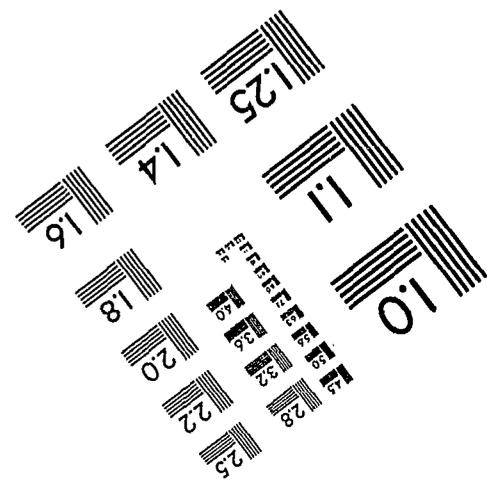
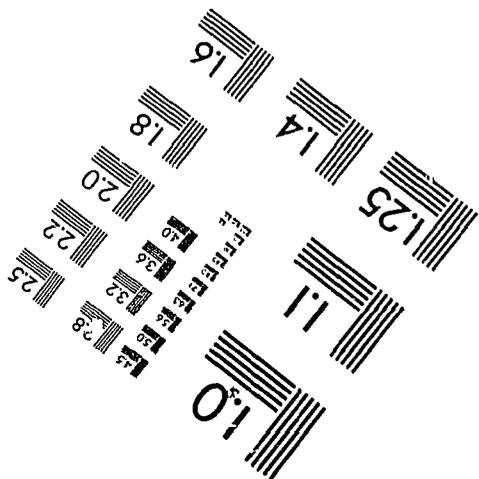
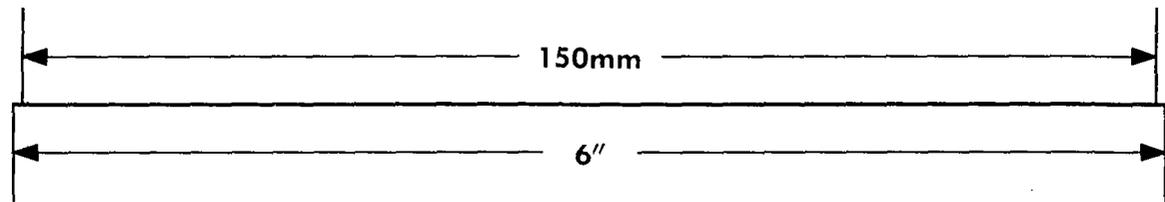
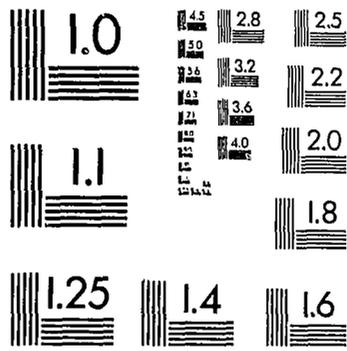
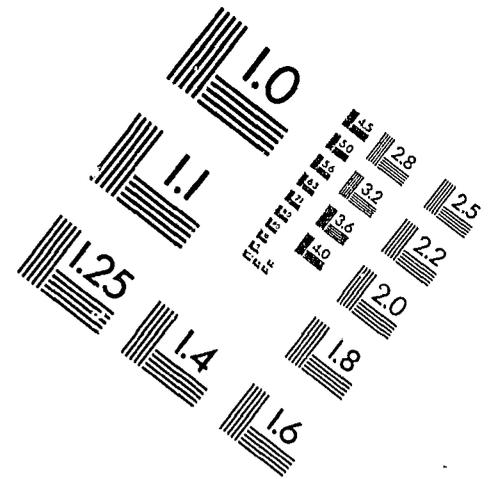
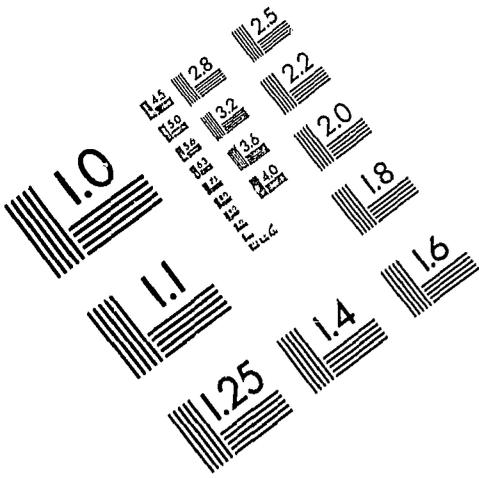


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IMAGE EVALUATION TEST TARGET (MT-3)



PHOTOGRAPHIC SCIENCES CORPORATION

770 BASKET ROAD

P.O. BOX 338

WEBSTER, NEW YORK 14580

(716) 265-1600

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

K8422607



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

SEP 13 1984

Timothy A. Williams, RRT
Alpha Medical Systems
1534 Almedia Ct. #C
Miamisburg, Ohio 45342

Re: K842607A
Infant Apnea Bed Stimulator
Model AA-010
Regulatory Product Class III
Dated: August 8, 1984
Received: August 14, 1984

Dear Mr. Williams:

We have reviewed your Section 510(k) notification of intent to market the above device and we have determined that the information in your submission

(b)(4) deficiencies

Therefore, your device is classified by statute in class III (Premarket Approval), under Section 513(f) of the Federal Food, Drug, and Cosmetic Act (Act).

Section 515(a)(2) of the Act requires class III devices to have an approved premarket approval application (PMA) before they can be legally marketed unless the device has been reclassified.

Premarket Approval. To prepare a premarket approval application, statutory provisions appearing in Section 515(c) of the Act must be followed. To assist you in preparing a PMA, we have enclosed a copy of the proposed PMA procedures regulation and a "Guideline for the Arrangement and Content of a PMA."

Investigational Use. In the absence of an approved premarket approval application, a Class III device may be distributed only for investigational use. Enclosed is a copy of the investigational device exemption regulation which must be followed if your device is used in a clinical investigation.

Petition for Reclassification. If you believe that your device should not have to undergo premarket approval before it is commercially distributed, you may petition FDA for reclassification of your device under Section 513(f)(2) of the Act.

Premarket approval applications, investigational device exemption requests, and petitions for reclassification should be submitted to:

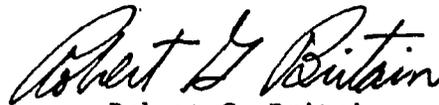
Page 2 - Mr. Timothy A. Williams, RRT

Food and Drug Administration
Office of Device Evaluation
Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, Maryland 20910

Any commercial distribution of this device prior to approval of an application for premarket approval or the effective date of any order by the FDA reclassifying your device into class I or II, would be a violation of the Act. Clinical investigations of your device must be in accordance with the investigational device exemption regulation.

If you have additional information that may alter this decision or if you need any information concerning our decision or the alternatives available to you under the law, please contact Mr. Robert Gatling, Jr., Chief, General Use Devices Branch, at (301) 427-7750.

Sincerely yours,



Robert G. Britain
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Date
8/22/84

ROUTING AND TRANSMITTAL SLIP

TO: (Name, office symbol, room number, building, Agency/Post)	Initials	Date
1. <i>Don</i>	<i>Don</i>	<i>8/27/84</i>
2. <i>Glenn</i>	<i>Glenn</i>	<i>9/6/84</i>
3. <i>Don</i>		
4. <i>Britaine</i>		
5.		

Action	File	Note and Return
Approval	For Clearance	Per Conversation
As Requested	For Correction	Prepare Reply
Circulate	For Your Information	See Me
Comment	Investigate	Signature
Coordination	Justify	

REMARKS

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions

FROM: (Name, org. symbol, Agency/Post)	Room No.—Bldg.
	Phone No.

Sylvia

5041-102 * GPO : 1983 O - 381-529 (308) OPTIONAL FORM 41 (Rev. 7-76)
Prescribed by GSA
 FPMR (41 CFR) 101-11.206

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SEP 1 8 1984

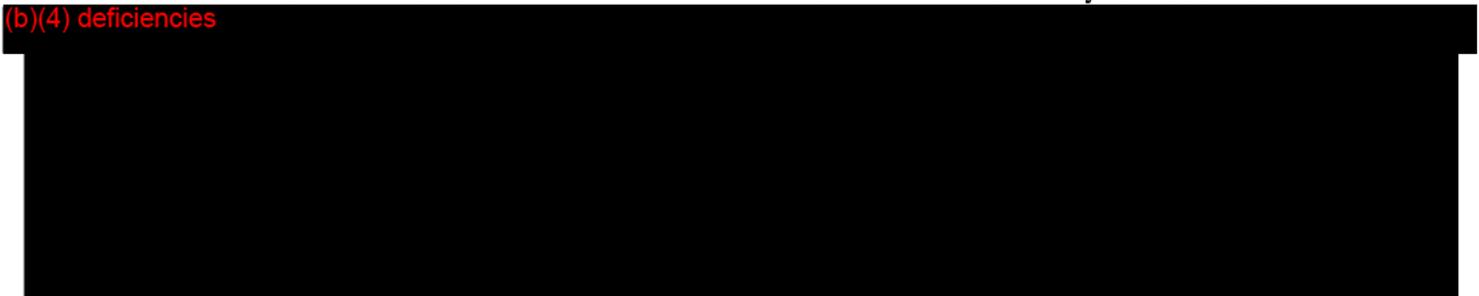
Timothy A. Williams, RRT
Alpha Medical Systems
1534 Almedia Ct. #C
Miamisburg, Ohio 45342

Re: K842607A
Infant Apnea Bed Stimulator
Model AA-010
Regulatory Product Class III
Dated: August 3, 1984
Received: August 14, 1984

Dear Mr. Williams:

We have reviewed your Section 510(k) notification of intent to market the above device and we have determined that the information in your submission

(b)(4) deficiencies



Therefore, your device is classified by statute in class III (Premarket Approval), under Section 513(f) of the Federal Food, Drug, and Cosmetic Act (Act).

Section 515(a)(2) of the Act requires class III devices to have an approved premarket approval application (PMA) before they can be legally marketed unless the device has been reclassified.

Premarket Approval. To prepare a premarket approval application, statutory provisions appearing in Section 515(c) of the Act must be followed. To assist you in preparing a PMA, we have enclosed a copy of the proposed PMA procedures regulation and a "Guideline for the Arrangement and Content of a PMA."

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Premarket approval applications, investigational device exemption requests, and petitions for reclassification should be submitted to:

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Page 2 - Mr. Timothy A. Williams, RRT

Food and Drug Administration
 Office of Device Evaluation
 Document Mail Center (HFZ-401)
 8757 Georgia Avenue
 Silver Spring, Maryland 20910

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If you have additional information that may alter this decision or if you need any information concerning our decision or the alternatives available to you under the law, please contact Mr. Robert Gatling, Jr., Chief, General Use Devices Branch, at (301) 427-7750.

Sincerely yours,

Robert G. Britain
 Director
 Office of Device Evaluation
 Center for Devices and
 Radiological Health

Enclosures

- cc: HFZ-401
- HFZ-400 RGBritain
- HFZ-402 RICHissler
- HFZ-420 FVillarroel - File
- HFZ-420 RGatling
- HFZ-420 RWilliams
- HFZ-420 RW Chron

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HFZ-420/RWilliams/sm/8/23/84 Thu 7:28:58

**FILE
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OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFZ-401	Williams	8/20	2420	Villarroel	9/6/84			
HFZ-401	Gatling	9/14	407	Chron	9/14			
2420	Gatling	9/14	420	Williams	9/14			

-- INDEX OF DOCUMENTS --

Drive: 1, Name: FOURHO, # of Docs: 42, Blocks left: 217 (of 779)

Document Number	Name	Created	Modified	Size	Version	Elapsed Time	
						Last	Total
42	k842607	8/22/84	8/22/84 2:49	1	1	0:00	0:00

8/22/84 Wed 2:50:48

ROUTING AND TRANSMITTAL SLIP

TO:	INITIALS	DATE
1. <u>R. Rubendall</u>	<u>RR</u>	<u>8/29/84</u>
2. <u>R. Williams</u>	<u>RJW</u>	<u>8/30/84</u>
3. <u>R. Gathers</u>	<u>R</u>	<u>9/1/84</u>
4. <u>Dr. Villard</u>	<u>vt</u>	<u>9/4/84</u>
5. <u>Linda Rosato</u>	_____	_____
6. <u>Mr. Chisler</u>	<u>[Signature]</u>	<u>9/7/84</u>
7. <u>Mr. Butera</u>	_____	_____
8. <u>DGGD</u>	_____	_____
9. <u>DMC</u>	_____	_____

Action	File	Note and Return
Approval	For Clearance	Per Conversation
As Requested	For Correction	Prepare Reply
Circulate	For Your Information	See Me
Comment	Investigate	Signature <input checked="" type="checkbox"/>
Coordination	Justify	

FROM: HFZ-420/DGGD RM: 1442 PHONE: 427-7750

SIGNED

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service



Memorandum

Date 8/21/84

From REVIEWER(S) - NAME(S) Richard J. Williams

Subject 510(k) NOTIFICATION K842607A

To THE RECORD

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

- (A) Is substantially equivalent to marketed devices.
- (B) Requires premarket approval. NOT substantially equivalent to marketed devices.
- (C) Requires more data.
- (D) Is an incomplete submission. (See Submission Sheet).

Additional Comments:

(b)(5) FDA internal opinions/recommendations and deliberations

The submitter requests:

Class Code w/Panel:

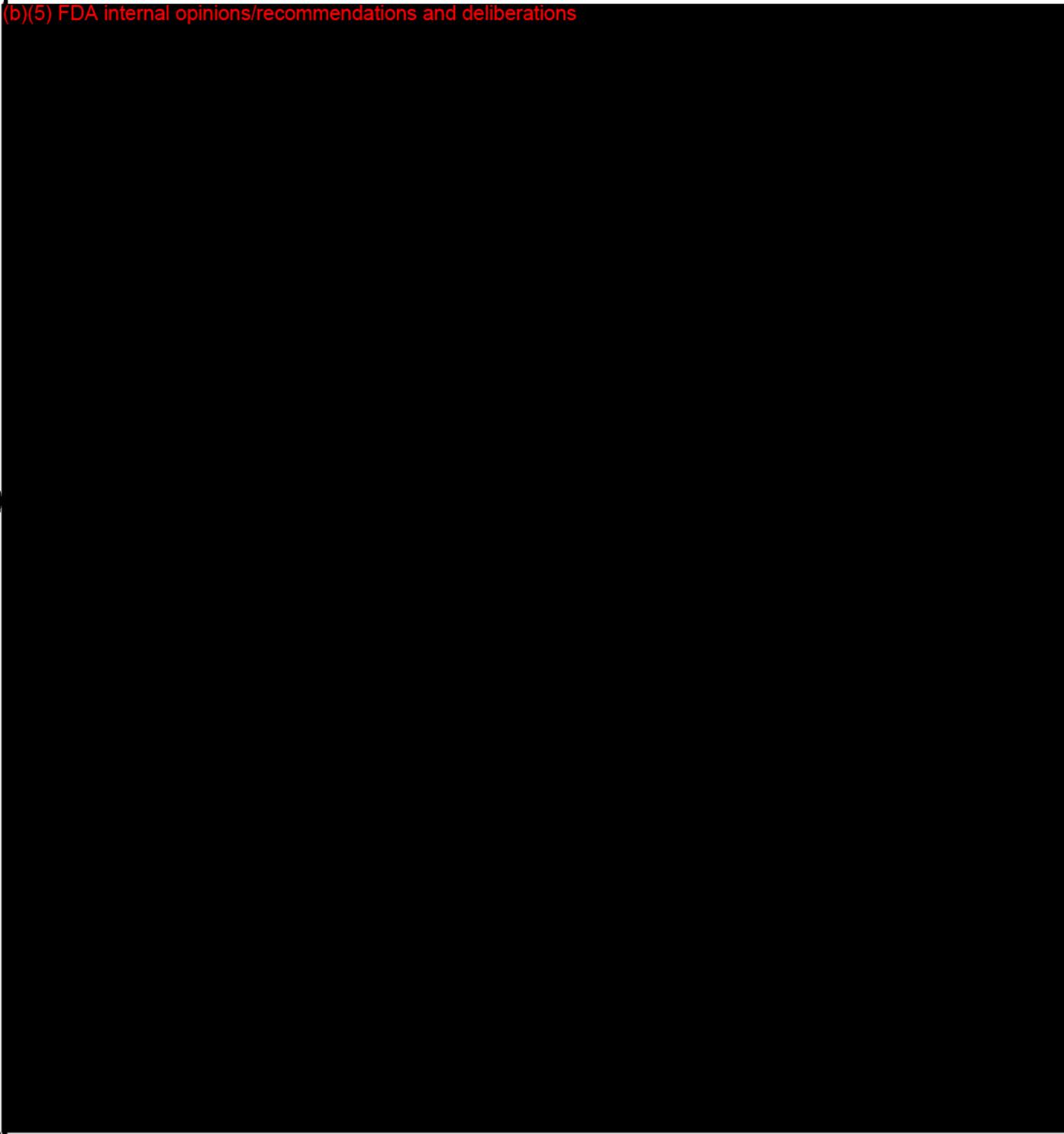
- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

REVIEW: *[Signature]* 9/15/84
 (BRANCH CHIEF) (DATE)

FINAL REVIEW: *[Signature]* 9/16/84
 (DIVISION DIRECTOR) (DATE)

MEMO RECORD	AVOID ERRORS PUT IT IN WRITING	DATE 8/20/84 Mon
FROM: BIOMEDICAL ENGINEER		OFFICE HFK-420
TO: THE RECORD		DIVISION DGGD
SUBJECT: Alpha Medical Systems Infant Apnea Bed Stimulator Model AA-010		
SUMMARY K842607A		

(b)(5) FDA internal opinions/recommendations and deliberations



SIGNATURE <i>Richard J. Williams</i>	DOCUMENT NO.
---	--------------

K842607A

Food and Drug Administration
Bureau of Medical Devices
Attention Richard Williams (HFZ-420)
8757 Georgia Ave.
Silver Spring, MD 20910

RE: Ref. No. k842607

8-8-84

RECEIVED
FEDERAL BUREAU OF INVESTIGATION
U.S. DEPARTMENT OF JUSTICE
AUG 11 11:22 AM '84
FEDERAL BUREAU OF INVESTIGATION
CENTER

Dear Mr. Williams;

Enclosed you will find the information you requested concerning the Medpro Apnea bed stimulator. As I stated on the telephone the hospital I work in currently owns two of these units and has a third on loan from a nearby hospital. Enclosed is a copy of the listing of the Medpro company in the American Hospital Supply Catalog Directory of Suppliers as well as packaging enclosures, articles supporting the use of rhythmic stimulation and photostat copies of the device labeling itself. I hope that this information will help you in establishing substantial equivalence of my device with the Medpro Apnea Bed Stimulator.

Thank you for your help.

Sincerely...

Timothy A. Williams RRT

Timothy A Williams RRT
Alpha Medical Systems
1534 Almedia Ct. #C
Miamisburg, Oh 45342
Reg. # 1526588



THE MEDPRO NEO-FLOAT™ NEONATAL FLOTATION SYSTEM

complete with oscillating, dual frequency, RHYTHMIC WAVE STIMULATOR

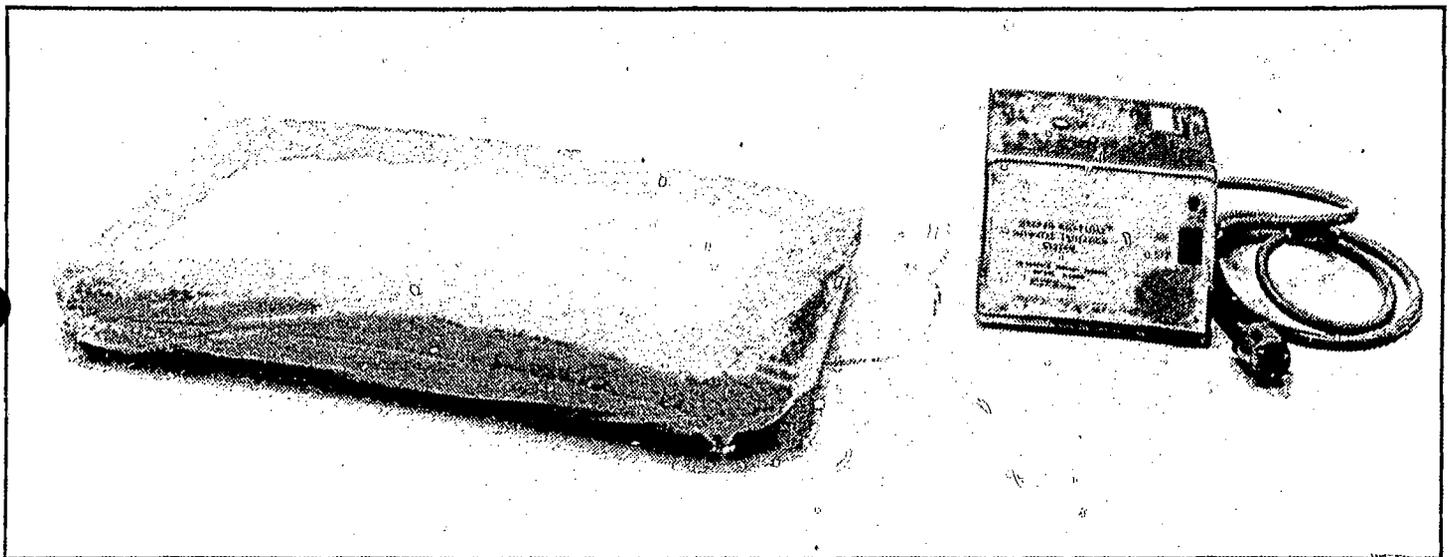
For the Incubator, Radiant Warmer, or Bassinet

The extremely SAFE, CONVENIENT, INEXPENSIVE and EFFECTIVE method of providing Flotation Support and Rhythmic Stimulation for preterm or full term infants.

Designed from the standpoint of safety, the NEO-FLOAT™ replaces the dangerous practice of using plastic sandwich bags or other unsafe simple bladders filled with water.

The NEO-FLOAT™ NEONATAL FLOTATION SYSTEM is covered by four U.S. Patents¹ and is the FIRST infant water mattress designed to meet the critical needs of the Neonatal Intensive Care Unit. It's THE SAFE ONE.™

Published studies² have shown that rhythmic stimulation provided to preterm infants while on an oscillating water mattress can reduce the number of episodes of apnea in those infants with apnea of prematurity. The NEO-FLOAT™ provides such stimulation.



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COPY

- The NEO-FLOAT™, due to its unique internal structure, may be tilted at an angle to elevate the head of the infant without loss of flotation.
- The NEO-FLOAT™ is also extremely stable when filled, which allows it to be easily carried from one location to another.
- The NEO-FLOAT™ provides a weightless environment that is highly responsive to the infant's own movements.
- The NEO-FLOAT™ helps to avoid pressure points so as not to restrict circulation through fragile skin tissue.
- The NEO-FLOAT™ molds to the infant's head shape and offers less direct constraint to normal growth processes.
- In addition, the NEO-FLOAT™ helps to recreate the intrauterine atmosphere, providing a more comfortable and natural environment.

¹ U.S. Patent Nos. 3,983,587; 4,065,819; 4,121,310; 4,135,500 with additional foreign patents pending.

² Effects of Waterbed Flotation on Premature Infants: A Pilot Study, Anneliese F. Korner, et al., Pediatrics 56:361, 1975.

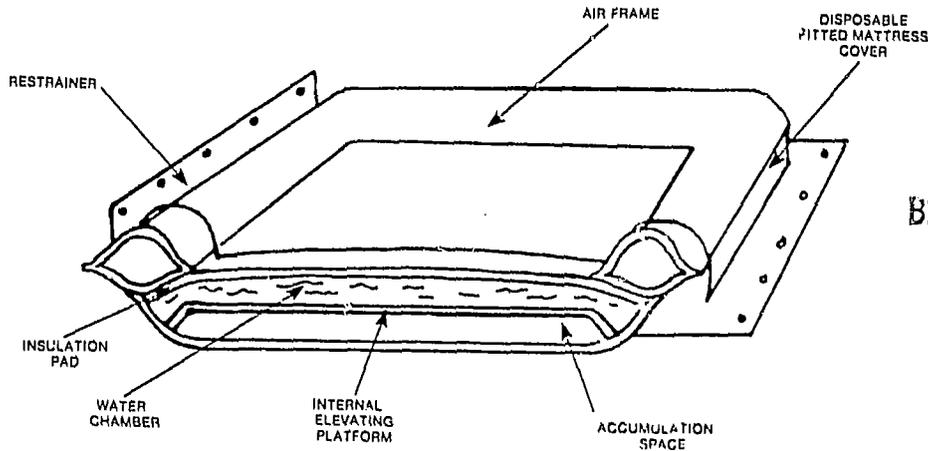
Reduction of Sleep Apnea and Bradycardia in Preterm Infants on Oscillating Water Beds: A Controlled Polygraphic Study, Anneliese F. Korner, et al., Pediatrics 61:528, 1978.

MEDPRO, INC. 275 Highway 18 East Brunswick, New Jersey 08816 (201) 238-1444

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

The **RHYTHMIC WAVE STIMULATOR** produces low amplitude foot to head waves in the **NEO-FLOAT™ NEONATAL FLOTATION MATTRESS** at a choice of either 16 or 32 pulsations per minute through the transmission of rhythmic air pulses through the **INFLATION BLADDER**. The **STIMULATOR** is capable of producing such waves in two **NEO-FLOAT™ NEONATAL FLOTATION MATTRESSES** simultaneously.

The **RHYTHMIC WAVE STIMULATOR** is safe and simple to use and there is no electrical connection between it and the **NEO-FLOAT™ NEONATAL FLOTATION MATTRESS**.



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NEO-FLOAT™ NEONATAL FLOTATION MATTRESS — Components For Safety

<p><u>AIR FRAME</u> is water-tight and serves as both a resilient bumper as well as a safety liner which will contain any possible leakage from the <u>WATER CHAMBER</u>.</p>	
<p><u>INTERNAL ELEVATING PLATFORM</u> rests within the <u>AIR FRAME</u> and creates an accumulation space below the <u>WATER CHAMBER</u> to which any possible leakage would flow. If a leak in the <u>WATER CHAMBER</u> should occur, the <u>PLATFORM</u> elevates and isolates the infant above the level of the water.</p>	
<p><u>WATER CHAMBER</u> rests on top of the <u>INTERNAL ELEVATING PLATFORM</u> within the confines of the <u>AIR FRAME</u> and is filled with 3.75 liters (one gallon) of water.</p>	
<p><u>INSULATION PAD</u> covers the <u>WATER CHAMBER</u> and is made from a non-absorbing, waterproof closed-cell foam which effectively insulates the infant from any temperature differential with the water in the <u>WATER CHAMBER</u>.</p>	
<p><u>DISPOSABLE FITTED MATTRESS COVER</u> is waterproof and further isolates and protects the infant from any contact with the water.</p>	
<p><u>RESTRAINER</u> makes it simple to immobilize the infant for certain procedures by providing an area for the attachment of gauze strips or other similar material after they are wrapped around the infant's extremities.</p>	
<p><u>RIGIDIZER</u> is placed underneath the infant on the <u>FLOTATION MATTRESS</u> to create a solid unyielding surface at those times when special procedures warrant that the infant be resting on such a surface.</p>	
<p><u>INFLATION BLADDER</u> is positioned on top of the <u>INTERNAL ELEVATING PLATFORM</u> underneath the <u>WATER CHAMBER</u>, and transmits the rhythmic air pulses from the <u>STIMULATOR</u> to the <u>WATER CHAMBER</u>.</p>	

Specifications:

NEO-FLOAT™ NEONATAL FLOTATION MATTRESS
 No. 0950
 (when filled)

SIZE: Approx. 14" x 24" x 3.5"
 WEIGHT: Approx. 11 lbs.

RHYTHMIC WAVE STIMULATOR
 No. 0951

HEIGHT: 6" DEPTH: 6"
 WIDTH: 9" WEIGHT: 7 lbs.

115 Volts 60 Hz, 7 watts maximum
 Maximum Leakage: 10 micro amperes

COPY

MEDPRO, INC.
275 HIGHWAY 18
EAST BRUNSWICK, NJ 08816
201 238-1444

**MEDPRO NEO-FLOAT™ NEONATAL
FLOTATION SYSTEM
RYTHMIC WAVE STIMULATOR**

NO 0951

115 Volts, 60 Hz, 7 Watts Maximum

Maximum Current Leakage - 10 micro amperes

SERIAL NO

11

INSTRUCTIONS FOR USE OF RHYTHMIC WAVE STIMULATOR (See Instruction Sheets for explanatory diagrams and service recommendations)

- A. Using some water to act as a lubricant, moisten approximately the last three inches of one end of the clear INFLATION BLADDER tubing.
- B. From outside the AIR FRAME, insert the wet end of the tubing through the tubing port (valve) or the underside of the AIR FRAME. If the tubing should become stuck, moisten it with a bit more water. From within the AIR FRAME, pull the tubing through about two inches and connect it to the black tubing connector on the INFLATION BLADDER. Center the INFLATION BLADDER on the edge of the INTERNAL ELEVATING PLATFORM adjacent to the tubing port (valve), in such a manner that only the BLADDER and the black tubing connector rest on the PLATFORM.
- C. Connect the other end of the clear INFLATION BLADDER tubing to the "straight-through" stem on the acid colored 3-way valve.

- D. Connect the end of the short piece of tubing (which is connected at one end to the other "straight-through" stem) directly to the air outlet stem on the rear of the RHYTHMIC WAVE STIMULATOR.
- E. The intensity of the wave impulse to the FLOTATION MATTRESS may be reduced by opening the 3-way valve and venting off air through the remaining "T" stem. This is done by turning the small knob on top of the 3-way valve in a counter clockwise direction.
- F. If wave impulses are to be produced, two "NEO-FLOAT" NEONATAL FLOTATION MATTRESSES simultaneously, the tubing from the second INFLATION BLADDER is to be connected to the remaining "T" stem on the 3-way valve and the valve is to be opened.
- G. Choose the desired wave pulse frequency of either 16 or 32 pulsations per minute by positioning the lever located on the top of the STIMULATOR at the corresponding setting.
- H. After confirming that the power cord from the STIMULATOR is connected to a properly grounded outlet, turn on the power switch located on the front of the STIMULATOR.

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32

MEDICAL DEVICE REGISTER

BATH, SITZ, POWERED (cont'd)

- GRAHAM-FIELD SURGICAL CO., INC. (516) 328-0500
415 Second Avenue, New Hyde Park, NY 11040
- HOWLIN ENTERPRISES, INC. (516) 333-8230
7 Portland Ave., Westbury, NY 11590
- ILLE DIVISION OF MARKET FORGE (717) 323-9491
2245 Reach Road, Williamsport, Pa 17701
- KOHLER CO. (414) 565-3381
High Street, Kohler, WI 53044
- MAC BICK (201) 277-8000
Div C R Bard Inc.
111 Spring St., Murray Hill, NJ 07974
- MADDAK, INC. (201) 694-0500
6 Industrial Rd., Pequannock, NJ 07440
- MEDI, INC. (800) 225-8634
27 Maple Ave., Holbrook, Ma 02343
- POSEY CO., J.T. (800) 423-4292
5635 Peck Rd., Arcada, Ca 91006
- TR-STATE HOSPITAL SUPPLY CORPORATION (517) 546-5400
301 Catrell Drive, Howell, Mi 48843

BATHOPHENANTHROLINE, COLORIMETRY, IRON (NON-HEME) (Chemistry) 75CFM

- BIO-ANALYTIC LABORATORIES, INC. (305) 287-3340
3473 Palm City School Rd PO Box 333, Palm City, Fl 33490
- BRUNO LANGE GMBH
Koenigsweg 10, 1000 Berlin 37, Fd Rp Germany
- DCA-DIAGNOSTIC CORP OF AMERICA (817) 460-5000
2100 Road to Six Flags, Arlington, Tx 76011
- SUMAR CORP (415) 349-8488
1157 Triton Dr Ste C, Foster City, Ca 94404

BATHOPHENANTHROLINE, IRON BINDING CAPACITY

- (Chemistry) 75JQF
- BIO-ANALYTIC LABORATORIES, INC. (305) 287-3340
3473 Palm City School Rd PO Box 333, Palm City, Fl 33490
- SUMAR CORP (415) 349-8488
1157 Triton Dr Ste C, Foster City, Ca 94404

BATHTUB, PORTABLE (General) 80QCZ

- WHIRL-SPA INC. (800) 327-5589
5320 NW 10th Terr, Ft. Lauderdale, Fl 33309

BATTERY, PACEMAKER (Cardiovascular) 74DSZ

- MED ELECTRONICS LTD. (203) 668-0226
8515 E. Orchard Rd., Englewood, Co 80111
- TELETRONICS PROPRIETARY LTD (800) 525-7001
8515 E. Orchard Rd., Englewood, Co 80111

BEAM-LIMITING DEVICE, TELETHERAPY, RADIONUCLIDE

- (Radiology) 90IWD
- PHILIPS MEDICAL SYSTEMS, INC. (203) 366-7674
710 Bridgeport Avenue, Shelton, Ct 06484
- PICKER CORPORATION (203) 484-2711
12 Clintonville Road, Northford, Ct 06472

BED CRADLE (General) 80QDA

- ABCO DEALERS, INC. (414) 351-1107
6637 North Sidney Pl., Glendale, WI 53209
- CAM INTERNATIONAL INC. (517) 787-1600
P.O. Box 89, Jackson, MI 49204
- GRAHAM-FIELD SURGICAL CO., INC. (516) 328-0500
415 Second Avenue, New Hyde Park, NY 11040
- MEDIPEDIC INC. (587) 787-2720
109 West Washington, Jackson, MI 49201
- ORTHOPEDIC EQUIPMENT CO INC (219) 342-3415
Quad & Ecker Sts, Bourbon, In 46504
- POSEY CO., J.T. (800) 423-4292
5635 Peck Rd., Arcada, Ca 91006
- WAL-JAN SURGICAL PRODUCTS INC. (516) 239-6880
25 Buena Vista Ave, Lawrence Li, NY 11518
- ZIMMER, USA (219) 267-6131
P. O. Box 708, Warsaw, In 46580

BED OCCUPANCY MONITOR (General) 80QDB

- ARMSTRONG INDUSTRIES INC. (800) 323-4220
3660 Commercial Ave, Northbrook, Il 60062
- BED-CHECK CORP. (918) 584-5531
507 South Main Suite 705, Tulsa, Ok 74103
- ELECTRONIC MONITORS, INC. (817) 283-0859
101 East Fuller Drive, Evless, Tx 76039
- K & L GERIATRIC SERVICES CORP. (212) 339-1179
802 Avenue N., Brooklyn, NY 11230

BED OCCUPANCY MONITOR (cont'd)

- MICRO TECH MANUFACTURING INC. (617) 852-3515
703 Plantation St, Worcester, Ma 01605

BED, AC-POWERED ADJUSTABLE HOSPITAL (General) 80FNL

- ABCO DEALERS, INC. (414) 351-1107
6637 North Sidney Pl., Glendale, WI 53209
- AMERICAN ELECTRODYNAMICS (213) 477-5627
11242 Pearl St, West Los Angeles, Ca 90064
- BORG-WARNER HEALTH PRODUCTS, INC. (800) 325-4065
401 West North 2nd Street, Wright City, Mo 63390
- BURKE, INCORPORATED (800) 255-4147
P.O. Box 1064, Mission, Ks 66202
- CARRUM (800) 647-6194
Div. Affiliated Hospital Products
P. O. Box 389, Sardis, Ms 38666
- COSMO CAUTERY MANUFACTURING CO. (800) 325-1586
Div. Dentrex Int.
11649 Adia Rd, Maryland Heights, Mo 63043
- ELECTROPEDIC PRODUCTS INC (213) 849-3188
907 N Hollywood Way, Burbank, Ca 91505
- EMERSON COMPANY, J.H. (617) 864-1414
22 Cottage Park Avenue, Cambridge, Ma 02140
- FOSTER BROTHERS MANUFACTURING COMPANY (314) 773-3441
2025 South Vandeventer, St. Louis, Mo 63110
- GULF & WESTERN HEALTHCARE INC. (717) 845-6666
Hausted-Simmons
491 E. Princess St, Box 1587, York, Pa 17405
- HARD FURNITURE COMPANY (800) 828-7143
230 Grider Street, Buffalo, NY 14215
- HILL-ROM COMPANY, INC. (812) 934-7777
Highway 46, Batesville, In 47006
- INTERROYAL CORPORATION (212) 686-3500
1 Park Ave, New York, NY 10016
- JOERNS FURNITURE CO. (715) 341-3600
1 Park Ave, Stevens Point, WI 54481
- MCMILLIS, W H (415) 325-6952
431 Waverley, Palo Alto, Ca 94301
- MEDIC-AIDS OF AMERICA INC. (402) 476-2111
2218 N. St, Lincoln, NE 68510
- THONET INDUSTRIES, INC. (404) 449-5000
11900 Steele Creek Rd, Charlotte, NC 28210
- WAL-JAN SURGICAL PRODUCTS INC. (516) 239-6880
25 Buena Vista Ave, Lawrence Li, NY 11518
- BED, AIR FLUIDIZED** (Physical Med) 89INX
FLUIDOTHERAPY CORP. (713) 651-1253
7001 Mullins Ste. J, Houston, Tx 77081
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- MEDLON INC. (213) 954-9541
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- MEDPRO, INC. (201) 257-5145
275 Highway 18, East Brunswick, NJ 08816
- PHILIPS MEDICAL SYSTEMS, INC. (203) 366-7674
710 Bridgeport Avenue, Shelton, Ct 06484
- ROCHESTER MODULAR WATERBEDS (716) 544-8522
111 Oneta Road, Rochester, NY 14617
- SUPPORT SYSTEMS INTERNATIONAL, INC. (803) 559-0331
Brick House Plantation P.O. Box 570, Johns Island, SC 29455

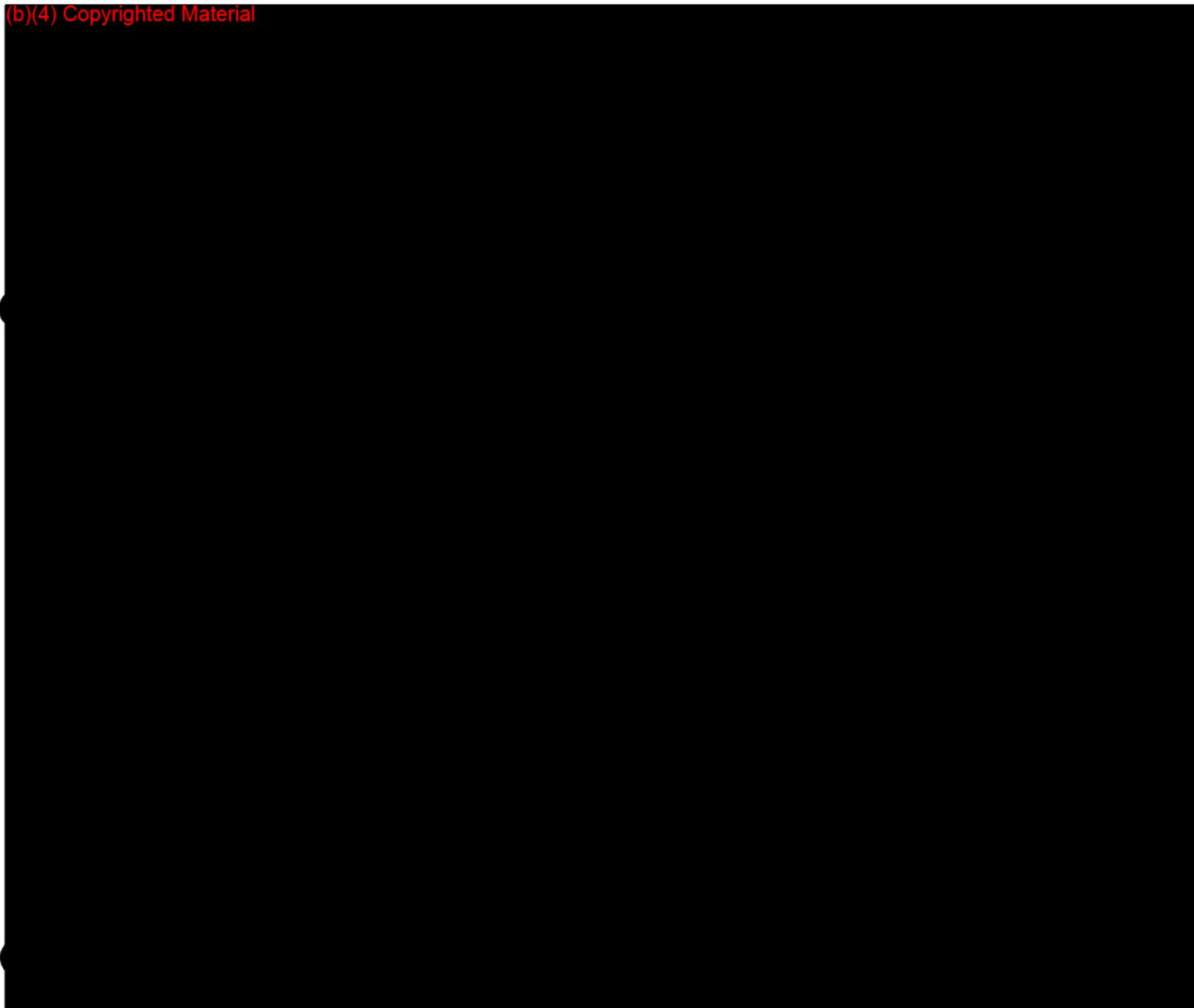
Effects of Waterbed Flotation on Premature Infants: A Pilot Study

Anneliese F. Korner, Ph.D., Helena C. Kraemer, Ph.D., M. Ellen Haffner, B.A., and
Lorna M. Cospoer, R.N.

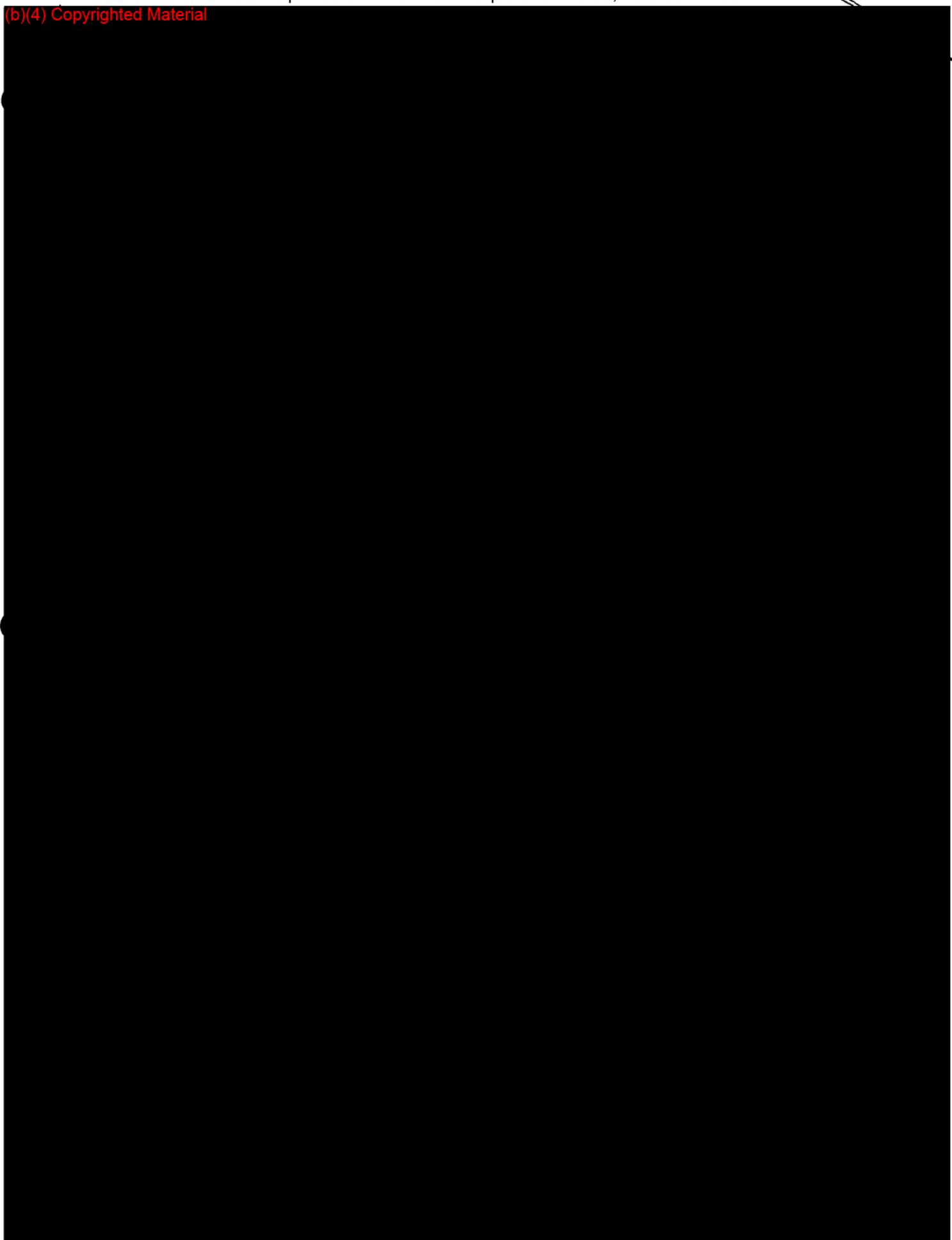
From the Department of Psychiatry, Stanford University School of Medicine, Stanford, California

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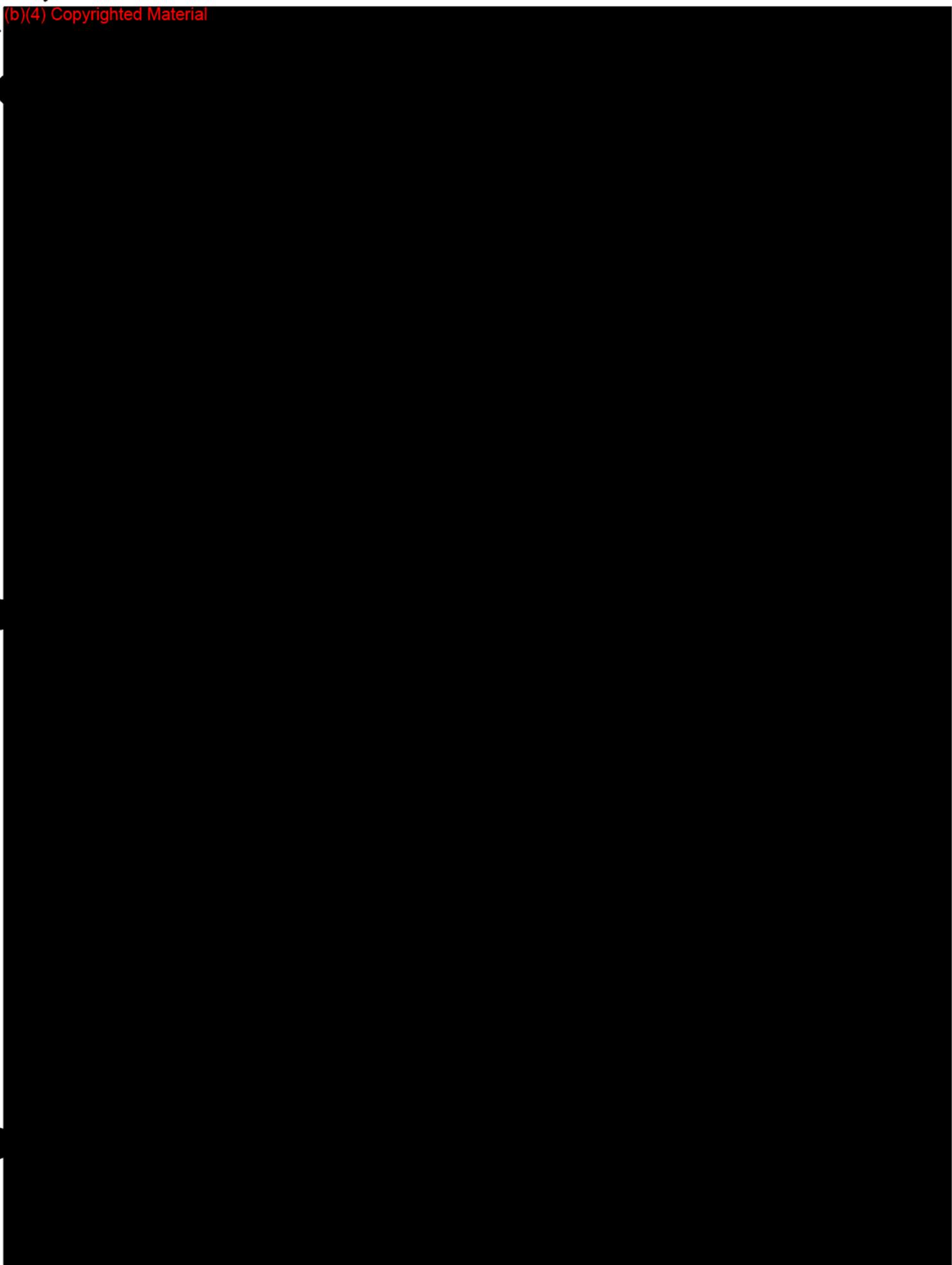
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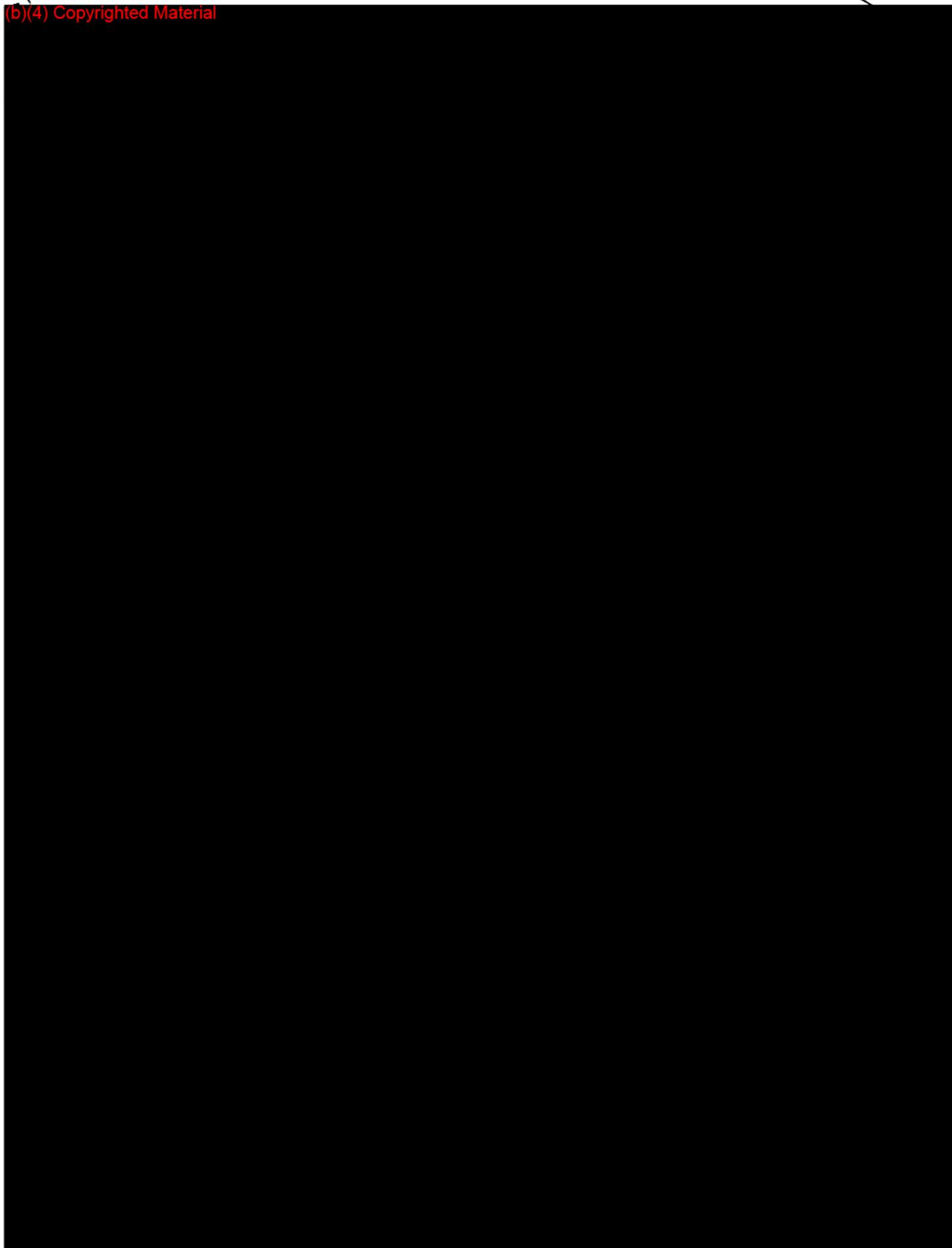
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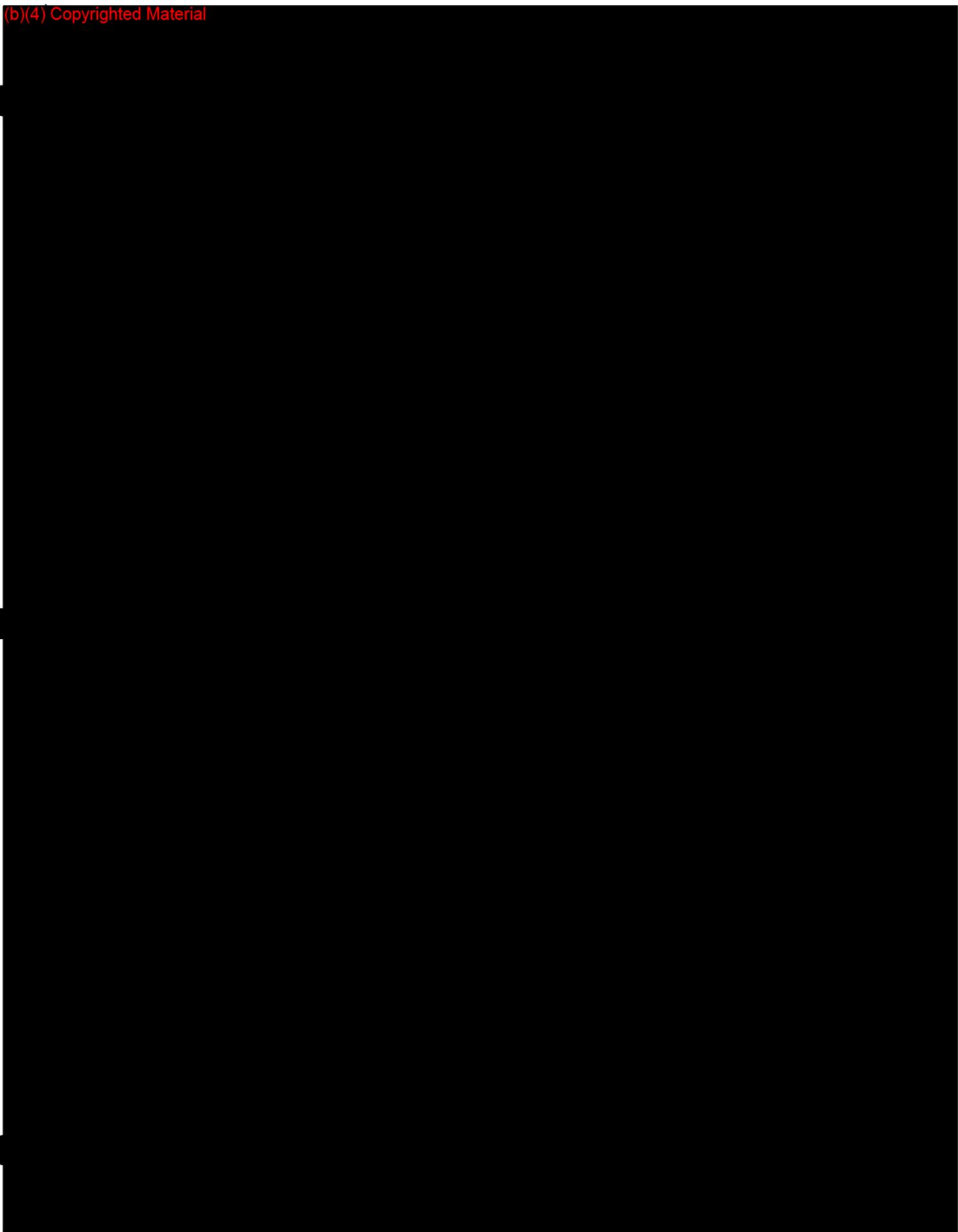
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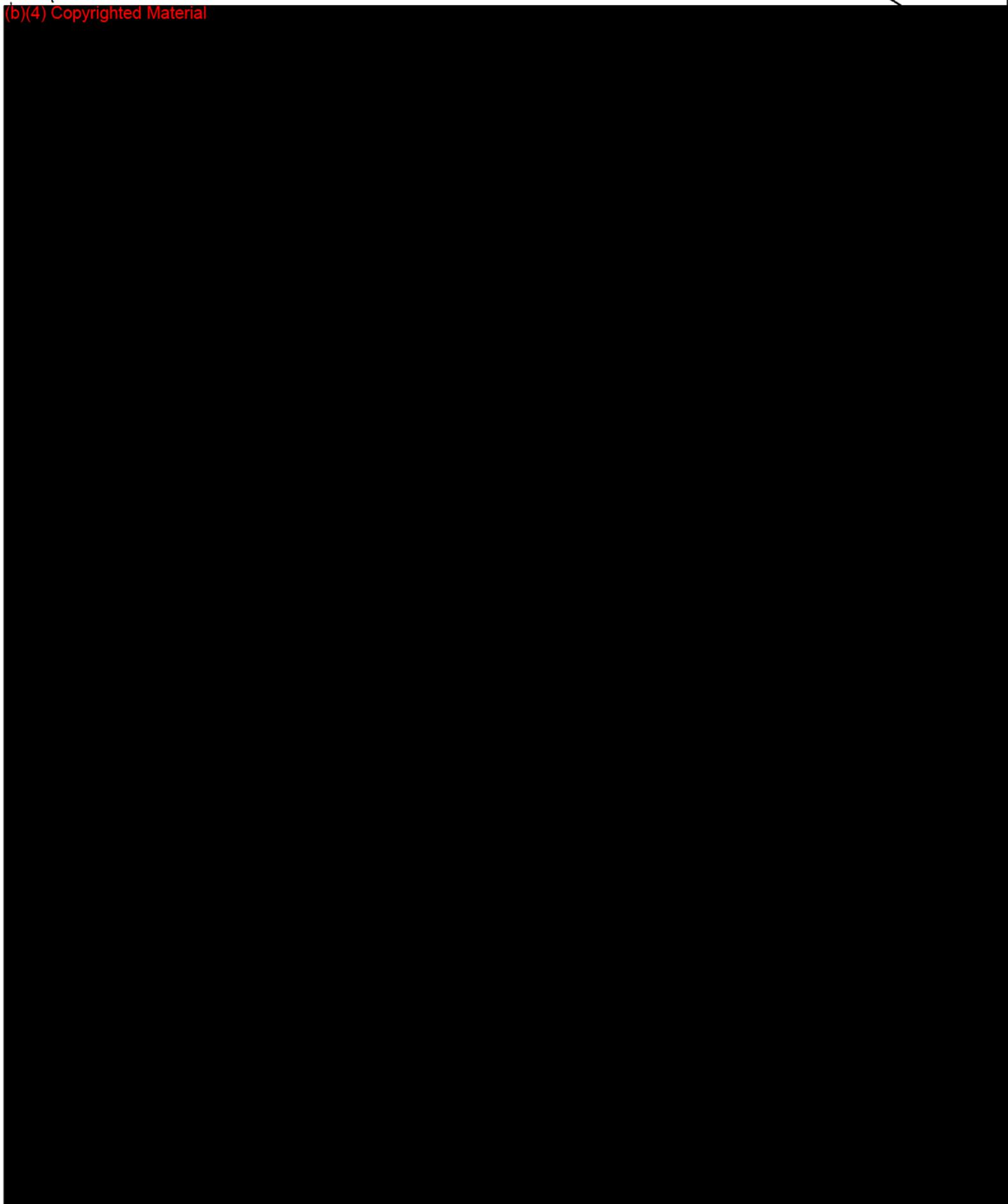
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56, 1981

A controlled trial of a regularly cycled oscillating waterbed 889

A controlled trial of a regularly cycled oscillating waterbed and a non-oscillating waterbed in the prevention of apnoea in the preterm infant

ROSAMOND A K JONES

Department of Paediatrics and Neonatal Medicine, Hammersmith Hospital, London

SUMMARY Fourteen preterm infants spent a mean of 23 hours divided into 4-hour periods with and without regular oscillations, 10 infants also being studied for control periods, before and afterwards. Electrocardiogram and impedance pneumogram were recorded continuously and analysed blindly. The waterbed, with or without oscillations, had no effect on apnoea or bradycardia when compared with control periods. Infants had appreciably more episodes of severe bradycardia while on the oscillating than on the non-oscillating waterbed.

starting theophylline (all 3 had stable blood theophylline levels throughout the investigation). Gestation ranged from 27.0 to 32.6 (median 29.4) weeks, birthweight from 930 to 1470 (median 1080) g, and postnatal age from 1 to 32 (median 8) days.

Procedure. The waterbed used was similar to that described by Korner *et al.*^{1,2} with an inflatable bladder placed under the head end. This could be connected to a ventilator pumping regularly at 12 to 14 cycles per minute, to produce an oscillation of only 1 to 2 mm amplitude at the mattress surface when no infant was in place, but visibly moving the resting infant. Infants spent a mean of 23 hours on the waterbed divided into 4-hour periods with and without oscillations, in random order. Ten of the infants were studied for a further 11 hours with the mattress emptied of water, divided between the beginning, middle, and end of the time on the waterbed. Electrocardiogram and impedance pneumogram were recorded continuously on to cassette tapes (Infant Monitor by Healthdyne Inc, adapted with cassette recorder by Oxford Medical Systems), and later printed on to paper through a replay unit by Oxford Medical Systems and a Mingograph Chart Recorder (Siemens Ltd).

In 1975, Korner *et al.*¹ reported that waterbed flotation reduced apnoea in preterm infants. They used a water-filled mattress with irregular head-to-foot oscillations at 12 to 14 per minute, hoping to enhance behavioural maturation by giving vestibulo-proprioceptive stimulation as *in utero*. Ten infants randomly assigned to the waterbed unexpectedly had fewer apnoeic episodes than did controls. The same authors confirmed these results in 8 infants with recurrent apnoea, studied on and off the mattress.² The present study aimed to see if similar benefit was obtained using a waterbed without oscillations or one with a regular cycle.

Tapes had code numbers and were analysed by me without knowing the patient or treatment. Strict criteria for distinguishing apnoea from shallow respiration were used (details available from the author). The duration of each apnoeic episode and each bradycardia was measured and the time noted and the hourly rates on each 'treatment' subsequently calculated. The percentages of recording time spent apnoeic and with a heart rate of 80 or below were also calculated. Using each infant as his own control, the differences were calculated between treatments and then compared by paired *t* test or Wilcoxon's signed rank sum test as appropriate.

Method

Patients. Infants of 32 weeks' gestation or less admitted to the neonatal intensive care unit at Hammersmith Hospital from September 1979 to June 1980 were eligible for the study, which was approved by the Ethical Committee. Infants with major congenital abnormality or clinical evidence of central nervous system disease were excluded, but those with respiratory distress were studied after recovery. Infants with recurrent apnoea of prematurity (defined as ≥ 10 seconds' apnoea with bradycardia < 100 /minute or cyanosis at least 3 times in 24 hours) were treated with theophylline before starting the waterbed investigation.

Results

Table 1 shows the results for 14 babies on the waterbed comparing periods with or without regular oscillation. There was no appreciable difference in apnoeic episodes of 3 to 9 seconds'

Informed parental consent was obtained. Fourteen infants were studied, 11 with mild (less than 3 episodes per day) or no clinically recognised apnoea, and 3 infants with severe apnoea studied after

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duration nor was there any difference in bradycardia of 80 or below. Only 6 infants had apnoeic attacks of 10 seconds or more, and in 5 these were more frequent on the oscillating bed. Eleven infants suffered severe bradycardia of 60 or less per minute and these episodes were significantly more frequent during periods of regular oscillation.

Table 2 shows results for the 10 infants in whom a control period with the waterbed emptied was recorded. None of the parameters measured showed

Table 1 Comparison of the waterbed with and without oscillations ($n = 14$)

	Oscillating bed minus non-oscillating bed (mean \pm SD)	P* (paired t test)
Apnoea		
3-9 seconds hourly rate	+0.46 \pm 1.14	>0.1
*Apnoea > 10 seconds hourly rate	+0.13**	>0.1**
% time apnoeic	(-0.01 to +0.31)	
Longest apnoea (seconds)	+0.08 \pm 0.16	0.05 < P < 0.1
Bradycardia \leq 80/min, hourly rate	+2.6 \pm 6.9	>0.1
% time with heart rate \leq 80/min	+0.08 \pm 0.35	>0.1
**Bradycardia \leq 60/min, hourly rate	+0.06 \pm 0.25	>0.1
Slowest heart rate, beats/min.	+0.19 \pm 0.21	<0.02
	-4.6 \pm 6.4	<0.02

*8 infants excluded had no apnoea \geq 10 seconds, that is $n = 6$.

**Differences expressed as median and range; Wilcoxon's signed rank sum test (differences not normally distributed).

***3 infants excluded had no bradycardia \leq 60/min—that is $n = 11$.

Table 2 Comparison of the non-oscillating waterbed and the oscillating waterbed with the control periods ($n = 10$)

	Non-oscillating waterbed minus control period (mean \pm SD)	Oscillating waterbed minus control period (mean \pm SD)
Apnoea		
3-9 seconds hourly rate	-0.21 \pm 1.04	+0.09 \pm 1.46
*Apnoea > 10 seconds hourly rate	-0.05**	+0.10**
Bradycardia \leq 80/min, hourly rate	(-0.25 \pm 0.09)	(-0.09 \pm 0.13)
**Bradycardia \leq 60/min, hourly rate	-0.03 \pm 0.37	+0.015 \pm 0.53
	-0.15 \pm 0.49	+0.05 \pm 0.65

*4 infants excluded had no apnoea \geq 10 seconds, that is $n = 6$.

**Differences expressed as median and range; Wilcoxon's signed rank sum test (differences not normally distributed).

***1 infant excluded had no bradycardia \leq 60/min, that is $n = 9$ P > 0.1 throughout (paired t test).

any significant difference between periods spent on or off the waterbed. Response to the waterbed appeared unaffected by maturity of the infants, severity of the apnoea, or use of theophylline.

Side effects. Mean body temperature while on the waterbed was 0.1°C lower than in the previous 24 hours (Wilcoxon's signed rank sum test, $P < 0.01$). The drop in temperature was generally slight, but one baby developed hypothermia of 35.2°C, persisting until the waterbed was removed, and a further 6 infants required an increase in the incubator setting in order to maintain their body temperatures. No increase in vomiting occurred.

Discussion

Recurrent apnoea in the preterm infant has a high mortality and morbidity. Treatment with xanthines or continuous positive airways pressure may be effective,^{3,4} but both have potential side effects. Cutaneous stimulation has also been shown to be effective, but is costly on nursing time. The possibility that a rocking waterbed may prevent attacks is thus very appealing. In Korner's study,^{1,2} an irregular cycle was deliberately chosen to mimic maternal respirations. The mechanism of the beneficial effect on apnoea is uncertain but they found a significant reduction in indeterminate sleep with waterbed use, and it was in this sleep state that apnoea and bradycardia were reduced.²

At the time of our study, no neonatal rocking waterbed was available commercially in the UK. However, a water-tight bag was easily made, and use of an outmoded ventilator allowed regular oscillations. The lack of demonstrable benefit from the non-oscillating or regularly oscillating waterbed compared with the control period was disappointing. The slight drop in body temperature associated with the use of the waterbed might have been expected to reduce apnoea.⁵ Before waterbeds enter widespread use, attention must be paid to temperature control and also to precautions against bacterial contamination and leakage.

Our findings suggest that a regularly-cycled (12-14/minute)-rocking waterbed may even be detrimental compared with a non-oscillating waterbed. Kramer and Pierpoint,⁶ using a waterbed rocked regularly at 25 to 30 cycles per minute plus auditory stimulation in a group of preterm infants, showed enhanced growth compared with controls, but did not mention the effect on apnoea.

Further study is needed to establish the exact benefits of waterbeds and to determine the optimum rhythm and rate for promoting growth and reducing apnoea.

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A controlled trial of a regularly cycled oscillating waterbed 891

I thank Dr David Southall for use of equipment for analysing the tapes, Professor M Healy for help with statistics, Dr Pamela Davies for advice throughout the study, and the parents and infants.

This work was generously supported by Action Research for the Crippled Child. Water mattresses were donated by Flotronaire Limited and cassette tapes by Sony Limited.

References

- ¹ Korner A F, Kraemer H C, Haffner M E, Cosper L M. Effects of waterbed flotation on premature infants: a pilot study. *Pediatrics* 1975; 56: 361-7.
- ² Korner A F, Guilleminault C, Van den Hoed J, Baldwin R B. Reduction of sleep apnea and bradycardia in preterm infants on oscillating waterbeds: a controlled polygraphic study. *Pediatrics* 1978; 61: 528-33.

- ³ Kuzenko J A, Paula J. Apnoeic attacks in the newborn treated with aminophylline. *Arch Dis Child* 1973; 48: 404-6.
- ⁴ Kuttwinkcl J, Nearman H S, Fanaroff A A, Katona P G, Klaus M H. Apnea of prematurity: comparative therapeutic effects of cutaneous stimulation and nasal continuous positive airway pressure. *J Pediatr* 1975; 86: 588-92.
- ⁵ Daily W J R, Klaus M, Meyer H B P. Apnea in premature infants: monitoring, incidence, heart rate changes, and an effect of environmental temperature. *Pediatrics* 1969; 43: 510-8.
- ⁶ Kramer L I, Pierpoint M E. Rocking waterbeds and auditory stimuli to enhance growth of preterm infants. *J Pediatr* 1976; 88: 297-9.

Correspondence to Dr R A K Jones, Jenny Lind Children's Department, Norfolk and Norwich Hospital, Brunswick Road, Norwich NR1 3SK.

Received 30 June 1981

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British Paediatric Association

Annual meetings

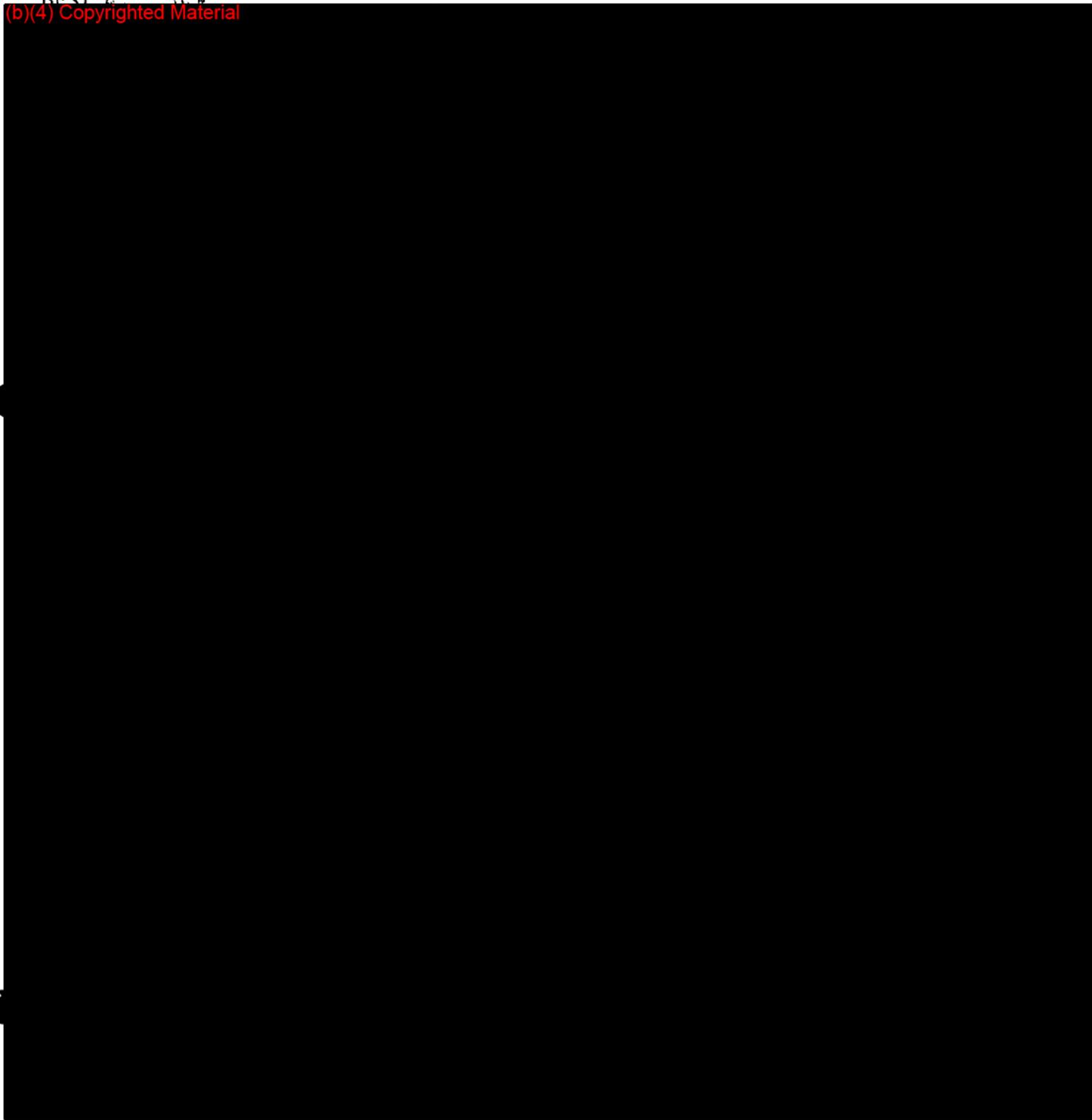
1982	20-24 April	Aviemore Centre, Scotland
1983	12-16 April	York University
1984	10-14 April	York University
1985	16-20 April	York University

Reduction of Sleep Apnea and Bradycardia in Preterm Infants on Oscillating Water Beds: A Controlled Polygraphic Study

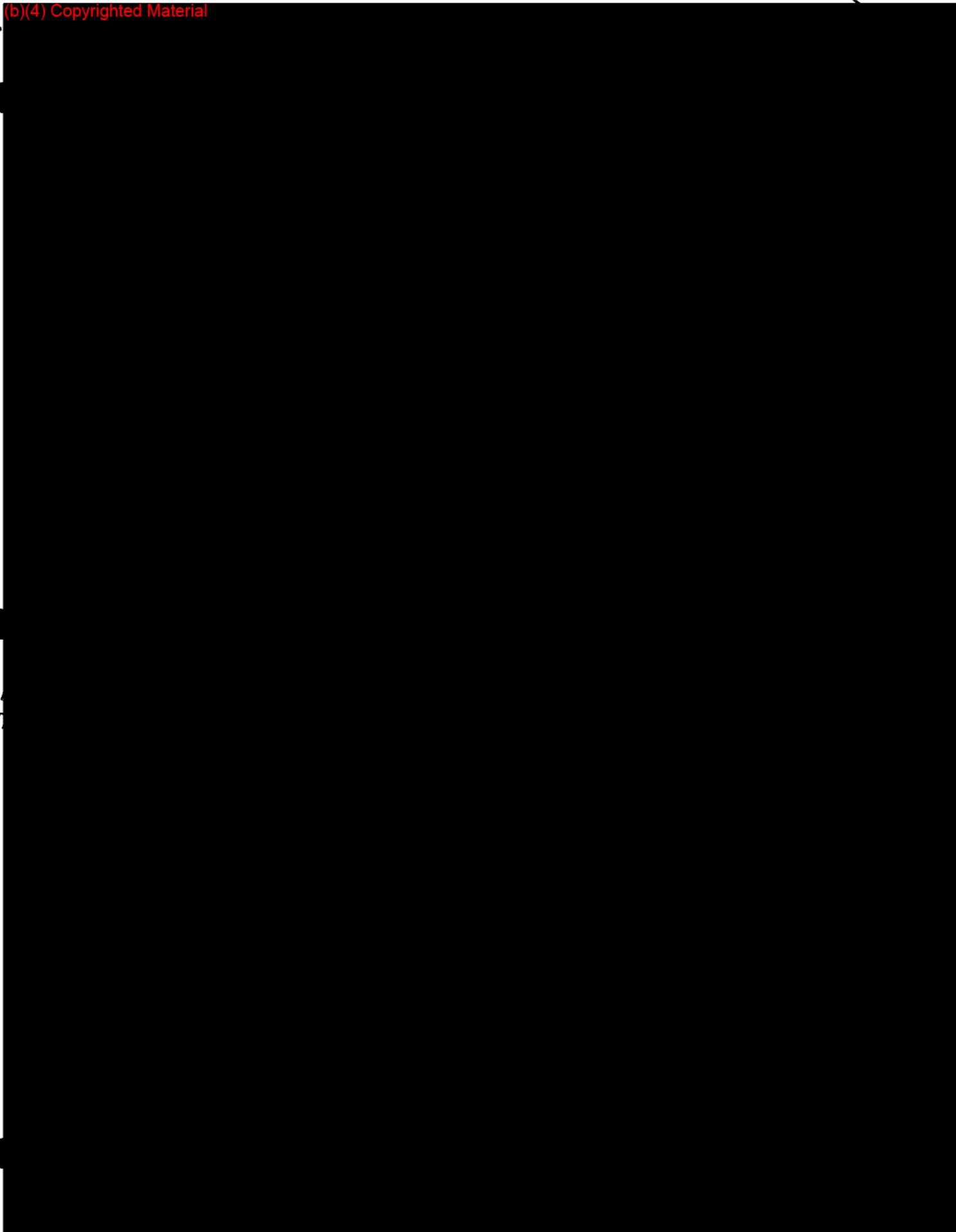
Anneliese F. Korner, Ph.D., Christian Guilleminault, M.D., Johanna Van den Hoed, M.D., and Roger B. Baldwin, M.A.

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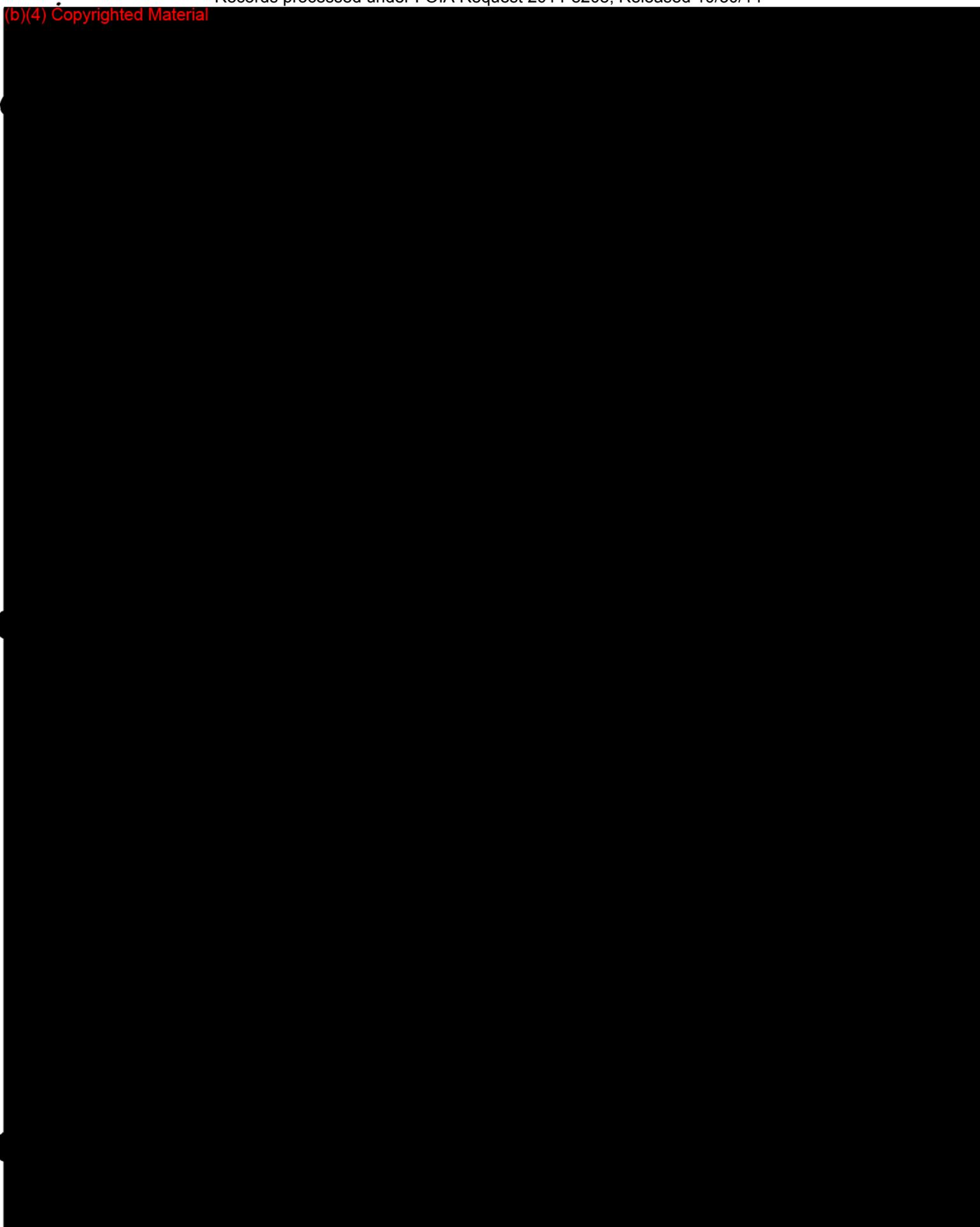


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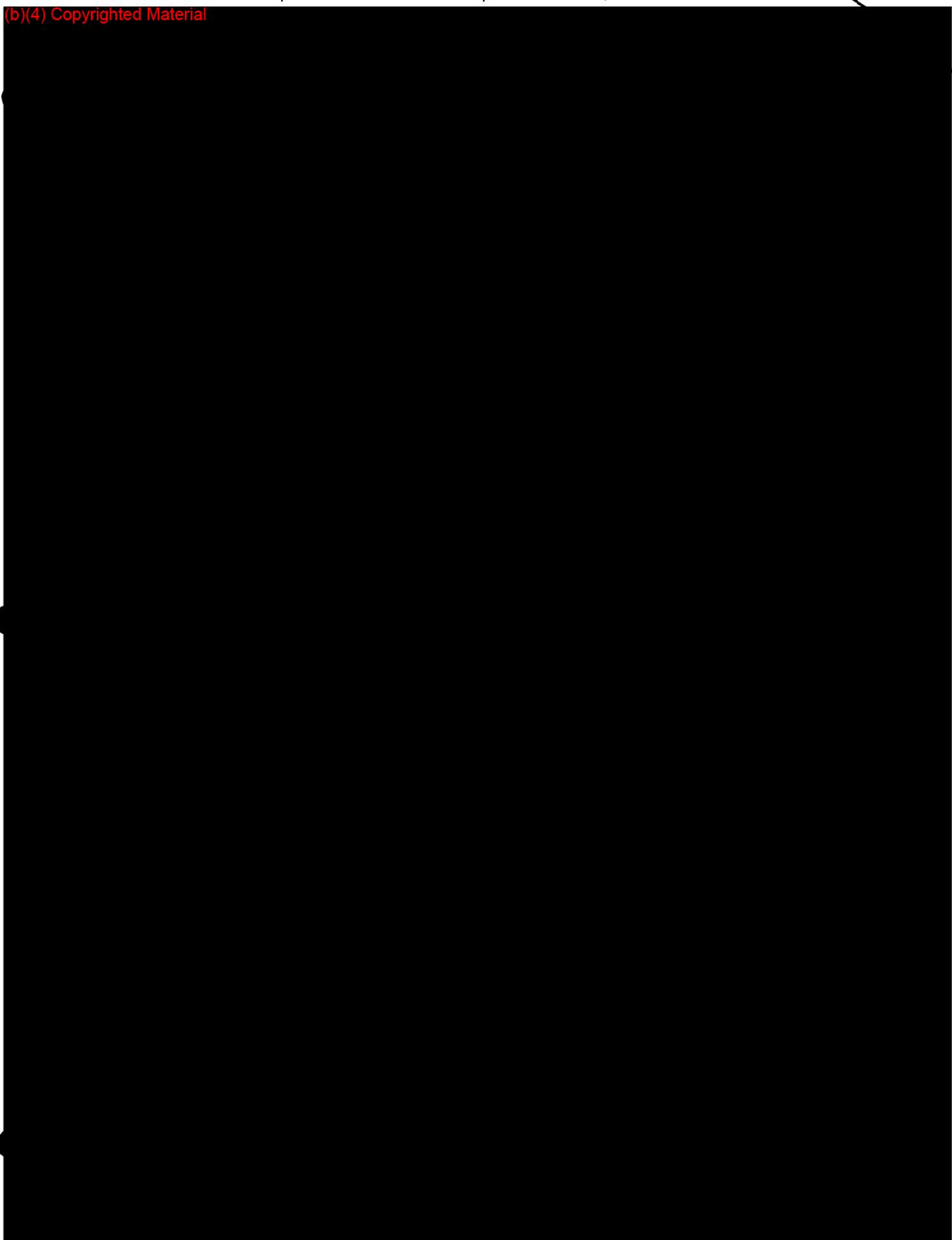
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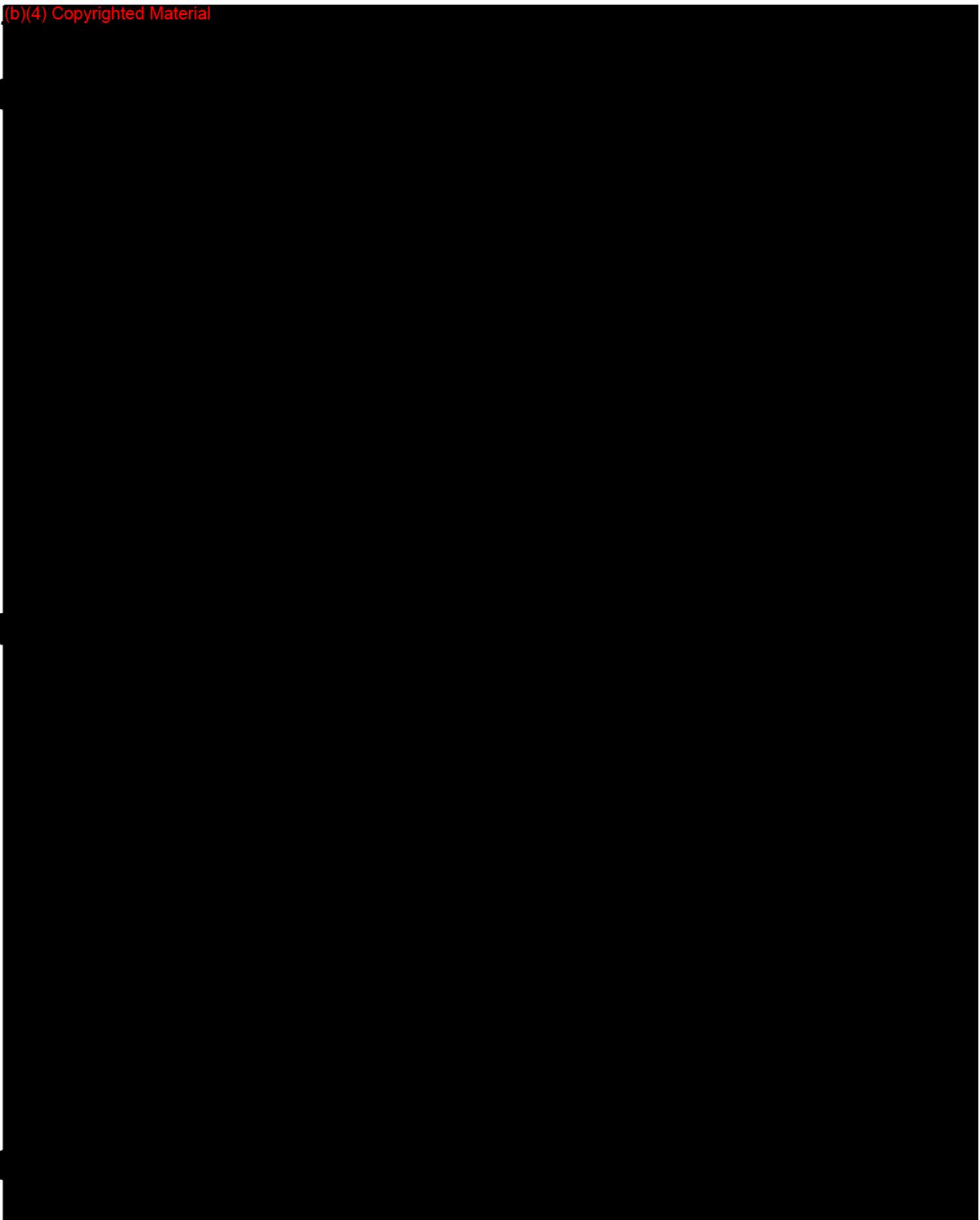


530 OSCILLATING WATER BED REDUCES APNEA

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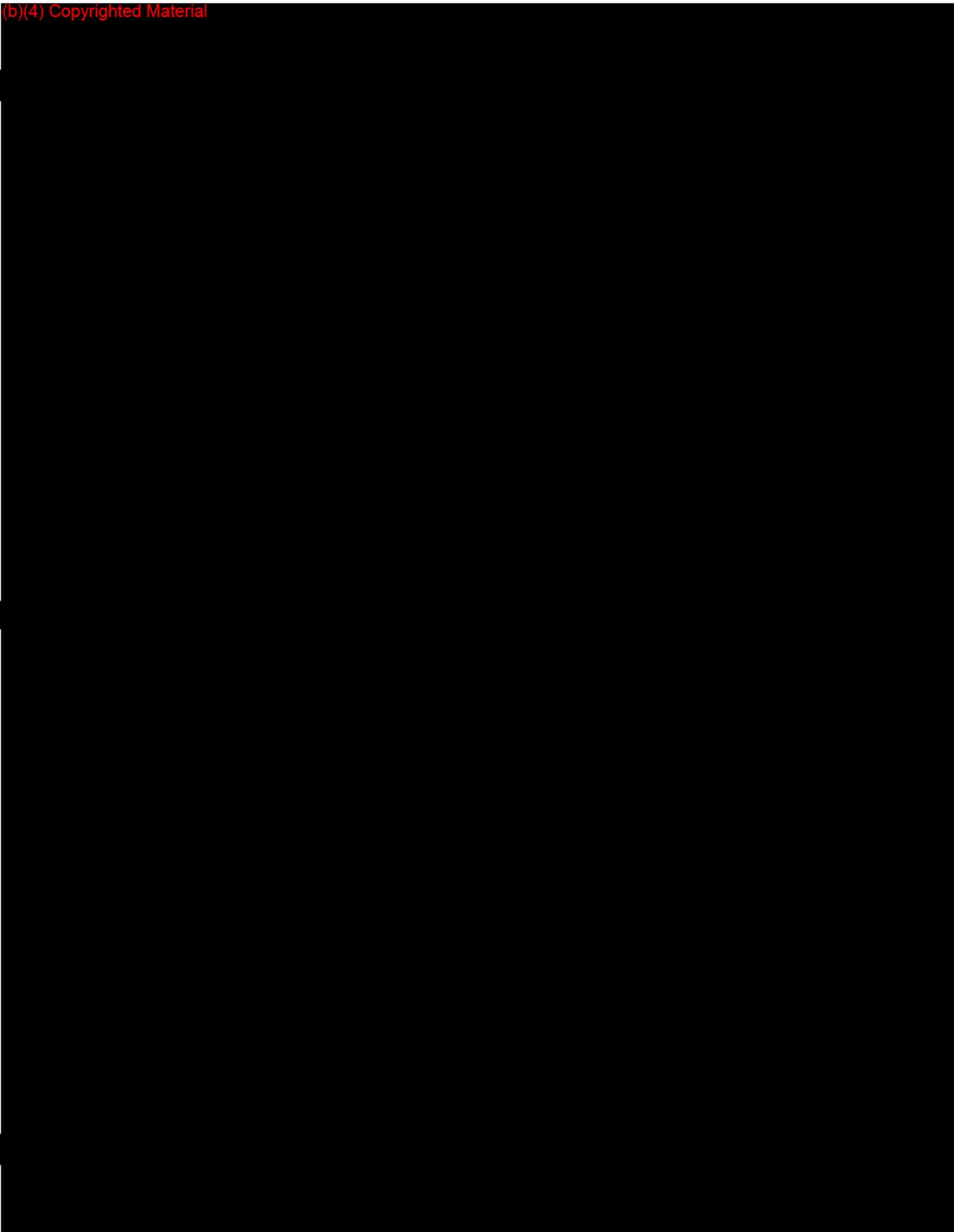
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532 OSCILLATING WATER BED REDUCES APNEA.

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ARTICLES 533



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

Date

From

REVIEWER(S) - NAME(S)

Richard J. Williams

Subject

510(k) NOTIFICATION

K842607

To

THE RECORD

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

- (A) Is substantially equivalent to marketed devices.
- (B) Requires premarket approval. NOT substantially equivalent to marketed devices.
- (C) Requires more data.
- (D) Is an incomplete submission. (See Submission Sheet).

Additional Comments:

Requires additional info

The submitter requests:

Class Code w/Panel:

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

REVIEW:

(BRANCH CHIEF)

(DATE)

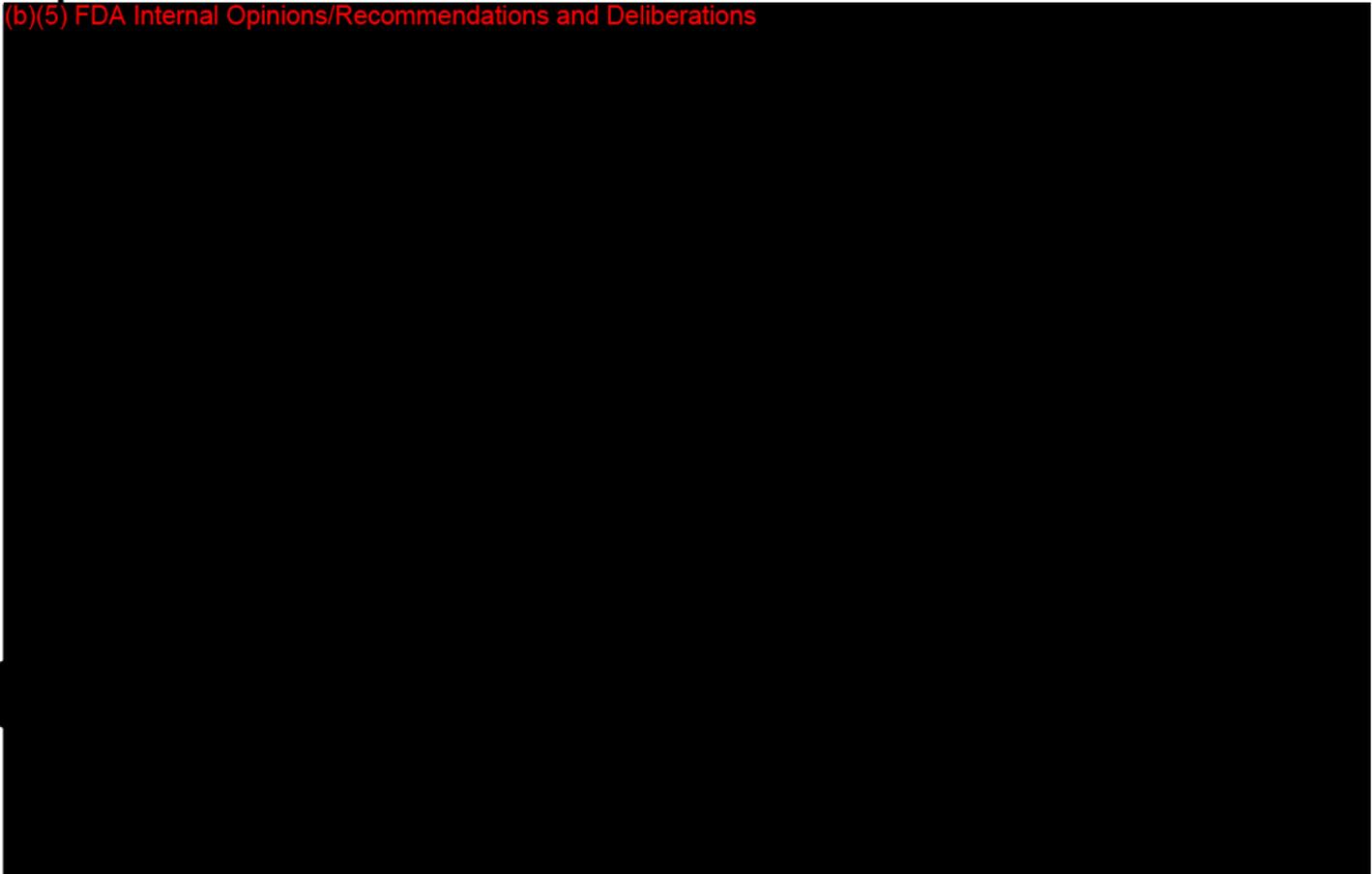
FINAL REVIEW:

(DIVISION DIRECTOR)

(DATE)

MEMO RECORD	<i>AVOID ERRORS PUT IT IN WRITING</i>	DATE 8/9/84 Thr
FROM: BIOMEDICAL ENGINEER		OFFICE HFK-420
TO: THE RECORD		DIVISION DGGD
SUBJECT: Alpha Medical Systems Infant Apnea Bed Stimulator Model AA-010 -		
SUMMARY K842607		

(b)(5) FDA Internal Opinions/Recommendations and Deliberations



SIGNATURE <i>Richard J. Williams</i>	DOCUMENT NO.
---	--------------



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

JUL 10 1984

Alpha, Medical Systems
Attr: Timothy A. Williams, RRT
1534 Almdia Ct. #C
Miamisburg, OH. 45342

D. C. Number : See Attached List
Date : 7-5-84
Product :

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The Preambles to the rules you have submitted to the Section 510(k) of the Federal Food, Drug and Cosmetic Act and the device has been received for review. The assigned review number is (D.C. Number 100). Please refer to this number in all correspondence concerning this device to this office.

We will notify you as soon as a decision has been made regarding your application. It is important that you continue to provide information to this office as requested. If you have any questions regarding the status of your application, please contact the office.

Director, Center for Devices and Radiological Controls
Food and Drug Administration
1015 North 1st Street
Washington, DC 20205
Telephone: (301) 427-7000

If you have any questions regarding the status of your application, please contact the office at (301) 427-7000.

Very truly yours,
Director

JUL 10 1984

D.C. Number

Product

K842607

Infant Apnea Bea Stimulator

Model AA-010

K842608

Infant Percussor Model PA-010

H842607

Food and Drug Administration
 Bureau of Medical Devices
 Document Control Center (HFK-20)
 8757 Georgia Ave.
 Silver Spring, MD 20910

06/29/84

Re: 510K Notification

Attention: Document Control Clerk

This is to notify you that Alpha Medical Systems intends to produce and market the following device:

Classification Name: Bed, water flotation, A-C powered - General Hospital Pannel

Common / Usual Name: Apnea Bed, Stimulator

Proprietary Name: Infant Apnea Bed Stimulator Model AA-010

Establishment Registration No: 1526588

Performance Standard: None established under section 514 of the act.

Labeling and Promotional Material: Draft copies of proposed device and package labeling as well as photostats of the prototype labeling.

Substantial Equivalence: We feel that the infant apnea bed stimulator is equivalent to the Medpro Neofloat Flotation Therapy System. Information on other apnea bed systems was unavailable however there are numerous listings of this type of equipment in the Health Care Systems Directory.

Enclosures: The following are enclosed to aid in establishing substantial equivalence:

- 1) Infant Apnea Bed Stimulator / System Data Sheet-Package Insert.
- 2) Draft copies of proposed device and package labeling.
- 3) Photostat of Medpro Stimulator.
- 4) Photostat of Alpha Medical Systems prototype apnea bed stimulator.

We consider our intent to produce this device confidential information at this time pending patent clearance. We will notify the FDA as soon as a clear patent is obtained. We request that this be kept confidential by your office and we have not disclosed our intent to market this device to anyone except employees of Alpha Medical Systems.

Thank you for your help.

Sincerely:

Timothy A. Williams

Timothy A. Williams RRT
 Alpha Medical Systems
 1534 Almedia CT. # C
 Miamisburg, OH 45342
 (513) 866-8226
 Reg. # 1526588

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Encl: 4

Alpha Medical Systems
Infant Apnea Bed Stimulator

Description: The Alpha Medical Systems Infant Apnea Bed Stimulator was designed to be used in conjunction with standard water flotation therapy systems to produce rhythmic waves in the management of apnea and bradycardia in the premature and newborn infants.

Features:

Ease of operation
Compatible with any water flotation therapy system
Variable system pressure relief valve
Automatic system pressure control
Variable frequency control

Specifications:

Frequency - (b)(4) specifications
Gas supply - (b)(4) specifications
Power - (b)(4) specifications

Warranty: The Alpha Medical Systems will warrant this device for one year to be free from flaws in material or workmanship.

Warnings: This device is designed to be used with water flotation therapy systems only.

This device is not suitable for use in the presence of flammable anesthetics.
Federal law restricts this device to use by or on the order of a physician.

Principle of operation: The Infant apnea Bed Stimulator utilizes the free flow characteristics of the water flotation by intermittently inflating a pillow with air underneath the mattress to produce a rhythmic movement of the bed and consequently the patient. The variable pressure and rate allow for different applications to different size and severity of patients. Many hospitals presently use a pressure ventilator to produce rhythmic movement of the bed, this system will allow more convenience and control to this therapy.

Operating instructions:

Set up and test bed before placing under patient.
Fill the mattress with warm water, remove all excess air. Fill to the level of the side.
Make certain the switch is in the off position.
Remove the two screws on the sides of the stimulator.
Install fresh "AA" alkaline batteries. Alkaline are recommended for longer life.
Connect the high pressure line to the rear of the stimulator and to the source gas.
Connect the pillow to the front of the stimulator.
place the pillow under the filled mattress approximately one third the distance from the head of the bed or under where the chest would be.
Test the bed before use.
If the movement is either too vigorous or too gentle refer to Fig. 1.
Place patient on the apnea bed and observe movement.

Note: Proper monitoring of bradycardia and apnea should continue and episodes of apnea or bradycardia should be documented.

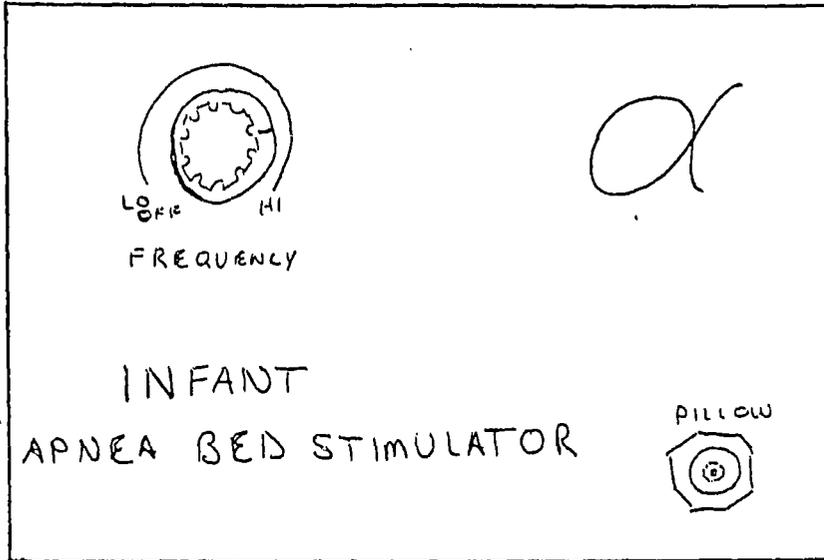
For any information or repair please contact Alpha Medical Systems.



PROPOSED DEVICE LABELING

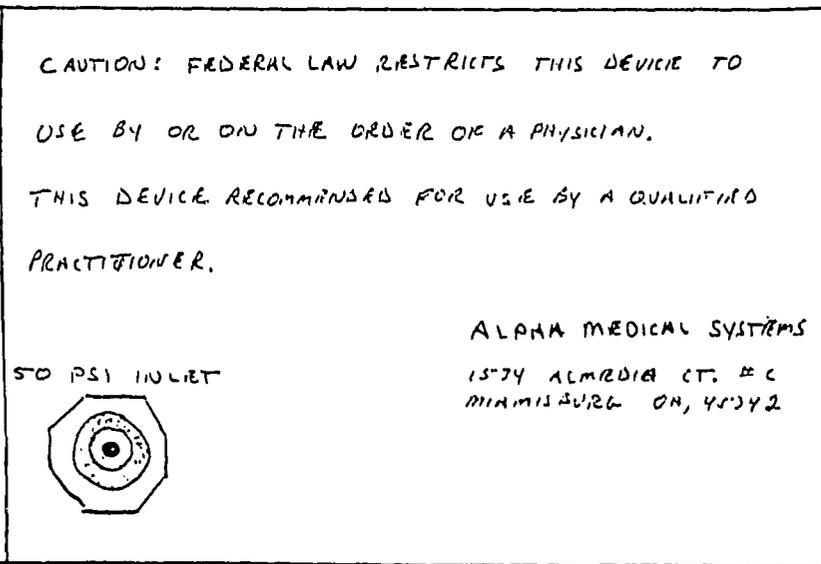
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ALPHA MEDICAL SYSTEMS APNEA BED STIMULATOR.



FRONT

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REAR

* PROPOSED PACKAGING LABELING

ALPHA MEDICAL SYSTEMS - APNEA BED STIMULATOR

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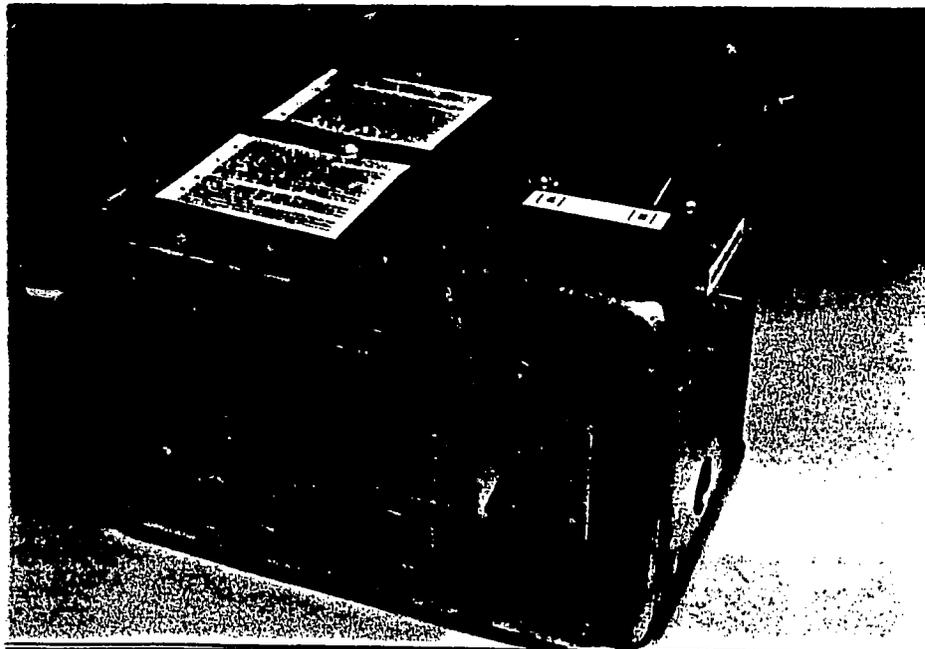
INFANT
APNEA BED STIMULATOR
CONTENTS - ONE STIMULATOR
ONE PILLOW

ALPHA MEDICAL SYSTEMS
1534 ALMIRIDA CT. # C
MIAMI BURG, OH 45342

CAUTION: READ PACKAGE INSERT BEFORE USE. THIS DEVICE RECOMMENDED
FOR USE BY OR ON THE ORDER OF A PHYSICIAN.

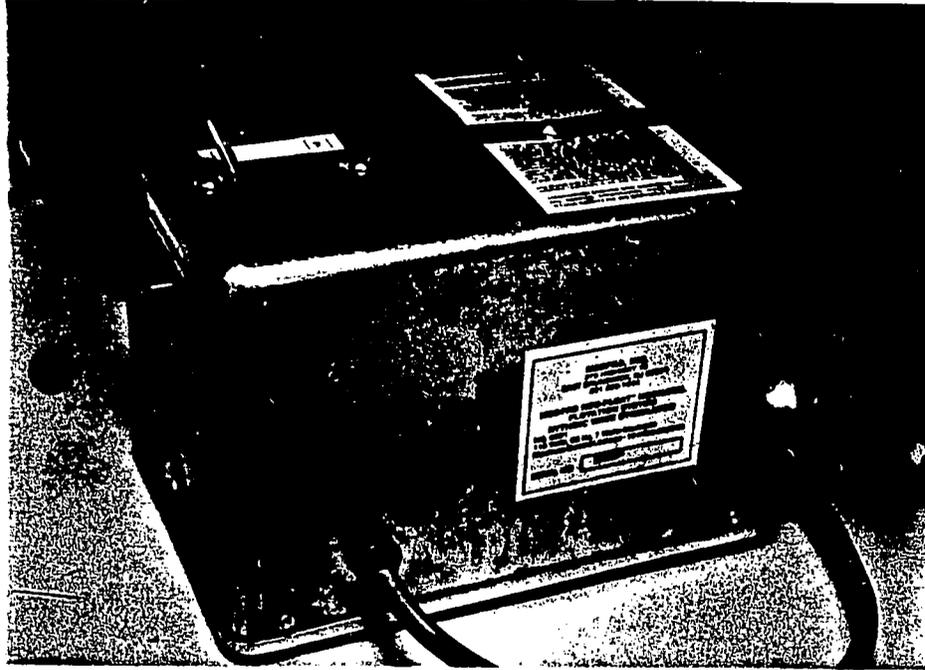
THIS LABELING WILL BE PRESENT ON TOP, ONE SIDE AND ONE END
OF THE BOX.

*
SIZE AND DIMENSIONS OF THE PACKAGING MATERIAL MAY VARY DUE
TO COST AND AVAILABILITY OF PROPOSED MATERIALS. ALL MATERIALS
USED WILL BE LABELED ACCORDING TO F.D.A. REGULATIONS AS DESCRIBED
IN THE CFR. TITLE 21 PART 801, AND WILL ENSURE MAXIMUM
SAFETY OF THE DEVICE AND ITS ATTACHMENTS.



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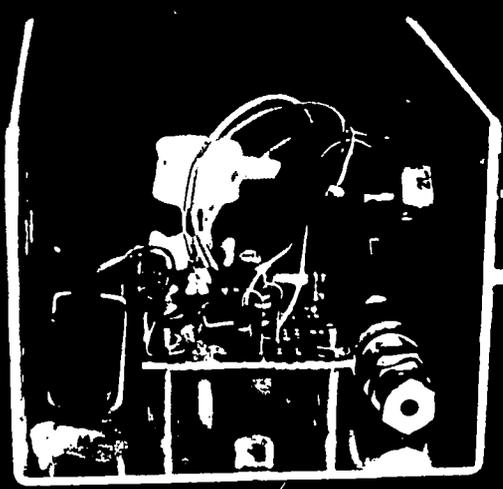
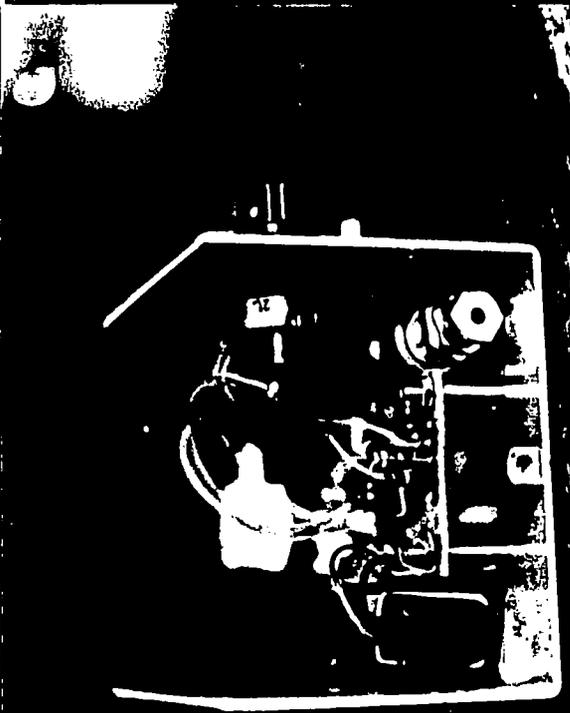
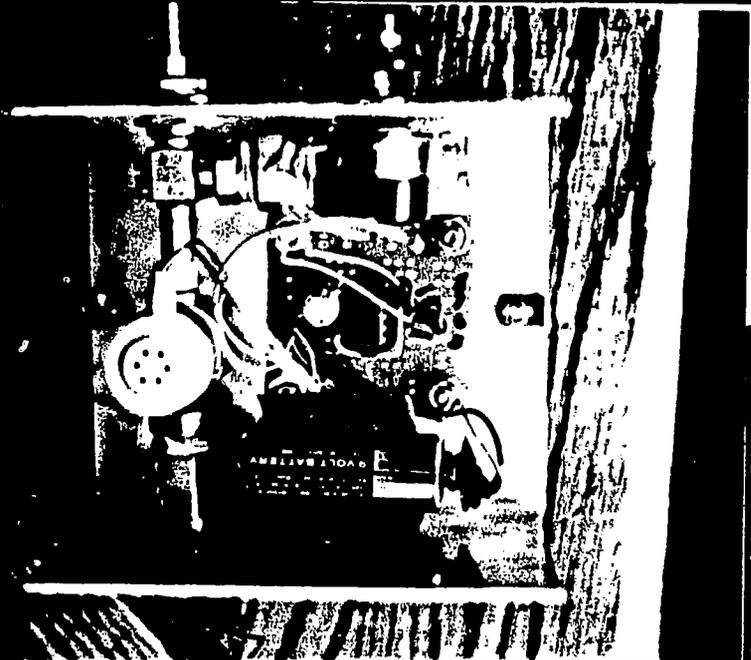
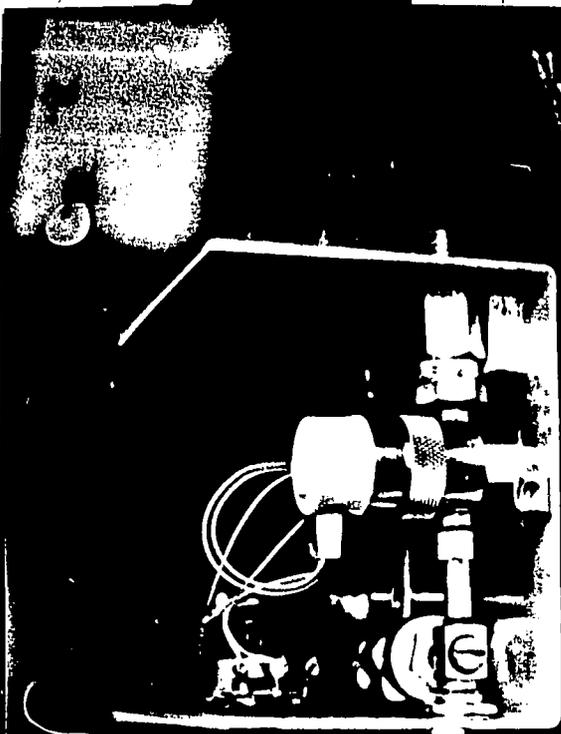
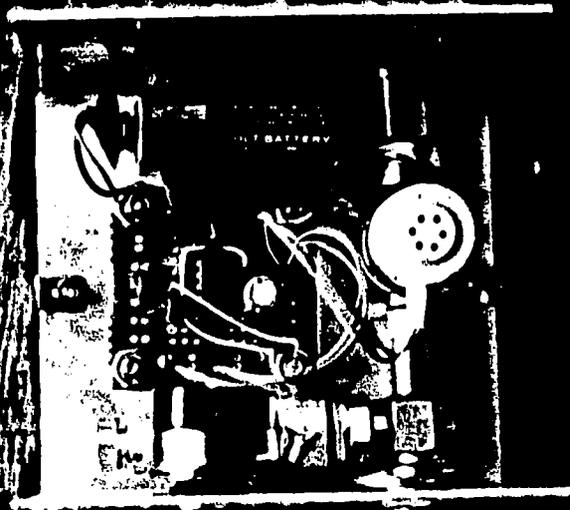
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CAUTION: FEDERAL LAW RESTRICTS THIS
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 OF A PHYSICIAN.

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 MIAMISBURG, OH





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