

K963597



JAN 23 1997

**Local Silence, Inc.****510(k) SUMMARY**

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

**Submitter's Name:** Local Silence, Inc.  
935 Fremont Avenue, Suite 115  
Los Altos, CA 94024 USA  
Telephone: (415) 917-9130  
**Contact Person:** Anthony Matouk, President

**Date of Summary:** January 21, 1997

**Device Name:** Silent Night I

**Device Classification:** Ventilatory Effort Recorder (73 MNR)

**Legally Marketed Device to Which Equivalence is Claimed:** The legally marketed predicate device is the EdenTec Model 3711 Digital Recorder (K910870), determined to be substantially equivalent to a legally marketed (preAmendment) device on August 29, 1991. The Silent Night I has been evaluated in the clinical setting in comparison to the Grass Model 7P511 High Performance AC Amplifier, a standard polysomnograph recording device.

**Device Description:** The Silent Night I (SNI) consists of a metal box measuring approximately 23 centimeters wide by 17 centimeters deep by 7.5 centimeters high. The device is portable, line-powered and weighs approximately three pounds. The box contains the operational components of the device and has two receptacle connectors: one for input power and another for the sensing microphone. This microphone is attached to the SNI by means of an eight-foot flexible cable and connector. Another microphone is built into the rear of the box and senses room ambient noise. A POWER switch is located on the back of the unit. A switch enabling the user to PAUSE and RESUME device operation is located on the side of the unit.

The device operates as follows: the sound field (breathing sounds + room ambient noise) is sensed by the two microphones and sent to the controller, which extracts breathing sounds from all sounds received. These signals are then sent through bandpass filters and the amplitude characteristics of the signals in the frequency realm are analyzed. The signals are then processed by the pattern recognizer, which differentiates between types of sounds and classifies them as regular snoring or breathing, hypopnea, or apnea. These classified events are logged cumulatively and shown on a liquid crystal display as Disordered Breathing Events (DBE) on the front control panel of the device.

**Intended Use:** The Silent Night I is indicated for use in the diagnostic evaluation of adults with possible Obstructive Sleep Apnea. It is intended to record a patient's respiratory pattern. The device is designed for use in home screening of adults with possible sleep disorders.

The legally marketed EdenTec Model 3711 Digital Recorder is intended to record physiologic data, including heart rate, impedance respiration, snoring sounds, air flow, body position and pulse oximetry in the home or in the hospital, and may be used on pediatric or adult patients. The device also provides a printout of recorded data.

The Grass Model 7P511 High Performance AC Amplifier is intended to record bioelectric signals such as the electroencephalograph, electrooculograph, electromyograph, electrocardiograph, and respiration.

The intended use of the Silent Night I is a subset of the intended use of the EdenTec Model 3711 Digital Recorder, as the Silent Night I records and analyzes only respiratory sounds, is intended for use only in adults, is designed for use in the home, and does not contain printing capability. The intended use of the Silent Night I is also a subset of the intended use of the Grass Model 7P511 High Performance AC Amplifier, as the Silent Night I records and analyzes only respiratory sounds, rather than a variety of physiologic signals.

**Descriptive Summary of Technological Characteristics and Those Of Predicate Device:** The Silent Night I is a portable, line-powered device which records and analyzes breathing sounds. The device components are housed in a metal box, which contains the hardware and software required for device function. The Silent Night I employs two microphones. One microphone, placed near the patient, is attached to the SNI by means of a cable and is used to sense the patient's respiratory sounds. Another microphone is built into the rear of the box and senses room ambient noise.

The legally marketed EdenTec Model 3711 Digital Recorder is intended to record physiologic data, including heart rate, impedance respiration, snoring sounds, air flow, body position and pulse oximetry. Device hardware and software are contained in a portable enclosure. Respiratory sounds are sensed by a microphone placed near the patient. The power source is a battery charger plugged into a 3-prong 120 VAC wall outlet.

The Grass Model 7P511 High Performance AC Amplifier is intended to record bioelectric signals such as the electroencephalograph, electrooculograph, electromyograph and electrocardiograph. The product is also used for amplifying respiratory signals from devices such as thermocouples and pneumographs, and breathing sounds detected by microphones. It is a high gain, low noise AC preamplifier and polygraph pen driver amplifier in a single 19-inch module. The amplifier has nine low frequency filter selections and ten high frequency filter selections. A rear chassis connector is provided for connection to the Grass Electrode Selector Panels.

**Performance Data:**

*Environmental:* The Silent Night I (SNI) was subjected to mechanical, environmental and electromagnetic compatibility testing in accordance with the requirements of applicable standards. All test units passed visual inspection and electrical characterization, and exhibited proper operation following all mechanical and environmental test sequences. The test results demonstrate that the Silent Night I possesses a degree of mechanical integrity and durability suitable for its intended-use environment. In addition, the Silent Night I passed all electromagnetic compatibility tests without failure. The test results demonstrate that the Silent Night I operates in compliance with appropriate emissions limits and possesses a degree of immunity to the effects of electromagnetic interference adequate for operation in its intended-use environment.

*Electrical Safety:* Electrical safety test data were obtained in conjunction with testing required for UL (Underwriters' Laboratories) listing. The Silent Night I demonstrated acceptable design and/or performance characteristics for all electrical safety parameters evaluated.

*Clinical:* The Silent Night I has been evaluated in the clinical setting. Patients were subjected to sleep laboratory evaluation with a standard polysomnograph (the Grass Model 7P511 High Performance AC Amplifier) and the additional use of the Silent Night I. The number of Disordered Breathing Events (DBE) and resulting Respiratory Disturbance Index (RDI) calculated by the Silent Night I were compared with data gathered simultaneously on these parameters by the Grass polysomnograph.

Statistical analysis of the test results indicated a high positive correlation between the measurements obtained by the two devices. Further analysis indicated that the measurements are not independent: there is a strong positive linear association between the measurements obtained from the two devices. Additional analysis indicated a high degree of both specificity and sensitivity.

The study results establish the efficacy of the Silent Night I in detecting Disordered Breathing Events, which can be indicative of sleep apnea or another sleep disorder. In view of the noninvasive, non-patient contact design and simple operational features of the device, the Silent Night I offers potential benefit as a cost-effective home-use device for the screening of patients with possible sleep disorders.

  
Lisa S. Jones  
Regulatory Affairs Consultant  
Local Silence, Inc.

  
Date



**Local Silence, Inc.**

January 21, 1997

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

**510(k) Amendment**  
**K963597**  
Silent Night™ I

FOA/CDRH/ODE/DHO

21 JAN 97 10 24

RECEIVED

K963597/A1

Dear Sir or Madam:

This amendment to the above-referenced 510(k) Notification is submitted in response to a telephone conversation held on January 17 between Ms. Christy Foreman, scientific reviewer in the Division of Cardiovascular, Respiratory and Neurological Devices, and Ms. Lisa Jones, regulatory affairs consultant for Local Silence, Inc.

As requested, Local Silence hereby provides a revised statement of indications for use and a revised 510(k) Summary.

Please contact the undersigned at (713) 664-6775 if further information is required.

Sincerely,

  
Lisa S. Jones, RAC  
Regulatory Affairs Consultant  
Local Silence, Inc.

SP-15

January 21, 1997

Page 1 of 1

510(k) Number: K963597

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\_\_\_\_\_  
(Concurrence of CDRH, Office of Device Evaluation (ODE))

Christy Jansen  
(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
510(k) Number K963597

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-the-Counter Use



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## Performance Data:

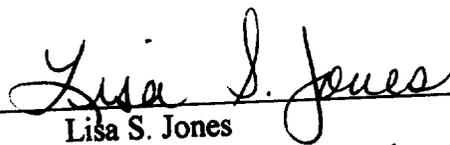
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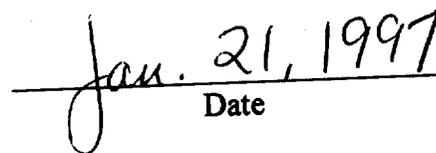
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Lisa S. Jones  
Regulatory Affairs Consultant  
Local Silence, Inc.

  
Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN 23 1997

Ms. Lisa S. Jones, RAC  
Local Silence, Inc.  
935 Fremont Avenue, Suite 115  
Los Altos, California 94024

Re: K963597  
Silent Night™ I  
Regulatory Class: II (two)  
Product Code: 73 MNR  
Dated: December 13, 1996  
Received: December 13, 1996

Dear Ms. Jones:

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 (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market 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. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21.CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, 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 sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Ms. Lisa S. Jones, RAC

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,



Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular,  
Respiratory, and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



January 21, 1997

Page 1 of 1

510(k) Number: K963597

Device Name: Silent Night I

Indications for Use: The Silent Night I is indicated for use in the diagnostic evaluation of adults with possible Obstructive Sleep Apnea. It is intended to record a patient's respiratory pattern. The device is designed for use in home screening of adults with possible sleep disorders.

(Concurrence of CDRH, Office of Device Evaluation (ODE))

Christy Lowman  
(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
510(k) Number K963597

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-the-Counter Use

3



Memorandum

1/16/97

From: Reviewer(s) - Name(s) Christy Foreman

Subject: 510(k) Number K963597 / s<sup>1</sup>

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Accepted for review \_\_\_\_\_
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Postmarket Surveillance?  YES  NO
- Is this device subject to the Tracking Regulation?  YES  NO
- Was clinical data necessary to support the review of this 510(k)?  YES  NO
- Is this a prescription device?  YES  NO
- Was this 510(k) reviewed by a Third Party?  YES  NO

This 510(k) contains:

- Truthful and Accurate Statement  Requested  Enclosed  
(required for originals received 3-14-95 and after)
- A 510(k) summary OR  A 510(k) statement
- The required certification and summary for class III devices *N/A*
- The indication for use form (required for originals received 1-1-96 and after)

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

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

Predicate Product Code with panel and class: 808.2375 Class II (two) Additional Product Code(s) with panel (optional):

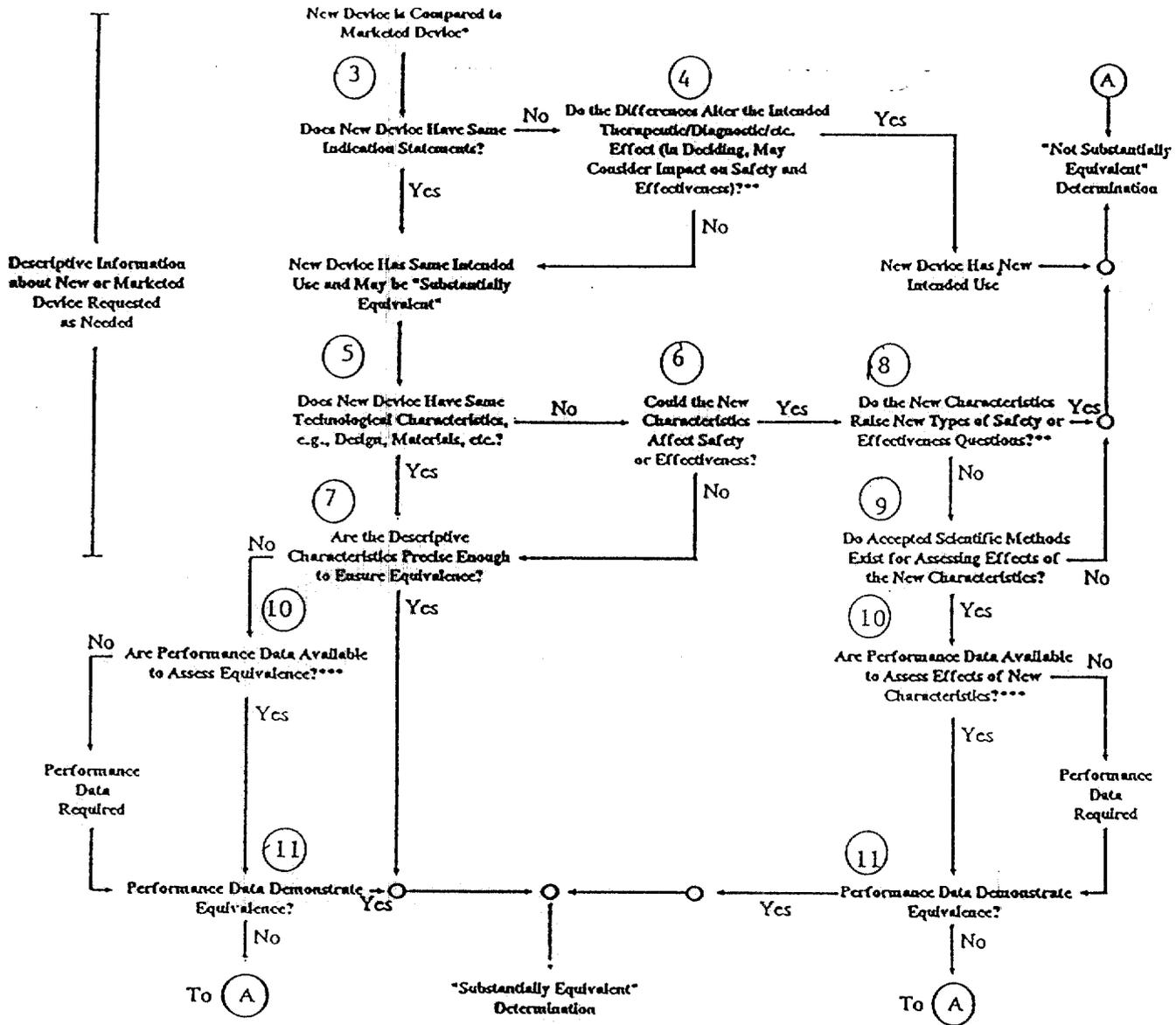
73 MNR Ventilatory Effort Recorder

Review: JAWentershaus ADDG 1-23-97  
(Branch Chief) (Branch Code) (Date)

Final Review: Richard Phillips 1-23-97  
(Division Director) (Date)

4

## 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.

Food and Drug Administration  
Office of Device Evaluation  
9200 Corporate Boulevard  
Rockville, MD 20850

**Premarket Notification [510(k)] Review**

**K963597**

Date: January 16, 1997

To: The Record  
From: Christy Foreman, Biomedical Engineer

Office: HFZ-450  
Division: DCRND/ADDG

Company Name: Local Silence, Inc  
Device Name: Silent Night I Adult Apnea Detector  
Contact: Lisa Jones Ph (713) 664-6775 Fax (713) 664-6070

**I. Purpose**

Local Silence, Inc. intends to introduce a new apnea detector into interstate commerce.

**II. Device Description**

**A. Intended Use/Indications for Use**

This device is intended for use in the diagnostic evaluation of adults with possible OSA. It is intended to monitor a patient's respiratory rate. The device is designed for use in home screening of adults with possible sleep orders.

**B. Summary**

Life-supporting or life-sustaining?	No
Implant?	No
Sterile?	No
Single use?	No
Prescription use?	Yes
Home use or portable?	Yes
Drug or biological combination product?	No
Kit?	No
Software driven?	Yes
Electrically Operated?	Yes

**C. Materials/Biocompatibility**

There are no patient contacting materials that would require biocompatibility information.

**D. Design/Specifications**

The Silent Night I consists of a metal box measuring approximately 23 centimeters wide by 17

centimeters deep by 7.5 centimeters high. The device is portable, line-powered and weighs approximately three pounds. The box contains the operational components of the device and has two receptacle connectors: one for input power and another for the sensing microphone. This microphone is attached to the SNI by means of an eight foot flexible cable and connector. Another microphone is built into the rear of the device and senses ambient room noise. A power switch is located on the back of the unit, and a switch enabling the user to pause and resume device operation is located on the side of the unit.

The device operates as follows: the sound field (breathing sounds + room ambient noise) is sensed by the two microphones and sent to the controller which extracts breathing sounds from all sounds received. These signals are then sent through bandpass filters and the amplitude characteristics of the signals in the frequency realm are analyzed. The signals are then processed by the pattern recognizer, which differentiates between types of sounds and classifies them as regular snoring or breathing, hypopnea, or apnea. These classified events are logged as cumulatively and shown on a LCD as Disordered Breathing Events (DBE) on the front control panel of the device.

**E. Sterilization**

N/A

**F. Labeling**

Outer package labels, device labels, promotional claims, a physician's manual and a patient manual were provided. This device is considered a prescription device and is labeled accordingly.

**G. Performance Testing**

The performance of this device was tested with recorded breathing events. The device's score was compared to an evaluator's score of the same information. The device performed well when compared to manual scoring.

**H. Clinical Testing**

A clinical trial was conducted with (b) subjects. The performance of the Silent Night I was compared to a Grass polysomnograph capable of recording DBEs. The statistical analysis of (b) subjects demonstrated a high positive correlation between the measurements. The complete details are contained in Section 5C.

**I. Software**

Version: (b)(4)  
Level of Concern: Minor

(b)(4)

(b)(4)

Refer to Section 9 and the additional information that was provided for detailed descriptions of the process.

**J. Environmental Testing**

The device successfully passed all environmental testing, refer to the referenced sections of the submission for specific details.

1. **Electrical Safety** - Provided in additional information.

2. **EMC** - Sections 7C and 7D

3. **Mechanical** - Sections 7A and 7B

**K. Certifications/Statements/Standards Met**

Summary of Safety and Effectiveness	-	page 14
Truthful and Accurate Statement	-	page 12
Indications for Use	-	page 1

**L. Predicate Devices**

EdenTec Model 3711 Digital Recorder K910870  
Grass Model 7P511 High Performance Amplifier

**III. Correspondence**

On December 4, 1996 Lisa Jones was informed that this submission would be placed on phone hold for electrical safety testing and software test results.

**RESPONSE:**

The company provided information that satisfactorily answered the above questions.

**IV. Substantial Equivalence**

There are no new types of safety and effectiveness questions with this device.

**V. Recommendation**

I believe that this device is substantially equivalent to:

**73 MNR            Ventilatory Effort Recorder**

Classification should be based on:

**868.2375            Class II (two)**

*Christy Foreman 1/17/97*  
Christy Foreman

*JAW*

*8*

# Devices for the Future, L.L.C.

Engineering and Regulatory Affairs Consulting Services

9223 Ilona Lane • Houston, TX 77025-4218  
Phone: (713) 664-6775 • Fax: (713) 664-6070  
E-mail: dftf@icsi.net

### FAX TRANSMISSION

DATE: 20 Jan 1997

TO: Christy Foreman  
FDA-CDRH-ODE-DCRND

FAX NUMBER:

FROM: Lisa Jones, Reg. Aff. Consultant, Local  
NUMBER OF PAGES IN THIS TRANSMISSION: 5  
Silence

MESSAGE:

Here is the information  
you requested.

Hard copy sent from my office  
today; should arrive at  
Document Mail tomorrow.

Best regards,  
Lisa



9

January 21, 1997

Page 1 of 1

510(k) Number: K963597

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The intended use of the Silent Night I is a subset of the intended use of the EdenTec Model 3711 Digital Recorder, as the Silent Night I records and analyzes only respiratory sounds, is intended for use only in adults, is designed for use in the home, and does not contain printing capability. The intended use of the Silent Night I is also a subset of the intended use of the Grass Model 7P511 High Performance AC Amplifier, as the Silent Night I records and analyzes only respiratory sounds, rather than a variety of physiologic signals.

**Descriptive Summary of Technological Characteristics and Those Of Predicate Device:** The Silent Night I is a portable, line-powered device which records and analyzes breathing sounds. The device components are housed in a metal box, which contains the hardware and software required for device function. The Silent Night I employs two microphones. One microphone, placed near the patient, is attached to the SNI by means of a cable and is used to sense the patient's respiratory sounds. Another microphone is built into the rear of the box and senses room ambient noise.

The legally marketed EdenTec Model 3711 Digital Recorder is intended to record physiologic data, including heart rate, impedance respiration, snoring sounds, air flow, body position and pulse oximetry. Device hardware and software are contained in a portable enclosure. Respiratory sounds are sensed by a microphone placed near the patient. The power source is a battery charger plugged into a 3-prong 120 VAC wall outlet.

The Grass Model 7P511 High Performance AC Amplifier is intended to record bioelectric signals such as the electroencephalograph, electrooculograph, electromyograph and electrocardiograph. The product is also used for amplifying respiratory signals from devices such as thermocouples and pneumographs, and breathing sounds detected by microphones. It is a high gain, low noise AC preamplifier and polygraph pen driver amplifier in a single 19-inch module. The amplifier has nine low frequency filter selections and ten high frequency filter selections. A rear chassis connector is provided for connection to the Grass Electrode Selector Panels.

**Performance Data:**

*Environmental:* The Silent Night I (SNI) was subjected to mechanical, environmental and electromagnetic compatibility testing in accordance with the requirements of applicable standards. All test units passed visual inspection and electrical characterization, and exhibited proper operation following all mechanical and environmental test sequences. The test results demonstrate that the Silent Night I possesses a degree of mechanical integrity and durability suitable for its intended-use environment. In addition, the Silent Night I passed all electromagnetic compatibility tests without failure. The test results demonstrate that the Silent Night I operates in compliance with appropriate emissions limits and possesses a degree of immunity to the effects of electromagnetic interference adequate for operation in its intended-use environment.

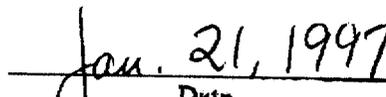
*Electrical Safety:* Electrical safety test data were obtained in conjunction with testing required for UL (Underwriters' Laboratories) listing. The Silent Night I demonstrated acceptable design and/or performance characteristics for all electrical safety parameters evaluated.

*Clinical:* The Silent Night I has been evaluated in the clinical setting. Patients were subjected to sleep laboratory evaluation with a standard polysomnograph (the Grass Model 7P511 High Performance AC Amplifier) and the additional use of the Silent Night I. The number of Disordered Breathing Events (DBE) and resulting Respiratory Disturbance Index (RDI) calculated by the Silent Night I were compared with data gathered simultaneously on these parameters by the Grass polysomnograph.

Statistical analysis of the test results indicated a high positive correlation between the measurements obtained by the two devices. Further analysis indicated that the measurements are not independent: there is a strong positive linear association between the measurements obtained from the two devices. Additional analysis indicated a high degree of both specificity and sensitivity.

The study results establish the efficacy of the Silent Night I in detecting Disordered Breathing Events, which can be indicative of sleep apnea or another sleep disorder. In view of the noninvasive, non-patient contact design and simple operational features of the device, the Silent Night I offers potential benefit as a cost-effective home-use device for the screening of patients with possible sleep disorders.

  
Lisa S. Jones  
Regulatory Affairs Consultant  
Local Silence, Inc.

  
Date

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

December 13, 1996

LOCAL SILENCE, INC.  
935 FREMONT AVENUE, SUITE 115  
LOS ALTOS, CA 94024  
ATTN: TONY MATOUK

510(k) Number: K963597  
Product: SILENT NIGHT I

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 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) 594-1190.

Sincerely yours,

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

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K963597/S'



**Local Silence, Inc.**

RECEIVED

December 13, 1996

13 Dec 96 10 30

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

FDA/CDRH/ODE/DMC

**510(k) Amendment**  
**K963597**  
**Silent Night™ I**

Dear Sir or Madam:

This amendment to the above-referenced 510(k) Notification is submitted in response to telephone conversations held on December 3 and 5 between Ms. Christy Foreman, scientific reviewer in the Division of Cardiovascular, Respiratory and Neurological Devices, and Ms. Lisa Jones, regulatory affairs consultant for Local Silence, Inc. FDA's questions are listed below in bold type; Local Silence's responses follow.

(b)(4)



Please contact the undersigned at (713) 664-6775 if further information is required.

Sincerely,

Lisa S. Jones, RAC  
Regulatory Affairs Consultant  
Local Silence, Inc.

St-6

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

December 06, 1996

LOCAL SILENCE, INC.  
935 FREMONT AVENUE, SUITE 115  
LOS ALTOS, CA 94024  
ATTN: TONY MATOUK

510(k) Number: K963597  
Product: SILENT NIGHT I

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefax material as part of your official premarket notification submission unless specifically requested of you by an FDA official.

If after 30 days the requested information, or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

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

Sincerely yours,

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

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Memorandum

12/5/94

From: Reviewer(s) - Name(s) Christy Foreman

Subject: 510(k) Number K963597

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Is substantially equivalent to marketed devices.
- Requires premarket approval. NOT substantially equivalent to marketed devices.
- Requires more data. Phone Hold JAW.
- Accepted for review \_\_\_\_\_  
(date)
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- |   |                              |                             |
|---|------------------------------|-----------------------------|
| Is this device subject to Postmarket Surveillance?                | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| Is this device subject to the Tracking Regulation?                | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| Was clinical data necessary to support the review of this 510(k)? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| Is this a prescription device?                                    | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| Was this 510(k) reviewed by a Third Party?                        | <input type="checkbox"/> YES | <input type="checkbox"/> NO |

his 510(k) contains:

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

- A 510(k) summary OR  A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form (required for originals received 1-1-96 and after)

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

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

Predicate Product Code with panel and class: \_\_\_\_\_ Additional Product Code(s) with panel (optional): \_\_\_\_\_

Review: \_\_\_\_\_  
(Branch Chief) (Branch Code) (Date)

Final Review: \_\_\_\_\_  
(Division Director) (Date)

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Food and Drug Administration  
Office of Device Evaluation  
9200 Corporate Boulevard  
Rockville, MD 20850

**Premarket Notification [510(k)] Review**

**K963597**

Date: December 3, 1996

To: The Record  
From: Christy Foreman, Biomedical Engineer

Office: HFZ-450  
Division: DCRND/ADDG

Company Name: Local Silence, Inc  
Device Name: Silent Night I Adult Apnea Detector  
Contact: Lisa Jones Ph (713) 664-6775 Fax (713) 664-6070

**I. Purpose**

Local Silence, Inc. intends to introduce a new apnea detector into interstate commerce.

**II. Device Description**

**A. Intended Use/Indications for Use**

This device is intended for use in the diagnostic evaluation of adults with possible OSA. It is intended to monitor a patient's respiratory rate. The device is designed for use in home screening of adults with possible sleep disorders.

**B. Summary**

Life-supporting or life-sustaining?	No
Implant?	No
Sterile?	No
Single use?	No
Prescription use?	Yes
Home use or portable?	Yes
Drug or biological combination product?	No
Kit?	No
Software driven?	Yes
Electrically Operated?	Yes

**C. Materials/Biocompatibility**

There are no patient contacting materials that would require biocompatibility information.

**D. Design/Specifications**

The Silent Night I consists of a metal box measuring approximately 23 centimeters wide by 17

centimeters deep by 7.5 centimeters high. The device is portable, line-powered and weighs approximately three pounds. The box contains the operational components of the device and has two receptacle connectors: one for input power and another for the sensing microphone. This microphone is attached to the SNI by means of an eight foot flexible cable and connector. Another microphone is built into the rear of the device and senses ambient room noise. A power switch is located on the back of the unit, and a switch enabling the user to pause and resume device operation is located on the side of the unit.

The device operates as follows: the sound field (breathing sounds + room ambient noise) is sensed by the two microphones and sent to the controller which extracts breathing sounds from all sounds received. These signals are then sent through bandpass filters and the amplitude characteristics of the signals in the frequency realm are analyzed. The signals are then processed by the pattern recognizer, which differentiates between types of sounds and classifies them as regular snoring or breathing, hypopnea, or apnea. These classified events are logged as cumulatively and shown on a LCD as Disordered Breathing Events (DBE) on the front control panel of the device.

**E. Sterilization**

N/A

**F. Labeling**

Outer package labels, device labels, promotional claims, a physician's manual and a patient manual were provided. This device is considered a prescription device and is labeled accordingly.

**G. Performance Testing**

**H. Clinical Testing**

A clinical trial was conducted with (b) subjects. The performance of the Silent Night I was compared to a Grass polysomnograph capable of recording DBEs. The statistical analysis on (b)(4) subjects demonstrated a high positive correlation between the measurements. The complete details are contained in Section 5C.

**I. Software**

**Version:**

**Level of Concern: Minor**

**J. Environmental Testing**

1. **Electrical Safety** - Requested
2. **EMC** - Sections 7C and 7D
3. **Mechanical** - Sections 7A and 7B

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**K. Certifications/Statements/Standards Met**

Summary of Safety and Effectiveness - page 14  
Truthful and Accurate Statement - page 12  
Indications for Use - page 1

**L. Predicate Devices**

EdenTec Model 3711 Digital Recorder K910870  
Grass Model 7P511 High Performance Amplifier

**III. Correspondence**

On December 4, 1996 Lisa Jones was informed that this submission would be placed on phone hold for electrical safety testing and software test results.

**IV. Substantial Equivalence**

**V. Recommendation**

I believe that additional information is required to determine substantial equivalence

Christy Foreman 12/4/96  
Christy Foreman

JAW 12.5.96

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## DCRND Screening Checklist for Premarket Notification 510(k)

Device: <u>Silent Night I</u>	K 963597		
Submitter: <u>Local Science, Inc.</u>			
Items which should be Included <i>(circle missing &amp; needed information)</i>	✓		✓ if Item Needed & MISSING
	Yes	No	
1. General information: a) trade name, b) common name, c) establishment registration #, d) address of manufacturer, e) device class, f) new or modification, g) predicate device identified, h) 513/514 compliance (none yet available), i) Truth and Accuracy Statement, j) Indications for Use Statement (separate sheet)	✓		
2. SMDA requirements: 510(k) summary or statement (any Class device)	✓		
Class III Certification & Summary (if Class III)	N/A		
3. Proposed Labeling: a) package labels, b) statement of intended use, c) advertisements or promotional materials, d) MRI compatibility (if claimed)	✓		
4. Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals	✓		
5. Comparison Information (similarities and differences) to named legally marketed/equivalent device (table preferred) should include: a) labeling, b) intended use, c) physical characteristics, d) anatomical sites, f) performance (bench, animal, clinical) testing, g) safety characteristics	✓		
6. Biocompatibility data for all patient-contacting materials, OR, certification of identical material/formulation: a) component & material, b) identify patient-contacting materials, c) biocompatibility of final sterilized product	N/A		
7. Sterilization and expiration dating information: a) sterilization method, b) SAL, c) packaging, d) specify pyrogen free, e) ETO residues, f) radiation dose	N/A		
8. Software validation & verification: a) hazard analysis, b) level of concern, c) development documentation, d) certification	✓		
9. Meets current DCRND guidelines and applicable standards for this device: a) specify guidance, b) comply with content	✓		

*Items shaded under "No" are necessary for all submissions. Circled items and items with checks in the "Needed & MISSING" column must be submitted before acceptance of the 510k application.*

1 Screening:  Yes  No

Reviewer: Senora Smallwood

Date: 9/13/96

**For DCRND Use Only**

**DCRND Classification Checklist  
for Premarket Notification 510(k)**

Device: <i>Silent Night I</i>	K 963597	
Submitter: <i>Local Science, Inc.</i>		
Date received: Original 510(k): <i>9-Sept-96</i> This submission: <i>9-Sept-96</i>	Review cycle <b>1</b>	
Review Tier (circle one): I, II, III <i>(for Tier I, complete items 1-5 on the Screening Checklist)</i>		
Question	Yes	No
A. Is the product a device?	X	
B. Is the device exempt from 510(k) by regulation or policy?		X
C. Expedited Review Status: Requested by sponsor		X
Identified by DCRND		X
Granted by DCRND		
D. Has this device has been the subject of a previous NSE decision?		
If yes, does this new 510(k) address the NSE Issues(s), e.g., performance data?		
E. Has the sponsor been the subject of an integrity investigation?		
If yes, has the ODE Integrity Officer given permission to proceed with the review?		

Administrative Reviewer Signature: *Senora Smallwood* Date: *9/13/96*  
Senora Smallwood

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PREMARKET NOTIFICATION (510(K)) CHECKLIST FOR ACCEPTANCE DECISION

Device Name \_\_\_\_\_

Division/Branch \_\_\_\_\_

Administrative Reviewer Signature \_\_\_\_\_ Date \_\_\_\_\_

Supervisory Signature \_\_\_\_\_ Date \_\_\_\_\_

Did the firm request expedited review? \_\_\_\_\_ Yes \_\_\_\_\_ No

Did we grant expedited review? \_\_\_\_\_ Yes \_\_\_\_\_ No

Truthful and accurate statement enclosed? \_\_\_\_\_ Yes \_\_\_\_\_ No

(If Not Enclosed, Must Be A Refuse To Accept Letter)

Required For Originals Received 3/14/95 And After

Is the Indication for Use Form enclosed? \_\_\_\_\_ YES \_\_\_\_\_ No

(Required for Original 510(k)s received 1/1/96 and after --

must be submitted on a separate sheet of paper)

Without reviewing this 510(k), do you believe this device type may be a preamendments class III device? \_\_\_\_\_ Yes \_\_\_\_\_ No (IF YES, NOTIFY POS IMMEDIATELY IF THE OUTSIDE OF THE 510(k) HAS NOT BEEN STAMPED CLASS III SO THAT THE GMP INSPECTION CAN BE SCHEDULED AS SOON AS POSSIBLE). Class III devices can not receive a determination of substantial equivalence until the GMP inspection process has been completed.

Is this a file that was determined to be substantially equivalent by ODE, but placed on hold due to GMP violations and deleted after 12 months on hold? -- If so, a new ODE review is not required, please forward to POS.

\_\_\_\_\_ Yes \_\_\_\_\_ No

\_\_\_\_\_  
Accepted

\_\_\_\_\_  
Refuse To  
Accept

I. CRITICAL ELEMENTS:	YES PRESENT OMISSION JUSTIFIED	NO INADEQUATE OMITTED
A. Is The Product A Device?	<input type="checkbox"/>	<input type="checkbox"/>
B. Is The Device Exempt From 510(k) By Regulation Or Policy?	<input type="checkbox"/>	<input type="checkbox"/>
C. Is Device Subject To Review By CDRH?	<input type="checkbox"/>	<input type="checkbox"/>
D. (i) Are You Aware That This Device Has Been The Subject Of A Previous NSE Decision?  (ii) If Yes, Does This New 510(k) Address The NSE Issue(s) (E.G., Performance Data)?	<input type="checkbox"/>	<input type="checkbox"/>
E. (i) Are You Aware Of The Submitter Being The Subject Of An Integrity Investigation?  If Yes, Consult The ODE Integrity Officer.  (ii) Has The ODE Integrity Officer Given Permission To Proceed With The Review? (Blue Book Memo #I91-2 And Federal Register 90N-0332, September 10, 1991.)	<input type="checkbox"/>	<input type="checkbox"/>
F. Does The Submission Contain The Information Required Under Sections 510(k), 513(f), And 513(i) Of The Federal Food, Drug, and Cosmetic Act (Act) And Subpart E Of Part 807 In Title 21 Of The Code Of Federal Regulations?:	<input type="checkbox"/>	<input type="checkbox"/>
1. Device Trade Or Proprietary Name	<input type="checkbox"/>	<input type="checkbox"/>
2. Device Common Or Usual Name Or Classification Name	<input type="checkbox"/>	<input type="checkbox"/>
3. Establishment Registration Number (Only Applies If Establishment Is Registered)	<input type="checkbox"/>	<input type="checkbox"/>
4. Class Into Which The Device Is Classified Under (21 CFR Parts 862 To 892)	<input type="checkbox"/>	<input type="checkbox"/>
5. Classification Panel	<input type="checkbox"/>	<input type="checkbox"/>
6. Action Taken To Comply With Section 514 Of The Act	<input type="checkbox"/>	<input type="checkbox"/>
7. Proposed Labels, Labeling And Advertisements (If Available) That Describe The Device, Its Intended Use, And Directions For Use (Blue Book Memo #G91-1)	<input type="checkbox"/>	<input type="checkbox"/>

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8. A 510(k) Summary Of Safety And Effectiveness Or A 510(k) Statement That Safety And Effectiveness Information Will Be Made Available To Any Person Upon Request	<input type="checkbox"/>	<input type="checkbox"/>
9. For Class III Devices Only, A Class III Certification And A Class III Summary	<input type="checkbox"/>	<input type="checkbox"/>
10. Photographs Of The Device	<input type="checkbox"/>	<input type="checkbox"/>
11. Engineering Drawings For The Device With Dimensions And Tolerances	<input type="checkbox"/>	<input type="checkbox"/>
12. The Marketed Device(s) To Which Equivalence Is Claimed Including Labeling And Description Of The Device	<input type="checkbox"/>	<input type="checkbox"/>
13. Statement Of Similarities And/Or Differences With Marketed Device(s)	<input type="checkbox"/>	<input type="checkbox"/>
14. Data To Show Consequences And Effects Of A Modified Device(s)	<input type="checkbox"/>	<input type="checkbox"/>
15. Truthful And Accurate Statement	<input type="checkbox"/>	<input type="checkbox"/>
II. Additional Information That <u>Is</u> Necessary Under 21 CFR 807.87(h) :	<input type="checkbox"/>	<input type="checkbox"/>
A. Submitter's Name And Address	<input type="checkbox"/>	<input type="checkbox"/>
B. Contact Person, Telephone Number And Fax Number	<input type="checkbox"/>	<input type="checkbox"/>
C. Representative/Consultant If Applicable	<input type="checkbox"/>	<input type="checkbox"/>
D. Table Of Contents With Pagination	<input type="checkbox"/>	<input type="checkbox"/>
E. Address Of Manufacturing Facility/Facilities And, If Appropriate, Sterilization Site(s)	<input type="checkbox"/>	<input type="checkbox"/>
III. Additional Information That <u>May Be</u> Necessary Under 21 CFR 807.87(h) :	<input type="checkbox"/>	<input type="checkbox"/>
A. Comparison Table Of The New Device To The Marketed Device(s)	<input type="checkbox"/>	<input type="checkbox"/>
B. Action Taken To Comply With Voluntary Standards	<input type="checkbox"/>	<input type="checkbox"/>
C. Performance Data	<input type="checkbox"/>	<input type="checkbox"/>
MARKETED DEVICE:	<input type="checkbox"/>	<input type="checkbox"/>
Bench Testing	<input type="checkbox"/>	<input type="checkbox"/>
Animal Testing	<input type="checkbox"/>	<input type="checkbox"/>
Clinical Data	<input type="checkbox"/>	<input type="checkbox"/>
NEW DEVICE:	<input type="checkbox"/>	<input type="checkbox"/>
Bench Testing	<input type="checkbox"/>	<input type="checkbox"/>
Animal Testing	<input type="checkbox"/>	<input type="checkbox"/>

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Clinical Data	<input type="checkbox"/>	<input type="checkbox"/>
D. Sterilization Information	<input type="checkbox"/>	<input type="checkbox"/>
E. Software Information	<input type="checkbox"/>	<input type="checkbox"/>
Hardware Information	<input type="checkbox"/>	<input type="checkbox"/>
G. If This 510(k) Is For A Kit, Has The Kit Certification Statement Been Provided?	<input type="checkbox"/>	<input type="checkbox"/>
H. Is This Device Subject To Issues That Have Been Addressed In Specific Guidance Document(s)?	<input type="checkbox"/>	<input type="checkbox"/>
If Yes, Continue Review With Checklist From Any Appropriate Guidance Documents.	<input type="checkbox"/>	<input type="checkbox"/>
If No, Is 510(k) Sufficiently Complete To Allow Substantive Review?	<input type="checkbox"/>	<input type="checkbox"/>
I. Other (Specify)	<input type="checkbox"/>	<input type="checkbox"/>

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THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENC" (SE) DECISION MAKING DOCUMENTATION

K \_\_\_\_\_

Reviewer: \_\_\_\_\_

Division/Branch: \_\_\_\_\_

Device Name: \_\_\_\_\_

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

YES NO

	YES	NO	
1. Is Product A Device			If NO = Stop
2. Is Device Subject To 510(k)?			If NO = Stop
3. Same Indication Statement?			If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?			If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?			If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?			If NO Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use:
2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:  
  
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

4a

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

September 10, 1996

LOCAL SILENCE, INC.  
935 FREMONT AVENUE, SUITE 115  
LOS ALTOS, CA 94024  
ATTN: TONY MATOUK

510(k) Number: K963597  
Received: 09-SEP-96  
Product: SILENT NIGHT I

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

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522 (a) (1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance at the number below for more information.

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. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

If you have procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or call me at (301) 594-1190.

Sincerely yours,

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

MD

K963597



Local Silence, Inc.

FEDERAL EXPRESS

September 9, 1996

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

RECEIVED  
9 SEP 96 14 09  
FDA/CDRH/ODE/DNC

510(k) Notification  
Silent Night™ I

Dear Sir or Madam:

Enclosed is the 510(k) Notification for the Silent Night I, the first in a series of ventilatory effort monitors manufactured for Local Silence, Inc.

This 510(k) Notification follows the recommended format and content of the "Draft Guidance for Format and Content for PreMarket Notification (510(k)) Submissions" issued by the Division of Cardiovascular, Respiratory and Neurological Devices, December 6, 1994.

Please contact this office if further information is required.

Sincerely,

Tony Matouk, President  
Local Silence, Inc.

Lisa S. Jones, RAC  
Regulatory Affairs Consultant

AN  
H

September 9, 1996

Page 1 of 1

510(k) Number: K963597

Device Name: Silent Night I

**Indications for Use:** The Silent Night I is indicated for use in the diagnostic evaluation of adults with possible Obstructive Sleep Apnea. It is intended to measure or monitor a patient's respiratory rate. The device is designed for use in home screening of adults with possible sleep disorders.

**(Division Sign-Off)**  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
510(k) Number K963597

✓

**CENTER FOR DEVICES AND RADIOLOGICAL HEALTH**  
**Premarket Submission Cover Sheet**

Date of Submission: September 9, 1996

FDA Document Number:

**Section A**

**Type of Submission**

- |   |   |  |  |
|---|---|--|--|
| <input checked="" type="checkbox"/> 510(k)        | <input type="checkbox"/> IDE            | <input type="checkbox"/> PMA           | <input type="checkbox"/> PMA Supplement- Regular     |
| <input type="checkbox"/> 510(k) Add'l information | <input type="checkbox"/> IDE Amendment  | <input type="checkbox"/> PMA Amendment | <input type="checkbox"/> PMA Supplement- Special     |
|   | <input type="checkbox"/> IDE Supplement | <input type="checkbox"/> PMA Report    | <input type="checkbox"/> PMA Supplement- 30 day      |
|   | <input type="checkbox"/> IDE Report     |  | <input type="checkbox"/> PMA Supplement- Panel Track |

**Section B1**

**Reason for Submission -- 510(k)s Only**

- |  |   |  |
|--|---|--|
| <input checked="" type="checkbox"/> New device   | <input type="checkbox"/> Additional or expanded indications | <input type="checkbox"/> Change in technology, design, materials, or manufacturing process |
| <input type="checkbox"/> Other reason (specify): |   |  |

**Section B2**

**Reason for Submission—PMA's Only**

- |   |   |  |
|---|---|--|
| <input type="checkbox"/> New device                         | <input type="checkbox"/> Change in design, component, or specification: | <input type="checkbox"/> Location change:    |
| <input type="checkbox"/> Withdrawal                         | <input type="checkbox"/> Software                                       | <input type="checkbox"/> Manufacturer        |
| <input type="checkbox"/> Additional or expanded indications | <input type="checkbox"/> Color Additive                                 | <input type="checkbox"/> Sterilizer          |
| <input type="checkbox"/> Licensing agreement                | <input type="checkbox"/> Other (specify below)                          | <input type="checkbox"/> Packager            |
|   |   | <input type="checkbox"/> Distributor         |
| <input type="checkbox"/> Labeling change:                   | <input type="checkbox"/> Process change:                                | <input type="checkbox"/> Report submission:  |
| <input type="checkbox"/> Indications                        | <input type="checkbox"/> Manufacturer                                   | <input type="checkbox"/> Annual or periodic  |
| <input type="checkbox"/> Instructions                       | <input type="checkbox"/> Sterilizer                                     | <input type="checkbox"/> Post-approval study |
| <input type="checkbox"/> Performance Characteristics        | <input type="checkbox"/> Packager                                       | <input type="checkbox"/> Adverse reaction    |
| <input type="checkbox"/> Shelf life                         |   | <input type="checkbox"/> Device defect       |
| <input type="checkbox"/> Trade name                         | <input type="checkbox"/> Response to FDA correspondence (specify below) | <input type="checkbox"/> Amendment           |
| <input type="checkbox"/> Other (specify below)              | <input type="checkbox"/> Request for applicant hold                     |  |
| <input type="checkbox"/> Change in ownership                | <input type="checkbox"/> Request for removal of applicant hold          |  |
| <input type="checkbox"/> Change in correspondent            | <input type="checkbox"/> Request for extension                          |  |
| <input type="checkbox"/> Other reason (specify):            | <input type="checkbox"/> Request to remove or add manufacturing site    |  |

**Section B3**

**Reason for Submission—IDEs Only**

- |  |  |  |
|--|--|--|
| <input type="checkbox"/> New device                    | <input type="checkbox"/> Change in:                | <input type="checkbox"/> Response to FDA letter concerning:          |
| <input type="checkbox"/> Addition of institution       | <input type="checkbox"/> Correspondent             | <input type="checkbox"/> Conditional approval                        |
| <input type="checkbox"/> Expansion/extension of study  | <input type="checkbox"/> Design                    | <input type="checkbox"/> Deemed approved                             |
| <input type="checkbox"/> IRB certification             | <input type="checkbox"/> Informed consent          | <input type="checkbox"/> Deficient final report                      |
| <input type="checkbox"/> Request hearing               | <input type="checkbox"/> Manufacturer              | <input type="checkbox"/> Deficient progress report                   |
| <input type="checkbox"/> Request waiver                | <input type="checkbox"/> Protocol—feasibility      | <input type="checkbox"/> Deficient investigator report               |
| <input type="checkbox"/> Termination of study          | <input type="checkbox"/> Protocol—other            | <input type="checkbox"/> Disapproval                                 |
| <input type="checkbox"/> Withdrawal of application     | <input type="checkbox"/> Sponsor                   | <input type="checkbox"/> Request extension of time to respond to FDA |
| <input type="checkbox"/> Unanticipated adverse effect  |  | <input type="checkbox"/> Request meeting                             |
| <input type="checkbox"/> Emergency use:                | <input type="checkbox"/> Report submission:        | <input type="checkbox"/> IOL submissions only:                       |
| <input type="checkbox"/> Notification of emergency use | <input type="checkbox"/> Current investigator      | <input type="checkbox"/> Change in IOL style                         |
| <input type="checkbox"/> Additional information        | <input type="checkbox"/> Annual progress           | <input type="checkbox"/> Request for protocol waiver                 |
| <input type="checkbox"/> Other reason (specify):       | <input type="checkbox"/> Site waiver limit reached |  |
|  | <input type="checkbox"/> Final                     |  |

FDA Document Number:

**Section C**

**Product Classification**

Product Code: 73 FLS

CFR Section: 21 CFR 868.2375

Device class:

Classification Panel: Anesthesiology and Respiratory Devices

- Class I
- Class II
- Class III
- Unclassified

**Section D**

**Information on 510(k) Submissions**

Product codes of devices to which substantial equivalence is claimed:

73 FLS

Summary of, or statement concerning, safety and effectiveness data:

- 510(k) summary attached
- 510(k) statement

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
K910870	EdenTrace II Digital Recorder Model 3711	Edentec, Inc.

**Section E**

**Product Information—Applicable to All Applications**

Common or usual name or classification name: Apnea Detector, Adult

Trade or proprietary or model name	Model number
Silent Night I	

FDA document numbers of all prior related submissions (regardless of outcome): NONE

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

Data included in submission:  Laboratory testing  Animal trials  Human trials

Indications (from labeling): The Silent Night I is indicated for use in the diagnostic evaluation of adults with possible Obstructive Sleep Apnea. It is intended to measure or monitor a patient's respiratory rate. The device is designed for use in home screening of adults with possible sleep disorders.

*M*

FDA Document Number:

**Section F Manufacturing/Packaging/Sterilization Sites**

Original  
 Add  Delete

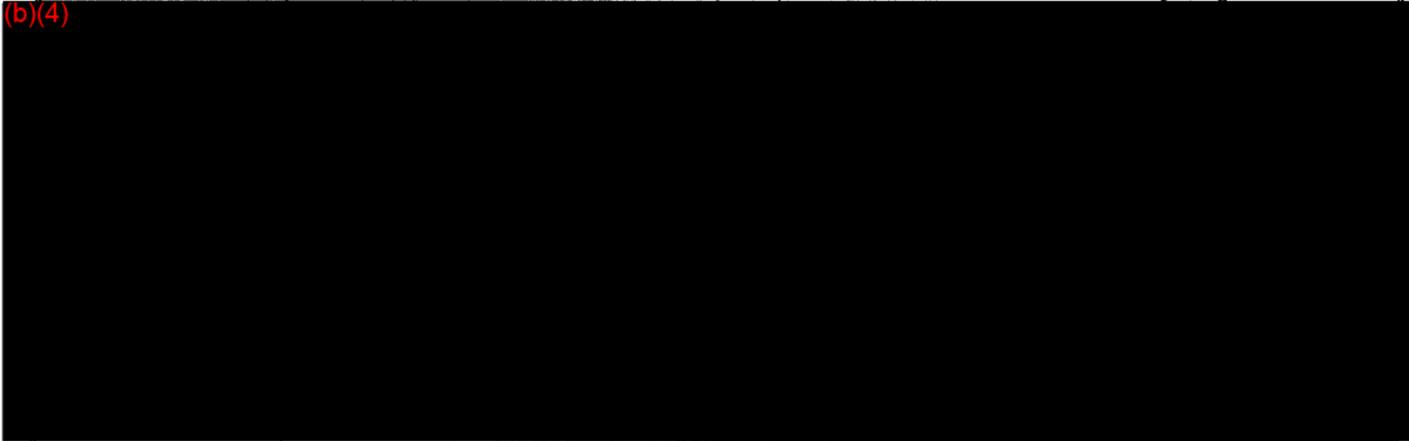
FDA establishment registration number: (b)(4)

Manufacturer

Contract sterilizer

Contract manufacturer

Repackager/relabeler



Original  
 Add  Delete

FDA establishment registration number:

Manufacturer

Contract sterilizer

Contract manufacturer

Repackager/relabeler

Company/Institution Name:

Division name (if applicable):

Phone number (include area code):

( )

Street address:

Fax number (include area code):

( )

City:

State/Province:

Country:

ZIP/Postal Code:

Contact name:

Contact title:

Original  
 Add  Delete

FDA establishment registration number:

Manufacturer

Contract sterilizer

Contract manufacturer

Repackager/relabeler

Company/Institution Name:

Division name (if applicable):

Phone number (include area code):

( )

Street address:

Fax number (include area code):

( )

City:

State/Province:

Country:

ZIP/Postal Code:

Contact name:

Contact title:

77

FDA Document Number:

**Section G Applicant or Sponsor**

Company/Institution Name: Local Silence, Inc.

FDA establishment registration number:  
Applied for

Division name (if applicable):

Phone number (include area code):  
(415) 917-9130

Street address: 935 Fremont Avenue, Suite 115

FAX number (include area code):  
(415) 917-9132

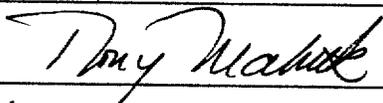
City: Los Altos

State/Province: CA

Country: USA

ZIP/Postal Code: 94024

Signature:



Name: Tony Matouk

Title: President

**Section H Submission correspondent (if different from above)**

Company/Institution Name: Devices for the Future, LLC

Division name (if applicable):

Phone number (include area code):  
(713) 664-6775

Street address: 9223 Ilona Lane

Fax number (include area code):  
(713) 664-6070

City: Houston

State/Province: TX

Country: USA

ZIP/Postal Code:  
77025-4218

Contact name: Lisa S. Jones

Contact title: Regulatory Affairs Consultant

520



Local Silence, Inc.

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9 SEP 96 14 10  
FDA/CDRH/ODE/DNO

FEDERAL EXPRESS

September 9, 1996

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

**510(k) Notification**  
Silent Night™ I

Dear Sir or Madam:

Enclosed is the 510(k) Notification for the Silent Night I, the first in a series of ventilatory effort monitors manufactured for Local Silence, Inc.

This 510(k) Notification follows the recommended format and content of the "Draft Guidance for Format and Content for PreMarket Notification (510(k)) Submissions" issued by the Division of Cardiovascular, Respiratory and Neurological Devices, December 6, 1994.

Please contact this office if further information is required.

Sincerely,

Tony Matouk, President  
Local Silence, Inc.

Lisa S. Jones, RAC  
Regulatory Affairs Consultant

## CONFIDENTIALITY STATEMENT

Local Silence, Inc. considers this 510(k) Notification of the Silent Night I as confidential commercial information.

Local Silence, Inc. has taken precautions to protect the existence of this submission. To the best of our knowledge, neither Local Silence nor any others has disclosed through advertisements or any other manner information concerning this submission. Under the provisions of 21 CFR 807.95, Local Silence hereby requests that FDA not disclose the data and information herein.

Local Silence has designated certain sections of this 510(k) Notification as CONFIDENTIAL. These are:

Section 4, Device Information

Section 5, Comparative Information

Section 7, Environmental Information

Section 9, Software Information

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**LOCAL SILENCE, INC. SILENT NIGHT I**

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## LIST OF ATTACHMENTS

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# SECTION 1

## GENERAL INFORMATION

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**SECTION 1  
GENERAL INFORMATION**

**Submission Date:** September 9, 1996

**Applicant:** Local Silence, Inc.  
935 Fremont Ave., Suite 115  
Los Altos, CA 94024  
Telephone: (415) 917-9130  
Fax: (415) 917-9132

**Contact Person:** Lisa S. Jones, RAC  
Regulatory Affairs Consultant  
Devices for the Future, LLC  
9223 Ilona Lane  
Houston, TX 77025-4218  
Telephone: (713) 664-6775  
Fax: (713) 664-6070

**Device Trade Name:** Silent Night I

**Device Classification Name:** Monitor (Apnea Detector), Ventilatory Effort (73 FLS);  
21 CFR 868.2375

**Establishment Registration Number:** Local Silence, Inc. has registered and listed with the FDA and applied for an establishment registration number. However, as of the date of this 510(k) Notification, the firm has not received the establishment registration number.

**Name and Address of Manufacturing Facility:** (b)(4) Third Party  
(b)(4) Third Party Information



**Section 513 Classification:** These types of devices have been placed into Class II and assigned to the Anesthesiology and Respiratory Devices Panel.

**Reason for 510(k) Notification:** New device

**Legally Marketed Predicate Device:** The legally marketed predicate device is the EdenTec Model 3711 Digital Recorder (K910870), determined to be substantially equivalent to a legally marketed (preAmendment) device on August 29, 1991. The Silent Night I has been evaluated in the clinical setting in comparison to the Grass Model 7P511 High Performance AC Amplifier, a standard polysomnograph recording device (FDA file number and date of determination of substantial equivalence not available).

**Compliance with Section 514:** No performance standards under Section 514 have been developed for these types of devices.

*6/3*

**510(k) CERTIFICATION**

In my capacity as the president of Local Silence, Inc., I believe, to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.



\_\_\_\_\_  
Tony Matouk

8/6/96

\_\_\_\_\_  
Date

**SECTION 2**

**510(K) SUMMARY**

625

K963597

**SECTION 2**  
**510(k) SUMMARY**

**Submitter's name:** Local Silence, Inc.

**Date of summary:** September 9, 1996

**Device name:** Silent Night I

**Legally marketed device to which equivalence is claimed:** The legally marketed predicate device is the EdenTec Model 3711 Digital Recorder (K910870), determined to be substantially equivalent to a legally marketed (preAmendment) device on August 29, 1991. The Silent Night I has been evaluated in the clinical setting in comparison to the Grass Model 7P511 High Performance AC Amplifier, a standard polysomnograph recording device.

**Device description:** The Silent Night I (SNI) consists of a metal box measuring approximately 23 centimeters wide by 17 centimeters deep by 7.5 centimeters high. The device is portable, line-powered and weighs approximately three pounds. The box contains the operational components of the device and has two receptacle connectors: one for input power and another for the sensing microphone. This microphone is attached to the SNI by means of an eight-foot flexible cable and connector. Another microphone is built into the rear of the box and senses room ambient noise. A POWER switch is located on the back of the unit. A switch enabling the user to PAUSE and RESUME device operation is located on the side of the unit.

The device operates as follows: the sound field (breathing sounds + room ambient noise) is sensed by the two microphones and sent to the controller, which extracts breathing sounds from all sounds received. These signals are then sent through bandpass filters and the amplitude characteristics of the signals in the frequency realm are analyzed. The signals are then processed by the pattern recognizer, which differentiates between types of sounds and classifies them as regular snoring or breathing, hypopnea, or apnea. These classified events are logged cumulatively and shown on a liquid crystal display as Disordered Breathing Events (DBE) on the front control panel of the device.

**Intended use:** The Silent Night I is indicated for use in the diagnostic evaluation of adults with possible Obstructive Sleep Apnea. It is intended to measure or monitor a patient's respiratory rate. The device is designed for use in home screening of adults with possible sleep disorders.

The legally marketed EdenTec Model 3711 Digital Recorder is intended to record physiologic data, including heart rate, impedance respiration, snoring sounds, air flow, body position and pulse oximetry in the home or in the hospital, and may be used on pediatric or adult patients. The device also provides a printout of recorded data.

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The Grass Model 7P511 High Performance AC Amplifier is intended to record bioelectric signals such as the electroencephalograph, electrooculograph, electromyograph, electrocardiograph, and respiration.

The intended use of the Silent Night I is a subset of the intended use of the EdenTec Model 3711 Digital Recorder, as the Silent Night I records and analyzes only respiratory sounds, is intended for use only in adults, is designed for use in the home, and does not contain printing capability. The intended use of the Silent Night I is also a subset of the intended use of the Grass Model 7P511 High Performance AC Amplifier, as the Silent Night I records and analyzes only respiratory sounds, rather than a variety of physiologic signals.

**Descriptive summary of technological characteristics and those of predicate device:** The Silent Night I is a portable, line-powered device which records and analyzes breathing sounds. The device components are housed in a metal box, which contains the hardware and software required for device function. The Silent Night I employs two microphones. One microphone, placed near the patient, is attached to the SNI by means of a cable and is used to sense the patient's respiratory sounds. Another microphone is built into the rear of the box and senses room ambient noise.

The legally marketed EdenTec Model 3711 Digital Recorder is intended to record physiologic data, including heart rate, impedance respiration, snoring sounds, air flow, body position and pulse oximetry. Device hardware and software are contained in a portable enclosure. Respiratory sounds are sensed by a microphone placed near the patient. The power source is a battery charger plugged into a 3-prong 120 VAC wall outlet.

The Grass Model 7P511 High Performance AC Amplifier is intended to record bioelectric signals such as the electroencephalograph, electrooculograph, electromyograph and electrocardiograph. The product is also used for amplifying respiratory signals from devices such as thermocouples and pneumographs, and breathing sounds detected by microphones. It is a high gain, low noise AC preamplifier and polygraph pen driver amplifier in a single 19-inch module. The amplifier has nine low frequency filter selections and ten high frequency filter selections. A rear chassis connector is provided for connection to the Grass Electrode Selector Panels.

## Performance data:

*Environmental* : The Silent Night I (SNI) was subjected to mechanical, environmental and electromagnetic compatibility testing in accordance with the relevant requirements of the following standards:

- IEC 68-2, "Basic Environmental Testing Procedures"
- prEN 45502-1:1993, "Active implantable medical devices Part 1: General requirements for safety, marking, and information for the clinician"
- European Norm standard CISPR 11, "Limits and Methods of Measurements of Radio Disturbance Characteristics of Industrial, Scientific and Medical (ISM) Radio-Frequency Equipment", 1990, Class B limits [residential use].
- EN 60601-1-2:1993 "Medical Electrical Equipment, Part 1: General Requirements for Safety, 2. Collateral Standard: Electromagnetic Compatibility-- Requirements and Tests"
- IEC 801

All test units passed visual inspection and electrical characterization, and exhibited proper operation following all mechanical and environmental test sequences. The test results demonstrate that the Silent Night I possesses a degree of mechanical integrity and durability suitable for its intended-use environment. In addition, the Silent Night I passed all electromagnetic compatibility tests without failure. The test results demonstrate that the Silent Night I operates in compliance with appropriate emissions limits and possesses a degree of immunity to the effects of electromagnetic interference adequate for operation in its intended-use environment.

*Clinical*: The Silent Night I has been evaluated in the clinical setting. Patients were subjected to sleep laboratory evaluation with a standard polysomnograph (the Grass Model 7P511 High Performance AC Amplifier) and the additional use of the Silent Night I. The number of Disordered Breathing Events (DBE) and resulting Respiratory Disturbance Index (RDI) calculated by the Silent Night I were compared with data gathered simultaneously on these parameters by the Grass polysomnograph.

Statistical analysis of the test results indicated a high positive correlation between the measurements obtained by the two devices. Further analysis indicated that the measurements are not independent: there is a strong positive linear association between the measurements obtained from the two devices. Additional analyses indicated a high degree of both specificity and sensitivity.

The study results establish the efficacy of the Silent Night I in detecting Disordered Breathing Events, which can be indicative of sleep apnea or another sleep disorder. In view of the noninvasive, non-patient contact design and simple operational features of the device, the Silent Night I offers potential benefit as a cost-effective home-use device for the screening of patients with possible sleep disorders.

# SECTION 3

## INTENDED USE

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**SECTION 3**  
**INTENDED USE**

The Silent Night I is indicated for use in the diagnostic evaluation of adults with possible Obstructive Sleep Apnea. It is intended to measure or monitor a patient's respiratory rate. The device is designed for use in home screening of adults with possible sleep disorders.

This intended use is a subset of the intended use of the legally marketed predicate device, the EdenTec Model 3711 Digital Recorder. The intended use of the Silent Night I is also a subset of the intended use of the Grass Model 7P511 High Performance AC Amplifier.

# SECTION 4

## DEVICE INFORMATION

## SECTION 4 DEVICE INFORMATION

**Executive Summary:** The Silent Night I is a device intended to monitor a patient's respiratory rate. The information obtained by the Silent Night I is used in the assessment and diagnosis of obstructive sleep apnea (OSA) in the adult. The device senses and monitors breathing and snoring sounds. It is designed to be of particular value in the home screening of patients with possible OSA, prior to extensive and costly evaluation in a sleep laboratory.

**Device Description:** The Silent Night I (SNI) consists of a metal enclosure measuring approximately 23 centimeters wide by 17 centimeters deep by 7.5 centimeters high, and weighing approximately 3.5 pounds. The unit is portable and line-powered via a UL-listed transformer which provides 700 milliamps at 5 volts DC.

The metal enclosure contains the following operational components of the device:

- The controller printed circuit board assembly
- The control panel assembly with a backlit liquid crystal display
- A receptacle for the input power connector
- A receptacle for the sensing microphone plug, which is attached to the SNI by means of an eight-foot flexible cable.
- The diagnostic port, used only for quality assurance testing and evaluation after manufacturing; not for use by the physician or patient
- The ambient noise microphone
- The power-on rocker switch
- A green power status light
- A PAUSE/RESUME switch

A block diagram of device operation is included in this section (*Attachment 4a*).

The device operates as follows: when the patient flips the **POWER** switch, the Silent Night I executes a self-test routine for several seconds, after which the green status light will illuminate, indicating that the system is ready for use. The sound field, consisting of breathing sounds and room ambient noise, is sensed by the two microphones: the sensing microphone is located in the vicinity of the patient's head to collect the breathing sounds, while room noise is sensed by the ambient noise microphone, located in the back of the Silent Night I unit. This sound signal is sent as input to the active noise controller, which extracts breathing sounds from all sounds received. The resulting signals are the sounds of snoring/breathing generated by the patient, with minimal contribution from background ambient noise.

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These signals are then sent through a bank of bandpass filters, where the signal-to-noise ratio is further enhanced. The appropriate bandpass filter for each signal characteristic is selected by a proprietary energy comparison software algorithm, which analyzes the amplitude characteristics of the signal in the frequency domain.

The signals are then processed by the pattern recognizer, which converts the sound signal to a new waveform that is closely correlated to the patient's airflow and respiration patterns. This conversion process, performed digitally in the discrete-time domain, is somewhat similar to high order integration in the continuous-time domain. The conversion process allows the Silent Night I to differentiate among types of sounds and classify them as regular snoring or breathing, hypopnea, or apnea.

These classified events are logged cumulatively and displayed as **Disordered Breathing Events (DBE)**, cumulative during the sleep study, on the liquid crystal display (LCD) on the device's control panel.

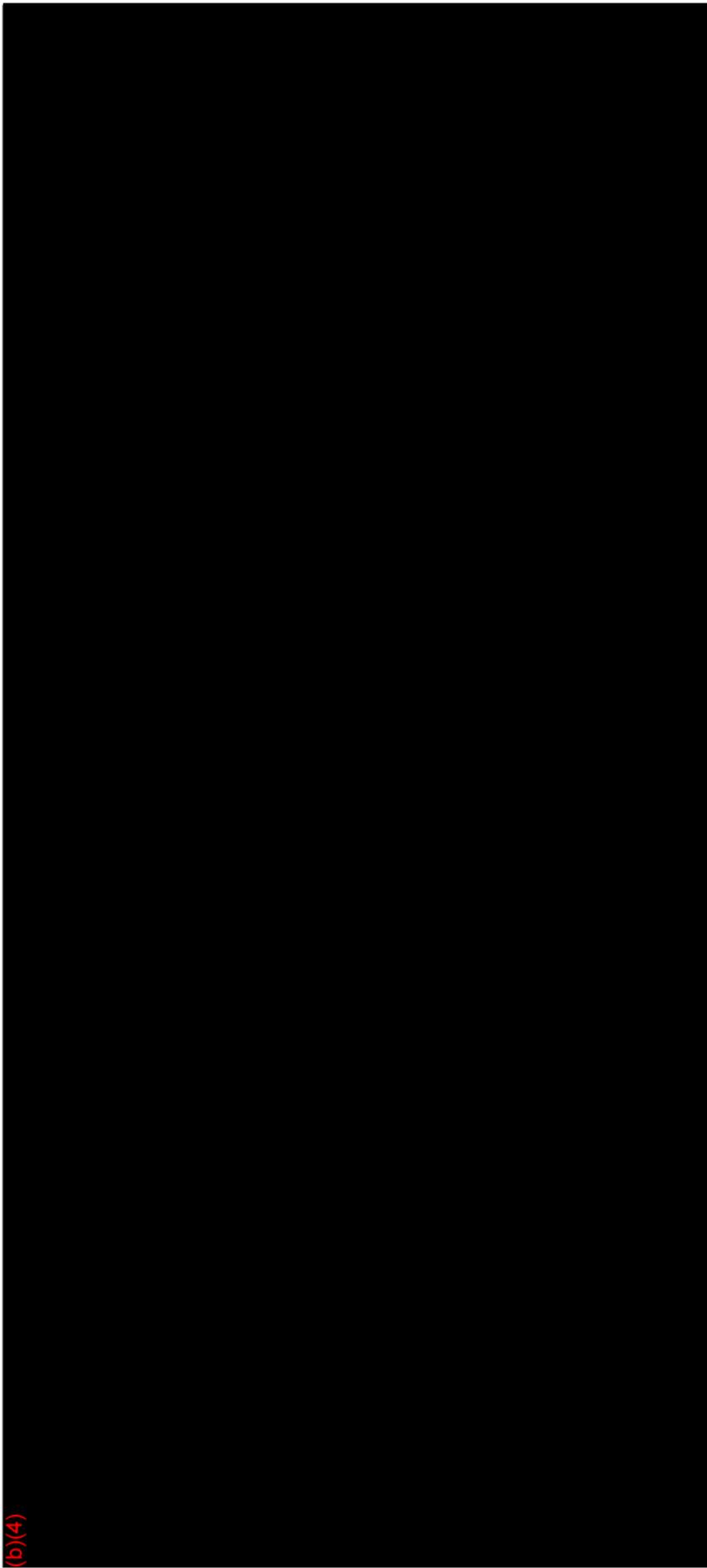
The Silent Night I is not a life-sustaining or life supporting device and is not an implant. It is intended for home use, is supplied non-sterile, and is entirely non-patient contacting when used in accordance with the labeling. The device will be made available for prescription use only, and may be reused. The Silent Night I has demonstrated compliance with applicable voluntary standards for mechanical and environmental testing and electromagnetic compatibility.

**Photographs:** Photographs (*Attachment 4b*) of the Silent Night I are included in this section.

**Engineering Drawings:** Engineering drawings (*Attachment 4c*) of the Silent Night I are included in this section.

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**CONFIDENTIAL**

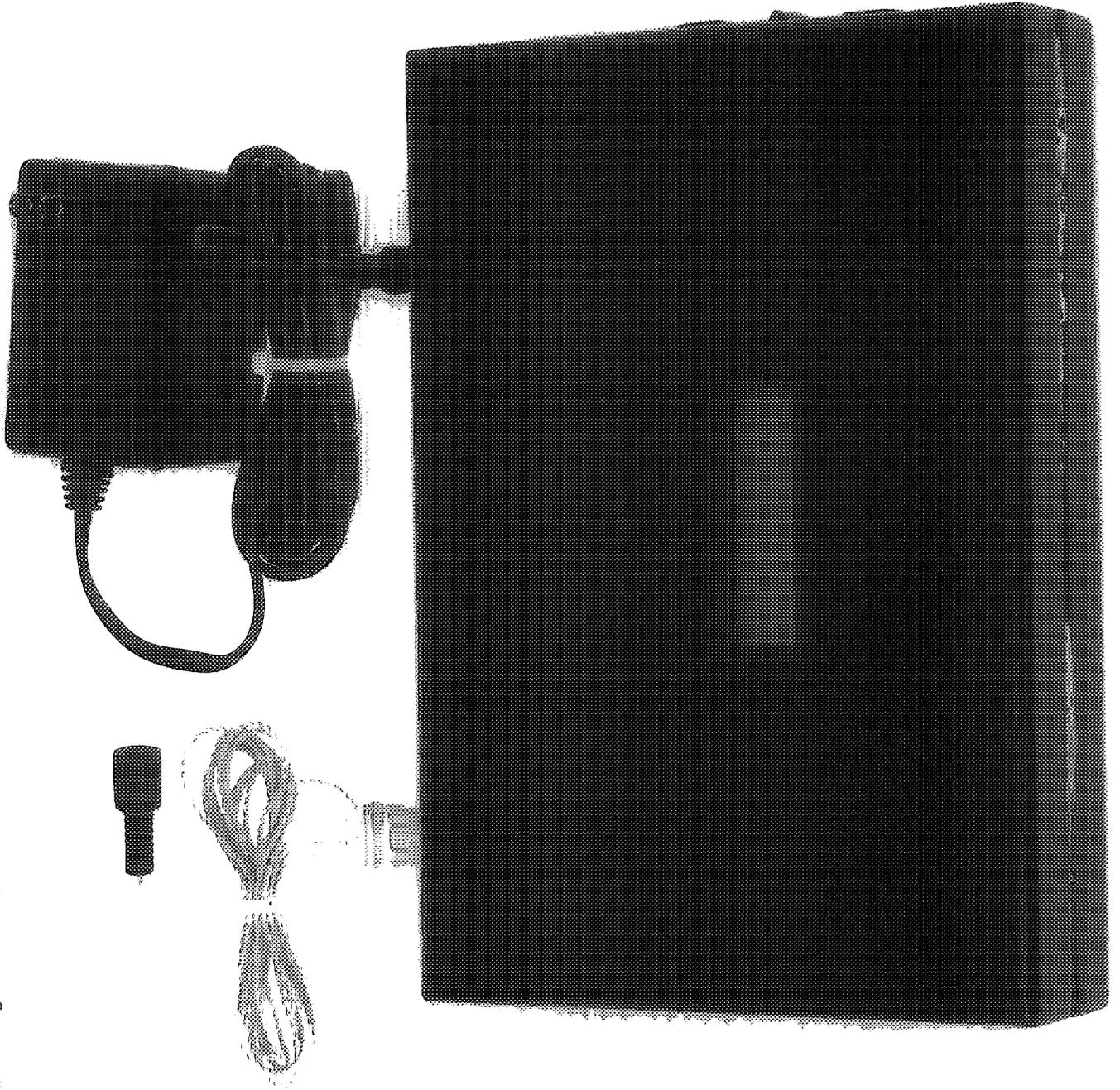


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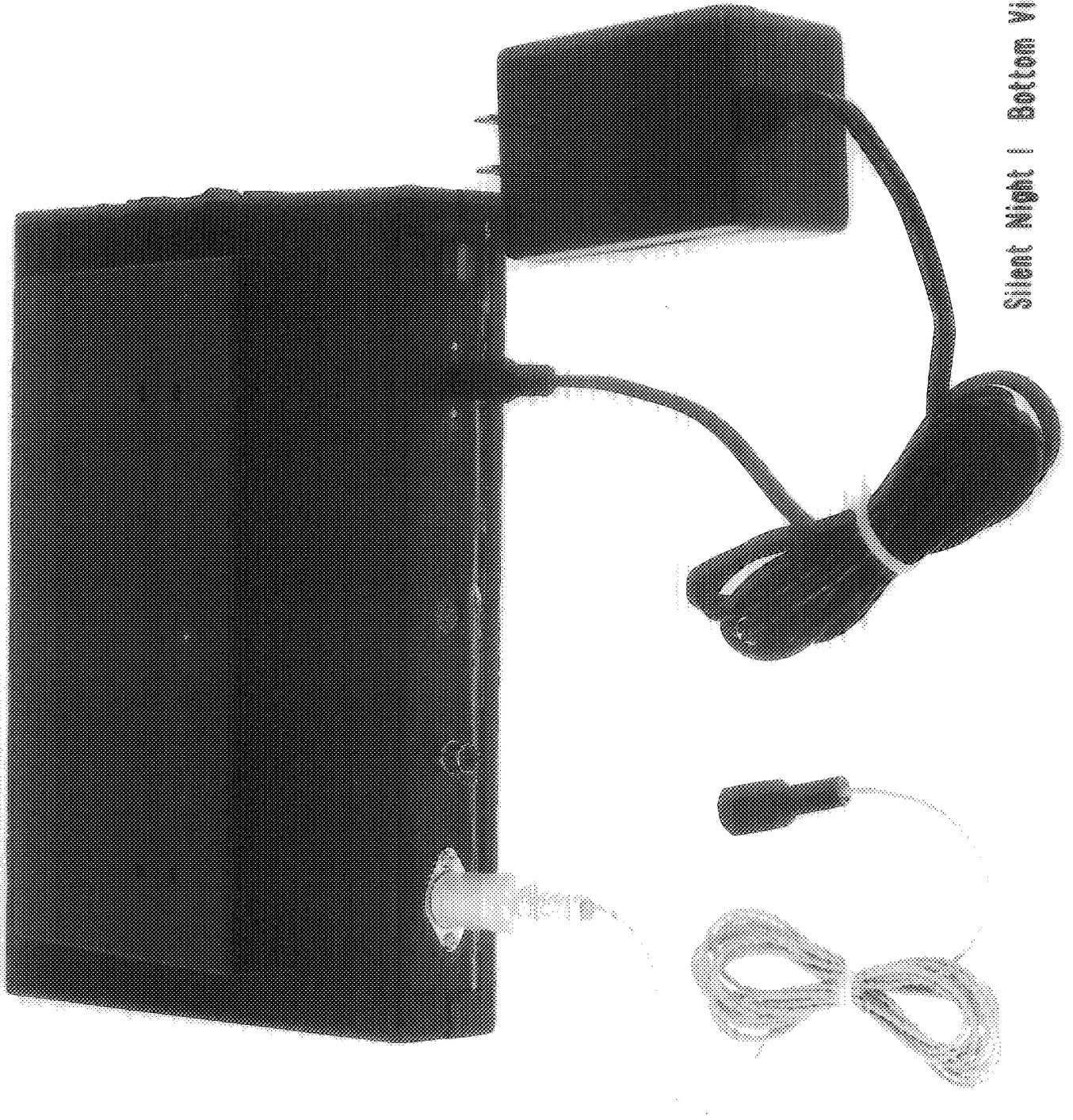
**OBSTRUCTIVE SLEEP APNEA - SILENT NIGHT  
BLOCK DIAGRAM**

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Silent Night I Top View



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Silent Night - Bottom View

06







# SECTION 5

## COMPARATIVE INFORMATION

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**SECTION 5  
COMPARATIVE INFORMATION**

**Table of Comparison to Legally Marketed Devices**

<u>PARAMETER</u>	<u>EDENTEC, INC. EDENTEC MODEL 3711 DIGITAL RECORDER</u>	<u>LOCAL SILENCE, INC. SILENT NIGHT I</u>	<u>GRASS INSTRUMENTS MODEL 7P511 HIGH PERFORMANCE AC AMPLIFIER</u>
<b>CLASSIFICATION NAME</b>	<p>Monitor (Apnea Detector), Ventilatory Effort (73 FLS); 21 CFR 868.2375</p>	<p>Monitor (Apnea Detector), Ventilatory Effort (73 FLS); 21 CFR 868.2375</p>	<p>Device classification unknown</p>
<b>INDICATION FOR USE</b>	<p>The EdenTec Model 3711 Digital Recorder is intended to record physiologic data into solid state memory. The product is to be used on pediatric or adult patients for recording of respiratory related parameters during sleep. The recorder may be used in the hospital (attended) or in the home (unattended).</p>	<p>The Silent Night I is indicated for use in the diagnostic evaluation of adults with possible Obstructive Sleep Apnea. It is intended to measure or monitor a patient's respiratory rate. The device is designed for use in home screening of adults with possible sleep disorders.</p>	<p>The Grass Model 7P511 High Performance AC Amplifier is intended to record bioelectric signals such as the electroencephalograph, electrooculograph, electromyograph and electrocardiograph. The product is also used for amplifying respiratory signals from devices such as thermocouples and pneumographs, and breathing sounds detected by microphones. The device is intended for use in a hospital or sleep laboratory setting.</p>

<u>PARAMETER</u>	<u>EDENTEC, INC.</u> <u>EDENTEC MODEL 3711</u> <u>DIGITAL RECORDER</u>	<u>LOCAL SILENCE, INC.</u> <u>SILENT NIGHT I</u>	<u>GRASS INSTRUMENTS</u> <u>MODEL 7P511 HIGH</u> <u>PERFORMANCE AC</u> <u>AMPLIFIER</u>
<b>TECHNICAL DESCRIPTION/ PARAMETERS MEASURED</b>	Four-channel recording system: records waveforms of heart rate, impedance respiration, snoring sounds, airflow, body position, oxygen saturation	Single-channel recording system: records and analyzes breathing events	Multi-channel recording system: records bioelectric signals such as the electroencephalograph, electrooculograph, electromyograph, electrocardiograph and respiration
<b>SYSTEM COMPONENTS</b>	Recorder box with printer-to-recorder interface cable, power supply (battery charger), airflow sensor, multi-sensor extension cable and yoke, oximeter probe, extension cable, microphone cable, electrodes, patient belt. Interfaces to Model 3710 Digital Printer.	Metal box with built-in microphone and patient microphone on extended cord; plug-in power cord	High gain, low noise AC preamplifier and polygraph pen driver amplifier in a single 19-inch module. The amplifier has nine low frequency filter selections and ten high frequency filter selections. A rear chassis connector is provided for connection to the Grass Electrode Selector Panels. Provided with calibrator with 5 voltage values and line frequency filter.
<b>ALARMS</b>	Sensor fault	None	Unknown
<b>STORAGE CAPACITY</b>	13 hours	None	Unknown

2

<u>PARAMETER</u>	<u>EDENTEC, INC. EDENTEC MODEL 3711 DIGITAL RECORDER</u>	<u>LOCAL SILENCE, INC. SILENT NIGHT I</u>	<u>GRASS INSTRUMENTS MODEL 7P511 HIGH PERFORMANCE AC AMPLIFIER</u>
<u>PATIENT RESPONSIBILITIES</u>	Following initial device setup and channel/parameter selection by clinician, pt. must perform cable/power hookup, perform sensor electrode placement, check all connections, initiate recording, check recording status, detach finger probe and multi-sensor cable if sleep is interrupted	Place device at bedside, place microphone near head, turn on POWER, write down sleep start and stop times, turn off POWER, write down number of DBE's; press PAUSE/RESUME switch if sleep is interrupted	None: device is set up and patient is connected to device by sleep laboratory technologist.
<u>APPLICABLE STANDARDS</u>	Unknown	Tested to voluntary standards for mechanical and environmental integrity and electromagnetic compatibility	Unknown
<u>POWER SOURCE</u>	Custom battery charger plugs into 120 VAC wall outlet	UL-listed transformer plugs into 120 VAC wall outlet	Unknown
<u>DIMENSIONS</u>	Unknown 10 pounds	23 cm x 17 cm x 7.5 cm 3.5 pounds	48.3 cm x 4.4 cm x 21 cm 4 pounds, 6 ounces
<u>STORAGE TEMPERATURE RANGE</u>	-15 to 60 degrees C	-20 to 55 degrees C	Unknown



### Discussion of Similarities and Differences

The Silent Night I is indicated for use in the diagnostic evaluation of adults with possible Obstructive Sleep Apnea. It is intended to measure or monitor a patient's respiratory rate. The device is designed for use in home screening of adults with possible sleep disorders.

**As stated in the product labeling on page 38 of this 510(k) Notification**, the legally marketed EdenTec Model 3711 Digital Recorder is intended to record physiologic data, including heart rate, impedance respiration, snoring sounds, air flow, body position and pulse oximetry in the home or in the hospital, and may be used on pediatric or adult patients. The device also provides a printout of recorded data. The EdenTec product requires several accessories to support these features.

**As stated in the product labeling on page 61 of this 510(k) Notification**, the Grass Model 7P511 High Performance AC Amplifier is intended to record a wide variety of bioelectric signals such as the electroencephalograph, electrooculograph, electromyograph and electrocardiograph. The product may also be used for amplifying respiratory signals from devices such as thermocouples and pneumographs, and breathing sounds detected by microphones. The device is intended for use by a professional sleep laboratory technologist or physician in a hospital or sleep laboratory setting.

The *intended use* of the Silent Night I is a **subset** of the intended use of the EdenTec Model 3711 Digital Recorder, as the Silent Night I records and analyzes only respiratory sounds, is intended for use only in adults, and is designed for use in the home. Further, the intended use of the Silent Night I is also a subset of the intended use of the Grass Model 7P511 High Performance AC Amplifier, as the Silent Night I records and analyzes only respiratory sounds.

The *features and capabilities* of the Silent Night I are also a **subset** of those present in the EdenTec Digital Recorder. The Silent Night I does not contain data memory or printing capability. In addition, use of the EdenTec device necessitates an alarm when sensors are not connected or functioning properly. Because it is entirely non-patient contacting and uses only a microphone to gather respiratory data, the Silent Night I does not require such an alarm.

The information in the comparison table and product labeling establish that the Silent Night I is a subset of the EdenTec Model 3711 Digital Recorder in intended use and technological features. The differences between the two devices (b)(4) and these differences do not substantially alter the diagnostic effect. It is apparent that the technological characteristics of the two devices are substantially equivalent.

The information in the comparison table and product labeling establish that the Silent Night I is a subset of the Grass Model 7P511 High Performance AC Amplifier in intended use. The information in the clinical report establishes that the Silent Night I is substantially equivalent

to the Grass Model 7P511 High Performance AC Amplifier in its ability to detect and record Disordered Breathing Events.

The descriptive characteristics presented in this 510(k) Notification are sufficiently precise to ensure equivalence. In addition, the data and information presented in this 510(k) Notification are sufficient to assess and demonstrate equivalence.

The FDA substantial equivalence letter and Operator's Manual for the EdenTec Model 3711 Digital Recorder are included in *Attachment 5a* of this section. Device specifications and information on equipment controls for the Grass Model 7P511 High Performance AC Amplifier are contained in *Attachment 5b*.

**Clinical Performance Evaluation and Data**

The Silent Night I has been evaluated in the clinical setting. Patients were subjected to sleep laboratory evaluation by polysomnography with the Grass Model 7P511 High Performance AC Amplifier, with the additional use of the Silent Night I. The number of Disordered Breathing Events (DBE) and resulting Respiratory Disturbance Index (RDI) calculated by the Silent Night I were compared with data gathered simultaneously on these parameters by standard polysomnography.

Statistical analysis of the test results indicated a high positive correlation between the measurements obtained by the two devices. Further analysis indicated that the measurements are not independent; that there is a strong positive linear association between the measurements obtained from the two devices.

(b)(4) (b)(4) (b)(4) (b)(4)  
(b)(4) Additional analyses (b)(4)  
indicated a high degree of both specificity and sensitivity.

The study results establish the efficacy of the Silent Night I in detecting Disordered Breathing Events, which can be indicative of sleep apnea or another sleep disorder.

(b)(4) (b)(4)

In view of the noninvasive, non-patient contact design and simple operational features of the device, the Silent Night I offers potential benefit as a cost-effective home-use device for the screening of patients with possible sleep disorders.

The report of the clinical experience is included in *Attachment 5c* of this section.

*Attachment 5d* contains a copy of the literature article, referenced in the clinical report, titled "Cardiopulmonary and neurological consequences of obstructive sleep apnea" by Strohl, K.P.; Roth, T.; Redline, S., published in Fairbanks and Fujita, eds. Snoring and Obstructive Sleep Apnea, second edition. New York: Raven Press, Ltd., 1994.



AUG 29 1991

Re: K910870A

Food and Drug Administration  
1390 Piccard Drive  
Rockville, MD 20850Mr. Gary Syring  
Edentac®  
10252 Valley View Road  
Eden Prairie, Minnesota 55344Digital Recorder Model 3711  
Dated: July 3, 1991  
Received: July 5, 1991  
Regulatory Class: II

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 practices, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market 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, Regulatory Guidance Branch (HFZ-323) at (301) 427-1116. 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



**EDENTEC**

A Nellcor Company

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# EdenTec Model 3711 Digital Recorder

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Operator's Manual

Manual Part Number 241-3143  
Revision D

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Manufactured By:

EdenTec Corporation  
10252 Valley View Road  
Eden Prairie, Minnesota 55344  
(800) 826-2069

## DESCRIPTION

The EdenTec Model 3711 Digital Recorder is intended to record physiologic data into solid state memory. Physiologic data can be selected from:

- Heart Rate
- Impedance Respiration
- Snoring Sounds
- Air Flow
- Body Position
- Pulse Oximetry

In addition, with appropriate interfaces, the following signals can be recorded:

- CPAP
- Strain Gauge
- Auxilliary input signals (0-1 volt range)

## INTENDED USE

This product is to be used on pediatric or adult patients for recording of respiratory related parameters during sleep. The recorder may be used in the hospital (attended) or in the home (unattended).

The recorder is intended for use as a diagnostic device. No physiologic alarms are present. The recorder is not a monitor.

## WARNINGS

Do NOT connect the Model 4097 Multi-Sensor Yoke to the oximeter input.

The EdenTec Model 4097 Multi-Sensor Yoke contains a mercury switch. Do NOT use any multi-sensor yoke that is cracked or appears broken. Return all defective multi-sensor yokes to EdenTec Technical Support for proper disposal.

Do NOT use the recorder in the presence of flammable anesthetics.

This recorder is not intended for use during surgical procedures. Do NOT use this recorder in the presence of electrocautery equipment.

The presence of carboxyhemoglobin may erroneously increase SpO<sub>2</sub> readings. Dyes, or other substances that contain dyes, that change usual arterial pigmentation may cause erroneous SpO<sub>2</sub> readings. Do NOT expose the Nellcor oximeter probe to strong ambient light when it is being used to measure SpO<sub>2</sub> of a patient. A poor signal and erroneous readings may result.

Do NOT soak or immerse probes in any liquid solution or autoclave Nellcor oximeter probes. Probes may be low temperature gas sterilized.

Do NOT defibrillate a patient while attached to the recorder.

Use only EdenTec or Nellcor supplied pulse oximeter probes. Use of non-Nellcor oximeter probes may cause equipment malfunction or serious injury at the probe site.

The recorder is intended for use as a diagnostic device. No physiologic alarms are present. The recorder is not a monitor.

Do NOT store the recorder at temperatures below 5 degrees and above 140 degrees Fahrenheit (-15 degrees to 60 degrees Celsius).

### Interference:

Electrical appliances (electric blankets, waterbed heaters, etc), electric drills, microwave ovens, television sets, radio or TV transmission towers, radio transmission sources (CB radio, HAM radio, etc), and other sources of electrical transmissions can be a source of interference to the recorder. This interference can cause recorder malfunction. Keep the recorder a practical distance from these items. Never place the recorder on top of these types of items.

**Cables/Probes/Sensors:**

Use only EdenTec cables, multi-sensor yokes, and recommended probes and electrodes. Use of non-EdenTec accessories can cause malfunction. Do NOT use skin creams, electrode gels, etc. under electrodes. If skin irritation occurs, change to another type of electrode.

**Cleaning:**

Detach all cables from the recorder before cleaning. Unplug the recorder power cable. Use only a damp cloth to wipe the recorder. Do NOT use hospital cleaning agents or chemicals at greater than recommended strengths. Do NOT allow fluids into the recorder. Fluid in the recorder can cause malfunction.

**Malfunction:**

Insects, dirt, and other foreign material in the enclosure of the recorder may cause malfunction. Do NOT place the recorder near a source of high humidity, such as a vaporizer. Moisture in the recorder can cause malfunction.

**External Inputs:**

The recorder can record external signals from a CPAP pressure meter, strain gauge and/or auxiliary input. These recorder inputs are not isolated. Signal inputs to the connections must be electrically isolated. If you have questions, contact EdenTec Technical Support at (800) 826-2069.

**PRECAUTIONS**

Federal law restricts this device to sale by or on the order of a licensed medical practitioner.

Always use clinical judgment when interpreting data gathered from this recorder. If recorder malfunction is suspected, contact EdenTec Technical Support at (800) 826-2069.

**Use Only One Recorder:**

Interference may occur if more than one recorder is on a patient or if an apnea monitor and recorder are on the same patient. If more than one recorder is used in the same area, keep recorders, patient cables, multi-sensor yokes, and lead wires separated.

**Memory Capacity:**

The Model 3711 Digital Recorder will store up to 13 hours of patient data. (See Technical Specifications).

**Static Electricity:**

Static electricity can cause recorder malfunction. Touch a grounded metal object before attaching electrodes.

**Bathing:**

The patient must remove ALL electrodes, belts, cables and wires before bathing.

**Cables/Probes/Sensors:**

These items are fragile in nature. Handle with care. A duplicate set of cables, probes and sensors should be available at all times.

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**SpO2:**

The oxygen saturation value displayed on the Model 3711 Digital Recorder is referred to as SpO2. In accordance with common usage, SpO2 is used to differentiate an arterial oxygen saturation which has been determined via pulse oximetry rather than by direct sampling of arterial blood.

**Clearing Memory:**

It is important to clear the recorder memory of old patient data prior to performing a new study. Failure to do so will result in new patient data being added to existing data until the memory is full.

**Service:**

There are no user serviceable parts inside the recorder. For service, contact EdenTec Technical Support at (800) 826-2069.

**Technical Specifications:**

Refer to Appendix B at the end of the manual.

## FEATURES

- Uses ONLY Nellcor Pulse Oximeter Probes
- EdenTrace Motion Annotation System (MAS) – places a motion annotation signal on the EdenTrace printout to alert clinicians to motion and possible periods of false desaturation due to motion, poor signals or misapplication of the oximeter probe.
- A diagnostic oximeter

## EQUIPMENT REQUIREMENTS:

- Printer to Recorder Interface Cable (EdenTec Model 4036)
- Power Supply (EdenTec Model 4146 Locking Battery Charger)
- Adult Airflow Sensor \* (EdenTec Model 971)
- Multi-Sensor Extension Cable (EdenTec Model 4099)
- Multi-Sensor Yoke (EdenTec Model 4097)
- Nellcor D-25 Oximeter Probe (EdenTec Model 4094)
- Nellcor EC8 8' Extension Cable (EdenTec Model 4095)
- Microphone Cable (EdenTec Model 4098)
- Pregelled Electrodes (2 each) (EdenTec Model 2414018)
- Patient Belt (EdenTec Model 4100)

\* Other models of the EdenTec Airflow Sensor may be used. Contact EdenTec Customer Service.

- Model 972 Small Adult Airflow Sensor
- Model 974 Child Airflow Sensor

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# RECORDER OPERATION

The Model 3711 Digital Recorder is designed to receive physiologic signals from sensors on the patient. The Recorder has two front panel buttons, which are used along with prompts on the digital display (Figure 1).

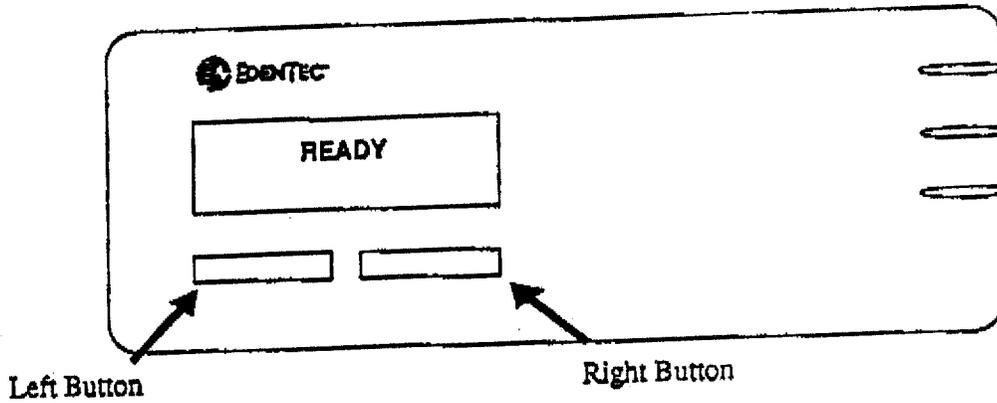


Figure 1  
Front Panel of Recorder

Attach the Model 4146 Battery Charger to the recorder at the POWER INPUT connection on the recorder (Figure 2). Plug in the battery charger to a 3-prong, 120 VAC wall outlet.

Do NOT connect the Model 4146 Battery Charger to an outlet controlled by a switch. Use only an Edentec Model 4146(AULT 5318-000-028) Battery Charger. Recorder malfunction can occur if an Edentec Model 4146 is not used.

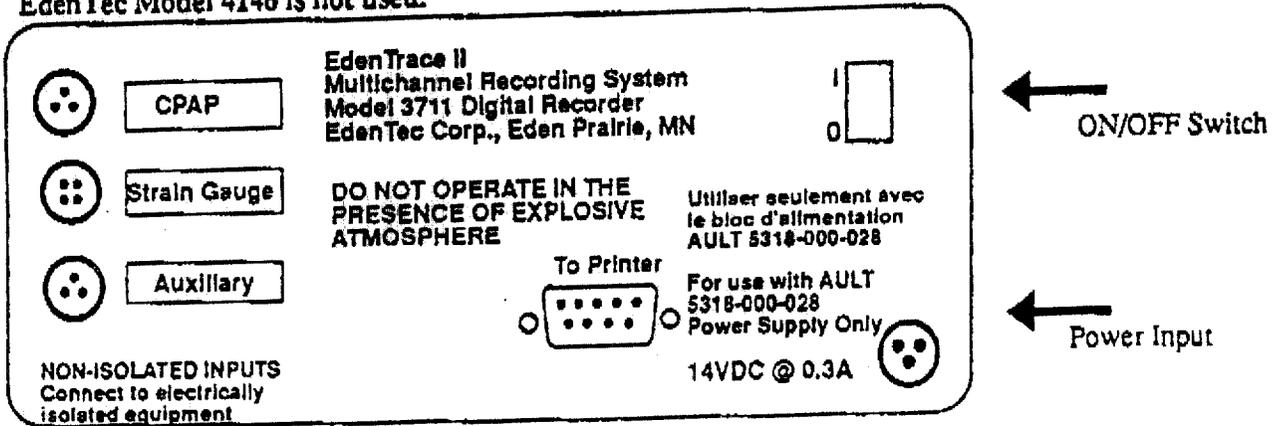


Figure 2  
Rear Panel of Recorder

## CLINICIAN SETUP

### Turning the recorder ON:

While holding down the left button on the front of the recorder, turn the recorder ON using the ON/OFF switch on the rear of the recorder (Figure 2). The display will show:

SETUP MODE  
YES NO

If the recorder memory contains data when turned ON, the 'RETAIN MEMORY' message will appear. Refer to the section entitled CLEARING MEMORY.

### Setting parameters/channels:

At 'SETUP MODE', press 'YES'. (This is the front panel button located under the word 'YES' on the display.) The display will show:

CH1 = HEARTRATE OK  
YES NO

A display will appear indicating which parameter is located on channel 1. Choosing 'YES' will accept the specified parameter for channel 1. Choosing 'NO' will assign a new parameter to channel 1. Press 'NO' until the desired parameter appears and then press 'YES' to accept. When 'YES' has been pressed, the parameter for channel 2 will appear.

Repeat the above procedure to select the remaining channels/parameters. You may choose from heart rate, respiration, airflow, SpO2, CPAP, strain gauge and auxiliary. Any parameter may be selected for any channel. Body position and snoring sounds are always available. If keeping the channels/parameters the same on consecutive studies, you may select 'NO' at 'SETUP MODE' and proceed with attachment and 'CHECK SIGNALS'.

### Setting time/date:

When completed with channel selection you will see:

TIME 21:30 OK  
YES NO

Choose 'YES' to accept the current time or 'NO' to change the time.

A display similar to the following will appear:

MINS 30 OK  
 YES NO

Press 'NO' to change the minutes to the desired time. You may simply hold the button down until the correct number appears. Press 'YES' at the correct number. Repeat the steps for 'HOURS'.

When the correct time has been accepted, DATE will appear. Follow the same procedure as above to accept or change the date, beginning with 'DAY', followed by 'MONTH' and 'YEAR'.

**Sensor disconnect alarm:**

After the correct DATE has been accepted, this display will appear. The recorder will alarm if a sensor disconnect occurs if 'YES' is chosen. No alarms will sound if 'NO' is chosen.

SENSOR ALARM ?  
 YES NO

**Cable attachment:**

Attach the multi-sensor yoke to the multi-sensor extension cable (Figure 3). Connect the multi-sensor extension cable, Nellcor oximeter probe or other cables to the recorder as indicated in Figures 4 and 5. Make all connections to the patient. (Refer to Appendix A for proper sensor connections.)

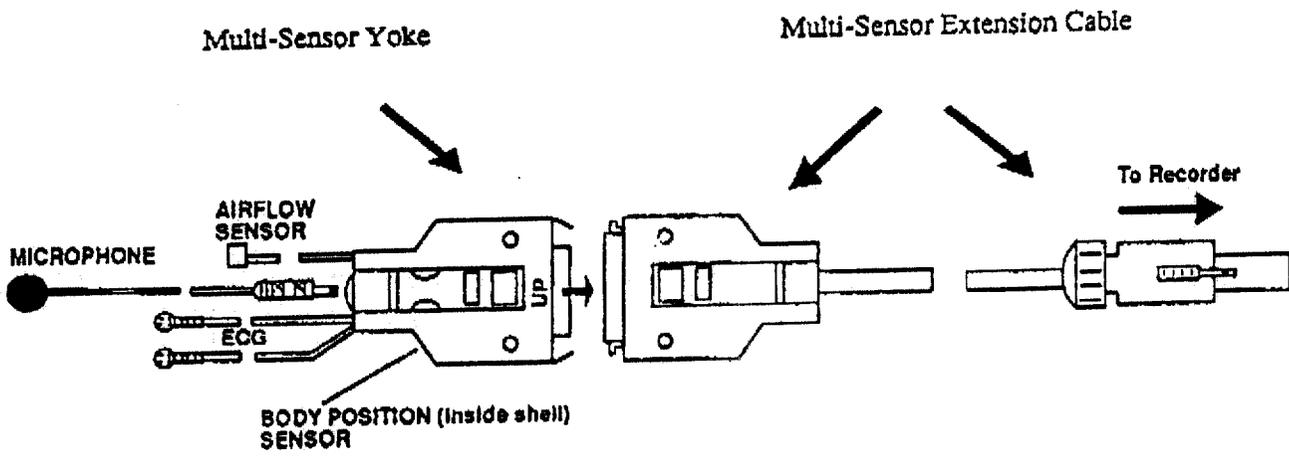


Figure 3

EdenTec Multi-Sensor Yoke and Extension Cable

*dp*

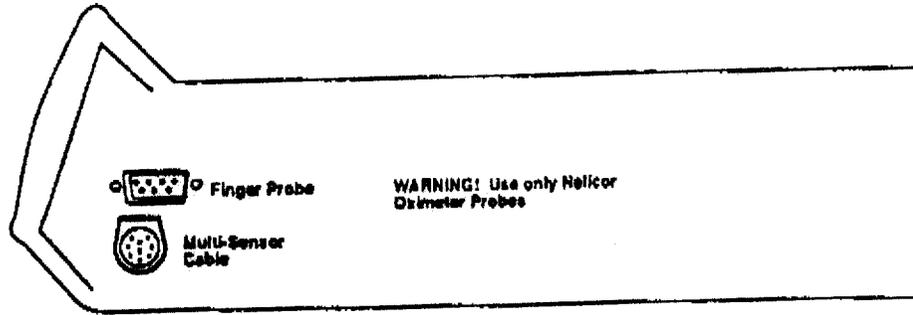


Figure 4  
Side Panel of Recorder

**WARNING: Do NOT connect the multi-sensor yoke to the Finger Probe connection.**

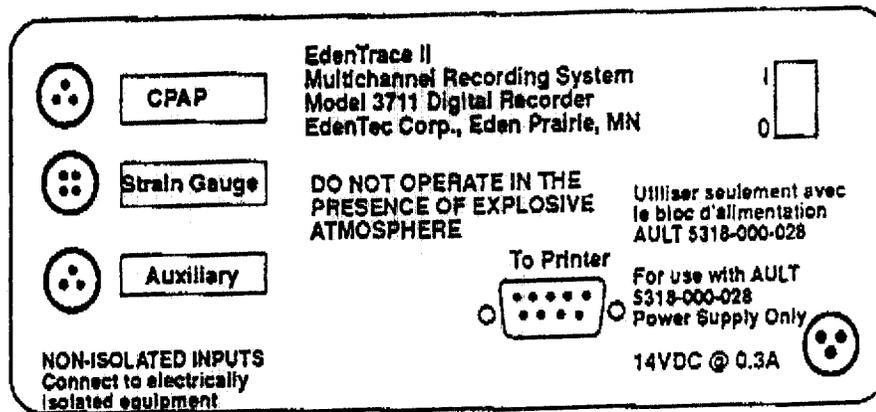


Figure 5  
Rear Panel of Recorder

**NOTE: The recorder can record external signals from a CPAP pressure meter, strain gauge and auxiliary input. These recorder inputs are not isolated. Signal inputs to the connections must be electrically isolated. Contact EdenTec Technical Support with any questions (800) 826-2069.**

**Checking physiologic signals:**

You may wish to check whether the physiologic signals are working properly.

CHECK SIGNALS  
YES NO

To check the physiologic signals choose 'YES' after sensor connections to the patient have been made. (Selecting 'NO' will put the recorder into the 'READY' mode.)

Heart rate, SpO2 and CPAP will display a numeric value while other signals move a bar across the display. Stronger signals will exhibit a larger deflection across the display blocks. If any signals look incorrect or low in amplitude, reposition sensors. Pressing either button will advance the display to the next channel/parameter.

After all four channels have been checked, you may check Body Position and Snoring.

BODY POSITION - S  
SNORING - NONE

The patient should simulate a "snore". Check for a "LOW" or "HIGH" in place of "NONE" on the display:

BODY POSITION - S  
SNORING - HIGH

Press either button to advance. Choose 'NO' at the 'CHECK SIGNALS' menu to advance to the 'READY' mode or choose 'YES' to repeat 'CHECK SIGNALS'.

**Begin recording:**

If all connections have been properly made and the display shows 'READY', the following message will appear within ten (10) seconds:

READY  
SENSORS OK

Recording will begin within thirty (30) seconds and you will see:

RECORDING DATA  
SENSORS OK

If sensor connections have not been properly made the 'READY' indicator will continue until all sensor connections have been properly made.

#### Sensor disconnect:

Recording will continue while all cables are properly attached. If a sensor disconnect occurs, a message will appear on the display indicating the source of the fault. The alarm will sound unless it has been disabled. The fault should be corrected to continue recording that parameter.

If the fault cannot be corrected, the alarm may be silenced by pressing either button on the recorder front panel. Pressing either button will silence the alarm for 60 seconds. During this 60 seconds the display will continue to indicate the source of the fault. If the fault is corrected within 60 seconds the recorder will resume recording this parameter.

If, after 60 seconds, the problem has not been corrected, the alarm will sound again. Pressing either button will silence the alarm indefinitely for that fault condition. If a different fault condition occurs, this new fault condition will be indicated on the display and the alarm will sound again. The above process may be repeated to silence the alarm or the fault condition should be corrected.

#### End of recording:

Recording will end when:

- 1) the memory fills ('DATA MEMORY FULL'), or
- 2) all cables are detached from the recorder, or
- 3) the power supply is disconnected, or
- 4) the recorder is turned OFF.

## PATIENT SETUP

If a patient is to conduct an unattended study in the home, the clinician should:

- 1) Perform initial setup procedure - i.e. channel/parameter selection (see CLINICIAN SETUP).
- 2) Instruct the patient in proper cable/power hook up to the recorder. The clinician may wish to connect the multi-sensor yoke to the multi-sensor extension cable and place the assembly in the loop on the patient belt. This reduces the number of connections the patient must make.
- 3) Instruct the patient in proper sensor/electrode placement on himself/herself. (See Appendix A).

The patient may initiate recording by simply turning the recorder ON. The recorder will display 'READY'. If all connections have been properly made, within forty (40) seconds the recorder will display:

RECORDING DATA  
SENSORS OK

If a patient wishes to disconnect during the night, the patient should detach the finger probe and multi-sensor cable from the recorder. This automatically puts the recorder into the 'READY' mode. (A sensor fault alarm will sound until all cables have been detached from the recorder.) The patient should be advised to keep the belt and all sensors on if they get up for a short time, then re-attach the finger probe and multi-sensor cable to the recorder. Recording will resume.

### End of recording:

Recording will end when:

- 1) the memory fills ('DATA MEMORY FULL'), or
- 2) all cables are detached from the recorder, or
- 3) the power supply is disconnected, or
- 4) the recorder is turned OFF.

(V)

## RETRIEVAL AND PRINTING OF DATA

To retrieve and print data stored in the Model 3711 Digital Recorder, you need to connect the recorder to a Model 3710 Digital Printer.

- 1) Connect the interface cable from the recorder to the printer.
- 2) Turn ON both the printer and the recorder. (It is not necessary to hold in the button on the front of the recorder.)
- 3) Push the PRINT button on the front of the printer. If properly connected, this message will appear on the recorder display and printing will begin.

DATA BEING SENT  
BLOCK #0001

If this message does not appear, check cable connections and power.

- 4) To interrupt printing, push the printer PRINT button. Printing will stop and 'READY' will appear on the recorder display again.

To resume printing, push the printer PRINT button again. Printing will resume on the next page after the point at which it was stopped.

- 5) After all of the data has been printed the recorder will prompt 'RETAIN MEMORY?'. Refer to the CLEARING MEMORY section.
- 6) If you wish to print data at the time of recording (on-line mode) check the recorder for the message 'RECORDING DATA - SENSORS OK'. When this message appears press the printer PRINT button.
- 7) Printer speeds of 0.5 mm/sec and 1.0 mm/sec are available in either the on-line or playback modes. Select the PRINT SPEED button on the rear of the printer. (Refer to the Model 3710 Digital Printer Operator's Manual).

## CLEARING MEMORY

1. Immediately after retrieval and printing of data, or when turning the recorder ON with the left button pushed in (if the recorder memory contains data) this message will appear:

RETAIN MEMORY?  
YES NO

2. Choose 'NO' to clear the recorder memory. (If 'YES' is chosen, you will return to the set-up mode, 'SENSOR ALARM?' display. Existing data will be retained and new data will be appended onto the existing data. See note below.)

ARE YOU SURE?  
YES NO

Choose 'YES' to clear memory. You will see:

CLEARING MEMORY  
01% COMPLETE

The memory will take approximately 10 minutes to clear regardless of the length of study (quantity of data) in the memory.

**NOTE:** If the recorder contains data when the unit is powered ON and the left button is not pushed (i.e. "patient mode"), 'READY' will appear. Recording will begin if all cables/sensors are connected properly. New data will be added to the existing study data until the memory is full. It is important to clear the memory of old patient data prior to performing a new study.

## TROUBLESHOOTING

**NOTE:** If any attempts at problem correction are not successful, contact EdenTec Technical Support at (800) 826-2069.

### Problem

### Suggested Cause and Correction

Low Oximetry Values

- 1) Are values clinically correct?
- 2) Probe placement is critical.  
Check and adjust probe placement.
- 3) Try another probe.

Sensor Fault Alarm

- 1) Check sensor connections from the patient to the multi-sensor yoke.
- 2) Check connection between the multi-sensor yoke and the multi-sensor extension cable.
- 3) Check the extension cable connection to the recorder.
- 4) Try another sensor, if applicable.
- 5) Try another multi-sensor yoke.
- 6) Try another extension cable.
- 7) Try new electrodes.

Recorder will not display  
"RECORDING DATA"

- 1) Sensors are not properly connected to patient or recorder.
- 2) Turn recorder OFF, then ON. Repeat set-up sequence.

Signals have a low deflection when  
viewed by "CHECK SIGNALS"

- 1) Reposition sensors.
- 2) Try another sensor.

Unable to transfer data from the  
recorder to the Digital Printer

- 1) Check all cable connections to the recorder and printer.
- 2) Turn the recorder and printer off.  
Turn the printer ON, followed by the recorder.

## LIMITED WARRANTY FOR EDENTRACE™ II RECORDING PRODUCTS

1. **EQUIPMENT.** The EdenTrace™ II Multichannel Recording System (Model 3711 Digital Recorder and Model 3710 Digital Printer) consists of a recording and/or printing device, a power supply or power cord, patient cables and sensors, lead wires, electrodes, and other accessories. Hereafter referred to as the "System".
2. **WARNING.** EdenTec makes no representation or warranty as to the effectiveness of the System as a treatment.
3. **LIMITATIONS.** The System is sold in an "as is" condition. The entire risk as to the quality and performance of the System is with the buyer, except to the extent set forth in Section 5. This Limited Warranty is expressly in lieu of any and all other representations, conditions, and warranties, expressed or implied, including any implied warranty of merchantability of fitness for a particular purpose, whether arising from statute, common law, custom or otherwise. The remedies set forth in this Limited Warranty shall be the exclusive remedy available to any person. No person has any authority to bind EdenTec to any representation, condition, or warranty except this Limited Warranty.
4. **DISCLAIMER ON SENSORS, CABLES AND ELECTRODES.** EdenTec makes no warranty or replacement credit whatsoever as to the cables, electrodes, sensors, power and interconnect cables. This is more fully described in the disclaimer packaged with each sensor cable and electrode.
5. **LIMITED WARRANTY ON THE SYSTEMS.** EdenTec warrants the electronics of all EdenTrace II Systems to be free from defects in material and workmanship for one (1) year following the delivery of the equipment to the original purchaser. EdenTec warrants the mechanical components (i.e. printer component) for ninety (90) days following the delivery of the equipment to the original purchaser. EdenTec shall repair or replace any part or parts of the systems upon which EdenTec's examination shall disclose to have become defective within the warranty period; or at EdenTec's discretion, it may elect to supply a substantially similar new or newly remanufactured replacement component or system. To qualify for such repair, or replacement, the defective equipment must be returned within (30) days after discovery of the defect. Such repair, or replacement does not apply to any system which has been repaired or altered outside of EdenTec's facility in any way so as, in the judgment of EdenTec, to affect its stability and reliability, or which has been subjected to misuse, negligence, or accident.
6. **MISCELLANEOUS.** EdenTec shall not be liable for any medical expenses or any direct or consequential damages resulting from or caused by any defect, failure, or malfunction of the System, whether a claim for such damages is based upon warranty, contract, tort or otherwise.

This Warranty gives you specific legal rights and you may have other rights which vary from state to state.

## APPENDIX A - SENSOR PLACEMENT

### Patient Cable Connection for Heart Rate and Respiration via Transthoracic Impedance:

- 1) Place two (2) high-quality adhesive electrodes on either side of the patient's chest. These should be placed along the patient's mid-axillary area at or slightly below the nipple line. (Figure 6)

EdenTec Customer Service can provide a list of recommended electrodes.

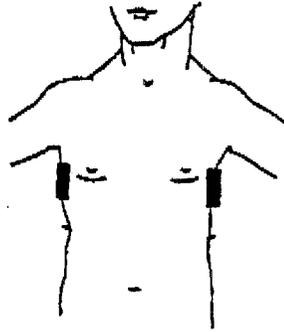


Figure 6

### Adult Electrode Placement

**NOTE:** Make sure the skin surface is clean and free of lotions and oil where the electrodes are to be placed.

- 2) Place Model 4100 Patient Belt around the patient's abdomen with the small loop facing away from the patient. (Figure 7) Secure belt with the Velcro™ tab.

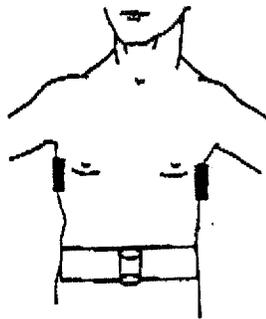


Figure 7

- 3) Attach the white lead wire of the multi-sensor yoke to the electrode on the patient's right side. Attach the black lead wire to the electrode on the patient's left side.
- 4) Thread the yoke connector down through the small loop on the patient belt.

1 08

5) Attach the multi-sensor yoke to the extension cable. (Figure 8)

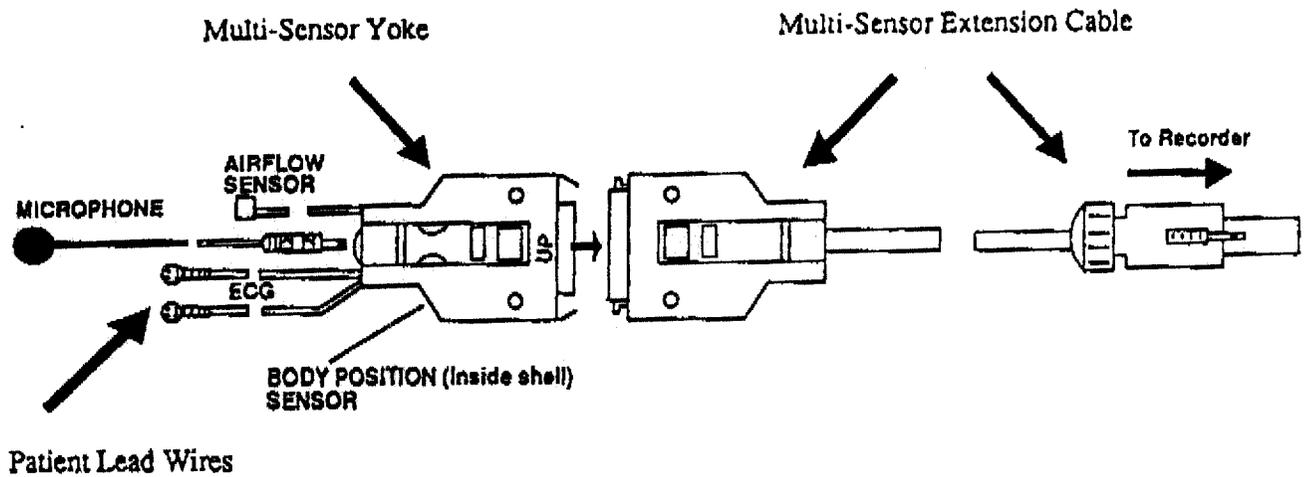


Figure 8

Multi-Sensor Yoke and Extension Cable

6) Secure the junction of the multi-sensor yoke and the multi-sensor extension cable inside the small loop on the patient belt. (Figure 9) The word UP must face away from the patient.

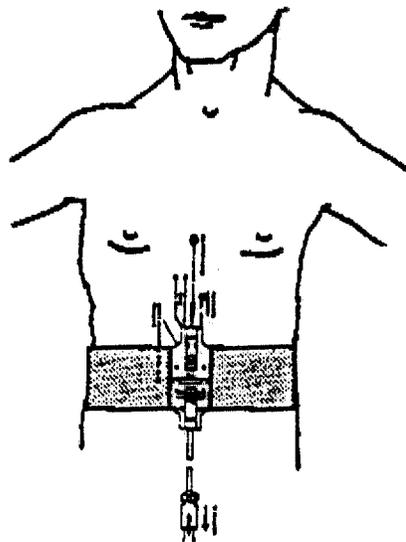


Figure 9

7) Attach the extension cable connector to the "MULTI-SENSOR CABLE" receptacle on the Model 3711 Digital Recorder. (Figure 10)

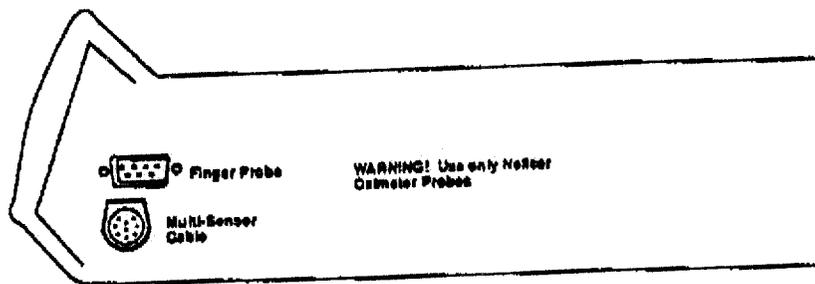


Figure 10

Recorder Side View

**NOTE:** The patient cable has a locking connector. To detach the cable from the recorder, press and hold the buttons on the cable connector. DO NOT attempt to detach the cable without first pressing and holding this button.

**Snoring Sounds Microphone:**

- 1) Place the microphone alongside the patient's throat, approximately level with the thyroid cartilage ("Adam's Apple") or higher.
- 2) Tape securely in place.
- 3) Attach the microphone cable to the multi-sensor yoke. (Figure 8)

**Airflow Sensor:**

- 1) Apply the EdenTec Airflow Sensor to the patient as directed in the package insert.
- 2) Attach the airflow sensor to the airflow sensor receptacle on the multi-sensor yoke. (Figure 8)

**Nellcor Oximeter Probe:**

- 1) Select a test site that will ensure proper coverage of the photodetector, either a fingernail or toenail.
- 2) Position the emitter or the "light source" side of the probe on the nail bed. Place the detector or receiver side of the probe opposite the nail bed.
- 3) Position the two sides of the probe directly opposite one another. Misalignment will result in erroneous oxygen saturation readings with motion indicated on the printer printout.

4) Wrap tape around the probe site to hold the probe in place. **DO NOT RESTRICT THE CIRCULATION.**

**WARNING:** After application, ensure that continued circulation at the probe site is present. Reduced circulation may be harmful to the patient and will result in erroneous oxygen saturation readings with motion indicated on the printer printout.

5) Attach the oximeter probe to the 8 foot Nellcor extension cable (EdenTec Model 4095).

6) Attach the extension cable to the recorder at the **FINGER PROBE** input. (Figure 10)

7) Move the probe if there is any sign of skin irritation or impaired circulation.

8) If a probe is damaged in any way, discontinue use immediately. Use another probe.

**WARNING:** Use only Nellcor Oximeter Probes. Serious injury at the probe site can occur if non-Nellcor probes are used.

Connect only a Nellcor oximeter probe to the Finger Probe connector on the recorder.

Do NOT connect the Multi-sensor yoke to the Finger Probe input.

# APPENDIX B - MODEL 3711 DIGITAL RECORDER TECHNICAL SPECIFICATIONS

## SpO2 Accuracy:

Adult (using Nellcor D-25 sensor)

70% - 100%	± 2 percentage points
60% - 70%	± 3 percentage points
0% - 60%	unspecified

Heart Rate Detection: 0.25 mv to 5.0 mv Rates to 200 BPM

## CPAP/AUXILIARY:

0-1 volt input, DC to 5 Hz signal bandwidth (non-isolated signal inputs)

## STRAIN GAUGE:

0 - 2.5v input, DC to 5Hz signal bandwidth (non-isolated signal inputs)

## Internal Lithium Battery Life:

3 years (for clock/calendar)

## Snoring Sounds:

Low level detection - 90 db ± 4 db at 500 Hz (on skin)

High level detection - 96 db ± 4 db at 500Hz

Frequency response - 100 - 1000 Hz

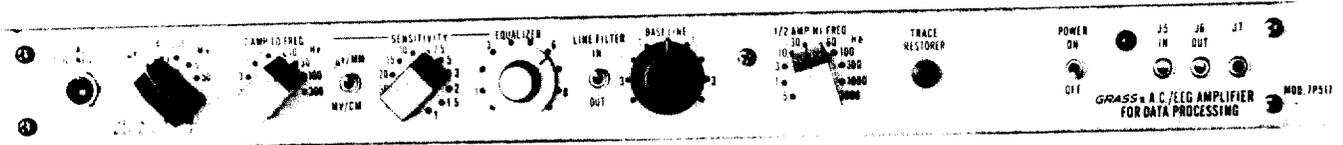
Memory Capacity: Up to 13 hours (12 1/2 hours minimum)

105 57

NOTES

# HIGH PERFORMANCE AC AMPLIFIER

for EEG, EMG, ECG, Respiration  
in Model 7, 78, and 79 Polygraphs



## ®GRASS MODEL 7P511 SPECIFICATIONS

### GENERAL DESCRIPTION

The 7P511 Amplifier is a high gain, low noise AC preamplifier and polygraph pen driver amplifier in a single compact 19" (48.3 cm) module. It is suitable for recording EEG, EMG, ECG, respiration and many other bioelectric signals.

The amplifier features nine low frequency filter selections and ten high frequency filter positions. A rear chassis connector is provided for connection to the Grass Electrode Selector Panels. A calibrator with 5 voltage values is provided for calibration. A line frequency filter is provided.

The optional F-7HIP5 Series High Impedance Probes can be interfaced with the 7P511 for applications involving the use of microelectrodes or other high impedance electrodes. For clinical monitoring from patients in high risk areas, an optional isolated input cable is available.

### INPUT IMPEDANCE

- 20 megohms, differential

### NOISE LEVEL: (referred to input)

- 10  $\mu$ V, peak to peak, (3 kHz bandwidth) at J6
- 2  $\mu$ V, peak to peak, at pens

### COMMON MODE REJECTION

- Adjustable to 10,000:1 at 100 Hz

### SENSITIVITY

- Amplification to the J6 output can be varied from about 10 to a maximum of 200,000
- Calibrated pen sensitivity can be varied from 75 mV/cm to 1  $\mu$ V/mm
- Uncalibrated from 150 mV/cm to about 0.5  $\mu$ V/mm

### CALIBRATION

- Five DC voltages: 5 and 50  $\mu$ V; 0.5, 5 and 50 mV, accurate to  $\pm 2\%$

### BASELINE

- Can be set within the range of the channel
  - 30 mm, EEG type oscillograph
  - 50 mm, Polygraph type oscillograph

### FREQUENCY RESPONSE: see over

- HIGH FILTER: 1/2 Amplitude (-6 dB)  
J6 Output: 3000, 1000, 300, 100, 60, 30, 10, 3, 1 and 0.5 Hz
- LOW FILTER: 1/2 Amplitude (-6 dB)  
0.01, 0.1, 0.3, 1, 3, 10, 30, 100 and 300 Hz
- Line frequency filter rejects interference from AC power sources

### OUTPUTS

- **J6 Output Jack**
  - For monitoring with CRO, tape, computer, etc.
  - Impedance less than 100 ohms, single-sided
  - Load tolerance of 3 kilohms or greater
  - Frequency response 0.01 Hz to 3 kHz  
1/2 Amplitude (-6 dB)
- **J7 Output Jack**
  - Higher signal level with less fidelity than at J6, parallels inkwriting oscillograph
  - Output impedance 55 ohms, single-sided
  - Frequency response 0.01 Hz to 300 Hz  
1/2 Amplitude (-6 dB)
  - Output voltage 16 V, peak to peak, for full scale pen deflection

GRASS INSTRUMENT DIVISION  
Astro-Med, Inc.

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# MODEL 7P511 SPECIFICATIONS continued

## TRACE RESTORER

- Pushbutton returns output to zero volts

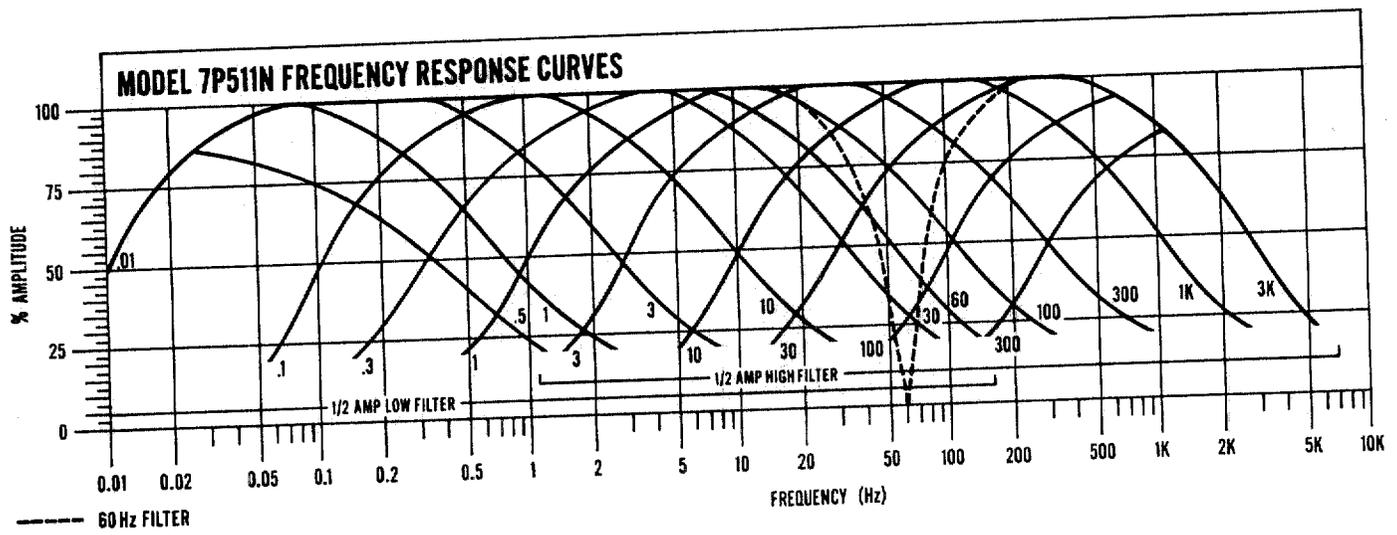
- Sensitivity adjustable 1.5 to 7.5 V, peak to peak, for full scale
- Separate adjustment of baseline provided

## HIGH LEVEL INPUT

- J5 Input Jack
  - For tape, computer, telemeter "playback"
  - Impedance 1.2 megohms, single-sided
  - Frequency response DC to 90 Hz 1/2 Amplitude (-6 dB) with the EEG Oscillograph
- Sensitivity 1 V RMS (2.8 V peak to peak) is equal to full scale pen deflection

## PHYSICAL SIZE

- 19" W x 1-3/4" H x 8-1/4" D (48.3 cm x 4.4 cm x 21 cm)
- Weight: 4 lbs. 6 ozs. (2 kg)



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# FRONT PANEL CONTROLS

## Section 2.1

### FRONT PANEL CONTROLS

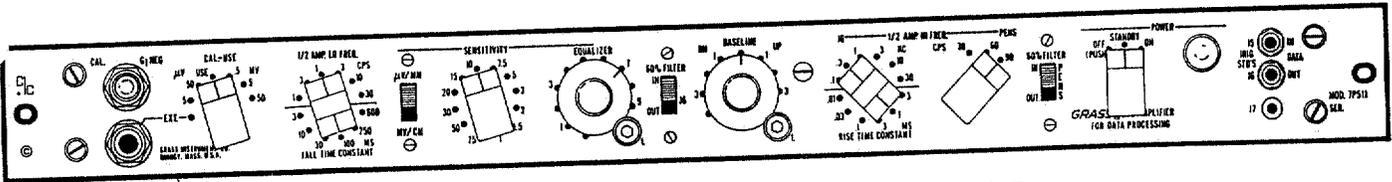
#### 2.1 General Considerations

2.1.1 The 7P511 Amplifier was originally intended for research electroencephalography where a wide range of filters was desired and an output suitable for digitizing and tape recording was required. As evoked potential applications emerged, additional filters were added to allow the 7P511 to be used for interfacing signal averagers and computers for evoked potential applications.

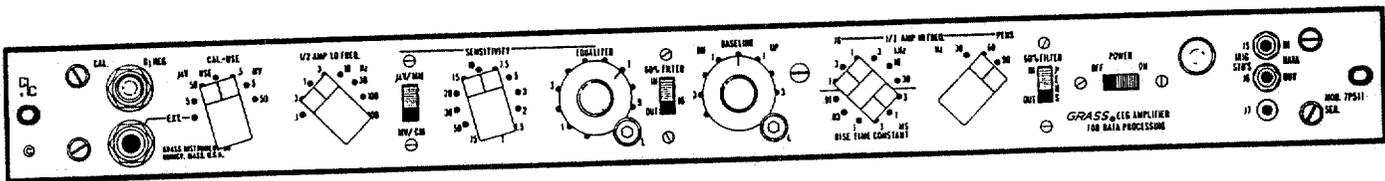
2.1.2 The 7P511 is a combined preamplifier and pen driving amplifier in a single package. It is similar to the Model 7P5 plug-in Preamplifier and Model 7DA Driver Amplifier.

2.1.3 The wide range of sensitivity and filters offered by the 7P511 makes it a very flexible amplifier. In the area of sleep disorders, for example, the 7P511 is used for amplifying EEG, EMG, EOG (REM), ECG, respiratory signals from devices such as thermocouples, pneumographs, etc., breathing sounds detected by microphones and other variables.

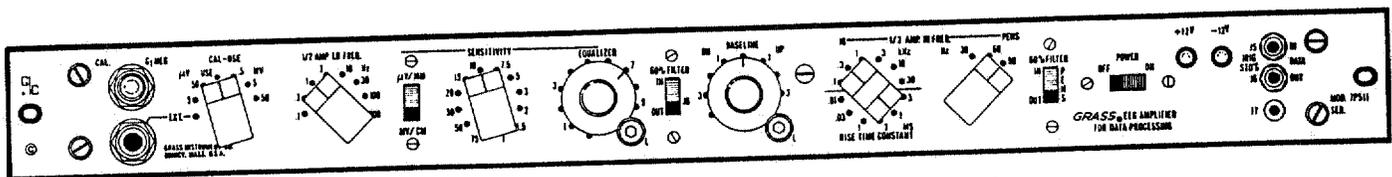
2.1.4 The 7P511 has both front and rear panel J6 output jacks at IRIG levels appropriate for interfacing a wide range of ancillary instruments. It is possible to simultaneously record on the chart paper while outputting to other devices via the J6 output jacks.



FRONT PANEL CONTROLS MODELS 7P511A and B  
FIGURE 2.1.1a



FRONT PANEL CONTROLS MODELS 7P511C to G  
FIGURE 2.1.1b



FRONT PANEL CONTROLS MODELS 7P511H and later  
FIGURE 2.1.1c

## FRONT PANEL CONTROLS

### Sections 2.1-2.2

2.1.5 Although the 7P511 was designed specifically to record the EEG, its large variation in sensitivity and excellent frequency response extend its usefulness for other AC variables such as the EKG and EMG.

2.1.6 Each 7P511 Amplifier is 1-3/4 inch high and mounts in the standard 19 inch rack space provided in the Model 78 EEG/Polygraph console and the Model 79 Series bench-top Polygraph. To provide power to the Amplifier, plug the ten-prong P310CCT connector at the left rear of the 7P511 into the appropriate socket in the rear Power Distribution Strip on the console. The input connector on the rear chassis is a Cannon WK-6-32S. The wiring of this connector is  $G_1 = 2$ ,  $G_2 = 3$  and Ground = 6. The mating connector is Cannon WK-6-21C. Input to this connector should be made via the Grass Input Cable #4281 or 7IG3 (for high risk applications) or the optional Model 78ES25 and 78ES36 Electro Selector Panels.

2.1.7 Normally, the 7P511 is coupled with the low excursion Oscillograph in a Model 78 or 79 recording system. For some applications, however, it is possible to utilize the wide excursion Oscillograph (requiring wide excursion writeout).

2.1.8 Each 7P511 can be removed by disconnecting the input and power connectors, removing the screws at each end of the panel, and pulling outward.

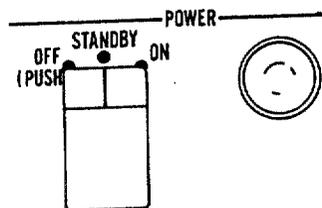
2.1.9 Refer to Figures 2.1.1a, b and c for the locations and settings of the controls described in the following sections.

## 2.2 Off-On Switch

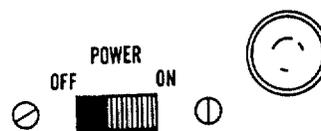
2.2.1 The OFF-ON switch controls the voltages from the Power Supply to the individual Amplifier.

2.2.2 In the OFF position, no voltages are supplied to the Amplifier. The ON position makes the Amplifier completely operational. The adjacent indicating lights glow when this switch is in the ON position.

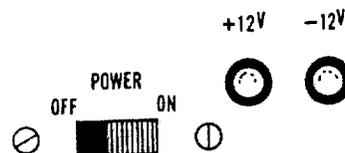
2.2.3 Turn an Amplifier OFF only if it will not be in use or if it is defective and producing artifacts in other channels.



ON-OFF SWITCH MODELS A and B  
FIGURE 2.2.1a



ON-OFF SWITCH MODELS C to G  
FIGURE 2.2.1b



ON-OFF SWITCH MODELS H and later  
FIGURE 2.2.1c

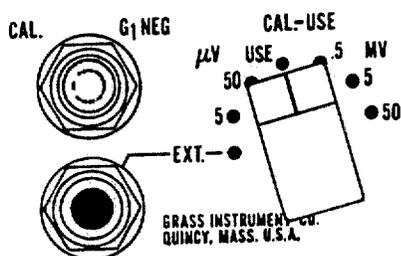
# FRONT PANEL CONTROLS

## Section 2.3

### 2.3 Calibration Controls

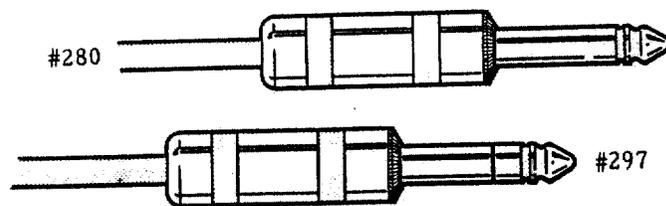
2.3.1 The CAL-USE switch selects calibration voltages or the USE mode. The CAL positions to the left provide calibration voltages of 5 and 50 microvolts (within the standard EEG calibration ranges). The CAL positions to the right provide larger calibration voltages of 0.5, 5 and 50 millivolts for other applications. Once the 7P511 has been calibrated, turn the CAL-USE switch to the USE position for recording. If the 7P511 CAL-USE switch is in the USE position, all channels may be calibrated simultaneously via the Electrode Selector Panel.

2.3.2 The size of the CAL signal is set on the CAL-USE switch. Pressing the  $G_1$  NEG button introduces the selected calibration voltage making Gate 1 ( $G_1$ ) negative with respect to Gate 2 ( $G_2$ ). This results in an upward deflection of the pen. When this button is released, the pen deflects downwards. The pen should always be allowed to return fully to the baseline between successive deflections; otherwise, an incorrect value of calibration may result.



NOTE: Beginning with 7P511G models, the 1.35 volt calibration battery was eliminated. The calibration voltages are derived from the polygraph power supply.

2.3.3 The extreme counterclockwise position of the CAL-USE switch is marked EXT and is employed when only one or two channels are to be used, eliminating inputs through the Electrode Board. See Figure in Section 2.3.2. In this position, the EXT jack makes connection with the input gates of the amplifier via the front panel, independent of the rear input connections. Thus, signals applied to the EXT jack on the front panel are recorded in preference to those applied at the rear IN receptacle. The EXT jack requires a mating phone plug such as the #297 for push-pull operation or the #280 for single-ended input. See Figure 2.3.3.



PHONE PLUGS #280 AND #297  
FIGURE 2.3.3

2.3.4 To wire Switchcraft #297 or #280 plug, proceed as follows:

- a. To wire the Switchcraft #297 for push-pull operation, solder  $G_1$  lead of the 2-conductor shielded cable to the shortest of the three metal shafts ( $G_1$ ) on the #297 plug. See Figure 2.3.4a. Solder  $G_2$  lead to the intermediate length shaft ( $G_2$ ) and connect the shield to the longest ground shaft (GND).

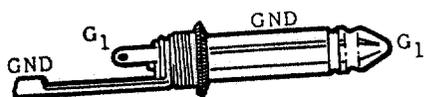


SWITCHCRAFT #297 PHONE JACK  
FIGURE 2.3.4a

## FRONT PANEL CONTROLS

### Sections 2.3-2.4

- b. To wire the Switchcraft #280 for single-ended operation, solder  $G_1$  lead of the single conductor shielded cable to the shortest shaft ( $G_1$ ) on the #280 plug. See Figure 2.3.4b. The shield is then connected to the long ground shaft (GND).



SWITCHCRAFT #280 PHONE JACK  
FIGURE 2.3.4b

## 2.4 Sensitivity Controls

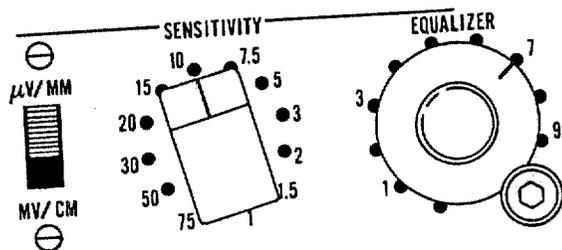
2.4.1 The  $\mu\text{V}/\text{MM}$ - $\text{MV}/\text{CM}$  switch selects the correct sensitivity (amplification) range for the voltage of the incoming signal. In the  $\text{MV}/\text{CM}$  position, the total amplification is one hundredth (1/100) of that available when it is set to  $\mu\text{V}/\text{MM}$ .

2.4.2 There are twelve positions on the SENSITIVITY switch that range from 1 to 75 microvolts per millimeter ( $\mu\text{V}/\text{MM}$  position) and from 1 to 75 millivolts per centimeter ( $\text{MV}/\text{CM}$  position). The combined  $\mu\text{V}/\text{MM}$ - $\text{MV}/\text{CM}$  switch and 12 position SENSITIVITY switch yields a sensitivity ratio of 7500:1 (1  $\mu\text{V}/\text{mm}$  to 75  $\text{mV}/\text{cm}$ ). Together with the  $\mu\text{V}/\text{MM}$ - $\text{MV}/\text{CM}$  switch and the EQUALIZER control, the SENSITIVITY switch determines the precise setting of sensitivity.

2.4.3 The EEG is generally recorded at an arbitrary sensitivity of 7.5  $\mu\text{V}/\text{mm}$  with variations depending on the input voltage level.

2.4.4 EEG signals are in the microvolt range. The  $\text{MV}/\text{CM}$  sensitivity setting is not normally used for conventional EEG recording, but is useful for recording EKG or for other applications where input signals are in the millivolt range.

2.4.5 The SENSITIVITY EQUALIZER control adjusts the sensitivity of each 7P511 so that all channels deflect equally in response to the same calibration signal. This control may occasionally need readjustment. With a SENSITIVITY setting of 1 microvolt/millimeter and the EQUALIZER control at its maximum clockwise position, the amplification factor from the input to the J6 jack is in excess of 200,000.



2.4.6 A 5/32 inch Allen wrench is provided for locking or unlocking the EQUALIZER control. Full lock is achieved by making the screw adjustment snug. Do not over-tighten the screw. When locking the control, hold the knob firmly to prevent slight rotation during the tightening of the lock.

## FRONT PANEL CONTROLS

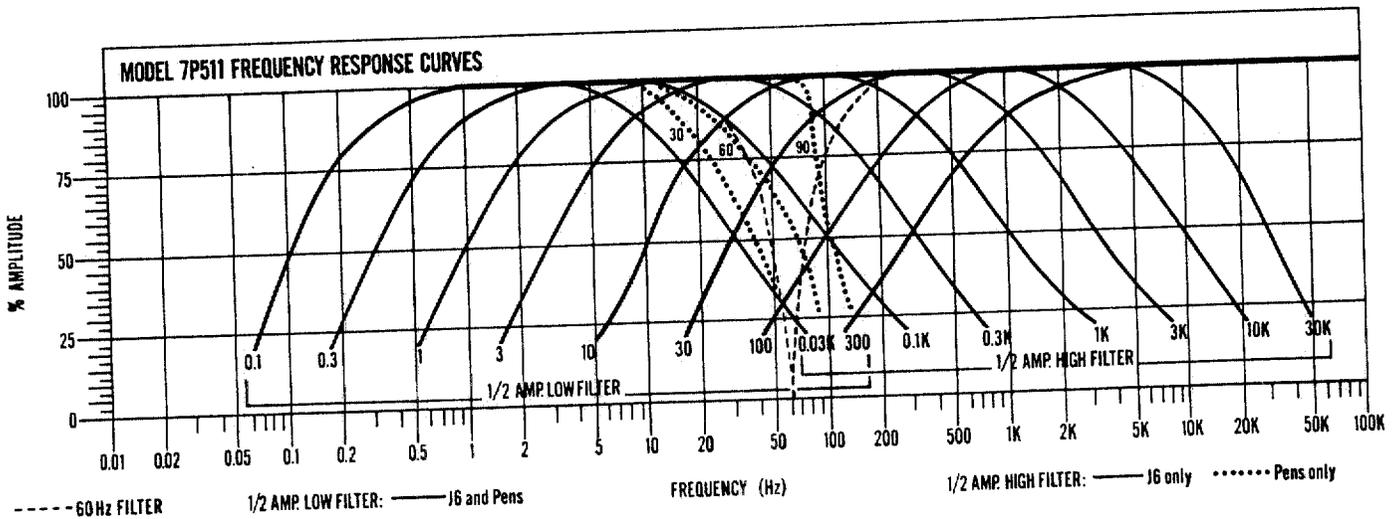
### Sections 2.4-2.5

2.4.7 Example: to set the overall channel sensitivity at 5 microvolts/millimeter:

- a. Set the  $\mu\text{V}/\text{MM}-\text{MV}/\text{CM}$  switch to  $\mu\text{V}/\text{MM}$ .
- b. Set the SENSITIVITY switch to 5.
- c. Set the CAL-USE switch to the 50  $\mu\text{V}$  position.
- d. Depress the CAL G<sub>1</sub> NEG pushbutton and adjust the EQUALIZER control until a deflection of 1 centimeter is obtained.
- e. When the correct deflection has been obtained, tighten the locking nut. Recheck. Repeat for the remaining channels containing 7P511 Amplifiers.
- f. Other positions of the SENSITIVITY switch now read the actual sensitivity values in microvolts/millimeter or millivolts/centimeter.

## 2.5 1/2 Amp Lo Freq Switch

2.5.1 The 1/2 AMP LO FREQ switch permits selection of the proper frequency range of the phenomenon under observation. Low frequency response of the 7P511H and J can be adjusted by means of this 8-position switch. Half-amplitude frequency response is the frequency at which the output signal is reduced to one-half the amplitude obtained at frequencies where the response is maximum. Half-amplitude frequencies of 0.1, 0.3, 1, 3, 10, 30, 100 and 300 Hz can be selected. These are shown on the upper part of the switch. For example, if, at a low frequency setting of 0.1 Hz, a 10 Hz signal produces a pen deflection of 10 millimeters, then a 0.1 Hz signal will produce approximately 5 millimeters pen deflection. Similarly, a 0.3 Hz signal will produce 5 millimeters pen deflection at a low frequency of 0.3, a 1 Hz signal will produce 5 millimeters pen deflection at a low frequency setting of 1 Hz, etc.

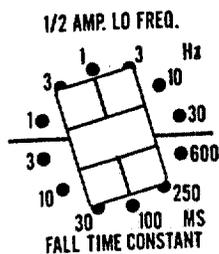


MODEL 7P511 FREQUENCY RESPONSE CURVES  
FIGURE 2.5.1

## FRONT PANEL CONTROLS

### Section 2.5

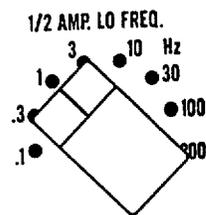
2.5.2 For Models 7P511A to G, the fall time constants corresponding to the 0.1, 0.3, 1, 3, 10 and 30 Hz positions are 600, 250, 100, 30, 10 and 3 milliseconds, respectively. The frequency and corresponding fall time constants are indicated on the double-indicator knob. The top pointer indicates the low frequency response in Hertz and the bottom pointer indicates the corresponding fall time constant in milliseconds.



1/2 AMP LO FREQUENCY SWITCH  
MODELS A to G  
FIGURE 2.5.2

2.5.3 While it is common practice to record EEGs with the 1/2 AMP LO FREQ switch at 1, the most accurate reproduction of slow wave activity (below 2 Hz) is attained by the use of the 0.1 position. Occasionally, low frequency artifacts may make this latter setting undesirable.

2.5.4 Beginning with the 7P511H model, a 100 Hz and 300 Hz Low Frequency filter was added to the amplifier to facilitate amplifying and conditioning signals for evoked potential studies. This change eliminated the Fall Time Constant nomenclature from this switch on the panel.



1/2 AMP LO FREQUENCY SWITCH  
MODELS H and later  
FIGURE 2.5.4

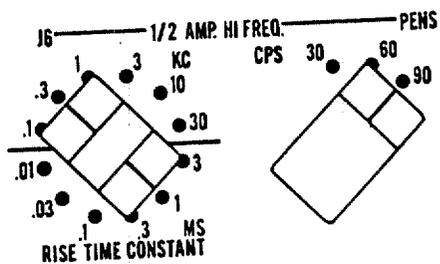
# FRONT PANEL CONTROLS

## Section 2.6

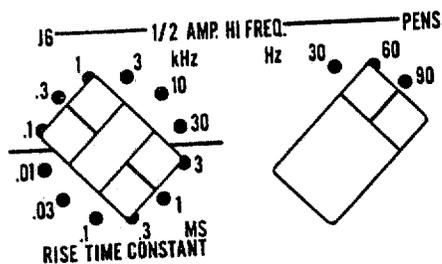
### 2.6 1/2 Amp Hi Freq Switch

2.6.1 There are two high frequency filter switches:

a. The 1/2 AMP HI FREQ (J6) switch determines the upper limit of frequency response at J6 on the 7P511. The 0.1 kHz position on the J6 switch may slightly affect the pen responses, in that this approaches the half amplitude response of the pens. The upper values on the 1/2 AMP HI FREQ (J6) switch are the frequencies at which the high end of the high frequency response curve has attenuated to half-amplitude. For example, if at a high frequency setting of 30 kHz, a 100 Hz signal will produce a CRO deflection of eight divisions, then a 30 kHz signal will produce a CRO deflection of four divisions. Similarly, a 10 kHz signal will be attenuated 50% at a high frequency setting of 10kHz. When recording with an oscilloscope, set the 1/2 AMP HI FREQ (J6) switch for the desired high frequency response. Connect the oscilloscope to the J6 output jack.



1/2 AMP HI FREQUENCY SWITCH  
MODELS A and B  
FIGURE 2.6.1a



1/2 AMP HI FREQUENCY SWITCH  
MODELS C and later  
FIGURE 2.6.1b

b. The 1/2 AMP HI FREQ (PENS) switch determines the high frequency response of the EEG oscillograph pens only (maximum excursion of 30 millimeters). The setting of this control does not affect the high frequency response at J6.

2.6.2 The rise time constants corresponding to the 0.1, 0.3, 1, 3, 10 and 30 kHz positions are 3, 1, 0.3, 0.1, 0.03 and 0.01 milliseconds respectively. The frequency and corresponding rise time constants are indicated on the double-indicator knob. The top pointer indicates the high frequency response and the bottom pointer indicates the appropriate rise time constants in milliseconds. See Figure 2.5.1.

1 19

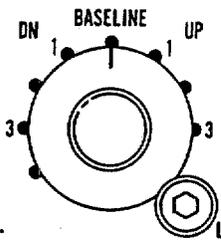
## FRONT PANEL CONTROLS

### Sections 2.7-2.8

#### 2.7 Baseline Position Control

2.7.1 The BASELINE control permits electrical centering of the pen for each channel. This is also a locking control, operated by means of the 5/32 inch Allen wrench.

2.7.2 If the OFF-ON power switch is set to ON, and the pen baseline deviates more than 1 millimeter from the pen's mechanical zero, electrical centering should be corrected in the following manner:



- Loosen the locking nut with the 5/32 inch Allen wrench.
- Set the CAL-USE switch to any of the CAL positions.
- Turn the BASELINE position knob slightly until the pen is at the desired baseline and the pen does not shift level when the OFF-ON switch is set to ON.
- Tighten the locking screw slightly.

#### 2.8 60 Hz Filters (50 Hz Filters)

NOTE: 50 Hz filters are provided on instruments operating on a line frequency of 50 Hz.

2.8.1 There are two 60 Hz filters on each Amplifier. Not ALL models.

2.8.2 The 60 HZ FILTER (PENS) switch rejects interference from AC sources, if present, by means of a notch filter having fairly sharp attenuation. See Figure 2.8.2. This filter affects the pen response only.



FIGURE 2.8.2



FIGURE 2.8.3

2.8.3 The 60 HZ FILTER (J6) switch rejects interference from AC sources, if present, by means of a notch filter having fairly sharp attenuation. This filter affects the amplifier response when monitored at the J6 output. See Figure 2.8.3.

2.8.4 Switching these controls to IN filters out a reasonable amount of 60 Hz artifact with very little loss of desired frequencies. If the filters are switched to IN, a notation of this fact should be made on the recording when the change is made. NOTE: These filters are designed for emergency use (as in operating room recording) and are not intended as a substitute for proper installation and techniques in a permanent laboratory set-up.

# FRONT PANEL CONTROLS

## Section 2.9

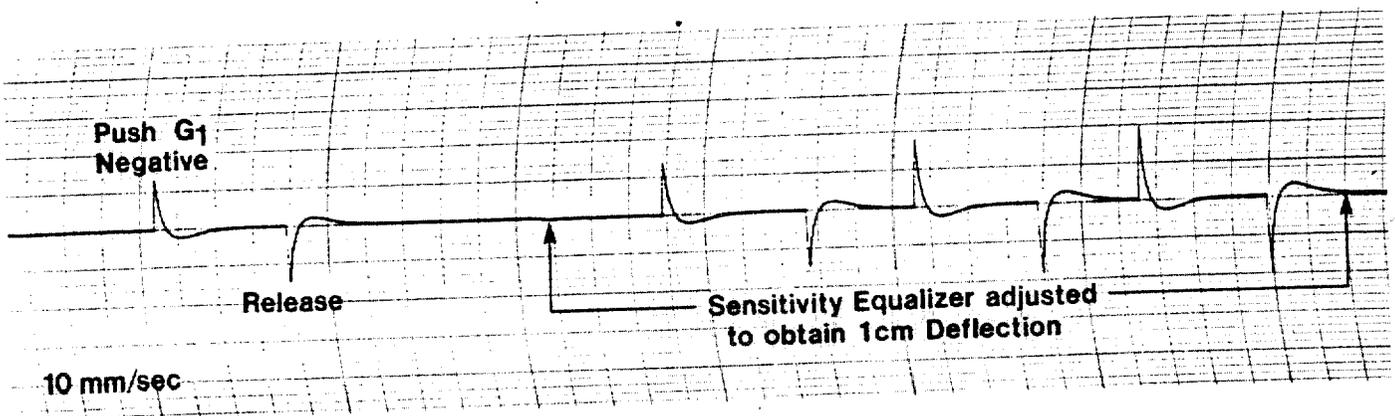
### 2.9 Calibration of the 7P511 Amplifier

2.9.1 Ground the console as described in the specific manual (Model 7/78 or Model 79 Series). Proceed to calibrate as follows:

- a. Select a convenient chart speed (10, 15 or 30 millimeters/second) and make sure that the paper is tracking correctly.
- b. By using the appropriate control settings indicated below, the 7P511 can be calibrated so that 50 microvolts = 1 centimeter. This procedure will ensure the accuracy of the remaining sensitivity selections.

CAL-USE	= 50 $\mu$ V
1/2 AMP LO FREQ	= 1 Hz
$\mu$ V/MM-MV/CM	= $\mu$ V/MM
SENSITIVITY	= 5
EQUALIZER	= Adjust so that 50 $\mu$ V signal gives 1 cm
BASELINE	= Set to center pen
1/2 AMP HI FREQ (J6)	= 30 kHz
1/2 AMP HI FREQ (PENS)	= 90 Hz
BOTH 60 Hz FILTERS	= OUT
POWER	= ON

- c. With the MASTER WRITER switch at the CHART & PENS position, depress the CAL G<sub>1</sub> NEG pushbutton switch on the 7P511 and let it remain until the pen has returned to its original baseline (produces an upward pen deflection).
- d. Release the CAL G<sub>1</sub> NEG pushbutton and note the downward deflection of the pen and its subsequent return to the baseline.
- e. With a metric rule, measure the upward deflection from the baseline to the peak of the decay point, ignore any overshoot. It should be exactly 10 millimeters (1 centimeter). If it is not, rotate the EQUALIZER control (clockwise for a higher deflection, counterclockwise for a lower deflection) slightly.
- f. Repeat Steps d through e until the calibration deflection is exactly 10 millimeters. All other positions of the sensitivity step attenuator will now be correct. Always let the pen return to its baseline between successive deflections.



MODEL 7P511 CALIBRATION RECORDING  
FIGURE 2.9.1

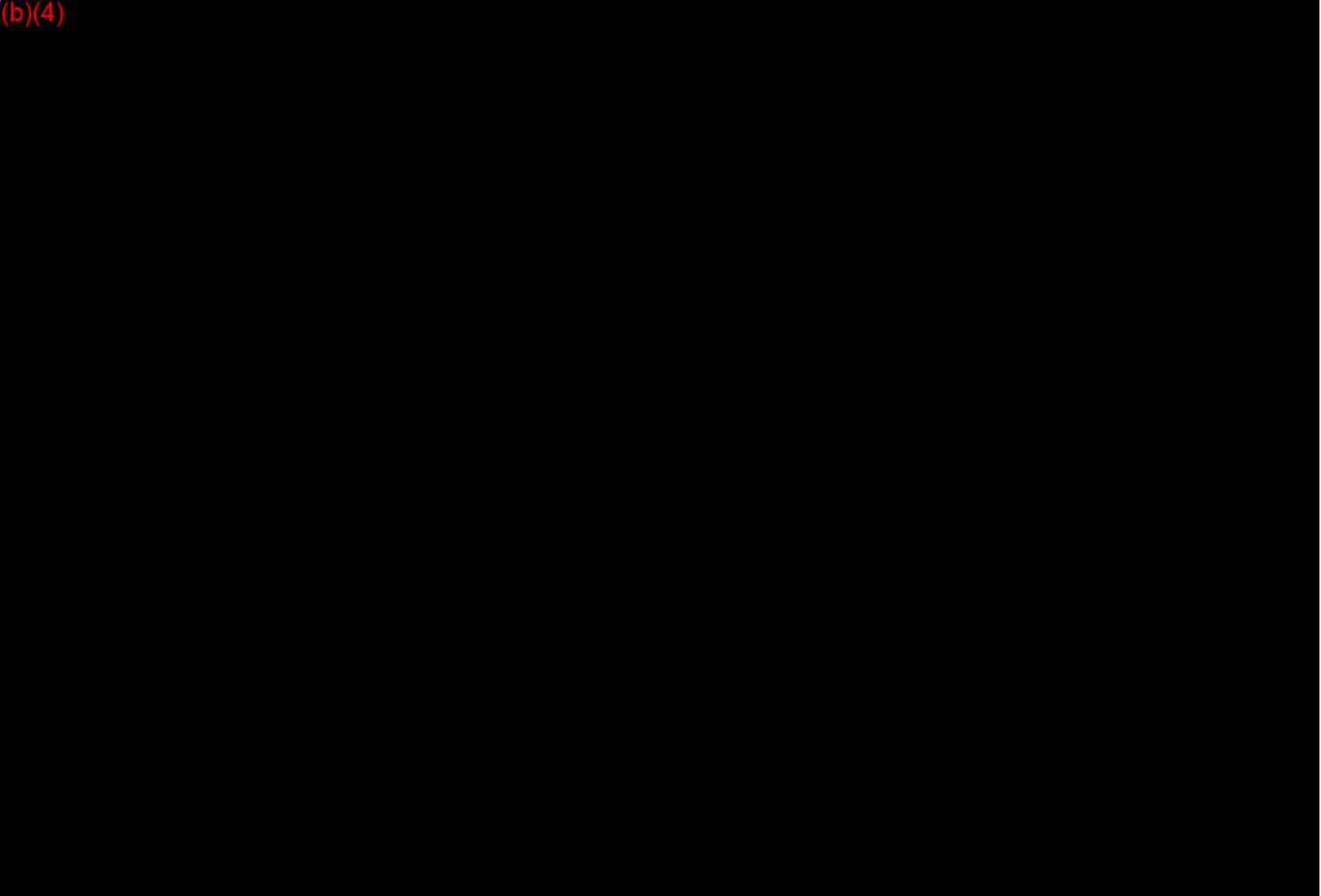


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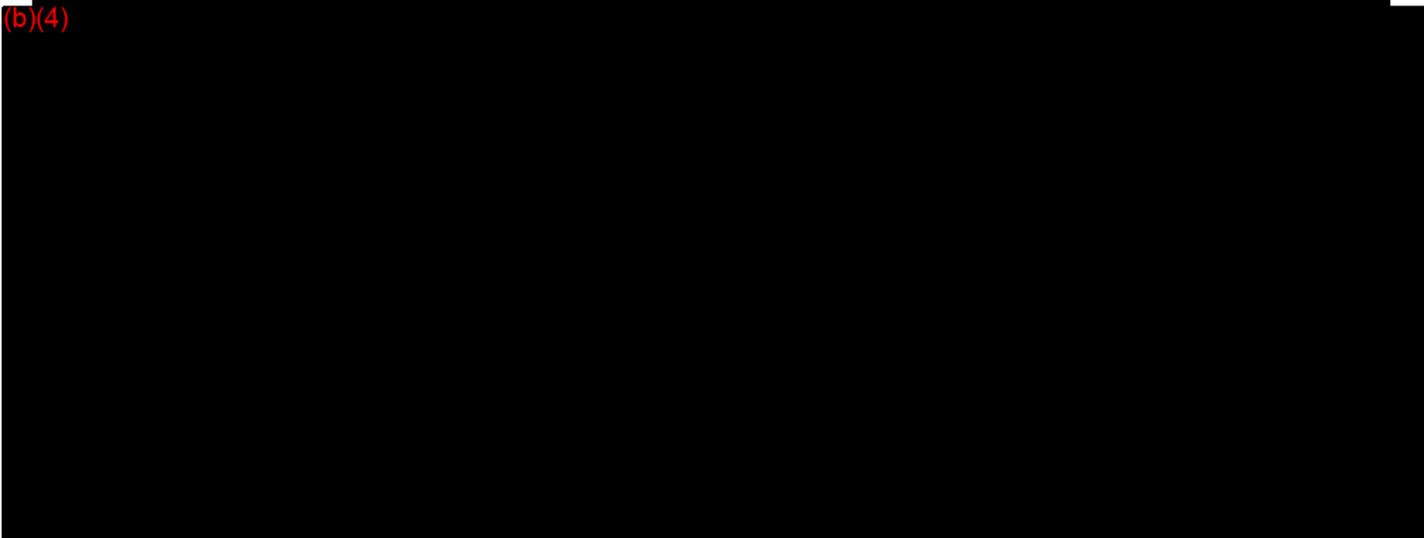
# REPORT OF CLINICAL EXPERIENCE WITH SILENT NIGHT I

## Introduction and Study Objectives

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3

## Cardiopulmonary and Neurological Consequences of Obstructive Sleep Apnea

\*<sup>†</sup>Kingman P. Strohl, <sup>†,‡</sup>Thomas Roth, and <sup>§</sup>Susan Redline

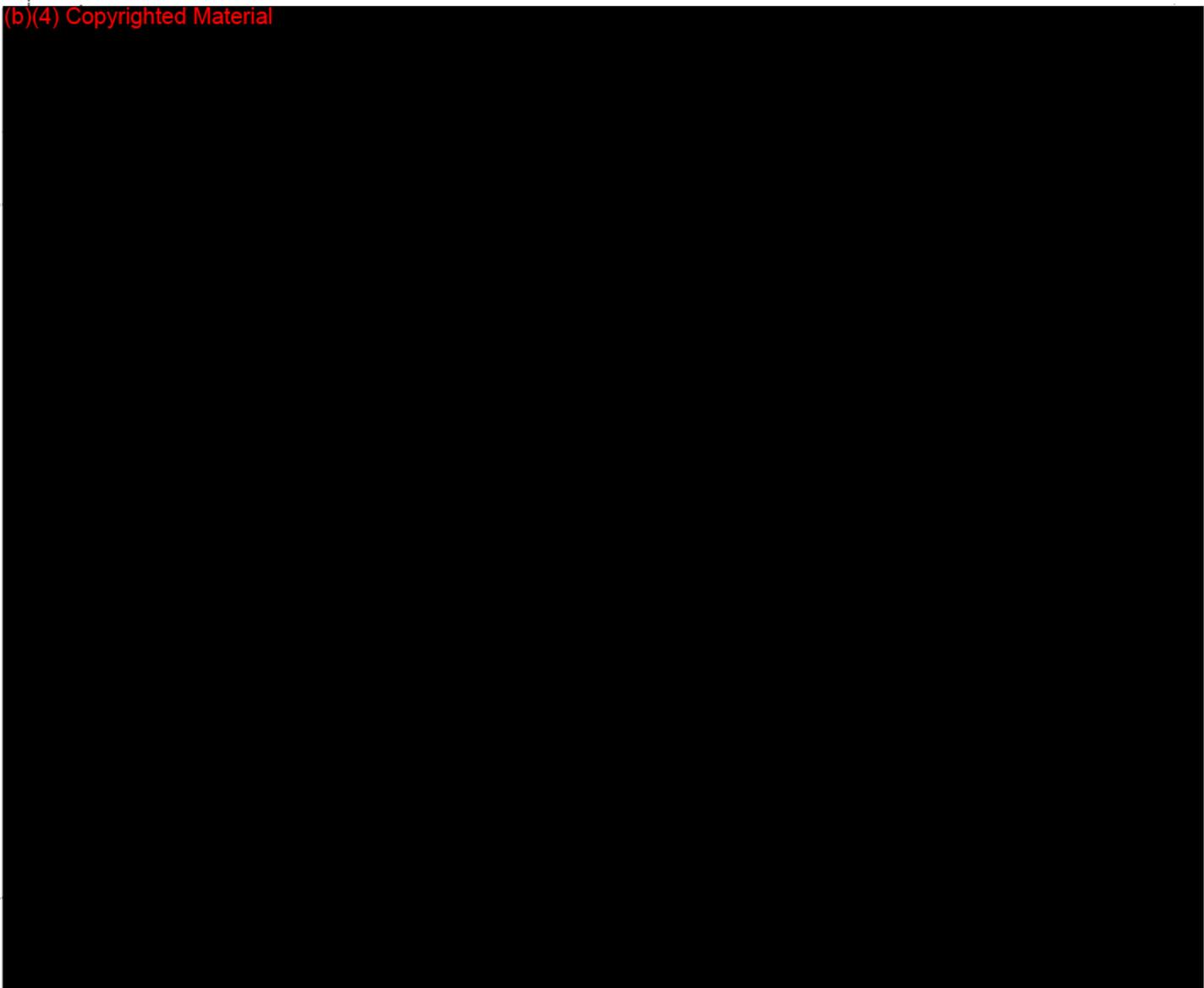
*\*Department of Medicine, Division of Pulmonary and Critical Care Medicine,  
University Hospitals of Cleveland, Cleveland, Ohio 44106;*

*‡Sleep Research and Disorders Center, Henry Ford Hospital, Detroit, Michigan 48202;*

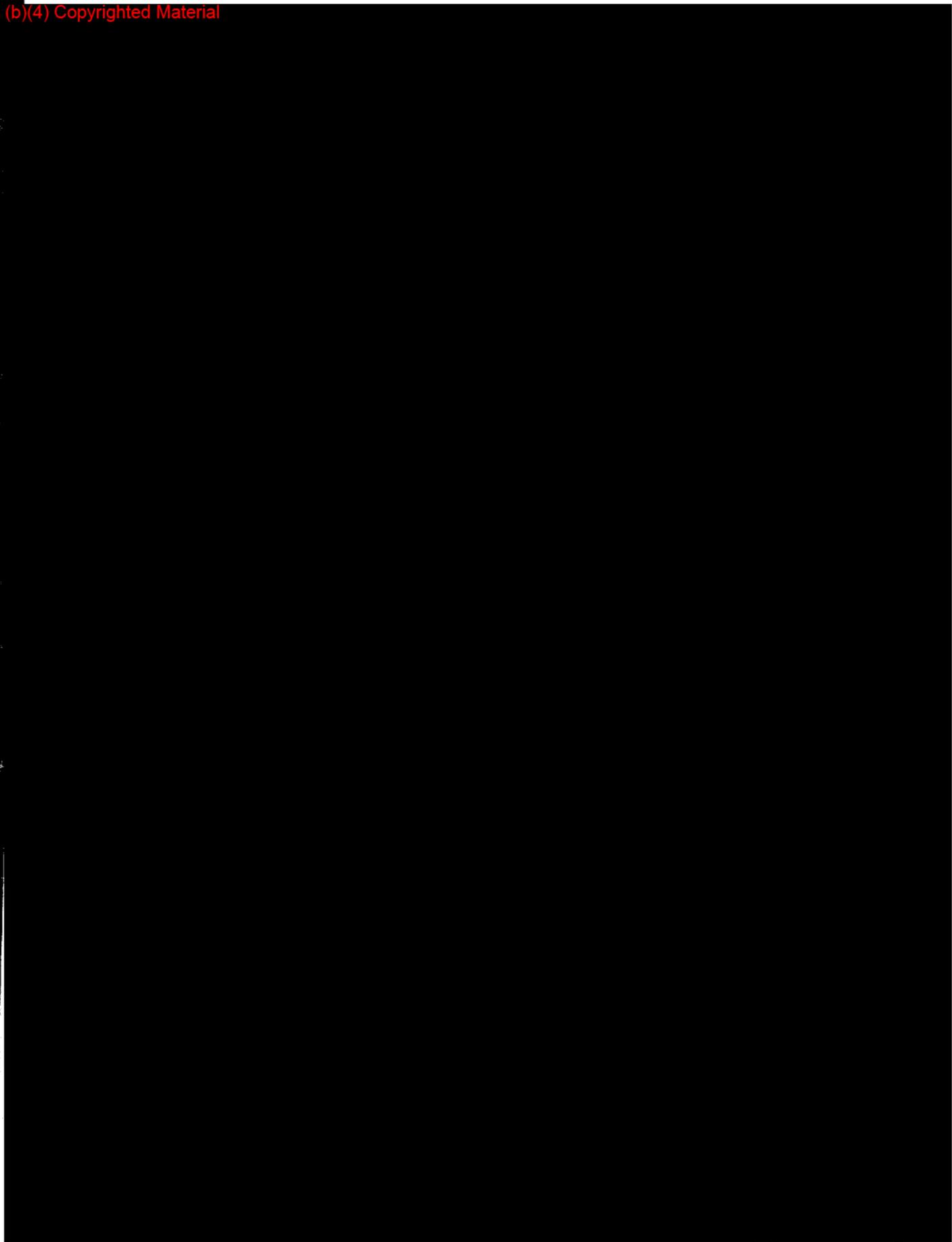
*§Pulmonary Section, Veterans Administration Medical Center, Cleveland, Ohio 44106; and*

*†Department of Medicine, Case Western Reserve University, Cleveland, Ohio 44106*

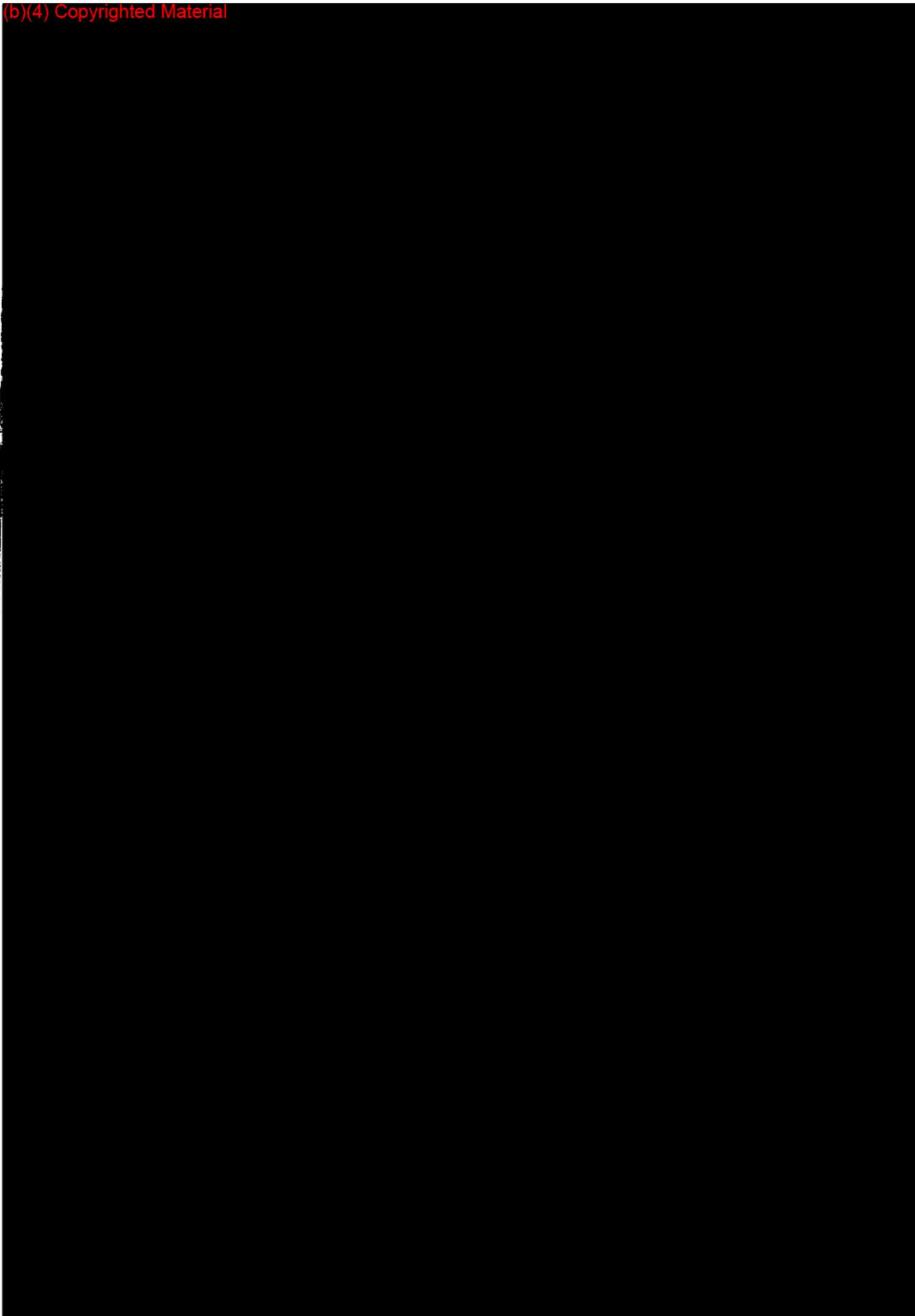
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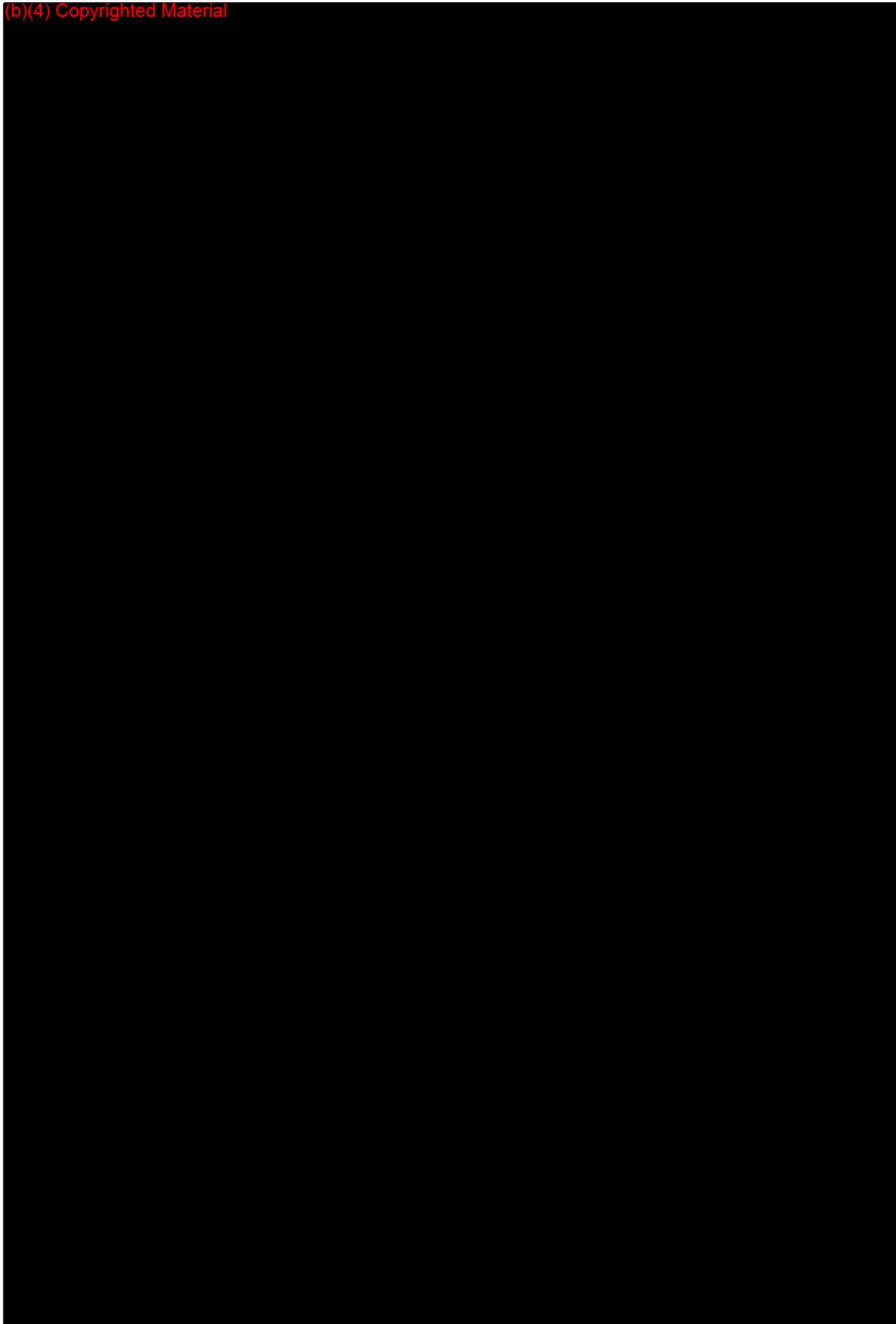
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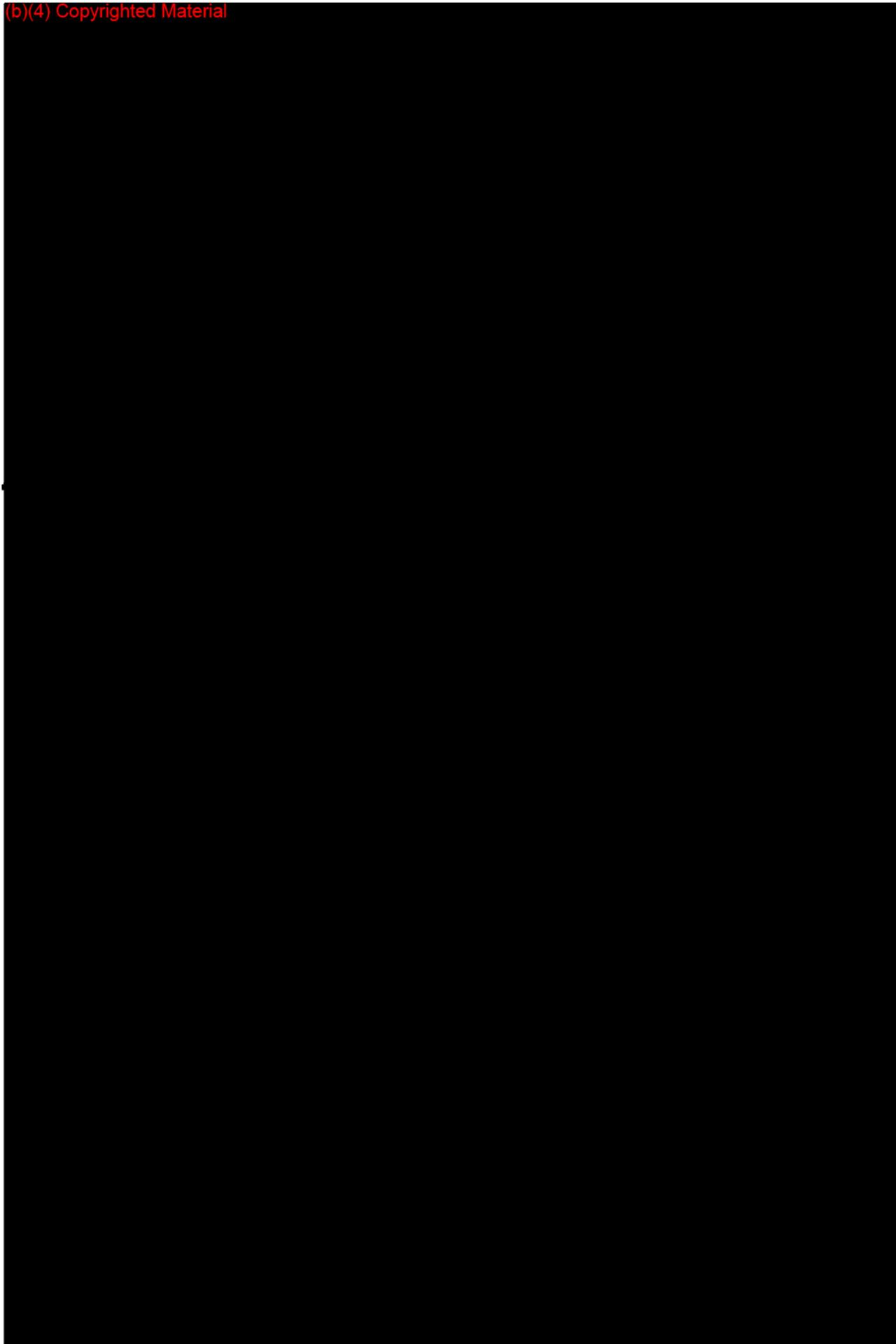
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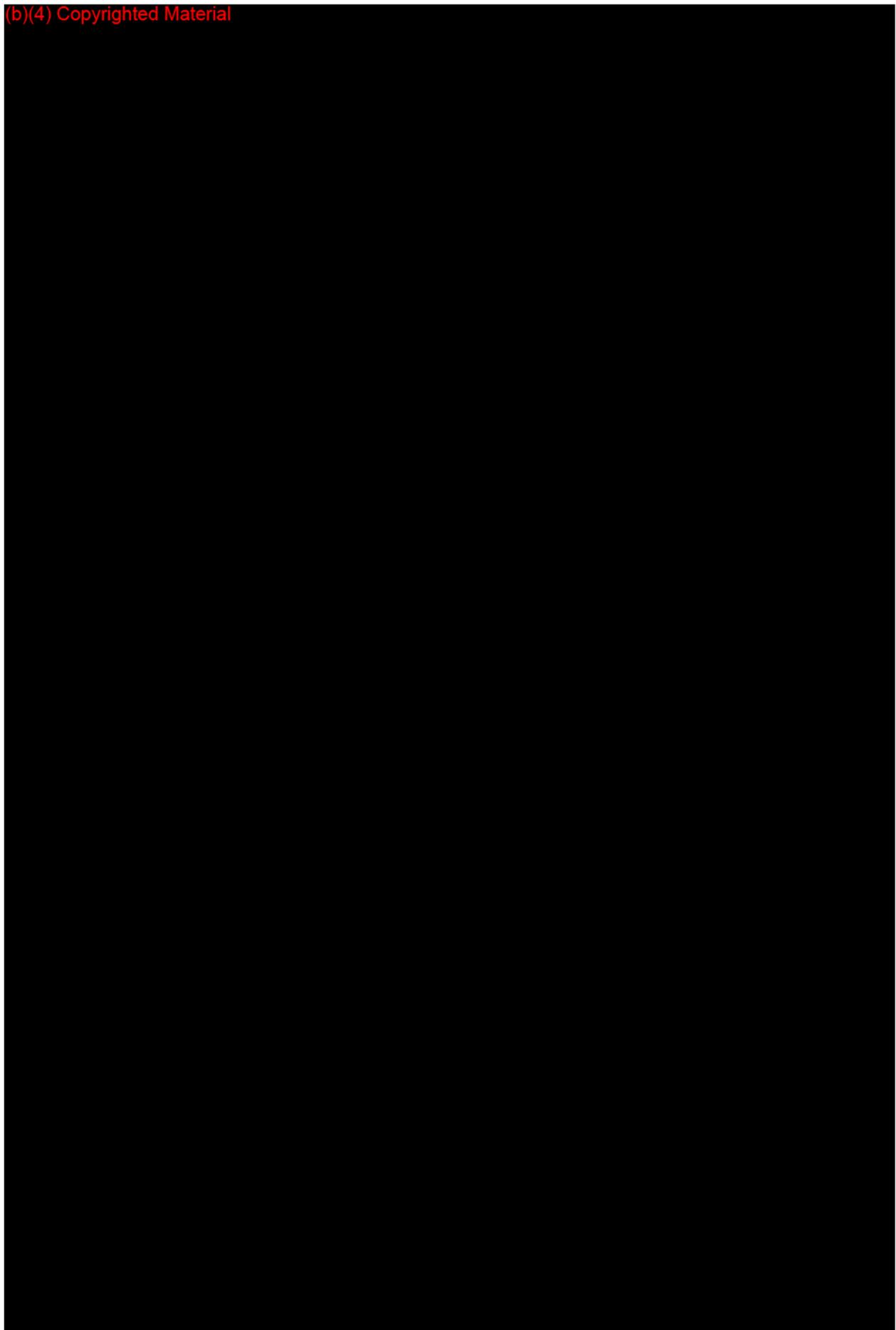
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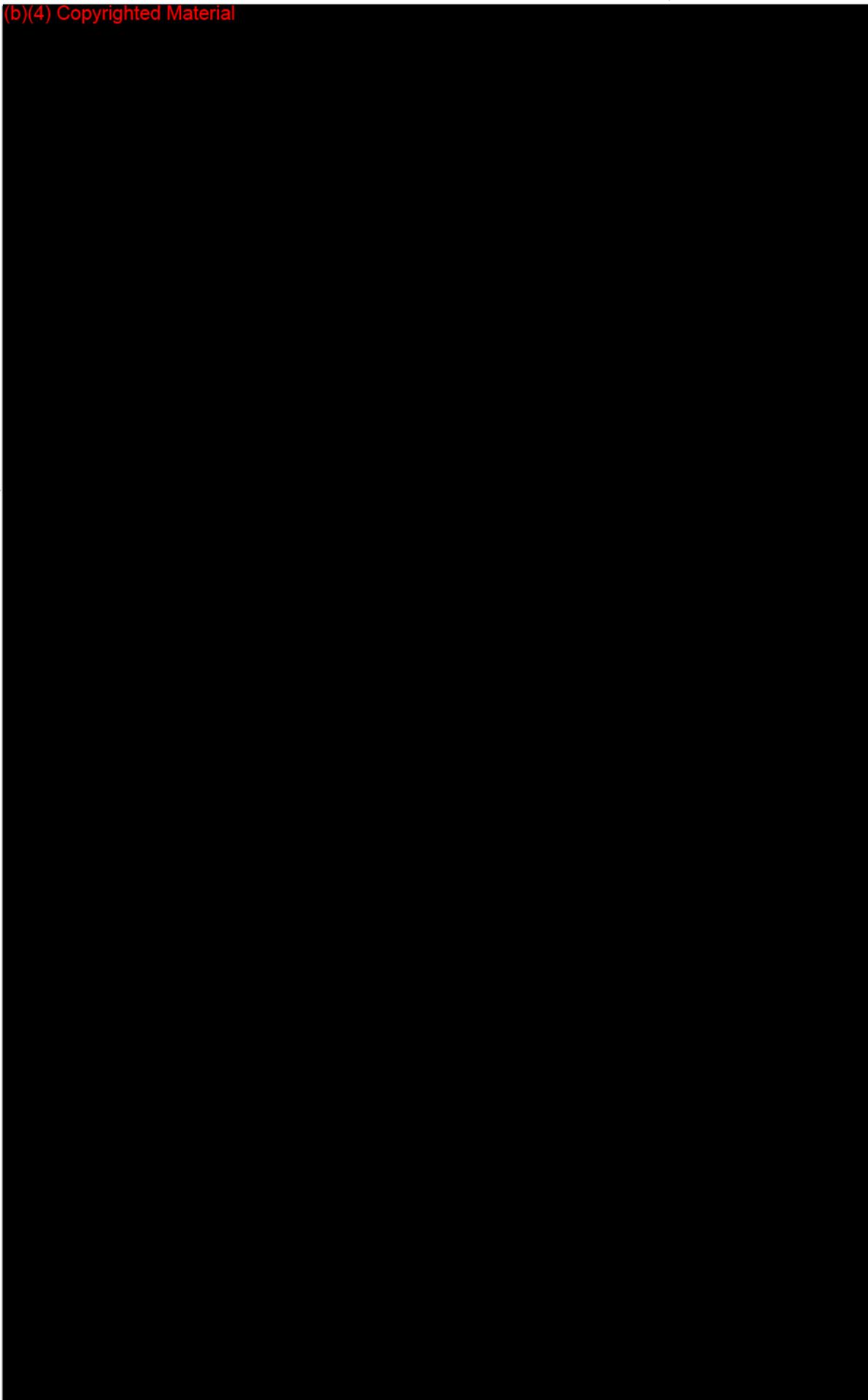
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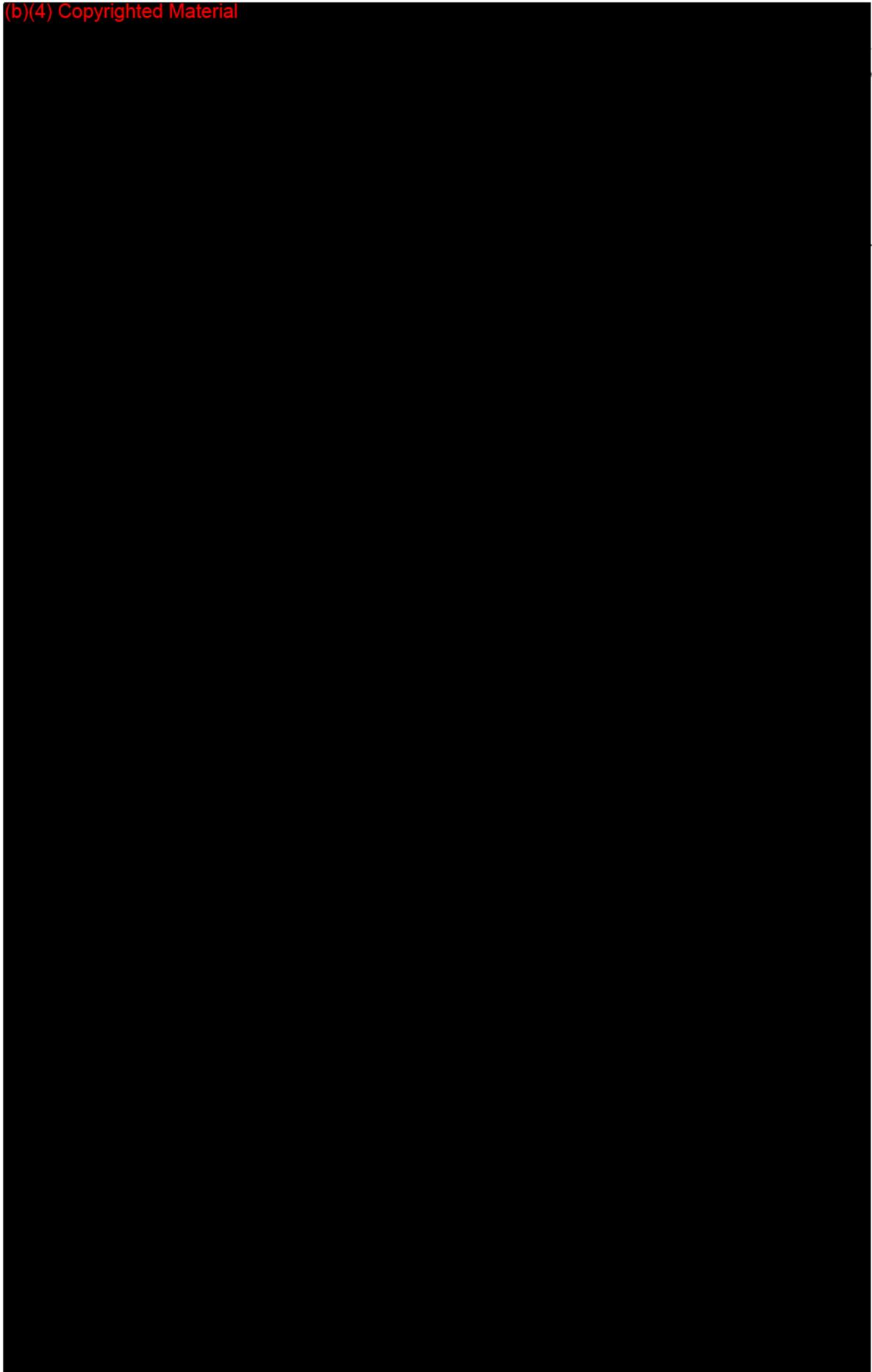
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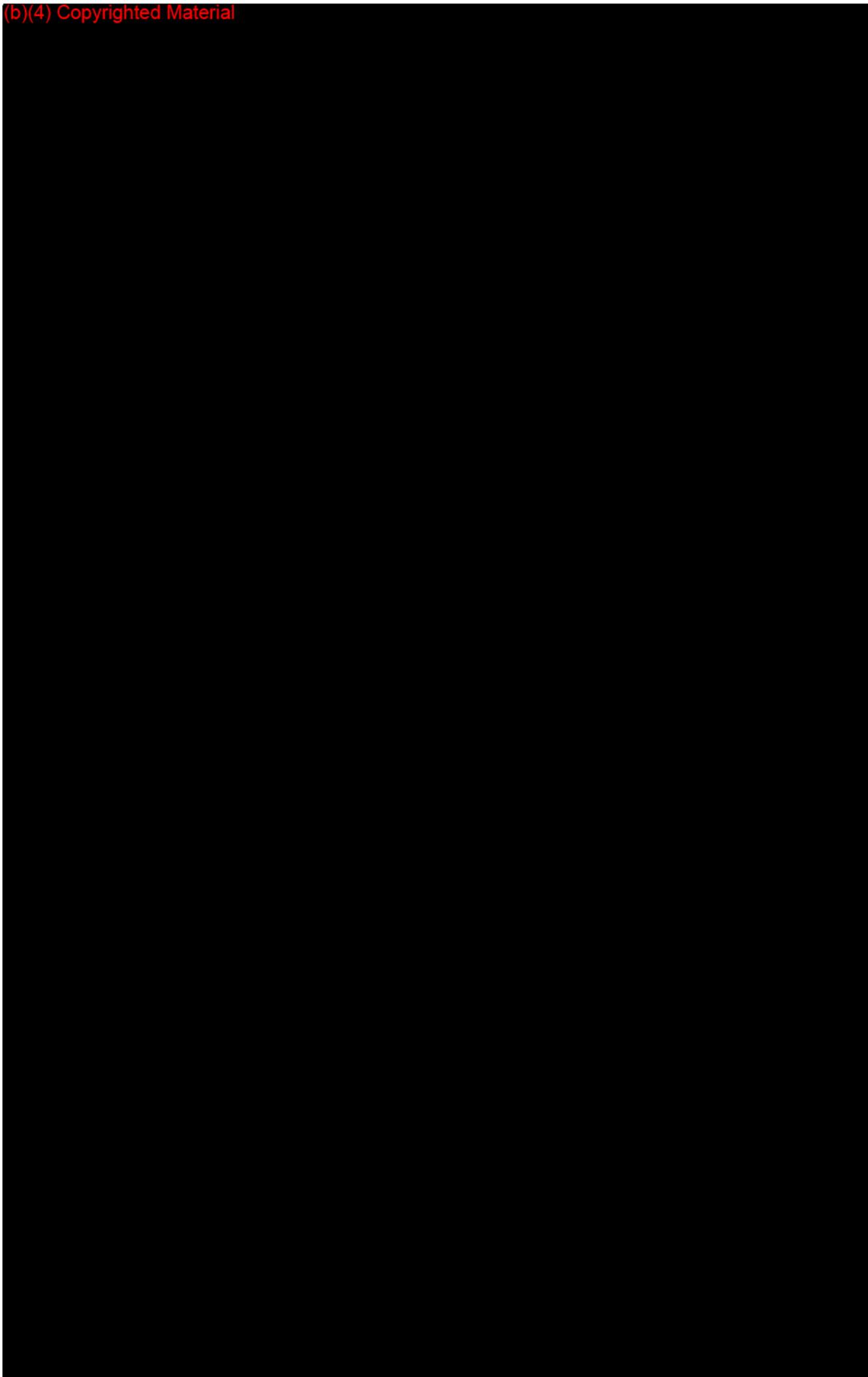
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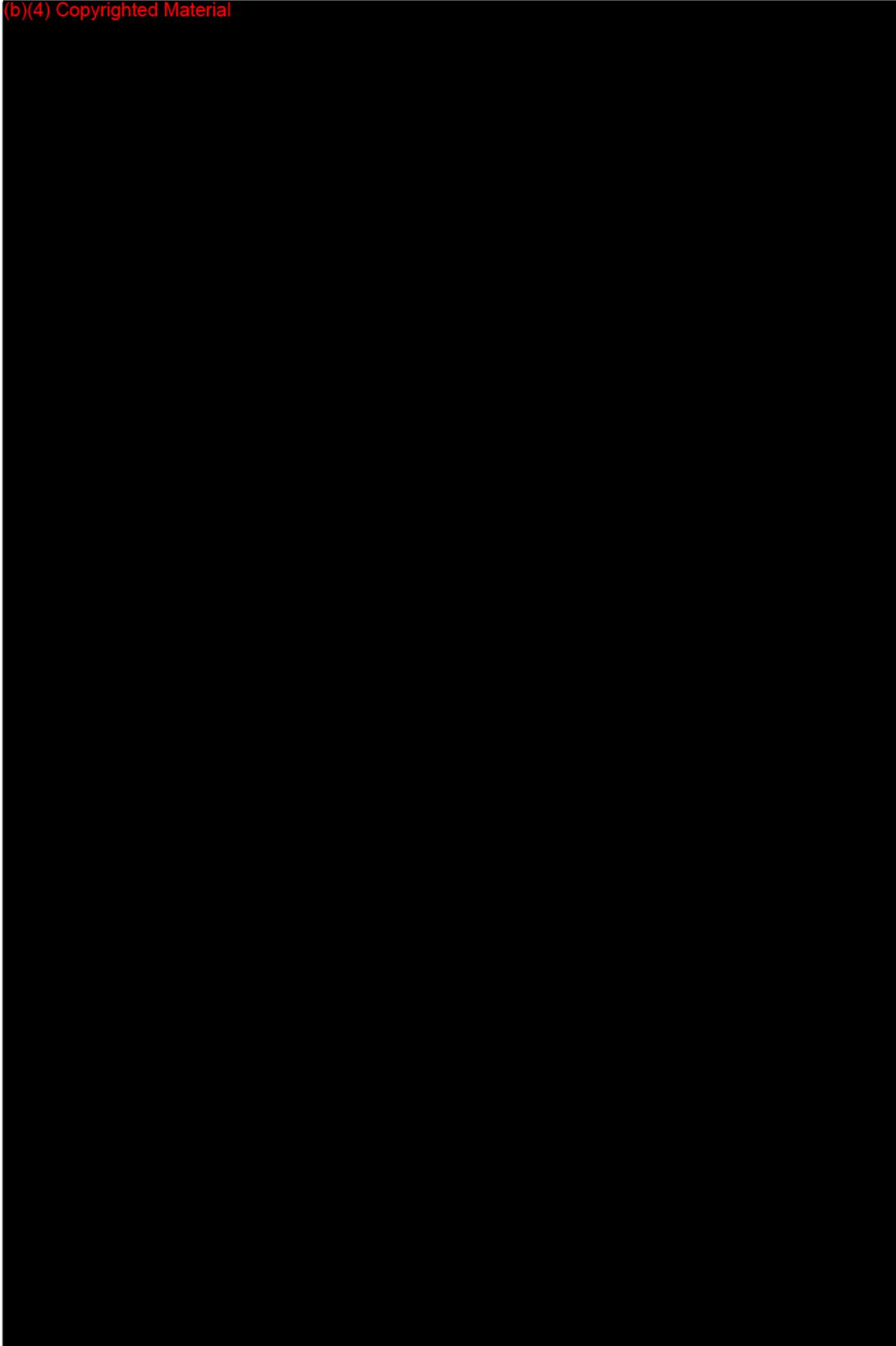
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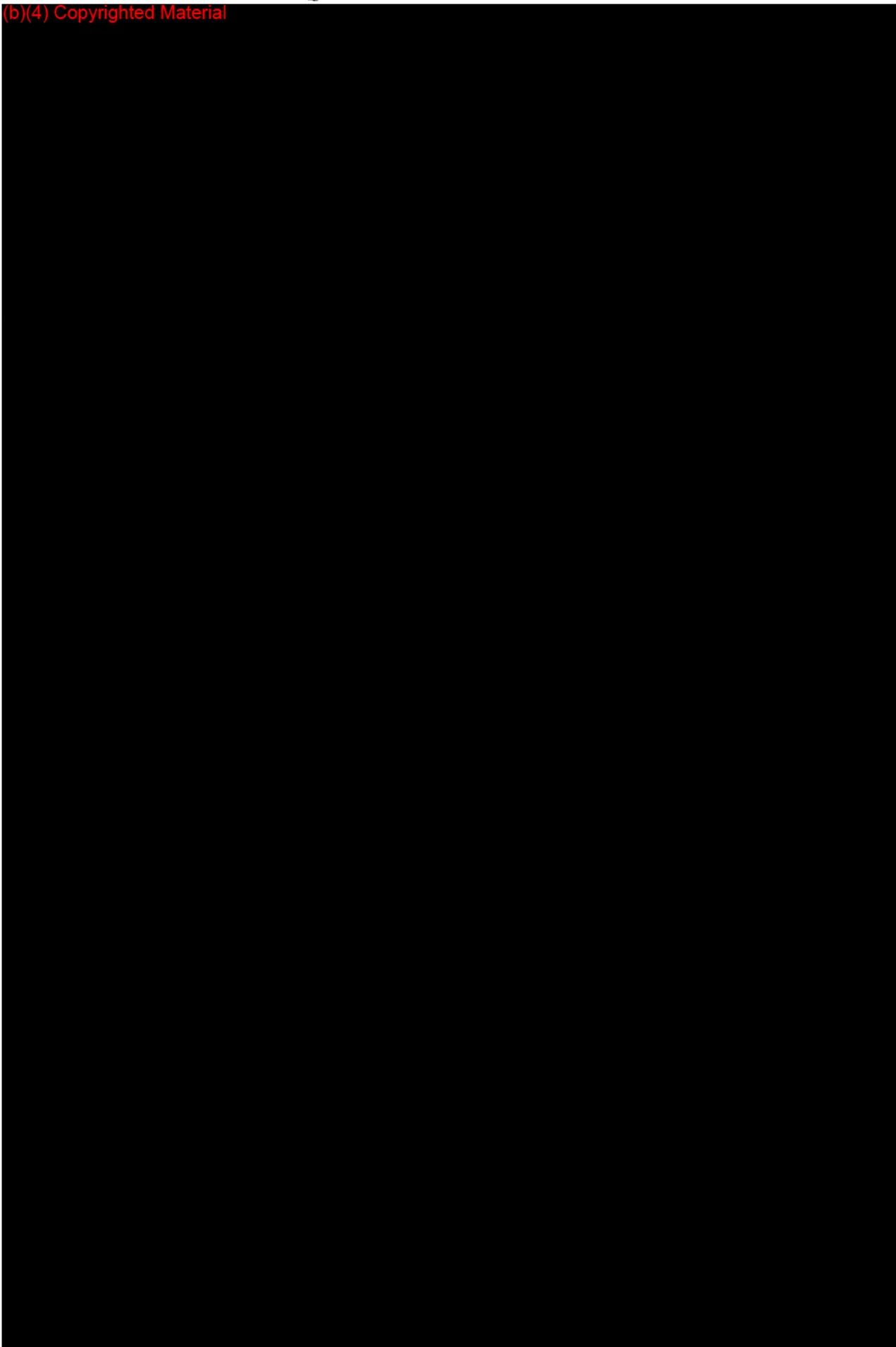


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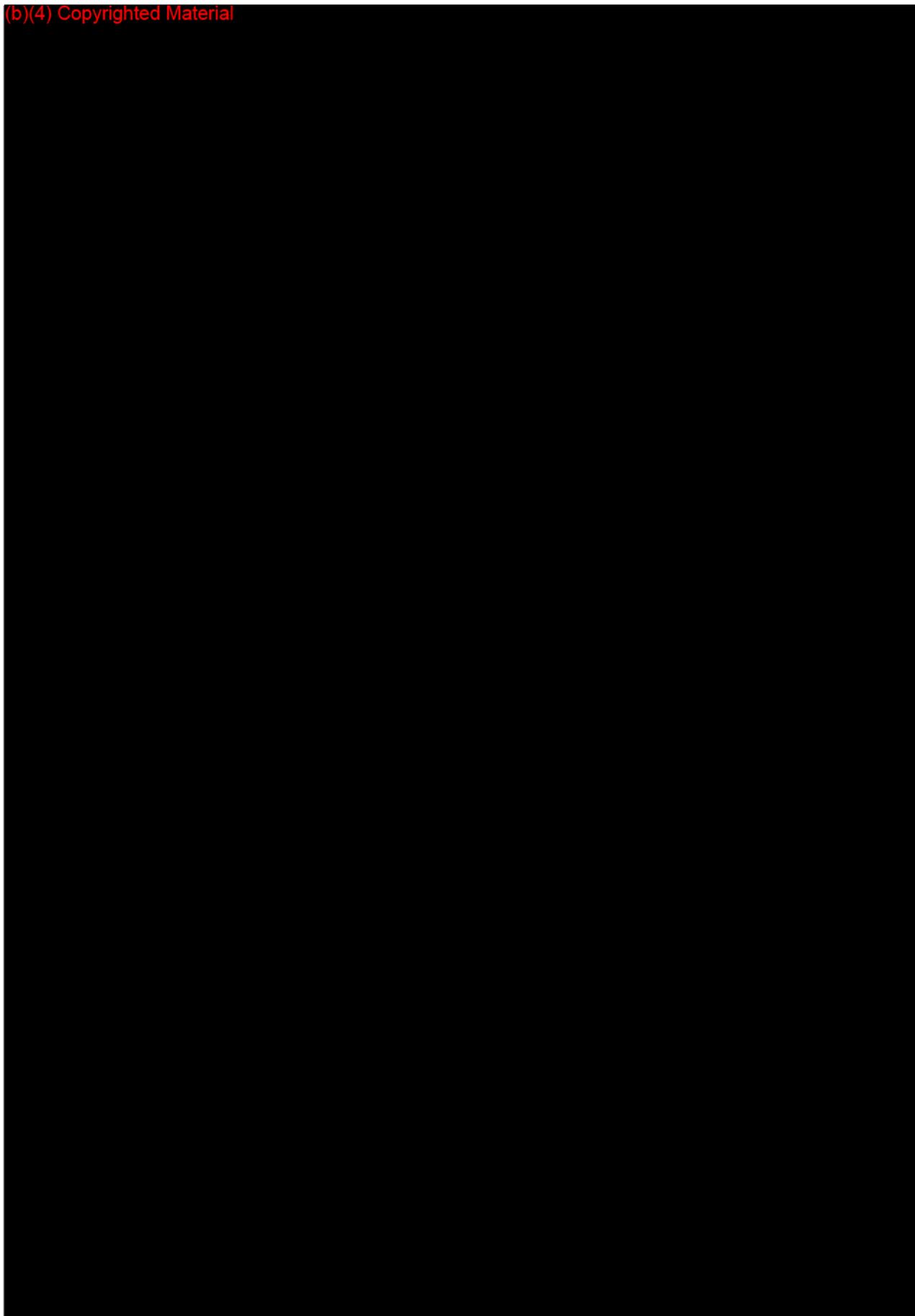


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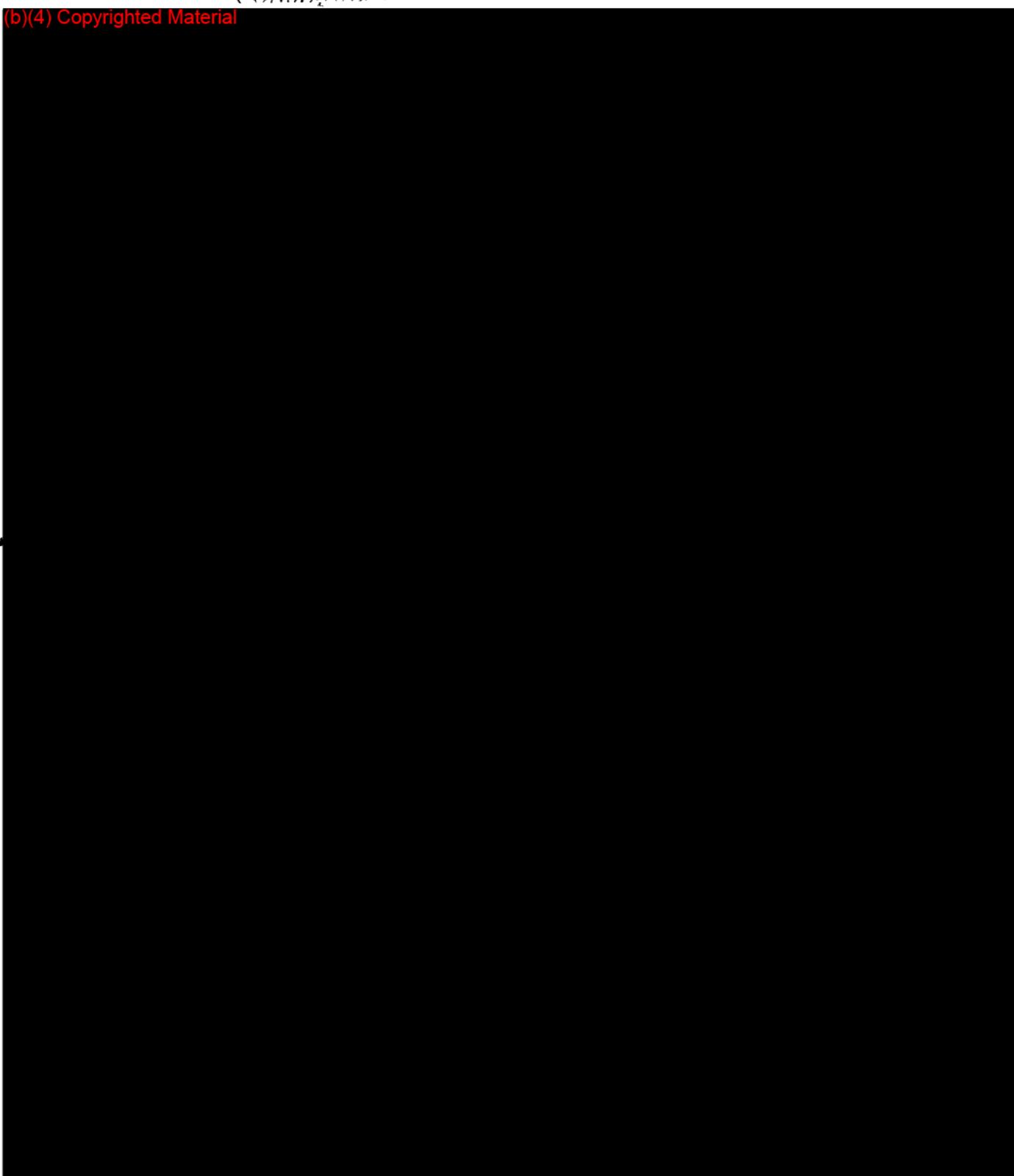
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# SECTION 6

## PROPOSED LABELING

**SECTION 6  
PROPOSED LABELING**

**Package Inserts:** Included in this section are the Instructions for Use for the Physician (*Attachment 6a*) and Patient Information and Instructions for Use (*Attachment 6b*).

**Product Labels:** Also included in this section are labels placed on the outer package and on the device (*Attachment 6c*).

**Proposed Promotional Claims:** This section also contains a list of proposed promotional claims for the Silent Night I (*Attachment 6d*).

**INSTRUCTIONS FOR USE  
for PHYSICIAN**

DRAFT

LOCAL SILENCE, INC.

**SILENT NIGHT I  
Ventilatory Effort Monitor  
Apnea Detector**

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

**Device description:** The Silent Night I is a portable, line-powered ventilatory effort monitor, consisting of a metal enclosure measuring approximately 23 centimeters wide by 17 centimeters deep by 7.5 centimeters high, and weighing approximately three pounds. The enclosure contains the operational components of the device and has two receptacle connectors: one for input power and another for the sensing microphone. This microphone is attached to the SNI by means of an eight-foot flexible cable and connector and senses breathing sounds during sleep. Another microphone is built into the rear of the box and senses room ambient noise. A POWER switch is located on the back of the unit. A switch enabling the user to PAUSE and RESUME device operation is located on the side of the unit.

(Insert Figure here)

The device operates as follows: the sound field (breathing sounds + room ambient noise) is sensed by the two microphones and sent to the controller, which extracts breathing sounds from all sounds received. These signals are then sent through filters and analyzed. The signals are processed and the device differentiates among types of sounds and classifies them as regular snoring or breathing, hypopnea, or apnea. These classified events are logged cumulatively and displayed on the control panel on the front of the device.

(Insert Figure here)

**Indications for use:** The Silent Night I is indicated for use in the diagnostic evaluation of adults with possible Obstructive Sleep Apnea. It is intended to measure a patient's respiratory rate. The device is designed for use in home screening of adults with possible sleep disorders.

The Silent Night I is intended for use as a diagnostic device in conjunction with information from physical examination and laboratory data. No physiologic alarms are present.

**Precautions and warnings:** Because of its sensitivity to ambient noise and breathing sounds, the Silent Night I should not be used in the presence of a ticking watch.

**Contraindications:** The Silent Night I is not intended for use with infants or children.

**Complications:** There are no known complications associated with use of the Silent Night I.

### **Instructions for Use:**

**Device Setup:** The patient should be given the "Patient Information and Instructions for Use" pamphlet, and instructed to set up the Silent Night I as follows:

1. Remove the unit from the box and place it on a table or nightstand next to the patient's bed. The control panel should be placed at a 45-degree angle from the edge of the bed.
2. Check to see that the POWER switch on the back of the unit is in the OFF position.
3. Attach the sensing microphone mounting bracket to the bed frame as shown in the figure below. (Insert figure here)
4. Plug the connector end of the power cord into the receptacle on the back of the unit, then plug the pronged end of the cord into a wall outlet.
5. Plug the connector end of the microphone into the receptacle on the back of the unit, then attach the microphone to the mounting bracket.

### **Conducting the Sleep Study:**

1. When the patient is ready for sleep, he or she should flip the POWER switch on the back of the unit to the ON position and record the time the switch was flipped. The green power-on light on the front control panel will illuminate, indicating that the unit is operating.
2. If the sleep study is interrupted, by, for example the patient arising during the night, the patient should flip the PAUSE/RESUME rocker switch, located on the side of the Silent Night I unit, to the PAUSE position. When the patient is ready to return to sleep, they should flip the switch to the RESUME position. This PAUSE/RESUME activity is important to ensure the appropriate calculation of the relationship of breathing events to duration of sleep. If the PAUSE/RESUME switch is not pressed, the device software will listen for two minutes. If breathing sounds do not resume, the device will automatically enter the PAUSE mode automatically. When breathing sounds resume, the Silent Night I will again record and analyze the sounds.

3. When the patient awakens in the morning, they should immediately flip the POWER switch on the back of the unit to the OFF position to terminate the sleep study. The patient should then write down the time the switch was flipped and the DBE's shown on the liquid crystal display.

#### **After the Sleep Study:**

The patient should be instructed to bring the record of start and stop times and number of DBE's when he or she returns to the clinic. The physician can then calculate the Respiratory Disturbance Index as follows: Divide the total number of DBE's by the total sleep time in minutes, then dividing this number by 60. This index represents the average number of DBE's per hour. Based on the RDI, patient signs and symptoms and other diagnostic criteria, the physician can then determine the need for additional evaluation.

#### **Cleaning, handling, maintenance, reuse**

The Silent Night I has not been tested for fluid spill resistance. Hence, proper operation cannot be assured if the device is immersed or exposed to fluids. The device may, however, be wiped clean with a damp cloth.

The Silent Night I has been constructed of durable materials and tested for proper operation following mechanical and environmental stresses. It should, however, be handled with care to avoid damage to the box and components. It should be stored in the shipping package when not in use. The device should be stored within the temperature range of -20 to 55 degrees C (-6 to 136 degrees F).

As long as the Silent Night I is not damaged and there is no evidence of malfunction, each unit may be reused many times. If damage or malfunction is noted, please document the problem and promptly contact a technical service representative at Local Silence, Inc. No routine maintenance or repairs can be performed by the user.

#### **Manufactured for:**

Local Silence, Inc.  
934 Fremont Ave., Suite 115  
Los Altos, CA 94024 USA  
Telephone (415) 917-9130  
Fax (415) 917-9132

Document number XXX-XXX-XX  
Revision 0, September, 1996

DRAFT

**PATIENT INFORMATION  
and  
INSTRUCTIONS FOR USE**

**LOCAL SILENCE, INC.**

**SILENT NIGHT I  
Ventilatory Effort Monitor  
Apnea Detector**

**Introduction**

The Silent Night I is a portable ventilatory effort monitor (apnea detector) for adults. Your doctor has determined that you should use the Silent Night I to provide information about your breathing patterns during sleep at home. Your doctor will use the information from your use of the Silent Night I, along with information from other evaluations, to arrive at a diagnosis.

The Silent Night I records and analyzes the breathing sounds made during sleep. The device has specially-developed software to enable it to distinguish among different sounds, such as normal breathing, snoring, and abnormal breathing patterns. Certain abnormal breathing patterns may be classified by the Silent Night I as Disordered Breathing Events, or DBE's. You will be asked to write down the number of DBE's recorded by the Silent Night I, as well as the start and stop times of your sleep cycle. Only your physician can determine the significance of the number of DBE's recorded by the Silent Night I. If you have any questions about the DBE's or any other aspect of the sleep study, please discuss them with your doctor.

Before you use the Silent Night I in your home during a regular night's sleep, you will be instructed by your doctor on the operation of the device. Listed below for your reference are the instructions for use for the Silent Night I. Following these instructions closely is critical to obtaining useful information from your sleep study. Again, if you have any questions about the operation of the Silent Night I or what you need to do, please ask your doctor.

**Device Setup:**

1. Remove the unit from the box and place it on a table or nightstand next to your bed. The control panel should be placed at a 45-degree angle from the edge of the bed.
2. Check to see that the POWER switch on the back of the unit is in the OFF position.

3. Attach the sensing microphone mounting bracket to the bed frame as shown in the figure below. (Insert figure here)
4. Plug the connector end of the power cord into the receptacle on the back of the unit, then plug the pronged end of the cord into a wall outlet.
5. Plug the connector end of the microphone into the receptacle on the back of the unit, then attach the microphone to the mounting bracket.
6. Place a pencil and paper at the bedside for writing down sleep study information.

**Conducting the Sleep Study:** The most important things to remember are shown in **bold type** and are underlined.

1. When you are ready for sleep, flip the **POWER** switch on the back of the unit to the **ON** position and write down the time the switch was flipped. The green power-on light on the front control panel will light up, indicating that the unit is operating.
2. If the sleep study is interrupted during the night-- for example, if you need to get up for any reason-- press the PAUSE/RESUME switch, located on the side of the Silent Night I unit, to the **PAUSE** position. When you are ready to return to sleep, press the switch to the RESUME position. This PAUSE/RESUME activity is important to ensure accurate recording of breathing events by the Silent Night I, but if you forget to do this, continue with the rest of the instructions and the sleep study.
3. When you awaken in the morning, you should immediately flip the POWER switch on the back of the unit to the **OFF** position. Then write down the time the switch was flipped and the DBE number shown in the display on the top of the device.

**After the Sleep Study:**

When you return to your doctor's office, it is important to bring your written record of start and stop times and number of DBE's so that your doctor can evaluate your sleep study with the Silent Night I.

DRAFT

**Cleaning, handling, maintenance**

- The Silent Night I should be handled with care to avoid damage to the box and components. It should be stored in the shipping package when not in use. The device should be stored within the temperature range of -20 to 55 degrees C (-6 to 136 degrees F).
- If you notice any damage to the Silent Night I or if does not seem to be working properly, contact your doctor for help or a replacement unit.
- The Silent Night I has not been tested for fluid spill resistance. Therefore, do not expose the unit to liquids. The device may, however, be wiped clean with a damp cloth.

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

Local Silence, Inc.  
934 Fremont Ave., Suite 115  
Los Altos, CA 94024 USA  
Telephone (415) 917-9130  
Fax (415) 917-9132

Document number XXX-XXX-XX  
Revision 0, September, 1996

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**Local Silence, Inc.**

**Silent Night I**

Ventilatory Effort Monitor

Package contents: One (1) Silent Night I monitor with accessories  
Serial number:

Manufactured for:  
Local Silence, Inc.  
935 Fremont Ave., Suite 115  
Los Altos, CA 94024 USA  
Telephone (415) 917-9130  
Fax (415) 917-9132

Store between -20 and 55 degrees C (-6 and 136 degrees F)

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

**FRAGILE**

**Handle with Care**

**Outer package labels**

10

**Local Silence**

**Label for Top of Silent Night I**

**Power**

**Label for Power Cord Outlet**

**Ambient  
Microphone**

**Label for Ambient Microphone**

**Diagnostic Port  
(Local Silence  
use only)**

**Label for Diagnostic Port**

**External  
Microphone**

**Label for External Microphone Outlet**

**PAUSE/RESET**

**Label for Pause/Reset Button**

**Device labels**

DRAFT

**PROPOSED PROMOTIONAL CLAIMS**

Proposed promotional claims for the Silent Night I are listed below, along with the page number reference on which supporting data may be found.

<b>PROPOSED CLAIM</b>	<b>PAGE NO.</b>
The Silent Night I provides a low-cost method of screening possible sleep apnea patients prior to sleep lab evaluation, potentially accelerating the diagnostic process.	99
High level of correlation with polysomnograph data.	73
Simple design and operation make the device easy to understand and use for both physician and patient, and suitable for unattended home use.	99, 103
Non-patient contacting design eliminates need for technician fittings.	31, 99
Simple set-up and non-patient contacting design eliminate inconvenience and discomfort of multiple sensors and attachments, thereby enhancing patient comfort and providing more realistic assessment of routine sleep patterns.	31, 99, 103
Provides simple, low-cost method of follow-up after medical or surgical intervention, thereby improving quality of post-operative assessment.	99

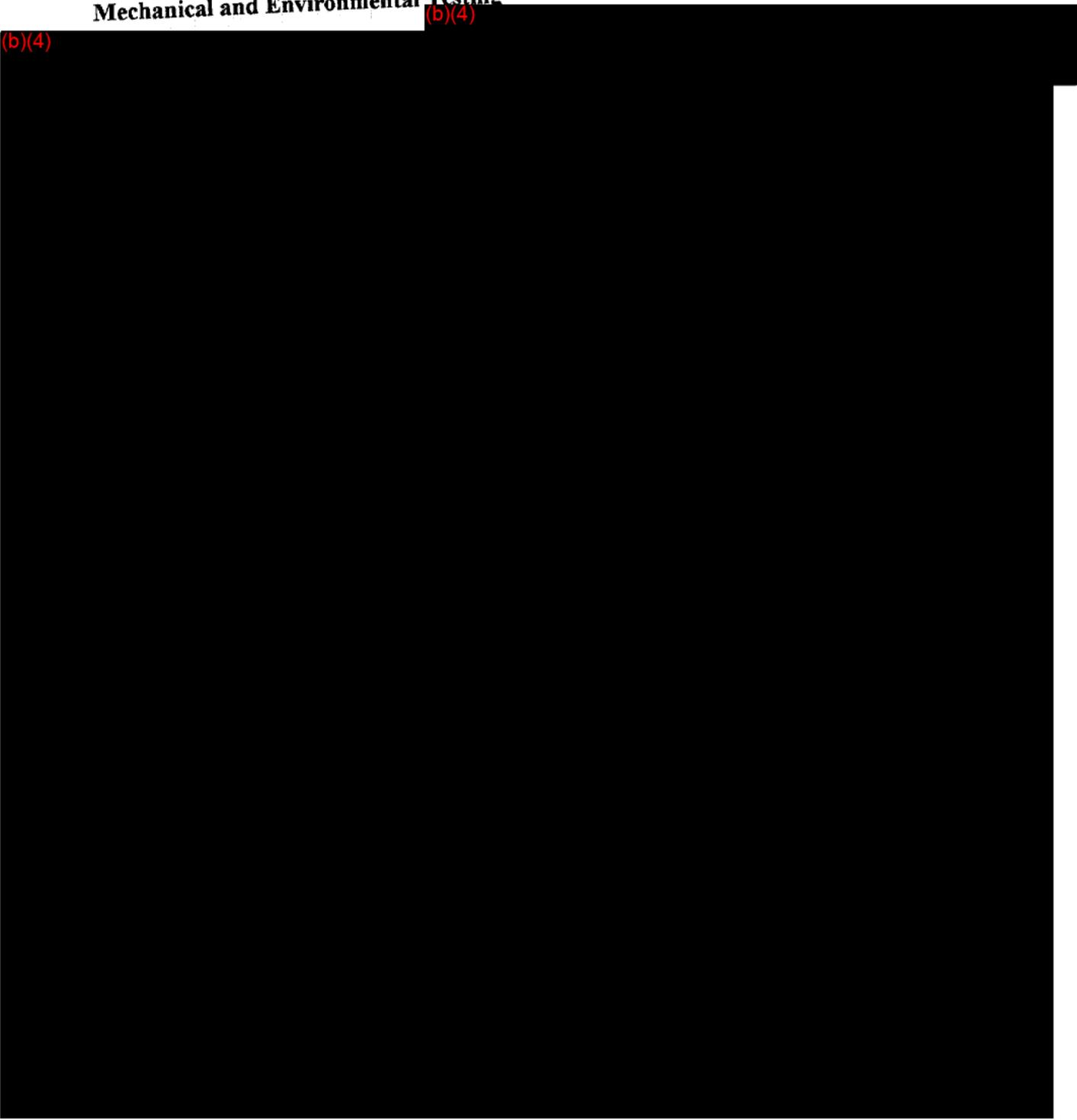
# SECTION 7

## ENVIRONMENTAL INFORMATION

160 208

**SECTION 7  
ENVIRONMENTAL INFORMATION**

**Mechanical and Environmental Testing**

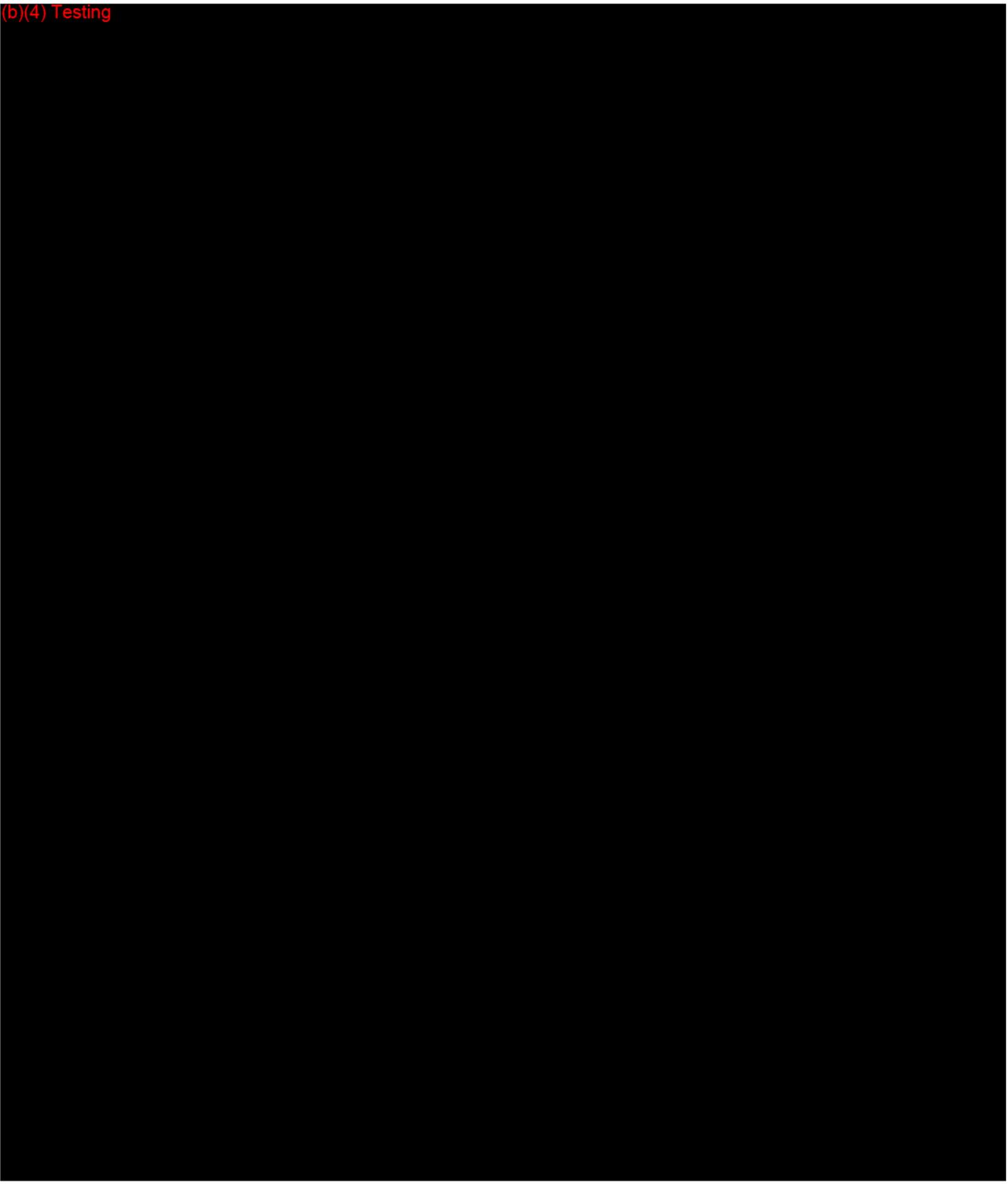


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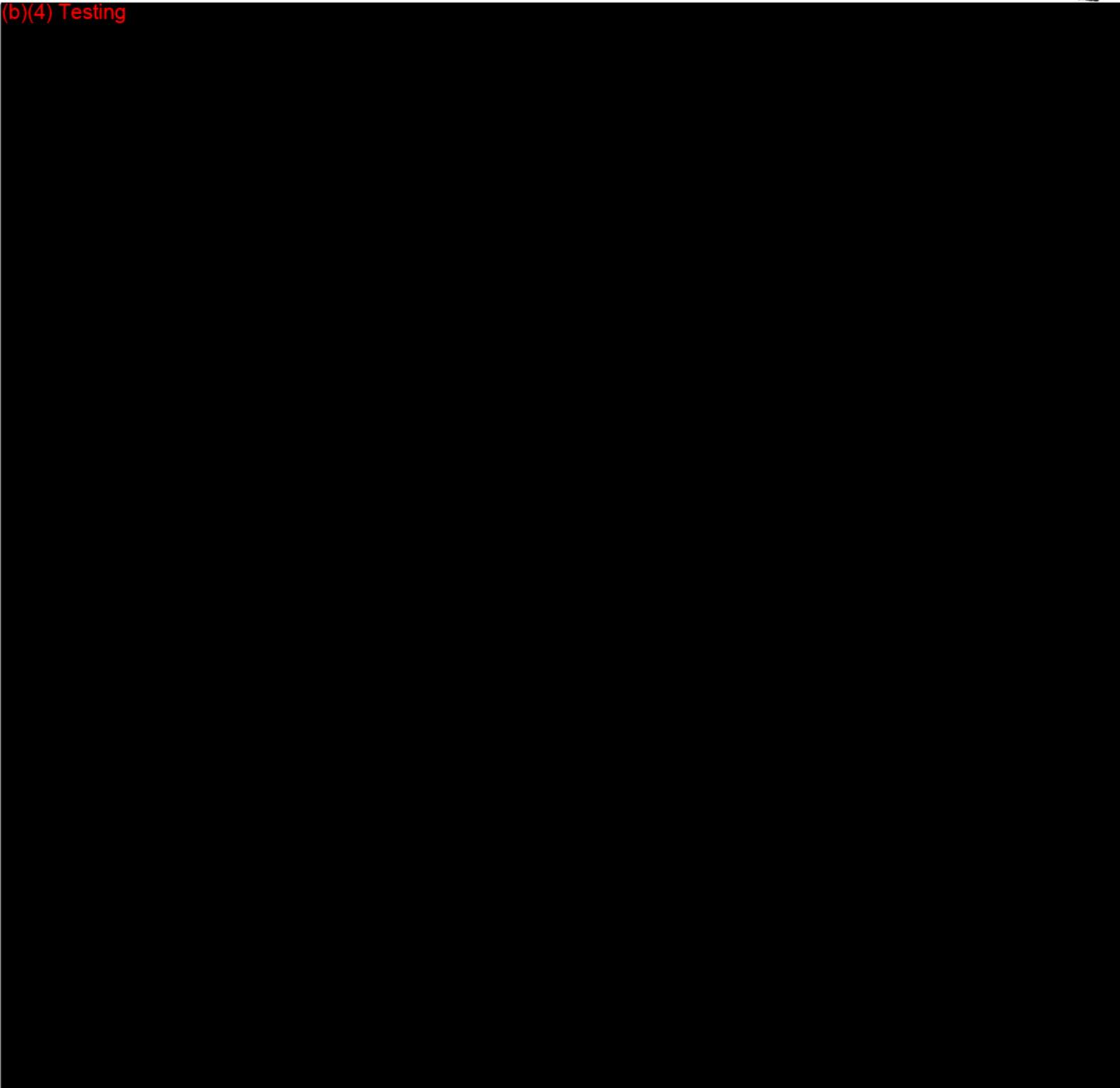
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161

(b)(4) Testing



(b)(4) Testing



1 b/s

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**Local Silence, Inc.**

**SILENT NIGHT 1**

**MECHANICAL AND  
ENVIRONMENTAL TEST  
SPECIFICATIONS**







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**MECHANICAL AND ENVIRONMENTAL TESTING**

**DATA SHEETS**

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## SECTION 8

# BIOCOMPATIBILITY ASSESSMENT

**SECTION 8**  
**BIOCOMPATIBILITY ASSESSMENT**

The Silent Night I has no components or parts which contact human tissue during use. The device is an external ventilatory effort monitor and all parts are located outside the body. For this reason, the section is not applicable.

## SECTION 9

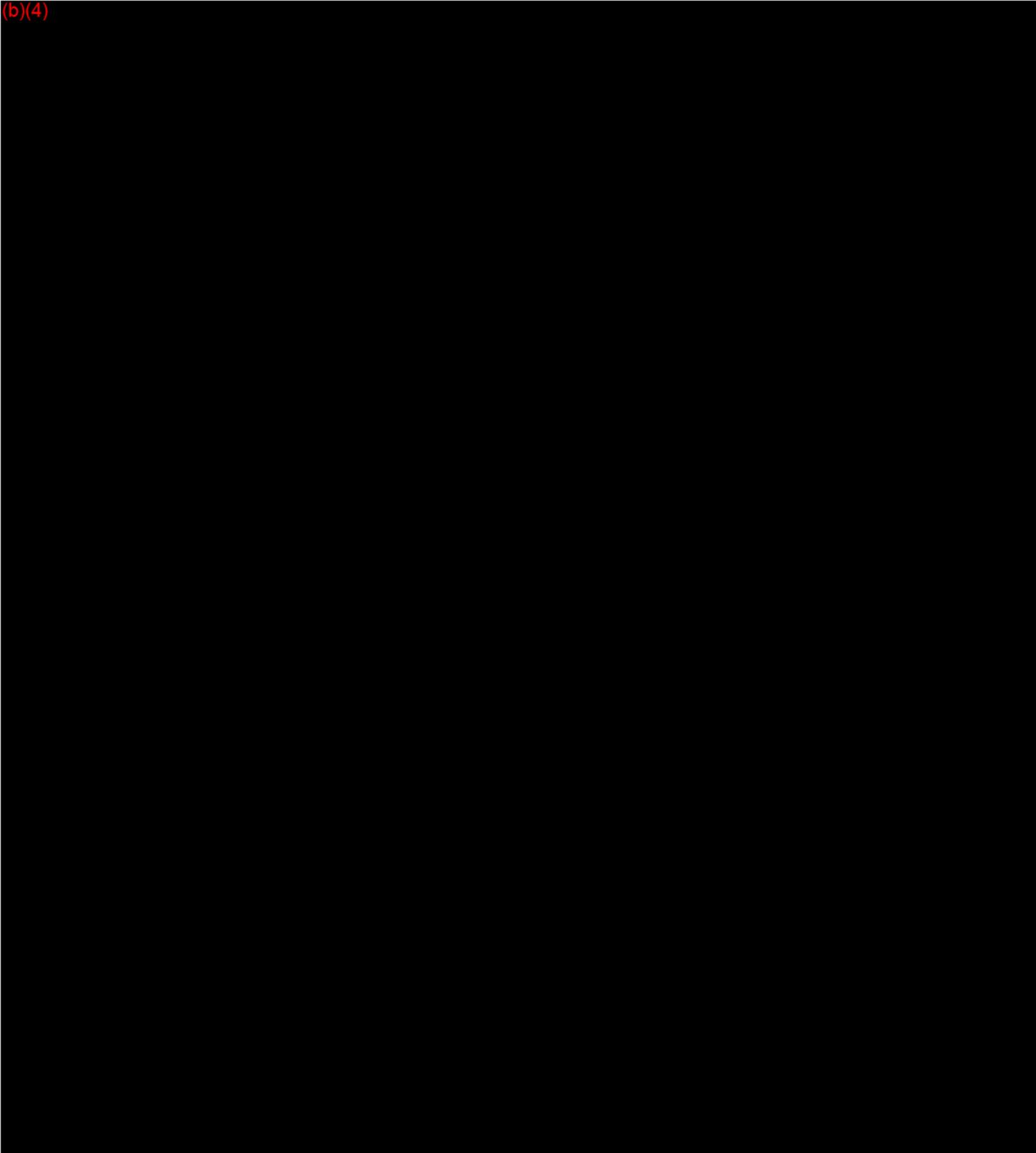
# SOFTWARE INFORMATION

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**SECTION 9  
SOFTWARE INFORMATION**

**CONFIDENTIAL**

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007















**Local Silence, Inc.**

# ENGINEERING ACTION REQUEST

EAR NO.

SHT

OF

DOCUMENT NUMBER

REV

DESCRIPTION

REASON FOR CHANGE:

RECOMMENDED CHANGE:

(Continue on sheet 2 and attach red-lined drawings if required)

PRELIMINARY RESPONSE TO BE PROVIDED WITHIN 48 HOURS BY: \_\_\_\_\_

RESPONSIBLE ENGINEER ASSIGNED TO: \_\_\_\_\_

ACTION TO BE TAKEN: \_\_\_\_\_ DATE TO BE COMPLETED BY: \_\_\_\_\_

(Continue on sheet 2 if more space is required)

FINAL RESOLUTION:

ECO NUMBER: \_\_\_\_\_

OTHER ACTION TAKEN:

## SIGNATURES / DATE

ORIGINATOR:

DATE:

RESPONSIBLE ENGINEER:

DATE:

ORIGINATOR'S MANAGER:

DATE:

DOC CONTROL RECEIVED DATE:

DOC CONTROL CLOSED DATE:

**SECTION 10**  
**STERILIZATION INFORMATION**

The Silent Night I is not a sterile device. Since neither the device nor its components or accessories are supplied sterile or intended to be sterilized, this section is not applicable.

**SECTION 11**

**STANDARDS AND GUIDANCES**

## SECTION 11 STANDARDS AND GUIDANCES

The Silent Night I has been tested to the following voluntary standards:

- EN 60601-1-2: 1993: Electrostatic discharge tests
- IEC 801-2:1991: Electrostatic discharge tests
- EN 60601-1-2: 1993 and IEC 801-3:1992: Radiated susceptibility tests
- IEC 801-4:1988: Electrical fast transient tests
- EN 60601-1-2: 1993: Surge tests
- IEC 801-5:1993: Surge tests
- European Norm standard CISPR 11, "Limits and Methods of Measurements of Radio Disturbance Characteristics of Industrial, Scientific and Medical (ISM) Radio-Frequency Equipment", 1990, Class B limits: Conducted emissions tests
- European Norm standard CISPR 11, "Limits and Methods of Measurements of Radio Disturbance Characteristics of Industrial, Scientific and Medical (ISM) Radio-Frequency Equipment", 1990, Class B limits: Radiated emissions tests
- IEC 68-2-27: Mechanical shock
- IEC 68-2-6: Sinusoidal vibration
- IEC 68-2-34: Random vibration
- prEN 45502-1:1993: Storage temperature