55011 Amendment No. 1:1999	Amendment 1 to EN550011:1998
EN 55011 Amendment No. 2:2002	Amendment 2 to EN550011:1998
EN 55014-1:2000	Electromagnetic Compatibility. Part 1 : Emission Production family standard.
EN 55014-1 Amendment No. 1:2001	Amendment 1 to EN 55014-1:2000
EN 55014-1 Amendment No. 2:2002	Amendment 2 to EN 55014-1:2000
EN 61000-3-2:2000	Electromagnetic Compatibility (EMC) Part 3 Section 2 - Limits for Harmonic Current Emissions.
EN 61000-3-3:1995	Electromagnetic Compatibility (EMC) Part 3 Section 3 - Limitation of Voltage Fluctuactions and Flicker.
EN 61000-3-3 Amendment No. 1:2001	Amendment 1 to EN 61000-3-3:1995
EN 61000-4-2:1995	Electromagnetic Compatibility (EMC) Part 4 Section 2 -Electrostatic Discharge Immunity.
EN 61000-4-2 Amendment No 1:1998	Amendment 1 to EN 61000-4-2:1995
EN 61000-4-2 Amendment No 2:2001	Amendment 1 to EN 61000-4-2:1995
EN 61000-4-3:1996	Electromagnetic Compatibility (EMC) Part 4 Section 3 - Radiated, Radiofrequency Electromagnetic Field Immunity.
EN 61000-4-3 Amendment No. 1:1998	Amendment 1 to EN 61000-4-3:1996
EN 61000-4-3 Amendment No. 2:2001	Amendment 2 to EN 61000-4-3:1996
EN 61000-4-4:1995	Electromagnetic Compatibility (EMC) Part 4 Section 4 - Electrical Fast Transient/Burst Immunity.
EN 61000-4-4 Amendment No. 1:2001	Amendment 1 to EN 61000-4-4:1995
EN 61000-4-4 Amendment No. 2:2001	Amendment 2 to EN 61000-4-4:1995
EN 61000-4-5:1995	Electromagnetic Compatibility (EMC) Part 4 Section 5 - Surge Immunity..
EN 61000-4-5 Amendment No. 1:2001	Amendment 1 to EN 61000-4-5:1995
EN 61000-4-6:1996	Electromagnetic Compatibility (EMC) Part 4 Section 6 - Immunity to Conducted Disturbances introduces by Radio-frequency fields.
EN 61000-4-6 Amendment No. 1:2001	Amendment 1 to EN 61000-4-6:1996
EN 61000-4-8:1993	Electromagnetic Compatibility (EMC) Part 4 Section 8 - Power Frequency Magnetic Field Immunity.
EN 61000-4-8 Amendment No. 1:2001	Amendment 1 to EN 61000-4-8:1993
EN 61000-4-11:1994	Electromagnetic Compatibility (EMC) Part 4 Section 11 - Voltage Dips. Short Interruptions and Voltage Variation Immunity.
EN 61000-4-11 Amendment No. 1:2001	Amendment 1 to EN 61000-4-11:1994

The present Manufacturer's Declaration of Conformity is based on CB-scheme Test Reports (ref. Test Report number 27SG00137 and 80SG00210) issued by IMQ body (3rd party IECEE-international board accredited testing laboratory/certification body). The conformity to the listed standard is also certified by the cCSAus Certificate of Compliance (ref. certificate n 1807305) issued by CSA certification body .

Signature

Ing. A. Torsoli - Managing Director
EB Neuro S.p.A.

July 7, 2006
Date

Software Information

1 Introduction

The information in this section is given in accordance with the "***Guidance for the Content of Premarket Submissions for Software contained in Medical Devices***". issued by FDA on May 11, 2005. In the rest of this section this guidance will be referred to as "Software Guidance"

1.1 Terminology

DAM – Digital Acquisition Module (also called the Recorder Unit)
ARM – Analog Reconfigurable Module (also called the Yoke, Amplifier, or Headbox)

1.2 Software Version

The software contained in the Sandman Pocket is version number 1.00. There have been no previous versions of this software. The software code is: B8630103100. The software release date is: May 2, 2006.

2 Level of Concern

The Sandman Pocket amplifier has been assessed to carry a **Minor Level of Concern**. This decision has been made using the tables available in the Software Guidance. **However, Ms. Ann Graham at FDA has stated that this device is of Moderate Level of Concern due to the QRS algorithm. Therefore, the appropriate documentation for a Moderate Level of Concern has been provided.**
The term "Software Device" refers to the embedded Sandman Pocket firmware.

Table 1 Major Level of Concern - If the answer to any one question below is Yes, the Level of Concern for the Software Device is likely to be Major.

1_1. Does the Software Device qualify as Blood Establishment Computer Software?
NO – The Sandman Pocket is not a Blood Establishment Computer Software.

1_2. Is the Software Device intended to be used in combination with a drug or biologic?
NO - The Sandman Pocket is not intended to be used in combination with drugs or biologics.

1_3. Is the Software Device an accessory to a medical device that has a Major Level of Concern?
NO - The Sandman Pocket is not intended to be used as an accessory of a Medical Device carrying a Major Level of Concern

1_4. Prior to mitigation of hazards, could a failure of the Software Device result in death or serious injury, either to a patient or to a user of the device?
NO, in the event of a software failure, the acquisition may be abnormally interrupted or the data recorded and/or transferred to the host computer may be corrupted and consequently not usable. In the event of corrupted data, the host computer software and clinical judgment would be exercised to override the information provided by the amplifier.
The monitored data is not intended to alarm or trigger alarm for any conditions.

Examples of this include the following:

a. Does the Software Device control a life supporting or life sustaining function?
NO, the software embedded on the SANDMAN POCKET system is only used to collect physiological data, record them on an on-board memory, and to transfer the recorded data to a host computer through a standard USB interface.

b. Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators?

NO, the software controls no delivery of energy at all.

c. Does the Software Device control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury?

NO, the software embedded on the SANDMAN POCKET system is only used to collect physiological data, store them on an on-board memory, and to transfer the acquired data to a host computer, in real time, during the acquisition or in a successive time, reading back the on-board memory. The software does not interpret the acquired data in any way, nor does the software assign any "*diagnostic meaning*" to particular signals.

d. Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death?

NO, the software embedded on the SANDMAN POCKET system is only used to collect physiological data, store them on an on-board memory, and to transfer the acquired data to a host computer, in real time, during the acquisition or in a successive time, reading back the on-board memory. The software does not interpret the acquired data in any way, nor does the software assign any "*diagnostic meaning*" to particular signals.

e. Does the Software Device provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary?

NO, the SANDMAN POCKET is simply a "recording device", the embedded software is only used to collect physiological data, store them on an on-board memory, and to transfer the acquired data to a host computer, in real time, during the acquisition or, more typically, in a successive time, reading back the on-board memory. The software does not provide any alarm mechanism based on the acquired data, nor does it "control" in any way vital parameters. Any eventual real time elaboration performed on the acquired signals by the host computer is outside the scope of the recorder and is the responsibility of the "medical system" of which the SANDMAN POCKET is only one part.

Table 2 Moderate Level of Concern - If the Software Device is not Major Level of Concern and the answer to any one question below is Yes, the Level of Concern is likely to be Moderate.

2_1. Is the Software Device an accessory to a medical device that has a Moderate Level of Concern?

NO - The Sandman Pocket is not intended to be used as an accessory of a Medical Device carrying a Moderate Level of Concern.

2_2. Prior to mitigation of hazards, could a failure of the Software Device result in Minor Injury, either to a patient or to a user of the device?

NO, in the event of a software failure, the acquisition may be abnormally interrupted or the data recorded and transferred to the host computer may be corrupted and consequently unusable. In the event of corrupted data, the host computer software and clinical judgment would be exercised to override the information provided by the recorder.
The monitored data is not intended to alarm or trigger alarm for any conditions.

2_3. Could a malfunction of, or a latent design flaw in, the Software Device lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury?

NO, for the same reason as stated in the question above.

If the answers to all of the questions in Tables 1 and 2 above are No, the Level of Concern is Minor.

CONCLUSION

The Sandman Pocket software carries a **Minor Level of Concern. However, Ms. Ann Graham at FDA has stated that this device is of Moderate Level of Concern due to the QRS algorithm. Therefore, the appropriate documentation for a Moderate Level of Concern has been provided.**

3 Software Description / Requirement

The functional software embedded in the acquisition system (later on referred to as "firmware") is distributed on each of the two functional modules constituting the system:

1) Digital Acquisition Unit (DAM)
2) Amplifier box (Yoke/ARM)

Digital Acquisition Module
This is the main module of the device. It communicates with the amplifier unit via an asynchronous serial link and with the host PC via a USB connection. It can acquire data under the direct contol of the host PC (attended mode) or store them in the internal memory at the preprogrammed time.

Amplifier box (Yoke/ARM)
This module hosts the amplifier chains and the Analog to Digital converters, and communicates with the digital module via a RS485 serial link.

DAM hosts a programmable DSP, and Yoke hosts a programmable microcontroller. Both modules run a firmware stored in the on-board Flash EEPROM. Once programmed in the factory, the firmware can be upgraded in both modules via the USB link. Details of the communication protocol between DAM and host PC can be found in the document B86100103100_W1.

3.1.1 Device Features Controlled by Software.

3.1.1.1 Acquisition System Recognition.

DAM is connected via a standard USB link to the host PC, and performs device identification and enumeration according to the specifications of USB_2.0 (or USB_1.1, if the host PC supports only this standard).

3.1.1.2 Host PC – DAM communication interface

DAM is a slave of the host PC: commands are actually issued only from the host PC to DAM. The communication protocols require 4 USB pipes:

- A bulk OUT pipe to send command from PC to DAM
- A bulk IN pipe to transport back parameters from DMM to PC
- A Bulk IN pipe to transport acquired data from DAM to the PC.
- An interrupt pipe to notify the presence of acquired data to host PC.

Low level data transport, including packet handshaking and data integrity is performed by the USB interface.
The use of different pipes for data transefer and command handshaking make it possible to issue commands and acquire status information without stopping the data flow.

3.1.1.3 Sampled Data Collection.

Sampled data returned from the Yoke are downsampled to the rate required by the host PC, stored internally in a large buffer and sent to the host PC via the appropriate IN pipe. If selected, data can be stored also in the internal Mass storage memory and downloaded at the end of the recording.

No data compression is performed on such data samples: they are 2's complement 16 bit data.

3.1.1.4 DAM unit - Amplifiers box interfacing.

The communication interface between the two units is a bidirectional, RS-485 asynchronous serial link. The forward direction (from DAM to Amplifier box) is used to issue simple commands and to ask for device information and status parameters; the reverse direction (from Amplifier box to DAM) is used to transfer the data acquired by the sampling logic and to return the parameters requested by DAM.

3.1.1.5 Acquisition programming.

Data acquisition can be programmed by the host PC: enabled channels, sampling rates, coupling and other parameters can be modified according by the user. The device can store up to seven different presets at the same time in the internal memory.
Multirate sampling (different sampling rates for different channels) is supported. Data are transferred on a "per packet " basis: data are transferred at the minimum samplig rate and each packet contains all (and only) the data sampled during that timeslice. The unit performs a digital downsampling to assure the appropriate bandwidth for each channel.

3.1.2 Other Features Controlled by Software.

3.1.2.1 Acquisition control.

The system acquires signals whose analysis is performed by an application running on the host PC: the unit's firmware is not capable of interpreting or classifying the acquired data. It only calculates the Pulse Transit Time (PTT) measurement as the time elapsed between two specific events in the EKG and oxymetry signals. Specifically, the PTT calculation is derived using proven, widely recognized algorithms that calculate the time difference between R-wave of the QRS complex of the ECG signal (the most prominent part of the ECG waveform) and 50% of the ascending edge of the Pressure wave, as measured by a pulse oximeter. If required, the unit is also capable of measuring the impedance of the electrodes and leads used for data acquisition. Impedance values are either stored in the internal memory (unattended recording) or sent to the host PC if requested by a specific command.

3.1.2.2 LCD user interface.

On DAM module, there is a graphical LCD display of 128x128 pixels, together with a 5 positions control pad. The graphic interface is capable to display status informations and to select a simple subset of features:

- System selftest
- Acquisition mode and status information (available memory, battery status, time and data display.
- Impedance evaluation
- Alerts
- Generic text and graphic printout under the control of the host pc.

3.1.3 External device interfacing.

DAM is equipped with two standard RS-232 channels: one is used to communicate via the embedded oximeter board (Nellcor Puritan Bennet Nell-1 oximeter); the other is available for communication with any external serial devices. The communication with this device is under the control of the host PC. The unit is, however, capable to communicating with a GK425 device to retrieve the status parameters.

3.1.4 Software Limitations, Customization and Update.

This acquisition system is not intended to perform vital signs monitoring: therefore its firmware performs NO analysis of the signals and provides NO alarms of clinical relevance.

The resident firmware code, allocated into a Flash EEPROM, can be updated via the control software without opening the device's case.

Serial number, device identification data, and samples adjusting factors are stored in a dedicated Flas EEPROM section and are not erased by the firmware upgrade

4 Software Architecture.

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4.2 Software Flowchart.

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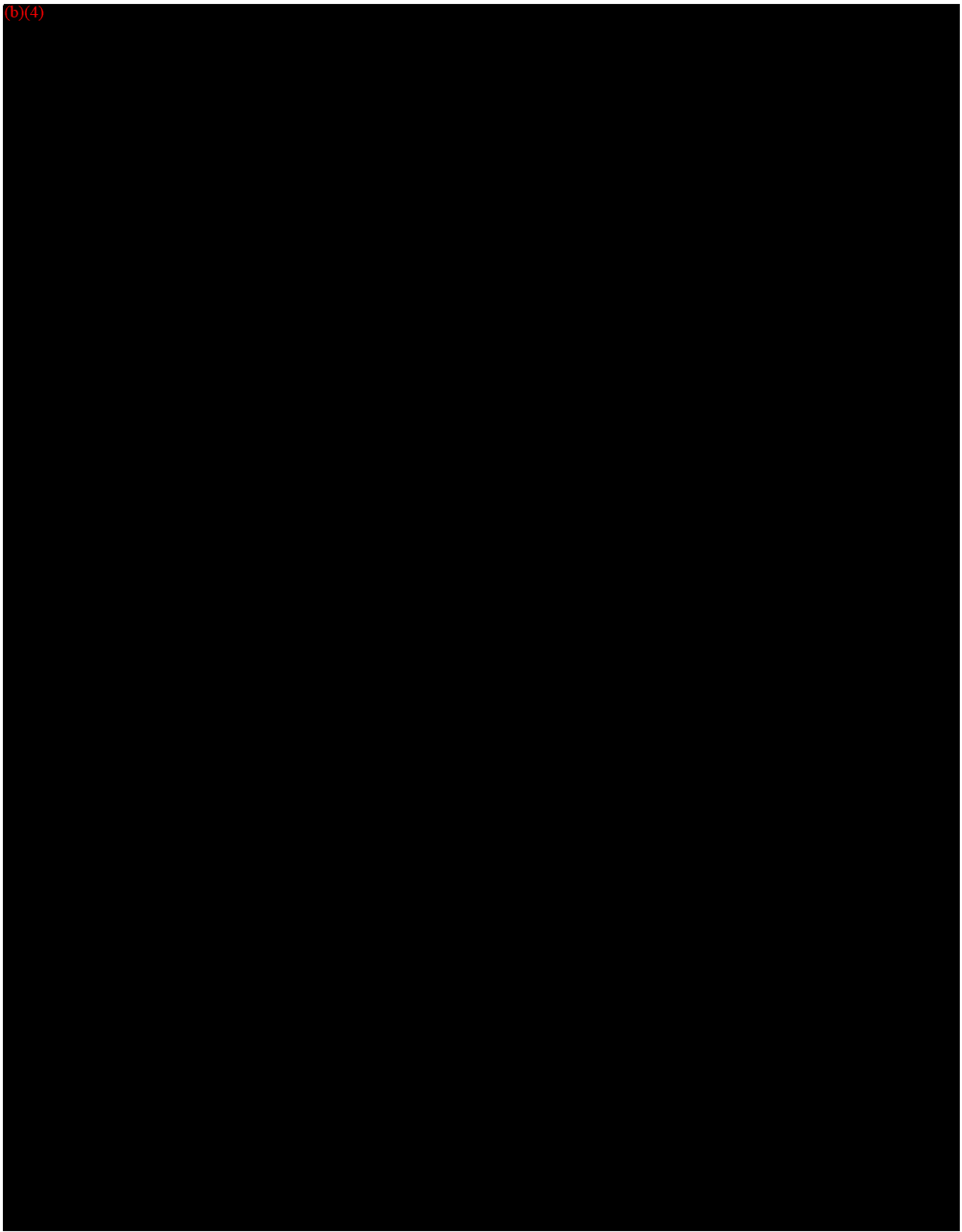

4.2.2 ARM

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5 Software Hazard Analysis

Hazard analysis related to the software is included in the Risk Analysis section of this submission.

6 Software Development Environment.

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1 Introduction

1.1 Purpose

This document identifies the hazards related to the use of the SANDMAN POCKET system and demonstrates the means used to control those hazards.
The document summarizes the content of the original EBNeuro documents "Risk Analysis" developed following the EBNeuro Quality Procedures and originally written in Italian.

1.2 Risk Analysis Method

The hazards are identified within different groups (electrical hazards, software depending hazards,...). For each hazard, the risk is assessed by using the method described hereafter, following the method suggested by ISO 14971.

Severity

This quantifies the consequence that could result from the occurrence of the hazard

1 – Negligible : hazard has small or no potential to cause an injury.
2 – Marginal : hazard has potential to cause an injury.
3 – Critic : hazard has potential to cause a death or a serious injury.
4 – Catastrophic : hazard has potential to cause multiple deaths or serious injuries

Occurrence

This quantifies the probability for such a hazard to occur. It is estimated considering the intended use of the devices

1 – Incredible
2 – Unlikely
3 – Rare
4 – Occasional
5 – Likely
6 – Frequent

Level of Risk

This is the association of the severity and the occurrence. There are three defined "zones" of risk: Intolerable, ALARP, Widely acceptable

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- **Intolerable (I) :** The risk is intolerable. Methods must be adopted to reduce the severity of the risk and/or its frequency of occurrence.
- **ALARP (L) :** As Low As Reasonably Possible region. Risk is tolerable only if the risk management cost (to further reduce the risk) is too high in comparison to the benefits.
- **Widely accepted (A) :** the risk is acceptable.

1.3 Risk Management

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2 Intended Use

The Sandman Pocket is intended for use in collecting and recording physiological data to be used in polysomnography and sleep disorder studies. This device may be used in the home or hospital setting. The Sandman Pocket is not intended for use as a life supporting equipment, such as a vital sign monitor in an intensive care unit. The device does not produce alarms and is not intended as an automated opera monitor.

The SANDMAN POCKET is an amplifier system that amplifies bioelectric signal captured through appropriate sensors attached to the surface of the human body, converts those signal in digital form and stores them on an on board memory. No compression mechanism is used. The recorded data can be passed to a host system through an USB standard connection. The device does not modify the signal with the obvious exception of its "analog" conditioning and the conversion in numeric form.

Target Population: The EBNeuro Sandman Pocket Amplifier is intended to be used on both the adult and pediatric populations, without exclusion of any pediatric subgroups (Neonatal, Infant, Child, Adolescent; ref. to *FDA Guidance for Industry and FDA Staff – Premarket Assessment of Pediatric Medical Devices*). EBNeuro design and technical specifications (input signal characteristics, sampling rates, etc) of the device have been developed in accordance to this assertion.

The Sandman Pocket is only for use under the direction or supervision of a physician, technologist or clinician.

3 General Hazard Analysis

The device carries a Minor Level of Concern: this assumption is based on the following factors:

- The possible risk or danger to the patient or user from use of the device.

  There is no risk of injury to the patient or operator due to the use of this device. It is powered by 3 internal 1,5 Volts, AA size dry cell batteries. The device is fully compliant with the requirements of the normative IEC 601-1 / IEC 601-1-1 (medical devices safety) and IEC 601-1-2:2003 (Edit. 2) (EMC)

- The degree to which the device can influence therapy or patient diagnosis.

  The device does not control, either directly or indirectly, any therapy administration. It does not monitor the status of critical physiologic parameters and has no alarming mechanism for this purpose. The device does not provide any patient diagnosis.

  The EBNeuro Sandman Pocket is only to be used under the direction and/or supervision of a physician, technologist or clinician. It does not perform any life supporting or life sustaining fuction.

  The device does not produce alarms and is not intended as an automated apnea monitor.

In conclusion, the SANDMAN POCKET system is a non invasive data-collecting device that poses no risk to the patient or to the operator.
The device is intended to collect and record on internal memory patient data collected using surface electrodes. The collected data can be later passed to a host system for its own purposes. The analysis performed by a clinician using the review and analysis software on the host system is outside of the scope of the SANDMAN POCKET system, whose role is to accurately and reliably acquire and store the mentioned data.

NOTE 1

The risk analysis has been conducted taking into account the devices intended use and in particular the following points:

a) The EBNeuro Sandman Pocket is not intended for the "end user", rather it is intended as an OEM product to be used by a "System Builder" as a piece of its own Medical Systems. It is the responsibility of the System Builder to use the EBNeuro Sandman Pocket Recorder strictly following any technical specification and precaution of use described in the Sandman Pocket OEM User Manual provided by EBNeuro.
b) EBNeuro is not providing any sensor, lead, cable, or any wearing system to the System Builder.
c) The Sandman Pocket, as manufactured by EBNeuro, is intended to be used both in adult and pediatric populations without exclusion of any pediatric subgroups (ie Neonatal, Infant, Child, Adolescent; ref. to *FDA Guidance for Industry and FDA Staff – Premarket Assessment of Pediatric Medical Devices*). EBNeuro design and technical specifications (input signal characteristics, sampling rates etc) of the device have been developed in

accordance with this assertion.
Due to the fact that EBNeuro is not providing any sensor, lead, cable, or any wearing system, it is completely under the responsibility of the System Builder to address any safety and effectiveness questions linked to the entire medical system he is "manufacturing"; in other words, the System Builder should conduct any risk management activities linked to the overall intended use and target population of its own medical system (for example, the risk linked to the accessories, any eventual wearing system and any related instruction and warnings against the correct connections and units/cable placement to avoid any possible strangulation risk). This applies in particular to the use of Sandman Pocked based system in pediatric studies.

The situation described in the above points is clearly stated in the Sandman Pocket labeling (EBNeuro Sandman Pocket OEM User Manual).

NOTE 2

The following risks have been evaluated and have been established as "not applicable" to the Sandman Pocket:

- Substances delivered/extracted from the patient.
- Biological material processed.
- Sterility (no applied part provided with Sandman Pocket).
- Modify the patient environment.
- Mechanical forces.

4 Electrical, Mechanical, Thermal and Environmental Hazard Analysis

The device fully conforms to the requirements of the IEC 601-1, IEC 601-1-1 and IEC 601-1-2:2003, so the hazard related to electrical safety aspect and environmental aspect (EMC) are briefly treated in this document due to the fact that the risk management is covered by the requirements of the mentioned normative. However, electrical safety risks will be listed in the summary table in the last section of this document (see section 5).
Only some hazards of these categories are briefly discussed below, for the others hazards (whose management is "covered" by the IEC 60601-1 or IEC 60601-1-2 conformance) refer directly to the summary table.

Hazard (B1- B2)

Electrical shock when using the device

Management

Device fully complies with IEC 60601-1- standards. (class II - BF type)

Hazard (B3)

Electrical shock when powering the unit through the host computer USB port

Management

Labeling clearly warns about this situation by imposing the use of an isolation transformer to feed the host computer.
However, if this precaution should be missed and the host computer meets EN 60950 Information Technology standards, the power feeding the Sandman Pocket is considered a "safe low voltage" so the probability to cause injuries may be considered at the limit of the "incredible" threshold.

Hazard (B4)

Battery inserted in the wrong way

Management

Power circuit designed in a way to be protected from the battery inversion. The device in this condition simply does not work. Any damage to the battery or to the device is avoided.

Hazard (D3)

Susceptibility in operating, transport or storage environment to temperature and humidity

Management

Device complies with IEC 60601-1 recommended temperature and humidity range both operating and storage (non-operating).

Labeling clearly indicates such limits.

Hazard (D4)

Use in presence of flammable anesthetic or oxygen enhanced environment.

Management

User Manual clearly warns about these situations and states not to use the unit in such environments.
If this restriction is not observed, the risk of fire is improbable because of the technology used in the Pocket. For examle, the Pocket is battery powered, very low power supply, and circuit or assembly that may cause ignition.

Hazard (A1 – A2)

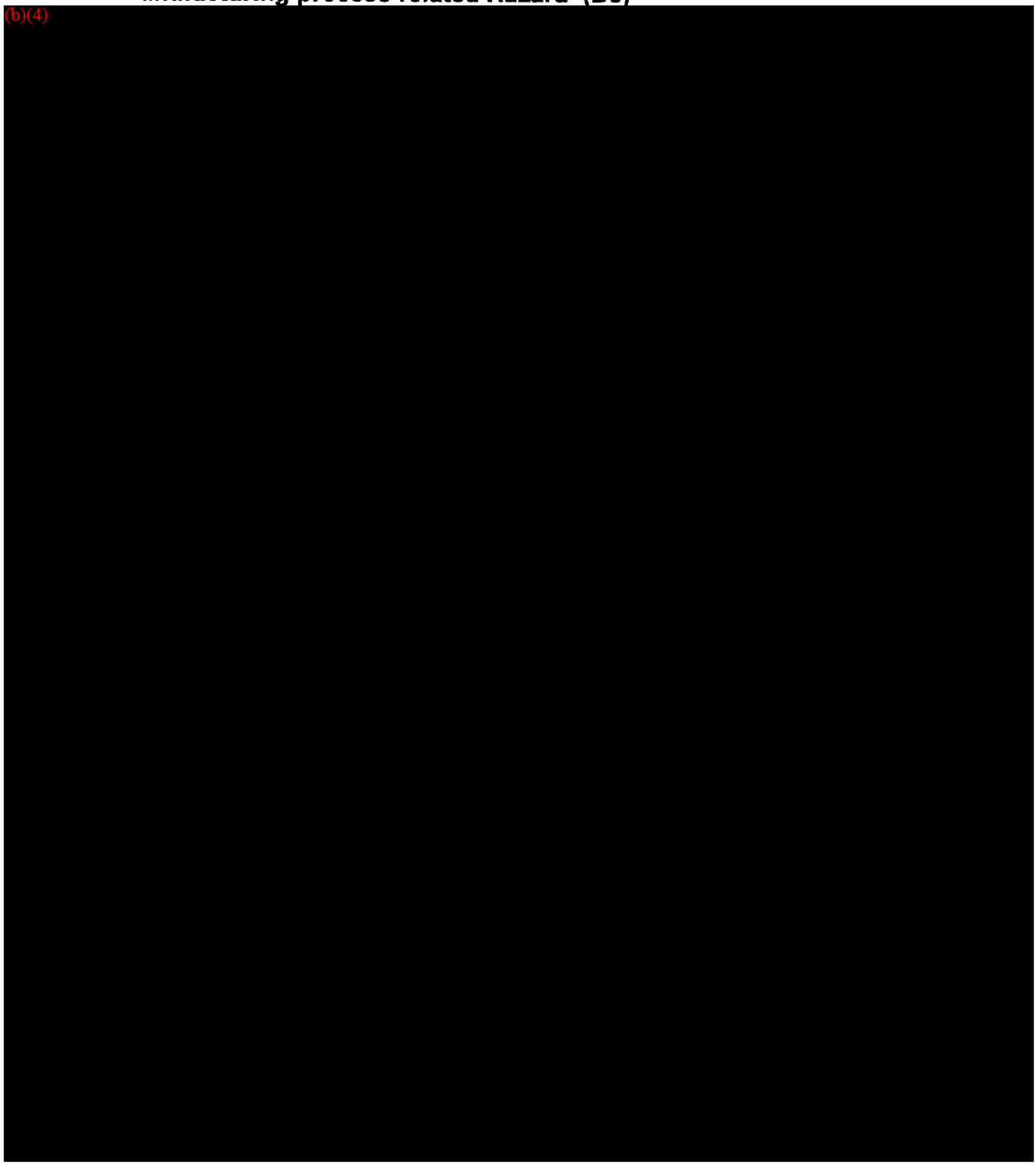
Biocompatibility.

Management

No part of the Sandman Pocket is specified to be in direct and continuous contact with the patient body. However, the Sandman Pocket enclosure is made of non-toxic material (Polycarbonate). The Sandman Pocket recorder is provided without any applied parts (electrodes, sensors etc). EBNeuro only specifies that any accessory of the device should conform to FDA requirements for North America and European Directive 93/42/EEC for Europe. It is the responsibility of the system builder to conform to these requirements. Labeling (chapter 8) gives instructions and warnings related to the use of batteries (new or discharged) and the use of the Pocket in the event of a broken LCD display, which contains material that may irritate in the skin.

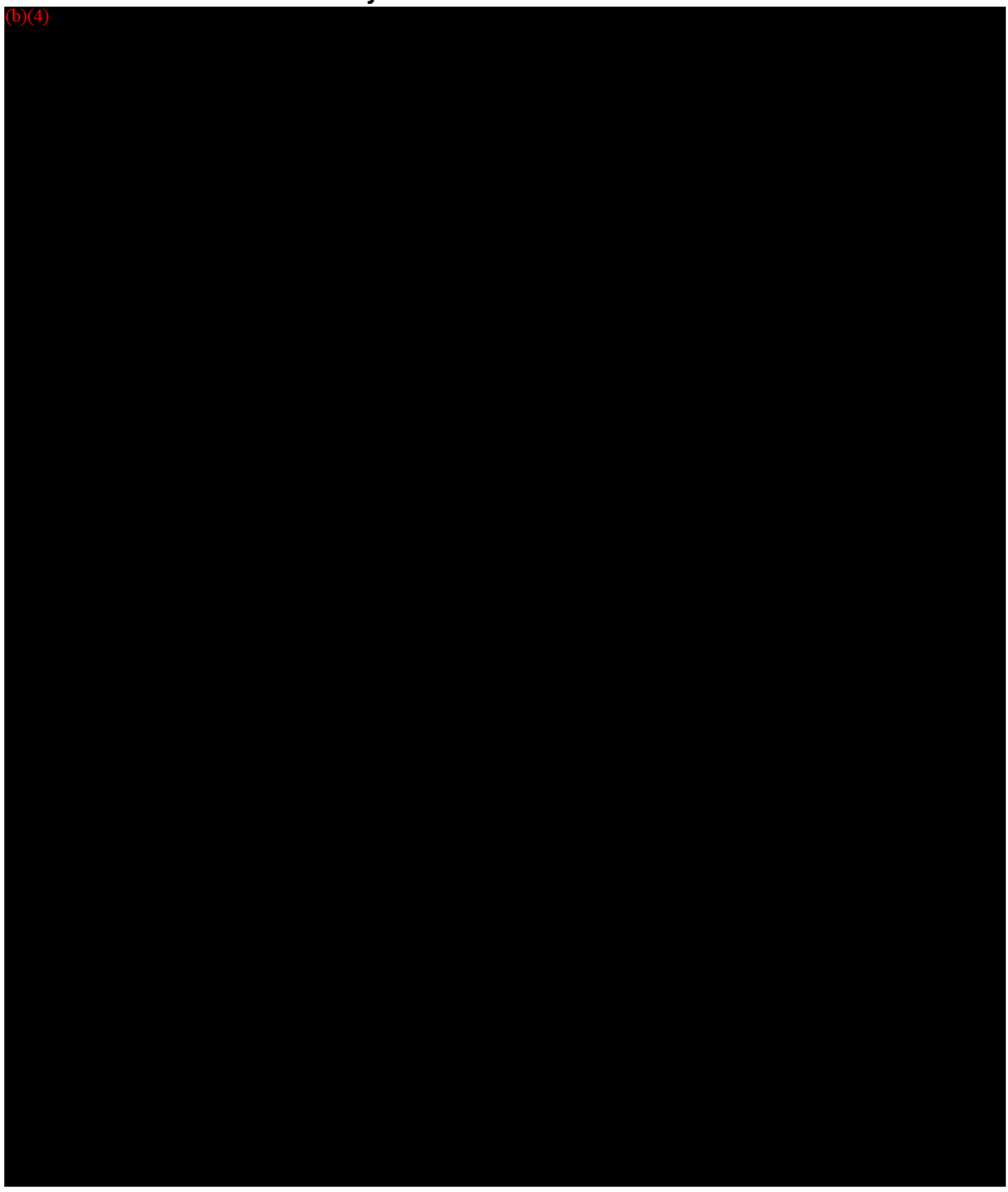
5 Manufacturing process related Hazard (D5)

(b)(4)

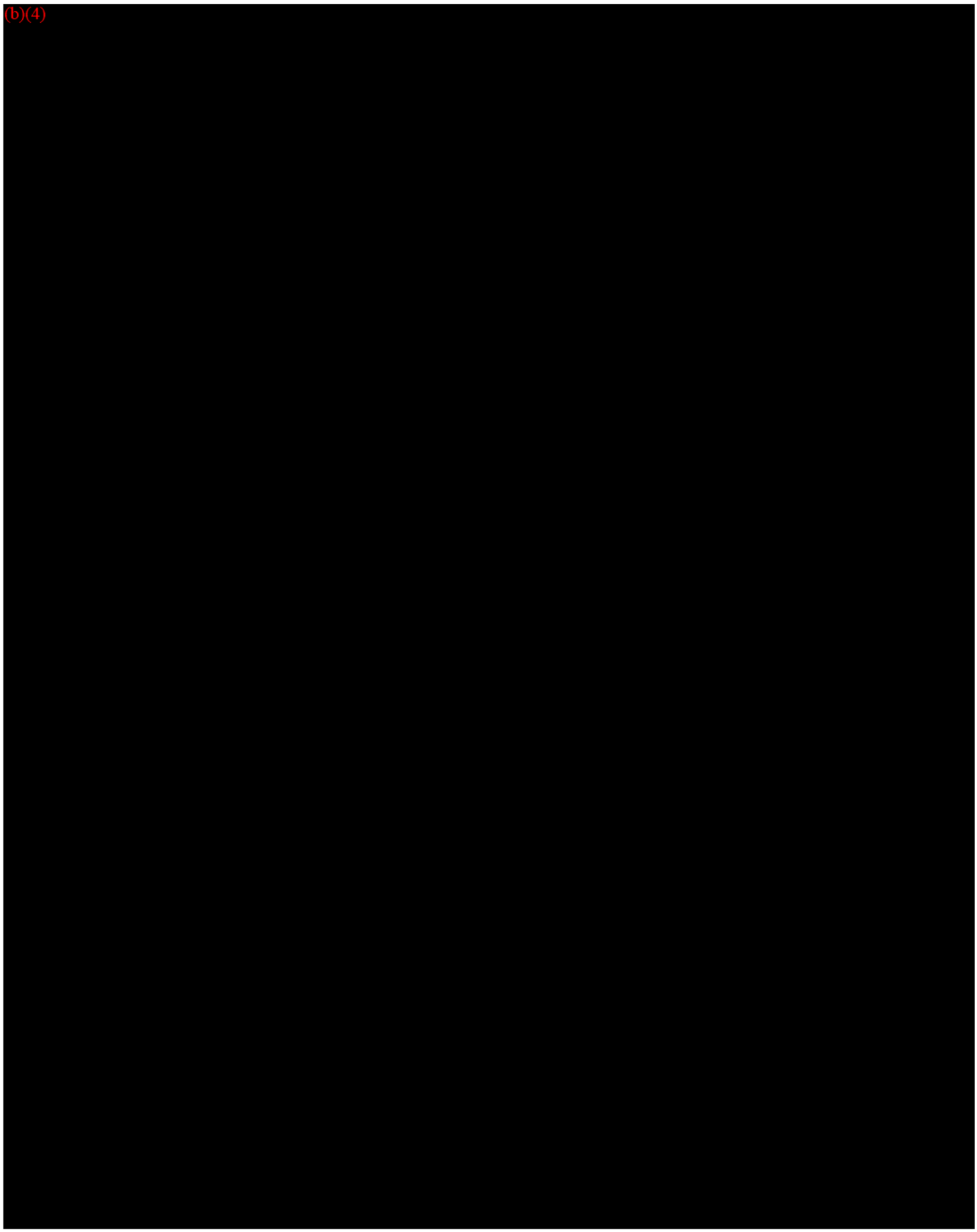


8 Software Hazard Analysis

(b)(4)



(b)(4)



(b)(4)

[redacted]

CONCLUSION

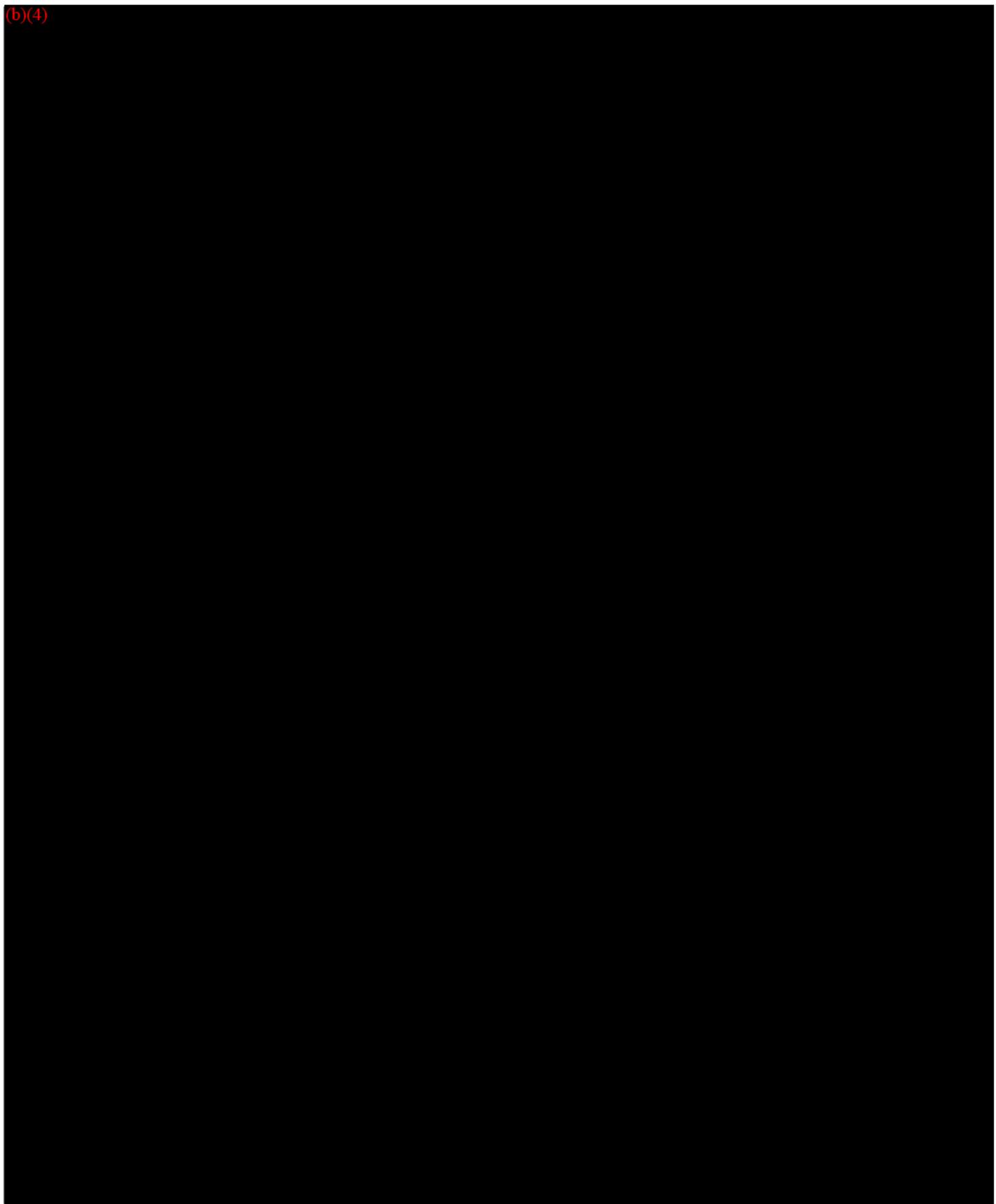
The Sandman Pocket carries a **Minor Level of Concern.**

8.1 Internal channels sampling.

(b)(4)

[redacted]

(b)(4)



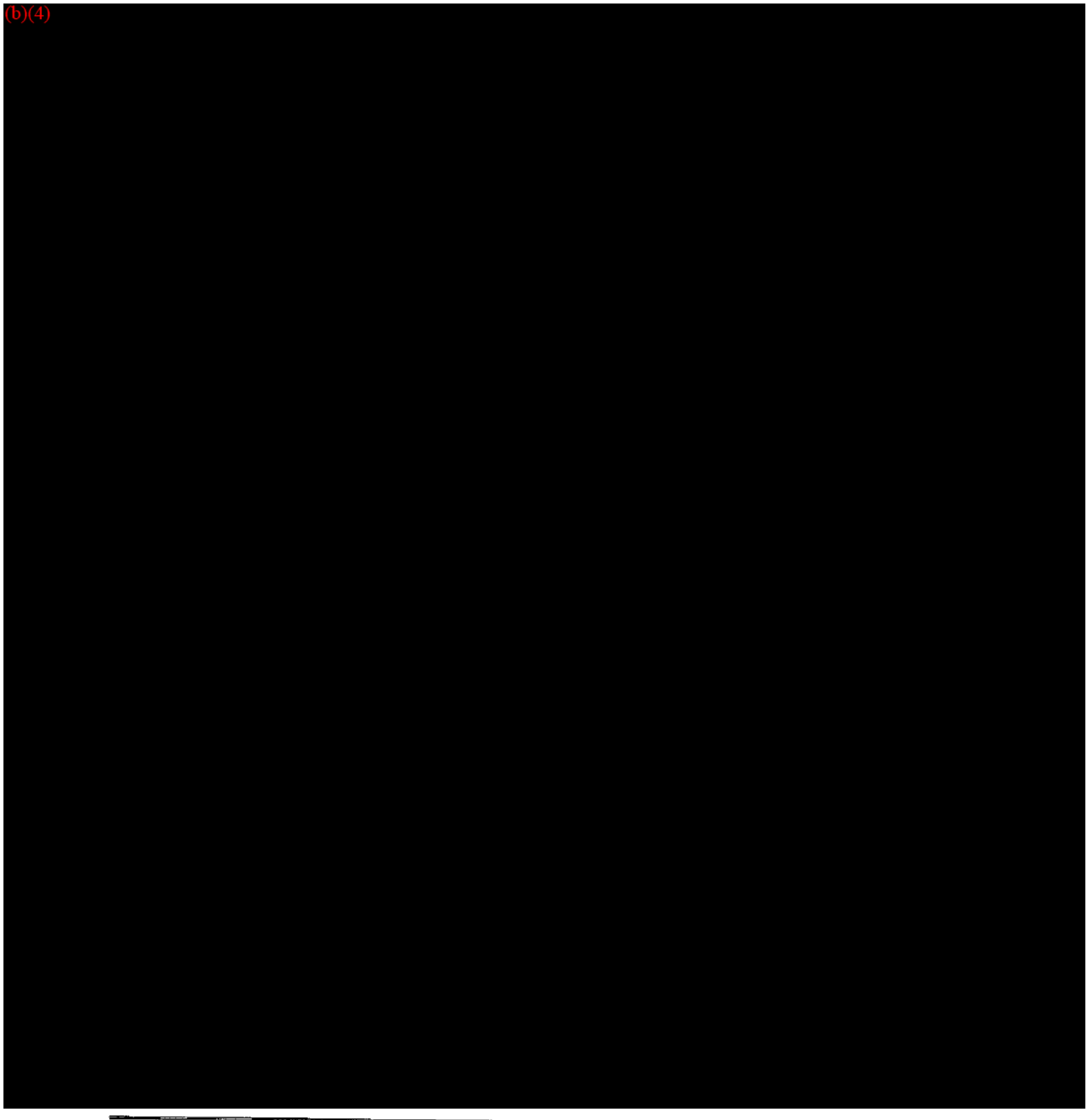
(b)(4)

Hazard (E4)

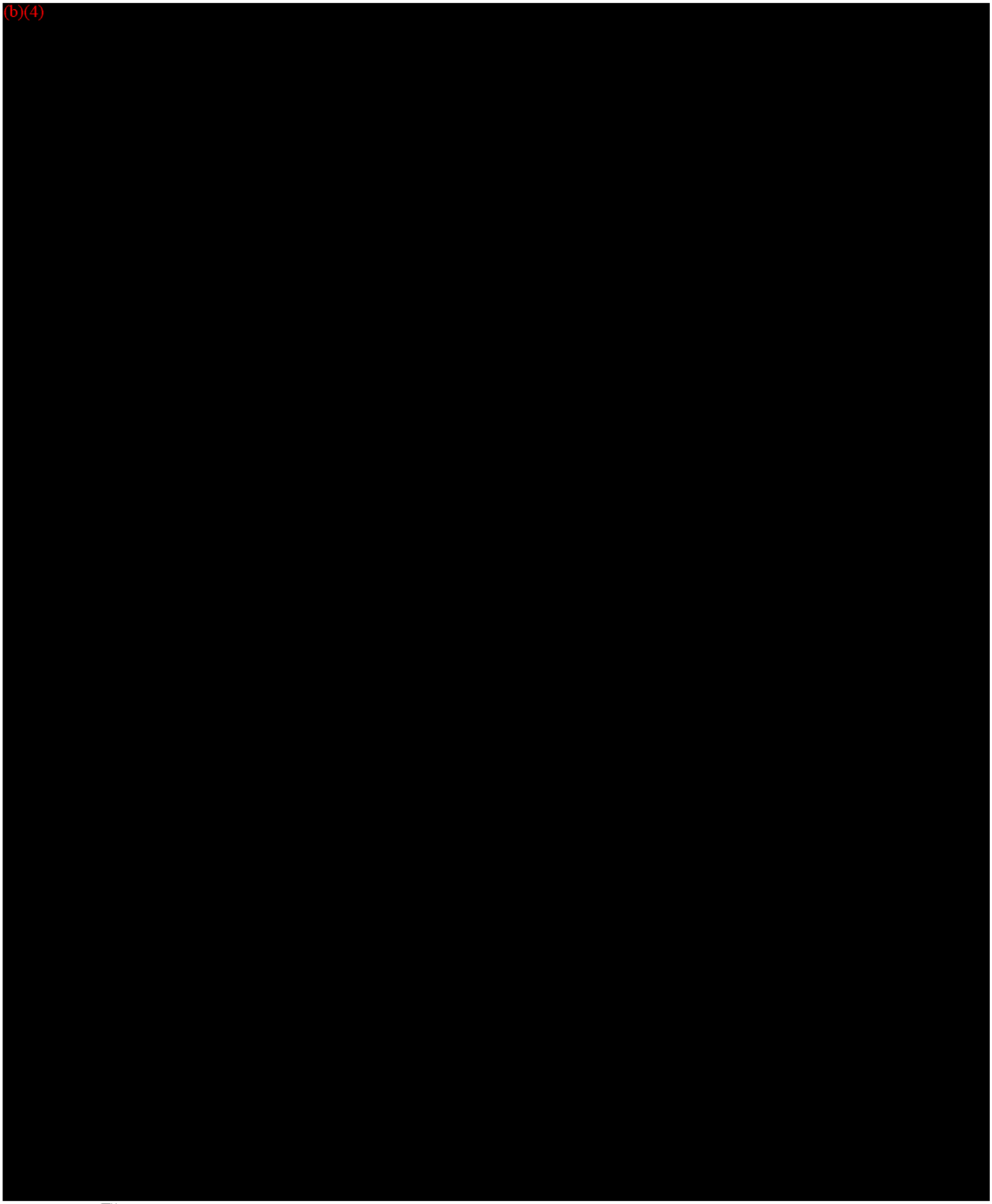
PTT calculation error/failure
The calculation of the Pulse Transit Time gives erroneous result or does not produce any output.

Management

(b)(4)



(b)(4)



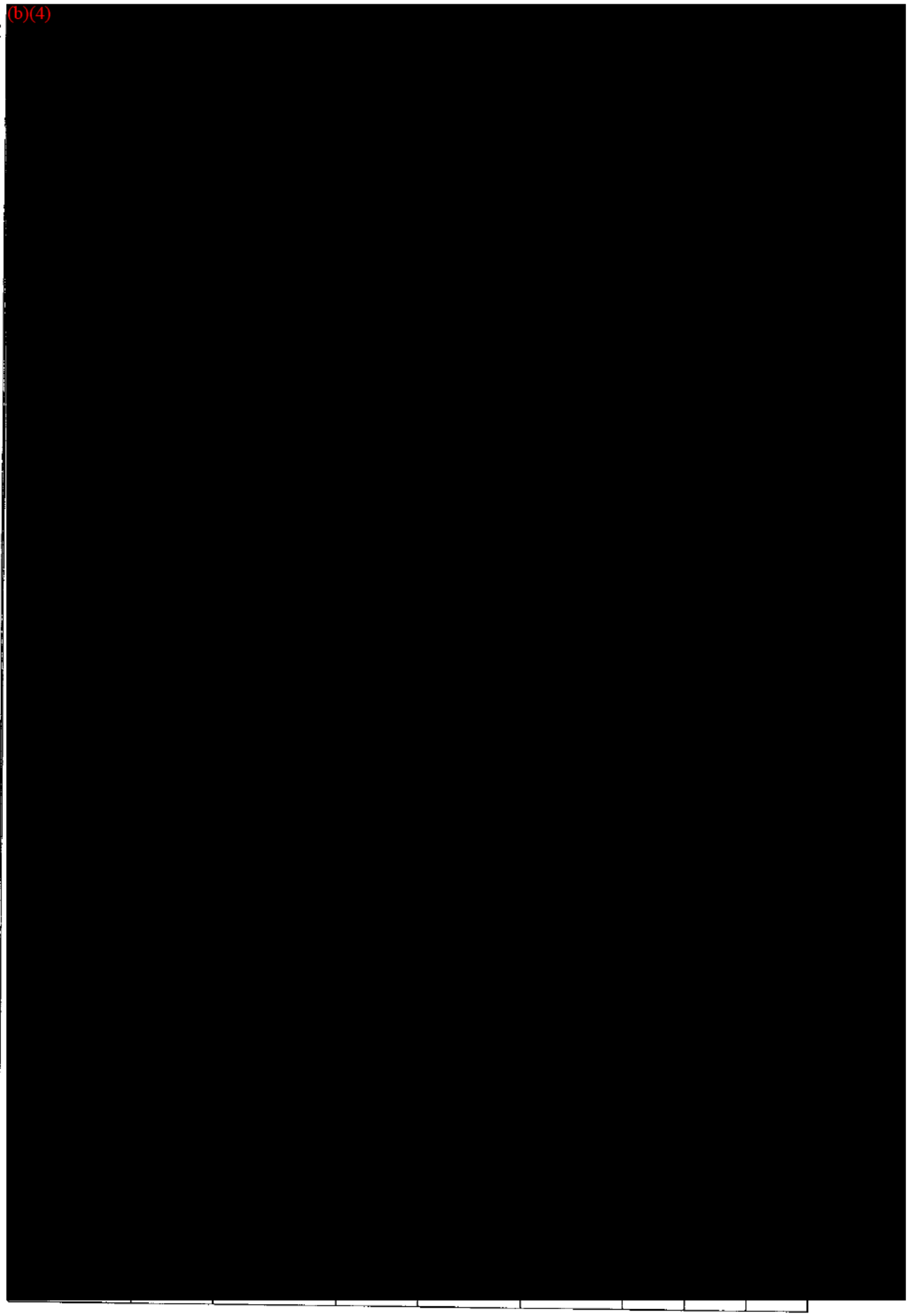
(b)(4)

9 Hazard Analysis and Risk Management Summary

(b)(4)

[redacted]

(b)(4)



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[redacted]

(b)(4)

[redacted]

(b)(4)

EBNeuro

Report Interno

Titolo : SandMan Pocket Pulse Transit Time Measurement algorithm validation		Cod : 0065RPT_20 Rev: A pag 1 / 16
Compilato:	Approvato:	Data 02-05-06

(b)(4)

[redacted]

(b)(4) Software Validation

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(b)(4) Software Validation

(b)(4) Software Validation

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EBNeuro

Revision History Level

Titolo: SD8 Functional firmware – Revision History Level	Codice: **0065_ RLH** Rev: **A** pag **1 / 1**

Compilato: E. Carnati	Approvato (Rdp) : P. Giovagnola	Data: 02-05-06

1. Release 1.00

First release of the firmware.

This is the release described and tested in:

- Software design specification: 0065_SDS rel. A
- Architecture design chart: 0065_ADC rel. A
- Software design specification: 0065_SDS rel. A
- Traceability analysis: 0065_TA rel. A
- Software development Environment description: 0065_SDED rel. A
- Verification and Validation: 0065_VV rel. A
- Unresolved anomalies: 0065_UA rel. A

(b)(4) Design document

(b)(4) Design document

(b)(4) Design document

(b)(4) Design document

(b)(4) Design document

(b)(4) Design document

Report Interno

Titolo : **Pocket functionality Verification and Validation**			Cod : **0065RPT_30** Rev: **A** pag **1 / 13**
Compilato: P. Giovagnola	Controllato: E. Carnati	Approvato:V. Roma	Data: 02-05-06

(b)(4) Software Verification Validation report

[redacted]

(b)(4) Software Verification Validation report

(b)(4) Software Verification Validation report

(b)(4) Software Verification Validation report

(b)(4) Software Verification Validation report

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CHAPTER 1
INFORMATION ABOUT SAFETY

1.1 INFORMATION ABOUT THE MANUAL

Information in this document is subject to change and revision without notice.

Issues:

First edition: **B830 0065 411 - Rev. A - May 2006**

This manual is to be considered as an important component of the equipment. When installing the system for the first time, the user should accurately check the content of the Manual in order to verify its integrity and completeness.

In the event that the Operator Manual should be ruined, incomplete or inadequate, please contact EBNeuro in order to immediately restore or replace the uncompliant Manual.

The official versions of the Operator Manual, of which EBNeuro is directly responsible, are the Italian and the English versions. For countries in which languages other than Italian or English are spoken, the official Manual is the version in English. EBNeuro does not undertake any responsibility for any translations in other languages made by distributors or users or third parties.

Observance of the operating procedures and the warnings described in this Manual is a basic requirement for the correct working of the equipment and to guarantee the patient's and user's safety.

The Manual must be read in full in front of the equipment prior to use, in order to become familiar with the operating procedures, the commands, the connections to the peripheral instruments, and the precautions for a correct and safe usage.

The Operator Manual should be kept, complete and readable in every part, in a safe place. It should be easily accessible to the user when using the equipment.

The equipment Service Manual is available upon request. This Manual contains all information directed to the qualified staff in charge for servicing.

1.1.1 CONVENTIONS

In this Operator Manual, the following conventions are used:

NOTE

NOTE messages contain important information to be underlined with respect to the rest of the text. They generally contain information useful to the user to correctly perform and use the operating procedures of the equipment.

WARNING

WARNING messages appear in the Manual prior to procedures or operations that should be observed in order to avoid any data losses or damages to the equipment.

CAUTION

CAUTION messages appear in the Manual with reference to the description of procedures and operations that, if not performed correctly, could cause harm to the user or the patient.

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1.2 DECLARATION OF RESPONSIBILITY BY THE MANUFACTURER

MANUFACTURER: **EBNeuro S.p.A.**
Operating office:
FIRENZE
Via Pietro Fanfani, 111/A
50127 - Firenze
Phone +39 055 4565111
Fax +39 055 4565123

EBNeuro is responsible for safety, reliability and performances of the equipment only when the equipment is used in compliance with the following conditions:

- Calibrations, modifications or servicing must be performed by qualified staff expressly authorized by EBNeuro.
- The equipment must only be opened and its internal parts must be accessed to by maintenance qualified staff expressly authorized by EBNeuro.
- The environment where the equipment is used must be in compliance with the safety directions.
- The electric wiring of the building must be designed according to local standards and perfectly working.
- Parts and accessories of the equipment that can be replaced by the user, must be replaced with items of the same kind and with the same characteristics.
- The connection of the equipment with peripherals or other instruments supplied by the mains electricity must be performed according to the EN 60601-1-1 standards (standards for Electro-medical systems) and to the EN 60601-1-2 standards (standards for electromagnetic compatibility).
- Usage and maintenance of the equipment and its accessories must be performed in compliance with the instructions described in this Manual.
- All parts of this Manual must be maintained as a complete and readable document.
- The equipment is used and serviced until its "End of Life".

1.3 USAGE RESTRICTIONS AND SAFETY PRECAUTIONS

In order for the system to be operated in a safe manner, and to ensure the safety of both the patient and the user, it is important that all precautions listed below are followed:

CAUTION

Prior to usage, verify that all the safety requirements are satisfied.
The equipment must not be supplied by or connected to other instruments until such safety conditions are restored.

CAUTION

The EBNeuro Sandman Pocket Recorder is not intended for the "end user", rather it is intended as an OEM product to be used by a "System Builder" as a piece of its own medical systems.

It is the responsibility of the System Builder to use the EBNeuro Sandman Pocket Recorder strictly following any technical specification and precaution of use described in this manual.

EBNeuro is not providing any sensor, lead or cable, nor any wearing system to the System Builder, nor is EBNeuro providing any "system software" suitable for a complete polysomnographic or sleep study system.

It is completely under the responsibility of the System Builder to provide all the accessories and any eventual wearing system. System Builder should address any safety and effectiveness consideration related to the whole medical system he is "manufacturing" and should provide any instructions and warnings against the correct connection and units/cable placing of any system's part (as an example to avoid any possible strangulation risk). This applies in particular to the use of EBNeuro Sandman Pocket Recorder in pediatric studies.

CAUTION

The EBNeuro Sandman Pocket Recorder is only to be used under the direction and supervision of a physician, technologist or clinician. It will not prevent or restore the interruption or loss of any physiological system.

1.3.1 ELECTRIC SAFETY

Leakage current
The maximum patient leakage current from the equipment, measured according to the IEC 601-1 standard (for Class I Type CF) is less than 10 μA.

Patient Connection
All patient connections to the *Sandman Pocket* amplifier are through the *Sandman Pocket* headbox using the input sockets provided, or through the dedicated connectors for pressure, body position, oximeter sensors. Any patient electrodes or sensors connected to the device by any other means constitutes an unsafe condition that could result in injury or death to the patient.

CAUTION

All connections on the headbox are isolated from AC power ground.
Do NOT join these connections to earth ground or AC power ground since such an action constitutes an unsafe condition that could result in serious injury or accidental death to the patient.

CAUTION

The electrode and sensor through which the signal is captured from the body of the patient are not part of the amplifier system. In any case, it is MANDATORY to use only electrodes or sensors approved for commercial use by FDA (USA) or CE marked (93/42EEC European directive), depending on the country the system is used.

CAUTION

It is strongly recommended to check the overall functionality of the system before starting any recording.
In case any anomalies or malfunctioning should be noticed, immediately disconnect the patient from the system (if a patient is already connected), switch off the system and ask for service from qualified personnel.
In particular (for example) if, with a patient connected to the system, some "flat" tracing should be noticed on the monitor during recording In this case, if the problem should not be easily solved (poor electrode connection, broken lead etc) immediately disconnect the patient, do not use the system and ask for servicing.

CAUTION

During "long term recording" it is strongly recommended to periodically check that the system works regularly without any sign of malfunctioning. If any anomalies or flat traces should be noted, disconnect the patient, do not use the system and ask for servicing.

CAUTION

If skin irritation occurs, discontinue recording and disconnect the patient.
Refer to the user instructions of the sensors, electrodes and paste for further information. Use only electrodes, sensors and paste according to the requirements of FDA (USA) or 93/42/EEC Medical Devices Directive (CE mark for European Community).

To ensure the safety of the patient and the operator, please follow all the warnings and cautions listed in this manual.

- **Take care when using the equipment at the same time as other instruments.** In the event that the patient is connected to several instruments at the same time, it is important to remember that the sum of the leakage currents produced by each instrument may endanger the patient.

- **Take care when using the equipment at the same time as other instruments that emit radio frequency.** In the event that the equipment is used in an operating room at the same time as a radio knife (Radio-Frequency instrument = RF), it is necessary to hold the radio knife point as far as possible from the electrodes, in order to reduce the risk of RF currents flowing through the electrodes which may result in burns to the patient. This may be reduced by using electrodes with a larger surface area, in order to limit the RF current density to acceptable values. If it is not possible to use the proper electrodes, it is recommended to disconnect the patient from the equipment before using radio-frequency instruments.

- **The equipment is not protected against the defibrillator discharges.** Please remember that the equipment is not protected against the defibrillator discharges. If it is necessary to use a defibrillator, it is necessary to disconnect the patient from the equipment in order to avoid the possibility of patient being burned in the electrode contact areas and the equipment experiencing irreversible damages.

- **Prevent contact of patient and electrodes with other conductive metal items.** When the equipment is connected to other instruments supplied by the mains supply, the whole input circuit to which the patient is connected is electrically isolated (*floating* isolation). It is necessary to prevent the patient, and any conductive part of the system connected to the patient (electrodes, connectors, and transducers), from coming into contact with conductive parts (ground included) of other devices. Please observe this precaution to avoid compromising the equipment isolation level. This precaution must be observed in order to avoid that accessible metal parts of the device touching external conductive parts, thus damaging the isolation level of the equipment.

- **Do not connect additional Multiple Portable Socket-Outlet or extension cords.** Multiple Portable Socket-Outlet or extension cords shall not be connected to the system.

- **Observe the EN 60601-1-1 and the EN 60601-1-2 standards when connecting the system to other instruments.** The connection of the equipment with other devices is allowed only when the safety requirements for the patient, the user and the environment are not compromised. If the Manual does not contain enough information about the possibility of interconnection with other devices, the user should contact the manufacturer or the nearest authorized servicing center to have information about the effects that coupling devices may have on the patient, the user and the environment.

- **Replace damaged parts immediately**. Cables, connectors, accessories, or other parts of the equipment must be replaced immediately when damaged or if they are not working correctly. Please contact the nearest authorized service center immediately for replacement parts.

- **Use only accessories and peripherals of type specified by EBNeuro**. In order to guarantee all the safety requirements, it is necessary to use only the accessories and peripherals specified in this Manual as part of the system, which have been tested with the equipment. The usage of accessories and consumer goods supplied by other manufacturers or not specifically indicated by EBNeuro do not guarantee the safety and the correct working of the equipment. Use only peripherals in compliance with the standards of the class they belong to.

- **Check the functionality of the system before starting any recording.** It is strongly recommended to check the overall functionality of the system before starting any recording. In case any anomalies or malfunctioning should be noticed, immediately disconnect the patient from the system (if a patient is already connected), switch off the system and ask for service from a qualified personnel. In particular (for example) if, with a patient connected to the system, some anomalous tracing, like isoelectric or greatly artefacted signal, should be noticed on the monitor during recording. If the problem can not be solved with the assembly standard technique (poor electrode connection, broken lead, etc), immediately disconnect the patient, do not use the system and ask for servicing.

- **Periodically check that the system works regularly during "long term recording".** During "long term recording" (more than one hour), it is strongly recommended to periodically check that the system works regularly without any sign of malfunctioning. If any anomalies or flat traces should be noted, immediately disconnect the patient, do not use the system and ask for servicing. In particular, any electrode site used for long term must be checked for irritation and redness. Check each electrode periodically to evaluate the skin condition under the electrode. Redness, blistering and permanent skin scarring can occur if electrodes are not regularly monitored.

- **Take care when using the equipment on patients with a heart pace-maker**. It is necessary to use caution when using the equipment in patients with implanted electric devices, especially heart pace-makers, because the equipment may cause the cardiac stimulator to malfunction. Patients with cardiac pacemakers should not undergo any examination with this equipment without authorization and close supervision of a specialized physician.

- **The equipment works with non rechargeable AA Alkaline batteries.** Batteries must be replaced at the beginning of each recording. Batteries are not supplied by EBNeuro and are not part of the amplifier. Take care to connect each battery with the correct polarity (see section 4.2).

1.3.2 SAFETY OF THE OPERATING ENVIRONMENT

- **The equipment is not designed to be used in locations with flammable vapors or gases that may cause explosions**. The equipment must not be used in atmospheres with a high concentration of oxygen or in buildings where flammable substances or anesthetic agents are present. The atmosphere is considered as oxygen-saturated when the oxygen or nitrous oxide (NO_2) concentration contained in the environment is over 24%.

- **The equipment and its internal parts are not protected against the inflow of liquids.** Avoid operating the equipment in an environment where there is a risk of water dripping, sprinkling or immersion. Do not use the system in an environment where liquid inflow is likely. Instruments that have been subject to liquid penetration must be immediately cleaned and checked by authorized qualified staff.

- **Use the equipment within the environmental limits of temperature, humidity and pressure specified**. The equipment is designed to work in environmental conditions that, in compliance with the IEC 601-1 directions, are defined as standard:

- temperature	+5°C / +40°C
- relative humidity	30% / 75% RH
- atmospheric pressure	700 / 1060 hPa

  It is important to remember that since the equipment is portable it can be used outside hospital. It is important not to use it when the above mentioned environmental conditions are not satisfied. In particular, take care in protecting the equipment from humidity when moving it from one place to another.

- **Be careful using the equipment when it is moved between locations with different temperatures to avoid any possible internal condensation**. If the equipment is stored or kept in a cold place and is rapidly moved to a warmer building, condensation may occur (humidity or misting over the internal or external surface of the equipment). In this case, it is necessary to wait for the condensation to be completely evaporated before powering up and using the equipment.

- **Make sure the electric wiring of the building is safe when connecting to other mains powered devices**. When the equipment is connected to peripherals or other mains powered devices, make sure that the latter are connected only to mains outlets with protective grounding. This protection is fundamental for the patient's and the user's safety: therefore, it is necessary that the electric wiring of the building guarantees efficient protective grounding.

- **Be careful using the equipment in locations disturbed by strong magnetic fields**. The equipment is compliant with the EMC requirements (ElectroMagnetic Compatibility) according to that specified by the 89/336/EEC European Directive. In every case it is recommended to keep the equipment

away from significance sources and induced electromagnetic fields that surpass the values prescribed by the standard in order to avoid any possible instabilities and malfunctioning of the equipment

- **Be careful when using the equipment near short-wave or micro-wave devices**. If the equipment is used in an area where there are also therapeutic short-wave or micro-wave devices, it is necessary to remember that these may cause instability and interfere with the correct performance of the equipment. Do not place the equipment near X-ray or diathermy devices.

1.3.3 PULSE-OXIMETER WARNING NOTES

A Pulse-Oximeter module is installed inside the *Sandman Pocket* recorder. This device is the NELL-1 pulse-oximetry module board manufactured by Nellcor Puritan Bennett (USA).

When utilizing the pulse oximeter module integrated in the *Sandman Pocket* device in its own system, System Builder must observe the following safety precautions and usage restriction notes:

- **Intended use of the option.** The *Sandman Pocket* device constitutes "simply" the acquiring front end of SpO_2 and pulse rate data. In particular notice that:
  - The *Sandman Pocket* device limits its role to allow the host system to control the NELL-1 module and to read the calculated data values and store this data on the recorder memory and/or pass it to the host computer.
  - The *Sandman Pocket* device does not rely in any way with the processing of the SpO_2 and pulse rate data. These eventual process are under the complete control and responsibility of the host system software.
  - The *Sandman Pocket* does not interpret or evaluate data retrieved from NELL-1 oximeter. PTT is simply calculated as a "time interval" between two fiducial points.
  - The *Sandman Pocket* supports the NPB (Tyco) GK420E, GK425ST and GK425 CPAP models.
  - **The *Sandman Pocket* device is NOT involved in any alarm managing. The Pulse-Oximetry module of *Sandman Pocket* device is NOT intended FOR CONTINUOUS MONITORING.**
  - The System Builder application software is responsible for the use and display of the oximetry data. In particular, the System builder may assure that this use will meet the requirements of the EN 865 and ISO 9919 standards (if applicable).

- **Allowable sensors.** The *Sandman Pocket* device is provide without standard sensors. System Builder should integrate the device with Nellcor Puritan Bennett approved sensors only and specified for the usage with NELL-1 module.
  Information regarding this point can be obtained directly by Nellcor Puritan Bennett or EBNeuro S.p.A.
  In any case it is mandatory to use only sensors approved for commercial use by FDA (USA) and/or CE marked according to 93/42/EEC directive.

- **Accuracy of acquired data.** The accuracy of oximetry data depends on the sensor used with the device. System Builder should determine the accuracy according to the technical characteristics of the chosen sensor(s). Please reference the manufacturer's documentation for the sensors.

  In operation, the accuracy of the oximetry data can be affected by the following external conditions:

  - High-frequency electrical noise, including electrosurgical equipment and defibrillators;
  - Possible interference with magnetic resonance imaging (MRI) procedures;
  - Excessive patient movement;
  - Intravascular dye injections;
  - Significant concentrations of dysfunctional hemoglobin, such as carboxyhemoglobin and methemoglobin;
  - Sensor temperature (maintain between 28°C and 42°C for best operation);
  - External illumination more than 5000 lumens/square meter (typical office lighting);
  - Improper sensor application;
  - Venous pulsation;
  - Placement of the sensor on an extremity that has a blood pressure cuff, arterial catheter or intravascular line;

1.4 GRAPHIC SYMBOLS IN COMPLIANCE WITH THE IEC 60601-1 STANDARDS

The following table shows description and localization of all graphic symbols in compliance with the IEC 60601-1 safety standards present on the equipment panels and on any other instruments or external devices to which the equipment may be connected.

IEC 601-1 SYMBOL	DESCRIPTION	POSITION
	**Alternating current**	Symbol placed on the connection points between the equipment and the mains (alternating current source).
	**Direct current**	Symbol placed on the connection points to direct current source.
	**Equipotential terminal**	Symbol placed on the outlet connecting the equipment to the equipotential node of the building, if any.
	**Protective earth (ground)**	Symbol placed on the connection points between the equipment and the protective grounding.
	**High voltage**	Symbol placed on circuits or equipment parts with high voltage.
	**CAUTION! Refer to the attached instructions.**	Symbol placed on items for which it is important to read the Operator Manual for relevant information (see CAUTION paragraph).
	**Device with CF-type applied parts**	Symbol placed on applied parts to the patient with a CF-protection level.
	**Device with BF-type applied parts**	Symbol placed on applied parts to the patient with a BF-protection level.
	**Device with B-type applied parts**	Symbol placed on applied parts to the patient with a B-protection level.

IEC 601-1 SYMBOL	DESCRIPTION	POSITION
	**Off (disconnected from the mains)**	Symbol placed on the off/on positions of the whole equipment general power switch.
	On (connected to the mains)	Symbol placed on the off/on positions of the whole equipment general power switch.
	**Off (for a single part of equipment)**	Symbol placed on the off/on switch of a single part of the equipment.
	**On (for a single part of the equipment)**	Symbol placed on the off/on switch of a single part of the equipment.

1.5 OTHER GRAPHIC SYMBOLS

The following table shows description and localization of all symbols placed on the equipment panels and on any other instruments or external devices to which the equipment may be connected.

SYMBOL	DESCRIPTION	POSITION
	**Input**	Symbol placed on the signal input or mains voltage input connectors of the equipment.
	**Output**	Symbol placed on the signal output or the mains voltage output connectors of the equipment.
+	**Positive**	Symbol placed on the battery insertion points. The symbol indicates the position of the battery positive pole.
—	**Negative**	Symbol placed on the battery insertion point. The symbol indicates the position of the battery negative pole.
LOT	**Lot number**	Symbol placed on the identification label of the medical device together with the device lot number.
REF	**Reference number**	Symbol placed on the identification label of the medical device together with the device reference number.
SN	**Serial number**	Symbol placed on the identification label of the medical device together with the device serial number.
	**Date of manufacture**	Symbol placed on the identification label of the medical device together with the device manufacture date.
	**Crossed-out wheeled bin**	Symbol placed on the identification label of the medical device. This symbol indicates the prohibition of throw the medical device in the household wheeled bin device when at its "end of life".
	**Use by**	Symbol placed on the identification label of the medical device together with the device expiration date.
	**Do not reuse**	Symbol placed on the identification label of the medical device. This symbol indicates that the device is a disposable one and cannot be used more than once.

SYMBOL	DESCRIPTION	POSITION
STERILE	**Sterile**	Symbol placed on the identification label of the medical device indicating a sterile device.
STERILE	**Sterilization with steam or dry heat**	Symbol placed on the identification label of the medical device indicating a sterile device and the sterilization method used (steam or dry heat).
STERILE EO	**Sterilization with ethylene oxide**	Symbol placed on the identification label of the medical device indicating a sterile device and the sterilization method used (ethylene oxide).
STERILE R	**Sterilization by irradiation**	Symbol placed on the identification label of the medical device indicating a sterile device and the sterilization method used (irradiation).

1.6 CAUTION SYMBOL

The **CAUTION** symbol shown below, placed on the equipment casing, refers the user to the Operator Manual for information, warnings and suggestions which are particularly important for a correct and safe use of the equipment.

In particular, when it is placed on points connecting cables to peripherals, this symbol refers the user to carefully read the Operator Manual for instructions concerning the nature of such cables and peripherals and the modalities for a correct and safe connection.

For location of the CAUTION symbols placed on the equipment, please refer to chapter "*Installation and connections*" of this Operator Manual. That chapter shows the pictures of the equipment panels with the corresponding commands, connections, symbols, and labels. Each CAUTION symbol comes with a detailed explanation of its meaning.

1.7 CROSSED-OUT WHEELED BIN

The symbol shown below placed on the product or on its packaging indicates that this product must not be disposed of with your other household waste at its "End of Life". Instead, it is your responsibility to dispose of your waste equipment by handing it over to a designated collection point for the recycling of waste electrical and electronic equipment.

The separate collection and recycling of your waste equipment at the time of disposal will help to conserve natural resources and ensure that it is recycled in a manner that protects human health and the environment.
For more information about where you can drop off at its "End of Life" your waste equipment for recycling, please contact your local city office, your household waste disposal service or the shop where you purchased the product or contact the manufacturer of device at www.ebneuro.com or at support@ebneuro.com or contact the EBNeuro main office (par 11.2 of the manual).

Safety, performances and effectiveness of device and availability of its spare parts are guaranteed by the manufacturer until device "End of Life".
EBNeuro, as manufacturer, define the "*End of Life*" time for *Sandman Pocket* modules in 7 (seven) years starting from the production date (see identification label).

1.8 PRODUCT TRACEABILITY

In order to guarantee the traceability of the product, according to ISO 13485 quality standards and the 93/42/EEC European Directive on Medical Devices, EBNeuro kindly requests the original owner of the equipment provides information regarding the transfer of the system to a third party, by sending a photocopy of the completely filled-in Product traceability form (see enclosure 1.7), or by communicating in writing the data indicated in the form.
The data concerning the device can be found on its identification label.

The form can be sent either directly or through any subsidiary or the nearest authorized distributor to the Quality Assurance Department of any EBNeuro operating office. The list of the main EBNeuro head and branch offices in Italy and overseas is contained in chapter "*Request for assistance*" of this manual.

1.9 VIGILANCE SYSTEM

The device is subject to a vigilance system (post-marketing vigilance) that EBNeuro and its distributors and retailers apply to the products that are put on the market to safeguard the patient and the physician from serious or potentially serious hazards during the normal use of the equipment, in order to be able to remove the source of such hazards with the best efficiency and timing.

To the purpose of helping EBNeuro take any timely and effective corrective measure, it is extremely important that the user performs a careful inspection of the equipment performance in order to identify or foresee any dangerous situation for the patient's and the user's health.

For this reason, the user shall give immediate communication of any malfunction or deterioration of the characteristics or the performances of the equipment or any mistake found in these instructions that caused or could cause serious damages to the patient's and the user's health.
In this case, the user may send a photocopy of the proper duly filled-in *Post-Marketing Vigilance Form* (see enclosure 1.8), or communicate in writing the data indicated in the form.

The instrument's data can be collected from it's identification label.

The form shall be sent either directly or through any subsidiary or the nearest authorized distributor to the Quality Assurance Department of any EBNeuro operating office. The list of the main EBNeuro head and branch offices in Italy and abroad is contained in chapter "*Request for assistance*" of this manual.

Enclosure 1-7

PRODUCT TRACEABILITY FORM

To: EBNeuro S.p.A.
Quality Assurance Department
Via Pietro Fanfani, 111/A
50127 Florence

System/device name.....

Device code / reference number (REF) .....

Device serial (SN) / lot number (LOT) .....

Name and address of the former owner .....
.....
.....
.....

Name and address of the present owner .....
.....
.....
.....

Date:.....

Signature

.....

(please name in full)

(ref. Operator Manual code B830 0065 411 Rev. A)

enclosure 1-8

POST-MARKETING VIGILANCE FORM

To: EBNeuro S.p.A.
Quality Assurance Department
Via Pietro Fanfani, 111/A
50127 Florence

System/device name.....

Device code/reference number (REF) .....

Device serial (SN)/lot number(LOT) .....

Description of the real or potential hazard.....
.....
.....
.....
.....

User's comments/suggestions .....
.....
.....
.....
.....

User's address.....
Phone..... Fax .....

Department where the device is installed.....
Person in charge of the department.....

Data:.....

Signature

.....

(please name in full)

(ref. Operator Manual code B830 0065 411 Rev. A)

1.10 INFORMATION ABOUT RECYCLING OF MATERIALS

In accordance with the specific European directives, EBNeuro aims to continuously improve the design and the manufacture of electromedical devices in order to reduce as much as possible any negative impact on the environment caused by the management of component parts, consumer materials, packaging and the disposal of devices when at their "end of life".

Packaging materials were designed and produced so as to allow the easy reuse and the salvage, including recycling, of most parts of the material and to reduce the quantity of garbage or residual products for discharge as much as possible. In particular, packaging materials have been produced so as to limit the presence of harmful metals and of other dangerous substances to minimum quantities in emissions, ashes or lixiviation residual products. The total concentration levels of heavy metals such as Lead, Cadmium, Mercury and hexavalent Chrome contained in the packaging materials are in accordance with the limits established by the directives in force related to this subject.

In order to minimize the consequences to the environment, the design of the device includes the highest possible miniaturization of the circuits, with the least possible differentiation of materials and components, with a selection of substances that guarantee the highest possibility to recycle and re-use the components and to dispose of them without risks to the environment.

The device is designed to guarantee the easy separation or disassembling of the materials containing polluting substances from the others, in particular during the operations of servicing and replacing parts. In particular, the largest plastic components are marked according to their plastic contents in order to make it easier to recycle the product.

CAUTION

Please refer to local codes and laws for proper disposal/recycle requirements of packaging and consumer materials and of the device when at its "end of life".

1.11 ELECTROMAGNETIC COMPATIBILITY

The device is designed for use in the electromagnetic environments declared in the tables below, in compliance with the IEC 60601-1-2:2001 (second edition) standard. The operator must assure that the device is used in an environment compliant to this standard.

Table 1 - Electromagnetic Emissions

Emission Test	Compliance	Electromagnetic Environment
Radiated and conducted RF emission CISPR 11	Class B	The device is suitable for use in domestic establishment and in all establishments directly connected to the low voltage power supply network (electrical mains) which supplies buildings used for domestic purpose.
	Group 1	The device use RF energy only for its internal function and to operate. Therefore, the RF emission is very low and not likely to cause any interference in nereby electronic equipment.
Harmonic emission IEC 61000-3-2	Complies	The device is suitable for use in establishments directly connected to a public low voltage power supply network (electrical mains)
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	The device is suitable for use in establishments directly connected to a public low voltage power supply network (electrical mains)

Table 2 - Electromagnetic Immunity

Immunity Test	IEC 60601-1-2 Test Level	Compliance	Electromagnetic environment
Electrostatic Discharge (ESD) IEC 61000-4-2	6 kV in contact 8 kV on air	IEC 60601-1-2 Test Levels	Residential **(Note 1)**
Electrical fast transient/burst IEC 61000-4-4	2 kV for power supply line 1 kV for input/output lines >3m	IEC 60601-1-2 Test Levels	Residential **(Note 2)** **(Note 3)**
Surge IEC 61000-4-5	1 kv differential mode 2 kV common mode	IEC 60601-1-2 Test Levels	Residential **(Note 2)** **(Note 3)**

Voltage dips, short interruptions and voltage variation on power supply input lines IEC 61000-4-11	0 % of rated voltage (voltage dip 100 %) for 0.5 cycles 40 % of rated voltage (voltage dip 60 %) for 5 cycles 70 % of rated voltage (voltage dip 30 %) for 25 cycles 0 % of rated voltage (voltage dip 100 %) for 5 cycles		
Magnetic fields at mains frequency (50/60 Hz) IEC 61000-4-8	3 A/m		
Radiated RF fields IEC 61000-4-3	Non-life-supporting equipment 3 V/m form 80 MHz to 2.5 GHz	IEC 60601-1-2 Test Levels	Residential **(Note 4)**
Radiated RF fields IEC 61000-4-6	Non-life-supporting equipment 3 V form 150 kHz to 80 MHz		

Measures to be taken

Note 1: The foor should be in antistatic material (wood, ceramic, ect.). If covered by synthetic material, relative humidity should be maintained at least at 30%

Note 2: The qualily of the electrical power supply and the mains frequency magnetic fields should be typical of domestic, commercial and hospital environments.

Note 3: If the operator must work without a break while power supply is interrupted, it is necessary to have power supplied through a UPS (Uninterruptible Power Supply) unit.

Note 4: Mobile or portable radio frequency (RF) communication appliances should be used at longer distances than those indicated on the following Table 3.
Electromagnetic transient can happen near appliances bearing the symbol shown below

1.11.1 Recommended distances from Radiofrequency (RF) communication systems

As stated in this chapter 1 "Information about safety" of this operator manual, it is recommended to not use Radiofrequency (RF) transmission system near the *Sandman Pocket* amplifier system. RF systems can cause interference which may cause instability and interfere with the correct working of the equipment and it may alters the EEG signal acquired tracings.

The operator can prevent interference caused by electromagnetic field by maintaining a minimum distance between the *Sandman Pocket* amplifier system and the RF communication system being used (cell phones, mobile phones, etc,). The following table shows the minimum distances in meters, according to the maximum power at RF system output.

Table 3 – Recommended separation distances from RF sources

RF Source	Typical Rated Power (W)	Distance (m)
Microcellular phone CT1, CT2, CT3	0.01	0.3
DECT cellular phone, Wireless Information Technology equipments (modems, LANs)	0.25	2
Cellular phone, hand-held (USA)	0.6	2
Cellular phone, hand-held (e.g. GSM and NMT, Europe DECS 1800)	2 8	4 7
Walkie-talkie (rescue, police, fire, maintenance)	5	3
Cellular phone, bag	16	10
Mobile radio (rescue, police, fire)	100	30

For transmitters that have a maximum output power of which is not within the value ranges in the table, the recommended minimum distance can be estimated by analyzing the equation in the table applicable to the transmitter frequency:

For transmitters using frequencies ranging from **150 kHz to 80 MHz** and from **80 MHz to 800 MHz**, the distance can be estimated using the equation:

$$d = 1.2\sqrt{P}$$

For transmitters using frequencies ranging from **800 MHz to 2.5 GHz**, the distance can be estimated using the equation:

$$d = 2.3\sqrt{P}$$

P is the rated power of the transmitter in Watt (W) according to the transmitter manufacturer specifications.

Note: As a precaution, always apply the greater distance supplied by the table.

Note: Electromagnetic fields are subjected to absorption and reflection in the presence of structures, objects and people. The values in the table are general guidelines.

The operator must remember that the intensity of the electromagnetic fields generated by fixed transmitters (radio-base stations for cellular or cordless phone, TV and radio transmissions, amateur radio transmission, etc.) cannot be predicted on theoretical basis.
Consequently, a direct measure may be necessary in the used environment of *Sandman Pocket* system.

If the intensity of the electromagnetic fields exceeds that specified in the immunity levels shown in the previous tables, and the bioelectric signal Amplifier system behaves incorrectly, additional measures may be necessary. I.e. orienting or locating the *Sandman Pocket* system in a different way.

1.12 BIOCOMPATIBILITY AND INFECTIONS CONTROL

No system components are intended to be in contact with the patient.
Electrodes and sensors are not intended to be parts of the "*Sandman Pocket*" system.
The body contacting material are no part of the system. In any case, electrodes and sensors MUST meet the requirements of FDA (USA) or 93/42/EEC Medical Devices Directive (CE marked).

CAUTION

The residual products of every exam (disposable electrodes, gel or paste residues, etc.) must be considered as potentially infected and therefore treated as special waste. Please refer to local codes for proper disposal of such materials.

1.13 DECLARATION OF CONFORMITY

CE 0051

The equipment has been manufactured by applying the quality guarantee system approved for design, manufacturing and final check of the product and meets the requirements of **Annex II** of the **93/42/EEC** Directive on Medical Devices (**MDD**). For these reasons the equipment is marked with the **CE** mark.
The approval is issued by IMQ S.p.A. (Milan – Italy) as Notified Body notified by European Commission. IMQ Notified Body identifier number is **0051**.

C SP US

The equipment is marked with the **cCSAus** quality mark. This safety mark is valid in both Canadian and U.S. markets.

1.14 CAUTION FOR THE U.S. MARKET

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

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CHAPTER 2
DESCRIPTION OF THE DEVICE

2.1 DESCRIPTION OF THE SYSTEM

The *Sandman Pocket* is part of a Polysomnography system. It consists of two units: the **Recorder Unit**, which stores the data and sends it to a USB port; and the **Headbox Unit**, which is the connection point for all patient sensors, with the exception of the oximetry probe.

Intended use:

The Sandman Pocket is to be used for collecting and recording physiological data to be used in polisomnography and sleep disorder studies. The Sandman Pocket is intended for pediatric through adult patient populations can be used in either home or hospital environments.

The *Sandman Pocket* role is only to capture the data and pass them to the host with the necessary accuracy and reliability following the specification of the product and those of the communication control.

A fundamental characteristic of the *Sandman Pocket* is to be an ambulatory/portable equipment: small size and light weight (about 210 gr included battery), compact and solid.

The **Headbox Unit** is used for insertion of patient electrodes and sensors. It includes Bipolar channels, pressure sensors, and supply power for a dedicated body position sensor, a abdomen sensor, a chest sensor, an snore sensor and a thermistor.

The patient inputs are isolated with a CF type isolation level.

The **Headbox Unit** captures the biological signals from the human body surface through specialized sensors and electrodes, while the **Recorder Unit** amplifies the very low electrical signal, filters it to accomplishe an antialiasing, in order to make an optimal ANALOG to DIGITAL conversion. The data, once converted in numerical form, are "passed" to a host computer that, at this point, is free to elaborate the data following the logic of the application software running on the host. The host can "program" the amplifier behavior setting, sampling frequency, dynamic range allowed, and so on.

The host computer reads the acquired data through a dedicated interchange protocol, and then elaborates the data with its own internal logic. The requirement

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posed by the *Sandman Pocket* device to the host PC when the recorder is connected to PC and, at the same time the patient too is connected the the Sandman Pocket Headbox, is to be a "Medical Grade PC" (with isolation transformer or medical power supply) or a battery supplied laptop.
The *Sandman Pocket* system will not be in any way involved in the data management performed by the host.
The host computer must operate under one of the following Operating System:
Microsoft Windows 98 / ME / NT / 2K / XP.

The device has a built-in impedance meter. This function allows to check the electrode contact impedance and display the result of the check on the display. The display is located in the Recorder Unit while the circuitry controlling the impedance meter is located in the Headbox Unit.

The *Sandman Pocket* can be powered through 3 Alkaline 1.5V standard non rechargeable batteries or via the USB cable. Be sure to use a medical grade type PC.

The *Sandman Pocket* "system" consists of 2 interconnected units: the Headbox Unit and the Recorder Unit.

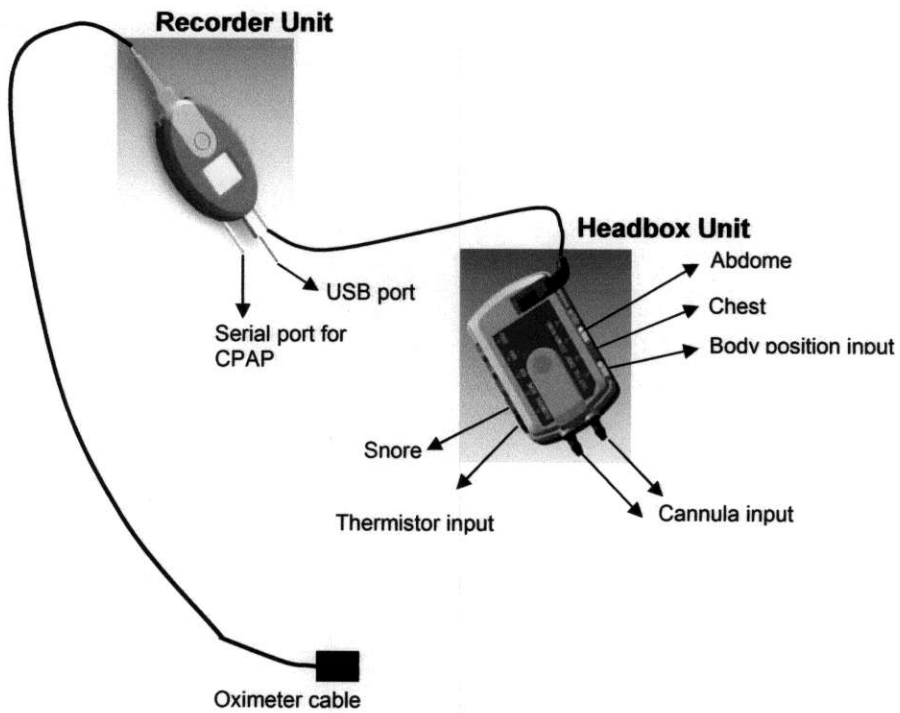

Figure 2-1 SANDMAN POCKET system connection diagram

The **Headbox Unit** has the following functions:

- Physically connects the source of signals (the patient) to the amplifier.
- Provide impedance testing capabilities
- Provide Analog to Digital (A/D) conversion

The **Recorder Unit** has the following functions:

- Amplify and isolate signals coming from the electrodes
- Reference input channels
- Generate calibration pulse
- Provide dynamic range (gain), sampling rate and active channels selection
- Provide the opportune antialiasing filtering to perform optimal Analog to Digital conversion
- Send the digital data trough the USB interface
- Provide the Oximeter option
- Provide to the display management
- Manage the Time
- Manage the batteries power supply

:

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2.2 SANDMAN POCKET HEADBOX DESCRIPTION

The following figures show the SANDMAN POCKET **Headbox Unit** in which the main parts are indicated:

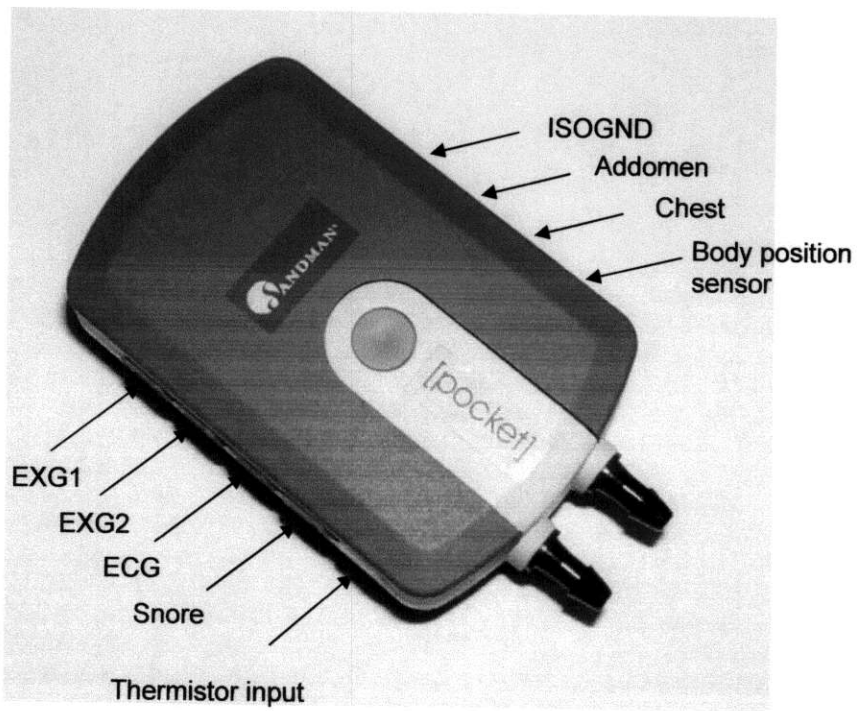

Figure 2-3 SANDMAN POCKET Headbox Unit

2.2.1 PATIENT INPUT SOCKETS DESCRIPTION

The following figure shows the 9 patient input sockets configuration in which the different types of input are indicated:

N° 1 EKG bipolar inputs with AC coupling

N° 5 dedicated bipolar input for Snore, Chest, Abdomen, Thermistor, Body Position

N° 2 EXG bipolar inputs (AC or DC coupling, settable via software).

N° 1 sockets for isolated patient ground

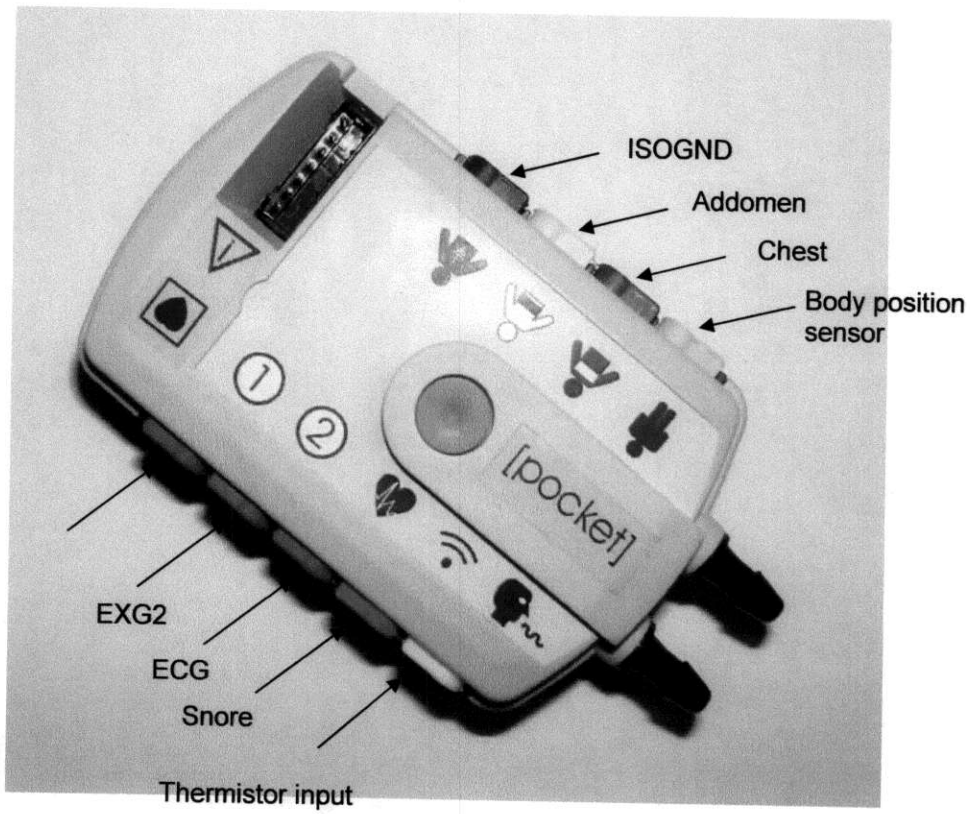

Figure 2-4 SANDMAN POCKET patient input sockets.

In details:

Bipolar Inputs.

① **EXG1** **1 connector (blu).** This connector is used to connect **EEG, EKG** electrodes.

② **EXG2** **1 connector (blu).** This connector is used to connect **EEG, EKG** electrodes.

♥ **EKG** **1 connector (red).** This connector is used to connect a dedicated **EKG** electrode.

CAUTION

All the patient applied parts and corresponding input sockets of SANDMAN POCKET acquisition module (patient inputs) are electrically isolated from the mains according to IEC 60601-1 standard requirements for Class I, Type CF equipments. This characteristic is indicated to the operator with the proper symbol placed on the external cover of the device in correspondence of the input sockets (see description of par. 1.4 of the manual).

CAUTION

All the n° 9 input sockets of SANDMAN POCKET acquisition module accept Female 2 pole 1mm standard touchproof safety connectors.

CAUTION

The SANDMAN POCKET amplifier system is provided without accessories, electrodes and sensor probes for signals acquisition from patient body. It is necessary to integrate the device with sensors and electrodes CE marked according to 93/42/EEC European directive (MDD) on Medical Devices. For usage in the US market, it is mandatory to use only sensors approved for commercial use by FDA (USA.)

Dedicated Bipolar Inputs.

🧍 **BODY POSITION** connector (light gray). This connector is used to connect a dedicated body position sensor.

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CAUTION

This channel has been designed to work with the PRO-TECH body position sensor model SPI or electrically/functionally equivalent.
The SANDMAN POCKET guarantees only the respect of the technical specification regarding this input (range, conversion factor), regulatory aspects of the physical transducer (for example FDA clearance, CE marking) falls under the responsibility of the system builder's who utilize the SANDMAN POCKET Amplifier to build a complete system.

THERMISTOR connector (orange). This connector is used to connect a dedicated airflow thermistor sensor.

CAUTION

This channel has been designed to work with an Edentec Breathsensor model 971 or electrically/functionally equivalent.
The SANDMAN POCKET guarantees only the respect of the technical specification regarding this input (range, conversion factor), regulatory aspects of the physical transducer (for example FDA clearance, CE marking) falls under the responsibility of the system builders who utilize the SANDMAN POCKET Amplifier to build a complete system.
The headbox contains the necessary circuitry to feed the thermistor, so no additional components are required to use the sensor. Typical output of the thermocouple is 400 uVp-p. The maximum output of the thermistor is 1mVp-p, with a temperature excursion of 20 °C. The Nellcor Breathsensor is connect via a standard connections. The inputs must be AC-coupled, self-referenced, differential amplifiers.

CAUTION

The Thermistor must be a disposable component.

SNORE connector (white). This connector is used to connect a dedicated Snore sensor.

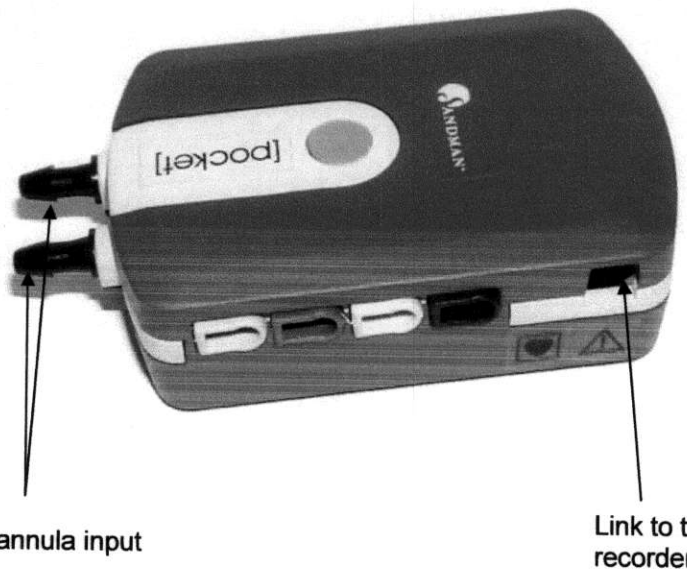
CHEST connector (dark gray). This connector is used to connect a dedicated Chest sensor.

ABDOMEN connector (light gray). This connector is used to connect a dedicated Abdomen sensor.

ISOGND connector (back). This connector is used to connect a dedicated isolated patient ground electrode.

2.2.2 CONNECTORS DESCRIPTION

The following figures show in detail the connectors of SANDMAN POCKET acquisition module:



Figures 2-4 and 2-5 – Acquisition module connectors

- **CANNULA INPUT** This input is used to connect a pressure sensor capable of measuring Nasal Cannula pressure.

CAUTION

The SANDMAN POCKET has incorporated a pressure transducer HONEYWELL mod 26PC01SMT.
Scope of this input is to be connected to an external device (for example, a Nasal Cannula) which provides a "pressure" to the SANDMAN POCKET. By means of the transducer the SANDMAN POCKET amplifier "converts" the pressure value in a voltage and passes this information to the host computer.
This information is intended to be used as reference only (for example, to allow the host computer to create a trends of the pressure value), it is intended not useful to "control" any external device whose behavior should be critical for the patient.

CAUTION

The Cannula must be a disposable component.

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- **SANDMAN HEADBOX CABLE** connector. This connector is used to connect the Headbox Unit with the Recorder Unit.

2.2.3 EVENT MARKER BUTTON

The following figure shows the event marker button placed on the front cover of the SANDMAN POCKET acquisition module.

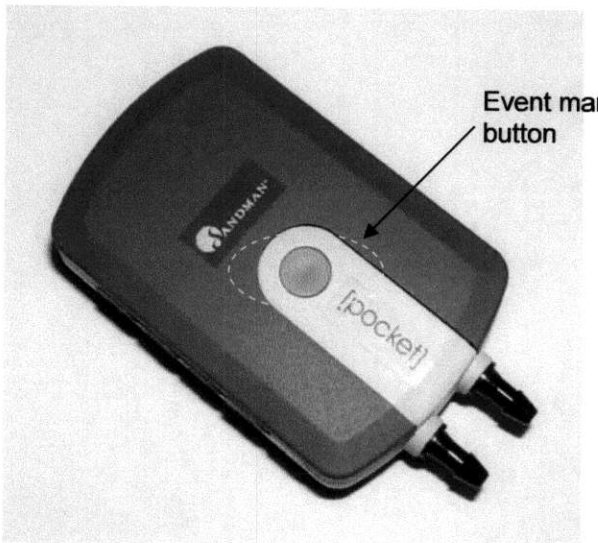


Figure 2-7 – Event marker button

The event marker button allows the user to register the timeat which a particular event occurred.

2.3 SANDMAN POCKET RECORDER UNIT DESCRIPTION

The following figure shows the SANDMAN POCKET amplifier box in which the main parts are indicated:

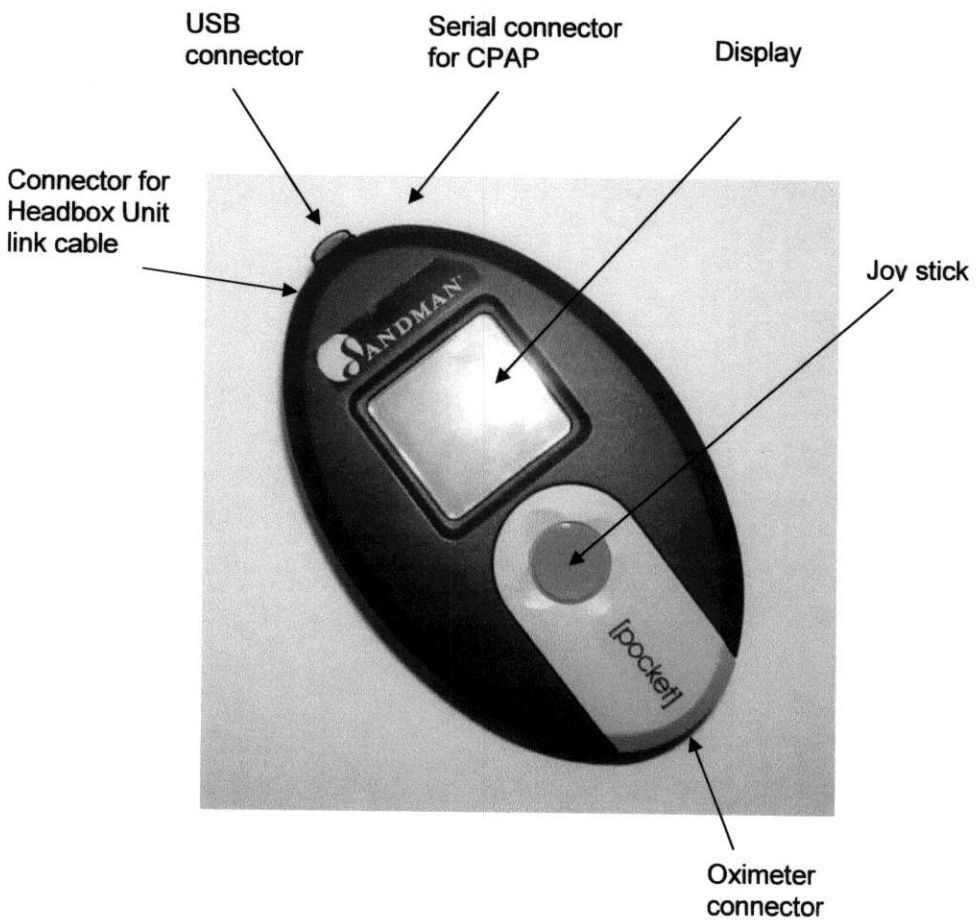
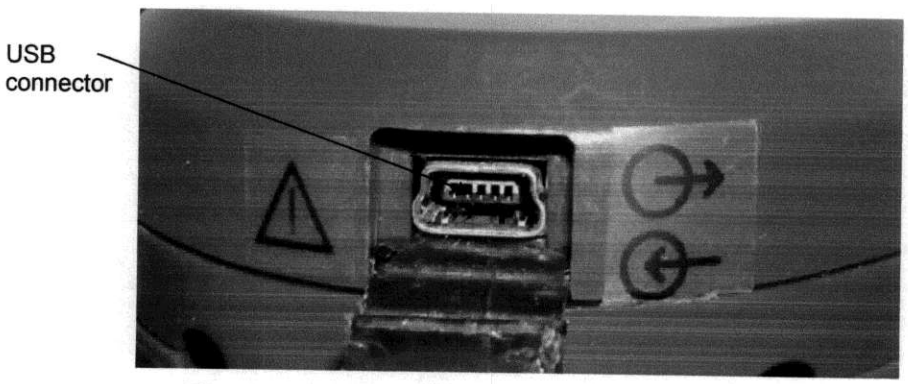


Figure 2-8 – SANDMAN POCKET amplifier box

2.3.1 CONNECTORS DESCRIPTION

The following figures show in details the connectors of SANDMAN POCKET amplifier module:



Figures 2-9, 2-10 and 2-11 – Amplifier module connectors

Where:

1. **SERIAL CONNECTOR** (RS232 connector). This connector is used to connect the SANDMAN POCKET to the CPAP.

2. **USB** connector (USB 2.0 miniB). This connector is used to connect the SANDMAN POCKET to PC.

3. **SANDMAN HEADBOX CABLE** connector. This connector is used to connect the Recorder Unit with the Headbox Unit.

4. **OXIMETER LINK** connector (shroud). This connector is used to connect axclusively an oxymetry sensor (Nellcor Puritan Bennett model DS-100 A).

CAUTION

The amplifier uses a Nellcor Puritan Bennet (NPB) NELL-1 Pulse Oximetry module inside.
Use only with DS-100 A sensors or equivalent.

CAUTION

Use a serial connector to connect Sandman Pocket Recorder to NPB (Tyco) model GoodKnight 420/425 series CPAP device only or equivalent.

CAUTION

Use USB connector to connect sandman Pocket Recorder to a USB port of a host PC only.
Host PC must comply to IEC 60950 safety standard and powered through an IEC 60601-1 safety standard compliant.

CAUTION

The OXIMETER LINK connector is protected from dust and dirt by a plug. Remove this plug in when connecting the oximetry sensor (NPB DS-100 A). When is the sensor removed, replace the protection plug.

CAUTION

The USB connector is protected from dut and dirt by a plug. Remove this plug when connecting to the Host PC. When the Host PC connection is removed, replace the protection.

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2.4 PULSE OXIMETRY MODULE

The SANDMAN POCKET recorder unit contains the Nellcor pulse oximetry module, model NELL-1. The NELL-1's major features are to interface with sensors and provide a Host system with patient data such as:

- Oxygen saturation (SpO2)
- Pulse rate
- Pulse waveform and pulse amplitude modulation (Blip)
- Motion indicator
- Sensor disconnect indicator
- Sensor off patient indicator

The NELL-1 is capable of communicating with the Host via a serial communication link.

2.4.1 INTENDED USE OF THE PULSE OXIMETRY MODULE.

The SANDMAN POCKET device constitutes "simply" the acquiring front end of SpO_2 and pulse rate data. In particular, notice that:

- The SANDMAN POCKET device limits its role to allow the host system to control of the NELL-1 module and to read the calculated data values.
- The SANDMAN POCKET device does not rely in any way with the processing of the SpO_2 and pulse rate data. These process are under the complete control and responsibility of the host system software.
- **The SANDMAN POCKET device is NOT involved in any alarm managing. The Pulse-Oximetry module of SANDMAN POCKET device is NOT intended for continuous monitoring.**
- The System Builder is responsible of the use of the oximetry data. In particular, the System Builder may assure that this use will meet the requirements of the EN 865 and ISO 9919 standards (if applicable).

CAUTION

Refer to section 1.3 of this manual for further warning notes on the Pulse Oximetry Module usage

For your notes:

CHAPTER 4
HOST COMPUTER - BATTERY

4.1 REQUIREMENTS FOR HOST COMPUTER

Application software on the host computer is under the responsibility of the System Builder. The System Builder must evaluate and validate the specific host, its Operative System, its minimum hardware/software and its safety requirements relating to the intended use / technical specification of the entire system.

When used to download the recorded data, the host computer must only provide a standard USB 2.0 compliant interface to be connected to the Sandman Pocket Recorder.

When the host computer is connected to the Sandman Pocket recorder during set-up or data acquisition monitoring (with the patient attached to the headbox unit of the recorder), the computer should be :

- a computer fully conforming to IEC 60601-1 standards (Medical grade computer)
- a computer conforming to IEC 60950 standard provided with an Isolation power transformer (IEC 60601-1 compliant).
- a battery powered laptop conforming to IEC 60950 standard

4.2 GENERAL PRECAUTIONS USING BATTERY

When the Sandman Pocket recorder is working in "Holter" modality, the only power source are the internal batteries. The batteries are housed in the specific space provided in the bottom part of the recorder unit of the Sandman Pocket. The batteries must always be present in the instrument during usage.

During the installation procedure of the batteries, observe the following warnings:

- Before replacing the batteries, make sure the device is not connected to the host PC.
- Remove the batteries when the recording has ended or when the device is not in use.
- Use completely full-charged batteries for each new recording.
- The use of batteries, which do not comply with the given ratings, will not guarantee a correct functioning and especially the recording endurance characteristics of the instrument.
- Alkaline batteries are not rechargeable and must be disposed of by following the regulations of the specific Country.

CAUTION

The Holter modality requires the internal battery kit. Use new batteries at each new recording session.

CAUTION

The Sandman Pocket Recorder must be equipped with the following battery cells: n°3 alkaline dry cell AA Size - V =1.5 Vn.

4.3 BATTERY REPLACEMENT

The condition of low charge batteries is shown on the display of the device by a dedicated message. With reference to the following figure, replace the internal main batteries by following the suggested procedure.

The batteries must necessarily be substituted with batteries having the same characteristics. The use of batteries that differ from those specified does not guarantee a correct functioning of the instrument with special regards to the recording range of the instrument.

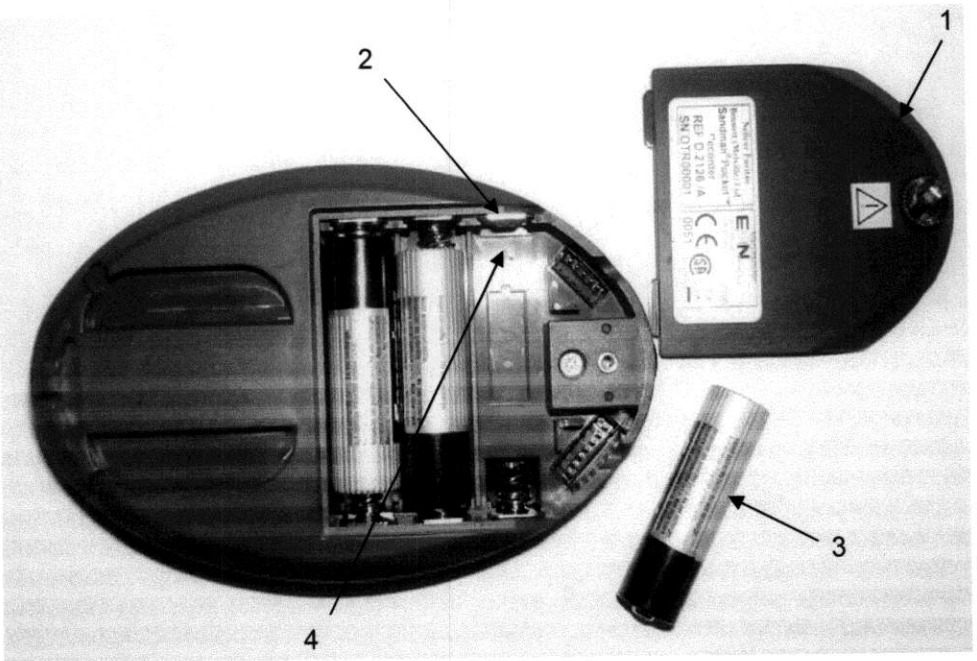

Fig. 4.2.1 – Replacement of the batteries

To replace the batteries :

- Disconnect the device from any other system or auxiliary unit.
- Remove the cover (ref. **1**) of the battery housing placed on the instrument's lower panel by pressing with a finger towards the direction shown on the cover itself.
- Remove the 3 battery cells from the housing one at a time, avoiding damage to the electric contacts (ref. **2**) placed on the internal side of the housing.
- Keep the discharged batteries separate from the new ones. The discharged batteries cannot be used again and they must be disposed of.
- Wait at least 30 seconds and then insert the 3 new battery cells (ref. **3**) paying CAUTION to the polarity as shown on the bottom of the housing (ref. **4**). The newly inserted batteries must absolutely correspond to the type indicated by EBNeuro and must also have the same characteristics.
- Replace the cover of the battery housing by inserting it in the proper runners and push it until it is completely closed. The correct positioning is signaled by a "click".

Before using the instrument, ensure that the batteries have been correctly inserted in their housing by checking also their polarity orientation. Remove batteries from the instrument each time the recording has ended and when the instrument is not in use.

The replaced batteries cannot be used again in any way. The discharged batteries must be disposed of in accordance with the waste regulations of the country in which the instrument is in use.

CHAPTER 5
CONNECTIONS

5.1 CONNECTING THE SYSTEM

With reference to the description of the device (chapter 2 of this manual) please install the SANDMAN POCKET amplifier system by performing the connections described in the following steps and images.

5.1.1 HOLTER MODALITY

In this modality, the SANDMAN POCKET works stand-alone. The Recorder Unit does not utilize all peripherals in Low Power Mode (LPM). The SANDMAN POCKET executes the data acquisition, the A/D conversion and the storage in the internal memory.
In Holter modality the only power sources are the batteries.

CAUTION

The EBNeuro Sandman Pocket Recorder is not intended for the "end user", rather it is intended as an OEM product to be used by a "System Builder" as a piece of its own medical systems.

It is the responsibility of the System Builder to use the EBNeuro Sandman Pocket Recorder strictly following any technical specification and precaution of use described in this manual.

EBNeuro is not providing any sensor, lead or cable, nor any wearing system to the System Builder.

It is completely under the responsibility of the System Builder to provide all the accessories, any eventual wearing system and any related instruction in its system labeling and any necessary warnings against the correct connection and units/cable placing to avoid any possible strangulation risk. This applies in particular to the use of EBNeuro Sandman Pocket Recorder in pediatric studies.

CAUTION

The following figures are provided for reference only to show the interconnection of the parts of the system.

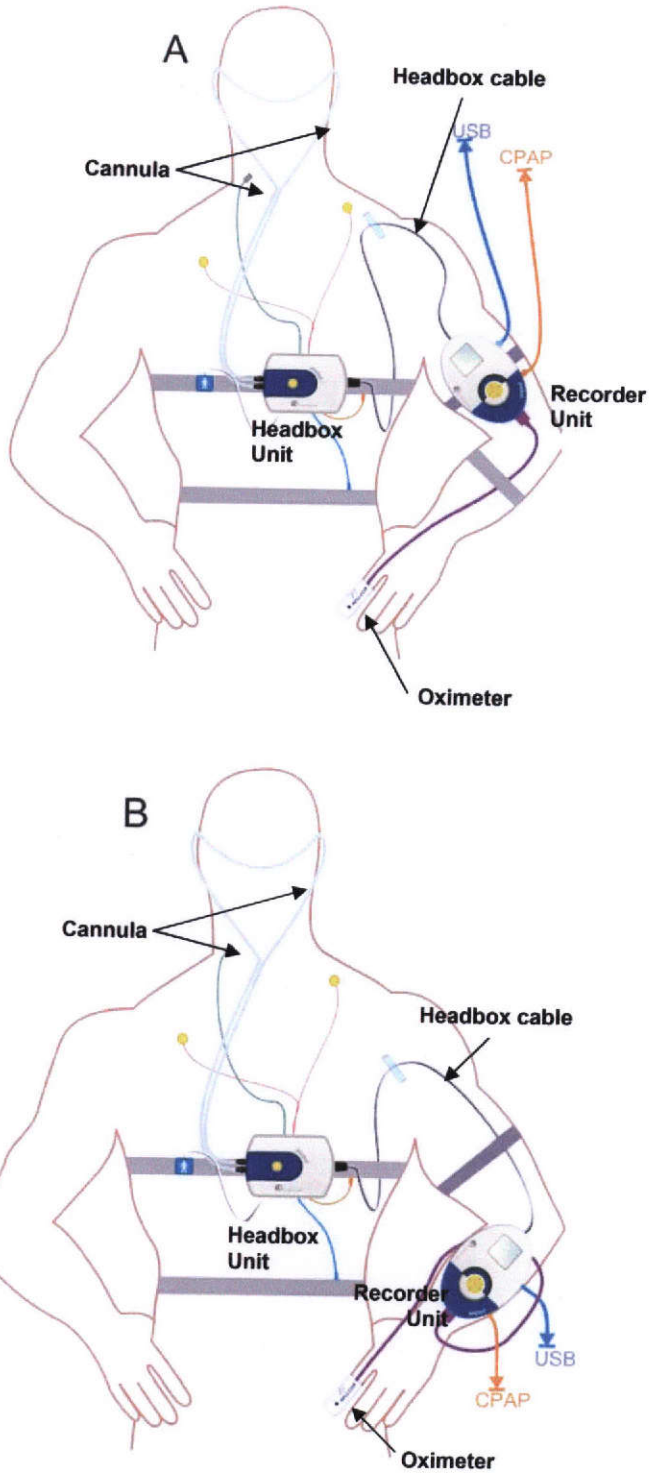

Figure 5.1.1 – SANDMAN POCKET amplifier system installation (reference examples only)

5.1.2 MONITORING MODALITY

In this modality, the SANDMAN POCKET is connected to a PC and executes the data transfer to the PC. The USB channel is active; the power supply can be draw from PC (500mA to 5V).

- Connect the Headbox Unit to the Recorder Unit with the **Headbox cable cod. B9730701001**.
- Connect through the USB port on the SANDMAN POCKET to the USB port of the HOST PC.

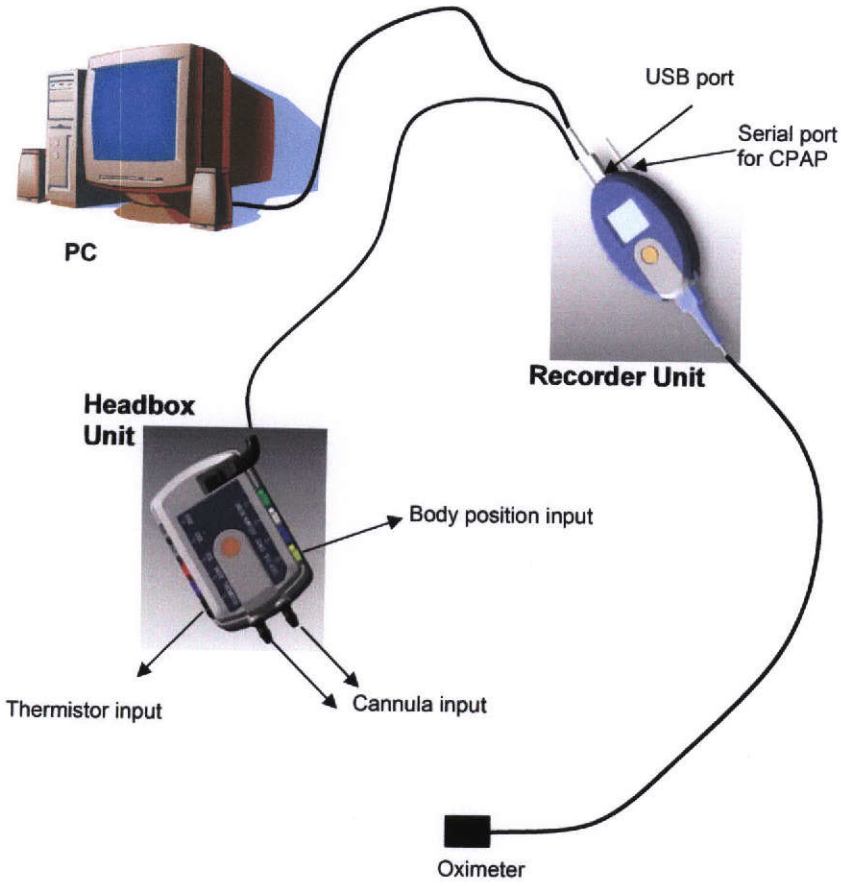

Figure 5.1.2 – SANDMAN POCKET Host Computer Connection

5.2 FINAL WARNINGS FOR THE PATIENT

Before leaving the laboratory, warn the patient that the electrodes must not be touched or moistened and that the lead wires must not be pulled in any way.

The unit has an event recorder button. Patient can press the key to highlight an event. Physician must inform the patient about the correct use of these features.

CAUTION

The patient should be informed on the correct use of the recorder's functional keys.

CAUTION

The patient must not remove the batteries cover.

CAUTION

The patient must not connect any device to the USB connector and must not open the USB plug.

CAUTION

The patient must not remove electrodes.

Physician must inform the patient about the correct use of the unit .

CHAPTER 8
MAINTENANCE

8.1 GENERAL INFORMATION ABOUT MAINTENANCE

In order to keep the device working for a long time and to ensure the patient's and the operator's safety, it is necessary that the general checks indicated below are periodically performed by medical or paramedical qualified staff or by technical staff authorized by EBNeuro.

- Perform a sight inspection of all the components, the accessories, and the connections of the device to the peripherals in order to identify any traces of failure, damage, or disconnection.
- Verify that all labels and any warning or instructions printed on the device are readable.
- Check that the performances and the workings of the device are correct.
- Clean the external surface of the device carefully with the recommended products only.
- Replace parts or accessories only with others having the same characteristics or those expressly indicated by EBNeuro.
- Discard replaced parts, accessories, and the device at its "end of life" according to the local standards and directives currently in force.

For all ordinary maintenance operations pertaining to the devices of the SANDMAN POCKET system (electromedical system to which the SANDMAN POCKET device is connected or auxiliary components not produced by EBNeuro such as personal computers, monitors, printers, consumers accessories and so on), please refer to the corresponding user's manual provided with them.

For detailed information on battery installation, substitution and recharge operation of the auxiliary batteries of the SANDMAN POCKET system, refer to the appropriate paragraphs of Chapter 6.

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8.2 SAFETY CHECKS

It is essential to periodically check the equipment and the devices or systems it is connected to and all the interconnection cables in order to ensure that the equipment continues working efficiently and safely. It is also necessary to check the equipment to remove any dust deposits. Preventive or corrective maintenance operations must be performed by qualified technical staff expressly authorized by EBNeuro.

A sight inspection of the interconnection cables, with particular care for the cable between equipment and the AC/DC adapter and for all the power cords (mains cable), can be performed also by medical or paramedical staff in order to remark any breaking or disconnection. In case of need, immediately contact a qualified technician to solve the problem detected before continuing to use the equipment or connecting it to other devices. For the technical assistance request procedures, please refer to chapter "Request for assistance" of the manual.

CAUTION

Safety checks must be accurately performed periodically and at least twice a year.

8.2.1 ENVIRONMENT ELECTRICAL EQUIPMENT

A danger for the patient's health is determined, first of all, by the efficiency of the electrical equipment of the building where the equipment is used. The isolation safety guaranteed by Class I to which the device belongs is useless, in the event the device is powered by the specified external AD/DC adapter or it is connected to a device or a system supplied by the mains, if the wiring is not provided with a good earth plate, accessible though the mains outlet.

It is fundamental that qualified technicians check the electric wiring periodically with particular care for efficiency of the main outlets.

CAUTION

If the integrity of the environment's electrical equipment, and in particular the protective earth, is not reliable for safety, do not power or use the equipment until the safety conditions are restored.

8.2.2 INTERCONNECTION CABLES AND CONNECTORS

It is necessary to check periodically the integrity of the interconnection cables between the instrument and the other devices that compose the system.

Elementary precautions may prevent prematurely breaking or deteriorating of the cables. Be careful when removing the cables from the corresponding connectors on the equipment panel; take the cable terminal connector resolutely, though with delicacy, out of the connector. Avoid twisting or tearing cables, which may cause breaks and interruptions to the conductors.

Monthly check cables for abrasion and wear. Replace any cable with exposed wire or shield.

Check the connectors on the ends of cable for bent or broken pins. Replace the cable with damaged connector.

8.3 CLEANING THE DEVICE

It is necessary to keep the equipment clean in order to avoid dust deposits, which could interfere with the efficiency of all the system components.

WARNING

Do not immerse the equipment nor its parts in liquids, do not oil any part of it and avoid cleaning the external surface with alcoholic disinfectants that could cause damages and decolorization of the printed surfaces

CAUTION

Before cleaning any part of the equipment turn off (O) the equipment power switch and disconnect the equipment from any other equipment or external devices and remove the internal batteries.

CAUTION

The external surface of the equipment must be cleaned with a cloth lightly moistened with warm water and soap. Wipe the washed parts with a dry cloth.

CAUTION

Make sure no liquid seeps into the instrument and check it's complete dryness before inserting the batteries or before connecting it with other devices, thus switching it on.

CAUTION

Avoid contact of the device with the patient's skin. If necessary, use a biocompatible bag.

8.4 PARTICULAR WARNINGS FOR CRITICAL COMPONENTS

The instrument is provided with a LCD (Liquid Crystal Display), and it uses alkaline battery cells, which contain small quantities of toxic materials.

In order to avoid personal injuries and to reduce the negative impact on the environment, make sure you carefully follow these instructions:

LDC Display:

- The LCD is fragile (glass) and must be treated with much care: for this reason we recommend protecting the device with the proper carrying bag during transportation or when it is not used.
- In the event that the LCD glass should break and liquid spill out of it, make sure you do not touch it. Wash with water for at least 15 minutes any body part that may have been in contact with it carefully. Should you experience any symptom after this period, ask for immediate medical help.

Batteries:

- Avoid terminal parts of the battery pack coming in contact with metal objects.
- Keep the battery pack away from heat sources or flames.
- Do not immerse the battery pack and avoid exposing it to rain or humidity.
- Avoid directly hitting the battery pack.
- Do not attempt to disassemble, burn or cause short-circuits to the battery. Such operations may cause a fire or emission of toxic chemical substances.
- Remove the battery at the end of the recording.

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CHAPTER 11
REQUEST FOR ASSISTANCE

11.1 OBTAINING SERVICE

In case of problems, such as failure of the device, or in case of partial or incorrect working that cannot be solved through usual maintenance operations, please contact one of the main offices or branches of EBNeuro or the nearest retailer or authorized servicing center.

CAUTION

In case of failure of the device or if it starts working in a way not complying with what is written in the manual, especially as far as safety is concerned, STOP USING IT IMMEDIATELY and contact the technical service. Do not use the device until the safety conditions have been checked and restored.

NOTE

In order to speed up the procedures to start the intervention of the technical service and to make it easier for the specialized technical staff to identify the problem on the first phone call by the customer, please fill in the form below in this page.
The equipment data may be found on the equipment identification label.

REQUEST FOR ASSISTANCE

EBNeuro Device/system name.....

EBNeuro Device code/reference number (REF) .....

Serial number (SN) or lot number (LOT) .....

Current software version (Rel) .....

11.2 EBNEURO MAIN OFFICES

Please find below the addresses of the EBNeuro main offices.

OPERATING OFFICES

EBNeuro S.p.A.
Operatine office:
FIRENZE
Via Pietro Fanfani, 111/A
50127 - Firenze
Phone 055-4565111
Fax 055-4565123

EBNeuro S.p.A.
Operatine office:
VERONA
Via Bologna, 1
37020 - Arbizzano di Valpolicella (VR)
Phone 045-6028111
Fax 045-6028100

