Records processed under FOIA Request # 2015-5161; Released by CDRH on 10-22-2015

tyco Healthcare

Puritan Bennett

Nellcor Puritan Bennett (Melville)
303 Terry Fox Drive
Suite 400
Kanata, Ontario K2K 3J1

Tele: 613 238-1840
Fax: 613 238-1291

K030611

510(k) Summary

MAR 2 4 2003

Submitter Information

Nellcor Puritan Bennett (Melville) Ltd.
400-303 Terry Fox Drive
Kanata, Ontario K2K 3J1
Canada

Contact person

Rob Matheson
Regulatory Affairs Associate
Phone: 613-238-1840 ext. 288
Fax: 613-238-1291

Date Prepared: February 24, 2003

Trade Name:	Suzanne Portable Recording system
Common Name:	Portable Polysomnographic Recorder
Classification Name:	Ventilatory Effort Recorder
Classification Number:	MNR-21CFR 868.2375

Predicate Devices

K990565	Suzanne Polysomnographic Recorder	Nellcor Puritan Bennett
K021090	N-550 Pulse Oximeter	Nellcor Puritan Bennett

Proposed Device Description

The *Suzanne System* is composed of a data recorder that contains the electronics and software necessary to capture the physiological information of each sensor and to store this information in a Flash card or to send it to a computer via a serial communication port.

The information that can be recorded by the *Suzanne System* is :

- EEG signals
- ECG signals
- Pressure signals
- Thoracic movements

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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- Abdominal movements
- Breath detection (through bucco-nasal thermistor)
- Flow (through pneumotachometer)
- Envelope of ambient sound
- Body position
- Ambient light detection
- Arterial oxyhemoglobin saturation (SpO_2)
- Pulse rate

The signals are amplified by different amplifiers contained in elements of the system known as headboxes. When used in a home environment, the data is recorded in the flash card and the clinician uses a setup unit to check that the system works correctly and to set the recording starting time.

When used in a clinical environment, the system can be used as described above or data can be recorded to a computer with the use of a PC application software.

The system is powered by an internal battery or by a DC power supply.

Intended Use

The Nellcor Puritan Bennett Suzanne is intended for use in collecting and recording physiological data to be used in diagnosing sleep disorders.

A pediatric through adult patient population is intended for the Suzanne, which can be used in either home or hospital environments.

Summary of Technological Characteristics of the Device Compared to the Legally Marketed (Unmodified) Device

The proposed Suzanne has the same technological characteristics as the above referenced predicate device, the unmodified Suzanne. The proposed version of the device has been modified by adding new pulse oximetry technology.

Tests Performed to Support Determination of Substantial Equivalence

Clinical and non-clinical tests were performed to support the determination of substantial equivalence.

Conclusions

The technological characteristics of the modified Suzanne and the results of clinical and non-clinical tests do not raise any new questions of safety or effectiveness when compared to the legally marketed (unmodified) device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5161; Released by CDRH on 10-22-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 4 2003

Mr. Rob Matheson
Regulatory Affairs Associate
Nellcor Puritan Bennett (Melville) Limited
400-303 Terry Fox Drive
Kanata, Ontario K2K 3J1
CANADA

Re: K030611
Trade/Device Name: Suzanne Polysomnograph System
Regulation Number: 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: February 25, 2003
Received: February 26, 2003

Dear Mr. Matheson:

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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5161; Released by CDRH on 10-22-2015

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 (301) 594-4646. 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/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5161; Released by CDRH on 10-22-2015

510(k) Number (if known): _____

Device Name: Suzanne Polysomnograph System

Indications for Use:

The Nellcor Puritan Bennett Suzanne is intended for use in collecting and recording physiological data to be used in diagnosing sleep disorders.

A pediatric through adult patient population is intended for the Suzanne, which can be used in either home or hospital environments.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number K030611

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5161; Released by CDRH on 10-22-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services
Food and Drug Administration

Memorandum

Date: 9-22-09

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K030611/A1

To: Division Director: AN/DAGID

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

_____ Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

_____ Additional information requires a new 510(k); however, the information submitted is incomplete; (Notify company to submit a new 510(k); [Prepare the K30 Letter on the LAN]

_____ No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement, change of address, phone number, or fax number).

CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440

_____ Information requires a **CLIA CATEGORIZATION**; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

_____ Additional information requires a **CLIA CATEGORIZATION**; however, the information submitted is incomplete; (call or fax firm)

_____ No response necessary

This information should be returned to the DMC within 10 working days from the date of this Memorandum.

Reviewed by: [signature] 11/16/09

Date: 11/16/09

POS

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5161; Released by CDRH on 10-22-2015

K030611/A1

COVIDIEN

September 16, 2009

FDA CDRH DMC

SEP 22 2009

Received

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Re: Transfer of Ownership of 510(k)s

Dear Sir/Madam:

This letter is to notify FDA that Covidien (formerly known as Tyco Heathcare or Puritan Bennett) has sold the following 510(k)s to Embla Systems, Inc.:

- K934599, Sandman
- K030611, Modification to Suzanne Portable Polysomnograph

As Embla Systems is the manufacturer and 510(k) holder, Covidien requests that FDA transfer ownership of these 510(k) numbers to Embla.

If you have any questions regarding this notification, please contact me at:

tel: 303-305-2362
email address: fran.harrison@covidien.com

Respectfully,

Frances E. Harrison, RAC
Vice President, Regulatory Affairs

1435

6135 Gunbarrel Avenue
Boulder, CO
80301

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5161; Released by CDRH on 10-22-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 4 2003

Mr. Rob Matheson
Regulatory Affairs Associate
Nellcor Puritan Bennett (Melville) Limited
400-303 Terry Fox Drive
Kanata, Ontario K2K 3J1
CANADA

Re: K030611
Trade/Device Name: Suzanne Polysomnograph System
Regulation Number: 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: February 25, 2003
Received: February 26, 2003

Dear Mr. Matheson:

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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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5161; Released by CDRH on 10-22-2015

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 (301) 594-4646. 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/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5161; Released by CDRH on 10-22-2015

510(k) Number (if known): _____

Device Name: Suzanne Polysomnograph System

Indications for Use:

The Nellcor Puritan Bennett Suzanne is intended for use in collecting and recording physiological data to be used in diagnosing sleep disorders.

A pediatric through adult patient population is intended for the Suzanne, which can be used in either home or hospital environments.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K030611

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5161; Released by CDRH on 10-22-2015

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

February 26, 2003

NELLCOR PURITAN BENNETT (MELVILLE)
400-303 TERRY FOX DRIVE
KANATA, ONTARIO,
CANADA K2K 3J1
ATTN: ROB MATHESON

510(k) Number: K030611
Received: 26-FEB-2003
Product: MODIFICATION TO SUZANNE PORTABLE POLYSOMNOGRAPH SYSTEM

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification 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.

As a reminder, we would like to mention that FDA requires all 510(k) submitters to provide an indications for use statement on a separate page. If you have not included this indications for use statement in addition to your 510(k) summary (807.92), or a 510(k) statement (807.93), and your Truthful and Accurate statement, please do so as soon as possible. If the above mentioned requirements have been submitted, please do not submit them again. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at the telephone or web site below for more information.

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 DMC 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.

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMICA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

K 030611

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tyco Healthcare

Puritan Bennett

Nellcor Puritan Bennett (Melville) Ltd.
303 Terry Fox Drive, Suite 400
Kanata, ON K2K 3J1

Tele: 613 238-1840
Fax: 613 238-1291

February 25, 2003

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

2003 FEB 26 P 12:15

Subject: Nellcor Puritan Bennett (Melville) Ltd.
Suzanne Polysomnograph system
Special 510(k)

Dear Sir or Madam:

Pursuant to the requirements of Section 510(k) of the Federal Food, Drug and Cosmetic Act, Nellcor Puritan Bennett (Melville) Ltd., hereby notifies the FDA of our intention to market the above referenced device.

The purpose of this Special 510(k) submission for the ***Suzanne***™ polysomnograph system is to document the replacement of Nellcor MP205 pulse oximetry with Nellcor MP506 pulse oximetry. The MP205 pulse oximeter was cleared with the ***Suzanne*** system via K990565.

This submission does not involve any changes to the indications for use of the ***Suzanne*** system.

A previous Special 510(k) (K022628) was found NSE on the grounds of non-responsiveness. A memo found under TAB 2 of this submission clarifies the issue that resulted in the NSE finding.

We believe that the information contained herein sufficiently demonstrates substantial equivalence to a legally marketed device. Should additional information be required, it can be requested from the company representative listed below.

We appreciate the FDA's time and consideration in reviewing this submission and hope that a decision will be reached as quickly as possible.

Sincerely,

Rob Matheson

Rob Matheson
Regulatory Affairs Associate
Nellcor Puritan Bennett (Melville) Ltd.
(613) 238-1840 ext. 288
(613) 238-1291 fax
rob.matheson@tycohealthcare.com

AW II

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

K020 20

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Table of Contents

1 Table of Contents

2 Memo of Clarification on K022628

3 CDRH Submission Cover Sheet

4 Screening Checklist for 510(k)

5 Truthful and Accurate Statement

6 Administrative Information

7 Indications for Use Statement

8 510(k) Summary

9 Device Modification Description

10 Enhancements Made Since K990565

11 Substantial Equivalence Comparison

12 Oximeter Extension Cable Drawing (F090654)

13 Software

14 Biocompatibility and Sterility

15 Scientific Technology Statement

16 Proposed Labeling – Clinician's Guide

17 Proposed Labeling – Marketing Brochure

18 Declaration of Conformity with Design Controls

19 Design Control Activities

20 Risk Analysis

21 Benchtop Verification Tests

22 Clinical Validation Tests

23 Safety Standards

24

25

26

27

28

29

30

31

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5161; Released by CDRH on 10-22-2015

Memo of Clarification on K022628

The FDA raised a number of issues pertaining to K022628. Some issues were not completely resolved by the time K022628 was found NSE by reason of non-responsiveness.

These issues were addressed in a conference call with Joanna Weitershausen (FDA) and Nellcor Puritan Bennett (Melville) Ltd. representatives on February 20, 2003. An explanation of the issues follows.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5161; Released by CDRH on 10-22-2015

CDRH SUBMISSION COVER SHEET

Date of Submission: February 24, 2003 **FDA Document Number:**

Section A — Type of Submission

PMA	PMA Supplement	PDP	510(k)	Meeting
Original Submission ☐ Modular Submission ☐ Amendment ☐ Report ☐ Report Amendment	☐ Regular ☐ Special ☐ Panel Track ☐ 30-day Supplement ☐ 30-day Notice ☐ 135-day Supplement ☐ Real-time Review ☐ Amendment to PMA Supplement	☐ Presubmission Summary ☐ Original PDP ☐ Notice of intent to start clinical trials ☐ Intention to submit Notice of Completion ☐ Notice of Completion ☐ Amendment to PDP ☐ Report	Original Submission: ☐ Traditional ☒ Special ☐ Abbreviated ☐ Additional Information: ☐ Traditional ☐ Special ☐ Abbreviated ☐ Report Amendment	☐ Pre-IDE mtg. ☐ Pre-PMA mtg. ☐ Pre-PDP mtg. ☐ 180-Day mtg. ☐ Other (specify):

IDE	Humanitarian Device Exemption	Class II Exemption	Evaluation of Automatic Class III Designation	Other Submission
☐ Original submission ☐ Amendment ☐ Supplement	☐ Original submission ☐ Amendment ☐ Supplement ☐ Report	☐ Original Submission ☐ Additional Information	☐ Original Submission ☐ Additional Information	Describe Submission:

Section B — Applicant or Sponsor

Company/Institution Name: **Nellcor Puritan Bennett (Melville) Ltd.**	Establishment registration number: **9680138**
Division Name (if applicable):	Phone number (include area code): **613-238-1840 ext. 288**
Street Address: **400-303 Terry Fox Drive**	Fax number (include area code): **613-238-1291**

City: **Kanata**	State/Province: **Ontario**	Zip code: **K2K 3J1**	Country: **Canada**

Contact Name: **Rob Matheson**

Contact Title: **Regulatory Affairs Associate**	Contact e-mail address: **rob.matheson@tycohealthcare.com**

Section C — Submission Correspondent (if different from above)

Company/Institution Name:	Establishment registration number:
Division name (if applicable)	Phone number (include area code):
Street Address:	Fax number (include area code):

City:	State/Province:	Zip Code:	Country

Contact Name:

23

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5161; Released by CDRH on 10-22-2015

Section D1 — Reason for Submission – PMA,PDP, or HDE

☐ New Device
☐ Withdrawal
☐ Additional or Expanded Indications
☐ Licensing Agreement

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

☐ Location Change:
☐ Manufacturer
☐ Sterilizer
☐ Packager
☐ Distributor

☐ Processing Change:
☐ Manufacturing
☐ Sterilization
☐ Packaging
☐ Other (specify below)

☐ Labeling Change:
☐ Indications
☐ Instructions
☐ Performance Characteristics
☐ Shelf Life
☐ Trade Name
☐ Other (specify below)_

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

☐ Response to FDA correspondence:
☐ Request for applicant hold
☐ Request for removal of applicant hold
☐ Request for extension
☐ Request to remove or add manufacturing site

☐ Change in Ownership
☐ Change in correspondent

☐ Other Reason (specify):

Section D2 — Reason for Submission - IDE

☐ New device
☐ Addition of institution
☐ Expansion/extension of study
☐ IRB certification
☐ Request hearing
☐ Request waiver
☐ Termination of study
☐ Withdrawal of application
☐ Unanticipated adverse effect
☐ Notification of emergency use
☐ Compassionate use request
☐ Treatment IDE
☐ Continuing availability request

Change in:
☐ Correspondent
☐ Design
☐ Informed consent
☐ Manufacturer
☐ Manufacturing process
☐ Protocol – feasibility
☐ Protocol – other
☐ Sponsor

☐ Report Submission:
☐ Current investigator
☐ Annual progress
☐ Site waiver limit reached
☐ Final

☐ Response to FDA letter concerning:
☐ Conditional approval
☐ Deemed approval
☐ Deficient final report
☐ Deficient progress report
☐ Deficient investigator report
☐ Disapproval
☐ Request extension for time to respond to FDA
☐ Request meeting

☐ Other reason (specify):

Section D3 — Reason for Submission – 510(k)

☐ New Device
☐ Additional or expanded indications
☐ Other reason (specify):

☐ Change in technology
X Change in design

☐ Change in materials
☐ Change in manufacturing process

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5161; Released by CDRH on 10-22-2015

Section E **Additional Information on 510(k) Submissions**

Product codes of devices to which substantial equivalence is claimed:				Summary of, or statement concerning safety and effectiveness data:
1 **MNR**	2 **DQA**	3 **DPZ**	4	x 510(k) summary attached
5	6	7	8	☐ 510(k) statement

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade of Proprietary or model name	Manufacturer
1 **012891**	1 **Oximax Pulse Oximetry System**	1 **Nellcor Puritan Bennett**
2 **021090**	2 **OxiMax N-550 Pulse Oximeter**	2 **Nellcor Puritan Bennett**
3 **990565**	3 **Suzanne Portable Polysomnograph System**	3 **Nellcor Puritan Bennett**
4	4	4
5	5	5
6	6	6

Section F **Product Information – Applicable to All Applications**

Common or usual name or classification name: *Ventilatory Effort Recorder*

Trade or proprietary or model name	Model Number
1 **Suzanne Portable Polysomnograph** System	1
2	2
3	3
4	4
5	5

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

1 **990565**	2 **971946**	3 **923402**	4 **910452**	5 **964433**	6 **961643**
7 **844809**	8 **964494**	9 **021090**	10 **012891**	11 **022628**	12 **913749**

Data included in submission: x Laboratory Testing ☐ Animal Trials ☐ Human Trials

Section G **Product Classification – Applicable to All Applicants**

Product code: **MNR**	C.F.R. Section 868.2375	Device Class: ☐ Class I x Class II ☐ Class III ☐ Unclassified
Classification Panel: **Anesthesiology**		
Indications (from labeling): **See Indications for Use Section of Submission**		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5161; Released by CDRH on 10-22-2015

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

Section H **Manufacturing/Packaging/Sterilization Sites Relating to a Submission**

x Original ☐ Add ☐ Delete	FDA establishment registration number: 9680138	x Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager/relabeler
Company/Institution name: **Nellcor Puritan Bennett (Melville) Ltd.**		Establishment registration number: **9680138**	
Division name (if applicable):		Phone number (include area code): **613-238-1840 ext. 28**	
Street address: **400-303 Terry Fox Drive**		FAX number (include area code): **613-238-1291**	
City **Kanata**	State/Province **Ontario**	Zip code: **K2K 3J1**	Country **Canada**
Contact name: **Rob Matheson**			
Contact title: **Regulatory Affairs Associate**			

☐ 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 (include area code):	
Street address:		FAX number (include 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 (include area code):	
Street address:		FAX number (include area code):	
City:	State/Province:	Zip code:	Country:
Contact name:			
Contact title:		Contact e-mail address:	

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SCREENING CHECKLIST FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: _____

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

X Special 510(k) - Do Sections 1 and 2

☐ Abbreviated 510(k) - Do Sections 1, 3 and 4

☐ Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present	Inadequate or Missing
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.	**FIRST PAGE**	
Table of Contents.	**TAB 1**	
Truthful and Accurate Statement.	**TAB 5**	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	**TAB 6**	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	**TAB 6**	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.	**TAB 16, 17**	
Statement of Indications for Use that is on a separate page in the premarket submission.	**TAB 7**	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510)] Manual.	**TAB 11**	
510(k) Summary or 510(k) Statement.	**TAB 8**	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	**TAB 9**	
Identification of legally marketed predicate device. •	**TAB 8**	
Compliance with performance standards. • [See Section 514 of the Act and 21 CFR 807.87 (d).]		
Class III Certification and Summary. **		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]		
510(k) Kit Certification ***		

• - May not be applicable for Special 510(k)s.

** - Required for Class III devices, only.

*** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

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Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing
Name and 510(k) number of the sponsor's own, unmodified predicate device.	TAB 8	
A description of the modified device and a comparison to the sponsor's predicate device.	TAB 11	
A statement that the intended use(s) and indications of the modified device, as described in its labeling, are the same as the intended uses and indications for the sponsor's unmodified predicate device.	TAB 7	
A statement that the modification has not altered the fundamental technology of the sponsor's predicate device.	TAB 15	
A Design Control Activities Summary that includes the following elements (a-e):	(no entry here)	(no entry here)
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.	TAB 20	
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.	TAB 21, 22, 23	
c. A Declaration of Conformity with design controls that includes the following statements:	TAB 18	

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A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.	**TAB 20**	
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.	**TAB 18**	

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE Required Elements for a Declaration of Conformity to a Recognized Standard, which is posted with the 510(k) boilers on the H drive.]		

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For a submission, which relies on a recognized *standard without a declaration of conformity*, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has not been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in *order to determine substantial equivalence.*		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

• - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:		
b) Sterilization and expiration dating information:		
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
c) Software Documentation:		

Items with checks in the "Present but Deficient" column require additional information from the sponsor. Items with checks in the "Missing" column must be submitted before substantive review of the document.

Passed Screening _____Yes _____No

Reviewer:_____

Concurrence by Review Branch:_____

Date:_____

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Puritan Bennett

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Tele: 613 238-1840
Fax: 613 238-1291

Premarket Notification
Truthful and Accurate Statement

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Regulatory Affairs Associate of Nellcor Puritan Bennett (Melville) Ltd., 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.

Rob MaTheson
Signature

Rob Matheson, Regulatory Affairs Associate

2/25/03
Date

Premarket Notification [510(k)] Number

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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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, Nellcor Puritan Bennett (Melville) Ltd. submits the following information as premarket notification.

Type of Submission:	Special 510(k)
Proprietary Name:	Suzanne Polysomnograph System
Classification Name:	Ventilatory Effort Recorder
Classification Number:	MNR-21 CFR 868.2375
Classification:	Class II
Classification Panel:	Anesthesiology
Performance Standard:	None established under section 514
Applicant Registration:	Nellcor Puritan Bennett (Melville) Ltd.'s Owner/Operator # is 9007043 and its Registration # is 9680138.
Address:	Nellcor Puritan Bennett (Melville) Ltd. 400-303 Terry Fox Drive Kanata, Ontario K2K 3J1 Canada

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Fax: 613 238 1291

I certify that in my capacity as Regulatory Affairs Associate of Nellcor Puritan Bennett (Melville), Ltd. that the modifications described in the labeling of this Special 510(k) submission do not change the intended use and indications of the device.

R. L. Matheson

Name: Rob Matheson
Title: Regulatory Affairs Associate
Company: Nellcor Puritan Bennett (Melville) Ltd.

2/25/03
Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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510(k) Number (if known): _____

Device Name: Suzanne Polysomnograph System

Indications for Use:

The Nellcor Puritan Bennett Suzanne is intended for use in collecting and recording physiological data to be used in diagnosing sleep disorders.

A pediatric through adult patient population is intended for the Suzanne, which can be used in either home or hospital environments.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

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Puritan Bennett

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510(k) Summary

Submitter Information

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400-303 Terry Fox Drive
Kanata, Ontario K2K 3J1
Canada

Contact person

Rob Matheson
Regulatory Affairs Associate
Phone: 613-238-1840 ext. 288
Fax: 613-238-1291

Date Prepared: February 24, 2003

Trade Name:	Suzanne Portable Recording system
Common Name:	Portable Polysomnographic Recorder
Classification Name:	Ventilatory Effort Recorder
Classification Number:	MNR-21CFR 868.2375

Predicate Devices

K990565	Suzanne Polysomnographic Recorder	Nellcor Puritan Bennett
K021090	N-550 Pulse Oximeter	Nellcor Puritan Bennett

Proposed Device Description

The *Suzanne System* is composed of a data recorder that contains the electronics and software necessary to capture the physiological information of each sensor and to store this information in a Flash card or to send it to a computer via a serial communication port.

The information that can be recorded by the *Suzanne System* is :

- EEG signals
- ECG signals
- Pressure signals
- Thoracic movements

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- Abdominal movements
- Breath detection (through bucco-nasal thermistor)
- Flow (through pneumotachometer)
- Envelope of ambient sound
- Body position
- Ambient light detection
- Arterial oxyhemoglobin saturation (SpO_2)
- Pulse rate

The signals are amplified by different amplifiers contained in elements of the system known as headboxes. When used in a home environment, the data is recorded in the flash card and the clinician uses a setup unit to check that the system works correctly and to set the recording starting time.

When used in a clinical environment, the system can be used as described above or data can be recorded to a computer with the use of a PC application software.

The system is powered by an internal battery or by a DC power supply.

Intended Use

The Nellcor Puritan Bennett Suzanne is intended for use in collecting and recording physiological data to be used in diagnosing sleep disorders.

A pediatric through adult patient population is intended for the Suzanne, which can be used in either home or hospital environments.

Summary of Technological Characteristics of the Device Compared to the Legally Marketed (Unmodified) Device

The proposed Suzanne has the same technological characteristics as the above referenced predicate device, the unmodified Suzanne. The proposed version of the device has been modified by adding new pulse oximetry technology.

Tests Performed to Support Determination of Substantial Equivalence

Clinical and non-clinical tests were performed to support the determination of substantial equivalence.

Conclusions

The technological characteristics of the modified Suzanne and the results of clinical and non-clinical tests do not raise any new questions of safety or effectiveness when compared to the legally marketed (unmodified) device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Device Modification Description

The purpose of this submission is to document the replacement of the MP205 pulse oximetry printed circuit board in the ***Suzanne***™ Polysomnographic Recorder with the MP506 pulse oximetry printed circuit board. The ***Suzanne*** Polysomnographic Recorder was cleared under K990565 which included the MP205 board. In addition, the MP506 uses (b)(4) [redacted]

This submission is also intended to document the replacement of the external oximeter extension cable. The previous oximeter extension cable's circular connector had seven pins. (b)(4) [redacted] See attached drawing (b)(4) [redacted] (b)(4) [redacted].

The ***Sandman***® software used for reviewing data collected by the ***Suzanne*** system has not needed to change in order to work with the updated ***Suzanne*** system. The ***Sandman*** software is cleared under K934599. No new data streams are introduced to the software as a result of the replacement of the MP205 board with the MP506 board.

The replacement of the MP205 pulse oximetry printed circuit board with the MP506 pulse oximetry printed circuit board does not add new functions or intended uses to the Suzanne system but rather improves the existing performance in collecting oximetry data. The improved performance characteristics are listed below:

- MP506 oximetry technology utilizes a motion tolerant algorithm. This translates to more reliable oximetry readings when patient motion is present.
- Improved front end electronics for better signal processing performance in patients having reduced perfusion.

The MP506 pulse oximetry board includes a (b)(4) [redacted] was not available on the MP205 pulse oximetry board.

The MP506 board continues to provide the following data to the ***Suzanne*** system that was supplied by the MP205 board :

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- Oxygen saturation (SpO_2) – Blood oxygen saturation (specifications included on page 41 of Clinician's Guide)
- Pulse rate (specifications included on page 41 of Clinician's Guide)
- Pulse waveform and pulse amplitude modulation
- Sensor disconnection indicator

The oximetry feature is referenced on page 37 of the Clinician's Guide.

The following components are referenced in the Clinician's Guide and were also included in the original ***Suzanne*** 510(k) 990565. Where applicable the original 510(k) clearance number of the corresponding component is indicated.

Sensor	Manufacturer	FDA Clearance	Use
Pneumotachograph Kit	Hamilton Medical	K844809	CPAP airflow
Suzanne Effort Belt	Pro-Tech Services	K923402	Respiratory effort
Suzanne Airflow Sensor	Nellcor Puritan Bennett	K910452	Reusable airflow sensor
Patient Guide	Nellcor Puritan Bennett	N/A	Information piece for patients. One page in length covering what the unit does along with patient safety instructions
Fiber Optic Receiver and Communication Cable	Nellcor Puritan Bennett	K990565	Used in PC mode to avoid electrical link between Suzanne system and the computer

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The following components are newly referenced in the Clinician's Guide and were not included in the original ***Suzanne*** 510(k) 990565. Where applicable the original 510(k) clearance number of the component is indicated.
BreathSensors™ were incorporated into the ***Suzanne*** System via a Letter to File dated, April 14, 2000. The other sensors listed are being incorporated into the ***Suzanne*** system via this Special 510(k) submission, as they are required to take advantage of the MP506 pulse oximetry technology.

Adult BreathSensor	Edentec Corp.	K913749	Disposable airflow sensor
Child BreathSensor	Edentec Corp.	K913749	Disposable airflow sensor
Max-A Adhesive Sensor	Nellcor Puritan Bennett	K012891	Disposable Pulse Oximetry Sensor
Max-P Adhesive Sensor	Nellcor Puritan Bennett	K012891	Disposable Pulse Oximetry Sensor
OxiCliq A	Nellcor Puritan Bennett	K012891	Disposable Pulse Oximetry Sensor
OxiCliq P	Nellcor Puritan Bennett	K012891	Disposable Pulse Oximetry Sensor
Maxfast Adhesive Forehead Sensor	Nellcor Puritan Bennett	K012891	Disposable Pulse Oximetry Sensor

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Enhancements Made Since Last 510(k) Clearance (K990565)

The following changes to the Suzanne Polysomnograph System have been implemented, verified and validated since the last 510(k) clearance for the Suzanne Polysomnograph System, K990565. The changes are summarized below. These changes were validated and verified by a number of Technical Reports completed as part of the Design Control process. These changes were assessed per the CDRH 510(k) Memorandum # K97-1 *Deciding When to Submit a 510(k) for a Change to an Existing Device* and were determined not to require a new 510(k) premarket notification. Changes were documented as a rationale-to-file maintained on file at Nellcor Puritan Bennett (Melville) Ltd.

From a Letter to File dated November 15, 1999 the following changes were initiated to improve the Suzanne System for a number of practical reasons.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

(b)(4)

(b)(4)

(b)(4)

From a Letter to File dated April 14, 2000, the following changes were initiated to improve the Suzanne System for a number of practical reasons.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Labeling Changes

The changes listed above prompted changes in the Suzanne system's labeling. Many of the changes would not be perceived by the enduser (e.g. adding a more accurate 60Hz notch filter) and are not referenced in the Clinician's Guide. Other changes such as the internalization of the fiber optic transmitter or the ability to use Breathsensors required updates to the Clinician's Guide.

The following design changes in the Suzanne system required revisions to the Clinician's Guide:

(b)(4)

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Substantial Equivalence Comparison

The legally marketed (unmodified) predicate device for the Suzanne with MP506 oximetry is the current Suzanne with MP205 oximetry (cleared under 510(k) #K990565 on 8/18/99). The following table shows the similarities and differences between the MP506 Suzanne and the legally marketed MP205 Suzanne predicate device. The N-550 Oximeter, cleared under K021090, is used as a predicate as it employs the same MP506 pulse oximetry technology proposed for use with the Suzanne system.

The Suzanne system is capable of measuring and recording a range of physiological signals besides pulse oximetry. All signals other than pulse oximetry signals (e.g., EEG, EOG, EMG, respiratory, body motion, sound) remain unaffected in the way they are processed and recorded.

The terms, "substantially equivalent" and "substantial equivalence," are used in the context of Section 510(k) of the U.S. Food, Drug, and Cosmetic Act and have no bearing on matters pertaining to patents.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Substantial Equivalence Table

	K990565 Suzanne Polysomnographic Recorder	K021090 N-550 Pulse Oximeter	To be cleared with this submission MP506 Pulse Oximeter Board for use w/Suzanne
Pulse Oximeter Board	**MP205**	**MP506**	**MP506**
Motion Tolerant Algorithm	No	Yes	Yes
Calculation of Saturation / Rate in Simulated Motion Conditions	No	Yes	Yes
Front End Electronics / Signal Processing to perform in low Perfusion	No	Yes	Yes
Digital Sensor Interface / Calibration to Function w/MAXFAST Adhesive Forehead Sensor	No	Yes	Yes
Input	(b)(4)		
Oximeter sensors			
R11			
Negative Supply	-VSA0	N/A	N/A
Sp02 Saturation	Yes	Yes	Yes
Pulse rate	Yes	Yes	Yes
Pulse waveform	Yes	No	Yes
Pulse amplitude indicator	Yes	Yes	Yes
Sensor disconnected indicator	Yes	Yes	Yes

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Schematic Drawings

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Software

There have been no changes to the Suzanne System's firmware due to the addition of MP506 oximetry. The only changes to the Suzanne System's internal software since the original clearance (K990565) were recorded in memos to file dated, November 15, 1999 and April 14, 2000. These changes are addressed in the Enhancements Made Since K990565 section of this submission (see TAB 10).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Biocompatibility & Sterility

Biocompatibility does not apply to the Suzanne polysomnograph system since the unit is not intended to come into direct contact with the patient.

Sterility does not apply to the Suzanne polysomnograph system since the unit does not require sterilization.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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I certify that in my capacity as Regulatory Affairs Associate of Nellcor Puritan Bennett (Melville) Ltd. that the modifications described in this Special 510(k) submission do not change the fundamental scientific technology of the device.

Rob Matheson

Name: Rob Matheson
Title: Regulatory Affairs Associate
Company: Nellcor Puritan Bennett (Melville) Ltd.

2/25/13

Date

50

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

SANDMAN®

Clinician's Guide

The Suzanne™ Polysomnograph Recording System

tyco Healthcare

F182239

51

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Caution: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

Registered trademarks are property of their respective owners.
OxiCliq, Sandman and Nellcor are registered trademarks of Nellcor Puritan Bennett Inc.
MaxFast, OxiMax, BreathSensor and the Suzanne system are trademarks of Nellcor Puritan Bennett Inc.
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Manufacturer

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Mansfield, MA 02048
Tel. 1-800-962-9888

Corporate Headquarters

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675 McDonnell Blvd.
Hazelwood, MO 63042
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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TABLE OF CONTENTS

BEFORE YOU BEGIN 1
Introduction 1
Indications for Use 1
Warnings 2
Cautions 2
Symbols 3
Electrical Safety and Electromagnetic Compatibility 3
Unpacking and Inspecting the Suzanne system 4
Attended Configuration 4
Unattended Configuration 4
Related Publications 4
THE SUZANNE SYSTEM COMPONENTS 5
Recorder Plus 6
Operation 7
Headbox Combinations 8
Built-in Oximeter 8
Battery Operation 9
Battery Charging 9
DC Supply 9
Set Up Module 10
Slow Wave Headbox 11
Fast Wave Headbox 12
Fiber Optic Receiver 13
DC Isolation Module 13
USING THE SUZANNE SYSTEM 14
Patient Self-Preparation 14
Calibration 14
Assembling the Suzanne System 14
Attaching Sensors 16
Attaching Fast Wave Sensors 16
EEG Sensors 17
EMG Sensors 17
EOG Sensors 18
ECG Sensors 18
Attaching Slow Wave Sensors 19
Effort Belts 19
Thorax 19
Abdominal 19
Nasal/Oral Airflow (Reusable or Disposable) 20
Thermistor (Reusable) 20

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Records processed under FOIA Request # 2015-5161; Released by CDRH on 10-22-2015

BreathSensor™ (Disposable) 20
Microphone 20
External DC Input 21
Pressure Sensors 21
Flow Sensor Port 21
Pressure Sensor Port 21
Pneumotachograph Kit 22
SpO_2 and Pulse Rate Sensor (Nellcor OxiMax Pulse Oximeter) 23
USING THE SUZANNE SYSTEM WITH THE SETUP MODULE 24
Preparing for Setup 24
Setup and Configuration 25
USING THE SUZANNE SYSTEM WITH A PC 29
Setting Up 29
CHARGING THE BATTERY 30
CHANNEL ASSIGNMENTS - HEADBOX TO RECORDER PLUS 31
TROUBLESHOOTING 32
Common Problems 33
MAINTENANCE 34
Modules and Cables 34
Wearing System 34
Sensors 34
Pneumotachograph Kit 35
Battery Pack 35
TECHNICAL CHARACTERISTICS 36
Environmental Conditions 36
Battery Specifications 36
Power Consumption 36
Archiving of Flashcard Data 37
Recorder Plus 37
Set Up Module 38
Slow Wave Headbox 38
Fast Wave Headbox 39
DC Isolation Module 39
DC Power Supply 40
MP506 Performance 41
LIMITED WARRANTY 43
THE SUZANNE SYSTEM **ORDER NUMBERS 44**

55

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BEFORE YOU BEGIN

Introduction

The Suzanne™ System is a portable multi-channel polysomnograph recording system that digitally amplifies physiological activity and records data onto a PC flash memory card (flashcard) or sends it directly to a PC. The Suzanne system is modular in design. It consists of a Recorder Plus, two different types of data acquisition modules called "headboxes", and additional support modules. The system is typically used with two headboxes; however, it can be configured for use with up to four headboxes at one time with direct connection to a PC. 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 recording to be done in the patient's home.

The clinician must perform the following tasks when using the Suzanne system:

- Tell the patient how to prepare for a recording session.
- Prepare the patient for a recording by attaching sensors.
- Set up and configure the Suzanne system to record patient data.
- Ensure the sensor information is being gathered properly.
- Retrieve the recorded patient data.

This document contains valuable warnings and instructions. Read it completely before using The Suzanne System.

Indications for Use

The Nellcor Puritan Bennett Suzanne is intended for use in collecting and recording physiological data to be used in diagnosing sleep disorders.

A pediatric through adult patient population is intended for the Suzanne, which can be used in either home or hospital environments.

⚠ **Warning**

Data can be collected in either unattended or attended situations, except for pediatric studies that must be attended.

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⚠ Warnings

- The warning symbol ⚠ on a the Suzanne system component indicates a warning. When you see this, refer to this document for further information.
- The recorded signals are for use in assessing sleep disorder. The signals are not of adequate quality for diagnosing seizure activity, heart disease, or other similar conditions. The Recorder Plus uses a "lossy" data compression algorithm in Flashcard mode, which means recorded waveforms may not be precisely identical to the originally detected waveforms.
- The Suzanne system should only be used by a trained operator.
- Use only the accessories described in this document. Failure to do so can reduce the performance of the device or can represent a risk to the patient.
- Keep all the Suzanne system components away from flames.
- Do not use the Suzanne system in the presence of flammable anesthetics or compounds, or for any purpose other than its intended use.
- Do not use the Suzanne system in conjunction with a defibrillator.
- Avoid getting the Suzanne system wet. Advise the patient not to wear The Suzanne System in the bathtub or shower and to keep all of the units away from any kind of water source.
- Ensure that the patient does not experience irritation caused by sensor adhesives. Advise the patient to consult you if the sensors cause irritation.
- Ensure that you have properly prepared the patient for the recording session as described in this document.
- Use only sensors and accessories authorized by Nellcor Puritan Bennett.
- All studies should be attended for patients who are not physically able to use the provided wearing system.
- The Suzanne system is only to be used with the Ault SW173 power supply provided with the system

Cautions

- Clean all the equipment before each use (including the first use) according to the recommendations given in the maintenance section of this document.
- Do not set anything on top of the Suzanne system.
- Be aware that incorrect placement of a sensor may cause inaccurate readings.

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Symbols

	Year of manufacture.
S/N:	Serial number of the device.
	Attention, consult accompanying documentation.
	Degree of protection against electrical shock.
IXP1 Drip Proof	Protection against dripping water.
	CSA and NRTL mark. Meets CSA C22.2 No. 601-1-M90 and equivalent UL requirements.
15 VDC ⎓ 2.2	15 Volts, 2.2 Amps direct current

Electrical Safety and Electromagnetic Compatibility

The Suzanne system meets CSA C22.2 No. 601-1-M90 and UL 2601 requirements for electrical safety.

The Suzanne system is compliant with the following standards for electromagnetic compatibility (EMC).

IEC 601-1	Medical Electrical Equipment
IEC801-2, IEC 1000-4-2	Electrostatic Discharge Immunity
IEC 1000-4-3	Radiated Electromagnetic Field Immunity
IEC 1000-4-6	Conducted Electromagnetic Immunity
Mil Std 462D	Magnetic Field Exposure Immunity
IEC 61000-4-4	Electrical Fast Transient Immunity
IEC 61000-4-5	Surge Immunity
EN55011 Class B	Radiated and Conducted Immunity

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Unpacking and Inspecting the Suzanne system

When you receive the Suzanne system, ensure that you have received all the necessary items and that nothing has been damaged during shipping. If you find that something is damaged or missing, do not continue the study. Immediately contact the shipping service or technical support.

Attended Configuration

The Suzanne system is modular and can be configured in a number of different ways. A typical attended study configuration may include some or all of the following components:

- Recorder Plus
- Set Up Module
- Slow Wave Headbox
- Fast Wave Headbox
- DC Isolation Module
- Fiber Optic Receiver
- Fiber Optic Communication Cable
- A Sandisk SDP3B series flashcard in 32 (standard), 64, or 128 Mbyte size.
- DC Power Supply
- 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 Plus pouch, 2 headbox pockets, DC pocket)
- *The Suzanne Polysomnograph Recording System Clinician's Guide*
- *The Suzanne Polysomnograph Recording System Patient's Guide*
- Carrying Case

Unattended Configuration

The Suzanne system can also be configured in an unattended study mode. In this configuration, the Fiber Optic Receiver and Fiber Optic Communication Cable may not be required, as recordings are stored directly onto the flashcard and not a PC.

Related Publications

- *The Suzanne Polysomnograph Recording System Patient's Guide*
- *Sandman® Software Training Guide*

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THE SUZANNE SYSTEM COMPONENTS

You must fully understand the components of the Suzanne system recording system before using it on a patient. The following components are illustrated and described in this section:

- **Recorder Plus**
  The Recorder Plus is the central module of the Suzanne system. It records data from connected Slow Wave and Fast Wave headboxes and an integrated oximeter either to a flash memory card (flashcard) or to a PC by way of a fiber optic interface. The Recorder Plus is setup for flashcard recording by use of the Set Up module. The Recorder Plus operates from a DC Supply or an internal rechargeable battery pack.

- **Set Up Module**
  The Set Up module is used to setup and configure the Recorder Plus for flashcard recording. This module allows the user to set the current and recording start times and to view patient signals prior to starting the study.

- **Slow Wave Headbox**
  The Slow Wave headbox is used to collect up to 9 channels of slowly varying signals from the patient. The channels for this headbox include: airflow sensor (reusable thermistor or disposable BreathSensor™), 2 effort belts, sound, pressure, flow, body position, light, and a DC Input (for use with the DC Isolation module only). A typical user configuration features one Slow Wave (and one Fast Wave) headbox.

- **Fast Wave Headbox**
  The Fast Wave headbox is used to collect up to 8 channels of fast varying signals from the patient. This module has 8 general purpose EEG-style inputs. Up to 4 Fast Wave headboxes may be connected to the Recorder Plus at one time (PC Mode only). A typical user configuration features one Fast Wave (and one Slow Wave) headbox.

- **DC Isolation Module**
  The DC Isolation module is used to connect an external input into the Suzanne system for recording purposes. It provides a high level of isolation (4000VAC) to protect the patient from any potential safety hazards. It connects to the Slow Wave headbox.

- **Fiber Optic Receiver**
  The Fiber Optic module receives fiber optic data sent by the recorder via a fiber optic cable and converts this signal for use by the user's PC.

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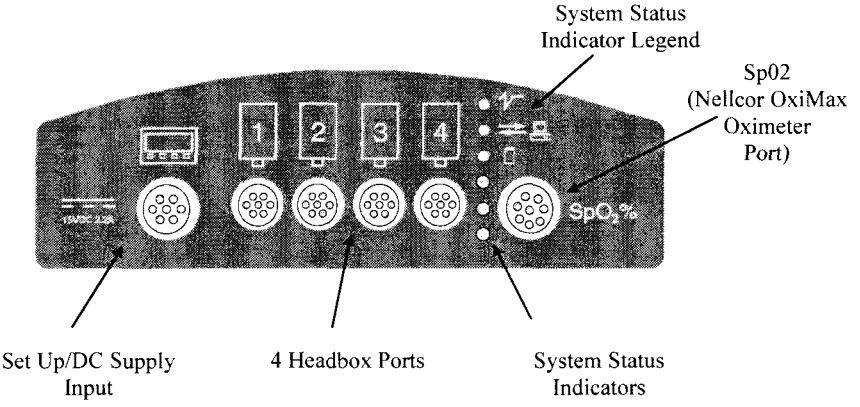
Recorder Plus

The Recorder Plus is the central module of the Suzanne system. The Slow Wave headbox, Fast Wave headbox, Set Up module, The Suzanne system Nellcor OxiMax™ SpO_2 Oximeter Extension Cable, Fiber Optic cable, and DC Supply connect to the Recorder Plus.

Recorder Plus Front Face



Recorder Plus Rear Face

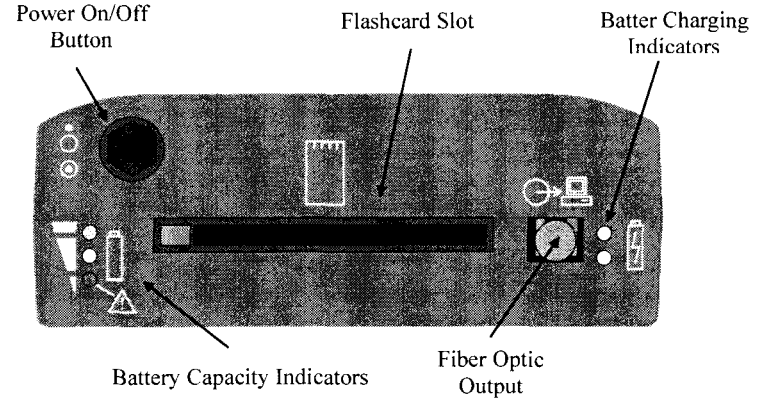


Figure 1: Recorder Plus

61

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System Status Indicator Legend	Identifies the current operations being performed by the Recorder Plus (headbox data acquisition, PC/Set Up communication, flashcard access) and error status conditions.	
System Status Indicators	Lights indicating current Recorder Plus function as shown by the *System Status Indicator Legend.*	
SpO_2 (Oximeter) Port	SpO_2 Oximeter Extension Cable Port.	
Headbox Ports	Slow Wave and Fast Wave headbox connection ports.	
Set Up/DC Supply Input	Set Up and DC Supply port (dual use).	
Power On/Off Button	ON/OFF button.	
Flashcard Slot	PC Card slot. Use only Sandisk SDP3B series 32, 64, and 128 Mbyte flashcards.	
Fiber Optic Output	Fiber optic cable port.	
Battery Charging Indicators	*Green*	Battery charged.
	Yellow	Charging battery (blinking).
Battery Capacity Indicators	*Green*	Battery at full capacity (80-100%).
	Yellow	Battery not at full capacity (20-80%).
	Red	Battery capacity low (less than 20%).

Operation

The Recorder Plus operates in one of two primary modes of operation during normal use: *Flashcard Mode* or *PC Mode*. The mode to be used is determined by the Recorder Plus when it is initially turned ON and devices connected to it. To switch modes, you must turn the Recorder Plus OFF and change the system configuration as needed for the particular mode of operation desired. In Flashcard mode, the Recorder Plus writes data onto the flashcard that you insert into the flashcard slot. You must insert the flashcard and connect the Set Up module prior to turning the Recorder Plus ON to enter this mode. In PC Mode, the acquired data is sent directly to a PC by way of the fiber optic interface. To enter this mode, the flashcard must be removed and the Set Up module disconnected. You cannot use the Set Up module when the system is connected to a PC.

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Three *System Status Indicators* (see Figure 1) illuminate to indicate the kind of operations being performed by the Recorder Plus.

- During initialization, all lights blink for several seconds while The Suzanne System performs an auto self-test.
- During normal operation, the top light indicates headbox data acquisition, the middle light indicates PC/Set Up module communication, and the bottom light indicates flashcard memory access.
- When the battery power is low, the top and bottom lights flash alternately to indicate low battery power. For all other errors, the three lights flash successively.

Data is acquired from the patient through Slow Wave and/or Fast Wave headboxes which connect to the Recorder Plus's headbox ports. Up to four headboxes may be connected at any one time.

Headbox Combinations

The following headbox configurations are currently supported.

Connected Headboxes	Flashcard Mode	PC Mode
1 Fast	YES	YES
1 Slow	YES	YES
1 Fast, 1 Slow	YES	YES
2 Fast, 1 Slow	YES	YES
3 Fast, 1 Slow	NO	YES
4 Fast	NO	YES

The Recorder Plus will enter an error mode if an unsupported headbox configuration is attempted. If the Set Up module is attached during an error event, an error message will be displayed on the Set Up screen.

Built-in Oximeter

The Recorder Plus has a built-in Nellcor Puritan Bennett oximeter. A Nellcor OxiMax SpO_2 Oximeter extension cable is used to connect the SpO_2 sensor to the Recorder Plus. Note: the Recorder Plus must have a Slow Wave headbox connected in order to record SpO_2 and pulse rate information.

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Battery Operation

The Recorder Plus can be powered directly from the DC Supply or by the built-in battery pack. The Recorder Plus runs from the DC Supply until it is disconnected, at which point it will run from the battery pack. The Recorder Plus can run for up to 20 hours on a single battery pack charge depending on system configuration. During this time the *Battery Capacity Indicators* (see Figure 1) will typically light as follows: Green for 2 hours or longer, Yellow for 16 hours or longer, Red for 2 hours minimum. This assumes the battery pack has been recently recharged.

In the Flashcard mode of operation the unit will run until the flashcard is full of data at which time the unit will stop recording and enter a power down mode. In the PC mode of operation, the Recorder Plus will run until the user turns the system off or until the battery pack is exhausted.

The battery pack must be replaced after 400 cycles or two years, whichever occurs first. The Recorder Plus must be returned to NPB Technical Service for battery replacement.

Battery Charging

The Recorder Plus's built-in battery pack is recharged by connecting the DC Supply to the Recorder Plus's Set Up/DC Supply port. Battery recharging is independent of the ON/OFF state of the Recorder Plus.

The Battery Charging Indicators (see Figure 1) indicate Battery charging status. The yellow (*charging battery*) LED will blink while the battery is charging at a high rate. The green *(battery charged)* indicator will activate once high rate charging is complete. This indicates the Recorder Plus is ready to be used to conduct a study. Battery charging will typically take about two hours with a maximum time of four hours.

Note: battery-charging time depends on the battery capacity remaining in the battery pack from the previous use.

DC Supply

The DC Supply is a high quality medical grade AC to DC power supply used to supply power to the Recorder Plus so it may both operate and recharge its internal battery pack. This supply plugs directly into any available wall outlet (110-250VAC, 50-60Hz) and the Recorder Plus's Set Up/DC Supply Port (see Figure 1). The Suzanne system is only to be used with the Ault SW173 power supply provided with the system.

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Set Up Module

The Set Up module (see Figure 2) is used to monitor the setup of the flashcard and allows the user to enter the current time and a start time for the study. The Set Up module also allows you to scroll through various waveform screens to verify that the sensors are working correctly.

The Set Up module must be connected prior to turning the Recorder Plus ON in order to use the The Suzanne System for flashcard recording. Once the Recorder Plus is turned ON, the user navigates through the various screens until the *Disconnect Screen* is reached, at which time the user disconnects the Set Up module. See *Using the Suzanne System with Set Up Module* for more information on screen navigation.

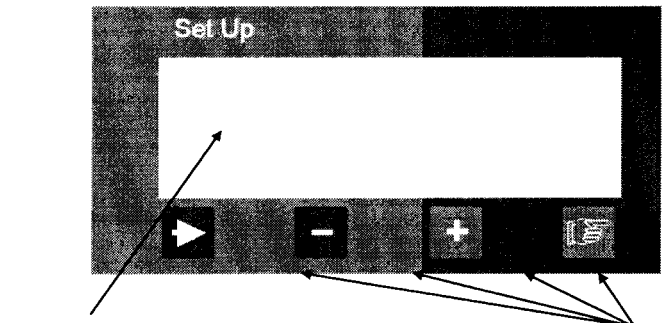

Figure 2: Set Up Module

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Slow Wave Headbox

The Slow Wave headbox (see Figure 3) is used to acquire slowly varying signals from the patient. The supported channels are: airflow (nasal and oral using a reusable thermistor or disposable BreathSensor™), 2 respiratory effort belts (thorax and abdominal), ambient noise/snoring, CPAP/Bi-level pressure (cmH_2O), CPAP/Bi-level flow (pneumotachography), body position, ambient light, and an external DC Input. Data for these channels are recorded at 12 samples per second (12 Hz) with the exception of the flow (pneumotachography) channel that is recorded at 24 Hz.

The Slow Wave headbox has a built-in 4-way body position sensor and a built-in ambient light sensor. These built-in sensors do not have to be connected to the patient separately. The ambient light sensor records the presence of ambient light, but does not record the light intensity. Note: If data from the light sensor is needed for an accurate study, ensure that the *Ambient Light Window* (see Figure 3) is not covered during the recording.

The DC Input port allows the user to connect to the DC Isolation module. The Suzanne system will then record the signal from the DC Isolation Module.

Finally, the sensor ports are color-coded with port-to-connector alignment markings for easy sensor connection.

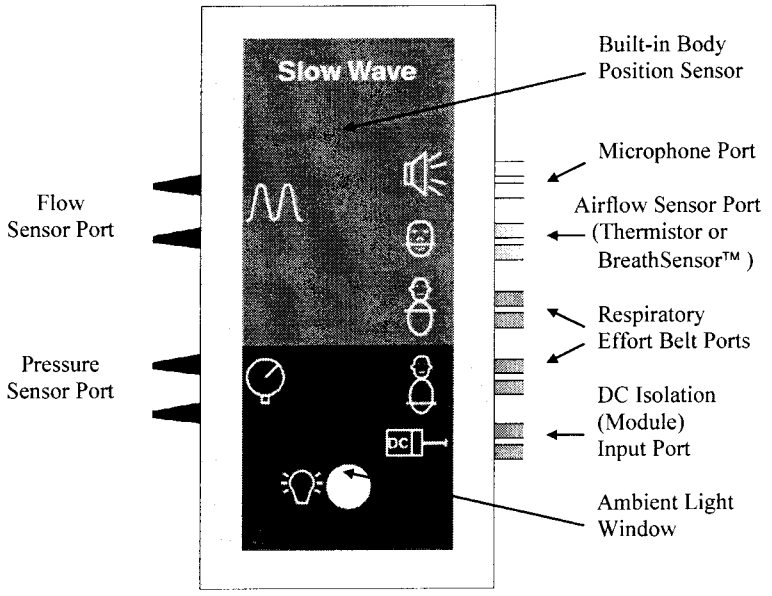

Figure 3: Slow Wave Headbox

66

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Fast Wave Headbox

The Fast Wave headbox (see Figure 4) are used to collect up to 8 channels of "fast" varying signals from the patient. These headbox have eight sensor ports for amplification of EEG, EOG, EMG, ECG, LEGS (EMG) signals and ground (ISO) inputs. Data is recorded at 120 times per second (120 Hz). For each signal, an active and a reference point may be input. In the case where the reference must be used for one or more active sites, jumpers may be used – i.e. A1 and A2.

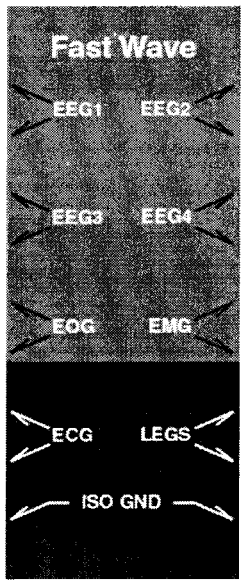

Figure 4: Fast Wave Headbox

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Fiber Optic Receiver

The Fiber Optic Receiver module receives the fiber optic signal sent from the Recorder Plus and converts this signal into useable information for the user's PC. This module plugs directly into the user PC's COM1 or COM2 ports. The Fiber Optic receiver connects to the Recorder Plus by way of a 30M (100ft) fiber optic communication cable.

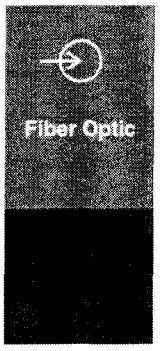

Figure 5: Fiber Optic Receiver

DC Isolation Module

The DC Isolation module is used to connect a user-supplied external DC input of -2.5 to +2.5 Volts directly into the Suzanne system for recording purposes. It provides a high level of isolation (4000VAC) to protect the patient from any potential safety hazards that might be introduced by connection of a non-isolated external device into the Suzanne system. It connects to the Slow Wave headbox DC Input port.

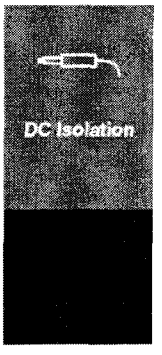

Figure 6: DC Isolation Module

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Patient Self-Preparation

To optimize the recording, recommendations normally given to the patient before the scheduled testing are:

- Shower and wash hair.
- Remove all makeup, nail polish, and body lotions.
- Mustaches and/or beards are acceptable. However, sensor placement works best on areas with no facial hair.
- Braided hair may need to be unbraided to allow placement of sensors.
- Prior to connecting sensors, the patient should have eaten the last meal of the day to prevent damage to the airflow sensor (thermistor).

Calibration

The Suzanne system is a digital signal amplifier system and therefore does not require signal calibration as previously required by the ADA for older analog signal amplifier systems. The Pressure channel will be influenced by location and as a result can be calibrated to improve accuracy.

Assembling the Suzanne System

To assemble The Suzanne System, perform the following steps:

1. Insert the Slow Wave and Fast Wave headboxes into their corresponding headbox pockets.
2. Connect the desired headbox(es) to the Recorder Plus. Headboxes should be plugged into the #1 and #2 (See Figure 1) Recorder Plus headbox ports when using the Suzanne system with only two headboxes (Fast and Slow). This facilitates the montage setup of the Sandman software for analysis purposes. See Section *Headbox to Recorder Plus Channel Assignments* for more on headbox/channel assignments.

NOTE: The headbox cable connectors and Recorder Plus headbox ports are color-coded (blue) and have alignment markings to ensure proper connector to port insertion. Failure to insert the headbox cable connectors as indicated by the color-coding and alignment indicators can result in broken connector pins.

3. Attach each sensor to the patient and to the sensor's respective headbox (see Section *Attaching Sensors* for more on this process). The thorax effort belt Velcro® straps (non-sensor strap) can be used to secure both

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headboxes to the patient's torso. The MAX-A OxiMax Sensor connects to the SpO_2 oximeter extension cable that in turn connects directly to the SpO_2 oximeter port on the Recorder Plus.

NOTE: The Slow Wave sensor ports (see Figure 3) and individual sensor connectors are color-coded and have alignment markings to ensure proper connector to port insertion. Failure to insert sensor connectors as indicated by the color coding and alignment indicators can result in broken connector pins.

4. Place the Recorder Plus pouch around the waist of the patient and fasten it.
5. Connect the headboxes to the thorax effort belt using either the provided headbox pocket holders or the built-in headbox clips (see Figure 7: Headbox Clip).

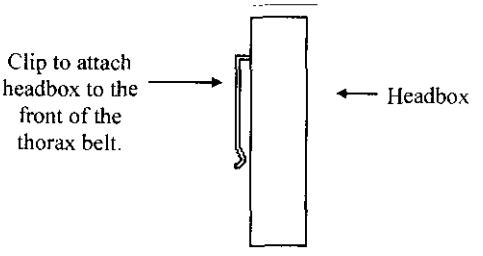

Figure 7: Headbox Clip

6. Follow the setup and configuration procedure, described in Section *Setup and Configuration.*
7. Place the Recorder Plus into the Recorder pouch.

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Attaching Sensors

This section describes how to connect sensors to a patient.

In general, you should attach the different sensor types in this order:

1. Attach all EEG, EMG, EOG, ECG, and LEGS (EMG) sensors as per your laboratory protocol.
2. Position the thorax belt.
3. Position the abdominal belt.
4. Attach the nasal/airflow sensor.
5. Attach the microphone, if desired.
6. Attach the SpO_2 sensor if desired (this will also record pulse rate).

NOTE: The body position sensor and the ambient light sensor are built into the Slow Wave headbox and therefore do not need to be separately attached.

Attaching Fast Wave Sensors

The International 10 - 20 Electrode Placement System (Jasper, 1958) is recommended for use with the derivations chosen from the following list: Fz, Cz, Pz, Fp1, Fp2, F3, F4, F7, F8, T3, T4, T5, T6, C3, C4, P3, P4, O1, O2.

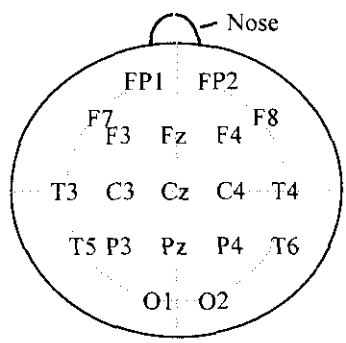

Figure 8: Electrode Placement in the International 10 - 20 Electrode Placement System (Jasper, 1958)

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The type of setup shown in Figure 9 is often used for its ease of placement using electrodes. Common electrode placements include C3 - A2 and C4 - A1.

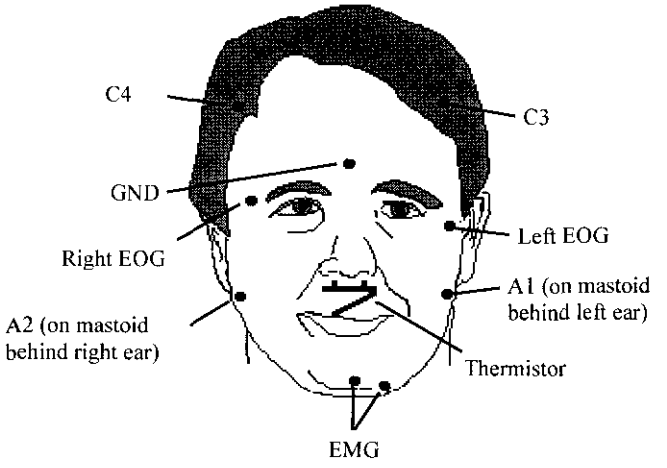

Figure 9: Montage for common derivations

EEG Sensors

1. Sites on the scalp may be measured using the International 10-20 Electrode Placement System.
2. The scalp may be marked with a marking pencil.
3. Use a cotton swab to apply an abrasive skin prep to the sites and vigorously rub a 1 cm area at the site.
4. Attach electrodes and run the leads behind the ears.

EMG Sensors

1. Identify the sites. These may be swabbed with alcohol to ensure the tape adheres well.
2. Sites may be marked with a marking pencil.
3. Use a cotton swab to apply an abrasive skin prep to the sites and vigorously rub a 1 cm area around the site.
4. Attach electrodes and run the leads behind the ears.

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EOG Sensors

1. Identify the sites.
2. Sites may be marked with a marking pencil.
3. Use a cotton swab to apply an abrasive skin prep to the sites and vigorously rub a 1 cm area around the site.
4. Attach the electrodes and run the leads behind the ears.

ECG Sensors

1. Sites for ECG placement require special placement for use with The Suzanne System (Lead II ECG placement – between the neck and the shoulder, in the middle of the left and right trapezoidal muscle).
2. Mark the sites with a marking pencil.
3. Use a cotton swab to apply an abrasive prep to the sites and vigorously rub a 1 cm area around each site.
4. Attach the electrodes.

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Attaching Slow Wave Sensors

This section describes how to attach Slow Wave sensors to the patient. The Slow Wave headbox includes a built-in 4-way body position sensor and a built-in ambient light sensor, which does not have to be attached to the patient separately. The Slow Wave headbox must remain attached securely to the thorax effort belt Velcro® strap (non-sensor part) on the patient in order to record body position accurately.

Effort Belts

You can plug two effort belts into the Slow Wave headbox.

Thorax

1. Insert the effort sensor into the belt using the Velcro to attach it.
2. Position the thorax belt on the chest above the nipple line.
3. Install the belt with the patient standing or sitting and adjust it when the patient is lying down. Ensure it is snug, but not tight.
4. Plug the effort belt connector into the Respiratory Effort Belt port on the Slow Wave headbox.

Abdominal

1. Insert the effort sensor into the belt using the Velcro to attach it.
2. Position the abdominal belt below the rib cage, so as not to pass over the bottom ribs.
3. Install the belt with the patient standing or sitting and adjust it when the patient is lying down. Again, ensure it is snug, but not tight.
4. Plug the effort belt connector into the Respiratory Effort Belt port on the Slow Wave headbox.

Note: do not clip the Slow Wave or Fast Wave headboxes to the effort sensor (elastic band) part of the effort belts as this may result in unreliable function of the effort belts during patient use.

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Nasal/Oral Airflow (Reusable or Disposable)

Nasal/oral airflow can be obtained by either using the reusable mustache-type thermistor sensor or the disposable BreathSensor™ with BreathSensor™ Airflow Cable.

Thermistor (Reusable)

The reusable mustache-type thermistor sensor is flexible and adjustable to mold to the patient's facial contours.

1. Position the thermistor on the patient's face with the two beads placed directly under the nostrils and the third bead just below the upper lip.
2. Drape the thermistor wires over the ears, and tighten the slide fastener under the chin so that the thermistor is securely fastened but comfortable.
3. Plug the thermistor connector into the Airflow Sensor port on the Slow Wave headbox.

NOTE: You can use tape on the face to further secure the sensor.

BreathSensor™ (Disposable)

The disposable BreathSensor™ is a flexible single-use sensor designed to be applied to fit the patient's facial contours. It is available in adult and pediatric sizes (see Section The Suzanne System *Order Numbers* for ordering information). It is used in conjunction with the BreathSensor™ Airflow Cable, which is an optional The Suzanne System component and must be ordered separately.

1. Plug the BreathSensor™ into the BreathSensor™ Airflow Cable and secure the sensor to the cable with the supplied snap.
2. Position the sensor on the patient's face with the two outside leads placed directly under the nostrils and the third inside lead placed just below the upper lip.
4. Plug the BreathSensor™ Airflow Cable connector into the Airflow Sensor port on the Slow Wave headbox.

NOTE: You can use tape to further secure the cable to the patient.

Microphone

This microphone is a highly sensitive piezo-electric microphone. It should be placed near the shoulder under the chin area. This records the intensity of any sound.

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External DC Input

The DC Isolation module is used to connect a user-supplied external DC input of -2.5 to +2.5 Volts directly into the Suzanne system for recording purposes. This module connects to the DC Isolation Input port of the Slow Wave headbox.

Note: connecting an external input, which exceeds the -2.5 to +2.5 Volt input range may damage the DC Isolation module.

Pressure Sensors

There are two pressure sensor ports for CPAP/Bi-level or esophageal recordings, Flow and Pressure.

Flow Sensor Port

The Flow channel is designed for high sensitivity while the Pressure channel is designed for a wide pressure range. The Flow sensor has a full-scale range of ±3.5 cmH_2O with a sensitivity to include differential pressure changes of 0.01 cmH_2O. This is a qualitative input primarily intended for pneumotachography when used with the provided Pneumotachograph Kit.

Pressure Sensor Port

The Pressure sensor is a differential pressure sensor with a full-scale range of ±70cmH_2O. This range is expected to be suitable for measuring CPAP/Bi-level pressure or esophageal pressure. The accuracy of this channel is ±2.0 cmH_2O with the assistance of a "Zero Cal" by the Sandman software if in attended/PC mode, and ±1 cmH_2O if a 2-point calibration is performed at the beginning of the study.

See the following section for more information on how to use the Slow Wave pressure ports with the Pneumotachograph Kit for measuring flow and pressure.

Note: Bacterial filters such as DUALEX Bacterial filters must be used when connecting various apparatus to the two pressure sensor ports. Failure to use these filters may result in damage to the Slow Wave headbox.

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Pneumotachograph Kit

The Pneumotachograph Kit is used with the Suzanne system to permit flow and/or pressure measurement at the mask out-take while under nasal CPAP/Bi-level ventilation. To measure flow and pressure, connect the Pneumotach Kit to the Slow Wave pressure ports and the mask and CPAP/Bi-level as described below.

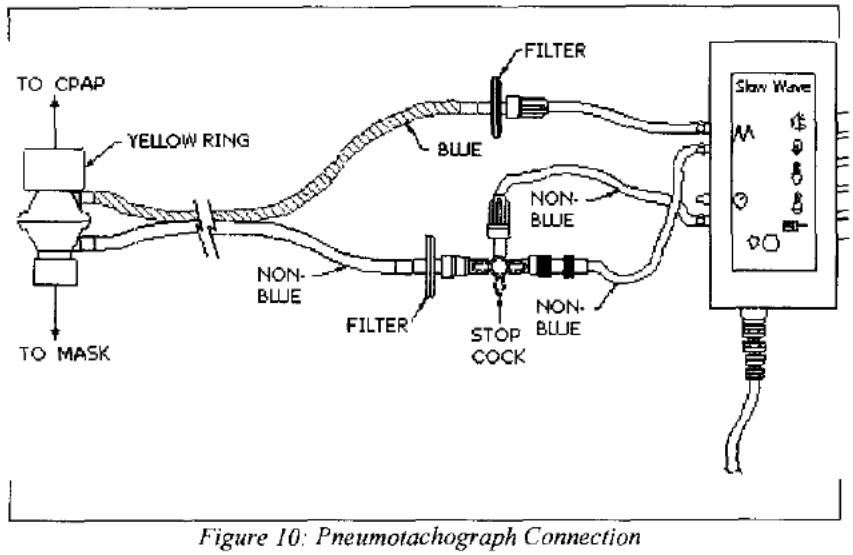

Figure 10: Pneumotachograph Connection

Installation:

- Connect the Pneumotachograph tubes to the Slow Wave pressure ports as indicated in Figure 10.
- Turn the 3-way valve to measure flow, pressure, or both.
- Connect the mask and CPAP/Bi-level to the Pneumotachograph as indicated in Figure 10.

⚠ The Pneumotachograph tubes must be positioned vertically to avoid bending and moisture accumulation.

The tubing and filters of the Pneumotach must be replaced after each use or a new Pneumotachograph should be used.

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SpO_2 and Pulse Rate Sensor (Nellcor OxiMax Pulse Oximeter)

The SpO_2 sensor attaches to the Nellcor OxiMax SpO_2 Oximeter extension cable, which in turn connects directly to the dedicated OxiMax SpO_2% Oximeter sensor port on the Recorder Plus (see Figure 1). You can use the following Nellcor Puritan Bennett sensors:

Disposable	Reusable
Max-A	OxiCliq® A
Max-P	OxiCliq P
MAX-FAST™ Adhesive Forehead Sensor	N/A

NOTE: Before placing the sensor, remove any fingernail polish from the finger on which the sensor is to be placed.

1. Attach the sensor on the non-dominant hand at the tip of the finger (index, for example), by placing the receiver section (part closest to the cable) on the fingernail side. Ensure that the sensor transmitting section (red light) and the receiving section are aligned.
2. If using a tape sensor, wrap flexible tape around the finger, but do not restrict blood flow. If using a clip sensor, clip the sensor to the finger.
3. Fix the sensor wire to the wrist, leaving a little extra length to ensure that any tension on it will not move the sensor.
4. Connect the SpO_2 sensor to the Nellcor OxiMax SpO_2 Oximeter extension cable.
5. Connect Nellcor OxiMax SpO_2 Oximeter extension cable to the Recorder Plus's OxiMax SpO_2% sensor port.

NOTE: The bright purple sensor connector plug easily identifies OxiMax compatible sensors.

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USING THE SUZANNE SYSTEM WITH THE SETUP MODULE

Preparing for Setup

1. Be sure that the Recorder Plus is OFF.
2. Insert a Sandisk SDP3B series flashcard card into the slot of the Recorder Plus. The flashcard must be inserted with its "Mallinckrodt" label facing up. Information is recorded directly onto the flashcard.

   NOTE: Use Sandisk SDP3B series flashcards in 32, 64, or 128 Mbyte sizes. Earlier versions of the The Suzanne System used Intel Series II flashcards in 10 or 20 Mbyte sizes. While this functionality has been retained in the Recorder Plus version of the The Suzanne System, use of these cards is not recommended due to limited recording time.
3. Connect the desired headbox(es) and sensors to The Suzanne System. The flashcard storage capabilities allow a maximum of 1 Slow Wave headbox and 2 Fast Wave headboxes. Headboxes should be plugged into the #1 and #2 (See Figure 1) Recorder Plus headbox ports when using the The Suzanne System with only two headboxes (Fast and Slow). This facilitates the montage setup of the Sandman software for analysis purposes. See Section *Headbox to Recorder Plus Channel Assignments* for more on headbox/channel assignments.
4. Connect the Set Up module to the Recorder Plus.
5. Press the ON/OFF button on the Recorder Plus.

   NOTE: A built-in audible indicator sounds during power up with a rising pitch and during error or fault situations with a falling pitch.
6. Ensure the Recorder Plus's *Battery Capacity Indicator* (see Figure 1) is Green indicating the battery is at full charge. If the Green indicator is not on, you should recharge the battery by turning the Recorder Plus OFF and connecting the DC Supply to the Recorder Plus.
7. The screen on the Set Up module briefly displays The Suzanne System copyright information. Follow the prompts on the screen as described in the following section, "Setup and Configuration".

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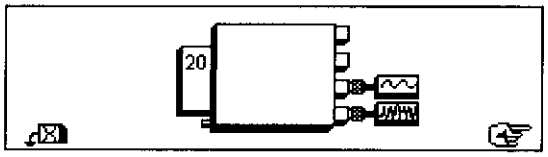
Setup and Configuration

Once you establish communication between the Recorder Plus and the Set Up module, a copyright screen will momentarily be displayed on the Set Up module. The initial The Suzanne System setup screen shown below will follow this screen. Follow the steps below to proceed with the setup and configuration process:

1. At the initial screen press the Continue button to begin the setup.

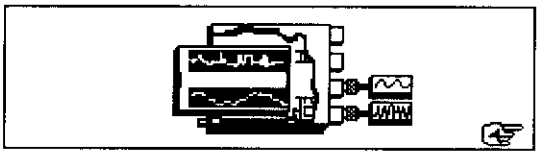
NOTE: An error message displays if you have not inserted the flashcard. Turn the Recorder Plus OFF, insert the flashcard, and turn the power back ON to correct this problem.

2. The Set Up module identifies the attached headboxes. Press the Continue button to continue, or press the Stop button to end the setup.



CAUTION: Before pressing the Continue button, ensure that you no longer need the patient recording contained on the flashcard.

3. The Suzanne System identifies the type of inserted flashcard. If an Intel flashcard is found, the Suzanne system will begin formatting the card for recording. This can take up to five minutes. The Sandisk flashcard does not require formatting.



4. Press the Continue button.

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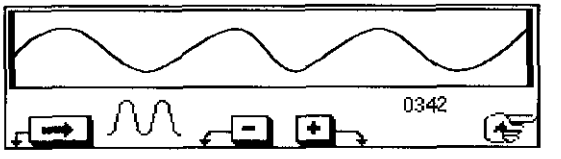
5. The waveform display screen appears. Press the Arrow button to scroll through the waveforms and ensure that the sensors are connected properly. You can adjust the graphic definition of the waveforms, by pressing the plus (+) and minus (-) buttons as each waveform appears. Note: Scrolling may only be done in one direction. To return to previously viewed waveforms, the user must scroll through the remaining waveforms and continue through until the previously viewed waveform is seen again.



The following screens will be displayed by pressing the advance key:

- EEG1 - EEG8 (EEG5 = EOG, EEG6 = EMG, EEG7 = ECG, EEG8 = LEGS)
- Airflow (3-bead Thermistor or BreathSensor™)
- DC Input (by way of DC Isolation module:)
- Flow
- Pressure
- Thorax Effort
- Abdominal Effort
- Microphone

For the Flow, Pressure, and DC waveform screens, a 12-bit A/D count value will be displayed. The range of this signal is +2047 to –2048 counts with a scale of 1.22mV/count.

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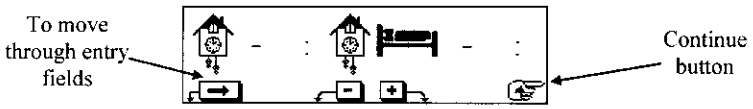
At the end of the waveform screens, SpO_2%, pulse, and battery information is displayed. Scroll through all the waveforms to access this information.

NOTE: To exit the waveform screens at any time, press the Continue button. You will not see the SpO_2%, pulse, and battery information screen.

6. Press the Continue button.

7. Press the arrow button to move through the entry fields. Press the plus (+) and minus (-) buttons to adjust the time settings.



Enter the current time using the format HH:MM (example: 22:30). Note: These clocks use the 24-hour nomenclature to set the time of day and therefore do not refer to A.M. or P.M. Enter the time you want to start the recording in the same manner. If the difference between the current time and the recording start time is greater than 12 hours, the recording begins immediately. Press the Continue button when you finish entering times.

NOTE: If you do not enter any information into this screen, the recording begins immediately. However, it is best to set current and start times so they can be recorded as reference information during the analysis.

8. Press the Continue button to exit.

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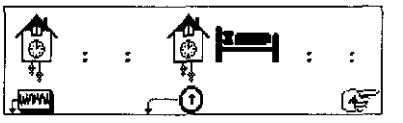
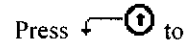
9. The display screen below reminds you of the current and start times you set, and allows you to take another look at the waves. Press Continue to exit the setup/configuration screens.

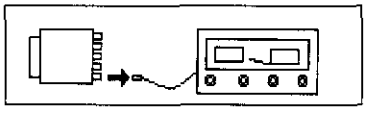


10. Press  to return to the set time screen.

11. Press to return to the view waveform screen.

12. The screen below reminds you to disconnect your Set Up module from The Suzanne System Recorder Plus. The Recorder Plus should remain powered on during recording.

CAUTION: Pressing the power button during a recording stops the study.



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USING THE SUZANNE SYSTEM WITH A PC

Setting Up

1. Plug your Fiber Optic receiver module into your computer's COM1 or COM2 port. Once this is done, the Fiber Optic module may be left permanently connected to the computer.
2. Connect the dark Grey end of the *Fiber Optic Communication Cable* to the connector on the Fiber Optic Receiver.

   NOTE: The *Fiber Optic Communication Cable* has color-coded ends: dark Grey (Fiber Optic module end) and light Grey (Recorder Plus end). The port connectors on both the Fiber Optic receiver and the Recorder Plus are similarly colored to assist with this task. Ensure the proper connections are made according to these color codes.
3. Be sure that the Recorder Plus's power is OFF, the flashcard is not inserted, and the Set Up module is not connected.
4. Connect the desired headbox(es) and sensors to the Recorder Plus. Headboxes should be plugged into the #1 and #2 (See Figure 1) Recorder Plus headbox ports when using the The Suzanne System with only two headboxes (Fast and Slow). This facilitates the montage setup of the Sandman software for analysis purposes. See Section *Headbox to Recorder Plus Channel Assignments* for more on headbox/channel assignments.
5. Connect the light Gray end of the *Fiber Optic Communication Cable* to the connector on the Recorder Plus.
6. Turn the Recorder Plus ON.
7. The Suzanne System conducts its internal test as indicated by beeps and flashing lights.
8. After The Suzanne System has completed its internal tests, data is immediately transmitted to the PC so that it may be collected and displayed by the Sandman software.

Note: The Sandman software is the only software approved to be used with the Suzanne system (sold separately).

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CHARGING THE BATTERY

The Suzanne System uses a rechargeable built-in battery pack for power during recordings when the DC Supply is not connected. The recording capacity of The Suzanne System depends on the memory capacity of your flashcard and the battery charge level.

To charge the battery:

1. Plug in the DC Supply into any available (100-250VAC, 50-60Hz) power outlet.
2. Connect the DC Supply directly to the Recorder Plus's Set Up/DC Supply port connector (see Figure 1). The Recorder Plus's Yellow *Battery Charging Indicator* (see Figure 1) will blink indicating that the Recorder Plus is receiving power from the DC Supply and is charging the battery. Charging the battery typically takes about two hours, with a maximum of 4 hours.

When the Recorder Plus's Green Battery Charging Indicator light is activated, the The Suzanne System is ready for a recording session using battery power.

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CHANNEL ASSIGNMENTS - HEADBOX TO RECORDER PLUS

The order in which the Fast Wave and Slow Wave headboxes are connected to the Recorder Plus's #1 - #4 (See Figure 1) headbox ports determines the channel ordering used to store data on the flashcard. Since Sandman downloads this data from the flashcard for analysis, you must follow a common procedure for how you connect your headboxes to the Recorder Plus or the ordering of the channel data may not correspond to the Sandman montage you have previously defined. Therefore, when using the The Suzanne System in standard configuration (one Fastwave and one Slowwave headbox), headbox ports #1 and #2 should be used to facilitate the Sandman montage setup. When this setup procedure is followed, the following channel ordering should be used for Sandman montage setup.

Channel #	The Suzanne System (Fast=Port1, Slow=Port2)	The Suzanne System (Slow=Port1, Fast=Port2)
1	SpO_2	SpO_2
2	Pulse	Pulse
3	SpO_2 Quality	SpO_2 Quality
4	Light	Light
5	EEG1	Body Pos.
6	EEG2	Pressure (CPAP 1)
7	EEG3	Flow (CPAP 2)
8	EEG4	Snore
9	EOG	Airflow
10	EMG	DC Isolation
11	ECG	Chest Effort
12	LEG	Abdomen Effort
13	Body Position	EEG1
14	Pressure (CPAP 1)	EEG2
15	Flow (CPAP 2)	EEG3
16	Snore	EEG4
17	Airflow	EOG
18	DC Isolation	EMG
19	Chest Effort	ECG
20	Abdomen Effort	LEG

When configurations other than those recommended here are used, the order in which data is stored on the flashcard will change as indicated by the examples shown above.

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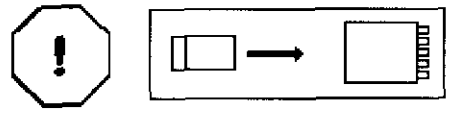
Error Screens

If there are errors during setup and configuration, one of the screens shown below may appear on the Set Up module.

Insert Flashcard

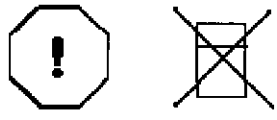
If you begin the setup and configuration process without inserting the flashcard, this screen displays.



To correct this problem, turn the unit off, insert the flashcard into the Recorder Plus and press the power button.

Corrupt Flashcard

If there is a problem with the type of flashcard you are using, or if the flashcard you are using is no longer working for some reason, this screen displays.



This warning appears when using the older Intel Series II flashcards if the *Write Protect* switch on the flashcard is enabled. The Sandisk series of flashcards does not have this functionality. If you are not using the flashcard provided with your the Suzanne system or have changed the setting of the Intel flashcard supplied by enabling *Write Protect*, change the setting back to disabled. If this does not correct the problem a new flashcard may be required.

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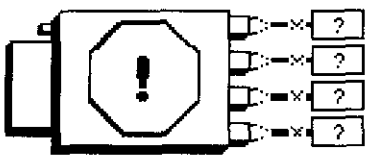
Headbox Missing

The Recorder Plus requires that a minimum of one headbox be connected. If there is no headbox connected, this screen displays:



You also receive this message if you attempt to connect an unsupported configuration of headboxes. You must connect the headboxes before you begin the setup and configuration process.

Common Problems

Several common problems and their solutions are described below.

60 Hz (Fast Wave) Electrical Artifact

Check the integrity and impedance of the ground/ISO electrode. Check the integrity of the additional electrodes.

Electrode Popping

Check the integrity of the electrode. Change the electrode if necessary.

Power Problems

Ensure that the battery is recharged. The battery pack (inside the Recorder Plus) must be replaced after 400 cycles or two years, whichever occurs first. The Recorder Plus must be returned to NPB Technical Service for battery replacement. Call Technical Support if replacing the battery pack or recharging the battery does not solve the problem.

SpO_2 Recording is Missing

Ensure that the oximeter sensor is properly connected to the patient and the Recorder Plus. Also, ensure that the Slow Wave headbox is connected to the Recorder Plus.

Ensure you have an OxiMax sensor connected to an OxiMax compatible sensor cable. The bright purple sensor connector plug easily identifies OxiMax compatible sensor cables.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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MAINTENANCE

Modules and Cables

Clean the Suzanne System's modules (i.e., Recorder Plus and headboxes) and cables by wiping down with 70% isopropyl alcohol in water after each use or as required.

Note: When cleaning always allow a sufficient amount of time for each of the components to dry completely before reuse.

CAUTION: Do not use ether or acetone since those chemicals can cause the plastic materials to deteriorate.

Ensure periodically that the cables are not damaged. Contact Technical Service in case of problems.

Wearing System

Clean the Recorder Pouch, Headbox Pockets, and DC Pocket (if used) after each use. Hand-wash these in cold water. After washing, hang to dry.

Sensors

Thermistor — Clean with isopropyl alcohol after each use or as required. Care should be taken to avoid contact of the alcohol with the open end of the connector.

Microphone — Clean by wiping with isopropyl alcohol after each use or as required. Care should be taken to avoid excessive contact of the alcohol with the microphone head or open end of the connector.

Effort Belts — Clean the sensor straps and Velcro® belts by soaking them in clean hospital grade laundry detergent (*No hot water on sensor straps!*) and then air-drying. Care should be taken to avoid contact of the cleaning solution with the open end of the connectors.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Pneumotachograph Kit

The tubing and filters of the Pneumotach must be replaced after each use or a new Pneumotachograph should be used.

Battery Pack

The battery pack (inside the Recorder Plus) must be replaced after 400 cycles or two years, whichever occurs first. The Recorder Plus must be returned to NPB Technical Service for battery replacement.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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TECHNICAL CHARACTERISTICS

Environmental Conditions

Operational temperature	5°C to 40°C
Storage temperature	-20°C to 60°C at relative humidity up to 95% non-condensing
Relative humidity	15% to 95%

NOTE: Battery life may be reduced at the temperature limits.

Battery Specifications

Battery type	Nickel Metal Hydride – NiMH
Size	6 cells (series configuration)
Voltage	7.2 V (nominal)
Capacity	3.35 Amp/Hrs (nominal)
Charge time	2 hours typical, 4 hours maximum, depending on the initial state of the batteries.
Charging Sensor	Built-in temperature sensor
Life span	400 charge/discharge cycles
	Only qualified personnel should replace batteries.

Power Consumption

During battery power operation, the system operates from a nominal battery voltage of 7.2 VDC. It typically uses 0.94W (1 Fast Wave, 1 Slow Wave) to 1.24W (3 Fast Wave, 1 Slow Wave). Typical power consumption levels are as follows:

Recorder Plus	77 mA @ 7.2V
Flashcard	7 mA @ 7.2V
Fast Wave Headbox	21 mA @ 7.2V
Slow Wave Headbox	20 mA @ 7.2V
DC Isolation	5 mA @ 7.2V

NOTE: The Fiber Optic Module draws power from the PC it is connected to and therefore requires no additional power sources for operation.

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Archiving of Flashcard Data

Archiving of flashcard data is done by inserting a flashcard into the computer's flashcard reader or by direct link to a PC. Data is collected from the flashcard using the Sandman software.

Recorder Plus

Size	5.7" x 5.5" x 2.4"
Weight	1.85 lbs.
Channels	Up to 4 headboxes (3 Fast, 1 Slow) plus SpO_2 and pulse rate, for a total of 35 maximum channels.
Battery	6 Cell Nickel Metal Hydride Battery Pack
Battery life span	400 charge/discharge cycles
Battery Life:	20 hours typical (1 Fast and 1 Slow Wave).
Recharge time	4 hours maximum
Data storage	Sandisk SDP3B series flash memory cards in 32, 64, or 128 Mbyte sizes.
Communication (to PC)	Fiber Optic Transmitter, 115kBaud
Set Up Module Interface	RS232 serial communication
Number of headbox ports	4
Oximeter	Built-in Nellcor OxiMax MP-506 oximeter technology. Note: This oximeter can be used during both motion and no motion conditions and for patients who are either well or poorly perfused.
Power consumption	84 mA @ 7.2V, Flashcard 604 mW typical 77 mA @ 7.2V, PC mode 554 mW typical

Equipment Classifications

Shock Protection: Class I

Degree of Protection Against Shock: Type BF Applied Parts

Degree of Protection against Harmful Ingress of Water: Drip-proof (IPX1)

Degree of Safety in the Presence of Flammable Anesthetic Mixture with Air with Oxygen of Nitrous Oxide: Not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

Model of Operation: Continuous Operation

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Set Up Module

Size	7.5" x 3.9" x 1.7"
Weight	17 ounces
Screen	LCD, 64 x 240 pixels
Interface	four-button controller panel
Power	Battery power from the Recorder Plus
Communication	RS232 serial interface with Recorder Plus
Power consumption	17 mA @ 7.2V, 122 mW typical

Slow Wave Headbox

Size	4.7" x 2.9" x 1.4"
Weight	9 ounces
Channels	9
Sampling Frequency	12 Hz (all channels except Flow), 24 Hz Flow
Nasal/Oral Airflow	3-Bead Thermistor, Nom. Value 25.8 kΩ (25°) BreathSensor™, Nom. Value 1.5 kΩ (23° C)
Respiratory Effort Belts	Piezo-electric belt, 294 μV
Ambient sound	Microphone, 250 mV for 90 dB
Flow	Internal, full scale, ±3.5 cmH_2O, Sensitivity of ±0.01 cmH_2O
Pressure	Internal, ±70 cmH_2O range, Accuracy ±2 to ±1 cmH_2O depending on Sandman calibration technique used.
Body position	Internal, 4 position metal (non-mercury) tilt switches (1 = prone, 2 = right, 3 = left, 4 = supine)
Ambient light	Internal, light (lux)
DC Input	See *DC Isolation Module* technical characteristics.
Output	12 bits
Power consumption	25 mA @ 7.2V, 180 mW typical (includes DC Isolation)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Fast Wave Headbox

Size	4.7" x 2.4" x 1.4"
Weight	7.6 ounces
Channels	8 channels plus 2 references: Any combination of EEG, EMG, EOG, LEGS (EMG) and ECG
Electrode montage	Bipolar
Signal calibration	Not Required
Signal digitization	12 bits
Sampling Frequency	120 Hz
Maximum Gain	4350 +/-5%
Frequency Response	- 3 dB: 0.7 Hz to 17 Hz -10dB: 0.25 Hz to 30.5 Hz -15dB: 0.18 Hz to 42 Hz
Notch Filter Attenuation	-50 dB (60Hz)
Output	12 bits
Input	full scale $\pm$ 700 μV
Electrodes	1.5 mm male plug Pressure (for adhesive electrodes) Lead cup (single-use or reusable)
Power consumption	21 mA @ 7.2V, 151 mW typical

DC Isolation Module

Size	3.5" x 2.0" x 1.1"
Weight	3.2 ounces
Isolation	4000 VAC, IEC601-1 Compliant
Input Range	±2.5 Volts
Accuracy	± 10mV for inputs $\leq \lvert 1 \rvert$ Volt, ± 1% for inputs $> \lvert 1 \rvert$ Volt
Frequency Response	0 to 5 Hz
Power consumption	5 mA @ 7.2V, 36 mW typical

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DC Power Supply

Manufacturer Specification	Ault SW173 Power Supply
Size	5.1" x 3.1" x 1.6"
Weight	13 ounces (excluding cord)
Power Rating	33 W
Input Voltage	100-250 VAC, -10%, +6%
Input Line Frequency	50-60Hz
Output Voltage	15V, ±1%
Output Current	2.20 A
Isolation	4000VAC
Protection	Foldback overcurrent protection
Safety Approvals	UL2601, CSA601, TUV/IEC 601-1 Complies with EMC Directives

Note: Circuit Diagrams and Component parts lists will be made available to qualified repair personnel only.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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MP506 Performance

Measurement Range	
SpO_2	1% to 100%
Pulse Rate	0 and 20 beats per minute (BPM) to 250 BPM
Perfusion Range	0.03% to 20%

Accuracy and Motion Tolerance	
Saturation	
Without Motion[1]	70 to 100% ±2 digits
With Motion[2]	70 to 100% ±3 digits
Low Perfusion[3]	70 to 100% ±2 digits

[1] Adult specifications are shown for *OxiMax* MAX-A sensors with the MP506 oximeter technology. Saturation accuracy will vary by sensor type.
[2] Applicability: *OxiMax* MAX-A, and MAX-P sensors.
[3] Specification applies to monitor performance and was validated with Biotek and Nellcor simulators.

Accuracy and Motion Tolerance	
Pulse Rate	
Without Motion[4]	20 to 250 BPM ±3 digits
With Motion	normal physiologic range (55 - 125 BPM) ±5 digits
Low Perfusion[4]	20 to 250 bpm ±3 digits

[4]Specification applies to MP506 performance and was validated with Biotek and Nellcor simulators.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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LIMITED WARRANTY

Nellcor Puritan Bennett (Melville) Ltd. warrants the The Suzanne System Polysomnograph Recording System components, consisting of the Recorder Plus, Set Up module, Slow Wave headbox, Fast Wave headbox, DC Isolation module, Fiber Optic module, and DC Power Supply, to be free of any defect in materials and workmanship for a period of one year from the date of purchase by the original purchaser. In addition, Nellcor Puritan Bennett (Melville) Ltd. warrants the Suzanne System Polysomnograph Recording System sensors and accessories consisting of the Airflow Sensor, Effort Belt, Microphone, BreathSensor™ Airflow Cable, Oximeter Extension Cable, and Fiber Optic Cable to be free of any defect in materials and workmanship for a period of three months from the date of purchase. In the event that you notify Nellcor Puritan Bennett (Melville) Ltd. of such a defect within the warranty period, Nellcor Puritan Bennett (Melville) Ltd. will repair or replace the defective component(s) at no cost to you provided that you return the defective components, postage prepaid, along with a note outlining the problem to Nellcor Puritan Bennett (Melville) Ltd. during the warranty period.

This warranty, together with any express written warranty that Nellcor Puritan Bennett (Melville) Ltd. may issue, is the sole and exclusive warranty as to the Suzanne system and its associated components and extends only to the original purchaser, and is expressly in lieu of any other warranty, oral or implied, including without limitation any oral or implied warranty of merchantability or fitness for particular purpose. Nellcor Puritan Bennett (Melville) Ltd. shall not be liable for any incidental special or consequential loss, damage, or expense (including, without limitation, lost profits) directly or indirectly arising from the use, anticipated use, or attempted use of any product.

Upon a warranty claim, you should first get the appropriate return authorization number from Nellcor Puritan Bennett (Melville) Ltd. Technical Support before shipping the defective component(s), packaged in their original or equivalent container, postage prepaid. This number must be clearly displayed on the return package.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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THE SUZANNE SYSTEM ***ORDER NUMBERS***

Order Number	Description
D.2099	The Suzanne System PSG System, Base
D.2091	The Suzanne System Recorder Plus
D.2094	The Suzanne System Set Up Module
D.2092	The Suzanne System Slow Wave Headbox
D.2093	The Suzanne System Fast Wave Headbox
D.2096	The Suzanne System DC Isolation Module
D.2095	The Suzanne System Fiber Optic Module
D.7140	DC Power Supply
D.5209	Power Cord, North American
D.5210	Recorder Plus Pouch
D.5211	DC Isolation Pouch
D.5212	Headbox Pocket
D.5382	The Suzanne System Wearing System
D.4094	PC Flash Memory Card, 32Mb Sandisk
D.4098	PC Flash Memory Card, 64Mb Sandisk
D.4099	PC Flash Memory Card, 128Mb Sandisk
D.7139	Fiber Optic Cable 30 Meters
D.5208	Carrying Case
D.8036	The Suzanne System Patient's Guide
D.0164	Pneumotachograph Kit - North America
D.5203	The Suzanne System Effort Belt
D.7182	The Suzanne System *Nellcor OxiMax* Oximeter Extension Cable
D.5204	The Suzanne System Airflow Sensor
D.5202	The Suzanne System Microphone
D.5315	The Suzanne System BreathSensor™ Airflow Cable
D.0163	Electrode Accessory Kit
D.5215	Model 971 Adult BreathSensor™ (24)
D.5271	Model 974 Child BreathSensor™ (24)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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An integral part of the OxiMax Pulse Oximetry System in the Suzanne system is our new breed of intelligent, interactive OxiMax sensors providing improved functionality for clinicians.

OxiMax Adhesive Sensors: Single Patient Use

Order #	Description	Weight Range
D.5504	MAX-FAST Adhesive Forehead Sensor	>40 kg
D.5505	MAX-FAST Headband	
D.5506	MAX-A Adhesive Sensor	>30 kg
D.5508	MAX-P Adhesive Sensor	20-50 kg

OxiMax OxiCliq® Sensors: Reusable cable with adhesive sensor bandage

Order #	Description	Weight Range
D.5511	OxiCliq A	>30 kg
D.5513	OxiCliq P	20-50 kg

To place an order or for further information, please call 1-800-663-3336.

More information about Sandman software is available by contacting your sales representative or dialing 1-800-663-3336.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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[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 24 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®

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

101

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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
- European version available

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

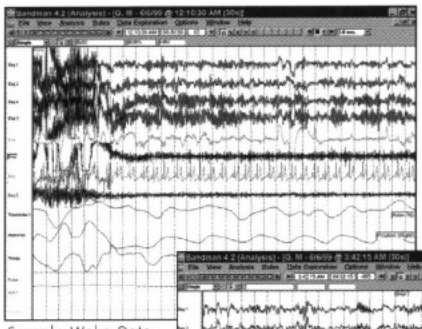
Recorder

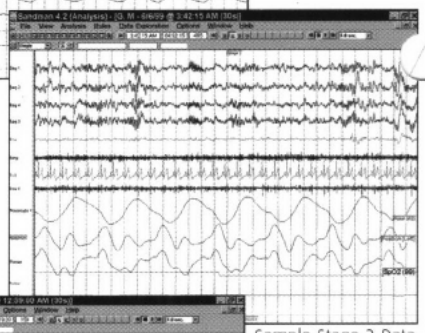
- SpO_2
- Pulse Rate
- Sandman Disposable Breath sensor (optional)

Plug and Play Module (options)

Flash Card
1 Fast wave
1 Slow wave
1 Fast wave & 1 Slow wave
2 Fast wave & 1 Slow wave

Real Time (with computer)
1 Fast wave
1 Slow wave
1 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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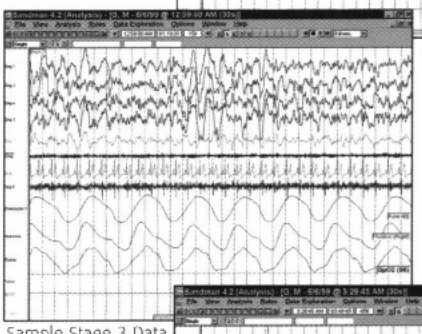
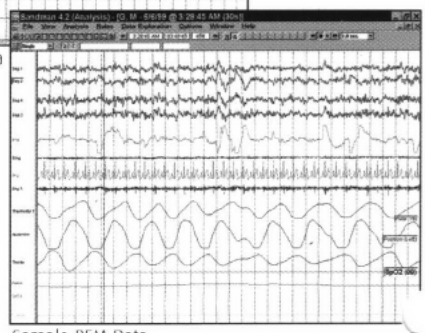

Sample Stage 3 Data


Sample REM Data

Specifications subject to change without notice.
Doc No. D.MK000002.00 REV A03

tyco Healthcare

Nellcor Puritan Bennett (Melville) Ltd.
303 Terry Fox Drive, Suite 400
Kanata, Ontario, K2K 3J1
Canada

For more information or to place an order call:
toll free: 800.663.3336
www.sandmansleep.com

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102

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tyco Healthcare

Puritan Bennett

Nellcor Puritan Bennett (Melville)
303 Terry Fox Drive
Suite 400
Kanata, Ontario K2K 3J1

Tele: 613 238-1840
Fax: 613 238-1291

Declaration of Conformity with Design Controls

1. As required by the risk analysis, all verification and validation activities were performed by the designated individuals and the results demonstrated that the predetermined acceptance criteria were met; and

2. The manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

Rob Matheson
Signature
Rob Matheson, Regulatory Affairs Associate
Nellcor Puritan Bennett (Melville) Ltd.

2/25/03
Date

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Design Control Activities

A number of scientific methods were employed to ensure that the modified Suzanne system is both safe and effective for use.

A risk analysis was performed to analyze any new risks posed by (b)(4) (b)(4) The process used to identify and measure risk as well as the risk mitigation measures used are shown in TAB 20 of this submission.

Nellcor Puritan Bennett engineering located in Pleasanton, California performed (b)(4) testing of the modified Suzanne system. The results of the performance testing are included in TAB 21 of this submission.

The modified Suzanne system was used in clinical (b)(4) site testing in (b)(4). The results of this testing are summarized in TAB 22 of this submission.

The unmodified Suzanne and the modified Suzanne are certified by CSA International to meet the safety requirements for electromedical equipment in both the U.S.A. and Canada. The most recent copy of this certificate addressing the oximetry modification is included in TAB 23. The CSA testing did not include EMC evaluation.

(b)(4) evaluated the (b)(4) compatibility of the modified Suzanne system. A results summary is included in TAB 23 of this submission.

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Risk Analysis

The Risk Analysis method used and the results of the analysis and verification and validation activities, methods/tests and acceptance criteria applied are detailed in the attached documents:

- Suzanne MP506 Risk Analysis, (b)(4) Rev. (b)(4)
- Hardware verification Test Reports dated May 8 & 9, 2002 (Approved May 14, 2002)
- Summary of (b)(4) Clinical (b)(4) Tests
- CSA Certificate of Compliance for USA and Canada
- Summary of (b)(4) Validation Tests

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tyco Healthcare	PROJECT NAME	DOCUMENT NUMBER	REV	PAGE
	Suzanne MP506	(b)(4)	(b)(4)	1 of 8
DOCUMENT TYPE: Safety Hazard Analysis		TITLE: Risk Analysis		

(b)(4)

(b)(6)

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1. INTRODUCTION 3
   1.1 Purpose 3
   1.2 Scope 3
   1.3 References 3
   1.4 Abbreviations, Definitions, and Acronyms 3
2. OVERVIEW 4
3. RISK ASSESSMENT 5
4. (b)(4) 5
   4.1 5
   4.2 5
   4.3 5
   4.4 5
   4.5 6
   4.6 6
   4.7 6
   4.8 6
   4.9 7

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1. INTRODUCTION

1.1 Purpose

(b)(4)

1.2 Scope

(b)(4)

1.3 References

1.4 Abbreviations, Definitions, and Acronyms

(b)(4)

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2 OVERVIEW

(b)(4) [redacted]

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3. RISK ASSESSMENT

(b)(4)

(b)(4)

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(b)(4)

[redacted]

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tyco Healthcare	PROJECT NAME	DOCUMENT NUMBER	REV	PAGE
	Suzanne MP506	(b)(4)	(b)(4)	Page 7 of 8
DOCUMENT TYPE: Safety Hazard Analysis	TITLE:			*Risk Analysis*

4.9 Safety Hazard Analysis Matrix

APPENDIX A: Hardware Hazard Identification (b)(4)

(b)(4)

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tyco Healthcare

DOCUMENT TYPE:	PROJECT NAME	DOCUMENT NUMBER	REV	PAGE
Safety Hazard Analysis	Suzanne MP506	(b)(4)	(b)(4)	Page 8 of 8

TITLE: *Risk Analysis*

(b)(4)

(b)(4)

(b)(4)

113

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SUMMARY REPORT

SUZANNE POLYSOMNOGRAPH RECORDING SYSTEM (b)(4) Testing STUDY USING (b)(4) Testi

TITLE: (b)(4) Testing

STUDY DATE:

PURPOSE:

MATERIALS:

TESTING FACILITY:

METHOD:

RESULTS:

DISCUSSION:

CONCLUSION:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5161; Released by CDRH on 10-22-2015

Report Written By: (b)(6) Date: 5-9-2002

Sr. Engineering Technician

Approved By: (b)(6) Date: 5-14-2002

OEM Support Engineer

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NELLCOR PURITAN BENNETT

(b)(4) Testing [redacted]

Suzanne Polysomnograph Recorder

ata spreadsheet prepared in accordance with Department Procedure (b)(4) Testing Rev (b)(4) (2-11-2002)

(b)(4) [redacted]

(b)(4) Testing StudySuzanne.xls 5/9/2002 10:42 AM

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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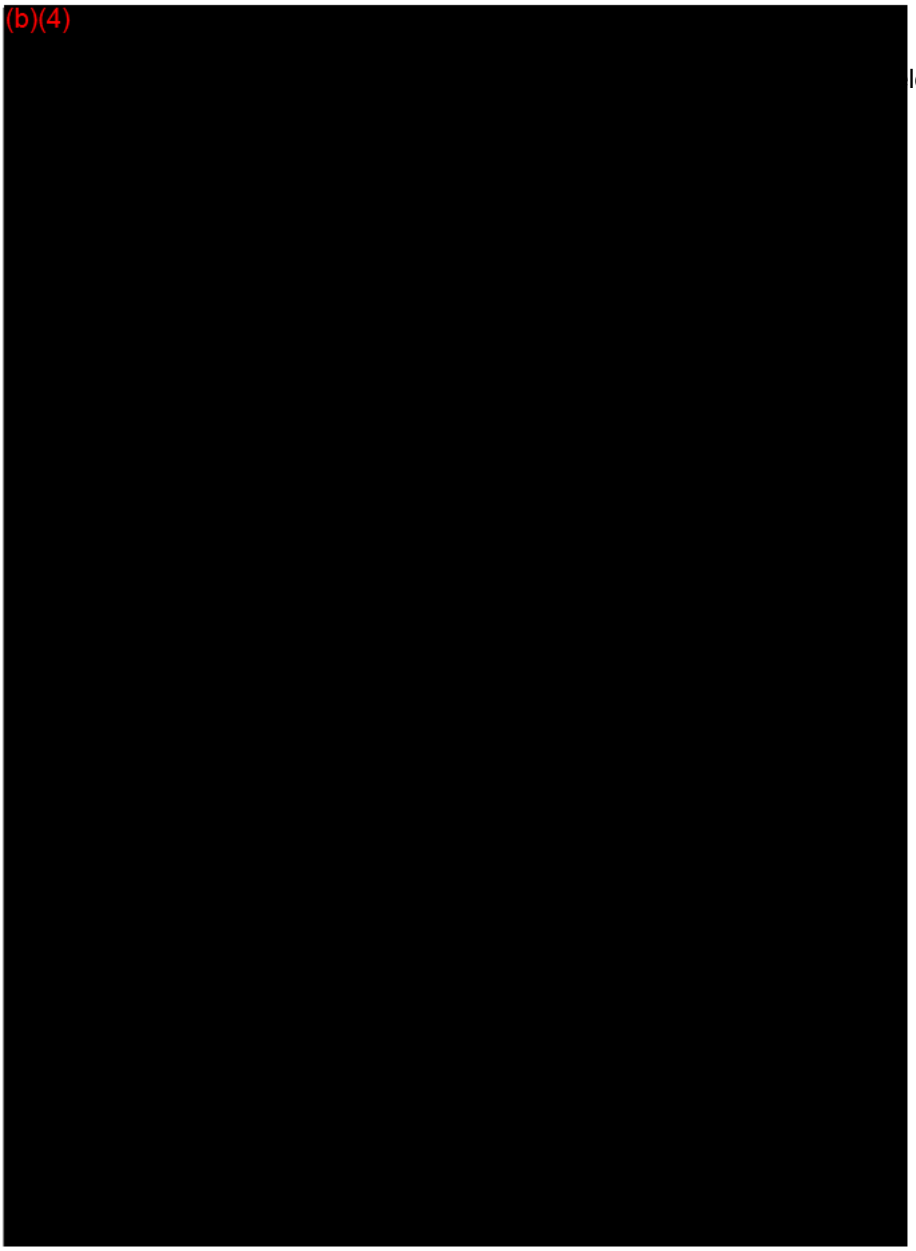

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Attachment C

Study Worksheet (CRF)

(b)(4) STUDY WORKSHEET

DATE: 5/8/2002

Oximeter Type: Survivor Recorder

(b)(4)

(b)(6)

Tester's Name:

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SUMMARY REPORT

SUZANNE POLYSOMNOGRAPH RECORDING SYSTEM (b)(4) STUDY USING (b)(4)

TITLE: (b)(4)

STUDY DATE:

PURPOSE:

MATERIALS:

TESTING FACILITY:

METHOD:

RESULTS:

DISCUSSION:

CONCLUSION:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5161; Released by CDRH on 10-22-2015

Report Written By: (b)(6) Date: 5-7-2002

OEM Sr. Engineering Technician

Approved By: (b)(6) Date: 5-14-2002

OEM Support Engineer

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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NELLCOR PURITAN BENNETT

(b)(4)

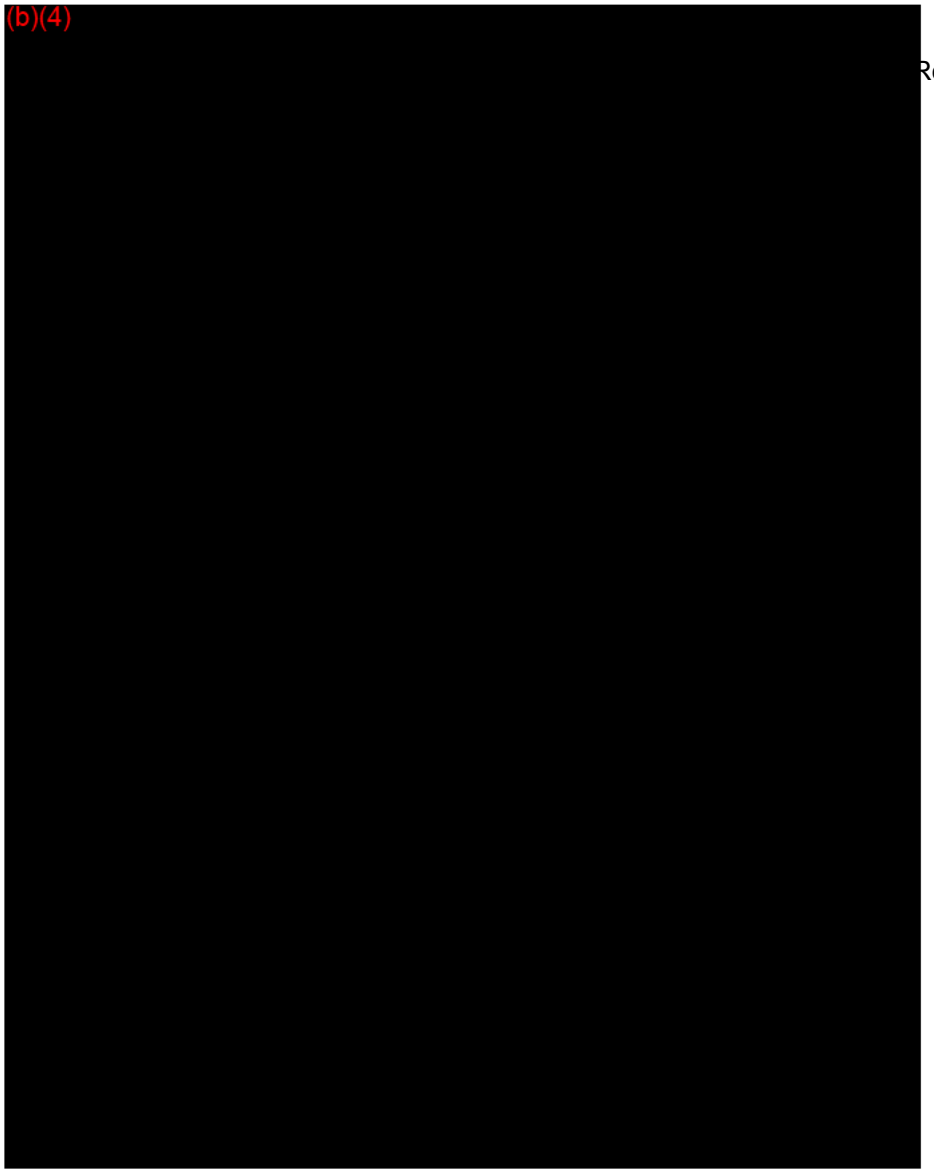
Suzanne Polysomnograph Recording System

Data spreadsheet prepared in accordance with Department Procedure (b)(4) Rev (b)(4) (8/1/2002)

(b)(4)

(b)(4)

[redacted]



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Attachment C

(b)(4) **STUDY WORKSHEET**

DATE: 5/8/2002

Oximeter Type: Suzanne Polysomnograph Recording System

(b)(4)

Tester's Name: (b)(6)

(b)(4)

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SUMMARY REPORT

SUZANNE POLYSOMNOGRAPH RECORDING SYSTEM (b)(4) STUDY USING PS II SIMULATOR

TITLE:

STUDY DATE:

PURPOSE:

MATERIALS:

TESTING FACILITY:

METHOD:

RESULTS:

DISCUSSION:

CONCLUSION:

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Report Written By: (b)(6) Date: 5-9-2002

OEM Sr. Engineering Technician

Approved By: (b)(6) Date: 5-14-2002

OEM Support Engineer

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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NELLCOR PURITAN BENNETT

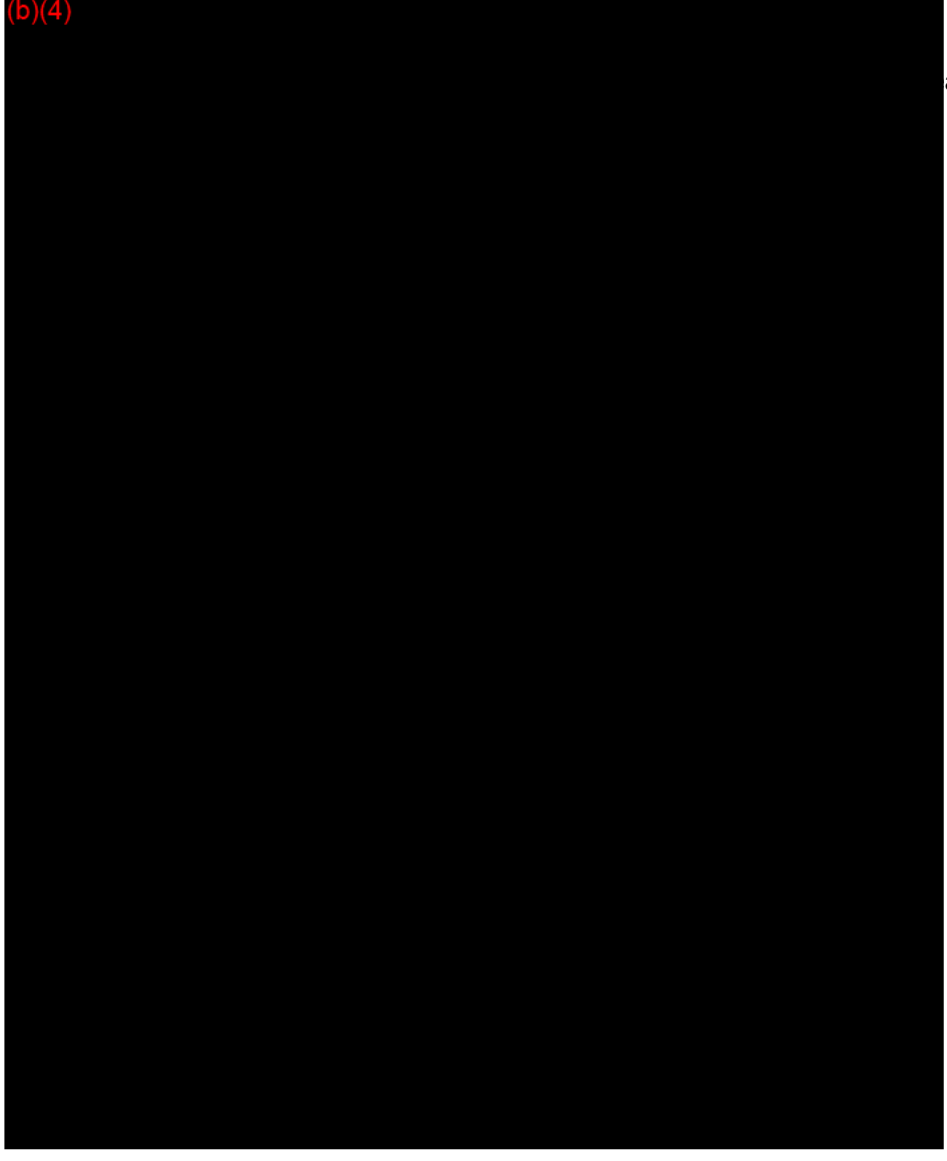
(b)(4)

SUZANNE POLYSOMNOGRAPH RECORDING SYSTEM (b)(4)

Data spreadsheet prepared in accordance with Department Procedure (b)(4) Rev (b)(4) 2-11-2002)

(b)(4)

(b)(4)



ased by CDRH on 10-22-2015

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) [redacted] STUDY WORKSHEET

DATE: 5/9/2002

Oximeter Type: Sunrise Pulsometer with Recording System

(b)(4) [redacted]

Tester's Name: (b)(6) [redacted]

(b)(4) [redacted]

Effective Date: 2/11/02

Printed on 5/8/2002

Do not use this procedure if today's date is more than 48 hours after the printed date

Records processed under FOIA Request # 2015-5161; Released by CDRH on 10-22-2015

Summary of (b)(4) Cinical (b)(4) Tests

(b)(4)

Records processed under FOIA Request # 2015-5161; Released by CDRH on 10-22-2015

CSA INTERNATIONAL

Certificate of Compliance

Certificate: 1200078 **Master Contract:** (b)(4)

Project: (b)(4) **Date Issued:** October 7, 2002

Issued to: **Nellcor Puritan Bennett (Melville) Ltd.**
A Division of Tyco Healthcare
141 Laurier Ave., Suite 700
Ottawa, ON K1P 5J3
CANADA
Attention: Mr. Rob Matheson

The products listed below are eligible to bear the CSA Mark shown with adjacent indicators 'C' and 'US'

C US

Issued by: Peter Wong, P.Eng.

Authorized by: Ray Fatavi, P.Eng., MBA
Operations Manager

PRODUCTS

CLASS 8750 01 - MEDICAL ELECTRICAL EQUIPMENT
CLASS 8750 81 - MEDICAL ELECTRICAL EQUIPMENT - CERTIFIED TO U.S. STANDARDS

Suzanne Sleep Recorder, Class I Equipment with type BF Applied parts, rated 100-240V ac, 50-60Hz, 0.75-0.35A (specified power supply), Continuous Operation, cord connected, Drip Proof IPX1.

APPLICABLE REQUIREMENTS

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 I: 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. 601.1B-98	-	Amendment 2 to CAN/CSA-C22.2 No. 601.1-M90, "Medical Electrical Equipment"

The 'C' and 'US' indicators adjacent to the CSA Mark signify that the product has been evaluated to the applicable CSA and ANSI/UL Standards, for use in Canada and the U.S., respectively. This 'US' indicator includes products eligible to bear the 'NRTL' indicator. NRTL, i.e. National Recognized Testing Laboratory, is a designation granted by the U.S. Occupational Safety and Health Administration (OSHA) to laboratories which have been recognized to perform certification to U.S. Standards.

DQD 507WD 2002/04/30

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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CSA INTERNATIONAL

Certificate: 1200078 **Master Contract:** (b)(4)

Project: (b)(4) **Date:** October 7, 2002

IEC Standards:

IEC 60601-1 (1988-12)	-	Medical Electrical Equipment - Part 1: General Requirements for Safety)
IEC 60601-1-AM1 (1991-11)	-	Medical Electrical Equipment - Part 1: General Requirements for Safety)
IEC 60601-1-AM2 (1995-03)	-	Medical Electrical Equipment - Part 1: General Requirements for Safety)

UL Standards:

UL Std No.	2601.1 (1994)	-	Medical Electrical Equipment Part I: General Requirements for Safety.

Subject to the following qualifications:

1. Units provided with other than CSA Certified power supply cord sets are Certified without the power supply cord set as components only.

2. Evaluated to IEC/CSA 601-1 Amendment 2 excluding requirements for Electromagnetic Compatibility (Clause 36), Biocompatibility (Clause 48) and Programmable Electronic Systems (Clause 52.1).

DOD 507WD 2002/04/30

131

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5161; Released by CDRH on 10-22-2015

CSA INTERNATIONAL

Supplement to Certificate of Compliance

Certificate: 1200078 **Master Contract:** (b)(4)

The products listed, including the latest revision described below, are eligible to be marked in accordance with the referenced Certificate.

Product Certification History

Project	Date	Description
(l(b)(4)	October 7, 2002	Update to (b)(4)
(b)(4)	February 15, 2002	Update to (
(b)(4)	Jan 15, 2002	Update to (b)(4)
(b)(4)	May 3, 2001	Original Certification. Transferred from (

DQD 507WD 2002/04/30

132

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under (b)(4) Request # 2015-5161; Released by CDRH on 10-22-2015

(b)(4)

TEST REPORT

SUZANNE

DESIGN VALIDATION – (b)(4)

1.0 INTRODUCTION

(b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5161; Released by CDRH on 10-22-2015

(b)(4) TEST SUMMARY

FOR

SUZANNE OXIMETER MODULE DESIGN VALIDATION FOR (b)(4)

SUZANNE *Design Validation for* (b)(4) *Tests and Results:*

Test Name	*Test Definition*	*Test Request #*	Test Results
(b)(4)			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5487, Released by CDRH on 10-22-2015

SPECIAL 510(k): Device Modification
ODE Review Memorandum

To: THE FILE **RE:** DOCUMENT NUMBER K030611

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable:

1. The name and 510(k) number of the SUBMITTER'S previously cleared device:

   Suzanne Portable Polysomnograph System (K990565), Oximax Pulse Oximetry System (K012891), OxiMax N-550 Pulse Oximeter (K021090).

2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials:

   The Nellcor Puritan Bennett Suzanne is intended for use in collecting and recording physiological data to be used in diagnosing sleep disorders. A pediatric through adult patient population is intended for the Suzanne, which can be used in either home or hospital environments. The indications for use remains the same.

3. A description of the device **MODIFICATION(S),** including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed.**

   The submission (Section 9) lists the modification made to the approved predicate (K990565). (b)(4) [redacted] (b)(4)

   The following previously approved sensors that will be added to this file:

Adult Breath Sensor	K913749	Disposable airflow sensor
Child Breath Sensor	K913749	Disposable
Max-A Adhesive Sensor	K012891	Disposable Pulse Oximetry Sensor (DPOS)
Max-P Adhesive Sensor	K012891	DPOS
OxiCliq-A	K012891	DPOS
OxiCliq-P	K012891	DPOS
MaxFast Forehead Sensor	K012891	DPOS

Other previous enhancements made to the predicate are: — that did not require a 510(k).

- Improvement of communication capabilities
- Improvement of rechargeable battery system
- Improvement of fiber optic capability
- Enhanced electromagnetic interference protection
- Headbox interface cables shielded
- Enclosures shielded
- A more accurate 60Hz notch filter added

A Clinician's Guide for the Suzanne Polysomnograph has been provided in Section 16 and Promotional Brochure in Section 17. The fundamental scientific technology of the Suzanne device has not changed.

 Records processed under FOIA Request # 2015-5161; Released by CDRH on 10-22-2015

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, and physical characteristics have been provided in Section 11. The subject device was compared to two predicates on with MP506 board (K021090) and the other with MP205 board (K990565). The subject device (Suzanne) with MP506 board is very similar in technology and characteristics with the N-550 OxiMax Pulse Oximter with MP506 board (K021090). It is also similar in basic features with Suzanne with MP205 board.

5. A **Design Control Activities Summary** which includes:
   a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis

   Design control activities have been provided in Section 19, and Section 20. The Risk Analysis activities include Risk Analysis methodology and results, verification and validation information. (b)(4) test reports, Summary of (b)(4) Clinical (b) Tests, CSA Certificate of Compliance and Summary of (b) Validation tests.

   b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied

   The required information has been provided.

   c) A declaration of conformity with design controls. The declaration of conformity should include:
      i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and

      ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

   A Declaration of Conformity with Design Controls has been included in Section 18. It satisfies both the requirements stated in (i) and (ii) above.

6. A **Truthful and Accurate Statement**, a **510(k) Summary or Statement** and the **Indications for Use Enclosure (and Class III Summary for Class III devices).**

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their pre amendment) device.

Truthful and Accurate Statement, 510(K) Summary and Indications for use have been included. Clinical, performance and environmental testing have been performed. The submission is judged to be substantially equivalent.

(Reviewer's Signature) 3/21/03 (Date)

Comments

revised:3/27/98

V. Correspondence

VI. Substantial Equivalence

Yes

VII. Recommendation

SE

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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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

(To be attached to the SE Review Memo)

510K #: K030611

Reviewer: Joydeb Roy **Division/Branch:** DAGID/ARDB

Device Name: Modification to Suzanne Portable Polysomnograph System

Product to Which Compared (510(K) Number If Known): Suzanne Polysomnograph Recorder (K990565)

		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?		X	If **NO** = Request Data
11.	Data Demonstrate Equivalence?	X		**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:** The Nellcor Puritan Bennett Suzanne is intended for use in collecting and recording physiological data to be used in diagnosing sleep disorders. A pediatric through adult patient population in intended for the Suzanne, which can be used in either home or hospital environments.

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 for home use 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.

   The Suzanne System is composed of a data recorder that contains the electronics and software necessary to capture the physiological information of each sensor and store this information in a Flash card or send it to a computer.

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:**

   Several clarifications on sensors and design control information were needed.

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:**

    Clarification on new sensors and risk analysis.

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

    All information was provided.

ATTACH ADDITIONAL SUPPORTING INFORMATION

Records processed under FOIA Request # 2015-5161; Released by CDRH on 10-22-2015

SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: K030611

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

☒ Special 510(k) - Do Sections 1 and 2

☐ Abbreviated 510(k) - Do Sections 1; 3 and 4

☐ Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.	✓	
Table of Contents.	✓	
Truthful and Accurate Statement.	✓	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	✓	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	✓	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.	✓	
Statement of Indications for Use that is on a separate page in the premarket submission.	✓	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510)] Manual.	✓	
510(k) Summary or 510(k) Statement.	✓	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	✓	
Identification of legally marketed predicate device. *		
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]		
Class III Certification and Summary. **		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]		
510(k) Kit Certification ***		

* - May not be applicable for Special 510(k)s.

** - Required for Class III devices, only.

*** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5161; Released by CDRH on 10-22-2015

Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.		
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE **Required Elements for a Declaration of Conformity to a Recognized Standard,** which		

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is posted with the 510(k) boilers on the H drive.]		
For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has not been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:		
b) Sterilization and expiration dating information:		
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
viii) Traditional Method or Non-Traditional Method		
c) Software Documentation:		

Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the " Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening ✓ Yes ___ No

Reviewer: _____

Concurrence by Review Branch: _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Date: FEB 2 6 2003

The deficiencies identified above 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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5161; Released by CDRH on 10-22-2015

REVISED:3/14/95

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"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K_____

Reviewer:_____

Division/Branch:_____

Device Name:_____

Product To Which Compared (510(K) Number If Known):_____

	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:

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.

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1. Intended Use:

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.

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:

ATTACH ADDITIONAL SUPPORTING INFORMATION

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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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.		✓

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5161; Released by CDRH on 10-22-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) Joydeb Roy

Subject: 510(k) Number K030611

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.

De Novo Classification Candidate?	☐ YES	☑ NO
☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)		
Is this device subject to 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

This 510(k) contains:

Truthful and Accurate Statement ☐ Requested ☑ Enclosed
(required for originals received 3-14-95 and after)

☑ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices

☐ The indication for use form (required for originals received 1-1-96 and after)

Animal Tissue Source ☐ 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 da

Predicate Product Code with class: MNR, II, CFR868.2375

Additional Product Code(s) with panel (optional):

Review: _____ (Branch Chief) ARDB (Branch Code) 3/24/03 (Date)

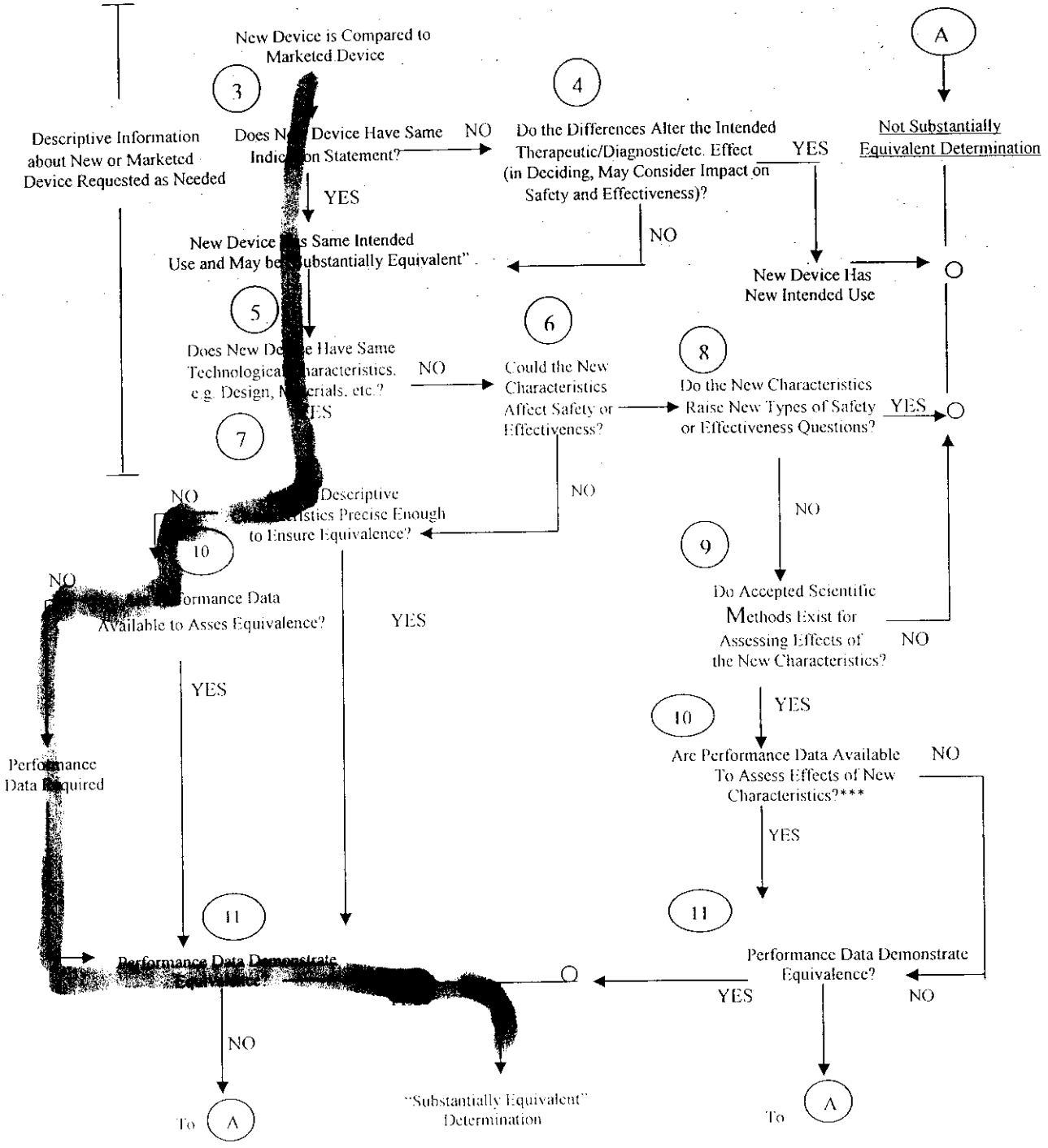
Final Review: _____ (Division Director) 3/24/03 (Date)

Revised:8/17/99

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5161; Released by CDRH on 10-22-2015

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.