DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services
Food and Drug Administration

Memorandum

Date: 10/27/09

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K913749 | M1

To: Division Director: AW (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 Transfer of Ownership

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

Reviewed by: _____

Date: _____

POS

K913749/A1

COVIDIEN

FDA CDRH DMC

OCT 27 2009

Received

October 22, 2009

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

K43

Re: Transfer of Ownership of 510(k)

To Whom It May Concern:

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

- K913749 – Edentrace Airflow 3171/Sleep Lab Airflow 3170

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

If you have any questions regarding this notification, please contact me at 303-305-2362 or at fran.harrison@covidien.com.

Respectfully,

Frances E. Harrison, RAC
Vice President, Regulatory Affairs

6135 Gunbarrel Avenue
Boulder, CO
80301

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services
Food and Drug Administration

Memorandum

Date: 11/25/10

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K913749/A2

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: _____

Date: _____

POS

embla®
CLOSER TO OUR CUSTOMERS™

Global Headquarters
11001 West 120th Ave.
Broomfield, CO 80021 USA
t: 888.662.7632
f: 303.962.1810
www.embla.com

K913749/A2

January 12, 2010

FDA CDRH DMC
JAN 15 2010
Received
K-23

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

RE: **510(k) Notification for a Change in Manufacturer**

Attention: **Document Control Clerk**

Subject: **EDENTRACE AIRFLOW 3171/SLEEP LAB AIRFLOW 3170 – K913749**

Embla Systems Inc. (Registration No.:3005844579) has purchased the rights to market and re-label the subject devices.

There is no change in the design (except for labeling with new mfg name), manufacturing location or processes, or the indications for use for the devices.

If there any questions regarding this notification, please contact the undersigned.

Sincerely,

Robert Schueppert

Robert Schueppert
Regulatory Manager
Embla Systems, Inc.
11001 W. 120th Ave., Suite 200
Broomfield, Colorado USA
Phone: 303-962-1786
Fax: 303-962-1810

FDA CDRH DMC
JAN 2 5 2010
Received

JAN 2 5 2010
Received

January 12, 2010

TRUTHFUL AND ACCURATE STATEMENT

In my capacity as Manager of Regulatory Affairs for Embla Systems Inc, I hereby certify that all information submitted in this notification is truthful and accurate to the best of my knowledge and that no material fact has been knowingly omitted.

Robert Schueppert

Robert Schueppert
Regulatory Manager
Embla Systems, Inc

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services
Food and Drug Administration

Memorandum

Date:

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K913749/A3

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]

__X__ 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]

Date: 6/22/11

DCC 6/23/11

Global Headquarters
11001 West 120th Ave.
Broomfield, CO 80021 USA
t: 888.662.7632
f: 303.962.1810
www.embla.com

embla®

USER TO OUR CUSTOMERS™

April 5, 2011

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-002

RE: 510(k) K913749; Edentrace airflow 3171/Sleep Lab Airflow 3170

Subject: Notification For Change of Manufacturer

Attention: Document Control Clerk

Embla Systems Inc. has recently acquired the referenced Edentrace airflow 3171/Sleep Lab Airflow 3170 (herein referred to as BreathSensors) devices (K913749). Therefore, Embla Systems intends to market the devices under their own name and to change contract manufacturers.

The BreathSensor is indicated for use as a single use device in sleep studies where breath signals are detected and recorded.

The Embla BreathSensor is basically an airflow thermistor that is used as an accessory to a polysomnograph or similar device to detect breathing. The BreathSensor family is comprised of four different sizes (Models 971, 974, 976 and 978) to accommodate adults, pediatrics, infants and premies.

The BreathSensors are for use with any standard PSG amplifier or recorder. They can also be adapted for use with most commercially available systems as long as a compatible interface cable is available.

The intended patient population(s) and medical condition(s) to be diagnosed and/or treated by the device (indications for use) are un-changed.

There is no change in the design, materials or labeling (except the manufacturer's name) of the BreathSensors or the indications for use.

If there any questions regarding this submission, please contact the undersigned.

K-35

Sincerely,

Robert G. Schueppert

Robert Schueppert
Director of Regulatory Affairs
Embla Systems, Inc.
11001 W. 120th Ave., Suite 200
Broomfield, Colorado USA
Phone: 303-962-1786, Fax: 303-962-1810

Attachments:
A – Truthful and accurate statement

ATTACHMENT A

April 5, 2011

TRUTHFUL AND ACCURATE STATEMENT

In my capacity as the Director of Regulatory Affairs for Embla Systems Inc, I hereby certify in accordance with 21 CFR 807.87(k), that all information submitted in this notification is truthful and accurate to the best of my knowledge and that no material fact has been knowingly omitted.

Robert G. Schueppert

Robert Schueppert
Director of Regulatory Affairs
Embla Systems

DO NOT REMOVE THIS ROUTE SLIP!!!!

K-91-3749

4/21/92

FROM:
EDENTEC
ATTN: GARY SYRING
10252 VALLEY VIEW ROAD

EDEN PRAIRIE, MN 55344

SHORT NAME: EDENTEC

LETTER DATE: 08/19/91
LOGIN DATE: 08/21/91
DUE DATE: 07/16/92

TYPE OF DOCUMENT: 510 (k) ST

CONTROL #: K913749

PHONE NO: 612-941-3006
ESTABLISHMENT NO: 2183597 N

SE

TO:
ODE/DMC

CONT. CONF.: ?
STATUS : R
REV PANEL : AN
PAN/PROD CODE(S): AN/ / Y /

FA

BZQ JUL 2 1992

SUBJECT:
EDENTRACE AIRFLOW 3171/SLEEP LAB AIRFLOW 3170

DECISION:
DECISION DATE: / /

RQST INFO DATE: 11/06/91
DATE: 02/24/92
DATE: / /
DATE: / /
DATE: / /
DATE: / /

INFO DUE DATE: 12/06/91
DATE: 04/30/92
DATE: / /
DATE: / /
DATE: / /
DATE: / /

ARDB

SUPPLEMENT: 01 LTR DATE: 911127 LOGIN DATE: 911129
SUPPLEMENT: 02 LTR DATE: 920416 LOGIN DATE: 920417

SE
7/2/92

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

JUL 2 1992

Re: K913749/B
EdenTrace Airflow Cable Model 3171 and Sleep Lab Airflow Cable Model 3170
Dated: April 16, 1992
Received: April 17, 1992
Regulatory Class: II

Mr. Gary Syring
EdenTec
10252 Valley View Road
Eden Prairie, Minnesota 55344

Dear Mr. Syring:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) 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 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal laws or regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device, please contact the Division of Compliance Operations, Device Labeling Compliance Branch (HFZ-326) at (301) 427-1165. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Abhijit Acharya, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date 7/1/92

From REVIEWER(S) - NAME(S) Daryl Zuk

Subject 510(k) NOTIFICATION K913749 /B

To THE RECORD

It is my recommendation that the subject 510(k) Notification:

- ✓ (A) Is substantially equivalent to marketed devices.
- ____ (B) Requires premarket approval. NOT substantially equivalent to marketed devices.
- ____ (C) Requires more data.
- ____ (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Additional Comments: See Memo

Is this device subject to Postmarket Surveillance? Yes ☐ No ☒

This 510(k) contains: (check appropriate box(es))

- ☐ A 510(k) summary of safety and effectiveness, or
- ☑ A 510(k) statement that safety and effectiveness information will be made available
- ☐ The required certification and summary for class III devices

The submitter requests under 21 CFR 807.95:*

- ____ No Confidentiality
- ✓ Confidentiality for 90 days
- ____ Continued Confidentiality exceeding 90 days

Predicate Product Code w/panel and class: Brady Eng. mark 73 BZQ Class II

Additional Product Code(s) w/Panel (optional):

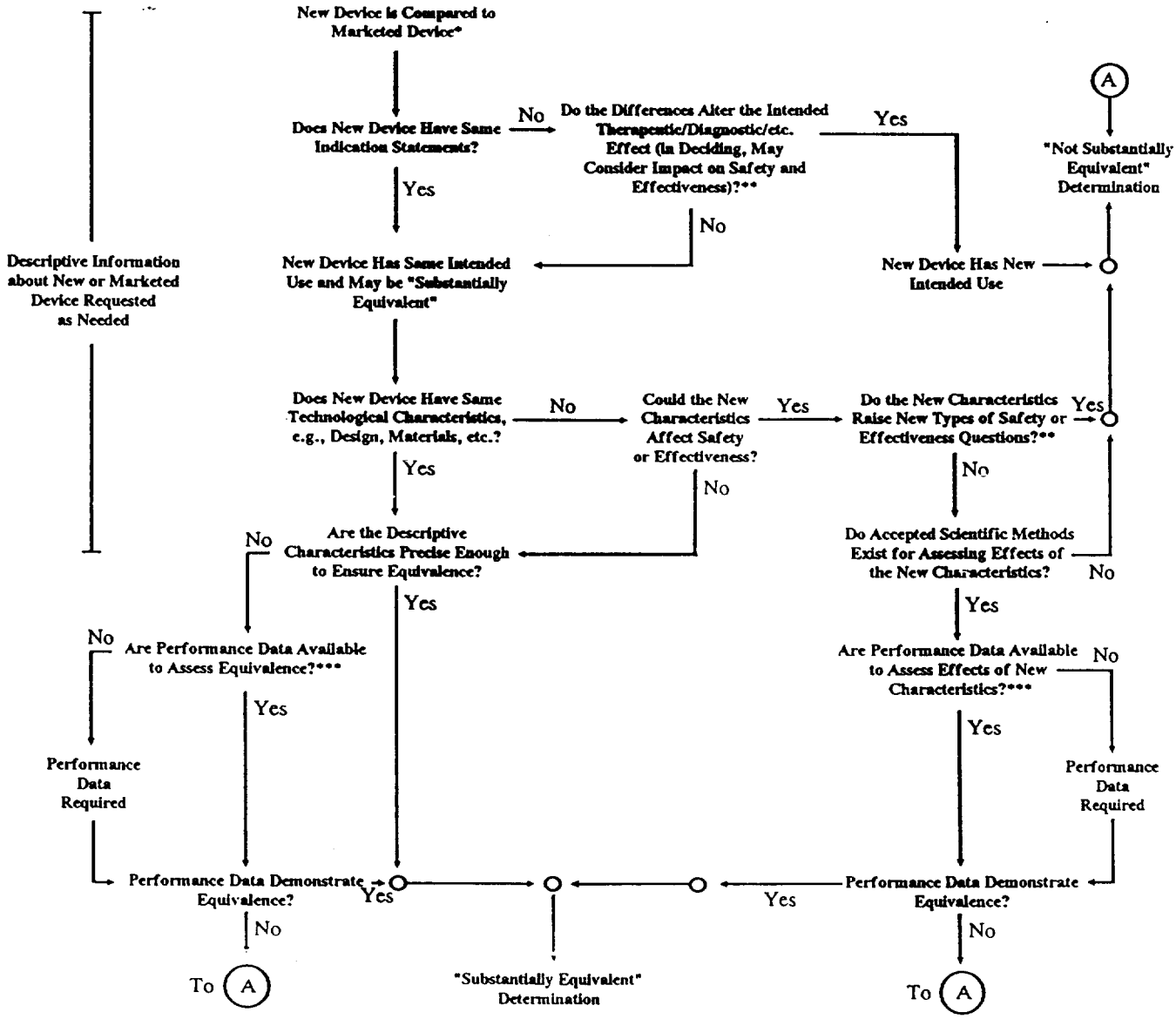
REVIEW: [signature] 28 Pages marked confidential (BRANCH CHIEF) ARDB (BRANCH CODE) 7/2/92 (DATE)

FINAL REVIEW: [signature] A. Carlson (DIVISION DIRECTOR) ADCR 7/2/92 (DATE)

*DOES NOT APPLY TO ANY "SE" DECISIONS

 Revised 11/18/91

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



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

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

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

K 913749 "SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

REVIEWER: David Ze DIVISION/BRANCH: DCRND/BRDB

TRADE NAME: Model 3170, 3171 COMMON NAME: Ultrasound Scanner/Cable

PRODUCT TO WHICH COMPARED:
(510(k) NUMBER IF KNOWN)

	YES	NO	
1. IS PRODUCT A DEVICE?			- IF NO STOP
2. 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 DAT.
(11.) DATA DEMONSTRATE EQUIVALENCE?	✓		

7/2/92

NOTE: IN ADDITION TO COMPLETING PAGE TWO, "YES" RESPONSES TO QUESTIONS 4, 6, 8, AND 11, AND EVERY "NO" RESPONSE REQUIRES AN EXPLANATION ON PAGE THREE AND/OR FOUR

NARRATIVE DEVICE DESCRIPTION

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. The following should be considered when preparing the summary of the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain 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.

SUMMARY: _____

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

MEMO TO THE RECORD
510(k) REVIEW

K913749/B

DATE: 7/1/91
FROM: David A. Zier

OFFICE: HFZ-450
DIVISION: DCRND/ARDE

COMPANY NAME: Edentec
DEVICE NAME: Edentrace Airflow 3171/ Sleep Lab Airflow 3170

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION-MAKING DOCUMENTATION

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

1. INTENDED USE:

The devices are intended to provice an airflow signal to a recording device. The firm included a statement in each of the operator's manuals (3171 and 3170) that states that the device does not provide an alarm on the absence of airflow. The 510(k) also includes the airflow sensors.

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

7/1/92

7/2/92

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

APRIL 21, 1992

EDENTEC
ATTN: GARY SYRING
10252 VALLEY VIEW ROAD
EDEN PRAIRIE, MN 55344

510(k) Number: K913749
Received: 04-17-92
Product: EDENTRACE AIRFLOW 3171/SLEEP LAB AIRFLOW 3170

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so within 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Robert I. Chissler
Chief, Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

EDENTEC®
A Nellcor Company

K913749B

April 16, 1992

Mr. David Zier
Office of Medical Devices (HFZ-401)
Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

Regarding: Requested 510(K) follow-up information:

Re: K913749A
EdenTrace Airflow Cable
Model 3171 and Sleep Lab
Airflow Cable Model 3170

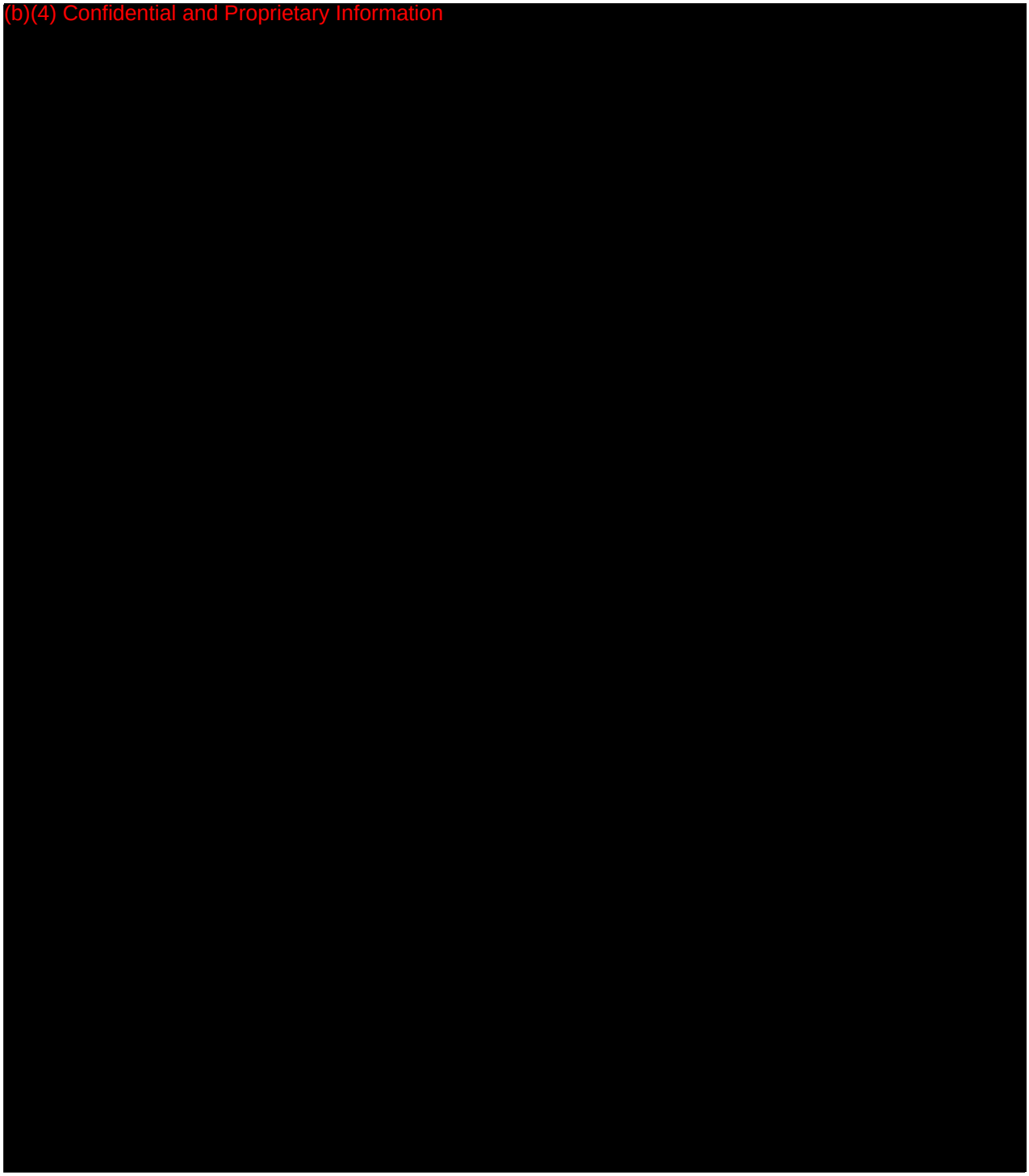
Dated: February 24, 1992
Received: February 28, 1992

(b)(4) Confidential and Proprietary Information

[redacted]

10252 Valley View Road • Eden Prairie, Minnesota 55344 • (612) 941-3006 • FAX (612) 829-5423

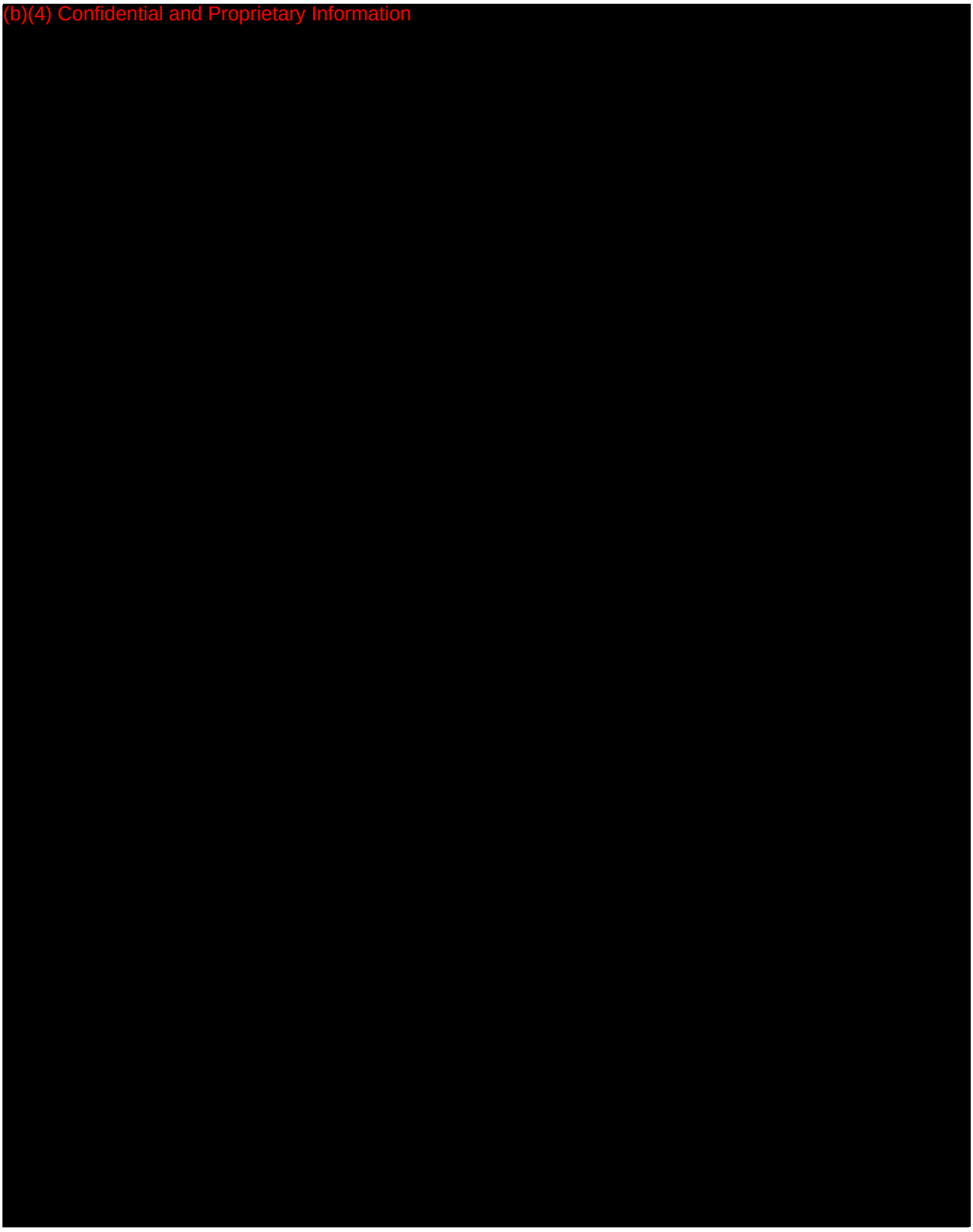
14



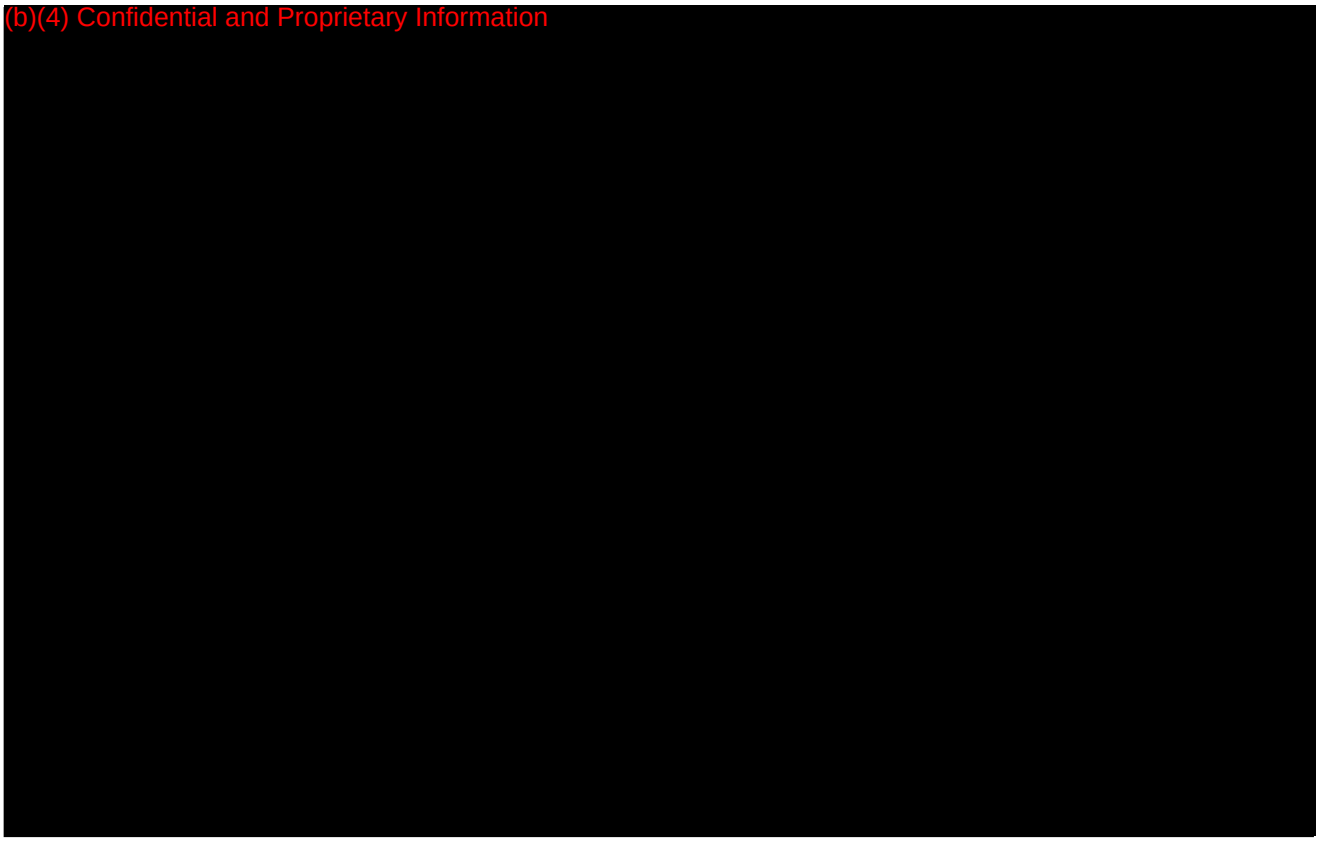
(b)(4) Confidential and Proprietary Information

16

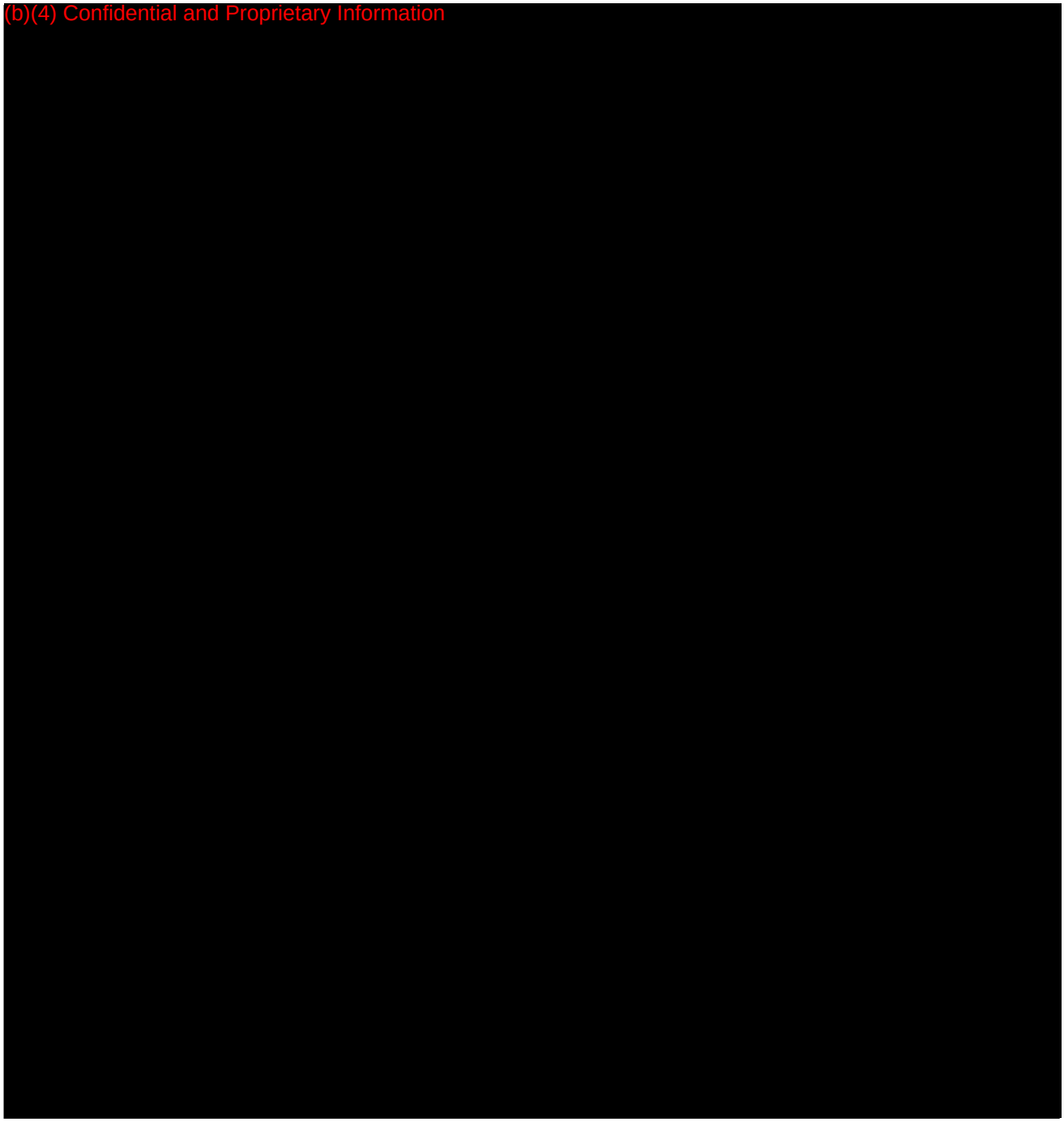
(b)(4) Confidential and Proprietary Information

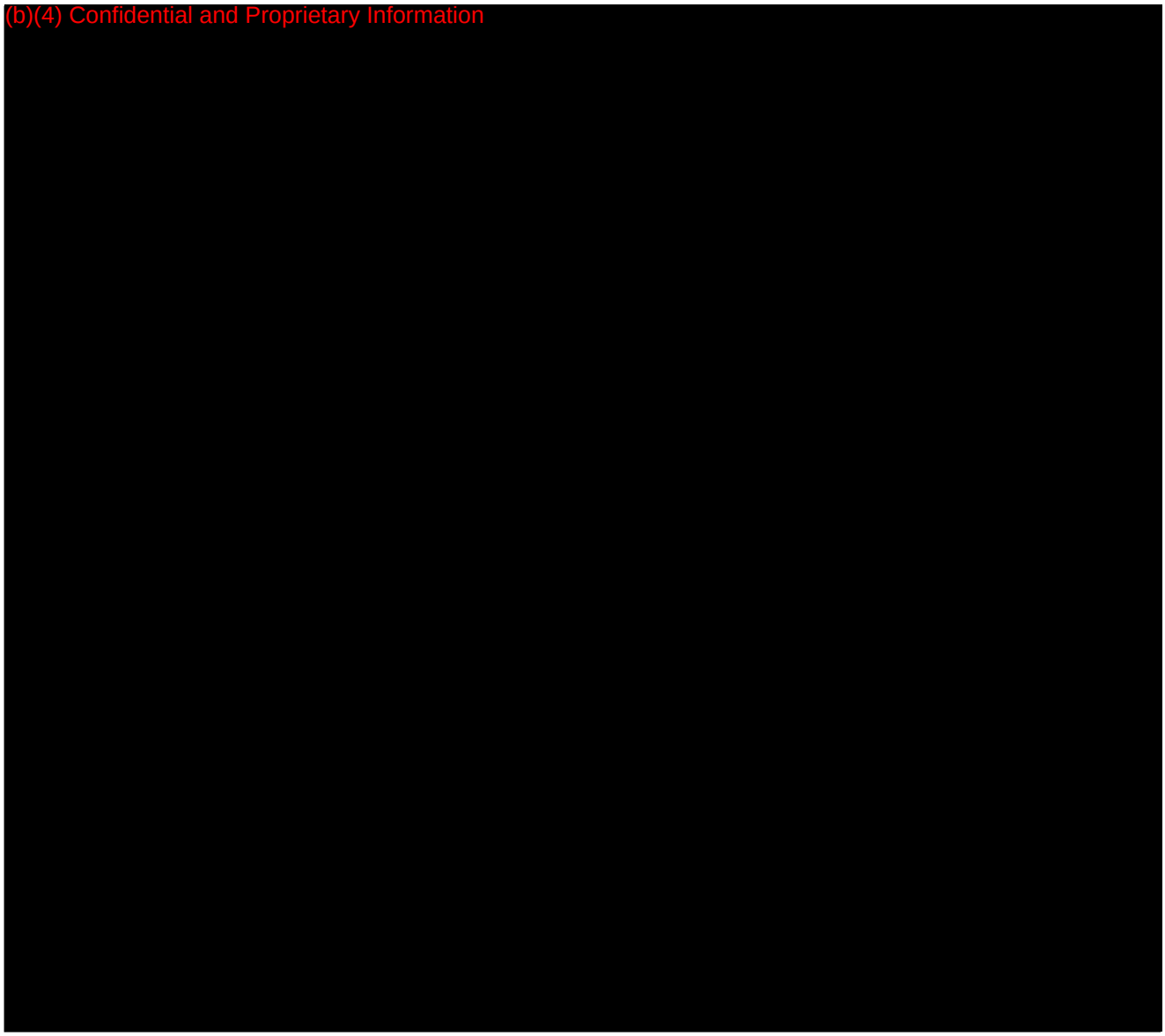


(b)(4) Confidential and Proprietary Information



(b)(4) Confidential and Proprietary Information





(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

Please call me with any questions.

Sincerely,

Gary Syring

Gary Syring
Director Quality Assurance

file: garys\airflow.392

DEPARTMENT OF HEALTH AND HUMAN SERVICES **Public Health Service**

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

MARCH 26, 1992

EDENTEC
ATTN: GARY SYRING
10252 VALLEY VIEW ROAD
EDEN PRAIRIE, MN 55344

510(k) Number: K913749
Product: EDENTRACE AIRFLOW
3171/SLEEP LAB
AIRFLOW 3170

Extended Until: 04/30/92

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

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

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Robert I. Chissler
Chief, Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

EDENTEC®
A Nellcor Company

March 20, 1992

Mr. David Zier
Office of Medical Devices (HFZ-401)
Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

Regarding: Requested 510(K) follow-up information:
Re: K913749A
EdenTrace Airflow Cable
Model 3171 and Sleep Lab
Airflow Cable Model 3170

Dated: February 24, 1992
Received: February 28, 1992

We are preparing a response to the questions you have asked concerning this premarket notification. Our response will be supplied by April 30, 1992. We request this time extension to provide a complete reply.

Please contact me with any questions.

Sincerely,

Gary Syring

Gary Syring
Director Quality Assurance

10252 Valley View Road • Eden Prairie, Minnesota 55344 • (612) 941-3006 • FAX (612) 829-5423

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

FEB 24 1992

Re: K913749A
EdenTrace Airflow Cable
Model 3171 and Sleep Lab
Airflow Cable Model 3170
Dated: November 27, 1991
Received: November 29, 1991

Mr. Gary Syring
Director Quality Assurance
EdenTec
10252 Valley View Road
Eden Prairie, Minnesota 55344

Dear Mr. Syring:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a device marketed prior to May 28, 1976, the enactment date of the Medical Device Amendments, based solely on the information you provided. In order for us to complete the review of your submission, we require the following information:

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a pre-Amendments device with regard to its safety and effectiveness.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(f) and (h), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act).

If the requested information is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be re-submitted so that your new 510(k) is complete.

If you have questions concerning the contents of this letter, please contact David Zier at (301) 427-1053. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

for Abhijit Acharya, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

DO NOT REMOVE THIS ROUTE SLIP!!!!

K-91-3749

2/24/92

FROM: EDENTEC ATTN: GARY SYRING 10252 VALLEY VIEW ROAD EDEN PRAIRIE, MN 55344 SHORT NAME: EDENTEC	LETTER DATE 08/19/91	LOGIN DATE 08/21/91	DUE DATE 02/27/92
	TYPE OF DOCUMENT: 510 (k)		CONTROL # K913749
	PHONE NO: 612-941-3006 ESTABLISHMENT NO: 2183597		
TO: ODE/DMC	CONT. CONF.: ? STATUS : H REV PANEL : AN PAN/PROD CODE(S): AN/ / /		
SUBJECT: EDENTRACE AIRFLOW 3171/SLEEP LAB AIRFLOW 3170			
DECISION: DECISION DATE: / /	RQST INFO DATE: 11/06/91 DATE: 02/24/92 DATE: / / DATE: / / DATE: / / DATE: / /	INFO DUE DATE: 12/06/91 DATE: 03/25/92 DATE: / / DATE: / / DATE: / / DATE: / /	

SUPPLEMENT: 01 LTR DATE: 911127 LOGIN DATE: 911129

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date

From REVIEWER(S) - NAME(S) Paul A Zhu

Subject 510(k) NOTIFICATION K913749 /A

To THE RECORD

It is my recommendation that the subject 510(k) Notification:

_____ (A) Is substantially equivalent to marketed devices.

_____ (B) Requires premarket approval. NOT substantially equivalent to marketed devices.

✓ (C) Requires more data.

_____ (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Additional Comments: See review

Is this device subject to Postmarket Surveillance? Yes ☐ No ☑

This 510(k) contains: (check appropriate box(es))

☑ A 510(k) summary of safety and effectiveness, or

☐ A 510(k) statement that safety and effectiveness information will be made available

☐ The required certification and summary for class III devices

The submitter requests under 21 CFR 807.95:*

_____ No Confidentiality

✓ Confidentiality for 90 days

_____ Continued Confidentiality exceeding 90 days

Predicate Product Code w/panel and class:

Additional Product Code(s) w/Panel (optional):

REVIEW: [signature] (BRANCH CHIEF) ARDB BRANCH CODE 2/21/92 (DATE)

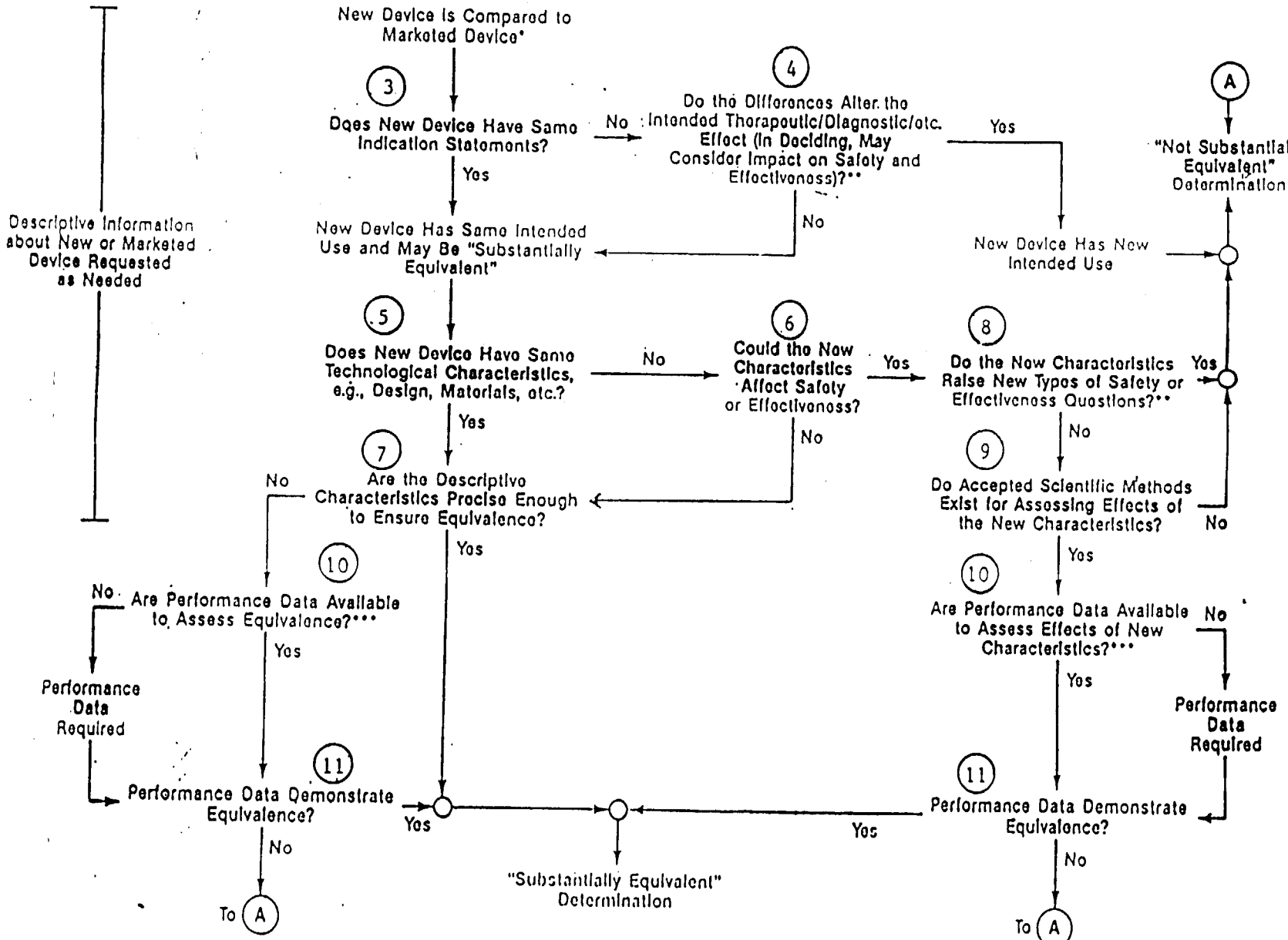
FINAL REVIEW: _____ (DIVISION DIRECTOR) _____ (DATE)

*DOES NOT APPLY TO ANY "SE" DECISIONS

90

Revised 11/18/91

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information If the Relationship Between Marketed and "Predicate" (Pre-Amendments or Reclassified Post-Amendments) Devices Is Unclear.

** This Decision Is Normally Based on Descriptive Information Alone, But Limited Testing Information Is Sometimes Required.

*** Data May Be in the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

MEMO TO THE RECORD

K913849

DATE: 2/20/92
FROM: David A. Zier

OFFICE: HFZ-450
DIVISION: DCRND/ARDB

COMPANY NAME: Edentec
DEVICE NAME: Airflow 3171/Sleepflow 3170

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

DEPARTMENT OF HEALTH AND HUMAN SERVICES **Public Health Service**

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

DECEMBER 3, 1991

EDENTEC
ATTN: GARY SYRING
10252 VALLEY VIEW ROAD
EDEN PRAIRIE, MN 55344

510(k) Number: K913749
Received: 11-29-91
Product: EDENTRACE AIRFLOW 3171/SLEEP LAB AIRFLOW 3170

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

The Safe Medical Devices Act of 1990, signed on November 28, states that ou may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so within 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Robert I. Chissler
Chief, Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

MEMO TO THE RECORD
TELEPHONE CONVERSATION

K 913749

DATE: 2/20/92
FROM: David A. Zier, Electrical Engineer

OFFICE: HFZ-450
DIVISION: DANRD/AD

COMPANY NAME: Edentec
DEVICE NAME: Airflow 3171/Sleepflow 3170

Between: David A. Zier, Electrical Engineer
DCRND/ARDB, HFZ-430

And: Gary Syring
ph# 612-941-3006

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

MEMO TO THE RECORD
TELEPHONE CONVERSATION

K 913749

DATE: 2/13/92
FROM: David A. Zier, Electrical Engineer

OFFICE: HFZ-450
DIVISION: DANRD/ADB

COMPANY NAME: Edentec
DEVICE NAME: Airflow 3171/Sleepflow 3170

Between: David A. Zier, Electrical Engineer
DCRND/ARDB, HFZ-430

And: Gary Syring
ph# 612-941-3006

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

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3/

MEMO TO THE RECORD
TELEPHONE CONVERSATION

K 913749

DATE: 2/13/92
FROM: David A. Zier, Electrical Engineer

OFFICE: HFZ-450
DIVISION: DANRD/AD

COMPANY NAME: Edentec
DEVICE NAME: Airflow 3171/Sleepflow 3170

Between: David A. Zier, Electrical Engineer
DCRND/ARDB, HFZ-430

And: Gary Syring
ph# 612-941-3006

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

38

MEMO TO THE RECORD
TELEPHONE CONVERSATION

K 913749

DATE: 2/13/92
FROM: David A. Zier, Electrical Engineer

OFFICE: HFZ-450
DIVISION: DANRD/AD

COMPANY NAME: Edentec
DEVICE NAME: Air-flow 3171/Sleepflow 3170

Between: David A. Zier, Electrical Engineer
DCRND/ARDB, HFZ-430

And: Gary Syring
ph# 612-941-3006

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

<>

MEMO TO THE RECORD
TELEPHONE CONVERSATION

K 913749

DATE: 2/13/92
FROM: David A. Zier, Electrical Engineer

OFFICE: HFZ-450
DIVISION: DANRD/AD

COMPANY NAME: Edentec
DEVICE NAME: Airflow 3171/Sleepflow 3170

Between: David A. Zier, Electrical Engineer
DCRND/ARDB, HFZ-430

And: Gary Syring
ph# 612-941-3006

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

EDENTEC®
A Nellcor Company

February 18, 1992

Mr. David Zier
Food and Drug Administration
Center for Devices and Radiological Health
Office of Medical Device (HFZ-401)
1390 Piccard Drive
Rockville, MD 20850

Regarding requested information
concerning 510(k): K913749
EdenTrace Airflow Cable Model 3171 and
Sleep Lab Airflow Cable Model 3170

This response is in reference your telephone request for information concerning the disposable air flow sensors:

(b)(4) Confidential and Proprietary Information

[redacted]

10252 Valley View Road • Eden Prairie, Minnesota 55344 • (612) 941-3006 • FAX (612) 829-5423

(b)(4) Confidential and Proprietary Information

[redacted]

If you have any questions, please contact me.

Sincerely,

Gary Syring
Director Quality Assurance

K913749/A

EDENTEC®

November 27, 1991

Mr. David Zier
Food and Drug Administration
Center for Devices and Radiological Health
Office of Medical Device (HFZ-401)
1390 Piccard Drive
Rockville, MD 20850

Regarding requested information
concerning 510(k): K913749
EdenTrace Airflow Cable Model 3171 and
Sleep Lab Airflow Cable Model 3170

This is a response to your written request for information, dated November 6, 1991. For reference a copy of this request is Attachment A.

I have listed my response by the same number as your question.

(b)(4) Confidential and Proprietary Information

[redacted]

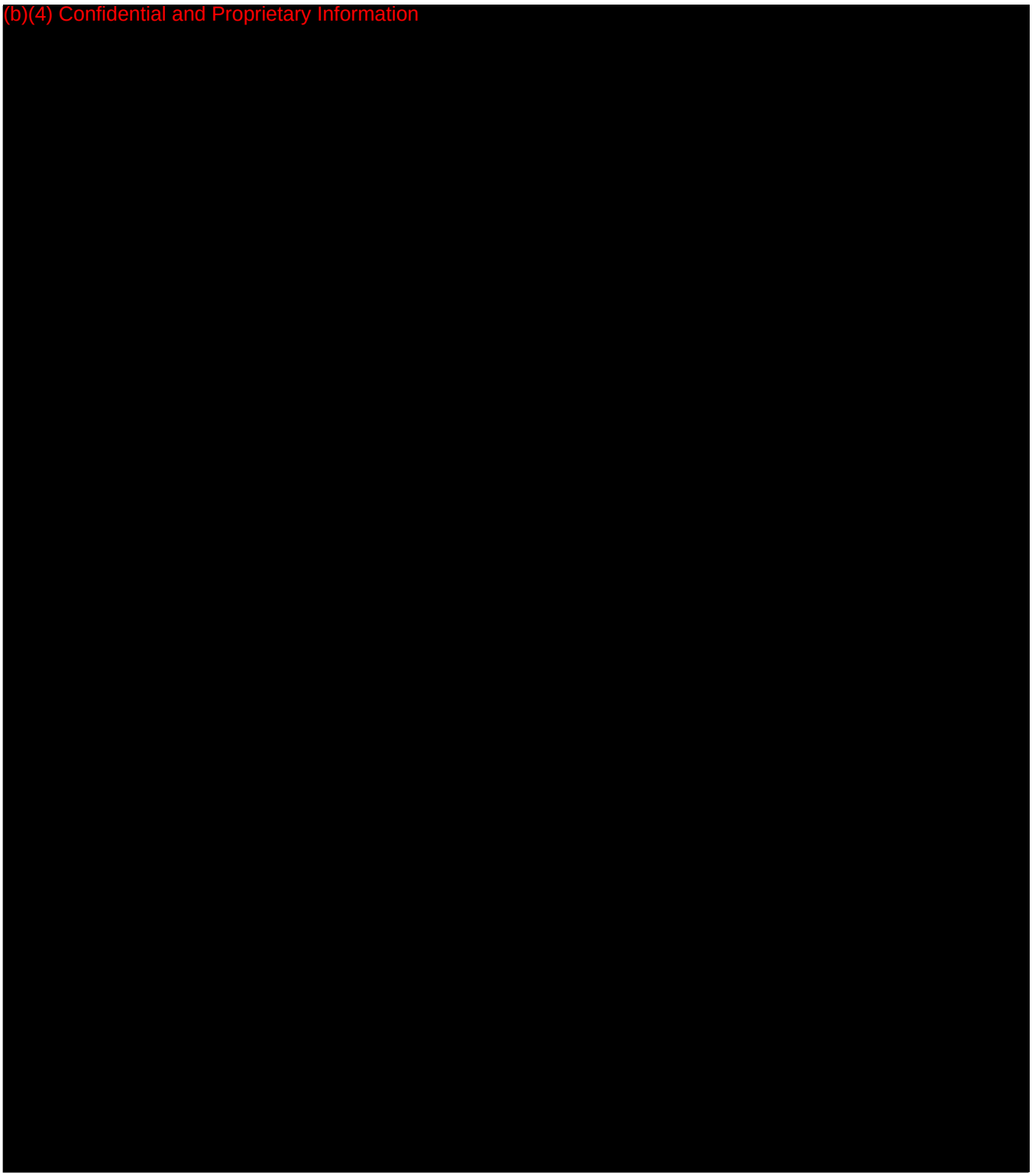
10252 Valley View Road • Eden Prairie, Minnesota 55344 • (612) 941-3006 • FAX (612) 829-5423

42

(b)(4) Confidential and Proprietary Information

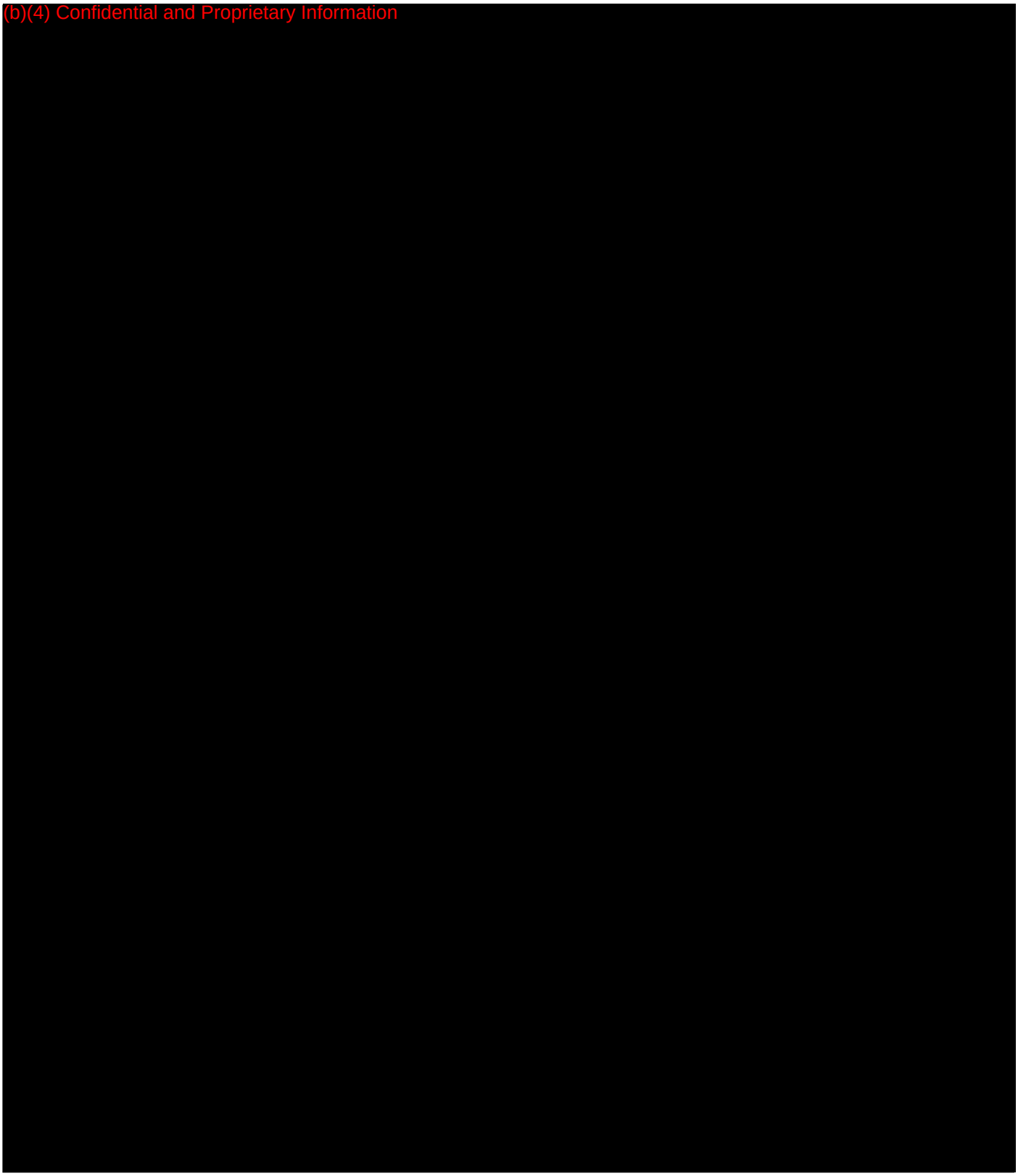
[redacted]

(b)(4) Confidential and Proprietary Information



CONFIDENTIAL

(b)(4) Confidential and Proprietary Information



CONFIDENTIAL

(b)(4) Confidential and Proprietary Information

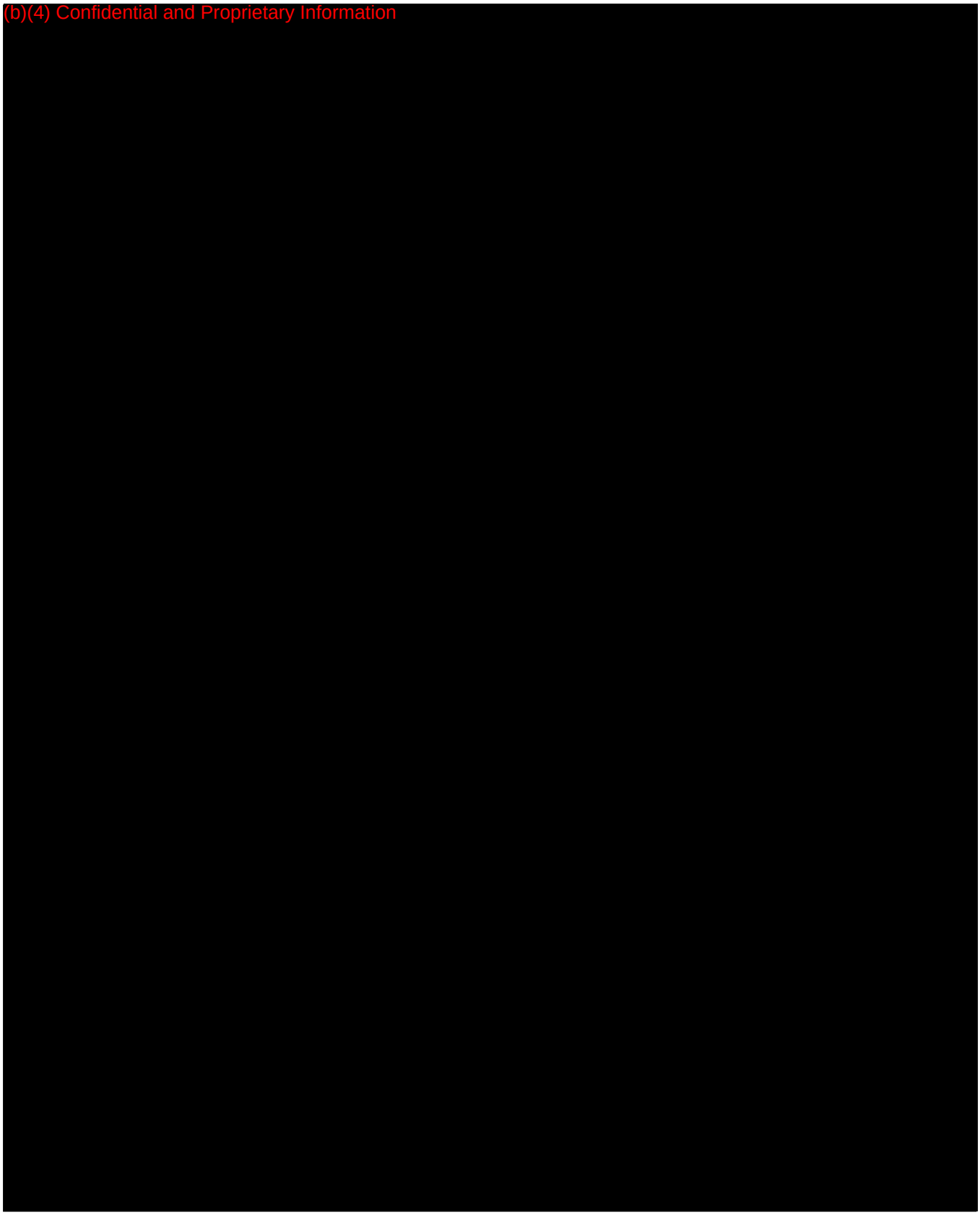
[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

CONFIDENTIAL

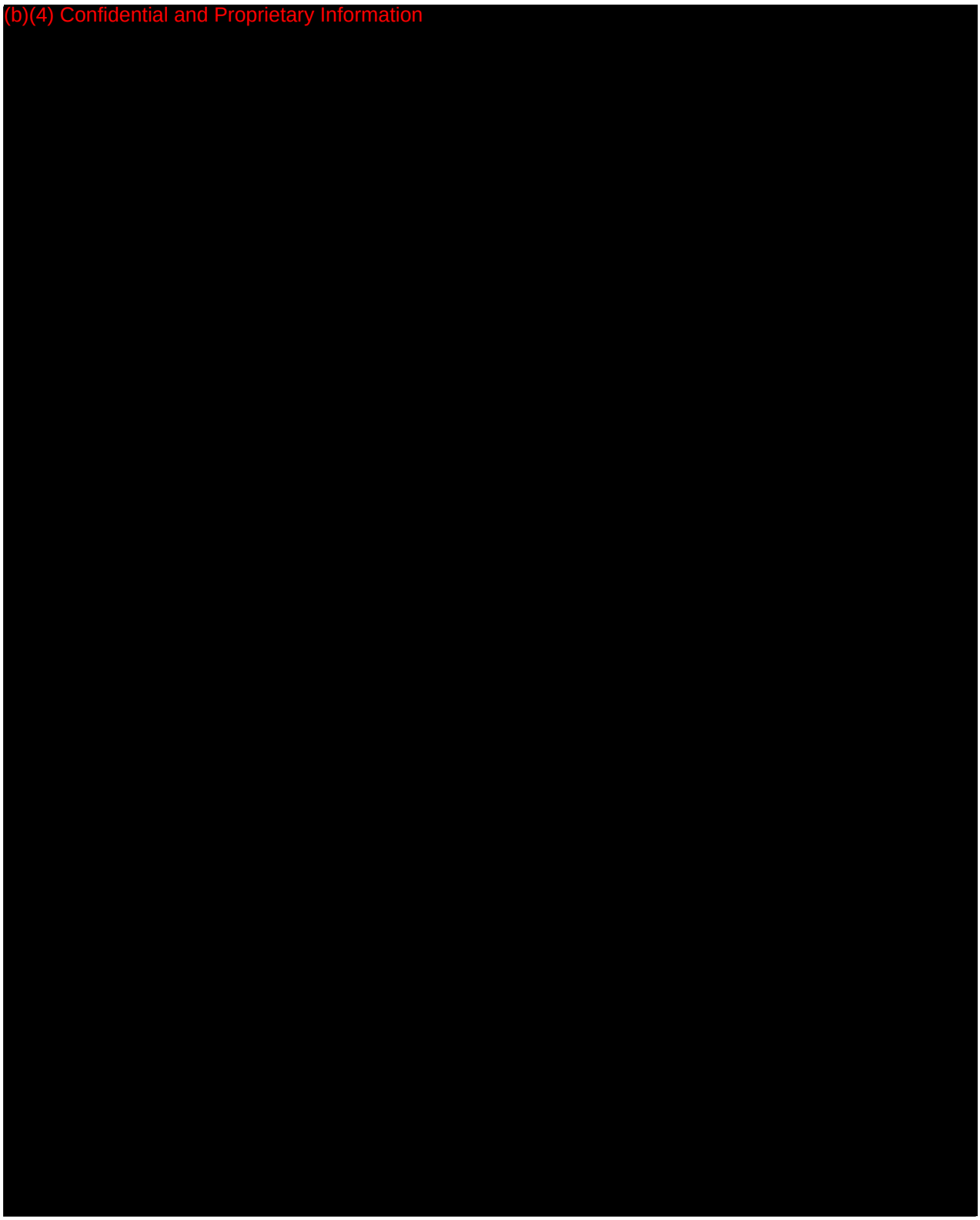
(b)(4) Confidential and Proprietary Information



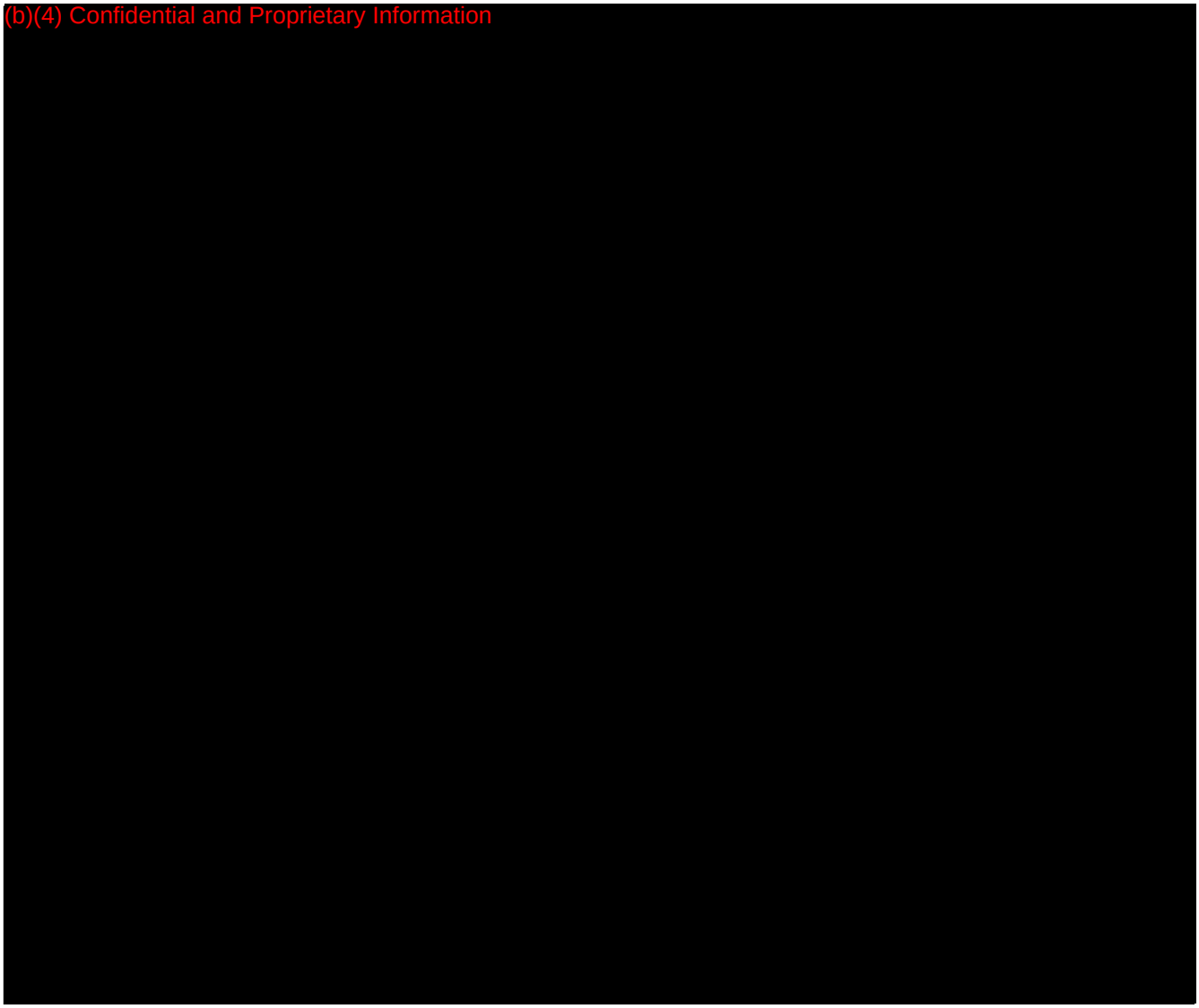
(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information



(b)(4) Confidential and Proprietary Information



I believe this information answers your questions. If you have any questions concerning this information, please call me. I believe we can save each other time if we discuss this material over the phone.

Thank you for your time.

Sincerely,

Gary Syring
Director Quality Assurance

file: airflow.510

ATTACHMENT A

Attachment A

Request for information, dated November 6, 1991

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

NOV 6 1991

Mr. Gary Syring
Director of Quality Assurance
EdenTec
10252 Valley View Road
Eden Prairie, Minnesota 55344

Re: K913749
EdenTrace Airflow Cable Model 3171
Sleep Lab Airflow Cable Model 3170
Dated: August 19, 1991
Received: August 21, 1991

Dear Mr. Syring:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a device marketed prior to May 28, 1976, the enactment date of the Medical Device Amendments, based solely on the information you provided. In order for us to complete the review of your submission, we require the following information:

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a pre-Amendments device with regard to its safety and effectiveness.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(f) and (h), and you have received a letter from FDA allowing you to do so. If you market the device

without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act).

If the requested information is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be re-submitted so that your new 510(k) is complete.

If you have questions concerning the contents of this letter, please contact David A. Zier at (301) 427-1053. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Abhijit Acharya, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

ATTACHMENT B

Attachment B

EdenTec Model 3170 Sleep Lab Airflow Cable and Model 970 series Airflow Sensor Instruction Manual
P/N 241-3144
Draft 4

EdenTec Model 3171 EdenTrace Airflow Cable and Model 970 series Airflow Sensor Instruction Manual
P/N 241-3145
Draft 2

Application Notes for EdenTec Airflow Sensors.

EDENTEC MODEL 3170 SLEEP LAB AIRFLOW CABLE AND MODEL 970 SERIES AIRFLOW SENSOR INSTRUCTION MANUAL

EdenTec Corporation
10252 Valley View Road
Eden Prairie, MN 55344
(612) 941-3006
Part No. 241-3144
Draft 4

TABLE OF CONTENTS

DESCRIPTION

The EdenTec Model 3170 Sleep Lab Airflow Cable is a self-contained active cable designed to interface the EdenTec Model 970-series single use airflow sensors to the headboard of any of the standard polygraph recorders.

The Model 970-series airflow sensors and Model 3170 Sleep Lab Airflow Cable measure the temperature change between ambient and inhaled/exhaled airflow from the nose and/or mouth of a patient. The sleep lab airflow sensor cable converts the resistance change from the sensor to an electrical signal that can be used with commercially available multichannel polygraphs - e.g. Grass Instruments, Nihon Kohden, etc.

The cable contains a lithium battery. It is designed to provide power for more than 800 8-hour studies. The device automatically turns itself "ON" when an airflow sensor is attached and "OFF" when the sensor is detached.

The airflow sensor is attached to a patient as described in the Patient Set-up sections.

INTENDED USE

The Model 3170 Sleep Lab Airflow Cable is designed to provide an airflow signal to a recording device. The airflow signal is a qualitative, not a quantitative signal. The airflow signal is provided by oral and/or nasal temperature sensitive components.

The cable is intended for use in qualitative airflow recordings that may assist in airflow analysis and sleep. The cable is not intended to alarm on the absence of airflow.

Accessory single use airflow sensors are used to provide resistance changes as affected by temperature changes in airflow representing inhaled and exhaled air.

These sensors come in six (6) sizes with the intended population of use dependent on patient size, not age:

Model 971 Adult Airflow Sensor	(nasal/oral)
Model 972 Small Adult Airflow Sensor	(nasal/oral)
Model 974 Child Airflow Sensor	(nasal/oral)
Model 976 Infant Airflow Sensor	(nasal/oral)
Model 977 Infant Nasal Airflow Sensor	(nasal only)
Model 978 Premie Nasal Airflow Sensor	(nasal only)

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WARNINGS AND PRECAUTIONS

1. The Model 3170 Sleep Lab Airflow Cable is intended for use only with Model 970 series single use airflow sensors.

2. Failure to apply the airflow sensor properly may cause a reduced signal level or no signal output.

3. The airflow sensor must be inspected once every 8 hours to ensure adhesion, skin integrity and correct placement. If skin integrity changes, remove or reposition the sensor if possible.

4. The airflow sensors are indicated for single-patient use.

5. The airflow sensors are shipped non-sterile.

6. Do not immerse the airflow sensor in water or cleaning solutions.

7. The Model 3170 Sleep Lab Airflow Cable and airflow sensors are designed for use with polygraph recorders with electrically isolated amplifiers manufactured by Grass Instruments, Nihon Kohden or equivalent.

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

9. Connect the Model 3170 Sleep Lab Airflow cable to an electrically isolated input. Patient injury can occur if the cable is not connected properly.

10. The Model 3170 Sleep Lab Airflow cable has an internal lithium battery. Dispose of the cable properly.

11. EdenTec recommends replacing the Model 3170 Sleep Lab Airflow cable two years after date of purchase.

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EQUIPMENT CHECK LIST

The following items are supplied with each Model 3170 Sleep Lab Airflow cable assembly:

1 - Model 3170 Sleep Lab Airflow Cable (Figure 1)

1 - 971 Adult - Nasal/Oral Airflow Sensor

1 - Instruction Manual P/N 241-3144

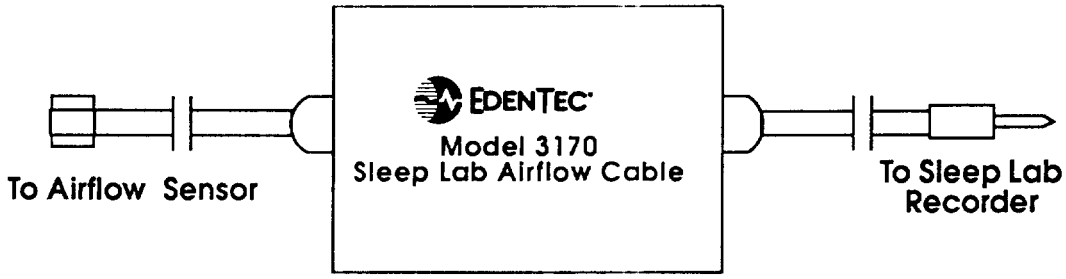


Figure 1

Model 3170 Sleep Lab Airflow Cable

GENERAL EQUIPMENT SET-UP

1. Attach the Model 3170 Sleep Lab Airflow Cable to the appropriate size Model 970 series airflow sensor. (Figure 2).

2. Attach the Model 3170 Sleep Lab Airflow Cable to a polygraph recorder isolated signal input.

   WARNING: Connection to a non-isolated signal input may result in injury.

3. Attach the airflow sensor on the patient as described in the Patient Set-up sections.

4. Monitor the signal level by selecting the appropriate channel on the polygraph recorder and observing the signal.

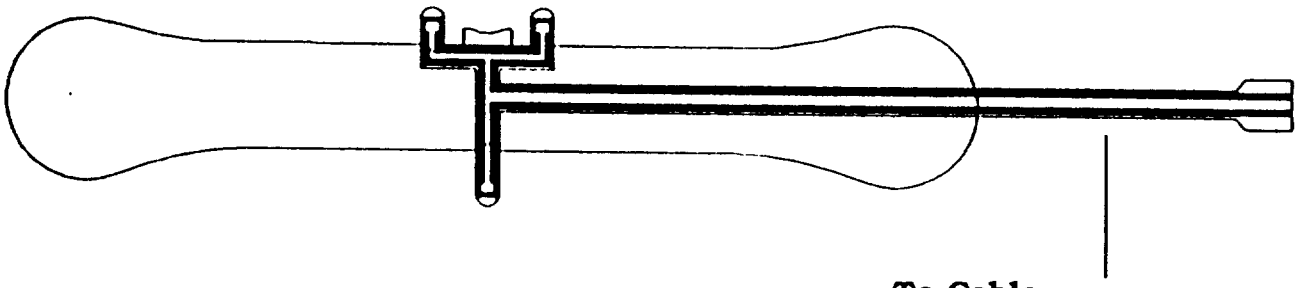


Figure 2

Model 971 Adult Airflow Sensor

PATIENT SET-UP - INFANT AND PREMIE

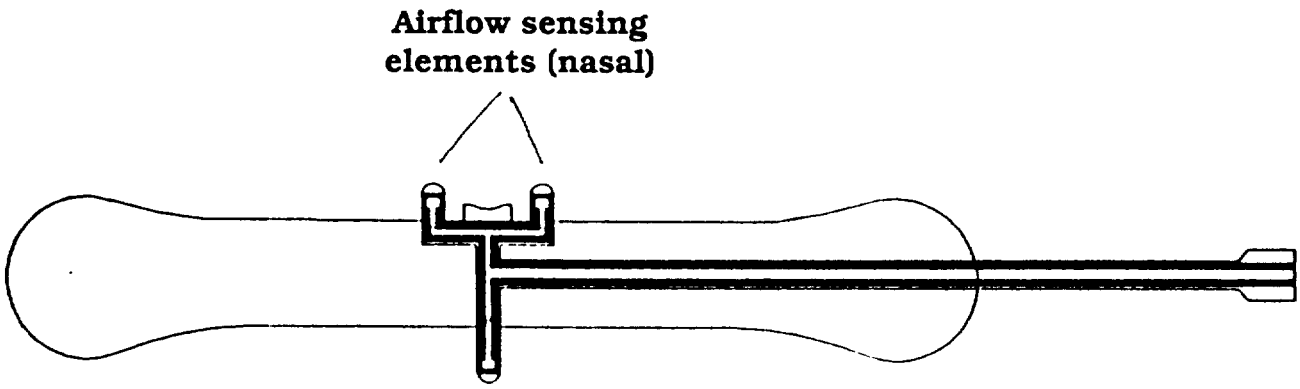
Models 976, 977 and 978 Airflow Sensors.

The airflow sensor should be placed directly under the baby's nasal openings. Secure the airflow sensor in place with the adhesive tape to ensure that the sensor will not become dislodged easily.

Do not cover the black edges of the airflow sensor with tape. This will reduce the amplitude of the airflow signal.

Do not obstruct the nostrils with the airflow sensor elements.

If any skin irritation is observed, discontinue the study. Try another type of tape.



PATIENT SET-UP - CHILD AND ADULT

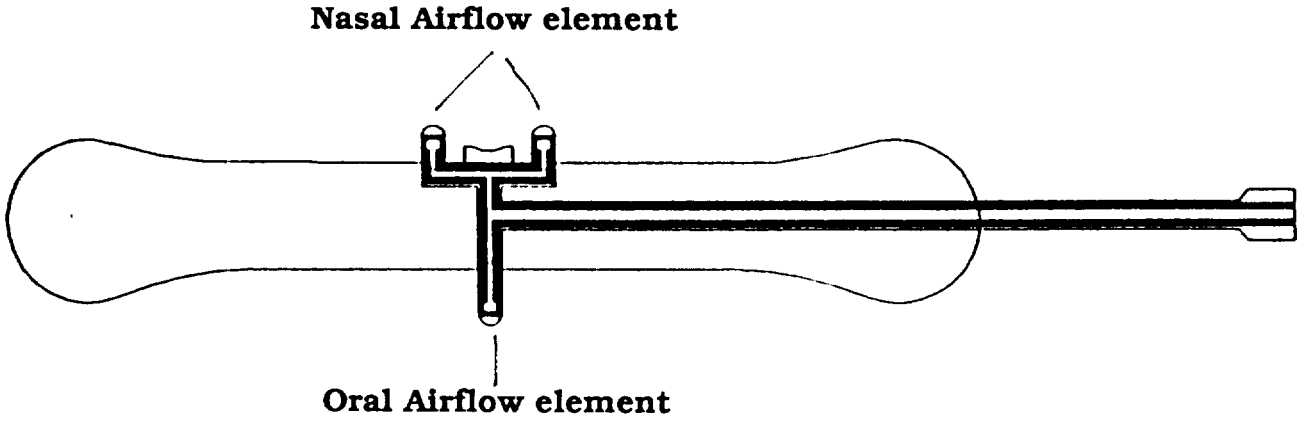
Models 971, 972 and 974 Airflow Sensors.

The child and adult sized sensors should be placed with the top two sensing elements pointing directly outside the nostrils. The single oral sensor should protrude just below the top lip. Additional taping of the sensor might be required to insure the sensor does not become dislodged in an unattended study.

Do not cover the black nasal and oral sensor elements with tape.

Do not obstruct the nostrils with the sensor elements.

If skin irritation occurs, discontinue use of that type. Try another type of tape.



POLYGRAPH SET UP

The following is a list of compatible polygraph amplifiers and settings for use with the Model 3170 Sleep Lab Cable. Other amplifiers of equivalent specification may also be compatible.

Model 3170 Specifications:

Input: EdenTec Model 970-series disposable airflow sensors
Output: Nominal 4 mv peak to peak signal for "typical" breathing, resting respiration

Suggested Use:

Grass - Low Level AC Amplifier 7P511J
1/2 Amp, Lo Freq.
mv/mm
Equalizer 0
60 Hz IN
1/2 Amp Hi 0.1 & 60

Low Level DC Amplifier 7P122D
Input Selection - DC20
Balance Voltage 0
Sensitivity 120mv/cm
1/2 Amp. Hi Freq. 0.5-3
60 Hz - IN

Nihon Kohden - Sensitivity 300
TC 5.0
Hi 35

WARNINGS: This cable is battery powered but is NOT ELECTRICALLY ISOLATED. It must only be used with electrically isolated amplifiers available with polygraphs. Check your polygraph amplifiers for isolated inputs.

CAUTION: This cable is powered whenever the sensor is attached. To conserve power, remove sensor when not in use.

TROUBLESHOOTING GUIDE

Problem	Possible Cause and Action
No output signal or weak signal during breathing.	1) The Model 970 series airflow sensor is improperly placed on the patient - check placement. 2) Sensor is not operational - replace sensor. 3) The Model 3170 Sleep Lab Airflow Cable assembly is damaged - replace cable assembly. 4) The internal battery in the cable assembly is depleted. Replace the cable assembly. The battery cannot be replaced. Send unit back to EdenTec for proper disposal.
Sensor changes position on patient	1) Tape does not hold the airflow sensor in place properly. Place additional tape on the sensor to better hold it in position.

WARRANTY

The Model 3170 Sleep Lab Airflow Cable and Model 970-series airflow sensors are sold as is. No warranty, repair or replacement agreement whatsoever is made or given. Cables and sensors may be easily damaged by improper handling or use due to their unavoidably fragile character, which is dictated by the requirement of their application.

EDENTEC MODEL 3171 EDENTRACE AIRFLOW CABLE AND MODEL 970 SERIES AIRFLOW SENSOR INSTRUCTION MANUAL

EdenTec Corporation
10252 Valley View Road
Eden Prairie, MN 55344
(612) 941-3006
Part No. 241-3145
Draft 2

Table of Contents

1.0 Description

The Model 970 Series Airflow Sensor and Model 3171 EdenTrace Airflow Cable are designed to measure the temperature change between ambient and inhaled/exhaled airflow from the nose and/or mouth of a patient.

The airflow sensor is attached to a patient as described in section 5. The EdenTrace airflow sensor cable Model 3171 converts the resistance change from the airflow sensor to a electrical signal that can be used with EdenTec multichannel recording system Model 2700. The Model 2700 recorder is a component of the 670, 680 and 700 systems described in section 4.

The airflow signal is one of several signals that is recorded by the EdenTrace recording system for later interpretation by health care professionals of the breathing patterns of the individual patient under study.

Intended Use, Cable

The EdenTrace Airflow Cable Model 3171 is designed to provide an air flow signal to a recording device. The air flow signal is a qualitative, not a quantitative signal. The air flow signal is provided by oral and/or nasal temperature sensitive resistive components.

The cable is intended for use in qualitative air flow recordings that may assist in air flow analysis and sleep. The cable is not intended to alarm on the absence of air flow.

Accessory Disposable Air flow sensors are used to provide resistance changes as affected by temperature changes in airflow, representing airflow inhaled and exhaled.

These sensors come in six (6) sizes with the intended population of use dependent on patient size, not age:

Adult	Model 971	(nasal/oral)
Small Adult	Model 972	(nasal/oral)
Child	Model 974	(nasal/oral)
Infant	Model 976	(nasal/oral)
Infant Nasal	Model 977	(nasal only)
Premie	Model 978	(nasal only)

2.0 Warning and Precautions

a. The Model 3171 EdenTrace Airflow Cable is for use only with Model 970 series single use airflow sensors.

b. Failure to apply the 970 sensor properly may cause a reduced signal level or no signal output.

c. The 970 series sensor must be inspected once every 8 hours to ensure adhesion, skin integrity and correct placement. If skin integrity changes remove the sensor or reposition if possible. Try another type of tape that will cause less irritation.

d. The 970 series airflow sensor is indicated for single-patient use.

e. The 970 series airflow sensor is shipped non-sterile.

f. Do not immerse the 970 series sensor in water or cleaning solutions.

g. The Model 3171 EdenTrace Airflow Cable designed ONLY for use with EdenTec Model 2700 recording systems. EdenTec does not recommend or support use of this cable with non-EdenTec equipment. The Model 2700 Multichannel Recorder is a component of the 670, 680 and 700 recording systems.

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

3.0 Equipment Check List

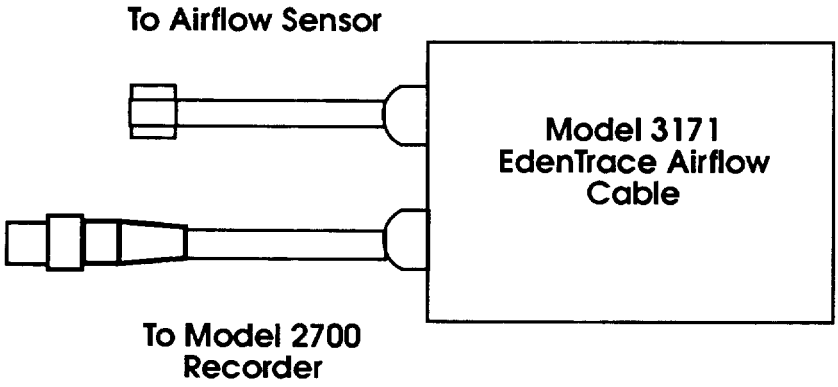
The following items are supplied with each Model 3071 EdenTrace Airflow cable assembly system.

1 - Model 3071 Interface Cable

1 - 971 Adult - Nasal/Oral Airflow Sensor

1 - Instruction Manual P/N 241-3145

In addition you will need a Model 2700 Multichannel Recorder. This recorder is also part of the 670, 680 and 700 systems.



4.0 General Equipment Set-Up

1. Follow instructions in the Model 2700 MultiChannel Recorder manual for set up of a thermistor study.

2. Attach Model 3171 EdenTrace Airflow Interface Cable into the appropriate size Model 970 series airflow sensor. The size you choose is based upon the patient. It is important that the temperature sensing elements are beneath the nostrils. The oral temperature sensing element must reside in the oral airway, not on the lips. See figure 1.

3. Attach the connector to the SENSOR input jack on Model 2700 EdenTrace recorder. See figure 2.

4. Attach the airflow sensor on the patient as described in section 5.

5. Monitor the signal level by selecting the appropriate CHANNEL on the Model 2700 Recorder signal channel and observing the signal strength on the rear panel meter. See figure 3.

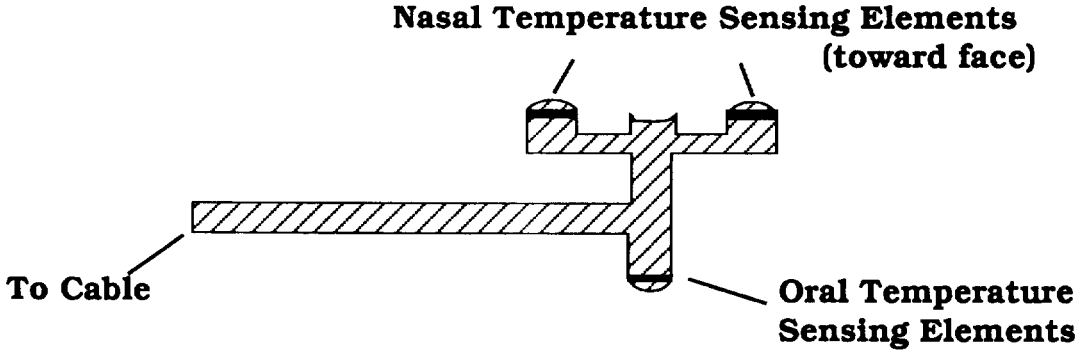


Figure 1

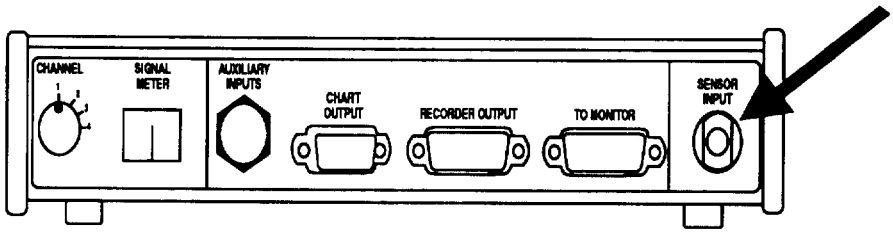


Figure 2

Model 2700 Multichannel Recorder Back Panel

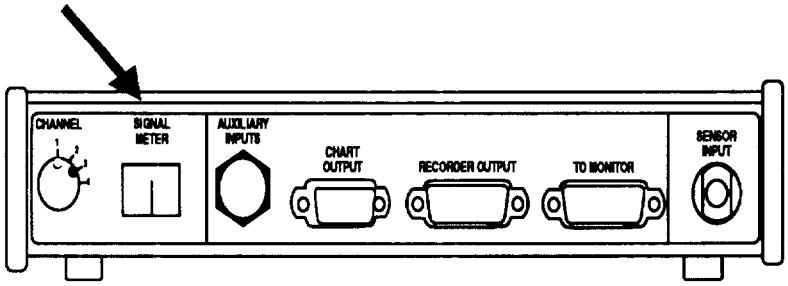


Figure 3

Model 2700 Multichannel Recorder Back Panel

5.0 Patient Set-Up - Infant

Model 976 and Model 978 Airflow Sensors.

The infant or premie airflow sensor should be placed directly under the baby's nasal openings. The black edges of the airflow sensor face the baby/child. Secure the airflow sensors in place with surgical grade adhesive tape to assure the sensor will not become dislodged easily.

I you select a Model 974 or 976, the oral temperature sensing element must be over the mouth, not touching the lips.

Do not obstruct the nostrils with the airflow sensor elements.

If any skin irritation is observed, discontinue the study. Try another type of tape.

Model 3171 Airflow Cable

Attach to EdenTrace Recorder

Figure 4

Infant - Setup

5.0 Patient Set-Up - Adult

Model 971, 972 and 974.

The child to adult sensor should be placed with the top two sensing elements pointing directly outside the nostrils. The single oral sensor should protrude just below the top lip. Additional taping of the sensor might be required to insure the sensor does not become dislodged in an unattended study.

Do not cover the black nasal and oral sensor elements with tape.

Do not obstruct the nostrils with the sensor elements.

If skin irritation occurs, discontinue use of that type. Try another type of tape.

Model 3171 Airflow Cable

Attach to EdenTrace Recorder

Figure 5

Adult - Setup

6.0 Troubleshooting Guide

Problem	Possible Cause and Action
No output signal or weak signal during breathing patient.	1) The Model 970 series airflow sensor is improperly placed on the patient - check placement. 2) Sensor is not operational - replace 970 series airflow sensor. 3) The Model 3071 EdenTrace Airflow cable assembly is damaged - replace Model 3071 cable assembly. 4) The internal battery in the cable assembly is depleted - replace Model 3071 cable assembly.
Sensor changes position on patient	1) The Model 970 series airflow sensor tape does not hold the sensor in place properly. Place additional tape on the sensor to better hold it in position.

7.0 Warranty

The Model 3071 EdenTrace Airflow Cable and Model 970 Series Airflow Sensors are sold as is. No warranty, repair or replacement agreement whatsoever is made or given. Cables and sensors may be easily damaged by improper handling or use, due to their unavoidably fragile character, which is dictated by the requirement of their application.

EDENTEC

Application Note

Model 971 Disposable Airflow Sensor Adult

This package contains the Model 971 Disposable Airflow Sensor designed for use on adults. This device is intended for use only on adults.

Application
Remove the Model 971 Disposable Airflow Sensor from the package. Peel the airflow sensor/tape assembly away from the backing.

Position the airflow sensor so that the two projections are lined-up under the patient's nostrils. The single bottom projection should be positioned between the lips.

The adhesive surface of the tape should be against the patient's skin holding the airflow sensor in place. The EdenTec logo will be visible. (Figure 1)

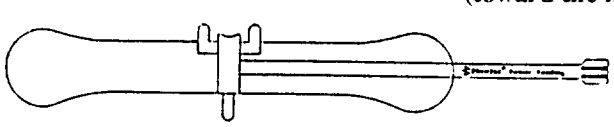


Figure 1

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Attach the free end of the airflow sensor cable input as indicated in Figure 2. The connection should fit snugly in place. It may be desirable to wrap a small piece of tape around the connector and sensor attachment to insure that the sensor is not accidentally detached.

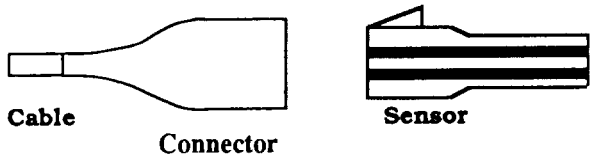

Figure 2

NOTE: DO NOT CLEAN. The Model 971 Disposable Airflow Sensor is designed for single patient use. Attempts to clean the airflow sensor may result in damage and loss of airflow sensor function.

Discontinue use if skin irritation occurs.

CABLES AND SENSORS. No warranty, repair or replacement agreement whatsoever is made as to cables and sensors as they may be easily damaged by improper handling or use due to their unavoidably fragile character, which is dictated by the requirements of their application.

CAUTION: Federal Law (USA) restricts this device to sale by or on order of a physician.

Instruction Sheet Re-order # 241-3146 Rev. C

EDENTEC

Application Note

Model 972 Disposable Airflow Sensor Small Adult

This package contains the Model 972 Disposable Airflow Sensor designed for use on small adults. This device is intended for use only on small adults.

Application

Remove the Model 972 Disposable Airflow Sensor from the package. Peel the airflow sensor/tape assembly away from the backing.

Apply the airflow sensor to the patient's face. Position the airflow sensor so that the two projections are under the patient's nostrils. The single bottom projection will be over the patient's mouth.

The adhesive surface of the tape should be against the patient's skin holding the airflow sensor in place. The EdenTec logo will be visible. (Figure 1)

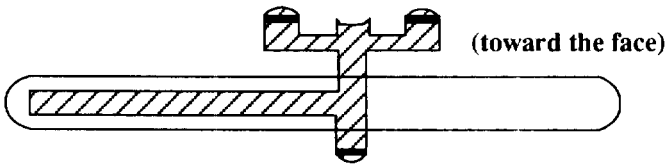

Figure 1

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Attach the free end of the airflow sensor to the airflow sensor cable input as indicated in Figure 2. The connection should fit snugly in place

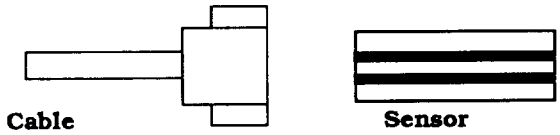

Figure 2

NOTE: DO NOT CLEAN. The Model 972 Disposable Airflow Sensor is designed for single patient use. Attempts to clean the airflow sensor may result in damage and loss of airflow sensor function.

CABLES AND SENSORS. No warranty or repair or replacement agreement whatsoever is made or given as to cables and sensors as they may be easily damaged by improper handling or use due to their unavoidably fragile character, which is dictated by the requirements of their application.

CAUTION: Federal Law (USA) restricts this device to sale by or on order of a physician.

Instruction Sheet Re-order # 241-3147 Rev. B

EDENTEC

Application Note

Model 974 Disposable Airflow Sensor Child

This package contains the Model 974 Disposable Airflow Sensor designed for use on children. This device is intended for use only on children.

Application
Remove the Model 974 Disposable Airflow Sensor from the package. Peel the airflow sensor/tape assembly away from the backing.

Apply the airflow sensor to the patient's face. Position the airflow sensor so that the two projections are under the patient's nostrils. The single bottom projection will be over the patient's mouth.

The adhesive surface of the tape should be against the patient's skin holding the airflow sensor in place. The EdenTec logo will be visible. (Figure 1)

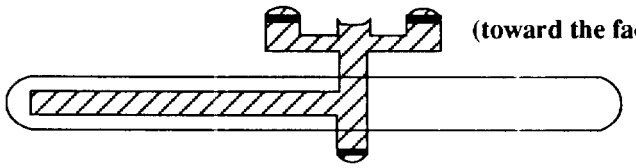

Figure 1

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Attach the free end of the airflow sensor to the airflow sensor cable input as indicated in Figure 2. The connection should fit snugly in place

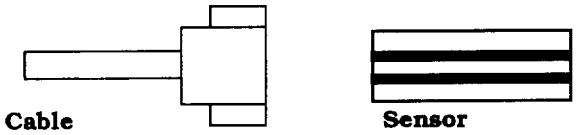

Figure 2

NOTE: DO NOT CLEAN. The Model 974 Disposable Airflow Sensor is designed for single patient use. Attempts to clean the airflow sensor may result in damage and loss of airflow sensor function.

CABLES AND SENSORS. No warranty or repair or replacement agreement whatsoever is made or given as to cables and sensors as they may be easily damaged by improper handling or use due to their unavoidably fragile character, which is dictated by the requirements of their application.

CAUTION: Federal Law (USA) restricts this device to sale by or on order of a physician.

Instruction Sheet Re-order # 241- 3148 Rev. B

EDENTEC

Application Note

Model 976 Disposable Airflow Sensor Infant

This package contains the Model 976 Disposable Airflow Sensor designed for use on infants. This device is intended for use only on infants.

Application
Remove the Model 976 Disposable Airflow Sensor from the package. Peel the airflow sensor/tape assembly away from the backing.

Apply the airflow sensor to the patient's face. Position the airflow sensor so that the two projections are under the patient's nostrils. The single bottom projection will be over the patient's mouth.

The adhesive surface of the tape should be against the patient's skin holding the airflow sensor in place. The EdenTec logo will be visible. (Figure 1)

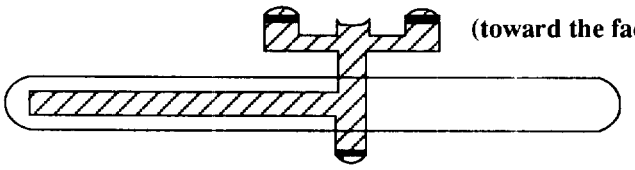

Figure 1

'52 Valley View Road • Eden Prairie, MN 55344 • (800) 826-2069

Attach the free end of the airflow sensor to the airflow sensor cable input as indicated in Figure 2. The connection should fit snugly in place.

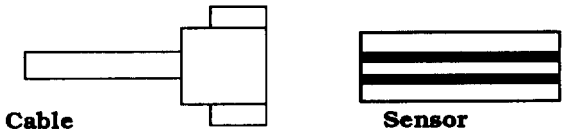

Figure 2

NOTE: DO NOT CLEAN. The Model 976 Disposable Airflow Sensor is designed for single patient use. Attempts to clean the airflow sensor may result in damage and loss of airflow sensor function.

CABLES AND SENSORS. No warranty or repair or replacement agreement whatsoever is made or given as to cables and sensors as they may be easily damaged by improper handling or use due to their unavoidably fragile character, which is dictated by the requirements of their application.

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Instruction Sheet Re-order # 241-3149 Rev. B

EDENTEC

Application Note

Model 977 Disposable Airflow Sensor Infant

This package contains the Model 977 Disposable Airflow Sensor designed for use on infants. This device is intended for use only on infants.

Application
Remove the Model 978 Disposable Airflow Sensor from the package. Peel the airflow sensor/tape assembly away from the backing.

Apply the airflow sensor to the patient's face. Position the airflow sensor so that the two projections are under the patient's nostrils.

The adhesive surface of the tape should be against the patient's skin holding the airflow sensor in place. The EdenTec logo will be visible. (Figure 1)

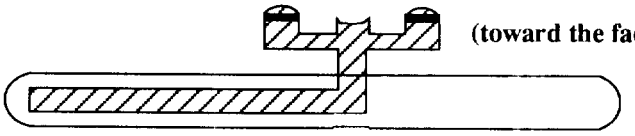

Figure 1

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Attach the free end of the airflow sensor to the airflow sensor cable input as indicated in Figure 2. The connection should fit snugly in place.

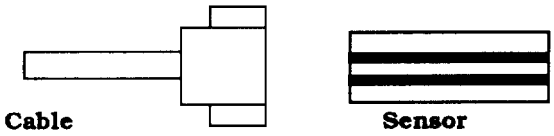

Figure 2

NOTE: DO NOT CLEAN. The Model 977 Disposable Airflow Sensor is designed for single patient use. Attempts to clean the airflow sensor may result in damage and loss of airflow sensor function.

CABLES AND SENSORS. No warranty or repair or replacement agreement whatsoever is made or given as to cables and sensors as they may be easily damaged by improper handling or use due to their unavoidably fragile character, which is dictated by the requirements of their application.

CAUTION: Federal Law (USA) restricts this device to sale by or on order of a physician.

Instruction Sheet Re-order # 241-XXXX Rev. A

EDENTEC

Application Note

Model 978 Disposable Airflow Sensor Premie

This package contains the Model 978 Disposable Airflow Sensor designed for use on premies. This device is intended for use only on premies.

Application
Remove the Model 978 Disposable Airflow Sensor from the package. Peel the airflow sensor/tape assembly away from the backing.

Apply the airflow sensor to the patient's face. Position the airflow sensor so that the two projections are under the patient's nostrils.

The adhesive surface of the tape should be against the patient's skin holding the airflow sensor in place. The EdenTec logo will be visible. (Figure 1)

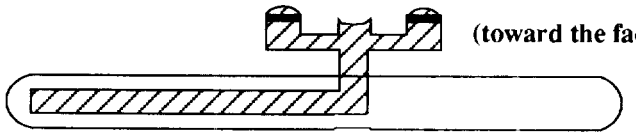

Figure 1

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Attach the free end of the airflow sensor to the airflow sensor cable input as indicated in Figure 2. The connection should fit snugly in place.

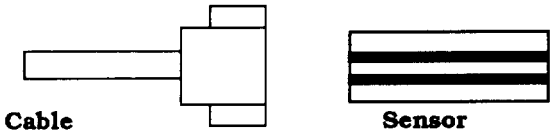


Figure 2

NOTE: DO NOT CLEAN. The Model 978 Disposable Airflow Sensor is designed for single patient use. Attempts to clean the airflow sensor may result in damage and loss of airflow sensor function.

CABLES AND SENSORS. No warranty or repair or replacement agreement whatsoever is made or given as to cables and sensors as they may be easily damaged by improper handling or use due to their unavoidably fragile character, which is dictated by the requirements of their application.

CAUTION: Federal Law (USA) restricts this device to sale by or on order of a physician.

Instruction Sheet Re-order # 241-3150 Rev. B

ATTACHMENT C

Attachment C

Schematic for Model 3170 Electronics,

(b)(4) Confidential and Proprietary Information

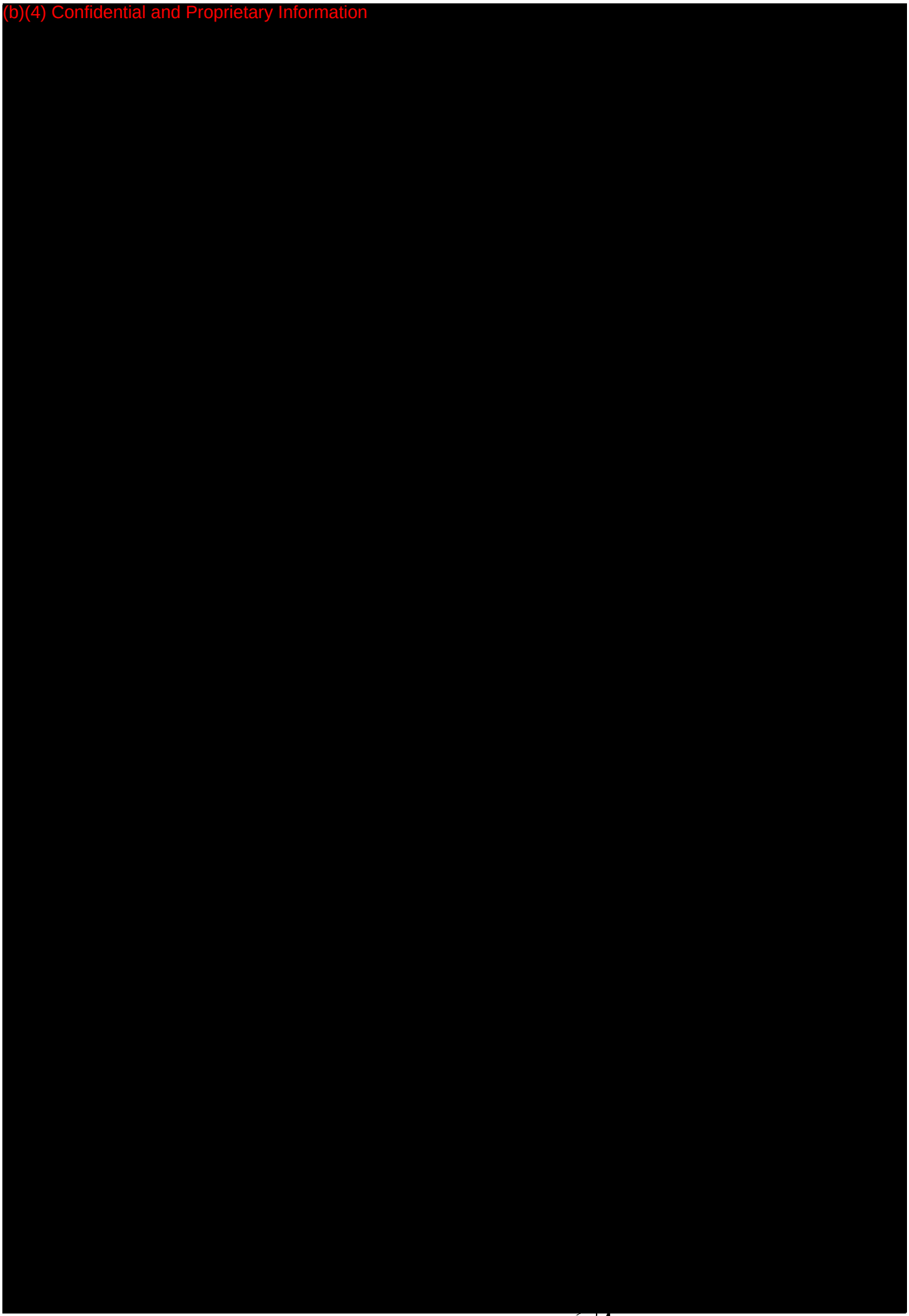
Schematic for Model 3171 Electronics,

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information



ATTACHMENT D

Attachment D

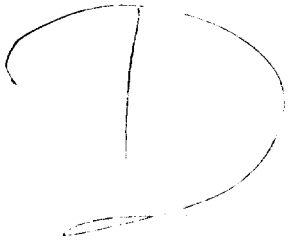
(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information



Attachment E

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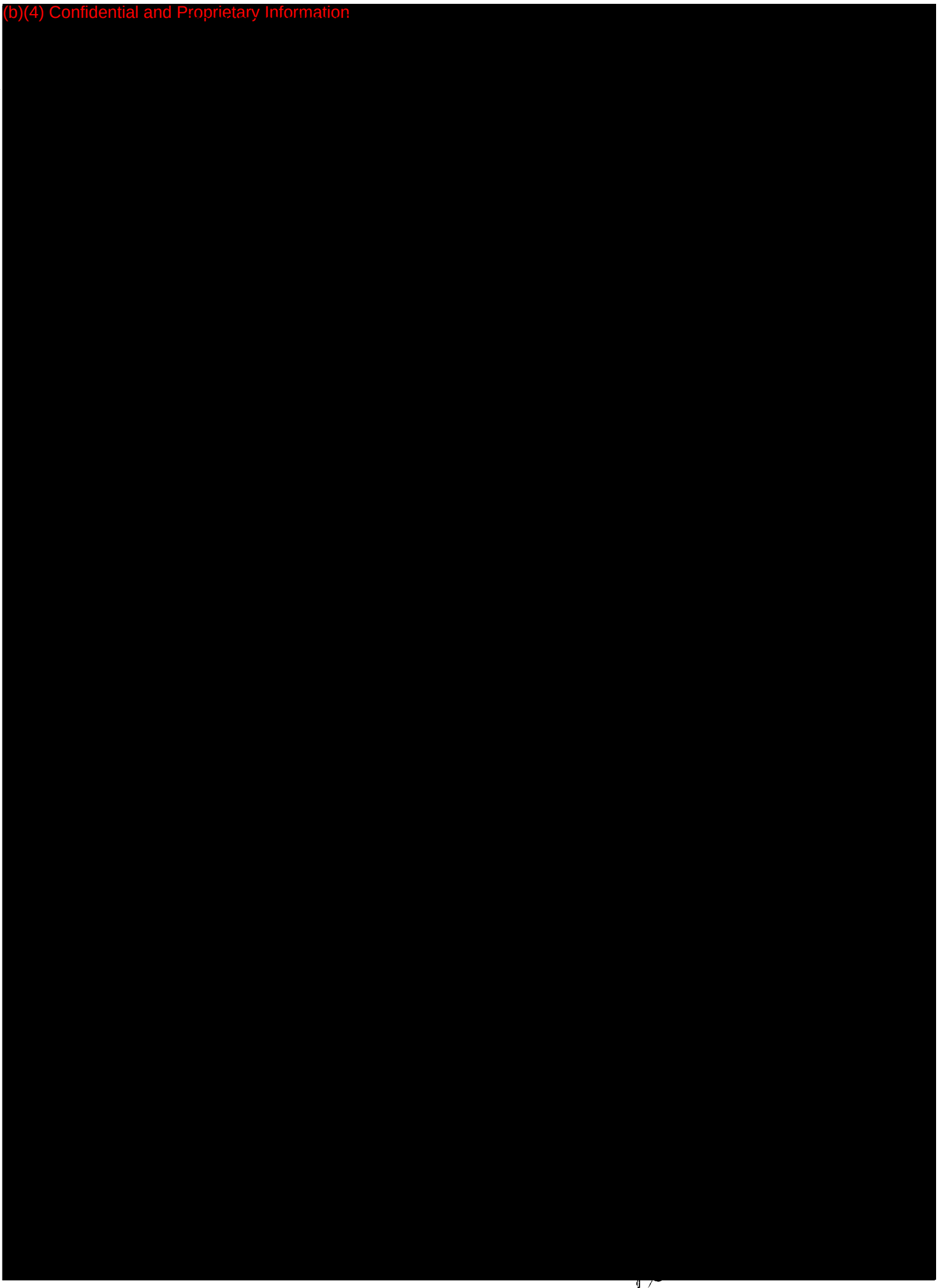
(b)(4) Confidential and Proprietary Information



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ATTACHMENT F

Attachment F

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EdenTec

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, Maryland 20910

Re: 510 (K) Notification

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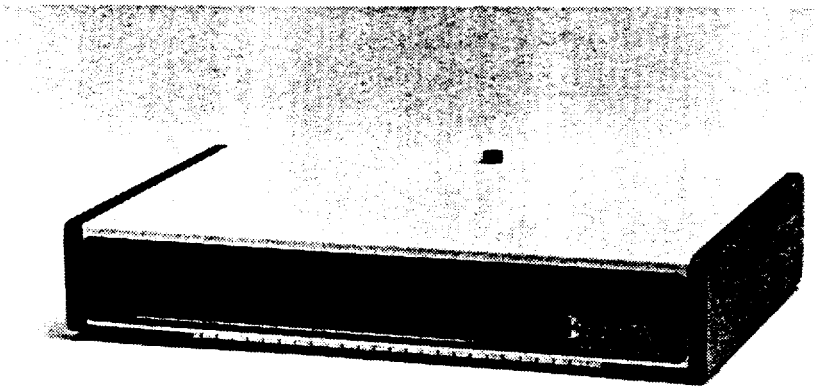
[redacted]

Sincerely,

Edward Schuck
President

ES/mf

EdenTec Model 2700 Multi-Channel Recorder
Option 3 and Option 4
Instruction Manual



HISTORY
Date: _____
Apprvd.: _____

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Eden Prairie, MN 55344
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REV A P/N 241-3075

TABLE OF CONTENTS PAGE

SECTION ONE: MODEL 2700 MULTI-CHANNEL WARNINGS AND PRECAUTIONS

OPERATION

The EdenTec Model 2700 Multi-Channel is an accessory to the EdenTec Model 2000W and 2000W Option H Heart and Respiration Rate Apnea Monitors. It will function properly only when connected to one of these monitors.

TRANSDUCERS

Do not use transducers other than EdenTec supplied or recommended strain gauges and nasal thermistors.

STATIC ELECTRICITY

Under certain circumstances, it is possible to build up a static charge by walking across carpeting in dry climates. We recommend you touch a metal object before touching the Multi-Channel System.

CLEANING

The Multi-Channel System can be wiped down with most mild cleansing agents. Do not immerse or allow fluid to run over the case.

INTERFERENCE

The Multi-Channel Recorder should be placed as close as possible to the EdenTec Monitor while in use. EdenTec recommends placing the Multi-Channel either on top of or underneath the Monitor. Some electrical appliances may cause electrical interference with the monitors. The Monitor and Multi-Channel System should not be placed on or close to electric drills, microwave ovens, televisions, or other electrical appliances.

SECTION TWO: EQUIPMENT REQUIREMENTS

- Multi-Channel Recorder Model 2700 Option 3 or Option 4

- EdenTec Model 2000W or 2000W Option H Monitor

- Monitor/Recorder interconnect cable Model 4030

- Nasal thermistor + thermistor patient cable (if applicable)

- Strain gauge + strain gauge patient cable (if applicable)

- Oximeter (if applicable), see Appendix B or contact EdenTec for compatible manufacturers

- Oximeter connect cable (if applicable)

- Instruction guide

- Low noise/high bias 60-minute recording tape* (good for one 12 hour recording)

- Small, phillips screwdriver (for set up panel)

- Small, flat head screwdriver (for connecting cables)

*The high bias tape is recommended for enhanced accuracy in recording signals requiring calibrated amplitudes. (A normal bias tape may be used when calibration is not critical.)

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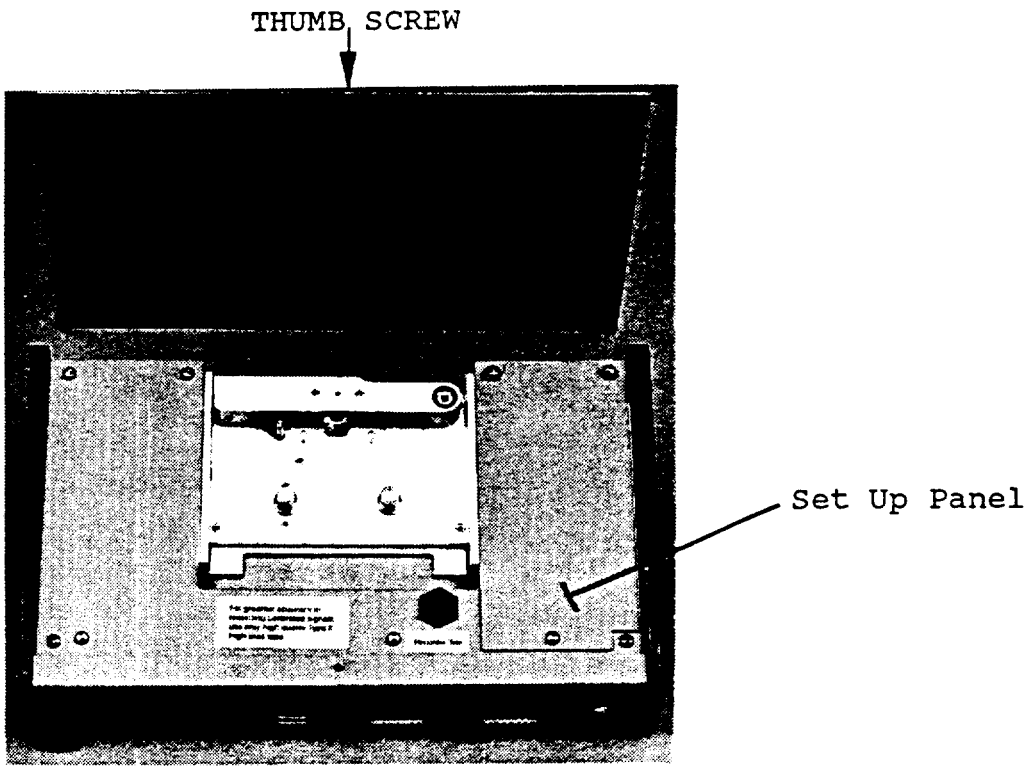
SECTION THREE: GENERAL EQUIPMENT SET-UP

Opening The Unit

The cover of the Multi-Channel Recorder is held closed by a thumb screw. To open the cover, turn the thumb screw counterclockwise until the cover can be lifted as shown below:



Check behind the panel to the right side of the recorder to verify proper set up. To remove the panel, unscrew the single phillips screw at the bottom of the panel. Removing this panel cover will disclose the set up switches shown on the next page.

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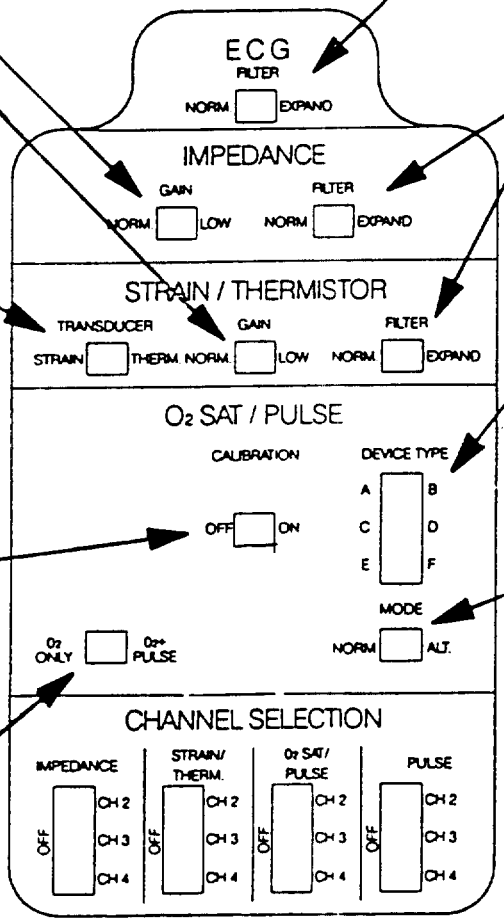
Set-Up Panel - Explanation of Settings

Set to NORM for normal pneumogram respiratory amplitude. Set to LOW for a more physiologic waveform with greater dynamic range.

If either a strain gauge or nasal thermistor is used, choose the desired sensor here.

Set to ON to record calibration signals on tape during the first 6 minutes (see next page for details on calibration).

Set to 02 ONLY if 02 saturation is to be recorded. Set to 02 + PULSE to multiplex both 02 saturation and the pulse plethysmagraphic signal onto one channel. Note: Must use oximeter with pulse signal available if 02 + PULSE is selected.



Set to NORM for normal pneumogram. Set to EXPAND for more physiologic ECG waveform.

Set to NORM for normal pneumogram. Set to EXPAND for more physiologic waveform.

If oximetry is used, check device type code in Appendix B and set according to oximeter manufacturer.

Set to NORM for calibration levels of 25, 50, 75 and 100% 02 saturation. Set to ALT for levels of 0, 50 and 100% 02 saturation.

Select the desired channels for the physiologic signals utilized. ECG is always on channel one.

Calibration Signals

When the calibration switch beneath the set up panel shown on the previous page is set ON, calibration signals are recorded on tape during the first 6 minutes each time the recorder is powered on. The calibration signals recorded depend on the physiologic channels chosen to be recorded. These are listed below:

ECG -	0.5 mV, 120 beats per minute
Impedance -	0.5 ohm, 30 breaths per minute
Strain Gauge -	30 breaths per minute reference
Nasal Thermistor -	30 breaths per minute reference
02 Saturation -	Repeating sequence of either 4 saturation levels of 25%, 50%, 75% and 100% if the mode switch on the set-up panel is set to NORM or 3 levels of 0%, 50%, and 100% if the mode switch is set to ALT. Each calibration level lasts 4 seconds. Additionally, every 6 minutes a single cycle calibration sequence, 4 seconds per level, occurs. Once each hour the sequence doubles in duration to 8 seconds per level. If a calibration sequence occurs during a possible desaturation event ($\leq$ 88% 02 saturation) the sequence is abbreviated to be only 0.5 seconds duration per level.

Explanation Of Mode Setting

The MODE switch on the set up panel is set according to the requirements of the pneumogram reading service and/or the physician interpreting the record. When this switch is set to NORM, 4 levels of calibration are recorded on tape (if the calibration switch is set ON) corresponding to 25%, 50%, 75%, and 100% 02 saturation. This allows the reader to calibrate the strip chart during playback to show 0-100% full scale or 50-100% full scale and still have at least 3 calibration levels for reference.

When the mode swich is set to ALT, 3 levels of calibration are recorded corresponding to 0, 50 and 100% 02 saturation.

Note: Check with your reading service to verify the desired setting.

Channel Selection

The Model 2700 Multi-Channel Recorder is offered as either an Option 3 in which it is set up at the factory as a 3 channel physiologic recorder or as an Option 4 in which it is set up at the factory as a 4 channel physiologic recorder.

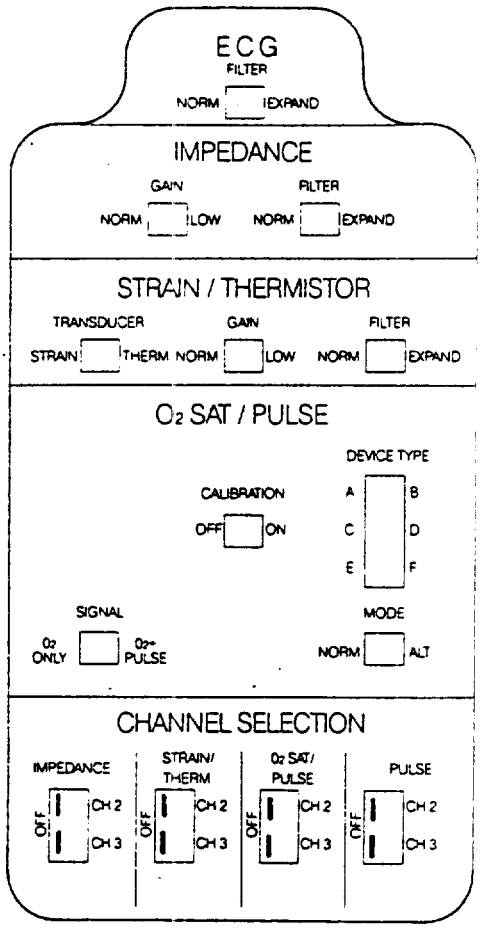
In both Option 3 and Option 4, the ECG signal automatically records on channel 1. The Option 3 automatically records a time track on channel 4, leaving channels 2 and 3 free for other physiologic channels. The Option 4 sacrifices the time track and leaves channels 2,3 and 4 free for other physiologic channels.

The choices for other physiologic channels are the same for Option 3 and Option 4 as follows:

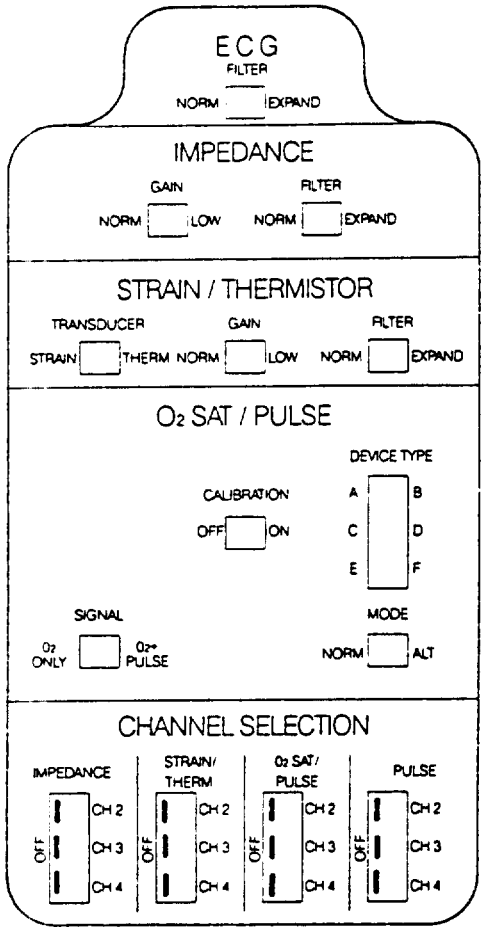
respiratory impedance
strain gauge or nasal thermistor
oxygen saturation*
oxygen saturation plus pulse plethysmographic waveform*
pulse plethysmographic signal*

*To record these signals requires a pulse oximeter. Some oximeters do not provide the pulse plethysmographic waveform as an output.

OPTION 3
3 - Channel



OPTION 4
4 - Channel

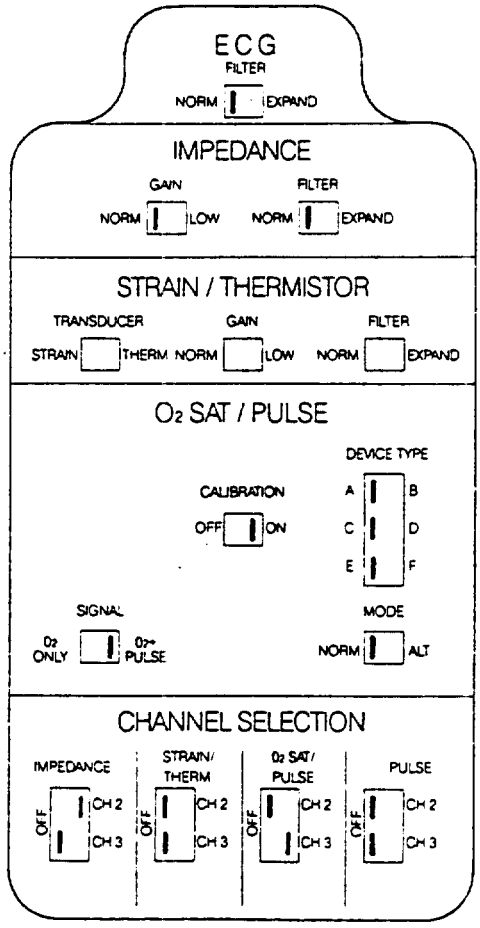


Set all channel selection switches to OFF position except those desired to be recorded. Choose only one physiologic signal for each available channel.

SECTION FOUR: EXAMPLES OF OPTION 3 - 3 CHANNEL SET UP

To Set Up A 3-Channel Infant Recording With:

Channel 1 as ECG
Channel 2 as Impedance Respiration
Channel 3 as 02 Sat plus Pulse



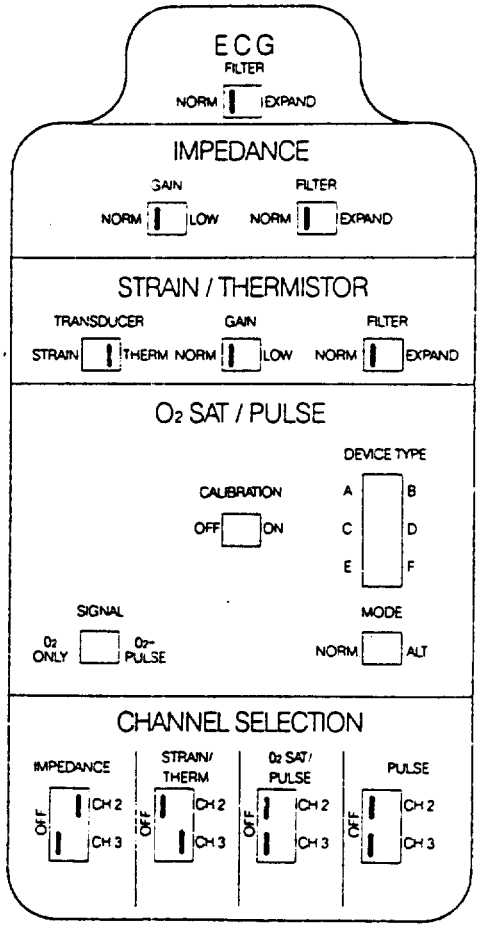
Skip - These settings are not needed for this particular recording.

See Appendix B for additional information regarding compatibility of different oximeters.

Once the parameters have been set - turn to Section 6, Patient Application.

To Set Up a 3-Channel Infant Recording With:

Channel 1 as ECG
Channel 2 as Impedance Respiration
Channel 3 as Nasal Thermistor*



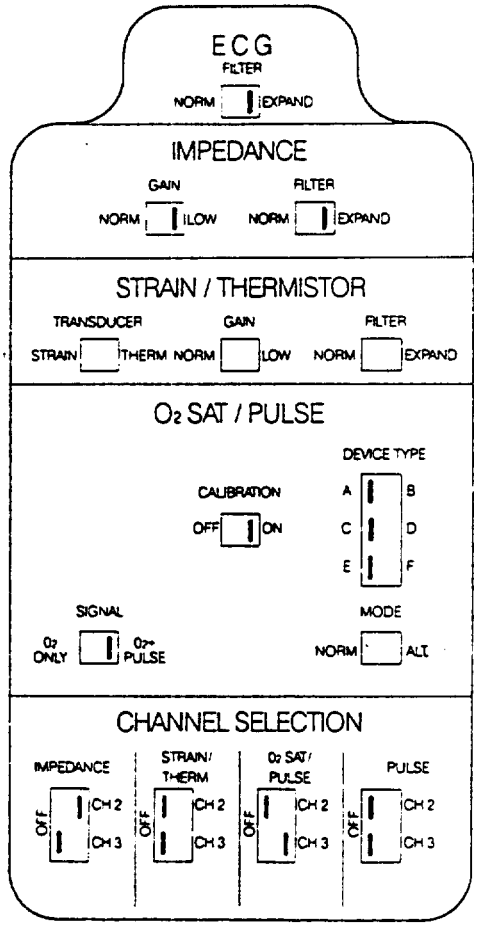
These settings are not utilized in this recording.

Once the parameters have been set - turn to Section 6, Patient Application.

*To set up a 3 channel strain gauge study, simply change the transducer switch from "THERM" to "STRAIN".

To Set Up a 3-Channel Adult Recording With:

Channel 1 as ECG
Channel 2 as Impedance Respiration
Channel 3 as 02 Sat plus Pulse



These settings are not utilized in this example.

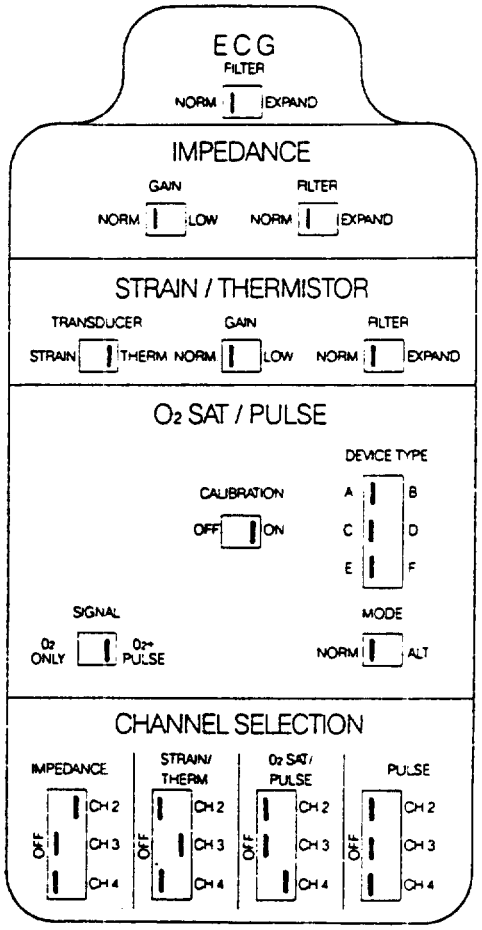
See Appendix B for additional information regarding compatibility of different oximeters.

Once the parameters have been set - turn to Section 6, Patient Application.

SECTION FIVE: EXAMPLES OF OPTION 4 - 4 CHANNEL SET UP

To Set Up a 4-Channel Infant Recording With:

Channel 1 as ECG
Channel 2 as Impedance Respiration
Channel 3 as Nasal Thermistor*
Channel 4 as 02 Sat plus Pulse



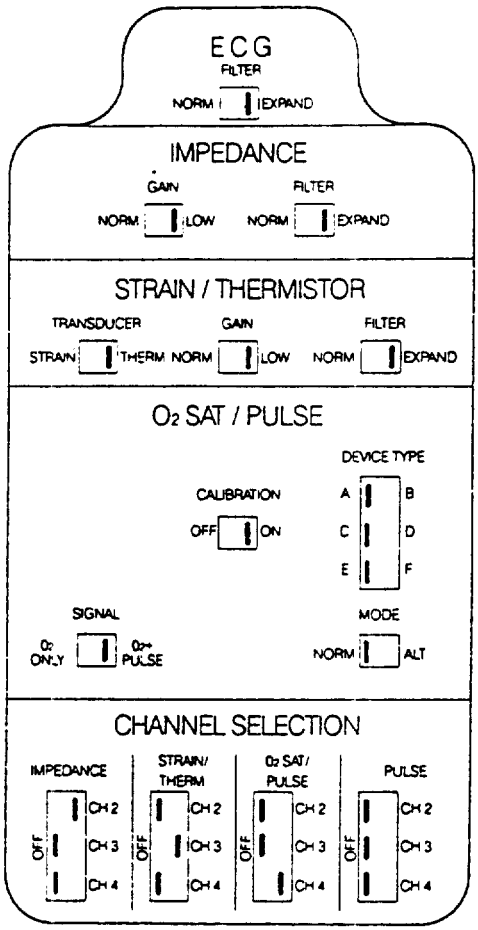
See Appendix B for additional information regarding compatibility of different oximeters.

Once the parameters have been set - turn to Section 6, Patient Application.

*To set up a 4-channel study with the strain gauge as the third channel, simply change the transducer switch from "THERM" to "STRAIN".

To Set Up a 4-Channel Adult Recording With:

Channel 1 as ECG
Channel 2 as Impedance Respiration
Channel 3 as Nasal Thermistor*
Channel 4 as 02 Sat plus Pulse



See Appendix B for additional information regarding compatibility of different oximeters.

Once the parameters have been set - turn to Section 6, Patient Application.

*To set up a 4-channel study with the strain gauge as the third channel, simply change the transducer switch from "THERM" to "STRAIN".

SECTION SIX: PATIENT APPLICATION

To assure sufficient battery power for the study - have the battery charger connected to the monitor.

To nasal thermistor or strain gauge patient cable.

Channel Select

To Oximeter

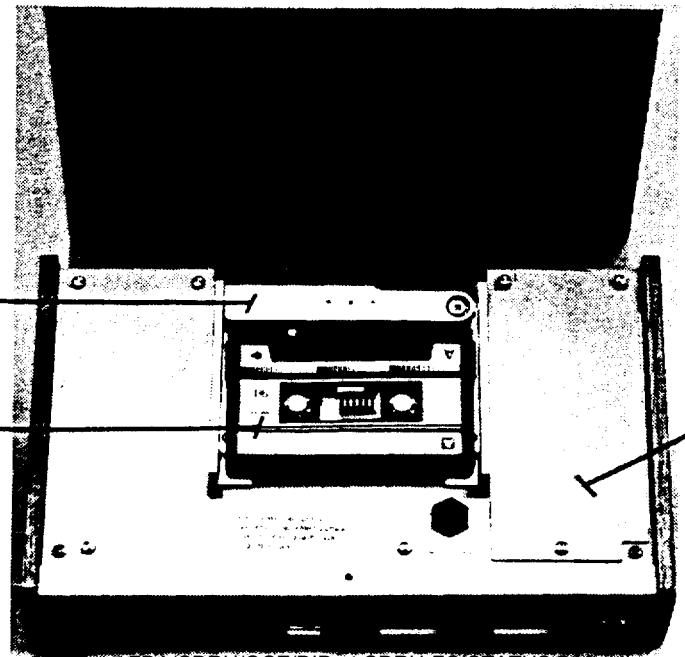
Signal Meter

Secure the interconnect cable with screws provided.

Once the parameters have been set, replace the set up panel cover and secure it with the screw.

Swing out the arm of the recorder (see photo below) and drop in the tape, the A or 1 side facing up. Be sure the tape is properly set in the recorder, otherwise the tape will not wind correctly. Press the recorder arm back into place. Make sure recorder arm snaps into place.

Once all of the connections have been made between the monitor, the patient and the oximeter (if utilized), turn the monitor on. (see following pages for guidelines in setting up specific transducers). The multi-channel will run off of the monitor's battery. It is always a good idea to have the monitor attached to the battery charger with the charger plugged into a power outlet when doing a recording.

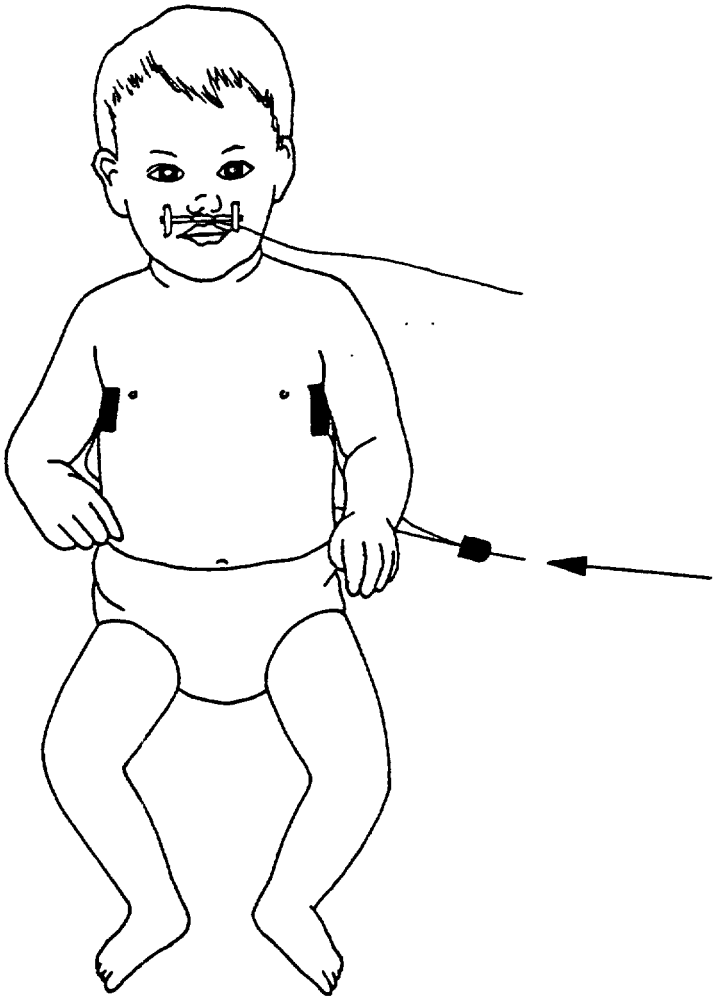


Recorder Arm

Cassette Tape

Set Up Panel

Thermistor Application - Infant

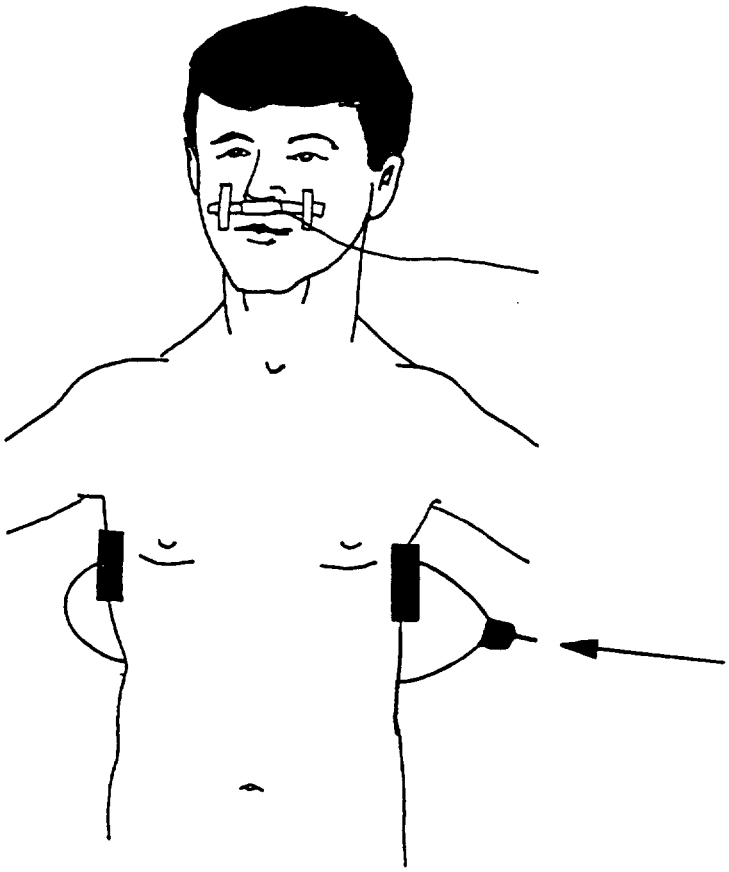


The infant-size thermistor should be placed directly underneath the baby's nose, with the two thermistor beads pointing up towards the nostrils. SECURE the thermistor in place with tape.

If the thermistor beads are pushed up against the skin or the thermistor becomes dislodged, an alarm will sound and a "SENSOR" light will illuminate on the front panel of the multi-channel. To correct this, reposition the thermistor and secure it.

Electrode Patient Cable

Thermistor Application - Adult



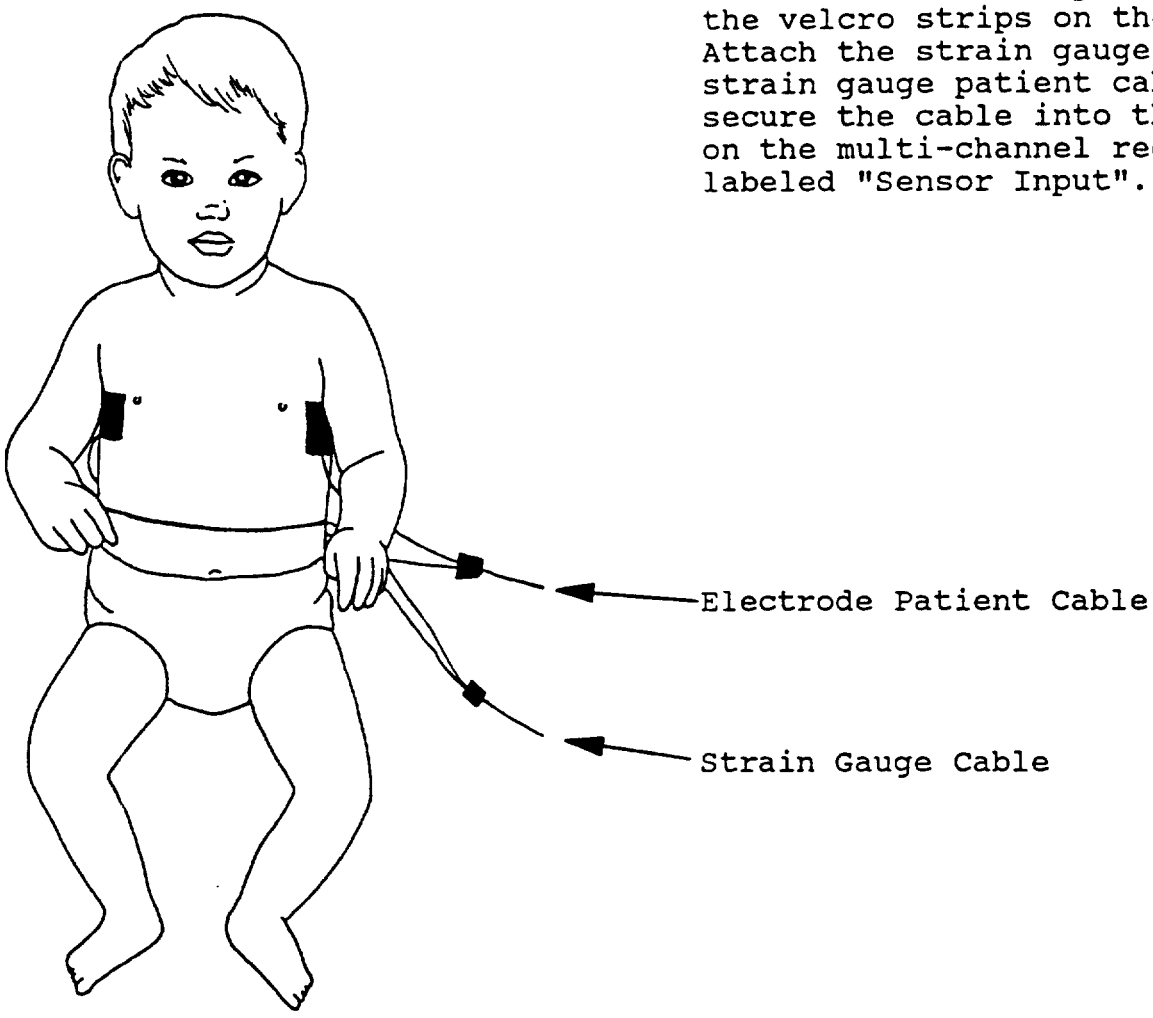
The adult-size thermistor should be placed directly beneath the patient's nose with the thermistor beads pointing up towards the nostrils. SECURE the thermistor in place with tape.

If the thermistor beads are pushed up against the skin or the thermistor becomes dislodged, an alarm will sound and a "SENSOR" light will illuminate on the front panel of the multi-channel. To correct this, reposition the thermistor and secure it.

Electrode Patient Cable

Abdominal Strain Gauge Application

Stretch the strain gauge across the abdominal cavity and attach the velcro strips on the back. Attach the strain gauge to the strain gauge patient cable and secure the cable into the jack on the multi-channel recorder labeled "Sensor Input".



Oximeter Application

Attach the oximeter cable to the EdenTec Monitor in the jack labeled auxiliary input. Attach the two ends of the cable into the oximeter jacks labeled PULSE and 02 SAT.

SEE APPENDIX B FOR OXIMETER MANUFACTURER COMPATIBILITY

PART SIX: TROUBLESHOOTING GUIDE

PROBLEM	POSSIBLE CAUSE AND ACTION
A) Front panel green ON light not illuminated.	1) The ON light illuminates only when the Model 2700 is connected to an EdenTec Model 2000W or 2000W Option H Monitor. Verify proper connection of the Model 4030 interface cable.
	2) A defective interface cable. Replace cable.
	3) The ON light is not functional, return unit for service.
B) Recorder motor does not sound like it is running.	1) Verify problem (A) does not exist.
	2) Return unit for service.
C) SENSOR LED on front panel and audible alarm.	1) A transducer, strain gauge or nasal thermistor is not connected to the sensor input. Connect a transducer.
	2) Adequate signal is not seen by the multi-channel system. Reposition the sensor to pick up a better signal.
	3) The signal detected by the transducer is occurring at less than 4 breaths per minute. Verify by observing the patient.
	4) An open circuit exists in the sensor or sensor cable. Return both for service.

D) Improper signal deviation, or absence of signal deviation on signal meter (shown on p. 13).	1) Verify proper interface cable connection. 2) Verify proper oximeter settings, if problem is with oximeter channel. 3) Verify proper sensor placement if problem is the transducer channel.
E) Tape has been taken up on cassette but no signal is seen on playback, i.e., all channels are blank.	1) The tape has not been placed properly in the recorder. See Section 6, Patient Application. 2) All of the channels are switched off.

APPENDIX A

Cleaning The Thermistor and Strain Gauge

The thermistor must be cleaned before application to any patient. The thermistor and its cable can be cleaned with mild soaps or hospital cleaners and may be low temperature gas sterilized.

The thermistor can be put under warm running water but not left immersed for extended periods.

The strain gauge should not be immersed. Wiping it with mild soap or hospital cleaner on a cloth is advised. The strain gauge is a disposable sensor and once the seal on the bag has been broken, it has approximately a 48 hour shelf-life.

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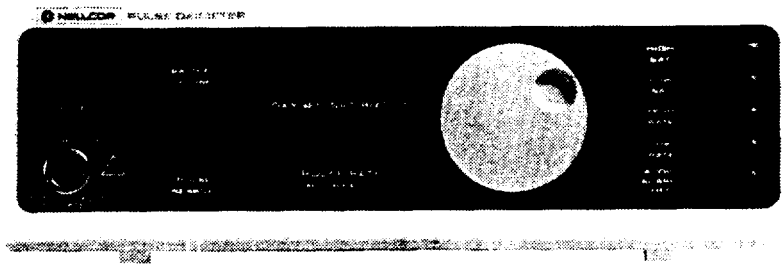
APPENDIX B

Compatible Oximeters

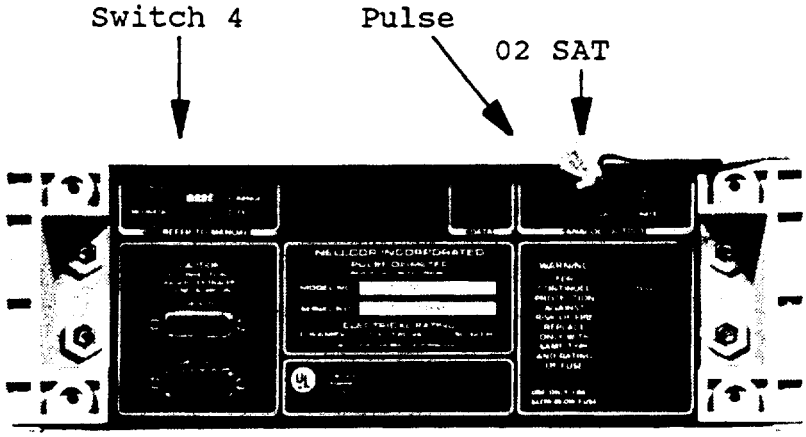
The EdenTec Model 2700 Multi-Channel is compatible with the following oximeters:

Nelcor N-100

select DEVICE TYPE - ACE on the set up panel of the multi-channel recorder.
select oximeter mode to 2 (described below).
set oximeter to 0 to 1.0 volt output (described below).



Attach the Nellcor Oximeter to the patient using the manufacturer's procedure. Once the Nellcor is set and running, depress high rate and low rate at the same time and move the white dial so that the number "2" appears in the window. Any time the oximeter is turned off, you will have to reset it to mode 2. Mode 2 gives the quickest response time to a desaturation.



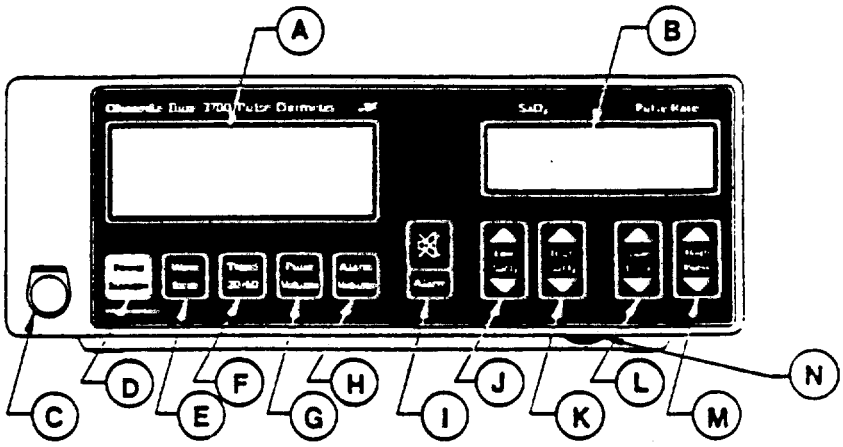
Also make sure the number 4 switch on the Nellcor's rear panel is set to the 1.0 volt range or the down position.

Check that the inner-connect cable between the recorder and oximeter are properly connected as shown.

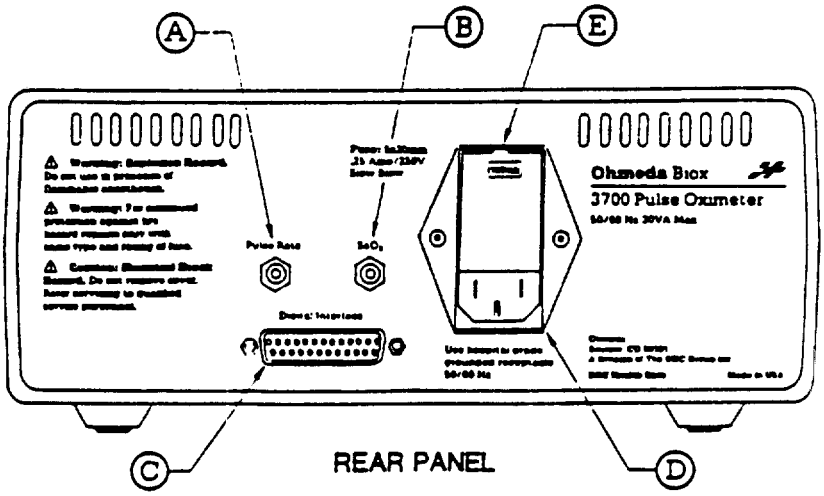
Ohmeda/Biox 3700

select DEVICE TYPE - ACE on the set up panel of the multi-channel recorder.

select SIGNAL - 02 ONLY on the set up panel.



Attach the Ohmeda Oximeter to the patient using the manufacturer's procedure. Once the oximeter is set and running, set the oximeter to fast response mode (3 second SaO2 averaging time) by holding the WAVEFORM key (E) for 3 seconds. The Status message FAST RESPONSE SELECTED will momentarily appear and the letter "F" will appear along side the plethysmographic waveform (A). To return to Slow Response Mode, hold the Waveform key for 3 seconds.

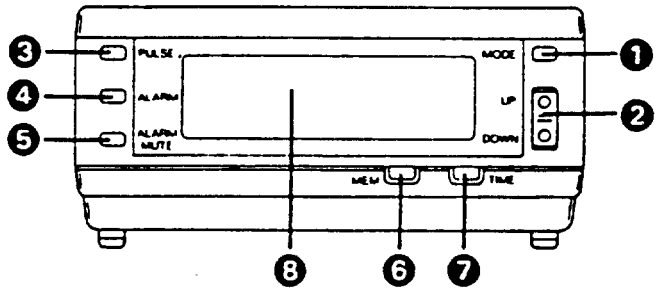


Check that the inner-connect cable between the recorder and oximeter are properly connected as shown. The cable should be plugged into connector "B" labeled "Sa02".

Minolta/Marquest Pulsex-7

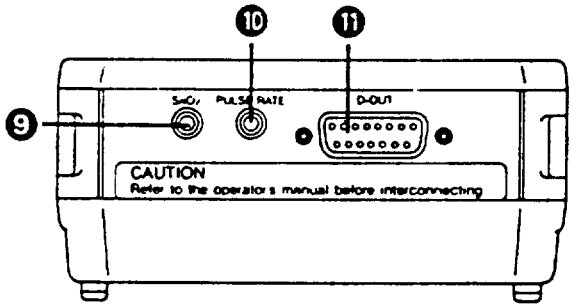
select DEVICE TYPE - ACE on the set up panel of the multi-channel recorder.

select SIGNAL - 02 ONLY on the set up panel.



FRONT VIEW

Attach the Minolta Oximeter to the patient using the manufacturer's procedure.



REAR VIEW

Check that the inner-connect cable between the recorder and oximeter are properly connected as shown. The cable should be plugged into connector "9" labeled "Sa02".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

NOV 6 1991

Mr. Gary Syring
Director of Quality Assurance
EdenTec
10252 Valley View Road
Eden Prairie, Minnesota 55344

Re: K913749
EdenTrace Airflow Cable Model 3171
Sleep Lab Airflow Cable Model 3170
Dated: August 19, 1991
Received: August 21, 1991

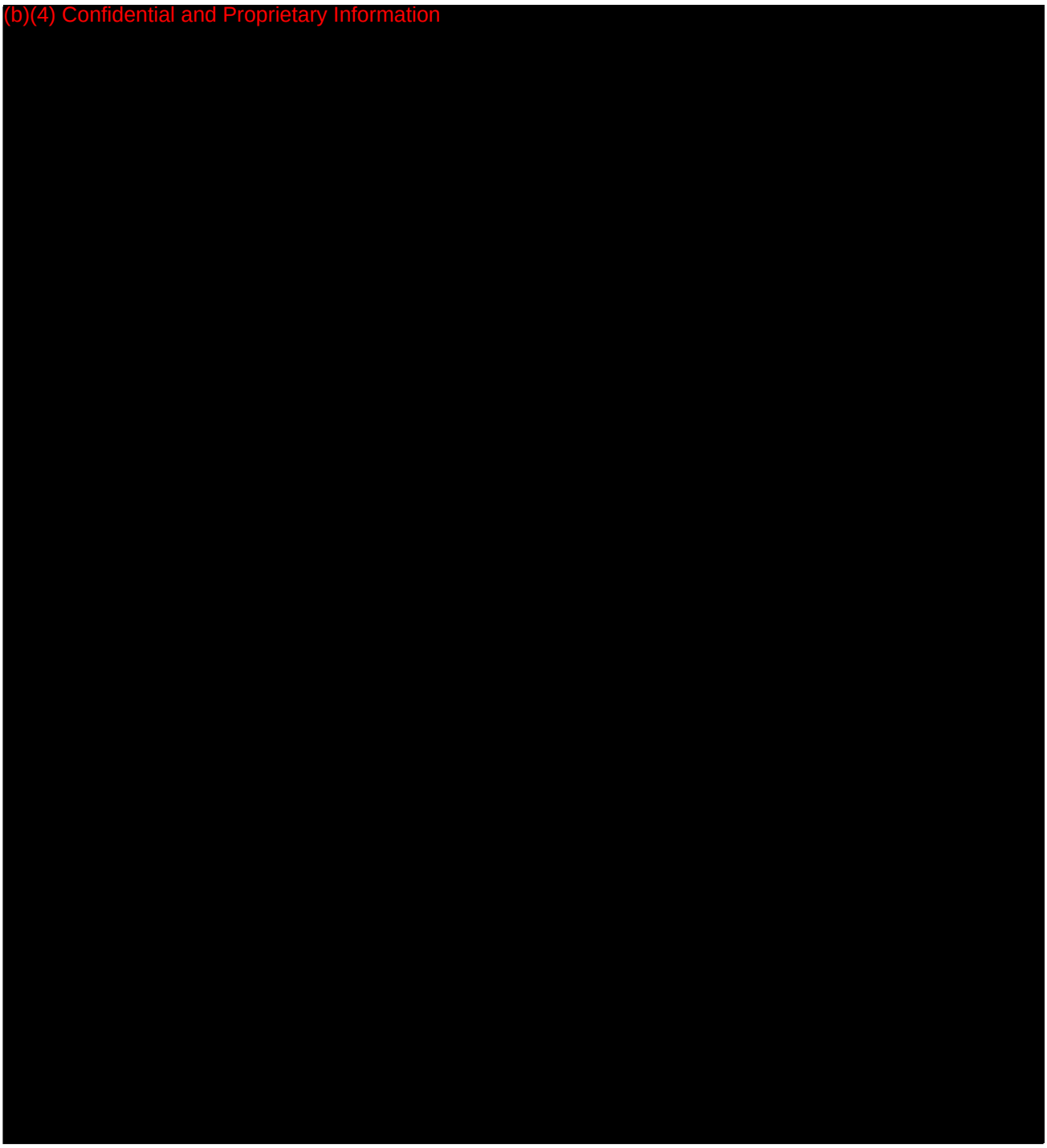
Dear Mr. Syring:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a device marketed prior to May 28, 1976, the enactment date of the Medical Device Amendments, based solely on the information you provided. In order for us to complete the review of your submission, we require the following information:

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information



We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a pre-Amendments device with regard to its safety and effectiveness.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(f) and (h), and you have received a letter from FDA allowing you to do so. If you market the device

without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act).

If the requested information is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be re-submitted so that your new 510(k) is complete.

If you have questions concerning the contents of this letter, please contact David A. Zier at (301) 427-1053. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Abhijit Acharya, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date 10/31

From REVIEWER(S) - NAME(S) Pauline

Subject 510(k) NOTIFICATION K913749

To THE RECORD

It is my recommendation that the subject 510(k) Notification:

_____ (A) Is substantially equivalent to marketed devices.

_____ (B) Requires premarket approval. NOT substantially equivalent to marketed devices.

_____ (C) Requires more data.

_____ (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Additional Comments:

See above

This 510(k) contains: (check appropriate box(es))

☐ A 510(k) summary of safety and effectiveness, or

☐ A 510(k) statement that safety and effectiveness information will be made available

☐ The required certification and summary for class III devices

The submitter requests under 21 CFR 807.95:*

_____ No Confidentiality

_____ Confidentiality for 90 days

_____ Continued Confidentiality exceeding 90 days

Predicate Product Code w/panel and class:

_____

Additional Product Code(s) w/Panel (optional):

_____

REVIEW:		
(BRANCH CHIEF)	(BRANCH CODE)	(DATE)
	AHOD	11/5/91

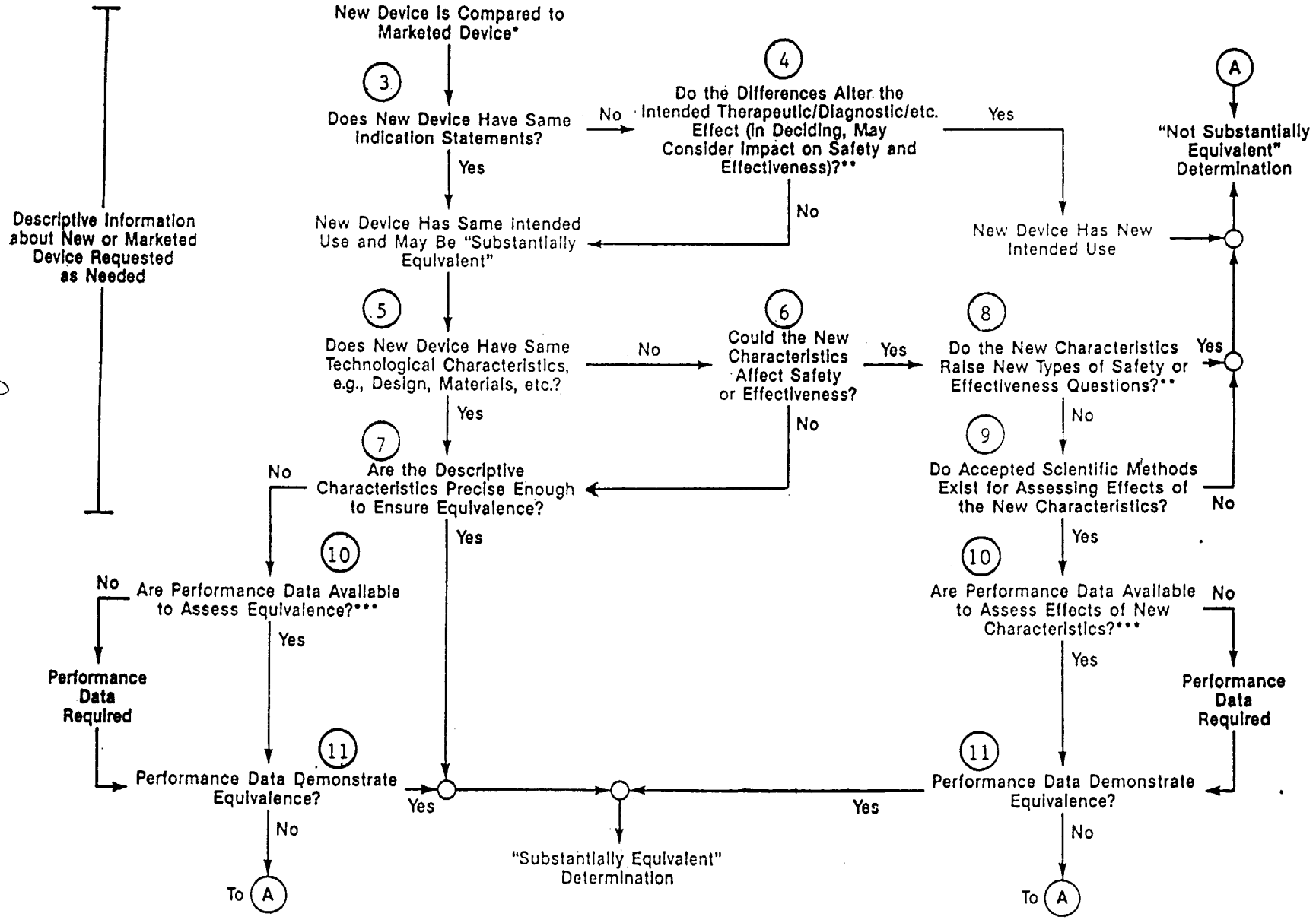
FINAL REVIEW: _____

(DIVISION DIRECTOR) (DATE)

*DOES NOT APPLY TO ANY "SE" DECISIONS

Revised 5/31/91

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information If the Relationship Between Marketed and "Predicate" (Pre-Amendments or Reclassified Post-Amendments) Devices Is Unclear.

** This Decision Is Normally Based on Descriptive Information Alone, But Limited Testing Information Is Sometimes Required.

*** Data May Be In the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

MEMO TO THE RECORD

K913749

DATE: 10/31/91
FROM: David A. Zier
COMPANY NAME: Edentec
DEVICE NAME: Edentrace Airflow 3171, Sleep Lab Airflow 3170

OFFICE: HFZ-450
DIVISION: DCRND/ARDB

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

DEPARTMENT OF HEALTH AND HUMAN SERVICES **Public Health Service**

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

AUGUST 26, 1991

EDENTEC
ATTN: GARY SYRING
10252 VALLEY VIEW ROAD
EDEN PRAIRIE, MN 55344

510(k) Number: K913749
Received: 08-21-91
Product: EDENTRACE AIRFLOW
3171/SLEEP LAB
AIRFLOW 3170

We have 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.

The Safe Medical Devices Act of 1990 (SMDA), signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so within 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date, you may want to check with FDA to determine the status of your submission.

In addition, the SMDA requires all persons submitting a premarket notification submission to include either (1) a summary of the safety and effectiveness information in the premarket notification submission upon which an equivalence determination could be based (510(k) summary), OR (2) a statement that safety and effectiveness information will be made available to interested persons upon request (510(k) statement). Safety and effectiveness information refers to information in the premarket notification submission, including adverse safety and effectiveness information, that is relevant to an assessment of substantial equivalence. The information could be descriptive information about the new and predicate device(s), or performance or clinical testing information. We cannot issue a final decision on your 510(k) unless you comply with this requirement.

Although FDA acknowledges that the law provides the 510(k) submitter an alternative, FDA encourages manufacturers to provide a 510(k) statement to FDA and to make their safety and effectiveness information available to the public, excluding confidential manufacturing process information, in lieu of submitting a 510(k) summary to the agency until FDA promulgates a regulation on the content and format of 510(k) summaries. Since the law

requires that FDA must make the 510(k) summary, or the source of information referred to in the 510(k) statement, publicly available within 30 days of making a substantial equivalence determination, we advise you that we may no longer honor any request for extended confidentiality under 21 CFR 807.95.

Additionally, the new legislation also requires any person who asserts that a device is substantially equivalent to a class III device to (1) certify that he or she has conducted a reasonable search of all information known, or otherwise available, about the generic type of device, AND (2) provide a summary description of the types of safety and effectiveness problems associated with the type of device and a citation to the literature, or other sources of information, upon which they have based the description (class III summary and certification). The description should be sufficiently comprehensive to demonstrate that an applicant is fully aware of the types of problems to which the device is susceptible. If you have not provided this class III summary and certification in your premarket notification, please provide it as soon as possible. We cannot complete the review of your submission until you do so.

Please note that the SMDA may have additional requirements affecting your device. You will be informed of these requirements as they become effective.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Robert I. Chissler
Chief, Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

K913749

EDENTEC®

August 19, 1991

Food and Drug Administration
Center for Devices and Radiolological Health
Office of Medical Devices (HFZ-401)
1390 Piccard Drive
Rockville, MD 20850

Re: 510(k) Notification

In accordance with the provisions of section 510(k) of the Federal Food, Drug and Cosmetic act, we hereby request the authorization to introduce into Commercial distribution the EdenTrace Airflow Cable Model 3171 and the Sleep Lab Airflow Cable Model 3170 90 days from the Food and Drug Administration receipt of this notification.

1. PRODUCT NAME
   A. EdenTrace Airflow Cable Model 3171
   B. Sleep Lab Airflow Cable Model 3170

2. REGISTRATION NUMBER - 2183597
   Manufacturer and facility of manufacture
   EdenTec Incorporated
   10252 Valley View Road
   Eden Prairie, MN 55344

3. CLASS - These devices are presently referred to as class II devices.

4. PERFORMANCE STANDARD - To our knowledge, no performance standards have been set for these devices.

5. LABELING
   Attachment A - Operators Manual, Model 3171, draft copy.
   Attachment B - Operators Manual, Model 3170
   Attachment C - Device Labels, Model 3170 and Model 3171

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10252 Valley View Road • Eden Prairie, Minnesota 55344 • (612) 941-3006 • FAX (612) 829-5423

6. SUBSTANTIAL EQUIVALENCE

The EdenTrace Airflow Cable Model 3171 and the Sleep Lab Airflow Cable Model 3170 are designed to provide an air flow signal to recording devices. The air flow signal is a qualitative, not a quantitative signal. The air flow signal is provided by oral and/or nasal temperature sensitive resistive components.

Both cables are intended for use in qualitative air flow recordings that may assist in air flow analysis and sleep. Neither cable is intended to alarm on the absence of air flow.

The EdenTrace Airflow cable Model 3171 will interface directly to the EdenTec Multi-channel Recorder Model 2700 (K873081). The Sleep Lab Airflow cable Model 3170 will interface to a Sleep Lab Recorder, not provided by EdenTec.

An accessory Disposable Air flow sensor is used to provide resistance changes as affected by temperature changes in airflow representing airflow inhaled and exhaled. The sensors are substantially equivalent to the EdenTec Adult Nasal Thermistor Model 946, the Infant Nasal Thermistor Model 942, and the Infant/Premie Nasal Thermistor Model 941.

These sensors come in five (5) sizes with the intended population of use dependant on patient size, not age:

Adult	Model 971	(nasal/oral)
Small Adult	Model 972	(nasal/oral)
Child	Model 974	(nasal/oral)
Infant	Model 976	(nasal/oral)
Premie	Model 978	(nasal only)

7. ATTACHMENTS -

D. Product Specifications and descriptions for cables and sensors
E. Graphs showing Airflow Sensor Substantial equivalence
F. EdenTec Model 2700 Multi-Channel Recorder Instruction Manual P/N 241-3075
G. Summary of safety and effectiveness
H. Model 970 sensor labels
I. Table of equivalence to Model 2700 Multichannel Recorder

EdenTec views all information in this submission as confidential. EdenTec views our intent to market this device as confidential commercial information. EdenTec has not disclosed our intent to market this device to scientists, market analysts, exporters, or other individuals that have not signed a non disclosure agreement or are employees or paid consultant of EdenTec.

Contact me with any questions.

Sincerely,

Gary Syring
Director of Quality Assurance

ATTACHMENT A

EDENTEC MODEL 3171 EDENTRACE AIRFLOW CABLE AND MODEL 970 SERIES AIRFLOW SENSOR INSTRUCTION MANUAL

EdenTec Corporation
10252 Valley View Road
Eden Prairie, MN 55344
(612) 941-3006
Part No. 241-3145
Rev. A

Table of Contents

1.0 Description

The Model 970 Series Airflow Sensor and Model 3171 EdenTrace Airflow Cable are designed to measure the temperature change between ambient and inhaled/exhaled airflow from the nose and/or mouth of a patient.

The airflow sensor is attached to a patient as described in section 5. The EdenTrace airflow sensor cable Model 3171 converts the resistance change from the airflow sensor to a electrical signal that can be used with EdenTec multichannel recording system Model 2700. The Model 2700 recorder is a component of the 670, 680 and 700 systems described in section 4.

The airflow signal is one of several signals that is recorded by the EdenTrace recording system for later interpretation by health care professionals of the breathing patterns of the individual patient under study.

Intended Use, Cable

The EdenTrace Airflow Cable Model 3171 is designed to provide an air flow signal to a recording device. The air flow signal is a qualitative, not a quantitative signal. The air flow signal is provided by oral and/or nasal temperature sensitive resistive components.

The cable is intended for use in qualitative air flow recordings that may assist in air flow analysis and sleep. The cable is not intended to alarm on the absence of air flow.

Accessory Disposable Air flow sensors are used to provide resistance changes as affected by temperature changes in airflow, representing airflow inhaled and exhaled.

These sensors come in five (5) sizes with the intended population of use dependent on patient size, not age:

Adult	Model 971	(nasal/oral)
Small Adult	Model 972	(nasal/oral)
Child	Model 974	(nasal/oral)
Infant	Model 976	(nasal/oral)
Premie	Model 978	(nasal only)

2.0 Warning and Precautions

a. The Model 3171 EdenTrace Airflow Cable is for use only with Model 970 series single use airflow sensors.

b. Failure to apply the 970 sensor properly may cause a reduced signal level or no signal output.

c. The 970 series sensor must be inspected once every 8 hours to ensure adhesion, skin integrity and correct placement. If skin integrity changes remove the sensor or reposition if possible. Try another type of tape that will cause less irritation.

d. The 970 series airflow sensor is indicated for single-patient use.

e. The 970 series airflow sensor is shipped non-sterile.

f. Do not immerse the 970 series sensor in water or cleaning solutions.

g. The Model 3171 EdenTrace Airflow Cable and 970 series airflow sensors are designed ONLY for use with EdenTec Model 2700 recording systems. EdenTec does not recommend or support use of this cable with non-EdenTec equipment. The Model 2700 Multichannel Recorder is a component of the 670, 680 and 700 recording systems.

h. Federal law (USA) restricts sale of this device by or on the order of a health care professional.

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3.0 Equipment Check List

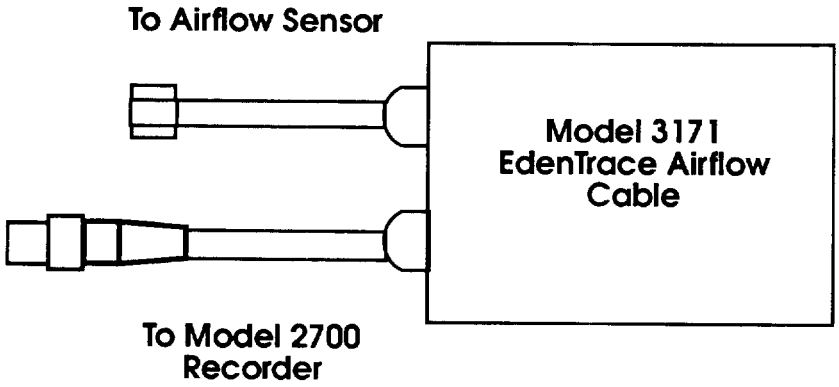
The following items are supplied with each Model 3071 EdenTrace Airflow cable assembly system.

1 - Model 3071 Interface Cable

1 - 971 Adult - Nasal/Oral Airflow Sensor
1 - 972 Small Adult - Nasal/Oral Airflow Sensor
1 - 974 Child - Nasal/Oral Airflow Sensor
1 - 976 Infant - Nasal/Oral Airflow Sensor
1 - 978 Premie - Nasal Airflow Sensor

1 - Instruction Manual P/N 241-3145

In addition you will need a Model 2700 Multichannel Recorder. This recorder is also part of the 670, 680 and 700 systems.



4.0 General Equipment Set-Up

1. Follow instructions in the Model 2700 MultiChannel Recorder manual for set up of a thermistor study.

2. Attach Model 3171 EdenTrace Airflow Interface Cable into the appropriate size Model 970 series airflow sensor. The size you choose is based upon the patient. It is important that the temperature sensing elements are beneath the nostrils. The oral temperature sensing element must reside in the oral airway, not on the lips. See figure 1.

3. Attach the connector to the SENSOR input jack on Model 2700 EdenTrace recorder. See figure 2.

4. Attach the airflow sensor on the patient as described in section 5.

5. Monitor the signal level by selecting the appropriate CHANNEL on the Model 2700 Recorder signal channel and observing the signal strength on the rear panel meter. See figure 3.

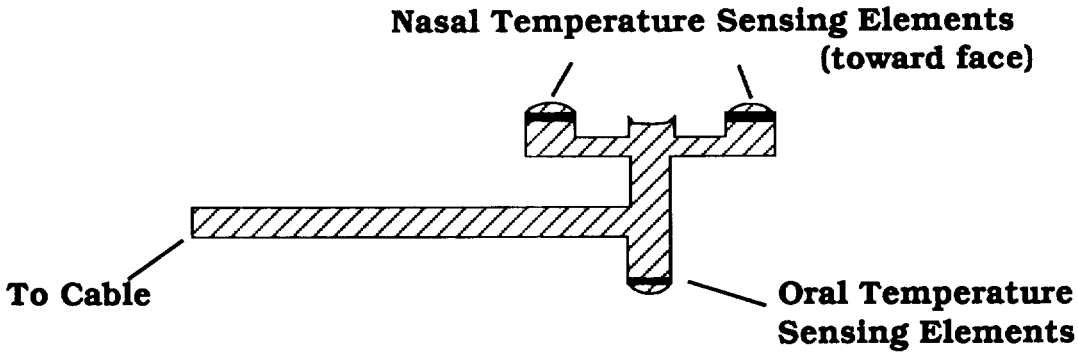


Figure 1

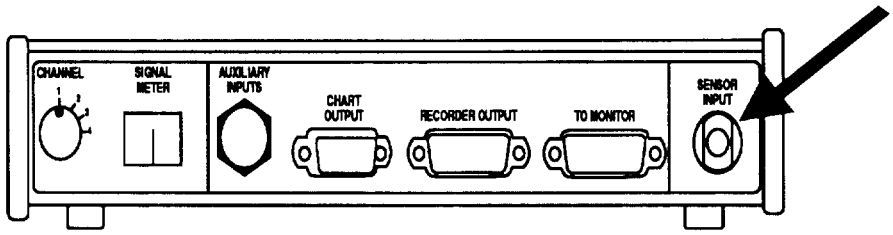


Figure 2

Model 2700 Multichannel Recorder Back Panel

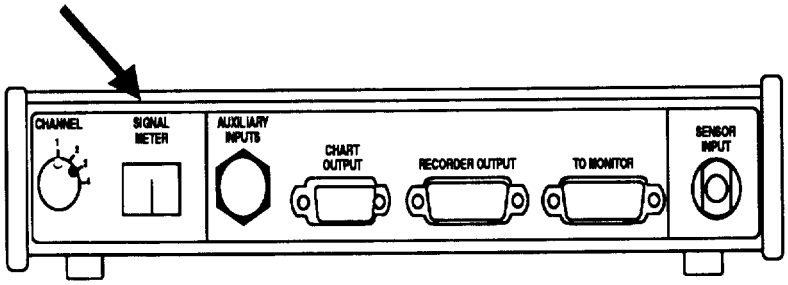


Figure 3

Model 2700 Multichannel Recorder Back Panel

5.0 Patient Set-Up - Infant

Model 976 and Model 978 Airflow Sensors.

The infant or premie airflow sensor should be placed directly under the baby's nasal openings. The black edges of the airflow sensor face the baby/child. Secure the airflow sensors in place with surgical grade adhesive tape to assure the sensor will not become dislodged easily.

I you select a Model 974 or 976, the oral temperature sensing element must be over the mouth, not touching the lips.

Do not obstruct the nostrils with the airflow sensor elements.

If any skin irritation is observed, discontinue the study. Try another type of tape.

Model 3171 Airflow Cable

Attach to EdenTrace Recorder

Figure 4

Infant - Setup

5.0 Patient Set-Up - Adult

Model 971, 972 and 974.

The child to adult sensor should be placed with the top two sensing elements pointing directly outside the nostrils. The single oral sensor should protrude just below the top lip. Additional taping of the sensor might be required to insure the sensor does not become dislodged in an unattended study.

Do not cover the black nasal and oral sensor elements with tape.

Do not obstruct the nostrils with the sensor elements.

If skin irritation occurs, discontinue use of that type. Try another type of tape.

Model 3171 Airflow Cable

Attach to EdenTrace Recorder

Figure 5

Adult - Setup

6.0 Troubleshooting Guide

Problem	Possible Cause and Action
No output signal or weak signal during breathing patient.	1) The Model 970 series airflow sensor is improperly placed on the patient - check placement. 2) Sensor is not operational - replace 970 series airflow sensor. 3) The Model 3071 EdenTrace Airflow cable assembly is damaged - replace Model 3071 cable assembly. 4) The internal battery in the cable assembly is depleted - replace Model 3071 cable assembly.
Sensor changes position on patient	1) The Model 970 series airflow sensor tape does not hold the sensor in place properly. Place additional tape on the sensor to better hold it in position.

7.0 Warranty

The Model 3071 EdenTrace Airflow Cable and Model 970 Series Airflow Sensors are sold as is. No warranty, repair or replacement agreement whatsoever is made or given. Cables and sensors may be easily damaged by improper handling or use, due to their unavoidably fragile character, which is dictated by the requirement of their application.

ATTACHMENT B

EDENTEC MODEL 3170 SLEEP LAB AIRFLOW CABLE AND MODEL 970 SERIES AIRFLOW SENSOR INSTRUCTION MANUAL

EdenTec Corporation
10252 Valley View Road
Eden Prairie, MN 55344
(612) 941-3006
Part No. 241-3144
Rev. A

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Table of Contents

1.0 Description

The Model 970 Series Airflow Sensors and Model 3170 Sleep Lab Airflow Cable are designed to measure the temperature change between ambient and inhaled/exhaled airflow from the nose and/or mouth of a patient.

The airflow sensor is attached to a patient as described in section 5. The sleep lab airflow sensor cable Model 3170 converts the resistance change from the sensor to a electrical signal that can be used with commercially available multichannel polygraph i.e. Grass Instruments and Nihon Kohden as an example.

Intended Use, Cable

The Sleep lab Airflow Cable Model 3170 is designed to provide an air flow signal to a recording device. The air flow signal is a qualitative, not a quantiative signal. The air flow signal is provided by oral and/or nasal temperature sensitive components.

The cable is intended for use in qualitative air flow recordings that may assist in air flow analysis and sleep. The cable is not intended to alarm on the absence of air flow.

Accessory Disposable Air flow sensors are used to provide resistance changes as affected by temperature changes in airflow, representing airflow inhaled and exhaled.

These sensors come in five (5) sizes with the intended population of use dependent on patient size, not age:

Adult	Model 971	(nasal/oral)
Small Adult	Model 972	(nasal/oral)
Child	Model 974	(nasal/oral)
Infant	Model 976	(nasal/oral)
Premie	Model 978	(nasal only)

2.0 Warning and Precautions

a. The Model 3170 Sleep lab Airflow Cable is for use only with Model 970 series single use airflow sensors.

b. Failure to apply the 970 sensor properly may cause a reduced signal level or no signal output.

c. The 970 series sensor must be inspected once every 8 hours to ensure adhesion, skin integrity and correct placement. If skin integrity changes remove the sensor or reposition if possible.

d. The 970 series sensor is indicated for single-patient use.

e. The 970 series sensor is shipped non-sterile.

f. Do not immerse the 970 series sensor in water or cleaning solutions.

g. The Model 3170 Sleep Lab Airflow Cable and 970 series sensors are designed for use with polygraph recorders manufactured by Grass Instruments, Nihon Kohden or equivalent.

h. Federal law (USA) restricts sale of this device to or on the order of a health care professional.

I. Connect the Model 3170 Sleep Lab Airflow cable to an electrically isolated input. Patient injury can ocur if the cable is not connected properly.

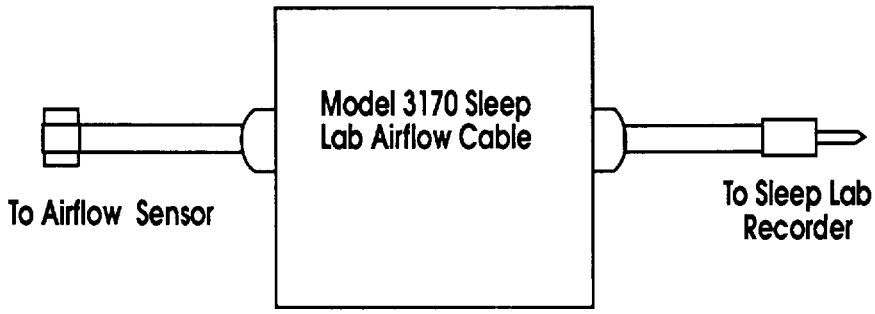
3.0 Equipment Check List

The following items are supplied with each Model 3070 Sleep Lab Airflow cable assembly.

1 - Model 3070 Interface Cable

1 - 971 Adult - Nasal/Oral Airflow Sensor
1 - 972 Small Adult - Nasal/Oral Airflow Sensor
1 - 974 Child - Nasal/Oral Airflow Sensor
1 - 976 Infant - Nasal/Oral Airflow Sensor
1 - 978 Premie - Nasal Airflow Sensor

1 - Instruction Manual P/N 241-3144



4.0 General Equipment Set-Up

1. Attach Model 3170 Sleep Lab Airflow Cable into the appropriate size Model 970 series airflow sensor. Shown in figure 1.

2. Attach the Model 3170 Sleep Lab Airflow cable to a polygraph recorder isolated signal input.

   WARNING: Connection to a non-isolated signal input may result in injury.

3. Attach the airflow sensor on the patient as described in section 5.

4. Monitor the signal level by selecting the appropriate channel on the polygraph recorder and observing the signal.

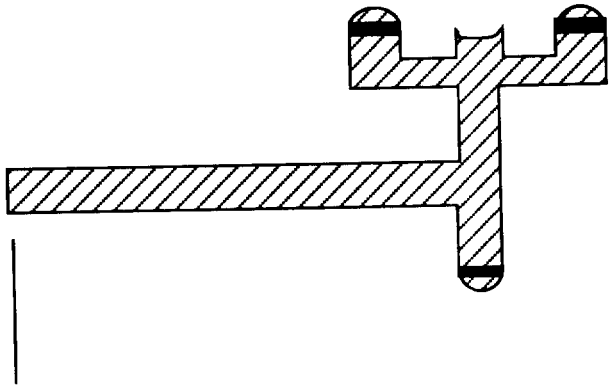


Figure 1

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5.0 Patient Set-Up - Infant

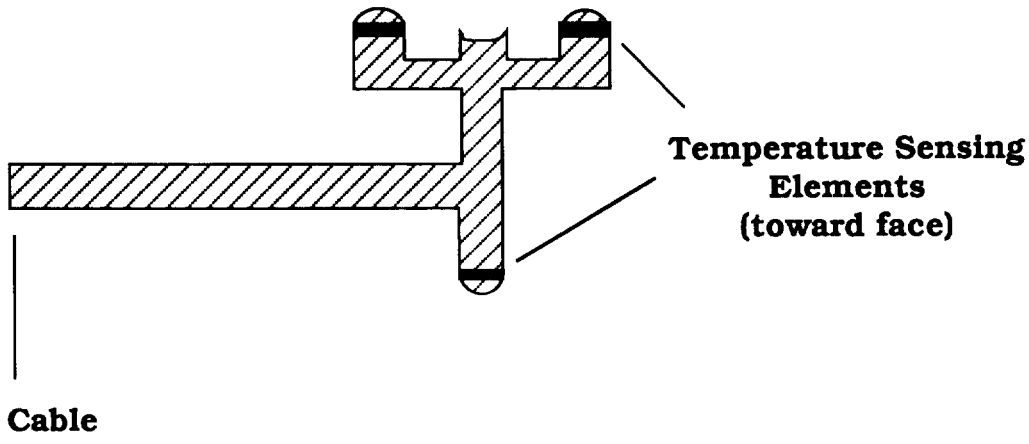
Model 974 and Model 978 Aiflow Sensors.

The infant or premie airflow sensor should be placed directly under the baby's nasal openings. Secure the airflow sensors in place with surgical grade adhesive tape to assure the sensor will not become dislodged easily.

Do not cover the black edges of the airflow sensor with tape. This will reduce the amplitude of the airflow signal.

Do not obstruct the nostrils with the airflow sensor elements.

If any skin irritation is observed, discontinue the study. Try another type of tape.



Infant Setup

5.0 Patient Set-Up - Adult

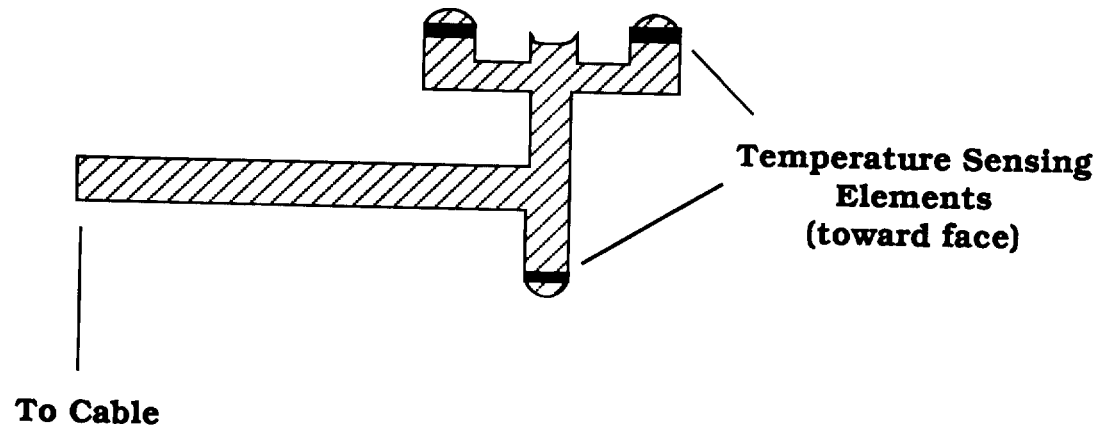
Model 971, 972 and 974.

The child to adult sensor should be placed with the top two sensing elements pointing directly outside the nostrils. The single oral sensor should protrude just below the top lip. Additional taping of the sensor might be required to insure the sensor does not become dislodged in an unattended study.

Do not cover the black nasal and oral sensor elements with tape.

Do not obstruct the nostrils with the sensor elements.

If skin irritation occurs, discontinue use of that type. Try another type of tape.



Adult Setup

6.0 Troubleshooting Guide

Problem	Possible Cause and Action
No output signal or weak signal during breathing patient.	1) The Model 970 series airflow sensor is improperly placed on the patient - check placement. 2) Sensor is not operational - replace 970 series sensor. 3) The Model 3070 Sleep Lab Airflow cable assembly is damaged - replace Model 3071 cable assembly. 4) The internal battery in the cable assembly is depleted - replace Model 3070 cable assembly.
Sensor changes position on patient	1) The Model 970 series sensor tape does not hold the sensor in place properly. Place additional tape on the sensor to better hold it in position.

7.0 Warranty

The Model 3071 EdenTrace Airflow Cable and Model 970 Series Airflow Sensors are sold as is. No warranty, repair or replacement agreement whatsoever is made or given. Cables and sensors may be easily damaged by improper handling or use, due to their unavoidably fragile character, which is dictated by the requirement of their application.

ATTACHMENT C

MODEL 3170 SLEEP LAB
AIRFLOW CABLE

FOR HOSPITAL USE ONLY.

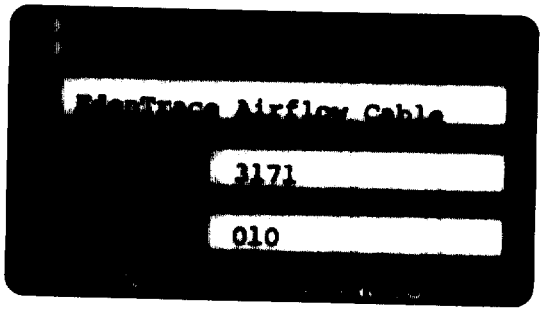
INTERNAL LITHIUM BATTERY
DISPOSE OF PROPERLY.

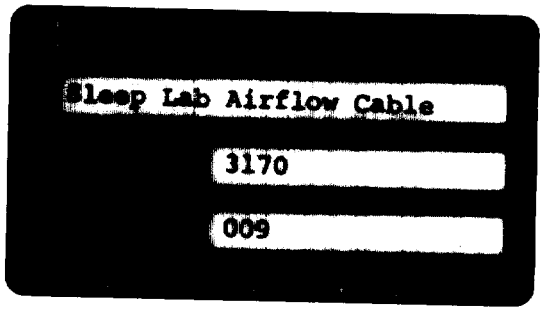
WARNING: CONNECT TO
ELECTRICALLY ISOLATED INPUT.

MODEL 3171 EDENTRACE AIRFLOW CABLE

FOR USE WITH EDENTRACE MODEL 2700 ONLY.

INTERNAL LITHIUM BATTERY DISPOSE OF PROPERLY.





ATTACHMENT D

(b)(4) Confidential and Proprietary Information

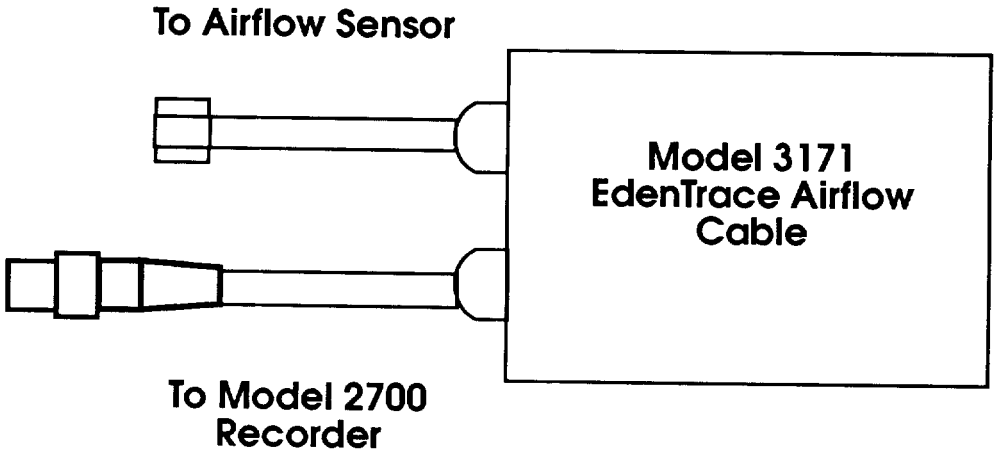
[redacted]

Device Description: Model 3171 EdenTrace Airflow Cable

This cable is intended to be used with an EdenTec Model 2700 Multichannel Recorder. The cable will allows interface of a Disposable Air Flow Sensor to the Sensor input of the Multichannel Recorder.

The cable is intended to be used in a sleep lab or home environment. The cable connects to a Disposable Air Flow Sensor and an EdenTec Model 2700 Multichannel Recorder.

The Disposable Air Flow Sensor converts a temperature change to a resistance change. The EdenTrace Airflow Cable converts the resistance change to a resistance change that is compatible with the Model 2700 Multichannel Recorder Sensor Input.



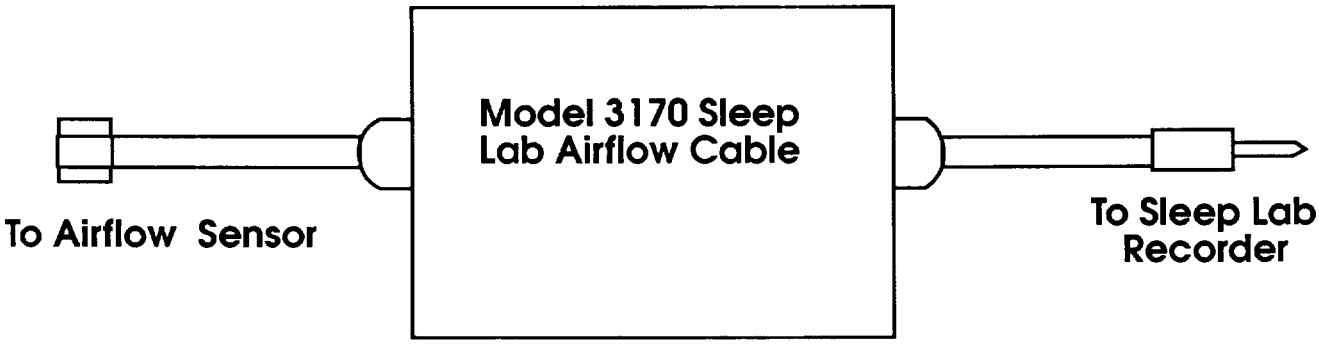
(b)(4) Confidential and Proprietary Information

[redacted]

Device Description: Model 3170 Sleep Lab Airflow Cable

This cable is intended to be used in a sleep lab environment. The cable connects to a Disposable Air Flow Sensor and a sleep lab recorder.

The Disposable Air Flow Sensor converts a temperature change to a resistance change. The Sleep Lab Airflow Cable converts the resistance change to a voltage that can be applied to any sleep lab recorder that can accept the signal output.



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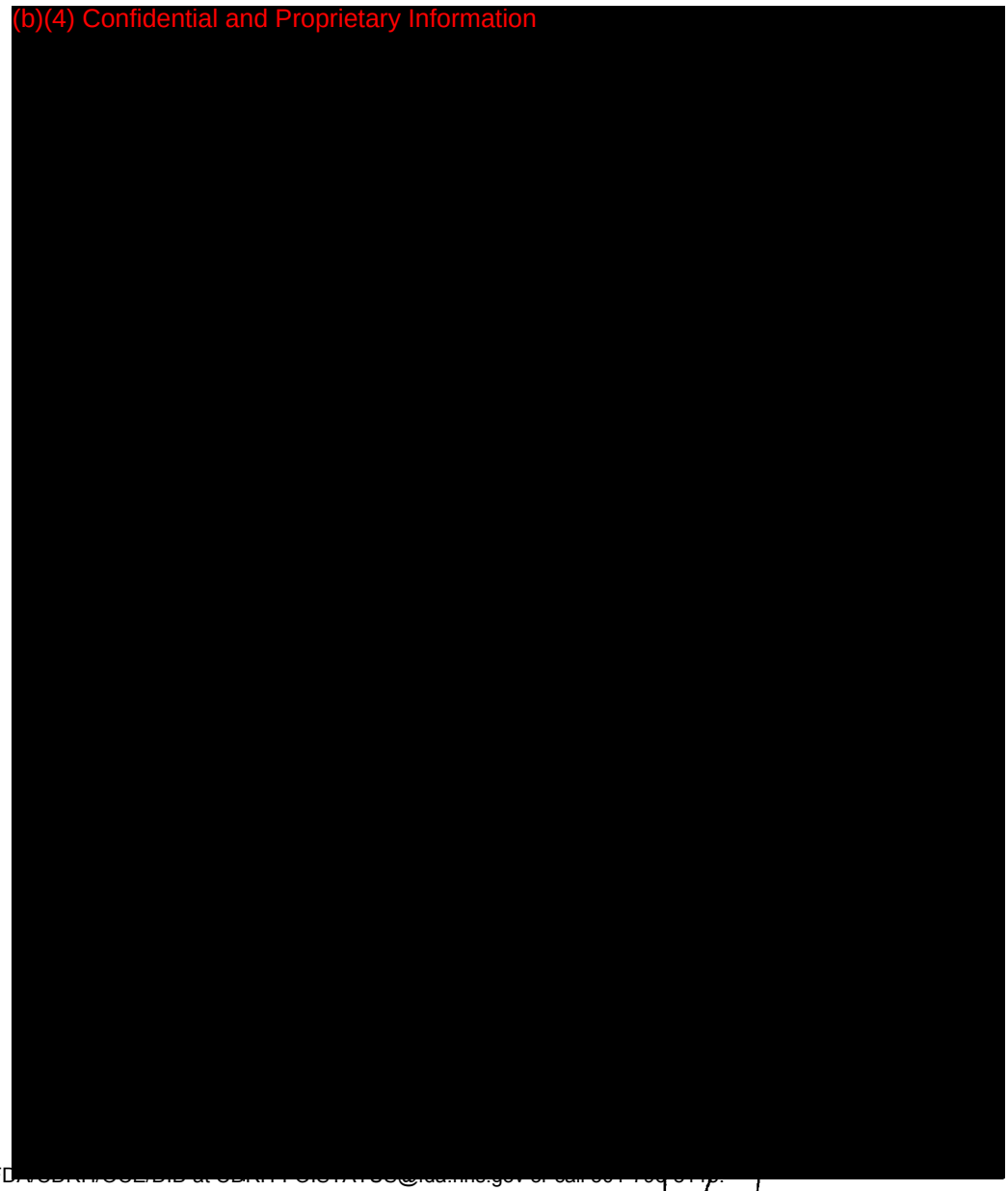
(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information



ATTACHMENT E

(b)(4) Confidential and Proprietary Information

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(b)(4) Confidential and Proprietary Information

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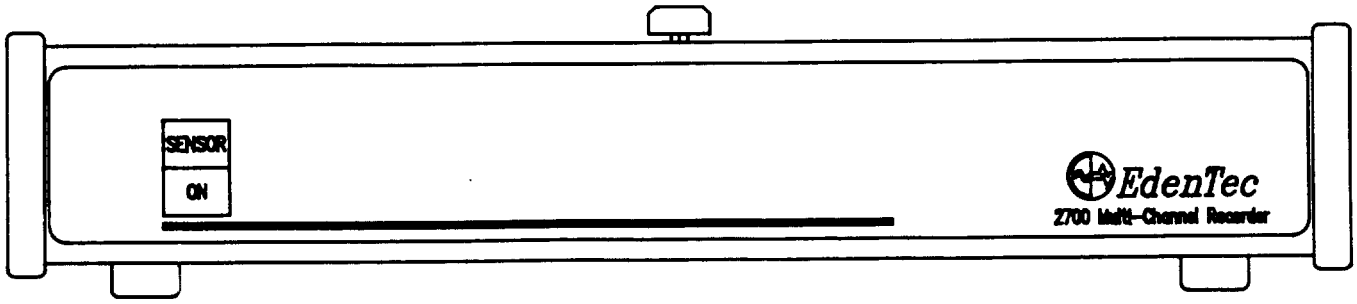
ATTACHMENT F

EdenTec Model 2700 Multi-Channel Recorder
Instruction Manual



10252 Valley View Road
Eden Prairie, MN 55344
(800) 826-2069
REV D Re-Order Number 241-3075

TABLE OF CONTENTS PAGE

SECTION ONE: MODEL 2700 MULTI-CHANNEL WARNINGS AND PRECAUTIONS

OPERATION

The EdenTec Model 2700 Multi-Channel is an accessory to the EdenTec Model 2000W and 2000W Option H Heart and Respiration Rate Monitors. It will function properly only when connected to one of these monitors. See Section 3, Equipment/Set-Up.

The Multi-Channel Recorder is powered by an EdenTec Model 2000W or 2000W Option H Monitor. The ECG and impedance respiration from the monitor is used by the Multi-Channel Recorder.

TRANSDUCERS

Do not use transducers (sensors) other than EdenTec supplied or recommended strain gauges and nasal thermistors.

STATIC ELECTRICITY

Under certain circumstances, it is possible to build up a static charge by walking across carpeting in dry climates. We recommend you touch a metal object before contacting the Multi-Channel System.

CLEANING

The Multi-Channel System can be wiped down with most mild cleansing agents. Do not immerse or allow fluid to run over the case.

INTERFERENCE

The Multi-Channel Recorder should be placed as close as possible to the EdenTec Monitor while in use. EdenTec recommends placing the Multi-Channel either on top of or underneath the Monitor. Some electrical appliances may cause electrical interference with the monitor and recorder. The Monitor and Multi-Channel Systems should not be placed on or close to electric drills, microwave ovens, televisions, or other electrical appliances.

SECTION TWO: EQUIPMENT CHECK LIST

- 4 Channel Multi-Channel Recorder Model 2700

- EdenTec Model 2000W or 2000W Option H Monitor

- Monitor/Recorder Interconnect Cable Model 4030

- Nasal Thermistor + Model 3074 Thermistor Patient Cable (if applicable)

- Strain Gauge + Model 3073 Strain Gauge Patient Cable (if applicable)

- Oximeter (if applicable), contact EdenTec for compatible manufacturers

- Oximeter Connect Cable (if applicable)

- Multi-Channel Instruction Manual

- Low noise C 60 cassette recording tape (good for one 12 hour recording), or C 90 cassette recording tape, (good for 18 hour recording)

- Small, Phillips Screwdriver (for set-up panel)

- Small, Flat Head Screwdriver (for connecting cables)

SECTION THREE: GENERAL EQUIPMENT/SET-UP

FRONT PANEL

The front panel of the Multi-Channel Recorder has two indicators. A green ON light will illuminate when the Multi-Channel Recorder is properly connected to an EdenTec Monitor and the monitor is powered on.

A red SENSOR light will be illuminated when there is a sensor alarm. A sensor alarm will occur when:

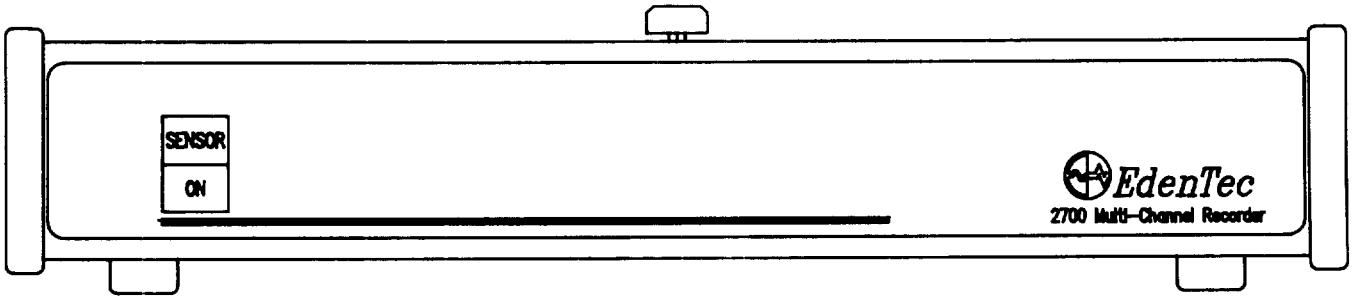
1) A SENSOR is selected ON one of the CHANNEL SELECTION switches. (see SET-UP Panel, SWITCH SETTINGS)

AND

2) There is an incomplete connection in the sensor system:
   - broken strain gauge or nasal thermistor
   - broken thermistor or strain gauge cable

OR

3) The detected respiration rate from the sensor is less than 2 BPM. This may be due to poor placement of the sensor (see section 6), or the sensor not picking up air flow or effort properly. Cleaning the nasal thermistor or repositioning the strain gauge may help.



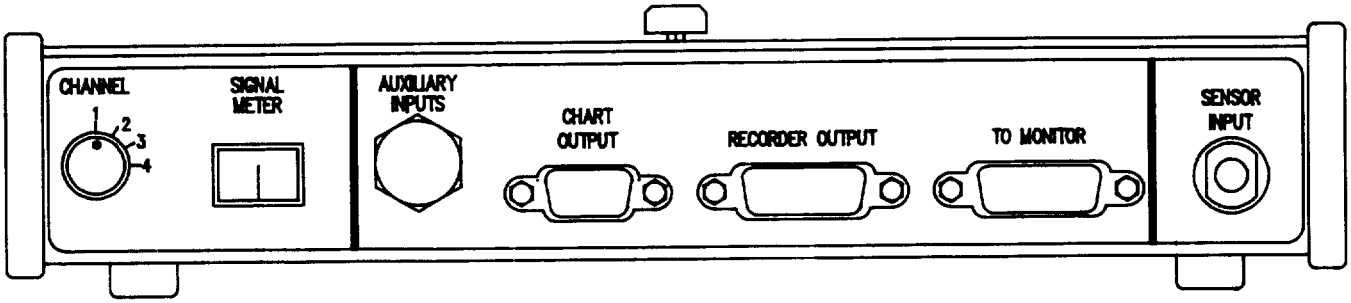
Multi-Channel Front Panel

Back Panel

The back panel of the Multi-Channel Recorder consists of connectors for:

- AUXILIARY INPUT
- TO MONITOR
- RECORDER OUTPUT
- SENSOR INPUT
- CHART OUTPUT

There also is a SIGNAL METER with a CHANNEL select switch.



Multi-Channel Back Panel

CHANNEL / SIGNAL METER

The CHANNEL switch selects which channel will be indicated on the SIGNAL METER.

AUXILIARY INPUTS

The AUXILIARY INPUT connects to:

- A pulse oximeter

AND/OR

- A device with a 0.0 to 1.0 Volt output, and a frequency response of less than 10 HZ. Contact EdenTec for information about interface and compatibility.

TO MONITOR

Connect a Model 4030 cable here and to the RECORDER connector on an EdenTec Monitor. Securely connect the Model 4030 cable to the Multi-Channel Recorder and EdenTec monitor by the cable screws.

RECORDER OUTPUT

If an additional RECORDER interface is required, connect the cable here that you would have connected to the EdenTec Monitor RECORDER connector. i.e., Alarm Logger, Model 4049 ECG Interface Cable.

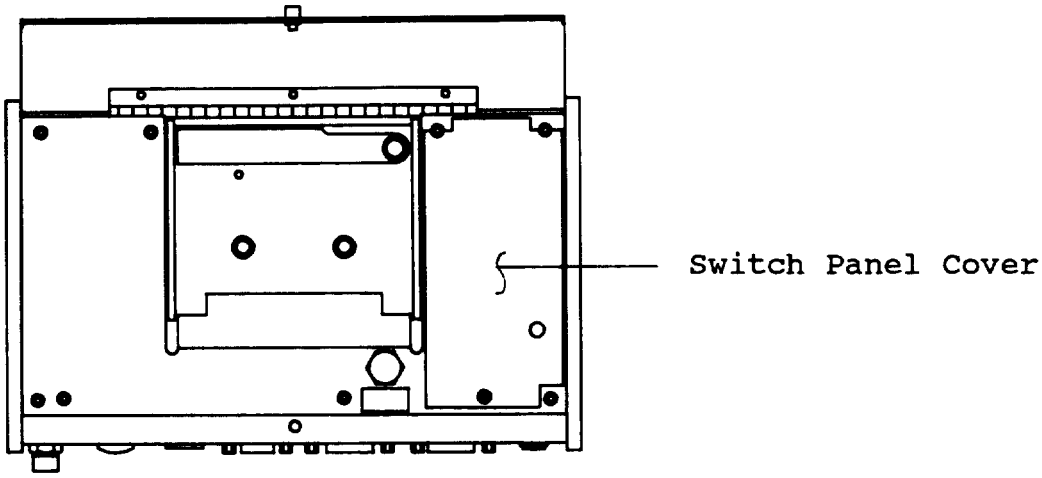
CHART OUTPUT

This connector is used for connection to the EdenTec Model 3700 Charter for direct chart recording of the 4 channel data. Contact EdenTec Customer service for information on the EdenTec Model 3700 Charter.

pening The Unit

The cover of the Multi-Channel Recorder is held closed by a thumb screw. To open the cover, turn the thumb screw counterclockwise until the cover can be lifted as shown below:

THUMB SCREW



Check behind the panel to the right side of the recorder to verify proper set up, this panel can be removed by removing the single phillips screw at the bottom of the panel. Removing this cover will disclose the set up switches shown on the next page.

Take care to put the set-up panel screw in a safe place. Do not drop the screw into the Multi-Channel Recorder.

Switch Panel - Explanation of Settings

NOTE: This switch panel is valid for Model 2700's with Serial Number 27045 and above.

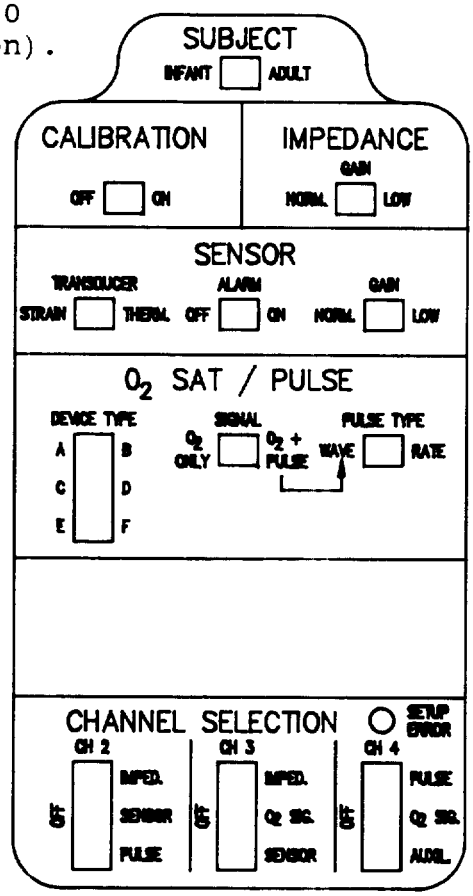
CALIBRATION:
Set to ON to record calibration signals on tape for 6 minutes (see page 10 for details on calibration).

TRANSDUCER:
Select either a strain gauge or nasal thermistor

ALARM:
ON allows audible SENSOR alarm. OFF disables audible alarm.

DEVICE TYPE:
If oximeter is used, set DEVICE TYPE code according to oximeter manufacturer in Appendix B.

SIGNAL:
Set to 0_2 ONLY if 02 saturation is to be recorded. Set to 0_2 + PULSE to multiplex both 0_2 saturation and the pulse plethysmographic (wave) signal onto one channel. (Note: An oximeter with pulse wave signal available must be used if 0_2 + PULSE is selected. A PULSE RATE cannot be multiplexed with the 0_2 SIGNAL.)



SUBJECT:
Set to INFANT for Infant Subject. Set to ADULT for adult and child subjects.

GAIN:
Set to NORM for normal pneumogram signal amplitude. Set to LOW for more physiologic waveform.

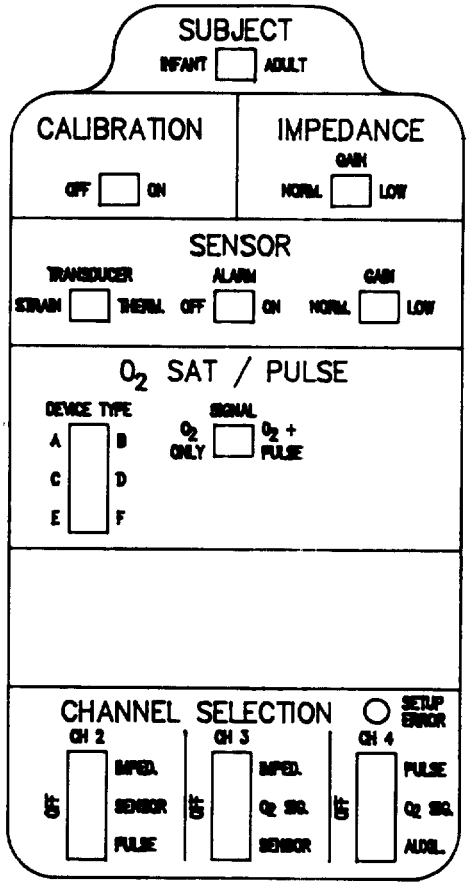
PULSE TYPE:
Select type of PULSE signal input. If 0_2 + PULSE is selected, PULSE WAVE input must be available from oximeter.

CHANNEL SELECTION:
Select the desired channels for the physiologic signals desired. ECG is always recorded on channel one.

If more that one signal is ON per channel, a visual SET-UP ERROR will occur.

Switch Panel - Explanation of Settings

NOTE: This Switch panel is valid for Model 2700's with Serial Number 27001 through 27043.



CALIBRATION:
Set to ON to record calibration signals on tape during the first 6 minutes (see next page for details on calibration).

TRANSDUCER:
Select either a strain gauge or nasal thermistor.

ALARM:
ON allows audible SENSOR alarm. OFF disables audible alarm.

DEVICE TYPE:
If oximetry is used, set DEVICE TYPE code according to oximeter manufacturer in Appendix B.

SIGNAL:
Set to 02 ONLY if 02 saturation is to be recorded. Set to 02 + PULSE to multiplex both 02 saturation and the pulse plethysmographic (wave) signal onto one channel. NOTE: Must use oximeter with pulse (wave) signal available if 02 + PULSE is selected. A PULSE RATE signal cannot be multiplexed with the 02 signal.

SUBJECT:
Set to INFANT for infant subject. Set ADULT for adult and child subjects.

GAIN
Set to NORM for normal pneumogram signal amplitude. Set to LOW for more physiologic waveform.

CHANNEL SELECTION:
Select the desired channels for the physiologic signals desired. ECG is always on channel one.

If more than one signal is ON per channel, a visual SET-UP ERROR will occur.

Calibration Signals

When the calibration switch beneath the set up panel shown on the previous pages is ON, calibration signals are recorded on tape during the first 6 minutes each time the recorder is powered on. Changing the calibration switch from "off" to "on" while the recorder is running will also start a 6 minute calibration sequence. To stop a 6 minute calibration sequence, move the calibration switch to the "off" position. The calibration signals recorded depend on the physiologic channels chosen to be recorded. Calibration signals are:

ECG - 0.5 mV, 120 beats per minute

Impedance - 0.5 ohm, 30 breaths per minute

Strain Gauge - 30 breaths per minute reference

Nasal Thermistor - 30 breaths per minute reference

02 Saturation - Repeating sequence of saturation levels of 0%, 100%, 50% and 75%. Each calibration level lasts 3 seconds.

Additionally, once each 6 minutes a single cycle calibration sequence, 3 seconds per level, occurs. Once per hour the sequence doubles in duration to 6 seconds per level. This calibration sequence occurs regardless of the calibration switch position.

If a calibration sequence occurs during a possible desaturation event (less than 88% 0_2 saturation) the sequence is abbreviated to be only 0.5 seconds duration per level.

Sensor

Alarm - Switch set to OFF will inhibit an audible SENSOR Alarm.
Switch set to ON will allow a SENSOR Alarm
A constant tone audible alarm will occur when a SENSOR is selected ON a channel and:

1) There is a broken sensor
2) There is a broken sensor cable
3) There are less than 2 BPM of respiration detected by the sensor. The audible tone will be a pulsed tone at a rate of 1 pulse every 2 seconds, on SERIAL NUMBER 27045 and above. The audible tone will be a constant tone on SERIAL NUMBER 27044 and below.

02 SAT/PULSE

02 ONLY / 02 + PULSE - If 02 ONLY is to be placed on a channel, select 02 ONLY and set channel selector for that channel to 02 SIG. Pulse signal, rate or wave, may be selected on another channel by selecting PULSE on that channel.

If 02 + PULSE is desired to be recorded on a channel, select 02 + PULSE. Also select 02 SIG to the ON position of the desired channel. The oximeter must have a PULSE WAVE output. The 02 Signal and Pulse signal will be muliplexed onto the selected channel.

Channel Selection

The ECG signal automatically records on channel 1. Channels 2, 3, and 4 may be OFF or record a physiologic signal.

For each channel, select which physiologic signal you want to record. Select only one signal per channel. If more than one signal is ON per channel, a SET-UP ERROR will be indicated.

The choices for physiologic signals are:

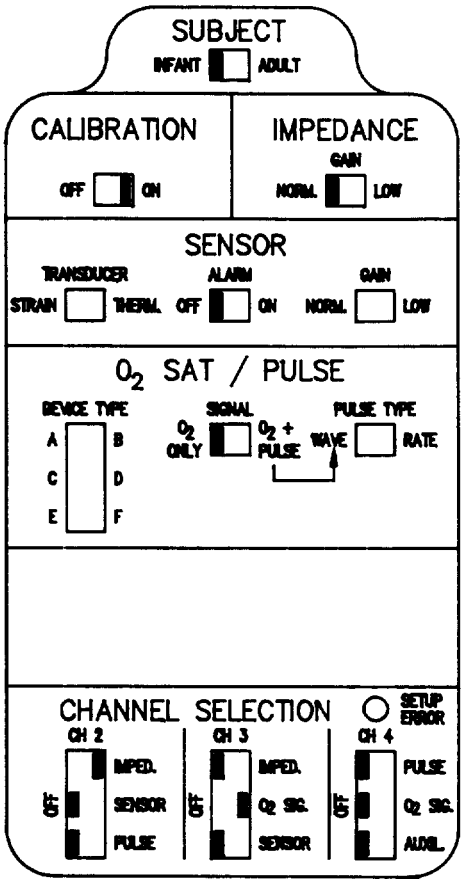
respiration impedance
strain gauge or nasal thermistor
oxygen saturation
oxygen saturation plus pulse plethysmographic waveform*
pulse plethysmographic or pulse rate signal
auxiliary input of 0.0 to + 1.0 Volt amplitude (contact EdenTec for compatability)

*To record these two signals on one channel requires a pulse oximeter with pulse plethysmographic output, sometimes labeled PULSE WAVE. Some oximeters do not provide the pulse plethysmographic waveform as an output.

SECTION FOUR: RECORDING 3 CHANNELS OF PHYSIOLOGIC DATA

To Set Up A 3-Channel Infant Recording With:

Channel 1 as ECG
Channel 2 as Impedance Respiration
Channel 3 as O_2 Sat only



SENSOR settings are not needed for this particular recording.

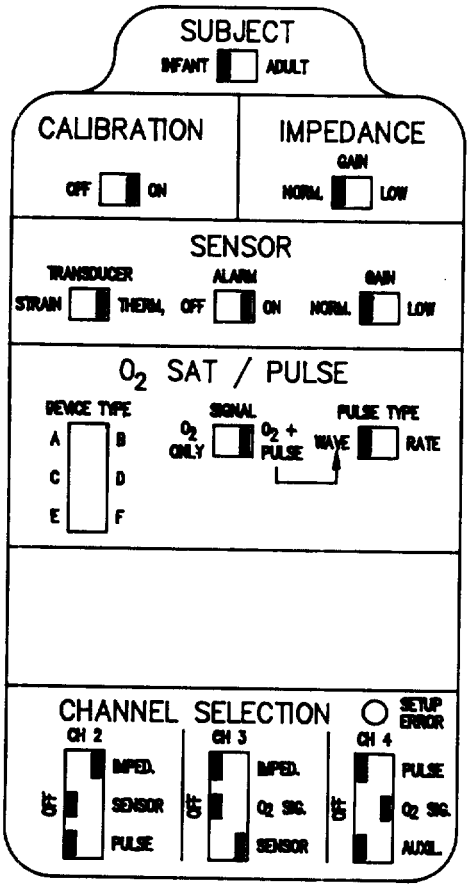
DEVICE TYPE
See Appendix B for additional information regarding compatability of different oximeters.

Once the parameters have been set - turn to Section 6, Patient Application.

SECTION FIVE: EXAMPLES 4 CHANNEL SET UP

To Set Up a 4-Channel Infant Recording With:

Channel 1 as ECG
Channel 2 as Impedance Respiration
Channel 3 as Nasal Thermistor*
Channel 4 as 0_2 Sat plus Pulse.



DEVICE TYPE
See Appendix B for additional information regarding compatability of different oximeters.

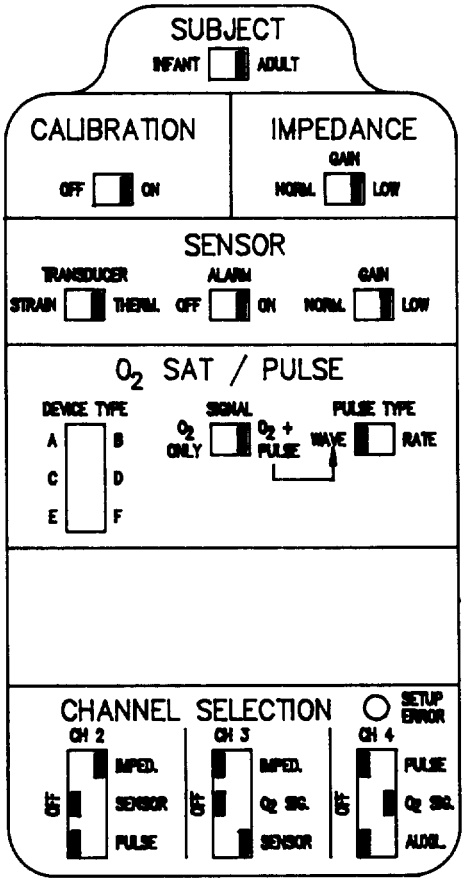
Once the parameters have been set - turn to Section 6, Patient Application.

NOTE:
The 0_2 signal is multiplexed automatically. You do not need to choose pulse and 0_2 Sig. on channel 4.

*To set up a 4-channel study with the strain gauge as the third channel, simply change the TRANSDUCER switch from "THERM" to "STRAIN".

To Set Up a 4-Channel Adult Recording With:

Channel 1 as ECG
Channel 2 as Impedance Respiration
Channel 3 as Nasal Thermistor*
Channel 4 as 0_2 Sat plus Pulse



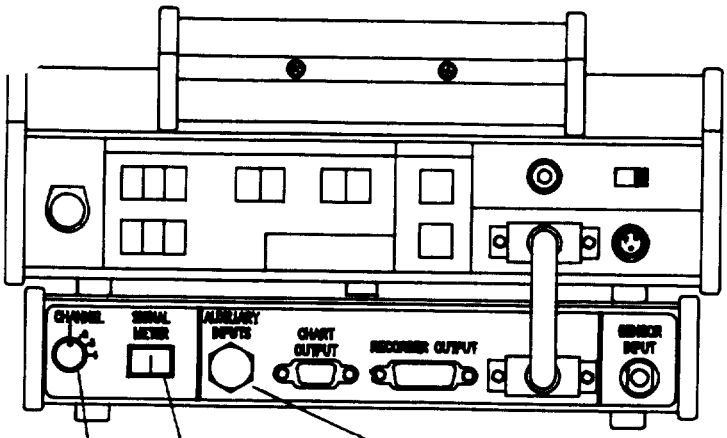
DEVICE TYPE:
See Appendix B for additional information regarding compatability of different oximeters.

Once the parameters have been set - turn to Section 6, Patient Application.

NOTE:
The 0_2 is multiplexed automatically. You do not need to choose pulse and 0_2 Sig. on channel 4.

*To set up a 4-channel study with the strain gauge as the third channel, simply change the TRANSDUCER switch from "THERM" to "STRAIN".

SECTION SIX: PATIENT APPLICATION



To assure sufficient battery power for the study - have the battery charger connected to the monitor.

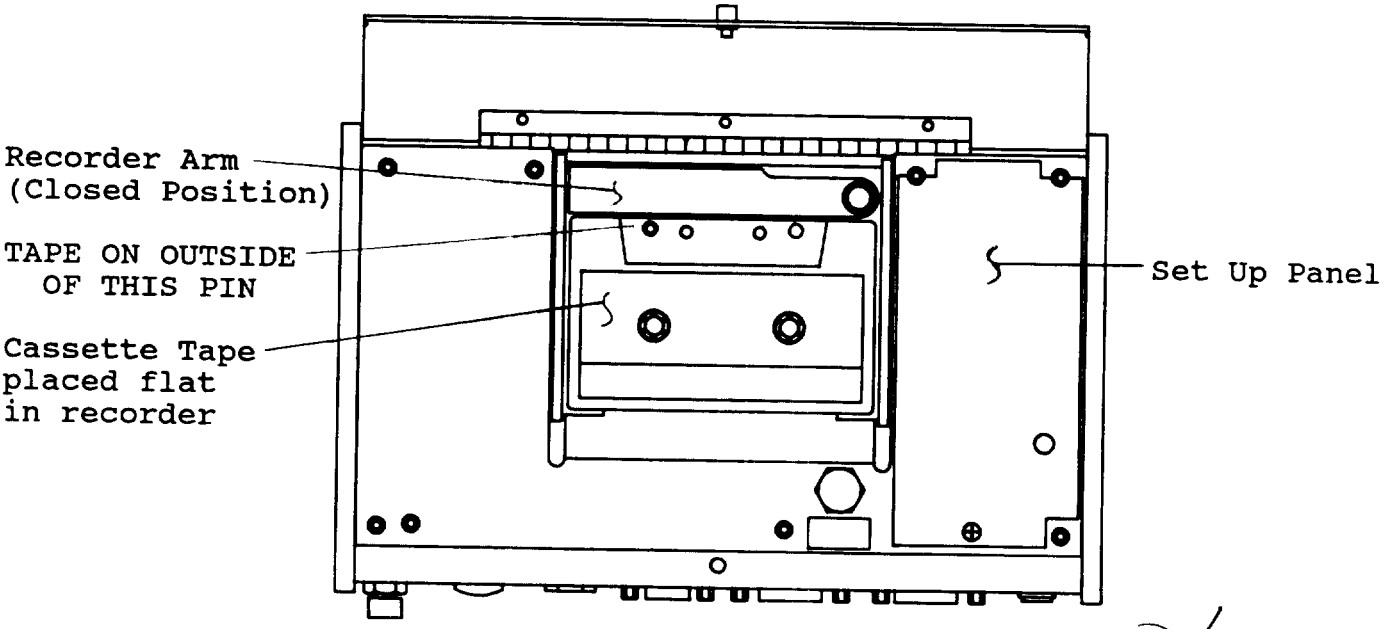
SENSOR INPUT:
To nasal thermistor or strain gauge patient cable.

Secure the interconnect cable with screws provided.

Once the parameters have been set, replace the set up panel cover and secure it with the screw.

Swing out the arm of the recorder (see photo below) and place the tape down flat in the recorder, the A or 1 side facing up. Advance the tape past the clear header. The tape must be tight in the cassette. Be sure the tape is properly set in the recorder, otherwise the tape will not wind correctly. Press the recorder arm back into place. Make sure recorder arm snaps completely into place.

Once all of the connections have been made between the monitor, the subject and the oximeter (if utilized), turn the monitor on. (see following pages for guidelines in setting up specific transducers). The multi-channel will receive its power from the monitor's battery. Always have the monitor attached to the battery charger, with the charger plugged into a power outlet, when recording.



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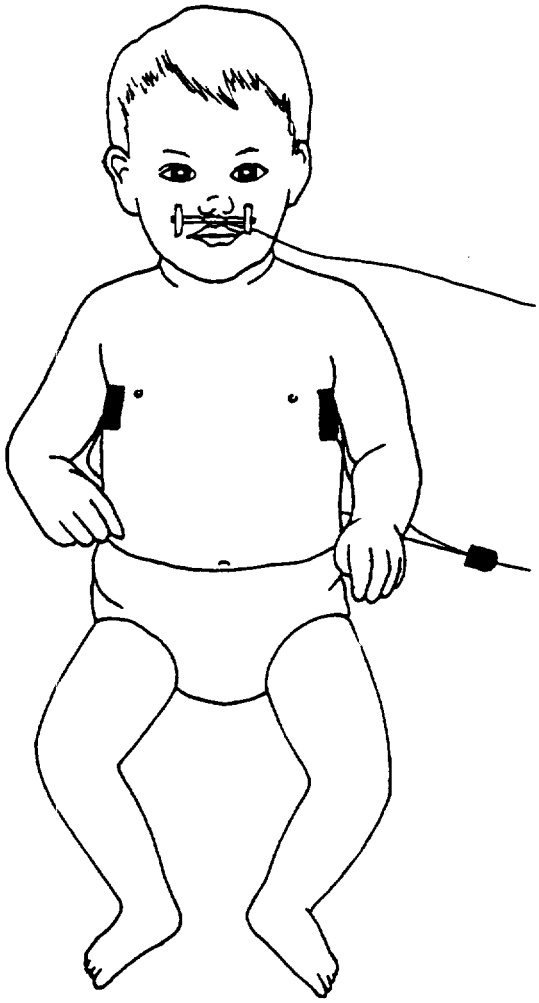
Thermistor Application - Infant



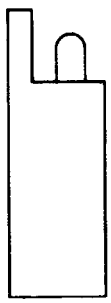
The infant sized thermistor should be placed directly underneath the baby's nose, with the two thermistor beads pointing up towards the nostrils. SECURE the thermistor in place with double sided tape.
Enough tape must be used to assure the thermistor will not become dislodged easily.

If the thermistor becomes dislodged and the SENSOR ALARM switch is "ON", an alarm will sound and a "SENSOR" light will illuminate on the front panel of the multi-channel. To correct this, reposition the thermistor and secure it. If the SENSOR ALARM switch is OFF, no audible SENSOR alarm will occur, but the front panel SENSOR light will illuminate.

Electrode Patient Cable

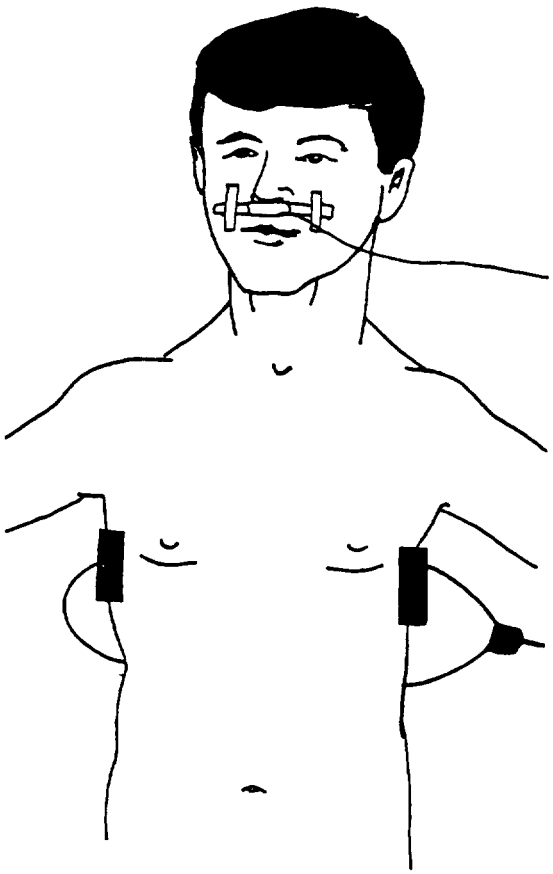
NOTE: The thermistor should be placed with the beads towards the nostrils. The guard strip should be on the outside, away from the face.

guard strip



This side toward face.

Thermistor Application - Adult

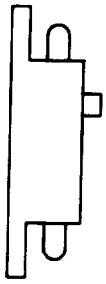


The adult sized thermistor should be placed directly beneath the patient's nose with two of the thermistor beads pointing up towards the nostrils. There will be two beads pointed down towards the mouth. SECURE the thermistor in place with tape.

If the thermistor becomes dislodged, and the SENSOR ALARM switch is switched "ON", an alarm will sound and a "SENSOR" light will illuminate on the front panel of the multi-channel. To correct this, reposition the thermistor and secure it. If the SENSOR ALARM switch is OFF, no audible SENSOR alarm will occur.

Electrode Patient Cable

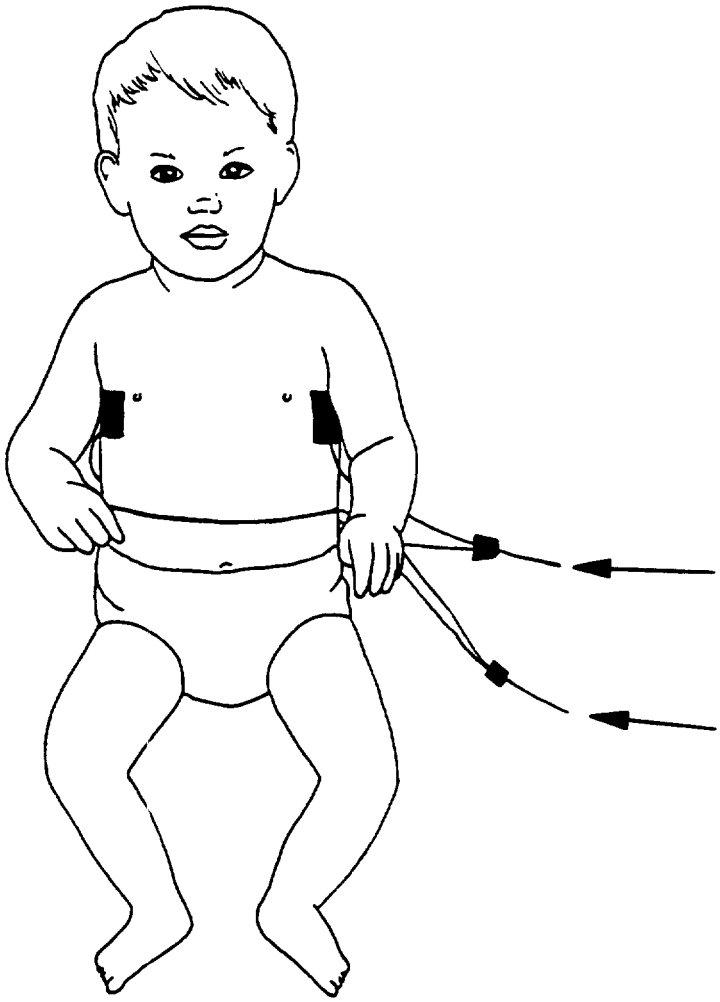
NOTE: The thermistor should be placed with the beads toward the face.



This side toward face.

Abdominal Strain Gauge Application

Stretch the strain gauge across the abdominal cavity and attach the velcro strips to a foam strip on the back. Stretch the strain gauge enough to take-up the slack. Pulling the strain gauge too tight can cause a SENSOR alarm. Attach the strain gauge to the strain gauge patient cable and secure the cable into the jack on the multi-channel recorder labelled "SENSOR INPUT".



OXIMETER APPLICATION

Attach the oximeter cable to the EdenTec Multi-Channel in the jack labelled AUXILIARY INPUT. Attach the ends of the cable into the oximeter jacks labelled PULSE RATE and/or PULSE WAVE, and O_2 SAT.

SEE APPENDIX B FOR OXIMETER MANUFACTURER COMPATABILITY

NOTE: To use the multiplexed O_2 SAT and PULSE feature of the Multi-Channel Recorder, the oximeter must have a PULSE WAVE output.

SECTION SEVEN: TROUBLESHOOTING GUIDE

PROBLEM	POSSIBLE CAUSE AND ACTION
A) Front panel ON light (Green) is not illuminated.	1) The ON light illuminates only when the Model 2700 is connected to an EdenTec Model 2000W or 2000W Option H Monitor. Verify proper connection of the Model 4030 interface cable.
	2) A defective interface cable. Replace Model 4030 cable.
	3) The ON light is not functional, return unit for service.
B) Recorder motor does not sound like it is running, and tape is not moving. (It moves very slowly.	1) Verify problem (A) does not exist.
	2) Return unit for service.
C) SENSOR LIGHT (RED) and/or audible alarm are occurring.	1) A strain gauge or nasal thermistor is not connected to the sensor input. Connect appropriate sensor.
	2) Adequate signal is not seen by the Multi-Channel System. Reposition the sensor to pick up a better signal.
	3) The signal detected by the sensor is occurring at less than 2 breaths per minute. Verify by observing the subject.
	4) A break exists in the sensor or sensor cable. Try another sensor or cable.
	5) Return unit for service.

D) Improper signal deviation, or absence of signal deviation on signal meter (shown on p. 5).

1) Verify proper interface cable connection.

2) Verify proper oximeter settings, if problem is with oximeter channel.

3) Verify proper sensor placement if problem is the sensor channel.

4) Verify paper electrode placement if ECG/Impedance Respiration problem.

5) Return unit for service.

E) Tape has been taken up on cassette but no signal is seen on playback, i.e., all channels are blank.

1) The tape has not been placed properly in the recorder. See Section 6, Patient Application.

2) All of the channels are switched off.

3) Tape has not been placed around pin in the recorder, see page 15.

4) Faulty recorder. Return unit for service.

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APPENDIX A

Cleaning The Thermistor and Strain Gauge

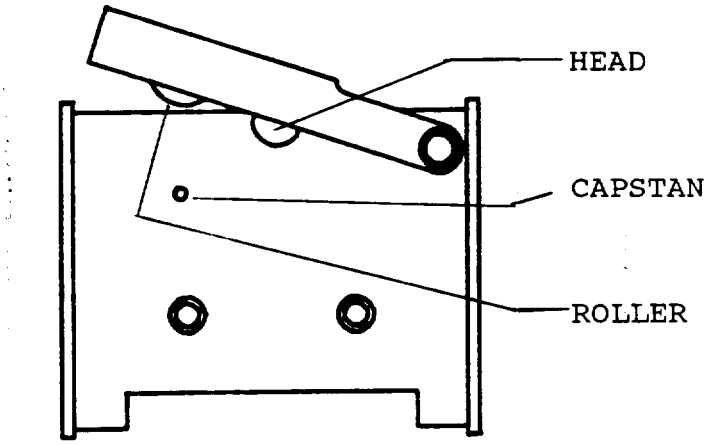
The thermistor must be cleaned before application to any patient. The thermistor and its cable can be cleaned with mild soaps or hospital cleaners and may be low temperature gas sterilized.

Use warm water, not hot. The thermistor can be put under running water or immersed.

The strain gauge should not be immersed. Wiping it with mild soap or hospital cleaner on a cloth is advised. The strain gauge is a disposable sensor and once the seal on the bag has been broken, it has approximately a 48 hour life.

Cleaning and Care of the Recording Mechanism

The tape head, pressure roller, and capstan need to be cleaned to assure proper operation.



Tape Head: Clean the tape head weekly with a quality tape head cleaner. Use a cotton swab to clean tape debrie from head. Be careful not to leave behind cotton fibers.

Pressure Roller: The pressure roller can be cleaned with a cotton swab and denatured alcohol or tape head cleaner. Wipe all around the roller to remove tape debrie. Clean weekly.

Capstan: The capstan, the metal pin that the pressure roler presses against, needs to be cleaned after each use. Use denatured alcohol or head cleaner and a cotton swab to clean around the capstan. Clean weekly.

CAUTION: Do not allow fluid to drain down into the bearings of the capstan shaft.

APPENDIX B

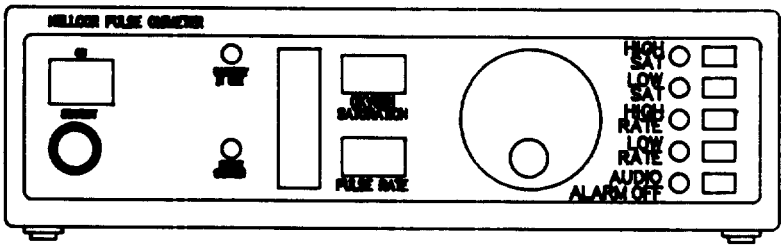
Compatible Oximeters

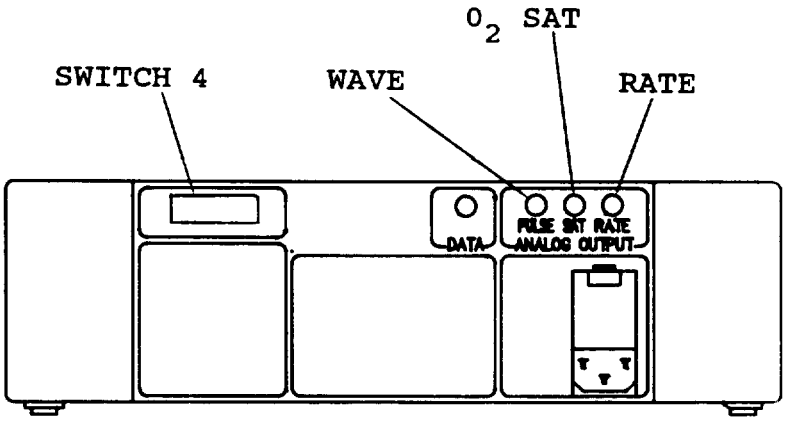
The EdenTec Model 2700 Multi-Channel is compatible with the following oximeters. (Contact EdenTec for information on other oximeters.)

Nelcor N-100

MULTI-CHANNEL RECORDER: Select DEVICE TYPE A-C-E on the set up panel of the multi-channel recorder.
Select O_2 ONLY or O_2 + PULSE on the set-up panel.
Select desired PULSE TYPE.
OXIMETER:
Select oximeter mode to 2 (described below).
Set oximeter to 0 to 1.0 volt output (described below).

Use EdenTec Model 3072 Oximeter Cable





Attach the Nellcor Oximeter to the patient using the manufaturer's procedure. Once the Nellcor is set and running, depress HIGH RATE and LOW RATE at the same time and move the white dial so that the number "2" appears in the window. Any time the oximeter is turned off, you will have to reset it to mode 2. Mode 2 gives the quickest response time to a desaturation.

Also make sure the number 4 switch on the Nellcor's rear panel is set to the 1.0 volt range or the down position.

Check that the innerconnect cable between the recorder and oximeter are properly connected. (SAT to SAT, PULSE to PULSE)

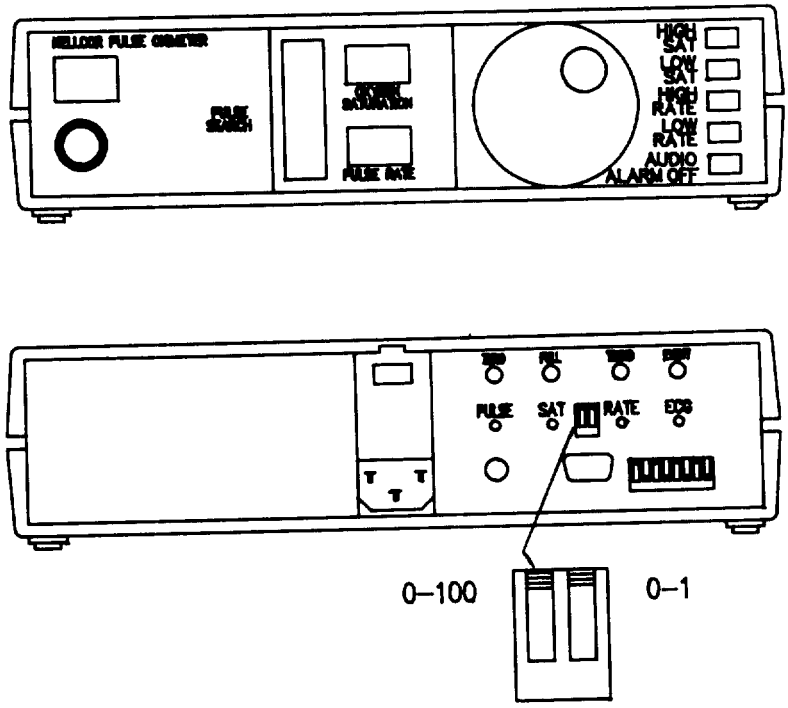
Nelcor N - 200

MULTI-CHANNEL RECORDER:
Select DEVICE TYPE A-C-E on the set-up panel of the multi-channel recorder.
Select 02 ONLY or 02 + PULSE on the set-up panel.
Select desired PULSE TYPE.

OXIMETER:
Select oximeter mode to 2 (descibed below).
Set oximeter to 0 to 1.0 volt output (described below).

Use EdenTec Model 3072 Oximeter cable.

For use of the Nelcor C-LOCK feature, connect EdenTec Model 4049 ECG Interface Cable to the RECORDER OUT of the Multi-Channel Recorder. Connect the ECG plug into the ECG IN/OUT jack on the rear of the N-200. Secure the Model 4049 Interface to the multi-channel recorder.



Attach the Nellcor Oximeter to the patient using the manufacturer's procedure. Once the Nellcor is set and running, depress HIGH RAT. and LOW RATE at the same time and move the white dial so that the number "2" appears in the window. Any time the oximter is turned off, you will have to reset it to mode 2. Mode 2 gives the quickest resonse time to a desaturation.

Also make sure the VOLT switch on the Nellcor's rear panel is set to the 0-1 volt range or the up position. And the Sa02% SCALE switch is set to 0-100, or the up position.

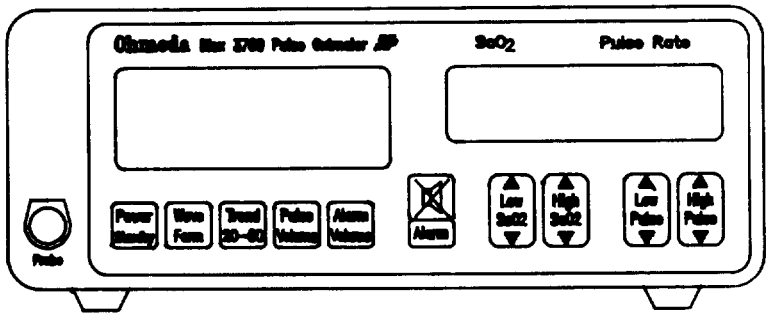
Check that the innerconnect cable between the recorder and oximeter are properly connected. (SAT to SAT, PULSE to PULSE).

Ohmeda/Biox 3700

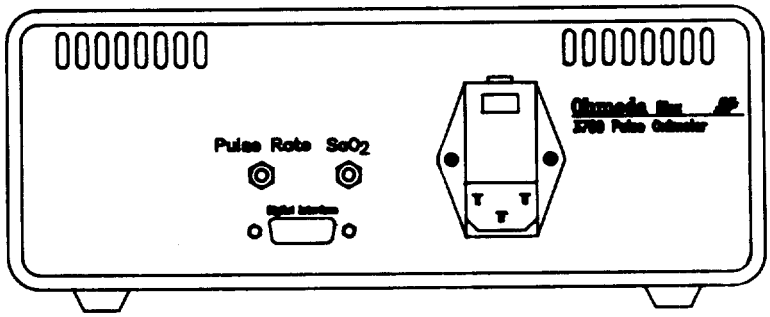
MULIT-CHANNEL RECORDER

Select DEVICE TYPE - ACE on the set up panel of the multi-channel recorder.
Select SIGNAL - 02 ONLY on the set up panel.
Select PULSE TYPE - RATE on the set-up panel.

Use EdenTec Model 3077 interface cable.



Attach the Ohmeda Oximeter to the patient using the manufacturer's procedure. Once the oximeter is set and running, set the oximeter to fast response mode (3 second SaO2 averaging time) by holding the WAVEFORM key for 3 seconds. The Status message FAST RESPONSE SELECTED will momentarily appear and the letter "F" will appear along side the plethysmographic waveform. To return to Slow Response Mode, hold the Waveform key for 3 seconds.



Check that the inner-connect cable between the recorder and oximeter are properly connected as shown. The SAT cable should be plugged into connector labeled "Sa02" and RATE plugged into "PULSE RATE".

NOTE: A multiplexed O2 SAT + PULSE signal cannot be implimented with the Ohmeda/Biox Oximeter.

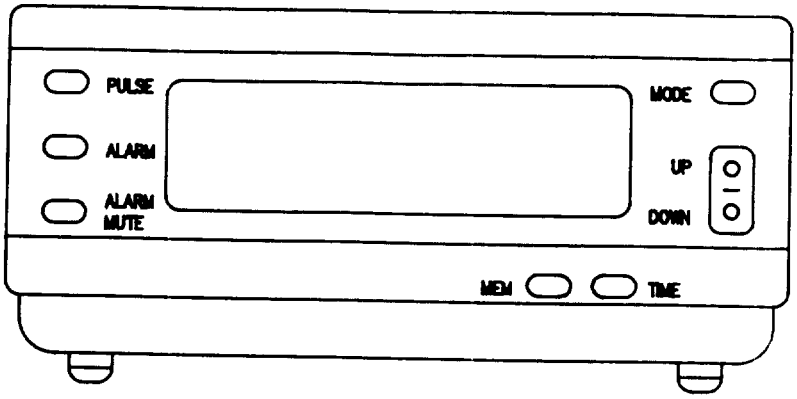
Minolta/Marquest Pulsex-7

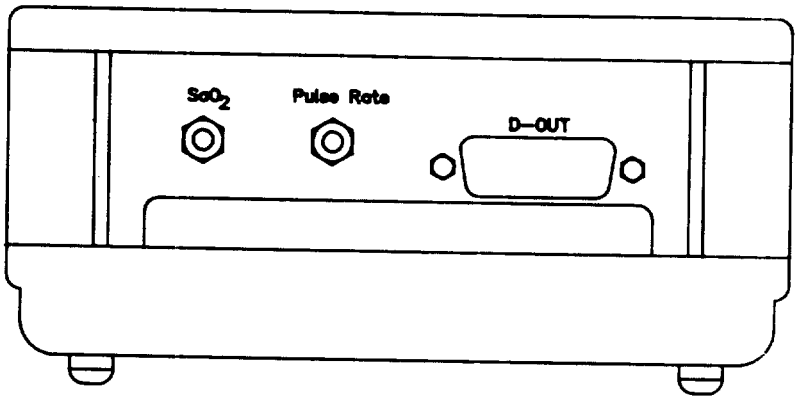
MULTI-CHANNEL RECORDER

Select DEVICE TYPE - ACE on the set up panel of the multi-channel recorder.
Select SIGNAL - 02 ONLY on the set up panel.
Select PULSE TYPE - PULSE RATE in the set-up panel

Use EdenTec Model 3088 Oximeter interface cable

Attach the Minolta Oximeter to the patient using the manufacturer's procedure.





Check that the inner-connect cable between the recorder and oximeter are properly connected as shown. The SAT cable should be plugged into connector "Sa02" and the RATE cable plugged into "PULSE RATE".

NOTE: A multiplexed 02 SAT + PULSE signal cannot be implimented with the Minolta/Marquest Pulsex.

ATTACHMENT G

Summary of Safety and Effectiveness

A) A review of the Medical Device Reports for the predicate device has been completed. No information was present in these reports that raise safety and effectiveness questions on the new devices.

B) I am not aware of any literature that makes claims concerning safety or effectiveness.

C) The devices are labeled for appropriate use.

D) The air flow sensor is a disposable, one use device.

I certify that the safety and effectiveness search has been completed.

Upon the request of any person, EdenTec will provide safety and effectiveness information supporting a substantially equivalent determination.

Signature: Gary Syring Date: 8/20/91

Gary Syring
Director Quality Assurance
EdenTec Incorporated
10252 Valley View Road
Eden Prairie, MN 55344
(612) 941-3006

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ATTACHMENT H

EDENTEC

Application Note

Model 971 Disposable Airflow Sensor Adult

This package contains the Model 971 Disposable Airflow Sensor designed for use on adults. This device is intended for use only on adults.

Application
Remove the Model 971 Disposable Airflow Sensor from the package. Peel the airflow sensor/tape assembly away from the backing.

Apply the airflow sensor to the patient's face. Position the airflow sensor so that the two projections are under the patient's nostrils. The single bottom projection will be over the patient's mouth.

The adhesive surface of the tape should be against the patient's skin holding the airflow sensor in place. The EdenTec logo will be visible. (Figure 1)

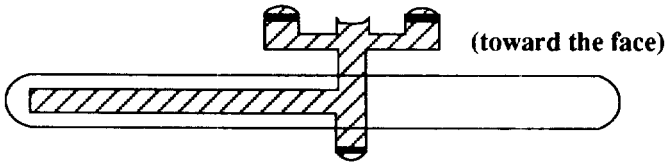

Figure 1

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Attach the free end of the airflow sensor to the airflow sensor cable input as indicated in Figure 2. The connection should fit snugly in place

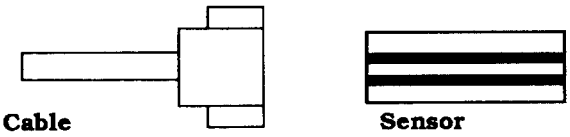

Figure 2

NOTE: DO NOT CLEAN. The Model 971 Disposable Airflow Sensor is designed for single patient use. Attempts to clean the airflow sensor may result in damage and loss of airflow sensor function.

CABLES AND SENSORS. No warranty or repair or replacement agreement whatsoever is made or given as to cables and sensors as they may be easily damaged by improper handling or use due to their unavoidably fragile character, which is dictated by the requirements of their application.

Instruction Sheet Re-order # 241-3146 Rev. A

EDENTEC **Application Note**

Model 972 Disposable Airflow Sensor Small Adult

This package contains the Model 972 Disposable Airflow Sensor designed for use on adults. This device is intended for use only on adults.

Application
Remove the Model 972 Disposable Airflow Sensor from the package. Peel the airflow sensor/tape assembly away from the backing.

Apply the airflow sensor to the patient's face. Position the airflow sensor so that the two projections are under the patient's nostrils. The single bottom projection will be over the patient's mouth.

The adhesive surface of the tape should be against the patient's skin holding the airflow sensor in place. The EdenTec logo will be visible. (Figure 1)

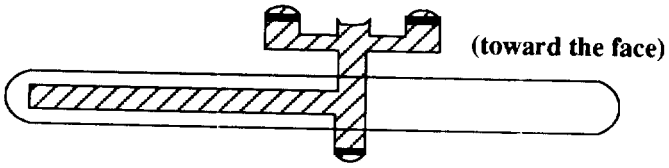

Figure 1

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Attach the free end of the airflow sensor to the airflow sensor cable input as indicated in Figure 2. The connection should fit snugly in place

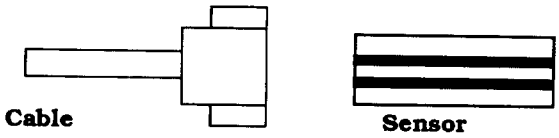

Figure 2

NOTE: DO NOT CLEAN. The Model 972 Disposable Airflow Sensor is designed for single patient use. Attempts to clean the airflow sensor may result in damage and loss of airflow sensor function.

CABLES AND SENSORS. No warranty or repair or replacement agreement whatsoever is made or given as to cables and sensors as they may be easily damaged by improper handling or use due to their unavoidably fragile character, which is dictated by the requirements of their application.

Instruction Sheet Re-order # 241-3147 Rev. A

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EDENTEC

Application Note

Model 974 Disposable Airflow Sensor Child

This package contains the Model 974 Disposable Airflow Sensor designed for use on adults. This device is intended for use only on adults.

Application
Remove the Model 974 Disposable Airflow Sensor from the package. Peel the airflow sensor/tape assembly away from the backing.

Apply the airflow sensor to the patient's face. Position the airflow sensor so that the two projections are under the patient's nostrils. The single bottom projection will be over the patient's mouth.

The adhesive surface of the tape should be against the patient's skin holding the airflow sensor in place. The EdenTec logo will be visible. (Figure 1)

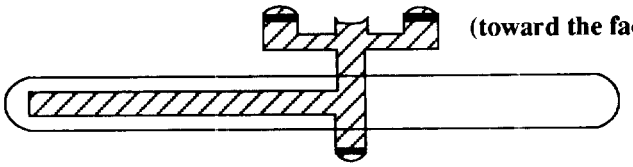

Figure 1

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Attach the free end of the airflow sensor to the airflow sensor cable input as indicated in Figure 2. The connection should fit snugly in place.

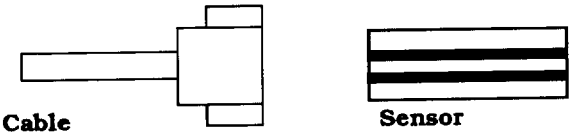

Figure 2

NOTE: DO NOT CLEAN. The Model 974 Disposable Airflow Sensor is designed for single patient use. Attempts to clean the airflow sensor may result in damage and loss of airflow sensor function.

CABLES AND SENSORS. No warranty or repair or replacement agreement whatsoever is made or given as to cables and sensors as they may be easily damaged by improper handling or use due to their unavoidably fragile character, which is dictated by the requirements of their application.

Instruction Sheet Re-order # 241- 3148 Rev. A

EDENTEC

Application Note

Model 976 Disposable Airflow Sensor Infant

This package contains the Model 976 Disposable Airflow Sensor designed for use on adults. This device is intended for use only on adults.

Application
Remove the Model 976 Disposable Airflow Sensor from the package. Peel the airflow sensor/tape assembly away from the backing.

Apply the airflow sensor to the patient's face. Position the airflow sensor so that the two projections are under the patient's nostrils. The single bottom projection will be over the patient's mouth.

The adhesive surface of the tape should be against the patient's skin holding the airflow sensor in place. The EdenTec logo will be visible. (Figure 1)

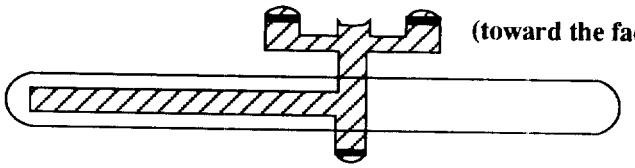

Figure 1

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Attach the free end of the airflow sensor to the airflow sensor cable input as indicated in Figure 2. The connection should fit snugly in place

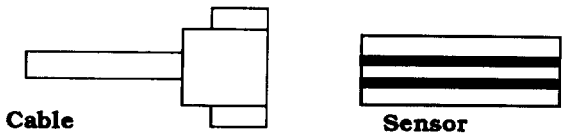

Figure 2

NOTE: DO NOT CLEAN. The Model 976 Disposable Airflow Sensor is designed for single patient use. Attempts to clean the airflow sensor may result in damage and loss of airflow sensor function.

CABLES AND SENSORS. No warranty or repair or replacement agreement whatsoever is made or given as to cables and sensors as they may be easily damaged by improper handling or use due to their unavoidably fragile character, which is dictated by the requirements of their application.

Instruction Sheet Re-order # 241-3149 Rev. A

EDENTEC

Application Note

Model 978 Disposable Airflow Sensor Premie

This package contains the Model 978 Disposable Airflow Sensor designed for use on adults. This device is intended for use only on adults.

Application
Remove the Model 978 Disposable Airflow Sensor from the package. Peel the airflow sensor/tape assembly away from the backing.

Apply the airflow sensor to the patient's face. Position the airflow sensor so that the two projections are under the patient's nostrils. The single bottom projection will be over the patient's mouth.

The adhesive surface of the tape should be against the patient's skin holding the airflow sensor in place. The EdenTec logo will be visible. (Figure 1)

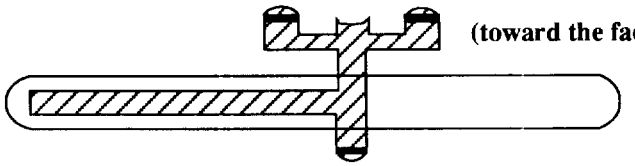

Figure 1

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Attach the free end of the airflow sensor to the airflow sensor cable input as indicated in Figure 2. The connection should fit snugly in place.

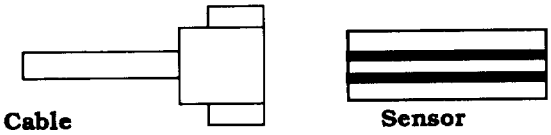


Figure 2

NOTE: DO NOT CLEAN. The Model 978 Disposable Airflow Sensor is designed for single patient use. Attempts to clean the airflow sensor may result in damage and loss of airflow sensor function.

CABLES AND SENSORS. No warranty or repair or replacement agreement whatsoever is made or given as to cables and sensors as they may be easily damaged by improper handling or use due to their unavoidably fragile character, which is dictated by the requirements of their application.

Instruction Sheet Re-order # 241-3150 Rev. A

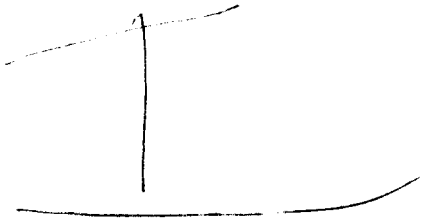
Adult
Model 971
Disposable Airflow Sensor

Small Adult
Model 972
Disposable Airflow Sensor

Child
Model 974
Disposable Airflow Sensor

Infant
Model 976
Disposable Airflow Sensor

Premie
Model 978
Disposable Airflow Sensor



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(b)(4) Confidential and Proprietary Information

[redacted]