

H 935674 DEC 1 1993

510(k) Summary

Date:

December 7, 1993

Submitter and manufacturer:

Physio-Control Corporation
11811 Willows Road N.E.
P.O. Box 97006
Redmond, Washington 98073-9706

Contact Person:

Sherri L. Pocock
Senior Regulatory Affairs Specialist
(206) 867-4332

Device:

LIFEPAK® 9 defibrillator/monitor

Classification:

FDA has classified low-energy DC Defibrillators and cardiac monitors into Class II (Federal Register Vol. 45, No. 25, Tuesday, February 5, 1980.)

Substantial Equivalence:

Note: As used herein, the term "substantial equivalence" is only as used in 21 CFR 807.81.

The intended use and function of the LIFEPAK 9 defibrillator/monitor are substantially equivalent to those of the LIFEPAK 9 defibrillator/monitor K905510, K881153.

The subject of this 510(k) is an incremental product improvement: a diode was mounted vertically instead of angled; a capacitor from a new supplier with identical electrical characteristics was substituted for the original capacitor.

Description:

DC defibrillators apply a brief, high energy pulse of electricity to the heart. This energy may be delivered through external paddles, electrodes on the chest, or through internal paddles applied directly to the heart.

Intended Use:

The LIFEPAK 9 defibrillator/monitor is a cardiac life support system used in the diagnosis and treatment of cardiac dysrhythmias.

Summary of Testing:

Qualification test data were provided that demonstrate that the LIFEPAK 9 defibrillator/monitor with subject component changes performs as well as or better than the LIFEPAK 9 without the component changes.

510(K) ROUTE SLIP

10(k) NUMBER K935674 PANEL CV DIVISION DCRND BRANCH

TRADE NAME LIFEPAK 9 DEFIBRILLATOR/MONITOR

COMMON NAME _____

PRODUCT CODE

LDD

PEDB

APPLICANT PHYSIO-CONTROL CORP.

SHORT NAME PHYSCONT

CONTACT SHERRI L POCOCK

DIVISION _____

ADDRESS 11811 WILLOWS ROAD N.E.

P.O. BOX 97006

REDMOND, WA 980739706

PHONE NO. (206) 867-4332

FAX NO. () - -

MANUFACTURER PHYSIO-CONTROL CORP.

REGISTRATION NO. _____

DATE ON SUBMISSION 07-DEC-93

DATE DUE TO 510(K) STAFF 21-FEB-94

DATE RECEIVED IN ODE 08-DEC-93

DATE DECISION DUE 08-MAR-94

DECISION

FA

DECISION DATE

DEC 16 1993

Su

N

510(K) ROUTE SLIP

510(k) NUMBER K934674 PANEL DE DIVISION DGRD BRANCH DEDB

TRADE NAME IDENTITY

COMMON NAME DENTAL IDENTIFICATION TAG

PRODUCT CODE _____

APPLICANT GARY JAGMIN, D.D.S.

SHORT NAME GARYJAGM

CONTACT GARY JAGMIN

DIVISION _____

ADDRESS 875 ST. ANDREWS WAY

FRANKFURT, IL 60423

PHONE NO. (815) 469-0544

FAX NO. (____) ____-____

ND

MANUFACTURER GARY JAGMIN, D.D.S.

REGISTRATION NO. _____

DATE ON SUBMISSION 13-SEP-93

DATE DUE TO 510(K) STAFF 14-DEC-93

DATE RECEIVED IN ODE 30-SEP-93

DATE DECISION DUE 29-DEC-93

DECISION _____

DECISION DATE MAR 22 1994

Branch 11/30/93

Grey

Refuse to accept 11/2



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 16 1993

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

Mr. Michael D. Willingham
Director, Regulatory Affairs & Standards
Physio-Control Corporation
11811 Willows Road Northeast
Redmond, Washington 98073-9706

Re: K935674
Lifepak 9 Defibrillator/Monitor
Regulatory Class: II
Dated: December 7, 1993
Received: December 8, 1993

Dear Mr. Willingham:

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 (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal laws or regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device, please contact the Division of Compliance Operations, Promotion and Advertising Policy Staff (HFZ-326) at (301) 594-4639. 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,

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



Memorandum

Date 12/13/93

From REVIEWER(S) - NAME(S) Albert Noyah

Subject 510(k) NOTIFICATION K935674

To THE RECORD

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

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

Additional Comments:

Is this device subject to Postmarket Surveillance? Yes No

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

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

The submitter requests under 21 CFR 807.95:*

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

Predicate Product Code w/panel and class:

LDD-II

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

REVIEW: [Signature]
(BRANCH CHIEF)

PE03 12/15/93
BRANCH CODE (DATE)

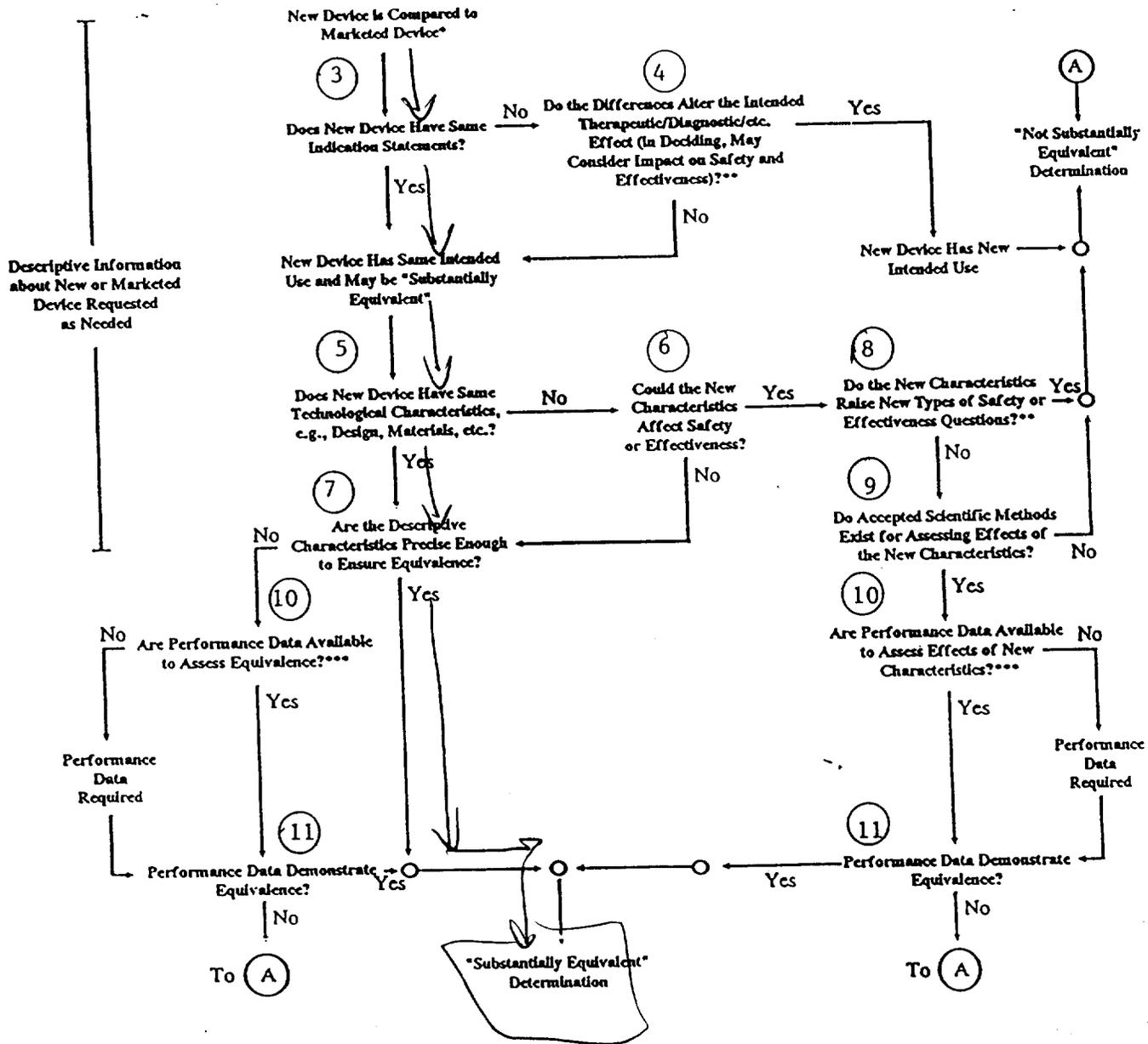
FINAL REVIEW: [Signature]
(DIVISION DIRECTOR)

DEC 16 1993
(DATE)

*DOES NOT APPLY TO ANY "SE" DECISIONS

2

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.

DEC 1 1988

Handwritten signature

REVIEWER: A. Moyal DIVISION/BRANCH: DCRND / PED3
 TRADE NAME: LifePak 9 COMMON NAME: Defibrillator
 PRODUCT TO WHICH COMPARED: LIFEPAK 9
 (510(k) NUMBER IF KNOWN)

YES	(NO)
-----	------

1. IS PRODUCT A DEVICE?

<input checked="" type="checkbox"/>	<input type="checkbox"/>
-------------------------------------	--------------------------

 - IF NO STOP
2. DEVICE SUBJECT TO 510(k)?

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------

 - IF NO STOP
3. SAME INDICATION STATEMENT?

<input checked="" type="checkbox"/>	<input type="checkbox"/>
-------------------------------------	--------------------------

 - IF YES GO TO 5
4. DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS?

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------

 - IF YES STOP 
5. SAME TECHNOLOGICAL CHARACTERISTICS?

<input checked="" type="checkbox"/>	<input type="checkbox"/>
-------------------------------------	--------------------------

 - IF YES GO TO 7
6. COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS?

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------

 - IF YES GO TO 8
7. DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?

<input checked="" type="checkbox"/>	<input type="checkbox"/>
-------------------------------------	--------------------------

 - IF NO GO TO 10 
 - IF YES STOP
8. NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS?

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------

 - IF YES STOP 
9. ACCEPTED SCIENTIFIC METHODS EXIST?

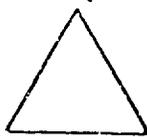
<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------

 - IF NO STOP 
10. PERFORMANCE DATA AVAILABLE?

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------

 - IF NO REQUEST DATA
11. DATA DEMONSTRATE EQUIVALENCE?

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------



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

1. EXPLAIN WHY NOT A DEVICE: _____

2. EXPLAIN WHY NOT SUBJECT TO 510(k): _____

3. HOW DOES THE NEW INDICATION DIFFER FROM THE PREDICATE DEVICE'S INDICATION: _____

4. EXPLAIN WHY THERE IS OR IS NOT A NEW EFFECT OR SAFETY OR EFFECTIVENESS ISSUE: _____

5. DESCRIBE THE NEW TECHNOLOGICAL CHARACTERISTICS: _____

6. EXPLAIN HOW NEW CHARACTERISTICS COULD OR COULD NOT AFFECT SAFETY OR EFFECTIVENESS: _____



7. EXPLAIN HOW DESCRIPTIVE CHARACTERISTICS ARE NOT PRECISE ENOUGH: _____

8. EXPLAIN NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS RAISED OR WHY THE QUESTIONS ARE NOT NEW: _____

9. EXPLAIN WHY EXISTING SCIENTIFIC METHODS CAN NOT BE USED: _____

10. EXPLAIN WHAT PERFORMANCE DATA IS NEEDED: _____

11. EXPLAIN HOW THE PERFORMANCE DATA DEMONSTRATES THAT THE DEVICE IS OR IS NOT SUBSTANTIALLY EQUIVALENT: _____

ATTACH ADDITIONAL SUPPORTING INFORMATION

9

Revised: 8-20-93

Premarket Notification (510(k)) Checklist for Acceptance Decision

K 935674 Date DMC Received 12/10/93

Device Trade Name: LIFEPAK 9

Reason for 510(k) Change in Components

Division/Branch: DCRND / PEDB

Administrative Reviewer Signature: Allert Moyal Date 12/13/93

Supervisory Signature: _____ Date _____

Did the firm request expedited review Yes

Did we grant expedited review Yes

accepted

refuse to accept

Yes
Present
Omission Justified

No
Inadequate
Omitted

I. Critical Elements:		
A. Is the product a device?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
B. Is the device exempt from 510(k) by regulation or policy?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
C. Is device subject to review by CDRH?	<input checked="" 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 checked="" type="checkbox"/>
E. (i) Are you aware of the submitter being the subject of an integrity investigation? If yes, consult the ODE Integrity Officer.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
(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 checked="" type="checkbox"/>	<input type="checkbox"/>

6

Yes
Present
Omission Justified

No
Inadequate
Omitted

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?:		
1. Device trade or proprietary name	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. Device common or usual name or classification name	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. Establishment registration number (only applies if establishment is registered)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4. Class into which the device is classified under (21 CFR Parts 862 to 892)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5. Classification Panel	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6. Action taken to comply with Section 514 of the Act	<input checked="" 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 checked="" type="checkbox"/>	<input type="checkbox"/>

10

	Yes Present Omission Justified	No Inadequate Omitted
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 checked="" 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 checked="" type="checkbox"/>
11. Engineering drawings for the device with dimensions and tolerances	<input checked="" type="checkbox"/>	<input type="checkbox"/>
12. The marketed device(s) to which equivalence is claimed including labeling and description of the device	<input checked="" type="checkbox"/>	<input type="checkbox"/>
13. Statement of similarities and/or differences with marketed device(s)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
14. Data to show consequences and effects of a modified device(s)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
II. Additional Information that <u>is</u> necessary under 21 CFR 807.87(h):		
A. Submitter's name and address	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Yes
Present
Omission Justified

No
Inadequate
Omitted

B. Contact person, telephone number and fax number	<input checked="" type="checkbox"/>	<input type="checkbox"/>
C. Representative/Consultant if applicable	<input checked="" type="checkbox"/>	<input type="checkbox"/>
D. Table of Contents with pagination	<input type="checkbox"/>	<input checked="" type="checkbox"/>
E. Address of manufacturing facility/facilities and, if appropriate, sterilization site(s)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
III. Additional Information that <u>may be necessary</u> under 21 CFR 807.87(h):		
A. Comparison table of the new device to the marketed device(s)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
B. Action taken to comply with voluntary standards	<input checked="" type="checkbox"/>	<input type="checkbox"/>
C. Performance data		
marketed device		
bench testing	<input checked="" type="checkbox"/>	<input type="checkbox"/>
animal testing	<input type="checkbox"/>	<input checked="" type="checkbox"/>
clinical data	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Handwritten mark

Yes Present Omission Justified No Inadequate Omitted

	Yes Present Omission Justified	No Inadequate Omitted
new device		
bench testing	<input checked="" type="checkbox"/>	<input type="checkbox"/>
animal testing	<input type="checkbox"/>	<input checked="" type="checkbox"/>
clinical data	<input type="checkbox"/>	<input checked="" type="checkbox"/>
D. Sterilization information	<input type="checkbox"/>	<input checked="" type="checkbox"/>
E. Software information	<input checked="" type="checkbox"/>	<input type="checkbox"/>
F. Hardware information	<input checked="" 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 checked="" type="checkbox"/>	<input type="checkbox"/>
If yes, continue review with checklist from any appropriate guidance documents.		
If no, is 510(k) sufficiently complete to allow substantive review?		

Yes
Present
Omission Justified

No
Inadequate
Omitted

I. Other (specify)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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PACING AND ELECTROPHYSIOLOGY DEVICES REVIEW FORM FOR 510K

Albert E. Moyal

510(k): K935674

DATE: 12/10/93

1. **State the reason(s) for the application (including differences from similar devices):**
Application has been submitted as a result of component changes.

2. **Identify the Product**

Applicant's Name:	Physio-Control, Corp.
Trade Name:	Defibrillator/Monitor
Model Number:	Lifepak 9
Software revision:	N/A
Previous 510K:	K905510 & K881153
FDA Procode(s):	LDD
Class:	II

3. **Description:** Portable Defibrillator/Monitor for use in Hospitals.

4. **Intended use:** To monitor and defibrillate those patients in need of such therapy.

Part of a System?	Y N
--------------------------	------------

5. **Site of use:** X Hospital Home Emerg squad other

6. **Age Group of Pts:** X Adult X Child Neonate

7. **Predicate Device:** Lifepak 9

Predicate 510K:	K905510, K881153
Intended use of predicate:	Same
Different Age group?	Y N
Different Site of use?	Y N
Part of a System?	Y N

8. **Labeling:**

Intended use stated?	Y N
Instructions for use?	Y N
Specifications:	Y N

9. **Voluntary standards:**

10. **Testing:**

Quality/Reliability	Y N (only for components)
Functional	Y N
Clinical	Y N

DATE: 11/9/93

TO: Don Dahms, BC, PEDB

FROM: Biomedical Engineer, PEDB **COMP:** Physio-Control, Inc.

DEVICE: Lifepak 9P - Components (C1 & CR1)

SUBJECT: Review of Information sent in by Company.

I have reviewed the response sent in by Physio-Control (PC) regarding the October 13 letter sent them by the office of compliance (OC). Physio has responded to the questions asked in three sections.

The first section details information separating the Lifepak (LP) 9P from the Lifepak 9 device. The company is adamant that there is no connection between the two devices regarding the component failures. They state that the LP 9P received 5109k) authorization on February 25, 1991, which is after the December 6, 1990 cut-off date for the FDA recommended recall. Physio feels that they were wrongly asked to include the 9P in the requests stated in the October 13, 1993 FDA letter. They have also provided information stating that the LP 9P sold and distributed in 1991 contained the changes to the components, C1 and CR1.

The second section provides an overview and related documentation on PC's product performance monitoring and recall decision process. They state that the two component changes were evaluated consistently with the company's standard operating procedures and was determined to be below their threshold for field action. The LP 9P field performance is stated to be 14.9 years Mean Time between failure (MTBF).

The last section describes the company's product design change and 510(k) decision process. The component changes are stated to have been evaluated consistent with the PC decision tree and determined that no new 510(k) application was needed.

The overall attitude by the company is that they should be able to market the Lifepak 9 and 9P defibrillators without a new 510(k) submission nor a recall of the devices. It is recommended by this reviewer that a consensus be initiated regarding further action on Physio-Control.

Albert E. Moyal

CC: Lynne A. Reamer, AD, PEDB & NEDB;
Tom J. Callahan, Div. Director, DCRND



DATE: 10/8/93

TO: OC, CV Branch, Colin Figueroa

FROM: Biomedical Engineer, PEDB **COMP:** Physio-Control, Inc.

DEVICE: Lifepak 9/9P Components (C1 & CR1)

SUBJECT: Review of 510(k)'s - K881153, K902288, K905510

I have researched and read through parts of the above listed 510(k)'s regarding the Lifepak 9 and 9P. The responses to the questions listed in the October 1 memorandum are as follows:

- 1) The above listed 510(k)'s did not include changes to the C1 nor to the CR1 components.
- 2) Application K905510 is for a modification to the Lifepak 9. Apparently, a problem occurring with baseline measurement led to the addition of a notch filter.

The 510(k) submitted for the Lifepak 9P is K902288. This submission was for a modified Lifepak 9 that included an external pacemaker connected to the defibrillator/monitor aspect of the LP9.

- 3) The Lifepak 9P application had the Lifepaks 8 and 9 listed as the predicate devices. I have not found the exact predicate devices listed for the LP9, although it appears to most likely be the Lifepak 8. Additional 510(k) applications listed for the LP 9 are K881153 and K892005.

If there is any other information that is needed please inform me at any time.

Albert E. Moyal

Records processed under FOIA Request 2014-7264; Released 10/21/14
Physio-Control Corporation
11811 Willows Road Northeast
Post Office Box 97006
Redmond, WA 98073-9706 USA
Telephone: 206.867.4000
Fax: 206.867.4202

K935674

VIA OVERNIGHT MAIL
December 7, 1993



REVIEWER'S DESK COPY
Two copies have also been sent to
FDA Document Mail Center
PHYSIO-CONTROL CORPORATION

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

Dear Mr. Dahms:

Physio-Control Corporation has been informed that the Office of Device Evaluation has determined that a 510(k) submission is needed for the changes to the LIFEPAK® 9 defibrillator/monitor (but not the LIFEPAK® 9P defibrillator/monitor/pacemaker) discussed in our submission dated October 22, 1993. Physio-Control Corporation agrees that the submission dated October 22, 1993 constitutes the 510(k) notification for the LIFEPAK® 9 defibrillator/monitor. We have attached a summary of the safety and effectiveness information as required under the statute.

Very truly yours,

PHYSIO-CONTROL CORPORATION

Michael D. Willingham
Director of Regulatory Affairs
and Standards

Enclosure
lib/letters/ODE-Flannery

PHYSIO-CONTROL
0 Dec 93 12 16
FDA/CDRH/OCE/DME

510(k) Summary

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Classification:

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Substantial Equivalence:

Note: As used herein, the term "substantial equivalence" is only as used in 21 CFR 807.81.

The intended use and function of the LIFEPAK 9 defibrillator/monitor are substantially equivalent to those of the LIFEPAK 9 defibrillator/monitor K905510, K881153.

The subject of this 510(k) is an incremental product improvement: a diode was mounted vertically instead of angled; a capacitor from a new supplier with identical electrical characteristics was substituted for the original capacitor.

Description:

DC defibrillators apply a brief, high energy pulse of electricity to the heart. This energy may be delivered through external paddles, electrodes on the chest, or through internal paddles applied directly to the heart.

Intended Use:

The LIFEPAK 9 defibrillator/monitor is a cardiac life support system used in the diagnosis and treatment of cardiac dysrhythmias.

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Qualification test data were provided that demonstrate that the LIFEPAK 9 defibrillator/monitor with subject component changes performs as well as or better than the LIFEPAK 9 without the component changes.



Physio-Control Corporation
11811 Willows Road Northeast
Post Office Box 97006
Redmond, WA 98073-9706 USA
Telephone: 206.867.4000
Fax: 206.867.4202

RECEIVED

8 DEC 93 12 15



VIA OVERNIGHT MAIL
December 7, 1993

FDA/CDRH/ODE/DNC

Mr. Don Dahms
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Fax: 206.867.4202

RECEIVED

8 DEC 93 12 15

FDA/CDRH/ODE/DHC

VIA OVERNIGHT MAIL
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Director of Regulatory Affairs
and Standards

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lib/letters/ODE-Flannery

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Date:

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Redmond, Washington 98073-9706

Contact Person:

Sherri L. Pocock
Senior Regulatory Affairs Specialist
(206) 867-4332

Device:

LIFEPAK® 9 defibrillator/monitor

Classification:

FDA has classified low-energy DC Defibrillators and cardiac monitors into Class II (Federal Register Vol. 45, No. 25, Tuesday, February 5, 1980.)

Substantial Equivalence:

Note: As used herein, the term "substantial equivalence" is only as used in 21 CFR 807.81.

The intended use and function of the LIFEPAK 9 defibrillator/monitor are substantially equivalent to those of the LIFEPAK 9 defibrillator/monitor K905510, K881153.

The subject of this 510(k) is an incremental product improvement: a diode was mounted vertically instead of angled; a capacitor from a new supplier with identical electrical characteristics was substituted for the original capacitor.

Description:

DC defibrillators apply a brief, high energy pulse of electricity to the heart. This energy may be delivered through external paddles, electrodes on the chest, or through internal paddles applied directly to the heart.

Intended Use:

The LIFEPAK 9 defibrillator/monitor is a cardiac life support system used in the diagnosis and treatment of cardiac dysrhythmias.

Summary of Testing:

Qualification test data were provided that demonstrate that the LIFEPAK 9 defibrillator/monitor with subject component changes performs as well as or better than the LIFEPAK 9 without the component changes.



Physio-Control Corporation
11811 Willows Road Northeast
Post Office Box 97006
Redmond, WA 98073-9706 USA
Telephone: 206.867.4000
Fax: 206.867.4202

RECEIVED

8 DEC 93 12 15

VIA OVERNIGHT MAIL
December 7, 1993

FDA/CDRH/OCE/DMC



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

Dear Mr. Dahms:

Physio-Control Corporation has been informed that the Office of Device Evaluation has determined that a 510(k) submission is needed for the changes to the LIFEPAK® 9 defibrillator/monitor (but not the LIFEPAK® 9P defibrillator/monitor/pacemaker) discussed in our submission dated October 22, 1993. Physio-Control Corporation agrees that the submission dated October 22, 1993 constitutes the 510(k) notification for the LIFEPAK® 9 defibrillator/monitor. We have attached a summary of the safety and effectiveness information as required under the statute.

Very truly yours,

PHYSIO-CONTROL CORPORATION

Michael D. Willingham
Director of Regulatory Affairs
and Standards

Enclosure

llb/letters/OCE-Flannery

510(k) Summary

Date:

December 7, 1993

Submitter and manufacturer:

Physio-Control Corporation
11811 Willows Road N.E.
P.O. Box 97006
Redmond, Washington 98073-9706

Contact Person:

Sherri L. Pocock
Senior Regulatory Affairs Specialist
(206) 867-4332

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

December 10, 1993

PHYSIO-CONTROL CORP.
11811 WILLOWS ROAD N.E.
P.O. BOX 97006
REDMOND, WA 98073
ATTN: SHERRI L. POCOCK

510(k) Number: K935674
Received: 08-DEC-93
Product: LIFEPAK 9
DEFIBRILLATOR/MO
NITOR

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.

The Safe Medical Devices Act of 1990 (SMDA), signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. Although the traditional timeframes for reviewing 510(k)s has been 90 days, it is now taking longer. These increasing response times have been caused by many factors, including a sharp increase in ODE's workload and increasingly complex device submissions. During 1992, we received about 1,500 more total submissions than we did the preceding year. We are troubled by these increases in response times and are making every effort to regain predictability in the timing of 510(k) reviews. Due to the increase in response times, CDRH has established a 510(k) Status Reporting System through which submitters may receive a status report on their 510(k) submissions(s) as follows:

- o Beginning 90 days after ODE receives your 510(k) submission, you may begin requesting status information. Submit requests via fax (301-443-8818) or via mail to:
510(k) Status Coordinator
Division of Small Manufacturers Assistance (DSMA) (HFZ-220)
Center for Devices and Radiological Health, FDA
5600 Fishers Lane
Rockville, Maryland 20857 USA
Because of staff limitations, we cannot answer telephone status requests.
- o 510(k) status requests should include:
 - (1) submitter's name and mailing address;
 - (2) requester's name, affiliation with the 510(k) submitter, mailing address, fax number (if applicable), telephone number, and signature; and

- (3) 510(k) information, including product name, 510(k) number, date logged in by ODE (as identified in acknowledgment letter from ODE), and name of contact person identified on firm's 510(k) submission.

Enclosed is a suggested format that you may use to ensure that you include all of the required information.

- o Within three working days after DSMA receives a submitter's status request, DSMA will send the submitter a fax or letter that includes:
 - (1) the branch to which the 510(k) has been assigned;
 - (2) the last action, and date of that action, that CDRH has taken regarding the 510(k), e.g., logging in an amendment, preparing a decision letter; and
 - (3) the position of the 510(k) in the reviewer's queue.

We request that 510(k) submitters make status inquiries no more than every four weeks. We do not have the resources to respond more frequently.

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

Although FDA acknowledges that the law provides the 510(k) submitter an alternative, FDA encourages 510(k) submitters to provide a 510(k) statement to FDA and to make their safety and effectiveness information available to the public, excluding confidential manufacturing process information, in lieu of submitting a 510(k) summary to the agency until FDA promulgates a regulation on the content and format of 510(k) summaries. Since the law requires that FDA must make the 510(k) summary, or the source of information referred to in the 510(k) statement, publicly available within 30 days of making a substantial equivalence determination, we advise you that we may no longer honor any request for extended confidentiality under 21 CFR 807.95.

Additionally, the new legislation also requires any person who asserts that their device is substantially equivalent to a class III device to (1) certify that he or she has conducted a reasonable search of all information known, or otherwise available, about the generic type of device, AND (2) provide a summary description of the types of safety and effectiveness problems associated with the type of device and a citation to the literature, or other sources of information, upon which they have based the description (class III summary and certification). The

description should be sufficiently comprehensive to demonstrate that an applicant is fully aware of the types of problems to which the device is susceptible. If you have not provided this class III summary and certification in your premarket notification, please provide it as soon as possible. We cannot complete the review of your submission until you do so.

As of March 9, 1993, FDA has implemented the Good Manufacturing Practice(GMP) Pre-Clearance Inspection Program for all class III devices that are being reviewed under the premarket notification program. A letter of substantial equivalence cannot be sent until the finished device manufacturing site(s) and sterilization sites(s) as appropriate, have been identified and FDA has determined that the manufacturer(s) is in compliance with the GMP regulation (21 CFR Part 820).

Furthermore, the new legislation, section 522(a)(1), of the Act, states that if your device is a permanent implant the failure of which may cause death, you may be subject to required postmarket surveillance. If the premarket notification for your device was originally received on or after November 8, 1991, is subsequently found to be substantially equivalent to an Aneurysm Clip, Annuloplasty Ring, Artificial Embolization Device, Automatic Implanted Cardioverter Defibrillator System, Cardiovascular Intravascular Filter, Cardiovascular Permanent Pacemaker Electrode (Lead), Central Nervous System Fluid Shunt, Coronary Vascular Stent, Implantable Pacemaker Pulse Generator, Implanted Diaphragmatic/ Phrenic Nerve Stimulator, Intracardiac Patch or Pledget, Intravascular Occluding Catheter, Replacement Heart Valve, Total Artificial Heart, Tracheal Prosthesis, Vascular Graft Prosthesis (less than 6 mm diameter), Vascular Graft Prosthesis (6 mm or greater diameter), Vena Cava Clip, or Ventricular Assist Device - Implant, you will be subject to the required postmarket surveillance and so notified of this determination in your substantially equivalent letter. (Some of the above listed types of devices may require a premarket approval application). This list is subject to change without notification. If you have any questions as to whether or not your device may be subject to postmarket surveillance or about this program, please contact the Postmarket Surveillance Studies Branch at (301) 594-0006.

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

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

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

Sincerely yours,

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

Physio-Control Corporation
11811 Willows Road Northeast
Post Office Box 97006
Redmond, WA 98073-9706 USA
Telephone: 206.867.4000
Fax: 206.867.4154

K935674

LIFESAVING TOOLS FOR LIFESAVING TEAMS



22 October 1993

Mr. Fred Hooten
Director, Division of Enforcement III (HFZ-300)
Office of Compliance
Center for Devices and Radiological Health
U.S. Food and Drug Administration
2098 Gaither Road
Rockville, MD 20850

Subject: Supplement to our meeting of 14 October 1993

Mr. Hooten:

As agreed in our meeting of 14 October 1993, I am providing the following information for your consideration:

- 1) Attachment 1 provides documentation which we believe demonstrates that the LIFEPAK ® 9P defibrillator/monitor/pacemaker is not subject to FDA's 13 October 1993 letter requesting recall and 510(k) for products distributed prior to 6 December 1990. This product was not marketed nor made available for sale until 1991. The attachments show that this product received 510(k) authorization on 25 February 1991 (see attachment 1a). Also provided are manufacturing and distribution records demonstrating that the first LIFEPAK 9P defibrillator/ monitor/ pacemakers sold and distributed in 1991 contained the changes to components C1 and CR1.

Our review of manufacturing records found that the first nineteen LIFEPAK 9P devices were built for evaluation during product development in late 1990. These units included the change to CR1 but did not include the change to C1. Note this is contrary to the statement made in my 22 September 1993 letter to Mr. R. Andros on page 3, "All LIFEPAK 9P defibrillator/monitor/pacemakers have the improvements to C1 and CR1." These early development devices were not considered in this statement, as they were built for the purpose of test and evaluation only and not intended for sales distribution.

LIFEPAK 9P defibrillator/monitor/pacemakers manufactured after the first nineteen devices (serial numbers ≥ 120) include the changes to C1 and CR1. Records for serial number 120 are provided in Attachments 1b-d demonstrating this configuration.

Therefore, we believe the LIFEPAK 9P defibrillator was wrongly included in the scope of the requests in FDA's 13 October 1993 letter and we ask that it be excluded from the those requests. Furthermore, our evaluation of the the subject component changes indicates that no recall or 510(k) notification is warranted, consistent with our procedures discussed below.

36

22 October 1993
Page Two

- 2) Attachment 2 provides an overview and related SOPs for Physio-Control's product performance monitoring and recall decision process. The two subject LIFEPAK 9 component changes, C1 and CR1, were evaluated consistent with our SOPs and determined to be below our threshold for field action. Further supporting this decision, we note that the LIFEPAK 9 field performance is 14.9 years Mean Time Between Failure (MTBF) - much better than a competitive device authorized for market which was estimated to perform at a 6 year MTBF (as discussed in my 22 September 1993 letter).

While your office may not be able to "approve" these procedures, in the interest of fairness, I would appreciate your review and comments on any areas which you believe need revision under the GMP regulation.

- 3) Attachment 3 provides an overview and decision tree for Physio-Control's product design change and 510(k) decision process. The two subject component changes, C1 and CR1, have been evaluated consistent with this decision tree and determined that no 510(k) notification was needed for this change.

Again, I would appreciate review and comment by the Office of Device Evaluation (a copy for Dr. Callahan is enclosed) for any areas that you believe might lead to decisions inconsistent with the 510(k) regulation.

We request an expedited review and determination of this information by FDA. For the reasons stated above, we believe the LIFEPAK 9 and 9P defibrillators should be allowed to be marketed without a 510(k) submission or recall. In addition, we emphasize that we followed our procedures, as discussed at our meeting and described herein, and we believe that these procedures comply with the regulation. We are anxious to receive feedback so we can come to a common understanding. We will continue to follow these procedures unless advised otherwise.

Sincerely,

PHYSIO-CONTROL CORPORATION



Michael D. Willingham
Director, Regulatory Affairs & Standards

cc: (w/enclosures) Mr. Richard Andros, FDA SEA-DO

2

Attachment 1

Contents

- a. LIFEPAK 9P defibrillator/monitor/pacemaker 510(k) premarket notification authorization letter from Dr. A.Acharya dated 25 February 1993.
- b. Physio-Control Advance Change Notice (reference ECS No. 19842, revision "B2"), released 8/23/90, documenting the change to the mounting of diode CR1 on the Power Conversion PCB Assembly (reference part number 803724).
- c. Physio-Control Advance Change Notice (reference ECS No. 20548, revision "C5"), released 12/6/90, documenting the change to capacitor C1 on the Power Conversion PCB Assembly (reference part number 803724).
- d. Physio-Control Unit Configuration Traveler (primary Device History Record document) for LIFEPAK 9P defibrillator/monitor/pacemaker serial number 120. This record shows the instrument was manufactured to a configuration containing the modifications to C1 and CR1. Note the configuration number of part number 803724 (Power Conversion PCB Assembly) is "005, C5, C6" (arrow added to exhibit for reference). This reference indicates that the Power Conversion PCB Assembly incorporates all revisions through "C6." Therefore, this device contained changes referenced in b) and c) above (revisions "B2" and "C5", respectively).





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 25 1991

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

Ms. Sherri L. Pocock
Senior Regulatory Affairs Specialist
Physio-Control Corporation
11811 Willows Road Northeast
Post Office Box 97006
Redmond, WA 98073-9706

Re: K902288
Trade Name: Lifepak 9P
Regulatory Class: III
Dated: December 20, 1990
Received: December 21, 1990

1a.

Dear Ms. Pocock:

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 (Performance Standards) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a pre-amendments 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 Devices
Office of Device Evaluation
Center for Devices and
Radiological Health



PRODUCT NAME LP9 SHEET: 1 OF 1

WG NO. 813724 REV C5 EFF POINT 2 EFF NOTES lc.

TITLE PCB ASSY - POWER LEVER SWITCH, LP9 NEXT ASSY 803800 ORIGINATOR K. Warner DATE 12/1/90 CHECKING NA RELEASE M. Butler 1/9/90

REASON FOR CHANGE Capacitor unable to meet drawing specs PART NUMBER STATUS no charge - 02

REVISE DRAWING AS FOLLOWS PL

CONFIDENTIAL

4	delete	805323-01	cap-mf, pe, hv, axl .0047 uF, 8KV	C1	
4	add	202210-000	cap-ceramic, disc, axl, 4700pF, 9KV	C1	
ITEM NO.		PART NUMBER	PART DESCRIPTION	REFERENCE INFORMATION	CP CODE

Handwritten signature



805460-00 000120

END ITEM UNIT CONFIGURATION TRAVELER

P/N 805460-00

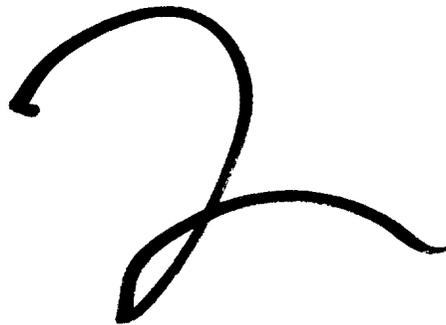
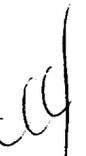
S/N 000120

LIFEPAK 9P-ENGLISH.120V

*CRITICAL OPERATIONS SPECIFIED		DATE	STAMP
* TORQUE PADDLE KEPNUTS		12/31/90	()
* HIPOT & CONT. TEST PADDLES		12/31/90	()
N/A QC AUDIT ONLY			(1d.)
* FUNCTIONAL TEST		1/2/91	()
* END ITEM HIPOT TEST		1/2/91	()
* POWERAGE		1/9/91	()
* FINAL END ITEM TEST		1/9/91	()
Q.C. INSPECT-ELECT		1.9.91	()
DRAWING P/N	CONFIG.	ADDITIONAL CONFIG.	
805460	005	(b)(4)	
Wabash OK			

PART #	LOC/REF	CONTROL NO.	CONFIGURATION	PART #	LOC/REF	CONTROL NO.	CONFIGURATION
Traceable				Traceable			
803705-00	CAP	(b)(4)		803723-05	(b)(4)		
802793-05	INDT			803724-02			
805471-00				200881-003			
805472-00	A5			803704-01			
202116-001	U7			800240-11			
202116-001	U9			800448-04			
202116-001	U10			800249-04			
202116-001	U12			802901-06			
805534-01	T1			803728-01			
201155-003	R74			803756-11			
805473-01	PCB			804697-03			
805474-00	PCB			804697-03			
201597-000	U49			804697-03			
202045-000	K1			803709-00			
201155-000	R131			803709-01			
201155-000	R132			803710-903			
250015-003	U1			803710-003			
250015-003	U30			Controlled			
805576-00	U9			803706-00			
805575-00	U25			803726-01			
803710-902	U27						
803710-902	U14			Traceable			
201597-000	U7			805474-00			
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				803710-004			

12

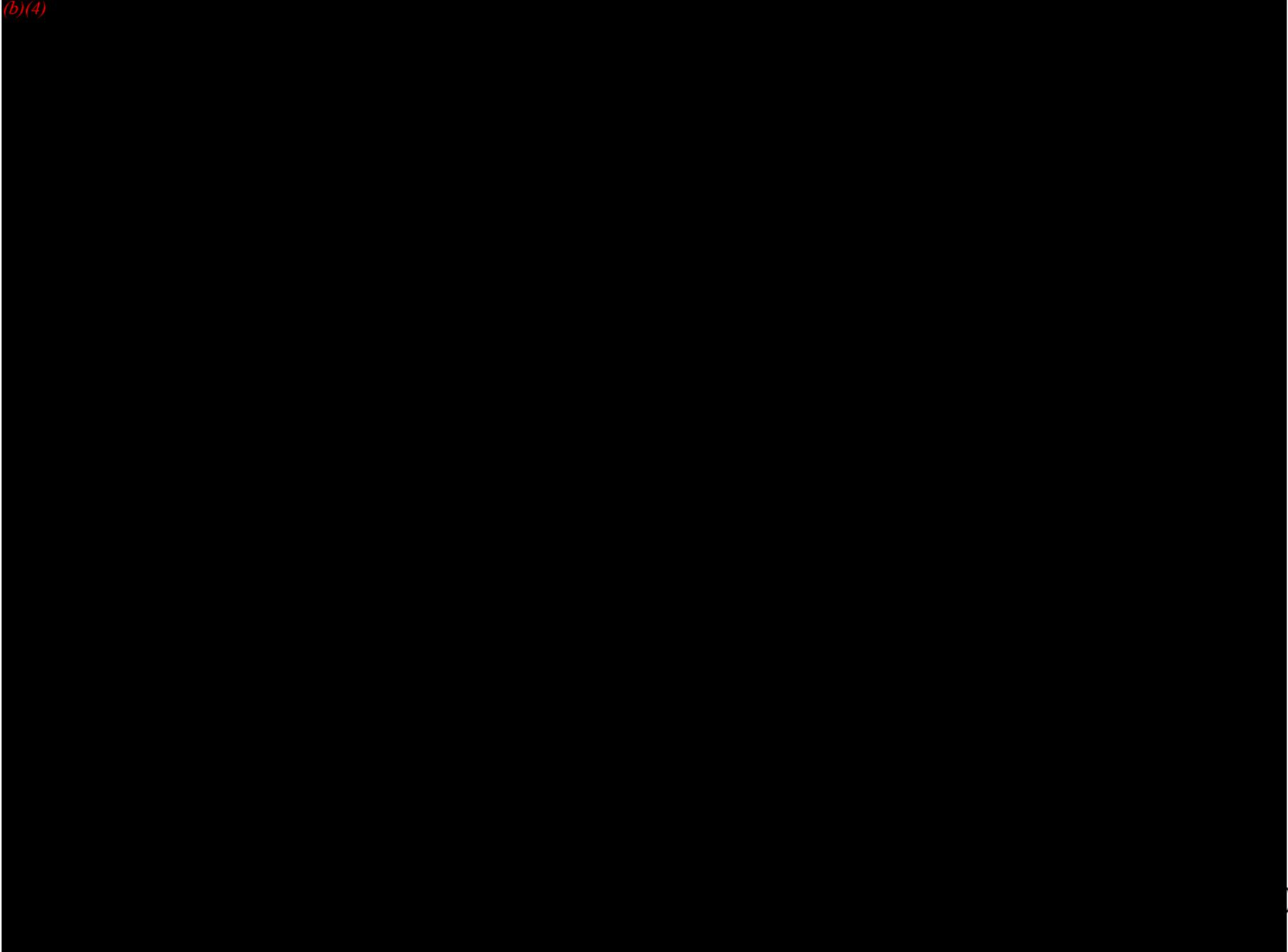
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Attachment 2

Contents

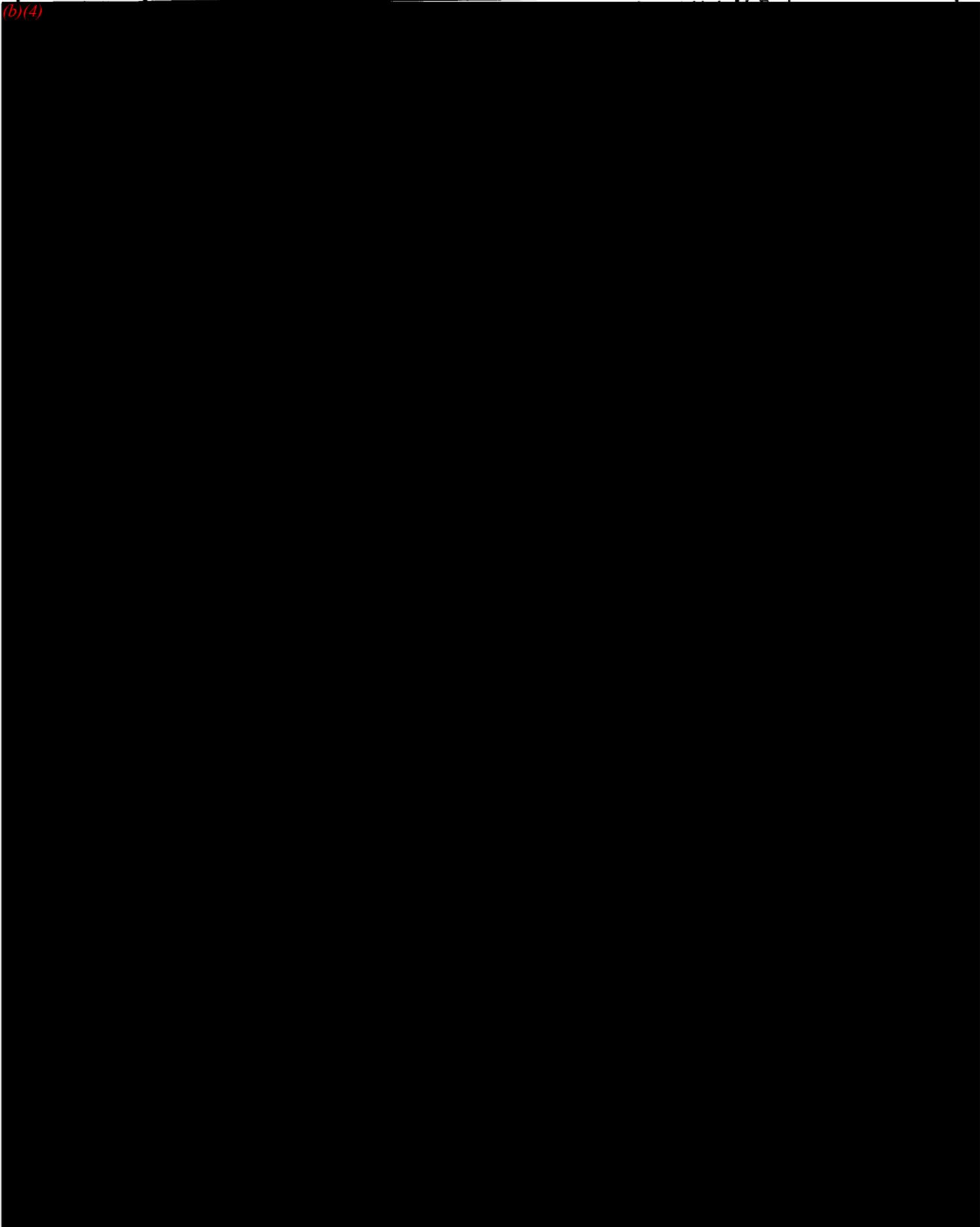
- a) System overview of Physio-Control's product performance monitoring and field action decision process with referenced SOPs.
- b) Data Collection, Triggers and Trending procedure (2000-260). This procedure describes product performance data collection methods - data sources, frequency of collection and assessment, and metrics. Appendix B of this document provides an overview of the data trending criteria.
- c) Investigations and Corrective Action procedure (2000-245). This procedure describes the investigation process, including failure analyses and corrective action decisions. In particular, section 8 of the procedure describes the root cause assessment and related decisions.
- d) Field Action Decision procedure (2006-076). Section 8.7 of this procedure describes the basic process of risk quantification in terms of severity and probability and corresponding guidelines for field action decisions. For "critical" failure modes, the probability threshold for field action is 10% of the device's MTBF reliability goal.
- e) Recall/Safety Alert procedure (2000-048). This procedure describes the process for recall or safety alert strategy development and conduct.
- f) Field Action Decision form for evaluation of the LIFEPAK 9 defibrillator CR1 component investigation (reference #393022). This document indicates that the investigation was assessed in accordance with the Field Action Decision procedure 2006-076 and found to have a probability of occurrence below the threshold for field action. Reference section 8.7 of procedure 2006-076 for definitions.
- g) Field Action Decision form for evaluation of the LIFEPAK 9 defibrillator C1 component investigation (reference #10-92-068). This document indicates that the investigation was assessed in accordance with the Field Action Decision procedure 2006-076 and found to have a probability of occurrence below the threshold for field action. Reference section 8.7 of procedure 2006-076 for definitions.

Field Action Review Process Overview



PT 07 1993

REV. LTR.	REV. DATE	DESCRIPTION	APPD
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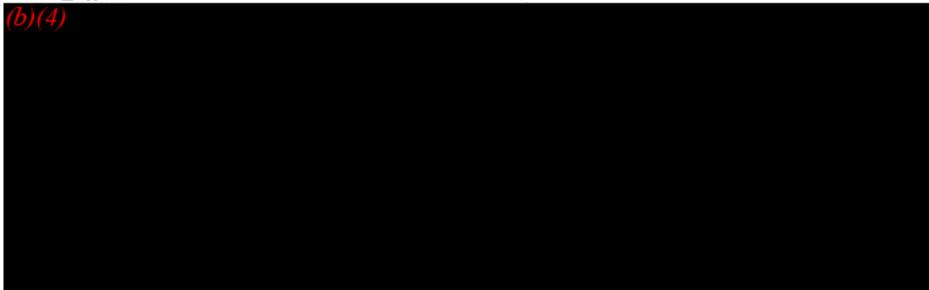


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Table of Contents

- 1.0 Purpose
- 2.0 Scope
- 3.0 Reference Documents
- 4.0 Definitions
- 5.0 Data Collection



- 6.0 Trending and Triggering

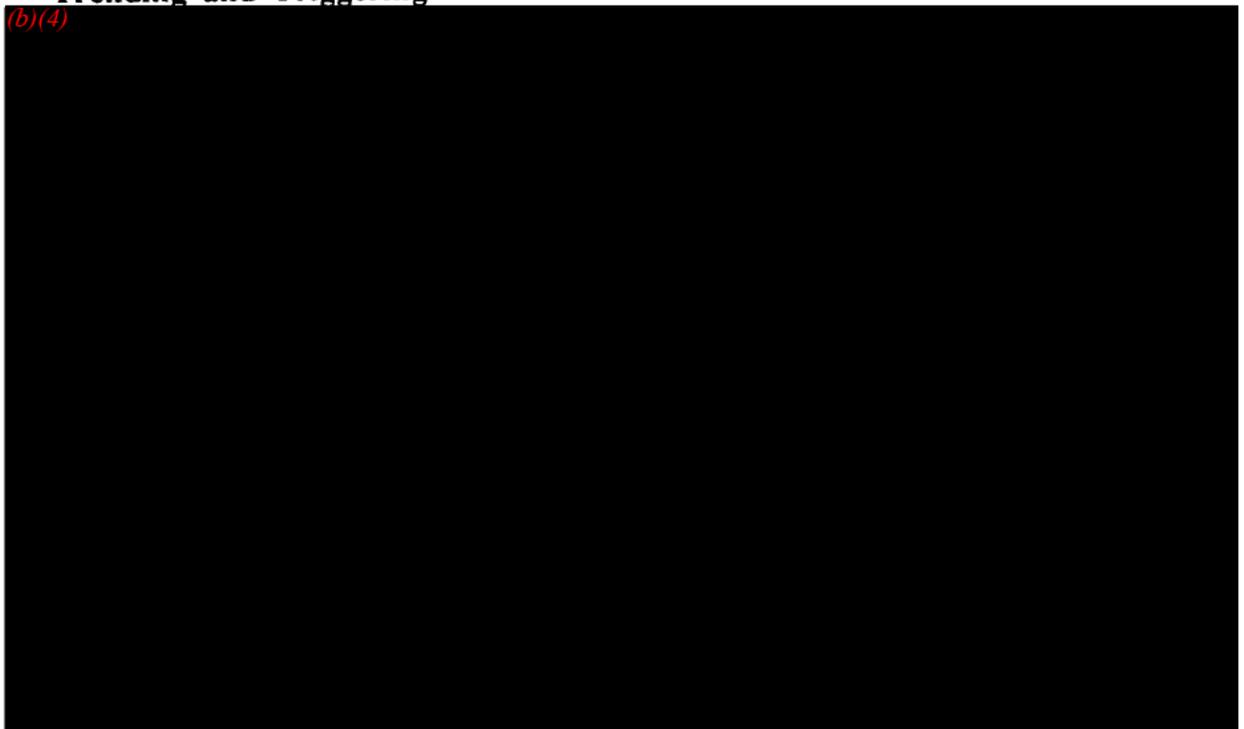


Table I Data Collection Matrix

Table II Summary of Triggers

1.0 PURPOSE

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2.0 SCOPE

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3.0 REFERENCE DOCUMENTS

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4.0 DEFINITIONS

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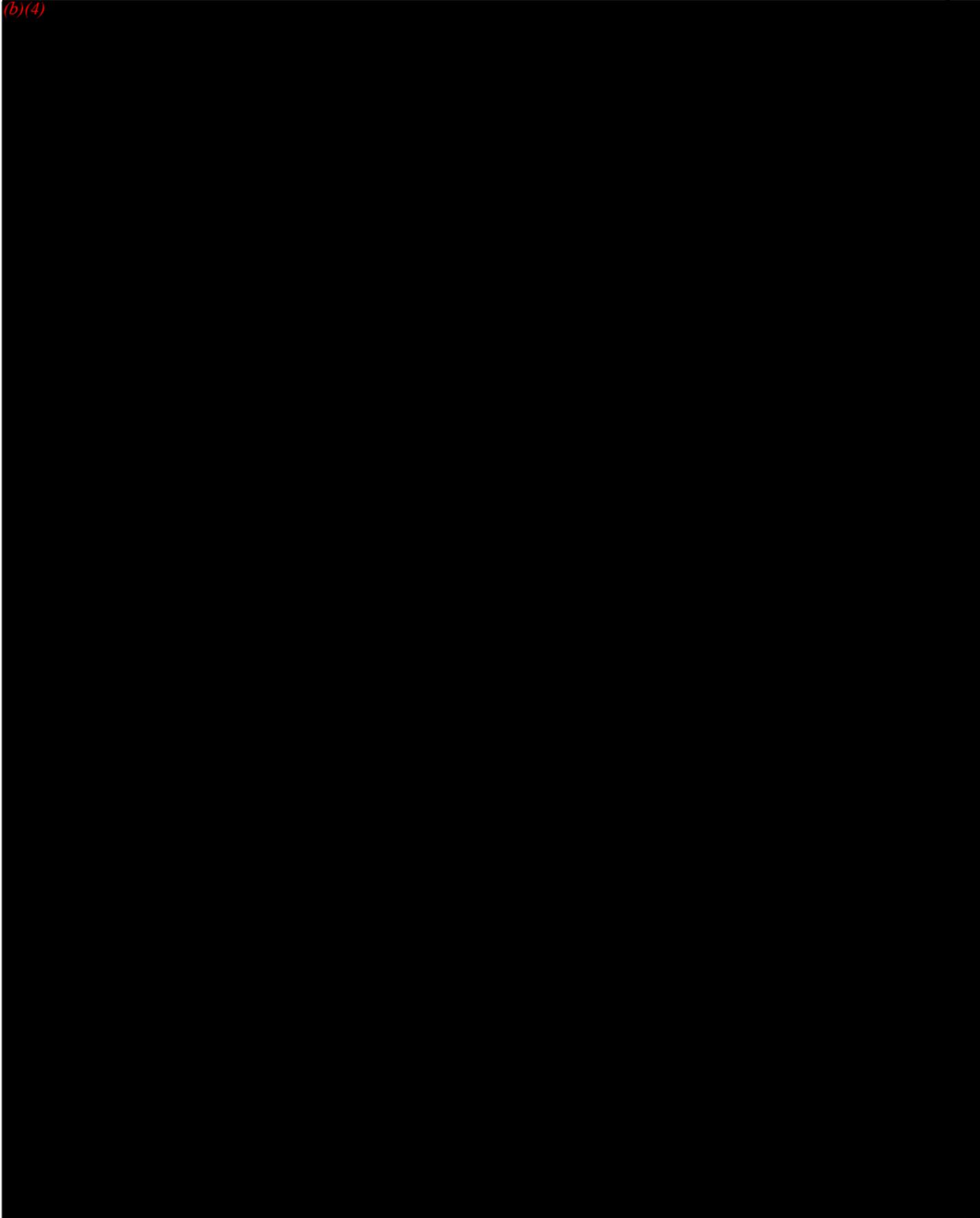
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SHT 4 OF 14

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SHT 5 OF 14

5.0 DATA COLLECTION

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6.0 TRENDING AND TRIGGERING

(b)(4)

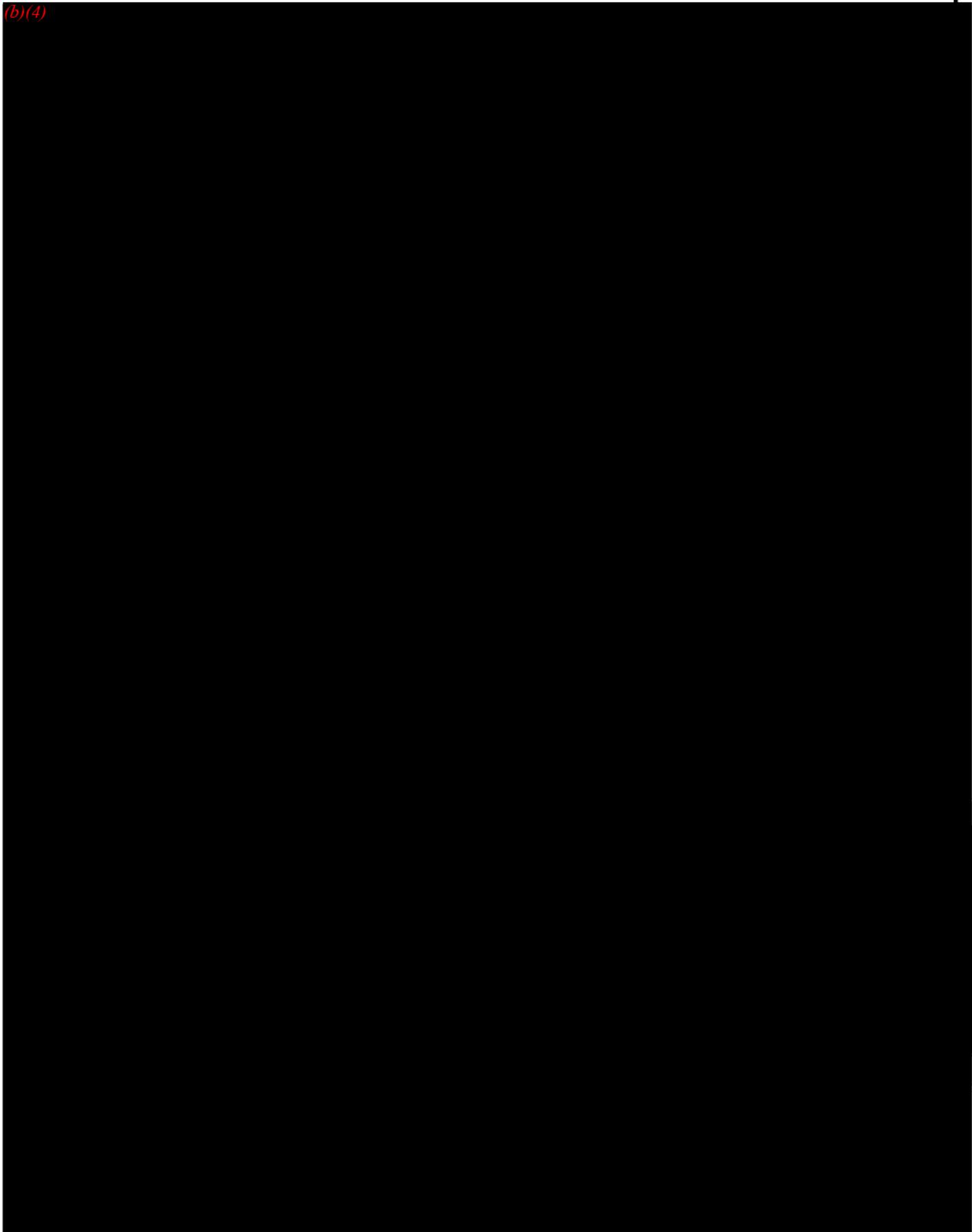
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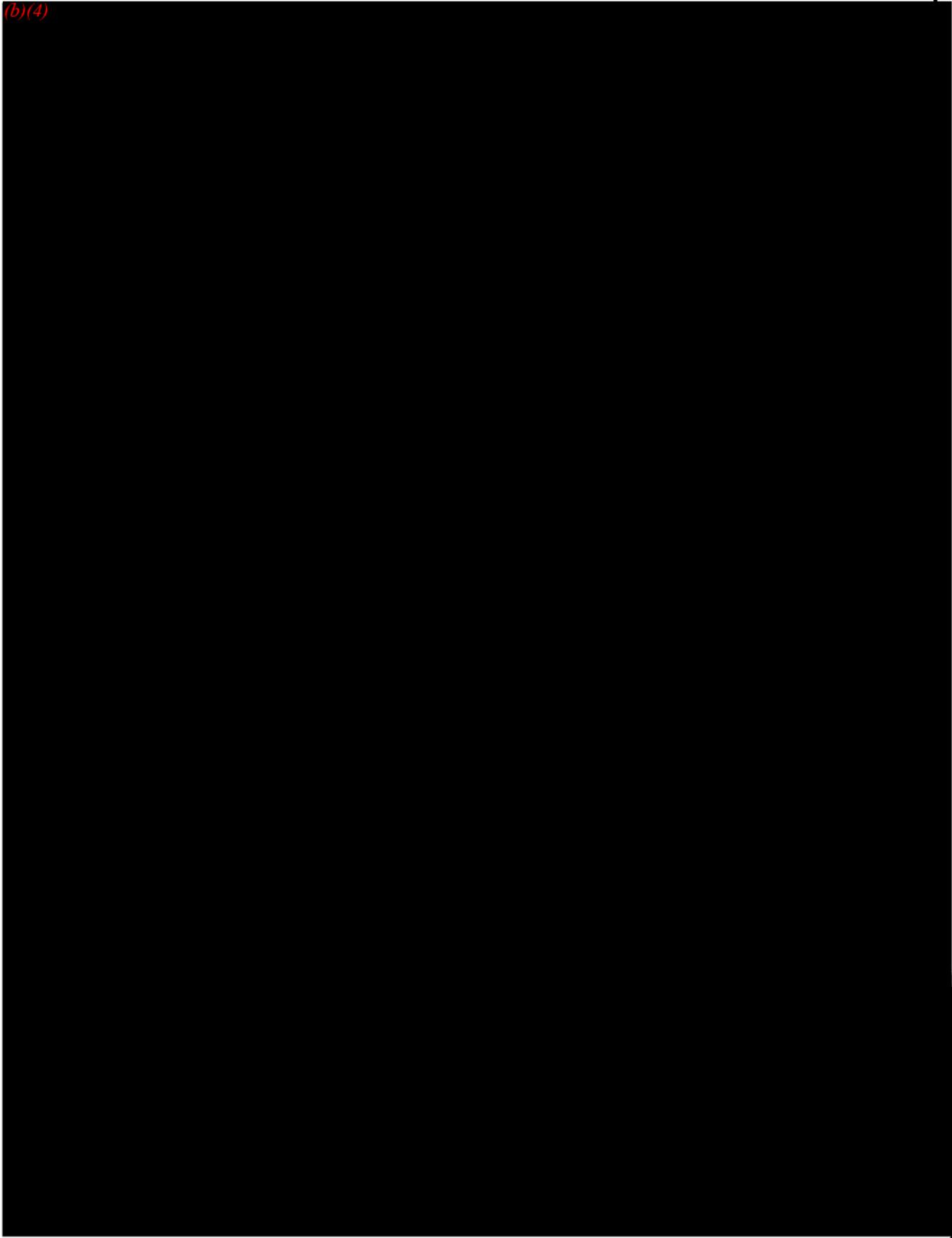
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SHT 8 OF 14

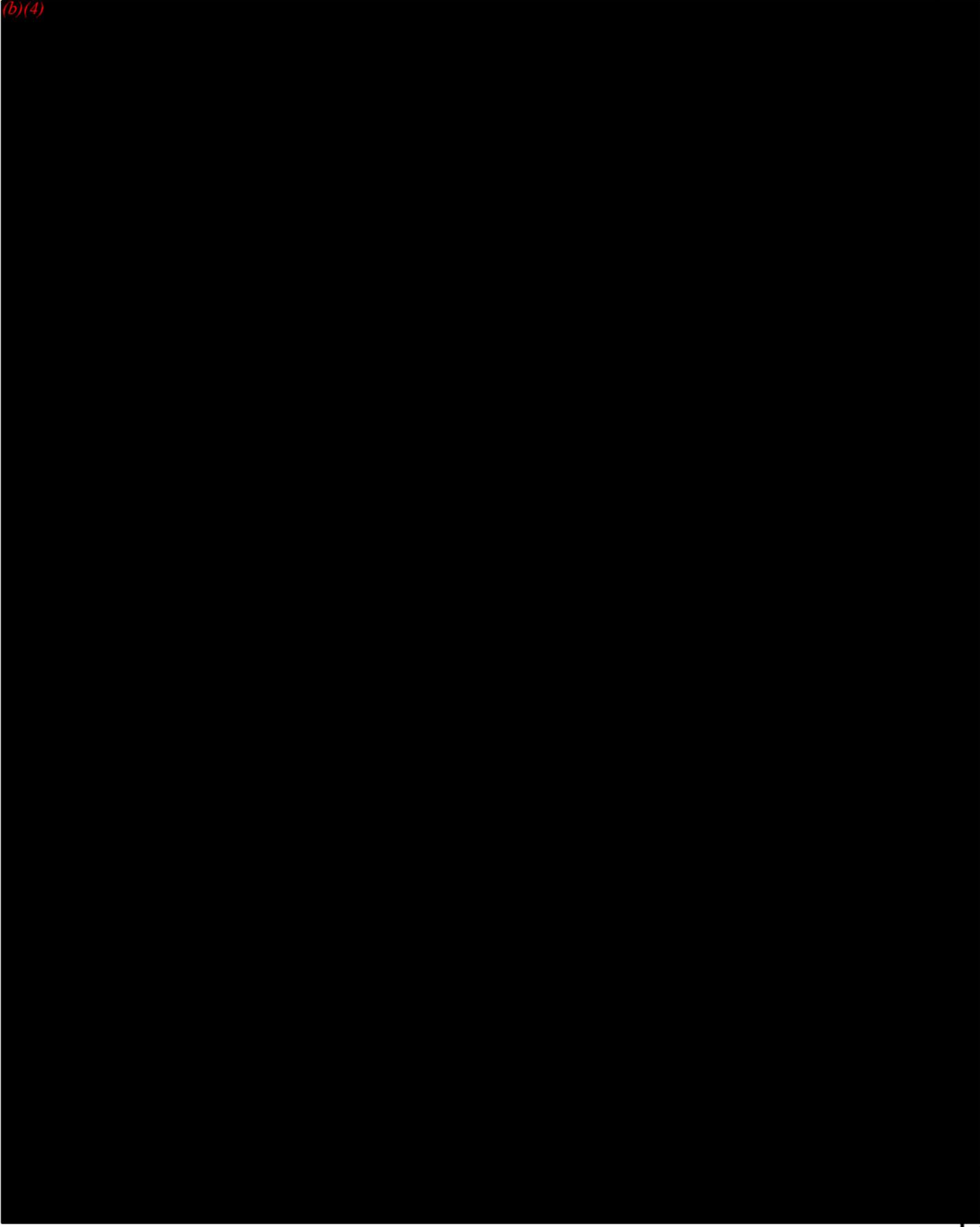
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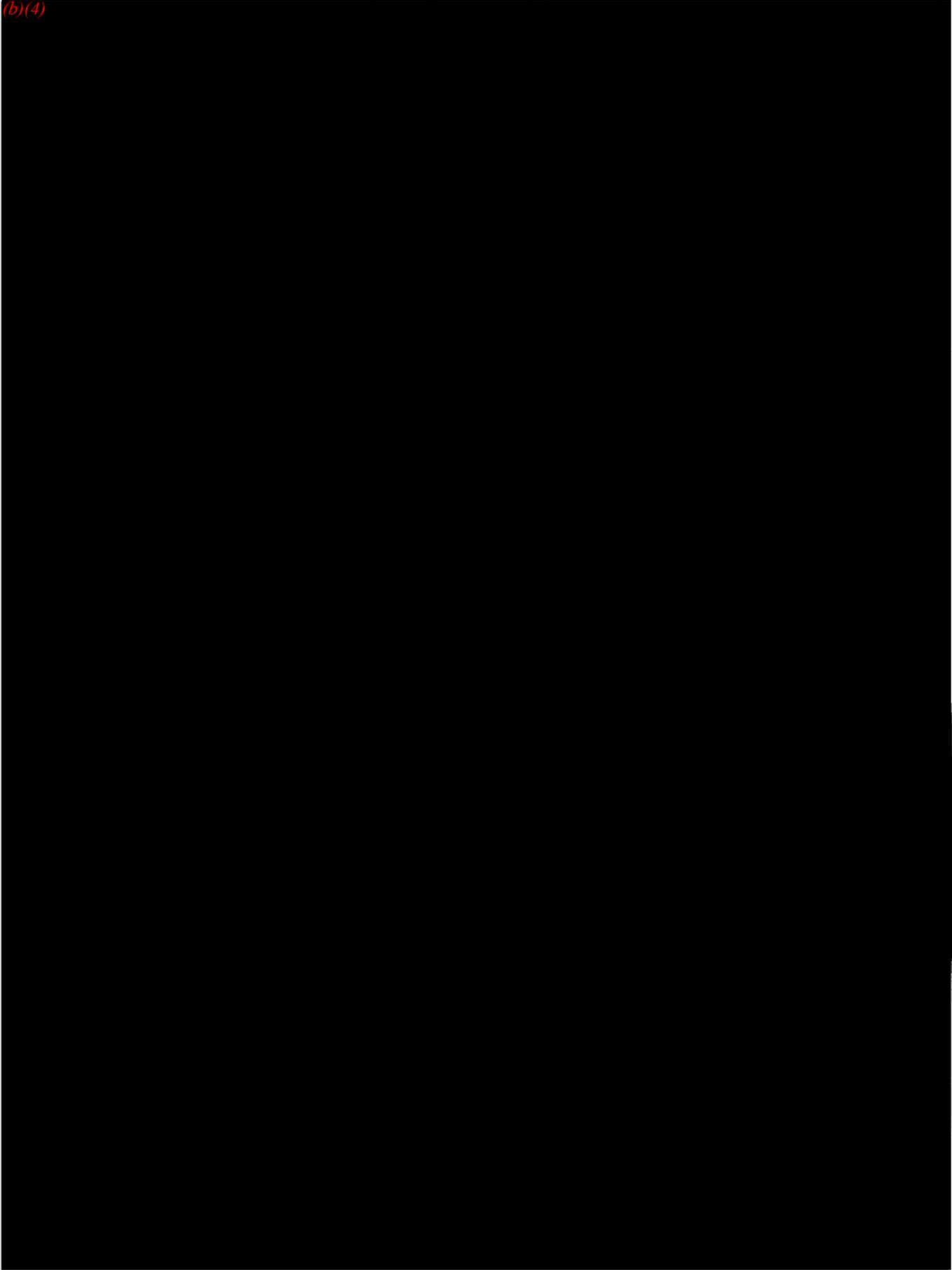
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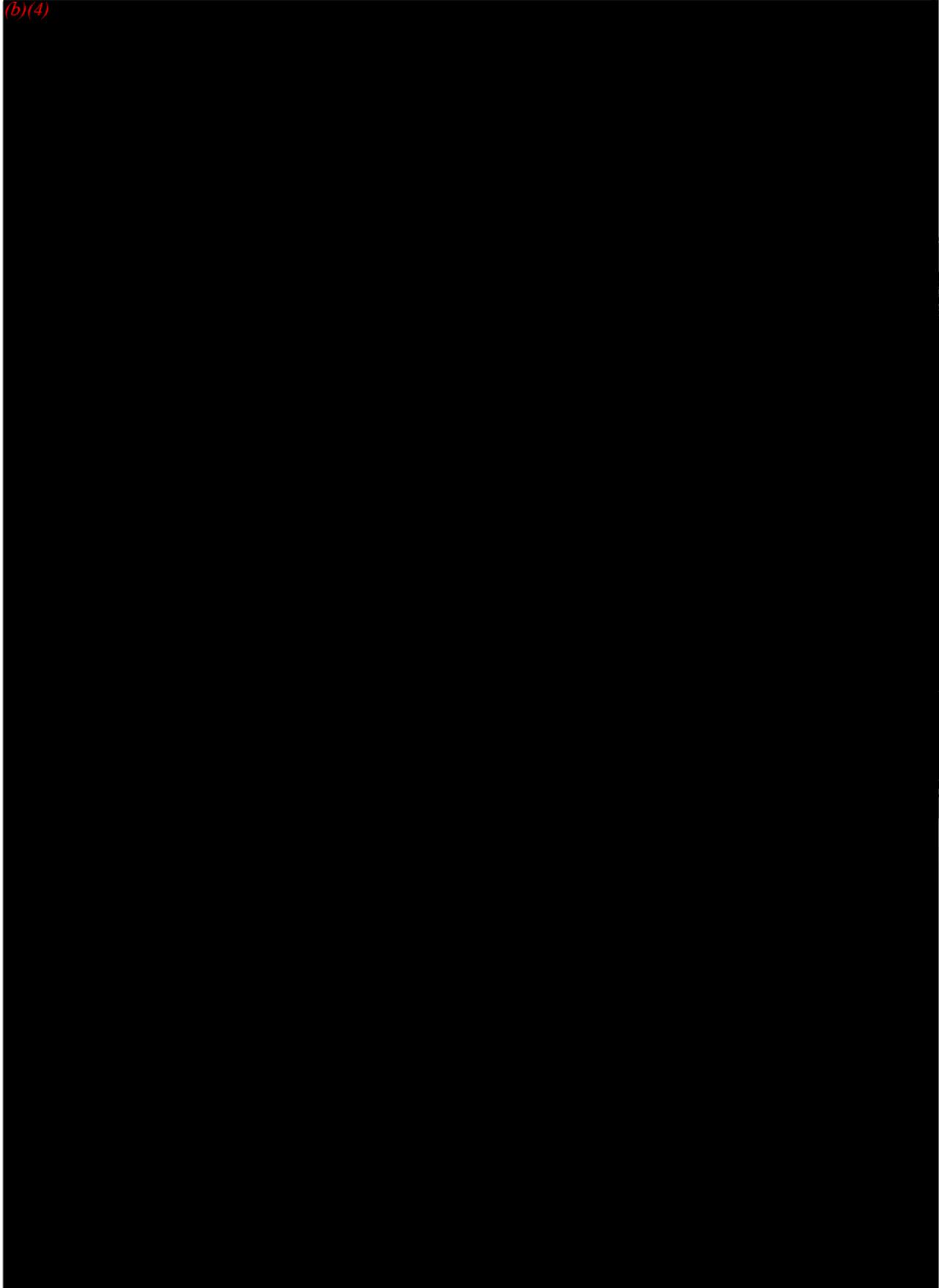
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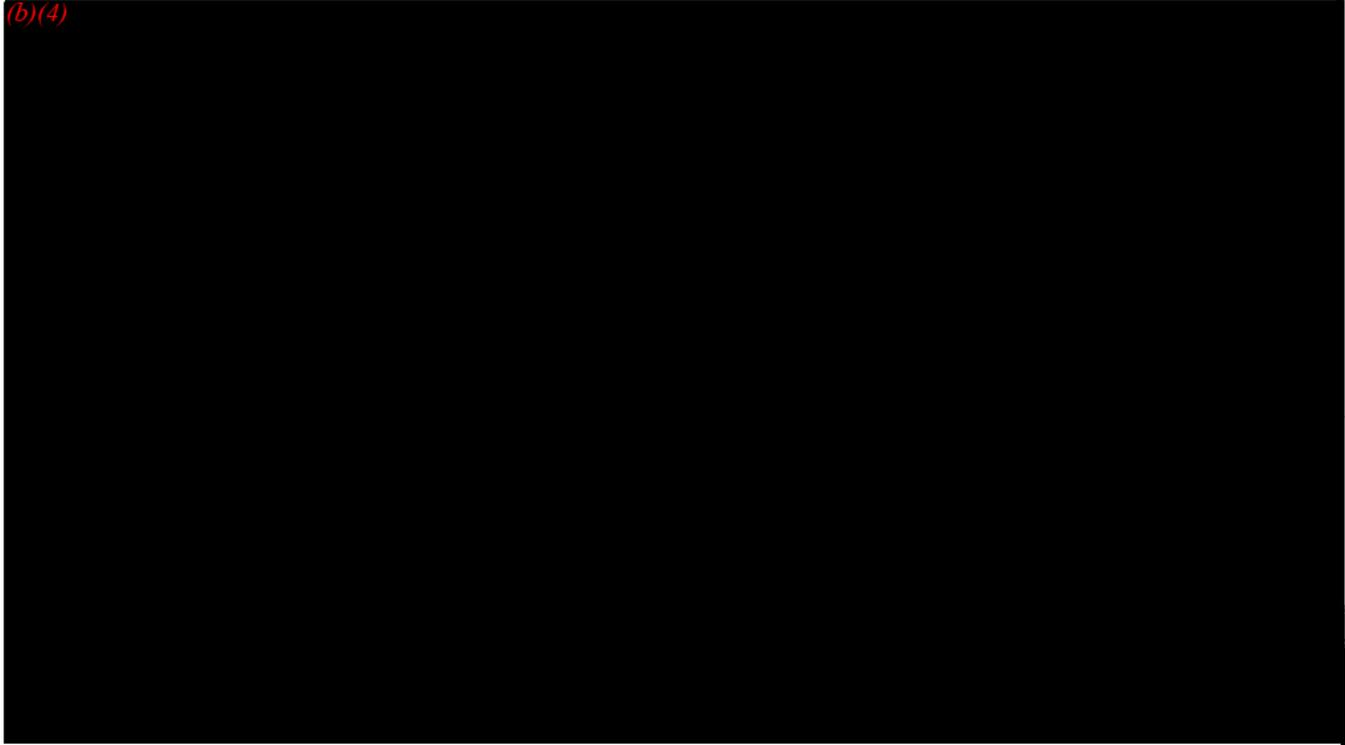
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(b)(4)

DOC. NO

REV J

SHT 13 OF 14

TABLE I DATA COLLECTION MATRIX

<u>Area</u>	<u>Data Collection and Entry Responsibility</u>	<u>Data Focal Point</u>	<u>Data Storage Location</u>
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(b)(4)



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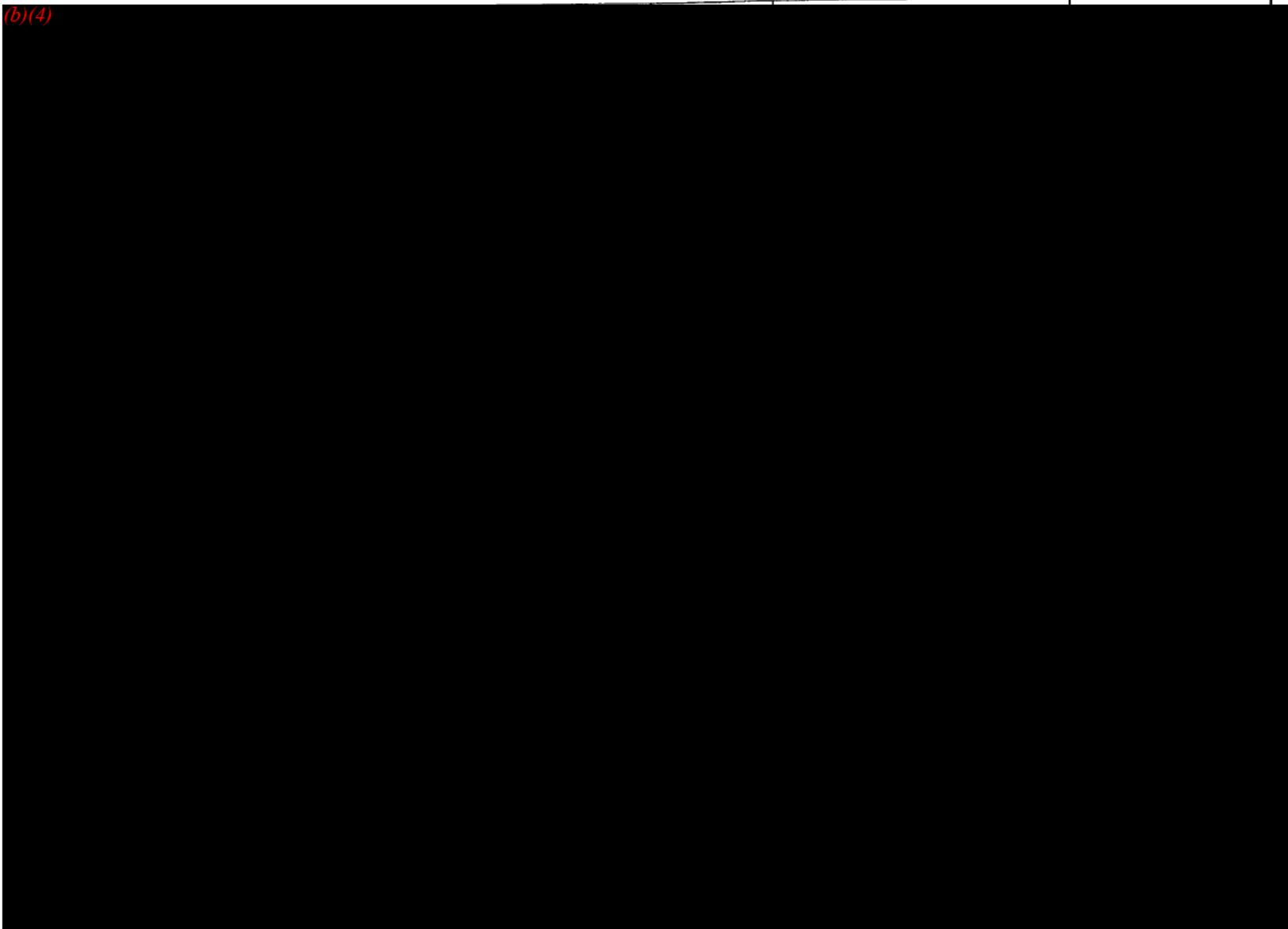
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(b)(4)

APPENDIX B

Summary of Trending/Triggering

(b)(4)



2006-076, APPENDIX II
PHYSIO-CONTROL CORPORATION
PRODUCT REVIEW BOARD
DECISION FORM

2f.

(b)(4)

Investigation #:

Product(s) and Situation:

LP 9
Trouble shooting of Power Conversion Boards replaced by service showed failures of CR1 diode. Component failure could lead to failure to charge.

Is situation obvious to user?:
If Yes, how?

No _____ Yes X

Failure of device to charge is obvious.
Cause of failure is not obvious to user

Is corrective action possible by user?:
If Yes, how?

No X Yes _____

Probability of Occurrence:

Inherent _____ Probable _____ Unlikely X Indeterminate _____

Severity:

Hazard _____ Critical X Serious _____ Minor _____

Action Matrix Guideline:

- 1. Field action _____
- 2. FGI action _____
- 3. Lift stop ship _____
- 4. Approve specification change _____
- 5. Monitor _____
- 6. No field action X
- 7. Other _____ (Explain below)

Recommendations: (Include data collection plan and action thresholds for decision to monitor)

1. No Field Action recommended

Rationale for decision:

- 1. Low frequency of occurrence (.approx .02% / Mo)
- 2. Relevant population limited to product before 8/90 (7000 units)

Team Members present:

PRB:
Other:

(b) (6)

Meeting Date:

4/6/93

Prepared by:

B May

B. May
for Bob May

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2006-076, APPENDIX II
PHYSIO-CONTROL CORPORATION
PRODUCT REVIEW BOARD
DECISION FORM

Investigation #: (b)(4)

Product(s) and Situation: LP9 defibrillator/monitors
Units with certain versions of Power Conversion PCBs may intermittently fail to reach full charge. Charge starts, but terminates prior to full charge, charge light continues to flash and discharge switches are inactive. Displayed energy accurately displays partial charge level. Failure is intermittent.

Is situation obvious to user?: No _____ Yes
If Yes, how? Audible (charge tone) and visual (energy meter) provide feedback.

Is corrective action possible by user?: No _____ Yes
If Yes, how? Depressing the energy select switch (dump) or cycling unit power will return the unit to normal operation.

Probability of Occurrence: Inherent Probable _____ Unlikely Indeterminate _____

Severity: Hazard _____ Critical Serious _____ Minor _____

Action Matrix Guideline: 1. Field action _____ 2. FGI action _____ 3. Lift stop ship _____
4. Approve specification change _____ 5. Monitor _____ 6. No field action
7. Other _____ (Explain below)

Recommendations: (Include data collection plan and action thresholds for decision to monitor)
• No field action
• Investigation team should follow-up with vendor to assure that part is not susceptible to progressive failure with this mechanism. If negative, recommendation stands. If positive, reconvene with PRB.

Rationale for decision:
• low rate of occurrence
• no adverse effects
• based on high unit population and several months of installed base.

Team Members present:
(b)(6)

Meeting Date: 8 February 1993

Prepared by: Mike Willingham
Mike Willingham

BO

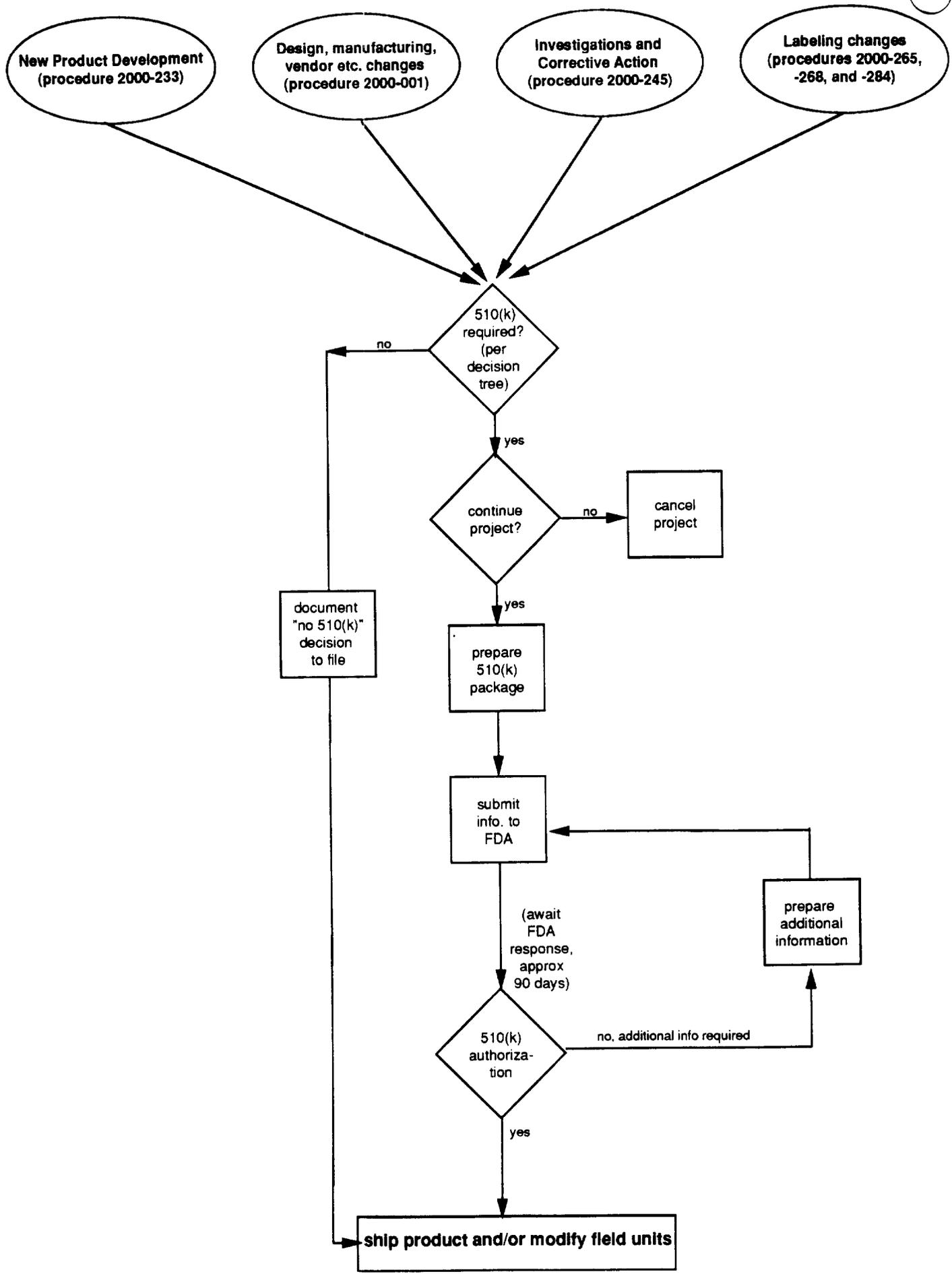
A large, handwritten scribble or signature in black ink, consisting of several overlapping loops and curves.

Attachment 3

Contents

- a) System overview of the 510(k) Premarket Notification determination process
- b) Physio-Control's decision tree for 510(k) evaluation
- c) References and rationale for Physio-Control's 510(k) decision tree. **This document should be read in conjunction with item b) to best understand the basis of the content and construct of the decision tree.**
- d) 510(k) Premarket Notification Evaluation Form for the LIFEPAK 9 defibrillator component change to C1.
- e) 510(k) Premarket Notification Evaluation Form for the LIFEPAK 9 defibrillator component change to CR1.

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510(K) Premarket Notification Evaluation Form

SUMMARY OF CHANGE:

Product Name:

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Describe change(s) to the device, e.g. changes in design, materials, energy source, components

Describe change(s) to manufacturing method or process other than those required to implement design change

Describe what changes will be visible to the user. Describe any features or functions that will be added/deleted/changed:

What is the reason for the change/modification? What is driving it? What is it intended to accomplish?

What changes will be made to device label and/or operating instructions?

Describe changes, if any, to the intended use of the device (skill level of operator, patient population, indications for use, etc.):

How will the change be assessed/tested/verified? Full qual test? Limited qual test? V & V per procedure? Clinical evaluation? Other?

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ANALYSIS:

Intended Use:

Does the change allow or arise from:

(1) a new physiological purpose?

yes:

510(k) REQUIRED! Skip to line 19

no:

(2) a new condition or disease to be treated or diagnosed?

yes:

510(k) REQUIRED! Skip to line 19

no:

(3) a significant change in the type of patient or user? (e.g. from professional to lay user or from adult to neonate patient?)

yes:

510(k) REQUIRED! Skip to line 19

no:

(4) Does the proposed change require a significant change to the device operating instructions or other device labeling in order to use the device safely or effectively, or to warn against some hazard?

yes:

510(k) REQUIRED! Skip to line 19

no:

(5) Will the change significantly affect the range, accuracy, sensitivity/specificity or other specifications of the device as stated in labeling?

yes:

510(k) REQUIRED! Skip to line 19

no:

Manufacturing/Process Change:

(6) Will there be a change in manufacturing method or process other than what is required to incorporate a design change?

no:

Skip to question 12

yes:

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(7) If the manufacturing process being changed were performed incorrectly, could it result in the failure of the device during use by a customer (i.e. could it result in a latent device failure or a failure which might not be noted during production?)

no: → Skip to question 12

yes:

(8) If the manufacturing process resulted in a device failure during use by a customer, could the failure result in an inability to resuscitate a patient?

no: → Skip to question 12

yes:

(9) Do we intend to change the device?

yes: → Treat as design change; skip to question 12

no:

(10) Are there quality control procedures or component or finished device tests that can ensure that components and finished devices still meet their original specifications?

no: → **510(k) REQUIRED!** Skip to line 19

yes:

(11) Are the original specifications detailed, accurate, precise, and understood well enough to ensure that conformance to original specifications will guarantee that the device has not changed?

no: → **510(k) REQUIRED!** Skip to line 19

yes:

Design Change:

(12) Is a design change proposed? (e.g. a change in component or material specifications, chemical composition, energy source, operational principle/algorithm)

no: → 510(k) not required; skip to line 19

yes:

(13) If the particular aspect, feature, or component being affected by the design change malfunctioned, could the device fail and could such failure result in death, serious injury, or inability to resuscitate?

no: → 510(k) not required; skip to line 19

yes:

(14) Is the device being modified to correct in-house or out of house device failures subject to MDR reporting?

no: → Skip to line 17

yes:

(15) Has the product review board determined that field remedial action is required?

no: → Skip to line 17

yes:

(16) Is the change in the field remedial action plan intended to bring the device back into its original specifications?

no: → **510(k) REQUIRED!** Skip to line 19

yes:

(17) Is there a reasonably accepted method for assessing the effect of the change? (i.e. can the effects of the change be assessed?)

no: → **510(k) REQUIRED!** Skip to line 19

yes:

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(18) Is the method for assessing the change very complex or does it require the accumulation of large quantities of testing data?

For example,

For software changes ask:

Does assessment of the change require more than validation per procedure 2002-057?

no:



510(k) not required; go to line 19

yes:



510(k) REQUIRED! go to line 19

For all design changes:

Does the modified device require substantial additional clinical evaluation to verify performance, safety, or efficacy? (i.e., Is there uncertainty about the effect of the proposed change which can only be resolved by clinical testing?)

(19) CONCLUSION:

Check one: A 510(k) premarket notification is required for this change _____

A 510(k) premarket notification is not required for this change _____

COMMENTS:

Originator

Title

Regulatory Affairs

Other signatures upon request of Originator or Regulatory Affairs:

Engineering

Marketing

Quality Engineering

Clinical Affairs

Rationale and reference for Physio-Control's 510(k) evaluation form

Note: Unless otherwise noted all quotations are from the 510(k) guidance presented on June 5, 1990 by Office of Device Evaluation Director Robert Sheridan to the Food and Drug Law Institute. Dr. Acharya, Director of the Division of Cardiovascular and Respiratory Devices indicated during a HIMA device submissions workshop on July 30, 1992 that this guidance is still appropriate. Much of this decision tree is based on this guidance. As such, it is important to consider individual questions in the context of the guidance and any follow-on questions of the decision tree.

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Text of Physio-Control's 510(k) evaluation form:	Purpose and/or source of question:
<p><u>Product Description</u></p> <p>(a) Product Name:</p> <p>(b) Describe change(s) to the device, e.g. changes in design, materials, energy source, components.</p> <p>(c) Describe change(s) to manufacturing method or process other than those required to implement design change.</p> <p>(d) Describe what changes will be visible to the user. Describe any features or functions that will be added/deleted/changed:</p> <p>(e) What is the reason for the change/modification? What is driving it? What is it intended to accomplish?</p> <p>(f) What changes will be made to device label and/or operating instructions?</p> <p>(g) Describe changes, if any, to the intended use of the device (skill level of operator, patient population, indications for use, etc.)</p> <p>(h) How will the change be assessed/tested/verified? Full qual test? Limited qual test? V & V per procedure? Clinical evaluation? Other?</p> <p><u>Intended Use</u></p> <p>Does the change allow or arise from:</p> <p>(1) a new physiological purpose?</p> <p>(2) a new condition or disease to be treated or diagnosed?</p> <p>(3) a significant change in the type of patient or user? (e.g. from professional to lay user or from adult to neonate patient?)</p>	<p>(a) identifies model</p> <p>(b) - (h) The purpose of these questions is to determine the nature of the change, the reason for the change, the impact of the change on intended use and labeling, and the complexity of assessing the effects of the change. This information builds the foundation for assessing the significance of the change.</p> <p>(1) - (5) This section contains questions which are likely to indicate whether there is a significant or major change in intended use.</p>

all

(4) Does the proposed change require a significant change to the device operating instructions or other device labeling in order to use the device safely or effectively, or to warn against some hazard?

(5) Will the change significantly affect the range, accuracy, sensitivity/specificity or other specifications of the device as stated in labeling?

Manufacturing/Process Change:

(6) Will there be a change in manufacturing method or process other than what is required to incorporate a design change?

(7) If the manufacturing process being changed were performed incorrectly, could it result in the failure of the device during use by a customer (i.e. could it result in a latent device failure or a failure which might not be noted during production?)

(8) If the manufacturing process resulted in a device failure during use by a customer, could the failure result in an inability to resuscitate a patient?

(9) Do we intend to change the device?

(10) Are there quality control procedures or component or finished device tests that can ensure that components and finished devices still meet their original specifications?

(11) Are the original specifications detailed, accurate, precise, and understood well enough to ensure that conformance to original specifications will guarantee that the device has not changed?

(6) The purpose of this question is to separate true manufacturing process changes from those incidental to the incorporation of design changes. The latter will be evaluated as part of the Design Change section.

(7) "The 510(k) authority was aimed at ensuring that new not-substantially -equivalent devices are classified in class III and undergo premarket approval or reclassification before they are marketed, not at ensuring that all existing devices are manufactured properly. Other regulatory activities, like the inspection program and issuance of Good Manufacturing Practice regulations can generally perform that function."

If an improper, undesired result of a manufacturing change would be picked up or detected during the manufacturing process then GMP controls should ensure that the device remains substantially equivalent.

(8) A 510(k) would be required "only for changes in manufacturing methods that could significantly affect the safety or effectiveness of the device and for which GMP controls will not ensure that the device remains substantially equivalent." This question has been tailored to defibrillator/monitor/pacemakers.

(9) is intended to identify device changes made to reduce/eliminate manufacturing process variability. These should be evaluated as part of the Design Change Section.

(9), (10) and (11) are intended to identify manufacturing process changes "for which GMP controls will not ensure that the device remains substantially equivalent. We could describe the changes for which GMP controls are adequate as those changes for which: (1) there is no intent to change the device; (2) there are quality control procedures or component or finished device tests that can ensure that components and finished devices still meet their original specifications; and (3) the original specifications are detailed, accurate, precise, and understood well enough to ensure that conformance to original specifications will guarantee that the device has not changed."

Design Change

(12) Is a design change proposed? (e.g. a change in component or material specifications, chemical composition, energy source, operational principle/algorithm)

(13) If the particular aspect, feature, or component being affected by the design change malfunctioned, could the device fail and could such failure result in death, serious injury, or inability to resuscitate?

(14) Is the device being modified to correct in-house or out of house device failures subject to MDR reporting?

(15) Has the Product Review Board determined that field remedial action is required?

(16) Is the change in the field remedial action plan intended to bring the device back into its original specifications?

(13) "If the particular aspect, feature, or component being affected by the design change malfunctioned would the device be any less safe or effective? If not, a 510(k) is certainly not necessary...If so, the manufacturer should consider the remaining 3 factors...If someone is designing a device whose failure can result, for example in death, temporary or permanent loss of body function,... the manufacturer should certainly consider the remaining two factors to determine if a 510(k) is needed." (The remaining two factors are addressed by questions 14 through 18.)

This question has been tailored to defibrillator/monitor/pacemakers.

(14) "If the device is being modified in an effort to correct unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures, and the device is a high risk device..."

(15) The Product Review Board makes a determination of the significance of a reliability improvement per the Field Action Decision Procedure (2006-076)

Whether a design change related to a defibrillator failure is significant and warrants a 510(k) submittal is based on the same criteria used by the Product Review Board in determining whether existing product must be recalled for incorporation of the improvement. Thus, routine reliability improvements as defined in the Field Action Decision Procedure will not require 510(k) notification. This is consistent with the discussions at our October 14, 1993 meeting with FDA.

(16) Director of CDRH James Benson's presentation to NEMA, 9/14/92: "a significant change in a device requires a new 510(k), whether the change is made as a marketing decision or as a corrective action to a recall. If the change in the corrective action plan is to bring the device back into its original specifications, then no 510(k) will be needed."

(17) Is there a reasonably accepted method for assessing the effect of the change? (i.e. can the effects of the change be assessed?)

(18) Is the method for assessing the change very complex or does it require the accumulation of large quantities of testing data?

For example, for software changes ask:
Does assessment of the change require more than validation per procedure 2002-057? For all design changes: Does the modified device require substantial additional clinical evaluation to verify performance, safety, or efficacy? (i.e., Is there uncertainty about the effect of the proposed change which can only be resolved by clinical testing?)

(17), (18) "If there is no reasonably accepted method for assessing the effect of the change, I believe a 510(k) is mandatory. Also, if the method for assessing the change is very complex or requires the accumulation or large quantities of testing data, I believe a 510(k) should be submitted. Otherwise I believe a company should have discretion."

SUMMARY OF CHANGE:

Product Name: LP9 Defibrillator/Monitor

Describe change(s) to the device, e.g. changes in design, materials, energy source, components:

Changed Capacitor(C1) from a Metal Film Technology, P/N805323-01, to a Ceramic Technology, P/N202210-000 on the Power Conversion Board

Describe change(s) to manufacturing method or process other than those required to implement design change:

None

Describe what changes will be visible to the user. Describe any features or functions that will be added/deleted/changed:

None

What is the reason for the change/modification? What is driving it? What is it intended to accomplish?

Intermittent failure to reach full charge, which is due to a phenomenon known as "clearing" in C1 components of the Metalized Film Technology.

What changes will be made to device label and/or operating instructions?

None

Describe changes, if any, to the intended use of the device (skill level of operator, patient population, indications for use, etc.):

None

How will the change be assessed/tested/verified? Full qual test? Limited qual test? Clinical evaluation? Other?

The change was assessed , tested , and verified by Engineering.

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ANALYSIS:

Intended Use:

Does the change allow or arise from:

(1) a new physiological purpose?

yes:

510(k) REQUIRED! Skip to line 19

no:

(2) a new condition or disease to be treated or diagnosed?

yes:

510(k) REQUIRED! Skip to line 19

no:

(3) a significant change in the type of patient or user? (e.g. from professional to lay user or from adult to neonate patient?)

yes:

510(k) REQUIRED! Skip to line 19

no:

(4) Does the proposed change require a significant change to the device operating instructions or other device labeling in order to use the device safely or effectively, or to warn against some hazard?

yes:

510(k) REQUIRED! Skip to line 19

no:

(5) Will the change significantly affect the range, accuracy, sensitivity/specificity or other specifications of the device as stated in labeling?

yes:

510(k) REQUIRED! Skip to line 19

no:

Manufacturing/Process Change:

(6) Will there be a change in manufacturing method or process other than what is required to incorporate a design change?

no:

Skip to question 12

yes:

(7) If the manufacturing process being changed were performed incorrectly, could it result in the failure of the device during use by a customer (i.e. could it result in a latent device failure or a failure which might not be noted during production?)

no:

Skip to question 12

yes:

(8) If the manufacturing process resulted in a device failure during use by a customer, could the failure result in an inability to resuscitate a patient?

no:

Skip to question 12

yes:

(9) Do we intend to change the device?

yes:

Treat as design change; skip to question 12

no:

(10) Are there quality control procedures or component or finished device tests that can ensure that components and finished devices still meet their original specifications?

no:

510(k) REQUIRED! Skip to line 19

yes:

(11) Are the original specifications detailed, accurate, precise, and understood well enough to ensure that conformance to original specifications will guarantee that the device has not changed?

no:

510(k) REQUIRED! Skip to line 19

yes:

Design Change:

(12) Is a design change proposed? (e.g. a change in component or material specifications, chemical composition, energy source, operational principle/algorithm)

no:

510(k) not required; skip to line 19

yes:

(13) If the particular aspect, feature, or component being affected by the design change malfunctioned, could the device fail and could such failure result in death, serious injury, or inability to resuscitate?

no:

510(k) not required; skip to line 19

yes:

(14) Is the device being modified to correct in-house or out of house device failures subject to MDR reporting?

no:

Skip to line 17

yes:

(15) Has the product review board determined that field remedial action is required?

no:

Skip to line 17

yes:

(16) Is the change in the field remedial action plan intended to bring the device back into its original specifications?

no:

510(k) REQUIRED! Skip to line 19

yes:

(17) Is there a reasonably accepted method for assessing the effect of the change? (i.e. can the effects of the change be assessed?)

no:

510(k) REQUIRED! Skip to line 19

yes:

(18) Is the method for assessing the change very complex or does it require the accumulation of large quantities of testing data?

For example,

For software changes ask:

Does assessment of the change require more than validation per procedure 2002-057?

no: →

yes: →

510(k) not required; go to line 19

510(k) REQUIRED! go to line 19

For all design changes:

Does the modified device require substantial additional clinical evaluation to verify performance, safety, or efficacy? (i.e., Is there uncertainty about the effect of the proposed change which can only be resolved by clinical testing?)

(19) CONCLUSION:

Check one: A 510(k) premarket notification is required for this change _____

A 510(k) premarket notification is not required for this change X

COMMENTS:

Rockland W. Nordness, Electrical Engineer
Originator Title

[Signature]
Regulatory Affairs

Other signatures upon request of Originator or Regulatory Affairs:

Kim Warner
Engineering

Marketing

Quality Engineering

Clinical Affairs

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510(K) Premarket Notification Evaluation Form

SUMMARY OF CHANGE:

Product Name: LP9

CONFIDENTIAL

Describe change(s) to the device, e.g. changes in design, materials, energy source, components

Changed mechanical mounting method for CR1, Power Conversion PCB

Describe change(s) to manufacturing method or process other than those required to implement design change

None

Describe what changes will be visible to the user. Describe any features or functions that will be added/deleted/changed:

None

What is the reason for the change/modification? What is driving it? What is it intended to accomplish?

Improve shock resistance of leads

What changes will be made to device label and/or operating instructions?

None

Describe changes, if any, to the intended use of the device (skill level of operator, patient population, indications for use, etc.):

None.

How will the change be assessed/tested/verified? Full qual test? Limited qual test? V & V per procedure? Clinical evaluation? Other?

Qual test.

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ANALYSIS:

Intended Use:

Does the change allow or arise from:

(1) a new physiological purpose?

yes:

510(k) REQUIRED! Skip to line 19

no:

(2) a new condition or disease to be treated or diagnosed?

yes:

510(k) REQUIRED! Skip to line 19

no:

(3) a significant change in the type of patient or user? (e.g. from professional to lay user or from adult to neonate patient?)

yes:

510(k) REQUIRED! Skip to line 19

no:

(4) Does the proposed change require a significant change to the device operating instructions or other device labeling in order to use the device safely or effectively, or to warn against some hazard?

yes:

510(k) REQUIRED! Skip to line 19

no:

(5) Will the change significantly affect the range, accuracy, sensitivity/specificity or other specifications of the device as stated in labeling?

yes:

510(k) REQUIRED! Skip to line 19

no:

Manufacturing/Process Change:

(6) Will there be a change in manufacturing method or process other than what is required to incorporate a design change?

no:

Skip to question 12

yes:

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(7) If the manufacturing process being changed were performed incorrectly, could it result in the failure of the device during use by a customer (i.e. could it result in a latent device failure or a failure which might not be noted during production?)

no:

Skip to question 12

yes:

(8) If the manufacturing process resulted in a device failure during use by a customer, could the failure result in an inability to resuscitate a patient?

no:

Skip to question 12

yes:

(9) Do we intend to change the device?

yes:

Treat as design change; skip to question 12

no:

(10) Are there quality control procedures or component or finished device tests that can ensure that components and finished devices still meet their original specifications?

no:

510(k) REQUIRED! Skip to line 19

yes:

(11) Are the original specifications detailed, accurate, precise, and understood well enough to ensure that conformance to original specifications will guarantee that the device has not changed?

no:

510(k) REQUIRED! Skip to line 19

yes:

Design Change:

(12) Is a design change proposed? (e.g. a change in component or material specifications, chemical composition, energy source, operational principle/algorithm)

no:

510(k) not required; skip to line 19

yes: (*mounting method changed*)

(13) If the particular aspect, feature, or component being affected by the design change malfunctioned, could the device fail and could such failure result in death, serious injury, or inability to resuscitate?

no:

510(k) not required; skip to line 19

yes:

(14) Is the device being modified to correct in-house or out of house device failures subject to MDR reporting?

no:

Skip to line 17

yes: (*3 to date per Bill Gorka*)

(15) Has the product review board determined that field remedial action is required?

no:

Skip to line 17

yes:

(16) Is the change in the field remedial action plan intended to bring the device back into its original specifications?

no:

510(k) REQUIRED! Skip to line 19

yes:

(17) Is there a reasonably accepted method for assessing the effect of the change? (i.e. can the effects of the change be assessed?)

no:

510(k) REQUIRED! Skip to line 19

yes:

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